Medtronic

LEADPOINT™

User Guide

CE 0543

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.

Contents

Safety Information

Safety Requirements

This equipment has been designed and tested in accordance with IEC Publication 60601-1 (EN 60601 / BS 5724) Medical Electrical Equipment. The present User Guide contains some information and warnings, which will have to be followed by the user to ensure safe operation and to retain the equipment in safe condition.

This piece of equipment is intended to be used by qualified medical personnel, knowledgeable in the field of electro physiology and with the appropriate education and special training.

The equipment has been designed for indoor use at temperatures between +10°C and +40°C (+50°F to +104°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.

WARNING Any interruption to the protective earth conductor inside or outside the equipment or disconnection of the protective earth connector is likely to make the equipment dangerous. Intentional interruption is prohibited. The protective earth (ground) conductor should be checked regularly.

NOTE In order to meet classifications, approvals, and necessary performances *use only* Notebooks and PCs sold or specified by Medtronic A/S

For the combination of this equipment with other equipment and / or for its connection to installations, the following applies:

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 equipment, please pay attention to the requirements of IEC 60601-1-1, Safety Requirements for medical electrical systems.

When the equipment 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 equipment must be disconnected from all voltage sources before being opened for any adjustment, replacement, maintenance or repair.

Service must be referred to Medtronic A/S authorized service personnel, except for such works described in this User Guide 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 a patient, attention must be paid to the summation of patient leakage currents.

Whenever it is likely that the protection has been impaired, the equipment shall be made inoperative and be secured against any unintended operation.

In that case, call qualified service personnel to conduct at least a functional test and additionally a safety check including 1) an insulation test, 2) a ground continuity test and 3) a leakage current test, according to IEC 60601-1.

The protection is likely to be impaired if, for example, the equipment:

- Shows visible damage
- Fails to perform the intended function(s)
- Has been subjected to severe transport stresses.

Indications for use

The Leadpoint™ is intended to be used in electrophysiological tests. The Leadpoint™ is intended to monitor signals from the central nervous system.

Contraindications

It is a medical decision, whether the risk of use clearly outweighs any possible benefit in the individual case.

Age and sex do not in themselves present contraindications for any procedure. In conditions with bleeding tendency, certain care should be taken when needles are used. Conventional precautions should be taken in patients with infectious diseases.

A pacemaker is not a contraindication for the use of Leadpoint™. Please refer to contraindications for implant systems for references to pacemakers.

Please refer to possible contraindications given with the needles / electrodes used.

Warnings

Please refer to the above of this chapter and to the description of the current stimulator.

Precautions

In case of bleeding from needle electrode insertions, protective wear should be used according to local regulations.

Adverse Reactions

No other adverse reactions than bleeding (see section Contraindications) and transient pain due to needle electrode insertion are present.

WARNING Do not use this PC-based equipment for anything else than 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 the Leadpoint™ Software. Medtronic A/S assumes no responsibility when not used as described in this manual.

WARNING The device is not compatible for use in an MRI magnetic field.

CAUTION In the United States, Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner.

Symbols

Warnings

DANGER Possible explosion hazard if used in the presence of flammable anesthetics.

CAUTION Electric shock hazard. Do not remove cover. Refer servicing to qualified service personnel.

CAUTION Before connecting, read instructions.

Rear Panel / Bottom

24V⎓ Supply Voltage

PC Card Connection

External Trigger in/out

Footswitch

Temperature probe (redundant)

Functional earth (not Patient Ground).

STIM CC Stimulator

AEP Headset

VEP Visual Goggles Stim out

VEP Pattern Stimulator out
Monitor signal: VGA.

CE 0543 The device complies with the EC directive 93/42/EEC on medical devices.

Front Panel

Standby indicator

Power ON indicator

Equipment is of Type BF, i.e. the applied part is electrically isolated.

Sweep Speed / Sensitivity

Marker / Trigger (redundant)

Intensity Mode

Trigger Mode (redundant)

Stimulus Intensity

Stimulus Release Indicator

Repetition Rate

Stimulus Duration

Single Stimulus

Repetitive stimulus

Amplifier Input

Patient Earth (Ground)

Loudspeaker OFF/ON

Left-hand Side of Equipment

Power standby / ON button

Right-hand Side of Equipment

EP Head box connector (only on Leadpoint™ 4 model).

System Elements

Portable Models

Overview

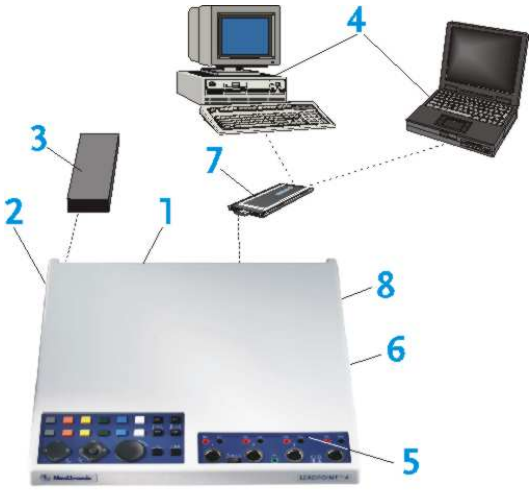

Fig. 1. Front view of the Leadpoint™ .

1. Stimulator output
2. Power Switch
3. Power Supply
4. Notebook or stationary PC
5. Amplifier inputs
6. Patient Unit
7. PC Card
8. EP Head box connector

Patient Unit

Signal Rear Panel

Fig. 2. Rear panel of the Patient Unit.

Left-hand Side of Device

Power standby / ON button

Rear Panel

24V Power connection to the separate Power supply Unit.

VEP Pattern Stimulator out

Connect the Pattern Stimulator Monitor to this connector. Monitor signal: VGA.

VEP Visual Goggles Stim out
Connect the Visual Goggle Stimulator to this connector.

AEP Headset

Connect the Auditory Stimulator headsets to this connector.

Magnetic Stimulation/ Tendon Hammer

Input and output for synchronization of external trigger or external stimulation acquisition.

Footswitch

CC Stimulator
Connection for CC Stimulator

PC PC Card Connection
Connection to the PC is done to this connector. The connector features optical cables for input/output to the PC Card to be inserted in the PC.

Functional earth (not Patient Ground).
Holes with various threads directly connected to the enclosure of the Patient Unit. Through the Power Supply, the functional earth is connected to the Protective earth of the mains.

Temperature in

Bottom of Device

CE 0543

The device complies with the EC directive 93/42/EEC on medical devices.

Right-hand side of Device

Amplifier input from Headbox. Connector for EP Headbox. (Keypoint® 4 only)

Grounding

While using a PC without a grounded printer connected, an earth cable may be necessary to reduce signal interference between the Patient Unit and the PC. Connect the earth cable from one of the spade connectors on the Patient Unit to a locking screw thread on the PC.

Fig. 3 Grounding (rear panel of the Patient Unit)

Interference

Line hum interference may be introduced by placing the Power Supply Unit close to the Patient Unit. Use of a shielded power line cable for the PC Notebook is recommended.

Overview of Cable Connections

Portable Models

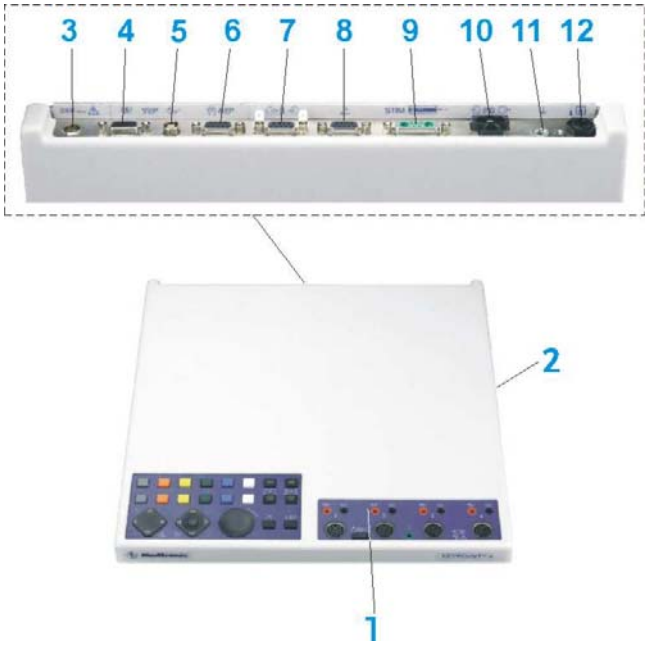

Fig. 4

1. Electrode Inputs	**2.** EP-Headbox
3. Power Supply	**4.** Pattern Stimulator
5. Visual Goggles Stimulator	**6.** Auditory Stimulator
7. Magnetic Stimulator / Tendon Hammer	**8.** Footswitch
9. CC Stimulator	**10.** PC Card
11. Functional Earth	**12.** Temperature

Cart-mounted When mounting the Leadpoint™ on the cart, the Patient Unit must be electrically connected to the cart.

Cable Connections

Before operating the Leadpoint™, the system parts should be connected. For a detailed description of the connectors used, refer to the sections above.

1. Connect the current stimulator, or optical loop back plug to the rear panel, or the Patient Unit. The current stimulator is optional.
2. Connect the PC Card to the PC Notebook (optional).
3. Connect the footswitch to the footswitch connector (optional).
4. Connect the printer to the printer connector on the PC Notebook (optional).
5. Connect the external mouse to the mouse socket on the PC Notebook (optional).
6. Connect the external slave monitor to the monitor connector on the PC Notebook (optional).
7. Connect the earth cable between Patient Unit and PC Notebook. This cable is only needed if there is no grounded printer connected to the PC.
8. Connect the PC card optical cable to the Patient Unit.
9. Connect the Patient Unit to its Power Supply Unit.
10. Connect the equipment setup to Mains.
11. Each monitor and printer must be connected to separate wall socket outputs.
12. Head box connector.
13. Connect the EP Head box to the EP H.
14. If the microTargeting Drive with the Motor Option//Encoder Option is to be connected, connect it to the PC COM port.
15. Connect the goggles to the visual goggle output connector (5).
16. Connect the headset to the auditory stimulator connector (6).
17. Connect the pattern stim monitor to the VEP connector (6).

IMPORTANT Use only external monitors (31F111 and 31F112) and mains supplies (80D103, 80D107 and 80D109) specified by Medtronic A/S in order to comply with IEC 60601-1-1.

Workstation Models

Overview of System Elements

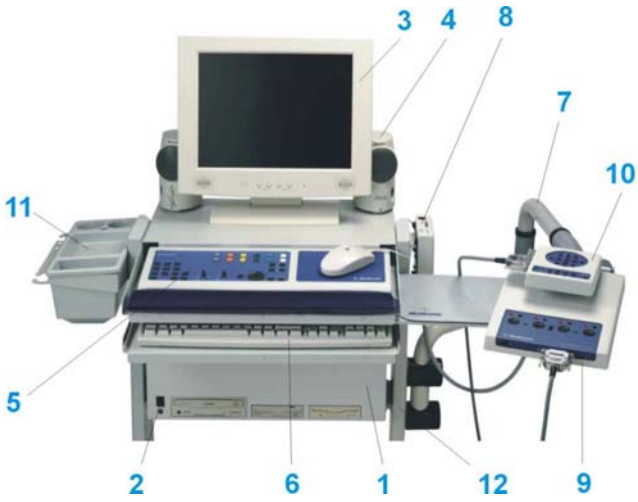

Fig. 5 Workstation Model

1	Computer	2	Power Switch
3	Screen	4	Speakers
5	Dedicated Keyboard	6	PC Keyboard
7	Electrode Arm	8	Current Stimulator (optional)
9	Electrode Box	10	EP-Head box
11	Container	12	Cart

All positions of optional devices are examples only.

CE 0543 The device complies with the EC directive 93/42/EEC on medical devices.

The device is of Type BF, i.e. the applied part is electrically isolated.

Connections: Dedicated Keyboard

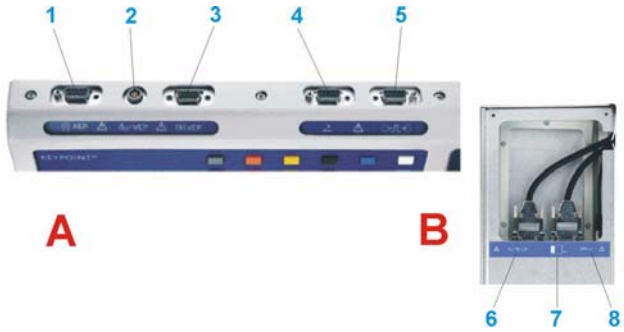

Fig. 6: A Rear Side and B is the bottom of the keyboard.

AEP	1	Headset
VEP	2	Visual Goggles Stim out
VEP	3	Pattern Stimulator out Monitor signal: VGA.
	4	Footswitch
	5	**Input / Output** Magnetic Stimulation/Tendon Hammer or Synchronization of external trigger or external stimulation acquisition.

B Bottom of Keyboard

PC	6	Computer connection
	7	Electrode box connection
24V⎓	8	Power Inlet

Interference

Always use shielded power line cables from Medtronic A/S to avoid hum line interference, especially near patient, amplifier or EP-Head box.

Overview of Cable Connections

Workstation Models

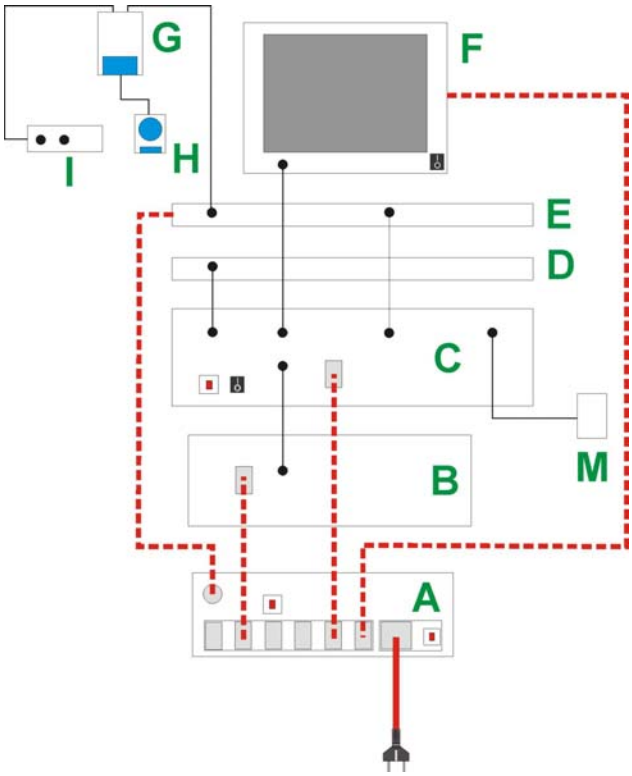

Fig. 7 Cable Connections on the Workstation Models

A	Power Supply	B	Printer (optional)
C	Computer	D	PC Keyboard
E	Dedicated Keyboard	F	Screen
G	Electrode Box	H	EP-Head box
I	Current Stimulator	M	Mouse

Cable Connections

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

1. Connect all signal interface cables shown in Fig. 7 above (black / thin).
2. Connect all power interface cables shown in Fig. 7 above, except for the main cables to the wall outlet (red / dotted).
3. Check that all voltage selectors on the drawing have the correct voltage setting.
4. Turn on all switches on the drawing (the switch of the computer is located on the rear side).
5. Connect the mains cable to the wall outlet / Turn on the main switch of the wall outlet.
6. Turn on the switch on the front of the computer unit (**C**).

Electrode Connections (An Example)

1. Connect the grounding electrode to the Patient Ground jack.
2. Connect the reference electrode to a Ref. jack.
3. Connect the active electrode to the Act. Jack on a channel.
4. Connect the needle electrode to an input socket.
5. Connect the stimulation electrode to a Stimulator output socket on the Stimulator box.

IMPORTANT Use only the external monitors (31F111 and 31F112) specified by Medtronic A/S in order to comply with IEC 60601-1-1.

NOTE Pulling out the power line cable from the mains input on the power supply disconnects the mains power of the complete system.

IMPORTANT Use only external monitors (31F111 and 31F112) and mains supplies (80D103, 80D107 and 80D109) specified by Medtronic A/S in order to comply with IEC 60601-1-1.

IEC 60601-1-1

CAUTION
When connecting options such as a slave monitor and/or a printer, attention must be paid to:

IEC 60601-1-1 Medical Electrical Equipment, Part 1:
General Requirements for Safety.
1. Collateral Standard
Safety Requirements for 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) 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 additional protective earthing.

Or

   b) Supplied from an extra isolating transformer, limiting the enclosure leakage current to a value not exceeding 0.5 mA

Or

   c) Supplied from a floating power supply, limiting the enclosure leakage current to a value not exceeding 0.5 mA

Please refer to IEC 60601-1-1.

Controls

Portable Models

The Dedicated Keyboard

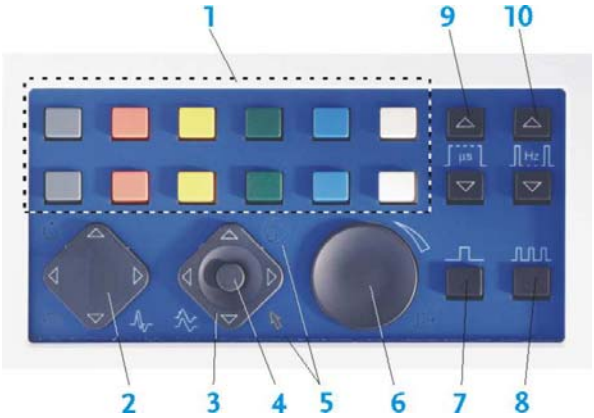

Fig. 8 The Dedicated Keyboard

1	Function Keys	2	Sweep Speed / Sensitivity
3	Move/Position	4	Wheel Mode Button
5	Mode indicators	6	Intensity Wheel
7	Single Stimulus	8	Repetitive Stimulation
9	Stimulus Duration	10	Repetition Rate

Function Keys (1)

The colored function keys on the dedicated keyboard correspond to the 12 function buttons on the screen.

Sweep Speed/ Sensitivity (2)

Sweep Speed	▷Right	Increases the Sweep Speed.
	◁ Left	Decreases the Sweep Speed.
Sensitivity	△ Up	Increases the Sensitivity
	▽ Down	Decreases the Sensitivity

Move/Position Button (3)

▽△ Up/down arrows. Select trace in the Trace Window.

Wheel Mode Button (4)

Toggles between Intensity Mode and Cursor Mode. When set to Cursor Mode, the selected Trace Window is set to Triggered Mode, too. If the test includes a stimulated modality, the mode returns to Intensity Mode immediately.

Intensity Wheel (6)

The wheel controls the stimulus intensity, or simulates cursor movements without using the mouse. If it is in cursor mode, the trigger/clipping level may be adjusted.

Mode Indicators (5)

The Wheel mode status is indicated by light diodes.

Workstation Models

The Dedicated Keyboard

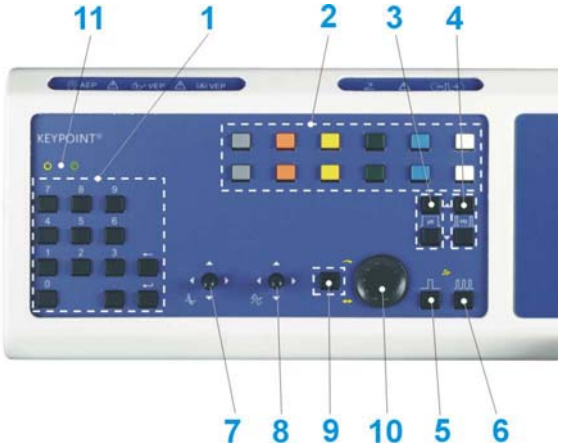

Fig. 9 The Dedicated Keyboard

1	Numeric Keyboard	2	Function Keys
3	Stimulus duration	4	Repetition Rate
5	Single Stimulus	6	Repetitive Stimulus
7	Sweep Speed / Sensitivity	8	Marker/trigger
9	Wheel Mode Button	10	Intensity Wheel

Function Keys (2)

The function keys have the same function and color as the soft keys on the screen.

Sweep Speed / Sensitivity (7)

	Sweep Speed
▷ Right	Increases the Sweep Speed.
◁ Left	Decreases the Sweep Speed.

	Sensitivity
△ Up	Increases the Sensitivity
▽ Down	Decreases the Sensitivity

Marker / Trigger (8)

Controls the cursor movements, etc. (see table of Wheel Modes).

Wheel Mode Button (9)

Toggles between ***Stimulus Intensity Mode*** and ***Cursor Mode***. Press any button, dedicated keys, or the mouse to return to Stimulus Intensity Mode (default).

Intensity Wheel (10)

The wheel controls the stimulus intensity or simulates cursor movements without using the mouse (see table of Wheel Modes).

Mode Indicators

The Wheel Mode status is indicated by light diodes.

WARNING Do not touch the Wheel Mode Button, while moving cursors, or changing trigger levels, using the intensity wheel, as you might unintentionally increase the stimulation intensity.

Interference

Always use shielded power line cables from Medtronic A/S to avoid hum line interference, especially near the patient, the amplifier, or the EP-Head box.

Mouse

The Leadpoint™ is partly mouse-controlled. To activate a function, move the mouse pointer to the desired position, and click any mouse button.

Fig. 10 External Mouse.

Automatic Mouse Positioning

To minimize the use of the mouse during an investigation, Leadpoint™ offers *Automatic Mouse Positioning*, a feature found in the System Setup (system part). Having turned the Automatic Mouse Positioning on, the mouse automatically jumps to the most probable position on screen. Clicking the mouse without moving it will often be sufficient. The mouse position is just a suggestion and can be changed manually. The left mouse button is connected in parallel with Footswitch A.

Footswitches

Footswitches can be supplied, either as a triple pedal model (A, B and C) or as a mono pedal model (B).

A Left mouse button
B Start/stop stim. (hold down for 1 second to start repetitive stimuli).
C Run / Pause.

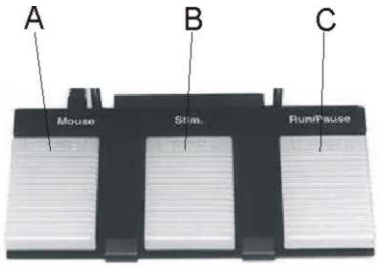

Fig. 11 Footswitches A, B and C

PC Keyboard

Text: Upon marking a data field in, for example, the Patient Database, a text cursor will appear in the field. Press the enter key to accept the data, and proceed to the next field.

Data: The arrow keys work in parallel with the Sweep Speed / Sensitivity button (2):

◁▷ arrows Control the sweep speed.
△▽ arrows Control the sensitivity.

NOTE If any editable field is open, the arrows move the text insertion cursor. In this case, keep the CRTL key pressed while using the arrow keys to change the sweep speed.

PC Function Keys

F1 - F6 activate the lower row of soft keys seen on the screen. F7 - F12 activate the upper row of soft keys seen on screen (alternatively SHIFT F1 - F6).

Amplifiers

Portable Models

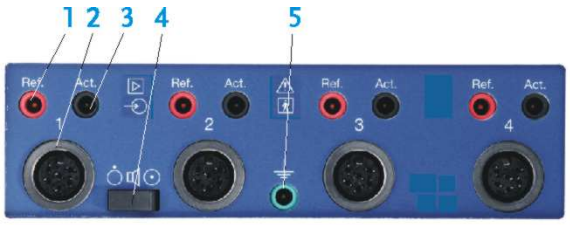

Fig. 12 Electrode Input

Amplifier Sockets 1-2 / 1-4* (2)

Each amplifier input features both a DIN-type socket and a pair of 1.5mm touch-proof jacks.

* Only Leadpoint™ 4.

Ref. and Act. (1 and 3)

Red reference Jack and black active jack.

Patient Ground (5)

Connect the patient's earthing / grounding electrode to this jack (green).

IMPORTANT Do not connect "patient ground" to the functional earth connection on the rear panel of Leadpoint™, or to any other "earth/ground" connections, as the electrode inputs are galvanic isolated.

Workstation Models

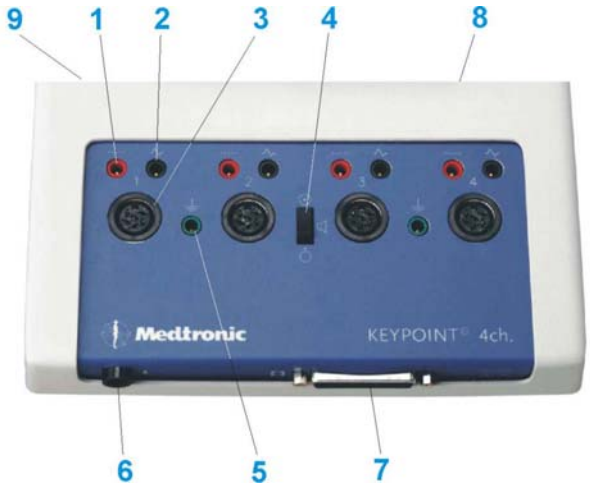

Fig. 13 Electrode Box

1	Reference Electrode	2	Active Electrode
3	Amplifier Sockets	4	Loudspeaker ON/OFF
5	Patient Ground	6	Temperature
7	EP-Head box Connector*)	8	Dedicated Keyboard
9	Current stimulator		

Amplifier Sockets 1-2 and 1-4*) (3)

Each amplifier input features both a DIN-type socket and a pair of 1.5mm touch-proof jacks.

*) 4- and 8-channel models only.

Ref. and Act. (1 and 2) ----

Red reference jack and black active jack.

Patient Ground (5)

Connect the patient's earthing / grounding electrode to this jack (green).

IMPORTANT Do not connect "patient ground" to the protective earth connection on the rear panel of the Power Supply Unit, or to any other "earth/ground" connections, as the electrode inputs are galvanic isolated.

Loudspeaker OFF/ON (4)

Turn the switch ON to listen to the electrode signals through the loudspeakers.

Temperature (6)

Connect the temperature sensor (optional) to this input jack. Range 15-45ºC (59-113ºF).

EP-Head box (7)

Terminal for EP-Head box cable connection.

Current Stimulator (9)

Volume (PC)

To control the volume, use the controls on the PC and/or the external speaker. Please note that Windows sound settings may also influence the volume.

EP Head Box (Optional)

List of Input Jacks

A1, A2, C3, C4, Cz, Fp1, Fp2, Fpz, Fz, O1, O2, Oz, Pz, 1, 2, 3, 4, 5, 6, 7, 8.

Each channel input can be connected to a pair of these 1.5mm touch-proof jacks. Channels can share the same reference pin, One of the inputs is the active (Act.) and the other one is the reference (Ref.).

Use cables equipped with touch-proof jack:

- 13P72 Electrode Cables are used together with disposable Monopolar Electrodes, Reference needle Electrode (13S61-66) and Reference Surface electrode (13L45).
- 13P78 Electrode Cables are used together with Platinum Needle Electrode (13L70), Disposable Scalp Needle Electrode (13R31), Silver Chloride Disc Electrode (13L20) and Plate-shaped Electrode (13L29).

The EP Head box has a 1.5m cable connecting to the connector on the right-hand side of the Leadpoint™.

Patient Ground

Connect the patient's grounding electrode to this jack.

Impedance Test

Press the Knob! Acceptable impedance is indicated by all LEDs off. Slightly too high impedance is shown as blinking LEDs and much too high as constantly lit LEDs.

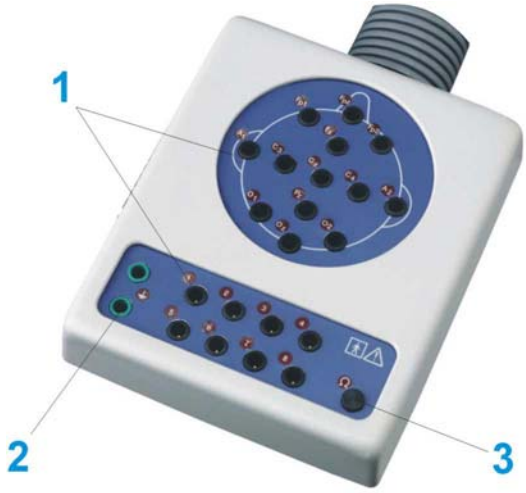

Fig. 14 The EP Head Box

1 Input Jacks
2 Patient Ground
3 Impedance Test button

Fig. 15 The Connector

WARNING Do not connect „patient ground“ to the Leadpoint™ functional earth or to any other „ground“, as the EP Head box is galvanic isolated.

Stimulators

Active Stimulator Handgrip

Fig. 16 Part no 31E15

4 Output electrode pins
5 Intensity / reset
6 Stimulus release
7 Polarity LEDs

Single-Stim

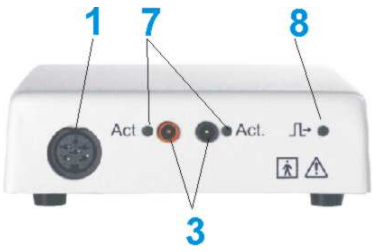

Fig. 17 Part No 31E11 / 31E16

1 Output socket, support for active handgrip
3 Output jacks, touch proof
7 Polarity LEDs
8 Stimulus LEDs

Multi-Stim

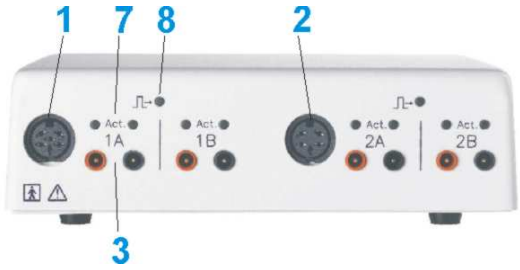

Fig. 18 Part No 31E12 / 31E13

1 Output socket, support for active handgrip
2 Output socket
3 Output jacks, touch proof
7 Polarity LEDs
8 Stimulus LEDs

Controls

Output Sockets (2)

For connection of stimulation electrodes with DIN plugs.

Output Socket, Support for Active Handgrip (1)

For connection of stimulation electrodes with DIN plugs. Support for Active Handgrip.

Output Jacks, Touch Proof (3)

For connection of stimulation electrodes with touch proof connectors.

Output Electrode Pins (4)

For direct stimulation on the skin, please see the description of Stimulation Electrodes, later in this section.

Intensity / Reset (5)

Increase or decrease current intensity by
Model 31E15: Turning the knob.
All Models: turning the Intensity knob on the control panel.

Stimulus Release (6)

Single Stimulus

Model 31E15: shortly press the button on the handle

All Models: shortly press footswitch B, or press the Single-Stim button on the control panel.

Repetitive Stimuli:

Models 31E15: hold down the button on the handle for at least 1 second.

All Models: hold down the footswitch B for at least 1 second, or press the Rept-Stim button on the control panel.

Stop Simulator:

Models 31E15: shortly press the button on the handle.

All Models: shortly press footswitch B, or press the Rept-Stim or the Single button on the control panel.

Polarity LEDs / Active (7)

LEDs indicating the active (cathode) stimulation electrode.

Stimulus LEDs (8)

Flashes for stimulus pulse.

WARNING Dangerous physiological effects! The current stimulator may give off dangerous currents and voltage.

WARNING When operating the current stimulators, take care not to expose the patient to high currents. Therefore, before connecting, or disconnecting the stimulation electrode, always "reset" the stimulator.

ADVICE A patient with an implanted electronic device (for example a cardiac pacemaker) should not be subject to electrical stimulation, unless specialist medical opinion has been obtained.

ADVICE

- Avoid transthoracic stimulation.
- Avoid electrical stimulation for extended period of time.
- Avoid accidental contact between connected but unapplied electrodes and other conductive parts including those connected to protective earth.

WARNING 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. 1 m) to short wave, or microwave therapy equipment may produce instability in the electrical stimulator output.

Source Voltage

The source voltage for the current stimulators is approx. 300 V. If the load impedance exceeds 300 V/I_{skin}, where I_{skin} 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 approx. 0.5 W. This may limit the output current for fast stimulations.

Electrode Setup

Recording with Micro and Semi microelectrodes

When recording with micro and semi microelectrodes, eliminating noise is a very important issue. Therefore it is extremely important to use only active shielded electrode cables.

External noise sources, such as monitors, PCs, printers and instruments used during the surgical procedure can introduce noise into the recording, i.e. proper grounding of this equipment is of great importance. This is also the case for the stereotactic frame, which may act as an antenna, introducing noise into the recording, if not properly grounded to the patient.

The power supply for the Leadpoint™ Patient Unit must be grounded via a **shielded** power cable. The notebook must be powered by a **shielded** power cable via a short converter cable. Do **not** use the standard notebook PC power cable. If a grounded printer is **not** attached, you must connect the Leadpoint™ Patient Unit and the Notebook PC with the small yellow wire.

If the system is placed on a metal trolley or table (or a table with legs made of metal), the metal parts must be grounded, i.e. connected to the Leadpoint™ Patient Unit.

NOTE The notebook, the trolley, etc. must be grounded to the **rear** panel of the Patent Unit, **not** to the ground connector of the amplifier. The ground connector of the amplifier is intended for patient use **only**.

When recording from microelectrodes inserted into the brain, a lot of background EEG activity will contaminate the signal of interest. Therefore, it is good recording practice to set the filtering bandwidth (default settings) from 500Hz to 5kHz. This will reduce the impact of the EEG activity and of the mains interference (50/60Hz).

Getting Started

Starting the Leadpoint™

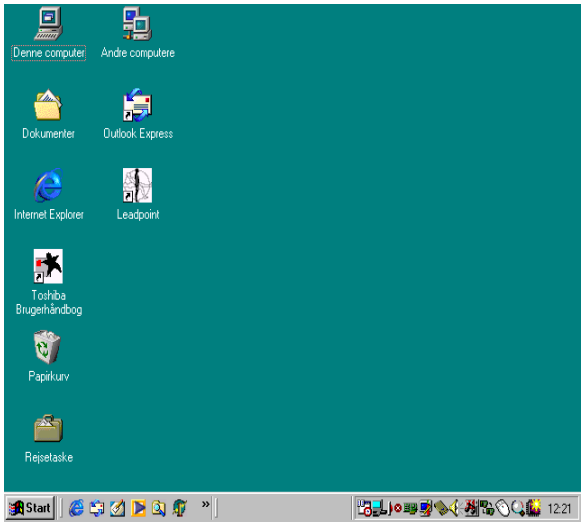

Fig. 19. The Windows Desktop.

- Turn the computer on.
- Turn the Power Switch on the left-hand side of the equipment on.
- 

Start the Leadpoint™ from the Windows desktop by double-clicking the Leadpoint™ icon, or from the Start menu (via Programs).
- Leadpoint™ performs an internal hardware test, before displaying the start page.

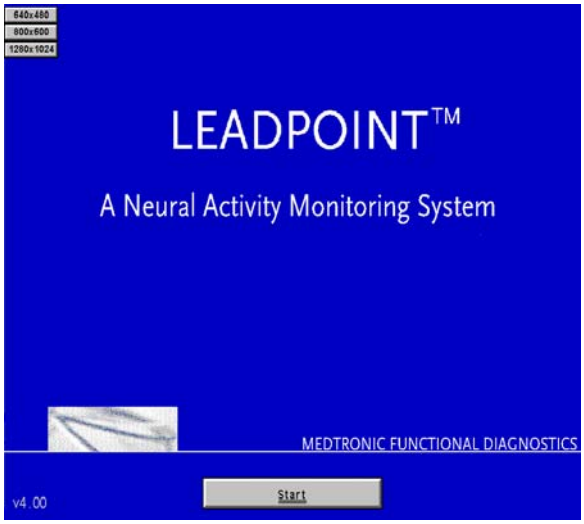

Fig. 20. Start page of Leadpoint™.

Shut Leadpoint™ Down

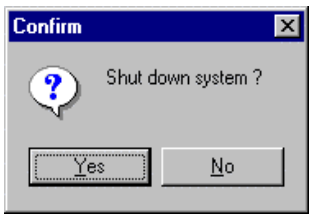

Fig. 21. The Shutdown Dialog Box

- Quit the Leadpoint™ program from the Patient Page.
  - The shutdown dialog box appears. If you want to shut down Windows, click the ***Yes*** button.
  - If you want to continue in Windows, click the ***No*** button, instead.

Patient Data

Click on ***START*** to activate the Patient Data page.

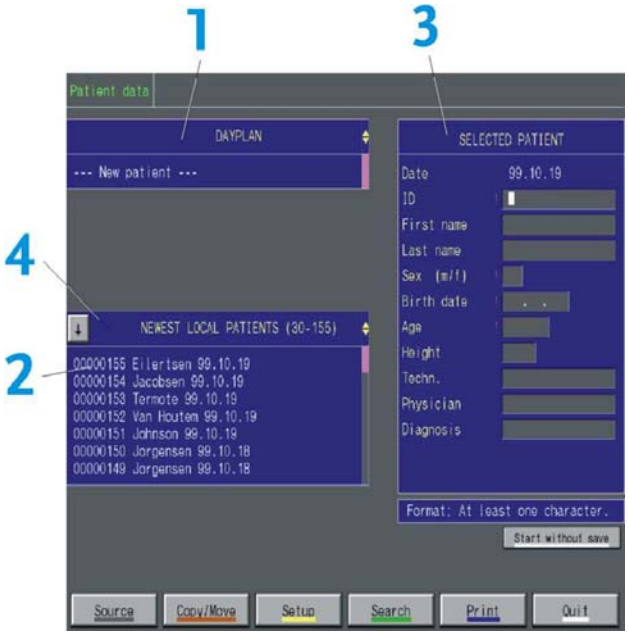

Fig. 22. Patient Data Window.

Creating, or Editing Patient Data

Patient Data Fields (Selected Patient) (3)

Move between the data fields using ↑, ↓, ↵, [TAB], [Shift TAB], or the mouse.

- Type *ID*, usually a civil registration number containing the date of birth.
- Fill in *First Name*, *Last Name* and *Sex*. *Date of Birth* and *age* may be created automatically by the system, depending on the system setup.
- The remaining 3 fields are Technician, Physician and Diagnosis.
- Accept the new, or modified Patient data clicking on ***OK,*** or by using ***TAB*** right after the diagnosis field in the Selected Patient Box.

The Test Menu appears, and the investigation can begin.

NOTE A beep is heard, if the Patient Data contains invalid data fields with !

Patient Catalogue (4)

If a patient's data are already in the system, a new investigation can be started by finding and by selecting the patient. Then click on NEW INVEST button to open the Main Menu.

TIP Clicking the double arrow in the corner of the catalogue, invokes a simple search box.

NOTE If one of the data fields is marked with a red "!", the format of the date in the field may be incorrect (look at the help line in the bottom of the screen).

Investigation without Patient Data

Click on ***START WITHOUT SAVE*** to initialize a new investigation without typing the patient data. All data will be erased when returning to the patient page.

Dayplan (1)

If a patient booking system (e.g. ProMan) is connected, the Dayplan window lists the patients scheduled for today. Selecting a patient from this window will move the patient data to the Selected Patient Window.

NOTE The Patient Data Screen automatically turns itself off after 1 min due to security reasons.

Window Overview

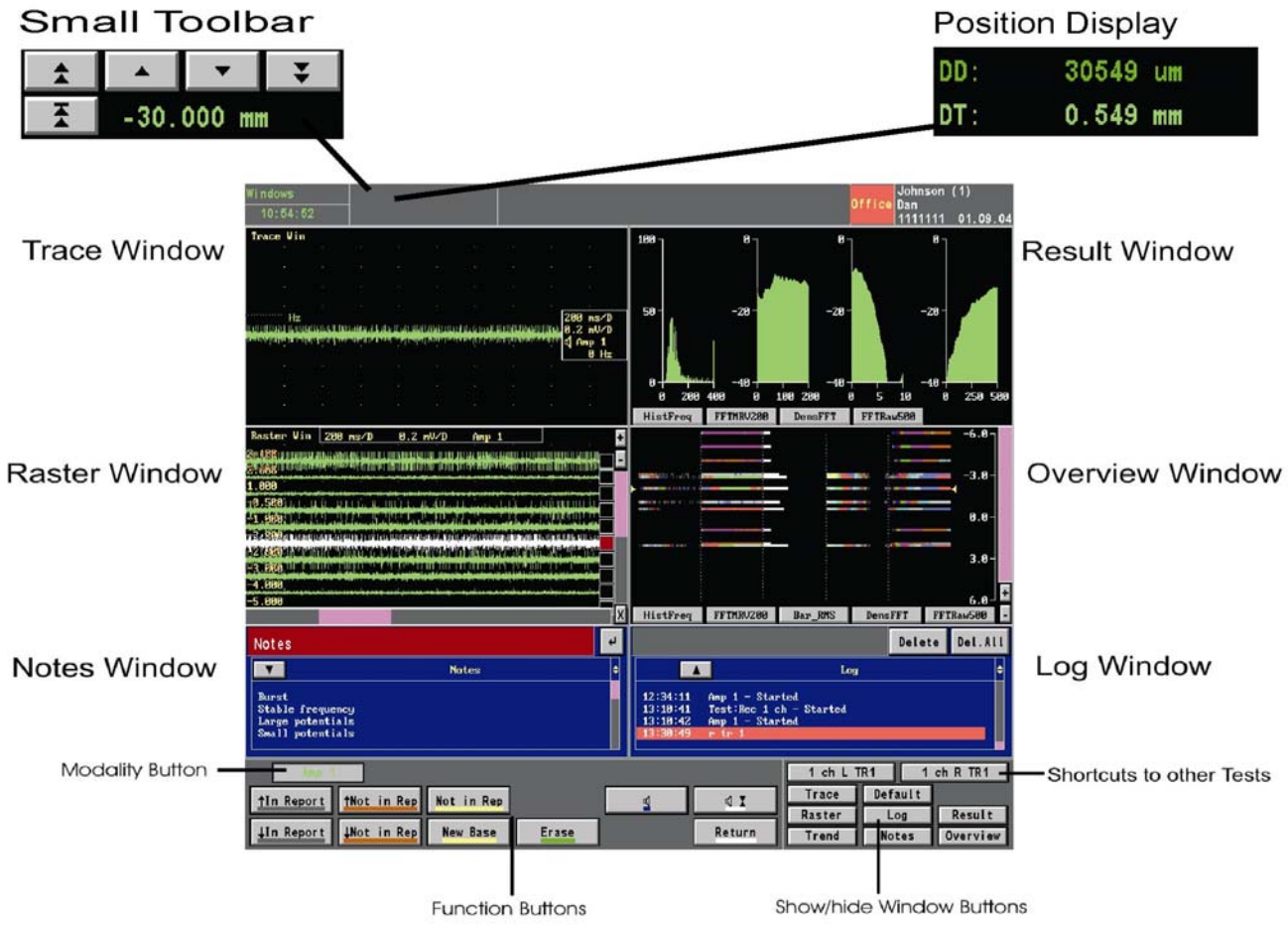

Figure 23

The screen layout is user-definable, and can be customized to suit your requirements. The example above is an illustrative example on a customized window setup. The window setup consists of:

- ***The Trace Window*** provides you with an on-line view of the microelectrode recording findings.
- ***The Raster Window*** to which all signals are transferred , when they are saved in the Trace Window.
- ***The Notes Window*** contains a list of 16 predefined and editable notes, plus space available for free text notation.
- ***The Log Window*** encompasses all notes, the time of saving, and the start of a modality.
- ***The Result Window*** provides a graphical representation of the analysis of the signal selected in the Raster Window.
- ***The Overview Window*** provides you with an overview of the signal behaviour through a whole trajectory.

- ***Buttons***: the Modality Button, the Function Buttons, the Shortcuts to other Tests, the Show/hide Buttons.
- ***The Small Toolbar*** displays the current position of the electrode. If no Motor Option/Encoder Option is active, five control buttons are available to manually enter the position. The Small Toolbar provides the controls, which make it possible to decrease, or increase the distance to the target by mm macro steps and by mm micro steps.
- ***The Position Display*** shows the current position of the electrode when the Motor Option/Encoder Option is active. The Distance to the Target (DT) value is displayed in green figures. When the position is changed, the color turns yellow. Both the Distance Driven and the Distance to the Target are displayed

Warnings

Warning and Error Messages

Gain Errors in Amplifiers, max. error:
Gain in amplifiers, as tested during power up, exceeds the accepted calibration limits. Exit the Leadpoint™ program and verify the cable connection. Recalibration may be necessary.

Current Stimulator may be malfunctioning
Problem occurred during power up test of the stimulator. Exit the Leadpoint™ program and verify the cable connection. Do not use the current stimulator, when this message is shown, as the stimulator might be defective.

Maintenance

Cleaning and Disinfecting Procedures

The maintenance that can be performed by the operator is limited to the cleaning and disinfecting the Leadpoint™. Any internal maintenance of the equipment must be performed by qualified service personnel.

- Surface electrodes, etc. in direct contact with the patient should be cleaned with a water-based disinfectant as soon as possible after use and followed by proper sterilization or disinfecting. Please refer to the Instructions on the package.
- The Leadpoint™ patient unit and trolley:
  - Before cleaning the Leadpoint™ units, switch off the mains. Use a cloth gently wrung in a recommended disinfectant as listed below.
  - Dilute the disinfectant properly, as stated by the manufacturer.

For routine cleaning use

Phenoles (Bacillotex®, etc.) or 70% alcohol, 0.5% chlorohexidine.

If hepatitis or any other dangerous virus contamination is suspected: Aldehydes (Cidex®, Korsolin®) or chlorinates (Diversol BX®).

Be careful not to drip water or disinfectant directly into the input and output plugs and other openings in the cover. Remove excess disinfectant with a dry cloth.

CAUTION Do not use solvent silicon-based or abrasive cleaning agents, especially on the keyboard.

Make sure that no liquids enter the equipment at push buttons and other openings in the enclosure.

Before using disinfectants other than those specified, please contact Medtronic A/S for further information.

Waste management

Leadpoint™ and its accessories must be disposed of separately as electronic waste (see the individual Instructions for Use of each accessory / part).

Safety Checks

The following safety checks should be conducted (by qualified personnel) at least once a year and in the event of repair:

1. Inspection for visible damage to equipment.
2. Inspection of mains cord and connecting cables.
3. Check of electrode cables and patient connections.
4. Check of current stimulator output in all ranges (load 500Ω, curve to be monitored on an oscilloscope).
5. Possibly: insulation resistance.
6. Measurement of leakage currents.
7. Measurement of resistance of protective earth conductor.

Classification

Classification requirements

- 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 or disinfecting recommended by the manufacturer: Please, see section on “Maintenance”.

- 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).
- 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.

Technical Data

Units

Amplifiers	Input Impedance	Balanced: 200Mohm Common Mode: >1000 MOhm/25pF
	Noise Level typical (RMS)	0.6µV (2 Hz-10kHz) shorted Input
	Isolation Mode Rejection	>160dB
	Common Mode Rejection Ratio	>100dB
	Sensitivity	0.5µV/D - 20 mV/D (15 Steps)
	Display Sensitivity	0.05µV/D – 20 mV/D (18 Steps)
	Filters	Program dependant: High Pass 0Hz*), 0.1Hz to 3kHz (16 steps) Low Pass 20 Hz -Open (12 Steps)
	Connection Types	1.5mm Touch Proof/ DIN connector EP Headbox connector 37pin D sub (Headbox)*)
	Calibration Signal	Yes
	Resolution	16 Bits
	Sampling Rate	48.0kHz per amplifier Hw sample rate 3.072MHz
Averager	Max. Averager per Channel	9,990 Sweeps/Averager.
	Points per Channel	Program dependent Up to 12,000
Acquisition	Sweep Speeds	Program dependent 0.1ms/d – 16 S/d (29 steps) 0.1ms/d – 200ms/d (6 steps)
	Delay Line	EMG –400 ms - +0 ms EP ± 15 ms Max ± 600ms
	Repetition Rates	0.1 – 200Hz
Electrical Stimulators	Max. Output	100mA Software controllable
	Max intensity Resolution	0.1/0.02mA
	Stimulus Duration	40µs - 1 ms
	Safety Features	Power Limitation, Power Up Test
	DC component	Duration x Frequency x Current

	Overload Safety	The selected current will flow as long as the following conditions are fulfilled: 1): I **Á** 400 V / R I(mean)**Á**1.00 mA 300V <Uoutput **Á**400V I(mean)=1.20 mA 250V <Uoutput **Á**380V I(mean)=1.40 mA 230V <Uoutput **Á**350 V I(mean)=1.60 mA 210V <Uoutput **Á**310 V I(mean)=1.80 mA 190V <Uoutput **Á**275 V I(mean)=2.00 mA 170V <Uoutput **Á**250 V I(mean)=2.20 mA 150V <Uoutput **Á**225 V I(mean)=2.40 mA 110V <Uoutput **Á**200 V I(mean)=2.60 mA 80V <Uoutput **Á**180 V I(mean)=2.80 mA 40V <Uoutput <170 V I(mean)=3.00 mA 0V <Uoutput <150 V I(mean)=3.40 mA 0V <Uoutput <50 V 2): P (mean) <0.5 W R indicates the load impedance, I the selected stimulus current, I(mean) the maximum possible mean current in repetition mode. P(mean) the output power in repetition mode.
Auditory Stimulators	Stimulus Shape	Clicks, Tone, Burst, Pips, Half Sine, Full Sine (Shape/Type)
	Click	50 - 100 µs
	Max. intensity	Software dependant: 132 dB peSPL (1.0dB Steps)
	Masking level	-15 to 99 dB peSPL
Visual Stimulators	Pattern Type	Checkerboard, horizontal bars, vertical bars
Display	Resolution	Up to 1280x1024 on external monitor 1024x768 / 800x600 / 640x480 on notebook monitor.

*) Keypoint® 4 with Headbox only

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