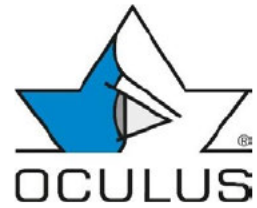


Urgent safety information

# Corrective Action

Urgent - Immediate notice required



Software-Update of OCULUS Pentacam® Software version 1.26r26 & 1.26r27

OCULUS Optikgeräte GmbH, Münchholzhäuser Straße 29, 35582 Wetzlar

<Name>

<Address>

<zip code / City>

Wetzlar, 08.07.2022

## **Applies to Pentacam® HR (Type 70900), Pentacam® AXL (Type 70100) and Pentacam® AXL Wave with software version 1.26r26 and 1.26r27**

Dear Sir and Madam,

thank you for your trust in OCULUS products. The quality of our products and the safety of our users and their patients are very important to us. 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 are the owner of product that may be affected by this action.

### **Problem Description:**

We would like to inform you about a **software error in the software version 1.26r26 and 1.26r27 in the IOL calculator of the Pentacam® software.**

During post-market surveillance, we have found that the IOL calculator printout often does not accurately reflect the alignment axis and incision position when planning toric IOLs. The information displayed directly in the software is correct.

### **Possible hazards:**

Unless the user notices the difference from what is correctly displayed in the software, the error can result in a toric IOL not being properly aligned when it is implanted.

### **Affected products:**

This only applies to OCULUS Pentacam® HR (Type 70900) with IOL calculator additional license, OCULUS Pentacam® AXL (Type 70100) and OCULUS Pentacam AXL Wave (Type 70020) each with software version 1.26r26 or 1.26r27.

### **Measures to be taken:**

A software update to version 1.26r28 (or higher) must be performed on all computers used and affected in connection with the Pentacam®.

Do not use the printout of the IOL calculator until after the software update has been carried out.

Please identify the software versions you have installed by using the procedure described in the attachment and report them back to us using the **reply form** also attached **by July 20, 2022 at the latest**.

If you are affected by the measure, an OCULUS service technician will contact you immediately to arrange an appointment to carry out the corrective measure.

**Disclosure of the information described here:**

Please make sure that all users of the above Products and other persons to be informed (e.g. the representative for medical device safety according to §6 MPBetreibV) are made aware of this urgent safety information in your organization.

If you have given the products to a third party, please forward a copy of this information or inform the contact person given below.

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

The Federal Institute for Drugs and Medical Devices has received a copy of this "Field Safety Notice".

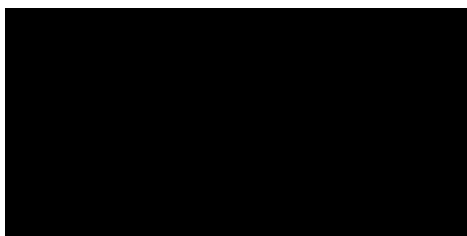
**Further information and support:**

If you require further information or support with this problem, please get in touch with your personal OCULUS contact or with OCULUS Service on 0641/2005-800 or write an e-mail to [fsca@oculus.de](mailto: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**

- Customer reply form
- Guidance for identifying the software version