WAVE Lens Designer

Instruction Manual

Version 9.70

WAVE CONTACT® LENS SYSTEM
Engineering Better Vision

Table of Contents

1 General Information

1.1 About this Manual

- Carefully read through the Instruction Manual.
- Observe the legal regulations with regards to accident prevention.

1.2 Disclaimer

The WAVE Lens Designer is intended for the use by certified Eye Care Practitioners, who, with appropriate training, knowledge, and practical experience, are able to ensure proper handling of the software.
It is the responsibility of the certified Eye Care Practitioner to decide if the fitting of a contact lens with the WAVE Lens Designer is suitable for the patient.
In addition, the user is responsible for the accuracy of the data entered into the software.

1.3 Safety Instructions for Use

Any serious incident that has occurred in relation to the Wave Lens Designer should be reported by contacting info@wavecontactlenses.com.

Instructions for Operating Personnel

The WAVE Lens Designer may only be used to design customized contact lenses by personnel certified by WAVE, who, with appropriate training, knowledge, and practical experience, are able to ensure proper handling of the software.

1.4 Intended Use

The WAVE Lens Designer is intended to be used by a qualified Eye Care Practitioner to design a fully customized Gas Permeable (GP) contact lens based on patients' corneal topography and/or tomography maps, and to send the design to the lab for production.

Intended medical indication

Design of customized contact lenses for complex ocular conditions and refractive errors.

Contraindication

None known

Possible side effects

None known

Intended users

The WAVE Lens Designer is to be used exclusively by Eye Care Practitioners who:

- can guarantee proper handling due to their knowledge, training, and practical experience.
- are trained in topographical analysis
- are skilled and certified to use the WAVE Lens Designer

Patient group

No restrictions on age, weight, health, and condition.

2 Introduction to WAVE Lens Designer Software

WAVE Lens Designer provides a qualified Eye Care Practitioner (ECP) with a sophisticated and robust CAD/CAM software platform to design a fully customized GP contact lens based on patients' corneal topography and/or tomography maps. The design is then sent directly to the manufacturing lab for production.

The ECP should be trained in topographical analysis to benefit from the WAVE Lens Designer. Default settings and designs created as a result of using software tools should not be used without user's input and user's final review. When designing a lens and selecting an appropriate lens parameter, the eye care practitioner should consider all factors that affect lens performance and the patient's ocular health; including but not limited to, oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

Every WAVE lens is uniquely designed by the doctor for each individual patient to provide excellent visual outcome and maximum comfort. The lens design, after creation, is intellectual property of the designing doctor and any person who intends on dispensing a duplicate lens or utilizing that design must get written consent from the designing doctor to use their design.

All WAVE designs have multiple aspheric curves as small as 10 microns in diameter to closely follow the corneal shape. WAVE lenses may be designed as,

- Corneal GP lenses
- Scleral lenses
- Ortho K lenses

Depending on the corneal topography and the patient's refractive error, WAVE lens designs can have a front toric, back toric, bi-toric optical design, combined with a multifocal surface (both for center near and center distance), and/or prism for rotation control.

Lens Geometries

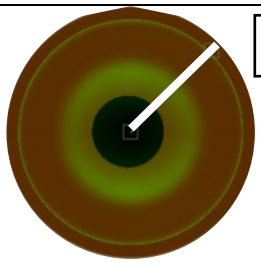
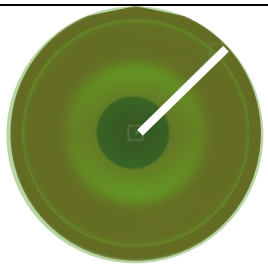
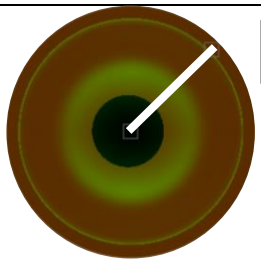
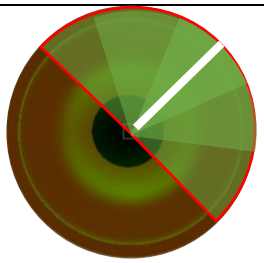
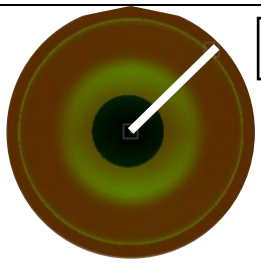
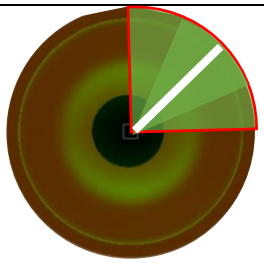
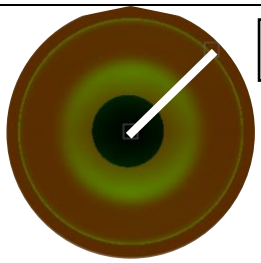
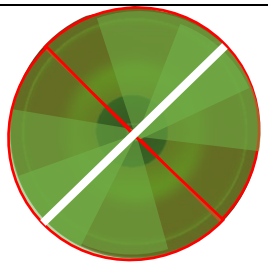
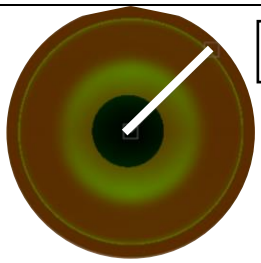
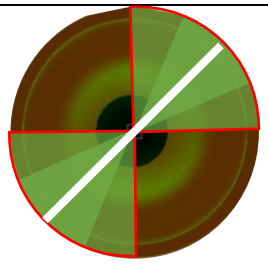
Optimizing a WAVE fit is accomplished by adjusting the parameters in eight semi-meridians. Depending on the selected geometry, the designer has varying levels of control of the semi-meridians. Depending on the Rx, corneal topography and the lens type, the WAVE lenses may be designed in the following geometries:

- Rotationally Symmetric (also referred to as RSym or **R**): Adjustment at any of the eight semi-meridians has the same equal effect on all semi-meridians.
- Geometrically Symmetric (also referred to as GSym or **G**): Adjustment at one of the eight semi-meridians is mirrored on the opposite semi-meridian.
- Free Form (also referred to as FForm or F): Asymmetric geometry. Adjustment at one of the eight semi-meridians only affects that semi-meridian.

To manually modify the design, you can click and drag the design modification control points or click on the design modification control points and arrows will appear. Clicking on the arrows will change the position of the control point by the modification increment selected in the Manual Modification section.

Depending on the selected lens geometry (R, G or F), you can apply your changes to all meridians of the lens, to a half or to a quarter referencing the selected semi-meridian. (Refer to Table 1).

Table 1. Examples of changes made to RSym, GSym, FForm Lens Designs

RSym GSym FForm	 Changes made in this mode to **RSym, GSym, FForm**	 are applied 360° to the **entire** lens
Free Form	 Changes made in **1/2** mode to a **FForm** design	 are applied to ½ of the lens with a gradually reduced effect
Free Form	 Changes made in **1/4** mode to a **FFrom** design	 are applied to ¼ of the lens with a gradually reduced effect
GSym	 Changes made in **1/2** mode to a **GSym** design	 are applied to ½ of the lens with gradually reduced effect **AND** are **mirrored** along opposite meridian
GSym	 Changes made in **1/4** mode to a **GSym** design	 are applied to ¼ of the lens with gradually reduced effect **AND** are **mirrored** along opposite meridian

3 Getting Started with WAVE

3.1 Software Installation

After the Eye Care Practitioner has successfully completed the WAVE certification course and established an account with WAVE, the installation of the WAVE Lens Designer is completed by an authorized WAVE representative.

For future updates, the WAVE software auto updater will automatically check for new updates and prompt the user to download and install the latest version of WAVE.

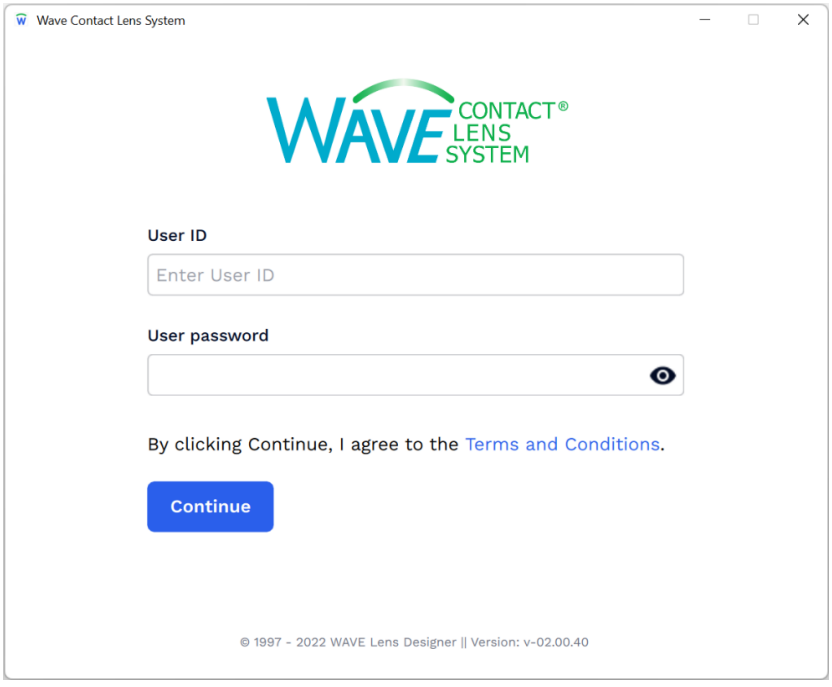
3.2 Easy Steps to Design and Order a Lens

The **quality** of the source Topography/Tomography/Interferometry map is **fundamental** for the design of a well-fitting lens. The first-fit success rate is reduced when using low quality maps. If the scan quality is poor, WAVE recommends repeating the scans.

Step 1: Data Import

Open your corneal topographer software. Find the patient you would like to design a custom WAVE lens for and select a good quality topography map. Check the topography map for coverage and repeatability. Initiate the data export into the WAVE Lens Designer software.

The WAVE Lens Designer login screen will open.

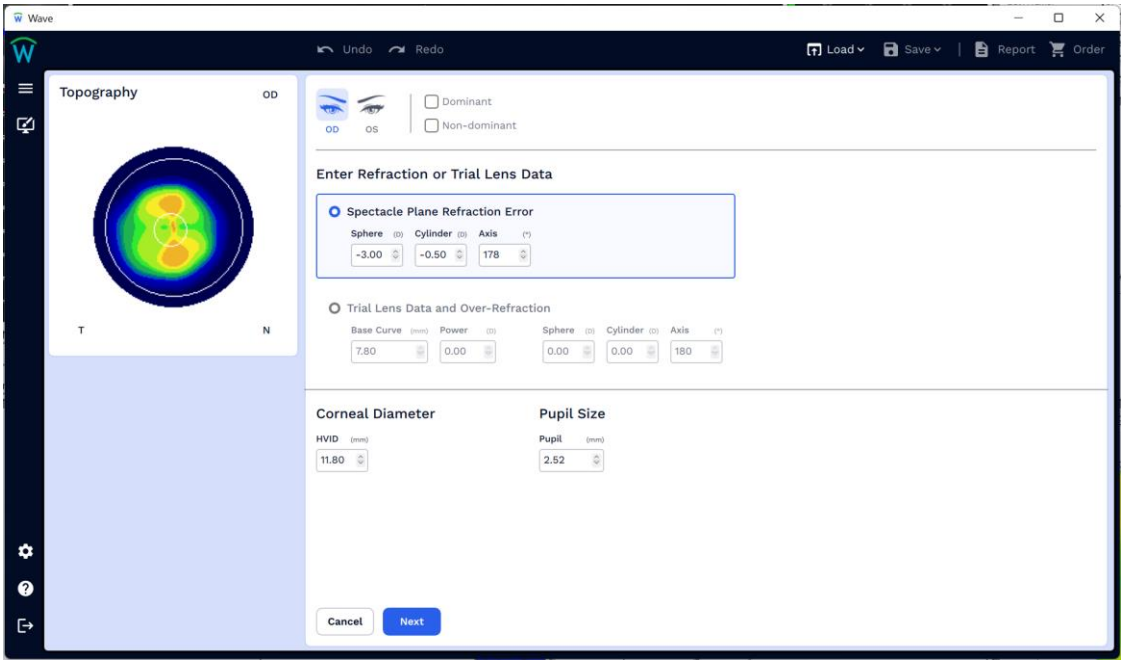


Enter your login credentials, then click on **Continue** to open the software. By clicking continue you agree to the Terms and Conditions.

Login credentials are assigned when you set up an account with WAVE. If you have any questions or need assistance, please contact info@WAVEcontactlenses.com.

Step 2: Enter Patient's Biometric Data

WAVE Lens Designer opens. Check the imported topography map and the OD/OS indication to confirm the correct map is imported into WAVE. You can mark which eye is dominant.



You will be asked to enter or confirm the patient's biometric data. You will have a choice between entering the refraction or trial lens over-refraction data:

- **Spectacle Plane Refraction Error**

  You can enter the patient's Spectacle Plane Refractive Error. This option works well if a reliable and repeatable subjective refraction can be obtained.

- **Trial Lens Data and Over-Refraction**

  If a reliable subjective refraction cannot be obtained (for example, for an irregular cornea, advanced Keratoconus, or Post-graft), you may use a trial lens to measure the over-refraction. You can enter the trial lens parameters here.

Next, enter or confirm the Corneal Diameter and Pupil Size. Most compatible devices, automatically measure these parameters. However, WAVE recommends checking these fields for accuracy and modify these parameters if needed.

Once all the patient's biometric data has been entered, click on **Next**.

NOTE: The User of the WAVE Lens Designer is responsible in confirming that the data entered in the software is accurate and complete.

Step 3: Select Lens Type and Parameters

You can now select the Lens Type, Lens Templates, and Lens parameters to design a WAVE lens.

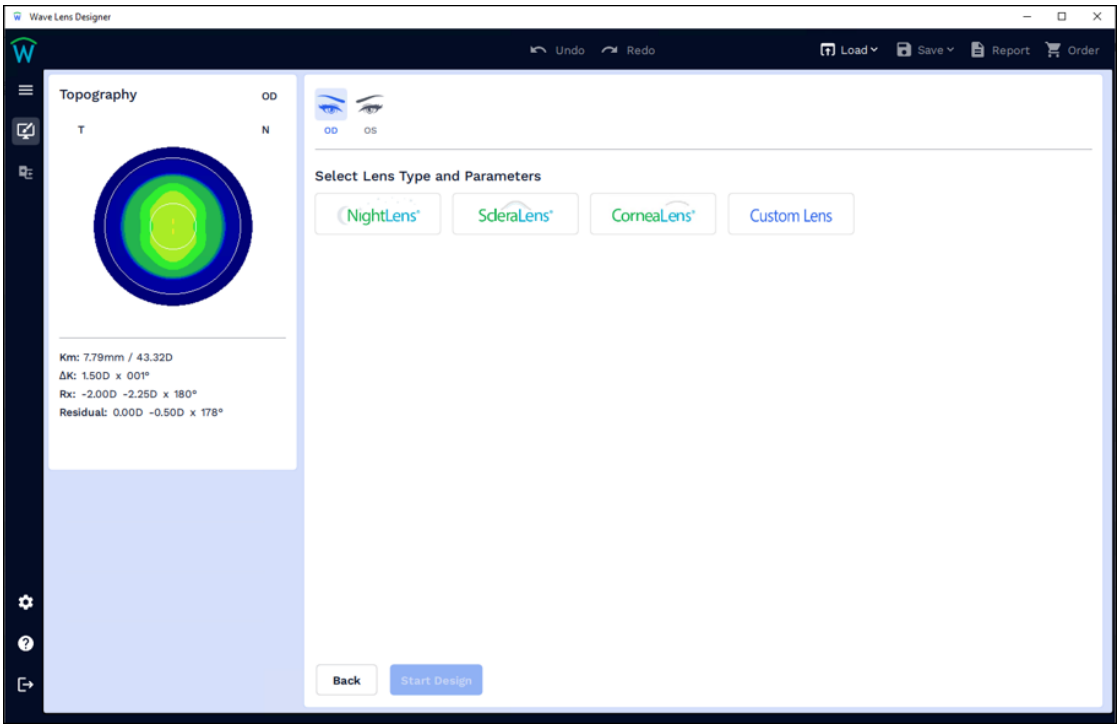
Based on the patient's topography and biometric data, the following parameters are displayed:

- **Km**: Mean K
- **ΔK**: Average Astigmatism in central 3mm
- **Rx**: Entered Refraction
- **Residual**: Expected Residual Refraction

Possible choices are,

- WAVE NightLens® for Orthokeratology
- WAVE ScleraLens®
- WAVE CorneaLens®
- Custom Lens, where you can create a design from scratch.

For detailed instructions on how to design a specific lens type, please refer to chapter 6 of this manual.



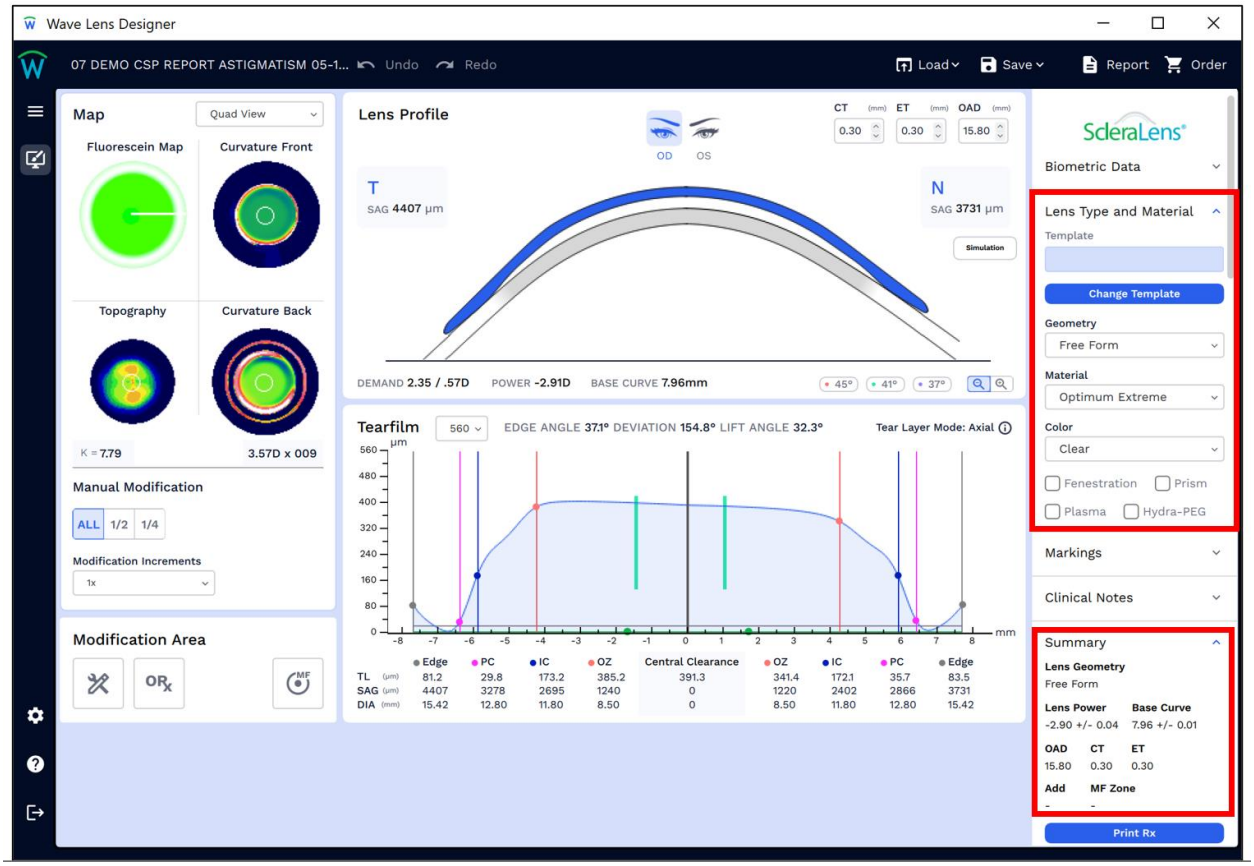
After selecting the Lens Type and entering the lens parameters, click **Start Design**.

WAVE Lens Designer will now calculate the initial lens design.

Step 4: Review the Design

Before ordering the lens, please review the design and make any final modifications:

- ✓ Check all meridians for lens alignment and look for appropriate edge clearance and a nice edge profile. Pay attention to the Lens Profile, Tearfilm Graph, and Simulated Fluorescein map.
- ✓ Check back surface of the lens (Quad View or Back Curvature Map).
- ✓ On the Right Menu, check the Lens Summary: Lens Geometry, Lens Diameter, Central Thickness, Edge Thickness, Lens Power, Multifocal Parameters (if any)
- ✓ On the Right Menu, check the Material and Color. Choose any add-ons such as Plasma Treatment, Hydra-PEG coating, or Fenestrations.
- ✓ Make any necessary modifications
- ✓ SAVE your design.



The Clinical Notes comment box is for your own reference only and will not be reviewed by the lab.

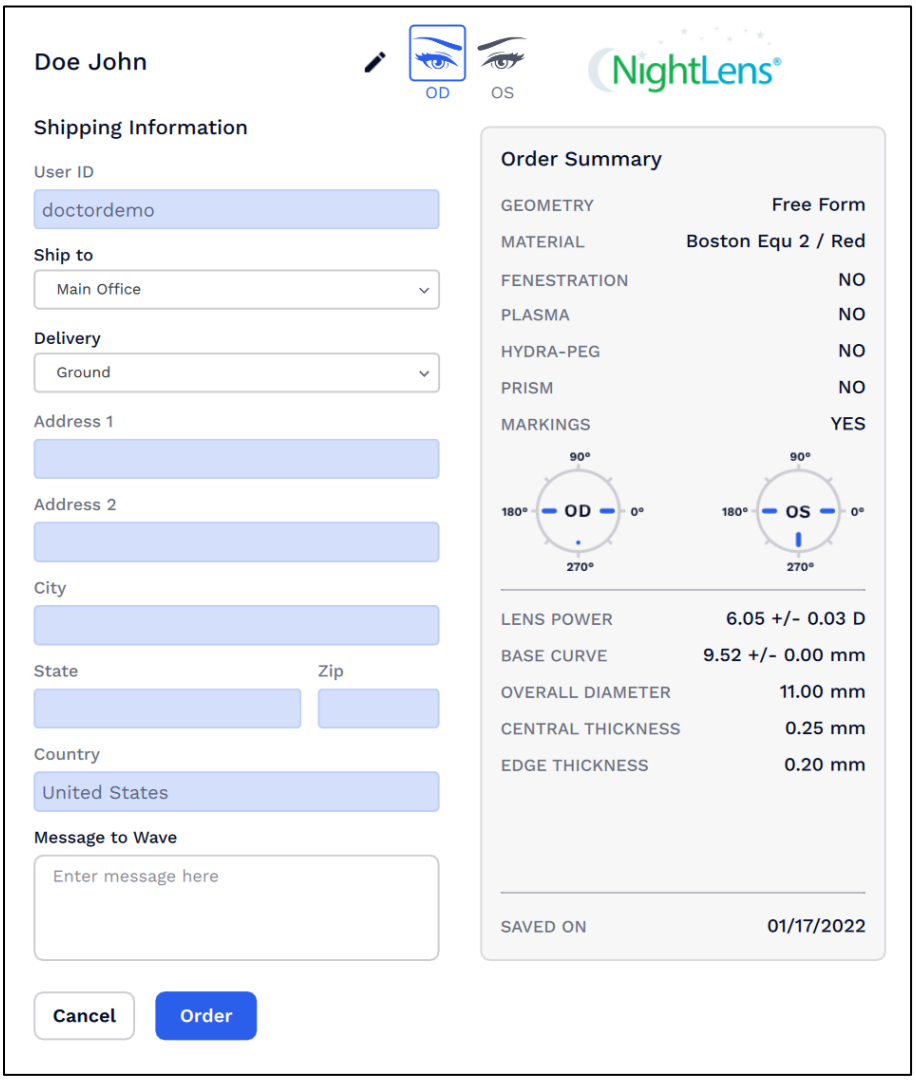
To order the lens click on the shopping cart icon titled **Order** in the Top Menu.

Step 5: Order

The laboratory order form opens. On this page you have the option to enter **Shipment** and **Delivery** method. You can choose to ship the lenses to your main office or to an alternate office. Main office is the default shipping address based on the primary shipping address on file for the account. If the default address needs to be changed, contact Customer Support.

You can use the comment box for **Message to WAVE**. Please note that adding a message to WAVE may delay the order.

Review the **Order Summary** section to confirm the accuracy of the lens details, the design parameters as well as the material and markings selection.



When satisfied with the lens, press **Order** to proceed with placing your order.

4 Main Menus and Displays

4.1 Main Design Display

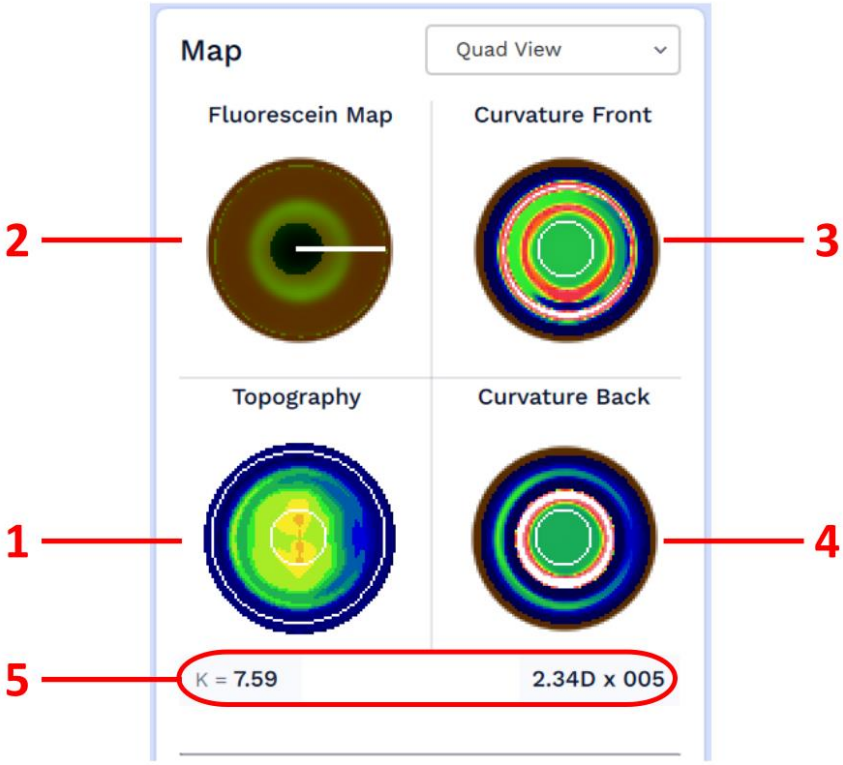
Once the lens parameters have been entered and the initial design has been calculated, WAVE Lens Designer shows the main Design display. It consists of the following sections:

1. Map view
2. Manual Modification
3. Modification Tools
4. Lens Profile
5. Tear Film Graph
6. Right Menu
7. Top Menu
8. Left Menu

4.1.1 Map View

All the necessary maps for designing a custom lens are displayed in the Map View section of the WAVE Contact Lens Design Window. By default, Quad View is displayed. Double right click on any map will enlarge it. To exit you can double right click or select a map from the dropdown

Lens design can be viewed or modified along the following 8 semi-meridians: 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. The white line in any of the maps shows the selection of 1 of the 8 semi-meridians. Use the mouse to click and select a different semi-meridian.



Quad View:

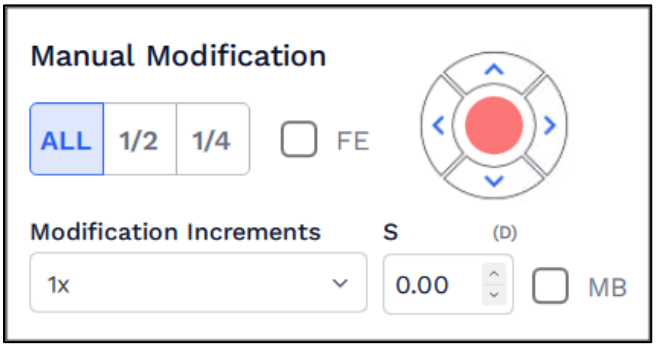
1. Source Topography Map.
2. Simulated Fluorescein Map
3. Front Curvature of the Contact Lens: Prism and Multifocal adjustment are displayed here
4. Back Curvature of the Contact Lens: Back Surface Asphericity of Optic Zone and Blending are displayed here.
5. K = Average K readings in mm. Hovering over it will display the average K readings in diopters.
   The numbers below the Back Curvature map show average astigmatism in 3 mm zone.

4.1.2 Manual Modification

Manual modifications to the lens design are achieved by making changes to the Tear Layer Thickness, the area under the blue line in the Tear Film Graph, along the following 8 semi-meridians: 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.

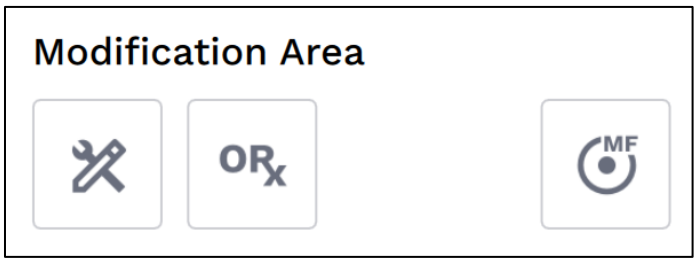
The white line, or the meridian marker, is selectable within any of the maps in the Map View section. To select a different semi-meridian, use the mouse to click and select it. By selecting a new semi-meridian within the simulated fluorescein view, the Lens Profile and Tear Film Graph will change accordingly.

Choose ALL or ½ or ¼ (quadrant specific changes) and the modification increments. Click on Red, Blue, Pink, and Black control bars on the Tear Film Graph and adjust them as needed.



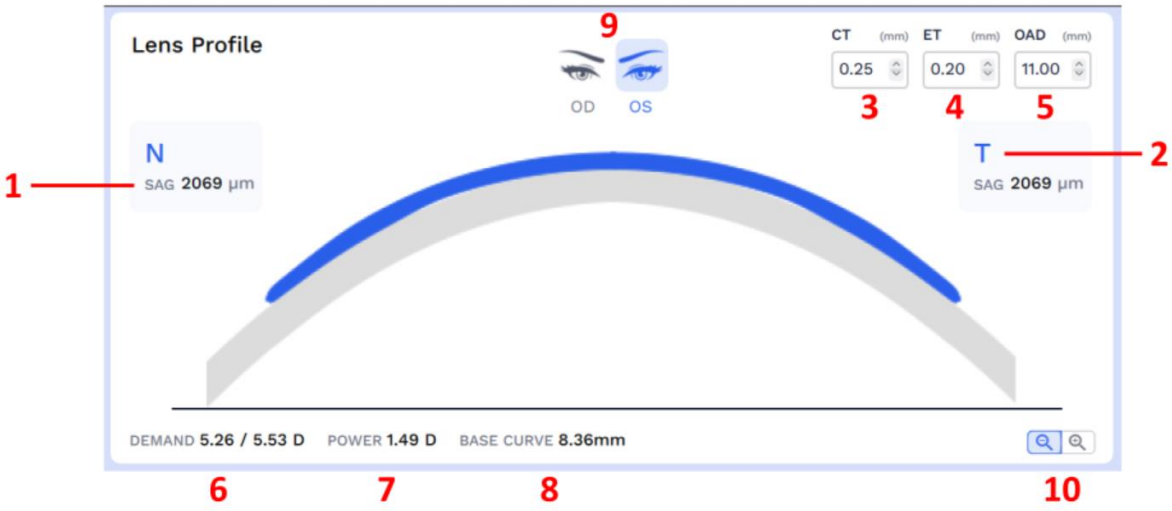
4.1.3 Modification Tool

These are the easy modification tools. The modification tools available for each design depend on the lens type. For details, please refer to Chapter 6.



4.1.4 Lens Profile View

This is the Lens Profile window. It shows the contact lens in blue and the cornea in grey. There is an indication for OD and OS on top.

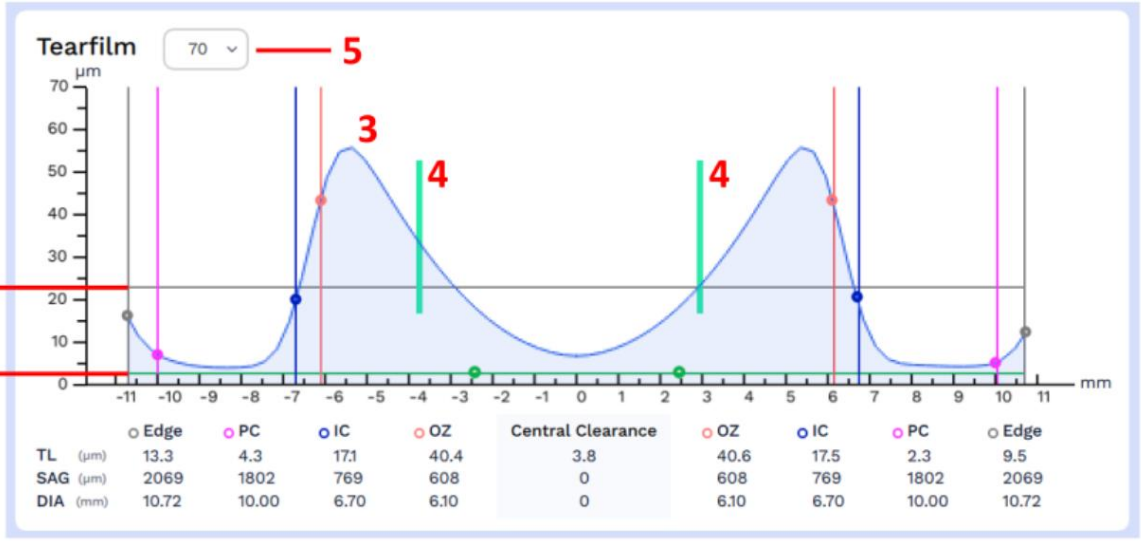


This part of the main design screen will display the following information:

1. **Sag**: Sagittal depth at Lens Edge (microns)
2. **Selected Lens Meridian** – **N** for Nasal, **T** for Temporal, **I** for Inferior, **S** for Superior
3. **Center Lens Thickness:** Click and modify with the arrows
4. **Lens Edge Thickness:** Click and modify with the arrows
5. **Overall Diameter:** Increase or decrease the lens OAD
6. **Demand**: The demand is the difference between the average back surface axial curvature on the contact lens and the average axial curvature within the pupil. The second number is the difference between the flat axial curve within the pupil of a toric cornea and the base curve of the lens.
7. **Power:** Resultant Contact Lens Power in the semi meridian displayed
8. **Base curve**: The base curve display is for the semi meridian that is highlighted in the upper right corner graphic. Please note that this is NOT the base curve across the entire meridian because the base curve may be different on one side than the other.
9. **OD** for Right Eye, **OS** for Left Eye
10. **Magnification:** Click to switch between **Meridian** or **Edge** views of the lens profile.

4.1.5 Tear Film Graph

This is the Tear Film Graph. WAVE designers think in terms of Tear Layer Thickness (TLT). Modifications to the lens design are achieved by making changes to the TLT along 8 semi-meridians.



	Edge	PC	IC	OZ	Central Clearance	OZ	IC	PC	Edge
TL (μm)	13.3	4.3	17.1	40.4	3.8	40.6	17.5	2.3	9.5
SAG (μm)	2069	1802	769	608	0	608	769	1802	2069
DIA (mm)	10.72	10.00	6.70	6.10	0	6.10	6.70	10.00	10.72

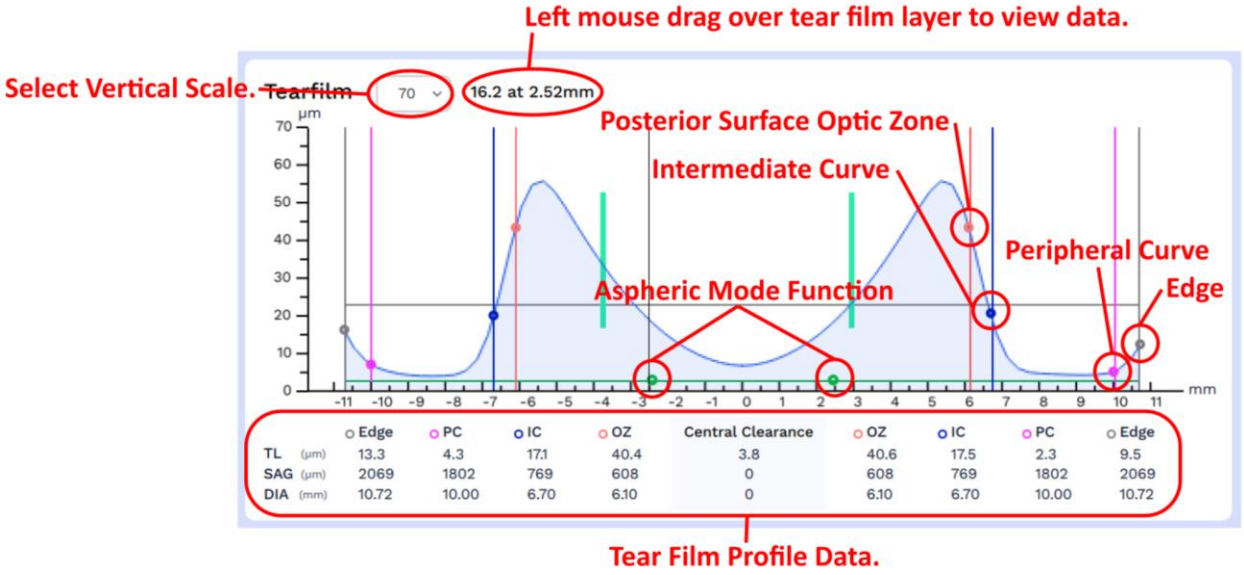
1. Green Horizontal Line: Cornea Surface
2. Dark Grey Horizontal Line: 20μ Line
3. Blue Curved Line: Tear Layer Thickness (TLT) between the back surface of the contact lens and the cornea
4. Vertical Green Lines: Pupil Diameter
5. Scale (microns): Select 70 μ, 140 μ, 280 μ or 560 μ from drop down

Design modification control points:

- Back Optic Zone (OZ)
- Intermediate Curve (IC)
- Peripheral Curve (PC)
- Edge Lift
- Aspheric Mode Function/ Location

Note: Hold the left mouse button down and drag to view data at cursor location. In the Lens Profile Window above, you can see the Tear Layer, Lens Sag, and Distance from center.

More details:

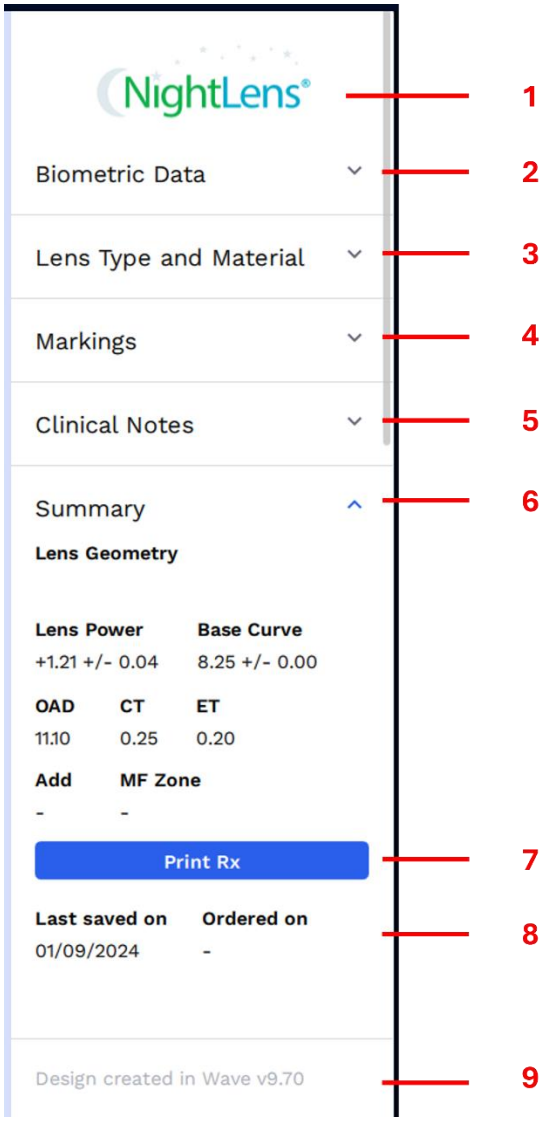


	Edge	PC	IC	OZ	Central Clearance	OZ	IC	PC	Edge
TL (µm)	13.3	4.3	17.1	40.4	3.8	40.6	17.5	2.3	9.5
SAG (µm)	2069	1802	769	608	0	608	769	1802	2069
DIA (mm)	10.72	10.00	6.70	6.10	0	6.10	6.70	10.00	10.72

4.1.6 Right Menu

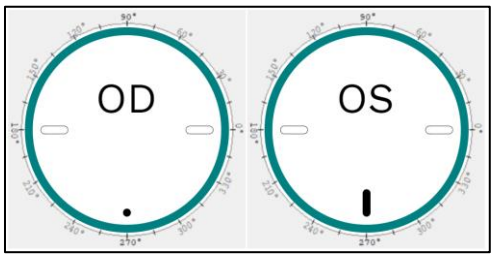
Right menu contains the patient biometric information, lens summary. Changes to the material and color and optional add-ons can be made here.

The Right Menu consists of several sections that can be minimized or expanded. Scroll up and down with the mouse wheel or with the right sidebar to navigate the right menu.

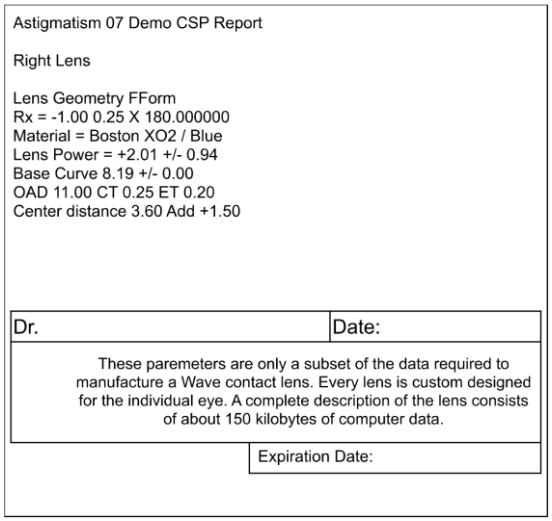


1. **Product Logo**: shows the lens brand. Lens type can be changed by right clicking on the lens logo. This only affects lens type displayed in Wave and does not change the initial design.
2. **Biometric Data:** In the Biometric Data section, the user can modify the patient data that has been entered in the Patient Biometric Data Entry window after the topography map import.

3. **Lens Type and Material**: The lens design template can be changed in this section, as well as the lens geometry. The user can also select the lens material, color, coating, fenestration, and markings, as well as adding a prism.
4. **Markings**: Select diagnostic markings
   When diagnostic markings option is selected, the lens will have 2 clear lines at 0° and 180° and a black dot or line at 270° like the diagram below:



5. **Clinical notes:** Use this section to add any information for future reference. The Clinical Notes comment box is for your own reference only and will not be reviewed by the lab.
6. **Summary**: This section provides a summary of the lens design:
   - **Lens Geometry:** RSym, GSym or Free Form.
   - **Lens Power:** Displays the average lens power from the center to 1.5mm from the apex (central 3mm) and gives the range of powers in all meridians.
   - **Base Curve:** Displays the average base curve from the center to 1.5mm from the apex (central 3mm) and gives the range of base curves in all meridians.
   - **OAD:** Over All Diameter, **CT:** Center Thickness, and **ET:** Edge Thickness.
   - **Add:** for multifocal lenses it shows the Add value.
   - **MF Zone:** displays how large is the multifocal zone, and whether it is Center Distance or Center Near
7. **Print Rx:** Print Refraction and Lens Details:


Astigmatism 07 Demo CSP Report

Right Lens

Lens Geometry FForm
Rx = -1.00 0.25 X 180.000000
Material = Boston XO2 / Blue
Lens Power = +2.01 +/- 0.94
Base Curve 8.19 +/- 0.00
OAD 11.00 CT 0.25 ET 0.20
Center distance 3.60 Add +1.50

Dr.	Date:
These paremeters are only a subset of the data required to manufacture a Wave contact lens. Every lens is custom designed for the individual eye. A complete description of the lens consists of about 150 kilobytes of computer data.	
	Expiration Date:

8. **Status of the Lens Design:** Saved (date) or Not Saved, ordered (date) or Not Ordered.

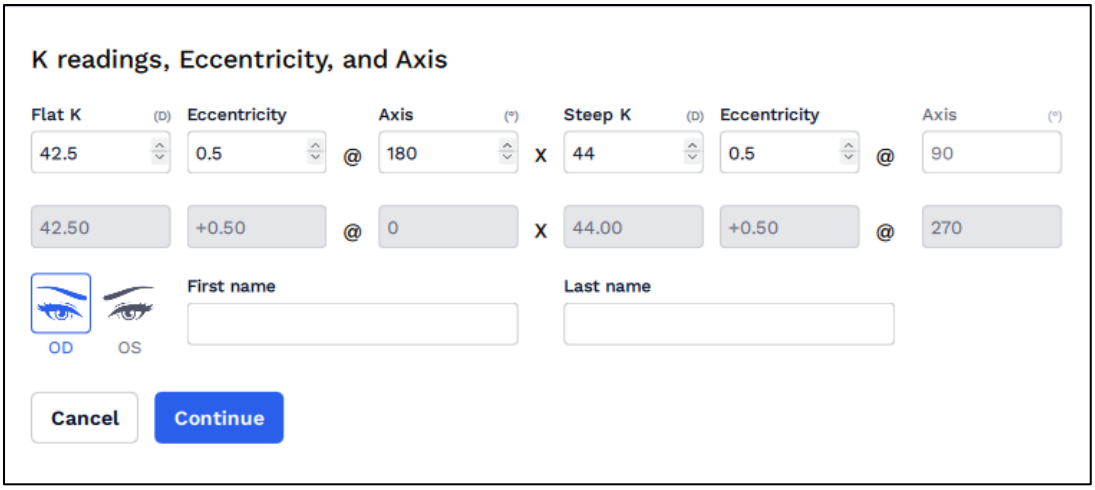
4.1.7 Top Menu

Top menu provides quick access to Order, Save, Report, Undo/Redo and load.

1. **Undo / Redo:** Button(s) allow user to **Undo** or **Redo** (reapply) a modification up to 5 steps.

2. **Load:** Imports a previous WAVE lens design. Useful for re-designing a lens starting with an older design that worked better than the most recent design.

   It is also possible to design a WAVE lens without topography and using K readings. To use this option, from the Load drop down menu, select New Simulation, Enter K-readings, eccentricity, and Axis.

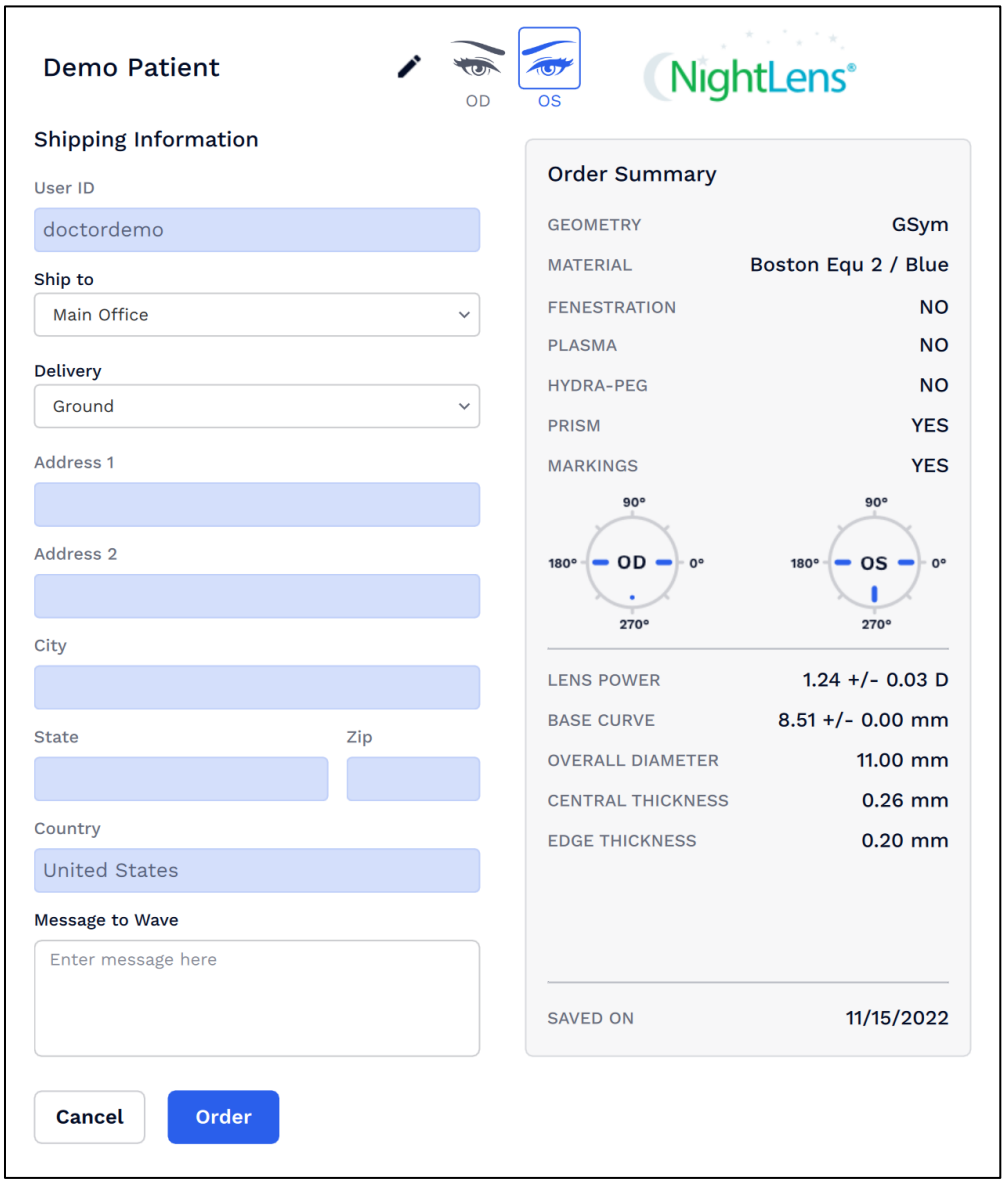


3. **Save** the design or the template.

4. **Report:** Displays a summary of the lens design with tear layer graphs along 8 semi-meridians.

Report Print Preview

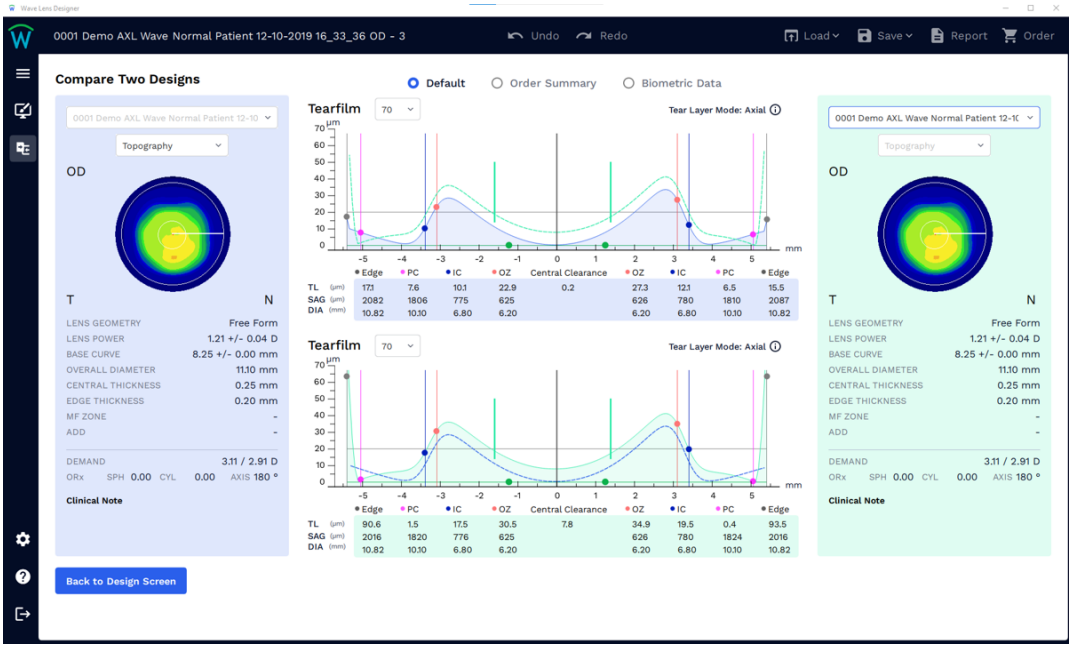
5. **Order**: The Laboratory Order Form appears.



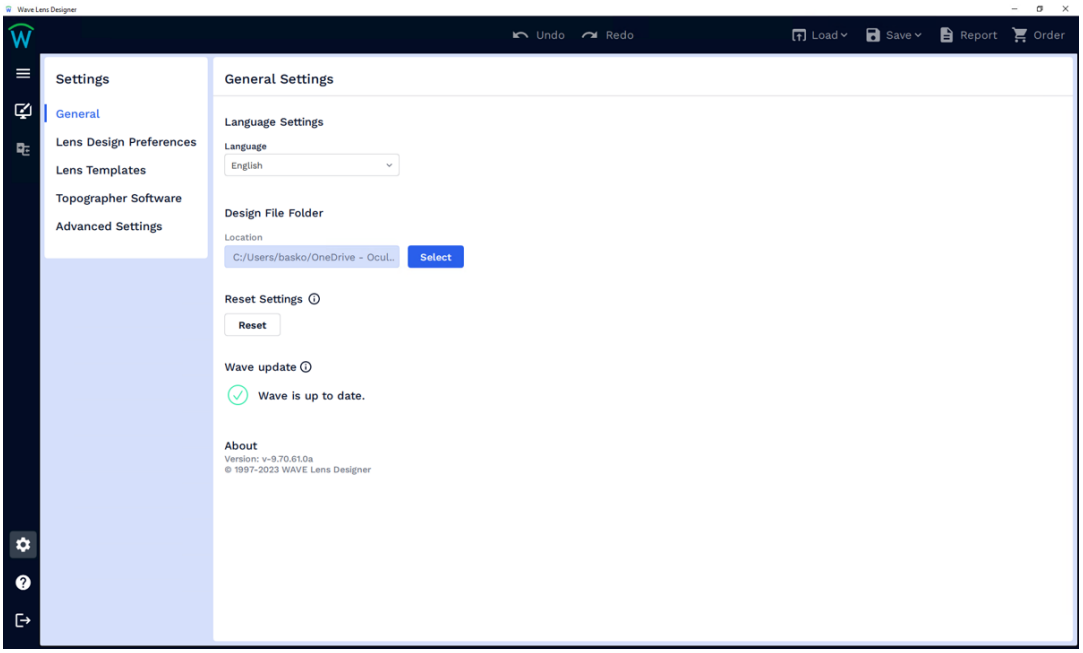
4.1.8 Left Menu

Left Menu contains Help, Settings, and return to main design screen options.

1. **Design Screen**: Clicking on **Design Screen** will take you back to main design screen
2. **Compare Screen**: To compare two WAVE lens designs in the same window

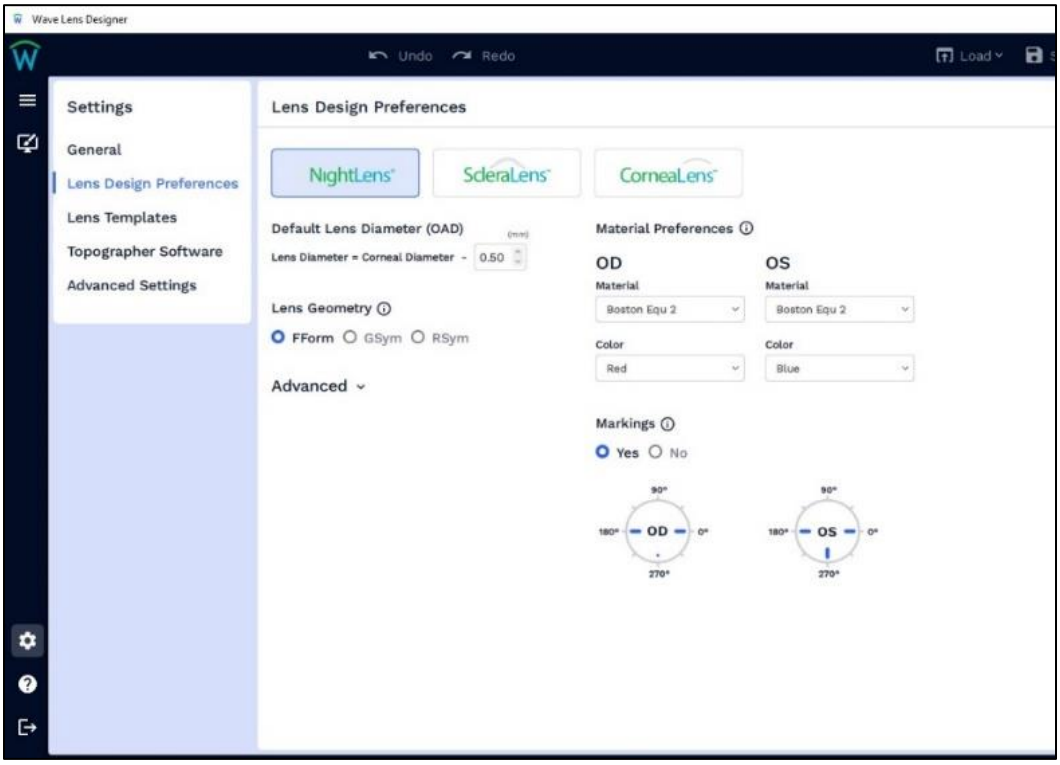


3. **Settings:** the user can change the settings in this section. See details below:
    a. **General Settings:** ability to change **Language**, location of **Design File Folder** (can be shared over network), and ability to **Reset Settings** to default. The current software version, and whether the software is up to date, is also displayed here.



b. Lens Design Preferences

These settings allow the user to set defaults for all lens types. Users have the possibility to specify Tear Layer Mode, set a Default Lens Diameter (adding or subtracting in mm), Averaging Astigmatism, Lens Geometry, and ability choose a default material, color, and markings in Material Preference.



Example) Lens Design Preference – NightLens®

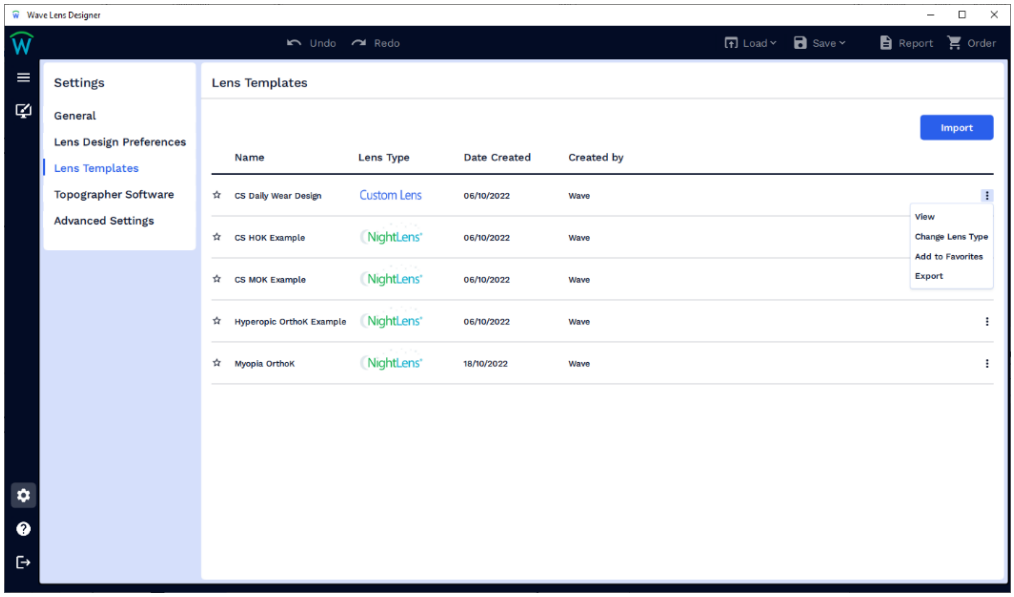
c. Lens Templates

Templates can be created during the design process.

Templates can be imported from previous versions of the software into newer versions, but if created in a newer version of software they can't be imported to a previous version.

Templates will show **Name, Lens Type, Date Created** and **Created by.** Users will be able to **Add to Favorites, Remove from Favorites**, **Edit, Export, Import** or **Delete.** The custom template file is located here: C:\Wave\Customdesignsettings.txt

WAVE templates, when attached or created under a certain Lens Type, will only be available for use when you select that Lens Type in Choose Lens screen.

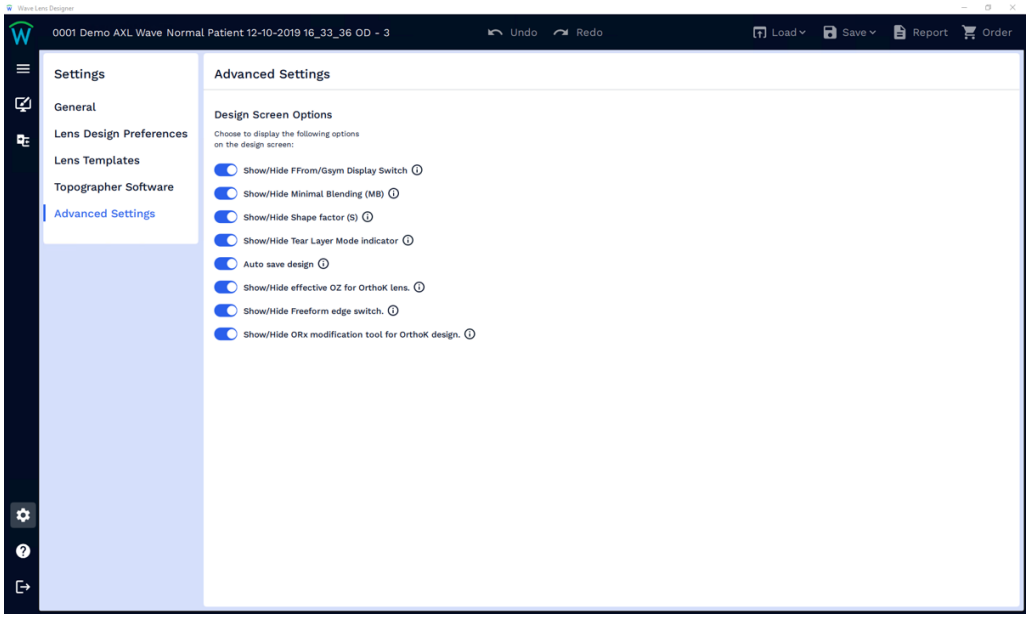


d. Topographer Software

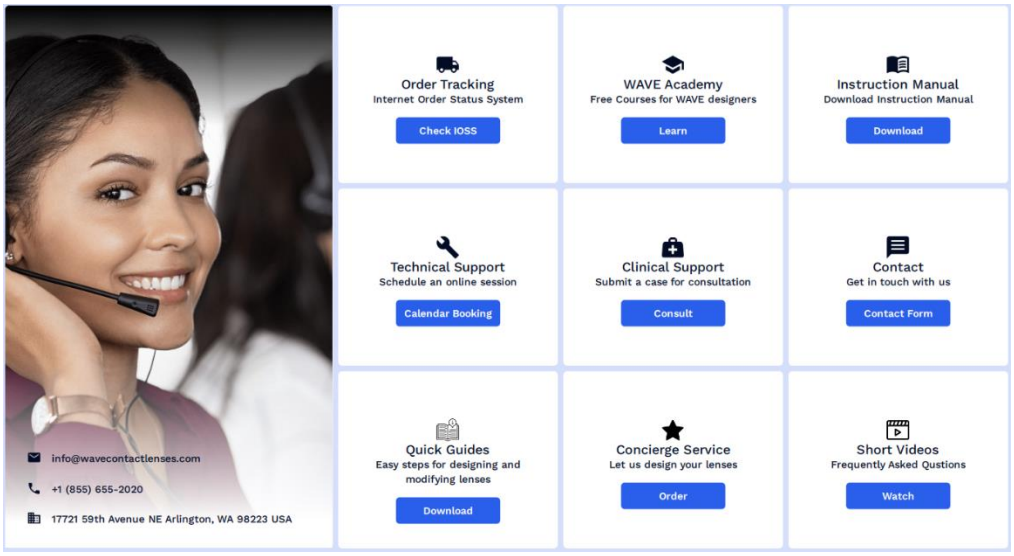
With assistance from WAVE Technical support this setting allows for Topographer/Tomographer setup.

e. Advanced Settings: Design Screen Options. Here you can control which advanced functions you would like to display on the main lens design screen. To avoid clutter, we recommend that you only activate the display switch for functions you use on a regular basis.

- FForm / GSym Display Switch: Allows toggling between the FForm and Gsym displays. Toggling this switch only changes how the design is displayed on the screen and does not change the actual lens geometry.
- Minimal Blending (MB): Used in conjunction with Shape Factor (S) to allow a simplified optic zone asphericity.
- Shape Factor(s): Allows + (high) or — (low) aspheric values when Minimal Blending in the optic zone is desired.
- Tear Layer Mode Indicator: Shows Tear Layer Mode in which lens is designed.
- Auto save design: Wave will automaticaly save design, when new design is created.
- Effective OZ: This will show or hide the effective OZ for OrthoK lens.
- Freeform egde: This will show or hide the Freeform edge switch.
- ORx modification tool: This will show or hide the modification tool for OrthoK design.



4. **Help Button :** WAVE support resources are available in our WAVE help button



5. **Logout,** allows user to logout of WAVE for other users to login

5 Instructions for compatible topographers

It is important to become familiar with your topography device and learn how to capture good scans and analyze the quality of the data before starting the custom lens design.

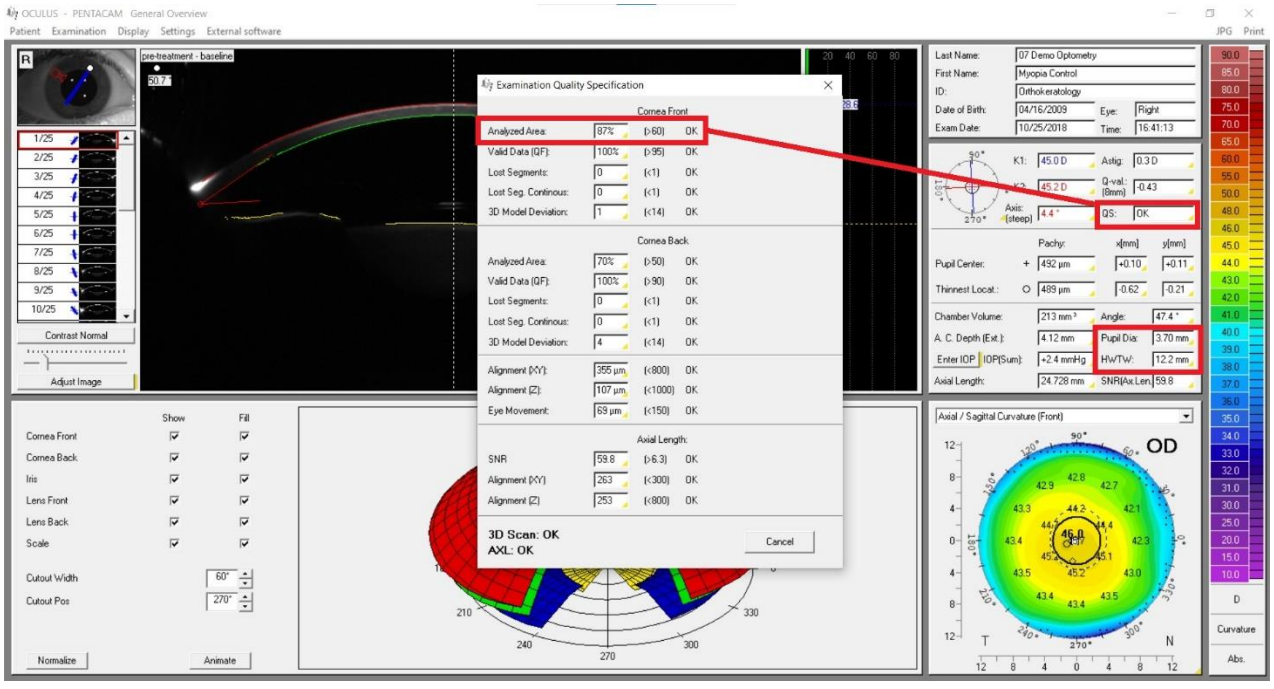
5.1 OCULUS Pentacam® and Corneal Scleral Profile (CSP) Report

If you are using any OCULUS Pentacam® device, WAVE recommends (when possible) capturing the tomography with automatic capture. This will ensure optimal alignment and reproducibility.

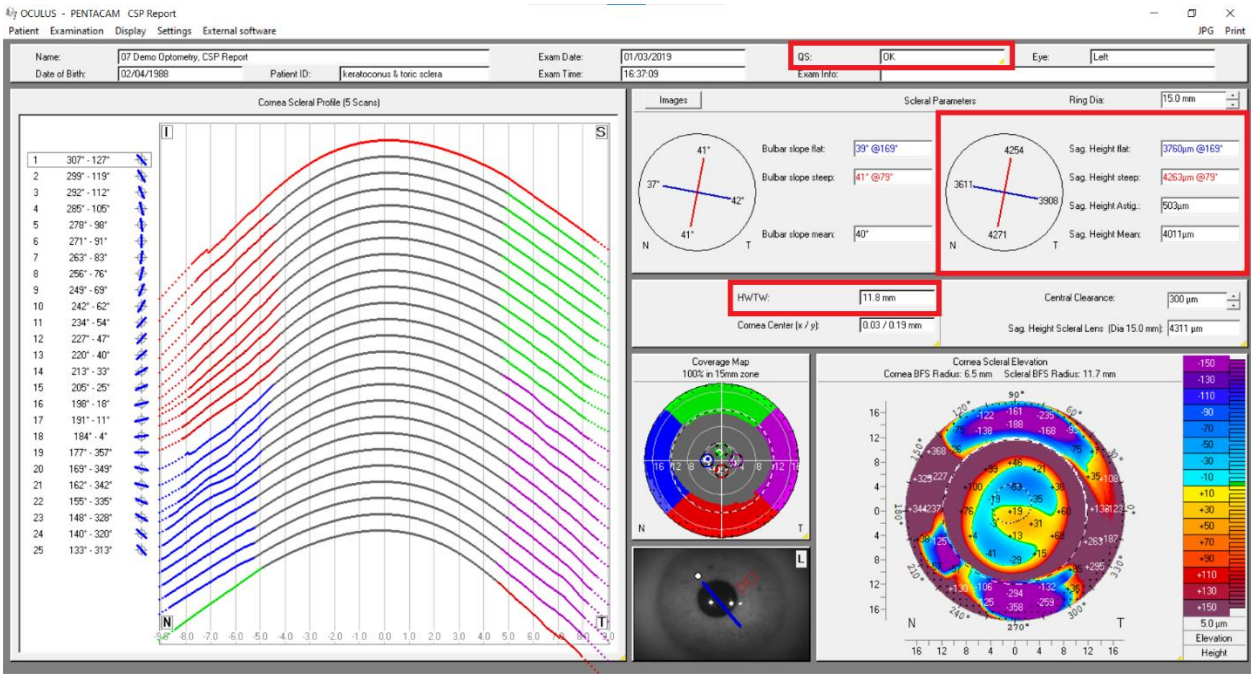
Please check the QS (Quality Specification) and coverage. If the quality of the scan is poor, recapturing the scan is advised. Good scores will show OK, scores that are borderline will be yellow with an error message (these can be used if parameters are close to OK specifications), and red scans should be redone.

Good scans for use with WAVE should have an OK quality score and over 85% Analyzed Area. In the image below, the QS is showing OK. If you click in the QS box, the specifications will appear and give the analyzed area for Cornea Front as well as other parameters.

Pentacam® Central Scan

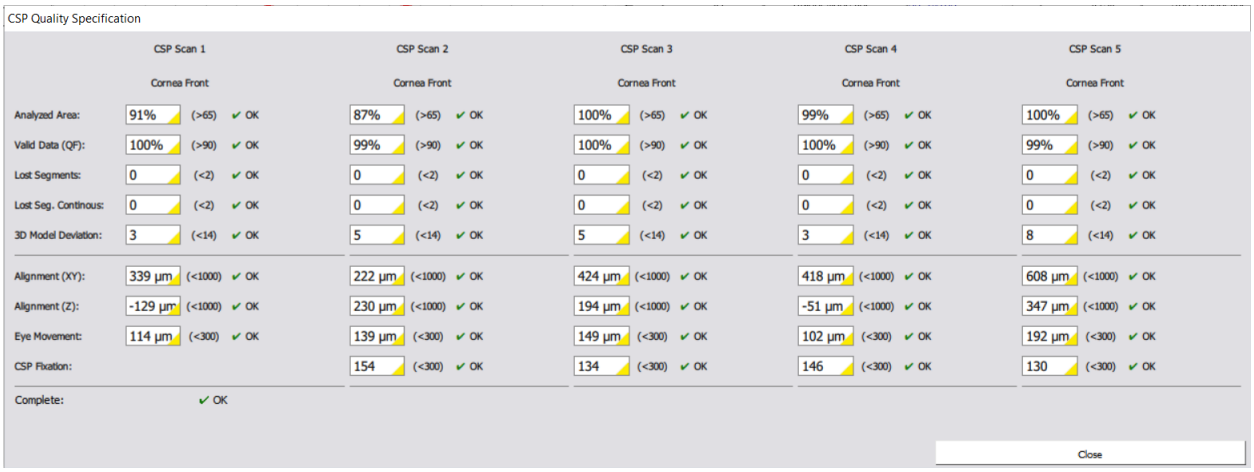


QS = OK, Pupil Diameter and HWTW are measured and will be sent to WAVE

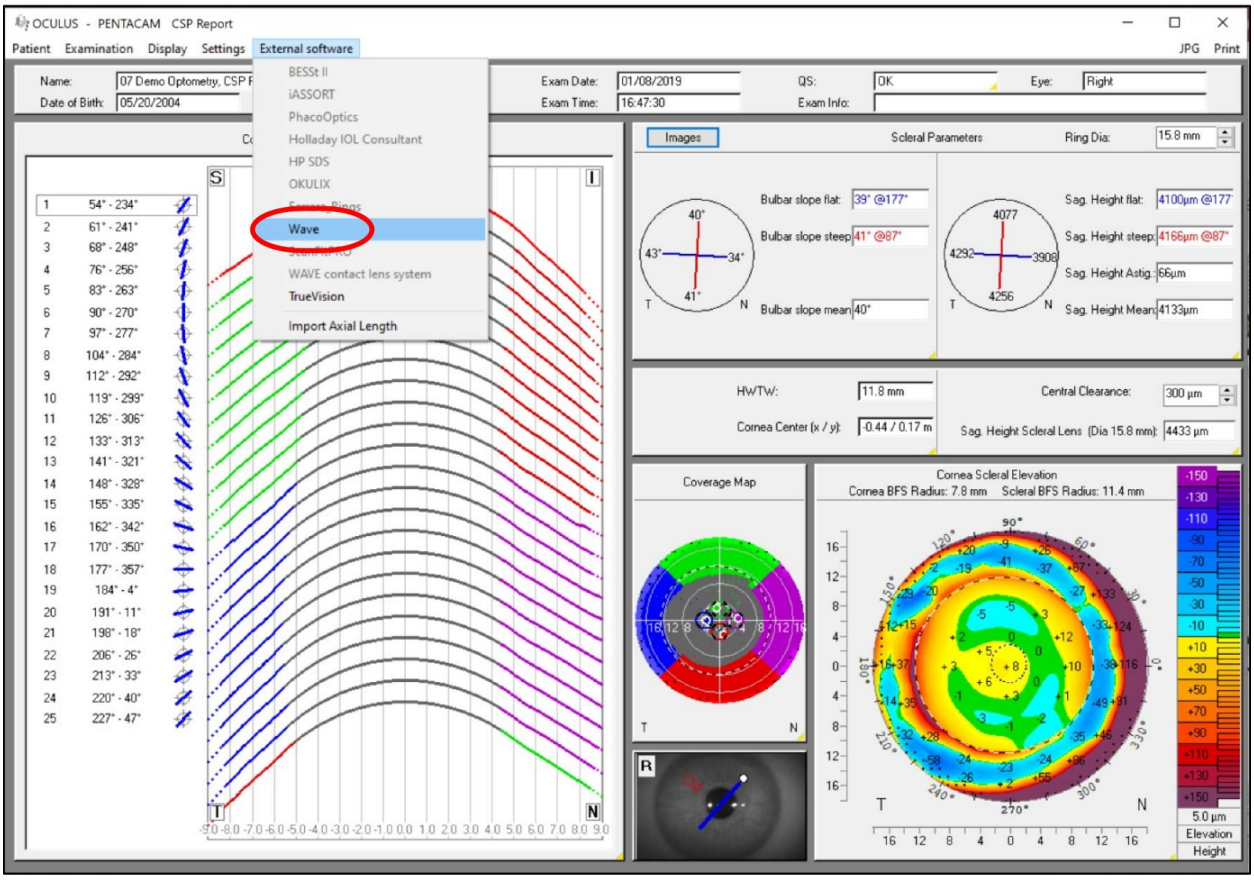


Corneal Scleral Profile (CSP) will give the user a QS value, Coverage Map (showing any extrapolations with dots), Sagittal Height for flat and steep axis, and HWTW. The Pupil Size is not shown but can be seen on the general overview display and will be sent to WAVE automatically.

To see the Analyzed Area for a CSP scan, click anywhere inside the QS box to see the Quality Specification data. Below, the image shows the percentage of analyzed area for each scan as well as other quality specifications.



Once you have the best scans possible, proceed to External Software button on the top of OCULUS Patient Data Management Software and Choose WAVE.

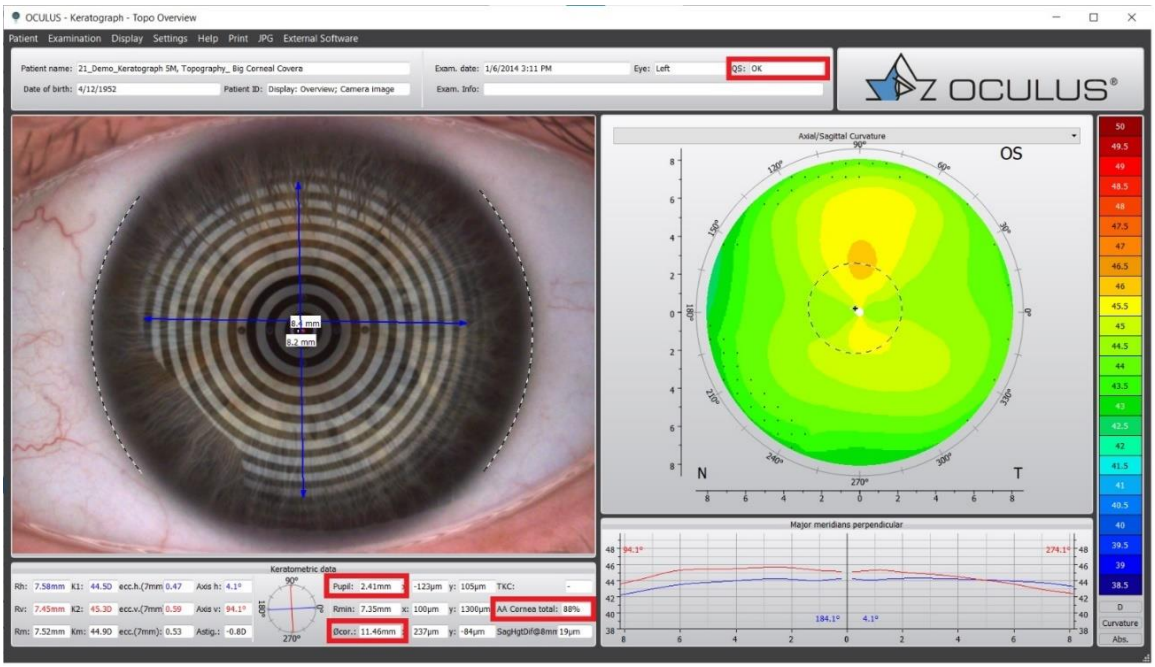


5.2 OCULUS Keratograph®

If you are using an OCULUS Keratograph®, WAVE recommends (when possible) capturing the topography with automatic capture.

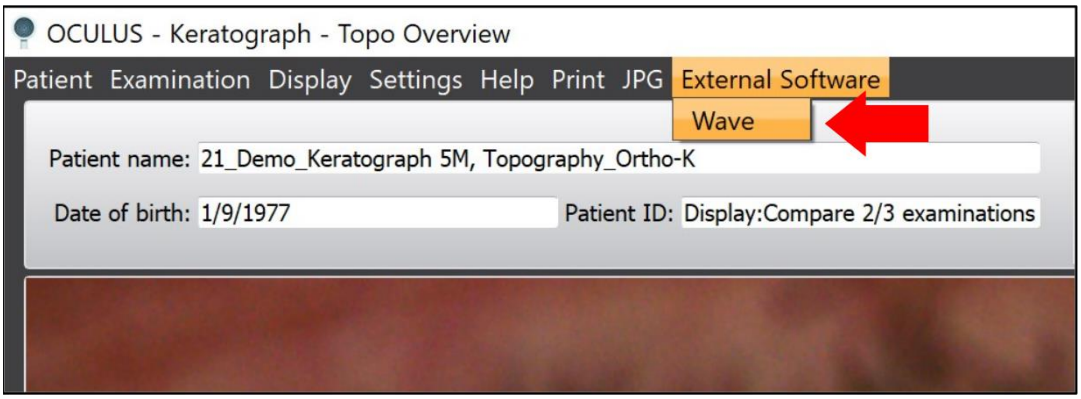
When using a Placido topographer, please examine the quality of the mires. Poor tear quality, Dry Eye Syndrome, and excessive tearing can interfere with the results of a Placido topographer.

Please check the Quality Specification (QS), Analyzed Area (AA) is 75% or higher and coverage. For coverage we are looking for greater than 7.5mm of coverage in all directions. If the quality of the scan is poor, recapturing the scan is advised.



QS = OK, **Corneal Diameter**, **Pupil Size** and **AA (analyzed area)** are present in Topo Overview. The calipers can be used to measure the mires and coverage of the scan. The superior meridian is often affected by lash or lid, so getting a scan with better superior coverage is top priority. Please instruct the patient to open wide on this scan.

Once you have the best scans possible, proceed to External Software button on the top of OCULUS Patient Data Management Software and Choose WAVE.

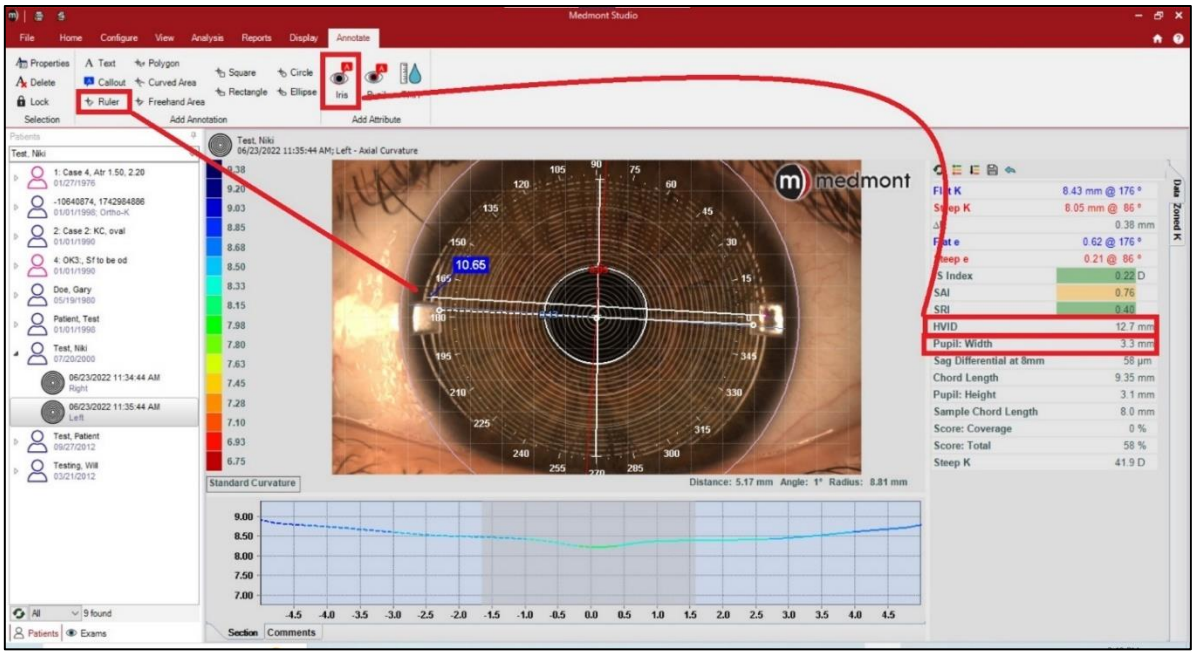


5.3 Medmont Topographers

When using a Placido topographer, examine the quality of mires. Poor tear quality, Dry Eye Syndrome, and excessive tearing can interfere with the results.

When measuring with the Medmont, WAVE recommends taking 2-4 good scans of each eye for reproducibility and best possible coverage. WAVE designs do best with greater than 8mm of coverage in all directions.

To measure the coverage, use the ruler tool to access the mires and get the amount of coverage in millimeters. This is also a helpful tool in acquiring HVID or oblique measure. If you use the Ruler function to measure your HVID you will have to manually enter in Corneal Diameter box when inside the Enter Refraction page. To have the HVID automatically sent into the WAVE Software, you will have to use the Annotation tool Define Iris shown below. This will give you the HVID on the right-side bar as well as your Pupil Width. Both of those values will be sent to WAVE directly.



Once you have the best scans possible to design with, click on the HOME tab. Click on the WAVE icon in the LINKED APPLICATIONS section to import the data into WAVE.

5.4 Eaglet Eye Surface Profiler

When measuring with the Eye Surface Profiler (ESP) Eaglet Eye recommends taking 3 scans of each eye. Please check the Quality Indicators and the scan quality as indicated below to choose the best one. If the quality of the measurement is poor recapturing the scan is advised.

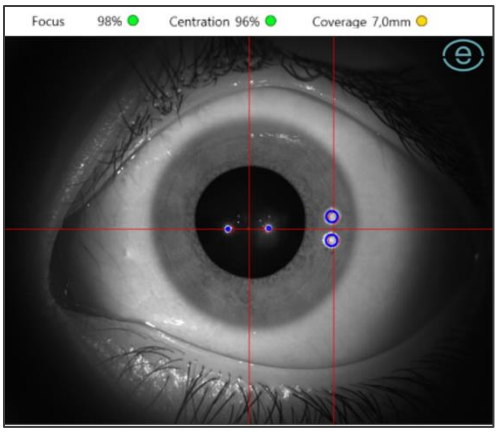
Quality of a measurement

For every scan you take, there are quality indicators on top of the image to help you assess the quality of the measurement. These give some objective numbers and also follow an intuitive traffic light system:

red = "not good enough";

yellow = "caution";

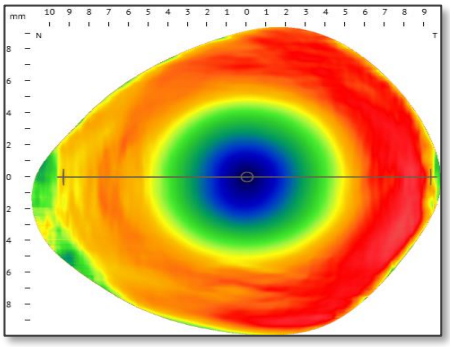
green = "good"



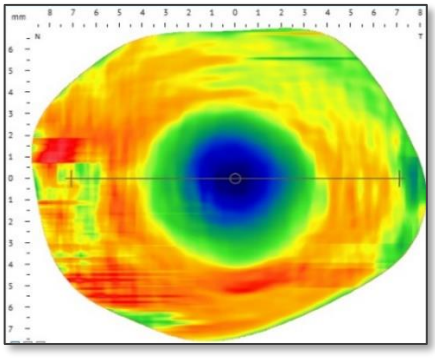
- Focus: good focus is very important for all specialty lens fitting.
- Centration: centration is most important for orthoK, it needs "green"; for sclerals yellow may be good enough.
- Coverage: the ESP gathers directly height data from the whole cornea and the sclera in a single shot with no extrapolation, which means that the more you open the eyelids the bigger the scan will be. This is
- especially relevant for large scleral lenses, whereas for OrthoK fitting seeing the limbus is enough.

After processing the measurement, the quality of the scan needs to be checked. The Source map shows the indicators. The Tangent angles map is also helpful to check for dryness or fluo break up. Interfering horizontal lines on the sclera indicate dryness which will impact the quality of the data.

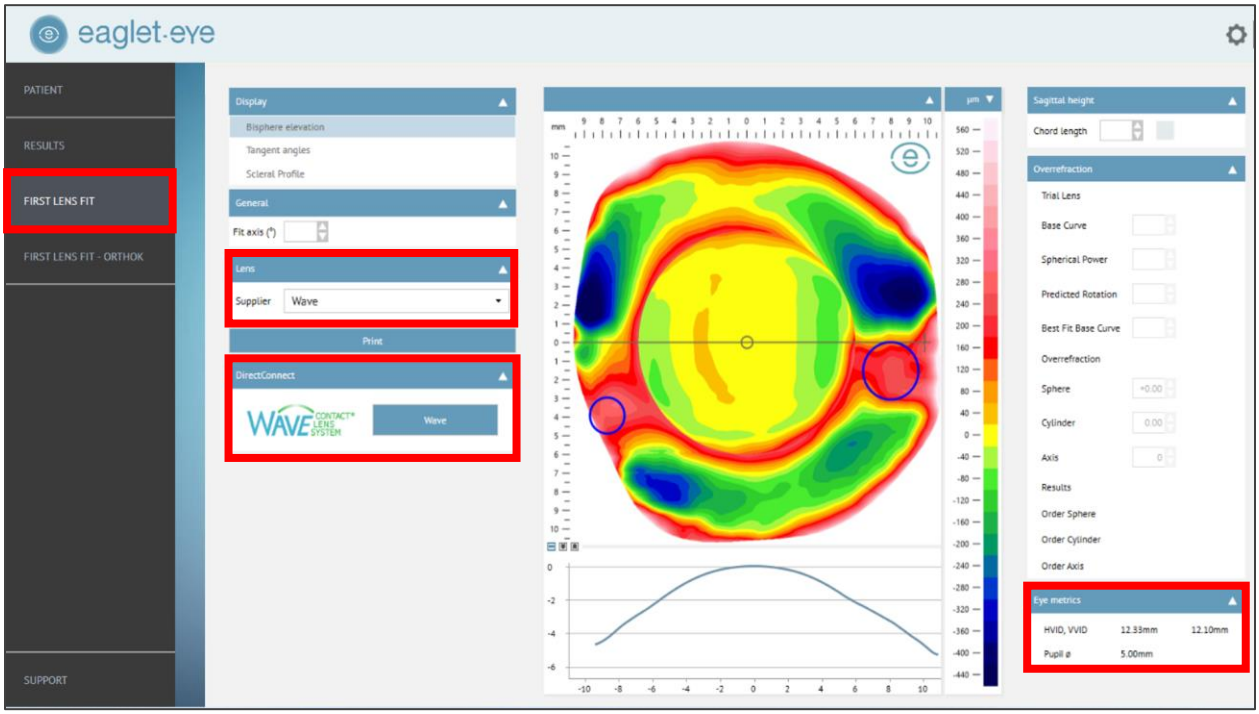
Good map



Bad Map



Once you open the best patient scan, select FIRST LENS FIT on the left menu. Under Lens section select the dropdown for Supplier, then click WAVE. Once selected a DirectConnect™ box will appear where you can click on the WAVE button to import the complete eye data into WAVE. HVID and Pupil diameter will also be sent to WAVE.



6 How to design a WAVE Lens?

6.1 WAVE NightLens®

WAVE Ortho-K lenses are branded as NightLens®. WAVE NightLens® uses the patient's corneal topography to design custom Orthokeratology lenses under Bausch + Lomb Vision Shaping Treatment (VST) parameters for treating low to moderate myopia (-1.00D to -5.00D) and low astigmatism (up to -1.5D cylinder).

Multiple micro aspheric curves create a reverse geometry lens design, while the lens periphery is made to closely match the corneal periphery curvature.

The procedure for fitting WAVE Orthokeratology lenses is straightforward:

- Perform a routine ocular evaluation
- Perform topography
- Determine lens parameters using the default VST settings or customized design.
- Evaluate lens parameters using the software and order the lens
- Perform overnight trial - Instruct patient to use unpreserved artificial tears night and morning as directed.

Pre-Design Considerations:

- Develop understanding of how Ortho-K works and WAVE terminology, tools, and features.
- Categorize the purpose or objective of doing Ortho-K in every case:
    - Adults (after myopia is stable, myopia correction)
    - Children/Young Adults
- Examine the corneal topography and elevation maps to determine the amount of corneal astigmatism.
- Evaluate the pupil size accurately in dim and normal illumination. Depending on the amount of attempted myopic reduction, the expected treatment area in overnight Orthokeratology is usually 5-7 mm in size. Therefore, adult patients with pupils greater than 5 mm in normal illumination and or greater than 7 mm in low illumination may complain of halos, glare, or peripheral distortion in dim lighting conditions.
- Evaluate the corneal diameter accurately. Measure the corneal diameter with the horizontal and vertical meridian or at least in the diagonal meridian.
- Confirm the patient is a good candidate for Orthokeratology.

Patient Selection for Orthokeratology:

The range of myopic correction reduction approved with Vision Shaping Treatment (VST) is -1.00D to -5.00D. The most successful Ortho-K candidates are moderate to low level

myopes, patients with a low amount of cylinder (less than or equal to 1.5 D), those whose corneal shapes have eccentricity or e-values of 0.5 and higher, or patients currently wearing soft lenses or spectacles.

Patients with low corneal eccentricity measurements, flat corneas and against the rule astigmatism greater than three quarters of a diopter can be more challenging for achieving successful outcomes. These types of patients may not be as well suited for Vision Shaping Treatment. Also, proceed with caution with previous or current rigid lens wearers. Current rigid lens wearers should remain out of their lenses until the cornea and refractive measurements have stabilized, typically three to four weeks or more.

Candidates for WAVE Orthokeratology treatment, should not have any active or chronic ocular disorders, dystrophies, or contra-indications to GP lens wear.

Good Candidate Parameters for Lens Design:

- ✓ Flat K readings between 40 D and 46 D
- ✓ Moderate to low level myopes (-1.00D to -5.00D)
- ✓ ≤1.50D with-the-rule (WTR) astigmatism or ≤ 0.75D against-the-rule (ATR) astigmatism
- ✓ Corneal eccentricity (“e” values) of 0.5 and higher
- ✓ Soft lens / spectacle wearers

Poor Candidate Parameters for Lens Design

- × Against the rule astigmatism > 0.75D
- × Low corneal eccentricity

Recommended Progress Visits:

Once the lenses have been ordered and received, instruct the patient on application and removal, lens care and handling, and proceed to the overnight trial. Remember to instruct the patient to instill several drops of recommended re-wetting solution prior to sleeping with the lenses and then again upon waking in the morning.

Once the patient's final lenses have been dispensed, schedule the patient for follow up visits. It is recommended to have the patient return the morning after the first night of overnight wear, and then at one week, two weeks, one month, two to three months, and every six months thereafter. Subsequent visits after the first morning should be scheduled later in the day, 6 to 8 hours after lens removal.

At each progress visit, check unaided visual acuity and take topography maps. Use difference maps to follow the treatment progression and centration. Perform Bio-microscopy and a manifest refraction. Take photos/videos with lenses on for documentation. It is also advised to check the lenses with a radiuscope for warpage and to evaluate lens cleanliness. Always check for lens deposits that may degrade visual or

comfort performance. At each of these follow up visits, stress the importance of good hygiene and adherence to the follow up care schedule.

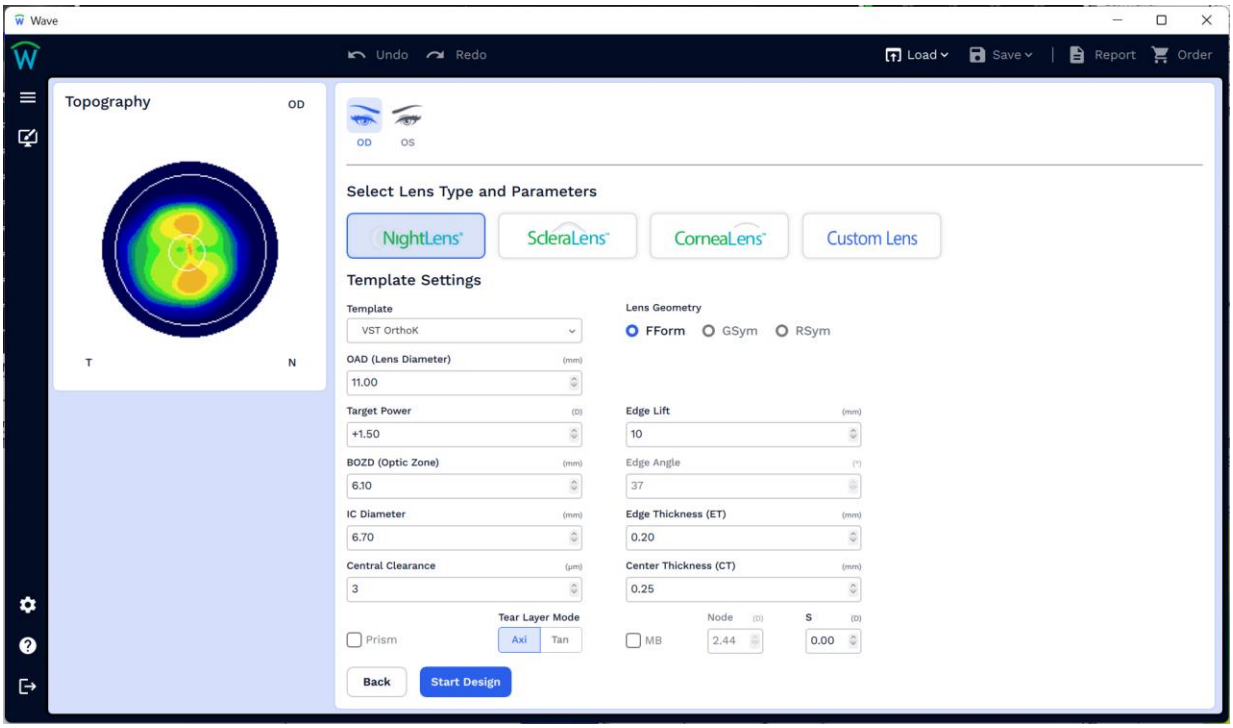
Cleaning, handling, and patient compliance are critical. The wearer should be instructed to use only those solutions recommended by the practitioner. The storage case should be cleaned and allowed to dry nightly, or while the lenses are being worn. And it should be replaced regularly according to manufacturer or practitioner recommendations. Handle the lenses with clean, dry fingers. Lastly, ensure that patients comply with the follow up schedule to monitor ongoing corneal health. Each patient should receive a copy of the IFU included with the lens.

6.1.1 How to design a WAVE NightLens®

** WAVE NightLens® is an approved Bausch + Lomb Vision Shaping Treatment (VST) design.*

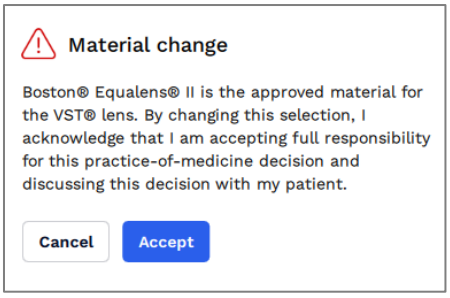
Follow the steps described in Chapter 3 of this manual to import the Corneal Topography map into the WAVE lens designer and enter the patient biometric data.

On the Lens Type and Parameter page, select NightLens®*. Now you can select NightLens® templates and adjust the parameters for the Ortho-K lens you want to design.



NightLens® Templates:

The template defaults to **VST Ortho-K** if the Patient Biometric Data are within the Bausch + Lomb Vision Shaping Treatment (VST) parameters for treating low to moderate myopia (-1.00D to -5.00D) and low astigmatism (up to -1.5D cylinder) using Boston® Equalens® 2 material. If an alternative material is selected, the ECP can continue by acknowledging their awareness of the approved material.



Alternatively, you can choose any of your previously saved templates from the drop-down menu.

The Template Settings for Ortho-K lenses consists of several parameters.

Default settings for VST template

The default VST Ortho-K design parameters work well for designing an Ortho-K lens.

If spherical equivalent refractive error myopia is less than or equal to -3.00, then
Lens power = +1.25
Optic zone = 6.2
Intermediate curve width = 6.8
Apical Clearance is set at 2.0

If spherical equivalent refractive error myopia is less than or equal to -4.00 but greater than -3.00, then
Lens power = +1.50
Optic zone = 6.1
Intermediate curve width = 6.7
Apical Clearance is set at 3.0

If spherical equivalent refractive error myopia is less than or equal to -6.50 but greater than -4.00, then
Lens power = +1.75
Optic zone = 6.0
Intermediate curve width = 6.6
Apical Clearance is set at 4.0

Lens Geometry

A WAVE NightLens® is typically designed in **GSym** or **Freeform** modes. Select Geometrically symmetric **(G)** design mode for symmetrical and Toric corneas. Select Free Form **(F)** for asymmetric corneas.

Lens Diameter (Overall Diameter =**OAD**)

Set the lens diameter 0.2 to 0.5 mm smaller than the visible iris diameter.
A well centered treatment zone is critical to a successful Ortho-K result. Larger lenses tend to center better than smaller lenses because they are less affected by the upper eyelid forces when the eyes are closed. For example, if the visible iris diameter is 11.6 mm, the recommended diameter of the WAVE NightLens® would be 11.1 to 11.4 mm.

- In the presence of a pterygium/pinguecula/raised epithelial defect, make the lens diameter > 0.5 mm smaller than the innermost location of the lesion.

Target Lens Power

Default is set at +1.25D.
For higher refractive errors or for low e values (< 0.4), the Target Lens Power may need to be changed to +1.50D, +1.75D or +2.00D.

Optic Zone (Back Optic Zone Diameter =**BOZD**)

By default, the standard Ortho-K will provide an optic zone of 6.2mm. Optimizing OZ size for each patient depends on the Ortho-K category, lifestyle/vision needs, degree of refractive error, eye dominance, corneal eccentricity, and pupil size.

a) Adults require large enough OZ for halo-free vision in low light conditions.
b) Myopia management patients require a smaller OZ to maximize relative plus power inside the pupil area.
c) Higher refractive errors and low corneal eccentricity (< 0.40) may require a smaller OZ to move a sufficient volume of epithelium to create full refractive treatment. Too large an OZ may result in insufficient suction, insufficient epithelial displacement, insufficient treatment, and false islands seen in follow-up topographies.
d) Larger pupil size may require a larger OZ.
e) Smaller pupil size may allow for a smaller OZ.

IC Diameter (Intermediate Curve = **IC**)

The typical IC setting is 0.6 mm larger than BOZD. By default, the standard Ortho-K design will use an BOZD of 6.2mm, and an Intermediate Curve width of 6.80. This **0.6 mm** area is good for an Ortho-K design and represents the size of the reverse curve zone. If it is necessary to change the size of the optic zone, be sure to change the size of the Intermediate Curve width as well, to keep the 0.6 mm difference to provide for the reverse curve.

Central Clearance

The default central clearance is set at 2 microns but may be customized to a different level. Keeping at least 1 or 2 microns clearance will reduce the potential for central cornea staining. If corneal staining does occur centrally, the amount of apical clearance may need to be increased.

Center Thickness (CT)

The center thickness should be at least 0.20 mm to help create a stable lens that will provide the treatment needed.

- The higher the corneal cylinder, the more likely a lens will warp, causing incomplete astigmatism molding. Increasing the CT will reduce lens warp and allow more of the corneal cylinder to be corrected.

- If the desire is to maintain or even increase corneal cylinder, decreasing the CT will create more lens warp, which causes less corneal cylinder molding.

Edge Thickness (ET) and Edge Lift

The default setting for the edge thickness is 0.20 mm and the edge lift is set at 10 microns.
As with all the settings, these can be customized to follow a specific fitting philosophy, or the individual needs of the patient.

Edge Angle

Edge angle can be modified if desired.

Prism

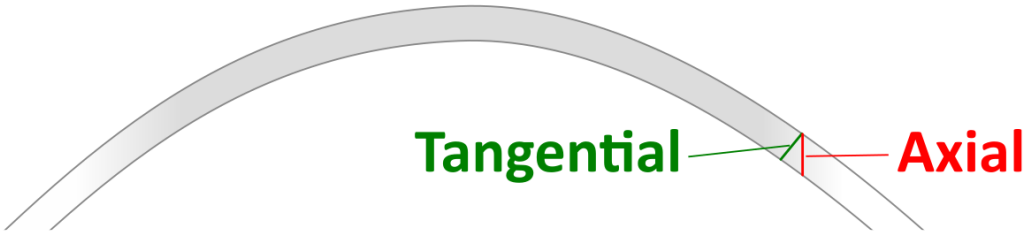
Prism can be added to the design, if desired. In some cases, it may help with lens orientation and rotational stability.

Tear Layer Mode

You have a choice to design lenses using the Tangential or Axial Tear Layer Mode. Axial Mode produces lenses that fit flatter centrally and steeper peripherally, while Tangential Mode produces lenses that fit steeper centrally and flatter peripherally. It is recommended that you choose either Tangential or Axial Tear Layer design mode and stick with it until you become more familiar with the software.

In the diagram below:

a) The red line shows an axial measurement of the tear layer.
b) The green line shows a tangential measurement of the tear layer.



Axial design mode is selected by default. Selecting the Axial mode will provide a snug fit and a good seal in the alignment zone, which will aid in lens centration.

MB and S

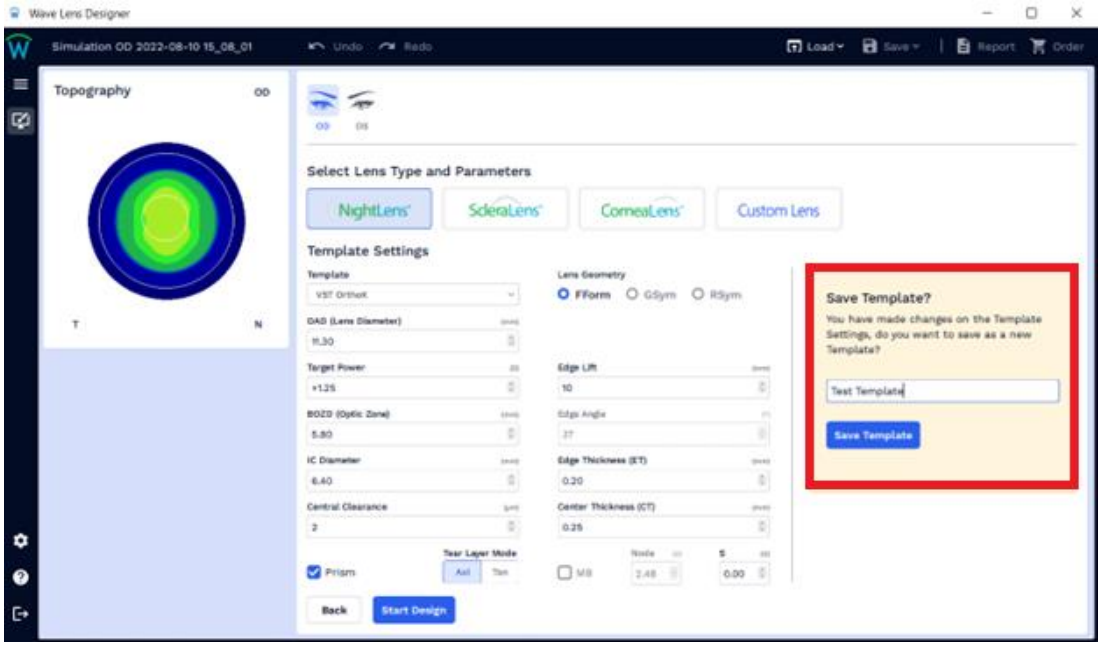
Minimal Blending (MB) and asphericity (S) of the optic zone. When minimal blending is checked and a non-zero asphericity value is selected, a simplified optic zone asphericity is created. These settings apply to the back surface of the contact lens. Changes can be viewed in the Tear layer graph and Back Curvature Map.

Customize and save your settings for future use:

Settings for customized myopia management may be saved with your own template. As an example, optical zone diameter may be altered.

If the settings have been customized to meet the Ortho-K fitting philosophy of the practitioner, the settings can be renamed, saved, and easily used for future designs. Simply type the desired name in the **Save Template?** box to rename the template and click on **Save Template**. It will be available in your dropdown menu from this point on.

An optional description can be entered for easy reference.



One value you may regularly change from default, is the **Lens Diameter** (OAD). This is dependent on the patient's corneal diameter and based on fitting philosophy. This is customizable under Lens Design Preferences Settings.

In the preference setting, you can set a default diameter by making lens diameter 0.2 to 0.5 mm smaller than the visible iris diameter.

A well centered treatment zone is critical to a successful Ortho-K result. Larger lenses tend to center better than smaller lenses because they are less affected by the upper eyelid forces when the eyes are closed. For example, if the visible iris diameter is 11.6 mm, the recommended diameter of the WAVE NightLens® would be 11.1 mm to 11.4 mm.

To proceed with the Ortho-K lens design, click **Start Design**. WAVE Lens Designer will now calculate the initial lens design for an Ortho-K lens based on the source topography map and the
designer's input.

Review the design

Before ordering the lens, the ECP should evaluate the initial lens design carefully along all eight semi-meridians and make any necessary adjustments.

- Review the result in the design window. Adjust the edge lift if necessary.

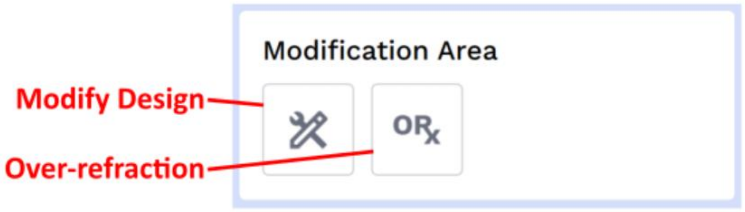
- Make sure the outside slopes of the Return Zone to the Alignment Zone in all 8 meridians are smooth and similarly shaped, with no unusual crimps or deviations.
- Check the Center Thickness (CT) and Edge Thickness (ET).
  In cases where the Refractive cylinder is equal to Corneal cylinder, make the CT thicker than normal (~ 0.26 mm) to help prevent lens flexure. In cases where Refractive cylinder is less than Corneal cylinder, make the CT thinner than normal (~0.18 mm) to promote lens flexure.
- Proceed to save and order the lens.

6.1.2 How to modify a WAVE NightLens®

If a patient's results are not as expected, it is recommended to NOT make parameter changes until you are convinced that the patient has reached a stable point in the treatment. It may be 3-4 weeks from dispensing before full molding occurs.

The most common adjustments to improve the fit or centration of the NightLens® are modifications of the alignment zone and return zone. If the periphery fits accordingly, adjustments to the treatment amount can be made by modifying the Base Curve

These can be achieved either with the Modification Tools or manually.

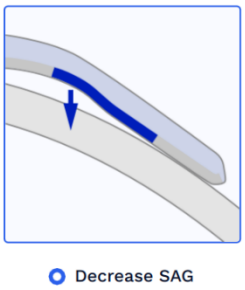


NOTE: The Over-refraction (ORX) function will modify the font power of the lens if there is an ORX with lens-on-eye. This only helps with vision while the lens is on eye. It does not change the mold treatment amount (base curve) and cannot be used to design a toric OZ in case of a toric ORX.

6.1.2.1 How to increase the Treatment amount

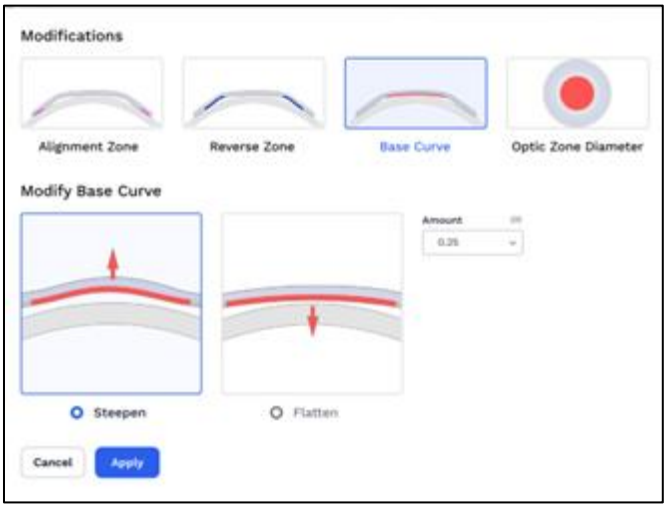
If the patient is not fully corrected with the lens, click on the modification tools in the Modification Area, select **Base Curve** and Flatten the base curve by desired amount in diopters.

For more than 1.00D of under-correction, modify the **Reverse Zone** by decreasing the SAG.

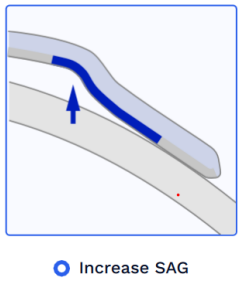


6.1.2.2 How to decrease the Treatment amount

If the treatment over corrects the patient and you need to lessen the treatment amount, click on the modification tools in the Modification Area, select **Base Curve** and Steepen the base curve by desired amount in Diopters.

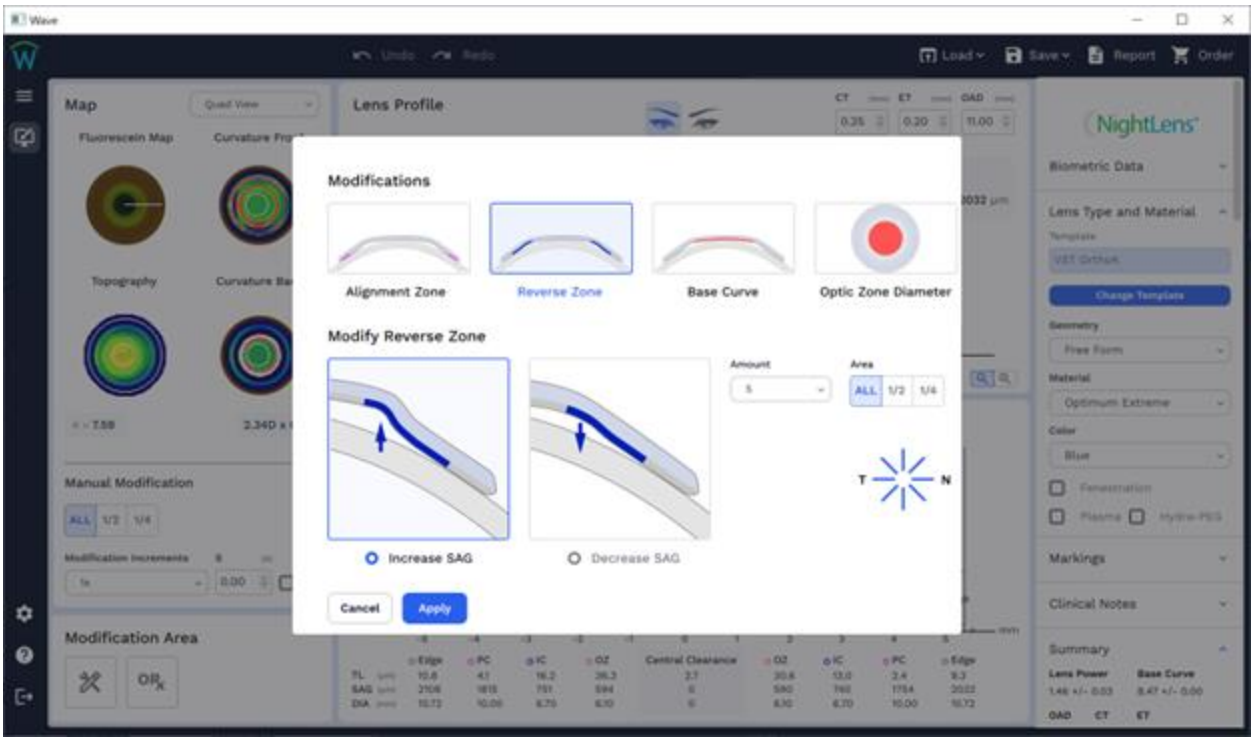


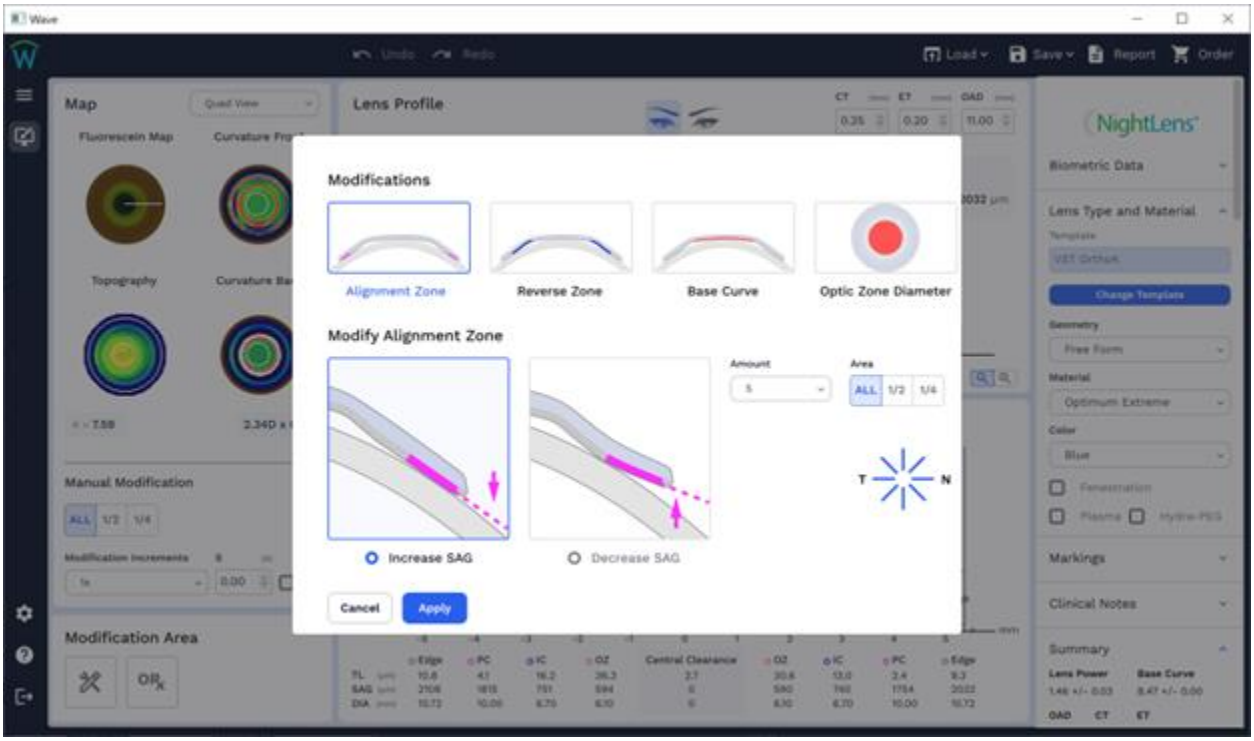
In case of over-correction, you can also increase SAG in the **Reverse Zone**.



6.1.2.3 How to change Optic Zone, Reverse Zone, and Alignment Zone

To modify OZ Diameter, Reverse Zone, and the Alignment Zone it is recommended to use the modification tools. Click on the Modification Tools where you can adjust these parameters.


Wave
Undo
Redo
Load
Save
Report
Order
Map
Lens Profile
Modifications
Alignment Zone
Reverse Zone
Base Curve
Optic Zone Diameter
Modify Reverse Zone
Amount
Area
ALL
1/2
1/4
Increase SAG
Decrease SAG
Cancel
Apply
Manual Modification
Modification Area
NightLens
Biometric Data
Lens Type and Material
Markings
Clinical Notes
Summary


Wave
Undo
Redo
Load
Save
Report
Order
Map
Lens Profile
Modifications
Alignment Zone
Reverse Zone
Base Curve
Optic Zone Diameter
Modify Alignment Zone
Amount
Area
ALL
1/2
1/4
Increase SAG
Decrease SAG
Cancel
Apply
Manual Modification
Modification Area
NightLens
Biometric Data
Lens Type and Material
Markings
Clinical Notes
Summary

6.2 WAVE ScleraLens®

WAVE scleral lenses are branded as ScleraLens®. The WAVE ScleraLens® is a premium brand of custom Scleral contact lenses designed to provide maximum comfort and excellent visual outcome for your patients.

You can design a WAVE ScleraLens® from a compatible topographer or from a device that can measure the cornea scleral profile (scleral profilometry), such as the OCULUS Pentacam® CSP (Cornea Scleral Profile) report or ,the Eaglet-Eye ESP (Eye Surface Profiler).

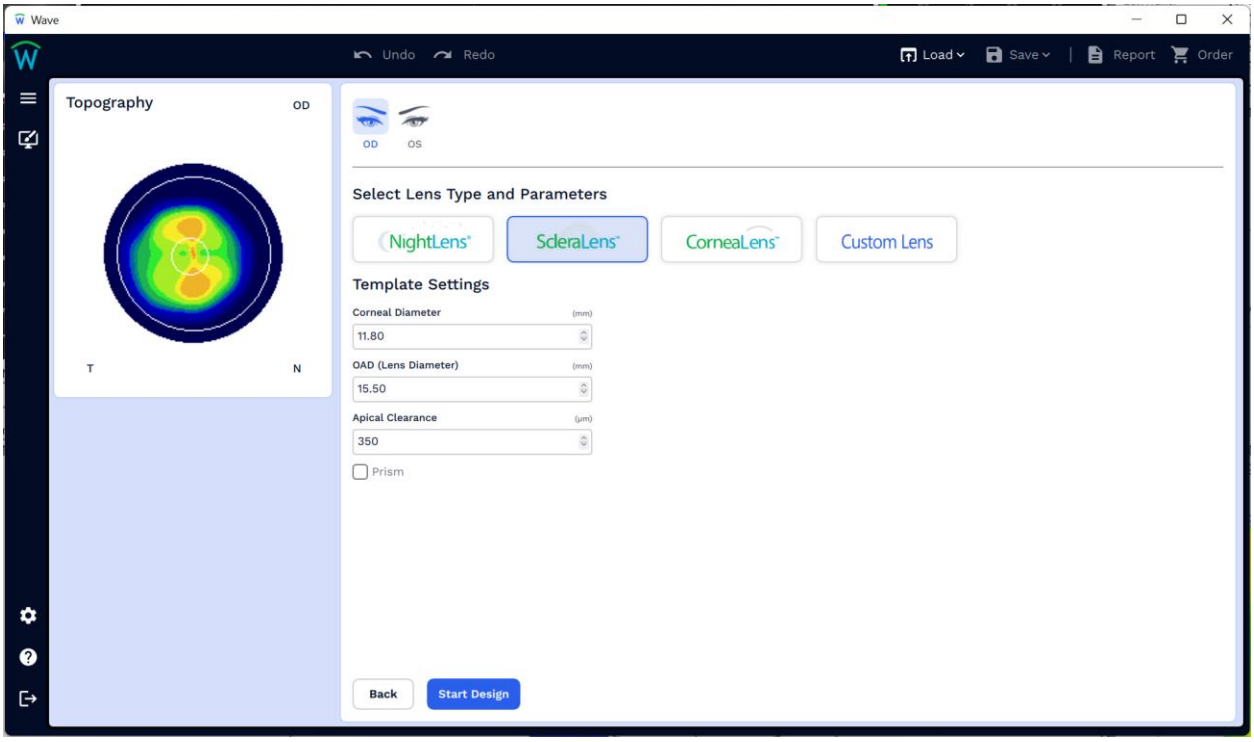
The main difference with scleral profilometry is that these instruments allow us to map the cornea and sclera. The scleral profile produced can then be used to perfectly customize a scleral contact lens, improving the initial fit and reducing the time it takes to produce a perfectly fitting lens.

If a corneal topography map without scleral profilometry is used to design a scleral lens, the WAVE software uses extrapolated/estimated data to design the lens and cannot take into consideration the anatomical changes that occur peripheral to the limbus. The peripheral alignment area in the resultant design is targeted to be at an angle of about 37 degrees in all meridians because the topography software does not provide data in these areas.

6.2.1 How to design a WAVE ScleraLens®

Follow the steps described in Chapter 3 of this manual to import the Corneal Topography map into the WAVE lens designer and enter the patient biometric data.

By choosing WAVE ScleraLens®, the Template Settings for scleral lenses will be displayed.



Confirm the **Corneal Diameter**, enter **Lens Diameter** (OAD) and **Central Clearance**. One value you may regularly change from default is the **Lens Diameter** (OAD). This is dependent on the patient corneal diameter and based on your fitting philosophy. This is customizable in our Lens Design Preferences Settings.

In the preference setting you can set a default diameter by adding 4 mm larger than the visible iris diameter. It is recommended to enter a central clearance 100-150 Microns more than what you would like to see after the lens settling.

Typically, 300-350 microns will give you a good initial lens when using the Pentacam® CSP data. For Eaglet-Eye E400-450 microns of central clearance will give you a good initial lens.

When using corneal topography data for Scleral Lens designs, the central clearance specification should be approximately 50-80 microns LESS than when designing with the Pentacam® CSP report.

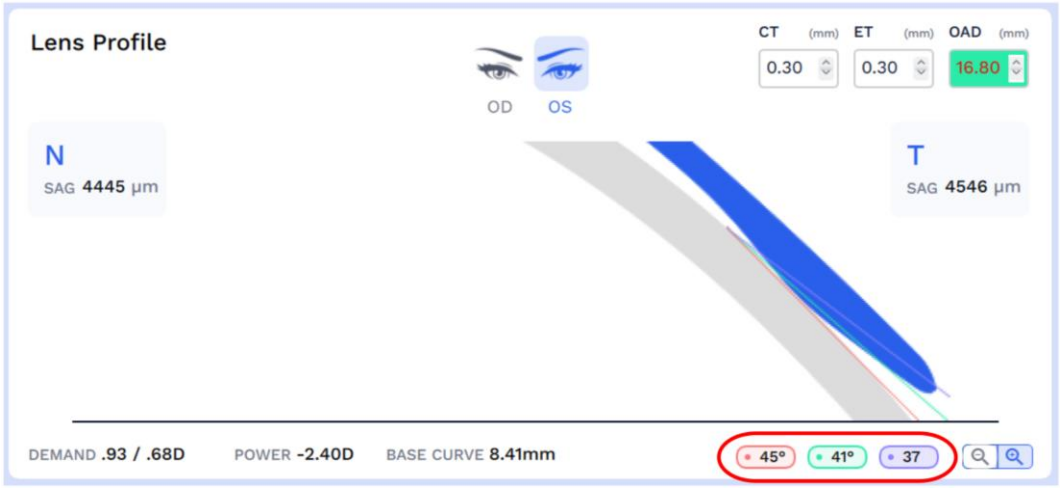
This is because the scleral data is extrapolated based on the corneal topography data alone and cannot take into consideration the anatomical changes that occur peripheral to the limbus.

NOTE: Designing a scleral lens when using corneal topographies with a very steep periphery, such as, corneal transplants or post refractive surgery complications, can be challenging because the extrapolated scleral data is usually much steeper than the true sclera and can cause the design to be too steep and excessively vault the cornea when on the eye.

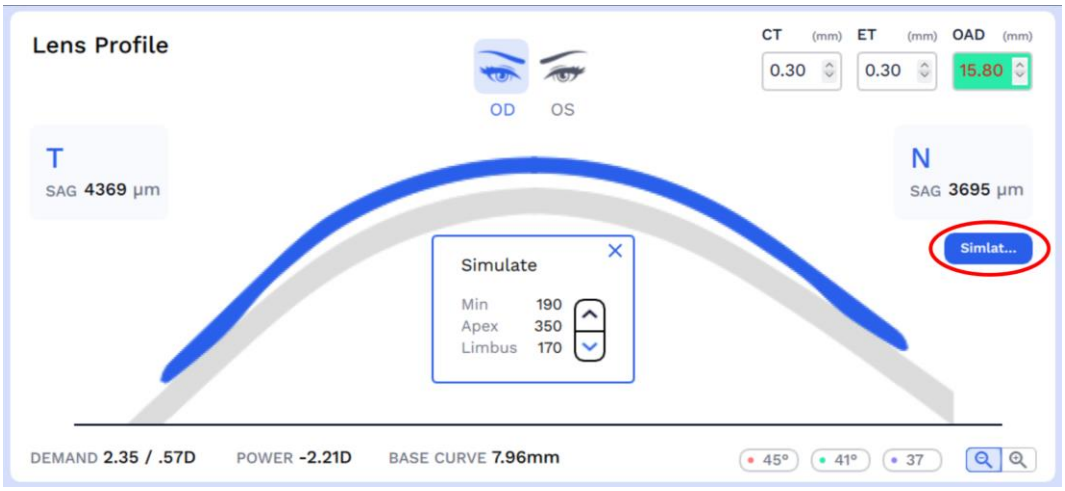
To proceed with the scleral lens design, click **Start Design**. WAVE Lens Designer will now calculate the initial lens design.

After selecting ScleraLens®, WAVE Lens Designer presents an initial custom lens design for a scleral lens based on the source data and the designer's input.

The ECP should evaluate the initial lens design carefully along all eight meridians and make any necessary adjustments before ordering the lens.



Three color coded construction lines (Red line **45°**, Green line **41°**, Blue line **37°**) can be individually displayed, so that the user can easily see and modify the peripheral angles, especially in absence of real scleral data.



To help the user simulate the lens settling only for Pentacam® CSP and Eaglet-Eye ESP based scleral lenses, the button Simulate appears in the Lens Profile window. Clicking on it, a window with **Apex, Min, Limbus** values is shown. The user can use the down and up arrows to simulate the lens settling and observe the minimum clearance and limbal clearance, then adjust the design if needed.

Differences between designing a WAVE lens using Pentacam® CSP report & Eaglet-Eye ESP, and a Corneal Topography map (Medmont and other):

The main difference between designing a WAVE lens using Pentacam® CSP report and Eaglet-Eye ESP, or a Corneal Topography map is that when you use the corneal topography map to design a scleral lens with WAVE Lens Designer, the WAVE Lens Designer uses

extrapolated/estimated data to design the scleral lens and cannot take into consideration the anatomical changes that occur peripheral to the limbus.

The peripheral alignment area in the resultant design is targeted to be at an angle of about 37 degrees all the way around because we do not have actual data there.

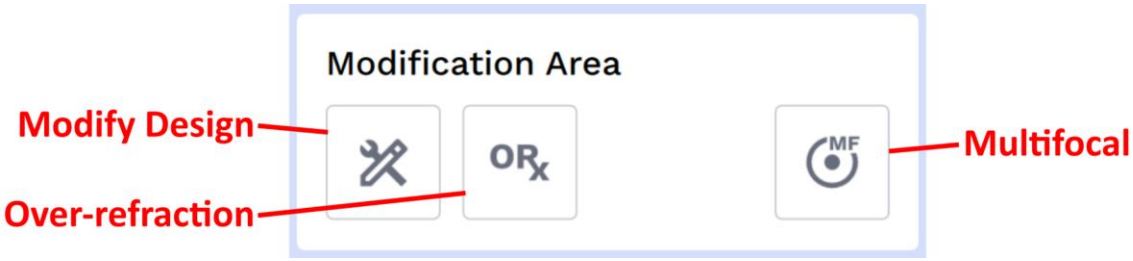
When there is no scleral data, WAVE Lens Designer automatically displays the construction lines in order to help the user easily see and modify the peripheral angles. After that, it is a matter of changes made based on observation.

As referenced above, the Simulate button will only appear for Pentacam® CSP and Eaglet-Eye ESP for ScleraLens® designs.

6.2.2 How to modify a WAVE ScleraLens®

If you find that you need to modify the fit, WAVE Lens Designer has a great set of modification tools to make specific fit adjustments.

You can find them in the Modification Area.



The most common adjustments to the lens design are the following:

- Modify Central Clearance
- Modify Limbal Clearance
- Modify Alignment Angle

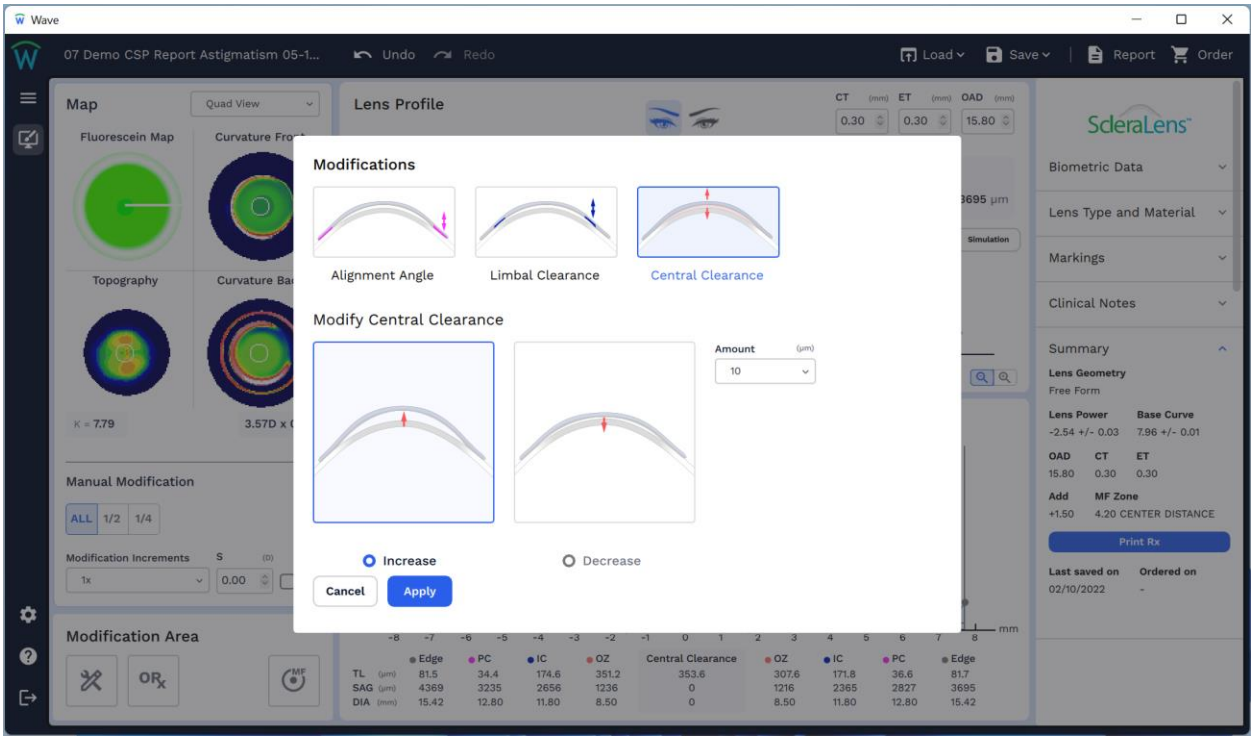
6.2.2.1 How to modify Central Clearance

Oxygen must diffuse through the tear layer as well as the contact lens, so if the tear layer is too thick, there may be an increased risk of hypoxia.

On the other hand, because the conjunctiva is soft and "squishy", the lens will settle down and cause the tear layer to become thinner, even perhaps so thin that the lens ends up touching the cornea. This may increase the risk of abrasions, inflammation, and infection.

To adjust, in the Modification Area click on the modification tools and select "Modify Central Clearance".

Select “Increase” or “Decrease” and the “Amount” (µ) that you wish to change. Apply.



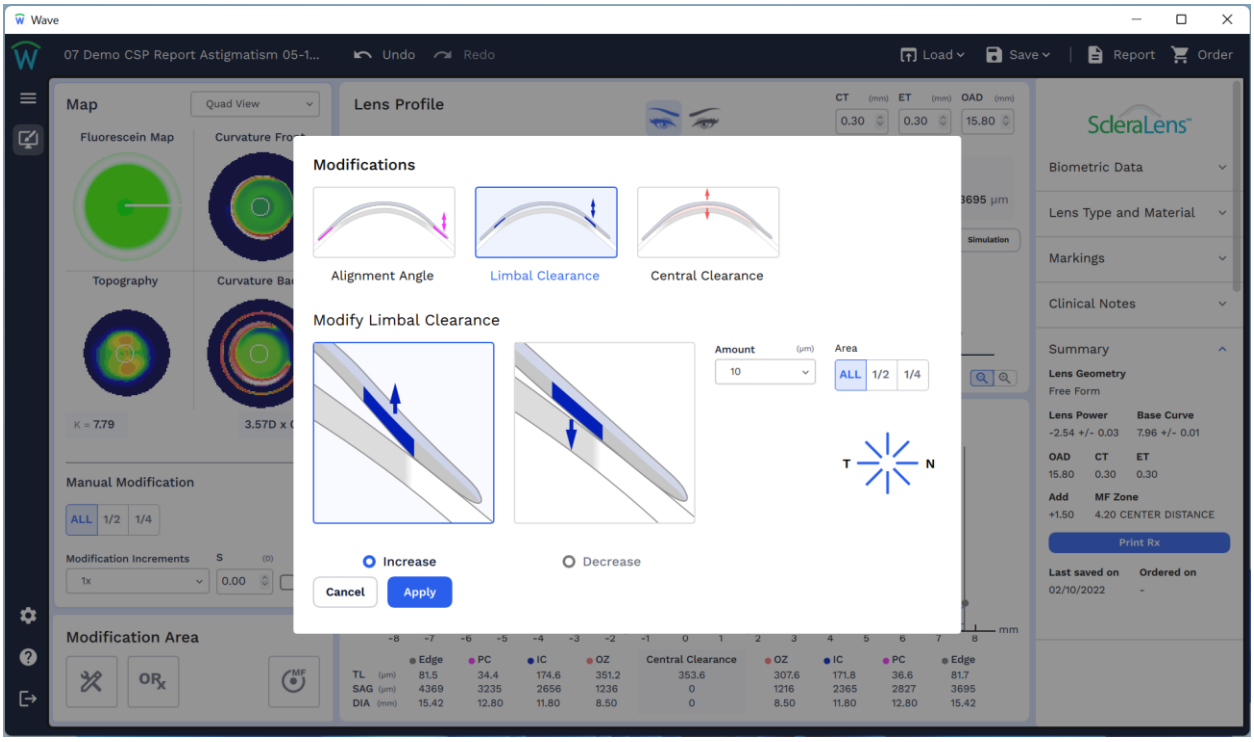
6.2.2.2 How to modify Limbal Clearance

Sometimes the Limbal Clearance must be raised (e.g., the central vault is appropriate, but the lens touches the limbus as a result of settling) or lowered.

To adjust, in the Modification Area click on the modification tools and select “Modify Limbal Clearance”.

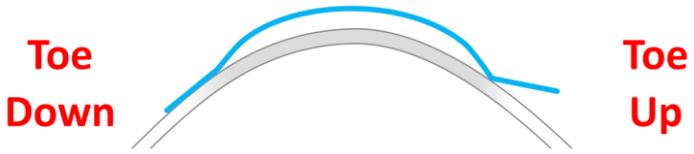
Select “Increase” or “Decrease” and the “Amount” (µ) that you wish to change.

Under “Area”, choose the % of the lens area that you wish to change (All, ½, ¼), then select the axis (axes) where you want the change localized. Click then Apply.



6.2.2.3 How to modify Alignment Angle

The edge alignment angle is important for obtaining optimal comfort and lens orientation. Maximum comfort and orientation are achieved when the edge aligns (parallel) to the scleral angle all the way around the lens. “Toe down” or “toe up” edge fit results in excessive scleral compression and blood vessel impingement, both of which can lead to discomfort, subconjunctival hemorrhages, and reduced wearing time.

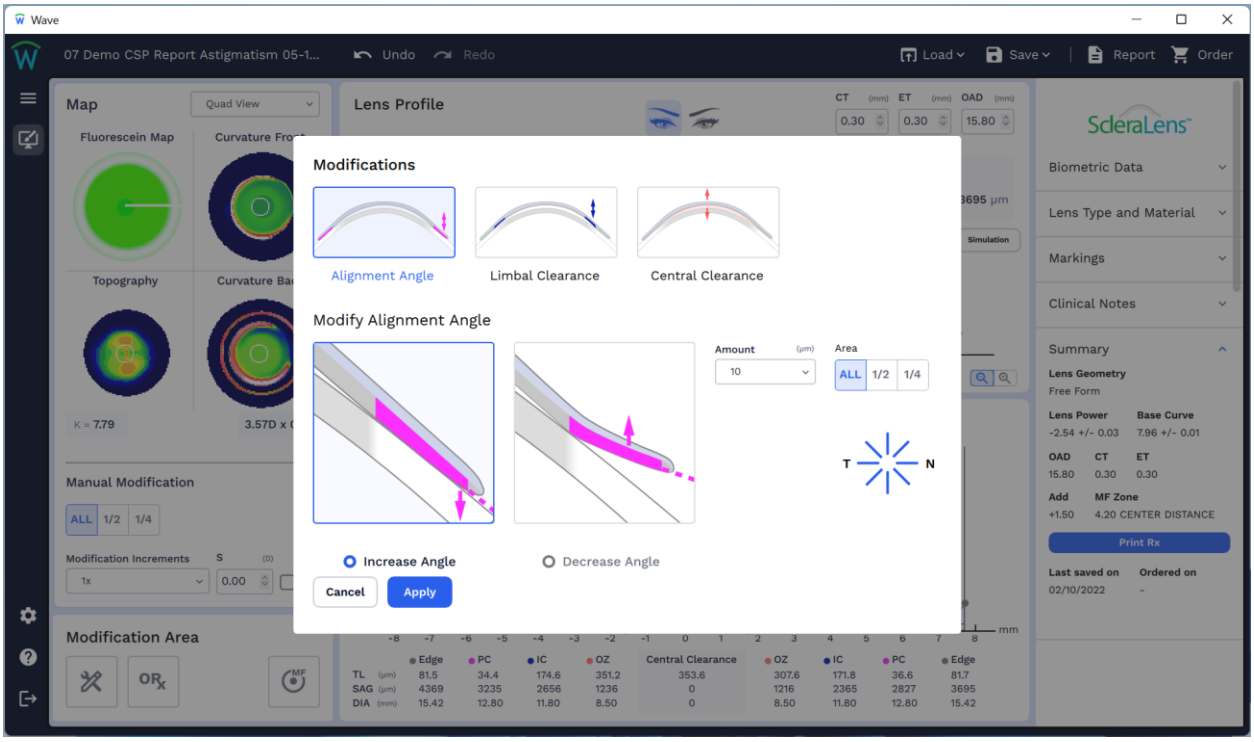


The angle used for the Scleral area of the design can be displayed on the lens profile window when scanning with the mouse. The most useful point to measure is midway between the Pink and Black control points.

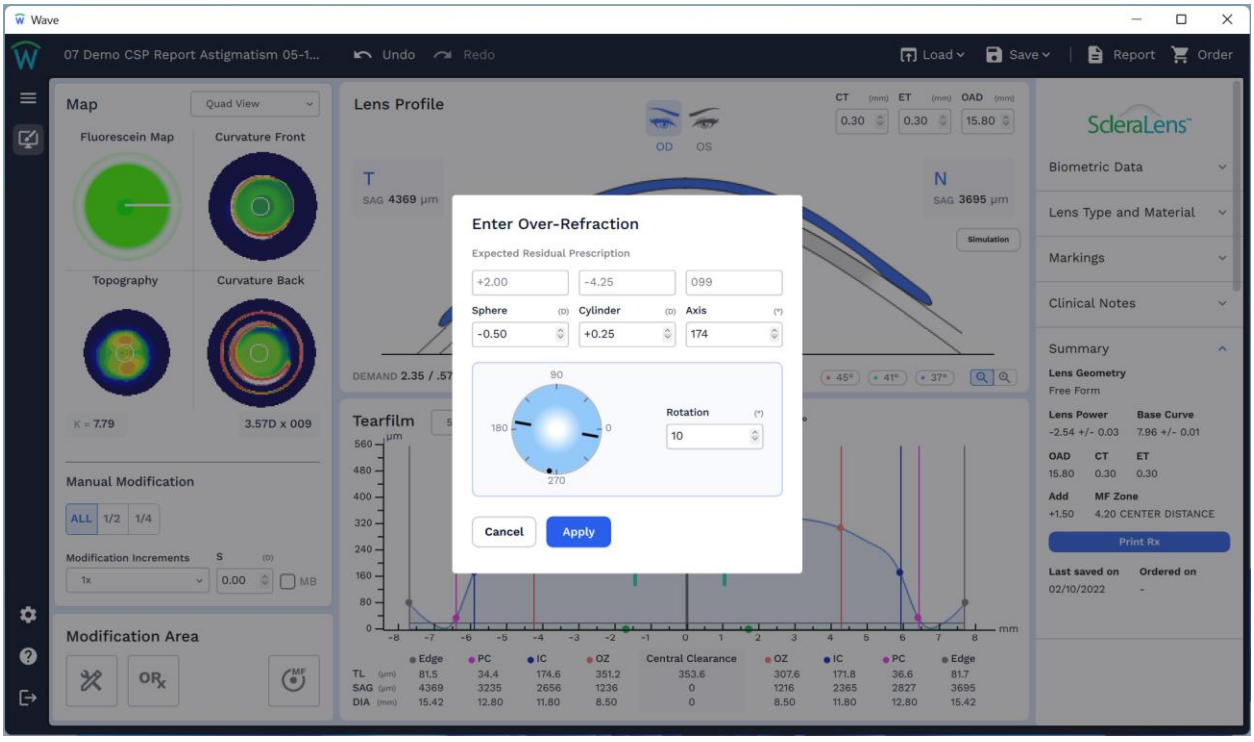
To adjust, in the Modification Area click on the modification tools and select “Modify Alignment Angle”.

Select “Increase” or “Decrease” and choose the “Amount” (µ) that you wish to change.

Select the Area you wish to change (All, ½, ¼) and the axis (axes) where you want the change localized. Click then Apply.



6.2.2.4 How to enter Over-Refraction (ORx)

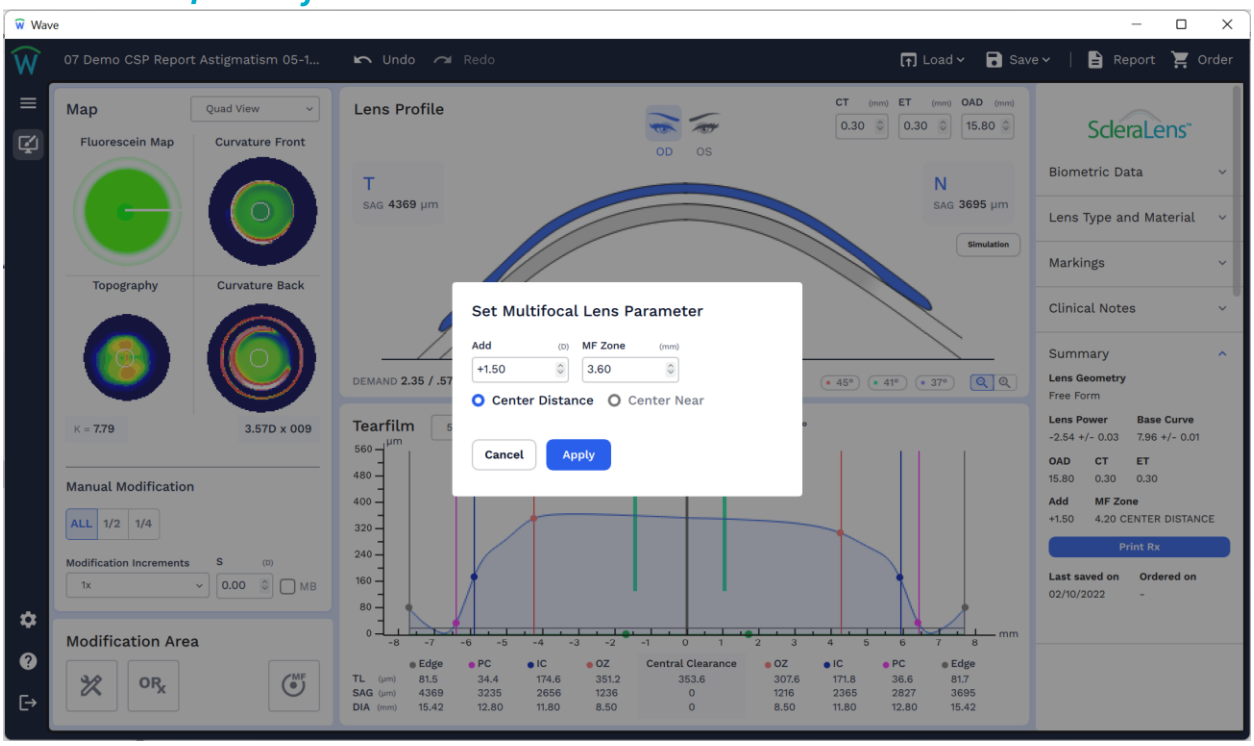


After ordering the WAVE ScleraLens® for a patient, you may need to perform an over-refraction to fine-tune the lens power.

To enter the over-refraction, click on Over Refraction button in the Modification Area.

In the dialogue box you can enter the Over Refraction of the WAVE ScleraLens® and click Apply.

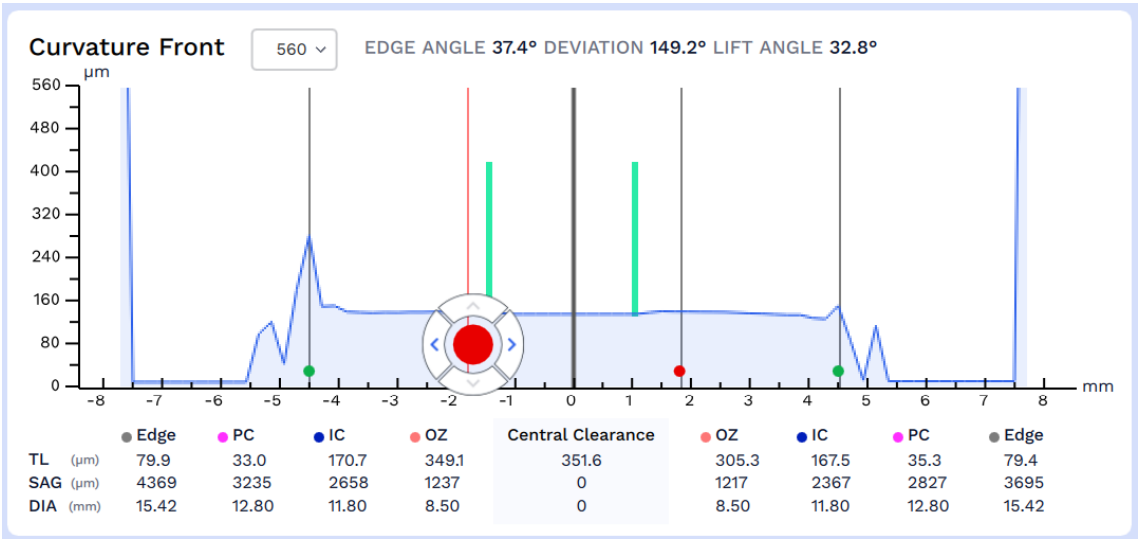
6.2.2.5 Multifocal Adjustment



You can design a multifocal scleral lens with WAVE Lens Designer. To do so, click on Multifocal Adjustment and enter the ADD value in the refraction box.

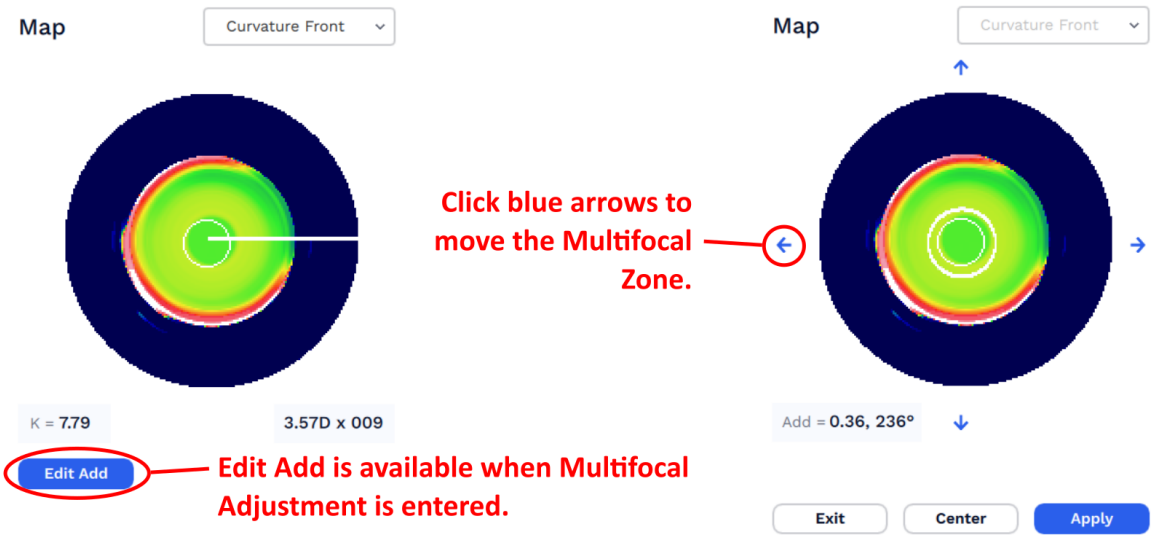
You have the option to design a lens with CENTER NEAR or CENTER DISTANCE. Click on continue and WAVE Lens Designer designs a multifocal lens.

If you double right click on the **Front Surface Curvature** map or select from the dropdown menu you can modify the diameter of the CD or CN zone and its position.



The red control balls show the Multifocal zone width and the green control balls show the front optical zone width.

Clicking on Edit Add you can move the CD or CN zone position.



For a successful multifocal design,

- Start with a lens design that provides good distance vision and is well centered.
- Determine which eye is the dominant eye. What is the average pupil size? What is the patient currently wearing, under-minus, mono-vision or previous MF lenses?
- You may want to maximize the plus for both eyes when considering power. Sometimes even adding +0.25D or +0.50D in the nondominant eye can be helpful.
- It is also important to set the patient expectations!

6.3 WAVE CorneaLens®

Intracorneal lens designs are branded as WAVE CorneaLens®. This lens design uses the corneal topography to calculate a customized lens design.

Multiple micro aspheric curves create a lens design that can be further modified for regular and different types of irregular corneas.

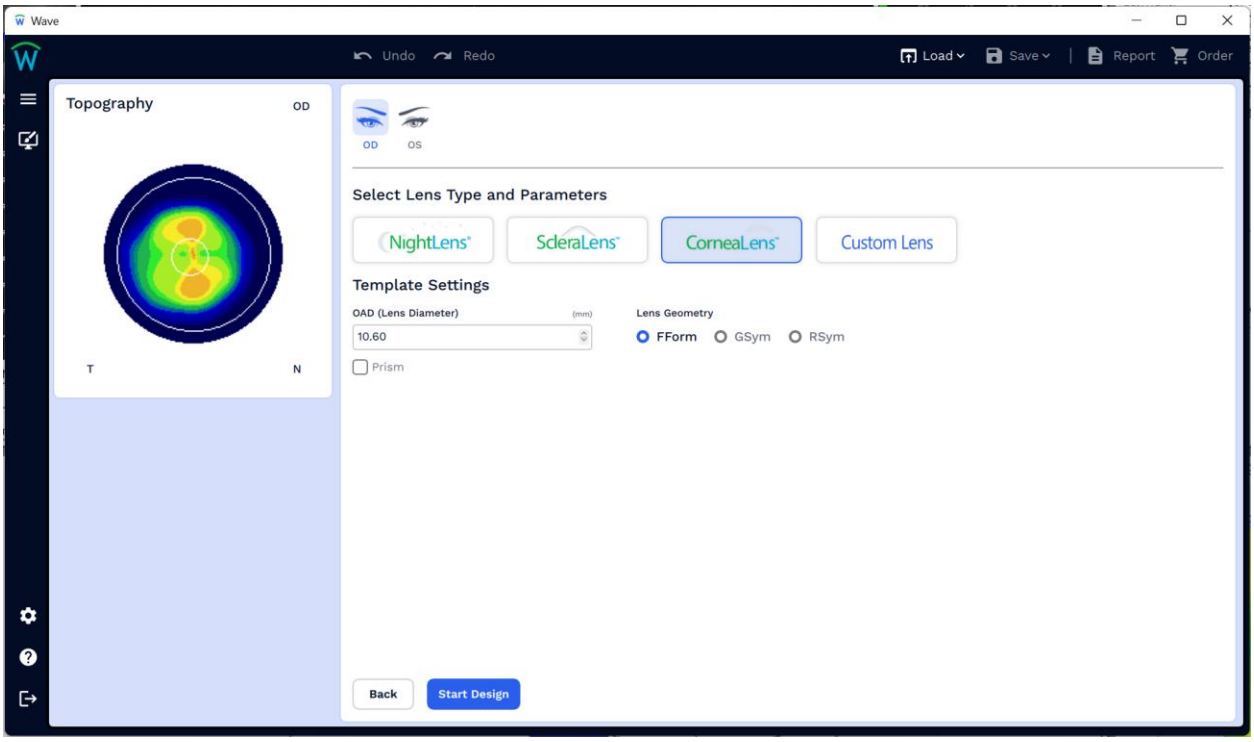
6.3.1 How to design a WAVE CorneaLens®

Follow the steps described in Chapter 3 of this manual to import the Corneal Topography map into the WAVE lens designer and enter the patient biometric data.

By choosing CorneaLens®, template for selecting the lens parameters will be displayed.

Depending on the patient corneal diameter and based on your measured HVID and your fitting philosophy, you may regularly change the **Lens Diameter** (OAD) from default.

When using FForm or GSYM lens designs a bigger lens diameter is recommended to support the correct orientation of the lens. This is customizable in Lens Design Preferences Settings. In the preference setting you can set a default diameter by making lens diameter 1.5 mm to 0.8 mm smaller than the visible iris diameter.



To proceed with the corneal lens design, click **Start Design**. WAVE Lens Designer will now calculate the initial lens design based on the source topography map and the designer's input.

You can review the design along each of the 8 semi-meridians. As you click on each meridian, pay attention to the Tear Film Graph and the Simulated Fluorescein map.

A well-fitting lens will have a nice lens back surface profile line that reasonably mirrors the cornea line all the way across the cornea. The most important area of the profile line is the area near the periphery known as the alignment zone (between blue and pink points). Here, we want to avoid considerable down turning or too much of an upturn. This is important for lens stability and comfort.

A GP lens with a small edge lift is very uncomfortable and can easily adhere to the eye surface due to lack of tear film exchange.

Central thickness of 0.2 or more should be adequate to reduce lens flexure in corneal lenses. Increasing the central thickness reduces the likelihood of lens flexure, but also reduces the oxygen transmission. Edge thickness of 0.16 or more should be adequate to reduce the chance of chipping and cracking around the edge.

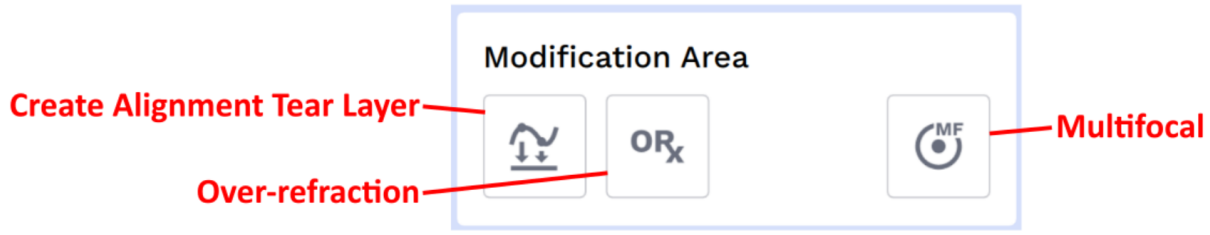
6.3.2 How to modify a WAVE CorneaLens®

You can use the colored control points in tear film graph to increase or decrease tear thickness to modify the lens design. Depending on the selected geometry (R, G or F), the designer has different controls of the eight meridians. (Refer to Table 1)

You can drag the control points to adjust the tear thickness and zone diameter or click on the arrows that appear selecting the control ball. As you do that, the amount of change is shown in the upper center area of the Tear Film Graph.

As the parameters are modified, WAVE Lens Designer redesigns the lens.

In addition, the modification tools in the Modification Area can be used:



6.3.2.1 How to create Alignment Tear Layer

By selecting Create Alignment Tear Layer, WAVE Lens Designer applies the current settings (lens diameter, design mode) to the design and aligns the tear layer thickness graph to the corneal reference line. **Please note that if you click on this after making modifications to the lens, it will reset all manual adjustments.**

This alignment design may need to be adjusted to avoid lens adhesion.

6.3.2.2 How to enter Over-Refraction (ORx)

After ordering the WAVE lens for a patient, you may need to perform an over-refraction to fine-tune the lens power.

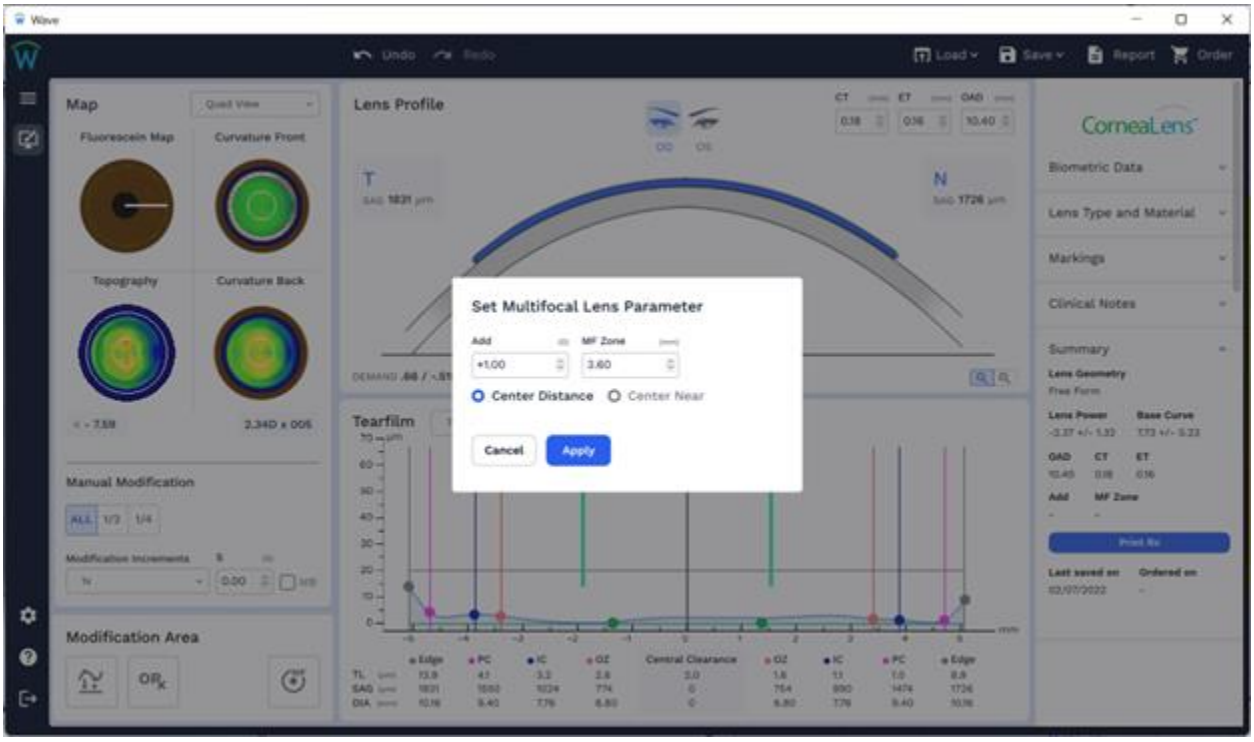
To enter the over-refraction, click on Over Refraction button in the Modification Area.

In the dialogue box you can enter the Over Refraction of the WAVE lens.

If you notice that the lens is rotated, you can enter the rotation angle here.

The grayed-out fields show the expected residual prescription (internal astigmatisms).

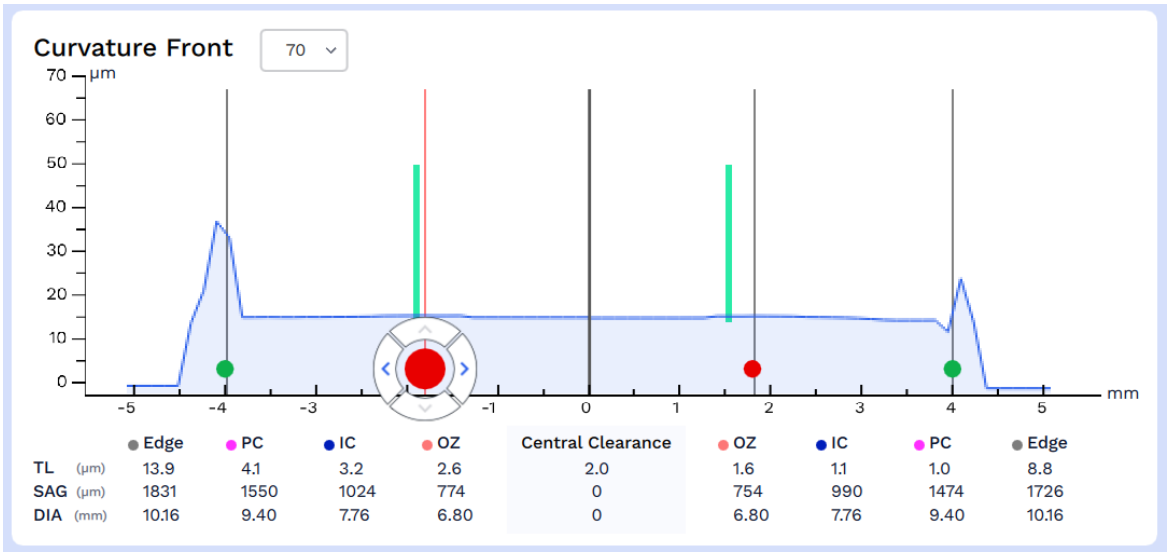
6.3.2.3 Multifocal Adjustment



You can design a multifocal corneal lens with WAVE Lens Designer. To do so, click on Multifocal Adjustment and enter the ADD value in the refraction box.

You have the option to design a lens with CENTER NEAR or CENTER DISTANCE. Click on continue and WAVE Lens Designer designs a multifocal lens.

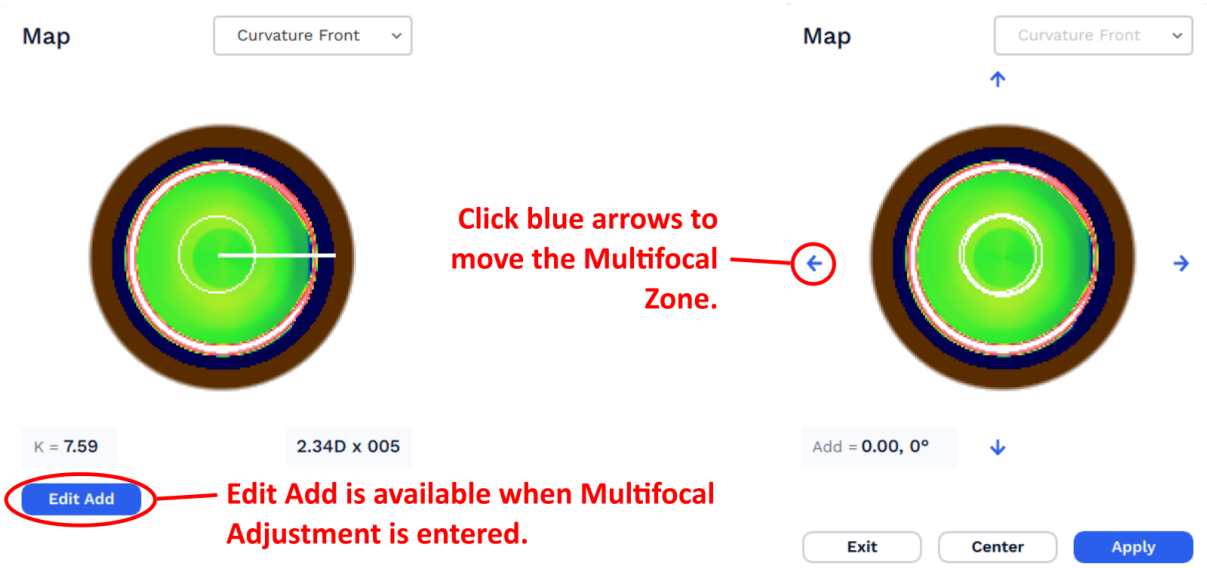
If you click on the front surface curvature map you can modify the diameter of the CD or CN zone and its position.



		Edge	PC	IC	OZ	Central Clearance	OZ	IC	PC	Edge
TL	(µm)	13.9	4.1	3.2	2.6	2.0	1.6	1.1	1.0	8.8
SAG	(µm)	1831	1550	1024	774	0	754	990	1474	1726
DIA	(mm)	10.16	9.40	7.76	6.80	0	6.80	7.76	9.40	10.16

The red control balls show the Multifocal zone width and the green control balls show the front optical zone width.

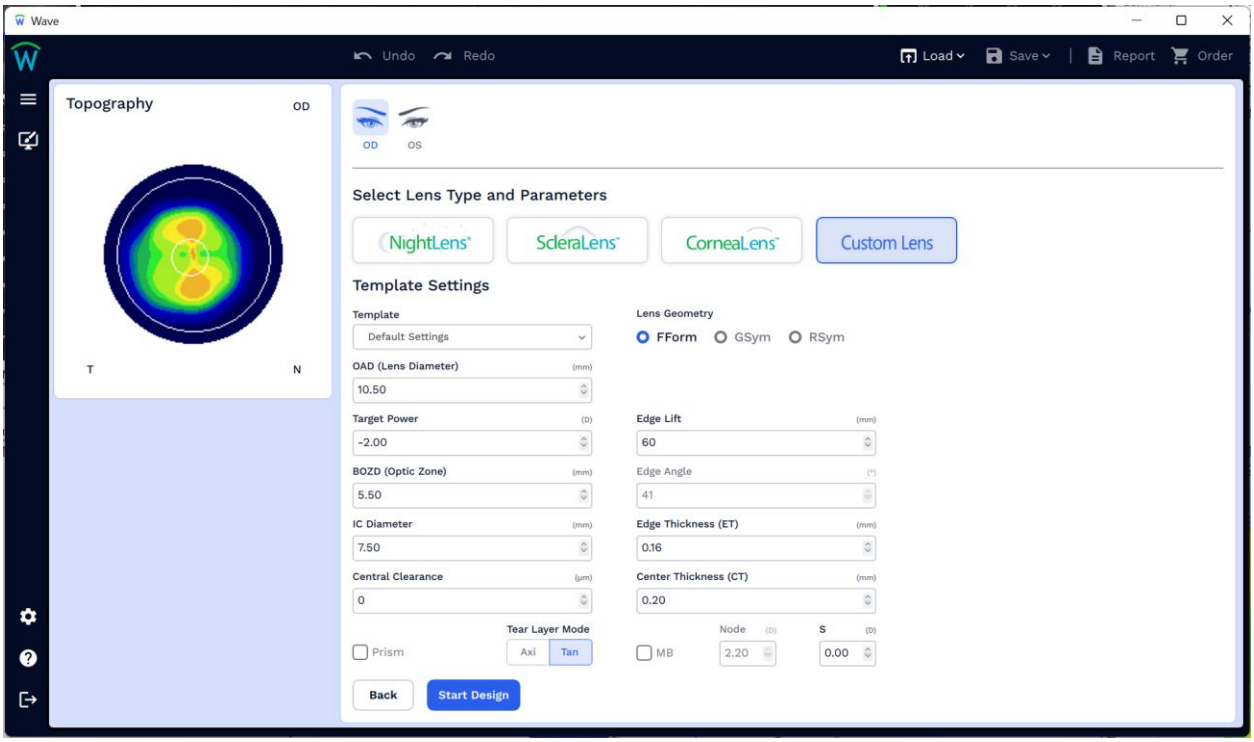
Clicking on Edit Add you can move the CD or CN zone position.



For a successful multifocal design,

- Start with a lens design that provides good distance vision and is well centered.
- Determine which eye is the dominant eye. What is the average pupil size? What is the patient currently wearing, under-minus, mono-vision, or previous MF lenses?
- You may want to maximize the plus for both eyes when considering power. Sometimes even adding +0.25D or +0.50D in the nondominant eye can be helpful.
- It is also important to set the patient expectations!

6.4 Custom Lens



By choosing Custom Lens, you have the full control to design a completely custom lens.

It is recommended that only experienced practitioners select this option.

NOTE: The User of the WAVE Lens Designer is responsible in confirming that the data entered in the software is accurate and complete.

7 Maintenance and Support

The user is responsible to carry out updates to the WAVE Lens Designer software when provided by the manufacturer.

7.1 Technical Data

Minimum Computer Requirements	
Operating system	Windows® 10
Processor	Intel® Core™ i5
RAM	8 GB
Screen resolution	1920 x 1080 Pixel (Full HD)
Graphic card	Intel® HD Graphics
Compatible Corneal Topographer/Tomographer	OCULUS Pentacam® OCULUS Keratograph® Medmont Topographers Eaglet-Eye Eye Surface Profiler

7.2 Customer Support

If you have any questions, or need technical or clinical support, please contact us.

WAVE Contact Lens System

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