

URGENT-FIELD SAFETY NOTICE
2015-03-31

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

Subject: Risk of leakage due to accidental displacement of patient cassette

Products affected:

Product	S/N
6677200 FLOW-i C20 6677300 FLOW-i C30 6677400 FLOW-i C40	All serial numbers up to 2753

Dear Valued Customer,

The purpose of this letter is to inform about a potential leakage situation due to an accidental displacement (e.g when switching patient tubings or replacing the CO₂ absorber) of the patient cassette.

There are no reported injuries. It is only a low likelihood that this situation will lead to a clinical dangerous situation.

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

MAQUET has discovered that the patient cassette in rare cases accidentally can be displaced e.g when switching patient tubings or replacing the CO₂ absorber.

Indications

If you do a system checkout and the patient cassette is displaced the system checkout will not pass.

If the patient cassette is displaced when the machine is ventilating the leakage can be identified by a large discrepancy between inspired and expired tidal volume. The clinical consequence is stop of ventilation and the notification for the user is the leakage alarm, an

apnea alarm and an expiratory minute volume low alarm. There is also an indication showing “absorber bypassed” on the screen.

In manual mode, the filling of the bag will be slower and the pressure cannot be kept.

Potential hazards

The leakage can lead to improper ventilation which is a potentially dangerous situation for the patient if not corrected by the user.

Precautions

Always make sure that you set an appropriate minute volume alarm and pay attention to a large difference between inspired and expired tidal volume. Try to avoid excessive forces when switching patient tubings and CO₂ absorber.

If you press the patient cassette back into position, the leakage will stop. This can be done quickly and the anesthesia does not have to be switched off.

Corrective action

A field action is initiated to implement an improved patient cassette latch on affected installed base. This Field Safety Notice is only applicable until the unit has been updated with the improved patient cassette latch.

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
Global Product Manager Anesthesia

Lars Berken
Vice President Quality Management

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