

Field Safety Notice

№2021-02

31.05.2021

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

Subject: Application features of the Multigas Analyzer AMG-06 with an uneven capnogram plateau in the expiratory phase.

Recently the Triton Electronic Systems Ltd has known about possibility of single erroneous measurements of EtAx in cases of an uneven capnogram plateau in the expiratory phase (fluctuation within expiratory phase). Make sure that all potential users in your establishment are acknowledged with the warning and recommended actions.

Products the notice is applied to Multigas Analyzers AMG-06, released from January 2021 to April 2021.

Safety problem During post-production observation, the information was obtained on the occurrence of single erroneous EtAx measurements in cases of an uneven capnogram plateau in the expiratory phase. It was found that the specified unevenness can lead to single failures of the algorithm for determining the phases of inspiration / expiration and, as a consequence, to an error in determining EtAx.

Recommended actions for a notice receiver You can continue using the Multigas Analyzer AMG-06 taking into consideration the above mentioned possible problems when evaluating EtAx. Single erroneous measurements of EtAx (the concentration of anesthetic in the breathing mixture during the expiratory phase) are not critical because a doctor has the ability to clarify digital readings of EtAx (the graph and scale are displayed on the screen) according to the graph of the anesthetic concentration, displayed on the device in real time. To eliminate single failures in the EtAx measurement, 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 The firmware of the Multigas Analyzer AMG-06 was updated since May 2021 to increase the stability of algorithms for determining the phases of inspiration / expiration, which made it possible to achieve a stable measurement of EtAx.

Contact information Triton Electronic Systems Ltd., +7 (343) 304-60-50, +7 (343) 304-60-52 (service department), e-mail: mail@triton.ru

Best regards,
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