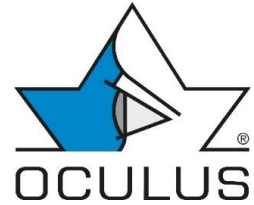Urgent safety information
Corrective Action
Urgent - Immediate notice required

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

OCULUS

«Firma»
«Firma_2»
«Firma_3»
«Straße»
«PLZ» «Ort»
«Land»

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 or 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 have received products that may be affected by this action or you downloaded the relevant software version from the distributor download tool.

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 and 1.26r27.

Measures to be taken:
A **software update to version 1.26r28** must be performed on all computers used and affected in connection with the Pentacam® and additional workstations.

Users should refrain from using the printout of the IOL calculator for affected installations until after the software update has been carried out.

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

Inform the identified customers of this field safety notice and update affected devices/ installations to version 1.26r28 immediately.

You can find a procedure how to identify the installed software version in the attachment.

Please **return** the attached **reply form by July 31, 2022 at the latest**.

Disclosure of the information described here:
Please make sure that all customers of the affected products and other persons to be informed in your organization are made aware of this urgent safety information.

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.

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 +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

Matthias Krug
Safety officer for medical devices

OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29
35582 Wetzlar
GERMANY

Tel. +49 641 2005-470
Fax +49 641 2005-455
Mobile +49 151 2816 0580

Attachment
- Distributor reply form
- Guidance for identifying the software version

Field Safety Notice

- Distributor Reply Form -

OCULUS®

1. Field Safety Notice (FSN) details	
FSN Reference number*	470-2022-01
FSN Date*	08.07.2022
Product/ Device name*	Pentacam ® HR *(with IOL-Calculator additional Licence) Pentacam ® AXL Pentacam ® AXL Wave
Product Code(s)	70900 *(only with IOL-Calculator additional Licence 70120) 70100 70020
Batch/Serial Number (s)	Software Version 1.26r26 & 1.26r27

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address [if different to above]	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to sender	
Email	fsca@oculus.de
Postal Address	OCULUS Optikgeraete GmbH Quality & Regulatory Affairs Muenchholzhaeuser Str. 29 35582 Wetzlar GERMANY
Fax	+49 641 2005-455
Deadline for returning the Distributor/Importer reply form*	31st July 2022

Field Safety Notice
- Distributor Reply Form -

4. **Distributors/Importers** [Tick all that apply]		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device/software	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have updated affected devices/installations to version **1.26r28** or higher- enter serial number of devices/installations and date complete.	Add quantity, Lot/Serial Number/Date (use supplementary sheet if necessary and attach to this form)
☐	Neither I nor any of my customers has any affected devices/installations in inventory	
Print Name*	Distributor/Importer print name here	
Signature*	Distributor/Importer sign here	
Date*	Distributor/Importer enter date here	

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

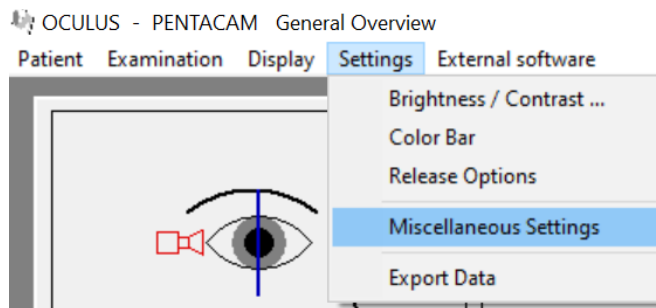Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Field Safety Notice
- Identification of software version -

Guidance for identifying the Pentacam® software version

1. Start the Pentacam® Software

2. Select a patient from the patient database

3. Click the Pentacam button, the Pentacam® software will start automatically

4. In the Pentacam® software, click the "Settings" button and then click the "Miscellaneous Settings" button in the drop-down menu

5. The Pentacam® software version can be found on the bottom left, see image below.