SL-OCT™
Slit Lamp-OCT™
Anterior Segment Imaging

Operating Instructions
Software Version 1.0.2.0

**HEIDELBERG
ENGINEERING**

This product is manufactured under one or more of the following patents:

DE 100 35 835, DE 198 12 297, EP 0 941 692, US 6,095,648

TABLE OF CONTENTS

1   GENERAL INFORMATION

This is an introduction to the Heidelberg Slit Lamp-OCT™ (SL-OCT™) with operating software version 1.0.2.0. These operation instructions also contain important safety information.

1.1   Intended use

The SL-OCT is a tomographic device for the viewing and axial, cross sectional imaging of anterior ocular structures. It is used for the in vivo imaging and measurement of the anterior segment structures of the eye.

The SL-OCT is intended for use as a diagnostic device to assist in the diagnosis of the anterior segment of the eye.

1.2   Operational Environment

The intended operational environment of the device is a clinical setting, medical practise or similar location under the direction of a trained ophthalmologist or optometrist.

1.3   Principles of the technology

The SL-OCT combines slit lamp technology with optical coherence tomography (OCT). The OCT imaging component of the SL-OCT is of a time domain OCT interferometer. The principle of time domain OCT is well known from the literature and is described elsewhere. The SL-OCT device uses a short coherent infrared light source. The light source is a super-luminescent light emitting diode with a central wavelength around 1310 nm. The source beam is divided into two components, the sample beam which enters and is reflected back from the eye and the reference beam which passes a delay line. The length of the delay line is modulated over the measurement depth within one A-scan. The beams are recombined, and the OCT signal is calculated from the resulting interference patterns. This OCT signal is used to produce an A-scan with precise depth information. The SL-OCT scanning beam moves across the eye providing multiple A-scans which are combined to form a two-dimensional, cross-section scan, like an ultrasound B-scan.

1.4   Cautions, Warnings, and Contraindications

WARNING   Carefully read the operation manual before operating the device. Misuse of the device may lead to incorrect diagnostic results.

WARNING   Do not open the device component housings. Doing so may result in electrical shock and laser radiation.

WARNING   Do not use the device outside the scope of its "Intended use". Doing so may lead to malfunctions or damage of the device.

WARNING   Do not use PCs, components or accessories that have not been approved by Heidelberg Engineering. Do not install other software as this may interfere with the functionality of the Heidelberg Engineering software or equipment. This could include damage to the system as well as incorrect measurement results.

WARNING   Do not use a network connection without network isolation in accordance with IEC 60601-1. In the event of a failure in the network, user and patient could be at risk of electrical shock.

WARNING   Make sure that the environmental requirements are met when the system is operated. Exceeding environmental conditions may damage the system or lead to incorrect measuring results.

WARNING   Make sure the patient is correctly positioned in front of the device before starting the examination. Wrong positioning may lead to poor images and incorrect diagnostic results.

WARNING   Artifacts on the images could falsify the measured results. Do not use the measured results for further treatment if there are artefacts in the images.

WARNING   Do not make a diagnostic decision on the basis of one single examination. The device is not clinically evaluated for the diagnosis of specific pathologies. So always use alternative information; history data etc. to assist in a final diagnostic determination.

WARNING   Do not use the analyse results from patients with Pathological Eyes without an inspection of the segmentation. In case of pathological eyes the segmentation might be incorrect, and lead to wrong calculations of the analyse results.

WARNING   Prepare safeguards to ensure that only authorized personnel can access the patient data. Data loss impedes follow-up analyses and may result in inappropriate diagnostic decisions.

WARNING   Be sure to perform periodic data backup procedures. Check the success of the backup to avoid data loss caused by backup errors.

WARNING   To avoid the risk of electric shock, this equipment must only be connected to a grounded power supply.

WARNING   To avoid the risk of electric shock, do not touch conductive parts of connectors and the patient simultaneously.

WARNING   Do not operate the system directly after large temperature changes. Let the device acclimate itself for a minimum of 2 hours to avoid device damage or incorrect measurement results.

CAUTION   Never leave the patient alone with the instrument during the examination!

CAUTION   The instrument must not be used under any circumstances if mechanical, optical or electrical faults occur. Any change or addition to the system must comply with the relevant legal guidelines. Repairs, particularly to the electronic and optical components, must be carried out only by Heidelberg engineering authorized, trained personnel.

CAUTION   Unusual noises and/or vibrations can indicate a fault. Should this happen, please turn the instrument off immediately and contact the technical support center responsible for your area. Do not attempt to repair the instrument yourself in the event of a fault.

CAUTION   This instrument contains a diode laser and emits invisible laser light through the slit lamp. The Heidelberg SL-OCT is a Class I laser system. The laser does not pose any safety hazard.

CAUTION   This equipment was tested in accordance to IEC 60601-1-2, Electromagnetic Compatibility (EMC). Nevertheless, it might be affected by strong electromagnetic fields. Portable high frequency communication devices may affect the device.

CAUTION   The operator must be sure that the device settings and adjustments are correct before starting an examination and making any diagnostic decision. Wrong settings and adjustments may lead to poor image quality or incorrect examination information.

CAUTION   The physician must be sure to have the correct patient data before making a diagnostic decision. Mismatched patient data may lead to inappropriate diagnostic decisions.

CAUTION   Read subsection "Imaging Process" carefully before starting the examination. Incorrect preparation of the patient may lead to poor image quality and incorrect diagnoses.

CAUTION   Do not start an examination without informing the patient about the examination procedure. Inappropriate patient behavior during the examination may lead to poor image quality and incorrect diagnoses.

CAUTION   Read subsection "Service Maintenance and Cleaning" carefully. A failure to carry out maintenance or incorrect adjustment of the device may lead to poor image quality and incorrect diagnoses.

CAUTION   Before starting the system check the regional power supply specifications to verify that they comply with the required tolerances (100V < U < 240V; 50Hz < f < 60Hz). Wrong power supply conditions may lead to malfunctions of the system.

CAUTION   A computer failure during image acquisition or analysis could lead to incorrect results

CAUTION   United States of America:
Federal law restricts this device to sale by or on the order of a Physician or Practitioner

CONTRAINDICATIONS   No contraindications are known.

For the United States of America only:

The laser class label "Laser Class 1" is located on the rear of the OCT housing. The Laser safety class is approved and defined in accordance to IEC 60825 part 1 and part 2 and in accordance to the 21 CFR Part 1040 "Performance Standard for Light emitting Products".
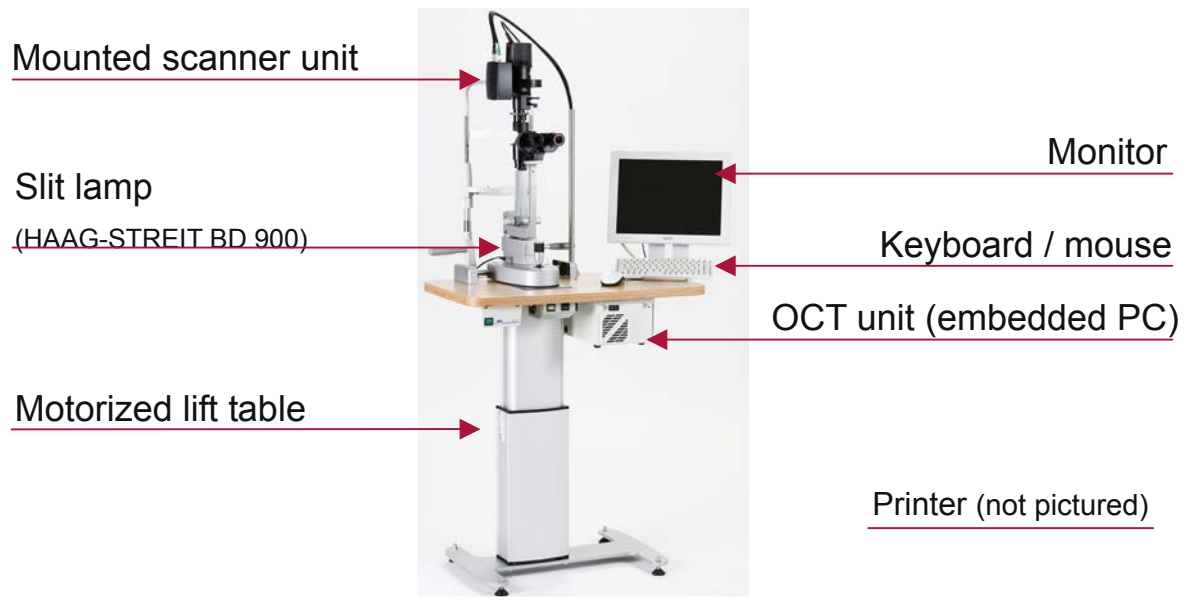

LASER CLASS 1

1.5   System installation

Accompanying these operating instructions you will find detailed installation instructions in the document "Installation Instructions for SL-OCT™".

NOTE: To ensure the overall safety of the system, the SL-OCT must be installed by certified staff of your local Heidelberg Engineering distributor.

1.6 System components

SL-OCT HARDWARE COMPONENTS

Mounted scanner unit

Slit lamp
(HAAG-STREIT BD 900)

Motorized lift table

Monitor

Keyboard / mouse

OCT unit (embedded PC)

Printer (not pictured)

The SL- OCT examination system is based on a slit lamp modified for use with an OCT device. The slit lamp's functionality is in no way impaired by this modification. The scanner unit is permanently attached to the slit lamp illumination and projects the OCT measurement beam over the same path as the visible slit lamp beam.

1.7 Maintenance

The Heidelberg SL-OCT is a precision optical measuring instrument. Protect the instrument against dust and moisture, and avoid shocks and the action of strong forces.

Please maintain the slit lamp according to the instructions in the **slit lamp operations manual** (provides with this document). When necessary, the inclined mirror on the front of the slit lamp can be carefully cleaned using a lens cloth and a small amount of isopropyl alcohol or distilled water.

The non-optical surfaces of the instrument can be cleaned and/or disinfected with traditional products as necessary. Any standard cleaning product appropriate for plastic surfaces which do **not contain acetone or hydrogen peroxide** (e.g. ethanol and isopropyl alcohol disinfectants) may be used for this purpose. Before doing this, please turn off the system power at the main switch.

A yearly inspection of the device by a Heidelberg Engineering Service unit is highly recommended to ensure proper and exact operation.

2   SOFTWARE CONFIGURATION

2.1   Heidelberg Eye Explorer

The software of instruments from Heidelberg Engineering runs on the Heidelberg Eye Explorer (**HEYEX**), a platform operating within the Microsoft Windows Operating System™. The HEYEX platform provides all basic functions of the patient database and patient records.

2.2   Viewing software

In addition to the complete operating software (image acquisition and viewing) installed on the instrument, optional HEYEX SL-OCT Viewing Software is available. This allows for analysis and review of images on PC's separate from the SL-OCT system. Please contact Heidelberg Engineering or your local distributor for further information.

2.3   Network environments

For simultaneous use of the software on several computers within a network, additional networking licenses can be purchased. For more information, please contact Heidelberg Engineering or your local distributor.

2.4   Integration with EMR or practice-management software

The HEYEX operation system can be connected to patient data management software systems (e.g. ICSP med, Fidus, IFA, Medistar, Duria, SEDOC, VIP Vision, WinPro, NextGen, IPRO, Turbomed, Dr. Notes, and Medisoft). This enables quick and convenient import of patient data into the digital patient record. Should your patient data management system currently not offer connection to the HEYEX, Heidelberg Engineering can supply the data exchange program to your provider for implementation. Please contact Heidelberg Engineering or your local distributor for further information.

3   STARTING AND POWERING DOWN THE SYSTEM

3.1   Hardware power on

To facilitate daily operation, power supplies for all SL-OCT hardware components are connected to a single, *main power switch*.

The main power switch is on the control box of the motorized lift table (*table*) (see illustration).

OR

Original Configuration

The daily power on process is simply:

- Confirm power cables are properly connected
- Confirm Slit lamp and OCT unit are switched on
- Power on system using the *main power switch*
    - >>   Green lights on the three switches will light up
    - >>   System will power up to password protected login screen.
    - >>   User name: SL-OCT is automatically supplied
- Enter password: "sloct" (**Note**: password is case sensitive and has no spaces)
    - >>   System opens to windows desktop
- Start HEYEX operating software with the HEYEX desktop icon

Note: The main power switch located close to the lift table *raise/lower control switch*. When adjusting table height, be careful not to inadvertently power off the device; if you do, unsaved images or data entries will be lost.

3.2   Verify software installation

In order to use the Heidelberg SL-OCT, the hardware and software must first be correctly installed. To confirm the software is present:

- Go to the Windows desktop.
- Click on *Start –– Settings – Control Panel – Add/Remove Programs.*

The following items must be listed:
- ***Heidelberg Eye Explorer***
- ***Heidelberg Eye Explorer License Manager***
- ***SL-OCT***

If these programs are not listed, please contact technical support.

3.3   Starting HEYEX

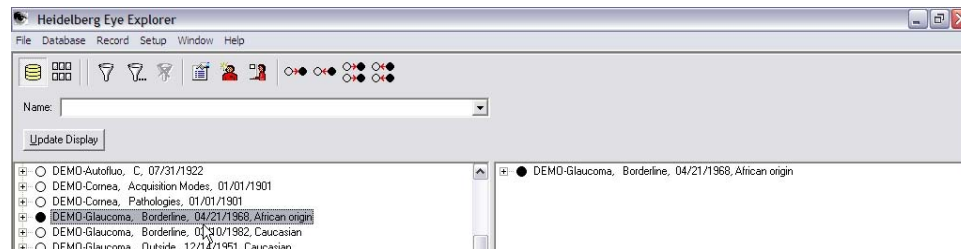Start HEYEX by double-clicking the Eye Explorer desktop icon:

OR

By using the windows Start Menu:

Start → Programs → Heidelberg Eye Explorer → *Heidelberg Eye Explorer*

The software opens to the ***Database Viewing Window***. (See section 4 for details.)

3.4   Exiting HEYEX

To close the program, click the button at the upper-right corner of the screen.

OR

With the File menu: *File → Exit*.
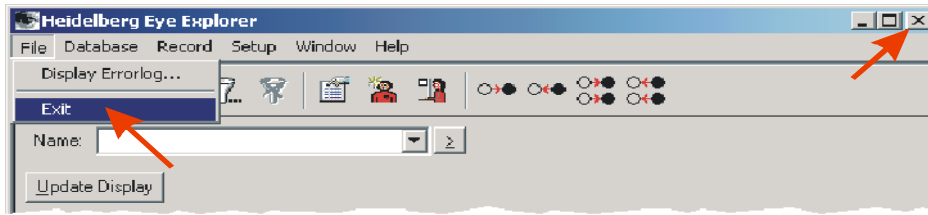
Select *Yes* when prompted with "Do you want to exit the program?"

HEYEX is programmed to pop-up a confirmation window before closing the program. This is a configurable option which can be switched off.   (See chapter 11, *Setup / Configurable Options*).

3.5   Hardware power off

Power down is a typical Windows process.

- Exit HEYEX and all open applications

- Click: *Start → Shut down→ Shut down*

>>   Computer will power down and give a "Safe to Turn Off" message.

- Use the *main power switc*h (section 3.1) to turn off system power

4   DATABASE VIEWING WINDOW

4.1   Overview

The left side of the *Database Viewing* window shows all patient records in the database. The right side of the window lists "active" patient records available for new examinations, review or batch processing.

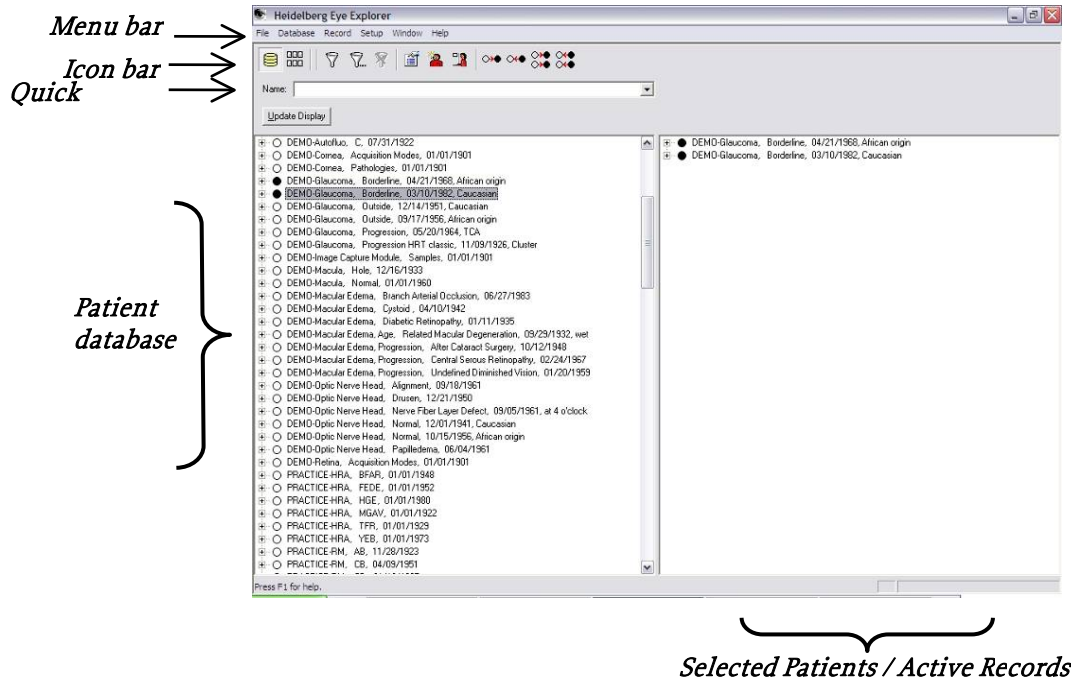<p align="center">*Database Viewing Win-*</p>

Selected Patients / Active Records

Closing the Database Viewing window will shut down the HEYEX program. HEYEX is programmed to pop-up a confirmation window before closing the program. This is a configurable option which can be switched off (See chapter 11, *Setup / Configurable Options*).

4.2   Database Viewing Window toolbar
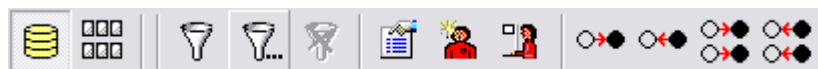
    The *Database Window* icon brings you to the *database viewing window.*

    The *Image Window* icon brings you to the *image viewing window* (section 6).

    The *Filter*, *Load Filter*, and *No Filter* icon functions are described in section 4.3.

The *Properties* icon opens the *Patient Data window* (section 5.1) for the selected patient. If no patient record is selected, it is inactive.

The *New Patient* icon opens a new *Patient Data* window for creating a new patient record. (See chapter 5, *Patient Records* for details)

The *New Examination* icon opens a new *Examination Data* window to begin a new examination for the selected patient. (See chapter 5, *Patient Records* for details.)

The *Load* icon "loads" the selected patient or exam record(s) into the active, right-hand side of the database window.

The *Unload* icon moves the selected record(s) out of the active side of the database window.

The *Load All* icon moves ALL records into the active window. This is generally used only for database export functions.

The *Unload All* icon removes all records from the active side of the database window

4.3   Search filters

4.3.1   Quick Search

This feature allows users to quickly filter the database by patient name. For example, entering the letters "Mu" and then pressing *Enter* (or clicking *Update Display)* will update the database window with only those patients whose last names begin with "Mu".
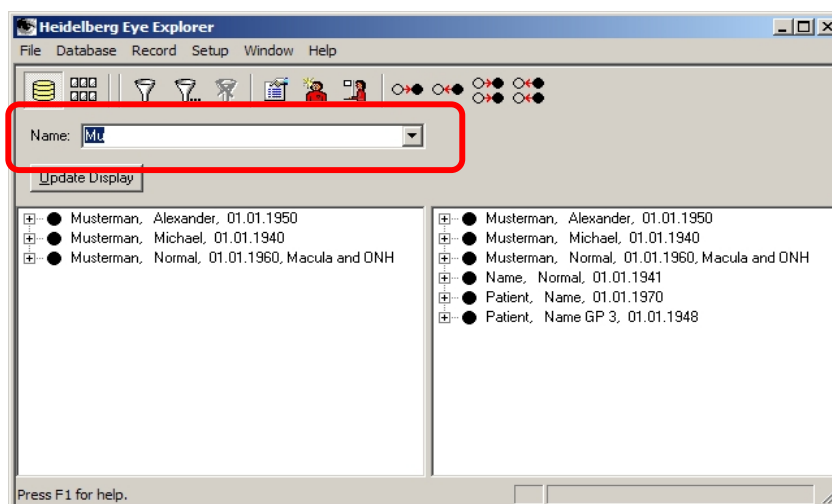
It is also possible to search by both last and first names. For example, if the entry "Mu,n" is entered, only patients with a last name starting with "Mu" and first name starting with "N" will be displayed.

The quick search by name works only on the left side (patient database) window. It will not affect the right side (selected patient) window.

4.3.2   Filtering

More complex filter operations are available using the Filter icons. With these tools the database can quickly be filtered by: patient name, referring physician or clinic, time (date range), diagnosis, participation in a study or the acquisition device. Multiple filter criteria can be used on a single sort.

The *Filter* icon (section 4.2) opens the *Database filter* window with several filtering options. In the example shown below, all patients that have been examined within the last 10 days, AND that have an exam marked as part of the "Angles in darkness" study, will be displayed.

A set filter parameters (like those in the example above) can be named and saved for future use with the [*Save as*] button. A list of previously saved searches can be viewed via the *Load Filter* icon (section 4.2).

The *No Filter* icon removes all filter criteria, returning the database display to the full list.

5   PATIENT RECORDS

5.1   Creating a new patient record

When examining a patient for the first time, a patient record must be created. As with many other program functions, there are several ways to open the Patient Data window.

Click the *New Patient* icon.

OR
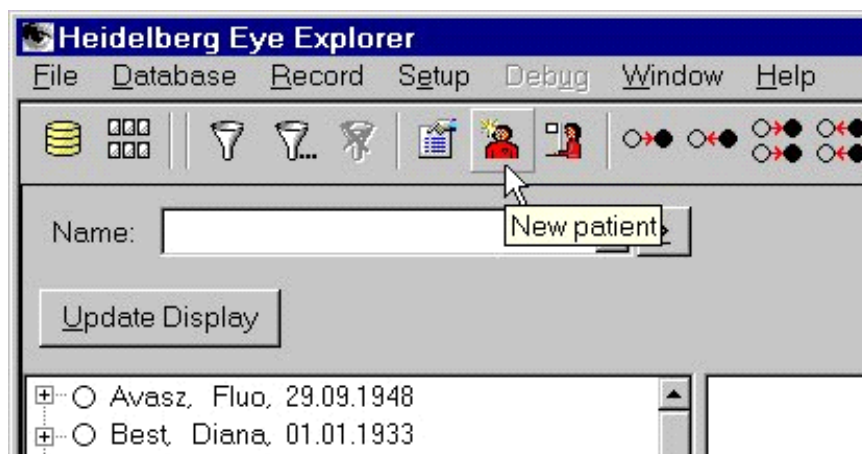
Use the Record menu: *Record* > *New Patient*.
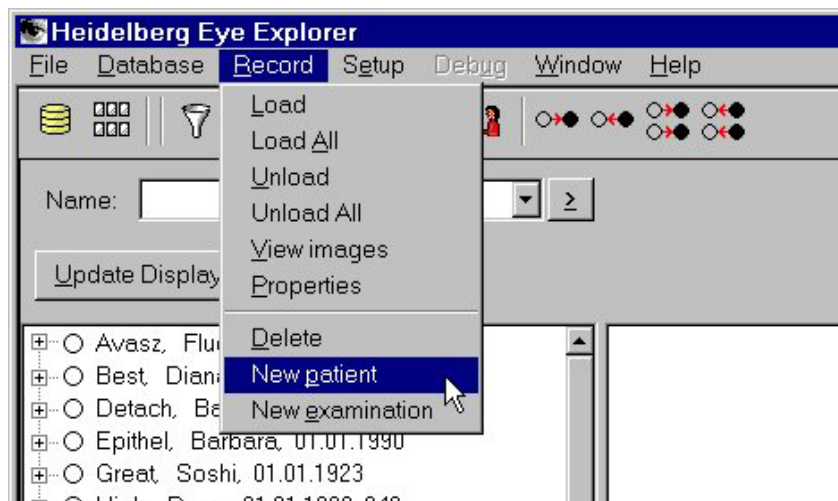
5.1.1 Patient Data Tab

Enter last name, first name, date of birth and gender (sex). All other data are optional.

Use the tab key to move to the next data entry field.

Once all entries have been made, click OK to save the new patient record and begin the examination.   (See sections 7 and 9, *Image Acquisition Window* and *Imaging Process*).

The Cancel button ends the procedure and the patient record will not be created or saved.

Clicking the Close Window button (⊠) in the top right corner of the window will also cancel the procedure and no patient record will be created.

5.1.2   More Data Tab

The More Date tab has a number of optional data fields including one to associate patients with their referring physician or clinic. The Filter function can sort by this field (see "Search Filters").

5.1.3   Memo Tab

Open the Memo window by clicking on the last tab in the Patient Data window. In this section, additional patient information and/or an anamnesis (medical history) can be entered.

This section can be used as an updatable record. Add a date and time stamp to each entry by clicking on [Insert time].

The information in this section does <u>not</u> appear on the printed examination report(s).

5.2 Opening an existing patient record

As with many other program functions, there are several ways to open and existing patient record.

To open an existing patient record, select the patient record and then *right-click* to open the context menu and click *View Images*.

OR
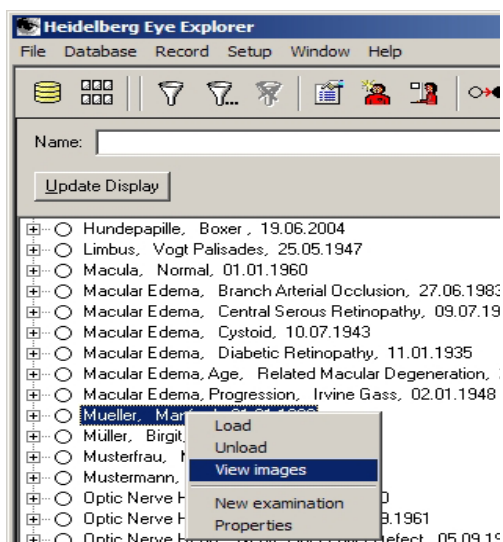
Use the Record menu: *Record > View Images.*
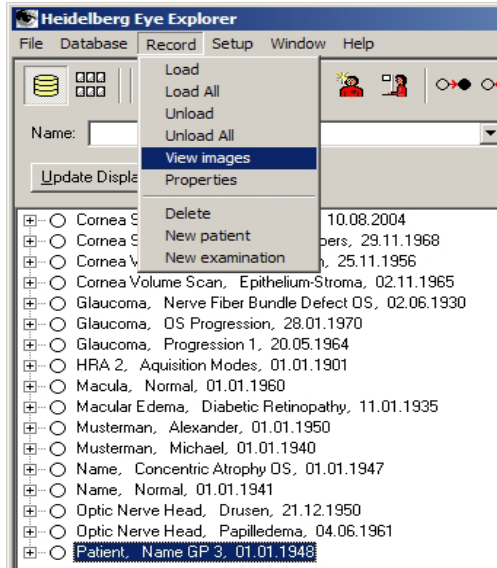
Patient records are opened into the *Image Viewing* window (section 6).

5.3 Examination tabs

Within the patient record saved images are organized on Examination tabs. The tabs are presented chronologically by exam date and are created automatically by the software when images are saved. (See Section 6 – *Image Viewing window.*)

Note: If multiple SL-OCT exams are conducted on the same day, images from the additional exams can either be added to the existing tab for that day, OR saved to a new tab(s). In the second case, the patient record will contain multiple tabs with the same date.

5.3.1   Adding images to an existing exam tab

To add new images to an existing exam tab, begin the additional exam(s) in the *Image Viewing* window or by continuing image acquisition after saving images.

Select the desired exam tab. Click the *New examination* icon. The *Examination Data* window will NOT open.

Saved images from this exam will be added into the existing exam tab for that day.

Images can only be added to a tab from the CURRENT day.

5.3.2   Creating additional tabs on one day

To save images from multiple exams given on the same day on separate exam tabs, begin the additional exam(s) from the *Database viewing* window.

Select the patient's name. Click the *New examination* icon. The *Examination Data* window opens; allowing the operator to be verified or changed. The Study can also be changed.

Saved images from this exam will be placed on a new tab with the same date.

5.4 Loading multiple records for batch functions

Loading multiple records allow the user to quickly review several patient records without switching between the *Database* and *Image Viewing* windows. It is also used for batch functions (e.g. exporting).

A patient record can be activated or "loaded" in several ways:

- Click the marker circle to the left of the patient name.
- Double-click the patient name.
- Right-click the patient name, and select *Load* from the Context menu
- Drag and drop the patient name into the active window
- Highlight the patient name, and then click on the *Load* icon from the toolbar.
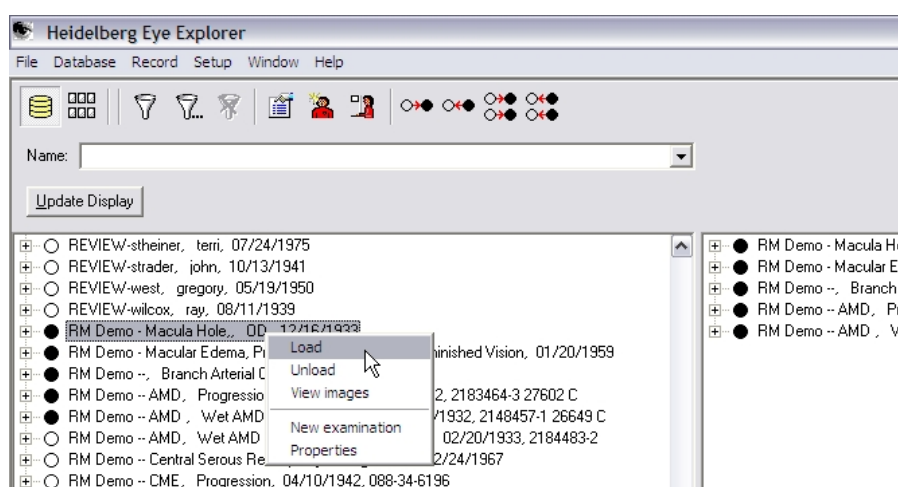
6   IMAGE VIEWING WINDOW

6.1   Overview

Opening (double-clicking) any active patient record in the Database Viewing window opens the *Image Viewing* window. The *Image Viewing* window is like a digital **patient record**; it provides access to all the images and data saved for the selected patient.
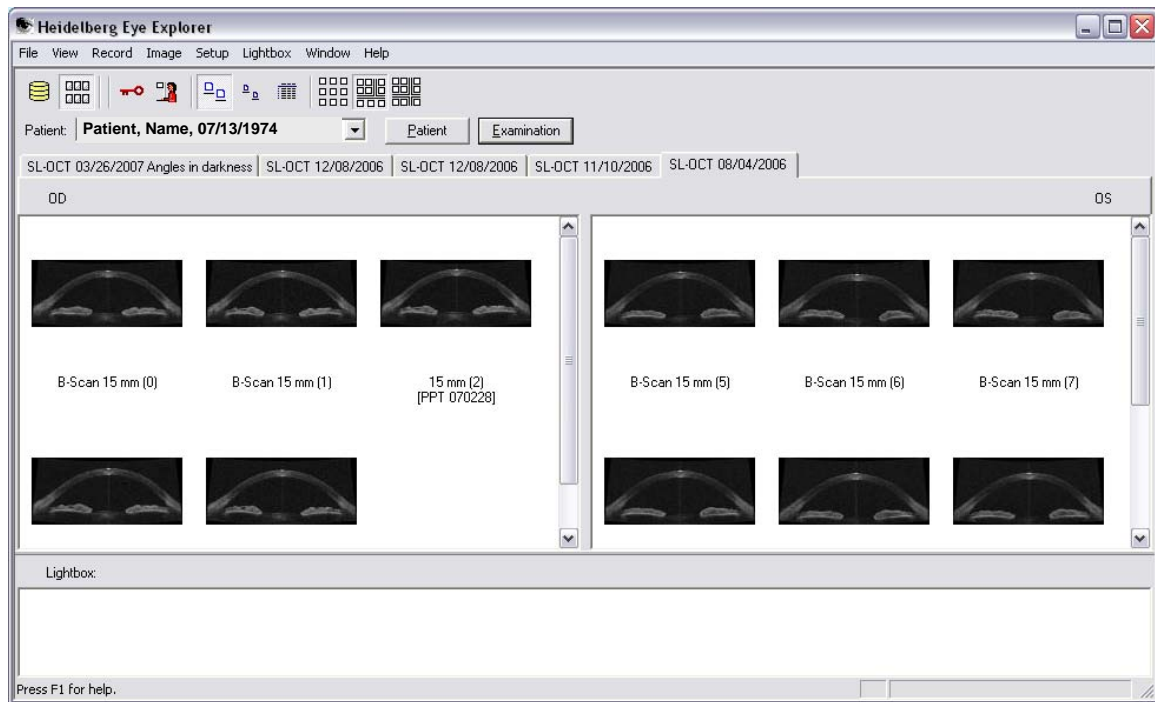
In this window, each examination is shown on a separate tab identified by exam date. Within an individual exam tab scans are displayed in OD (right eye) and OS (left eye) windows.

6.2   Image Viewing window tool bar

    The *Database Window* icon brings you to the *Database Viewing* window (Section 4).

    The *Image Window* icon brings you to the *Image Viewing* window.

The *Lock/Unlock Examination* icon "locks" the selected examination tab. This function is to protect data in networked systems.

The *New Examination* icon opens a new Examination Data window to begin a new examination for the selected patient. (See chapter 5, *Patient Records* for details.)
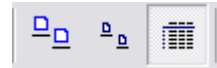
The *Large Icons*, *Small Icons*, and *List* icons change the appearance of the individual image files in the *Image viewing* window.

The *No Split*, *Split Exam*, and *Split Exam & Lightbox* icons allow you to divide the Image Viewing window files by eye (OD/OS).

6.3 Editing and viewing functions

6.3.1 Patient Dropdown Menu

All active patient records (those in the right-side of the database viewing window) can are listed in the *Patient* drop-down menu. Using this list, the user can switch between patient records without returning to the *Database Viewing* window.
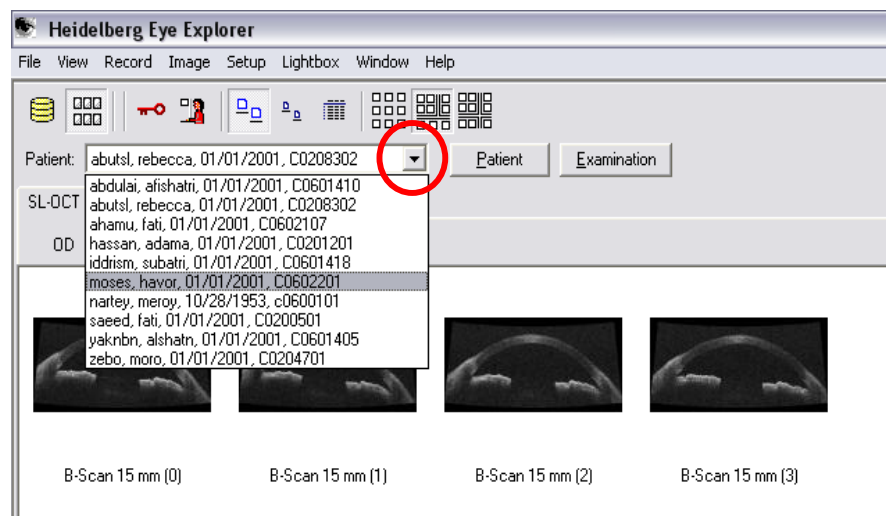
6.3.2 Editing Patient Information

Patient information including name, date of birth, gender, and patient ID number are input before the patient's initial exam. This information and additional patient record details can be viewed and edited by clicking the **[Patient]** button. Patient name changes will not be visible in database viewing window until the program is restarted.

6.3.3   Editing Examination Data

Examination information can be viewed and edited by clicking the **[Examination]** button. Some fields, for example, examination date are not editable in these windows. Some changes to this information will not be visible until the program is restarted.

6.3.4   View Settings

There are a number of options for displaying information in the *Image Viewing* window. Individual images can be represented as Large icons, Small icons, or List entries and the window can be split into separate OD (right eye) and OS (left eye) panels. Images in the Lightbox can also be similarly combined or split.

The **View** command and the toolbar icons (shown below) can be used to select the desired view settings.
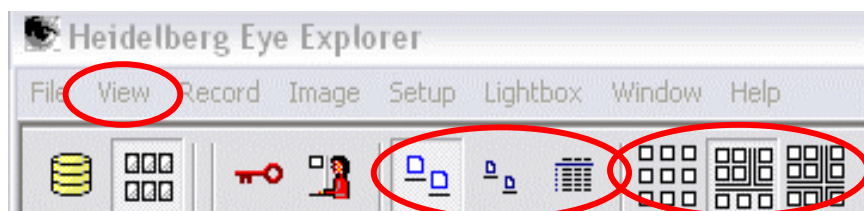
6.4   Examination Tabs

Within the patient record saved images are organized on **Examination tabs**. Exam tabs are created by the software when images are saved (see Section 5.3) and are presented chronologically by exam date. The tab title contains three parts:

1) the device used for the image (in this case, SL-OCT)

2) exam date

3) study (This appears only if a study was flagged for that exam and can be edited via the [Examination] button).

6.5   Lightbox

The *Lightbox* is located at the bottom of the Image Viewing window and can be used to mark specific images for review at a later time.

 To **copy images into the Lightbox** drag and drop OR right click to access the context menu, select *Add to light box*.

To **save a given lightbox**, r*ight-click* anywhere in the *Lightbox;* from the context menu, select the *Save lightbox* command.

To **review a saved lightbox**, select the name of the lightbox session from the drop-down menu.
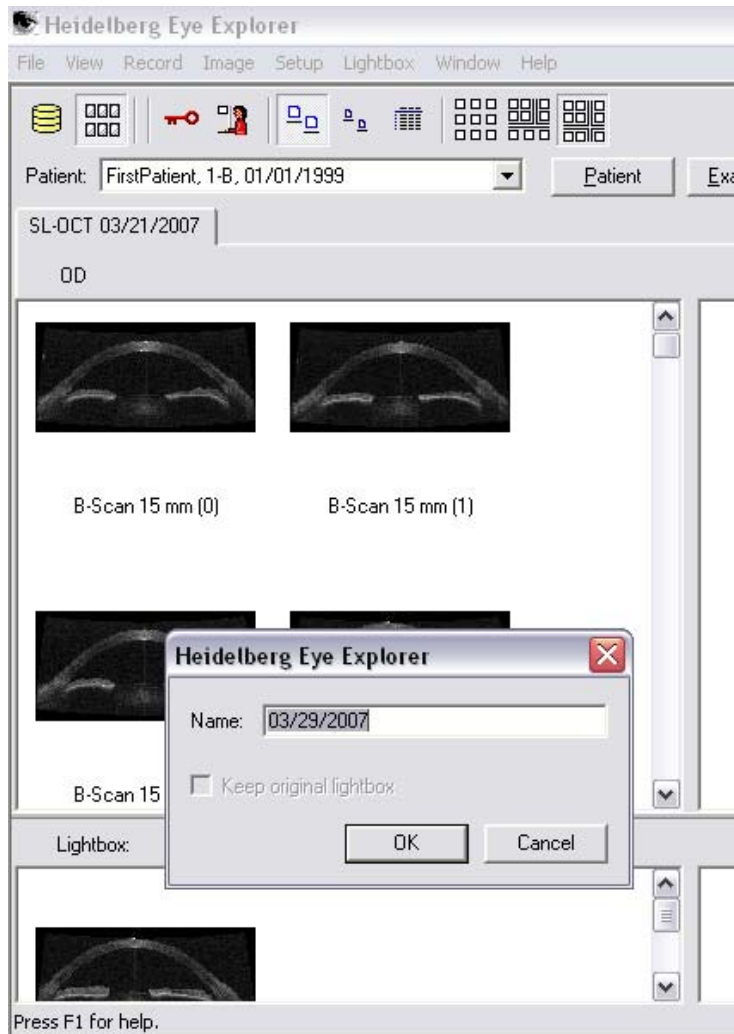
6.6   Preview pane

The Preview pane allows the user to quickly preview images to determine which to analyze or save in the Lightbox for future review.

The Preview pane Comment field allows users to add a 15 character caption to the selected image. Once saved, the caption is visible in the Image Viewing window below the image file name. It also appears in the title of the image viewing window and in the "additional information" stored with the image.

7 IMAGE ACQUISITION WINDOW

7.1 Overview

Once a new patient has been created or a new examination has been started for an existing patient, the acquisition window opens.
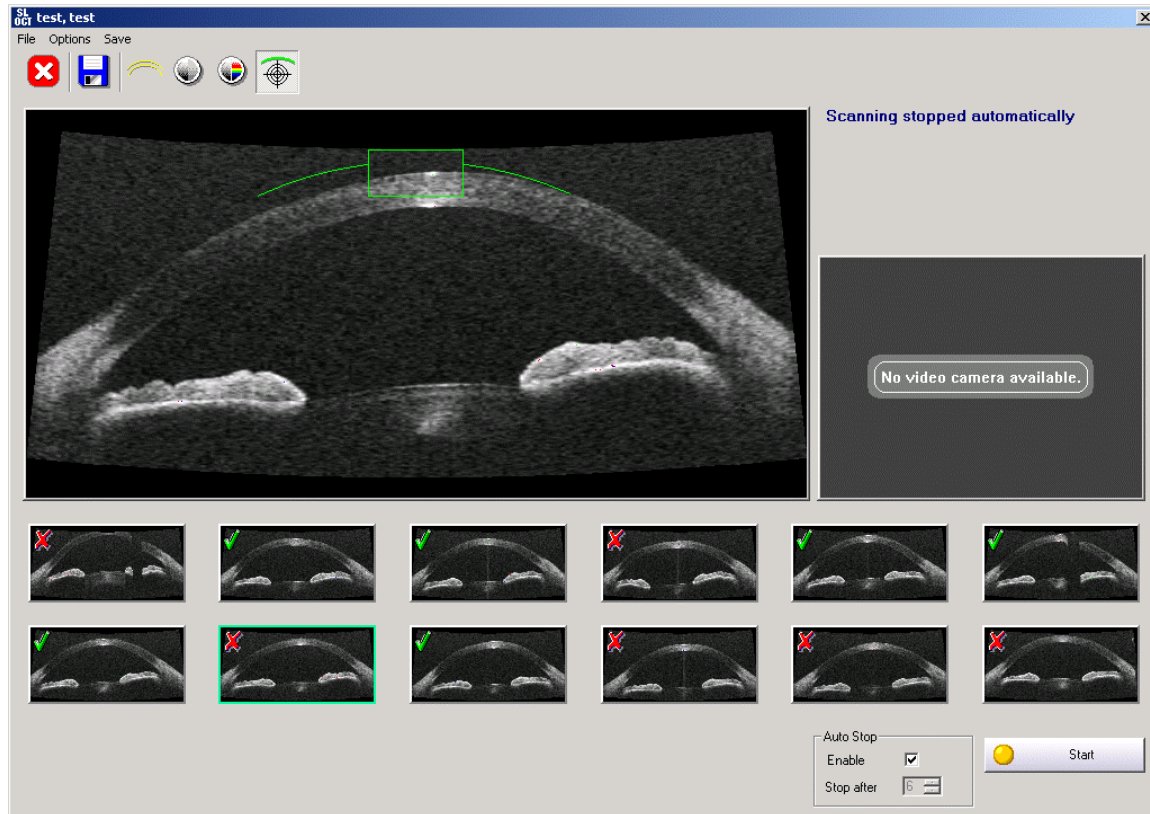
During acquisition, the current image is shown in the large window at upper left. If the slit lamp is equipped with the optional camera module, the current camera image is displayed in the video window at the upper right.

Beneath the two larger windows are 12 smaller, temporary storage windows. These show the last twelve (12) B-scans. As image acquisition continues, the oldest B-scan is overwritten. The current scan is identified by a green frame.

When acquisition is stopped any of the 12 temporary B-scans can be viewed in the large window by clicking the desired scan. The green border indicates which of the 12 scans is in the large window.

These 12 B-scans are available for saving into the patient's record.

7.2   Image Acquisition window toolbar and controls

The *Exit* icon closes the Acquisition window and returns the program to the Image viewing window. (This function can also be completed using the File menu.)

The *Save* icon opens the *Image Save* dialog box. (See section 7.4, *Saving images*.) (This function can also be completed using the Save menu.)

The *Display Segmentation* icon toggles the segmentation line on/off in the 12 temporary image windows. (This function can also be completed using the Options menu.)

The *Brightness/Contrast* icon provides access to the Brightness & Contrast control window. This tool allows users to adjust brightness and contrast at the same time. Different brightness/contrast settings bring out greater detail in different areas of the image. (This function can also be completed using the Options menu.) This control works for both gray and color scale views.
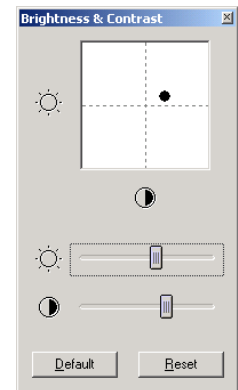
Tip: set the brightness and contrast before examining a patient, using the adjustment rod of the slit lamp as the measurement object.

The *Color Scale* icon toggles the image appearance between gray-scale and color-scale. (This function can also be completed using the Options menu.)

The *Aiming Circle* icon toggles the aiming circle on/off in the large, current image window. Note: The Aiming Circle display will update (appear/disappear) only during acquisition. (This function can also be completed using the Options menu.)
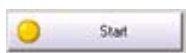
The *Start [Stop]* button starts and stops the image acquisition process.

Note: If the measurement is stopped and then started again, all previously acquired B-scans will be deleted. A pop-up confirmation window must be clicked before images are deleted and acquisition restarts.
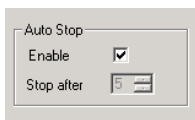
The *Auto Stop* feature will automatically stop acquisition when the user defined (*Stop after*) number of good images are captured in the temporary image windows.

Note: The feature cannot be enabled/disabled during acquisition.

7.3   On-line quality screening

During the scanning process, the system applies an on-line quality screening to each temporary image. If an image fails the on-line screen, it is marked with a red X. If it passes, it is marked with a green checkmark. Any temporary image may be saved for future viewing. However, images that fail the on-line quality screen (those marked with a red X) should not be analyzed with the measurement tools.

It is important to understand that the on-line screen is a quick check only. While all images that fail the screen are not suitable for quantitative analysis **not all images marked with the green checkmark are suitable for quantitative analysis**. The user should review each green-checked scan and select only the best image(s) for analysis.

Goods scans will have:
- no movement artifacts, no bumps or dents in the cornea, no wave in the lens
- both chamber angles visible
- sharp cornea contour in the 10 o'clock and 2o'clock positions
- bright spot (reflex) on the corneal surfaces and lens surface connected by the bright reflex line

7.4   Saving images

Before clicking [**Save**] (or the *Save* icon), the user must select the image(s) to be saved by double-clicking them.   Images selected for save will be marked with a save icon (🖫).   **Warning:** When the selected images are saved, the unselected images are discarded. At that point there is no way to retrieve them.

Clicking **[Save]** opens the Save Data window. Select eye scanned (right/left). Click [**OK**] to save selected images to the patient's record.

Slit rotation angle. If scan direction was changed from default (horizontal), the user should indicate the precise scan angle using the *Slit rotation angle* feature. The angle measurement is taken from the scan direction indicator on the slit lamp head.

Comment. The *Save Data Comment* section is a 90 character text field where image-specific notes can be stored. The first 30 characters of this field are visible in the Comment section of the printed report. This comment can be accessed and edited later in the *Image Analysis* window with the *Additional Information* icon (section 8).

It is recommended that for each eye examination (each eye) the three or four best scans are saved.

The selected scans are saved to an exam tab in the patient's record. The tab is named with the current date. The saved scans are now available for review and analysis. The user can now scan the other eye, take additional scans of the current eye, or exit the acquisition window.
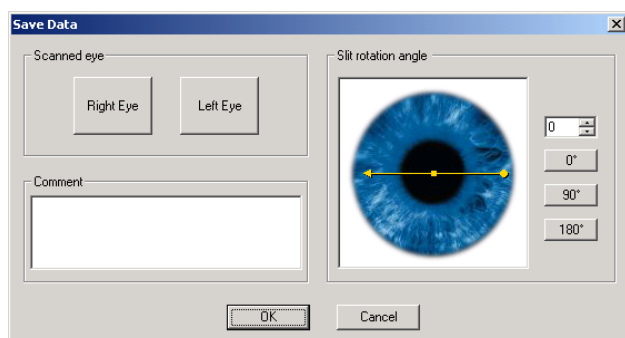
8   IMAGE ANALYSIS WINDOW

8.1   Overview

Clicking [**Biometric Analysis**] in the preview pane opens the ***Image Analysis*** window.

If the image quality is sufficient, the elements of the anterior chamber will be automatically segmented and a refraction correction calculated on the basis of the cornea segmentation. The B-scan will then be displayed in corrected form.

Note: the biometric analysis takes approximately 18 seconds. Once the analysis is completed for a given image that image opens without the analysis lag.
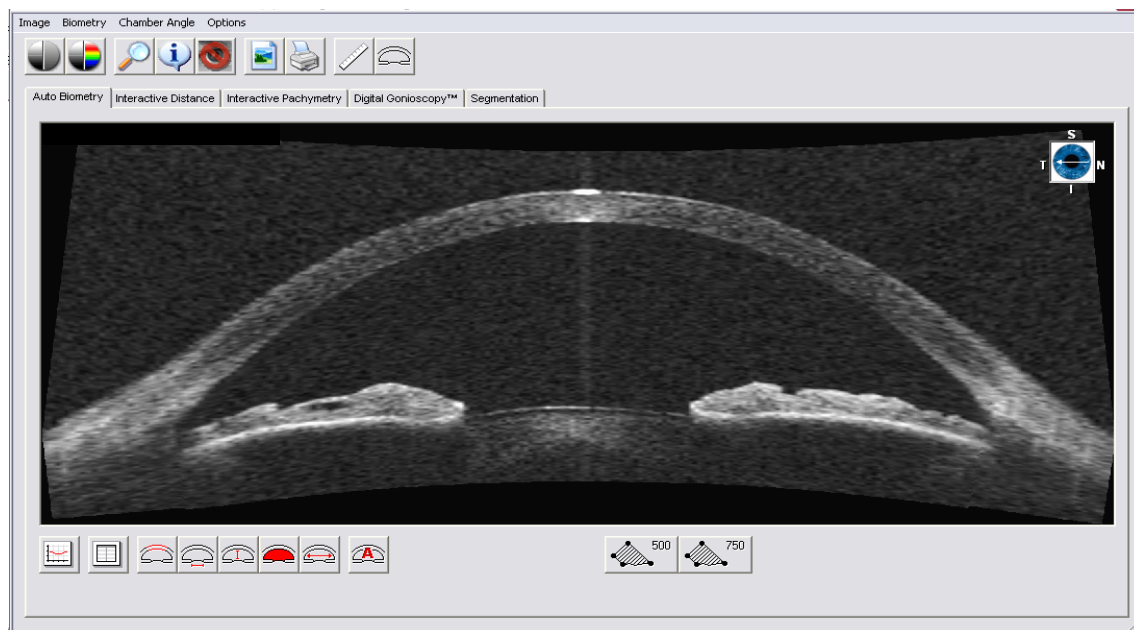
The ***Image Analysis*** window allows detailed viewing, measurement, and report printing of individual scans. Key elements of the image analysis window are:

- The **window menu and toolbar** are available on all analysis window tabs. Their functions are detailed below in section 8.2.

- The **Segmentation tab**. The segmentation tab shows the raw image without refractive correction and an approximate placement of the scleral spur points. These points must be verified by the user to activate some of the auto-analysis tools. This is explained in further detail in section 8.3 below.

- The analysis tool tabs: ***Auto-biometry, Interactive Distance, Interactive Pachymetry,*** and ***Digital Gonioscopy***™.   Details of these functions are provided below in sections 8.4 –8.7.

8.2   Image analysis window toolbar

The image analysis window tool bar functions are visible and active on all five of the image analysis tabs. If the scleral spur placement for the image has NOT been confirmed (see section 8.3 below), the tool bar will include as a tenth icon a red exclamation (circled below). If spur placement has been confirmed for that image, this icon will not be visible. The tab functions are described in sections 8.3 –8.7 below.

The ***Brightness and contrast*** icon provides access to the Brightness & Contrast control window. This tool allows users to adjust brightness and contrast at the same time. This control works for both gray and color scale views.

Different brightness/contrast settings bring out greater detail in different areas of the image.

The ***Color mode*** icon toggles the image appearance between gray-scale and color-scale.

The ***Zoom*** icon opens the ***Zoom*** window. In the zoom window, select the area of interest by clicking and dragging the red frame. Chose a zoom level (100%, 200%, 300%, 400%,
or   500%) with the [+] or [-] icons.

The ***Additional information*** icon opens an information window with exam details. In this window the user can edit the image caption discussed in Section 6.6 and the image comment discussed in Section 7.4.

The ***Display video image*** icon opens a window with the photo image taken simultaneously with the OCT scan. (**Note**: This icon is active only if the optional video kit is installed.)

The ***Save image as picture file*** icon opens a Save As window. With this tool the image can be saved as a BMP, JPEG, TIF, or PNG file.

The ***Print a report*** icon opens the Print Report window. Each analysis window tool tab offers a report specific to that analysis. Note: This icon is not active on the *Segmentation* tab.

The ***Distance measuring tool*** icon displays a movable measuring tool. The user can place the ends at any two points on the image and see the distance between the points in mm. Note: This icon is not active on the *Segmentation* tab.

The ***Segmentation*** icon displays software generated segmentation lines and points. The segmentation lines also appear on the intensity profiles on the ***Interactive Distance*** and

Pachymetry profile tabs.

WARNING: The user should always visually check the automated segmentation before proceeding with quantitative analysis of the image. To do this, click the *Segmentation* icon and inspect the colored segmentation lines. If they are not correctly placed at the edges of the eye structures, select another image for quantitative analysis.

The *Scleral spurs not confirmed* icon is a visual indicator that spur placement for this image has not been confirmed by the user. The icon will take you to the *Segmentation* tab.

8.3   Segmentation tab

The *Segmentation* tab shows the "raw" image before refractive correction. In this image the anterior chamber appears deeper and less concave. On this tab, the user can view and evaluate software generated placement of the scleral spur markers -- yellow dots.

Spur marker placement must be "accepted and saved" before automatic functions measured from the scleral spurs are available; this process is described below.

In addition to confirming scleral spur placement, the user should always visually check the automated segmentation before proceeding with quantitative analysis of the image. To do this, click the *Segmentation* icon and inspect the colored segmentation lines. If they are not correctly placed at the edges of the eye structures, select another image for quantitative analysis.

8.3.1   Scleral Spur Placement

If the automatically generated scleral spur makers are judged by the operator to be in the correct place, the operator can "accept and save" the maker placement with no adjustments. (See section 8.3.2 below.)

To move the marker(s), pass mouse pointer over the point to be moved. Pointer will change from standard pointer to the double arrow "move" cursor. Click and hold left mouse button to move the point.

Note: To facilitate precise placement, **hide the "move" (double arrow) cursor** by holding down the right mouse button as well. At this point only the yellow dot is visible, and it moves like the mouse pointer. Release mouse buttons to drop/place dot at desired point. For more precise placement the *zoom* tool can be used. Also, activating the *color-scale* and varying the *brightness/contrast* may help bring out additional detail in the area of interest.

8.3.2   Accept and Save

When spur markers are properly placed, left click the green check mark button at lower left of window – see image above. This opens a *Confirmation* window. The operator must enter his/her name and click **[OK]** to save and accept the current placement of the markers.

8.3.3   Reset all Settings

To return the scleral spur markers to the automatically generated positions click the red X button at the lower left of the window – see image.

Before returning the points to original positions the software opens a *Segmentation* window which warns that the operation cannot be undone. To proceed, click **[Yes]**.
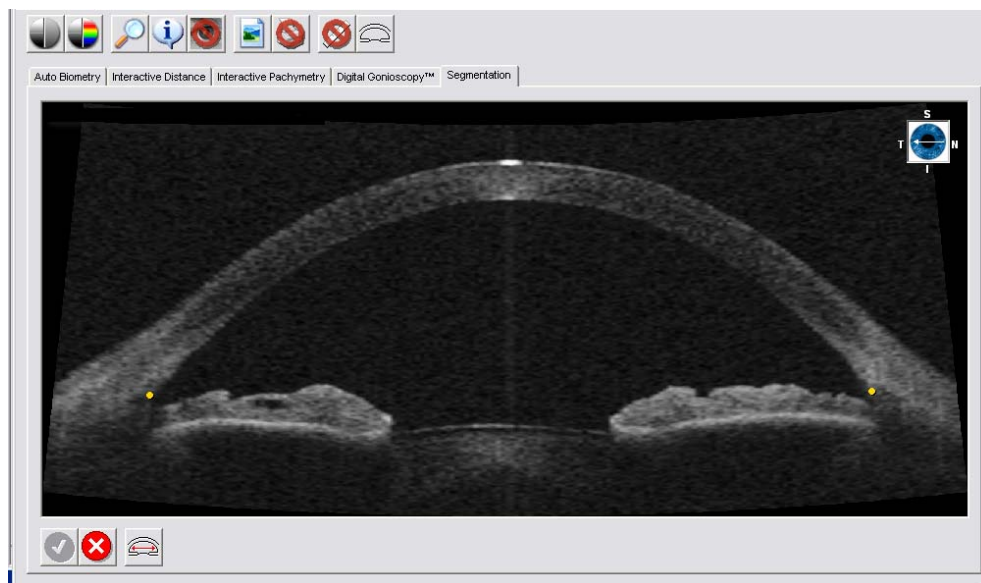
8.4   Auto-Biometry™ tab

The *Auto-Biometry* tab provides one-touch measurements of: central corneal thickness, anterior and posterior corneal radii, pupil diameter, anterior chamber depth, estimated anterior chamber volume, spur to spur distance, angle opening distance, and trabecular iris space area. The tool icons and functions are detailed below.
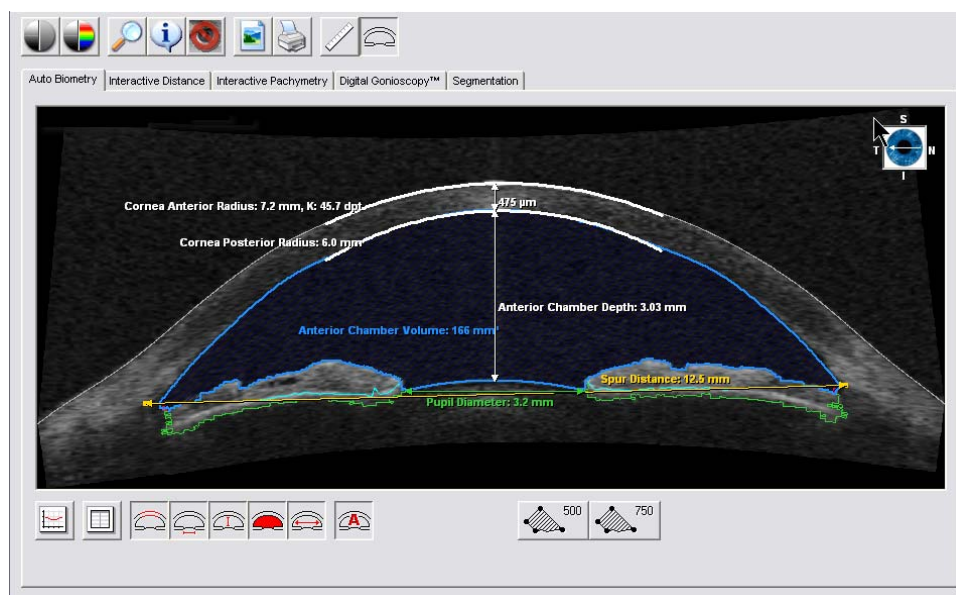
 The *Pachymetry Profile* icon opens the interactive pachymetry profile (see below).
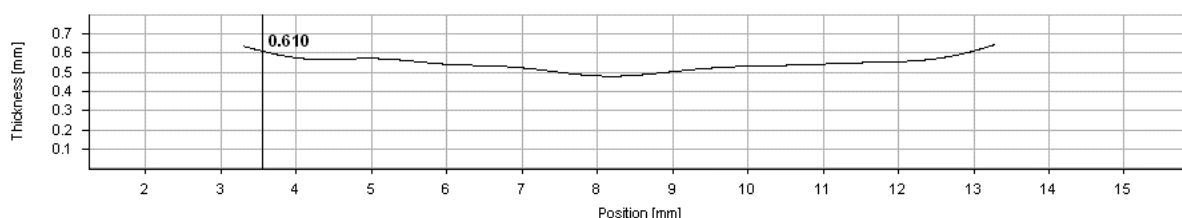
The *Pachymetry Profile* is a graph of corneal thickness across the image. The mouse pointer can be placed at any point on the graph to see the thickness value at that point. In the B-scan image, a white point on the corneal surface will appear and move with the pointer to show the corresponding location on the image.

 The *Biometric data list* icon opens a numerical summary of all measured parameters for the image.

 The *Corneal curvature and thickness* icon highlights and displays the numeric values of the anterior and posterior cornea radii and displays the central corneal thickness measurement.

The ***Pupil diameter*** icon highlights and displays the numeric value of the pupil diameter.

The ***Anterior chamber depth*** icon highlights and displays the numeric value of the anterior chamber depth measured from posterior surface of the cornea to anterior surface of the lens. Both this parameter and the *total anterior chamber depth* measurement which includes the central corneal thickness are provided in the biometric data list.

The Anterior chamber volume icon highlights and displays the estimated anterior chamber volume. To estimate volume, the software uses the measured 2-D area of the B-scan and presumes rotational symmetry of the chamber.

The ***Distance between scleral spurs*** icon highlights and displays the numeric value of the spur to spur distance. **Note**: Scleral spur placement must be verified to activate this tool. This is con explained in further detail in section 8.3. Clicking this button before spur placement is confirmed results in a reminder window. Clicking **[Cancel]** in the reminder window clears the reminder. Clicking **[OK]** takes you to the *Segmentation Tab* to complete the confirmation.

The ***Display all values*** icon highlights and displays the numeric value of all of the above-listed parameters.

The ***AOD and TISA 500***[1] icon highlights and displays the numeric values for *Angle Opening Distance* and *Trabecular Iris Space Area* measured at 500 microns from the scleral spur. **Note**: Scleral spur placement must be verified to activate this tool. This explained in further detail in section 8.3. (See Section 8.7, Digital Gonioscopy™ tab for details.)

The ***AOD and TISA 750*** icon highlights and displays the numeric values for *Angle Opening Distance* and *Trabecular Iris Space Area* measured at 750 microns from the scleral spur. **Note**: Scleral spur placement must be verified to activate this tool. This explained in further detail in section 8.3. (See Section 8.7, Digital Gonioscopy™ tab for details.)

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[1] AOD and TISA are defined by Sunita Radhakrishnan, MD; Jason Goldsmith, MD; David Huang, MD; Joseph A. Izatt, PhD; et. al. in: *Comparison of Optical Coherence Tomography and Ultrasound Biomicroscopy for Detection of Narrow Anterior Chamber Angles*, Arch Ophthalmol. Vol 123, Aug 2005.

8.5   Interactive Distance tab

The *Interactive Distance* tab provides interactive tools for measuring virtually any vertical or horizontal distance in the image. In addition, this window graphically shows the signal intensity along the red axis.

The tool icons and functions available on this tab are detailed below.

8.5.1   Measuring Axis Tools

The Measuring Axis icons allow the user to activate up to four (4) movable measure axis tools. The axes can be activated in any combination and can be moved relative to each other and the image by clicking and dragging the line to be moved.

The white and red axes have special functions as detailed below.

The *White reference axis* icon toggles the white axis on/off.

This axis provides an automatically generated reference to the center of the image. Horizontal   and vertical distances between the reference axis and any other active axes are displayed in   mm. For additional measuring flexibility, the distances between the green and blue axes are   also displayed. If the reference axis is moved it can be reset using the *reset reference axis* icon   (see below).

The *Red intensity profile axis* icon toggles the red axis on/off.

The signal intensity along the red axis is displayed in the red graphs below and to the right of   the image. As the red axis lines are moved across the image the changes in the corresponding   graph show the variations in the signal intensity.

The *Green measuring axis* icon toggles the green axis on/off. When both the green and blue measuring axes are active, the horizontal and vertical distances between them are displayed.

The *Blue measuring axis* icon toggles the blue axis on/off. When both the blue and green measuring axes are active, the horizontal and vertical distances between them are displayed.

The *Reset reference axis* icon resets the white reference axis to its default position.

To facilitate precise placement of the measuring axes, when the mouse pointer is in either the "precision select" or "move" form it can be hidden from view by holding down the right mouse button. This makes it easier to see and position the line being moved.

8.5.2   Intensity Profiles

The signal intensity for the portion of the image marked by the red axis is displayed in the red intensity profile graphs below and to the right of the image. As the red axis lines are moved across the image the changes in the corresponding profile show the variations in the signal intensity across the image.

Peaks in the signal intensity are associated with transitions between tissue/areas with different optical behavior like the corneal and lens surfaces. The intensity profile graphs can be adjusted using the *intensity profile controls* described below.

The *Average intensity profiles* icon toggles the intensity profiles between graphs of each data point separately OR graphs of averaged points calculated from the values of five (5) neighboring A-scans.

The *Normalize intensity profiles* icon toggles the top of the intensity profile scales between maximum value in the image OR maximum value in the data in the graph.

8.6   Interactive Pachymetry tab

The *Interactive Pachymetry* tab provides interactive caliper tools for measuring perpendicular distances in and across the cornea. In addition, this window graphically shows the A-scan which is the signal intensity along the "active" caliper.
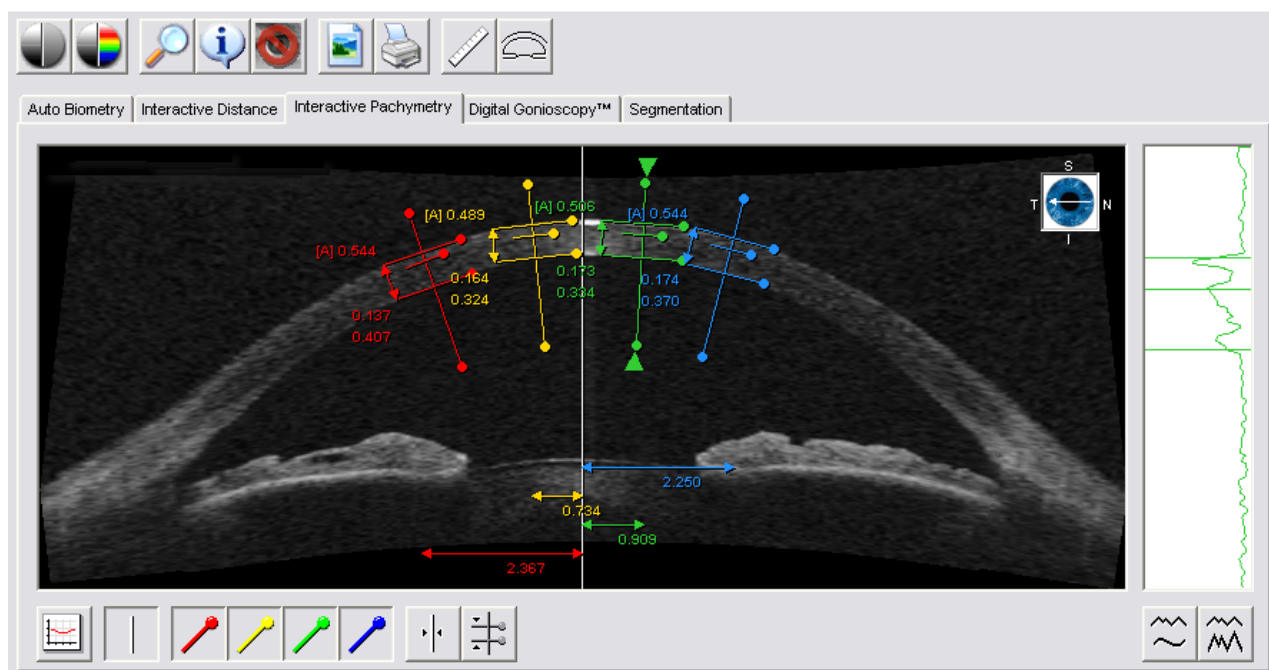
8.6.1   Pachymetry profile

 Use the *Pachymetry Profile* icon to open the interactive pachymetry profile.

The *Pachymetry Profile* is a graph of corneal thickness across the image. The mouse pointer can be placed at any point on the graph to see the thickness value at that point. In the B-scan image, a white point on the corneal surface will appear and move with the pointer to show the corresponding location on the image.
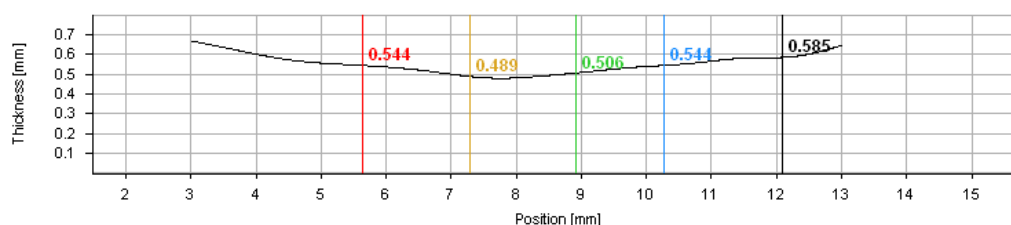
8.6.2   Interactive pachymetry tools

The four colored *Pachymetry tool* icons each activate an interactive measuring caliper of the corresponding color.

The tools measure perpendiculars distances in and across the cornea. For each active caliper, three numerical measurements (mm) are displayed. These are, the distance between the "jaws" of the caliper and the distances from each jaw to the middle line. The line of measurement is the long line at the center of tool.

Each caliper can be moved independently in the following ways:

- Move the caliper tool across the surface of the cornea to desired location by clicking and dragging one of the dots at the end of the long line that runs perpendicular to the cornea.

- Move the caliper jaws by clicking and dragging the dots at the end of the jaw lines.

- Move the middle distance line to the desired point between the jaws by clicking and dragging the dot at the right-hand side of the line.

The *Display reference axis* icon toggles on/off the white, central reference axis (see below). The reference axis can be moved by clicking and dragging. Reset the axis position with the _____ *Reset reference axis* icon (see below).

When both the axis and one or more caliper tools are visible the horizontal distance (mm) from the central reference axis to the caliper point on the anterior corneal surface is displayed.

The *Reset reference axis* icon returns the reference axis to the default position.

The *Automatic positioning* icon moves the caliper "jaws" of the <u>active caliper</u> to the corneal surfaces. It does not move the middle line.

An individual caliper tool becomes "<u>active</u>" when the user moves it. The *intensity profile* (section 8.6.3 below) associated with that caliper will be displayed it the intensity profile window (see above). The color of the profile corresponds with caliper color.

8.6.3   *Intensity profiles*

The A-scan marked by the center line of the active caliper tool is displayed in the graph to the right of the image. As the active caliper is moved across the surface of the cornea, changes in the A-scan graph show the variations in the signal intensity across the image.

Peaks in the signal intensity are associated with transitions between tissue/areas with different optical behavior like air to cornea. The A-scan graphs can be adjusted using the *intensity profile controls* described below.

The *intensity profile* is helpful when using the interactive pachymetry tools to measure within the cornea. While slowly moving a caliper across the area of interest, watch the intensity profile and choose the point with the most clearly defined peaks. Use the automatic positioning tool (see

above) to set the caliper jaws on the surfaces of the cornea. Then adjust the middle line to the desired A-scan peak.

The *zoom* tool can also be used with these tools.

The ***Average intensity profiles*** icon toggles the intensify profiles between graphs of each data point separately OR graphs of averaged points calculated from the values of three (3) neighboring A-scans.

The ***Normalize intensity profiles*** icon toggles the top of the intensity profile scales between maximum value in the image OR maximum value in the data in the graph.

8.7   Digital Gonioscopy™ tab

The *Digital Gonioscopy* tab offers one-touch, automatic angle measurements and an interactive "freehand" angle measuring tool.

Note: Scleral spur placement must be verified to activate the automatic tools; this explained in further detail in section 8.3.

Note: For greater angle measurement precision, the operator should average the angle measurements of at least three separate B-scans.
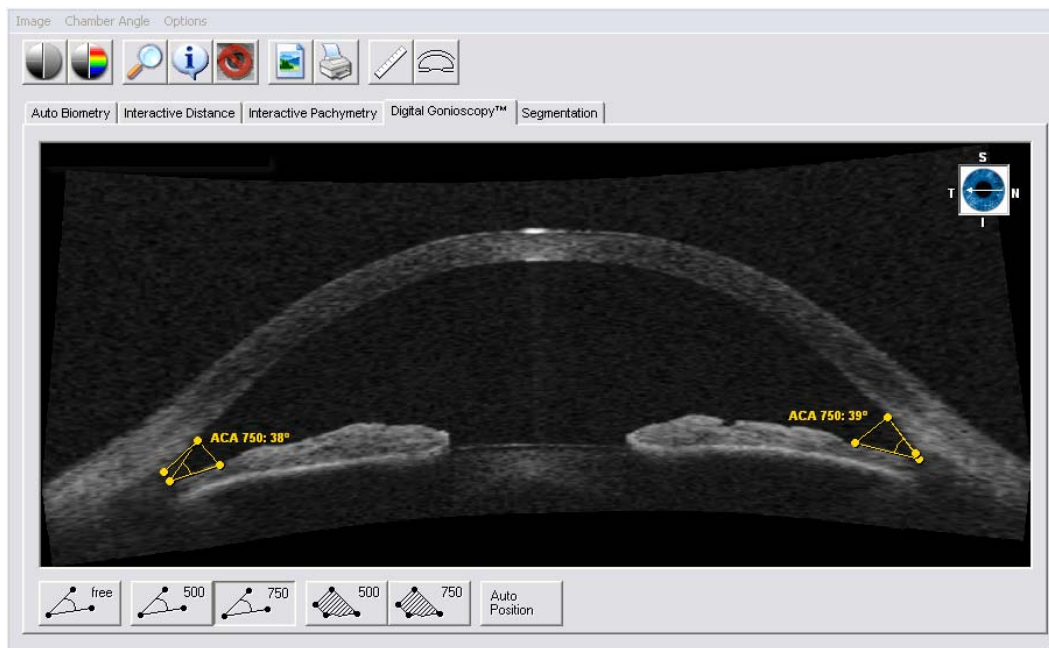
8.7.1   One-touch angle tools

The one-touch Digital Gonioscopy tools provide variations of the following measurements:

- Anterior Chamber Angle (measured in degrees)
- Angle Opening Distance (measured in mm)
- Trabecular Iris Space Area (measured in mm^2)

These measurements are defined below with the illustrations of the related button. The one-touch tools become active for a given image after the scleral spur placement is confirmed for that image (see section 8.3). Clicking these buttons before spur placement is confirmed results in a reminder window. Clicking **[Cancel]** in the reminder window simply clears the reminder. Clicking **[OK]** takes you to the *Segmentation Tab* to complete the confirmation.

Anterior Chamber Angle

Anterior Chamber Angle (ACA) is a traditional parameter used in visual assessment of the anterior chamber. Because three points are required to define the angle this measurement is more

subjective than AOD and TISA (defined below) which are measured from anatomical landmarks – scleral spur and surfaces of the cornea and iris.

The *Digital Gonioscopy* definition of ACA begins with the scleral spur and AOD (defined below). The angle rays begin with the endpoints of the AOD500 or AOD750 line. The rays are drawn from these points back toward the angle, and meeting at a software-determined angle-root point. *ACA500* and *ACA750* be displayed using the corresponding icons shown at right. All of the defining points can be manually moved. Points can be reset to the software generated defaults with the *Auto Position* icon shown below.

The *ACA500* and *ACA 750* icons display the software generated angle measurements.

Angle Opening Distance

Angle Opening Distance (AOD) [2] is an objective measurement of the open space in the area of the trabecular meshwork.

It is defined by the perpendicular distance (mm) from the inner surface of the cornea to the iris at a defined distance from the scleral spur measured along the inner surface of the cornea. AOD is most commonly measured at either 500 μm or 750 μm from the scleral spur. *AOD500* and *AOD750* can be displayed using the corresponding icons shown below. All of the defining points can be manually moved. Points can be reset to the software generated defaults with the *Auto Position* icon shown below. Note: AOD and TISA are displayed with the same icon.

The *AOD & TISA500* and *AOD & TISA750* icons display the software generated angle measurements.

Trabecular Iris Space Area

Trabecular Iris Space Area (TISA)[2] is an objective measure if the open space in the area of the trabecular meshwork. It is an area measurement (mm^2). TISA is limited by the AOD (500 or 750) the posterior corneal surface, the anterior iris surface, and a line parallel to the AOD running from scleral spur to the surface of the iris. Like AOD, it is most commonly at either 500 μm or 750 μm from the scleral spur. *TISA500* and *TISA750* can be displayed using the corresponding icon shown above. (Note: AOD and TISA are displayed with the same icon.) All of the defining points can be manually moved. Points can be reset to the software generated defaults with the *Auto Position* icon shown below.

The *Auto Position* icon restores the software generated angle measurement points.

8.7.2   Freehand angle tool

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[2] AOD 500 and TISA500 are defined by Sunita Radhakrishnan, MD; Jason Goldsmith, MD; David Huang, MD; Joseph A. Izatt, PhD; et. al. in: *Comparison of Optical Coherence Tomography and Ultrasound Biomicroscopy for Detection of Narrow Anterior Chamber Angles*, Arch Ophthalmol. Vol 123, Aug 2005.

The ***ACA Freehand*** icon activates the freehand measuring tool. The freehand tool is available even if spur placement has not been confirmed. The default position of the angle points is the ACA750 default position. When the image file is closed the

points return to default. To save a user defined angle configuration use either the *Save as picture* or the *Print report* feature.

8.8 Printing Reports

Custom reports are available for each type of analysis.

To print a report, open the target image in the *Image Analysis window*. Select the tab for the desired type of analysis (see Section 8, ***Image Analysis window***). From the desired tab, click the ***Print a report*** icon. The Print Report window will open. Complete fields as appropriate and click [**Print**].

9   IMAGING PROCESS

This section provides a detailed, step-by-step process for SL-OCT imaging. It is intended as an aid to new users and to help users optimize image quality for accurate analysis. Once a user is familiar with the SL-OCT system and the imaging process, the complete preparation and exam takes only a few minutes.

For best results the manufacturer recommends new users receive training from an experienced user and that new users are comfortable with system operation and image optimization before imaging patients for clinical assessment.

The SL-OCT auto analysis software is designed for white-to-white scans; however, SL-OCT can be used to scan at virtually any angle. (See sample images below.)
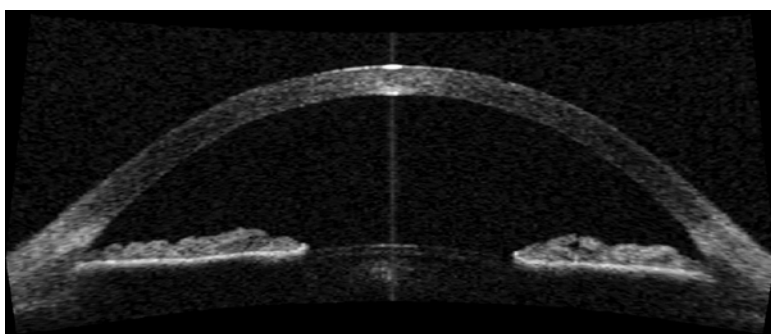
Horizontal (white to white) Scan
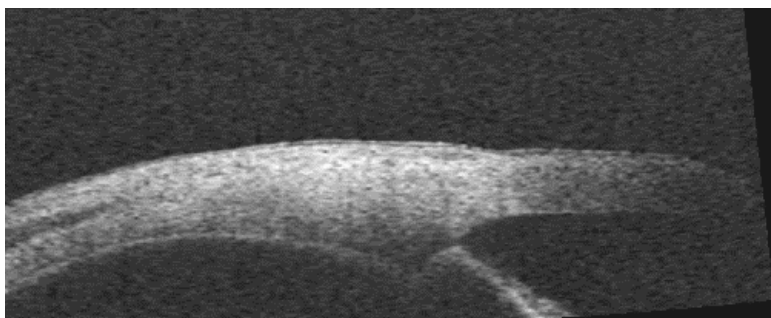
Angled Scan of Sclera

Warning: Only white to white scans which are properly centered with the corneal and lens reflexes situated in the center of the eye (see Section 9.4) can be accurately analyzed. Poorly centered images produce measurement errors.

9.1 Preparing the device

System preparation

- Turn on the main power switch (confirm slit lamp and OCT power switches are on)
- Start HEYEX
- Using either the *New Patient* or *New Examination* icon, open the patient's record
- Enter required patient and exam data to open the *Image Acquisition window*
- Activate the aiming circle, and confirm desired auto-stop setting
- Place cursor over the **[Start]** button

Slit lamp preparation (See slit lamp operation manual for slit lamp operation details.)

- Adjust scan direction (horizontal, vertical, or other)
- Be sure chin and head rest are cleaned between each patient
- With your hand in the approximate position of the patient's eye, adjust the slip lamp beam to   as narrow as possible
- Adjust beam intensity to lowest level easily seen by the operator
  Note: Minimizing slit beam intensity will make the patient more comfortable which may help decrease patient motion and blinking.

9.2 Preparing the patient

Before beginning, explain the process to the patient. Reassure him/her that the device will not contact the eye. The process should be quick and comfortable. Also let the patient know that while he/she must remain still during imaging he/she can blink during most of the imaging process. Once the image is properly aligned (section 9.4), ask the patient not to blink for just a few seconds. Be sure:

- Patient's eyes are properly aligned to the device
- Patient's chin is settled in chin rest and forehead is resting against head rest strap
- Patient is sitting in a stable position. (Note: Patient motion will adversely affect image quality, so ensure the patient is in a comfortable position he/she can maintain throughout the scanning process.)
- A fixation target is visible to the patient AND at the level of the patient's line of sight

9.3 Fixation Targets

If the patient is looking up or down during imaging measurement error will occur.

A **wall-mounted external fixation target** can be used. It should be easy for the patient to see and must be adjusted to the level of the patient's eyes when the patient is positioned at the device. The operator must use care not to block the patient's line of sight to the target during the imaging process.

The slit lamp is equipped with a **slit lamp mounted external fixation target**; instructions for its use are in the accompanying slit lamp manual.

If the slit lamp is equipped with an **internal fixation target**, the patient can see a green target light when the slit lamp is grossly adjusted to his/her eye. The internal target is not visible if the slit lamp beam is shining in the patient's eye. There is an eight degree angle between the optical axis and fovea, so B-scans taken *with* the internal fixation target will be slightly tilted. Image alignment is corrected with the image refractive correction.

9.4   Align the image

- Press the [Start] button – image acquisition will begin.

- **Looking at the patient's eye** (NOT the imaging screen), adjust the slit lamp beam so it
is   sharp and narrow over the apex of the cornea. (Experienced slit-lamp operators may
accomplish this by looking through the slit-lamp; when the iris is in focus, the gross
positioning should be correct.)

- Use the joystick adjustment to position the slit beam until it is directly over the apex of
the   cornea. When the beam is properly positioned at the corneal apex, the scanning beam
reflex   is visible as a bright white light shining in the patient's pupil.

- **Looking at the imaging screen**, move the slit lamp to position the image shown in the
Image Capture window. For quality white-to-white images, it is important that:
  o   Both right and left side angles are visible. (Move device side/side to adjust.)
  o   Apex of cornea is visible. (Move device toward/away from patient to adjust.)
  o   The image is level. (If image is tilted, moving inner slit-lamp arm, the one with
the SL-OCT scanner box, slightly right or left.)

- Use the joystick to, SLOWLY adjust beam to apex of cornea. When the beam is
approaching the correct place you will see *bright reflex spots* appearing at the anterior
surface of the cornea. (See sample image "A" below.)

- At this point, ask the patient not to blink or move. Continue fine-tuning with the
joystick until the *reflex* appears <u>on both outer and inner corneal surfaces *and* the sharp
reflex beam is visible through the anterior chamber</u>. (See sample image "B" below.)
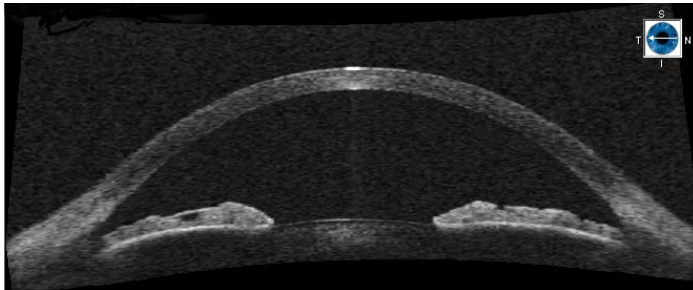
Sample Image A
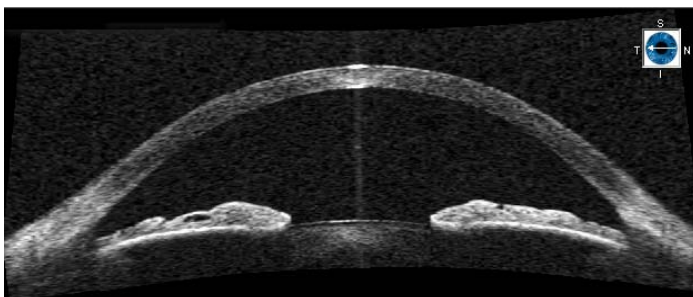
Sample Image B

9.5   Stop/Auto-stop

When the desired number of good quality images is visible in the temporary image windows, click
[**Stop**] to stop acquisition.

If the *Auto Stop* feature is enabled the system will automatically stop acquisition when the user
defined (*Stop afte*r) number of good images are captured in the temporary image windows.

Select and save the desired image(s). See Sections 7.4 *Saving images* and 7.3 *On-line quality screening*.

Once the images are saved, the user can now scan the other eye, take additional scans of the current eye, or exit the acquisition window.

9.6   Vertical imaging

The SL-OCT scanning beam follows the same path as the visible light beam of the slit lamp. An adjustment in the direction of the slit lamp beam results in a corresponding adjustment in the OCT scanning beam.

The process for vertical imaging is the same as the horizontal process described above with the following changes:

- Adjust the slit lamp beam to the vertical direction
- To position the slit at the corneal apex, move the joystick very gently right/left
- To get a clear angle detail in the vertical, the operator may need to gently hold the patient's eyelids apart. It is best to correctly position the image first, and then hold the eyelids during reflex fine tuning and final image capture.

  Note: The operator should always wash his/her hands before beginning the imaging process. He/she should explain to the patient in advance that he/she may touch the eyelids for a moment during imaging. Before reaching toward the patient's eye, the operator should warn that he/she is now going to touch the eyes and remind the patient not to move.

10   EXPORT AND IMPORT OF IMAGES AND DATA

10.1 Export

There are several options to export data from the ***HEYEX*** Database:

10.1.1 Export Data ("E2E") File

The complete dataset of individual images can be exported in the "E2E" file format. Individual images or a series of images (***Batch***) can be exported. E2E files can be exported to a Jumpdrive for import into another SL-OCT device or for viewing and analysis on a separate PC. Viewing on a separate PC requires the ***Eye Explorer Viewer*** software (***SL-OCT module)*** and a dongle. These are available for separate purchase.

To access the E2E export function right-click an image in the Image Viewing window (for individual image export), or any record name in the right-hand side (selected records) of the Database Viewing window (batch export). Select, "Export E2E" (for batch export you must first select "SL-OCT Batch >"). In the "Export Options" window select the destination and chose whether to anonymize the data.

By default, the file name is composed of the patient's name and an ascending number, e.g. SMITH01J.E2E, SMITH02J.E2E, etc. The ***Use file name prefix*** option allows you to generate file names such as EXP001.E2E, EXP002.E2E, etc.

You may enter your institution, practice, company name, or other desired identifying information in the ***Location*** section.

WARNING	**If "Patient ID" is selected to make the data anonymous, and the Patient ID field is blank, the patient's last name will be used as the file identifier. In this case, to preserve patient anonymity, use the "First letter only" option.**
NOTE	Once the data are imported into a different database, they will appear under a ***Patient Record*** with the personal data as specified here. If the exported images are going to be imported into a ***Patient Record*** that already exists in a different database, the exact *last name, first name, date of birth and patient ID* of this existing ***Patient Record*** must be specified in the ***Export Options*** dialog box. If the patient details in the target database do not exactly match this information, then a duplicate patient record will be created.

10.1.2 Export Image as Graphic File

Individual images can be exported as graphics files in BMP, JPG, TIF, or PNG, format. These files do not require the ***Eye Explorer*** viewing software. However, some patient data, analysis information and raw image data is not included in the export.

The Export as Graphic file function is available in the ***Image Analysis*** window via the Picture (save this image as a picture file) icon. In the "Save As" window select the file type and destination. The default setting for this window is NOT to include any file of patient info. Use the ***Options*** section of the window to ad desired file information.

10.1.3 Export Data into Spreadsheet

Parameter values for image files can be exported to a tab-delimited file such as Microsoft EXCEL^{TM}. On images where scleral spur placement has not been confirmed, related

measurements will not be available. Some parameters may also not be available for images with sub-optimal quality.

To export data to spreadsheet file, right-click an image in the *Image Viewing* window (for individual file export) or any file name in the right-hand side (selected files) of the *Database Viewing* window (batch export).   Select, "Export Data" (for batch export you must first select "SL-OCT Batch >"). In the "Save As" window select file type and destination.

10.2   Importing

To import data (E2E files) previously exported from a different SL-OCT database:

1. Insert the media containing the exported data (E2E files) into the appropriate drive.

2. From the main *Database Viewing* window, select the menu item *Import E2E Files* from the *Database* menu.

3. The *Import Examination Data* window will open. Navigate to the drive and folder that contains the E2E file(s) to be imported. The content of the selected folder is displayed in the window.

4. Select the E2E files you want to import in the window and click the *Open* button. To select all files displayed in the window, hold down the *CTRL* key and the *A* key simultaneously.

5. The *Database Import* window opens next. Here you can specify which patient data to include in the import. Click the *OK* button to import the *Patient Records*.

6. After the import, a list of all patients that have been added to the database appears in the right window of the *Database Viewing* window. The *Patient Records* are now available for viewing and data analysis.

11   SETUP /CONFIGURABLE OPTIONS

HEYEX software has a number of user-configurable options and information tabs. These can be viewed and/or configured via the Setup option on the main menu bar. Clicking "Options…" brings up the Options window shown below.

11.1   General

● *Icons*:   Icon size and spacing can be modified.

● *Settings*: Closing the window of the **HEYEX** will shut down the program. The program default provides a pop-up confirmation window to prevent inadvertent shut-down. To turn off the confirmation window, uncheck the box.

11.2   Disk space

• *Disk Space* shows total, used, and available patient data disk space.

• The *Clean-up now* function is disabled when archiving to hard-disk.

• The *Automated clean u*p allows you to preset points for automatic clean-up.
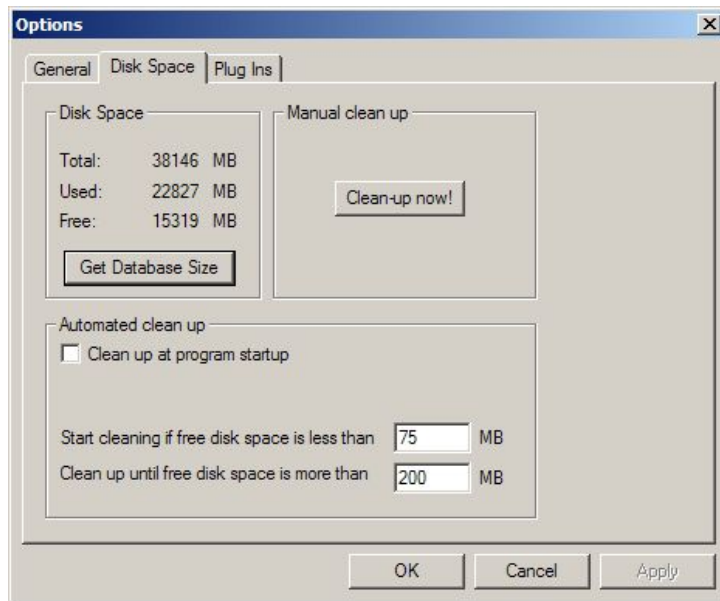
11.3   Plug Ins

This tab shows details about the device-specific, installed software modules. For details on the HEYEX software configuration see Section 2: *Software Configuration*.
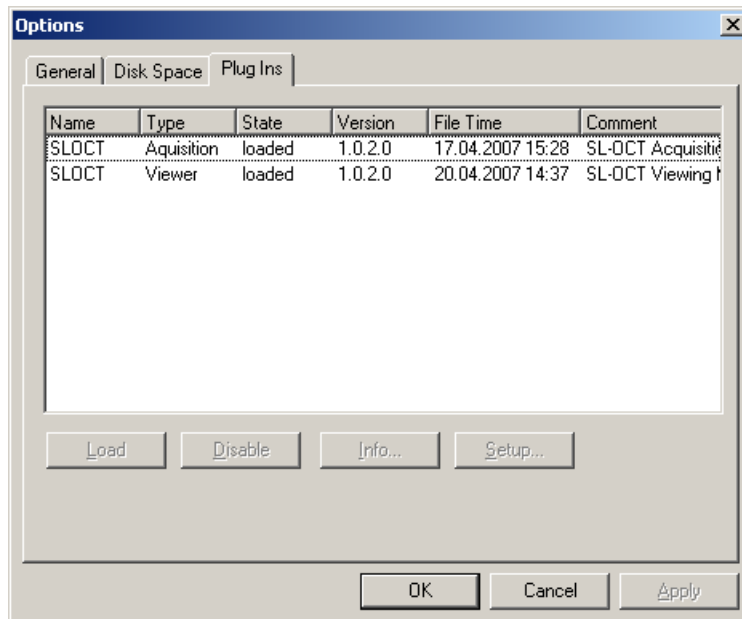
12   TECHNICAL SPECIFICATIONS

12.1   Model Type and Manufacturer

Model type: SL-OCT

Manufacturer: Heidelberg Engineering GmbH
                               Tiergartenstr. 15
                               69121 Heidelberg
                               Germany

12.2   Environmental Specifications

Operating		Non operating	
Temperature:	15°C - 30°C	Temperature:	-30°C - 60°C
Relative humidity:	10% - 90%	Relative humidity:	10% - 100%

The system must not be used in potentially explosive atmospheres.
Do not operate the system directly after large temperature changes. Let the device acclimate itself for a minimum of 2 hours to avoid device damage or incorrect measurement results.

12.3   Electrical Safety

Electrical safety: Application Part Type B

Power Supply and Fuses

Input voltage:	100 V – 240 V
Frequency:	50 Hz – 60 Hz
Fuse 230V:	2.5 A T
Fuse 115V:	5.0 A T
Amperes:	1.2 A
Power consumption:	150 W

Caution! Use isolation transformer conforming to IEC 60601-1

12.4   Laser Source

Diode laser 1310nm, Laser Class 1
Diode laser 1550nm, Laser Class 1 (Internal only. This wavelength does not leave the base unit.
                               Neither patient nor User are exposed to that laser wavelength))

12.5   Scanning Specifications

Scan size:	15 mm
Scan depth:	7 mm
A-Scan frequency:	200 Hz
B-Scan frequency:	1 Hz
Lateral optical resolution capacity:	<100 μm
Lateral digitalized resolution capacity:	75 μm
Axial optical resolution capacity:	<25 μm
Axial digitalized resolution capacity:	10 μm
SNR (signal-to-noise ratio)	>90 dB

Technical specifications are subject to change without notice.

12.6   Service, Maintenance and Cleaning

- Please be aware that only authorized service personnel is allowed to perform service and repair operations of the SL-OCT, so do not open the device as otherwise you will forfeit the warranty. If the device fails, please call your local distributor or the Heidelberg Engineering support department.

- The SL-OCT is a precision optical measuring instrument. Protect the instrument against dust and moisture, and avoid shocks and strong forces.

- The optical components of the slit lamp should be carefully cleaned at regular intervals. To do so, follow the instructions provided by the slit lamp manufacturer.

- The non-optical surfaces of the instrument can be cleaned and/or disinfected as usual whenever necessary. Before doing this, turn the instrument off and pull the power plug out.

- A yearly inspection of the device by a Heidelberg Engineering Service unit is highly recommended to ensure proper and exact operation.

- Please observe the operation manual of the slit lamp when cleaning the optical components of the slit lamp.

WARNING:
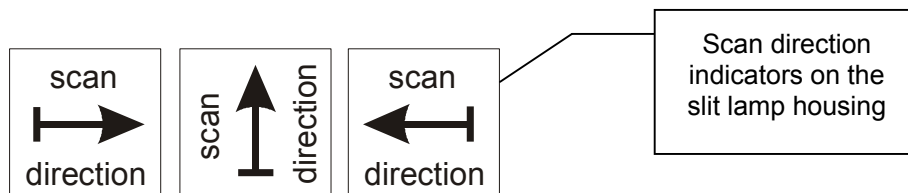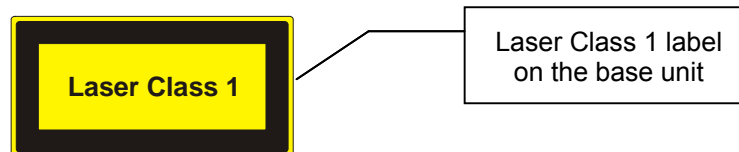Do not modify this equipment and do not open the housing!

12.7   Operational Environment and User training

The intended operational environment of the device is a clinical setting, medical practise or similar location under the direction of a trained ophthalmologist or optometrist

Only a qualified Heidelberg Engineering employee or distributor shall initially train the user.

Heidelberg Engineering periodically offers user training courses for clinicians, researchers, physician assistants and technicians.

12.8   Labeling

HEIDELBERG ENGINEERING

Heidelberg Engineering GmbH
69121 Heidelberg, Germany

Model:	SL-OCT Ver. B01
Serial No.:	00010508
Voltage:	100-240 V
Frequency:	50-60 Hz ~
Amperes:	1,2 A
Temperature:	15°-30° C

CE 0482

Type label on
the base unit

Serial number
of base unit

Maximum current

Operating temperature

Read Operation
Manual

Application Part
Type B

HEIDELBERG ENGINEERING
Heidelberg Engineering GmbH
69121 Heidelberg, Germany

230 V ~ : 2 x T 2,5A / 250V
110 V ~ : 2 x T 5,0A / 250V

Fuse label on
the base unit

Fuses to be
used

Laser Class 1

Laser Class 1 label
on the base unit

scan
→
direction

scan
↑
direction

scan
←
direction

Scan direction
indicators on the
slit lamp housing

APPENDIX A: TECHNICAL NOTES

A.1   Repeatability

The repeatability of the biometric measurements is defined as the standard deviation estimate of large test series. It describes the variation of measurements of the same eye under the same circumstances.

Measurement	Repeatability (standard deviation)	Repeatability (95% confidence interval)
Central Cornea Thickness	± 5.6 µm	± 11 µm
Anterior Chamber Depth	± 11µm	± 21 µm
Anterior Chamber Volume	± 4.1 mm³	± 8.0 mm³
Cornea Anterior Radius	± 0.56 mm	± 1.1 mm
Cornea Posterior Radius	± 0.36 mm	± 0.70 mm
Pupil Diameter	± 0.27 mm	± 0.52 mm
Scleral Spur Distance*	± 0.14 mm	± 0.28 mm
Angle Opening Distance AOD 500*	± 59 µm	± 120 µm
Angle Opening Distance AOD 750*	± 65 µm	± 130 µm

* User confirmation of scleral spur placement is required.

A.2   Refractive index

Refractive index cornea =1.376
Refractive index vitreous =1.336

These refractive indices are used in the literature for the model of Gullstrand of the human eye. These indices are for visible light. In the SL-OCT infrared light with λ=1300 *nm* is used.

There is one published paper concerning the refractive index of the human cornea at this wavelength in vitro (Lin et al., Opt Lett 2004:29:83-85). Until additional information on the refractive index at 1300 nm in vivo becomes available, the Gullstrand indices as above will be used in the SL-OCT software.

APPENDIX B: DISPOSAL

Within the European Union:
The device must be returned to Heidelberg Engineering for disposal.