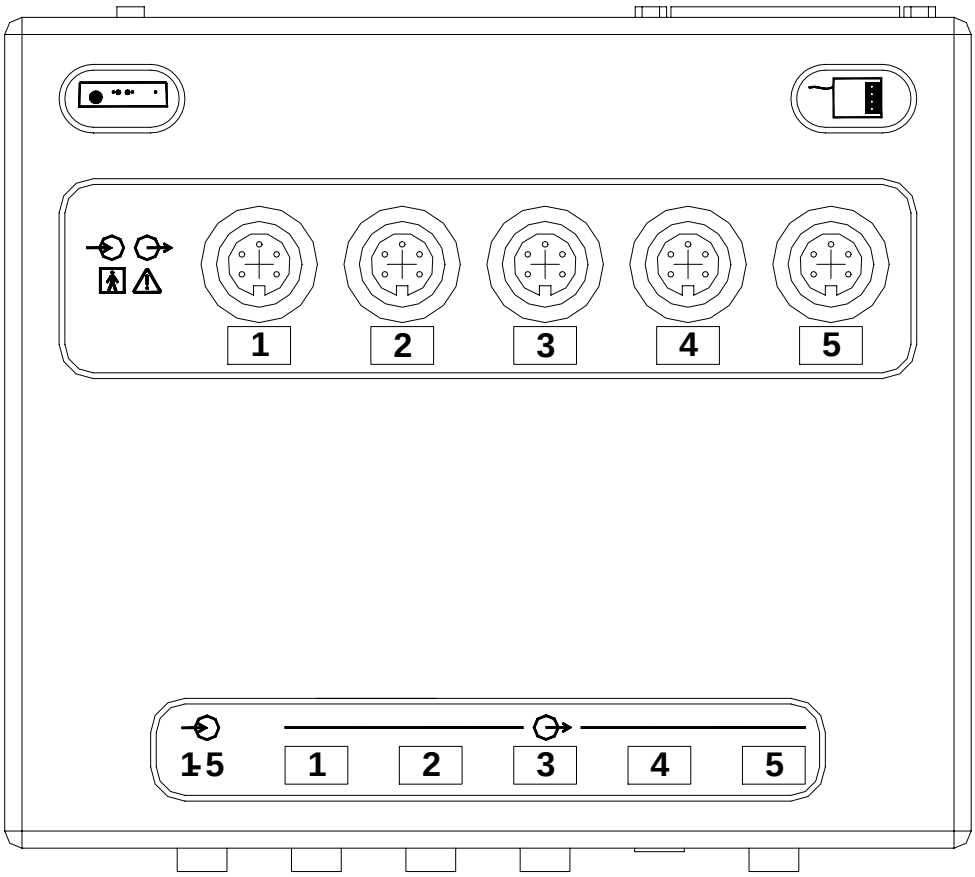
Medtronic

5 Channels Amplifier Box



Addendum to the Leadpoint System User Guide

CE 0543

At the time of printing / transfer to the CD-ROM, this manual correctly described the software / hardware 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 software / hardware.

The following situations void any guarantee(s) and obligations for Medtronic A/S:
- The software / hardware is not used according to the enclosed manuals and other accompanying documentation.
- The software / hardware is installed or modified by persons other than Medtronic A/S service technicians

Table of Contents

General Information

NOTE This manual is an addendum to the Leadpoint User Guide.

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

This device 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 device has been designed for the 8 channels Leadpoint workstation system.

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

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

1. Service must be referred to Medtronic authorized service personnel, except for such works described in this manual as being performed by the operator.
2. Whenever it is likely that the protection has been impaired, the device shall be made inoperative and be secured against any unintended operation.
3. 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.
4. The protection is likely to be impaired if, for example, the device:
   - Shows visible damage
   - Fails to perform the intended function(s)
   - Has been subjected to severe transport stresses.

Indications for Use

NOTE See the Leadpoint User Guide

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

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

For warnings, contraindications, precautions and adverse reactions: Please see the Leadpoint User Guide.

5 Channels Amplifier Box

Use of the Amplifier Box

NOTE See the Leadpoint User Guide

The device is an alternative to the existing headbox and switchbox regarding connections and fixation. The device is connected to the electrode box and to the stimulator box. It is possible to connect up to 5 patient applied microelectrodes. You may either record MER signals from all channels simultaneously, or stimulate via one selected channel without changing cables, or electrodes. The device has 5 mechanical channel switches and one release switch. Each channel has a high impedance preamplifier with a shield driver.

- The amplifier box allows for 5 identical high impedance input amplifiers, (4 high impedance plus 4 limited impedance amplifiers in the existing system) resulting in simpler and faster use.
- The switching of stimulator connections will be faster and simpler.
- The *simple use* will reduce the risk of operator errors.
- The *fast use* also reduces surgery time, and thereby reduces the risk to the patient.

General Warnings

⚠ Carefully read the warnings below and in the Leadpoint User Guides.

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

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

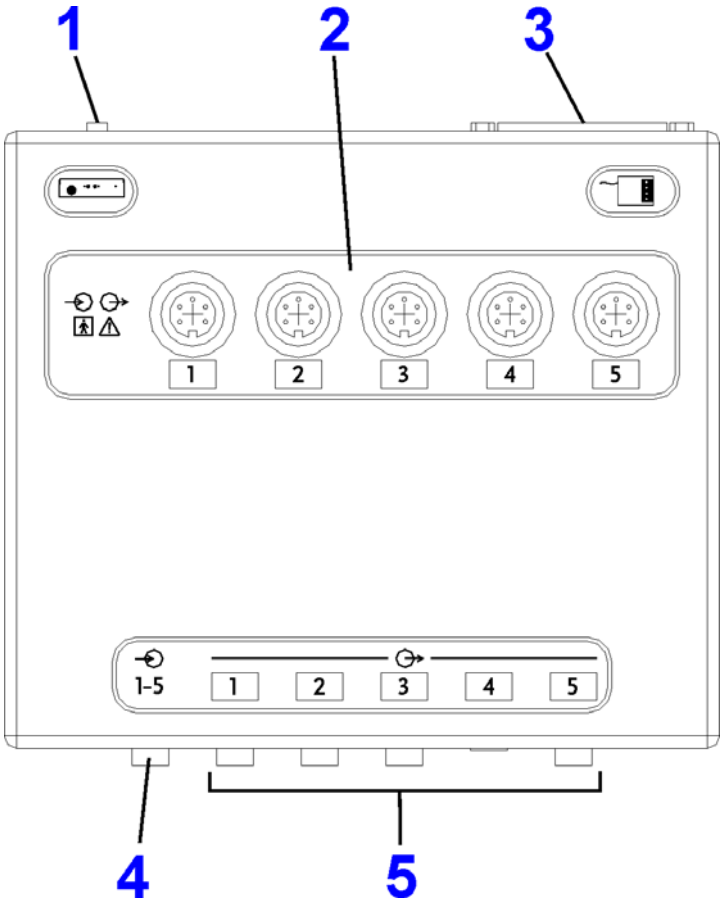
CAUTION Before connecting, please read the instructions.

Kit Check List

1 5 channels amplifier box
1 Electrode box cable
1 Stimulator cable
1 User Guide Addendum
1 Setup CD

Installation

Controls and Symbols



1 Stimulator connector
2 input/output sockets (5 channels)
3 Electrode Box Connector
4 Release switch
5 Switch buttons, one for each electrode (5 channels)

Signal in

Signal out

Stimulator

Electrode box

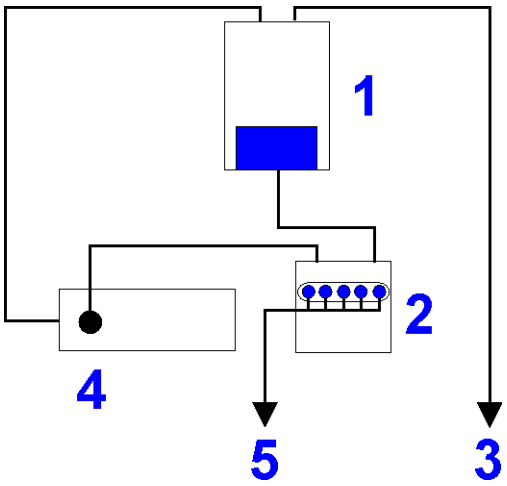
CE 0543

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.

See the accompanying documentation and carefully read the user guide before using the device.

System Connections



1 Electrode box (8 channels)

2 Amplifier box (5 channels)

3 Dedicated keyboard

4 Current stimulator

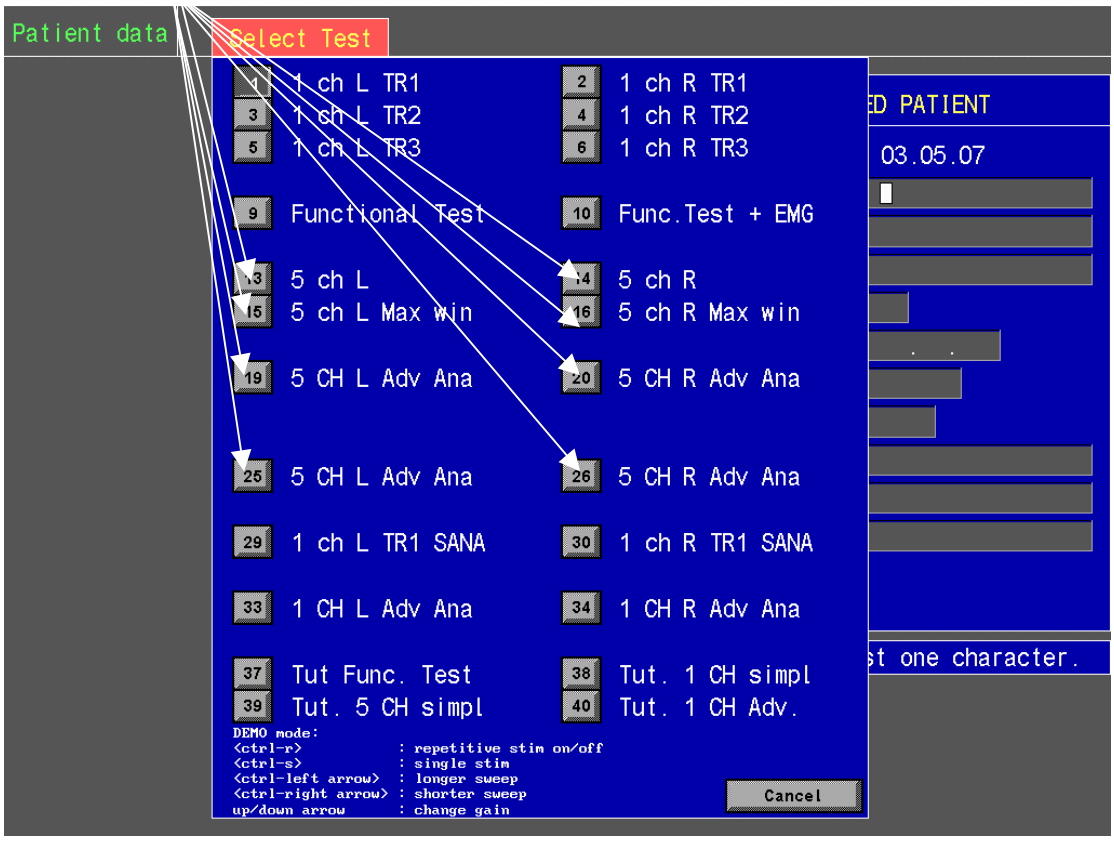
5 Electrode cables to patient

Setup

- Insert the Installation CD in your CD-drive.
- Open the Windows Explorer [+ E] and open the CD-drive.
- Double click on the file “install.bat” and the necessary files will be installed.

NOTE: this procedure will overwrite all your existing Leadpoint settings including the Acquire Page and Window set-up

The following test is set up and ready for 5 channels recording



Manual Setup for 5 Channels Amplifier Box

Check you Leadpoint Clinical manual for details on how to change amplifier. For access to the amplifier setting please set the following settings:

Amplifier #	Act	Ref
1	P2	P1
2	Oz	Pz
3	O2	C4
4	FP2	A2
5	O1	A1

Maintenance

Cleaning and Disinfecting Procedures

The maintenance that can be performed by the operator is limited to cleaning and disinfecting the device. Any maintenance inside the device must be performed by qualified service personnel.

- Before cleaning the device 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.

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

Waste Management

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

Hardware Testing

Test Equipment

- 8 CH Leadpoint WS with test installed (Leadpoint plus test CD).
- Single Stim
- 9031V1161, Test cable DIF, and COM., for stimulator-amplifier test.
- 9031V1151, Leadpoint Test Adapter.

IMPORTANT: If the Leadpoint Stimulus adapter 9013C053x isn't used, omit the Leadpoint Test Adapter 9031V1151.

Test

LP5 S/N: _____, date _____, Initial _____.

Start the Leadpoint program:

- Press "Start"
- Press "Start without save"
- Choose "Amp. test"

Plug test cable 9031V1161, Stim connector into the Test Adapter 9031V1151
Plug test cable 9031V1161 into LP5

- Stim in connector 1 (including Test Adapter)
- CM in connector 2 and
- DIFF in connector 3

Press grey button on LP5.

Select "TEST 1"

- Press "Stop"
- Press "Start"
- Start repetitive stimulation.

WARNING Do not touch the connectors while stimulating.

Noise on upper curve (CH2) must be less than 10µVpp ☐ OK

- Press button 1 on LP5, this routes stimulation to connector 1
- Turn stimulator intensity to 10mA

Common Mode signal on upper curve (CH2) shall be less than 20µVp ☐ OK

Stimulation on lower curve (CH3). Amplitude approximately 1mV ☐ OK

Pulse top is falling approximately 0.5mV (0.4 to 0.8mV) ☐ OK

Select "TEST 2"

- Press "Start"
- Move test cable:

- Stim in connector 2
- CM in connector 3
- DIFF in connector 4

- Press grey button on LP5.
- Start repetitive stimulation.

Noise on upper curve (CH3) must be less than 10µVpp ☐ OK

- Press button 2 on LP5, this routes stimulation to connector 2
- Turn stimulator intensity to 10mA

Common Mode signal on upper curve (CH3) must be less than 20µVp ☐ OK

- Stimulation on lower curve (CH4). Amplitude approximately 1mV ☐ OK
- Pulse top is falling approximately 0.5mV (0.4 to 0.8mV) ☐ OK

Select "TEST 3"

- Press "Start"
- Move test cable:

- Stim in connector 3
- CM in connector 4
- DIFF in connector 5

- Press grey button on LP5.
- Start repetitive stimulation.

Noise on upper curve (CH4) must be less than 10µVpp ☐ OK

- Press button 3 on LP5, this routes stimulation to connector 3.
- Turn stimulator intensity to 10mA.

Common Mode signal on upper curve (CH4) shall be less than 20µVp ☐ OK

- Stimulation on lower curve (CH5). Amplitude approximately 1mV ☐ OK
- Pulse top is falling approximately 0.5mV (0.4 to 0.8mV) ☐ OK

Select "TEST 4"

- Press "Start"
- Move test cable:

- Stim in connector 4
- CM in connector 5
- DIFF in connector 1

- Press grey button on LP5.
- Start repetitive stimulation.

Noise on upper curve (CH5) shall be less than 10µVpp ☐ OK

- Press button 4 on LP5, this routes stimulation to connector 4
- Turn stimulator intensity to 10mA.

Common Mode signal on upper curve (CH5) must be less than 20µVp ☐ OK

- Stimulation on lower curve (CH1). Amplitude approximately 1mV ☐ OK
- Pulse top is falling approximately 0.5mV (0.4 to 0.8mV) ☐ OK

Select "TEST 5"

- Press "Start"
- Move test cable:

- Stim i connector 5
- CM i connector 1
- DIFF i connector 2

Press grey button on LP5.
Start repetitive stimulation.

Noise on upper curve (CH1) shall be less than 10µVpp ☐ OK

- Press button 5 on LP5, this routes stimulation to connector 5.
- Turn stimulator intensity to 10mA.

Common Mode signal on upper curve (CH1) shall be less than 20µVp ☐ OK

- Stimulation on lower curve (CH2). Amplitude approximately 1mV ☐ OK
- Pulse top is falling approximately 0.5mV (0.4 to 0.8mV) ☐ OK

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 device.
2. Inspection of connecting cables.
3. Check of current stimulator output in all ranges (load 1000Ω, curve to be monitored on an oscilloscope).
4. Possibly: insulation resistance.
5. Measurement of leakage currents.

Classification

Classification Requirements

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.

Service Centers

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