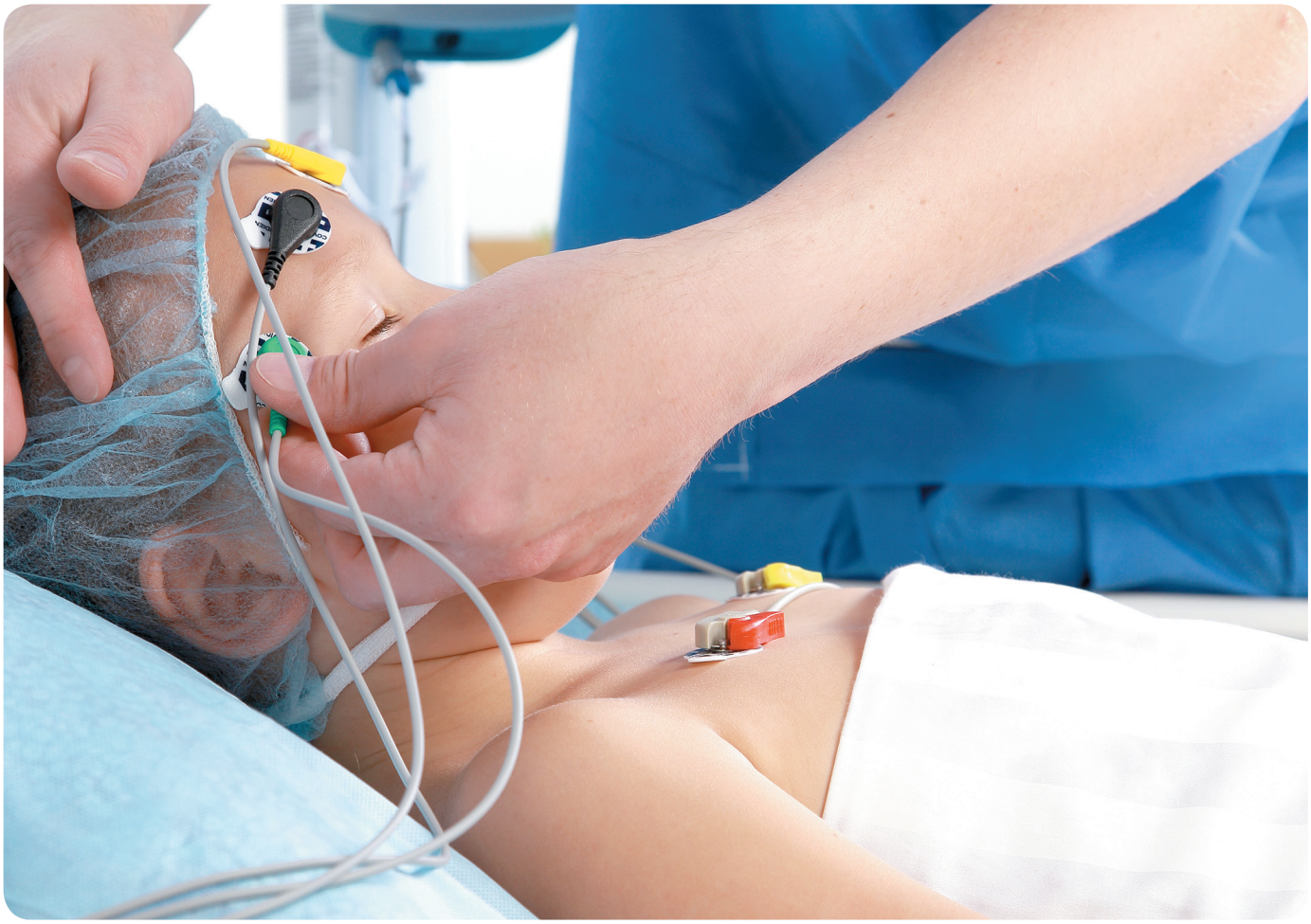
# Depth of Anesthesia and Sedation Module

OEM solution

Complete solution for anesthesiologists:
Monitoring of Sedation Level

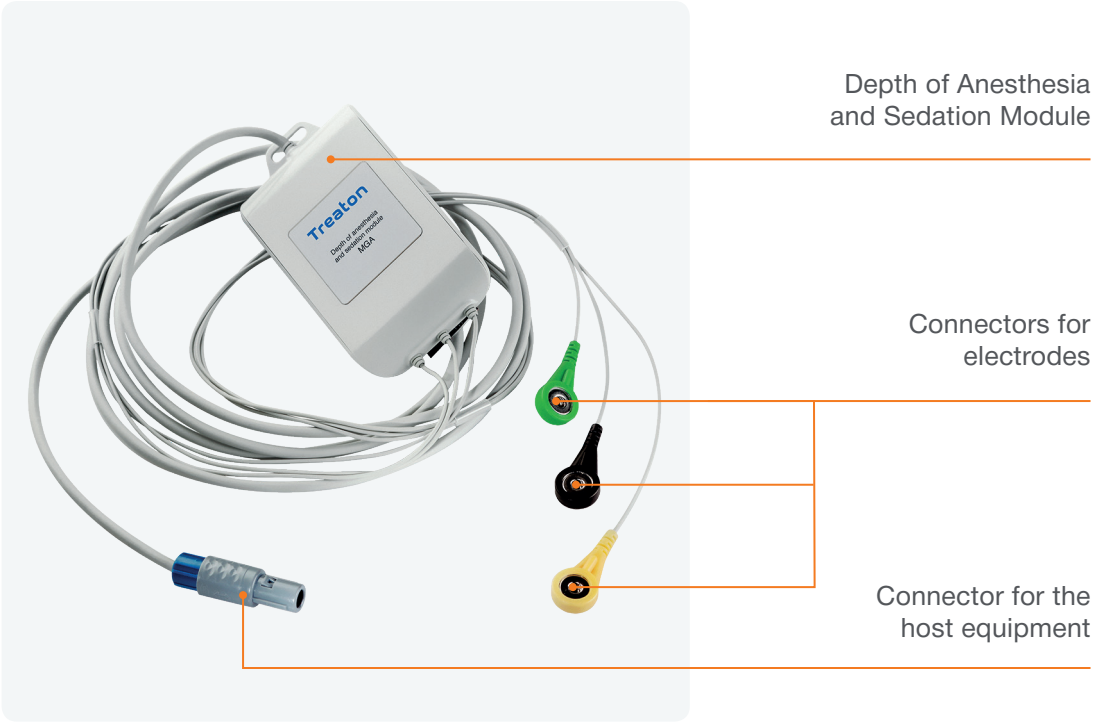


Depth of Anesthesia and Sedation Module is designed to provide long and continuous monitoring of the Brain Activity Index (AI).

**Application:** anesthesiology, including perioperative period, resuscitation, intensive care, procedural sedation.

This is the solution for the daily routine depth of anesthesia monitoring, a standard monitoring tool in a medical institution, thereby increasing the patient's safety and quality of patient care.

Depth of Anesthesia and Sedation Module can be connected to the monitoring host device and transfers parameters of the Brain Activity Index, Signal Quantity Index, Electromiographic Component, Suppression Rate and additional states and statuses.



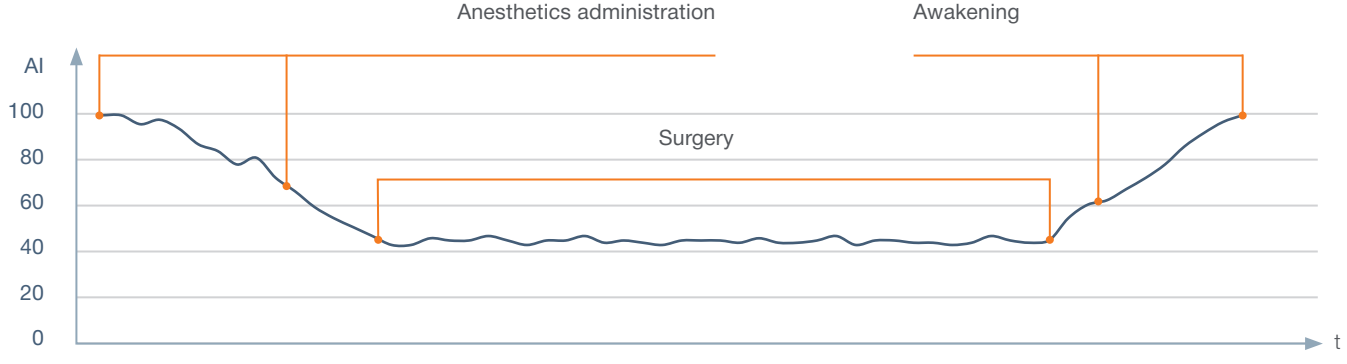

## Identified Parameters

| | | |
|---|---|---|
| AI | Brain Activity Index | Indicates the level of consciousness depression by analyzing EEG, taking into account information on typical signs of anesthetics' impact on patients |
| SR | EEG Signal Suppression Rate | Reflects the relative duration of EEG suppression segments in the current time interval |
| SQI | EEG Signal Quality Index | Reflects noise influence on EEG signal |
| EMG | Electromyographic Component Level | Indicates the level of electrical activity of facial muscles |
| Z1, Z2, Z3 | Electrode impedance | Demonstrates the quality of electrodes application and electrodes' electric contact with the patients' skin |

## Interpreting AI (Brain Activity Index) Data*

| AI value | Clinical stages of anesthesia | Clinical signs |
|---|---|---|
| 90–100 | Awake | |
| 80–90 | Anesthesia stage I — light sedation | Incomplete awakening, patient opens eyes and maintains visual contact in response to a voice for 10 seconds or less |
| 60–80 | Anesthesia stage II — sedation | Patient moves and opens eyes in reaction to voice but does not fix the eyes — no visual contact or no response to voice but eye movements and eye opening after a physical stimulation persists |
| 40–60 | Anesthesia stage III — surgical state | No response to voice or physical irritants |
| 30–40 | Anesthesia stage IV — deep anesthesia, BS (burst–suppression) patterns emerge | |
| 20–30 | Anesthesia stage V — deeper anesthesia compared to stage IV, length of suppression episodes may reach 10 seconds | |
| 0–10 | Anesthesia stage VII — extremely deep anesthesia, suppression episodes constitute 75% and more of the whole signal duration | |

* According to a generally accepted classification of anesthesia stages.



# Advantages of Anesthesia Depth Monitoring

## Potential Effects of Inadequate Sedation*

With continuously raising requirements to ensuring patient's safety, physicians have to provide more careful control of using anesthetics, hypnotic drugs or sedatives. According to the statistics, more than 69% of patients demonstrate inadequate sedation — either insufficient or too deep.
This can cause adverse effects both during the surgery and at the post-operative stage.

## Potential Effects of Inadequate Sedation*

| Insufficient sedation | Excessive sedation |
|---|---|
| Excitation | Depressed breathing, hypotonia, depressed gastrointestinal tract motility |
| Sleep violations | Prolonged depression of consciousness |
| Myocardial ischemia | Prolonged ventilation duration |
| Unsynchronized ventilation | Prolonged stay at ICU and clinic in general |
| Self-extubation | Increased healthcare costs |
| Posttraumatic distress and depression | |

* Mehta S. Sedation Strategies in the Critically Ill // Yearbook of Intensive Care and Emergency Medicine, 2005.

Using MGA minimizes the adverse effects of inadequate sedation, ensuring optimal and predictable sedation level and patient's quicker recovery from anesthesia.

## Preventing Anesthesia Awareness

Anesthesia awareness is post-operative recollections of the event happening during general anesthesia, caused by misalignment between the need for anesthetic and its delivery.

The following patients are in the risk group for anesthesia awareness:

- taking opiates or alcohol;
- using neuromuscular relaxants;
- suffering from respiratory problems;
- with previous cases of accidental awakening during the surgery;
- with a co-pathology;
- elderly.

Anesthesia awareness cannot be measured directly. Traditional clinical signs like motions, tachycardia, hypertension, pupillary reaction and lacrimation are supposed to be unreliable predictors of anesthesia awareness but they must be monitored in every patient and considered substantially.

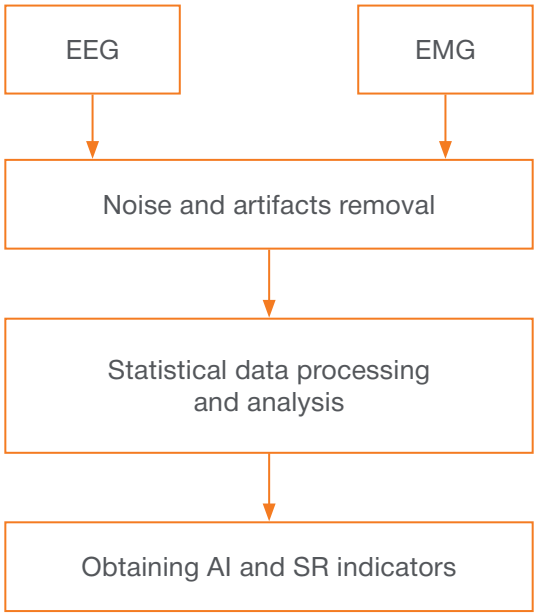
## Individual Selection of Sedative Doses

Selecting the optimal drug dosage with MGA is based on EEG analysis and displaying the AI (Brain Activity Index), taking into account individual body features and the clinical situation.

This approach ensures:

- maximum safety and efficiency of the delivered anesthetic support;
- reducing the risk of drugs' adverse effect on the body;
- saving expensive drugs.

# Algorithm of AI (Brain Activity Index) Calculation




Anesthesia depth assessment is based on a comprehensive electroencephalogram (EEG) analysis using unique algorithms developed by Triton Electronic Systems engineers. A simplified algorithm for AI (Brain Activity Index) calculation is performed below.

EEG and EMG signals are registered from the electrodes applied on the frontotemporal area of the patient's head.

The registered signal is subjected to digital filtration: motion artifacts, power main disturbances and noise from electrosurgical equipment, other bioelectrical signals, etc. are removed.

The algorithm of EEG analysis includes statistical information on typical signs of various groups of anesthetics' impact on the patient's EEG. During the analysis, the level of compliance is established between the registered EEG signal and each type of conscience depression.

**As a result of data analysis, the following indicator values are obtained:**

AI (Brain Activity Index);
SR — EEG Signal Suppression Rate, taking into account the total duration of segments with low-voltage activity (suppression segments) over the last minute. Displayed as a percentage.
SR > 0 is usual at AI < 50.

## Signal quality

To get accurate data on anesthesia depth monitoring:

- assess the signal quality continuously;
- provide control of electrodes' impedance;
- prevent impedance values from increasing;
- minimize artifacts and other noise.

**For this purpose, the following technical solutions are implemented in MGA Module:**

SQI (Signal Quality Index) is continuously monitored. It takes into account the values of EEG cable electrode' impedance, noise level from artifacts, high-frequency noise and power main disturbances within EEG, etc.

If SQI = 0, displaying the values of AI (Brain Activity Index), SR and EMG Component Level is blocked. A message on the most significant cause for SQI dropping is transferred.

The level of EEG signal noise is measured continuously.

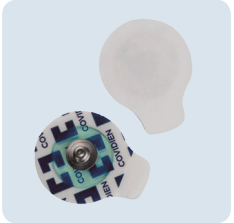
Electrode impedance is an important parameter to indicate a quality of contact between skin and electrodes. Low impedance is an essential condition to get high quality signal.

# Technical Specification

| | |
|---|---|
| Patient age groups | Adults and children over 10 years old |
| Anesthetics | Works with both inhaled and intravenous anesthetics |
| Displayed parameters | Brain Activity Index<br>EEG Signal Suppression Rate<br>EEG Signal Quality Index<br>Electromyographic Component Level<br>Electrodes impedance (Z1–Z3) |
| The recommended types of electrodes | 31.1245.21, 24 mm, Covidien LLC, USA;<br>F9079/RU3236-100, FIAB SpA, Italy;<br>White Sensor 40713, Ambu A/S, Denmark;<br>G210C/F-150S, Nihon Kohden Corporation, Japan |
| Dimensions & Weght | 115x65x25 mm, 0.2 kg |
| Power | Voltage: 5.0 V±5% DC. Power consumption: 2 W |
| Environment | 0–40°C, RH 40–80% (at air temperature 25°C), 600–800 mmHg |
| Integration | UART interface, ODU connector |
| Standards | Developed in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26, IEC 60601-2-40 |

# OEM Delivery Kit

| | | |
|---|---|---|
| Depth of Anesthesia and Sedation Module MGA | TESM.943129.007-02 | 1 pcs. |
| Electrodes | 100 pcs. | |



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