



January 12th, 2022

Medical Device Recall

CIRRUS AngioPlex – Optic Nerve Head (ONH) Angiography 4.5x4.5mm Scan

Dear Valued CIRRUS AngioPlex Customer:

The purpose of this letter is to advise you that Carl Zeiss Meditec, Inc. (CZMI) is performing a voluntary recall on the feature known as ONH Angiography 4.5x4.5mm Scan, on the CIRRUS HD-OCT Models 5000 AngioPlex and 6000 AngioPlex. Please take the necessary actions as outlined in this letter.

Reason for the Recall

CZMI commercialized the ONH Angiography 4.5x4.5mm scan in May 2019 based on its interpretation of the applicable FDA guidance documents¹. Not all changes to cleared devices require additional FDA review in the form of a pre-market notification, 510(k). In November 2021, the FDA did not agree with CZMI's assessment, and has requested that CZMI turn off the ONH Angiography 4.5x4.5mm scan in the US market until pre-market clearance has been obtained.

Risk to Health

A Health Hazard Evaluation conducted by CZMI concludes that there is no additional health hazard associated with the use of the ONH Angiography 4.5x4.5mm Scan. There have been no reports of serious injury, death, or unreasonable risk of substantial harm to public health.

Actions to be taken by Manufacturer

1. CZMI is providing you with CIRRUS Software version 11.5.3, which will turn off the acquisition of the ONH Angiography 4.5x4.5mm Scan, along with updated Instructions for Use (IFU).
2. CZMI is currently working with the FDA to evaluate options for resolution.

Actions to be taken by the Customer/User

1. Until further notice, please discontinue the acquisition of the ONH Angiography 4.5x4.5mm Scan.
2. Using the provided software kit(s), install the CIRRUS software version 11.5.3 on **all** your CIRRUS AngioPlex instruments that are running Windows 10 and software versions 11.5, 11.5.1 and 11.5.2. You will be receiving one software kit per affected instrument according to our records. An excerpt of the IFU has been included Section 4.7 *Update Instrument Software*, these instructions apply to all CIRRUS models. Refer to the IFU Section 4 for the full installation instructions.
3. Please complete and return the Acknowledgement Form per the instructions in the attachment. In case you no longer have the device, we ask that you inform CZMI and forward this letter to the new owner.

Should you require any assistance with the installation of the CIRRUS 11.5.3 Software, or in case of questions, please contact your local Customer Service organization at 1.800.341.6968 (select option 1, 1).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. This voluntary recall has been reported by the Manufacturer to the FDA.

We strive to ensure a high level of performance on any ZEISS device and an excellent experience for our customers. We apologize for any inconvenience you may experience. We will do our best to address your individual needs and concerns.

Sincerely,

Manjaya Hegde
Carl Zeiss Meditec USA, Inc.
Head of Quality Management

¹ "Deciding When to Submit a 510(k) for a Change to an Existing Device" (October 25, 2017), and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (October 25, 2017).



- Attachment 1: Acknowledgement Form
- Attachment 2: Software Installation Guide, applicable for all CIRRUS models
(excerpt of document 2660021178946 Rev B 2021-12, pages 50-53 of 500)
- Enclosure 1: CIRRUS 11.5.3 Software and Instructions for Use

4.7 Update Instrument Software

NOTE

If an error message appears

the software did not install successfully.

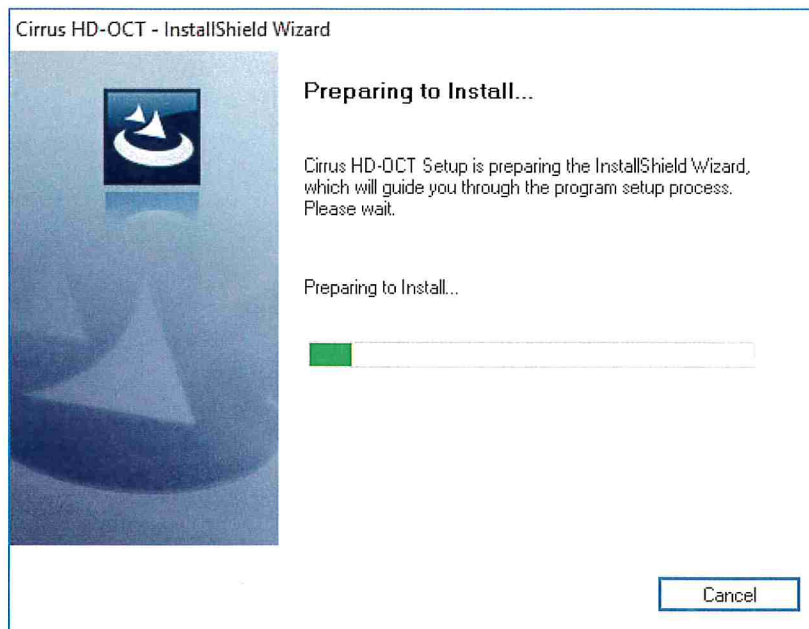
- ▶ Press the **Print Screen** button on your keyboard and save the error message to inform ZEISS Customer Support: 800-341-6968. Outside the U.S., contact your local Zeiss distributor.

Prerequisite

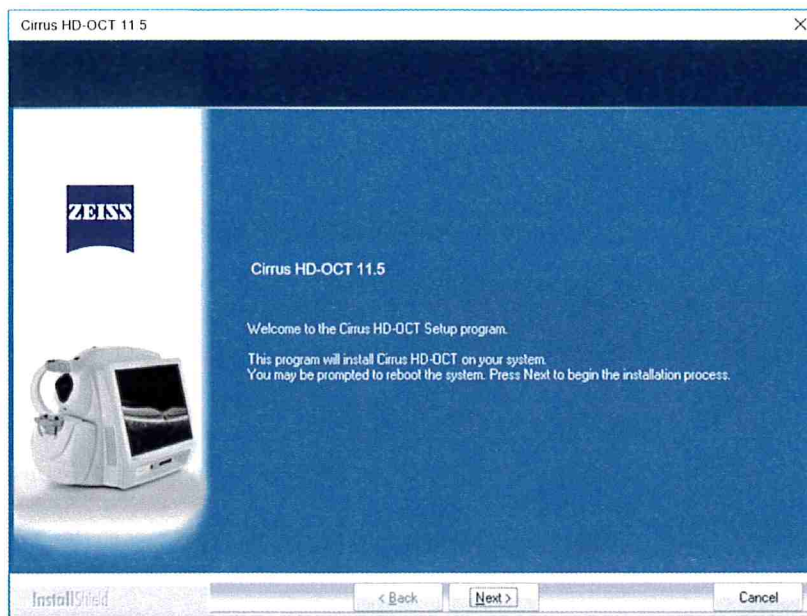
- The installation media kit is available (see: Software and Document Media).

Action

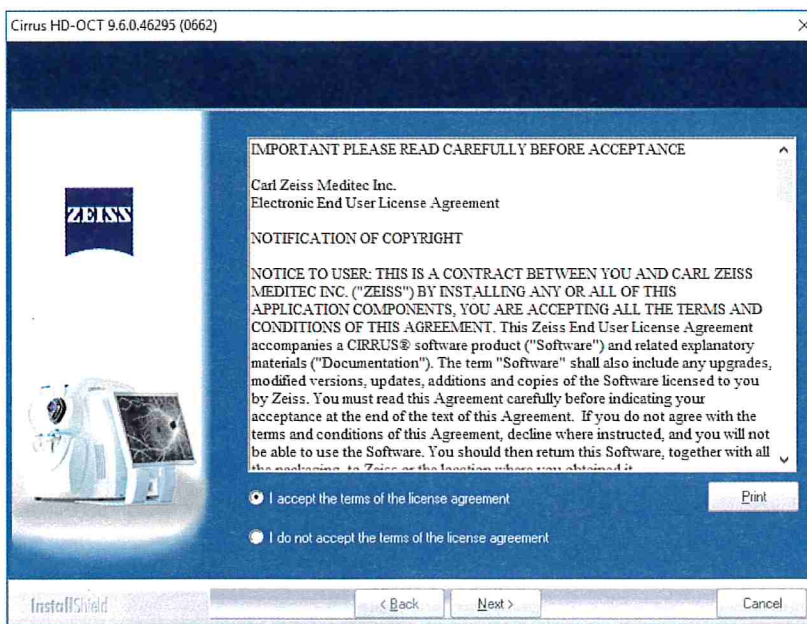
1. Insert the CIRRUS 500/5000 USB flash drive (**SW**) into the computer's USB port.
2. Navigate to the USB drive.
3. Double-click **Setup.exe**.
 - ⇒ Installation takes a few moments to prepare before the installation wizard opens.



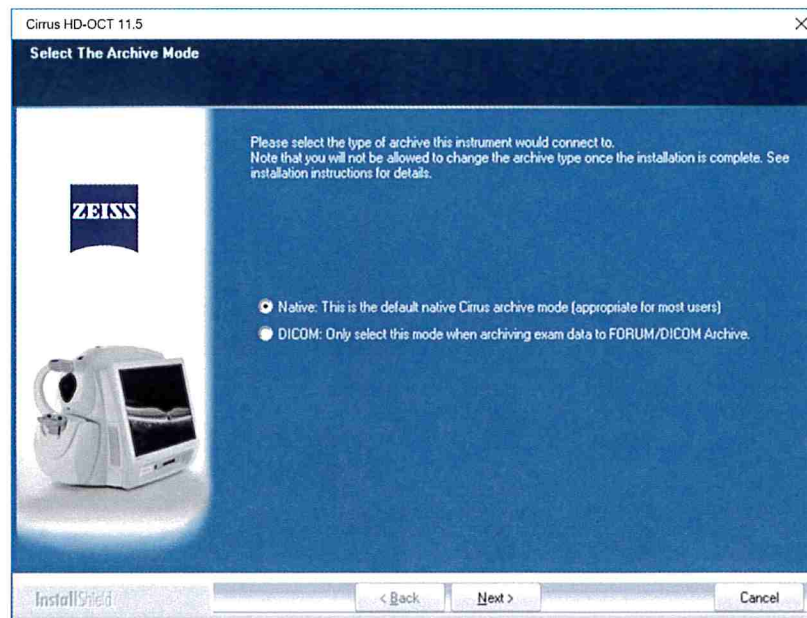
⇒ When preparation completes, the welcome page opens.



4. Click **Next**.
⇒ The license agreement page opens.



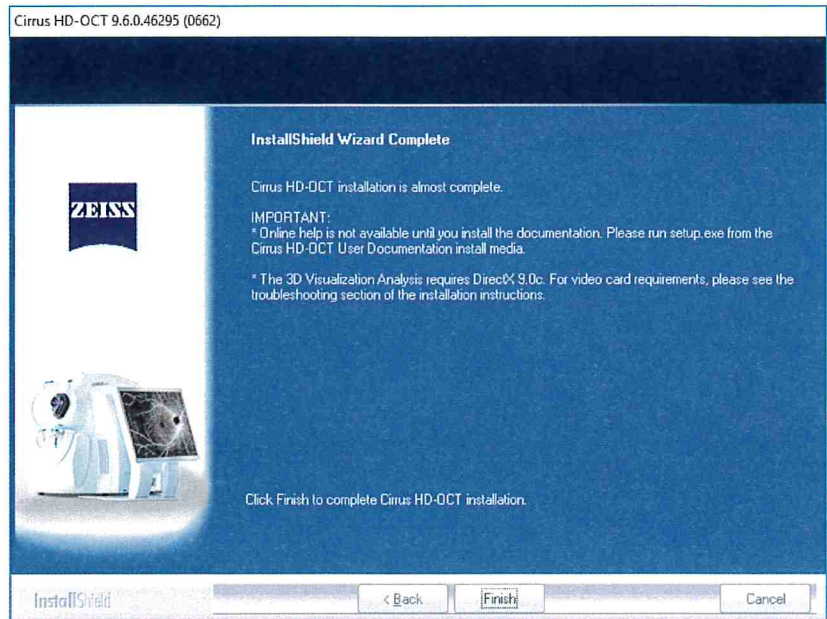
5. Read and accept the license agreement.
6. Click **Next**.
⇒ The mode selection window opens.



7. If you archive exam data using the FORUM database environment, choose **DICOM**.
 - ⇒ For more information about FORUM, see: About Data Storage [42].
8. If you do not, choose **Native**.
9. Click **Next**.
 - ⇒ Software installation takes a few minutes to complete. Progress bars indicate the progress as installation progresses.
 - ⇒ When installation completes, the anterior segment calibration prompt opens.



10. To calibrate Anterior Segment, check **Launch Anterior Segment Calibration Wizard now** and refer to: Calibrate the Anterior Segment Lenses [▶ 400].
11. To skip Anterior Segment calibration, uncheck **Launch Anterior Segment Calibration Wizard now**.
12. Click **Next**.



13. Click **Finish**.
 - ⇒ The CIRRUS 500/5000 shortcut appears on the computer's desktop.
14. Remove the USB flash drive from the USB port and return it to the media kit.