Frequently Asked Questions

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1. Do comorbidities affect the NOL index?

Arrhythmia

Arrhythmia interrupts the normal heart rhythm and causes an irregular beat. Some rhythms, like atrial or ventricular premature beats occurring sporadically, do not have haemodynamic effects.
Other more severe arrhythmias, like atrial fibrillation/flutter, and ventricular tachycardia or fibrillation, as well as cardiac arrest, do not allow proper signal acquisition and analysis and are contraindications for the use of the NOL index.

Diabetes

Diabetes is not a contraindication to pain monitoring by the NOL Index. Diabetes can cause a chronic, subtle insufficiency of the small vessels in the periphery, as well as evolving peripheral neuropathy, and may cause a reduction in blood flow in the peripheral vessels where the measurements are taken. However, since the device is calibrated per patient and measures the changes in parameters, the parameters at basal level are recorded during the calibration of the device for the specific patient and will respond to noxious stimuli.
If perfusion challenges impact the PPG signal, the signal quality alert will notify the physician that the signal is not valid.

Peripheral vascular disease

Similarly to the previous (diabetes) section, as long as there is a physiological response to the noxious/painful stimuli, the system should recognize the change. In cases where peripheral vascular disease affects the signal in such a way that the signal is not adequate for measurement, the system's signal quality alert will be shown.

Obesity

Obesity is not a contraindication to pain monitoring by the NOL index. Some of the studies performed with NOL have included patients with BMI of 30 and higher. No noticeable differences in performance were found within this target population. However, obese patients may exhibit increased variability in their response to opioid therapy due to PkPd considerations in this cohort (Ingrande & Lemmens, 2010). Thus, NOL monitoring would be very valuable for this population.

Perioperative hypothermia and/or hyperthermia

NOL is not directly impacted by temperature. However, extreme heat or cold conditions may affect blood flow and sweating. For this reason, NOL was validated over a wide range of temperatures. Outside the validated range, a 'TEMP' alert is shown on the monitor while NOL is still presented.

Trendelenburg Positioning

Trendelenburg positioning may result in sharp changes to systolic, diastolic and mean arterial blood pressure, while mean heart rate decreases. The system will recognize the event using the accelerometer, activate the ACC alert (blue indicator)

and freeze the NOL value (appearing as a straight line on the graph). After ~30 seconds, NOL will calibrate and continue to measure the physiological state of the patient as usual.

2. Is NOL intended for use throughout the surgical continuum of care?

PACU, ICU, Surgical ward

The majority of clinical evidence today has been generated in an OR setting. Initial indications from early studies in ICU are encouraging and show that NOL monitoring can distinguish between painful procedures (endotracheal suctioning), non-painful procedures (blood cuff inflation) and periods of rest in ICU ventilated patients. NOL was significantly associated with pain intensity and CPOT scores. (Shahiri et al, 2020). NOL is mentioned in the ICU Guidelines for the Prevention and Management of Pain. (Devlin et al, 2018). With regards to physiological measures of pain, the guidelines recommend that when behavioral scales are impossible to use (i.e. in unresponsive patients), other technology should be explored such as NOL. Clinical guidance for the use of NOL in awake patient scenarios will be available following future validation studies.

3. How do different drugs affect the NOLindex?

Vasoactive drugs

As these medications affect the autonomic system and the vital signs, NOL is affected by such drugs. The effect can be associated with two aspects:
Medications *administered prior to calibration.* The effect of these medications is an integral part of the calibration, and the changes in NOL values will be based on changes in physiological parameters from that point forward.

Medications administered during the monitoring. These medications will have a mostly transient effect on NOL values (e.g., vasoactive drugs will affect NOL values for 2-3 minutes, until the body adjusts to the changes and the NOL returns to previous levels).Based on our observations, after administration of boluses of ephedrine or phenylephrine, it takes about 2-3 minutes for NOL Index values to revert. These drugs have a transient effect on NOL values (seconds to minutes).

Beta blockers

The NOL index shows significant reaction to noxious stimuli even in patients receiving chronic beta-blocker treatments. NOL monitoring during surgery for patients receiving chronic beta- blocker therapy was shown to be just as reliable as for patients not receiving such treatment (Bergeron et al, 2021).. For more information, please see our full list of publications - https://medasense.com/wp-content/uploads/Medasense-LIST-of-publications.pdf

Opioids

Opioids are the most common analgesic agents used in the OR. To date, NOL index performance has been studied in patients treated with the following opioids: fentanyl, remifentanil, sufentanil, morphine, hydromorphone. All intraoperative opioids induce a decrease in the NOL Index as they provide analgesia. There will be differences in the time and duration of the NOL response depending on the type of opioid (short acting vs long acting) - and the dosage and the administration method.

Can NOL be used with all analgesia protocols? (Opioids, OFA, volatile, TIVA)

Based on our experience, NOL can be used with various analgesia protocols including short-term and long-term opioids, opioid free analgesia (OFA), volatile and TIVA.

Peripheral nerve blocks

Peripheral nerve blocks combined with general anaesthesia can reduce surgical pain and should be well reflected by NOL. Decreased NOL values in this context would not be an artifact, but instead the expected response to an analgesic treatment. NOL values close to zero when using regional blocks and epidurals may be observed reflecting the blocking of the nociceptive input.

Epidural analgesia

Epidural analgesia combined with general anaesthesia can reduce surgical pain and should be well reflected in NOL. Decreased NOL in this context would not be an artifact, but instead the expected response to an analgesic treatment.

Is NOL affected by muscle relaxants?

NOL values are not affected by administration of muscle relaxants, as the muscle relaxant acts via a separate molecular mechanism. In validation studies, administration of rocuronium (or other similar agents) did not alter NOL values, demonstrating that muscle relaxants do not affect the NOL Index.

Ketamine

Ketamine is used as either an analgesic supplement or the main analgesic drug in many opioid free anaesthesia (OFA) protocols.

Keep in mind two important considerations relating to ketamine:

a. Administration of a significant ketamine bolus (e.g. during induction) may cause an INCREASE in heart rate as well as blood pressure (unlike opioids,which cause the reverse effect). Due to its effect on haemodynamics, ketamine may cause a TRANSIENT NOL INCREASE that may last up to 4 minutes (max ~90-120 secs after the injection). This NOL response is dose dependent. This should be anticipated when interpreting the NOL trend in these scenarios.

b. Due to haemodynamic instabilities caused by ketamine, it is usually administered (especially in OFA protocols) with stabilizing drugs like alpha agonists (e.g. clonidine). Alpha agonists administered alone significantly decrease the

haemodynamic response, causing heart rate and blood pressure to become almost unresponsive (even during noxious events). These combinations may also marginally decrease NOL reactivity. However, NOL should still be able to respond and detect nociceptive stimuli better than all other parameters/indices. We intend to provide specific recommendations and evidence in the future.

Please refer to the 'NOL Intraoperative Medication Guide' for more information on how different drugs affect both the NOL index and other measurements.

CO2 (insufflation)

Insufflation with CO2 increases intra-abdominal pressure (pneumoperitoneum).

Laparoscopic surgery involves insufflation of a gas (usually carbon dioxide) into the peritoneal cavity producing a pneumoperitoneum. This causes an increase in intra-abdominal pressure (IAP). Carbon dioxide is insufflated into the peritoneal cavity at a rate of 4–6 liter/ min to a pressure of 10–20 mm Hg. The pneumoperitoneum is maintained by a constant gas flow of 200–400 ml/min. The raised intra-abdominal pressure of the pneumoperitoneum, alteration in the patient's position and effects of carbon dioxide absorption cause changes in physiology, especially within the cardiovascular and respiratory systems. As a result, HR and BP may increase. During insufflation there is a transient increase in NOL values due to pressure/nociception. As we understand, the pressure caused by insufflation may introduce a nociceptive response picked up by the NOL (see above).

Methylene Blue

Methylene blue does not affect the NOL index, despite altering pulse oximetry readings due to the wavelength. NOL only has one wavelength, whereas pulse oximetry has two, so they will not be affected in the same manner.

4. Technical FAQs

Is NOL a black box algorithm?

The NOL index is not a black box algorithm. The algorithm development process is described in the Journal of Clinical Monitoring and Computing (2013) 27: 659:"Monitoring the nociception level: a multi-parameter approach" by Nir Ben-Israel, Mark Kliger,Galit Zuckerman, Yeshayahu Katz and Ruth Edry, as well as in a white paper created by the company.

The NOL algorithm was developed using a Random Forest machine-learning method. A Random Forest model is a collection of hundreds of decision trees.

Each of these trees represent an expert that was trained to understand the patient's nociceptive states by analyzing the physiologic responses features to a noxious stimuli. Each tree was trained by a different subset of physiological responses, where some subsets overlap, which increase the "individual" decision making of each tree. This approach is highly important in a complex system such as the ANS. The NOL approach considers multiple experts to get a more reliable overview of the patient's nociceptive state.

During the training phase, a database comprising multiple examples of pairs was constructed. Each pair is comprised of the physiological features and the corresponding reference clinical score of nociception. This clinical score, named the Combined Index of Stimulus and Analgesia (CISA), is a linear combination of the stimulus intensity during surgery and the effect of the analgesic drugs. The model was trained to recognize the combinations of physiological features that would produce a CISA level of a certain score, to be able to detect and reflect nociception. The resulting model captures the patterns that best describe the response of all parameters and derivatives matching the different CISA levels.

The resulting NOL algorithm is loaded in the monitor and is not further refined or "taught" during the clinical use of the monitor.

During monitoring sessions, the algorithm draws on hundreds of decision trees, each of which is based on a large number of variables. Each such tree makes an independent decision regarding the estimated nociception level of the patient, based on the data it analyzed. Each of the decision trees is constantly "polled" by the algorithm and a mathematical combination of the output of all the decision trees delivers a value that is then processed and displayed as the NOL index on a scale of 0-100. The more the pattern is similar to "high nociception response" examples – the higher the NOL Index will be. Conversely, the more the pattern is similar to "lower nociception response" examples – the lower the NOL Index will be.

NOL is a continuous, relative, personalized measure of nociception. The initial NOL values for any given patient are calculated based on normalisation to a preloaded population database while monitoring. As the patient's own data accumulates during the monitoring session, the calculation of the NOL value is normalized more to the patient's data and less to the large population statistics.

Does NOL provide information about hypnosis? If not, how can it be that hypnosis, analgesia and the respective drugs are related?

Both hypnosis and analgesia are part of the anaesthesia procedure. Each part is controlled and managed by different biological mechanisms and medications. The NOL index was developed on the basis of pain-related physiological parameters. Thus, it is intended to detect nociception during the surgical procedure. Hypnosis is not intended to be monitored by the NOL Index.

However, there is some synergy between them. Common practice today suggests that the two are linked by the fact that the deeper the hypnosis, the less analgesia is required, and vice versa. However, always keep in mind that both these elements need to be optimized and overdose/underdose of hypnotic and/or analgesic medication may have negative outcomes.

Due to this synergy, when the hypnotic component is insufficient, it is common to see both NOL and BIS reflect this (by increasing), because the sympathetic response will be impacted by the depth of anaesthesia.

During our clinical studies, the bispectral (BIS) index was used to monitor the patient's depth of anaesthesia. Data analysis demonstrated that the BIS index did not change

when the physician applied a tetanic stimulus to the patient, while the NOL Index increased significantly following the stimulus and declined thereafter to its basal level. This finding illustrates the difference between the analgesia and anaesthesia mechanisms.

For more details, please review this white paper – https://medasense.com/nol-technology-resources?doc-title=NOL%20ALGORITHM%20WHITE%20PAPER

How does the system react on awake, healthy subjects? Any correlation?

The current NOL technology was trained and validated on patients under general anaesthesia. Our experience with awake patients is limited but early results indicate that NOL can assess pain in awake subjects, if the subject is quiet, relaxed and does not move.

How does patient movement impact NOL?

In general, patients under general anaesthesia do not move, since they are subjected to adequate hypnosis and are often given muscle relaxants. However, the PMD-200 also detects movement, using an accelerometer that provides with the necessary information regarding movement,. The software analyzes the data, takes into account whether the movement is related to the procedure, (e.g., Trendelenburg position or a change in the patient's position during the surgery), an artifact or other type of movement, and uses this information during the analysis. The system identifies whenthe data is valid or not, and presents an alert for movements/artifact, if necessary.

Why are heart rate and blood pressure not sufficient factors to measure pain?

Heart rate (HR) and blood pressure (BP) are the most important vital signs in monitoring the human body. However, they are not pain-specific parameters. There are many clinical and medical factors that can lead to changes in HR and BP, even if there is no change in the patient's pain level. Thus, the sensitivity and specificity of HR and BP to changes in pain level is relatively low, as shown by Edry R et al. (Anesthesiology, Jul. 2016).

If HR and BP are not sufficient why were they used vs. NOL in validation trials?

Although HR and BP are not sensitive and specific indicators, they have been used as the standard tool to detect pain since there was no other parameter or index shown to be superior to these vital signs… until the NOL Index.

When do you establish the baseline? After or before induction?

In general, we recommend initiating monitoring right before induction of anaesthesia when the patient is in their final position. However, the index only has clinical utility after induction.

How does the NOL calibrate for an individual patient?

The NOL index is displayed after 30-60 seconds of gathering data, and is refreshed on the screen every 5 seconds.

NOL is a continuous, relative, personalized measure of nociception. The initial NOL values for any given patient are calculated based on normalisation to a preloaded

population database. While monitoring, as the patient's own data accumulates during the monitoring session, the calculation of the NOL value is normalized more to the patient's data and less to the large population statistics.

Is NOL an absolute scale?

NOL is a relative scale with values between 0 to 100. NOL is calibrated per patient at the beginning of the monitoring session. Once the calibration step is complete and the initial NOL value is set, the patient's physiological parameters are used to continuously calculate the NOL. The values displayed over time are normalized to the patient's data and to the large population data pre-loaded in the data base –providing a personalized nociception measure.

How accurate is your system?

A series of clinical validation studies demonstrated the high accuracy of NOL with an AUC of 0.93, sensitivity of 0.89 and specificity of 0.97 (Edry et al., Anesthesiology, 2016). It has also been demonstrated that NOL remains unaffected by changes in haemodynamic states of the patient at different doses of analgesia (Martini et al., Anesthesiology 2015).

Can NOL be used during paediatric surgeries?

There are no regulatory restrictions to using NOL with patients under 18 in the EU, Israel, Australia and Canada. The main limiting factor is the size of the finger probe. We are conducting ongoing studies on paediatric patients and the initial feedback from clinicians has been positive. An initial pilot study has been published in the Journal of Paediatric Anesthesia demonstrating the performance of the device in children aged 1-5 years. Physician discretion should be exercised when using the device in paediatric surgeries.

Are the NOL values different for gender/age/type of surgery? If women are generally more pain-sensitive, how can you see no difference in your subgroup analysis?

To date, clinical studies did not find a difference in the NOL response for age or gender for different types of surgery. Since the algorithm is personalized to each patient,and measures the changes within the patient, and the patients are under general anesthesia, NOL is not influenced by any subjective differences in pain sensitivity that have been reported in awake men and women.

A retrospective study was conducted based on a database of 447 patients to support the generalizability of the algorithm). The NOL number was found to be agnostic to different patient demographics (age, sex, BMI, ASA status) and anesthetic approaches (remifentanil/fentanyl, sevoflurane/desflurane, propofol).

What if the finger probe is not able to pick up any of the signals or parameters (cardiac variability, accelerometer, skin temperature or skin conductance)?

PMD-200 is a complex monitoring technology intended for use as an adjunct monitor, a supplement to clinical judgment. As with any monitored parameter, artifacts and poor signal quality may affect measurement. The NOL technology is able to recognize poor signal quality

PRIOR to any algorithm calculations. A signal quality alert is displayed in the status bar at the top of the screen.

How does the algorithm compensate when the signal quality of one parameter is poor?

The core capability of the multiparameter-based approach, is accuracy (or performance) of the index due to the multiple data streams and interactions between them.

When a channel of information/parameters is compromised, the algorithm will compensate for this missing information as long as the information received from the other channels/parameters provides a clear enough picture. It does this by applying the data received from other measurement channels as well as some parameter derivatives that collect information over longer time periods (even minutes), and therefore is less sensitive to a momentary loss of signal.

However, this is only possible to the extent that there is still sufficient information to provide a reliable NOL.

If the entire signal quality is poor, or one of the information signals disappears completely such that it doesn't enable the rest of the signals to compensate for the data loss, an alert will be turned ON for the relevant measurement channel. If there is no improvement and the algorithm cannot identify a clear physiological pattern, no index value/trend will be displayed. When the problem is solved, the NOL Index and trend will be displayed again.

This mechanism ensures that as long as the NOL is displayed, it is clinically relevant and reliable.

How much weight (or signal strength) does each parameter have in the NOL Index calculation?

NOL is not a linear combination of parameters, and as such it is not relevant to quantify the weight of each parameter.

The algorithm quantifies a complex pattern of correlations and relationships between the different parameters as well as their mathematical derivatives and their changes over time.

The PPG and GSR signals and their parameters and derivatives, are the most critical, while the TMP and ACC and their parameters and derivatives have a secondary contribution. However, the combination of all signals is required to reach NOL performance level. For detailed information, please refer to our white paper, white paper, "Introducing the NOL® Nociception Level index Algorithm – Technical Overview".

Is there a paper illustrating and explaining the mechanism by which the nociceptive stimulus affects the central nervous system to cause more postoperative pain, leading to increased use of analgesics?

Yes. Please review the following:

Chronic Pain as an Outcome of Surgery: A Review of Predictive Factors

Preventive Analgesia to Reduce Wound Hyperalgesia and Persistent Postsurgical Pain: Not an Easy Path

Persistent postsurgical pain: risk factors and prevention

Surgically-Induced Neuropathic Pain (SNPP): Understanding the Perioperative Process

Which surgeries are most useful to target with NOL?

In general, NOL seems to demonstrate strong utility when monitoring long surgeries that are more painful, or/and when the patient is atypical of the general population (e.g., frail/opioid tolerant/obese). The following surgeries are good targets for NOL:

SURGERY	The Clinical Challenge	NOL Solution/ Utility
THORACIC	Painful surgery. Post-operative pain is particularly undesirable as it impedes patient's recovery of respiratory function	NOL-guided surgery improves postoperative pain scores
	Regional blocks are typically used with systemic opioids	NOL can help quantify technique's impactand help surgeons adjust surgical techniques and analgesia regimen
ABDOMINAL	Opioids contribute to postop ileus, slowing the return of bowel function, extending hospital length of stay (big component of ERAS outcomes)	NOL guides less remifentanil use intraoperatively, with a potential reduction in LOS
	Recovery from major procedures and patient satisfaction levels diminish when pain is inadequately managed	Reduced post-operative pain and prevention of chronic pain development through adequate intraoperative analgesia
BARIATRIC	Patients are susceptible to opioid induced respiratory depression (OIRD) due to high prevalence of obstructive sleep apnea & difficulties with accurate dosing.	NOL guided surgery helps personalize opioid sparing and opioid free regimens to patient's requirement
	Hence opioid sparing and opioid free regimens are recommended which can be difficult to tailor and may cause HD instability	NOL helps the clinician evaluate the analgesic effect regardless of analgesic regimen
SPINE	Spine procedures are long and require short acting opioids.	Big opportunity for opioids reduction.
	Often don't include muscle relaxation agents	NOL allows close titration to avoid painrelated movement
	Opioid tolerant patients – difficult to identify effective dosing	NOL may better reflect patient's nociception level

	Tend to use regional nerve blocks, but when combining with general anaesthesia, it can be difficult to quantify block effectiveness	NOL identifies partial, complete or non- effectiveness of the block and allows better titration of analgesia according to patient needs
ORTHOPEDIC	Total hip replacement surgeries are very common in elderly patients with additional comorbidities. These patients are particularly sensitive to opioids and at higher risk of overdose	NOL allows a better titration of analgesiato meet individual needs and safely reduce opioid dosages where possible.

Can NOL-guided analgesia impact postoperative pain?
In a two-center randomized controlled trial, it was found that patients receiving intraoperative NOL-guided fentanyl administration during sevoflurane anesthesia for abdominal surgery demonstrated decreased pain in the PACU (Meijer et al, 2020). These results are likely due to improved objective intraoperative fentanyl management. However, in this trial postoperative pain scores were taken only within 90 minutes post-surgery and future studies in larger, more diverse populations should address the long-term benefits of intraoperative analgesia guided by the NOL index. These results were replicated in the Fuica et al study from 2022.

Can NOL-guided surgery reduce the cost of care?
Reducing hypotension events during surgery can reduce the burden of care related with AKI and MI, and enable ROI within the first year of purchase (Saunders R., Weissbrod R., 2020). A dedicated excel model that can calculate hospital specific data, can estimate the time to achieve ROI for a specific hospital.
Furthermore, reduced postoperative pain scores can reduce the associated cost of care. An economic value assessment examined cost savings related to acute postoperative pain treatment following NOL-guided anaesthesia. For further details on this please contact your Medasense representative.

The study by Ruetzler et al (2023) showed no reduction in post operative pain at 60 minutes with NOL guided fentanyl analgesia. How can this be explained?
This was a controlled study in mainly colorectal surgery (n=72). The primary endpoint was an improvement of 1.25 in NRS pain scores in the PACU in the group that received intraoperative NOL guided fentanyl analgesia.
The study results did not show a difference in pain scores at 60 minutes. Patients in the NOL guided group received higher doses of intraoperative fentanyl than in the control group but less morphine in the PACU. No safety events were noted in the study.
The study *did not follow the manufacturer's recommended clinical guidance* to consider dosing fentanyl if the NOL is above 25 for 60 seconds or more that was followed in previous studies. In the CCF protocol the waiting period was 30 seconds which likely contributed to the difference in fentanyl between the groups but did not translate into improved pain scores (although less morphine was given in the

PACU).
Therefore it is important to educate users on the validated clinical guidance.

How does NOL perform in patients with dark skin tone?
The photoplethysmograph (PPG) signal and derived measurements in the PMD-200 are used for assessing volumetric changes during pulsatile flow in the vascular bed of the patient's finger. The PPG sensor measures the light reflectance at a single wavelength (940 nm).
In contrast, PPG sensors used to derive arterial oxygen saturation (SpO2) shine light through the skin and measure the difference in light absorbance at two wavelengths (660 nm and 940 nm).
The absorption of epidermal melanin (present at higher levels in dark skinned individuals) is high in the visible region of the spectrum (660 nm) and very low in the near infra-red region of the spectrum (940 nm) – the wavelength used in NOL technology.
Although SpO2 and NOL derive a physiologic measurement from the PPG, they do so using different wavelengths and properties of light. NOL uses a single wavelength that is not affected by skin tone.
A grading analysis depicting the NOL response range to noxious stimuli of different intensities was conducted based on a database of 447 patients (the retrospective study cohort used to support the generalizability of the algorithm). Included in this analysis were 8 patients with dark skin pigmentation. 32 datapoints obtained from dark skinned patients were identified and analysed. The results demonstrated that all datapoints from black and multiracial patients fell within the range of the existing box plots with no outliers. Although the sample size did not allow statistical analysis, the descriptive data suggests that NOL performance in black and multiracial patients is not different to the performance shown for the large database.

Is the accuracy of NOL affected if the finger probe is placed on different fingers on the same patient?
No, Medasense has verified in a study that placing the finger probe on different fingers does not affect the accuracy of NOL readings.