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FIELD SAFETY CORRECTIVE ACTION

Software Update ZEISS IOLMaster 700 with Software Versions 1.90.2.09 and 1.90.8.06

Dear valued Customer,

Thank you very much for purchasing a ZEISS IOLMaster 700. As you know, high quality and innovation is our main goal, but your and your patients' safety and satisfaction is our first priority. To ensure that you are able to continue the reliable use of our system/ products with the level of high quality you expect, Carl Zeiss Meditec is planning to perform a Field Corrective Action.

Problem description:

With this letter, we would like to inform you about a **software error with the ZEISS IOLMaster 700 software versions 1.90.2.09 and 1.90.8.06**. We want to give you a precise description of the situation and provide clear guidance on how to avoid any inconveniences with your patients and in your center.

Based on post market surveillance activities, we found that the ZEISS IOLMaster 700 with software version 1.90.2.09 and 1.90.8.06, when used in conjunction with modality worklist (MWL) functionality, is not performing as expected. In rare cases this 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).

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's with software 1.90.2.09 and 1.90.8.06. The error only occurs, however, when the device is used in conjunction with a MWL functionality.

Actions to be taken:

In brief, a software update needs to be installed on your device, or the MWL functionality needs to be deactivated in cases where you are unable to install the software update immediately.

The software update can be downloaded starting December 7th 2020, 5 pm CET via www.zeiss.com/iolmaster-700-software-update

The software will also be made available on a USB drive at a later point.

If you are using MWL, we kindly ask you to repeat all measurements and IOL power calculations of patients that underwent measurements with software 1.90.2.09 or 1.90.8.06 and have not yet undergone surgery to mitigate the risk of wrong patient-measurement assignments and implantation of the incorrect IOL.

Attached you can find a detailed description on how to update the software to ensure full functionality of your ZEISS IOLMaster 700 and how to acknowledge the successful device update.

We thank you for your careful attention and cooperation in this matter. We sincerely apologize for any inconvenience and we will do our best to address your needs and concerns.

Please do not hesitate to contact us should you have any questions.

Best regards,

Carl Zeiss Meditec AG

SSC Signatures: Q and PC Manager/ SSC Head

Attachment 1: "Acknowledgement and Receipt Form"

Attachments 2-4: "Software Installation Quick Guide" (ENG, ESP, DE)

Attachment 5: "Detailed Problem Description and Action to be Taken"