ANI-MR

ANI computation version: ANI OEM v2.8

ECG processing version: 3.1.0.0

Instruction for use

MD/PRD/IN16.ANIMR V.04 – 14/12/2021

MDoloris Medical Systems is registered trademark.

ANI is a protected trademark.

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 essential performance identified for the ANI-MR is the display of ANI index if the signal quality is good.

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

This instructions for use intend to provide the necessary information for proper operation of the ANI-MR.

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

This user's manual describes how ANI-MR information is displayed when used with BeneVision™ monitor (N22/N19/N17/N15/N12/N12C), including display details as well as accessing and changing user-configurable settings. For additional information related to BeneVision ™ monitor, refer to the instruction of use for BeneVision ™.

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

CE 2797

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About this manual

This manual explains how to set and use the ANI-MR. Important safety instructions for the general use of the ANI-MR are presented in this manual. Read and observe all warnings throughout this manual. The following information is a security explanation and warning.

A *warning* is given when an action may result in a serious outcome (e.g. injury, serious adverse reaction, death) for the patient or user.

WARNING : this is an example of a warning.

Product Description

In partnership with Shenzhen Mindray Bio-Medical Electronics, MDoloris Medical Systems has developed the ANI-MR device for the supervision and monitoring of patients with the BeneVision™ Mindray monitor. Connecting the ANI-MR module on the BeneVision™ monitor allows the visualization of the ANI index.

The ANI-MR device and its sensors are designed to be used for adult patients and for paediatric patients from 12 years old.

ANI-MR is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel specifically trained for its use (anaesthesiologist-resuscitators and anaesthesiologists nurses) in a medical environment.

Intended Use

ANI-MR allows the 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-MR is intended for use as a complement to clinical judgment. Clinical judgment should always be used when interpreting the ANI index in conjunction with other available clinical signs.

WARNING: *Reliance on ANI alone for interpreting analgesic management is not recommended.*

Indication for use

Clinical benefits are as follows:

- Predictivity of haemodynamic reactivity
- Better than rate and blood pressure variations to detect nociception
- Helpful to diagnose the aetiology of a haemodynamic event
- Refines opioids titration
- Reduces per-operative opioid consumption
- Reduces post-operative pain
- Predicts post-extubation pain
- Reduce length of stay in outpatient surgery units

Contraindications

ANI measures cannot be performed in case of:

- Arrhythmia or heart rate out of the range 30 – 150 bpm
- Apnoea (e.g., apnoea induced by anaesthesia)
- Respiratory rate lower than 9 cycles/min or higher than 30
- Electric noise during the measurement period (64 seconds)
- Irregular spontaneous ventilation (patient speaking, laughing, or coughing)
- Pacemaker (some types)
- Heart transplant
- Drugs affecting the sinus node (atropine and other anticholinergic drugs, etc.)

Side-effects

No undesirable side-effects up to date, the use of the sensor with the ANI-MR may lead to undesirable side-effects. Please refer to Sensor Manual for more information.

Warning and cautions

Caution: read this entire manual carefully before using the ANI-MR in a clinical environment.

Safety warnings and cautions

WARNING : Do not use the ANI-MR if it appears or is suspected to be damaged.

WARNING : Always use ANI-MR in conjunction with BeneVision™ monitor. Do not use parts from other systems. Injury to personnel or equipment damage could occur.

WARNING : Always use ANI-MR with device compliant with 60601-1 and CF type applied parts.

WARNING : Do not adjust, repair, open, disassemble, or modify the ANI-MR. Injury to personnel or equipment damage could occur.

WARNING : Do not use ANI-MR and the sensors during magnetic resonance imaging (MRI) or in an MRI environment.

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

WARNING : To protect against injury, follow the instructions 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-MR while monitoring patient.

WARNING : As with all medical equipment, carefully route patient cabling to reduce the risk of patient entanglement or strangulation.

WARNING : Ground leakage current must be checked by a qualified biomedical engineering technician whenever the instrument case is opened.

WARNING : Protection against heart defibrillation shock depends on the use of appropriate cables.

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

WARNING : To minimize the risk of patient burns from the neutral electrode using a diathermy knife, do not put the ANI sensors between the surgical site and the electrosurgical unit's return electrode.

WARNING : Not place the ANI sensors between defibrillator paddles when they are used on a patient connected to the ANI-MR.

WARNING : Observe universal precautions to prevent any contact with blood or other potentially infectious materials. Contaminated materials must be handled in accordance with the facility's applicable health and safety regulations.

WARNING : Never modify the ANI-MR when opened.

WARNING : The staff should avoid touching simultaneously patient and the ANI-MR.

WARNING : 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.

WARNING : In operating rooms, the ANI-MR must be placed outside the explosion hazard zone.

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

WARNING : 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.

WARNING : Never put sensors on skin injuries.

WARNING : 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.

WARNING : Reusing a sensor could reduce adhesion, leading to a possible decrease in ANI input signal acquisition performance.

WARNING : Reusing a sensor could reduce its adhesive strength due to an initial application, removal, and a new use.

WARNING : Protect the ANI-MR against sudden temperature changes that could lead to condensation inside the device.

WARNING : To minimize condensation, avoid moving the system between heated buildings and outside storage. Once moved inside, allow the ANI-MR to stabilize in the unopened shipping container at room temperature before unpacking and placing into service.

WARNING : Before operating the system, wipe down all visible condensation and allow the system to reach equilibrium at room temperature.

WARNING : The ANI-MR is not designed for use in areas containing flammable gases or vapours.

WARNING : Do not pull on the patient cable, it may tear and you will no longer be able to use it.

WARNING : Do not pull on the communication cable, it may tear and you will not be able to use it anymore.

Performance warnings and cautions

WARNING : The ANI-MR may be used during electrosurgery, but this may affect the accuracy or availability of the parameters and measurements.

WARNING : The ANI-MR may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

WARNING : The ANI-MR may be used during defibrillation; however, the display may require up to 15 seconds to return to normal operation.

WARNING : The ANI MR is intended only as an adjunct device in the patient's 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.

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

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

Cleaning and service warnings and cautions

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

WARNING : Make sure the ANI-MR is installed outside the liquid projections hazard zone (e.g., Perfusion bag).

WARNING : Do not autoclave the ANI-MR. Autoclaving will seriously damage the components.

WARNING : To avoid any kind of contamination or infection of the personnel, the environment or equipment, be sure you have properly disinfected and decontaminated the ANI-MR before you dispose of your system. Respect local regulations regarding electric and electronic items.

WARNING : Do not throw the device into the household trash, see the procedure at the end of the user manual.

Compliance warnings and cautions

WARNING : When using electro-convulsive therapy (ECT) equipment during ANI monitoring: place ECT sensors as far as possible from the ANI sensor to minimize the effect of interferences. Some ECT equipment may interfere with the ANI-MR signal. Check the equipment compatibility during patient preparation.

WARNING : Using accessories and cables other than specified or provided by the manufacturer of the ANI-MR (MDoloris Medical Systems) may result in increased electromagnetic emissions or decreased electromagnetic immunity of the ANI-MR and may result in an inappropriate operation.

WARNING : The ANI-MR complies with the electromagnetic compatibility requirements of IEC 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

WARNING : The use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in an improper operation. If such use is necessary, this equipment should be observed to verify that it operates normally.

WARNING : The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in an improper operation.

WARNING : Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ANI-MR, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

WARNING : Changes or modifications not expressly approved by MDoloris Medical Systems shall avoid the warranty for this equipment.

WARNING : The use of the monitor cannot be done without prior training. If training is needed, please contact your MDoloris Medical Systems interlocutor.

Chapter 1: Technology overview

ANI (Analgesia Nociception Index) is a standardized continuous measurement of the relative pΣ tone (parasympathetic tone).

The ANI technology is intended to acquire and analyse electrocardiographic information and to measure heart rate variability.

ANI calculation is based on R-R interval variability in ECG. Since the monitors are not an ECG monitor, the ANI Sensor products have been designed to retrieve information related to QRS complexes. The acquisition of cardiac vector is enough to get an ANI calculation.

Each respiratory cycle (spontaneous and artificial) induces a fast, temporary decrease of the parasympathetic 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 quatity” of parasympathetic 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 and displayed on a scale of 0 and 100. However, the lower limit attainable is 12 due to the algorithm design. The raw ANI value is computed on a time window of 64 sec. This number shows the relative parasympathetic activity as a part of ANS activity: it expresses the relative amount of parasympathetic tone present as compared to sum of sympathetic and parasympathetic activities.

ANI-MR provides two averaged ANI measurements: ANIi results from the average of the raw ANI measured over the previous 56 sec, and ANIm results from the average of the raw 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.

In the particular context of surgery under general anaesthesia or intensive care unit:

- ANIm is related to the imbalance between analgesia and nociception
- ANIi is related to the acute parasympathetic response to stimulus
- Energy is an index related to the amount of total ANS activity a short period (64 second).

Chapter 2: System description

The use of the ANI-MR involves:

- BeneVision™ Mindray monitor
- Mindray ANI single slot module
- ANI-MR module
- ANI Sensor V1 PLUS

BeneVision™ monitor

BeneVision™ monitor displays the following parameters:

- ANIi (Instantaneous)
- ANIm (Averaged)
- Energy

The ANI-MR is compatible with the N22/N19/N17/N15/N12/N12C BeneVision™ monitor from Mindray.

For more information about the Mindray monitor, please read Operator's Manual for BeneVision™ monitor.

Mindray ANI single slot communication module

This Mindray ANI single slot communication module allows you to obtain the ANI data through the connection between the ANI-MR module and the Mindray monitor.

ANI-MR

The ANI-MR computes the ANI with signals acquired from the ANI Sensors. In turn, these measurements are displayed on the BeneVision™ monitor.

ANI Sensor V1 PLUS

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

The sensors can adhere to the skin for a maximum period of 24 hours.

The shelf life of the sensors is indicated on the 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, please read User's manual of ANI V1 PLUS sensors.

Chapter 3: Setting Up ANI-MR with ANI Sensors

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

Unpacking and inspecting the system

1. Remove the components from the shipping box and examine them to find signs of shipping damage.
2. Check that all materials listed on the packing list are present. Keep all packing materials, invoice. These may be required to process a claim with the carrier.
3. If any element is missing or damaged, contact the MDoloris Medical Systems Technical Service.

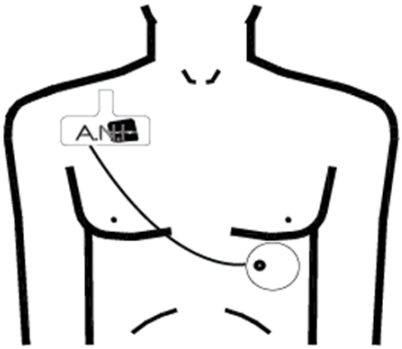
Preparation for use

Prior to using ANI-MR for monitoring:

1. Check that you have all system components:
   - BeneVision™ Mindray monitor
   - Mindray ANI single slot communication module
   - Module ANI-MR
   - ANI Sensor V1 PLUS
2. Check that BeneVision™ monitor has a sufficient battery power level.

Connecting ANI Sensor V1 PLUS to the ANI-MR module

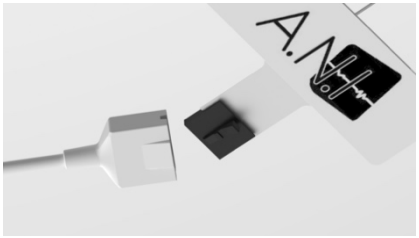
1. Position the sensor as describe on the picture below.



Sensor positioning

2. Connect the sensor to the sensor cable.

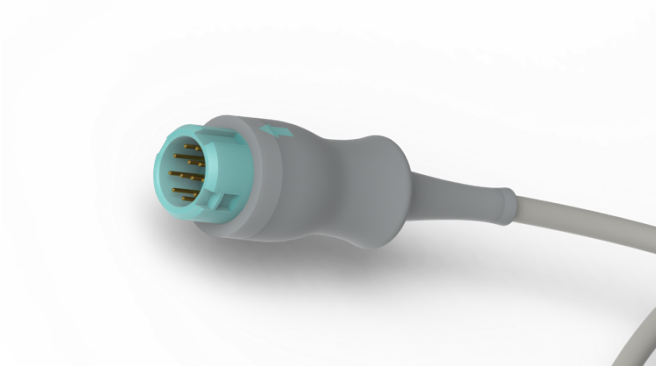
Before connecting, carefully align the notches of the ANI Sensor V1 PLUS on the connection sheet to make the pins correspond perfectly with the patient cable. To disconnect the sensors, grasp the plastic part while pressing on the locking mechanism and pull gently. **Do not pull by grasping the sensors themselves.**



Locking mechanism

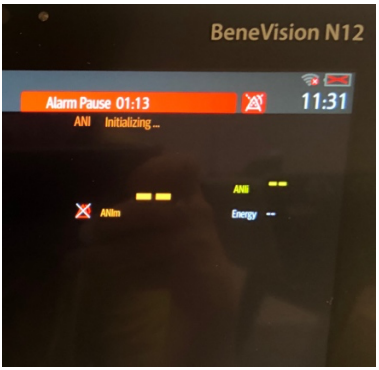
Connecting the ANI-MR module

1. Identify the communication connector of the module, as illustrated in the image below.



2. Insert firmly the ANI-MR connector into the Mindray ANI single slot communication module port, itself inserted on the BeneVision™ monitor.

3. The ANI-MR module is now connected. An initialization begin.



4. The ANI-MR module is now activated. This is verified when the ANI-MR parameters are displayed on the BeneVisionTM monitor.

For more information on the ANI-MR window, please read **The ANI-MR window** section.

Chapter 4: Operation

The following sections describe how the ANI-MR information is displayed when used with the Mindray monitor, including the display details. For additional information on Mindray monitor, please read **Operator's Manual** for BeneVision™ monitor.

The ANI-MR window

When an ANI-MR is connected to BeneVision™ Mindray monitor, ANI parameters are displayed in the ANI Module window as numeric values with a graphic representation.

When multiple technologies are connected to the BeneVision™ monitor, each technology's parameters are displayed in an individual window. The relative size of each window can be configured using the "Setup" feature, which is accessible by pressing the "Setup" button in the main menu or in the ANI window. For more information, please read **Operator's Manual** for BeneVision™ monitor.

The ANI module window shows the information about the measurement acquired by ANI-MR. Three parameters are provided by the module:

- ANIi (instant)
- ANIm (averaged)
- Energy

All parameters windows can be configured using the “Setup” feature, which is accessible by pressing the “Setup” button in the main menu or in the ANI window. For more information, please read **Operator's Manual** for BeneVision™ monitor.

Mode of operation

Once the module is connected to the patient with the sensor and to the BeneVision™ monitor the calculation algorithm starts automatically.

ANI input signal acquisition

In the upper part of the BeneVision™ monitor screen, check that the ANI computation is correct. Otherwise, warning messages will be displayed:

- “ANI Low Input Signal” with any parameters displayed: the input signal is heavily disturbed.
- “Check ANI potential disturbances” with all parameters displayed: the input signal is moderately disturbed.
- “ANI Input Signal Rate Out of Range” with only the energy value displayed: the heart frequency rate value is out of the acceptable range for the ANI technology to work properly.
- “ANI Energy Out of Range” with only the energy value displayed: the energy value is out of the acceptable range for the ANI technology to work properly.
- “ANI Sensor Disconnected” with any parameters displayed: the sensor connected to the device is poorly attached or not attached to the patient. The sensor is disconnected from the sensor cable.
- “ANI No Cable” with any parameters displayed: the cable is disconnected from the monitor.

WARNING: *always check the quality messages of the signal. If the input signal is not within ANI technology functional limits, the ANI index will not be reliable.*

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 is averaged over two time periods: a short average (average of the last 56 seconds) and a longer average (average of the last 176 seconds).

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

Chapter 5: Troubleshooting

To troubleshoot issues with BeneVision™ monitor please read the **Operator's Manual** for BeneVision™ monitor. To troubleshoot issues with the sensors, please read the **Instruction for Use of the ANI Sensor V1 PLUS**.

Alert information	Possible cause	Solution
ANI Low Input Signal Quality	• Wrong sensor position • Poor bonding of the sensor on the skin • Electromagnetic disturbances (Electrical Surgery Unit, heating blanket…)	• Check that sensors are properly placed along an imaginary line through the heart (acquisition of an electrical QRS axis). • Check that no other device can interfere.
Check ANI potential disturbances	• Wrong sensor position • Poor bonding of the sensor on the skin • Electromagnetic disturbances (Electrical Surgery Unit, heating blanket…)	• Check that sensors are properly placed along an imaginary line through the heart (acquisition of an electrical QRS axis). • Check that any other device can interfere.
ANI Input Signal Rate Out of Range	The patient heart rate is lower than 30 bpm or greater that 150 bpm.	Wait for the patient's heart rate to return the valid range of [30bpm;150bpm] for the ANI calculation.

ANI Energy Out of Range	Physiological causes that make the energy value go under 0.05 or over 2.5.	• Make sure the bond between the sensor and the patient is correct. • Make sure the sensor is connected to the patient cable.
ANI Sensor Disconnected	• The sensor connected to the device is poorly attached or not attached to the patient. • The sensor is disconnected from the sensor cable	Reconnect the sensors to the patient and to the sensor cable
ANI No Cable	• ANI-MR disconnected from Mindray BeneVision device • Possible ANI-MR software crash	• Disconnect and reconnect the ANI-MR • An initialization for a new patient will begin
ANI has unloaded successfully	• The ANI single slot module disconnected from Mindray BeneVision	• Reconnect the ANI single slot module

Chapter 6: Specifications

Performance Characteristics

ANI	
ANI index display range	[0;100]
ANI index display resolution	1 point
ANI index precision tolerance	+/- 2 points
ANI index refresh rate	1 second
Energy	
Energy display resolution	[0 ;0.01]
Energy useful range	[0.05 ;2.5]
ANI Input signal	
ANI input signal rate useful range	[30; 150]
Filter frequency	Band pass filter: [0.67 Hz;40 Hz] Notch filter: 50 Hz and 60 Hz ESIS filter: Yes

Environmental specifications

Operating Conditions	
Temperature at ambient humidity	5°C to 40°C
Humidity	10 % to 95 %
Atmospheric pressure	700 hPa to 1060 hPa
Storage Conditions	
Temperature at ambient humidity	-20°C to 60°C
Humidity	10% to 95%
Atmospheric pressure	700 hPa to 1060 hPa

Mechanical specifications

Module without cable	
Width	54 mm
Length	116 mm
Thickness	22 mm
Cable specifications	
Patient cable length	2 m
Communication cable length	2 m
Weight	250g

Electrical specifications

Voltage Input	+5 VDC +/- 10%
Maximum current draw	200 mA
Input voltage ripple	<100 mV For frequencies <100kHz

Regulatory Symbols

The following symbols are on the product hardware or packaging

Symbole	Description	Symbole	Description
	Manufacturer		Date of manufacture
	CE marking logo		Serial number
	Lot number		Catalogue reference
	Defibrillation-proof type CF applied part		Refer to instruction manual /booklet
	Fragile; handle with care	**Rx only**	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 limits		Keep away from rain
	Humidity limits		Atmospheric pressure limits
IP2X	IP classification		Needs special waste disposal
	Medical device		

Conformity

Safety conformity
IEC 60601-1 :2005 + AMD1 :2012

EMC conformity
IEC 60601-1-2, class B

Safety Classification according to IEC 60601-1	
Type of Protection	Class II
Degree of Protection against Electric Shock	CF-type
Degree of Protection against liquid inlet	IP 2X according to IEC 60601-1
Mode of Operation	Continuous

Chapter 7: Service and Maintenance

Cleaning and disinfection

ANI-MR is a reusable non-sterile device.

The cleaning of the ANI-MR should be performed when traces of dirt are visible on the device and at regular intervals and/or in accordance with hospitals policy, as well as local and governmental regulations. Clean any blood or liquid spilled on the device immediately. Dried blood is very difficult to clean.

Use 'Wip'Anios' wipes (impregnated with Didecyldimethylammonium chloride) from 'Laboratoires ANIOS' or any other medical grade wipes with a Didecyldimethylammonium chloride base.

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

Please read the **Warning and caution instructions** section.

General maintenance

Safety tests should be carried out 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-MR:

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

Repair Policy

An authorized after sales service must perform warranty repair and service. Do not use malfunctioning equipment. Have the instrument repaired. The ANI-MR cannot be repaired by the user, any attempt at repair by the user will void the warranty.

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

To request a product repair or replacement (under warranty), the purchaser should contact Mindray directly.

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. Within the framework of the warranty service, MDoloris Medical Systems may, but shall not be required to bring technical 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 shipping costs of the repaired product or of the replacement product to the purchaser.

All other shipping costs shall be paid by the purchaser. Risks of loss or damage during shipments under this warranty shall be borne by the party shipping the product. Products shipped by the purchaser under this warranty shall be packaged in the original shipping container or equivalent packaging to protect the product. If the purchaser ships a product to MDoloris Medical Systems in an inadequate packaging, any physical damage present in the product on receipt by MDoloris Medical Systems (and not previously reported) will be presumed to have occurred during transit and will be the responsibility of purchaser.

Warranty

MDoloris Medical Systems warrants to the initial purchaser that the ANI-MR will be free from defects in workmanship or materials, when the given normal, proper, and intended usage for a period of two years (“warranty period”) from the date of its initial shipment to the customer. Excluded from this warranty are consumables and items such as accessories. MDoloris Medical Systems’ obligations under this warranty are to repair or replace any product (or part thereof) that MDoloris Medical Systems reasonably determines to be covered by this warranty, 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 prepaid freight. Repair or replacement of products under this warranty does not extend the warranty period.

This warranty does not cover any products 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, and/or reassembled by a person other than MDoloris Medical Systems, unless authorized by MDoloris Medical Systems. MDoloris Medical Systems shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear. MDoloris Medical Systems makes no warranty (a) with respect to any products that are not warranted products, (b) with respect to any products purchased from a person other than MDoloris Medical Systems or its official distributor (c) with respect to any product sold under a brand name other than MDoloris Medical Systems.

This warranty is the sole and exclusive warranty for MDoloris Medical Systems products, it extends only to the purchaser, and is expressly in lieu of any other expressed or implied warranties including without limitation any warranty as to merchantability or fitness for a particular purpose. MDoloris Medical Systems' maximum liability arising out of the sale of the products or their use, whether based on warranty, contract, tort, or other, shall not exceed the actual payments received by MDoloris Medical Systems in connection therewith. MDoloris Medical Systems shall not be liable for any incidental, special, or consequential loss, damage or expense (including without limitation lost profits) directly or indirectly arising from the sale, inability to sell, use loss of use of any product. except as set forth herein, all products are supplied “as is” without warranty of any kind, either express or implied.

Software License Agreement

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In no event shall MDoloris Medical Systems be liable to you (a) for any incidental, consequential, or indirect damages (including damages for loss of business profits, business interruption, loss of business information, and the like) arising out of the use of or inability to use any licensed software even if MDoloris Medical Systems or any authorized MDoloris Medical Systems representative has been advised of the possibility of such damages, or (b) for any claim by any other party.

GENERAL: this License Agreement will be construed under French laws. If any provision of this License Agreement shall be held by a court of competent jurisdiction to be contrary to law that provision will be enforced to the maximum extent permissible and the remaining provisions of this Agreement will remain in full force and effect.

Should you have any questions concerning this License Agreement, you may contact your MDoloris Medical Systems representative.

This license agreement is the complete and exclusive statement of the agreement between you and MDoloris Medical Systems and supersedes any proposal or prior agreement, oral or written, and any other communications between you and MDoloris Medical Systems relating to the subject matter of this agreement.

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-MR that it places on the market by financing the WEEE Pro recycling system that collects and recycles free of charge (For more information, contact your MDoloris Medical Systems representative)

WARNING: to avoid any kind of contamination or infection of the personnel, the environment or equipment, be sure you have properly disinfected and decontaminated the ANI-MR before you dispose of your system. Respect local regulations regarding electric and electronic items.

All of the device parts meet the RoHS3 (EU directive 2015/863).

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.

You can check that the manual you have available is up to date.

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