URGENT Field Safety Notice

Corrective Action

Urgent - Immediate notice required

Possible malfunction of the BIOM® 6 when used with certain LEICA surgical microscopes

OCULUS

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BVI Denmark
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DENMARK

Wetzlar, 27.08.2026

Applies to OCULUS BIOM® 6 (REF 10034820)

Article: Magnetic Drive Controller with Prism Adapter (Article number 10036796)
Affected serial numbers for Denmark: see page 2

Dear valued OCULUS partner,

Thank you for your continued cooperation with OCULUS. The safety and reliable functioning of our products are our highest priority.

As part of our post-market surveillance activities and the subsequent technical investigation, a malfunction was identified in a BIOM® 6. The root cause analysis determined that the assembly defect occurred in the supplier's manufacturing process and was not reliably detected by the supplier's inspection process.

OCULUS is therefore carrying out a Field Safety Corrective Action (FSCA) as a precaution and will replace the affected devices. You are receiving this Field Safety Notice because our records indicate that one or more affected devices were supplied to your organisation or through your distribution channel.

Immediately quarantine any affected BIOM® 6 devices in your possession. Do not further distribute these devices or use them in combination with a LEICA PROVEO 8/8x, M844, M822 or M820 surgical microscope.

Problem description:
The BIOM® 6 is detected by the connected LEICA surgical microscope via an electrical interface. In the investigated device, the resistor R26 required for this detection was missing from the Control PCB.

An affected device may initially operate normally after power-up and during the functional test. During subsequent use, however, correct recognition of the BIOM® 6 by the surgical microscope may be lost.

In the investigated failure condition, this caused the image inverter of the surgical microscope to switch unexpectedly and the illumination to be switched on. The BIOM® 6 could then no longer be controlled as intended.

The described malfunction was reproduced during the technical investigation.

Possible effects:
If the described malfunction occurs during use, the BIOM® 6 cannot be used as intended. It may be necessary to discontinue use of the BIOM® 6 and switch to an alternative viewing method.

In one case known to date, the malfunction occurred during surgery. The BIOM® 6 was swung out of the optical path and the procedure was continued using a contact lens as an alternative viewing method. No patient injury, clinically relevant delay, or deterioration of the surgical outcome was reported.

Affected products:
This corrective action applies to the following devices:

Product: BIOM® 6 (REF 10034820)
Article: Magnetic Drive Controller with Prism Adapter (Article number 10036796)

Affected serial number(s) for Denmark: 10036796 6301 6220

This safety measure concerns the use of these devices in combination with LEICA PROVEO 8/8x, M844, M822 and M820 surgical microscopes.

Measures to be taken by your organisation:

- Check your stock, demonstration/test inventory and distribution records and confirm the current physical location and holder of each affected device listed above.
- Immediately quarantine all affected devices in your possession. Ensure that they are not further distributed or used in combination with a LEICA PROVEO 8/8x, M844, M822 or M820 surgical microscope until replacement.
- Identify all customers or other downstream recipients that received or currently possess an affected device.
- **Inform all identified recipients without delay. You may use the prepared local-language Customer Field Safety Notice provided by OCULUS for this purpose.** If another communication format is used, ensure that the information provided clearly communicates the affected device(s), the identified malfunction, the applicable restriction of use and the planned replacement. In particular, recipients shall be informed that the affected devices must no longer be used in combination with a LEICA PROVEO 8/8x, M844, M822 or M820 surgical microscope until replacement, and that a successfully completed pre-use functional test does not reliably exclude occurrence of the malfunction during use.
- **Ensure that the customer communication is appropriately documented and that evidence of its dissemination and follow-up is available. Where practicable, receipt or implementation of the safety information should also be documented.**

- For each affected serial number, provide OCULUS with the current location/holder and, where applicable, the name, address and contact details of the downstream recipient.
- Please complete the attached Distributor Reply Form (Appendix A) and return it to OCULUS (fsca@oculus.de) promptly, but no later than 14 days after receipt. By completing the form, you acknowledge receipt of this URGENT Field Safety Notice and confirm the status and reconciliation of the affected devices.
- Maintain documented follow-up until all affected devices have been reconciled and their return or replacement has been completed.

Actions planned by OCULUS to resolve the issue:
OCULUS will replace the devices affected by this corrective action. An OCULUS employee will coordinate the replacement and return of the affected devices with you.
OCULUS will provide the technical information and prepared local-language customer communication materials required to support the local implementation of this field action.

Further information and support:
If you require further information or support in connection with this corrective action, please contact your personal OCULUS representative, OCULUS Service at +49 641 2005-800, or send an e-mail to **fsca@oculus.de**

We regret any inconvenience caused by this action and thank you for your support in implementing this corrective action.

Yours sincerely

OCULUS Optikgeräte GmbH

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Attachments
A - Distributor Reply Form