User Manual
PhysioDoloris Monitor V1
Software version: V1.4.1.0

$C\!\epsilon$ 1370

(CE mark first approved on September 2010)

Important information about using continuous analgesia monitoring system:

The Mdoloris Medical Systems' continuous analgesia 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 analgesia monitoring system is intended for use on adult and pediatric patients, providing patient care by monitoring the parasympathetic nervous tones activity by data acquisition of ECG signals.

The continuous analgesia monitoring system, and all its associated parameters, may be used as an aid in monitoring the effects of certain analgesic agents.

ANI is a complex monitoring technology intended for use as an adjunct to clinical judgment. Clinical judgment should always be used when interpreting the ANI index in conjunction with other available clinical signs. Reliance on ANI alone for interpreting analgesic management is not recommended. As with any monitored parameter, artifacts and poor signal quality may lead to inappropriate ANI values. Potential artifacts may be caused by high impedance of ECG source system, muscle activity or rigidity, patient motion, improper sensor placement or electrical interference.

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

ANI is a protected trademark.

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021

Table of contents

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021

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 PhysioDoloris Monitor V1 are explained at the end of this section.

1.1   Warnings

⚠

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

⚠

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

⚠

IN OPERATING ROOMS THE PhysioDoloris Monitor V1 MUST BE PLACED OUTSIDE THE EXPLOSION HAZARD ZONE.

⚠

MAKE SURE THE MONITOR IS INSTALLED OUTSIDE THE LIQUID PROJECTIONS HAZARD ZONE, E.G. PERFUSION BAG.

⚠

THE PhysioDoloris Monitor V1 IS NOT DESIGNED FOR USE IN THE MRI ENVIRONMENT.

⚠

THE CHARACTERISTICS OF PhysioDoloris Monitor V1 EMISSIONS ALLOW IT TO BE USED IN INDUSTRIAL AREAS AND HOSPITALS (CISPR 11 CLASS A). WHEN USED IN RESIDENTIAL ENVIRONMENTS (FOR WHICH CISPR 11 CLASS B IS REQUIRED), PhysioDoloris Monitor V1 CANNOT GUARANTEE PROVISION OF ADEQUATE PROTECTION OF RADIO FREQUENCY COMMUNICATION. THE USER MIGHT NEED TO PERFORM CORRECTIVE ACTIONS, SUCH AS REIMPLANTATION OR REORIENTATION OF THE PhysioDoloris Monitor V1.

⚠

THIS PhysioDoloris Monitor V1 COULD NOT BE IN ANY CASE CONSIDERED AS AN ECG MONITORING SYSTEM.

⚠

CONSIDERATIONS WHEN USING ELECTRO-CONVULSIVE THERAPY (ECT) EQUIPMENT DURING THE PHYSIODOLORIS 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 PhysioDoloris 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 PhysioDoloris Monitor V1 SHOULD NOT BE USED.

⚠

BE SURE THE MONITOR IS INSTALLED SECURELY TO AVOID PERSONAL OR PATIENT INJURY.

⚠

WHEN CONNECTING EXTERNAL EQUIPMENT (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 PhysioDoloris Monitor V1 (MDOLORIS MEDICAL SYSTEMS) MAY RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED ELECTROMAGNETIC IMMUNITY OF THE PhysioDoloris 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 PhysioDoloris Monitor V1

⚠

THE CONNECTORS SHOULD NOT CONTACT OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

⚠️

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'S INSPECTION OF THIS APPARATUS 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.

⚠️

IT IS NECESSARY TO USE THE DEVICE'S POWER RECEPTACLE OR POWER PEDESTAL, TO CUT THE ELECTRIC POWER SUPPLY. THE POWER RECEPTACLE AND THE POWER PEDESTAL SHOULD REMAIN ACCESSIBLE IN NORMAL USE.

⚠️

UNIVERSAL PRECAUTIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. CONTAMINATED MATERIALS MUST BE PLACED IN A FACILY IN ACCORDANCE WITH ALL APPLICABLE HYGIENE STANDARDS AND REGULATIONS.

⚠️

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021

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

⚠

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

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

OR PLEASE CONTACT YOUR MDOLORIS MEDICAL SYSTEMS REPRESENTATIVE.

⚠

TO AVOID THE HAZARD OF BURNS BE SURE THE MONITOR IS INSTALLED OUTSIDE THE SURGICAL SECURITY AREA AND AS FAR AS POSSIBLE FROM LIQUID INGRESS TO PREVENT SYSTEM DAMAGE (e.g. UNDER AN I.V. BAG).

⚠

MODIFICATIONS OF THE DEVICE ARE STRICTLY PROHIBITED.

⚠

USE OF PhysioDoloris 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 PhysioDoloris Monitor V1, INCLUDING CABLES SPECIFIED BY THE MANUFACTURER. OTHERWISE, DEGRADATION OF THE PERFORMANCE OF THIS EQUIPMENT COULD RESULT.

1.2   Cautions

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

Before starting, please ensure there are no USB devices (USB stick for example) connected to the monitor.

Equipment should not be reachable directly or undirectly by the patient, for example, placed on a metallic material reachable by the patient.

Patient and equipment should not be touched simultaneously by the doctor.

Check that the ECG analog output of the multi-parameters scope on which is connected the PhysioDoloris Monitor V1 respects the patient isolation.

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

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

Do not block ventilation inlet holes on the sides of monitor.

Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the PhysioDoloris Monitor V1.

PhysioDoloris Monitor V1 should not be used adjacent or stacked with other equipment. If adjacent or stacked use is necessary, the monitor should be observed to verify normal operation in the configuration in which it will be used.

Only Mdoloris Medical Systems qualified biomedical technicians must perform service or repairs on PhysioDoloris Monitor V1. Only the following elements may be replaced or substituted by a staff untrained in technical maintenance (by respecting the manufacturer's references):

- The different connectors and extensions ;
- Power cord ;
- Power supply.

The recycling of this medical equipment (including the packaging) must be done in accordance with the national laws of the country on electronic wastes and environment.

Be sure the multi-parametric monitors on which PhysioDoloris Monitor V1 is connected complies with the electromagnetic compatibility requirements of double patient isolation IEC 60601-1.
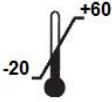
Ask for the multi-parameter monitors list compatible with the PhysioDoloris Monitor V1 from your Mdoloris Medical Systems representative. Each of these monitoring systems needs a specific connection. Please ensure you have passed these specifications on your Mdoloris Medical Systems representative.

1.3   Notes

The « **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**
YYYY-MM	**Manufacturer + Manufacturing Date**	$C\epsilon$	**European compliance Mark of compliance with the European Medical Device Directive**

	Do not expose to sunlight		**This way up**
	Check the packaging quality upon delivery		**Needs special waste disposal**
	Upper and lower temperature limits (Shipping and Storage Environment)		**Keep dry**
	Fragile; handle with care		**Direct current, DC**
	General safety sign		

2   PhysioDoloris Monitor V1 presentation

ANI (Analgesia Nociception Index) is an online continuous and normalized measurement of the Autonomic Nervous System (ANS) parasympathetic (pΣ) component. It use the punctual heart rate modulation induced by each respiratory cycle (spontaneous or artificial) and which is related to the "relative quantity" of pΣ tone.

This modulation can be evaluated through Heart Rate Variability (HRV) analysis. Indeed, the ANS pΣ component mainly influences HRV in the high frequency domain ([0.15 – 0.5 Hz]). ANI is able to evaluate the pΣ tone by specific algorithms allowing normalizing, isolating and quantifying heart rate high frequency variations. The PhysioDoloris Monitor V1 then allows to visualize the high frequency modulation induced by respiration ("respiratory pattern" on the monitor screen) as well as its numerical value (ANI).

The ANI index is expressed on a scale between 0 and 100. It gives a reading of the proportion of pΣ tone in the ANS. The ANI display is the result of computations average over 60 seconds, with a 1 second moving window (that is to say a new ANI value is computed every second).

The monitor displays two parameters: in yellow, the instantaneous ANI, resulting from the process previously described; in orange, the ANI averaged over 4 minutes.

The more the pΣ tone is important, the more the respiratory pattern surface is important and the higher ANI is.

There are multiple ways to interpret the ANI results but ANI has been developed in order to predict hemodynamic reactivity during general anesthesia. Indeed, during preliminary studies, when surgical stimulation was constant, all hemodynamic reactivity episodes (20% increase of heart rate or systolic arterial pressure during the last 5 minutes) were associated with a decreased ANI up to 5 or 10 min beforehand. The predictive threshold need yet to be confirmed, but preliminary studies suggest that:

- When ANI values are situated between 50 and 70, hemodynamic will probably remain stable.
- When ANI values are lower than 50, a hemodynamic event will probably occur in the next 10 minutes.

ANI measure is not reliable in the following situations:
- Non sinusal heart rhythm (arrhythmia, pacemaker, cardiac surgery…).
- Absence of respiration (apnea induces by tracheal intubation).
- Respiratory rate lower than 9 cycles/min or higher than 30 cycles/min.
- Use of medication or pathology altering ANS activity or cardiac sinusal activity.

Even if ANI is based on HRV analysis computed from the ECG, the PhysioDoloris Monitor V1 can't be considered as an ECG monitor.

3 PhysioDoloris Monitor V1 installation

3.1   Clamping support

Position the monitor in order to use easily the power plug. The monitor could be installed on a vertical clamp (figure 1). Mount the monitor using the pole clamp on a pole diameter from 19 to 38 mm. **Please ensure that the pole is compatible.**

Figure 1

3.2 ECG monitor connexion

Connect the acquisition device of the PhysioDoloris Monitor V1 to the analogic port of the ECG monitor (e.g. on Philips MP50: see picture next page) by using the recommended interface cable provided by your Mdoloris Medical Systems representative (to identify the analogic port of your multi-parameters monitors, please consult the appropriate operating manual).

Connect the other cable of the acquisition device to the PhysioDoloris Monitor V1, on the inferior side (to one of the USB ports). See figure 2 next page.

USB ports

Figure 2   lower side of the monitor

Ask for the multi-parameter monitors list compatible with the PhysioDoloris Monitor V1 from your Mdoloris Medical Systems representative.

Figure 3 - example with the MP50 Philips monitor

Each of these monitors needs a specific connection. Please ensure you have passed these specifications on your Mdoloris Medical Systems representative.

4 Beginning the PhysioDoloris monitoring

To turn on the monitor, press the ON/OFF switch located under the screen.

On/Off switch

12V DC power input

The monitor will start by showing successively the Mdoloris Medical Systems' logo and animations. The main screen will then indicate "Calibration" (figure 4). The first measure of the ANI will take at around 80 seconds. No data can be interpreted before this initialization time lapse.

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021

Figure 4
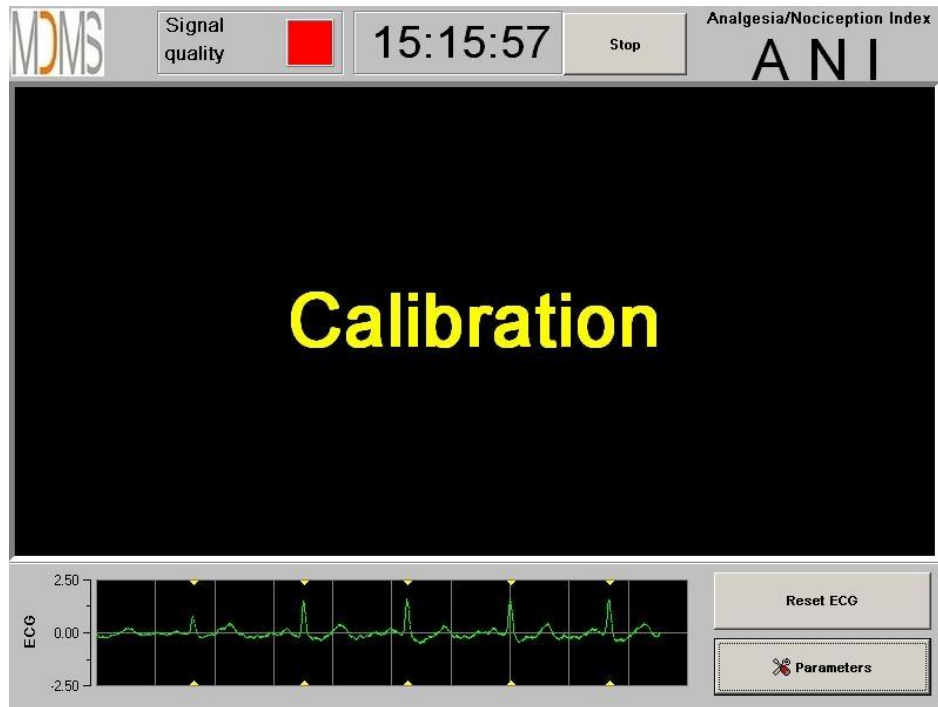
Once the monitor is connected to the patient with electrodes and the initialization phase is completed, the algorithm will automatically begin (see figure 5 next page).

To Note: *The PhysioDoloris technology can be used with a conscious patient as well as with an unconscious one. It can be installed whenever the physician needs it.*

Figure 5

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021
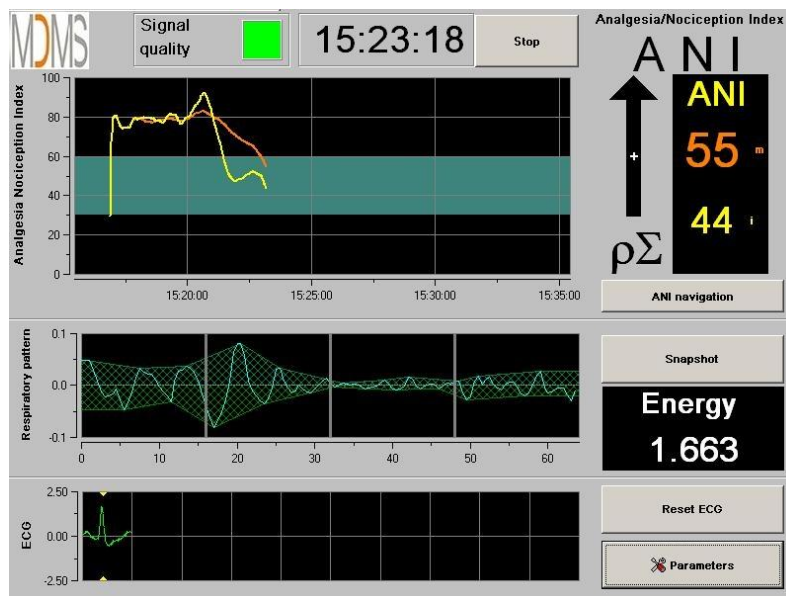
Ensure the good quality of the ECG signal in the inferior part of the screen. If there is no signal whatsoever, check the connection between the monitor and electrodes. Please try once to unplug and plug again the acquisition device to recover the ECG signal. If the display is not coherent, check the correctness of the electrodes position and also the quality of the connection between electrodes and the amplifier.

WARNING: *always check in the upper screen that the "Signal quality" is good (green color). The ANI index wouldn't be reliable if this quality indicator is not good (red color).*

If the user thinks the ECG amplitude is too low, pressing the button **[Reset ECG]** will automatically reset the initialization of the signal acquired.

5   PhysioDoloris Monitor V1 computing process

5.1   ECG Capture

At the bottom of the screen a sub-window displays the ECG acquired (figure 6). This ECG is filtered from all technical artifacts as well as from physiological ones (e.g. extrasystoles).

Figure 6

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021

5.2 Respiratory Pattern

The surface of influence of respiratory patterns in the RR series is measured and displayed in stripes over the RR series (figures 7 and 8). The bigger the surface is, the strongest the pΣ tone is. The smaller the surface is, the lower the pΣ tone is.

smaller stripped surface = low pΣ tone
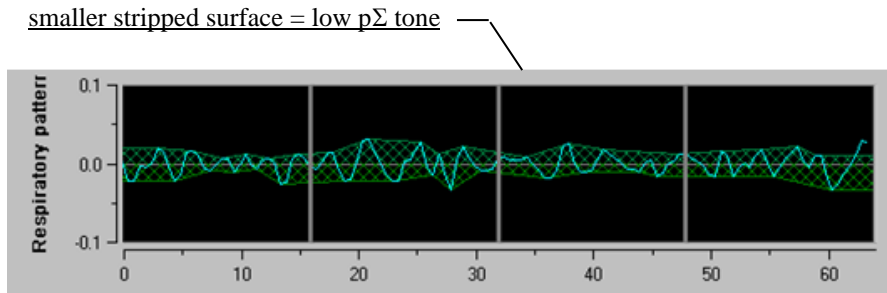
Figure 7: R-R normalized series: low sinus respiratory arrhythmia amplitude

bigger stripped surface = high pΣ tone
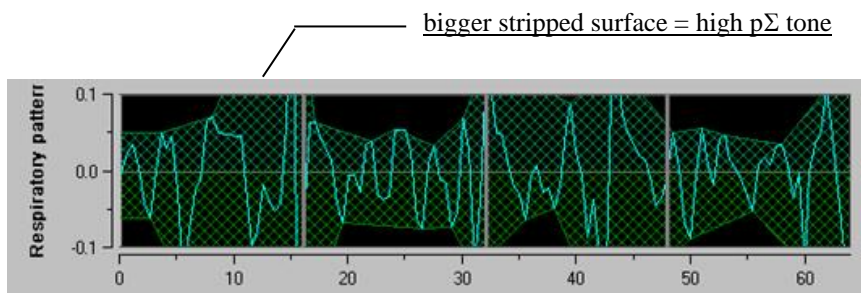
Figure 18: R-R normalized series: high sinus respiratory arrhythmia amplitude

5.3 ANI Index

We have developed an innovating algorithm based on the amplitude assessment of respiratory patterns of the RR series. In order to consider the amplitude variability and the respiratory pattern period, we have developed a methodology based on the area under the curve measurement (figure 9) called AUCmin (Minima of the areas under the curve).
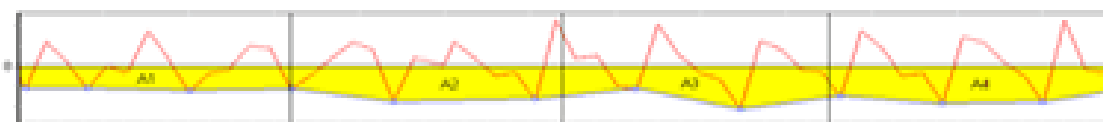
Figure 9: principle of index calculation

Therefore, we display continuously an index (each measurement based on the respiratory patterns window of 64 seconds with 1 second moving window) that reflects the parasympathetic

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021

tone activity. Two parameters are displayed (figure 10): in yellow color, the instantaneous index (called "i") and in orange color the patient tendency with a 4 minutes average (called "m"). Those indexes could prevent hemodynamic reactivity during surgery under general anesthesia.
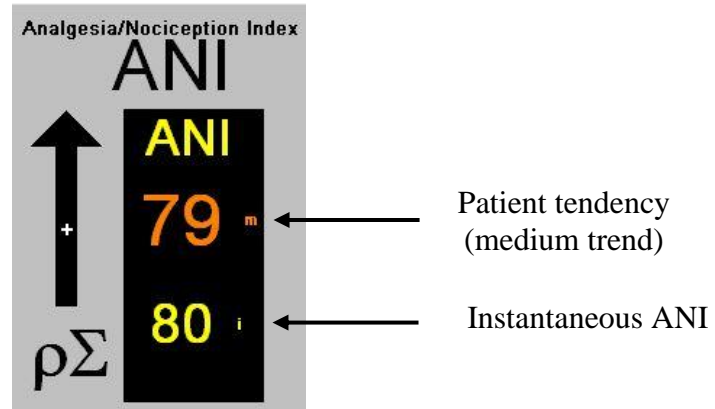
Figure 10

So the monitor displays in the left window two curves (yellow and orange) that reflect the patient tendencies with time scale (figure 11).
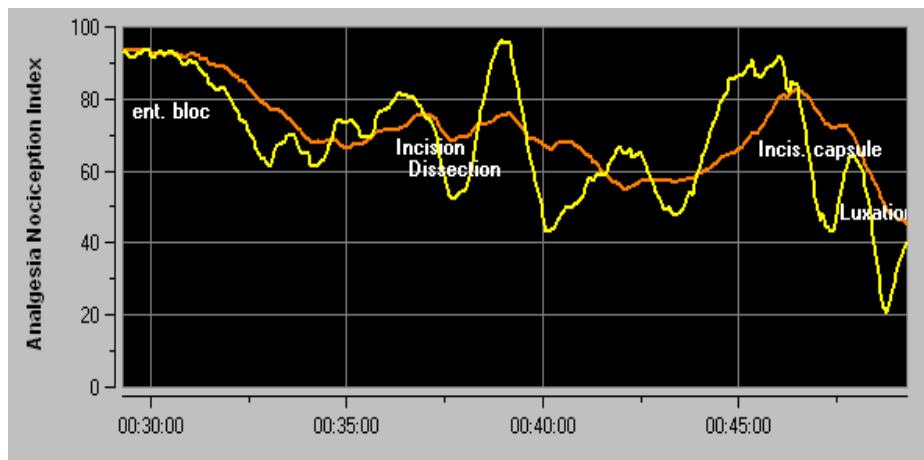
Figure 11

If R waves are not correctly detected, or too many ectopic beats are corrected, ANI measurements are suspended until ECG detection is correct or normal sinus rhythm is back.

5.4   Navigation panel

Pressing the **[ANI navigation]** button, during the monitoring, will open a new window and give the possibility to go forward and backward on the ANI measurements and captured events (figure 12).

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021

Figure 12

Pressing the **[X]** button will close this window. ECG acquisition and HRV measures are not disturbed, even if not displayed, when the navigation window has been opened.

6 PhysioDoloris Monitor V1 setup

Pressing the button **[Parameters]** in the bottom right hand corner of the screen during the monitoring gives the possibility to access to the following settings.

6.1 Set up language

The user can choose the language (figure 13). The different languages are displayed in a drop-down list (figure 13). Choose the language and press **[X]** to close the parameters window and set up the new language.
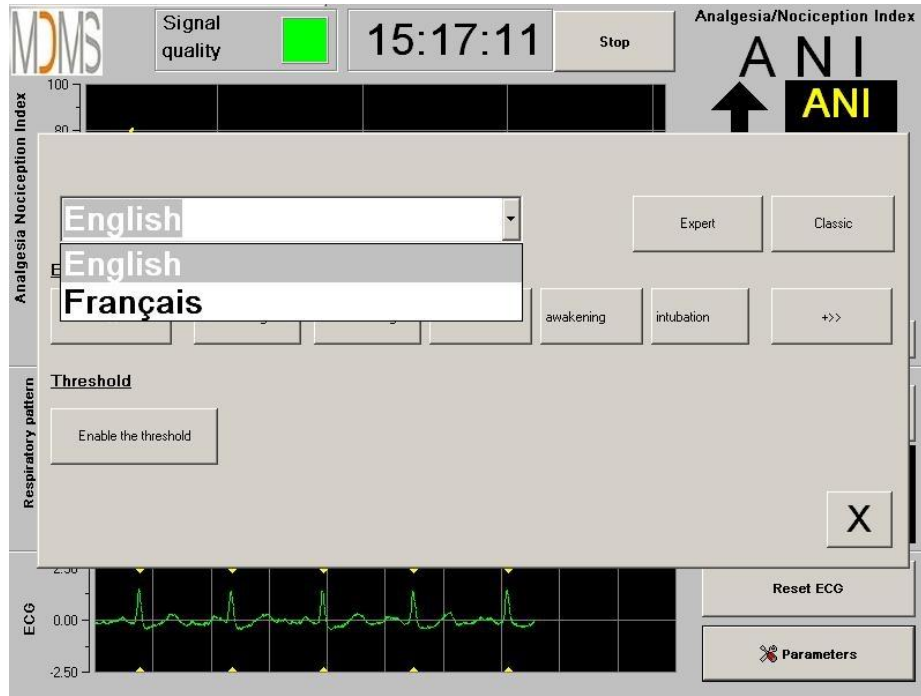
Figure 13

6.2 Threshold

As shown in the screen below (figure 14), here you have the possibility to select the threshold values pressing the button **[Enable the threshold].**

Figure 14

If you click on the **[X]** button without capturing the threshold values, a new window will appear (figure 15): click on **[OK]**.
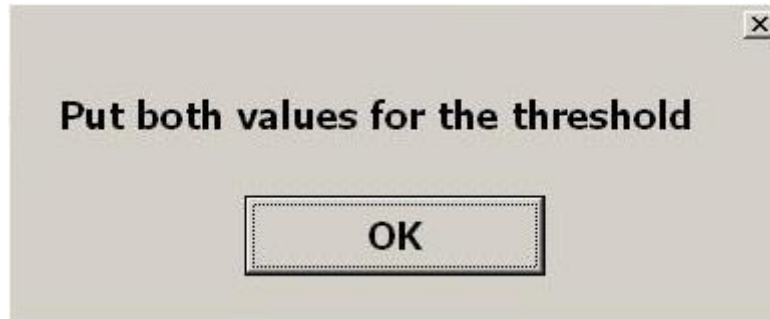
Figure 15

Click on the first input field and enter a first threshold value (figure 16). Click on **[Validate]** to validate. Do the same for the second input field.
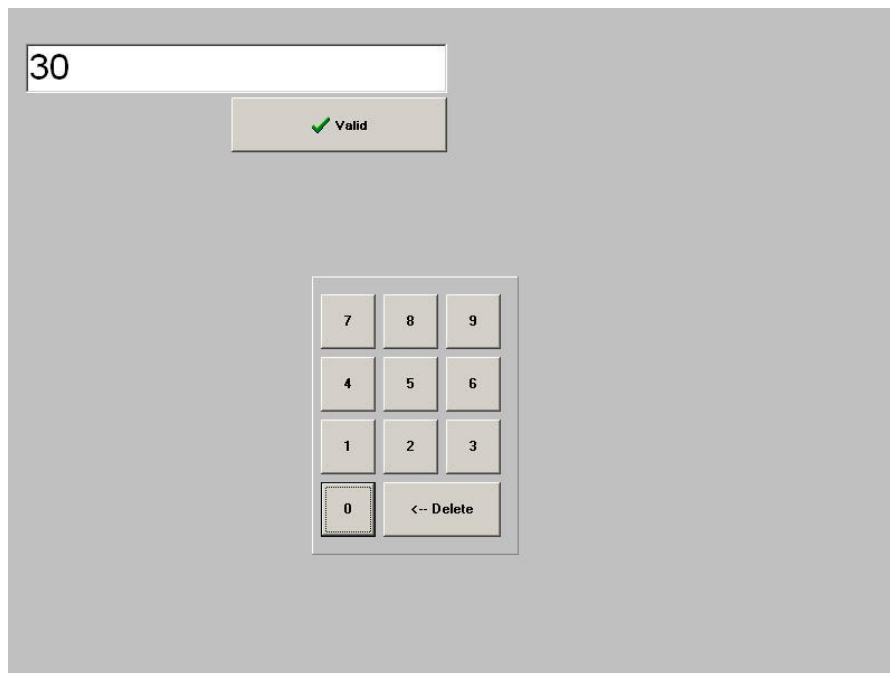
Figure 16

Figure 17: example with the two chosen threshold values

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021
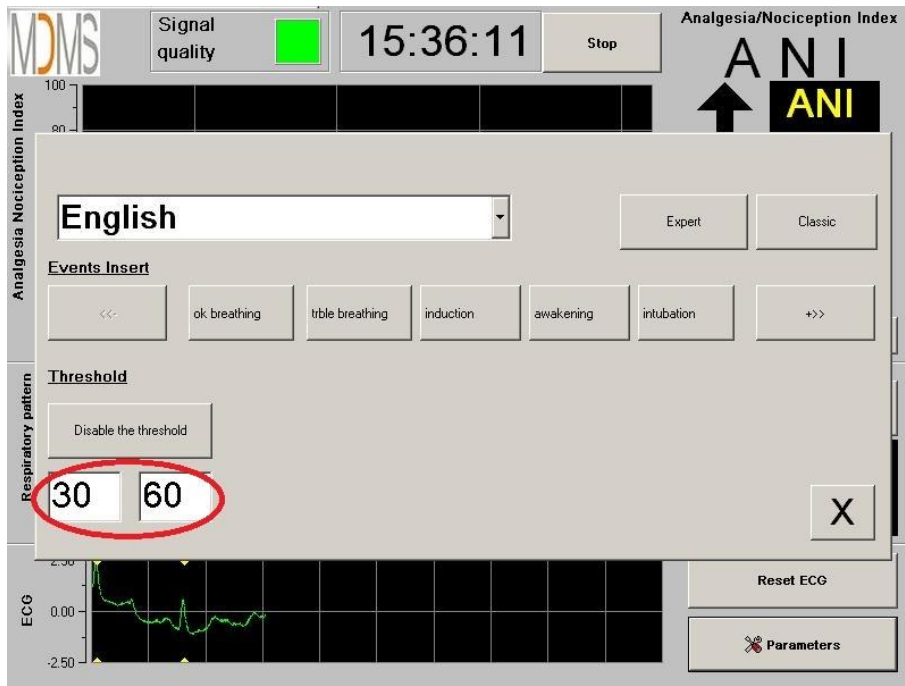
Figure 17

Figure 18: Threshold values
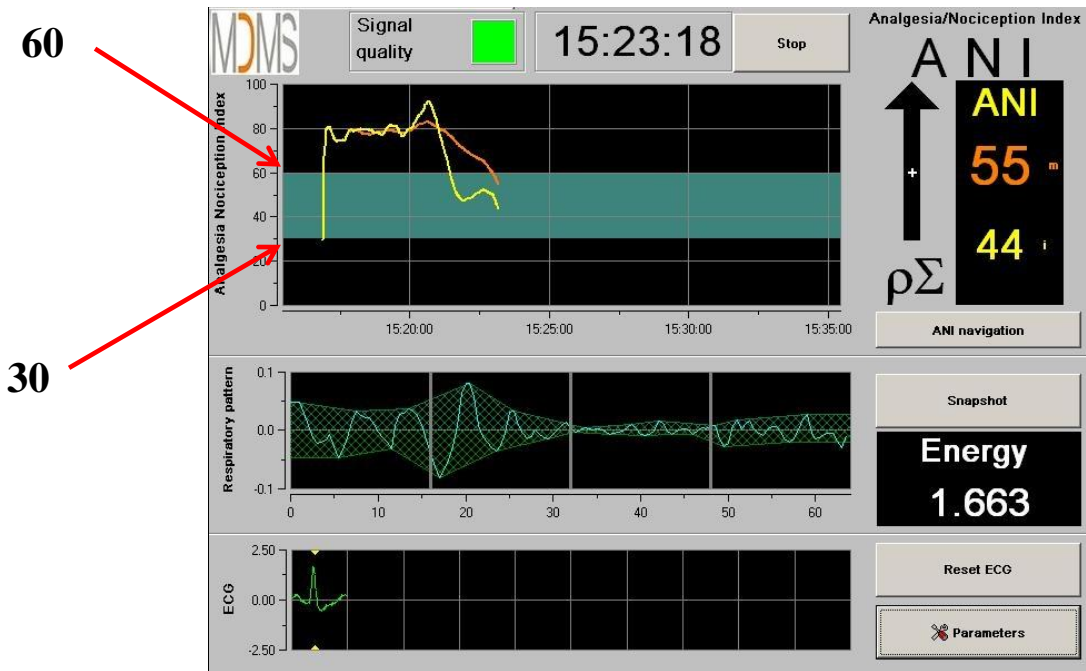
Figure 18

6.3   Events insert

As shown in the screen below (figure 19), here you have the possibility to insert clinic events so that they can be visible into the tendencies curves and also in the exportable data. Pressing anyone of these buttons inserts a mark in the ANI trend panel and in the recorded RR file.

An example of a file's content is given below:

Figure 19

- ok breathing
- trble breathing
- induction
- awakening
- intubation

- extubation
- no stimulation
- surg stimulation
- hemo reaction
- movements

- cough
- re-inject morphinic
- re-inject hypnotic
- VAS

The insertion of one of these events among the list leads automatically to the memorization in the "Index" file type. It is possible to download this file on a USB stick for further analysis (see chapter 8.7 below). It is also possible to edit your own list of desired events (see chapter 8.8 below).

6.4   Expert mode and Energy index

There are two modes:

- **"Classic" mode** : no energy, no respiratory pattern (figure 20)

Figure 20

- **"Expert" mode** which displays respiratory pattern and one more function called "*Energy*" (figure 21)

Figure 21

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021

The *Energy* index is equivalent to the "total spectral power of the autonomous nervous system". When the value of the *Energy* index varies dramatically, it means that the ANI calculated at this specific moment is not significant of the patient's parasympathetic tone value. If the *Energy* index is lower than 0.05 or above 2.5, the ANI calculation is interrupted even if the ECG is still acquired. An *Energy* index lower than 0.05 or above 2.5 is not significant of the patient's parasympathetic tone. The *Energy* index doesn't mean at any moment a concept of patient's energy or patient's parasympathetic tone but an ECG signal norm acquired by the PhysioDoloris Monitor V1.

To set up the "Expert" mode, once entered in parameters setup (button **[Parameters]**), touch the button **[Expert]** then the button **[X]** to return to the main screen.

To cancel the "Expert" mode and return to the "Classic" mode, do the same procedure but touch the button **[Classic]** (figure 22).

Figure 22

7 Operating the PhysioDoloris Monitor V1

7.1 Quit Patient

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021

Pushing the button **[Stop]** in the top of the screen will end the monitoring and give access to the main menu. A confirmation window will appear before definitively stopping the monitoring (figure 23).
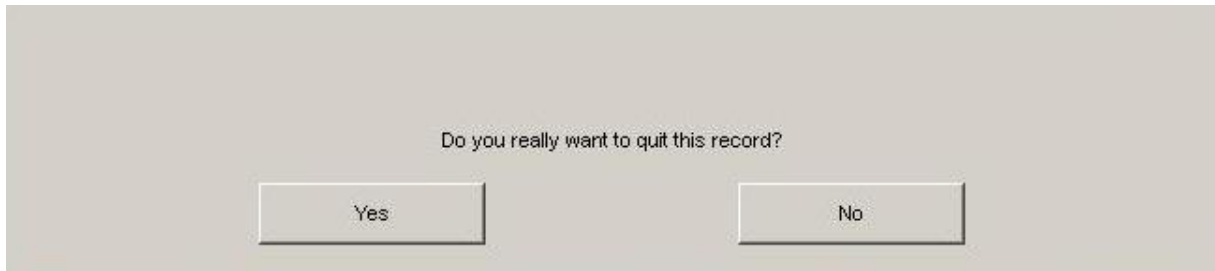
Figure 23

To note: *by clicking on* ***[Yes]****, no return to current patient will be possible.*

If you choose "**Yes**", the main menu window will be displayed (figure 24):
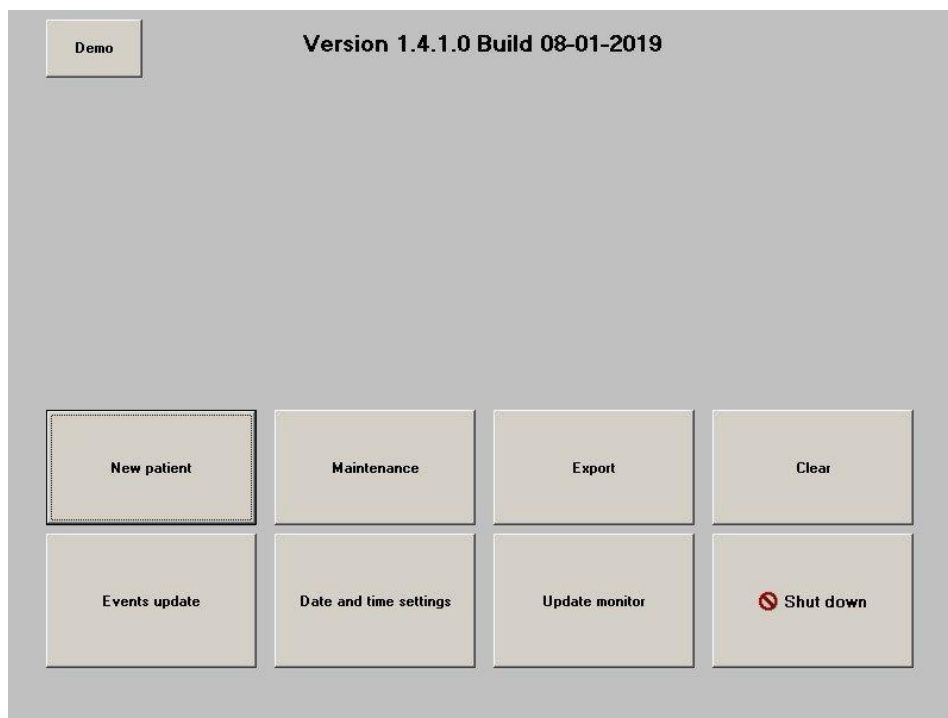
Figure 24

7.2   *Demo*

Selecting **[Demo]** (figure 24) shows you a video of ANI functioning.

7.3   New patient

Selecting **[New patient]** (figure 24) initializes the monitoring and launches a new patient data including new file storage.

7.4   Maintenance

Selecting **[Maintenance]** (figure 24) opens a window with an input field (see figure 25 next page). This access is protected by a code that will be forwarded on request to Mdoloris Medical Systems.
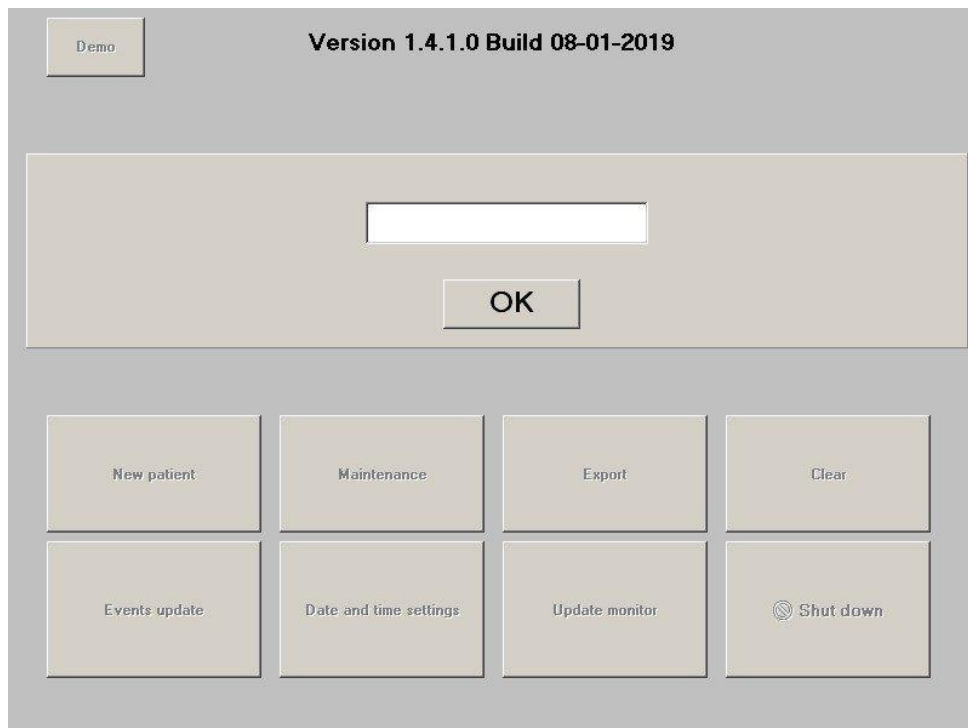
Figure 25

k

7.5   Delete patients data

Pressing the button **[Clear]** deletes all data previously computed and saved. A message will appear to confirm the action (figure 26).

Do you really want to suppress all the records?

Yes   No
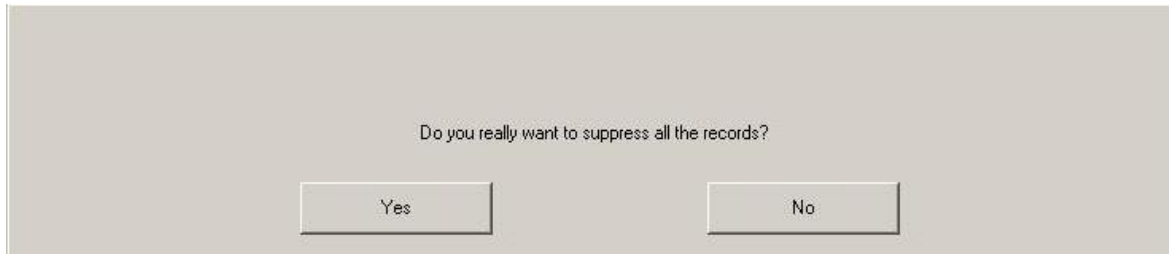
Figure 26

When all data are deleted, another window will appear to confirm that the action is successfully done (figure 27). Press the button **[OK]** to return to the main menu (figure 24).

Suppression successfully done
OK

Figure 27

7.6   Screen shot

When the user presses the button **[Screen shot]**, information displayed is saved in the monitor's memory as picture format. Each time the user decides to get a screen shot, one picture will be saved in the monitor's memory.

A message will appear to confirm the success of the screen shot (figure 28). Press the button **[OK]**.

Figure 37

Snapshot
OK

Figure 28

To get these pictures, a USB stick has to be plugged in the USB port called "Data Export". Then the user selects **[Stop]** in the top of the screen. In the new window opened (figure 24), choose **[Export]**. The pictures will be saved in a file. Each file name will follow this rule: Hour – Minute – Month – Day - Year.

7.7 Export Data

A press on the button **[Export]** (figure 24) sends all data saved in the monitor memory into a USB stick. To export the data you need to connect a USB stick in USB port called "*Data Export*". If the monitor doesn't detect any USB stick (USB stick isn't plugged or bad connection), a message will appear to inform the user (figure 29). When the USB stick is well connected, press on **[OK]** and **[Export]** again to start the data export.

Figure 29

At the end of this step, a message will appear to confirm the success of the export (figure 30). Press the button **[OK]** to back to the main menu.

Figure 30

Note:

Data are automatically saved into a file including the date and hour on of the beginning of the monitoring. File exporting format is text extension like this for an easy secondary use. Each file name will follow this rule: Hour – Minute – Month – Day - Year.

Example: 08_46_04_15_11Index
Document texte
15,4 Ko

It is also possible to do a permanent download by connecting a computer on serial port "3" located on the rear side.

<u>***NOTE***</u>: *if the cable happens to be disconnected during the recording of the data, connect the items concerned again in the acquisition chain as soon as possible. The recording which will start up after this interruption will be considered as a new one. You must therefore enter an event for this interruption so that this interruption in the data can be taken in account in the next data processing.*

7.8 Update of events

As explained previously (see chapter 7.3), events corresponding to several clinical moments are predefined in the system. The use can display those different events on the ANI trend panel. A press on the button **[Stop]** in the top of the screen will end the monitoring and will access to the main menu (figure 24). A confirmation window will appear (see figure 23, chapter 8.1).

To note: *by clicking on **[Yes]**, no return to current patient will be possible. You will have access to the main menu (figure 24).*

To access and update the events list, press **[Events update]**. The events update menu will appear (figure 31).
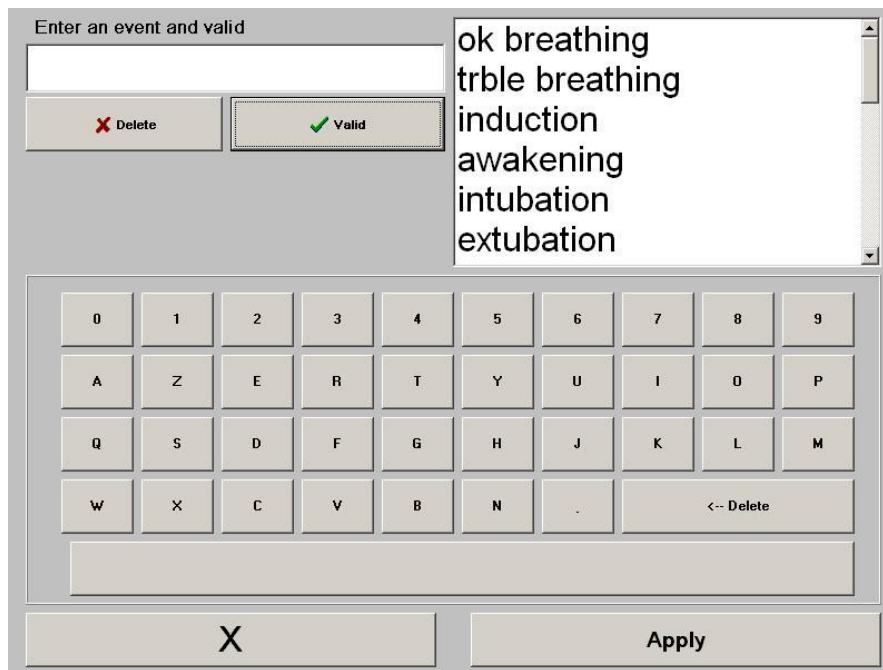
Figure 31

To add new events in the list, you have to use the virtual keyboard on the screen and then validate with the button **[✓ Validate]**. 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. To see it, you have to use the scrollbar. To delete an event, you have to select it in the list by touching the word on the screen and touch the button **[✗ Delete]**.

To validate the changes done (add or deletion of one or more events) you have to confirm that by touching the button **[Apply]** then **[X]** to close the window.

7.9   Date and time settings

To set the clock or the date, you have to select **[Stop]** to reach the main menu (figure 24):

Then select **[Date and time settings]**. The following window will appear:
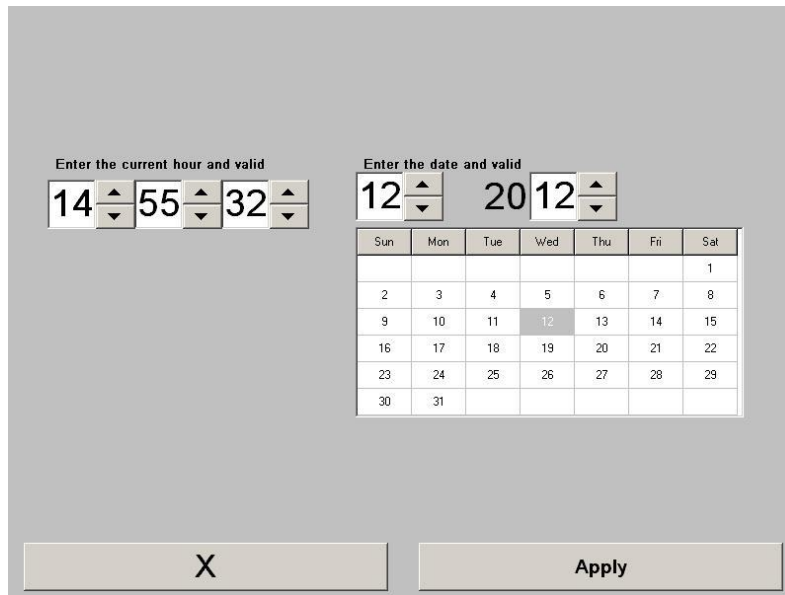
Figure 32

Use the arrows to choose the modifications you want. To validate the changes done, you have to confirm by touching **[Apply]** then press **[X]** to close the window.

7.10 Update monitor

In the main menu (figure 24), select **[Update monitor]**. Plug an USB stick with the new version of "PhysioM_INT.exe" provided by your Mdoloris Medical Systems representative. Then select **[Update monitor]** (see figure 33 next page).

Figure 33

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021
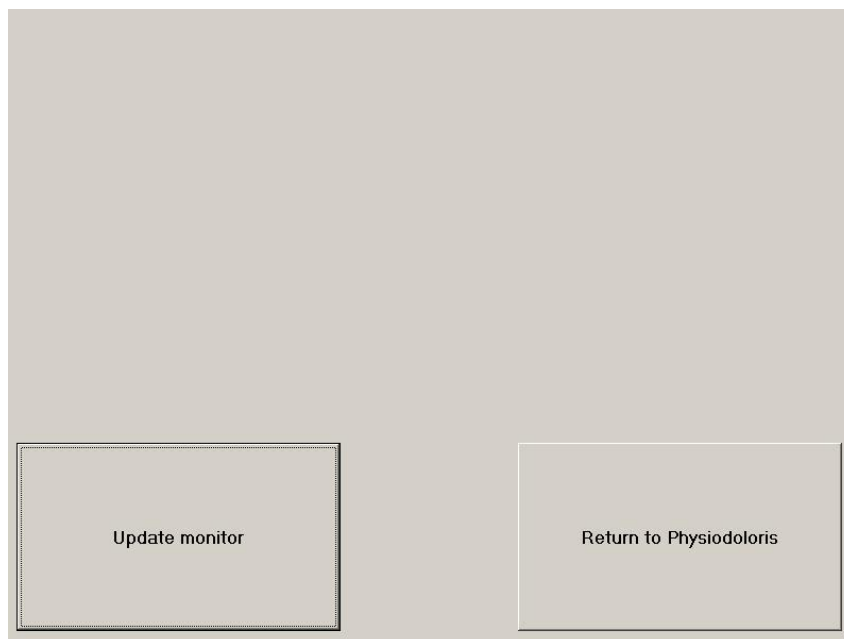
A message will appear to confirm the success of the updating (figure 34). After 5 seconds, press on **[Return to Physiodoloris monitor]**.
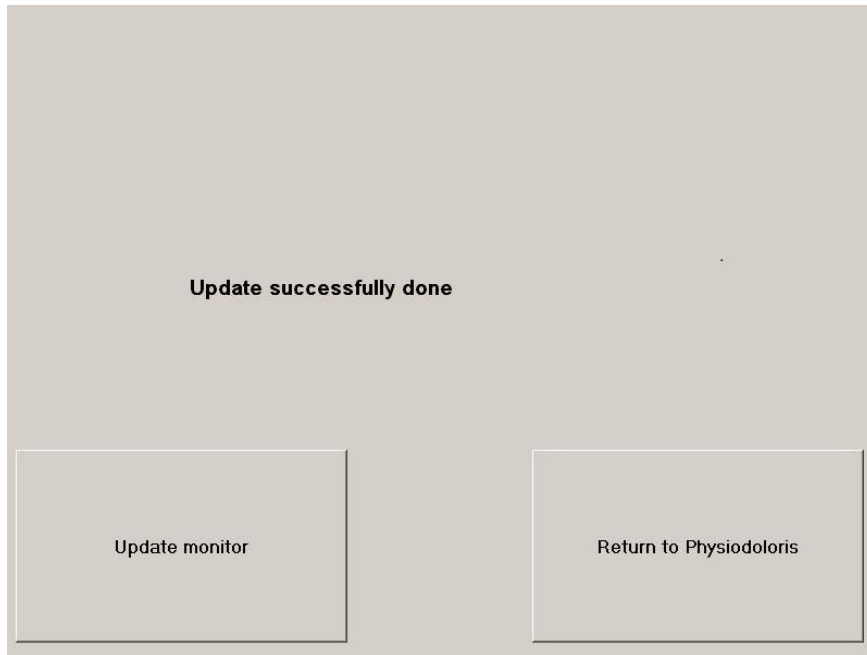
Figure 34

If an USB stick isn't plugged, a message will appear to inform the user (figure 35):
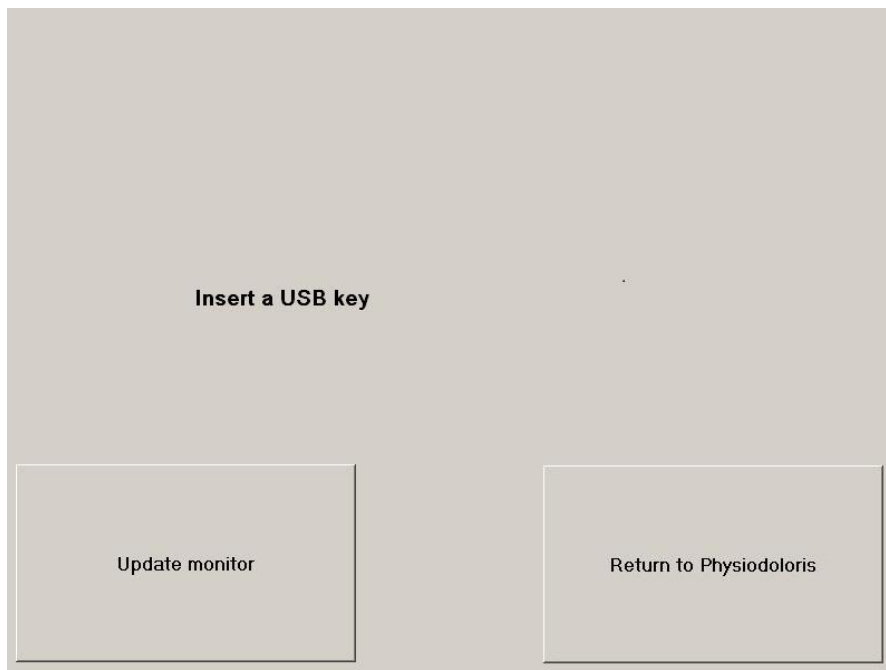
Figure 35

If the "PhysioM_INT.exe" isn't present on the USB stick, a message appears (figure 36):

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021
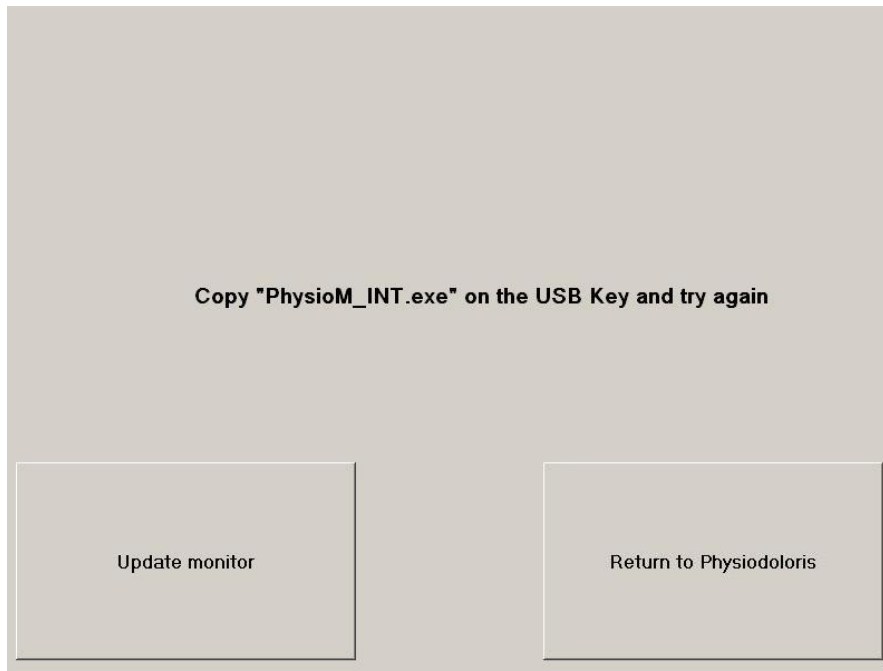
Figure 36

7.11 Shutting down the PhysioDoloris Monitor V1

Pressing the button **[⊘ Shut down]** (figure 24) ends the session and will shut down the PhysioDoloris Monitor V1.

NOTE: *it is also possible to shut down the monitor by switching directly the ON/OFF switch located on the lower side of the monitor, only if you cannot 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 PhysioDoloris Monitor V1 IS BEING USED, IT COULD AFFECT THE MONITOR'S PROPER WORKING ORDER.

8 Problem solving

Problem	Perform the following tasks	If failure :
There is no ECG signal displayed on the monitor.	Check that the monitor is correctly connected to the multi-parameters scope.	Contact Mdoloris Medical Systems interlocutor
An ECG signal is displayed but seem aberrant (flat tracing, irregular, parasite…)	Check the good quality of the wiring and positioning of ECG electrodes.	Contact Mdoloris Medical Systems interlocutor
ECG signal waves seem physiologically incorrect.	Check the color coding in the connection of electrodes related to the source monitor.	Contact Mdoloris Medical Systems interlocutor
Mdoloris Medical Systems interface does not appear automatically at the monitor starting up.	Contact Mdoloris Medical Systems interlocutor	
The cabling for the connection on the multi-parameters scopes is not the good one.	Contact Mdoloris Medical Systems interlocutor	
Touch button do not function.	Reboot the monitor by pressing the button ON/OFF.	Contact Mdoloris Medical Systems interlocutor

9 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 monitor before you dispose of your system. You should respect local regulations regarding electric and electronic items.

You can disassemble the monitor and the acquisition device:

- The acquisition device is in steel.
- The screen is recovered by a laminated layer resistant to the touch.
- You can recycle the user manual printed on paper.
- All the electronic elements of the system respond to the Directive RoHS.

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.

10 Environnement

10.1 Shipping and Storage Environnement

The PhysioDoloris 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 to condensation within the instrument. To minimize the risk of condensation, avoid moving the system between heated buildings and outside storage. Once moved inside, allow the monitor to stabilize in its unopened shipping container, at the inside 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.

10.2 Operating Environnement

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

WARNING: *EXPLOSION HAZARD: DO NOT USE THE PhysioDoloris Monitor V1 IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.*

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021

The PhysioDoloris Monitor V1 is designed to operate safely in a temperature from 5° to 40° C to an altitude of 2000m, in a humidity range from 15% to 95% (non-condensing) and a pressure from 480 hPa à 1066 hPa. Conditions that exceed those limits may modify its reliability.

10.3 Power Requirements and System Grounding

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

To protect operating personnel and patients, the monitor must be properly grounded. Accordingly, the monitor is equipped with a hospital grade line cord. The power cord grounds the system to the power line ground when plugged into an appropriate three-wire receptacle.

CAUTION: *FOR PROPER GROUNDING, THE POWER RECEPTACLE 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.*

11 Cleaning and disinfection

11.1 Cleaning

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

Cleaning the monitor and acquisition device:
clean any spillage of blood or solutions on either the monitor or acquisition device. The 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 monitor screen:

Clean the monitor 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 and the acquisition device:

Use lint-free absorbent towels dampened with a 10% bleach solution, or a commercial disinfectant. After cleaning, dry all areas except the monitor 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.*

CAUTION: 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.

11.2 Leakage Current

The PhysioDoloris 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
- Pole clamp.

12 Specifications, warranty and software license agreement

12.1   Specifications

Power Requirements: 100-240 Volts, 50/60 Hz, 3A

Consummation: < 32 W

Electrical Safety: category I conforms to IEC 60601-1.

Weight of the monitor (without any accessory): 2.73 lb.

Weight of the acquisition device: 0.57 lb.

Dimensions of the monitor (inches): 9.21 width x 7.24 height x 1.62 thick

Dimensions of the acquisition device (inches): 1.97 width x 1.04 height x 5.31 length (stuffing box included)²

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: Mdoloris Medical Systems reference: MN-PHY-V1

  Manufacturer: IEI (product reference: AFL-08A-N270)
- Acquisition device: Mdoloris Medical Systems reference: BA-PHY-V1

  Manufacturer: RHEA Electronique
- Adaptator AC/DC FSP 036

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 be under tension in the event of a failure of the basic insulation.

Protection against the ingress of liquids:
Be sure to install the PhysioDoloris Monitor V1 (Screen and acquisition device) outside any area with a risk of blood or liquids ingress.

System functioning:
Continuously: operation under normal load for a normal period without exceeding the specified limits of temperature.

Electrosurgery Interference/Defibrillation/Electromagnetic disturbance:
The PhysioDoloris Monitor V1 is comply with standard IEC 60601-1-2: 2014 (Ed.4)
The PhysioDoloris 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 A
- IIa Electro-Medical Equipment

12.2 Warranty

Mdoloris Medical Systems warrants to the initial Purchaser that the PhysioDoloris Monitor V1 and the acquisition device ("Warranted Product") will be free from defects in workmanship or materials, when given normal, appropriate, and intended usage for a period of one year ("Warranty Period") from the date of its initial shipment to Purchaser. Excluded from this

MD/PRD/IN16.PHYSIO V.15 – 29 SEP 2021

warranty are expendable components and supply items such as, but not limited to, cables, touch screen and other 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 (see contact information on the last page of this manual). 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. During the warranty period, 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 shipping costs of 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 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 external causes 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, repaired, or reassembled by anyone other than Mdoloris Medical Systems, unless authorized by Mdoloris Medical Systems. Mdoloris Medical Systems shall

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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

<u>For any other problem</u>:

please contact your Mdoloris Medical Systems representative

or contact@mdoloris.com