WAVE Contact Lens System

User Guide

Version 9.30

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1. General Information

WAVE Contact Lens Design System 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, and to send the design to the lab for production.

The ECP should be trained in topographical analysis to benefit from the WAVE design software. 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 created by the doctor for each individual patient to provide excellent visual outcome and maximum comfort. All WAVE designs have multiple aspheric curves as small as 10 microns in diameter to closely follow the corneal shape.

Possible lens designs include, Corneal GP, Orthokeratology lenses and Scleral lenses. Designing Toric, bi-toric, multifocal (both for center near and center distance), large diameter lenses up to 18 mm and lenses with or without front surface prism are also possible with WAVE.

Lens Geometries

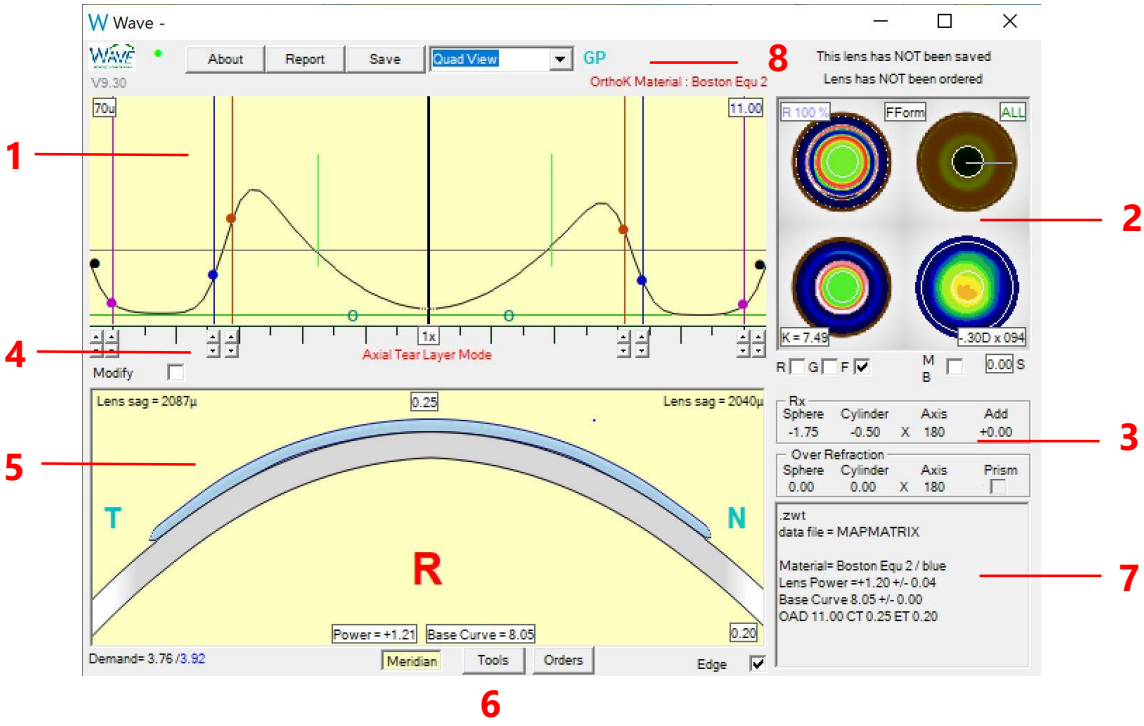
Depending on the Rx, corneal topography and the lens type, the WAVE lenses may be designed in Rotationally Symmetric (spherical shaped geometry), Geometrically Symmetric (toric shaped geometry) or Free Form (asymmetric).

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:

- Rotationally Symmetric (also referred to as RSym or **R**): Adjustment of 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 of 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 of one of the eight semi-meridians only affects that semi-meridian.

1.1. WAVE Software Overview

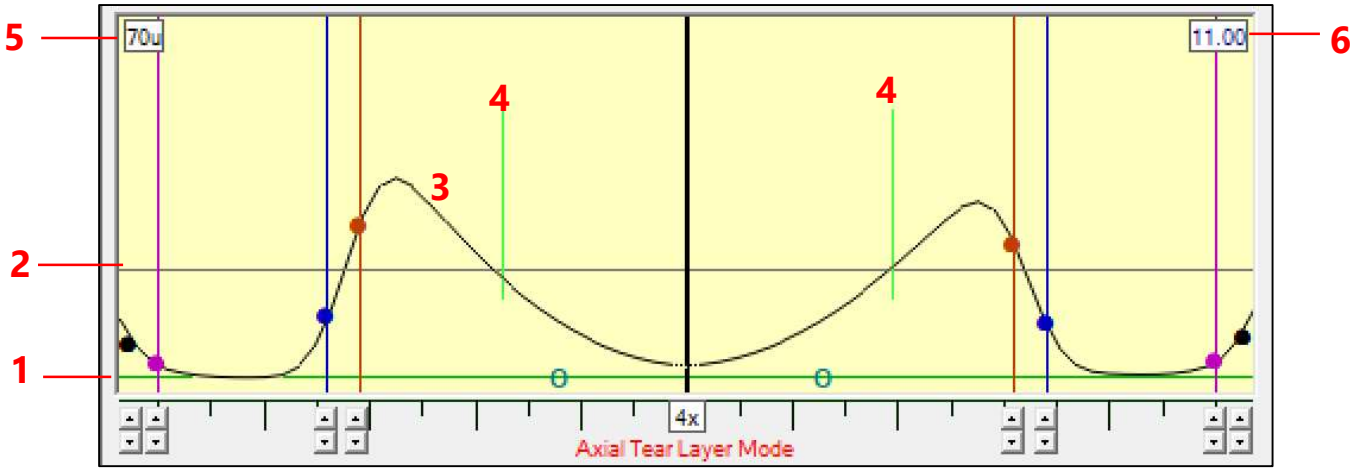
This is the WAVE Contact Lens design window. It consists of the following sections:



1. Tear Film Graph
2. Map View
3. Refraction and Over Refraction
4. Control Bar
5. Lens Profile View
6. Design Tools
7. Patient and Lens Data
8. Upper Bar

1.1.1. 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.



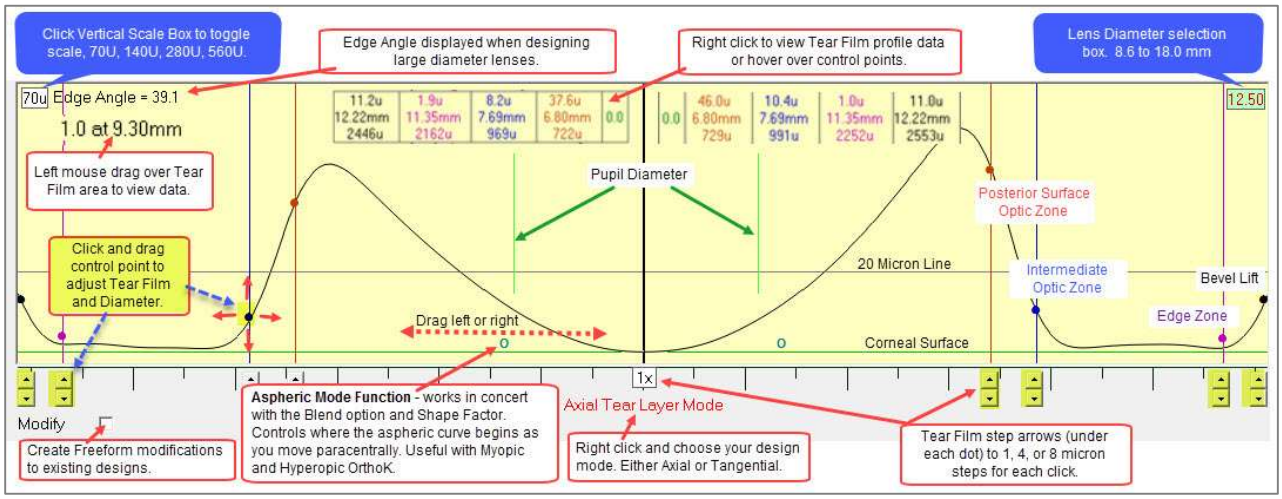
1. Green Horizontal Line: Cornea Surface
2. Dark Grey Horizontal Line: 20µ Line
3. Black Curved Line: Tear Layer Thickness (TLT) between the back surface of the contact lens and the cornea
4. Vertical Green Lines: Pupil Diameter
5. Scale (microns): Select 70 µ, 140 µ, 280 µ or 560 µ from drop down
6.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

Design modification control points:

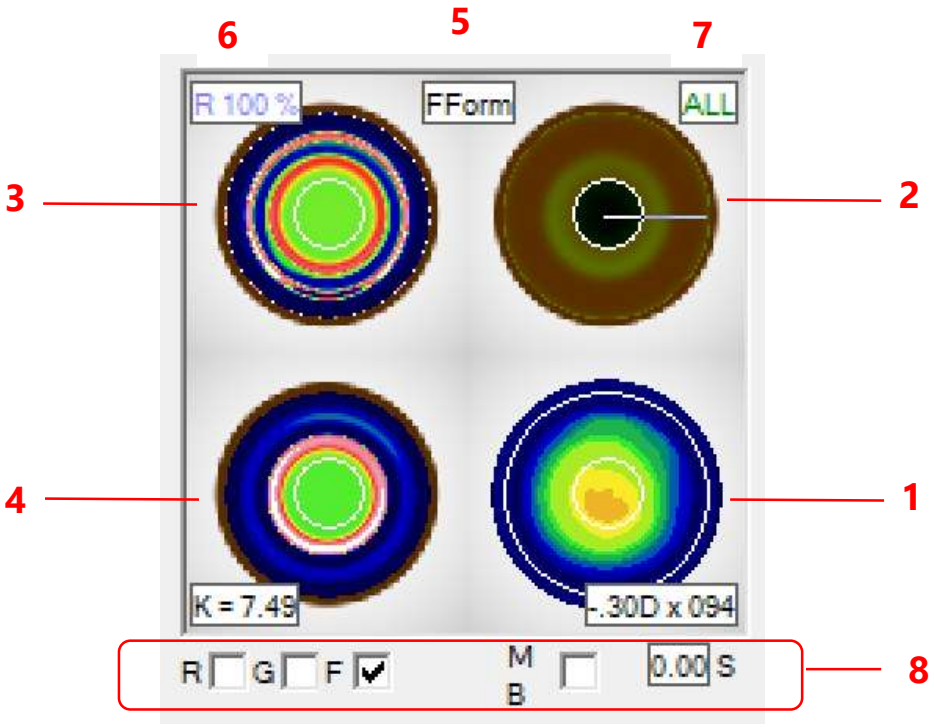
- Posterior Surface Optic Zone (OZ)
- Intermediate Curve (IC)
- Edge Zone
- Bevel Lift
- Aspheric Mode Function/ Location

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

More details:



1.1.2. Map View



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: (Located on top right corner of the design window)

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

Double click on any map to enlarge. Double click again to return to Quad View.

5. Shows the Free Form or Geometrically Symmetric view for the Tear Film Graph and Fluorescein Map. Click on **FForm** to switch to **GSym** view.

6. R 100%
   - R, L indicate Right Eye or Left Eye
   - Text in Blue means Peripheral Astigmatism is not averaged
   - Text in Red means Peripheral Astigmatism is Averaged
   - % of raw data captured (For Scout topographers only)

7. **ALL** This box shows how the adjustments are applied to the design:

   - Selecting **ALL** means changes made to the lens design along one semi-meridian, are applied to the entire lens (360 degrees). This mode can be used for R-Sym, G-Sym and FForm designs.
   - Selecting **1/2** means changes made to the lens design along one semi-meridian, are applied to 1/2 of the lens (180 degrees), with a gradually reduced effect. This can be used for G-Sym and FForm designs.
   - Selecting **1/4** means changes made to the lens design along one semi-meridian, are applied to 1/4 of the lens (90 degrees), with a gradually reduced effect. This can be used for G-Sym and FForm designs.

   See Table 1 for an example.

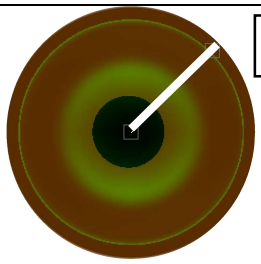
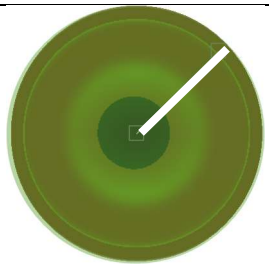
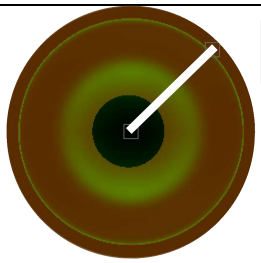
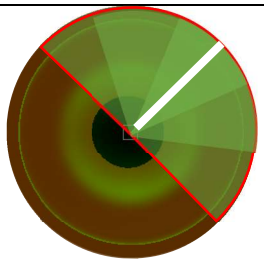
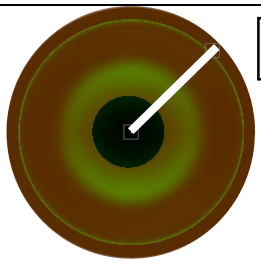
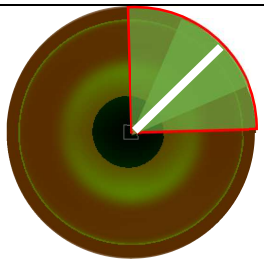
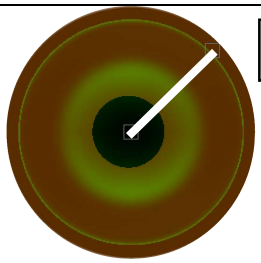
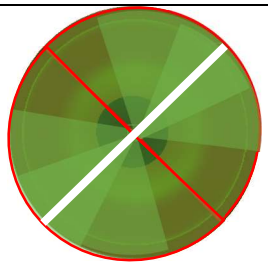
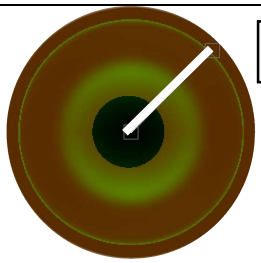
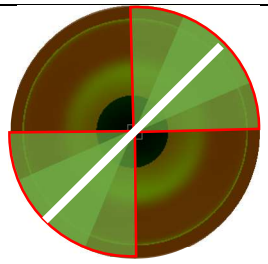
8. Design modes**: R, G, F**

   The check box shows the design mode: **R** (Rotationally Symmetric), **G** (Geometrically Symmetric), **F** (Free Form)

   S = Shape factor, Asphericity of Optic Zone

   MB = Minimal Blending when checked. When nonzero [S] value is selected, simplified optic zone asphericity is created. Applies to the back surface of the contact lens. Changes can be viewed in the Back Curvature Map.

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

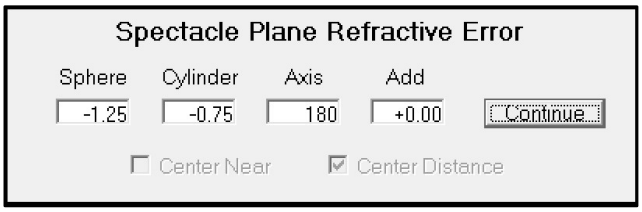
1.1.3. Refraction and Over Refraction

To design a lens for a patient, first we need to enter the refractive error.

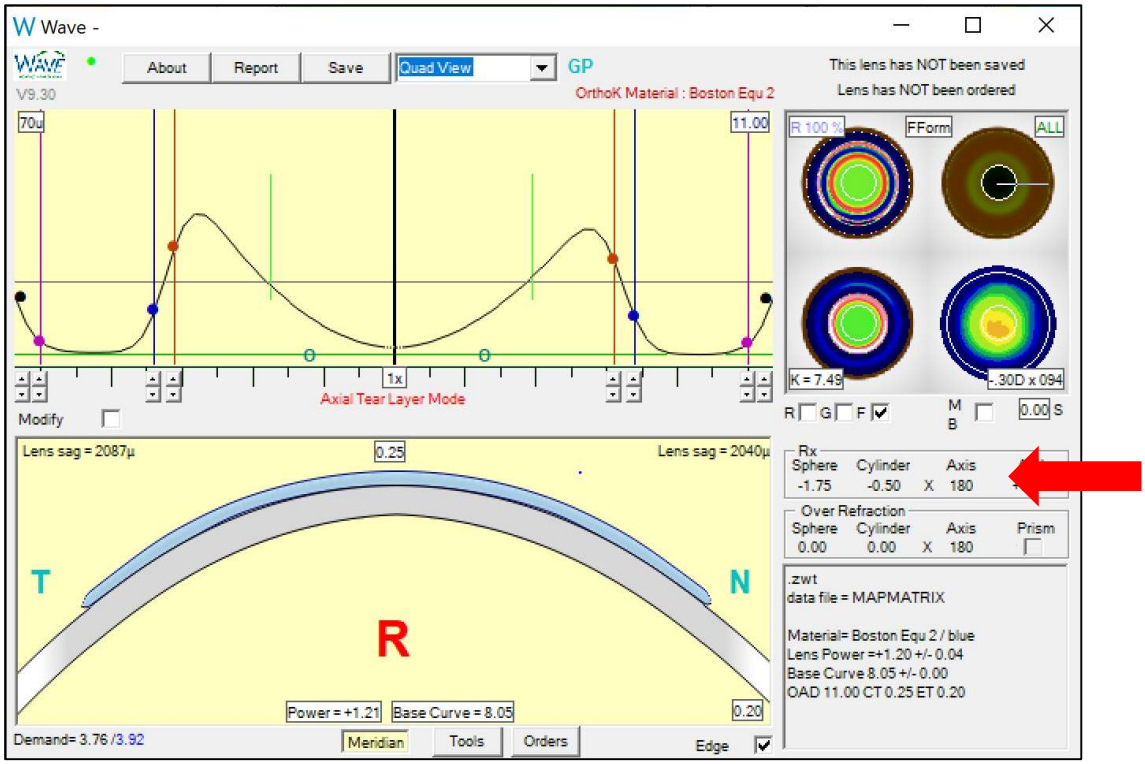
1.1.3.1 Enter Subjective Refraction

When you start a new lens design the Spectacle Plane Refractive Error dialogue box opens. Enter the Sphere, Cylinder and Axis. To make the contact lens multifocal, enter the Add value and select Center Near or Center Distance.

You can enter the refraction here in minus cylinder or plus cylinder form.



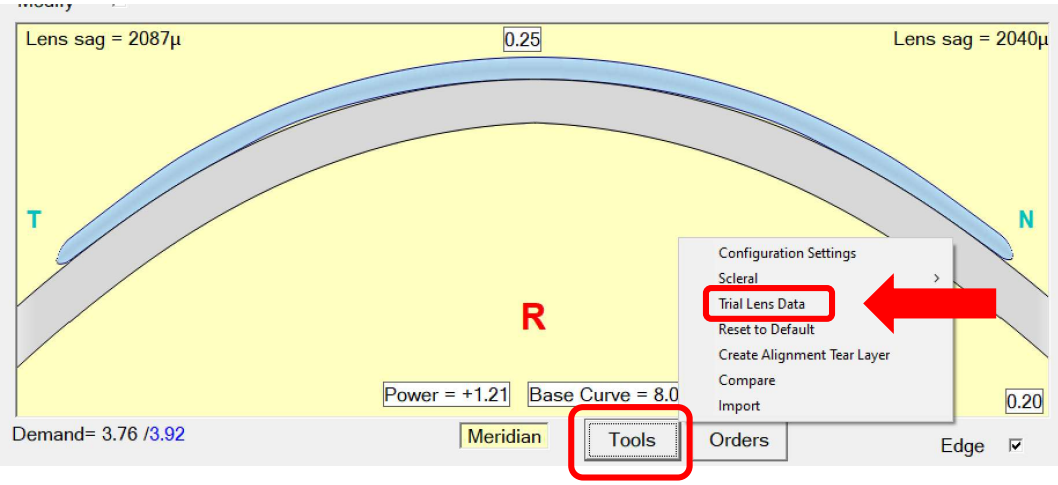
You can also open the Spectacle Plane Refractive Error box by clicking on the Rx section of the WAVE window.



1.1.3.2. Using a diagnostic GP trial lens to get an over-refraction

To make sure your refraction is accurate, you can use a diagnostic GP trial lens as a part of your diagnostic work-up to get a meticulous over-refraction. This step is particularly helpful if you have an overly complicated refraction or you do not trust the refractive data due to irregularities.

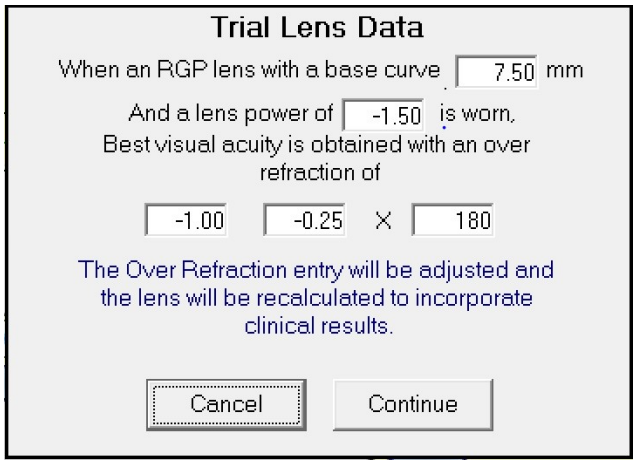
If you are using a trial lens for over-refraction, Click on TOOLS, select TRIAL LENS DATA.



In the dialogue box that pops up enter the trial lens details (base curve, lens power) and the over-refraction values.

The base curve of the trial lens should be as close to the K value as possible. When using a Scleral trial lens, for best results the trial lens should vault and not touch the central cornea.

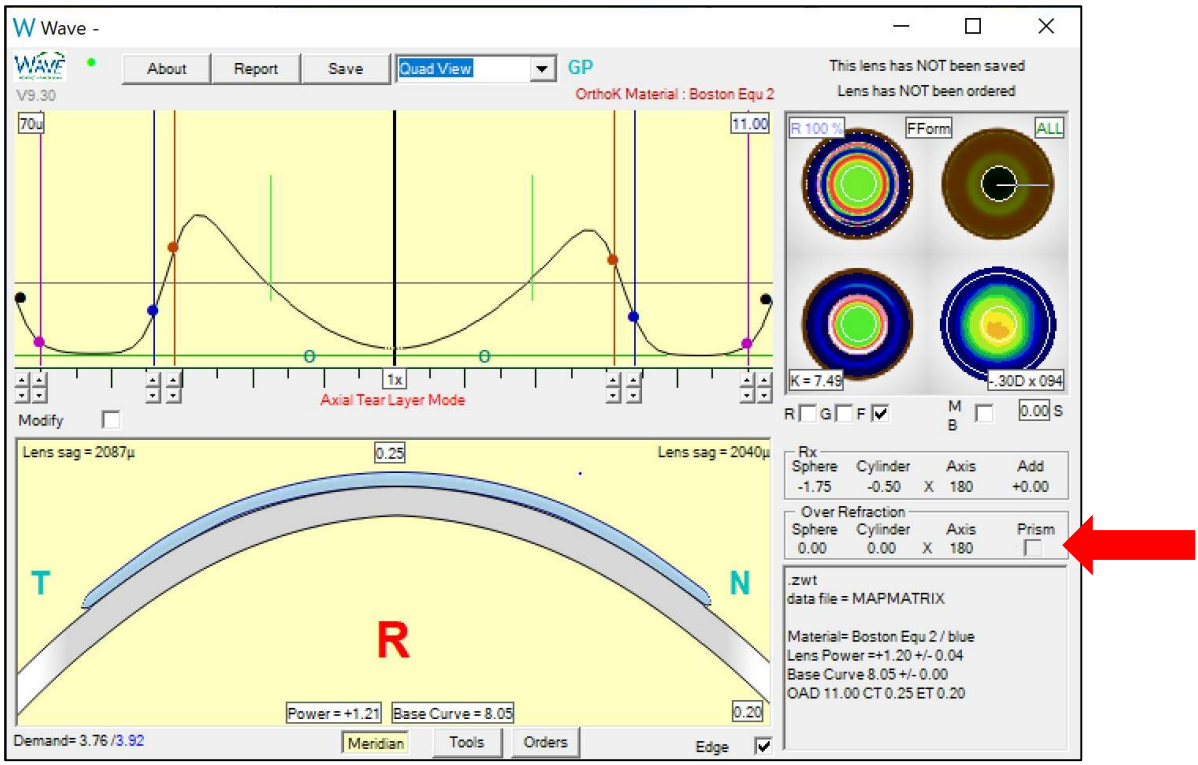
Click CONTINUE.



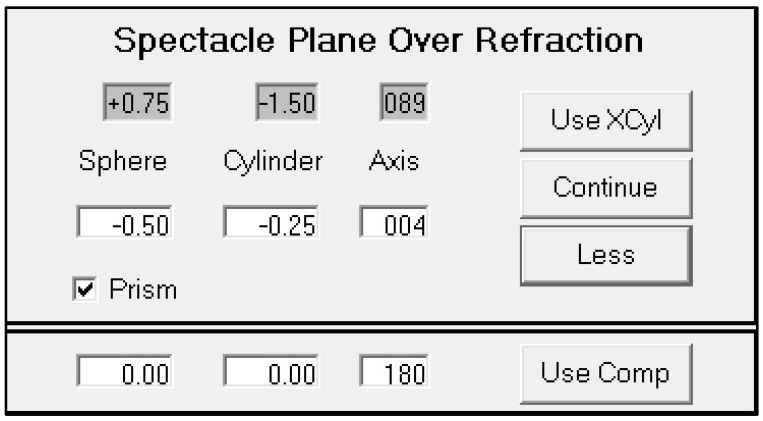
1.1.3.3 Over-Refraction and Compound Refraction

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 section of the WAVE window.



A dialogue box pops open.

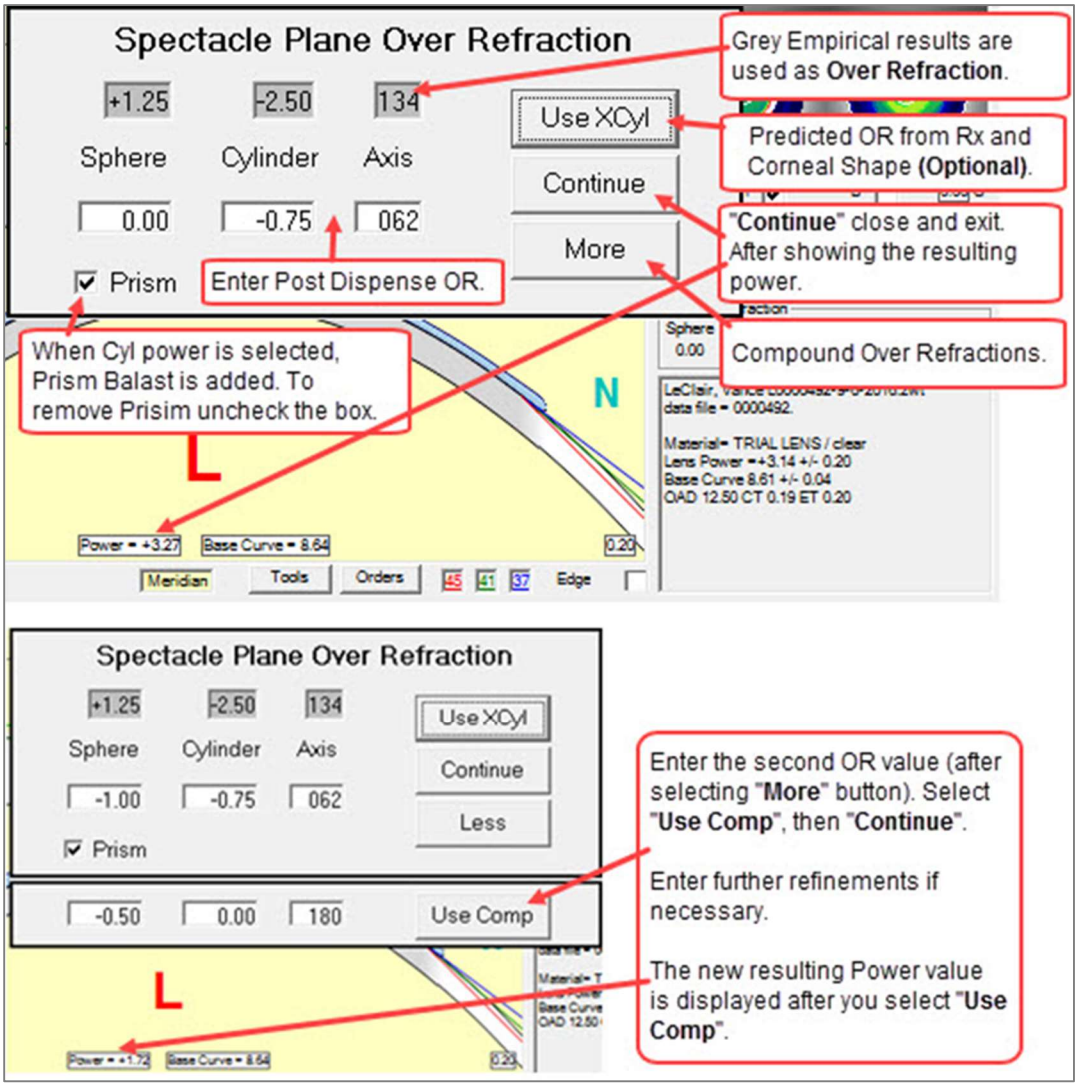


In the white boxes, you can enter the Over Refraction of the WAVE lens and click CONTINUE.

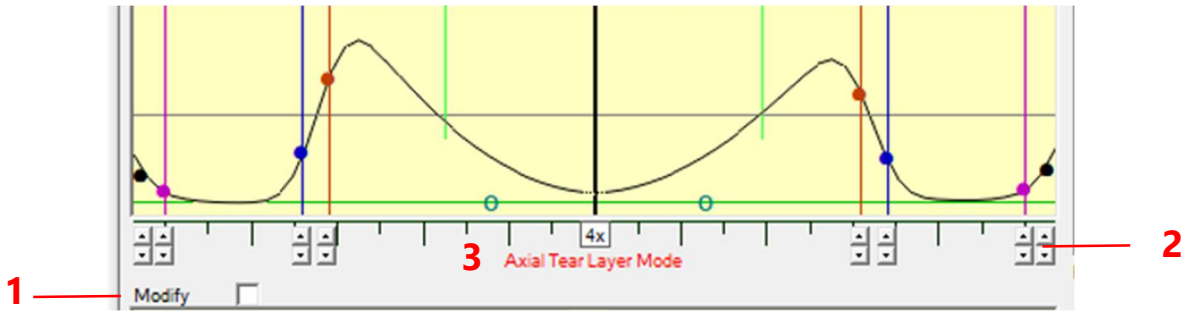
If the addition of this Over-Refraction to the re-designed lens does not achieve the desired VA, resulting in a subsequent Over-Refraction, it too can be added using the Compound Over-Refraction Tool. To enter Compound Over-Refraction, click on MORE, enter the Over-Refraction and click on USE COMP, then click on CONTINUE.

To improve lens stability, you can check the Prism checkbox to add prism ballast to the front surface of the lens.

The greyed-out boxes show the predicted Over Refraction calculated by WAVE software based on spectacle prescription and corneal shape. If you click on "Use XCyl", grey empirical results will be used as the Over-Refraction.



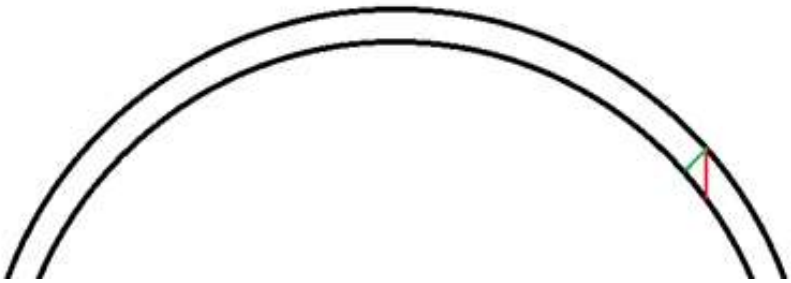
1.1.4. Control Bar



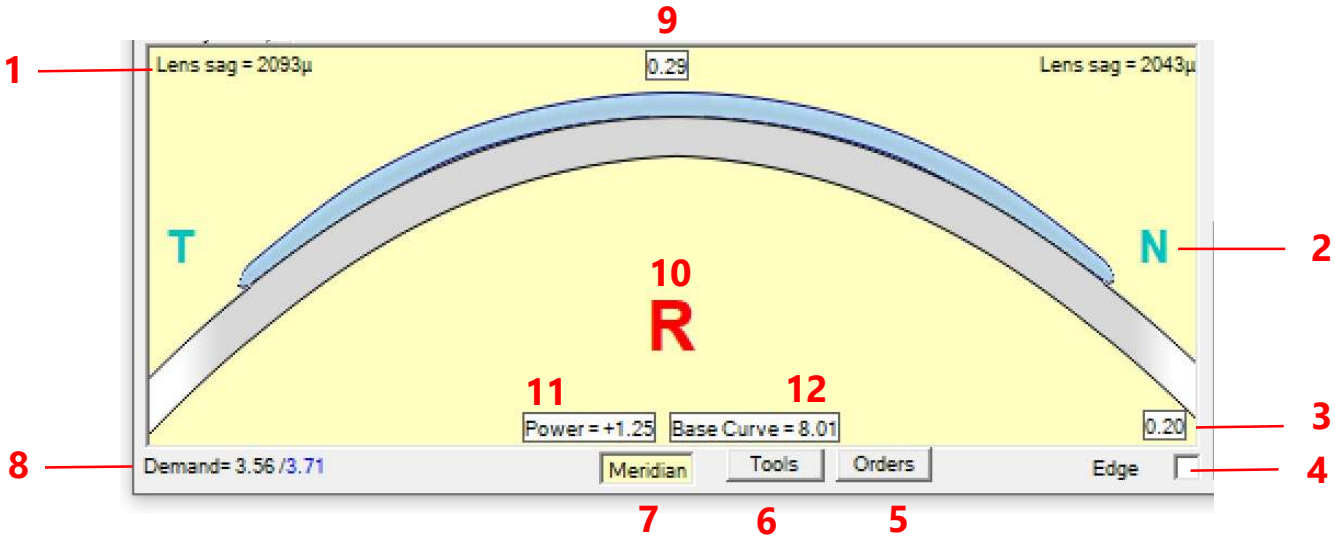
1. **Modify:** Checking this box allows the user to make FreeForm modifications to the periphery of an Rsym or Gsym lens. The red control points are not modifiable, which reduces the risk of making accidental unwanted changes to the base curve, lens power, and optic zone width. Only the blue, pink, and black control points may be modified.

2. **Up/Down Arrows**: can be used to increase or decrease the Tear Layer Thickness in 1µ, 4µ or 8µ steps at each control point (red, blue, pink, black). 1x means each click on the up or down arrow moves the control point by 1 micron. You can click on 1x to change it to 4x or 8x to move the control points up or down in larger steps.

3. **Tear Layer Mode**: The Tear Layer Mode is displayed under the tear film graph. 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.

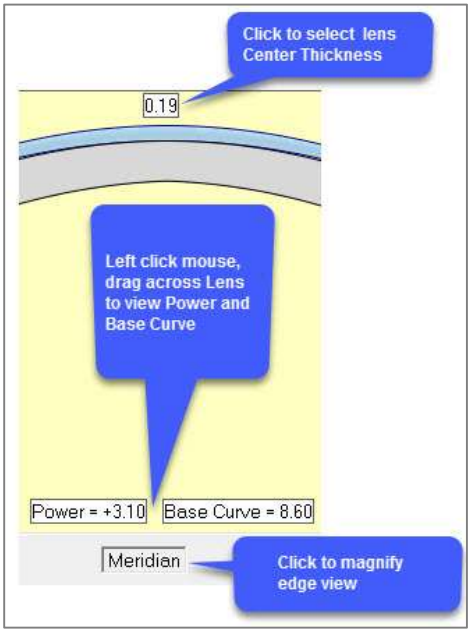


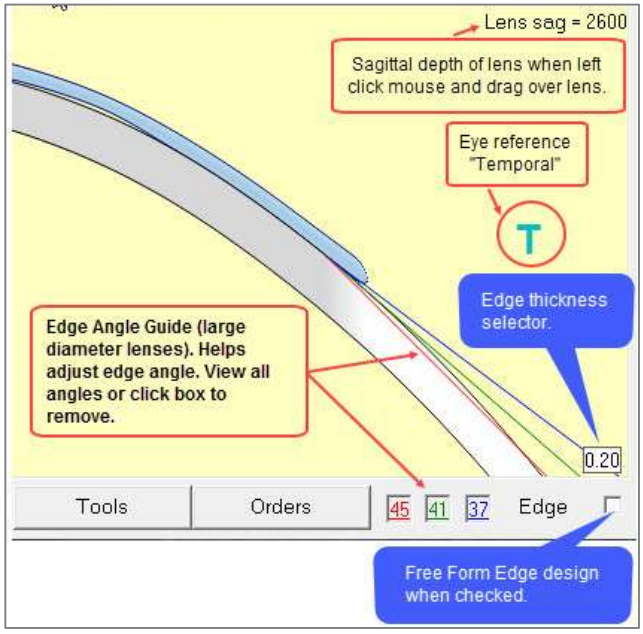
1.1.5. Lens Profile View



1. **Lens Sag**: Sagittal depth at Lens Edge (microns)
2. **Orientation of the lens** – **N** for Nasal, **T** for Temporal, **I** for Inferior, **S** for Superior
3. **Lens Edge Thickness:** Click and modify from dropdown menu
4. **Edge:** Free Form Edge Design. Checking this box can improve the edge design.
5. **Orders:** Opens window to initiate the ordering process
6. **Tools:** Opens window for Design Tools
7. Click to switch between **Meridian** or **Edge** views of the lens profile.
8. **Demand**: The first number displayed is the Average Corneal Curvature in central 3mm. The second number displayed is the Average Keratometry of Topography.
9. **Center Lens Thickness:** Click and modify from dropdown menu
10. **R** for Right Eye, **L** for Left Eye
11. **Power:** Resultant Contact Lens Power in the semi meridian displayed
12. **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 lens because the base curve may be different on one side than the other. Hover over to display diopters.

More details:

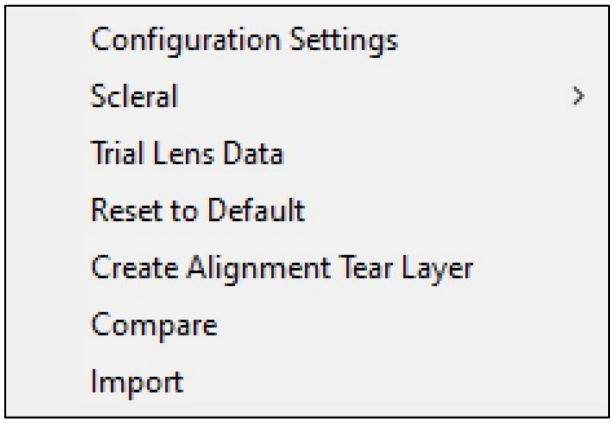




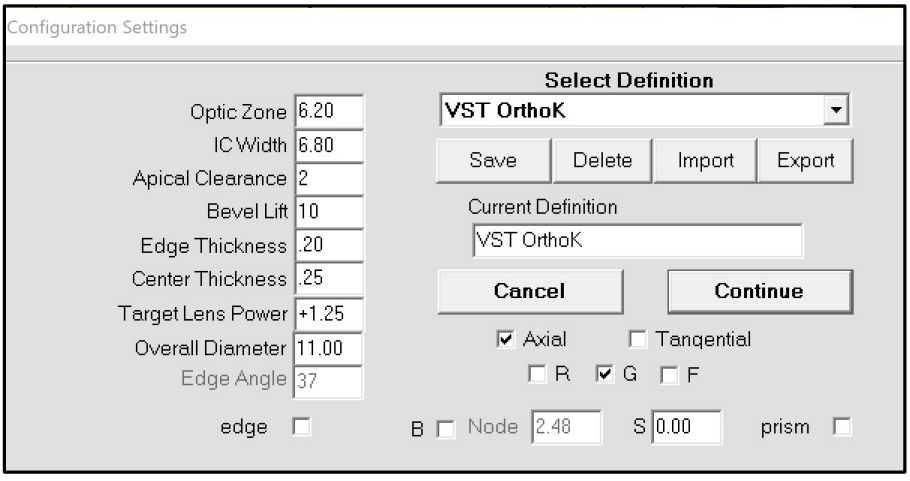
1.1.6. Design Tools

The design tools are located at the bottom of the WAVE design window.

Tools

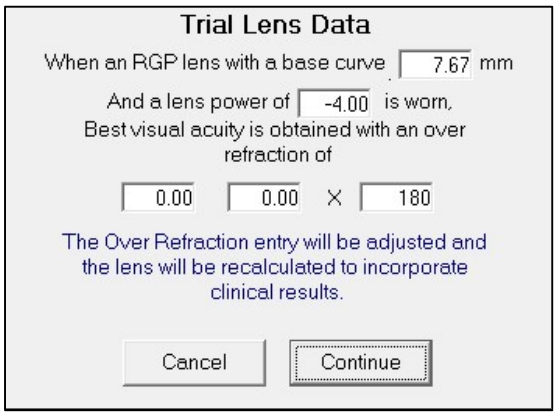


- **Configuration Settings**: Select a starting point with WAVE designs from pre-defined parameters. Lens designer can save their preferred lens parameters for future access. To design an Ortho-K lens within the VST approved range of treatment, select the **VST OrthoK** option from the **Select Definition** dropdown menu.



- **Scleral**: is used to design a Scleral Lens or to modify a previously designed Scleral lens.

- **Trial Lens Data:** is used to enter over-refection from a trial lens.



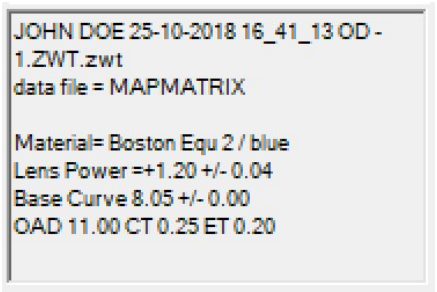
- **Reset to Default:** Resets parameters back to original source topography import but does not adjust lens geometry back to original.

- **Create Alignment Tear Layer** (in earlier versions of the software, this was labeled as ***Current Settings***): Can be used for designing corneal GP lenses. It 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.

- **Compare**: To compare two WAVE lens designs in the same window

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

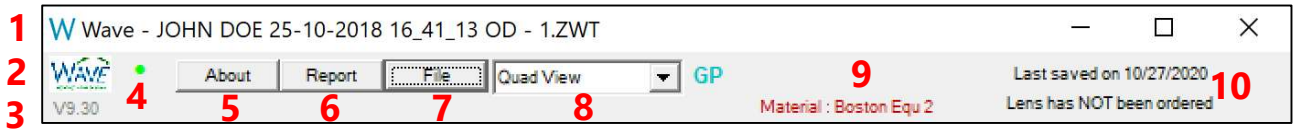
1.1.7. Patient Data



This section provides a summary of the lens design and patient information.

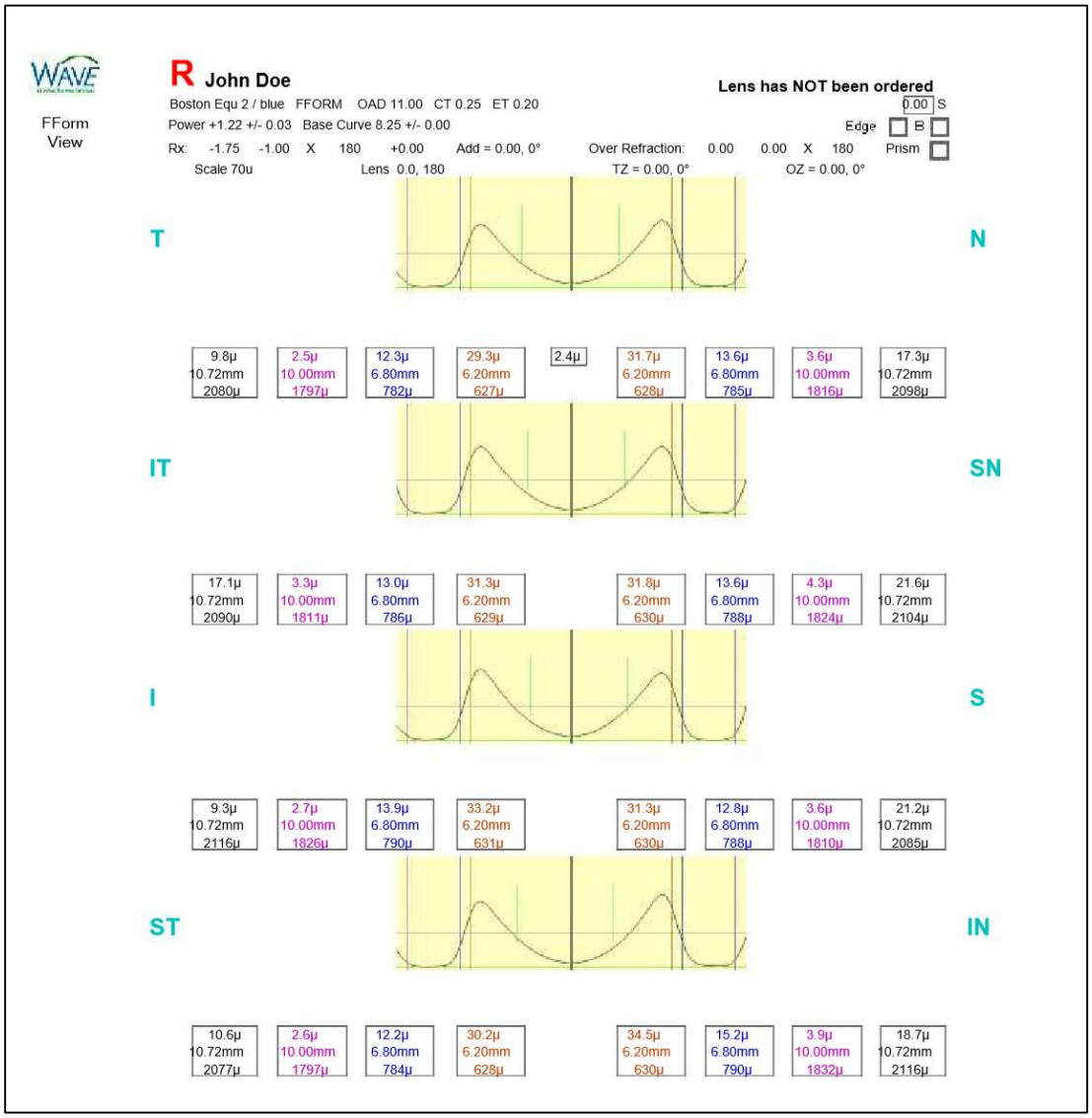
- **Design Sequence:** File name, which eye, version of lens design
- **Material:** Selected lens material which can be modified in the laboratory order form
- **Lens Power:** Displays the average lens power from the center to 1.5mm from the apex (central 3mm) and gives the range of powers in all meridians.
- **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
- **ET:** Edge Thickness

1.1.8. Upper Bar



1. **Design Sequence**: File name, which eye, version of lens design
2. **WAVE Logo:** Hover over WAVE logo and last saved date will display
3. **WAVE software version** the lens was designed in or will be designed in
4. **Status Indicator:** Red ● (design in process), Green ● (design is completed)
5. **About:** Information about the WAVE software version, Order Folder location path, Design File Folder location path and quick links to Internet Order Status System, training and support webpages.

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



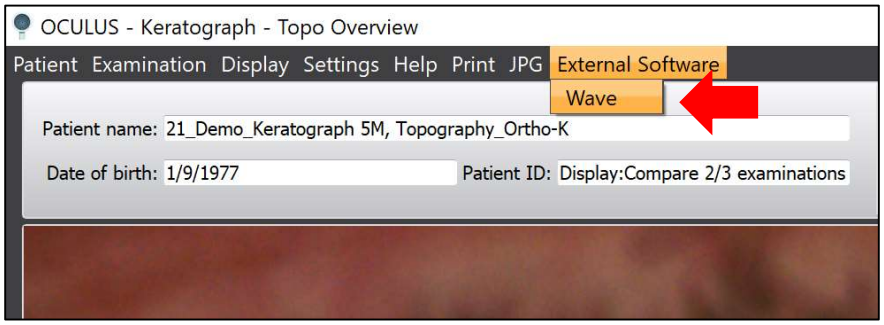
7. **Save/File**: Saves the lens design. File provides options for New Simulation, Load or Save.
8. **Maps View Selection:** Dropdown menu to select maps view
9. **Lens material:** Defaults to material used for the last design. This can be easily changed when you save and order the new design.
10. **Status of the Lens Design:** Saved (date) or Not Saved, Ordered (date) or Not Ordered

2. Data Import

Always start with a good quality topography map. Check the map for coverage and repeatability. If you are using a Placido topographer, examine the quality of the mires. Poor tear quality, Dry Eye Syndrome, and excessive tearing can interfere with the results of a Placido topographer. If you are using an OCULUS Pentacam® or a Keratograph® check the QS (Quality Specification).

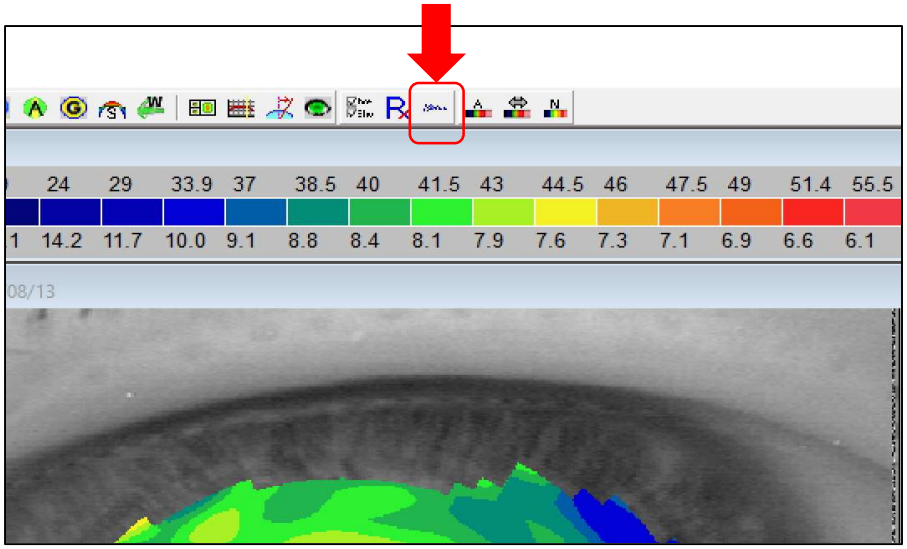
2.1. Data Import from the OCULUS Pentacam® and Keratograph®

Open the Pentacam® or Keratograph® patient data management software. Select a topography map. Click on EXTERNAL SOFTWARE and select WAVE.



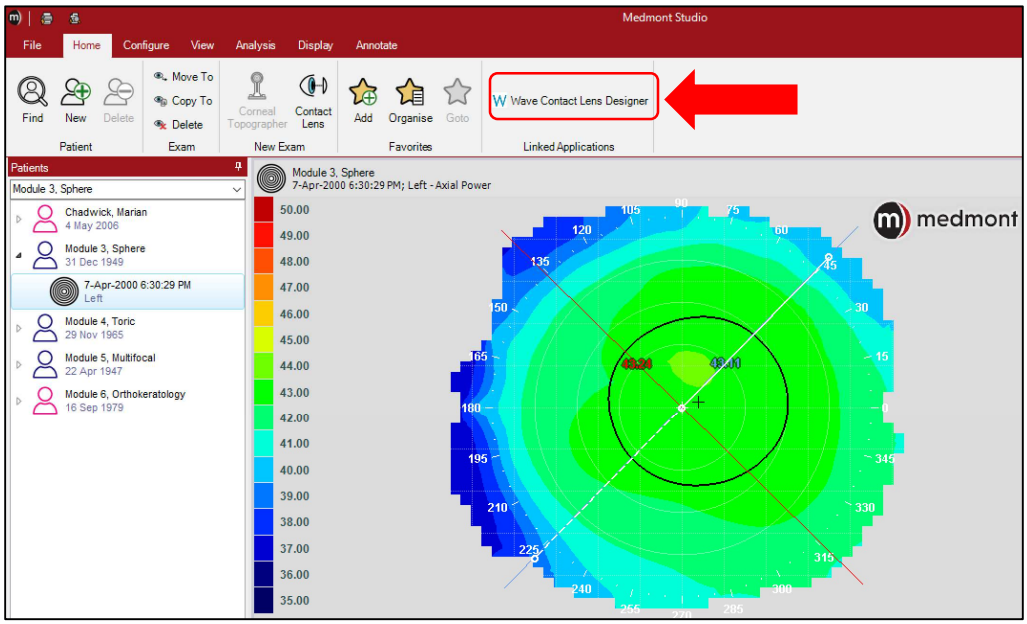
2.2. Data Import from the Keratron Scout Topographer

Open the Keratron software and select a topography map. Click on the WAVE icon to import the topography into the WAVE software.



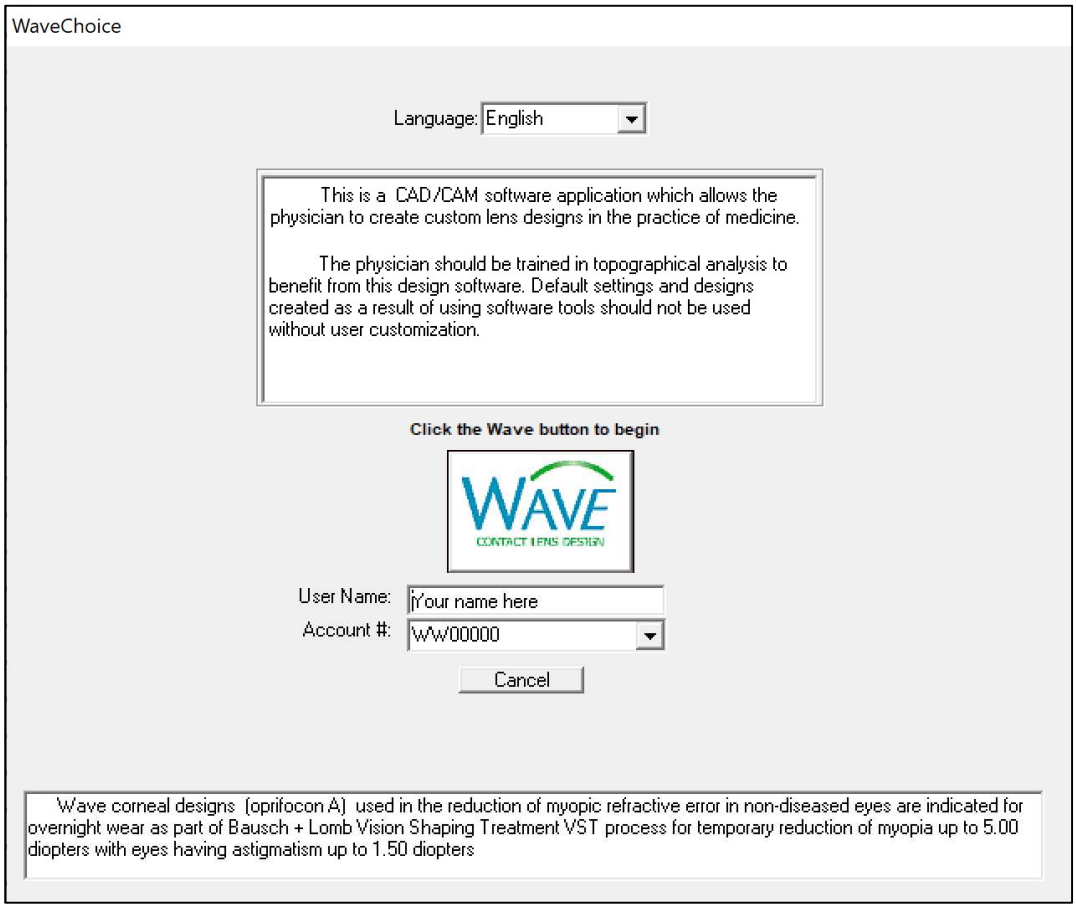
2.3. Data Import from the Medmont Topographer

Open the Medmont software, select a topography map and click on the HOME tab. Click on the WAVE icon in the LINKED APPLICATIONS section to import the data into WAVE.



If you do not see WAVE listed as an option on your topographer, please contact WAVE technical support for assistance.

To complete the import of the topography data from your corneal topographer into WAVE, please follow the prompts. Enter your WAVE username and account #, then click on WAVE logo to open the software. Patient's topography will be imported into WAVE.

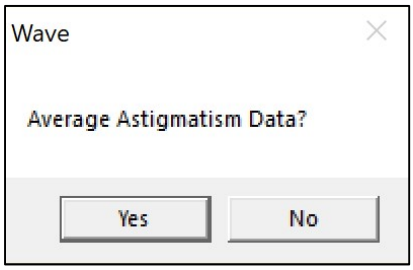


When the WAVE software opens you may be asked if you want to Average Astigmatism. If you choose to average the astigmatism data, as WAVE is importing the topography, it averages out the data along each Meridian to make it a little more consistent. For the OrthoK and Scleral lenses, select NO.

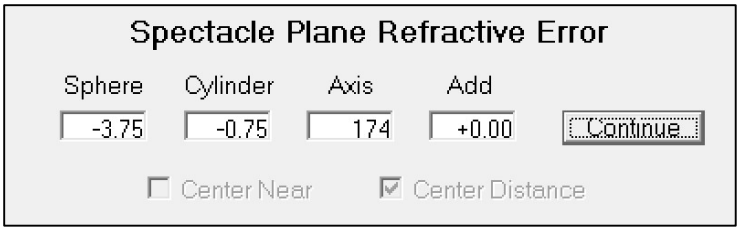
3. Design a WAVE Lens

3.1. Design a Single Vision or Toric Corneal GP Lens

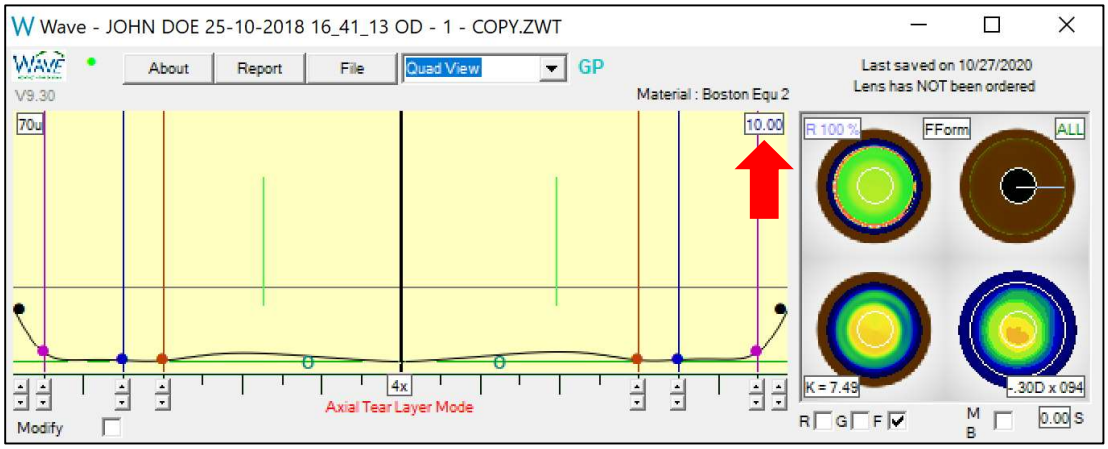
- Import the corneal topography data into WAVE.
- **Average astigmatism?** This refers to the peripheral astigmatism, not the central astigmatism. Select YES if you would like to smooth out the source topography map. Select No if you would like to use the original source topography map for lens design.



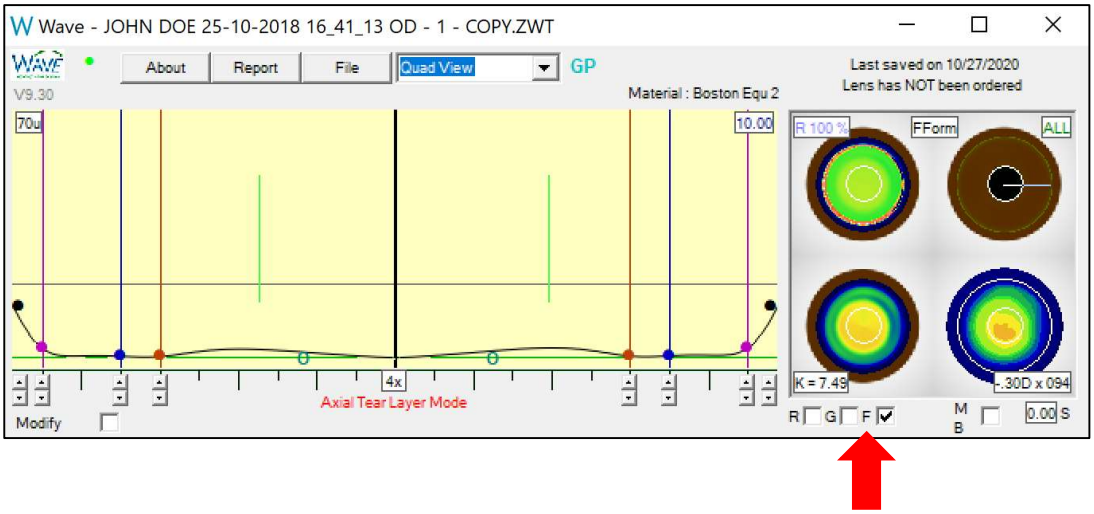
- Enter the spectacle Rx. You may choose to also enter the trial lens over-refraction. To enter trial lens over-refraction, go to Tools and select Trial Lens Data.



- You can change the lens diameter based on the patient's corneal diameter.



- Select the design mode: **R** (Spherical), **G** (Toric) or **F** (FreeFrom).



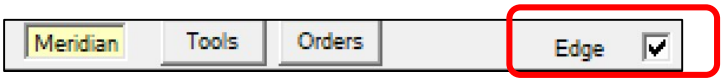
WAVE software presents an initial custom lens design for a corneal GP lens based on the source topography map and the designer's input.

Review the design:

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 traditional landing zone (between blue and pink balls). Here, we want to avoid considerable down turning or too much of an upturn. This is important for lens stability and comfort.

If you design in Freeform, checking the **Edge** box at the bottom of the design window can improve the edge design.



Modify the design:

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

The red balls control the Posterior Surface Optic Zone (OZ) and lens power. The Blue balls control the Intermediate Curve (IC). The Pink balls control the Edge zone and the Black balls control the Bevel lift.

You can drag the control balls to adjust the tear thickness and zone diameter. As you do that, the amount of change is shown in upper left corner.

Use the up/down black arrows to move the control balls up and down to adjust the tear layer thickness as needed. Adjustments can be made in 1, 4 or 8 micron steps. Click on 1x to change the steps.

As the parameters are modified, WAVE redesigns the lens. While WAVE is processing the data and designing a lens, a red indicator is displayed next to WAVE Logo. When it turns green, it means the data processing is completed.

Check, Save, and Order the Lens

Before ordering the lens, please review the design and make any final modifications. Here is a checklist:

- ✓ Check the Lens Diameter
- ✓ Check Refraction and Over-refraction
- ✓ Check different meridians for lens alignment
- ✓ Look for appropriate edge clearance and a nice edge profile
- ✓ Check back surface of the lens (Quad View lower left or Back Curvature Map). You are looking for a nice smooth transition line. Minor adjustments can be made to smooth out the design, but it is not necessary.
- ✓ Make sure the lens central thickness and lens edge thickness are set appropriately. 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.
- ✓ Check the Simulated Fluorescein map to assess how the lens will sit on the eye.
- ✓ SAVE your design. The laboratory order form opens.

On this page you have the option to enter Patient info, Shipment and delivery method. You can also choose the material, color, lens coating and other instructions for the lab. You may want to add dots and lines to the lens.

You can use the comment box for Message to WAVE. Please note that adding a message to WAVE may delay the order. The Clinical Notes comment box is for your own reference only and will not be reviewed by the lab.

To place an order, click on ACCEPT. (See Orders section of this manual for more details)

3.2. Orthokeratology Lens: 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)
    - Children/Young Adults
- Examine the corneal topography and elevation maps for 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.
- Confirm the patient is a good candidate for Orthokeratology.

Patient Selection for Orthokeratology:

The range of myopic correction reduction approved with Vision Shaping Treatment is minus one to minus five diopters. 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 GP and PMMA lens wearers. Current GP 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 di sorders, dystrophies or contra-indications to GP lens wear.

Good Candidates:

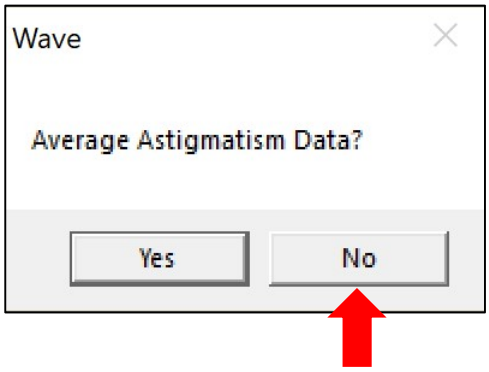
- ✓ Flat K readings between 40 D and 46 D
- ✓ Moderate to low level myopes (-1.00D to -5.00D)
- ✓ ≤1.50D with-the-rule (WTR) astigmatism or ≤ 0.75D against-the-rule (ATR) astigmatism
- ✓ Corneal eccentricity ("e" values) of 0.5 and higher
- ✓ Soft lens / spectacle wearers

Poor Candidates:

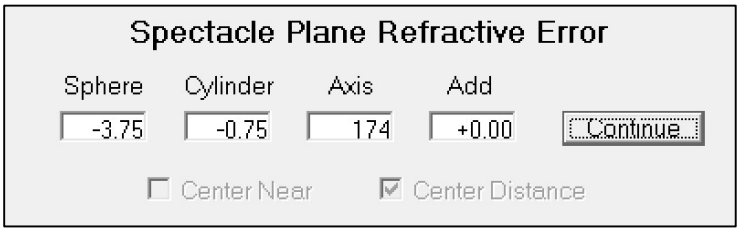
- × Against the rule astigmatism > 0.75D
- × Low corneal eccentricity

WAVE Ortho-K Lens Design Steps

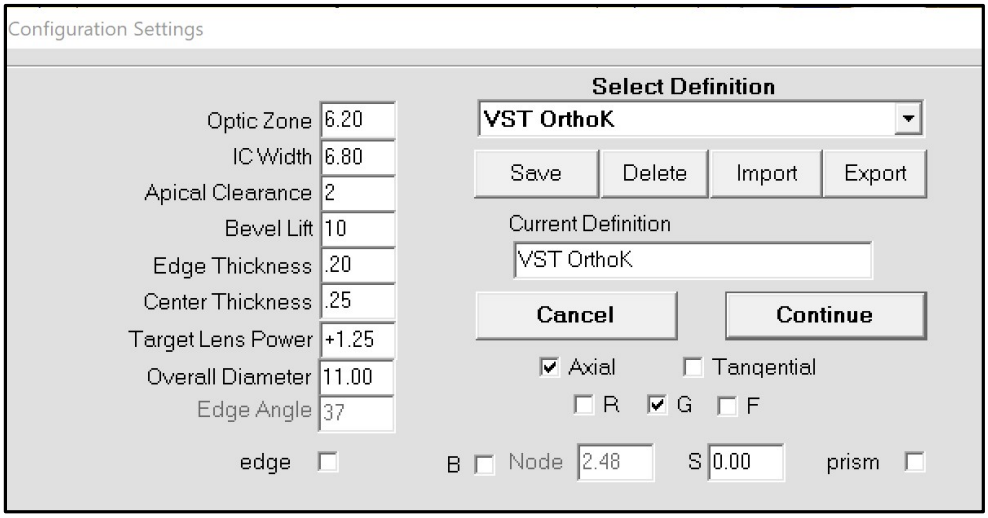
- Import the corneal topography into WAVE.
- Average astigmatism? Select **No** for Ortho-K.



- Enter the spectacle Rx.



- Go to **Tools** and select **Configuration Settings**. This window will open:



- Under **Select Definition**, choose **VST OrthoK** from the drop-down menu.

Let's review the design parameters:

Optic Zone (Optic Zone diameter =**OZ)**

By default, the standard OrthoK 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 Width (Intermediate Curve = **IC**)

The typical IC setting is 0.6 mm larger than OZ. By default, the standard OrthoK design will use an OZ of 6.2mm, and an Intermediate Curve width of 6.80. This **0.6 mm** area is good for an OrthoK 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.

Apical Clearance (AC)

The default apical 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.

Bevel Lift (BL) and Edge Thickness (ET)

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

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 cyl, the more likely a CL will warp, causing incomplete astigmatism molding. Increasing the CT will reduce lens warp and allow more of the corneal cyl to be corrected.

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

Target Lens Power (TLP)

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 increased to +1.50D, +1.75D or +2.00D.

Overall Diameter (DIA)

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 OrthoK 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/dellen/raised epithelial defect, make the lens diameter > 0.5 mm smaller than the innermost location of the lesion.

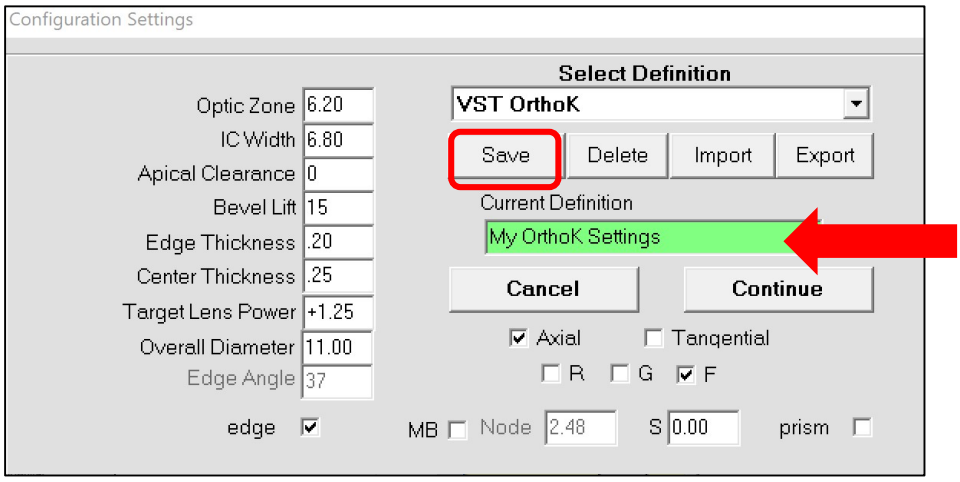
Design Modes

Axial design mode is selected by default. WAVE designers have a choice to design their lenses using the Tangential or Axial Tear Layer Mode. Selecting the Axial mode will provide a snug fit and a good seal in the alignment zone, which will aid in lens centration.

A WAVE NighLens® 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.

Customize and save your settings for future use:

If the settings have been customized to meet the OrthoK fitting philosophy of the practitioner, the settings can be renamed, saved and easily used for future designs. Simply type the desired name in the **Current Definition** box to rename the settings and **Save** the definition. It will be available in your dropdown menu from this point on.



- To proceed with the OrthoK lens design, click **Continue**. WAVE will now calculate the initial lens design.

Check, Save, and Order the Lens

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 bevel 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 cyl = Corneal cyl, make the CT thicker than normal (~ 0.26 mm) to help prevent lens flexure. In cases where Refractive cyl < Corneal cyl, make the CT thinner than normal (~0.18 mm) to promote lens flexure.
- For more details, please refer to the check list in the previous section of this manual.
- Proceed to save and order the lens.

Making modifications to a WAVE Ortho-K Lens:

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.

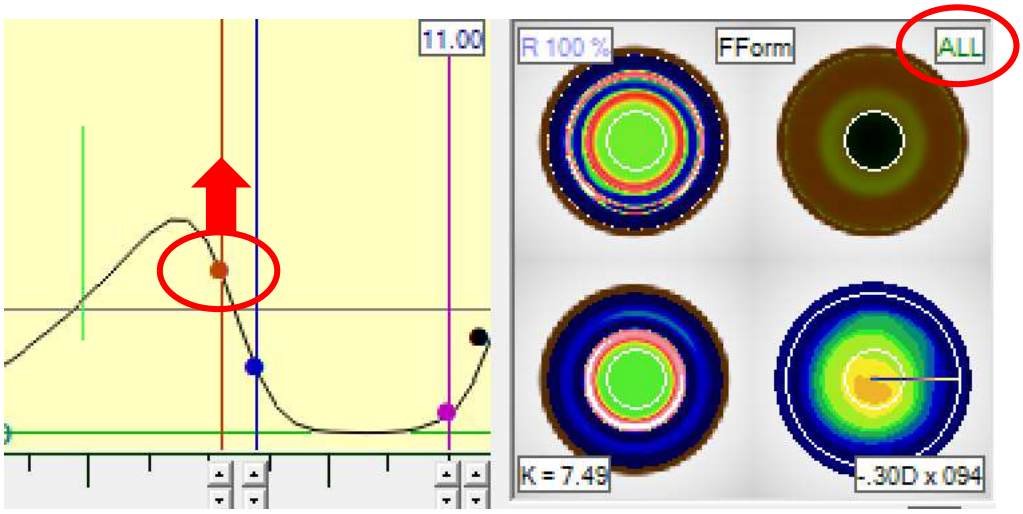
Here are the most common adjustments to the treatment:

How to Increase the Treatment amount?

If the patient is not fully corrected with the lens and you need to increase the treatment amount, you can raise the red control point in the Tear Layer Display. Doing so will flatten the BC and increase the lens power.

Be sure to set the modification option (top right display in the Quad Window) to ALL.

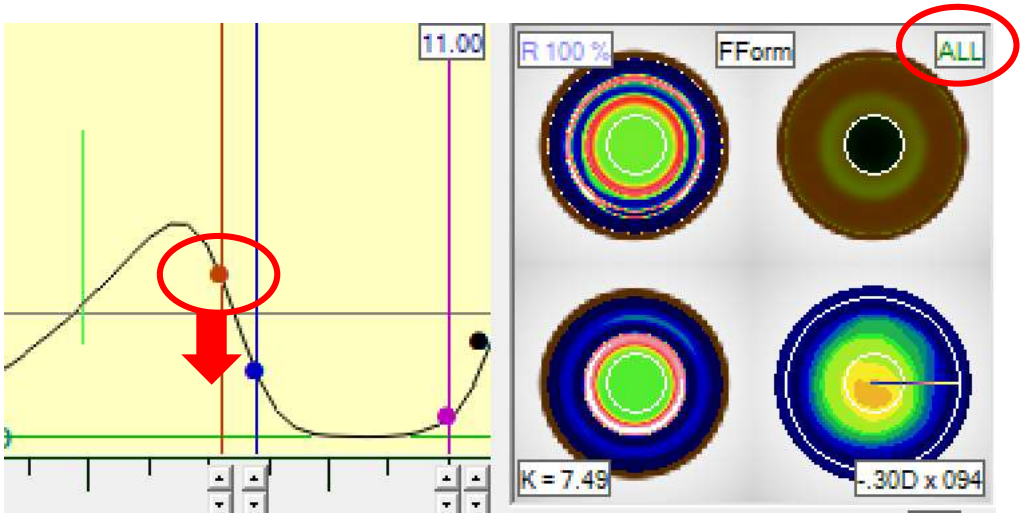
Not doing this will create a lens with multiple irregular base curves and lens powers!



How to Decrease the Treatment amount?

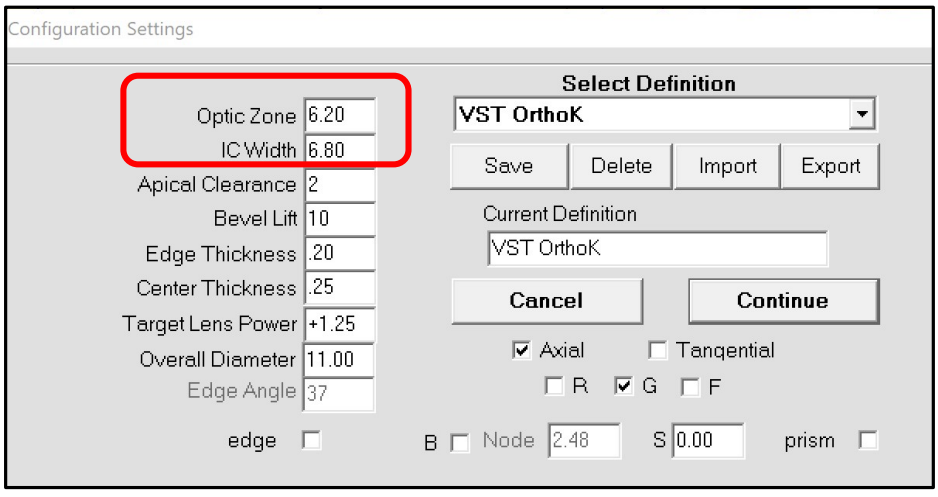
If the treatment over corrects the patient and you need to decrease the treatment amount, you can lower the red control point in the Tear Layer Display. Doing so will steepen the BC and decrease the lens power.

Be sure to set the modification option (top right display in the Quad Window) to ALL. Not doing this will create a lens with multiple irregular base curves and lens powers!



How to change the Optic Zone (OZ) and Intermediate Curve (IC)?

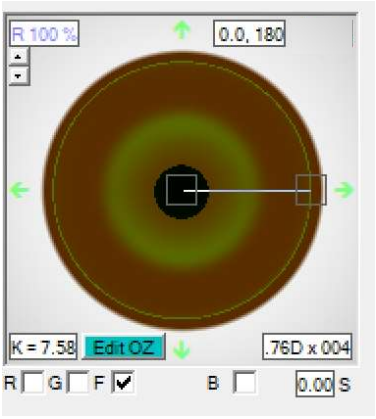
To modify OZ and IC it is recommended to go back to **Tools >> Configuration Settings** and use the auto design. This will reduce the risk of mistakenly changing the design if the setting is inadvertently set at **1/2** or **1/4** (top right corner of Map View).

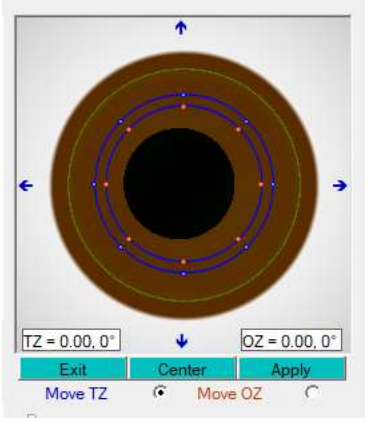


How to modify the Treatment Zone? (Edit OZ is only available for FreeForm designs)

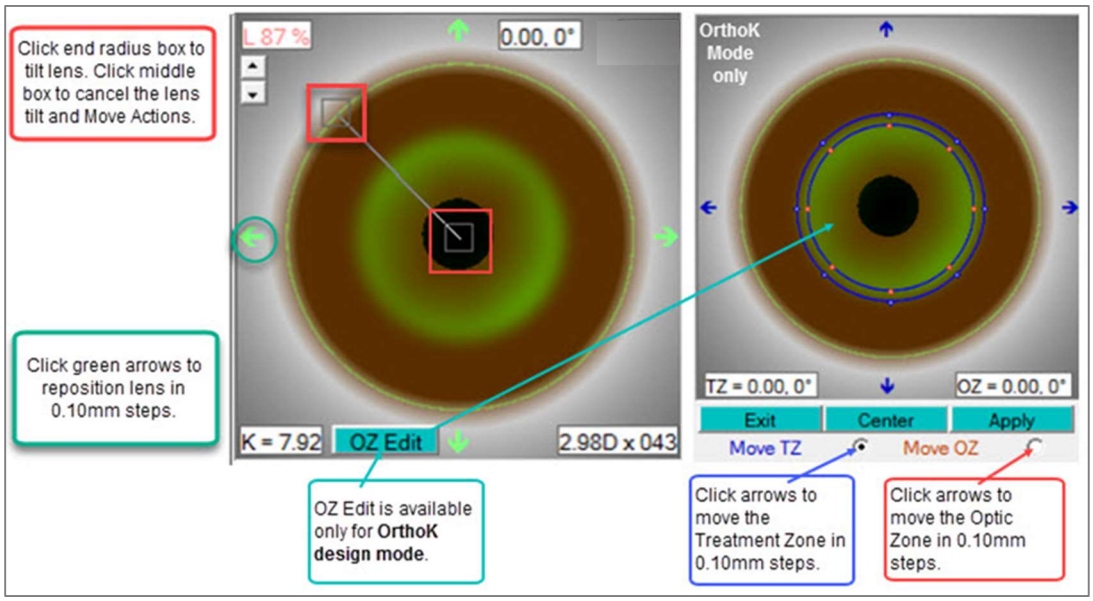
An important indicator of potential flare or glare is the proximity of the molding transition zone to the pupil diameter.

To modify the treatment zone, double click on simulated fluorescein map to enlarge it. You will see the "Edit OZ" button under the fluorescein map. Select "Edit OZ" to move Treatment Zone or Optical zone in 0.1 mm steps using the arrows. Apply the changes.





Watch the simulated fluorescein map and the tear graph as you make modifications. When you are finished with modifications, click on "Exit".



Recommended Progress Visits:

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 1st night of overnight wear, and then at one week, two weeks, one month, two to three months, and every six months thereafter.

At each progress visit, check unaided visual acuity and take topography maps. Perform Biomicroscopy and manifest refraction. Examine lenses for warpage and lens cleanliness. Review and reinforce wearing and lens care regimen.

Visits should be scheduled 6 to 8 hours after lens removal.

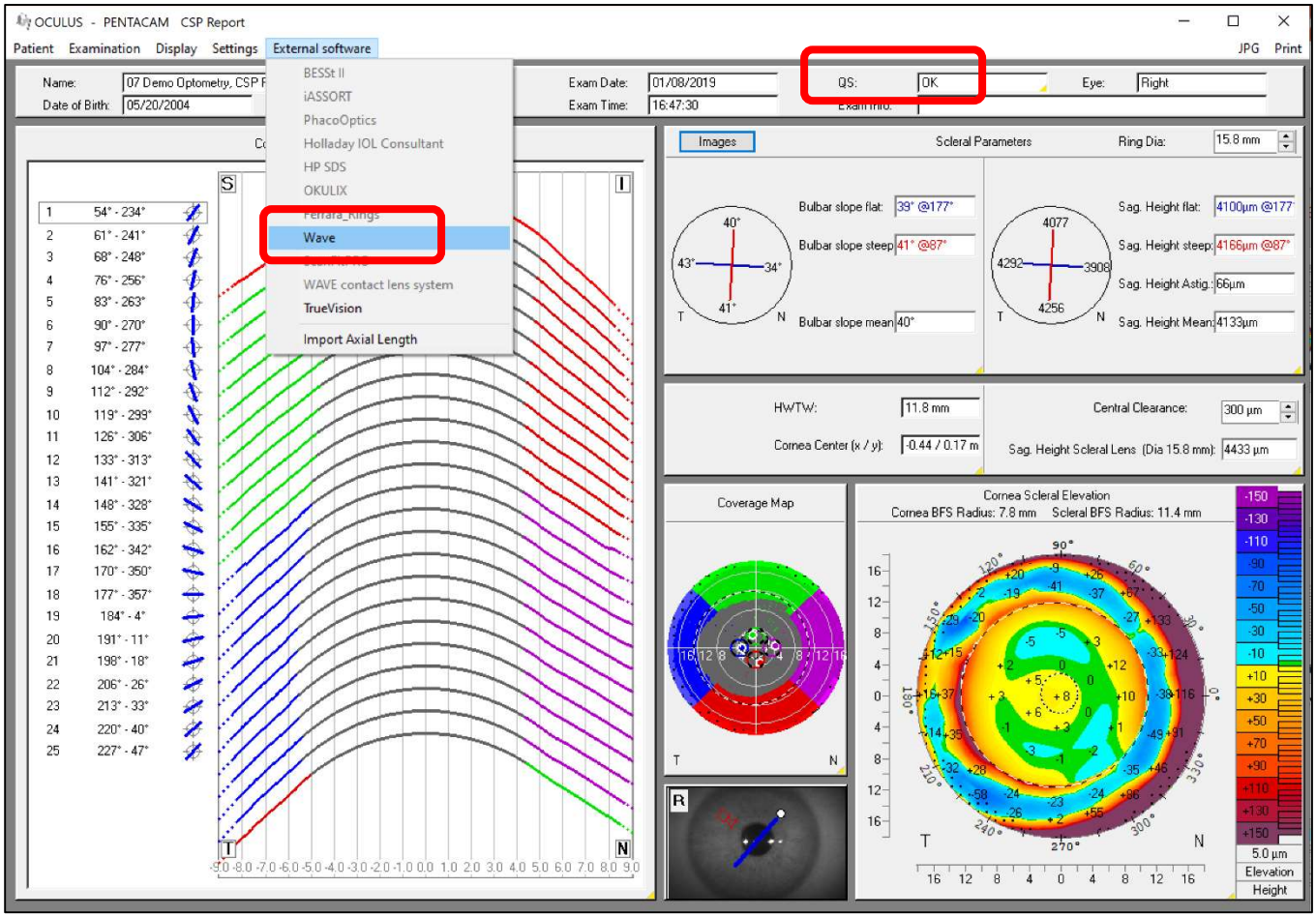
Cleaning, handling, and patient compliance are critical. The wearer should be instructed to use only those solutions recommended by the practitioner. The storage case should be cleaned and allowed to dry nightly, or while the retainers are being worn. And it should be replaced regularly according to 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.

3.3. Scleral Lens

You can design a WAVE scleral lens from the OCULUS Pentacam® CSP (Cornea Scleral Profile) report or from a corneal topography map from a compatible device. The steps are described in the following chapters.

3.3.1. Design a WAVE lens using the OCULUS Pentacam® CSP Report:

- Start with a good Pentacam® CSP (Cornea Scleral Profile) report. Check QS (Quality Specification) and coverage. Examine the Cornea and Scleral elevation maps on the screen.
- Next, click on External software and select WAVE.

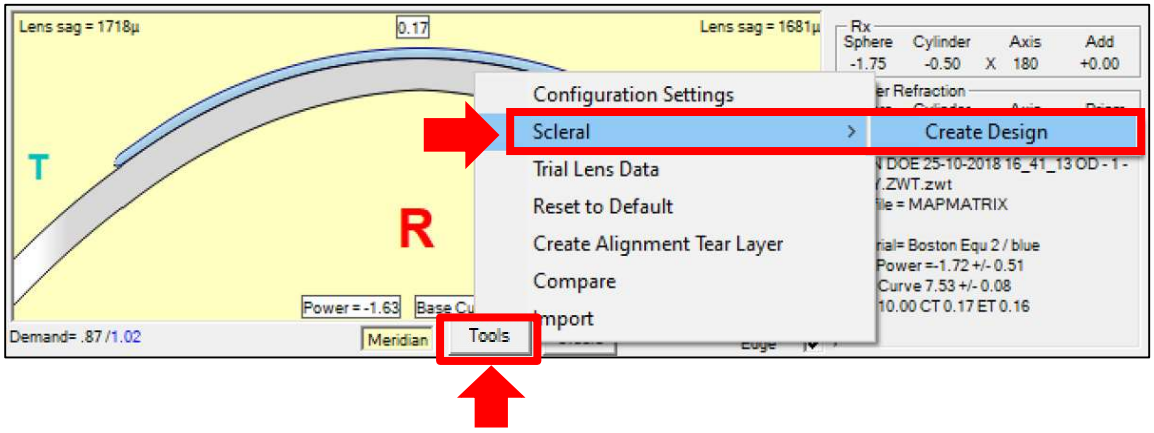


This will import that CSP data into the WAVE Contact Lens Design software.

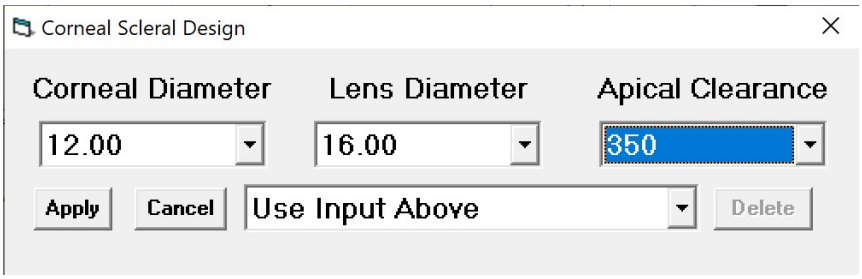
When the WAVE software opens,

- Enter the spectacle Rx. You may choose to also enter the trial lens over-refraction. To enter trial lens over-refraction, go to *Tools* and select *Trial Lens Data*.

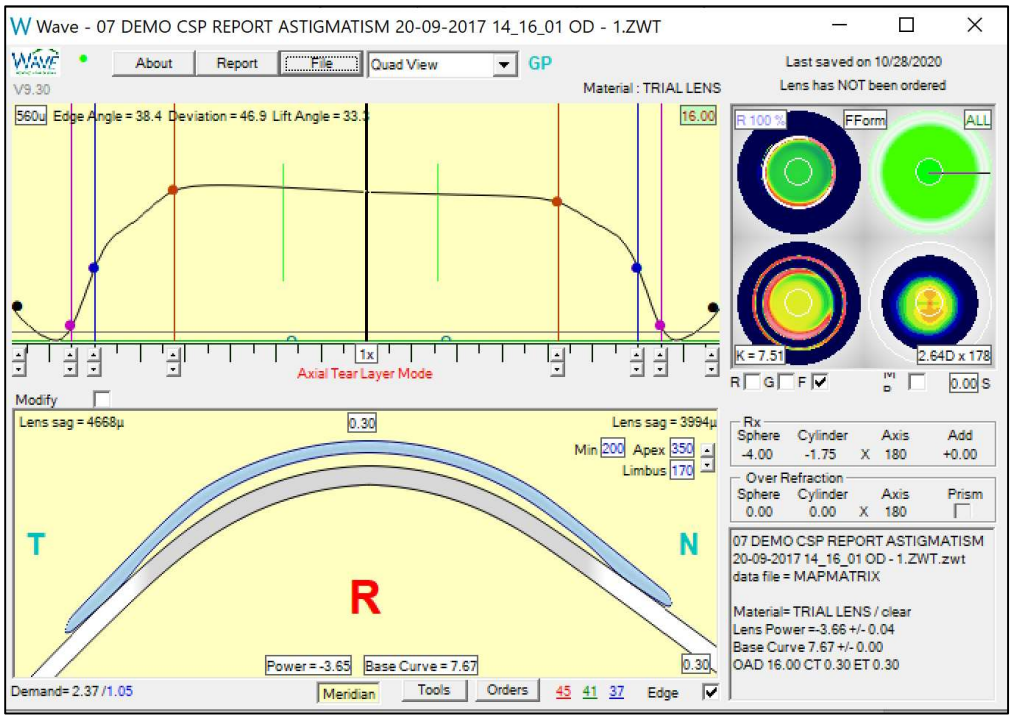
- Go to **Tools**, select **Scleral** and then **Create Design**.



- A new window opens for entering the Scleral Lens parameters.
  When you use the Pentacam, the Corneal Diameter field is automatically populated with the Pentacam HWTW measurement.
  Enter Lens Diameter and Apical Clearance. It is recommended to enter an Apical 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.

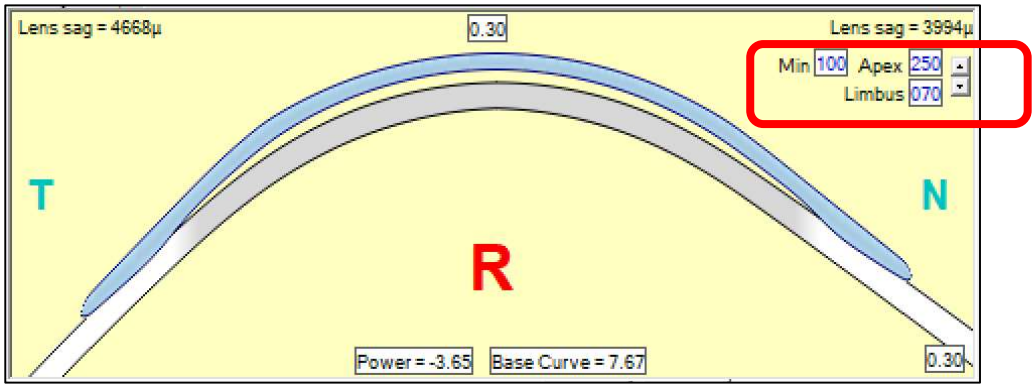


- Click APPLY. WAVE will create the initial lens design. WAVE Scleral lenses are designed in Freeform mode.



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

A new feature is added in software version 9.30 to help the user simulate the lens settling for Pentacam® CSP based scleral lenses. See **Apex, Min, Limbus** values at the top right corner of the Lens Profile window. 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.



Another new feature allows the Pentacam® CSP users to save the preferred design parameters to a library for future use. To use this feature, click on **Tools >> Scleral >> Save to Library.**

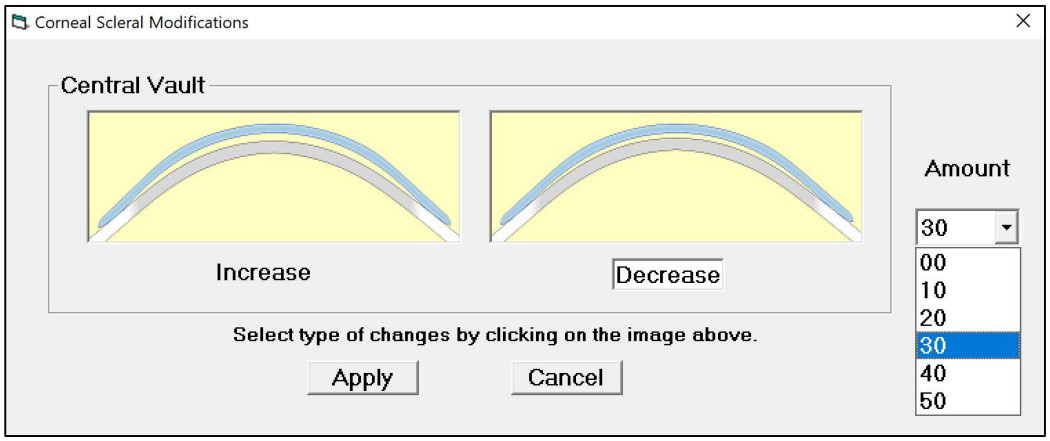
3.3.2. Making modifications to Scleral Lens Design:

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

- Go to **Tools.** Select **Scleral**, then select **Modify Design.**
  Here you can easily make the following adjustments:
  - Modify Central Vault
  - Modify Limbal Clearance
  - Modify Alignment Angle

A) Modify Central Vault:
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.

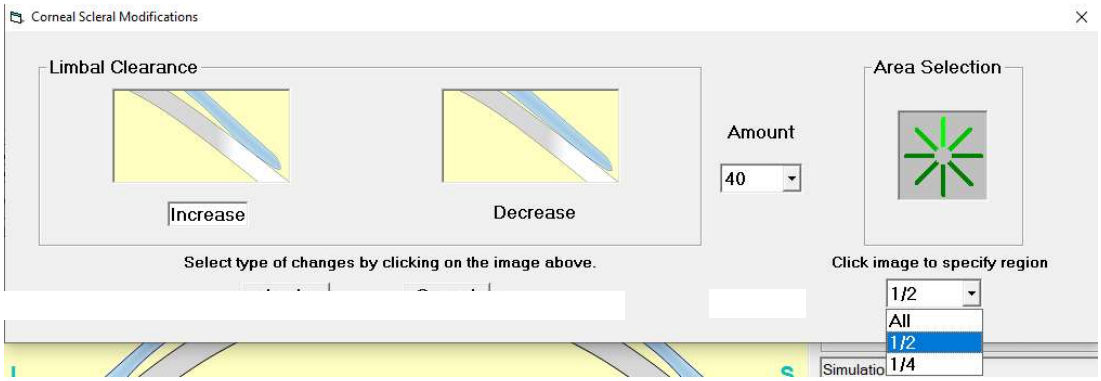
To adjust, select "Modify Central Vault".
- Select "Increase" or "Decrease".
- Select the "Amount" (μ) that you wish to change.
- Apply



B) 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 (e.g. if the lens lands at so acute an angle that it places excessive pressure on the sclera.)

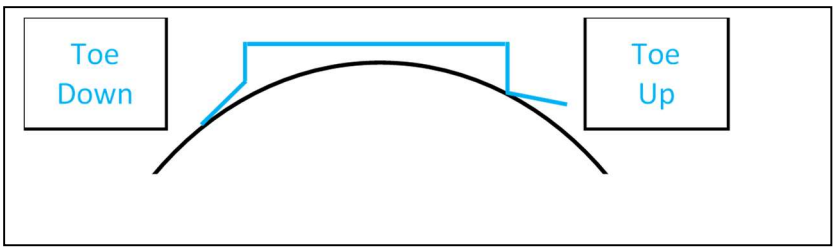
To adjust, select "Modify Limbal Clearance".

- Select "Increase" or "Decrease".
- Choose the "Amount" (μ) that you wish to change.
- Under "Area Selection", 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.
- Apply



C) 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.

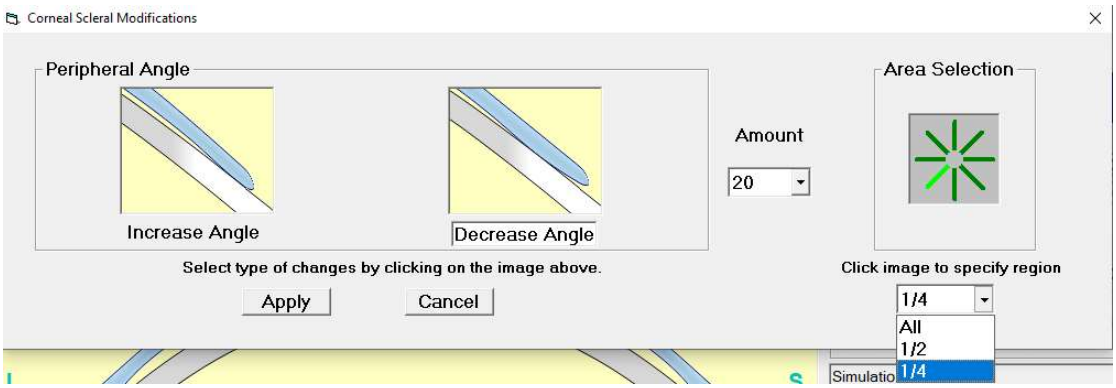


The angle used for the Scleral area of the design can be displayed on the lens profile window when scanning with the mouse. The most useful point to measure is midway between the Pink and Black control points.

To adjust, select "Modify Alignment Angle".

- Select "Increase Angle" or "Decrease Angle".
- 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.
- Apply



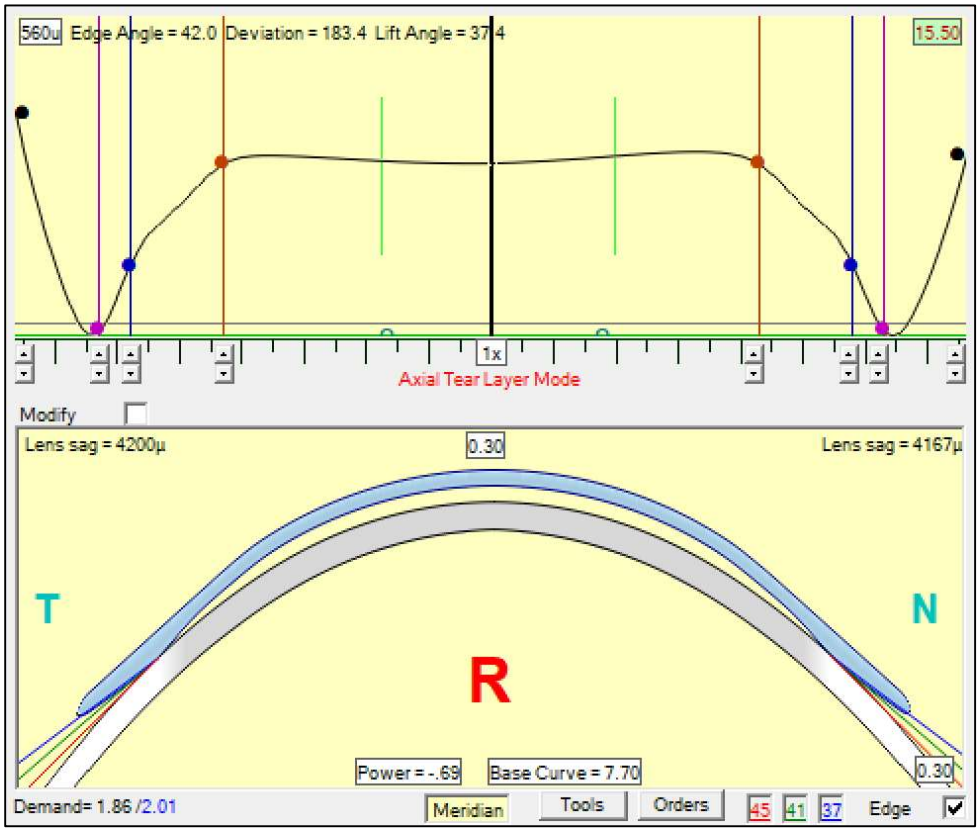
3.3.3. Design a WAVE lens using a Corneal Topography map

If you do not have the Pentacam® CSP, you can use the WAVE software to design a scleral lens from a corneal topography map following the same steps described above.

The main difference is that when you use the corneal topography map to design a scleral lens with WAVE, the WAVE software uses extrapolated/estimated data to design the scleral lens.

The auto design steps are the same except for entering the apical clearance for the initial lens. When using corneal topography data for Scleral Len design, the apical 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.

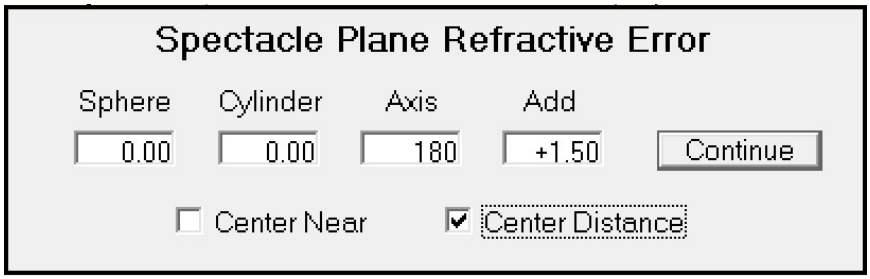
The peripheral alignment area in the resultant design is targeted to be at an angle of about 35 degrees all the way around because we do not have actual data there. When there is no scleral data, WAVE displays 3 color coded construction lines (Red line **45°**, Green line **41°**, Blue line **37°**) so that the user can easily see and modify the peripheral angles. After that, it is a matter of changes made based on observation.



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.

3.4 Multifocal Lens

You can design a Multifocal lens with WAVE. To do so, enter the ADD value in the refraction box.



You have the option to design a lens with CENTER NEAR or CENTER DISTANCE. Typically, Center Near is used for scleral lenses and Center Distance for corneal GP lenses. Click on continue and WAVE designs a multifocal lens.

If you click on the front surface curvature map you can modify the multifocality of the lens.

The orange control balls show distance pupil size and the green control balls show the front optical zone width.

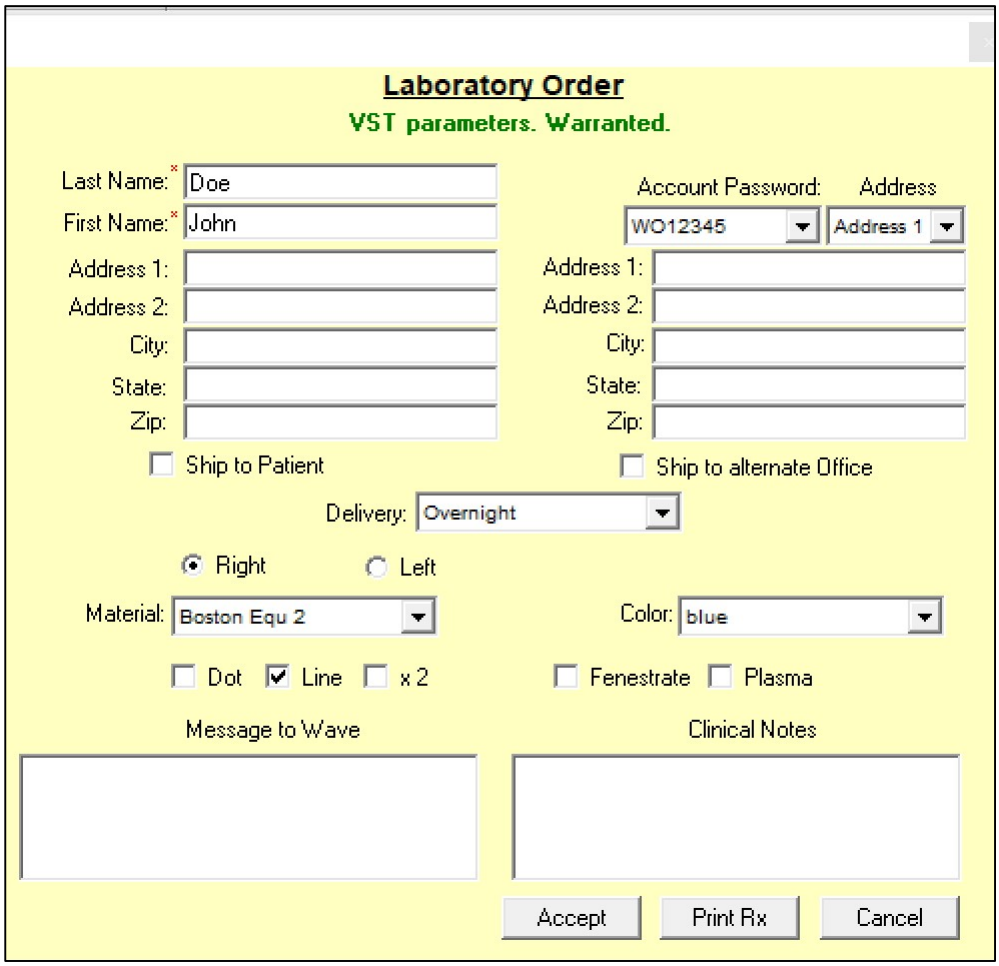
For a successful multifocal design,

- 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!

4. Orders

4.1. Laboratory Order Form

Laboratory Order form contains the warranty information, shipping details, and instructions for the lab about lens material and color. On this form the user can also request the lab to add dots and lines, fenestration or special coating to the lens.



4.1.1 Warranty Information

When saving the lens or ordering the lens, the top of the Laboratory Order Form will state if the lens is warranted.

WAVE differentiates between VST Ortho-K, non VST Ortho-K and other non-Ortho-K lenses for warranty purposes.

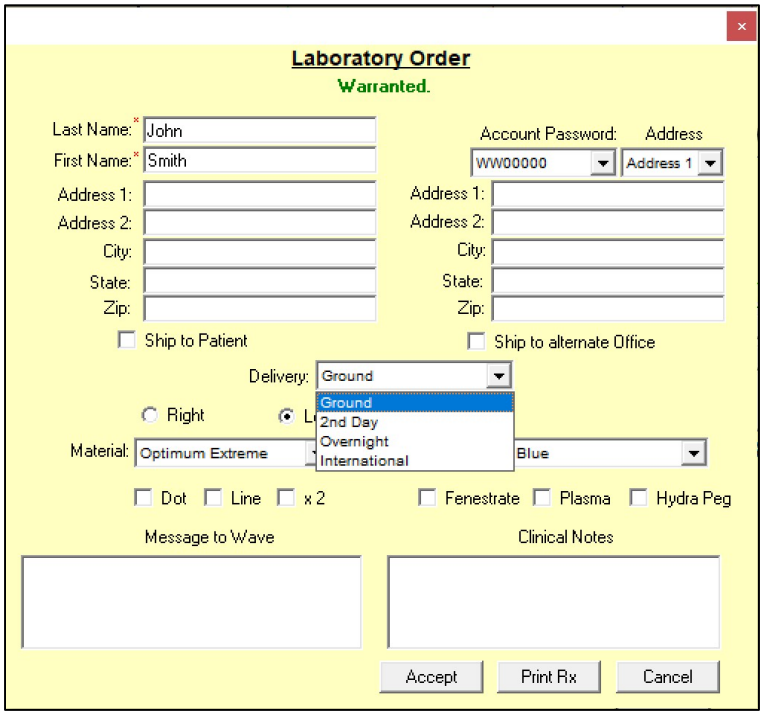
Any design with a topo demand > 2.0 is considered an Ortho-K lens. When the design is considered an Ortho-K design the "material text" (upper right corner of design screen and on the laboratory order form) turns RED. If the lens design exceeds the VST limits, the Ortho-K design carries no Warranty.

If the lens design has an OAD of 12 mm or less AND the Myopia is less than -5 diopters OR the cylinder is less than -1.5 diopters, the lens is classified as a VST Ortho-K and carries a Warranty.

If WAVE designates a lens design as Ortho-K and the actual application is not for Ortho-K AND the topo demand cannot be reduced to less than 2.0, use the Message to WAVE box on the Laboratory Order Form to explain the design is not Ortho-K and the lens will be warranted.

4.1.2 Shipping and Delivery

You can enter the shipping and delivery information on this page. In the United States, you can request the lens to be shipped directly to the patient, if desired.



4.1.3 Lens Material

WAVE lenses can be ordered in a variety of popular lens material. Choose the desired lens material from the drop-down menu. If you cannot find the material you are looking for in the software, please contact WAVE.

4.1.4 Lens Color

Lens color can be modified from the drop-down menu. Additional colors may be available. If you have a question about other color options, please contact WAVE. Lens colors are limited by the chosen material and/or lens diameter.

4.1.5 Adding Dots, Lines

The user can instruct the lab to add DOTs or LINEs (scribe marks) to the lens.

DOT: Dots are added to the lens after fabrication. Choices are Black (default) or Red, 1 or 2 dots. If you check the box next to DOT without further instructions, the lab will add 1 dot in black to the lens. If you also check the X2 box, the lab will add 2 black dots to the lens. Use the Message to WAVE comment box to request RED dots. For Toric lenses you can request the dot to be placed at a certain location.

LINE: Lines (scribe marks) are incorporated in the design file that is sent to the lab and cannot be added once the order is placed. Choices are Clear (default), Black or Red, 1 line or 2 lines. Lines are added to the lens at 6 o'clock orientation. Use the Message to WAVE comment box to request RED or BLACK line(s). At this time, only X-Cel Contacts can produce lenses with lines.

- **If you select x2 without checking Dot or Line box, no marks will be placed on the lens!**

4.1.6 Fenestration, Plasma and Hydra-PEG to the lens

You can request fenestration, Plasma or Hydra-PEG coating when you order the lens. Additional charges may apply. Please review the current lens pricing document.

4.1.7 Message to WAVE

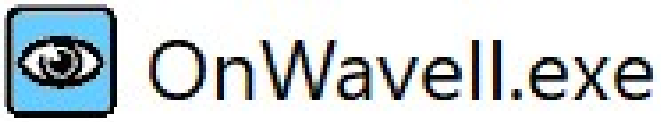
You can add special instructions for WAVE in the Message to WAVE comment box. Please note that if you type a message the order will be placed on hold until the message has been resolved. This may delay your order. You will not be able to see the order until it is taken off hold.

4.1.8 Clinical Notes

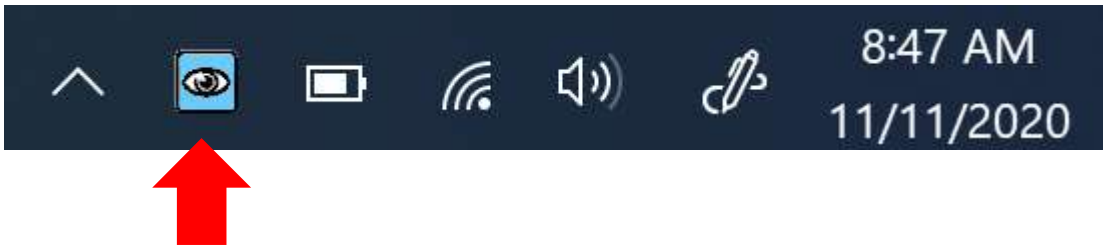
These notes will NOT be reviewed at the lab. They are for your own future reference only. Please avoid entering special characters. It may prevent the order being transmitted to the lab.

4.2. OnWaveII Order Transmission Software

To order the lens, you need to have the **OnWaveII** software installed on your computer. The OnWaveII order transmission software links your WAVE Contact Lens Design software to WAVE's Internet Order Status System (IOSS) and sends design files to WAVE Contact Lens System Lab for processing.



During the ordering process the OnWaveII icon needs to be active in the lower right side of the Task bar.



When you send an order through the system you will go through software prompts on the computer screen. As you go through these prompts, the OnWaveII icon will turn RED to indicate that the WAVE Contact Lens order is being transmitted to the Lab. Once the order transmission is complete, the OnWaveII icon will turn BLUE again.

The icon turning RED temporarily means that the OnWaveII is sending the order to the lab.

How OnWaveII Transmits WAVE Orders:

When you install the WAVE program two folders will be created on your local computer on the C:\ drive. The first folder will be the C:\WAVE. This folder will contain the actual files that make the WAVE program operate, like the engine of the program.

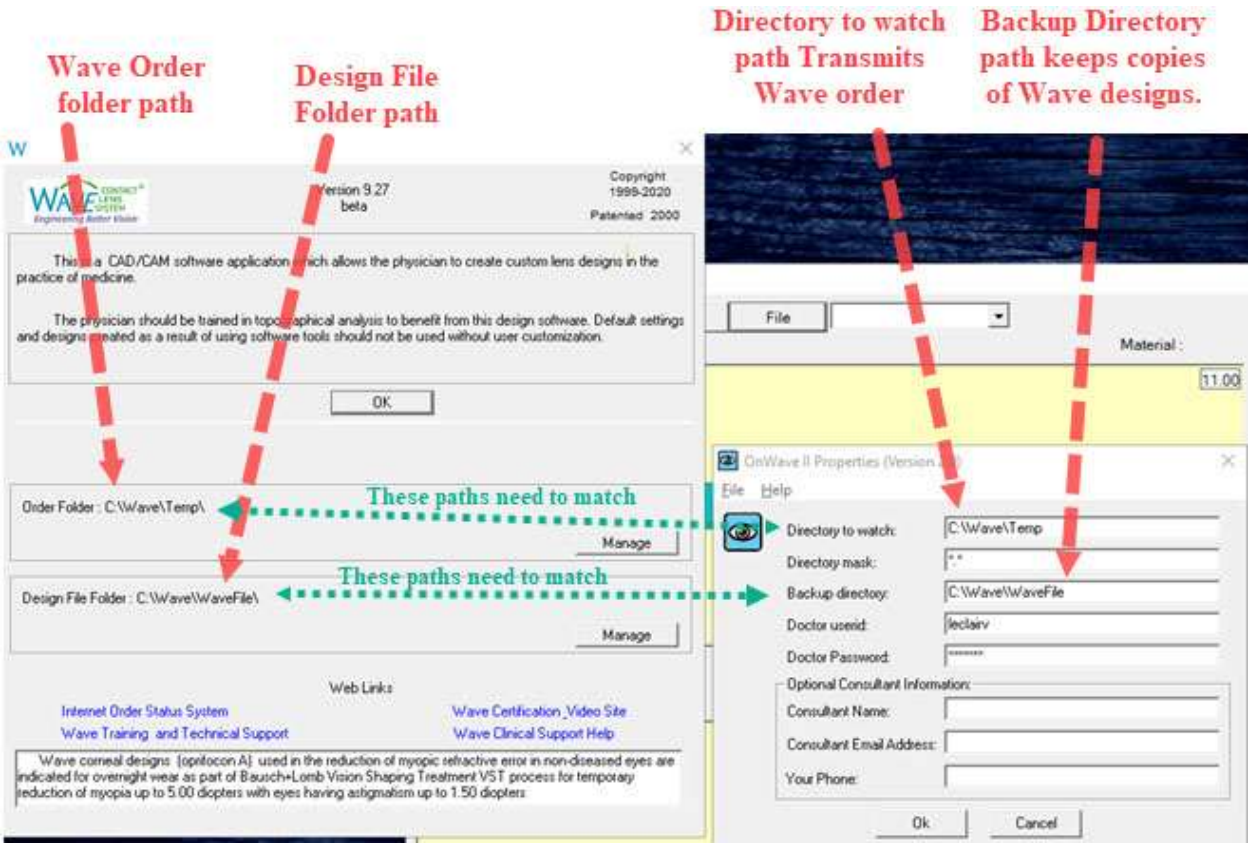
Address location and contents of folder: C:\WAVE

The second folder will be created under the C:\WAVE folder. When you order a WAVE Lens, the WAVE order will be sent to the C:\WAVE Folder, Temp Folder.

Address location and contents of folder: C:\WAVE\Temp

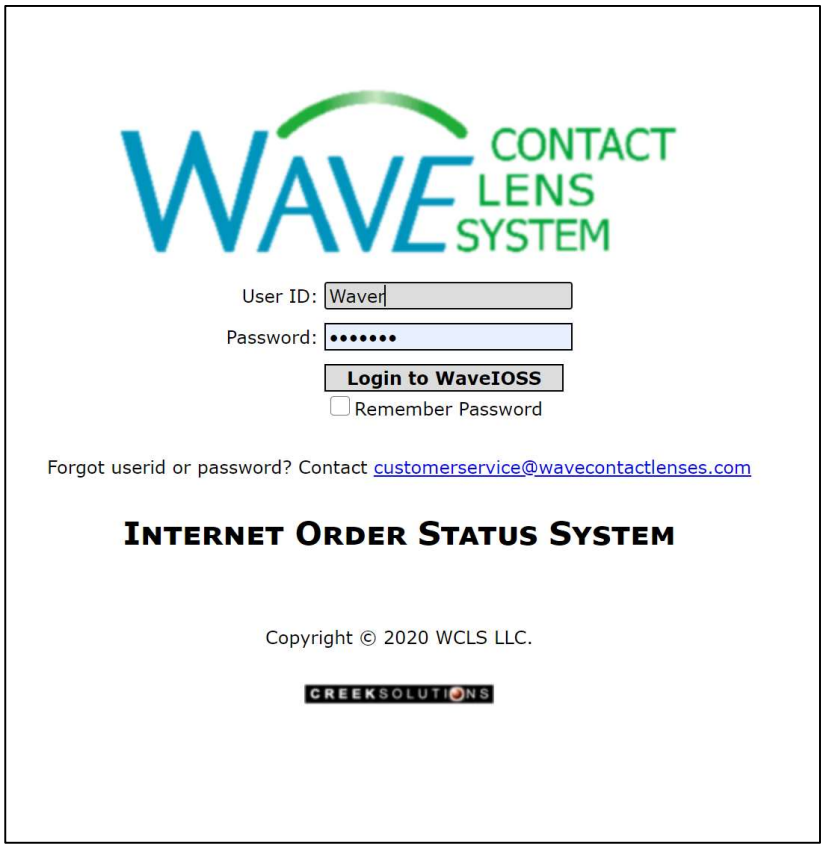
OnWaveII software, Directory to watch, monitors the Temp Folder. When it sees the WAVE order hit the C:\WAVE\Temp folder, it will transmit the WAVE order to the Lab and will place a Backup copy of the WAVE Lens order into the C\WAVE\WAVEFile folder.

Order Folder and Directory to watch paths need to be the same. Design File Folder and Backup directory paths need to match.

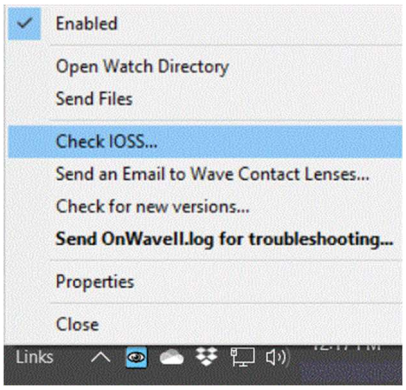


4.3. Using the WAVE Internet Order Status System (IOSS) to order a lens

You can check the status of your orders from the WAVE Internet Order Status System (IOSS) by visiting www.WAVEcontactlenses.com/WAVEioss. Use your WAVE user ID and password to log into the IOSS.



A shortcut to IOSS is available through the OnWaveII icon. Right click on the OnWaveII blue eyeball icon and select "Check IOSS" from the menu.



4.3.1. IOSS Confirmation Emails

IOSS will send an email to the address listed in the Doctor Record.

An order confirmation email is sent when an order is successfully received and processed into IOSS and an Invoice/Shipping confirmation email is sent when an order is marked shipped.

In addition, UPS sends the tracking number to the same email address whenever a shipping label is printed.

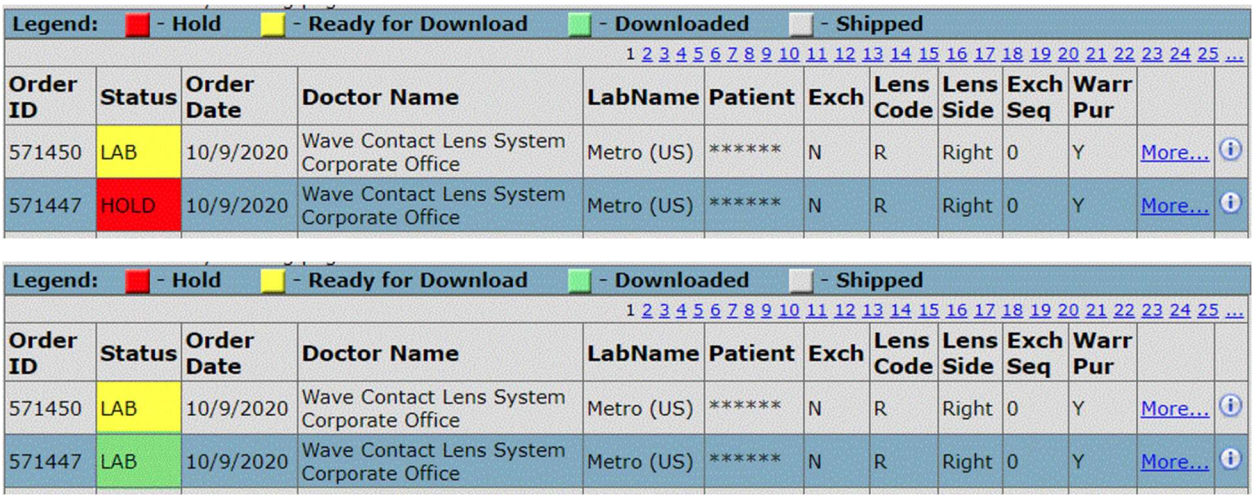
4.3.2. Managing Orders

IOSS processes orders every 10 minutes. Therefor it may take up to 10 minutes for an order to appear in IOSS after the order has been placed. For example, if an order is placed between 3:30 and 3:39 pm, the order will not show up in IOSS until 3:40 pm.

Each order is assigned a unique six-digit OrderID number. When contacting WAVE staff about an order issue, providing the OrderID is preferred, but the patient's name can also be used.

Once an order is in IOSS, WAVE staff cannot make any changes to the design and only minor changes to the order. Staff may be able to change the ship to address, shipping method, or lens color depending on when the request is made.

The Status of new orders in IOSS will appear as either RED or YELLOW. Once the lab has downloaded the order and manufacturing has begun, the Status will turn to GREEN. Once the order is marked shipped the Status becomes Grey.



Legend: - Hold - Ready for Download - Downloaded - Shipped

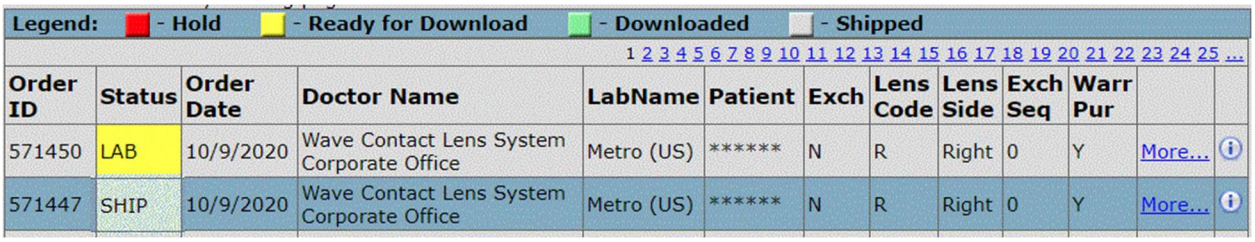
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 ...

Order ID	Status	Order Date	Doctor Name	LabName	Patient	Exch	Lens Code	Lens Side	Exch Seq	Warr Pur		
571450	LAB	10/9/2020	Wave Contact Lens System Corporate Office	Metro (US)	******	N	R	Right	0	Y	More...	
571447	HOLD	10/9/2020	Wave Contact Lens System Corporate Office	Metro (US)	******	N	R	Right	0	Y	More...	

Legend: - Hold - Ready for Download - Downloaded - Shipped

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 ...

Order ID	Status	Order Date	Doctor Name	LabName	Patient	Exch	Lens Code	Lens Side	Exch Seq	Warr Pur		
571450	LAB	10/9/2020	Wave Contact Lens System Corporate Office	Metro (US)	******	N	R	Right	0	Y	More...	
571447	LAB	10/9/2020	Wave Contact Lens System Corporate Office	Metro (US)	******	N	R	Right	0	Y	More...	



Legend: - Hold - Ready for Download - Downloaded - Shipped

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 ...

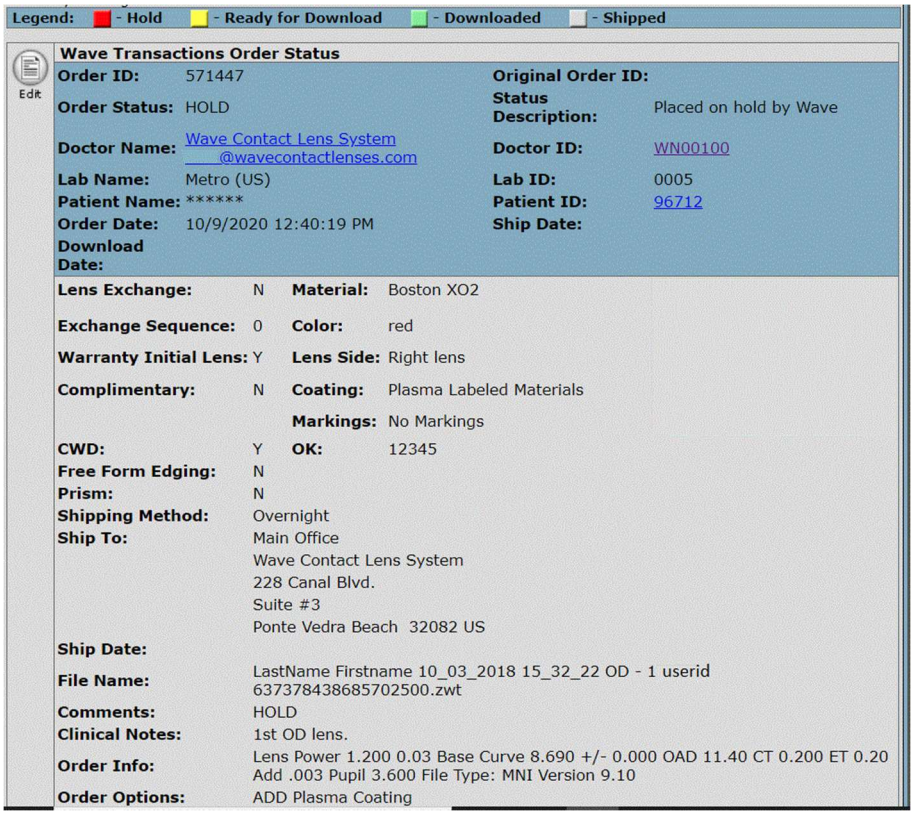
Order ID	Status	Order Date	Doctor Name	LabName	Patient	Exch	Lens Code	Lens Side	Exch Seq	Warr Pur		
571450	LAB	10/9/2020	Wave Contact Lens System Corporate Office	Metro (US)	******	N	R	Right	0	Y	More...	
571447	SHIP	10/9/2020	Wave Contact Lens System Corporate Office	Metro (US)	******	N	R	Right	0	Y	More...	

The doctor retains control of the order when the Status is RED or YELLOW. The doctor can delete RED or YELLOW orders from IOSS without contacting the WAVE office.

When the order Status is GREEN, the WAVE staff must be contacted to determine if an order can be deleted without penalty. If manufacturing has begun on the lens order, the order will be deleted, and the WAVE account will be charged $30.

4.3.3. Deleting Orders

When the Status of an order is either RED or Yellow, the doctor can delete the order by selecting the "More" link located at the right side of the order row.



Legend: - Hold - Ready for Download - Downloaded - Shipped

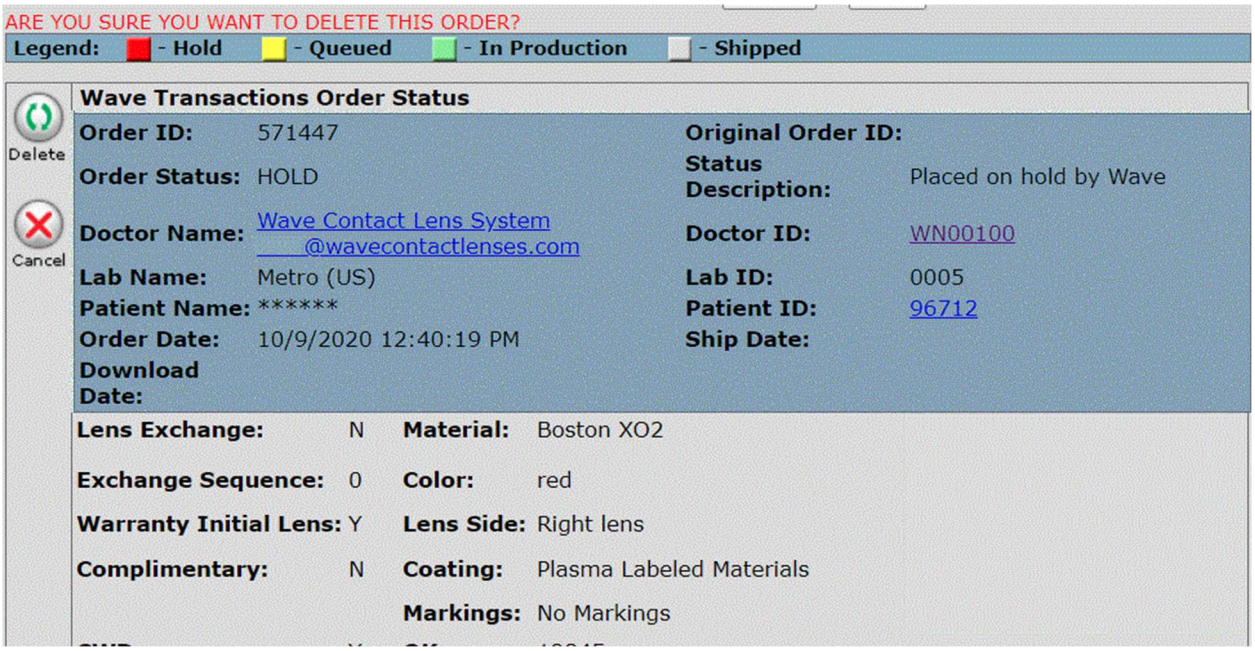
Edit

Wave Transactions Order Status

Order ID:	571447	**Original Order ID:**	
Order Status:	HOLD	**Status Description:**	Placed on hold by Wave
Doctor Name:	Wave Contact Lens System @wavecontactlenses.com	**Doctor ID:**	WN00100
Lab Name:	Metro (US)	**Lab ID:**	0005
Patient Name:	******	**Patient ID:**	96712
Order Date:	10/9/2020 12:40:19 PM	**Ship Date:**	
Download Date:			

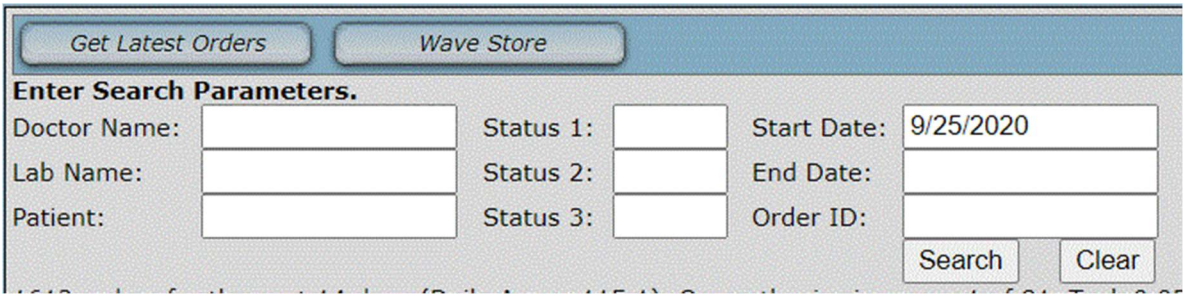
Lens Exchange:	N	**Material:**	Boston XO2
Exchange Sequence:	0	**Color:**	red
Warranty Initial Lens:	Y	**Lens Side:**	Right lens
Complimentary:	N	**Coating:**	Plasma Labeled Materials
		Markings:	No Markings
CWD:	Y	**OK:**	12345
Free Form Edging:	N		
Prism:	N		
Shipping Method:	Overnight		
Ship To:	Main Office Wave Contact Lens System 228 Canal Blvd. Suite #3 Ponte Vedra Beach 32082 US		
Ship Date:			
File Name:	LastName Firstname 10_03_2018 15_32_22 OD - 1 userid 637378438685702500.zwt		
Comments:	HOLD		
Clinical Notes:	1st OD lens.		
Order Info:	Lens Power 1.200 0.03 Base Curve 8.690 +/- 0.000 OAD 11.40 CT 0.200 ET 0.20 Add .003 Pupil 3.600 File Type: MNI Version 9.10		
Order Options:	ADD Plasma Coating		

Click the "Edit" button on the left side of the More page.



Select "Cancel" to cancel the operation and NOT delete the order. Select "Delete" to remove the order from IOSS.

4.3.4. Using the IOSS Search Features



At the top of the IOSS home page are 3 columns of white rectangle search fields. In the right most column, the Start Date is populated with a date to show all orders from the last 14 days. If the search is outside this range, use the "Clear" button to clear all field.

When searching on a patient's name, either first name or last name or both can be used.

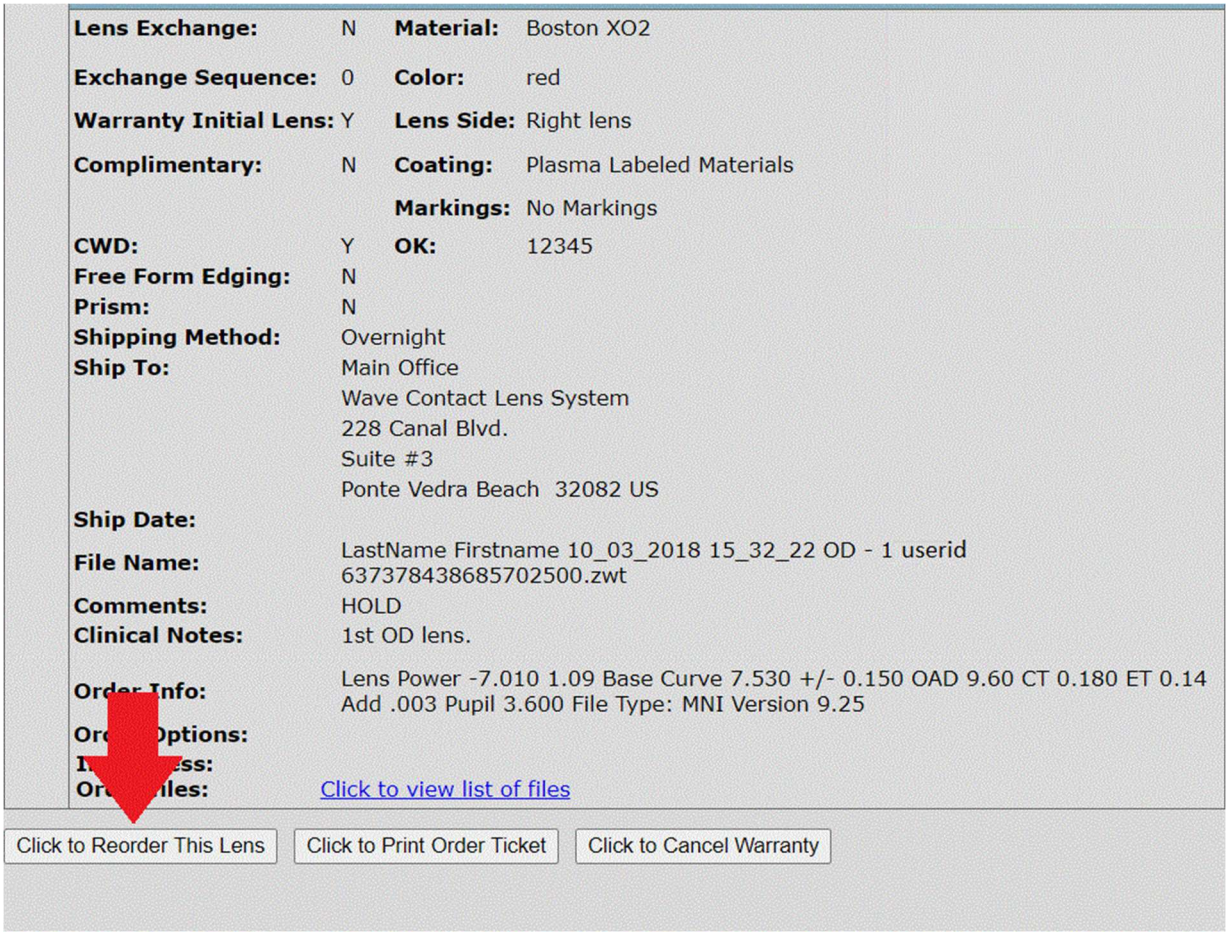
Once you have found the patient's record, you can get the entire WAVE lens order history for that patient by going to the "More" page and clicking on the Patient Name or Patient ID.

4.3.5. Re-Ordering a Duplicate lens from Internet Order Status System

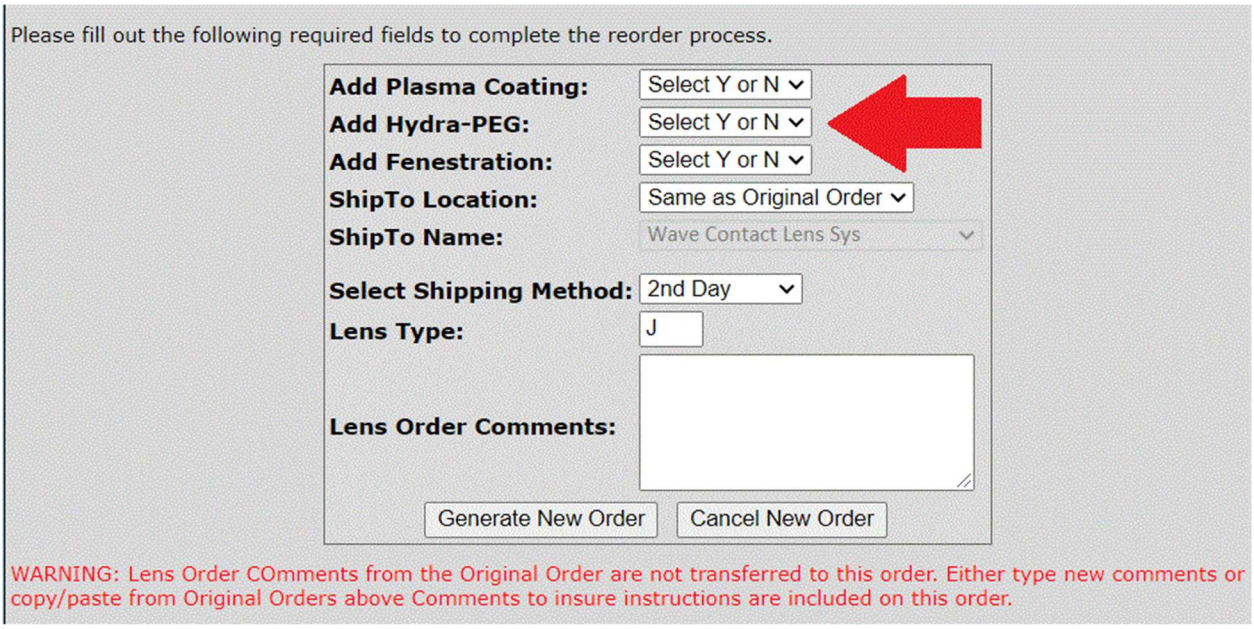
The Internet Order Status System (IOSS) provides a means to a duplicate of any order that is marked shipped. To begin the process, access IOSS.

Use the search fields to locate the lens to be duplicated.

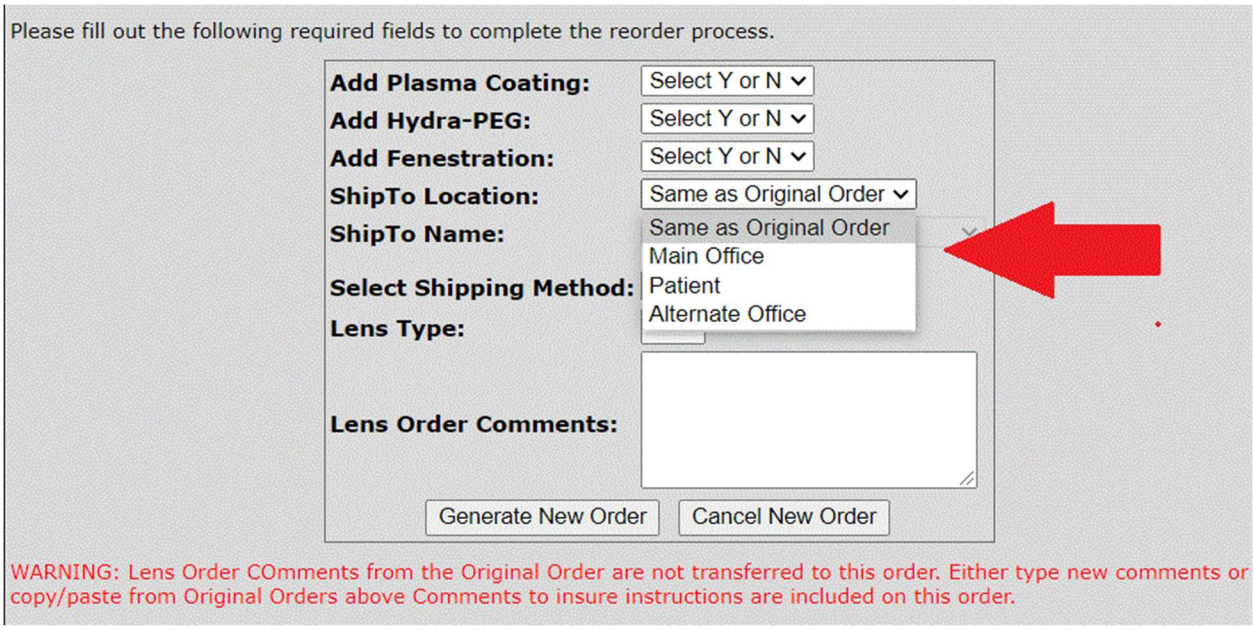
Open the "More" page for that specific order.



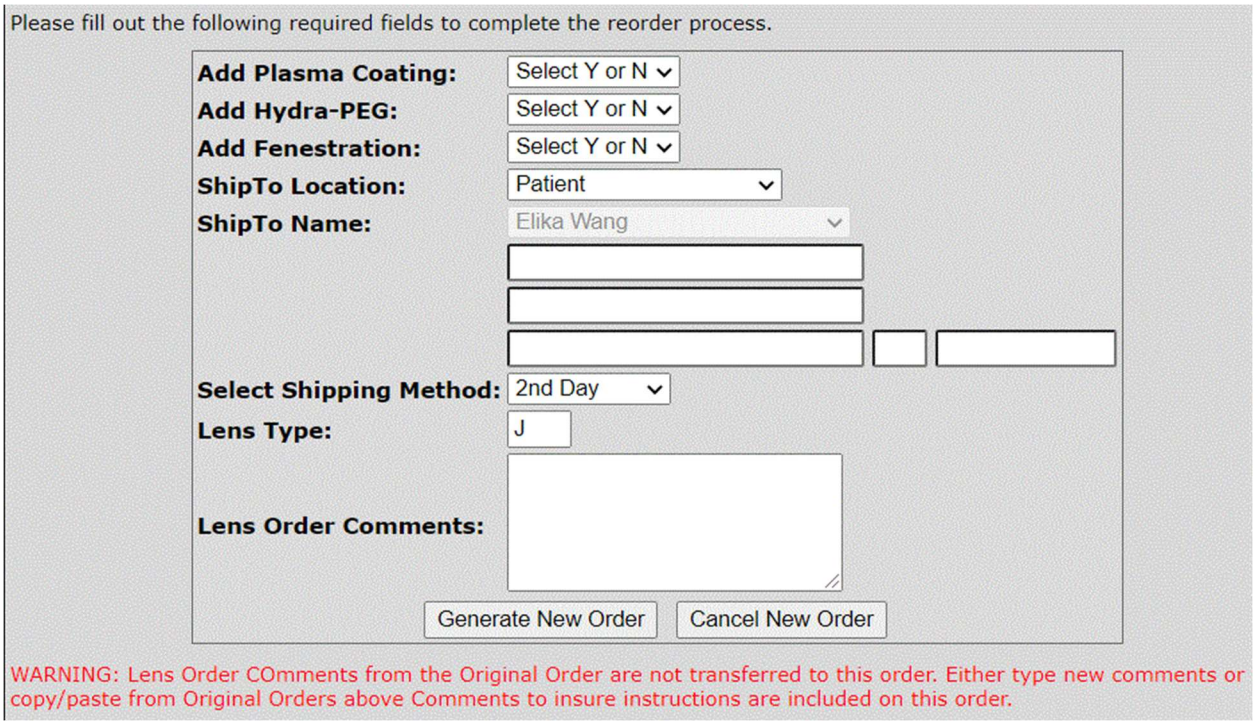
In the lower left corner of the "More" page select "Click to Reorder This Lens" button.



Choose which option to add.



Choose where you wish to ship. The Main office is the default shipping address stored in IOSS.



If Patient or Alternative Office is chosen, additional fields become available to type in the address. Please note when shipping to a patient, request the patient go to UPS.com and sign up for the free MyChoice program to track the shipment.

Click the “Generate New Order” button. The order will immediately appear in IOSS.

5. Customer Support

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

WAVE Contact Lens System

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Fax: +1 877 393 1888