Analgesia Nociception Index

ANI Monitor V1

User manual

Software version 1.1.4.0

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<u>Important information about using the continuous analgesia monitoring system</u>:

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 system is intended for use on adult and pediatric patients, in a facility providing patient care by monitoring parasympathetic nervous tone activity.

The continuous analgesia monitoring system may be used to monitor the effects of certain analgesic agents.

The Analgesia Nociception Index (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 muscle activity or rigidity, patient motion, improper sensor placement or electrical interference. The essential performance identified for the ANI Monitor V1 is the display of ANI index if the signal quality is good.

The ANI Monitor V1 needs special precautions regarding environments. The ANI 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.

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 ANI Monitor V1 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 ANI Monitor V1 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 ANI Monitor V1 CANNOT BE IN ANY CASE CONSIDERED AS AN ECG MONITORING SYSTEM.

⚠

WHEN USING ELECTRO-CONVULSIVE THERAPY (ECT) EQUIPMENT DURING ANI MONITORING: place ECT electrodes as far away as possible from the sensor to minimize the effect of interference. Some ECT equipment may interfere with the ANI Monitor V1 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 ANI Monitor V1.

⚠

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.

⚠

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

⚠

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 ANI ELECTRODES BETWEEN THE SURGICAL SITE AND THE ELECTROSURGICAL UNIT'S RETURN ELECTRODE.

⚠

ENSURE PROPER CONTACT OF THE ELECTROSURGERY RETURN ELECTRODE TO AVOID POSSIBLE BURNS ON THE PATIENT VIA ANI ELECTRODES.

THE CHARACTERISTICS OF ANI 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), ANI 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 ANI Monitor V1.

⚠

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 ANI Monitor V1.

⚠

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 ANI Monitor V1, 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 ANI Monitor V1 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 ANI 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.

⚠

NEVER MODIFY THE MONITOR WHEN OPEN.

⚠

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

1.2 Caution

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

Before 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 ANI Monitor V1.

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 ANI Monitor V1.

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 ANI Monitor V1 should not be used near or placed on top of another electrical equipment. If however this is unavoidable, check regularly that the ANI Monitor V1 operates properly in this configuration.

Only Mdoloris Medical Systems qualified biomedical technicians are trained to perform service or repairs on ANI Monitor V1.

The ANI Monitor V1 contains an internal battery. This battery must be removed by an authorized technician and discarded or recycled in accordance with local regulations. Contact Mdoloris Medical Systems or the local distributor for battery maintenance.

The internal battery is not designed for long-term monitoring. The ANI Monitor V1 internal battery allows the system to keep calculating the ANI while the patient is being moved or in

case of temporary interruption of the main power supply. Mdoloris Medical Systems recommends using the ANI Monitor V1 without power supply (battery mode) for 15 minutes maximum.

Check the battery charge symbol before unplugging the main power supply; if the internal battery is insufficiently charged, the ANI Monitor V1 will switch off automatically.

After reconnecting the ANI Monitor V1 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 ANI Monitor V1 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 ANI Monitor V1. However, the following elements may be replaced by personnel untrained in technical maintenance (following the manufacturer's instructions):

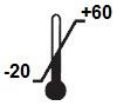
- End User Cable;
- Power cord;
- Acquisition unit (BA-ANI-V1);
- Pole clamp.

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

1.3 Notes

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

1.4 Key to symbols

Symbol	Description	Symbol	Description
	Operator's manual; operating instructions		Serial number
	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)		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		BF Type equipment, protects against defibrillation
	General safety sign		Manufacturer + Manufacturing Date
	Protective earth; protective ground		

2 ANI Monitor V1

Indications for use:

The Mdoloris Medical Systems SAS ANI Monitor V1 is intended to acquire, display, and analyze electrocardiographic information and to measure-heart rate variability. 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.

ANI (Analgesia Nociception Index) is a standardized continuous measurement of the relative pΣ tone. Each respiratory cycle (spontaneous and artificial) induces a fast, temporary decrease of the pΣ tone, which accounts for Respiratory Sinus Arrhythmia, and leads to a transient shortening of the R-R intervals (increased heart rate). ANI quantifies these "respiratory patterns" in order to measure the "relative quantity" of pΣ tone (see 5.2).

The series of normal, non-ectopic, R-R intervals is displayed on the screen of the ANI Monitor V1 after normalization, resampling and filtering. The amount of pΣ tone 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 pΣ, the higher the shaded surface, and reciprocally.

ANI measurement cannot be interpreted in the following situations:

- arrhythmia
- 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 ANI is expressed between 0 and 100. Each ANI value is computed on one time window of 64 sec. This number shows the relative pΣ activity as a part of ANS activity: it expresses the relative amount of pΣ tone present as compared to sum of sympathetic and pΣ activities. The ANI Monitor V1 displays two averaged ANI measurements: ANIi results from the average of ANI measured over the last 120 sec, and ANIm results from the average of ANI measured over the last 240 sec.

There are multiple ways of interpreting an ANI value: one is probabilistic, as this index has been developed in order to predict hemodynamic reactivity during nociceptive stimulation. When surgical stimulation was constant, all hemodynamic reactivity episodes (20% increase of heart rate or systolic blood pressure compared to a reference) were associated with a decreased ANI up to 10 min beforehand. The predictive thresholds need yet to be established, but preliminary studies suggest:

- that an ANIm measure between 50 and 70 during surgery makes a hemodynamic reactivity episode ***unlikely*** in the following 10 minutes;
- that an ANIm lower than 50 makes hemodynamic reactivity ***very likely*** in the following 10 minutes.

3 Installing the ANI Monitor V1

3.1 Perfusion stand

Position the ANI Monitor V1 in order for the main power supply to be easily plugged in. The monitor can be installed on a perfusion stand (figure 1) 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.**

Figure 1

3.2 ANI Sensor V1 / ANI Sensor V2 / ANI Sensor V1 PLUS

ANI calculation is based on R-R interval variability in ECG. Since the ANI Monitor V1 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 ANI calculation.

The electrodes are composed of a two-part device: a dual sensor and a single sensor connected together by an electrical thread (figure 2).

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 (figure 3).

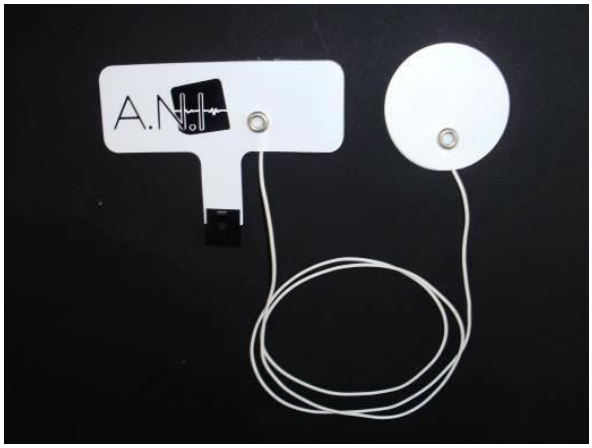


Figure 2

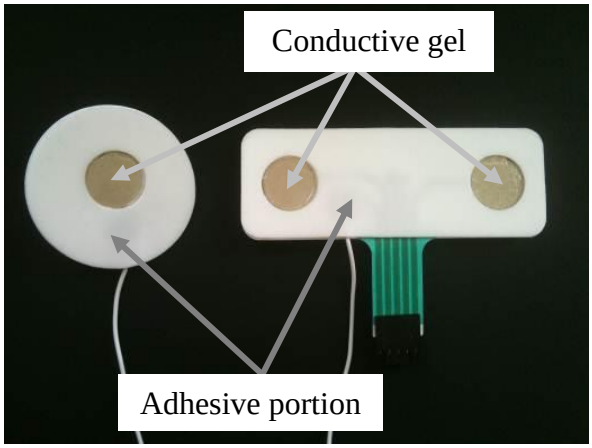


Figure 3

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 (see figure 4).

WARNING:

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.

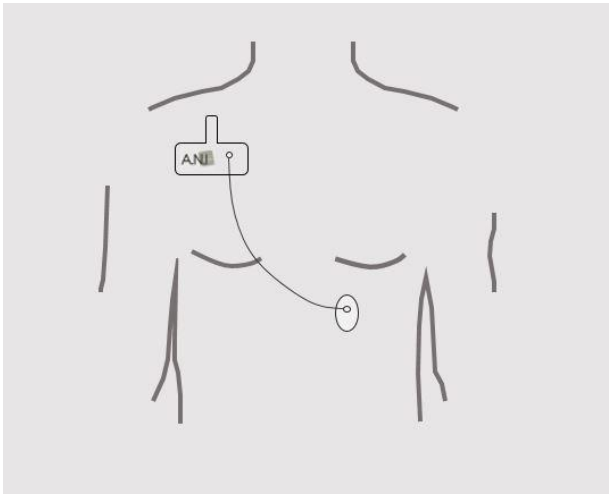


Figure 4

NOTE: The ANI Monitor V1 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 (figures 5 and 7). To disconnect the electrodes, grasp the plastic portion while pressing on the locking mechanism and pull gently to disengage it (figure 6). **Do not pull by grasping the electrode itself.**

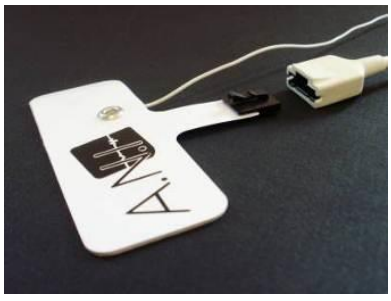


Figure 5

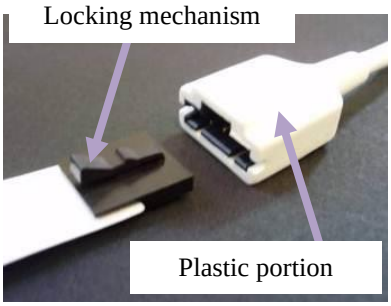


Figure 6

Figure 7

3.3 ANI Monitor V1 connection

Connect the electrodes to the acquisition device using the cable provided by your Mdoloris Medical Systems representative (figures 8 and 9).

Figure 8

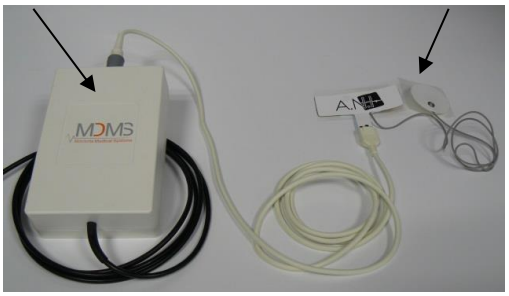


Figure 9

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 (figures 10 and 11).

Figure 10

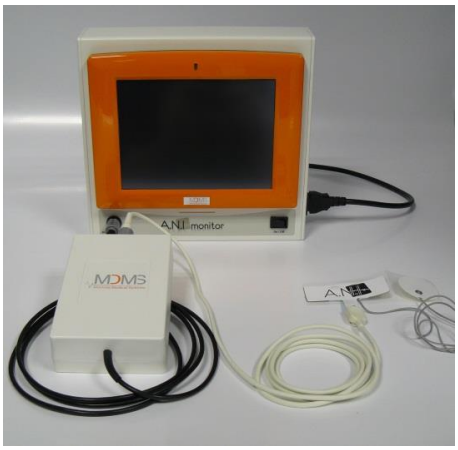


Figure 11

ANI Sensor	Sensor cable
ANI Sensor V1 ANI-SENS-V1	ANI-SC-V1
ANI Sensor V2 ANI-SENS-V2	ANI-SC-V1
ANI Sensor V1 PLUS ANI-SENS-V1PLUS	ANI-SC-V1PLUS

ANI-SC-V1

ANI-SC-V1PLUS

3.4 Battery

The ANI Monitor V1 contains an internal battery. The battery means the system can keep calculating the ANI 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 ANI index is still calculated during this time.

NOTE: plug the ANI Monitor V1 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 ANI Monitor V1 will switch off automatically.

After reconnecting the ANI Monitor V1 to the main power supply, press the power switch on the front side of the monitor (figure 12). In case the monitor does not start, press the switch at the back of the monitor (figure 13) in order to reboot the device.

Never use the ANI Monitor V1 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 ANI Monitoring

Turn the monitor on using the switch on the front at the bottom right (figure 12).

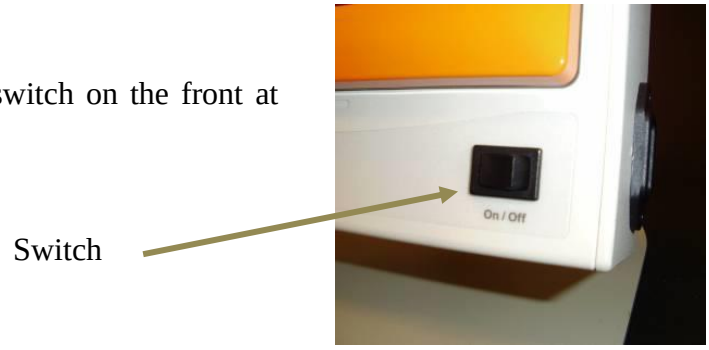


Figure 12

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 (figure 13).

WARNING: *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.*

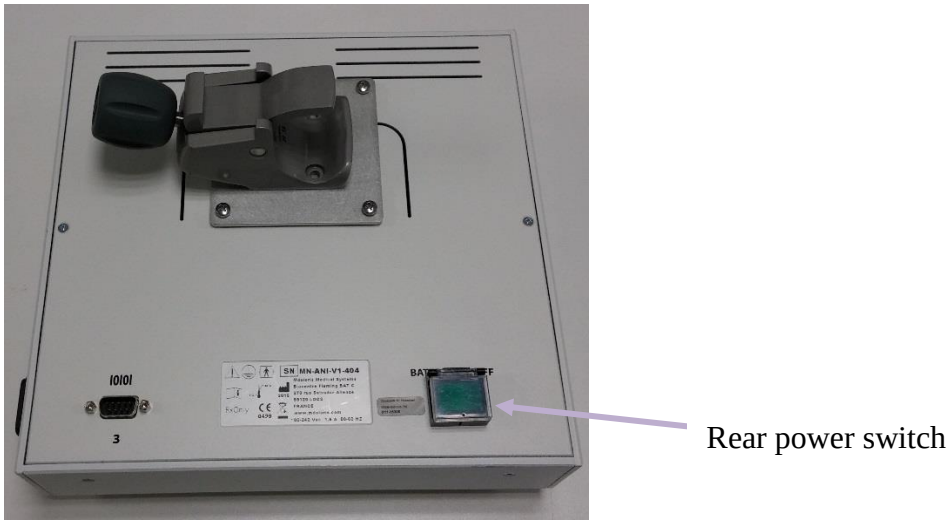


Figure 13

The monitor will start by showing the Mdoloris Medical Systems logo animations successively. The screen will then show the start page automatically, indicating “Calibration” on the central screen (figure 14). The first ANI measurement will take at least 80 seconds. No data can be interpreted before this initialization time lapse.

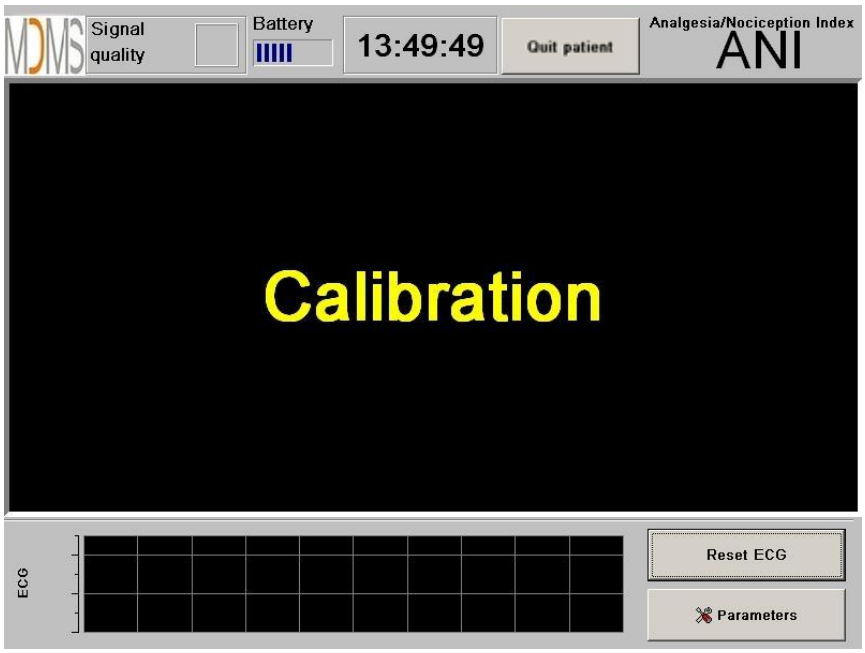


Figure 14

Once the monitor is connected to the patient with the electrodes, the calculation algorithm will automatically begin (see figure 15 next page).

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

Figure 15

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 ANI 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 recalibrate the ECG signal acquisition.

5 Using the ANI Monitor V1 and setting parameters

5.1 ECG Capture

The lower window shows the ECG acquired by the monitor (figure 16). This ECG is filtered of all technical and physiological artifacts (e.g. premature ventricular contractions).

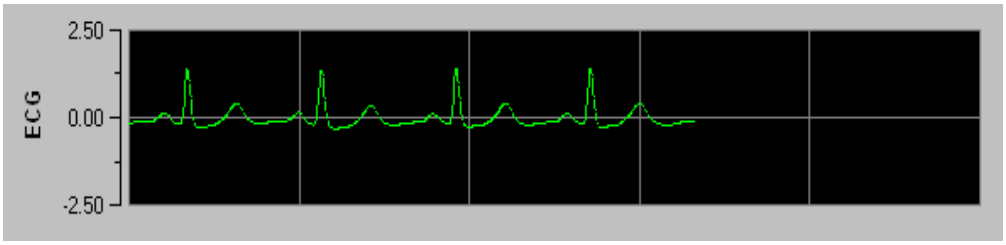


Figure 16

5.2 Respiratory pattern

The surface area generated by "respiratory patterns" in the R-R series is measured and displayed in a hatched surface (figures 17 and 18). The higher the surface, the stronger the relative pΣ tone.

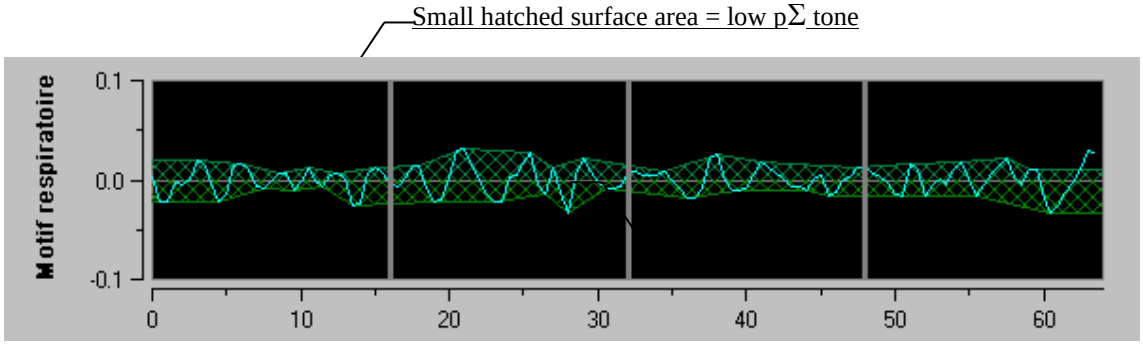


Figure 17: R-R normalized series with low amplitude respiratory sinus arrhythmia

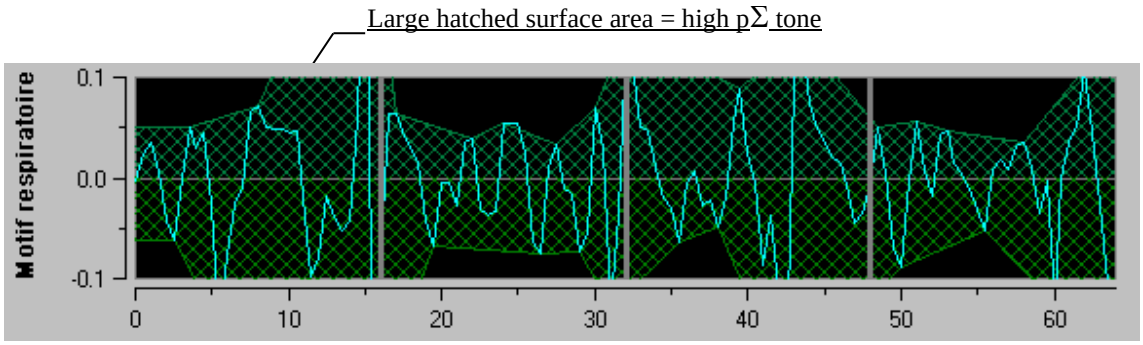


Figure 18: R-R normalized series with high amplitude respiratory sinus arrhythmia

5.3 ANI index

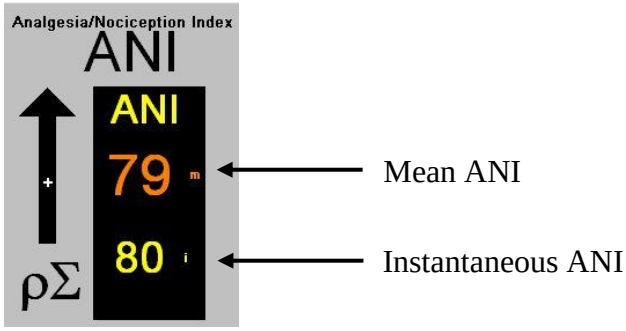


Figure 19

In the neighboring window two trends of ANIi and ANIm are displayed (yellow and orange) (figure 20).

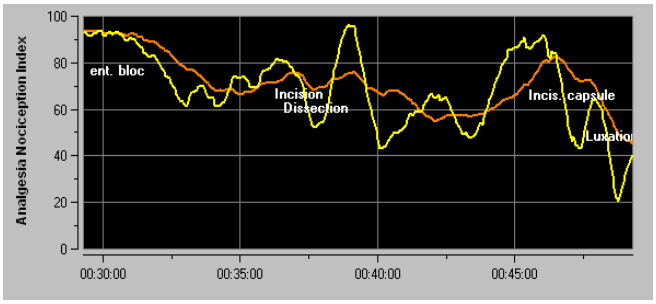


Figure 20

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

5.4 ANI navigation

Selecting **[ANI navigation]** under the index window will open a navigation window (figure 21) in which the user can scroll through the ANI measurements and see the events captured.

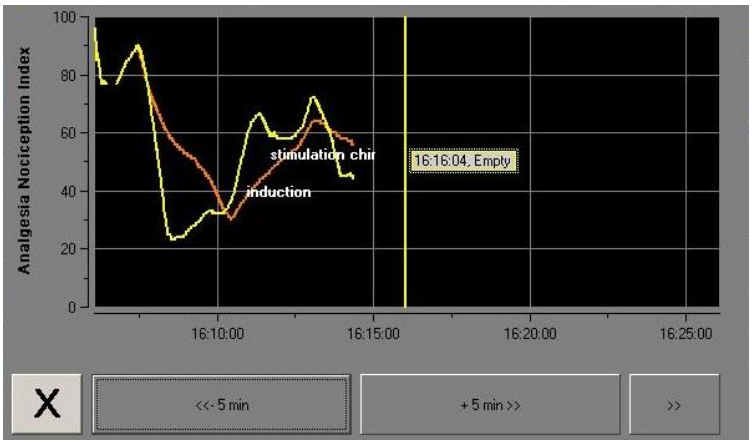


Figure 21

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

6 ANI Monitor V1 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 (figure 22). Choose the language and press [**X**] to close the **[Parameters]** window and set up the new language.

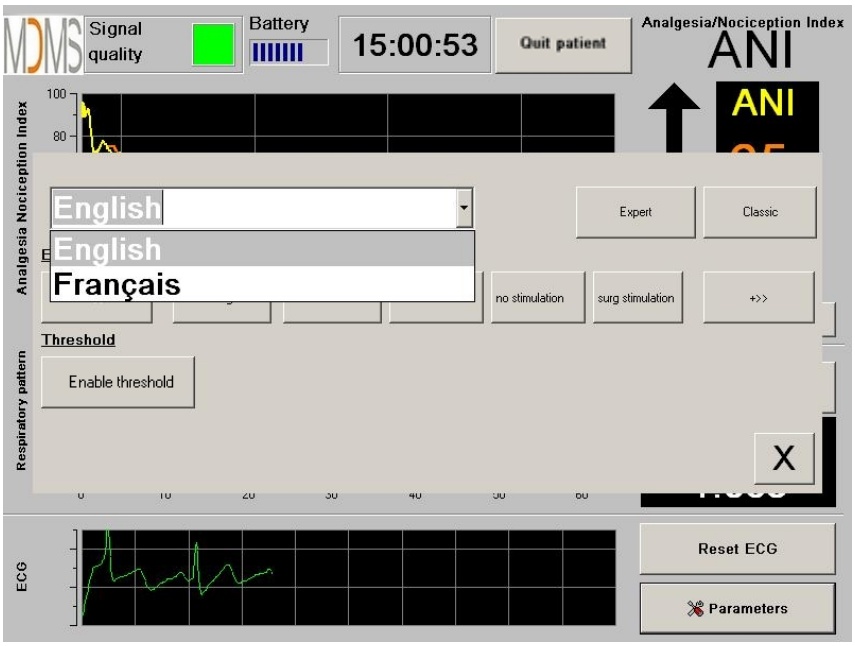


Figure 22

6.2 Threshold

As shown in the screen below (figure 23), threshold values can be set here. Select **[Enable threshold]**.

Figure 23

If you click on the [**X**] button without capturing the threshold values, a new window will appear (figure 24): click on [**OK**].

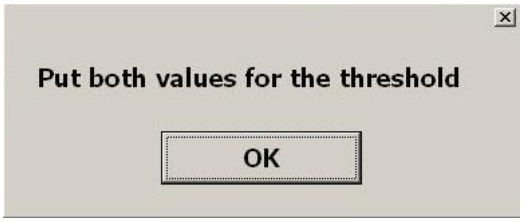


Figure 24

Click on the first input field and enter a first threshold value (figure 25). Click on **[Validate]** to validate. Do the same for the second input field.

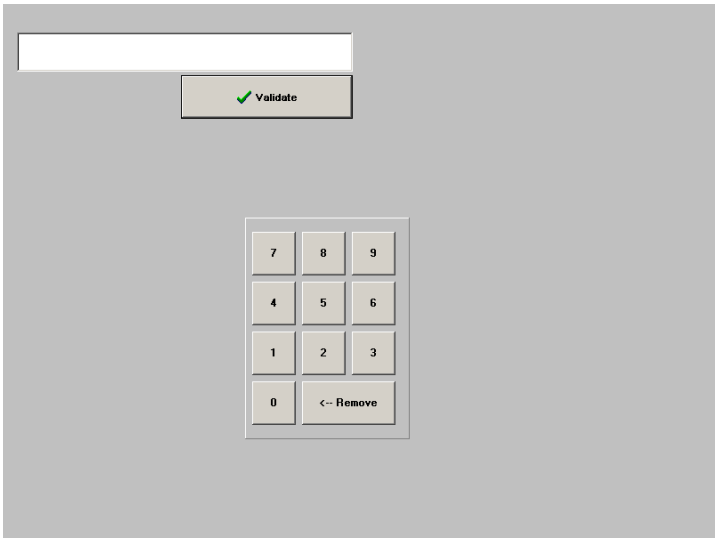


Figure 25

Figure 26: example with two threshold values captured

Figure 26

Figure 27: Threshold values

Figure 27

6.3 Events

As shown in the screen below (figure 28), 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.

Figure 28

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 respiratory pattern display (figure 29)

Figure 29

- **"Expert mode"**: display of respiratory pattern and an additional function called "Energy" (figure 30)

Figure 30

The Energy index is equivalent to the total spectral power of the autonomous nervous system. When the value of the Energy index varies out of the range [0.05 – 2.5], it means that the ANI calculated at this specific moment is probably influenced by other conditions than the patient's pΣ tone. In that case, ANI 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; it is used for ANI computation, but has no direct relation with the pΣ tone of the patient.

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]** (figure 31).

Figure 31

7 Ending ANI 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 (figure 32):

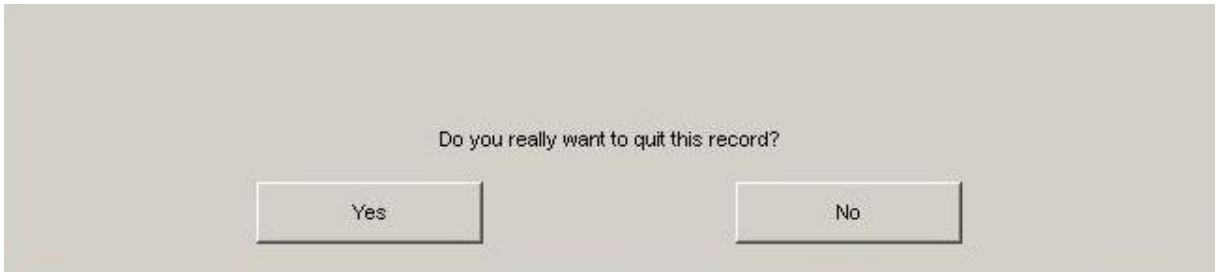


Figure 32

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

If you respond **[Yes]**, the ANI Monitor V1 displays the main menu (figure 33):

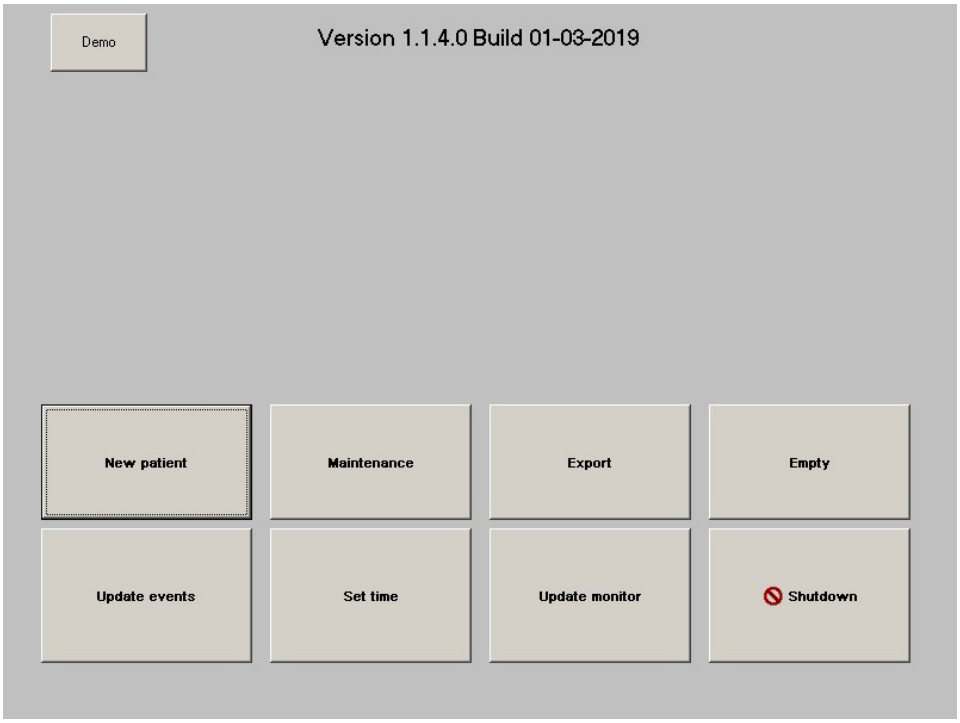


Figure 33

7.2 Demo

Selecting **[Demo]** displays a video of the ANI Monitor V1 operating

7.3 New patient

Selecting [**New patient**] (figure 33) initializes monitoring and launches a new patient monitoring session, as well as a new set of exportable data files.

7.4 Maintenance

Selecting [**Maintenance**] (figure 33) opens a window with an input field (see figure 34). Access to this area is protected by a code that will be sent to you by Mdoloris Medical Systems if you request it.

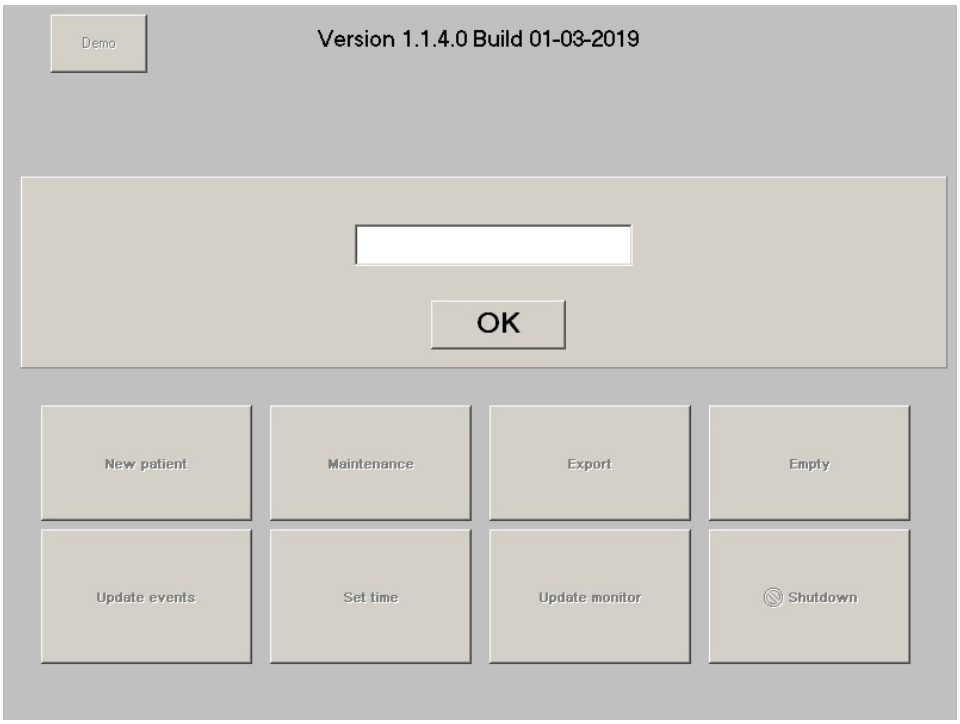


Figure 34

7.5 Deleting patient data

Selecting [**Empty**] (figure 33) erases all the data stored previously. You will be asked to confirm that you want to erase the records (figure 35).

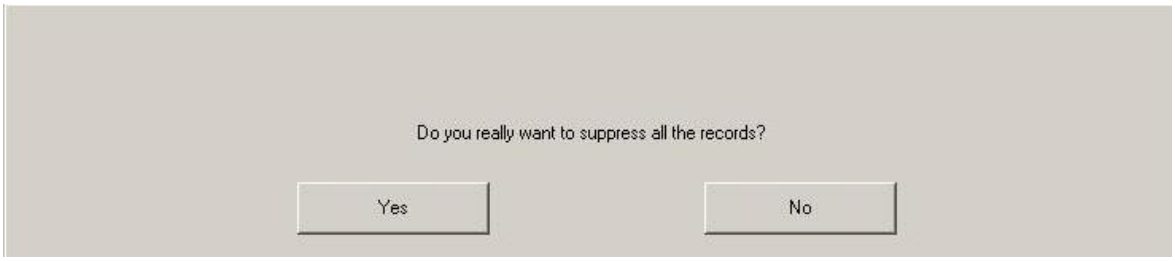


Figure 35

Once all data has been deleted, another window appears for confirmation (figure 36). Select [**OK**] to return to the main menu (figure 33).

Figure 36

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 (figure 37). Select [**OK**] to return to the main display.

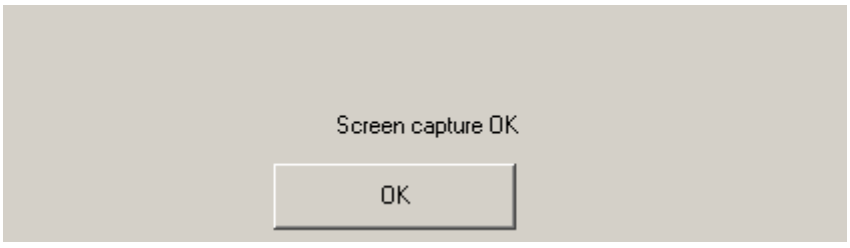


Figure 37

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 (figure 33), 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]** (figure 33) 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 (figure 38). Once the USB is inserted correctly, select [**OK**] to begin exporting the data.

Figure 38

Once the files have been exported successfully, a confirmation window appears (figure 39). Select [**OK**] to return to the main menu.

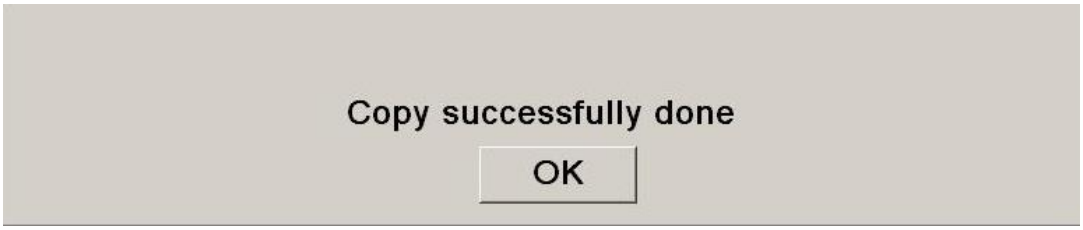
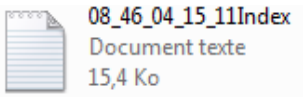


Figure 39

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 ANI 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 (figure 32):

***Note:** if you respond [**Yes**] you will not be able to return to the current patient. You will then see the main menu (figure 33).*

To access and reconfigure the list of events, select **[Update events].** The input screen for events then appears (figure 40):

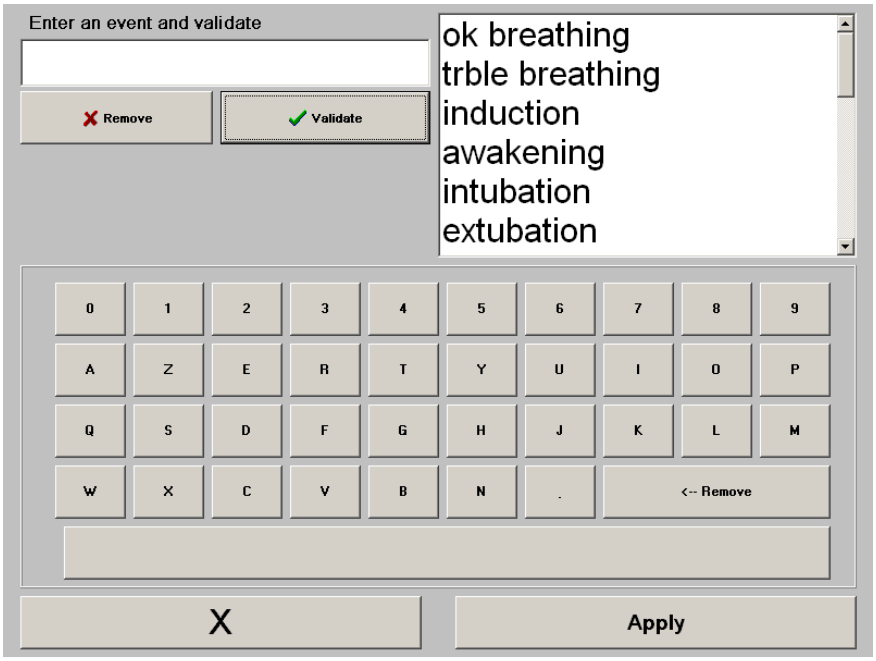


Figure 40

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 (figure 33):

Select **[Set time].**

The following window appears:

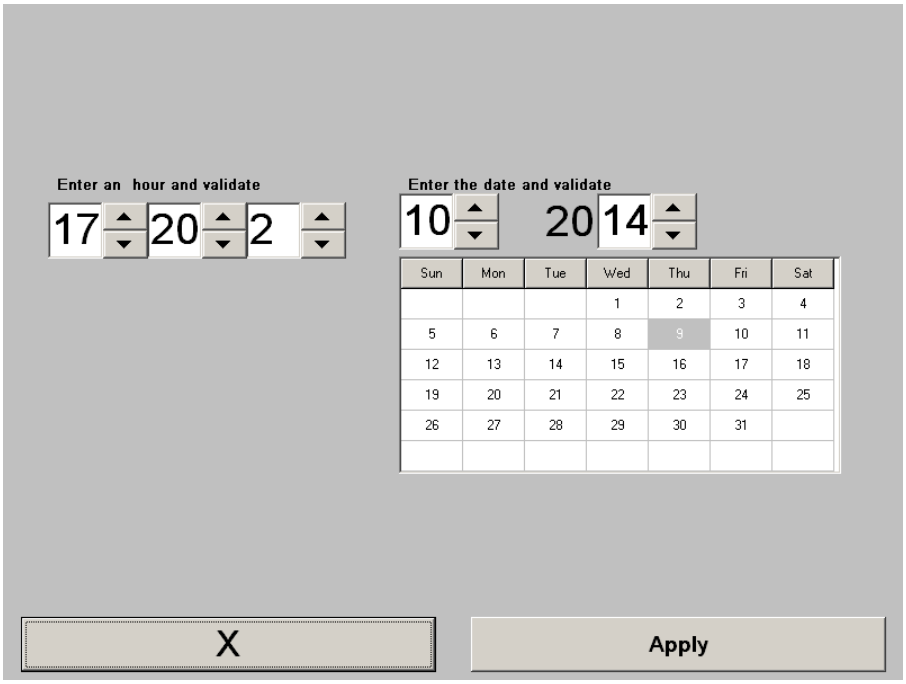


Figure 41

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 (figure 33), click on **[Update monitor].** Connect a USB key with the new version of "AniM_INT.exe" provided by your Mdoloris Medical Systems representative. Next, select **[Update monitor]** (figure 42).

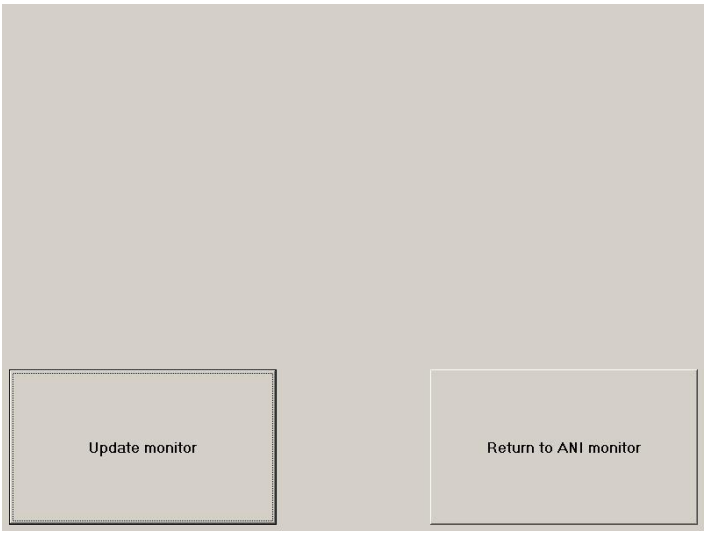


Figure 42

A message will appear to confirm that the update was successful (figure 43). After 5 seconds, click on **[Return to the ANI monitor].**

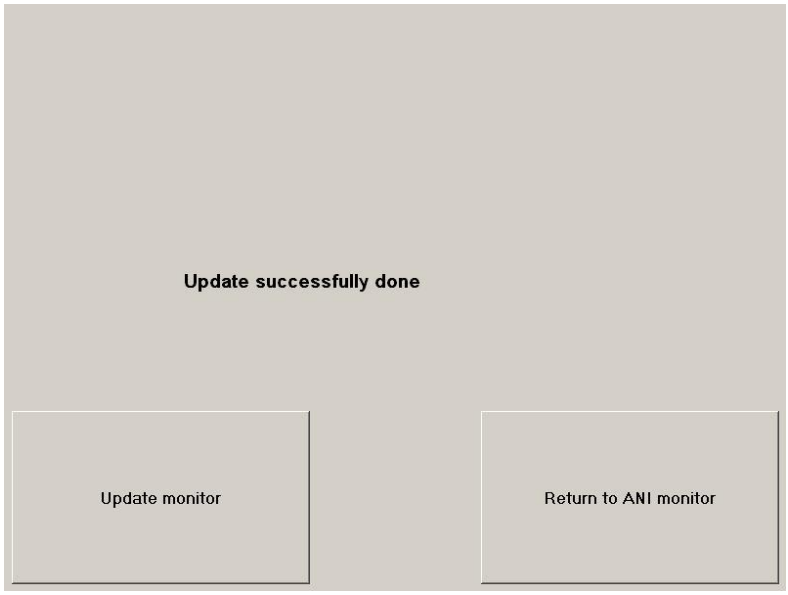


Figure 43

If there is no USB key connected, a message will appear to tell the user (figure 44):

Figure 44

If the file “AniM_INT.exe” is not present on the USB key, a message will appear (figure 45):

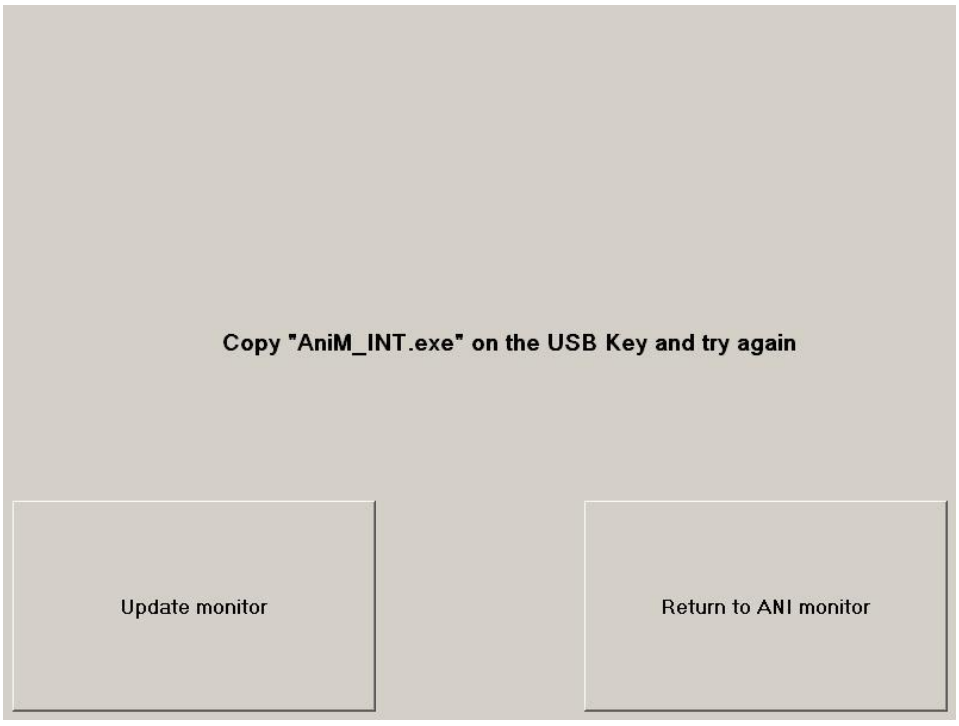


Figure 45

7.11 Shutting down

Selecting ⊘ **[Shutdown]** (figure 33) switches off the ANI Monitor V1.

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. See figure 12) 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 4 of section 4.2.
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 ANI Monitor V1 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).

Problem	Solution
The monitor doesn’t boot.	Check that the battery's power indicator is on (figure 13) when the monitor is connected to a power supply. If the power indicator is off, remove the transparent cover and push the button.
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 ANI Monitor V1 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.

10.2 Operating Environment

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

WARNING: *Explosion hazard: do not use the ANI Monitor V1 in an inflammable atmosphere or where concentrations of inflammable anesthetics may accumulate.*

The ANI Monitor V1 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.

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

The monitor operates satisfactorily at sea level or above and is not affected by extremes or altitude changes up to 2000 m or atmospheric pressures ranging from 360 mmHg to 800 mmHg.

10.3 Power requirements and grounding

The ANI 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 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

The ANI Monitor V1 can support 1,000 cleaning cycles.

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

Cleaning 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 damp lint-free absorbent cloths to clean spillage. Dampen the towel with detergent and lukewarm water to aid in cleaning. After cleaning, wipe the end of the connector 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 monitor cleaner for computer screens. To avoid scratching the screen, never use abrasive cleaners.

Disinfecting the monitor and acquisition device:
Use lint-free absorbent towels dampened with isopropyl alcohol, a 10% bleach solution, or a commercial disinfectant.

After cleaning, dry all areas except the monitor display screen with a lint-free absorbent cloth. Wipe the connector ends with alcohol and allow them 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 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 ANI 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;
- Pole clamp.

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): 3.17 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 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 included with the ANI Monitor V1:

- Monitor: Mdoloris Medical Systems Ref: MN-ANI-V1
  Manufactured by IEI (product reference: AFL-08A-N270)
- Acquisition case: Mdoloris Medical Systems Ref: BA-ANI-V1
  Manufactured by RHEA Electronique
- Sensor cable: Mdoloris Medical Systems Ref: ANI-SC-V1 (ANI Sensor V1/ANI Sensor V2) ; ANI-SC-V1PLUS (ANI Sensor V1 PLUS)
  Manufactured by AXON
- Power cable: Mdoloris Medical Systems Ref: ANI-PW-V1-x.

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 ANI Monitor V1 (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.

Electrosurgery Interference/Defibrillation/Electromagnetic disturbance:

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

The ANI 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 Electronic Medical Equipment

12.2 Warranty

Mdoloris Medical Systems warrants to the initial Purchaser that the ANI Monitor V1 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.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY FOR MDOLORIS MEDICAL SYSTEMS PRODUCTS, EXTENDS ONLY TO THE PURCHASER, AND IS

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12.3 Software License Agreement

The computer software (“Licensed Software”) loaded on the ANI Monitor V1 (“System”) is licensed, not sold, to you for use only under the terms of this license. Mdoloris Medical Systems reserves any rights not explicitly granted. You own the System, but Mdoloris Medical Systems retains all ownership rights and title to the Licensed Software itself.

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