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To whom it may concern

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Our ref.:FCA 2020-007
Date: 4.12.2020

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Your contact: fca-jen.med.de@zeiss.com

FIELD SAFETY CORRECTIVE ACTION

Installation of a software update on active ZEISS IOLMaster 700 with software 1.90.2.09 and 1.90.8.06

Dear Colleagues and Sales Partners,

As part of Carl Zeiss Meditec's continuous focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of the ZEISS IOLMaster 700, we have identified a potential issue that may affect the performance of the equipment under certain conditions. This letter is to inform you about a Field Safety Corrective Action (FSCA) for the ZEISS IOLMaster 700 with software 1.90.2.09 and 1.90.8.06 with the aim to deactivate modality worklist functionality (MWL) on all affected devices.

Software 1.90.2.09 or 1.90.8.06 is a prerequisite to run, amongst others, the Central Topography license and the Barrett True-K TK formula.

A software update to fix all affected devices in the field will be provided as a download on December 7th 2020, 5 pm CET, on:

www.zeiss.com/iolmaster-700-software-update

Problem description:

With this letter, we would like to inform you about a mandatory software update for the ZEISS IOLMaster 700. We want to give you a precise description of the situation and provide clear guidance on how to avoid any inconveniences with your customers.

Based on feedback from the field, we have found that, when used in conjunction with the modality worklist (MWL[1]) functionality, in rare cases the patient management on the ZEISS IOLMaster 700 with software 1.90.2.09 and 1.90.8.06 is not performing as expected. All other versions of the ZEISS IOLMaster 700 are not affected.

This sporadic behavior leads to a false display of patients in the patient manager screen, which can subsequently lead to the implantation of a wrong intraocular lens (IOL). Therefore, a software update needs to be installed or the MWL functionality needs to be deactivated until the software update can be installed.

Detailed description

If the ZEISS IOLMaster 700 runs on software 1.90.2.09 or 1.90.8.06 and uses MWL functionality for patient data transfer to the ZEISS IOLMaster 700, the selection of the patient in the patient list of the patient management system may in rare cases not match the patient information displayed on the right side of the screen. There are two known manifestations of this bug:

1. The user has selected patient « A » in the patient list, but patient « B » is displayed on the right side (Figure 1).

2. The user has selected patient « A » in the patient list, patient « A » is correctly displayed in the top right, but patient « B » is displayed in the bottom right (Figure 2).

[1] DICOM Modality Worklists (MWL) make patient demographic information from a PACS system (e.g. FORUM), EMRs, EHRs, or another patient management and clinic management systems available at a modality (In this case the ZEISS IOLMaster 700), eliminating dual data entry and providing data integrity. If the patient data is entered anywhere else but manually on the device itself, likely a MWL functionality is used.

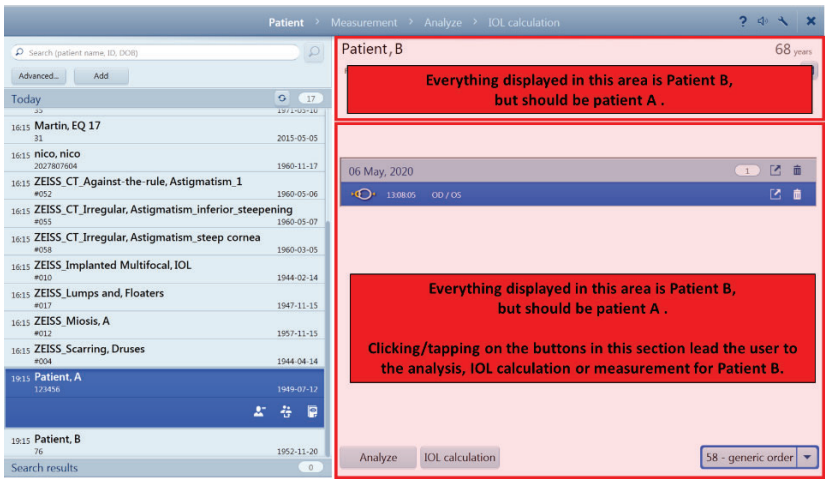


Figure 1: Mismatch between patient list and right side of patient manager.

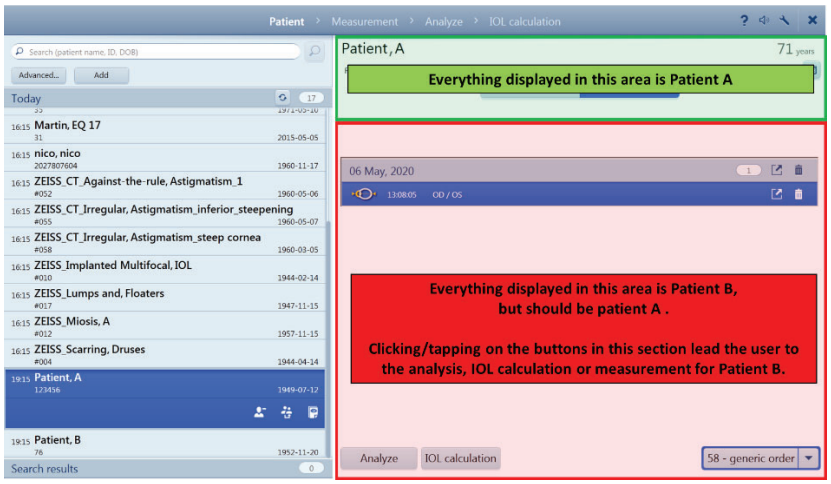


Figure 2: Mismatch between patient list / upper right side and lower right side of patient manager.

Hazard involved:

Carl Zeiss Meditec AG has received no reports about injuries or any other adverse effects associated with the described failure. In very rare cases the failure could lead to wrong measurements and subsequently wrong IOL calculation and implantation.

Affected products:

This applies only to ZEISS IOLMaster 700 with software 1.90.2.09 or 1.90.8.06. The error only occurs, however, when the device is used in conjunction with a modality worklist functionality.

Actions to be taken:

To ensure best usability of the ZEISS IOLMaster 700, we ask you to perform the field action by doing the following steps:

1) Check your local inventory and determine if products are affected. Update those devices before sending to customers.
2) Check if any upgrades to software 1.90.2.09 or 1.90.8.06 and / or Windows 10 are scheduled in your territory by ZEISS personnel. Perform those updates with the new software version.
3) Identify all "Affected Customers" in your territory. Customers using ZEISS IOLMaster 700 with software version 1.90 are considered "Affected Customers", whether they use MWL functionality or not. **Please send a comprehensive list of all affected customers in your region to fca-jen.med.de@zeiss.com not later than December 11thth 2020.**
4) Send out
    1. the "Customer Letter" (attachment 1),
    2. the "Acknowledgement Form" (attachment 2),
    3. the "Detailed Problem Description and Action to be Taken" (attachment 3), and
    4. the "Software Installation Quick Guides" (attachments 4-6)

    to "Affected Customers" and contact your "Affected Customers" by email or phone, as needed.

    The Attachments provide amongst other things guidelines on how to download and install the software update to fix the error and how to deactivate MWL functionality on devices where the software update cannot be installed immediately.

    If needed, please translate the "Customer Letter", the "Detailed Problem Description and Action to be Taken", and "Acknowledgement Form" into local language. Assist the "Affected Customers" in the software update and in deactivating the MWL functionality of their ZEISS IOLMaster 700, where required.

    Please make sure respective ZEISS personal is familiar with the procedure to download and install the software update and to deactivate MWL functionality as described in the customer letter and software installation quick guide.

    The download is available on December 7th 2020, 5 pm CET at http://www.zeiss.com/iolmaster-700-software-update

    If you have questions concerning the software update or deactivation of MWL functionality, or if you are not able to update the software or deactivate MWL functionality, please contact 2nd level support by using the E-mail support.ophthalmology@zeiss.com.

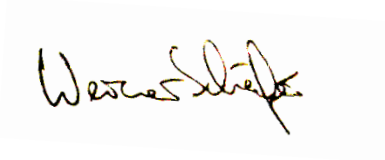
    - If a software update or the deactivation of MWL functionality is not an option for your "Affected Customer", or if you have any other questions, please contact your regional business manager for further support. (AMERICAS: vinicius.pires@zeiss.com, EMEA: ahmad.husain@zeiss.com, APAC: jukka.ruhannen@zeiss.com)
5) Ensure the return of a signed "Acknowledgement Form" from your "Affected Customers" to **fca-jen.med.de@zeiss.com not later than December 17thth 2020.**
6) This FSCA is reportable to authorities of all affected countries. Please provide required notifications of authorities with reference "FCA 2020-007" to: fca-jen.med.de@zeiss.com.

7) The FSCA is considered completed when all "Affected Customers" have been contacted, Software Update has been installed on all affected ZEISS IOLMaster 700 Devices, and Acknowlegement Receipt Forms has been signed. Please send the completion of your field action with reference "FCA 2020-007" to: fca-jen.med.de@zeiss.com. We expect completion by 31.12.2020.

We thank you very much for your careful attention, your consequent feedback and your continuous support. We apologize for any inconvenience this situation might cause. If you have any questions, please contact us.

Best regards

Carl Zeiss Meditec AG



i.V. Dr. Werner Schäfer
Head of Product Management Biometry
and Cataract Solutions

i.V. Heiko Ballauf
Head of Quality
Management Jena

Attachments:

1. Customer Letter
2. Attachment to Customer Letter "Detailed Problem Description and Actions to be Taken"
3. Acknowledgement and Receipt Form
4. Software Installation Quick Guides (DE, EN, ESP)