NINDEX-Notebook

USER MANUAL

NINDEX Software version: 3.10.x

MADOC1 version: 2.2

Document revision: May 17, 2017

LIABILITY LIMITATION / DISCLAIMER

The Software is provided in an "as is" condition. The User is entirely responsible for any risk regarding the quality and performance of the Software itself. The Author makes no other warranty regarding the Software and specifically (a) waives any warranty related to the fitness for any particular purpose, (b) denies that the Software shall operate without interruptions or errors and (c) denies that errors of the Software (if any) shall be corrected.

The Author assumes no liability nor does it grant any other express or implicit warranty in relation with any harmful consequences (damages, loss of profit, etc.) that might arise against the User or third parties as a result of the use of the Software.

CONSIDERATIONS FOR NINDEX MONITORING

Clinical judgment should always be used when interpreting the NINDEX values. *Reliance on the NINDEX alone for anesthetic drug delivery is not recommended.* As with any monitoring, artifacts or low signal quality may cause improper NINDEX values. Potential artifact sources are poor skin to electrode contact, head and body motion, eye blinks, muscle activity, improper electrode placement or electrical interference. NINDEX values should be interpreted with caution in patients with known neurological disorders or taking psichoactive drugs, due to limited clinical experience in those applications.

INDICE

INTRODUCING THE NINDEX-Notebook MONITOR

Indications for use

NINDEX-Notebook monitor does a continuous evaluation of the state of the brain based on EEG processing, intended for use in the operating room, intensive care unit and clinical research.

The result of the EEG processing is a number called NINDEX, which may be used as an aid in monitoring the effects of anesthetic drugs in male and female patients above the age of 2 years, with no known neurological disorder and not taking psichoactive drugs.

General information

NINDEX-Notebook monitor is intended to monitor the depth of anesthesia based on EEG processing. It continuously calculates a number called NINDEX, which correlates with the patient depth of anesthesia.

NINDEX-Notebook monitor uses a MADOC1 EEG acquisition device, which communicates to NINDEX software via Bluetooth.

NINDEX software runs on either a PC, a Netbook or a Notebook under control of Windows XP SP2, Windows XP SP3, Windows Vista or Windows 7 operating systems.

NINDEX software provides a simple user friendly Graphical User Interface (GUI) which consists of:

- Current NINDEX number
- Current BSR number
- NINDEX trend plot

- Raw EEG waveform plot

- Signal Quality (SQ) indicator

- Current time and date

- Monitoring start time

- Patient identifier

- Electrode impedance levels (optional)

- BSR trend plot (optional).

NINDEX software GUI has two buttons for starting and ending a case, and for displaying the program Menu Dialog. The Menu Dialog allows to mark user-defined events, to configure the GUI appearance and to configure sound alarms.

NINDEX software generates sound alarms if current NINDEX number is greater than a high threshold or smaller than a low threshold. Alarms may be silenced by the user.

NINDEX software automatically stores monitoring data to disk. NINDEXMN software for Windows, which can be downloaded from www.controles.com website, allows reviewing recorded historical trend data and event markers.

SAFETY PRECAUTIONS

Warnings, cautions and notes

The terms warning, caution and note have specific meanings in this manual.

- A WARNING advises against certain actions or situations that could result in personal injury or death

- A CAUTION advices against actions or situations that could produce inaccurate data

- A NOTE provides useful information regarding a function or procedure.

Warnings

DO NOT USE THE MONITOR IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

NOT DESIGNED FOR USE IN MRI ENVIRONMENT.

SHOCK HAZARD: DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET OR DIRTY HANDS.

AVOID THE CONTACT OF CONDUCTIVE PARTS OF ELECTRODES TO OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

DO NOT LOCATE ELECTRODES BETWEEN THE SURGICAL SITE AND THE ELECTROSURGICAL UNIT RETURN ELECTRODE, TO REDUCE THE HAZARD OF BURNS DUE TO THE HIGH-FREQUENCY SURGICAL CURRENTS TO THE NEUTRAL ELECTRODE CONNECTION.

APPLIED PARTS ARE NOT PROTECTED FROM THE EFFECT OF CARDIAC DEFIBRILLATION ACCORDING TO IEC 60601-2-26.

WHEN A DEFIBRILLATOR IS USED ON A PATIENT CONNECTED TO THE MONITOR, THE ELECTRODES SHALL NOT BE LOCATED BETWEEN DEFIBRILLATOR PADS.

THE MONITOR SHALL BE MOUNTED SECURELY TO AVOID PERSONAL OR PATIENT INJURY.

CHECK GROUND WIRE LEAKAGE CURRENT AFTER AN EQUIPMENT CASE OPENING AND CLOSING.

ELECTRICAL SHOCK HAZARD: DO NOT REMOVE EQUIPMENT COVERS WHILE POWER IS CONNECTED.

ELECTRICAL SHOCK HAZARD: THE MANUFACTURER VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED IN THE IEC60601-1 STANDARD. THESE CURRENTS SHOULD BE VERIFIED PERIODICALLY. WHENEVER A LIQUID SPILLAGE OCCURS, VERIFY THE CURRENTS BEFORE FURTHER USE.

TAKE UNIVERSAL PRECAUTIONS TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS.

CAUTIONS

The distance between electrodes 1 and 2 shall be at least 10 cm. If this distance is not achieved through placing the electrodes in the same head hemisphere, the electrode 1 should be placed in one hemisphere and the electrode 2 in the other, as shown in Figure 4.

Good skin to electrode contact is essential for the reliability of the data provided by the software.

Strictly follow the electrode placement procedure described in this manual.

To proper patch to skin adhesion, avoid wetting the electrode self-adhesive part when placing the electrodes.

In normal use, verify the LED indicators status of MADOC1 as established in corresponding user manual.

The data provided by the software is not considered reliable if the software shows up a bad electrode contact warning.

Automatic impedance checking may need to be disabled if the 6 uA 128 Hz impedance check current interferes with other equipment, e.g., evoked potential monitors. Refer to MADOC1 user manual for instructions.

Do not autoclave any part of the equipment. The autoclaved part will be damaged.

Do not open the EEG acquisition device. Equipment waterproofing may be damaged. Service should be performed only by qualified technicians.

Do not wet the electrode clips. Liquids may degrade the EEG acquisition device function.

In order not to lose monitoring data, back up the data after maximum 100 monitoring hours.

Operation of the monitor may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:
- **increase separation between devices**
- **re-orient device cabling**
- **plug devices into separate outlet circuit branches.**

Do not touch the exposed parts of connectors when connecting or disconnecting the EEG acquisition device. Damage due to electrostatic discharge may result.

The use of accessories other than those specified may result in increased electrical interference on the EEG, decreasing the reliability of data provided by the monitor.

The EEG acquisition device should not be used over or close to other equipment. If this situation is unavoidable, check the normal function for the particular case.

The software requires the c:\eegdata folder for proper operation. If this folder is accidentally deleted then the monitoring and configuration data will be lost.

Avoid any liquid spillage over the Notebook.

INSTALLATION AND PREPARATION FOR USE

Caution:
Carefully read this section before installing the equipment.

This section provides installation instructions for NINDEX-Notebook monitor It includes:

- Parts checklist

- Accessories

- Environmental conditions

- Power requirements

- Monitor installation

- System components

- NINDEX Software setup

- MADOC1 dongle driver setup

- Connections

- Starting and ending the software

- Screen size setup

- Communication setup.

Parts checklist

Open packages and inspect for the following components:

- One NDXKEYCO dongle

- One MADOC1

- One MADOC1 dongle.

In addition, the NINDEX license file NINDEXxxxxx.lic is required to run the NINDEX software.

Accessories

- Standard pre-gelled silver/silver chloride electrodes normally used for ECG, e.g. "Swaromed" or "Medi-Trace" ECG electrodes.

Environmental conditions

WARNING!
DO NOT USE THE MONITOR IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

Refer to the MADOC1 user manual.

Power requirements

Refer to the MADOC1 user manual.

Monitor installation

The NINDEX-Notebook monitor may either be installed permanently over the anesthesia machine or moved between surgical blocks.

WARNING!
THE MONITOR SHALL BE MOUNTED SECURELY TO AVOID PERSONAL OR PATIENT INJURY.

System components

The NINDEX-Notebook monitor consists of the following components (Figure 1):

- MADOC1 EEG acquisition device
- MADOC1 dongle
- Notebook, Netbook or PC, hereinafter referred as "Notebook"
- NDXKEYCO dongle
- NINDEX license file, NINDEXxxxx.lic

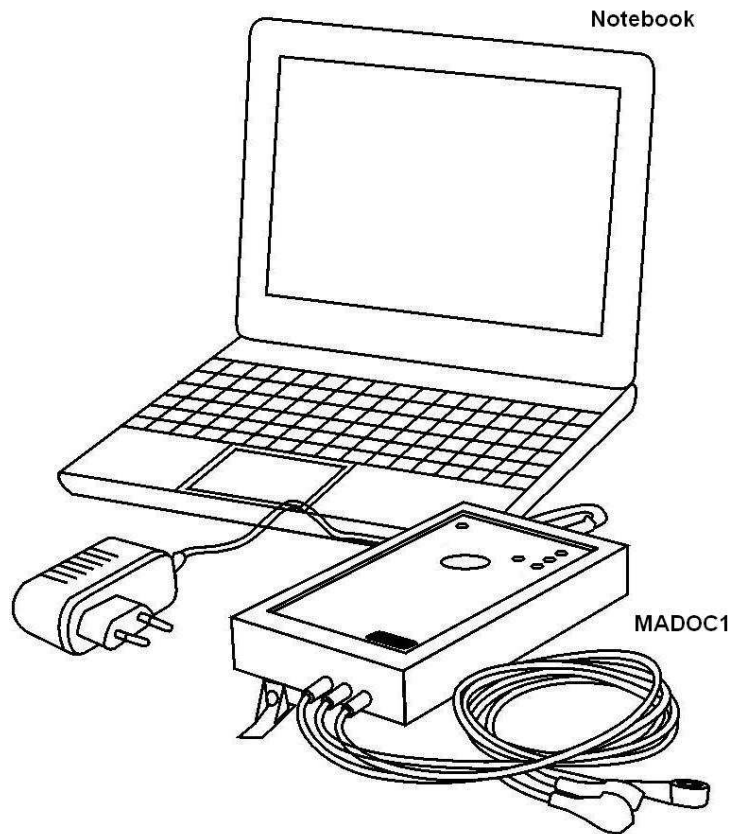- NINDEX software, which runs on the Notebook.

Figure 1

The EEG acquisition device

NINDEX-Notebook monitor uses a MADOC1 EEG acquisition device, which communicates to NINDEX software via Bluetooth. Refer to the MADOC1 user manual for corresponding description.

MADOC1 dongle

The MADOC1 dongle plugs into an USB port from the Notebook running the software NINDEX. It receives the data transmitted by MADOC1 and brings it

into NINDEX software. It requires a Windows driver installed in the Notebook (refer to "MADOC1 dongle driver setup"). Refer to the MADOC1 user manual for the MADOC1 dongle description.

NINDEX Software setup

System requirements

Recommended system requirements:

- Windows XP SP2, Windows XP SP3, Windows Vista or Windows 7 operating systems
- Display: 8 inches 15:9 and higher, resolution 1024 x 768 pixels and higher
- USB port to attach the hardware dongle
- USB port to attach the EEG acquisition device
- Free space on disk: 100 MB to install the program and 300 MB to store monitoring data
- Main memory: 1 GB and higher
- Processor: Intel Pentium with 1.6 GHz clock rate and higher.

Setup

To start the NINDEX program setup, as local administrator double click InsNINDEX-mm-x.y.z.exe installer software and follow the instructions.

Note:
The software features multiple language support. A language-selection dialog is displayed the first time the software is installed. The language may be modified through the following registry value:
HKEY_CURRENT_USER\Software\Controles\inhsbc\Settings\IDIOMA

The installer software does the following:

- Creates a c:\eegdata folder for NINDEX monitoring data and configuration data storage

Caution:
The software requires the c:\eegdata folder for proper operation. If this folder is accidentally deleted then the monitoring and configuration data will be lost.

- Creates a folder for NINDEX program installation

- Creates a "NINDEX" shortcut on the Desktop

- Creates a "NINDEX" group on Windows' Start Menu All Programs list.

License file

After setup, copy the license file NINDEXxxxx.lic to the c:\eegdata folder.

Note:
The software requires the license file in the c:\eegdata directory. If either the file does not exist or is incorrect, the software will end with the error messages "NDXKEY 8" or "NDXKEY 9".

MADOC1 dongle driver setup

The MADOC1 dongle driver installation is automatic on Windows Vista or Windows 7, provided that the Notebook is connected to Internet when the MADOC1 dongle is plugged for the first time.

In addition, the installer for the driver may be downloaded from www.controles.com. For driver setup follow these instructions:

1. Right click the driver installer and then click "Run as administrator"

2. Follow the setup instructions

3. Restart the computer.

Connections

In order to prepare the system for operation follow these instructions:

1. Plug the EEG acquisition device power cord into a properly power outlet (see "Power requirements")

2. Plug the MADOC1 dongle into an USB port from the Notebook

3. Plug the license dongle into an USB port from the Notebook.

Starting and ending the software

To start NINDEX software follow these steps:

1. Connect the hardware dongle to an USB port

2. Double click "NINDEX" shortcut on the Desktop.

To end NINDEX software follow these steps:

1. Click the Menu button

2. Click the "Close NINDEX" button.

Screen size setup

Upon executing NINDEX software for the first time, it shows up a "Screen Dimensions" dialog (Figure 2). Enter the screen dimensions (in mm) and then click the OK button.
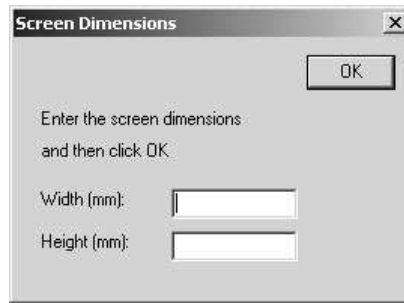
Figure 2

Communication setup

For proper functioning of NINDEX software in combination with the EEG acquisition device MADOC1, the MADOC1 dongle serial port must be setup (refer to MADOC1 User manual).

To setup the MADOC1 dongle serial port follow these steps:

1. On Windows Device Manager identify "COMx" port assigned to the MADOC1 Dongle

2. Start the NINDEX software and then click the Menu button

3. Click the "Communications" button

4. Expand the "Serial port" drop down list by clicking the expand arrow

5. Select the port

6. Click the "OK" button.

USING THE EQUIPMENT

Caution:
Carefully read this section before using the monitor in a clinical setting.

This section provides instructions for using NINDEX software in a clinical setting. It includes:

- Preparing for operation

- Monitoring start

- Monitoring display

- The Menu Dialog

- Accelerator keys

- Monitoring end.

Preparing for operation

Follow these steps to prepare the equipment for operation:

1. Power up the system following instructions in the "INSTALLATION " section

2. Attach the electrodes

   NINDEX measurement uses one EEG channel recording acquired by 2 electrodes at locations 1 and 2 of, and a third reference electrode at location 3 of Figure 3. Electrode locations 1, 2 and 3 are defined as follows:

   Location 1: intersection of the horizontal line across the middle of the forehead and the vertical line across the middle of the eyebrow

   Location 2: in front of the ear on the same side of the head as location 1, with a minimum distance of 10 cm to location 1

Location 3: intersection of the horizontal line across the middle of the forehead and the vertical line across the nose.
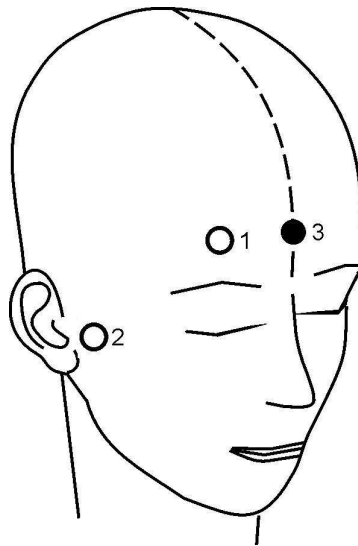

Figure 3

Caution:
The distance between electrodes 1 and 2 shall be at least 10 cm. If this distance is not achieved through placing the electrodes in the same head hemisphere, the electrode 1 should be placed in one hemisphere and the electrode 2 in the other, as shown in Figure 4.
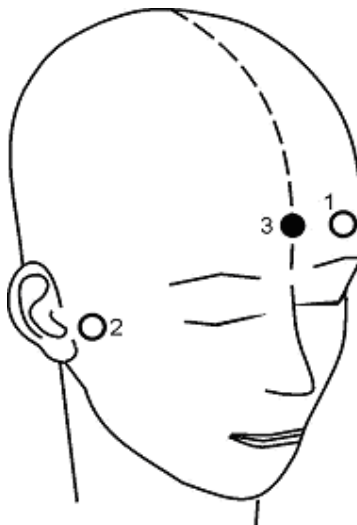

Figure 4

Caution:
The use of accessories other than those specified may result in increased electrical interference on the EEG, decreasing the reliability of data provided by the software.

For electrode placement follow steps in Figure 5.

A	Rub the skin 10 times in a circular motion using a gauze and 70% isopropanol or alcohol	
B	Remove the electrode protective foil	
C	Wet the electrode with a drop of saline, with special care to not wet the self-adhesive part	
D	Attach the electrode to skin, ensuring complete adherence of self-adhesive part	

Figure 5

Caution:
Proper electrode placement is essential for the reliability of the data provided by the software.

Good skin to electrode contact is essential for the reliability of the data provided by the software.

Strictly follow the electrode placement procedure described in this manual.

Connect the electrode at location 1 to the red snap connector, the electrode at location 2 to the white snap connector and electrode at location 3 to the black snap connector.

WARNING!
AVOID THE CONTACT OF CONDUCTIVE PARTS OF ELECTRODES TO OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

DO NOT LOCATE ELECTRODES BETWEEN THE SURGICAL SITE AND THE ELECTROSURGICAL UNIT RETURN ELECTRODE, TO REDUCE THE HAZARD OF BURNS DUE TO THE HIGH-FREQUENCY SURGICAL CURRENTS TO THE NEUTRAL ELECTRODE CONNECTION.

WHEN A DEFIBRILLATOR IS USED ON A PATIENT CONNECTED TO THE MONITOR, THE ELECTRODES SHALL NOT BE LOCATED BETWEEN DEFIBRILLATOR PADS.

Monitoring start

Once the electrodes are correctly placed and connected to the EEG acquisition device, to start the monitoring click the [Monitoring Start / Stop] button .

Caution:
In normal use, verify the LED indicators status of MADOC1 as established in corresponding user manual..

Monitoring display

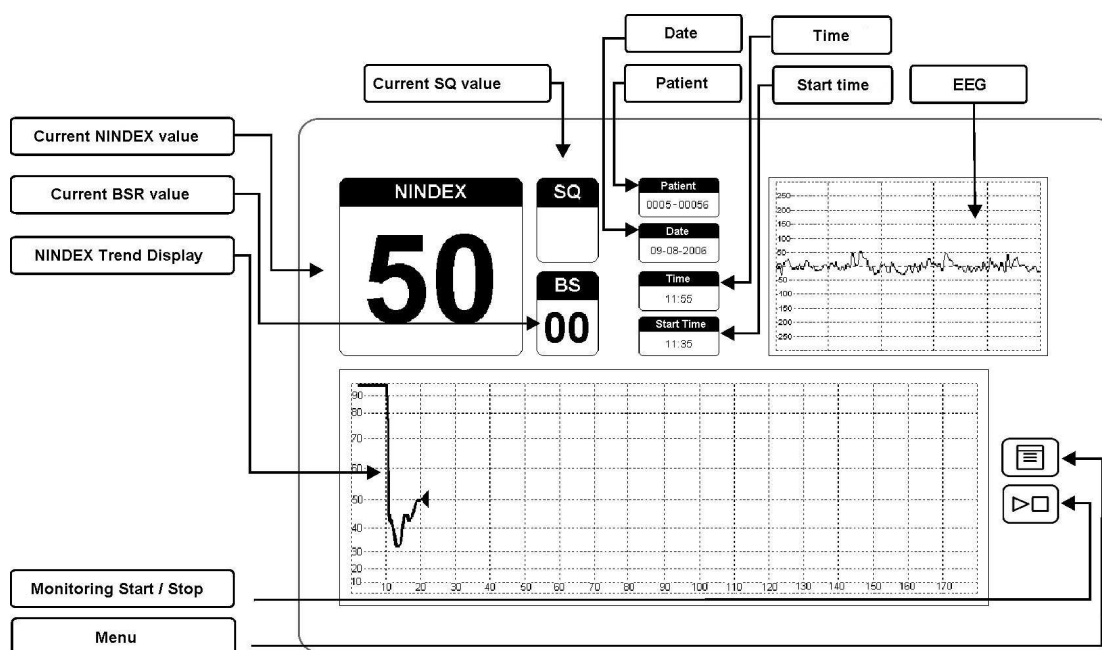Figure 6 shows the monitoring display.

Figure 6

The monitoring display size should be approximately 16 cm x 10 cm. The monitoring display consists of four regions: the numeric region, the monitoring general data region, the graphics region and the buttons region.

The numeric region

The numeric region is in the upper left corner of the monitoring display. By default it consists of the rectangles "NINDEX", "SQ" and "BS", and optionally it adds the rectangle "Z". It is updated once every 3 s.

"NINDEX" rectangle in the upper left corner displays current NINDEX value in large, easily readable font. The number displayed disappears when SQ is red (low signal quality).

The "BS" rectangle displays current BSR (Burst Suppression Ratio) value. BSR is a calculated parameter to give the user an indication when an isoelectric EEG condition may exist. It is the percentage of time over the last minute period that the signal is considered to be in the suppressed state. For example, BSR = 20

means isoelectric EEG over 20% of the last minute review. The number displayed disappears when SQ is red (low signal quality).

The "SQ" (Signal Quality) rectangle displays current EEG signal quality value, which may be green, yellow or red. SQ relates to the percentage of discarded data (because of artifact detection) over the last minute of EEG processing. SQ is green if the percentage of discarded data is less than 25%; SQ is yellow if the percentage of discarded data is greater than 25% and less de 50%, or if the percentage of discarded data is greater than 50% and 15% or more of the data is considered to have ocular artifacts; SQ is red if the percentage of discarded data is greater than 50% and less than 15% of the data is considered to have ocular artifacts.

Figure 7

The "Z" rectangle may be added to the numeric region by selecting "Yes" in the "Show impedance" option in the "Settings" dialog (see "The Settings Dialog"). This rectangle shows impedance of electrode 1 to electrode 3 and impedance of electrode 2 to electrode 3 (see "Preparing for operation"), in units of 4 kΩ. For example "0-1" means that electrode 1 to electrode 3 impedance is less than 4 kΩ y and that electrode 2 to electrode 3 impedance is greater than 4 kΩ and less than 8 kΩ.

Monitoring general data region

The monitoring general data region is located in the upper center of the monitoring display. It consists of the rectangles "Patient", "Date", "Time" and "Start time".

"Patient" rectangle displays the two numbers that identify the monitoring. The first number is a 4-digit serial number unique to each NINDEX hardware dongle. The second is a 5-digit monitoring number which automatically increments upon each monitoring start.

"Date" rectangle displays current date in DD-MM-YYYY format.

"Time" rectangle displays current time in 24 hour format.

"Start Time" rectangle displays monitoring starting time in 24 hour format.

Graphics region

The graphics region consists of the EEG Waveform Display, in the upper right of the monitoring display, and the NINDEX Trend Display on the bottom left of the monitoring display.

The EEG Waveform Display shows a plot of raw EEG waveform over a 5-second time period. It is updated once every 1.5 seconds. Horizontal resolution is 1 second/div and vertical resolution can be set to 50 uV/div, 25 uV/div or 12,5 uV/div (see "The Settings Dialog"). Discarded data because of artifact detection is crossed by yellow lines (Figure 8).
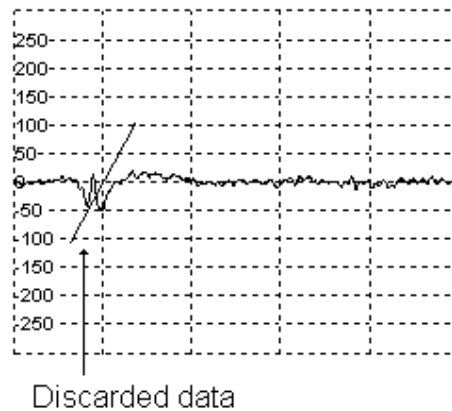
Figure 8

NINDEX Trend Display shows a red plot of NINDEX value over a 90 minute, 180 minute o 270 minute time period. It is updated once every 15 s. Current NINDEX trend value is shown with a gray cursor, and is calculated as the median of NINDEX current value over last 15 second time period. The cursor disappears and the trend will not be displayed if SQ is red (low signal quality).

Due to relationship with clinical anesthesia and the emergence phase, NINDEX range from 45 to 99 is considered the most interesting for the user. NINDEX Trend Display vertical scale resolution is transformed by a nonlinear function for optimal visual resolution in this range.

The BSR trend plot may be added to the NINDEX Trend Display by selecting "Yes" in the "Show BS trend" option in the "Settings" dialog (see "The Settings Dialog"). BSR trend is plotted in blue. Current BSR trend value is calculated as the median of BSR current value over last 15 second time period. The trend will not be displayed if SQ is red (low signal quality).

Horizontal NINDEX Trend Display resolution can be set to 10 min/div, 20 min/div or 30 min/div (see "The Settings Dialog").

If the monitoring time period exceeds NINDEX Trend Display time period, NINDEX trend plot is shifted one horizontal division towards left and the time origin is incremented.

Buttons region

The buttons region is located in the bottom right of the monitoring display. It consists of the [Menu] button ▤ and the [Monitoring Start / Stop] button ▷□ .

Optional windows

The SEF window

The SEF window (Figure 9) may be enabled or disabled by menu (see "The Menu Dialog"). It displays the current SEF value and the SEF trend plot. The window size is approximately 15 cm x 3 cm. It may be moved by left-clicking on the window and then moving the mouse.
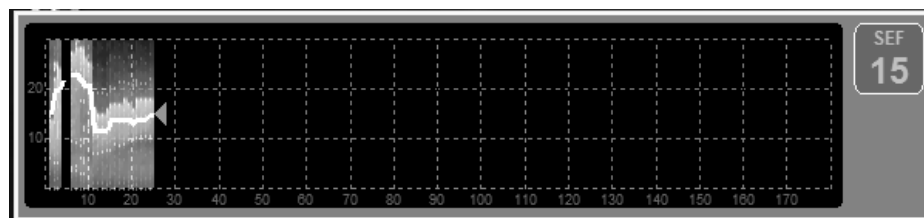

Figure 9

The "SEF" rectangle shows the current value of the BcSEF (Burst Compensated Spectral Edge Frequency) parameter. If SEF95 is defined as the frequency (in Hz) below which 95 percent of the total power of the EEG in the 1 to 30 Hz band is located, then the parameter BcSEF is determined as follows:

$$BcSEF = SEF95 * (1 - BSR/100).$$

Current BcSEF value is updated once every 3 s. The displayed number disappears when SQ is red (low signal quality).

The SEF trend plot shows a white plot of BcSEF value and the density spectral array (DSA). The DSA shows the spectral density of the signal in colors, so that warmer colors (i.e. red and orange) correspond to higher densities and colder colors (i.e. sky blue and blue) to lower densities.

The SEF trend plot is updated once every 60 s. The horizontal scale may be set by menu to 10 min/div, 20 min/div or 30 min/div. Current BcSEF trend value is shown by a gray cursor. The cursor disappears and the trend will not be displayed if SQ is red (low signal quality).

The Menu Dialog

To open the Menu Dialog click the [Menu] button 📋.

The Menu Dialog consists of buttons with specific functions.

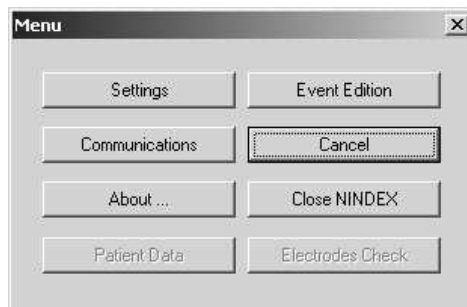If monitoring is not activated, Menu Dialog functions are (Figure 10):

Figure 10

- Settings: shows the Settings Dialog
- Event Edition: shows the Event Edition Dialog
- Communication: shows the Communications Dialog
- Cancel: closes the Menu Dialog

- About ...: displays the software release, the NINDEX hardware dongle serial number, the software building (MADOC1) and general information about the software manufacturer Controles S.A.

- Close NINDEX: ends NINDEX software.

If monitoring is activated, Menu Dialog functions are (Figure 11):

Figure 11

- Settings: shows the Settings Dialog

- Event: shows the Event Dialog

- Cancel: closes the Menu Dialog

- About ...: displays the software version, the NINDEX hardware dongle serial number, the software building (MADOC1) and general information about the software manufacturer Controles S.A.

- Close NINDEX: ends NINDEX software

- Patient Data: shows the Patient Data Dialog

- Electrodes Check: disabled.

The Settings Dialog

Figure 12

Settings Dialog (Figure 12) consists of the following options:

- Trend Plot Period (min): NINDEX Trend Display time period. May be 90 min (10 min/div), 180 min (20 min/div) o 270 min (30 min/div)

- EEG Amplitude: EEG Waveform Display Amplitude. May be x1 (50 uV/div), x2 (25 uV/div) or x4 (12,5 uV/div)

- Show BS Trend: If "Yes" adds BSR trend to NINDEX Trend Display (see "Monitoring display")

- Show Impedance: If "Yes" adds the "Z" rectangle to the numeric region of the monitoring display (see "Monitoring display")

- High Alarm: if "Yes" enables the High Alarm (see "Alarms")

- Low Alarm: if "Yes" enables the Low Alarm (see "Alarms")

- Impedance Warnings: If "No" disables either of the warnings for bad electrode contact and the warning for automatic impedance checking disabled. The software automatically enables the alarms upon each monitoring start

- SEF: If "Yes" enables the SEF window when monitoring is active (see "The SEF window").
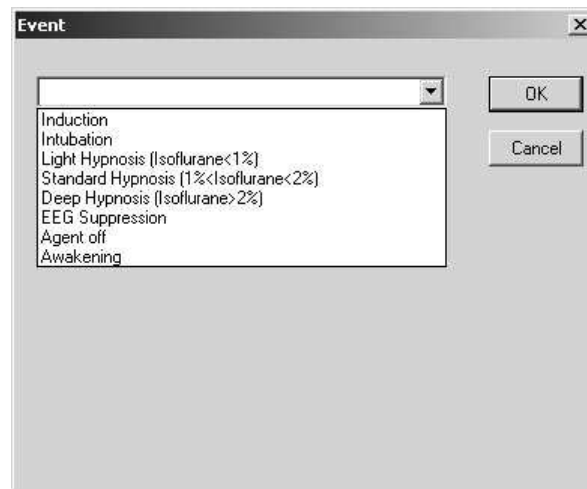
The Event Dialog

Figure 13

The Event Dialog (Figure 13) allows the user to add event markers in monitoring time. The user can create her/his own event types (see "The Event Edition Dialog"). The event markers are saved to disk and added to NINDEX Trend Display. Each event marker consists of a label identifying the event type and a time stamp relative to monitoring start time. The default event type list is:

- Induction

- Intubation

- Light Hypnosis (Isoflurane < 1%)

- Standard Hypnosis (1% < Isoflurane < 2%)

- Deep Hypnosis (Isoflurane > 2%)

- EEG Suppression

- Agent off

- Awakening.

To add an event marker, follow these steps in the Event Dialog:

3. Expand the Event Description drop down list by clicking the expand arrow

4. Select the corresponding Event Description

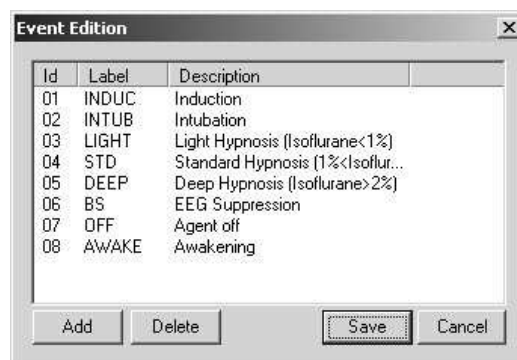5. Click the "OK" button.

The Event Edition Dialog

Figure 14

The Event Edition Dialog (Figure 14) displays the Event Type Edition List, which allows the user to replace the default event types by custom event types. The Event Type List may include up to 14 event types.

Each event type consists of:

- Identifier (Id column): 2-digit number that identifies the event type, from 01 to 14

- Label: character string that identifies the event type in NINDEX Trend Display and when the event marker is saved to disk. Up to 12 characters

- Description: character string that identifies the event type in the Event Dialog (see "The Event Dialog"). Up to 50 characters.

To edit an event type Label follow these steps in the Event Edition Dialog:

1) Click on the specific label string

2) Enter the new Label string in the edit box

3) On the keyboard press the "Enter" key.

Note:
Changes are not saved to disk until the "Save" button is clicked.

To edit an event type description follow these steps in the Event Edition Dialog:

1) Click on the specific Description string

2) Enter the new Description string in the edit box

3) On the keyboard press the "Enter" key.

Note:
Changes are not saved to disk until the "Save" button is clicked.

To add an event type, follow these steps in the Event Edition Dialog:

1) Click the "Add" button

2) Edit the event type Label and Description as described above.

Note:
Changes are not saved to disk until the "Save" button is clicked.

To delete an event type, follow these steps in the Event Edition Dialog:

1) Click on the specific event type "Id" column

2) Click the "Delete" button.

Note:
Changes are not saved to disk until the "Save" button is clicked.
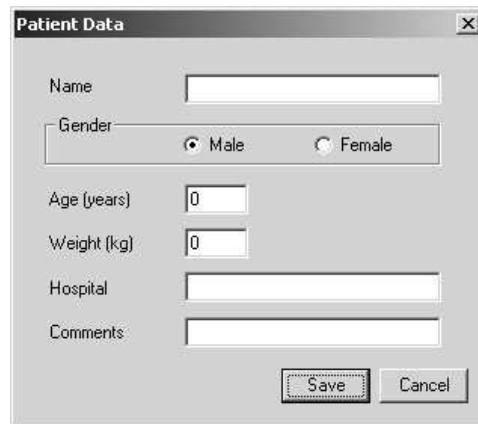
The Patient Data Dialog

Figure 15

The Patient Data Dialog (Figure 15) allows editing patient data (name, gender, age and weight), the Hospital name and general comments. When the "Save" button is clicked the edited data is saved to disk.

Accelerator keys

NINDEX software allows adding specific parameters in monitoring time by pressing some accelerator keys. These functions are available:

- "D" key: allows adding current dose of Propofol and Remifentanil. The data is added to the NINDEX Trend Display and saved to disk along with a time stamp

- "H" key: allows adding current value of hemodynamic variables. The data is added to the NINDEX Trend Display and saved to disk along with a time stamp

- "C" key: allows editing a comment. The edited text is saved to disk along with a time stamp

- "T" key: allows adding patient's temperature. The data is added to the NINDEX Trend Display and saved to disk along with a time stamp
- "A" key: shows a help screen with accelerator key functions.

Monitoring end

To end the monitoring click follow these steps:

1. Click the [Monitoring Start / Stop] button ▷□

2. Disconnect the electrode snap connectors from the electrodes

3. Remove the electrodes from the patient

4. Be sure to leave the EEG acquisition with the Notebook so that it is not inadvertently discarded.

5. If this is the last procedure of the day, end NINDEX software following the instructions in "Starting and ending the software".

WARNING!
SHOCK HAZARD: DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET OR DIRTY HANDS.

SYSTEM FEATURES

Caution:
Carefully read this section before using the monitor in a clinical setting.

This section provides a description of NINDEX-Notebook main features. It includes:

- Anesthetic depth monitoring

- Checking skin to electrode contact

- Alarms

- Data storage to disk.

Anesthetic depth monitoring

The EEG acquisition device amplifies and the digitizes patient's EEG signal, then sends it directly to NINDEX software.

NINDEX software filters the EEG digital data and then analyzes it for artifact. Artifact detection is necessary to correctly interpret the EEG. As NINDEX software is intended to provide only highly reliable data, it is therefore programmed not to display data whenever excessive artifact corruption occurs.

Data considered artifact-free is processed using digital signal processing techniques to compute a large number of EEG features, which are input into a multivariate statistical algorithm to do an automatic EEG classification according to a refinement of Kugler EEG scale. The result is expressed as the NINDEX number, which correlates to the patient's anesthetic depth such as NINDEX = 99 indicates awake state and NINDEX = 0 indicates flat line EEG.

Checking skin to electrode contact

The impedance checking is done automatically each minute by the EEG acquisition device, or when pressing the "Electrode check" button on the device.

It determines the impedance of electrode 1 to electrode 3 and the impedance of electrode 2 to electrode 3 (see "Preparing for operation"). The software displays a warning if either:

- the impedance levels of the electrodes are not within acceptable limits
- the automatic impedance checking is disabled.

Caution:
The data provided by the software is not considered reliable if the software shows up a bad electrode contact warning.

Caution:
Automatic impedance checking may need to be disabled if the 6 uA 128 Hz impedance check current interferes with other equipment, e.g., evoked potential monitors. Refer to MADOC1 user manual for instructions.

Alarms

NINDEX software generates two sound alarms: a high alarm and a low alarm. Any alarm may be silenced by the user (see "The Menu Dialog").

A high alarm condition is triggered when NINDEX current value exceeds 75, and remains active if NINDEX current value is greater than 73.

A low alarm condition is triggered when NINDEX current value is below 36, and remains active if NINDEX current value is less than 38.

When an alarm is active, the software generates a 6-second alarm sound every one minute.

Data storage to disk

Monitoring data

Recorded data for the XXXX-YYYYY monitoring (see "Monitoring general data region") is stored in the "c:\eegdata\patientXXXX-YYYYY" folder.

Features of monitoring data storage to disk:

- Data storage: NINDEX, BSR and SEF trend, electrode impedance, raw EEG waveform, event markers, patient data, date and time
- Storage time period: 15 s
- Storage capability: greater than 100 hours.

Software settings

Software settings are stored in the "c:\eegdata" folder.

Disk storage managing

The software verifies the size of the folder "c:\eegdata" upon startup. If the size is greater than 250 MB, then the software displays the following warning: "C:\\eegdata folder size is greater than 250 MB. Do you want to delete old files?".

If the "Yes" button is clicked, monitoring data is deleted using FIFO algorithm, until one of the following is fulfilled:

- The size of the folder "c:\eegdata" is less than 100 MB
- There is no more "patientXXXX-YYYYY" folders in the folder "c:\eegdata".

Caution:
In order not to lose monitoring data, back up the data after maximum 100 monitoring hours.

SOFTWARE UPDATE

To update NINDEX software follow these steps:

1. Contact the software manufacturer (Controles S.A.) to get the installer software for the update (see contact information on the foot of the first page of this manual)

2. Execute the installer software for the update and follow the instructions.

MONITORING DATA REVIEW

This section provides instructions to review NINDEX software's monitoring data using NINDEXMN software. It includes:

- Introduction
- Opening the monitoring data for review
- The monitoring data review display.

Introduction

NINDEXMN software for Windows 2000 or greater allows the user to review NINDEX software's monitoring data, including the review of trend data, event markers and patient data.

Opening the monitoring data for review

To review stored data for a specific monitoring follow these steps:

1. Click the "File Open" button in the program Toolbar

2. In the opening dialog box browse to the monitoring data folder, then select the *.htr file and then click the Open button. In the example below (Figure 16), the monitoring data folder is "c:\eegdata\patient020-00040" and the *.htr file is "p00040m.htr".
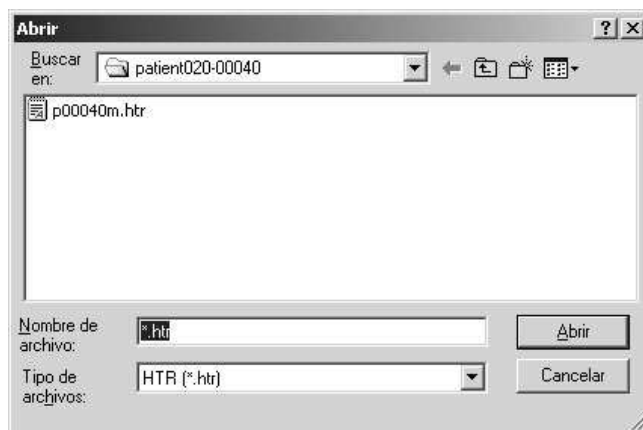
Figure 16

The monitoring data review display

The monitoring data review display is shown in Figure 17. The NINDEX Trend Display is on the top and the BSR Trend Display is on the bottom. Horizontal resolution for NINDEX and BSR Trend Display is 10 min/div. All marked events are displayed in the NINDEX Trend Display. The NINDEXMN window title shows the monitoring number, patient's name and age (if available), the monitoring date and the monitoring time. In the example below (Figure 17), the monitoring identifier is "paciente020-00040", patient's name is "Juan", patient's age is 13 years, the monitoring date is 17/03/2011 and the monitoring time is 09:25.
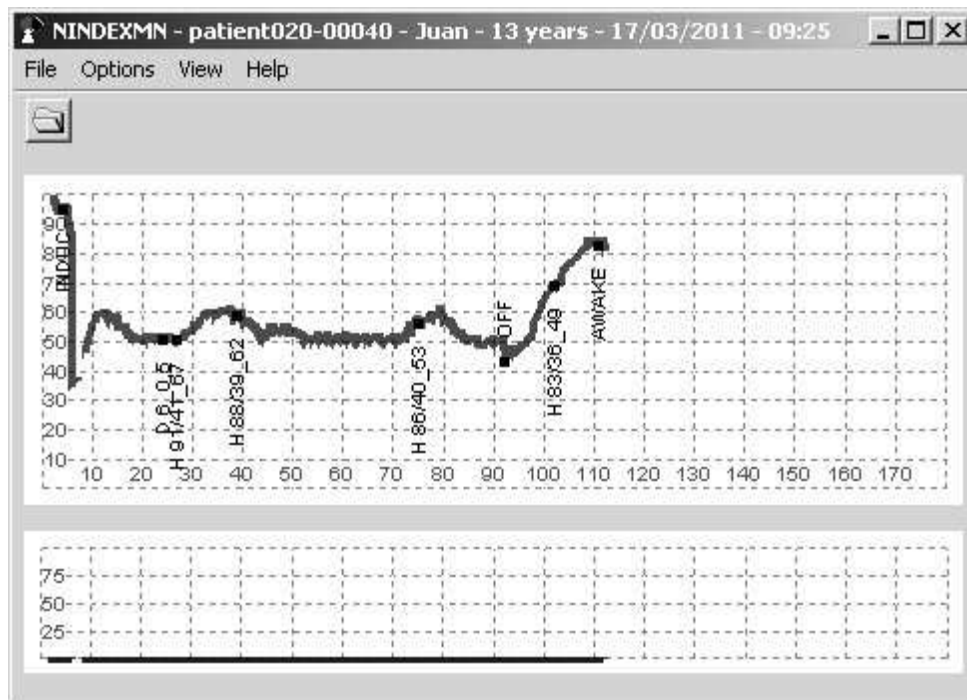
Figure 17

To review monitoring comment list click View on the program menu option and then click Comments.

To review monitoring patient's data click View on the program menu and the click Patient data.

To view the NINDEX Trend Display with constant (i.e. linear) vertical resolution follow these steps:

1) Click Options on the program menu and then click Display settings

2) Enable the check Linear NINDEX plot

3) Click the OK button.

In order to not display trend values if the impedance levels of the electrodes are not within acceptable limits (see bellow) follow these steps:

1) Click Options on the program menu and then click Display settings

2) Enable the check Do not display if bad electrodes

3) Click the OK button.

To set the acceptable limit of the electrode impedance levels for the review follow these steps:

1) Click Options on the program menu and then click Thresholds

2) Set the desired limit value on "Maximum electrode impedance"

3) Click the OK button.

PREVENTIVE MAINTENANCE, CARE AND CLEANING

Care and cleaning

WARNING!
TAKE UNIVERSAL PRECAUTIONS TO PREVENT CONTACT WITH
BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS.

Care and cleaning of the Notebook

Clean any spillage of blood or solutions on the Notebook as soon as possible. Dried blood is difficult to remove. Use lint-free absorbent towels for spill cleanups. Dampen the towel with detergent and lukewarm water for eaiser cleaning.

In order for disinfecting the Notebook, use lint-free absorbent towels dampened either with a 10% bleach solution or a commercial disinfectant. After cleaning, dry all areas except the Notebook display screen with a lint-free absorbent paper towel.

Clean the Notebook display screen with either a mild solution of detergent and lukewarm water or a commercial display screen cleaner, available through personal computer dealers. Do not use abrasive cleaners, to avoid scratching the screen.

Caution:
Avoid any liquid spillage over the Notebook.

Care and cleaning of MADOC1

Refer to the MADOC1 user manual.

Identification

For MADOC1 identification, refer to the MADOC1 user manual.

TECHNICAL SPECIFICATIONS

EEG acquisition device

Refer to MADOC1 user manual.

Electrical Safety

Refer to MADOC1 user manual.