Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No.24/23. dated 19/11/23. Regarding NCMDR Field Safety Notice of Maquet SAS' examination and surgical lights put into service from (mfr: MAQUET Inc).

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
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سلطنة عُمان
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مسقط

Circular No. 242/ 2023

05 -05-1445 H
19 -11-2023

Field Safety Notice of Maquet SAS' examination and surgical lights put into service from MAQUET Inc

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19758
Product	Maquet SAS' examination and surgical lights put into service.
Description	Surgical Light for operating Room.
Manufacturer	MAQUET Inc.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Please refer to the attachment for list of affected products.
Reason	The potential for one of light systems listed in the attachment to fall in the operating room.
Action	1. Please distribute the attachment and forward the link in it to access manuals to anyone who may need to use the manuals, and especially to your service or service provider who performs your maintenance. 2. Please refer to the attachment for more details. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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Urgent Medical Device Field Action

OCT-26-2023 | REF-808092 | Rev A

GETINGE

Subject: Maintenance and Service on Maquet SAS' OR Light Systems [MSA-808092]

Products affected: Maquet SAS' examination and surgical lights put into service.

Products in the scope

This correction includes all product ranges, which includes active, discontinued and serviced, as well as product that has been fully discontinued, but may still be serviced because some of the parts are shared with active or serviced devices (Refer to table below for list of affected products).

Active	Discontinued and serviced	Fully discontinued
Maquet PowerLEDII	PowerLED / HLED	Prismalix
Volista	Axcel / Axcel +	Hanaulux HLX2000
Lucea - Lucea10/40, Lucea50/100	Hanaulux HLX3000	Hanaulux 2006/2007
Maquet Rolite	XTen	G8 / G8E
Maquet Equipment		Blue 100
Maquet Orchide		Blue 130/90
PowerLED300		Blue Series 30/80
		Blueline Series 30/80
		Prismatic

Description of the issue

Dear Hospital Contact,

Maquet SAS/Getinge is initiating a voluntary Urgent Medical Device Correction for Maquet SASs OR lights due to the potential for a light system to fall in the operating room.

Maquet SAS/Getinge has received a customer complaint regarding a fall of a light system in an operating room in Hong Kong. Investigation into this event demonstrated that the recommendation of maintenance and service were not performed as instructed in the current user and maintenance manuals.

No serious injury has been reported as a result of this occurrence; however the risk of the fall of a light on a patient or healthcare provider is known and identified in Maquet SAS' Risk Management File as a severe risk, which could result in death, even if unlikely.

Throughout our investigations, it came to our attention that maintenance instructions and programs have been continuously enhanced over time, taking into account the insights gained during the medical devices' lifecycle and post-market surveillance. These associated updates may not have been communicated back to customers, particularly those customers who do not have relationships with Getinge and its subsidiaries.

You are receiving this Field Safety Notice because you have been identified as having purchased at least one of model of one of these product ranges.

This notification communicates retrospectively current maintenance instructions and programs to customers with particular attention on the suspension fixing screw, which is a high severity risk.

Potential hazards

Globally to preserve the device's original performance and reliability levels, annual maintenance and inspections should be performed[1]. And, based on the device risk analysis, some potential hazards are mitigated by the current maintenance schedule.

Description	Maintenance interval		
	1 year	3 years	6 years
General maintenance of the device	X		
All brakes on the device	X		
Suspension mounting screws			X
Spring arm locking screws			X
Spring arm safety segment			X
Batteries		X	

Table 1 : excerpt from the user and maintenance manuals

Actions to be taken by Customer

Please distribute this Field Safety notice and forward the link to access manuals to anyone within your organization who may need to use the manuals, and especially to your service or service provider who perform your maintenance.

Should you have questions or require additional information, please do not hesitate to contact Maquet SAS/Getinge or your local representative.

Actions to be taken by Maquet SAS/Getinge

As the majority of customers may not have regular contact with Getinge services or authorized Getinge representatives and therefore may not be aware of current maintenance recommendations, Maquet SAS/Getinge is notifying you and providing customers with the current maintenance manuals.
The main purpose of this notice is to communicate directly with you about any dispositions or recommendations that mitigate some risks and to maximize:

- Early detection and preventive maintenance: inform or remind that annual checks performed by your service providers, as proposed by the maintenance manuals, are important detection points to prevent adverse events,
- Preventive maintenance: communicate or refresh your service providers with the current maintenance manuals and programs so as to maintain the device within its specifications,
- Availability of Manuals: make available to you or your service providers the current version of the maintenance programs and manuals,
- Light fixing: considered as the highest severity risk and following the incident in Hong Kong, a specific focus and clarification is made on the fixing of our medical devices, and the frequency of the replacement proposed in our current maintenance program.

Corrective actions

1/ Manuals
A web portal has been developed for obtaining the relevant electronic and controlled manuals.
This portal is accessible at:

[1] *As instructed by the user manual of the light system: during the guarantee period, maintenance and inspections must be performed by a Getinge technician or a Getinge-approved dealer. After this period, maintenance and inspections may be performed by a Getinge technician, a Getinge-approved dealer or a hospital technician trained by Getinge. The health facility to contact its dealer to undergo the technical training required.*

https://www.getinge.com/int/campaigns/maintenance-and-service-on-or-light-system/
Manuals are sorted per product ranges and are available on PDF format.
Maintenance manuals are available in English.

In addition, user manuals are made available on your official language(s)

Should you prefer to receive printed manuals please contact Maquet SAS/Getinge by e-mail on **MSA808092.sw@getinge.com**

2/ light system fixing and other replacements
Regarding :
- the fixing of the light systems : suspensions fixing screws, adapter fixing screws, bushing fixing screws
- the brake screws
- the safety segments
- the batteries,

a dedicated instruction named "Preventive Maintenance – Wearing Part Replacement Cycle" illustrates and facilitates understanding of what to replace and what to order for replacement.

The instruction is available in English on the web portal **https://www.getinge.com/int/campaigns/maintenance-and-service-on-or-light-system/**, and upon request on **MSA808092.sw@getinge.com**

Furthermore, your local Getinge representative is here to help in any case.

The competent authority has been informed about this communication and issue.

Sincerely,

Sebastien Lepage
Technical Department Manager

Pascal JAY
Quality and Regulatory Compliance Director

Maquet SAS / Getinge
Parc de Limère, Avenue de la Pomme de Pin
CS 10008 Ardon, 45074 Orléans Cedex2
FRANCE

Please acknowledge receipt of this communication by returning a copy or a scan copy to: mubashir.javed@getinge.com

Name – Family Name	
Function	
Organization	
Signature	
Stamp (optional)	