Cirrus HD-OCT

Model 4000
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Anterior Segment

The Cirrus™ HD-OCT is primarily used for imaging and measuring structures in the posterior eye. By changing the focus of the OCT beam, it can also be used to image and measure structures in the anterior segment such as the cornea. This addendum provides instructions and information about imaging and measuring the anterior segment with the Cirrus HD-OCT. Additional information on all facets of the Cirrus instrument can be found in the Cirrus User Manual.

Carl Zeiss Meditec designed this Addendum to serve as a training, usage and reference guide for proper scanning and operation. We assume that users are clinicians or technicians with professional training or experience in the use of ophthalmic imaging equipment, and in diagnostic interpretation of the images generated. While we offer training in the use of the Cirrus HD-OCT, we do not offer instruction in diagnostic interpretation of the images generated. This manual does not attempt to do so.

Intended Use

The Cirrus HD-OCT with Retinal Nerve Fiber Layer and Macular Normative Databases is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures.

Indications for Use

The Cirrus HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including cornea, retina, retinal nerve fiber layer, macula, and optic disc. The Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL) and Macular Normative Databases is a quantitative tool for the comparison of retinal nerve fiber layer and the macula in the human retina to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.

Note: The Cirrus HD-OCT is not intended to be used as the sole diagnostic for disease.
Acquiring Anterior Segment Scans

These instructions address two scan acquisition options, and subsequent analyses, for the Anterior Segment. The acquire options are:

- Anterior Segment Cube 512x128
- Anterior Segment 5 Line Raster

The HD-OCT imaging specifications for anterior segment scanning are the same as described in Chapter 10, Specifications, of the Cirrus HD-OCT User Manual, within the central 0.5 mm depth and central 2 mm width of the displayed tomograms. The best imaging performance occurs in the center of the imaging region.

Upon choosing an anterior segment scan,

- The LSO illumination of the retina is turned off.
- The internal fixation target is centered.
- The iris illumination is dimmed by default. This is to avoid causing pupillary constriction.
- You will hear a click as the internal lens is brought into position.

Some controls and displays used for posterior eye scanning are not present for anterior segment image acquisition. These are:

- The Center control (Z-offset) for the OCT scan display is not present. The OCT display can be centered vertically in the live OCT window by using the Chinrest control buttons or the mouse scroll wheel.
- Even though there is no fundus image, the Focus control buttons are still available for adjusting the focus of the fixation target.
- The scan pattern is now displayed over the iris image. The scan pattern cannot be moved, and the size of the scan is fixed. The 5-line raster scans can be rotated.
**Anterior Segment Cube 512x128**

This scan mode generates a volume of data through a 4 millimeter square grid by acquiring a series of 128 horizontal scan lines each composed of 512 A-scans. It also acquires a pair of high definition scans through the center of the cube in the vertical and horizontal directions that are composed of 1024 A-scans each. The Anterior Segment Cube 512x128 has the same scan characteristics as the Macular Cube 512x128. This scan can be used for measuring the central corneal thickness and create a 3-D image of the data. Choosing this option produces the Anterior Segment 512x128 Cube Acquire screen, Figure 1.

![Figure 1 Acquire Screen, Anterior Segment Cube 512x128](image-url)
**Anterior Segment**

**Anterior Segment 5 Line Raster**

This mode scans through 5 parallel lines of equal length. This scan can be used to view high resolution images of the anterior chamber angle and cornea. The line length is fixed at 3 mm, but the rotation and spacing are adjustable. Each line is composed of 4096 A-scans. By default, the lines are horizontal and separated by 250 μm (0.25 mm), so that the 5 lines together cover 1 mm width. See Figure 3. Choosing this option produces the Anterior Segment 5 Line Raster Acquire Screen, Figure 2.
Menu selections on the Acquire Screen

Under the iris viewport, select this button to bring up the Custom Scan Pattern menu shown on the left. This allows you to adjust the rotation and spacing of the 5 Line Raster scan. All adjustments apply to all 5 lines jointly.

- For Rotation (default 0 degrees is horizontal), click the up arrow (for counterclockwise rotation) or down arrow (for clockwise rotation) or type in a value to adjust the angle in the ranges of 0 to 90 or 270 to 359 degrees. Values typed in from 91 to 269 are automatically changed to the corresponding value 180 degrees opposite.
- For line Spacing, you can select among the following options, in millimeters: 0 (five lines in same location), 0.01, 0.025, 0.05, 0.075, 0.125, 0.2, 0.25.

Options and Reset buttons

Each area has an Options button, which opens additional controls to adjust the image settings for that viewport. These controls include brightness, contrast and/or illumination. An example appears at left, for the iris image. Each area also has a Reset button, to return the settings to their default or initial positions.

Alignment for Scanning the Central Cornea

These instructions are applicable to both Anterior Segment 512x128 Cube Scan and the Anterior Segment 5 Line Raster.

1. From the ID Patient screen, click Acquire.
2. Before the patient puts his or her chin on the chinrest, click to select the desired scan type for either eye. You might hear a click sound as the auxiliary lens is moved into position. You can have the patient look at the internal fixation, which will always be straight ahead, or the external fixation device. You may optionally adjust the focus of the internal fixation for the patient using the manual Focus adjustment.
3. Adjust the region of the iris visible in the iris viewport. Coarse adjustments are made by using the X-Y controls to move the chinrest, as needed, until the pupil is visible. Clicking on a chinrest control arrow moves the eye in the direction indicated by the arrow. See Figure 3.
4. Center the pupil in the iris viewport by clicking the center of the pupil. Clicking anywhere in the iris viewport centers the field of view of the camera over the click point.

5. Adjust the distance to the patient using the chinrest control until you see the cornea in the OCT scan display. The mouse scroll wheel may be used to make fine adjustments. The best OCT image is obtained when the cornea is placed between the gray bars alongside the scan display. See Figure 4.

6. Click the Enhance button to improve the quality of the OCT image.

Note: The Optimize button does not position the scan when taking Anterior Segment scans. It only performs the Enhance function.

Note: If the patient’s cornea is perfectly centered, a strong reflection from the anterior cornea can produce bright artifacts in the OCT scan display (Figure 5). The
scan alignment should be slightly offset from the center by adjusting the chinrest to avoid the corneal reflection.

7. When satisfied with the scan adjustments you have made, click on the Capture button. Figure 5 shows the Review Screen of the acquired data.

8. Click Save to save the image and return to the Acquire screen. If you do not want to save the image, click Try Again.

Note: The instrument focuses the OCT beam onto the anterior segment. The OCT beam scans in an arc to allow the curved cornea to better fit into the 2 mm scan depth. This will cause the cornea to appear flat in the display during alignment and acquisition. This effect is partially corrected for after acquisition, so the cornea will appear with the expected curvature during review and analysis.

Alignment for Scanning the Anterior Chamber Angle

The Anterior Segment 5 line raster scan is the preferred scan type for imaging the anterior chamber angle because it can be rotated to image a cross section perpendicular to the limbus at any location. The following instructions apply when using any of the scans for anterior chamber angle imaging:

1. When scanning the anterior chamber, you will need to use the external fixation target to direct your patient’s gaze beyond the ocular lens housing. This moves the eye position to expose the limbus optimally, allowing scanning to be done without
interference from the eyelids. In scanning the superior angle, the iris illumination light can be used as a fixation target. When imaging the temporal angle, it is helpful to cover the fellow eye, to allow the patient to fixate with the scanned eye.

2. Adjust the area of the eye visible in the iris viewport until you are able to view the corneoscleral junction. Coarse adjustments are made by using the X-Y controls to move the chinrest, as needed, until the pupil is visible. Clicking on a chinrest control arrow moves the eye in the direction indicated by the arrow. The angle recess often appears shadowed by the sclera. Moving the scan slightly to another location along the limbus can sometimes avoid local shadowing.

3. Center the scan on the corneal limbus. The live OCT image should show the top of the cornea and should be almost horizontally aligned; a slight tilt is acceptable and can improve visualization of angle structures. Figure 6 shows a well-aligned scan and live OCT image. Note that the iris may not be well focused when scanning the angle.

4. Proceed with Enhance and Capture, then review the scan as described in the section on corneal scanning.

Figure 6 Anterior Chamber Angle Scan

4. Proceed with Enhance and Capture, then review the scan as described in the section on corneal scanning.
Scan Review

Scan review of anterior segment images (Figure 7) is similar to that of posterior scan images. For more detailed information, see the Cirrus 4.0 User Manual. The following differences, however, should be noted.

Iris Video Image Window – Cube 512x128

The overlay on the iris image (upper left in Figure 7) indicates the location of the acquired OCT data scan.

LSO Window

The LSO window, located on the lower left side of the Scan Review screen (Figure 7), is not illuminated for Anterior Segment scans. However, navigation sliders are available in this window, allowing for easier navigation through the cube data in the scan.

Note: The signal strength indicator is not displayed for anterior segment review; it is only displayed for posterior scans.
Iris Video Image Window – 5 Line Raster

The 5 Line Raster overlay on the iris image (upper left in Figure 8) indicates the location of the acquired OCT data scan. Scan review is accomplished by clicking on an individual line of the 5 Line Raster scan overlay. The scan line selected is then highlighted in dark blue. The vertical row of images on the right side of the scan review screen correspond to each of the individual scan lines. The selected scan line is magnified for greater clarity of detail, as shown in the middle image of the review screen (Figure 8).

The fundus (LSO) image is not displayed. Also, the signal strength indicator is not displayed for the anterior segment review; it is only displayed for posterior scans.
Anterior Segment Scan Analysis

To analyze or print either an Anterior Segment 5 Line Raster or an Anterior Segment Cube 512x128 scan, click Analyze from the ID Patient screen. Select the desired Anterior Segment scan from the scan list on the left then click on the appropriate analysis in the right-hand column. The Anterior Segment Analysis is the only analysis protocol available for the Anterior Segment Cube 512x128 scan.

Figure 9 Anterior Segment Cube Analysis Screen

The Anterior Segment Analysis screen (Figure 9) for the Anterior Segment Cube 512x128 scan displays the Iris Viewport with the scan area and scan navigators superimposed. The X slice (fast - B scan) is shown in the upper OCT image and the Y slice (slow - B scan) is shown below it. You may click on either OCT window and use the scroll wheel on the mouse to scroll through the slices or move the slice navigators in the Iris Viewport.
The High Definition Image Analysis

The High Definition Image Analysis is the only analysis available for the Anterior Segment Five line raster. The analysis screen displays the Iris Viewport with the scan pattern superimposed. The thumbnails of the 5 slices are shown below the Iris Viewport. The large scan image on the right corresponds to the thumbnail surrounded by a blue frame and the highlighted scan line. Clicking on another thumbnail image or the line will replace the large image with the chosen scan. Figure 10 shows a high definition analysis screen of an anterior chamber angle.

Figure 10 Anterior Segment 5 Line Raster Analysis Screen

Anterior Segment Imaging

The Cirrus HD-OCT can produce high resolution images of the anterior segment allowing visualization of fine details of the corneal and anterior chamber anatomy.
The Central Cornea

The corneal epithelium, Bowman's membrane and stroma are generally visible in the tomograms. (Figure 11). Measurement of the Central Corneal Thickness (CCT) can be done and is described in this manual.

Figure 11 Corneal Image
The Anterior Chamber Angle

The termination of the Descemet's membrane called Schwalbe's line, Schlemm's canal and anterior iris can often be seen and identified by trained clinicians. (Figure 12) The angle recess and scleral spur may be difficult to visualize at times. The shorter wavelength (840 nm) used by the Cirrus is more strongly scattered by the sclera and iris. Scattering by the sclera causes the angle recess to be often obscured in shadow.

[Image: Figure 12 Angle Scan]

Central Corneal Thickness (CCT) Measurement

The operator is advised to evaluate the scanned image prior to making CCT measurements. The corneal image should have well-defined posterior and anterior surfaces, should not have excessive motion artifacts and corneal reflections on the central cornea, especially within the area where the measurement caliper is to be placed.

The following conditions may affect the ability to obtain a good corneal image for CCT measurements:

1. Inability of the patient to maintain fixation, including patients with poor visual acuity.
2. Excessive corneal reflection resulting from certain intraocular lenses, corneal abrasions and corneal opacities.
3. Presence of contact lenses. The junction of some contact lenses and the corneal surface may not be easy to visualize. Patients should remove contact lenses prior to scanning for a CCT measurement.
Central corneal measurements should be made at the apex of the cornea. To determine the apical area:

1. Estimate where the center of the pupil is on the image and move the scan navigators so that they intersect at that point.
2. Click on the ruler button, and align the ruler vertically against the mauve slice navigator on the horizontal scan.
3. The apical area, being closest to the instrument lens, has the highest scans of the entire scan volume. Check to make sure that the measurement is being made on the highest scans by moving the slice navigators up and down. Use the ruler as a reference point in doing so.
4. The CCT measurement should be made at the intersection of the highest horizontal and vertical scans, using the ruler on the horizontal scan. The intersection of the scans is identified by the position of the mauve slice navigator. Adjust the position of the ruler and place the white horizontal lines of the ruler ends on the anterior and posterior surfaces of the cornea. The measurement is in microns. See Figure 13 for the correct position of the ruler and the proper placement of the calipers.

![Figure 13 Positioning the Ruler](image)

Note: Vertical distances on the tomogram reliably show tissue thickness and tissue refractive index. Horizontal distances cannot be measured quantitatively on these tomograms. When applied to Anterior Segment Scans, the Ruler measures only vertical distances, with the scale factor set appropriately for measurements within the cornea.

Note: The Ruler is calibrated for measuring corneal tissue only, based on the refractive index of the cornea. It is not calibrated for other tissue types.

Note: The Anterior Scan Cube 512x128 will initially be presented in the High-definition mode. Click on the Show/Hide High-Resolution Images button to...
allow scrolling through the cube images or move a slice navigator to a different slice.

Note: For the Anterior Segment 5 Line Raster scan, only the ruler buttons are available.

**Anterior Segment Function Buttons**

Many of the function buttons found on the Advanced Visualization screen for macula scans are found on the Anterior Segment Analysis screen for the Anterior Segment Cube 512x128 scan. You may toggle back and forth between the high-resolution images, add one or more rulers to the image to create measurements or view the Anterior Segment Cube 512x128 scan as a 3-D cube volume as in **Figure 14**.

- Toggle 3D volume rendering
- Measurement ruler
- Delete all selected measurement lines
- Snap scan navigator lines to center
- Show/hide high resolution images

Select **Figure 14**: 3-D Volume Rendering of the Anterior Segment Cube 512x128

Printing out any Anterior Segment analysis is done in the same way as Macular scans (see User Manual, Chapter 4, *Reports and Printing*). Typical printout styles appear below.
Anterior Segment Cube 512x128 Printout

The standard printout for the Anterior Segment Cube 512x128 analysis includes all the information on screen (Figure 15) when you click Print:

![Anterior Segment Analysis Printout](image_url)

**Figure 15 Anterior Segment Analysis Printout, Anterior Segment Cube 512x128**
Anterior Segment 5 Line Raster Printout

The standard printout for the Anterior Segment 5 Line Raster analysis includes all the information on screen (Figure 16) when you click Print:

![High Definition Images Printout, Anterior Segment 5 Line Raster](image)

Figure 16 High Definition Images Printout, Anterior Segment 5 Line Raster
Anterior Segment Accuracy, Repeatability and Reproducibility

Benchtop Scanning Accuracy, Repeatability and Reproducibility

Accuracy, repeatability, and reproducibility of scanning in the Cirrus HD-OCT have been measured in benchtop studies. Table 1 below summarizes the results for axial dimensions in the basic image geometry.

Accuracy is reported as a 95% confidence interval for the absolute difference between a measured and actual distance. Repeatability and reproducibility are given both as standard deviation (SD) estimates and as estimates for the 95% upper limit of the difference between two measurements. The Repeatability Limit = 2.8 X Repeatability SD. The Reproducibility Limit = 2.8 X Reproducibility SD.

Table 1 Cirrus HD-OCT Benchtop Accuracy, Repeatability and Reproducibility

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Accuracy (μm)</th>
<th>Repeatability SD (μm)</th>
<th>Repeatability Limit (μm)(^1)</th>
<th>Reproducibility SD (μm)</th>
<th>Reproducibility Limit (μm)(^2)</th>
<th>Average Measurement (μm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axial Distance in Tissue</td>
<td>6.2</td>
<td>2.6</td>
<td>7.1</td>
<td>2.7</td>
<td>7.6</td>
<td>1165.6</td>
</tr>
</tbody>
</table>

\(^1\)Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.

\(^2\)Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Each test object was imaged three times by two operators on each of five instruments. Per ISO 5725-1 and ISO 5725-6, Reproducibility Limit = 2.8 x Reproducibility SD.

Cirrus HD-OCT Repeatability in Measuring Central Corneal Thickness

A study was conducted to determine repeatability and reproducibility of the Cirrus HD-OCT instrument measurements of central corneal thickness (CCT). Phase I of the study enrolled 28 subjects and was designed to determine inter-device variability, wherein each subject was imaged 3 times during a single visit on each of three Cirrus OCT instruments by one operator. Phase II enrolled 22 subjects and was designed to determine inter-operator variability, wherein each subject was imaged three times during a single visit by each of three operators. Phases I and II enrolled different subjects.

The Cirrus HD-OCT repeatability and reproducibility are shown in Table 2. Mean thickness of each phase and overall (Phase I and II combined) are also shown. Since the random error variability from Phase II of the study was larger than that from Phase I, the variance components from Phase II were used to estimate the random measurement variability and the repeatability standard deviation.

Repeatability SD is the standard deviation under repeatability conditions. The Repeatability Limit = 2.8 X Repeatability SD. It provides a 95% upper limit for the difference of two independent repeated measurements of the same cornea measured at the same study site. Reproducibility SD is the standard deviation under reproducibility conditions. The Reproducibility Limit = 2.8 X Reproducibility SD. The reproducibility standard deviation was
estimated by the square root of the sum of random measurement variability, inter-device variability, and inter-operator variability.

Table 2 Cirrus HD-OCT repeatability and reproducibility in measuring central corneal thickness

<table>
<thead>
<tr>
<th>Cirrus HD-OCT Repeatability</th>
<th>Cirrus HD-OCT Reproducibility</th>
<th>Mean Thickness (μm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeatability SD (μm)</td>
<td>Repeatability Limits (μm)₁</td>
<td>Reproducibility SD (μm)</td>
</tr>
<tr>
<td>4.08</td>
<td>11.42</td>
<td>4.23</td>
</tr>
<tr>
<td></td>
<td>Repeatability Limits (μm)²</td>
<td>Reproducibility Limits (μm)²</td>
</tr>
<tr>
<td></td>
<td>11.84</td>
<td>544.25</td>
</tr>
<tr>
<td></td>
<td>Phase I</td>
<td>Phase II</td>
</tr>
<tr>
<td></td>
<td>Overall</td>
<td></td>
</tr>
<tr>
<td></td>
<td>532.25</td>
<td>538.25</td>
</tr>
</tbody>
</table>

₁Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD

₂Reproducibility Limit is the upper 95% limit calculated for the difference between results repeated using different operators. Each subject was imaged three times during a single visit by each of three operators. Per ISO 5725-1 and ISO 5725-6, Reproducibility Limit = 2.8 x Reproducibility SD.

Difference in Central Corneal Thickness measurement Between Cirrus HD-OCT and Ultrasound Pachymetry

Table 3 shows the mean difference in central corneal thickness measurements between Cirrus HD-OCT and ultrasound pachymetry. The negative difference means that the Cirrus CCT measurement is thinner than the ultrasound CCT measurement. This data was taken from a total of 50 eyes enrolled in one site measured by a single operator for each device.

Table 3 Difference in Central Corneal Thickness Measurement Between Cirrus HD-OCT and Ultrasound Pachymetry

<table>
<thead>
<tr>
<th>Mean Difference</th>
<th>95% CI of the Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>-9.06</td>
<td>SD: 5.63</td>
</tr>
<tr>
<td></td>
<td>Lower: -10.66</td>
</tr>
<tr>
<td></td>
<td>Upper: -7.46</td>
</tr>
</tbody>
</table>

OCT devices in general measure thinner than ultrasound pachymetry. The Visante User Manual reports an average measurement difference of 15.1 microns. In the literature, reported differences between OCT and ultrasound pachymetry range from 11.64 to 49.4 microns (see References).

Cirrus HD-OCT 4.0 Addendum
Anterior Segment Imaging
Specifications subject to change without notice