

## Field Safety Notice

№2021-03

20.08.2021

To whom: Hospital administrators, heads of ICUs and ORs, resuscitation specialists, anesthesiologists.

Tema: Application features of the Multigas Analyzer AMG-06 (hereinafter the device) with the simultaneous occurrence of two technical events.

Triton Electronic Systems Ltd. recently obtained the information about a single case of EtCO<sub>2</sub>, FiCO<sub>2</sub>, EtAx, FiAx, RSP measurements discontinuation during the operation of the device. The case occurred during the simultaneous occurrence of two technical events in the device: a technical alarm "Occlusion" and a short-term (random) technical alarm on a pump malfunction.

**Make sure that all potential users in your establishment are acknowledged with the warning and recommended actions.**

**Products the notice is applied to safety problem**

Multigas Analyzers AMG-06, released from January 2021 to May 2021.

The device consists of the display and control monitor with a 5-inch TFT touchscreen, water trap, sampling tube, exhaust gas tube and power adapter. Supplied non-sterile. The device is intended for continuous noninvasive monitoring of CO<sub>2</sub>, Isoflurane (ISO), Sevoflurane (SEV), Desflurane (DES) gases in inhaled (FiAx) and exhaled (EtAx) breathing mixture and a respiratory rate (RSP) in terms of operation rooms and when providing anesthesia.

During post-production observation, the information was obtained from the customer at the place of device operation about a single case of EtCO<sub>2</sub>, FiCO<sub>2</sub>, EtAx, FiAx, RSP measurement discontinuation due to the simultaneous occurrence of two technical events in the device:

- technical alarm "Occlusion";
- short-term (random) technical alarm - pump malfunction.

It was found that the device displays dash in the EtCO<sub>2</sub>, FiCO<sub>2</sub>, EtAx, FiAx, RSP parameter windows when the specified case occurs. In this case, constant values are recorded in the trend log, which correspond to the last measured values before the occurrence of the specified case.

1) *When providing an anesthesia, the measurement discontinuation creates uncertainty in assessing the quality of anesthesia for the anesthesiologist and distracts him from performing his main duties.*

2) *The event of a technical alarm about a pump malfunction is not recorded in the alarm log of the device, which makes it difficult for the user to diagnose the technical condition of the device.*

The discontinuation of EtCO<sub>2</sub>, FiCO<sub>2</sub>, EtAx, FiAx measurement is not critical malfunction and does not bring additional risks to the user and the patient, because the user (physician) has the ability to control these parameters according to the set value on the anesthetic vaporizer, and the RSP parameter according to the set value of the respiratory rate on the anesthesia machine.

**Recommended actions for a Field safety notice receiver**

You can continue using the Multigas Analyzer AMG-06. The probability of the simultaneous occurrence of these technical events in the device is extremely low. If this situation occurs, turn off the device for a period of at least 10 seconds, then turn it on again. The device should recover.

Triton Electronic Systems Ltd.

**Factory address:**  
Sibirskiy Trakt str., 12/5  
Ekaterinburg, Russia, 620100

**phone:** +7 (343) 304-60-57  
**e-mail:** [info@treat-on.com](mailto:info@treat-on.com)  
[www.treat-on.com](http://www.treat-on.com)

To eliminate single failures in the measurement discontinuation, it is necessary to contact the service department of Triton Electronic Systems Ltd. or the supplier to update the firmware.

**Corrective actions from the manufacturer**

In August 2021, the following changes were made to the Multigas analyzer AMG-06:

- 1) firmware revision completed:
  - the gas analysis parameters and the respiratory rate measurement discontinuation is excluded when the two above technical events are superimposed;
  - identification of a pump malfunction technical event is provided with the recording of a corresponding message in the alarm log;
  - in the trends log it is excluded the possibility of recording significant indicators in case of measurement discontinuation;
  - in the graphs area of the device display, the output of critical messages in large red font is implemented;
- 2) in the user manual of the device, a message has been added to the table of technical alarms corresponding to a pump failure;

**Contact information about manufacturer**

Triton Electronic Systems Ltd.  
e-mail: [info@treat-on.com](mailto:info@treat-on.com)  
Tel. (343) 304-60-57 or, (343) 304-60-52 (service department)  
620100, Russia, Ekaterinburg, Sibirskiy trakt 12/5

**Contact information about Authorized representative in EU**

Wladimir Wollert  
e-mail: [wladimir-wollert@web.de](mailto:wladimir-wollert@web.de)  
+49 9332 5994095  
Otto-Selzer Straße 16, D-97340 Marktbreit, Germany

**Contact information about importer/distributor**

Sedana Medical AB  
e-mail: [info@sedanamedical.com](mailto:info@sedanamedical.com)  
+46 (0)8-124 05 200  
Vendevägen 89, 182 32 Danderyd, Sweden

**Transfer of the present Field safety notice**

The present Field safety notice should be shared with everyone who needs to know about it.  
Share the Field safety notice with other organizations operating the devices.  
Please read the Field safety notice carefully to ensure that corrective actions are applied effectively.  
Please report all device-related incidents to the manufacturer, distributor or authorized representative in the EU, and to the national competent authority, if necessary, as this provides an important feedback.

Sincerely,  
Quality director  
Triton Electronic Systems Ltd.



Vladimir Polunin

Annexes to the Field safety notice No. 2021-03:

1. The updated User manual for Multigas analyzer AMG-06;
2. The information about user interface updates (PDF presentation);

Triton Electronic Systems Ltd.

**Factory address:**  
Sibirskiy Trakt str., 12/5  
Ekaterinburg, Russia, 620100

**phone:** +7 (343) 304-60-57  
**e-mail:** [info@treat-on.com](mailto:info@treat-on.com)  
[www.treat-on.com](http://www.treat-on.com)