Analgesia Nociception Index

ANI Monitor V1

User manual

Software version 1.1.4.0

$C\epsilon$ 1370

(CE mark first approved on April 2012)

ANI is a registered trademark.

Important information about using continuous analgesia monitoring system:

The Mdoloris Medical Systems' continuous analgesia monitoring system is intended for use in a medical environment and under the direct supervision of a licensed healthcare practitioner or by personnel specifically trained for its use. The continuous analgesia monitoring system is intended for use on adult and pediatric patients, providing patient care by monitoring the parasympathetic nervous tones activity by data acquisition of ECG signals.

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

ANI Monitor V1 is a complex monitoring technology intended for use as an adjunct to clinical judgment. Clinical judgment should always be used when interpreting the ANI index in conjunction with other available clinical signs. Reliance on ANI alone for interpreting analgesic management is not recommended. As with any monitored parameter, artifacts and poor signal quality may lead to inappropriate ANI values. Potential artifacts may be caused by high impedance of ECG source system, muscle activity or rigidity, patient motion, improper sensor placement or electrical interference.

ANI is a protected trademark.

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1   Safety precautions

INTRODUCTION:

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

WARNINGS, CAUTIONS AND NOTES

The terms warning, caution, and note have specific meanings in this manual.

- A WARNING advises against certain actions or situations that could result in physical injury or death.

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

- 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   Warnings

⚠

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

⚠

PROTECTION AGAINST HEART DEFIBRILLATION SHOCK DEPENDS ON THE APPROPRIATE CABLE USE.

⚠

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 SKIN ELECTRODES ARE DESIGNED FOR USE IN THE MRI ENVIRONMENT.

⚠️

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

⚠️

CONSIDERATIONS WHEN USING ELECTRO-CONVULSIVE THERAPY (ECT) EQUIPMENT DURING THE ANI MONITORING: place ECT electrodes as far away as possible from the sensors to minimize the effect of interference. Some ECT equipment may interfere with the proper functioning of the ANI Monitor V1. Check for compatibility of equipment during patient setup.

⚠️

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

⚠️

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

⚠️

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

⚠️

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

⚠

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE MANUFACTURERS REQUIREMENTS MAY INFLUENCE THE SAFETY OF THE RESULTING SYSTEM. CONSIDERATION RELATING TO THE CHOICE OF EQUIPMENT SHALL INCLUDE:

- USE OF THE ACCESSORY IN THE PATIENT VICINITY AND OR SURGERY VICINITY

- EVIDENCE THAT THE SAFETY CERTIFICATION « CE » OF THE ACCESSORY AS BEEN PERFORMED IN ACCORDANCE TO THE HARMONIZED STANDARD (IEC 60601-1 AND/OR IEC 60601-1-1) APPLIED TO THE ANI Monitor V1.

⚠

BE SURE NOT TO PLACE THE INTERFACE EQUIPMENT DIRECTLY IN PROLONGED CONTACT WITH SKIN TO AVOID PERSONAL OR PATIENT INJURY DUE TO HIGH SURFACE TEMPERATURE.

⚠

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

⚠

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

⚠

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.

⚠️

THE INTERFACE WIRE HAS TO BE CAREFULLY PLACED AND HELD DOWN TO PREVENT ANY PATIENT STRANGULATION RISK.

⚠️

DO NOT PLACE SKIN ELECTRODES BETWEEN DEFIBRILLATOR PADLLE WHEN IT'S USED ON A PATIENT CONNECTED TO THE ANI Monitor V1.

⚠️

USE AGAIN AN ARRAY ALREADY USED ON PREVIOUS PATIENT COULD LEAD RISK OF CROSS-CONTAMINATION.

⚠️

IF THE PATIENT DEVELOPS A CUTANEOUS RASH OR OTHERS UNUSUAL SYMPTOMS, REMOVE THE ARRAY. IT IS IMPORTANT TO ADAPT A PARTICULAR CARE TO PATIENTS SUFFERING FROM DERMATOLOGICAL PROBLEMS.

⚠️

NEVER PUT ELECTRODES ON INJURIES.

⚠️

ON ELECTRICAL SHOCK HAZARD :
- *DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET HANDS.*
- *DO NOT REMOVE MONITOR COVERS DURING OPERATION OR WHILE POWER IS CONNECTED TO MONITOR.*
- *THE MANUFACTURER'S INSPECTION OF THIS APPARATUS VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED BY*

THE APPLICABLE SAFETY STANDARDS. AS A MATTER OF SAFE PRACTICE, THE INSTITUTION SHOULD ALSO CONDUCT TESTS TO VERIFY THESE CURRENTS ESPECIALLY WHEN A QUALIFIED BIOMEDICAL ENGINEERING TECHNICIAN PERIODICALLY OPENS THE INSTRUMENT CASE.

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

⚠️

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

⚠️

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

⚠️

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

 - INCREASE SEPARATION BETWEEN DEVICES
 - CHANGE THE ORIENTATION OF DEVICE CABLING
 - PLUG DEVICES INTO SEPARATE CIRCUIT OUTLET
OR PLEASE CONTACT YOUR MDOLORIS MEDICAL SYSTEMS REPRESENTATIVE.

⚠

THE ANI Monitor V1 IN OPERATING SURGICAL ROOM MUST BE PLACED OUTSIDE THE SAFETY CONE OF EXPLOSION RISK.

⚠

TO AVOID THE HAZARD OF BURNS BE SURE THE MONITOR IS INSTALLED OUTSIDE THE SURGICAL SECURITY AREA AND AS FAR AS POSSIBLE FROM LIQUID INGRESS TO PREVENT SYSTEM DAMAGE.

⚠

IF THE MONITOR SHOULD BE OPEN ANY MODIFICATIONS ARE ALLOWED TO BE DONE.

1.2   Cautions

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

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

Equipment should not be reachable by the patient.

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

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

Unused monitor ports should not be connected with other devices.

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

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

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

Using electrode arrays different from those sold by Mdoloris Medical Systems could damage the device or lead a risk for the user or the patient.

Use again an array could reduce the adhesion, leading to a possible decrease in electrical performance.

Use again an array could damage the capacitor due to application, removal and reapplication.

Only Mdoloris Medical Systems qualified biomedical technicians must 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 national regulatory in force in the country. Contact Mdoloris Medical Systems or the local distributor for the battery maintenance.

The internal battery is not designed to withstand alone a long time monitoring. The internal battery of the ANI Monitor V1 allows the system to keep calculating the ANI while the patient is moved to another room or in case of temporary interruption of electrical main supply.

To ignite the monitor, it has to be plugged in first intention to prevent a sudden electrical crash in case of the battery is not enough charged. Check the battery charge symbol displayed before unplugged: the battery could be not sufficiently charged and interrupt the electrical supply of the ANI Monitor V1.

Never use the ANI Monitor V1 while a surgery only with the battery power. The monitor must be plugged on electrical main supply, especially while an electrical bistoury is used.

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

1.3 Notes

The « **Notes** » can be found at the end of each related chapter.

1.4 Key to Symbols

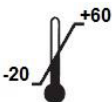| Symbol	Description	Symbol	Description
	Operator's manual; operating instructions	SN	Serial number
RxOnly	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)	CE	European compliance Mark of compliance with the European Medical Device Directive
	Do not expose to sunlight		This way up
	Check the packaging quality upon delivery		Needs special waste disposal
+60 -20	Upper and lower temperature limits (Shipping and Storage Environment)		Keep dry
	Fragile; handle with care		BF Type equipment, protects against defibrillation

⚠️	General safety sign		
⏚	Protective earth; protective ground	YYYY-MM	Manufacturer + Manufacturing Date

2 ANI Monitor V1 presentation

ANI (Analgesia Nociception Index) is an online continuous measurement of the parasympathetic tone (pΣ), which is a part of the autonomous system (ANS). Each respiratory cycle induces in the ANS a temporary fall of pΣ tone, which can be measured on the normalized RR series by the resulting amplitude of "respiratory pattern".

Rapid pΣ tone variations express themselves directly on the sinus mode by way of the vagal nerve issued from the brain stem, where it is connected with afferent stimuli from bronchial stretch sensors. Each respiratory cycle (spontaneous or in positive pressure) gives an information about the instantaneous pΣ tone by measuring the amplitude of the associated sharp decrease in the normalized RR series (respiratory pattern).

The RR series is established by means of an electrocardiogram, by detecting the R waves and measuring the time interval between adjacent R waves. After normalization and resampling, the pΣ compound of the RR series is obtained by filtering in order to keep only high frequency signals in the RR series. The surface delineated by successive respiratory patterns is directly related to the instantaneous pΣ tone: the more pΣ tone there is, the bigger the surface.

To note: ANI measurement cannot be interpreted in the following situations:

- *arrythmia*
- *apnoea (e.g. apnoea induced by anesthesia)*
- *respiratory frequency of less than 9 cycles/min*
- *variable tidal volume during the measurement period (64 seconds)*

- *irregular spontaneous ventilation (patient speaking, laughing or coughing)*
- *pace maker (certain types)*
- *cardiac graft*
- *drugs affecting the sinus node (atropine, glycopyrrolate, etc.)*

The ANI index is expressed on a scale between 0 and 100. It gives a reading of the proportion of pΣ tone in the ANS. The ANI displayed is the result of measurements computation made during 64 seconds, with a 1 second moving window.

There are multiple ways of interpreting the ANI result. One is probabilistic, as this ANI index has been developed in order to predict hemodynamic reactivity during general anesthesia (GA). When surgical stimulation was constant, all hemodynamic reactivity episodes (20% increase of heart rate or systolic arterial pressure) were associated with a decreased ANI up to 10 min beforehand. The predictive threshold need yet to be established, but preliminary studies suggest:

- that an ANI measure between 50 and 70 during surgery under GA makes a hemodynamic reactivity episode **unlikely** in the following 10 min
- that an ANI of less than 50 makes hemodynamic reactivity **very likely** in the following 10 min

3 ANI Monitor V1 installation

3.1 Clamping support

Position the monitor in order to use easily the power plug. The monitor could be installed on a vertical clamp (figure 1). Mount the monitor using the pole clamp on a pole diameter from 0.75 to 1.49 inches. **Please ensure the pole is compatible.**

Figure 1

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

The ANI calculation is based on the RR intervals variability of ECG. The ANI Monitor V1 being not an ECG monitor, the electrodes have been designed to retrieve information related to QRS complex. The acquisition of a cardiac vector is enough to get an ANI calculation.

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

The sensor itself is divided into two areas. One of them is an adhesive area and the other one, the active area, is covered with conductive gel (figure 3).
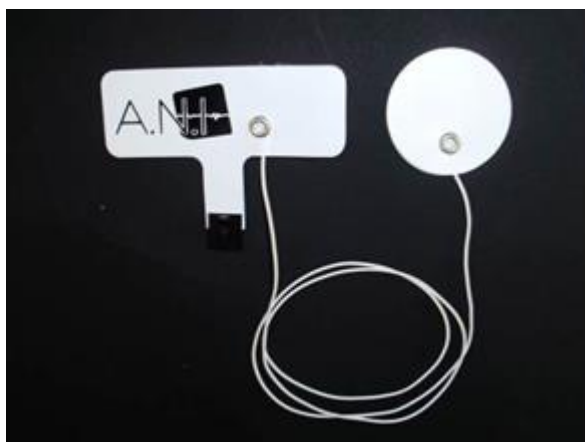

Figure 2

Conductive gel

Adhesive area
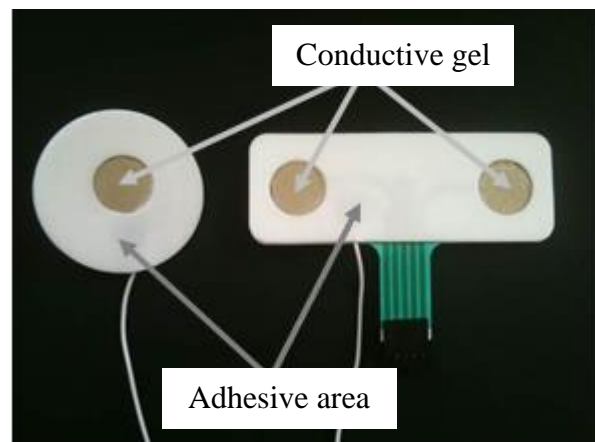
Figure 3

The principle of this patch in two parts is to be placed 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 we can apply the dual sensor on a hairless area of the upper chest and the single sensor on the left side of the abdomen (see next page the example with figure 4).

WARNINGS:

Use again an array already used on previous patient could lead risk of cross-contamination.

If the patient develops a cutaneous rash or others unusual symptoms, remove the array. It is important to adapt a particular care to patients suffering from dermatological problems.

Never put electrodes on injuries.
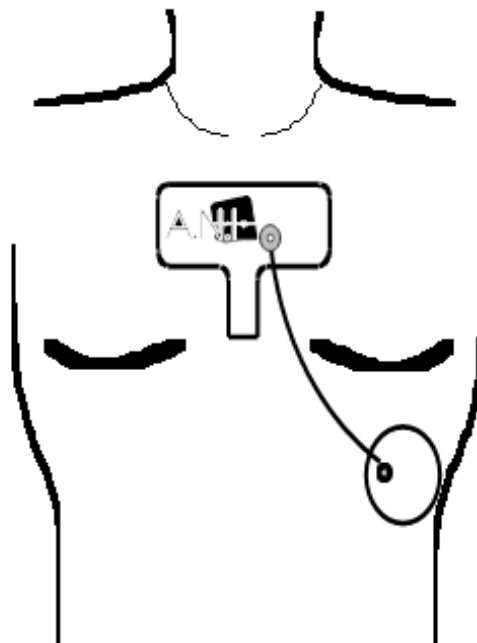
Figure 4

NOTE: The ANI Monitor V1 has been designed to work with specific disposable electrodes. It is inadvisable using another kind of electrode.

The electrode packaging is ten per bag. The purchase of new electrodes is available through a box with ten bags inside thus in total one hundred arrays.

The maximum consecutive period within the electrodes are able to remain on the skin is 24 hours. The electrodes shelf-life is noted on the outer white pouch: in a closed white pouch, it is two years. In an opened white pouch, the electrodes shelf-life is six months.

The biocompatibility has been made on every Mdoloris Medical Systems' array. They match with ISO10993-5 and 10993-10.

Before connecting, carefully align the notches on the connection support for a perfect match pins (figures 5 and 7). To disconnect the electrodes, grasp the plastic support by pressing on the locking mechanism and pull it normally to disengage it (figure 6). **Do not pull by grasping directly the electrode**.

Locking mechanism

Plastic support

| **Figure 5** | **Figure 6** | **Figure 7** |

3.3 ANI Monitor V1 connexion

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

Acquisition device

Skin electrodes
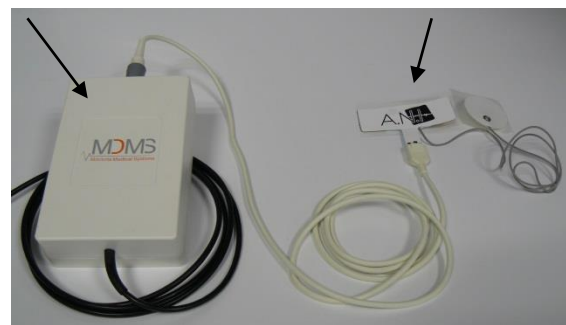
Figure 8

Figure 9

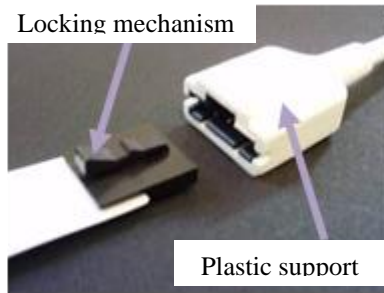Then connect the black wire from the acquisition device to the monitor into the plug in the bottom left hand corner of the monitor front side (figures 10 and 11).

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

The ANI Monitor V1 contains an internal battery. The internal battery of the ANI Monitor V1 allows the system to keep calculating the ANI while the patient is moved to another room or in case of temporary interruption of electrical main supply. The internal battery is not designed to withstand alone a long time monitoring. The battery gauge has ten graduations; each symbolizes around 10 min of battery life. As soon as the electrical main supply is interrupted, a message appears on the screen with a warning bell in order to push the user to plug the monitor into an electrical main supply quickly. The ANI index is still calculated during this event.

NOTE: *To ignite the monitor, it has to be plugged in first intention to prevent a sudden electrical crash in case of the battery is not enough charged.*

Check the battery charge gauge displayed before unplugged: the battery could be not sufficiently charged and interrupt the electrical supply of the ANI Monitor V1.

If the power plug has been disconnected whereas the battery was not sufficiently charged, the battery could be unable to supply the energy the monitor needs, so it will brutally stopped. Once you plug again the monitor and if the front switch (see figure 12 below) doesn't reboot it please use the green rear button (see figure 13 below) to power the monitor up again. The power indicator becomes bright.

Never use the ANI Monitor V1 while a surgery only with the battery power. The monitor must be plugged on electrical main supply, especially while an electrical bistoury is used.

4 Beginning the ANI monitoring

Ignite the monitor thanks to the switch in the bottom right hand corner of the front side (figure 12).

Front Switch

Figure 12

NOTE: if the front switch doesn't reboot the monitor, check the green rear button is really bright. If this power indicator is still dim, lift up the transparent shell and push on this green button in order to power the monitor up and reboot it.

Rear push button

Figure 13

WARNING: *use this green rear push button only to power the monitor up. Never use it to shut down the device. As a brutal stop, it could occur serious damages for next ignition and prevent a correct use.*

The monitor will start by showing Mdoloris Medical Systems logo animations successively. The first measure of the ANI will take at least 80 seconds. No data can be interpreted before this initialization time lapse. The screen will then indicate "Calibration" (figure 14).
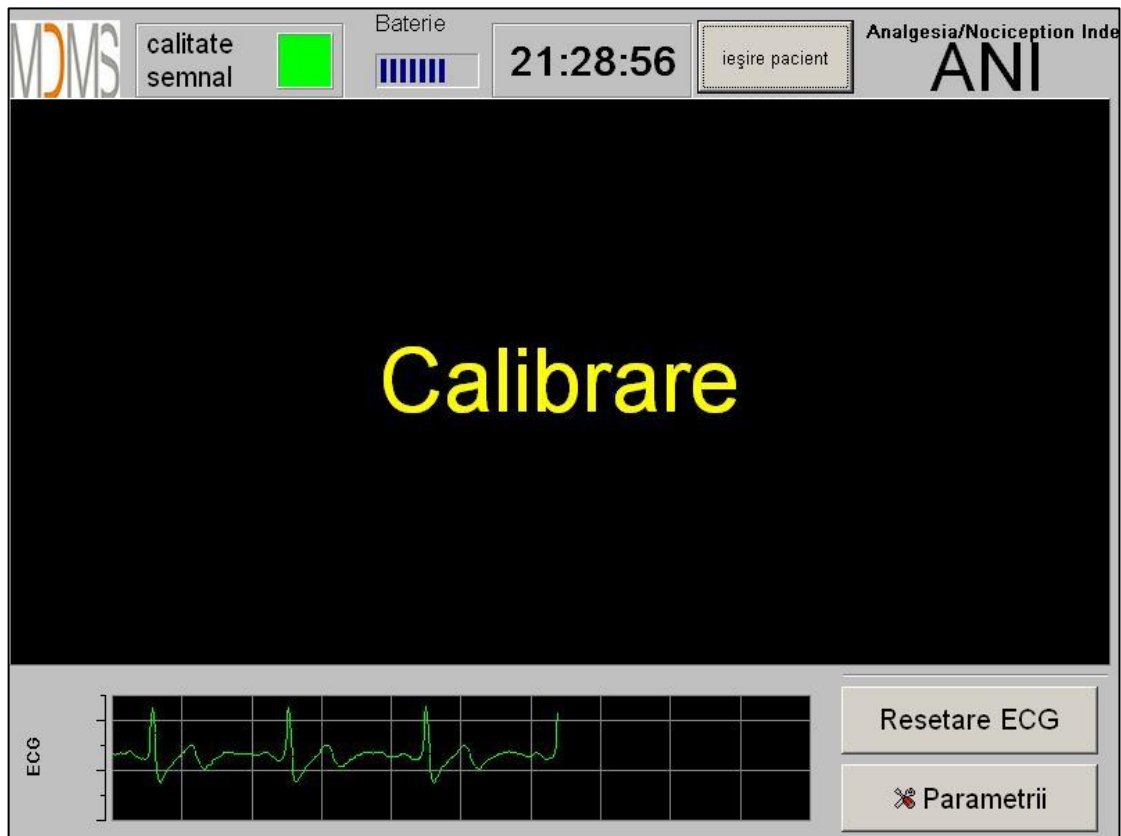

Figure 14

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

To Note: *The ANI technology can be used with a conscious patient as well as with an unconscious one. It can be installed whenever the physician needs it.*
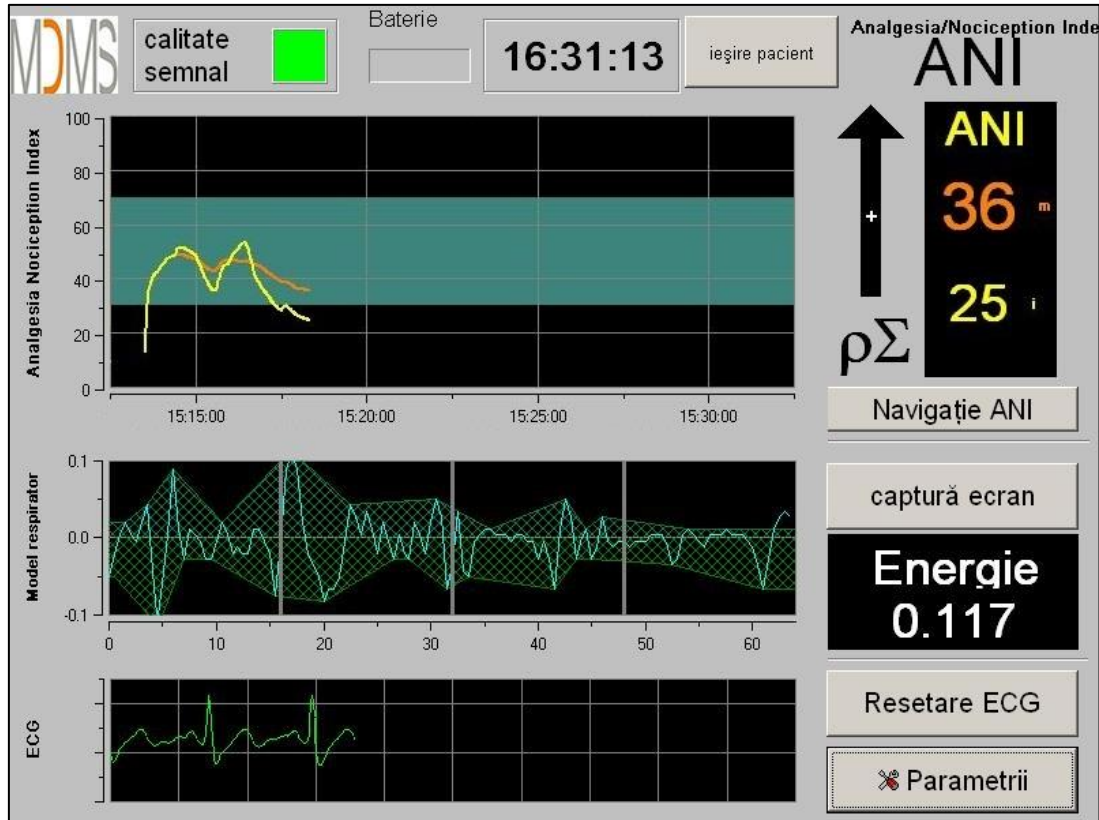
Figure 15

Ensure the good quality of the ECG signal in the inferior part of the screen. If there is no signal whatsoever, check the USB connection between the monitor and the acquisition device. Please try once to unplug and plug again the acquisition device to recover the ECG signal. If the display is not coherent, check the correctness of the electrodes position and also the quality of the connection between electrodes and the amplifier.

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

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

5   ANI computing process

5.1   ECG Capture

At the bottom of the screen a sub-window displays the ECG acquired (figure 16). This ECG is filtered from all technical artifacts as well as from physiological ones (e.g. extrasystoles). In addition to this first step, we have developed an innovating algorithm based on the Fast Wavelets Transform, allowing us to precisely identify the R spics from the QRS signal.

Figure 16

5.2   Respiratory Pattern

The surface of influence of respiratory patterns in the RR series is measured and displayed in stripes over the RR series (figures 17 and 18). The bigger the surface is, the strongest the pΣ tone is. The smaller the surface is, the lower the pΣ tone is.
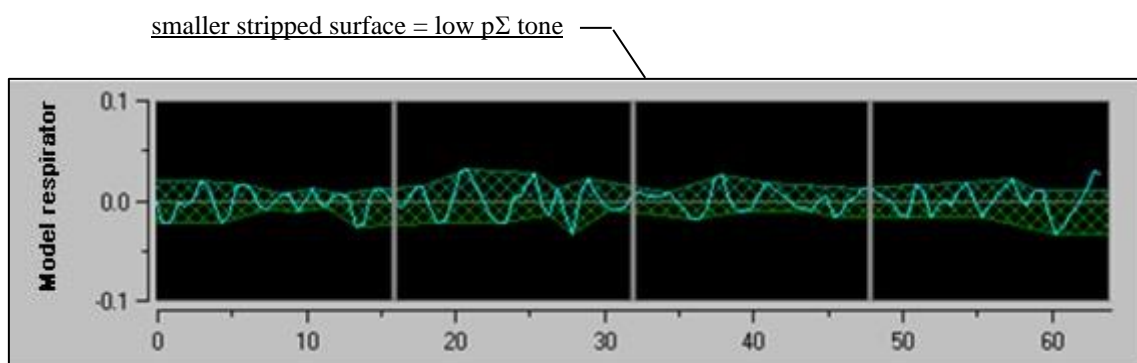
Figure 17: R-R normalized series: low sinus respiratory arrhythmia amplitude

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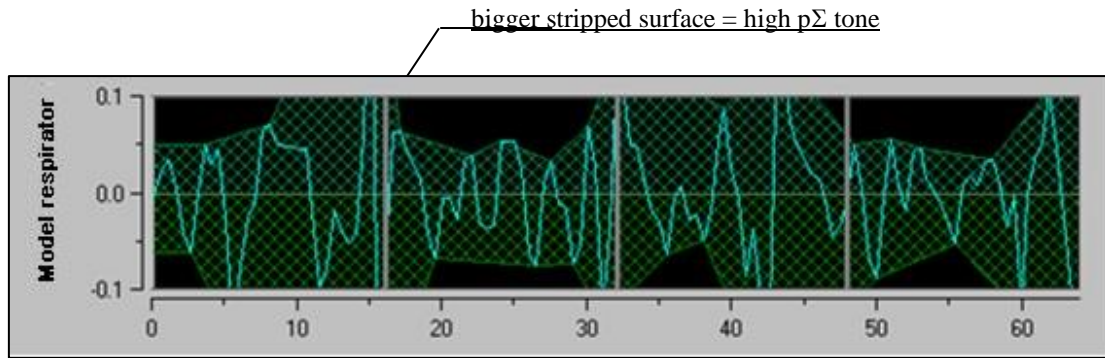
Figure 18: R-R normalized series: high sinus respiratory arrhythmia amplitude

5.3   ANI Index

We have developed an innovating algorithm based on the amplitude assessment of respiratory patterns of the RR series. In order to consider the amplitude variability and the respiratory pattern period, we have developed a methodology based on the area under the curve measurement (figure 19) called AUCmin (Minima of the areas under the curve).
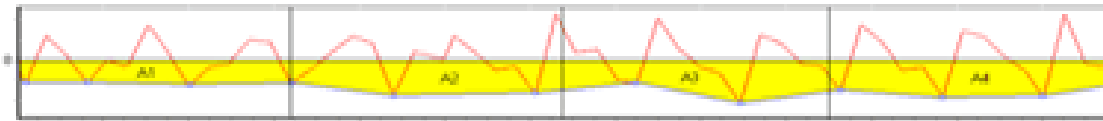
Figure 19: principle of index calculation

Therefore, we display continuously an index (each measurement based on the respiratory patterns window of 64 seconds with 1 second moving window) that reflects the parasympathetic tone activity. Two parameters are displayed (figure 20): in yellow color, the instantaneous index (called "i") and in orange color the patient tendency with a 4 minutes average (called "m"). Those indexes could prevent hemodynamic reactivity during surgery under general anesthesia.
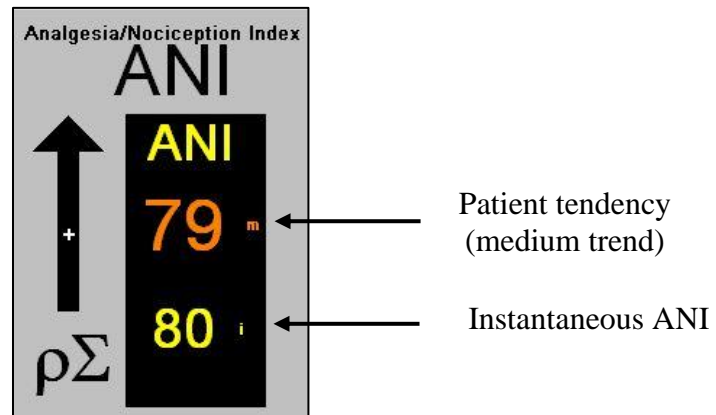
Figure 20

So we give in the left window two curves (yellow and orange) that reflect the patient tendencies with time scale (figure 21).
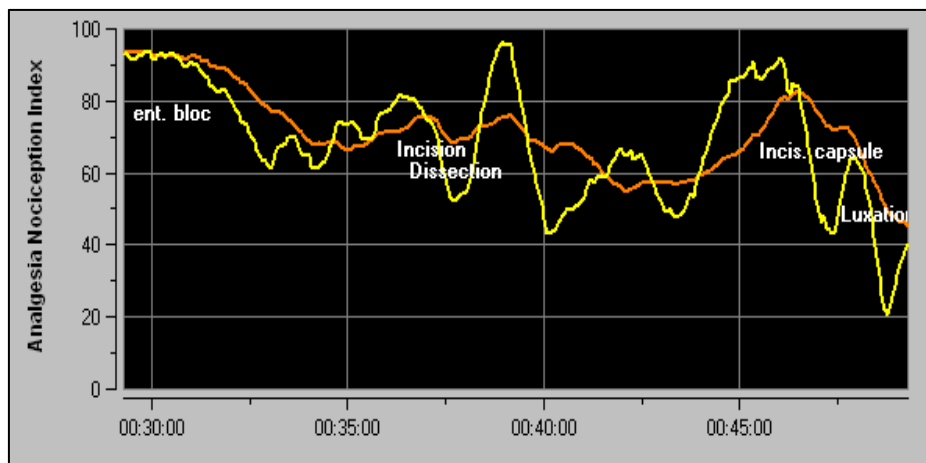
Figure 21

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

5.4 Navigation panel

Pressing the **[Navigaţie ANI]** button will open a new window and give the possibility to go forward and backward on the ANI measurements and captured events (figure 22).
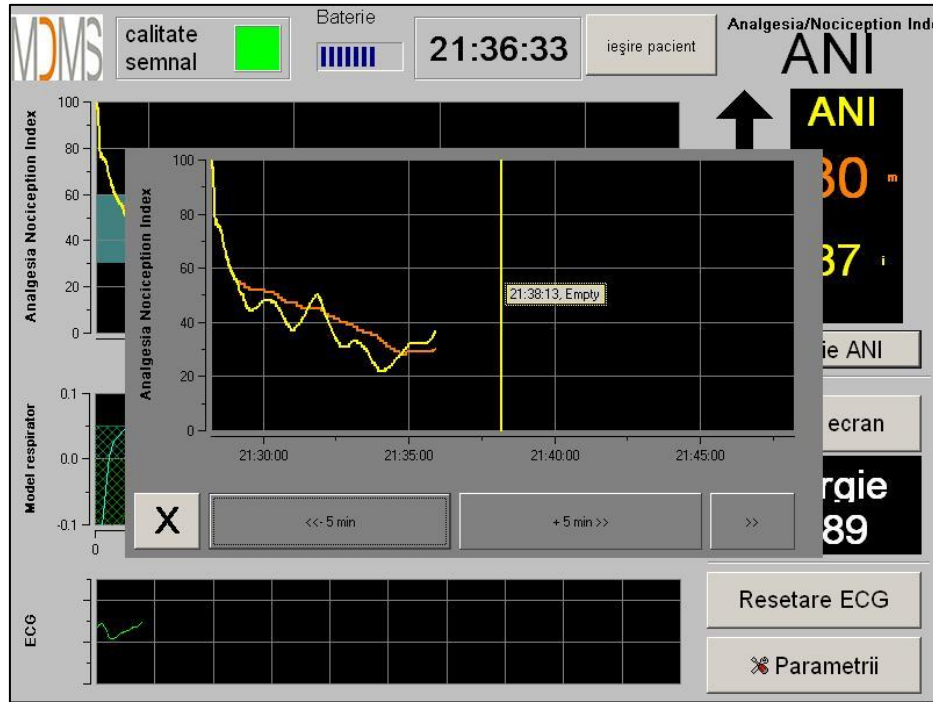
Figure 22

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

6 ANI Monitor V1 setup

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

6.1 Threshold

As shown in the screen below (figure 23), here you have the possibility to select the threshold values pressing the button **[Activaţi pragul].**
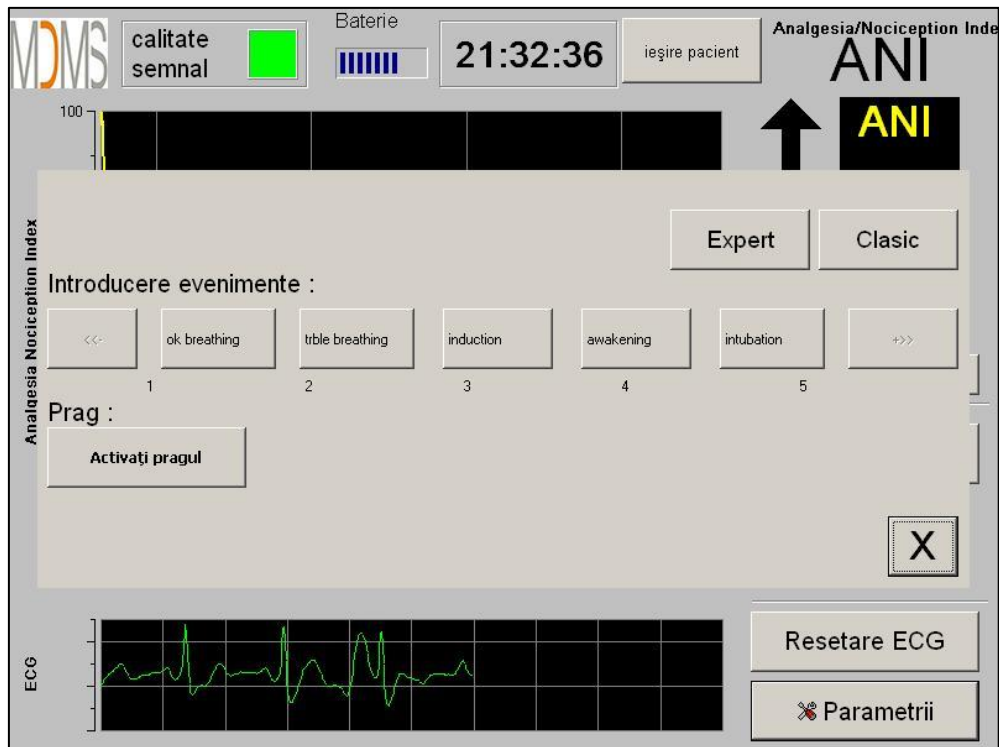
Figure 23

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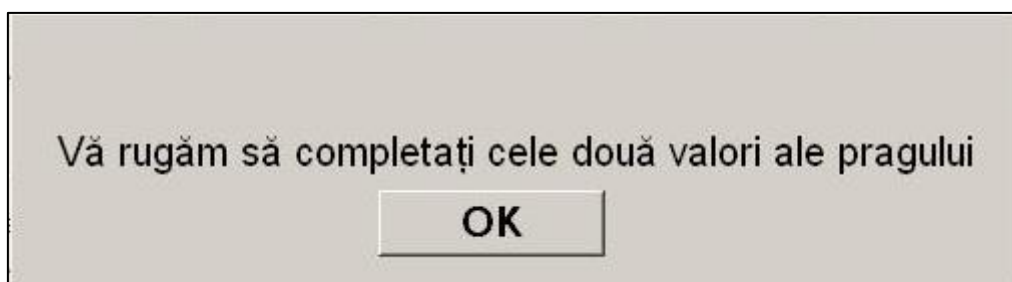
Figure 24

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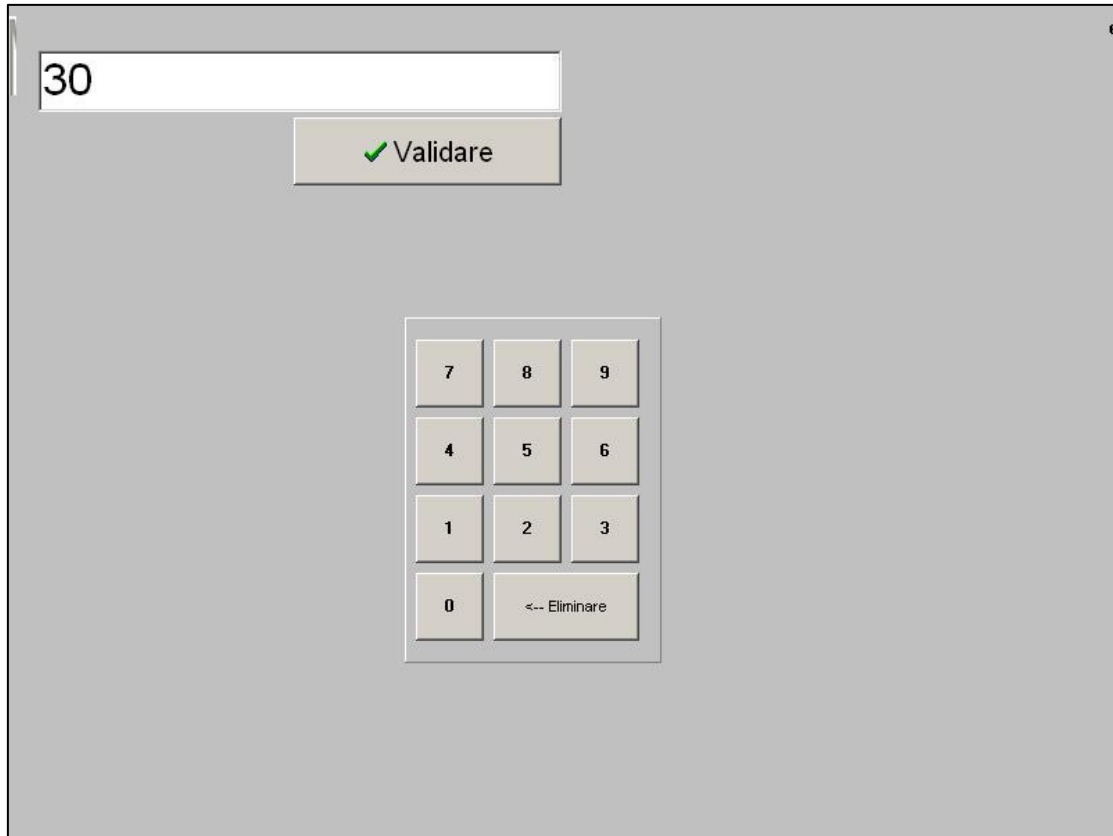
Figure 25

Figure 26: example with the two captured threshold values
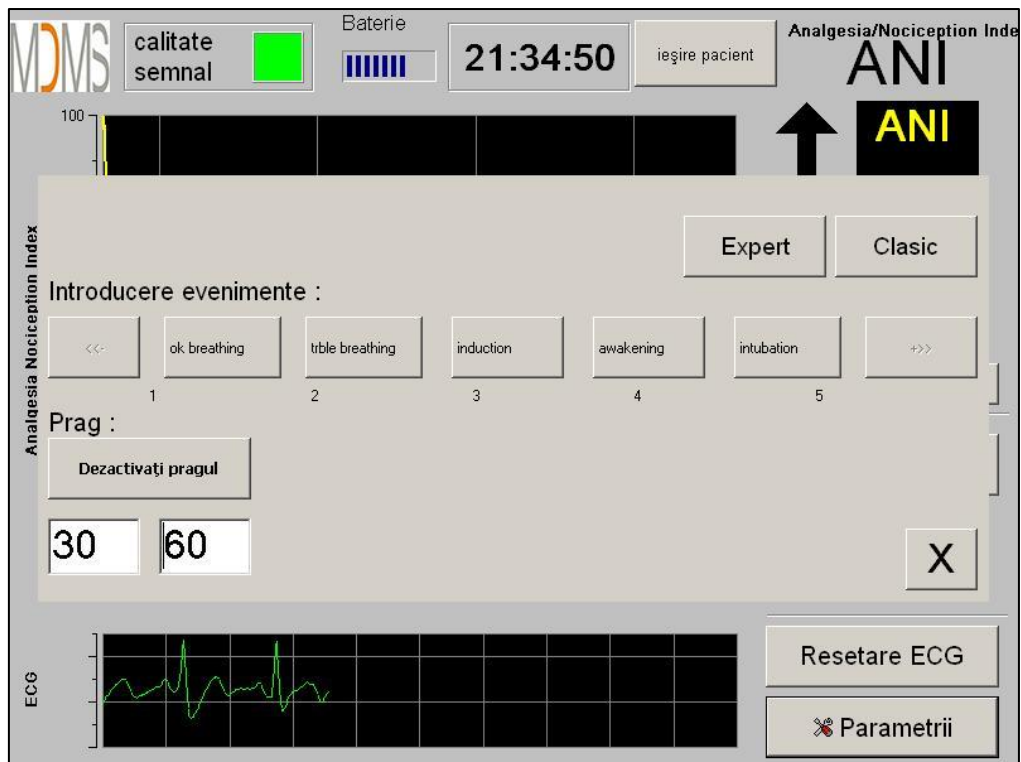
Figure 26

Figure 27: Threshold values
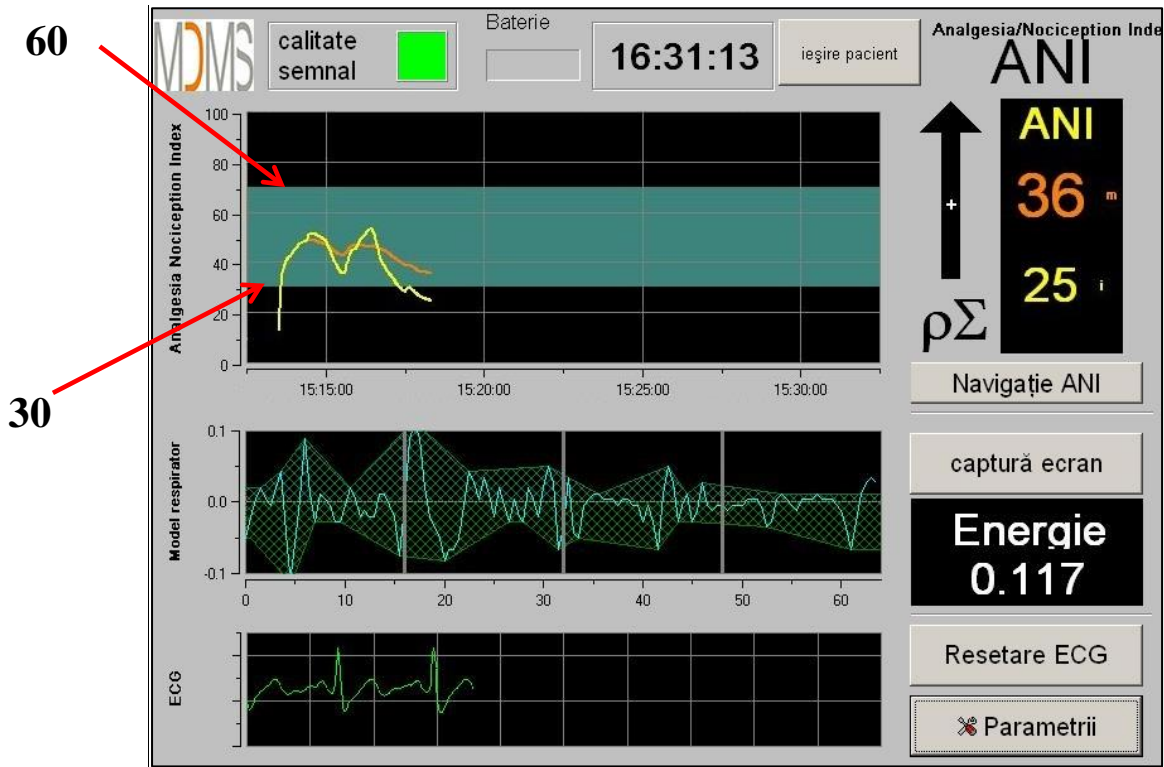
Figure 27

6.2   *Events insert*

As shown in the screen below (figure 28), here you have the possibility to insert clinic events so that they can be visible into the tendencies curves and also in the exportable data. Pressing anyone of these buttons inserts a mark in the ANI trend panel and in the recorded RR file.

Figure 28

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

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

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

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

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

6.3   Expert mode and Energy index

There are two modes:

- **"Classic" mode** : no energy, no respiratory pattern (figure 29)
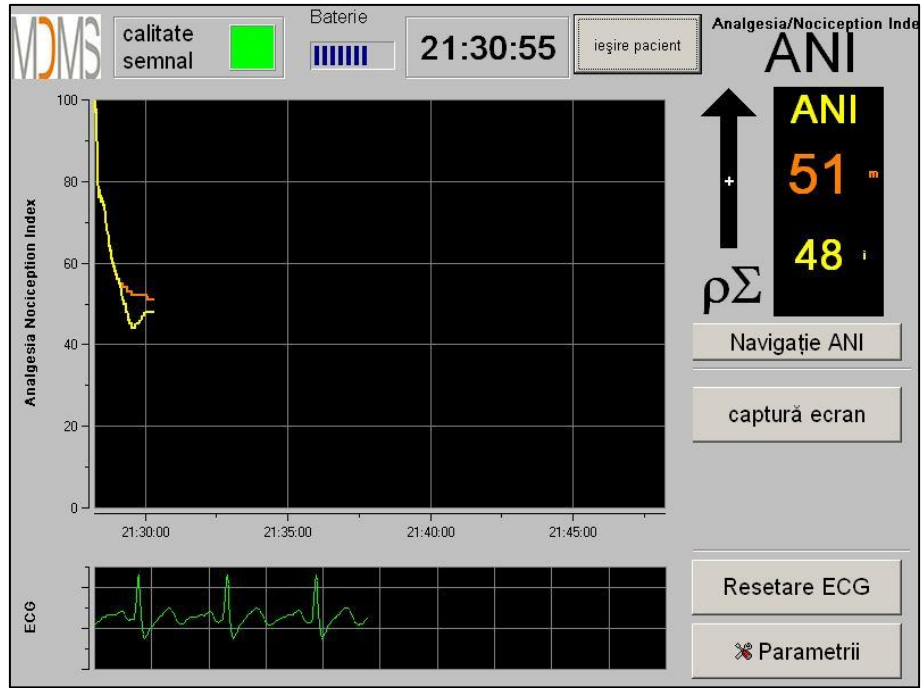
Figure 29

- **"Expert" mode** which displays respiratory pattern and one more function called "*Energy*" (figure 30)
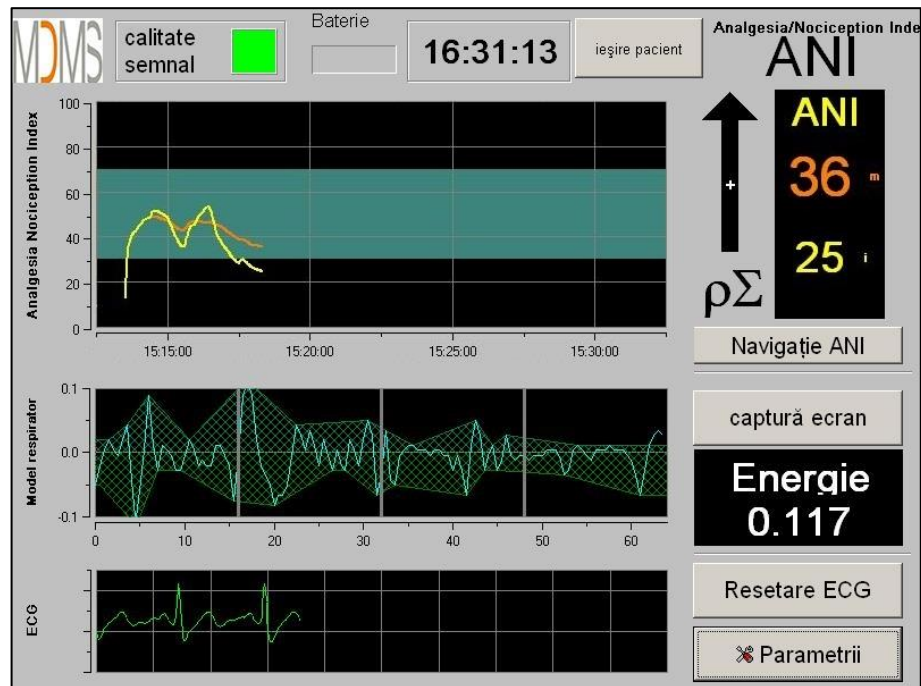
Figure 30

The *Energy* index is equivalent to the "total spectral power of the autonomous nervous system". When the value of the *Energy* index varies dramatically, it means that the ANI

calculated at this specific moment is not significant of the patient's parasympathetic tone value. If the *Energy* index is lower than 0.05 or above 2.5, the ANI calculation is interrupted even if the ECG is still acquired. An *Energy* index lower than 0.05 or above 2.5 is not significant of the patient's parasympathetic tone. It means something "abnormal" in regard to the organism (non-physiological situation). The *Energy* index could drop under 0.05 when a pacemaker leads the heart rate, when ephedrine or atropine for example is injected. The *Energy* could increase upper than 2.5 when artifacts are produced around the patient (like the use of electrical bistoury). The *Energy* index doesn't mean at any moment a concept of patient's energy or patient's parasympathetic tone but an ECG signal norm acquired by the ANI Monitor V1.

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

To cancel the "Expert" mode and back to the "Classic" mode, do the same procedure but touch the button **[Clasic]** (figure 31).

Figure 31

7 Operating the ANI Monitor V1

7.1 Quit Patient

Pushing the button **[ieşire pacient]** in the top of the screen will end the monitoring and give access to main menu. A confirmation window will appear before definitively stop the monitoring (figure 32).

Vreţi într-adevăr să ieşiţi din această înregistrare?

| Da | Nu |

Figure 32

To note: *by clicking on **[Da]**, no come back to current patient will be possible.*

If you choose "**Yes**", the main menu window will be displayed (figure 33):

Demo

| Pacient nou | Întreţinere | Export | Golire |
| Actualizare evenimente | Reglare date | Actualizare monitor | 🚫 Oprire |
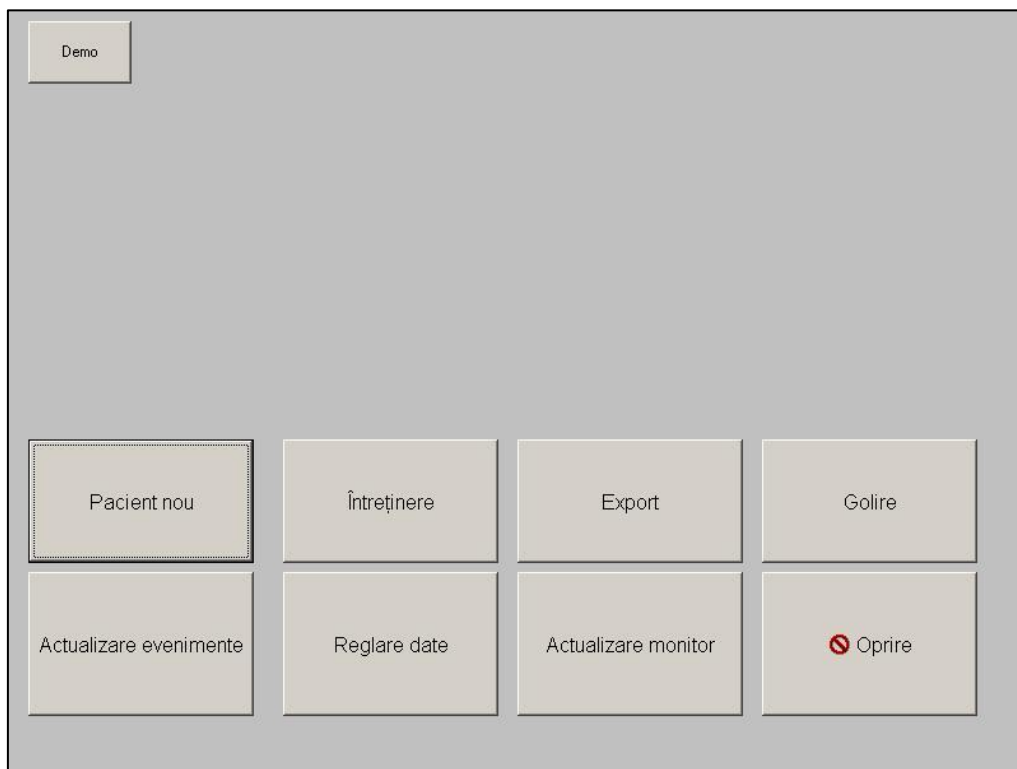
Figure 33

7.2   Demo

Selecting **[Demo]** (figure 33) shows you a video of ANI functioning.

7.3   New patient

Selecting **[Pacient nou]** (figure 33) initializes the monitoring and launches a new patient data including new file storage.

7.4   Maintenance

Selecting **[Întreţinere]** (figure 33) opens a window with an input field (see figure 34 next page). This access is protected by a code that will be forwarded on request to Mdoloris Medical Systems.
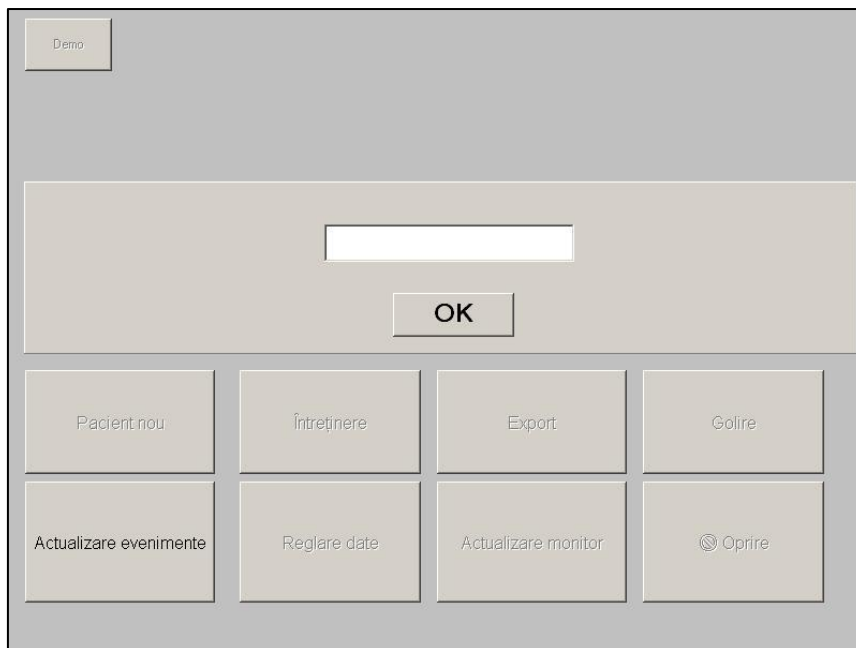
Figure 34

7.5   Delete patients data

Pressing the button **[Golire]** deletes all data previously computed and saved. A first window will ask for confirmation of this action (figure 35).
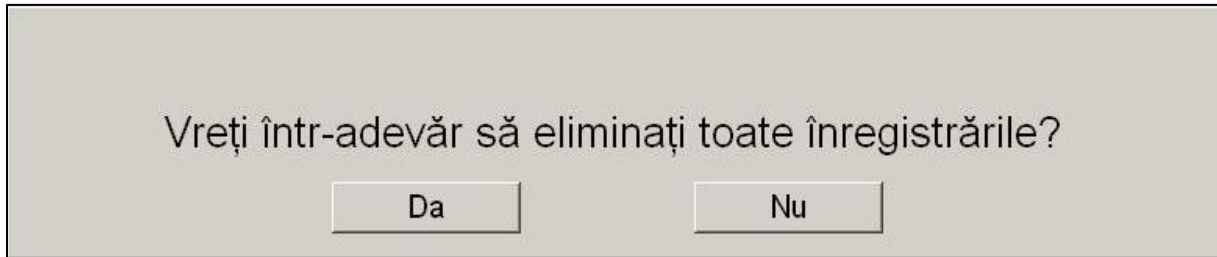
Figure 35

When all data are deleted, another window will appear to confirm that the action is done (figure 36). Press the button **[OK]** to back to the main menu (figure 33).
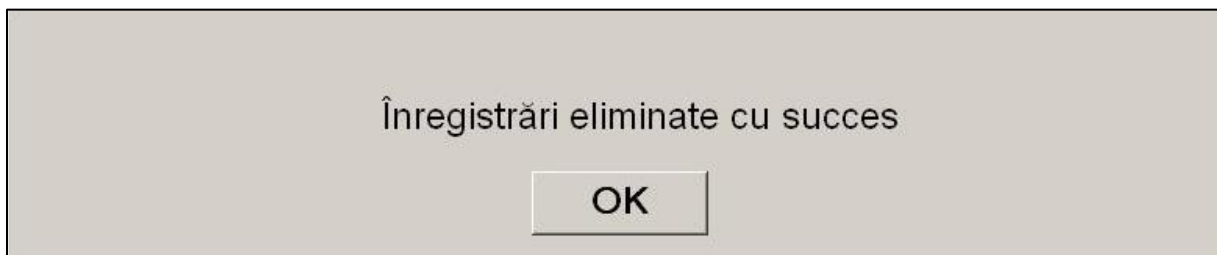
Figure 36

7.6   Screen shot

When the user pushes on the button **[captură ecran]**, the information displayed are saved in the monitor's memory as picture format. Each time the user decides to get a screen shot, one picture will be saved in the monitor's memory.

A message will appear to confirm the success of the snapshot (figure 37). Press the button **[OK]**.
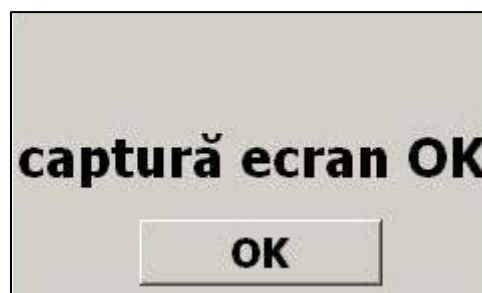
Figure 37

To get these pictures, a USB stick has to be plugged in the USB port called "Data Export". Then the user selects **[ieşire pacient]** in the top of the screen. In the new window opened (figure 33), choose **[Export]**. The pictures will be saved in a file. Each file name will follow this rule: Hour – Minute – Month – Day - Year.

7.7 Export Data

A press on the button **[Export]** sends all data saved in the monitor memory into a USB stick. To export the data you need to connect a USB stick in USB port called "*Data Export*". If the monitor doesn't detect any USB stick (USB stick doesn't plugged or bad connection), a message will appear to inform the user (figure 38). When the USB stick is well connected, press on **[OK]** and **[Export]** again to start the data export.

Figure 38

At the end of this step, a message will appear to confirm the success of the export (figure 39). Press the button **[OK]** to back to the main menu.

Figure 39

Note:

Data are automatically saved into a file including the date and hour on the monitoring started. Accessing those files is possible with the « Export » function (file exporting format is text extension like this for an easy secondary use). A file named "Export" will automatically

be created on the USB device. Each file name will follow this rule: Hour – Minute – Month – Day - Year.

Example: 08_46_04_15_11Index
            Document texte
            15,4 Ko

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

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

7.8   Update of events

As explained previously (see chapter 7.3), events corresponding to several clinical moments are predefined in the system. The list can be modified by the user in order to provide displayed marks on the ANI trend panel and in the recorded variables, for further analysis.

A press on the button **[ieşire pacient]** in the top of the screen will end the monitoring and will access to the main menu (figure 33). A confirmation window will appear (see figure 32, chapter 8.1).

To access and update the events list, press **[Actualizare evenimente]**. The events update menu will appear (figure 40).
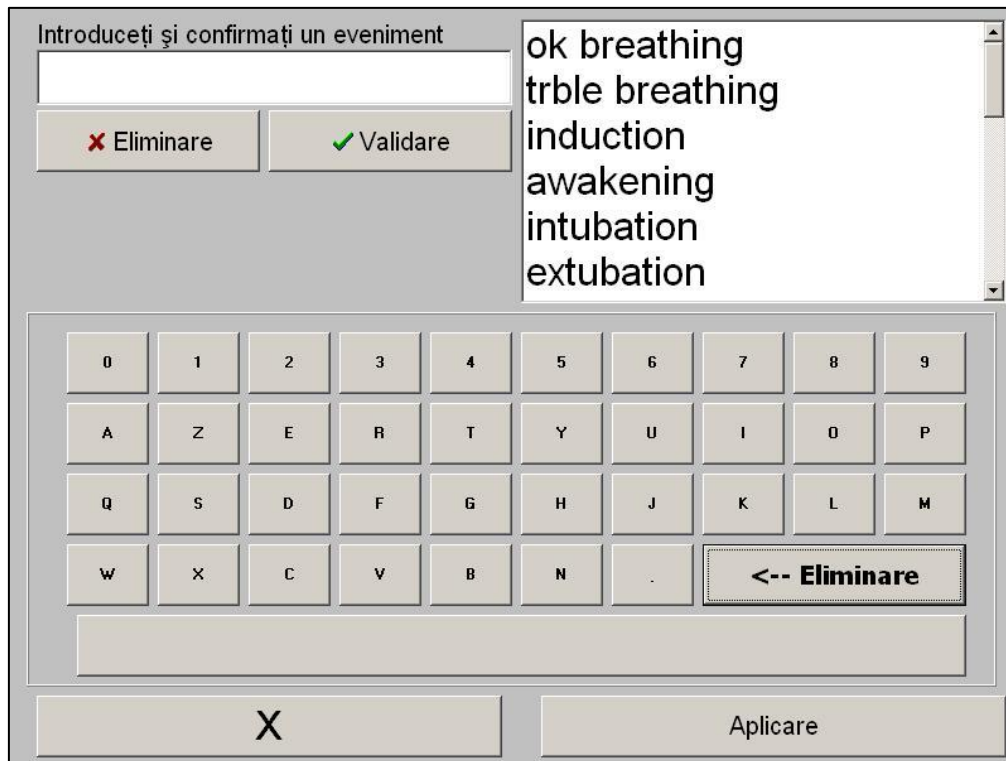
Figure 40

To add new event in the list, you have to use the virtual keyboard on the touch screen and then valid with the button **[✓ Validare]**. Word size is limited to 18 characters.

The new event will be added at the end of the drop-down list displayed on the right. To see it, you have to use the scrollbar. To delete an event, you have to select it in the list by touching the word on the screen and touch the button **[✗ Eliminare]**.

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

7.9   Date and time settings

To set the clock or the date, you have to select **[ieşire pacient]** to reach the main menu (figure 33):

Then select **[Reglare date]**. The following window will appear:
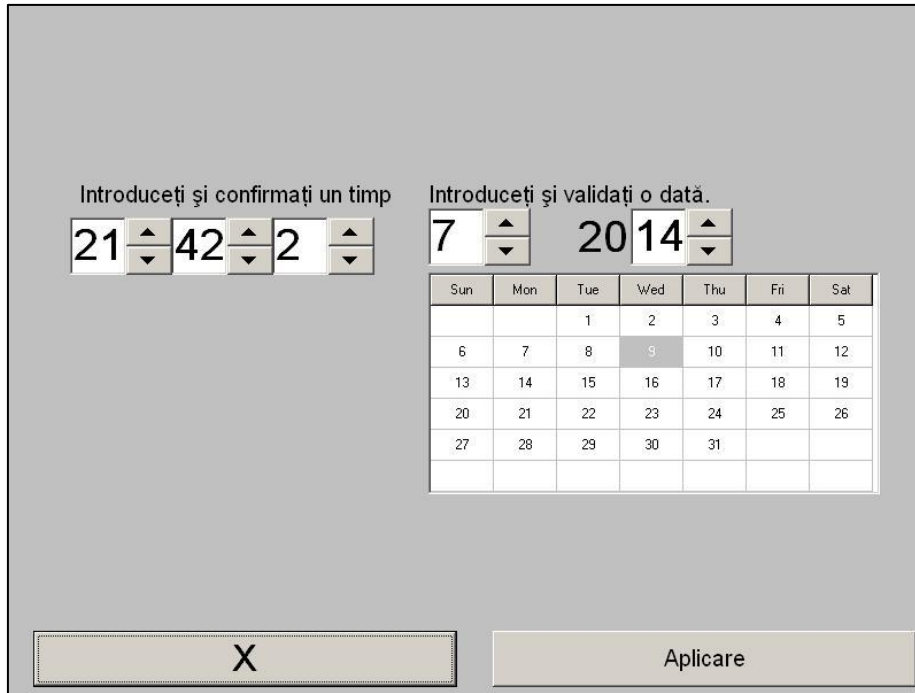
Figure 41

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

7.10 Update monitor

In the main menu, select **[Actualizare monitor]**. Plug an USB stick with the new version of "AniM_INT.exe" provided by your Mdoloris Medical Systems representative. Then select **[Actualizare monitor]** (see figure 42 next page).
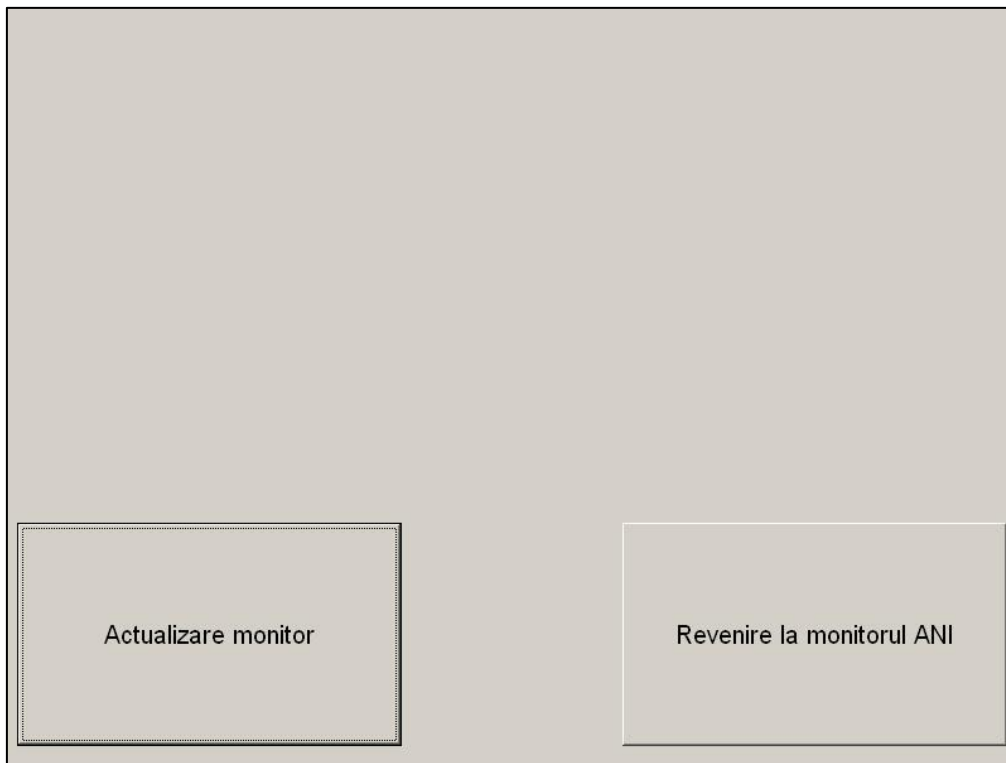
Figure 42

A message will appear to confirm the success of the updating (figure 43). After 5 seconds, press on **[Revenire la monitorul ANI]**.

Figure 43

If an USB stick isn't plugged, a message will appear to inform the user (figure 44):

Introduceți o cheie USB

Actualizare monitor   Revenire la monitorul ANI
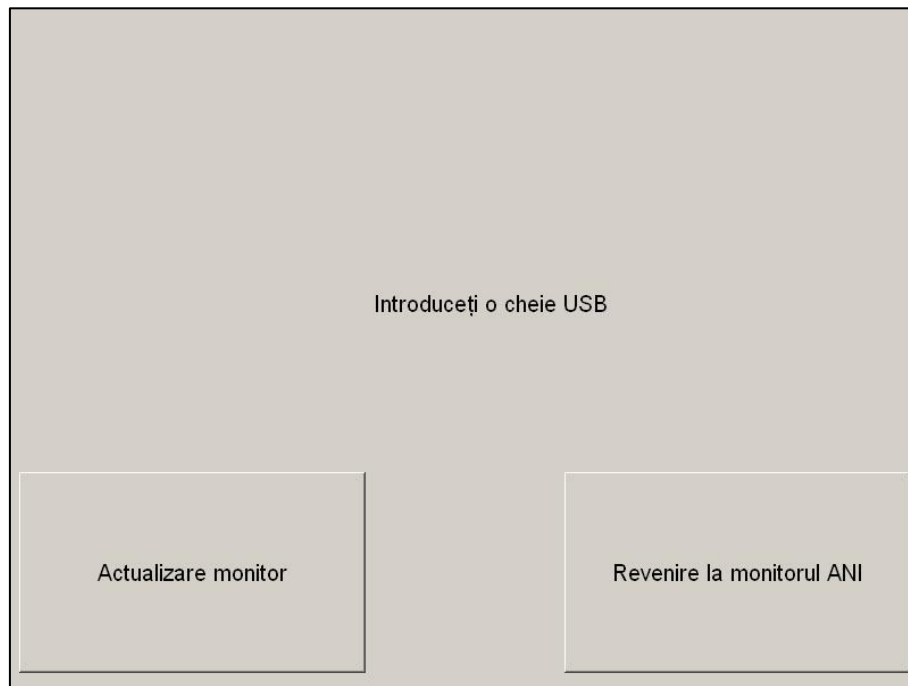
Figure 44

If the "AniM_INT.exe" isn't present on the USB stick, a message appears (figure 45):

Copiați "AniM_Rou.exe" pe cheia USB şi încercați din nou

Actualizare monitor   Revenire la monitorul ANI
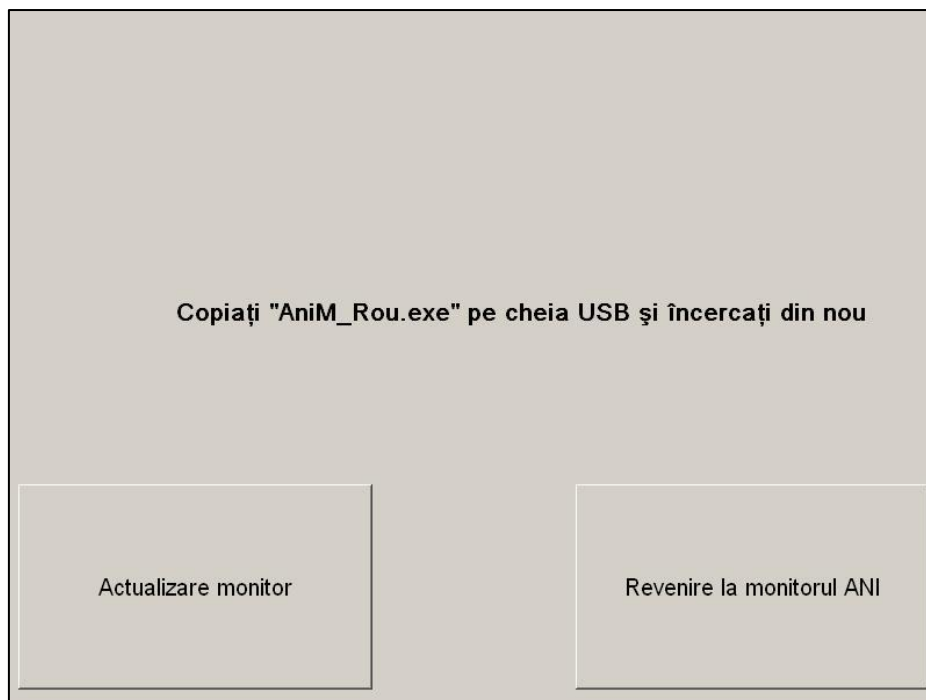
Figure 45

7.11 Shutting down the ANI Monitor V1

Pressing the button **[⊘ Oprire]** (figure 33) ends the session and will shut down the ANI Monitor V1.

NOTE: *it is possible to shut down the monitor by pressing directly the switch located on bottom right hand corner of the front side (see figure 12) only if the context prevent you to reach the main menu (figure 34). This is however not recommended because it could affect the monitor's proper functioning.*

8 Troubleshooting

Problems	Diagnoses
No ECG displayed on the monitor.	Check the connection wire from the acquisition device to the monitor. Try to unplug and plug again the acquisition device from the monitor.
An ECG signal is detected but seems to be incoherent (flat, irregular, interfered…)	Check the electrodes are well stuck on the skin. Check also the electrodes position (see chapter 4.2)
ECG waves seem physiologically incorrect	Check that electrodes are well placed along an imaginary line through the heart.
The Mdoloris Medical Systems software does not start when the monitor is booted.	Reboot the monitor thanks to the switch on the front side. If the problem continues, please contact your Mdoloris Medical Systems representative.
The ANI Monitor V1 shuts down by itself without reason.	Check the power supply wire is connected to the monitor and reboot the monitor like explained in this user's manual (chapter 5).

The monitor doesn't boot.	Check the power indicator is bright (figure 13) when the monitor is connected to power supply. If the power indicator is dim, lift up the transparent shell and push on the button.

9   Monitor disposal

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

- There are no metallic items inside the acquisition device's box
- The acquisition device's box is ABS plastic
- The EMC protection in the acquisition device is stainless steel
- The screen has a touch proof stratified layer
- You can recycle the paper print operating manual
- All electronic items are under the RoHS normalized rules

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

10   Environnement

10.1 Shipping and Storage Environnement

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

Temperature: -20°C to +60°C

Humidity: 15% to 95% (non-condensing)

Pressure: 360 mmHg to 800 mmHg

Protect the monitor from sudden temperature changes that can 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 the inside ambient temperature before unpacking and placing into service. Before operating the system, wipe down all visible condensation and allow the system to reach equilibrium at room temperature.

10.2 Operating Environnement

The 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 A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.*

The ANI Monitor V1 is designed to operate safely in a temperature from 5° to 40° C to an altitude of 2000m, in a humidity range from 15% to 95% (non-condensing) and a pressure from 360mm Hg to 800mm Hg.

10.3 Power Requirements and System Grounding

The ANI Monitor V1 requires a power source of 100-240 VAC, 50-60Hz. Current consumption is 0.7 ampere maximum.

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

CAUTION: *FOR PROPER GROUNDING, THE POWER RECEPTACLE MUST BE A THREE-WIRE GROUNDED OUTLET. A HOSPITAL GRADE OUTLET IS REQUIRED. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.*

THE MONITOR SHOULD BE USE ONLY WITH A HARMONIZED POWER CABLE WITH A SURFACE SECTION SUPERIOR TO 0.75 mm².

11 Care, cleaning and maintenance

11.1 Care and Cleaning

ANI Monitor V1 can support a thousand cleaning cycles.

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

Cleaning the monitor and acquisition device:
clean any spillage of blood or solutions on either the monitor or acquisition device as soon as possible because dried blood is very difficult to remove. Use lint-free absorbent towels to clean spillage. Dampen the towel with detergent and lukewarm water to aid in cleaning. After cleaning, wipe the connector ends with alcohol and allow it to dry completely. Residual moisture inside the connector may affect the monitoring performance.

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

Disinfecting the monitor and acquisition device:

Use lint-free absorbent towels dampened with a 10% bleach solution, or a commercial disinfectant. After cleaning, dry all areas except the monitor display screen with a lint-free absorbent paper towel. Wipe the connector ends with alcohol and allow it to dry completely.

WARNING: *WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST LEAKAGE CURRENT BEFORE FURTHER USE. DO NOT MIX DISINFECTING SOLUTIONS AS HAZARDOUS GASES MAY RESULT.*

CAUTION: do not autoclave the acquisition device or monitor. Autoclaving will seriously damage both components.

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

11.2 Maintenance

The ANI Monitor V1 is designed so that no periodic maintenance is required.

Suggested routine maintenance includes: periodic checking of cable integrity and checking of leakage current (systematically after a saline or blood spill, or immediately after a major surge in the house electrical system, or at least once a year).

Instructions on checking leakage current are included in the next chapter.

11.3 Leakage Current

Leakage current is a primary indicator of electrical shock hazard to personnel making contact with any exposed outer surface of the equipment. Each ANI Monitor V1 is carefully checked at the factory to verify that leakage current meets the IEC60601-1 safety standards.

The ANI Monitor V1 should be checked routinely for leakage current at least once a year.

Always have the leakage current checked after a saline or blood spill, or immediately after a major surge in the house electrical system and every time the monitor case has been opened.

12 Specifications, warranty and software license agreement

12.1 Specifications

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

Consummation: < 32 W

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

Battery: Li-ion, output: 12 V $^{+}$/-5%, 3800mAH. Around 90 minutes of full using.

Power connexion: cable plug

Weight of the monitor (without any accessory): 6.99 lb.

Weight of the acquisition device (without the ANI sensors cable): 0.88 lb.

Dimensions of the monitor (inches): 10.43 width x 9.72 height x 3.13 thick

Screen size: 8.4'', resolution 800 x 600

Dimensions of the acquisition device (inches): 6.18 length x 4.06 width x 2.7 thick

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

Material included in the ANI Monitor V1:
- Panel PC: Mdoloris Medical Systems reference: MN-ANI-V1
  Manufacturer: IEI (product reference: AFL-08A-N270)
- Acquisition device: Mdoloris Medical Systems reference: BA-ANI-V1
  Manufacturer: RHEA Electronique
- Sensors cable: Mdoloris Medical Systems reference: ANI-SC-V1 (ANI Sensor V1 / ANI Sensor V2) ; ANI-SC-V1PLUS (ANI Sensor V1 PLUS)
  Manufacturer: Axon
- Power cable: Mdoloris Medical Systems reference: ANI-PW-V1-x.

Degree of protection against electric shock of the system:

Class 1: equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution. Means are provided for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.

Protection against the ingress of liquids:

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

System functioning:

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

Classification:

- CISPR 11: Class A

- IIa Electro-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 expendable components and supply items such as, but not limited to, electrodes, cables, touch screen and other accessories. Mdoloris Medical Systems' obligations under this warranty are to repair or replace any Warranted Product (or part thereof) that Mdoloris Medical Systems reasonably determines to be covered by this warranty and to be defective in workmanship or materials provided that the Purchaser has given notice of such warranty claim within the Warranty Period and the Warranted Product is returned to the factory with freight prepaid. Repair or replacement of Products under this warranty does not extend the Warranty Period.

To request repair or replacement under this warranty, Purchaser should contact Mdoloris Medical Systems directly (see contact information on the last page of this manual). Mdoloris Medical Systems will authorize Purchaser to return the Warranted Product (or part thereof) to Mdoloris Medical Systems. Mdoloris Medical Systems shall determine whether to repair or replace Products and parts covered by this warranty and all Products or parts replaced shall become Mdoloris Medical Systems' property. 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 by anyone other than Mdoloris Medical Systems ; or that have been disassembled, serviced, or reassembled by anyone other than Mdoloris Medical Systems, unless authorized by Mdoloris Medical Systems. Mdoloris Medical Systems shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear. Mdoloris Medical Systems makes no warranty (a) with respect to any products that are not Warranted Products, (b) with respect to any products purchased from a person other than Mdoloris Medical Systems or (c) with respect to any product sold under a brand name other than Mdoloris Medical Systems.

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**For any incident, please report to Mdoloris Medical Systems at
service.qualite@mdoloris.com and/or to the National Competent Authority**

**For any other problem: please contact your Mdoloris Medical Systems representative or
contact@mdoloris.com**