

CC to Chairman Medical Board and Relevant Head of Department

URGENT - FIELD SAFETY NOTICE

**MAQUET HLX 2004-5 DF, HLX 3004-5 DF and XTEN DF
Field Action MSA/2017/002/IU**

Date: 27 March 2018

Product Issue: Breaking of AC2000 spring arms in use with HLX2004-5 DF, HLX 3004-5 DF and XTEN DF cupolas .

Affected Product: 5017 MAQUET HLX 2004-5 DF, HLX 3004-5 DF, XTEN DF cupolas in use with ONDAL Acrobat 2000 spring arms manufactured between January 2004 and December 2006

Resolution: MAQUET proposes to replace the affected spring arms with new ones to make sure all devices present in the market are working effectively and safely.

Affected Serial Nos.:	Spring arm part number	Up to Ondal SN
	ARD569002996	011102751560
	ARD569002998	49060043398
	ARD569002999	4306038616
	ARD567910901	35060032600
	ARD567910910	44060038859
	ARD567801093	36060033055
	ARD567801094	45060039322

Field Correction Notice: MSA/2017/002/IU

Pages: 4

Dear Customer:

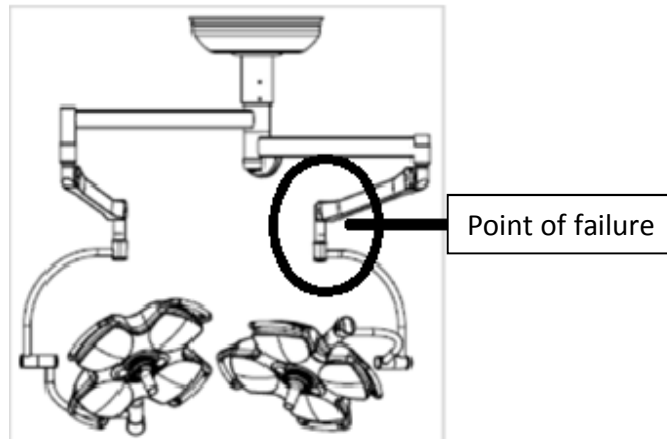
Our records indicate that you bought one or more HLX 2004-5 DF, HLX 3004-5 DF or XTEN DF cupolas, which may be in use with an AC2000 spring arm manufactured between January 2004 and December 2006.

This letter is to inform you of a corrective action that consists of replacing all potentially affected spring arms still in use with new ones. This action will be performed to prevent any possible hazard to persons and equipment.

From our investigation it was concluded that there is a low failure rate that only can present itself on the devices of types and production identified in this letter. The issue relates to a crack in the metal of the spring arms that has the potential develop into a break. The devices are over ten years old and even so

the vast majority have not failed. We have received related complaints, however to date no events involving injury have been reported to us.

In 2009 we have performed a field action on this issue and these device units. The field action consisted of a visual check and depending on the outcome of that check, a replacement of parts. However signals from the market have shown that there remains a risk that the light cupola detaches. To exclude this entirely we have decided to replace all related spring arms that are identified to be involved, even although they are over ten years old.



This potential for malfunction is caused by fissures near the weld seam at the front pivot of the spring arm. The design of the spring arm was improved in 2006. The devices involved for your market are limited to those listed in the attached Consignee list.

Next Steps

1. Please make sure that all caregivers and users of the HLX 2000, HLX 3000 and XTEN devices referenced on the previous page are made aware of this Field Notice and all listed devices at your facility are available to be replaced by a trained and authorized MAQUET service technician.
2. Complete and sign the enclosed Customer Response Form and return this form to the local MAQUET office. A MAQUET Sales or Service person will contact the person you listed on the Customer Response Form to schedule service to replace your device, free of charge.

Transmission of this Field Notice:

This MAQUET HLX 2000, HLX 3000 and XTEN Field Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action.

In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, MAQUET cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice.

Additional Comment

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure correct product performance. If you have any further questions or require assistance completing the Customer Response Form, please contact MAQUET.

Customer Response Form

MSA/2017/002/IU

Reference: Urgent Field Safety Notice, MAQUET HLX 2000, HLX 3000, XTEN

Our records indicate that the device shown below was delivered to your location. Please verify if you have any of the listed devices that are potentially affected and complete the information below.

MAQUET ORDER NO.	ITEM NO.	SERIAL NO.	MANUFACTURING DATE
X	1	XXXX	<Date>
Y	2	YYYY	<Date>
	-		

Record the total number of affected device currently located at your facility here please → ____.

Please check the appropriate boxes below:

☐ We have read the **HLX2000, HLX3000, XTEN** Field Safety Notice and we understand the communication and the required actions.

If checked : please provide information where the affected devices are physically located.

Field Safety Notice Receipt and Customer Response Form Completion and Certification

Current Facility Name			
Contact Name / Title			
Address (no PO boxes, please)			
City, State, Zip			
Phone Number		Fax:	
E-Mail Address:			

☐ We have sold/moved our **HLX2000, HLX3000, XTEN** to another facility.

If checked : please provide new facility information below.

New Facility Name			
Contact Name / Title			
Address*			
City, State, Zip			
Phone Number		Fax:	
E-Mail Address:			

PLEASE RETURN YOUR COMPLETED FORM TO:

MAIL

<local SSU address line 1>
 <local SSU address line 2>
 <local SSU address line 3>
 <local SSU address line 4>

CONTACT

<contact address>@getinge.com
 Tel: <SSU contact phone number>
 Fax: <SSU contact fax number>