

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. 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 performed¹. 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, 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.

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.

Corrective actions

1/ Manuals

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

<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 [enter name here] has been informed about this communication and issue.

Sincerely,

Sebastien Lepage
Technical Department Manager

Pascal JAY
Quality and Regulatory Compliance Director

Maquet SAS / Getinge

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FRANCE

Contact details of local representative for your market

Contact Name

Contact e-mail

Contact phone

Contact office address

Please acknowledge receipt of this communication by returning a copy or a scan copy to:

Getinge xxxxxxxxx
Street – Town – country

e-mail: xxxxxxx@getinge.com

Name – Family Name

Function

Organization

Signature

Stamp (optional)