

URGENT FIELD SAFETY NOTICE

Leica M525 F50 Surgical Microscope

FSCA-Identifier: CAPA-2012-04-003-H

Field Safety Corrective Action

Review of Illumination Failure Back-up Procedure in User
Manual – Effective Immediately

Heerbrugg, August 29, 2012

To whom it may concern

Dear Leica M525 F50 User and Business Partner:

Leica Microsystems would like to inform you about a field safety corrective action on **Leica M525 F50** surgical microscopes.

Description of the Problem and Root Cause:

Leica Microsystems evaluated data showing that a malfunction resulting in an illumination shutdown of Leica M525 F50 surgical microscope if used with a low nominal voltage power supply of 100V +/-10V (i.e. 90V). A back-up (auxiliary) illumination is available if the main illumination shut off (fails) during a surgical procedure. The user can switch to the back-up (auxiliary) illumination system and the user can continue with the surgical procedure.

The root cause of the malfunction is caused by overheating of the xenon power supplies due to generated heat resulting in inefficiency of power supply driven at continuous low nominal voltage supply of 100V +/-10V (i.e. 90V). The continuous low nominal voltage supply can only be observed in Japan.

Details on Affected Devices:

This Field Safety Notice is applicable to all Leica Surgical Microscope **Leica M525 F50 (Article No. 10448422)** distributed in Japan only with the following serial numbers:

300311001, 300311002, 250311001, 10711001, 290711001, 10811001, 310811001, 40112002, 110112001, 130112001, 130212001, 240312001, 270212001, 290312001

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Aktiengesellschaft mit Sitz in Balgach · Handelsregisteramt St. Gallen CH-270.3.012.009-0
Geschäftsführer: Andreas Hedinger · Herbert Stuetzler
www.leica-microsystems.com



Handwritten signature and initials in blue ink.

Advice on Action to be Taken by the User:

- Leica Microsystems is requesting that you review the back-up procedure (“Switch manually to auxiliary illumination”) as described on page 24 of the Leica M525 F50 user manual in order to act accordingly if the main illumination shut down (“fails”) during a surgical procedure.

Switch manually to auxiliary illumination.



Warning

Failure of the illumination can be dangerous for the patient!

→ If the main illuminator fails, switch to the auxiliary illuminator immediately.

→ Turn the rotary knob (1) from Position 1 to Position 2.
The illumination is switched to the auxiliary illuminator.



Replace the defective main illuminator at the next opportunity, then switch back to the main illuminator.



- A Leica Microsystems representative will be contacting your facility to make the necessary arrangements to install metal cooling sheet on the xenon power supplies of your Leica M525 F50 Surgical Microscope.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We kindly ask you to acknowledge the receipt of this Field Safety Notice and to confirm the remote control is disconnected from the Leica M525 F50 surgical microscope, if provided, by signing and dating the attached Acknowledgment Form. Please return this acknowledgment form preferably by email to: md.quality-assurance@leica-microsystems.com or alternatively by faxing back to us 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 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



Leica
MICROSYSTEMS

Leica Microsystems (Schweiz) AG
Max Schmidheiny-Strasse 201
CH-9435 Heerbrugg
Switzerland

ACKNOWLEDGEMENT FORM

Installation of Cooling Sheet on the Xenon Power Supplies of Leica M525 F50 Surgical Microscope

- I hereby acknowledge receipt of the Leica M525 F50 Surgical Microscope's Urgent Field Safety Notice. I will take the necessary steps outlined in the Urgent Field Safety Notice while I wait for the installation of the cooling sheet on the xenon power supplies to be performed.
- I confirm that I have read and understood the back-up procedure ("Switch manually to auxiliary illumination") as described on page 24 of the Leica M525 F50 user manual in order for me to act accordingly if the main illumination shuts down ("fails") during a surgical procedure.

Unit(s) affected in my laboratory/hospital is (are) listed below (Serial Number(s) - S/N).

Leica M525 F50 surgical microscope stand (Article No. 10448422) – S/N: _____

Please return this acknowledgment form as soon as possible, latest within 10 working days after receipt of field safety notice / medical device correction notification.

Facility Name (Please Print)

Facility Address (Please Print)

Contact Person (Please Print)

Signature

Date

***Please fax or email the signed form to the following:
Fax No.: +41 71 726 3249 or email to: md.quality-assurance@leica-microsystems.com***

M525 F50 COOLING SHEET METAL INSTALLATION

To Whom mit may concern
Author H. Gantner
Info to MD Service Team

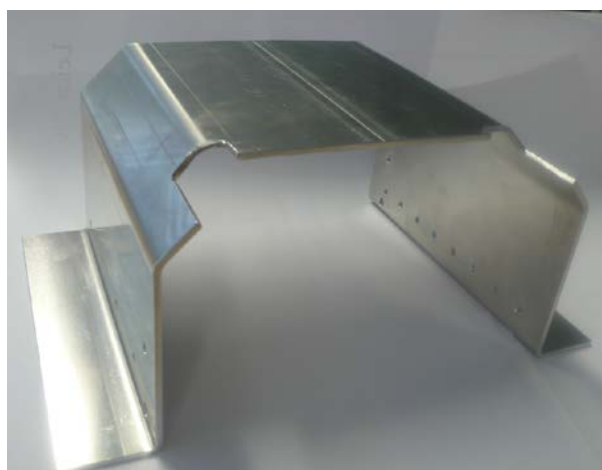
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Date 2012-06-22

Installation Description

Cooling sheet metal:

Weight: 600g
Mass: 180mm x 270mm x 115mm
Material: Aluminum

Enclosed with delivery:
8x Phillips screws M3x10
8x Tooth-lock-washer
1x description (this document)



F50 COOLING SHEET METAL INSTALLATION

Date 2012-06-22

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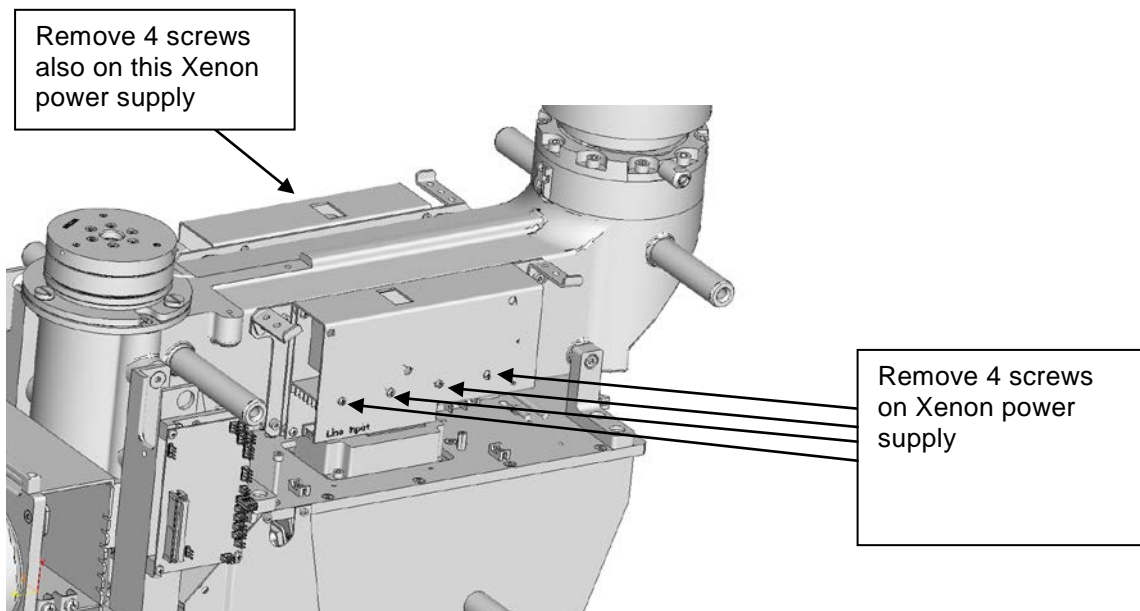
Installation Procedure



Caution – ESD Protection

Possible damage to electronic devices due to electrostatic charge.
Protect devices from charging electrostatically.

- Switch off and disconnect power cord from M525 F50
- Remove side covers from horizontal arm
- On both Xenon power supplies remove 4 screws (Torx T9 M3x4)

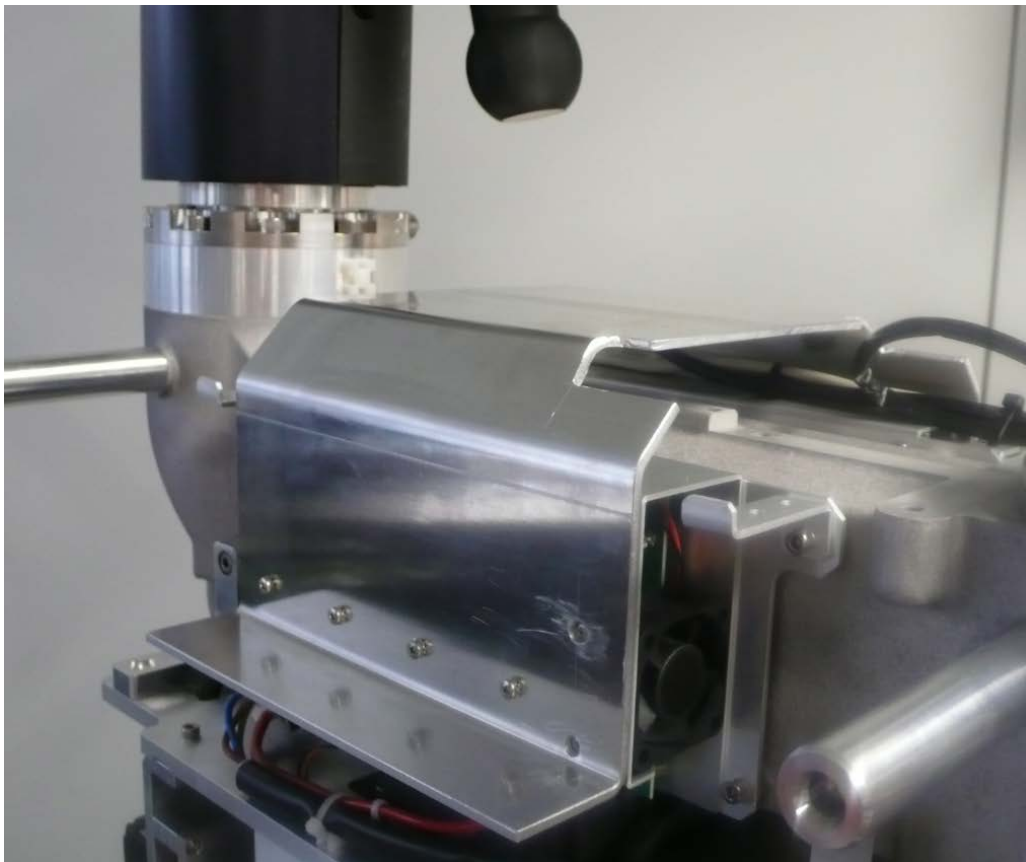


F50 COOLING SHEET METAL INSTALLATION

Date 2012-06-22

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- Insert sheet metal



- Fix sheet metal with 8 screws and tooth-lock-washer
- Install side covers back to the horizontal arm
- Connect power cord and switch system on
- Check illumination functions
- Check all other functions of stand, microscope and documentation

FSCA Upgrade Report Form:

**Leica M525 F50 Surgical Microscope (Xenon Power Supplies):
Installation (Upgrade) with Cooling Sheet Metal
Ref. # CAPA-2012-04-003-H**

Please return this page filled in, signed and dated to RA/QA Department – Heerbrugg:

- preferred by e-Mail to: md.quality-assurance@leica-microsystems.com
- or by fax to: +41 71 726 3249

Reporting unit:

Agency:

Country:

Responsible Person:

Customer Information:

Name of Facility or Hospital:

Address:

Medical Device Information: Leica M525 F50 Surgical Microscope

Leica M525 F50 Stand System (Article # 10448422) S/N:

I herewith confirm that the xenon power supplies of the Leica M525 F50 Stand System, mentioned above (Article # 10448422), has been successfully installed (upgraded) with cooling sheet metal (Article # 10744059) according to the Installation Manual – "M525 F50 COOLING SHEET METAL INSTALLATION", dated 2012-06-22.

In addition, I herewith confirm that after the upgrade, the Leica M525 F50 surgical microscope system has been tested according to test protocol on page 2. Check 1 and Check 2 are passed, and the surgical microscope has been put back into normal use and operation.

Other things to report on this unit / Comments:

.....
.....
.....

Place: _____ Date: _____ Signature: _____
(Leica-Representative)

Test Protocol (Ref. # CAPA-2012-04-003-H)

Leica M525 F50 Stand System (Article # 10448422) S/N:

Check 1

1.1 Cooling sheet metal installed successfully? Yes No

Check 1 Passed: Yes, cooling sheet metal was installed successfully.
 No

Check 2

2.1 After update, switch on again.
Check device list and align it to your actual configuration. Done

2.2 Check zoom and focus functions: Magnification and focus can be moved up/down by handgrips and by touch panel. Done

2.3 Check main illumination - switch on light and increase/decrease brightness: The brightness in the object field dims up and down. Done

2.4 Check auxiliary (back-up) illumination - switch on light and increase/decrease brightness: The brightness in the object field dims up and down. Done

2.5 Check brakes - press rear button of handgrip left and right: All brakes release. Done

2.6 If XY unit present:
Check XY functions, press assigned handgrip buttons (X+, X-, Y+, Y-): The microscope moves in commanded directions. Done N/A

Check 2 Passed: Yes, Points 2.1 to 2.5 and 2.6 (if present) are done.
 No

Place: _____ Date: _____ Signature: _____
(Leica-Representative)

If you need any assistance, please contact our LMS-Heerbrugg Service Hotline under: +41 71 726 3111