ANI MOC-9

OEM version: ANI OEM v2.5

IHM version: 3.1.0.0

Instruction for use

MDoloris Medical Systems

General knowledge of parasympathetic nervous system and an understanding of the features and functions of the ANI MOC-9 are prerequisites for proper use.

These operating instructions intend to provide the necessary information for proper operation of the ANI MOC-9.

Do not operate the ANI MOC-9 without completely reading and understanding these instructions.

This User's Manual describes how ANI MOC-9 information is displayed when used with Root®, including display details as well as accessing and changing user-configurable settings. For additional information related to Root, refer to the Operator's Manual for Root.

For further information contact:

MDOLORIS MEDICAL SYSTEMS SAS

Biocentre Fleming

Bâtiment C - Epi de Soil

270, rue Salvador Allende

59120 LOOS

Tel: +33 (0)3 62 09 20 80 - Fax: +33 (0)9 72 38 75 27

www.mdoloris.com

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Contents

Product Description

In partnership with Masimo Corporation, Mdoloris Medical Systems has developed ANI MOC-9 for a connectivity platforms and patient monitoring: Root monitor. By connecting the ANI MOC-9 on the Root monitor from Masimo, it allows the visualization of the ANI index.

The Mdoloris Medical Module ANI MOC-9 and its sensors are designed to be used for adult and paediatric patients from the age of 12 years.

ANI MOC-9 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 nurse anaesthetists) in a medical environment.

Intended Use

ANI MOC-9 allows monitoring of the tone of the parasympathetic nervous system by computing the ANI parameter for conscious and unconscious patients. It may be used to monitor the balance between analgesia and nociception.

ANI MOC-9 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.

Contraindications

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.)

Warning and caution instructions

Caution: read this entire manual carefully before using the ANI MOC-9 in a clinical setting.

Safety warnings and cautions

⚠ Do not use the ANI MOC-9 if it appears or is suspected to be damaged.

⚠ Always use ANI MOC-9 in conjunction with Root. Do not use parts from other systems. Injury to personnel or equipment damage could occur.

⚠ Do not adjust, repair, open, disassemble, or modify the ANI MOC-9. Injury to personnel or equipment damage could occur.

⚠ Do not use ANI MOC-9 and the sensors during magnetic resonance imaging (MRI) or in an MRI environment.

⚠ Explosion hazard: Do not use the ANI MOC-9 in the presence of flammable anaesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

⚠ To protect against injury, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Use cleaning solutions only as instructed in this User's Manual.
- Do not attempt to clean ANI MOC-9 while monitoring patient.

⚠ As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

⚠ 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.

⚠ The conductive parts of sensors and connectors should not contact other conductive parts, including earth.

⚠ To minimize the risk of patient burns from the neutral electrode for HF surgery, do not put the ANI sensors between the surgical site and the electrosurgical unit's return electrode.

⚠ Not place the ANI sensors between defibrillator paddles when they are use on a patient connected to the ANI MOC-9.

⚠ 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.

⚠ Never modify the ANI MOC-9 when open.

⚠ Staff should avoid touching simultaneously patient and ANI MOC-9.

⚠ 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.

⚠ In operating rooms, the ANI MOC-9 must be placed outside the explosion hazard zone.

⚠ 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 sensors. It is important to take particular care with patients suffering from dermatological problems.

⚠ Never put sensors on skin injuries.

⚠ Using 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.

Performance warnings and cautions

⚠ The ANI MOC-9 may be used during electrosurgery, but this may affect the accuracy or availability of the parameters and measurements.

⚠ The ANI MOC-9 may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

⚠ The ANI MOC-9 may be used during defibrillation; however, the display may require up to 15 seconds to return to normal operation.

⚠ The ANI MOC-9 is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.

⚠ Inaccurate ANI readings or no ANI readings may be caused by:

- Moisture on the skin.
- Excessive motion.
- Muscle activity
- Metal plate or other foreign object in sensor path.
- Electrosurgical interference.
- Improperly applied sensor.
- Adjacent placement of any sensor that is not connected to the same ANI MOC-9.

Cleaning and service warnings and cautions

⚠ Do not mix disinfecting solutions (e.g., bleach and ammonia), as toxic gases may result.

⚠ Make sure the ANI MOC-9 is installed outside the liquid projections hazard zone, e.g. Perfusion bag.

⚠ Do not autoclave the ANI MOC-9. Autoclaving will seriously damage both components.

Compliance warnings and cautions

⚠ When using electro-convulsive therapy (ECT) equipment during ANI monitoring: place ECT sensors as far away as possible from the ANI sensor to minimize the effect of interference. Some ECT equipment may interfere with the ANI MOC-9 signal. Check for equipment compatibility during patient setup.

⚠ Using accessories and cables other than specified or provided by the manufacturer of the ANI MOC-9 (Mdoloris Medical Systems) may result in increased electromagnetic emissions or decreased electromagnetic immunity of the ANI MOC-9 and may result in an inappropriate operation.

⚠ The ANI MOC-9 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.

⚠ The characteristics of ANI MOC-9 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 MOC-9 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 MOC-9.

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

⚠ Changes or modifications not expressly approved by Mdoloris Medical Systems shall avoid the warranty for this equipment.

Chapter 1: Technology overview

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

The series of normal, non-ectopic, R-R intervals is processed after normalization, resampling and filtering. The amount of pΣ tone is measured in relation to the total window surface through the area comprised between the lower and the upper envelope of the RR series. The higher the pΣ, the higher the shaded surface is, 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 pΣ activity as a part of ANS activity: it expresses the relative amount of pΣ tone present as compared to sum of sympathetic and pΣ activities. ANI MOC-9 displays two averaged ANI measurements: ANIi results from the average of ANI measured over the previous 56 sec, and ANIm results from the average of ANI measured over the previous 176 sec.

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

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

Chapter 2: System description

The ANI MOC-9 system is composed of three (3) components:

• Root

• ANI MOC-9

• ANI Sensor V1 PLUS

Root

Root displays the following parameters:

- Instantaneous ANI
- Average ANI
- Quality of the measure
- Energy.

For more information about Root, see Operator's Manual for Root.

ANI MOC-9

The ANI MOC-9 computes ANI using signals acquired from the ANI Sensors. In turn, these measurements are displayed on the Root.

ANI Sensor V1 PLUS

NOTE: The ANI MOC-9 has been designed to work with specific disposable sensors. It is inadvisable to use another kind of electrode.

The maximum consecutive period that the sensors can adhere to the skin is 24 hours.

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

The ANI Sensor V1 PLUS allows the acquisition of signal in order to process the algorithm.

For more information about the ANI Sensor V1 PLUS, see the documentation provide with the sensor.

Chapter 3: Setting Up ANI MOC-9 with ANI Sensors

For initial use of ANI MOC-9 module, the following setup instructions must be followed.

Unpacking and inspecting the system

1. Remove the components from the shipping carton and examine them for signs of shipping damage.
2. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.
3. If anything is missing or damaged, contact the Mdoloris Medical Systems Technical Service Department.

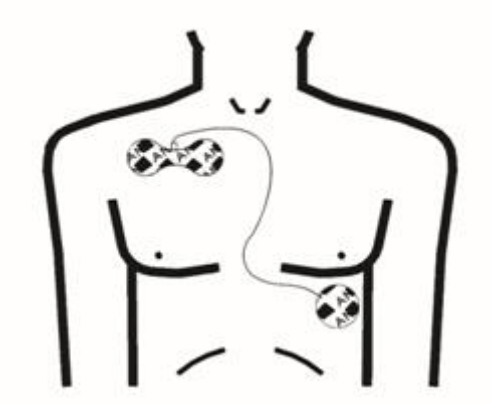
Preparation for use

Prior to using ANI MOC-9 for monitoring

1. Confirm that you have all system components:
   - Root
   - ANI MOC-9
   - ANI Sensor V1 PLUS
2. Confirm that Root holds adequate battery power.

Connecting the ANI Sensor V1 PLUS to the ANI MOC-9 module

1. Position the sensor as describe on the picture below.

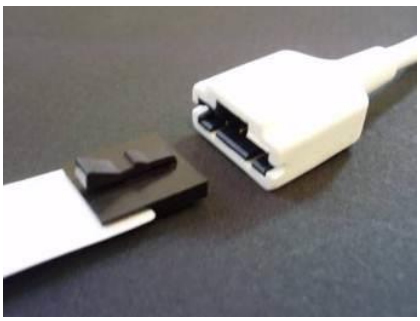


Sensors' positionning

2. Connect the sensors to the sensor cable.

Before connecting, carefully align the notches on the connection sheet to make the pins correspond perfectly. To disconnect the sensors, grasp the plastic portion while pressing on

the locking mechanism and pull gently to disengage it. **Do not pull by grasping the sensors itself.**



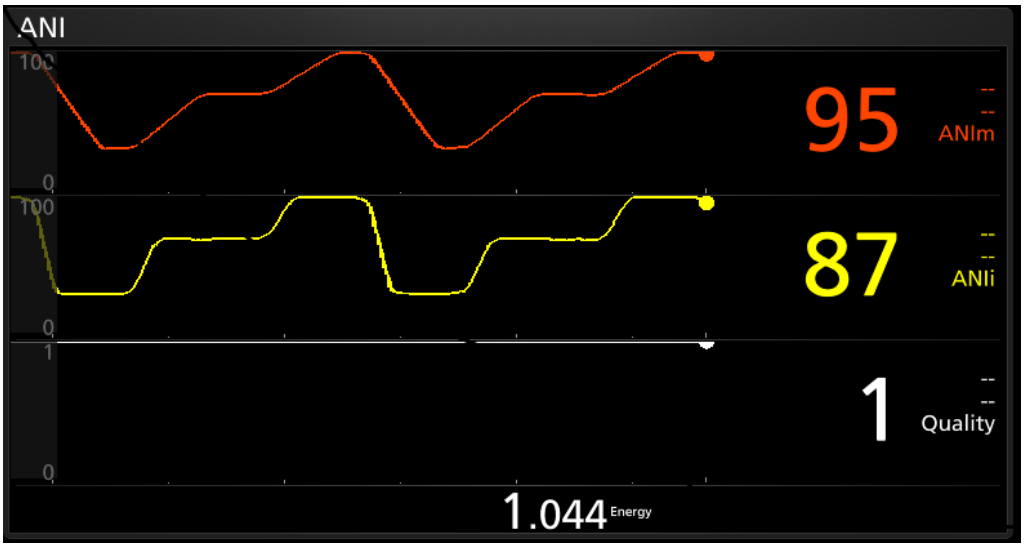
Locking mechanism

Connecting the ANI MOC-9 module

1. Identify the Masimo Open Connect connector on the module, as illustrated in the image below.

2. Insert the MOC-9 connector securely into a MOC-9 Port on Root, as illustrated in the image below.

3. The module is now activated. This is verified when the ANI MOC-9 window displays on Root.



For more information on the ANI MOC-9 window, see ***The ANI MOC-9 Window*** section.

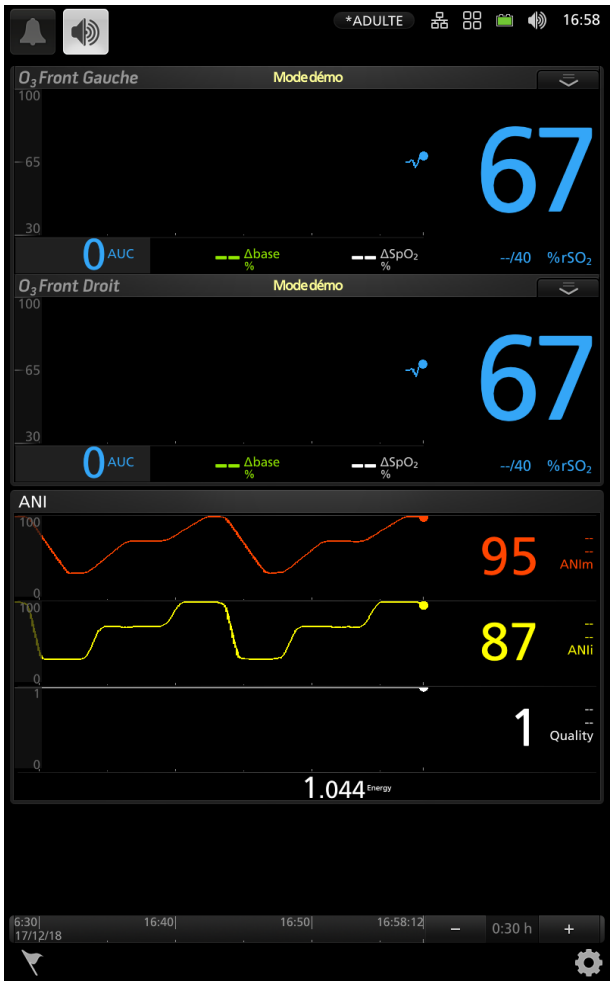
Chapter 4: Operation

The following sections describe how ANI MOC-9 information is displayed when used with Root, including display details. For additional information on Root, see Operator's Manual for Root.

The ANI MOC-9 window

When an ANI MOC-9 is connected to Root, ANI parameters and measurements display in the ANI Module window as numeric values with graphical representation.

When multiple technologies are connected to Root, each technology's parameters are displayed in an individual window. The relative size of each window can be configured using the Layout feature, which is accessible by pressing the Layout icon in the Main Menu. For more information, see Operator's Manual for Root. In the image below, O_3 parameters and measurements are displayed in their own windows; and ANI MOC-9 parameters and measurements are displayed in a separate ANI Module window.



The ANI module window shows information about measurement proceed by ANI MOC-9. Four parameters are provided by the module:

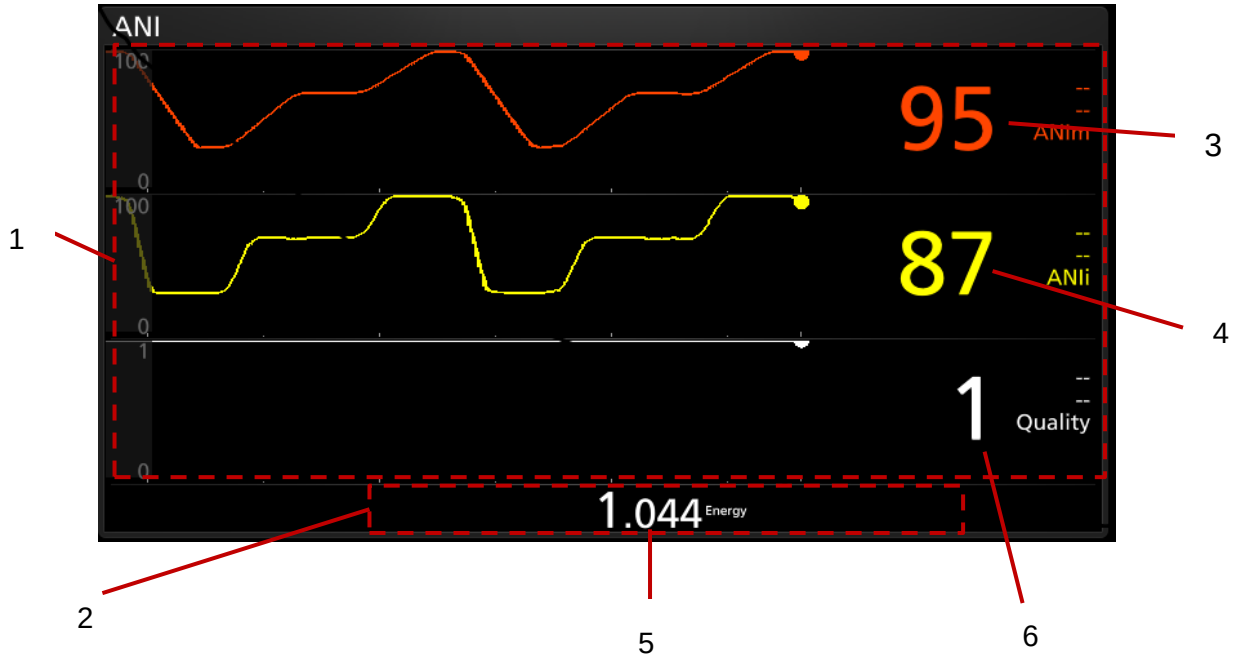
- ANIi
- ANIm
- Quality
- Energy.

The window is composed by 2 slots:

1. slot with trend line and value of a selected parameter and,
2. slot with the values of the other parameters.

Only one trend can be displayed on the first slot. You can choose this parameter by dragging and dropping the corresponding value from the slot 2 to the slot 1.

The window is outlined in the illustration and each part is explained in more detail in the table below.



Réf	Feature	Description
1	Slot 1	Displays the level and the value of the selected parameter
2	Slot 2	Displays the value of the other parameters

3	ANIm	Averaged value of the ANI between 0 and 100
4	ANIi	Instantaneous value of the ANI between 0 and 100
5	Energy	Energy of the RR series
6	Computation quality	Quality of the measurement. Values ranging from 0 to1 • 0 = bad quality • 1 = good quality

Mode of operation

Once the module is connected to the patient with the sensor and to the root, 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.*

ECG acquisition

Check for good computation in the lower part of the Root screen.

If the indication shows poor measurement quality (Value equal to 0) the data displayed cannot be consider, the ANI index is not displayed anymore, the curve freezes. In that case, check the proper position of the sensor and their adhesion to the skin. If necessary, reposition or change them.

WARNING: *always check the quality parameter. The ANI index will not be reliable if the signal quality is bad.*

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 on 56 seconds) and a longer average (average on 176 seconds).

The Root monitor displays two parameters: the orange one is the value of the longer average (marked as “m”) and the yellow one is the instantaneous ANI (marked as “i”), resulting from the short average. These indexes can anticipate a hemodynamic reactivity during the nociceptive stimuli. “.

Chapter 5: Trouble shooting

To troubleshoot issues with Root, see the Operator's Manual for Root. To troubleshoot issues with sensors, see the Instruction for Use of the ANI Sensor V1 PLUS.

Problem	Possible Cause	Solution
Bad computation quality	Cable is disconnected	Check the patient cable is correctly connected to the sensor.
	Cable and connectors are damaged	Check that the cables and connectors are in good working order.
	Sensors are misplaced	Check that sensors are properly placed along an imaginary line through the heart (acquisition of an electrical QRS axis).
	Too much noise on the signal	Check that any other device can interfere.
ANI MOC-9 module is not recognized	Power is not established Module is not recognized	Unplug the module then restart Root Monitor.

Chapter 6: Specifications

Environment

Operating Conditions:	
Temperature at ambient humidity:	5°C to 40°C
Humidity:	10 % to 95 %
Storage Conditions:	
Temperature at ambient humidity:	-20°C to 60°C
Humidity:	0% to 95%

Protect the ANI MOC-9 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 ANI MOC-9 to stabilize in the unopened shipping container at room temperature before unpacking and placing into service. Before operating the system, wipe down all visible condensation and allow the system to reach equilibrium at room temperature.

The ANI MOC-9 is not designed for use in areas containing flammable gases or vapours.

Physical Characteristics of the module

Width:	54 millimetres
Length:	155,3 millimetres
Thickness:	22 millimetres
Weight:	330 grams

Regulatory Symbols

The following symbols are on the product hardware or packaging

Symbole	Description	Symbole	Description
	Manufacturer		Date of manufacture
	CE Marking of Conformity (93/42/EEC Directive)		Serial number
	Defibrillation-proof type CF applied part		Refer to instruction manual /booklet
	Fragile; handle with care	RxOnly	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)
	Keep away from sunlight		Do not use if package is damaged
	Temperature limit		Keep away from rain
	Humidity limitation		Needs special waste disposal
IP X1	IP classification		

Conformity

Safety conformity
CEI 60601-1 :2005 + AMD1 :2011

EMC conformity
CEI 60601-1-2, class A

Safety Classification according to IEC 60601-1	
Type of Protection	Class II
Degree of Protection against Electric Shock	CF-type
Degree of Protection against the Ingress of Liquid	IP X1 according to IEC 60601-1
Mode of Operation	Continuous

Chapter 7: Service and Maintenance

Cleaning and disinfection

Cleaning of the ANI MOC-9 should be performed at regular intervals or in accordance with hospital, as well as local and governmental regulations.

See ***Warning and caution instructions*** section.

ANI MOC-9 is a reusable instrument which is supplied non-sterile.

Clean any blood or liquid spill on module immediately. Dried blood is very difficult to remove. Use the maker's wipes called "linget' Anios" wipes (impregnated with ethanol) or "Wip'Anios" wipes (impregnated with Didecyldimethylammonium chloride) or ethanol-based wipes.

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

General maintenance

Safety tests should be done by qualified personnel only. Safety checks should be performed at regular intervals or in, accordance with hospital, as well as local and government regulations.

The following is a checklist for the general maintenance of the ANI MOC-9:

- Visually inspect equipment for functional or structural damage, including poor seals, cracks, damaged springs, etc.
- Visually inspect cable, connector, and connector pins for signs of damage or wear,
- Visually inspect product identification labels to ensure they are clear and legible,
- System check and leakage current check according to the 62353 standard.

However leakage current must be checked systematically after every blood or liquid spill, or immediately after a major surge in the electrical system.

Service Instructions

ANI MOC-9 has no customer serviceable parts. Attempting to service ANI MOC-9 Module will avoid the warranty.

Repair Policy

Mdoloris Medical Systems or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. Have the instrument repaired.

Please clean contaminated and/or dirty equipment before returning, following the cleaning procedure described in ***Cleaning and disinfection*** section. Make sure the equipment is fully dry before packing.

To request repair or replacement under the 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.

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

Warranty

Mdoloris Medical Systems warrants to the initial Purchaser that the ANI MOC-9 ("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.

This warranty does not extend to any Warranted Products or part thereof that have been subject to misuse, neglect, or accident; that have been damaged by causes external to the Warranted Product, including but not limited to failure of or faulty electrical power; that have been used in violation of Mdoloris Medical Systems' instructions; that have been affixed to any nonstandard accessory attachment; on which the serial number has been removed or made illegible; that have been modified, disassembled, serviced, or reassembled by anyone other than Mdoloris Medical Systems, unless authorized by Mdoloris Medical Systems. Mdoloris Medical Systems shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear. Mdoloris Medical Systems makes no warranty (a) with respect to any products that are not Warranted Products, (b) with respect to any products purchased from a person other than Mdoloris Medical Systems or its official distributor (c) with respect to any product sold under a brand name other than Mdoloris Medical Systems.

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Device 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 MOC-9 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 ANI MOC-9 before you dispose of your system. Respect local regulations regarding electric and electronic items.

The ANI MOC-9 can be dismantled:

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.

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