

«Account_Name»
«Salutation» «Degree» «First_Name»
«Last_Name»
«Account_Street_Address»
«Account_Postal_Code» «Account_City»

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Datum: 20. Juli 2018

Corrective Action
Alcon LuxOR™ E71 Ophthalmic Microscope
Alcon LuxOR™ E71 Q-Vue™ Ophthalmic Microscope

Dear «Degree_2» «Last_Name»

This letter is to advise you of a voluntary Field Safety Corrective Action being initiated by Alcon for the Alcon LuxOR™ E71 Ophthalmic Microscope; Alcon LuxOR™ E71 Q-Vue™ Ophthalmic Microscope used for low magnification visualization during ophthalmic surgical procedures for cataract, retina and cornea. Alcon has identified the following impacted microscope(s) within your facility.

Affected Product(s):

Product	Catalog Number	Serial Number
<<insert information>>	<<insert information>>	<<insert information>>

The Alcon LX3 Ophthalmic Microscope is not affected.

Description of the potential condition:

Through our monitoring process, Alcon has observed there is a potential for the optical head to detach from the stand on the Alcon LuxOR™ E71 Ophthalmic Microscope and Alcon LuxOR™ E71 Q-Vue™ Ophthalmic Microscope due to the lack of thread adhesive. This adhesive is designed to prevent unthreading of the mounting post.

As instructed in the E71 Operator's Manual, in order to ensure safe use of the device, Alcon recommends ensuring all mechanical lock knobs used for holding components together are secure.

During rotation of the optical head, if the Friction knob is engaged and the mounting post has no thread adhesive, the mounting post can potentially unthread and detach from the Microscope Stand. This may lead to the potential for physical injury from the dropping of a detached optical head. There have been no known incidents of physical injury reported in conjunction with this issue.

Out of an abundance of caution, Alcon is voluntarily inspecting and if required, replacing the mounting post of the Alcon LuxOR™ E71 Ophthalmic Microscope and Alcon LuxOR™ E71 Q-



Vue™ Ophthalmic Microscope if thread adhesive is not present or damage of the mounting post is observed.

The Alcon LuxOR™ E71 Ophthalmic Microscope and Alcon LuxOR™ E71 Q-Vue™ Ophthalmic Microscope is designed to be locked and unlocked through use of a series of friction knobs on the Microscope Stand.

As instructed in the E71 Operator's Manual, in order to ensure safe use of the device, Alcon recommends performing the following prior to each use*:

- Make sure all mechanical lock knobs used for holding components together are secure.
- Make sure all necessary optical components are securely attached to the LIBERO-XYTM™ system.
- Be sure all set screws applicable to the suspension system are securely tightened.
-

*Please refer to the operator's manual for further instruction.

Action to be taken by the user:

Our records indicate you have an Ophthalmic Microscope as indicated above within your facility. Alcon will contact you to schedule an appointment with one of our Field Service Engineers to inspect the unit and replace the unit's mounting post if necessary, at your convenience.

A functional and visual inspection can be performed to identify the issue with the mounting post. **If you choose to continue using the Ophthalmic Microscope while awaiting this inspection, please perform both the Functional and Visual tests use the following instructions:**

Functional Inspection Test:

- Lock the Rotational Friction Knob.
- Attempt to rotate the Optical Head and Libero assembly (see Figure 1).
 - PASS: The Optical Head and Libero cannot be rotated when the Friction knob is engaged and locked.
 - FAIL: The Optical Head and Libero can be rotated when the Friction knob is engaged and locked. If your device fails this test, stop use of the device immediately and notify Alcon.

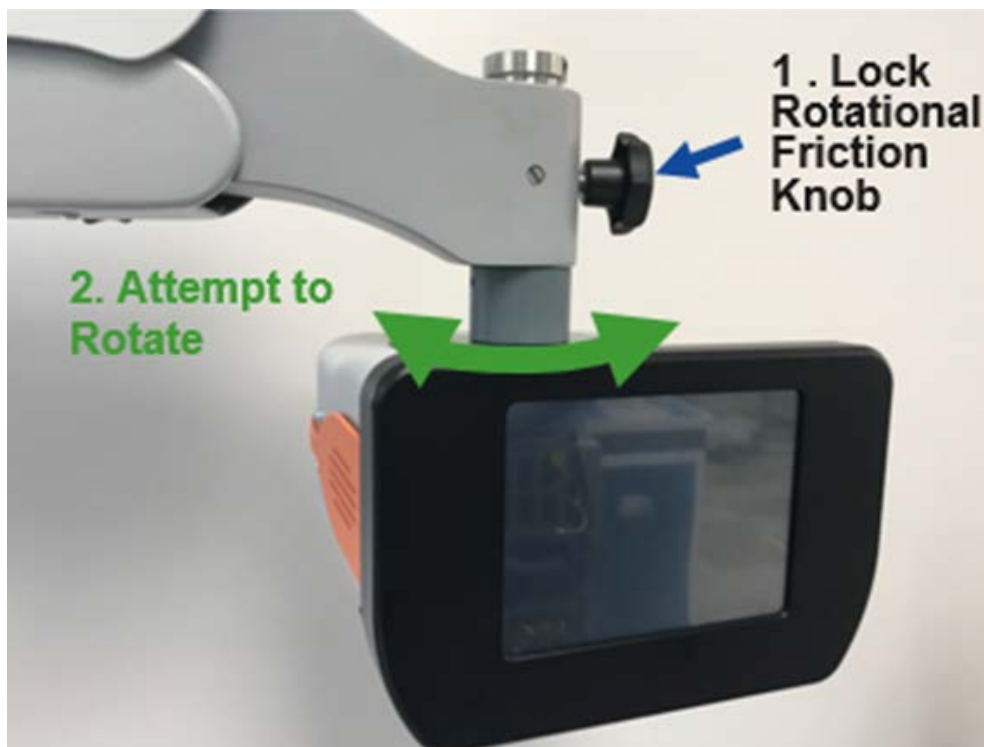


Figure 1: Functional Inspection Instructions

Visual Inspection Test:

1. Visually inspect gap between Knuckle and Coupler.
 - PASS: Minimal gap between the coupler and knuckle is present. Note that it is acceptable to see minimal light between the knuckle and coupler as shown in the "PASS" image in Figure 2. The gap observed between the coupler and knuckle should be less than the thickness of a credit card (approximately 1/32nd of an inch or 0.76mm).
 - FAIL: The gap observed between the coupler and knuckle is greater than or equal to the thickness of a credit card (approximately 1/32nd of an inch or 0.76mm) as shown in the "Fail" image in Figure 3. If your device fails this test, stop using the device immediately and notify Alcon.

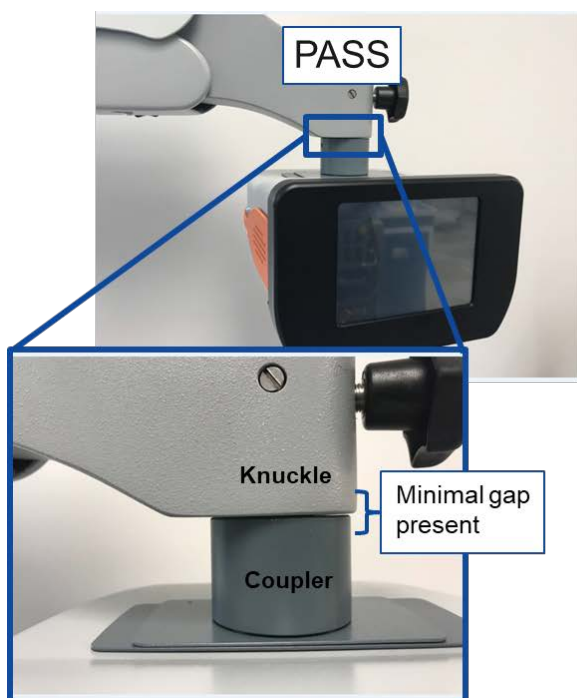


Figure 2: Pass Image

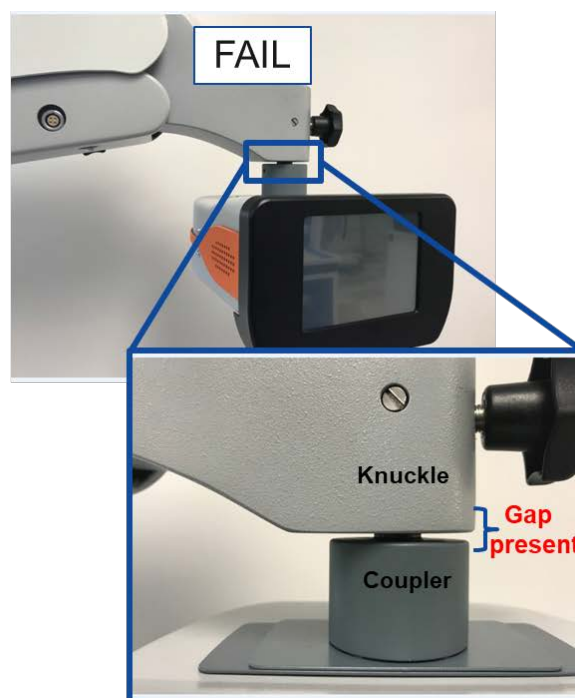


Figure 3: Fail Image

Regardless of your findings, a similar inspection will be performed by Alcon Field Service during a scheduled onsite visit.

To assist us in this voluntary Field Safety Corrective Action, please take the following steps:

1. Inspect your microscope per the instruction above.
2. If either the Functional or Visual tests have failed, stop use of the device immediately and notify Alcon.
3. Forward this information immediately to all departments within your organization who may be using the Alcon LuxOR™ E71 Ophthalmic Microscope and Alcon LuxOR™ E71 Q-Vue™ Ophthalmic Microscope.
4. If applicable, provide a copy of this notification to any other organization / location to which the Alcon LuxOR™ E71 Ophthalmic Microscope and Alcon LuxOR™ E71 Q-Vue™ Ophthalmic Microscope has been sold or moved.
5. Return the attached Response Form via fax or email to Alcon.

Transmission of this Field Safety Corrective Action:

Please immediately forward this information to all departments within your organization who may be using the Alcon LuxOR™ E71 Ophthalmic Microscope; Alcon LuxOR™ E71 Q-Vue™ Ophthalmic Microscope. If you have moved or sold your Alcon LuxOR™ E71 Ophthalmic Microscope; Alcon LuxOR™ E71 Q-Vue™ Ophthalmic Microscope (to another location or organization), please provide a copy of this notification to the recipient(s) so they may contact Alcon to schedule their inspection.

Contact reference person:

We appreciate your cooperation and sincerely regret any inconvenience that this may cause you and your patients.

Should you have any questions or concerns about this matter, please contact Alcon at

Dr. Wilko Nölken, phone: 0761 / 1304 – 263
Dr. Sebastian Broy, phone 0761 / 1304 – 331.

Sincerely

Alcon Pharma GmbH

i.A.

i. A.

Dr. Wilko Nölken
Fachreferent Qualitätssicherung

Dr. Sebastian Broy
Fachreferent Qualitätssicherung

Attachment: Acknowledgement Form

ACKNOWLEDGEMENT Form

Corrective Action
Alcon LuxOR™ E71 Ophthalmic Microscope
Alcon LuxOR™ E71 Q-Vue™ Ophthalmic Microscope

Serial Number: << INSERT SERIAL NUMBER >>

Please follow these important steps:

1. Inspect your microscope per the instruction above.
2. If either the Functional or Visual tests have failed, stop use of the device immediately and notify Alcon.
3. Forward this information immediately to all departments within your organization who may be using the Alcon LuxOR™ E71 Ophthalmic Microscope and Alcon LuxOR™ E71 Q-Vue™ Ophthalmic Microscope.
4. If applicable, provide a copy of this notification to any other organization / location to which the Alcon LuxOR™ E71 Ophthalmic Microscope and Alcon LuxOR™ E71 Q-Vue™ Ophthalmic Microscope has been sold or moved.
5. Return the attached Response Form via fax or email to Alcon.

Fax number: 0761 / 1304 – 99421

E-Mail: fbalde.00063@alcon.com

Your signature below attests that you have read and understood this Alcon Voluntary Field Safety Corrective Action.

Signature of Facility Representative:

Printed Name and Title:

Date:

«Account_Name»
«Salutation» «Degree» «First_Name» «Last_Name»
«Account_Street_Address»
«Account_Postal_Code» «Account_City»