

User manual

PTA™ monitor

Software version: V2.3.0.0



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Important information about the use of PTA monitor:

The Mdoloris Medical Systems' PTA monitor is intended for use in a medical environment and under the direct supervision of a licensed healthcare practitioner or by personnel specifically trained for its use. The PTA monitor is intended to be used on animals (dogs, cats, horses) in a veterinary clinic or in research center, in order to monitor the parasympathetic tone thanks to the ECG signal acquisition.

The PTA monitor can be used to monitor the effects of certain analgesic agents.

PTA is a complex monitoring technology intended to be used as an adjunct to clinical judgment and to clinical experience. The interpretation of the PTA value must always be submitted to the clinical judgment and with other available clinical signs observed. It is advisable to not rely only on the PTA index for monitoring the patient's analgesia level. As with all monitored parameters, artifacts and poor signal quality may lead to inappropriate PTA values. The potential artifacts can be caused by high impedance from the source ECG collection device, by muscle activity or rigidity, patient motion, improper sensor placement or electrical interference.

PTA 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 environment.

WARNING

A warning of this level of danger advises against potentially dangerous situation that could results in physical injury or death. Accidents may be caused by the inability to avoid dangerous situation. That is why it is important to follow guidelines in this warning, to avoid physical injuries.

CAUTION

A caution of this level of danger advises actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure, although personal injury is unlikely.

NOTE

A note provides useful information regarding a function or procedure.

DEFINITION OF SYMBOLS

Symbols used with the PTA monitor are explained at the end of this section (section 1.4, page 09).

1.1 Warnings



IT IS FORBIDDEN TO KEEP CONNECTED THE PTA MONITOR ON ANIMAL WHEN A DEFIBRILLATOR DEVICE IS USED.



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



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



THIS MONITOR IS NOT DESIGNED FOR USE IN THE MRI ENVIRONMENT.



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 PTA MONITOR SHOULD NOT BE USED.



BE SURE THE MONITOR IS INSTALLED SECURELY TO AVOID ANY INJURY FOR THE STAFF OR FOR THE PATIENT.



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

**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 OF THIS DEVICE HAS 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.



IN CASE OF EMERGENCY FOR INTERRUPTING THE ELECTRICAL POWER, IT IS NECESSARY TO USE THE MALE END OF THE POWER CORD OR THE WALL SOCKET. THE ACCESS OF THE POWER PLUG AND THE WALL SOCKET HAVE TO STAY REACHABLE DURING THE NORMAL USE.



CURRENT PRECAUTIONS SHALL BE OBSERVED TO PREVENT ANY CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. CONTAMINATED MATERIALS MUST BE DEALT IN ACCORDANCE WITH ALL APPLICABLE HYGIENE STANDARDS AND REGULATIONS.



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



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

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

IN CASE OF PERSISTENT DYSFUNCTION, PLEASE CONTACT YOUR MDOLORIS MEDICAL SYSTEMS REPRESENTATIVE.



THE PTA MONITOR IN OPERATING SURGICAL ROOM MUST BE PLACED OUTSIDE THE SAFETY CONE OF EXPLOSION RISK.



BE SURE THAT THE MONITOR IS PLACED OUT OF AN AREA PRESENTING A RISK OF PROJECTION OF LIQUID (E.G.: UNDER AN I.V. BAG).



ANY MODIFICATION IN THE MONITOR IS STRICTLY FORBIDDEN.



THE USB PLUG MUST NOT BE CONNECTED TO ANY OTHER EQUIPMENT THAN A USB STICK.

1.2 Caution

The equipment should not be reachable by the patient, directly or indirectly, like placed on a metallic material reachable by the patient.

The patient and the equipment should not be touched simultaneously by the doctor.

Do not put the monitor in an autoclave. Putting the monitor in an autoclave will seriously damage the PTA monitor.

It is forbidden to use accessories other than those specified (e.g.: ECG cable, power cord) because it may result in increased electromagnetic emissions or decreased electromagnetic immunity of the monitor.

The PTA Monitor should not be used adjacent or stacked on other equipment. If adjacent or stacked use is necessary, check regularly that the functioning is normal in this configuration.

Only staff of Mdloris Medical Systems is allowed to perform maintenance operations or repairs. Only the following elements can be replaced or substituted by an untrained staff to the technical maintenance (respecting the manufacturer references):
















- ECG cable and associated accessories (e.g.: crocodile clips) ;
- The power cord ;
- The power supply box.

The recycling of this medical equipment, its components and 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
	Consult the operating manual	SN	Manufacturer's serial number
	Do not expose to liquids	CE	European conformity. Mark of conformity to European medical device directive
	Do not expose to sunlight		General hazard symbol
	Do not use if the packaging is damaged		This symbol indicates that electric and electronic wastes must not be disposed as unsorted household waste and must be collected separately.
	The device has a functional electrical insulation with a ground terminal and an equipotential connection		Direct current
REF	Reference		Temperature range
	Manufacturer (company's name and date of production)		Symbol of package handling (Fragile, to handle with caution)
	Symbol of package handling (keep in dry conditions)		Symbol of package handling (handle with caution)
	to handle with caution (keep in upright position)		BF equipment

2 PTA monitor introduction

PTA (Parasympathetic Tone Activity) is a normalized and continuous measure of the parasympathetic tone ($p\Sigma$) which is a part of the autonomous system (ANS). It uses the punctual and quick increase of $p\Sigma$ tone induced by each respiratory cycle (spontaneous or artificial) to measure the “relative quantity” of $p\Sigma$ tone.

These rapid changes in $p\Sigma$ tone express in the sinus node of the heart by changes in the time intervals between two R waves of the electrocardiogram. The normal next RR series (stemming from a cardiac cycle and not from an extrasystole) establish the RR series. After filtering, normalization and resampling, the $p\Sigma$ compound of the RR series is obtained by measuring the generated surface by the respiratory cycles (figure 15). More important is the $p\Sigma$ tone, bigger is the measured area.

PTA measurement cannot be interpreted in the following situations:

- arrhythmia
- lack of breathing (e.g.: apnea due to the intubation)
- respiratory rate lower than 8 cycles/min
- variable tidal volume during the period of measurement for calculations, that is to say 64 seconds
- irregular breathing (when the patient sneezes/coughs, or produces a noise [e.g.: a growl])
- Use of medicine having an impact on the sinus node activity (atropine or others catecholamines)

The PTA index is expressed on a scale between 0 and 100. It reflects the activity of the parasympathetic nervous system. It gives a reading of the proportion of $p\Sigma$ tone compared to the Σ tonus in the autonomous nervous system. The PTA displayed represents the successions of computed measures: each elementary measure is carried out on 64 seconds, with a 1 second moving window.

2.1 PTA index

We have developed an innovating algorithm based on the amplitude assessment of respiratory patterns of the RR series.

An index is continuously displayed, reflecting the parasympathetic tone activity: the average PTA (in orange, indicated “mean” on the right of the screen). A strong nociceptive stimulation leads an almost instantaneous decrease of the amplitudes of the RR series’ respiratory modulations because of the quick decrease of the parasympathetic tone. This sudden variation will be expressed by the apparition of a red curve which will be displayed as long as the parasympathetic tone will not recover its initial value, the one before the nociceptive stimulation. This additional parameter is the instantaneous PTA.

In case of R wave detection mistakes, the PTA calculation is interrupted until a correct ECG signal is recovered.

2.2 Position of sensors and ECG acquisition

Conventionally the cardiac lead most used is the basis-apex lead. The sensors are crocodile clips, so they will be positioned where the folds of skin are thin (folds of elbow for the front limbs, folds of stifle for the back limbs). For making better the signal conduction, it is advised to soak the hairs and skin with alcohol, or conductive solution like ultrasound gel.

Three sensors are used in order to get an ECG signal:

- The yellow sensor on the fold of the left front limb
- The red sensor on the fold of the of the right front limb
- The black sensor on the fold of the right back limb

At the bottom of the screen a sub-window displays the ECG acquired (figure 1). This ECG is filtered from all technical artifacts as well as from physiological ones (e.g.: extrasystoles).



Figure 1

2.3 Monitor setting

Position the monitor in order to use easily the power plug. The power cable has to be screwed on the appropriate socket on the lower side of the monitor. The acquisition box has to be plugged on the RS232/422/485 port (figure 2).

The monitor can be set on a flat surface thanks to the retractable support system.



Figure 2

2.4 Demo mode

Select the button “**Demo**” in the top left hand corner of the main menu (figure 3) to see a demonstration of the PTA monitoring.

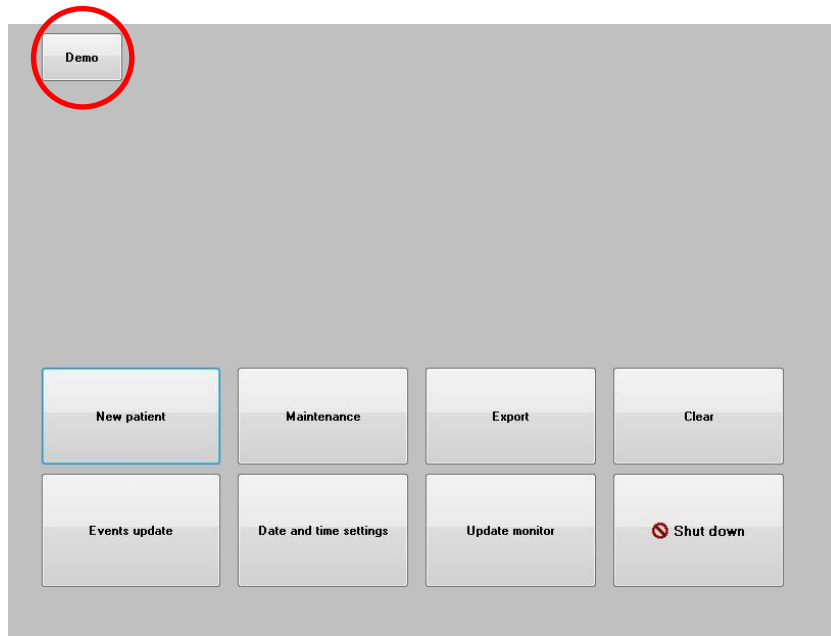


Figure 3

3 Start the PTA monitoring

When the power cable is plugged on socket of power supply, a power light indicator above the screen will become orange. The monitor can be ignited by pressing during 3 seconds the interrupter located on the low side of the monitor (figure 4).



Figure 4

Then the power light indicator becomes green and the monitor will reach and display automatically the homepage and the following parameters (figure 5):

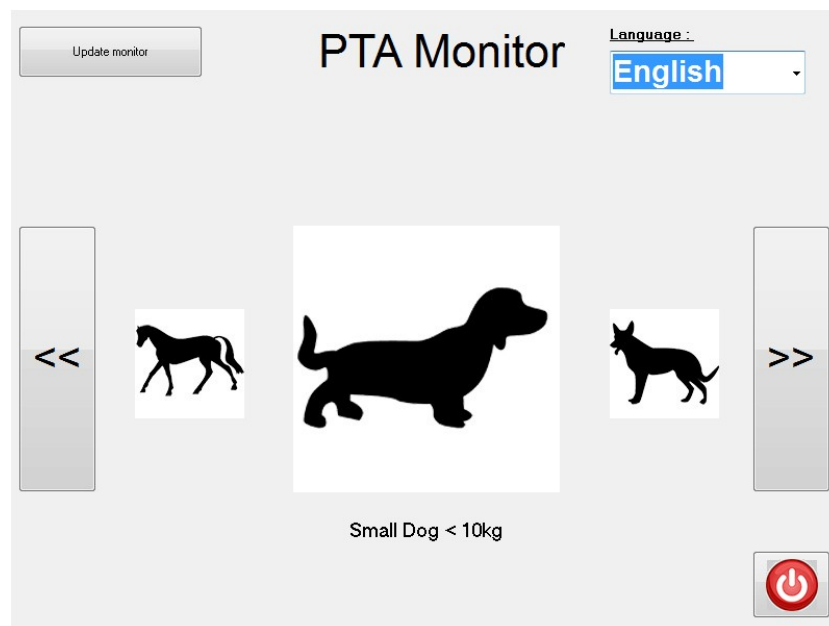


Figure 5

Three pictures of species are displayed on the homepage: cats, dogs and horses. Select the specie you want by touching the picture with your finger (figure 5). When the specie is chosen, the monitor will display the monitoring page with “calibration” for the launch of the calculations.

Put the clips on the patient and moisten the contacts skin/clips with alcohol.

If the user judges that the amplitude of the ECG is too low, by touching the button “**Reset ECG**” it will allow the automatic recalibration of the ECG signal acquisition (figure 6).

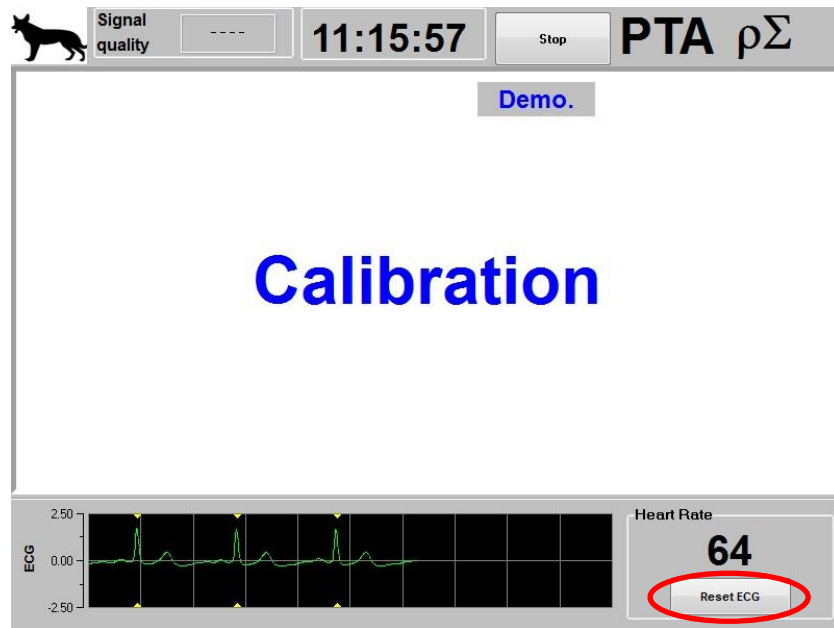


Figure 6

Check the good quality of the ECG signal in the bottom of the screen (figure 1). If no signal is viewable, check the connections from the clips to the PTA monitor. Try at least once to unplug and plug again in order to recover a better and correct ECG signal enough.

Then try at least once to moisten again with alcohol the clips on the skin. If a signal appears but seems abnormal, check the points of contact of the clips with the skin and with the cable.

WARNING: *always check that the signal quality is satisfactory (indicator with green color on the top of the screen). If the signal quality is reported as insufficient by the monitor (indicator with orange color on the top of the screen), there is no possible interpretation (PTA index and heart rate non viewable).*

Once the PTA monitor is connected to the patient via the clips and the ECG signal is good, the calculation algorithm will start automatically.

To note: *The PTA monitor can be used on a conscious or unconscious animal whenever the veterinarian wants.*

4 Use and settings

The selection of “**Parameters**” localized on the right of the screen during the monitoring will allow to reach different settings introduced in the following chapters.

4.1 Languages

The user can choose the language display. Select the touch “**Parameters**”. Then choose the desired language dropdown list and select the language desired to activate it (figure 7).

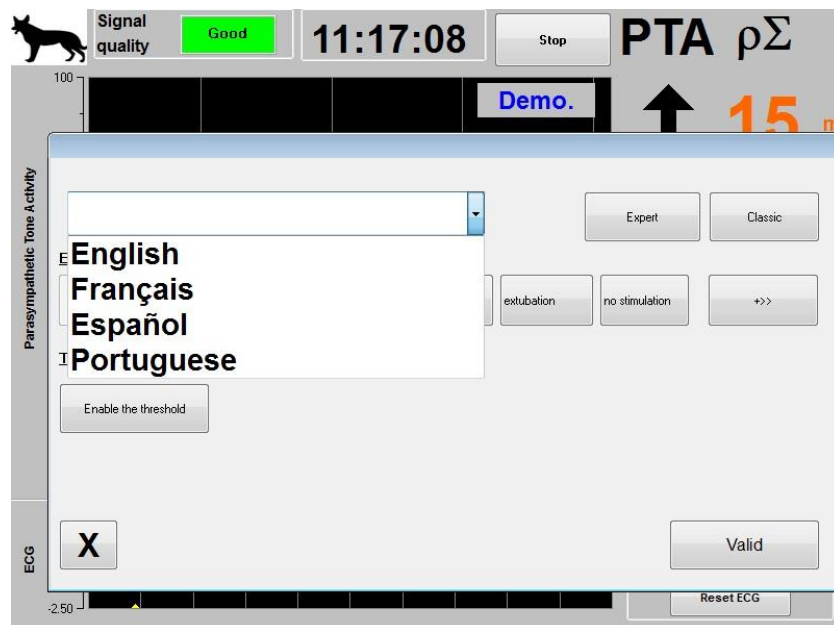


Figure 7

4.2 Thresholds

The user can choose values of thresholds by selecting the button “**enable the threshold**”. Select the values by touching the buttons “+” and “-” (figure 7).

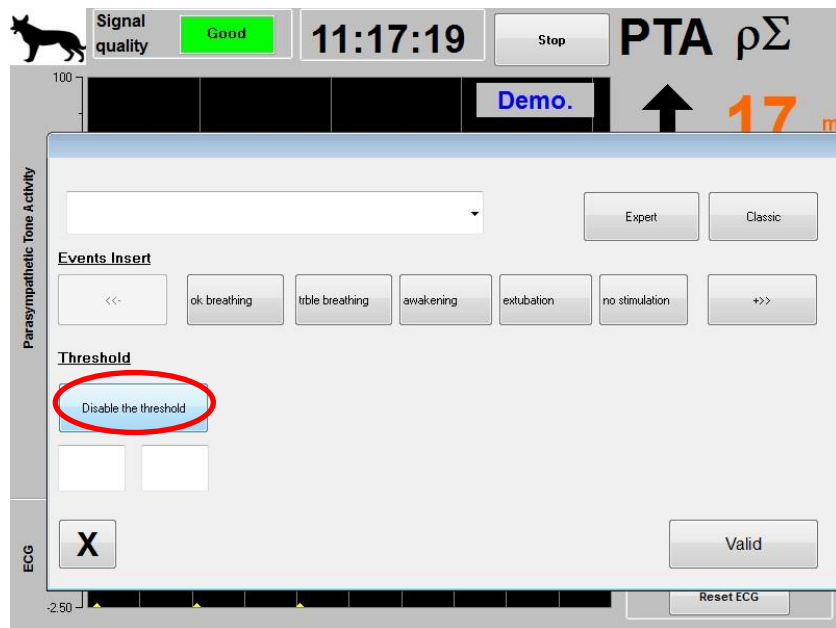


Figure 8

If you select the button “X” without any values, a window will appear (figure 9): select “OK”.



Figure 9

Select the first blank square and put the low values that you want (figure 10). Then select “Valid”. Do the same process for the high value of the threshold.

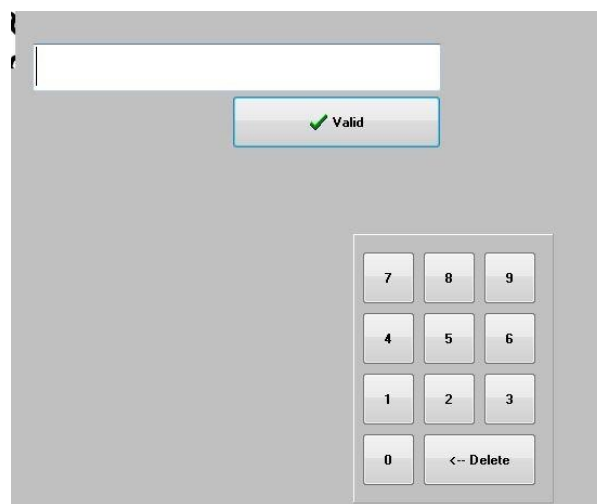


Figure 10

Then the parameters window displays the values chosen (figure 11). Select “Valid” for activating and displaying the thresholds on the monitoring display.

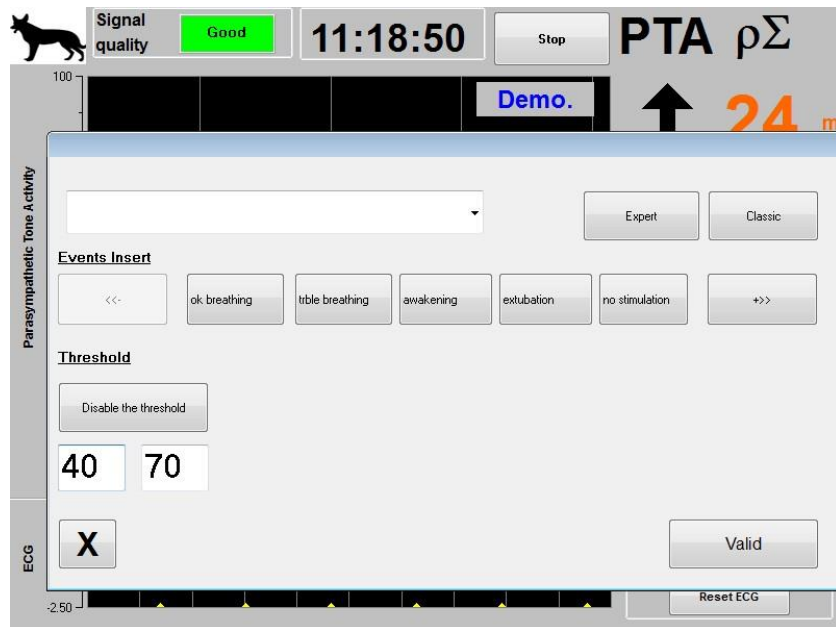


Figure 11

The threshold area will be displayed on the monitoring in progress (figure 12):

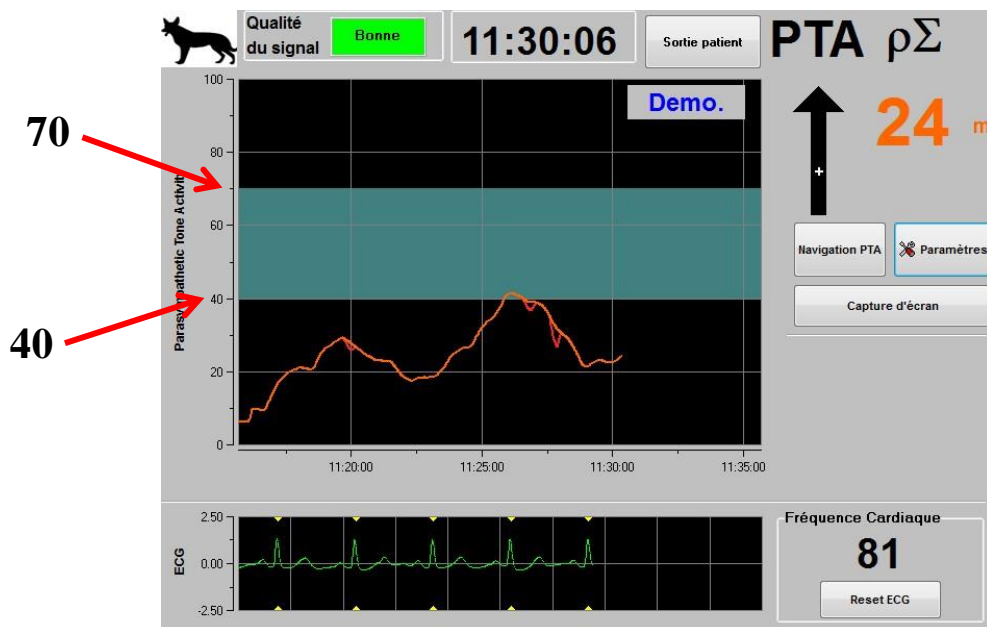


Figure 12

4.3 Events

As showed on the figure 7, the user can insert some events in order to get the corresponding plot on the curve. The events inserted will also be present in the data that the user could export. The user has just to select “**Parameters**” and then chooses one event in the list. This event will be automatically displayed on the curve and added in the data files of the RR series (figure 9).

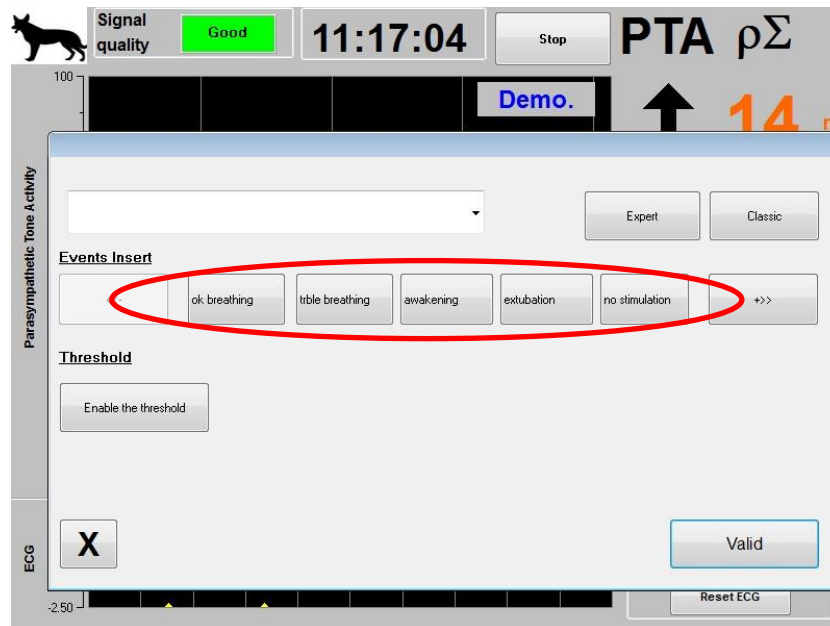


Figure 13

The insertion of one of these events among the list leads automatically the memorization in the kind of file named “Index”. It is possible to download this file on a USB stick for further analysis (see chapter 5.5 below). It is also possible to edit your own list of wanted events (see chapter 5.6 below).

4.4 Expert mode and Energy index

The user has the choice between two kinds of monitoring:

- “**Classic**” mode: there is no Energy index and no respiratory pattern. Only the composite curve and the ECG are displayed (figure 14).

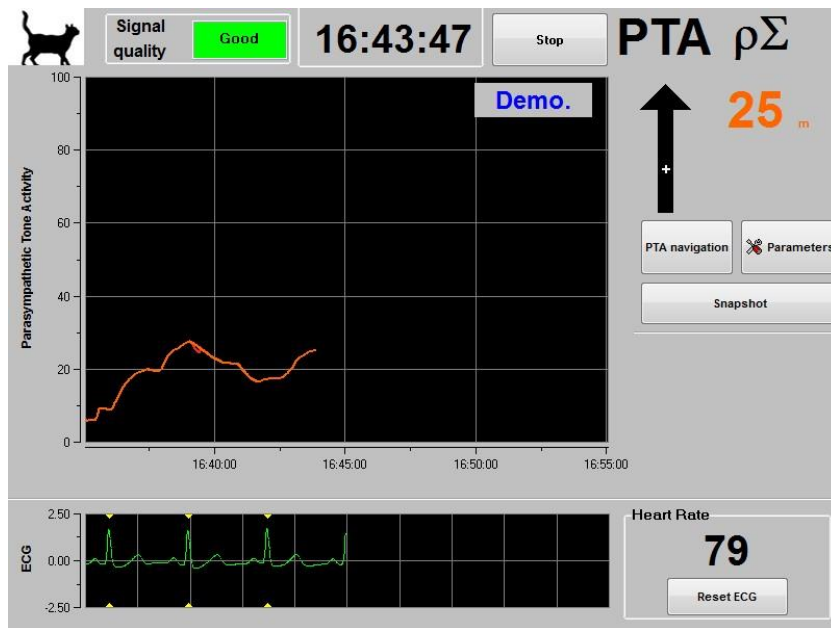


Figure 14

- **“Expert” mode:** the respiratory pattern and the Energy index are displayed and two curves (an instantaneous one and an averaged one) substitute the composite curve (figure 15).

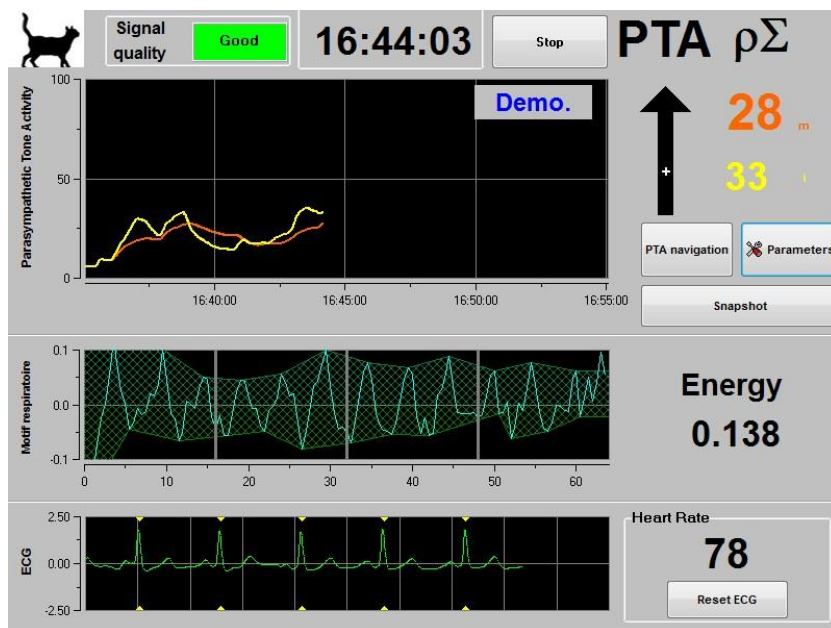


Figure 15

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 PTA calculated at this specific moment is not significant of the patient’s parasympathetic tone value. 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 PTA Monitor.

To set up the “Expert” mode, once entered in parameters setup (button “Parameters”), touch the button “Expert” then the button “Valid” to return to the main screen.

To cancel the “Expert” mode and return to the “Classic” mode, do the same procedure but touch the button “Classic” (figure 16).

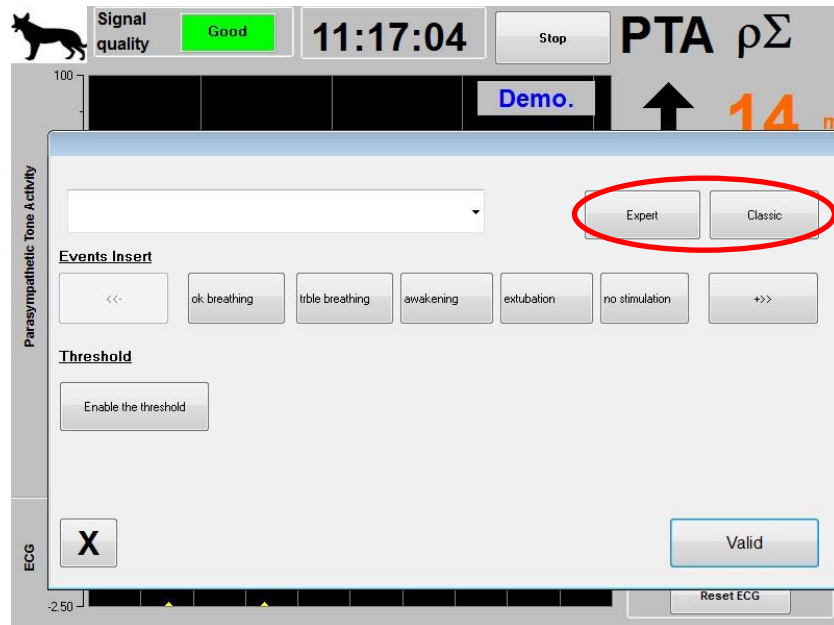


Figure 16

4.5 Snapshot

When the user touch the button “Snapshot”, information displayed is saved in the monitor’s memory as picture format. Each time the user decides to get a snapshot, one picture will be saved in the monitor’s memory.

A message will appear to confirm the success of the snapshot (figure 17). Press the button “OK”.



Figure 17

To get these pictures, a USB stick has to be plugged in the USB port called “Data Export”. Then the user selects “Stop” in the top of the screen. In the new window opened (figure 3),

choose **“Export”**. The pictures will be saved in a file. Each file name will follow this rule:
Hour – Minute – Month – Day - Year.

5 End of the PTA monitoring

5.1 Quit the current recording

The selection of the button **“Stop”** situated in the top of the display during the monitoring enables to end the session and to get access to the main menu. A message is displayed to confirm that the monitoring has been (figure 18).

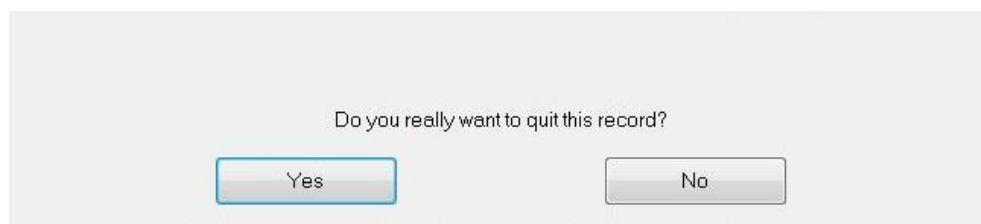


Figure 18

5.2 New patient

The selection of **“New patient”** will start a new monitoring with new data (figure 3).

5.3 Maintenance

Selecting **“Maintenance”** (figure 19) opens a window with an input field (see figure 25 next page). This access is protected by a code that will be forwarded on request to Mdloris Medical Systems.

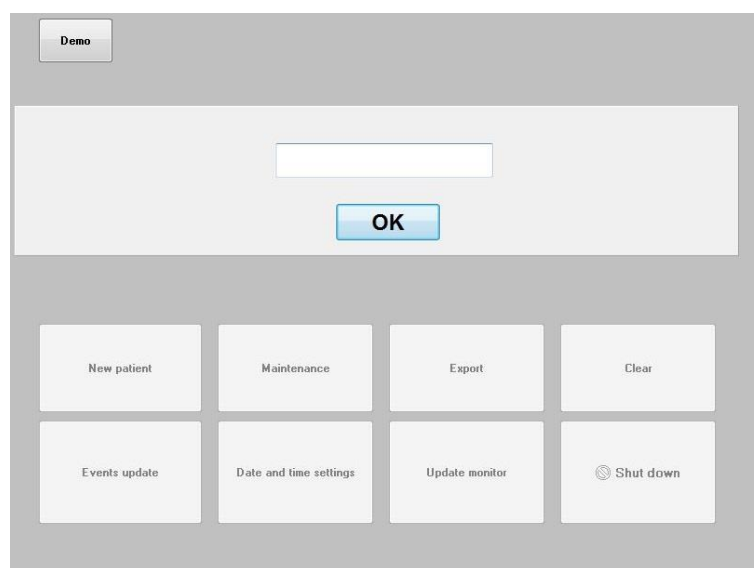


Figure 19

5.4 Export the data recorded

The selection of the button “**Export**” (figure 3) will send all data saved from the monitor memory into a USB key. The USB key should have been plugged before on the lower side of the monitor. If the monitor doesn’t detect any USB key, the export will not work.

When the entire export has been done, a message appears to confirm the success of the export.

Note:

Data are automatically saved as text files for an easy secondary reprocessing (with Windows Excel for example). The files will be exported in a folder created on the USB key. The title of each file indicates the date and hour when the monitoring started. Each file name will follow this rule: hour-minute-month-day-year.

5.5 Deletion of patient’s data

The selection of the button “**Clear**” (figure 3) will lead the deletion of all data previously saved in the memory. A request for confirmation is proposed.

When all data are deleted, another window will appear to confirm that the action is done.

5.6 Events update

Events correspond to different clinical moments predefined in the system. The user can display those different events on the PTA trend panel.

A press on the button “**Stop**” in the top of the screen will end the monitoring and will access to the main menu (figure 3).

To note: by clicking on “**Yes**”, no return to current patient will be possible. You will have access to the main menu.

To access and update the events list, press “**Events update**”. The events update menu will appear (figure 20).

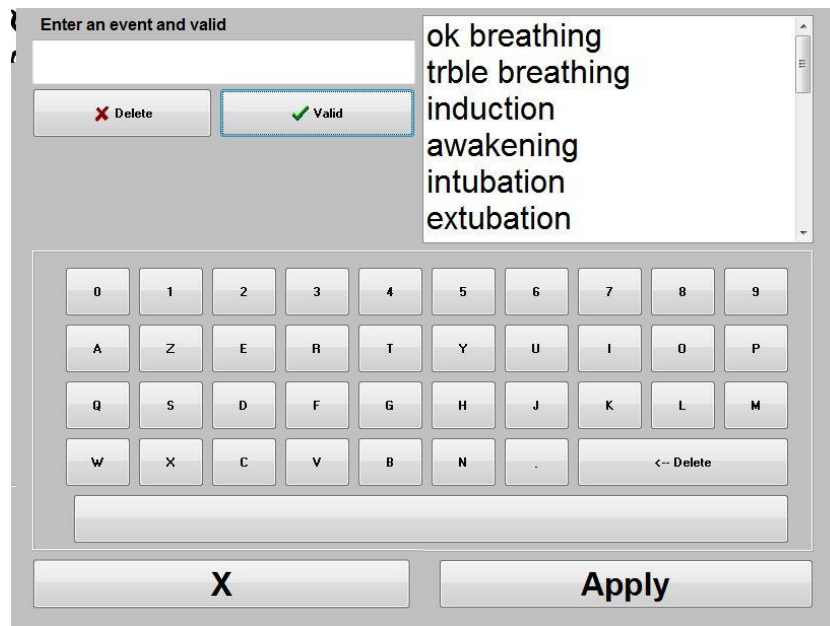


Figure 20

To add new events in the list, you have to use the virtual keyboard on the screen and then valid with the button “ ✓ **Valid**”. Word size is limited to 18 characters.

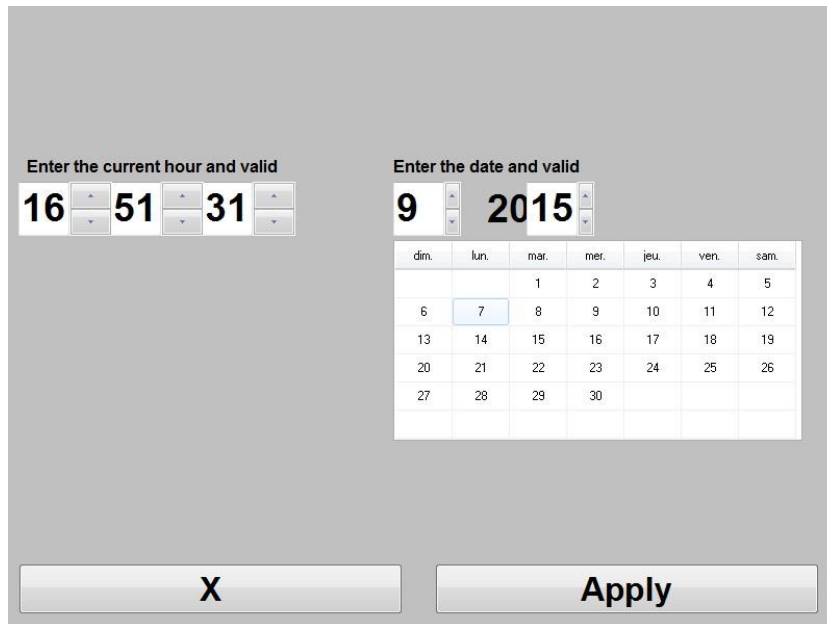
The new event will be added at the end of the drop-down list displayed on the right. To see it, you have to use the scrollbar. To delete an event, you have to select it in the list by touching the word on the screen and touch the button “ **X Delete**”.

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

5.7 Date and time settings

To set the clock or the date, you have to select “ **Stop**” to reach the main menu (figure 3).

Then select “ **Date and time settings**”. The following window will appear:



Enter the current hour and valid

16 51 31

Enter the date and valid

9 2015

dim.	lun.	mar.	mer.	jeu.	ven.	sab.
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

X Apply

Figure 21

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

5.8 Update monitor

In the main menu (figure 3), select **“Update monitor”**. Plug an USB stick with the new version of the PTA software provided by your Mdoloris Medical Systems representative. Then select **“Update monitor”** (figure 3).

5.9 Shut down

In the main menu (figure 3), select **“⊘ Shut down”** and the monitor will shut down. The data in the internal memory will be not deleted and will remain saved.



DO NOT UNPLUG THE POWER CABLE WHILE THE PTA MONITOR IS BEING USED, IT COULD AFFECT THE MONITOR’S PROPER WORKING ORDER.

6 Troubleshooting

Problems	Perform the following tasks:	If failure remains:
An ECG signal is detected but seems to be incoherent (flat, irregular, interfered...).	Check that all cables are correctly connected and the good positioning of ECG electrodes.	Contact your Mdoloris Medical Systems interlocutor.
The ECG waveforms seem to be incoherent (sinusoid...).	Check the color code of the crocodile clips on the patient.	Contact your Mdoloris Medical Systems interlocutor.
The Mdoloris Medical Systems software does not start when the monitor is booted.	Reboot the monitor.	Contact your Mdoloris Medical Systems interlocutor.
Some R waves are regularly not detected.	Check that we can easily distinguish the amplitude of R waves from the P and T waves. If not, move the red and yellow sensors in order to increase the distance between both.	Contact your Mdoloris Medical Systems interlocutor.
The message “There was a mistake” appears at the end of the recording.	Reboot the monitor.	Contact your Mdoloris Medical Systems interlocutor.
The hour and the date are reset at every boot.	The bios battery has to be substituted.	Contact your Mdoloris Medical Systems interlocutor.

7 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 PTA monitor*

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

You can dismantle the monitor:

- No metal element is molded in the thickness of the monitor's housing
- You can recycle the paper print operating manual
- All electronic items of the system are under the RoHS2 normalized rules



Do not waste the electric and electronic equipment in a public bin without waste sorting and even less in a household bin. Collect the different parts separately in order to reuse, treat, recycled or salvage them correctly and in a safe way.

8 Environnement

8.1 *Shipping and Storage Environnement*

The PTA monitor 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:

Shipping and storage temperature: - 20 to + 60 °C

Humidity: 15 to 95% (non-condensing)

Pressure: 480 hPa to 1066 hPa

Protect the monitor from sudden temperature changes that can lead a condensation within the instrument. To minimize the risk of condensation, avoid moving the system between heated buildings and outside storage. Once moved inside, let the monitor in the unopened shipping container to reach the room 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.

8.2 *Operating Environnement*

Temperature: The monitor is designed to operate safely in a temperature from 5 to 30 °C. The conditions that exceed these limits may modify its reliability.

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

Pressure: The monitor works correctly in conditions of sea level and below, and is not affected by extremes or by altitude modifications within a range of atmospheric altitude from 480 hPa to 1066 hPa.

8.3 *Power Requirements and System Grounding*

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

To protect operating personnel and patients, the monitor must be properly grounded. The power cord grounds the system to the power line ground when plugged into an appropriate three-wire socket.

CAUTION: *FOR PROPER GROUNDING, THE POWER SOCKET MUST BE A 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, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.*

9 **Cleaning and disinfection**

9.1 *Cleaning*

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:

Clean any spillage of blood or solutions on the monitor. 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 screen:

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:

Use lint-free absorbent towels dampened with isopropyl alcohol, 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.

9.2 Leakage Current

The PTA monitor is designed so that it does not need any adjusting or calibration. However, the leakage current should be checked systematically after saline or blood projection or after a major high voltage surge in the internal house electrical system or at least once a year.

Leakage current is a primary indicator of electrical shock hazard to personnel making contact with any exposed outer surface of the equipment.

Security tests have been realized on our monitors to verify that leakage current meets the IEC60601-1 safety standards.

10 Specifications, warranty and software license agreement

10.1 Specifications

Power requirements:

Input: voltage: 100-240 Vac

Frequency: 50 – 60 Hz

Current: 1.5 A

Output: voltage: + 12 VDC

Current: 3.0 A

Electrical Safety: Class 1 conforms to IEC 60601-1

Weight of the monitor with collet fixture: 1.9 Kg.

Weight of acquisition device (without connection cable for electrodes) = 0.4 Kg.

Dimensions of the monitor with the retractable support system in cm (height x width x depth):
19 x 24 x 6.

Acquisition device dimensions in cm (width x height x depth): 15.7 x 10.3 x 6.85

Screen size: 8.4”.

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

Composition of the PTA equipment

MN-PTA-V3	Monitor
BA-PTA-V3.1	Acquisition box
FSP036-RBBN2	Convertisseur AC/DC
PTA-PW-V1	Power cable
SP216	ECG cable
PTA-CC-V1	Crocodile clips
ICP-VSTAND-A10	Retractable support system + screws

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.

System functioning:

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

10.2 Warranty

Mdoloris Medical Systems warrants to the initial Purchaser that the PTA monitor (“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 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 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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10.3 Software Licence Agreement

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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