

USER MANUAL



Software for Retina 400



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DISCLAIMER

Each device manufactured, marketed and / or otherwise placed on the market - directly and / or indirectly by the manufacturer is made in accordance with the provisions and regulations in force in their user manuals contain the necessary information to ensure intended use and to identify the manufacturer, whilst taking into account the training / experience and knowledge of its intended users.

This information, including that contained in the accompanying manuals for our products and our technical advice, whether verbal, in writing or by way of demo and experiment, is provided on the basis of our best knowledge. However, they must be considered as information without any binding effect, including those with respect to any industrial property rights of third parties, and do not exempt the customer from checking the current versions of our advice and suggestions, in particular of our material safety data sheets, instruction manuals and technical information, and products supplied by us, in order to estimate their suitability for the intended purpose and processes.

The application, use and processing of our products and the products manufactured by the customer on the basis of our technical advice and / or maintenance activities occur outside of our control and fall, therefore, entirely under the customer's own responsibility, for which the manufacturer assumes no responsibility as set out below.

The technical results and / or data resulting from handling or use of our devices must be analyzed by experienced professionals in various fields of application of the specific product being otherwise compromised the correct reading and analysis of data.

The sale of our products is governed by our General Conditions of Sale and Delivery as amended.

The software provided by us in conjunction with our products or otherwise made available for download on your computer or for use online are the exclusive property of the manufacturer which disclaims any responsibility for the accuracy of the results obtained with the programs or algorithms used by the programs themselves or liability resulting from the incorrect use of the software.

For data security, please refer to the management of Windows security. It is recommended to enter a password to access the account used.

Before performing an upgrade of the application or the archive, and / or at least before any maintenance operation, we advise to make a backup of the complete patient database. It is also recommended you periodically (every week at least) make a backup on a different medium of the one normally used (e.g. CD-ROM or DVD). The manufacturer srl bears no liability for loss of data due to improper handling of the archive.

All measured data, calculated and interpreted and subsequently displayed to the user must be considered subject entirely to customer's responsibility. The manufacturer remembers that any data and / or information arising from the use of the above software must necessarily be compared and verified with results from other devices in order to verify the exact calibration of the instruments and their proper functioning according to the specific parameters provided by the customer.

It should be noted, more specifically, that the indices of keratoconus screening provide mere indications which however are not sufficient for assessing either instrument calibration status nor the patient's clinical situation. Therefore, these indices are considered tools that the user can use to provide a diagnosis but cannot be considered themselves a diagnostic interpretation of keratoconus. Therefore, we recommend the user to exercise caution in evaluating these values and to correlate with other indices of screening tests and the clinical picture of the patient.

The manufacturer does not assume any responsibility for damage of any kind howsoever arising and especially the application of the results of the Summary of Cataract in the software, including those arising from an incorrect calculation of the IOL. The user of the program must verify by plausibility considerations that the proposed values do not contain gross mistakes.

The manufacturer assumes no responsibility and makes no guarantee of accuracy, calibration and / or exact measurements provided by the Products and / or software with which they operate even if provided by the manufacturer itself.

Consequently, the manufacturer will not and cannot be held responsible in any way or for any reason for any direct, indirect, consequential in general, of image, or profit loss, or moreover of any kind or species whether they are persons, property or other equipment or products that the customer complaints as a direct or indirect consequence of the use of our products and our software.

1. START-UP

1.1 AnaEyes Program

Regarding Windows 8 users: after having installed AnaEyes on the Operating System Windows 8, it is necessary to start the program with an elevated level of privilege. We advise to choose the setting from properties like below:

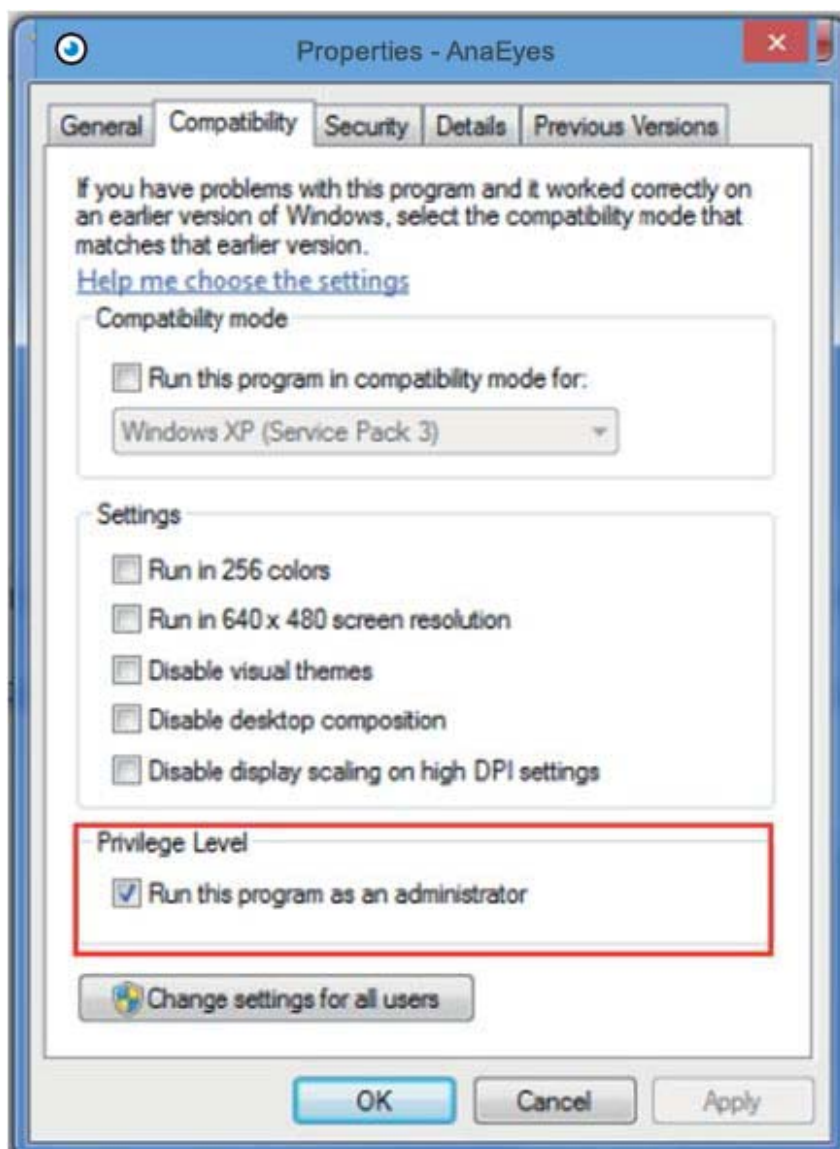


Figure 1-8 Set the privilege level

Click the AnaEyes icon on the desktop. The screen shown below will appear, asking the user to send an e-mail containing the code for unlocking the software.

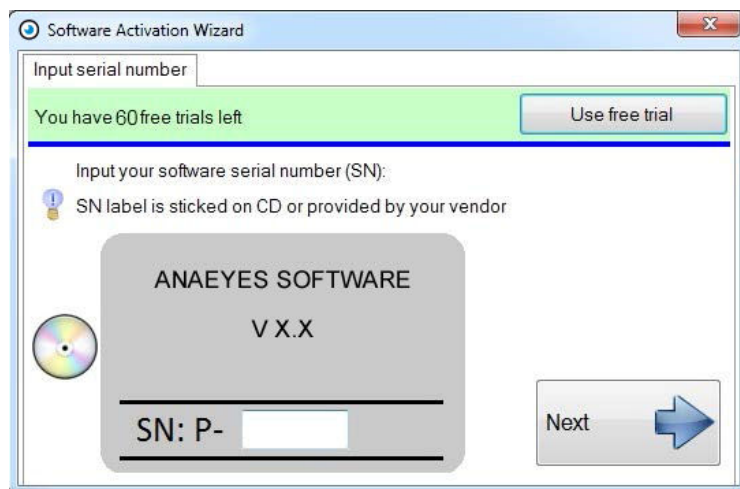
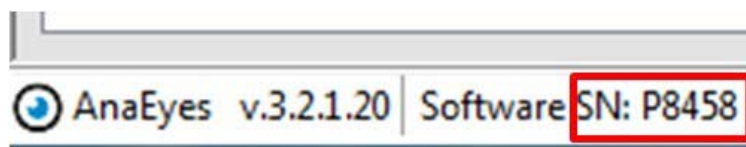


Figure 1-9: Registration Screen

Remark : RETINA400 connected with USB3 interface are delivered without labels with P-codes. The P code is displayed at the bottom of the screen.



You need to connect the database when you open the first time the software. Press OK if the database has been created during the installation and AnaEyes is ready to use.

If the database is just present, press browse button and select AnaEyes.mdb. You need to connect the root.essilor file contents in the same database folder. Open the Miscellaneous menu in the settings and check if the Image root field is complete. Otherwise search the root.essilor that will be in the database AnaEyes.mdb folder (see 4.4).



Figure 1-10: Database connection

Confirm pressing OK. The main screen will open.

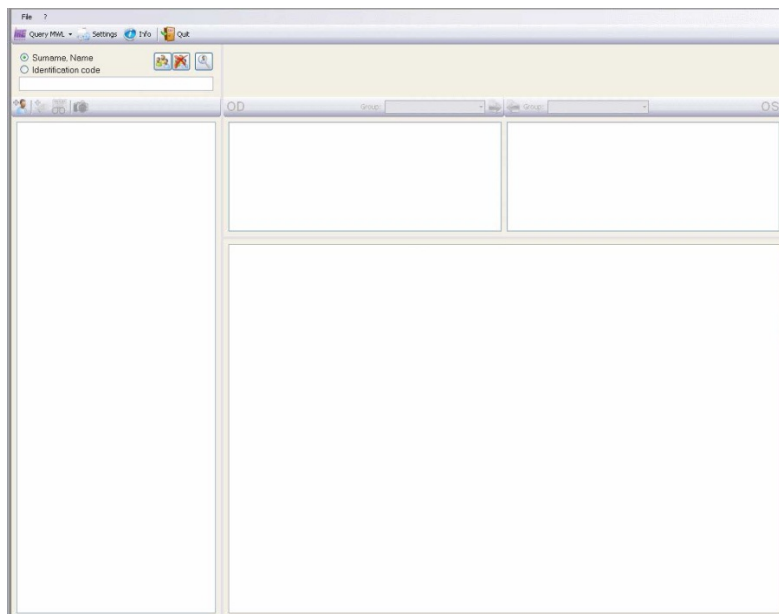


Figure 1-11: Main Screen of the AnaEyes Program

This first screen allows the user to manage the database of patients and the examinations associated with each. It is made up of various sections and menus.

When the program is launched, all the windows are empty.

1.2 File Menu



Settings

Allows the user to select the software language, manage groups and instruments, and make other settings (see Chapter 4). This menu may be accessed only if the patient list is not displayed.

If patients are displayed in the list, click  [Clear Patient List] to enable the Settings function.



Esc

Exits and closes the program.



Figure 1-12: Confirm Exit from Program

Selecting the suitable box on the Settings/Other menu (see Chapter 4), displays a request for confirmation of exit from program. Click Yes to exit or No to continue using the program.



All data measured, calculated and successively displayed to the user are to be considered subject to the user's full responsibility. The manufacturer shall use its best endeavors in order to ensure that all the data displayed in the software is complete and accurate. Nevertheless the instrument's manufacturer bears no liability for any consequential damages and will not accept claims that result from incorrect data, and successive incorrect interpretations. Data obtained from the software should always be compared and scrutinized with results of different instruments.

2. PATIENTS DATABASE

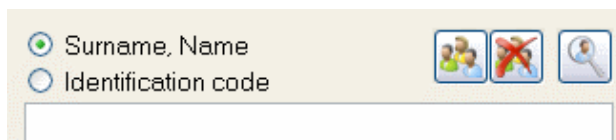


Figure 2-1: Search Panel

Each patient is identified by Last Name, First Name, and an Identification Code that is automatically generated by the program.

To locate a patient in the Database, type the Last Name and First Name in the Patient Box or type the Identification Code.

To select a search criterion, click the button alongside Last Name, First Name or alongside the Identification Code. To view a patient, type his/her Last Name, First Name (or Identification Code) in the Patient Box. As the letters or numbers are typed, the pull-down list will display patients meeting the criteria. If the typed characters

do not yield any results, a warning icon will appear  The warning icon is also displayed in the case an excessive number of results is returned.

Once a patient is selected, his/her Last Name, First Name (with Identification Code and date of birth) will be displayed in large type in the top portion of the screen.



Fill Patient List

Displays all the patients entered in the database.



Empty Patient List

Empties the contents of the window in which the patient list is displayed but does not delete the patients from the database.



Search

Permits searching patients in the database by gender, date of birth, check-in number, examination date, patient age, referring physician, instrument, or group (see Paragraph 2.5).





To enter a new patient in the database, click the  icon on the main screen to open a new window. Enter the patient data in the window: last name, first name, date of birth, and gender. Typing a Last Name, First Name pair in the Patient Box automatically opens the window for entering the data for the new patient.



Figure 2-2: New Patient Data Window

Date of birth must be entered in the form: two digits for the day, two digits for the month, and four digits for the year. Entering an invalid datum will cause a warning icon  to be displayed.



Entering a patient whose data are identical to those of a patient already contained in the database will likewise open a window containing a warning message.

The identification code is automatically entered by the system unless a different option is selected from the DICOM Settings menu. See Chapter 4.4.

To confirm new patient entry, press the Enter key or click the [OK] button. To cancel, click [Cancel].

Whenever a new patient is created, an examination associated with that patient is also created. A window for selecting the examination type then opens (See New Exam below).

2.1 Patients List

Any new patient entered is displayed in the patients list window on the left-hand side of the screen. To view the list of all the patients entered, click the  button. To empty the contents of the patients list from the main screen, click the  button.

2.2 Patient Data

When a patient is selected, the entered data will be displayed on the main screen (red rectangle).

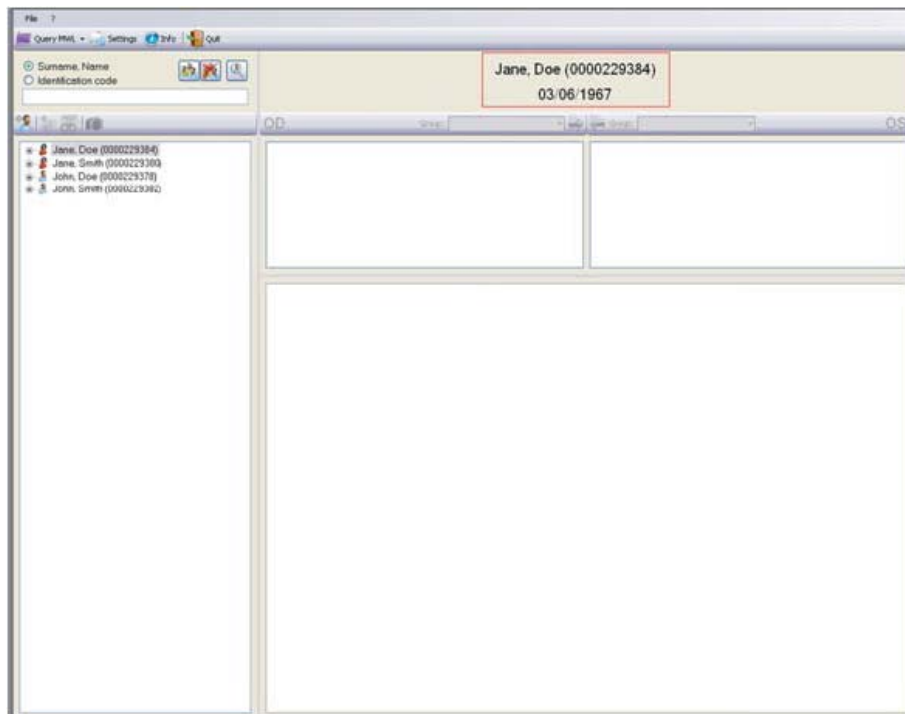



Figure 2-3: Patient Data



2.3 Editing Patient Data

To edit the patient data, move the mouse pointer to the patient name and right-click. Select

 Edit patient data, which reopens the patient data window for editing the last name, first name, date of birth, and/or gender. Click OK after having made all required changes.

2.4 Selecting a Patient

A patient already listed in the database can be selected in a number of different ways:

- Type a last name and first name in the Patient Box. In order to insert the last name and name correctly you must type: Last Name comma First Name, without spaces. If the typed name does not correspond to any patient already present in the database, press Enter to open the window for entering a new patient.
- Click the  button and use the ↑ ↓ keyboard keys to scroll the patients list or select a patient directly from the list. With the Patient Box empty, press Enter or double-click the highlighted patient name. A patient archive may be opened by clicking the  button to the left of the name.
- Type in a portion of the Last Name, First Name string to display a list of patient names meeting the criteria. To select a particular patient, proceed as described in the previous point. For instance, you may display all the patients whose names begin with a given letter, or who have the same last name, or who have the same last name and the same first-name initial, etc.



When a patient is selected, the list of associated examinations opens automatically (see Chapter 3: Examinations Database).

2.5 Advanced Search



Click the button to access the advanced search function.


Figure 2-4: Advanced Search

For each of these categories, clicking the  button so as to check (select) it , visualizes the boxes for entering search criteria:

- by gender: male or female
- by date of birth: start and end dates of the interval to be searched
- by check-in number: a box for entering the number; this field features the automatic completion function
- by examination date: start and end dates of the interval to be searched
- by patient age: minimum and maximum age
- by referring physician: a box in which to type the physician's name
- by instrument: a list of possible examination capture instruments (for example, Fundus camera, kerato scope, pupillographer, Scheimpflug camera, slit lamp biomicroscope)
- by group: a list of the groups created via the Settings function (see Chapter 19)
- by caption: the caption added to a single acquisition is used as a search parameter

Select the boxes that permit establishing the search criteria. Click [Search] to display the search results.

2.6 Delete Patient

To delete a patient name, right-click the patient, select  Delete patient and then confirm the deletion request warning message.

Warning: deleting a patient also deletes all the examinations associated with that patient and the relative images.

3. EXAMINATIONS DATABASE

An unlimited number of examinations may be associated with each patient; the examinations are defined on the basis of the instrument used and the date of creation.

3.1 New Exam

After a new patient is created, an examination will also be created.

To create a new examination for an existing patient, click the  button.

If working with a single instrument, the image capture mode will be automatically accessed. Otherwise, if at least two instruments are used, the window shown below will open. Select the instrument to be associated with the current examination. After selection, the capture mode is accessed.

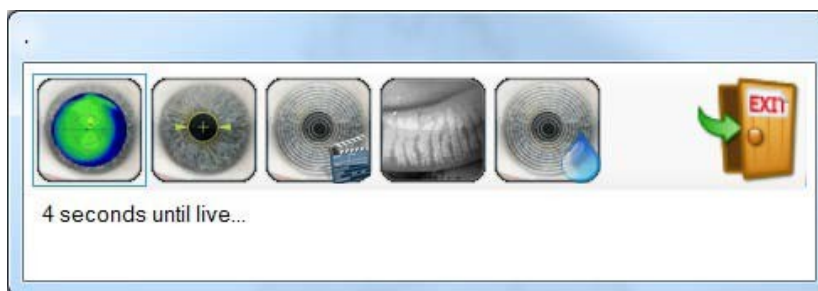



Figure 3-1: Instrument Selection

Each examination is filed by date of creation and instrument type. It is also possible to attribute a pathology group [Group]. Classifying the examinations by codified groups is useful for conducting searches. The groups list may be edited from the Settings menu (see Paragraph 4.3).


3.2 Selecting an Examination

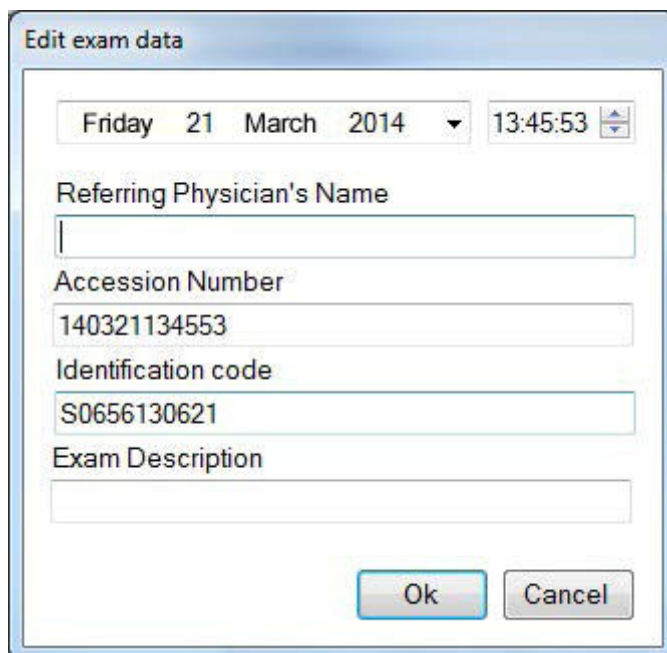
Once a patient has been selected, click the  button or press Enter or double-click with the mouse to access the Examinations Database.

Clicking the + symbol to the left of the patient name opens the list of examinations associated with that patient. The + symbol becomes a –. Click the – symbol to close the list.

Alternatively, open the list by pressing the → arrow key on the keyboard and close it by pressing the ← arrow key. To select a previously-stored examination, use the mouse or scroll with the ↓↑ keyboard arrows to highlight one examination after another and, for each, view the relative images in the window on the right-hand side of the screen.

3.3 Editing Examination data

To edit the data for an examination, select the exam, right-click, and select the  *edit exam data* command [Edit Exam Data].




The 'Edit exam data' dialog box contains the following fields and controls:

- Date and Time: A date picker showing 'Friday 21 March 2014' and a time spinner showing '13:45:53'.
- Referring Physician's Name: A text input field.
- Accession Number: A text input field containing '140321134553'.
- Identification code: A text input field containing 'S0656130621'.
- Exam Description: A text input field.
- Buttons: 'Ok' and 'Cancel' buttons at the bottom right.

Figure 3-2: Editing Exam Data

This action opens a window in which the user may edit the date and time of the exam, enter the name of a referring physician and add a description of the exam. Click OK to confirm the changes; otherwise, click Cancel.

3.4 Deleting an Examination

To eliminate a patient examination from the database, select the examination to be deleted by right-clicking, then clicking  *Delete exam* and confirming the deletion request warning message.

Warning: deleting an examination also deletes all the images associated with it.

3.5 Refraction



When an exam is selected, the *(Refraction) icon goes active. Selecting the Refraction icon opens a window from which to enter the patient refraction data.*



Sph[D]	Cyl[D]	Ax[°]	@[mm]
+0.50	+0.75	15	12.5
+1.27	-0.77	105	0

UCVA BCVA

Ok Cancel

Figure 3-3: Entering Refraction Data

Two labels permit opening the right eye (OD) or left eye (OS) chart. If the refraction value entered is the value measured on eyeglasses and the corneal apex-to-lens distance is entered in the box for that purpose, the system calculates the refraction at the corneal vertex. Enter the values of the sphere in diopters (Sph), the cylinder in diopters (Cyl), the cylinder axis in degrees (Ax), and the distance to test eyeglass in mm (@) in the

relative fields. If the data is incomplete, the warning icon  will appear. If the data are correctly entered, the  icon will be displayed

The patient's natural visual acuity is entered in the UCVA (Uncorrected Visual Acuity) box; the maximum visual acuity attainable with correction is entered in the BCVA (Best Corrected Visual Acuity) box.

The [Cancel] button closes the window without saving the changes. To save the entered data, click the [OK] button or press [Enter].

3.6 Capture



The *Capture icon goes active when a new exam is created or when an empty exam is selected. It permits selecting the instrument with which to capture the exam and accessing the capture environment.*

3.7 Image Gallery

When an exam previously stored as described above is called up, the Gallery window on the right-hand side of the main screen will show the images relative to each exam as it is selected.

The images are subdivided by OD (right eye) and OS (left eye).

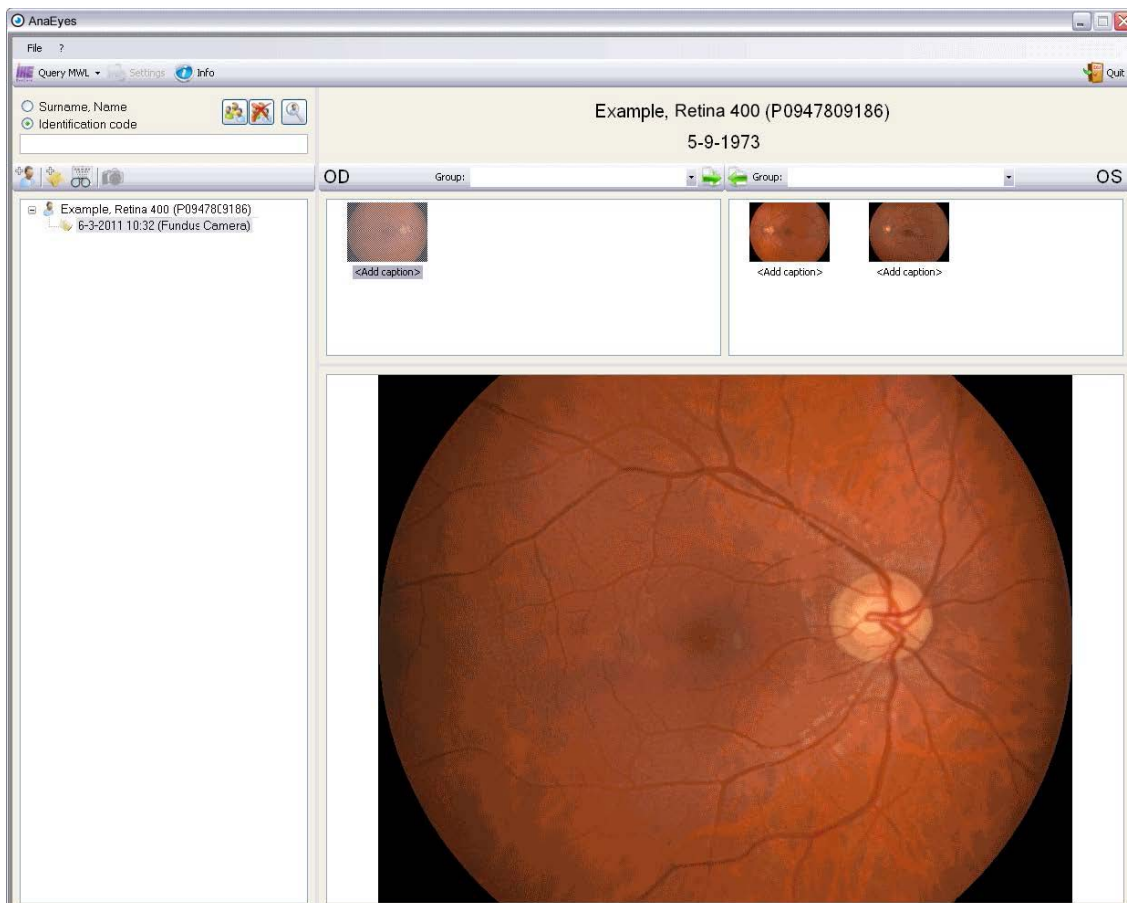



Figure 3-4: Image Gallery

A type group may be defined for each eye in order to facilitate future searches.



Figure 3-5: Groups

Click the  button to open the pull-down menu of the groups entered in the Settings/Groups menu (see Chapter 19). To enter the eye being examined in a yet-to-be-defined group, select <new group> to open a box in which to enter the name of the new group.

Select a group. The  buttons permit associating the right eye group with the left, and vice-versa.

You can filter the list of thumbnails in the gallery by selecting one of the filter elements from the dropdown menu: All (default choice), only images, only reports, only movie frames, only lenses or only mosaics.

Clicking an image displays a preview of the summary of the selected examination in the lower portion of the screen.

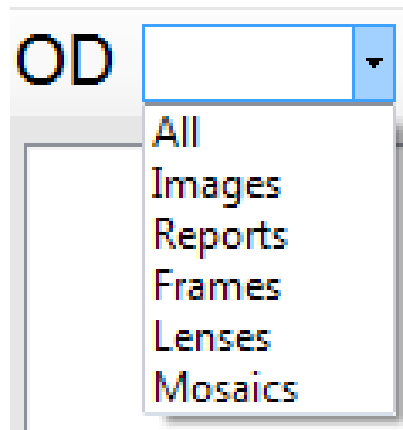




Figure 3-6: Filter



Double-clicking an image opens the processed image summary (Chapter 5).

Right-click a gallery image and select  Add caption F2 to add a brief description. To eliminate an image, click  Delete acquisition CANC.

To open an image, double-click with the left mouse key or press Enter:

- If the selected image is a previously-processed map, the topographic maps viewing environment will open.
- If the selected image is a still-to-be-processed Scheimpflug capture, the image is first processed and the summary environment is then opened
- If the selected image is pupillographic, the pupillography examination will open.
- If the selected image is an image acquired with the slit lamp, the image viewing environment will open.

4. SETTINGS

The Settings menu may be accessed only if the Patients List is not displayed on the main screen. Click the  button to empty the patients list. Then click  or open the File menu and select Settings.

4.1 Language

After selecting Settings, the menu for setting the system language will open.



Figure 4-1: Settings

Select the language to be used by the software and click [OK].

4.2 Instruments

Clicking the Instruments label accesses the section for managing the instruments to be used.

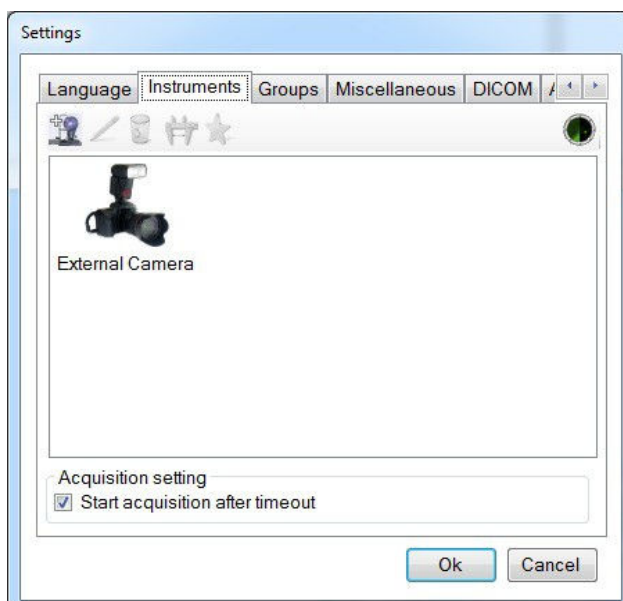



Figure 4-2: Instruments Management

Connect all the instruments to use and press the Instruments wizard button  . You will see the next window with the instruments installed.

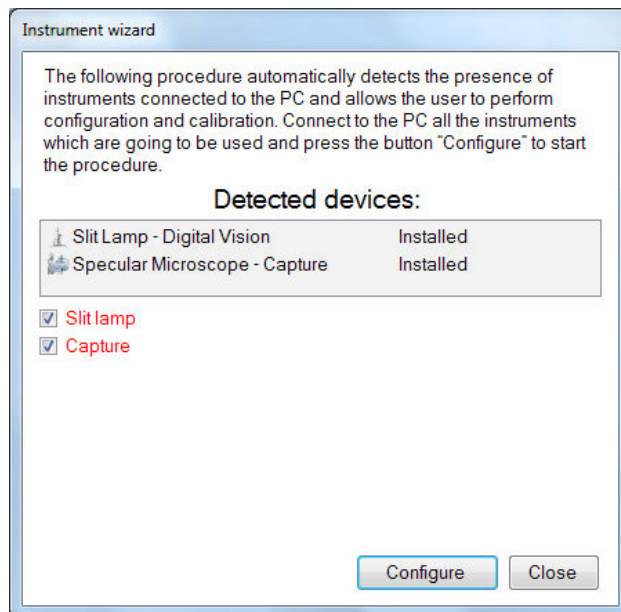



Figure 4-3: Installed instruments

Press the Configure button to modify the settings. You will see the Figure 4-4.

The  button permits inserting manually a new instrument for use. The instruments must be inserted using the wizard.

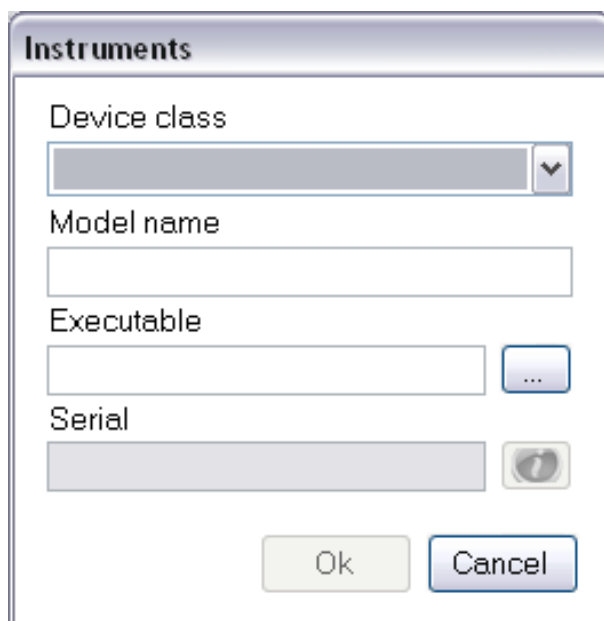




Figure 4-4: Inserting a New Instrument

Enter the model name (reported alongside the exam) and an Executable File (select the SCLive executable file), then select the class from the pull-down window shown in Figure 4 4. When done, click [OK].

After the system has automatically installed the instruments Scheimpflug camera and topographer, it will start the first calibration, (see the next paragraph).

The  button permits editing an existing instrument.

To eliminate an instrument from the list, select it and click .

Click the  button to calibrate the instrument. For calibrating, see next paragraph.

In the following setting, you can choose whether to set a timeout in choosing the instrument (5 seconds), after which the instrument's live application will be launched automatically. When not checked, the acquisition choice screen will be shown until the user makes his choice.

4.3 Groups

For creating, editing, or deleting groups of examinations.

Cataloguing the examinations by homogeneous type groups (for example: keratoconus, PRK myopia, PPK hypermetrophy, trauma, etc.) is useful as a search aid.

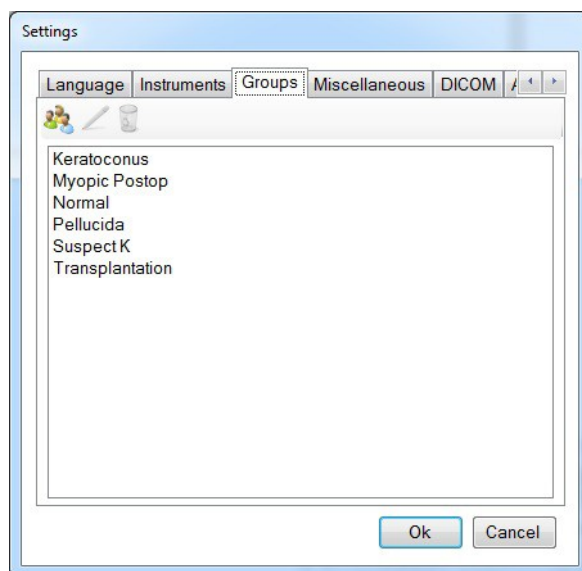





Figure 4-5: Groups Menu

Click the  button to insert a new group.

The  button can be used to edit pre-existing groups. This button goes active when a group is selected for editing.

The  button is instead used to delete a group. It goes active when a group is selected for deletion.

4.4 Miscellaneous (Other)

Clicking [Other] accesses the window shown below:

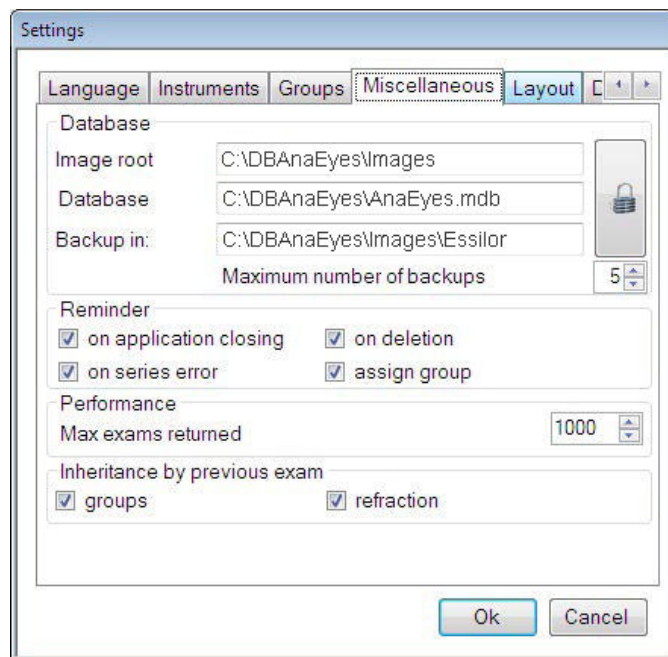


Figure 4-6: Other Information Menu

Database





Click the unlock button  to change image root and Database.

Image root: Clicking the  button in this section selects the image management file called root.essilor.

Database: Using the  button to select a file from the database AnaEyes.mdb.

Backup in: Using the  button you can choose the destination folder fo backup files. You can choose the maximum number of backups to perform.

Reminder

The user may select among the following options:

- Close application: displays the message requesting confirmation to close the application.
- Delete: displays the message requesting confirmation to delete an image from the gallery
- Series error: this warning is given when traces of images erroneously moved to other folders or files remain in the examination in question.
- Assign group: after performing an acquisition a reminder is presented for classification (group assignment) of the assigned series

Performance

Max exams returned sets a limit to the maximum number of examinations upon database queries Might be set in case of network environment, to tune performance.

4.5 Layout

Clicking [Layout] accesses the following screen:

Patient Management

Deselecting Patient ID (external option box) also deselects the other two options (mode and PMS) and it will be possible to insert the ID code at the moment a patient is created.

If this option box is instead selected, it will not be possible to enter the ID code manually. Select one of the following two options:

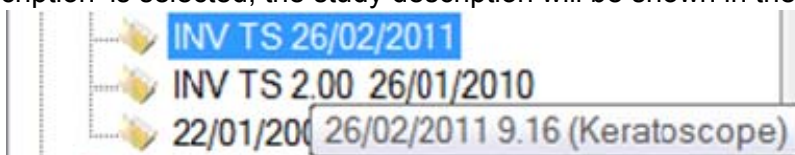
- Modality: the ID code is automatically assigned by AnaEyes when a patient is created.
- PMS: The ID code and relative personal data will be crossloaded to AnaEyes from an external database. The ID of the agency or institution providing the data must be entered in the field alongside the PMS item.



Note that in the latter case, the insertion of patient is deactivated.

Study Management

- When 'Show description' is selected, the study description will be shown in the main patient tree.



- Otherwise the description will be visible in overlay (meaning, that when the mouse passes over the examination, the description will be visible as a tooltip)

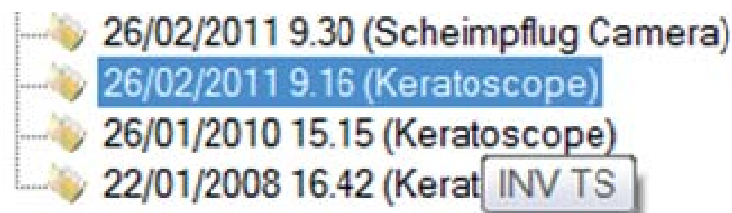


Image Management

Selecting 'Immediate Image Refresh' will offer immediate access to the single acquisitions. Upon examination loading, as soon as a single image is loaded, it will be accessible in the gallery. Otherwise, all images are pre-loaded and then made available.

Instrument Management

- When 'Show calibration shortcut' is selected, the main gallery will show shortcuts to the calibration procedure for both Scheimpflug camera as Topographer.
- Automatic ordering – setting as available until now, where the latest acquisitions are shown first in gallery
- Manual ordering – latest acquisitions are visualized first in gallery, unless the operator chooses to change manually their ordering, by drag-n-drop

4.6 DICOM (Digital Imaging and Communications in Medicine)

DICOM is a medical computer standard adopted by many health agencies and hospitals in all parts of the world, which permits medical operators to exchange images and other information via computer systems adopting this standard.

Deselect the “Suppress DICOM messages” box to show any errors that do not interfere with image capture.

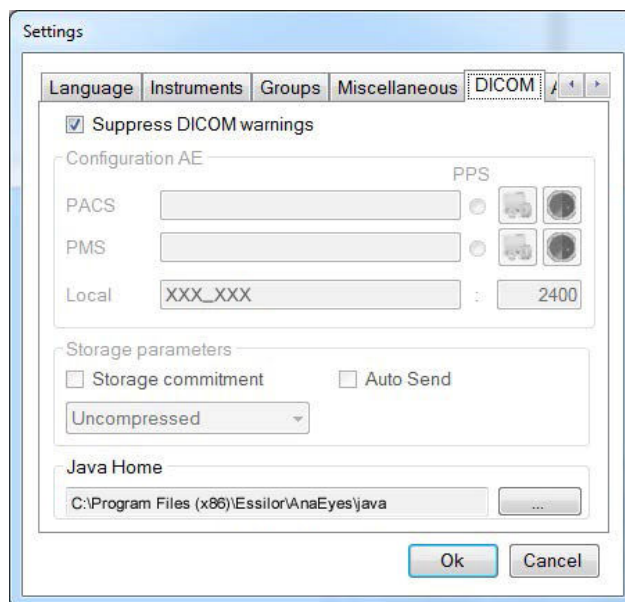


Figure 4-7: DICOM

If DICOM is instead selected, the remaining menus must be used.

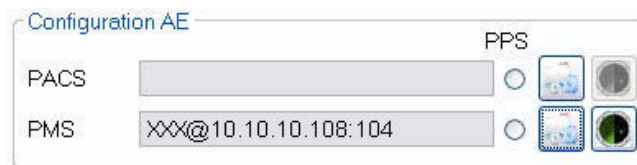



Figure 4-8: AE Configuration

Click the  PACS or PMS button to open the following windows:

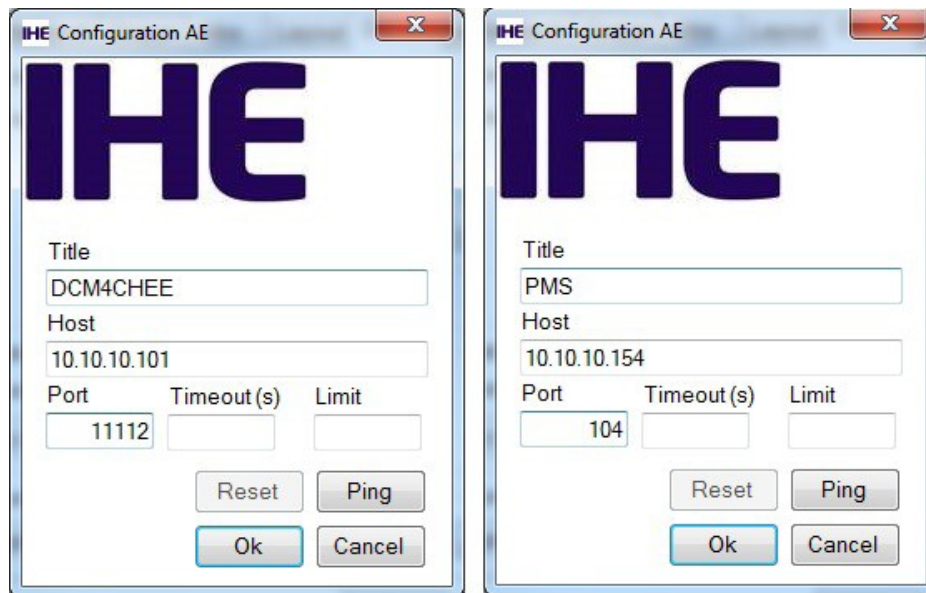


Figure 4-9: PACS and PMS Configuration

This window allows the user to identify the PACS system that will receive his information or the PMS system from which information may be requested.

In the relative fields, enter:

- Title: PACS/PMS ID.
- Host: PACS/PMS IP address.
- Port: PC port to which PACS/PMS is referred.
- Timeout(s): maximum waiting time before disconnecting a call.
- Limit: for PMS configuration only, identifies the maximum number of exams that may be received. If the field is left blank, any number of exams may be received.

Click [OK] to save the settings as entered; otherwise click [Cancel].

Click [Ping] to initiate a call to the PACS/PMS system.

Click [Reset] to remove PACS/PMS Setting

Under local you can configure the local Application Entity name and port.

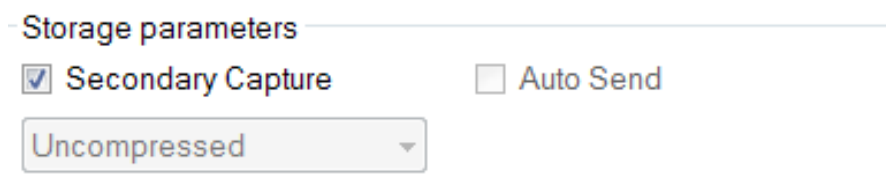


Figure 4-10: Save Parameters

The Storage Parameters allow the user to specify several data storage options:

- Secondary capture: by choosing this checkbox, the secondary capture will be sent, instead of the original acquisition. This is in fact the image that is shown in the gallery, created in a second moment, after original acquisition.
- Auto-send: by choosing this checkbox, AnaEyes will be configured to send images immediately after acquisition. This option is not available when secondary capture is chosen.

- **Lossless:** select this box to select the type of compression used for sending, in a 5% to 100% ratio in 5% steps, in .jpeg format. Otherwise, the files are sent in the original, uncompressed format. Note that this principal is based on a best-first algorithm: when images are originally acquired uncompressed, all compression options can be performed; when the image is acquired lossless, it can be forwarded also lossy, but not uncompressed; finally, when the image is acquired lossy, it can't be forwarded other than lossy. This option is not available when secondary capture is chosen

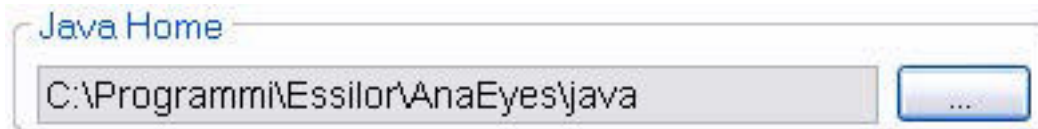


Figure 4-11: Java Runtime Environment

This parameter, defining the environment required for using the functions offered by DICOM, is configured at end of software installation.

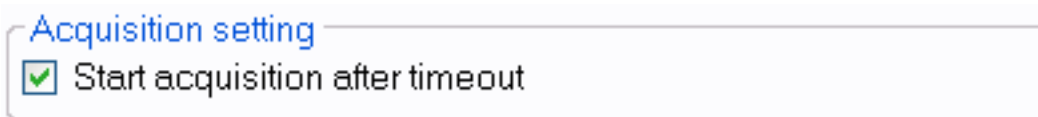
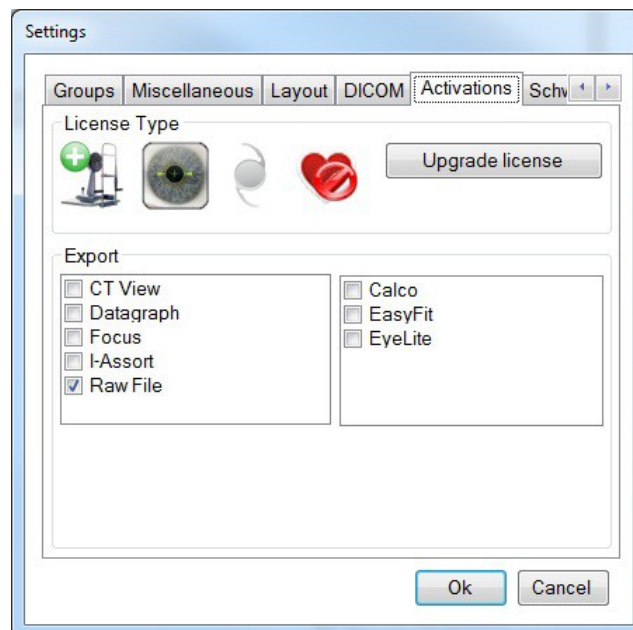


Figure 4-12: Choice time-out

4.7 Activations

In this section it is possible to upgrade the license of the software.



In the section Export it is possible to enable the data export to external applications.


Figure 4-13: Activation settings

For a number of external applications it is possible to configure the export on the main gallery. The default can be chosen from the combo box. Check the reminder if you want a reminder message for exporting both eyes contemporarily to the external application.

4.8 Schwind

In the 'Schwind' section the user may configure some settings solely for Schwind exports. The back-up folder for schwind exports and the export file name format

5. CAPTURE

The  Capture icon goes active when a new exam is created or when an empty exam is selected. This function allows the user to select the instrument with which to capture the examination and to access the capture environment.

Capture window Toolbar

BUTTON	SHORTCUT	ICON	FUNCTION
Settings	-		Opens the panel for setting general capture parameters.
Focus Indicator	-		Reactivates the focusing support window (if deactivated).
Exit	-		Exits the Capture window.

Toolbar Buttons Summary

The window shown below will open.

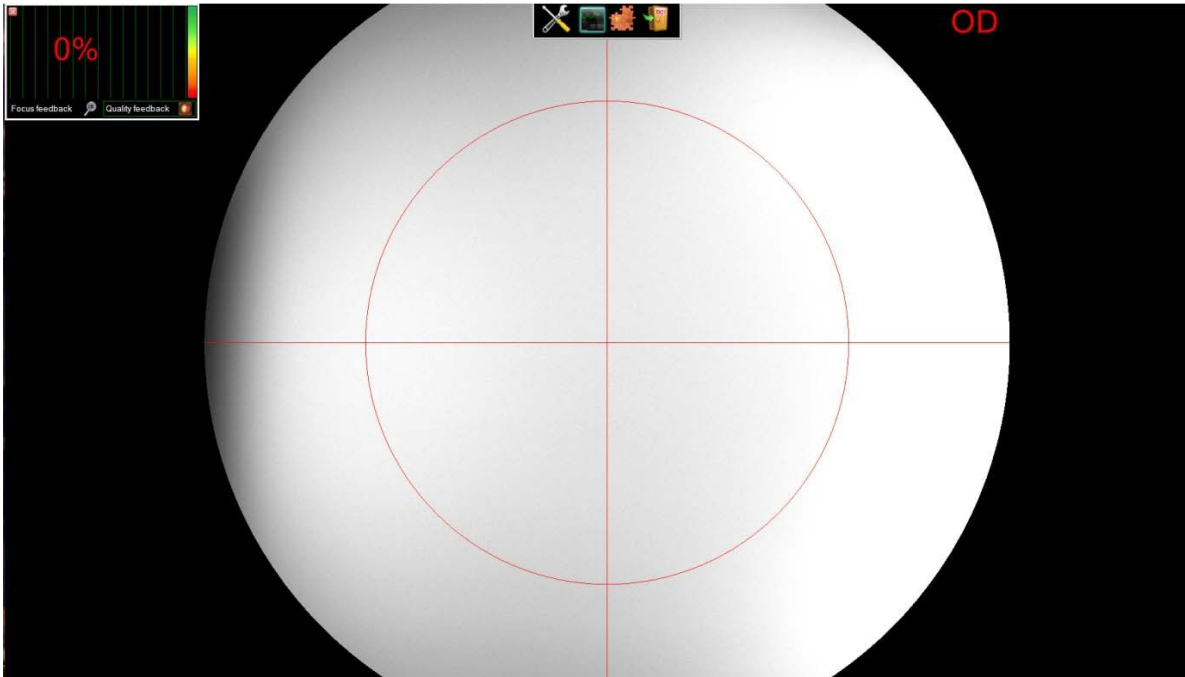


Figure 5-1: Capture Window

If the software is set for operation in the one-shot (single capture) mode, a message will request that the user press the joystick button to start capture. The previous window will be shown after the button is pressed.

5.1 Centering

The first step in running an exam is to center the patient's retina, using the infrared LED.

- Move in slowly toward the pupil, which will appear as a brighter region in the image shown on the screen (brightness is increased when the auto-gain function is active).

Center this region on the screen: raise or lower the instrument, using the appropriate joystick knob. Invite the patient to look directly and steadily at the orange fixation point generated by the instrument.

- Once the pupil is centered, continue to move in, very slowly, until the patient's retina becomes visible. If necessary, focus the image by turning the upper knob. If enabled, the focusing support window will provide visual feedback showing improvement/worsening of the focus.

Turn the focus knob in the same direction as long as the lighted indicator continues to rise; stop turning the moment it begins to descend. Generally speaking, an ascending path indicates that image focus is improving, while a descending line indicates a worsening of the focus. The focus indicator should nevertheless be considered significant only when the retina image is stable and correctly illuminated.

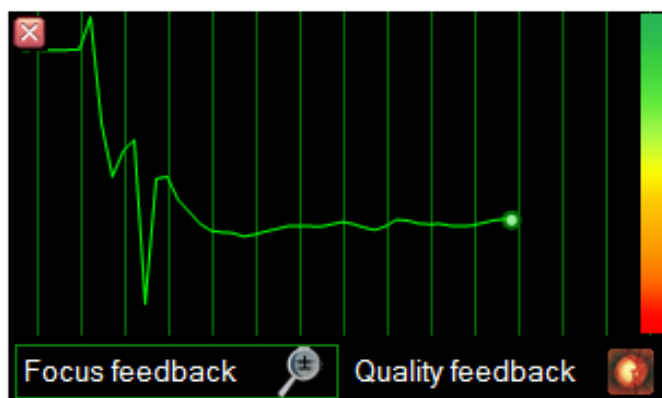


Figure 5-2: Focus Indicator

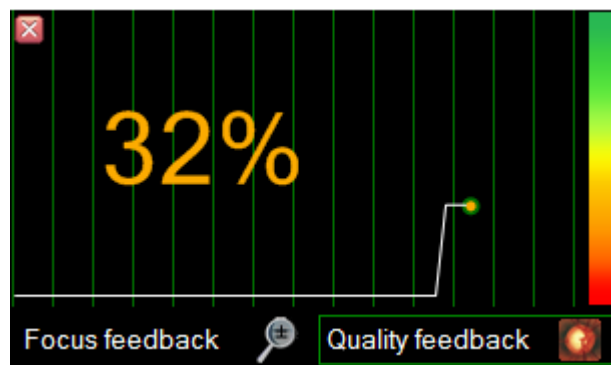


Figure 5-3: Mode Quality feedback

- Stabilize the image as much as possible: wait until the patient is immobile and check that the light does not flicker. The image must be uniformly illuminated (see example image). Do not move in further when the image is clear; too close a proximity could generate undesired reflections.
- Press the joystick button to capture the image. The captured image will be saved in the OD (right eye) or OS (left eye) gallery, depending on the eye to which the captured image refers.

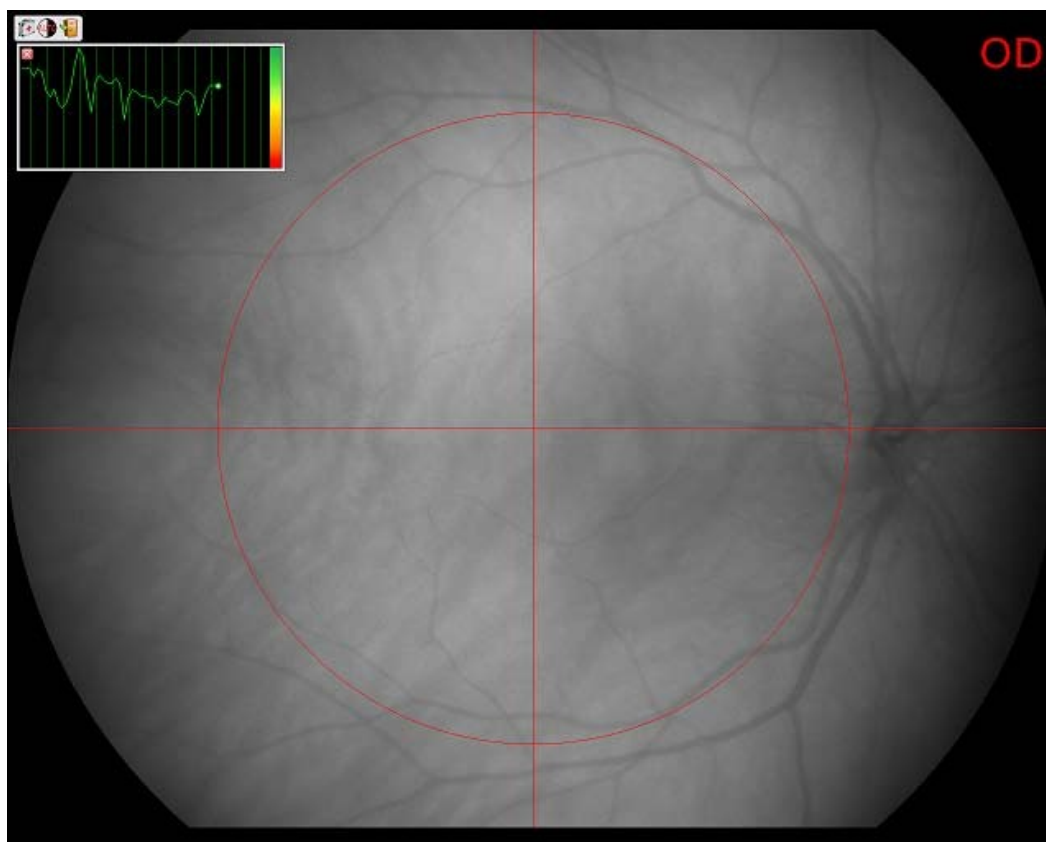


Figure 5-4: Example of Optimal Centering

5.2 Viewing

The instrument performs simultaneous capture of two images of the central portion of the retina: one obtained with visible-spectrum illumination (white light) and one obtained with infrared spectrum illumination. The visible-light image is available in the gallery immediately after capture; left-click the thumbnail to display a full-screen view.



Figure 5-5: Visible-light Capture

To view the infrared-spectrum image, right-click the thumbnail and select Show IR from the pull-down menu (select Delete to delete the selected image).

The infrared-spectrum image provides a different diagnostic picture, since the infrared light penetrates the tissues to a greater degree; this mode permits capturing the structure of the choroid and so facilitates diagnosis of nevi and other pathologies of the retina.



Figure 5-6: Gallery Menu



Figure 5-7: Infrared Capture

5.3 Settings



The icon displays the current application settings.



Figure 5-8: General Settings

Image format: Selects the format for saving the captured images (visible-spectrum and IR). The user may specify the quality in the case of Jpeg compression (default setting).

Acquisition mode: Selects the working mode. In the One-shot mode, the instrument takes one shot and the image is automatically displayed on the screen. After capture, the instrument immediately enters the stand-by mode. With the instrument in stand-by, every time the capture software is launched the user must press the joystick button to “wake” the instrument. In the Non-stop mode, the instrument does not go to standby (except after the elapsed preset stand-by time) and images may be captured one after the other; in this case, the images are not displayed immediately after capture. The instrument starts up automatically each time, with no need to press the joystick button.

Autogain enabled: Enables the auto-gain function. If activated, the instrument continually adjusts image brightness for optimal values; this feature facilitates centering, especially in cases of patients with very small pupil diameters. This function also permits the operator to view the patient’s face clearly before beginning the approach to the pupil, which is thus facilitated.

Stand-by time: Time-out for stand-by mode. From stand-by, press the joystick button to “wake” the instrument.


5.4 Mosaic-preview mode

This feature is available only on multi-core processor PCs, since real-time mosaic building is a very time-consuming process.

Please note that this function only enables the mosaic-preview mode, which purpose is to provide a real-time feedback of how the acquired images are merging correctly together. The final mosaic can be built later and can also be edited manually using AnaEyes software as explained in 9.4.

Therefore, the final mosaic picture will not be available after closing the Live acquisition software, only a preview of it will be available in order to understand if mosaic “pieces” have been captured with sufficient quality.



Press  to start mosaic-preview mode, “mosaic mode on” label is shown on the screen top-right corner.

This mode exits automatically when laterality is changed, or manually when the toolbar button is pressed again.

Pictures can be acquired normally in any order, although it is advisable to start from the central retina image to shorten computation time.

Immediately after every acquisition a background process evaluates the acquired images and a pop-up window asserts whether the last acquired image merges with the previous ones. If this is not the case, the picture can still be merged with other future acquisitions, so you should not delete it unless it is clearly a bad quality image.

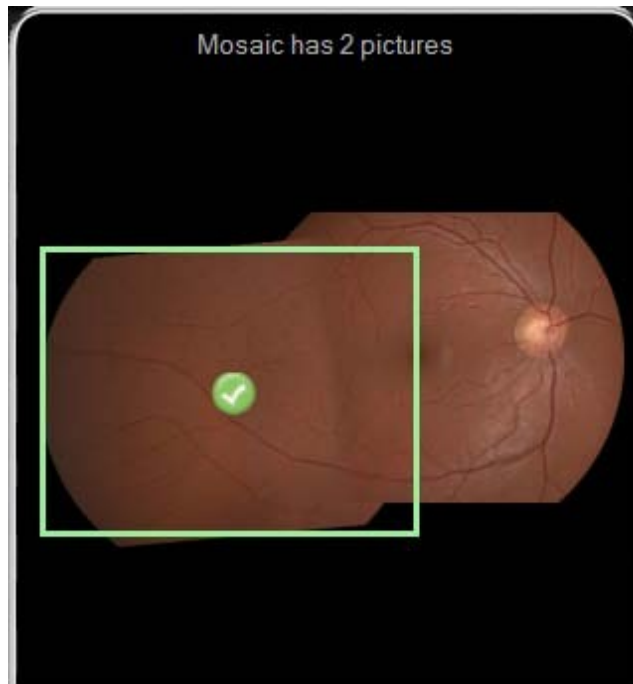


Figure 5-9: Mosaic preview

After exiting mosaic-preview mode a summary window pops up and displays a bigger preview of the valid mosaic pictures merged together.

This is how the mosaic pictures will be automatically merged together later in AnaEyes without any manual editing. If mosaic preview is not satisfactory you can manually edit the produced mosaic, for example in case of bad quality images or in presence of retina diseases / anomalies that interfere with automatic mosaic reconstruction.

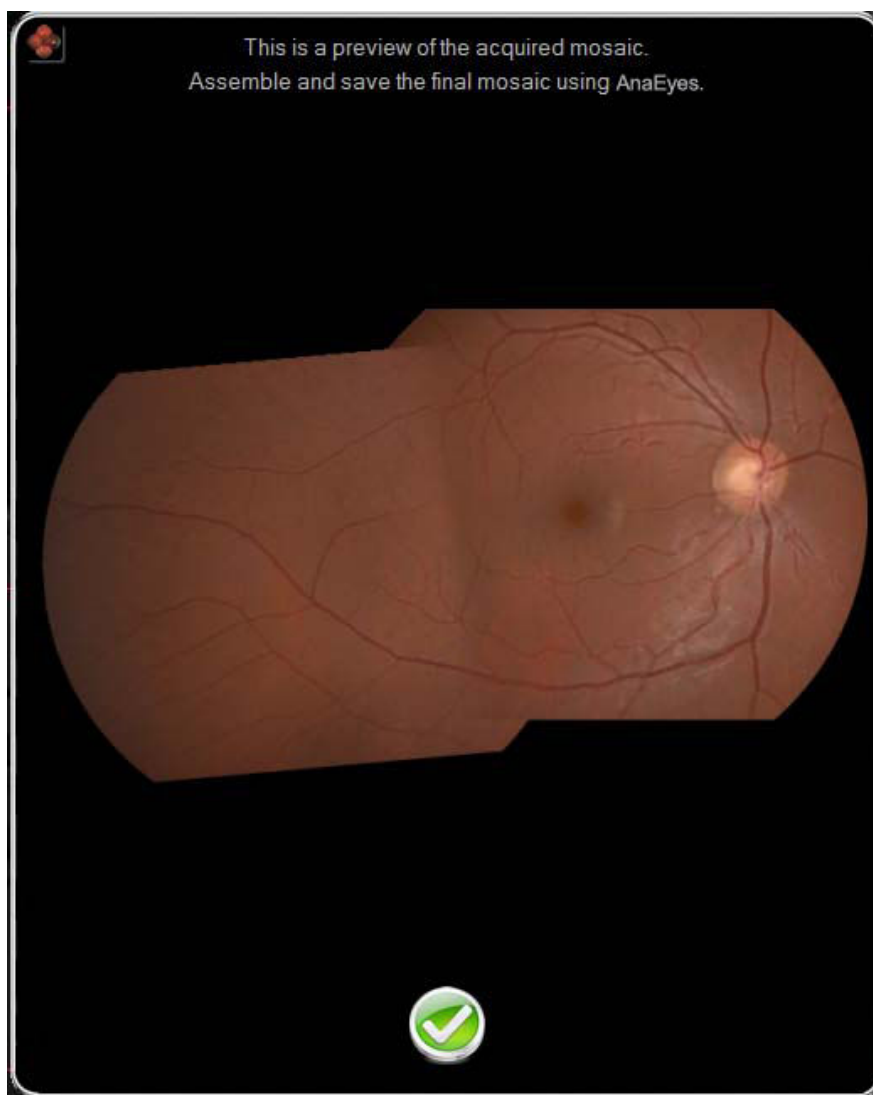




Figure 5-10: Preview mosaic

6. VIEWING AND MANAGEMENT OF SINGLE IMAGES

Double-click any image in the gallery to open the window for displaying and managing the single fundus images.




Figure 6-1: Fundus Image Management Window

This window displays the fundus images captured in the Live mode. Click the  and  buttons to scroll all the images captured during the same exam.

To browse the various displays available in the fundus imaging module, use the options available in the menu at the top of the screen or the toolbar. Depending on the position in the program, some items may not be displayed and/or may be disabled. For a detailed description of the functions of each menu or button, see 7

To use the measurement or overlay functions, click the appropriate buttons on the toolbar to the left of the image.

6.1. Linear Measurements

To make linear measurements, click the  button on the toolbar or in the menu. Measurements are made in degrees. Since the retina image is enlarged by an unknown power, the measurements supplied by this function are purely indicative.

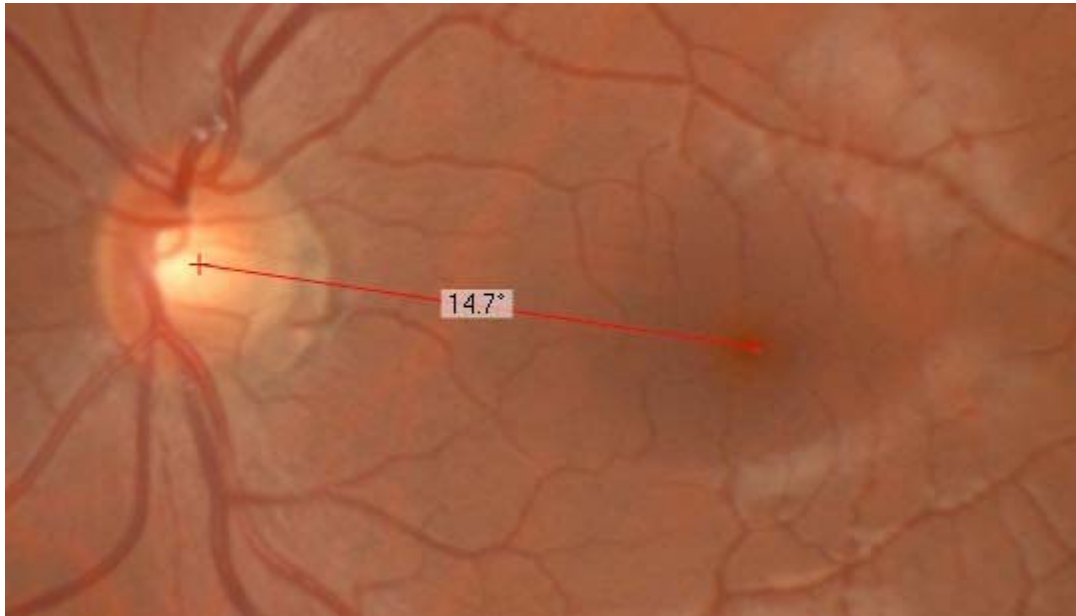



Figure 6-2: Linear Measurement on the Retina.





6.2 Cup-to-Disc Ratio

Click the  button on the toolbar or menu to measure the cup-to-disc ratio. After this measurement mode is selected, the user is requested to indicate three points on the disc and three points on the cup. The first system calculation of the ratios to calculate the ratios between the areas (Cup:Disc (A)) and between the diameters (Cup:Disc (\emptyset)) is based on evaluation of the circles passing through the three points. That is, it considers the cup and the disc as two circles and then calculates an approximate evaluation of the ratio. The system will then ask if the user wants to refine the evaluation of the cup-to-disc ratio with advanced measurement.






















Click Yes to enter an editing environment in which the cup and the disc are not considered simply as circles but as 32-endpoint polylines; in this environment, the user can manually adjust the cup and disc through many degrees and thus with great precision.

6.3 Overlay

For overlaying arrows, rectangles, and text on the image, use the , , and  menu or toolbar buttons. Click  to delete the last overlay.

7. TOOLBAR AND MENUS

7.1 Toolbar

BUTTON	SHORTCUT	ICON	FUNCTION
Single Image	-		Accesses the window for displaying the images as single fundus images.
Wavelength Divider	-		Accesses the window for displaying the images at different wavelengths.
Comparison	-		Accesses the environment for comparing various fundus images from the gallery.
Full Screen	F11		Accesses the full-screen mode.
Stereo Imaging	-		Accesses the stereo-imaging window. (superimposition).
Mosaic	-		Accesses the Mosaic window.
Unfiltered	-		Returns to the three-color view of the image.
Infrared Image	-		Displays only the IR component.
Choroid	-		Displays only the choroid component.
Vascular	-		Displays only the vascular component.
Red-free	-		Displays only the red-free component.
Nerve Fibers	-		Displays only the nerve-fiber component.
Delete	DEL		Deletes the display image.
Close	-		Closes the fundus image management window and returns to the gallery.
Scroll back	PgDn		Scrolls back through the gallery images.
Scroll forward	PgUp		Scrolls forward through the gallery images.
Zoom	-		Enables activation of the zoom function (with the mouse wheel) or the panning function (drag).
View measurements toolbar	-		Displays or hides the measurement buttons.
Distance	-		Measures distances on the retina, in degrees.






Cup-to-Disc ratio	-		Calculates the ratio between two circular areas defined by the user, in surface and area.
line	-		Draws a straight line on the image.
Rectangle			Draws a rectangle on the image.
Text			Allows the user to type a line of text on the image.
Delete			Deletes drawings and text overlaid on the image.

Table 1: Toolbar Buttons Summary

7.2 Menu bar

The bar at the top of the screen contains the menus shown below:

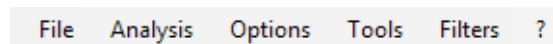





Figure 7-1: Fundus Image Management Menu

7.2.1 “File” Menu

 Save screenshot as image	Save a screenshot (print screen) in a user-selected format: JPEG, BITMAP, GIF, PNG, or TIFF.
Save image	Saves the image in a user-selected format: JPEG, BITMAP, GIF, PNG, or TIFF.
 Close	Closes and returns to the main window.
 Print Screen	Prints the screen containing the image. A Preview window is shown before printing.


Print	
Print Screen (immediate)	Prints the screen containing the image without showing the Preview.
Print	Allows the user to print up to 4 selected fundus images on a single page (cfr. Section 10 Printing). A Preview window is shown before printing.
Print (immediate)	Allows the user to print up to 4 selected fundus images on a single page without showing the Preview.
 Exit	Exits the program.

Table 2: File Menu

7.2.2 “Analysis” Menu







 Single image	Accesses the single-image display window.
 Full screen	Accesses the full-screen mode.
 Wavelength Divider	Accesses window for viewing the image at different wavelengths.
 Comparison	Accesses the window for comparing different fundus images from the gallery.
 Stereo Imaging	Accesses the Stereo-imaging window (superimposition).
 Mosaic	Accesses the Mosaic window.

Table 3: Analysis Menu

7.2.3 “Options” Menu








 Show Information	Displays general information about the patient and the current exam.
Toggle smoothing	Using interpolation, smooths out the image to eliminate the pixelating effect that appears when the image is greatly enlarged.
Overlay ► Font	Allows the user to change the font (character) used for the overlay text.
 Overlay ► Color for Measurement	Allows the user to change color of overlay text/line.
Overlay ► Line Width	Allows the user to change the width (thickness) of the overlay line.

Table 4: Options Menu

7.2.4 “Tools” Menu

 Zoom	Allows the user to activate the zoom function (with the mouse wheel) and the panning function (drag).
 Distance	Measurement of distances on the retina, in degrees.
 Cup to Disc ratio	Calculates the ratio between two circular areas defined by the user, in surface and area.
 Draw Arrow	Draws an arrow on the image.
 Draw Rectangle	Draws a rectangle on the image.


 Add Text	Allows the user to insert a line of text in the image.
---	--

Table 5: Tools Menu

7.2.5 “Filters” Menu
















 Gamma	Allows the user to activate the zoom function (with the mouse wheel) and the panning function (drag);
 Restore	Returns to the default Gamma.
 Barrier filters ► Unfiltered	Returns to the three-color view of the image.
 Barrier filters ► Infrared Image	Shows only the IR component.
 Barrier filters ► Choroid	Shows only the choroid component.
 Barrier filters ► Vascular	Shows only the vascular component.
 Barrier filters ► Red-free	Shows only the red-free component.
 Barrier filters ► Nerve Fibers	Shows only the nerve-fiber component.

Table 6: Filters Menu

8. WAVELENGTH DIVISION

Click the  button in the Analysis menu or on the toolbar to access the wavelength divider window. The window shown in Figure 8 1 displays:

- the original image (top left). To insert this filter on the single screened image, click the  button.
- the infrared image (top center). To insert this filter on the single screened image, click the  button.
- the red-free image (top right). To insert this filter on the single screened image, click the  button.
- the choroid image (bottom left), obtained by considering only the red component. To insert this filter on the single screened image, click the  button.
- the vascular image (bottom center), obtained by considering only the green component. To insert this filter on the single screened image, click the  button.
- the image of the nerve fibers (bottom right), obtained by considering only the blue component.

To insert this filter on the single screened image, click the  button.

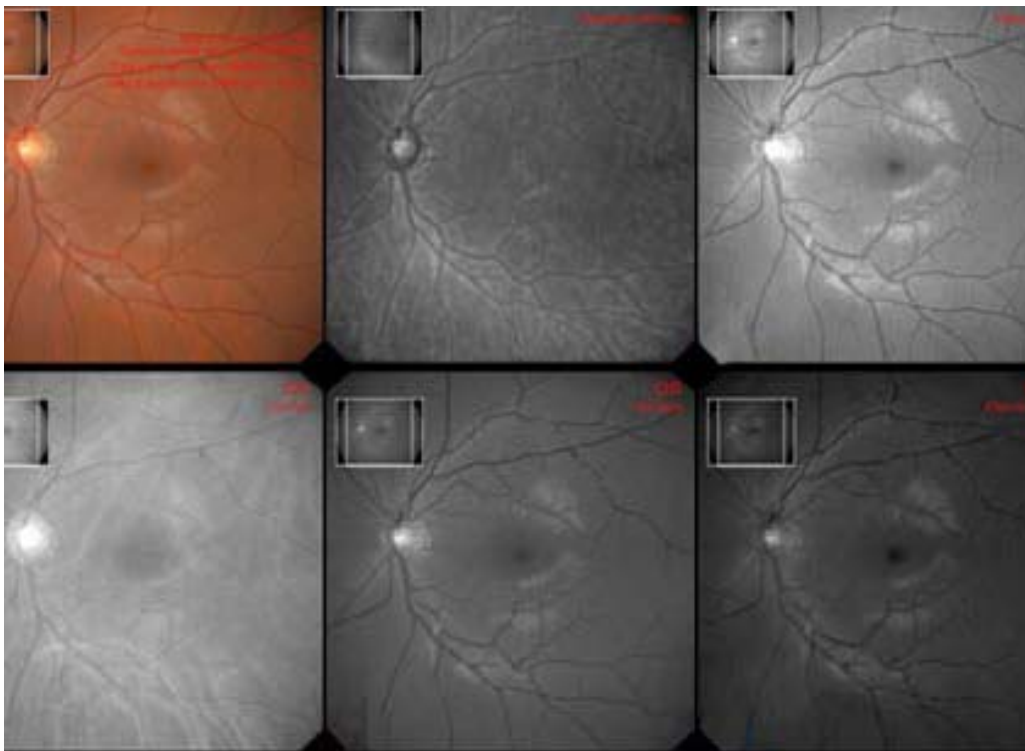



Figure 8-1 Wavelength Division

9. SECONDARY FUNCTIONS

9.1 Comparison

Click the  button in the Analysis menu or in the toolbar to access the comparison function.

9.1.1 Image Selection

The capture image selection window will be displayed. From this window, the user may select up to six images by double-clicking the gallery images. Should the images to be compared belong to a different exam or patient, click the ▼ button on the “Patient Management” bar to access the search functions. The selected images will be shown in the column on the right. Click the Ok button to confirm; click the Cancel button to cancel and return to the previous window.

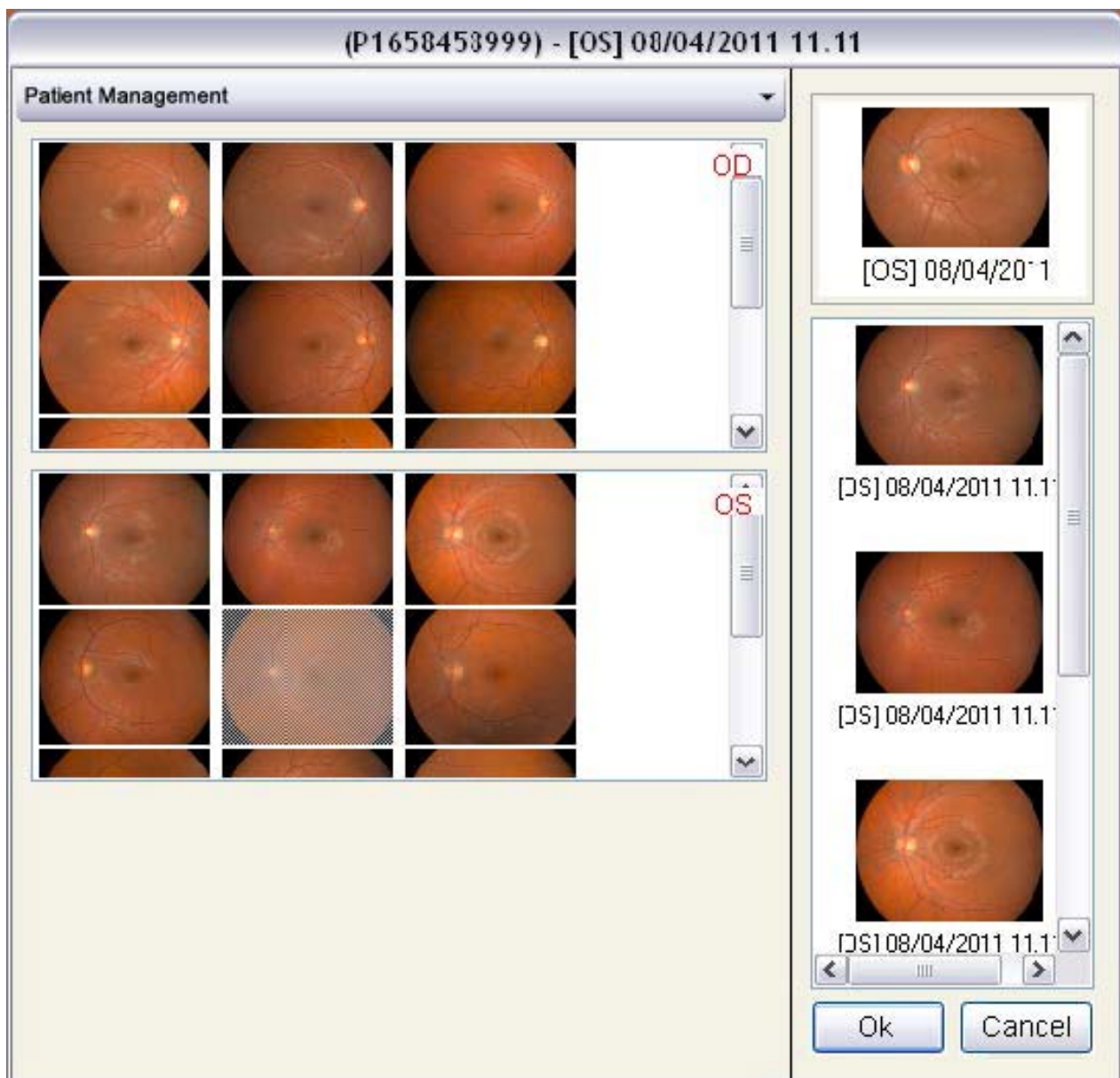


Figure 9-1: Selecting Images for Comparison


9.1.2 Comparison Window




The selected fundus images will now be displayed in the comparison window, as shown in Figure 9 2. The zoom and panning functions on the various fundus images are linked in order to permit observing all the images in the same position at the same enlargement.




Figure 9-2: Fundus Image Comparison

9.2 Full Screen

The Analysis menu or toolbar allows the user to access the full-screen view by clicking the  button. In this mode, the image occupies the entire monitor screen area. Analogously to the functions explained in Section 0,

the  and  buttons allow the user to scroll the images captured during a single exam. The  button, instead, starts automatic scrolling of the images at constant time intervals.

9.3 Stereo Imaging (Overlay of Fundus Images)

Click the  button on the Analysis menu or toolbar to access the fundus-image stereo imaging (overlay) window. The user will be requested to select a second image of the same eye captured in such a position as to permit evaluating a disparity (use the Image Selection window 9.1.1 to select). When the selection is confirmed, the program accesses the fundus image superimposition window; in this window, the user may:

- enlarge or reduce the sizes of the two fundus images, using the mouse wheel.
- move the first image: hold down the left mouse button and drag the image to the desired position.
- move the second image: hold down the right mouse button and drag the image to the desired position.


- change the relative percentages of transparency: hold down the Shift key and rotate the mouse wheel.

9.4 Mosaic

This feature is available only on multi-core processor PCs, since real-time mosaic building is a very time-consuming process.

Please use the mosaic mode only if the currently selected acquisition belongs to a study containing at least one more image acquired satisfying mosaic criteria (i.e. one central retina image followed by one or more peripheral images). Otherwise, starting mosaic mode may result in a long time-consuming routine which obviously will not produce any result.



From the Analysis menu or toolbar, click the  button to access the Mosaic mode. This mode can be accessed from any acquisition in the study, then all other study acquisitions will be automatically added to the mosaic, up to a total of 7 acquisitions. If the study contains more than 7 acquisitions, the Image Selection window (9.1.1) is presented to select the desired acquisitions until the maximum allowed number is reached.

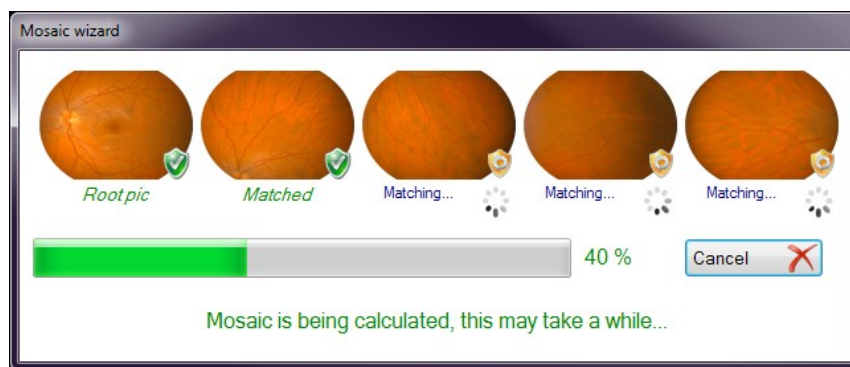


Figure 9-3 Progress mosaic window

The above image indicates that the mosaic is being generated: this process requires a certain amount of time, depending on the number of acquisitions and their “complexity”. In case the process takes too long (more than a minute) it can be stopped anytime by pressing the Cancel button on the window.

The reconstructed mosaic is then displayed on screen.

Three modalities are available in the mosaic window, and they provide the functionalities that lead to the creation of the final mosaic image:



This button activates global view mode (which is activated by default just after the mosaic is reconstructed) as displayed in the next screenshot. The mosaic is shown as a set of fixed overlapping pictures and the global image can be moved and zoomed in or out using mouse and mouse wheel.

Single mosaic pictures cannot be moved or rotated here.

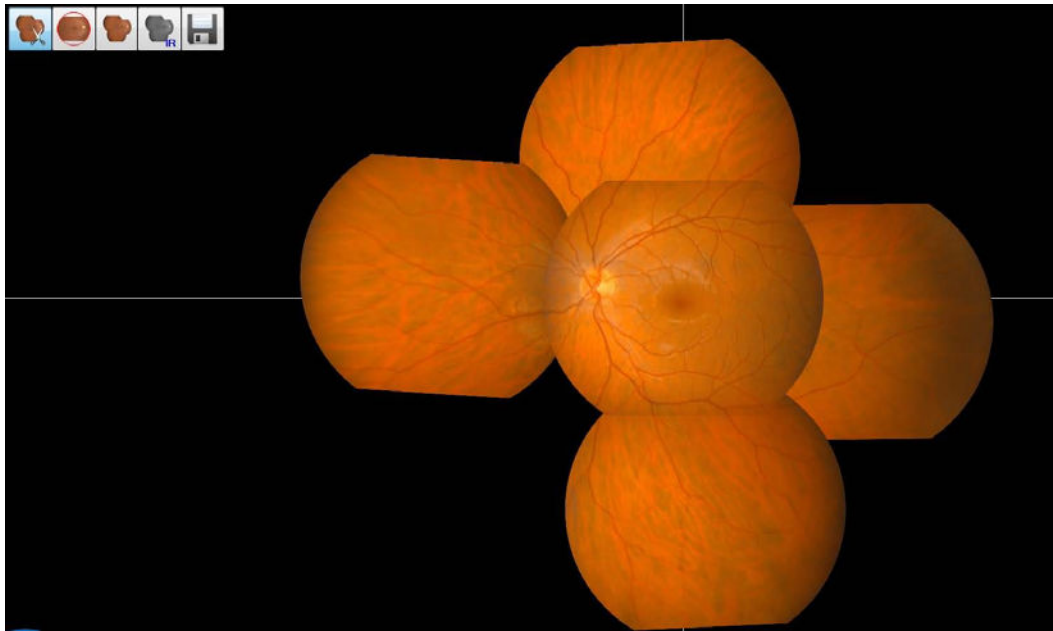


Figure 9-4: Mosaic assembly



This button activates manual edit mode. Every single mosaic picture is now selectable (circled in red) and can be dragged using the left mouse button or rotated using the mouse wheel.

While being dragged the mosaic picture becomes transparent to make manual linking easier. This way any issue due to the automatic reconstruction can be fixed manually.

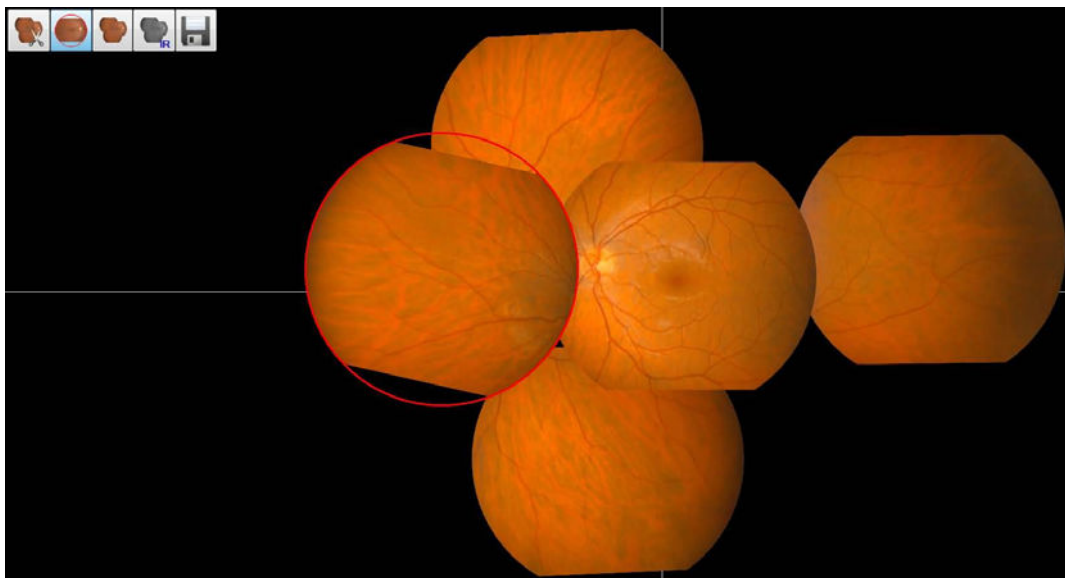


Figure 9-5: Rotate a single acquisition

Right-clicking on a single picture brings up a pop up menu that allows to remove that picture from the mosaic. Removed pictures are placed in a gallery on the bottom of the screen. All images that were not selected for the automatic reconstruction process are also placed in this gallery. They can be re-inserted manually in the mosaic by double-clicking them from the gallery.

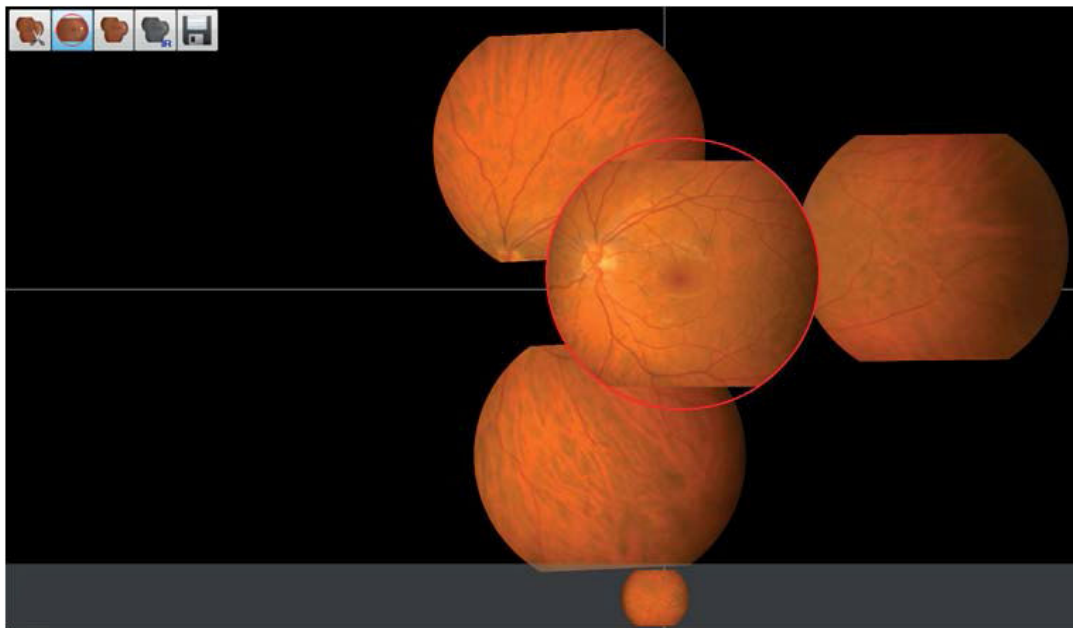


Figure 9-6: Gallery of discarded acquisitions



This button finalizes mosaic creation as it merges all overlapping pictures together in a single image, excluding of course all the pictures that have been placed in the discarded gallery.

All pictures edges are smoothed and image transitions combined in a more uniform image.

If you are satisfied with the final mosaic image, you can print or save the diagnostic report choosing File -> Print screen capture.

If the mosaic has been finalized using the currently described procedure, then all pictures are merged together and mosaic image is optimized for printing (i.e. black background is turned to white). Otherwise a normal screenshot is proposed.

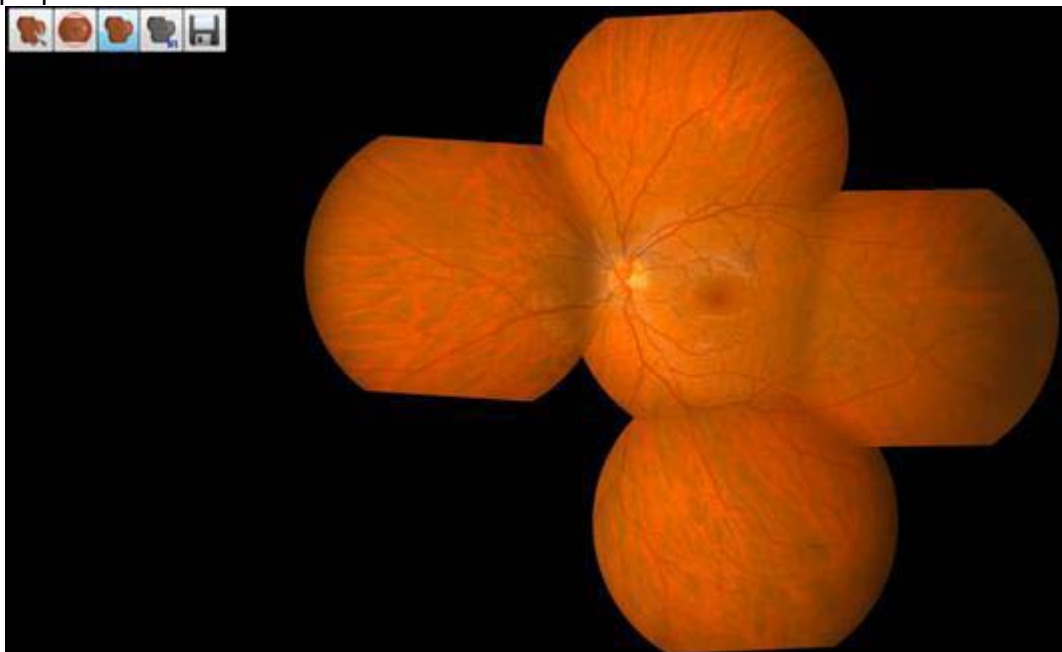


Figure 9-7: Finalize mosaic

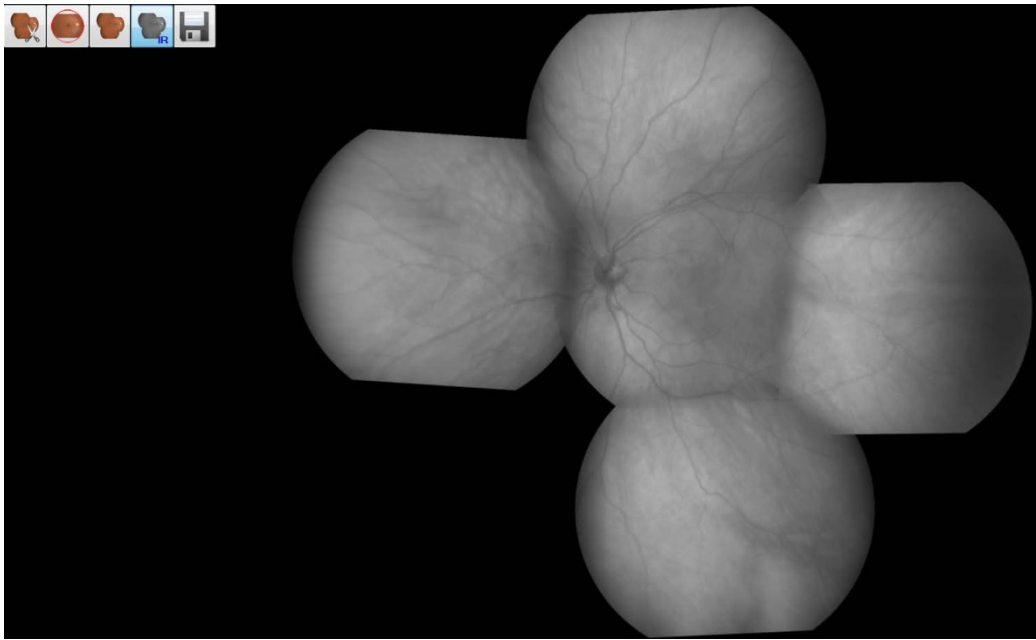


Figure 9-8 Print preview

10 PRINTING

The user may print a single image or several images selected for comparison. Select Print from the File menu (7.2.1): the Preview/Image Selection window will open.

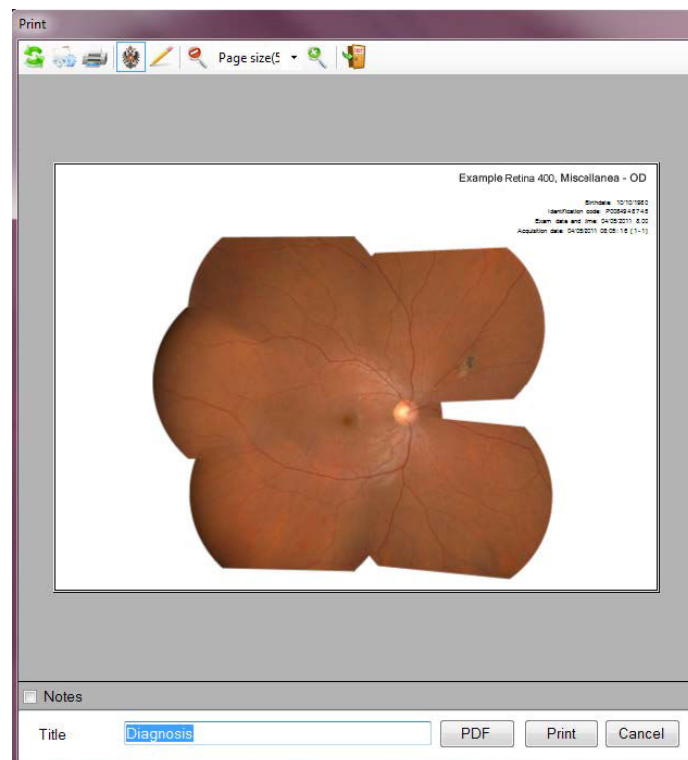


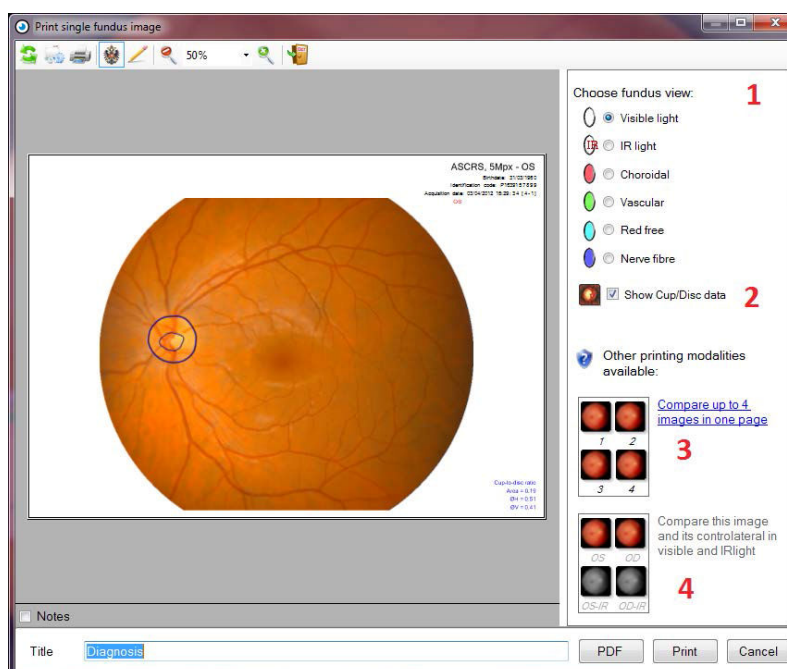
Figure 10-1: Selecting Images for Printing

Select the images to print (up to 4 images) by double-clicking in the gallery on the right of the screen. The selected images will be shown in the bottom right-hand box.

The image/s may be printed on paper (Print button) or converted to PDF format (PDF button).

In the first case, the PC must be connected to a printer.






In the second, the user may choose the file destination: desktop or gallery.



Click Yes or No.



10.1 Printing Toolbar

	Refreshes the print preview image to show modifications.
	Permits changing the print settings.
	Prints the page shown in the Preview
	Displays or hides the heading (if inserted) and relative logo.
	Permits changing the text of the heading and the logo: click the button to show the heading data entry/change form (Figure 10-1).

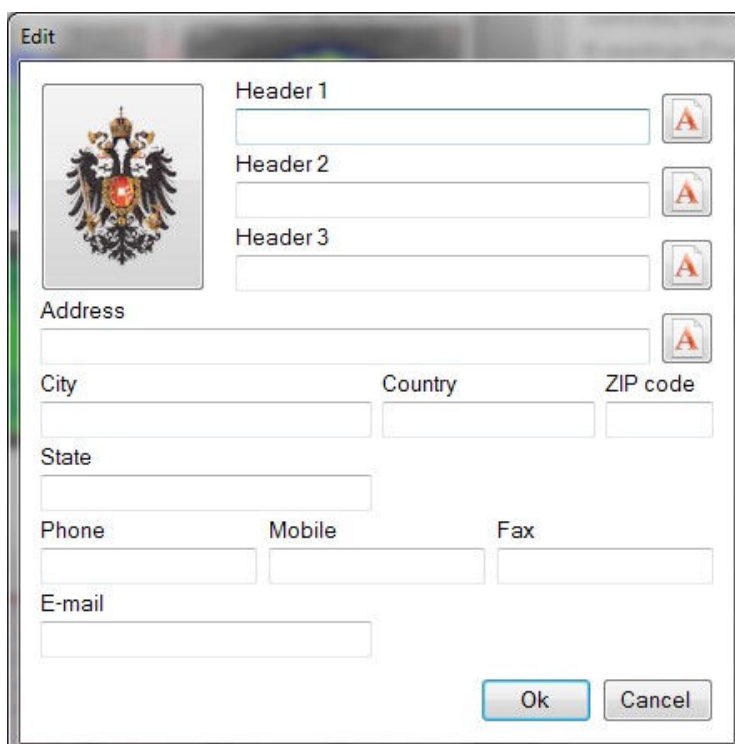




Figure 10-2: Company Data

Click the  button to insert a logo.

Type the other company/practice data in the empty fields shown in the window.
Click **OK** to confirm.

	Enlarge – Reduce Preview (%) of the image.
	Exits the Printing window.

11 RETINAL VASCULAR ANALYSIS

Retinal vascular analysis consists in evaluating the calibre (diameter) of the veins and arteries present in the image of the ocular background, with aim of calculating the mean value of the ratios of the calibres between individual pairs of adjacent blood vessels.

The vascularisation status of the retina and, in particular, the AVR (Arteriolar to Venular Ratio), are highly indicative of potential cardiovascular problems and are fundamental to screening examinations, since they can highlight arterial restrictions which may require more detailed follow-up examinations to reduce the risk of cerebral and cardiac infarction.

Clinical studies and statistical results are available in the following article, currently considered the state of the art in this subject:

Wong TY, Klein R, Couper DJ, Cooper LS, Shahar E, Hubbard LD, Wofford MR, Sharrett AR. Retinal microvascular abnormalities and incident strokes: the Atherosclerosis Risk in the Communities study. *Lancet*.2001;358:1134-1140

The new retinal analysis environment provided by the AnaEyes software (version XXX and later) is dedicated exclusively to the Retina 400 instrument, and is capable of automatically identifying the principal retinal blood vessels, discriminate between arteries and veins, and select the most reliable pairs for use in calculating the AVR.

The result of the AVR calculation is presented in an intuitive manner by using a representation of the normal statistical distribution of the value for the patient's age population. The numerical value is accompanied by graphic and textual aids to comprehension of the results, while the examination is assigned a reliability index which indicates the need for more detailed manual measurements, following on-screen prompts. The following section describes the entire examination procedure, starting from image capturing, through marking of the optic disk and of artery-vein pairs, to the final evaluation of the result.

11.1 Clinical AVR measurement procedure

Two examination protocols have been formally established in recent years: the Japanese method and the US method.

The US method, implemented in this case, consists in marking from 3 to 5 pairs of adjacent veins and arteries, exiting from the optic nerve and tracing approximately parallel paths at a close distance to each other. The marking area is a ring covering the area between 2 to 3 radii of the optic disk, starting from the centre of the disk itself.

For each pair, the AVR ratio (arteriolar calibre over venular calibre) is calculated, after which the mean of these values is taken to obtain the final AVR.

12 GUIDE TO THE EXAMINATION

12.1 Capturing

The first step consists in acquiring the image of the fundus, bearing in mind two basic rules:

- The patient's fixation point must be set so that the optic disk is located as close as possible to the centre of the image, since the vascular calibre measurements are taken in a specific area of the disk itself. If the optic disk is too peripheral, the analysis can be run anyway, but certain significant vessels may be outside the image field (Figure 2-1)
- The image must be sharply focused: the edges of the blood vessels around the disk must be clearly defined, illuminated and contrasted, otherwise the system may not detect them correctly; even manual corrections are made more difficult if the image is incorrectly focused.

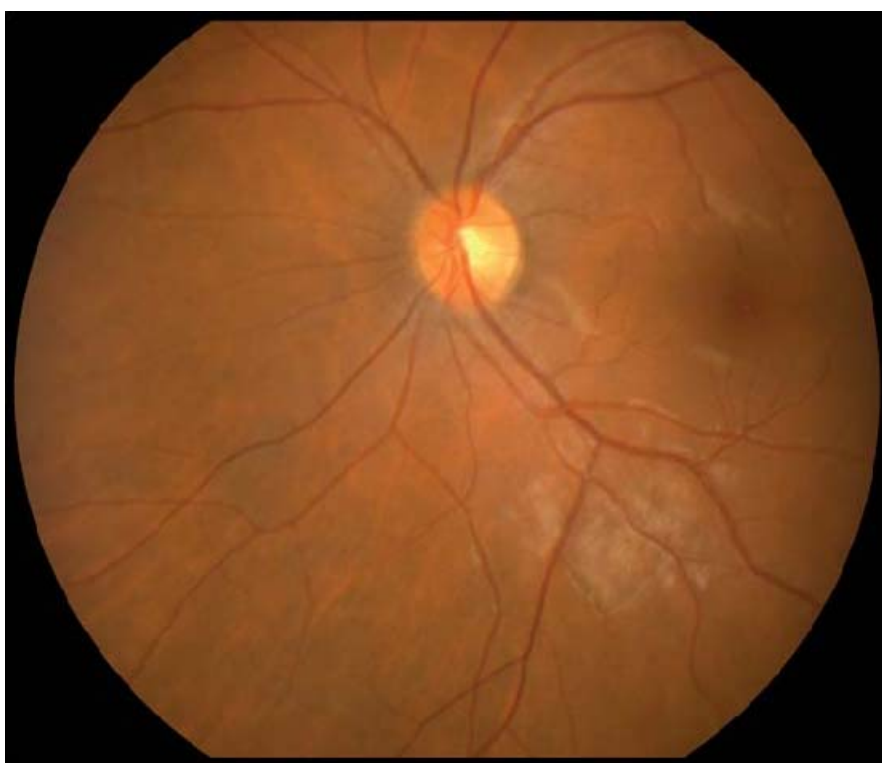


Figure 12-1: Fundus capture with properly centred optic disk

12.2 Marking the optic disk

Before running the vascular examination itself, the position of the disk on the fundus must be properly marked.

The calculation of the cup/disk ratio, already present in previous versions of the AnaEyes software, has been improved with the introduction of the AVR analysis system.

The position and outline of the disk and cup are detected automatically by the system and may also be measured manually for an even more precise result using a quick measurement system which marks six points, as well as an advanced editing interface for unbeatable precision.

Automatic position detection is sufficiently precise in most cases, but if the disk is not circular, or one wishes to obtain a very precise cup/disk ratio, it is advisable nonetheless to use manual editing.

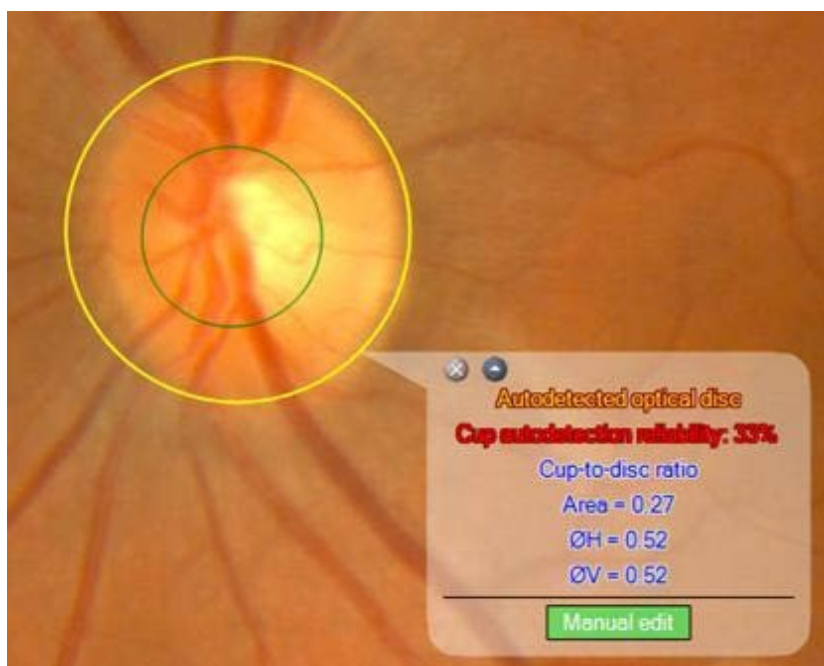


Figure 12-2: Automatic cup / disk detection

Click on Manual Edit to launch the advanced cup/disk editing interface. On the right, select the type of modification (for instance, left click to define the outline of the disk and right click to define the outline of the cup), then trace the outlines of the cup and disk on the image (Figure 2-3).

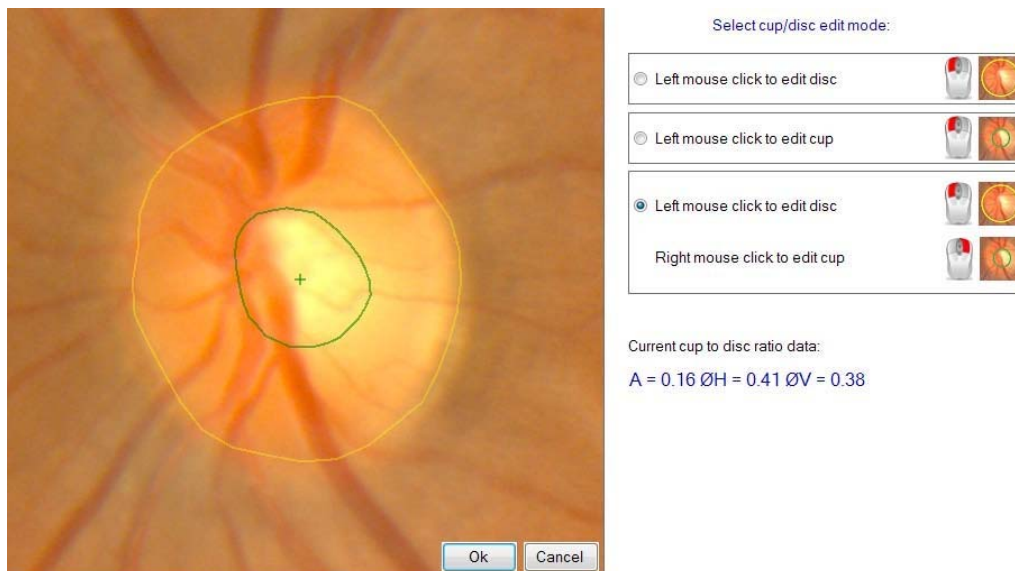



Figure 12-3: Manual cup / disk editing

When editing is completed, you can view the updated cup/disk ratio values (Figure 2-4).




Figure 12-4: Manual cup / disk marking

When you are satisfied with the marking of the disk, simply click on icon  to launch vascular analysis.

N.B.: there is no need to define the cup when running vascular analysis, since it is not always identifiable on the image of the fundus. The outline of the disk is the only requisite for the analysis.

12.3 Automatic vascular analysis

Click on icon  to run the analysis automatically.

N.B.: the analysis run by the system is sufficiently precise, so long as the image quality is very good. However, even when the image is a good one, it is still recommended that you carefully review each pair of vessels, and manually edit the pairs as necessary, adding new ones or deleting incorrectly detected ones, so as to optimise the quality of the examination.

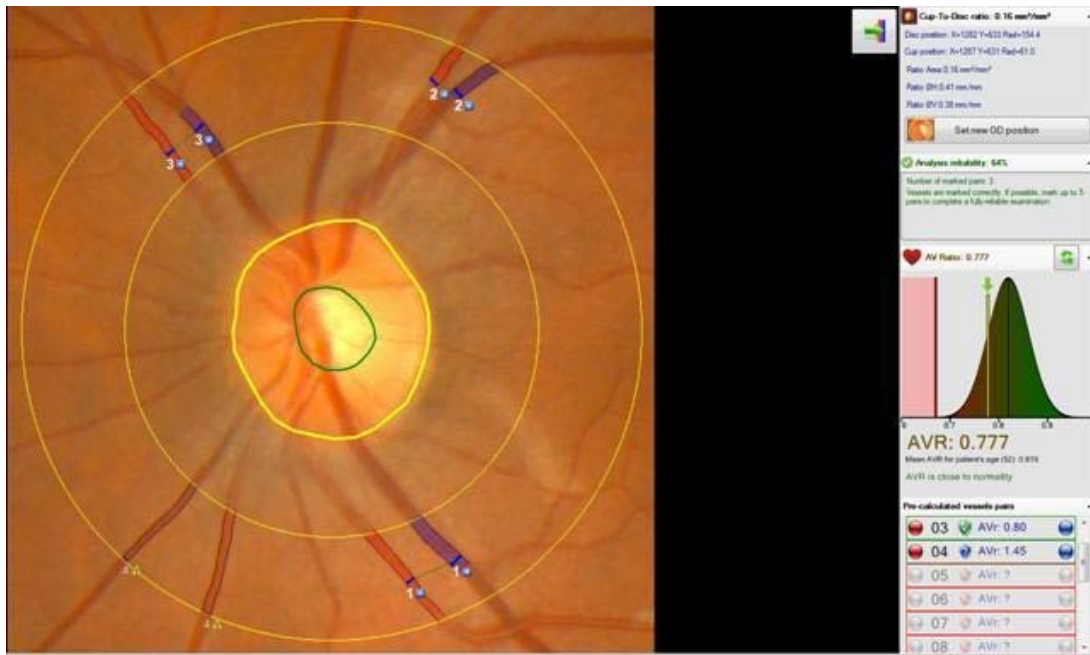





Figure 12-5: Main AVR measurement interface

The system attempts to identify pairs of adjacent veins and arteries in the area of interest, calculated in relation to the position and size of the optic disk (see section 1.1).

The system automatically distinguishes between veins and arteries, and the calibre is calculated in the most reliable section.

The system can also run self-diagnostics and assess the accuracy of its analysis: each pair of vessels can be confirmed if not sufficiently reliable, or modified manually, or eliminated from the overall calculation, as follows:

-  The light blue symbol “+” indicates an automatically detected pair which is judged to be sufficiently reliable, and hence included in the overall calculation AVR.
-  The yellow exclamation mark indicates an automatically detected pair which the system judges to be doubtful, and which is hence not included in the overall calculation AVR. Click on the pair and select whether to accept it or eliminate it from the screen (as shown in section 2.4).
-  A green check mark indicates that the pair has been reviewed and accepted manually (as shown in section 2.4)

The reliability of each pair, together with the number of pairs marked on the screen, contribute to the overall reliability score (expressed as a percentage).

Manual confirmation of the pairs obviously greatly increases the final reliability score: scores above 60% can be considered to be reliable.

Along with the numerical value, a short tutorial is also available which indicates any problems and suggests how to improve the marking.

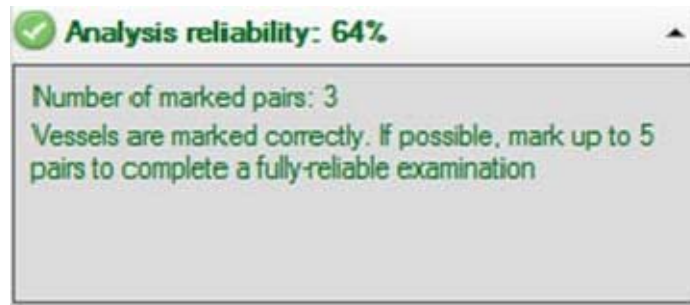


Figure 12-6: Reliability feedback

12.4 Confirmation and deletion of existing pairs

Click on a vein/artery pair to display a context menu:

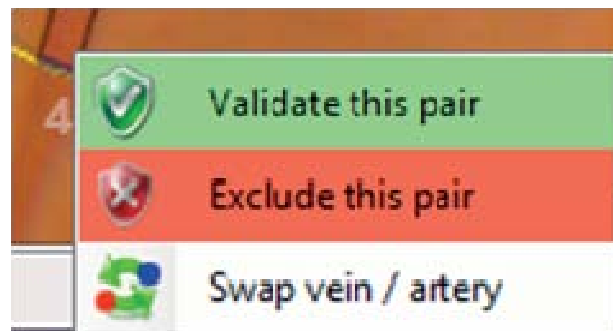


Figure 12-7: AV pair context menu

This menu allows you to confirm the pair, if it has been judged doubtful by the system, or eliminate it completely, or change the classification from vein to artery or vice-versa if the automatic classification is incorrect.

Pre-calculated vessels pairs				
	01		AVr: 0.66	
	02		AVr: 0.89	
	03		AVr: 0.80	
	04		AVr: 1.45	
	05		AVr: ?	
	06		AVr: ?	
	07		AVr: ?	
	08		AVr: ?	
	09		AVr: ?	
	10		AVr: ?	
	11		AVr: ?	
	12		AVr: ?	
	13		AVr: ?	
	14		AVr: ?	
	15		AVr: ?	

If several pairs are overlapping or it is difficult to select pairs on the image, a list of all pairs detected by the system is displayed on the right, both those highlighted on the image as reliable and those which are not included but available for review and manual inclusion if necessary.

Touching a pair in the list with the cursor highlights it in the image. The number of the pair in the list matches that of the pair on the image. The shield symbol indicates the status of the pair: reliable and included in the calculation (green shield), not reliable and excluded from the calculation, but available for review and confirmation (light blue shield), not reliable and excluded from the calculation (red shield). Clicking on a pair in the list displays the context menu shown in figure 2-7, with the difference that in this case the system also displays pairs not shown on the image itself.

Figure 12-8 Pair selection panel

12.5 Modifying existing AV pairs



In the event that the automatically calculated calibre is incorrect, move the mouse over the vessel you wish to edit, at the point in which their cross-section is marked graphically: click when the pencil tool displays, which displays the advanced editing dialogue:

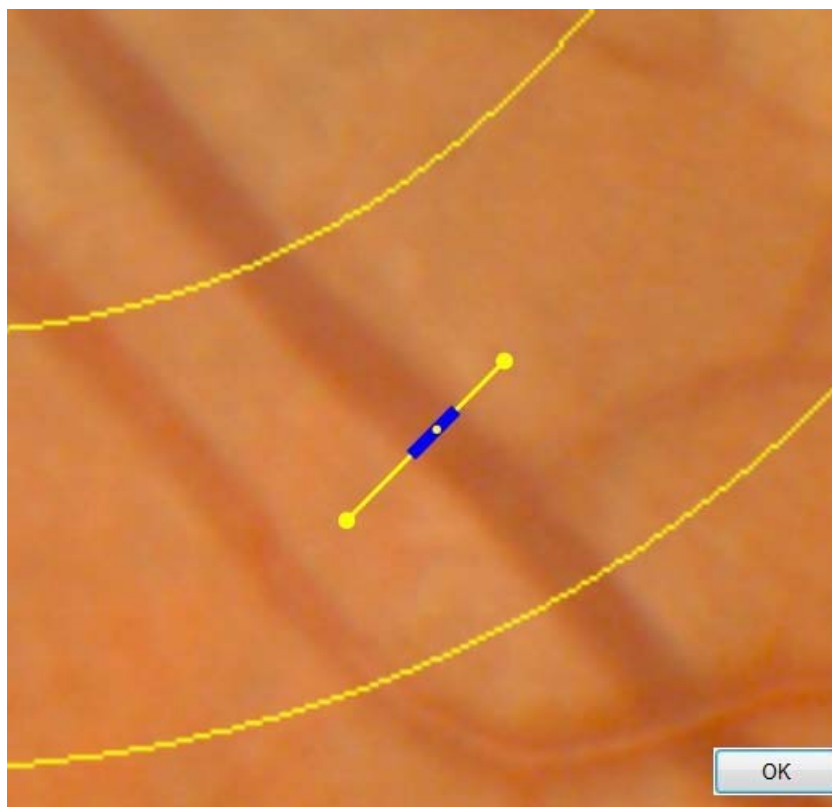


Figure 12-9: Advanced vessel editing

To modify the selection of the vessel's calibre, you can move, rotate and change the size of the blue marker: use the yellow side indicators to rotate and widen/narrow the section, or use the yellow central indicator to move the entire section.

Click on OK to confirm the selection.

Vessels which have been modified manually display with a green check mark and will increase the examination's reliability score.

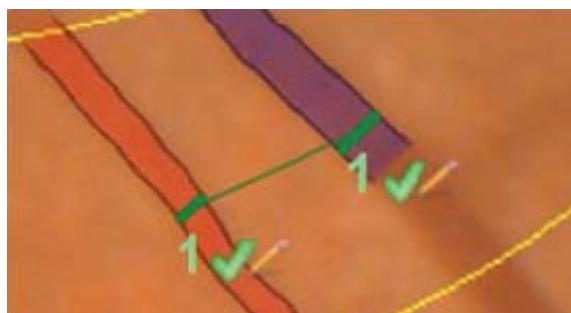



Figure 12-10: Manually confirmed vein/artery pair

12.6 Creating new AV pairs

You cannot always rely on the pairs chosen automatically by the software, especially if the image is of poor quality.

However, you can choose new pairs among those listed by the software as potential hits, as described in section 2.4.

Otherwise, you can use the add manually mode by clicking on the icon  at the top right:

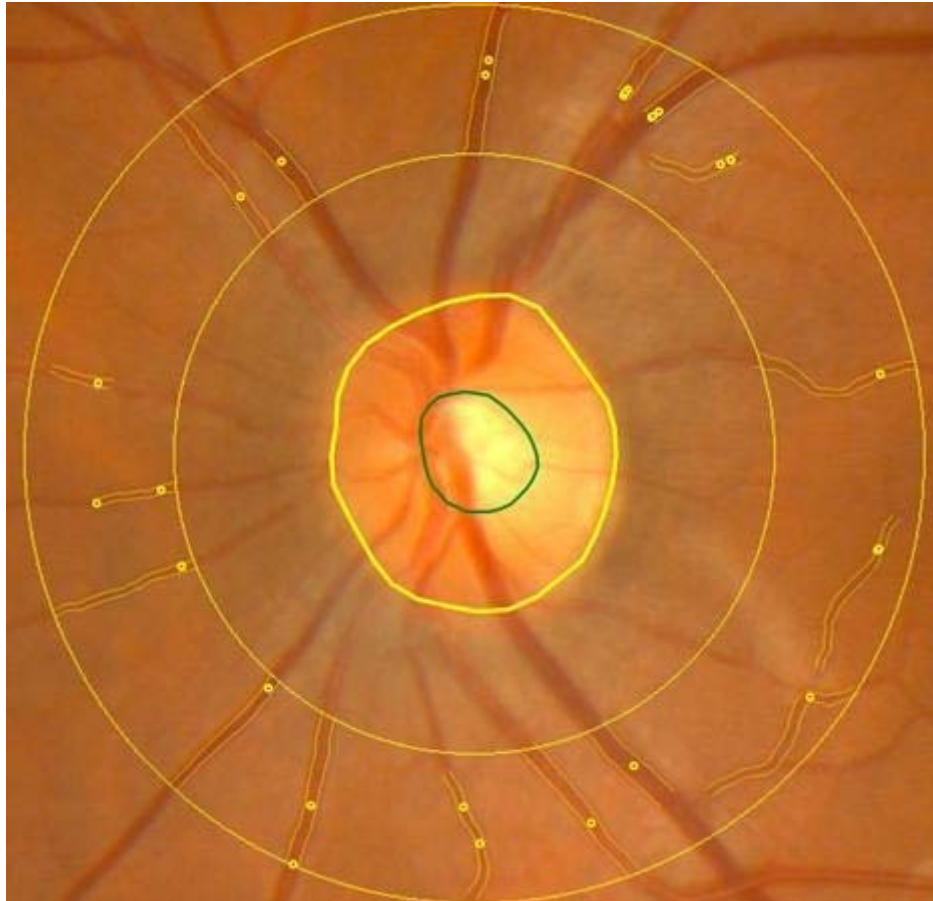


Figure 12-11: Vessel hotspot in add manually mode

The yellow points are hot-spots, i.e. points of the image in which the system has identified potential vessels for use in creating new pairs.

Click on a hot-spot to select a vessel. Click on the second vessel of the pair to complete and confirm the pair automatically:

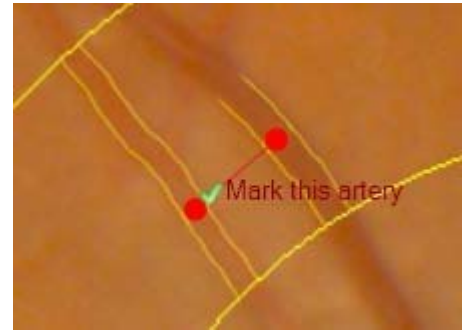


Figure 12-12: Manual selection of hot-spot vessels

The AV pair is created automatically using information detected previously by the system, such as the vein/artery classification and calibre of the vessel (each hot-spot already contains this information).

However, you may wish to mark vessels which have not been detected by the system and, therefore, for which no hot-spot exists.

To select such vessels, simply move the cursor onto any point of the zone of interest to add a new vessel: this opens the advanced manual editing dialogue (section 2.5) with which you can manually position the calibre indicator.

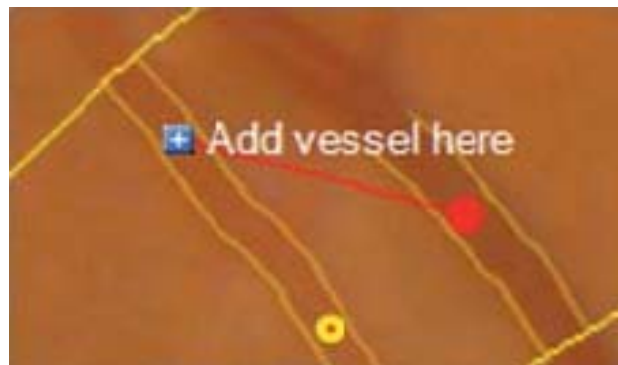


Figure 12-13: Add new vessel without using hot-spot

13 READING THE AVR RESULT

If the reliability score of the examination is greater than 60%, we can consider the resulting Arteriolar to Venular Ratio reliable, as described in section 2.3.

The AVR value is the mean of the individual AVR's of the reliable pairs of veins and arteries. The result is given in the following panel which displays automatically on the right of the screen when the examination reaches a high enough score.

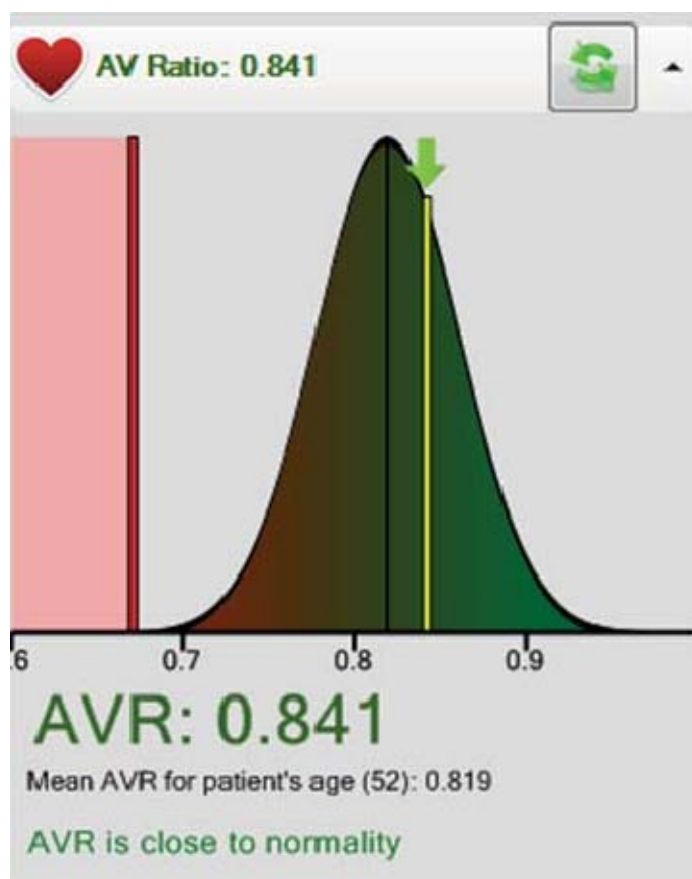


Figure 13-1: Result panel: healthy patient

The Gaussian curve gives the statistical distribution of AVR values over the population, generated in relation to the patient's age.

The mean value of the distribution (0.819 in the example) is the optimal value.

The red line is the threshold below which one can consider it possible that the patient is affected by a significant arterial restriction. This threshold depends largely on the age, however in general one can say that such restriction is certainly present for AVR's less than or equal to 0.60.

The yellow line indicates the calculated AVR, and is positioned in relation to the normal distribution. Below please find an example of an examination whose result is significantly below the norm:

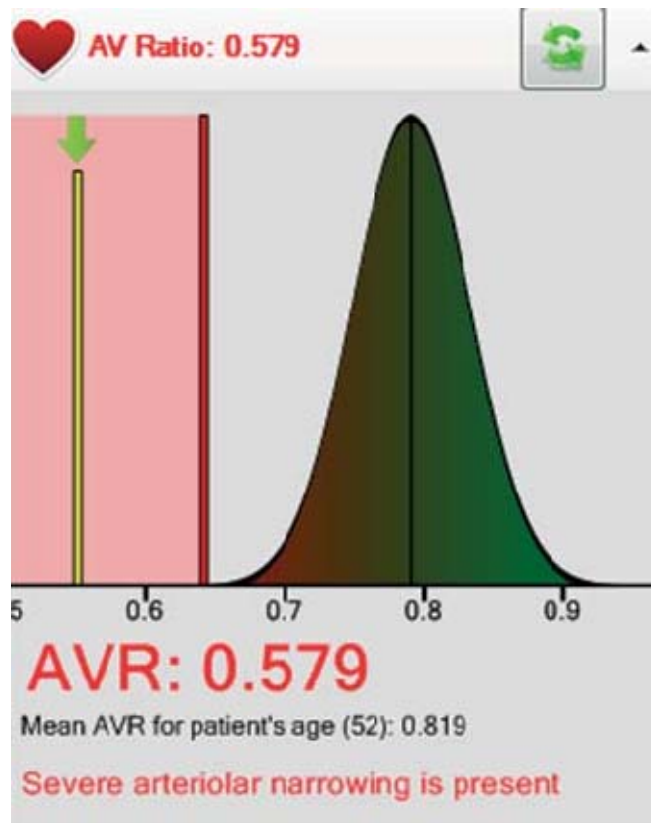



Figure 13-2: Result panel: patient with arterial restriction

Once you have obtained a satisfactory result, you can quit the examination procedure; the current status is saved and will be displayed when the AVR form is next opened, unless you delete the current cup / disk measurement and make a new one.

In this case, the old examination no longer applies to the new position and size of the disk, and a new examination procedure must be run.



Clicking on the icon , next to the AVR value, discards all existing manual modifications and processes the image anew, as if it has just been opened for the first time.

14 MEIBOGRAPHY

Meibography is an examination in which the health of meibomian glands is evaluated.

Once the IR images of meibomian glands have been acquired using the Live acquisition software, they can be manually processed inside AnaEyes in order to calculate the gland health score and save it for further patient evaluation.

Basically, the glands' health tends to decrease as its area becomes smaller inside the eye-lid: while a healthy eye presents the inside of upper and lower eye-lids completely filled with meibomian glands, a suffering (dry) eye presents a surface of "eroded" meibomian glands. So the main idea is to calculate the ratio between the area covered with glands and the total eye-lid area. A low ratio determines a high probability of suffering dry eye.

14.1 Acquiring meibography images

The procedure explained here is very simple and is replicable using Retina 400 live acquisition.

- Start the live acquisition and prepare the patient by exposing the upper-lid and lower-lid meibomian glands, in any order.
- Center the glands on-screen and focus the image moving the instrument forwards or backwards (or using the focus handle in case of Retina 400).
- Take the picture using joystick button. Acquired picture will be showed on screen as a thumbnail. Acquire at least one image for the upper-lid and one for the lower-lid.
- When a satisfactory amount of images has been acquired, exit Live acquisition.

14.2 Processing the examination

Enter the meibography examination gallery and double-click on the desired image to start meibomian glands evaluation. The procedure is computer-assisted but requires manual tracing of glands points.

After evaluation is completed, a gland-health score will be saved and will be available for further patient consulting.



Figure 14-1 Image capture

14.2.1 Starting evaluation



These buttons start the evaluation for upper-lid and lower-lid, respectively; in the above case the lower lid evaluation is selected.

The same buttons can be used to delete the evaluation measure and restart. Deletion is preceded by a confirmation message.

Deleting the measurement means that all control points displayed will be lost.

14.2.2 Tracing eye-lid bounds

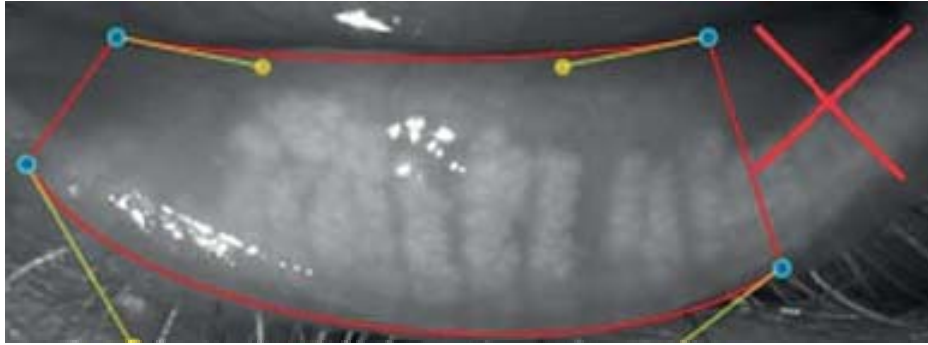


Figure 14-2 - Define boundaries

Four (4) control points must be set in order to define a very raw bound of the eye-lid's area of interest.

Place the blue points in order to build a trapezoidal shape. Exclude lid areas that are not completely reverted, since they are not useful for the computation.

One point (in the example case the left-most one) should be placed near the tear punctum, while the opposite side points (the right-most ones) should be placed on the end-fold of the eye-lid or, as stated before, where the eye-lid is not completely reverted anymore. All the control points that have already been set can still be canceled until the last point is set by hovering the mouse on them and left-clicking when the white cross appears.

The bounds (red lines) do not need to be very precise in this phase, since they will be adjusted automatically in the next phase.



Figure 14-3 Adjust boundaries by moving the blue and yellow control points

Use the all yellow points to adjust the red shape. Try to move the points (including the 4 manually set points) and see how their movement affects the global shape.

The yellow points at the end of the yellow lines can be stretched, such as to modify the curvature of the red shape.

The mechanism is very intuitive anyway: try to approximate the eye-lid shape, but remember that there is no need to be too strict in this approximation.

14.2.3 Tracing gland-points

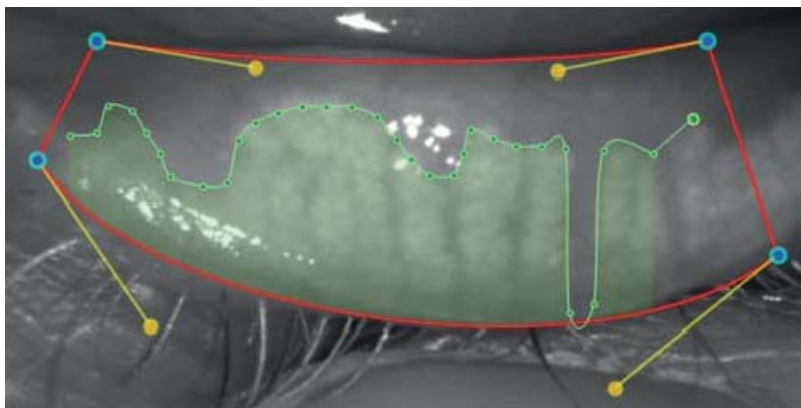


Figure 14-4 Trace gland points

Highlight the glands area by left-clicking on the upper glands bounds (or lower bounds, in case of upper eye-lid meibography).

Every click adds a green gland-point: the more points are set, the more accurate the gland area is. It is also possible to keep the mouse button clicked, then moving the mouse to draw the glands bound: green points will be automatically set.

Avoid crossing lines or creating loops or complex paths.

It is not possible to create gland points outside of the red bounds: a mouse-click outside the red borders will result in the adding of a gland point on the nearest red bound.

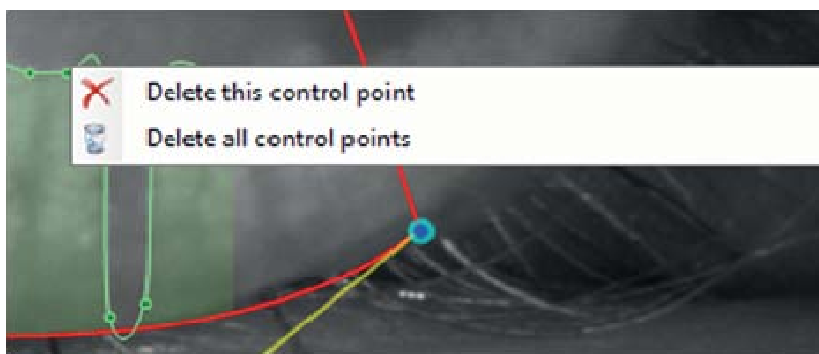
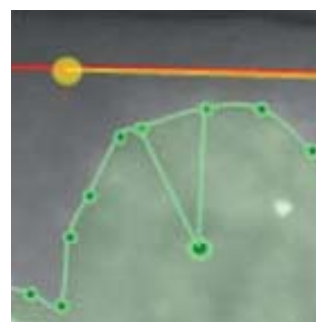


Figure 14-5 Edit points

Defined points can be removed by left-clicking the mouse; a white cross appears on the point when the mouse passes over the point. Right-click on a single point pops up a context menu which allows removing the single point or all the gland points defined so far.

New points can also be set between existing ones in order to refine the green line shape. Just move the mouse between points to obtain a preview of the new point's influence, then left-click to add it to the points set definitively.



14.2.4 Zooming and tracing

This is an advanced editing option.

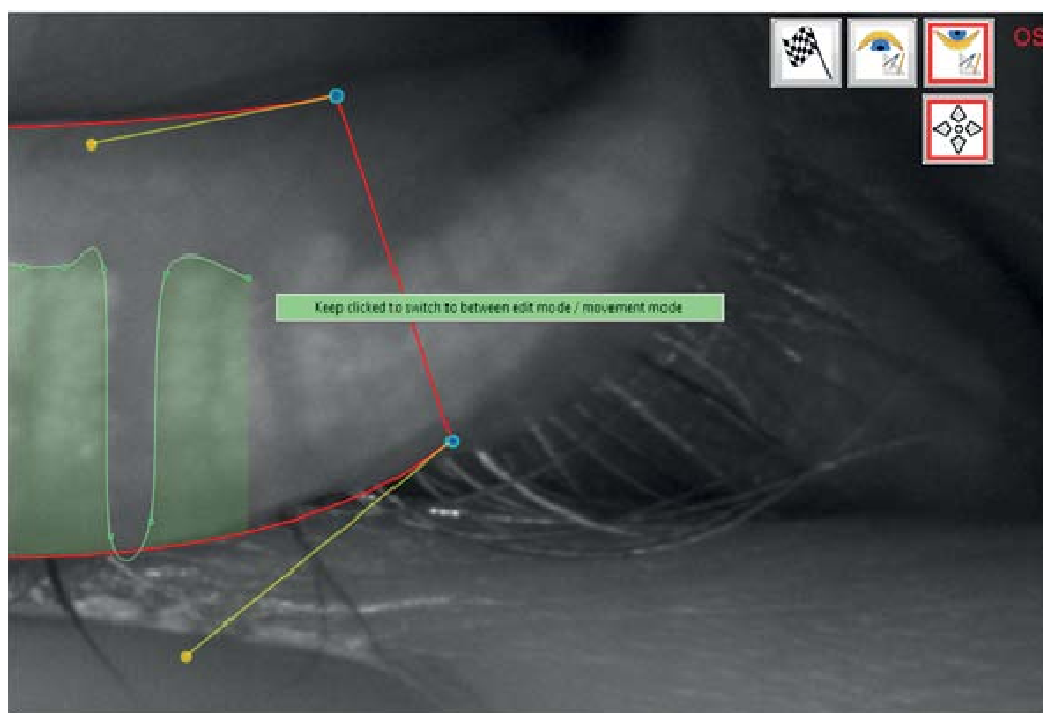


Figure 14-6 Switch edit / zoom mode

Sometimes it is necessary to zoom in the image to obtain more precision in tracing gland points.

While tracing points on a zoomed meibography image, it is no longer possible to move the zoomed image as usual, since a left-click on the image would produce a new gland point, not a “moving grip” as it would in normal image viewing.

To by-pass this behavior, click and keep clicked the right mouse button (an alert appears as shown in the screenshot) to switch between points-tracing mode and standard zoom mode (which allows moving the image).



The same switching function can be obtained by clicking the button which appears only when image is zoomed in.

14.2.5 Finalizing meibography examination

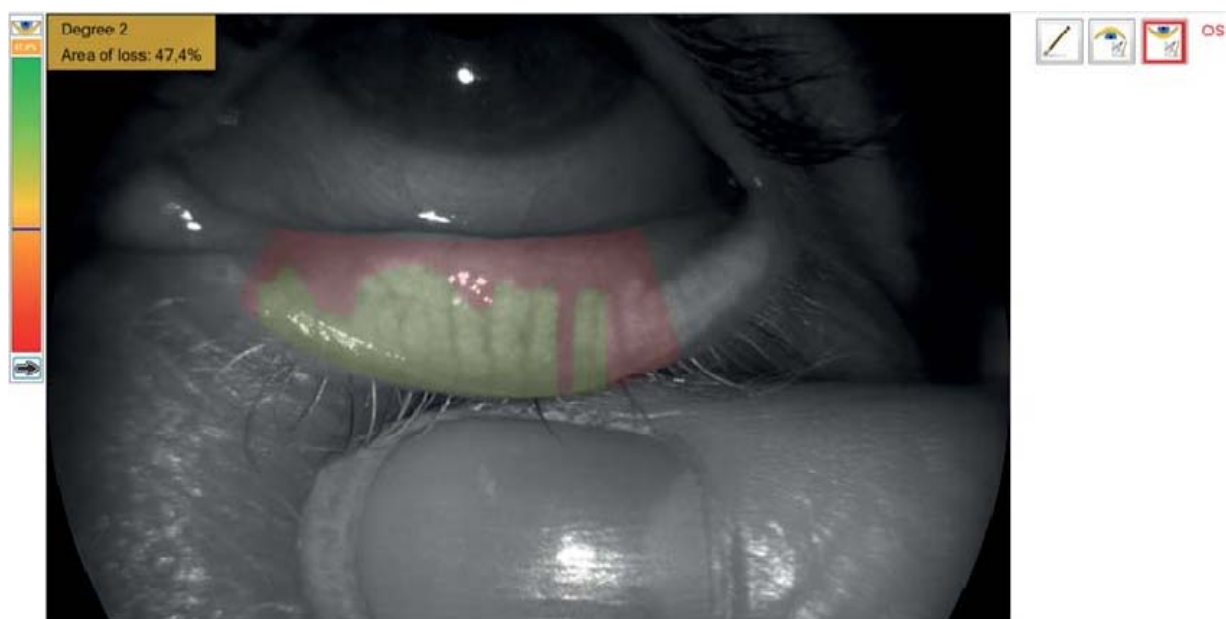


Figure 14-7 Finalizing examination



Once all gland points have been placed, click the button to end the editing phase. Healthy gland area will be drawn in green, while loss area will be red.

Area of loss score is calculated together with a pre-established degree in the meibomian scale.

Score and degree are printed and visible directly on the image, while a detailed review of the attributed score is available in a separate window which appears on the top left corner of the main form.

Meibography score is automatically calculated even if the flag-button is not pressed and edit mode is closed by clicking the quit button.

The updated image can now be printed (alone or compared with other processed or unprocessed meibographies), saved in pdf format etc.



It is possible to return to the editing mode by clicking the button which becomes visible after the meibography has been validated with the flag-button.

This way the examination is always editable after re-entering it in the future.

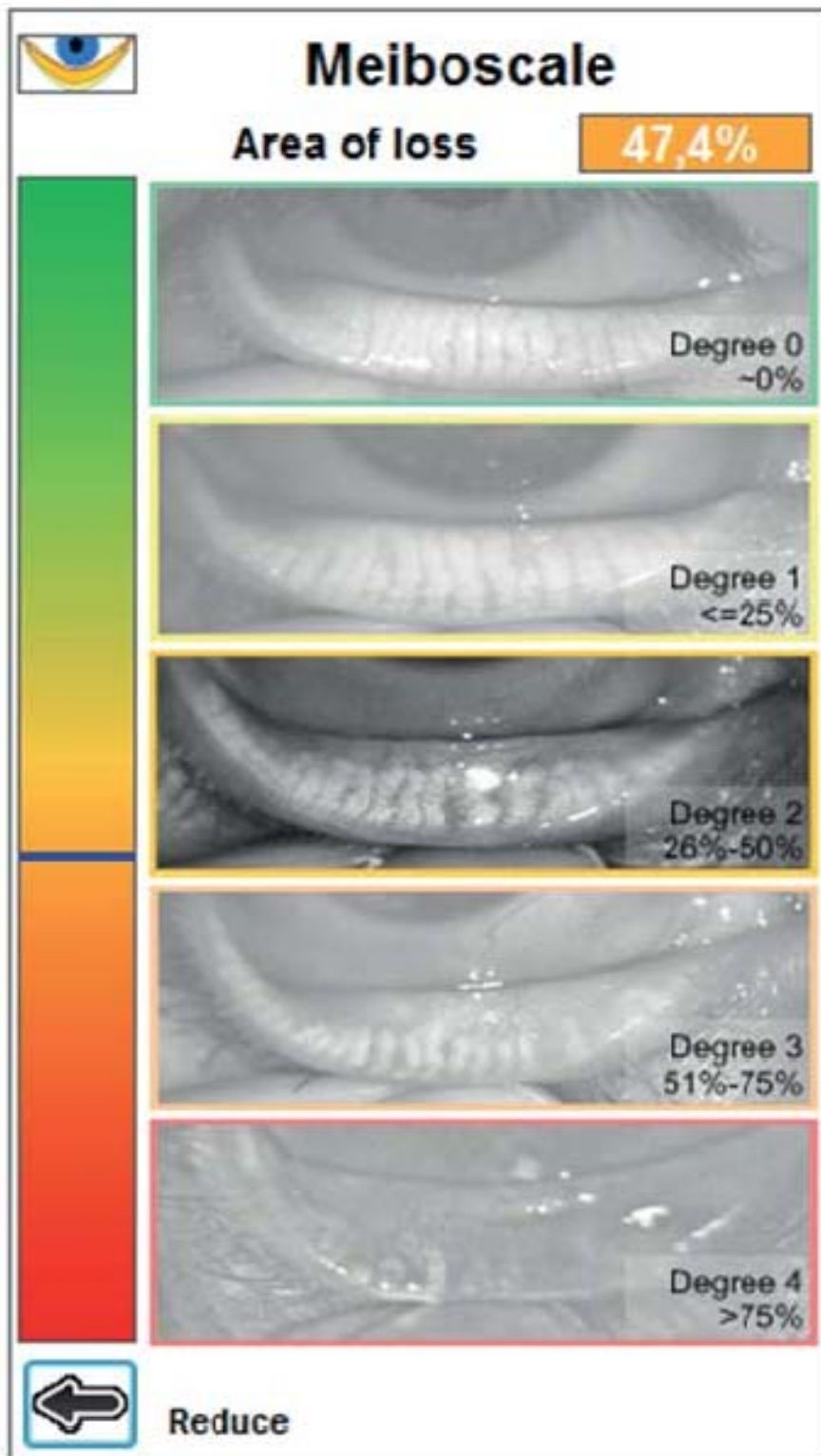


Figure 14-8 Meibo scale

The meibo-scale window in the top left corner of the screen can be expanded (and then collapsed again) for further reviewing of the attributed score.

Here 5 scale samples are available for consulting and visual comparison with the current examination image.

Those samples may help to understand if the whole process has been completed correctly, so that the sample image reflects the health state of the processed image with a coherent area of loss score.

14.3 Meibography thumbnails and gallery preview

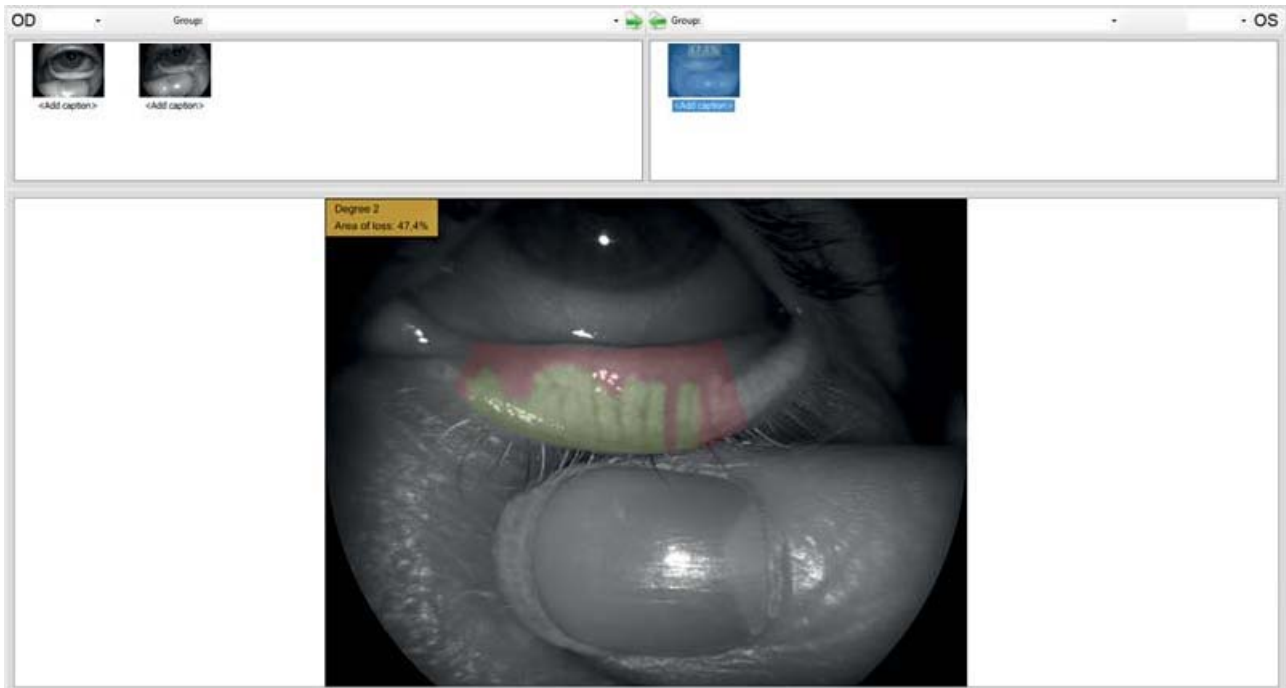


Figure 14-9 Gallery meibography acquisitions

After closing the examination the image thumbnail is updated with the area of loss score and degree, and areas of interest (healthy vs. unhealthy) are drawn in different colors.

The gallery preview also contains all needed information so it is not strictly necessary to re-open the examination for future patient evaluations.

APPENDIX A. IMPORT-EXPORT EXAMS

1. Exporting an examination

Exporting an examination or a patient, select with right-button of the mouse on the examination and click export.



Figure A-1: Export examination

You will see the editing screen of the anagrafic data to be exported.

Edit the data if you want and select OK.

It will be exported the file.zcs.



Figure A-2: Export file

2. Importing an examination

To import a previously exported file.zcs, you must open the archive containing the file, and drag the column occupied by the patient list, as shown in the next window:

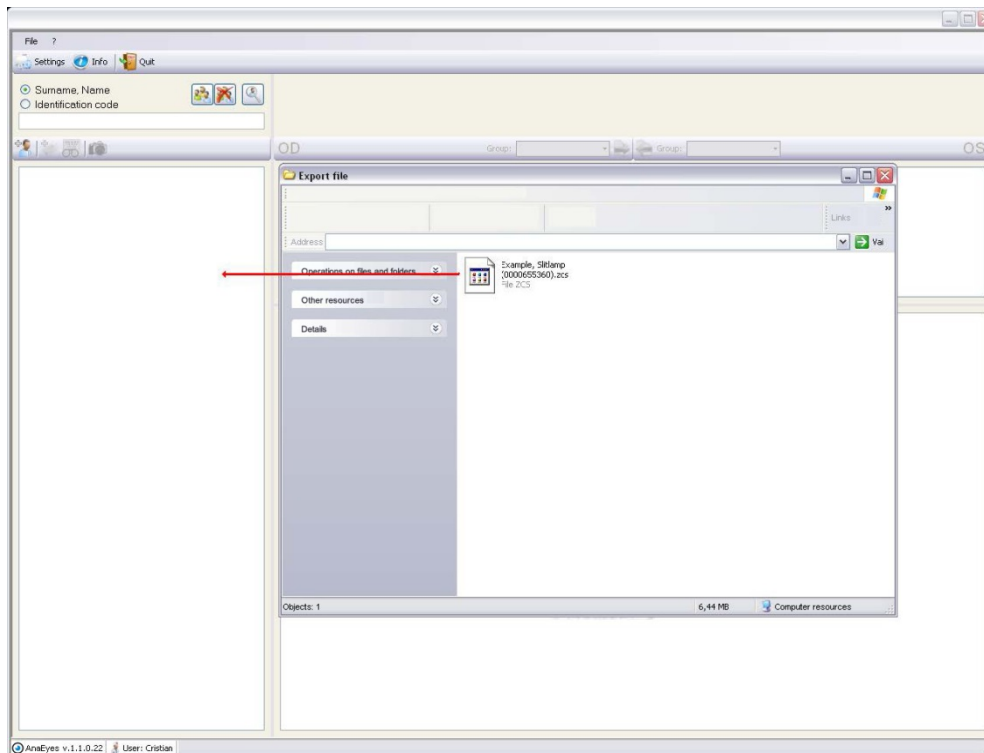



Figure A-3: Import file

Wait a few seconds and the patient will appear in the list.

APPENDIX B. SAFETY

For data security, please refer to the management of Windows security. It is recommended to enter a password to access the account used.

This software is the accessory of medical device; it is compliant with the Directive 93/42/CE, amended by Directive 2007/47/CE and is classified as Class I for  marking
Date of 1st marking: August 2014

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