

User manual

ANI Technology

ANI Monitor V2

Software version: 2.2.3.0



1370

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**Important information about the intended use of ANI Monitor V2:**

The Mdoloris Medical Systems' ANI Monitor V2 is designed to be used for adult and paediatric patients from the age of 2 years.

ANI Monitor V2 is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel specifically trained for its use (resuscitators, anaesthesiologists, state-registered nurses anaesthetists) in a medical environment, non-sterile.

ANI Monitor V2 allows monitoring the tone of the parasympathetic nervous system. It may be used to monitor the effects of certain analgesic agents.  
ANI Monitor V2 is 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.

**Known contraindications where the ANI measurement cannot be interpreted:**

- 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.)

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## 1 Safety precautions

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

### 1.1 Warnings and safety instructions



**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 V2 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 V2 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 V2 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.**



**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 V2 (MDOLORIS MEDICAL SYSTEMS) MAY RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED ELECTROMAGNETIC IMMUNITY OF THE ANI Monitor V2 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 V2.**



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



**TO MINIMIZE THE RISK OF PATIENT STRANGULATION, THE PATIENT 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 V2.**



**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 V2, 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 V2 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 V2 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.**



**THE CHARACTERISTICS OF ANI Monitor V2 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 V2 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 V2.**



**ANI Monitor V2 THE SHOULD NOT BE USED ADJACENT TO OTHER DEVICES OR STACKED WITH THEM ON PAIN OF CAUSING MALFUNCTIONS. IN THE EVENT THAT SUCH USE PROVES NECESSARY ANI Monitor V2 SHOULD BE SUPERVIZED WITH THE OTHER DEVICES IN ORDER TO CHECK THEY OPERATE IN THE NORMAL WAY.**



**STAFF SHOULD AVOID TOUCHING SIMULTANEOUSLY PATIENT AND ANI Monitor V2.**



**WHEN CHANGING THE POLE CLAMP, USE ONLY NYLON SCREWS TO ENSURE INSULATION.**



**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.**



**DO NOT AUTOCLAVE THE MONITOR. AUTOCLAVING WILL SERIOUSLY DAMAGE BOTH COMPONENTS.**

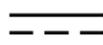


**DO NOT BLOCK VENTILATION INLET HOLES OF MONITOR.**



**THIS MEDICAL EQUIPMENT, ITS COMPONENTS AND PACKAGING MUST BE RECYCLED IN ACCORDANCE WITH LOCAL REGULATIONS ON THE ENVIRONMENT AND DISPOSAL OF ELECTRIC WASTE.**

1.2 Key to symbols

Symbol	Description	Symbol	Description
	Manufacturer + Manufacturing Date		Fragile; handle with care
	Serial number		Direct current, DC
	Class II equipment		BF Type equipment, protects against defibrillation
	European compliance Mark of compliance with the European Medical Device Directive		Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)
	Consult operating manual		Needs special waste disposal
	General safety sign		Upper and lower temperature limits (Shipping and Storage Environment)
	Do not expose to sunlight		Check the packaging quality upon delivery
	Keep dry		This way up

## 2 ANI Monitor V2

ANI (Analgesia Nociception Index) is a standardized continuous measurement of the relative  $p\Sigma$  tone (parasympathetic tone). Each respiratory cycle (spontaneous and artificial) induces a fast, temporary decrease of the  $p\Sigma$  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  $p\Sigma$  tone.

The series of normal, non-ectopic, R-R intervals is displayed on the screen of the ANI Monitor V2 after normalization, resampling and filtering. The amount of  $p\Sigma$  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  $p\Sigma$ , the higher the shaded surface, and reciprocally.

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  $p\Sigma$  activity as a part of ANS activity: it expresses the relative amount of  $p\Sigma$  tone present as compared to sum of sympathetic and  $p\Sigma$  activities. ANI Monitor V2 displays two averaged ANI measurements: ANI<sub>i</sub> results from the average of ANI measured over the previous 120 sec, and ANI<sub>m</sub> results from the average of ANI measured over the previous 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 ANI<sub>m</sub> measure between 50 and 70 during surgery makes a hemodynamic reactivity episode unlikely in the following 10 minutes;
- that an ANI<sub>m</sub> lower than 50 makes hemodynamic reactivity very likely in the following 10 minutes.

ANI calculation is based on R-R interval variability in ECG. Since the ANI Monitor V2 is not an ECG or a cardiac 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.

### 3 Installing the ANI Monitor V2

#### 3.1 Perfusion stand

Position the ANI Monitor V2 so that the main power supply can 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.**

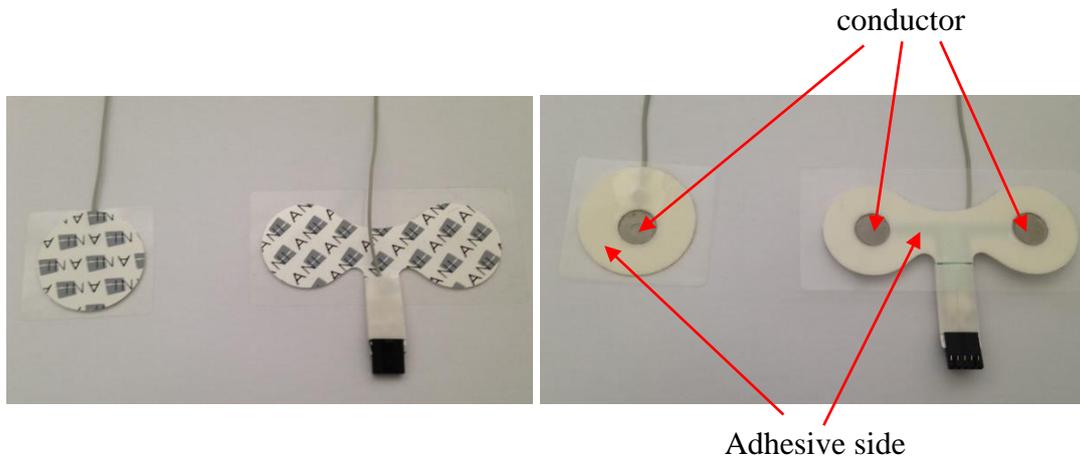
#### 3.2 Table

A system available for ANI Monitor V2 allows it to be placed on a flat surface.

#### 3.3 ANI Sensor V1 / ANI Sensor V2 / ANI Sensor V1 PLUS

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.

**WARNINGS:**

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

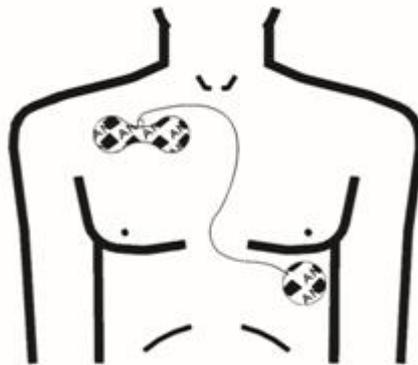
*If the patient develops a skin reaction or other unusual symptoms, remove the electrodes. It is important to take particular care with patients suffering from dermatological problems.*

*Never put electrodes on skin injuries.*

*Using electrode sensors other than those specified by Mdoloris Medical Systems can damage the device or result in a 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 adhesive strength due to an initial application, withdrawal and a new application.*



**Sensors' positioning**

**NOTE:** The ANI Monitor V2 has been designed to work with specific disposable sensors. It is inadvisable to use another kind of electrode.

The maximum consecutive period that the electrodes can adhere to the skin is 24 hrs.

The shelf life of the electrodes is indicated on their packaging.

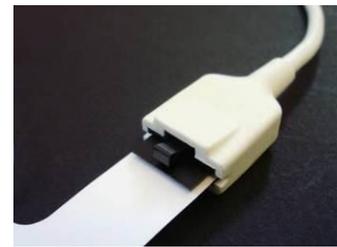
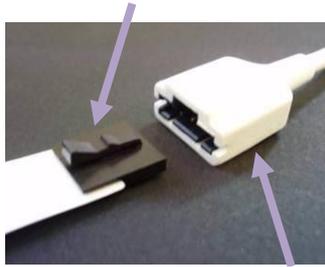
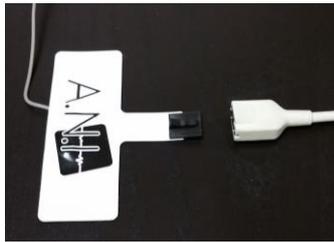
Biocompatibility has been tested on all Mdoloris Medical Systems sensors. They meet standards ISO 10993-5 and ISO 10993-10.

### 3.4 ANI Monitor V2 Connection

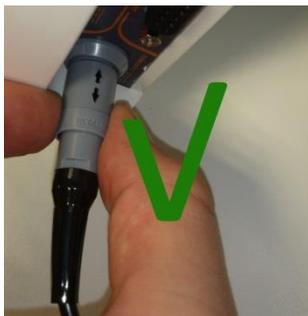
Connect the sensors to the sensor cable then connect it to the monitor.

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

Locking mechanism



Plastic portion



SENSOR	SENSOR CABLE
ANI Sensor V1 ANI-SENS-V1	ANI-SC-V2
ANI Sensor V2 ANI-SENS-V2	ANI-SC-V2
ANI Sensor V1 PLUS ANI-SENS-V1PLUS	ANI-SC-V2PLUS



#### 4 Beginning ANI Monitor V2

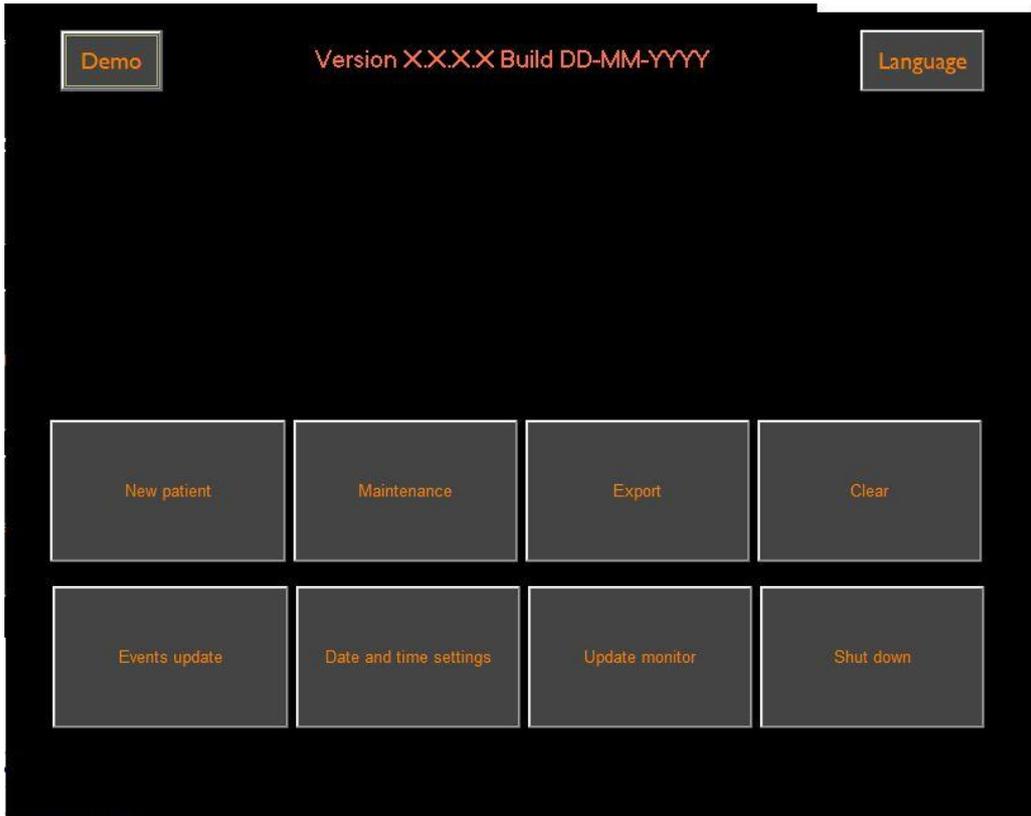
After connecting the monitor to the electrical socket, press the touch-sensitive switch situated at the bottom centre of the screen.



**NOTE:**

- When the monitor is turned on, the LED lights up green.
- When the monitor is on stand-by mode, the LED lights up orange.

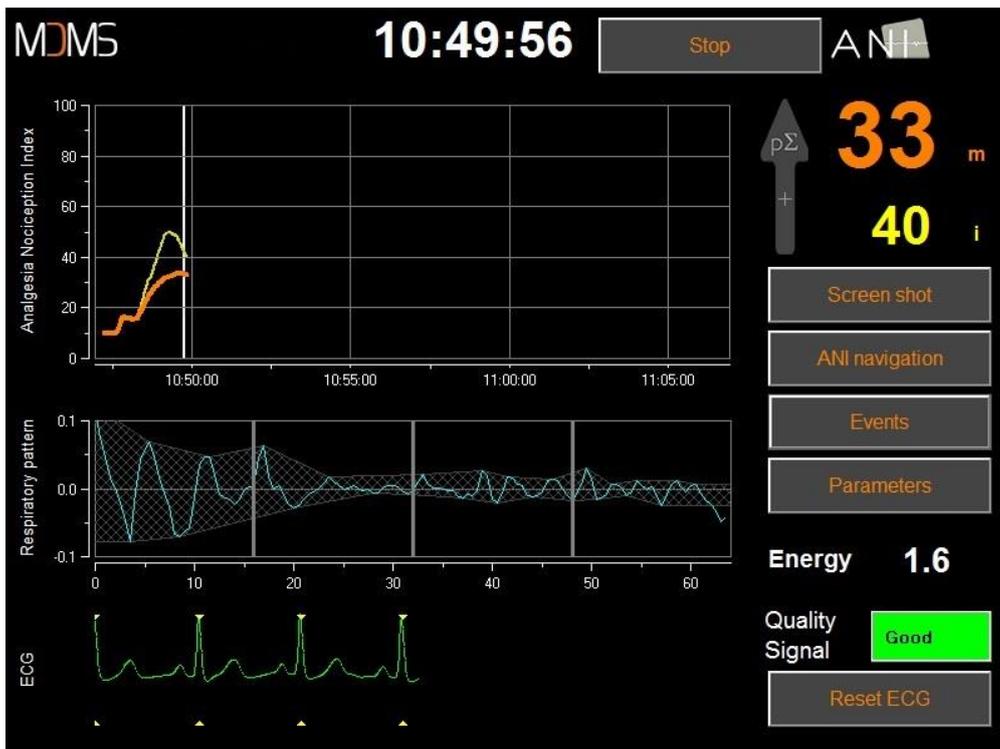
The monitor will start displaying the Mdoloris Medical Systems logo animations successively. The screen will then, automatically display the start menu.



**Main menu**

Once the monitor is connected to the patient with the electrodes, the calculation algorithm will automatically begin.

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



### Main view

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 V2 and setting parameters

### 5.1 ECG Capture

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



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

- 1) Both with the morphology signal and the scrolling on the ECG display
- 2) looking at the bottom right corner of the screen :

-	Good quality signal	Quality Signal	Good
-	Medium quality signal	Quality Signal	Medium
-	Poor quality signal	Quality Signal	Bad

**Case n°1 - No signal is displayed**

You must try, at least once, to replace the sensor.

**Case n°2 – Medium signal quality**

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

**Case n°3 – Poor signal quality**

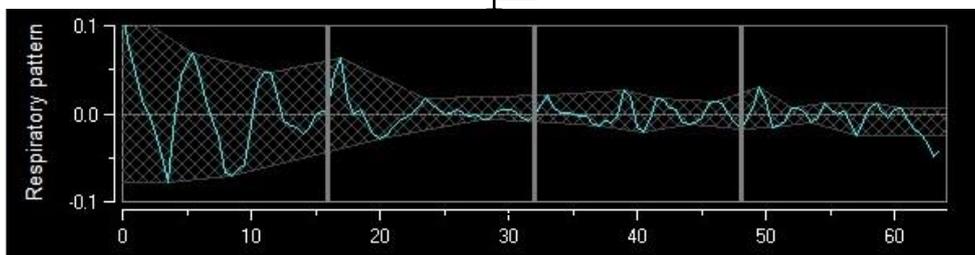
If the indication shows poor signal quality (red indication is lit) the data displayed cannot be taken into account. In that case, the ANI index is not displayed anymore, the curve freezes and a message “poor signal quality” appears in the middle of the screen to warn the user.

- Select the button “Auto-gain” in the bottom right corner of the screen to automatically recover the ECG signal.
- If the signal quality is **still medium or poor**, check the proper position of the electrodes and their adhesion to the skin. If necessary, reposition or change them.

**5.2 Respiratory pattern**

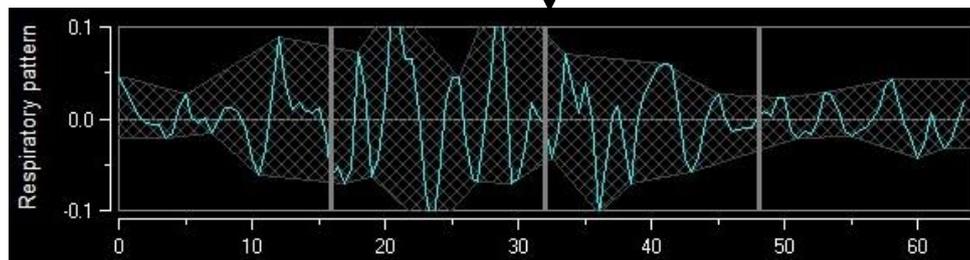
The surface area generated by "respiratory patterns" in the R-R series is measured and displayed in a hatched surface. The higher the surface, the stronger the relative  $p\Sigma$  tone.

Small hatched surface area = low  $p\Sigma$  tone



**R-R normalized series with low amplitude respiratory sinus arrhythmia**

Large hatched surface area = high  $p\Sigma$  tone

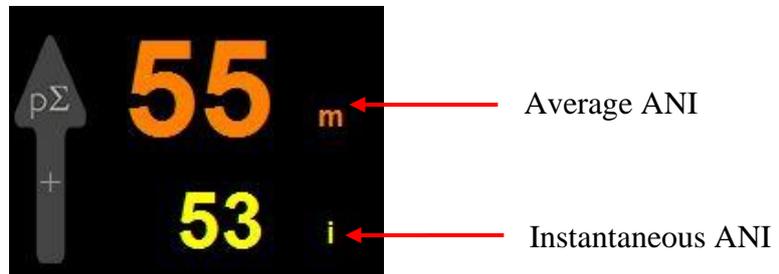


**R-R normalized series with high amplitude respiratory sinus arrhythmia**

### 5.3 ANI index

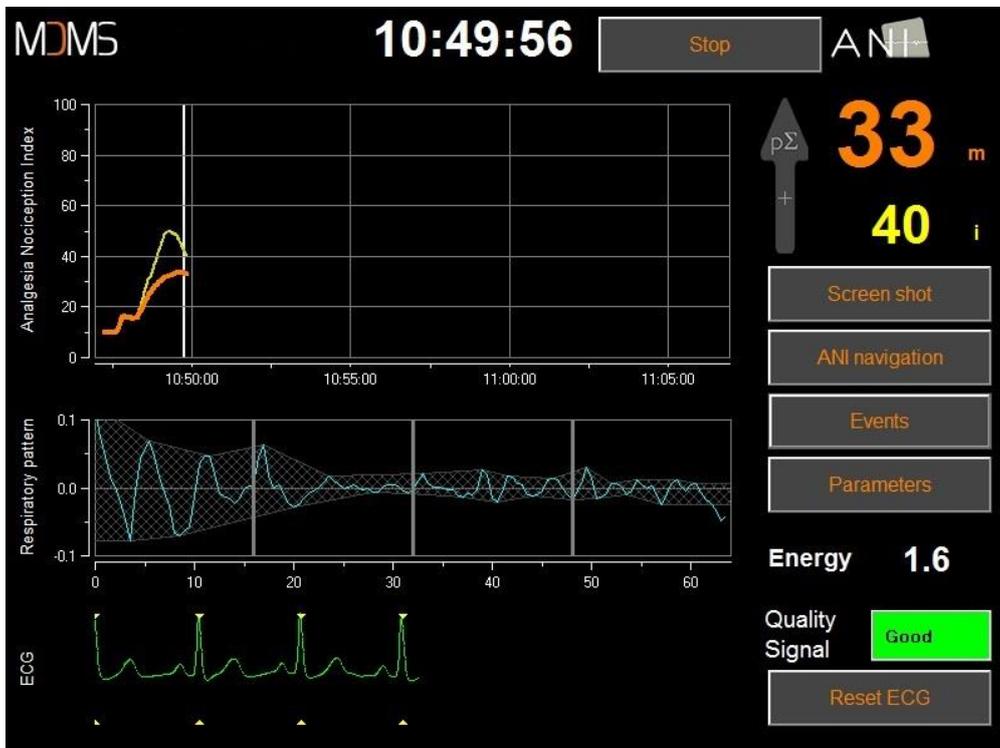
We have developed calculation algorithms based on the amplitude measurement of the respiratory modulation of RR interval time series.

A continuous index is displayed (each basic measurement is performed on 64 seconds of data with a sliding window every second) that reflects the parasympathetic tone of the patient. A calculation is made every second and then averaged over two time periods: a short average (average over two minutes) and a longer average (average over 4 minutes). The monitor displays two parameters: the yellow one is the instantaneous ANI (marked as “i”), resulting from the short average; the orange one is the value of the longer average (marked as “m”). These indexes can anticipate a hemodynamic reactivity during the nociceptive stimuli. “



**Index**

Therefore we display in the adjoining window of trends, a yellow curve and an orange curve reflecting these two indexes over time.



**Curves**

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 in which the user can scroll through the ANI measurements and see the events captured.



ANI navigation

Select « X » to close this window. Signal acquisition is not disturbed while the navigation window is opened.

## 6 ANI Monitor V2 settings

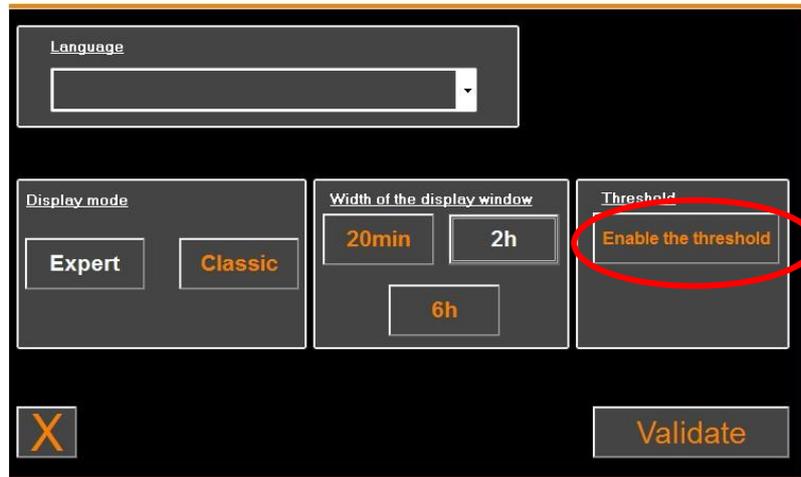
To access the settings described in this section, select « **Parameters** » on the bottom right of the screen during monitoring.

### 6.1 Language parameters

The user can choose the language. Available languages are shown in the drop-down list. Choose the language and press « X » to close the « **Parameters** » window and set up the new language.

## 6.2 Threshold

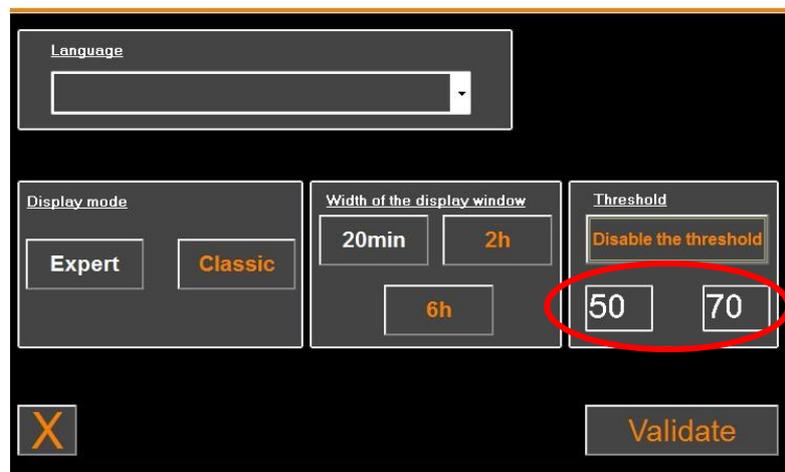
As shown in the screen below (figure 23), threshold values can be set here. Select «**Enable threshold**».



The screenshot shows a configuration interface with a dark background and orange accents. At the top is a 'Language' dropdown menu. Below it are three main sections: 'Display mode' with 'Expert' and 'Classic' buttons; 'Width of the display window' with '20min', '2h', and '6h' buttons; and 'Threshold' with an 'Enable the threshold' button circled in red. At the bottom left is a close button with an 'X' icon, and at the bottom right is a 'Validate' button.

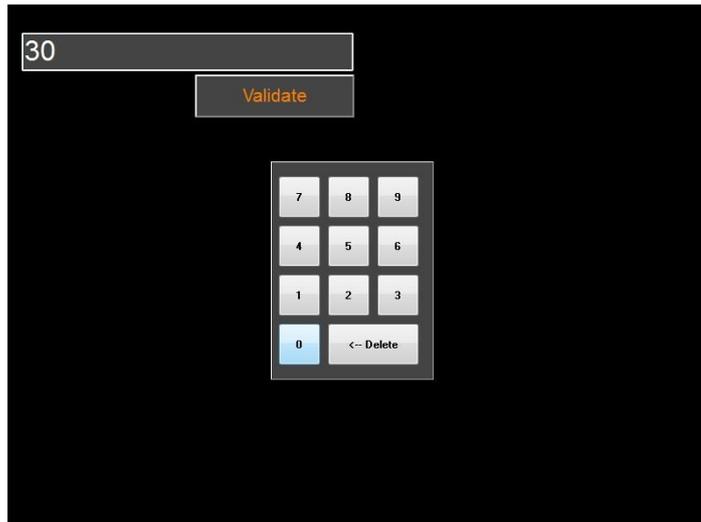
**Enable threshold**

Default values appear below in the data input (50/70).



This screenshot is similar to the previous one but shows the 'Threshold' section with 'Disable the threshold' selected. Below the text are two input fields containing the values '50' and '70', which are circled in red. The 'Validate' button is visible at the bottom right.

Click on the first input field and enter a first threshold value. Click on «Validate» to validate. Do the same for the second input field.

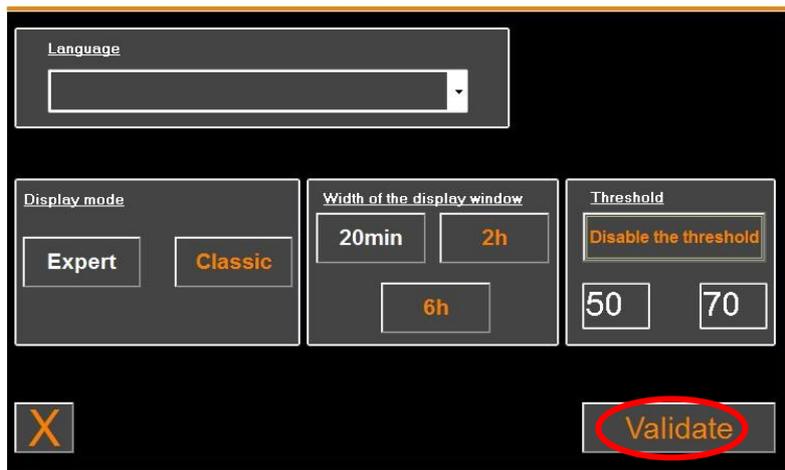


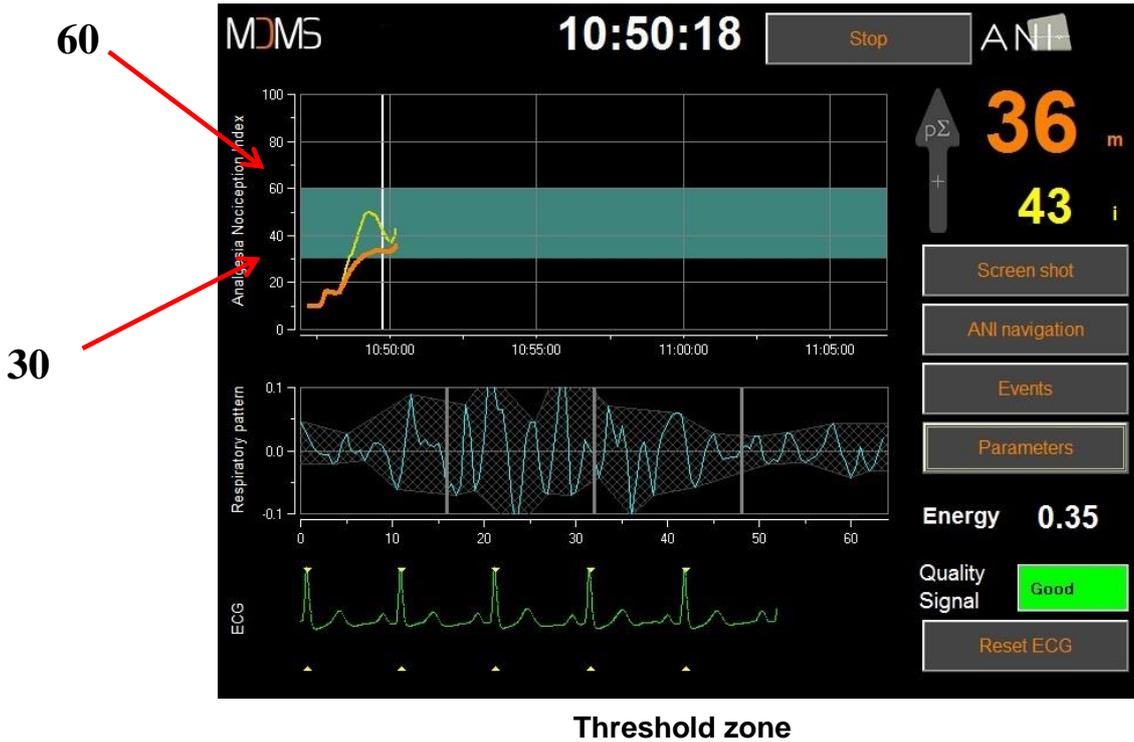
**Input data**

If the user confirms without entering data, he will be asked to insert a value between 0 and 100.



Once data have been entered, click **“VALIDATE”**.





### 6.3 Events

As shown in the screen below, 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. Click one of these buttons to insert a line through the ANI curve and the event will be recorded in the R-R series log.

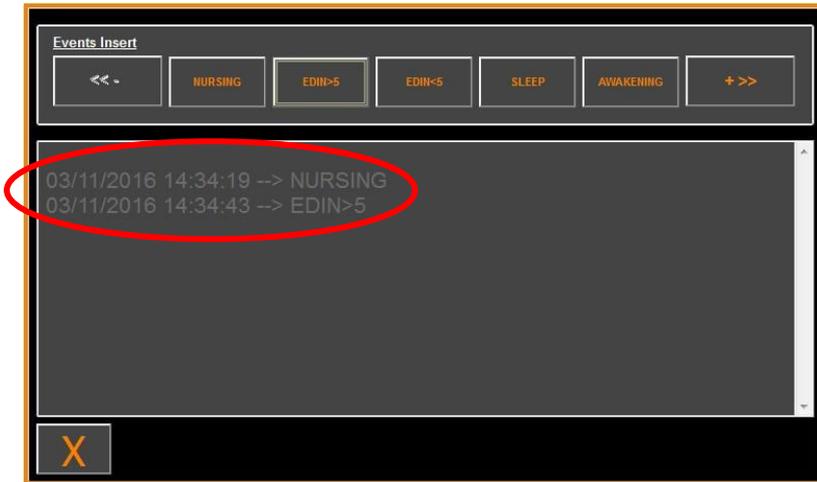


**Events**

Example of events that may be relevant:

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

Once inserted, the event will be displayed by clicking on the button "events".



**Events display**

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 7.7 below). It is also possible to edit your own list of events (see section 7.8 below).

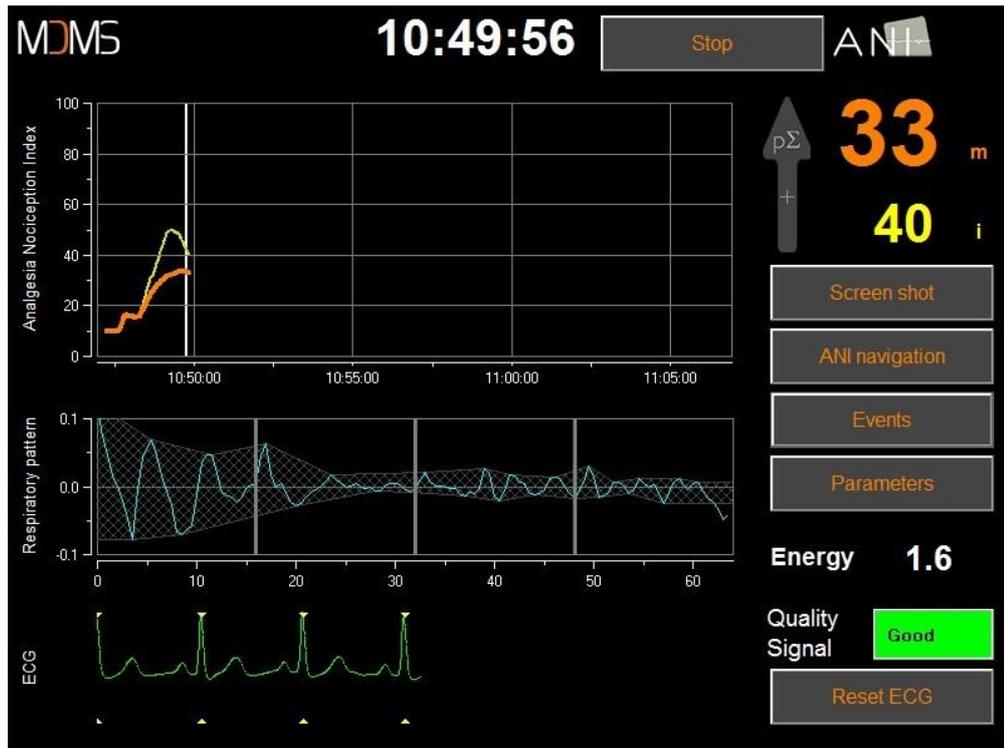
#### **6.4 Expert mode and energy index**

There are two modes:

- « **Classic** » mode: no energy display, no respiratory pattern display, no instantaneous ANI curve. Nevertheless, a sharp drop of the instantaneous ANI characterized by a yellow peak can appear in response to a painful or stressful stimulus. In the same time zone, the display of the instantaneous ANI value appears on the screen. Both of them disappear at the end of the painful or stressful stimulus.



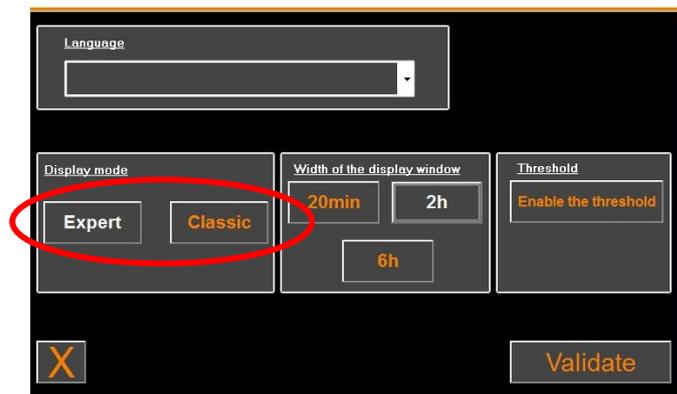
- « **Expert** » mode: display of respiratory pattern and an additional function called: «Energy» index.



Expert mode

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  $p\Sigma$  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  $p\Sigma$  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**».



## 7 Ending ANI monitoring

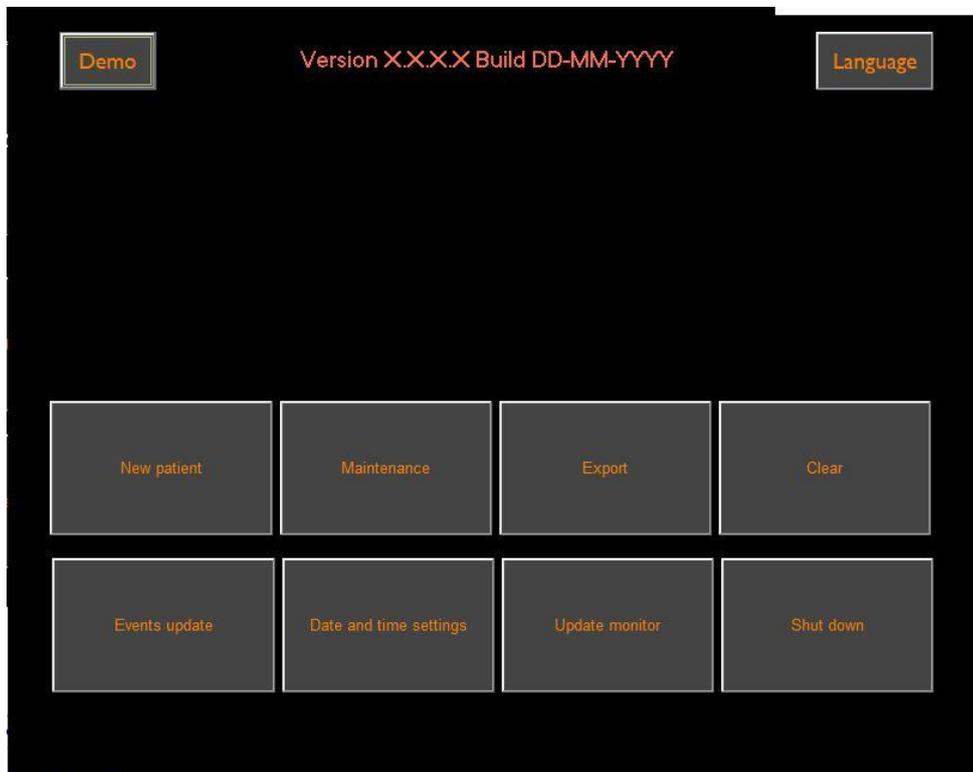
### 7.1 Stopping the recording of a case

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 (Do you really want to quit this recording?).

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

If you respond « **Yes** », the ANI Monitor displays the main menu:



### 7.2 Demo

Selecting «**Demo**» at the top left, displays a video of the ANI Monitor V2 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 (Do you really want to delete all of the recordings?).

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. In order to not saturate the memory, a confirmation message is displayed when a screenshot 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, select «**Export**». The screenshots are saved in a file named according to time and date: Hour - Minute - Month - Day - Year.

## 7.7 Exporting data files

Selecting “**Export**” opens a new window with the files available in the memory and the files to be exported.



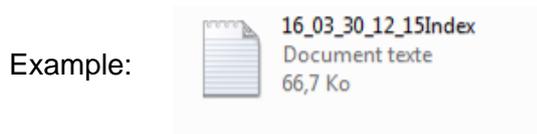
The user can select the files to be exported by selecting “**Export Selection**” or can export all of the files by selecting “**Export Totality**”.

If the monitor does not detect the USB drive (no drive present, or inserted incorrectly), a message is displayed to indicate this (« Insert a USB key »). Once the USB is inserted correctly, select «**OK**» to begin exporting the data.

Once the files have been exported successfully, a confirmation window appears (« Export done successfully »). 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.



Once the file is open, the data appear in the following format:

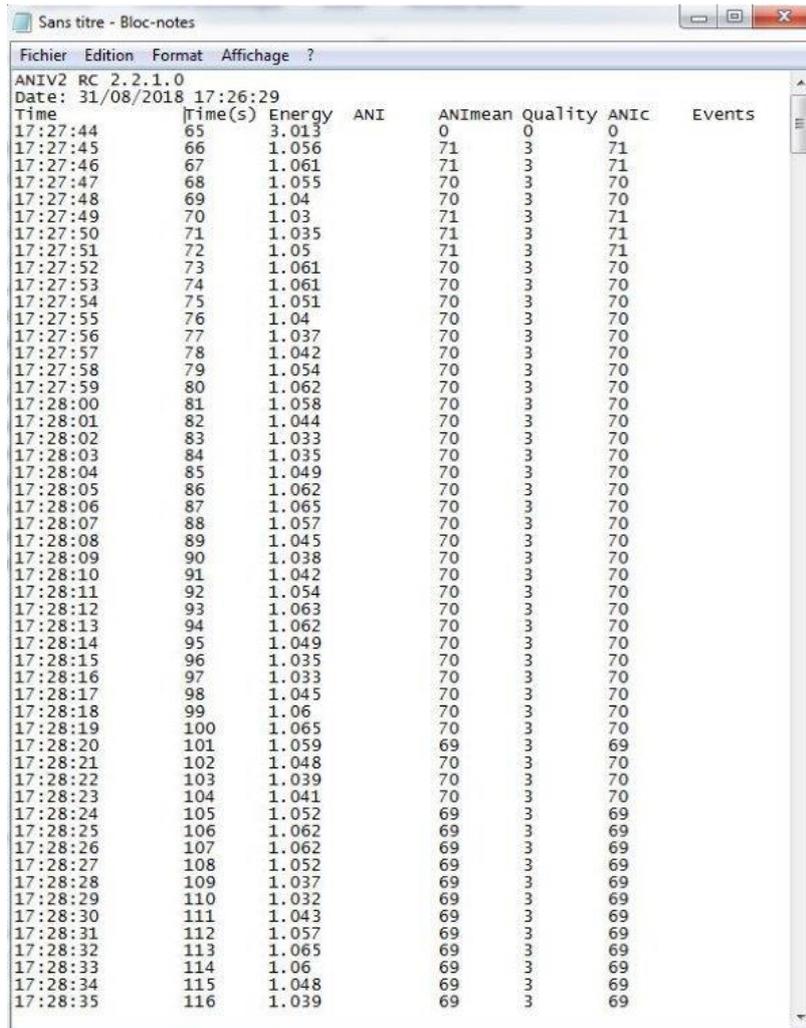
17\_26\_31\_08\_18Index.log - Bloc-notes

Fichier Edition Format Affichage ?

ANIV2 RC 2.2.1.0  
Date: 31/08/2018 17:26:29

Time	Time(s)	Energy	ANI	ANImean	Quality	ANIC	Events
17:27:44	65	3.013	0	0	0		
17:27:45	66	1.056	71	71	3		
17:27:46	67	1.061	71	71	3		
17:27:47	68	1.055	70	70	3		
17:27:48	69	1.04	70	70	3		
17:27:49	70	1.03	71	71	3		
17:27:50	71	1.035	71	71	3		
17:27:51	72	1.05	71	71	3		
17:27:52	73	1.061	70	70	3		
17:27:53	74	1.061	70	70	3		
17:27:54	75	1.051	70	70	3		
17:27:55	76	1.04	70	70	3		
17:27:56	77	1.037	70	70	3		
17:27:57	78	1.042	70	70	3		
17:27:58	79	1.054	70	70	3		
17:27:59	80	1.062	70	70	3		
17:28:00	81	1.058	70	70	3		
17:28:01	82	1.044	70	70	3		
17:28:02	83	1.033	70	70	3		
17:28:03	84	1.035	70	70	3		
17:28:04	85	1.049	70	70	3		
17:28:05	86	1.062	70	70	3		
17:28:06	87	1.065	70	70	3		
17:28:07	88	1.057	70	70	3		
17:28:08	89	1.045	70	70	3		
17:28:09	90	1.038	70	70	3		
17:28:10	91	1.042	70	70	3		
17:28:11	92	1.054	70	70	3		
17:28:12	93	1.063	70	70	3		
17:28:13	94	1.062	70	70	3		
17:28:14	95	1.049	70	70	3		
17:28:15	96	1.035	70	70	3		
17:28:16	97	1.033	70	70	3		
17:28:17	98	1.045	70	70	3		
17:28:18	99	1.06	70	70	3		
17:28:19	100	1.065	70	70	3		
17:28:20	101	1.059	69	69	3		
17:28:21	102	1.048	70	70	3		
17:28:22	103	1.039	70	70	3		
17:28:23	104	1.041	70	70	3		
17:28:24	105	1.052	69	69	3		
17:28:25	106	1.062	69	69	3		
17:28:26	107	1.062	69	69	3		
17:28:27	108	1.052	69	69	3		
17:28:28	109	1.037	69	69	3		
17:28:29	110	1.032	69	69	3		
17:28:30	111	1.043	69	69	3		
17:28:31	112	1.057	69	69	3		
17:28:32	113	1.065	69	69	3		
17:28:33	114	1.06	69	69	3		
17:28:34	115	1.048	69	69	3		
17:28:35	116	1.039	69	69	3		

Expert mode



Time	Time(s)	Energy	ANI	ANImean	Quality	ANIc	Events
17:27:44	65	3.013	0	0	0	0	
17:27:45	66	1.056	71	3	71		
17:27:46	67	1.061	71	3	71		
17:27:47	68	1.055	70	3	70		
17:27:48	69	1.04	70	3	70		
17:27:49	70	1.03	71	3	71		
17:27:50	71	1.035	71	3	71		
17:27:51	72	1.05	71	3	71		
17:27:52	73	1.061	70	3	70		
17:27:53	74	1.061	70	3	70		
17:27:54	75	1.051	70	3	70		
17:27:55	76	1.04	70	3	70		
17:27:56	77	1.037	70	3	70		
17:27:57	78	1.042	70	3	70		
17:27:58	79	1.054	70	3	70		
17:27:59	80	1.062	70	3	70		
17:28:00	81	1.058	70	3	70		
17:28:01	82	1.044	70	3	70		
17:28:02	83	1.033	70	3	70		
17:28:03	84	1.035	70	3	70		
17:28:04	85	1.049	70	3	70		
17:28:05	86	1.062	70	3	70		
17:28:06	87	1.065	70	3	70		
17:28:07	88	1.057	70	3	70		
17:28:08	89	1.045	70	3	70		
17:28:09	90	1.038	70	3	70		
17:28:10	91	1.042	70	3	70		
17:28:11	92	1.054	70	3	70		
17:28:12	93	1.063	70	3	70		
17:28:13	94	1.062	70	3	70		
17:28:14	95	1.049	70	3	70		
17:28:15	96	1.035	70	3	70		
17:28:16	97	1.033	70	3	70		
17:28:17	98	1.045	70	3	70		
17:28:18	99	1.06	70	3	70		
17:28:19	100	1.065	70	3	70		
17:28:20	101	1.059	69	3	69		
17:28:21	102	1.048	70	3	70		
17:28:22	103	1.039	70	3	70		
17:28:23	104	1.041	70	3	70		
17:28:24	105	1.052	69	3	69		
17:28:25	106	1.062	69	3	69		
17:28:26	107	1.062	69	3	69		
17:28:27	108	1.052	69	3	69		
17:28:28	109	1.037	69	3	69		
17:28:29	110	1.032	69	3	69		
17:28:30	111	1.043	69	3	69		
17:28:31	112	1.057	69	3	69		
17:28:32	113	1.065	69	3	69		
17:28:33	114	1.06	69	3	69		
17:28:34	115	1.048	69	3	69		
17:28:35	116	1.039	69	3	69		

**Classic Mode**

<b>Date</b>	format DD/MM/YYYY
<b>Time</b>	Format of the time HH:MM:SS
<b>Time(s)</b>	Sampling in seconds
<b>Energy</b>	Signal Energy
<b>ANI</b>	Instantaneous value of the ANI between 0 and 100 (Expert Mode)
<b>ANImean</b>	Averaged value of the ANI between 0 and 100
<b>ANIc</b>	Instantaneous value of the ANI between 0 and 100 (Classical (Standard?) Mode)
<b>Quality</b>	Quality of the signal. Values ranging from 0 to 3 <ul style="list-style-type: none"> <li>- 0 = bad signal quality</li> <li>- 1 = average signal quality</li> <li>- 2 = average signal quality</li> <li>- 3 = good signal quality</li> </ul>
<b>Events</b>	Events added by the user

Real time data from the monitor can be retrieved by connecting a computer to the “real-time export” port on the right side of the monitor. The character string can be displayed by a terminal type software application (to get the protocol available in the technical manual, please contact your Mdoloris agent).

**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.

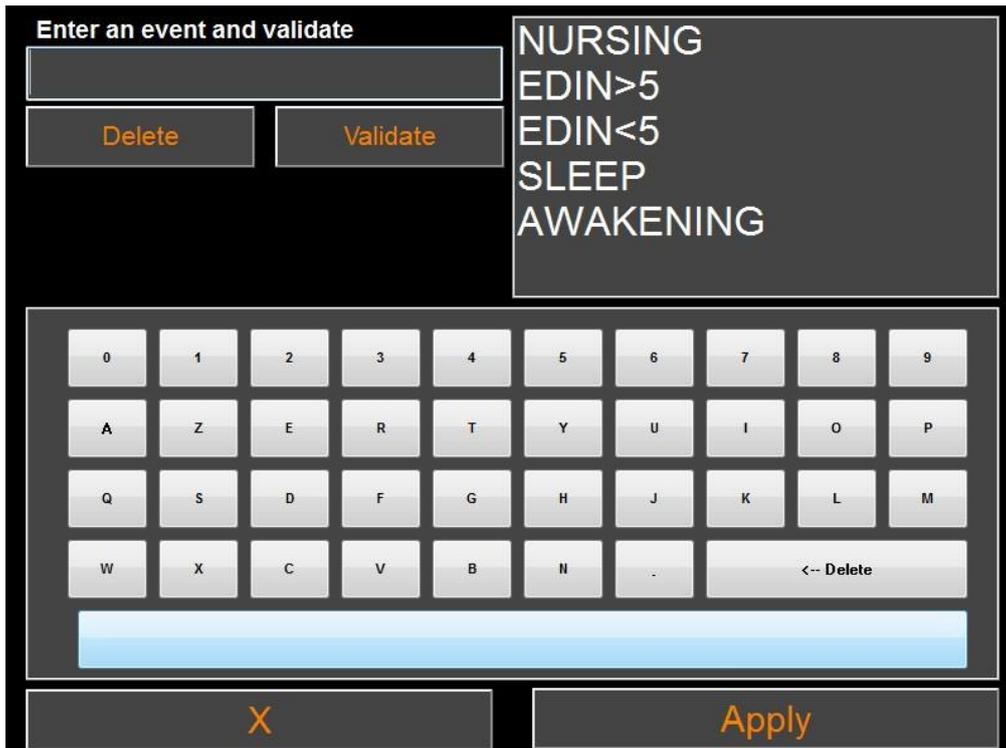
## 7.8 Updating events

As explained above (see section 6.3), 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.

***Note:** if you respond « Yes » you will not be able to return to the current patient. You will then see the 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.

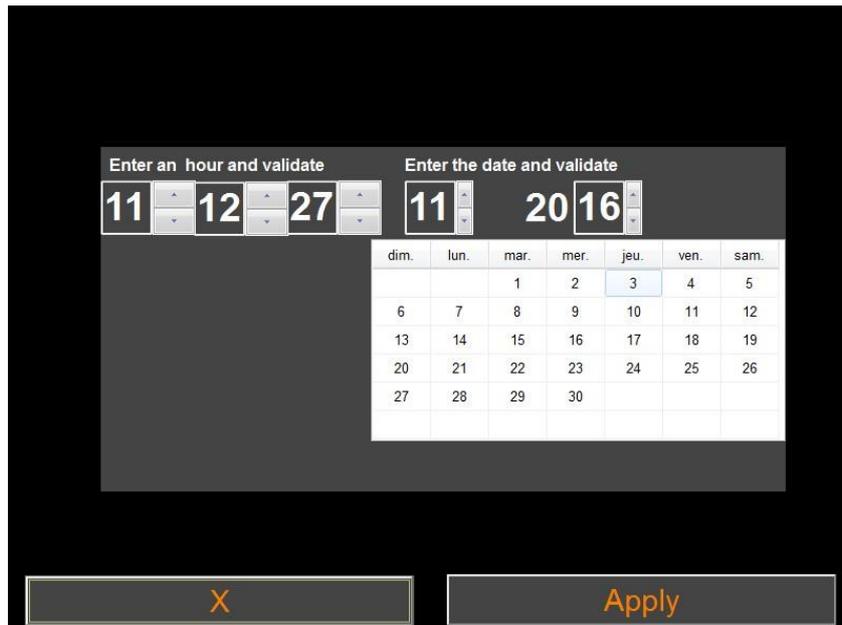
The new event is then added to the event-list displayed on the right. Use the scroll bar if the added event does not appear. An event can be removed from the list by touching it, and selecting « **X Remove** ».

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** ».

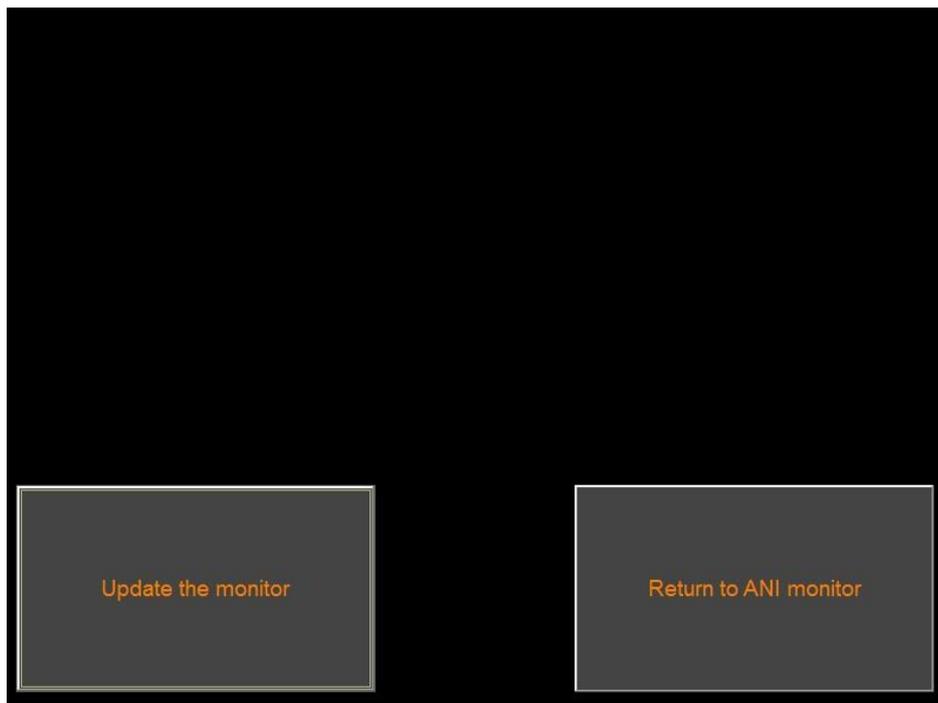
The following window appears:



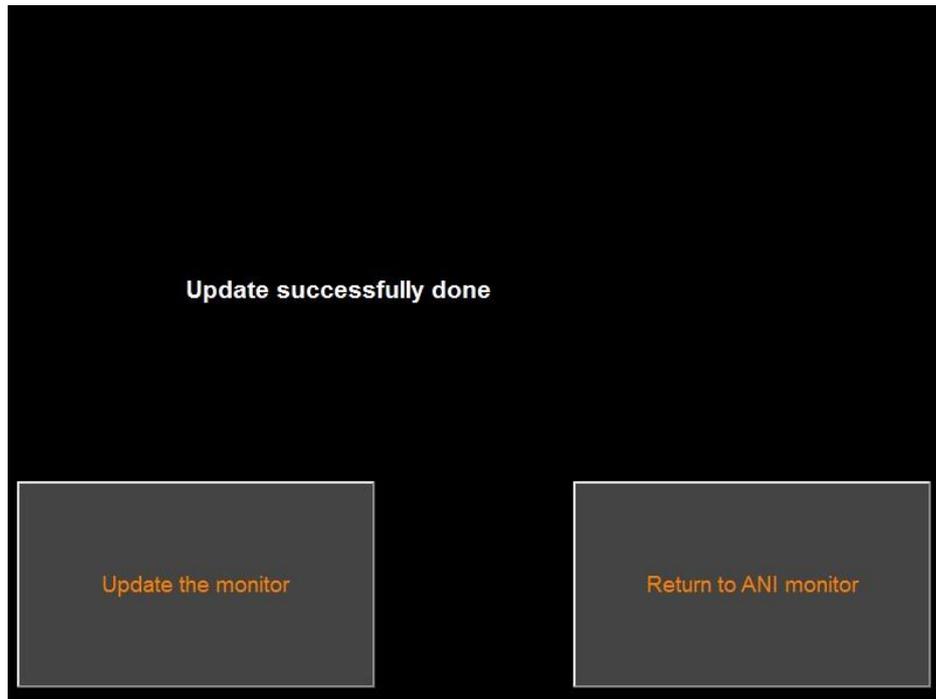
Use the arrows to select the desired change. Validate the changes before closing the window by selecting «Apply». Select «X» to close the window.

### 7.10 Updating monitor

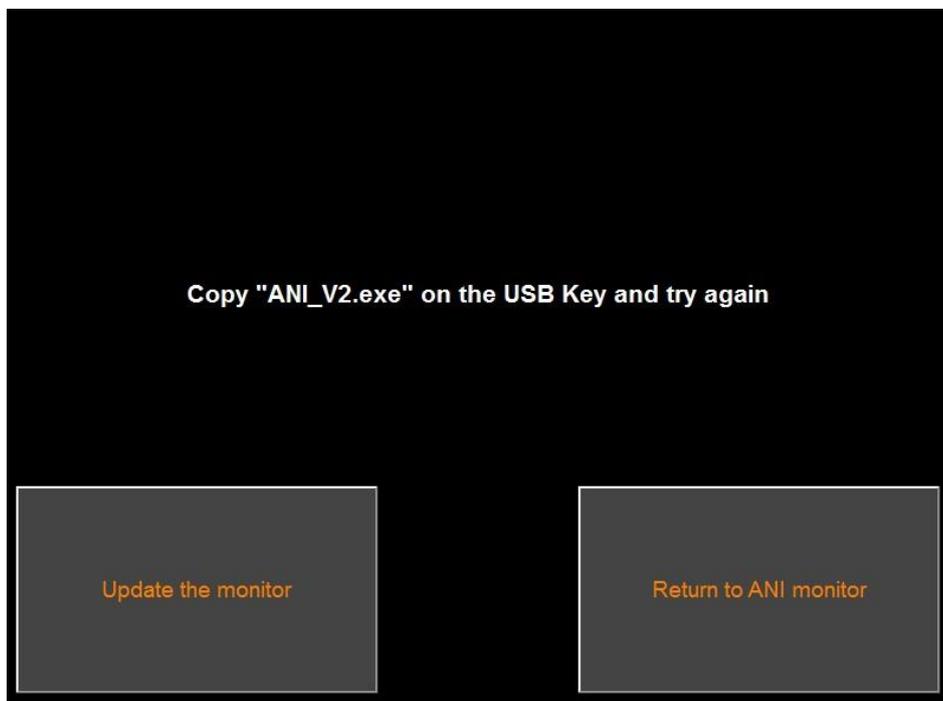
In the main menu, click on « **Update monitor** ». Connect a USB key with the new version of “ANI\_V2.exe” provided by your Mdoloris Medical Systems representative. Next, select « **Update monitor** ».



A message will appear to confirm that the update was successful. After 5 seconds, click on « **Return to the ANI monitor** ».



If there is no USB key connected, a message will appear to tell the user (Insert a USB key).  
If the file "ANI\_V2.exe" is not present on the USB key, a message will appear:



**7.11 Shutting down**

Selecting «  **Shutdown** » switches off the ANI Monitor V2.

**NOTE:** Turning the monitor off cannot be done with the power button on the front.

**8 Trouble shooting**

<u>Problem</u>	<u>Solution</u>
The monitor is not displaying an ECG signal.	Check the patient cable is correctly connected to the monitor. Check that there is a flat signal in the ECG window. If no signal appears, contact your Mdoloris agent.
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 § 3.3
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 V2 shuts down by itself without reason.	Check that the power supply cable is connected to the monitor and reboot the monitor as explained here (§ 4). If the problem persists, contact your Mdoloris representative.
The monitor doesn't boot.	Check that the battery's power indicator is on when the monitor is connected to a power supply. Check the power cable is correctly connected. If the problem persists, contact your Mdoloris agent.
The touch screen does not work.	Reboot the monitor using touch-sensitive switch situated bottom center of the screen (§ 4). Contact your Mdoloris Medical Systems

	agent.
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## **9 Monitor disposal**



Recycling electrical equipment helps preserve natural resources and prevents risk of pollution. In this respect, Mdoloris Medical Systems fulfils its obligations concerning the end-of-life of the ANI Monitor V2 that it places on the market by financing the DEEE Pro recycling system that collects and recycles free of charge (For more information contact your Mdoloris agent)

**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.*

The monitor can be dismantled:

- No metal parts are permanently attached inside the monitor housing
- All of the electrical parts meet the RoHS2 standard.



■ 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 V2 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

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 V2 is not designed for use in areas containing flammable gases or vapors.

**WARNING:** *Explosion hazard: do not use the ANI Monitor V2 in an inflammable atmosphere or where concentrations of inflammable anaesthetics may accumulate.*

The ANI Monitor V2 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 operates satisfactorily at sea level or above and is not affected by extremes or altitude changes up to 2000 m.

## **10.3 Power requirements and grounding**

The ANI Monitor V2 requires a power source of 100-240 VAC, 50-60Hz.

**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.*

# **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 the monitor, power supply unit 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 the maker's wipes called "linget' Anios" wipes or ethanol-based wipes.

After cleaning, allow it to dry completely. Residual moisture inside the connector may affect the monitoring performance.

Do not use abrasive detergents to avoid scratching the screen.

**WARNING:** *DO NOT MIX DISINFECTING SOLUTIONS AS TOXIC GASES MAY RESULT.*

**Caution:**

Avoid liquid ingress with the connection cables. This could interfere with acquisition performance.

## 11.2 Maintenance

The ANI Monitor V2 is designed so that no periodic maintenance is required.

Leakage current is a primary indicator of electrical shock hazard for personnel who touches 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 IEC 60601-1.

Preventive maintenance is recommended once a year: cable check, integrity of labels, system check and leakage current 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;
- AC-DC Power supply;
- Pole clamp.

## 12 Specifications, warranty and software license contract

### 12.1 Specifications

Electricity supply: 100/240 Volts

Maximum power: 40 W

Current: 3.4 A

Frequency: 50/60 Hz

Electrical safety: class II in electrical safety

Weight of monitor alone (without any accessories): 2.5 kg

Monitor dimensions (width x height x depth): 25.6 cm x 21.4 cm x 8.1 cm

Screen size: 8.4 inches, resolution 800 x 600

AC-DC power supply: manufacturer SL POWER, reference ME40A1203F01

Life span of power supply unit: minimum 1 000 000 h

USB/ Serial port: electrical insulation 5 kV DC

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

#### **Annex IX (Directive 93/42/EEC, consolidated by 2007/47/EC):**

##### **Classification:**

- CISPR 11: Class A
- IIa Electro-Medical Equipment

##### **Type of protection against electric shocks:**

**Class II** : electrical equipment in which the protection against electric shock is not only based on BASIC INSULATION, but includes additional security measures such as DOUBLE INSULATION or REINFORCED INSULATION, this protection is realized without using ground protection and is not dependent on the conditions of installation

##### **Protection against the projection of liquids:**

Always ensure that ANI Monitor V2 is placed away from any area that would be at risk from blood or solute spillage.

##### **System operation:**

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

## 12.2 Accessories



1



2



3



4



5



6

Number	Identification
1	ANI Monitor V2
2	Sensor
3	End User Cable
4	Power cord
5	AC/DC Power supply
6	Pole clamp

### 12.3 Warranty

Mdoloris Medical Systems warrants to the initial Purchaser that the ANI Monitor V2 (“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 EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MDOLORIS MEDICAL SYSTEMS' MAXIMUM LIABILITY ARISING OUT OF THE SALE OF THE PRODUCTS OR THEIR USE, WHETHER BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE, SHALL NOT EXCEED THE ACTUAL PAYMENTS RECEIVED BY MDOLORIS MEDICAL SYSTEMS IN CONNECTION THEREWITH. MDOLORIS MEDICAL SYSTEMS SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE (INCLUDING WITHOUT LIMITATION LOST PROFITS) DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, INABILITY TO SELL, USE OR LOSS OF USE OF ANY PRODUCT. EXCEPT AS SET FORTH HEREIN, ALL PRODUCTS ARE SUPPLIED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED.

#### **12.4 Software License Agreement**

The computer software ("Licensed Software") loaded on the ANI Monitor V2 ("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.

1. LICENSE: you are hereby granted the non-exclusive right to use the Licensed Software solely with the specific System on which the Licensed Software was provided to you.
2. RESTRICTIONS: you shall not transfer the Licensed Software in any manner from the System to any other computer or system without the prior written consent of Mdoloris Medical Systems. You shall not distribute copies of the Licensed Software or its

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