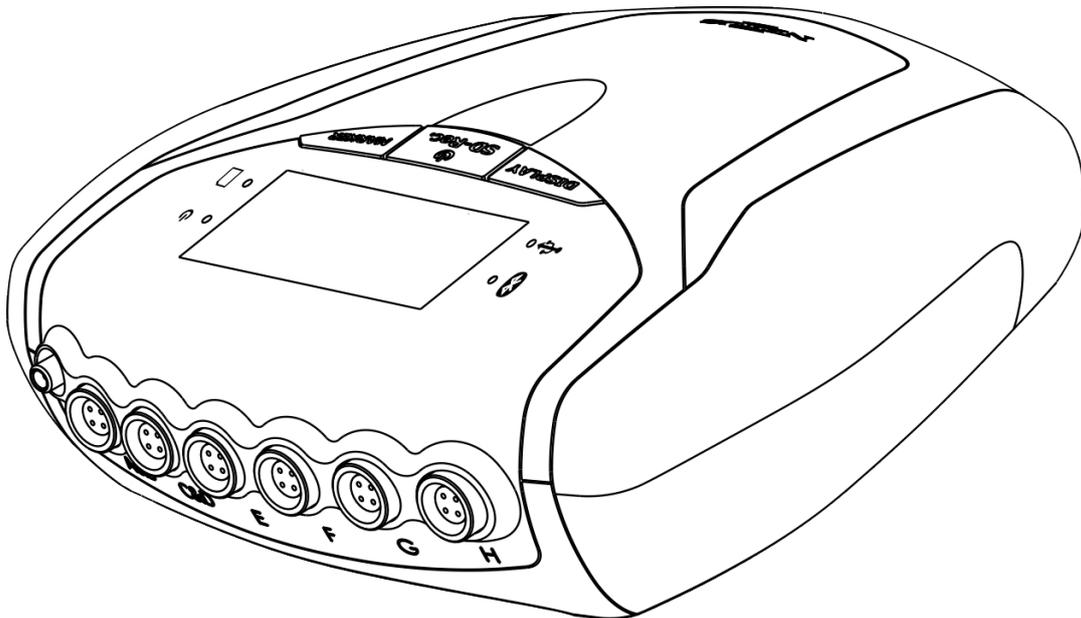




MINDMEDIA
NEURO AND BIOFEEDBACK SYSTEMS

NeXus-10 MKII

User Manual



Version 2.0

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1 Service and support

1.1 About this manual

This manual is intended for the user of the NeXus-10 MKII system – referred to as ‘product’ throughout this manual. It contains general operating instructions, precautionary measures, maintenance instructions and information for use of the product. Read this manual carefully and familiarize yourself with the various controls and accessories before starting to use the product.

1.2 Contact information

This product is exclusively manufactured by Twente Medical Systems International B.V. for Mind Media B.V. Distribution and service is exclusively performed by or through Mind Media B.V.

Mind Media Support can be reached via email (support@mindmedia.nl) or by phone during office hours (CET). Visit our Support section on www.mindmedia.com, because this may resolve your problem. Always provide as much information on your problem as possible, including serial numbers of the products.

Address

Mind Media B.V.

Louis Eijssenweg 2B
6049CD Herten
The Netherlands

Phone +31 (0) 475410123

Website www.mindmedia.com/

Important



In case of need for repair **ALWAYS** first contact Mind Media Support. The support staff will supply you with an RMA number in case a return is required. Never ship products back to Mind Media without this authorization and/or RMA number.

1.3 Warranty information

The product, except its cables and accessories, is warranted against failure of materials and workmanship for a period of 2 years from the date of delivery. Cables and accessories have a warranty period of 6 months.

Repairs can only be performed by the manufacturer. Warranty will terminate automatically when the product is opened by any person other than qualified personnel (authorized by Mind Media).

The warranty does not cover the following:

- failure resulting from misuse, accident, modification, unsuitable physical or operating environment, or improper maintenance
- failure caused by a product for which Mind Media is not responsible
- damage resulting from use of non-approved accessories
- any non-Mind Media products

The warranty is voided by removal or alteration of identification labels on the product or its parts. Warranty is also voided in case seals on the enclosure are broken. Mind Media does not warrant uninterrupted or error-free operation of wired or wireless data transmission.

Any technical or other support provided for a product under warranty, such as assistance with “how-to” questions and those regarding device set-up and installation, is provided without warranty.

2 Safety information

This section contains general warnings, explanation of markings, limitations of use, safety measures, and precautionary measures that are important for the safe use of the product.

2.1 Explanation of markings

This section explains the various markings and symbols used with the product.



Attention: read important safety information



Important information / guidance for use



Consult instructions for use



Device has type BF applied parts



Ingress protection rating



Keep dry



CE-certified (93/42/EC Annex XII), see declaration of conformity



Identification of the manufacturer



Date of manufacture with adjacent year of manufacture



Reference number



Serial number



Contains transmitter module



Bluetooth connected



Bluetooth disconnected



USB component



USB connected



USB disconnected

-  Power symbol
-  Recording to SD memory card
-  Data logging on
-  SD memory card
-  Power pack remaining charge level
-  Charging
-  Channel indicator (A-H)
-  Sensor indicator
-  Unauthorized access
-  Direct current
-  Special EU instructions for disposal are applicable to a product on which this symbol is placed. The Maintenance section of this manual contains information on how to dispose of this equipment.

2.2 Limitations of use

Limitations of use

- Under federal law (only applicable to the USA) this product may only be sold by or on the order of a physician or licensed practitioner.
- The product may only be used under the constant supervision of or on the instructions of a physician or other authorized medical professional.
- The user must have knowledge of current good practice in physiological measurement in science and clinical application.

The product is NOT intended for:

- critical patient monitoring
- use in life support systems

The product is NOT to be:

- used near MRI equipment
- exposed to ionizing radiation
- used on patients undergoing electro surgery
- used in oxygen rich environments (concentration > 25 % at 1 atm)



The product is NOT:

- suitable for use in an inflammable mixture of anesthetics or agents and air, oxygen or nitrous oxide
- defibrillator proof
- suitable for sterilization

Do not use, store or transport the product outside the specified environmental conditions, this may damage the product.

Do not store or use in environments with Magnetic Resonance Imaging (MRI) equipment, or equipment capable of emitting diagnostic levels of ionizing radiation.

Apart from the above, there are no contra-indications. There are no known side effects from the use of this product.

2.3 Safety measures and warnings

Warnings



- IEC60601-1 compliance is the responsibility of the end user. To ensure compliance to IEC60601-1, the system must meet the following conditions:
 1. The PC and peripherals (e.g. USB hubs) must comply with IEC60950 or equivalent, and must be located outside the patient environment (the patient environment is defined as the area within 1.5 m (6 ft around and 7.5 ft above) of the patient;
- AND
 2. The enclosure leakage current from any device within the patient environment, including any parts of equipment which extend into that environment, is not more than 0.1 mA in normal condition and 0.5 mA in single fault conditions.
- The required low enclosure leakage current may be achieved by powering the PC and peripherals from an isolation transformer. It is not recommended that the equipment be connected to other non-isolated monitoring equipment or communication networks. In this event it is the end user's responsibility to ensure compliance with IEC60601-1.

-
- Make sure the computer is installed according to local regulations and safety precautions. If the computer is equipped with a safety earth conductor, use it and connect it to a well-earthed wall socket.

-
- The only mains power adapter that may be used is the original adapter, type Meanwell GS18A12-P2L, included with the product. Do NOT replace it with anything else. If any other type of mains power supply is used neither safety nor correct operation of the product can be guaranteed.

-
- Do not place the mains power adapter in the patient environment, i.e. within typically 1.5 meters from the patient.

-
- Do not combine the use of the product with any other electronic equipment, except those specified in this manual. Doing so may impair the product's emissions and immunity regarding EMC.



-
- The device can only be used with the accessories designated by the manufacturer. The use of other accessories may impair the product's emissions and immunity regarding EMC.

-
- The accessories supplied with the device can only be used with Mind Media approved devices.

-
- Do not connect active sensors or electrodes to any of the inputs unless they have been approved by the manufacturer.

-
- Transmission quality decreases when there are other radio devices in the neighborhood. The wireless transmission may be interfered with by other equipment.

-
- The product should not be used adjacent to or stacked with other equipment. If this is required, then it should be observed if normal operation of the product in that configuration is confirmed.

-
- Do not immerse the product in any liquid.
-

-
- The product is to be kept dry. If operated out of office, it must be fitted in a carrying case that provides an ingress protection of at least IP02.
-
- Do not expose the product to direct sunlight, heat from a source of thermal radiation, excessive amounts of dust, moisture, vibrations, or mechanical shocks.
-
- Do not incinerate any part of the product.
-
- If liquids or moisture penetrate any part of the product, disconnect the affected part from all other product parts. If in doubt about safety or performance of the equipment, have it checked by the manufacturer.
-
- Take care in arranging patient and sensor cables to avoid risk of patient entanglement or strangulation.
-
- No modification of this product is allowed. The product should not be tampered with.
-
- Do not use a power pack other than specified.
-
- The patient must not touch the connector of the power pack. The operator must not touch the patient and connector of the power pack simultaneously.
-
- Do not touch the connector pins of interface plugs or receptacles.
-
- Do not open the product using tools.
-
- The product is not to be used when it is clearly damaged or wet, or suspected to be wet inside.
-
- The product connectors contain nickel, avoid prolonged skin contact with patients with nickel allergy.
-
- Disposable electrodes, which are used for electrophysiological measurements, may be a biohazard. Handle, and when applicable dispose of these materials in accordance with accepted medical practice and any applicable local, state and federal laws and regulations.
-
- Reusable electrodes present a potential risk of cross-infection especially when used on abraded skin, unless they are restricted to a single patient.
-
- To prevent contamination: store electrodes in a separate bag within the packaging.
-
- Do not attempt to service any part of the product while it is in use or connected to a patient.
-
- There are no user serviceable parts within the product. Repairs can only be performed by the manufacturer.
-
- When connecting the product in an IT-network:
Simultaneous connection of other equipment to the same USB or Bluetooth network may result in previously unidentified risks to patients, operators or third parties. Such risks must be identified, analyzed, evaluated and controlled. Subsequent changes to the USB or Bluetooth network can introduce new risks that require additional analysis. Changes to the IT-network include: changes to its configuration, connecting additional items, disconnecting items, updates and upgrades of connected equipment.
-
- Clean the product only according to the cleaning instructions in this manual. Before cleaning, make sure the device is switched off. Never use any aggressive chemicals to clean the product.
-



2.4 Precautionary measures

Precautionary measures



- Make sure that the wall socket is well earthed, to reduce 50 or 60Hz disturbances.

- Reliability of the signal transmission decreases when the distance between the Bluetooth PC receiver and the device increases or when there are conducting materials in the straight line between the Bluetooth PC receiver and the device.

- Do not use an operating cellular phone within 50 cm of the device to avoid excessive noise on the signals.

- Sharp bends or winding the cables in a loop smaller than 5 cm diameter may damage the cables.

- Do not use sharp objects such as pencil-points or pen-tips to manipulate the buttons on the control panel, as this can cause damage.

- Dispose of the power pack according to local regulations.

2.5 Disclosure of residual risk

The risk analysis process for the product has determined that there are no residual risks which need to be disclosed for the product.

2.6 Information for lays

Operators must convey the following information to patients in case they carry the product out of the professional's office:

- There are no contra-indications.
- Keep the product dry, shield it from direct sunlight and other sources of heat and keep it away from sources of electromagnetic fields (antennas etc.).
- Be careful when interacting with children and pets that cables are pulled loose, keep away from sources of dust, dirt and/or pests.
- Make sure electrodes remain attached where they are, be careful not to get entangled in wires, not to pull on cables and prevent to fold cables or bend them too sharply.
- If there's any indicator or message to look out for on the display, and how to react to it.
- How to replace the power pack (if necessary), as described in section 6.2.
- To contact the operator in case of unexpected operation or events.

3 NeXus-10 MKII parts

Compare the contents of your purchase with the list below to verify whether all NeXus-10 MKII parts are present*.

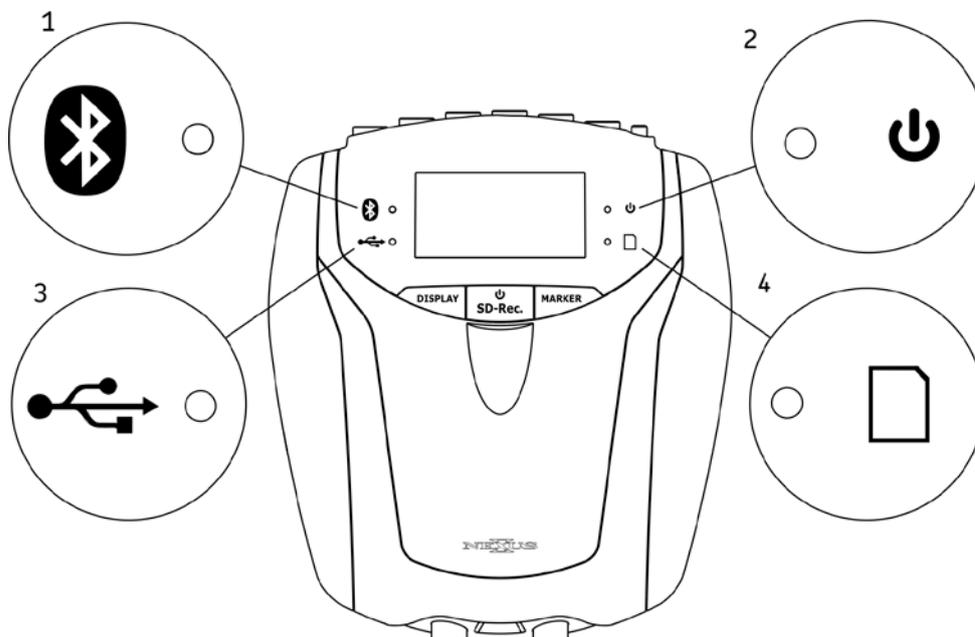
#	Item	Description
1.	Device	The data acquisition device (NeXus-10 MKII device). See Section 3.1.
2.	Power pack	The internal power supply for the device. See Section 3.2.
3.	Mains power adapter	The mains power adapter for charging the power pack. See Section 3.3.
4.	Bluetooth USB dongle	Bluetooth interface to be used on the PC side to provide wireless IT network with the device. See Section 3.4.
5.	USB cable	USB cable to connect device to the PC. See Section 3.5.
6.	Installation CDs	Device driver with application programming interface. The device is supplied to you either on CD or via email (download). See Section 3.6.
7.	Documentation	User manual.

* Actual items may differ from this typical scope of delivery. Check package list for actual package contents. In case of unexpected package contents, contact Mind Media support.

3.1 NeXus-10 MKII main unit

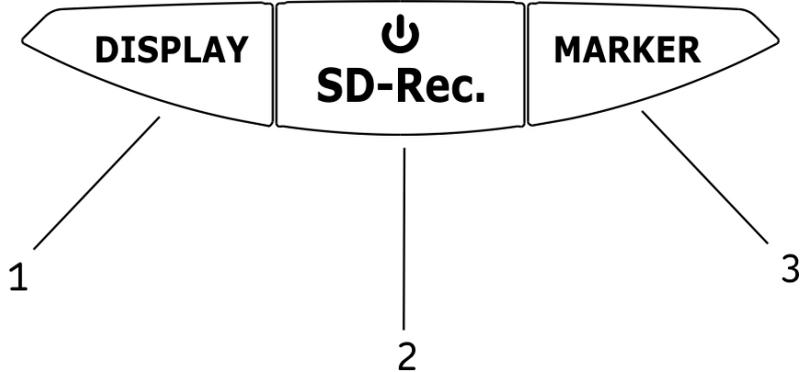
The NeXus-10 MKII main unit contains electronics for measurement, data storage and transmission.

NeXus-10 MKII main unit - Top view



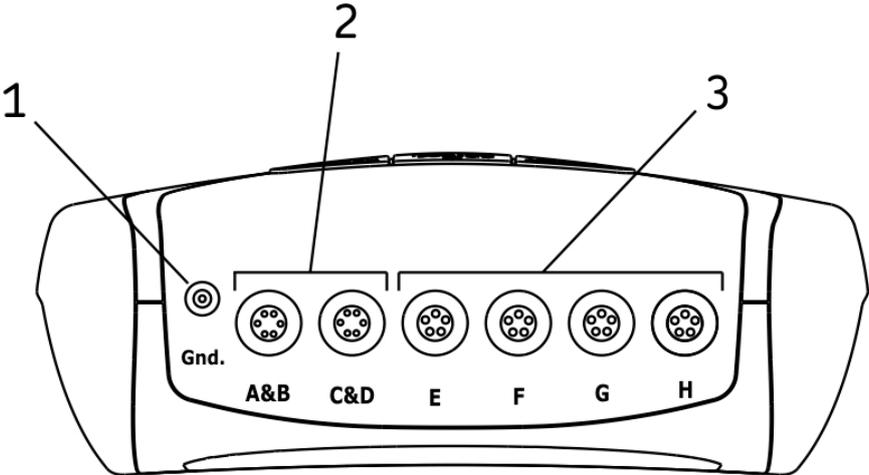
#	Description
1.	Bluetooth indicator light.
2.	Power on/off indicator light.
3.	USB indicator light.
4.	Memory card indicator light.

NeXus-10 MKII main unit - Buttons



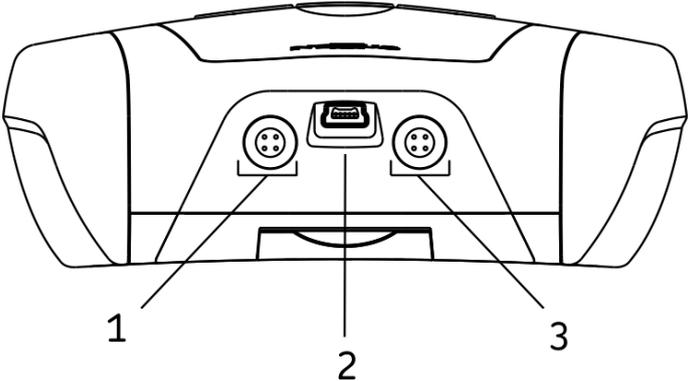
#	Description
1.	Display button.
2.	Power/ Memory card recording button.
3.	Marker button.

NeXus-10 MKII main unit – Front view



#	Description
1.	Patient Ground input.
2.	A&B - C&D (bipolar) inputs.
3.	E – H (auxiliary) inputs.

NeXus-10 MKII main unit – Rear view

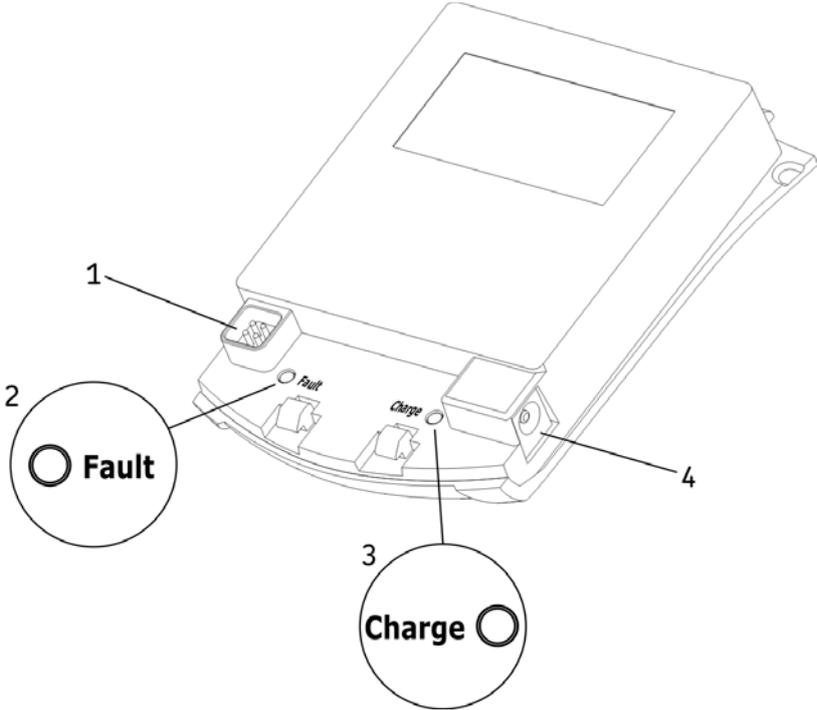


#	Description
1.	Oximetry sensor input.
2.	USB port.
3.	Serial sensor input.

3.2 Power pack

The power pack is a rechargeable battery, for use with the NeXus-10 MKII main unit.

Power pack



#	Description
1.	Connector to NeXus-10 MKII main unit.
2.	Power pack fault indicator light.
3.	Power pack charge indicator light.
4.	Connector for mains power adapter.

3.3 Mains power adapter

Provides power to recharge the power pack. Type Meanwell GS18A12-P2L, see label on the adapter for technical details.

Mains power adapter



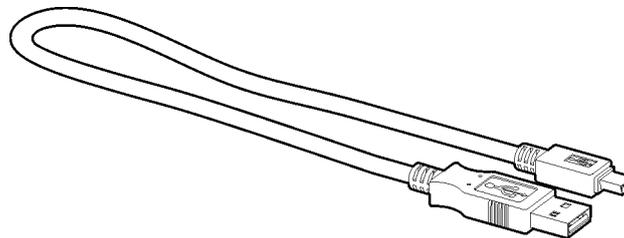
3.4 Bluetooth USB dongle

For wireless communication with the computer a Bluetooth dongle (i.e. Bluetooth USB adapter) is used.

3.5 USB cable

For connecting the NeXus-10 MKII to a computer.

USB cable



Note: Only use USB 2.0 compatible cable.

3.6 Installation CDs

Contain software for the NeXus-10 MKII. To identify, refer to the label on the CD.

3.7 Device labels

For identification of the NeXus-10 MKII parts, there are three labels: two on the NeXus-10 MKII main unit (exterior and interior) and one on the power pack.

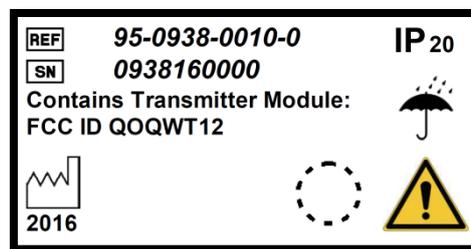
Exterior label

The outside label is located on the bottom of the NeXus-10 MKII device and contains generic information. An example of the outside label is displayed below. Please note that the actual outside label may be different from the picture shown here. Refer to 2.1 for an explanation of the symbols used.



Interior label

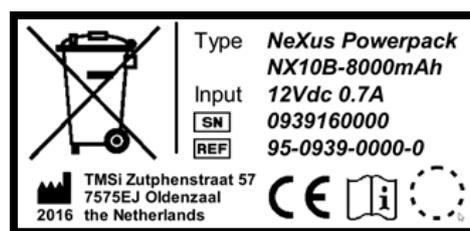
The interior label can be found in the power pack compartment of the NeXus-10 MKII, near the memory card slot. An example of the interior label is displayed below. Please note that the actual label may be different from the picture shown here. It contains specific information such as the product code and serial number.



#	Description
SN	Serial number.
REF	Product code.

Power pack label

The power pack label is placed on the bottom of the power pack. An example of the power pack label is displayed below. Please note that the actual label may be different from the picture shown here.



#	Description
SN	Serial number.
Input	Power supply requirements.
REF	Product code.

4 Description and operational principles

4.1 Intended use

The NeXus-10 MKII is intended to

- Acquire high quality bio-electrical and other physiological signals
- Transfer these signals to a computer for processing and analysis

The product is designed for measuring a wide range of physiological signals. These signals include EEG, EMG, ECG, respiration, temperature, oxygen saturation and signals that describe body movement.

The NeXus-10 MKII is intended for use in research applications in the field of psychophysiology and for clinical biofeedback and neurofeedback, by or under supervision of a medical professional.

The NeXus-10 MKII is not intended for use in diagnosis, nor in critical and/or life supporting applications.

The NeXus-10 MKII is intended for use on humans.

The NeXus-10 MKII is intended for use in a laboratory or medical office environment, or to be set-up in such environment after which the patient can be sent out for ambulatory recording and subsequent data retrieval after return.

The NeXus-10 MKII is intended to be used with approved NeXus10 MKII accessories only.

The device supports the following active accessories:

- Accelerometer (ACC) sensor for the measurement of position, acceleration and movement.
- Blood Volume Pulse (BVP) and Heart Rate (HR) sensor for the measurement of heart rate.
- Galvanic Skin Response (GSR) sensor for the measurement of conductivity of the skin.
- Oximetry sensor for the measurement of the oxygen saturation level, blood volume pressure and heart rate using one –optical- sensor.

Important



The product does **not** perform any signal interpretation or signal analysis. This is left to the researcher/physician.

The product is **not** intended for use in a life support application.

For stationary measurements the device transfers the data to the PC by means of a wired USB or wireless (Bluetooth) connection, where the signals can be viewed or stored for further processing. The device is powered by an internal power supply.

For ambulatory measurements the data can be stored on a SDHC card within the NeXus-10 MKII.

4.2 Product description

The NeXus-10 MKII is a general purpose signal acquisition system for high-quality physiological measurements. It is intended for use with application software for data analysis and presentation.

The NeXus-10 MKII main unit (NeXus-10) contains the electronics for amplification, digitization, storage, and wireless transmission. The NeXus-10 MKII uses an exchangeable power pack as power supply, which contains a rechargeable lithium-polymer battery. Sensors and electrodes simultaneously connect to the NeXus-10 MKII.

The power pack is charged (while not connected to the NeXus-10 MKII) through a mains power adapter. The NeXus-10 MKII is able to interface through USB or a wireless Bluetooth connection to a computer. The latter requires installation of the Bluetooth dongle on a USB 2.0 port of the

computer. In addition, NeXus-10 MKII is capable of storing measurement data on a SDHC memory card.

The NeXus-10 MKII contains true DC amplifiers with very low input noise, very high input impedance and very high common mode rejection.

4.3 Bipolar input channels

The input stage for measuring bipolar electrophysiological signals is configured as an instrumentation amplifier. The difference between a 'plus' and 'minus' signal is amplified. The patient ground electrode is required to keep patient potential and amplifier potential at about the same level.

All electrode cables are shielded with the average of the 'plus' and 'minus' electrode signal (active shielding). The active shielding ensures that disturbances such as cable movement artefacts and mains interference (50/60 Hz) are reduced to a minimum.

After the first amplifier stage (gain = 20) the signals go directly to the ADC. No high pass or low pass filters are present that can cause significant signal phase shifts or filter overflows for frequencies up to half of the sampling frequency.

4.4 Auxiliary input channels

Each auxiliary input has a 5-pin connector. Signals on this connector are +5V output, -5V output, GND, +signal input and -signal input. The +5V/-5V/GND pins can be used to power an active sensor. The + and - inputs are connected to an instrumentation amplifier with a gain of 1. The output of the amplifier goes to the ADCs without any filtering for frequencies up to half of the sampling frequency.

4.5 Transfer data to PC

Both USB and Bluetooth IT-network connections are supported by the product. The purpose of the IT-network connection is for device control and/or data transfer. The intended information flow is:

- Control from a PC to the device
- Raw data from the device to the PC

The supported versions of the IT network connections are:

- USB: 2.0 and higher
- Bluetooth: 1.1 and higher

The following section describes the installation of the USB link and Bluetooth IT-network connections.

Please note: No hazardous situations have been identified for the product due to loss of the IT-network functionality.

5 Installation

5.1 General installation

Install the NeXus-10 MKII according to the following steps.

#	Description
1	First install NeXus-10 MKII driver software onto the computer as described in Section 5.2.
2	Connect the mains power adapter to a wall socket and the power pack. Charging of the power pack begins. Note that the power pack may become warm during charging. This is normal behavior. Do not cover the power pack during charging, to prevent it from becoming hot.
3	As soon as charging of the power pack is complete (see Section 6.1), disconnect the mains power adapter and place the power pack in the NeXus-10 MKII main unit (see Section 6.2).
4	Perform the Bluetooth device pairing procedure between NeXus-10 MKII and computer.
5	Installation is complete; the NeXus-10 MKII is now ready for use.

5.2 NeXus-10 MKII driver installation

Software, that is needed to use the product, is supplied to you as download or by one or more CDs in the package. It is recommended and may be required to download the most up-to-date software via <http://www.mindmedia.com> if the software has already been installed.

PC requirements

Hardware

- Processor: > 1 GHz
- RAM: > 1 GB
- HDD: > 50 GB (> 250 GB recommended)
- Internet connection or CD/DVD Drive

Operating system

Windows

- Windows 10 (64-bit)
- Windows 8.1 (64-bit)
- Windows 7 (32-bit & 64-bit)

Important



Disconnect all Mind Media products from the PC before installing any Mind Media software. It is recommended to uninstall older versions of the driver before installing new drivers.

Mind Media Driver

Start the installer by clicking *setup.exe*. The Mind Media Driver Setup Wizard starts and guides you through the process of installation of the driver. Follow the steps on screen.

5.3 Connecting the device

Now connect the NeXus-10 MKII to the computer, by connecting the USB cable to the NeXus-10 MKII main unit and to a USB 2.0 port on your computer.

Next, you will see the following picture in the bottom right corner of your screen.

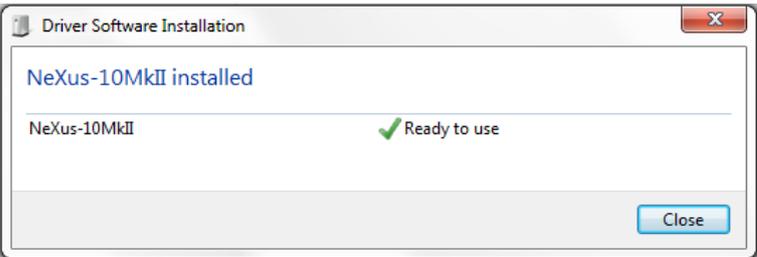
Note: Example is for Windows 7. The actual notice may be slightly different.

Installing USB driver software



When the second step of the 'driver installation' is finished, a popup is shown.

Ready to use



The USB driver is now installed.

5.4 Bluetooth pairing process

Connect the Bluetooth dongle to a USB 2.0 port of your computer.

The following notification window appears near the bottom right corner of your screen.

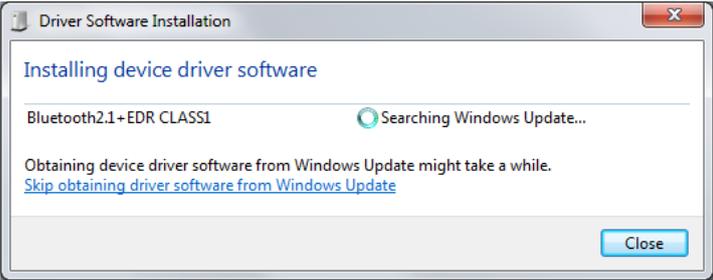
Note: Example is for Windows 7. The actual notice may be slightly different.

1. Insert the Bluetooth dongle in a USB port. Wait for Windows Update to install the drivers for the Bluetooth dongle.



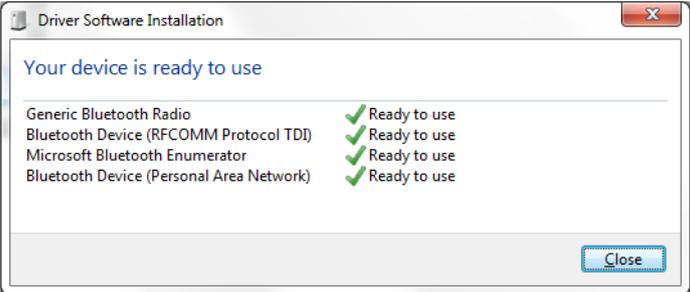
The next picture shows the progress of the installation.

Installing device driver software



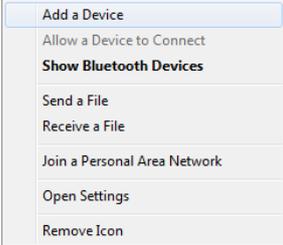
When the installation is done, the following pop-up is shown.

Device ready to use



The Bluetooth dongle is now installed. The driver installation procedure is now successfully completed.

2. After Windows has finished installing the Bluetooth drivers, click the Bluetooth tray icon in the right bottom corner of the Windows taskbar.
3. Click, 'Add a device'. If you do not see the Bluetooth tray icon, click *Start > Devices and Printers > Add a device*
4. Windows will start scanning the environment. Make sure the NeXus-10 MKII is powered on. The NeXus-10 MKII should automatically show up in the list.
5. Select the device and click 'Next'. Windows will ask for a pairing code. The pairing code consists of the last four digits of the serial number. The serial number can be found on the back of the NeXus-10 MKII on the device label next to 'SN'. Click *Next* to finish the Bluetooth setup.
6. Windows may report that drivers are being installed. Wait until Windows reports that the 'Device is ready to use'.



6 Operation

This section describes how to use the main functions of the NeXus-10 MKII.

Prerequisites

1. Make sure that all software is installed on the computer according to the installation instructions.
2. Refer to the corresponding user manuals for information.

N.B.: Specific application software needs to be installed on the computer in order to use the NeXus-10 MKII. Refer to the installation manual of this software.

Operation of the product requires no specific, nor preferred positions of operator, patient and other persons.

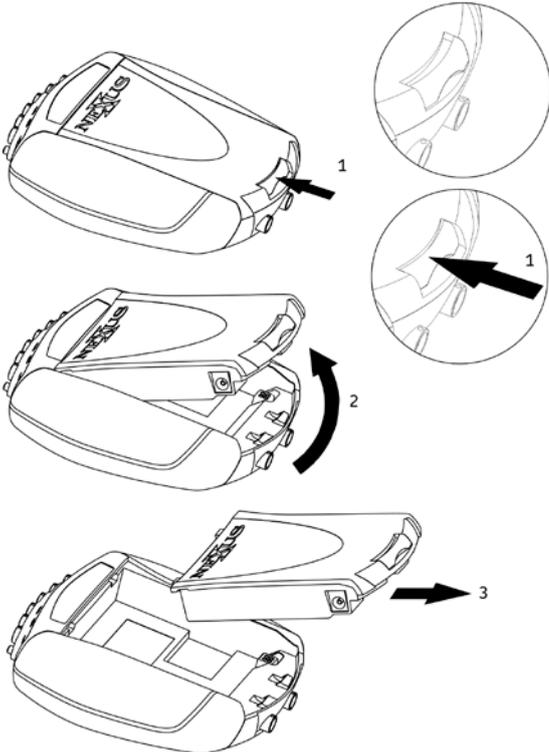
6.1 Recharging power pack

1. Connect the power pack to the mains power adapter.
2. Connect the mains power adapter to a wall socket. The charge indicator light will switch on.
3. The power pack is fully charged as soon as the charge indicator light is switched off.

6.2 (Re)placing power pack

1. In case a power pack is present on the NeXus-10 MKII: release the power pack by pressing the release button as indicated in the Figure.
2. Remove the power pack.
3. Insert a (fully charged) power pack (Reverse sequence). You should hear a clear 'click' to indicate that the power pack is placed correctly. The device is now ready for use.

Placement of the power pack

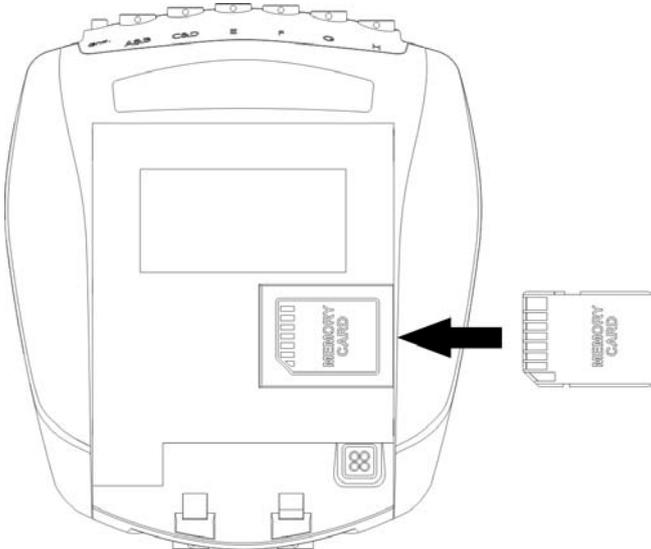


The NeXus-10 MKII features a back-up power facility, which enables replacement of the power pack without interrupting an ongoing recording session. For details on replacing the power pack during recording, see Section 6.15.

6.3 Inserting memory card

- 1. Make sure the NeXus-10 MKII is switched off.
- 2. Remove the power pack (if one is inserted).
- 3. Remove the SDHC memory card (if necessary) by pushing the card slightly **into the card slot** until a clicking sound is produced. The card is now released and can be removed.
- 4. Insert the SDHC memory card into the card slot until a clicking sound is produced. The memory card is now locked in the card slot.

Inserting memory card





Only FAT32 formatted memory cards (SDHC, capacity 4 GB up to 32 GB) can be used. SD cards are not supported.

5. Put the power pack back in place.

6.4 Switching on

1. Press the power/memory card recording button until the start-up message appears on the display (about half a second).

Start-up message

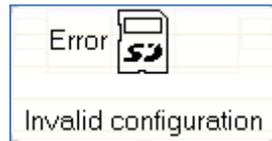


2. To save battery power, the display will shut off automatically after 5 seconds. To reactivate the display at any time, press any button.
3. If a memory card with valid measurement configuration file is detected, the memory card indicator light will switch on and a message is displayed on the screen.



In case a memory card with invalid measurement configuration file is present during start-up, the NeXus-10 MKII displays an error message. The memory card recording indicator light blinks fast. Remove the memory card or replace it with one that has a valid measurement configuration file.

Invalid measurement configuration file error message



6.5 Switching off

1. Press the power/memory card recording button for more than 0.5 seconds **but no longer than 3 seconds** (pressing the button for more than 3 seconds activates memory card recording, see Section 6.7). A shutdown message is displayed.

Shutdown



2. **Auto power off:** if the NeXus-10 MKII is not recording, it automatically switches off after 10 minutes if no buttons are pressed.

Auto power off



6.6 Display of device information

1. Make sure the NeXus-10 MKII is switched on and **not recording** (for display of device information during recording, see Section 6.14). The display is off.
2. Press the display button. The display shows current date, time and power pack status. If no button is pressed within 5 seconds, the display turns off to save power. If the display button is pressed again within the 5 seconds, it shows the next status screen. In this way 8 different status screens can be shown, which are described in the remainder of Section 6.6.

Default display



3. Within 5 seconds, press the display button again. If a memory card with a valid configuration is inserted, the NeXus-10 MKII displays memory card configuration and status.

Memory card configuration and status



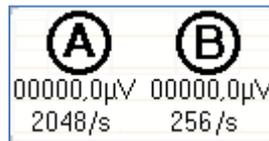
If a timed acquisition has been programmed in the configuration file, the start date, start time and duration is displayed.

For details on programming a timed acquisition, see application software manual.

If no memory card is inserted, this screen is skipped and the channel A and B status is displayed immediately (see below).

4. Within 5 seconds, press the display button again. The status of channel A and B is displayed.

Channel A and B status



The measured actual values of channel A and B are displayed in either μV or mV . If a memory card with valid measurement configuration file is inserted, the configured sample rates for channel A and B are shown.

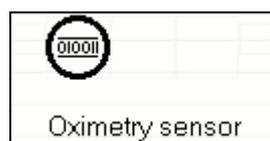


The displayed values are instantaneous (not-averaged) and only intended as a quick sensor/electrode check. A value of exactly 0 indicates that the electrode is not connected.

If a memory card is inserted, the selected sample rates (specified in the measurement configuration file) for channel A and B are shown.

5. Within 5 seconds, press the display button again. The status of channel C and D is displayed (in the same way as described for A and B).
6. Within 5 seconds, press the display button again. The status of channel E and F is displayed (in the same way as described for A and B).
7. Within 5 seconds, press the display button again. The status of channel G and H is displayed (in the same way as described for A and B).
8. Within 5 seconds, press the display button again. The status of the oximetry sensor is displayed.

Oximetry sensor status



9. Within 5 seconds, press the display button again. In case a serial sensor is attached to the NeXus-10 MKII, the information text of the sensor is displayed.

Serial input status



10. Within 5 seconds, press the display button again. The current firmware (DSP FW and UI FW) and hardware versions (UI HW) are displayed.
11. Within 5 seconds, press the display button again. The current date, time and power pack status are displayed (6.6).

6.7 Activating memory card recording

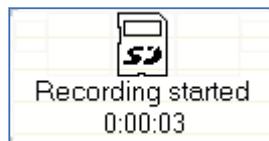
1. Prepare the memory card for recording using application software on a PC.
2. Insert the prepared memory card in the NeXus-10 MKII.
3. Switch on the NeXus-10 MKII.
4. Make sure the memory card indicator light is on.
5. Make sure the power pack is sufficiently charged.
6. Press and hold the power/memory card recording button **for more than 3 seconds**. The NeXus-10 MKII asks for confirmation to start memory card recording.

Memory card recording confirmation



1. Press the power/memory card recording button again (briefly). To cancel, wait 5 seconds until the display switches off automatically.
2. The NeXus-10 MKII starts recording and saves the data to the memory card as specified in the measurement configuration file. During active recording to the memory card, the NeXus-10 MKII displays a memory card symbol and recording time (press the display button in case the display is off). The memory card recording indicator light blinks.

Display during active memory card recording



3. To stop recording, press the memory card recording button **for more than 3 seconds**. The NeXus-10 MKII asks for confirmation to stop memory card recording.

Confirmation to stop memory card recording



4. Press the power/memory card recording button again (briefly). To cancel, wait 5 seconds until the display switches off automatically.

6.8 Establishing a Bluetooth connection

1. Make sure the NeXus-10 MKII has successfully been paired with the computer. See Section 5.4.
2. Switch on NeXus-10 MKII and computer and activate Bluetooth on your computer. The NeXus-10 MKII starts searching for available Bluetooth devices. The Bluetooth indicator light blinks fast.
3. As soon as NeXus-10 MKII finds a computer it can communicate with, a message appears on the display to indicate successful Bluetooth connection. The Bluetooth indicator light on the NeXus-10 MKII is on.

Bluetooth connected



4. The NeXus-10 MKII can now be controlled by the computer through the Bluetooth connection.
5. The NeXus-10 MKII displays a message in case the Bluetooth connection is lost or terminated from the computer. The Bluetooth indicator light is off.

Bluetooth connection lost



6.9 Activating Bluetooth recording



Use of this functionality requires that specific application software is correctly installed on your computer.

1. Make sure a Bluetooth connection to the computer has been established (see Section 5.4).
2. Start recording using the application software. The NeXus-10 MKII starts recording according to the settings in the application software.

It displays the recording time and transmits data to the computer. The Bluetooth indicator light blinks.

Bluetooth data recording started



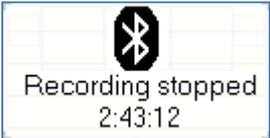
3. During recording, the NeXus-10 MKII displays power pack status and recording timer upon pressing the display button.

Bluetooth recording active



4. Stop recording using the application software. The NeXus-10 MKII indicates that the recording has been stopped. The Bluetooth indicator light stops blinking.

Bluetooth recording stopped



- 5. If the Bluetooth connection is lost during recording, the NeXus-10 MKII will stop and display an error message. The Bluetooth indicator light is off.

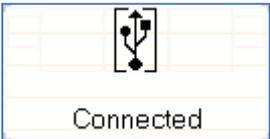
Bluetooth connection lost during recording



6.10 Establishing a USB connection

- 1. Connect the USB cable to the NeXus-10 MKII and computer. Switch on the NeXus-10 MKII and computer.
- 2. The NeXus-10 MKII starts searching for available USB devices. The USB indicator light blinks fast.
- 3. As soon as NeXus-10 MKII finds a computer it can communicate with, a message appears on the display to indicate successful USB connection. The USB indicator light on the NeXus-10 MKII is on.

USB connected



- 4. The NeXus-10 MKII can now be controlled by the computer through the USB connection.



If a USB connection is established while a Bluetooth connection is active but not recording, the NeXus-10 MKII automatically terminates the Bluetooth connection. The Bluetooth indicator light switches off.

- 5. The NeXus-10 MKII displays a message in case the USB connection is lost.

USB connection lost



6.11 Activating USB recording



Use of this functionality requires that specific application software is correctly installed on your computer. For details on the installation and use of the application software, refer to its manual.

1. Make sure a USB connection to the computer has been established (see Section 6.10).
2. Start recording using the application software. The NeXus-10 MKII starts recording according to the settings in the application software. It displays the recording time and transmits data to the computer. The USB indicator light blinks.

USB recording active



3. During recording, the NeXus-10 MKII displays power pack status and recording timer upon pressing the display button.
4. Stop recording using the application software. The NeXus-10 MKII indicates that the recording has been stopped. The USB indicator light stops blinking.
5. If the USB connection is lost during recording, the NeXus-10 MKII stops and displays an error message. The USB indicator light is off.

USB recording stopped



6. To reconnect, disconnect the USB cable and reconnect it again.

6.12 Activating Bluetooth/USB recording with memory card logging

The NeXus-10 MKII is able to send recorded data through a Bluetooth or USB connection while simultaneously logging it to a memory card. This is called memory card logging mode and can only be activated through specific application software. Please refer to the manual for further details.



During memory card logging, data is stored on the memory card according to the measurement configuration file. Therefore, the channels and sampling rates that are stored to the memory card can be very different from those sent over the Bluetooth or USB connection.

1. Make sure a Bluetooth or USB connection to the computer has been established (see Section 6.8 or 6.10).
2. Start recording with memory card logging using the application software. The NeXus-10 MKII starts recording, transmits the data according to the settings in the software and simultaneously logs the data according to the measurement configuration file on the memory card. It displays the recording time and transmits data to the computer. The Bluetooth or USB indicator light and the memory card indicator light blinks.

Bluetooth recording and memory card logging active



3. During recording, the NeXus-10 MKII displays power pack status and recording timer upon pressing the display button.
4. Stop recording using the application software. The NeXus-10 MKII indicates that both the USB recording and memory card logging have been stopped. The Bluetooth/USB indicator light and memory card indicator light stop blinking.
5. If memory card logging is active, the recording does NOT stop automatically in case the Bluetooth or USB connection is lost. The NeXus-10 MKII displays a message to indicate that the connection is lost, but memory card logging is still active.

USB disconnected while memory card logging active



6. To stop memory card logging, press the memory card recording button **for more than 3 seconds**. The NeXus-10 MKII asks for confirmation to stop memory card logging.

Confirmation to stop memory card logging



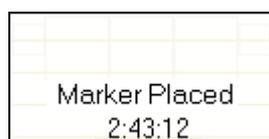
7. Press the power/memory card recording button again (briefly) to confirm and stop the memory card logging. To cancel, wait 5 seconds until display switches off automatically, the memory card logging will continue without interruptions.

6.13 Adding markers

It is possible to add markers to indicate events of interest during recording.

1. Make sure the NeXus-10 MKII is switched and recording to memory card (see Section 6.7) and/or through a Bluetooth (Section 6.9) or USB (Section 6.11) connection.
2. Press the Marker button. A marker is added to the recording.

Marker added to recording



6.14 Display of device information during recording

1. Make sure the NeXus-10 MKII is switched on and recording to memory card (see Section 6.7) and/or through a Bluetooth (Section 6.9) or USB (Section 6.11) connection (for display of device information while not recording, see Section 6.6). Display is off.

2. Press the display button. The display shows recording time and power pack status (see Section 6.9).
3. Within 5 seconds, press the display button again. If a memory card is inserted, the NeXus-10 MKII displays memory card configuration and status.

Memory card configuration and status



The on/off mode and remaining memory space for recording are displayed. The on/off mode indicates whether starting (in case memory card recording is not active) or stopping (in case memory card recording is active) is performed manually or at a pre-set time. Please refer to your application software manual for details.



The remaining memory space is for indicative purposes only. Please make sure a memory card with sufficient free space is placed before the recording/logging is started to avoid data loss.

If no memory card is inserted, this screen is skipped and channel A and B status are displayed immediately. By pressing the display button again, each time within 5 seconds, all 8 status displays can be shown as described in Section 6.6 "Display of device information".

6.15 Exchange of power pack during recording

The NeXus-10 MKII features a back-up power facility which enables replacement of the power pack without interruption of a recording session.

1. Establish the need to exchange the power pack through power pack status display (see Section 6.6). If the power pack runs low, the NeXus-10 MKII displays a message and the power indicator light starts to blink slowly.

Power pack low message



2. Check that the 'Charging' symbol (see Section 6.9) is absent to ensure that sufficient backup power is available to bridge 10 seconds absence of the power pack. Release the power pack by pressing the release button. The display switches off. Remove the power pack. The power indicator light starts to blink fast.
3. Insert a (fully charged) power pack (as indicated in section 6.2) **within 10 seconds after removing the empty power pack**. You should hear a clear 'click' to indicate that the power pack is placed correctly. The power indicator light goes on.



The power pack needs to be replaced within 10 seconds. If not, the NeXus-10 MKII shuts down automatically and data will be lost.

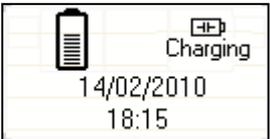
- 4. The NeXus-10 MKII display switches on again and indicates successful exchange of the power pack.

Power pack changed message



- 5. In the default display, the NeXus-10 MKII indicates that the back-up power is recharging. The 'charging' symbol disappears as soon as the back-up power is fully recharged.

Back-up power recharging



The back-up power needs to reload for approximately 10 minutes after exchanging the power pack. Do NOT attempt to replace the power pack as long as the 'Charging' symbol is visible in the display, because the device can shut down within the time required to replace the power pack, which will cause loss of data.

7 Troubleshooting

The NeXus-10 MKII does not switch on

The most likely cause is that the power pack is empty. Make sure the power pack is fully charged and correctly inserted into the NeXus-10 MKII main unit.

The NeXus-10 does not switch on, but power indicator light is blinking

Boot error. NeXus-10 MKII was unable to start. Please contact Mind Media support for assistance.

Device locked

An “Unauthorized Access” message appears on the screen of NeXus-10 MKII.

- Cause: use of unauthorized software to gain access to the NeXus-10 MKII. NeXus-10 MKII can only be used in combination with authorized software.

Unauthorized access message



No Bluetooth connection possible

Make sure the distance between the NeXus-10 MKII and the Bluetooth dongle is less than 10 meters and there are no conducting materials shielding either of them. Make sure drivers are installed correctly on your computer. The NeXus-10 MKII functions best in combination with Microsoft Bluetooth drivers. If possible, check correct functioning of the Bluetooth interface with any other Bluetooth device.

Bad signal / no signal on channels with electrodes

Replace the electrodes on the skin of the patient, including the patient ground. If this does not remedy the situation, move all electrode cables and check if this results in intermittent signals on the PC. When this happens the cable is broken and needs to be replaced. If signal remains bad or absent, try to exchange the electrode used as patient ground with another electrode currently connected to channel A, B, C or D.

Invalid measurement configuration file

An “Error: Invalid configuration” message appears on the screen of NeXus-10 MKII. Cause: a memory card is inserted with an invalid measurement configuration file. The same message is displayed in case there is no measurement configuration file present. Remedy: insert memory card with valid measurement configuration file. For details on creating measurement configuration files, see the application software manual.

Error: Invalid configuration message



Main unit – Indicator lights

Indicator light ¹	Condition	Status
Power	Off	Device Off
	On	Device On
	Slow blink (1s/1s)	Boot error
	Fast blink (0,5s/0,5s)	Power pack removed during device on
Memory card	Off	No memory card inserted
	On	Memory card with valid measurement configuration file inserted (ready)
	Slow blink (1s/1s)	Memory card recording active
	Fast blink (0,5s/0,5s)	Memory card inserted with invalid measurement configuration file
Bluetooth	Off	No Bluetooth connection
	On	Bluetooth connection made
	Slow blink (1s/1s)	Transmitting data
	Fast blink (0,5s/0,5s)	Searching for available Bluetooth connections
USB	Off	No USB connection
	On	USB connection made
	Slow blink (1s/1s)	Transmitting data

See Section 3.1 for the physical location of these indicators.

Power pack – Indicator lights

	Indicator light ¹		Charging Status
	Charge	Fault	
Off	Off		Not charging
Off	On		Bad power pack
On	Off		Charging
On	On		Temperature too high – charging temporarily stopped

See Section 3.2 for the physical location of these indicators.

8 Maintenance

The product does not contain user serviceable parts. Maintenance is limited to regular cleaning. Repairs can only be performed by the manufacturer, contact support@mindmedia.nl in case the product needs to be repaired. Mind Media Support staff will determine whether a repair is required and possible.

The product does not require regular servicing or re-calibration during its expected service life of 10 years. If the product is intended to be used after its expected service life, contact Mind Media to have the product inspected before continued use.

Cleaning

- Before cleaning, make sure the product is switched off and not in contact with a patient.
- Use only tap water, if necessary with a mild detergent, applied through a soft damp cloth.
- Do not spill fluids or submerge product in liquids.
- Never use sharp tools or aggressive chemicals for cleaning or disinfecting.
- Do not sterilize the product.

Environmental protection



Special EU instructions for disposal are applicable to a product on which this symbol is placed. These instructions apply to all parts of the product.

When the product has reached End of Life, it must not be disposed of with other waste. Instead, it is the user's responsibility to dispose of their waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment.

The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.

For more information about where you can dispose of your waste equipment for recycling, please contact your local city office, your household waste disposal service, or Mind Media.

9 Electromagnetic guidance

Portable and mobile RF communications equipment can affect the product. The product needs special precautions regarding EMC and must be installed and put into service according to the EMC information outlined below.

Guidance and manufacturer's declaration - electromagnetic emissions

The NeXus-10 MKII is intended for use in the electromagnetic environment specified below. The customer or the user of the NeXus-10 MKII should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The NeXus-10 MKII uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The NeXus-10 MKII is suitable for use in all establishments, including domestic establishments 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	Not applicable Battery powered equipment	
Voltage fluctuations/flicker emissions 61000-3-3	Not applicable Battery powered equipment	

Guidance and manufacturer's declaration - electromagnetic immunity			
The NeXus-10 MKII is intended for use in the electromagnetic environment specified below. The customer or the user of the NeXus-10 MKII 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	±6 kV contact ±8 kV air	± 4 kV contact See notes 2 and 3 below ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. Take ESD precautions to prevent that the NeXus-10 MKII loses its USB connection during use. The NeXus-10 MKII should not be used near earthed metal objects to which an electrostatic discharge may be applied.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable Battery powered equipment ±1 kV for input/output lines	
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable Battery powered equipment Not applicable Battery powered equipment	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not applicable Battery powered equipment Not applicable Battery powered equipment Not applicable Battery powered equipment Not applicable Battery powered equipment	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE 1: U_T is the a.c. mains voltage prior to application of the test level.

NOTE 2: ESD testing was conducted at 2, 4 and 6 kV. When the 6 kV discharges were applied the device lost its USB connection. There was no interruption during the 2 and 4 kV discharges.

NOTE 3: During some aspects of EMC testing (immunity: ESD), the device may lose its USB connection. This will be characterized by the display message "USB recording stopped" (see 6.11). This condition is considered acceptable as the measurement will only be interrupted until the USB is connected again. Safety of both patient and device are not compromised.

Guidance and manufacturer's declaration – electromagnetic immunity			
The NeXus-10 MKII is intended for use in the electromagnetic environment specified below. The customer or the user of the NeXus-10 MKII should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			<p>Portable and mobile RF communications equipment should be used no closer to any part of the NeXus-10 MKII, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</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 site survey,^a should be less than the compliance level in each frequency range.^b</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.			
<p>^a 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 the NeXus-10 MKII is used exceeds the applicable RF compliance level above, the NeXus-10 MKII should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NeXus-10 MKII.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the NeXus-10 MKII			
The NeXus-10 MKII is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NeXus-10 MKII can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NeXus-10 MKII as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.			

Essential performance

The performance of the NeXus-10 MKII can be generally described as to measure and digitize, transmit or store (electro-)physiological signals.

This functionality can fail in two distinct ways:

- Partly: signal data is e.g. inaccurate.
- Wholly: signal data is lost.

Since the intended use excludes diagnosis as well as critical and/or life-supporting applications, the possible risk is limited to failure in obtaining (accurate) signal data. The measurement must be repeated, with repaired or replacement NeXus-10 MKII, to get the (accurate) signal data. In both cases the risk is considered acceptable.

The NeXus-10 MKII has no essential performance.

10 Technical specifications

General Specifications

Type	NeXus-10 MKII
TMS code / REF	<ul style="list-style-type: none"> Device: 95-0938-0010-0 Power pack: 95-0939-0000-0
Size (device only)	120 mm x 140 mm x 45 mm (l x b x h)
Weight	Approximately 540 g including power pack

Regulatory Specifications

MDD class (Annex IX)	Ila
Power source	Internally powered
Mode of operation	Continuous operation
Electric shock protection	Applied parts: Class BF
Applied parts	<ul style="list-style-type: none"> The front-side receptacles (pins and shield) on the device enclosure. The patient accessories.
Accessible parts	<ul style="list-style-type: none"> Enclosure of the NeXus-10-MKII device including the cavity where the power pack is inserted, and the metal outside of the back-side receptacles. Enclosure of the power pack.
Software safety class per IEC 62304	A
Ingress protection	<ul style="list-style-type: none"> Main unit: IP20 Requires carrying case: IP02

Power pack

Type	NeXus Power pack NX10B – 8000 mAh
Battery type	Li-polymer with protection circuit
Capacity	8000 mAh
Input	12V DC, 0.7 A

Mains power adapter (For charging only)

Type	Meanwell GS18A12-P2L
Input voltage	100-240V AC, 50 / 60 Hz
Output voltage	12V DC, 1.5 A
Safety class	Class II
Applied standard	EN60950:2001, refer to the declaration of conformity

Bipolar inputs	
Differential range	-100 mV to +100 mV
Common mode range	-2.0 V to +2.0 V
Gain factor	20
Noise	< 1 μ V RMS (1 – 64 Hz)
Input impedance	> 1 G Ω
CMRR	> 90 dB
Accuracy	\pm 2 % (of full range)
Connector	LEMO 0B series 6 pin (2 channels)

Auxiliary inputs	
Signal range	-2.0 V to +2.0 V
Common mode range	-1.0 V to +1.0 V
Gain factor	1
Noise	< 3 μ V RMS (1 to 64 Hz)
Input impedance	> 1 G Ω
CMRR	> 80 dB
Supply output voltage	+5 V & -5 V, 5 mA per channel
Accuracy	\pm 2 %
Connector	LEMO 0B series 5 pin

A/D Conversion	
Resolution	Bipolar 12.2 nV/bit, auxiliary 0.238 μ V/bit
Sample frequency (Bipolar) USB	8192 Hz, 4096 Hz, 2048 Hz, 1024 Hz, 512 Hz
Sample frequency (auxiliary) USB	1024 Hz, 512 Hz
Sample frequency (Bipolar) Bluetooth	2048 Hz, 1024 Hz, 512 Hz, 256 Hz, 128 Hz
Sample frequency (auxiliary) Bluetooth	256 Hz, 128 Hz
Channel bandwidth	DC up to 0.4 * sample frequency

Filtering	
Type	No filtering within channel bandwidth.

Channel list					
Nr.	Name	Function		Resolution/bit	Signal range
1	A	Bipolar signal A		0.012215 μ V	-100 mV to +100 mV
2	B	Bipolar signal B		0.012215 μ V	-100 mV to +100 mV
3	C	Bipolar signal C		0.012215 μ V	-100 mV to +100 mV
4	D	Bipolar signal D		0.012215 μ V	-100 mV to +100 mV
5	E	Auxiliary signal E		0.2384186 μ V	-2.0 V to +2.0 V
6	F	Auxiliary signal F		0.2384186 μ V	-2.0 V to +2.0 V
7	G	Auxiliary signal G		0.2384186 μ V	-2.0 V to +2.0 V
8	H	Auxiliary signal H		0.2384186 μ V	-2.0 V to +2.0 V
9	SaO2	Oxygen saturation		1 %	0 % to 100 %, 127 = invalid
10	Pleth	Plethysmographic waveform		1 (bit)	0 to 255
11	HRate	Pulseoximeter heart rate		1 BPM	0 BPM to 255 BPM
12	Status	Pulseoximeter status		1 (bit)	0 to 255
13	Dig1	0x01	1 = Marker button pressed	1 (bit)	NA
		0x02	1 = Power pack low		
		0x04	1 = Power pack empty		
		0x08	External trigger		
		0x10	always 0		
		0x20	always 0		
		0x40	always 0		
		0x80	always 0		
14	Dig2	Serial sensor		NA	2 bytes
15	Batt	Power pack status		1 %	0 % to 100 %
16	Saw	Saw tooth test signal, 1 bit step		1 (bit)	1 to 16384

Bluetooth Communication

RF transmitter	Bluetooth v2.0+EDR Class 2	
Maximum output power	+2.5 dBm	
Profile	SPP	
Range	Typical > 10 m (indoors)	

Data storage

Memory card	4 GB up to 32 GB, SDHC only. SanDisk SDHC cards recommended.
Format	FAT32

Transportation Conditions

Temperature	-25°C to +70°C
Humidity	15% to 93%
Pressure	500 hPa to 1060 hPa

Storage Conditions

Temperature	0°C to +40°C
Humidity	15% to 93%
Pressure	500 hPa to 1060 hPa

Usage Conditions

Temperature	+5°C to +40°C
Humidity	15% to 93%
Pressure	700 hPa to 1060 hPa

It may take up to one hour to warm up the product from minimal storage temperature to minimal usage temperature.

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