

## URGENT FIELD SAFETY NOTICE

Leica Ceiling Mounts MSF-1, MS-1F, MC-1F  
Inspection and Maintenance Required

Heerbrugg, August 30, 2013

**To our customers using the  
Leica Ceiling Mounts MSF-1, MS-1F or MC-1F**

Dear Sir / Madam:

This Medical Device Field Correction has been initiated due to Leica Microsystems being made aware of an important safety issue concerning the Ceiling Supply Units CSU 80xx / CSU 60xx, manufactured from 1997 – 2003 by our supplier Dräger. If you are receiving this letter you have received a product that is subject to this Field Correction.

Affected Leica Ceiling Mounts			
Description	Supply Voltage	Art. Number	Additional Information
Leica Ceiling Mount MSF-1	230V	10446781	Used for the M841 or M501 operating microscope
	110V	10446782	
Leica Ceiling Mount MS-1F & MC-1F	110V	10446657	Used for M500 N operating microscope
	220V	10446658	

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Leica Microsystems (Schweiz) AG · Medical Division · Max Schmidheiny-Strasse 201 · CH-9435 Heerbrugg  
Aktiengesellschaft mit Sitz in Balgach · Handelsregisteramt St. Gallen CH-270.3.012.009-0  
Geschäftsführer: Heinrich Dreyer  
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The ceiling mount supplier encountered an event in which the drive screw in the motor unit, which lifts and lowers the lower lift arm, broke. As a result, the lift arm fell down approx. 60 cm (23.6 inches). Leica Microsystems has currently not received any reported cases, however, as a preventative measure Leica Microsystems plans to perform a field correction of all microscope systems affected by this potential failure mode

Further review has determined that the potential failure can be detected by performing a visual inspection. Additionally, if maintenance has been performed according to manufacturers' recommendations there is remote risk that a failure will be experienced.

Your Leica Microsystems representative will contact you to make the necessary arrangements to complete the inspection of the ceiling mount, per manufacturer's recommendations and to provide additional Preventative Maintenance and Inspection protocols for these devices.

Please confirm receipt of this notice by signing and dating the attached Acknowledgement Form and returning it back to us preferably by email to: [md.quality-assurance@leica-microsystems.com](mailto:md.quality-assurance@leica-microsystems.com) or alternatively by faxing at **+41 71 726 3249** within 10 working days after receipt of field safety notice.

We sincerely apologize for the inconvenience this may have caused. Leica Microsystems aims to continue provide you with products of the highest quality.

Thank you for your patience and support.

Sincerely,



Roland Jehle

Regulatory Affairs/Quality Assurance Manager  
Leica Microsystems (Schweiz) AG

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## ACKNOWLEDGEMENT FORM

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### Leica Ceiling Mounts MSF-1 / MS-1F / MC-1F

Number of Ceiling Mounts: \_\_\_\_\_

Article No. / Description of Ceiling Mount: \_\_\_\_\_

Serial Number(s): \_\_\_\_\_

***I hereby acknowledge receipt of the Medical Device Field Correction involving a Leica Ceiling Mount regarding a potential mechanical failure resulting in the lift arm falling approx. 60 cm (23.6 inches).***

\_\_\_\_\_  
Contact Person (Please Print)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date (month-day-year)

\_\_\_\_\_  
Facility Name (Please Print)

**Please scan and send to:**  
**[md.quality-assurance@leica-microsystems.com](mailto:md.quality-assurance@leica-microsystems.com)**  
**or**  
**fax this form to the following number:**  
**+41 71 726 3249**