

FIELD SAFETY NOTICE

APRIL XX, 2013

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

This Field Safety Notice supersedes the Field Safety Notice issued March 11, 2013.

Subject: Battery modules for use with MAQUET SERVO-i Ventilator Systems

Products affected: SERVO-i Battery Modules

Part number: 6487180

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

Issue

Some battery modules, with manufacturing date codes between 1005 and 1243 (February 1, 2010 and October 25, 2012), which are frequently charged/discharged, i.e., used for transport, have experienced a shorter than expected life time. If a battery alarm/message is issued, and the battery module is further charged/discharged, this can lead to a shorter than expected run time. There are no reported injuries associated with this issue.

Actions to be taken by SERVO-i users:

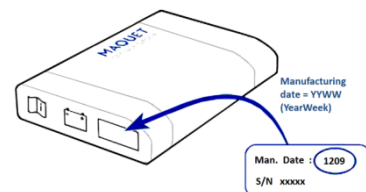
1. Check the manufacturing date code of installed battery modules in all your SERVO-i units.

Each SERVO-i unit should, at a minimum, be equipped with two or more battery modules. If you have one or more battery modules from manufacturing date codes 1005 through 1243 in your SERVO-i, you can contact your local MAQUET representative to receive one additional battery module per SERVO-i unit, free of charge. Replacing or adding a new battery module in your SERVO-i will provide supplemental backup in the unlikely event that you might experience a premature failure.

2. Before use or transport, identify battery modules in SERVO-i's which have generated the **"Replace battery"** message, and immediately replace them.

The **"Replace battery"** message is displayed in the "status" window on the user interface.

Battery modules with manufacturing codes 1005-1243 that have generated a **"Replace battery"** message before expiry date will be replaced at no cost. Please contact your local MAQUET representative to arrange for replacements.



3. In case of a **"Low battery voltage"** alarm, **reconnect** the ventilator to mains power, or add additional fully charged battery modules.

4. **Ensure** that at least two fully charged battery modules are installed at all times, and that sufficient resuscitation equipment is accessible to the ventilator, per the User's manual. Note that the SERVO-i can accommodate up to six battery modules.

Additional information:

- Information regarding battery related alarms, requirements for transport, and battery power can be found in the SERVO-i User's Manual, Sections 1 "Introduction" and 3 "Power Supply".
- Be aware that the use of a single battery module to power the SERVO-i is contrary to the User's Manual. To guarantee reliable battery backup, two fully charged battery modules must be installed at all times.
- In the event of a total loss of power, an audible alarm will sound for at least 2 minutes, and the SERVO-i will enter a "ventilator safe" state.
- MAQUET has discontinued production of the potentially affected battery modules. However, users can continue to safely use battery modules with the manufacturing date codes above, if they comply with the instructions in this Field Safety Notice and the User Manual.
- The SERVO-i should not be used for interhospital transportation without a written "*Interhospital Transport Agreement*" with MAQUET, and installation of the "*Interhospital Transport Kit, SERVO-i*".
- Note that more than 99% of the battery modules with the manufacturing date codes above are expected to perform properly and be fully usable for the battery lifetime.

MAQUET appreciates your understanding, and regrets any inconvenience this issue has caused. Should you have questions or require additional information, please contact your local MAQUET representative.

Sincerely,

Signed

Signed


Product Manager Ventilation


Director Regulatory Affairs,
Compliance and Environmental
Management

MAQUET Critical Care AB
Röntgenvägen 2,
SE-171 54 Solna, Sweden

www.maquet.com