



Park View, Riverside Way
Watchmoor Park,
Camberley,
Surrey GU15 3YL

T: +44 (0)1276 673311
F: +44 (0)1276 673313
W: www.uk.alcon.com

URGENT: FIELD SAFETY NOTICE

Commercial Name of Affected Product: LX3 Microscope Floor Stand
Reference(s): 8065752560
FSCA Identifier: 2015.046
Type of Action: Medical Device Correction

August 13, 2015

«Account_Name»
«Account_Address»
«Contact_Name»

Dear Valued Alcon Customer,

This letter is to advise you of a Field Safety Corrective Action being initiated by Alcon for the LX3 Microscope Floor Stand used with the LuxOR™ Ophthalmic Microscope and LuxOR™ Ophthalmic Microscope with Q-VUE™ 3D Assistant Visualization for low magnification visualization during ophthalmic surgical procedures for cataract, retina and cornea.

Affected Product(s):

LX3 Microscope Floor Stand, Alcon Product Number 8065752560
Serial Numbers: 1402548501X to 1502857606X

Description of the potential condition:

Alcon is conducting a voluntary medical device correction of all LX3 Microscope Floor Stands after receiving reports concerning loss of functionality due to issues with the cabling between the power, host and illumination modules, potentially causing the system to display a system message (4XX), and/or resulting in illumination failure. Alcon will retrofit the cable design on any impacted LX3 Microscope Floor Stands.

Loss of system functionality during surgery due to issues within the microscope modules or illumination failure will result in the loss of visualization by the surgeon during the procedure, which can lead to the potential for patient injury. This could include scleral/corneal trauma, intraocular tissue damage, capsule injury, retinal tear/detachment, endothelial cell damage, corneal edema or intraocular bleeding.

Action to be taken by the user:

An Alcon Service Engineer will be contacting you to retrofit your unit with the new cable design. **If you opt to continue using your LX3 Microscope Floor Stand prior to the retrofit, Alcon recommends that you have a backup microscope and light source available for use in the unlikely event that your LX3 Microscope Floor Stand loses illumination during surgery.**



If loss of illumination is experienced or the lamp bulb stops working, please first verify functionality of the bulb. In the event of lamp failure (other than lamp failure due to a non-functioning bulb), or if you detect burning odor, or observe melting of the exterior microscope skin during use, immediately turn the power off or unplug the unit, and contact Alcon Technical Services team for an immediate service call at:

Telephone: 0371 376 1449

If you see system message 4XX and the system locks up, immediately turn the power off or unplug the unit and contact Alcon.

Please sign and return the attached 'Acknowledgement Form' via fax or email for confirmation that you understand the potential condition and actions to be taken.

Fax: +44 1276 673971

Email: gb.medicaldepartment@alcon.com

Transmission of this Voluntary Medical Device Correction:

Please immediately forward this information to professionals within your organization who may be using the LX3 Microscope Floor Stand. Additionally, please ensure that a copy of this notification is provided to any other organizations to which the affected floor stand has been transferred.

Contact reference person:

We appreciate your cooperation and sincerely regret any inconvenience that this may cause you. We hope this action reassures you of our commitment to provide you with the highest quality vision care products and continued quality excellence for you and your patients.

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

Telephone: +44 (0) 345 266 9363

Email: gb.medicaldepartment@alcon.com

Yours Sincerely,



Tim Cripps

Head of Regulatory Affairs UK & Ireland

Alcon LX3 Microscope Floor Stand ACKNOWLEDGEMENT Form MA# 2015.046
<p>Please follow these important steps:</p> <p>1) Return the completed Acknowledgement Form via fax or email to Alcon.</p> <p>Fax: +44 1276 673971 Email: gb.medicaldepartment@alcon.com</p> <p><i>Your signature below attests that you have read and understood Alcon's medical device correction.</i></p>
Signature of Facility Representative:
Printed Name and Title:
Date:

<<Enter Customer Information>>
<<Enter Customer Information>>
<<Enter Customer Information>>
<<Customer number>>