URGENT-FIELD SAFETY NOTICE
2011-11-25

Please forward this information to all relevant users, biomedical staff and risk management department concerned in your facility

Subject: FLOW-i SOFTWARE UPDATE TO SYSTEM VERSION 2.1- IMMEDIATE UPDATE

Products affected:

Product	Serial Number (S/N)
FLOW-i anesthesia system	501 – 521 and 1001 – 1259 Except the following serial numbers, 1058 – 1060, 1167, 1169 – 1170, 1172, 1200 – 1204, 1224 – 1226.

Dear Customer,

The purpose of this letter is to inform you as a FLOW-i customer that we have identified a software problem with the MAN/AUTO switch (used for switching between manual and automatic ventilation) in the FLOW-i system.

Our records indicate you have received one or more of these devices. Please inform us of the quantity of units you have and the disposition of units that you no longer have.

Description and Indications

When changing ventilation mode from manual to automatic with the MAN/AUTO switch and the switch is kept in a "in- between position" for more than 5 seconds, this can generate a technical alarm (TE 613).

Activation of the technical alarm TE 613 causes the system to remain in the mode that was running before the switch was turned. To deactivate the technical alarm TE 613, the system must be restarted.

Potential hazards

MAQUET see this system behavior as a risk in some situations and it might affect your workflow as you need to go to standby mode and restart the system again to have full functionality of the MAN/AUTO switch.

Precautions

To avoid this issue when operating the MAN/AUTO switch, please do not hold the switch in an "in-between position" for more than 5 seconds.

Corrective action

In the new System version 2.1 this issue is corrected and the alarm has been deactivated when the alarm condition cease due to that the switch is set in an "in-between position".

The update also offers other additional improvement and functions such as the anesthetic usage calculation tool.

The new System version 2.1 has been implemented in all new delivered units from factory.

A field action is initiated to implement the new System version 2.1 for all affected units. This Field Safety Notice is only applicable until the unit has been updated with the new System version 2.1.

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

Should you have questions or require additional information, please contact your local MAQUET representative.

Sincerely,

Hans Bocké
Product Manager Anesthesia

Mikael Johansson
Vice President Quality
Management

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Document title	Doc-ID
FLOW-i Software update to System version 2.1	MTS-11-0030_00

UPDATE INSTRUCTIONS MCC/11/006/IU

PRODUCT: FLOW-i

TITLE: FLOW-i SOFTWARE UPDATE TO SYSTEM VERSION 2.1

ISSUE DATE: 2011-11-25

UPDATE TYPE: IMMEDIATE UPDATE

COMPLETION DATE: 2012-03-31

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1 RESPONSIBILITY OF SSU/SSP

1.1 PLANNING

This update is mandatory. The MAQUET Sales & Service Unit (SSU) and the Sales & Service Partner (SSP) are responsible for planning of performance of the update and ordering necessary material in order to fulfill the implementation according to:

- Immediate Update: Promptly, within the specified completion time frame.
- Normal Update: At next planned site visit, within the specified completion time frame.
- Possible priority list attached to the Update Instructions (UI) and the installed volume list for the SSU/SSP.

1.2 IMPLEMENTATION

The SSU/SSP is responsible for coordinating the customer completion date and placing material orders in a timely manner. The SSU/SSP is responsible for regulating the issuance of update orders to Field Service Engineer (FSE) along with all necessary information.

If a system cannot be updated because:

- it is not affected
- it cannot be located
- the customer refuses the update, this information must be reported by authorized personnel from SSU/SSP to MAQUET Critical Care (MCC).

1.3 REPORTING AND MONITORING

Reporting and monitoring of this update is required:

- Completion of the update must be reported to MCC. Use the web application MBase for reporting the completion of the update (if not possible to use MBase send a confirmation to Update-Reporting.MCC@maquet.com)
- The SSU/SSP is responsible for monitoring the completion date and the number of updates completed. A report shall be sent to MCC, by authorized personnel.

NOTE: SSU/SSP:s is responsible for maintenance of MBase.

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2   UPDATE INFORMATION

2.1   SYSTEMS / PRODUCTS AFFECTED

FLOW-i with serial numbers 501-521 and 1001-1259 except serial numbers 1058-1060, 1167, 1169-1170, 1172, 1200-1204, 1224-1226.

2.2   REASON FOR THE UPDATE

New System version to improve stabilization as well as new functions on FLOW-i

For further information about System version 2.1 refer to MCC Express:

- FLOW-i release System version 2.1 (dated 10 October 2011, Doc. ID MX-0930)
  https://mpower.maquet.com/content/Documents/MCC_Express_Products/MCC%20Express_Flow-i%20release%202.1.pdf
- FLOW-i System version 2.1 - Field Service Aspects (dated 10 October 2011, Doc. ID MTS-11-0029)
  https://mpower.maquet.com/content/Documents/MCC_Express_Service/MCCExpress_SERVICENEWS_MTS-11-0029Express_EN_Non-US.pdf

2.3   PREREQUISITES

Before performing this update, it is required that previous mandatory updates have been carried out and reported.

All updates must be performed consecutively.

2.4   SPECIAL TOOLS / DOCUMENTS

- Approved USB memory with Software version 02.01.00 or later.
- Service key to access Service & Settings.
- Tool to press the Boot enable switch, e.g. a 2 mm hexagonal wrench.
- Service Manual, P/N 66 76 980 revision 02 or later.

2.5   ORDERING INFORMATION

- System software can be downloaded via MCC SW Download.
- FLOW-i 2.1 User's Manuals can be ordered via MPrint, refer to web link on MPower.
  Manuals are also available in PDF format on MPower.

2.6   RETURNS

Use MReturn to apply for credit for User's Manuals ordered via MPrint. In MReturn, select "other" from the menu, enter your CustomerID and update number MCC/11/006/IU.

2.7   SPARE PARTS HANDLING

N/A

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3 UPDATE IMPLEMENTATION

3.1 UPDATE PROCEDURES

Update the System software according to chapter '5 Service procedures', section 'System software installation' in the Service Manual.

Note: Before starting software installation, read the complete 'System software installation' section in the Service Manual to be familiar with the procedure.

	CAUTION: The unit must not be switched off during the Installer update process. Such interrupt of the Installer update will make the concerned PC board defective and the PC board must be replaced.

3.2 COMPLETING THE UPDATE

- Replace the User's Manual for the updated unit.
- Inform the customer about the reasons of the update.
- Report the update according to instructions in 1.3 Reporting and Monitoring.