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

OCULUS

OCULUS Optikgeräte GmbH, Münchholzhäuser Straße 29, 35582 Wetzlar

«Firma»
«Straße»
«PLZ» «Ort»
«Land»

Wetzlar, 01.08.2023

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

Dear valued OCULUS partner,

thank you for your appreciated cooperation with OCULUS. 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).
You are receiving this Field Safety Notice because our records indicate that you have received one or more devices affected by this action.
With this URGENT field safety notice, we would like to inform you that your customers 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 or contact lens 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 your organisation to avoid patient harm:

- Please check your stock and inventory and identify customers that received or may have received affected products.
  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.

- Inform the identified customers of this field safety notice immediately. Inform all identified customers that they immediately have to stop using the affected devices for axial length measurement (affected devices are to be marked with a warning) or that they must take them out of service immediately.

  This URGENT Field Safety Notice must be passed on to all users of the affected products and others who need to be informed so that they are aware of the issue.
  It is important that the meaning of this notification is understood.
  You may use the URGENT Field Safety Notice for end customers prepared by OCULUS (see Appendix C).

- Please report back to OCULUS immediately the names, locations and contact details of your identified customers for each serial number. This information is required by the competent authority.

  Please fill out the attached form (Appendix A) and send it back to OCULUS promptly, 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.

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

Further information and support:
If you require further information or support with this problem, please get in touch with your personal OCULUS contact of the export department or with OCULUS Service on +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.

Yours sincerely

OCULUS Optikgeräte GmbH

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Attachment

A – Distributor reply form
B – List of serial numbers of affected devices in your region
C – FSN for End-Customers