

Dantec® Clavis™

User Guide



natus®

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This manual correctly describes 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:

- The device is not used according to the enclosed manuals and other accompanying documentation.











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Table of Contents

Description of Symbols	4
Safety Information	6
Safety Requirements	6
Intended Use.....	6
Essential Performance	6
Contraindications	7
Side Effects.....	8
Residual Risks	8
Clinical Performance.....	8
Clinical Benefits	8
Patient Target Group	8
Intended Users.....	8
Patient Population.....	8
Operating Dantec Clavis	9
Description	9
Control Panel Overview	9
Start – AutoTest	10
EMG Mode.....	11
Electrodes.....	11
EMG Buttons	12
Stimulation Mode	12
Electrodes.....	12
Stimulation Buttons	13
Maintenance	15
Cleaning.....	15
Replacing the Battery.....	15
Neurodiagnostic Supplies	17
Technical Data	18
Mode of Operation	18
WEEE Statement	19
Safety & Standards Conformity	20
Standards of Compliance and Normative References	20
Declaration of Compliance for IEC 60601-1-2, 4th Edition.....	22
Declaration of Compliance for FCC	25

Description of Symbols

NOTE: The front panel symbols and buttons can be found in the control panel overview in the section “Operating Dantec Clavis”.

 ISO 60601-1 Table D.2 #2	Warnings associated with this device. A warning indicates that there is a risk of death or serious injury to the user or patient.
 ISO 15223-1 Symbol 5.4.4 ISO 60601-1 Table D.1 #10	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.
 ISO 15223-1 Symbol 5.4.3 ISO 60601-1 Table D.1 #11	Consult instructions for use. Indicates the need for the user to consult the instructions for use. Please read the instruction manual before using this device.
 ISO 60601-1 Table D.2 #10	Follow instructions for use.
 IEC 606011:2005+ AMD1:2012 EN 60601-1:2006+A1:2013	Type BF Applied Part Defines the degree of protection against electric shock. The Dantec Clavis system is classified as type BF. Complies with Type BF requirements of IEC 60601-1:2005+AMD1:2012 and EN 60601-1:2006+A1:2013.
	Double Insulated (Class II) symbol.
 EN 50419	Defines the correct disposal Information, provided in the Waste Management section
 ISO 15223-1 Symbol 5.1.6	Reference Number. This is the part number for the device.
 ISO 15223-1 Symbol 5.1.7	Includes the year of manufacture, a letter, the serial number of the device, and a three-letter revision code.
 ISO 15223-1 Symbol 5.1.1	The manufacturer information is adjacent to this symbol

 ISO 15223-1 Symbol 5.1.3	The manufacture date is adjacent to this symbol.
<p style="text-align: center;">IPX1</p>	Ingress of liquids: The Clavis Unit is classified as an ordinary equipment regarding ingress of liquids; it is not drip-proof, splash-proof, or watertight. Protection from dripping water from above device for at least 10 minutes according to IEC 60529.
 Intertek	Medical device listing mark for U.S. and Canada by Intertek Testing Service.
	The device is not user serviceable.
	Battery type.
<p style="text-align: center;">Rx Only</p>	CAUTION: USA Federal law restricts this device to sale or on the order of a licensed medical physician.
<p style="text-align: center;">Medical Device</p>	Medical Device. Indicates that the item is a medical device.
 ISO 15223-1 Symbol 5.3.7	Indicates the upper and lower limits of temperature to which the medical device can be safely exposed. The temperature is indicated adjacent to the horizontal lines.
 ISO 15223-1 Symbol 5.3.8	Indicates the upper and lower limits of humidity limitation to which the medical device can be safely exposed. The humidity limitation is indicated adjacent to the horizontal lines.
	Dantec®CLAVIS™ device.
	Carton.
 ISO 15223-1 Symbol 5.2.8	Do not use if package is damaged.

Referenced standards

- ISO 15223-1:2016: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- [IEC 60601-1:2005+AMD1:2012 Consolidated version General requirements for basic safety and essential performance](#)
- [IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety](#)

Safety Information

Safety Requirements

This device is intended to be used by qualified medical personnel, knowledgeable in the field of electrophysiology and with the appropriate education and special training. Before using the instrument, please read these operating instructions carefully. Follow the warnings indicated on the instrument and the safety precautions recommended in this manual.

This device has been designed and tested in accordance with the IEC Publication 60601-1 (EN 60601-1) Medical Electrical Equipment.

Do not use this device for anything other than what it is intended for by the manufacturer. Natus Neuro assumes no responsibility when not used as described in this user guide.

Medical electrical equipment needs special precautions regarding EMC, and requires installation and servicing according to the information provided in this user guide.

The device has been designed for indoor use at temperatures between +10°C and +40°C (+50°F to +104°F). Situate the unit away from heat sources such as radiators and warming lamps as exposure to high temperatures may affect operation or cause damage.

Do not use damaged or defective devices. Protect this instrument from immersion, spills, the impact of falling objects, and exposure to excessive smoke, dust, mechanical vibration, or shock.

Any serious incident that has occurred in relation to the Dantec Clavis device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Intended Use

Dantec Clavis is a medical device intended as a stimulator for nerve localization as well as an aid for guidance of injections into the muscles.

Essential Performance

Essential performances of the Dantec Clavis product are identified in the standard IEC 60601-2-40:2016 specifying requirements for the basic safety and essential performance of electromyography and evoked response equipment. Essential performance relates to the quality of the signal recorded from the amplifier.

In the EMG mode:

- The essential performance for Dantec Clavis supports needle electrode examinations.
- Throughout the procedure, Dantec Clavis will emit a series of audible signals varying in intensity and frequency that will help monitor the localization of the targeted muscle or nerve.
- Additional essential performance also includes the ability of the health care professional to inject any necessary drugs to the patient through the use of the Bo-ject needles.

Stimulation Mode:

The Clavis system can apply a current pulse train to the patient.

The Stimulation Level bar facilitates the monitoring of the stimuli.

Contraindications

- Patients with an implanted electronic device, e.g., a cardiac pacemaker or with cardiac abnormalities should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained. Please refer to contraindications for implant systems for further information on pacemakers.

Warnings

- The device is not intended for cardiac application.
 - **Do Not** apply electrodes:
 1. Over the thoracic area
 2. Over the left and/or right temporal regions
 3. In the orbital region
- Use in an anesthetic environment: The Dantec Clavis system is not suitable for use in presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN or NITROUS OXIDE.
- This device must not be used simultaneously with other equipment, or near other equipment, which might give off electrical energy.
- The device is not compatible for use in an MRI magnetic field.
- Do not immerse the device in any liquid.

Cautions

- Always read the instructions accompanying the needles/electrodes used.
- In conditions with bleeding tendency, certain care should be taken when needles are used.
- Conventional precautions should be taken with patients with infectious diseases and broken skin.
- Dantec Clavis cannot be sterilized.
- After using an alcohol prep to clean the skin, make sure any flammable liquid and/or vapors have evaporated and dispersed before using the instrument.
- 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 Dantec Clavis System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals as well as residential environments. 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.
- The Dantec Clavis system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used. Refer to the Recommended Separation Distances table in the Safety & Standards Conformity section for minimum recommended separation distances.

Side Effects

There are no known side effects for procedures performed with Clavis.

Residual Risks

All risks related to the use of the device have been mitigated. Control measures including device labeling and information in the Instruction for Use are in place. Residual risk is outweighed by medical benefit use of device. Please read all safety information before use of the device.

Clinical Performance

Dantec Clavis is a medical device intended as a stimulator for nerve localization and as an aid for guidance of injections into muscles. Dantec Clavis provides both EMG monitoring and stimulation functions in a single, hand-held device.

Clinical Benefits

Dantec Clavis assists the physician during needle electrode examinations in the treatment of neuromuscular diseases such as Dystonia, Strabismus, Essential Tremor, Spasticity, and Temporomandibular Dysfunction. The portable, battery-operated unit provides easy transport and convenient access to patients.

Patient Target Group

The target patient population is the pediatric and adult patient population with neuromuscular disease.

Intended Users

The Dantec Clavis is intended for use by skilled physicians trained in the specialty of neuromuscular diseases, including Neurologists and Physiatrists.

Patient Population

The Dantec Clavis assists the physician in the treatment of patients with neuromuscular diseases such as Dystonia, Strabismus, Essential Tremor, and Spasticity for pediatric and adult patients.

Operating Dantec Clavis

Description

Dantec Clavis is a medical device intended to assist in the localization of the muscles and nerves in normal and pathological conditions. It is a handheld, battery-powered device with two main functions: Audio Electromyography (EMG) and Constant Current Stimulation (CCS). The Audio EMG provides a sound-based electromyography signal representing the electrical activity in muscles and nerves. The CCS provides current pulses used to stimulate muscles and nerves.

Control Panel Overview

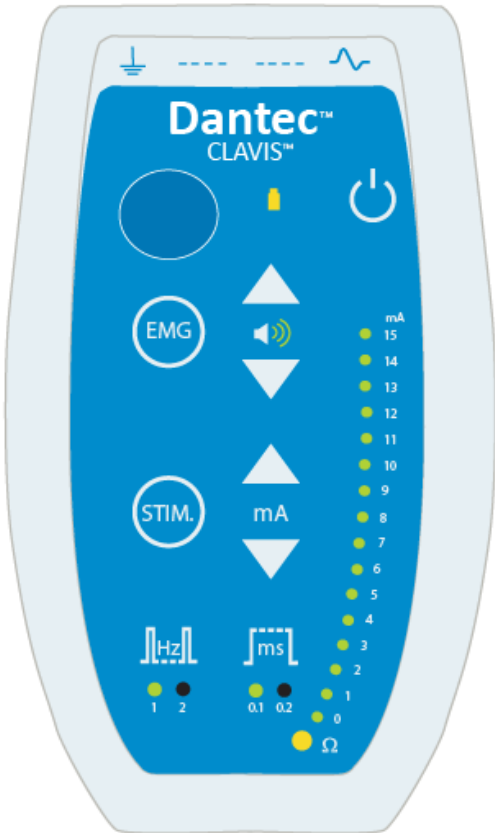



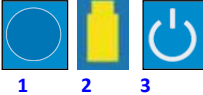



Dantec Clavis Front Panel	Button/ Symbol	Legend
 <p>The image shows the front panel of the Dantec Clavis device. It features a blue background with various controls. At the top, there are symbols for Patient Ground (a ground symbol), Reference (a dashed line), and EMG input (a waveform). Below these are a speaker icon, a yellow battery low power status indicator, and a power switch. The central area has an EMG button, a volume control knob, and a STIM. button. To the right of the STIM. button is a current stimulation level bar with green lights and a yellow overload light indicator. At the bottom, there are buttons for Pulse Rate (Hz) and Pulse Width (ms), each with associated yellow light indicators.</p>		Patient Ground.
		Reference.
		EMG input.
		1 Speaker 2 Battery low power status indicator– yellow light. 3 Power switch (on/off toggle).
		EMG 1 Activation button. 2 Volume controls.
	Stimulation 1 Activation button. 2 Stimulation Level controls. 3 Current Stimulation Level bar/ Green Lights indicator. 4 Yellow Overload Light indicator.	
	Pulse 1 Pulse Rate button/ Yellow Light indicator. 2 Pulse Width button/ Yellow Light indicator.	

Figure 1. Control Panel Overview

Start – AutoTest

Power On /Off



Press the Power button to switch on the device.

Press the Power button again to switch off the device.

When you switch on Dantec CLAVIS, it will start an internal auto test, while at the same time it will allow you to verify that the Sound and Indicator Light functions are working properly.

NOTE: The device automatically switches off after a period of ten minutes, if left unused.

Correct Functioning

- 1. Sound:** The device emits a series of clicks
- 2. Indicator Lights:** All the indicators —Current Stimulation Level Bar; Pulse Rate /Width; and Battery Status— will light up for a few seconds.

Incorrect Functioning

If an internal error is found, the device will go on a “**Fail Safe**” mode. In the Fail Safe mode, the following failure codes can appear:

- 1 mA LED: Intensity or Gain too low (first Intensity/Gain combination)
- 2 mA LED: Intensity or Gain too high (first Intensity/Gain combination)
- 3 mA LED: Intensity or Gain too low (second Intensity/Gain combination)
- 4 mA LED: Intensity or Gain too high (second Intensity/Gain combination)
- 5 mA LED: The reference Voltage is too low
- 6 mA LED: The reference Voltage is too high
- 7 mA LED: Overload detection failure
- 8 mA LED: Overload detection failure (Missing detection)
- 9 mA LED: Critical low battery voltage – exchange battery
- 10 mA LED: Current Limiter failure

If any of the failure codes appear, only the power button will remain operative. Attempt to power off and on the device. If the problems persist, please contact your local Natus representative.

NOTE: During the startup auto test the device should emit a series of clicks. If the clicks are not heard, or the speaker is not functioning, the device should not be used. Please contact your local Natus representative for support.

EMG Mode

In the EMG mode, the device is used for needle electrode examinations. Throughout the procedure, Dantec Clavis will emit a series of audible signals varying in intensity and frequency that will help monitoring the localization of the targeted muscle or nerve.

Note that the **Sound Signal** flashes a green light when EMG is activated.

Electrodes



CAUTION: Only electrodes recommended by Natus must be used. Refer to the Neurodiagnostics Supplies section of this user guide for further information.

Connecting the Electrode Leads to the Device

Before starting the procedure, connect the electrode leads to their corresponding color-coded connectors as shown in fig. 2 below.

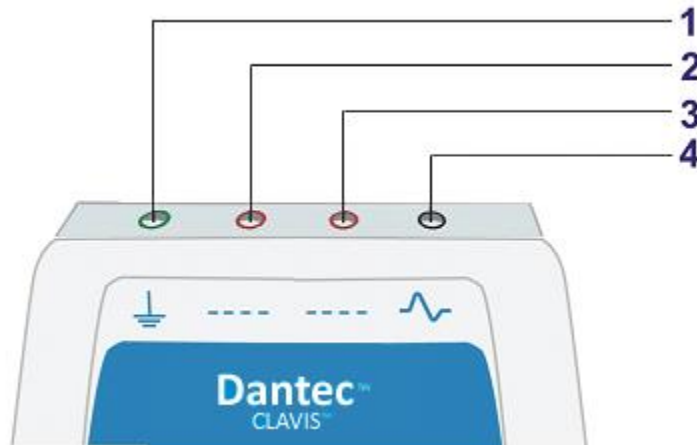


Figure 2. EMG Electrode Connections

Ref.	Symbol	EMG Electrodes	Color
1		Patient Ground	Green
2	-----	Reference	Red
3	-----	Reference (additional)	Red
4		EMG input (active)	Black

- Connect the ground electrode to the green patient ground connector () (1).
- Connect the reference electrode to the red reference connector (-----) (2).
- If needed to reduce impedance, connect another reference electrode to the additional red reference connector (-----) (3).
- Connect the EMG needle electrode to the black connector () (4).

Attaching the Electrodes to the Patient

Once the electrode leads have been connected to the device, you can attach the ground and reference electrodes to the patient, and when ready, proceed with the EMG needle electrode (active input).

EMG Buttons

Activating the EMG Mode



- Press the **EMG** button to activate the EMG mode.
- Press the **EMG** button again to stop the EMG mode.

Adjusting Volume



- Press the **Volume Up** button to increase the volume.
- Press the **Volume Down** button to decrease the volume.
- For continuous increase or decrease of the volume press and hold down the volume buttons.
- Note that the **Sound Signal** flashes a green light when EMG is activated.

NOTE: The volume can only be adjusted while in EMG mode.

NOTE: The stimulation level can also be adjusted while in EMG mode. Refer to the Stimulation section for a description of the stimulation mode and its buttons.


Stimulation Mode

In stimulation mode, a current pulse train is delivered to the patient.

The flashing indicators in the Stimulation Level bar allow you to control the level of current being delivered to the patient.

Electrodes

Connecting the Electrode Leads to the Device

 **CAUTION:** Only electrodes recommended by Natus must be used. Refer to the Neurodiagnostic Supplies section of this user guide for further information.

Before starting the procedure, connect the surface and needle electrode leads to their corresponding color-coded connectors as shown in fig. 3 below.

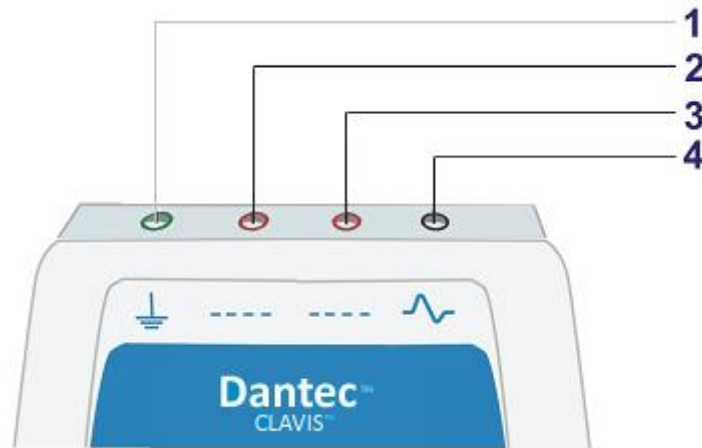


Figure 3. Electrode Stimulation Connections

Ref.	Sym- bol	Stimulation Electrodes	Color
1		Internally disconnected during stimulation	Green
2	-----	Anode	Red
3	-----	Anode (additional)	Red
4		Cathode (needle)	Black

- Connect the reference electrode lead to the red reference connector (-----) (2).
- If needed to reduce impedance, connect another reference electrode lead to the additional red reference connector (-----) (3).
- Connect the needle electrode lead to the black connector () (4).

Attaching the Electrodes to the Patient

Once the electrode leads have been connected to the device, you can attach the surface electrode/s (anode) to the patient, and when ready, proceed with the needle electrode (cathode).



WARNING: Avoid trans-thoracic stimulation. Keep the anode and cathode stimulation sites in close proximity.



WARNING: Do not use the stimulation mode while attaching the surface electrodes or introducing the needle electrode into the patient.

Stimulation Buttons

Activating the Stimulation Mode



- Press the **STIM** button to activate the current stimulation mode.
- Press the **STIM** button again to stop the current stimulation mode.

Setting the Pulse Rate and Width



- Press the **Hz** button to switch between **1Hz** and **2Hz** pulse rate.
- The **Green** light shows the pulse rate selected.



- Press the **ms** button to switch between **0.1ms** and **0.2ms** pulse width.
- The **Green** light shows the pulse width selected.

Adjusting the Stimulation Level



- Press the **Increase Stim Level** button to increase the stimulation level.
It is only possible to increase the STIM Level in steps of 1mA.
- Press the **Decrease Stim Level** button to decrease the stimulation level.
For continuous decrease of the STIM Level press and hold down the decrease button.

Stimulation Level Bar



- The **Stimulation Level** bar ranges from 0mA to 15mA.
- The **Stimulation Level** indicators show the level of current selected.
- When **Stimulation** mode is activated, the indicators are flashing.

Overload Indicator



- When the **Overload** indicator is lit up, it indicates that the device is unable to deliver the selected current.



CAUTION: Pay attention to the overload indicator during the stimulation mode. In case of overload, press the **STIM** button to stop the stimulation.



CAUTION: High impedance can be due to a weak connection between the device and the electrodes, or due to degradation of the electrodes.

Maintenance

Dantec Clavis requires no user maintenance other than cleaning the device after each use and replacing the battery periodically.

Cleaning

The cleaning procedure must be in accordance with your local hygiene authority's guidelines. The user/operator shall clean device after every use.

- 1 Before you start cleaning the device, make sure it is switched off and that the electrode leads are disconnected.
- 2 Wipe the device with a damp cloth.
- 3 Remove any excess of water with a dry cloth.
- 4 In case additional cleaning is required, gently wipe the device with a cloth moistened with a maximum of 80% alcohol solution.
- 5 Always wipe the device dry after using the alcohol solution.



WARNING: Do not immerse the device in any liquid, or drip water into the connectors, or any other openings in the cover.



CAUTION: Do not use solvent silicon based or abrasive cleaning agents to clean the device.

Replacing the Battery

Replace the battery when the indicator emits a yellow light.

Note that the device will automatically go into **“Fail Safe”** mode when the battery power is so low that it would affect the performance.



CAUTION: Do not use rechargeable batteries. Use only a standard 9V alkaline battery – see the section “Technical Data” in this user guide for further information.



CAUTION: Battery Leakage: If the unit is going to be stored for a prolonged period of time, we recommend that the battery is removed to protect the unit from damage caused by battery chemical leakage.

NOTE: Always follow the instructions accompanying the batteries.

Access to the Battery Compartment

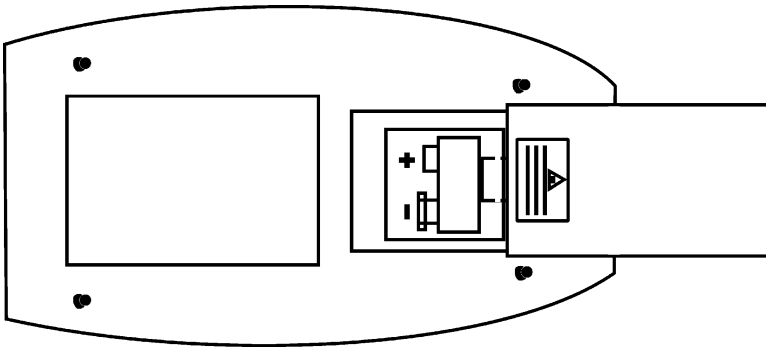


Figure 4. Dantec Clavis rear side, the battery compartment.

- 1 Turn off the device.
- 2 Slide open the battery compartment lid on the rear of the device.
- 3 Remove the old battery by pulling it up from the bottom end.
- 4 Insert the new battery into the battery compartment making sure that the plus and minus contacts are facing as indicated by the symbols.
- 5 Slide close the battery compartment lid until it locks in place.



CAUTION: Do not use the device if the battery compartment lid is open, or not correctly locked in place.

NOTE: It is recommended that the battery be removed from the device if it is not used for an extended period.

NOTE: Used batteries should be disposed of according to normal hospital/clinic policy or local regulations.

Neurodiagnostic Supplies

Natus recommends use of the following accessories with the Dantec Clavis.

Bo-ject® DHN Disposable Hypodermic Needle Electrode:

Part Number	Needle Length	Needle Diameter	Lead Color	Quantity
9013S0422	1" (25mm)	0.30mm (30G)	Tan	1/pouch- 10/box
9013S0432	1" (25mm)	0.41mm (27G)	Pink	1/pouch- 10/box
9013S0442	1.5" (37mm)	0.41mm (27G)	Light Blue	1/pouch- 10/box
9013S0472	1.5" (37mm)	0.46mm (26G)	Brown	1/pouch- 10/box
9013S0452	2" (50mm)	0.51mm (25G)	Grey	1/pouch- 10/box
9013S0462	3" (75mm)	0.71mm (22G)	Light Green	1/pouch- 10/box

Disposable Non-Gelled Surface Electrode:

Part Number	Recording Area	Lead Length	Lead Connector
9013L0203	7mm x 4mm	3" (8cm)	0.7mm male touchproof

Dantec reusable cables compatible with 9013L0203:

Part Number	Description	Length	Electrode End	Instrument End
9013C0152	Unsheilded Cable	32" (80cm)	0.7mm female touchproof	1.5mm female touchproof
9013C0242	Unshielded Cable	79" (2m)	0.7mm female touchproof	1.5mm female touchproof

See the Natus Neurodiagnostic Supplies Catalog for additional electrode options.

The catalog can be downloaded from natus.com

Technical Data

Power Supply
Power supply: internally powered equipment: one 9V alkaline battery. IEC-6LR61, ANSI-1604A. Power consumption: maximum 2 watts.
Weight
185 g. with battery (6.526 Oz) 140 g. without battery (4.938 Oz)
Dimension (L x W x H)
140 x 84 x 24 mm\
Operating Conditions
Temperatures: ranging from +10°C to +40°C (ranging from 50°F to 104°F). Humidity: ranging from 30% to 75%rh. Atmospheric pressure: ranging from 700hPa to 1060hPa.
Storage Conditions
Temperatures: ranging from -10°C to +50°C (ranging from -40°F to +122°F). Humidity: ranging from 10% to 100%rh. Atmospheric pressure: ranging from 700hPa to 1060hPa.
Mode of Operation
Continuous operation.
EMG Performance
Noise Level <2 μ Vrms \approx 10 μ Vpp
Amplifiers, EMG Mode Amplifier gain Min. 100,000. EMG amplifier bandwidth: 627Hz – 2.2kHz.
Patient Connections Active input: black 1.5mm TPC*. Reference inputs: red 1.5mm TPC*. Patient ground: green 1.5mm TPC*.
Volume Output Speaker bandwidth: 200Hz – 14kHz.
Stimulator Performance
STIM Mode Output current: 1.0 – 15.0mA \pm 10%. Adjustable in steps of 1mA. Electrode impedance: 200 – 7 k Ω . Maximum excitation voltage: 100V When impedance is higher than 7 k Ω , the device cannot deliver full current stimulus. The Overload indicator will be activated if the selected current level cannot be delivered.
STIM Level Stim frequency: 1Hz \pm 10%, or 2Hz \pm 10%. Pulse width: 0.1ms \pm 10%, or 0.2ms \pm 10%. Output waveforms: Monophasic Pulse.

Stimulator Performance (continued)**Patient Connections**

Active output: black 1.5mm TPC*.

Reference output: red 1.5mm TPC*.

* TPC: touch proof connectors.

WEEE Statement

Natus is committed to meeting the requirements of the European Union WEEE (Waste Electrical and Electronic Equipment) Regulations 2014. 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 take back 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 <https://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.



Safety & Standards Conformity

Standards of Compliance and Normative References

The **Dantec Clavis System** is powered by a 9V battery with the following levels of protection:

1. Type of protection against electric shock: Class II
2. Degree of protection against electric shock: Type BF
3. Degree of protection against ingress of water, IPX1
4. Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
5. Mode of operation: Continuous
6. Environmental Conditions: Normal: 10-40°C, 30-75% rH, 700-1060hPa

The **Clavis System** and its accessories have been designed to comply with the following national and international standards:

Table 1 – Safety Standard of Compliance and Normative References

CAN /CSA-C22.2 No. 60601-1: 08(R2013) + C2:2011 ANSI/AAMI ES60601-1:2005/(R)2012 + C1:2009/(R)2012 and A2:2010/(R)2012 IEC 60601-1:2005 + C1:2006 and C2:2007, Third Edition CENELEC EN 60601-1:2006 + A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6:2010, Edition 3.0 + A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62366:2007, Edition 1.0	Medical devices – Application of usability engineering to medical devices
IEC 60601-2-40:2016	Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

Table 2 – EMC Standard of Compliance and Normative References

IEC 60601-1-2, Edition 4.0, February 1, 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– collateral standard: electromagnetic compatibility – requirements and tests
IEC 61000-4-2:2008, Ed. 2.0	Electromagnetic Compatibility (EMC) Part 4-2: Testing and Measurement Techniques - Electro-static Discharge Immunity Test
IEC 61000-4-3 Ed. 3.0 with A1:2007+A2:2010	Electromagnetic Compatibility (EMC) Part 4-3: Testing and Measurement Techniques - Radiated, Radio-frequency, Electromagnetic Field Immunity Test
IEC 61000-4-4:2012, Ed. 3.0	Electromagnetic Compatibility (EMC) Part 4-4: Testing and Measurement Techniques - Electrical Fast Transient/Burst Immunity Test
IEC 61000-4-5:2014, Ed. 3.0	Electromagnetic Compatibility (EMC) Part 4-5: Testing and Measurement Techniques - Surge Immunity Test
IEC 61000-4-6 Ed. 2.0 with A1:2004 + A2:2006	Electromagnetic Compatibility (EMC) Part 4-6: Testing and Measurement Techniques - Immunity to Conducted Disturbances, Induced by Radio-frequency Fields
IEC 61000-4-8:2009, Ed. 2.0	Electromagnetic Compatibility (EMC) Part 4-8: Testing and Measurement Techniques - Power Frequency Magnetic Field Immunity Test
IEC 61000-4-11:2004, Ed. 2.0	Electromagnetic Compatibility (EMC) Part 4-11: Testing and Measurement Techniques - Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests
IEC 61000-3-2:2014, Ed. 4.0	Electromagnetic Compatibility (EMC) Part 3-2: Limits - Limits for Harmonic Current Emissions
IEC 61000-3-3:2013, Ed. 3.0	Electromagnetic Compatibility (EMC) Part 3-3: Limits - Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-voltage Supply Systems
CISPR 11 Ed. 5.0 with A1:2010	Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment - Electromagnetic Disturbance Characteristics - Limits and Methods of Measurement

Declaration of Compliance for IEC 60601-1-2, 4th Edition


Table 1 - Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Dantec Clavis is intended for use in the electromagnetic environment specified below. The customer or the user of the Dantec Clavis should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Dantec Clavis uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The Dantec Clavis is suitable for use in all establishments including 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	

Table 2 - Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Dantec Clavis is intended for use in the electromagnetic environment specified below. The customer or the user of the Dantec Clavis should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic fast transient/burst IEC 61000-4-4	±2 kV, 100Khz for power supply lines ±1 kV, 100Khz for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<100% drop, 0/5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods 40% dip for 5 cycles	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Dantec Clavis requires continued operation during power mains interruption, it is recommended that the Dantec Clavis is powered from a 9 Volt battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3 - Electromagnetic Immunity– for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer’s declaration – electromagnetic immunity			
The Dantec Clavis is intended for use in the electromagnetic environment specified below. The customer or the user of the Dantec Clavis should assure that it is used in such an environment			
Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz	6 V 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Dantec Clavis, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d=1.2 \times \sqrt{P}$ 150kHz to 80MHz</p> <p>$d=1.2 \times \sqrt{P}$ 80MHz to 800MHz</p> <p>$d=2.3 \times \sqrt{P}$ 800MHz to 2.5GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site¹ should be less than the compliance level in each frequency².</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

¹ Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Dantec Clavis is used exceeds the applicable RF compliance level above, Dantec Clavis should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as re-orienting or relocating Dantec Clavis.

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

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

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 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 modulation ^{b)} 18 Hz	2	0,3	28
870						
930						
1,720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0,3	28
1,845						
1,970						
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9
5,500						
5,785						
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						
^{a)} For some services, only the uplink frequencies are included.						
^{b)} The carrier shall be modulated using a 50 % duty cycle square wave signal.						
^{c)} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Declaration of Compliance for FCC

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.

⚠ Warning: Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Please consult natus.com for your local sales & service offices.



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