PMD-200™

Pain Monitoring System

with *NOL – Nociception Level Index®* Technology

User Manual

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PMD-200 User Manual

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Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

Disclaimer

Every care has been taken to ensure the accuracy of the information in this document. Medasense Biometrics Ltd. ("Medasense") assumes no liability for use of this document if any unauthorized changes to the content or format have been made. Medasense reserves the right to make changes to this User Manual and the product described herein without further notice.

To ensure proper use, handling and care of the products, user should consult the product specific literature, instruction manual, and/or labeling included with the product or otherwise available.

Before using the PMD-200 monitor, users must read and fully understand all information and instructions provided with the product. For additional information and questions, please contact our customer support representative.

This User Manual is a reference tool for users of the PMD-200; it does not constitute medical advice. The PMD-200 monitor is not a substitute for your professional judgment. The licensed healthcare practitioner using the product is responsible in full for assessing each situation, based on his or her own experience and on the patient's condition.

Intended Audience

This manual provides information to health-care professionals acting as caregivers and technical support staff in a hospital or hospital-type setting for operation and maintenance of the monitoring system. Refer to the institution for any additional training or skill requirements beyond those identified here for operation and maintenance of the monitoring system. Before operating, thoroughly read this manual.

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1. Important Safety Information

Before working with this equipment, make sure that you read, understand, and strictly observe all:

- Warnings
- Cautions
- Notes

Types of Notes

The format and description of the types of notes used in this manual appear below:

Warning

	A warning relates to a situation that could cause serious injury or death to a patient or operator if instructions are not followed.

Caution

	A caution relates to a situation that could cause possible damage to equipment or cause the system to function inaccurately.

Note

	A note contains important user information regarding the use of the system.

Warnings

Warnings

	The instructions in this section are warnings. Be careful to observe all instructions to avoid personal injury or death.

- Make sure that the monitor is installed securely to avoid injury to personnel or patients.
- If the system or any of its parts / component / accessories/ packaging including the finger probe, cables and single use sensors is damaged or obstructed, do not use the device.
- Do not use the device in a flammable atmosphere or where concentrations of flammable anesthetics may occur.
- Do not modify or replace any inner component of the PMD-200 system.
- Place all cables carefully and secure them to avoid patient strangulation.
- Make sure that the conductive parts of the sensor, finger probe, or connectors do not come in contact with other conductive parts including ground.
- If blood or liquid is spilled on the PMD-200, retest ground leakage current before further use.
- To avoid cross-contamination, do not reuse a single-use sensor on a different patient.
- To avoid cross-contamination do not use the finger probe on an open wound.
- Do not use the single-use sensor past its expiry date
- In case of device malfunction or failure, do not open the external cover to fix the device
- Battery access is permitted only to a trained technician and the battery pack should not be dismantled.
- Do not attempt to replace the system battery.
- Do not expose the PMD-200 to heat or fire.
- Do not attempt to short circuit any of the battery pack wires.
- Do not attempt to remove the battery pack and charge it externally.
- Do not use any battery pack other than the one supplied with the PMD-200 system.
- Do not swap between battery packs of PMD-200 systems.
- Do not drive sharp objects into the battery pack.
- Do not use the PMD-200 system in a Magnetic Resonance Imaging (MRI) environment.
- Do not transport or store the PMD-200 near a source of heat.

- Before using a defibrillator, disconnect the PMD-200 system from the patient.
- If the finger probe is tightly placed for long periods of time, tissue damage may occur. Check the finger periodically for signs of skin or tissue damage and reposition on a different finger as required.
- 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 PMD-200, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Cautions

Caution

	The instructions in this section are cautions. Be careful to observe all instructions to avoid possible damage to equipment or inaccurate system functioning.

- FEDERAL LAW (U.S.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
- Store the PMD-200 according to the recommended conditions described in the User Manual (see Technical Data)
- If the PMD-200 system will not be used for a long period of time, unplug the device.
- To disconnect the PMD-200 system from the mains, use the plug or the appliance coupler of the power supply cord.
- Make sure that the power cable is connected to the PMD-200 monitor correctly.
- Make sure that there is proper airflow around the PMD-200 system.
- Use the USB port to connect only a USB flash drive or external hard disk drive
- Keep all liquids away from the PMD-200 system.
- Make sure that the patient finger is inserted adequately into the finger probe.
- The internal battery is for backup use and not designed for long-term monitoring.
- Clean the PMD-200 system and finger probe prior to initial use and following each use according to the cleaning instructions.
- Do not open the PMD-200 external cover.
- Do not autoclave the PMD-200 system or its accessories.
- After prolonged storage (up to 6 months), it is recommended to charge and discharge battery several times in order to reach maximum performance.

- Follow the information on electromagnetic compatibility (EMC)provided in this user manual and observe the monitor operation after set up to verify that performance is as expected.
- PMD-200 may be used with original Medasense approved accessories and cables only. Use of unapproved accessories or cables may result in increased emissions or decreased immunity of the PMD-200 and void warranty.
- Ensure the PMD-200 system is properly grounded when operating on AC power
- Do not position the PMD-200 system so that it is difficult to disconnect the device.
- Do not switch the system between patients without starting a new monitoring session and applying a new single use sensor.
- To maintain signal quality, replace the single use sensor after a maximum of 24 hours of use.
- Do not transport or store the PMD-200 in a location where static electricity is present as this may create electrostatic discharge hazards affecting the device
- Do not place the finger probe on the same hand as other devices that may interfere with blood flow – such as non-invasive blood pressure cuffs or tourniquets.
- Always evaluate the clinical suitability of thresholds when guiding analgesia based on NOL trends.
- Do not place the PMD-200 system where it is exposed to direct sunlight or constant vibrations.
- Do not place the PMD-200 system close to heaters or air conditioners
- The performance of the PMD-200 has not been evaluated in patients with reported alcohol abuse, chronic pain, opioid tolerance and chronic use of psychoactive drugs. Clinical judgment should be practiced when using NOL with these populations.
- Studies evaluated by FDA included patients undergoing elective abdominal, gynecological & urological surgeries, with fentanyl/sevoflurane/rocuronium anesthesia excluding neuraxial/regional blocks. Clinical judgment by qualified anesthesia providers should be practiced when using NOL in different populations and settings.

Equipment Classification

Table 1: Equipment Classification

Parameter	Classification
Degree of protection against electric shock	Class I

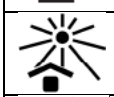
Parameter	Classification
Type of protection against electric shock	BF
Type of operation	Continuous
Protection against ingress of liquids	IPX1

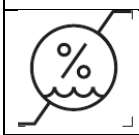
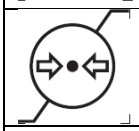
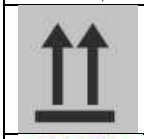
The system complies with IEC 60601-1 and IEC 60601-1-2 EMC (class A device – Restricted for Hospital and Clinic Use only).

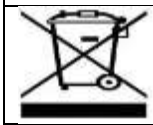
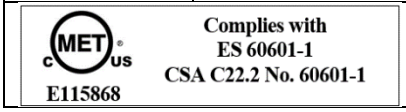
Equipment Symbols

The following table lists the key symbols and their meanings.

Table 2: Equipment Symbols

Symbol	Meaning	ISO/IEC symbol number and registration date
	Legal Manufacturer	ISO 7000-3082 2011-10-02
	Date of Manufacture	ISO 7000-2497 2004-01-15
	Country of Manufacture	IEC 60417-6049 2012-07-14
	Use by Date	ISO 7000-2607 2004-01-15
	Catalog number	ISO 7000-2493 2004-01-15
	Batch code	ISO 7000-2492 2004-01-15
	Serial number	ISO 7000-2498 2004-01-15
	Unique device identifier	ISO 15223-1
	Do not use if the package is damaged	ISO 7000-2606 2004-01-15
	Fragile, handle with care	ISO 7000-0621 2014-06-04
	Keep away from sunlight	ISO 7000-0624 2014-06-04
	Keep dry	ISO 7000-0626 2014-06-04

Symbol	Meaning	ISO/IEC symbol number and registration date
	Temperature limit	ISO 7000-0632 2014-06-04
	Humidity limitation	ISO 7000-2620 2004-01-15
	Atmospheric pressure limitation	ISO 7000-2621 2004-01-15
	Do not re-use	ISO 7000-1051 2004-01-15
	TYPE BF APPLIED PART	IEC 60417-5333 2002-10-07
	Refer to instruction manual/ booklet	ISO 7010-M002 2011-05-01
	Consult *instructions for use* or consult electronic *instructions for use*	ISO 7000-1641 2004-01-15
	Warning	ISO 7010-W001 2011-05-01
	Caution	ISO 7000-0434A 2004-01-15
	Packaging unit	ISO 7000-2794 2006-08-29
	Recycle	ISO 7000-1135 2004-01-15
	This End Up	ISO 7000-0623 2014-06-04
	No Heavy Load	ISO 7010-P012 2011-05-01
	Latex-free product	ISO 15223-1 5.4.5 Reference Annex B for the general prohibition symbol and negation symbol FDA Recognition #5-117
IPX1	IPX1 Dripping Water Ingress Protection	IEC 60529 No registration

Symbol	Meaning	ISO/IEC symbol number and registration date
EC REP	Authorized representative in the European Community	ISO 15223-1 No registration
MD	Medical device	ISO 15223-1 No registration
CE	Mark of compliance with the European Medical Device Directive	European Medical Directive 93 /42/EEC, Article 17 and Annex XII
	Disposal according to electronic scrap ordinance	IEC 60417-6414 2019-08-03
	Importer	ISO 7000-3725 2019-11-01
UK CA	Mark of compliance with UKCA requirements	https://www.gov.uk/guidance/using-the-ukca-marking
CH REP	Authorized representative in the Switzerland	www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/ch-rep
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner	21 CFR 801
		ANSI/AAMI ES60601-1:2005/A2:2021 CAN/CSA-C22.2 NO. 60601-1:14 + A2:22

2. Overview

Indications for Use

The PMD-200 with the *NOL - Nociception Level Index*® is indicated for use in a clinical setting that requires assessment of changes in nociception levels in adult patients under general anesthesia receiving opioid or opioid-sparing analgesia as part of their care.

The PMD-200 should be used as an adjunct to clinical judgment. Clinical judgment should always be used when interpreting the NOL index in conjunction with other available clinical and vital signs.

LIMITATIONS

The sale, distribution, and use of the PMD-200 with the NOL - Nociception Level Index are restricted to prescription use in accordance with 21 CFR § 801.109.

Contraindications and Limitations

Contraindicated Situations

The PMD-200 should not be used in the following situations:

- Cardiac arrhythmias including:
  - Atrial fibrillation / flutter
  - Ventricular fibrillation
  - Cardiac arrest
- During Cardiopulmonary resuscitation (CPR)
- During cardioversion/defibrillation
- Low perfusion states due to shock (septic, hypovolemic, cardiogenic or anaphylactic)
- Malignant hyperthermia, thyroid storm, untreated pheochromocytoma, neuroleptic malignant syndrome

Caution

	The performance of the PMD-200 has not been thoroughly evaluated in patients with reported alcohol abuse, chronic pain, opioid tolerance and chronic use of psychoactive drugs. Clinical judgment should be practiced when using NOL with these populations.

	Studies evaluated by FDA included patients undergoing elective abdominal, gynecological & urological surgeries, with fentanyl/sevoflurane/rocuronium anesthesia excluding neuraxial/regional blocks. Clinical judgment by qualified anesthesia providers should be practiced when using NOL in different populations and settings
Note	
	Physiological conditions such as excessive patient movement, external agents such as blood pressure cuff, tourniquet, etc., low perfusion, electrocautery interference, hypothermia, moisture on sensor may interfere with the monitoring system's ability to detect and display measurements. When signal quality is low or inadequate, an alert is displayed in the status bar (see troubleshooting). Carefully assess the clinical circumstances and use clinical judgment in these limiting conditions.
	Conditions affecting the autonomic nervous system and the volemic status of the patient (e.g. vasoactive medication, positioning, severe hypovolemia) may have a transient effect on NOL values. Carefully assess the clinical circumstances and use clinical judgment in these limiting conditions.

System Description and Operating Concept

The PMD-200 system consists of 4 main components:

- **Monitor** – acquisition and display of physiological raw data signals and NOL index and trend graph.
- **Software** includes two main components:
  - Calculation of the NOL index based on physiological parameters extracted from raw data signals
  - User interface – displays physiological raw data signals, NOL index and trend graph.
- **Finger probe** –includes the following sensors:
  - Photoplethysmogram (PPG or Pleth)
  - Thermistor for peripheral temperature (TMP)

- A 3-axis accelerometer for movement (ACC or Movement).
- Connectors for the Galvanic skin response sensor (GSR or Conductance)

- **Single use sensor** (connected to the finger probe) – includes the following sensor:
  - Bio-impedance Galvanic skin response sensor (GSR or Conductance)

The NOL index is a relative, non-linear measure with a range of 0–100, where 0 represents no pain /nociceptive response and 100 represents extreme pain/nociceptive response.

The NOL index and trend are intended to support clinical decisions concerning the administration of analgesic medications.

Clinical Guidance

Clinical evidence[1,2,3,4]suggests the following guidelines for procedures under general anesthesia:

- NOL above 25 for more than one minute may indicate the patient requires additional analgesic therapy. Higher values indicate a stronger nociceptive response.
- NOL between 0–25 represents an appropriately suppressed physiological response to noxious stimuli and suggests adequate analgesia.
- The NOL index cannot anticipate noxious stimuli and thus a minimal level of analgesics should always be maintained.

Note

	• The PMD-200 should be used as an adjunct to clinical judgment. Clinical judgment should always be used when interpreting the NOL index and trend line in conjunction with other available clinical and vital signs. • The magnitude above the NOL threshold of 25 does not provide guidance on the magnitude of the dose of analgesic, but rather indicates timing as to when additional analgesic dosing may be necessary, following a nociceptive response.

[1] Meijer, F et al/Reduced postoperative pain using Nociception Level-guided fentanyl dosing during sevoflurane anaesthesia: a randomised controlled trial/ British Journal of Anaesthesia 2020 September

[2] Meijer F et al/ Nociception-guided versus Standard Care during Remifentanil–Propofol Anesthesia: A Randomized Controlled Trial/Anesthesiology 2019 Feb.

[3] Ledowski, T., Schlueter, P. & Hall, N. Nociception level index: do intra-operative values allow the prediction of acute postoperative pain?. J Clin Monit Comput (2021).

[4] Martini CH et al Ability of the Nociception Level (NOL), a multiparameter composite of autonomic signals, to detect noxious stimuli during propofol-remifentanil anesthesia Anesthesiology 2015 Sept.

	• The suggested clinical guidance to consider administering additional analgesics if NOL is above 25 for over 60 seconds was validated in studies using fentanyl or remifentanil analgesia. Clinical judgment should be exercised by the qualified anesthesia provider when using other analgesic agents as clinically relevant timing may differ.

Training

Before working with the PMD-200, users should receive adequate training on its safe and effective use. Make sure that training is received in accordance with local laws and legal regulations. For information about training, contact your Medasense representative.

Note

	Further education resources are available on the Medasense website and Academy at www.medasense.com and the NOL pocket guide for clinicians is available by request from info@medasense.com
	For customer support email: customerservice-usa@medasense.com

Screen Layout

To enable easy navigation, the screen is divided into panes according to the types of information presented.

The details of screen content vary depending on the stage of the procedure. However, the general layout remains the same throughout all stages. The general layout is illustrated in the Monitoring Screen presented below:

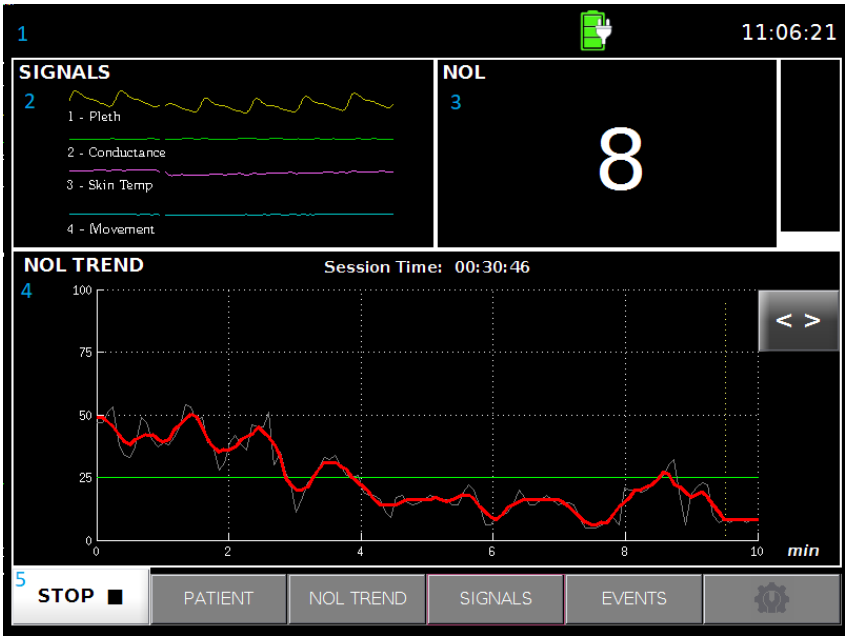


Figure 1: Monitoring Screen Layout

1	Status bar: Power indication, system clock, and alert display
2	Signal pane
3	NOL index pane
4	NOL trend pane with threshold level markers and review annotations button
5	Menu bar (with START/STOP button)

3. System Components

This chapter describes the parts that make up the PMD-200 monitoring system.

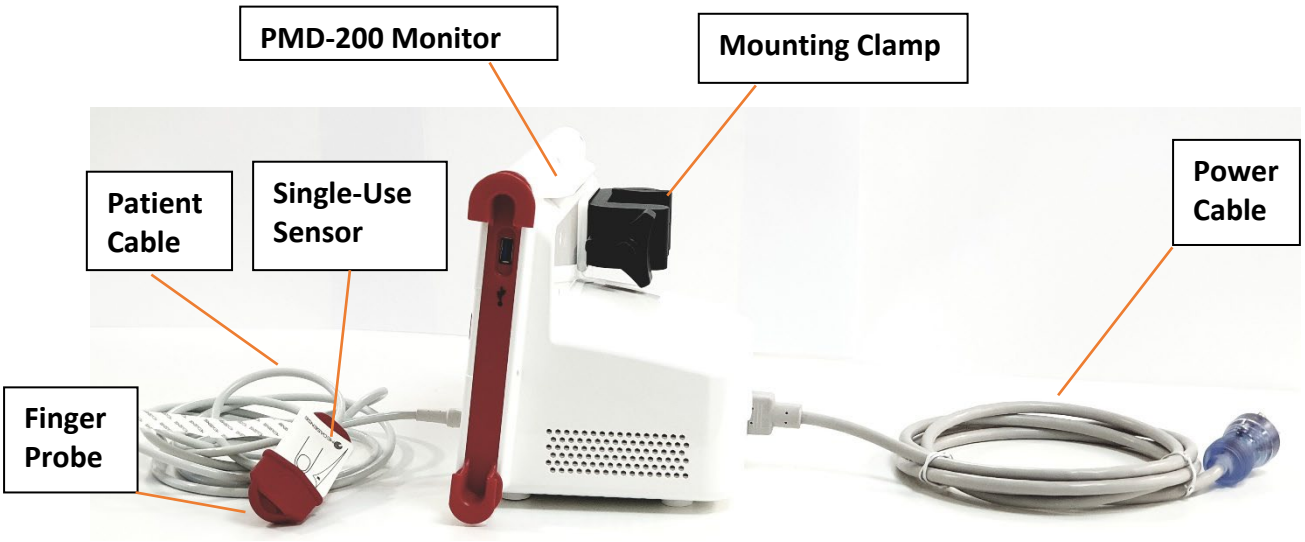


Figure 2: Schematic Diagram of the PMD-200 System

Description	Manufacturer	Model or P/N
PMD-200 Monitor	Medasense Biometrics	PMD200-2
Finger Probe	Medasense Biometrics	FP200-2
Single-use Sensor (PMD-200 Sensor)	Medasense Biometrics	MEK-0002

Monitor

Front Panel

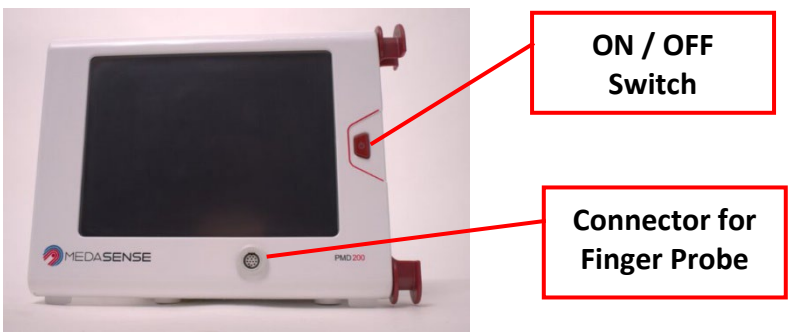


Figure 3: Monitor Front Panel

The monitor front panel includes:

- 8.4'' (21.3 cm) color LCD touchscreen.
  The interface is designed for easy operation also when wearing surgical gloves.
- An ON/OFF Power button.
  When the monitor is ON, the button is lit white. When the monitor is OFF, the button is lit blue.
- A socket for the finger probe.

Back Panel

The PMD-200 back panel includes an RS232 port allowing connectivity to Medasense approved systems (see section 12). The connectivity port can be closed using a built-in cover when not in use.

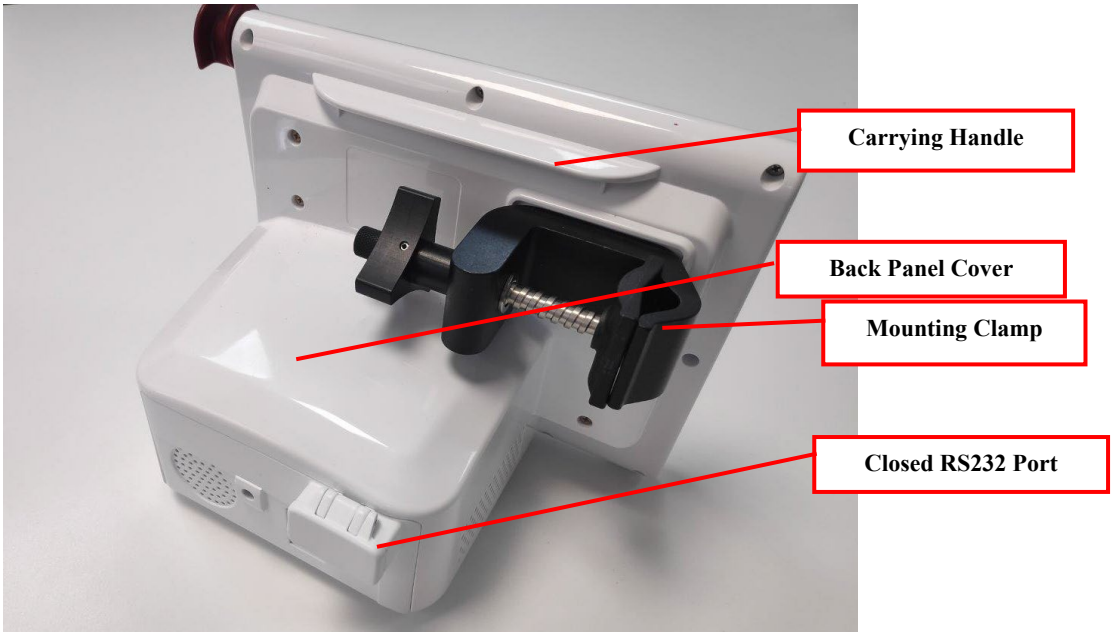


Figure 4: Monitor Back Panel

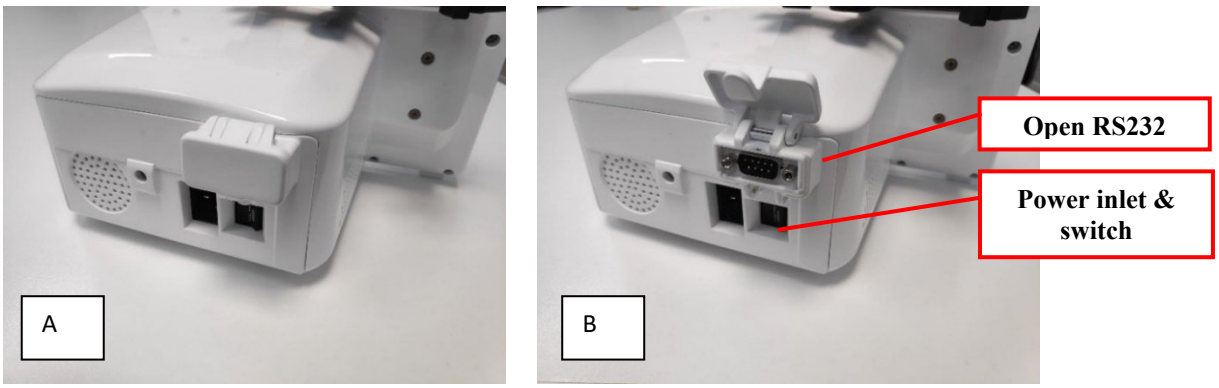


Figure 5: Monitor Back Panel - Connectivity Configuration. A. Closed connectivity port. B. Open connectivity port.

The PMD-200 back panel includes:

- Back Panel Cover with screw
- Power switch
- Socket for power cable
- Mounting clamps for mounting the monitor on a pole or rails
- A built-in carrying handle
- RS232 connectivity port

Side Panel

Figure 6: Side Panel

The PMD-200 side panel includes a standard USB port for connecting an external device or downloading data.

Note

	Use the USB port to connect only: • USB flash drive clean of viruses and malware • External hard disk drive • USB keyboard or mouse

Software

The PMD-200 System software consists of proprietary software and proprietary algorithms for the calculation of the NOL index.

The proprietary software and algorithms control the signal acquisition and analysis, data management and graphic user interface.

Cybersecurity During Use

The PMD-200 system is provided to the user with updated software & firmware. For software updates, contact your Medasense representative

The PMD-200 includes two types of ports:

1. RS232 port intended to enable connectivity with external vital sign monitors or information systems. The port can be connected to other closed systems only, and cannot be connected to a computer network.
2. USB port intended to download files. Use the USB port to downlead recordings only and make sure that the USB device used is clean of viruses and malware. Using the USB port for software updates is password protected and must be performed only be trained personnel. and may only be performed by Medasense personnel.

Troubleshooting and retention and recovery of device configuration shall be done by Medasense authorized personnel only.

Finger Probe

The finger probe is one size and can be connected to any of the patient's fingers. It is recommended to place the finger probe on the index finger and to reposition on the middle finger if the index finger is not available or if signal quality issues occur. The finger probe is a reusable part intended to be used multiple times, and connects to the system through a 2.8m (110 inches) cable.

It includes the following sensors:

- Photoplethysmogram (PPG or Pleth)
- Thermistor for peripheral temperature (TMP)
- A 3-axis accelerometer for movement (ACC or Movement).
- Connectors for the Galvanic skin response sensor (GSR or Conductance)

The finger probe is connected to the system by a 110 inches (2.8 m) cable

Figure 7: Finger Probe and Cable

Caution

⚠	The finger probe should be cleaned prior to initial use and following each use according to the instructions in section 8

Single use Sensor

The single-use sensor is intended for a single patient and must not be transferred between patients.

The single-use sensor is comprised of a removable adhesive protector, GSR sensor and a sticky hydrogel.

The single-use sensor is connected to the upper side of the finger probe.

The single-use sensor shelf life is 36 months, with expiry date clearly marked on the single-use sensor packaging ⌛ .

Figure 8: Single Use Sensor with pack

Warnings

⚠	Do not use an expired sensor. During long term monitoring, replace the single use sensor at least once every 24 hours. Do not re-use the single use sensor.

Power Cable

The power cable connects the PMD-200 monitor to the mains electricity socket.

Figure 9: Power Cable (US Configuration)

Warnings

	Do not use non-original cables. Ensure that the power cable is connected correctly. Ensure the PMD-200 system is properly grounded when operating on AC power

Power Requirements

AC Voltage Input: 100–240 VAC, 50-60 Hz, 700 mA.

Battery Backup

If there is a loss of AC power, the monitor continues uninterrupted operation for a period of up to 30 minutes. When supply of AC power resumes, the system switches back automatically to AC power mode.

The power status is indicated in the status bar at the top of the screen. A green battery with a plug indicates AC power. A red battery indicates battery power.

AC Power

Battery Power

Figure 10: Power Status Indications

The internal battery is rechargeable. The maximum charging time is 2 hours for a completely charged battery.

When the system is connected to AC power, the battery charges automatically.

Note

	Use the battery for backup only. For routine use connect the PMD-200 to the mains power supply socket.

4. Installation and Setup

Selecting a Location

When selecting a location for the PMD-200 system, follow these guidelines:

- Recommended: Keep the room temperature between 59°F–77°F (15°C and 25°C). Do not use PMD-200 if room temperature is below 50°F or above 95°F (10°C-35°C –).
- Make sure that there is enough space to perform regular system maintenance procedures.
- The PMD-200 system may be mounted on a pole or on the bed rails using the clamp on the monitor back panel.

Figure 11: Mounting Clamp

Warnings	▪ Make sure that the monitor is installed securely to avoid injury to personnel or patients ▪ If the system or any of its parts / component / accessories/ packaging including the finger probe, cables and single use sensors is damaged or obstructed, do not use the device ▪ Do not use the device in a flammable atmosphere or where concentrations of flammable anesthetics may occur ▪ Do not modify or replace any inner component of the PMD-200 system ▪ Place all cables carefully and secure them to avoid patient strangulation ▪ Make sure that the conductive parts of the sensor, finger probe, or connectors do not come in contact with other conductive parts including ground ▪ Ensure the PMD-200 system is properly grounded when operating on AC power ▪ Do not transport or store the PMD-200 near a source of heat

Caution

⚠	▪ Do not place the PMD-200 system where it is exposed to direct sunlight or constant vibrations. ▪ Do not place the PMD-200 system close to heaters or air conditioners ▪ Store the PMD-200 according to the recommended conditions described in the User Manual (see Technical Data) ▪ If the PMD-200 system will not be used for a long period of time, unplug the device ▪ Make sure that there is proper airflow around the PMD-200 system

Connecting the System

1. Connect the dedicated power cable to the PMD-200 and to the mains socket.
2. Connect the finger probe cable to its socket on the PMD-200 front panel. Make sure to insert the projection on the connector into the groove in the socket.

Figure 12: Connecting the Finger Probe Cable

Powering ON the PMD-200

Warnings

⚠	Do not use non-original cables, finger probes. **Do not re-use the single use sensor**. Ensure that the power cable is connected correctly.

1. Make sure that the Power switch on the back panel of the monitor is switched ON (–).

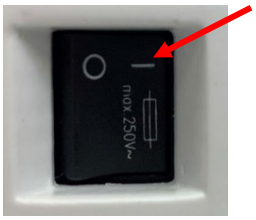


Figure 13: Power Switch on Back Panel

2. Press the Power button on the front panel of the monitor. Once On, the power button will be lit in white.

Figure 14: Power Button ON

The system tests communication between the monitor and the sensors. During initialization, the Loading screen is displayed.

Figure 15: Loading screen

When communication is established, the Home Screen is displayed.

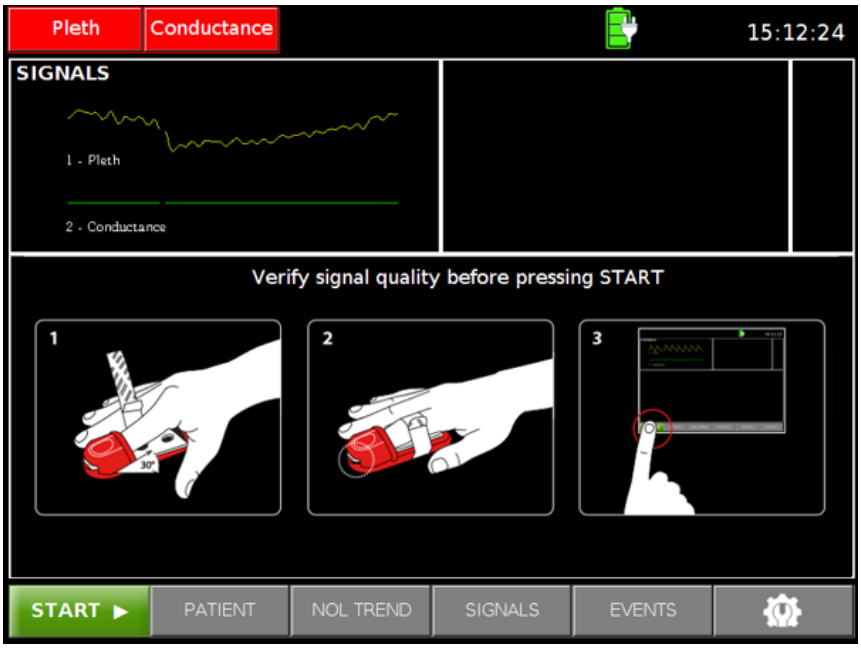


Figure 16: Home Screen

5. Monitoring Mode

Monitoring mode of the PMD-200 involves a simple 3-step process:

1. Connecting the patient to the PMD-200 via the finger probe and single use sensor and verifying the connection by checking signal quality on screen
2. Starting the monitoring session.

   After pressing the START button, a short automatic calibration process begins. After the calibration, monitoring begins.

   The Monitoring Screen displays real-time information relating to patient pain/nociceptive response.
3. Stopping the monitoring session.
   It is imperative to press STOP by the end of each monitoring session, to make sure the monitoring session is saved and can be exported if desired.

This chapter contains the instructions for operating PMD-200 in Monitoring mode.

In addition to basic use of PMD-200 in Monitoring mode, advanced tools for annotation, data display configuration, and export are available (see Advanced Tools)

1. Connecting the Patient to the PMD-200

Warnings	
	• Make sure that the conductive parts of the sensor, finger probe, and connectors do not come in contact with other conductive parts including earth. • To avoid cross-contamination, **do not reuse** a single-use sensor. • To avoid cross-contamination do not use the finger probe on an open wound

1. Make sure that all system connections are set up correctly (see Connecting the System), including the finger probe connection to the monitor.
2. Connect the single-use sensor to the finger probe. Make sure both snaps are properly connected, to enable adequate signal acquisition.

Once the PMD-200 is turned on, the home screen will display instructions.

Note

	When connecting a single use sensor, make sure that: • An original Medasense single-use sensor is being used

	• A new sensor is being used for each patient • The sensor snaps are well connected to the cavities in the finger probe

3. Choose the patient's most suitable finger, in size, length and volume. Absent other considerations (such as a deformity or an open wound on the finger), it is recommended to place the finger probe on the index finger and to reposition on the middle finger if the index finger is not available or if signal quality issues occur.
4. Remove the liner from the adhesive sensor pad.

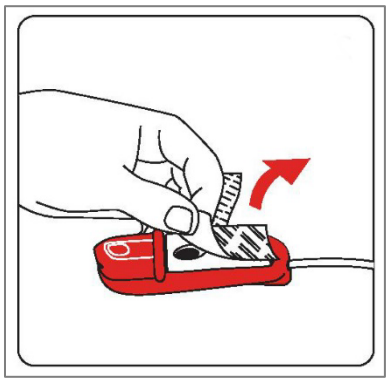


Figure 17: Removing the Liner

5. Insert the patient's finger at a 30^{o} angle so the fingertip touches the stopper at the end of the probe.

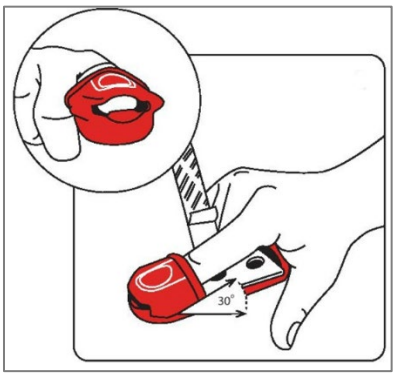


Figure 18: Correct placement of the finger into the Finger Probe

6. Make sure adequate signals are acquired. If either of the alerts in Figure 19 appear on screen, make sure the finger probe and single use sensor are well connected. Make sure no clinical conditions interfere with signal acquisition. For additional troubleshooting information, see section 11.

Figure 19: signal alerts are showing when finger is not properly inserted

Note

	Do not press START before securely connecting the patient finger to the finger probe and verifying no signal alerts are displayed.

7. Attach the sides of the sensor pad to the sides of the finger.

Remove the rest of the liner and wrap the adhesive strap around the finger probe to ensure continuous contact without wrapping too tightly.

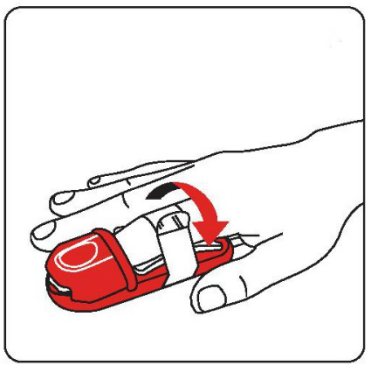


Figure 20: Adhesive Strap around Finger

Caution

	• Make sure that the patient finger is inserted securely into the finger probe and remains in place during the monitoring session. • DO NOT place the finger probe on the same hand as other devices that may interfere with blood flow such as non-invasive blood pressure cuff or tourniquets.
Note	
	• Make sure you turn the system ON only after the finger probe is connected to the monitor. • Press START only after the finger probe has been connected to the patient finger and adequate signals are measured. • It is advisable to connect the patient to the PMD-200 and start a session just before induction, to allow time for the system to collect the patient's physiological data and optimize the personalization of the NOL index prior to anesthesia maintenance period, were NOL-guided analgesia management is most needed (see **Information Provided by NOL**).

2. Starting the Monitoring Session

1. Observe the signals pane and verify good signal quality. Make sure the Pleth signal is cyclic, strong and adequate.

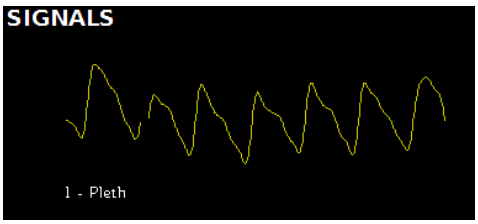


Figure 21 :Cyclic, strong PPG signal

2. If the measured Pleth signal is too weak or of low quality, a notification (see below) will appear advising the user to reposition the finger for better signal strength and quality. In these cases, check that perfusion is adequate, and move the finger slightly forwards or backwards inside the finger probe to achieve better alignment with the Pleth sensor.

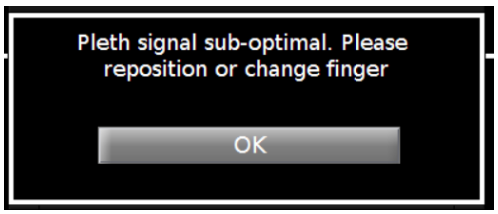


Figure 22: Pleth signal sub-optimal message

3. Observe the Conductance signal. There is no specific shape to the Conductance signal. As long as a GSR line is shown, and no Conductance Alert is on, the input signal is adequate.

4. If the measured Conductance signal is too weak or of low quality, a signal quality alert (see below) will appear. If pressed, a message advising the user to check the finger probe connection to the single use sensor will appear as well.

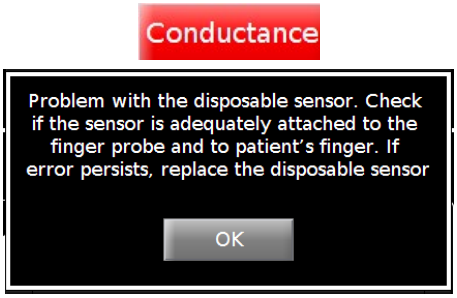


Figure 23: Conductance signal sub-optimal message

5. Press the START button (

).

   The system begins calibrating for the specific patient according to the initial signals acquired from the patient. The Calibration Screen is displayed.

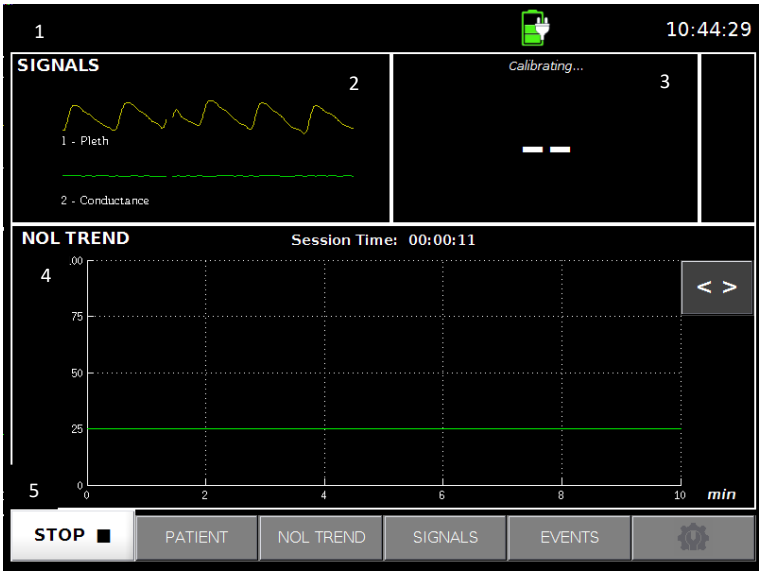


Figure 24: Calibration Screen

In the Information pane (1), the time and battery indication are displayed, as well as alerts and informational signals about issues during the procedure

In the Signals pane (2), the Pleth (PPG) signal and the Conductance (GSR) signal are displayed.

In the NOL Index Value pane (3), the status message Calibrating is displayed. No index value is displayed yet.

In the Trend pane (4), no trend is displayed yet. The session time (time elapsed from when the START button was pressed) is displayed. NOL thresholds (see below) is marked as horizontal green lines on the trend to easily discern threshold crossings. As factory default, a single high threshold has been set at 25, based on existing clinical evidence (section 2).

In the Menus toolbar (5), you can activate and deactivate a menu/screen by pressing the relevant button:

- Pressing

will start a new procedure from the home screen and initiate the calibration process (see above)
- Pressing

will stop the procedure and save the procedure recording (see “Stopping the Monitoring session”)
- Pressing

will activate the patient menu (see “adding patient details”)
- Pressing

will activate the NOL trend menu (see “Configuring NOL Trend Display”)
- Pressing

will activate the signals menu (see Configuring Signal Display)
- Pressing

will activate the events annotations menu (see “Annotating Events during the monitoring session”)Pressing displays the tools screen, where it is possible to review, export and delete procedure recordings, set systems preferences and view system information (see relevant sections in “Advanced Tools”)
  Note that the tools screen is not available during a monitoring session.

During calibration and initial use, the algorithm utilizes preloaded data from the training dataset alongside the patients’ evolving data to create the initial NOL reading. The NOL reading is updated over time, as the algorithm learns the patient patterns. There is an initial calibration period of 30 seconds for all patients.

It is advised to connect the patient to the PMD-200 just before induction, to allow time for the system to collect the patient’s physiological data and optimize the personalization of the NOL index prior to anesthesia maintenance period, where NOL-guided analgesia management is most relevant (see **Information Provided by NOL**).

When calibration is completed, the Monitoring Screen appears with the NOL index value displayed.

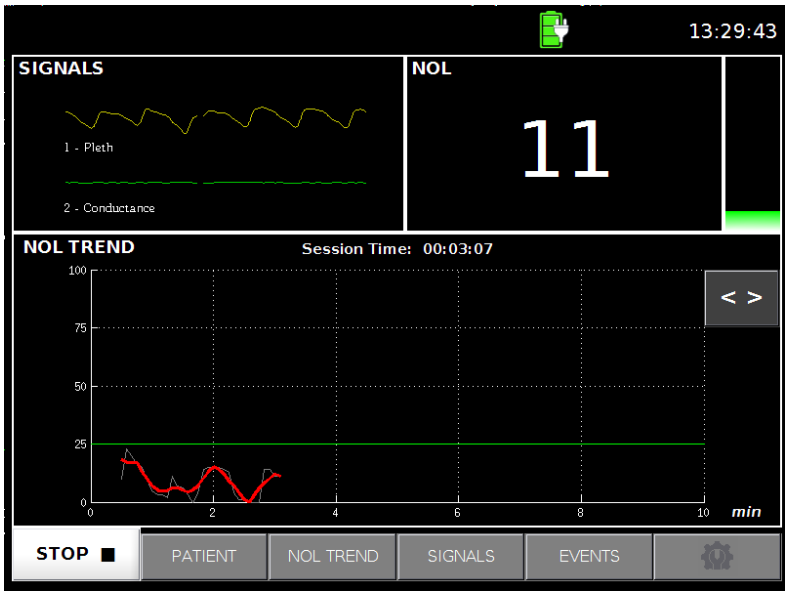


Figure 25: Monitoring Screen

6. Review the information according to the guidance in Starting a Monitoring Session 2 described above.

   In the Signal pane, the Pleth (PPG) signal and the Conductance (GSR) signal are displayed by default.

   Temperature (TMP) and Movement (ACC) signals are also available for display. For instructions about configuring signal display, see advanced tools section.

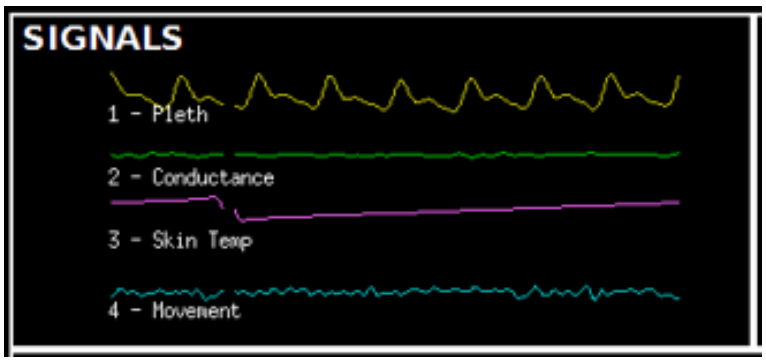


Figure 26: Signal Pane Showing 4 Signal Types

Note

	The signal waveforms are displayed in order to assist the user in confirming finger positioning and signal input adequacy as part of the setup process. The signals should not be considered as vital sign measurements.

In the NOL Index pane, the NOL index value (0–100) is displayed. A bar indicating the NOL value is displayed in the right of the pane. The height of the bar reflects the current NOL value and it is color coded based on the selected NOL threshold

Factory default for the threshold is 25, based on existing clinical evidence (section 2). Values below will be marked in green on the NOL bar and values above will be marked in red.

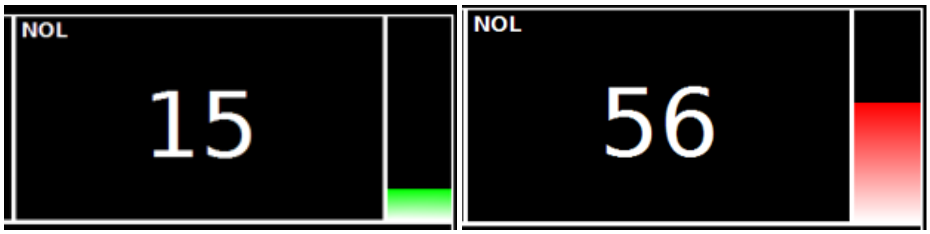


Figure 27: Examples of NOL Pane Showing NOL Index Value and Indicator Bar

In the Trend pane, a continuous graph of the NOL index over time (minutes or hours as set by user) is displayed. The default display is 10 minutes. For instructions about configuring the display of NOL index and trend, see Configuring NOL Trend Display.

The system displays a horizontal line (green) representing the threshold as set.

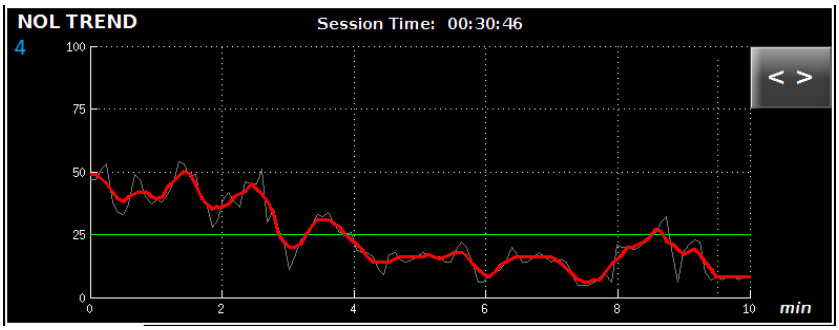


Figure 28: Trend Pane

When signal quality is low or inadequate, an alert is displayed in the information pane (see Alerts and **Informational Signals**)

Note

	The system assesses signal quality and will not display a NOL value if the signal quality is inadequate.

3. Stopping the Monitoring Session

1. Press the STOP button (STOP ■).
   A confirmation message is displayed.

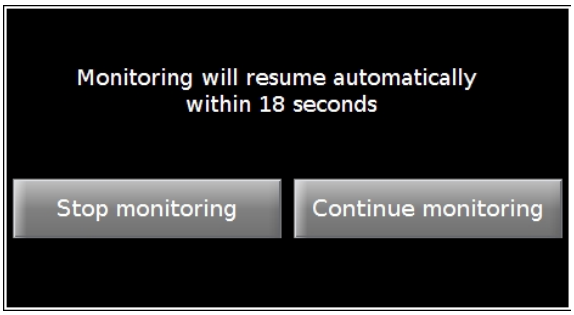


Figure 29: Confirmation Message for Stopping Monitoring

2. To stop the monitoring session, press Stop Monitoring.
   The system stops the monitoring session and saves the data. The Home Screen is displayed.

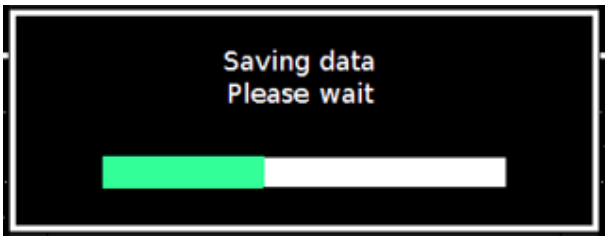


Figure 30: End of Monitoring Session

   If you do not press Stop Monitoring within 20 seconds, monitoring continues automatically.
3. Remove the finger probe and the sensor from the patient finger. Discard used single-use sensor as medical waste.
4. Shut down the system by pressing the Power button on the front panel of the monitor. Shut down menu will appear on screen.
5. Press Shut down now to power OFF the device or Cancel to abort shutdown request.

Figure 31: Shut Down Menu

Once the system is shut down, the power button will be lit in Blue.

Figure 32: Power Button OFF

Note

	Make sure to Stop monitoring and Start a new monitoring session between new patients.

Caution

	Discard used single-use sensors as medical waste. Do not reuse the single-use sensor If the PMD-200 system will not be used for a long period of time, unplug the device.

4. Information Provided by NOL

The NOL index provides nociception information throughout the medical procedure while the patient is under general anesthesia. It traces the patient's physiological response to nociceptive stimuli and to analgesics administration, continuously translating the physiological state of nociception to a numerical value.

The session may be divided into three phases of a "typical" general anesthetic case:

- Induction period (Including the intubation phase)
- Maintenance period
- Emergence period

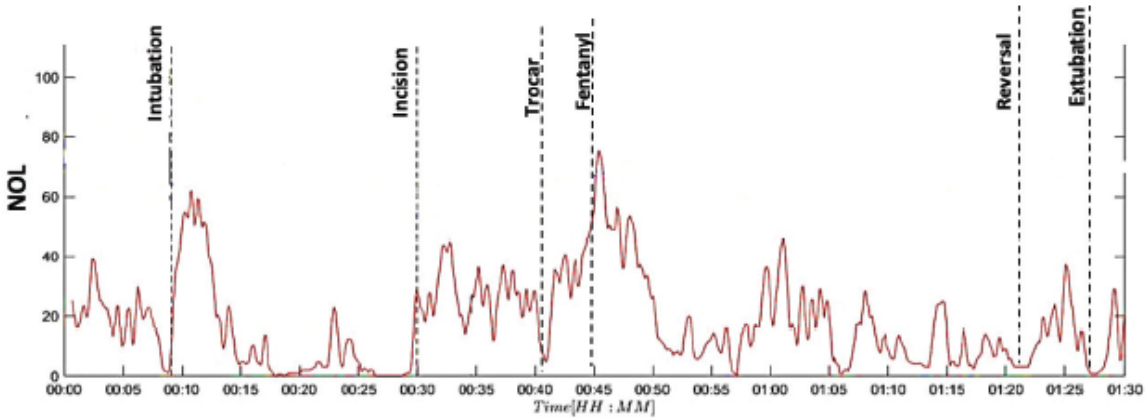


Figure 33: NOL tracing during general anesthesia

After placing the device finger probe on the patient's finger, a short calibration period of approximately 30 seconds takes place after which the NOL value is displayed on the monitor. It is advisable to connect the patient to the device sensors before induction, to allow time for the system to collect the patient's physiological data and optimize the personalization of the NOL index prior to anesthesia maintenance period, where NOL-guided analgesia management is most relevant. As the patient is still awake, the first NOL values displayed reflect the basic sympathetic tone of an awake person which is characterized by higher physiological parameter values compared to an anesthetized patient (heart rate, blood pressure, skin conductance, etc.). Therefore, NOL values above 25 may be expected until start of induction, depending on the patient's stress level.

After induction, NOL values will drop, reflecting the patient's nociceptive – anti nociceptive (NAN) balance at that period: No noxious stimulation with reduction of sympathetic tone due to loss of consciousness and administration of an analgesic. A NOL value below 25 should usually be expected.

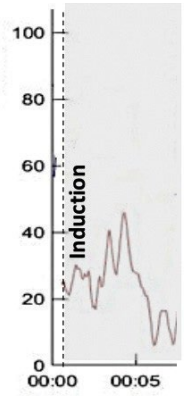


Figure 34: NOL tracing during induction

Note

	Regional nerve blocks and neuraxial anesthesia (e.g. epidural) in patients under general anesthesia are expected to result in attenuated NOL values whether placed before or after induction. Lower NOL values may confirm the effectiveness of the block. However, NOL will still respond to noxious stimuli that are not covered by the regional anesthesia with an increase in NOL values. Clinical judgment should be used at all times when interpreting the significance of NOL values while using neuraxial anesthesia or regional nerve blocks as an adjunct to General Anesthesia.

Intubation

Intubation is recognized as an intense noxious stimulus and normally prompts an increase in NOL values. Unexpectedly high NOL values during intubation may indicate that onboard analgesia administered during induction is not yet fully effective or is insufficient for the patient

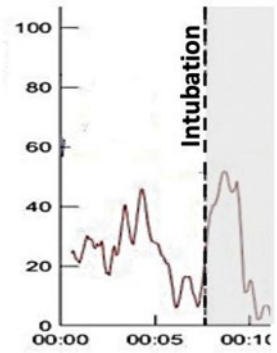


Figure 35: NOL tracing during intubation

NOL During Maintenance

During the maintenance period the clinician may follow the validated clinical guidance presented earlier in this document:

- NOL above 25 for more than one minute may indicate the patient requires additional analgesic therapy. Higher values indicate a stronger nociceptive response. Review the patient's signs and symptoms to consider whether additional analgesia may be needed.

Note

	• The PMD-200 should be used as an adjunct to clinical judgment. Clinical judgment should always be used when interpreting the NOL index and trend line in conjunction with other available clinical and vital signs. • The magnitude above the NOL threshold of 25 does not provide guidance on the magnitude of the dose of analgesic, but rather indicates timing as to when additional analgesic dosing may be necessary, following a nociceptive response.

- NOL between 0–25 represents an appropriately suppressed physiological response to noxious stimuli and suggests adequate analgesia.

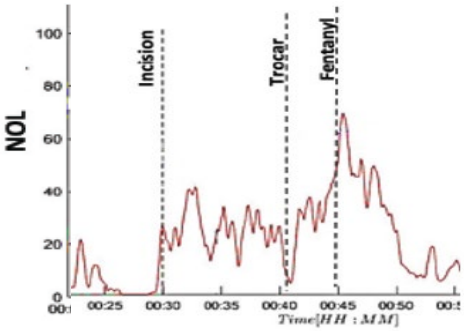


Figure 36: NOL tracing during maintenance

NOL During Emergence and Extubation

During emergence and extubation, NOL trend will reflect the rising sympathetic tone as the concentrations of hypnotics and opioids are diminishing at the end of surgery in preparation for emergence from anesthesia. Even in a patient with no pain upon emergence, an increase in NOL trend and eventually NOL values above threshold (>25) should be expected.

At tracheal extubation, NOL values will typically increase immediately to above 25.

Note

	• During emergence from General Anesthesia, NOL values are expected to rise above 25 as the patient regains consciousness. This is not indicative of a nociceptive response and should not be treated with analgesia. • Clinical judgment should always be used when interpreting the NOL index and trend line in conjunction with other available clinical and vital signs.

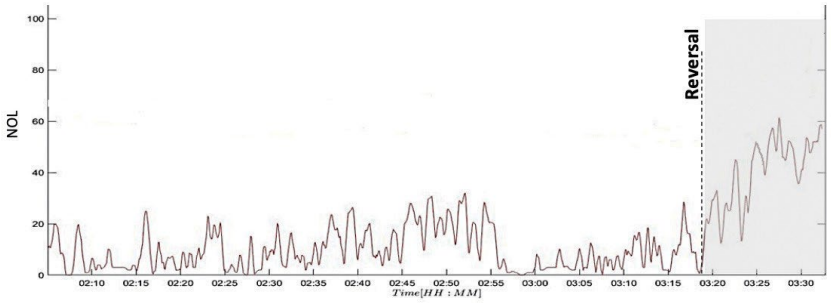


Figure 37: NOL tracing during emergence

6. Advanced Tools

The actions described in this chapter are not required for use of the PMD-200 in Monitoring mode. These actions enable changing the display of information on the screen, presenting advanced analytical data about the procedure, adding information to the saved monitoring session data, updating user/regional preferences and exporting the monitoring session data.

Some of the functions described in this section are password protected. Contact your Medasense representative if different settings are desired.

Adding Patient Details

Prior to or during a monitoring session, you can add patient information that will be saved with the monitoring session data.

Note

	Adding patient data will not affect NOL calculations in any way. This option is offered only to assist in recording procedure information.

1. On the menu bar, press the PATIENT button (PATIENT).

   The Patient data fields are displayed for updating patient data, in either metric or imperial units of measurements (see “Tools screen” for setting up units of measurement).

   Factory default for systems sold in the US is Imperial units of measurement. This function is password protected. Contact your Medasense representative if different settings are required

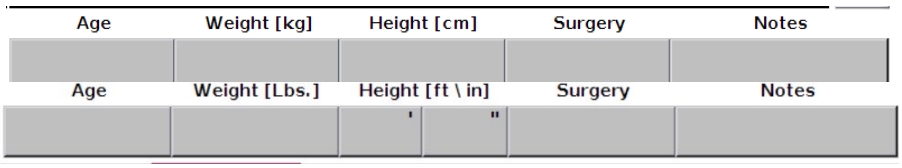


Figure 38: Patient Data Fields

2. Press the text box below the data field that you want to update.

   A virtual keyboard will be displayed.

Figure 39: Virtual Keyboard

3. Using the virtual keyboard, type the information that you want to enter:

   Age: Type a numeral (up to 120) for the patient's age in years.

   Weight: Type a numeral for the patient's weight in lbs. (0-665) or kilograms (0-300) (see “tools screen” for setting up units of measurement)

   Height: Type (a) numeral(s) for the patient's height in feet and inches (1’8”-8’2”) or in centimeters (50-250) (see “tools screen” for setting up units of measurement).

   Surgery: Type free text for the surgery type.

   Notes: Type free text for any required additional notes.

4. On the keyboard, press the Insert key (

) to enter the data in the field.

   If the information that you typed is not in the correct format or out of the defined range, a message appears prompting you to correct it.

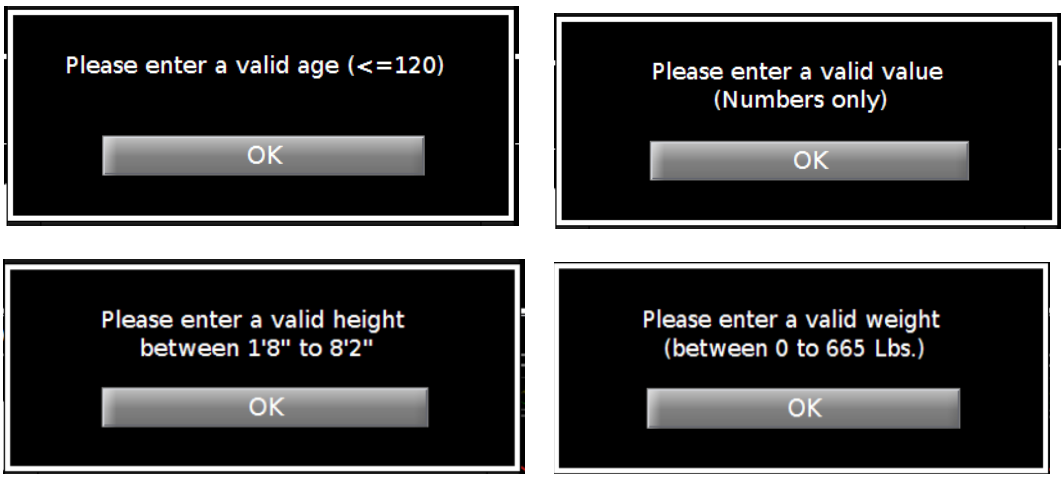
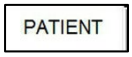


Figure 40: Invalid data inserted

   Repeat Steps 2-4 for any other fields that require update. It is also possible to edit or delete information that was already entered.

5. To close the Patient option bar and return to the Monitoring screen, press the PATIENT button (

) or the X button (

).

Configuring NOL Trend Display

You can change how the NOL trend is displayed in the NOL Trend pane and display live analytical information (if you want to disable live analytical display, contact your Medasense representative).

1. On the menu bar, press the NOL TREND button (NOL TREND).
   The NOL TREND option bar is displayed.

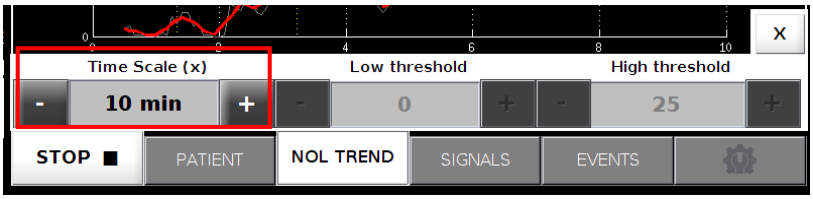


Figure 41: NOL TREND Option Bar – Only NOL time scale configuration is enabled

2. Use the buttons on the NOL TREND option bar to configure the NOL trend display:
   - Time Scale (x): Use these buttons to select the time interval displayed in the Trend pane (1 min, 2 min, 5 min, 10 min, 30 min, 1 hr, 2 hr, 3 hr, 4 hr, and more up to 24 hours. When choosing "total session" display will be adjusted to the closest whole hour).
   - Threshold Configuration: Factory default for systems sold in the US is an upper threshold of 25 and a lower threshold of 0, based on current clinical evidence.

Caution

⚠	Always evaluate the clinical suitability of thresholds when guiding analgesia based on NOL trends

3. To close the NOL TREND option bar and return to the Monitoring screen, press the NOL button (NOL TREND) or the X button (X).

Displaying advanced analytical data

If so configured, the NOL pane will include retrospective statistical insights about the current procedure, and the NOL value will show above the NOL color bar (see figure

34)

1. press the NOL TREND button (NOL TREND).

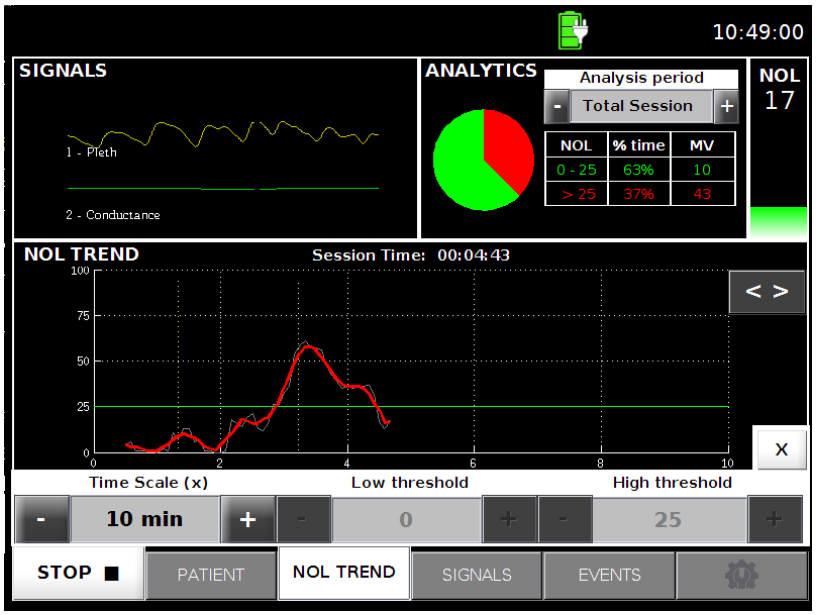


Figure 42: NOL TREND Option Bar with live analytics enabled

The table and accompanying color-coded pie chart present the amount of time (over the selected time base for analytics) that the NOL value was within each range based on the upper and lower thresholds as set by the user: above upper threshold in red, below lower threshold in white or between both in green. Factory default will display values above (red) or below (green) the threshold of 25.

2. Adjust the time base for analytics calculation by pressing the + and – signs. The time base is always calculated retrospectively from the present moment. Therefore choosing “30 minutes” will display the analysis for the last 30 minutes of the procedure.

Note

	Changing the Analysis Period does not impact NOL index calculation in any way. Do not confuse Analysis Period with NOL Trend display time (Time Scale (x)), located on the bottom tab.

The pie chart provided will reflect the statistical data of the time period selected in the Analysis Period.

NOL – details the chosen ranges

% time -details the percentage of time spent within each chosen range. Factory default will display values above or below the threshold of 25 in the selected analysis period.
MV – details the mean NOL value for each range (Factory default will display values above or below the threshold of 25).

Note

	Advanced analytics tools should be used in conjunction with the NOL trend line and all other available clinical information

Factory default for the "Live Analytics" option is enabled. This function is password protected. Contact your Medasense representative if different settings are required.

Configuring Signal Display

You may select the signals displayed in the Signal pane:

1. On the menu bar, press the SIGNALS button. The Signal option bar is displayed.

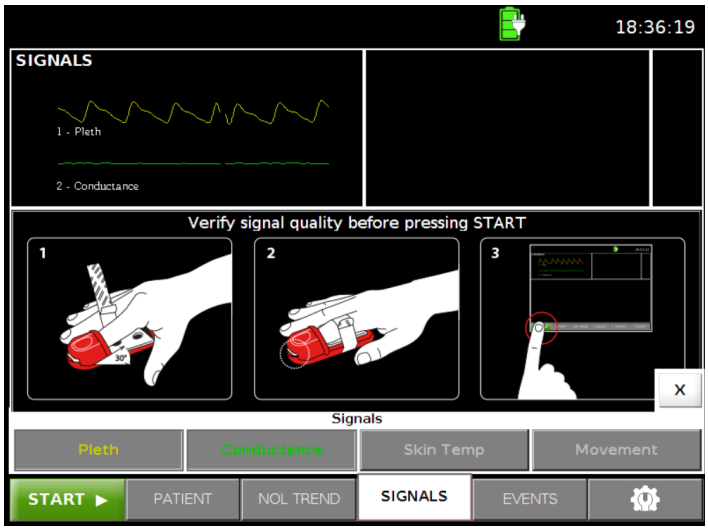


Figure 43: Signal Option Bar

2. Use the buttons on the Signal option bar to configure the signal display and select which of the 4 available signals are displayed (active signals will be colored):
    - Pleth **(PPG,** Plethysmograph pulse wave)
    - Conductance **(GSR,** Galvanic Skin Response)
    - Temperature (Peripheral temperature)
    - Movement **(ACC,** Accelerometer)
3. To close the Signal option bar and return to the Monitoring screen, press the SIGNALS button (SIGNALS) or the X button (X).

Annotating Events during the Monitoring Session

You can annotate any special event that occurs during the monitoring session.

4. On the menu bar, press the EVENTS button. The Event option bar is displayed.

Figure 44: Event Option Bar

5. Press the relevant category for the event:

   Medication

   Stimuli

   Clinical

   Favorites

   The annotation time is now saved and displayed in the relevant event category window.

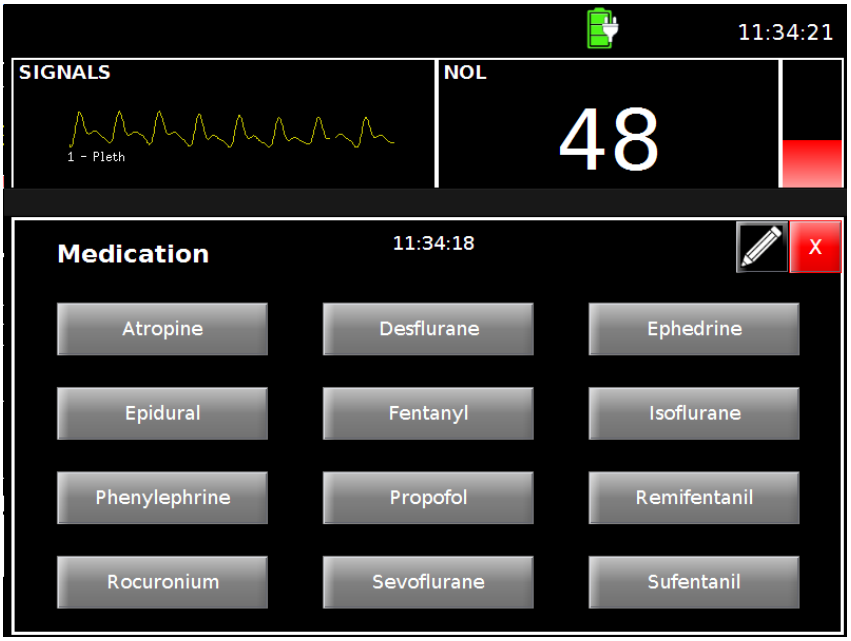


Figure 45: Event Annotation Options with Annotation Time Displayed

The time of annotation is marked on the trend graph by a dotted vertical line.

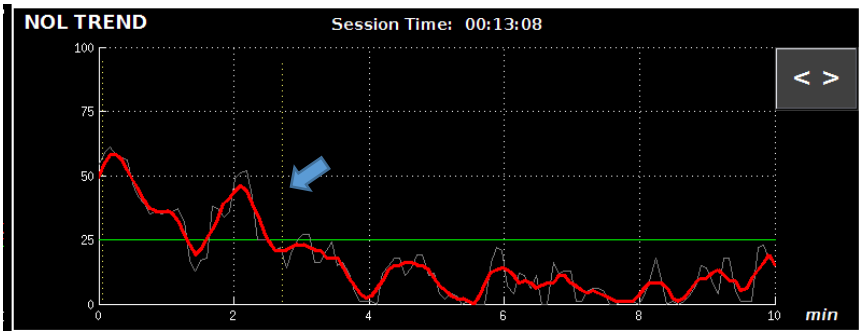
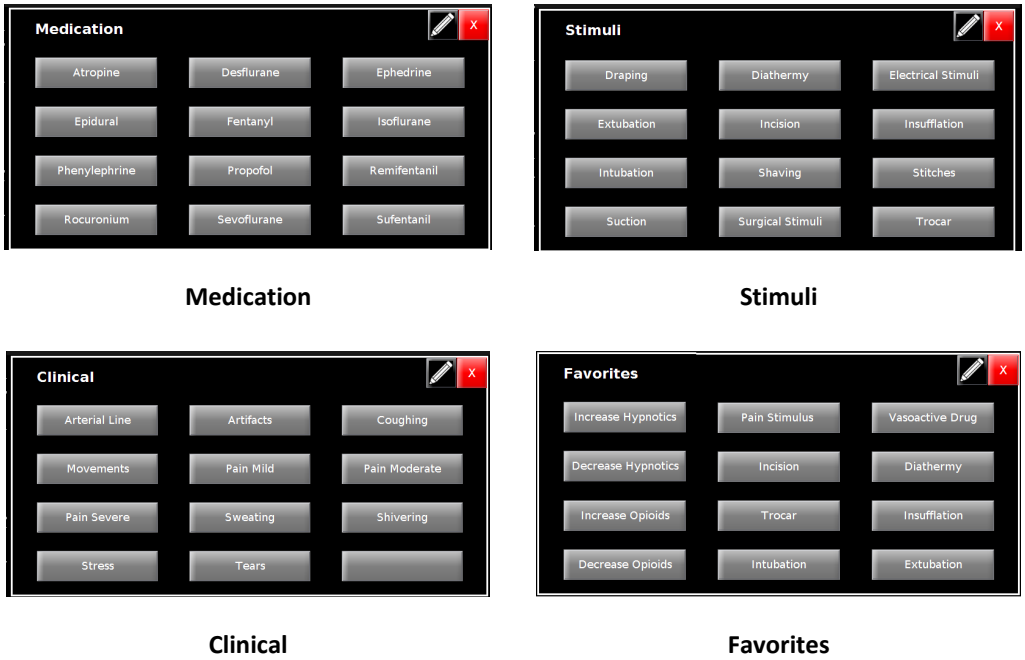


Figure 46: Annotation Displayed on NOL Trend

6. Choose the selected annotation from the menu.



Medication **Stimuli**

Clinical **Favorites**

Figure 47: Event Annotation Options

When the annotation is selected, it is displayed above the EVENTS tab.

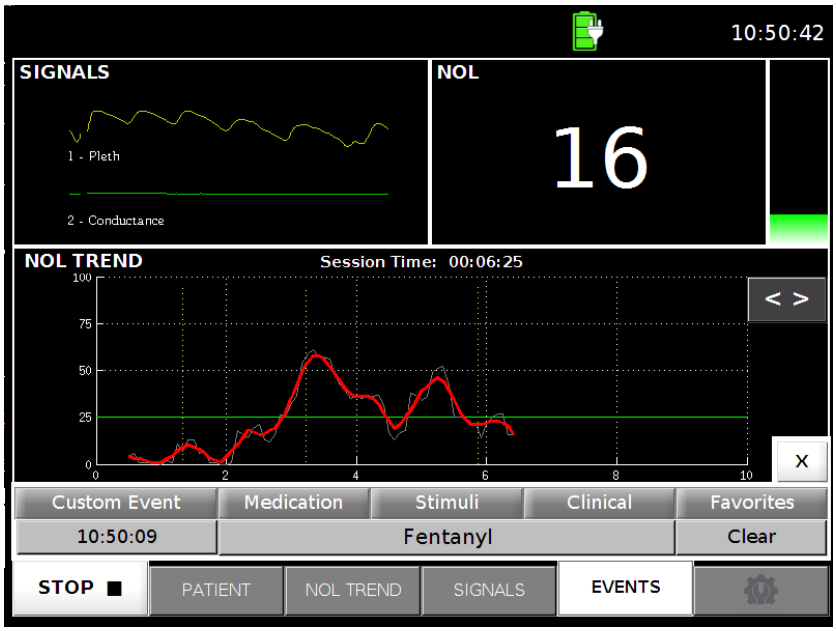


Figure 48: Annotation and Annotation Time Displayed

If you want to permanently set an annotation that is not listed in the menu, press the edit icon ( ) on the annotation options window.

The annotations will become highlighted in light green:

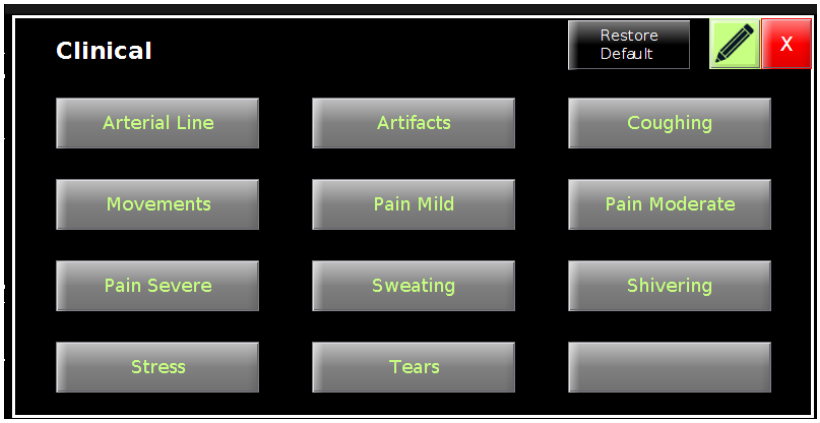


Figure 49: Annotation Options in Edit mode

Select an existing annotation space or an empty box to add free text, or to edit existing text. The virtual keyboard will be displayed (see figure 33)

Type the required free text and press the Insert button (

).

To exit the edit mode and to choose an annotation, press the edit icon ( ), make sure that the script on the Annotations buttons reverted to white and choose the required annotation.

To reset the annotation menu back to the default, press the “Restore Default” button and when prompted press “Yes” to confirm restoring to default setting.

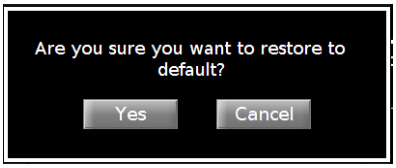


Figure 50: Restore default

7. To exit the annotation category window, press the ( ) icon.
8. To add an event which doesn’t exist in any of the categories, press the Custom Event button ( ) (the annotation time will now be saved and displayed), then enter free text by using the keyboard.
9. To close the Event option bar and return to the Monitoring screen, press the EVENTS button ( ) or the X button ( ).

Reviewing Events during the Monitoring Session

You can review previously annotated events during the monitoring session.

1. Set the NOL trend view to the appropriate time frame so the event of interest is visible on the trend (see “configuring NOL trend”).
2. Press the button on the upper right side of the trend pane. The last reviewed annotation content is displayed above the NOL trend, and the event marker is highlighted.
3. Press the right or left arrow to navigate between annotations in descending (left) or ascending (right) chronological order, until the correct event is highlighted.
4. Press the button again or wait for approximately 30 seconds to close the previous annotations viewer.

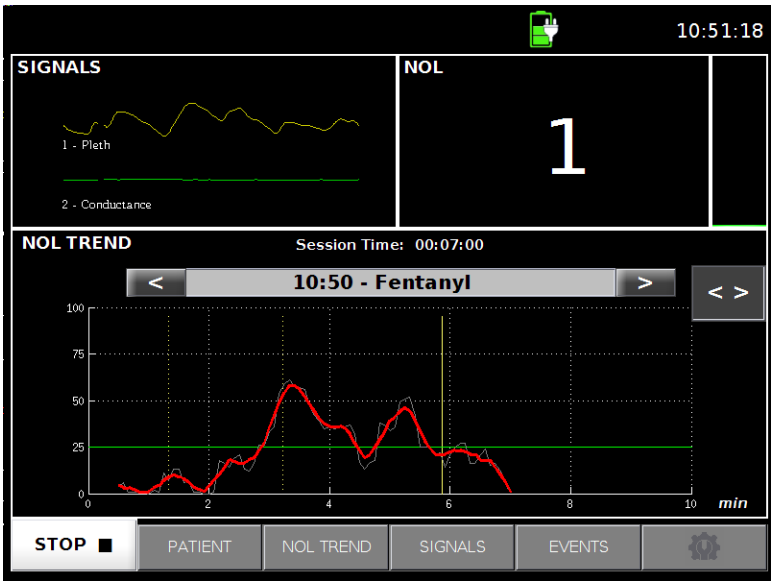


Figure 51: Reviewing a previous annotation

Visual Notification of NOL values above Threshold

The system displays a visual notification whenever the NOL value is above the threshold for over 60 seconds.

The blinking will stop automatically (and the event will be considered over) once the NOL values have returned below the 25 threshold for at least 48 seconds.

Blinking may be stopped at any time by pressing the NOL value on screen, and will not resume until the next event has been detected (i.e. after the NOL values have returned below 25 for at least 48 seconds, then have been detected above 25 for over 60 seconds)

This notification function is password protected.

Note

	Always consider the NOL Trend and any other available clinical information prior to making a clinical decision

Adjustable Strap Finger Probe

The PMD-200 finger probe may also be provided with an adjustable strap that can better accommodate different patient finger sizes. This configuration is provided separately, as an optional accessory. The finger probe is depicted in Figure 52, A & B

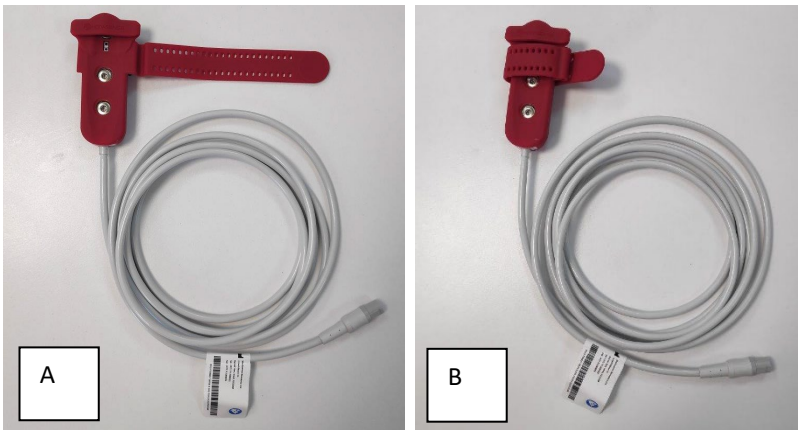


Figure 52: Adjustable strap configuration, open and closed

In order to place the patient's finger in the adjustable finger probe, the user should insert the patient's finger and wrap the adjustable strep around the patient's finger, securing it using the fasteners on the side of the finger probe. The user should make sure that the adjustable strap is secured to prevent finger movement, but is not over-tightened as this could affect PPG signal acquisition or place pressure on the patient's finger.

7. Tools Screen

Note

	The Tools screen is not available when a monitoring session is in progress. Some of the functions described in this section are password protected and therefore the buttons will appear as greyed out until activated. If you require a change in one of these settings, contact your Medasense representative.

Exporting and Deleting Data

You can export the recorded data and annotations through the tools screen.

1. Connect a USB flash drive or external hard disk drive in the USB port on the side panel of the monitor.
2. On the menu bar, press the tools button ( ).

   On the upper left side of the screen, is a list of procedure recordings. The recordings are arranged chronologically (newest on top) and their filenames are in the **YYYY-MM-DD_HHmm** format, based on their individual start time.

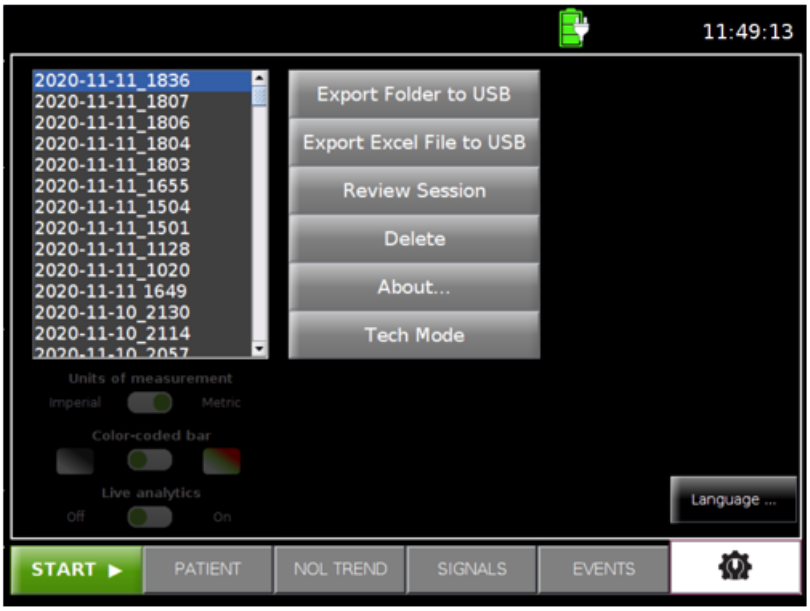


Figure 53: Tools Screen

3. On the recordings list on the left of the screen, select the recording(s) that you want to export. You can choose multiple (adjacent) recordings by dragging your finger across the required recordings.
4. On the actions menu in the center of the screen, press one of the options:
   - Press Export Folder to USB to export all the raw data of a specific monitoring session including the "Review Session" PDF file.
   - Press Export Excel File to USB to export a comma-separated Excel (.csv) file with the following parameters of a specific monitoring session:
     - Time
     - NOL index
     - Heart rate
     - Annotations

   The .csv file is saved both on the USB flash drive and in the patient folder.

   The export process begins and a progress indicator is displayed.

Figure 54: Export Progress Indicator

When the export is completed, a message is displayed.

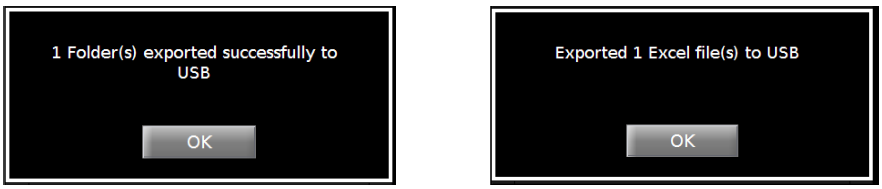


Figure 55: Examples of Completed Export Messages

5. Click OK on the message.

   If a USB flash drive is not connected, a message is displayed.

Figure 56: No USB Message

If the system cannot export the data, a message is displayed.

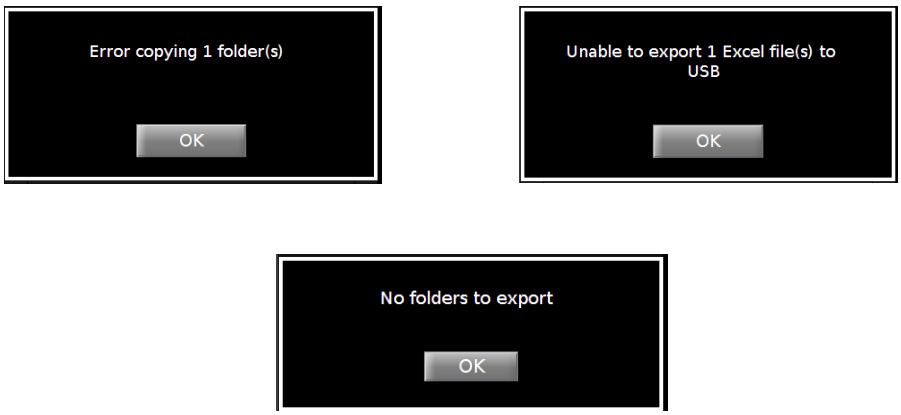
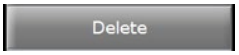


Figure 57: Unsuccessful Export Message

6. To close the Tools screen, press the button

From the Tools screen, you can also delete recordings.

1. On the recording list on the left of the screen, select the recording(s) that you want to delete.
2. On the actions menu in the center of the screen, press 

   A message is displayed asking for confirmation.

Figure 58: Confirmation Message

3. To delete the recording, press **Yes**.
   To cancel the deletion, press **Cancel**.

Note

	File deletion is permanent. After a file is deleted, it cannot be restored.

When the deletion is completed, a message is displayed.

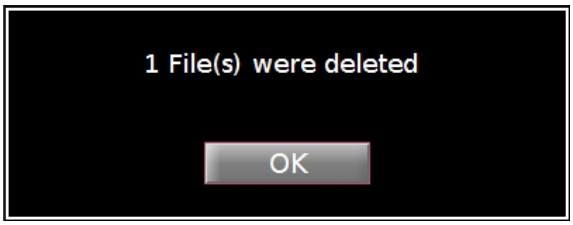


Figure 59: Completed Deletion Message

If there are no folders to delete, the following message will appear:

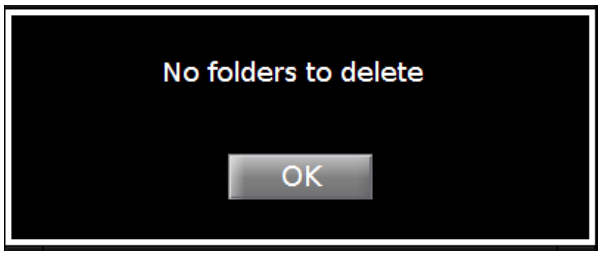
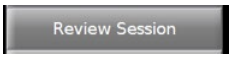


Figure 60: No folders to delete

Review Session

The Review Session option allows the user to review a previous recording session once it has been concluded.

1. Access the Tools screen by pressing
2. On the recording list on the left of the screen, select the session that you want to review – sessions are ordered by date and start time.
3. On the actions menu in the center of the screen, press 

A procedure recording will be displayed on the PMD-200 screen. Navigate between pages by pressing the right / left arrows at the bottom of the screen. The first page includes a summary of the NOL trend for the entire recording session. The second page will include a view of the live analytics information for the entire procedure (on the left) as well as the last displayed view for the user at the time the procedure was stopped.

If the session was longer than 30 minutes, additional pages will include 30 minutes segments of the session. In this case, for clarity, annotations will only be displayed on the 30 minutes segments (first page with full procedure will not display annotations)

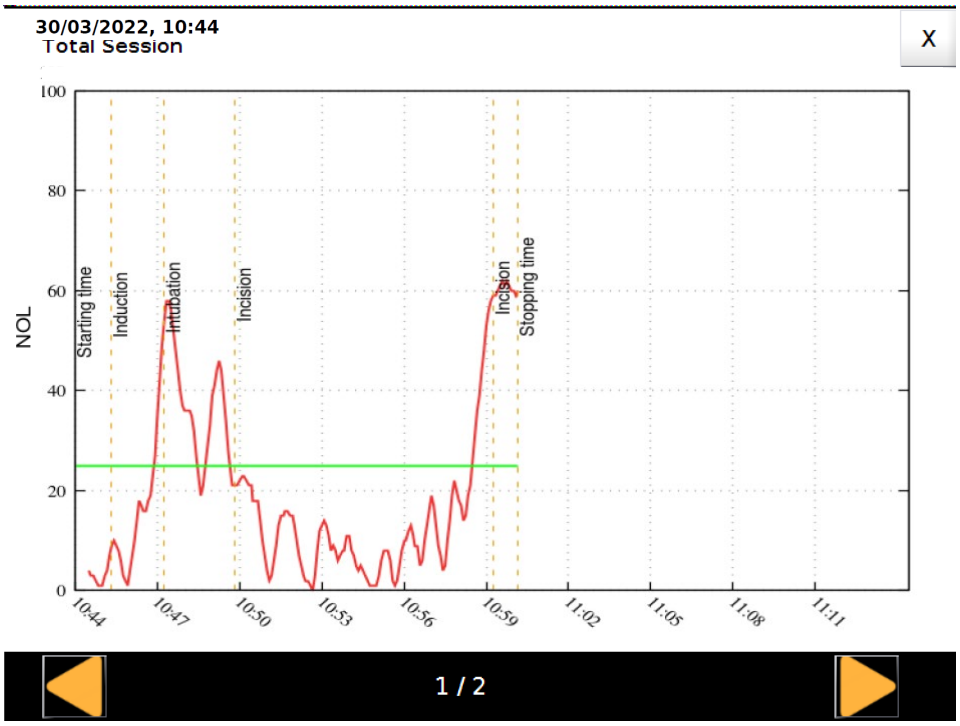


Figure 61: Review session - Full session

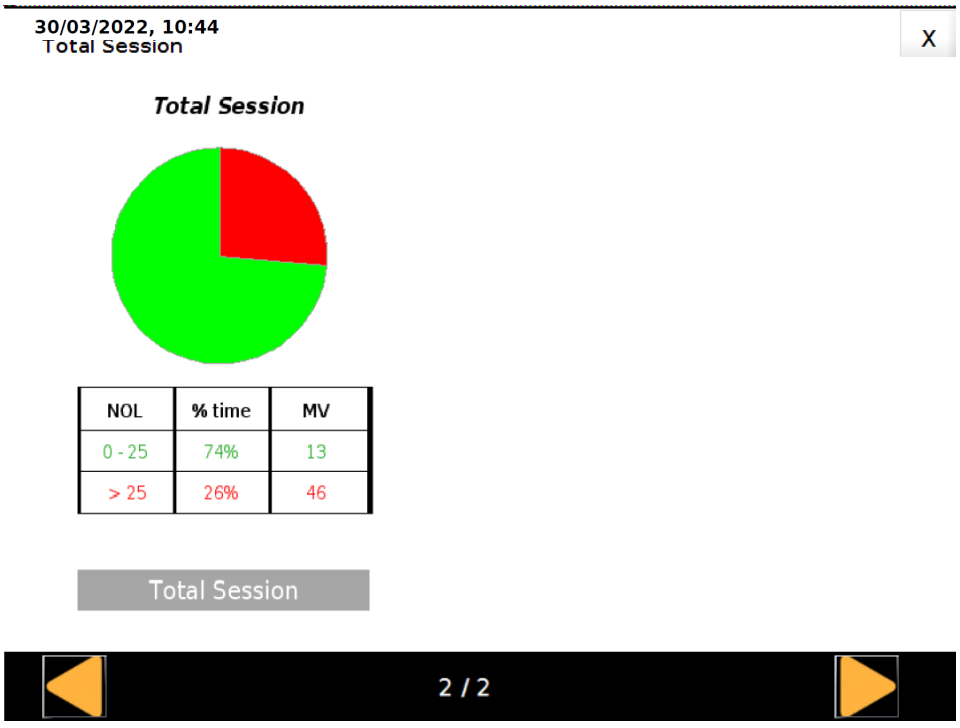


Figure 62: Review session – Analytics page

If the session was not properly concluded and saved (by pressing the “Stop” button) the system will display the following message:

Figure 63: Review mode unavailable

If there are no folders to review, the system will display the following message:

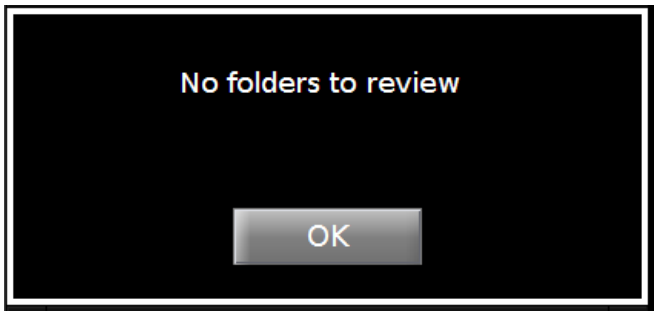


Figure 64: No folder to review

Exporting a folder to an external USB storage device enables the user to display the review session as a PDF file on any computer.

Additional tools

The **About** option displays information about the PMD-200 software (SW), firmware (FW) versions and the remaining free space on the internal hard drive.

The **Tech Mode** (Technician mode) option is password-protected. It is for use by Medasense technical personnel for service and maintenance procedures requiring access to the PMD-200 operating system and restricted software, and by local administrators to manage site preferences.

To close the Tools menu and return to the Home screen, press the button.

Changing preferences

Note

	The functions described in this section are password protected. Contact your Medasense representative if different settings are required.

To change the system preferences, contact your Medasense representative.

When enabled, the selections will be visible and the user will be able to change preferences using the touch screen. When disabled, selection will be greyed out and unresponsive.

Figure 65: Enables and Disabled preference selection

This option is not available when a monitoring session is in progress.

4. Access the Tools screen by pressing
5. Set the units of measurements by choosing between Imperial (Feet/Inches and Lbs.) or Metric (cm and Kg).
6. Set the NOL value bar to color-coded (white – under lower threshold, green – between both thresholds, red – above upper thresholds) or black & white (white bar will show on black background)
7. Enable or disable the analytics capabilities. When enabled, analytics data will be accessible in the “NOL trend” screen.

Figure 66: Tools Screen

Changing the system language

You can change the system display language from the Tools screen. This option is not available when a monitoring session is in progress.

1. Access the Tools screen by pressing
2. On the bottom right of the Tools screen, press the

button
3. Pressing the Language button opens a list of all available languages.
   The current system language is marked with a "-".
4. Choose a new language and press OK for the change to take place.

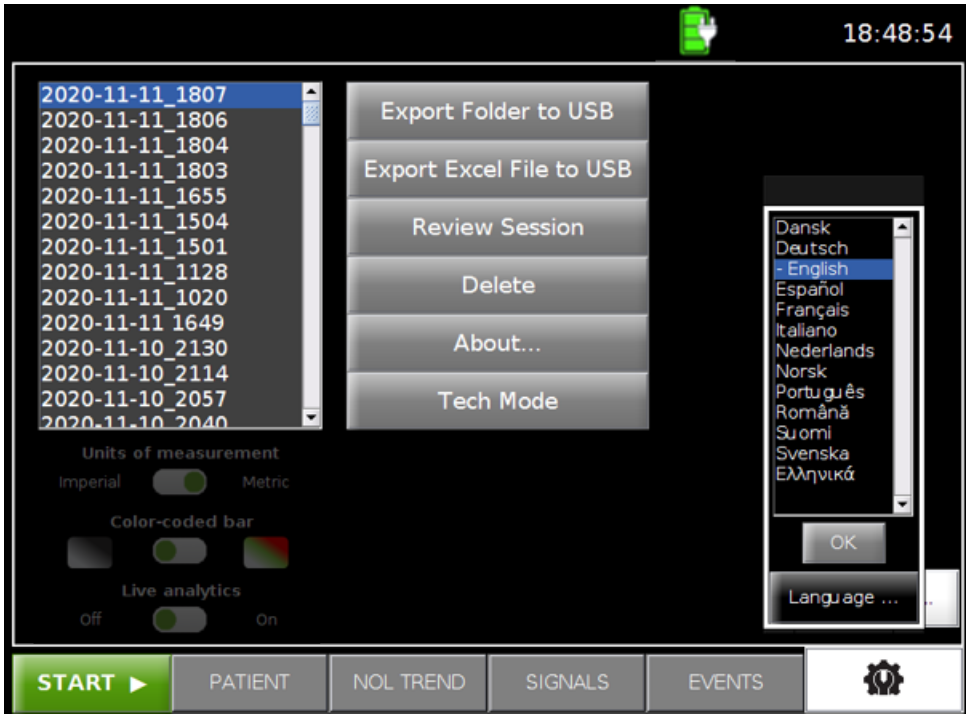


Figure 67: Language Selection Menu

After pressing OK, a restart message is displayed.

The user can restart the system by pressing Restart Now or wait 20 seconds for the system to restart automatically.

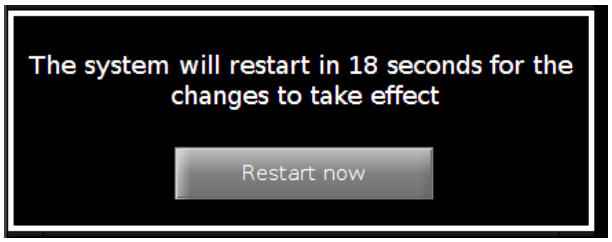


Figure 68: System Reset Confirmation Before Language Change

Changing the system Date and Time

You can adjust the system Date or Time while in Standby mode. This option is not available when a monitoring session is in progress.

1. Press on the Display Clock on the upper right corner of the screen.
2. A time and date configuration window will open.
3. Adjust the date/time by pressing "+" or "-" until the correct date/time is displayed. Press Change and Restart Now for the changes to take effect.

Figure 69: Change Date/Time screen

In case of Invalid date, an error message will be displayed. Press OK to close the error message.

Figure 70: Invalid Date message

Please correct the invalid values marked in red and press Change again.

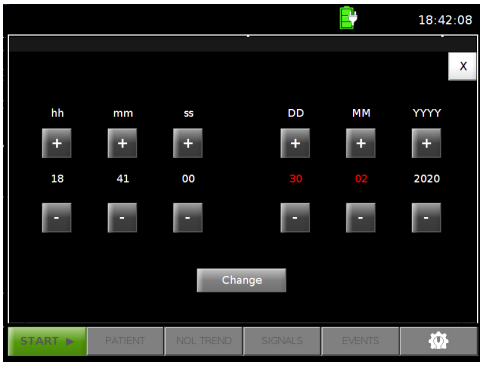


Figure 71: Invalid values marked in red

8. Clinical Evidence

Clinical Validation

A retrospective study was performed to assess the generalizability of the technology performance across multiple patient cohorts. The study was a retrospective review of a database including 447 adult patients which had been monitored with the PMD-200 monitor with NOL technology while under general anesthesia, comparing the sensitivity and specificity in distinguishing nociceptive and non-nociceptive periods and providing descriptive statistics considering the distribution of NOL values and the validation of the clinical implementation guidance.

Primary Endpoint

The primary endpoint was the ability of the NOL index to discriminate between noxious and non-noxious stimuli in various subgroups of adult surgical patients.

Methodology

NOL recordings from elective surgery procedures using the PMD-200 monitor between January 2015 to December 2020 were selected.

Data was analyzed according to the following patient subgroups:

- Age: 18-65 years old \ over 65 years old
- Sex: Female \ male
- BMI range: BMI < 25\25 < BMI < 30\ BMI > 30 kg* m−2
- Anesthesia type: Propofol \ Sevoflurane \ Desflurane
- ASA classification: ASA I \ ASA II \ ASA III
- Analgesia types – Fentanyl \ Remifentanil

Analysis Plan

The ability to discriminate between noxious and non-noxious stimuli was assessed using descriptive statistics (box plots and histograms of the NOL performance) and receiver operating characteristics (ROC) curve of the NOL response within the 3 minutes post stimulus. The post-stimulus reaction was defined as the mean NOL value during the 30 seconds with the highest NOL values for both noxious and non-noxious stimulus in the respective 3-minute window.

Acceptance criteria:

#	Test Name	Acceptance Criterion
1	AUC	0.85 (0.8 for low 95% CI)
2	Specificity	0.85 (0.75 for low 95% CI)

#	Test Name	Acceptance Criterion
3	Sensitivity	0.85 (0.75 for low 95% CI)
4	Cutoff point	25 +/- 3 NOL units
5	Accuracy	> 0.85
6	Clinical Relevance Score (CRS)*	CRS > 0.8

* CRS is a measure of applicability of the NOL algorithm in clinical practice, calculating the accuracy of the clinical guidance which recommends administration of additional analgesics if NOL is > 25 for 60 seconds or more.

Results

A total of 447 eligible patients were included in the analysis, with no exclusions from reasons other than data quality.

Subgroup	N (data points)	NOL Cutoff Point	AUC	Specificity	Sensitivity	Accuracy	CRS	Pass/Fail
Sex								
Female	483	25	0.97 (0.95-0.98) p < 0.0001	0.93 (0.89-0.96)	0.92 (0.88-0.95)	0.92	0.87	**Pass**
Male	219	25	0.96 (0.93-0.99) p < 0.0001	0.91 (0.85-0.95)	0.93 (0.85 – 0.97)	0.92	0.80	**Pass**
Age								
Age < 65	476	25	0.96 (0.95-0.98) p < 0.0001	0.94 (0.90-0.96)	0.90 (0.85-0.94)	0.92	0.86	**Pass**
Age > 65	217	23	0.95 (0.92- 0.98) p < 0.0001	0.93 (0.88 – 0.97)	0.91 (0.83 – 0.96)	0.92	0.83	**Pass**
BMI								
Normal 18-25	280	25	0.95 (0.93-0.98) p < 0.0001	0.90 (0.85-0.95)	0.93 (0.87–0.97)	0.92	0.85	**Pass**
Overweight 25-30	255	25	0.95 (0.92- 0.98) p < 0.0001	0.96 (0.91–0.99)	0.85 (0.77-0.91)	0.91	0.85	**Pass**
Obese 30+	162	25	0.98 (0.96-1.00) p < 0.0001	0.97 (0.91-0.99)	0.90 (0.81-0.96)	0.94	0.86	**Pass**
Anesthesia								
Desflurane	155	25	0.99 (0.98-1.00) p < 0.0001	0.99 (0.95–1.00)	0.95 (0.88 – 0.99)	0.97	155	**Pass**
Sevoflurane	354	25	0.95 (0.93-0.98) p < 0.0001	0.89 (0.84-0.93)	0.93 (0.88-0.97)	0.91	354	**Pass**

Subgroup	N (data points)	NOL Cutoff Point	AUC	Specificity	Sensitivity	Accuracy	CRS	Pass/Fail
Propofol	173	25	0.98 (0.97-1.00) p < 0.0001	0.96 (0.89-0.99)	0.89 (0.82-0.96)	0.92	173	**Pass**
ASA Classification								
ASA I	112	25	0.96 (0.94-0.99) p < 0.0001	0.90 (0.83-0.96)	0.90 (0.81-0.95)	0.90	0.88	**Pass**
ASA II	418	25	0.95 (0.93-0.98) p < 0.0001	0.95 (0.91-0.97)	0.89 (0.84-0.94)	0.92	0.84	**Pass**
ASA III	91	25	0.97 (0.94-1.00) p < 0.0001	0.94 (0.88-1.00)	0.92 (0.83-1.00)	0.93	0.85	**Pass**
Analgesia								
Remifentanil	265	24	0.97 (0.95-0.99) p < 0.0001	0.92 (0.87-0.96)	0.92 (0.85 – 0.96)	0.92	0.82	**Pass**
Fentanyl	395	25	0.96 (0.94-0.98) p < 0.0001	0.90 (0.85 – 0.94)	0.94 (0.89 – 0.97)	0.92	0.88	**Pass**

Conclusion

The NOL algorithm behaved consistently in multiple patient cohorts. The performance of the NOL index was thus reliable, independent of patient characteristics and anesthetic approach, and generalizes well across the intended use population.

All subgroups met predefined acceptance criteria, demonstrating that NOL values exceeding 25 for 60 seconds provide high sensitivity and specificity for nociception across a wide range of patient characteristics.

Controlled Studies

Two prospective, randomized and controlled studies comparing analgesia administration using NOL guidance vs. standard of clinical care in sevoflurane/fentanyl anesthesia were performed in adult patients undergoing elective major abdominal surgery procedures. In the NOL guided arm, fentanyl boluses were given during the maintenance phase when NOL values were above 25 for at least 60 seconds. If the NOL value was still above 25 after 5 minutes had elapsed another bolus could be considered. In the control arm fentanyl dosing was according to standard of care with clinician's assessment informed by HR & MAP monitoring. Both studies demonstrated a clinically meaningful and statistically significant reduction in post-operative pain scores, in the NOL-guided arm during 90 minutes of PACU (post anesthesia care unit) stay. In the SOLAR[1] study (n=50) a l reduction of 1.6 in the median pain score (NRS) was reported. In the Abdomi-NOL

study (n=75) (accepted for publication) a reduction of 1.5 in the median pain score was reported with NOL guided analgesia.

These reductions represent a 30-33% improvement in NRS pain scores in comparison to the standard of care control groups and were attributed to more personalized analgesia dosing in the NOL guided group.

No differences in the secondary endpoints were noted between the two groups in both studies.

Caution

	The performance of the PMD-200 has not been thoroughly evaluated in patients with reported alcohol abuse, chronic pain, opioid tolerance and chronic use of psychoactive drugs. Clinical judgment should be practiced when using NOL with these populations.
	Studies evaluated by FDA included patients undergoing elective abdominal, gynecological & urological surgeries, with fentanyl/sevoflurane/rocuronium anesthesia excluding neuraxial/regional blocks. Clinical judgment by qualified anesthesia providers should be practiced when using NOL in different populations and settings

9. Cleaning, Maintenance & Service Life

Caution

	The PMD-200 system and finger probe should be cleaned prior to initial use, and following each use.

Cleaning of the system and the finger probe should be performed using one of the two validated methods described below depending on the type of wipes used.

Cleaning Instructions using MEDIWIPES™ or any other similar disinfection wipes

Clean any blood or liquid spilled on the monitor, finger probe, or connecting cable immediately. Dried blood is very difficult to remove.

After cleaning, wipe the end of the connector with alcohol and allow it to dry completely. Residual moisture inside the connector may affect monitoring performance.

Cleaning and Disinfecting the Monitor Screen

Use 2-3 fresh disposable disinfecting wipes to wipe thoroughly all surfaces with special care to holes, edges and slots. Contact time should be at least 3 minutes.

Cleaning and Disinfecting the Finger Probe Cable

After each usage, disinfect the finger probe and the connecting cable.

1. Use 1-2 fresh disposable disinfecting wipes to wipe thoroughly the cable attached to the finger probe. Contact time should be at least 1 minute.
2. Visually inspect that the cable is clean from gross debris.
3. Leave the cable to be air dried, or alternatively, use a dry, lint free cloth to dry the surface of the cable.

Cleaning and Disinfecting the Finger Probe

4. Use 2-3 disposable disinfecting wipe to remove any gross debris.
5. Visually inspect all parts to ensure that no residues or debris remained prior to continuing to the next step.

6. Use 2-3 fresh disposable disinfecting wipes to wipe thoroughly all surfaces with special care to GSR electrodes button holes, edges and slots. Optionally, use sterile swabs to push the wipes into the slots and button holes, to verify good contact with the disinfection agent. Contact time should be at least 3 minutes.
7. Moisten a sterile lint free cloth with distilled water and wipe all surfaces for 30 seconds (make sure that the cloth is moist and not fully soaked with water).
8. Leave the finger probe to be air dried, or alternatively, use a dry, lint free cloth to dry the surfaces.

Cleaning Instructions Using Clinell™ universal sanitizing wipes or any other similar disinfection wipes

Clean any blood or liquid spilled on the monitor, finger probe, or connecting cable immediately. Dried blood is very difficult to remove.

After cleaning, wipe the end of the connector with alcohol and allow it to dry completely. Residual moisture inside the connector may affect monitoring performance.

Cleaning and Disinfecting the Monitor Screen

Use 2-3 fresh disposable disinfecting wipes to wipe thoroughly all surfaces with special care to holes, edges and slots. Contact time should be at least 5 minutes.

Cleaning and Disinfecting the Finger Probe Cable

After each usage, disinfect the finger probe and the connecting cable.

1. Use 1-2 fresh disposable disinfecting wipes to thoroughly clean the cable attached to the finger probe. Contact time should be at least 3 minutes.
2. Visually inspect that the cable is clean from gross debris.
3. Leave the cable to be air dried, or alternatively, use a dry lint free cloth to dry the surface of the cable.

Cleaning and Disinfecting the Finger Probe

4. Use 2-3 disposable disinfecting wipes to remove any gross debris.
5. Visually inspect all parts to ensure that no residues or debris remained prior to continuing to the next step.
6. Use 2-3 fresh disposable disinfecting wipes to thoroughly clean all surfaces, paying special care to GSR electrodes button holes, edges and slots. Optionally, use sterile swabs to push the wipes into the slots and button holes, in order to verify good contact with the disinfection agent. Contact time should be at least 5 minutes.
7. Moisten a sterile lint free cloth with distilled water and wipe all surfaces for 30 seconds (make sure that the cloth is moist and not fully soaked with water).

8. Leave the finger probe to be air dried, or alternatively, use a dry, lint free cloth, to dry the surfaces.

Warning

	If blood or liquid is spilled on the PMD-200, retest ground leakage current before further use.

Caution

	Do not autoclave the PMD-200 system or its accessories.

Maintenance

The PMD-200 Monitor is designed so that no periodic maintenance is required.

- Leakage current is a primary indicator of electrical shock hazard for personnel who touch any of the device's outer surfaces. Static electricity tests have been conducted on the PMD-200 monitor to ensure that the leakage current meets safety standards of IEC 60601-1.

Medasense recommends performing a leakage current test:

- In the event of blood or liquid spill on the system or its components
- Immediately after a major surge in the electrical system

Service Life

The service life of the PMD-200 monitor is defined as 5 years. There is no expectation for deterioration of performance during this period. If the system suffers from any mechanical damage, do not continue to use it and contact your Medasense representative.

The service life of the PMD-200 finger probe is defined as up to 600 usages. During this period, the finger probe will undergo usage and cleaning cycles which may cause a certain degradation to the finger probe appearance. The finger probe may continue to be used even if small tears are present. The user should not continue using the finger probe in the following instances:

1. Persistent signal quality alerts not relating to a specific patient
2. Major tear > 0.4 inch (10mm) in the finger probe cover or strap and > 0.3 inch (7mm) in the finger probe front hood
3. Multiple tears – if multiple tears appear in the probe cover or strap

10. Specifications

The PMD-200 is intended for use in the electromagnetic environment specified below.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The PMD-200 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The PMD-200 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Note

	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The PMD-200 is intended for use in the electromagnetic environment specified below. Ensure that it is used only in such an environment.

Table 3: Electromagnetic Immunity

Immunity test	IEC 60601 level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD), IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, IEC 61000-4-4	2 kV for power supply lines 1 kV for SIP/SOP lines	2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge, IEC 61000-4-5	1 kV line to line 2 kV line to earth	1 kV line to line 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips and interruptions on power supply input lines IEC 61000-4-11	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycles	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field, IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Immunity test	IEC 60601 level	Compliance level
IEC 61000-4-6 Conducted RF	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands (6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz) and amateur bands (1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz)	[*V*] = 3 Vrms [*V*] = 6 Vrms
IEC 61000-4-3 Radiated RF	3 V/m 80 MHz to 2.7 GHz	[*E*] = 3 V/m
Proximity fields from RF wireless communications equipment	385 MHz	27 V/m
	450 MHz	28 V/m
	710 MHz	9 V/m
	745 MHz	
	780 MHz	
	810 MHz	28 V/m
	870 MHz	
	930 MHz	
	1720 MHz	28 V/m
	1845 MHz	
	1970 MHz	
	2450 MHz	28 V/m
	5240 MHz	9 V/m
	5500 MHz	
	5785 MHz	
IEC 61000-4-39 Immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56 kHz	8 A/m, 30 kHz	8 A/m, 30 kHz
	65 A/m, 134.2 kHz	65 A/m, 134.2 kHz
	7.5 A/m, 13.56 MHz	7.5 A/m, 13.56 MHz

Recommended Separation Distance between Portable & Mobile RF Communications Equipment and PMD-200

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 PMD-200, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

When actively using diathermy (electrical cautery) during a procedure, make sure the Pleth and Conductance signal quality is adequate. In case of signal quality alerts, see section 11.

Essential Performance

All four signals (Pleth, Conductance, ACC, peripheral temperature) are considered part of the system's essential performance.

Note

	Pleth & Conductance are used for NOL index calculation. Movement and peripheral temperature are used as guardrails, but are not directly involved in NOL calculation. Due to the importance of NOL accuracy, all 4 signals are considered as part of the system's essential performance

Technical Data

This table lists technical specifications and capabilities of the PMD-200 system.

Table 4: Technical Specifications

PMD-200 Monitor	
Parameter	Specification
System temperature range during transport or storage	From 14°F to 140°F (-10°C-60°C)
Ambient operating temperature	From 50°F to 95°F (10°C-35°C)
Relative humidity during operation	30% – 70% non-condensing
Relative humidity during transportation, storage	30% – 70% non-condensing

PMD-200 Monitor	
Parameter	Specification
Air pressure during operation and transport	70 kPa – 105 kPa in operating mode 50 kPa – 106 kPa in non-operating mode
Liquid ingress	IPX1 Dripping Water Ingress Protection
Communication	1 USB port, 1 RS232 port
Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, ISO 10993, ROHS
Power supply	100 VAC– 240 VAC, 700 mA, 50/60 Hz
Power consumption	Approximately 60 W
Mode of operation	Continuous
Battery	• Cell Type: Li-Ion 3.7V, rechargeable • Basic cell Samsung ICR18650F • Battery capacity: 2.6Ah • Normal Voltage: 11.1V • Maximum charging time is 2 hours • Operating temperature: 0 to 45°C during charging and -20 to 60°C during discharging • Elevated temperature shut-off: 72°C
Dimensions	PMD-200 monitor: (H) 240 mm × (W) 193 mm × (D) 150 mm
Weight	PMD-200 monitor: approximately 7.7 lbs (3.5 kg) Shipping weight: 11 lbs (5kg)
User interface	Touchscreen and 1 button (ON/OFF)
Expected service life	5 years
Disposal	Dispose of according to local regulations

Finger Probe	
Parameter	**Specification**
Finger Probe temperature range during transportation or storage	From 14°F to 140°F (-10 °C-60 °C)

Finger Probe

Parameter	Specification
Ambient operating temperature	From 50°F to 95°F (10°C-35°C)
Relative humidity during operation	30% – 70% non-condensing
Relative humidity during transport or storage	30% – 70% non-condensing
Air pressure during operation and transport	70 kPa – 105 kPa in operating mode 50 kPa – 106 kPa in non-operating mode
Dimensions	Finger Probe: 3.35 inch X 1.58 inch (85 mm X 40 mm) Finger Probe + Cable: 118 inch (3000 mm)
Weight	Finger probe: 0.19 lb (0.090 Kg)
Expected service life	600 usages
Disposal	Dispose of according to local regulations
PVC Free, LATEX Free, DEHP free, Biocompatible	

Single use Sensor

Parameter	Specification
Product temperature range for transportation	From 14°F to 122°F (-10°C-50°C)
Ambient operating/storage temperature	From 50°F to 95°F (10°C-35°C)
Disposal of used sensors	Dispose of as biohazard
PVC Free, LATEX Free, DEHP free, Biocompatible sensor	

11. Troubleshooting

General Troubleshooting

Table 5: General Troubleshooting

Problem	Suggested Action
The monitor is not powered ON when you press the Power button.	1. Check if the power cable is connected to the electrical socket. 2. Check if the Power switch on the back panel is switched to ON.
The signals are not displayed on the screen.	1. Check if the finger probe cable is connected correctly to the PMD-200. 2. Check if the finger probe and the single-use sensor are connected correctly to the patient. 3. Restart the monitor by turning it off and on again.
The buttons on the menu bar do not respond.	1. Use a soft stylus tip and aim to the center of the button. 2. Press the Power button on the monitor front to turn off the monitor, then turn it back on. 3. If the problem persists, contact your Medasense representative.
Cannot change setting/field is greyed out	As default, some settings are password protected in the US. If you need to change one of these settings, contact your Medasense representative

Problem	Suggested Action
The signals are of poor quality or unstable.	1. Make sure the clinical setting is not the cause (pressure against patient's hand or arm, blood pressure cuff on same hand as the finger probe, etc.). 2. Make sure patient's condition is not the cause (hypovolemia, low perfusion, contraindication, etc.). 3. Make sure the finger probe cable is well connected to the PMD-200, and there is no electrical interference from other cables. 4. Make sure the finger probe is well positioned on patient's finger, that the pleth sensor is not aligned with a phalanx joint, and that the fingertip touches the nub of the probe. 5. Make sure there is a good contact between the finger probe and the single-use sensor. 6. After stages 1-5 wait 60 seconds to allow the signals to recover. 7. If problem persists, restart the monitor by turning it off and on again.

Alerts and Informational Signals

Alerts and informational signals are displayed in the status bar at the top of the screen if signal quality is inadequate or a power supply or hard drive problem occurs.

Note

	The system assesses signal quality will not display a NOL value if the signal quality is inadequate.

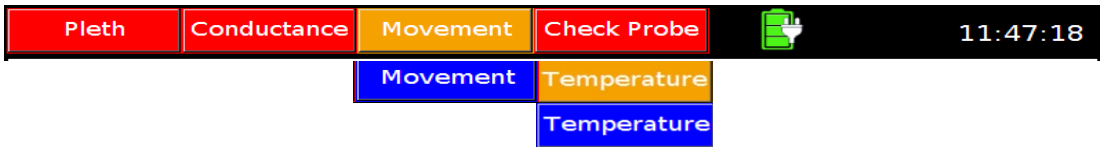


Figure 72: Alerts and informational signals displayed on the information pane

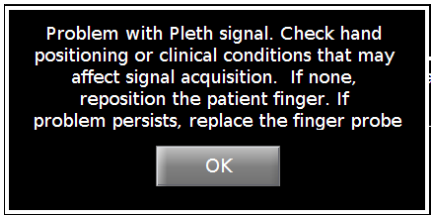
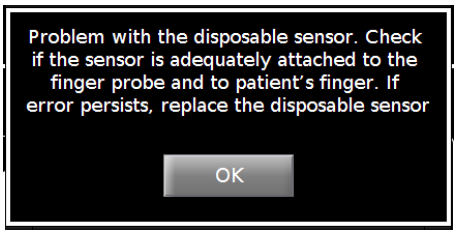
Alerts: Marked in red, representing a higher priority indication that should be addressed before continuing to use the NOL index value.

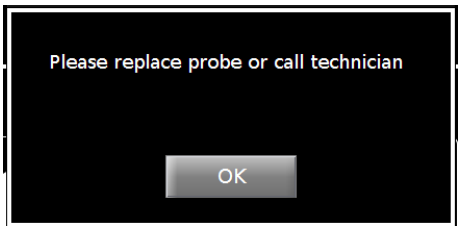
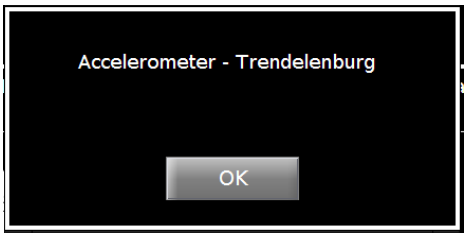
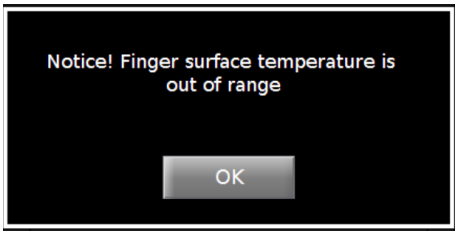
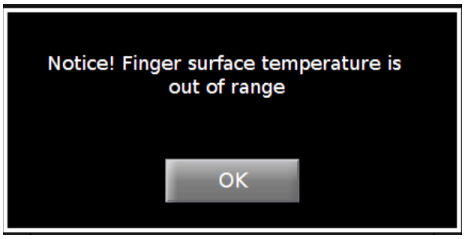
Informational signals: Marked in orange or blue, representing lower priority indications for the user's attention.

Pressing the indicator will open an internal message window with additional information about the detected issue.

The possible alerts and informational signals and their meanings are listed in the following table.

Table 6: Alerts and informational signals

Alert/Informational signal	**Meaning**	**Internal message** Pressing the indicator will provide additional information
Pleth	The Pleth (photoplethysmograph) signal is inadequate. The following reasons could apply: 1. Poor hand positioning or any limitation to proper perfusion. 2. Extreme clinical conditions (such as hypovolemia) which interfere with adequate signal acquisition. 3. The patient finger is not located properly inside the Finger Probe 4. The Finger Probe is faulty	
Conductance	The Galvanic Skin Response signal is inadequate. The following reasons could apply: 1. The single-use sensor is not located properly or not adhering adequately on the patient's finger. 2. The single-use sensor is not connected properly to the Finger Probe 3. The single-use sensor is faulty	

Alert/Informational signal	**Meaning**	**Internal message** Pressing the indicator will provide additional information
Check Probe	The system detected a problem with the Finger Probe. The following reasons could apply: 1. The Finger Probe is not connected to the monitor 2. The Finger Probe or one of its sensors is faulty - contact a Medasense representative.	
Movement	The system detects movement	
Movement	The system detects that the patient is moved to Trendelenburg/Anti-Trendelenburg position. NOL is frozen for 30 seconds.	
Temperature	The system detects that the peripheral temperature is above the validated range. Interpret NOL readings with care.	
Temperature	The system detects that the peripheral temperature is below the validated range. Interpret NOL readings with care.	

Alert/Informational signal	**Meaning**	**Internal message** Pressing the indicator will provide additional information
	Power status: Connected to power outlet (green with plug icon)	
	Battery operated with charge level indicator (red)	

If the system cannot calculate the NOL values for longer than 30 seconds, no index value is displayed in the NOL index value pane and the trend is interrupted. When the problem is solved, the NOL index and trend are displayed after a short recalibration period (the NOL pane will display the message “Recalibrating”).

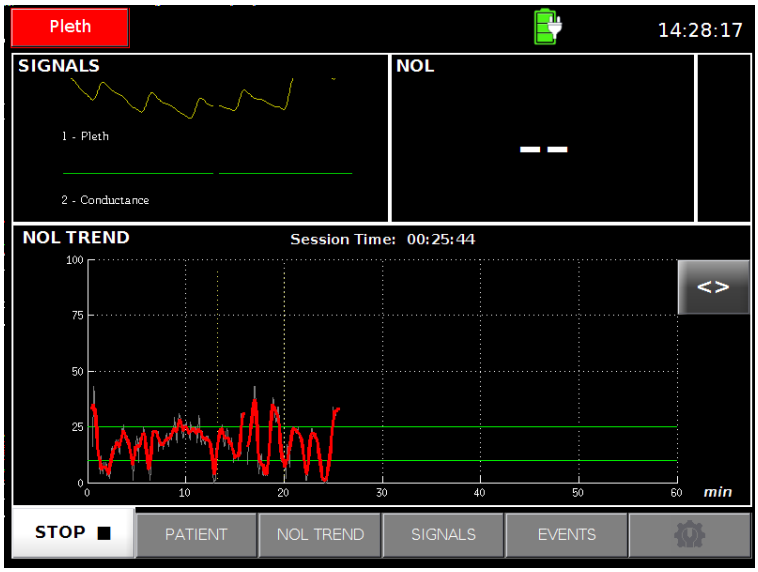


Figure 73: NOL is not displayed due to low signal quality

On-screen notifications

During routine usage of the PMD-200 system, the following on-screen notifications may appear:

Finger Probe not connected

When the system identifies that the Finger Probe is not connected to the system, the following on-screen notification will appear after 1min

Figure 74: Finger Probe not connected on-screen notification

Working on battery mode

When the system identifies switching to battery mode, the following on-screen notification will appear

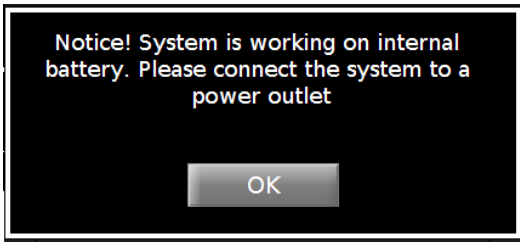


Figure 75: System is working on internal battery on-screen notification

The battery icons described in Table 6 will be red. When encountering this on-screen notification, please check the following:

1. System connection to power cable
2. Power switch is on (**–**)

RAM memory on-screen notification:

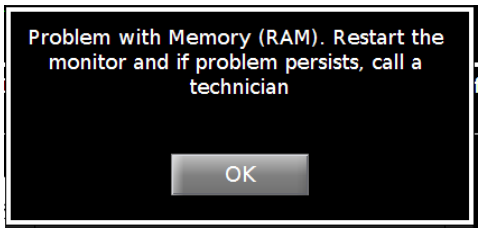


Figure 76: RAM memory on-screen notification

When encountering this on-screen notification, please restart the system. If the problem persists, please call a technician.

Low disk space

When the hard drive memory reaches 70% of its capacity the system will inform the user that the disk space is getting low.

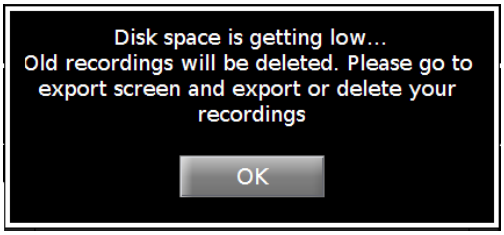


Figure 77: Low disk space on-screen notification

When encountering this on-screen notification do the following:

1. Export data in order to preserve past recording sessions
2. Delete old recordings

If the user will not delete old recordings, the system will do so automatically, in order to enable new recordings. The following on-screen notification will appear:

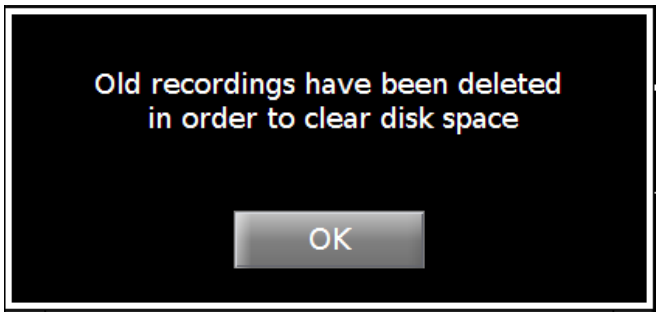


Figure 78: Old recordings have been deleted on-screen notification

Synchronization Error

When the system is powered ON, the system tests synchronization between the monitor and the sensors. If the test fails, the **Synchronization failed** on-screen notification is displayed. In the status bar, the synchronization failure icon is also displayed.

Figure 79: Synchronization Failed on-screen notification and Icon

In this case, contact your Medasense representative to arrange a service visit for testing the system.

Firmware Error

If the system firmware does not perform properly, the **Internal error** on-screen notification is displayed.

Figure 80: Internal Error on-screen notification

In this case, contact your Medasense representative to arrange a service visit for testing the system.

Processing Error

If during a recording the system identifies a processing error, the **Something went wrong** on-screen notification is displayed.

Figure 81: Something Went Wrong on-screen notification

In this case, contact your Medasense representative to arrange a service visit for testing the system.

12. Connectivity with other systems

PMD-200 has the capability to communicate and share NOL information with third-party systems in the hospital, such as the main vital sign monitors in the operating room.
This requires the installation of an optional connectivity kit (can be ordered through an official Medasense distributor) as well as set up of the third-party system by the relevant vendor.

Once connectivity is set up and installed, information from PMD-200 will be displayed on the third-party system, including (at least) the following:

1) NOL trend (and values)
2) Pleth tracings
3) Alerts and informational signals

Please note that a small but noticeable delay (usually of a few seconds) is expected between the information being displayed on the PMD-200 and it appearing on the third-party system.

At the time of writing this document, connectivity solutions are offered for displaying NOL information on:
Select Philips Intellivue™ monitors (through the Intellibridge™ connectivity platform)

Select Mindray Benevision™ monitors (through the Benelink™ connectivity platform)

Note:

Philips, Intellivue and Intellibridge are registered trademarks of Koninklijke Philips N.V.

Mindray, Benevision and Benelink are registered trademarks of Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Please contact your Medasense representative for up-to-date information about connectivity options.

13. Limited Warranty Certificate

This Limited Warranty Certificate (this “Warranty”) applies to PMD-200 monitor (the “Warranted Product”) manufactured by Medasense Biometrics Ltd. (“Medasense”), in accordance with the terms and conditions set forth below:

1. Medasense warrants that the PMD-200 Warranted Product will be free from material defects in workmanship or materials, when given normal, proper, and intended usage for a period of (i) fifteen (15) months from delivery, or (ii) twelve (12) month from installation, the shorter of the two periods or such other term as is required by applicable law to the extent longer than both periods ("Warranty Period"). Notwithstanding the above, the Warranty Period for the PMD-200 finger probe shall be three (3) months from installation.

2. Medasense’ sole obligations under this Warranty are to repair or replace any Warranted Product (or part thereof) that is determined by Medasense to be covered by this Warranty and to be materially defective in workmanship or materials provided that the customer or Medasense’ distributor, as applicable, has given written notice of such Warranty claim within the Warranty Period and shipped the Warranted Product back to Medasense’ factory or such other place designated in writing by Medasense with freight prepaid. All original Products or parts that were replaced by Medasense shall become Medasense’ property. Repair or replacement of Warranted Products under this warranty does not extend the Warranty Period.

3. Following receipt of a Warranted Product, if Medasense reasonably determines that a repair or replacement is covered by the Warranty, Medasense shall reimburse the costs of shipping the repaired or replacement Warranted Product to the customer. Risk of loss or damage during shipments under this Warranty shall be borne by the party who pays for the shipping of the Warranted Product. Warranted Products shipped by customer under this Warranty shall be packaged in the original shipping container or equivalent packaging to protect the Warranted Product. If customer ships a Warranted Product in unsuitable packaging, any physical damage present in the Warranted Product on receipt by Medasense (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of the customer.

4. This Warranty does not extend to any expendable components, single uses and/or supply items such as, but not limited to, electrodes, cables and/or Warranted Products or part thereof that have been: (i) subject to misuse, neglect, or accident;

(ii) damaged or are non-conforming by causes external to the Warranted Product, including but not limited to failure of or faulty electrical power; (iii) stored, installed, operated, used or maintained in violation of Medasense' instructions or specifications; (iv) employed or affixed with attachments, features or devices that are not supplied by Medasense for such use or are not approved in writing and in advance by Medasense for such use, or improper matching of Warranted Product components; (v) modified, disassembled, serviced, repaired or reassembled by anyone other than Medasense, unless authorized by Medasense. Medasense shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear. Medasense 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 Medasense or (c) with respect to any product sold under a brand name other than Medasense.

5. ALL PRODUCTS ARE SUPPLIED "AS IS". THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY FOR MEDASENSE PRODUCTS, EXTENDS ONLY TO THE CUSTOMER, AND IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

6. Medasense does not warrant nor make any representation regarding the results of its customer's and/or any third party's use or omission to use the respective Warranted Product and/or any information or data provided by the respective Warranted Product in terms of inter alia correctness, accuracy, completeness, reliability or otherwise.

7. THE REPAIR AND/OR REPLACEMENT OF WARRANTED PRODUCTS (AND/OR ANY COMPONENTS THEREOF) IN THE MANNER PROVIDED ABOVE WILL CONSTITUTE FULL AND FINAL FULFILLMENT OF ALL OF MEDASENSES' OBLIGATIONS WITH RESPECT THERETO, AND IN LIEU OF ALL OTHER WARRANTIES, GUARANTEES, PROMISES, OR REPRESENTATIONS, WHETHER WRITTEN, ORAL OR IMPLIED, WHICH ARE HEREBY SPECIFICALLY DISCLAIMED AND EXCLUDED, SUCH THAT ANY OTHER WARRANTY, INCLUDING WITHOUT LIMITATION WITH RESPECT TO MERCHANTABILITY, SATISFACTORY QUALITY, ACCURACY, UNINTERRUPTED PERFORMANCE OR FITNESS FOR A PARTICULAR PURPOSE IS HEREBY EXPLICITLY DISCLAIMED.

8. The effectiveness of this Warranty with respect to each Warranted Product shall be subject to and contingent upon the full payment of the consideration due for such Warranted Product by the customer to Medasense.

14. Appendix A: Algorithm Description

The proprietary signal acquisition sensor platform (the combination of the finger probe and the single-use sensor) acquires physiological signals. Using advanced algorithms, the system processes and analyses multiple nociception-related physiological parameters and their various derivatives, reflecting the sympathetic nervous system response to noxious stimuli.

Using the GSR and PPG signals, the NOL algorithm extracts and analyses nociception-related physiological parameters and derivatives: pulse rate, pulse rate variability, pulse wave amplitude, skin conductance level and their various derivatives. Then a patient's personalized nociception signature is established and continuously monitored.

The accelerometry (ACC) and Temperature signals are used as guardrails, and alert the user of conditions which may impact signal acquisition. These signals do not impact NOL calculation directly.

Note

	The PMD-200 temperature sensor does not measure core temperature. The aim of this sensor is to provide information to the user on conditions in which extreme peripheral temperatures may impact signal acquisition. The sensor does not provide information on the patient's clinical condition.

The NOL algorithm was developed using a random forest machine-learning model approach. The major strength of this method is the ability to integrate a substantial number of predictors (physiological features) of different nature and to describe their nonlinear relations, which contributes to the successful inference of its output.

The NOL algorithm was trained on tens of thousands of data points to characterize nociception patterns in terms of physiological response, interactions and correlations between different variables, including multiple mathematical derivatives and various time derivatives of the parameters taking analgesia medication levels into account.

Note

	For more information on NOL index training and development, see NOL white paper available at www.medasense.com.

The output of the algorithm is the Nociception Level (NOL), a discrete ordinal number between 0 and 100 with 0 indicating no nociception and 100 indicating extreme nociception.

The NOL algorithm was validated in bench tests and in clinical trials, and was found to be sensitive and specific when used according to the recommendations provided by the manufacturer. The algorithm is locked with no unsupervised learning occurring.

15. Appendix B: PERMITTED USE

The PMD-200 and/or indications, metrics, alerts, notices and other types of information and data that it may generate with regards to NOL - Nociception Level Index® ("**NOL Data**") may be used solely for the following purposes: (i) providing medical care to patients; (ii) conducting clinical research; and (iii) analyzing and predicting patient outcomes (collectively, "**Permitted Use**").

Any use of the PMD-200 and/or NOL Data for any purpose other than the Permitted Use and/or in order to develop or create a similar or competitive product or any commercial application, is expressly prohibited.

PROPRIETARY INFORMATION

The PMD-200 and its accompanying documentation contain proprietary information that is the property of Medasense. Medasense expressly retains any and all rights, title, and interest in and to all intellectual property rights incorporated into, associated with and/or covered within the PMD-200, as well as any and all insights, conclusions, interpretations, predictive models or other know-how ("**Insights**") generated, derived from, or made in connection with the use of the PMD-200, whether utilized independently or in combination with other systems or devices, and to any and all adaptations, modifications, and/or derivative works created based on such Insights.

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