
Customer Notification Letter

11 MARCH 2016

MAQUET
GETINGE GROUP

Please forward this information to all relevant users and biomedical staff in your facility

Subject: Technical alarm (TE63/64), FLOW-i system version 4.1

Dear Customer,

This letter informs you about a potential problem with falsely triggered technical alarm TE63/64 (with error code 201) in FLOW-i Anesthesia System which turns the vaporizer off.

Description and indications

The alarm TE63/64 is generated during some circumstances when the FLOW-i Anesthesia System believes that the internal communication does not work as intended. This falsely triggered technical alarm results in that the vaporizer is turned off due to timing issues between two sub systems.

Actions to be taken

The TE63/64 (error 201) technical alarm can be reset by disconnecting and reconnecting the Vaporizer. The vaporizer can then be activated and operated as usual.

Corrective actions

A new system software version 4.2.1 is available that will reduce this falsely triggered alarm, TE63/64 (error 201). Maquet has initiated an update of all affected FLOW-i Anesthesia Systems. Please contact your Maquet sales or service representative to plan for the update of your device.

We apologize for any inconvenience this may cause you and we will do our outmost to carry through this action as swiftly as possible.

Should you have questions or require additional information related to this matter, please contact MCC Anesthesia Product Management.

Sincerely,

Miray Kärnekull
Global Product Manager Anesthesia

Maquet Critical Care AB

Lisa Egelrud
VP Quality, Regulatory Affairs &
Environmental Management

Maquet Critical Care AB