

Depth of Anesthesia and Sedation Module MGA

OEM solution



Complete solution for anesthesiologists:
Monitoring of Sedation Level
and Depth of Anesthesia

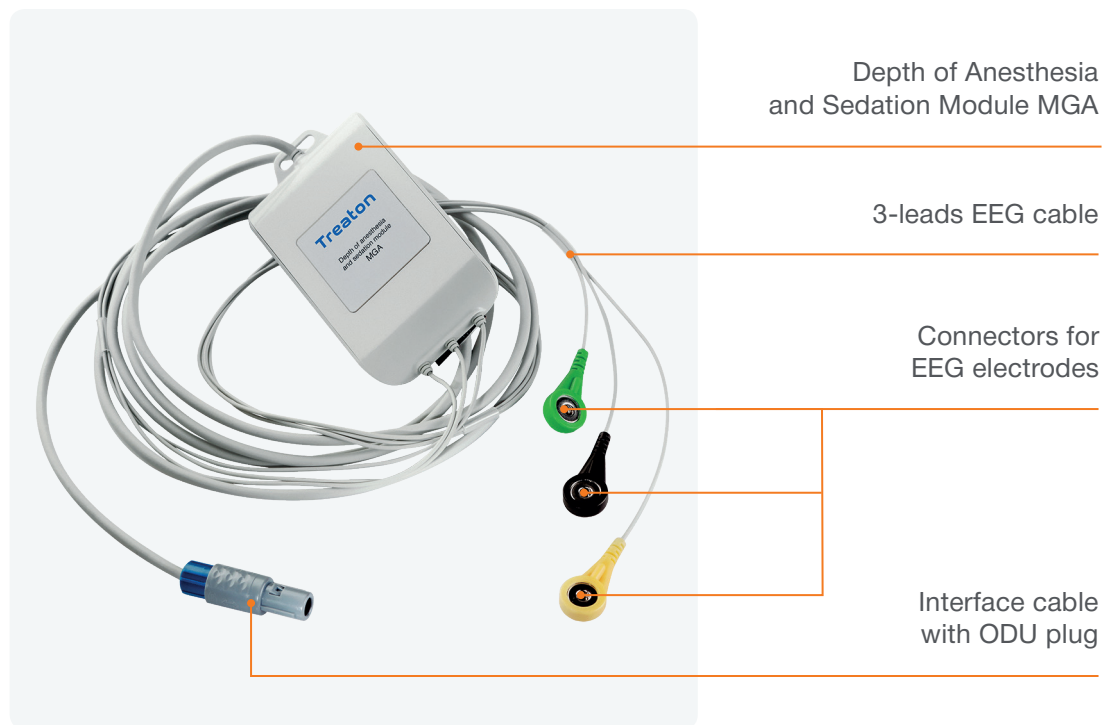


MGA Depth of Anesthesia and Sedation Module is designed to provide long and continuous monitoring of the Brain Activity Index (AI).

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, Electromyographic Component, Suppression Rate and additional states and statuses.



Identified Parameters

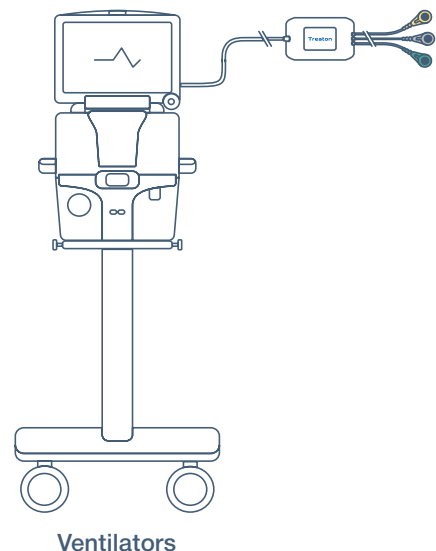
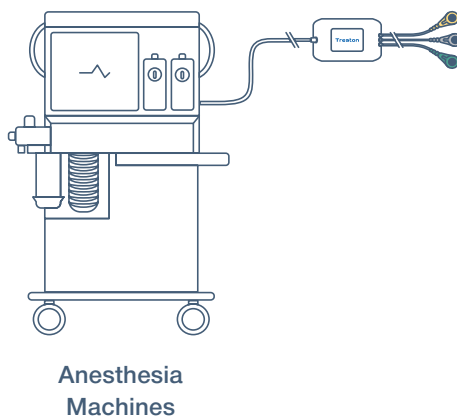
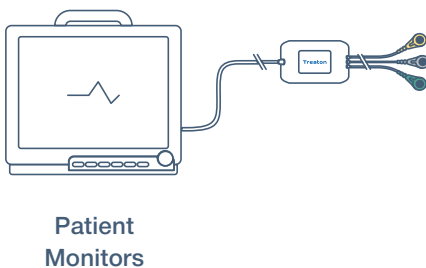
AI	Brain Activity Index	Indicates the level of consciousness depression by analyzing EEG, taking into account information on typical signs of anesthetics' impact on patients
SR	EEG Signal Suppression Rate	Reflects the relative duration of EEG suppression segments in the current time interval
SQI	EEG 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

According to a generally accepted classification of anesthesia stages

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	

The MGA module can be easily integrated into any medical host devices:



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

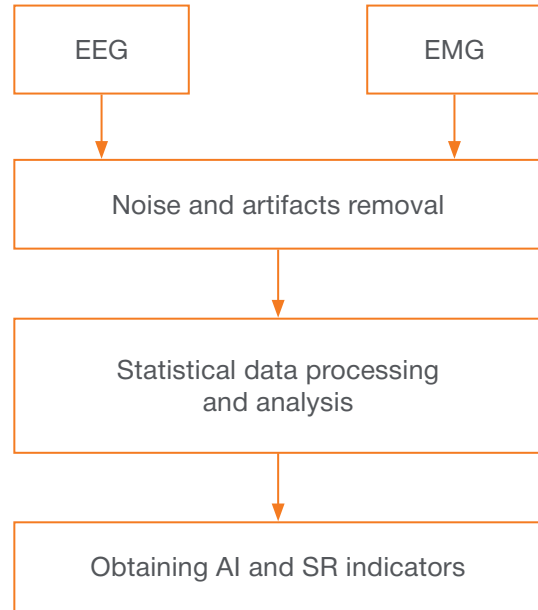
Selecting the optimal drug dosage with MGA is based on EEG analysis and displaying the AI (Brain Activity Index), taking into account individual body features and the clinical situation.

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 Ltd. 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.

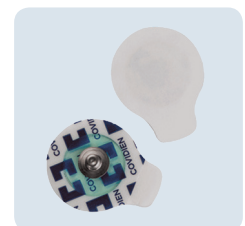
Technical Specification MGA module

Patient age groups	Adults, pediatrics, neonates
Anesthetics	Works with both inhaled and intravenous anesthetics
Monitoring parameters	Brain Activity Index EEG Signal Suppression Rate EEG Signal Quality Index Electromyographic Component Level Electrodes impedance (Z1–Z3)
The recommended types of electrodes	31.1245.21, 24 mm, Covidien LLC, USA; F9079/RU3236-100, FIAB SpA, Italy; White Sensor 40713, Ambu A/S, Denmark; G210C/F-150S, Nihon Kohden Corporation, Japan
Dimensions & Weight	115x65x25 mm, 0.3 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	The module meets the requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-2-40, EN IEC 80601-2-26, EN ISO 10993-1, EN 62304, EN 60601-1-6, EN 62366-1

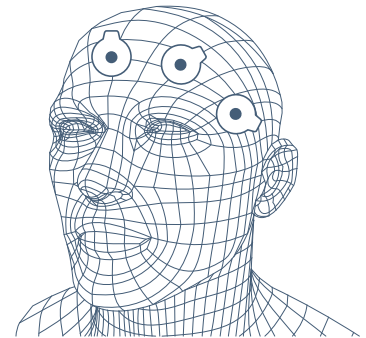
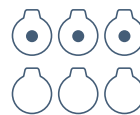
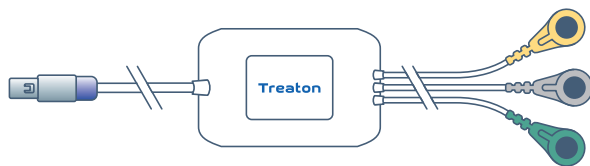
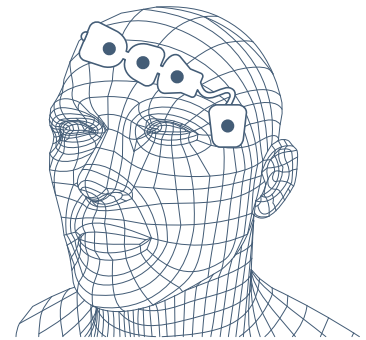
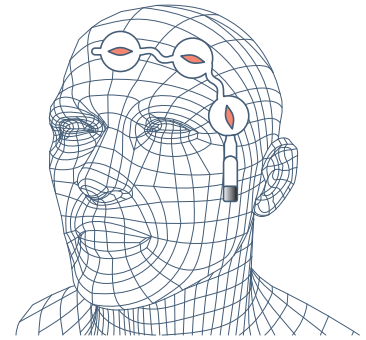
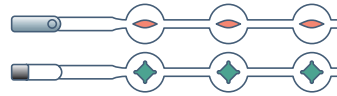
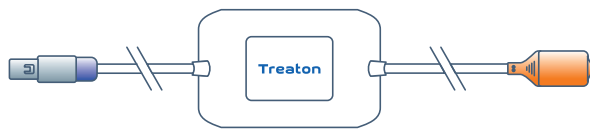
MGA Module

OEM Delivery Kit MGA module

Depth of Anesthesia and Sedation Module MGA	To be defined when ordering	1 pcs.
EEG Electrodes		100 pcs.
UART-USB adapter with cable	TESN.706157-01	1 pcs.



Options



Electrodes can be positioned to the left or right for ease of use.
Low and stable impedance provides a high-quality signal.

Module	Ref. No.	Recommended electrodes
MGA module compatible with GE-Entropy type EEG electrodes	TESM. 943129.007-14	MK-03 MedKer Tech
MGA module compatible with BIS type EEG electrodes	TESM. 943129.007-09	MK-01 / MK-02 MedKer Tech
MGA module compatible with any type of single use ECG electrodes	TESM. 943129.007-06	Most types of disposable ECG electrodes (Fiab, Ambu WhiteSensor, Vitrode F, Red Dot 3M and other brands)

We continuously improve the technological principles and implement new profitable solutions based on market demands



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Bajova str. 33
Ekaterinburg, 620133
Russian Federation

Quality management system certified as meeting the requirements of EN ISO 13485

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