

Narco**trend**[®] - Compact M

Brain Function Monitor for the Operating Room
and the Intensive Care Unit

(Version OR)

Operating Instructions

(Software version 3.2)

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- **Warning:**

The Medical Device Narcotrend is provided for the exclusive use of qualified physicians or personnel under their direct supervision. The numerical and graphical results from a recording must be examined with respect to the patient's overall clinical condition. The recording preparation quality and the general recorded data quality, which could affect the report data accuracy, must also be taken into account.

It is the physician's responsibility to make the diagnosis or to obtain expert opinion on the results and to institute correct treatment if indicated.

- **Caution:**

Federal law restricts this device to sale by or on the order of a physician.

Narcotrend[®]

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1 Introduction

The **Narcotrend-Compact M** serves the purpose of brain function monitoring and was developed specifically for use with hypnotically acting drugs in operating rooms, intensive care units and for clinical research. The **Narcotrend-Compact M** includes the Narcotrend-Index, a processed EEG parameter, which may be used as an aid in monitoring the effects of certain hypnotically acting anesthetic agents.

Under the influence of narcotics/anesthetics, the EEG reveals very characteristic changes. The EEG can therefore be used to assess the hypnotic status of the patient. Based on a large number of parameters derived from the EEG, multivariate statistical methods are used to carry out an automatic classification of the EEG on a scale ranging from stage A (conscious) to stage F (very deep hypnosis). This division of stages is refined by means of an EEG index (100 = conscious, 0 = very deep hypnosis).

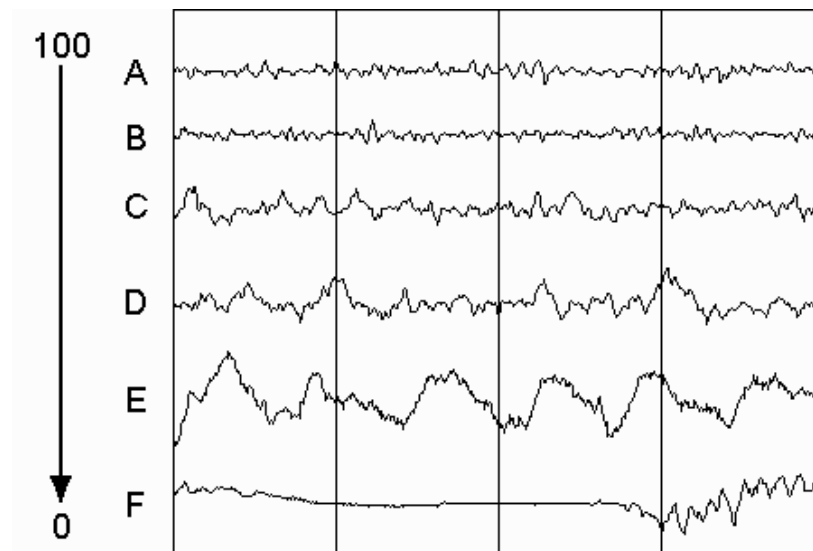


Fig. 1: EEG index, EEG stages und typical EEG patterns

The automatic classifications in variation of time constitute the **cerebrogram**. This cerebrogram provides the user with important information on the hypnotic status of the patient in the course of the recording.

An impedance check is available in order to ensure good signal quality. During an ongoing recording, the program carries out automatic electrode tests at regular intervals. In addition, extensive algorithms for automatic detection of artifacts have been implemented in the program.

- **The automatic assessment is not allowed to be the sole criterion of a narcosis or sedation controlling function. With respect to the dosing of narcotics and sedatives, the overall clinical findings must be taken into account.**

2 Equipment description

The Narcotrend consists of the following components:

- *Narcotrend-Compact M*
- *Narcotrend-Compact M* - power supply
- Patient lead 1-channel (PKM1)
- Patient lead 2-channel (PKM4) (optional)
- Mounting clamp (optional)

- **Use only the original *Narcotrend-Compact M* - power supply.**

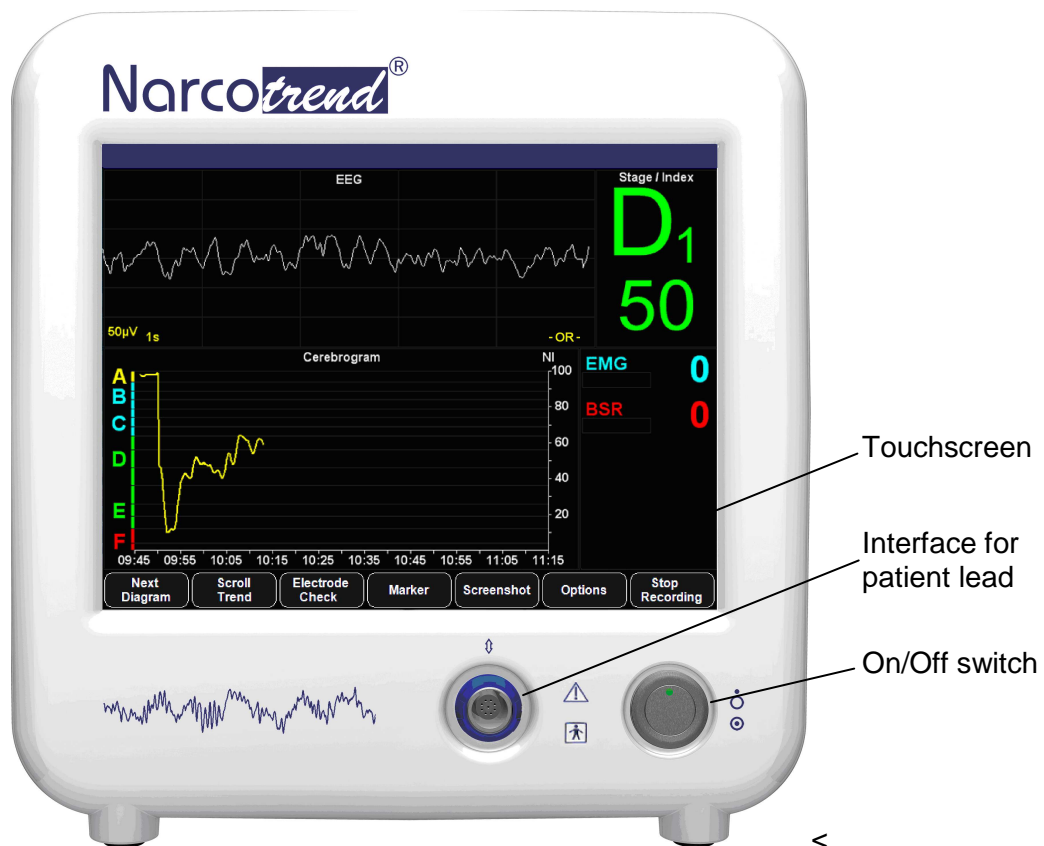


Fig. 2: *Narcotrend-Compact M*, front panel



Fig. 3: Narcotrend-Compact M, rear panel

2.1 Operation

The device is switched on by pressing the On/Off switch briefly.

The software is operated completely via the integrated touchscreen, i.e. all input operations are made by touching the screen briefly.

- **The touchscreen reacts very sensitively. Please don't use sharp or pointed objects like pens or pencils for operation.**

To switch off the device use the button QUIT on the screen.

2.2 Battery operation

The *Narcotrend-Compact M* is equipped with an integrated battery that allows the device to be used for at least 2 hours without being connected to a power supply system.

The battery charging time is approx. 2 hours when the device is switched off and approx. 8 hours when the device is switched on.

2.3 USB port

The USB 2.0 interface is provided for data backup of EEG measurements and to store PDF files on USB storage devices. In some cases, USB storage devices are not detected. To resolve this problem it is recommended to use another USB storage device.

USB flash drives can be connected.

- **The USB port provides 500 mA at 5 V.**
- **The USB port is used to archive stored recordings on the connected USB storage media.**

2.4 Bluetooth (IEEE 802.15.1)

The integrated Bluetooth interface enables the transmission of EEG signals and evaluated parameters to store or display the values on a Bluetooth-enabled external device.

The reception of data from the external device is not provided.

The point-to-point connection enables just one device to connect with the *Narcotrend-Compact M* at one time.

Thereby the risk of interference is reduced and the integrity of the data is ensured.

For further information see the document: "NAT_InterfaceSpecification_2017-09-26".

- **This device contains
FCC ID: PVH0946
IC: 5325A-0946**
- **This device complies with Part 15 of the FCC Rules.**
- **Operation is subject to the following two conditions;
(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.**

Bluetooth is a registered trademark of Bluetooth SIG, Inc.

2.5 IntelliBridge connector (optional)

The integrated IntelliBridge connector enables the transmission of EEG signals and evaluated parameters to preconfigured Philips-IntelliVue patient monitors of the series MP40-90 / MX700 / MX800.

Name and driver version of the Philips EC10 module:

865115/101 IntelliBridge EC10 Module with OpenInterface driver.

The OpenInterface driver must be the revision A.2. The accurate name of the driver is "ED101-A.2".

2.6 RS232 connector

The RS232 interface enables the transmission of EEG signals and evaluated parameters e.g. Narcotrend-Index to store or display the values on an external device (see also chapter 4.5 options -> configurations).

The reception of data from the external device is not provided.

Pin allocation:

Pin	Signal
2	RS232 TxD (Narcotrend-Compact M)
3	RS232 RxD (Narcotrend-Compact M)
5	RS232 Ground

For further information see the document: "NAT_InterfaceSpecification_2017-09-26".

- **Integrating the *Narcotrend-Compact M* into a network can lead to previously unidentified risks for the patient. These risks should be identified, analyzed, evaluated and controlled by the responsible organization.**
Changes to the network could introduce new risks that require additional analysis.

Changes to the network include:

- changes in network configuration
- connection of additional items
- disconnection of items
- update of equipment
- upgrade of equipment

For all Interfaces:

- **For evaluation purposes, primarily the data that is displayed by the *Narcotrend-Compact M* shall be used.**
- **As data communication errors cannot be excluded, data on the external device have to be checked with regard to plausibility.**
- **USB, RS232 and IntelliBridge are intended to be connected to medical electrical equipment complying with IEC 60601-1 with SELV.**
- **The length of the data cable used may not exceed 3 m.**

3 Safety instructions

- Read this entire manual of operating instructions carefully before putting the device into operation. Pay special attention to the marked instructions.
- This equipment is intended for use by healthcare professionals only.
- The automatic assessment is not allowed to be the sole criterion of a narcosis or sedation controlling function. With respect to the dosing of narcotics and sedatives, the overall clinical findings must be taken into account.
- Prior to each application, check the functional safety and proper condition of the device. A damaged device must not be put into operation.
- For safe use, connect the *Narcotrend-Compact M* - power supply to a protective earth conductor.
- Use only the power cords supplied by MT MonitorTechnik GmbH & Co. KG.
- For putting into operation use only the components that belong to the device. Only original parts from MT MonitorTechnik GmbH & Co. KG must be used in the system.
- The *Narcotrend-Compact M* - power supply is an essential part of the device *Narcotrend-Compact M*. No other power supply must be used.
- All the consumables that are used (e.g. electrodes, preparation paste, etc.) must comply with the equivalent safety requirements and/or harmonized national standards.
- The use of a defibrillator is restricted. The electrodes must not be placed between the defibrillator pads.
- Before putting the device into operation, check the connection cables for any signs of damage. Damaged cables and plug-and-socket devices must be replaced.
- Operating the device beyond the operation temperature range is not permissible (see technical documentation). Do not cover the air vents.
- No liquids must be penetrating into the device. Whenever any liquid does penetrate into the device, the device must not be put into operation again until it has been properly checked by an expert.
- The device is not intended to be used in the presence of oxygen enriched environments or flammable anesthetic mixtures.
- Whenever the device has been subjected to increased mechanical stress (dropping, strong vibrations or severe impact), the device must not be put into operation again until it has been properly checked by an expert.
- This device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as reorienting or relocating the equipment or shielding the location.
- The equipment needs special precautions regarding electromagnetic compatibility and needs to be installed and put into service according to information provided in accompanying documents.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the *Narcotrend-Compact M*.
- Portable and mobile radio frequency communication devices (incl. antennas) can affect the equipment. There should be a distance of at least 30 cm (12 inches) to the *Narcotrend-Compact M* and its accessories.
- The equipment is not designed for use in MRI environment.
- In case of simultaneous use of the device together with other systems or devices, the sum of all leakage currents is not allowed to exceed the permissible values:
(in accordance with IEC 60601-1: 100 μ A (AC) and 10 μ A (DC)).
- When using a high-frequency surgical device, care must be taken to ensure that the Narcotrend Electrodes are correctly placed (refer to the section "Applying the electrodes"). In order to reduce the risk of burns and irritation to the skin during use, Narcotrend Electrodes may not be situated between the operation area and the neutral electrode. It is also absolutely necessary to follow the use and safety instructions included with the high-frequency surgical device. It is forbidden to continue to operate the system if the neutral electrode is defective.
- During the use of diathermy/high-frequency surgical devices, disturbances may occur in the EEG signal or in automatic classification.
- Whenever the failure of the device or the limitation of the proper function of the device becomes detectable, this is always a clear indication of a defect. In such cases, further operation of the device is then no longer permissible. The device must then be subjected to proper inspection by an expert.
- No assembly tasks must be carried out on the components of the device, since trouble-free operation can no longer be guaranteed in such cases. It is not allowed to open the device and to make any changes to the cables or electrodes.
- The electrodes and the push button adapters may only be placed on the patient's head, because otherwise other patient's applications could be disturbed.
- The electrodes and the push buttons adapters must not come into contact with electrically conductive parts and earth.
- At any time, it must be possible to separate the device from the mains supply by disconnecting the mains plug. Consider this when placing the device.
- As a general rule, always avoid that anything external comes into contact with the electrical connector pins.
- The patient should not be touched at the same time as the interfaces and the DC connectors of the *Narcotrend-Compact M* - power supply.

4 Putting into operation

4.1 Device setup

When setting up the device, please proceed as described below:

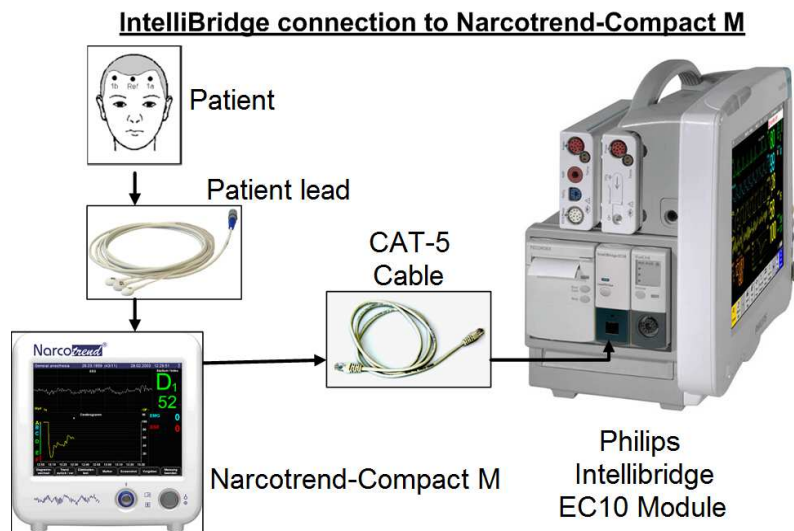
- Connect the *Narcotrend-Compact M* via its external power supply to a power socket.
- Switch on the *Narcotrend-Compact M*.
- Place the electrodes on the patient's head (see below).
- Connect the patient lead to the input on the front side of the *Narcotrend-Compact M*.
- (Optional) Connect the *RS232* interface connector to the parent host device.

- **Use only the components (power supply (incl. power cords, patient lead)) that belong to the device.**
- **For safe use, connect the *Narcotrend-Compact M* - power supply to a protective earth conductor.**
- **Prior to each application, check the functional safety and proper condition of the device. A damaged device must not be put into operation.**
- **Do not block the ventilation inlet holes on the equipment's rear panel.**
- **The touchscreen reacts very sensitively. Please don't use sharp or pointed objects like pens or pencils for operation.**

4.2 Device setup (IntelliBridge (optional))

When setting up the device, please proceed as described below:

- Plug the Philips-IntelliBridge EC10 module in a free slot space of the Philips-IntelliVue patient monitor.
- Connect the *Narcotrend-Compact M* to the connecting cable (CAT-5 cable) and the Philips IntelliBridge EC10 module.
- Place the electrodes on the patient's head.
- Connect the patient lead to the *Narcotrend-Compact M*.



Once the *Narcotrend-Compact M* is connected to the Philips-IntelliVue patient monitor, the data transfer begins including the EEG and the results of the automatic classification.

4.3 Applying the electrodes

As a standard procedure, the registration of the EEG is carried out with self-adhesive disposable electrodes, which are placed on the forehead. They are known for their simplified handling and long-lasting, firm fit. Use the following electrode:

Narcotrend Electrode EE-0203

- **The Narcotrend Electrodes are disposable and should not be re-used. The electrodes are unsuitable if they are re-used.**

- **Avoid kinking and vigorous pulling of the patient lead because both can result in cable defects.**
- **Always follow the instructions of the electrode manufacturer as well.**
- **Electrodes made of different materials must not be used together.**
- **Avoid placing the electrodes over bone gaps, scars or skin lesions.**
- **Whenever electrodes are placed on oedematous skin areas, it is important to note that the amplitudes can be lower here than over non-oedematous areas.**
- **Make sure that there are no moisture bridges between the electrodes.**
- **Lay the patient lead so that it moves as little as possible during the recording. Furthermore, the patient should not be lying on the electrodes or on the patient lead since this can result in malfunctions during the recording.**

The electrodes should be placed on the hairless skin area of the scalp. They should be positioned close to the hairline. In the region close to the eyes artifacts may occur, especially in stages of light hypnosis.

With carotid operations it is advisable to start a 2-channel recording. The electrodes for channel 2 should be positioned on the side where the operation will be carried out.

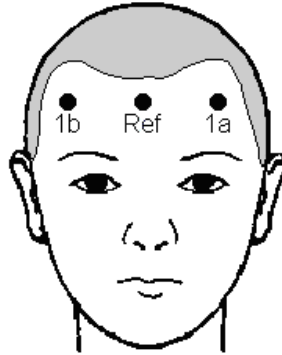
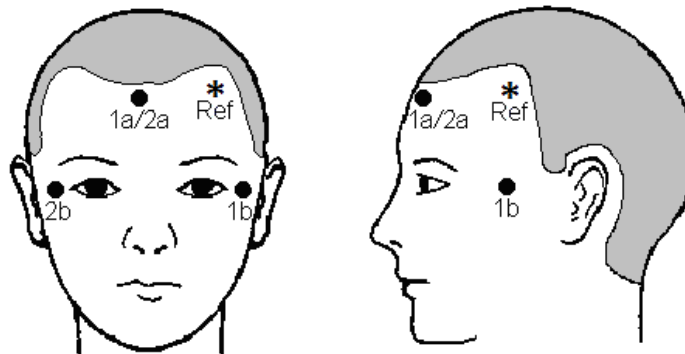


Fig. 4: Electrode positions for disposable electrodes, 1-channel (PKM1)



* The **Reference electrode (R)** can be placed anywhere in the forehead area.

Fig. 5: Electrode positions for disposable electrodes, 2-channel (PKM4)

- **Channel 1 (1a→1b)** is generally positioned on the **healthy side**; the evaluation always refers to channel 1.
Channel 2 (2a→2b) is positioned on the **side to be operated, or sick side**.

1. Wipe the skin at the electrode positions with alcohol or an alcohol pad.
2. Apply a drop of preparation cream (0.5 – 1 ml) to a gauze swab. Use the swab to treat the skin at the electrode positions carefully and thoroughly.
3. Rub the skin dry with a dry gauze swab.
4. Pull off the protective material from the electrodes and then stick the electrodes on the skin. Avoid exerting pressure on the center of the electrodes since this could cause the electrode gel to be pressed under the adhesive ring, thus reduces the electrode adhesion.
5. Connect the pushbutton adapters of the patient lead to the electrodes.
6. Seal the pouch with unused electrodes as airtight as possible.

- **Spacing: at least 8 cm (3 in) between**
1a and 1b (1-channel recording)
1a/2a and 1b, 1a/2a and 2b (2-channel recording)
- **Electrode impedances: < 2 kΩ (max. 8 kΩ)**
Ensure uniform impedance values to the extent possible.

4.4 Start recording / Start screen

After the *Narcotrend-Compact M* has been switched on, the dialogue for starting a new recording is displayed:

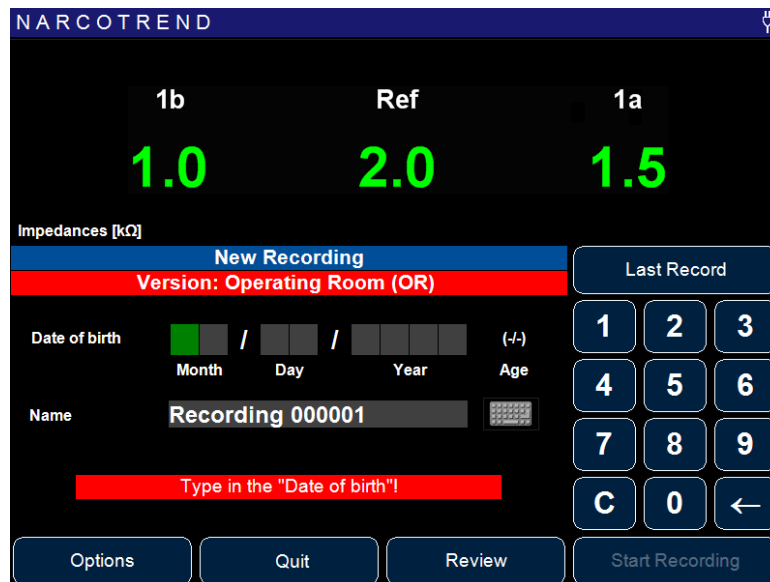


Fig. 6: Start screen

If the electrodes are already applied and the patient lead is connected, the impedances are displayed in the upper area of the screen.

The date of birth is entered by using the numeric keypad, as in the figure above.

You can also assign a name for the recording (e.g. patient name). Press the keyboard symbol on the right-hand side next to the input line for Name. The input operation is carried out via the displayed screen keyboard.

The button LAST RECORD accepts the date of birth and the name of the last record in the corresponding input lines.

To start a recording the following requirements must be fulfilled

- patient lead is connected
- a valid date of birth has been entered
- the input line “Name” is not empty
- the internal battery is not empty
- there is enough free space on the memory card

Not fulfilled conditions are displayed below the input fields.

If all conditions are fulfilled, start the recording via the button START RECORDING. The “Recording screen” appears and from now on the data will be stored.

It is not possible to make a 1-channel-recording with a 2-channel-lead.

The button REVIEW is used to show stored recordings (chapter 7).

The button QUIT is used to switch off the device.

- **The touchscreen reacts very sensitively. Please don't use sharp or pointed objects like pens or pencils for operation.**

4.5 Options / Start screen

On the Start screen, you can use the OPTIONS button to make global program settings. This includes:

Electrode Settings

<i>Select electrode type:</i>	<i>Standard or (Needle (currently not available))</i>
<i>Electrode Check Interval:</i>	The time interval between the automatic impedance measurements can be changed.
<i>Max. Impedance:</i>	Shows the set warning / limit value of the permissible impedance of an electrode.
<i>Max. Impedance Difference:</i>	Shows the set warning / limit value of the permissible impedance difference of the electrodes.

See also chapter 5.9, Electrode Check.

Date / Time

To change the time or date, change the corresponding values and confirm with the APPLY button.

Language

The language used for the device can be set by selecting the corresponding button.

Marker

Up to 20 different marker texts can be defined in order to access markers with the predefined texts during the measurement.

Configuration

- *User Preferences:*
 - If the option "Show query for channel 1" is activated, the position of the electrodes of channel 1 (left side of the head / right side of the head / alternative position) is requested before the start of the measurement.
A corresponding marker is set at the beginning of the measurement.
- *Service:* Setup and maintenance menu for service technicians.
- *Device Information:* Displays device and version information.

5 Recording screen

In the recording screen, all information about the recording are displayed. Using the button bar at the bottom margin of the screen, the program is controlled in the recording mode.

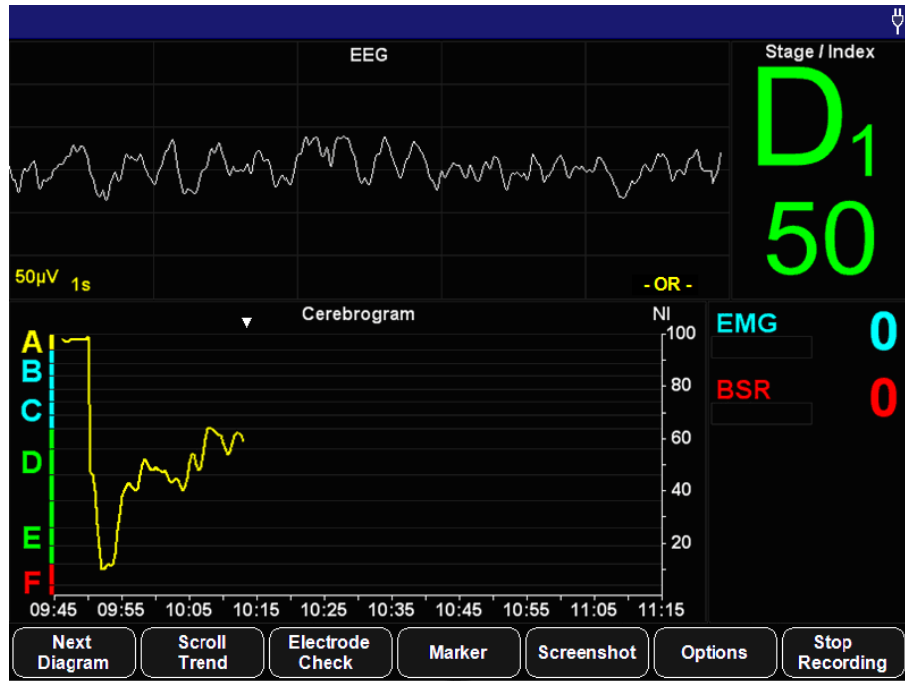


Fig. 7: Recording screen

5.1 Title line

The title line indicates the following information (from left to right):

- Name
- Date of birth and age in years/months
- Date and time
- Bluetooth / RS232-symbol (when function is switched on)
- Power supply symbol or battery symbol

In the title bar also system messages, such as information about the battery capacity are displayed.

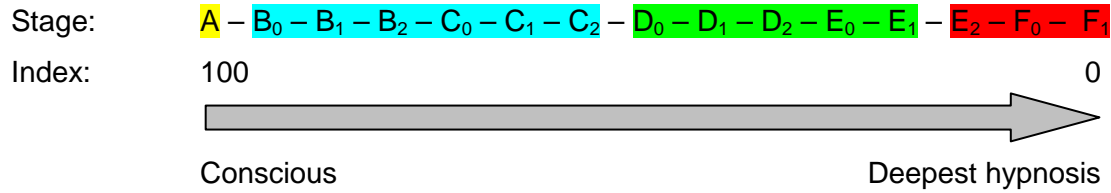
5.2 EEG

The EEG data currently coming from the patient are indicated in the raw EEG window. In the case of a 2-channel recording, the top curve indicates Channel 1, and the bottom curve indicates Channel 2.

Within the EEG window, information about artifacts and status messages are also displayed.

5.3 Stage / Index

The current automatically classified EEG stage and the EEG index are indicated in the right top part of the recording screen:



Every stage from A to F₁ refers explicitly to a range of indices.

Stage	Index
A	95 - 100
B0	90 - 94
B1	85 - 89
B2	80 - 84
C0	75 - 79
C1	70 - 74
C2	65 - 69
D0	57 - 64
D1	47 - 56
D2	37 - 46
E0	27 - 36
E1	20 - 26
E2	13 - 19
F0	5 - 12
F1	0 - 4

- The current assessment always refers to Channel 1.

5.4 Additional parameters

These parameters are displayed on the right side of the recording screen.

5.4.1 EMG

EMG = electromyogram

The EMG index is a measure for the intensity of the electrical muscle activity. The index is displayed on a scale from 0 (no muscle activity) to 100 (very high amount of muscle activity).

5.4.2 BSR

BSR = burst suppression ratio

The burst suppression ratio quantifies the suppression percentage of a 60 s EEG epoch. It is displayed on a scale from 0 (no suppression detected) to 100 (isoelectric EEG).

5.4.3 STI

STI = sharp transient intensity

The STI detection shows in three stages the frequency and the intensity of sharply contoured potentials within the last minute.



Artifacts may be involved in rare cases with the sharply contoured potentials detected (e.g. cautery).

5.5 Diagrams

The diagrams being offered are displayed in this window. The diagram changing operation is carried out via the button NEXT DIAGRAM.

In the basic version, the following diagrams are available

- Cerebrogram
- Relative Band Activities / Power

The other diagrams are available in the extended version.

5.5.1 Cerebrogram

The cerebrogram shows the results of the automatic assessments of the EEG in the course of time. In the 2-channel version, only the values from the channel 1 are displayed.

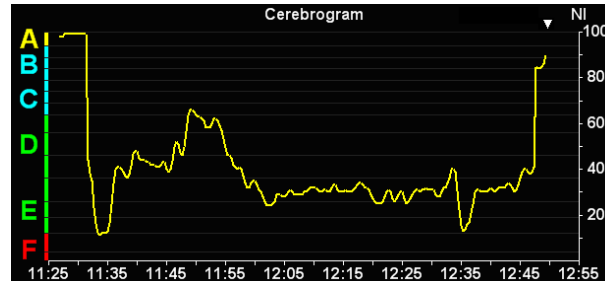


Fig. 8: Cerebrogram

The left axis shows the stages A - F with the corresponding sub-stages and the right axis shows the index range 0 to 100.

In an ongoing recording, a white triangle at the upper margin of the cerebrogram indicates the current time.

5.5.2 Relative Band Activities / Power

The percent activity proportions for the individual frequency bands and the absolute power are displayed.

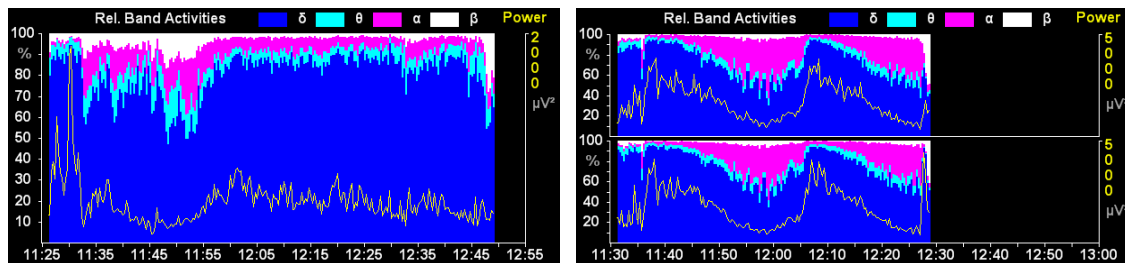


Fig. 9: Relative Band Activities / Power, 1-channel and 2-channel

5.5.3 Quantiles

This diagram shows the median (50% quantile) and the spectral edge frequency (95% quantile).

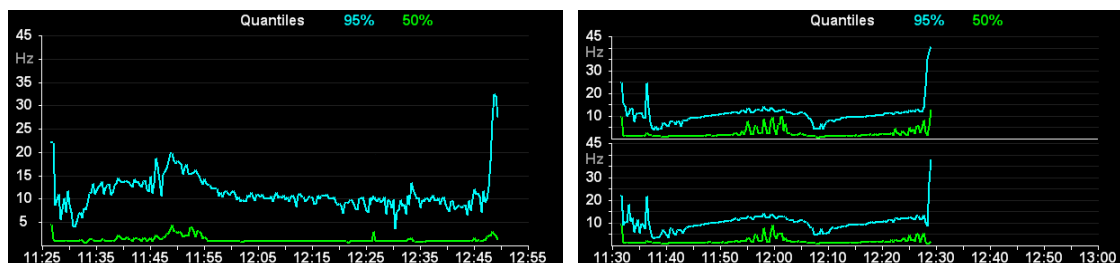


Fig. 10: Quantiles, 1-channel and 2-channel

5.5.4 Power Spectrum

The power is displayed in the power spectrum depending on the frequency. The individual frequency bands are delimited from one another by vertical lines:

δ (delta band)	: 0.5 – 3.5 Hz
θ (theta band)	: 3.5 – 7.5 Hz
α (alpha band)	: 7.5 – 12.5 Hz
β (beta band)	: > 12.5 Hz

In the very deep stages E₂, F₀ and F₁, the power spectrum is shown in gray.

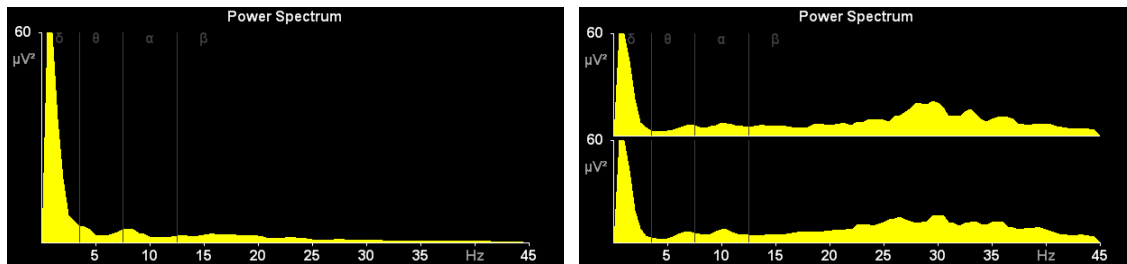


Fig. 11: Power Spectrum, 1-channel and 2-channel

5.5.5 DSA

The DSA (Density Spectral Array) is a color-coded representation of the frequency components of an EEG (violet = low power values, red = high power values).

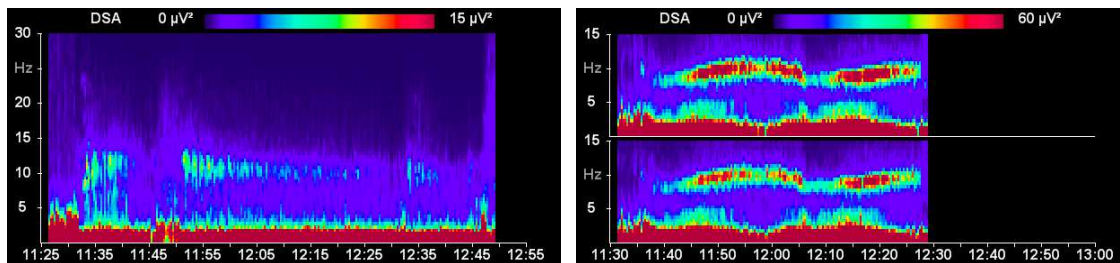


Fig. 12: DSA, 1-channel and 2-channel

5.6 EEG analysis for children in the first year of life

The analysability of anesthesia EEGs registered for children in the first months of life, will depend to a large extent on the children's level of development. Appearing from the age of approximately three months until the age of 12 months in an increasing number of children, are typical EEG anesthesia stages, which can be classified visually and automatically.

EEG classification among children under the age of 60 days

For this age group only EEG classifications for stages with implied or clear suppression lines (E_2 to F_1) are displayed. The scale of the cerebrogram is designed accordingly. If there is an EEG without suppression lines, the output is "Undiff. EEG". This stands for "undifferentiated EEG".

EEG classification among children between the age of 60 days and the age of 1



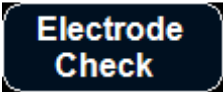




For children of this age the full A-F scale is displayed on the left side of the cerebrogram window.

From the outset of measurements the EEG is analysed for certain attributes, which suggest a mature and thus fully classifiable EEG.

As long as no fully classifiable EEG is detected, instead of an indication of stage or index, the output "Undiff. EEG" is displayed in the index field, if the raw EEG shows no sign of suppression lines. If the EEG has been graded as classifiable, from now on classifications can also be outputted throughout the stages E_2 to F_1 .

5.7 Button bar

The program is controlled in the recording mode via the button bar on the bottom edge of the screen:

Button	Action
	Changes the content of the diagram window.
	Starts the review mode.
	Starts the manual electrode check and shows the impedance values of each electrode. The button text is changed to “EEG”. Pressing the button again stops the manual electrode test and displays the EEG again.
	Shows the menu for setting and editing markers (only available in the extended version).
	Generates from the current screen a PNG image file.
	Opens a dialogue to change the program options.
	Stops the recording of the EEG. The Start screen is displayed again.

5.8 Review mode

To start the review mode, press the button SCROLL TREND. In the review mode it is possible to access previous EEG epochs and diagrams of the current recording. This mode enables the user to scroll back and forward within up to 24 hours of the current recording. The current EEG is still recorded, analysed and saved while the review mode is active.

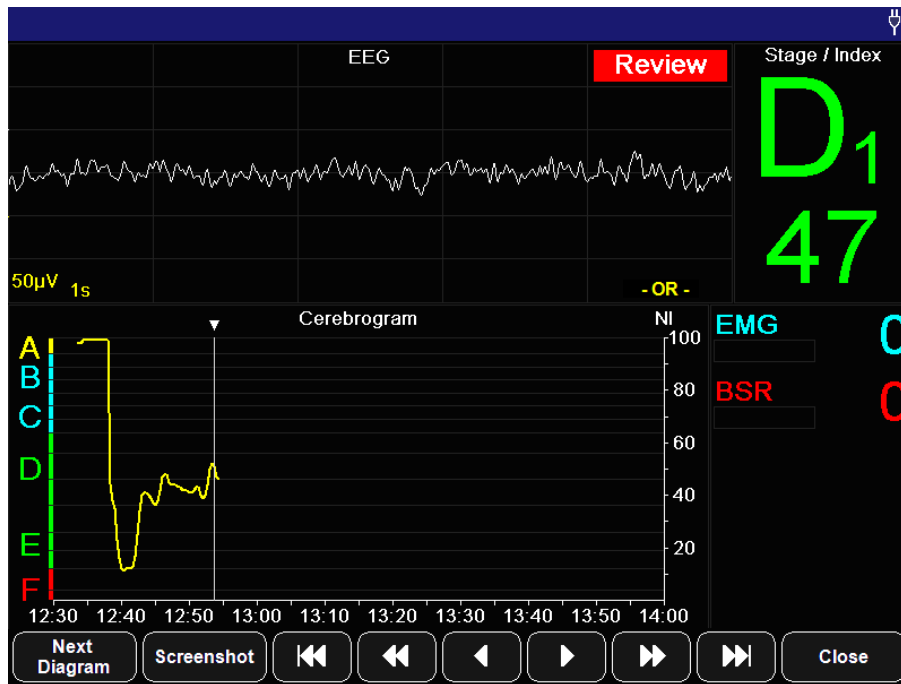








Fig. 13: Recording screen during the review mode

- In the review mode, the current EEG and classification is not shown. This is indicated by the red flashing message „Review“.

A vertical line in the diagrams with a time axis (e.g. Cerebrogram) marks the recording time of the displayed EEG and the related parameters.

It is possible to choose any point on the time axis by tapping on the touchscreen or to navigate through the recording via the following buttons.

The markers that are located within a time range of ± 2 minutes of the selected time will be displayed in a text box.

Button	Action
	Changes the content of the diagram window.
	Generates from the current screen a PNG image file.
	Jumps to the start / end of the recording.
	1 hour back / ahead.
	5 seconds back / ahead.
	Ends the review mode and returns to the recording screen to display the current values.

5.9 Electrode settings

A manual electrode check can be carried out at any time independent of the automatic electrode checks.

Adherence to the limit values for the impedances is required in order to ensure proper operation of the device. Furthermore, it is important to make sure that the impedance values of the individual electrodes are as uniform as possible. Whenever the limit values for the impedances or the differences between the impedances are exceeded, analysis of the incoming EEG data is impossible, and a corresponding message is shown.

Standard limit values:

	Impedances	Impedance differences
Standard electrodes	< 8 k Ω	< 5 k Ω

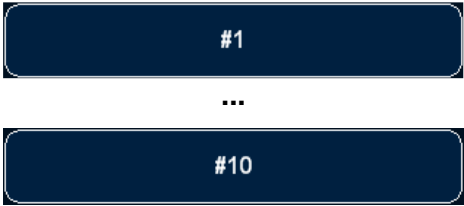





5.10 Marker

This menu is only available in the extended version.

The MARKER button displays a menu for setting and editing markers.



Fig. 14: Set and edit markers

Button	Action
	Sets markers with predefined text. The text can be changed through the global program requirements (OPTIONS button on the start screen).
	Shows the list of predefined markers 1-10.
	Shows the list of predefined markers 11-20.
	Sets markers with self-defined text.
	Shows the list of all set markers. The text of set markers can be changed.
	Closes the menu and switches back to the recording screen.

- When a marker has been set, it is indicated by a yellow triangle above the upper margin of diagrams with a time axis.

5.11 Options

This dialogue is used to adjust several program options.

The preferences for the automatic electrode check and the diagram scales can be changed.



Fig. 15: Menu - Options

- The settings in this dialogue are valid only for the current recording.

6 EEG and evaluations (RS232 / IntelliBridge connector)

The *Narcotrend-Compact M* provides the following values and evaluations via the RS232 / IntelliBridge connector.

6.1 EEG

Depending on the connected patient lead, the one-channel or two-channel EEG is transmitted (EEG or EEG1/EEG2).


6.2 Narcotrend-Index NI

Result of the automatic classification.

Only for IntelliBridge:

On the Philips-IntelliVue patient monitor only the Narcotrend-Index can be represented, the stage is not visible.

The following table shows the relationship between Narcotrend-Index and stage.

Narcotrend-Index	Stage	Comment
100 - 95	A	awake  deep hypnosis
94 - 90	B0	
89 - 85	B1	
84 - 80	B2	
79 - 75	C0	
74 - 70	C1	
69 - 65	C2	
64 - 57	D0	
56 - 47	D1	
46 - 37	D2	
36 - 27	E0	
26 - 20	E1	
19 - 13	E2	
12 - 5	F0	
4 - 0	F1	

- The Narcotrend-Index always refers to Channel 1.

6.3 Additional parameters

There are additional parameters like the EMG index, the BSR and the STI available, see table below.

Only for IntelliBridge:

To view the additional parameters in the IntelliBridge device data window, either

- select the setup key on the EC10-module, or
- select the External Devices SmartKey and then select the pop-up key with the device name on it, or
- direct tap on the EEG curve and select in the appearing window “External Devices”, then tap on „Show Device Data“.

*L/LT = Channel 1 (left)

*R/RT = Channel 2 (right)

Parameter	Label 1-Channel	Label 2-Channel	Description
EMG index	EMG	EMG	EMG index (EMG = electromyogram) is a measure of the intensity of the electrical muscular activity. The EMG index is shown on a scale of 0 (no muscle activity) to 100 (very strong muscle activity).
BSR	BSR	LT BSR RT BSR	The BSR (burst suppression ratio) is the percentage of suppression lines in the EEG. The value refers to the last 60 s and is issued as a value between 0 (no suppression lines) and 100 (continuous suppression line).
STI*	STI	STI	<i>STI = Sharp Transient Intensity</i> The STI detection shows on a scale of 0 to 100 the frequency and the intensity of sharp potentials within the last minute.
Delta	% DL	LT %DL RT %DL	Rel. spectrum power Delta: 0.5 – 3.5 Hz
Theta	% TH	LT %TH RT %TH	Rel. spectrum power Theta: 3.5 – 7.5 Hz
Alpha	% AL	LT %AL RT %AL	Rel. spectrum power Alpha: 7.5 – 12.5 Hz
Beta	% BE	LT %BE RT %BE	Rel. spectrum power Beta: > 12.5 Hz
Power	TP	LT TP RT TP	Total output [μV^2]
Median	MPF	LT MPF RT MPF	The median corresponds to the 50% quantile of the power spectrum [Hz]
Edge frequency	SEF	LT SEF RT SEF	The spectral edge frequency corresponds to the 95% quantile of the power spectrum [Hz]
Imp. 1a	1a	1a	Impedance for electrode 1a [k Ω]
Imp. 1b	1b	1b	Impedance for electrode 1b [k Ω]
Imp. Ref	Ref	Ref	Impedance for electrode Ref [k Ω]
Imp. 2a		2a	Impedance for electrode 2a [k Ω]
Imp. 2b		2b	Impedance for electrode 2b [k Ω]

6.4 Electrode check

To ensure the proper working of the system, the impedance values may not exceed a certain threshold. Furthermore, make sure that the impedance values of the individual electrodes are as uniform as possible. At too high impedances or impedance differences no evaluation of the incoming EEG data is possible, and an appropriate message (NARCOTR CHECK IMP) is outputted.

	Impedances	Differences of impedances
Threshold values	< 8 k Ω	< 5 k Ω

6.5 Error messages

The following error messages are outputted:

INOP	Description
NARCOTR LEAD OFF	Patient lead is not connected.
NARCOTR CHECK IMP	One or more impedance values have exceeded the maximum limit. Check the position of the electrodes on the patient's head and the connections at the electrode lead.
NARCOTR 50/60 HZ	AC artifacts occur in the signal.
NARCOTR INTERFER	Errors may occur in the EEG signal, e.g. by high-frequency surgery (cautery).
EMG	No classification due to high intensity of the electrical muscle activity.

- **In case of excessive load of artifacts the Narcotrend-Index is not calculated.**

7 Analyse recording

Select the button REVIEW in the start screen. The dialogue displays a list of all recordings or screenshots that have been stored. A recording or screenshot is selected by direct touch or via the buttons on the right-hand side next to the list.




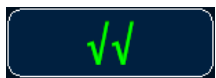



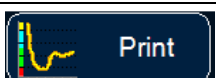

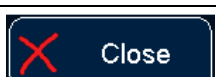
Only for recordings:

At the bottom of the screen the Cerebrogram of the selected recording is shown (max. the first 90 minutes).



Fig. 16: Dialogue „Review“

The buttons on the right have the following functions:

Button	Action
	Switchover from recordings to screenshots.
	Moves the selection bar up.
	Marks a selected recording/screenshot and moves the selection bar down.
	Marks all recordings/screenshots.
	Moves the selection bar down.
	Displays the selected recording/screenshot (review).
	Copies the selected recordings/screenshots to an USB flash drive.
	Creates a PDF-File on the USB flash drive.
	Deletes the selected recordings/screenshots.
	Closes the dialogue. Returns to the start screen.

7.1 View

The selected recording or screenshot is read and displayed.




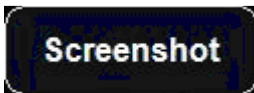
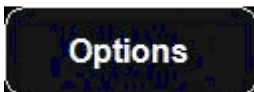

Only for recordings:

If recordings which are longer than 24 hours shall be displayed, at first the recording period (“day”) has to be selected. This day will then be shown completely.

Apart from the button bar, the screen is identical with the review mode screen of an ongoing recording.



Fig. 17: Screen “View” (review mode)

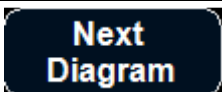
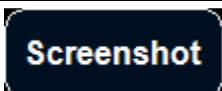




Button	Action
	Changes the content of the diagram window.
	Shows the button bar to navigate through the recording.
	Shows the list of all markers (only available in the extended version).
	Generates from the current screen a PNG image file.
	Opens a dialogue to change the diagram scales.
	Ends the display of the recording and returns to the dialogue „Analyse recording“.

A vertical line in the diagrams with a time axis (e.g. Cerebrogram) marks the recording time of the displayed EEG and the related parameters.

It is possible to select any point on the time axis by tapping on the touchscreen or to navigate through the recording via the buttons.

Date and time in the title line are identical with the currently marked and displayed recording time.

Via the button SCROLL TREND, it is possible to access a further button bar to navigate through the recording.

Button	Action
	Changes the content of the diagram window.
	Generates from the current screen a PNG image file.
	Jumps to the start / end of the recording.
	1 hour back / ahead.
	5 seconds back / ahead.
	Ends the review mode and returns to the recording screen to display the current values.

7.2 Save

The selected or all marked recordings or screenshots are saved on a USB flash drive.

- **This is possible when the USB storage medium has been recognized and accepted by the device.**
- **The connected USB storage medium has to be FAT32.**
- **Due to the great variety of existing USB storage media, we cannot guarantee that each USB storage medium will be accepted by the device.**
- **Depending on the memory capacity, the detection of a USB storage medium may take some minutes.**
- **The USB port provides 500mA at 5V.**

7.3 Print

For the selected or for all marked recordings, PDF files consisting of the cerebrogams are created on the connected USB flash drive. Each PDF file contains the whole course of a recording.

- **Please read the notes concerning USB storage media in section 7.2.**

7.4 Delete

Delete the selected or all marked recordings or screenshots definitely from the device.

8 Cleaning, maintenance, repair

8.1 Care and cleaning

To **clean** the *Narcotrend-Compact M* and the display surface use a lint-free cloth moistened with warm water (max. 40 °C / 104 °F) and soap, a thinned non-corrosive cleaner, or an ammonia/alcohol-based cleaner.

To **disinfect** the *Narcotrend-Compact M* and the display surface use a lint-free cloth dampened with a 10% bleach / 90% water solution (household bleach [containing less than 10% sodium hypochlorite]) or wipe the surfaces with disinfectant containing alcohol (e.g. Meliseptol[®]) or disinfectant with the active ingredient chlorine dioxide (e.g. Tristel Jet[®]).

After cleaning / disinfection, dry all areas with a lint-free absorbent paper towel. Sterilization is not carried out.

The **cleaning / disinfection** of the accessories, e.g. patient leads, are carried out in the same way described above.

- **Use cleaning and disinfecting agents always in observance to the manufacturer's instructions.**
- **Do not allow any water to enter the housing.**
- **Do not use abrasive detergents.**
- **Do not mix disinfectants (such as bleach and ammonia), dangerous gases can occur.**

8.2 Recommended checks

- The recommended checks must only be carried out by a qualified service technician.
- Before and during each application, observe the safety instructions included in Chapter 3.

Inspections related to safety and measuring technology are not required. However, it is advisable to carry out the following tests every 12 months.

Visual inspection

- Presence of all system components
- Signs of damage on the *Narcotrend-Compact M* (cracks, missing housing parts)
- Condition of the plug-in connections on the *Narcotrend-Compact M* (firmly seated in the housing, pins not bent)
- Condition of the patient lead (sheath, plug-in connections undamaged)
- Proper labeling (type plates fitted, legible)

Electrical measurements

- Patient leakage current (application part: electrode pushbutton adapter)

Functional test (if test adapter is available)

- Starting an EEG recording incl. impedance measurement after plugging a test adapter into the pushbutton adapter.
- A simulated zero line must be output. The impedance values must amount to approx. 1 k Ω .



Documentation

- Preparing a test report including identification of the inspector, the measuring method and the test results.

8.3 Error messages

Error messages	Description
No patient lead is connected	Patient lead is not connected to the monitor. To start a new measurement a patient lead must be connected.
Impedance too high! Adjust electrodes	The measured impedance value of one or more electrodes exceeds the maximum limit. Check the position of the electrodes on the patient's head and the connections to the patient cable. Press the pad gently or glue on a new electrode.
Impedance difference too high	The difference between two measured impedance values exceeds the maximum limit. Check the position of the electrodes on the patient's head and the connections to the patient cable. Press the pad gently or glue on a new electrode.
Check Electrodes!	One or more electrodes have no measurable contact with the skin. Check the position of the electrodes on the patient's head and the connections to the patient cable. Press the pad gently or glue on a new electrode.
Electrodes offline: (1a...2b) „Off“	
“?” Shown in screen “electrode check”	Check the placement/fit of the electrodes whose impedance levels are not displayed as green.
Connect 1-channel patient lead	Without the additional option 2-channel, 2-channel measurement cannot be started. Connect a 1-channel patient lead and then start a new measurement.
Type in the “Date of birth“!	To start a measurement you must enter a date of birth.
Check “Date of birth“!	The entered date of birth is incorrect or is in the future. Check the date of birth.
Type in the “Name“!	To start a measurement you must enter a name. The name of the measurement can also be "measurement 000001". You can also enter the patient's ID.
Battery is low. Connect power supply!	The monitor is operated on battery power and the battery is nearly empty. Connect the <i>Narcotrend-Compact M</i> - power supply to continue working.
Battery is empty. Connect power supply!	The monitor is operated on battery power and the battery is empty. Connect the <i>Narcotrend-Compact M</i> - power supply immediately to prevent that current measurement is automatically stopped before the power goes off.
Battery is empty. Recording is terminated!	The unit is operated on battery power and the battery is empty. To prevent data loss, the current measurement has been completed. Connect that <i>Narcotrend-Compact M</i> - power supply to prevent the device switches off.

Error messages	Description
Not enough free disk space. Recording terminated!	The current measurement was stopped because there is not enough space available to store the data. Push the button REVIEW to save or delete some of the past measurements and get free space on the hard disk.
EEG storage left: < 100 hours	The available capacity is less than 100 hours. It is possible to start measurements but it is recommended to delete measurements in the "Review mode". If necessary you can save the measurements beforehand.
Impedance	Due to high impedance values or impedance differences, a classification is impossible. Check the position of the electrodes on the patient's head and the connections to the patient cable. Press the pad gently or glue on a new electrode.
50 Hz or 60 Hz	AC artifacts occur. In case of excessive artifact load, the signal is not evaluated. If the error persists please contact support (see contact on the back of the cover page).
EMG	Due to excessive EMG artifacts, a classification is impossible. (EMG = electromyogram, intensity of electrical muscle activity)
Undiff. EEG	This message will only be displayed with the occurrence of an undifferentiated EEG in the case where measuring takes place in children aged 12 months or less. Such an undifferentiated EEG cannot be classified apart from E ₂ -F ₁ . In the case of the occurrence of a differentiated EEG, this message will not be displayed, but instead classified even in the case of children aged 12 months or less. Also see Chapter 5.6 in connection with this.

8.4 Battery

The internal battery is a consumable that loses its capacity after longer use. If the mains buffering time is no longer achieved the battery should be replaced.

8.4.1 Checking the battery

Connect the *Narcotrend-Compact M* to the mains for at least 2 hours. Interrupt the power supply and switch the equipment on. If the *Narcotrend-Compact M* can no longer be operated for 2 hours in battery mode the battery may be replaced.

8.4.2 Changing the battery

- **The internal battery must only be replaced by a qualified service technician.**
- **Do not change the battery while the *Narcotrend-Compact M* is in use with a patient.**
- **Use only original parts. See "Spare parts and part numbers."**

The following steps are to be carried out:

1. Unplug the power supply from the *Narcotrend-Compact M*.
2. Open the battery box by loosening the 2 screws at the back side.
3. Remove the battery by disconnecting the battery cable.
4. Plug in the battery cable of the new battery and place the battery in the battery box.
5. Replace the battery box cover and fix the 2 screws again.
6. Reconnect the power supply and test the device.

8.5 Disposal














- **Do not dispose of the device with unsorted household waste.**
- **The Narcotrend Electrodes are disposable and should not be re-used. The electrodes are unsuitable if they are re-used.**

The *Narcotrend-Compact M* (especially the battery) and the patient lead must be disposed by a disposal company for electronic wastes.

Disposable parts must be discarded according to hospital rules and in an environmentally safe way.


9 Technical data

9.1 Symbols

	Follow instructions for use		Manufacturer
	Consult the instructions for use		Date of manufacture
	Attention	REF	Order number
	Type BF applied part	SN	Serial number
	Indicates <i>ON</i> / <i>OFF</i> for a part of equipment	LOT	Lot number
IPX1	IP-Code (Protection against dripping water (vertically falling drops))		Expiration date
Rx only	Federal law (U.S.A.) restricts this device to sale by or on the order of a physician		For single use only
 <p>UL CERTIFIED SAFETY US-CA E497499</p>	<p>MEDICAL — GENERAL MEDICAL EQUIPMENT</p> <p>AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012)</p>		Temperature limit (from...to)
			Latex-free
			Do not dispose of the device with unsorted household waste

The last two digits of the serial number indicate the year of production (e.g. 18 = 2018, 19 = 2019).

9.2 Classification and technical data

Classification	
Product	Narcotrend
Type/Model	Narcotrend-Compact M
Manufacture	MT MonitorTechnik GmbH & Co. KG Maienbass 27 24576 Bad Bramstedt, Germany
Intended use	EEG - measurement and analysis with output a parameter for anesthesia and sedation control
Classification according to Annex IX of Directive 93/42/EWC concerning Medical Devices	IIb
UMDNS	EEG-Monitor 12-602
Class	Medical equipment of protection class II
Electromagnetic Compatibility	IEC 60601-1-2 Class A (not life-supporting)
IP-Code	IPX1
	MEDCERT Zertifizierungs-und Prüfungsgesellschaft für die Medizin GmbH Kennnummer: 0482
Operating conditions	
Operating mode	Continuous operation
Environmental temperature	0 °C to +34 °C (+32 °F to +93°F)
Storage temperature	-10 °C to +60 °C (+14 °F to +140 °F)
Max. relative humidity	85% (non-condensing)
Min. barometric pressure	70 kPa
Power Supply	
Identifier	E2DFMW3_E 30
Input	100–240 V~ / 50–60 Hz / 620-380 mA
Power Supply	<i>Narcotrend-Compact M</i> - power supply
Exchangeable mains plug system	IEC (CEE 7/7), USA (NEMA 5-15P (hospital grade))
Battery	
Type	Lithium-Ion
Battery operating time	Approx. 120 minutes
Monitor	
Type	TFT colour display
Size / Resolution	8.4" / 800 x 600 pixels
Touchscreen	Resistive

Interfaces	
USB 2.0	5 V, max. 500 mA
Bluetooth	IEEE 802.15.1
IntelliBridge connector	OpenInterface Revision IB-ED101-A.2
RS 232	5 VDC \pm 10%, 150 mA
EEG Inputs	
Input impedance	>10 M Ω
Bandwidth	0.53 Hz to 45 Hz
Dimensions, weight	
Width x height x depth	230 x 235 x 85 mm (9.06 x 9.25 x 3.25 in)
Weight	2.1 kg (4.63 lb)

9.3 Spare parts and article numbers

Article-No.	Article
NC-0124	<i>Narcotrend-Compact M (T5)</i>
NC-0115	Configuration OR Version
NC-0125	Option Philips IntelliBridge Interface
NC-0103	Option Extended Version
NC-0102	Option 2-Channel Version
EK-0301	Patient lead PKM1, 1-channel (3 electrodes)
EK-0306	Patient lead PKM4, 2-channel (4 electrodes)
EE-0203-25	Narcotrend Electrode EE-0203 (1 pouch à 25 pcs.)
EE-0203-250	Narcotrend Electrode EE-0203 (10 pouches à 25 pcs.)
NC-0110	<i>Narcotrend-Compact M - power supply</i>
NC-0113	Mains Cord for <i>Narcotrend-Compact M - power supply (US, 1,8 m)</i> <i>plug: NEMA 5-15P (hospital-grade), 125 V, 10 A</i> <i>mains cord: SJT 3/C 18, AWG, 300 V, VW-1/FT2, 105 °C</i> <i>appliance plug: 250 Vac, 10 A, C13</i>
NC-0114	Mains Cord for <i>Narcotrend-Compact M - power supply (US, 3 m)</i> <i>plug: NEMA 5-15P (hospital-grade), 125 V, 10 A</i> <i>mains cord: SJT 3/C 18, AWG, 300 V, VW-1/FT2, 105 °C</i> <i>appliance plug: 250 Vac, 10 A, C13</i>
NC-0122	Test adapter for Narcotrend device
NC-0123	Test adapter for Narcotrend patient lead
NC-0104	Mounting clamp, rotatable
NC-0109	Li-ion battery pack

9.4 EMC-Guidance

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The <i>Narcotrend-Compact M</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Narcotrend-Compact M</i> should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The <i>Narcotrend-Compact M</i> must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment could be affected.
RF emissions CISPR 11	Class A	The <i>Narcotrend-Compact M</i> is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	7. N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	8. N/A	

9.

10. Recommended separation distances between portable and mobile

11. RF communications equipment and the *Narcotrend-Compact M*

12. The *Narcotrend-Compact M* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Narcotrend-Compact M* can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Narcotrend-Compact M* as recommended below, according to the maximum output power of the communications equipment.

13. Rated maximum output power of transmitter [W]	14. Separation distance according to frequency of transmitter [m]		
	15. 150 kHz to 80 MHz 16. $d = 1.2\sqrt{P}$	17. 80 MHz to 800 MHz 18. $d = 1.2\sqrt{P}$	19. 800 MHz to 2,5 GHz 20. $d = 2.3\sqrt{P}$
21. 0.01	22. 0.12	23. 0.12	24. 0.23
25. 0.1	26. 0.38	27. 0.38	28. 0.73
29. 1	30. 1.2	31. 1.2	32. 2.3
33. 10	34. 3.8	35. 3.8	36. 7.3
37. 100	38. 12	39. 12	40. 23
41. For transmitters rated at a maximum output power not listed above, the			

recommended separation distance d in meters 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.

42. NOTE 1 - An additional factor of $10/3$ is used in calculating the recommended separation distance for transmitters in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.
43. NOTE 2 - These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

44.

45. Guidance and manufacturer's declaration - electromagnetic immunity

46. The *Narcotrend-Compact M* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Narcotrend-Compact M* should assure that it is used in such an environment.

47. Immunity test	48. EC 60601 test level	49. Compliance level	50. Electromagnetic environment - guidance
51. Electrostatic discharge (ESD) 52. IEC 61000-4-2	53. ± 8 kV contact 54. ± 15 kV air	55. ± 8 kV contact 56. ± 15 kV air	57. Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
58. Electrical fast transient/burst 59. IEC 61000-4-4	60. ± 2 kV for power supply lines 61. ± 1 kV for input/output lines	62. ± 2 kV for power supply lines 63. ± 1 kV for input/output lines	64. Mains power quality should be that of a typical commercial or hospital environment.
65. Surge 66. IEC 61000-4-5	67. ± 1 kV differential mode 68. ± 2 kV common mode 69. mode	70. ± 1 kV differential mode 71. ± 2 kV common mode	72. Mains power quality should be that of a typical commercial or hospital environment.
73. Voltage dips, short interruptions and voltage variations on power	75. $0\% U_T^{1)}$ 76. for 0.5 cycle 77. (0, 45, 90, 135, 180, 225, 270,	86. $0\% U_T^{1)}$ 87. for 0.5 cycle 88. (0, 45, 90, 135, 180, 225, 270,	97. Mains power quality should be that of a typical commercial or hospital environment. 98. If the user of the


<p>supply input lines</p> <p>74. IEC 61000-4-11</p>	<p>315 degree)</p> <p>78.</p> <p>79. 0% U_T</p> <p>80. for 1 cycle</p> <p>81. (0 degree)</p> <p>82.</p> <p>83. 70% U_T</p> <p>84. for 25/30 cycles</p> <p>85. (0 degree)</p>	<p>315 degree)</p> <p>89.</p> <p>90. 0% U_T</p> <p>91. for 1 cycle</p> <p>92. (0 degree)</p> <p>93.</p> <p>94. 70% U_T</p> <p>95. for 25/30 cycles</p> <p>96. (0 degree)</p>	<p><i>Narcotrend-Compact M</i> requires continued operation during power mains interruptions, it is recommended that the <i>Narcotrend-Compact M</i> is powered from an uninterruptible power supply or a battery.</p>
<p>99. Power frequency (50/60 Hz) magnetic field</p> <p>100. IEC 61000-4-8</p>	<p>101. 3 A/m</p>	<p>102. N/A</p>	<p>103. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>104. NOTE 1 - U_T is the AC mains voltage prior to the application of the test level.</p>			

105.

106. Guidance and manufacturer's declaration - electromagnetic immunity

107. The *Narcotrend-Compact M* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Narcotrend-Compact M* should assure that it is used in such an environment.

108. Im munity test	109. IE C 60601 test level	110. Co mpliance level	111. Electromagneti c environment - guidance
112. 113. 114. 115. 116. 117. 118. 119. 120. 121. 122. 123. 124. Co nducted RF 125. IE C 61000- 4-6 126. 127. Ra diated RF 128. IE C 61000- 4-3	129. 130. 131. 132. 133. 134. 135. 136. 137. 138. 139. 140. 141. 3 Vrms 142. 15 0 kHz to 80 MHz 143. 144. 3 V/m 145. 80 MHz to 5.8 GHz	146. 147. 148. 149. 150. 151. 152. 153. 154. 155. 156. 157. 158. 3 Vrms 159. 160. 161. 3 V/m	162. Portable and mobile RF communications equipment should be used no closer to any part of the <i>Narcotrend- Compact M</i> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. 163. 164. Recommended separation distance 165. 166. $d = 1.2\sqrt{P}$ 167. $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz 168. $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 169. 170. Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters. 171. Field strengths from fixed RF transmitters, as determined by an electromagnetic site

			<p>survey, should be less than the compliance level in each frequency range.</p> <p>172. Interference could occur in the vicinity of equipment marked with the following symbol:</p>  <p>173.</p>
<p>174. NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>175. NOTE 2 - These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			
<p>176. 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 <i>Narcotrend-Compact M</i> is used exceeds the applicable RF compliance level above, the <i>Narcotrend-Compact M</i> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the <i>Narcotrend-Compact M</i>.</p> <p>177. Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 7 V/m.</p>			

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