

ANI MOC-9

OEM version: ANI OEM v2.5

IHM version: 3.1.0.0

Instruction for use



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MOC-9 is a registered trademark.

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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.

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First CE mark: 16/04/2019

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.)

-  Never put sensors on skin injuries.
-  Using sensors other than those specified by Mdloris 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.

Chapter 1: Technology overview

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

The series of normal, non-ectopic, R-R intervals is processed after normalization, resampling and filtering. The amount of $p\Sigma$ tone is measured in relation to the total window surface through the area comprised between the lower and the upper envelope of the RR series. The higher the $p\Sigma$, 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 $p\Sigma$ activity as a part of ANS activity: it expresses the relative amount of $p\Sigma$ tone present as compared to sum of sympathetic and $p\Sigma$ activities. ANI MOC-9 displays two averaged ANI measurements: ANI_i results from the average of ANI measured over the previous 56 sec, and ANI_m 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 ANI_m measure between 50 and 70 during surgery makes a hemodynamic reactivity episode unlikely in the following 10 minutes;
- that an ANI_m 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.

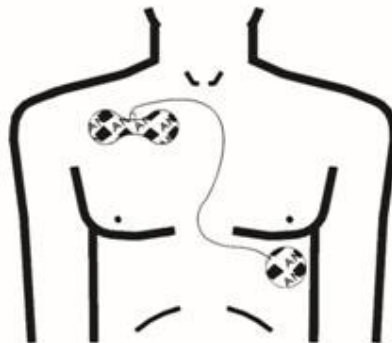
Preparation for use

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

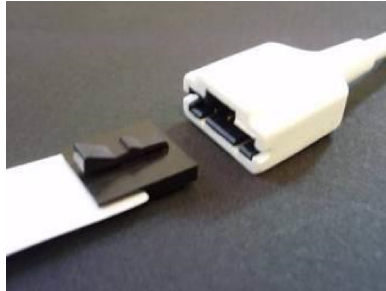
1. Position the sensor as describe on the picture below.



Sensors' positioning

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

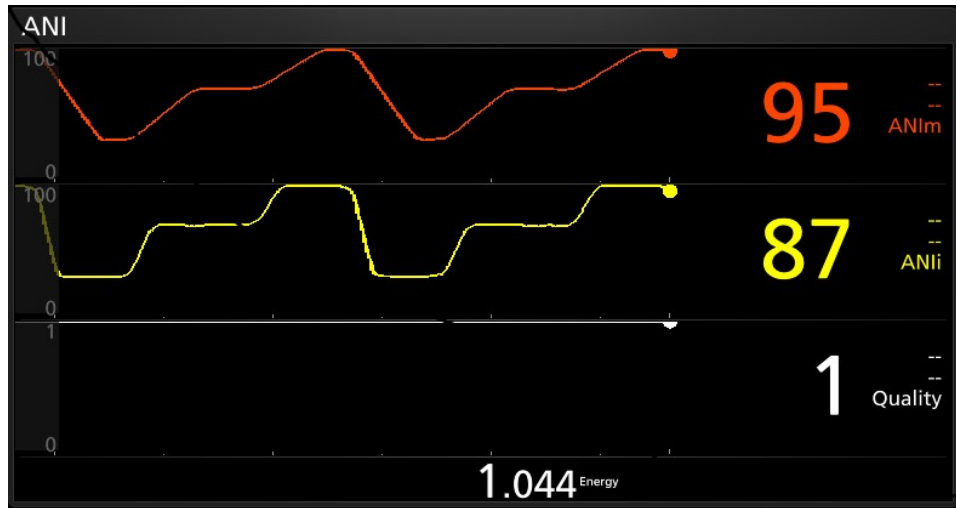
1. Identify the Masimo Open Connect connector on the module, as illustrated in the image below.



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.

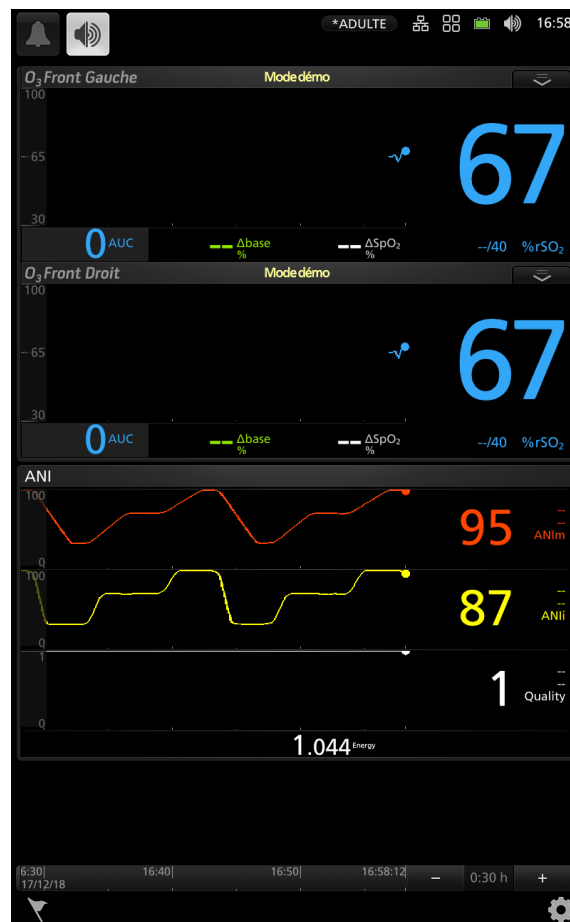
Chapter 4: Operation

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, O₂ 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:

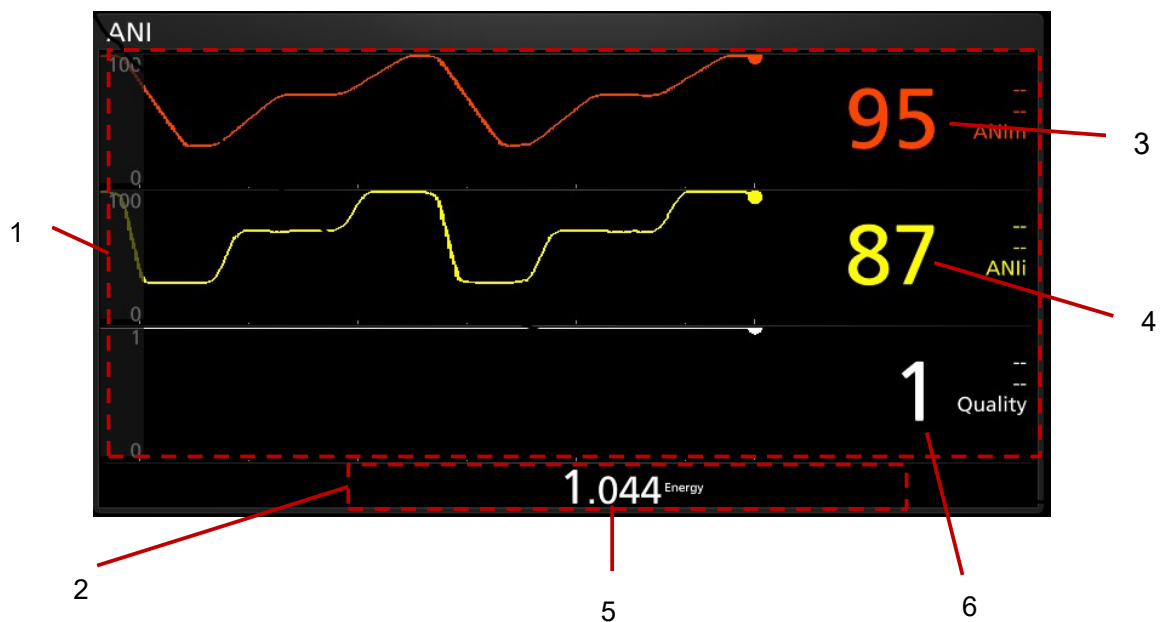
- ANIi
- ANIm
- Quality
- Energy.

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	ANli	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 to 1 <ul style="list-style-type: none"> • 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 considered, 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.

<u>Problem</u>	<u>Possible Cause</u>	<u>Solution</u>
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.