

# RTVue XR 100 Avanti Edition

- Model CAM



## **CAM User's Manual** ***International***

Software Version 2014



**Publishing details**

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# 1 Safety notes

## General

This XR system accessory has been developed and tested in accordance with the Optovue safety standards as well as national and international regulatory guidelines. A high degree of instrument safety has been ensured. Observe all safety notes and information in this manual and on the device labels.

## Proper instrument use

1. Always clean all patient contact surfaces (forehead and chin rest according to the cleaning method in the XR Users Manual.
2. Ensure the CAM lens is attached when capturing scans in “Cornea” category.
3. Note the working distance to the cornea surface for CAM lens (13mm for the CAM-L)
4. Align the eye to the proper eye position (canthus) indicator mark on the chin rest.
5. Illuminate the external eye structures using the Red LED illumination lights
6. Use the Live IR video image on the LCD monitor and the OCT scan window to monitor distance and focus relative to the patient’s eye.

## Intended Use

The CAM, an auxiliary lens adapter, when used in conjunction with XR, is indicated for *in vivo* imaging and measurement of the cornea and other ocular structures of the anterior segment of the eye, including pachymetry and corneal power.



**Note: Either XR or XR/CAM OCT is not intended to be used as the sole diagnostic aid in disease identification of classification.**

## Warning: Corneal Power Feature

**The Net Corneal Power value determined by the TCP function is NOT INTERCHANGEABLE with the corneal power value determined by any other device. The Net Corneal Power determined by the TCP function of the CAM option for XR is not intended to be used in lieu of, or replace a value from another device into your standard IOL calculation formula.**



**Warning: User Changes to Software or Hardware**

The XR and XR with CAM Option are medical devices. The software and hardware is designed in accordance with U.S., European and other international medical device design and manufacturing standards. Unauthorized modification of RTVue XR100 or RTVue XR with CAM Option software or hardware in any way can jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data. Modification of either of these in any way also voids the instrument warranty in its entirety.

### Product Compliance



### European Conformity

European Notified Body:

TÜV Rheinland LGA Products GmbH  
Tillystrasse 2, 90431 Nuremberg Germany  
CE 0197



### European Representative

Medical Device Safety Services (MDSS) GmbH  
Schiffgraben 41  
30175 Hannover, Germany



### Warning: Phototoxicity

The CAM Option is an accessory only for the RTVue XR system and has no function what-so-ever as an independent product. As such, the CAM option may not be used independently of the RTVue XR system, and should be kept in the storage (wooden) box when not in use.

There is no increase in the risk of phototoxicity from the RTVue XR system when used in conjunction with the CAM option. Please refer to the RTVue XR Users Manual for all Safety Notes pertaining to the use of the system.

### Lens Identification and Serial Number Location:

CAM-L Lens (also referred to as CAM Lens)



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## 2 Instrument Description

### What is the XR / CAM system?

XR/CAM is comprised of the XR system and the CAM option (cornea lens adapter) for use in imaging the cornea and anterior chamber of the eye.

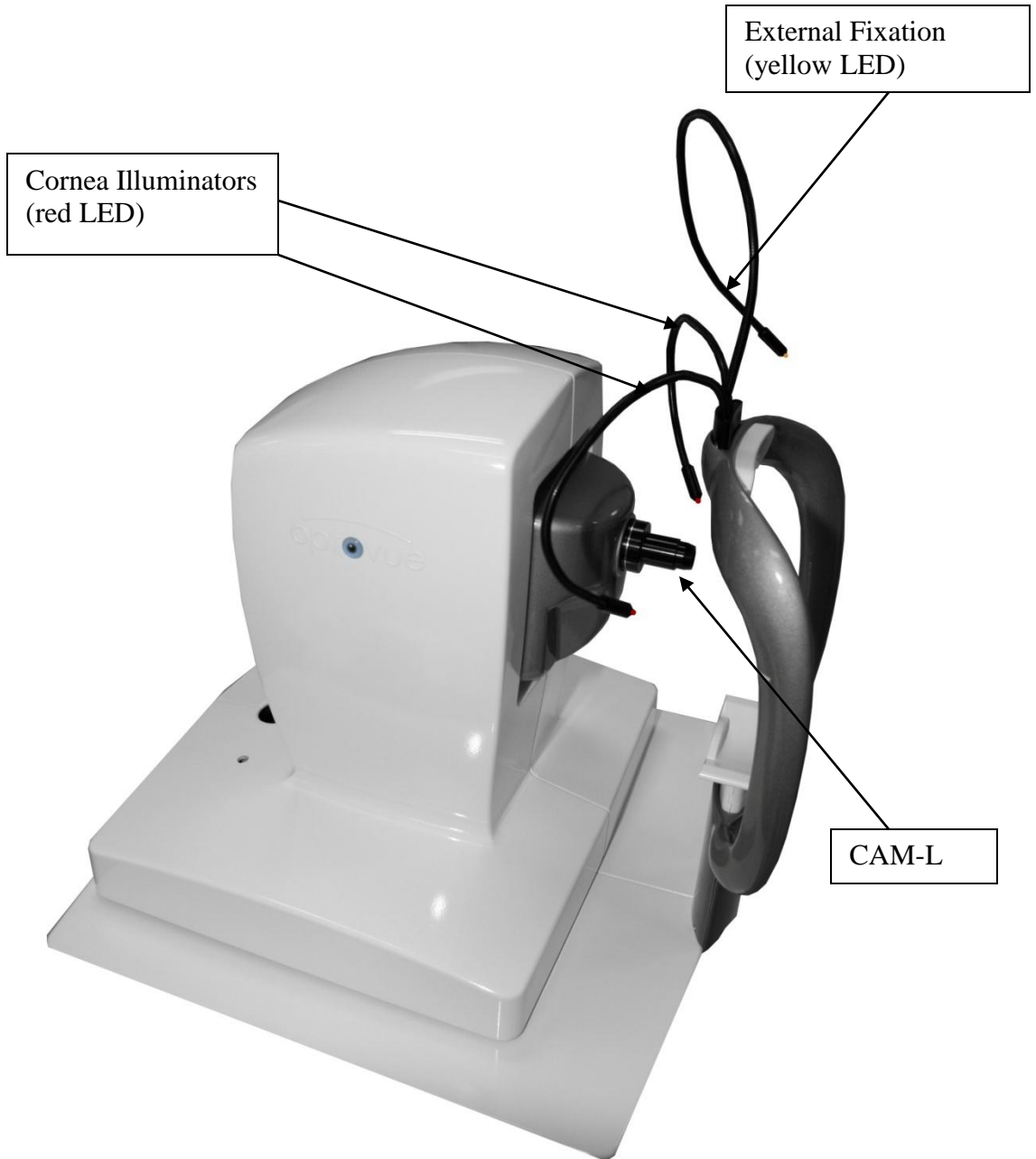
The lens adapter is attached and removed by a trained operator. The cornea scan patterns and analysis functions are enabled only after the XR/CAM license is purchased.

### 2.1 XR/CAM System Configuration:

The lens adapter with low magnifications (CAM-L) is not included in the standard XR systems:

1. XR Scanner:
2. Computer:
3. System Table:
4. Monitor (Computer Display):
5. Keyboard and Mouse
6. Printer
7. Cornea lens adapter (CAM)

***Please reference the XR User's Manual for detailed descriptions of each sub-systems.***



## 3 Getting Started

Please refer to the XR install Manual for unpacking/installation instructions for the XR system.

### 3.1 Mounting the lens adapters

1. The lens has a bayonet mount system.



**Note:** The working distance between the lens adapter and cornea is **13mm** on CAM-L model.

**Pull the scanner head all the way back, align using the live IR video image of the patient's eye, then gradually move the scanner head forward until OCT scan is in the target area. This will coincide approximately with the patient's iris coming into focus in the live IR video image.**

**Do not move the instrument head quickly and monitor proximity to patient in order to avoid incidentally hitting the patient's eye with the CAM lens surface.**

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## 4 **Patient Menu**

Please reference to the XR user manual for this entire section.

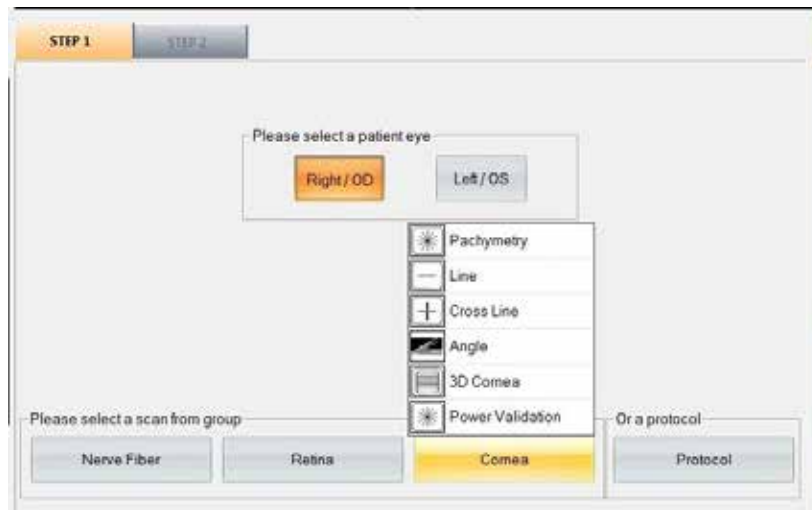
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## 5 Examine Menu

### 5.1 Scan Patterns

Select Cornea

Select scan pattern from pop up list and mouse click to activate scan acquisition (a list of scan patterns and specifications is provided in section 9).



### 5.2 Scan acquisition:

The following is a general procedure to acquire Cornea OCT images:

1. Turn off the exam room light (recommended)
2. Attach the CAM lens
3. Use the two red external illumination LED on headrest to illuminate the cornea (one for each eye).
4. Instruct patient to fixate on the center of light blue internal fixation target.
5. Use the yellow external fixation LED on headrest to guide patient fixation if required. For corneal power scan, use internal fixation target
  - a. Operator should center the scan on the pupil. If the misalignment exceeds 1 mm (pupil center exceeds the boundary of the smallest alignment circle), the scan should be excluded.
  - b. Operator should make sure that the eyelid or eyelashes are not blocking or shadowing a significant portion of the image in vertical meridians concentric circle on the screen. If there is blocking or shadowing, the scan should be excluded.
  - c. Operator should observe the measurement reliability index status on the report screen (for cornea power). A measurement with poor measurement reliability indicates increased risk of measurement variability. Measurements with poor reliability should be replaced if possible.

**Note: Corneal power measurements are not displayed for poor quality scans in which an algorithm failed. In this case, the scan should be repeated**

6. Align on the desired area to scan
7. Move forward until the iris is in focus in the live IR image (the image of the desired external scanned region should be within the target zone (two dashed red horizontal lines)).
8. Adjust scan beam to target zone and orientation with joystick.
9. Adjust image quality/scan strength (P-Motor adjustment)
10. Capture scan using joystick button or capture button on screen
11. Review and process (averaging) the OCT images
12. Save the scan

**Remember the follow key operation points:**

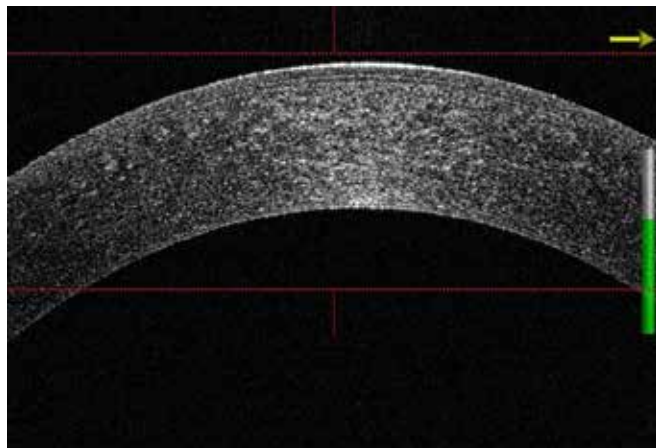
1. Use the XR with CAM like a Photo slit lamp in that when the live IR video image is in focus, stop forward motion of the scanning head as the scan should be in the target area (or very close).
2. Auto All and Auto-Z are disabled.
3. Minimal Focus motor adjustment may be used (only available in manual scan control options)
4. Use the P-Motor to optimize scan signal strength

The following items are pre-set and not adjustable.

1. Internal Illumination: Set to 0
2. Focus: default set to cornea (can be adjusted to optimize the image intensity for Line, Cross Line and Angle scans)
3. Z position: Set at constant value depends on the system

### 5.3 Scan alignment

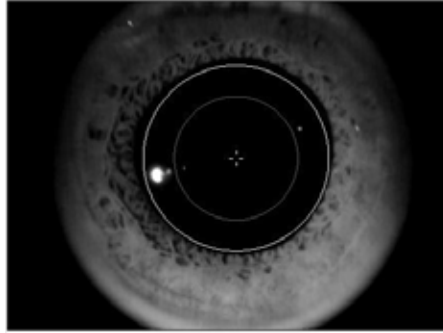
OCT scan window: Place the cornea B-scan image in between the two red guide lines to optimize the cornea scan images. Pachymetry and cross line scans will have two OCT windows, one for vertical b- scan, and one for horizontal b- scan.



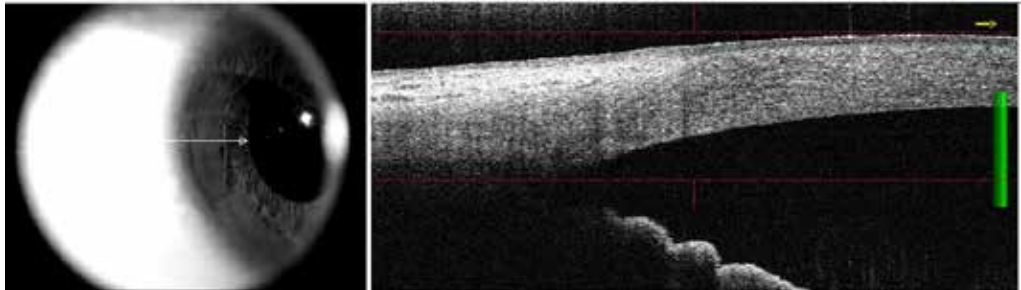


Live video window-alignment of scan pattern will depend on scan type chosen:

1. **Pachymetry scan:** Align the aiming circle (inner circle is 4mm diameter and outer circle is 6mm diameter) to the center of the pupil.

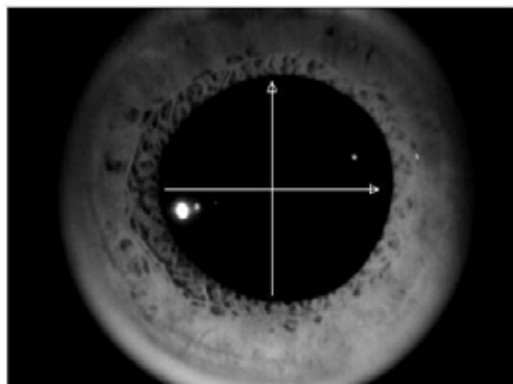


2. **Angle scan:** Use the external fixation (yellow light on gooseneck cable) to guide the patients fixation (of the fellow eye) until the cornea/sclera edge is **parallel and located in the red guided lines region**. Place center of scan line pattern on the limbus and cornea/scleral OCT image parallel to the red horizontal guidelines.



**Note:** Only when the posterior cornea/sclera tissue is parallel or contained inside the red lines (from left to right edge of scan) are the AOD/TISA measurements accurate.

3. **line, cross line, 3-D cornea:** these scans be centered on the pupil or particular area of interest.



#### **5.4 Technical Note of “Dewarp”**

“Dewarp” is a mathematic calculation (Snell’s Law) used to transfer the OCT image in “optical distance space” to “physical distance space”. A good example of the image in “optical distance space” is when you see a straw in a glass with half water full. The straw in the water seems bent at the interface between water and air, and the portion of the straw in the water looks thicker than the portion of the straw in the air.

There are two aspects to the dewarp calculation:

1. Shape change (like the bending of the straw): This is caused by the cornea surface that is not perpendicular to the scan beam. This cannot be avoided when scanning a length greater than 3mm of the cornea. If you scan on a relative flat surface of cornea or sclera, the incident beam is relatively perpendicular to the surface. In this instance the beam will not be bent or warped. For example, if you make the straw perpendicular to the water surface, the straw does not look bent or warped at the water and air interface.
2. Distance Change: The straw looks thicker because the index of refraction (n) of water is 1.33 times of the air (n=1.33). The cornea (n= 1.38) and aqueous (n=1.34) are very similar but are at a higher index than that of air. To make the physical distance measurement, the tissue thickness needs to be divided by the index of refraction of the media.

A dewarp calculation is used on the cornea Line, Cross line and Pachymetry scans to transfer the OCT image into a physical image of the cornea for both shape and distance. For all other scans, the live scan image is placed within the red dashed lines, so the incident beam is relatively perpendicular to the tissue surface. A distance scale factor is only applied in the measurement tool to get accurate distance and area measurements.

## 6 Review Menu

### 6.1 Review Layout

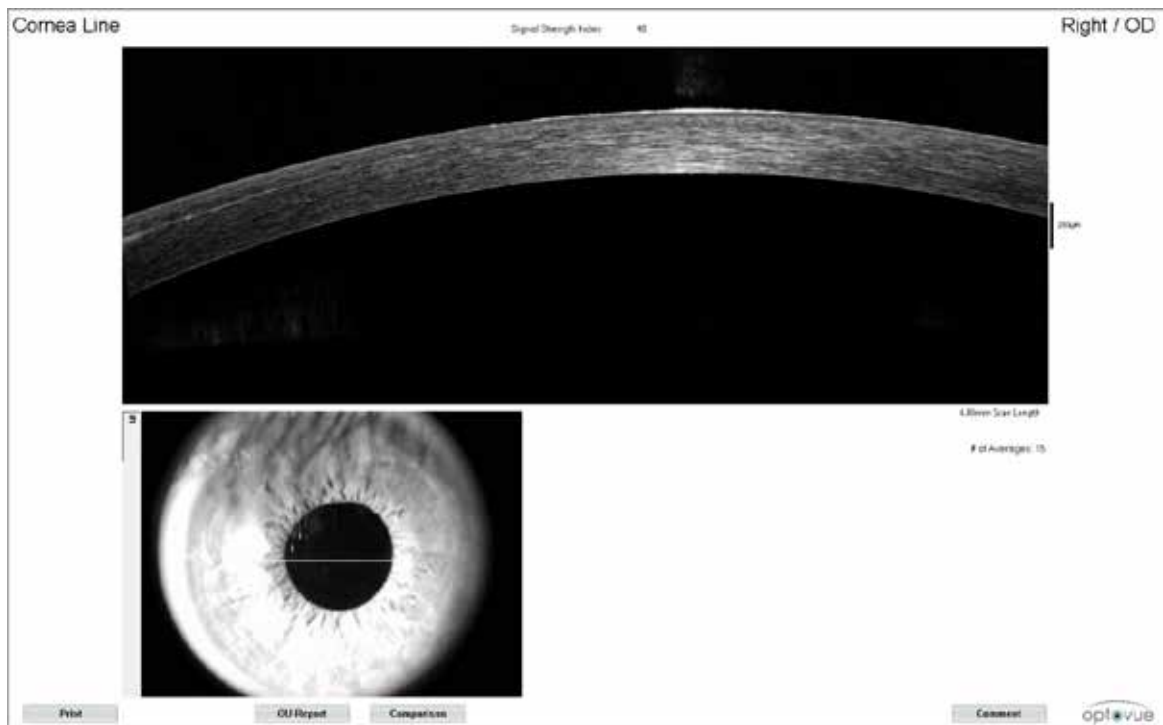
Please refer to XR Users Manual

### 6.2 Measurement

Please refer to XR Users Manual

### 6.3 Review Result Layout

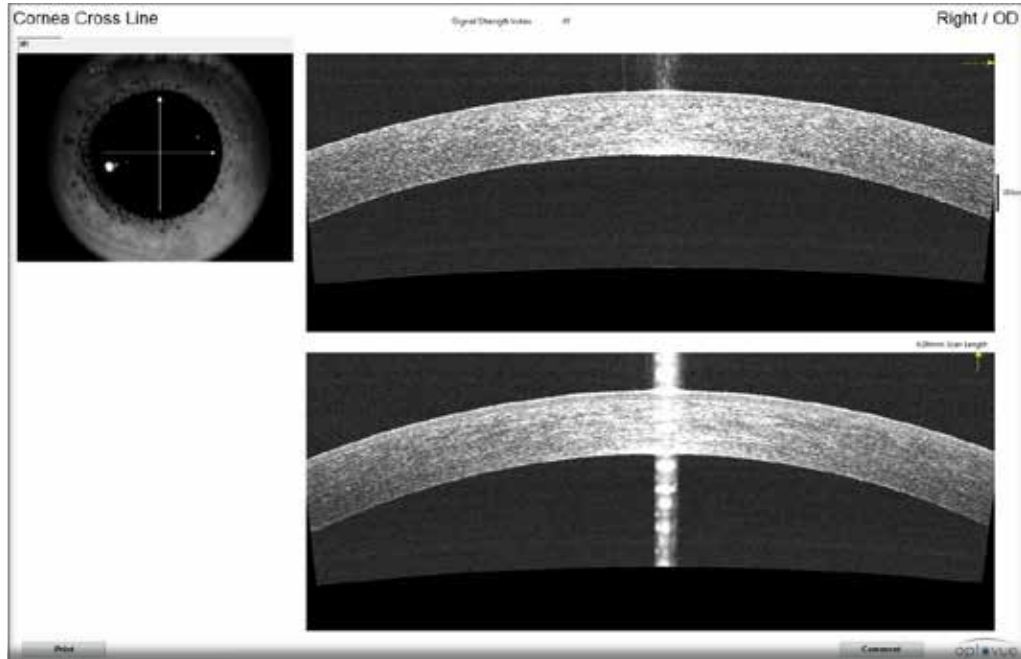
#### 6.3.1 Line



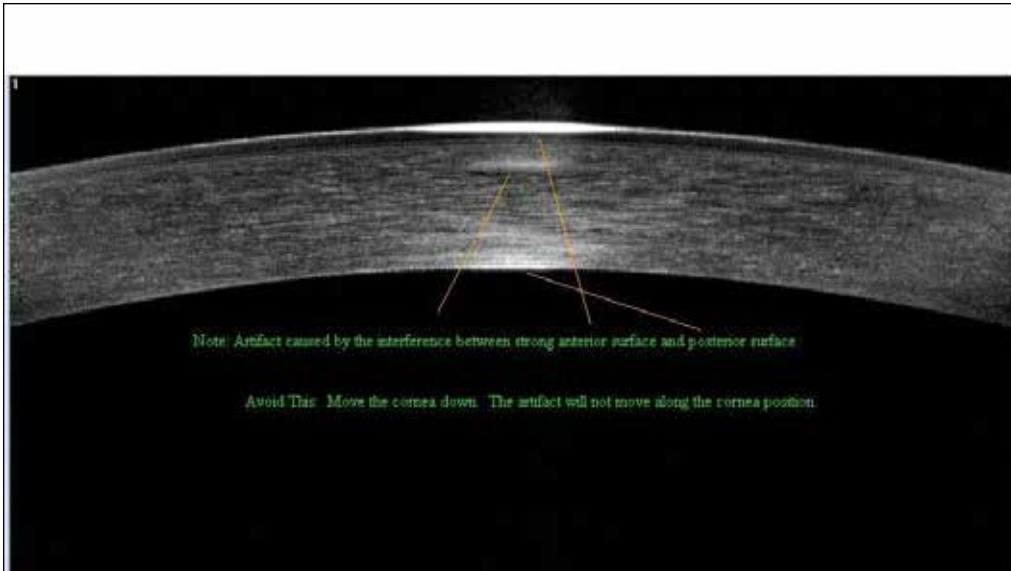
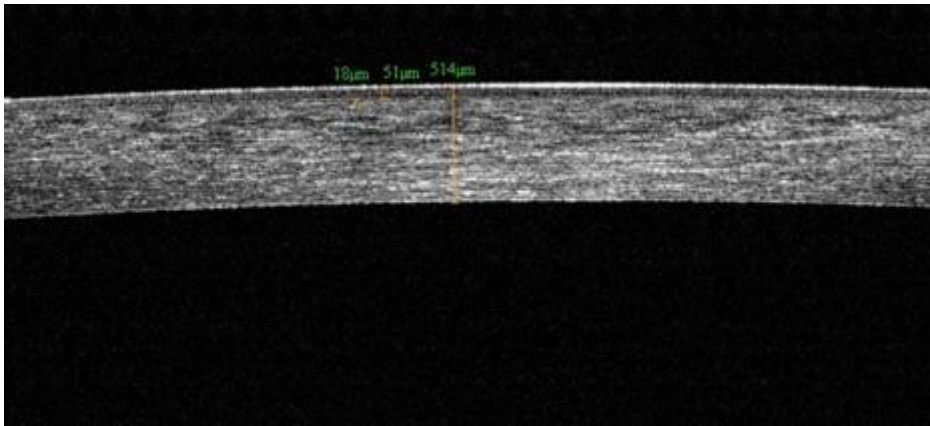
On both Line & Cross line scans, if the image saved is an average processed image, then both the averaged and single frame image will be saved.

### 6.3.2 Cross Line Scan

Showing both vertical and horizontal scan images of the cornea



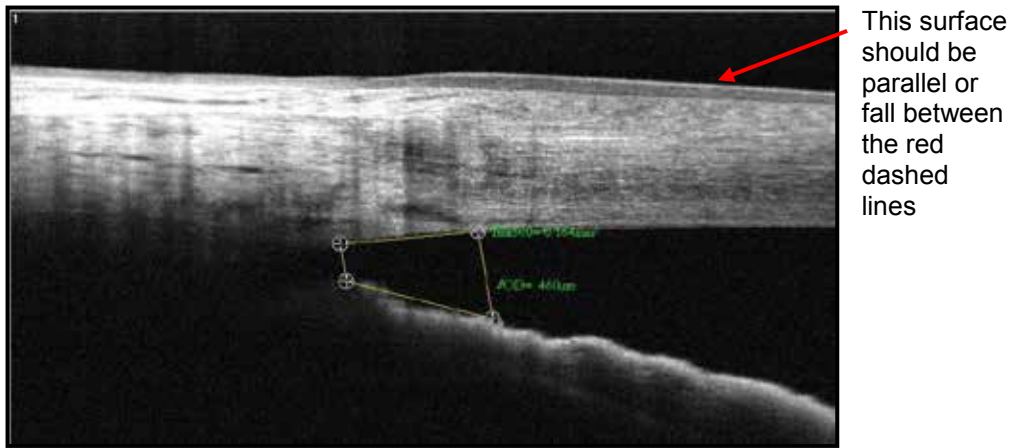
### 6.3.2.1 Scan with Thickness Measurement Tool



#### Note:

The artifact in the image is from an interference signal caused by the strong signal on both anterior and posterior cornea surface. The artifact is “fixed” at the same location. To avoid or remove the artifact from your scan, use the joystick to move the scan on the eye slightly up/down, left or right. (you may also use the chinrest elevation control up/down switch for chin adjustment down to avoid the artifact).

### 6.3.3 Angle

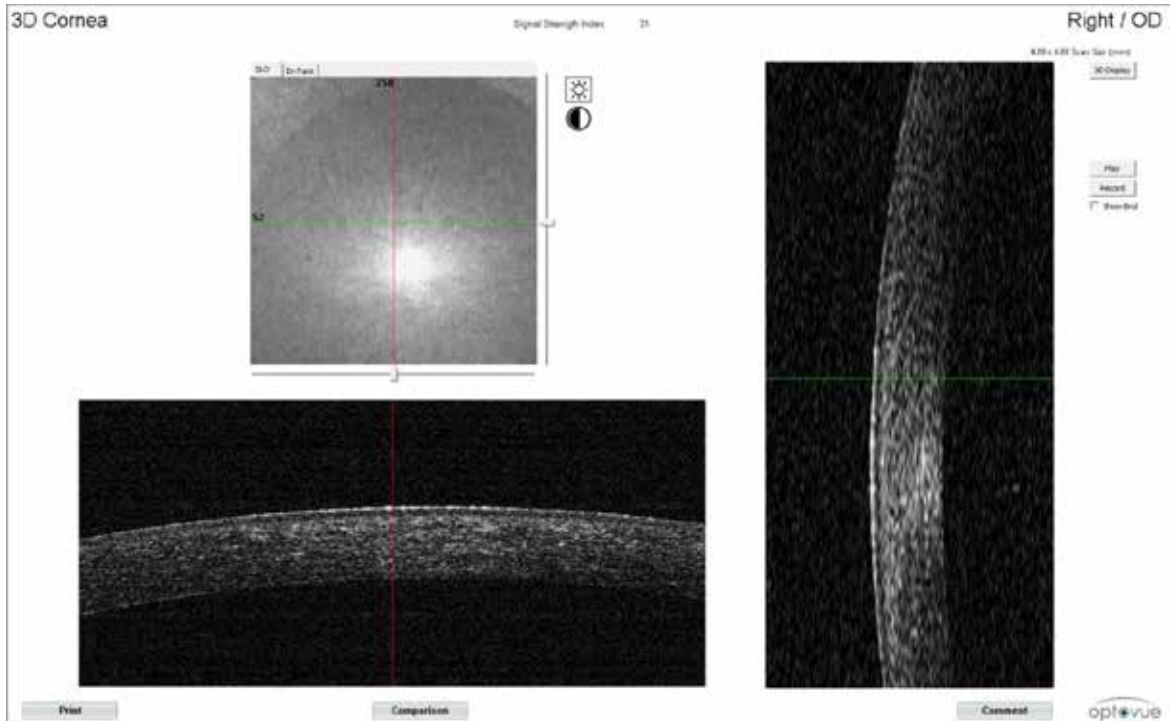


### 6.3.3.1 TISA/AOD Measurement Tool

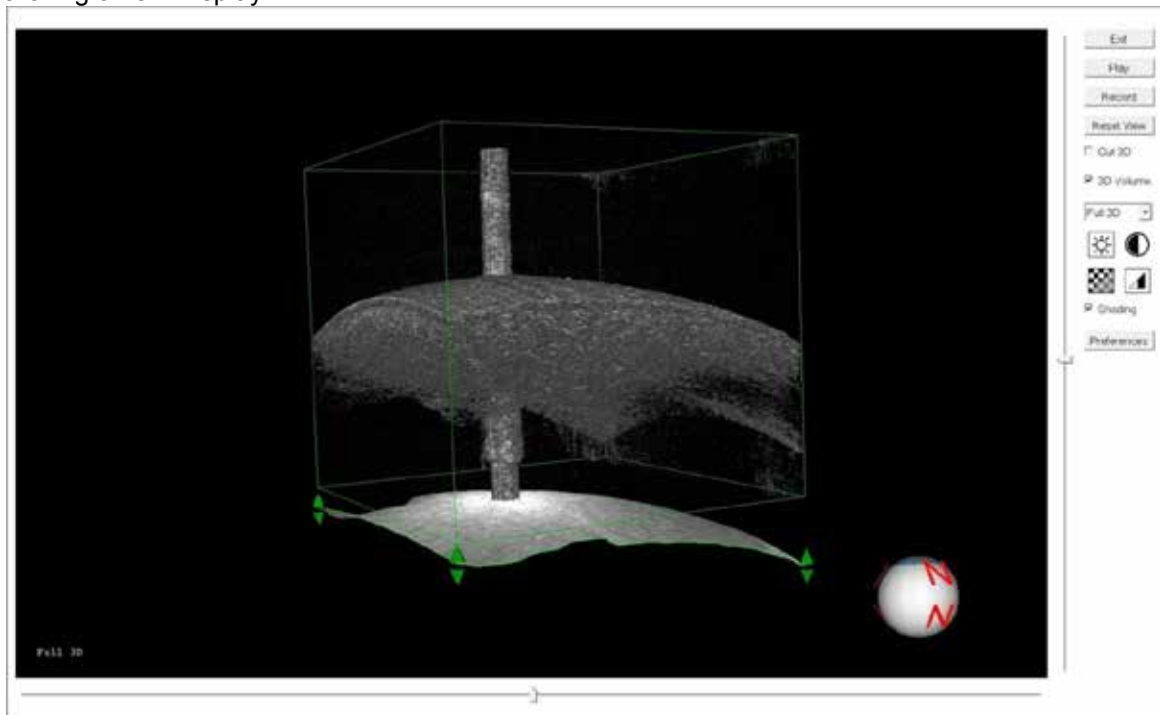
TISA (Trabecular Iris Surface Area) Measurement tool is used to measure the angle area and AOD (angle open distance) in the anterior chamber angle. The number 500 or 750 is the distance (in microns) measured between the two upper points along the posterior cornea surface. One of these two upper points shall be located on the sclera spur and the other one on the posterior cornea surface 500 or 750µm away from sclera spur. The AOD is the distance from cornea to iris. The area is measured as the trapezoidal area encompassed by these four points.

### 6.3.4 3D Cornea

The Cornea 3D scan has scan density of 513 A-scans and 101 B-scans.



See the RTVue XR User's Manual for more information about the 3D scan presentations. The 3D Cornea presentation is similar to that for the retinal 3D presentations (without retinal features). Below is a sample presentation created by clicking on 3D Display.



3D volume presentation of the 3D Cornea

### 6.3.5 Pachymetry

The pachymetry scan is a set of 8 radial meridians 6mm in length and centered on the pupil.



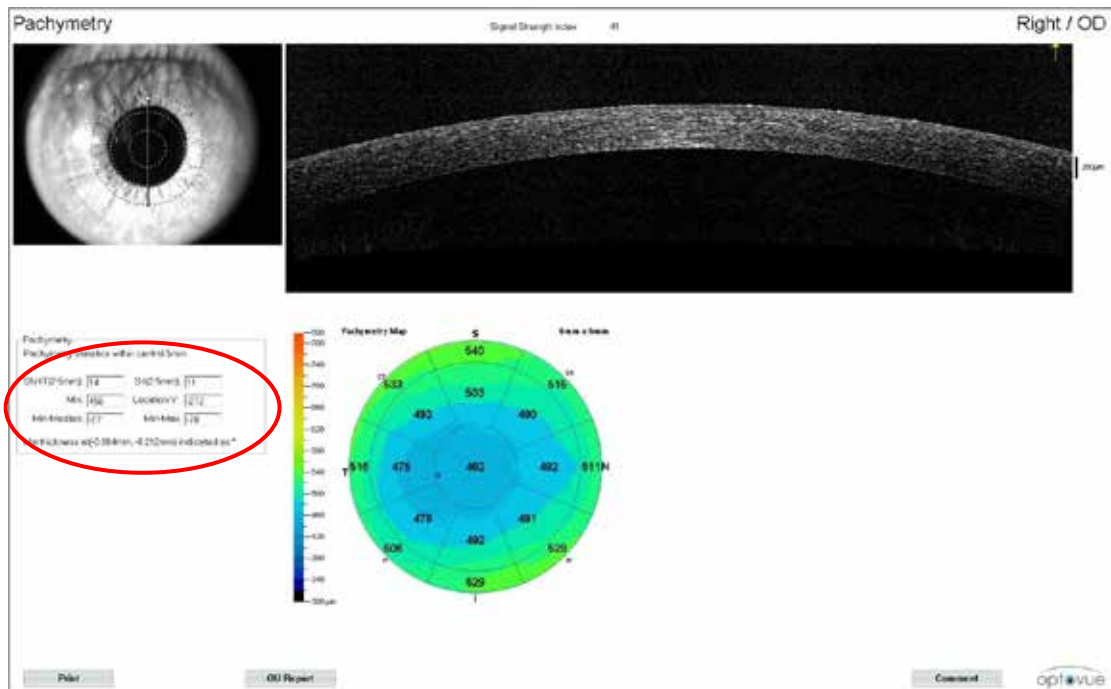
Illustration of Pachymetry scan pattern consists of 8 median scans 6mm in length.

The pachymetry report is a comprehensive collection of maps, tables, and images that provide qualitative and quantitative assessment of the cornea.

Cornea thickness results are presented as a color-coded map (6mm) and a color scale provides reference values for colors. Thicker values are hot colors like red and orange, while thinner values are cool colors like blue and black.

Individual B-scans are displayed in the presentation window above the map. Different B-scans can be displayed by clicking on the thickness map (making it interactive) and moving the cursor around slowly to the white lines (scan location indicators).

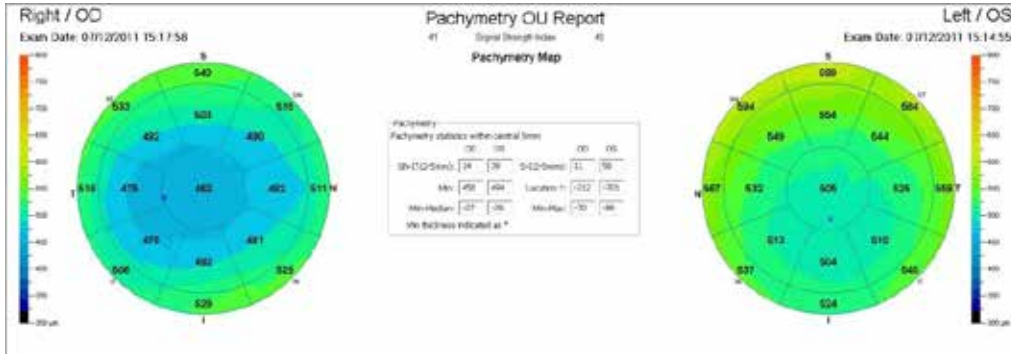




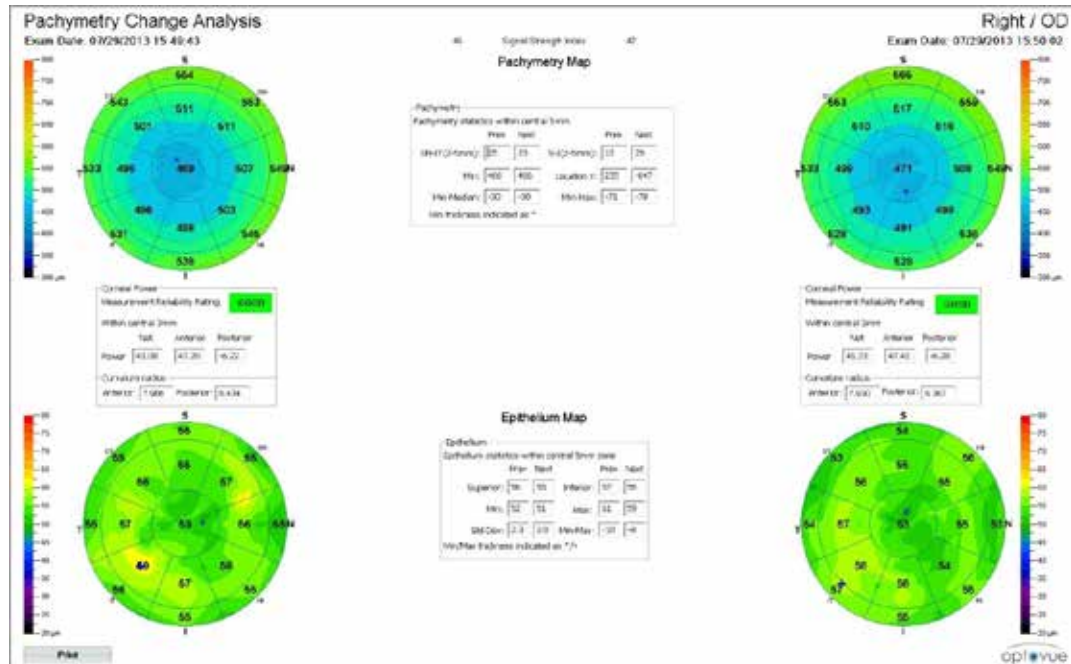
Pachymetry Assessment

The Pachymetry analysis provides some key thickness parameters in the table to the left of the Pachymetry report (note the values in the red circle above). It is suggested in literature that a difference (delta) of 50 microns or more between the superior and inferior sectors being compared is suspect.

### 6.3.5.1 Symmetry & Change Analysis



Symmetry analysis for Pachymetry results



Change Analysis results for Pachymetry, Cornea Power and Epithelial Map

### 6.3.5.2 Corneal Power

The Corneal Power feature is available to customers who have purchased the Corneal Power upgrade. For information on how to install and validate the cornea power tool, please refer to installation manual.

**The Net Corneal Power value determined by the TCP function is NOT INTERCHANGEABLE with the corneal power value determined by any other device. The Net Corneal Power determined by the TCP function of the CAM option for RTVue XR is not intended to be used in lieu of, or replace a value from another device into your standard IOL calculation formula.**

#### Summary description

Corneal power is one of the key input parameters for IOL power calculation in cataract surgery. In clinical practice, corneal power is commonly measured by manual or automated keratometry or by simulated keratometry (Sim-K) from Placido-ring corneal topographers. Corneal power provided by keratometry or topography is based on measuring the anterior surface curvature of the cornea and assuming a fixed ratio of 0.883 between posterior and anterior curvature to compute the total corneal power.<sup>3</sup> Corneal power measurement with keratometer or topographer works well enough in normal eyes, but the assumption of fixed ratio between anterior and posterior curvature could lead to erroneous corneal power assessment in eyes with corneal pathology or eyes with prior refractive surgery for obvious reasons.<sup>1,2,3</sup> Therefore, direct measurement of both anterior and posterior corneal curvatures to assess corneal refractive power as implemented in XR CAM could be advantageous.

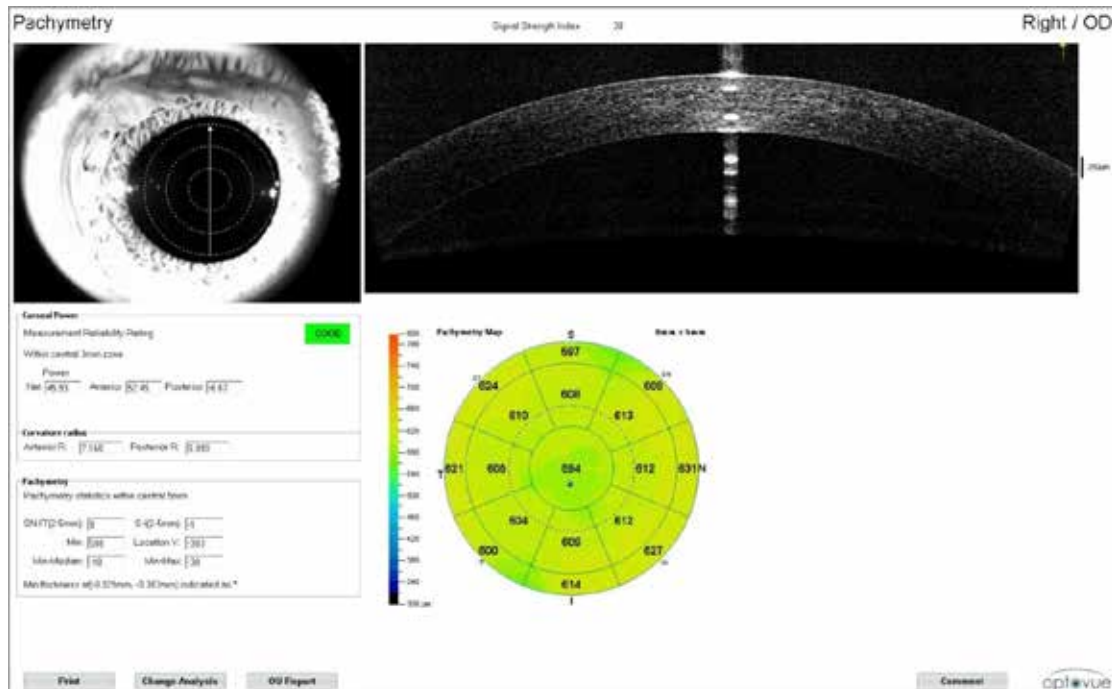
The XR CAM net corneal power is not clinically interchangeable with keratometric corneal power measurements or Pentacam net corneal power measurement for IOL Power calculation. In other words, the XR CAM corneal power measurements cannot be directly applied in existing IOL power formulas developed based on measurements provided by other devices, such as keratometer or Pentacam

XR corneal power scan is performed with CAM adaptor and with the “Pachymetry” scan protocol which consists of 5 sets of pachymetry scan. Each set of pachymetry scan consists of 8 evenly spaced meridian scans (6 mm in length each) centered on the pupil.

The corneal curvature radii are derived based on best fit sphere to the central 3 mm for anterior and posterior surfaces. The anterior and posterior corneal power is calculated based on refractive indices of 1.376 for the cornea and 1.336 for the aqueous. The net corneal power is calculated using a thick lens formula based on anterior corneal power, posterior corneal power, taking into account the central thickness of the cornea. See Appendix A for additional description.

## Summary Report

The results of the Corneal Power scan provides Net, Anterior, and Posterior power measurements, representing the net corneal power, anterior corneal power, and posterior corneal power respectively, in measurement unit of diopter (D). The radius of curvature measurements are also provided, in measurement unit of mm. A measurement reliability index for the corneal power measurement is also provided on the analysis report.



When acquiring Corneal Power scan, the following steps should be observed.

- Patient must be instructed to fixate on the center of light-blue internal fixation target with the test eye.
- Operator should center the scan on the pupil. If the misalignment exceeds 1 mm (pupil center exceeds the boundary of the smallest concentric circle on the screen), the scan should be excluded.
- Operator should set the working distance properly by placing the corneal cross-sectional images within the range defined by the two horizontal red lines to avoid image cropping.
- Operator should make sure that the lids of the eye are not blocking or shadowing a significant portion of the image in vertical meridians.
- Operator should observe the measurement reliability index status on the report screen. A measurement with poor measurement reliability indicates increased risk of measurement variability. Measurements with poor reliability should be replaced if possible.
- Corneal power measurements are not displayed for poor quality scans in which an algorithm failed. In this case, the scan should be repeated.

**Correct patient fixation and alignment centered on pupil are both critical to produce consistent corneal power measurement.**

Examples of corneal power scan quality problems to watch for are provided in Appendix A

### Repeatability

The repeatability (standard deviation) of the corneal power scan with XR CAM is summarized in the table below. The repeatability of corneal power parameters is better than 0.25D for a single scan in the normal eye and the post-laser refractive surgery eyes. For clinical use, it is recommended that a user takes at least 3 corneal power scans and calculate mean corneal power to further reduce measurement variability.

|                                       | Normal | Post-Laser Refractive Surgery | Pathological or Post-Incisional Surgery |
|---------------------------------------|--------|-------------------------------|---|
| Net Corneal Power (D)                 | 0.21   | 0.17                          | 0.35                                    |
| Anterior Corneal Power (n=1.3375) (D) | 0.20   | 0.16                          | 0.39                                    |
| Posterior Corneal Power (D)           | 0.05   | 0.05                          | 0.16                                    |
| Anterior Radius of Curvature (mm)     | 0.034  | 0.030                         | 0.064                                   |
| Posterior Radius of Curvature (mm)    | 0.050  | 0.048                         | 0.172                                   |
| Central Corneal Thickness (µm)        | 2.1    | 1.9                           | 3.8                                     |
| Thinnest Corneal Thickness (µm)       | 3.8    | 1.3                           | 18.0                                    |

### Validation

To ensure system stability overtime, the corneal power software automatically prompts for a weekly validation test. The validation test is performed with the corneal power validation tool stored with the instrument. The result of the validation test is compared with the stored value obtained during the initial corneal power calibration to verify system stability. The limit of acceptable difference is  $\pm 0.25D$ ; if exceeded, the software will not allow acquisition of corneal power scan. A warning message is displayed on screen with instructions for further actions. See Appendix A for instructions to perform the Validation Test.

If the weekly validation test is not performed on schedule, the corneal power feature will be automatically disabled and only pachymetry measurement will be produced. To reactivate corneal power measurement, select the validation test and perform the test according to instruction.

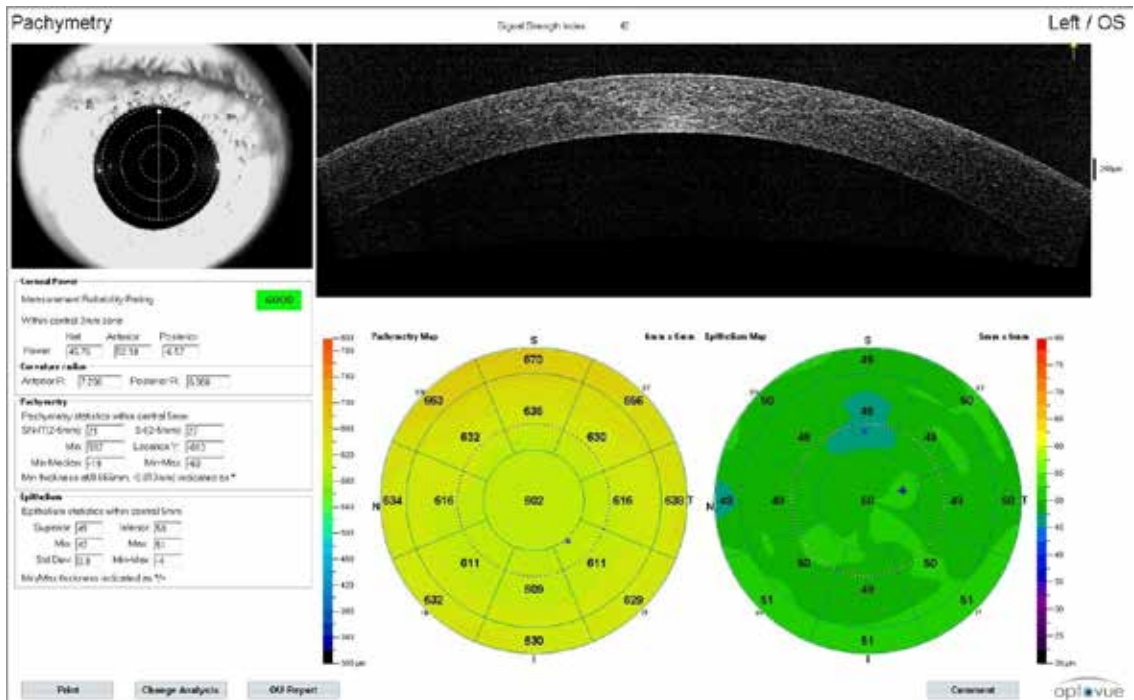
### References:

1. Seitz B, Langenbacher A, Nguyen NX, Kus MM, Ku'chle M. Underestimation of intraocular lens power for cataract surgery after myopic photorefractive keratectomy. *Ophthalmology* 1999; 106:6936–702.
2. Wang L, Hill WE, Koch DD. Evaluation of intraocular lens power prediction methods using the American Society of Cataract and Refractive Surgeons Post-Keratorefractive Intraocular Lens Power Calculator. *J Cataract Refract Surg* 2010; 36:1466–1473.
3. Tang M, Li Y, Avila M, Huang D. Measuring total corneal power before and after laser in situ keratomileusis with high-speed optical coherence tomography. *J Cataract Refract Surg*. 2006; 32:1843-50.

### 6.3.5.3 Epithelium Thickness Mapping

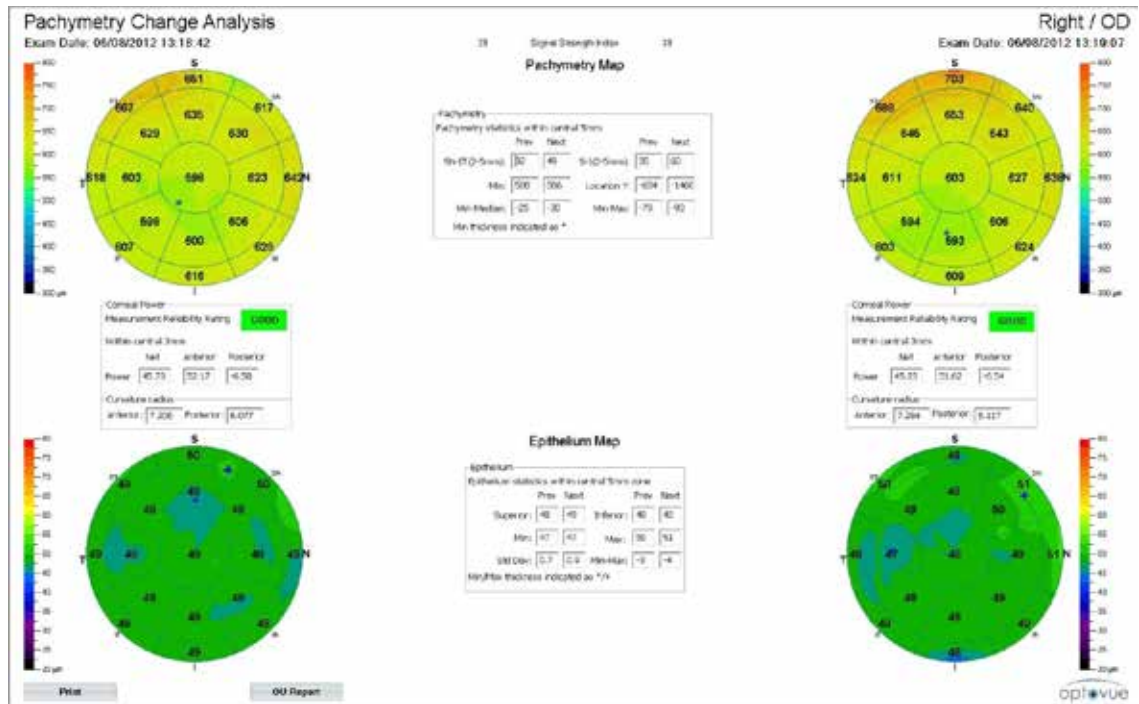
The Epithelium Thickness Mapping feature is available to customers who have purchased the Epithelium Thickness Mapping upgrade. It is not offered in the US or USCFG countries

There is a clinical need to measure epithelial cell layer separately from the pachymetry of the cornea. The thickness distribution of the layer is useful in the evaluation and follow up of patients for irregularities and/or changes due to pathologies, contact lens, or refractive surgeries. Epithelium Thickness measures the thickness from the epithelial cell surface to Bowman's membrane. The Epithelium Thickness Mapping feature is an upgrade to the pachymetry scan – a sample pachymetry report with epithelium thickness mapping is shown below.



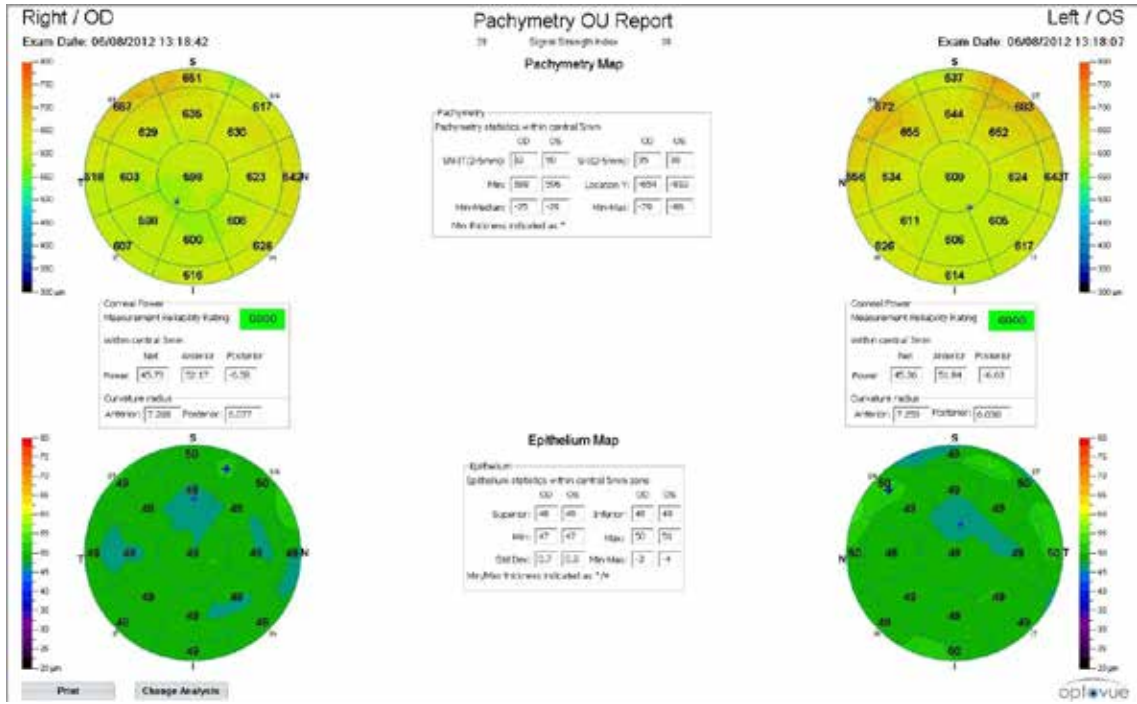
The scan report of epithelium thickness displays an Epithelium Map to the right of the pachymetry scan. Note: the Epithelium Map uses a different color legend than that for the Pachymetry Map. An Epithelium Thickness analysis is displayed underneath the Pachymetry analysis as well.

## Symmetry Analysis



Pachymetry change analysis with epithelial thickness and corneal power

# OU Report



Pachymetry OU report with epithelial mapping and corneal power



## 7 **File Management Menu**

Please reference to the XR manual for this entire section.

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## 8 Maintenance & Troubleshooting

***Please refer to the XR manual for this entire section plus additional CAM lens care.***

1. Keep the CAM lenses in the wooden case provided when not using
2. Routinely check the lens for dust, fingerprints, or smudges.
3. Use the same cleaning method as is recommended in the XR User Manual to use to clean the front ocular lens of the XR.

### **Cleaning the Corneal Power Validation Tool**

1. Keep the Corneal Power Validation Tool in the wooden case provided when not in use.
2. Routinely check the lens for dust, fingerprints, or smudges.
3. Use the same cleaning methods as is recommended in the XR User manual to clean the front ocular lens of the XR.

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## 9 Scan Pattern Specifications

| Name                       | Description   | # A-Scan<br>(without averaging)       | Adjustability  | Default         |
|----------------------------|---|---------------------------------------|--|-----------------|
| Scan Pattern               |   |                                       |  |                 |
| Pachymetry                 | 8 radial lines with 6mm scan length (1020 A-scans/line) and 22.5 degree interval.                                   | 1020 x 8                              | Fixed  | 6mm radial scan |
| Pachymetry + Corneal Power | 8 radial scans with 6mm scan length (1020 A-scans/line) and 22.5 degree interval.<br><br>5 repeated sets are taken. | 1020 x 8 x 5 (due to 5 repeated sets) | Fixed  | 6mm radial scan |
| Cornea Line                | 1020 A-scans/line with adjustable scan length   | 1020 x 1                              | Transverse: 2 -8 mm (0.5 mm increment)<br>Angle: -90° - 90° (1° increment) | 8mm, 0 degree   |
| Cornea Cross Line          | Two scan lines orthogonal to each other with adjustable scan length (1020 A-scans/line)                             | 1020 x 2                              | Transverse: 2 -8 mm (0.5 mm increment)<br>Angle: -90° - 90° (1° increment) | 8mm, 0 degree   |
| Angle                      | 1 scan line with adjustable scan length (1020 A-scans/line)   | 1020 x 1                              | Transverse: 2 -6 mm (0.5 mm increment)<br>Angle: -90° - 90° (1° increment) | 3mm, 0 degree   |
| 3D Cornea                  | 101 horizontal scan lines with 6mm scan length (513 A-scans/line) and 60 μm interval between each horizontal scan.  | 513 x 101                             | Transverse: 4mm -6mm (1mm increment)<br>Angle: fixed at 0°                 | 6 mm            |

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## 10 Technical Data

### 10.1 System Specifications

#### **A. Performance Specifications Summary:**

1. OCT Image Resolution: 5  $\mu\text{m}$  (in tissue)
2. OCT Image Scan Rate: 70,000 A-Scan/Second
3. Scan Depth: Maximum of 2.3 mm
4. Scan Length:
  - a. CAM-L: 2-8 mm
5. Cornea Image FOV:
  - a. FOV: 12mm x 8mm

#### **B. Cornea Imager:**

Monochrome CCD Camera: 811x 508 pixel 1/3" CCD Format  
NIR Illumination: 735nm LED

#### **C. Patient Interface:**

Working distance:  
CAM-L: 13 mm

Motorized Chin-Rest adjustable range: 65mm  
Joystick controlled X-Y-Z adjustment: X-100m, Y-85mm, Z-25mm  
Lock-mechanism: Manual

#### **D. Measurement Features:**

##### ***Cornea Analysis:***

- CAM-L:
  - i. Pachymetry map
    1. Cornea thickness map
    2. Flap/Stroma thickness Measurement
    3. Pachymetry Assessment
    4. Corneal Power Assessment
  - ii. Line: Flap/Stroma, Distance/Area measurement
  - iii. Cross line : Flap/Stroma, Distance, Area measurement
  - iv. Angle Scan (3mm scan length, 2.3mm depth)
    1. AOD 500/750 measurement
    2. TISA 500/750 measurement
    3. Angle in degrees

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## 11 Appendix –A

### *11.1 Licensing Corneal Power*

**This feature is a license controlled revenue product and payment for the license is in advance only.**

Please follow the activation instructions provided with the license key in the document titled **“Corneal Power License Key – Activation Instructions.”**

### *11.2 Validating Corneal Power Calibration Tool*

### **Corneal Power (Calibration) Validation**

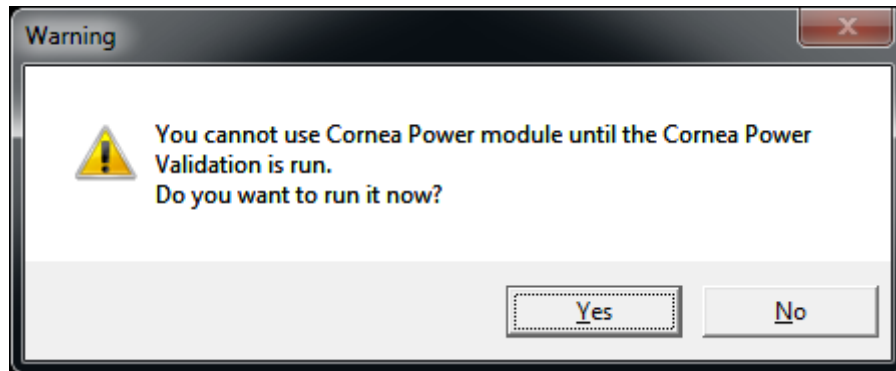
The Cornea Power scan must be re-calibrated every 7 days. Clinical staff should be trained to perform the below calibration validation steps every 7 days. Before using the calibration tool, please make sure tool is clean. Refer to **section 8 maintenance and troubleshooting** for steps to clean the calibration tool.

1. Attach the CAM lens onto the RTVue XR machine and slip the calibration tool on the end of the lens until it stops. Tighten the white lock nut as shown in the figure below.

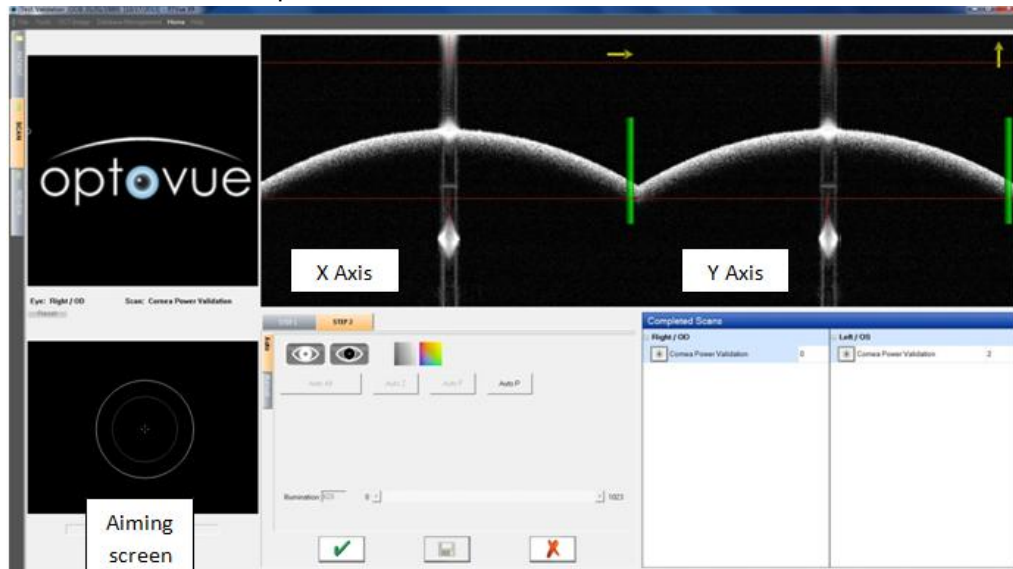


2. Select Test Patient

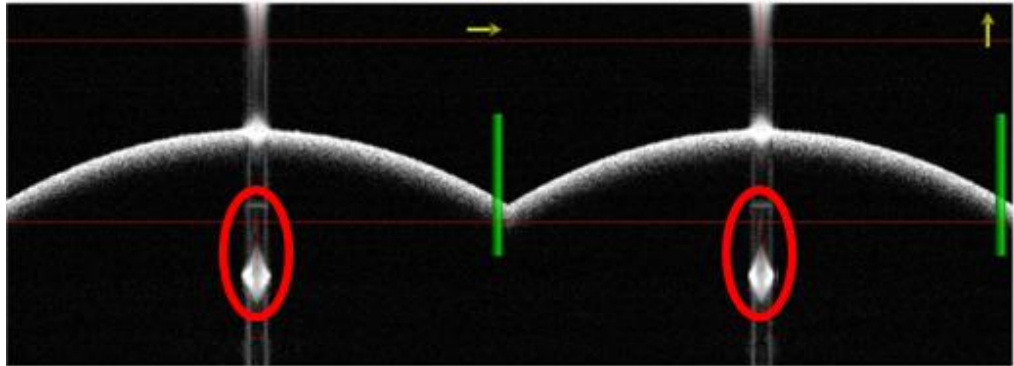
3. Click **Examine** and select the Pachymetry scan. A warning window will pop-up as shown in the below image. Click **Yes** in the window.



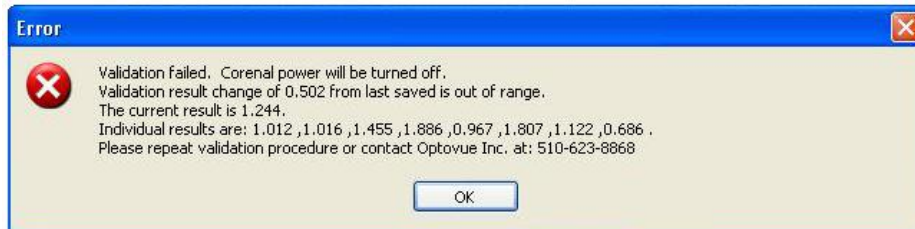
4. Start the scan
5. Click that the two images are between the red parallel lines. The 2 images are in the X and Y axis planes.



6. Using the mouse, click and hold the target on the aiming screen and move the aim LEFT or RIGHT to get a wide reflection on the image and to align the center of the reflection to the center guideline on the X Axis plane.
7. Using the mouse, click and hold the target on the aiming screen and move the aim UP or DOWN to get a wide reflection on the image and to align the center of the reflection to the center guideline on the Y Axis plane.



8. Press “**Auto P**” to optimize the signal.
9. Once the OCT reflection and red dotted line are aligned, click the green check mark, and save the scan. The machine will confirm calibration of cornea power.
10. The machine is now ready. *Note: The calibration procedure will need to be repeated every 7 days.*
11. If validation fails and error message similar to the one below appears, remove and clean the Validation tool.



12. Re-install the Validation tool over the CAM lens until it stops, tighten the white lock screw and retry validation.
13. If error message continues to appear when attempting the Validation, the TCP requires a re-installation. Contact your Optovue service department for assistance.

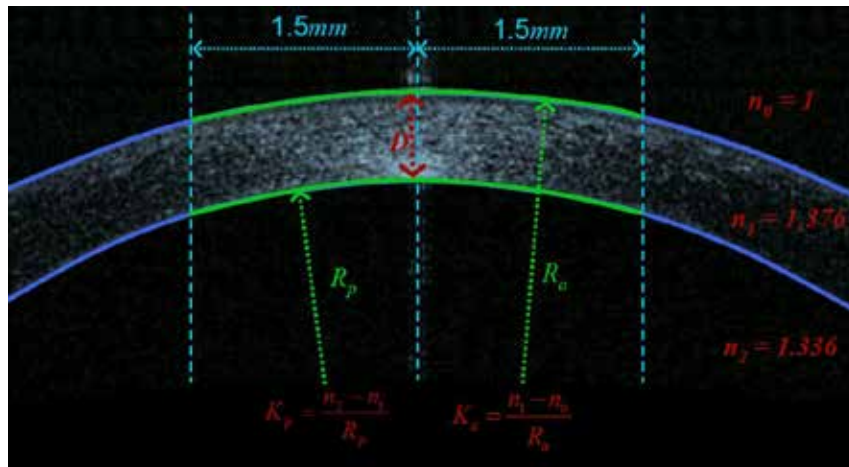
### 11.3 Corneal Power Scan and Calculations with RTVue XR CAM

The corneal power scan consists of 5 sets of pachymetry scans in rapid succession. Each set of pachymetry scan consists of 8 meridian scans of 6mm in length centered on the pupil.

As illustrated in the figure below, the anterior and posterior corneal curvature radii are calculated from 8 meridian corneal cross-sectional images based on the central 3 mm zone. The corneal anterior power ( $K_a$ ) and posterior power ( $K_p$ ) are calculated based on the anterior radius ( $R_a$ ) and the posterior radius ( $R_p$ ) as follow:

$$K_a = \frac{n_1 - n_0}{R_a}, \quad K_p = \frac{n_2 - n_1}{R_p}$$

where  $n_0 = 1$ ,  $n_1 = 1.376$  and  $n_2 = 1.336$ .

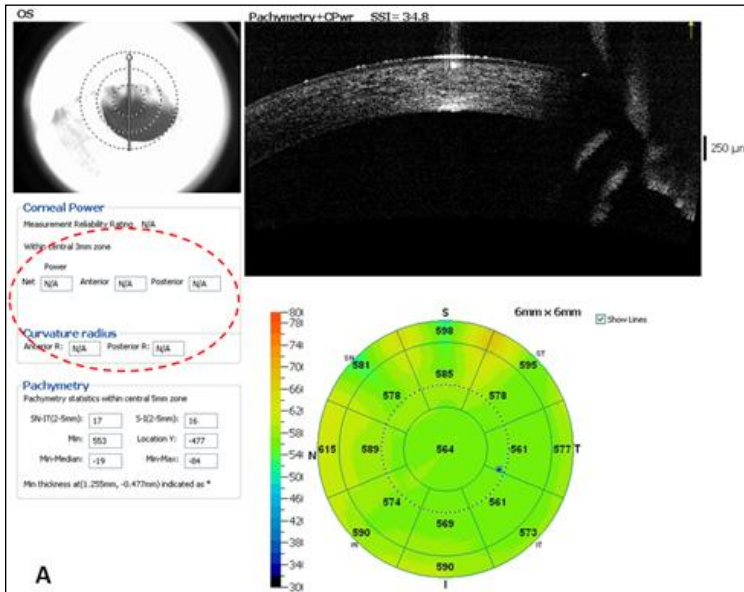


The net corneal power is computed using thick lens formula:

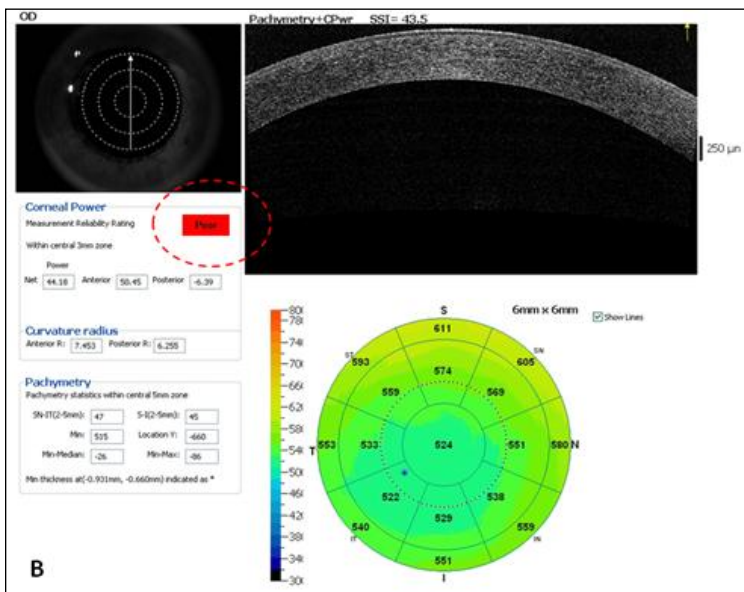
$$K = K_a + K_p - \frac{D}{n_1} * K_a * K_p$$

where  $D$  is the central corneal thickness.

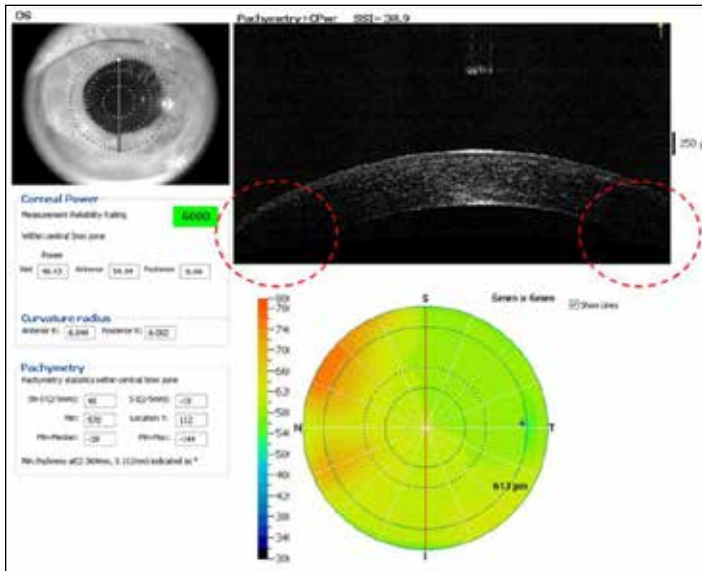
## 11.4 Examples of Poor or Borderline Quality Corneal Power Scan



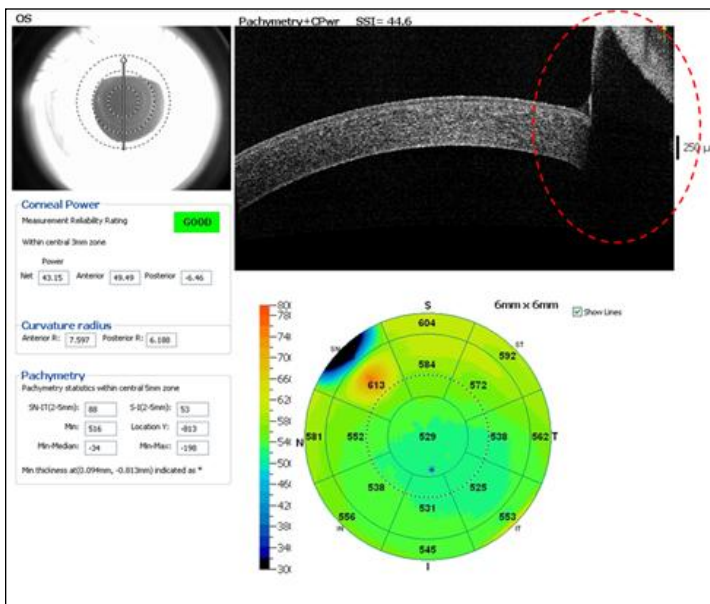
Invalid scan. No corneal power measurement are calculated



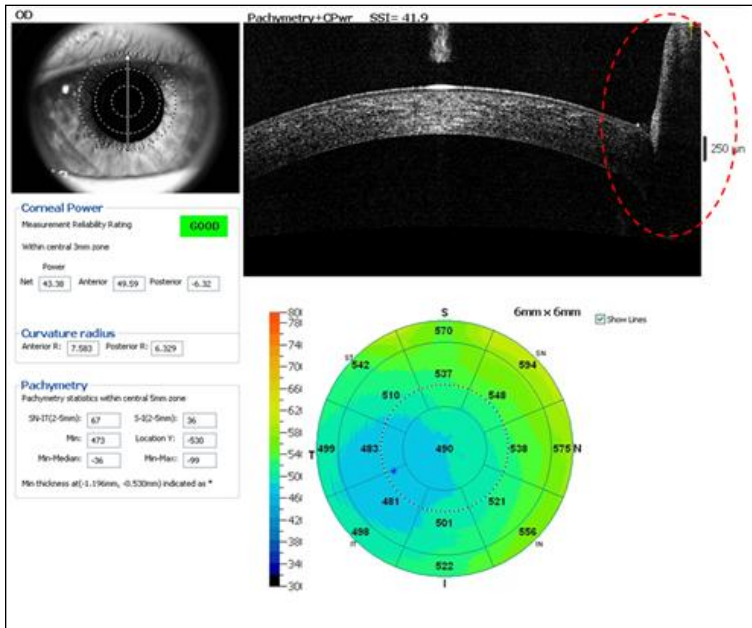
Poor reliability index.



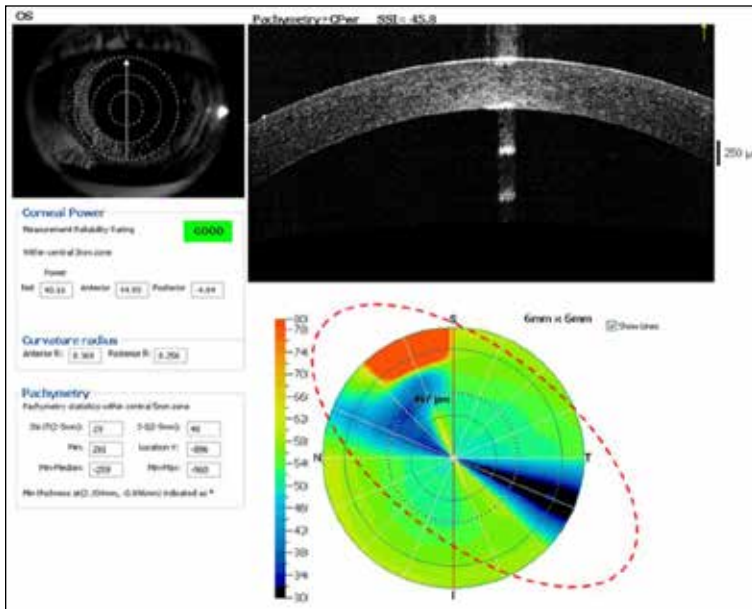
Scan out of range, placed too low in the window that part of the corneal cross-sectional OCT image is cropped.



Eyelid blocking more than 1mm of the image.

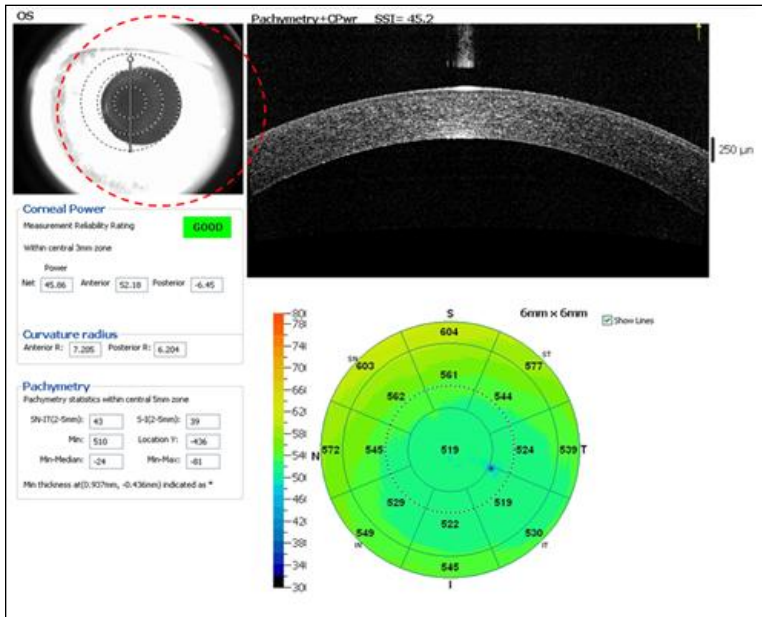


Eyelid blocking between 0.5mm ~ 1 mm of the image.

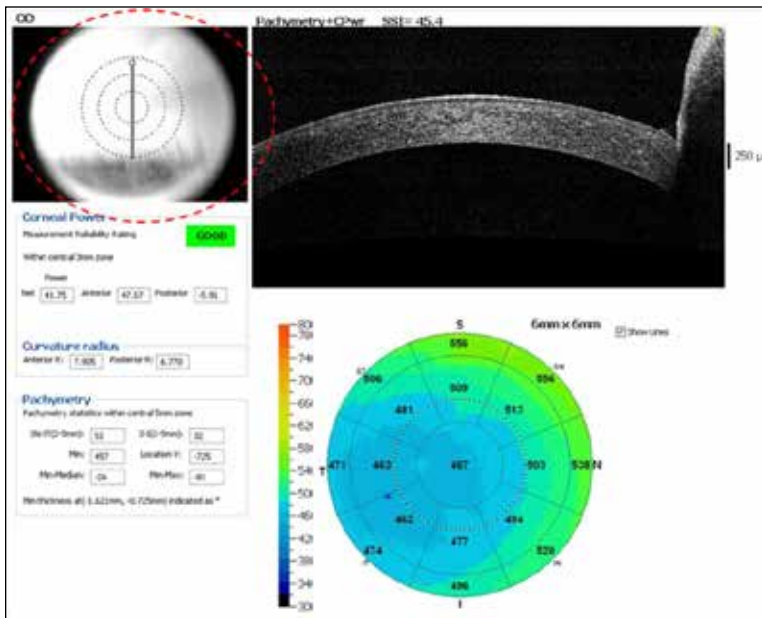


Occasionally, eyelid or eyelash artifact in meridians other than the vertical one (due to blinking) could cause obvious artifact in the pachymetry map but no obvious impact on  $CCP_{Net}$  measurement quality.





Misalignment on pupil between 0.5mm ~ 1mm.



Pupil blocked by eyelid in the video image and alignment cannot be assessed.

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## 12 **Appendix –B**

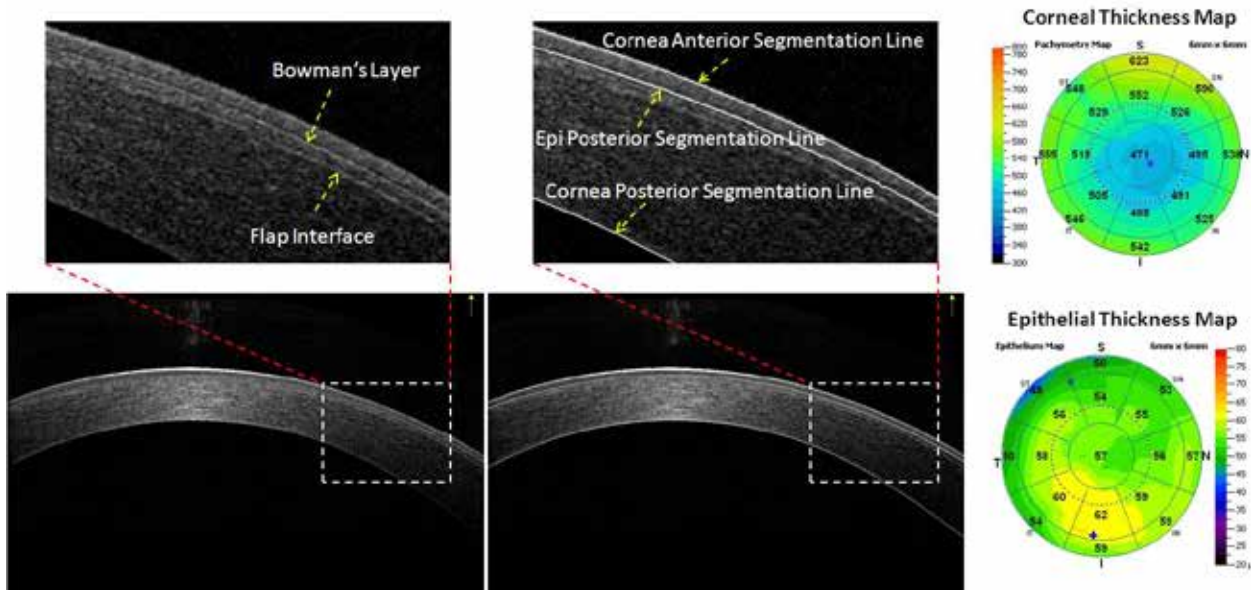
### *12.1 Licensing Epithelium Mapping*

**This feature is a license controlled revenue product and payment for the license is in advance only.**

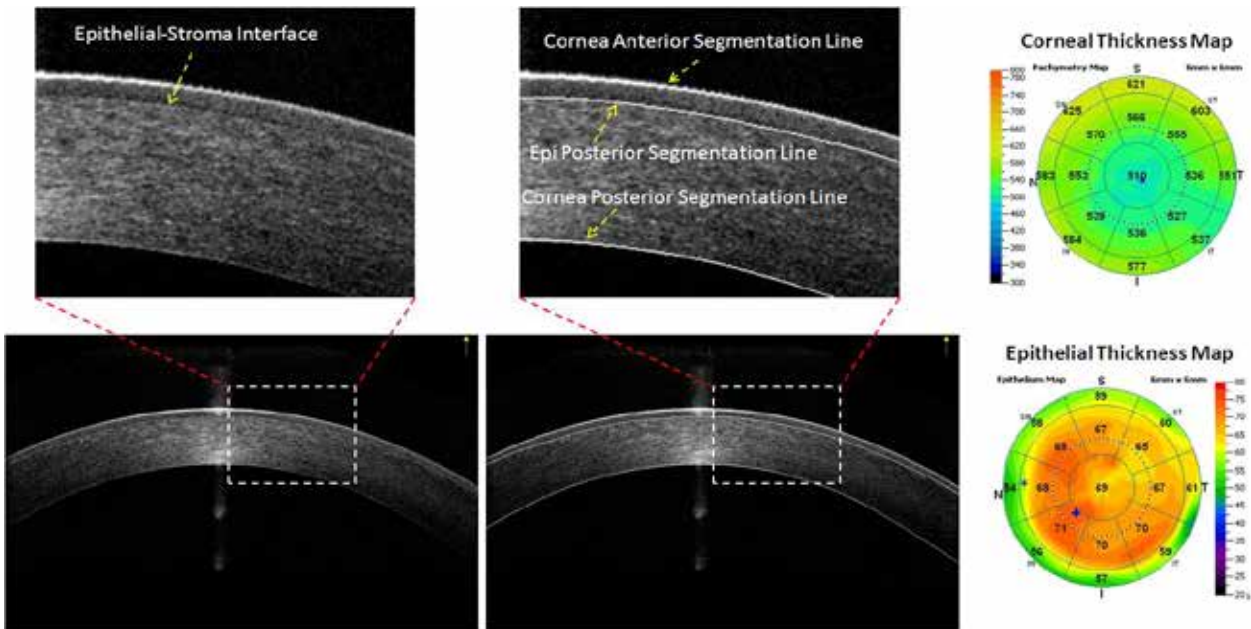
Please follow the activation instructions provided with the license key in the document titled **“Epithelium Mapping License Key – Activation Instructions.”**

## 12.2 Detection of Epithelial Boundaries

The automatic algorithm measures epithelial thickness from corneal anterior surface to the posterior boundary of the epithelia. The posterior boundary is defined as the interface of epithelia and Bowman's Layer. When the Bowman's layer is absent as in post-PRK eyes, the posterior boundary is defined as the interface of epithelia and the corneal stroma. There is characteristic reflectivity change at the interfaces which is utilized in the automatic algorithm for boundary detection. The automatic segmentation of the corneal anterior and posterior boundaries and epithelial posterior boundary and resulting corneal thickness map and epithelial thickness map are illustrated with a post-LASIK eye and with a post-PRK eye as illustrated in the following two images respectively. Because of the difference in the characteristics in the epithelial posterior boundary in LASIK and PRK eyes, for this validation study, we separated the post-laser refractive surgery eyes into LASIK group and PRK group in the data analysis.



Automatic segmentation of corneal and epithelial boundaries in the right eye of a 33 yrs. old male study subject with LASIK previously. The Bowman's layer is clearly visible and in some region, the LASIK flap interface is also visible. The automatic segmentation lines for the corneal and epithelial boundaries are shown in the middle. The resulting thickness maps are shown on the right.

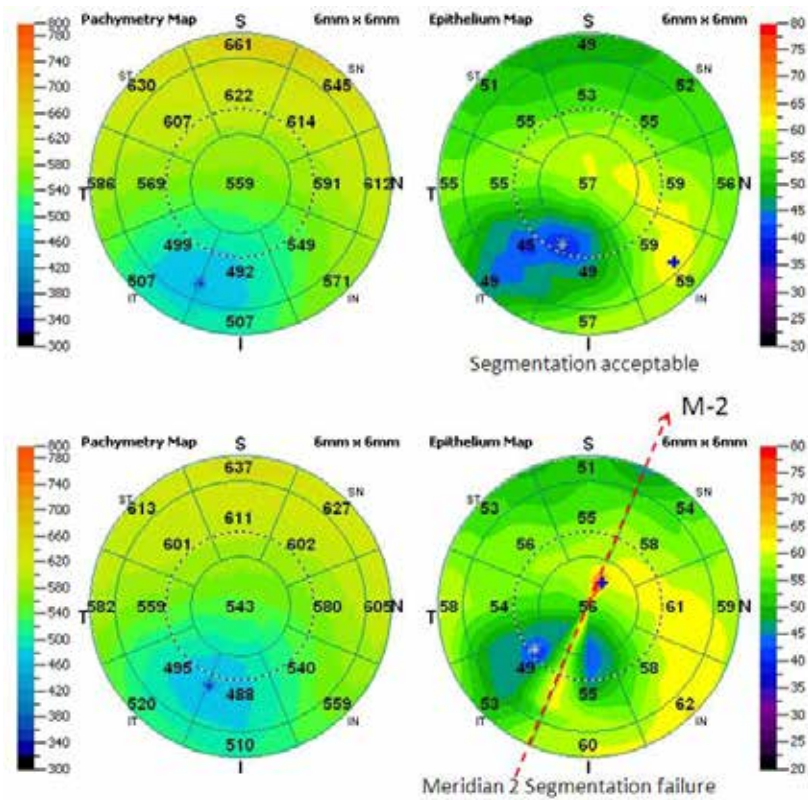


Automatic segmentation of corneal and epithelial boundaries in the left eye of a 42 yrs. old female study subject with PRK previously. The Bowman's Layer is absent as the result of the PRK procedure. The automatic segmentation lines for the corneal and epithelial boundaries are shown in the middle. The resulting thickness maps are shown on the right.

### 12.3 Identification of Segmentation Error and Manual Correction

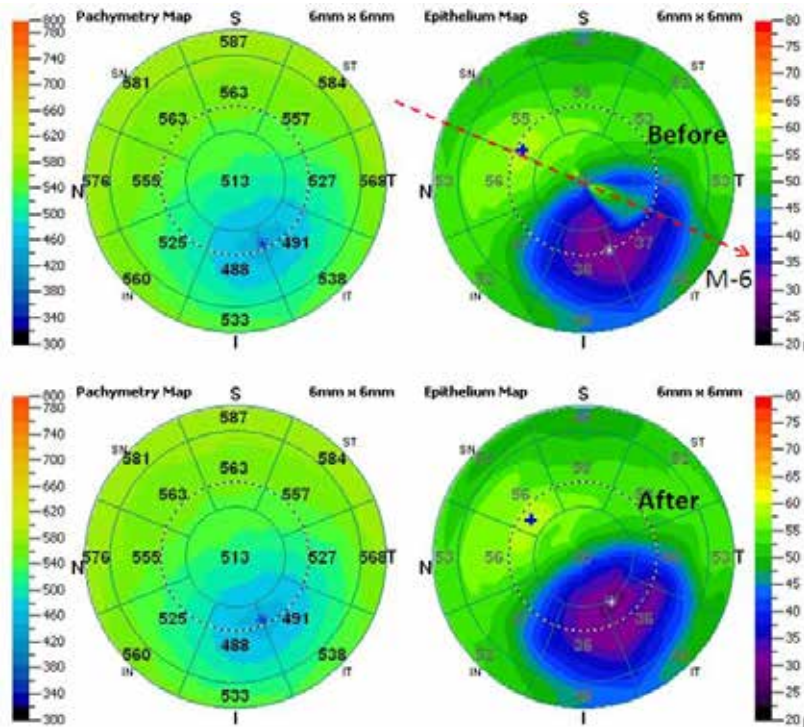
Check epithelial map for obvious segmentation error along the 8 meridian scan lines. When segmentation error was noted, corresponding cross-sectional OCT image with segmentation line overlay was reviewed for confirmation.

Examples of scans from the same eyes with successful segmentation and with obvious segmentation error are shown in the figure below.



Pachymetry maps (Left) and epithelial maps (Right) of a 44 yrs. old KCN patient. The epithelial segmentation was acceptable for the 1<sup>st</sup> scan (Top row) but failed in meridian 2 (M-2) in the 2<sup>nd</sup> scan (Bottom row). The segmentation error is easily recognized based on sharp color change along the scan lines.

Manual correction is quite feasible when the error is limited to a small number of meridians, and could be helpful when imaging difficult eyes. As illustrated in the figure below, the segmentation error in meridian 6 causing a visible artifact in the epithelial map (Top row), and with manual correction of the segmentation error in meridian 6, the artifact in the epithelial map is much reduced. Note that manual correction of the posterior boundary of the epithelial layer didn't affect the pachymetry map. If a scan has segmentation error in multiple meridians, it is probably more efficient to retake the scan instead of manually correcting each affected meridian.



Pachymetry map and epithelial map of the left eye of a 65 yrs. old male KCN patient. Note the artifact in the epithelial map in meridian 6 (M-6) in the Top row. After manually adjusting the epithelial segmentation line for Meridian 6, the epithelial map was reprocessed with the correction. Note the defect in the epithelial map after is much reduced (bottom row). The pachymetry map remains the same before and after.

## 12.4 Clinical Validation Study

Clinical validation of the software was performed based on the following study groups

- Normal cornea with no contact lens wearing history (Normal)
- Normal cornea with regular contact lens wearing history (CL)
- Post-laser refractive surgery cornea (Post-LRS), which was further separated into two sub groups in the analysis: post-LASIK group (LASIK) and post-PRK group (PRK)
- Keratoconus cornea (KCN)

While we do not expect the dry eye syndrome group to pose extra difficulty in the epithelial thickness automatic measurement algorithm as compared to the KCN group or the LASIK and PRK groups, **the performance data for the dry eye syndrome group has not been established and extra caution is recommended when using the device for the measurement of the dry eye subject group.**

### 12.4.1 Enrollment Criteria

#### 12.4.1.1 Normal

Subjects were recruited from staff volunteers, patients seeking refractive surgery consultation, and patients seeking cataract surgery consultation according to the following criteria

- 18 years of age or older
- No corneal pathology
- Not a contact lens wearer
- No prior ocular surgery and no prior laser refractive surgery

#### 12.4.1.2 CL

Subjects were recruited from staff volunteers, patients seeking refractive surgery consultation, and patients seeking cataract surgery consultation according to the following criteria

- 18 years of age or older
- A regular contact lens wearer
- No corneal pathology
- No prior ocular surgery and no prior laser refractive surgery

#### 12.4.1.3 LASIK

Subjects were recruited from the pool of post-LASIK patients according to the following criteria

- 18 years of age or older
- No corneal pathology
- No prior ocular surgery except laser refractive surgery
- At least 1 week post laser refractive surgery without complication

#### 12.4.1.4 PRK

Subjects were recruited from the pool of post-PRK patients according to the following criteria

- 18 years of age or older
- No corneal pathology
- No prior ocular surgery except laser refractive surgery



At least 1 week post laser refractive surgery without complication

#### 12.4.1.5 KCN

Subjects were recruited from the pool of patients with keratoconus diagnosis according to the following criteria

- 18 years of age or older
- Clinical diagnosis of keratoconus
- No prior laser refractive surgery

Epithelial measurement parameters evaluated:

- Min: Minimum epithelial thickness of the map
- Max: Maximum epithelial thickness of the map
- Std Dev: Standard deviation of the epithelial thickness of the map
- Superior: Average epithelial thickness of the superior region of the map between 2mm to 5mm in diameter
- Inferior: Average epithelial thickness of the inferior region of the map between 2mm to 5mm in diameter.
- Central: Average epithelial thickness of the central 2mm diameter region

#### 12.4.2 Study Subject Demographics and Characteristics

17 normal subjects, 10 CL subjects, 12 LASIK subjects, 9 PRK subjects, and 13 KCN patients were included in the validation study.

Age distribution by study group.

| Analysis Variable : Age |       |    |            |         |        |         |         |
|-------------------------|-------|----|------------|---------|--------|---------|---------|
| Group                   | N Obs | N  | Mean       | Std Dev | Range  | Minimum | Maximum |
| CL                      | 10    | 10 | 34.50<br>0 | 12.748  | 38.000 | 18.000  | 56.000  |
| KCN                     | 13    | 13 | 48.53<br>8 | 12.306  | 42.000 | 27.000  | 69.000  |
| LASIK                   | 12    | 12 | 50.58<br>3 | 12.937  | 39.000 | 26.000  | 65.000  |
| Normal                  | 17    | 17 | 46.29<br>4 | 15.280  | 46.000 | 19.000  | 65.000  |
| PRK                     | 9     | 9  | 41.77<br>8 | 12.969  | 41.000 | 23.000  | 64.000  |

Signal strength distribution by study group.

| Analysis Variable : SSI |       |    |            |         |        |         |         |
|-------------------------|-------|----|------------|---------|--------|---------|---------|
| Group                   | N Obs | N  | Mean       | Std Dev | Range  | Minimum | Maximum |
| CL                      | 10    | 10 | 40.91<br>3 | 3.548   | 12.590 | 36.097  | 48.686  |
| KCN                     | 13    | 13 | 42.13<br>5 | 8.810   | 29.304 | 33.072  | 62.376  |
| LASIK                   | 12    | 12 | 39.23<br>8 | 3.921   | 12.453 | 32.500  | 44.953  |
| Normal                  | 17    | 17 | 39.78<br>5 | 3.029   | 12.410 | 32.090  | 44.500  |
| PRK                     | 9     | 9  | 42.01<br>9 | 4.545   | 11.828 | 36.199  | 48.027  |

Central corneal thickness distribution by study group.

| Analysis Variable : CCT |       |    |             |         |             |         |         |
|-------------------------|-------|----|-------------|---------|-------------|---------|---------|
| Group                   | N Obs | N  | Mean        | Std Dev | Range       | Minimum | Maximum |
| CL                      | 10    | 10 | 525.70<br>9 | 16.174  | 58.267      | 497.644 | 555.911 |
| KCN                     | 13    | 13 | 486.50<br>7 | 54.382  | 182.26<br>5 | 367.665 | 549.930 |
| LASIK                   | 12    | 12 | 530.35<br>0 | 34.791  | 122.61<br>1 | 467.318 | 589.930 |
| Normal                  | 17    | 17 | 541.93<br>0 | 46.227  | 159.12<br>3 | 468.417 | 627.540 |
| PRK                     | 9     | 9  | 464.73<br>4 | 57.486  | 173.95<br>7 | 361.434 | 535.391 |

Thinnest corneal thickness distribution by study group.

| Analysis Variable : Thinnest_CT |       |    |         |         |         |         |         |
|---------------------------------|-------|----|---------|---------|---------|---------|---------|
| Group                           | N Obs | N  | Mean    | Std Dev | Range   | Minimum | Maximum |
| CL                              | 10    | 10 | 515.257 | 23.813  | 83.673  | 465.889 | 549.562 |
| KCN                             | 13    | 13 | 427.430 | 79.515  | 273.886 | 239.691 | 513.578 |
| LASIK                           | 12    | 12 | 522.215 | 35.396  | 126.346 | 457.260 | 583.606 |
| Normal                          | 17    | 17 | 534.254 | 46.444  | 164.254 | 457.860 | 622.114 |
| PRK                             | 9     | 9  | 455.636 | 57.296  | 170.372 | 353.674 | 524.047 |

### 12.4.3 Epithelial map measurement parameters

The descriptive statistics for the epithelial thickness map derived parameters are provided in the tables below.

Descriptive statistics for minimum epithelial thickness by study group.

| Analysis Variable : Min |       |    |        |         |        |         |         |
|-------------------------|-------|----|--------|---------|--------|---------|---------|
| Group                   | N Obs | N  | Mean   | Std Dev | Range  | Minimum | Maximum |
| CL                      | 10    | 10 | 47.890 | 5.320   | 17.809 | 36.545  | 54.354  |
| KCN                     | 13    | 8  | 37.682 | 6.727   | 20.220 | 25.436  | 45.656  |
| LASIK                   | 12    | 12 | 52.157 | 3.073   | 8.639  | 47.839  | 56.478  |
| Normal                  | 17    | 16 | 51.033 | 2.318   | 9.110  | 46.432  | 55.542  |
| PRK                     | 9     | 8  | 52.535 | 6.057   | 19.257 | 42.105  | 61.362  |

Descriptive statistics for maximum epithelial thickness by study group.

| Analysis Variable : Max |       |    |            |         |        |         |         |
|-------------------------|-------|----|------------|---------|--------|---------|---------|
| Group                   | N Obs | N  | Mean       | Std Dev | Range  | Minimum | Maximum |
| CL                      | 10    | 10 | 56.01<br>1 | 4.710   | 13.925 | 50.603  | 64.528  |
| KCN                     | 13    | 8  | 61.29<br>9 | 4.459   | 14.686 | 53.635  | 68.321  |
| LASIK                   | 12    | 12 | 62.07<br>2 | 3.620   | 12.184 | 55.970  | 68.154  |
| Normal                  | 17    | 16 | 58.53<br>1 | 3.443   | 13.710 | 53.741  | 67.452  |
| PRK                     | 9     | 8  | 63.34<br>1 | 6.285   | 20.470 | 54.738  | 75.208  |

Descriptive statistics for standard deviation of the epithelial map by study group.

| Analysis Variable : Std Dev |       |    |       |         |       |         |         |
|-----------------------------|-------|----|-------|---------|-------|---------|---------|
| Group                       | N Obs | N  | Mean  | Std Dev | Range | Minimum | Maximum |
| CL                          | 10    | 10 | 1.790 | 0.537   | 1.664 | 1.059   | 2.723   |
| KCN                         | 13    | 8  | 5.731 | 2.265   | 6.986 | 2.662   | 9.648   |
| LASIK                       | 12    | 12 | 2.299 | 0.854   | 2.623 | 1.457   | 4.080   |
| Normal                      | 17    | 16 | 1.783 | 0.923   | 3.699 | 0.788   | 4.487   |
| PRK                         | 9     | 8  | 2.587 | 0.988   | 2.963 | 1.615   | 4.578   |

Descriptive statistics for central epithelial thickness by study group.

| Analysis Variable : Central |       |    |            |         |        |         |         |
|-----------------------------|-------|----|------------|---------|--------|---------|---------|
| Group                       | N Obs | N  | Mean       | Std Dev | Range  | Minimum | Maximum |
| CL                          | 10    | 10 | 52.62<br>1 | 4.482   | 14.617 | 46.577  | 61.194  |
| KCN                         | 13    | 8  | 50.70<br>0 | 5.867   | 14.214 | 42.379  | 56.593  |
| LASIK                       | 12    | 12 | 57.97<br>7 | 4.489   | 17.259 | 49.258  | 66.517  |
| Normal                      | 17    | 16 | 55.26<br>3 | 2.739   | 9.578  | 51.014  | 60.592  |
| PRK                         | 9     | 8  | 56.90<br>3 | 7.229   | 22.800 | 45.082  | 67.882  |

Descriptive statistics for superior epithelial thickness by study group.

| Analysis Variable : Superior |       |    |            |         |        |         |         |
|------------------------------|-------|----|------------|---------|--------|---------|---------|
| Group                        | N Obs | N  | Mean       | Std Dev | Range  | Minimum | Maximum |
| CL                           | 10    | 10 | 51.88<br>2 | 4.319   | 13.774 | 44.528  | 58.302  |
| KCN                          | 13    | 8  | 52.17<br>8 | 6.448   | 20.869 | 39.955  | 60.824  |
| LASIK                        | 12    | 12 | 56.72<br>6 | 3.438   | 10.247 | 51.808  | 62.055  |
| Normal                       | 17    | 16 | 54.03<br>9 | 2.162   | 7.721  | 50.873  | 58.594  |
| PRK                          | 9     | 8  | 57.62<br>4 | 5.739   | 17.515 | 49.821  | 67.336  |

Descriptive statistics for inferior epithelial thickness by study group.

| Analysis Variable : Inferior |       |    |            |         |        |         |         |
|------------------------------|-------|----|------------|---------|--------|---------|---------|
| Group                        | N Obs | N  | Mean       | Std Dev | Range  | Minimum | Maximum |
| CL                           | 10    | 10 | 52.99<br>3 | 4.176   | 11.650 | 46.827  | 58.477  |
| KCN                          | 13    | 8  | 50.48<br>9 | 3.351   | 9.280  | 46.380  | 55.660  |
| LASIK                        | 12    | 12 | 58.18<br>9 | 3.413   | 12.416 | 51.682  | 64.098  |
| Normal                       | 17    | 16 | 56.08<br>4 | 3.163   | 11.229 | 51.337  | 62.566  |
| PRK                          | 9     | 8  | 59.15<br>7 | 6.420   | 19.837 | 50.678  | 70.515  |

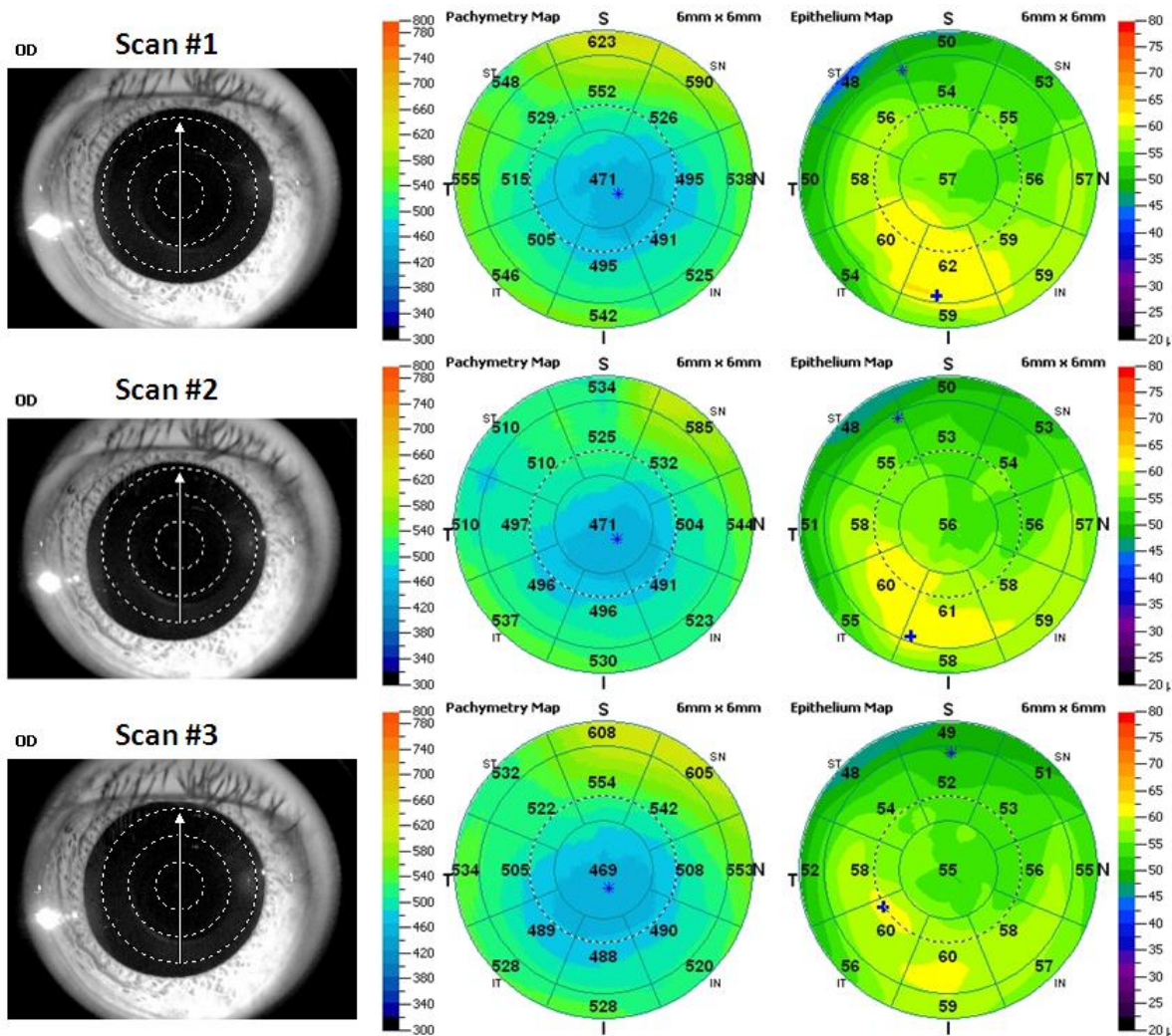
#### 12.4.4 Repeatability of Epithelial Mapping Software

Repeatability was assessed based on 3 repeated scans acquired per subjects. An example of typical repeated scans is shown in the figure below of a study subject in the LASK group. The video images in the left column shows good alignment on the eye for all 3 scans, the middle column shows the pachymetry maps, and the right column shows the epithelial maps.

For the automatic algorithm, the repeatability was assessed for the 6 measurement parameters respectively.

Repeatability (within-subject standard deviation) of epithelial parameters

| Group  | Central<br>(SD)<br>µm | Superior<br>(SD)<br>µm | Inferior<br>(SD)<br>µm | Std Dev<br>(SD)<br>µm | Max<br>(SD)<br>µm | Min<br>(SD)<br>µm |
|--------|-----------------------|------------------------|------------------------|-----------------------|-------------------|-------------------|
| CL     | 1.46                  | 1.51                   | 1.79                   | 0.37                  | 2.06              | 2.40              |
| KCN    | 1.23                  | 1.29                   | 1.10                   | 0.44                  | 1.59              | 0.97              |
| LASIK  | 0.79                  | 1.07                   | 0.67                   | 0.24                  | 1.18              | 1.20              |
| Normal | 0.84                  | 1.24                   | 0.69                   | 0.32                  | 0.78              | 1.50              |
| PRK    | 0.72                  | 0.90                   | 0.47                   | 0.34                  | 1.08              | 1.15              |



Three repeated scans from the right eye of a 33 yr. old male from the LASIK group. The left column shows alignment on the eye well centered on the pupil. The middle column shows the pachymetry maps, and the right column shows the epithelial thickness maps.