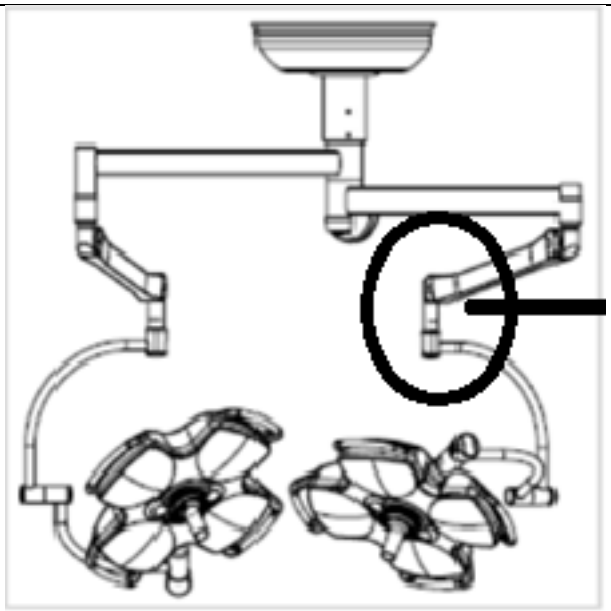
المركز الوطني للبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Safety Communication

Risk of Operating light detaches

Device/ Product Description:	Operating light
Brand Name:	MAQUET HLX 2004-5 DF, HLX 3004-5 DF, and XTEN DF
Lot numbers/Serials:	<table><tr><th>Spring arm part number</th><th>Up to Ondal SN</th></tr><tr><td>ARD569002996</td><td>11102751560</td></tr><tr><td>ARD569002998</td><td>49060043398</td></tr><tr><td>ARD569002999</td><td>4306038616</td></tr><tr><td>ARD567910901</td><td>35060032600</td></tr><tr><td>ARD567910910</td><td>44060038859</td></tr><tr><td>ARD567801093</td><td>36060033055</td></tr><tr><td>ARD567801094</td><td>45060039322</td></tr></table>
Manufacturer:	Getinge Disinfection AB
Problem:	ONDAL Acrobat 2000 spring arms manufactured between January 2004 and December 2006 may break due to a crack in the metal of the spring arms that may result in risk that the light cupola detaches.
Recommendation/Actions:	1- Check if your facility is affected or not (you could use the “List of potentially affected devices” in the link below. 2- If your facility is affected, contact the authorized representative to replace the affected parts You can find more information and recommendations from (HERE).

Devices/Products photo:	

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.

Healthcare Professionals should **report any adverse events** suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority
4904 northern ring branch rd - Hitteen Dist.
RIYADH 13513 - 7148
Tel: +966 (11) 2038222 Ext: 2995, 2952
Fax: +966 (11) 2757245
Or
Saudi Vigilance

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Sincerely,
NCMDR Team