Tracey VFA
Visual Function Analyzer

Model:

iTrace™

User's Guide:
Software Version 7.1

TRACEY™ TECHNOLOGIES
defining vision analysis

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CE 1639

EC REP

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LB093 RevA

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Preface

General Warnings and Notices

Important! Always follow these instructions to help guard against personal injury and damage to your Tracey iTrace Visual Function Analyzer system.

NOTE: The User(s) of the Tracey iTrace are responsible for ANY and ALL interpretations, diagnosis, and treatment plans using the data generated by the Tracey iTrace.

The Tracey iTrace Visual Function Analyzer should only be operated by trained ophthalmic technicians.

The safety and effectiveness of the Tracey iTrace Visual Function Analyzer have not been established by the USFDA for the use of the device as an accessory interfaced to a refractive laser for the treatment of higher order aberrations of the eye by photorefractive keratectomy (PRK), phototherapeutic keratectomy (PTK), or laser-assisted in situ keratomileusis (LASIK).

NOTE: The Tracey iTrace Visual Function Analyzer is a Class I laser product. It contains two laser diodes, one a Class 3B laser diode with a 785 nm wavelength, and one a Class 3R laser diode with a 655 nm wavelength. Please note additional specifications for these laser components in the symbol legend on page 9. To avoid inadvertent exposure to laser radiation, never operate the system with the covers opened or removed. Doing so may expose the user or others to stray laser radiation in excess of the Class 1 rating.

Power must be disconnected prior to opening or removal of covers.

Any service requiring access to the interior of the system should be performed only by Tracey Technologies authorized personnel or agents who have received specific system training.

Operate the external computer and peripheral devices and all computer software following all guidelines supplied by the computer and software manufacturer or supplier.

Operate the Tracey iTrace Visual Function Analyzer only from the type of power source indicated on the product-rating label. The iTrace is suitable for continuous operation.

Isolation from the power mains is provided by the medical grade power supplies specified and supplied by Tracey Technologies. In accordance with IEC 60601-1-2, in order to disconnect the mains from the iTrace Visual Function Analyzer, remove the power inlet cord from the wall power. Please ensure access to the power inlet cord and wall socket should disconnection be required.

Carefully read all instructions prior to use. Retain all safety and operating instructions for future use.

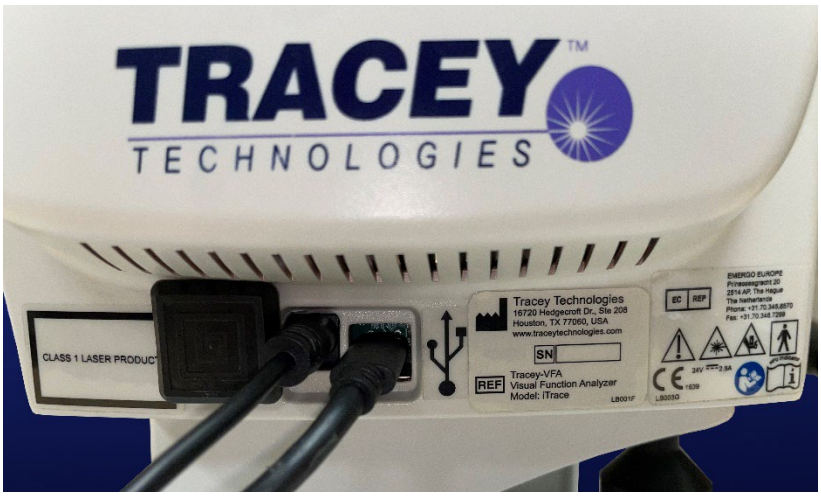
Observe all contra indications, warnings, and precautions noted on the precautionary labels located at the base of the iTrace near the power and USB ports and those within this manual.

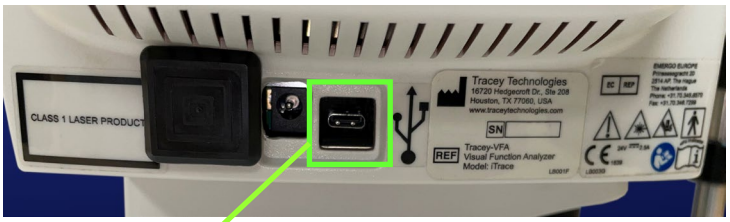
	WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
	WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
	WARNING: Please observe instructions for cleaning and disinfection of the Tracey iTrace Visual Function Analyzer found in the Cleaning and Maintenance section of this document.
	WARNING: The Tracey iTrace Visual Function Analyzer is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
	WARNING: Use of the Tracey iTrace Visual Function Analyzer adjacent to or stacked with other equipment should be avoided to because it could result in reciprocal interference or improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
	WARNING: The Tracey iTrace Visual Function Analyzer should be used with the cabling provided with the iTrace equipment. The use of cables other than those specified and provided by Tracey Technologies could result in increased electromagnetic emissions or decreased electromagnetic immunity of the iTrace and could result in improper operation.
	WARNING: To avoid reciprocal interference, portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in.) to any part of the Tracey iTrace Visual Function Analyzer and its cabling. Otherwise, degradation of the performance of the iTrace could

	result.
⚠	WARNING: During use of the iTrace while capturing patient exams, the operator should take care not to touch both the patient and the data acquisition unit (DAU) enclosure simultaneously.

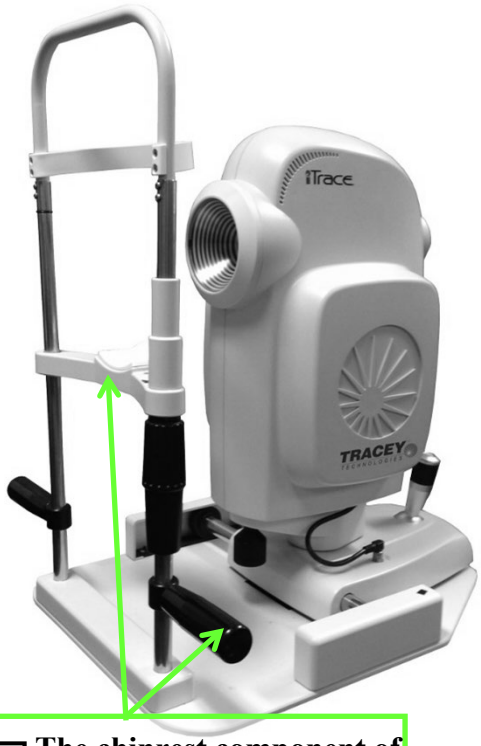
Identification and Certification/Precautionary Labeling

Please note the location of the product Identification/Traceability and Certification/Precautionary labels on either side of the power connection and peripheral ports at the base of the iTrace VFA as shown below.





USB port is for connection to the <u>supplied</u> USB 3 Type C to A cable to the separately approved (IEC 60601-1, IEC 60950-1 or IEC 62368-1) computer.



The chinrest component of the iTrace is the *Applied Part* of the device.

Refer to the requirements of IEC 60601-1:2005 +A1:2012 +A2:2020 when incorporating the iTrace into a Medical Electrical System (including the peripheral computer, table or other external system.)

List of cables, transducers and accessories used with the iTrace

Port Name on iTrace	Cable Description	QTY	Tracey P/N	Model #
USB	USB 3.0, Type C	1	202136	U428-006
AC Input	Medical Power Supply	1	200655	GTM96600 - 60VV.V-T3

The iTrace is suitable for use in medical facilities such as hospitals, clinics and physician offices. Care should be taken to avoid installation and use near active HF surgical and MRI equipment in the unlikely event of electromagnetic (EM) interference. If the iTrace is affected by EM disturbance, the user should monitor the device to verify it operates properly, including comparison with other measuring devices as necessary.

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The iTrace has been tested and conforms to the EN/IEC 60601-1-2:2020 Medical Electrical Equipment standard as detailed in the table below and does not deviate or make allowances from this standard. The user should take care in following these instructions for safety and heed warnings to maintain basic safety and essential performance regarding electromagnetic disturbances.

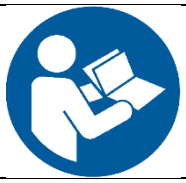
The user, as the responsible organization, shall refer to the requirements of IEC 60601-1:2005 +A1:2012 + A2:2020 when incorporating the Tracey iTrace Visual Function Analyzer into a Medical Electrical System (including the peripheral computer, table or other external system.)

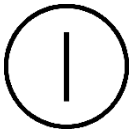
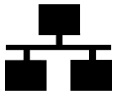
Reference	Tests	Basic EMC Standard	Limits	Compliant
EN/IEC 60601-1-2: 2020	Radiated Emissions	EN55011/CISPR 11	Group 1, Class A	Yes
	Conducted Emissions	EN55011/CISPR 11	Group 1, Class A	Yes
	Harmonics and Flicker	IEC 61000-3-2 &-3	Class A	Yes
	ESD	IEC 61000-4-2	±8 kV Contact ±2 kV, ±4kV, ±8kV, ±15kV air	Yes
	Radiated Immunity (Proximity Field Testing)	IEC 61000-4-3 Per Table 15	3 V/m	Yes
	Electrical Fast	IEC 61000-4-4	±2 kV	Yes

	Transients/Burst		100kHz repetition frequency	
	Surges	IEC 61000-4-5	±0.5 kV, ± 1 kV± 2 kV	Yes
	Conducted Immunity	IEC 61000-4-6	3 VRMS 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Yes
	Magnetic Immunity	IEC 61000-4-8	30 A/m	Yes
	Voltage Dips and Interruptions	IEC 61000-4-11	0% UT; ½ cycle at 0°,45°,90°,135°,180°,225°,270°,315°. 0% UT; 1 cycle and 70% UT; 25/30 cycles. Single phase: at 0°. 0% UT;250/300 cycle	Yes

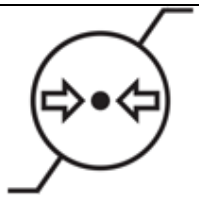
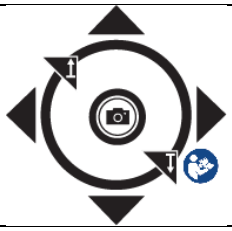
No deviations from standards have been used.

Symbol Legend

	Refer to instruction manual/booklet This iTrace User's Manual, also known as the Instructions for Use, must be followed for safe use and operation of the Tracey iTrace Visual Function Analyzer.
	<u>Consult electronic instructions for use</u> This iTrace User's Manual is provided in an electronic form as a PDF file.
 	<u>Class 1 Laser Product</u> - The Tracey iTrace Visual Function Analyzer is a Class 1 laser product by construction and measurement per testing and conformance to IEC 60825-1:2014. It contains two laser diodes: 1) Class 3B laser diode with a 785 nm wavelength, with maximum power of ≈50 mW and collimated beam with a maximum attenuated power of 4.6 mW; and 2) Class 3R laser diode with a 655 nm wavelength, with maximum power of less than or equal to 2.5mw, and 2mrad beam divergence. Please note the timing, angle and duration for these lasers during operation in the operating instructions within this manual.
	Applied Part symbol Type BF Equipment protection against electric shock does not rely on Basic Insulation only, but includes an additional safety precaution provided by connection of the Equipment to the protective earth conductor.

	Meets the leakage current requirements and the patient applied part is isolated from the equipment
	This symbol denotes the location of the on/off power button for the Tracey iTrace Visual Function Analyzer Data Acquisition Unit.
	This symbol denotes the location of the USB port on the device.
	This symbol denotes the location of the Ethernet port on the device.
IPXO	Ordinary protection against harmful ingress of water.
	This symbol denotes that this device must be disposed of in accordance with the WEEE. Further details can be found in EN 50419:2005; regulations as set out by the 2002/96/CE directive, subsequently superseded by 2003/108/CE. For disposal, please contact Tracey Technologies or your local distributor.
	Special precautions regarding Electromagnetic Compatibility (EMC) exist with the iTrace VFA and the equipment must be installed and put into service in compliance with the IEC standards. All iTrace users should be trained in electrostatic discharge (ESD) precautionary procedures.
	This symbol denotes that there is a crush hazard at the manipulator where the unit slides on the base plate. Please take necessary precautions to avoid possible injury.
	This symbol denotes the placement on labeling for the address of the manufacturer of the Tracey iTrace Visual Function Analyzer.
	This symbol indicates the placement on labeling for the date when the Tracey iTrace Visual Function Analyzer was manufactured.
MD	This symbol indicates that the Tracey iTrace Visual Function Analyzer is a medical device.

SN	This symbol denotes the placement on the labeling for the serial number of the device. Each Tracey iTrace Visual Function Analyzer is marked with a unique 4 digit serial number.
REF	This symbol denotes the placement on the labeling for the model of the Tracey Visual Function Analyzer.
UDI	This symbol denotes the placement on the labeling of the carrier (barcode) that contains unique device identifier information about the Tracey iTrace Visual Function Analyzer.
EC REP	This symbol denotes the placement on labeling for the European Authorized Representative.
	Please observe all warnings and cautionary statements in the instructions for use for the Tracey iTrace Visual Function Analyzer.
24V ⎓ 2.5A 24V ⎓ 1.5A	Direct Current. This symbol indicates that the Tracey iTrace Visual Function Analyzer Data Acquisition Unit should be powered only with a ***medical grade*** power supply as provided either Model #GTM96600-60VV.V-T3 (Tracey PN 200665), rated at 24V direct current, 2.5A or Model #SDM36-24-U-P5 (Tracey PN 200665) rated at 24V direct current, 1.5A. The external power supply is part of the Medical Electrical Equipment. Should isolation from the mains be necessary, in accordance with IEC 60601, to disconnect the mains from the iTrace Visual Function Analyzer, remove the power inlet cords from the wall power outlet. The equipment should be positioned to provide access to disconnect the power inlet cord should it be necessary to do so.

	The Tracey iTrace Visual Function Analyzer should be stored and transported at a temperature range of 5° C to 40° C / 41° F to 122° F. The iTrace should be operated at a temperature range of 15° C to 30° C / 60° F to 85° F.
	The Tracey iTrace Visual Function Analyzer should be stored and transported at a relative humidity range of 20% to 85% rH. The iTrace should be operated at a relative humidity range of 20% to 85% rH.
	The Tracey iTrace Visual Function Analyzer should be stored and transported at an atmospheric pressure range of 50 to 106 kPa. The iTrace should be operated at an altitude of 5,000 m or less.
	Do not use if package is damaged.
	These symbols located on the iTrace joystick/manipulator component, instruct the user on how to maneuver the iTrace using the joystick and manipulator. More information can be found on page 23 of this User's Manual.

Indications for Use and Safety Concerns

Indications for Use

The iTrace is used to measure the refractive, wavefront and corneal topographic data of the human optical system of any human patient that can be positioned in the chinrest and for whom the eyelid can be raised and is not limited to a specific age, race or gender.

Use Environment

The iTrace is intended to be used in an ophthalmic or optometric office, clinic or surgery center, by certified ophthalmic or optometric staff to measure patients' refractive, wavefront and corneal topographic data. Typical environmental conditions within these settings provide optimal operations for the device. In some circumstances, it is best to use the equipment in a room where lighting can be controlled depending on the measurements desired. Use environment should ensure the security of patient data through protocols that protect access to the device, both physical and digital access.

Physical security can be achieved through measures such as:

- Regulated and authenticated physical access enforced via suitable technical measures (e.g. badges)
- Physical security policy defining roles and access rights, including for physical access to the iTrace device
- Use of segregated, secure areas with appropriate access controls

Security controls can be created, such as:

- User access management (credentials for accessing software applications or devices, user access policy, etc.) which can be accomplished through the Windows OS of the computer connected to the iTrace.
- Antivirus / anti-malware software which can be installed in the Windows OS of the computer connected to the iTrace.
- Firewall which can be accomplished through the Windows OS of the computer connected to the iTrace.
- Application whitelisting / system hardening which can be accomplished through the Windows OS of the computer connected to the iTrace.
- Exclusive use of genuine software and ban of all illegitimate software and applications
- Session management measures (e.g. session timeouts) which can be accomplished through the Windows OS of the computer connected to the iTrace.
- Network segmentation
- Allowing Microsoft Windows OS security patch updates

Expected Service Life

The expected service life of critical components in iTrace unit should be at least 7 years.

Residual Risks or Use Concerns

The iTrace produces laser light energy. Over exposure to this energy is a safety concern. Mitigations per company processes and industry standards are in place to address this safety concern. Use of the iTrace adhering to the instructions in this manual will not impact the laser safety concerns. Any serious incident that has occurred in relation to the iTrace should be reported to Tracey Technologies and to the competent authority of the Member State or regulatory body for the country in which the user and/or patient is located.

Contraindications for Use

The iTrace has no contraindications for use.

System Specifications:*

Measurement Range:	+/-15 D sphere
	+/-10 D cylinder
Pupil Scan Size:	1.0 mm to 8.0 mm diameter
Accuracy:	+/- 0.10 D
Reproducibility:	+/- 0.10 D
Footprint Dimensions:	13.0 in (33.0 cm) x 17.0 in (43.2 cm)
Weight:	27.4 lb (12.4 kg)

**Specifications subject to change without notice.*

Chapter 1 Getting Started

Please read the Operator's Manual in its entirety before using your Tracey iTrace System.

Welcome New User

Congratulations on acquiring your new iTrace Visual Function Analyzer (iTrace). Chapter 2 acquaints you with your system's hardware: the data acquisition unit (DAU) and the computer. Chapter 3 covers the basics of using your system, from powering on and off to using your iTrace software and working with the screens. Chapter 4 of this manual reviews how to manage new and existing patients. Chapter 5 details how to perform an iTrace exam and Chapter 6 explains how to review the exam data.

With your new iTrace, you will have the ability to look at refraction of the eye with a high level of objective measurement and in detail. In fact, viewing a refractive map of the entrance pupil that covers the refractive power of the whole eye on a point-by-point basis, vs. a basic refractive numeric summary of sphere and cylinder will enhance your practice in terms of speed, accuracy and clinical care of your patients.

Measuring refraction on a spatially resolved basis requires the ability to look at wavefront aberrations of the eye on a point-by-point basis. The iTrace analyzes light directed into the eye and focused onto the retina creating a secondary light. The iTrace uses the fundamental thin beam principle of optical ray tracing to measure the refractive power of the eye on a point-by-point basis. The simplicity of measuring one point in the entrance pupil at a time is unique to the Tracey system.

Within microseconds, your iTrace system rapidly fires a sequential series of very small parallel light beams into the entrance pupil. These beams of light pass through the entrance pupil of the eye in an infinite selection of software selectable patterns. With new designs of the photo detector system, iTrace can easily measure a large dynamic range of aberrations and maintain high resolution. This should provide for a significant advantage when measuring a physiologic system, such as the eye, which can easily have a tremendous range of refractive errors.

Since each point is sequentially measured, there is no confusion of which entrance pupil location registers with the retinal spot detected. The iTrace system directly measures the point spread function of the eye with its retinal spot detection; thus, easily providing the data for full calculation of wavefront deformation of the eye.

Your iTrace system also captures and processes corneal topography data. Wavefront data of the cornea is combined with wavefront data of the eye to obtain the lenticular aberration analysis.

Getting Help

Telephone Support is available by calling **(281) 445-1666.**

Questions may be submitted via E-mail to **service@traceytech.com**

Or

by fax to **(281) 445-3050.**

Warranty Information

Your Tracey system comes with a standard one-year warranty for parts and labor on the components purchased from Tracey Technologies including software updates (see warranty information in the back of this manual). Extended Service Agreements are available from Tracey Technologies. Contact your sales representative or Tracey Technologies at (281) 445-1666 for more information.

NOTE: The User(s) of the Tracey iTrace are Responsible for ANY and ALL interpretations, diagnosis, and treatment plans using the data generated by the Tracey iTrace.

Chapter 2 Getting to Know Your System

The Tracey iTrace Visual Function Analyzer provides the ability to offer your patients accurate, repeatable, and prompt refractive measurements of the complete optical system in the eye. The iTrace performs these primary tasks:

- Captures an eye image.
- Measures 256 points of light projected through the pupil onto the retina.
- Plots the points and calculates Zernike polynomial wavefront data.
- Captures image of projected placido rings and calculates corneal topography data.
- Generates displays to view the data.
- Saves exam data in an organized database.
- Automatically centers, sizes the scan pattern within the pupil, and captures the data.
- Verifies focus and alignment.
- Combines corneal wavefront data and total eye wavefront data to generate a lenticular aberration analysis.

The system also has provisions for these functions:

- Displaying and analyzing exam data in intuitive formats
- Setting and changing system parameters
- Patient database management

This chapter describes the primary components of your system: the Data Acquisition Unit, the external computer, and the data storage recommendation. Chapter 3 discusses the basics of using your system, and navigating around the menus.

Data Acquisition Unit - DAU

This is the main component of the iTrace VFA system. It is used to project and record the points of light as they enter through the pupil and focus on the retina. The iTrace software uses these data points to produce the various displays. The Data Acquisition Unit (DAU) features an adjustable focusing target, a pupil size detector, and an OD/OS detector.

The DAU also features a Placido-based corneal topography analyzer. The back-lit Placido rings are projected onto the corneal tear film, and the image is auto-captured when device is at the proper working distance and the projected laser beam is centered in the live video image. The iTrace software then defines the ring edges and calculates corneal curvature, corneal refractive power, and corneal wavefront data. The DAU also contains an internal optometer. The optometer is the fixation device for alignment of the patient's line of sight with the laser axis. It also serves to relax the

patient's accommodation by providing a target of increasing/decreasing spherical correction from +7D to -5D primarily.

Additionally, the DAU contains the power supply and data transmission and image capture processing boards. This unit is NOT SERVICEABLE by the customer, and only trained Tracey service engineers should open and service this component due to possible exposure to hazardous laser radiation.

Cleaning and Maintenance

The iTrace chin rest, forehead strap, handles and any other part of the device which makes contact with the patient should be cleaned thoroughly before use and between patient usage with isopropyl alcohol disinfecting wipes using light pressure.

The exterior of these units, other than those listed above, may only be cleaned with a dry non-abrasive cloth or anti-microbial dry wipes. Avoid getting any moisture/liquid on/in the system. **DO NOT** touch the optics inside the eyepiece. If necessary, turn the system power off and use compressed air may to remove dust inside the optical eyepiece.

To properly maintain your iTrace Visual Function Analyzer, users should periodically **verify the device's calibration**. Please refer to the steps in Chapter 4, To Perform a Quick Calibration Check, page 35 and to Appendix D, Calibration Verification.

Computer Requirements

The computer is a separate and external device (laptop or desktop model). Laptop/Desktop computers must meet these minimum specifications*:

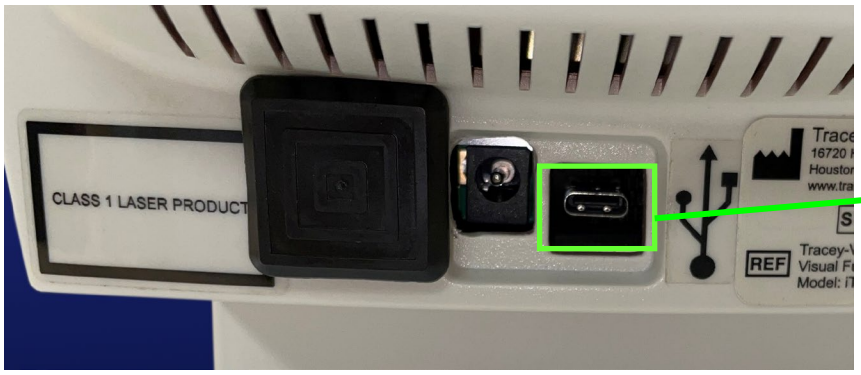
- CPU: Intel Core i7 or equivalent
- Graphic Display Resolution:
  - HD 1360x768, or
  - HD+ 1600x900, or
  - Full HD 1920x1080
- 16 GB RAM (Main Memory)
- HD Capacity: 1 TB GB SSD Minimum
- 2 USB 3.0 Ports for connecting iTrace acquisition unit and color printer
- Integrated 10/100 Ethernet LAN
- Microsoft Windows 10 or greater Professional OS – required for networking
- Color Printer (USB or wireless) for printing displays (Optional)
- Touchscreen display for ease of use (Optional)

Our tests have shown excellent result with the following preferred computer manufacturers: Sony, HP and Dell.

**These specifications are subject to change.*

DAU and Computer Setup

The iTrace DAU and Computer should be setup side by side and should utilize the medical grade power supply provided by Tracey Technologies. The DAU connects to the external computer via the supplied USB 3 Type C to A cable. The iTrace system should only be setup and operated with the supplied medical grade power supplies and cabling provided by Tracey Technologies.



The USB Type C port on the iTrace DAU is used to connect to the external computer via supplied cabling. For questions about the use of the supplied cabling, contact Tracey Technologies' technical support (contact information is found on page 17.)

Data Storage Recommendation

Tracey strongly advises that you back up your patient file databases on a server, or by other means as advised by your technology advisor. In doing so, your patient files can be restored readily in the event of a computer hardware failure or database corruption.

***NOTE**:* The User(s) of the Tracey iTrace is responsible for ensuring that patient data is backed-up and stored on an external source.

Cybersecurity Recommendation

As the computer that contains the software controlling the data acquisition and user interface is a separate and external device running within the Microsoft Windows OS environment, and as described previously in the Use Environment section, cybersecurity for the device is controlled mainly by the Windows OS. Likewise, such control is encouraged and given to the end user.

Tracey Technologies considers cybersecurity interference to be of very little risk, but the onus to maintain security in the use environment is on the end user. We suggest that the clinic consult with IT specialists regarding cybersecurity concerns.

The MDS2 Form for the iTrace is available on request.

Chapter 3 Learning the Basics

This chapter covers the basics of using the iTrace software. This chapter describes features and functionality available in the current version of software. This chapter includes the following topics:

- New User Installation and Training
- Installing your iTrace Software
- Special keyboard keys
- Using the Joystick
- Printing a screen
- Saving a display
- Using common display options
- Powering system on and off

New User Installation and Training

A Tracey-certified installation representative may install your new iTrace system and verify calibration.

A Tracey-certified training specialist may provide training. Training on the iTrace and its software should take a minimum of two hours per group session. However, the more training you receive, the more you will understand the capabilities of the iTrace software and equipment and be satisfied with your investment. If possible, it can be helpful to schedule some patients for an actual examination near the end of training. The training specialist will do the following:

- Explain the hardware components
- Train you on the operation of the hardware and software
- Train you on the iTrace exam processes and acceptance criteria
- Explain the different displays
- Explain how to customize displays based on your practice needs

To Install your iTrace Software

The computer may have the iTrace software pre-installed and ready to use. Simply double click on the iTrace icon  on the desktop to launch the software.

If you are supplying the computer, you will need to install the software. To do so, start your computer. Log on with your username. Your username must have **administrator privileges** to install new software. If not, please contact your system administrator for support.

1. Please disable any anti-virus program running on your computer. You will need to turn OFF the User Account Control feature. Please contact Tracey Technologies if you need instructions for this process.

2. Insert iTrace installation media or locate the Setup file on your computer. Double click the file named "Setup".

3. A window will open that asks you to accept the software license agreement. Click the radio button by accept and the "Next" button.

4. A window will open asking you to verify the location of the software installation. Click "Next" to accept the default location or choose another location and click Next.

5. A window will open asking if you would like a desktop shortcut to be created. Click "Next".

6. The software is now ready to be installed. Click "Install". The installation will take place while displaying a progress bar. If another window appears asking to install device drivers, click Install. A confirmation window will appear. Click "Finish" at this window. Follow any instruction to restart the computer.

7. Turn on the power of the iTrace Data Acquisition Unit (DAU). Setup instructions are provided in the companion iTrace Quick Setup Guide (see Appendix C in this manual).

8. Verify the USB cable is plugged into the iTrace DAU. Plug other end of USB cable into available USB 3.0 port on the computer.

9. Start the iTrace software by double-clicking the iTrace icon  on your Windows desktop. The software will perform a system test lasting a few seconds and display a welcome screen. The software is ready when the Main Patient List screen appears.

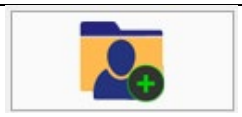
To Use the Joystick

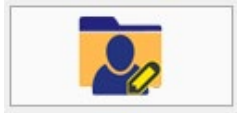
The joystick is used to position the DAU in front of the patient's eye for data acquisition. The four operations performed by moving the joystick are listed below:

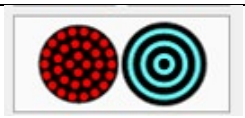
To move the image left or right in small increments, move the joystick in the left or right direction.
To move the image up or down, twist the joystick clockwise (up) or counter-clockwise (down).
To focus the image in small increments, tilt the joystick forward or backward.
To capture an image while in manual mode, press and release the acquisition button on top of the joystick.

Icons and Symbols Used in Software

The following symbols and icons are used throughout the software to interact and control the software and its displays.

Icon/Symbol	Description	Where is this found in software?
	Patient Database select storage location	Patient List Screen
	Cancel Patient List filter	Patient List Screen
	Backup patient database	Patient List Screen
	Refresh patient list from database	Patient List Screen
	Add patient record to database	Patient List Screen
	View selected patient's exam data	Patient List Screen

	Edit patient record	Patient List Screen
	Delete patient record	Patient List Screen
	Import patient(s) record(s)	Patient List Screen
	Export patient(s) record(s)	Patient List Screen
	Export patient exam data to CSV Files for spreadsheets	Patient List Screen
	Access software interface settings	Patient List Screen
	Software activation control	Patient List Screen
	Quick calibration check tool	Patient List Screen
	Software About Screen	Patient List Screen
	Exit software	Patient List Screen
	View lists of all exam types	Exam List Screen
	View simple list of only WF and CT exam types	Exam List Screen
	View exam information and acquisition data	Exam List Screen
	Select favorite exams	Exam List Screen

	Capture WF exam only	Exam List and Data Display Screens
	Capture CT exam only	Exam List and Data Display Screens
	Capture Dual WF and CT exam in sequence	Exam List and Data Display Screens
	Capture Tear Film Analysis exam	Exam List and Data Display Screens
	Capture External Eye Image – color or infrared	Exam List and Data Display Screens
	View selected exam(s) data displays	Exam List Screen
	Exit from the Exam List UI to the Patient List UI or Exit from the Display UI to the Exam List UI	Exam List and Data Display Screens
	Edit exam information	Exam List and Data Display Screens
	Delete exam	Exam List Screen
	Access patient survey	Exam List Screen
	Saves batch of display reports that are designated in Settings for selected exams	Exam List Screen
	Prints batch of display reports that are designated in Settings for selected exams	Exam List Screen
	Set of symbols that control the aberration masking for graphical representations between Total Aberrations, Higher Order Aberrations	Data Display Screens

	and Total, No Defocus Aberrations	
	Displayed with **Higher Order Total** aberrations only (with "spectacle correction".)	Data Display Screens
	Displayed with **Total, No Defocus** aberrations, in other words, all aberrations except the defocus term (with "spherical correction" only.)	Data Display Screens
	Displayed with **Total** aberrations, (without "spectacle correction".)	Data Display Screens
	Reduces the zone size of the WF data used in the graphical representation in display	Data Display Screens
	Increases the zone size of the WF data used in the graphical representation in display	Data Display Screens
	Decreases the size of the Snellen E in display or "zoom out" the details of a color map by increasing the step size used in the scaling of a color map	Data Display Screens
	Increases the size of the Snellen E in display or "zoom in" the details of a color map by decreasing the step size used in the scaling of a color map	Data Display Screens
	Decreases and increases the middle value of the scale on color map	Data Display Screens
	Signals the point which a small pupil size (2.5mm) affects the corneal performance index (CPI)	Data Display Screens
	Signals the point at which a large pupil size (4.5mm) affects the CPI	Data Display Screens
	Toggles the K data between WF Ks, Refractive Ks and Simulated K data	Data Display Screens
	Toggles the display to show full set of RMS bars or Indices	Data Display Screens
	Toggles the display to show abbreviated set of RMS bars or Indices	Data Display Screens

	Displays the Custom CL Display	Data Display Screens
	Creates the CL output file. Will be grayed out until the user places the lens dots within the Custom CL Display	Data Display Screens
	Exports Data to XML or Exports images to DICOM Store Server	Data Display Screens
	Saves current display to image file	Data Display Screens
	Prints current display to a connected printer	Data Display Screens

To Power the System On

1. Verify all cable and power connections to iTrace and the computer are set up. If possible, plug the computer and iTrace into the same outlet or power source.

2. If using a surge protector, locate the power switch on the surge protector and move to the *ON* position.

3. Locate the power switch/button on the laptop or desktop computer and place in the *ON* position.

4. Wait until computer has finished its boot-up process and shows the Windows desktop with all icons.

5. Locate the power button on the technician side of the iTrace DAU and press once to illuminate. If it fails to illuminate solid green after a test period of about eight seconds, contact Tracey Technologies as this indicates an error code.

6. Double click on the  icon on the Windows Desktop screen.

To Power the System Off:

1. Exit the iTrace program by repeat clicking  in the lower right corner of the iTrace screen until you get to the main menu screen, then click  . Confirm ***Yes*** to exit the program.

2. Remove and safely store any CD's from the computer.

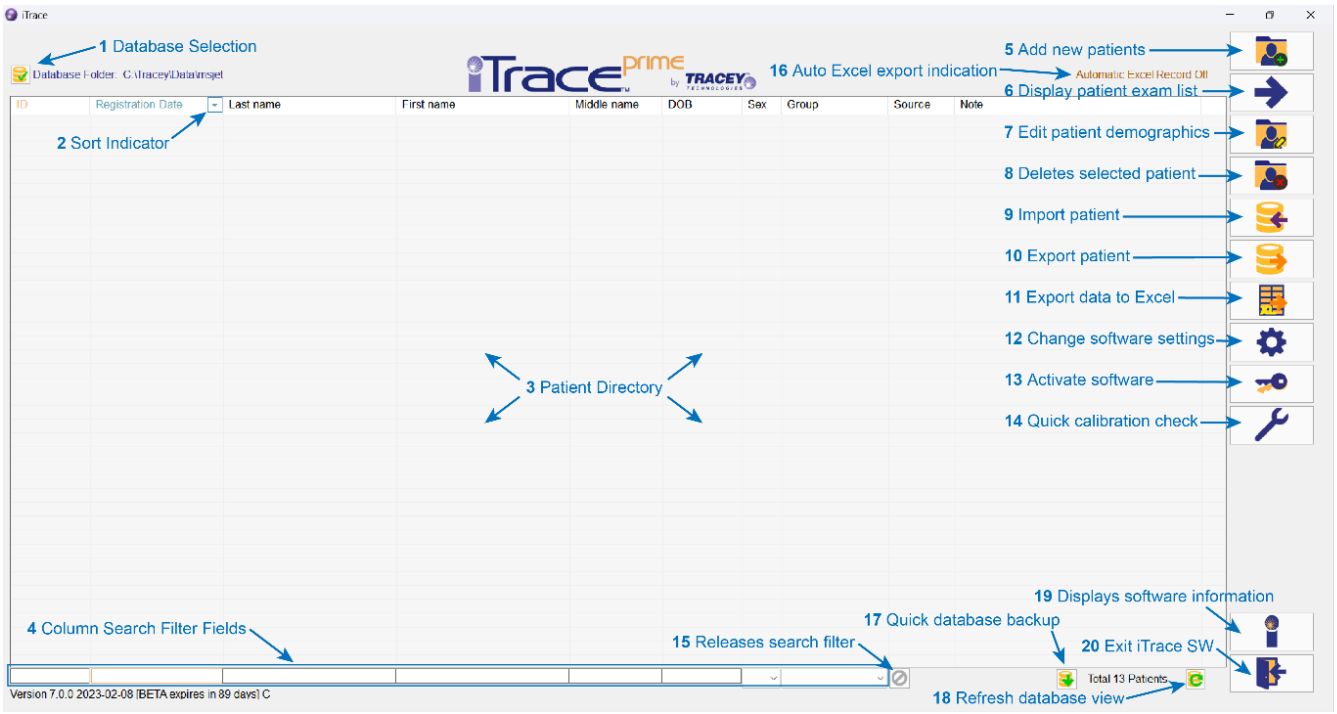
3. Click the *Start* button on the computer and select *Shut Down* or *Turn Off Computer* from the menu and the *Turn Off* option in the pop-up window if presented. The computer now will shut down.

4. Push the green power button on the iTrace DAU one time to de-illuminate.

5. If using a surge protector, place the surge protector power switch in the *OFF* position.

Chapter 4 New and Existing Patients

You will need to add all patients as new the first time they are examined. Once a patient's information is entered, you may select the patient's name from the patient directory. To proceed with an exam, go to the *Patient Exam List* by double clicking on the patient's name or select the patient's name and click  .



Key Features

1 **Database Selection** allows you to browse to create or select

2 **Sort indicator** organizes a column in ascending or descending order. Clicking on column header allows you to switch the current sort order.

3 **Patient Directory** displays patient information from the current database. Initially, this area will contain no data until either a database file containing information is selected or a new database file is created and new patients are added to it.

4 **Column Search and Filter Fields** allows data to be searched by column. Typing data in these fields will fetch the corresponding data column in the Patient Directory. Clicking on a column header will sort the Patient Directory listing by that column. Clicking will clear the search fields.

5  **Adds new patients** to the current database.

6  Moves forward in the process by displaying the **Exam List** for the highlighted patient in the Patient Directory. Note that double clicking an entry in the Patient Directory will achieve the same result.

7  Brings up the patient demographic data of a highlighted patient entry in the Patient Directory to enable **edits to demographic data**.

8  **Deletes** the highlighted Patient entry.

9  **Imports patient** and associated exams from a different iTrace database.

10  **Exports patient** and associated exams to another iTrace database.

11  **Exports and exam patient** data to a CSV file, as per parameters specified in Settings.

12  Displays the current **Preference Settings**. Initially it uses the default values. Preferences can be edited and backed-up in this window.

13  Opens the **Software Activation** window displaying the current iTrace software license type activated on the computer. It also enables the user to activate

additional features and functionality to the iTrace software though the license activation codes obtained from Tracey Technologies.

14  Will enable a quick **Verification** of wavefront **Calibration** of your iTrace DAU.

15 **Releases** the database **Search Filter** and resets list back to full database list.

16 Indicates if the software is set to **Automatically Export** data to CSV files as specified in Settings.

17 Perform a **Quick Backup** of the database to the location selected in the browse window.

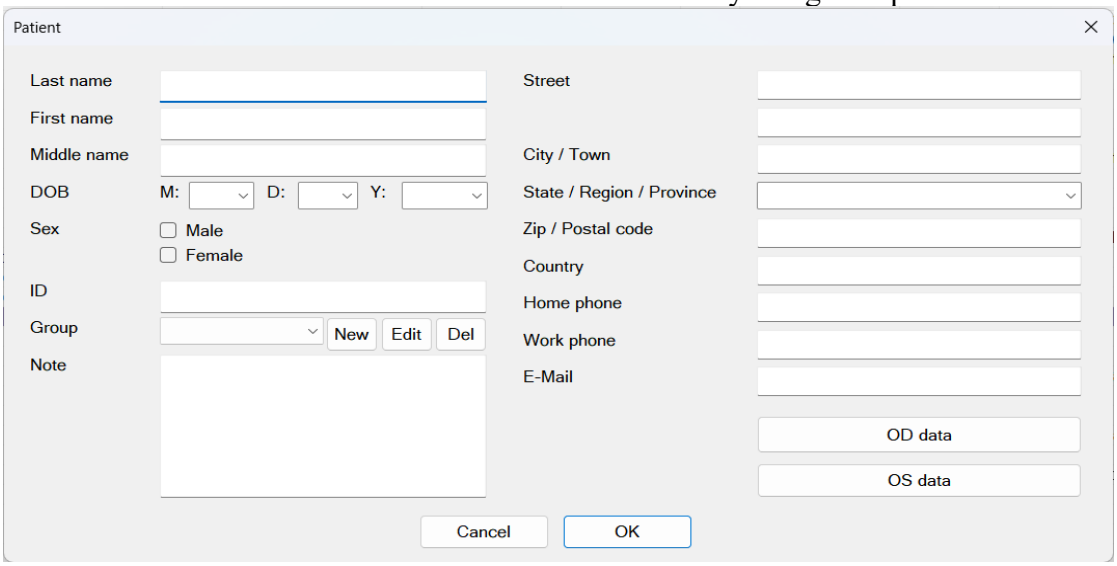
18 Clicking  will **Refresh** the database to include patients and exams recently added on the network. The total **Number of Patients** in the database is also shown in this area.

19 Displays **Software Information** such as version and legal details.

20  Will **Exit** the iTrace program.

To Add New Patient

1. Click on the  button next to the Patient Directory navigation panel.



2. Enter the patient's personal data using the ***Tab*** key to advance to next field and ***Shift*** + ***Tab*** key to jump to the previous field. Last name, First name, and DOB are required for new patients. Other data fields are optional. Enter information carefully to avoid potential duplications.

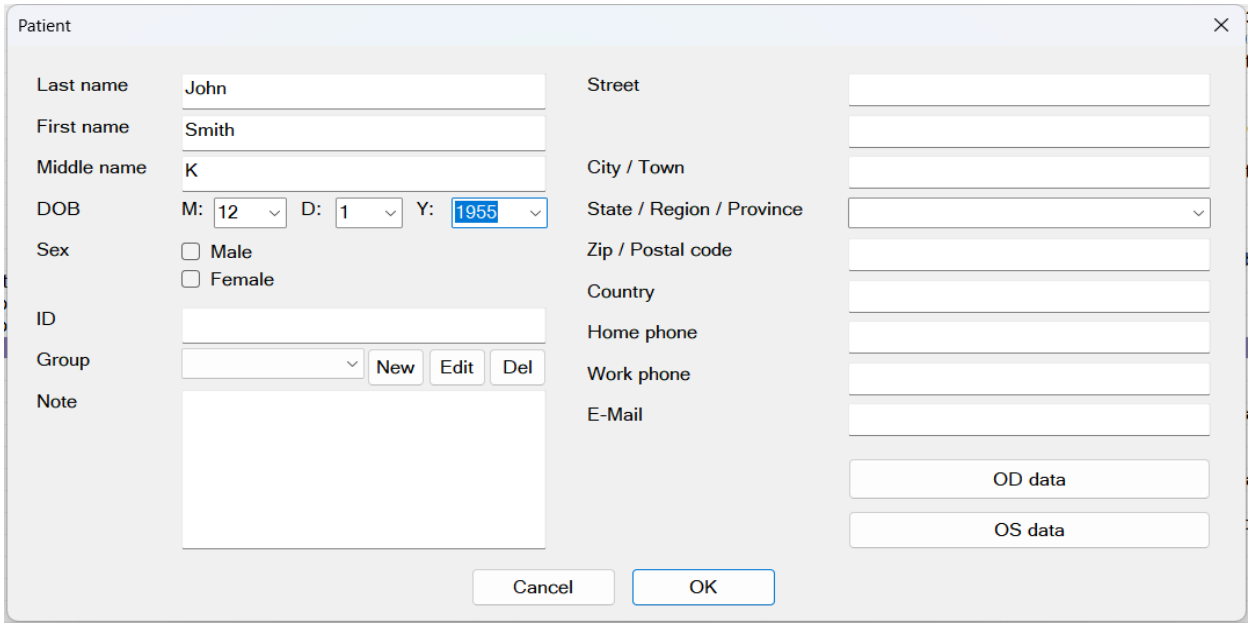
Click on the drop-down list arrow in *Group* field to select a list of previously entered data.

Enter OD and OS manifest refraction and keratometry data if desired by clicking on the appropriate OD or OS Data buttons.

3. Click ***OK*** to save.

To Edit Patient's Data

1. Select a patient.
2. Click  .
3. Modify the Patient's Data.



4. Click ***OK*** to save.
5. When editing the patient's name fields or the Date of Birth, the software will ask you to verify that you want to change this data.

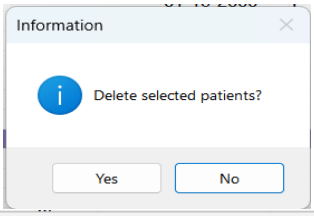
Note: Do not use the following characters in the Patient Last name, First name or Middle name fields: \ / : * ? " < > |

To Delete a Patient

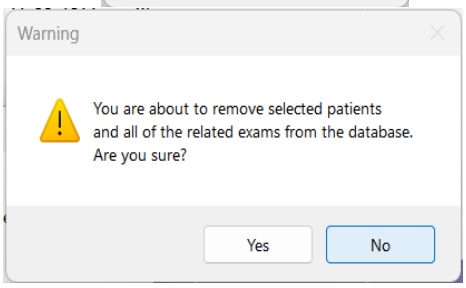
1. Select one patient or multiple patients by holding the *Ctrl* button while selecting each patient.

2. Click  then select "***Delete***" option.

3. Confirm the requested action.



4. If you answer ***Yes***, a second warning window appears letting you know that this action is permanent. Answering ***Yes*** again to this second warning will permanently delete your selected patient data from the database.



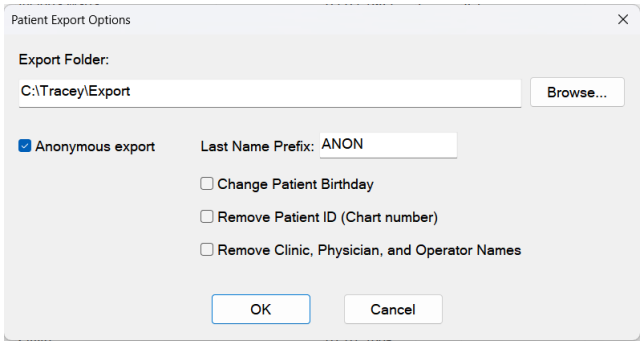
To Export Patient Data

1. Select one patient or multiple patients by holding the *Ctrl* button while selecting each patient.

2. Click  .

3. Patient's data will be exported to the Export file under the Tracey directory of the computer's hard drive, or you may choose another location in the ***Browse For Folder*** window that appears when you click Browse... A compressed file is created for each patient selected that can be copied to an external storage device, stored to a network and imported to another computer running iTrace software, or it can be emailed to import to another computer.

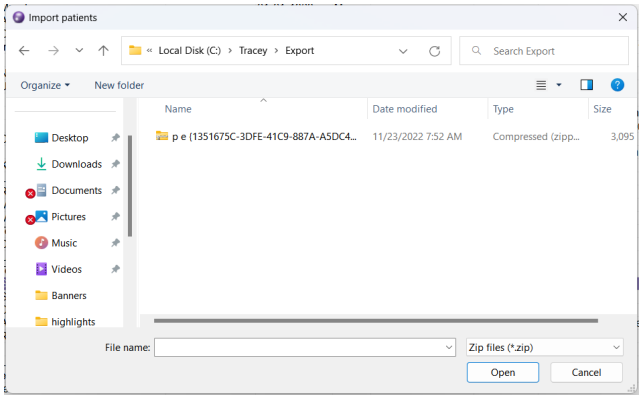
4. The Patient's data can be anonymized for privacy compliance by clicking the box next to **Anonymous export**. Various anonymization options are available to select for the export with the option to choose several for the level of privacy control you are seeking.



To Import Patient Data

1. Click  .
2. Locate patient's .zip file in the list.
3. Select patient's .zip file name and click ***Open***.

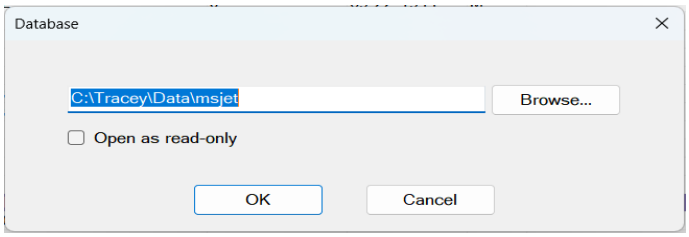
The patient is added to the database.



To Select or Change the Storage Location for Your Patient Data

By default, your patient data is stored within Microsoft Jet databases, located in a folder titled Data within the Tracey folder of your computer's hard drive. You have the option of creating a network accessible database folder with the iTrace software. Storing your patient data on a network accessible drive allows you and others to view the data from any computer on the network that runs iTrace software. For more information, see Appendix F. You can also create multiple databases. The current database storage path is listed on the Patient List screen in the top left corner. To change the location of your database or create a new database, follow these steps:

1. Click  or press ***CTRL*** + ***D***. The following dialog box will appear.
2. In the box, type in the folder address for the new database location or click ***Browse*** to locate and select it.



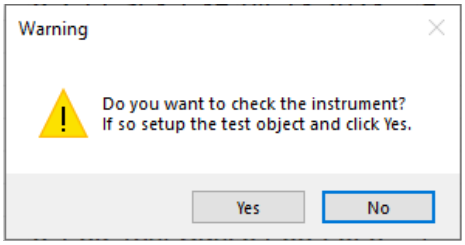
3. Click ***OK***. The iTrace software will store your patient data in this new database until you return to this screen and select another database.

Note: Please consult with your network administrator before creating a database on a network drive. It is the user's responsibility to ensure the integrity of their data on a network.

To Perform a Quick Wavefront Calibration Check

You can quickly check the Wavefront calibration of your iTrace by clicking the button on the Patient List screen. If you require a documented record of the calibration of your iTrace, (for example if the practice is participating in a clinical study) and for instructions for verifying the corneal topography calibration, please see Appendix D.

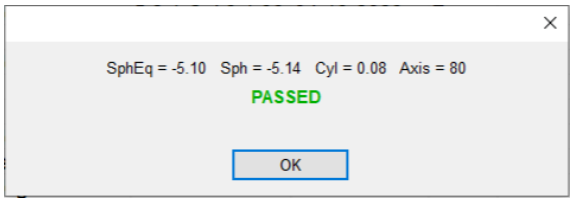
a. Click . The following dialog box will appear.

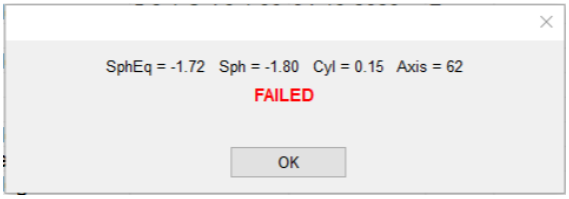


b. The center hole of the iTrace's Placido disk is threaded for the use of the calibration verification tool – a cylindrical object that shipped with your iTrace DAU. Insert the calibration verification tool into the center hole and turn until slightly tightened.

c. Click ***Yes***.

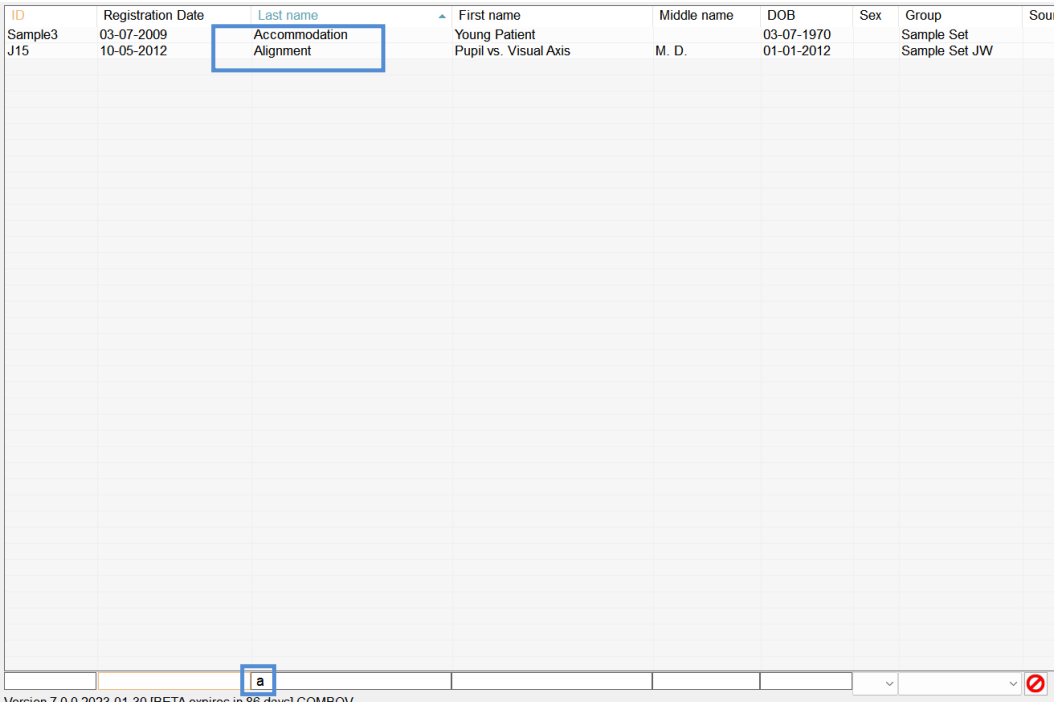
d. The software will automatically capture the exam and provide a window indicating if the calibration was within the accepted range. If the window indicates the test Failed, please contact Tracey customer support at **(281) 445-1666** or via email to **service@traceytech.com**.





To Search for a Patient

1. Search for an existing patient in the *Patient Directory* listing by using the scroll bar or by using the *Column Search Fields*. The program will try to match the entered criteria and then display the result in the corresponding *Parent Directory* column. For example, typing a "a" in the Last Name column search field will yield a list of patients that have last names starting with a letter "C".



The *Patient Directory* list will be empty if there is no match for the entered criteria. Clicking the ⊘ will delete the entered search criteria and return the *Patient Directory* list to the full database. Clicking on the drop-down list arrows will show the entered unique column values, i.e. Groups. Clicking on the button under the Registration Date column will enable a dialog box allowing you to search a range of dates for the patient's registration in the database (also known as the date the patient was created in the database). To release this filter, click *Cancel*.

2. Patients may be sorted by a specific field by clicking on the column header. For example, clicking on **First Name** will sort the patient list alphabetically (A-Z) in ascending order. If the list is already in ascending order then it will sort by descending order. The ▲ or ▼ symbol on the column header indicates ascending or descending order.

To Refresh the Database

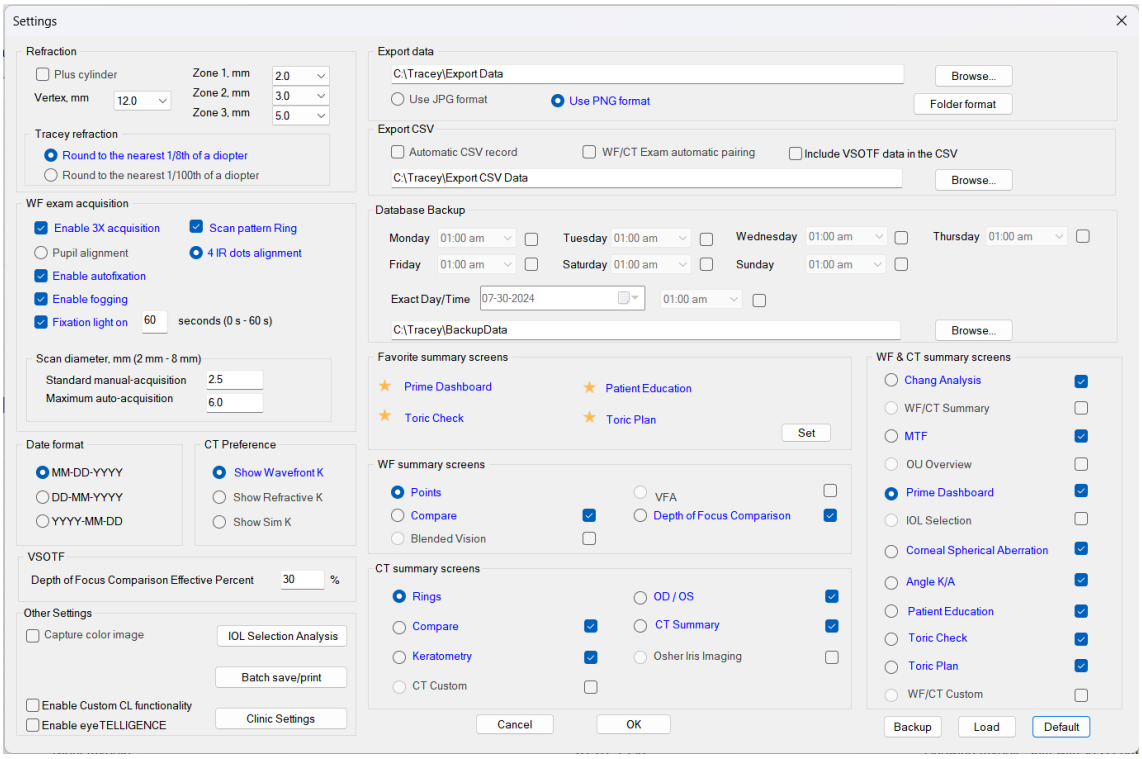
If using the iTrace software as a Viewer, you should refresh the database periodically. When looking for a patient name or exam that you expected to find and could not, selecting the Refresh button will ensure that you are viewing the most recent database entries. To refresh the database:

1. Click on  icon.

To Edit Settings

User preferences for the iTrace software are set and saved in the Settings dialog. Depending on the level of software activated (Prime vs Core), you may have fewer options than described for control of your preferences. To set or edit the user preferences:

1. Click on  button.



The ***Refraction*** box allows the user to select preferences for using plus or minus cylinder refraction, vertex distance, and the zone sizes for multi-zone refractions. It also provides options for rounding the refraction data.

The ***WF Exam Acquisition*** box controls the process of WF Exam Acquisition process including properties of the fixation target (Badal Optometer) that the patient views during an examination.

The ***Enable 3X Exam Acquisition*** is the preferred mechanism for capturing WF exams. Checking the checkbox allows you to capture three wavefront exams at a time and provide the optimum exam captured in the process.

The ***Pupil Alignment*** and ***IR Dot Alignment*** radio buttons give you the option to select your preferred centration alignment method for a single WF exam acquisition. You can choose to center the WF scan on the pupil center or the center of the infrared light image, which is an approximation of the visual axis. For a dual WF and CT Exam, the software will *only* acquire using the IR Dot centration method.

When ***Enable autofixation*** is checked the optometer is set to +6.5 D and 16 pre-exam laser spots are projected through the entrance pupil. This data is then used to calculate the patient's spherical equivalent. The fixation target is moved to the patient's far point (spherical equivalent plus ½ the cylinder) for the patient to view during the examination. If ***Enable fogging*** field is checked then the target is moved an additional 1D in the plus direction prior to capturing the exam data. Fogging can only be enabled if auto-fixation is enabled. It is recommended that both of these boxes be checked.

The ***Fixation light on*** check box sets the iTrace to leave the fixation target light turned on and is the recommended setting. You can also set a timer that will turn off the fixation target light after the specified number of seconds. There is an onscreen button or a keyboard temporary on/off switch that is available during acquisition as explained in Chapter 5. However, if using open-field acquisition and a fixation target positioned properly in the exam room, you can disable the fixation target light as a default with the check box unchecked here.

The ***Scan diameter*** box sets the iTrace to scan at this setting as the maximum scan pattern size when it is in automatic and manual acquisition mode. When in automatic acquisition mode, the iTrace will self-adjust to fit the scan pattern within the entrance pupil, up to the maximum scan size set here. When in manual acquisition mode, the user can adjust the scan size using the arrow keys as described in Chapter 5.

The ***Scan Pattern Ring*** selection will show the red ring as the overlay during a WF capture by default. Otherwise, the Scan Pattern will be used as the overlay. Either can be changed during the WF capture with the onscreen button.

Selecting ***Show animated scanning after new exam is taken*** will instruct the software to animate the scan points in the WF Verification display one cycle.

The ***Date format*** box enables you to select the date format you prefer to enter and display.

The ***CT Preference*** box enables you to specify which keratometry reading you wish to display on the simplified indices panels. You can choose to display Wavefront Ks, Simulated Ks or Refractive Ks. More information about these indices is available in the Glossary at the end of this User's Manual.

The ***VSOTF*** box allows you to specify the threshold for calculating the VSOTF Depth of Focus effective level.

If ***Capture color image*** is checked, the software will display the additional options of Automatically or Manually. Choosing Automatically will instruct the system to capture a color iris image immediately after a CT exam is acquired. Choosing Manually will allow you to use the Joystick button to capture the image. More instruction can be found in Chapter 5.

The ***IOL Selection Analysis*** button opens a new window in which you can adjust the thresholds used in the IOL Selection Analysis display. The iTrace software utilizes the thresholds as a basis for the analysis of IOL options to be considered.

The ***Batch Save/Print*** button opens a new window in which you can choose the displays you wish to create and save and the location for saving them when the Batch Save/Print button is clicked from the Exam List screen.

If ***Enable Custom CL functionality*** is checked, the features available to create custom soft contact lens orders (RTcl lenses) and create scleral contact lens design input files are activated.

If ***Enable eyeTELLIGENCE*** is checked, the B+L eyeTELLIGENCE export button is added to the navigation bar that will automatically export the data for the application to CSV files that can be retrieved for analysis from the Tracey/Export B+L folder.

The ***Export data*** box enables you to specify where exam and screen data are saved when the Export Data button is clicked on exam display screens. Exporting exam data is useful for research applications and/or if you are utilizing an EMR or Image Management (IM) System with the iTrace. If you are using an EMR or IM system, you will need to set this storage location based on the location specified by your IT system administrator. More information can be found in Appendix F.

The ***Export CSV*** box enables you to specify the functionality of the CSV spreadsheet data export. This functionality is useful for research institutions to quickly compile data. The details of these settings (including the Spreadsheet Settings button) and the data export functionality can be found in Appendix F.

The ***Database Backup*** box enables you to setup and control automatic backup of the patient/exam database. You can choose the frequency by selecting the day or days of the

week and time for the process to occur. You can choose an exact date and time for the process. And you can also choose the location where the backup will be saved.

The ***Favorites*** box enables you to choose the four displays you would like to be available with one click from the Display Screen Navigation menu.

Most ***WF Summary***, ***CT Summary*** and ***WF&CT Summary*** displays are customizable, and a default display can be selected for each. The default display for each display type is the first screen to appear when an exam is selected. To specify the default displays, select the desired display by clicking the radio button next to the display name.

You can choose which displays to have available in the navigation menu; although, certain displays (Points and Rings) are required, and at least one WF&CT display must be selected. To select the displays available in the navigation menu, click on the checkbox next to the display name.

The ***Backup***, ***Load*** and ***Default*** buttons allow you to save your customized settings, load your saved settings and return the settings to the default settings, as they were on installation. To Back up Settings data, click on the Backup button; choose a name and storage location and click OK. To Load, click the Load button, browse to your saved file and select it, click OK. To return the defaults that come with the software installation, click on the Default button. Click Yes to set the default settings to restore to the defaults that came with the software installation.

2. Select ***OK*** to save your changes to Settings.

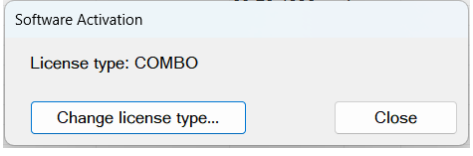
3. If you make custom changes, Tracey recommends that you **backup your settings** file in the event you make inadvertent changes and wish to re-load custom settings.

To Activate Software

The Software Activation window unlocks the features of your iTrace Software. Activations include the Combo activation, the Combo Viewer activation and other custom activations. Upon initial installation, the user will need to activate the software by clicking *Activation*. The user can also verify the currently activated software license by clicking *Activation*. The user must be logged in to the computer as the Windows Administrator to activate the software. If logged in as a different user, logoff and log back into Windows as the Administrator, and then re-open the software.

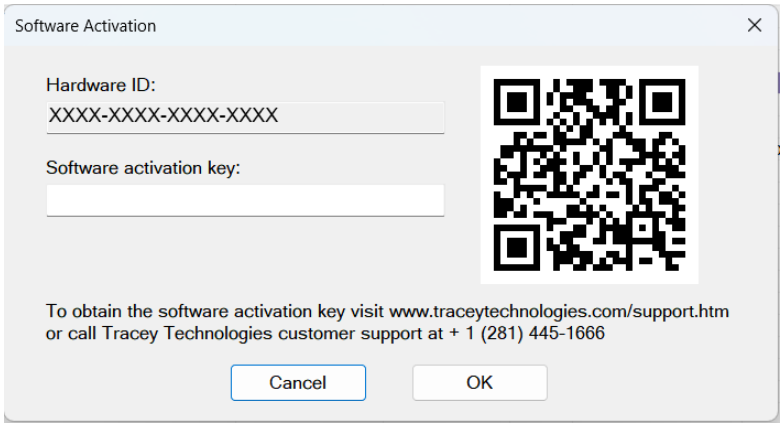
1. Click on  .

2. The Software Activation dialog box appears. To change the license type, click on *Change license type.* The Software Activation key entry



box will open. To exit, click on *Close*.

3. To activate your license, you must obtain a software activation key code from Tracey Technologies customer service. To do so visit https://www.traceytechnologies.com/support/ and click "Activate Your iTrace Software". You will need to provide the Hardware ID code from the Software Activation dialog box. This code consists of four sets of five alphanumeric characters. Be careful to distinguish I's and 1's and O's and 0's. The best way to ensure accuracy is to copy and paste the code directly to the website form. Complete the required information and click Submit to send us your hardware ID code. You will then receive the software activation key by email, which will be a different sequence of four sets of five alpha-numeric characters or a set of nine numeric characters.



4. Enter the key code you have received in the space provided and click *OK*. Again, copying and pasting prevents keystroke errors.

5. Exit the software and re-start to properly reset the settings for that activation.

Chapter 5 The Examination Process

To proceed with the exam process from the *Patient Directory*, go to the *Patient Exam List* by double clicking on the patient's name, or select the patient's name and click  .

This manual explains the wavefront and corneal topography as individual exam processes for full understanding of each. However, **the dual wavefront and topography exam is the preferred method of exam acquisition**. This ensures that the patient maintains the same position throughout the exam process. We encourage you to visit the Tracey Technologies website Support section to **view videos** showing proper acquisition of data with the iTrace.

Additionally, the iTrace Wavefront exams can be acquired in a Multi-Capture process. This process captures up to three wavefront exams in a row and the software compares the exams to ensure consistent results, then intelligently selects the best exam from the exams captured. This ensures more accurate results.

A **dark room** is ideal for acquiring an image from patients with larger pupils. The pupil must be at least 2.5 mm to acquire a standard wavefront image. Pharmacologically dilating the pupil removes the patient's ability to accommodate but may also inhibit the ability to accurately determine the difference between day and night vision. Dilation may alter lenticular aberrations and thus alter refraction measurements. However, pupil dilation using drops is the physician's prerogative based on the information needed. Exams may be conducted with various levels of lighting to analyze the patient's vision under different conditions.

Patient Positioning

NOTE: Patient positioning is critical for accurate examination and shortcuts in this step will cause the capture process to be more difficult.

1. Position the patient in front of the iTrace unit with chin fully forward against the chin cup and forehead resting against the headrest.

2. Adjust the chinrest height by twisting the chinrest knob so that the patient's forehead is pressed against the head strap. The motorized table may also be adjusted up or down for patient comfort. Ask patient to hold the handles to maintain stability while seated.

NOTE: You must not allow them to use any part of the iTrace when in the act of sitting or standing as this may destabilize the iTrace and cause injury to the patient.

3. Ask the patient to close their jaw so that their teeth are touching; the patient doesn't need to clench their teeth. Turn the patient head to the side opposite to the eye being captured by about 15-30 degrees so that the cone of the unit can move inside the plane of the patient's nose.

4. The eye not undergoing testing should be occluded, unless binocular testing is desired. If the optometer is not being used and the cap covering the line-of-sight is removed, ask the patient to fixate on a distant target while looking through the viewing path of the DAU. Do not block the patient's view, as this may promote accommodation and result in undesired refractive measurements.

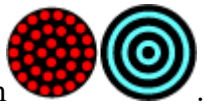
5. Make sure the patient's forehead is resting firmly and comfortably on the forehead strap.

6. Patient distance from the device is important, make sure to get the patient close enough to the machine so the patient doesn't need to lean over.

Capturing a Wavefront Exam

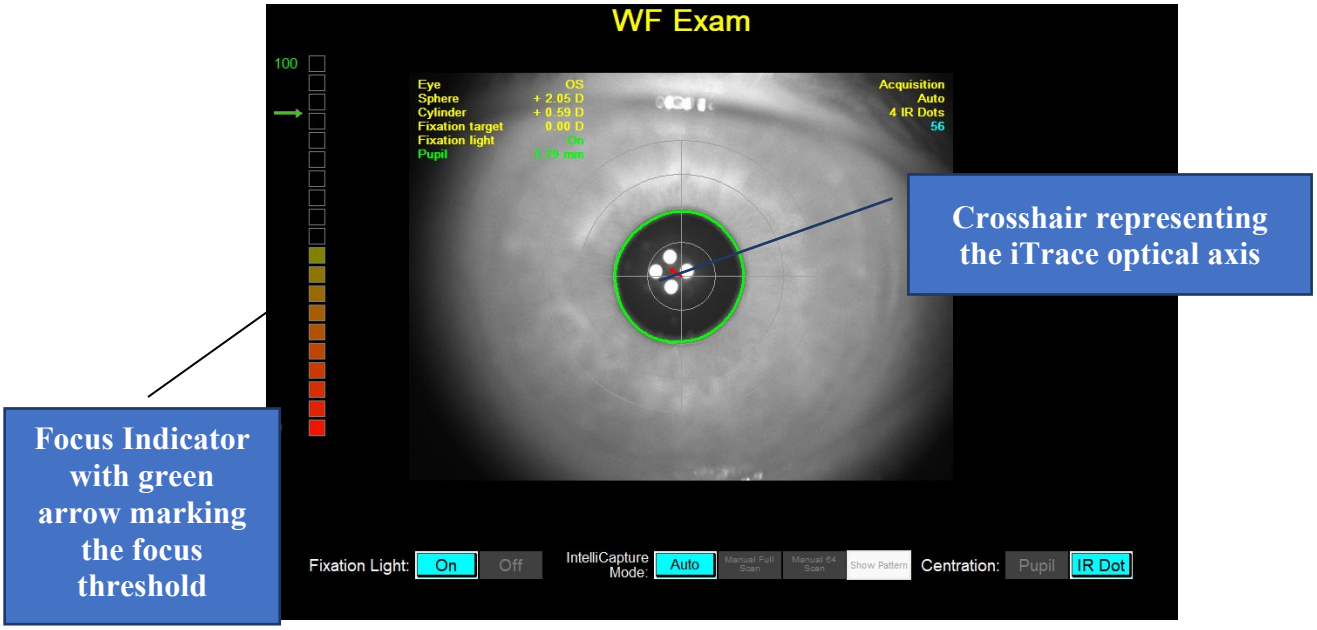
Automatic Multi-Capture or Single Capture Mode

1. Position the patient as instructed above.

2. From within the Exam List screen, click on WF capture button  or the combined WFCT capture button  . The capture process will begin.

Note: The combined WFCT capture button is the recommended approach to minimize time between scans and minimize patient position variation. If this method is used, please ensure patient maintains fixation on the target.

3. You will see a central cross hair mark representing the iTrace's optical axis and you will see a bar on the left side of the screen. This bar indicates the image alignment and focus quality representing how far you are from focus.


WF Exam
100
Eye OS
Sphere + 2.05 D
Cylinder + 0.59 D
Fixation target 0.00 D
Fixation light On
Pupil 3.79 mm
Acquisition
Auto
4 IR Dots
56
Fixation Light: On Off
IntelliCapture Mode: Auto Manual Full Scan Manual 64 Scan Show Pattern
Centration: Pupil IR Dot
Crosshair representing the iTrace optical axis
Focus Indicator with green arrow marking the focus threshold

4. Use the manipulator to move the iTrace and bring the patient's eye in view. When the patient's pupil is in the view, the pupil margin will light up in green.

5. The patient will see a red dot (if the fixation target is turned on). Ask the patient to look at the red dot. You can turn the fixation light on and off by tapping the F10 key on the computer keyboard or the Fixation On/Off buttons on the screen. An indicator on screen will signal if the fixation light is on or off. Utilizing the fixation light during closed-field acquisition is important. You should only turn off the acquisition light permanently (this can be done in Settings) if the exam is open-field and the patient has an alternative fixation target. You can also set a timer to automatically turn of the fixation light after the designated number of seconds.

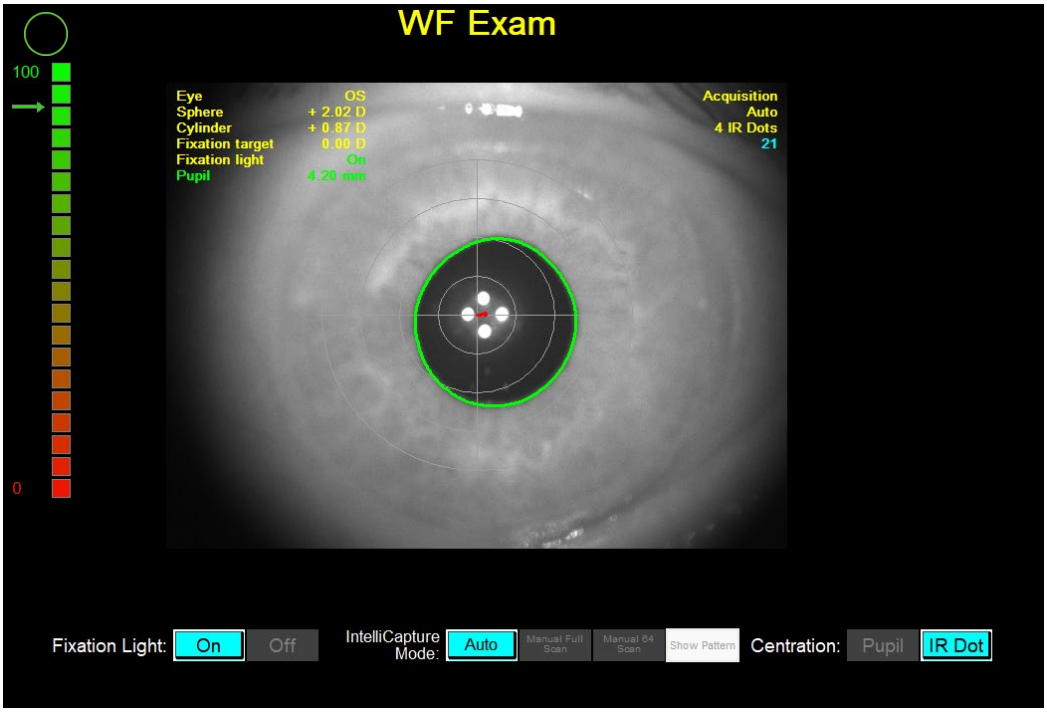
6. You will see four white dots inside the patient's pupil (first Purkinje images), approximately aligned to the patient's visual axis, and a red line appearing from the center of the dots to the crosshair. Collapse the red line until the crosshair and center of the 4 dots are aligned.

7. Use the manipulator to move toward then away from patient as necessary to get better image quality. The focus and alignment indicator bar will move up and down based on how far you are from the optimal capture distance.

8. Once the indicator reaches the threshold marker (green arrow) that indicates the optimal focus [*see Note below*] ask the patient to blink once softly. The iTrace will automatically capture a quick WF scan to find the initial refraction, which sets the optometer to the patient's near target. During this time the video will freeze for a few seconds.

NOTE: In some patients, the image focus quality will never meet the designated threshold due to corneal pathologies, irregular iris, etc. In such cases, follow these steps:

a. Move the device slowly all the way to the backward and away from patient then all the way forward and toward the patient while maintaining centration within the IR dots
b. Observe how far up the focus indicator bar reaches.
c. Click, hold and drag the threshold marker (green arrow) on the focus indicator bar just below the upper end of the highest observed value.
d. Restart the capture process at step 4. The software should capture at the optimal distance.
e. If the above steps do not work, switch to manual capture by following the steps under *Manual Multi-Capture or Manual Single-Capture Mode*.



9. After the capture, a countdown symbol will appear above the focus indicator.

It will countdown 4 seconds:  and then  .

10. When you see the blink symbol, ask the patient to blink softly then open wide. The software will capture the first full scan. If Multiple Capture mode is selected in settings, this capture process will repeat two more times, following the above steps 6 – 9. You will have 60 seconds total to capture the multiple exams. If the timer runs out with only two WF captures, the system will proceed to step 11.

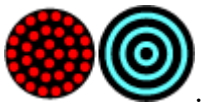
11. After the capture process is completed, the software will show you one of three screens: (1) The Exam Results of the IntelliSelected WF exam in which the system compared the three scans and chose the best one, (2) the WF Verification screen if the acceptance criteria for IntelliSelection was not met, or (3) the Corneal Topography capture window if Dual Exam process was clicked.

a. During IntelliSelection of a Multi-Capture WF Exam, the software will compare the exams to ensure they are within an acceptable variance range for Spherical Equivalent (SEQ) and Cylinder. The software will then pick the exam with the largest scan size from the exams that met the criteria.

b. If no exams met the criteria, the user will be presented with the WF Verification screens for each of the exams. The user can use the blue arrow buttons  in the top of the indices panel to cycle through the exams for review. See page 52 for details about how to read the Verification display. To select the preferred exam, click the Accept button: ✓.

Manual Multi-Capture or Single-Capture Mode

1. Position the patient as instructed above.

2. From within the Exam List screen, click on WF capture button  or  . (The combined WFCT capture button is the recommended approach to minimize time between scans and minimize patient position variation.) The capture process will begin.

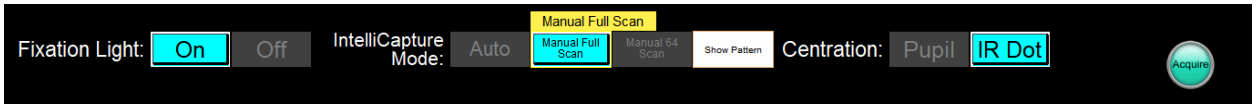
3. You will see a central cross hair mark representing the iTrace's optical axis and you will see a bar on the left side of the screen. This bar indicates the image contrast quality representing how far you are from focus.

4. Use the manipulator to move the iTrace and bring the patient's eye in view. When the patient's pupil is in the view, the pupil margin will light up in green.

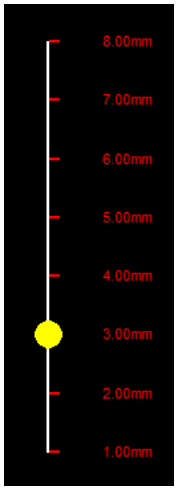
5. The patient will see a red dot (if the fixation target is turned on). Ask the patient to look at the red dot.

6. You will see four white dots inside the patient's pupil (first Purkinje images), approximately aligned to the patient's visual axis, and a red line appearing from the center of the dots to the crosshair. Collapse the red line until the crosshair and center of the 4 dots are aligned.

7. Click on the Manual Full Scan button at the bottom of the screen or press the Enter key on the keyboard.



8. Move the device toward then away from patient as necessary until the focus indicator bar reaches the highest level where if you move backward or forward the value is stable.



9. Ask the patient to blink then click the Acquire button on screen or the joystick button.

10. The software will show a red circle over the eye that designates the scan area and a red slider on the right side of the screen representing the scan size. Increase the scan size so that the red circle is as large as possible without touching the pupil margin (the green circle).

11. A countdown timer on the top left (the green circle) will display and cycle through the timer. Wait until you see the "blink" image then ask the patient to blink softly and open wide.

12. After the blink, click the Acquire button (on screen or on the joystick).

12. If using Multiple Capture mode, repeat Steps 9 to 12 two more times. You will have 60 seconds total to capture the multiple exams. If the timer runs out with only two WF captures, the system will proceed to step 13.

13. After the capture process is completed, the software will show you one of three screens: (1) The Exam Results of the IntelliSelected WF exam in which the system compares the three scans to ensure they are within an acceptable variance range for SEQ and Cylinder, and chooses the exam with the largest scan size, (2) the WF Verification screen if the acceptance criteria for IntelliSelection was not met, or (3) the Corneal Topography capture window if Dual Exam process was clicked.

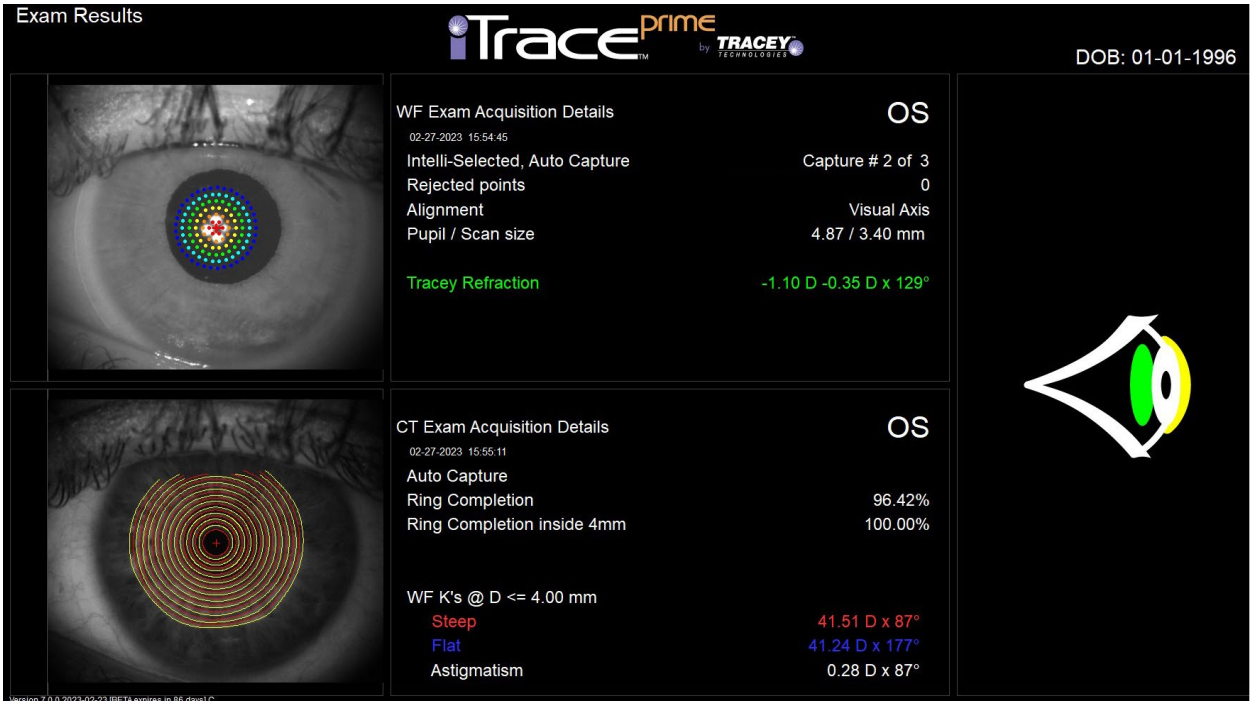
NOTE: During the WF capture process the iTrace will fire the 785 nm wavelength laser for approximately 0.25 seconds during the wavefront exam(s) capture.

If the exam(s) is not captured automatically or manually within 60 seconds, the exam process will terminate and must be restarted.

Exam Acceptance and Exam Results Display

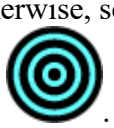
Whether capturing in automatic or manual mode, after the exam(s) are captured and either a successful IntelliSelection was made by the software or a user-acceptance of the exam was made, you will be presented with the Exam Results page. If you chose a dual WF and CT exam, then the CT capture window will appear first.

The Exam Results display shows you which of the three captures was selected and provides exam quality information. If excessive points were rejected, the exam will color code that value as suspect. When a dual exam was captured, the panel on the right side of the screen will display an icon with the areas of concern color coded green, yellow or red. This information can help the technician triage the patient for workups.

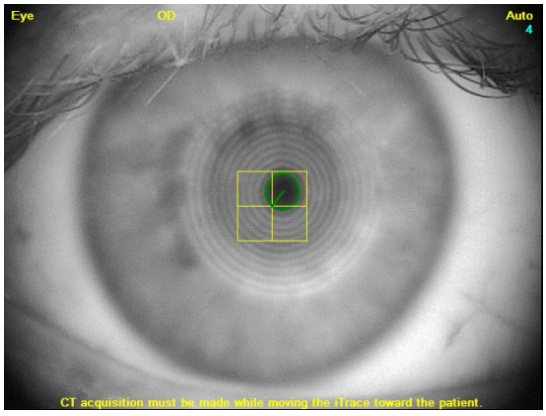


Capturing a Corneal Topography Exam

1. The patient should be positioned in the same manner as instructed above.

2. If Dual Exam was chosen, skip this step. Otherwise, select the patient from the database, view the exam list screen and click  . The iTrace automatically detects OD or OS.

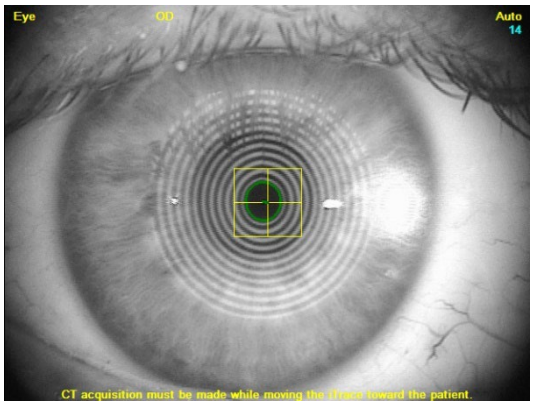
3. A video image will appear on the computer screen, showing the eye, the rings and the central target. The software will outline the middle ring with a green line.



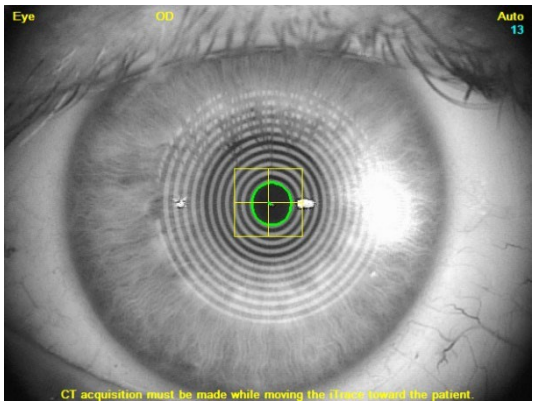
CT Acquisition window before operator centers and focuses image

4. Using the joystick, center the middle ring outlined in green in the crosshairs, collapsing the centration line as in a WF exam. When the line is collapsed, the green ring will glow brighter signifying that the image is centered. Slowly move the DAU toward the patient

until the white laser focusing spot crosses the center of the middle ring and crosshairs.

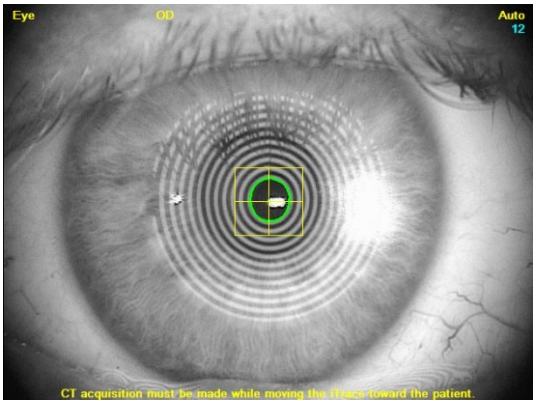


CT Acquisition window with image properly centered, slowly moving toward patient.



CT Acquisition window with image properly centered, and white laser focusing spot moving toward the crosshair center.

5. As it gets close, the software will begin tracking the location of the laser focusing spot. The iTrace will automatically acquire the exam when the middle ring and target are centered and the spot slowly crosses through the center of the green ring.



Laser focusing spot moves through center of green ring over the crosshairs and the software auto-captures the CT image.

NOTE: The CT exam must be acquired while moving toward the patient and when the spot crosses into the target area from the right side of the screen rather than when the spot crosses into the target area from the left side. If the spot crosses into the area on the left side, move the laser focusing spot to the right side of screen by moving the DAU away from patient. Re-focus moving toward patient.

The exam readings will not be accurate if this CT exam acquisition procedure is not followed.

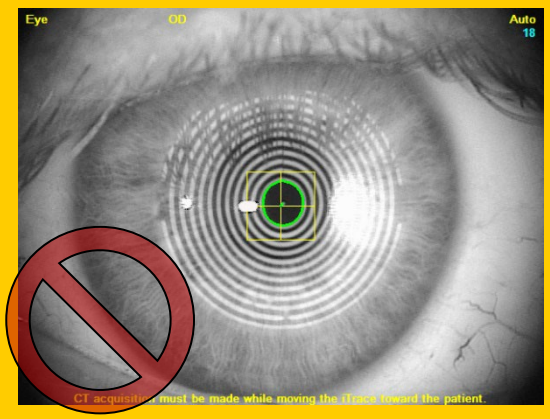


Figure 5-11 Laser focusing spot on the left side of screen indicating the DAU is too close to the patient and the image is out of focus.

4. If the CT exam does not auto-acquire after repeated attempts, manual capture mode is possible by clicking the *Enter* key, aligning as in Step 4 and pressing the joystick button when the red dot over the white laser spot is properly centered.

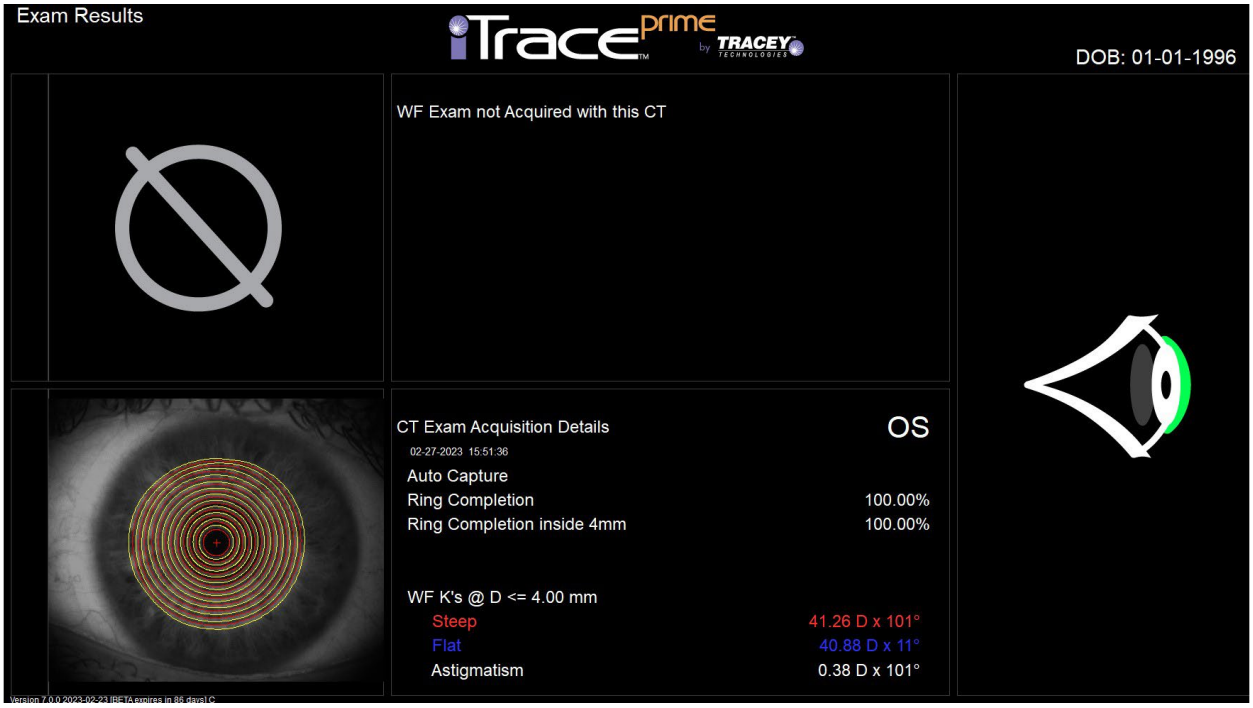
NOTE: The manual CT acquisition should only be used when absolutely necessary. Using the correct working distance in topography is extremely important and the laser spot must be in the proper location to provide the correct working distance. **The exam readings will not be accurate if the CT exam is acquired at the incorrect working distance.** The iTrace's auto-acquisition mode ensures correct working distance, while manual mode does not.

NOTE: The iTrace utilizes a 655 nm wavelength laser during the patient alignment procedure for corneal topography exams. For your protection, the laser automatically powers off after 30 seconds if the exam acquisition is not completed. Should this occur, you will need to click the New CT button again to restart the alignment procedure.

Exam Results Display

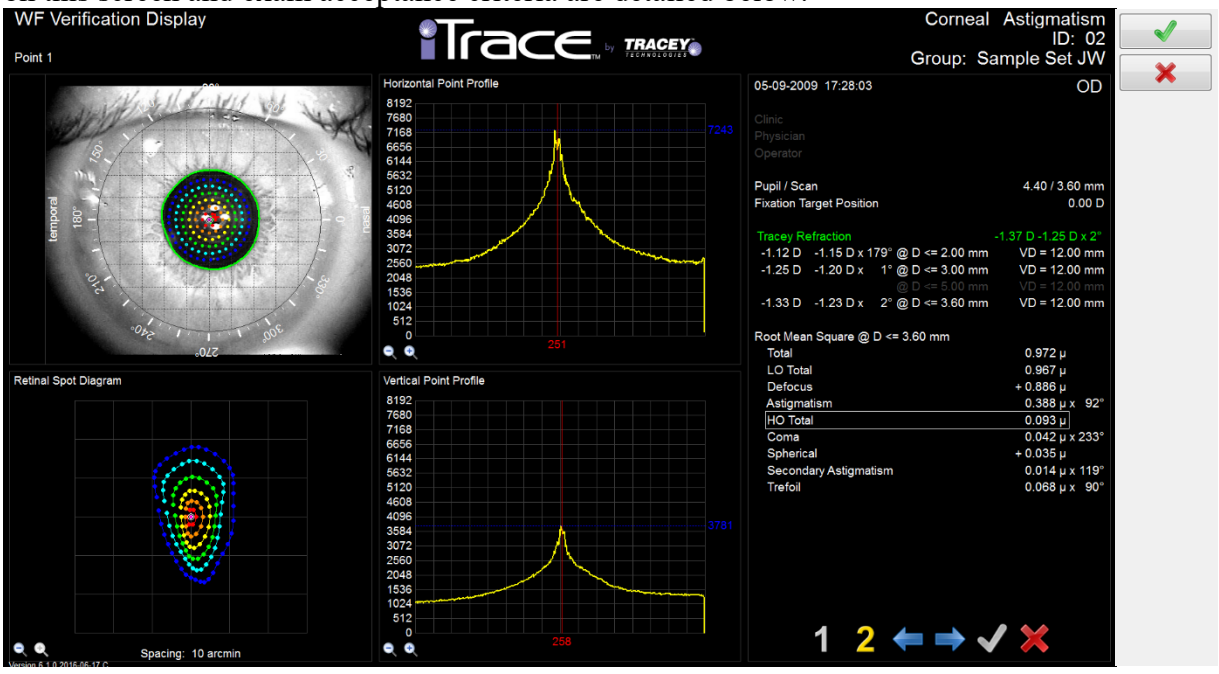
After the CT exam is captured, if it met acceptance criteria for ring detection (85% for the entire measured cornea and 99% within central 4mm zone of cornea) the software will present the Exam Results page. If acceptance criteria were not met, you will see the CT Exam Verification display where you must review the exam and accept it or reject it to retake the exam.

The Exam Results display shows you detail about the exam quality that consists of the ring detection completion overall and within the central zone. If there was an issue with ring detection, the exam will color code that value as suspect. If part of a dual exam, the panel on the right side of the screen will display an icon with the areas of concern color coded green, yellow or red. This information can help the technician triage the patient for workups. If not part of a dual exam, the cornea will color code and the internal will remain grayed out.



Verifying a WF Exam

If the acquired exams did not meet the minimum requirements for exam quality, the software will display the WF Verification Screen in which case the user must select to keep the exam. This screen should be used to verify the integrity of the data captured. The information available on this screen and exam acceptance criteria are detailed below.



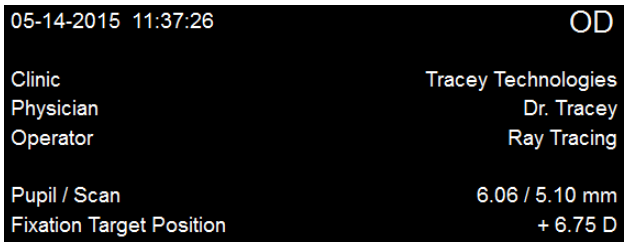
Eye Image

The eye image captured during the WF exam is displayed. The scan pattern is displayed, as is

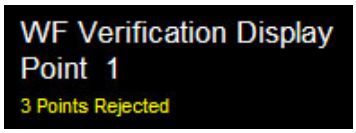
the detected pupil contour. The user should analyze the image to ensure that the scan pattern is within the pupil margin. If the scan pattern encroaches on or out of the pupil margin, or if there is an evident blink, the exam should be retaken. If the pupil was not properly detected, it can be edited by right-mouse-clicking on the eye image panel and selecting "Edit pupil and vertex".

Summary Data Screen

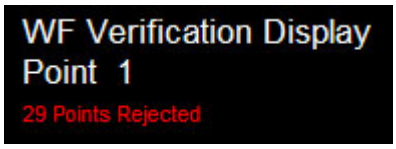
The patient data screen displays exam date and time, location, physician and operator detail filled in at the time of patient examination, the pupil diameter (best fit circle to actual pupil shape), the scan diameter (distance from center of laser spot on one side to the center of laser spot on the opposing side) that is always less than the pupil size, and the fixation target position (far point +1D with fogging).



The top left corner of the screen lists the name of the display, the point that is displaying, and the number of points rejected or missing (if any.) The rejected number of points is shown in *Yellow* (caution) when between 1 and 9 points are rejected.



The color *Red* indicates that the data acquired is compromised and the exam should be repeated because there are 10 or more rejected points.



Exams with 10 or more data points rejected should only be saved if this is the only data possible. The data should be considered compromised and used only for diagnostic purposes; no surgery plans should be made from this data.

NOTE: Patients with cataracts, scars or other vision obstacles may be measured with missing data points. The missing data points will indicate size and location of the impairment. The *Retinal Spot Diagram* and *Point Spread Function* displays will provide representation of light/images focusing on the retina around the cataract/scar.

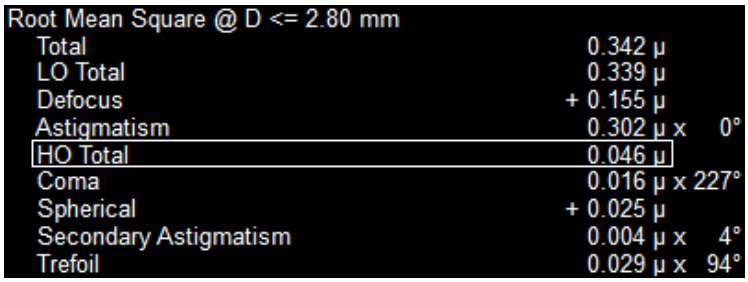
Refraction Data Screen

The Tracey Refraction number, in green here, is derived from the 4mm scan diameter (or the largest scan diameter if scan diameter is less than 4 mm). The sphere and cylinder are rounded to 1/8 D or 1/100 D, depending on the choice made in Settings. The Tracey Refraction number display provides a confidence indicator for the patient's refraction. Higher order aberrations (HOAs) can produce symptoms that could warrant the refraction information as suspect. If certain HOAs are present and meet a certain threshold, the number will appear yellow. If the HOAs meet a higher threshold, the number will appear red. Using these indications, you can discover at a glance if the patient's refraction information is reliable. For example, if the patient is likely to experience night myopia due to a shift in the refraction from a small pupil to a large pupil, the refraction will

appear yellow or red, depending on the severity of the shift.

Below the Tracey Refraction number is the multi-zone analysis. These zone values can be changed in the **Settings** option on the main menu.

Root Mean Square



The summary of the Combined Zernike RMS data determined at the full scan size. By Combined RMS Terms, we mean that for example the coma value is composed of both vertical and horizontal 3rd order coma as well as other higher order coma terms. Therefore, it is a measure of the total coma aberrations in the eye. Please note that in the RMS window shown, adding Low Order Aberrations to High Order Aberrations does not equal the Total.

You must square the LOA term, square the HOA term, add them together and then take the square root to get the Total value.

$$(3.468)^2 + (0.165)^2 = 12.054$$
$$\sqrt{12.054} = 3.472$$

This math is used for combining Zernike terms, whether two as above or 21 HOA terms to obtain the HOA value of 0.165 µm.

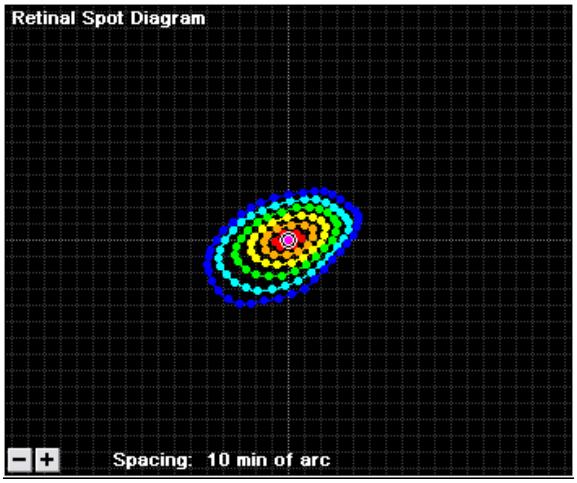
Notes

This area is reserved for exam notes that can be entered at the time the exam is saved. This area of the display will pre-populate a note if the pupil size was large (over 6 mm). See Note below concerning large pupil size.

NOTE: If the pupil size was larger than 6 mm, the user should check the scan size that may have been acquired at the large pupil size. If the user is acquiring data on which to base surgical decisions, a scan of larger than 6.5 mm should be carefully considered due to the nature of Zernike calculations at these larger scan sizes. In such cases a manual scan smaller than 6.5 mm should be acquired.

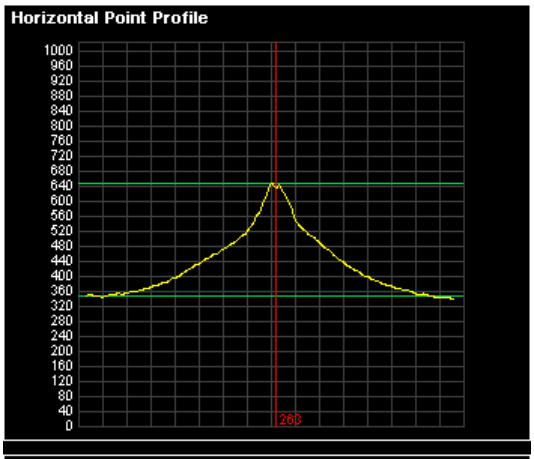
RSD Display

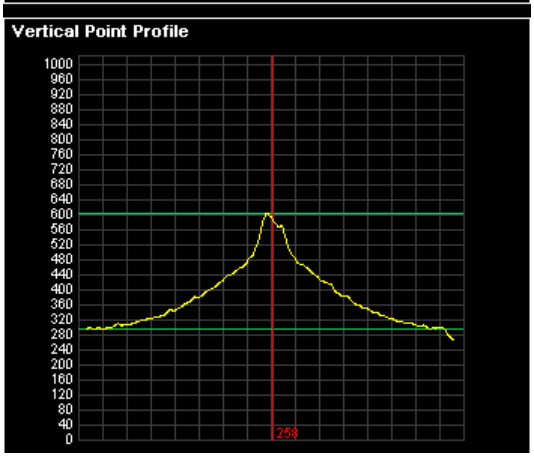
The RSD (Retinal Spot Diagram) is shown at bottom left of screen. This image showed a good data acquisition.



A RSD with severely skewed points may indicate an error in the scan, such as a blink, or an extremely aberrated eye. Either way, the exam should be retaken to confirm the analysis.

Horizontal Point Profile and Vertical Point Profile Displays





Verify the signals. The top display is the *Horizontal Point Profile*, and the lower shows the *Vertical Point Profile*. These show the position of the spot that was reflected from the retina, by finding the center of each profile in the X & Y planes, we can determine the location of each individual spot on the retina. Viewing each successive point using the ⬅ or ➡ buttons to the right of the *Vertical Point Profile* display will allow you to verify the quality of the captured laser signals for any exam. The software will reject points that exhibit flat point profiles. Points that exhibit almost flat profiles that are not automatically rejected should be considered for manual rejection (see instructions below).

Wavefront Data Verification Tool Bar

Use the 1 or 2 buttons to shift the scans between the two sets of 128 scan points. Use the ⬅ or ➡

buttons, or the left and right arrow keys on your keyboard, to move backward or forward through the signals in each set. The Point 1 message box in the upper left corner indicates the current point number and the point locating cross hair cursor in the ***Eye Image*** display also will highlight the current point on the pupil. Bad points (as noted by reviewing the point profiles) may be deleted at the user's discretion by clicking on the ✖ *Reject* button for each point you feel may be inaccurate. The user can accept the points that he or she rejected by clicking the ✔ *Accept* button. The user cannot accept points rejected by the software.

NOTE*:** The iTrace generates two sequential sets of 128 points each for capture. The ***1 and ***2*** buttons let you select and switch between the first and second set of points. It is important to verify and assess the quality and signal strength of each point acquired in *BOTH* sets of points prior to saving any exam data.

Accepting or Rejecting the Exam

If the exam is acceptable after review of the verification screen, you must accept the exam to continue. To Accept the exam:

1. Click the  in the top right corner of the display. The default Wavefront Summary display will appear. Details about the Exam Summary Displays are found in Chapter 6.

If the exam is not acceptable, you must reject the exam to continue. To Reject the exam:

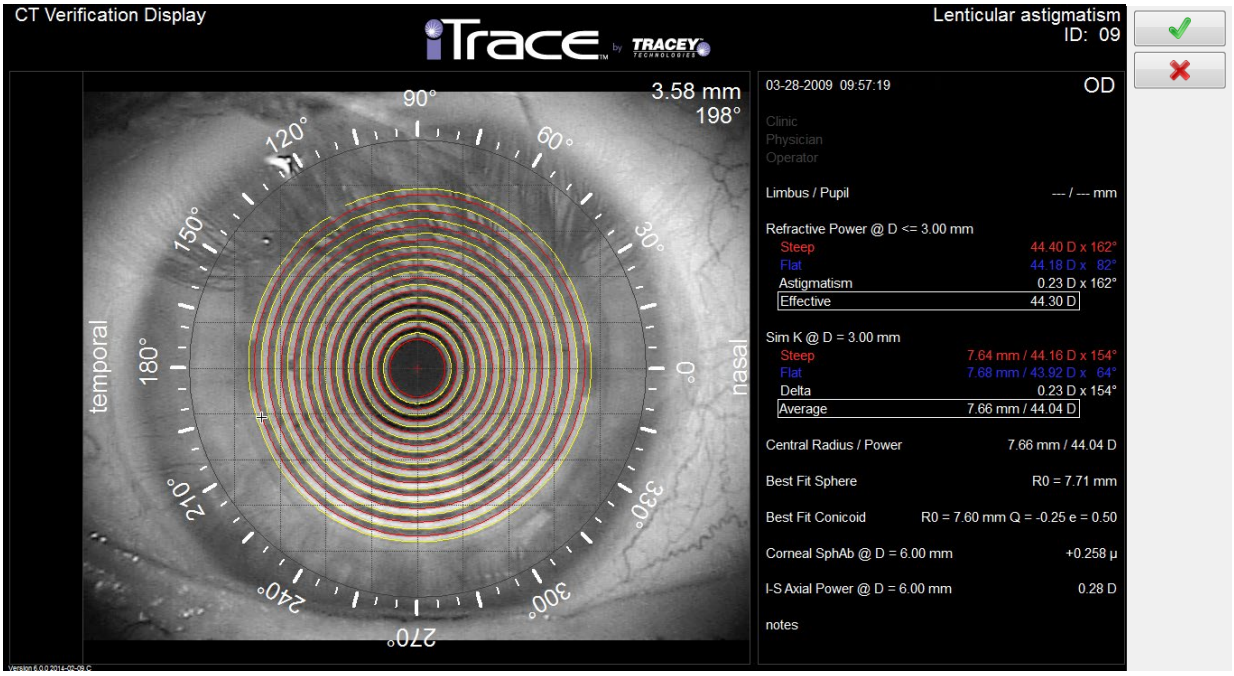
1. Click the  in the top right corner of the display. The acquired exam will be deleted and the software returns to the Exam List screen.

If the Multi-Capture Exam was used, you will be presented with up to three verification screens. Use  to cycle through each screen and pick the exam you wish to save.

Note: The exam is not saved until this process is complete.

Verifying the CT Exam

The *CT Verification Display* appears when the acquired CT exam did not meet minimum acceptance criteria for IntelliSelection. The display allows the user to examine the edge detection analysis performed by the software (red and yellow dots along alternating edges of the rings) to be certain no gross errors occurred (crossover of one color to the other side of the ring, missing ring edge detection, detection of non-ring edges, etc). If the ring data is acceptable, the user can accept the exam and continue. If errors have occurred, the exam should be rejected and repeated. The user cannot edit the ring information.



The CT Verification display, also called Rings, includes other important information, as detailed below.

Summary Data

The patient data screen displays exam date and time, location, physician and operator detail filled in at the time of patient examination, the white-to-white limbus diameter (as auto-detected or as drawn by the operator, the best fit circle to actual limbus shape), and the pupil diameter (as drawn by the operator, the best fit circle to actual pupil shape).

NOTE: The eye image display should also be examined to determine if the limbus was detected properly by the software. If it was not detected properly, the image can be edited as described on page 81. This is recommended to ensure accurate Angle Alpha measurements.

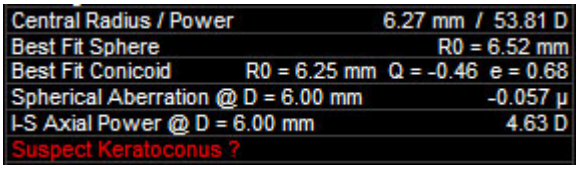
Refractive Power Data

The refractive power data is the refractive power over the entire area of the cornea within the central 3.00 mm zone. The box displays the steep and flat axis and meridian, the astigmatism and overall effective refractive power. The Refractive Power offers a better representation of those corneas that may be steeper or flatter centrally compared with the 3 mm periphery.

Simulated Keratometry Data

The Simulated Keratometry data provides the videokeratographic simulation of keratometry. Mimicking an auto-keratometer, data is sampled from four perpendicular data-points at a 1.5 mm radius from the corneal vertex. The steep, flat, and delta K with axes are displayed, along with the average K reading for that radius.

Corneal Indices Panel



This panel includes the Central Radius/Power measurement, the Best Fit Sphere and Conicoid, the Q and E values, the Corneal Spherical Aberration at the 6.00 mm zone and the I-S Axial Power at 4.40 mm. If the central corneal power is above 47.2 D *and* the I-S Axial Power is above 1.4 D, the software will display the "Suspect Keratoconus" message, as shown here. These thresholds are based on the Rabinowitz Keratoconus test. The message will only appear if both thresholds are met. However, a patient could be diagnosed with keratoconus after only exhibiting one of these parameters. Other testing should be completed before making a final diagnosis.

Accepting or Rejecting the Exam

If the exam is acceptable after review of the verification screen, you must accept the exam to continue. To accept the exam:

1. Click the  in the top right corner of the display. The default Corneal Topography Summary display will appear. Details about the Exam Summary Displays are found in Chapter 6.

If the exam is not acceptable, you must reject the exam to continue. To reject the exam:

1. Click the  in the top right corner of the display. The acquired exam will be deleted and the software returns to the Exam List screen.

Note: The exam is not saved until this process is complete.

Capturing a Color Iris Image with Corneal Topography Exam

In the iTrace Settings, you may choose to capture a color image of the eye showing more iris detail than the grayscale image of the WF or CT exams. Capturing the color image along with the CT exam will allow you to use the color image in the Toric Planner display that is described in Chapter 6 of this manual.

This color acquisition sequence will begin immediately after a CT exam or the dual WFCT exam as described below. The Settings options are either automatic or manual capture. Automatic capture will immediately turn on the white lights to illuminate the eye and capture the image directly after the corneal topography exam. No action is required of the operator. Using auto-acquisition can maintain the best alignment, but may surprise the patient. During the CT exam the operator should inform the patient about the bright lights that will appear.

Manual capture allows the operator to prepare the patient to expect the illumination lights to turn on and to coach the patient to maintain fixation, but alignment could be compromised.

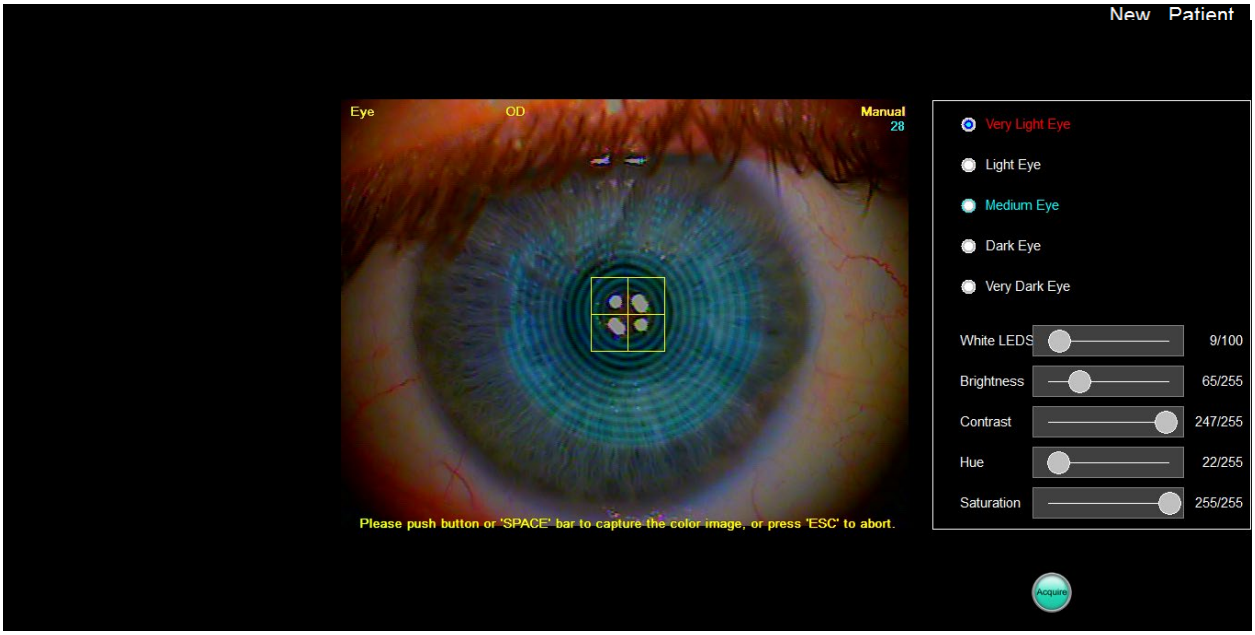
To acquire a color image automatically:

1. Immediately after the CT is captured, the software will automatically capture the color image. The operator should hold the DAU still at the position that the CT was captured. The white lights will flash and the image will capture. (The operator should inform the patient during the CT exam process to maintain fixation and expect the light.)

2. The software will first display the other exam verification screen(s) and then display the color image verification. If the exam(s) was rejected, the color image will also be rejected and the image verification screen will not display.

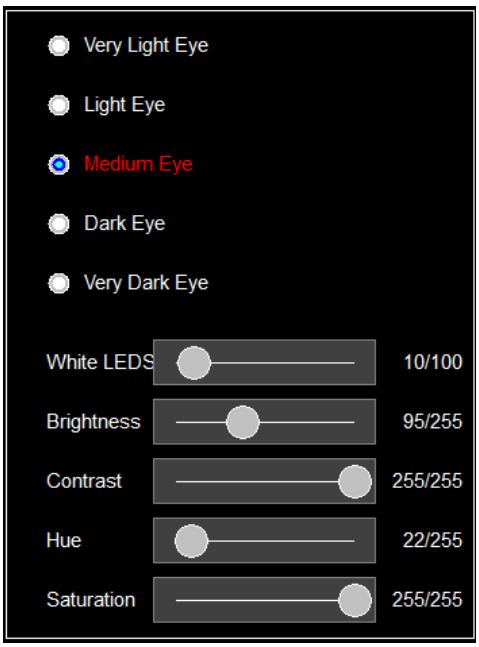
To acquire a color image manually:

1. Center the crosshairs over the center of the inner ring of the topography reflection.



2. Ask patient to continue to look at the red target and to expect the bright lights.

3. At this point you can adjust the camera settings if desired. Images of particularly dark eyes or lighter eyes can be improved by adjusting how the camera illuminates the eye and processes the image. To change the camera settings, use the control box that appears to the right of the live video image, as seen here:



a. You can choose one of the four other presets by clicking on the radio button labeled with the eye-color type of your patient. You can see the camera settings change and the live video image adjust accordingly.

b. You can also further adjust the camera by sliding the slider bars to the left or right, while you view the results on the live video image.

4. When patient is properly fixated and the DAU is centered, press the button on the joystick, the spacebar on the keyboard, or the Acquire button on screen. The light will flash and the image captures.

5. The software will first display the other exam verification screen(s) and then display the

color image verification. If the exam(s) were rejected, the color image will also be rejected and the image verification screen will not display.

Accepting or Rejecting the Color Image

If the image is acceptable after review of the verification screen, you must accept the image to continue. To accept the image:

1. Click the  in the top right corner of the display. The default exam display will appear. Details about the Exam Summary Displays are found in Chapter 6. The color image is only used in certain displays, also described in Chapter 6. If the color image is accepted, the corneal topography exam number in the Exam List screen will display pink rather than black.

If the image is not acceptable, you must reject the image to continue. To reject the image:

1. Click the  in the top right corner of the display. The acquired exam will be deleted and the software returns to the Exam List screen. The software will not reject the CT exam captured before the color image.

Some eyes may require an adjustment to the camera setting. Images of particularly dark eyes or lighter eyes can be improved by adjusting how the camera illuminates the eye and processes the image. If the image isn't acceptable and was taken with Automatic color image capture, reset the camera in Settings to *Capture color image: Manually*. Retake the exams and adjust the slider bars as described above.

Capturing a Tear Film Exam

With properly upgraded iTrace hardware, you may have the Tear Film Analysis activated in your iTrace software. Follow these instructions to capture a tear film exam with your iTrace device.

Patient Positioning

NOTE: Patient positioning is critical for accurate examination and shortcuts in this step will cause the capture process to be more difficult.

1. Position the patient in front of the iTrace unit with chin fully forward against the chin cup and forehead resting against the headrest.

2. Adjust the chinrest height by twisting the chinrest knob so that the patient's forehead is pressed against the head strap. The motorized table may also be adjusted up or down for patient comfort. Ask patient to hold the handles to maintain stability.

NOTE: You must not allow the patient to use any part of the iTrace when in the act of sitting or standing as this may destabilize the iTrace and cause injury to the patient.

3. Ask the patient to close their jaw so that their teeth are touching; the patient doesn't need to clench their teeth. Turn the patient head to the side opposite to the eye being captured by about 15-30 degrees so that the cone of the unit can move inside the plane of the patient's nose.

4. Make sure the patient forehead is resting firmly and comfortably on the forehead strap.

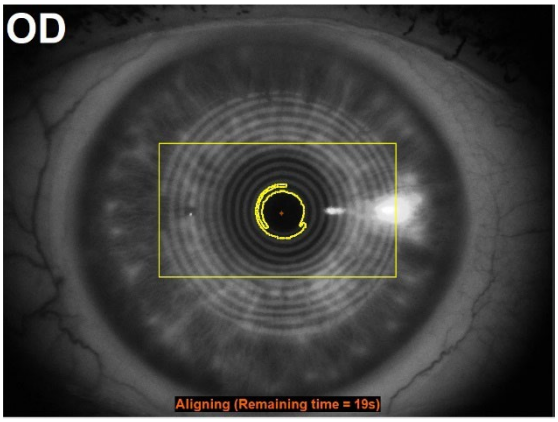
5. Patient distance from the device is important, make sure to get the patient close enough to the machine so the patient doesn't need to lean over.

Focusing and Processing

1. From the *Patient Exam List*, click  to begin the acquisition process. The iTrace automatically determines which eye is being examined: OD or OS. Check the eye label in the top left or top right corner of the video image to verify.

2. Start by finding the patient eye, move the device so that the pupil is in view, at this point you can click the joystick button or the **START** button in the bottom left corner

of the screen. During this time tell the patient that they will soon see a red dot, and ask them to focus on it once they see it.



3. Once the start button is pressed, you will see an alignment rectangle, a yellow ring on the display outlining the inner ring of the Placido disk, and a dot marking the center of the ring. Also, at this stage the alignment laser will turn on and you will see a white dot on the right side of the eye.

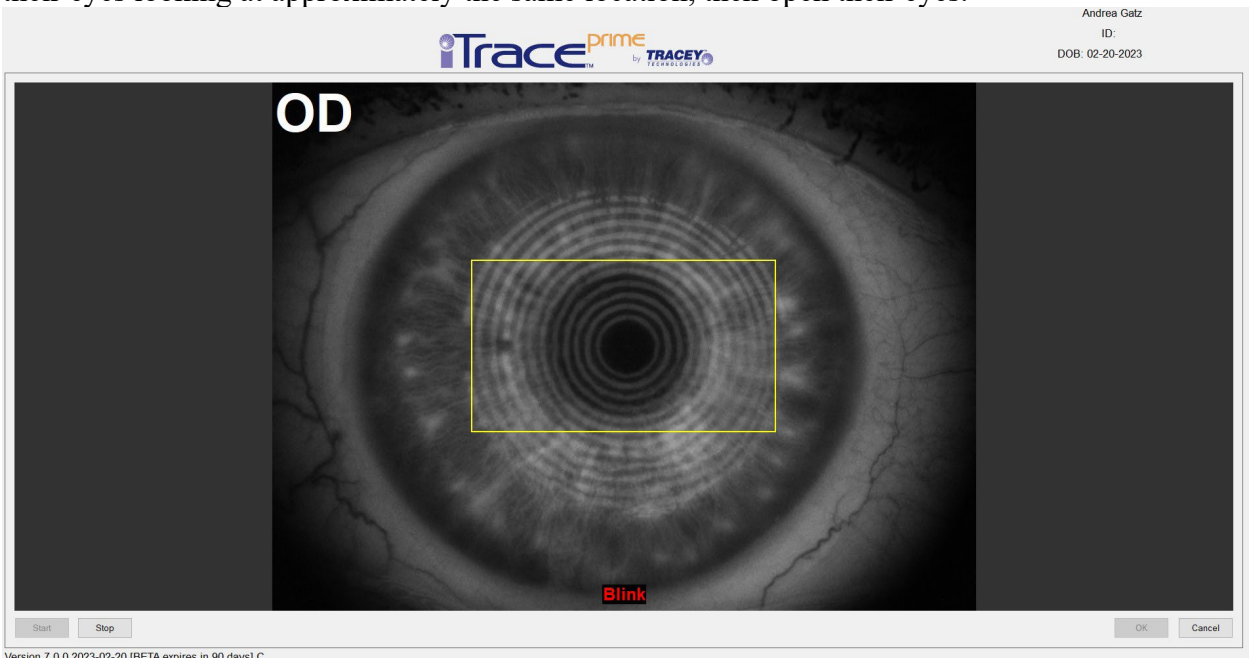
4. Proceed by moving the device up and down until the central ring is centered in the rectangle and the white dot is approximately the same height as the circle center. Then move the device forward, the white dot will move horizontally from the right to the left, once the white dot overlaps with the center of the circle, the capture process will start, you will know that the capture process started by 4 things:

   a. The laser will turn off

   b. The circle will disappear

   c. A count down timer will appear at the bottom.

5. Ask the patient to keep looking at the red dot, then close their eyes while keeping their eyes looking at approximately the same location, then open their eyes.

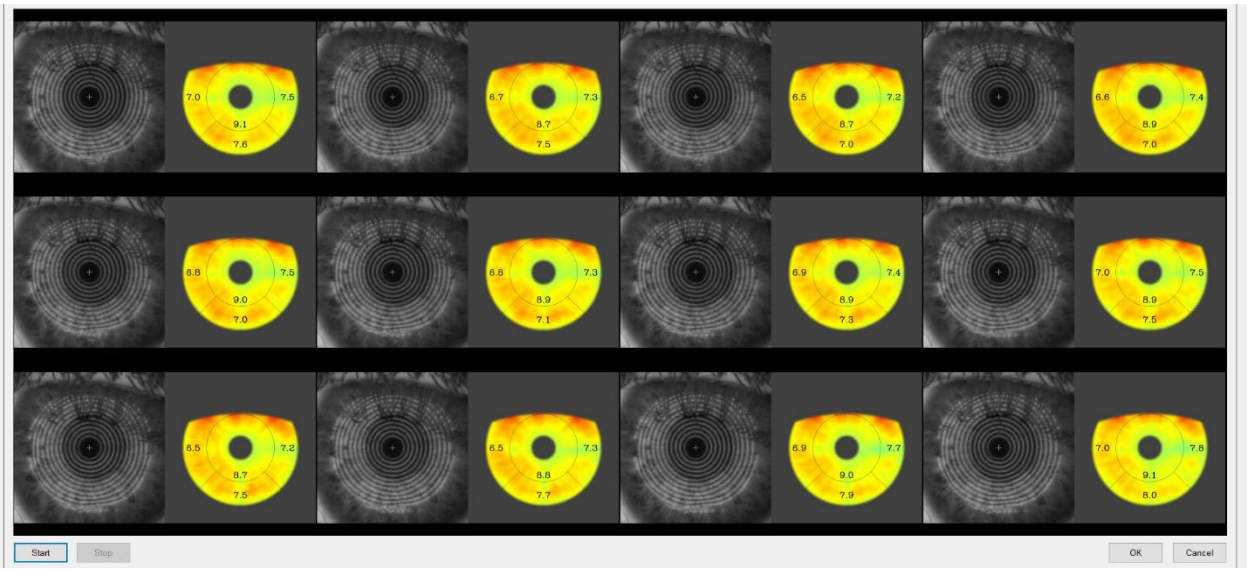


6. The countdown timer will restart after the eye opens. At this stage instruct the patient to keep looking at the red dot and do not blink while the image capturing is taking place. During the capture process, make sure to keep the central ring of the Placido inside the alignment rectangle. The exam process is considered acceptable after six

seconds of capture, however, the full twelve seconds is preferred.

7. Once the timer runs out or the patient blinks after the 6 second threshold, a text saying “Analyzing” will appear. The exam is done for the patient and they can sit back.

8. After the capture, you will see a screen showing a video frame from each of the seconds that were captured, along with the heat map. Review to ensure frames are acceptable and if so, click the ok button.



9. The dry eye analysis screen will popup, click the check mark to accept and save the captured data.

Troubleshooting:

1. If the patient blinks during the count-down timer, the timer will reset. If this happens, ask the patient to close their eyes and then open wide.
2. If the patient eyes are moving significantly, it may cause the countdown timer to reset, if this happens:
    a. Inspect the patient head position,
    b. Make sure that the patient position is comfortable,
    c. Make sure the table is at the right height,
    d. Check that the patient's forehead is resting on the forehead strap and not just touching it,
    e. Ask the patient to use the handlebars to steady themselves.

The exam process is more difficult when the patient is not sitting comfortably.

Capturing an External Image Outside of CT Exam

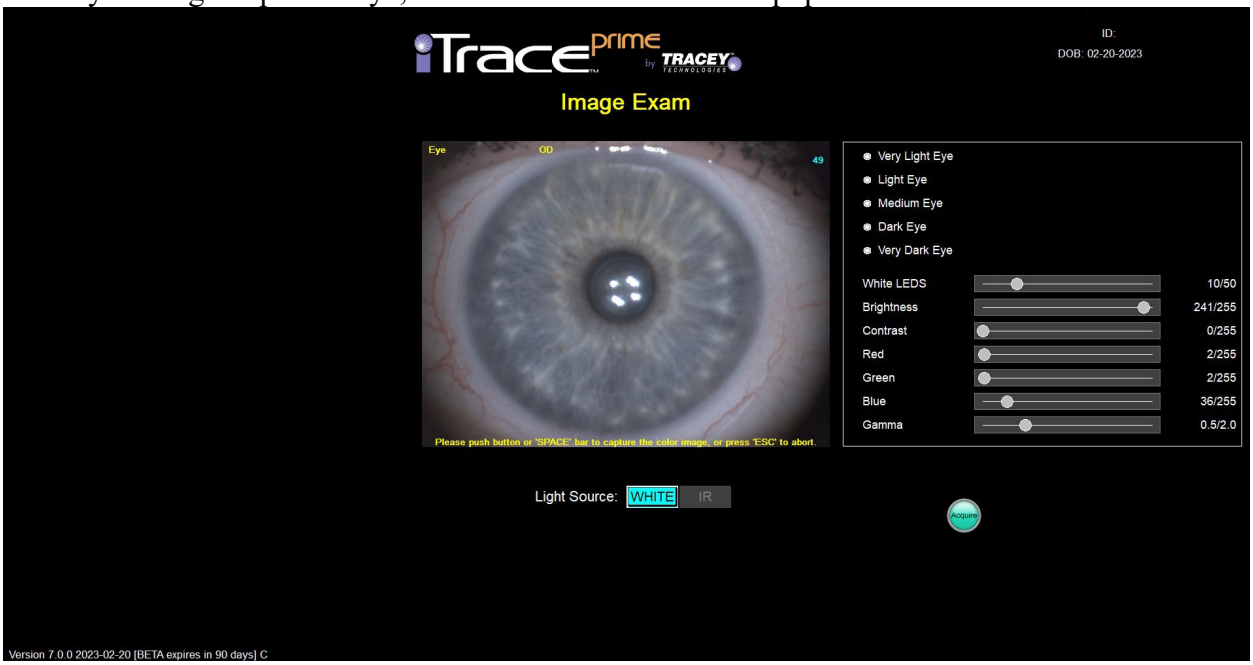
The iTrace will allow you to capture a single external eye image using either the Color mode or Infrared (IR). Capturing as a stand-along acquisition process will not allow the color image to be used in the Toric Planner display.

Prior to capturing the image, the operator should inform the patient that bright lights that will appear.

To acquire a color image:

6. From the *Patient Exam List*, click  to begin the acquisition process. The iTrace automatically determines which eye is being examined: OD or OS. Check the eye label in the top left or top right corner of the video image to verify.

7. Start by finding the patient eye, move the device so that the pupil is in view.



8. At this point you can adjust the camera settings if desired. Images of particularly dark eyes or lighter eyes can be improved by adjusting how the camera illuminates the eye and processes the image. To change the camera settings, use the control box that appears to the right of the live video image, as seen here:

    a. You can choose one of the four other presets by clicking on the radio button labeled with the eye-color type of your patient. You can see the camera settings change and the live video image adjust accordingly.

b. You can also further adjust the camera by sliding the slider bars to the left or right, while you view the results on the live video image.

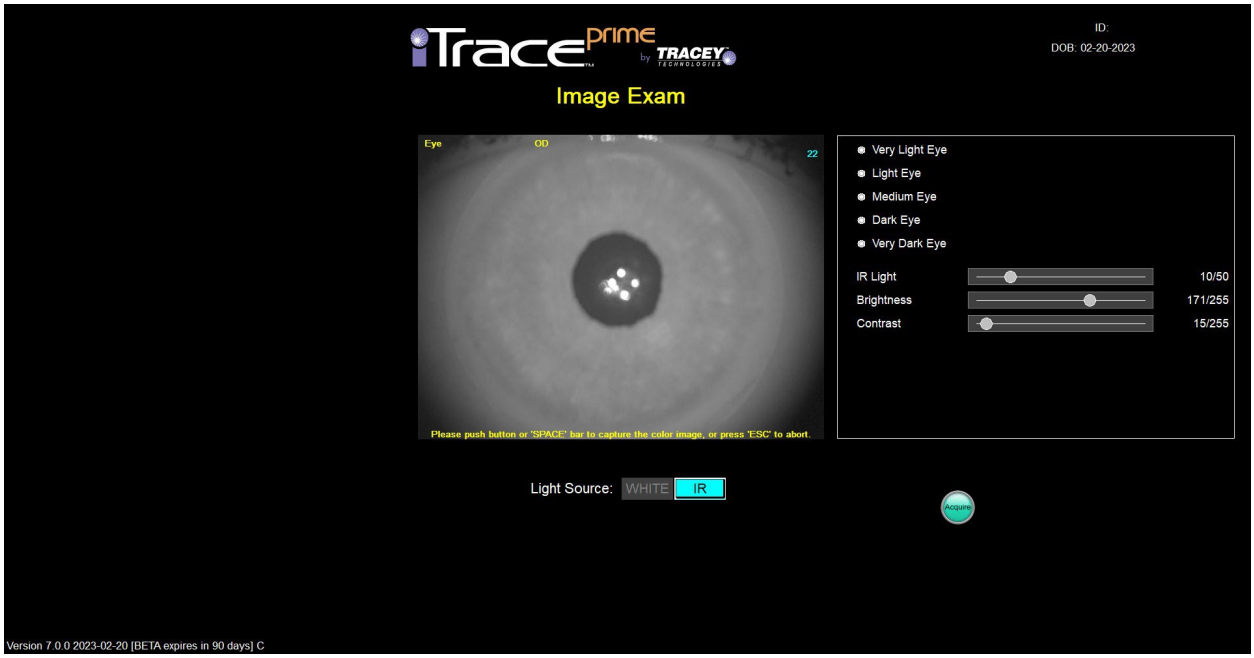
9. When patient is properly fixated and the DAU is centered, press the button on the joystick, the spacebar on the keyboard, or the Acquire button on screen. The image captures.

10. The software will display the color image verification screen.

To acquire an IR image:

1. Follow the steps above, but click on the onscreen button labeled "IR". This will switch the camera to the IR mode and the image will appear in grayscale.

2. The slider bars can be adjusted to control the IR camera.



Accepting or Rejecting the Image

If the image is acceptable after review of the verification screen, you must accept the image to continue. To accept the image:

2. Click the ✓ in the top right corner of the display. The default exam display will appear. Details about the Exam Summary Displays are found in Chapter 6. The color image is only used in certain displays, also described in Chapter 6.

If the image is not acceptable, you must reject the image to continue. To reject the image:

2. Click the  in the top right corner of the display. The acquired exam will be deleted and the software returns to the Exam List screen. The software will not reject the CT exam captured before the color image.

Some eyes may require an adjustment to the camera setting. Images of particularly dark eyes or lighter eyes can be improved by adjusting how the camera illuminates the eye and processes the image. If the image isn't acceptable and was taken with Automatic color image capture, reset the camera in Settings to *Capture color image: Manually*. Retake the exams and adjust the slider bars as described above.

Checking the OD/OS Sensor

The iTrace DAU has a sensor mechanism in the manipulator so that the eye being examined is automatically detected as a right eye or left eye. For each of the exam types, the iTrace software will display this identification.

The auto-detection can sometimes fail if the technician does not fully move the manipulator to the temporal position to engage the sensor. Therefore, the user should check during and after each exam to ensure that the identification was accurate. If not, the identification can be manually changed by the user.

To change the OD/OS identification:

1. From the Exam list screen, select the exam to be edited with a single mouse click.
2. Click on  . The Edit Exam window will open.
3. With the Edit Exam window open, hold the *CTRL* key down and hit the *E* key. Another pop-up window will ask you for a password. Type the password "tracey" and click OK. The Edit Exam window will now have the OD/OS override option enabled.
4. Click the radio button next to "Override auto OD/OS". Click OK.

5. Click “Yes” to confirm override and click OK at the confirmation window.

The exam will be changed to the opposite eye and on the display screens the label of OD or OS will be colored red to denote that the automatic identification was over-ridden.

Chapter 6 Patient Exam Review

This chapter explains how to select and display patient exams, and the main features of exam displays. All features are presented here; however, not all features are available with each software activation.

To View a Patient's exams

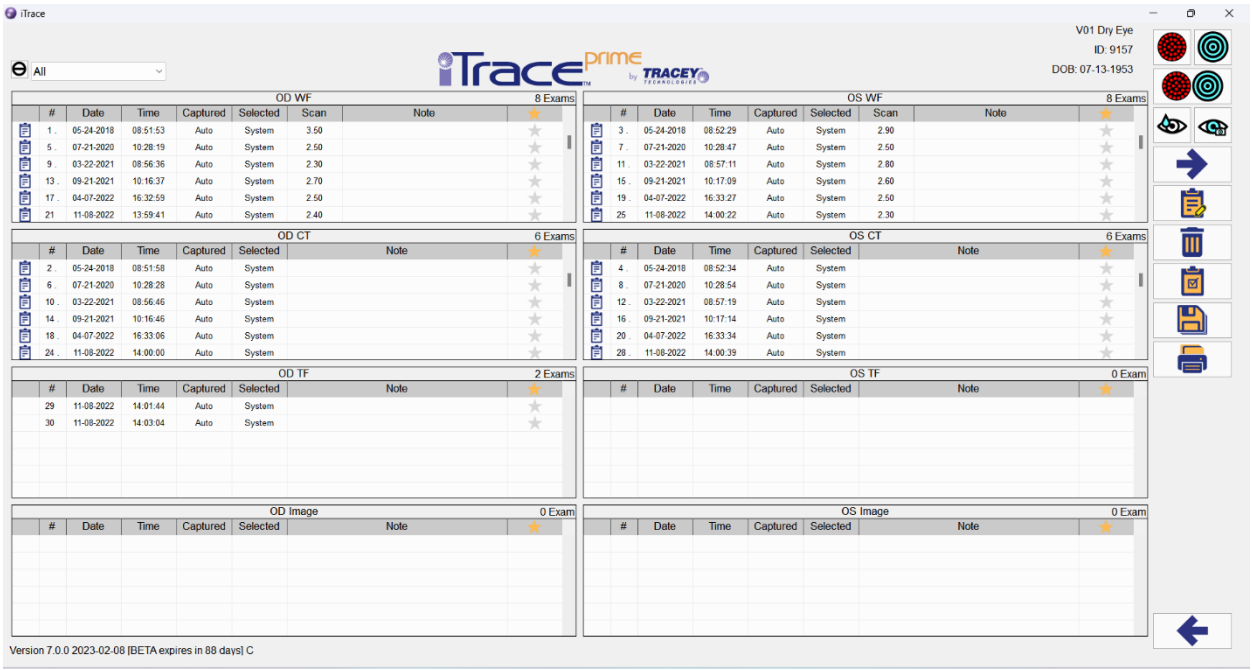
1. Highlight a patient in the *Patient Directory* list.
2. Click  or double-click on the highlighted patient.
3. The patient Exam List record is displayed.

The Exam List Screen

The Exam List screen lists all of the exams available for the patient. Exams are listed in two columns for each eye (*OD/OS*), two or four rows for each exam type (*WF/CT/TF and Image*), and then sequentially by exam number. The columns within each exam type indicate the exam number, the date, time, capture mode (auto vs. manual) the selection method (system vs. user), the scan size (WF only), the exam notes and the last column is a "favorites" column that you can use to designate exam favorites. Additional exam details can be viewed by clicking the note pad () next to each exam number.

Additionally, you can preview the eye image that was captured with each exam type by hovering over the exam number.

A combined WFCT exam will mutually highlight when either companion exam is selected. If a CT exam included a captured color image, the exam number for that CT exam displays in color.



From the Exam List screen, the user can select exams to view. From this screen, you can also perform administrative functions such as editing exam data, deleting exams and batch saving or printing display reports.

To Select and View Exams

1. By left mouse clicking, select a single WF exam, a single CT exam, multiple WF exams of the same eye, a single WF for each, a single CT for each eye, or a WF and CT of the same eye.

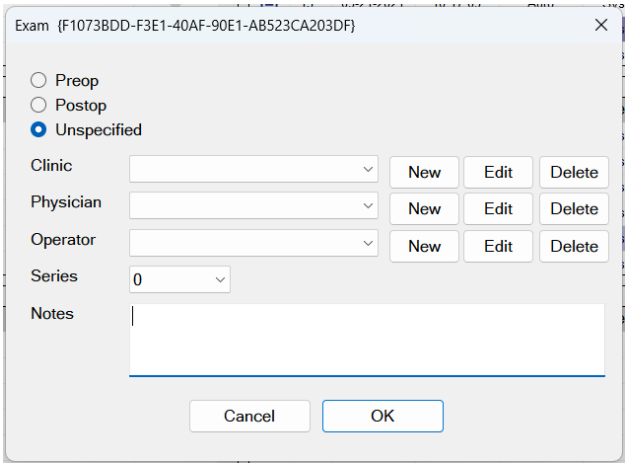
   If the WF or CT exam selected is a part of a combination WFCT exam, its companion exam will highlight to indicate the exams were part of the combination exam.

2. Click on  to view the exam(s). Double clicking on a single exam will achieve the same result.

3. The default display for that type of exam selection will appear along with the display navigation panel.

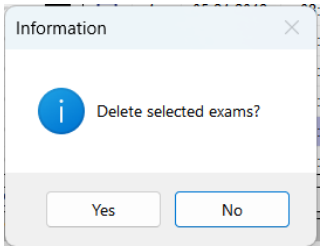
To Edit Exam Details

1. Select one exam.
2. Click  to edit the exam data.
3. Enter or edit exam details as desired.
4. Physician names entered will be used in the Toric Planner data entry.
5. Click *OK* button.



To Delete an Exam

1. Select one exam or multiple exams.
2. Click  to delete the exams(s).
3. Confirm the deletion by clicking ***Yes***.



Exam Summary Display Navigation – Full Set of Displays

The iTrace software provides many options to display exam information. These options vary by software activation, exam type and selection. For example, certain software activations purchased (i.e. Core) provide a limited number of displays and limited customization capabilities. Single WF exams will only display with WF Summary Displays, and likewise single CT exams will only display with CT Summary Displays. Combination WFCT exams or two WF and CT exams selected together will display in WF, CT or WF and CT Summary Displays. The user can also view dual eye displays such as the VFA and the CT OD/OS display.

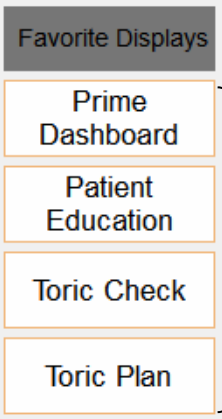
To facilitate viewing the various software displays available, the iTrace software provides a navigation panel for the full set of Summary Displays.

Administrative Buttons

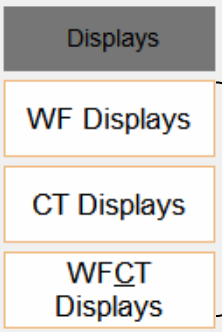
Each Exam Summary Display screen will include the bottom three rows of buttons and the functions initiated by these buttons remains constant.

- Click  to edit the exam information for the selected exam(s). Editing exam information is described on page 72. If viewing a WFCT combination exam, the Edit Exam dialog for WF will appear first and then the Edit Exam dialog for CT will appear.
- Click  to export the screen with patient demographic data and exam data as an XML data file for an Image Management System or research studies.
- Click  save the current screen to an image file.
- Click  to print the current screen.

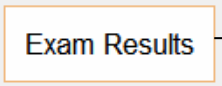
Exam Capture buttons for each exam type



Favorite Exams as selected in Settings (Prime)



Click to see a submenu of all displays available for WF and CT exams.



A quick look at exam quality information

or 

Click for Custom CL or eyeTelligence. Only appears if enabled in Settings.

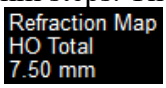
Display administration buttons.

WF Summary Displays

The following Wavefront only displays are available to choose from as you set up the navigation buttons: the WF Verification (Points) Display, the VFA Summary Display, the WF Compare Display and the Depth of Focus Comparison Display (Prime only).

- *Points* is also known as the *Wavefront Verification* display that is shown when the software requires user acceptance of the exam. It contains WF exam integrity information and is a default display in the Navigation menu.
- *VFA Summary* is configured to show both OD and OS Refraction, PSF and Snellen E displays along with other indices and data. It is an optional display to include in the Navigation menu from within Settings.
- *WF Compare Display* is configured to display side-by-side comparisons and the difference display between two same eye exams. It is a default display in the Navigation menu.
- *Depth of Focus Comparison Display* plots the *Visual Strehl Optical Transfer Function (VSOTF)* and approximates the effective range of focus between the two plots. It is an optional display to include in the Navigation menu. (Only available with Prime Activation.)

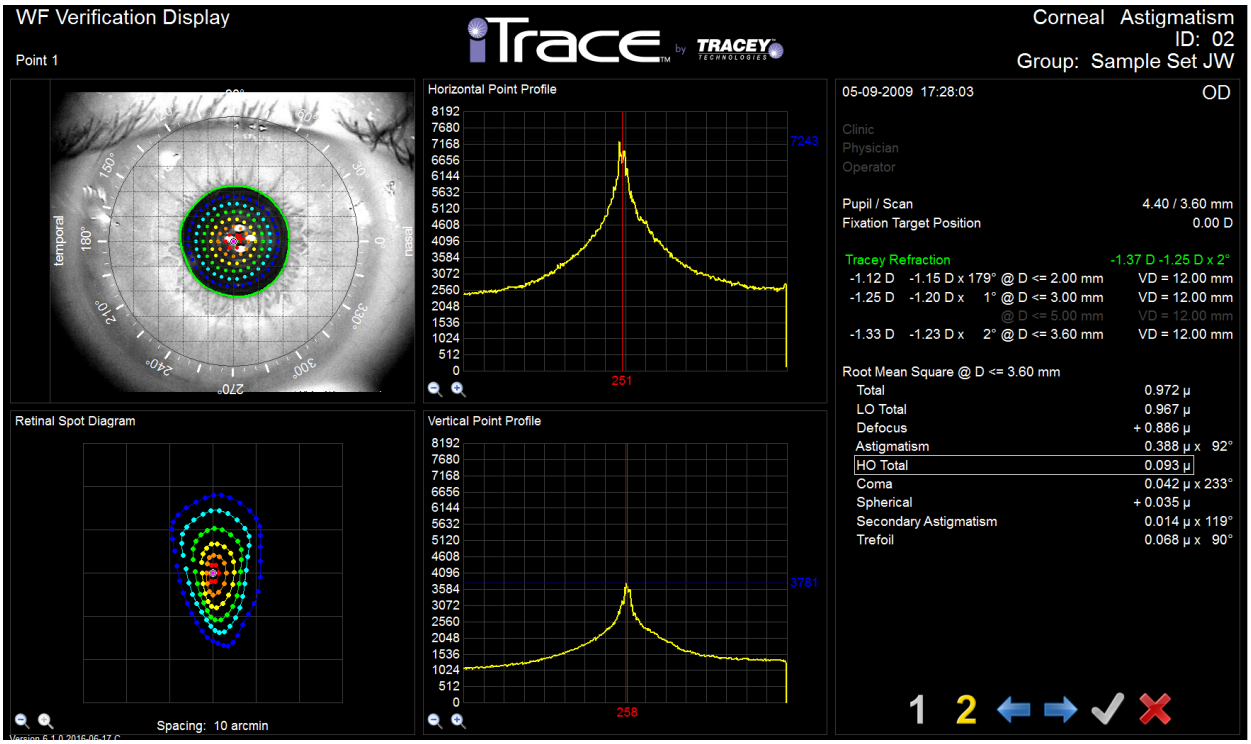
Key Features:

- Some displays have adjustable zoom buttons  to enlarge or decrease the display or to increase or decrease the scale step size.
- Some displays have adjustable buttons  to increase or decrease the scale level.
- Some displays have Zone Selection buttons  to increase or decrease the zone size in 0.50 mm steps. The zone size displayed can be viewed in the top right corner of the display: 

- Most displays include the Correction Toggle buttons  , Total;  , Total No Defocus; and  , Higher Order Total. Clicking the button once will switch the masking option to the next aberration masking option.
- Default display method for most displays is 2D. You can change to 3D display by *right-mouse-clicking* on a display to bring up the ***Options Menu*** and select 3D. While the display is in 3D mode, you can rotate the display to any viewing angle by holding down the left mouse button and the drag the mouse in any directions.

WF Verification Display

The WF Verification Display (Points) appears as it did when presented after the exam acquisition. The display includes valuable information and from this display, the user can edit pupil and vertex.

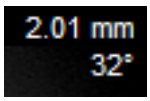


Key Features:

1. The WF Verification Display (Points) shows four default display panels: *Eye Image*, *Retinal Spot Diagram*, *Horizontal Point Profile*, and *Vertical Point Profile*. ***Options Menu*** is available with a *right-mouse-click* on the Eye Image and Retinal Spot Diagram.

2. Click
   1 or 2 to switch between first and second set of data points.
   ← or → to advance to previous or next point. The current point is displayed in the upper left corner of the display.
   ✓ to accept current point.
   ✗ to reject current point.

3. Click on a point on the *Eye Image* display or drag the cursor to a point in the pupil to see measurements in the upper right corner of the display.

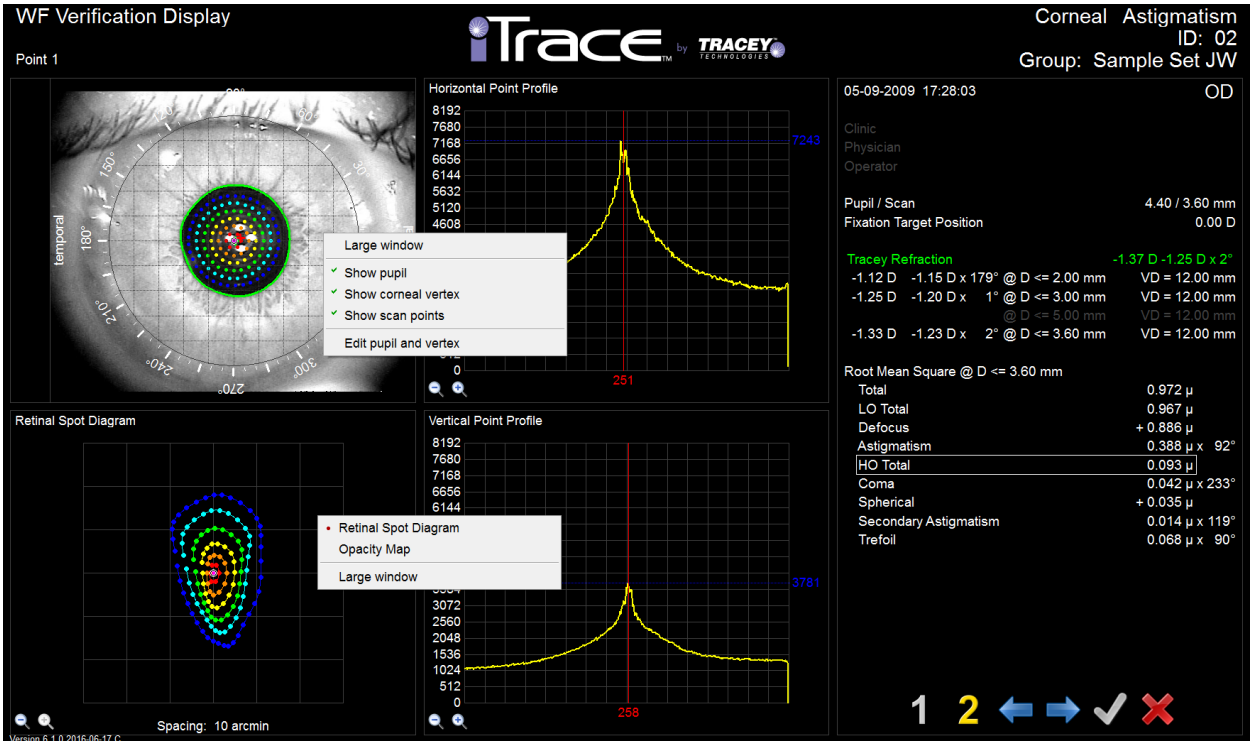


Reference	Explanation
#.## mm	Radial distance (mm) from center to the point of interest
##°	The axis at the point of interest

4. Click on the buttons to change the step size of the display.

WF Verification Options Menu Navigation

This menu is activated by a *right-mouse-click* on either the eye image or the RSD display panels. Please refer to Appendix A for display type descriptions.



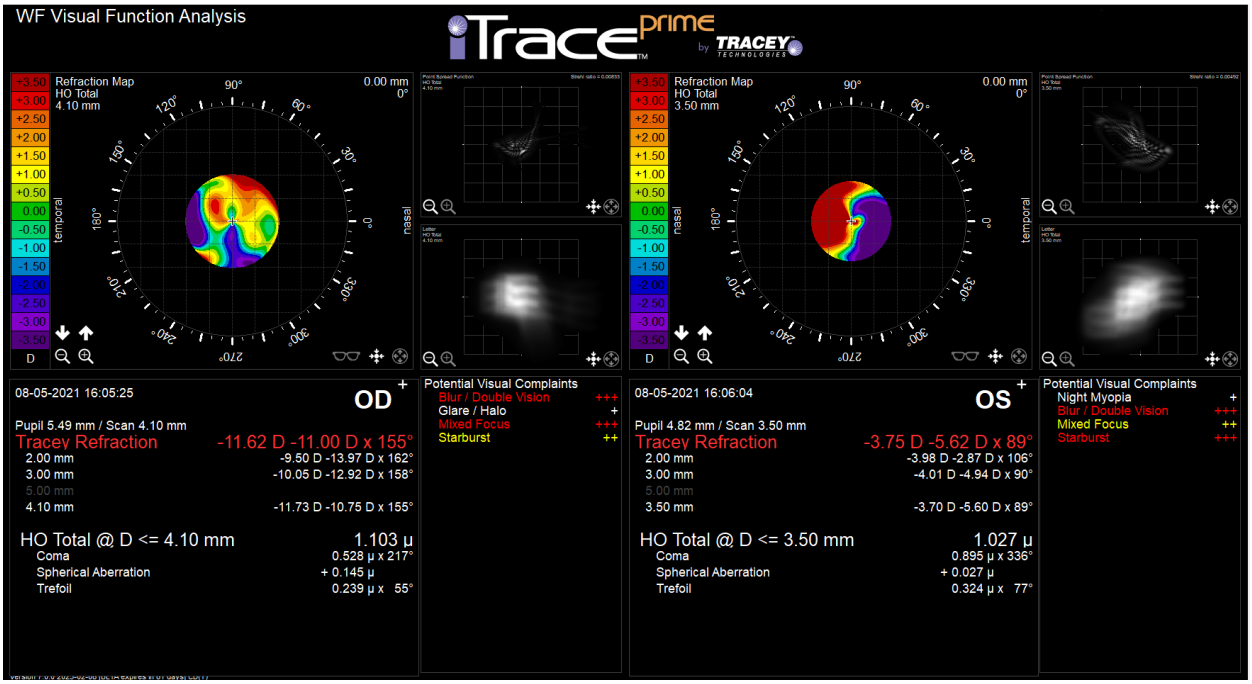
WF Options Menu – Editing Pupil and Vertex

Generally, the iTrace software will locate the pupil and vertex during a WF exam. The iTrace software enables the user to edit the pupil and the vertex, to obtain a pupil diameter or visual axis approximation should the software fail to auto-detect either. This functionality is also available in the Angle Kappa and Alpha display. Please refer to the Angle Kappa / Alpha display on Page 92 for information on how to edit the pupil or vertex.

VFA Summary Display

The VFA Summary Display (VFA) is an all-inclusive display that presents both eyes side-by-side. The default maps shown for each eye are: Wavefront Map HO Total, PSF HO Total and Simulated Snellen Letter HO Total. The ***Options Menu*** is available with a *right-mouse-click* on the wavefront maps. Unlike other WF Summary screens, changes made to the VFA Summary display will not be saved as the default display. The VFA Summary also provides exam data, auto-refraction, multi-zone refraction, RMS summary data and Potential Visual Complaints for each eye. Potential Visual Complaints are visual complaints commonly noted with particular

HO Aberrations. The iTrace software compares the RMS values for the patient and ranks the potential visual complaints using a "+" sign or signs and color coding.



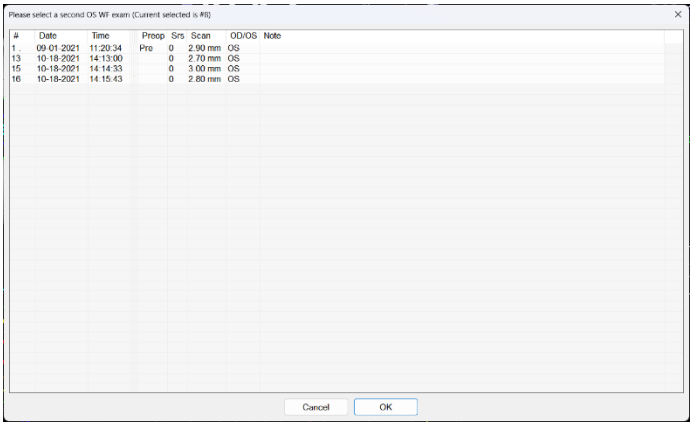
To View a VFA Summary Display

1. From the Patient Exam list, select an OD exam, and then select an OS exam.

2. Click on  to see the Tracey VFA Summary Display.

3. Choose another exam and click OK. (If only one exam exists, this exam will auto-select and display.)

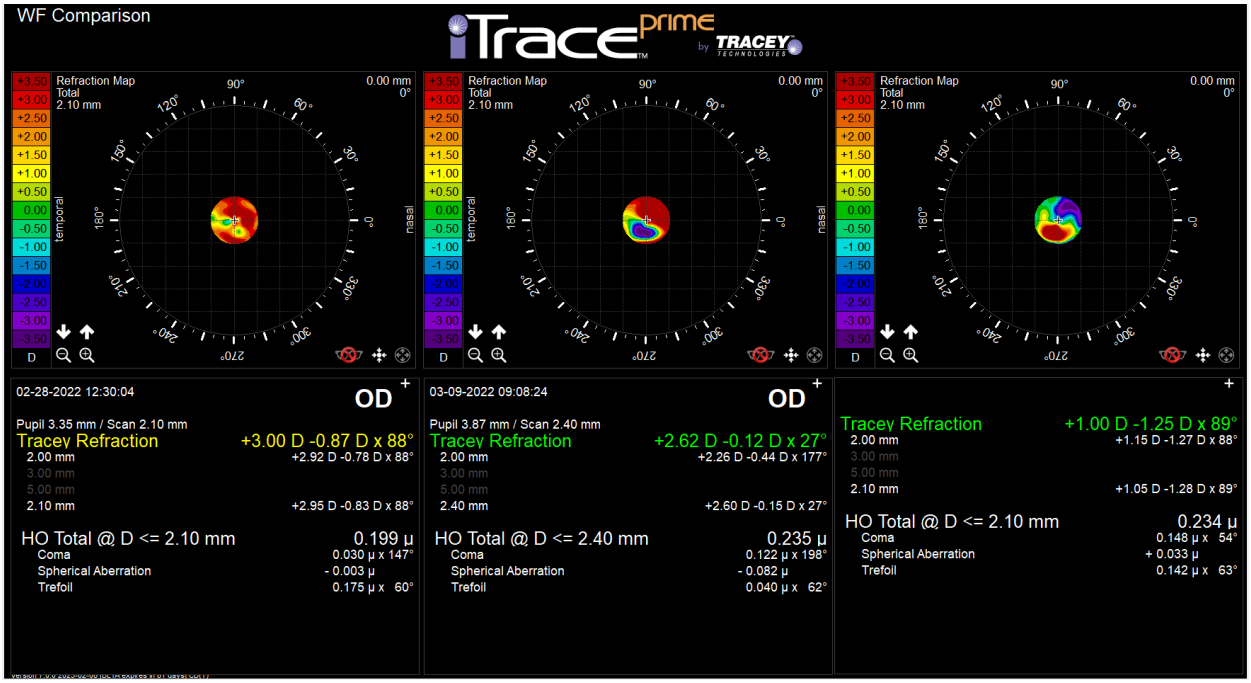
   Alternatively, you can choose either a WF OD or WF OS exam, and click the View Exam, then click the VFA button that appears on the Navigation Panel to get ***Select a second WF exam*** screen.



WF Comparison Display

The *Comparison Display* shows the differences of same-eye data between two exams. The left panels shows the data from the first exam. The middle panel shows the second exam data. The right panel is a map of the point-by-point difference between the first and second exams. The *Comparison Display* is commonly used to display accommodation amplitude and the surgical

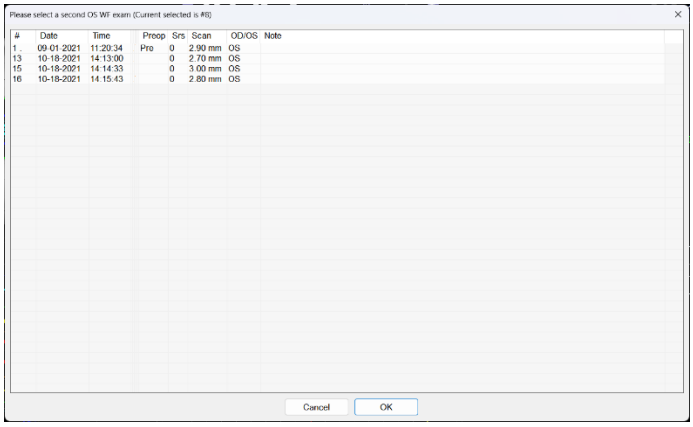
effect between pre-op and post-op exams. You can use the ***Options Menu*** to select other available methods and features for use in the comparison.



To View the WF Comparison Display

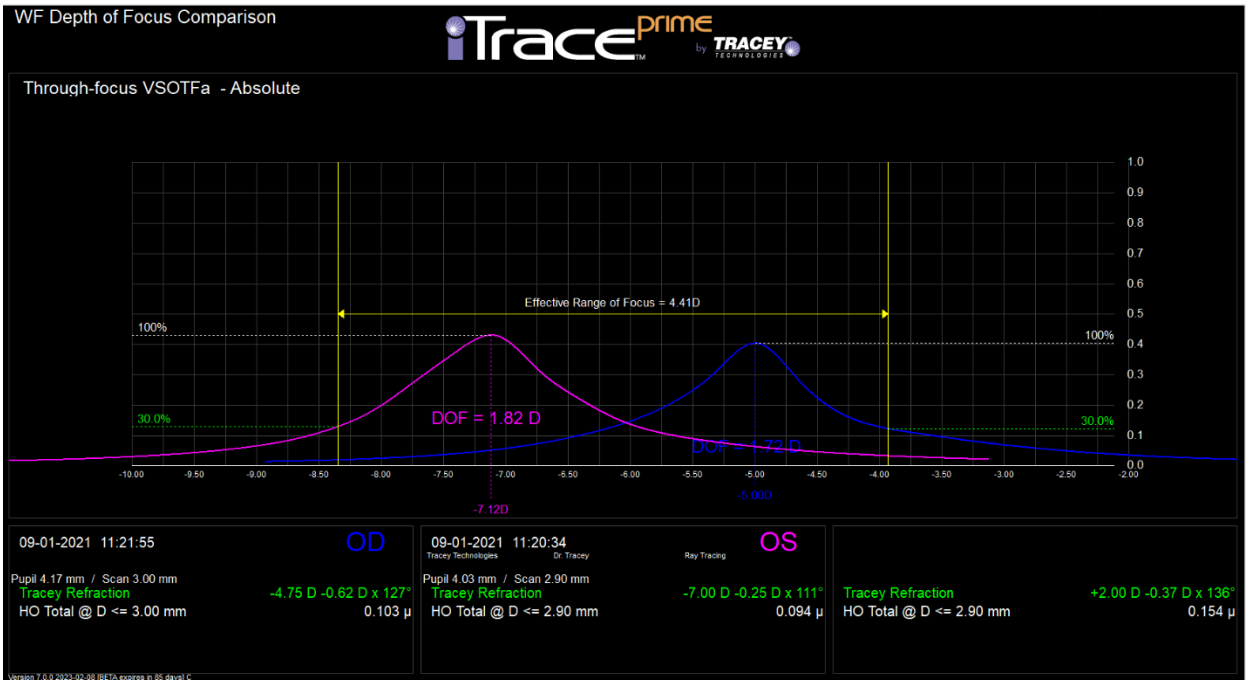
1. Click WF Compare button from Navigation menu to see ***Select a second WF exam*** screen.

2. Choose another exam and click OK.



Depth of Focus Comparison Display

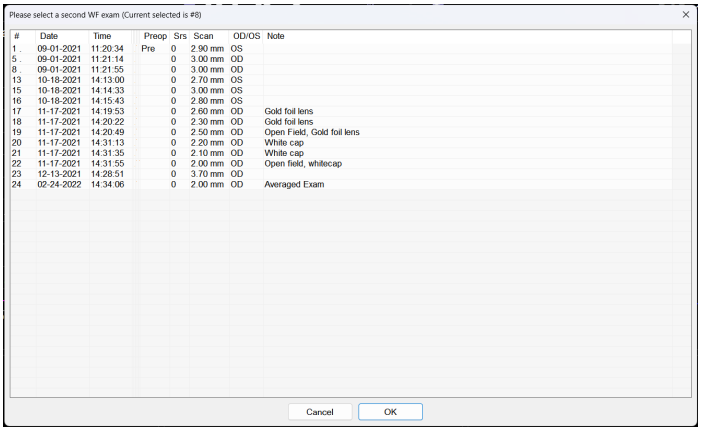
The Depth of Focus (DOF) Comparison Display (Prime only) plots the VSOTF curve of two eyes side-by-side and it overlays the dioptric range of the effective range of focus of that optical system. It can also be viewed as one curve if the same exam is selected in the second exam selection screen. More information about the VSOTF curves and their interpretations can be requested from Tracey Technologies.



To View the DOF Comparison Display

1. Click Depth of Focus Comparison button from Navigation menu to see ***Select a second WF exam*** screen.

2. Choose another exam and click OK.



Corneal Topography Summary Displays

The following Corneal Topography Summary displays are available for the navigation panel buttons in Settings.

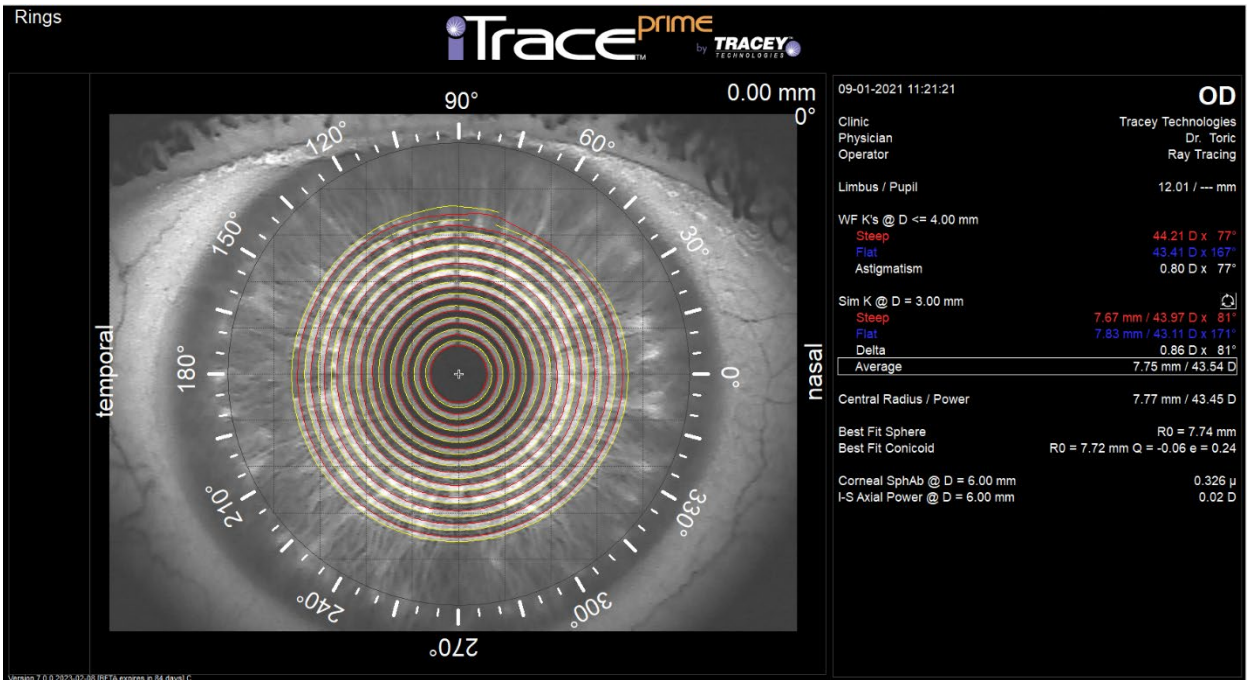
The available displays are:

- *Rings,* also known as *CT Verification,* is configured to display the eye image and detected ring edges along with CT indices.
- *OD/OS* is preset to display an Axial and a Local ROC map for each eye on one display.
- *CT Compare* is configured to display two axial maps and provide a difference map of the two maps.
- *CT Summary* is preset with Axial Map, RMS Bars @ 4mm, Corneal Snellen E HO Total, and a Placido Rings Eye Image.
- *Keratometry* is preset with large size Keratometry Map.
- *Osher Iris Imaging* (Prime only) is preset with the Osher Iris Imaging display of either the Placido image or a Color Image if available.

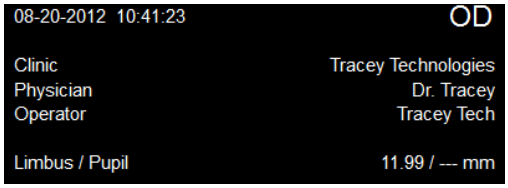
- *CT Custom* (Prime only) is preset with Axial, Local ROC, Z Elevation and Refraction maps and can be customized as desired. (Only available with Prime Activation.)
- *CT 3D Elevation* is a display used primarily in CL Fitting and is only available with Core Activation.

CT Verification Display

The CT Rings (Verification Display) appears as it did when presented after the exam acquisition. The display includes valuable information and from this display, the user can edit limbus and pupil (see page 81).



Summary Data



The patient data screen displays exam date and time, location, physician and operator detail filled in at the time of patient examination, the white-to-white limbus diameter (as detected or as drawn by the operator, the best fit circle to actual limbus shape), and the pupil diameter (as drawn by the operator, the best fit circle to actual pupil shape).

Wavefront Keratometry Data

The wavefront keratometry data is the refractive power over the entire area of the cornea within the central 4.00 mm zone, as calculated by the best spherocylindrical Zernike fit. The box displays the steep power and axis, the flat power and axis, and the astigmatism (difference.) The WF K's offers a better representation of those corneas that may be steeper or flatter centrally compared

with the 3 mm periphery and provide a more accurate astigmatism for corneas that are irregular or non-orthogonal.

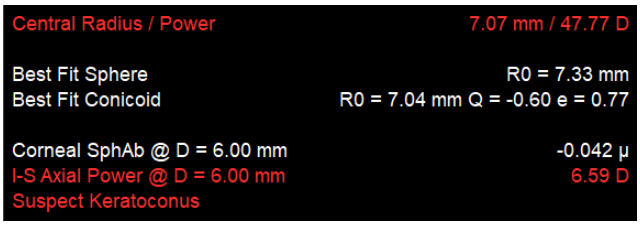
Simulated Keratometry Data

The Simulated Keratometry data provides the videokeratographic simulation of keratometry. Mimicking an auto-keratometer, the keratometry data is sampled from four perpendicular data points at a 1.5 mm radius from the corneal vertex. The steep, flat, and delta K with axes are displayed, along with the average K reading for that radial circle. Also in this area is a cycle button . Clicking this button will cycle between Sim Ks and Refractive Power.

Refractive Power Data

The refractive power data is the refractive power over the entire area of the cornea within the central 3.00 mm zone. The box displays the steep and flat axis and meridian, the astigmatism and overall effective refractive power. The Refractive Power offers a better representation of those corneas that may be steeper or flatter centrally compared with the 3 mm periphery. Also in this area is a cycle button . Clicking this button will cycle between Sim Ks and Refractive Power.

Corneal Indices Panel



This panel includes the Central Radius/Power measurement, the Best Fit Sphere and Conicoid, the Q and E values, the Corneal Spherical Aberration at the 6.00 mm zone and the I-S Axial Power at 6.00 mm. The software will display the "Suspect Keratoconus" message, as shown here, if the central corneal power is above 47.2 D *and* the I-S Axial Power is above 1.4. These thresholds are based on the Rabinowitz Keratoconus test. The message will only appear if both thresholds are met. However, the I-S and Central Radius/power indices will appear as red if their respective thresholds are met. A patient could be diagnosed with keratoconus after only exhibiting one of these parameters. Other testing should be completed before making a final diagnosis.

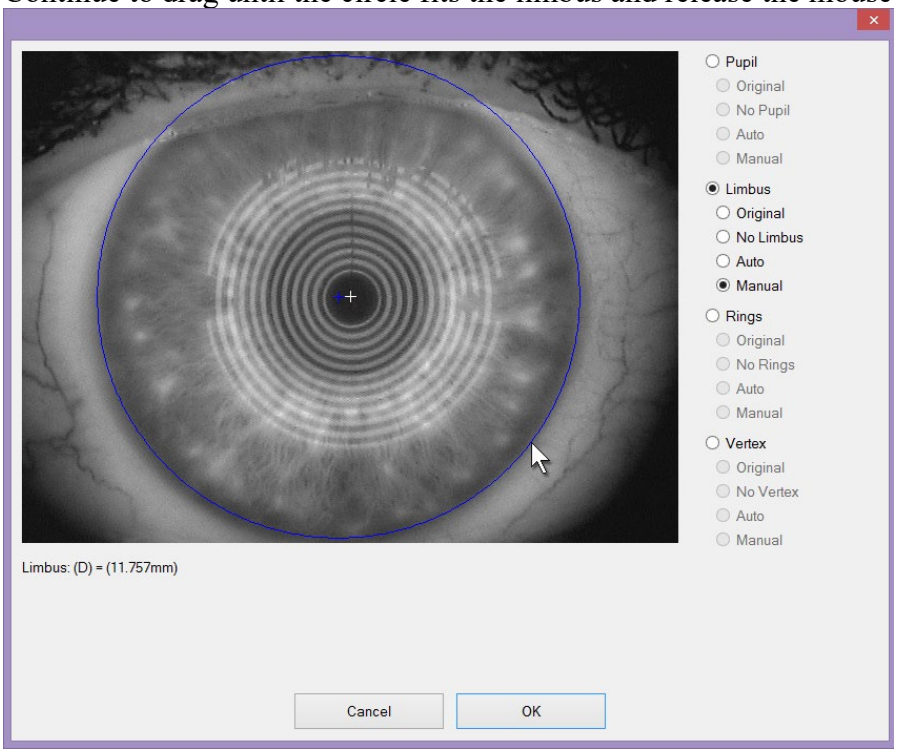
CT Verification Options Menu Navigation – Editing the Limbus

Ensuring that the auto-detected limbus line is correct is important so that the Angle Alpha measurements are correct. If the limbus needs to be edited, follow these steps.

This options menu is available by *right-mouse-click* action on the display.

Show Rings
Show Pupil
Show Limbus
Edit pupil, limbus and rings

1. Click on *Edit pupil, limbus and rings*.
2. To edit and the limbus, click on the radio button labeled “Limbus”.
3. Click the radio button next to Auto and the software will auto-detect the limbus. If the auto-detection is not acceptable, click the “Manual” radio button.
4. Click and hold the left mouse button on the edge of the limbus image and slowly drag the mouse across the image while holding down the mouse button. A blue circle will appear. Continue to drag until the circle fits the limbus and release the mouse button.

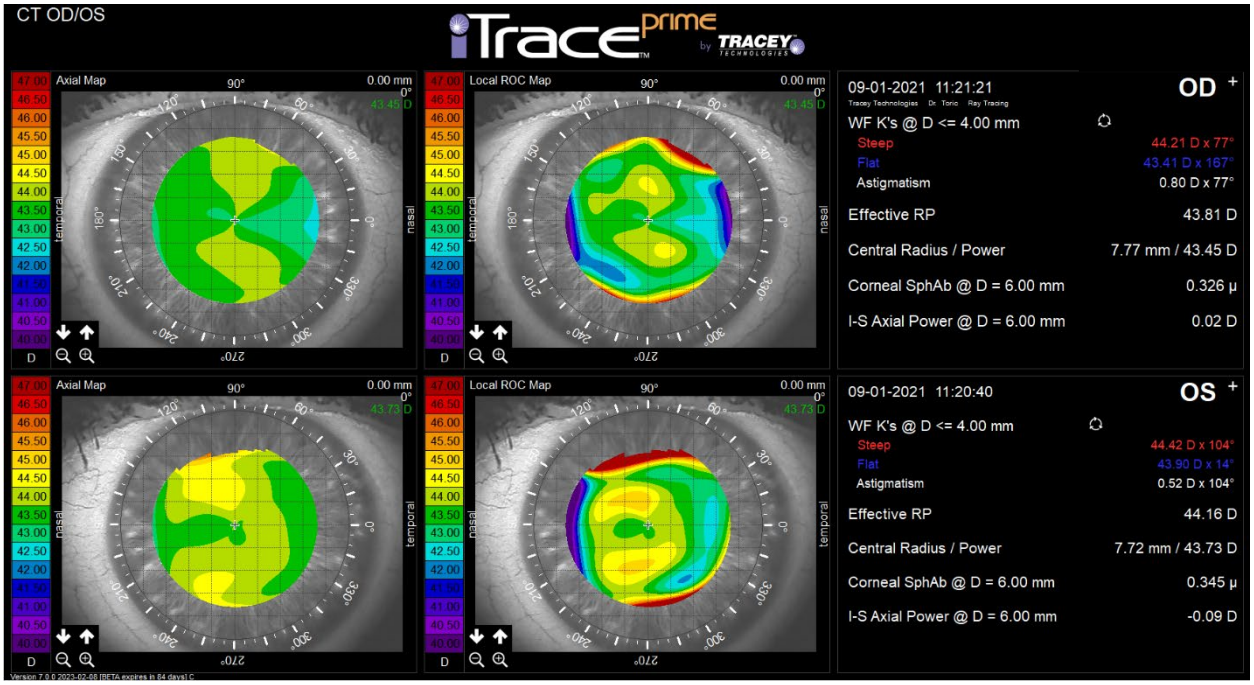


The limbus line will likely overlap the lids. The limbus diameter provided is only a close approximation of the actual limbus diameter.

5. To remove the limbus line, select the “No limbus” radio button. To return to the previously saved limbal line, click the radio button labeled “Original”.

OD/OS CT Summary Display

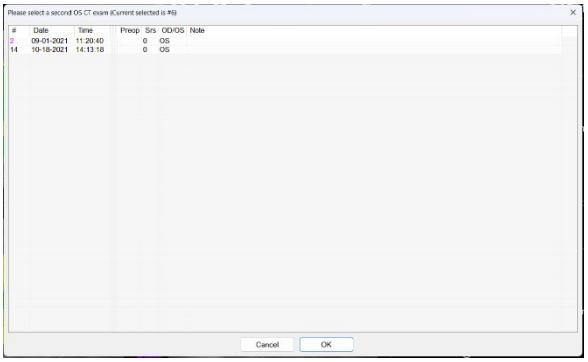
Much like the VFA WF Summary, the *OD/OS* button allows you to select the fellow eye’s CT exam to view both eyes simultaneously. Right clicking on any one of the three maps will bring up the Options Menu, which allows you to change the display type and certain features of the display.



To View the OD/OS Display

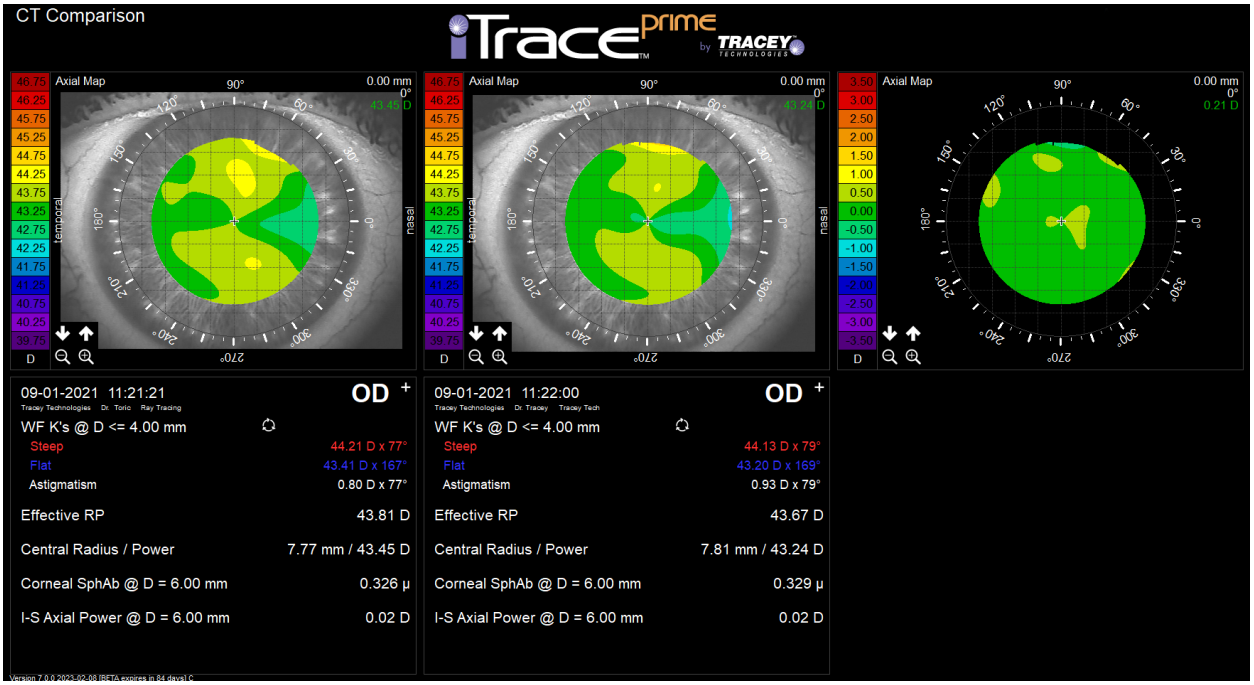
1. From a CT Summary Display, click OD/OS to get ***Select a second CT exam*** screen. If only one exam exists in the list, the display will automatically include this exam.

2. Choose the second exam and click OK.



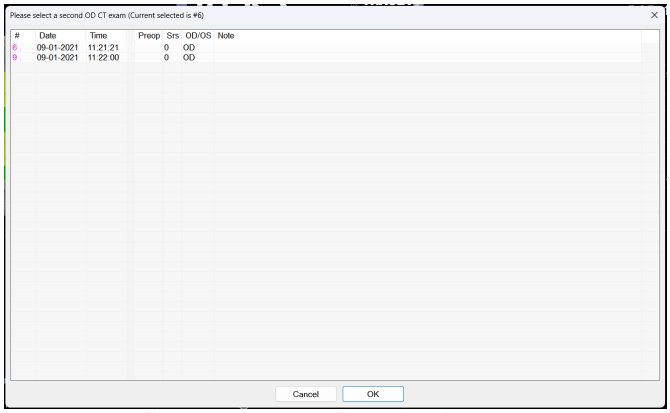
CT Comparison Display

The *Compare* button allows you to select another CT exam to view differences between two (2) exams. Right clicking on any one of the three maps will bring up the Options Menu, which allows you to change the display type and certain features of the display. Changes to one map will affect all three maps simultaneously.



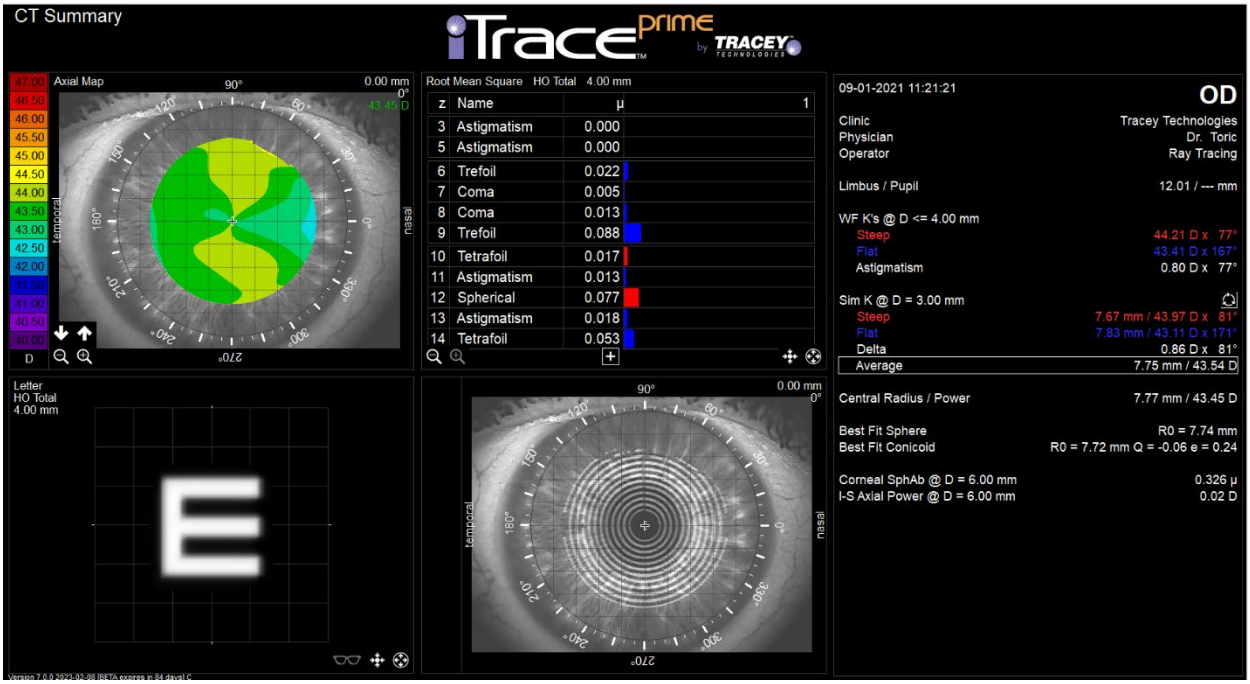
To View the CT Comparison Display

1. Click CT Compare button in CT Summary Display to get ***Select a second CT exam*** screen.
2. Choose another exam and click OK.



CT Summary Display

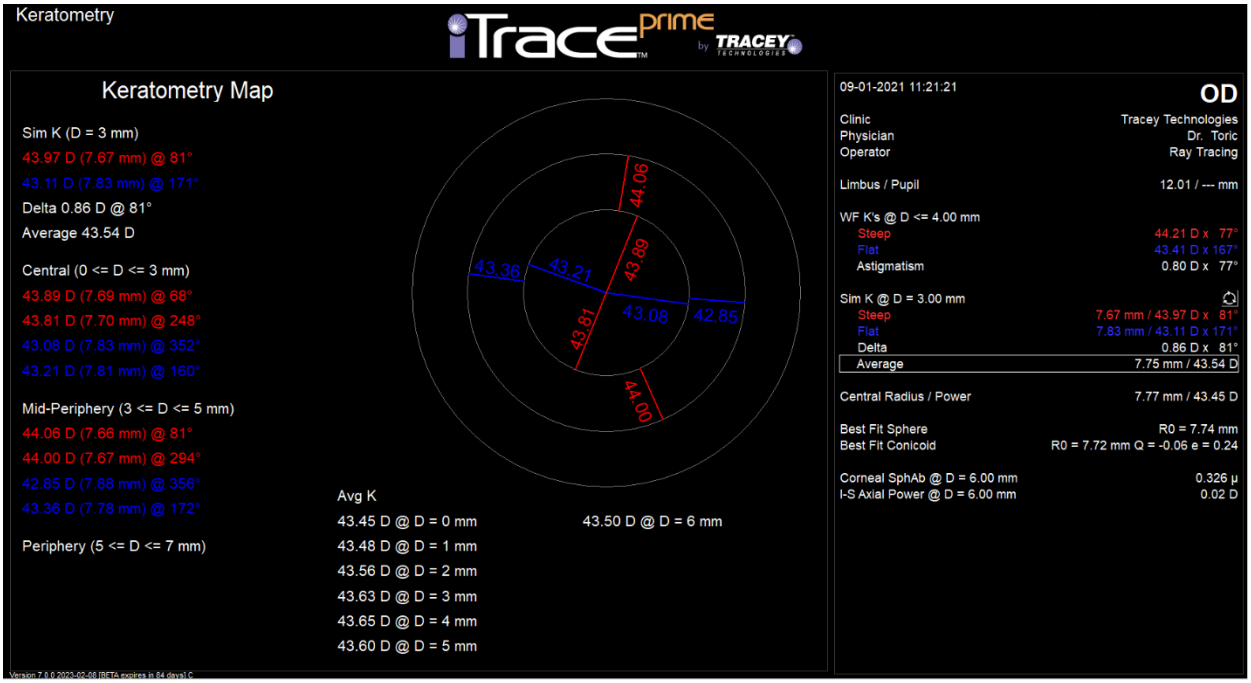
The *CT Summary* display provides four different panels to evaluate the patient's corneal topography. These panels can be customized and changes will be remembered until defaults are restored or new settings are loaded. Details for making these customizations are found in the Appendix A, Technical Information.



Keratometry Display

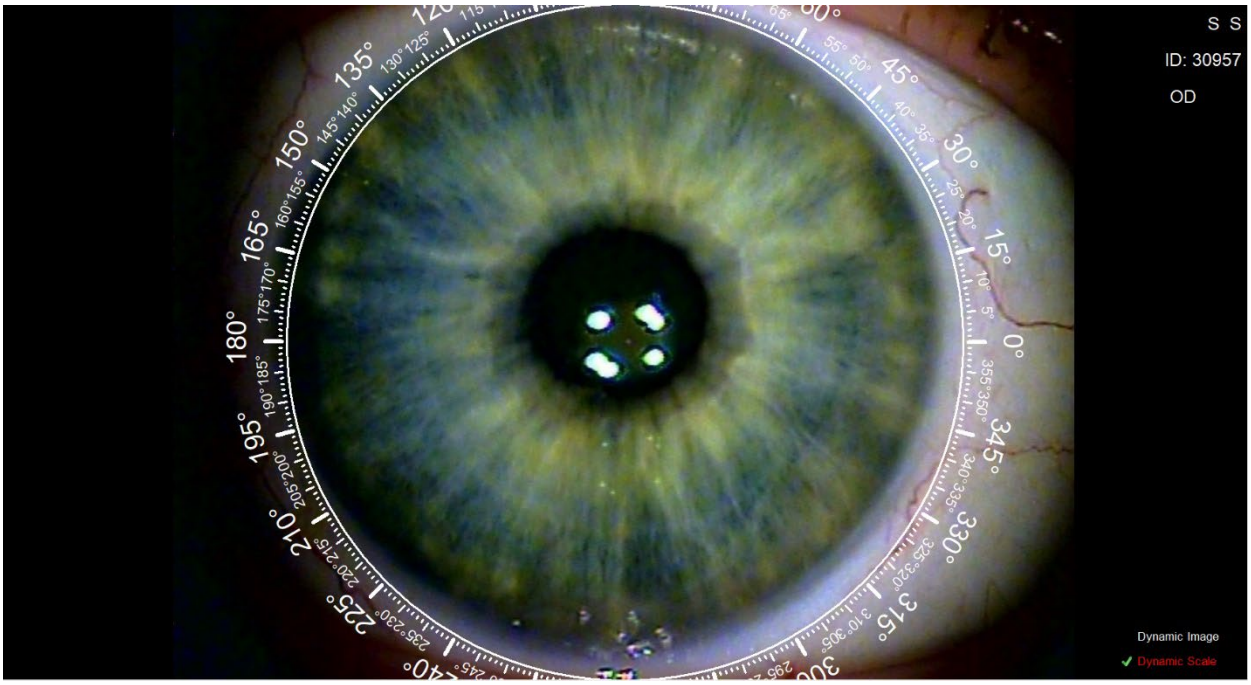
The *Keratometry* display provides the semi-meridian steep and flat axis data in three zones of the cornea. In the central 3mm zone, the steepest axis is identified in one semi-meridian, then the steepest axis in the opposite semi-meridian is found and show in red. Likewise, the flattest axis for each is found and shown in blue. This process is repeated for each zone. Also, this display provides the Average K values in 1mm ring steps from the center to the larges peripheral ring.

The display can be customized, and changes will be remembered until defaults are restored or new settings are loaded. Details for making these customizations are found in the Appendix A, Technical Information.



Osher Iris Imaging Display

The *Osher Iris Imaging* (Prime) enables the view of the eye image taken during CT or the color eye image taken immediately after the CT exam as part of the CT exam process. It includes tools like the Dynamic Scale that magnifies the angle scale to precisely locate iris details or limbal vessels. The Dynamic Image magnifies the image itself so that you can view the eye image in more detail. Lastly, you can edit the eye image by right-mouse click where you can add overlays like the radial ruler and linear ruler.

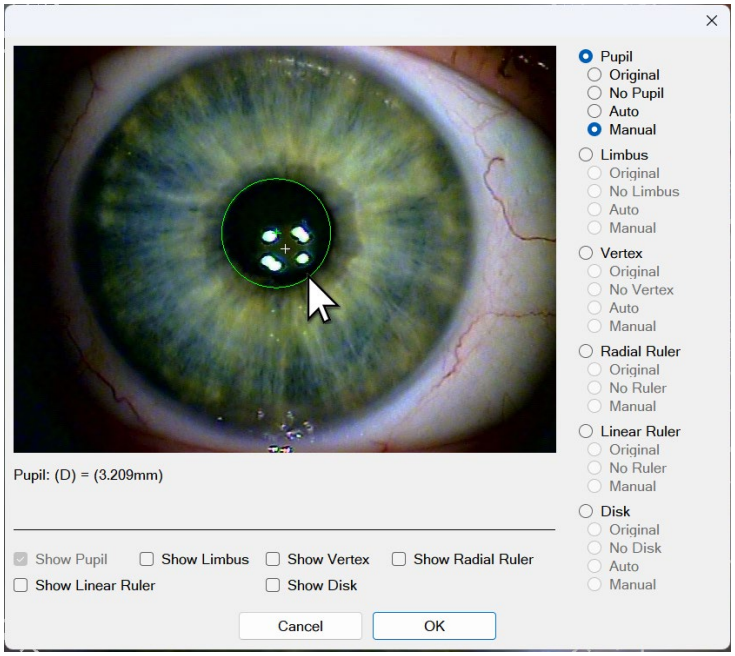


To Add Overlays to the Osher Iris Imaging Display

1. To adjust the detected anatomies or access other tools, *Right-mouse-click* on the eye image and select *"Edit limbus, vertex, ruler and disk"*.

2. The Edit Pupil, Limbus, Vertex, Ruler and Disk screen will appear. To edit the pupil, click on the radio button next to "*Pupil*" and then the radio button next to "*Manual*" to manually edit the pupil line.

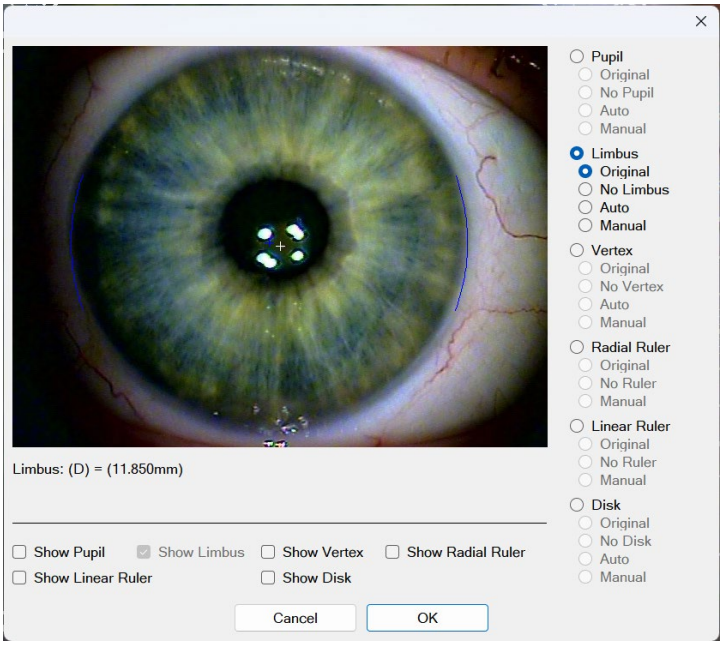
3. Click and hold the left mouse button on the edge of the pupil image and slowly drag the mouse across the image while holding down the mouse button. A green circle will appear. Continue to drag until the circle fits the pupil and release the mouse button.



4. To return to the pupil line previously saved, click on the radio button labeled "*Original*". The software can also reprocess the pupil line. To do so, click on the radio button labeled "*Auto*". To remove the pupil line, click on the button labeled "*No Pupil*".

5. If desired, lines and tools in this screen can be displayed by clicking the check boxes under the eye image.

6. To remove or auto-detect the limbus, click on the radio button labeled "*Limbus*".



7. To edit the limbus, click on the *"Limbus"* radio button and then on the *"Manual"* radio button to manually edit the limbus. The manually edited limbus will appear as a full blue circle. The software detected "Auto" limbus will appear as shown as blue arcs.

8. To edit the vertex, click on the "*Vertex*" radio button and then the "*Manual*" radio button to manually edit the vertex – which is the center of the four (4) brightest IR dot reflections.

9. Click and hold the left mouse button on vertex crosshair and slowly drag the mouse while holding down the mouse button until in the desired position, then release the mouse button.

10. To return to the vertex previously saved, click on the radio button labeled "*Original*". The software can also re-detect the vertex. To do so, click on the radio button labeled "*Auto*".

11. To edit the Radial Ruler, click on the radio button next to "*Radial Ruler*" and then the "*Manual*" radio button to manually add a circular "ruler". This may be helpful to find the center of the IOL optic in a dilated post-implant eye. Comparing it to the vertex can help to analyze surgical outcome.

12. Click and hold the left mouse button on the eye image and slowly drag the mouse while holding down the mouse button until the ruler is in the desired position, then release the mouse button. The diameter of the ruler displays on the circle and in the panel under the eye image. To move the ruler to any part of the image, click and hold the left mouse button on the center of the circle and slowly drag the mouse while holding down the mouse button until the ruler is in the desired position.

13. Click the OK button to accept the edits and return to the Osher Iris Imaging Display ay. The Radial Ruler will appear on the display. The diameter and the center coordinates of the ruler will appear on the bottom left of the eye image.

14. To return the Radial Ruler to the previously saved ruler, right-mouse-click on the eye image panel and select "*Edit pupil, limbus, vertex, ruler and disk"*. The Edit Pupil, Limbus, Vertex, Ruler and Disk screen will appear. Click on the radio button labeled "*Original*" or remove the ruler by clicking the "*No Ruler*" radio button.

15. To edit the Linear Ruler, click on the "*Linear Ruler*" radio button and then the "*Manual*" radio button to add a simple "ruler" line. This may be helpful to measure distances on the eye image.

16. Click and hold the left mouse button on the eye image and slowly drag the mouse while holding down the mouse button until the ruler is in the desired position, then release the mouse button. The diameter of the ruler displays on the line and in the panel under the eye image. To move the ruler to any part of the image, click and hold the left mouse button on the center of the line and slowly drag the mouse while holding down the mouse button until the ruler is in the desired position.

17. Click the OK button to accept the edits and return to the Osher Iris Imaging Display. The Linear Ruler will appear on the display. The length of the ruler will appear on the bottom left of the eye image.

18. To return the Linear Ruler to the previously saved ruler, right-mouse-click on the eye image panel and select "*Edit pupil, limbus, vertex, ruler and disk"*. The Edit Pupil, Limbus, Vertex, Ruler and Disk screen will appear. Click on the "*Original*" radio button or remove the ruler by clicking the radio button labeled "*No Ruler*".

19. The Disk can be used to simulate a corneal inlay or to approximate an ablation zone to again analyze the centration of the optics with the eye's optical centration. To edit the Disk, click on the "*Disk*" radio button, and then the "*Auto*" radio button to add the default circular overlay pattern. The default size is 2mm and it will automatically place the disk center on the vertex.

20. To change the disk size, click the "*Manual*" radio button. An input box appears allowing you to enter the exact outer diameter of the disk to display and to enter an inner diameter to simulate a central aperture. Once you enter these measurements click the Set button. In Manual mode, you can also change the position of the disk. To move the disk to a different position, click and hold the left mouse button on the disk center and slowly drag the mouse while holding down the mouse button until the disk is in the desired position.

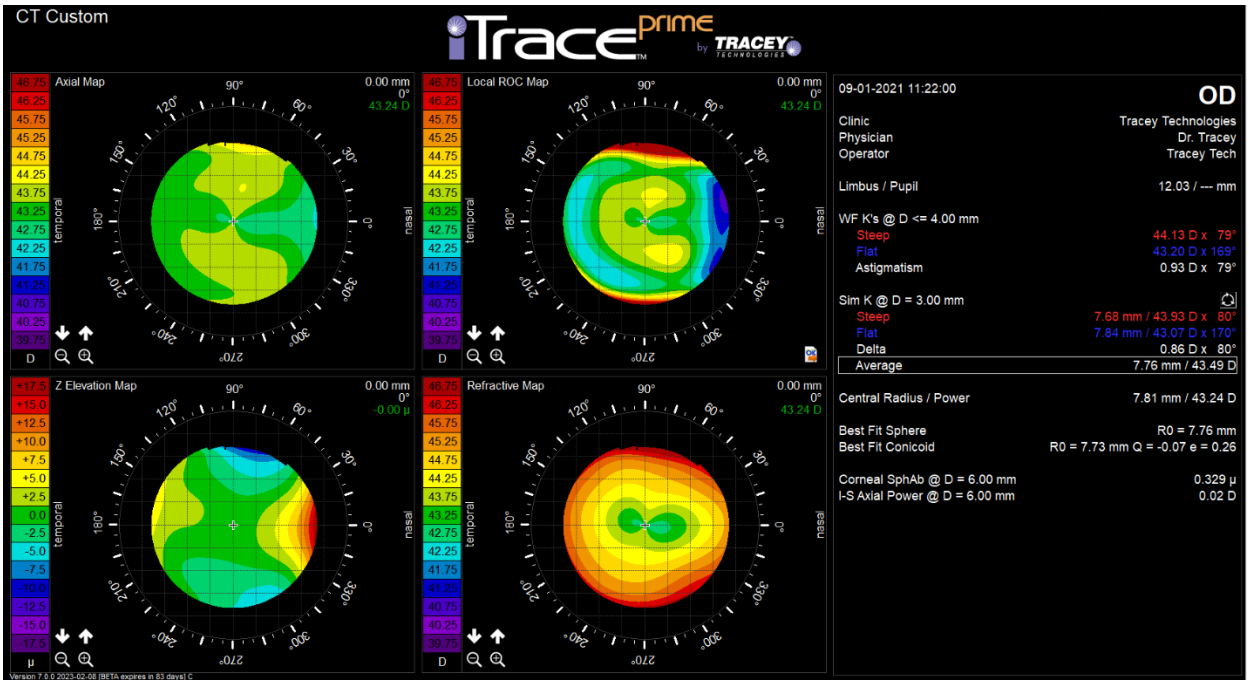
21. Click the OK button to accept the edits and return to the Osher Iris Imaging Display. The Disk will appear on the display. The disk will include the measurements in millimeters from the edge of the disk to the limbus at each side of the disk. The diameter and center coordinates display to the bottom left of the eye image.

22. To further edit or remove the disk, *right-mouse-click* on the eye image panel and select "*Edit pupil, limbus, vertex, ruler and disk"*. The Edit Pupil, Limbus, Vertex, Ruler and Disk screen will appear. Click on the radio button labeled *No Disk*, or further edit the disk or other parameters in the dialog.

The display can be customized and changes will be remembered until defaults are restored or new settings are loaded. Details for making these customizations are found in the Appendix A, Technical Information.

CT Custom Display

The *CT Custom* display (Prime) provides four different panels to evaluate the patient's corneal topography. These panels can be customized and changes will be remembered until defaults are restored or new settings are loaded. Details for making these customizations are found in the Appendix A, Technical Information.



WF and CT Summary Displays

The WF and CT Summary Displays use both exam types and provide a separation of the whole eye aberrations from the corneal aberrations to provide the lenticular aberrations. There are several specialized displays featuring this combination of WF and CT exams:

- *Chang Analysis* was specially developed to show the aberration breakdown with RMS Bar graphs between the optical components of the cornea, internal optics and total vision, and also the topographic information needed during cataract surgery planning.
- *WF/CT Summary* shows the aberration breakdown represented by a wavefront map for each of the optical components and an Axial CT map.
- *MTF* display show the Modulation Transfer Function for each of the optical components as well as the Axial CT map.
- *OU Overview* is similar to the VFA Display, but adds the CT data in an OD/OS side-by-side

overview.

- *Prime Dashboard* is configured to display a comprehensive data set needed for the surgeon and includes unique indices along with simulated Snellen E displays for each of the optical components. (Only available with Prime Activation.)
- *Core Dashboard* is configured to display a comprehensive data set to review the data measured from the WF, CT and Tearfilm Exams. (Only available with Core Activation.)
- *IOL Selection* is another overview screen that provides unique detail with the wavefront and CT data, along with a decision tree for considering optimal IOL candidacy. (Only available with Prime Activation.)
- *Corneal Spherical Aberration Function* graphs the CSA zonally from the center to the periphery of the cornea. (Only available with Prime Activation.)
- *Angle K/A* plots the centers of the pupil, limbus and visual axis and the distances and vectors of these centers. (Only available with Prime Activation.)
- *Patient Education,* previously known as the Dysfunctional Lens patient display, provides the simulated Snellen letters for each of the optical components and adds the unique indices for those components.
- *Toric Alignment Check (Toric Check)* can provide insight into whether the implanted toric IOL is aligned and powered correctly for the patient's cornea. (Only available with Prime Activation.)
- *Toric Plan* helps to calculate and plan for toric IOLs corrections. It includes the *Tracey Toric Calculator, Toric Planner display, Zaldivar Caliper* and *Osher Alignment*. (Only available with Prime Activation.)
- *WF/CT Custom* initially mimics the MTF display but can be customized to show any of the available map types in each of the panels. (Only available with Prime Activation.)
- *Custom CL* must be enabled in Settings. It is a unique display developed to help practitioners design Custom soft and scleral contact lenses.

To View WF & CT Summary Displays

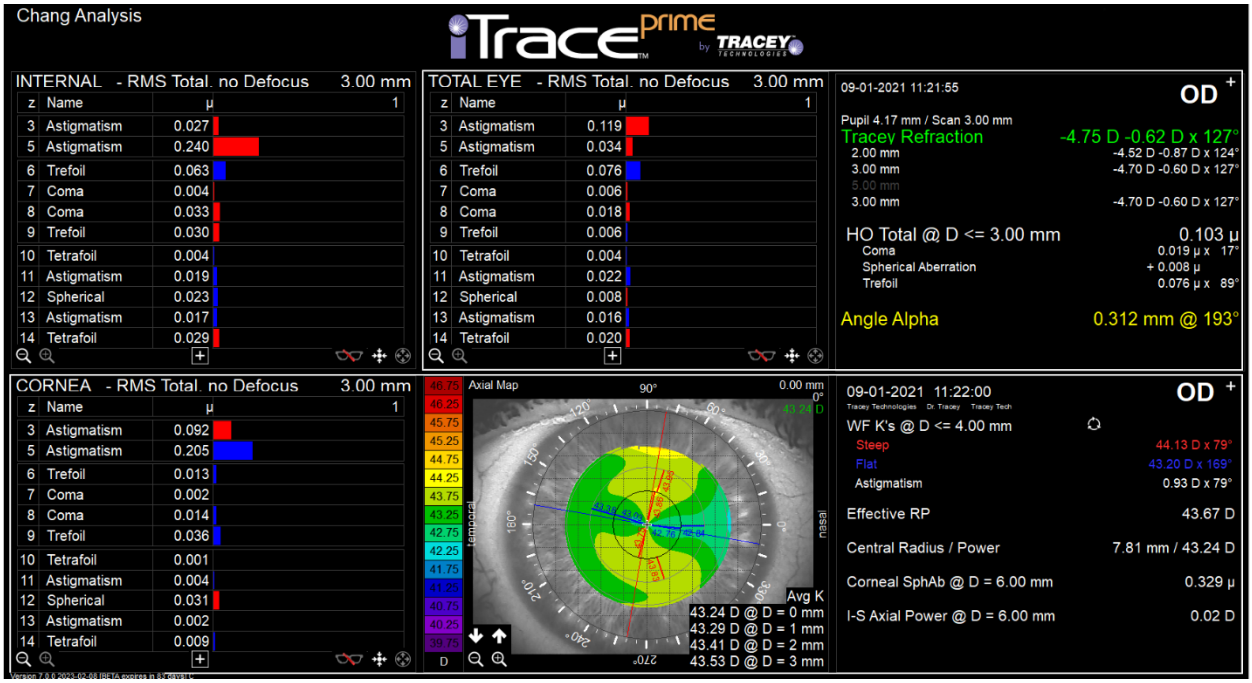
Select one of a paired WFCT exams and the companion exam will highlight. Select the highlighted exam and click  . The default *WF & CT Summary* will display.

Alternatively, select a WF exam and a CT exam for the same eye and click  and you will transfer to the default *WF and CT Summary* display.

Chang Analysis

The Chang Analysis display is set to show the individual RMS bar graphs for each of the wavefront displays. The default view shows Zernike terms through the fourth order and sets the scale to 1.00 µ. Any term over 1.00 µ will display a forward arrow at the end of the bar to signify the term is beyond 1.00 µ. Use the button to zoom the graph out and view the entire bar graph. To view up to the sixth order in the list of terms, click the Show Details button ( ). The terms are color coded to alert when a term exceeds certain threshold levels, with white as a normal range, yellow showing a mid-range and red showing the highest level of aberrations. These levels are based on a number of factors including the type of aberration and the pupil size.

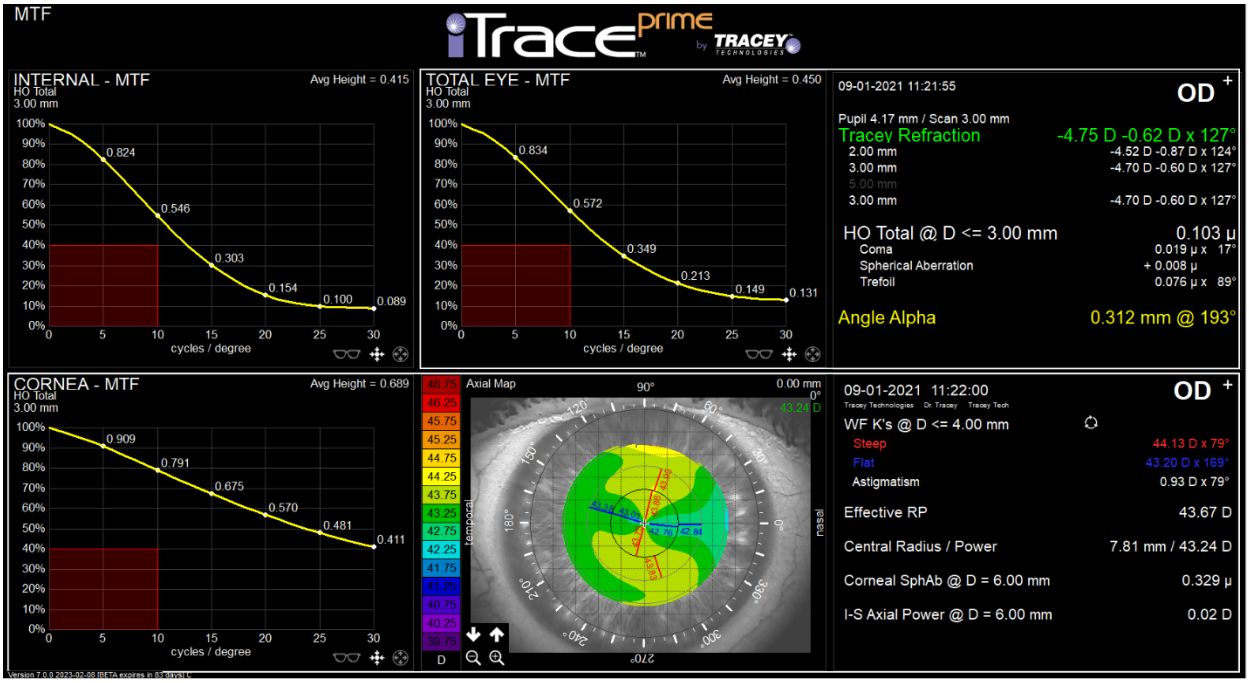
The Corneal Topography map in the lower right includes the average Ks from 0 to 3 mm rings (1.00 mm increments) and displays the keratometry overlay.



MTF

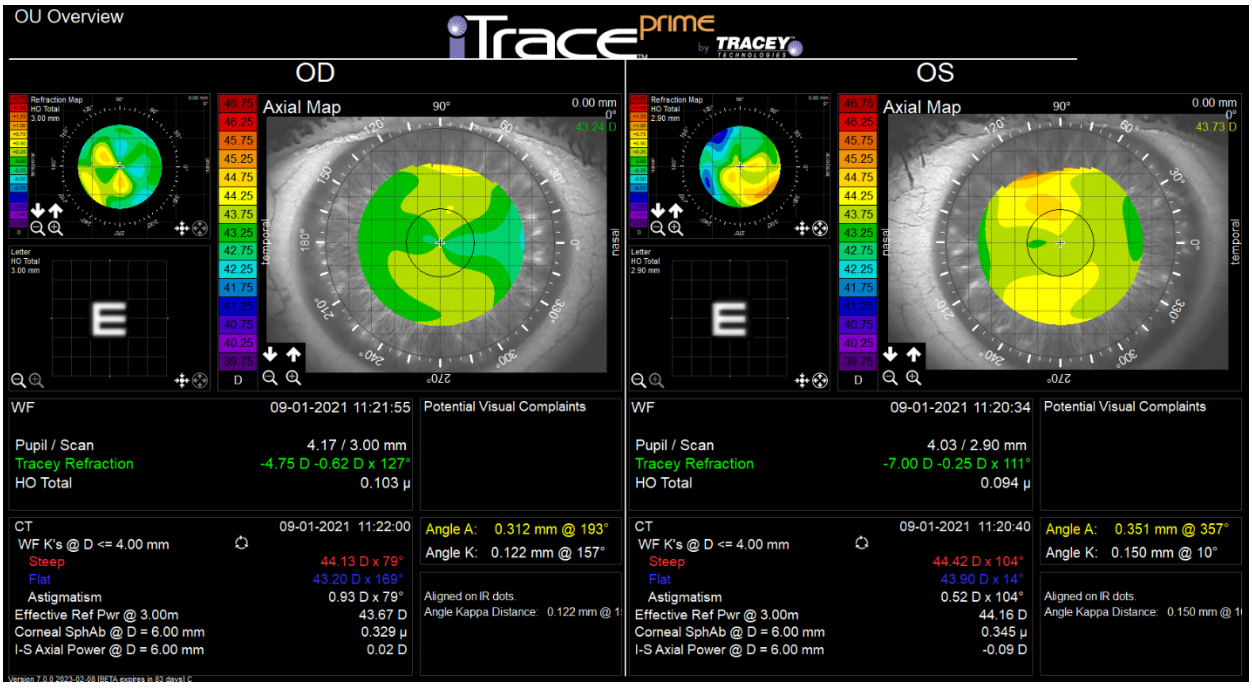
The Chang Analysis display provides the Modulation Transfer Functions (a measure of contrast sensitivity) of the three components of the eye: cornea, internal and total eye. The red box designates the area of concern within the MTF graph. If the plotted yellow line passes through the red box, the patient suffers significant loss of contrast within that component.

The Corneal Topography map in the lower right includes the keratometry overlay.



OU Overview

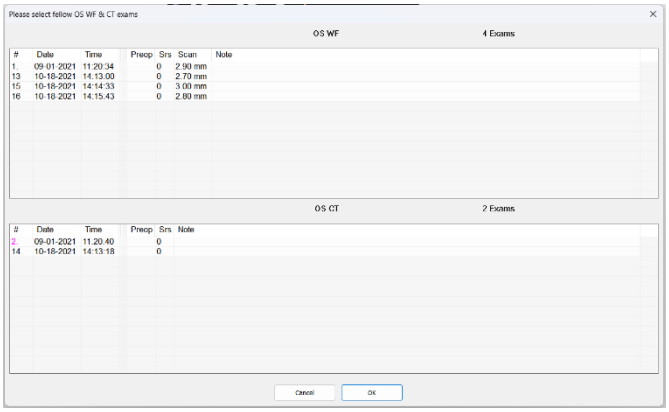
The OU Overview display is similar to the VFA display in that it displays both eyes on one screen. It simultaneously shows an overview of WF data and CT data for the right and left eyes.



To View an OU Overview

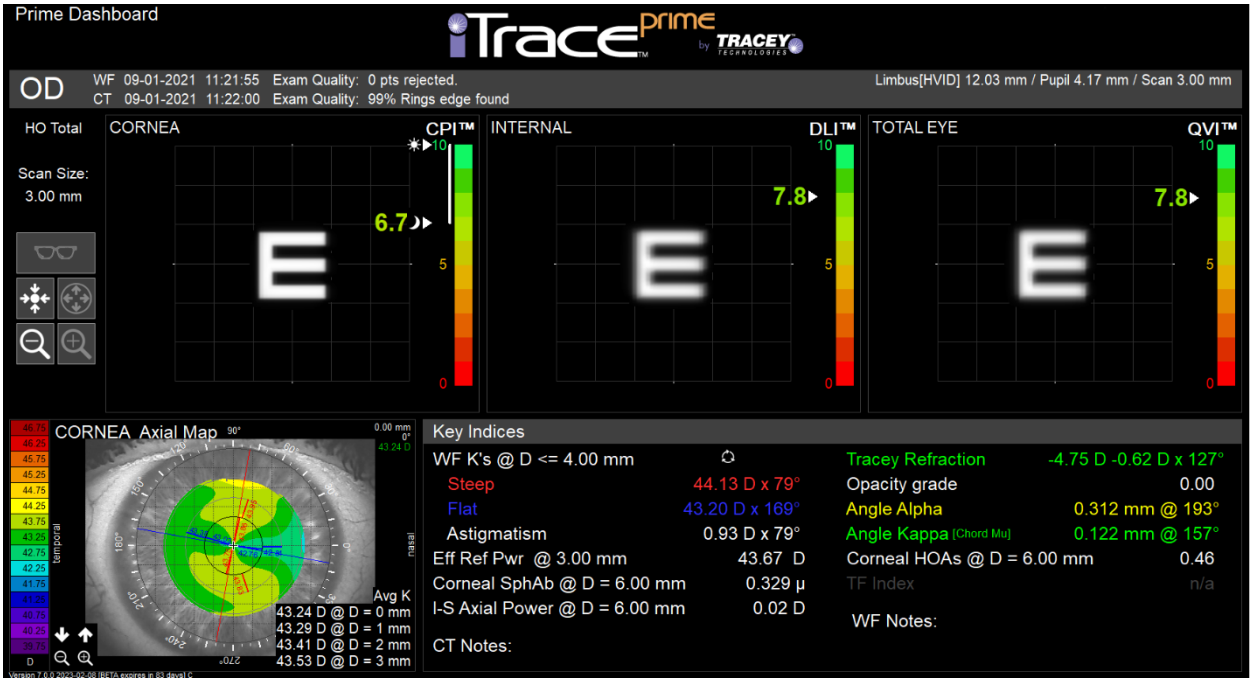
1. Click OU Overview button and the ***Select fellow OD or OS WF & CT exam*** screen will display.

2. Choose a WF and a CT exam and click OK.



Prime Dashboard

The Prime Dashboard provides the cataract surgeon with a comprehensive report of the most crucial information associated with the WF, CT and TF exams for the patient. The topmost gray bar provides exam date/time stamps, exam quality information, and limbus/pupil/scan sizes.



The optical component breakouts in the top panels of the display include not only the Simulated Snellen E representations from the cornea, internal and total eye, but also proprietary indices that score the quality of vision from each component.

The Corneal Performance Index (CPI™) is a singular number that scores the corneal quality of vision on a 0 to 10 scale with a bar that displays how that score would adjust based on the pupil size from 2.50mm to 4.00mm. The Corneal panel will also display a message "Check Optical Alignment" if the Angle Alpha is high. Both the CPI and the optical alignment can be key data points for determining premium IOL candidacy.

The Dysfunctional Lens Index (DLI™) calculation scores the quality of vision from the Internal Optics (predominately the lens) on a 0 to 10 scale. A lower number correlates to a more dysfunctional lens, which can indicate an early cataract; a higher number correlates with better lens performance. The software will also analyze the corneal higher order aberrations and indicate if there are significant to severe corneal HOAs. If the corneal HOAs are between 0.280µ and 0.449µ, "High Corneal Aberrations" will appear colored yellow above the Internal Snellen Letter. If they are above 0.450µ, "High Corneal Aberrations" will appear colored red. In either case, the DLI score may not be as accurate and may be lowered because of the cornea.

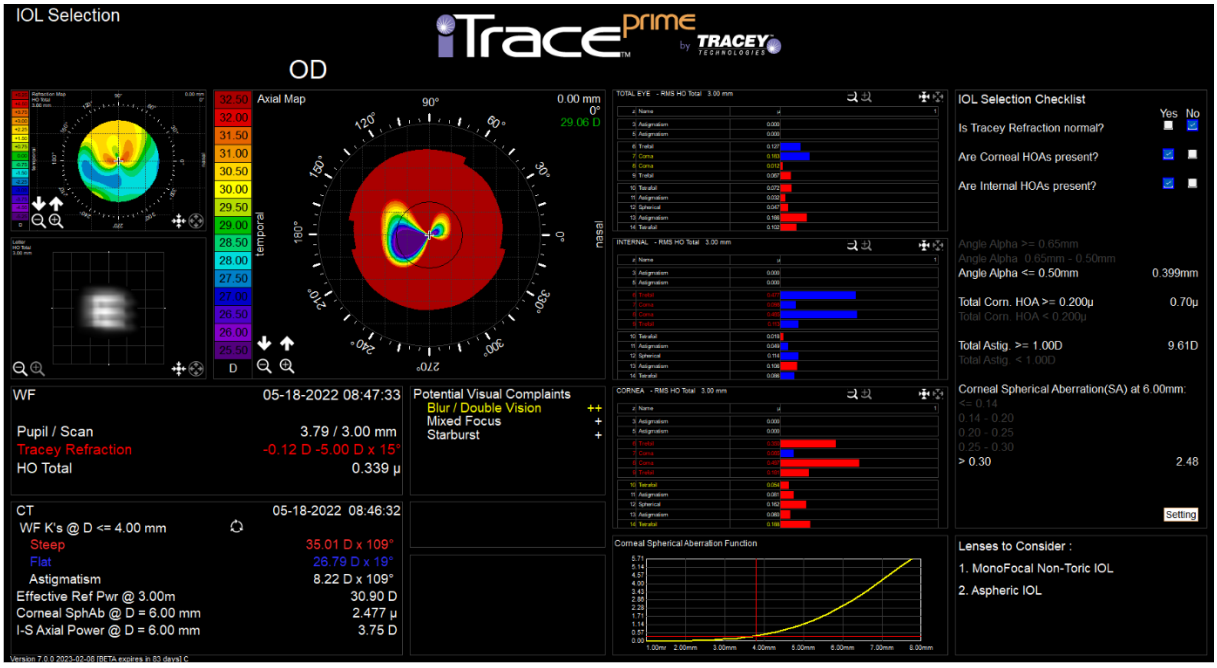
The Quality of Vision Index (QVI™) likewise scores the quality of vision from the total eye. This metric can be used to quantify and track vision.

This display can help you better understand how patient's corneal vision will equal their post-surgical vision. Using the spectacle button (, you can cycle through to illustrate how vision will change with a standard monofocal correction and a Toric correction. Likewise using the zone size buttons (and) you can simulate the vision that could result with a pinhole optic treatment.

The bottom panels include a corneal topography axial map with the keratometric details and a Key Indices panel. If a Tear Film Analysis was performed within the same day as the CT exam, the resulting TFI will automatically populate.

IOL Selection Analysis

The IOL Selection Analysis display helps narrow down possible lens options for patients, based on findings from the iTrace exam, including a patient's internal aberrations, corneal aberrations, corneal astigmatism, optical alignment and corneal spherical aberration. The display provides summary information on the left side of the screen, the RMS bar graphs in the middle (along with a plot of the patient's corneal spherical aberrations as pupil size increases), and offers a checklist and analysis in the far right panel. The *Lenses to Consider* list appears in the bottom right corner.



The RMS Bar graph displays can be changed to Visual Acuity Charts or Modulation Transfer Function displays, as desired, using the Display Options Menu by right-mouse-clicking on the displays.

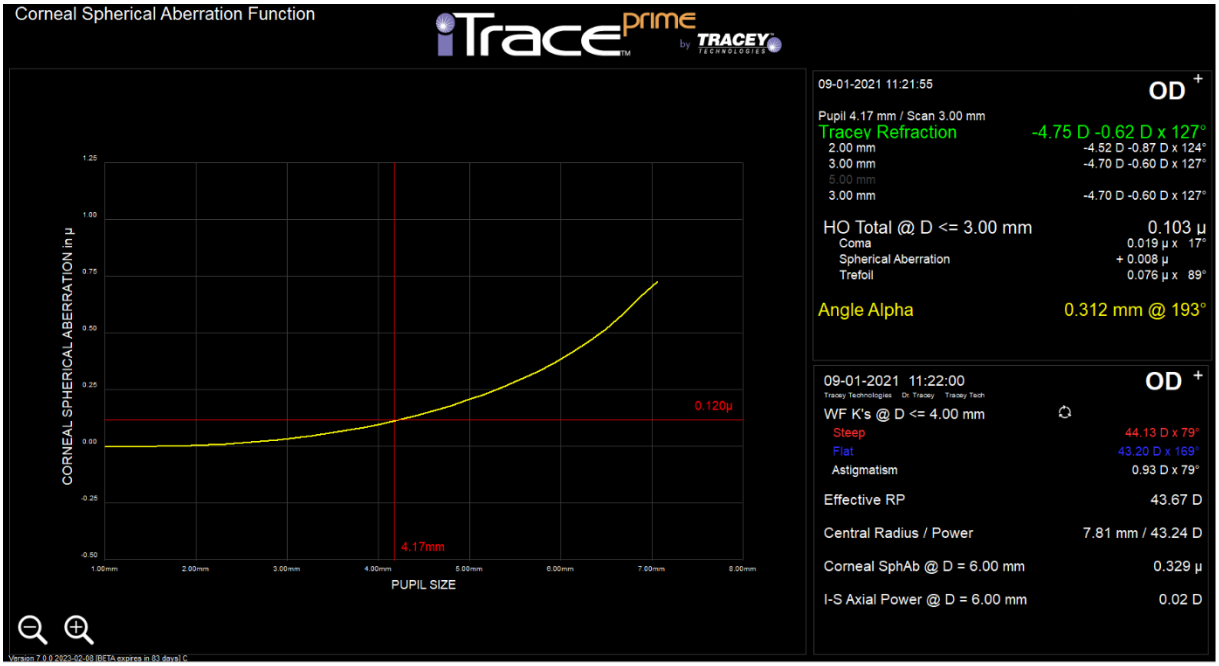
The IOL Selection checklist and analysis is interactive. The first three questions are answered by the iTrace measurements; however, they can be overridden by the user should the user feel that the findings are borderline. For example, there may be cornea and lens compensation that is giving the patient a good refraction; thus, stopping further analysis, but if the physician has already diagnosed a cataract, the question "Is Tracey Refraction Normal?" can be overruled by clicking the checkbox next to No. This enables the analysis to continue.

The next analysis studies the patient's angle alpha, corneal higher order aberrations, corneal astigmatism, and corneal spherical aberration to analyze which types of IOLs will be the best options for the patient given the measurements made by the iTrace exam. Currently, the *Lenses to Consider* are not customizable, but this may be an option in future software updates.

The user can change the thresholds of each analyses set within Settings from the Patient List screen, or by clicking the Settings button within the IOL Selection Analysis display.

Corneal Spherical Aberration Function

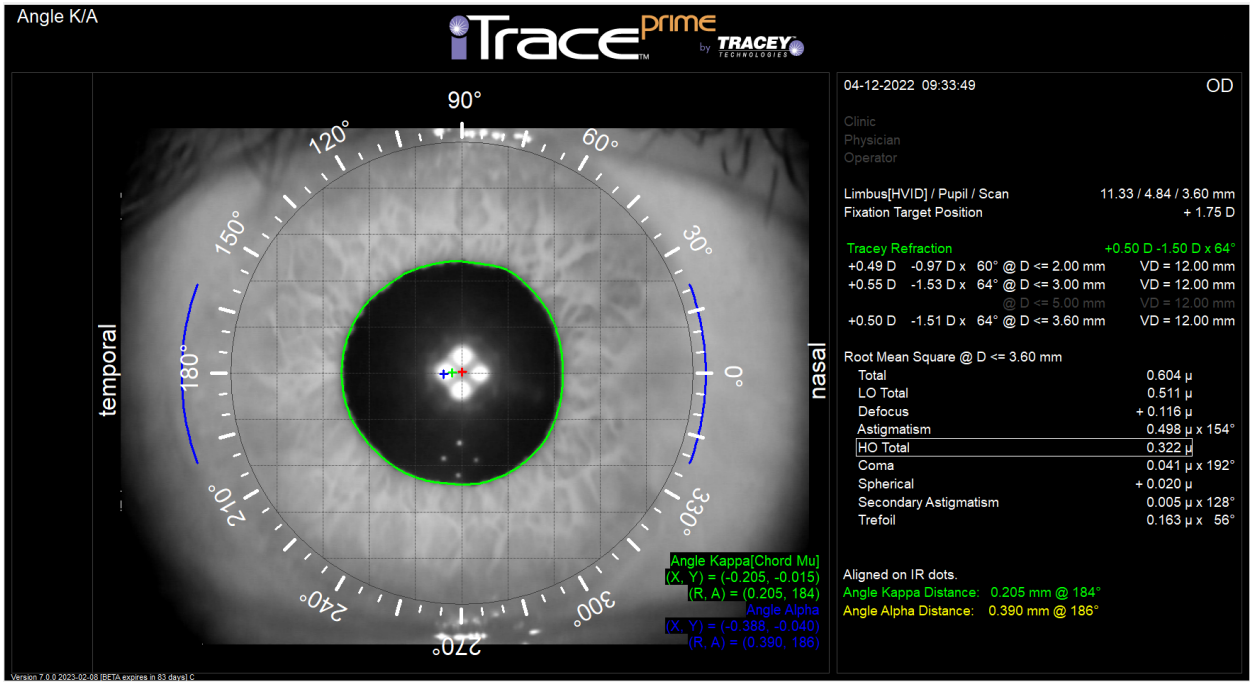
The Corneal SA display plots the patient's corneal spherical aberration as pupil size increases. It also denotes the pupil size as measured during the WF scan and provides the CSA at that pupil size.



Angle Kappa/Alpha Display

The Angle Kappa and Alpha Display can be used to analyze the optical centration of the pupil and limbus as they relate to the visual axis, which is marked with the red cross. This is important for assessing if a patient is a good candidate for a multi-focal or toric IOL. The iTrace software automatically detects the limbus and the pupil, giving you the white-to-white measurement and the pupil diameter. It then locates the center of these two ellipses (blue for limbus, green for pupil) and marks them with a blue cross and green cross respectively. The screen displays the measurements of these distances in both polar coordinates and rectilinear coordinates in the bottom left of the eye image.

You can use the ***Options Menu*** to select to edit these lines or to use other measuring tools to use in your analysis.



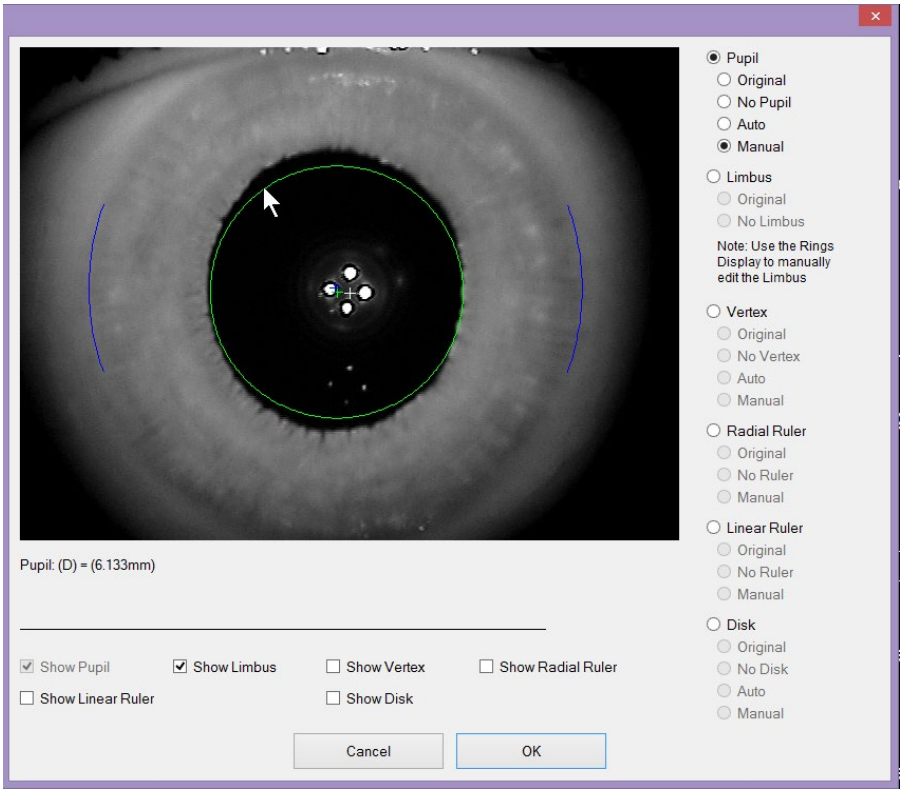
Note: The Angle Kappa and Alpha display is only available when viewing a WF and CT exam in which either they are a combination exam, or in which the WF was acquired using IR dot (visual axis) centration and not pupil centration. If these requirements were not met, you will get an error when clicking the Angle K/A button.

To Use the Angle Kappa and Alpha Display

1. To adjust the detected anatomies or access other tools, *Right-mouse-click* on the eye image panel and select "*Edit pupil,limbus, vertex, ruler and disk"*.

2. The Edit Pupil, Limbus, Vertex, Ruler and Disk screen will appear. To edit the pupil, click on the radio button next to "*Pupil*" and then the radio button next to "*Manual*" to manually edit the pupil line.

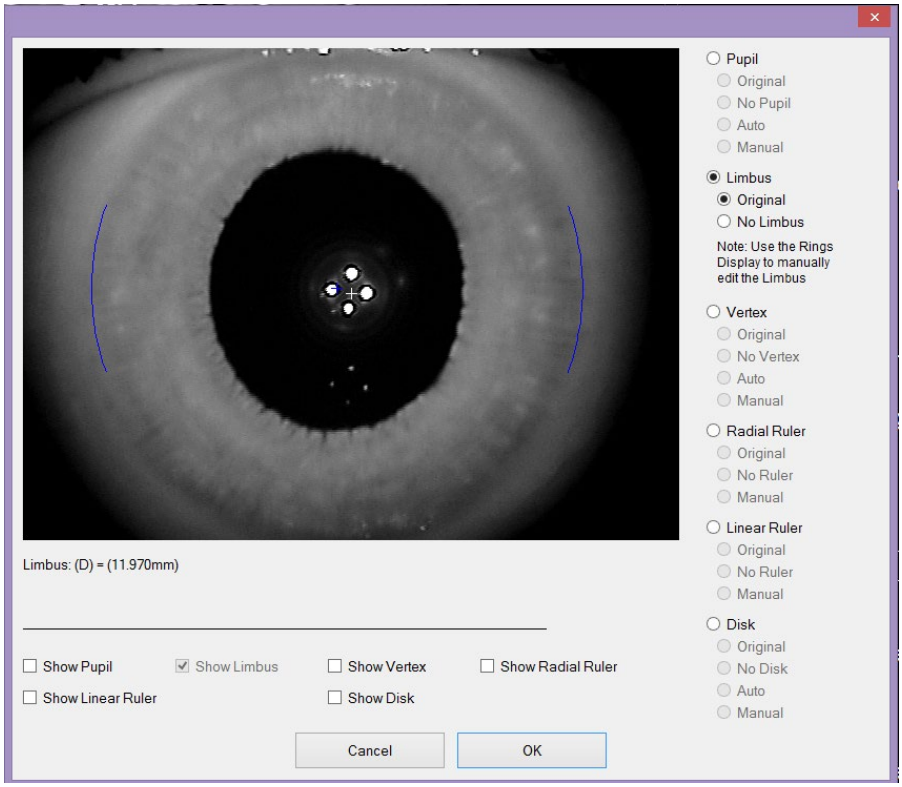
3. Click and hold the left mouse button on the edge of the pupil image and slowly drag the mouse across the image while holding down the mouse button. A green circle will appear. Continue to drag until the circle fits the pupil and release the mouse button.



4. To return to the pupil line previously saved, click on the radio button labeled "*Original*". The software can also reprocess the pupil line. To do so, click on the radio button labeled "*Auto*". To remove the pupil line, click on the button labeled "*No Pupil*".

5. If desired, lines and tools in this screen can be displayed by clicking the check boxes under the eye image.

6. To remove or auto-detect the limbus, click on the radio button labeled "*Limbus*".



7. You can only choose to view the originally detected limbus or to remove the limbus line.

8. To edit the limbus line for the Angle K/A display, you must do so within the Edit CT image display as explained on page 81.

9. To edit the vertex, click on the "*Vertex*" radio button and then the "*Manual*" radio button to manually edit the vertex – which is the center of the four (4) brightest IR dot reflections.

10. Click and hold the left mouse button on vertex crosshair and slowly drag the mouse while holding down the mouse button until in the desired position, then release the mouse button.

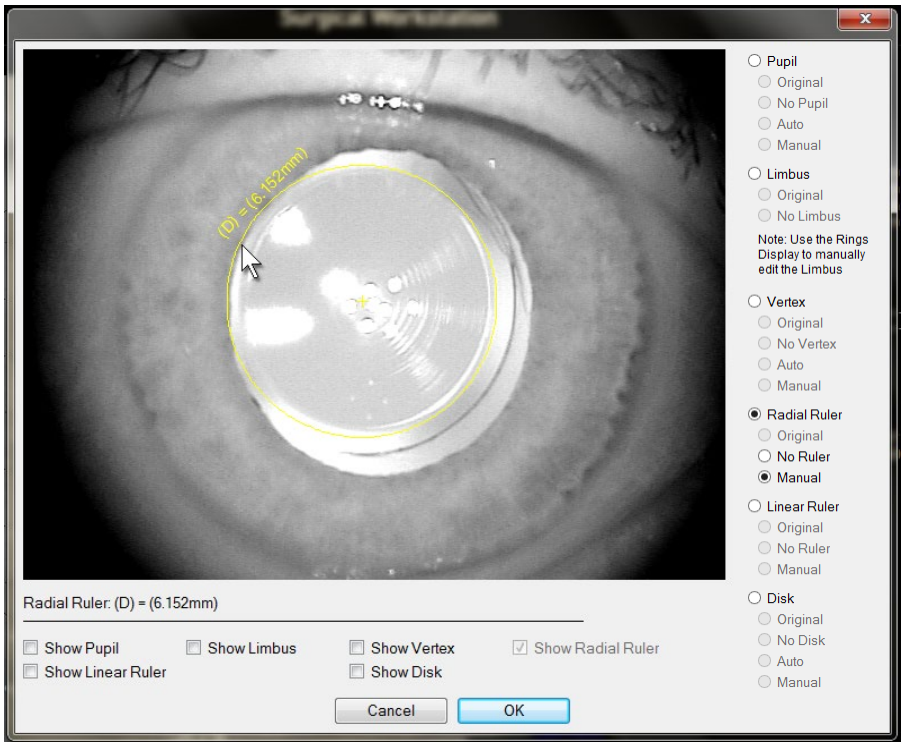
11. To return to the vertex previously saved, click on the radio button labeled "*Original*". The software can also re-detect the vertex. To do so, click on the radio button labeled "*Auto*".

12. To edit the Radial Ruler, click on the radio button next to "*Radial Ruler*" and then the "*Manual*" radio button to manually add a circular "ruler". This may be helpful to find the center of the IOL optic in a dilated post-implant eye. Comparing it to the vertex can help to analyze surgical outcome.

13. Click and hold the left mouse button on the eye image and slowly drag the mouse while holding down the mouse button until the ruler is in the desired position, then release the mouse button. The diameter of the ruler displays on the circle and in the panel under the eye image. To move the ruler to any part of the image, click and hold

the left mouse button on the center of the circle and slowly drag the mouse while holding down the mouse button until the ruler is in the desired position.

14. Click the OK button to accept the edits and return to the Angle Kappa/Alpha display. The Radial Ruler will appear on the display. The diameter and the center coordinates of the ruler will appear on the bottom left of the eye image.



15. To return the Radial Ruler to the previously saved ruler, right-mouse-click on the eye image panel and select "*Edit pupil, limbus, vertex, ruler and disk"*. The Edit Pupil, Limbus, Vertex, Ruler and Disk screen will appear. Click on the radio button labeled "*Original*" or remove the ruler by clicking the "*No Ruler*" radio button.

16. To edit the Linear Ruler, click on the "*Linear Ruler*" radio button and then the "*Manual*" radio button to add a simple "ruler" line. This may be helpful to measure distances on the eye image.

17. Click and hold the left mouse button on the eye image and slowly drag the mouse while holding down the mouse button until the ruler is in the desired position, then release the mouse button. The diameter of the ruler displays on the line and in the panel under the eye image. To move the ruler to any part of the image, click and hold the left mouse button on the center of the line and slowly drag the mouse while holding down the mouse button until the ruler is in the desired position.

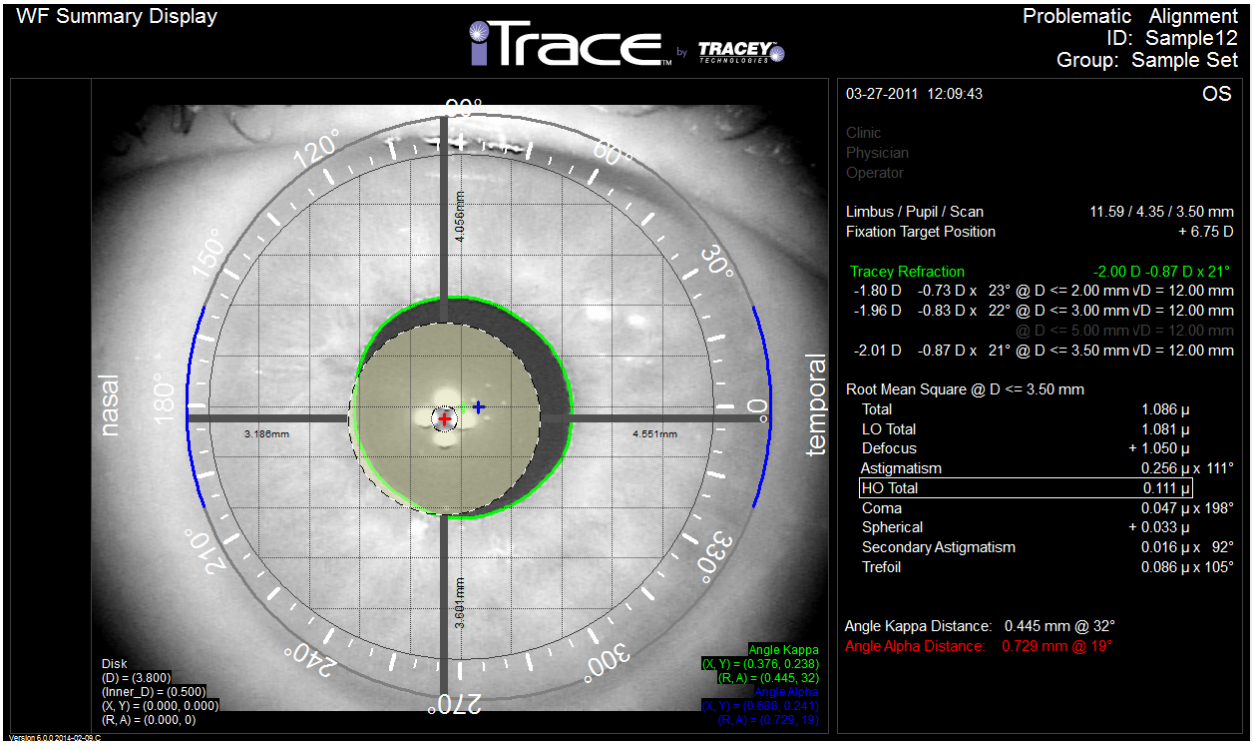
18. Click the OK button to accept the edits and return to the Angle Kappa/Alpha display. The Linear Ruler will appear on the display. The length of the ruler will appear on the bottom left of the eye image.

19. To return the Linear Ruler to the previously saved ruler, right-mouse-click on the eye image panel and select "*Edit pupil, limbus, vertex, ruler and disk"*. The Edit Pupil, Limbus, Vertex, Ruler and Disk screen will appear. Click on the "*Original*" radio button, or remove the ruler by clicking the radio button labeled "*No Ruler*".

20. The Disk can be used to simulate a corneal inlay or to approximate an ablation zone to again analyze the centration of the optics with the eye's optical centration. To edit the Disk, click on the "*Disk*" radio button, and then the "*Auto*" radio button to add the default circular overlay pattern. The default size is 2mm and it will automatically place the disk center on the vertex.

21. To change the disk size, click the "*Manual*" radio button. An input box appears allowing you to enter the exact outer diameter of the disk to display and to enter an inner diameter to simulate a central aperture. Once you enter these measurements click the Set button. In Manual mode, you can also change the position of the disk. To move the disk to a different position, click and hold the left mouse button on the disk center and slowly drag the mouse while holding down the mouse button until the disk is in the desired position.

22. Click the OK button to accept the edits and return to the Angle Kappa/Alpha display. The Disk will appear on the display. The disk will include the measurements in millimeters from the edge of the disk to the limbus at each side of the disk. The diameter and center coordinates display to the bottom left of the eye image.



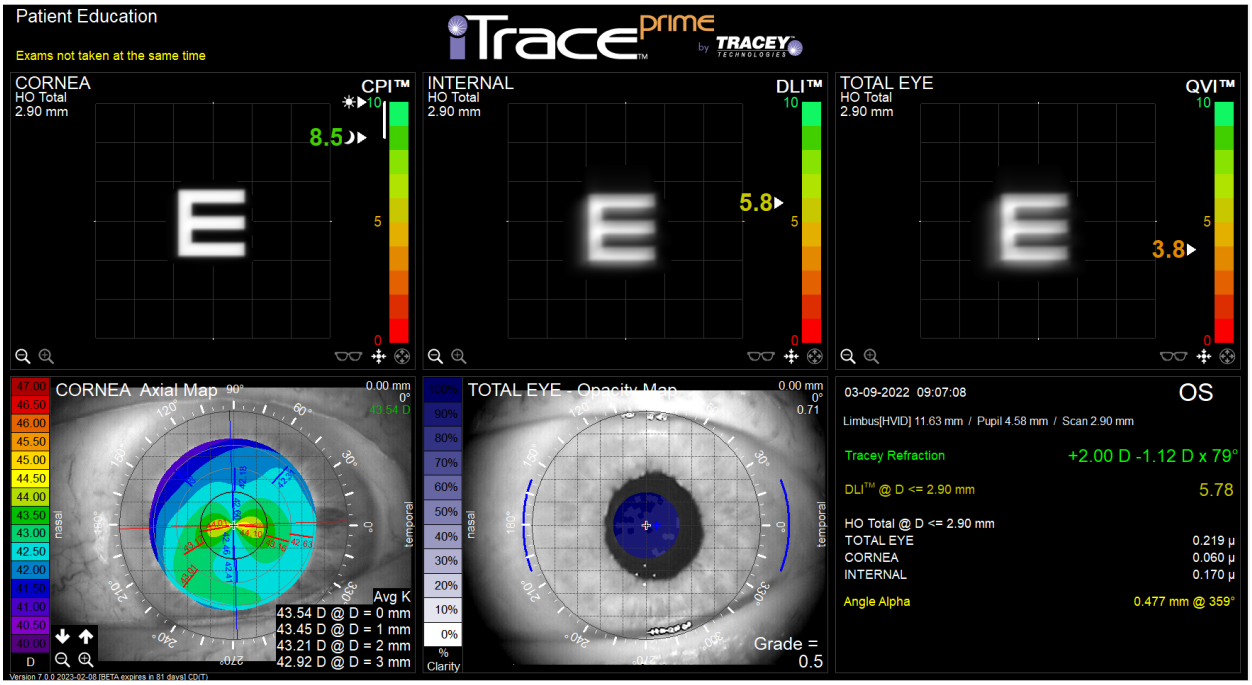
23. To further edit or remove the disk, *right-mouse-click* on the eye image panel and select "*Edit pupil, limbus, vertex, ruler and disk"*. The Edit Pupil, Limbus, Vertex,

Ruler and Disk screen will appear. Click on the radio button labeled *No Disk*, or further edit the disk or other parameters in the dialog.

Patient Education Display

The Patient Education Display (formerly called Dysfunctional Lens Analysis) provides the cataract surgeon with a patient educational tool designed to help the patient understand the impact on vision of the two major refractive components of the eye. This display can help patients better understand how their corneal vision will equal their post-surgical vision and also help them understand a dysfunctional lens syndrome diagnosis. Using the spectacle button ( ) you can cycle through and show the patient how their vision will change with a standard monofocal correction and a Toric correction. Likewise using the zone size buttons (and) you can simulate the vision that could result with a small aperture optic treatment.

It contains much of the same information from the Prime Dashboard display but in a patient-centric format. The top row of panels on the display show Snellen E representations of the patient's aberration profile for the cornea (left panel), the lens (middle panel), and the total eye (right panel) and the CPI, DLI and QVI indices and scales. The bottom panels include a corneal topography axial map, the opacity map and the simplified indices panel.



As in the Prime Dashboard, the software will alert you with "High Corneal Aberrations" displayed above the Internal Letter display panel if the corneal higher order aberrations are high.

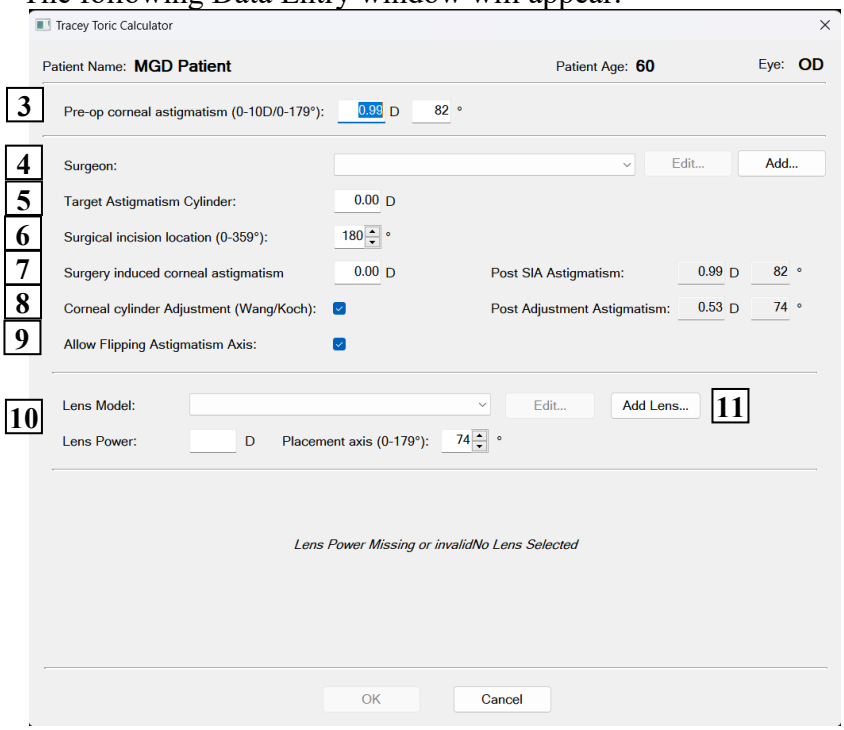
Toric Planner

The Toric Planner display is a comprehensive display developed to assist with selection and placement of Toric IOL implants.

To View and Use the Combo Toric Planner

1. Select a WF and CT paired exam, or one WF and one CT exam. Click on Toric Plan.

2. The following Data Entry window will appear:



3. The Pre-op corneal astigmatism from the iTrace corneal wavefront at 4mm will appear in the entry box. The user can choose an alternative astigmatism value from the iTrace, or the user can enter keratometry steep axis data from another device.

> ***Note***: For optimal calculation, care should be taken to ensure the largest WF scan size possible. Darken the exam room and occlude the fellow eye if possible.

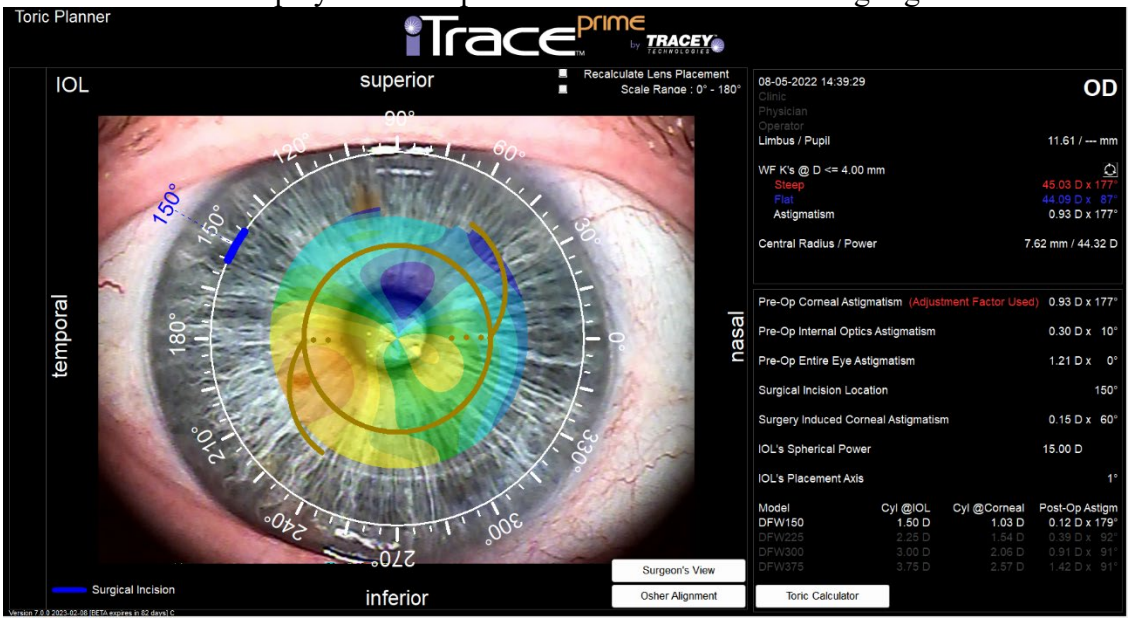
4. You can customize the software to enter specific surgeon parameters for surgically induced astigmatism (SIA), preferred incision location, etc. The surgeon names available will be those that were entered in the Edit Exam dialog as instructed on page 72 or those entered by clicking the Add… button.
5. Target Astigmatism is the desired post-op residual astigmatism.
6. Surgical incision location is the axis where you will place the surgical incision.
7. The surgically induced astigmatism is the surgeon's estimate of the astigmatism induced by the incision. Enter the value of the induced power, from 0.00 D to 2.00 D. The iTrace software will calculate the axis of induced astigmatism based on the axis entered in #6. The software will calculate the value of the post-op surgically induced astigmatism as it relates to the preop corneal astigmatism.

8. You can choose to activate the Baylor-Koch-Wang Nomogram to offset effects of potential posterior corneal astigmatism by clicking the checkbox next to “Use Pre-op Corneal Cylinder Adjustment”. The software will display the resulting effective corneal power and use this adjusted astigmatism power to display the residual astigmatism values from each toric power. More information about this nomogram is available by contacting Tracey Technologies.
9. You can tell the software if you would prefer that the post-op axis is not “flipped” from the pre-op axis.
10. The Lens Model offers a database of Toric IOL lens options. Enter the IOL Spherical Power that you have calculated for this patient and then choose your preferred lens model from the drop down menu.

    Once you select the lens model, the available toric powers for that model appear in the area below the selection section. The toric lens that best meets the requirements from steps 3 – 9 will be highlighted.

> ***Note***: These lens offerings are informative for the user; selection of one of these lenses should be based on the medical expertise of the surgical team to provide the best correction for their patient.

11. You can edit the lens database by clicking Edit… or Add Lens.
12. Click OK to continue.
13. The iTrace software will display an IOL image at the calculated axis of placement.
    The iTrace software will display the entered and calculated information in the bottom right panel, under the CT exam information.
    The software will display the lens options with the selected lens highlighted.



14. The incision location, and therefore the surgically induced astigmatism axes, can be adjusted by clicking and holding the mouse button on the blue solid line between the incision symbol and the edge of the IOL symbol. Hold the mouse button down and drag the line until the desired new location is found. As the incision location is adjusted on screen, the software will recalculate the residual astigmatism listed for each lens option on the right bottom panel.

15. To recalculate the axis of placement with adjustment of the incision line, click on the checkbox next to "Recalculate Lens Placement". To move the incision and lens independently, uncheck the checkbox.
16. The angle scale on the display can be shown as 0° to 360° (default setting) or by clicking the *Scale Range: 0° - 180°* checkbox, making the scale of 0° to 180° on the top and bottom display.
17. The display can be enhanced with right-mouse-click display options as available with other iTrace displays. Right-mouse-click on the display to add:

Selection denoted by green check circle (✓)

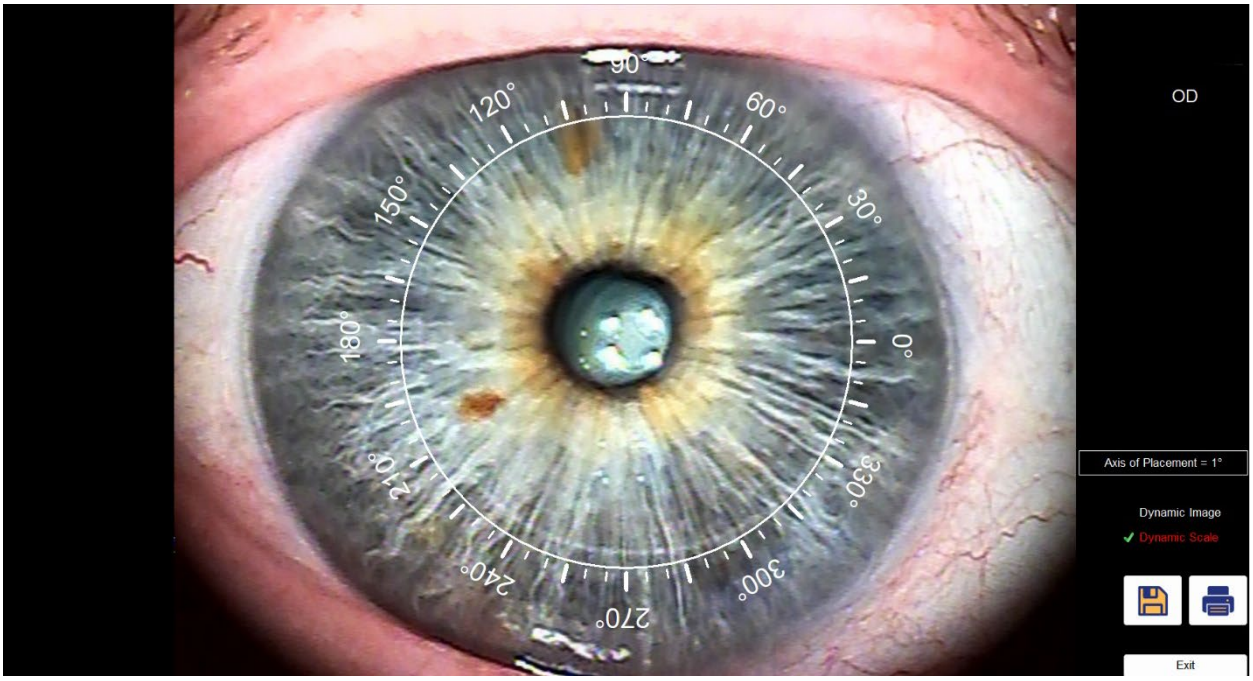
- *Show Eye Image – displays eye image behind the plan*
- *Show Color Eye Image*
- *Show Axial Map – displays translucent CT map behind the plan*
- *Unlock Dynamic Angle Scale – description to follow*
- *Show incision location*
- *Show pre-op corneal*
- *Show post-op entire eye*

18. To rotate the eye image and overlays and view the image as one would in the operating room from the Superior View, click "Surgeon's View" before printing the screen.
19. If changes to the data entered are desired, click the Toric Calculator button and modify the entries.

To View and Use the Osher Alignment

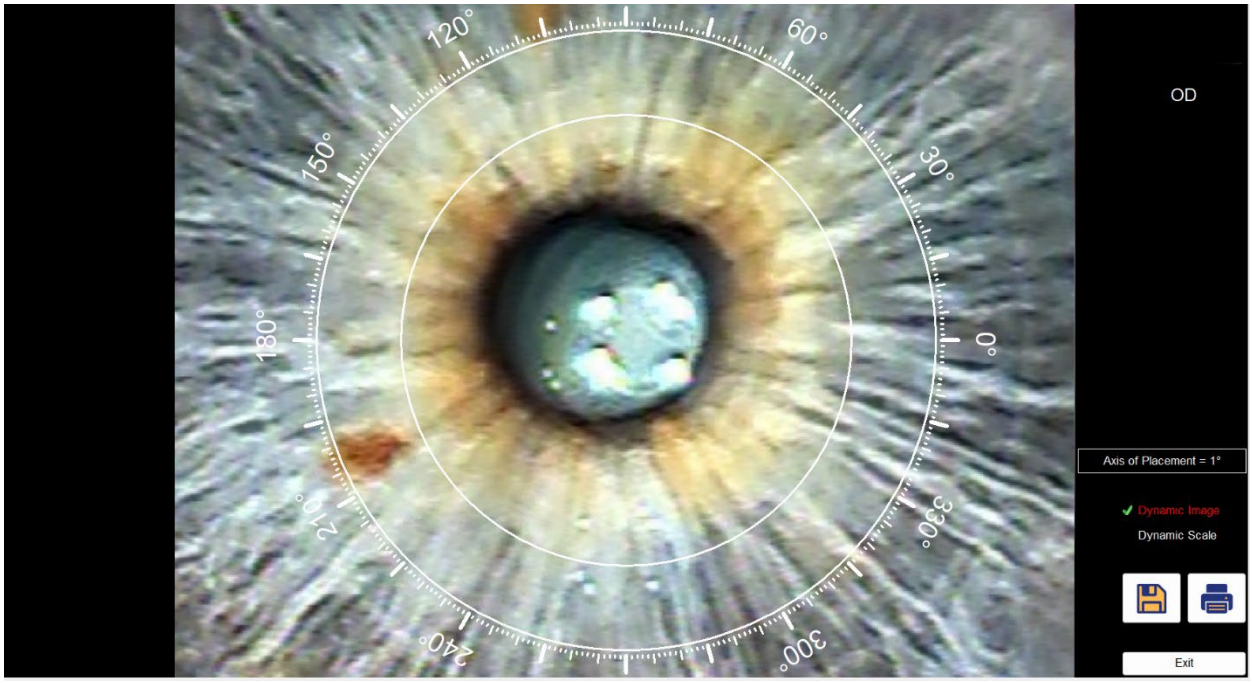
The Osher Alignment tool in the Combo Toric Planner can be used to more easily view the eye image to find iris detail, limbal vessels or to view surgical ink marks or other landmarks made prior to the exam acquisition. These landmarks can be used as references to find the location of the axis of placement for the toric lens.

On the Toric Planner display, click on the Osher Alignment button. The eye image will magnify.



1. The display has two modes: Dynamic Image and Dynamic Scale. The mode currently in control will be highlighted red and will have a green check mark. To switch between modes, simply click on the non-highlighted mode. Keeping Dynamic Image in control, you can use your mouse wheel or the slider bar along the right side of the laptop trackpad to magnify the image. Then by clicking and holding the left mouse button, the image can be dragged as you view the iris, vessel or other detail in the image.

2. When a landmark is identified, change control modes to Dynamic Scale. Again, use your mouse wheel or slider bar to magnify the angle scale. You can zoom the scale to the identified mark and know its exact angle location.

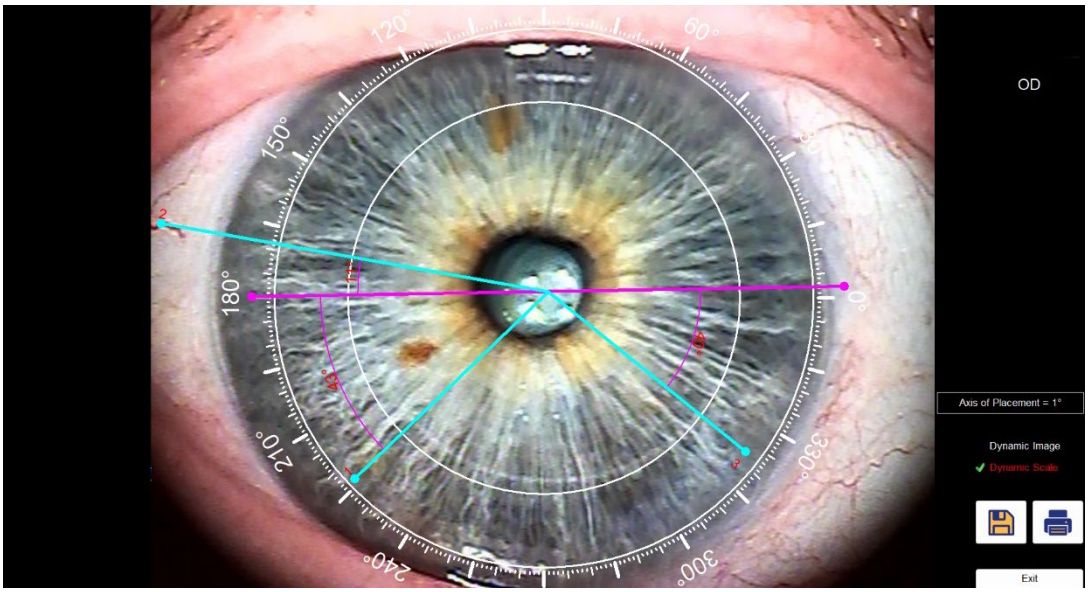


3. You can also use special Zalidvar Caliper overlays in this display to find the angle differences between your identified landmark and the axis of placement. This is described below.

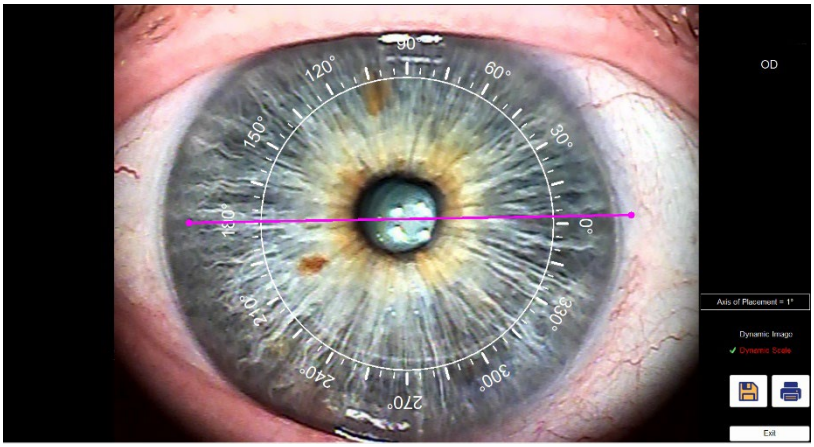
4. You can print the image, save the image, or return to the Toric Planner by clicking *Exit*. If you have used the Protractor Overlays, they will remain at the position you left them in and display at this position again in the Toric Planner display.

To View and Use the Protractor Overlays

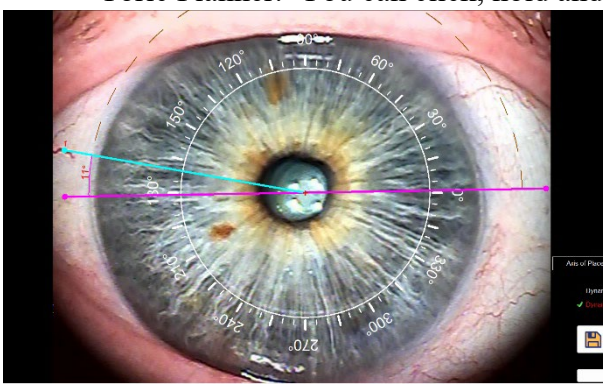
The Combo Toric Planner includes Protractor Overlays in the Osher Alignment window that assist with the precise placement of toric implants. The overlays can measure the angular distances between the axis of placement and limbal pre-surgical reference marks or landmarks such as vessels or iris details.

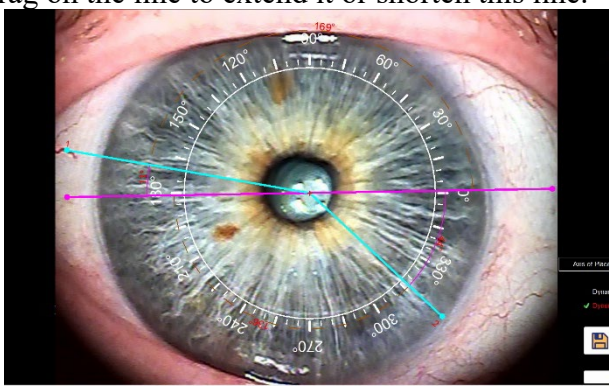


If applicable, surgical marks must be placed prior to the iTrace exam. Proceed with the iTrace WF and CT exam as described previously in this manual and then click Toric Planner. Calculate the toric lens power and axis of placement by following the steps described in the previous section. Once the power and axis of placement are finalized, right-mouse-click on the display. Click on the "Osher Alignment" button and follow the steps described below.



1. With Osher Alignment displayed, click on the Dynamic Image option. Click once on the eye image to display a line representing the axis of placement as calculated in the Combo Toric Planner. You can click, hold and drag on the line to extend it or shorten this line.

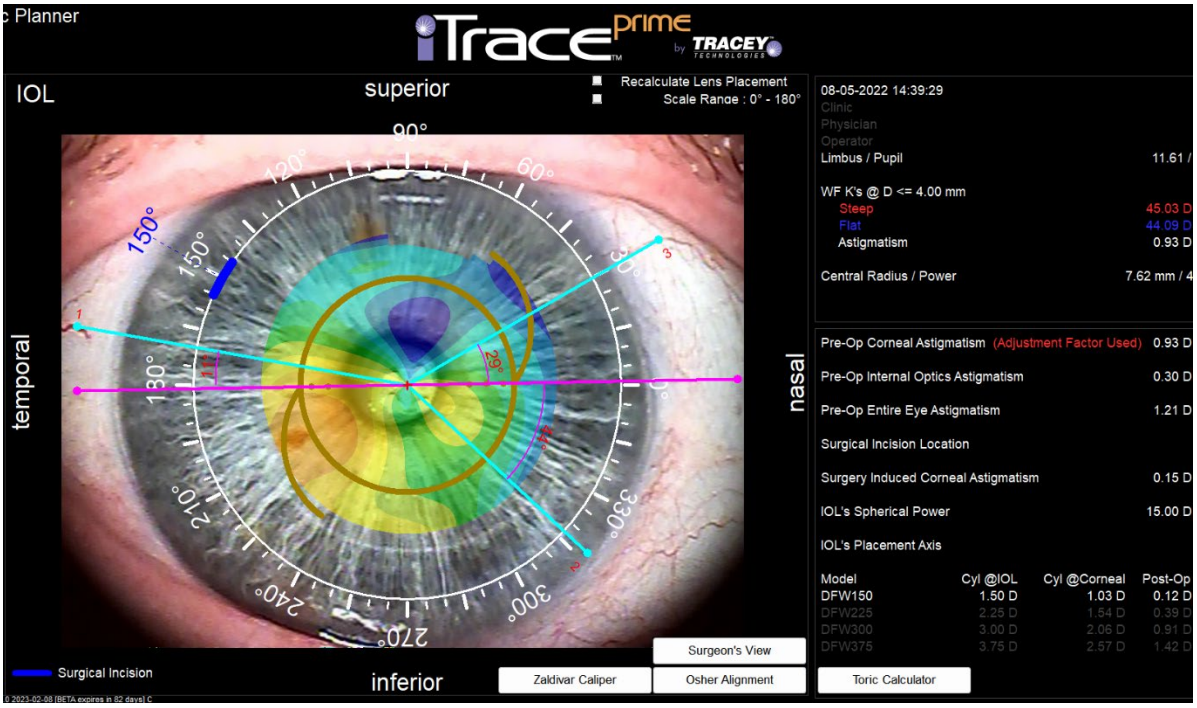




2. Click again on the eye image and the first protractor line appears. You can click the small circle at the end of the line to reposition the line over or near the landmark you wish to reference. The software calculates the angle between the protractor (1) and the axis of placement. Click a third time on the other side of the image to place another protractor and reposition, if necessary. The software calculates the angle between protractor 2 and the axis of placement. You can create a third protractor line by following the same steps.

3. To remove a placed protractor, click, hold and drag the small end circle to the center of the image. You can hide the protractors by clicking the Protractor button.

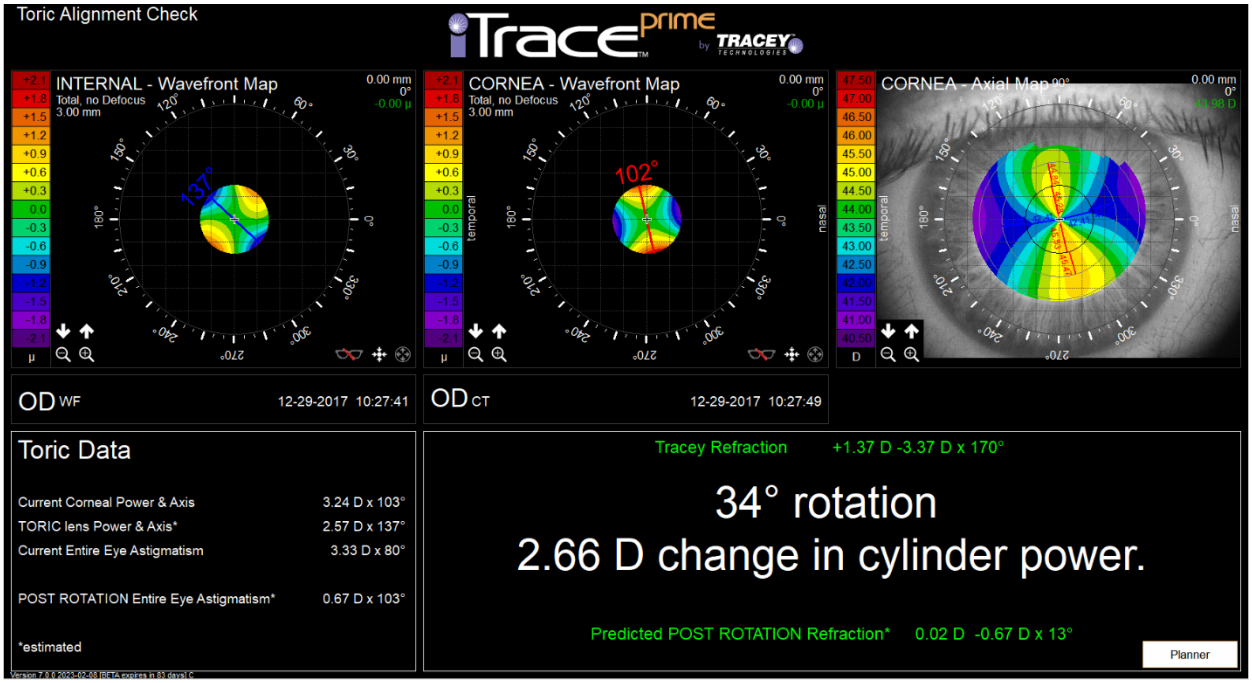
4. After you have finished placing the protractors, click the Exit button to return to the Combo Toric Planner. The protractors will appear on the eye image as placed in the Osher Alignment window.



5. You can click on the "Zaldivar Caliper" button to hide the protractors on the Toric Planner display.

Toric Alignment Check Display

The Toric Alignment Check display provides a fast and simple analysis of the alignment of the internal astigmatism and the corneal astigmatism, useful when determining if a Toric IOL rotated post-implant. This display provides measurements needed to assess if a post-op enhancement is necessary to correct a rotated Toric IOL.



To View and Use the Toric Alignment Check Display

1. Select and view a WF and CT paired exam, or one WF and one CT exam, taken post-Toric IOL implant (consider edema and cornea surface post-surgery to determine timing.)

2. Click on Toric Check from the navigation panel.

3. The Toric Alignment Check display appears.

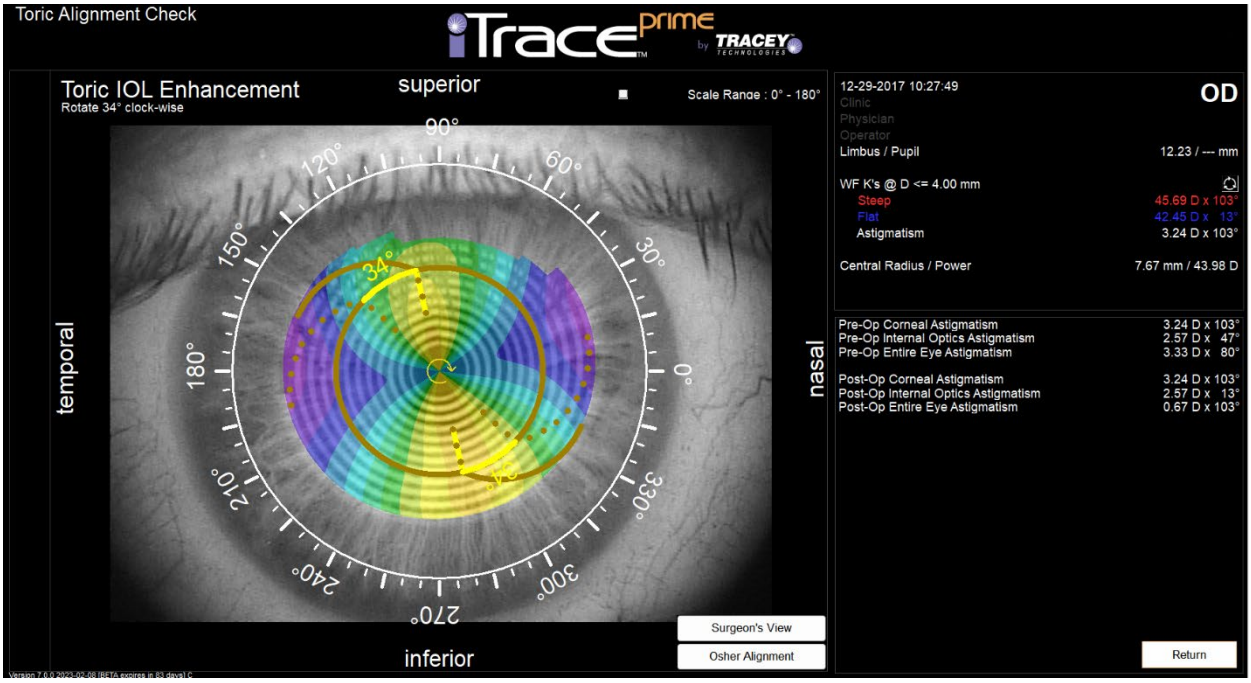
The top left panel on this display shows a Wavefront map of the internal optics. Over the map, a line is displayed that shows the flat axis of the internal power. This is measured at the 4mm diameter zone and is a combined analysis of the astigmatism aberrations that are calculated in the internal optics. The top middle panel shows a Wavefront map of the cornea. Over this map, a line is displayed that indicates the steep axis of the corneal power based on the combined Zernike analysis of the astigmatism aberrations that are calculated in the corneal surface. Viewing these lines and their orientation you can quickly see if the lines are at the same orientation and know if a rotation is necessary.

In the bottom left panel, the software displays the toric data associated with the selected exams, including the current corneal power and axis, the measured internal power and flat axis, and the measured entire eye astigmatism power and axis. The panel lists the estimated entire-eye-astigmatism after a potential rotation to re-align the axes. Using this information, you can assess the power and axis differentials as you decide on the enhancement procedure.

In the bottom right panel, which spans the rest of the bottom half of the screen, the software displays a summary of all of the data in terms of the patient's refraction, the amount of rotation that is required for the toric IOL to offset the corneal power, and how much change in overall cylinder power can be achieved by rotating the internal power.

The display does not show which way the internal power should be rotated, but rotation information is found in the Toric Planner, where you can use the iTrace software to plan the enhancement procedure in detail. You can jump to the Toric Planner for Toric IOL Enhancement by clicking the Planner button in the bottom right corner of the display.

To Use the Toric Planner – Toric IOL Enhancement



After clicking the Planner button in the Toric Check display, the iTrace software will open a special Toric Planner display for a Toric IOL Enhancement (rotation). The display includes an IOL image at its current position with lines indicating a suggested rotation to make to the internal optics to orthogonally off-set the corneal astigmatism. It can also display several axis lines, selectable as right-mouse-click options.

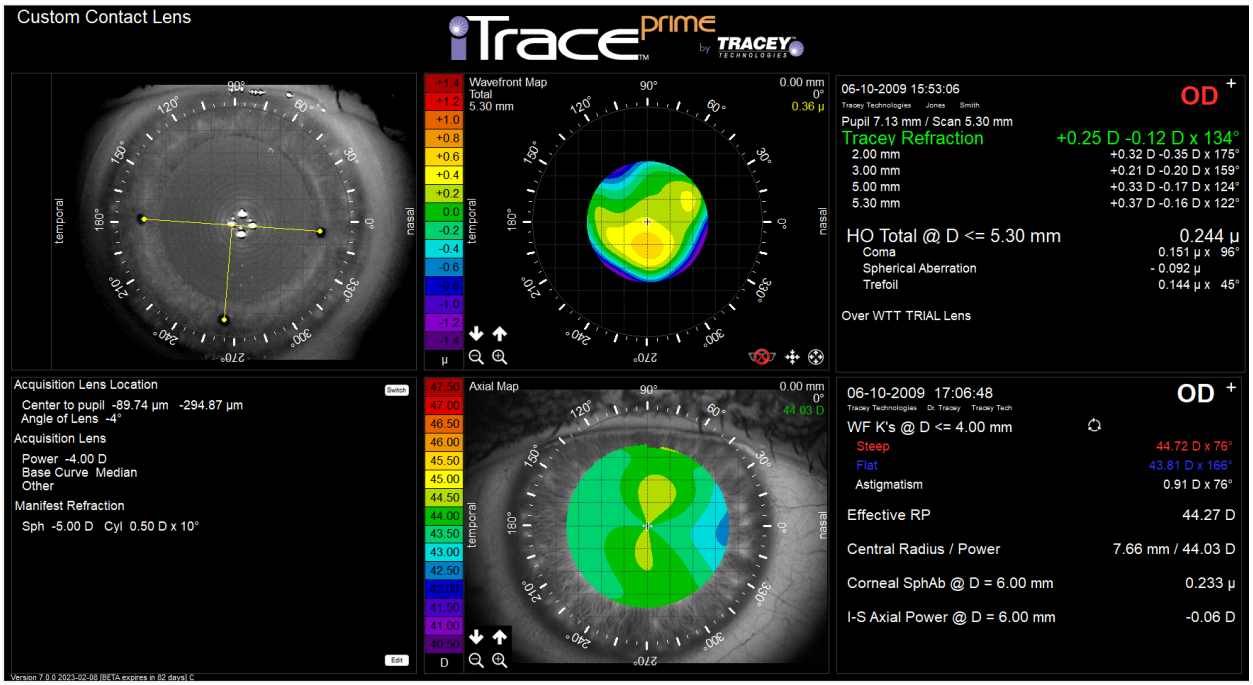
The iTrace software will also display the entered and calculated information in the bottom right panel under the CT exam information.

Custom Contact Lens Display

The Custom CL Display will assist users who are fitting patients with RTcl wavefront-guided soft contact lenses or custom scleral lenses. This screen is available if the Custom CL functionality is enabled in Settings (see page 39).

The upper left panel displays the eye image. You will usually have an acquisition lens (trial lens) that you've placed on the patient's eye. The lens marks are viewable on the eye image.

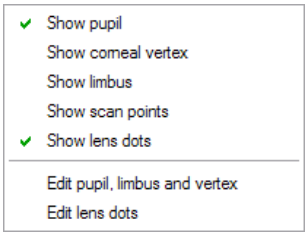
You must locate the lens dots in order to produce a lens order.



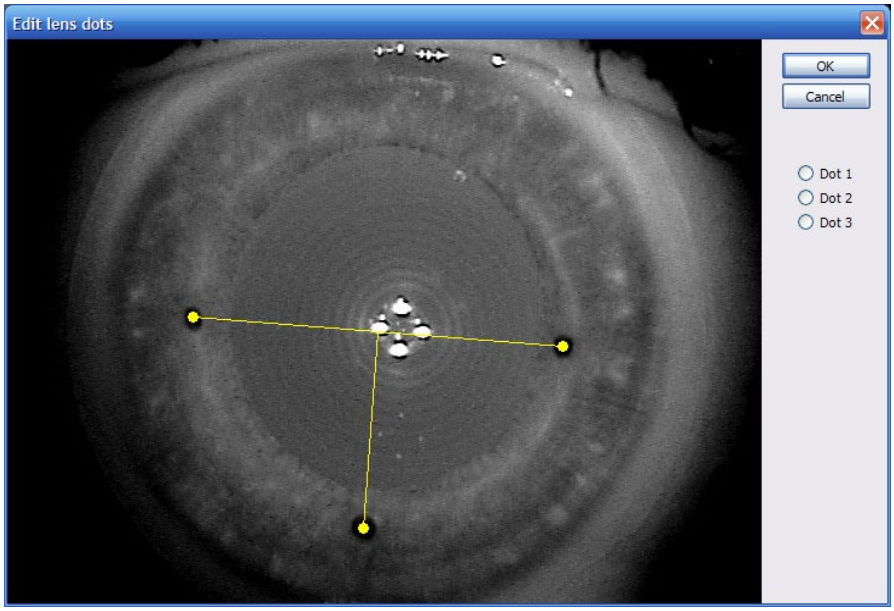
To View and Use the Custom CL Display

1. Select a WF exam and a CT exam for the same eye, click on  and you will view the exams in the Custom CL display.

2. Right-mouse-click on the eye image panel to view the display and edit options. The following window appears:



3. Select Edit lens dots to view the Edit lens dots window:



4. Click the *Dot 1* radio button to activate the dot within the "T". The activated dot will change from yellow to red, and you can now move the dot over the black acquisition dot on the image as necessary. Continue with Dot 2 and Dot 3 respectively until the dots are aligned over the acquisition lens dots.

5. Click *OK* when finished.

The upper-middle panel displays the wavefront map with Total aberrations. The upper-right panel displays the refraction and aberration data. The bottom-right panel displays the corneal topography indices. The bottom-middle panel displays the corneal topography axial map. The bottom-left panel displays the lens order information and has two control switches for the display:

- ***Centration Switch*** changes between "Center (of lens) to pupil" with resulting x/y measurement in µ and "Center (of lens) to visual axis" with resulting x/y measurements in µ.
- ***Angle Switch*** changes the displayed "Angle of Lens" between a symmetrical value and an asymmetrical value.

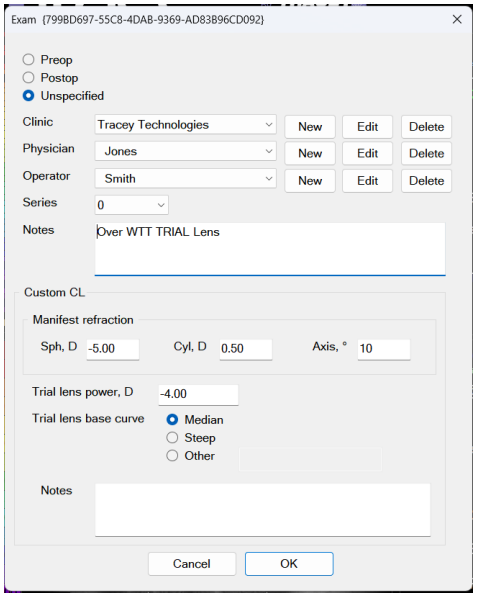
To edit the Acquisition Lens and MRx that is displayed:

1. Click the "Edit" button to edit the lens order. The following window appears:

2. If information was previously entered, the information will appear here.

3. Enter the trial lens power in diopters; select the trial lens base curve (if other, indicate in the box provided); and enter any notes that need to be provided to the lens manufacturer with the lens order. Step 3 is not required for scleral lens orders.

4. Click *OK*.



To Complete the Lens Order

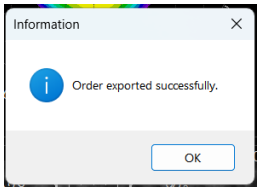
1. Click  to save the display and to export the necessary Custom CL and Scleral Lens wavefront data.

2. A message will appear asking if you have verified the lens dot placement. Click *Yes*, (or *No* if you need to go back to the display to place the lens dots).

3. A window will appear with a list of file locations for the Custom CL Order. The default folder name is Custom CL Orders. Click *OK*, or you can enter a new folder name or browse for another folder. The display and the wavefront text file will automatically be placed in a compressed folder ready to send to manufacturer.

4. A second window will appear with a list of file locations for the Scleral Lens Order. The default folder name is Scleral Lens Orders. Click *OK*, or you can enter a new folder name or browse for another folder. The display and the wavefront text file will automatically be placed in a compressed folder ready to send to your Scleral Lens provider.

5. A message will appear indicating the success of the export. Click *OK*.



6. When you are ready to place the lens order with your lens provider, browse to the applicable Orders folder and copy the files to send to the lens manufacturer per their instructions.

Other Functionality Available from Exam List Screen

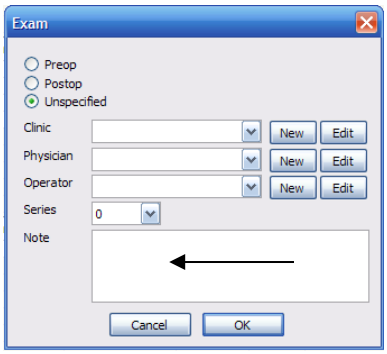
To Display a Multi-Exam

1. A multi-exam selection is valid only for WF exams on the same eye.

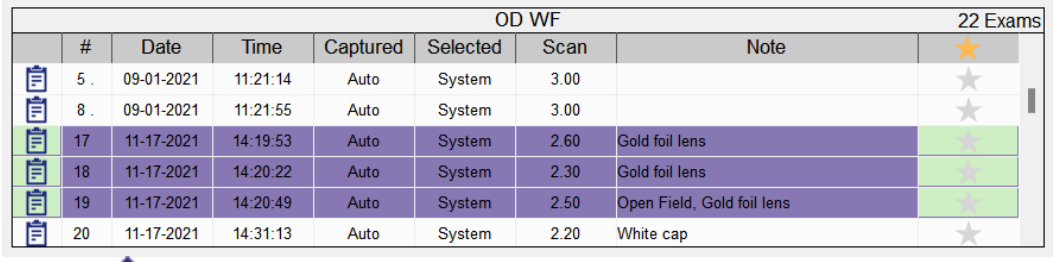
2. To prepare for a multi-exam viewing, exams must first be assigned a numerical order. This order is shown under the column named *Series*. By default, every exam is assigned the same order number of zero until the user manually changes it.

3. To assign a numerical order, select a WF exam and click  .

4. A *WF Exam Data* screen will appear. Use the drop down list in the *Series* field to assign a numerical order. Repeat for other exams.



5. On the patient exams record display, select all the exams in a series by pressing and holding the *Ctrl* key and then selecting each exam. To deselect a selection, hold down *Ctrl* key and left mouse click on it.



OD WF — 22 Exams

#	Date	Time	Captured	Selected	Scan	Note
5 .	09-01-2021	11:21:14	Auto	System	3.00	
8 .	09-01-2021	11:21:55	Auto	System	3.00	
17	11-17-2021	14:19:53	Auto	System	2.60	Gold foil lens
18	11-17-2021	14:20:22	Auto	System	2.30	Gold foil lens
19	11-17-2021	14:20:49	Auto	System	2.50	Open Field, Gold foil lens
20	11-17-2021	14:31:13	Auto	System	2.20	White cap

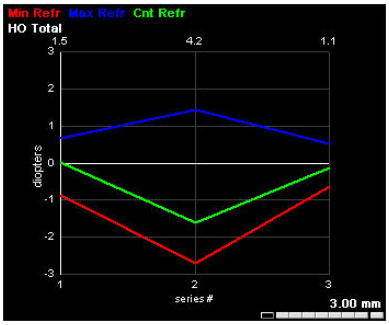
6. Click  to show a multi-exam summary display.

Key Features:

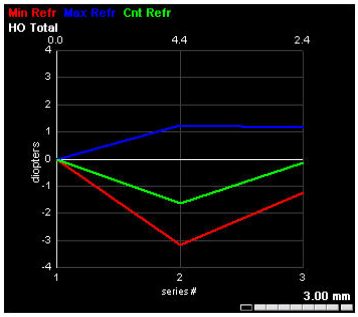
- Show maps that graph exam data points from the chosen series. Each map graphs data based on its own criteria. The Sph Eq-Sph-Cyl map show data gradation between exams for spherical and cylinder. The RMS map shows data from Total, Low Order, and High Order RMS. The third map shows the data from min, max, and center Refraction. The fourth map is the standard Refraction map.

  1. Right-mouse-click on any display to open an options menu that allows for customization of these displays. Not all options are available in all of the displays. One notable option is the *Difference* function, which will graph the data

differences from the first to the last exam in the series.



Difference function



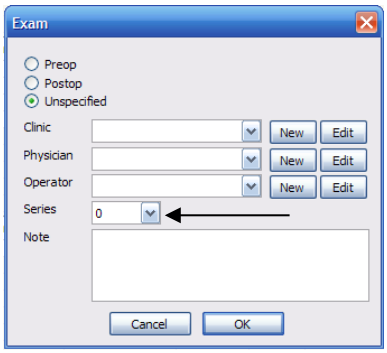
To Display an Average of Multiple Exams

1. A multi-exam average is only valid for WF exams. This option is available even if you did not choose to capture in the multi-exam / averaged exam mode.

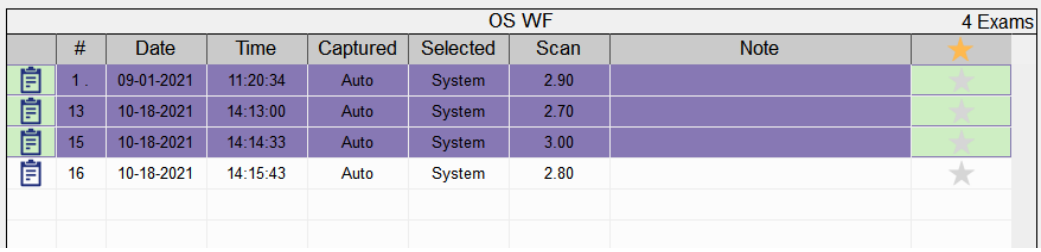
2. To prepare for a multi-exam viewing, exams first have to be assigned the same serial number. This order is shown under the column named *Series*. By default, every exam is assigned the same order number of zero until the user manually changes it, so unless the user has changed the series number, the following two steps will not be necessary and you can skip to Step 5.

3. To assign a numerical order, select a WF exam, and click  .

4. A *WF Exam Data* screen will appear. Use the drop down list in the *Series* field to assign the series number of 0 (if previously assigned another value). Repeat for other exams.



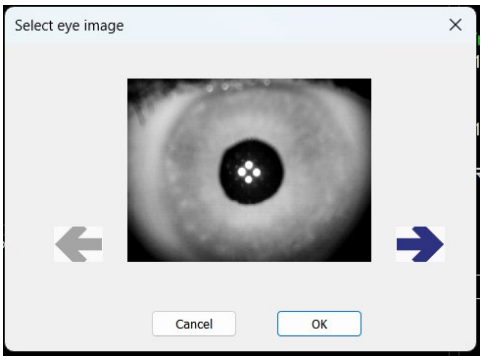
5. On the patient exams list display, select the exams to average by selecting the first exam, pressing and holding the *Ctrl* key, and clicking each of the other exams. To deselect a selection, control-left- mouse-click on the exam.



6. Click  to show an averaged summary display for multiple exams. The WF Verification Display will not show an eye image or the points profile displays because the software is averaging multiple exams. Other displays set to display an eye image underlay will not show an eye image. However, you can choose an eye image to use from the eye images available for the exams selected.

7. A dialog box appears to allow you to select the eye image. Scroll through the eye images available by clicking the blue arrows. The image appearing when you click the OK button will be the image used. This eye image is "forgotten" once you exit the exam view screens.

   Note: This is an important step because the eye image you choose will be the exam used to create the opacity map in certain displays.



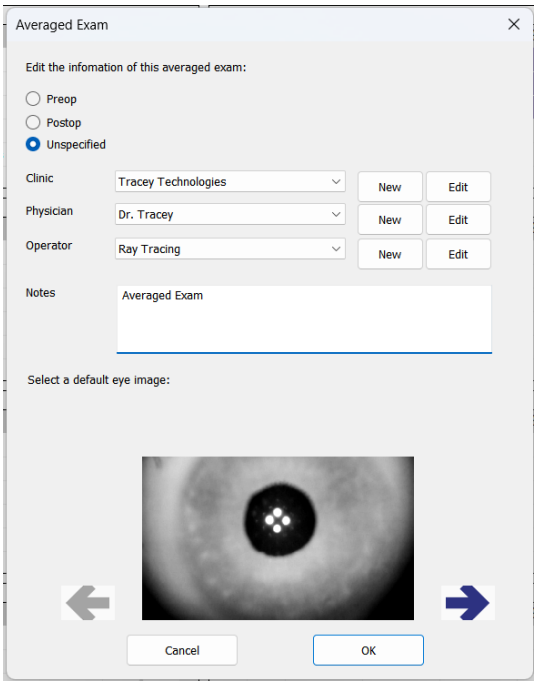
Alternatively, you can save the resulting averaged exam as a new exam.

1. After selecting the exams you wish to average, click the Edit Exam button  .

2. The Edit Exam dialog will appear with "Averaged Exam" pre-populated in the Notes section. You will be able to choose the eye image you wish to display in this box.

3. Click the view arrow button to scroll through the available eye images. The image you display here will be the image used for the new exam.

   Note: This is an important step because the eye image you choose will be the exam used to create the opacity map in certain displays.



4. Click OK to save the Averaged Exam as a new exam.

APPENDIX A Technical Information

Map Layers Options

Show Map
Displays the color map in according to the default map type or the selected map type.

Show Numbers
Displays an overlay of numeric values placed radially across the entrance pupil or cornea.

Show Eye Image
Digital image of the eye placed behind the display for reference.

Show Pupil
Displays the green pupil line either recognized automatically during the exam process, determined automatically by the software, or as edited by the user.

Show Limbus
Displays the blue limbal line as it was detected by the software or edited by the user.

Show Keratometry
Displays an overlay on the map that indicates the semi-meridianal steep and flat axes for three zones: 0mm to 3mm, 3mm to 5mm and 5mm to 7mm.

Show Astigmatism Axis
Displays an overlay indicating the steep and flat Zernike derived astigmatism axes.

Translucent Map
Sets the map layer to appear translucent so as to enable the user to view the eye image behind it.

Display Types

Eye Image: The eye image displays just the photograph of the eye that was captured during the examination process. It can be used to show the centers of the pupil, limbus and visual axis.

Wavefront Map: The wavefront map is a color display of the defects in optical systems that prevent light from focusing to a compact spot on the macular region of the retina. Where the patient's wavefront matches the perfect wavefront plane, the map color is green. Warmer colors indicate that the patient's wavefront is accelerated in front of the perfect wavefront plane, and conversely, cooler colors indicate that the patient's wavefront is retarded behind the perfect wavefront plane. This display is a more advanced description of the eye's refractive error. Aberrations are measured as the patient’s wavefront deviations

(distance in microns) differs when compared to a perfect wavefront plane.

Refraction Map: This map displays the refractive power span of the patient's eye in dioptric power. Emmetropia would appear green, warmer colors would indicate increasing myopia, and cooler colors would indicate hyperopic refraction.

Point Spread Function Map: This map shows the optical image seen on the retina that is created when a point source of light is viewed by the patient. For example, when looking at a star (point target at optical infinity), the PSF will show what that star will look like on the retina, or in other words, what the star looks like to the patient. The ideal PSF would be a sharp point of light on the retina.

Modulation Transfer Function Map: This map displays the optical frequency resolving quality of an optical system and is the inverse of the Point Spread Function (PSF). It depicts how objects of different spatial details are viewed by the patient's optical system. Both MTF and PSF help to describe the overall performance of an optical system.

Snellen Letter Map: This map displays how the patient's eye views the letter "E" as it appears on the Snellen Acuity Chart, commonly used to measure a patient's vision. Just like the Point Spread Function map shows how a point of light at infinity is viewed by the patient's retina, the Snellen Letter Map show us how a patient actually sees the letter "E" of various sizes, based on the effects of visual aberrations on visual acuity. The letter can be changed to a Landolt C and can be rotated by 90°, as needed. A Near Point Visual Acuity display is also available to simulate viewing the letters in near vision.

Root Mean Square (RMS): RMS is a measure of the magnitude of an aberration. Total RMS is the total aberration of the eye from the perfect wavefront. You can have RMS values for each specific Zernike term or component of the aberrations of the eye. On the display, the RMS values are presented independently as bar graphs or combined as color maps. The display also provides a visual indicator if the RMS values are beyond normal values. The aberration label will appear yellow if the RMS term is at a cautionary level, and it will appear red if the RMS term is at a more severe level.

Axial Map: This corneal topography map displays topographic corneal curvature, with hotter colors displaying the steeper points on the corneal surface, and cooler colors showing the flatter areas of the cornea. Axial Maps display the curvature at a certain point on the corneal surface in axial direction relative to the center. It requires the calculation of the center of the image. This map is used to display the optical power of the cornea.

Local Radius of Curvature Map: Very similar to the Axial Map, this corneal topography map displays topographic corneal curvature, with hotter colors displaying the steeper points on the corneal surface, and cooler colors showing the flatter areas of the cornea. The Local ROC Map measures the curvature at a certain point on the corneal surface in meridianal direction relative to the other points on the particular rings measured. This map is used to display the shape of the cornea.

Keratometry Map: This map displays the semi-meridianal steep and flat axes for three zones: 0mm to 3mm, 3mm to 5mm, and 5mm to 7mm. It also displays the average keratometry value starting at 0mm from center and increasing by 1mm increments out to periphery of map.

Z-Elevation Map: This map displays the difference in elevation of a point on the corneal surface relative to the same point on a spherical reference surface. The best mathematical approximation of the actual corneal surface, called best-fit sphere (displayed in the lower right corner of the map), is calculated by software for every point on the elevation map. The same surface would appear different when displayed against different reference radii.

Annular/Zonal Refraction Map: The zonal analysis measures the spherical aberration over a zone of corneal area, which includes the center region of the cornea. The annular analysis only calculates the spherical aberration in a series of one-millimeter annulus segments; therefore, it contains only the peripheral data and not any central data.

Encircled Energy Function. Encircled energy is calculated by first determining the total energy of the PSF, then determining the maximum of the PSF. Circles of increasing radii are then created at the PSF maximum, and the PSF energy within each circle is calculated and divided by the total energy. As the circle increases in radius, more of the PSF energy is enclosed, until the circle is sufficiently large to completely contain all the PSF energy. The encircled energy curve thus ranges from zero to one, or from 0 to 100 percent.

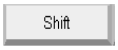
Depth of Focus. DOF can be simply defined as the variation in defocus that can be tolerated by the eye without causing any objectionable change in sharpness of the retinal image. The Depth of Focus (DOF) display plots the through focus Visual Strehl ratio based on the patient's optical transfer function (VSOTF), finds the 30% threshold level (or user defined threshold level) in which the range of defocus errors degrade the retinal image, and calculates this range as the DOF. The user can choose to display the VSOTF using a relative or an absolute scale.

Depth of Focus Comparison. Two VSOTF curves can be compared side by side to see an effective depth of focus between two target points. The user should choose a near-point-focused exam (reading) and a far-point-focused exam (distance) to see the effective depth of focus estimate for accommodative effort.

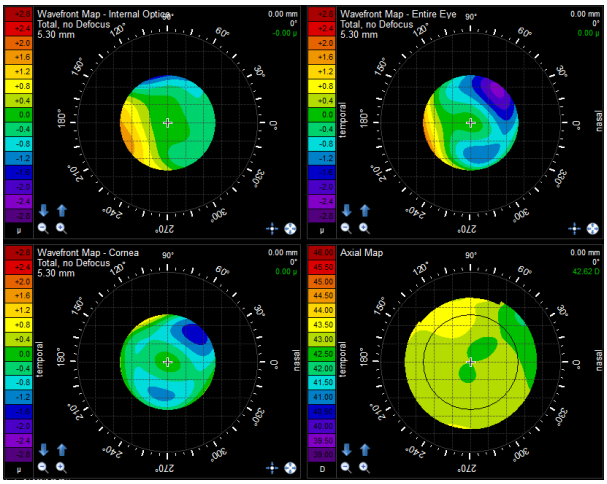
Near Vision Display. This display provides a near point fixation adjusted MTF that is used to create a simulated Snellen E Display for near vision. The display shows the Far Snellen E and the Near Snellen E side by side for the user's comparison. The display also allows the user to adjust the Near Point fixation target to analyze its effect on the MTF curve and Snellen E simulation.

Special Functions Keys

The iTrace program uses these special function keys frequently.

	Use to move from field to field. The **Shift + Tab** combination keys move the cursor to the previous field. Using the Tab key is an alternate way to move through fields vs. using the mouse.
	Use to move the cursor left, right, up, and down. The cursor indicates your position in a text entry field and takes the form of a blinking vertical bar. The up and down *arrow keys* also are used for manually adjusting the scan diameter size in the pupil during the acquisition process. The right and left *arrow keys* also are used to manually adjust the fixation target +/- diopter steps as set in the accommodation parameters.
	Also known as the *Return* key, the ***ENTER*** key can be used in lieu of clicking ***OK***. During the acquisition process the ***ENTER*** key is used to toggle between Manual and Auto acquisition functions for each exam type.
	Use in combination with other keys. For instance, holding down both the ***CTRL + ESC*** keys allows the selection of multiple patient exams for export or import. It is also used to de-select a highlighted exam. ***CTRL + D*** opens the database selection dialog. ***CTRL + A*** selects all patients. ***CTRL + S*** opens the camera settings dialog during iris image capture.
	Use in combination with other keys. For instance, holding down both the **Shift + Tab** keys is used to initiate image acquisition in lieu of the joystick button.
	Use ESC to cancel the acquisition process. Using the ESC key is an alternative way to using the mouse to navigate out of a screen in the software.
	Use during wavefront exam acquisition to toggle the scan centration between pupil center and IR dot (visual axis) center.
	Use during wavefront exam acquisition to toggle the fixation target light on and off.
	Change the C4 (defocus) term on the Retinal Spot Diagram display. It simulates moving the retina forward and backward through the Conoid of Schturm
	Use to reset the Retinal Spot Diagram after using ***F1/F2***.
	Use to provide continuous change in Retinal Spot Diagram over the range of +10 to -10 D of change.
	Use to begin a continuous one-time cycle through the signals for each sample point.
	Use during wavefront exam acquisition to reset fixation target to 0 diopters.

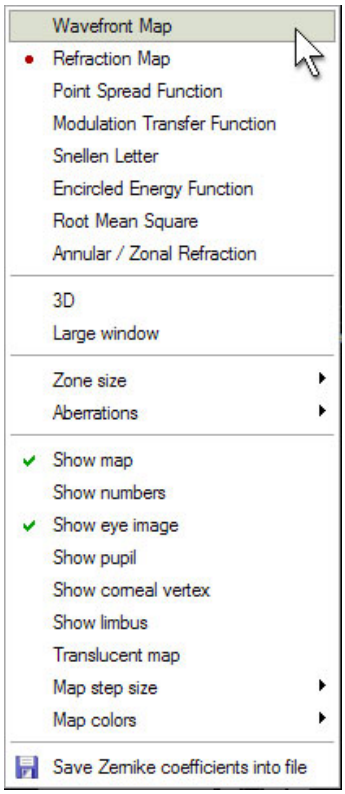
Common Display Options



The iTrace software comes with a variety of default display options, yet it is flexible to provide you the ability to change how the options appear on screen. In a Summary display mode, the default screen generally contains four (4) display panels. This display setting and other common default settings can be changed by *right-mouse-clicking* on any display to bring up the ***Options Menu*** and then select different options.

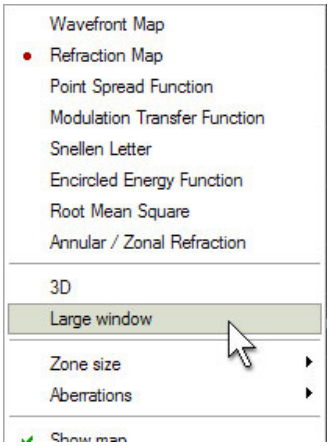
To Change the Current Display

Select the ***Options Menu,*** then choose another display type. After the display type is selected, a red dot will appear indicating the type of display that was selected for the screen.



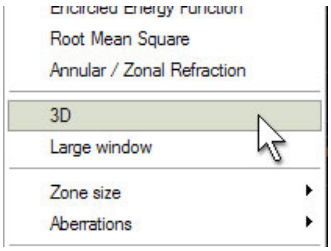
To Enlarge a Display

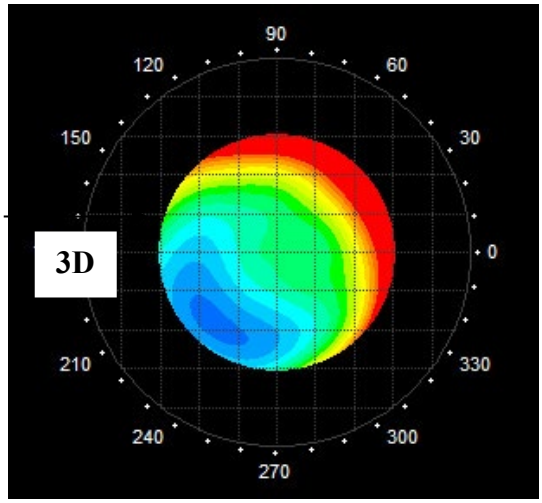
Select "*Large Window*" option from ***Options Menu***. This will enlarge the display to fit the whole display area.

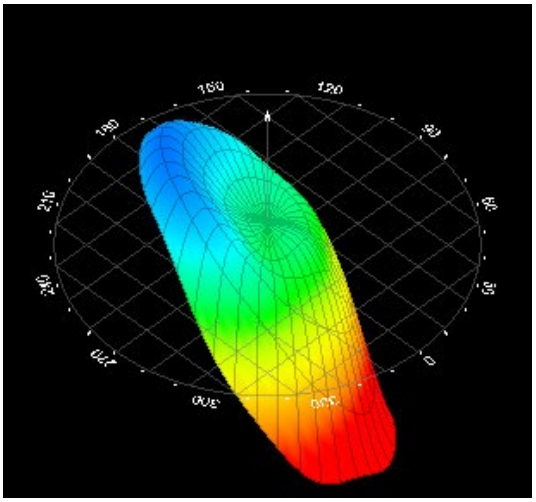


To View Display in 3D

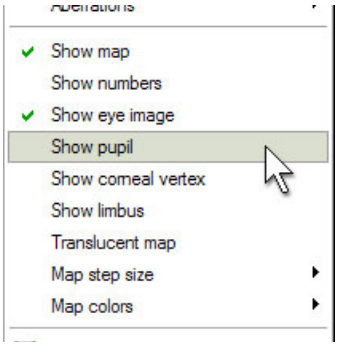
The default display method is 2D. *Display Method* option is available only in Summary display mode by clicking on one of five *Summary* buttons. *Right mouse click* to bring up the ***Options Menu***, highlight *Display Method* and choose *3D*.



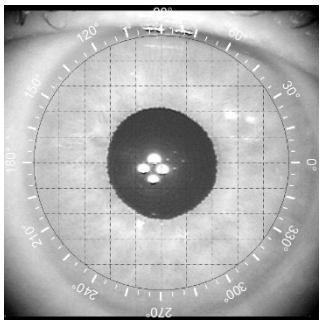




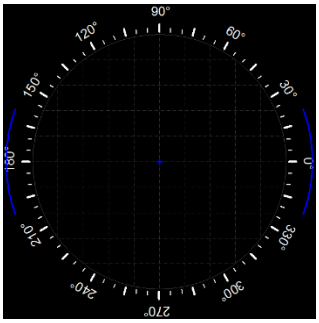
To Change Display Elements



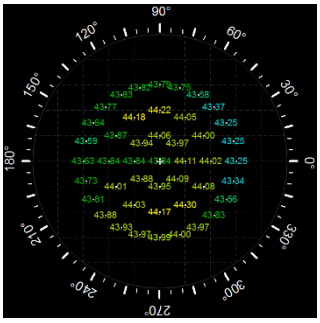
A display element is an overlay on the image which you can layer together to help with your data analysis. Not all displays contain all of the display elements. Some elements are specific to that display. Perform a *right-mouse-click* on any display to bring up the ***Options Menu***. Select any number of display element options toward the bottom of the menu list. As the elements are selected, a green check mark will appear next to the element on the menu list.



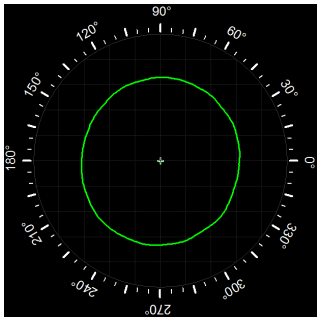
Eye



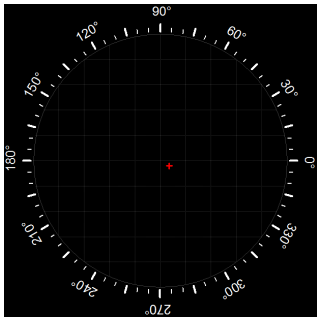
Limbus



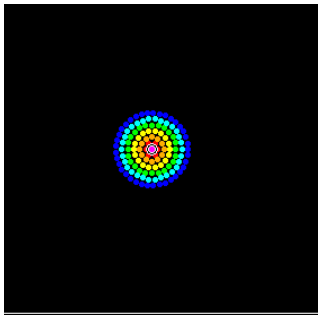
Number



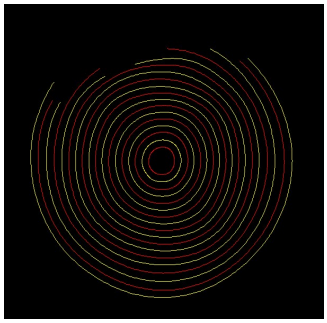
Pupi



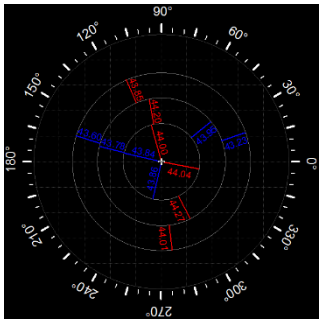
Corneal



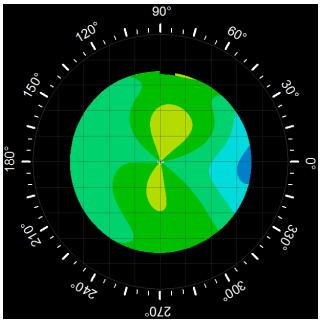
Scan



CT



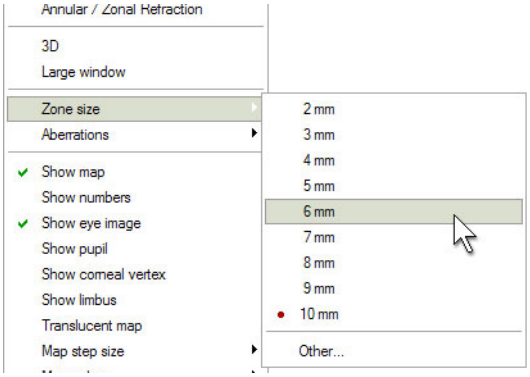
Keratometry



Map

To Select Zone Size

In ***Settings***, you can choose different scan zones to view for the multi-zone refraction display**.** To change zone size within the current display, right-mouse-click to bring up the **Options Menu**. Select *Zone* option and then make your selection. You can pick a distinct zone value from 2.0mm to 8.0mm, or *Full Scan* option for all the zones. *Other* allows you to choose an arbitrary value.



You can also click on the button in the bottom right corner of the display to decrease the zone size by 1 mm steps per click. The default zone size is 10 mm, so you will need to click the button several times to see the map change. Similarly, you can click the button to increase the zone size in 1 mm steps. Some displays provide a slider bar to change the zone size. The selected zone size is shown in the top left corner of the display panels.

To Compare Aberrations

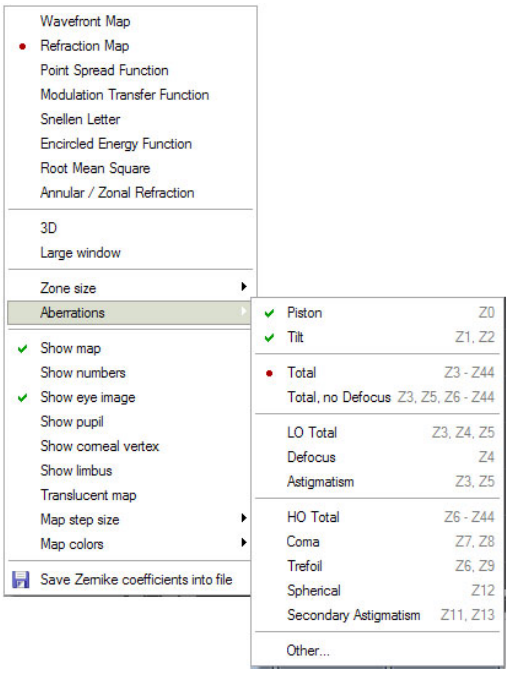
Aberrations are generally displayed as either **Total** aberrations, which use all aberrations in the display element; **Total No Defocus**, which use all aberrations except the Defocus term allowing you to view more details; and **Higher Order Total** aberrations, which removes the lower order terms defocus and astigmatism from the display element. You can quickly change the groups of aberrations that are being displayed by clicking the Correction Toggle icon located in the bottom right of most display panels. The choices that the toggle presents are:

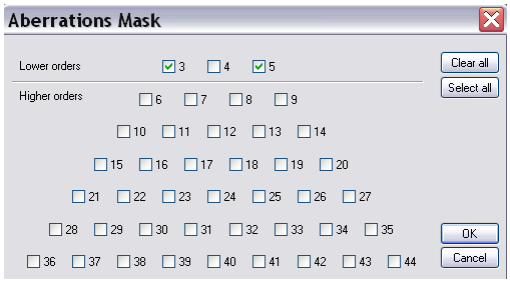
Displayed with **Higher Order Total** aberrations only (with “spectacle correction”.)

Displayed with **Total, No Defocus** aberrations, in other words, all aberrations except the defocus term (with “spherical correction” only.)

Displayed with **Total** aberrations, (without “spectacle correction”.)

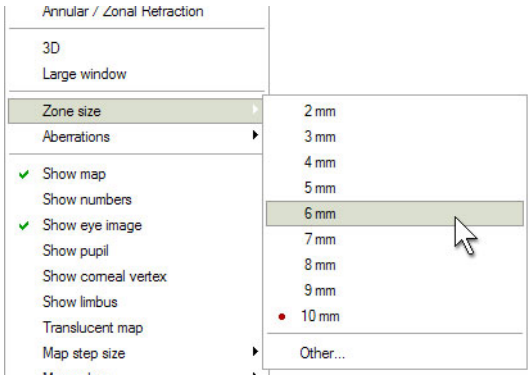
More options are available for masking aberration types by bringing up the ***Options Menu***. Highlight *Aberrations* option and then select the different types and the associated zones. In the iTrace software, you can select to display Total, Higher Order Total, or Lower Order Total. You can also choose to display only Defocus, Astigmatism, Coma, Spherical and Trefoil aberrations. Choosing *Other* option will bring up the Aberrations Mask screen.





To Navigate WF Summary Options Menu (Right Mouse Click)

This menu option is available in the summary displays in Prime. The options will vary depending on the display type selected. Use a *right-mouse-click* on any display to show this menu.



Selection denoted by red circle (●)

- *Eye Image*
- *Wavefront map*
- *Refraction map*
- *Point Spread function*
- *Modulation Transfer function*
- *Visual Acuity Chart*
- *Near Point Visual Acuity Chart*
- *Encircled Energy Function*
- *Root Mean Square*
- *Annular / Zonal Refraction*
- *Depth of Focus Function*

Selection denoted by green check circle (✓)

- *3D*
- *Large window*

- *Zone size* → *2.0 mm – 10.0 mm | Other*
- *Aberrations* → *Piston*, *Tilt*, *Total*, *Total, No Defocus*, *LO Total*, *Defocus*, *Astigmatism*, *HO Total*, *Coma*, *Trefoil*, *Spherical*, *Mixed Astigmatism*, *Other*

Selection denoted by green check (✓)

- *Show Map*
- *Show Numbers*
- *Show Eye Image*
- *Show Pupil*
- *Show Corneal Vertex*
- *Show Limbus*
- *Translucent Map*
- *Show Solid Surface or Show Wire Mesh (when in 3D display)*

Selection denoted by red circle (●)

- *Letter* → *Snellen E or Landolt C*
- *Letter Size* → *20/200, 20/100, … 20/20*
- *Letter Orientation* → *0°, 90°, 180°, 270°*

- *Map Step Size* → *.25 D, .50 D, .75 D… 2.00 D | Auto*
- *Map Colors* → *Colors 1, Colors 2, or Custom*

Selection denoted by green check (✓)

- *Show 50% Energy Circle* (when viewing PSF)*
- *Combined (when viewing RMS)*

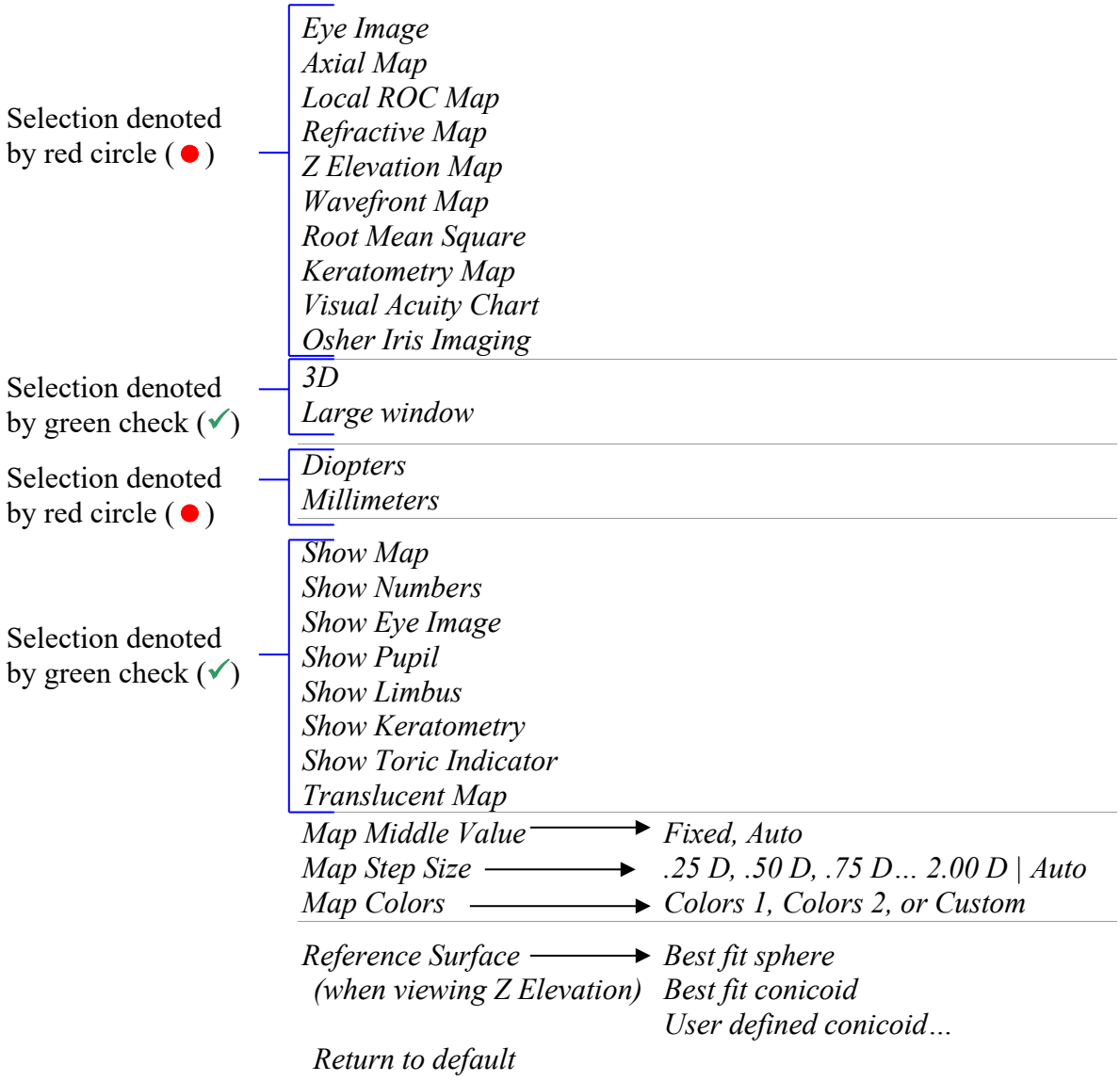
Selection denoted by red circle (●)

- *Circle Round Maximum (when viewing Encircled Energy Function)*
- *Circle Round Centroid (when viewing Encircled Energy Function)*

- *Save Zernike Coefficients to a file*
- *Return to Default*

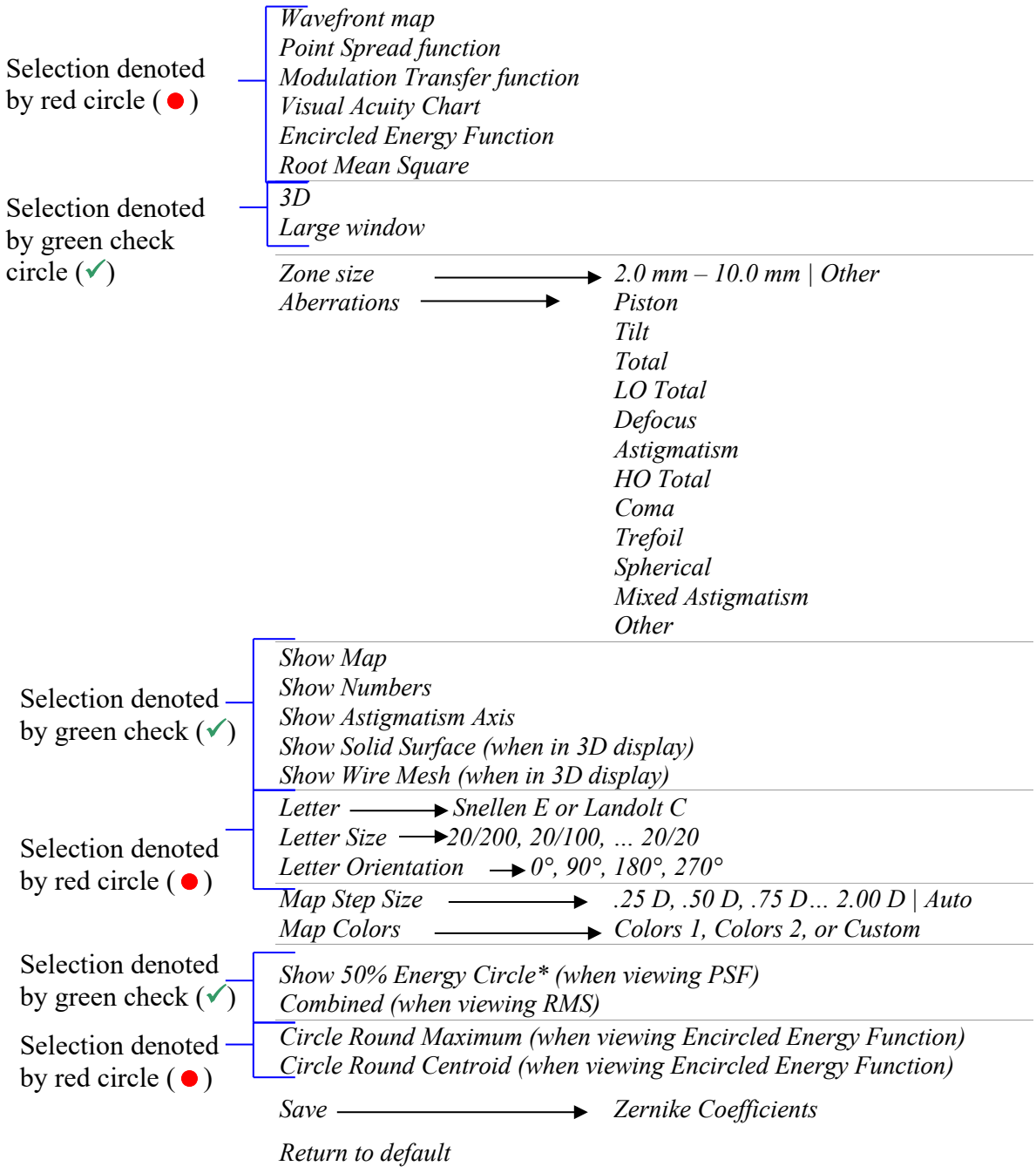
To Navigate CT Summary Options Menu (Right Mouse Click)

This option is active through a *right-mouse-click* on any display. The options available are dependent upon the display type selected or software activation type. Please refer to Appendix B for display type descriptions.



To Navigate WFCT Summary Options Menu (Right Mouse Click)

This menu option is available in the WF and CT summary displays. The options will vary depending on the display type selected and activation type. Use a *right-mouse-click* on any WF quadrant to show this menu. Please refer to Appendix B for display type descriptions.

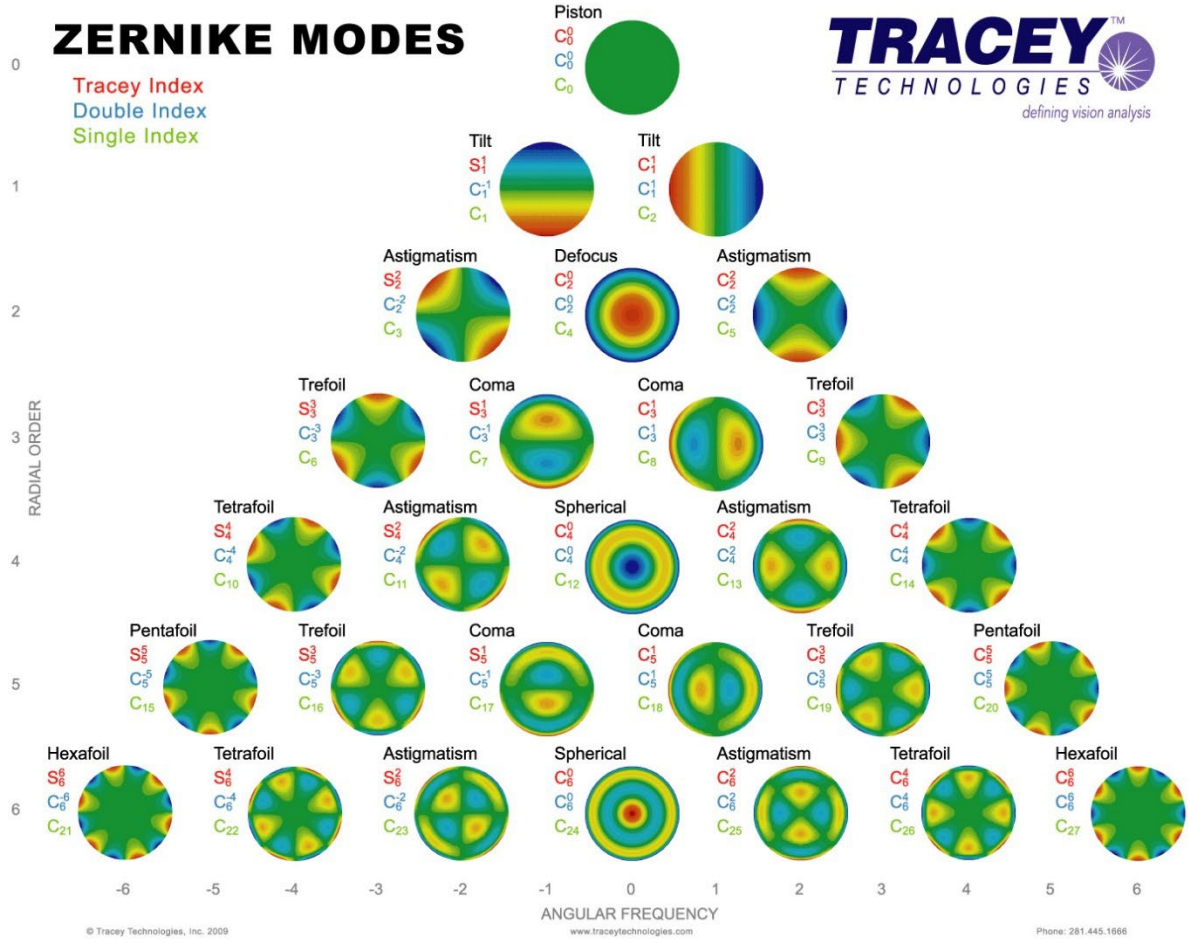


To Navigate Multi-Exam Options Menu

This menu is activated by a *right-mouse-click* on any display. Not all options are available to all displays. Some options will apply only to specific display type. Please refer to Appendix B for display type descriptions.

Series # ⟶ 1 | 2 | 3 | …
Zone Size ⟶ *2mm* | *3mm* | *4mm* | *...*
Aberrations ⟶ *Piston* | *Tilt* | *Total* | *LO Total* | *Defocus* | *Astigmatism* | *HO Total* | *Coma* | *Trefoil* | *Spherical* | *Mixed Astigmatism* | *Other…*
Difference
Spot Size
Step Size ⟶ .25 | .50 | .75 | 1.00 | … | *Auto*

APPENDIX B Zernike Modes Chart

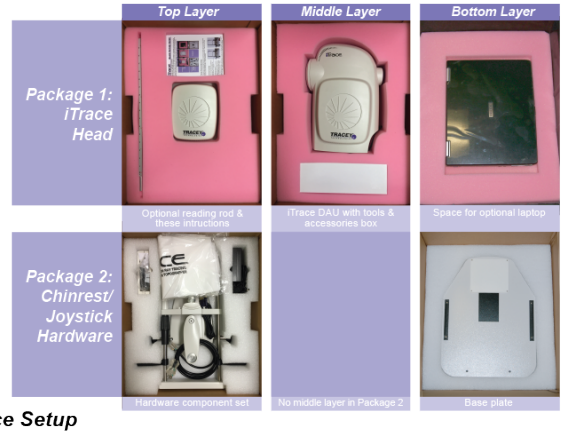


APPENDIX C DAU Installation Instructions

iTrace™ Quick Set-Up Guide

Verify your package contents

The Tracey iTrace Visual Function Analyzer system is shipped in two packages, one box containing the iTrace Diagnostic Acquisition Unit (DAU), accessory box, and optional laptop computer, and the second box containing the chinrest, base, cables, and power supplies. Please inspect each container for completeness.

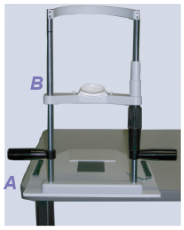


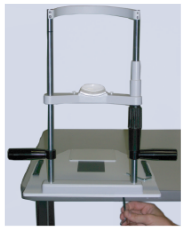
iTrace Setup

There are two components that require assembly to properly set-up your iTrace: the Chinrest Assembly and the Manipulator & DAU Assembly.

Chinrest Assembly

The Chinrest Assembly consists of two parts: From the bottom up, they are the Base (*A*) and the Chinrest (*B*).

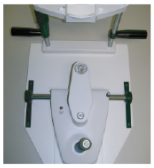


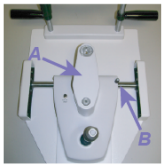


These two parts are assembled with the Base on the bottom, and the Chinrest on top of it, connected with two Allen screws from below the baseplate. Before tightening the two screws, verify that the Chinrest cup is facing outward, toward the patient-side of the Base. Tighten using the Allen screwdriver included with your shipment.

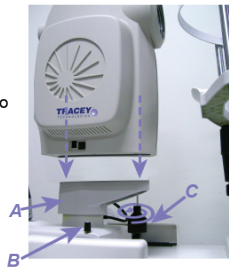
Manipulator & DAU Assembly

Place the wheels of the manipulator part onto the rails on the Base Assembly, making sure that the wheels are aligned properly. Place the rail covers over the wheels by sliding them in from the outer sides, and snapping them into place.





Tighten the locking pin (*B*) in the manipulator (*A*) to restrict movement. If present, remove the temporary bolt from the bottom of the iTrace DAU and retain to use if shipping your iTrace. Position the iTrace DAU with cone and rings facing forward toward the chinrest and mount to the manipulator component (*A*) using the black knurled knob (*C*). The knob is inserted under the patient side of the manipulator, and is tightened to the right to securely mount the iTrace DAU facing the patient. A control key will prevent incorrect positioning.



Final Connections

Connect the OD/OS sensor's black cable on the left side of the iTrace DAU to the connection on the left side of the manipulator.

Connect the iTrace DAU power supply cable to the middle connection on the iTrace DAU. Connect other end of power supply cable to a surge-protected power outlet.

Connect the small end of the USB cable to the supplied USB Type C port (right of the power inlet) on the iTrace DAU. The other end will connect to the USB port on the PC.

Proceed to the iTrace Quick Start Guide.

LB007 Rev F

APPENDIX D Calibration Verification

Verify WF and CT Calibration of your iTrace

Tracey Technologies recommends that you check the calibration of your iTrace routinely. If ongoing documentation of the calibration is required, please follow the steps below. If your iTrace fails to fall within the range of acceptable values, please contact Tracey customer support at **(281) 445-1666** or via E-mail to **service@traceytech.com.**

If a quick check of wavefront calibration is all that your circumstances require, you can follow the steps on page 35.

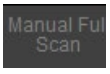
Verifying Wavefront Calibration

Included with your iTrace VFA is a cylindrical object called the Calibration Verification tool. Use this tool to verify the instrument's calibration.

1 The center hole of the iTrace's Placido disk is threaded for the use of the calibration verification tool. Insert the calibration verification tool into the center hole and turn right to slightly tighten.

2 Power on the system and launch the software.

3 Select *New Patient* and name the patient Calibration Test. Select the patient you have just created by double clicking on the patient. Click on WF capture button  .

4 When the new wavefront screen appears click the 

button which will light up blue when active. Press the joystick button or click the 

button on screen. If Enable Auto-fixation is selected in settings, the iTrace will take the first reading to adjust the optometer. If not, advance to next step.

5 The iTrace will display red circle and allow you to capture a manual scan. The scan size is displayed in the upper left of the screen. The scan size can be increased or decreased using the up and down arrow keys on the keyboard. If not already a 6mm, set the scan size to 6mm and then press the joystick or acquire button.

6 Repeat Step 5 as necessary if using Multi-capture WF mode.

7 The iTrace will acquire the exam(s) and display the Exam Results screen. In the center top panel of the display is the Tracey refraction. The Green Tracey refraction should read -5.00 +/- 0.12 diopters sphere. Save the exam as a permanent record of the calibration verification test.

Verifying Corneal Topography Calibration

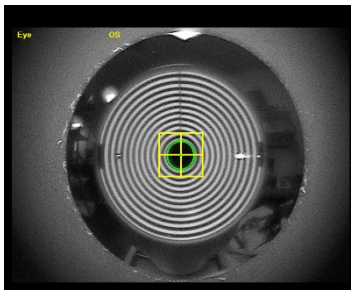
1 Insert CT Calibration Verification tool into the receptacle on the chinrest. The chinrest may need to be lowered so that the tool can be properly measured by the iTrace.

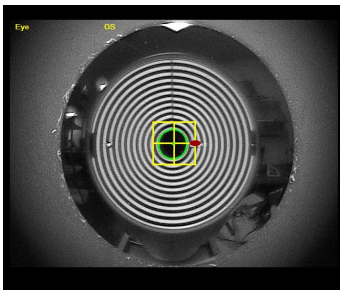
2 Ensure the cover of the verification sphere is fully open.

3 Enter the iTrace software and select Calibration Test patient or create a test patient if one does not exist.

4 Select “New CT Exam”.

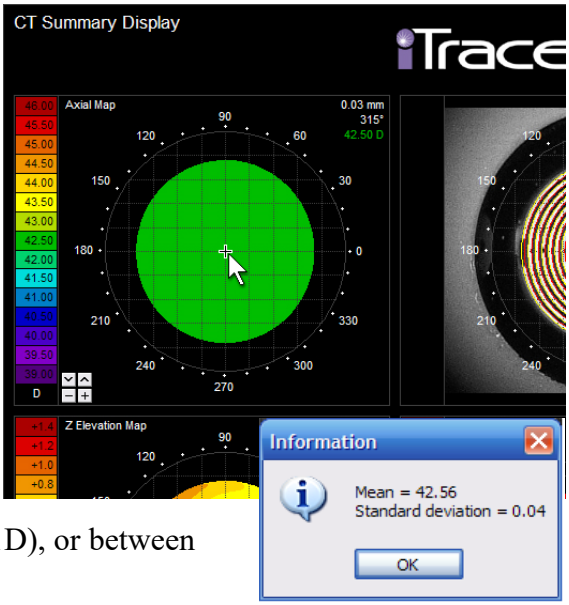
5 Center the machine on the verification sphere and move the machine in or out to auto-capture the CT exam.





6 After the exam is captured, select the display titled “CT Summary”.

7 Double click in the center of the axial map (upper left quadrant) and read the mean and standard deviation that appears on the dialog box.



The mean should be within +/- 0.25D of the verification sphere (42.51D), or between 42.26D and 42.76D.

APPENDIX E Networking and EMR Integration

Understanding the iTrace Device, Software and Database

The iTrace device, or Data Acquisition Unit (DAU), is fully controlled by the iTrace software. The iTrace DAU sends raw data to the iTrace software, where it is saved as raw, unprocessed data under the specific patient in a database.

The iTrace software is installed on a Windows computer, so the customer will have the full functionality of a windows computer at their disposal. The software can be installed on virtually any windows computer, provided that it meets the minimum specifications listed here:

- CPU: Intel Core i7 or equivalent
- Graphic Display Resolution:
  - HD 1360x768, or
  - HD+ 1600x900, or
  - Full HD 1920x1080
- 16 GB RAM (Main Memory)
- HD Capacity: 1 TB GB SSD Minimum
- 2 USB 3.0 Ports for connecting iTrace acquisition unit and color printer
- Integrated 10/100 Ethernet LAN
- Microsoft Windows 10 or greater Professional OS – required for networking
- Color Printer (USB or wireless) for printing displays (Optional)
- Touchscreen display for ease of use (Optional)

The iTrace uses an open Microsoft Access (MSJet) database, consisting of two types of raw data files: *.exam and *.cal files, and it also includes *.tdb files with the header information for the exams, demographics, and links from exams to patients.

For the iTrace software to function, **all Windows user account installations of the software require read/write (full control) access to the database folder**, otherwise the software cannot access the database.

Installing the iTrace software

The iTrace Installation Program is provided by Tracey Technologies upon purchase of a new iTrace machine by new clients or by request for existing clients. The software can be installed on networked computers within the clinic as described below, using the provided installer. More instruction for installing the iTrace software can be found on page 22 of this manual.

Activating the software

The first time you run the software after installation, you will need to activate the software. The software will display a dialogue box providing the Hardware ID in one text field and asking for an activation key in another.

To activate the software, you can fill the form at: https://www.traceytechnologies.com/sw-act-request

Alternatively, you can contact Tracey Technologies at 281-445-1666 and press 2 for customer service, and provide the following information:

1. Clinic name
2. Clinic address
3. Main Physician name
4. License type required (see below in License types)
5. iTrace serial number (4-digit number on the right-side sticker on the iTrace machine).

You will be provided with the activation key to enter in the space provided in the dialog box in the iTrace software.

Software License types

There are three types of licenses for the use of the iTrace software:

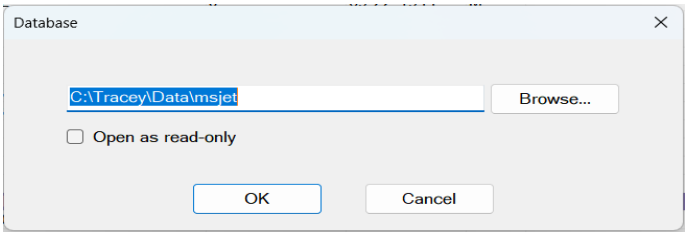
- **Prime / Core**:
  - This license allows the software to view patients, create new patients, delete pre-existing patients, modify demographics, edit screen views, and capture new exams.
  - Typically, only one **Prime or Core** license is provided per iTrace machine in a given clinic/practice
- **Prime / Core viewer**:
  - This license allows the software to view patients, create new patients, delete pre-existing patients, modify demographics, edit screen views.
  - This license type **cannot capture exams.**
  - Typically, we provide up to 10 viewing stations per clinic/iTrace device purchase free of charge.
  - If more than 10 viewing stations are required, further licenses can be provided for a fee per viewing station. For more information, please contact Tracey's Customer service.
- **Prime DICOM**:
  - This licence provides the functionality of the regular Prime activation and adds the libraries and user interfaces to communicate using the DICOM standard with other clinic information systems.

Changing the location of the database

By default, your patient data is stored within Microsoft Jet databases, located in a folder titled Data within the Tracey folder of your computer's hard drive. You have the option of creating a network accessible database folder with the iTrace software. Storing your patient

data on a network accessible drive allows you and others to view the data from any computer on the network that runs iTrace software. For more information, see Appendix F. You can also create multiple databases. The current database storage path is listed on the Patient List screen in the top left corner. To change the location of your database or create a new database, follow these steps:

1. Click  or press ***CTRL*** + ***D***. The following dialog box will appear.



2. In the box, type in the folder address for the new database location or click ***Browse*** to locate and select it.

3. Click ***OK***. The iTrace software will store your patient data in this new database until you return to this screen and select another database.

Note: Please consult with your network administrator before creating a database on a network drive. It is the user's responsibility to ensure the integrity of their data on a network. **Connectivity between the computer and the network share drive is the user's responsibility**.

Using the iTrace on a Domain

The iTrace computer can be setup into a domain and no special privileges are required to run the software. However, read/write privileges to the database are required for each instance of the iTrace software for the iTrace software to be able to access the database. This includes each Windows User Account.

Special Considerations for Connecting the iTrace on a Network

Connecting the iTrace to an IT Network can provide several added benefits such as the ability to easily back up the database on a network server, the ability to print screens to a network computer or store images on a server, and the ability to view patient data on other networked computers installed with the iTrace.

The user must ensure that the network has security in place to prevent unwanted data access, loss or theft. The iTrace data can only be viewed from another computer with the iTrace software installed and privileges for these viewer stations must be granted by the IT Administrator. Therefore, security is

assured. If saving screen captures or exporting patient data, security for this data is the responsibility of the user. Failure to maintain data integrity could result in unwanted data access, loss or theft.

Connection of the iTrace to an IT-Network that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties:

– the user and/or IT Administrator should identify, analyze, evaluate and control these risks;

– subsequent changes to the IT-Network could introduce new risks and require additional analysis; and

– changes to the IT-Network include:

- changes in the IT-network configuration;
- connection of additional items to the IT-Network;
- disconnecting items from the IT-Network;
- update of equipment connected to the IT-Network; and
- upgrade of equipment connected to the IT-Network.

Data Viewing Options

The software saves the data in a raw format, and this data gets processed each time the data is displayed on each report. This allows the iTrace displays to be dynamic and customizable using on-screen buttons, to simulate different conditions and their effect on the patient quality of vision.

There are several ways to access the iTrace display information:

- Install viewing stations – the preferred method
- Export data into an EMR:
  - Save image
  - Export image
- Print into pdf
- Print a display on paper

These options are discussed below in more detail.

Viewing stations

Viewing stations are computers where the iTrace viewer software is installed. These computers are typically lane computers found in the clinic, and could be either thick clients or thin clients,

These viewing stations need to have read/write access to the database. The local privileges to run the software are the same as for the iTrace DAU workstation “Prime” or “Core” software

Once you have installed the viewing stations as previously described, you will then need to direct the software to the location of the database.

Pros:

- Dynamic view: the data can be manipulated in the same manner as in the iTrace software.

- Changes to data are saved: e.g. if rulers are used or the pupil size/location is edited, the changes are saved to the database
- Less work for the Techs: you don't need to export each single display required into the EMR

Reviewing iTrace Screens within an EMR

As stated, the iTrace computer is a full windows computer with the iTrace software installed as a 3rd party application. Web-based EMRs can run on the iTrace computer using a web browser, while EMRs with an executable client side can be normally installed in the same manner as on any regular computer.

To export data from the iTrace into an EMR, the screen that is desired to be saved into the EMR must first be saved within the iTrace software, and the saved screen can be uploaded into the EMR.

Note: The customer maintains the responsibility of regulating the Export process into the EMR. Please consult with your IT personnel.

To Save a Screen in the iTrace:

This option saves the current screen as an image in a type and a location specified by the user. Once an image is saved, the software remembers the last location and extension used, and uses these options the next time the save button is clicked.

The following image extensions are currently provided:

- JPG
- PNG
- BMP
- DCM (a dicom image with embedded header containing patient demographic information)

To save an image:

1. Select the desired patient
2. Select the desired exams
3. Navigate to the desired screen
4. Click the save button on the bottom right corner  .
5. A dialogue box will appear; use it to specify the save location, file name and file extension
6. The default name used by the software is: "lastname.firstname_exportdate-exporttime.extension", the export time format is "Hr-Min", so if more than one screen is exported per minute, then the default name needs to be appended or modified.
7. After an image is saved, the selected settings-location and extension- are saved, so that the next time a user clicks the save button, the dialogue box will show in that location with the same file extension selected.
8. The next step will be to export the image to the EMR using scripts written by and within your EMR provider and system.

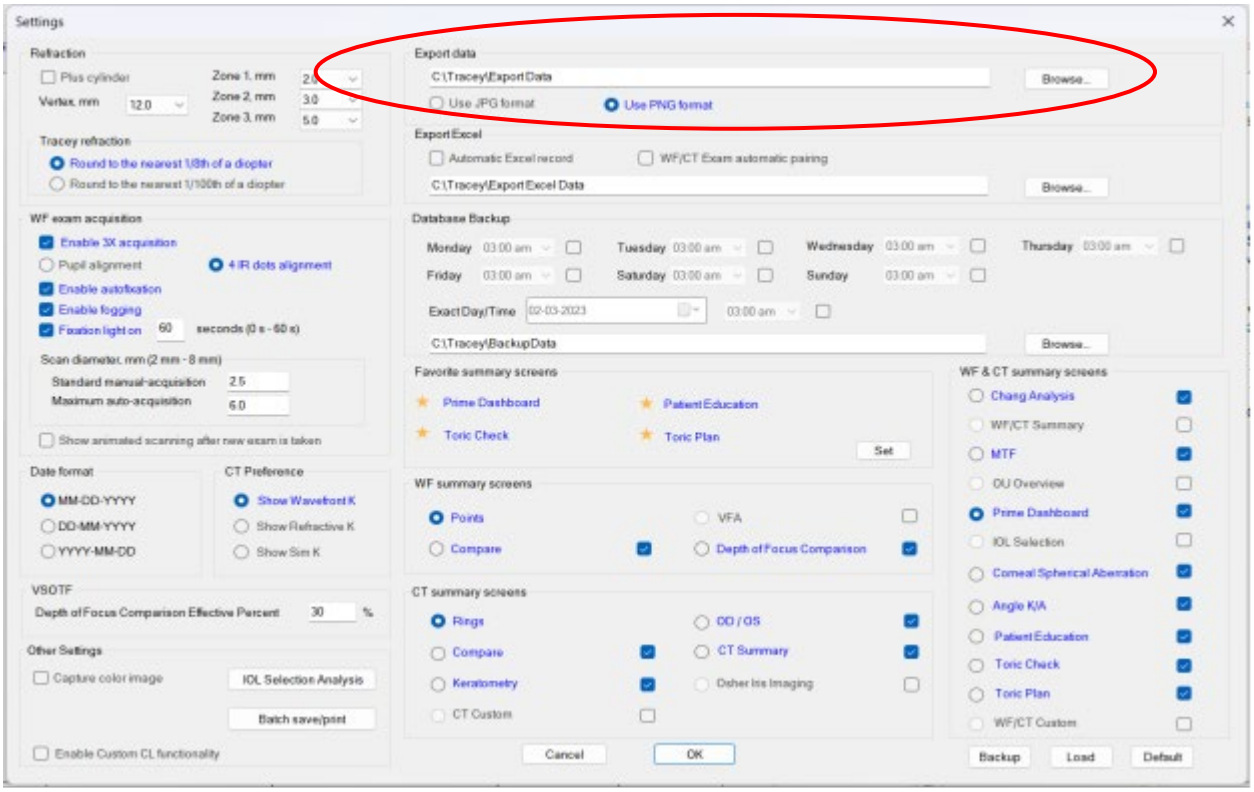
To Export Exam Data:

The export functionality allows immediate export of the current screen with pre-saved settings, along with xml files that contain patient demographics, and measured exam data. The export functionality helps empower IT techs who want to automate the process of export of the iTrace data into an EMR system.

a. To change the export settings:

In the main screen, click the Settings button  .

The following settings box displays, the section to set Export functionality is encircled in red. Here the user can specify which type of image format to use for the screen image and can choose the location where the image is to be exported.



b. To export a screen and exam data

1. Navigate to the desired screen
2. Click the export button  .
3. If DICOM functionality is enabled, choose the option “Standard” from the pop-up menu.
4. A message box will show up stating the export has been successful. The export function will do the following:
    i. Create a folder in the parent folder provided in the settings, the new folder name format: “lastname firstname {unique ID}”

ii. Inside that folder it will create another folder named according to the exams selected to be viewed and exported, the folder name format: "side_exam1type_dateofexport_timeofexport_side_exam2type_dateofexport_time_ofexport" (Date of export format: "YearMonthDay" and Time of export format: "HoursMinutesSeconds")

iii. Inside that folder another subfolder will be created, name format of the new folder: "dateofexport_timeofexport", same format used as for the above two variables

iv. Inside that folder the exported contents are found.

i. The exported folder contents include:

- XML files of 2 types: the **patient.xml** contains the patient demographics and the **exam.xml** files contain measured data from the exams used in the display
- Image of the exported screen: name format "screenshot.ext" where ".ext" is the extension selected in the settings
- Dicom image of the same exported screen: name format "screenshot.dcm"

c. When should the export functionality be used?

i. For automation of the export process: one scenario is to create a scanner application that scans the export folder at set intervals, and extracts the data from the xml files and folder names and exports the images to the EMR

ii. Use of the export functionality with manual export to the EMR is not recommended, as the multiple levels of folders hierarchy are designed to facilitate automated export, but it will be cumbersome to navigate manually.

d. How are the images and data saved to the EMR?

In general, there are two main ways of exporting images into an EMR:

i. Manually - most common, more work for the tech, less IT overhead, more prone to human errors. This step is different from one EMR to another, so please consult your EMR documentation. The clinic staff are expected to be knowledgeable about their specific EMR and know how to export images into their EMR system.

ii. Automated - less common, simpler for the Technician, more IT overhead, no issues if implemented correctly, however, more prone to scripting errors in the beginning.

Once that knowledge is established, the iTrace exams can be uploaded like other image files.

Note: Tracey Technologies is not responsible for how you handle your exported data outside the iTrace environment. These guidelines are a general overview and not intended to provide instructions about how to do the export to the EMR.

To Save/Export as PDF

If a pdf copy of a screen is required in the EMR, two options are available:

- Install a pdf printer software: e.g. Microsoft print to PDF, then use the print functionality. This option is preferred as it is simpler for the user. The image is going to be in a print-friendly format with a white background and dark foreground.
- Save an image using the save image button, then convert it to pdf using a 3rd party application. This option has more steps but will produce an image like viewed on screen with a black background and white lettering. See samples below.

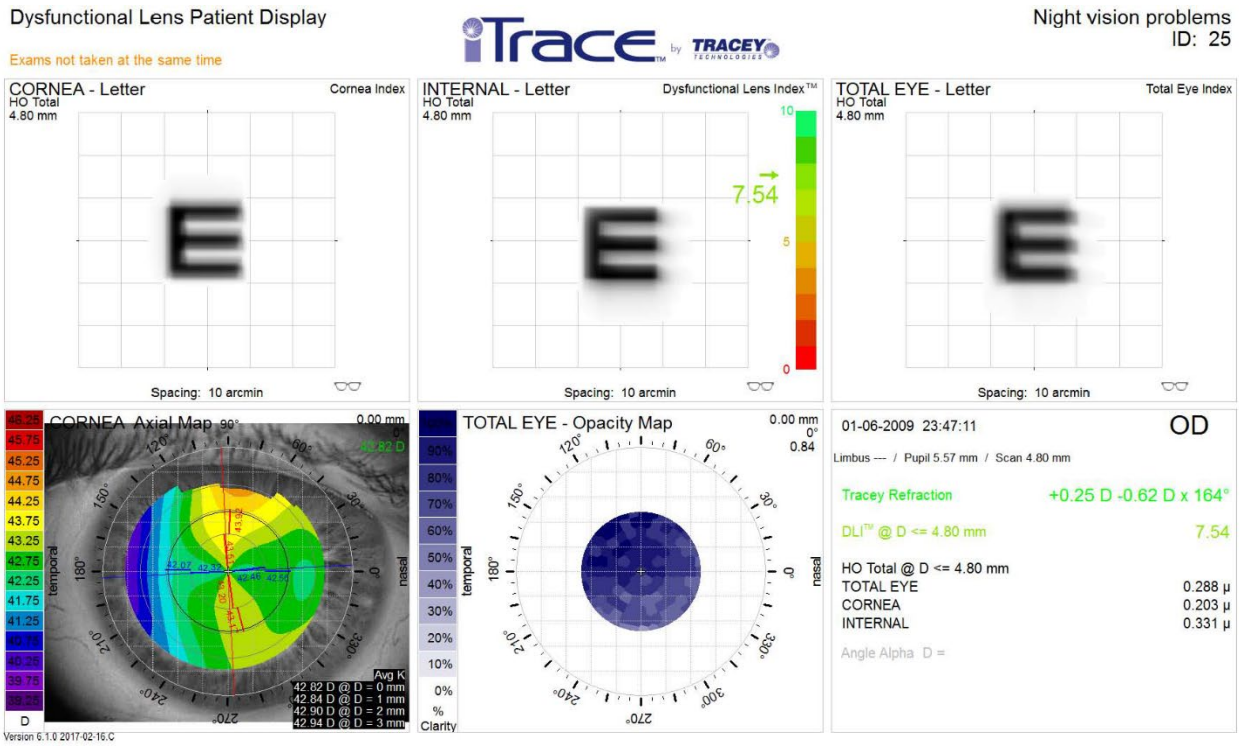


Image created using the PDF direct print

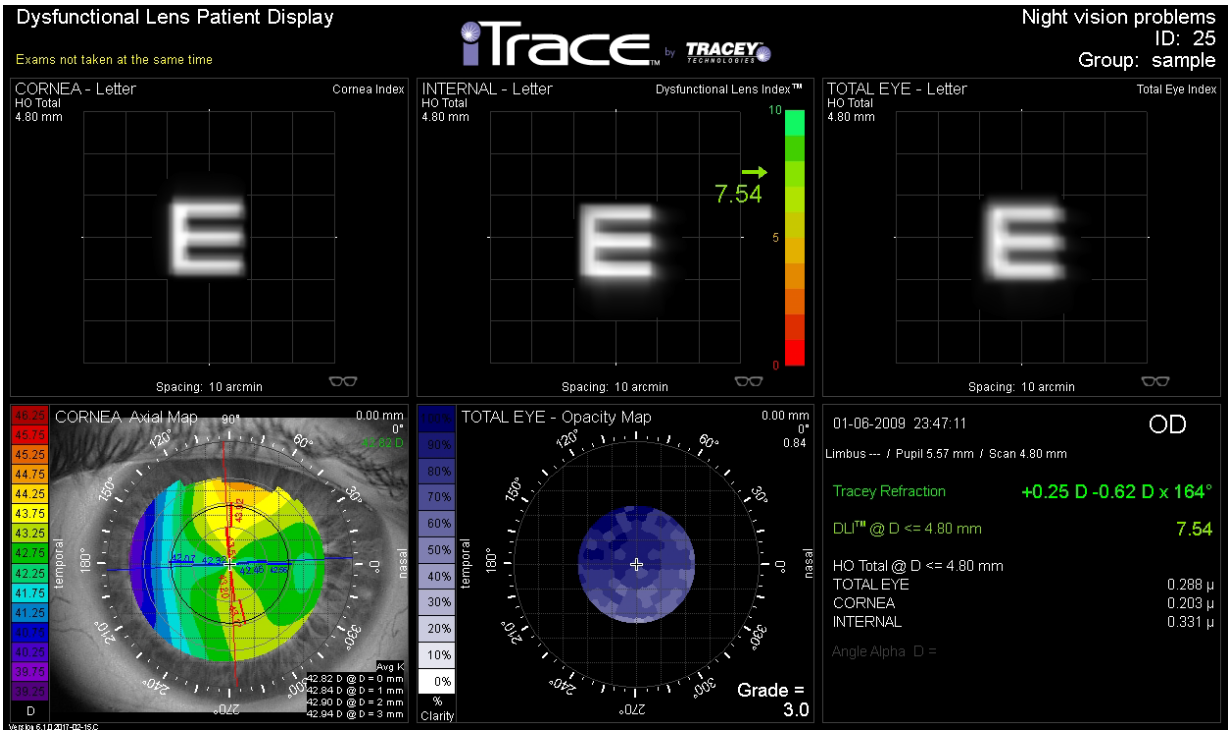


Image created using the save button, this is the standard software theme

Printing to paper

The iTrace software provides a print button that can be used to produce a print friendly version of the exams, instead of having a black background with white foreground, the print function inverts these colors-white background with black foreground.

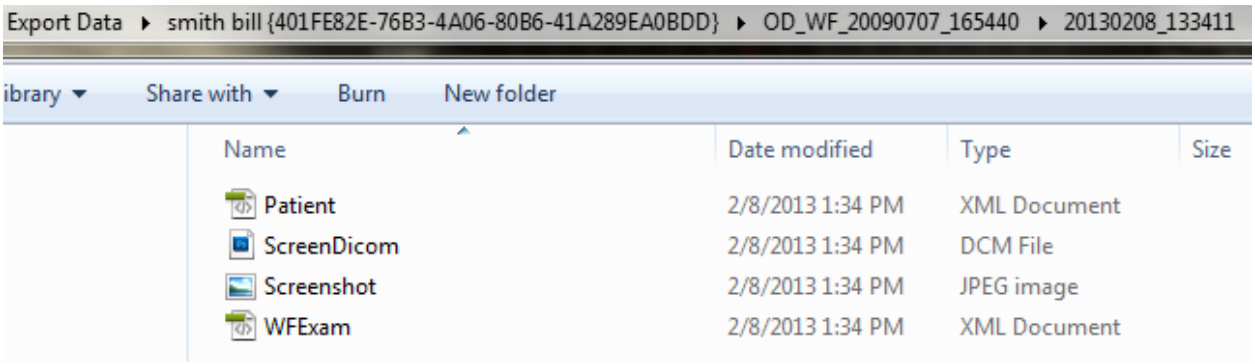
1. Installing a printer:
    a. Printer drivers should be provided by the customer, the process of drivers' installation is a straight forward process, just like in any personal computer. Once the drivers have been installed, the printer should be available for usage in the iTrace software.
2. To print a screen:
    a. Navigate to the required screen
    b. Click the print button  .
    c. Select the desired printer and proceed

APPENDIX F Data Export Options

There are several options for exporting data from the iTrace software for use in other systems or software programs. Here we describe exporting to XML data files, exporting to CSV files and saving screen shots with embedded data.

Exporting Patient, Exam Data and Screens to XML

Each exam display screen in the iTrace software includes an Export Data button:  . The button will initiate an export that includes both data fields and the screen capture that is currently displayed. The data will be saved in an XML format and the screen capture will be saved in the file format chosen in Settings. The location that the files are saved is also chosen in Settings. The software will create a hierarchy of file folders the parent of which is named as Lastname Firstname and Unique Identifier (UID). Within this folder are folders for each export named as OD or OS, exam (s) type and exam(s) date and time. Under this folder, the software places a folder named as the current date/time stamp. Within this folder the software places an XML file for the patient data, an XML file for the WF data, an XML file for the CT data, and an XML file for the data generated by the combined WF and CT information. Also within this folder is the screen capture.



The XML data can be imported into other programs like Microsoft Access or typical Image Management Systems.

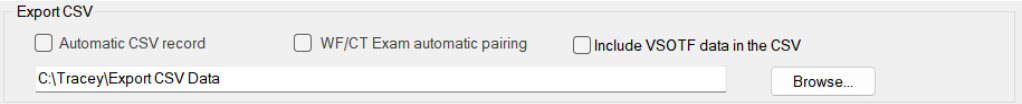
Exporting Patient and Exam Data for Spreadsheets (CSV)

The CSV export functionality is controlled in Settings. There are two options for exporting the data to CSV: Automatically export the exam data each time an exam is viewed or export manually only when a patient is selected in the Patient List screen and the button  is clicked. Automatically exporting may slow down the performance of the software each time an exam is taken and each time an exam is viewed. However, this may be the preferred method if all patient data is to be analyzed in your study.

Manually exporting may be the preferred method so that performance is only slowed at the interval when the user manually exports. It is also useful when exporting previously acquired data.

To Set Export Options

1. In Settings within the Export CSV box, choose to automatically record the data by clicking the checkbox labeled "*Automatic CSV record*". If you wish to export only when you choose to, do not click this checkbox.



2. To pair WF and CT exams that were not captured in the Dual Exam process, but were captured within 5 minutes of each other, click the checkbox labeled WF/CT Exam Automatic pairing.

3. You can choose to export the VSOTF (DOF Compare Screen) data. Inclusion of this parameter will significantly increase export time.

4. To choose the location to save your spreadsheet, enter the folder or browse to the desired folder by clicking "*Browse…*".

5. Click *OK* again at the main Settings window.

6. With the Automatically Export option chosen, the Patient List screen will display the message Automatic CSV Record On at the top of the screen. Choose a patient and choose an exam. The software will automatically create a spreadsheet file and save the data to the file. Then, for each exam of that same type that is viewed, the data will be added to the same spreadsheet.

   The software creates three different spreadsheet files when auto-recording: 700AutoRecord_CTExams, 700AutoRecord_WFExams and 700AutoRecord_WFCTExams. The WF and CT data will only be added to the 700AutoRecord_WFCTExams if the two exams were paired as selected in step 2 or taken as a dual exam.

7. When choosing to manually export, select one patient or multiple patients from the Patient List screen. To choose all patients, press and hold the CTRL key and press the A key (*CTRL-A*) on the keyboard. Click the CSV Export button.

8. The software will display a window indicating the number of patients and exams exporting, providing a count-down as they export. Please be prepared for this process to take a significant amount of time depending on the number of patients selected and the volume of exams for those patients.

9. The software creates five new and different spreadsheet files from those described in Step 7. It creates 700PatientExport_CTExams, 700PatientExport_WFExams and

700PatientExport_WFCTExams, 700PatientExportTearFilmExams, and Survey Data (if survey data is saved with the patient). Each row of the spreadsheet will contain the data for each exam exported. The spreadsheets will be updated with new rows of data each time a patient is selected and the Export CSV button is clicked.

The software will continue to add data to the CSV files as either exams are viewed with automatic export selected, or patients are exported.

APPENDIX G DICOM Activation

DICOM is a standard by which disparate medical imaging and information systems can communicate and share data. When activated, the iTrace software may include a module enabling the import of a DICOM modality worklist (MWL) and an export of preselected displays to work within a clinic desiring DICOM conformance. Details of conformance to the DICOM standard can be found in the iTrace DICOM Conformance Statement available from Tracey Technologies.

The DICOM functionality is not visible without a specific Software License Activation. To activate DICOM functionality, please contact Tracey Technologies' Customer Service.

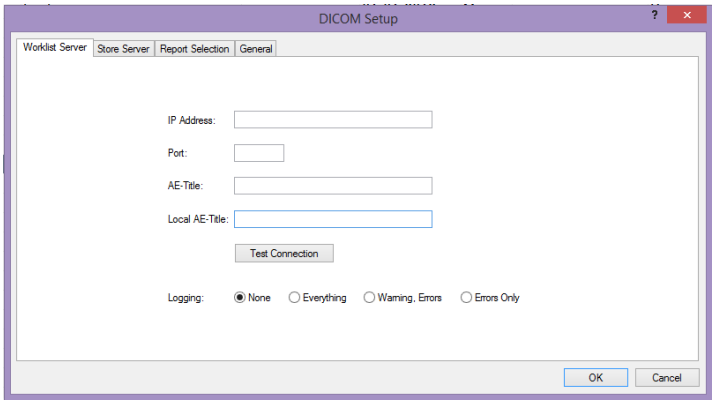
Using the DICOM Functionality

The iTrace system with the DICOM functionality implements the necessary DICOM services to retrieve a worklist from a DICOM worklist server and uses the list to create new patient records. It can also store DICOM formatted files of screen images to a DICOM Store Server.

DICOM Server Settings

The mapping to the DICOM servers and the display selection takes place within the Settings tab for DICOM. This can be a password protected dialog. If you need access to the settings, please see your IT administrator.

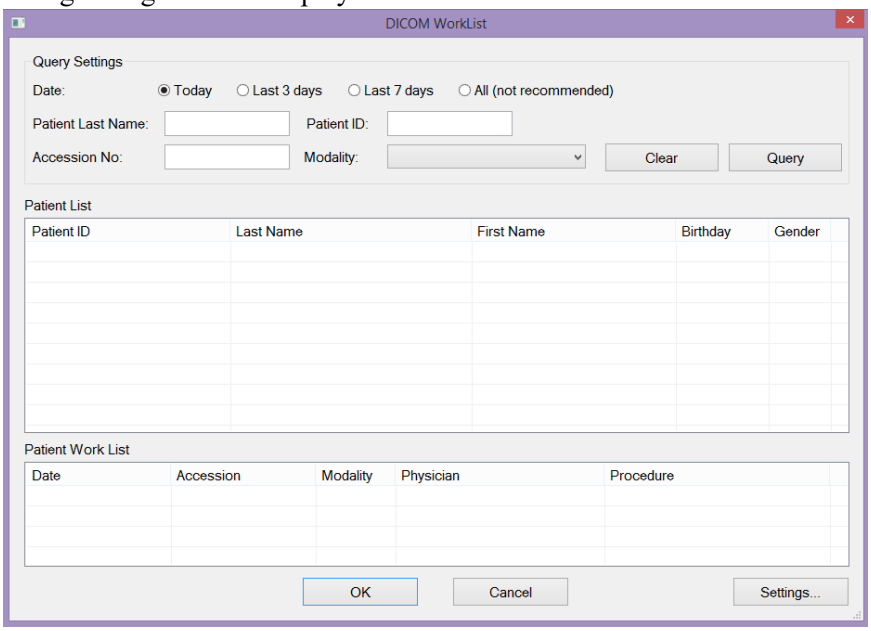
1. To set up the DICOM servers, click on  and choose the DICOM option.
2. Click on the Tab for the Server you wish to map to. You will need to enter the following items for both the Worklist Server and the Store Server (they may be different):
    a. IP Address
    b. Port
    c. AE-Title
    d. Local AE-Title
3. Test the connection to the server by clicking the "Test Connection" button.
4. You can choose to record a log of the events associated with the DICOM communications by selecting the radio button next to each log type.
5. Click on the Report Selection tab to choose which iTrace displays you will be sending during the DICOM Export process.
6. Click on the General tab to select the background format of the reports and to set a password to protect the DICOM settings.
7. Click OK to save the DICOM Settings.



To Import Patient Demographics from an MWL Server

The iTrace software with DICOM MWL functionality has the ability to pull in patient demographics from a MWL Server. The software automatically populates the patients within the patient list without the user re-entering patient demographic information. Follow these steps to query the list of patients for importing:

1. Click on Import Patients.
   a. From the Patient List Screen, click on  .
2. Choose the DICOM button from the sub-menu that appears.
   The following dialog box will display:



3. Enter the necessary filter information to limit the patients retrieved from the MWL, including scheduled date, Patient Last Name, Patient ID, Accession Number and Modality. Click the *Query* button.
4. The iTrace software will search the MWL Server and display those patients match the search criteria. Select a patient from the patient list box and a list of the work orders associated with that patient appears in the work list box.
5. Click OK. The patient will be added the iTrace Patient list and ready to select for performing the iTrace exam.
6. More details on the conformance of the software to the DICOM standard can be found in the iTrace DICOM Conformance Statement available from Tracey Technologies.

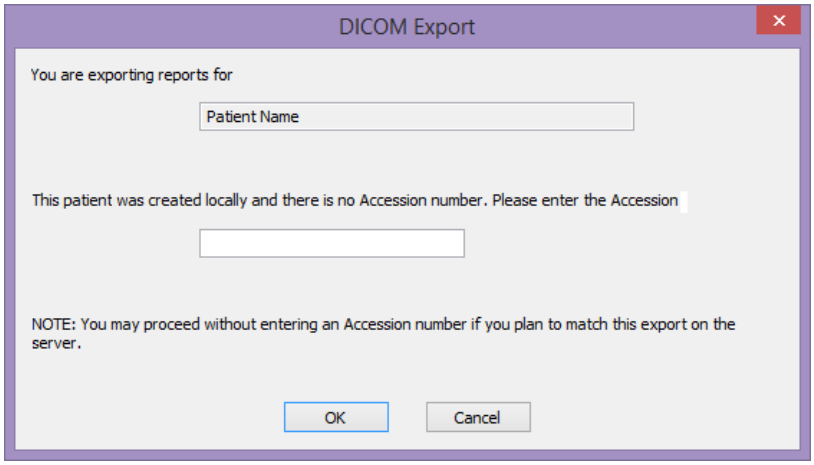
To Save Display Reports to a DICOM Storage Server

The iTrace software with DICOM functionality can save pre-selected displays to a connected Storage Server. The pre-selection of the displays is made in DICOM settings, accessible by a trained administrator for your location. Follow these steps to save the display reports:

1. Choose the patient and click the forward arrow button to view the patient's exams.

2. Choose the desired Wavefront and/or Corneal Topography exams to produce the reports by clicking on each to select them. The exams will be highlighted.
3. Click on the Export DICOM button 

. If the patient selected was imported from the MWL server, the process of exporting the display reports will proceed. The iTrace will display a message indicating that the exams were successfully exported.
4. If the patient was not added to the iTrace software from a MWL, the patient must have an Patient ID entered in the iTrace to have display reports exported through the DICOM Export. Also, a message box will appear asking you to enter an Accession number which will be required to automatically match the patient record in the Storage Server. Otherwise, you can match the export at the Server.



5. Alternatively, you can choose to export the preselected displays while viewing a display or to export only the display being viewed by clicking the Export Data button  from the navigation menu. A pop-up navigation menu will appear. To export only the display on screen, choose “DICOM Current”. To export all of the preselected displays, choose “DICOM All”.

GLOSSARY

Aberration. Aberrations describe the defects in optical systems that prevent light from focusing to a compact spot. For the eye, it is essentially a more advanced description of the eye's refractive error. Aberrations are measured as a wavefront deviation, in microns, of the distance from a patient's wavefront to a perfect wavefront plane. In the wavefront arena, lower order and higher order aberrations are used to describe a patient's vision and are arranged as 1st order, 2nd order, 3rd order, etc. Generally, the higher the order of the aberration, the smaller the impact on the patient's vision.

Aberrometer. A device for measuring the spatially resolved aberrations of the eye.

Angle Kappa. The Angle Kappa is the difference between the center of the pupil and the visual axis of the eye and can be expressed as a polar difference (distance and angle of direction) or a rectilinear difference (horizontal and vertical change in distance).

Angle Alpha. The Angle Alpha is the difference between the center of the limbus and the visual axis of the eye. It is also expressed as polar or rectilinear coordinates.

Coma. Coma is an aberration of the eye due to a misalignment of one or more optical components. For example, the lens and apertures of an optical system are usually constructed with their centers of each optical component along the optical axis. If one of these components is moved off center, coma is induced. A familiar clinical example is an excimer ablation not centered on the pupil.

Conjugate points. The location of the object and its corresponding image are called conjugate points. For example, when you focus on an object, an image is formed on your retina. In this case, your retina and the object you are looking at conjugate points.

Encircled Energy Function. Encircled energy is calculated by first determining the total energy of the PSF, then determining the maximum of the PSF. Circles of increasing radius are then created at that maximum and the PSF energy within each circle is calculated and divided by the total energy. As the circle increases in radius, more of the PSF energy is enclosed, until the circle is sufficiently large to completely contain all the PSF energy. The encircled energy curve thus ranges from zero to one, or from 0 to 100 percent.

Higher Order Aberration. These are all aberrations above the second order series aberrations (3rd order aberrations, 4th order aberrations, etc.). See the Zernike Pyramid. Higher order aberrations cannot be corrected with conventional spectacles. These are generally increasingly smaller percentage components of a patient's total refractive aberrations.

Lower Order Aberration. This is the second order series of the Zernike Polynomial expansion, which is sphere, with-the-rule cylinder, and oblique cylinder. The percentage mix between with the rule and oblique cylinder will provide the axis. Therefore, lower order aberration is simply the sphere, cylinder, and axis refractive errors in a patient's vision.

Modulation Transfer Function (MTF). This is the inverse of the Point Spread Function

(PSF). It describes how objects of different spatial details are viewed by the optical system. Both MTF and PSF help to describe the overall performance of an optical system.

Point Spread Function (PSF). The optical image on the retina created by an optical system when a point source of light is viewed. For example, when looking at a star, (point target at optical infinity), the PSF will show what that star will look like on the retina. In other words, what the star looks like to the patient. The ideal PSF would be a sharp point of light on the retina.

Refractive Keratometry. Refractive Ks are calculated based on all of the corneal topographic measurements made within the central disk of information 3mm in diameter. It averages over the entire area to give you the steepest and flattest axes without assuming orthogonality.

Root Mean Square (RMS): RMS is a measure of the magnitude of an aberration. This value is always positive. Total RMS is the total aberration deviation of the eye from the perfect wavefront. You can have RMS values for each specific Zernike term or component of the aberrations of the eye.

Simulated Keratometry. Simulated Keratometry simulates the steep and flat axes readings that would be taken with a traditional keratometer, finding the steepest point at the 3mm annulus, it's corresponding point 180 degrees away, and then assumes that 90 degrees away in each direction are the flattest points.

Tilt. Tilt in the wavefront describes how the PSF is displaced from the optical axis. Tilt terms can arise from a prismatic error in the eye.

Trefoil, Tetrafoil, Pentafoil, Hexafoil. These are higher order aberrations shaped much like 3-sided, 4-sided, 5-sided, 6-sided "potato chip" shapes.

Wavefront Keratometry. WF Ks are calculated based on all of the corneal topographic measurements made within the central disk of information 4mm in diameter. The detected ring data is translated to the closest sphero-cylindrical Zernike fit to give you the steepest and flattest axes without assuming orthogonality.

Zernike Coefficient. Zernike is the name of a mathematician who created polynomial fitting algorithms, which are an infinite series of orthogonal terms. This polynomial fitting routine is mathematically the ideal analysis for evaluating the individual components of an optical system's aberrations. Most typically, Tracey uses 44 terms of the Zernike expansion series, which completes through the 8^{th} order of the Zernike polynomials.

Software License and Warranty Statement

1. DEFINITIONS

1.1. "Licensed Software" shall mean the Tracey-iTrace software, in machine-readable object code form, along with any accompanying documentation, and including any Releases (as defined in Section 3.1) thereto delivered by Tracey to Customer.

1.2. "Hardware" shall mean Tracey equipment and other hardware to be delivered pursuant to this Agreement as set forth in Purchase Agreement. Hardware does not include PC/Laptop Computer hardware, even when purchased through Tracey.

1.3. "iTrace System" shall mean the Tracey Visual Function Analyzer Combination Ray Tracing Aberrometer/Topographer including the Licensed Software and the Hardware, or any component thereof, as identified in Purchase Agreement listed below.

1.4. "PC/Laptop Computer" shall mean Tracey supplied or Customer supplied personal or laptop computer that will run the Tracey iTrace software.

2. SOFTWARE LICENSE

Subject to the terms and conditions of this Agreement, Tracey hereby grants to Customer a nontransferable and nonexclusive license to use the Licensed Software solely as part of the iTrace System. Customer may make two (2), but not more than two (2) copies of the Licensed Software for archival purposes. Customer may not de-compile, reverse engineer or otherwise attempt to derive or modify the source code of the Licensed Software. Tracey reserves all rights and licenses not expressly granted to Customer. Title and copyrights to the Licensed Software and any copies made by Customer remain with Tracey or it suppliers or licensers.

3. MAINTENANCE

3.1. Maintenance Services. For a period of one (1) year following the Effective Date (date of installation) of the Agreement, Tracey shall provide Customer with the following maintenance and support services ("Maintenance Services): (i) enhancements and modifications ("Releases") of the Licensed Software when made generally available to Tracey's other Licensed Software customers; (ii) "hotline" telephone support during Tracey's normal business hours; (iii) updates to the documentation when made generally available to Tracey's other Licensed Software customers; (iv) customer bulletins; and (v) reasonable efforts at error correction with the level of effort commensurate with the severity of the error. Customer may obtain Maintenance Services for additional periods under a separate agreement with Tracey. Customer understands and acknowledges that hardware upgrades may be required to utilize new Releases provided hereunder. Customer is responsible for obtaining warranty/maintenance services on all peripheral hardware, whether purchased from Tracey or independently.

3.2. Exclusions. Notwithstanding the foregoing, Tracey shall not be required to provide any Maintenance Services relating to problems arising out of (i) Customer's failure to implement all Releases and updates to the Licensed Software, (ii) Customer's use of the Licensed Software with Hardware not obtained from Tracey; (iii) any alterations of or additions to the Licensed Software by parties other than Tracey; (iv) use of the Licensed Software in a manner for which it was not designed; (v) use of the Licensed Software in a manner or with hardware which it was not designed ; (vi) accident, negligence or misuse of the Licensed Software; (vii) interconnection of the Licensed Software with other software products not supplied by Tracey; (viii) inaccuracy in data entry. In addition, Tracey's obligation to provide Maintenance Services shall be contingent upon Customer providing Tracey reasonable access to all necessary personnel to answer questions about any problems reported by Customer regarding the Licensed Software.

4. LIMITED WARRANTY

4.1. Warranty.

a. Hardware. Tracey hereby warrants that the Hardware will be free from defects in materials and workmanship under normal use for a period of twelve (12) months from the Effective Date, or, with respect to any repaired, reconditioned or replaced part, ninety (90) days from the date of delivery of such to Customer.

b. Software. Tracey hereby warrants that the media or which the Licensed Software is recorded will free from defects under normal use for a period of ninety (90) days from the date of delivery to Customer. Customer's and exclusive remedy, and Tracey's sole and exclusive liability, under this warrant will be Tracey's replacement of the media.

4.2. Exclusions.

a. The express warranties set forth in Sections 4.1 above will not apply to defects arising out of the causes identified in subsections 3.2(i)-(viii) above.

b. PC/Laptop Computer Hardware. The PC or Laptop Computer is not warranted by Tracey Technologies. Customer is responsible for retaining warranty with the manufacturer of the PC or Laptop Computer, whether purchased through Tracey Technologies or supplied by Customer.

4.3. Warranty Procedures. Customer will send Products with defects covered by the foregoing warranty to a repair facility designated by Tracey. Customer will request authorization from Tracey prior to the return of the Products for repair or replacement by Tracey. Upon such requests, Tracey will provide Customer with an RMA tracer number to be prominently displayed on the shipping container for the defective Product. Once Tracey authorizes the return of any defective Product, Customer will ship such defective Product to the repair facility, freight prepaid, in its original shipping container. If original container is not available, Customer must purchase shipping container from Tracey. If such defective Product is received by Tracey during the applicable warranty period, Tracey will, at its sole option and expense, repair or replace such Product employing at its option new or used Products to make such repair or replacement, and

will ship the repaired or replaced Product to Customer at Customer's expense. As an alternative to return of Products to Tracey, Tracey may, at its option dispatch an authorized technician to resolve warranty concerns at Customer's site. The foregoing states the sole liability and obligation of Tracey arising out of this warranty.

4.4. Inspection and Testing Charge. In the event Tracey's inspection and testing discloses that the returned Product is not defective within the terms of this warranty, the Product will be subject to a one hundred dollar ($100.00) testing charge.

4.5. Stored Data. Customer will be responsible for saving or backing up data contained in any Product returned to Tracey for in warranty or out of warranty repairs or service. TRACEY WILL HAVE NO RESPONSIBILITY FOR SUCH DATA AND WILL HAVE NO LIABILITY ARISING OUT OF DAMAGE TO OR LOSS OF SUCH DATA WHILE THE PRODUCT IS IN TRACEY'S POSSESSION.

4.6. Disclaimer. EXCEPT FOR THE ABOVE EXPRESSED LIMITED WARRANTY SET FORTH IN SECTION 4.1 ABOVE, TRACEY MAKES AND CUSTOMER RECEIVES NO WARRANTIES OR CONDITIONS ON THE PRODUCTS, EXPRESS, IMPLIED, STATUTORY OR IN ANY OTHER PROVISION OF THE AGREEMENT OR COMMUNICATION WITH CUSTOMER, AND TRACEY SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OR MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE. TRACEY DOES NOT WARRANT THAT THE LICENSED SOFTWARE WILL MEET CUSTOMER'S REQUIREMENTS OR THAT THE OPERATION OF THE LICENSED SOFTWARE WILL BE UNINTERRUPTED OR ERROR FREE. CUSTOMER ASSUMES THAT RESPONSIBILITY FOR THE INSTALLATION, USE, AND RESULTS OBTAINED FROM THE LICENSED SOFTWARE. SOME STATES DO NOT ALLOW THE EXCLUSION OF IMPLIED WARRANTIES SO THE ABOVE EXCLUSIONS MAY NOT APPLY TO CUSTOMER. THIS LICENSE GIVES CUSTOMER SPECIFIC LEGAL RIGHTS. CUSTOMER MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM STATE TO STATE.

5. TERMINATION.

This Agreement is effective until terminated. Customer may terminate this Agreement upon notice to Tracey at any time by removing from Customer's system and destroying all copies of the Licensed Software. Unauthorized copying of the Software or the accompanying documentation or otherwise failing to comply with the terms and conditions of the Agreement will result in automatic termination of this license and will make available to Tracey other legal remedies. Upon termination of this Agreement, the license granted herein will terminate and Customer must immediately destroy the Licensed Software, and all copies thereof.

6. EXPORT RESTRICTION.

Customer agrees that Customer will not export or re-export the Software in any form

without the appropriate United States and foreign government licenses. Customer's failure to comply with this provision is a material breach of this Agreement.

7. U.S. GOVERNMENT RESTRICTED RIGHTS.

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8. LIMITATION OF LIABILITY.

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9. MISCELLANEOUS.

This is the entire agreement between the parties relating to the subject matter hereof and no waiver or modification of the Agreement shall be valid unless in writing signed by each party. The waiver of a breach of any term hereof shall in no way be construed as a waiver of any other term or breach hereof. If any provisions of this Agreement shall be held by a court of competent jurisdiction to be contrary to law, the remaining provisions of this Agreement shall remain in full force and effect. Tracey shall have no liability for its failure to perform its obligations hereunder when due to circumstances beyond Tracey's reasonable control. This Agreement shall inure to the benefit of and be binding upon each party's successors and assigns. This Agreement is governed by the laws of the State of Texas without reference to conflict of laws principles. All disputes arising out of this Agreement shall be subject to the exclusive jurisdiction of the State and Federal courts located in Houston, Texas and the parties agree and submit to the personal and exclusive jurisdiction and venue of these courts.

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