User Manual

NIPE Monitor V1
Software version: V2.4.0.0

CE 1370

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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' continuous comfort / discomfort of newborn infants monitoring system 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 using on patients younger than two years old in a hospital or in a health care facility in order to monitor the parasympathetic tone activity.

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

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 the clinical judgment and with other available clinical signs observed. It is advisable to not rely only on the NIPE index for monitoring the patient comfort. As with all monitored parameters, artifacts and poor signal quality may lead to inappropriate NIPE values. Potential artifacts may be caused by muscle activity or rigidity, patient motion, improper sensor placement or electrical interference.

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

Table of contents

1   Safety precautions

INTRODUCTION

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

⚠️   **WARNING**

A warning of this level of danger advises against potentially dangerous situation that could results in physical injury or death. Accidents may be caused by the inability to avoid dangerous situation. That is why it is important to follow guidelines in this warning, to avoid physical injuries.

⚠️   **CAUTION**

A caution of this level of danger advises 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 regarding 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

⚠️

LEAKAGE CURRENT MUST BE CHECKED BY A TECHNICIAN QUALIFIED IN BIOMEDICAL ENGINEERING WHENEVER INSTRUMENT CASE IS OPENED.

⚠️

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 THE MRI ENVIRONMENT.

⚠️

THIS MONITOR COULD NOT BE IN ANY CASE CONSIDERED AS AN ECG MONITORING SYSTEM.

⚠️

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.

⚠️

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

⚠️

IF THE INTEGRITY OF THE EXTERNAL PROTECTIVE EARTH GROUND IS IN DOUBT, THE NIPE MONITOR V1 SHOULD NOT BE USED.

⚠️

BE SURE THE MONITOR IS INSTALLED SECURELY TO AVOID ANY INJURY FOR THE STAFF OR FOR THE PATIENT.

⚠️

WHEN EXTERNAL EQUIPMENT IS CONNECTED (e.g., DATA CAPTURE COMPUTER), THE LEAKAGE SYSTEM CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC 60601-1-1 LIMIT.

⚠️

USING ACCESSORIES AND CABLES OTHER THAN SPECIFIED OR PROVIDED BY THE MANUFACTURER OF THE NIPE Monitor V1 (MDOLORIS MEDICAL SYSTEMS) MAY RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR

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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

⚠️

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

⚠️

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

⚠️

ON ELECTRICAL SHOCK HAZARD :
- DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET HANDS.
- DO NOT REMOVE MONITOR COVERS DURING OPERATION OR WHILE POWER IS CONNECTED TO MONITOR.
- THE MANUFACTURER OF THIS DEVICE HAS VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED BY THE APPLICABLE SAFETY STANDARDS. AS A MATTER OF SAFE PRACTICE, THE INSTITUTION SHOULD ALSO CONDUCT TESTS TO VERIFY THESE CURRENTS ESPECIALLY WHEN A QUALIFIED BIOMEDICAL

ENGINEERING TECHNICIAN PERIODICALLY OPENS THE INSTRUMENT CASE.

- WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST GROUND LEAKAGE CURRENT BEFORE FURTHER USE.

⚠️

IN CASE OF EMERGENCY FOR INTERRUPTING THE ELECTRICAL POWER, IT IS NECESSARY TO USE THE MALE END OF THE POWER CORD OR THE WALL SOCKET. THE ACCESS OF THE POWER PLUG AND THE WALL SOCKET HAVE TO STAY REACHABLE DURING THE NORMAL USE.

⚠️

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

⚠️

DO NOT MIX DISINFECTING SOLUTIONS (e.g., BLEACH AND AMMONIA). HAZARDOUS GASES MAY RESULT.

⚠️

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

- INCREASE THE SEPARATION BETWEEN DEVICES
- CHANGE THE ORIENTATION OF DEVICE CABLING
- PLUG DEVICES INTO SEPARATE CIRCUIT OUTLET

- PLEASE CONTACT YOUR MDOLORIS MEDICAL SYSTEMS REPRESENTATIVE.

⚠

BE SURE THAT THE MONITOR IS PLACED OUT OF AN AREA PRESENTING A RISK OF PROJECTION OF LIQUID (E.G.: UNDER AN I.V. BAG).

⚠

ANY MODIFICATION IN 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 ensure there is no USB peripheral connected to the monitor (USB stick for example).

The equipment should not be reachable by the patient, directly or indirectly, like placed on a metallic material reachable by the patient.

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The patient and the equipment should not be touched simultaneously by the doctor.

Before any use, check for compatible ECG source isolation corresponding to the applicable standards to increase patient isolation safety.

The signal provided by the ECG source must be a Very Low Security Tension output.

Do not put the monitor in an autoclave. Putting the monitor in an autoclave will 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 or stacked on other equipment. If adjacent or stacked use is necessary, check regularly that the functioning is normal in this configuration.

Only staff of Mdoloris Medical Systems is allowed to perform maintenance operations or repairs. Only the following elements can be replaced or substituted by an untrained staff to the technical maintenance (respecting the manufacturer references):
- « Monitor Link » cable and its different connectors ;
- The power cord ;
- The power supply box.

The recycling of this medical equipment, its components and packaging must be done in accordance with the national laws of the country on electronic wastes and environment.
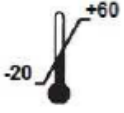
Be sure that the multi-parametric monitor on which the NIPE Monitor V1 is connected complies with the electromagnetic compatibility requirements of the IIa classification and the double patient isolation IEC 60601-1.

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

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1.3   Notes

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

1.4   Key to symbols

Symbol	Description	Symbol	Description
📖i	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 Environment)	⏻	"ON" / "OFF"

🍷	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 normalized and continuous measure of the parasympathetic tone (pΣ) which is a part of the autonomous system (ANS). It uses the punctual and quick increase of pΣ tone induced by each respiratory cycle (spontaneous or artificial) to measure the "relative quantity" of pΣ tone.

These rapid changes in pΣ tone express in the sinus node of the heart by changes in the time intervals between two R waves of the electrocardiogram. The pΣ component is evaluated after filtering, normalization and resampling of the RR series by measuring the area generated by the respiratory patterns. More important is the pΣ tone, bigger is the measured area.

Rapid pΣ tone variations express themselves directly on the sinus node by variations of time interval separating two R waves on the electrocardiogram. The normal next RR series (stemming from a cardiac cycle and not from an extrasystole) establish the RR series. After filtering, normalization and resampling, the pΣ compound of the RR series is obtained by measuring the generated surface by the respiratory cycles.

NIPE measurement cannot be interpreted in the following situations:

- Non-sinus cardiac rhythm;
- cardiac graft;
- drugs affecting the sinus node (Atropine…);
- post-conceptional age lower than 26 weeks.

The NIPE index is expressed on a scale between 0 and 100. It reflects the activity of the parasympathetic nervous system. It gives a reading of the proportion of pΣ tone compared to

the Σ tonus in the autonomous nervous system. The NIPE displayed represents the successions of computed measures: each elementary measure is carried out on 64 seconds, with a 1 second moving window.

The NIPE Monitor V1 is intended to be used by pediatricians and pediatric nurses. For a safety use of the NIPE Monitor V1, the user must know factors that could disturb/skew the NIPE index calculation related to the autonomous nervous system. The NIPE is a decision support tool; the user must take account of the other current clinical parameters before taking a decision or performing a diagnosis.

The diagnostic established with respect to the NIPE index value displayed on the monitor, is the doctor's responsibility.

3 Physiological principle of the NIPE measurement

Analysis of Heart Rate Variability (HRV) enables to evaluate the autonomous nervous system's variations, whose parasympathetic and sympathetic components control the cardiac rhythm and its short-term variations. HRV measurement methods are various and validated for many years: the normal or pathologic functioning of the ANS can be appreciated by these methods. Some studies showed that the cardiovascular system's regulatory processes are closely linked to the perception of pain [1, 2]. Analysis of the heart rate variability (HRV) is a well-known and non-invasive method for the measure of the cardiovascular system's regulation by the autonomous nervous system (ANS) [1, 3]. This analysis is based on the principle that the fluctuations of the cardiac rhythm are the reflect of the parasympathetic and sympathetic systems, main components of the ANS. Studies showed that fluctuations of the heart rate over 0.15 Hz are due to parasympathetic system's influence [4, 5]. Phenomena of pain, fear and anxiety, in adults, are accompanied by a decrease of the HRV in high frequencies (>0.15 Hz) that indicates a decrease of the parasympathetic tone during nociceptive stimuli and unpleasant emotions [6, 7, 8]. During a surgical operation, analysis of the HRV is correlated to the balance between nociception and analgesia rate [9]. A significant decrease of the spectral power in high frequencies, in children, has been observed during painful surgical acts. This suggests a decrease of the parasympathetic influence 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.

11.

4 Installation of the NIPE Monitor V1

4.1 Clamping support

Position the monitor in order to handle easily the power plug. The monitor could be installed on an intravenous stand with the collet fixture. The clamping system can be used on poles with diameter from 0.75 to 1.49 inches. **Please ensure that the pole is compatible.**

4.2 ECG monitor connexion

Connect the « Monitor Link » to the analogic port of the ECG monitor, then connect the other end of the "Monitor Link" cable to the NIPE Monitor V1 (see figure 1).

To identify the analogic ECG output on your multi-parameter monitor, please consult the operating manual of this multi-parameter monitor.
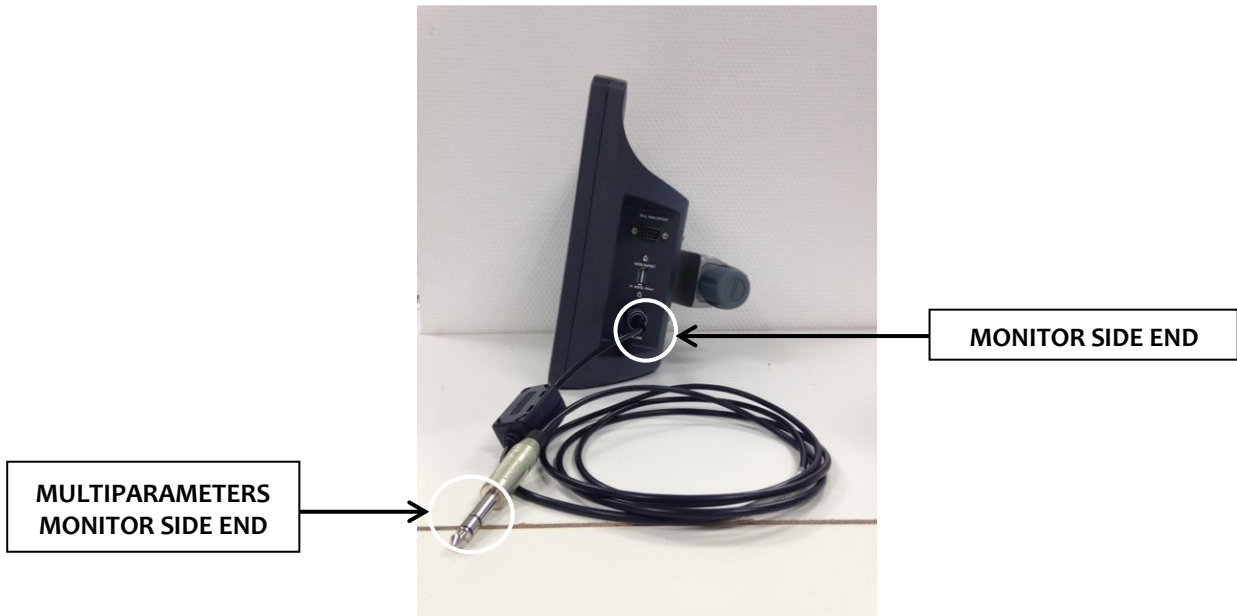
Figure 1: connexion cable

Figure 2: Example with the Philips MP50 monitor

Ask for Mdoloris Medical Systems representative if there is any problem.

4.3   Power connector

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

5. Start the NIPE Monitoring

Once the monitor is plugged and connected to the multi-parameter monitor, power up the monitor with the switch located on the left side of the NIPE Monitor V1 (figure 3).

The green light situated above the screen indicates that the monitor is starting up.

Figure 3

The monitor will start by showing successively Mdoloris Medical Systems' animations during the start-up phase. Then, the main menu screen will be displayed (figure 4).

Figure 4

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

5.1   Set up language

The user can change the language. Select the button **[Язык]** situated on the top right hand corner of the main menu (figure 4). The different languages are displayed in a drop down list (figure 5). Choose the language wanted and press **[X]** to quit and set up the new language.
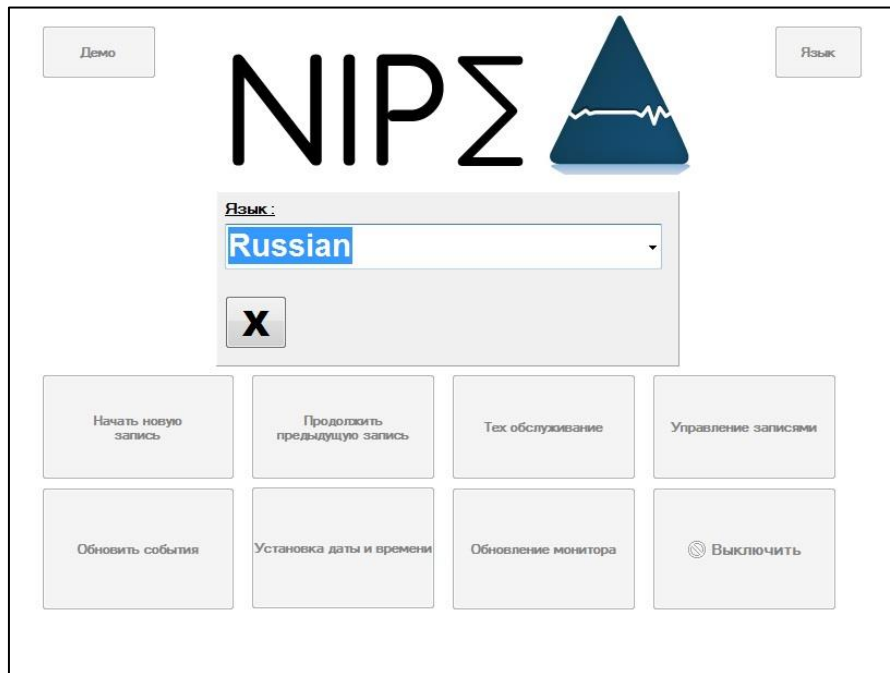
Figure 5

5.2   Demo mode

The selection of **[Демо]** on the top left hand corner of the main menu shows you a video of the NIPE functioning.

5.3   Start a new recording

The selection of **[Начать новую запись]** launches a new recording. Then the monitor displays the monitoring starting by an initialization step (figure 6). This initialization step takes a minimum of 80 seconds. No data can be interpreted before this initialization time.

Figure 6

When the initialization is done, the initialization of the index starts automatically and the monitoring display appears (figure 7).

Figure 7

5.4   Resume the previous recording

The selection of [**Продолжить предыдущую запись**] enables to resume the former recording.
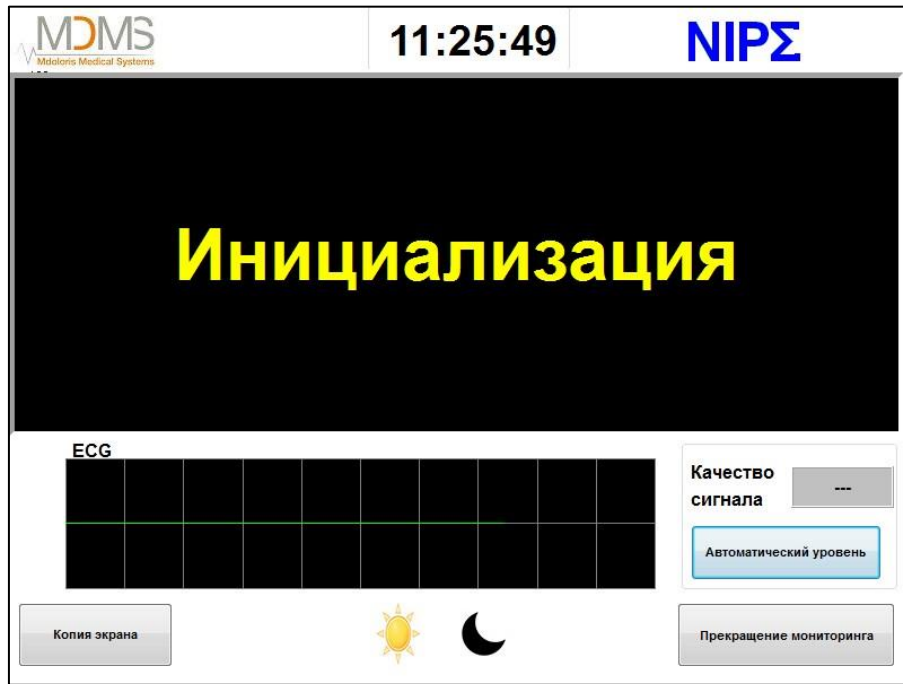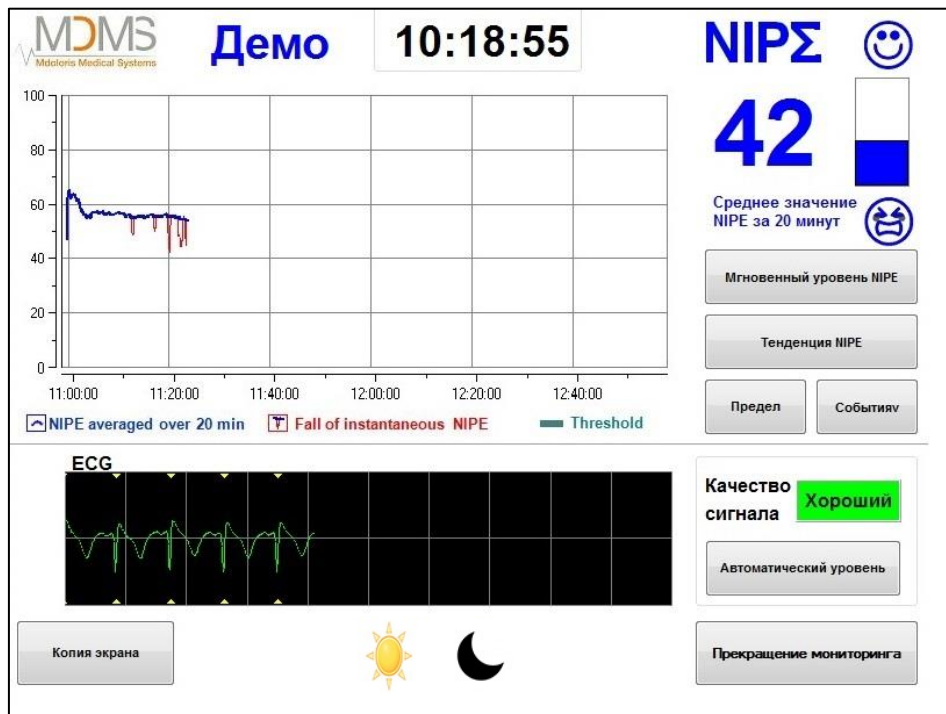
The other functions available from the main menu (figure 4) are presented in the following chapters:

- Maintenance : cf. Chapter 8.2
- Records management : cf. Chapter 8.3
- Events update : cf. Chapter 8.4
- Date and Time settings : cf. Chapter 8.5
- Update monitor : cf. Chapter 8.6
- Shutting down : cf. Chapter 8.7

To note: *The NIPE Monitoring can be used with a conscious patient as well as with an unconscious one, whenever the clinician needs it.*

6   NIPE display

6.1   ECG capture

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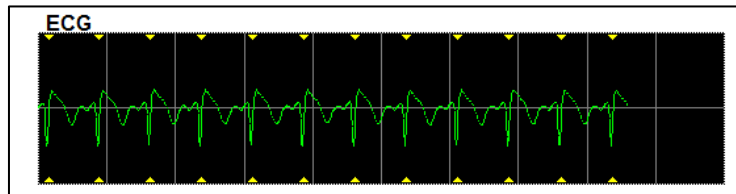

Figure 8 - ECG

WARNING:

On the main screen, always check the good quality of the ECG signal:

- At the same time with the signal morphology and the scrolling in the ECG scope.
- In the bottom right hand corner of the screen :

- Good quality signal

- Medium quality signal

Качество сигнала	Плохой

- Poor quality signal

Case n°1: No signal is displayed:

- Check the connection of the cable between the monitor and the multi-parameter monitor.
- Try at least one time to disconnect and plug again the connection between both monitors to get back a correct ECG signal.

Case n°2 – Medium quality signal:

When the quality signal is medium, it is to warn the user that the signal quality may become bad soon.

Case n°3 – Poor signal quality: The indications provided by the monitor can't be taken in account if the signal quality reported by the monitor is bad (red colored indicator).

In that case, the NIPE index is not displayed anymore, the curve is not dawned anymore and a message "poor signal quality" appears in the middle of the screen to warn the user.

- Select the button **"Автоматический уровень"** in the bottom right hand corner of the screen to recalibrate automatically the acquisition of the ECG signal.
- If the signal quality is still medium or poor, choose another ECG lead (on the multi parameters monitor). Finally, check the good position of the electrodes and their adhesion on the skin. Stick them again or change them if it is necessary.

6.2   NIPE index

A continuous indicator is displayed reflecting the patient parasympathetic tone (each elementary measure has been realized on 64 seconds with 1 second of sliding window). A calculation is realized every second then averaged within a "short" period and a "long" period. The monitor displays in blue the NIPE averaged over 20 minutes (long period) and, in red, the instantaneous NIPE when it falls suddenly (significant of the answer to a painful or stressful stimulus). See figure 9.
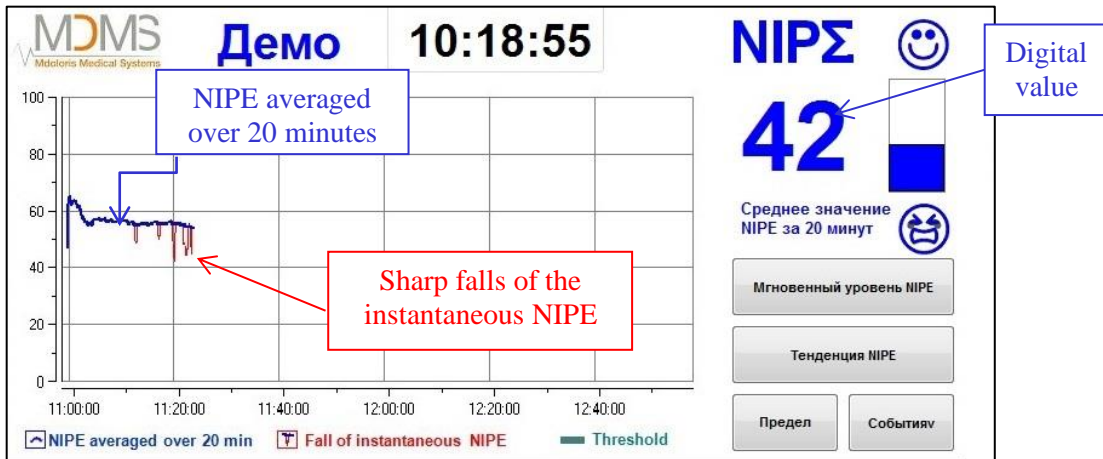
Figure 9

6.3 Display option of the instantaneous NIPE

The selection of the button **[Мгновенный уровень NIPE]** will allow you to follow the instantaneous NIPE on the screen. A window will open itself to display the instantaneous NIPE's curve (figure 10).

Figure 10

By selecting the button **[X]** in the bottom left hand corner of the window will close the display of the instantaneous NIPE. The signal acquisition keeps running despite the navigation through the instantaneous NIPE window.

6.4   NIPE browsing

The selection of the button [**Тенденция NIPE**] during the monitoring will display a navigation window (figure 11) which is used to move forwards and backwards the NIPE curve through time and to view the different events which were possibly inserted.
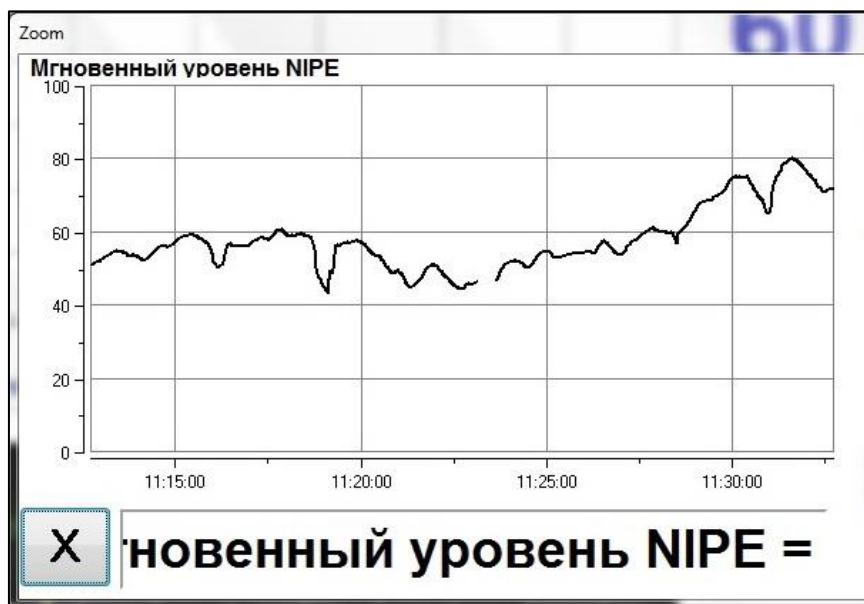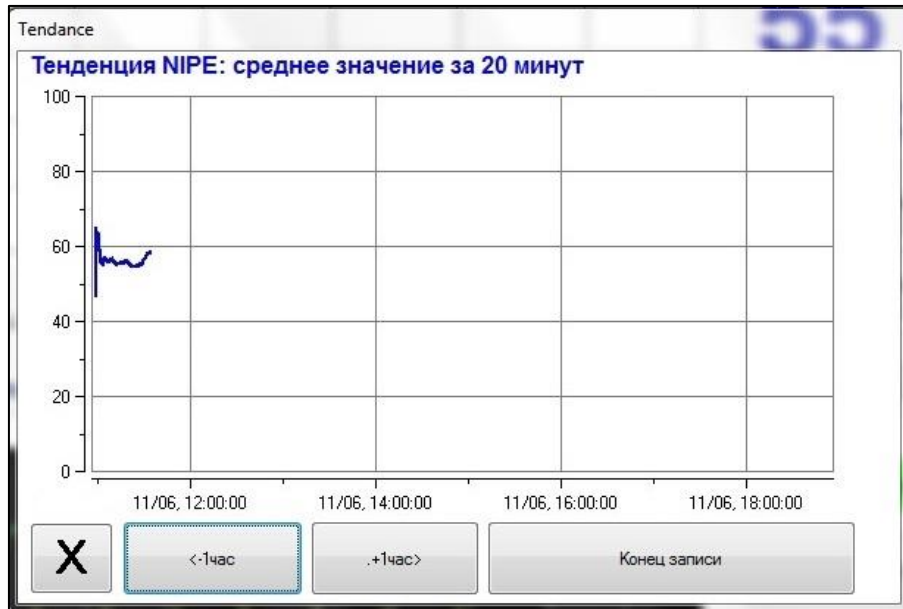

Figure 11

By selecting the button **[X]** the window of the NIPE browsing will close itself. The signal acquisition keeps running despite navigation through the NIPE browsing window.

6.5   Day / Night Mode

It is possible to adjust screen brightness thanks to 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).
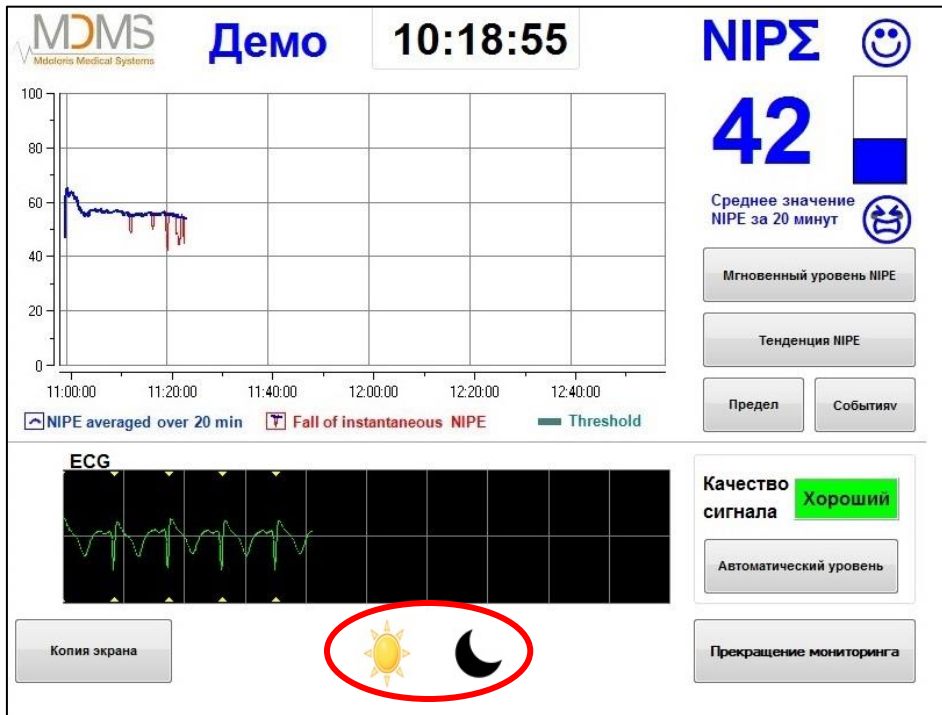
Figure 12 – Day / Night Mode

6.6 Standby screen

From 10 minutes of inactivity, the screen automatically switches to a standby screen (figure 13), except if one of these windows is opened: instantaneous NIPE, NIPE Navigation, Threshold, Events. To go back to the main screen, just touch the screen.
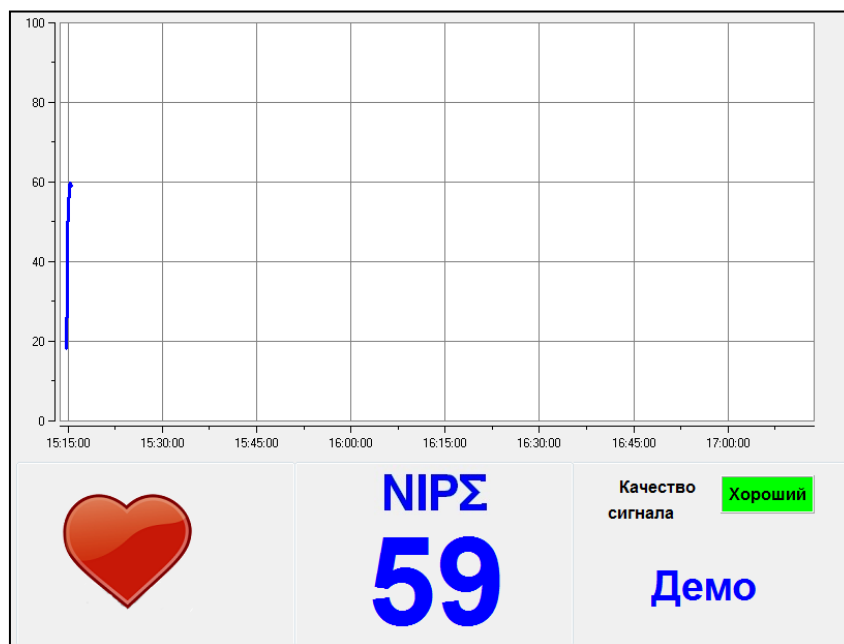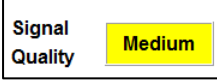
Figure 13 – Standby screen

WARNING: always check the good quality of the ECG signal:

1) Ensuring that the picture ❤️ always blinks.

2) In the bottom right hand corner of the screen :

- Good quality signal

Signal Quality	**Good**

- Medium quality signal

Signal Quality	**Medium**

- Poor quality signal

Signal Quality	**Poor**

7 NIPE Monitor V1 settings

7.1 Threshold setting

It is possible to add a threshold by pressing the button **[Предел].** A new window will be displayed (figure 14). Touch the small square next **[Установить предел]** in order to put a check mark in it and a blank rectangle will appear. Then click in the blank rectangle to activate it (figure 15).

☐ Установить предел	☑ Отключить предел
Подтвердить	Подтвердить
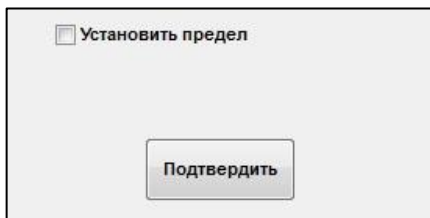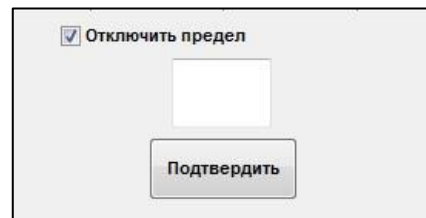
Figure 14   **Figure 15**

A keypad appears (figure 16), then you can enter the desired threshold and select **[Применить]** to validate your choice and then **[X]** to back to the monitoring display.
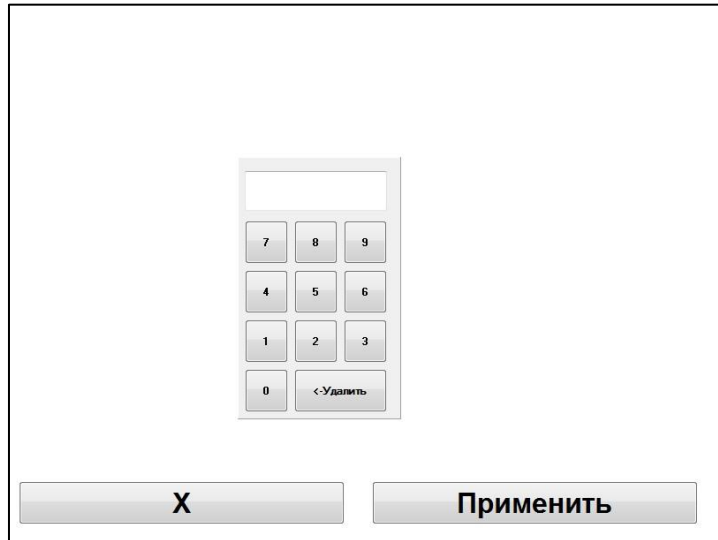
Figure 16

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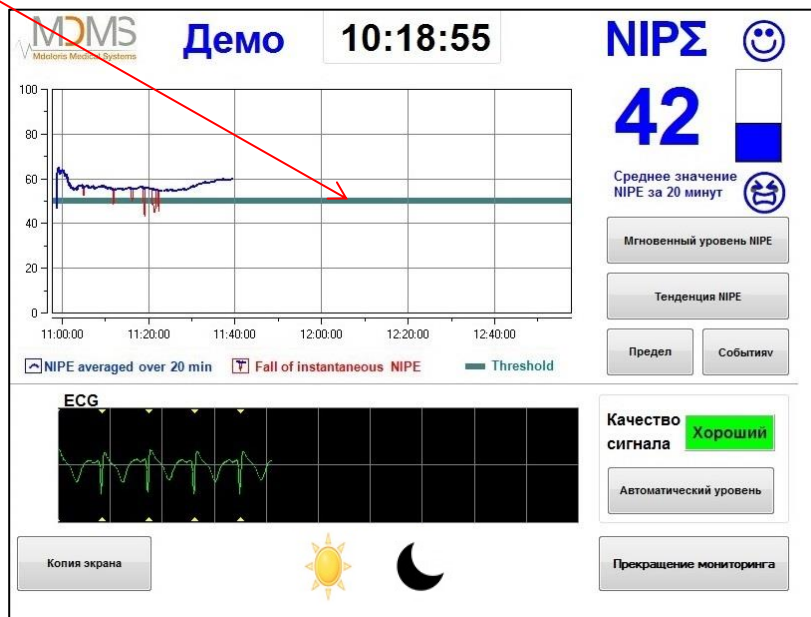
Figure 17

7.2   Insertion and deletion of events

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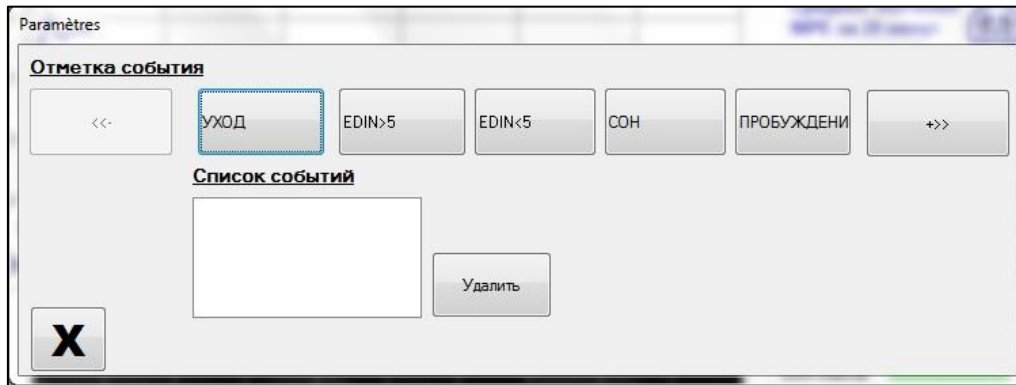
Figure 18

The events saved by default in the monitor are:

- УХОД
- EDIN > 5
- EDIN < 5
- СОН
- ПРОБУЖДЕНИЕ

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

The insertion of one of these events will be automatically saved in the "Index" type file, which can be retrieved with a USB key (see chapter 8.3). You have also the possibility to edit your own desired events list (see in that case the chapter 8.4).

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

7.3   Screenshot

When the user selects the button [**Копия экрана**], all the information displayed is saved in the monitor's memory as picture format. Each time the user decides to get a screenshot, one picture will be saved in the monitor's memory.

A message will appear to confirm the success of the screenshot (figure 19). Select the button [**OK]** to remove this confirmation from the display.

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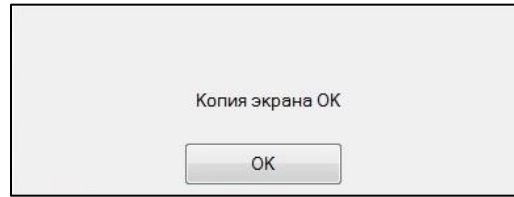
Figure 19

To get these pictures, you have to stop the monitoring. To do this, select **[Прекращение мониторинга]** in the bottom right hand corner of the display. Then plug a USB key in the USB port called "Data Export" on one of side of the monitor.

In the new display (the main menu), choose [**Управление записями**] then [**Записать на USB - ключ**]. The pictures will be saved in a folder created automatically on the USB key. The name of the folder follows this rule: Hour-Minute-Month-Day-Year.

8   End of the NIPE Monitoring

8.1   Quit the current recording

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

A request for confirmation is proposed before to quit the monitoring (figure 20):
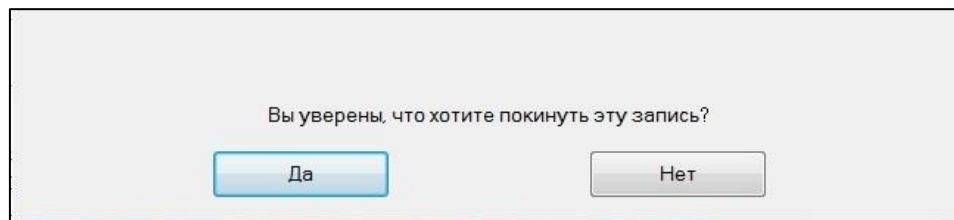
Figure 20

To note: by clicking on **[Да]**, *no coming back to the current patient will be possible.*

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

8.2   Maintenance

The selection of the button [**Тех обслуживание**] 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 on request by Mdoloris Medical Systems.

23
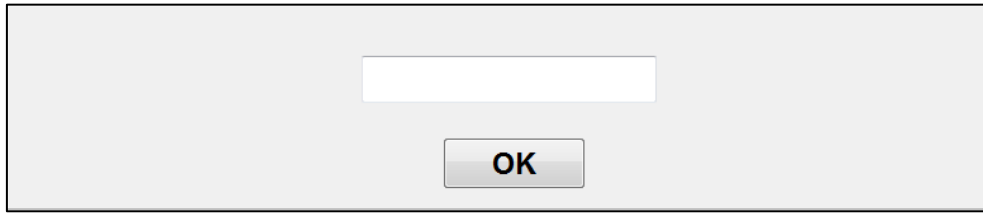
Figure 21

8.3   Records management

8.3.1 Export data recordings

The selection of the button [**Записать на USB - ключ**] will send all data saved in the monitor memory into a USB key. To export the data, you need to connect a USB key in USB port called "*Data Export*" situated on the right side of the monitor. If the monitor doesn't detect any USB key (USB key doesn't plugged or bad connection), a message will appear to inform the user (figure 22). When the USB key is well connected, press on [**OK**] to start the data export.
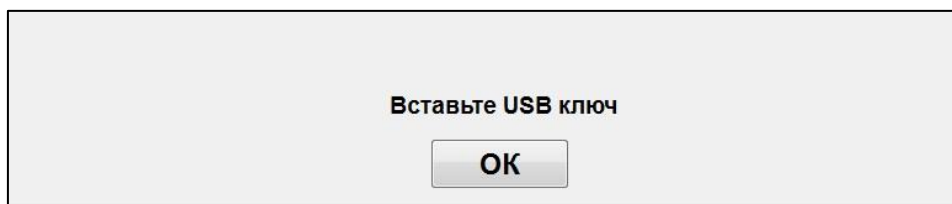
Figure 22

When the entire export has been done, a message appears to confirm the success of the export (figure 23). Press the button [**OK**] to return to the main menu.
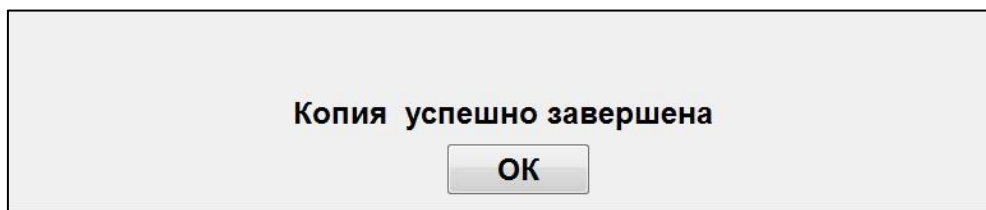
Figure 23

Note:

Data are automatically saved as text files for an easy secondary reprocessing (with Windows Excel for example). The files will be exported in a folder 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 name will follow this rule: Hour – Minute – Month – Day - Year.

Example:

08_46_04_15_11Index
Document texte
15,4 Ko
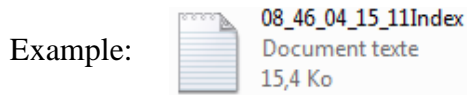
The NIPE Monitor V1 allows real time transfer data via an RS232 port to an external device.

WARNING: Mdoloris recommend the use of an insulation device on the link « RS232 output » between the NIPE Monitor V1 and the device to which it is connected, to respect the electrical insulation and the operator's protection means.

This device that we can denominate « serial isolator » or « RS232 isolator », should respect 60601-1-1 and 60601-1-2 standards.

The company Demetec GmBH markets a device referenced « Medical RS232 Isolation, type Rsl V1.2 » that meet these standards.

8.3.2 Deletion of data recorded

The selection of the button [**Стереть записи**] will lead the deletion of all data previously saved in the memory. A request for confirmation is proposed (figure 24).

Вы уверены, что хотите удалить все зарегистрированные данные?

Да   Нет
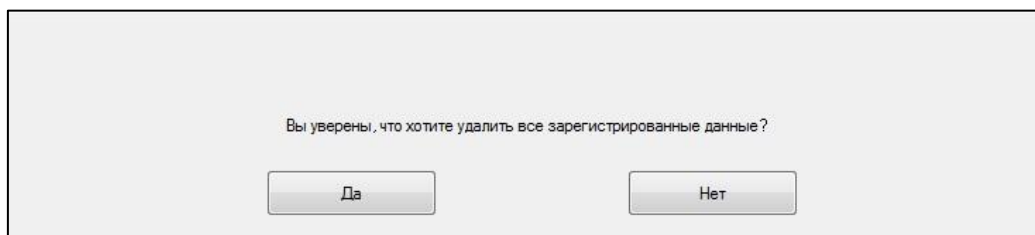
Figure 24

When all data are deleted, another window will appear to confirm that the action is done (figure 25). Press the button [**OK**] to back to the main menu.
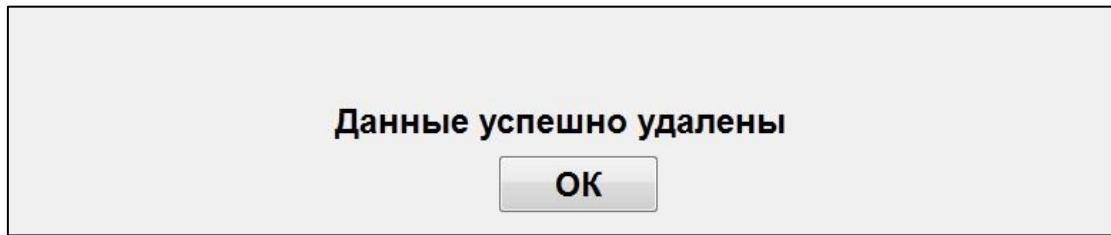
Figure 25

8.3.3 Setting of data-rates recorded

The selection of the button **[Частота записи]** will allow adjusting the recording frequency. Choose the frequency you want and select **[Подтвердить]** (figure 26).

Figure 26

8.4 Events update

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

The user can customize the list of events:

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

26
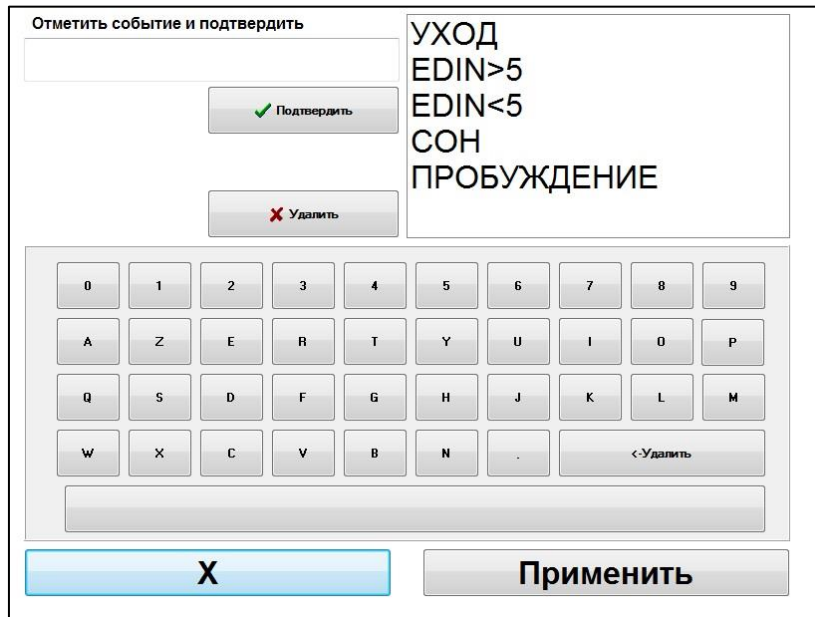
Figure 27

To add new event in the list, you have to use the virtual keyboard on the touch screen and then click on [✓ **Подтвердить**]. 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 there are 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 [✗**Удалить**].

To validate any change done (add or deletion of one or more events) you have to confirm by selecting the button [**Применить**] then [**X**] to close the events update menu.

8.5   Date and time settings

To set the clock or the date, you have to select [**Прекращение мониторинга**] to reach the main menu (figure 28). Then, select [**Установка даты и времени**].

The following window will appear:
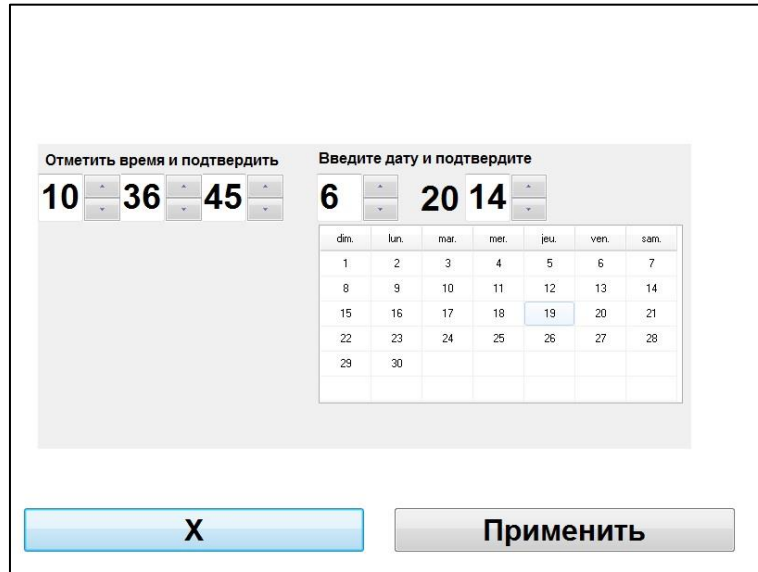
Figure 28

Use the arrows next each number to choose the modifications that you want. To validate the changes done, you have to confirm by selecting [**Применить**] then [**X**].

8.6 Update the monitor

In the main menu, select [**Обновление монитора**]. Plug an USB key with the new version of "NIPE.exe" provided by your Mdoloris Medical Systems representative. Then select [**Обновление программного обеспечения монитора**] (figure 29).
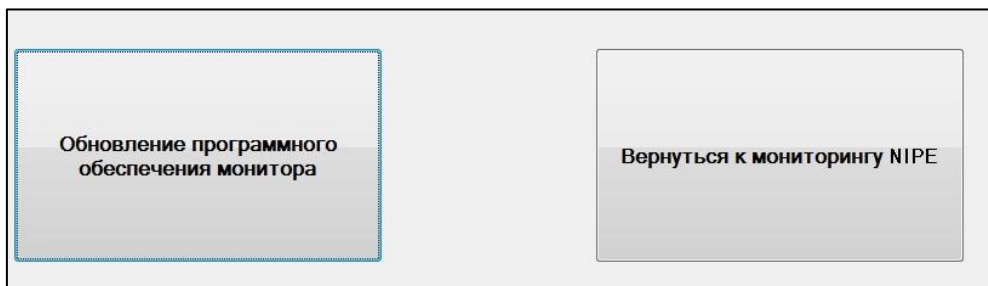
Figure 29

A message will appear to confirm the success of the updating (figure 30). Press on [**Вернуться к мониторингу NIPE**] to back to the main menu. This step could take few seconds due to the updating process.

Обновление успешно завершено

Figure 30

If no USB key is plugged or not detected yet, a message will appear to inform the user (figure 31):

Вставьте USB ключ

Figure 31

If the "NIPE.exe" is not present on the USB key, a message appears (figure 32):

Копировать "NIPE.exe" на USB-ключ и повторить ещё раз

Figure 32

8.7   Shut down

The selection of the button [🚫 **Выключить**] ends the session and will shut down the monitor.

<u>NOTE:</u> It is possible to shut down the monitor directly with the switch located on the left side of the monitor (the same that for booting) only if the context doesn't enable you to reach the main menu. This is however not recommended because it could affect the monitor's proper functioning.

⚠️ **DO NOT UNPLUG THE POWER CABLE WHILE THE MONITOR IS BEING USED. IT COULD AFFECT THE MONITOR'S PROPER WORKING ORDER.**

9 Troubleshooting

Problems	Perform the following tasks:	If failure remains:
No ECG displayed on the monitor.	Check that the monitor is correctly connected to the multi-parameter monitor.	Contact your Mdoloris Medical Systems interlocutor.
An ECG signal is detected but seems to be incoherent (flat, irregular, interfered…).	Check that all cables are correctly connected and the good positioning of ECG electrodes.	Contact your Mdoloris Medical Systems interlocutor.
ECG waves seem physiologically incorrect.	Check the color code of the electrodes related to the cardiac monitor.	Contact your Mdoloris Medical Systems interlocutor.
No one of the connection adaptors provided with the NIPE Monitor V1 matches with the analogic ECG output of the cardiac monitor.	Contact your Mdoloris Medical Systems interlocutor.	
The touch buttons do not work.	Reboot the monitor (use the switch if you cannot reach 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
	Plug a keypad on the monitor.
	Reboot the monitor.
	Once the MDMS picture is not displayed, press immediately on F3.
	Follow the instructions displayed on the screen.
	Remarks :
	  - During restoration, the recordings previously done are preserved.
	  - During restoration, the software version will be the one, originally set up at the monitor delivery.
		Contact your Mdoloris Medical Systems interlocutor.

Following the restoration, the software switched to the previous version.	Contact your Mdoloris Medical Systems interlocutor by e-mail to obtain the last available software update (executable).	

10   Monitor disposal

WARNING: *To avoid any kind of contamination or infection on persons, on environment or on equipment, be sure you have properly disinfected and decontaminated the NIPE Monitor V1 before you dispose of your system. You should respect local regulations regarding electric and electronic items.*

You can dismantle the monitor and the acquisition card:

- No metal element is molded in the thickness of the monitor's housing
- The inner surfaces of the housing are covered with a protection against electromagnetic interference
- The screen has a touch proof stratified layer
- You can recycle the paper print operating manual
- All electronic items are under the RoHS normalized rules

If you have to dispose of old electrical equipment, make sure it is recycled safely. The "crossed out wheelie bin" symbol found on many electrical items means that they should not be put with normal household rubbish.

11 Environnement

11.1 Shipping and Storage Environnement

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

Temperature: -20 °C to +60°C

Humidity: 15 to 95% (non-condensing)

Pressure: 480 hPa à 1066 hPa

Protect the monitor from sudden temperature changes that can lead a condensation within the instrument. To minimize the risk of condensation, avoid moving the system between heated buildings and outside storage. Once moved inside, let the monitor in the unopened shipping container to reach the room ambient temperature before unpacking and placing into service. Before operating the system, wipe down all visible condensation and allow the system to reach equilibrium at room temperature.

11.2 Operating Environnement

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

WARNING: *Explosion hazard: do not use the NIPE Monitor V1 in a flammable atmosphere or where concentrations of flammable anesthetics may occur.*

The monitor is designed to operate safely in a temperature from 5°C to 35°C to an altitude of 2000 meters. The conditions that exceed these limits may modify 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 to 2000 meters and a pressure from 480hPa to 1066hPa.

11.3 Power Requirements 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. Accordingly, the monitor is equipped with a hospital grade power supply cord. The power cord grounds the system to the power line ground when plugged into an appropriate three-wire socket.

CAUTION: *FOR PROPER GROUNDING, THE POWER SOCKET MUST BE A THREE-WIRE GROUNDED OUTLET. A HOSPITAL GRADE OUTLET IS REQUIRED. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT 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

WARNING:

UNIVERSAL PRECAUTIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. PUT CONTAMINATED MATERIALS IN REGULATED WASTE CONTAINER.

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. Dampen the towel with detergent and lukewarm water to aid in cleaning. After cleaning, wipe the connector ends with alcohol and allow it to dry completely. Residual moisture inside the connector may affect the monitoring performance.

Cleaning the screen:

Clean the monitor display screen with a mild solution of detergent and warm water or a commercial display screen cleaner, available through personal computer dealers. To avoid scratching the screen, never use abrasive cleaners.

Disinfecting the monitor:

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

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

WARNING: *WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST LEAKAGE CURRENT BEFORE FURTHER USE.*

DO NOT MIX DISINFECTING SOLUTIONS AS HAZARDOUS GASES MAY RESULT.

Cautions: Do not autoclave the acquisition device or monitor. Autoclaving will seriously damage both components.

Avoid liquid ingress with the connection cables. Contact of fluids with the connections cables can interfere with the acquisition performance.

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 Specifications, warranty and software license agreement

13.1 Specifications

Power requirements: 100-240 Volts

Consummation: 40 W

Current: < 3,4 A

Frequency: 50 Hz

Electrical Safety: Class 1 conforms to IEC 60601-1

Weight of the monitor with collet fixture (without accessories) = 2.02kg

Dimensions of the monitor with the collet 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 life time of the products (5 years from the manufacturing date).

Material :
- Panel Pc: manufacturer IEI (product reference : AFL-08A-N270)
- Power supply adaptator AC/DC SL POWER - ME40A1203F01
- Acquisition card: Mdoloris Medical Systems reference: BA-NIPE-V1

Degree of protection against electric shock of the system:

Class 1: equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution. Means are provided for the connection of 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 with a risk of blood or liquids ingress.

System functioning:

Continuous: operation under normal load for a normal period 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.

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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 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, Purchaser should contact Mdoloris Medical Systems directly. Mdoloris Medical Systems will authorize 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 Purchaser. All other shipping costs shall be paid by Purchaser. Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the Product. Products shipped by Purchaser under this warranty shall be packaged in the original shipping container or equivalent packaging to protect the Product. If Purchaser ships a

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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 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 Systems, unless authorized by Mdoloris Medical Systems. Mdoloris Medical Systems shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear. Mdoloris Medical Systems makes no warranty (a) with respect to any products that are not Warranted Products, (b) with respect to any products purchased from a person other than Mdoloris Medical Systems or (c) with respect to any product sold under a brand name other than Mdoloris Medical Systems.

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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**