MAQUET GmbH | Kehler Str. 31 | 76437 Rastatt

Field Safety Notice

May 21, 2015

Please forward this notice to all relevant staff and potential users of the device!

Preventive Corrective Action

concerning

MAGNUS Hybrid OR table column 1180.01B2

Dear customers,

with this letter we would like to inform you of a potential issue with the MAGNUS Hybrid OR table column 1180.01B2 when used in combination with the angiography-system Siemens Artis Zeego.

Description of the problem including the determined cause:

Within the framework of our market surveillance, we have been made aware of a complaint with a reported collision between the C-arm of the angiography-system and the MAGNUS OR table system.

The root cause analysis has shown that the MAGNUS column provided wrong position data of the longitudinal movement. Thus the collision calculation of the angiography-system led to a wrong result.

It was diagnosed that the MAGNUS OR table system may provide incorrect position data for particular movements in very rare cases after switching on the angiography-system. If this occurs, the system at the latest operates properly again after activating the corresponding movement.

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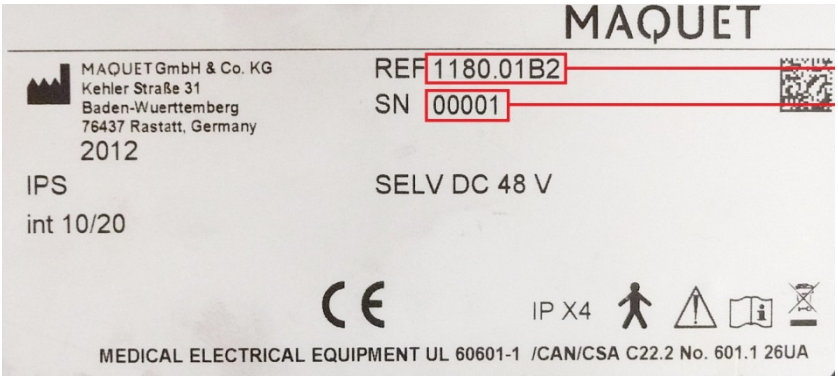
Identification of the affected medical devices:

Potentially affected by this issue are all OR table columns with the model number 1180.01B2 from serial number 00001 to 00100.

Model number and serial number are located on the type label onto the column head:



Model number
Serial number

Figure 1: Type label

Which measures are to be taken by the user?

Our sales records indicate that you own one of the affected 1180.01B2 OR table columns.

In order to exclude the described error the software of the potentially affected columns will be updated. MAQUET service or MAQUET authorised service technicians will be contacting you to arrange an appointment to update the software free of charge.

Until this appointment takes place, you should activate all movements of the OR table system for a short time after switching on the angiography-system. The operator always has to observe the movement of the C-arm to have the possibility to react early enough if required.

Passing on the information described here:

Please ensure that all persons within your organization who use the above-mentioned devices and anybody else who needs to know receive this field safety notice. If you have passed the product on to third parties, please forward a copy of this notice or inform the MAQUET contact persons you are aware of.

Please keep this notice at least until the corrective action has been completed.

Contact person:

For further questions, please do not hesitate to contact your MAQUET contact person. Should you require more information, please contact our safety officer for medical devices during normal business hours (contact data on the first page).

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This is a voluntary corrective action. Thus far, no incidence has been reported in which a person has been injured.

The appropriate authorities have received a copy of this field safety notice.

We apologise for any inconvenience, however, consider this action as a preventive action to increase safety.

Yours faithfully,

MAQUET GmbH

Th. Bille

Safety Officer for medical devices