

URGENT FIELD SAFETY NOTICE

Leica M525 OH4 / Leica M720 OH5 Surgical Microscopes with 400W Illumination

FSCA-Identifier: CAPA-2015-12-001-H

Replacement of cables in illumination unit required

Customer Name

January 19th, 2016

Institution

Leica Microsystems

Address

Dear valued Leica Customer,

Our goal at Leica Microsystems is to provide you with the best quality products and services to ensure highest customer satisfaction. Our Quality Management process has identified a potential system malfunction in our OH4/5 Series which might disturb normal system operation. No patient injury and no adverse event were reported. This is to inform you of an upcoming field action.

The field action is involving Leica OH4 / OH5 Surgical Microscope Stands with 400W illumination manufactured from 1st October 2012 until 1st September 2014 with Serial Numbers as listed in Attachment 1.

If you are receiving this letter you have received a product that is subject to this recall.
This letter contains important information that needs your immediate attention.

Description of the Problem:

It has come to our attention that an electronic component of the Leica M525 OH4 and Leica M720 OH5 surgical microscopes with 400W illumination could lead to an unforeseen behavior:

An electronic component in one of the two illumination units can potentially overheat, resulting in minimal smoke and odor emanating from the ventilation openings of the illumination units. The illumination units are located opposite and away from the surgeon / patient side of the surgical microscope (for details see picture 1 below).

In-depth investigation of these reported issues revealed that the root cause is caused by an output filter capacitor in the 400W Xenon Power Supply inside the illumination units. Replacing the power supply output cable of the illumination unit with an improved cable including a filter coil will prevent this failure.

Note: No patient injury and no adverse event were reported. The surgical microscope functions are not affected when the failure occurs in one illumination unit. The illumination unit in use will continue to function if the failure occurs. At no time is there a risk of ignition or fire.

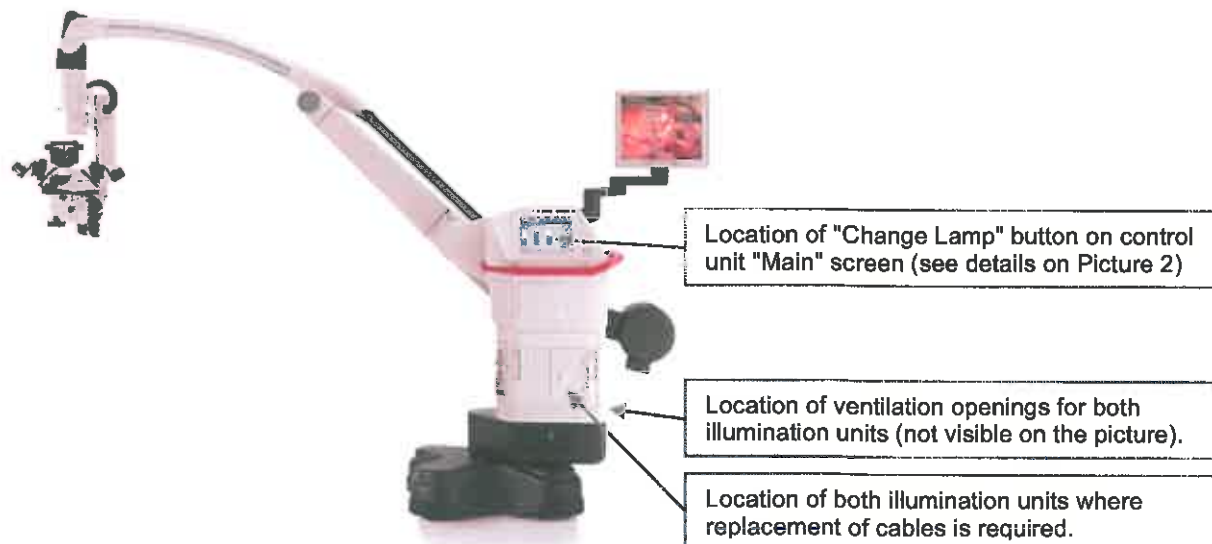
Regulatory Affairs / Quality Assurance · T +41 (0)71 726 32 16 · F +41 (0)71 726 3249 · md.quality-assurance@leica-microsystems.com

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

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Picture 1: showing a Leica M525 OH4 surgical microscope with marked illumination units, location of ventilation opening for both illumination units and location of the "Change Lamp" button.
This picture is also representative for Leica M720 OH5.

Advice on action to be taken by the user:

A Leica Microsystems representative will be contacting your facility to arrange the no-cost replacement of the power supply output cables with improved cables including a filter coil in both 400W illumination units of your instrument as soon as possible.

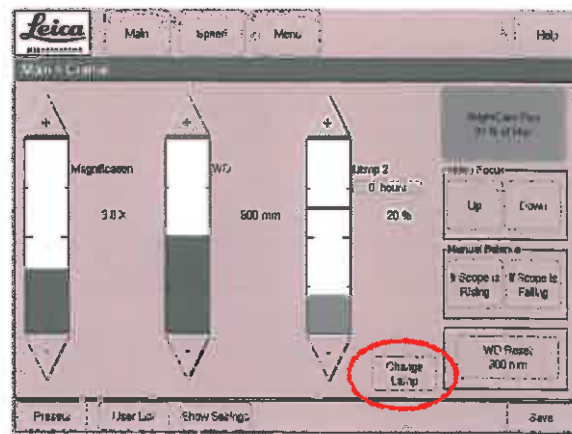
The failure cannot occur on systems with 300W illumination.

You can continue to use the system according to your User Manual. Both illumination units should be checked prior to beginning of any operation case. The Leica M525 OH4 and Leica M720 OH5 provide two redundant illumination units.

Independent from the issue explained previously, please be reminded that if you notice a failure in the illumination unit you are currently using, switch to the back-up illumination at the next opportunity during surgery by using the "Change Lamp" button on the control unit "Main" screen (see Picture 2 below) as described in user manual.

Changing lamps will interrupt the illumination for less than 5 seconds.

Contact your Leica Microsystems representative for repair of the defective illumination unit before using the instrument for the next surgery.



Picture 2: showing the "Main" screen with the "Change Lamp" button marked with a circle.

Note: The user manuals of the Leica M525 OH4 and Leica M720 OH5 state:

- "Never begin an operation with only one functioning xenon lamp!"
- "Like any other instrument in the operating theater this system may fail. Leica Microsystems therefore recommends that a backup system be kept ready during the operation."

The national competent authority has been informed of this field safety corrective action.

Transmission of this field notice:

This notice must be passed on to all those within your organization who need to be aware of it and to any organization where the affected devices have been sold, rented, leased or otherwise transferred.


Please confirm receipt of this notice by signing, dating and returning the attached 'Acknowledgement Form' with the serial number of your instrument back to us by email to:

md.quality-assurance@leica-microsystems.com

within 10 working days after receipt of field safety notice.

We sincerely apologize for any inconvenience this field action may have caused. Leica Microsystems (Schweiz) AG aims to provide you only with products of the highest quality.

Sincerely,


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

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