Customer Notification Letter

MAQUET
GETINGE GROUP

2014-09-11

Notification of Software Revision

Attention: all users of the below mentioned products.

Subject: **Mandatory Software Upgrade to version 3.4.6.0**

Products affected: **CARDIOHELP SYSTEM**

Dear CARDIOHELP Users,

The purpose of this letter is to notify you of the release of a new software version for the CARDIOHELP System. This new software version (version 3.4.6.0) corrects software bugs that resulted in the generation of incorrect "Battery Needs Service" error messages.

Maquet Cardiopulmonary has received several complaints from the field reporting that after startup with either AC or DC power, the CARDIOHELP System generated the pop-up window "Battery X Needs Service" or "Both Batteries Need Service" (X refers to the number of built-in battery, e.g. Battery 1). The alarm messages did not occur during device operation (including the switch from AC to DC power and vice versa).

This is a low priority technical alarm which does not limit the functionality of the device. As mentioned in the IFU, battery needs service message(s) indicate limited battery capacity and remaining time for operation on batteries is not correctly displayed. The IFU also recommends notification of an authorized service technician.

We have received no reports of any adverse patient outcomes as a result of this error message.

Our internal investigations have demonstrated there is a likely occurrence of the above mentioned error messages due to software bugs in the communication between the controller module and operating system. However, it is not possible for the user to distinguish the genuine alarm messages caused by batteries from the incorrect alarm messages caused by the software bugs. Since the IFU clearly states that both "Battery X needs Service" and "Both batteries need Service" messages are linked to genuine battery issues, this may result in an increased rate of requests for technical service.

The results of our internal Health Hazard Assessment indicates that the health hazard is LOW and that the error is very unlikely to result in adverse health consequences since the error only occurs during start-up and not during routine use, or the conversion from AC to DC (and vice-versa) operation modes.

To correct this software error, a Mandatory SW upgrade is being required. This Software revision and the method for upgrading your system will be provided via the normal Service Letter process.

Reporting to regulatory agencies is not required since the error does not pose a risk to health.

You will be contacted by your local MAQUET office regarding further necessary actions.

We appreciate your understanding and thank you for your continued support as we provide you with up-to-date information on the quality of our products. We apologize for any inconvenience or concern this field action may have caused you.

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

Sincerely,

[redacted]

Jörg Dalhöfer
COO

[redacted]

Michael Campbell
Medical Product Safety Officer

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