

# Urgent Device Correction

2015-11-26 | EVU-156256

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

## Subject: Failure when switching to battery in SERVO-air

### Products affected:

Product	Article No.	S/N or Batch No.
SERVO-air	6882000	10021-10023, 10026-10028, 10032-10035, 10036, 10041, 10044-10045, 10048-10050, 10054

Dear Customer,

The purpose of this letter is to inform the users of SERVO-air with serial numbers as listed above, that it has come to the attention of Maquet Critical Care AB (hereafter "MCC") that due to a production issue, the ventilator can show a behavior different from the expected one. There are no reported injuries associated to this event.

Our records indicate you have received one or more of these devices.

### Description

MCC has discovered that the power controlling circuit board in the SERVO-air has not been manufactured according to manufacturing specifications. This has, in one occasion, caused the ventilator to fail the switch to battery power when the mains power cable was removed, and the Power Loss alarm to sound intermittently.

The failure occurred during Pre Use Check, when a test of switch to battery test performed. Alarms will indicate that the test has failed.

## Indications

The issue is discovered during Pre Use Check. The SERVO-air cannot pass the Pre Use Check without performing the battery switch test. An alarm will be generated that the battery switching is not functioning. If ventilation is performed without a prior Pre Use Check, SERVO-air will prompt the user with a safety message. The power failure will set the Power Loss alarm which will sound, in the case of switching failure, but intermittently instead of continuously as it should.

## Potential hazards

The hazard connected with failure of back-up power is stop of ventilation.

## Precautions

A Pre Use Check shall always be performed before the SERVO-air is put into service. If present, this failure will be detected during Pre use Check. If a SERVO-air fails the battery switch test, it should be put out of service and updated by MAQUET representative according to the Update Instruction, MX-6417, before returned to use.

## Corrective action

MCC has initiated an immediate update, MX-6417, of SERVO-air. Customers with affected SERVO-air will be contacted by their local MAQUET representative for update of those units.

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,

  
Maquet Critical Care AB

  
Maquet Critical Care AB