

FIELD SAFETY NOTICE

MARCH 11, 2013

Please forward this information to all users and biomedical staff who may use or service SERVO-i Ventilators

Subject: Battery Modules for use with MAQUET SERVO-i ventilator systems

Products affected: SERVO-i Battery Modules

Part number: 6487180

Manufacturing dates: 1005 – 1243 (February 1, 2010 – October 25, 2012)

Dear Valued Customer,

It has come to MAQUET's attention that when using the SERVO-i on battery power, in a very limited number of cases, some battery modules distributed after February 15, 2010 have a shorter battery run time than expected. These cases have occurred during intra-hospital transportation.

There are no reported injuries. It is only a low likelihood that a battery will exhibit a shorter than expected battery run time during clinical use.

If this were to occur, a shorter battery run time could potentially cause an early power loss of the SERVO-i ventilator system without the normal sequence of alarms (see below), and lead to a stoppage of ventilation. In case of total power loss, an audible alarm will sound for at least 2 minutes and the SERVO-i will cease operation and enter a "ventilator safe" state, with open valves. The potential severity associated with such an event is moderate, a significant but temporary and reversible impairment may occur, i.e. temporary cessation of ventilation until the device is connected to AC power or a resuscitator is used. More severe patient consequences could potentially develop with unattended use of the device.

SERVO-i customers may have received battery modules with potentially shorter than expected battery run time. You can identify batteries with potentially shorter battery run time by inspecting the manufacturing date code on the label as indicated in the figure below. Battery modules with potentially shorter battery run time have manufacturing date codes between 1005 and 1243 (February 1, 2010 and October 25, 2012).

Please note that a natural decrease in run time occurs throughout the batteries life time. An instruction when to replace the battery module because of that the run time is too short is given by the SERVO-i. The expected life time of the battery module as written in the SERVO-i user's manual is 2.5 years from date of manufacturing.



Safety Information

MAQUET has noted the following statements in the introduction section of the SERVO-i User's Manual:

WARNINGS:

- Make sure there are at least two fully charged batteries installed at all times

CAUTIONS:

When the ventilator is connected to a patient:

- Do not leave the patient unattended.
- Make sure a resuscitator is readily available.

It is important to note that up to six battery modules can be installed in the SERVO-i ventilator.

As a reminder, the standard sequence of *high priority* battery-related alarms is as follows:

1. 'Limited battery capacity': audible and visible alarm (less than 10 minutes of battery operation remaining)
2. 'No battery capacity': audible and visible alarm (less than 3 minutes of battery operation remaining)
3. 'Low battery voltage': audible and visible alarm (cannot guarantee continued battery operation)
4. 'Replace Battery': Active instruction (The battery is no longer reliable; replace it immediately. Due to low capacity or more than 30 months from manufacturing date).

If 'low battery voltage' is the first battery alarm displayed or if a "replace battery" message is displayed, please change the power source to AC and replace the battery modules. In a low battery voltage event and/or replace battery state, the indicated remaining battery time may drop suddenly.

We apologize for any inconvenience this may cause you.

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

Sincerely,



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Lars Berken
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Management

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