

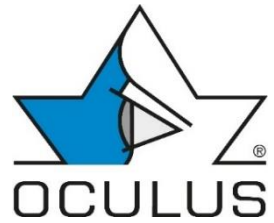


URGENT Field Safety Notice

Corrective Action

Urgent - Immediate notice required

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



OCULUS Optikgeräte GmbH, Münchholzhäuser Straße 29, 35582 Wetzlar

<Name>

<Address>

<zip code / City>

Wetzlar, 27.08.2026

Applies to OCULUS BIOM® 6 (REF 10034820)

Article: Magnetic Drive Controller with Prism Adapter (Article number 10036796)

Affected serial numbers in Germany: see page 2

Dear Sir or Madam,

The safety and reliable functioning of our products is 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.

Immediately stop using the BIOM® 6 devices with the serial numbers listed on page 2 in combination with a LEICA PROVEO 8/8x, M844, M822 or M820 surgical microscope.

Even a successfully completed functional test before surgery does not reliably exclude the occurrence of the described malfunction during use.

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. In this case, 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 described malfunction occurred during surgery. The BIOM® 6 was swung out of the optical path and the surgical procedure was continued using a contact lens as an alternative viewing method.

In this case, 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 numbers in Germany:	10036796 0301 5280
	10036796 2401 6220
	10036796 4001 5280

This safety measure concerns the use of these devices in combination with the following LEICA surgical microscopes:

- PROVEO 8
- PROVEO 8x
- M844
- M822
- M820

Measures to be taken by you:

- **Immediately stop using the BIOM® 6 devices with the serial numbers listed above in combination with a LEICA PROVEO 8/8x, M844, M822 or M820 surgical microscope.**
- Ensure that the affected devices are not inadvertently used in any of the combinations listed above until they have been replaced.
- Please note that a successfully completed functional test before surgery does not reliably exclude the occurrence of the described malfunction during subsequent use.
- Pass this Urgent Field Safety Notice immediately to all users of the affected devices and to any other persons within your organization who need to be informed.
- Please complete the enclosed Customer Reply Form (Appendix A) and return it **promptly, but no later than 14 days after receipt**, to OCULUS (fsca@oculus.de)
- If you have transferred an affected device to another organization or location, immediately forward this safety information to the current recipient and inform OCULUS accordingly.
- Please retain this Urgent Field Safety Notice until the corrective action for the affected devices has been completed.

Actions planned by OCULUS to resolve the issue:

OCULUS will **replace** the devices affected by this corrective action.

An OCULUS employee or your responsible OCULUS representative will contact you to coordinate the further procedure, including replacement and return of the affected device.

This corrective action has already been reported to the relevant competent authorities. The German Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this "URGENT Field Safety Notice".

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.

Best regards

OCULUS Optikgeräte GmbH

Matthias Krug

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Attachments

- Appendix A - Customer Reply Form

URGENT Field Safety Notice

- Customer Reply Form -



Instructions: Please complete this form in full and return it **promptly, but no later than 14 days after receipt** to OCULUS (fsca@oculus.de). By completing this form, you acknowledge receipt of the Urgent Field Safety Notice (FSN) and confirm that you understand the issue and the required actions.

1. Field Safety Notice (FSN) details	
FSN reference number:	RM-2026-01
FSN date:	27.08.2026
Product / Device name:	BIOM® 6 (REF 10034820)
Article:	Magnetic Drive Controller with Prism Adapter
Article number:	10036796
Affected serial number(s):	10036796 0301 5280 10036796 2401 6220 10036796 4001 5280
Affected use:	In combination with LEICA PROVEO 8/8x, M844, M822 or M820 surgical microscopes

2. Customer details	
Health organization name*	
Health organization address*	
Department	
Contact name*	
Telephone number*	
E-mail*	

It is important that your organization implements the measures described in the Urgent Field Safety Notice (FSN) and confirms that you have received and understood the FSN.

Your response provides OCULUS with evidence for implementation and follow-up of the corrective action.

Mandatory fields are marked with *

3. Measures to be taken by you

- Immediately stop using the BIOM® 6 devices with the serial numbers listed above in combination with a LEICA PROVEO 8/8x, M844, M822 or M820 surgical microscope.
- Ensure that the affected devices are not inadvertently used in any of the combinations listed above until they have been replaced. Please note that a successfully completed functional test before surgery does not reliably exclude the occurrence of the described malfunction during subsequent use.
- Pass this Urgent Field Safety Notice immediately to all users of the affected devices and to any other persons within your organization who need to be informed.
- If you have transferred an affected device to another organization or location, immediately forward this safety information to the current recipient and inform OCULUS accordingly.

4. Please confirm the measures:

We confirm that we have received and understood the URGENT Field Safety Notice and have implemented the required measures. The affected devices in our possession will not be used with the specified LEICA surgical microscopes until replacement, and the information has been communicated to all relevant users and other persons who need to be informed.

Affected serial number

10036796 0301 5280
10036796 2401 6220
10036796 4001 5280

Device is in our possession*

☐ No ☐ Yes
☐ No ☐ Yes
☐ No ☐ Yes

Affected device(s) transferred to another organization / location?*

If yes: serial number(s) and current recipient(s)
(organization, address, contact person / contact details)

☐ No ☐ Yes

Name*

[block letters]

Function

Signature*

Date*



Please return the completed Customer Reply Form to fsca@oculus.de