

# URGENT - Field Safety Notice

2016-06-01 | EVU-155312\_2 |

**MAQUET**  
GETINGE GROUP

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

## Subject: FLOW-i subsystem disabled – version 2

### Products affected:

Product	Article No.	S/N*
FLOW-i C20, C30, C40	6677200, 6677300, 6677400	3023, 3025, 3028, 3029, 3031-3041, 3043-3052, 3054, 3056-3074, 3076- 3100, 4001-4264, 4270- 4319, 4339, 4351, 4463, 5381, 5383, 5385-5406

\* Covers only serial numbers not included in the field action initiated 2015-11-23.

Dear Customer,

The purpose of this letter is to inform about a potential issue in the FLOW-i system which could cause restarts followed by disabling of one of the subsystems. There are no reported injuries.

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

## Description and indications

Maquet has discovered a potential issue caused by soldering problems, causing short circuit, on two different PC-boards in FLOW-i. This could cause restarts followed by disabling of one of the subsystems. On 2015-11-23 Maquet initiated a field action on this subject covering a batch of affected PC-boards. Maquet has now been informed by the supplier of the PC-boards that more batches are affected and therefore the field action is extended.

Depending on which PC-board that is affected the symptoms are different:

### PC board 1920 Control

In standby: Not possible to start case. TE10 shows.

During operation: Stop of ventilation. TE10 shows. Alarm sounds.

### PC board 1921 Monitoring

In standby: No parameters or metrics on standby screen. Not possible to start case. Alarm sounds after 10s.

During operation: Ventilation continues, but parameters and metrics missing on screen. Vaporizers shut off (no power). Alarm sounds after 10s.

## Potential hazards

FLOW-i system cannot be started or in worst case if during use, stop of ventilation.

## Precautions

If the fault occurs during operation, activate the built-in emergency ventilation and switch to an alternate anesthesia system or anesthesia method.

## Corrective action

A field action is initiated to replace all affected PC-boards on installed base. This Field Safety Notice is only applicable until the FLOW-i system has been updated with the exchange PC-boards.

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, please contact your local Maquet representative.

Sincerely,

Peter Wedar  
Technical Product Manager Anesthesia  
**Maquet Critical Care AB**

Lisa Egelrud  
Vice President Quality Management  
**Maquet Critical Care AB**