Tracey VFA
Visual Function Analyzer

Model:

iTrace™

Instructions for Use

TRACEY™ TECHNOLOGIES
defining vision analysis

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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.

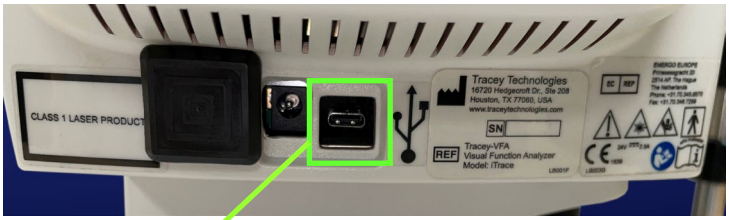
Observe all contra indications, warnings, and precautions noted on the precautionary labels located at the base of the iTrace near the power and USB ports and those within this manual.

	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

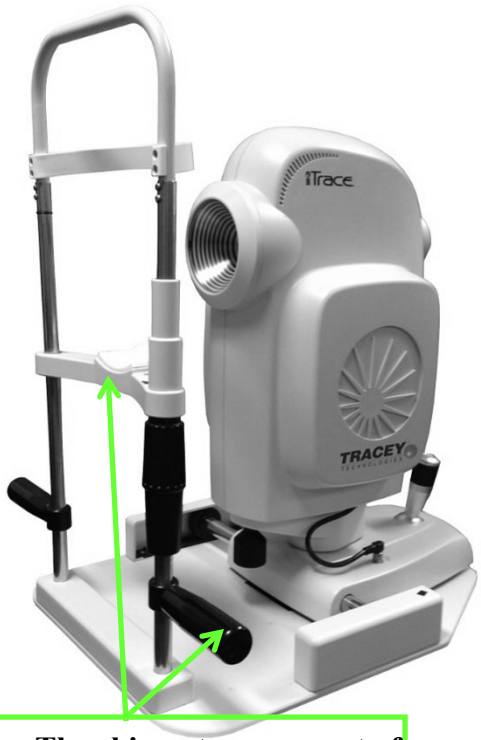
	cabling. Otherwise, degradation of the performance of the iTrace could result.
⚠	WARNING: During use of the iTrace while capturing patient exams, the operator should take care not to touch both the patient and the data acquisition unit (DAU) enclosure simultaneously.

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.

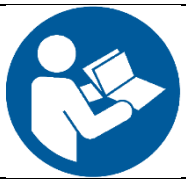
The user, as the responsible organization, shall refer to the requirements of IEC 60601-1:2005 +A1:2012 + A2:2020 when incorporating the Tracey iTrace Visual Function Analyzer into a Medical Electrical System (including the peripheral computer, table or other external system.)

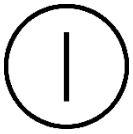
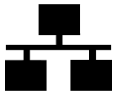
Reference	Tests	Basic EMC Standard	Limits	Compliant
EN/IEC 60601-1-2: 2020	Radiated Emissions	EN55011/CISPR 11	Group 1, Class A	Yes
	Conducted Emissions	EN55011/CISPR 11	Group 1, Class A	Yes
	Harmonics and Flicker	IEC 61000-3-2 &-3	Class A	Yes
	ESD	IEC 61000-4-2	±8 kV Contact ±2 kV, ±4kV, ±8kV, ±15kV 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

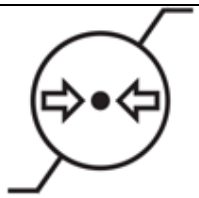
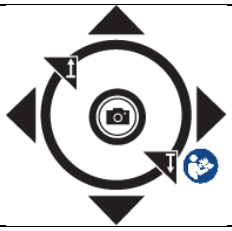
No deviations from standards have been used.

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*:

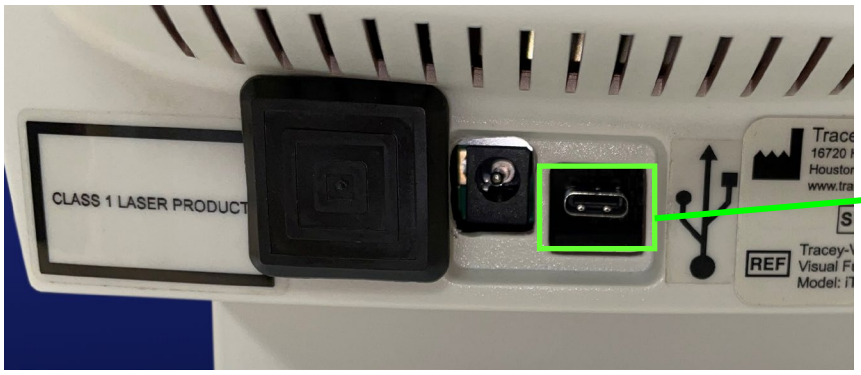
- CPU: Intel Core i7 or equivalent
- Graphic Display Resolution:
  - HD 1360x768, or
  - HD+ 1600x900, or
  - Full HD 1920x1080
- 16 GB RAM (Main Memory)
- HD Capacity: 1 TB GB SSD Minimum
- 2 USB 3.0 Ports for connecting iTrace acquisition unit and color printer
- Integrated 10/100 Ethernet LAN
- Microsoft 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 16.)

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.

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.

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

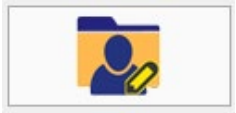
The joystick is used to position the DAU in front of the patient's eye for data acquisition. The four operations performed by moving the joystick are listed below:

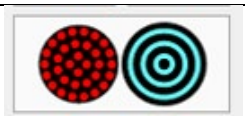
To move the image left or right in small increments, move the joystick in the left or right direction.
To move the image up or down, twist the joystick clockwise (up) or counter-clockwise (down).
To focus the image in small increments, tilt the joystick forward or backward.
To capture an image while 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.

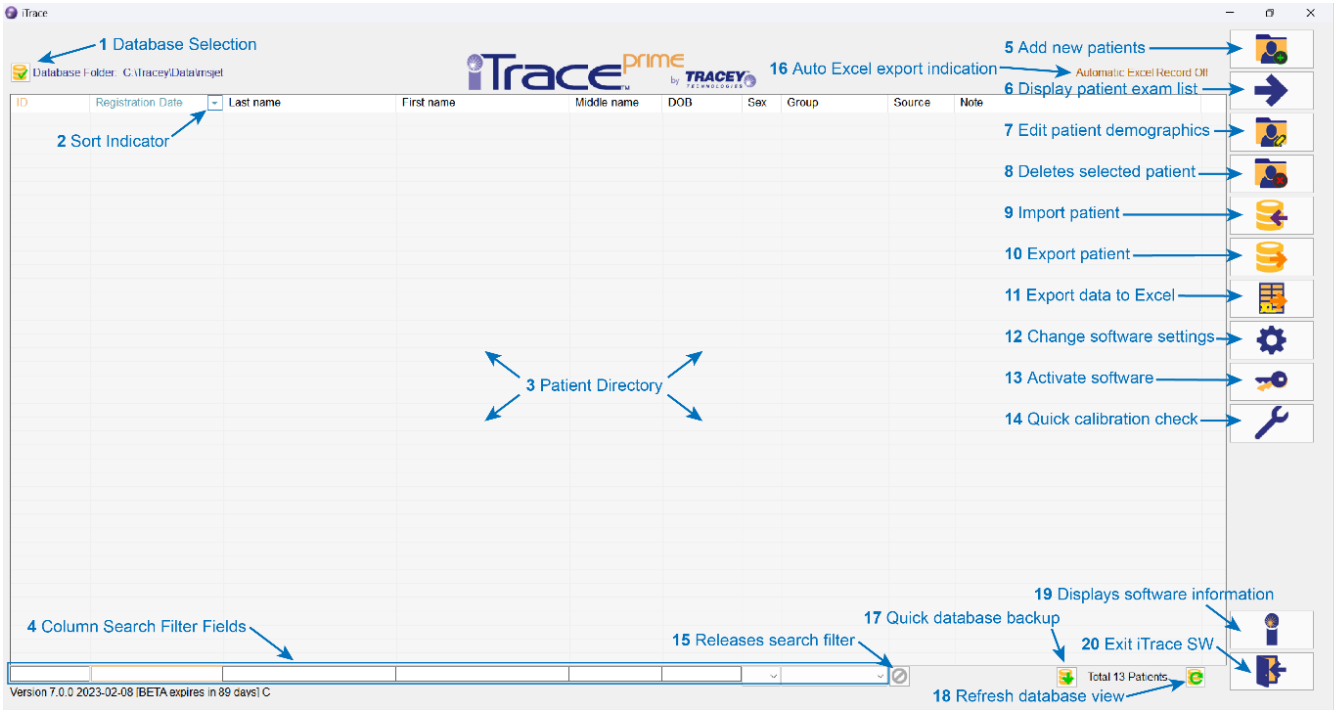
3. Click the *Start* button on the computer and select *Shut Down* or *Turn Off Computer* from the menu and the *Turn Off* option in the pop-up window if presented. The computer now will shut down.

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.

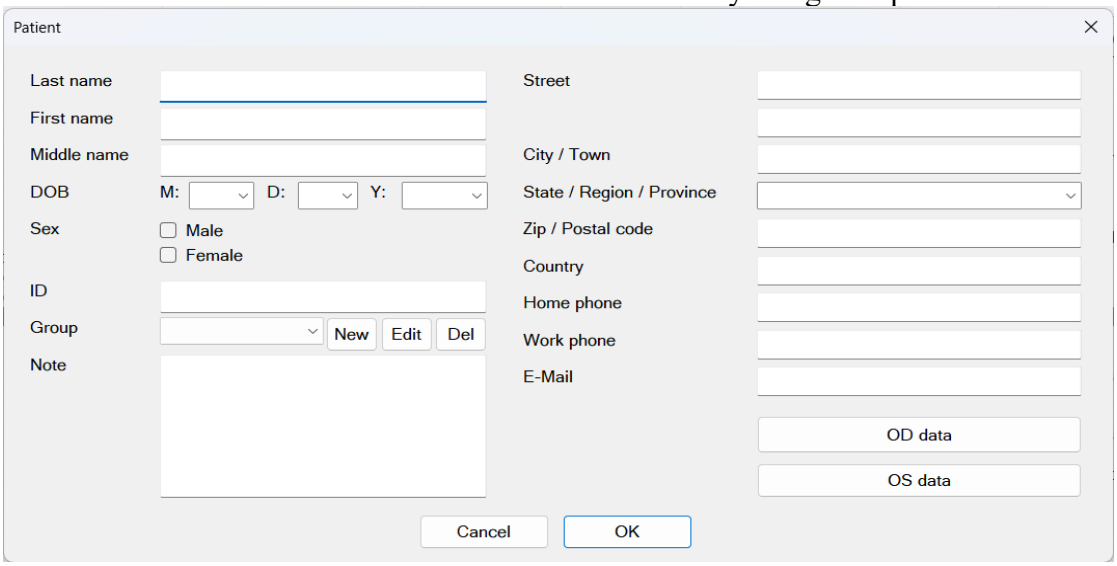
18 Clicking  will **Refresh** the database to include patients and exams recently added on the network. The total **Number of Patients** in the database is also shown in this area.

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.

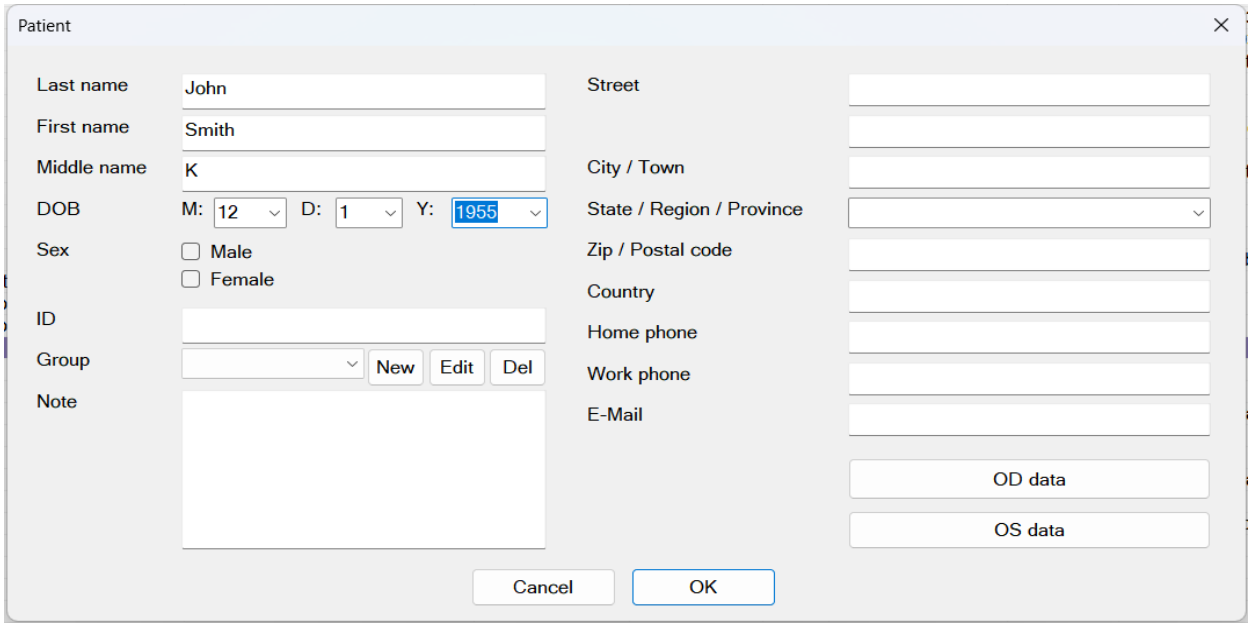
Click on the drop-down list arrow in *Group* field to select a list of previously entered data.

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.

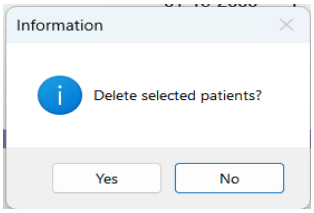
Note: Do not use the following characters in the Patient Last name, First name or Middle name fields: **\ / : * ? " < > |**

To Delete a Patient

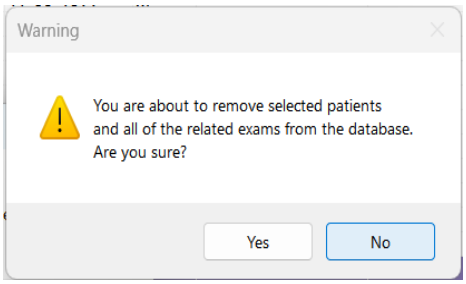
1. Select one patient or multiple patients by holding the *Ctrl* button while selecting each patient.

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.



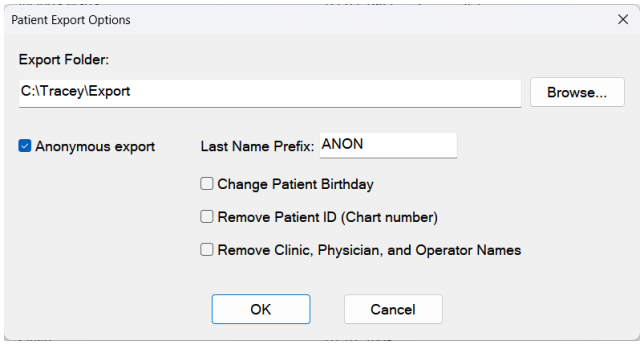
To Export Patient Data

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.

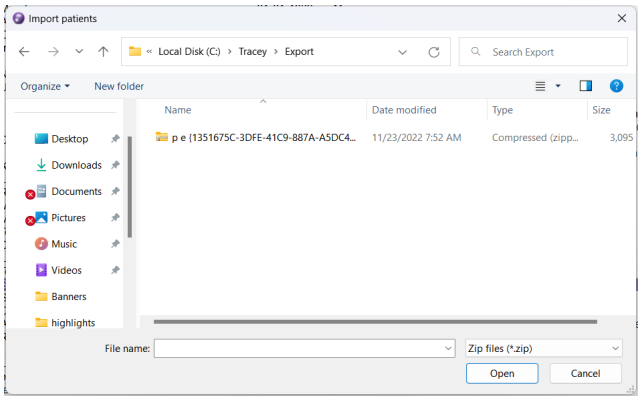
4. The Patient's data can be anonymized for privacy compliance by clicking the box next to **Anonymous export**. Various anonymization options are available to select for the export with the option to choose several for the level of privacy control you are seeking.



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***.

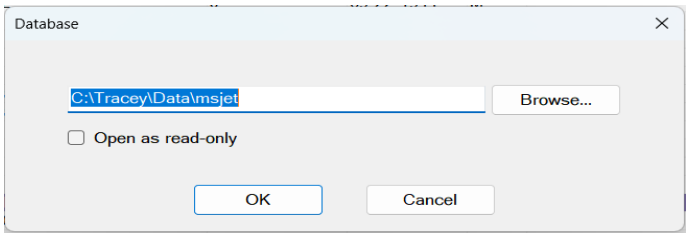
The patient is added to the database.



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.



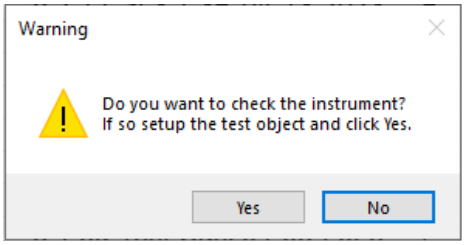
3. Click ***OK***. The iTrace software will store your patient data in this new database until you return to this screen and select another database.

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.

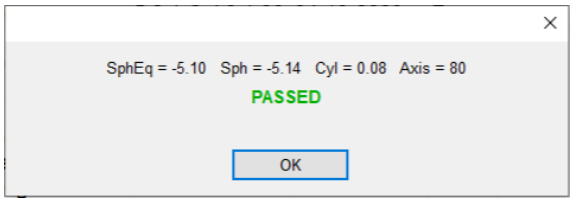
a. Click . The following dialog box will appear.

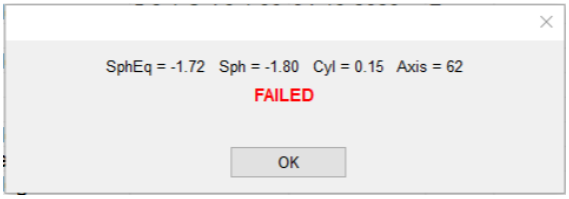


b. The center hole of the iTrace's Placido disk is threaded for the use of the calibration verification tool – a cylindrical object that shipped with your iTrace DAU. Insert the calibration verification tool into the center hole and turn until slightly tightened.

c. Click ***Yes***.

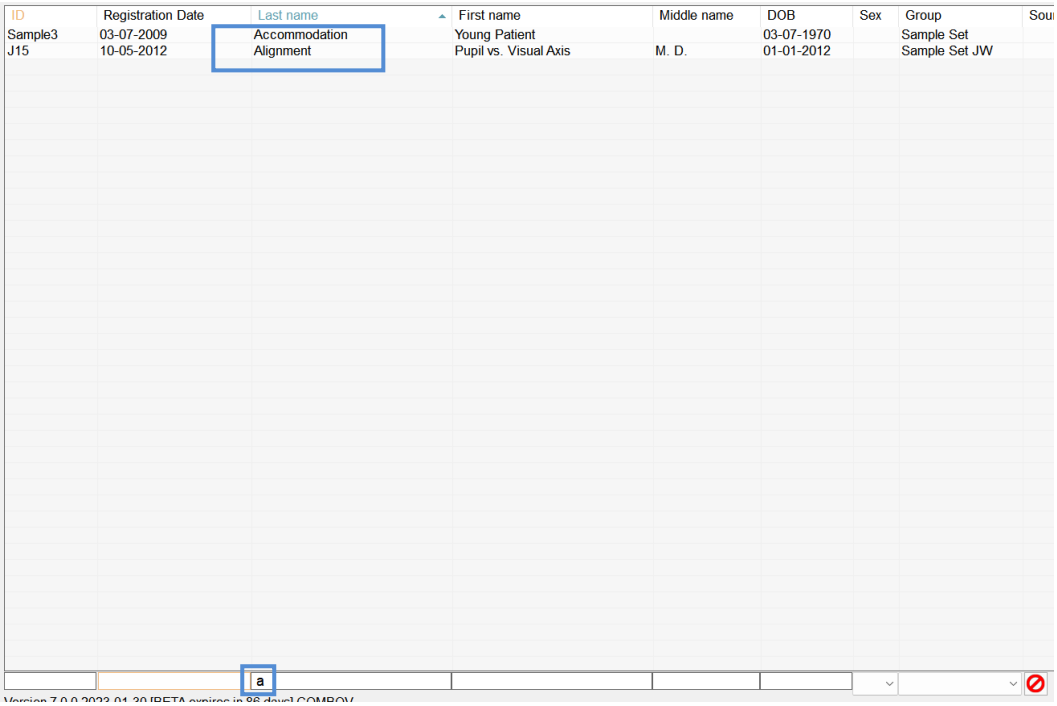
d. The software will automatically capture the exam and provide a window indicating if the calibration was within the accepted range. If the window indicates the test Failed, please contact Tracey customer support at **(281) 445-1666** or via email to **service@traceytech.com**.





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

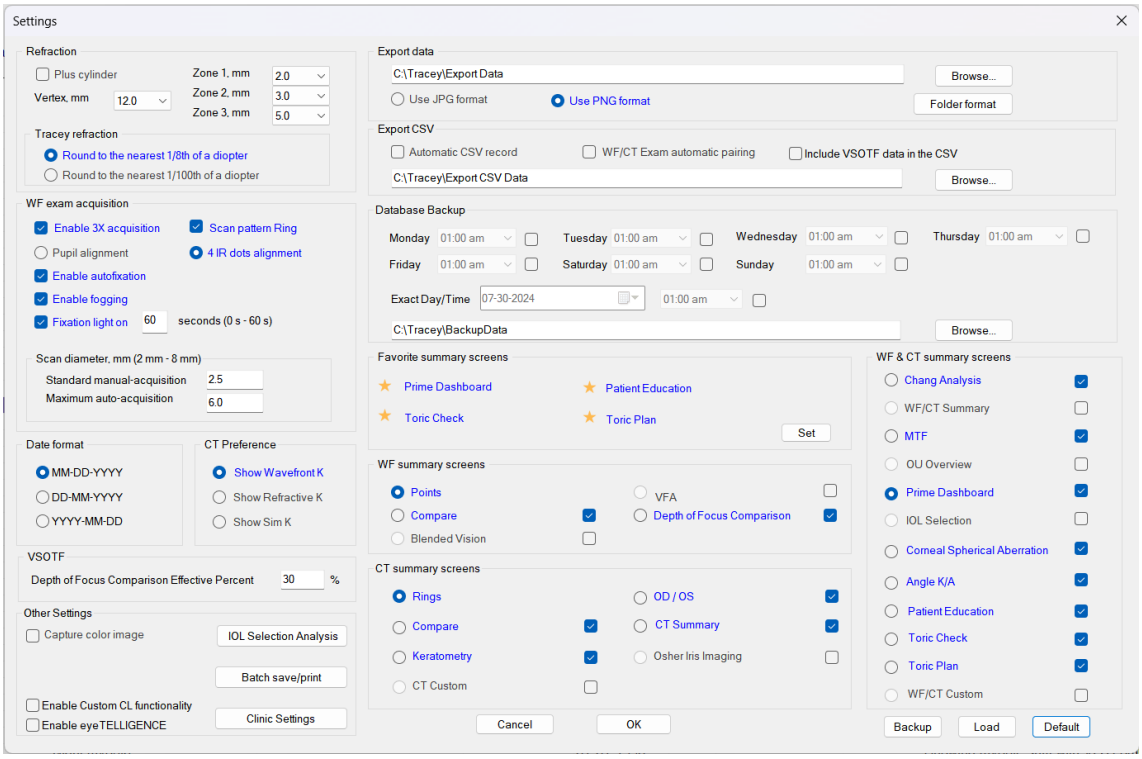
If using the iTrace software as a Viewer, you should refresh the database periodically. When looking for a patient name or exam that you expected to find and could not, selecting the Refresh button will ensure that you are viewing the most recent database entries. To refresh the database:

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.

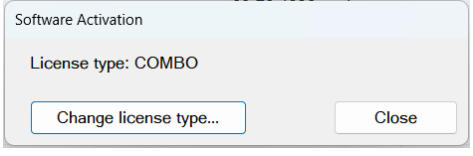
3. If you make custom changes, Tracey recommends that you **backup your settings** file in the event you make inadvertent changes and wish to re-load custom settings.

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.

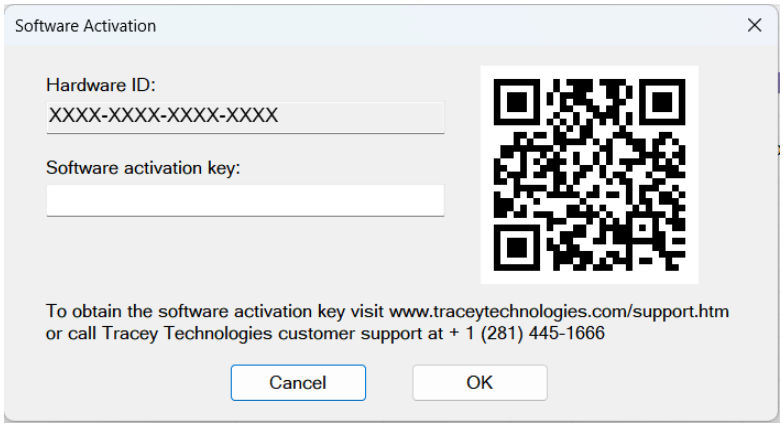
1. Click on  .

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.

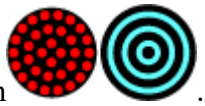
5. Make sure the patient's forehead is resting firmly and comfortably on the forehead strap.

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

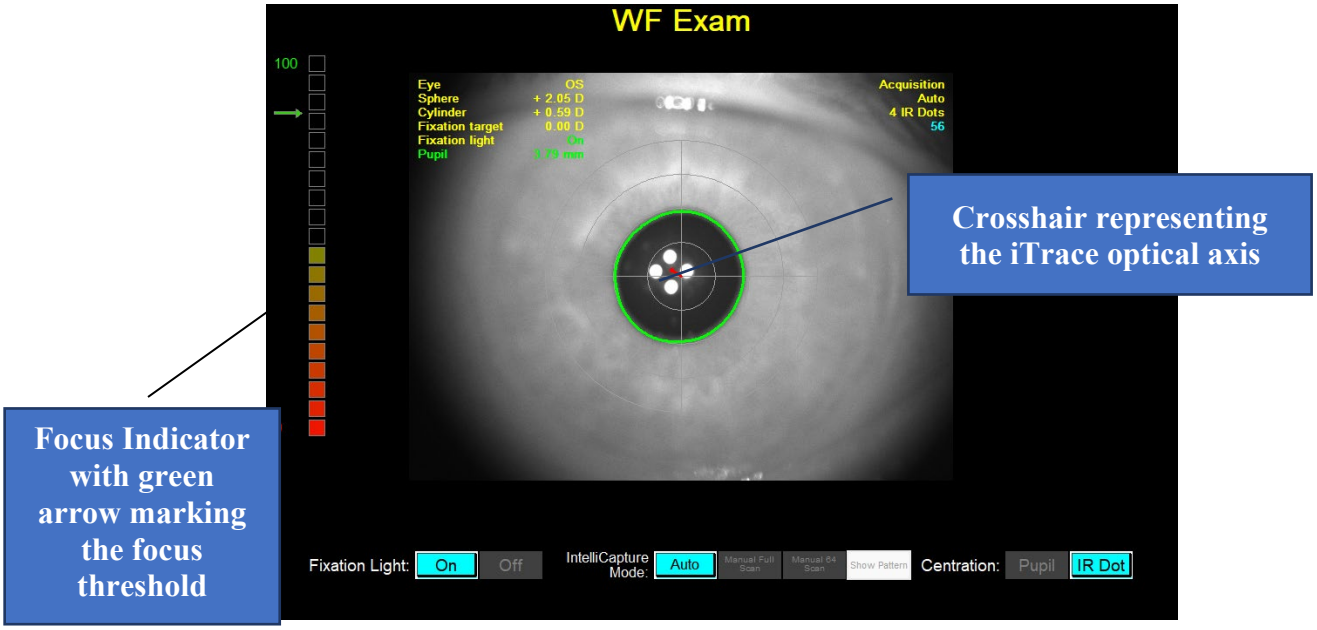
Automatic Multi-Capture or Single Capture Mode

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.

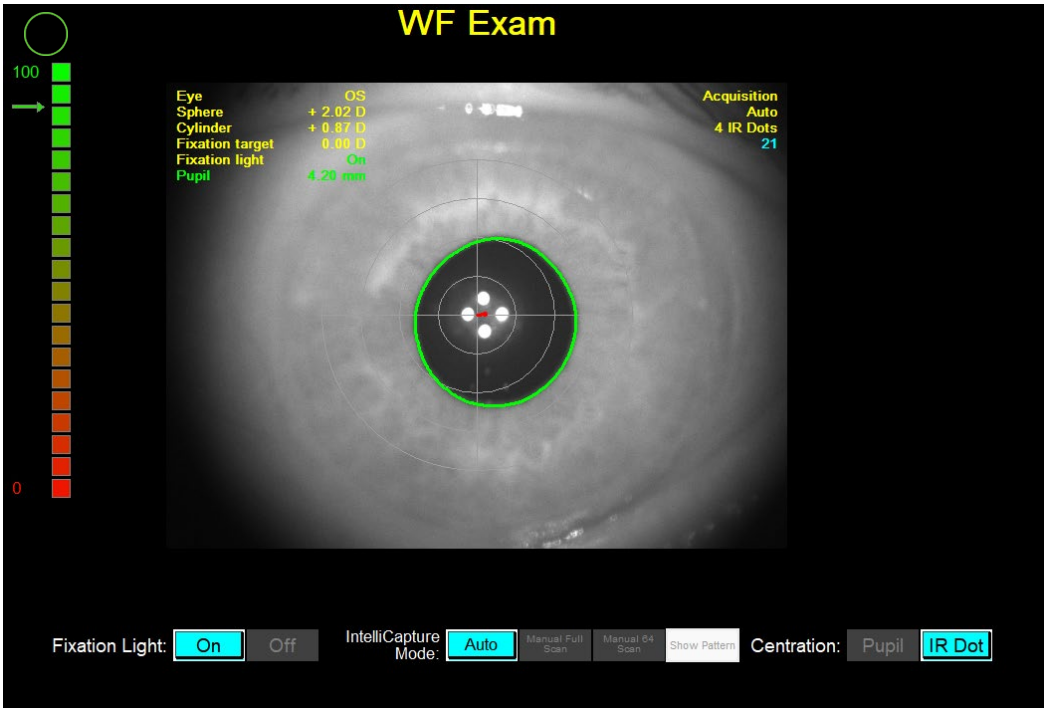
6. You will see four white dots inside the patient's pupil (first Purkinje images), approximately aligned to the patient's visual axis, and a red line appearing from the center of the dots to the crosshair. Collapse the red line until the crosshair and center of the 4 dots are aligned.

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.

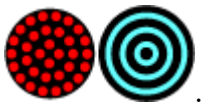
11. After the capture process is completed, the software will show you one of three screens: (1) The Exam Results of the IntelliSelected WF exam in which the system compared the three scans and chose the best one, (2) the WF Verification screen if the acceptance criteria for IntelliSelection was not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

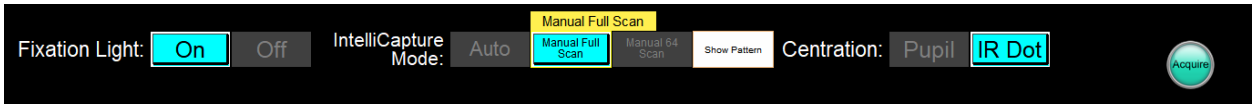
3. You will see a central cross hair mark representing the iTrace's optical axis and you will see a bar on the left side of the screen. This bar indicates the image contrast quality representing how far you are from focus.

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.

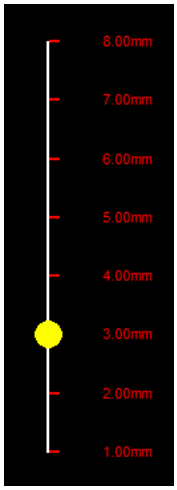
5. The patient will see a red dot (if the fixation target is turned on). Ask the patient to look at the red dot.

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.

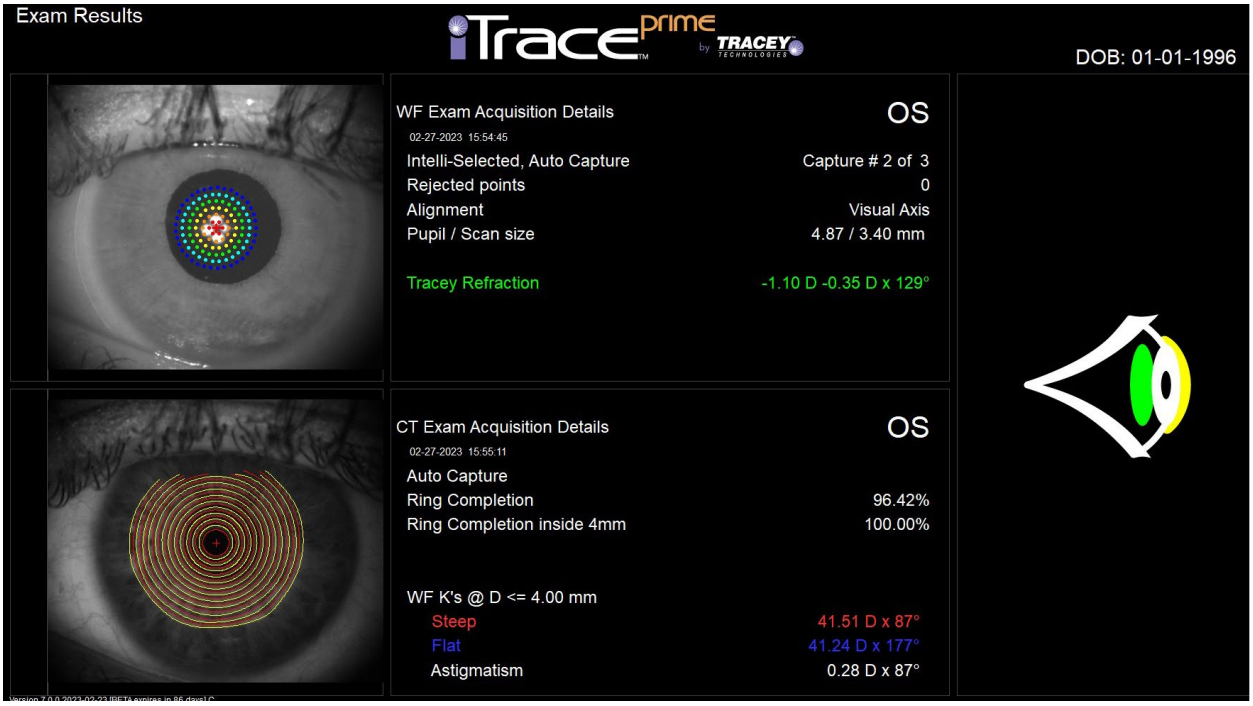
NOTE: During the WF capture process the iTrace will fire the 785 nm wavelength laser for approximately 0.25 seconds during the wavefront exam(s) capture.

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

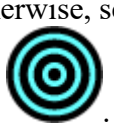
Whether capturing in automatic or manual mode, after the exam(s) are captured and either a successful IntelliSelection was made by the software or a user-acceptance of the exam was made, you will be presented with the Exam Results page. If you chose a dual WF and CT exam, then the CT capture window will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

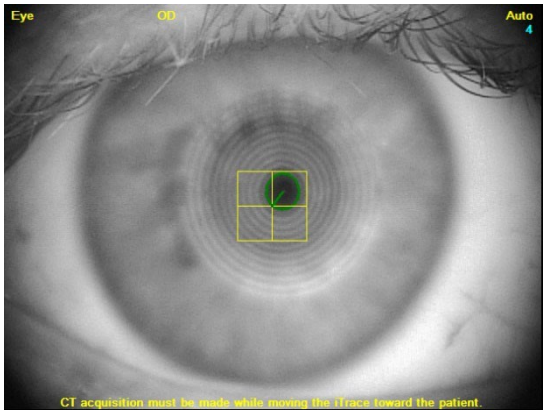


Capturing a Corneal Topography Exam

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.

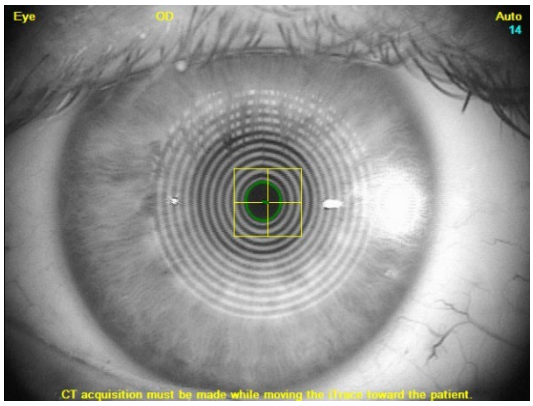
3. A video image will appear on the computer screen, showing the eye, the rings and the central target. The software will outline the middle ring with a green line.



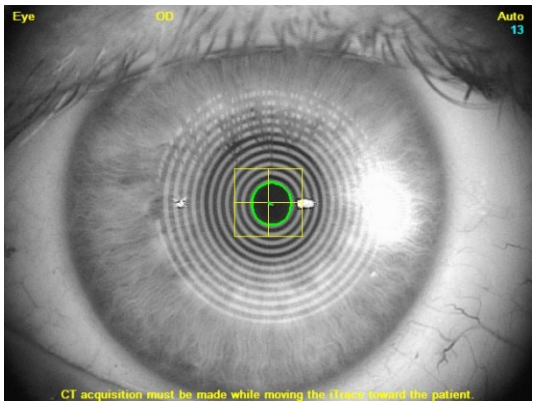
CT Acquisition window before operator centers and focuses image

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.

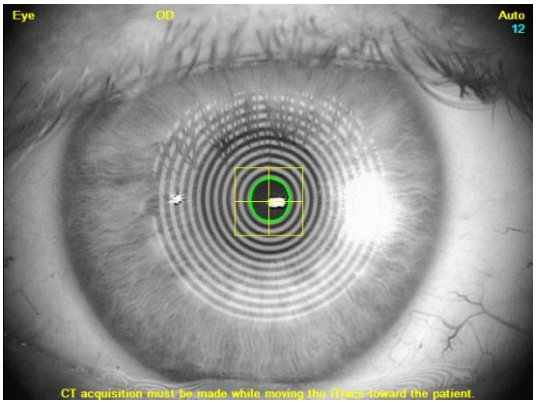


CT Acquisition window with image properly centered, slowly moving toward patient.



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.

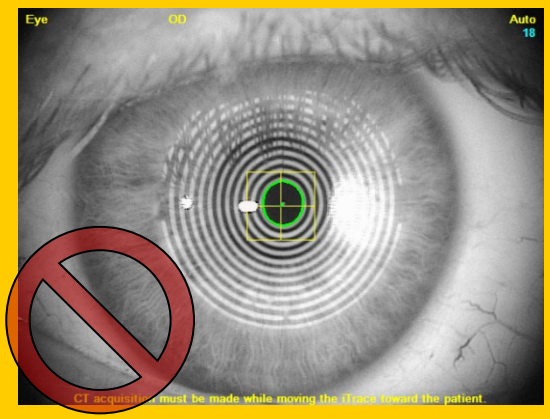


Figure 5-11 Laser focusing spot on the left side of screen indicating the DAU is too close to the patient and the image is out of focus.

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.

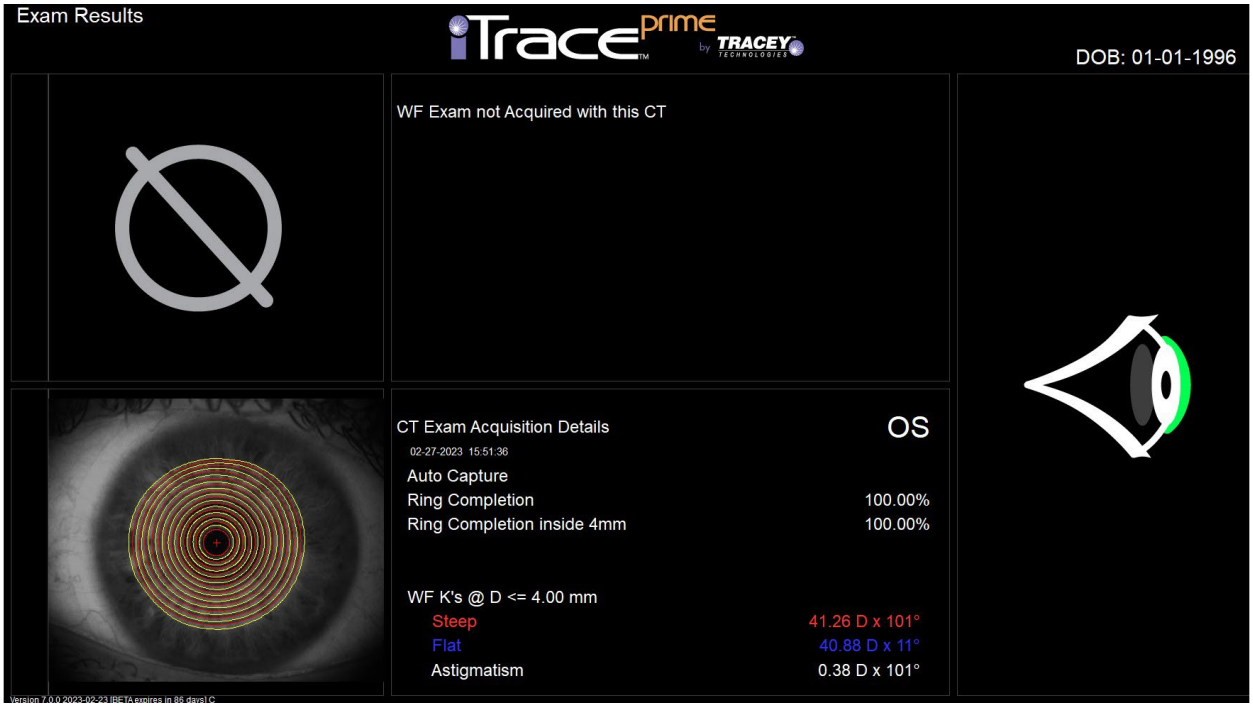
NOTE: The manual CT acquisition should only be used when absolutely necessary. Using the correct working distance in topography is extremely important and the laser spot must be in the proper location to provide the correct working distance. **The exam readings will not be accurate if the CT exam is 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

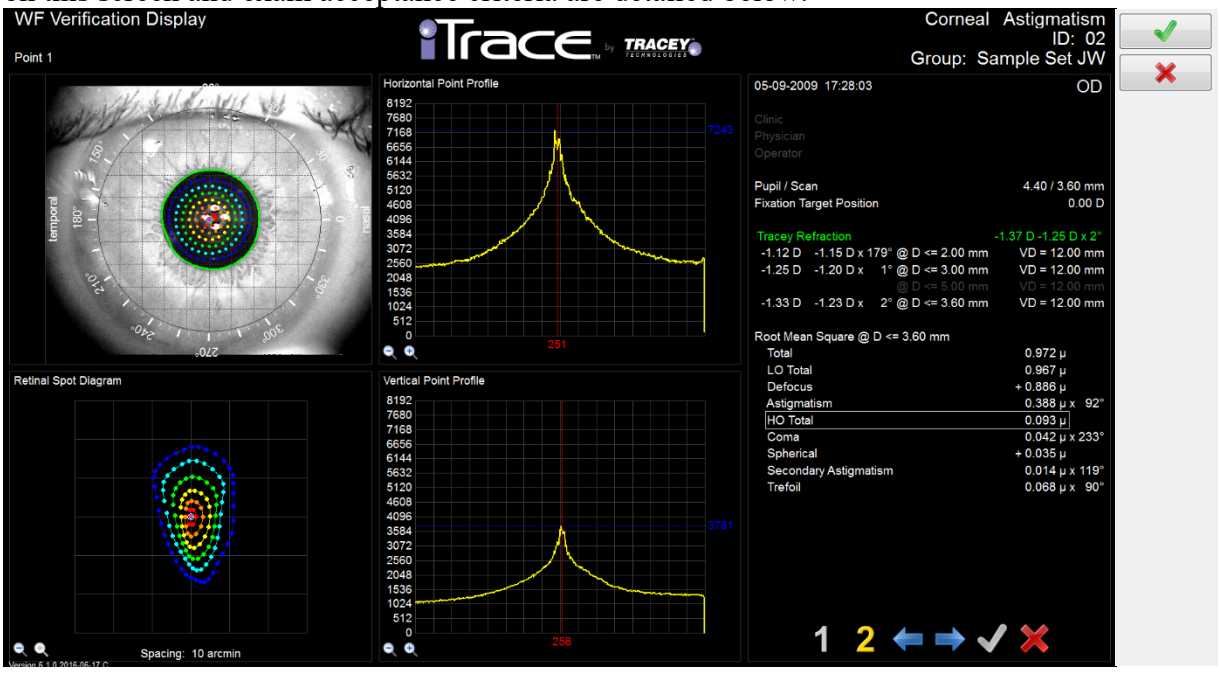
After the CT exam is captured, if it met acceptance criteria for ring detection (85% for the entire measured cornea and 99% within central 4mm zone of cornea) the software will present the Exam Results page. If acceptance criteria were not met, you will see the CT Exam Verification display where you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



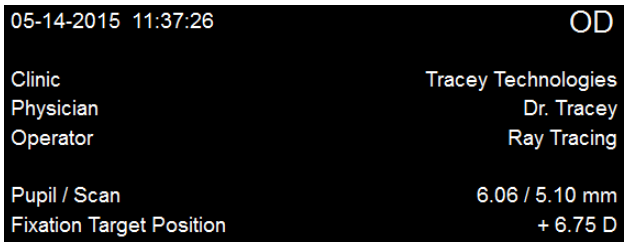
Eye Image

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

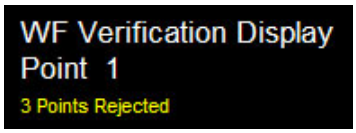
the detected pupil contour. The user should analyze the image to ensure that the scan pattern is within the pupil margin. If the scan pattern encroaches on or out of the pupil margin, or if there is an evident blink, the exam should be retaken. If the pupil was not properly detected, it can be edited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

Summary Data Screen

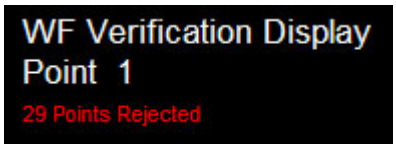
The patient data screen displays exam date and time, location, physician and operator detail filled in at the time of patient examination, the pupil diameter (best fit circle to actual pupil shape), the scan diameter (distance from center of laser spot on one side to the center of laser spot on the opposing 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.

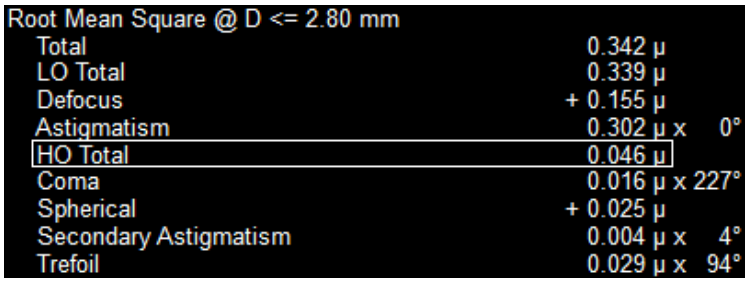
Refraction Data Screen

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.

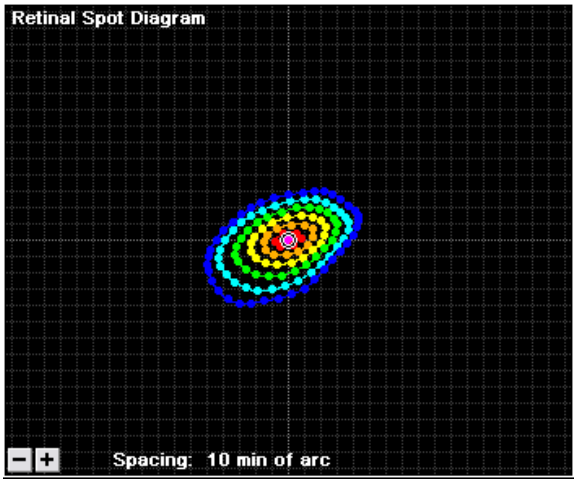
Notes

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.

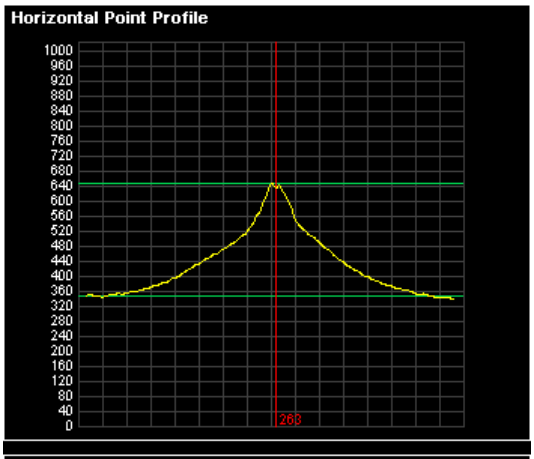
RSD Display

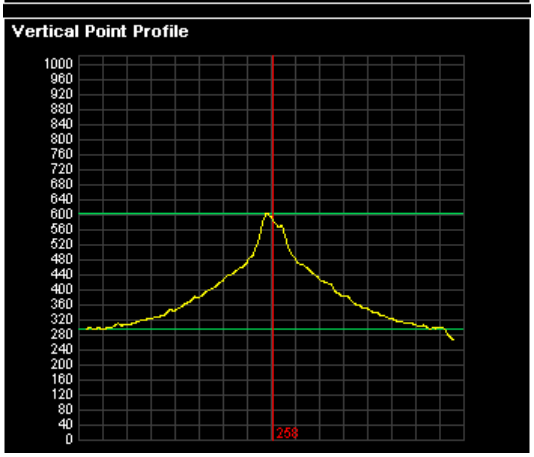
The RSD (Retinal Spot Diagram) is shown at bottom left of screen. This image showed a good data acquisition.



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:

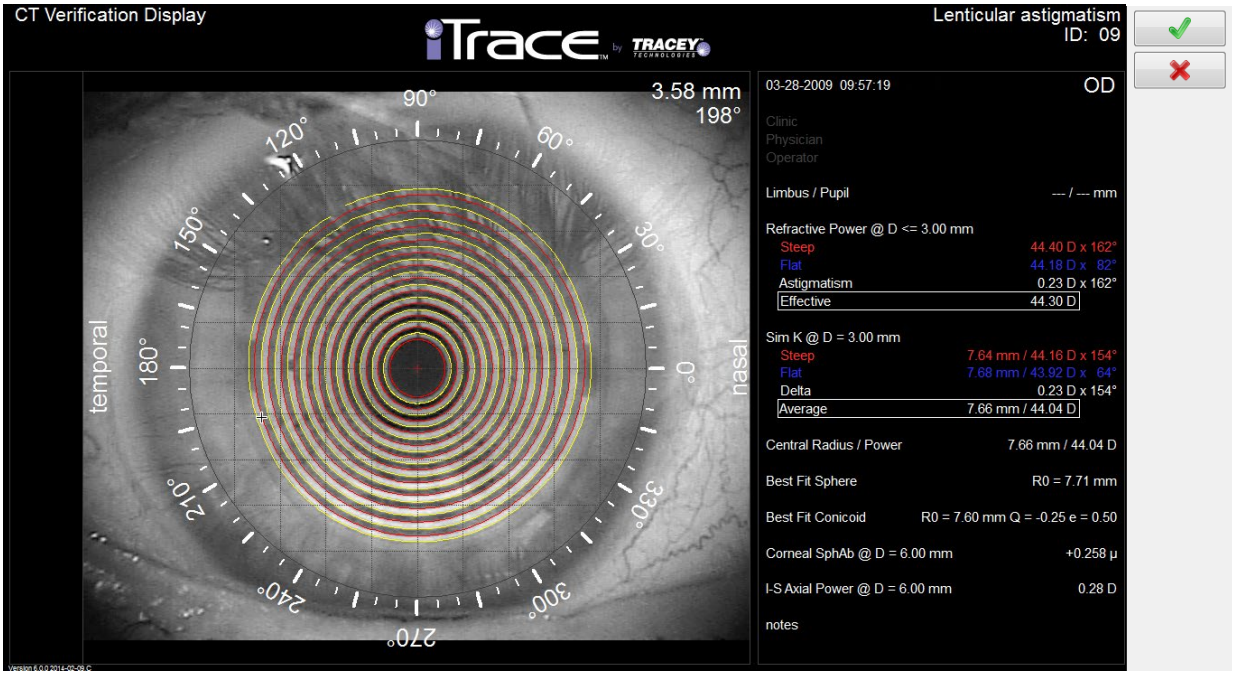
1. Click the  in the top right corner of the display. The acquired exam will be deleted and the software returns to the Exam List screen.

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 **Error! Bookmark not defined.**. This is recommended to ensure accurate Angle Alpha measurements.

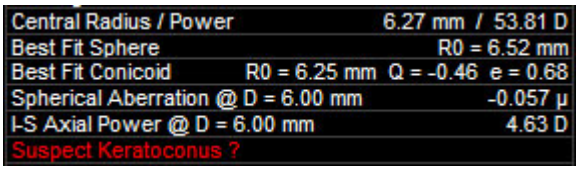
Refractive Power Data

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.

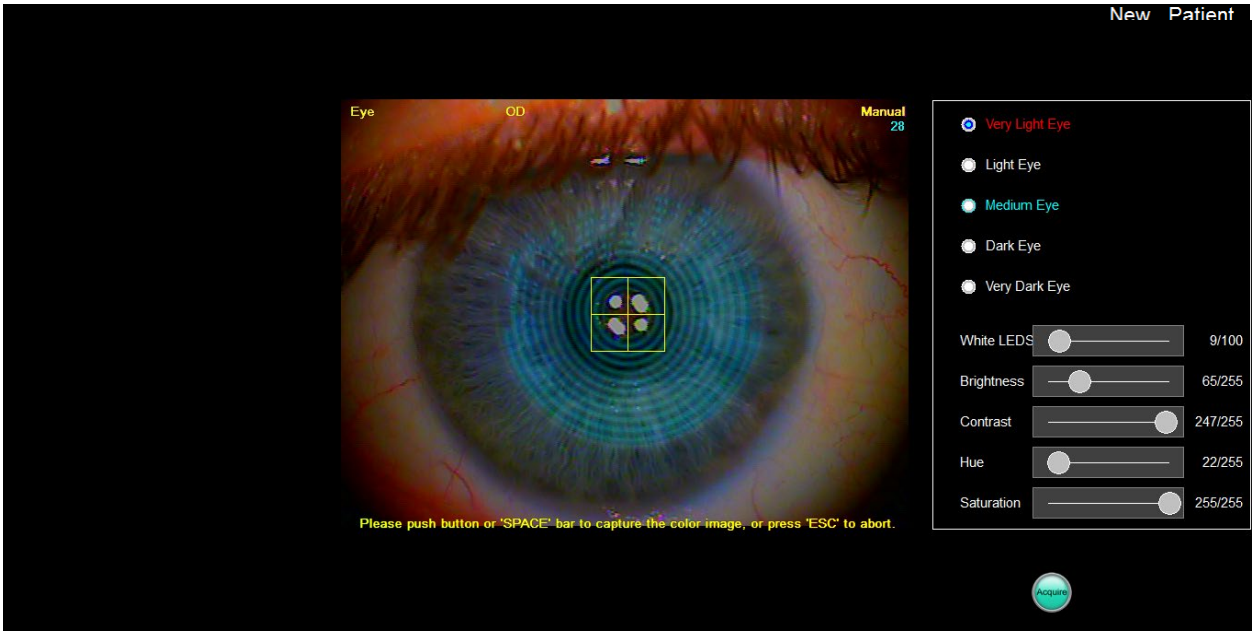
To acquire a color image automatically:

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.

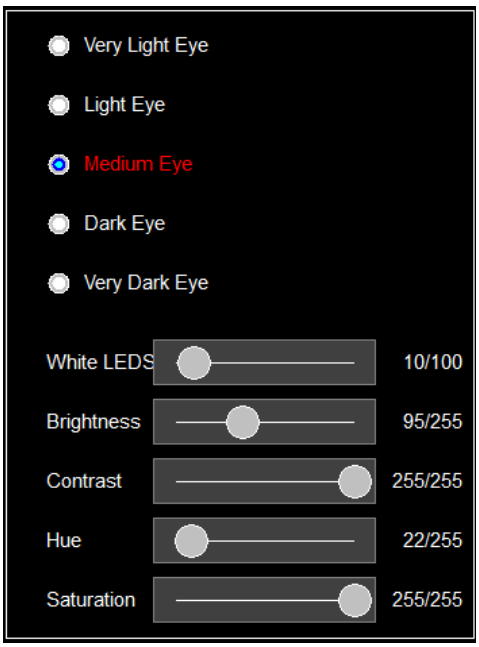
To acquire a color image manually:

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.

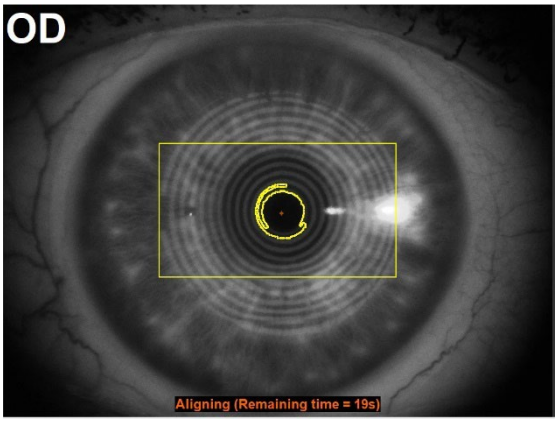
5. Patient distance from the device is important, make sure to get the patient close enough to the machine so the patient doesn't need to lean over.

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.

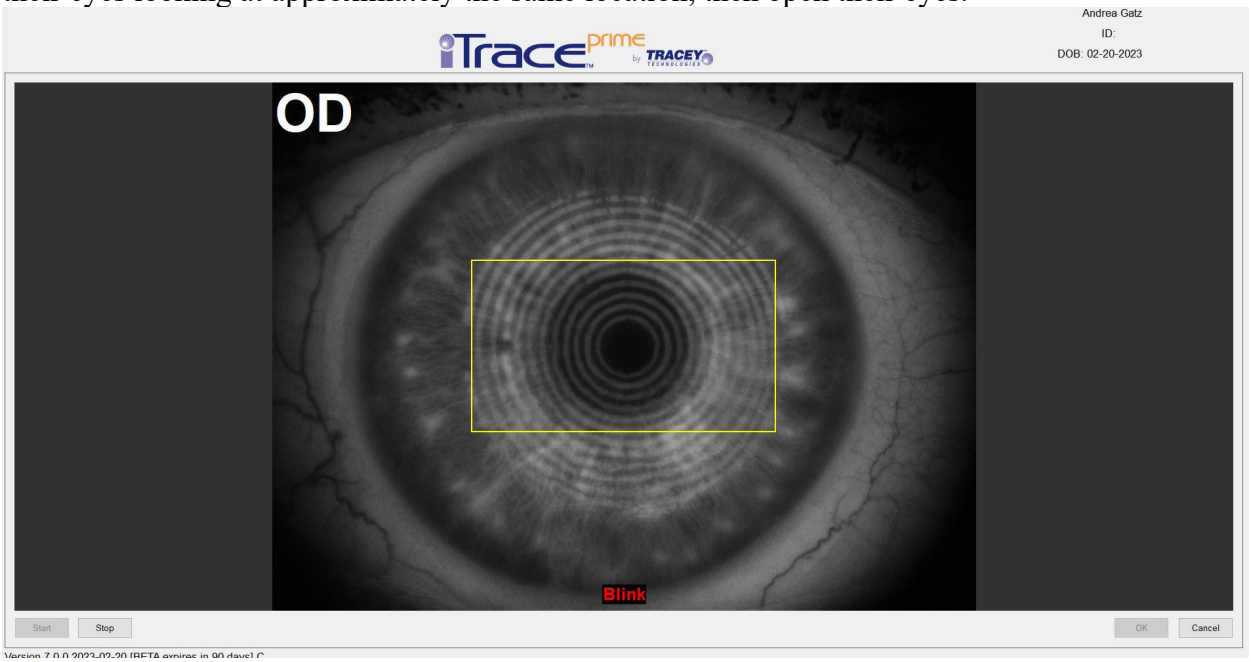
4. Proceed by moving the device up and down until the central ring is centered in the rectangle and the white dot is approximately the same height as the circle center. Then move the device forward, the white dot will move horizontally from the right to the left, once the white dot overlaps with the 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.

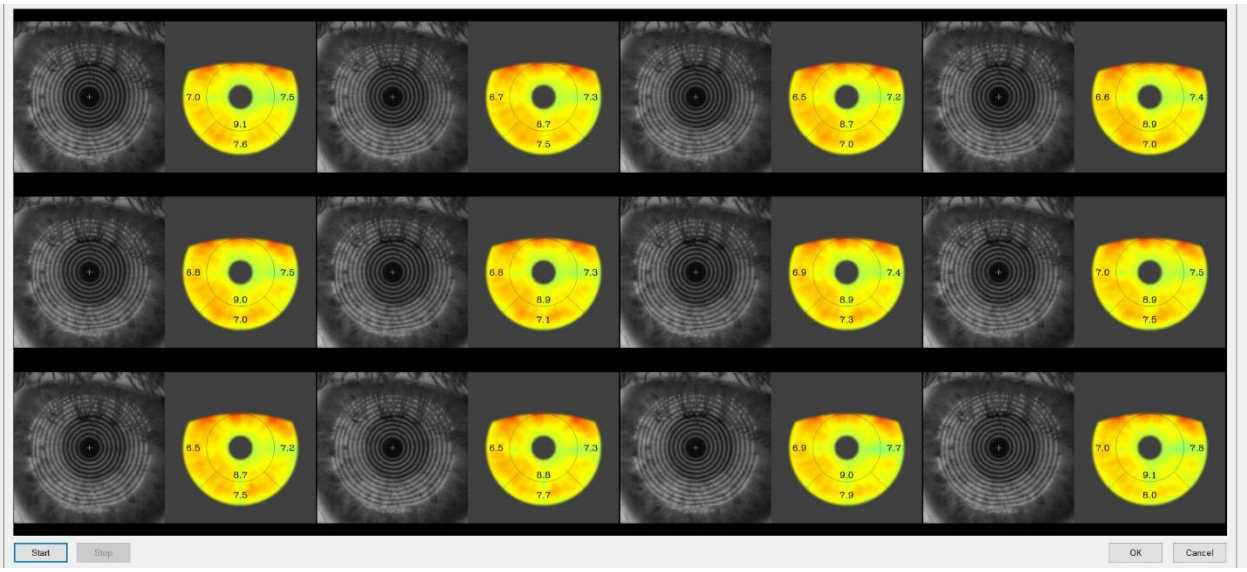


6. The countdown timer will restart after the eye opens. At this stage instruct the patient to keep looking at the red dot and do not blink while the image capturing is taking place. During the capture process, make sure to keep the central ring of the Placido inside the alignment rectangle. The exam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

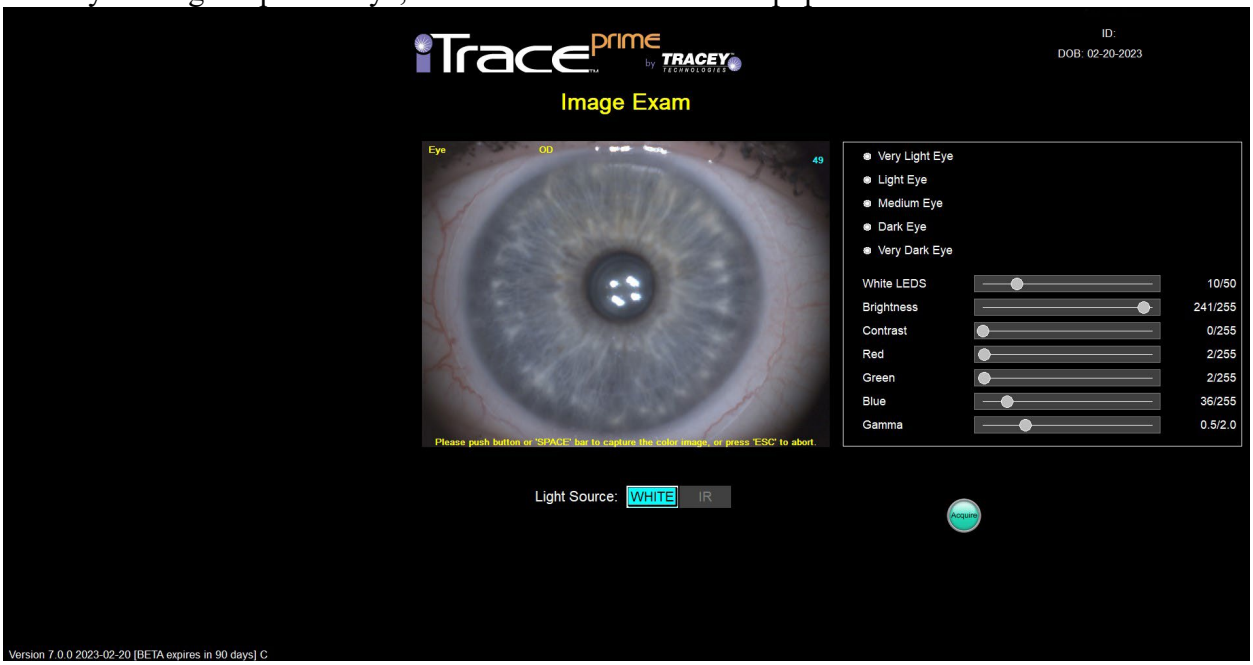
The iTrace will allow you to capture a single external eye image using either the Color mode or Infrared (IR). Capturing as a stand-along acquisition process will not allow the color image to be used in the Toric Planner display.

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.

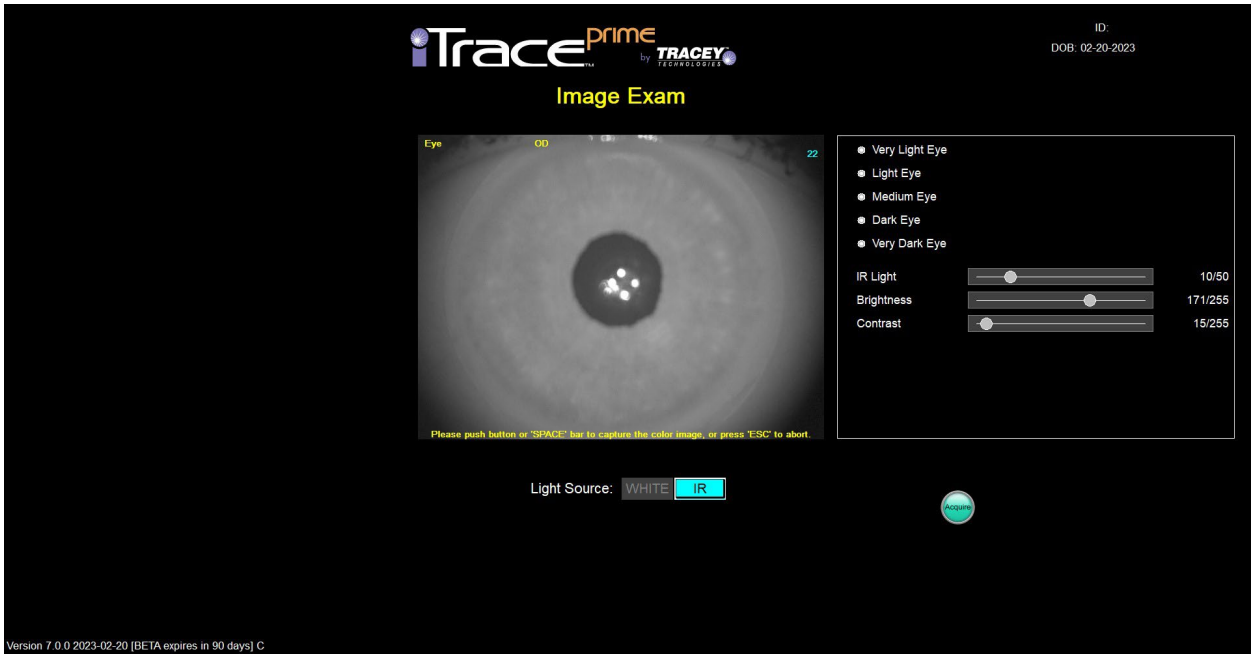
9. When patient is properly fixated and the DAU is centered, press the button on the joystick, the spacebar on the keyboard, or the Acquire button on screen. The image captures.

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 7 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.

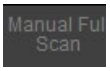
Verifying Wavefront Calibration

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

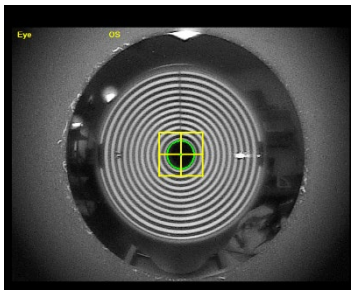
1 Insert CT Calibration Verification tool into the receptacle on the chinrest. The chinrest may need to be lowered so that the tool can be properly measured by the iTrace.

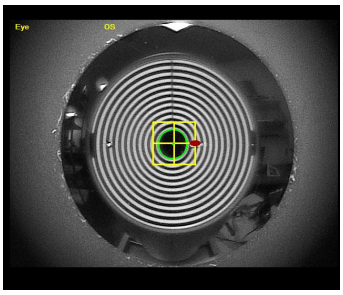
2 Ensure the cover of the verification sphere is fully open.

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”.

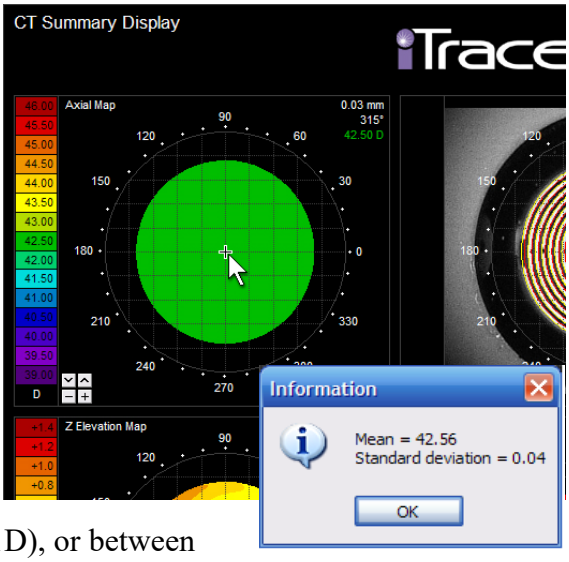
5 Center the machine on the verification sphere and move the machine in or out to auto-capture the CT exam.





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.

Contact Information

For Customer Service Contact:

Customer Support: (281) 445-1666
Fax: (281) 445-3050
E-mail: service@traceytech.com

Or visit

www.traceytechnologies.com/support