URGENT Field Safety Notice

Corrective Action

Urgent - Immediate notice required

Possibly incorrect axial length measurements due to insufficient anti-reflective coating of an internal optical component

Wetzlar, 01.08.2023

Applies to OCULUS Myopia Master® (Type 68120 & 10010728)

Dear Sir or Madam,

Thank you for your trust in OCULUS products. Maintaining the highest safety and quality standards is our top priority.
We have become aware of a potential safety issue with some Myopia Master® devices that may result in incorrect axial length measurements.
As a reliable partner, OCULUS will carry out a corrective action (Field Safety Corrective Action) for you.
You are receiving this URGENT Field Safety Notice because our records indicate that you have received one or more devices affected by this action.
With this URGENT safety information, we would like to inform you that you may no longer use the affected devices to measure the axial length of the eye.

Problem description:
One of our suppliers did not meet the specifications for an optical component inside the devices. An insufficient anti-reflective coating was found, which under certain circumstances can lead to an additional axial length signal.
If the correct axial length signal is weaker (e. g. due to an off-centre measurement or a cataract), an incorrect axial length value can be displayed.
OCULUS identified the problem within the production process. We have reviewed our records and identified previously shipped units where this issue is not likely, but not completely ruled out, to occur.
However, there have been no reports of physical injury or serious negative consequences.

Possible hazards:
If the user does not notice the faulty measurement or an incorrect axial length value, the error can subsequently lead to the wrong spectacle lens design or contact lens design being selected, for example. Furthermore, it is possible that the patient subsequently does not receive the intended treatment or receives insufficient treatment due to the inadequate device performance.

Affected products:
The error affects the axial length measurement function of specific devices of the product Myopia Master® (Type 68120 & 1001728). The serial numbers of potentially affected devices are listed in Appendix B.

All other functions and measurements of these devices are not affected and can still be used according to the instructions for use!

Measures to be taken by you to avoid patient harm:

- Immediately stop using the affected devices for axial length measurement (mark the affected devices with a note) or take them out of service immediately.
  Devices not listed in Appendix B are not affected by this corrective action and can continue to be used according to the instructions for use.

- Please fill out the attached form (Appendix A) and return it to OCULUS as soon as possible, but no later than 30 days after receipt.
  By completing this form, you acknowledge receipt of the Urgent Field Safety Notice and that you understand the issue and the actions required.

- Pass this urgent safety information on to all users of the affected products and other people who need to be informed so that they are aware of the problem. Please file this letter directly with your device and make sure that it is and remains visible to all users at the storage location.
  It is important that the meaning of this notification is understood.

If you have given the products to a third party, please forward a copy of this information immediately and please inform us accordingly.

Please keep this urgent safety information at least until the action has been completed.

Actions planned by OCULUS to resolve the issue:
OCULUS will replace or repair the affected devices. An OCULUS representative will contact you shortly and coordinate the further procedure with you (such as exchange, repair, supply of loan devices, etc.).

This corrective action has already been reported to the relevant authorities. The National Competent Authority has received a copy of this "URGENT Field Safety Information".

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

We would like to sincerely apologize to you for any inconvenience caused by this action.

Best regards

OCULUS Optikgeräte GmbH

Head of Product Safety & Risk Management
Quality & Regulatory Affairs

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Attachment

A – Customer reply form
B – List of serial numbers of affected devices in your region

DEUTSCHLAND

FSN/FSCA 470-2023-01-M

Seriennummer	RMA Nummer
68130 6001 2220	10121928
68120 9261 2201	10121889
68120 8931 2210	10121892
68120 8461 2201	10121926
68120 8361 2201	10121905
68120 8121 1240	10121886
68120 7841 2250	10121931
68120 7511 1220	10121891
68120 7361 2201	10121888
68120 6761 2211	10121885
68120 6731 2210	10121893
68120 6571 3230	10121887
68120 5761 2211	10121908
68120 5561 2211	10121890
68120 5411 0221	10121909
68120 3661 2211	10121884
68120 3471 3210	10121907
68120 3351 2270	10121929
68120 2931 2210	10121912
68120 2071 2221	10121910
68120 1661 2211	10121906
68120 1431 1211	10121843
10010728 9801 3220	10121938
10010728 9701 3220	10121939
10010728 9301 2270	10121955
10010728 8801 3220	10121944
10010728 8601 2221	10121950
10010728 7401 2280	10121954
10010728 6401 2280	10121956
10010728 6301 2270	10121966
10010728 5601 2221	10121951
10010728 4101 2220	10121945
10010728 3801 3220	10121943
10010728 2701 3210	10121941
10010728 1601 2201	10121952
10010728 1401 2270	10121961
10010728 0901 3220	10121942
10010728 0801 3220	10121940