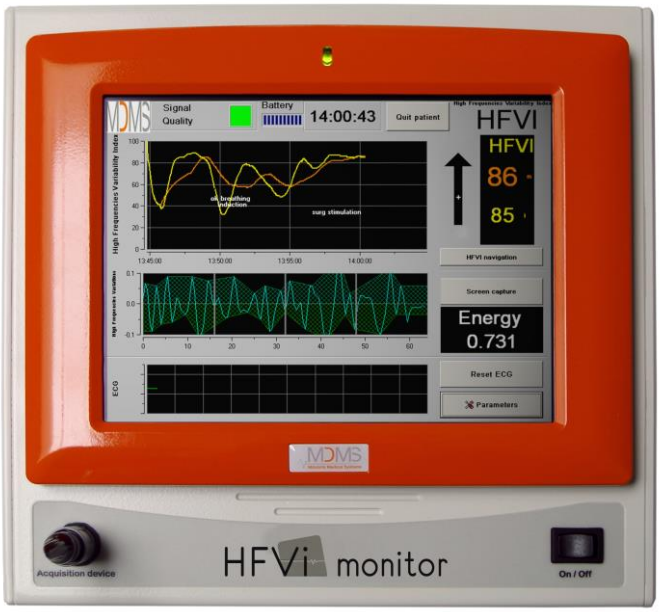
- HFVI Monitor-

User manual

Software Version 1.1.3.1



Mdoloris Medical Systems SAS
270, rue Salvador Allende
59120LOOS, FRANCE
Phone: +33 (0)3 62 09 20 80 - Fax: +33 (0)9 72 38 75 27

<u>Important information about using the Heart Rate Variability Monitor</u>:

The Mdoloris Medical Systems SAS HFVI Monitor 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 system is intended for use on adult and pediatric patients, in a facility providing patient care by monitoring heart rate variability.

The High Frequency Variability Index (HFVI) is a complex monitoring technology intended for use as an adjunct to clinical judgment. Clinical judgment should always be used when interpreting the HFVI in conjunction with other available clinical signs. As with any monitored parameter, artifacts and poor signal quality may lead to inappropriate HFVI values. Potential artifacts may be caused by muscle activity or rigidity, patient motion, improper sensor placement or electrical interference.

Contents

1 Safety precautions

INTRODUCTION

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

⚠ **WARNING**

A warning advises against certain actions or situations that could result in physical injury or death. Accidents may result from the inability to avoid a hazardous situation. This is why it is important to follow the instructions in these warnings, to prevent personal injury.

⚠ **CAUTION**

A caution advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure, when personal injury is unlikely.

⚠ **NOTE**

A note provides useful information regarding a function or procedure.

KEY TO SYMBOLS

A key to the symbols that may appear on the HFVI monitor appears at the end of this section.

1.1 Warning

⚠

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

⚠

PROTECTION AGAINST HEART DEFIBRILLATION SHOCK DEPENDS ON USING THE APPROPRIATE CABLES.

⚠

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

⚠

NEITHER THE MONITOR NOR THE ELECTRODES ARE DESIGNED FOR USE IN A MAGNETIC RESONANCE IMAGING (MRI) ENVIRONMENT.

⚠

THIS HFVI MONITOR CANNOT BE IN ANY CASE CONSIDERED AS AN ECG MONITORING SYSTEM.

⚠

WHEN USING ELECTRO-CONVULSIVE THERAPY (ECT) EQUIPMENT DURING HFVI MONITORING: place ECT electrodes as far away as possible from the HFVI sensor to minimize the effect of interference. Some ECT equipment may interfere with the HFVI monitor's signal. Check for equipment compatibility 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 GROUNDING IS IN DOUBT, DO NOT USE THE HFVI MONITOR.

⚠

BE SURE THE MONITOR IS INSTALLED SECURELY TO AVOID INJURY TO PERSONNEL OR PATIENTS.

⚠

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

⚠

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE MANUFACTURERS' REQUIREMENTS MAY INFLUENCE THE SAFETY OF THE RESULTING SYSTEM.

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 HFVI MONITOR.***

⚠

TO AVOID PATIENT INJURY DUE TO HIGH SURFACE TEMPERATURE, DO NOT PLACE THE INTERFACE EQUIPMENT DIRECTLY IN CONTACT WITH SKIN.

⚠

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

⚠

TO MINIMIZE THE RISK OF PATIENT BURNS FROM THE NEUTRAL ELECTRODE FOR HF SURGERY, DO NOT PUT THE HFVI ELECTRODES BETWEEN THE SURGICAL SITE AND THE ELECTROSURGICAL UNIT'S RETURN ELECTRODE.

⚠

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

⚠

DO NOT PLACE THE SKIN ELECTRODES BETWEEN DEFIBRILLATOR PADDLES WHEN THEY ARE USE ON A PATIENT CONNECTED TO THE HFVI MONITOR.

⚠

REUSING A SENSOR ALREADY USED ON ANOTHER PATIENT COULD LEAD TO CROSS-CONTAMINATION.

⚠

IF THE PATIENT DEVELOPS A SKIN REACTION OR OTHER UNUSUAL SYMPTOMS, REMOVE THE ELECTRODES. IT IS IMPORTANT TO TAKE PARTICULAR CARE WITH PATIENTS SUFFERING FROM DERMATOLOGICAL PROBLEMS.

⚠

NEVER PUT ELECTRODES ON SKIN INJURIES.

⚠

ELECTRICAL SHOCK:

- ***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 BELOW THE LIMITS SPECIFIED BY THE APPLICABLE SAFETY STANDARDS. AS A MATTER OF SAFE PRACTICE, THE FACILITY MUST CONDUCT TESTS TO VERIFY THESE CURRENTS ESPECIALLY***

WHEN A BIOMEDICAL ENGINEERING TECHNICIAN PERIODICALLY PERFORMS MAINTENANCE.

WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR LIQUIDS OCCURS on the HFVI Monitor, RE-TEST GROUND LEAKAGE CURRENT BEFORE FURTHER USE.

⚠

OBSERVE UNIVERSAL PRECAUTIONS TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. CONTAMINATED MATERIALS MUST BE HANDLED IN ACCORDANCE WITH THE FACILITY'S APPLICABLE HEALTH AND SAFETY REGULATIONS.

⚠

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

THE HFVI MONITOR COMPLIES WITH THE 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 OUTLETS***
- ***CONTACT YOUR MDOLORIS MEDICAL SYSTEMS REPRESENTATIVE.***

⚠

IN OPERATING ROOMS THE HFVI MONITOR MUST BE PLACED OUTSIDE THE EXPLOSION HAZARD ZONE.

⚠

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

⚠

NEVER MODIFY THE MONITOR WHEN OPEN.

1.2 Caution

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

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

The patient should not be able to reach the equipment directly or indirectly; avoid for instance placing equipment on top of another equipment with a metal casing.

To remove power supply from the monitor, unplug the power cable.

Staff should avoid touching simultaneously patient and HFVI Monitor.

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

Do not block ventilation inlet holes of monitor (there are some on top of it also).

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

Using electrode sensors other than those specified by the manufacturer can damage the device, and increases risk of harm to the user or the patient.

Reusing a sensor could reduce adhesion, leading to a possible decrease in ECG signal acquisition performance.

Reusing a sensor could reduce its adhesion.

The HFVI monitor should not be used near or placed on top of another electrical equipment. If however this is unavoidable, check regularly that the HFVI monitor operates properly in this configuration.

Only Mdoloris Medical Systems qualified biomedical technicians are trained to perform service or repairs on HFVI Monitors.

The HFVI monitor contains an internal battery. This battery is not user-replaceable. Contact Mdoloris Medical Systems or the local distributor for battery maintenance.

The internal battery is not designed for long-term monitoring. The HFVI monitor's internal battery allows the system to keep calculating the HFVI while the patient is being moved or in case of temporary interruption of the main power supply. The duration of the battery is from 90 to 100 minutes.

Check the battery charge symbol before unplugging the main power supply; if the internal battery is insufficiently charged, the HFVI Monitor will switch off automatically.

After reconnecting the HFVI Monitor to the main power supply, press the power switch on the front side of the monitor. In case the monitor does not start, press the switch at the back of the monitor in order to reboot the device.

Never use the HFVI monitor only on battery power during surgery. The monitor must be plugged on the main power supply, especially while an electric knife is being used.
Only personnel trained by Mdoloris Medical Systems can safely perform service or repairs on HFVI Monitors. However, the following elements may be replaced by personnel untrained in technical maintenance (following the manufacturer's instructions):

- End User Cable;
- Power cord;
- Acquisition unit (BA-HFVI-V1);
- Pole clamp.

This medical equipment, its components and packaging must be recycled in accordance with local regulations on the environment and disposal of electric wast

1.3 Notes

"Notes" can be found at the end of each section.

1.4 Key to symbols

	Consult operating manual		Serial number
	Class 1 Electric isolation		Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)
	Do not expose to sunlight		Caution: follow the recommendations in the operating manual
	Check the packaging quality upon delivery		Needs special waste disposal
	BF Type equipment, protects against defibrillation		Temperature range
	Date device manufactured		Do not expose to liquid projections
	Manufacturer		

2 HFVI Monitor

Indications for use:

The Mdoloris Medical Systems SAS HFVI Monitor is intended to acquire, display and analyze electrocardiographic information and to measure heart rate variability (HRV). These and other measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV and other parameters must be determined by the physician.

HFVI (High Frequency Variability Index) is a standardized continuous measurement of heart rate high frequency variations. The series of normal, non-ectopic, R-R intervals is displayed on the screen of the HFVI Monitor after normalization, resampling and filtering. The amount of high frequency variations is measured in relation to the total window surface through the area comprised between the lower and the upper envelope of the RR series, which is continuously displayed as a shaded area. The higher the HFVI, the higher the shaded surface, and reciprocally.

HFVI measurement cannot be interpreted in the following situations:

- apnea (e.g. apnea induced by anesthesia)
- respiratory rate lower than 9 cycles/min
- electric noise during the measurement period (64 seconds)
- irregular spontaneous ventilation (patient speaking, laughing or coughing)
- pace maker (certain types)
- heart transplant
- drugs affecting the sinus node (atropine and other anticholinergic drugs, etc.).

The HFVI is expressed between 0 and 100%. Each HFVI value is computed on one time window of 64 sec. This number shows the relative high frequency variations. The HFVI Monitor displays two averaged HFVI measurements: HFVIi results from the average of HFVI measured over the last 120 sec, and HFVIm results from the average of HFVI measured over the last 240 sec.

3 Installing the HFVI monitor

3.1 Perfusion stand

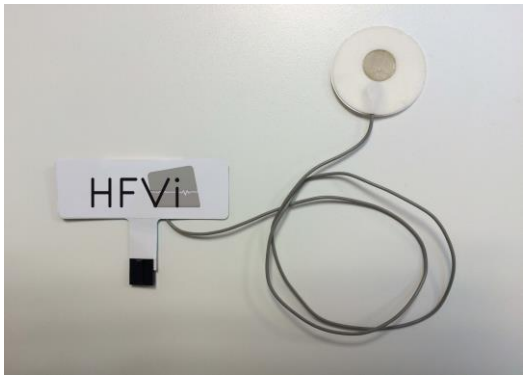
Position the HFVI Monitor in order for the main power supply to be easily plugged in. The monitor can be installed on a perfusion stand by using a specific "pole clamp", which fit pole diameters ranging from 19 to 38 mm. **The user is responsible for ensuring that a suitable stand is used.**

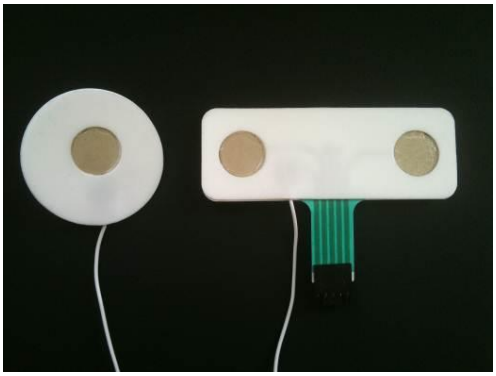
3.2 HFVI sensor

HFVI calculation is based on R-R interval variability in ECG. Since the HFVI monitor is not an ECG monitor, the electrodes have been designed to retrieve information related to QRS complexes. The acquisition of a cardiac vector is enough to get an HFVI calculation.

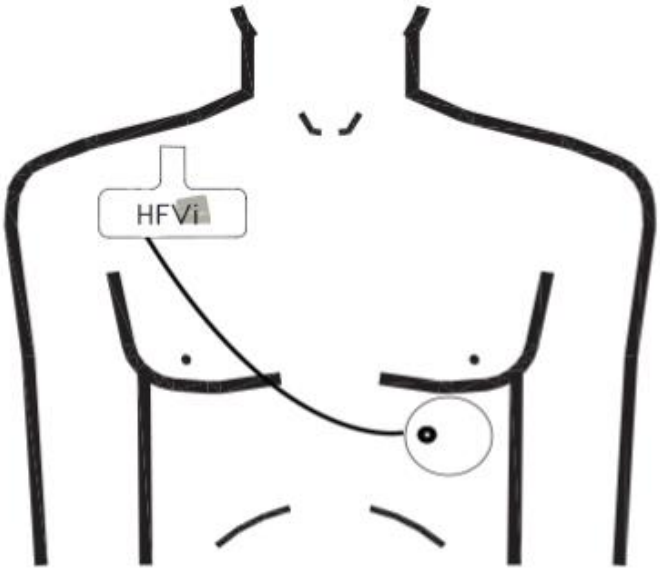
The electrodes are composed of a two-part device: a dual sensor and a single sensor connected together by an electrical thread.

The sensor itself is divided into two areas. One part is an adhesive area and the other, the active area, is covered with conductive gel.





The principle of this two-part device is to place it on each side of the heart (thus on each side of the chest) to get a cardiac vector (the axis of the average cardiac vector according to the reference anatomical position is: forward, down and left). In this case the dual sensor is applied on the patient's chest, the big patch on the upper chest and the small patch on the left side of the chest.



Sensors positioning

<u>WARNING</u>:

Reusing a sensor already used on another patient could lead to a risk of cross-contamination.

If the patient develops a skin reaction or other unusual symptoms, remove the electrodes. It is important to take particular care with patients suffering from dermatological problems.

Never put electrodes on skin injuries.

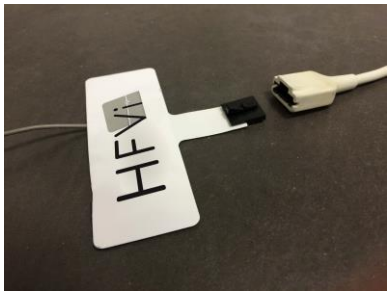
<u>NOTE</u>: The HFVI monitor has been designed to work with specific disposable sensors. It is inadvisable to use another kind of electrode.

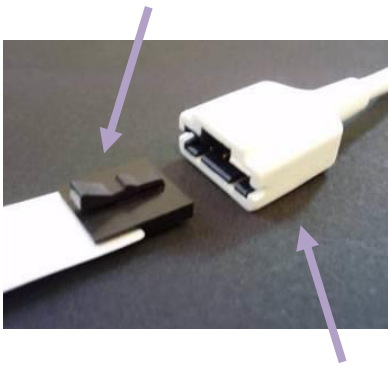
Electrodes are packaged ten per bag. New electrodes can be purchased in boxes of ten bags i.e. one hundred devices in total.

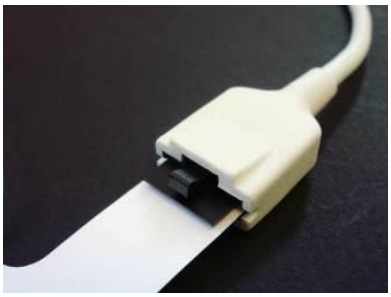
The maximum consecutive period that the electrodes can adhere to the skin is 24 hrs. The electrodes' shelf life is noted on the opaque white pouch: in an opaque white pouch, it is two years. In an opened opaque pouch, the electrodes' shelf life is six months.

Biocompatibility has been tested on all Mdoloris Medical Systems sensors. They meet standards ISO 10993-5 and ISO 10993-10.

Before connecting, carefully align the notches on the connection sheet to make the pins correspond perfectly (see pictures). To disconnect the electrodes, grasp the plastic portion while pressing on the locking mechanism and pull gently to disengage it (see picture).**Do not pull by grasping the electrode itself.**

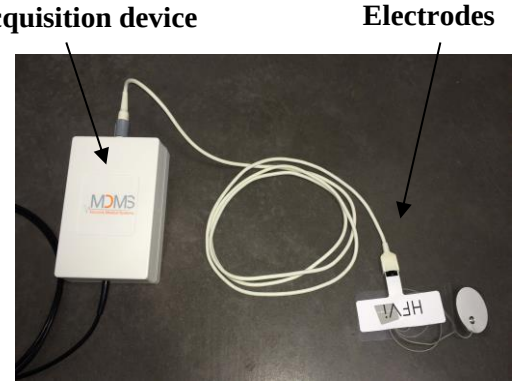






3.3 HFVI monitor connection

Connect the electrodes to the acquisition device using the cable provided by your Mdoloris Medical Systems representative (see pictures).



Connect the black cable of the acquisition device to the monitor at the plug in the bottom left hand corner of the monitor's front (see pictures).

3.4 Battery

The HFVI monitor contains an internal battery. The battery means the system can keep calculating the HFVI while the patient is being moved or in case of main power supply failure. The internal battery is not designed for long-term monitoring. The battery gauge has ten graduations; each symbolizes around 10 min of battery life. As soon as the power supply is interrupted, a message appears on the screen with a warning sound to ask the user to plug the monitor back on the main power supply. The HFVI is still calculated during this time.

NOTE: plug the HFVI Monitor on the main power supply before trying to switch it on.

Check the battery charge symbol before unplugging the main power supply; if the internal battery is insufficiently charged, the HFVI Monitor will switch off automatically.

After reconnecting the HFVI Monitor to the main power supply, press the power switch on the front side of the monitor (see picture below). In case the monitor does not start, press the switch at the back of the monitor (see picture Power switch) in order to reboot the device.

Never use the HFVI monitor only on battery power during surgery. The monitor must be plugged into the main power supply, especially while an electric knife is being used.

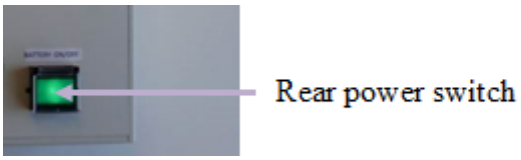
4 Beginning HFVI Monitoring

Turn the monitor on using the switch on the front at the bottom right (see picture).

Switch

NOTE: If the front switch does not turn the monitor on, check that the green rear button is lighted. If this power indicator is off, lift up the light's transparent cover and push the button to reboot the device.

<u>WARNING</u>: *Only use this green button on the rear to turn the monitor on. Never use it to shut the device down. Stopping suddenly could lead to dysfunction when it is next switched on and prevent normal use.*



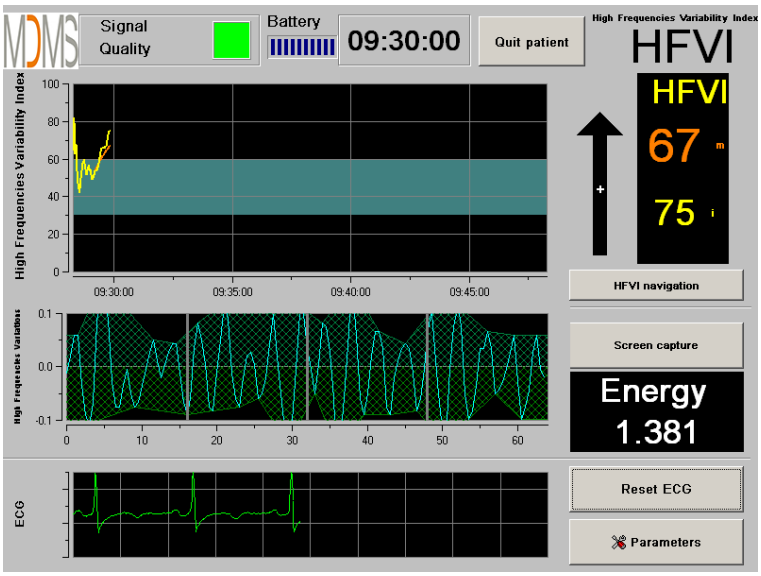
Power switch

The monitor will start by showing the Mdoloris Medical Systems logo animations successively. The screen will then show the start page automatically, indicating "Initialization" on the central screen (see figure **Initialization**).The first HFVI measurement will take at least 80 seconds. No data can be interpreted before this initialization time lapse.

Initialization

Once the monitor is connected to the patient with the electrodes, the calculation algorithm will automatically begin (see figure **Main display**).

***Note**: The HFVI technology can be used with both conscious and unconscious patients, whenever the physician wishes to use it.*



Main display

Check for good ECG signal quality in the lower part of the screen. If there is no signal, check the connection between the monitor and the electrodes. Try at least once to unplug and plug in the connection again to recover the ECG signal. If a signal is displayed but does not look right, check that the electrodes are properly placed and connected to the cable.

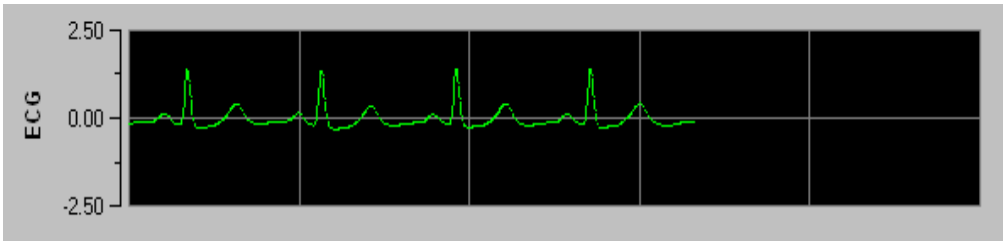
WARNING: *always check in the upper left window that the signal quality is satisfactory (green indicator). The HFVI index will not be reliable if the signal quality is not good enough (red indicator).*

If the user thinks the ECG amplitude is too low, select **[Reset ECG]** to automatically recalculate the gain of the the ECG signal acquisition.

5 Using the HFVI monitor and setting parameters

5.1 ECG Capture

The lower window shows the ECG acquired by the monitor (see figure **ECG**). This ECG is filtered of all technical and physiological artifacts (e.g. premature ventricular contractions).

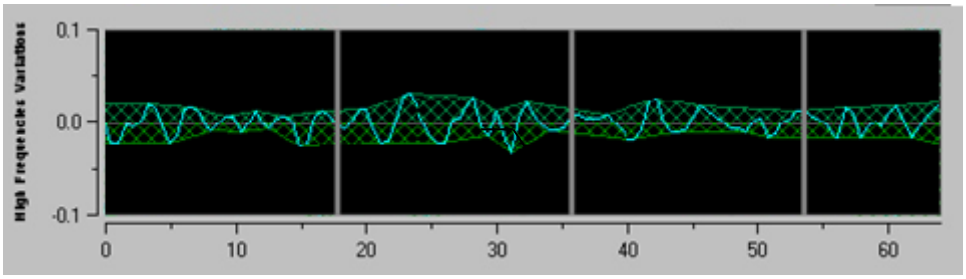


ECG

5.2 Filtered R-R series

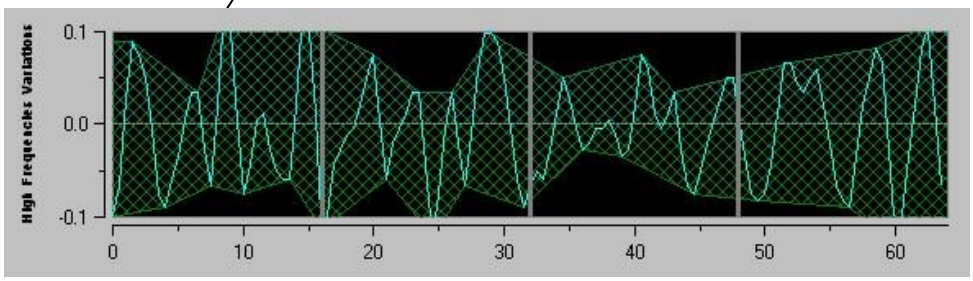
R waves are detected on the ECG signal in order to build the R-R series. The R-R series is mean-centered, normalized and filtered between 0.15 and 0.4 Hz in order to keep only high frequency variations. The surface area generated in the R-R series is measured and displayed in a hatched surface (see figures below). The higher the surface, the stronger the high frequency variations.

Small hatched surface area = low *High frequency variations*



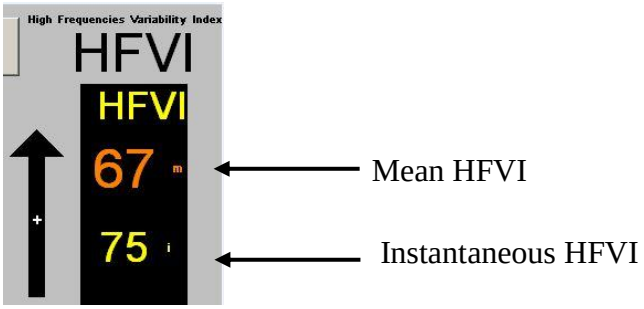
Mean-centered, normalized and filtered R-R series with low *High frequency variations*

Large hatched surface area = high *High frequency variations*



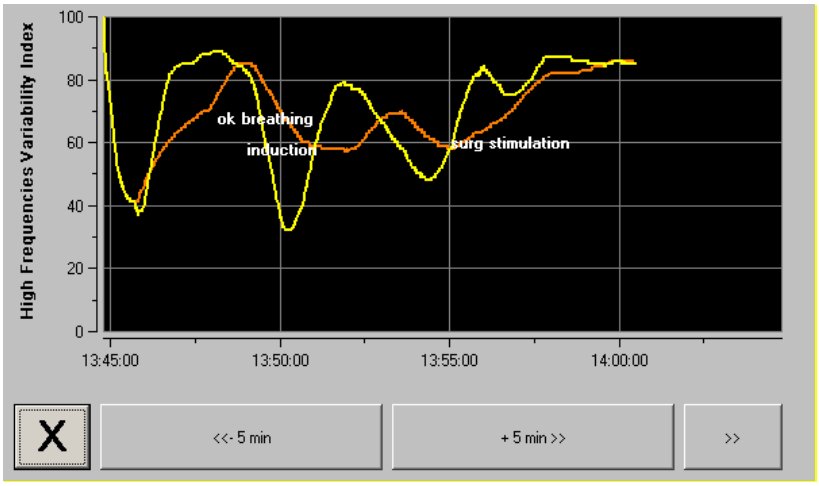
Mean-centered, normalized and filtered R-R series with high *High frequency variations*

5.3 HFVI index



Index

In the neighboring window two trends of HFVIi and HFVIm are displayed (yellow and orange) (see figure **curves**).

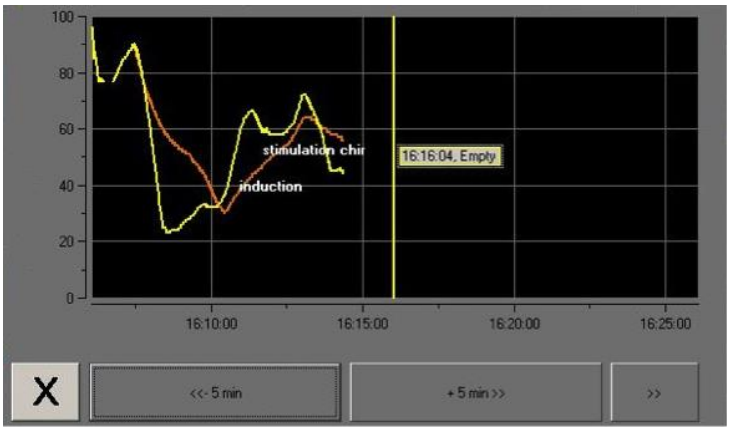


Curves

If R waves are not correctly detected, HFVI measurements are not displayed until ECG detection is correct again.

5.4 HFVI navigation

Selecting **[HFVI navigation]** under the index window will open a navigation window (see figure **HFVI navigation**) in which the user can scroll through the HFVI measurements and see the events captured.



HFVI navigation

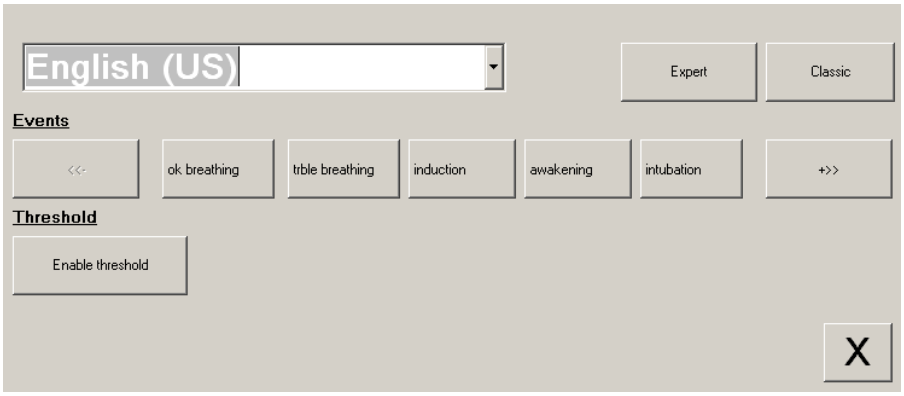
Select [**X**] to close this window. Signal acquisition is not disturbed while the navigation windowis opened.

6 HFVI Monitor settings

To access the settings described in this section, select **[Parameters]** on the bottom right of the screen during monitoring.

6.1 Language parameters

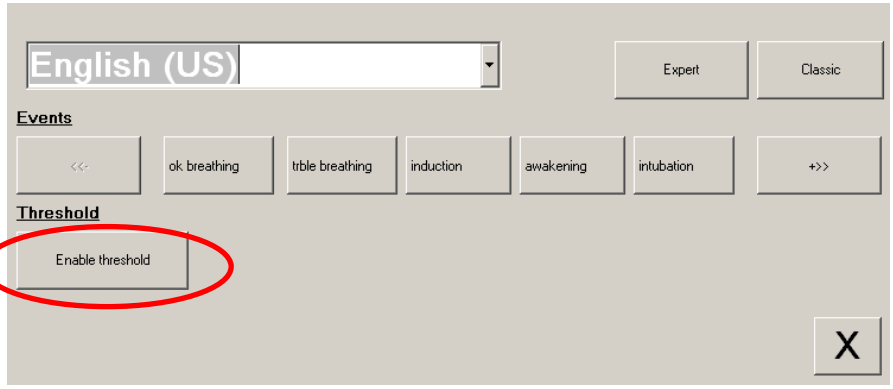
The user can choose the language. Available languages are shown in the drop-down list (see figure **Language**). Choose the language and press [**X**] to close the **[Parameters]** window and set up the new language.



Language

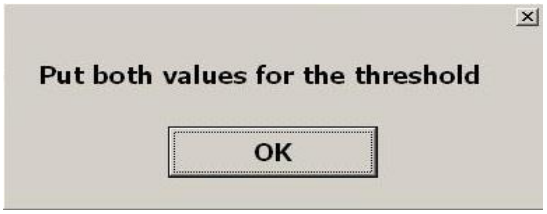
6.2 Threshold

As shown in the screen below (see figure **Enable threshold**), threshold values can be set here. Select **[Enable threshold]**.

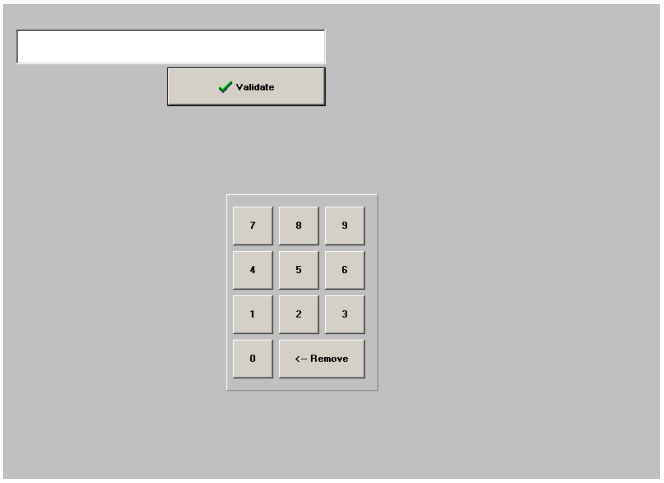


Enable threshold

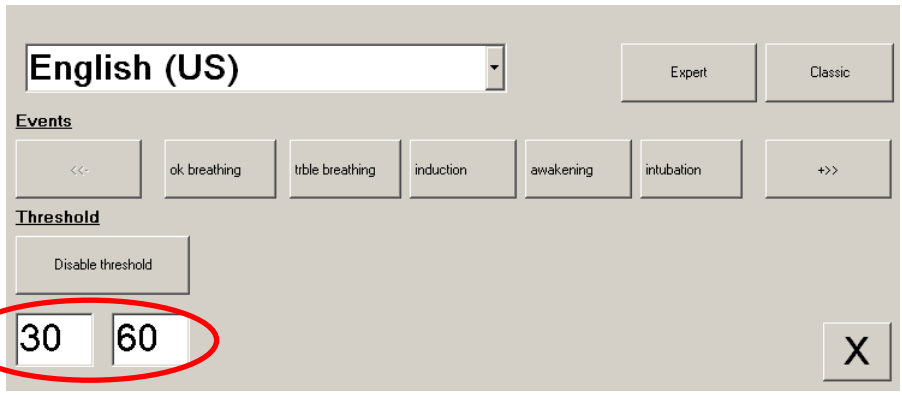
If you click on the [**X**] button without capturing the threshold values, a new window will appear: click on [**OK**].



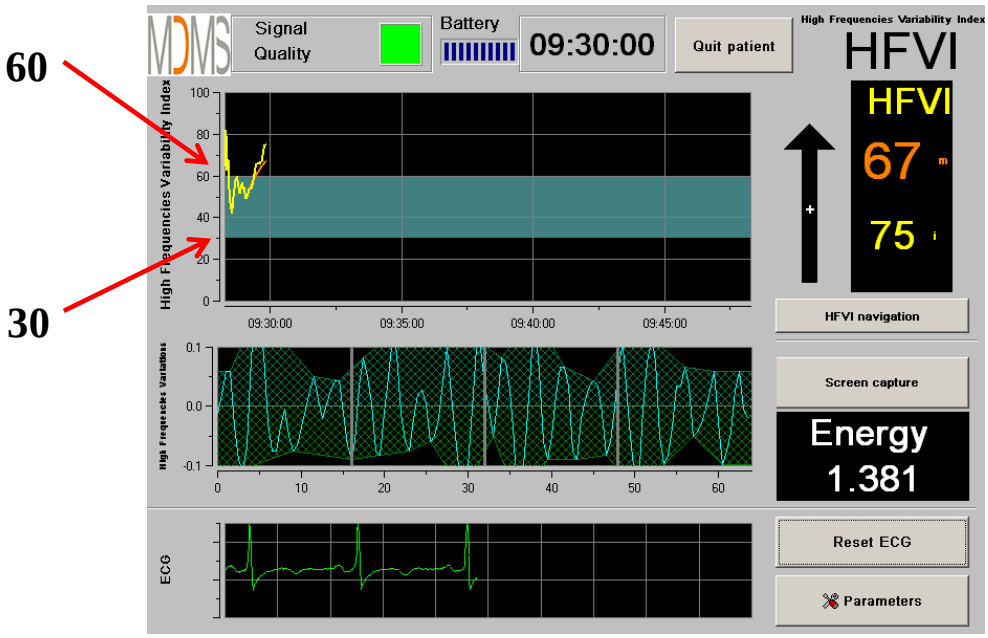
Click on the first input field and enter a first threshold value (see figure **Data entry**). Click on **[Validate]** to validate. Do the same for the second input field.



Data entry



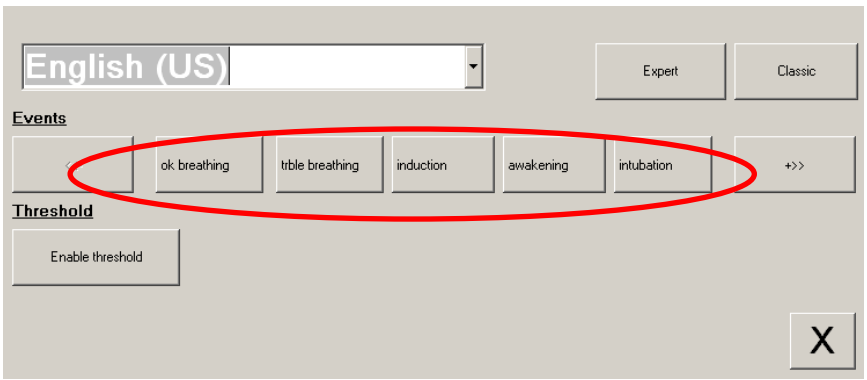
Example with two threshold values captured



Threshold values

6.3 Events

As shown in the screen below (see figure **Events**), in the menu you can insert clinical events so that they can be visible in the trend window and be recorded in the exportable data file.



Events

Example of events that may be relevant:

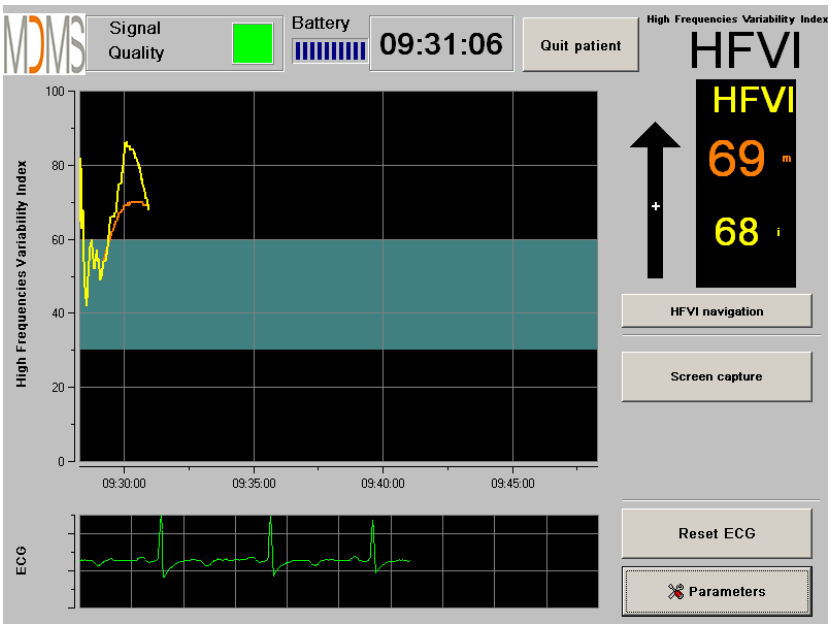
- ok breathing
- trble breathing
- induction
- awakening
- intubation
- extubation
- no stimulation
- surg stimulation
- hemo reaction
- movement
- cough
- reinject opioids
- reinject hypnotic
- VAS =

To insert one of these events means it is automatically memorized in the “Index” file type. This can be downloaded on a USB stick (see section 8.7 below). It is also possible to edit your own list of events (see section 8.8 below).

6.4 Expert mode and Energy index

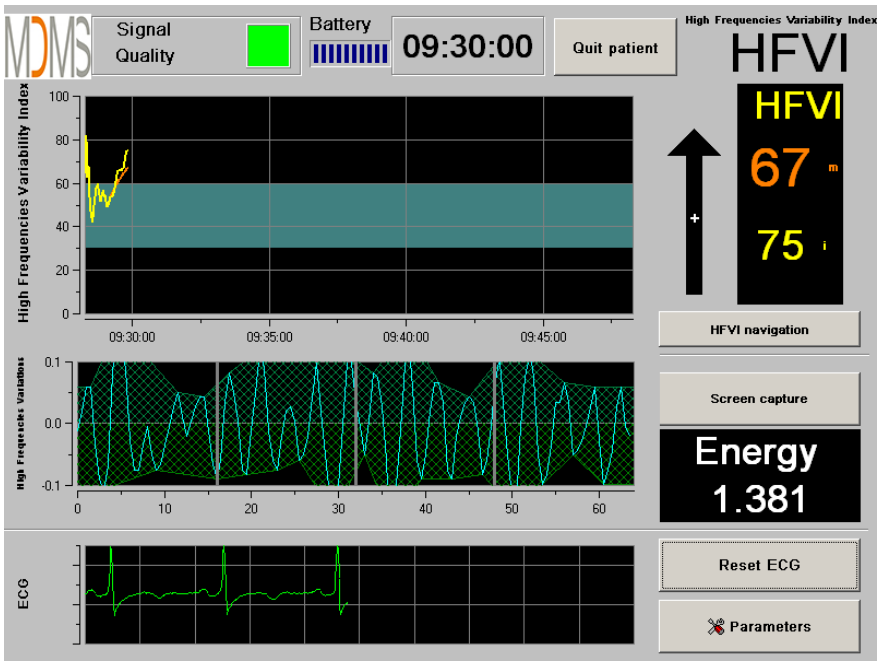
There are two modes:

- **"Classic Mode"**: no energy display, no filtered RR series display (see figure **Classic Mode**).



Classic Mode

- **"Expert mode"**: display of the filtered RR series and an additional function called "Energy" (see figure **Expert Mode**).



Expert Mode

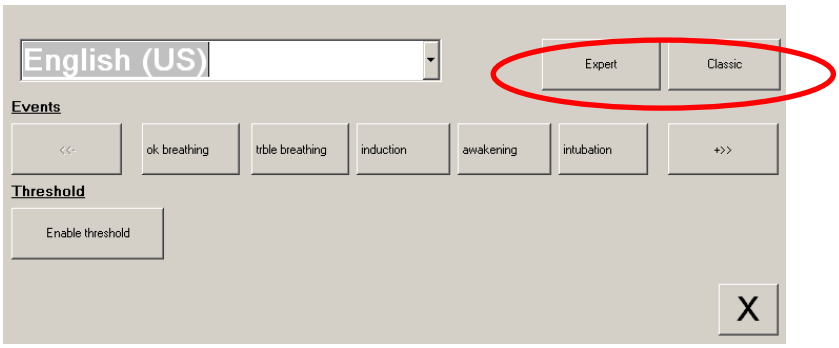
The Energy index represents the mathematical norm of the signal.

In a first step, the mean value (M) is computed as: $M = \frac{1}{N}\sum_{i=1}^{n}(RR_i)$, where RR_i represents the RR samples values and n the number of samples in the window.

The norm value (N) is then computed as: $N = \sqrt{\sum_{i=1}^{n}(RR_i - M)^2}$.

When the value of the Energy index varies out of the range [0.05 – 2.5], it means that the HFVI calculated at this specific moment is probably influenced by artefacts. In that case, HFVI calculation is interrupted even if the ECG is still being acquired. The Energy index is a mathematical function applied on the R-R series, and does not relate to the patient's energy.

To activate the "Expert" mode, in the Parameters section, select [**Expert**] then [**X**] to return to the main screen. To return the monitor display to the "Classic" mode, do the same but this time select **[Classic]** (see figure **Activate modes**).



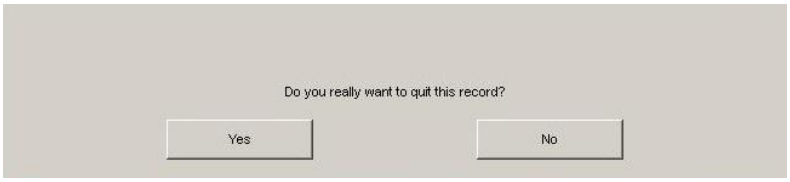
Activate modes

7 Ending HFVI monitoring

7.1 Stopping the recording of a case

Select **[Quit patient]** at the top of the screen during monitoring to stop the session and return to the main menu.

You will be asked to confirm this before you leave monitoring:



Note: *if you respond [**Yes**] you will not be able to return to the current patient.*

If you respond **[Yes]**, the HFVI Monitor displays the main menu:

Main menu

7.2 Demo

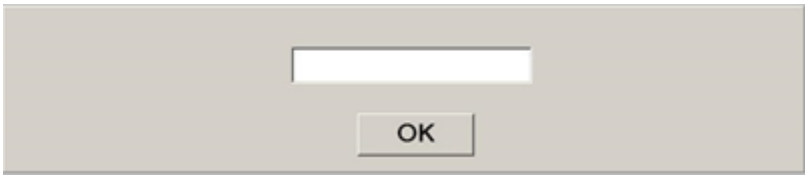
Selecting **[Demo]** displays a video of the HFVI monitor operating.

7.3 New patient

Selecting [**New patient**] initializes monitoring and launches a new patient monitoring session, as well as a new set of exportable data files.

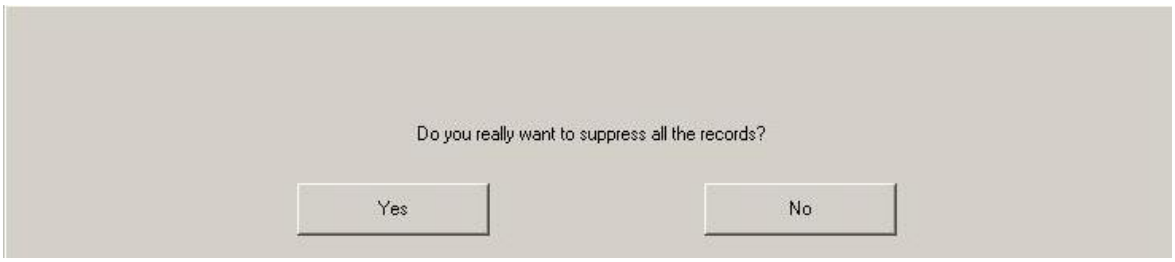
7.4 Maintenance

Selecting [**Maintenance**] opens a window with an input field. Access to this area is protected by a code that will be sent to you by Mdoloris Medical Systems if you request it.



7.5 Deleting patient data

Selecting [**Empty**] erases all the data stored previously. You will be asked to confirm that you want to erase the records.

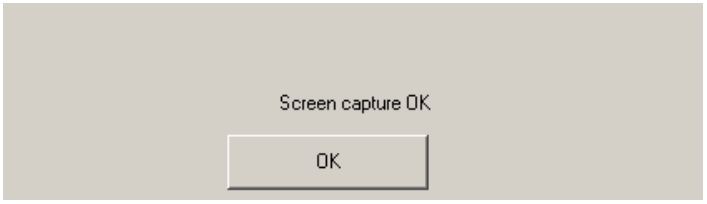


Once all data has been deleted, another window appears for confirmation. Select [**OK**] to return to the main menu.

7.6 Screen capture

When the user selects [**Screen capture**], the information on the screen is saved in image format in the monitor's internal memory. Each time the user takes a snapshot; one picture is saved in the monitor's memory.

A confirmation message is displayed when a snapshot has been successfully taken. Select [**OK**] to return to the main display.

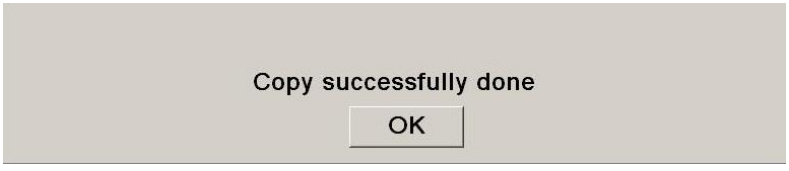


To recover these pictures, plug a USB stick into the USB port called "Data Export". Next select **[Stop]** at the top of the screen. The main menu is then displayed (see figure **Main menu**), select **[Export].** The snapshots are saved in a file named according to time and date: Hour - Minute - Month - Day - Year.

7.7 Exporting data files

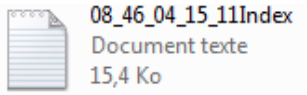
Select the button **[Export]** (see figure **Main menu**) to transfer all the data stored in the monitor's memory to a USB drive that is in the USB port called "*Data Export*" located on the monitor's side. If the monitor does not detect the USB drive (no drive present, or inserted incorrectly), a message is displayed to indicate this. Once the USB is inserted correctly, select [**OK**] to begin exporting the data.

Once the files have been exported successfully, a confirmation window appears. Select [**OK**] to return to the main menu.



Note:

Each data file is saved automatically in a file bearing the monitoring date and time as: Hour - Minute - Month - Day - Year. The data files are in "text" format.

Example: 

Real time data from the monitor can be retrieved by connecting a computer to the series port "3" on the rear side of the monitor.

NOTE: if a cable is inadvertently disconnected during a recording, reconnect the various elements in the acquisition system as quickly as possible. When recording resumes it will be considered by the program as a second complete recording. It is then crucial to indicate this interruption in recording as an event so that this error is taken into account later when data is processed.

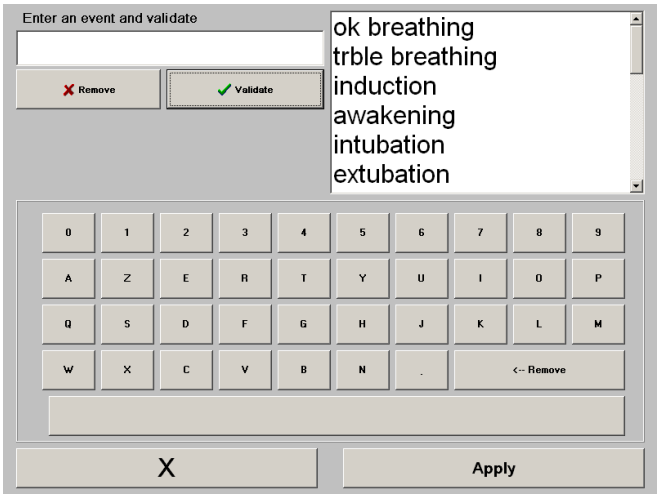
7.8 Updating events

As explained above (see section 7.3), events corresponding to different clinical moments are predefined in the system. The user can make these different events appear on the HFVI trend.

Select **[Quit patient]** at the top of the screen during monitoring to stop the session and return to the main menu. A message asks you to confirm:

Note: *if you respond [**Yes**] you will not be able to return to the current patient. You will then see the main menu (see figure **Main menu**).*

To access and reconfigure the list of events, select **[Update events].** The input screen for events then appears:



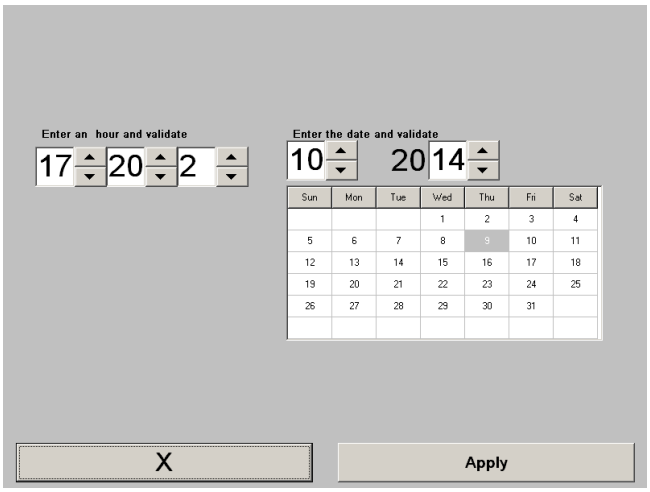
To add new events to the list, use the virtual keyboard on the touchscreen then select ✓**[Validate].** The character limit is 18 characters.

The new event is then added to the event-list displayed on the right. Use the scroll bar if the added event does not appear. An event can be removed from the list by touching it, and selecting ✗**[Remove].**

To validate any change (addition or deletion of one or more events), confirm by selecting **[Apply]** before closing the window by selecting [**X**].

7.9 Setting date and time

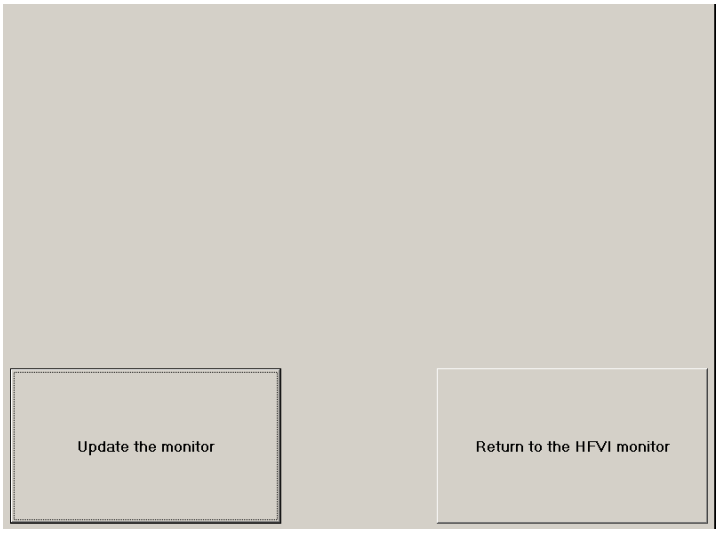
To set the date or time, select **[Quit patient]** to reach the main menu. Select **[Set time].**
The following window appears:



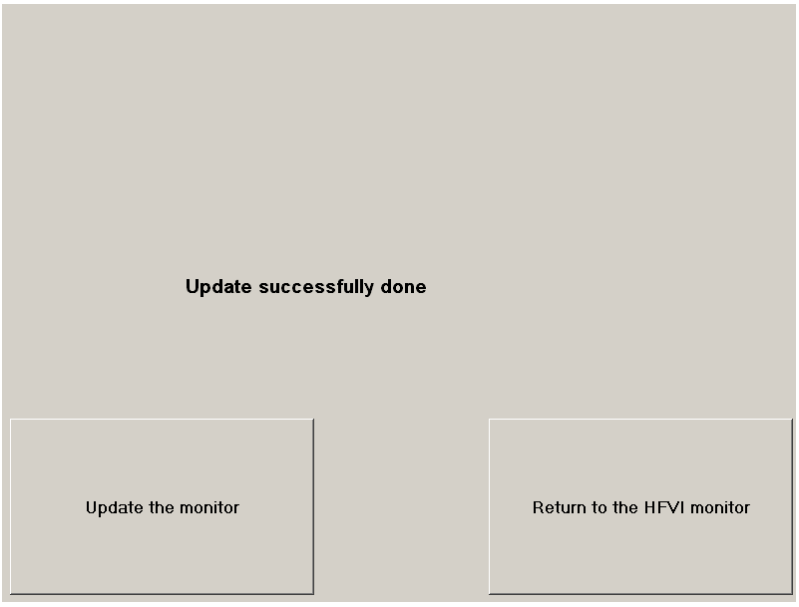
Use the arrows to select the desired change. Validate the changes before closing the window by selecting [**Apply].**Select [**X**] to close the window.

7.10 Updating monitor

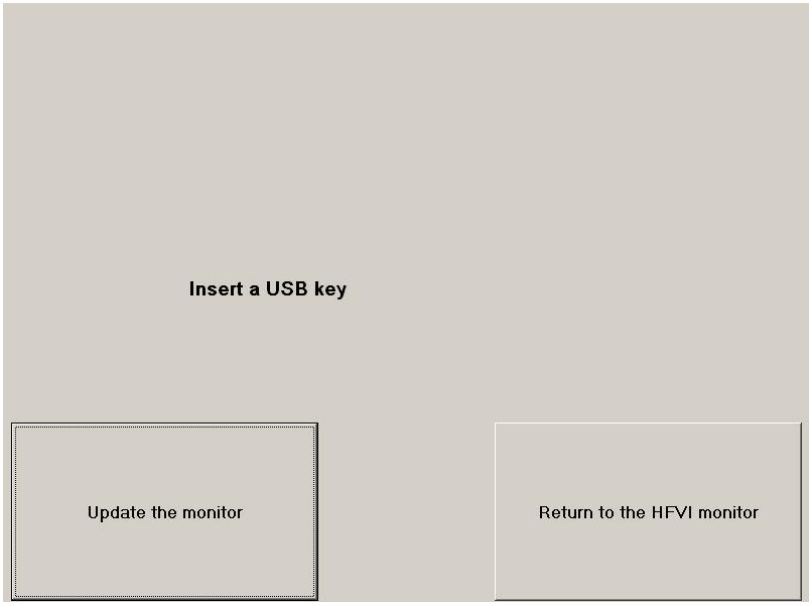
In the main menu (see figure **Main menu**), click on **[Update monitor].** Connect a USB key with the new version of "HFVI.exe" provided by your Mdoloris Medical Systems representative. Next, select **[Update monitor]**.



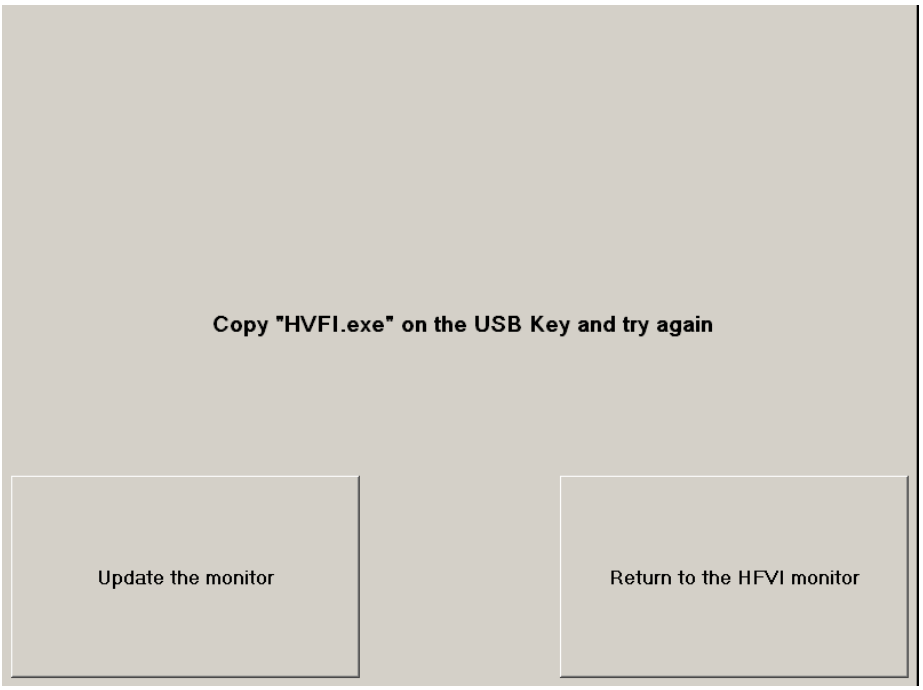
A message will appear to confirm that the update was successful. After 5 seconds, click on **[Return to the HFVI monitor].**



If there is no USB key connected, a message will appear to tell the user:



If the file “HFVIM_INT.exe” is not present on the USB key, a message will appear:



7.11 Shutting down

Selecting **[Shutdown]** switches off the HFVI Monitor.

NOTE: it is also possible to switch off the monitor directly by pushing the switch on the front (the same one as to turn it on) but only if the context does not allow you to reach the main menu. This is not recommended and could cause the monitor to dysfunction.

8 Trouble shooting

Problem	Solution
The monitor is not displaying an ECG signal.	Check that the device's cable from the acquisition device to the monitor. Try to unplug the acquisition device and plug it in again at least once. Check that there is a flat signal in the ECG window. If no signal appears, contact your Mdoloris representative.
An ECG signal is detected but seems to be incoherent (flat, irregular, interfered, etc).	Check that the cables and connectors are in good working order.
ECG waves seem physiologically incorrect.	Check that electrodes are properly placed along an imaginary line through the heart (acquisition of an electrical QRS axis). See figure Sensors positioning.
The Mdoloris Medical Systems software does not start automatically when the monitor is booted.	Reboot the monitor using the switch on the front. If the problem persists, contact your Mdoloris Medical Systems representative.
The HFVI monitor shuts down by itself without reason.	Check that the power supply cable is connected to the monitor and reboot the monitor as explained here (section 5).
The monitor doesn’t boot.	Check that the battery's power indicator is on (see picture Power Switch) when the monitor is connected to a power supply. If the power indicator is off, remove the transparent cover and push the button.

Problem	Solution
The touch screen does not work.	Reboot the monitor using the ON/OFF switch. Contact your Mdoloris Medical Systems representative.

9 Monitor disposal

WARNING: *to avoid any kind of contamination or infection to personnel, the environment or equipment, be sure you have properly disinfected and decontaminated the monitor before you dispose of your system. Respect local regulations regarding electric and electronic items.*

You can take apart the monitor and the acquisition device:

- There are no metallic parts inside the acquisition device's case
- The acquisition device's box is ABS plastic.
- The EMC protection in the acquisition device is metal.
- The screen has a touch-proof protective layer
- You can recycle the printed operating manual.
- All the electronic items fall under the RoHS2 directive.

If you have to dispose of old electrical equipment, make sure it is recycled safely. Collect it separately, away from normal waste cans, so that it can be reused, processed, recycled or recovered correctly and safely.

10 Environment

10.1 Shipping and storage conditions

The HFVI monitor and its accessories can be stored or shipped within the following environmental limits. These limits apply to non-operational storage and shipping situations.

Temperature: -20°C to +60°C
Humidity: 15 to 95% (non-condensing)
Pressure: 360 mmHg to 800 mmHg

Protect the monitor from sudden temperature changes that could lead to condensation within the instrument. To minimize condensation, avoid moving the system between heated buildings and outside storage. Once moved inside, allow the monitor to stabilize in the unopened shipping container at room 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.

The HFVI sensors have a storage temperature range of 0 to 40°C.

10.2 Operating Environment

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

WARNING: *Explosion hazard: do not use the HFVI monitor in an inflammable atmosphere or where concentrations of inflammable anesthetics may accumulate.*

The HFVI monitor is designed to operate safely at a temperature from 5°C to 40°C and at up to 2000 m altitude. Conditions outside these limits could make it less reliable.

10.3 Power requirements and grounding

The HFVI Monitor requires a power source of 110-240 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 cord. The power cord grounds the system when plugged into an appropriate three-prong plug.

WARNING: *FOR PROPER GROUNDING, THE POWER PLUG MUST BE A HOSPITAL-GRADE, THREE-WIRE GROUNDED OUTLET. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, HAVE IT REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.*
THE MONITOR SHOULD BE USED ONLY WITH A HARMONIZED POWER CABLE WITH A SURFACE CROSS SECTION GREATER THAN 0.75 MM².

11 Cleaning and disinfection

11.1 Cleaning

WARNING:
OBSERVE UNIVERSAL PRECAUTIONS TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. PUT CONTAMINATED MATERIALS IN THE APPROPRIATE CONTROLLED WASTE CONTAINERS.

Cleaning and disinfecting the monitor, acquisition device and end user cable: clean any blood or liquid spill on either the monitor or acquisition device immediately. Dried blood is very difficult to remove.
Use wet wipe with water. After cleaning, allow it to dry completely. Residual moisture inside the connector may affect the monitoring performance.

Cleaning the monitor screen:
Cloth – Although paper towels or tissues can be used, a soft, clean piece of cloth is recommended when cleaning the screen.
Water or rubbing alcohol – A cloth moistened with water or rubbing alcohol can be used to clean the screen.
Using solvents – the use of solvents is not recommended when cleaning the screen as they may
damage the plastic parts.
Vacuum cleaner – Using a vacuum specifically designed for computers is one of the best methods of cleaning the screen. Dust and dirt can restrict the airflow in the screen and cause its circuitry to corrode.
Cotton swabs – Cotton swaps moistened with rubbing alcohol or water are excellent tools for wiping hard to reach areas.
To avoid scratching the screen, never use abrasive cleaners.

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 TOXIC 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. This could interfere with acquisition performance.

11.2 Maintenance

The HFVI Monitor is designed so that no periodic maintenance is required. However leakage current must be checked after every blood or liquid spill, or immediately after a major surge in the electrical system, or at least once a year.

Leakage current is a primary indicator of electrical shock hazard for personnel who touch any of the device's outer surfaces. Static electricity tests have been conducted on our monitor to ensure that the leakage current meets safety standards CEI 60601-1.

12 Specifications, warranty and software license contract

12.1 Specifications

Electricity supply: 100/240 Volts
Consumption: < 32 W
Current: < 3 A
Frequency: 50/60 Hz
Electrical safety: category 1 according to IEC 60601-1.
Battery: Li ion, voltage produced: 12 V +/-5%, 3800 mAH capacity, about 90 minutes operation at full power.
Disconnection device: wall socket and cable
Weight of monitor alone (without any accessories): 3.14 kg
Weight of acquisition device (without connection cable for electrodes) = 0.4 kg
Monitor dimensions (width x height x depth): 26.5 cm x 24.7 cm x 7.95 cm
Acquisition device dimensions (width x height x depth): 15.7 cm x 10.3 cm x 6.85 cm
Screen size: 8.4 inches, resolution 800x600.

Material included with the HFVI Monitor:

- Monitor: Mdoloris Medical Systems Ref: MN-HFVI-V1
  Manufactured by IEI
- Acquisition case: Mdoloris Medical Systems Ref: BA-HFVI-V1
  Manufactured by RHEA Electronique
- Patient sensors: Mdoloris Medical Systems Ref: HFVI-SENS-V1
  Manufactured by Intelesens
- Sensor cable: Mdoloris Medical Systems Ref: HFVI-SC-V1
  Manufactured by AXON
- Power cable: Mdoloris Medical Systems Ref: HFVI-PW-V1-

CISPR 11: Class A equipment

Type of protection against electric shocks:

Class 1: Material for which protection against electric discharge does not lie only on isolating elements, but also on extra safety standards. Means are provided for connecting the equipment to the grounding 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 projection of liquids:

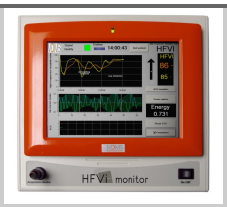
Take care to always position the HFVI monitor (screen and acquisition device) outside any area that would be at risk of having blood or liquids spill on it.

System operation:

Continuously: operation at a normal load for a normal duration, not exceeding the temperature limits set.

12.2 Accessories

The systems includes:

Monitor : MN-HFVI-V1	
Power cable : HFVI-PW-V1	
Pole clamp : CLP-V2	
Acquisition Device: BA-HFVI-V1	
Sensor cable: HFVI-SC-V1	

12.3 Warranty

Mdoloris Medical Systems warrants to the initial Purchaser that the HFVI monitor and the acquisition device ("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 consumables and 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 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, 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 its official distributor (c) with respect to any product sold under a brand name other than Mdoloris Medical Systems.

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12.4 Software License Agreement

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For any other problems:

Contact your Mdoloris Medical Systems representative or
contact@mdoloris.com