

MAQUET GmbH | Postfach 2162, 76411 Rastatt

April 8, 2013

**RECALL
IMPORTANT CUSTOMER NOTIFICATION
PRODUCT CORRECTION**

The purpose of this recall is to correct Extension Devices that contain a gap in the handle that could lead to pinching or cutting of the operators' hand during use.

Product Name	Part Number(s)	Serial Number(s)
YUNO Table Extension Device	1433.62A1 1433.62A0	1 to 90 All

Dear Valued Customer,

As a result of customer feedback, MAQUET conducted an investigation and identified a potential issue with the handle of the extension device 1433.62A1 and 1433.62A0 (See figure 1) used with the YUNO table.



Figure 1: Extension device 1433.62A1 / 1433.62A0

Identification of the problem:

By fully actuating the lever of the extension device handle, skin can enter a gap between the handle lever and a recess in the handle bar. When the lever is released, skin which might be within the gap could be pinched or cut (See figure 2).

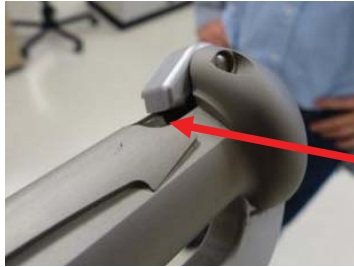


Figure 2: Left extension device handle

This gap at the upper edge of the left handle

Identification of affected Product:

Extension devices with part number 1433.62A1 serial numbers 00001 to 00090 and 1433.62A0 all serial numbers (see figure 3) contain the affected design. Maquet is implementing a protective insert to eliminate the gap (please see figure 4). MAQUET will upgrade the affected devices with this protective insert to ensure that all YUNO extension devices will no longer exhibit this behavior.



Model

Serial

Figure3: example of label

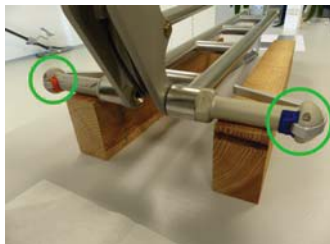


Figure 4: Extension device handle after upgrade

Adverse Effect on the patient:

There have been no reported patient injuries to date and this issue only affects the extension device operator.

Measures to be taken by the user

Our records indicate that your YUNO extension device is be affected by the issue described above. MAQUET Service, or MAQUET authorized Service Technicians, will contact you to arrange this with you.

In the meantime, if you have an affected lever, handle it carefully. We suggest using hands from the top technique pictured below:



Figure 5: Using hands from below →Potential risk



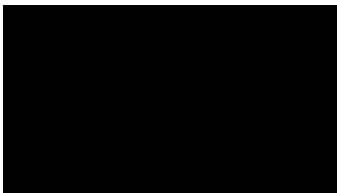
Figure 6: Using hands from Top →No Risk

Contact person:

We apologise for any inconvenience, however, consider this action a preventive measure to increase safety. If you have any questions or require more information regarding this field correction, please contact your MAQUET representative or our MAQUET safety representative for medical devices during normal business hours (contact data on the first page).

Sincerely,

MAQUET GmbH



Houssam Raad
Deputy Safety Representative for medical devices