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Your ref.:

Yours of:

Our ref.: CAB#3316

Date: October 26, 2015

**Advisory Note for Field Action:
“Mandatory Software Update IOLMaster”**

IMMEDIATE ACTION REQUIRED

Dear Colleagues and Sales Partners,

With this letter we would like to inform you about a mandatory software update for your IOLMaster devices with Software Version 7.5.2, 7.7.2 and 7.7.3 as well as Software updates to these versions and Option Reference Image including Software Update 7.7.2 or 7.7.3. All other versions are not affected.

These versions of software have a software defect which can result in incorrect IOL calculations being presented on screen and in a printout / export in rare cases when a specific non-standard workflow is used.

Chairman of the Supervisory Board:
Dr. Michael Kaschke

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Deutsche Bank Jena
Account: 624536900 (BIC 820 700 00)
S.W.I.F.T.-Code: DEUT DE 8EXXX
IBAN: DE90820700000624536900

Commercial Register:
Local Court Jena HRB 205623
VAT-ID. No. DE 811 922 737
WEEE-Reg.-Nr. DE55298748

Board of Management:
Dr. Ludwin Monz, President and CEO
Thomas Simmerer
Dr. Christian Mueller

Address for Delivery:
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07745 Jena, Germany

Commerzbank Jena
Account: 258072800 (BIC 820 400 00)
S.W.I.F.T.- Code: COBADEFFXXX
IBAN: DE31820400000258072800



HOW TO IDENTIFY AFFECTED SYSTEMS:

The Software Version can be checked by pressing the i-Symbol in the upper right corner of the screen.

The screenshot shows the 'Patient manager' window with tabs for 'New patient', 'Patient list', and 'Ultrasound'. The 'About IOLMaster' dialog box is open, displaying the following information:

About IOLMaster® Advanced Technology	
Copyright Carl Zeiss 1999, 2013	
IOLMaster, Version:	7.7.2.0000
Ker. DII :	2.00.0064
ACD. DII :	1.00.0002
Wzw. DII :	1.04.0006
GIF :	0.00.0000

Additional text in the dialog box includes: 'IOLMaster, SW Option Sonolink, © Carl Zeiss 1999, 2013' and 'IOLMaster, SW Option N, © Carl Zeiss 1999, 2008'.

To ensure correct IOL calculation display of the IOLMaster, we ask you to perform the field action by doing the following:

- 1) Order the Software Update based on the list with serial numbers you will receive. Please order the necessary number of USB sticks by **November 15, 2015**
Software Update 7.5.3 / 7.7.4 (part number 000000-2163-092)
Please note: The software update stick identifies the software version and will automatically install the software update. The update stick will only work with affected software versions (7.5.2, 7.7.2 and 7.7.3).
- 2) Only for Option Reference Image Kits you have on stock, you need to exchange the Software Update stick which is included. Please order based on the list with serial numbers you will receive the necessary number of USB sticks for the Software Update 7.7.4 (part number 000000-2162-463) by **November 15, 2015**.
- 3) Purge and destroy Software Update sticks 7.5 (part number 000000-1977-827) and Software Update 7.7 (part number 000000-2081-183) that you already have! Make sure that also the Software Update sticks included in the Option Reference Image Kit are removed, destroyed and replaced.

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- 4) Inform all affected IOLMaster customers with the attached customer letter about the mandatory software update as soon as you receive the Software Update:
 - a. If needed, please translate the attached customer letter, confirmation form and update instructions into your local language.
 - b. Identify all affected IOLMaster customers in your area with the help of the list of all devices (serial #), Option Reference Image Kits and Software Updates that have been delivered to your area and any upgrades that were shipped to your customers or performed by field service.
 - c. Send out the customer letter, confirmation form and update instructions together with the software update.
- 5) Ensure that the mandatory software update is installed on all affected IOLMaster devices in your area.
- 6) Support customers that need help in performing the software update.
- 7) Collect all Confirmation sheets from customers.
- 8) Please, send the list of serial numbers, completed and signed confirmation forms and indicate in the excel list (serial #) whether the software update has been performed to fca-jen.med.de@zeiss.com. We expect the mandatory software update to be completed by **February 29, 2016**.

We all strive to ensure high level of performance of any ZEISS device and an excellent experience of our customers.

We apologize for any inconvenience this mandatory software update is causing you.

Kind regards

Carl Zeiss Meditec AG

i.A.

i.V.

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