

Please include your header

URGENT MEDICAL DEVICE CORRECTION
MANDATORY SOFTWARE UPDATE IOLMASTER 500
IMMEDIATE ACTION REQUIRED

Dear Customer,

Thank you very much for purchasing an IOL Master 500 device from Zeiss. As you know, high quality and innovation is our main goal, but your safety and satisfaction is our first priority. To ensure that you are able to continue reliably use of our systems with the level of high quality you expect, Carl Zeiss is planning to perform a mandatory Field Corrective Action.

With this letter we would like to inform you about a mandatory software update for your IOLMaster. This applies only to IOLMaster devices with Software Version 7.5.2, 7.7.2 and 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.

The instructions for identifying your version of software and for installing a software update that fixes this defect are detailed below.

HOW TO IDENTIFY IF YOUR SYSTEM IS AFFECTED:

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

The screenshot shows the 'Patient manager' interface with a red box highlighting the 'i' symbol in the top right corner. The 'About IOLMaster' dialog box is open, displaying the following information:

About IOLMaster® Advanced Technology

ZEISS

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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
Database: 1.00.0003
Cornea. DII: 1.01
Piol DII: 1.02
Lasiol DII: 1.01
Lasiolh DII: 1.00
Ver. DLL: 3.2.0.18699
Computer name: WINXPWORK

IOLMaster,
SW Option Sonolink
© Carl Zeiss 1999, 2013

IOLMaster,
SW Option N
© Carl Zeiss 1999, 2008

IOLMaster,
SW Option T
© Carl Zeiss 1999, 2008

IOLMaster,
SW Option Holladay 2
© Carl Zeiss 1999, 2011

10 Years IOLMaster®
Beyond Biometry 2009

The Winner of
Innovationspreis Thüringen 2009

IOLMaster from Carl Zeiss

OK Print system information

HOW TO UPDATE YOUR SOFTWARE

To correct the software anomaly it is required that you perform the software update to version 7.5.3 or 7.7.4 using the enclosed USB stick and following the instructions from the attached update instruction.

If you are unsure how to perform the update, please contact your local representative and ask for support. *[please add your local contact details]*

MANDATORY CONFIRMATION

To ensure that all systems are updated, we require your confirmation that the software was successfully updated or that your system was not affected because it is not running on an affected software version. Please complete and return the attached confirmation form to:

[please add your local contact details]

as soon as your upgrade is complete or when you have verified that your IOLMaster is not running on an affected version of the software.

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

We apologize for any inconvenience you may experience. We will do our best to address your individual needs and concerns. In case of questions please contact *[please add your local contact details]*

With best regards

[please add your local contact details]

Attachments:

- A) Update instruction.
- B) USB Stick containing Software Update
- C) Confirmation Form

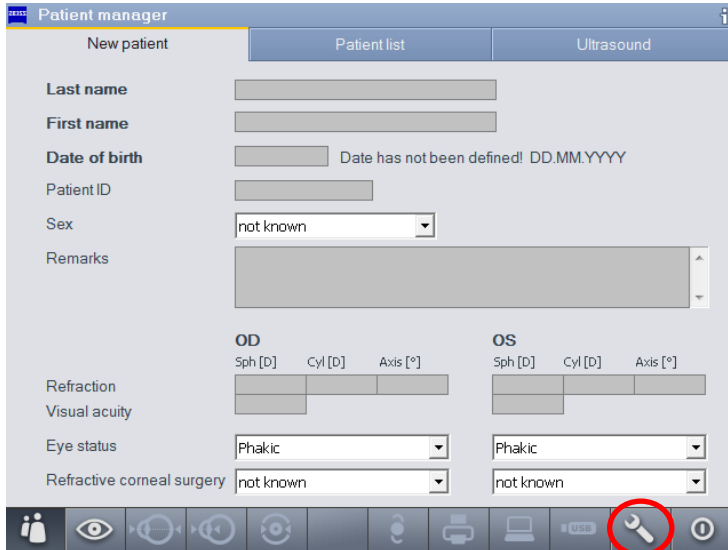
Attachment A: IOLMaster Software Update Instructions

The update to software version 7.5.3 (or 7.7.4) can be completed by following the steps below:

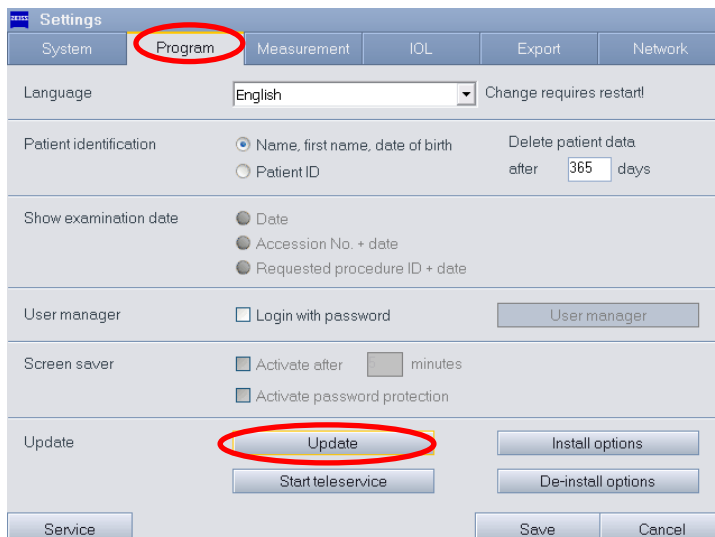
- 1) Insert the USB flash drive containing the update file.

Note: Prior to installation all other flash drives must be removed from the IOLMaster. During installation only the USB flash drive with the new software may be plugged in.

- 2) Under "Settings", navigate to "Program".



- 3) Left click on "Update"



- 4) Follow the onscreen instructions.

Note:

It can take up to two minutes until the software update is completed. Please do not interrupt or abort the update process.

Note:

If you have problems conducting the update please contact your local partner for support.

Attachment C: IOLMaster Software Update Mandatory Confirmation Form

Please send the filled form to:

#####[needs to be filled out by SSC]#####

- I received the notification from Carl Zeiss Meditec about the 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.
- I shared this information and the recommended actions with my colleagues and staff.
- I have performed the software update(s) as required.

Signature: _____

Name: _____

Date: _____

Institution: _____

Address: _____
