User manual

NIPE Monitor V1
Software version: V2.4.0.0

$\mathsf{C}\mathsf{E}$ 1370

(CE mark first approved: May 2014)

Mdoloris Medical Systems is a commercial registered trademark.

Important information about using continuous monitoring system of comfort / discomfort for newborn infants:

The Mdoloris Medical Systems' monitoring system for continuous surveillance of comfort / discomfort in newborn infants is intended for use in a medical environment and under the direct supervision of a licensed healthcare practitioner or by personnel specifically trained for its use. The continuous monitoring system of comfort/ discomfort for newborn infants is intended for the use with patients younger than two years and it may be used in a hospital or in a health care facility in order to monitor the activity of the parasympathetic tone.

The continuous monitoring system of comfort / discomfort for newborn infants can be used to monitor the effects of certain analgesic agents which will provide relief.

NIPE is a complex monitoring technology intended to be used as an adjunct to clinical judgment and to clinical experience. The interpretation of the NIPE value must always be submitted to proper clinical judgment and it is mandatory to put it in context with other available clinical signs observed. It is advisable not to rely exclusively on the NIPE index for monitoring the patient's comfort. As with all monitored parameters, artifacts and poor signal quality may lead to adulterated NIPE values. Potential artifacts may be due to muscle activity or rigidity, patient motion, improper placement of the sensors or electrical interference.

The NIPE Monitor V1 allows real time data transfer port to an external device via an RS232. In no case shall transferred data be used for diagnostic purposes. Only the values displayed on the NIPE software interface can be utilized for a medical interpretation.

The NIPE Monitor V1 needs special precautions regarding environments. The NIPE Monitor V1 has to be installed and put into service in hospitals and away from the RF source magnetic resonance imaging.

NIPE is a protected trademark.

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1   Safety measures

INTRODUCTION

CAUTION: carefully read this entire manual before using the monitor in a clinical setting.

⚠️   **WARNING**

A warning of this level of risk advises against a potentially dangerous situation that could results in physical injury or death. Accidents may result from the inability to avoid dangerous situations. Thus it is important to follow the guidelines in this warning, to evade physical injuries.

⚠️   **CAUTION**

A caution of this level of risk refers to actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure, although personal injury is unlikely.

⚠️   **NOTE**

A note provides useful information with regard to a function or procedure.

DEFINITION OF SYMBOLS

Symbols used with the NIPE Monitor V1 are explained at the end of this section.

1.1   Warnings

⚠️

WHENEVER THE INSTRUMENT CASE HAS BEEN OPENED, THE MONITOR HAS TO BE CHECKED FOR LEAKAGE CURRENT BY A TECHNICIAN QUALIFIED IN BIOMEDICAL ENGINEERING.

⚠️

EXPLOSION HAZARD: DO NOT USE THE NIPE MONITOR V1 IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

⚠️

THIS MONITOR IS NOT DESIGNED FOR USE IN MRI ENVIRONMENT.

⚠️

CONSIDERATIONS WHEN USING ELECTRO-CONVULSIVE THERAPY (ECT) EQUIPMENT DURING THE NIPE MONITORING: place ECT electrodes as far away as possible from the sensors to minimize the effect of interference. Some ECT equipment may interfere with the proper functioning of the NIPE Monitor V1. Check for compatibility of equipment during patient setup.

⚠️

THIS MONITOR IS IN NO CASE TO BE USED AS AN ECG MONITORING SYSTEM.

⚠️

ONLY USE THE POWER CORD SUPPLIED BY THE MANUFACTURER. NEVER ADAPT THE PLUG FROM THE MONITOR TO FIT IT IN A NON-STANDARD OUTLET.

⚠️

IF YOU HAVE DOUBTS ABOUT THE INTEGRITY OF THE EXTERNAL PROTECTIVE GROUNDING, THE NIPE MONITOR V1 SHOULD NOT BE USED.

⚠️

BE SURE THE MONITOR IS INSTALLED SAFELY TO AVOID ANY INJURY OF STAFF OR PATIENT.

⚠️

WHENEVER EXTERNAL EQUIPMENT IS CONNECTED (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED READING A VALUE WHICH IS LESS THAN THE ONE GIVEN IN IEC 60601-1-1.

⚠️

USING ACCESSORIES AND CABLES OTHER THAN SPECIFIED OR PROVIDED BY THE MANUFACTURER OF THE NIPE Monitor V1 (MDOLORIS MEDICAL

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SYSTEMS) MAY RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED ELECTROMAGNETIC IMMUNITY OF THE NIPE Monitor V1 AND MAY RESULT IN AN INAPPROPRIATE OPERATION.

CONSIDERATION RELATING TO THE CHOICE OF EQUIPMENT SHALL INCLUDE:

- EVIDENCE THAT USING THE ACCESSORY IN THE PATIENT VICINITY AND OR SURGERY VICINITY IS COMPLIANT

- EVIDENCE THAT THE ACCESSORY'S "CE" SAFETY CERTIFICATION COMPLIES WITH STANDARD (IEC 60601-1) AND THAT THE ACCESSORY IS COMPATIBLE WITH THE NIPE Monitor V1

⚠

CONDUCTIVE PARTS OF ELECTRODES OR SENSORS AND CONNECTORS SHOULD NOT TOUCH OTHER CONDUCTIVE PARTS, INCLUDING THE GROUND LOOP.

⚠

TO MINIMIZE THE RISK OF STRANGULATION OF THE PATIENT, THE CABLE OF THE PATIENT INTERFACE MUST BE CAREFULLY PLACED AND SECURED.

⚠

WITH RESPECT TO RISKS OF ELECTRICAL SHOCK:

-   DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH MOIST HANDS.

-   DO NOT REMOVE MONITOR COVERS DURING OPERATION OR WHILE THE POWER CORD IS CONNECTED TO MONITOR.

-   THE MANUFACTURER OF THIS DEVICE HAS VERIFIED THAT THE LEAKAGE CURRENT OF THE GROUNDING CABLE AND THE PATIENT SAFETY CURRENT ARE LESS THAN THE LIMITS AS SPECIFIED IN THE APPLICABLE SAFETY STANDARDS. ON THE GROUNDS OF OCCUPATIONAL SAFETY, THE INSTITUTION SHOULD ALSO CONDUCT TESTS TO VERIFY THESE CURRENTS, ESPECIALLY WHEN A QUALIFIED BIOMEDICAL ENGINEERING TECHNICIAN

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> **PERIODICALLY OPENS THE INSTRUMENT CASE AT REGULAR INTERVALS.**
>
> - **WHENEVER THERE IS SPILLAGE OF BLOOD OR SOLUTIONS, THE LEAKAGE CURRENT OF THE GROUNDING CABLE HAS TO BE RE-TESTED BEFORE FURTHER USE.**

⚠

WHENEVER AN EMERGENCY REQUIRES INTERRUPTION OF THE ELECTRICAL POWER, IT IS IMPERATIVE TO DISCONNECT THE MALE END OF THE POWER CORD FROM THE WALL SOCKET. ACCESS TO THE POWER PLUG AND THE WALL SOCKET HAS TO BE FREE DURING NORMAL USE.

⚠

CURRENT PRECAUTIONS SHALL BE OBSERVED TO PREVENT ANY CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIAL. CONTAMINATED MATERIAL MUST BE HANDLED IN ACCORDANCE WITH ALL APPLICABLE HYGIENE STANDARDS AND REGULATIONS.

⚠

DO NOT MIX DISINFECTANT SOLUTIONS (e.g., BLEACH AND AMMONIA SOLUTION) AS HAZARDOUS GASES MAY FORM.

⚠

THE NIPE MONITOR V1 COMPLIES WITH ALL REQUIREMENTS WITH RESPECT TO ELECTROMAGNETIC COMPATIBILITY ACCORDING TO ICE 60601-1-2. THE OPERATION OF THIS DEVICE MAY AFFECT OR BE AFFECTED BY OTHER EQUIPMENT IN THE VICINITY DUE TO ELECTROMAGNETIC INTERFERENCE (EMI). IF THIS OCCURS

> **- INCREASE THE DISTANCE BETWEEN DEVICES**
>
> **- CHANGE THE ORIENTATION OF DEVICE CABLING**
>
> **- PLUG DEVICES INTO SEPARATE CIRCUIT OUTLETS**
>
> **- PLEASE CONTACT YOUR MDOLORIS MEDICAL SYSTEMS REPRESENTATIVE.**

⚠️

BE SURE THAT THE MONITOR IS PLACED OUT OF REACH OF OBJECTS WHERE A SPILL OF LIQUIDS MAY OCCUR (E.G.: UNDER AN I.V. BAG).

⚠️

ANY MODIFICATION OF THE MONITOR IS STRICTLY FORBIDDEN.

⚠️

USE OF NIPE Monitor V1 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.

⚠️

PORTABLE RF COMMUNICATIONS EQUIPMENT (INCLUDING PERIPHERALS SUCH AS ANTENNA CABLES AND EXTERNAL ANTENNAS) SHOULD BE USED NO CLOSER THAN 30 CM (12 INCHES) TO ANY PART OF THE NIPE Monitor V1, INCLUDING CABLES SPECIFIED BY THE MANUFACTURER. OTHERWISE, DEGRADATION OF THE PERFORMANCE OF THIS EQUIPMENT COULD RESULT.

1.2 Caution

Read this entire manual carefully before using the monitor in a clinical setting.

Before you boot the monitor, please, make sure there is no USB peripheral device connected to the monitor (such as an USB stick).

The equipment should not be placed within direct or indirect reach of the patient like placed on a metallic material within the reach of the patient.

The doctor should not touch the patient and the equipment at the same time.

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Before any use, check for compatible ECG source isolation corresponds to the applicable standards to increase the patients' safety.

The signal provided by the ECG source must be a safety output with very low tension.

Never put the monitor into a sterilizer as this would seriously damage the NIPE Monitor V1.

Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the monitor.

The NIPE Monitor V1 should not be used adjacent to or stacked onto other equipment. If adjacent or stacked use is necessary, check the monitor regularly for proper functioning in this configuration.

Only staff of Mdoloris Medical Systems is allowed to perform maintenance or repair works. The only components which can be replaced or substituted by untrained staff following the instructions of the producer are the following:
- « Monitor Link » cable and the corresponding connectors ;
- The power cord ;
- The power supply unit.

Recycling of this medical equipment, its components and packaging must be done in accordance with the respective national laws on electronic waste and environment.
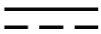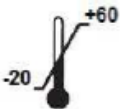
Make sure the multi-parameter monitor to be connected with the NIPE Monitor V1 is compliant to the requirements for electromagnetic compatibility of class IIa and double patient insulation according to IEC 60601-1.

Ask your Mdoloris Medical Systems representative for the list of multi-parameter monitors which are compatible with the NIPE Monitor V1. Each of these monitoring systems needs a specific connection adaptor. Please, ensure you have transmitted these specifications to your Mdoloris Medical Systems representative.

1.3 Notes

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"**NOTES**" can be found at the end of each related chapter.

1.4   Key to symbols

Symbol	Description	Symbol	Description
	Operator's manual; operating instructions	**SN**	Serial number
	Keep dry	CE	European compliance Mark of compliance with the European Medical Device Directive
	Do not expose to sunlight	⚠	General safety sign
	Check the packaging quality upon delivery		Needs special waste disposal
YYYY-MM	Manufacturer + Manufacturing Date		Direct current, DC
+60 -20	Upper and lower temperature limits (Shipping and Storage		"ON" / "OFF"

	Environment)		
▼	Fragile; handle with care	RxOnly	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)
⬆⬆	This way up		

2 Presentation of the NIPE Monitor V1

NIPE (Newborn Infant Parasympathetic Evaluation) is a standardized and continuous measurement of the new-born infant's parasympathetic tone (pΣ) which is a part of the autonomous nervous system (ANS). It uses the intermittent and quick modulation of the pΣ tone induced by each respiratory cycle (spontaneous or artificial) to measure the "relative quantity" of the pΣ tone.

These rapid changes in pΣ tone are reflected at the level of the sinus node of the heart by means of variations of time intervals between two R waves in the ECG. This sequence of standardized RR-intervals (as a result of sinus cardiac cycles cleaned up from extra systoles) is also called RR-series. After the RR-series have been filtered, evaluated, consolidated and resampled, the pΣ is subject to evaluation by measuring the area generated by the respiratory patterns. The more prominent the pΣ tone, the bigger is the measurement area. On the other hand, the measuring area diminishes in line with the reduction of the pΣ tone.

NIPE measurement cannot be used for interpretation in the following situations:

- non-sinus cardiac rhythm;
- heart transplantation;
- drugs affecting the sinus node (Atropine…);
- post-conceptual age lower than 26 weeks.

The NIPE index is expressed on a scale between 0 and 100. It reflects the activities of the parasympathetic nervous system. It provides a reading of the relative quantity of the pΣ tone compared to the Σ tone in the autonomous nervous system. The NIPE displayed represents a succession of computed measures: each elementary measure is carried out for 64 seconds, with 1 measurement per second.

The NIPE Monitor V1 is designed to be used by pediatricians and pediatric nurses. For a safe use of the NIPE Monitor V1, the users must be aware of all aspects which might disturb or influence the NIPE index calculations related to the autonomous nervous system. The NIPE assists in decision making, hence, users must take into account all other current clinical parameters before taking a decision or diagnosing.

The diagnosis made with the assistance of the NIPE index falls into the sole responsibility of the doctor.

3   Physiological principle of the NIPE measurement

An analysis of Heart Rate Variability (HRV) enables to evaluate the variations in the autonomous nervous system where its parasympathetic and sympathetic components control the cardiac rhythm and its short-term variations. There are various HRV measurement methods validated and in place for many years so far and all these methods serve to evaluate whether the ANS functions is normally or pathologically.

Selected studies have proved that the cardiovascular system's regulatory processes are closely related to the perception of pain [1, 2]. An analysis of the heart rate variability (HRV) is a well-known and non-invasive method for the measurement of the cardiovascular system's regulation by the autonomous nervous system (ANS) [1, 3]. This analysis is based on the principle that all fluctuations of the cardiac rhythm are reflected in the parasympathetic and sympathetic systems, the main components of the ANS. Studies documented that fluctuations of the heart rate above a frequency of 0.15 Hz are due to the influence of the parasympathetic system [4, 5]. Phenomena of pain, fear and anxiety in adults have proven to be accompanied by a decrease of the HRV in higher frequencies (>0.15 Hz), a fact that indicates to a decrease of the parasympathetic tone during nociceptive stimuli and unpleasant emotions [6, 7, 8]. During a surgical intervention the HRV is clearly correlated with the balance between nociception and the level of anesthesia [9]. During painful surgical interventions in children a significant decrease of the spectral power in high frequencies could be observed. This implies

a decrease of the influence of the parasympathetic nervous system during the nociceptive stimulus [1, 10].

1. Oberlander TF, Grunau RE, Pitfield S, et al. *The developmental character of cardiac autonomic responses to an acute noxious event in 4- and 8-month-old healthy infants.* Pediatr Res 1999; 45: 519-25.

2. Benarroch EE. *Pain-autonomic interactions.* Neurol Sci 2006; 27 (Suppl 2): S130-3.

3. Schäffer L, Burkhardt T, Müller-Vizentini D, et al. *Cardiac autonomic balance in small-for-gestational-age neonates.* Am J Physiol Heart Circ Physiol 2008; 294: H884-90.

4. Saul JP, Berger RD, Albrecht P, et al. *Transfer function analysis of the circulation: unique insights into cardiovascular regulation.* Am J Physiol 1991; 261: H1231-45.

5. Parati G, Mancia G, Di Rienzo M, et al. *Point: cardiovascular variability is/is not an index of autonomic control of circulation.* J Appl Physiol 2006; 101: 676-8; discussion 681-2.

6. Miu AC, Heilman RM, Miclea M. *Reduced heart rate variability and vagal tone in anxiety: trait versus state, and the effects of autogenic training.* Auton Neurosci 2009 28; 145: 99-103.

7. Demaree HA, Robinson JL, Everhart DE, et al. *Resting RSA is associated with natural and self-regulated responses to negative emotional stimuli.* Brain Cogn 2004; 56: 14-23.

8. Appelhans BM, Luecken LJ. *Heart rate variability and pain: associations of two interrelated homeostatic processes.* Psychol. 2008; 77: 174-82.

9. Jeanne M, Logier R, De Jonckheere J, et al. *Heart rate variability during total intravenous anaesthesia: effects of nociception and analgesia.* Auton Neurosci 2009; 147: 91-6.

10. Oberlander TF, Grunau RE, Whitfield MF, et al. *Biobehavioral pain responses in former extremely low birth weight infants at four months' corrected age.* Pediatrics. 2000; 105: e6.

4 Installation of the NIPE Monitor V1

4.1 Clamp mounting on an infusion stand

Position the monitor in a way to allow easy plug in of the power plug. The monitor may be mounted on an infusion stand with clamps. The clamp system may be used on supports with diameter ranging from 19 to 38 mm. **Please, ensure that the supports are compatible with the system.**

4.2 Mounting on an ECG monitor

Connect the plug for monitor connection with the analogue port of the ECG monitor, then connect the other end of the cable to the NIPE Monitor V1 (see figure 1).

To identify the analog ECG output on your multi-parameter monitor, please consult the operating manual of the latter.

PLUG NIPE MONITOR

PLUG MULTIPARAMETER MONITOR
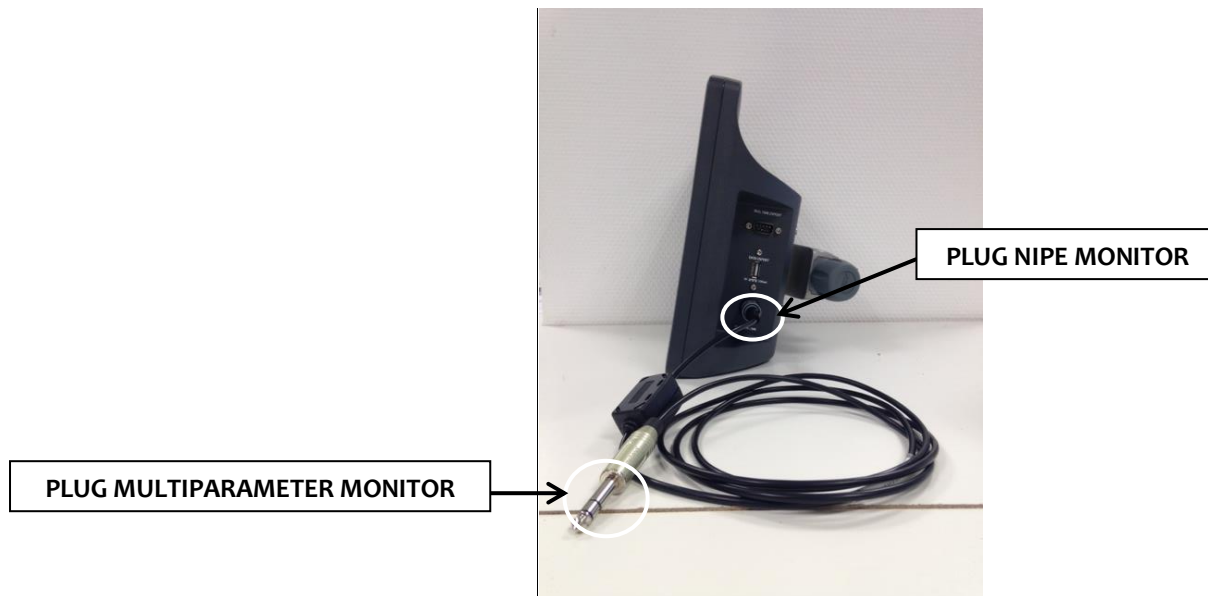
Figure 1: connection cable

Figure 2: Example for connecting to the Philips MP50 monitor

In case of problems contact your Mdoloris Medical Systems representative.

4.3 Power connector

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As usual, the power connector is plugged into the socket. To prevent any accidental disconnection, you can lock the coupling by screwing the nut on the base (from left to right, see picture above).

5.   **Start NIPE Monitoring**

Once the monitor is plugged in and connected to the multi-parameter monitor, boot the monitor with the switch located on the left side of the NIPE Monitor V1 (see figure 3).
The green light situated above the display indicates that the monitor is booting.

Figure 3

During start-up the monitor will show a sequence of animations from Mdoloris Medical Systems. After that, the main menu screen will be displayed (figure 4).

Figure 4 – Main menu

From the main menu, you have access to the following functions:

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5.1 Set up the language
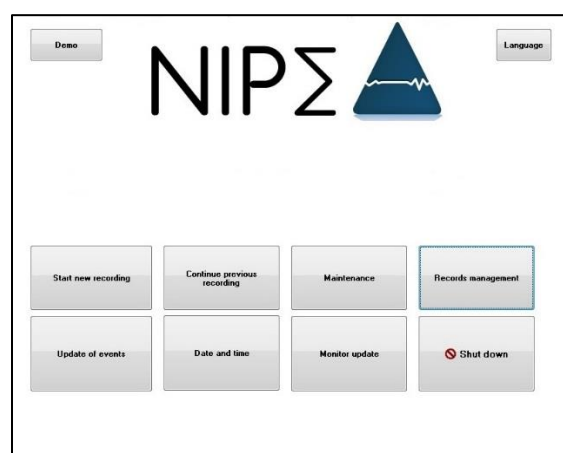
In this menu the user can select the system language. Select the button **[Language]** situated in the top right corner of the main menu (figure 4). The different languages are displayed in a drop down list (figure 5). Choose the language of your choice and press **[X]** to quit and set up the new language.
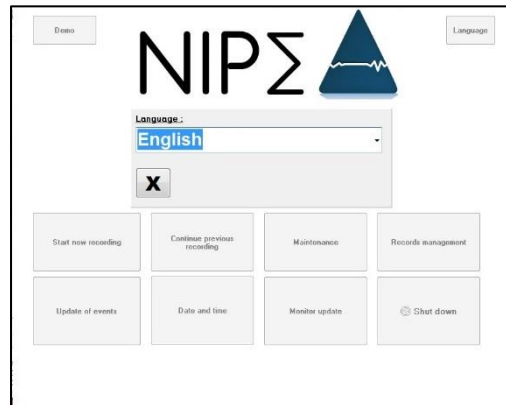
Figure 5 – Set up the language

5.2 Demo mode

By selecting **[Demo]** on the top left corner of the main menu a video of the NIPE functions is shown.

5.3 Start a new recording

The selection of **[Start new recording]** launches a new recording. Then the monitor initiates the monitoring by starting an initialization (figure 6). This step takes at least 80 seconds. No data can be interpreted before this initialization.
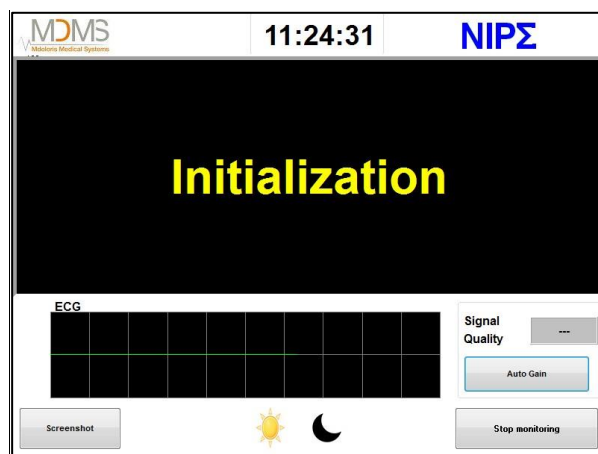
Figure 6 - Initialization

When the initialization is done, the calculation of the index starts automatically and the monitoring screen appears (figure 7).
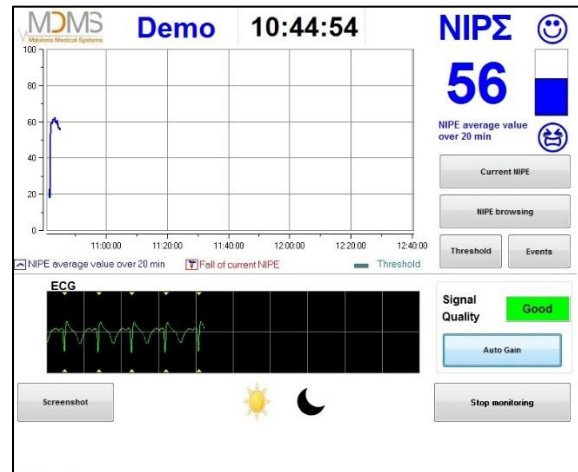
Figure 7 - Monitoring screen

5.4 Continue the previous recording

The selection of [**Continue previous recording**] enables to resume the former recording.

All other functions available in the main menu (figure 4) are presented in the following chapters:

- Maintenance : cf. chapter 8.2
- Records management : cf. chapter 8.3
- Update of events : cf. chapter 8.4
- Date and time settings : cf. chapter 8.5
- Update the monitor : cf. chapter 8.6
- Shut down : cf. chapter 8.7

Note: The NIPE Monitoring can be used with both, a conscious patient and an unconscious one.

6 The NIPE display

6.1 ECG capture

The lower sub-window displays the ECG data acquired by the monitor (figure 8).The ECG is cleaned up from all environmental artefacts.

Figure 8 - ECG

WARNING:

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Always check the good quality of the ECG signal on the main screen

1) at the same time with the signal structure and the scrolling in the ECG screen.

2) in the right bottom corner of the screen :

- Good signal quality

Signal Quality	Good

- Medium signal quality

Signal Quality	Medium

- Poor signal quality

Signal Quality	Poor

Case n°1 - No signal is displayed

- Check the cable connection between the monitor and the multi-parameter monitor.
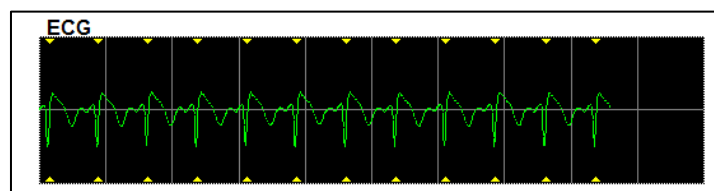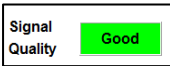- Try at least once to disconnect and reconnect the plug between the monitors to recover a correct ECG signal.

Case n°2 – Medium signal quality

When the signal quality is medium (yellow indication is lit), the user is warned that the signal quality may become worse soon.

Case n°3 – Poor signal quality

If the indication shows poor signal quality (red indication is lit) the data displayed cannot be takin into account. In that case, the NIPE index is not displayed anymore, the curve freezes and a message "poor signal quality" appears in the middle of the screen to warn the user.

- Select the button **"Auto-gain"** in the bottom right corner of the screen to automatically recover the ECG signal.

- If the signal quality is still medium or poor, choose another ECG lead on the multi parameters monitor. Finally, check the proper position of the electrodes and their adhesion to the skin. If necessary, reposition or change them.

6.2 The NIPE index

A continuous indicator is displayed reflecting the patient's parasympathetic tone (each elementary measure lasts for 64 seconds with 1 measurement per second). Each second a calculation is carried out to determine the average value between a "short" period and a "long" period. The monitor displays a blue NIPE index of the average value from the long

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period and, in red, when the NIPE index suddenly drops (significant as a reaction of painful or stressful stimulus) - see figure 9.
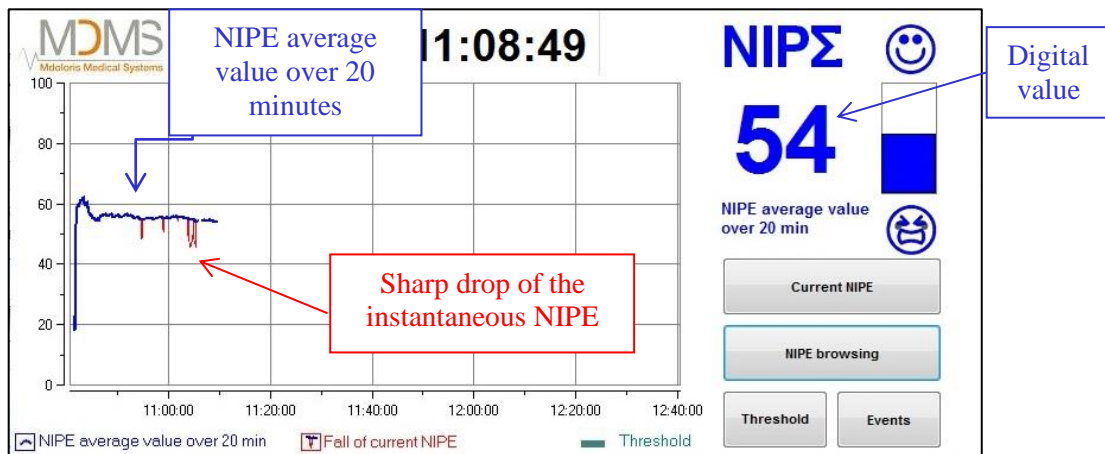
Figure 9

6.3 Optional display of the current NIPE

The selection of the button **[Current NIPE]** will allow you to follow the current NIPE index on the screen. A window will open to display the current NIPE's curve (figure 10).
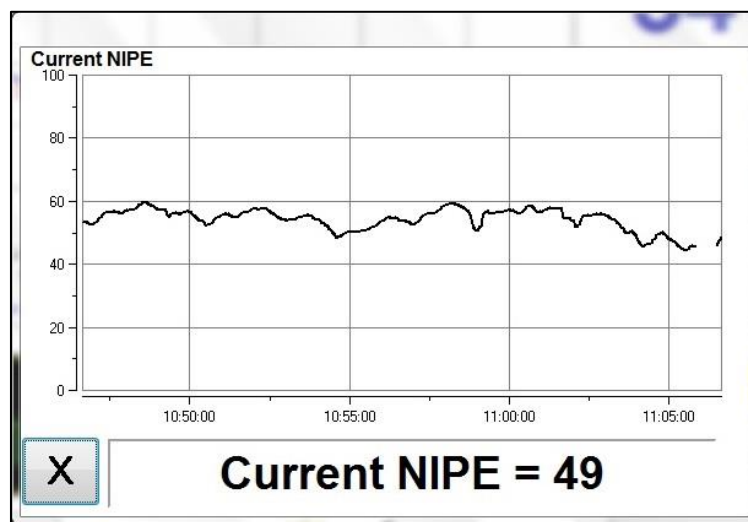
Figure 10 – Current NIPE

By selecting the button **[X]** in the bottom left corner, the window for the current NIPE will close. Signal sampling remains active despite the navigation through the current NIPE window.

6.4 NIPE browsing

The selection of the button [**NIPE browsing**] during monitoring will display a navigation window (figure 11) which serves to move forwards and backwards the NIPE index on the timeline to view the different events which might have occurred.
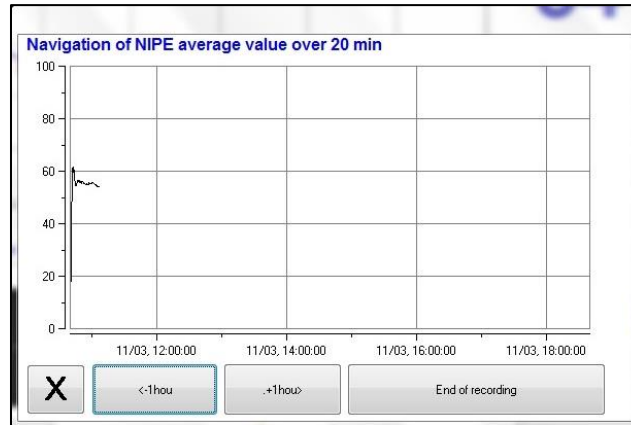
Figure 11 – NIPE browsing

By selecting the button **[X]** the window for NIPE browsing will close. The signal sampling remains active despite navigation through the NIPE browsing window.

6.5 Day / night mode

It is possible to adjust screen brightness with the Day/Night mode on the main screen.

To set the monitor on "Day" mode, touch the icon .

To set the monitor on "Night" mode, touch the icon (figure 12).
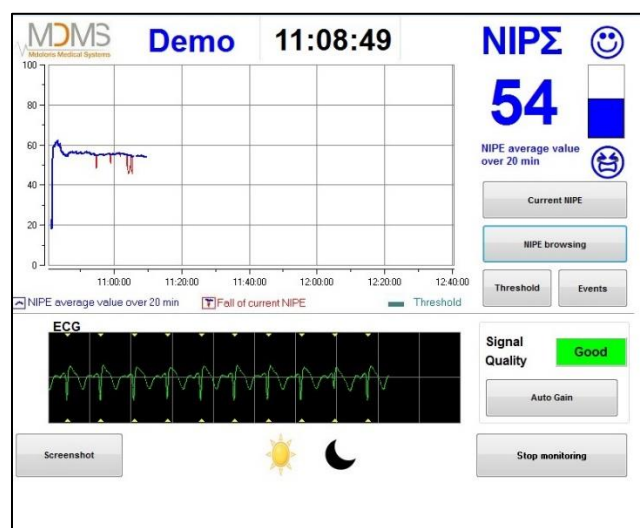
Figure 12 – Day / Night mode

6.6   Standby screen

After 10 minutes of inactivity, the screen automatically switches to standby (figure 13), except if one of the following windows is opened: instantaneous NIPE, NIPE navigation, threshold, events. To return to the main screen, just touch the screen.
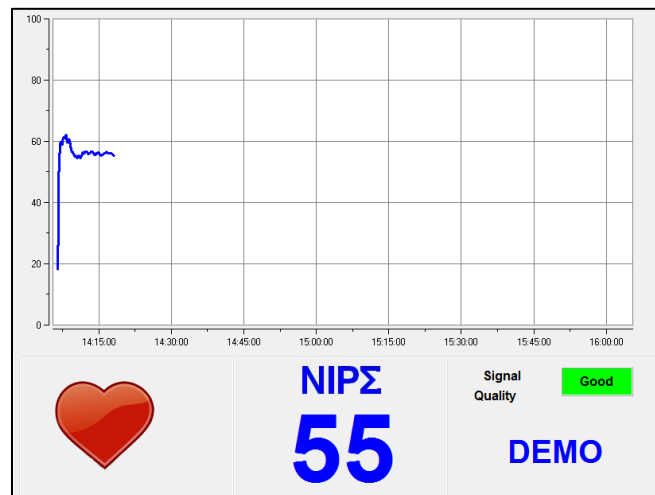
Figure 13 – Standby screen

WARNING: Always check the good quality of the ECG signal by

1) ensuring that the symbol always blinks.
2) looking at the bottom right corner of the screen :

-    Good quality signal

-    Medium quality signal
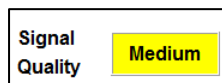
-    Poor quality signal

7 NIPE Monitor V1 settings

7.1   Threshold setting

It is possible to add a threshold by pressing the button **[Threshold].** A new window will open (figure 14). Touch the small square next to **[Activate threshold]** in order to add the check

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mark and a blank rectangle will appear. Then touch the blank rectangle to activate it (figure 15).

Figure 14 – Activate threshold

Figure 15 – Add value for threshold

A keypad will appear (figure 16) to enter the desired value for the threshold and select **[Apply]** to confirm your choice and then **[X]** to return to the monitoring display.
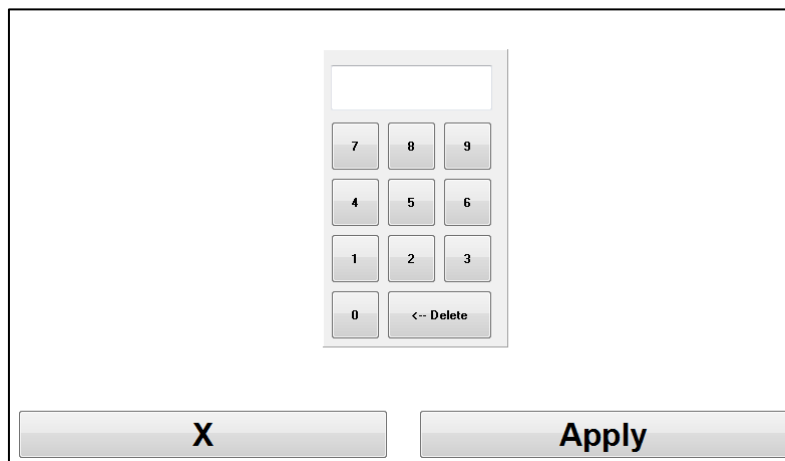
Figure 16 – Add the value

The threshold line will be displayed on the monitoring display as shown in figure 17 (see below).

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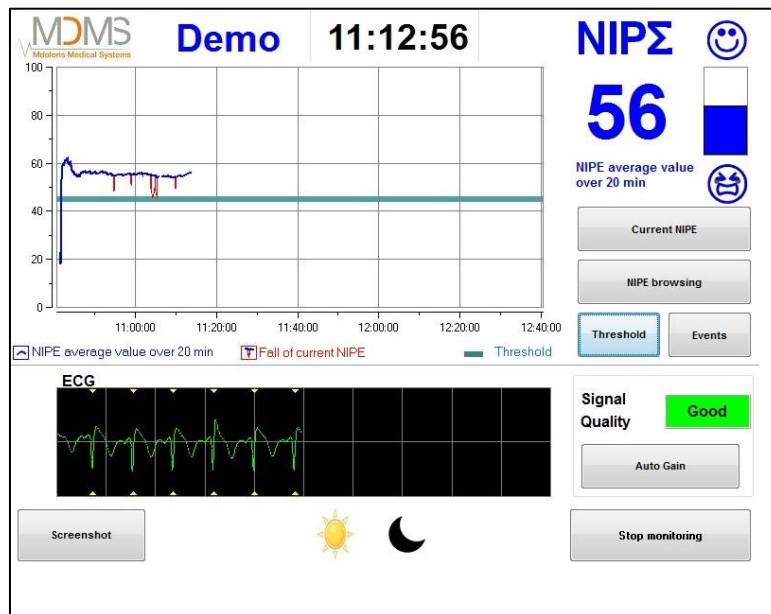
Figure 17 – Threshold value at the monitoring display

7.2 Insertion and deletion of events

The selection of the button **[Events]** on the monitoring display will open a new window (figure 18).

Figure 18 – Display of events

The events saved by default in the monitor are:

- CARE
- EDIN > 5
- EDIN < 5
- SLEEP
- AWAKE

By selecting one of these options, the chosen event will be inserted in the NIPE Monitoring display, and also in the *NIPE browsing* display and on the *current NIPE* display.

The insertion of one of these events will automatically be retrieved in the corresponding "Index" file, which can be read out with an USB key (see chapter 8.3). There is always a possibility to edit the personal events list (refer to chapter 8.4 for further information).

If you wish to delete an inserted event, select this event in the white square and select the button [**Delete**]. Then click on **[X]** to return to the monitoring display.

7.3   Screenshot

By selecting the button [**Screenshot**], all items of information displayed on the screen are saved in the monitor's memory in a picture format. Each time the user decides to obtain a screenshot, the picture will be saved in the monitor's memory.

A message will appear to confirm successful storage of the screenshot (figure 19). Select [**Okay**] to remove this confirmation from the display.

Screenshot OK

OK
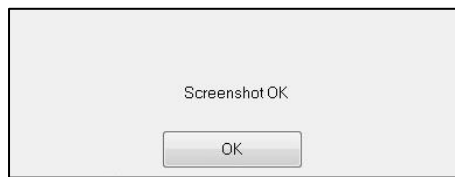
Figure 19 - Confirming the screenshot

To recall these pictures, monitoring has to be stopped. This is done by selecting **[End monitoring]** in the bottom right corner of the display. Then plug a USB stick in the USB port named "Data export" on the side of the monitor.

A new window will appear where you have to choose [**Records management**] and then [**Export to USB stick].** The pictures will be saved in a folder created automatically on the USB stick. Naming of the folder is done following this rule: Hour-Minute-Month-Day-Year.

8   Ending the NIPE Monitoring

8.1   Quit the current recording

The selection of the button **[End monitoring]** situated in the bottom right corner of the display during monitoring enables to end the session and to get access to the main menu.

A request for confirmation is proposed before quitting the monitoring (figure 20):

Do you really want to quit this record?

Yes   No
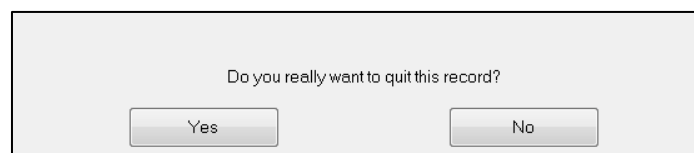
Figure 20 - Confirmation

Note: By choosing **[Yes]**, *it is not any longer possible to recall data from the patient to be monitored.*

If you choose **[Yes]**, the main menu will be displayed (see figure 4, page 16).

8.2   Maintenance

The selection of the button [**Maintenance]** in the main menu will open a window with an input field (see figure 21). This access is protected by a code that will be forwarded by Mdoloris Medical Systems upon request.
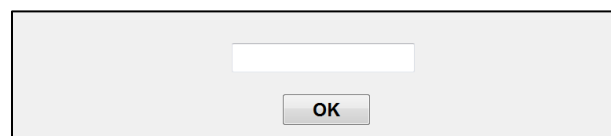
Figure 21 - Maintenance

8.3   Records management

8.3.1 Export data recordings

The selection of the button [**export to USB stick**] will send all data saved in the monitor's memory to a USB stick. To export the data, you need to connect a USB stick in the USB port called "*Data Export*" situated on the right side of the monitor. If the monitor doesn't detect the USB stick (USB stick not plugged in or a bad connection), a message will appear to inform the user (figure 22). When the USB stick is connected in the correct way, select [**Okay]** to start the data export.

Figure 22 – Connect USB stick

When the entire export has been done properly, a message appears to confirm the successful export (figure 23). Press [**Okay]** to return to the main menu.

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Copy successfully done

OK
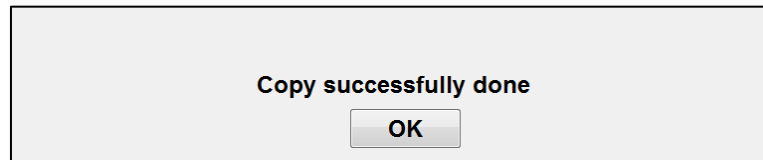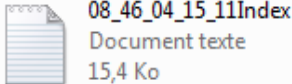
Figure 23 – Export finished

Note:

Data are automatically saved together with the storage time; for easy reprocessing (such as in MS Excel for example) data are converted into a "text format". The files will be exported in a folder which is created on the USB key (like for the screenshots, chapter 7.3). The title of each file indicates the date and hour when the monitoring started. Each file will be named following this rule: Hour – Minute – Month – Day - Year.

Example:

08_46_04_15_11Index
Document texte
15,4 Ko

The NIPE Monitor V1 allows transfer of data in real time via an RS232 port to an external device.

CAUTION: In order to respect insulation of electrical components and to protect the users, Mdoloris recommends the use of an insulator between the „ RS232 output " of the NIPE Monitor V1 and the device to which the monitor is connected.

This insulator, which can also be denominated as „ section insulator " or „ Insulator RS232 " has to be in accordance with IEC 60601-1-1 and 60601-1-2.

This product is offered by Demetec GMBH under the name „ Medical RS232 Isolation, type Rsl V1.2 " and it corresponds to the requirements in the standards.

8.3.2 Deletion of data recorded

By selecting [**Delete records**] all data previously saved in the memory will be deleted. A request for will be shown (figure 24).

Do you really want to suppress all the records?

Yes   No
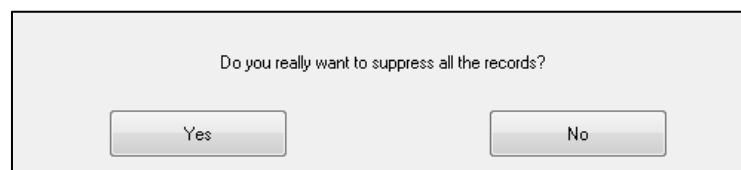
Figure 24 – Confirm deletion of records

When all data are deleted, another window will open to confirm that the action is finalized (figure 25). Press [**Okay**] to return to the main menu.

Records successfully deleted

OK

Figure 25

8.3.3 Setting of recording frequency

The selection of the button **[Recording frequency]** will allow adjusting the frequency. Choose the frequency you want and select **[Confirm]** (figure 26).

Recording frequency

1 second(s)   10 second(s)   1 minute(s)   5 minute(s)

Validate
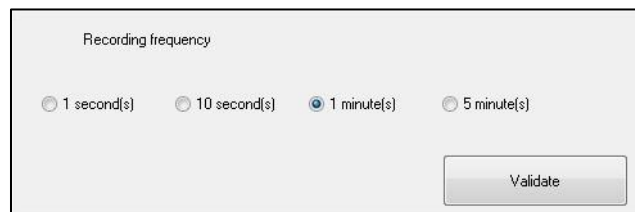
Figure 26 – Recording frequency

8.4   Update of events

As explained previously (see chapter 7.2), events corresponding to different clinical moments are predefined in the system. The events inserted during a monitoring procedure can be envisioned on different screens: on the *NIPE Monitoring* screen (chapter 6.2), the *current NIPE* screen (chapter 6.3) and the *NIPE browsing* screen (chapter 6.4).

The user can customize the list of events:

To access and update the events list, select [**Update of events**]. The events update menu will appear (figure 27):

Figure 27 – Update of events

To add a new event in the list, you have to use the virtual keyboard on the touch screen and then click on [✓ **Confirm**]. Word size is limited to 18 characters.

The new event will be added at the end of the drop-down list displayed on the right. If the list contains more than 6 events, you have to use the scrollbar on the right to see all the events of the list.

To delete an event, you have to select it in the list by touching the word on the screen and then select the button [✗**Delete**].

To confirm any change done (such as adding or deleting one or more events), first you have to select [**Apply**] and then [**X**] to close the menu for update of events.

8.5   Date and time settings

To set the date or the clock, you have to select [**End of monitoring**] to enter the main menu (figure 28). Then, select [**Date and Time**].

The following window will appear:

Figure 28 – Date and time setting

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Use the arrows keys next to the numbers to carry out the desired modifications. To confirm the changes done, you have to choose [**Apply]** and then [**X]**.

8.6   Update the monitor

In the main menu, select [**Monitor update]**. Plug in the USB stick containing the new version of "NIPE.exe" provided by your Mdoloris Medical Systems representative. Then select [**Update the monitor**] (figure 29).

Update the monitor   Back to monitor
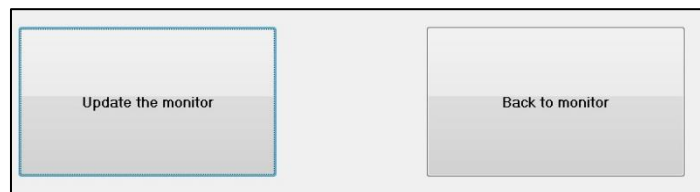
Figure 29

A message will appear to confirm successful updating (figure 30). Press [**Back to monitor]** to return to the main menu. This step could take few seconds due to the updating process.

Update successfully done
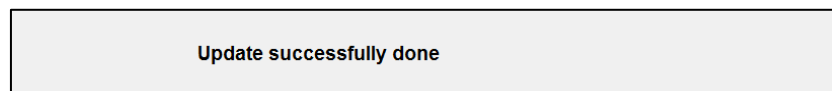
Figure 30

If the USB stick is not plugged in or it has not been detected yet, a message will appear to inform the user (figure 31).

Insert a USB stick

Figure 31

If the system cannot find "NIPE.exe" on the USB stick, the following message appears (figure 32):

Copy "NIPE.exe" on the USB stick and try again

Figure 32

26

8.7 Shut down

The selection of the button [⊘ **Shut down]** will end the session and the monitor will shut down.

NOTE: If you cannot enter the main menu, it is possible to shut down the monitor directly by means of the switch located on the left side of the monitor (the same switch is also used for booting). However, this is not recommended because it could affect the monitor's proper functioning.

⚠ **DO NOT UNPLUG THE MAINS CABLE WHILE THE MONITOR IS BEING USED AS THIS COULD AFFECT THE MONITOR'S PROPER FUNCTIONING.**

9 Troubleshooting

Problem encountered	Tasks to perform	If failure remains
No ECG displayed on the monitor.	Check that the monitor is properly connected to the multi-parameter monitor.	Contact your Mdoloris Medical Systems interlocutor.
An ECG signal is detected but it seems to be incoherent (flat, irregular, interfered…).	Check whether all cables are correctly connected and whether the ECG electrodes properly positioned.	Contact your Mdoloris Medical Systems interlocutor.
ECG waves seem to be physiologically incorrect.	Check the color code of the electrodes from the corresponding monitor.	Contact your Mdoloris Medical Systems interlocutor.
The connection adaptors provided with the NIPE Monitor V1 do not match with the analogue connectors of the multi-parameter monitor.	Contact your Mdoloris Medical Systems interlocutor.	

The keys on the touch screen do not work.	Reboot the monitor (use the switch if you cannot enter the main menu [see chapter 8.7]).	Contact your Mdoloris Medical Systems interlocutor.
The Mdoloris Medical Systems software does not start when the monitor is booted. Blue screen	Connect a keyboard to the monitor. Reboot the monitor. If the MDMS picture is not displayed, press immediately F3. Follow the instructions displayed on the screen. Notes: - During restoration prior recordings are preserved. - Restoration is carried out with the software version originally supplied with the monitor.	Contact your Mdoloris Medical Systems interlocutor.
After restoration, the system switches to the more current version of the software.	Get in touch with your contact person at Mdoloris Medical Systems.	

10   Monitor disposal

Recycling of electronic equipment helps to preserve natural resources and to avoid environmental pollution. For this very reason Mdoloris Medical Systems takes on its responsibility by organizing recycling free of charge for the NIPE Monitor V1 at the end of its lifetime (for detailed information go to www.recylum.com).

WARNING: *To avoid any kind of contamination from or infection of persons, environment or equipment, be sure you have properly disinfected and decontaminated the NIPE Monitor V1 before disposal of your system. Local laws and provisions with regard to disposal of electric and electronic items are to be observed.*

You can dismantle the monitor and the acquisition card:
-   No metal element is molded in the monitor's housing

- The inner surfaces of the housing are covered with a protection layer against electromagnetic interference
- The screen has a touch proof stratified layer
- You can recycle the hardcopy of the operating manual
- All electronic items are compliant to the RoHS Directive

If you have to dispose of old electrical equipment, make sure it is recycled safely. The "crossed out waste bin" symbol found on many electrical items means that they shall not be thrown away together with usual household rubbish.

11 Ambient conditions

11.1 Ambient conditions for shipping and storage

The NIPE Monitor V1 and its accessories can be stored or shipped under the following ambient conditions. Note that these limits only apply to non-operational storage and shipping situations:

Temperature: -20 °C to +60°C

Humidity: 15 to 95% (non-condensing)

Pressure: 480 hPa to 1066 hPa

Protect the monitor from sudden temperature changes as they can lead to condensation within the equipment. To minimize the risk of condensation, avoid moving the system between heated buildings and outside storage. Once moved inside a building, let the monitor rest in the unopened shipping container to reach room temperature before unpacking the device and putting it into operation. Before starting-up the system, wipe away all visible condensate and allow the system to reach equilibrium at room temperature.

11.2 Operating environment

The NIPE Monitor V1 is not designed for use in areas containing flammable gases or vapors.

WARNING: *Explosion hazard: never use the NIPE Monitor V1 in a flammable atmosphere or where concentrations of flammable anesthetics may occur.*

The monitor is designed to operate safely within a temperature range from 5°C to 35°C and up to an altitude of 2000 meters. The conditions that exceed these limits may have an impact on its reliability.

The monitor is designed to operate in a humidity range from 15% to 95% (non-condensing).

The monitor works correctly in conditions of sea level and below, and is not affected by extremes or by altitude modifications up to a maximum of 2000 meters and a pressure from 480hPa to 1066hPa.

11.3 Power supply and system grounding

The NIPE Monitor V1 requires a power source of 100 to 240 VAC, 50-60Hz.

To protect operating personnel and patients, the monitor must be properly grounded. For this purpose, the monitor is equipped with a power supply cord approved for hospitals. The power cord connects the system to the grounding whenever plugged into an appropriate three-wire socket.

CAUTION: *FOR PROPER GROUNDING, THE POWER SOCKET MUST BE A THREE-WIRE GROUNDED OUTLET APPROVED FOR THE USE IN HOSPITALS. NEVER ADAPT THE THREE-WIRED PLUG FROM THE MONITOR TO FIT INTO A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.*

12 Cleaning and disinfection

12.1 Cleaning

CAUTION:

GENERAL SAFETY REGULATIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. DISPOSAL OF CONTAMINATED MATERIALS HAS TO BE CARRIED OUT IN ACCORDANCE WITH STANDARDS AND REGULATIONS IN PLACE.

Cleaning the monitor:

Clean any spillage of blood or solutions on the monitor. Dried blood is very difficult to remove. Use lint-free absorbent towels to clean spillage. Moisten the towel with detergent and lukewarm water. After cleaning, wipe the connector ends with alcohol and allow them to dry completely. Residual moisture inside the connector may affect the monitoring performance.

Cleaning the display:

Clean the monitor display with a mild detergent and warm water or a common display screen cleaner, available through computer dealers. To avoid scratching the screen, never use abrasive cleaning agents.

Disinfecting the monitor:

Use lint-free absorbent towels dampened with isopropyl alcohol, with a 10% bleach solution, or a common disinfectant.

After cleaning, dry all areas except the monitor display with a lint-free absorbent paper towel. Wipe the connector ends with alcohol and allow them to dry completely.

WARNING: *WHENEVER THERE IS SPILLAGE OF BLOOD OR SOLUTIONS, CHECK THE LEAKAGE CURRENT AGAIN BEFORE FURTHER USE.*

DO NOT MIX VARIOUS DISINFECTING SOLUTIONS AS HAZARDOUS GASES MAY RESULT.

Caution: Do not put the monitor into an autoclave. Sterilizing in an autoclave may seriously damage the device.

Avoid liquid to enter into connection cables. Contact of fluids with the connections cables can have influence on the performance of the device.

12.2 Leakage current

The NIPE Monitor V1 is designed so that no periodic maintenance is required. However, leakage current should be systematically checked, after spillage of blood or solutions, or after a major surge in the house electrical system or at least once a year.

Preventive maintenance is recommended once a year: cable check, integrity of labels, system check and leakage courant check according to the 62353 standard (for more details, refer to

the technical manual available from Mdoloris). However leakage current must be checked systematically after every blood or liquid spill, or immediately after a major surge in the electrical system.

Only Mdoloris Medical Systems qualified technicians and engineers or trained staff are authorized to perform repairs and/or maintenance operations.

Only staff trained by Mdoloris Medical Systems can safely perform maintenance operations (such as software updating or system recovery). However, the following elements may be replaced or substituted by personnel untrained in technical maintenance (following the manufacturer's instructions):

-       End User Cable;

-       Power cord;

-       Power unit.

13   Technical details, warranty and software license agreement

13.1 Technical details

Power requirements: 100-240 Volts

Power consumption: 40 W

Current: < 3,4 A

Frequency: 50 Hz

Electrical Safety: class 1 according to IEC 60601-1

Weight of the monitor including clamp fixture (without accessories) = 2.02kg

Dimensions of the monitor including clamp fixture (cm): 27 (width) x 24.7 (height) x 14.5 (depth)

Screen size: 8.4'', resolution 800 x 600

The efficacy and security of the products are warranted during the lifetime of the products (5 years from the manufacturing date).

Material :
-   Panel PC: manufacturer IEI (product reference : AFL-08A-N270)
-   Mains adaptor AC/DC SL POWER - ME40A1203F01

- Acquisition card: Mdoloris Medical Systems reference: BA-NIPE-V1

Protection class for electric shock:

Class 1: equipment in which protection against electric shock does not rely on basic insulation only, but also includes additional safety measures. It is possible to connect the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.

Protection against the ingress of liquids:

Be sure to install the monitor outside any area where blood or liquids might penetrate.

System functioning:

Continuous operation: operation under normal load for a common period of time without exceeding the specified limits of temperature.

Electrosurgery Interference/Defibrillation/Electromagnetic disturbance:

The NIPE Monitor V1 is comply with standard IEC 60601-1-2: 2014 (Ed.4)

The NIPE Monitor V1 is compatible with the use of the HR surgery device.

The equipment returns to the previous operating mode within 10 seconds without loss of any stored data. Measurement accuracy may be temporarily decreased while performing electro-surgery or defibrillation. This does not affect patient or equipment safety.

In attendance of electromagnetic disturbances the performances listed below can be lost or degraded:

• ECG signal can be noisy

This does not affect patient or equipment safety.

Classification:
- CISPR 11: Class B
- IIa Electro-Medical Equipment

13.2 Warranty

Mdoloris Medical Systems warrants to the initial purchaser that the NIPE Monitor V1 ("Warranted Product") will be free from defects in workmanship or materials, when given normal, proper, and intended usage for a period of one year ("Warranty Period") from the date

of its initial shipment to the purchaser. Excluded from this warranty are items such as cables and accessories. Mdoloris Medical Systems' obligations under this warranty are to repair or replace any Warranted Product (or part thereof) that Mdoloris Medical Systems reasonably determines to be covered by this warranty and to be defective in workmanship or materials provided that the purchaser has given notice of such warranty claim within the Warranty Period and the Warranted Product is returned to the factory with freight prepaid. Repair or replacement of products under this warranty does not extend the Warranty Period.

To request repair or replacement under this warranty, the purchaser should contact Mdoloris Medical Systems directly. Mdoloris Medical Systems will authorize the purchaser to return the Warranted Product (or part thereof) to Mdoloris Medical Systems. Mdoloris Medical Systems shall determine whether to repair or replace Products and parts covered by this warranty and all products or parts replaced shall become Mdoloris Medical Systems' property. In the course of warranty service, Mdoloris Medical Systems may but shall not be required to make engineering improvements to the Warranted Product or part thereof. If Mdoloris Medical Systems reasonably determines that a repair or replacement is covered by the warranty, Mdoloris Medical Systems shall bear the costs of shipping the repaired or replacement product to the purchaser. All other shipping costs shall be paid by the purchaser. Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the product. Products shipped by the purchaser under this warranty shall be packaged in the original shipping container or equivalent packaging to protect the product. If the purchaser ships a product to Mdoloris Medical Systems in unsuitable packaging, any physical damage present in the product on receipt by Mdoloris Medical Systems (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of the purchaser.

This warranty does not extend to any Warranted Products or part thereof: that have been subject to misuse, neglect, or accident; that have been damaged by causes external to the Warranted Product, including but not limited to failure of or faulty electrical power; that have been used in violation of Mdoloris Medical Systems' instructions; that have been affixed to any nonstandard accessory attachment; on which the serial number has been removed or made illegible; that have been modified by anyone other than Mdoloris Medical Systems ; or that have been disassembled, serviced, or reassembled by anyone other than Mdoloris Medical

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For any incident, please report to Mdoloris Medical Systems at service.qualite@mdoloris.com and/or to the National Competent Authority

For any other problem: please contact your Mdoloris Medical Systems representative or contact@mdoloris.com

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