URGENT: FIELD SAFETY NOTICE
2014 – MAR –12

MSA/2014/001/IU

PLEASE FORWARD THIS INFORMATION TO ALL RELEVANT USERS AND BIOMEDICAL STAFF IN YOUR FACILITY.

SUBJECT	**Preventive Action:** - Replacement of MAQUET STANDOP VOLISTA spring arms
LETTER ADDRESSED TO	**All users and biomedical staff**
DEVICES CONCERNED	**MAQUET VOLISTA 400 equipped with spring arm:** **Part Numbers / Serial Numbers:** The complete list of potentially affected devices is provided in a separate document.

Dear Customer,

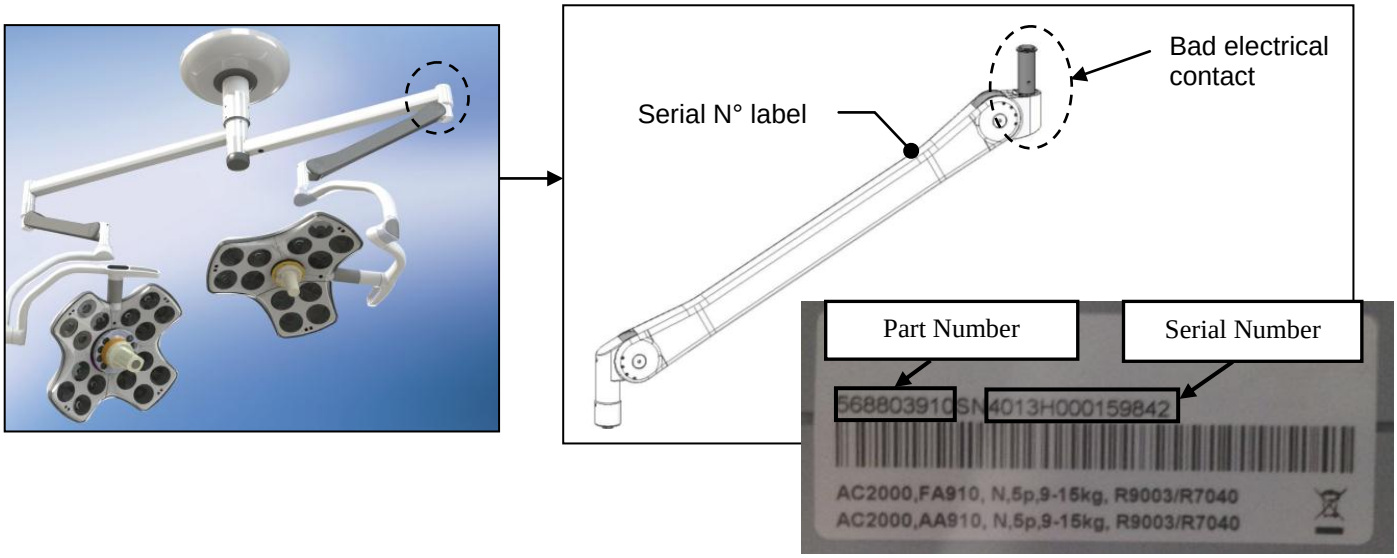
The purpose of this letter is to inform users of MAQUET surgical lights models STANDOP VOLISTA, about a replacement of spring arms.

Our records indicate you have received one or more of these devices. If you have any questions please call your local MAQUET office.

Technical Description

Spring arms allow a vertical adjustment of lightheads during the surgical act, with a high level of accuracy.

MAQUET identified that some STANDOP VOLISTA spring arms were defective.
The failure affects the 5-pole plug connectors and can generate a gap, allowing a potential electrical disconnection during use of the device. Depending on the width of the gap, a malfunction may not be detected during the installation activities.



Potential Hazard:

A defect on the 5-pole plug connector, in case it is not detected during the installation activities, may result in a sudden extinction of the light during an operation.

This situation could lead, in a minority of cases, to a patient injury depending on:

- the current surgical situation
- the time interval until a sufficient illumination can be re-established
- the reaction of the surgeon and the medical staff

Actions to be taken by the hospital / user:

Although MAQUET estimated that there is a low probability that the situation causes harm to a patient, MAQUET decides to replace all the potential defective spring arms.

Please immediately verify on the product label that your STANDOP VOLISTA light is in the scope of this Field Safety Corrective Action, and contact your local MAQUET office or distributor in order to organise a replacement.

We apologize for any inconvenience this may cause you and we will do our outmost to carry through with this action as swiftly as possible.

Should you have questions or need additional information, please contact your local MAQUET representative.
Sincerely,

12-MAR-2014

Bertrand LEAU
International Technical
Support Director

12-Mars-2014

Marie-Françoise CABEL
Quality and Regulatory Affairs Director

URGENT: FIELD SAFETY NOTICE– CUSTOMER FAX RESPONSE
MSA/2014/001/IU

PLEASE COMPLETE AND FAX/MAIL BACK

Subject: STANDOP VOLISTA spring arms replacement

As the responsible party for the hospital recipient of the Field Safety Notice related to the replacement of the STANDOP VOLISTA spring arms.

_____ [initial] I verify receipt of the following information: Field Safety Notice, replacement of the STANDOP VOLISTA spring arms.

☐ **We have _____ [#] STANDOP VOLISTA spring arms devices identified in the Field Safety Notice.**

Please list Spring Arm Serial number(s) described in the Field Safety Notice:

Product Code	SN

AND/OR

☐ **We do not have _____ [#]STANDOP VOLISTA spring arms devices identified in the Field Safety Notice. Please inform us about the disposition of units that you no longer have:**
[who sold to, trade in information, or scrapped] in attachment.

Product Code	SN

_____
Signature Date

_____ _____
Printed Name Title

Facility Name: _____

Address: _____

Phone Number: _____

Fax or mail back to your local Maquet representative