HD Analyzer™

An OQAS product by

Visiometrics

USER'S MANUAL

Version 2.2

English

CE

0318

MODEL: OQAS – HDA

Optical Quality Analysis System – High Definition Analyzer

TRADE MARK: HD Analyzer™

APLICABLE PARTS:

Chin rest (Type B)

CODE: 2

REV: 5

2015/12

Printed in Spain

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WARNINGS

READ THE USER'S MANUAL BEFORE PERFORMING ANY OPERATION WITH THIS EQUIPMENT.

THIS EQUIPMENT MUST BE OPERATED WITH THE POWER SUPPLY UNIT PROVIDED.

TO PREVENT FIRE OR ELECTRIC SHOCK HAZARD, DO NOT EXPOSE THIS HD Analyzer™ UNIT TO RAIN OR MOISTURE.

THE EQUIPMENT MUST NOT BE POSITIONED IN SUCH WAY THAT HINDERS ACCESS TO THE POWER CONNECTION JACK.

DO NOT ATTEMPT TO REMOVE UNIT COVER AND/OR MODIFY THE UNIT, OR WARRANTY WILL BE VOID.

ONLY STAFF FAMILIARIZED WITH OPHTHALMOLOGY DIAGNOSTIC AND CONTROL EQUIPMENT MUST OPERATE THIS INSTRUMENT (OPHTHALMOLOGIST, OPTOMETRIST, ETC…).

A QUICK CHECK (section 3.8.3) MUST BE DONE AFTER THE FIRST INSTALLATION AND AFTER ANY TRANSFER OF THE INSTRUMENT TO A NEW WORKPLACE.

THIS INSTRUMENT NEEDS ANNUAL CALIBRATION TO GUARANTEE PROPER PERFORMANCE.

KEEP THIS INSTRUMENT DRY.

FOR INDOORS USE ONLY. NOT INTENDED FOR OUTDOORS USE.

NOT SUITABLE FOR USE IN INFLAMABLE ENVIRONMENTS.

SWITCH OFF AND UNPLUG THE INSTRUMENT WHILE NOT USING IT.

THERE ARE NO PARTS INSIDE THE UNIT THAT MAY BE REPAIRED BY THE USER. PLEASE CONTACT THE THECHNICAL SUPPORT.

THIS INSTRUMENT IS NOT WATER OR SPLASH PROOF. IF ANY HUMIDITY, WATER OR LIQUID ENTERS INSIDE THE INSTRUMENT, UNPLUG IT INMEDIATELY AND CONTACT THE TECHNICAL SUPPORT BEFORE USING IT AGAIN.

SHOULD SOME OUTER PIECE SUFFER DAMAGE, PLEASE CONTACT WITH TECHNICAL SERVICE BEFORE USING THE DEVICE AGAIN.

PRECAUTIONS

Do not attempt to disassemble, modify or repair the HD Analyzer™ instrument. There is a class 3R laser device inside the HD Analyzer™ instrument. Avoid direct exposure to human eye. Contact VISIOMETRICS for help.

Do not expose the instrument to bright light, such as sunlight, for long periods of time. Do not operate the HD Analyzer™ instrument beyond the recommended temperature range. Do not use unregulated power supply sources.

This instrument must be plugged to the electrical power network. Take standard domestic precautions.

If the instrument stops working normally, several error messages may be shown on the computer screen. In this case, do not try to repair the instrument. Contact the technical support.

If the instrument stops working normally (showing error messages in the computer screen) due to exposure (in reasonable foreseeable environmental conditions) to magnetic fields, external electrical influences, electrostatic discharges, pressure or pressure variations, acceleration, thermal sources of ignition, …, do not try to repair the instrument. Contact the technical support.

Contact VISIOMETRICS if you need any help.

LIMITED WARRANTY

VISIOMETRICS warrants this HD Analyzer™ instrument to be free from defects in material and workmanship for two full years from the date of original purchase. This warranty covers failures or damages due to defects in material or workmanship, which might occur under normal use conditions. It does not cover damages or failures, which result from shipment, mishandling, abuse, misuse, or modification.

VISIOMETRICS estimates the equipment life span to be 5 years. Regular instrument usage over a period of 5 years still places usage below 15% of equipment dynamic elements life span.

A Return Material Authorization (RMA) number is required prior to returning any VISIOMETRICS product for service or replacement.

This proprietary document may not be reproduced or photocopied without VISIOMETRICS' consent. VISIOMETRICS makes no warranty or assumes no responsibility for any errors, which may appear in this document.

VISIOMETRICS reserves the right to make changes without notice or obligation.

For immediate technical assistance, please call (+34) 935 824 501 or email to technicalservice@visiometrics.com

1. INTRODUCTION

1.1. GENERAL DESCRIPTION

Due to the importance of and necessity for objectively measuring visual quality, VISIOMETRICS has developed HD Analyzer™, a new instrument based on the double-pass technique that provides an objective clinical evaluation of the eye's optical quality.

A point light source is imaged on the retina. After retinal reflection, light passes twice through ocular media. HD Analyzer™ analyses the size and the shape of the reflected light spot.

HD Analyzer™ images contain all the information about the optical quality of the eye including all the higher order aberrations and scattered light, being both generally missed by most aberrometric techniques. These higher order aberrations may have an important impact on refractive surgery, as scattered light on the aging eye.

HD Analyzer™ allows performing measurements in a wide range of clinical situations. Obviously, one of the most promising applications areas for HD Analyzer™ is cataract detection and classification, as well as refractive surgery. Furthermore, its functionalities for the evaluation of pseudo accommodation and the tear film degradation with time, have become very useful tools for the study of presbyopia and dry eye syndrome.

HD Analyzer™ provides a control and acquisition software. At the same time, additional advantages are available: easy to work with, intuitive user interface and real-time control.

1.1.1. Double-pass technique

Figure 1 shows an image of a double-pass system, similar to the HD Analyzer™ one.

The light source is a 780 nm laser diode. The light beam is filtered and collimated at L1. After reflecting through a beam splitter BS, the beam passes through two achromatic doublet lenses L2 and L3, and through the mobile Focus Corrector FC, with two mirrors attached to it. Spherical refraction of the patient's eye is corrected by modifying the optical paths between L2 and L3.

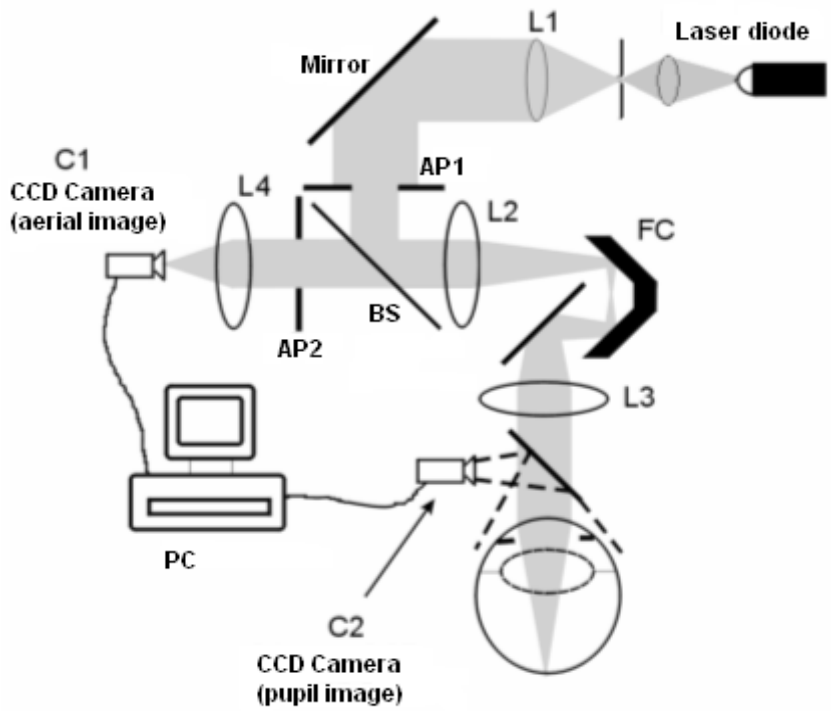


Figure 1. Scheme of the double-pass

The eye forms the image of the punctual source on the retina. The optical pathway from the laser source to the retina constitutes the first-pass of this system.

The double-pass is determined by the light on its way from the retina to the CCD camera (aerial image or double-pass). This pathway begins with light being reflected on the retina in a set pattern due to the retina's diffusing behavior. The

reflected light passes through the two doublet lenses and through the BS. Light transmitted through the BS encounters the second artificial pupil (AP2), which is conjugated with the eye's pupil plane. This pupil is variable and works as effective exit pupil when AP2 is smaller than the natural pupil. The effective exit pupil will be whichever of both, AP2 or natural pupil, is smaller. Since natural pupil is not static –it dilates and contracts- it is advised to set AP2 slightly smaller than natural pupil. An objective focuses the aerial image on a CCD camera. Measurements may be taken using different AP2 diameters.

1.1.2. What is OSI?

OSI = Objective Scattering Index

OSI is a parameter which allows to objectively evaluating the intraocular scattered light. It is computed by evaluating the amount of light on the periphery of the double-pass image in relation to the amount of light on the centre of it. In this way, the higher the OSI value, the higher the level of intraocular scattering.

It is the one and only parameter which allows the objective quantification of intraocular scattered light. It is useful in all clinical situations when scattered light may be important: cataract development and surgery, refractive surgery, intraocular lens, aging, dry eye syndrome, etc…

OSI is being used for a new objective classification of cataract development. For eyes with a normal degree of scattering (young eyes) OSI value is lower than 0.5. For eyes which are developing a cataract, OSI value stands between 1.5 and 4. For eyes with a mature cataract OSI is higher than 4.

1.1.3. What is MTF?

MTF = Modulation Transfer Function

MTF is a function which allows us to evaluate the degree of detail of an image after passing through an optical system, i.e. it evaluates the ratio between the contrast in the image formed by the system and the contrast in the original scene. In the case of the eye, the MTF represents the loss of contrast of the real scene after passing through the eye.

In any optical system, for instance, in the human eye, contrast reduction is higher for high spatial frequencies (fine details on an image). In this way, the MTF is a function of the spatial frequency.

If contrast in the image is the same as in the object, the MTF value is the maximum. This value can only be obtained for a spatial frequency of zero, i.e. when the object which is being watched is a uniform plane, with no bands nor borders and no intensity variations. As spatial frequency increases, MTF decreases because contrast in the image becomes lower than in the object.

MTF also changes with pupil diameter. In this way, it is important to consider the pupil diameter of a measurement before comparing it to another measurement. This value will be the one set as artificial pupil before performing the measurement, if it is smaller than the patient's pupil. Since patient's pupil dilates and contracts, we advice to carry out measurements with a set artificial pupil slightly smaller than the natural pupil, so that measurements can be reproduced.

1.2. FEATURES

- Quantitative and objective evaluation of intraocular scattered light.
- Quantitative and objective evaluation of the eye's optical quality.
- Quantitative and objective evaluation of the loss of optical quality due to the tear film degradation.
- Quantitative and objective evaluation of pseudo accommodation.
- Qualitative evaluation of the eye's optical quality by means of bi and three-dimensional maps of the double pass retinal image. A simulation of the image of a scene projected onto the retina is also provided.
- Optical axis position assessment with respect to the pupil center.
- When a KAMRA™ inlay is implanted, inlay position assessment with respect to pupil center and to optical axis.
- Tools for optimal visualization and quantification of the images, such as zoom, rotation, profiles and measurements.
- A useful and user-friendly patient database.
- Printable reports of the measurement parameters and results.
- Easy acquisition and manipulation of the images

1.3. APPLICATIONS

- Evaluation of the level of intraocular scattering (OSI) for the early detection of cataracts or for the determination of its degree of maturity. Objective measurement of halos and glare.
- Comparing pre and post cataract and refractive surgery measurements.
- Evaluation of tear film quality, especially on patients suffering from dry eye.
- Objective measurement of the amplitude of pseudo accommodation range.
- Diagnosis of pathologies.
- Precise measurements of the ocular MTF (Modulation Transfer Function) in all situations (overestimated by aberrometers when scattering exists, like in cataract patients).
- Showing the effect of ocular aberrations in visual acuity (including the higher order ones, not usually measured by standard aberrometers).
- Showing the effect of the tear film degradation on the quality of the retinal image.
- Purkinje image assessment of an eye with no KAMRA™ inlay implanted, detecting exact position of its optical axis with respect to the pupil center and allowing knowing the required position for the correct KAMRA™ inlay implantation.
- Purkinje image assessment of an eye with a KAMRA™ inlay implanted, detecting exact position of implanted inlay with respect to the eye's optical axis, allowing quantifying how close the inlay is from its optimal position (eye's optical axis).

1.4. HD Analyzer™ SPECIFICATIONS

1.4.1. Hardware Specifications

- Type B
- Measurement range: Min. +5 D to -8 D S.E. (higher ammetropias including astigmatism can be neutralized with an additional lens)
  - Reproducibility: +/- 0.25 D
  - Accuracy: +/- 0.25 D
- Best focus dioptric value repetitivity: ± 0.125 D of average
- Natural pupil diameter measurement: Automatic
  - Accuracy: +/- 0.5 mm (for an 8 mm pupil)
- Artificial pupil diameter: 2 to 7 mm
- Image capture time: 240 ms
- Laser diode wavelength: 780 nm
- Laser power selection: Automatic
- Maximum laser power at the pupil plane: 2.8 mW
- Best focus position: Automatic
- Fixation target: landscape with house
- XY translation: Joystick
- Size: 415 (L) x 350 (W) x 530 (H) mm
- Recommended working space: 2.5 m²
- Weight: 20 Kg
- External Power supply:
  - Input: 100-240 VAC, 50-60 Hz, max. 0.9 A
  - Output: 12 V DC, 3.0 A, 40 W
- Operating temperature and relative humidity: +10 ºC to +35 ºC, and 30% to 90%.
- Storage temperature and relative humidity: -10 ºC to +55 ºC, and 10% to 95%.
- Transport temperature and relative humidity: -40 ºC to +70 ºC, and 10% to 95%.

Class II	Class II double insulated equipment has the double square symbol indicating the equipment is double insulated and therefore has no earth wire.

With respect to Purkinje measurement:

- Laser power selection: Automatic or Manual
- Optimal distance between patient's eye and HD Analyzer™ is outlined green.
- Purkinje detection
  - Error below 142µm in more than 95% of measurements.
- Purkinje offset detection – KAMRA™ inlay
  - Error below 142µm in more than 95% of measurements.
- Pupil offset detection – KAMRA™ inlay
  - Error below 142µm in more than 95% of measurements.

1.4.2. Software Specifications

- 1.6 MHz or higher Pentium-compatible CPU
- 512 megabytes (MB) of RAM recommended minimum; more memory generally improves performance
- USB 2.0 port
- Screen resolution: recommended 1366 x 768; minimum 1280 x 768
- Windows XP, Windows Vista & Windows 7 (32 & 64 bits) compatible

1.4.3. Accessories

1.4.3.1. Computer (PC or laptop)

It is used to run the instrument control software. Minimum requirements:

- Processor: 2.10 GHz, 3 MB
- Screen: 39.6 cm (15.6") HD (1366x768)
- Memory: 4 GB 1600 MHz DDR3 Memory
- Hard disk: 320 GB

- Operating system: Windows 7 Professional (64Bit)
- Ports: 2x USB 2.0

1.4.3.2. Auxiliary tool for "Quick check" process

It is used to check the centering of the laser and focus parameters. Its use is explained in section 3.8.3. If you don't have it, ask to your provider.

Figure 2. Auxiliary tool for Quick check

1.4.4. Manufacturing compliance

- Electrical Safety: Designed and manufactured to comply with EN-60601-1:2008 + ERR: 2008.
- Electromagnetic compatibility (EMC): Designed and manufactured to comply with EN-60601-1-2:2008 + ERR: 201

1.5. USER'S MANUAL'S ACCURACY

It may happen that some of the screens shown on this user's manual are not exactly the screens shown on your software.

Small differences will be due only to different setup options.

2. HD Analyzer™ Hardware Setup

2.1. UNPACKING, INSPECTING AND INSTALLING HARDWARE

Open the shipping crate and verify that all the equipment necessary to operate the system has arrived undamaged.

It contains:

- HD Analyzer™ unit (HD Analyzer™ instrument)
- PC or laptop with specific hardware and software installed and ready to operate the device.
- Flat 15" or 17" monitor (only for PC).
- PC or laptop documents.
- Device's documents and brief unpacking and setup manual of the instrument.
- USB cable
- External power supply.
- Power supply cable

The next pictures explain briefly the unpacking process. Make sure to remove all packing material and desiccant bags before attempting to take the HD Analyzer™ instrument out of its crate. We recommend that two people lift and move the instrument to the prepared location, by grabbing it from its base.

Never lift the HD Analyzer™ instrument unless grabbing it from its base. The device's mobile part is very fragile and interior elements could get damaged.

1. Carry the crate to an appropriate location

2. Open the clips on the upper lid of the crate, using a screwdriver

3. Remove the clips on the upper lid of the crate, as shown

4. Remove the upper lid and the packaging plastics

5. Take out the laptop or PC and the rest of packaging material

6. Grab the HD Analyzer™ from its base and move it to a prepared location

Attach the USB connector to the instrument and the connector of the external power supply to the proper input on the connectors' side of the machine. The opposite end of the USB cable must be attached to the PC (or laptop) (USB port). Plug the power supply to a socket.

The power cords of both the HD Analyzer™ instrument and the computer must be plugged into a power outlet.

2.2. MAINTENANCE

The only maintenance task which user has to carry out is periodical cleaning. We recommend carrying out cleaning quarterly.

Cleaning

Always unplug your HD Analyzer™ instrument before cleaning it. Clean plastic surfaces with a soft and humid cloth. Do not use solvents or abrasive cleaners.

The HD Analyzer™ has a low infection risk derived from its usage, which can be classified as non-critical and therefore will need a low level of disinfection. Patient comes in contact with instrument through intact skin in the chin and front areas, which rest on the chinrest, and with his hands, which he may use to grab the chinrest.

These applicable parts may be periodically disinfected by using a low level disinfectant, such as quaternary ammonium compounds.

- ***Keep this device dry.***
- ***For indoors use only. Not designed for outdoors use. Professional use only.***
- ***Turn off or unplug when not in use.***
- ***This machine is not water or splash-proof. If moisture, water, or liquid gets inside the housing, immediately unplug the unit and contact a service technician or your dealer before using it again.***
- ***Disconnect the appliance from the electric supply before removing the cover.***
- ***No user serviceable parts inside. Refer to your dealer or other qualified service personnel***

Calibration

User must not carry out any calibration task on the equipment. Calibration must be carried out by manufacturer trained staff.

It is recommended to have a calibration carried out on annual basis.

3. HD ANALYZER™ FUNCTIONS

3.1. USING THE SOFTWARE WITHOUT THE HARDWARE

The user friendly software allows access to database without needing the HD Analyzer™ instrument to be switched on or even connected to the computer. All the utilities related to the database can be performed without instrument (see section 3.5).

The database will be also accessible if the software is running in pay-per-patient mode and there are no more available measurement credits. It will not be possible to perform new measurements until buying new credits.

3.2. PAY-PER-PATIENT MODE

Depending on the service that you have contracted, the HD Analyzer™ instrument can work in free mode or in pay-per-patient mode.

In free mode, you can perform as many measurements as you want, with no limitation.

In pay-per-patient mode, you have a limited number of measurement credits. Once a patient is measured with the instrument, a credit is subtracted from the counter. Please, read carefully section 3.6.3, where we explain in which cases a credit is subtracted, for each measurement type. If you finally run out of credits, the software will allow reviewing the results of previously saved measurements, but it will not allow performing new ones.

In order to get new measurement credits, you have to purchase them at Visiometrics' web site (www.visiometrics.com). Once entered the web site, click on *Client Access*, and enter your username and password. In this way, you will access your private account, where you can check your personal data (*User Profile*) and the list of your previous purchases. In section *Buy measurements*,

select the center where the HD Analyzer™ is installed, its serial number, and the number of credits you want to buy. After clicking on *Buy*, type in all the required data in order to complete the purchase process. The result of this process will be a 16 character code (activation code) with this format:

XXXX – XXXX – XXXX – XXXX

(For example: ABCD-1234-5678-efgh)

In order to have these new measurements available for using them in the HD Analyzer™ instrument, please follow these simple steps:

1. Write down the activation code.
2. Go to the computer connected to the HD Analyzer™ instrument and run the software.
3. In the home menu of the software (Home), click on License Manager. This will open the application for managing the activation codes. See section 3.7 for more information.
4. Click on Enter New Code. Just enter there the new code and click on Validate Code.
5. The new measurement credits will be added then to the previously available ones.
6. Close the License Manager. The HD Analyzer™ software will restart with the new number of available measurement credits.

NOTES:

- Activation codes do not expire.
- Each activation code can only be used once.
- Each activation code can only be used for the device selected during the purchase process.

If you have any doubt, please contact Visiometrics at this email address: technicalservice@visiometrics.com

3.3. GETTING STARTED

Instructions for use

Remember, the first time HD Analyzer™ is used after installing it in the workplace, or after transferring it to a new work place, a "Quick check" is needed. Instructions for perform it are described in section 3.8.3.

The HD Analyzer™ instrument allows carrying out measurements of the eye with or without neutralizations (glasses, contact lenses or intraocular lenses). When using conventional lenses (patient glasses or a trial frame) these should be slightly tilted to avoid reflections. We recommend the use of the instrument's lens frame instead, which has been already tilted.

When patient has more than 0.5 D of astigmatism, measurements must be taken with the corresponding correction in order to avoid incorrect results.

Directions to patients

It is important to place patient properly and in a comfortable position before beginning to take any measurements.

First of all, make sure that the hygienic protectors are correctly placed on the chinrest of the HD Analyzer™ instrument. Patient will be requested to sit down and place his chin on the hygienic protector, on the chin rest.

Using the HD Analyzer™ joystick, bring back the mobile part of the HD Analyzer™ instrument to the farthest point from patient and then push it forward until patient's pupil appears well focused on screen, paying special attention to avoiding touching patient's nose. Patient should feel comfortable and at ease.

During *Objective Refraction*, *Scatter Meter* and *Optical Quality* sequences, patient should be requested to casually look at the target, trying not to blink more than essential. It is recommended to warn the patient that during sequences, target is

defocused and in no way should this fact be taken as poor vision, but as a normal device feature.

During the pseudo accommodation sequence (*Pseudo Accommodation*), patient will be requested to try hard to focus on the target during the process.

During the tear film analysis sequence (*Tear Film Analysis*), patient should be requested to casually look at the target, trying hard not to blink during the whole process (20 seconds). If it is not possible for the patient to keep the eye opened so long, he should try to blink only the necessary.

Lastly, while performing the Purkinje sequence (*Purkinje*), patient will be requested to always look at the laser light (red light), focusing the eyes on it. Moreover, during the first moments when software is acquiring images, patient should be requested to try hard not to blink.

3.4. HOME MENU

After double-clicking the HD Analyzer™ icon, the program will start and will ask for the unit's Serial Number:

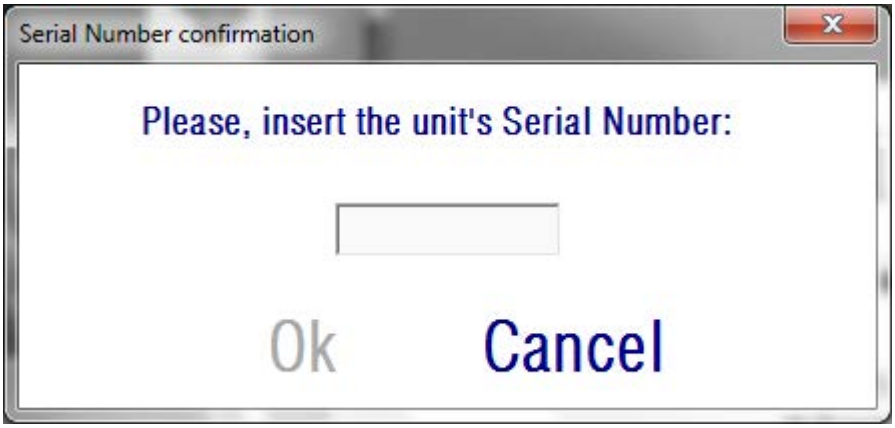


Figure 3. Serial number confirmation

This request will be asked for, at the most, once every 24h. If the introduced number does not agree with the one registered in the software, it will not be possible to proceed with measurements.

After introducing the unit's Serial Number and clicking OK, the *Home* screen will appear, as shown in Figure 4.

Figure 4. *Home* screen

This screen gives access to the following sections:

- *Database*: Gives access to patient database in order to edit, view, compare, print or delete previously saved results. The database will always be accessible through this button; even when running the software without having the HD Analyzer™ instrument connected, or if there are no available measurement credits in pay-per-patient mode.

- *Measurement*: When the HD Analyzer™ instrument is connected to the computer, switched on and introduced serial number is correct, this button will be enabled and will activate the screen which allows measurements to be taken. In pay-per-patient mode, this option will be enabled only if there are measurement credits available.

- *License Manager*: Gives access to the application for the system's license management. In that application, the user will be able to enter the purchase codes obtained from his account in Visiometrics web page. In this way, the new measurement credits bought by the user will be activated.

- *Setup*: This button activates the setup screen. The user will be able to modify some of the parameters of the system. The rest of parameters are protected with a password, which the manufacturer will provide only in case that the device needs some maintenance task. The password is not provided by default in order to avoid any unintended modification of the configuration parameters of the instrument.

Access to the Hardware Setup section is restricted to qualified staff. Some parameters, if changed, can cause the equipment malfunction.

- *Backup*: Allows carrying out a backup of patient database and associated images onto the desired directory.

3.5. DATABASE

HD Analyzer™ provides an easy to use patient database, which can be accessed by clicking the *Database* button.

Save data can also be accessed directly by using Microsoft Access™ (if you have installed it). See Appendix A for further information about the particular data stored in the database file.

Database

You can either take a measurement first and select a patient later or select the patient first and then carry out the measurements. In this case, enter the database screen by clicking the *Database* button. In this screen you can add new patients and modify or delete the existing ones. You can also select a patient for performing new measurements.

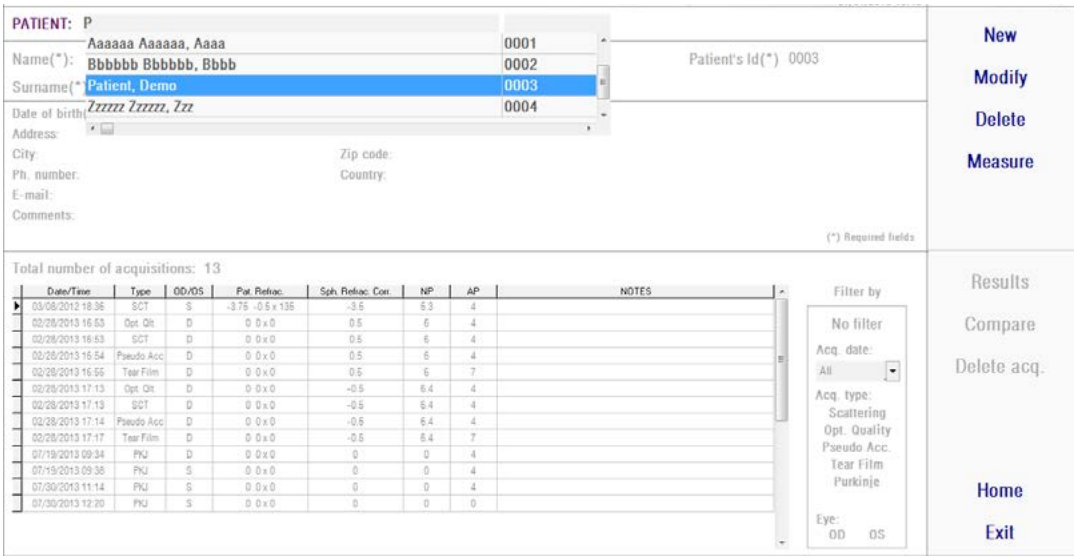


Figure 5. Patients database

Patient field allows quickly finding any patients' name. Just type the first letter of the patient's last name and a drop down list will appear, with all the patients whose last name starts with that letter. Patient's register can also be recalled by typing an *Id. Number* in the corresponding field. To select a patient, click over its name or press *Enter*. All the data fields will be filled in with the selected patient's data, as well as the list of the measurements performed to him. New acquisitions can now begin (*Measure*) or recorded data can be analyzed (*Results* or *Compare*).

The data shown in this screen is not editable. For any data modification, proceed using the button *Modify* (see section 3.5.2).

3.5.1. New

Click *New* button to add a new patient register to the database. All the data fields are now editable. It is mandatory to fill out the fields *Patient's Id*, *Name and Surname.* The fields *Gender, Date of birth, Address, City, Zip code, Country, Phone number, E-mail* and *Comments* are optional.

Click *OK* to validate new register or *Cancel* to return. Confirmation will be required before saving the new data.

3.5.2. Modify

Select a patient and then click the *Modify* button in order to modify a patient's register in the database.

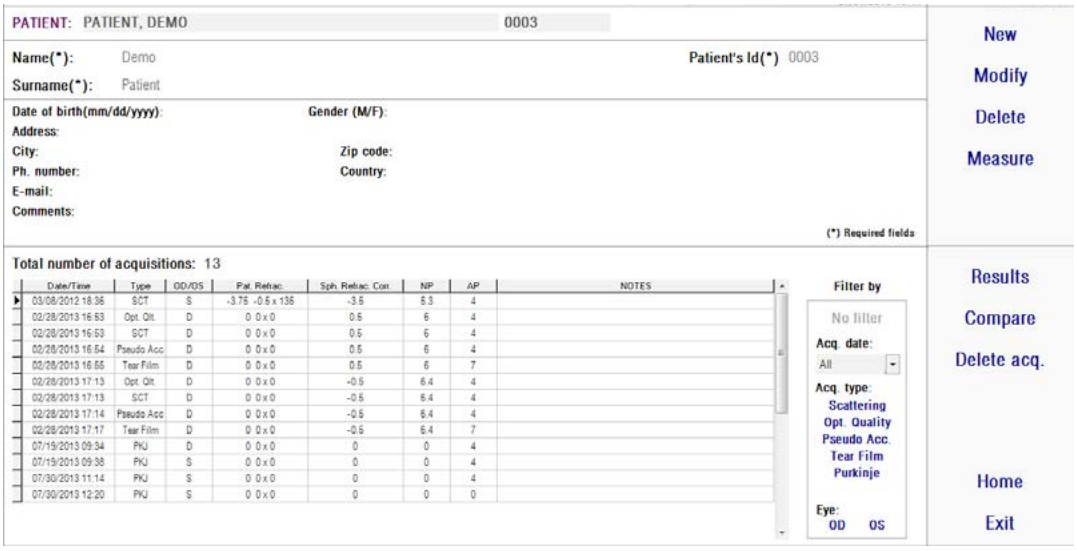


Figure 6. Data modification

Make the desired changes and then click *OK* to validate new data or click *Cancel* to return without saving the changes. Confirmation will be required before changing the data.

3.5.3. Delete: patient/acquisition

Select a patient and then click the *Delete* button in order to remove a patient's register from the database.

Confirmation is required before deleting a patient record.

Deleting a patient record will delete all data and images related to that patient. Make sure you have chosen the right patient and that you really want to delete it.

If you want to remove just one single measurement from a patient's history, select an acquisition from the list and click on *Delete acq.*

3.5.4. Results

Once the patient has been selected, all the measurements performed on him are shown on the list below (see Figure 7), and are now available for their analysis, printing, comparison, etc. The full list is shown by default. Different types of filters can be applied, using the buttons at the right of the list. The list can also be sorted by any of the available columns, just clicking on the column title.

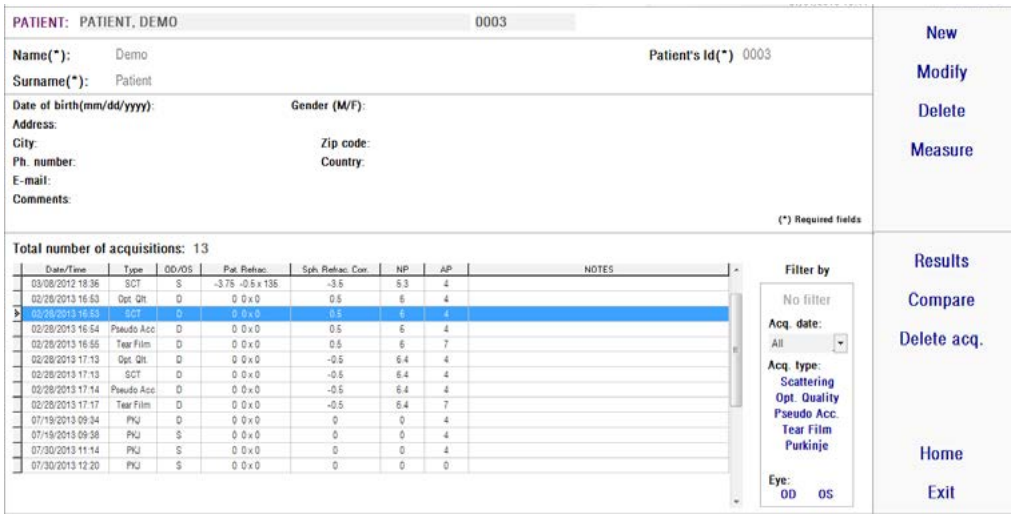


Figure 7. Open a measurement

These are the different parameters shown on the list to identify the measurements:

- *Date/Time*
- *Type*: *SCT* (Scatter Meter), *Opt. Qlt.* (Optical Quality), *Pseudo Acc.* (Pseudo Accommodation), *Tear Film* (Tear Film Analysis) and *PKJ* (Purkinje). Some of these features may not be available in your system.
- *OS/OD*: Left/Right eye
- *Pat. Refrac.* Subjective patient's refraction (*Sph*, *Cyl* and *Axis* values), typed by the user before performing the measurement.
- Sph. Refrac. Corr.: Defocus (spherical refraction) correction applied by the instrument during the measurement.
- NP.: Natural pupil diameter (in mm) determined by the instrument while performing the measurement. A 0 value indicates that this diameter was not measured.

- AP.: Artificial pupil diameter (in mm) used for performing the measurement.
- Notes: Acquisition notes, if any.

Select one acquisition clicking on it and then click on *Results* to continue.

3.5.5. Compare

This option allows loading two measurements of the same type and comparing them. In order to do this, click on *Compare*. You will be requested to select the first measurement to be compared and then click *OK.* Then, select the second measurement. It can belong to the same patient or to a different one, but it must always be of the same type. Again, click *OK*.

See section 3.6.4.4 for more information about the comparison screens.

It is important to stress that it is not possible to load and compare Purkinje measurements.

3.6. MEASUREMENTS

There are two ways for accessing the main measurement screen. The first is to click on the *Measurement* button of the Home menu, without selecting a patient. The other option is to enter in the database clicking on *Database*, selecting a patient and clicking on *Measure*.

In both cases, the user will be required to enter the values of the subjective refraction of the patient (see Figure 9). This information is needed by the HD Analyzer™ instrument to look for the best spherical correction around a dioptric range, thus resulting in more reliable and exact measurement and less time costing. The fields *Sph* (sphere), *Cyl* (cylinder) and *Axis* (axis) are required, for both eyes. The instrument is able to perform measurements in the range of spherical refractions between +5 D a -8 D, and the range of astigmatism between +0.5 D and -0.5 D. Out of that ranges, the refraction of the patient must be corrected by means of trial lenses (only for the astigmatism, or for both sphere and cylinder).

For that purpose, use the lens holder placed in the front part of the instrument. The user will have to choose as well the proper option in the field *Correction* of the measurement's main screen (see section 3.6.1).

The subjective refraction is needed for the process of determination of the best spherical correction to be applied in the measurements. If patient's refraction is ± 3D over the input values, this process will come out with a wrong result.

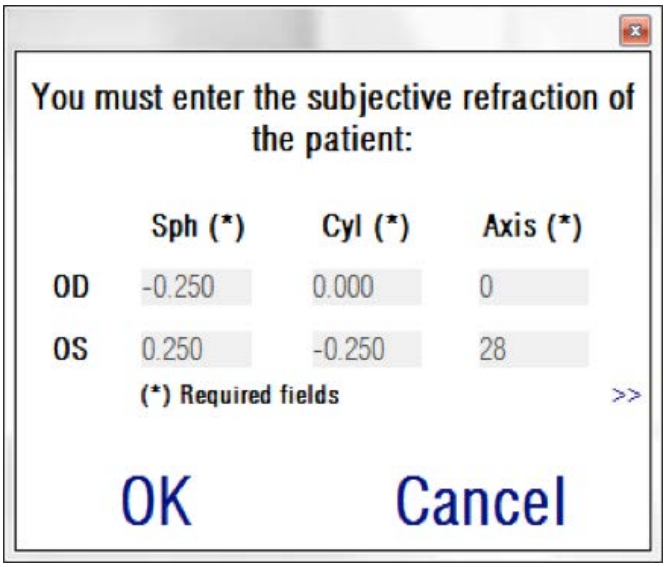


Figure 8. Subjective refraction (compacted view)

You can also enter the best corrected visual acuity (*BCVA*) and the uncorrected visual acuity (*UCVA*), as additional information that will be included in the printing reports of the measurement results. To do that, access to the enlarged view with button >>.

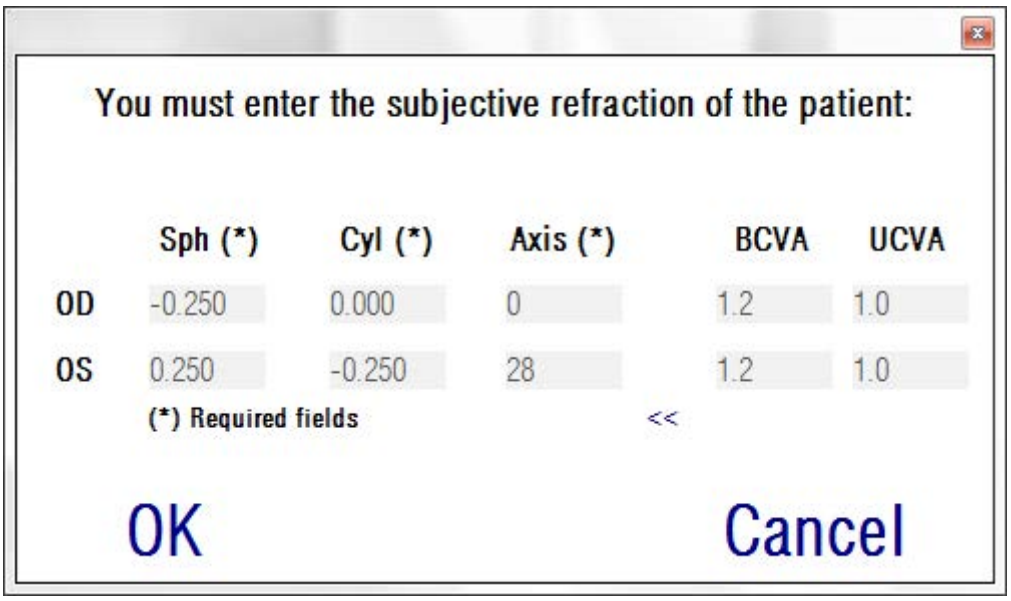


Figure 9. Subjective refraction (enlarged view)

Once all the refraction data has been entered, click on *OK*, to access the measurement's main screen.

3.6.1. How to carry out an acquisition

The measurement's main screen is divided into six areas (see Figure 10):

A. **System information:** The information shown at the top of the screen can be customized to include the name of the centre and person who operates the HD Analyzer™ instrument. This information can be accessed and modified through the Setup button at the Home menu (see section 3.8). If the software is running in pay-per-patient mode, the system also shows the number of available measurement credits.

B. **Main functions:** These buttons allow performing common actions on the data, such as accessing the database (see section 3.5), saving or printing the results.

C. **Measurement processes:** Some of the buttons become available only when Objective Refraction has been carried out. See the following

sections for more information. (Note: not all the measurement options may be available in your system)

D. Live image: This window shows patient eye in real time, allowing the user to center and focus the image.

E. Input data: This section shows selected patient's data, and allows setting and changing the input parameters used in the measurement (further information later in this section).

F. This section shows two different types of information:

- Visualization of the Objective Refraction process: This section shows the progress and results of the process for the determination of the best spherical refraction correction.

- Measurement Results: Once the measurement process has finished, results are shown for: Scatter Meter, Optical Quality, Pseudo Accommodation and Tear Film Analysis, as well as parameters typed in by the user (see section 3.6.4)

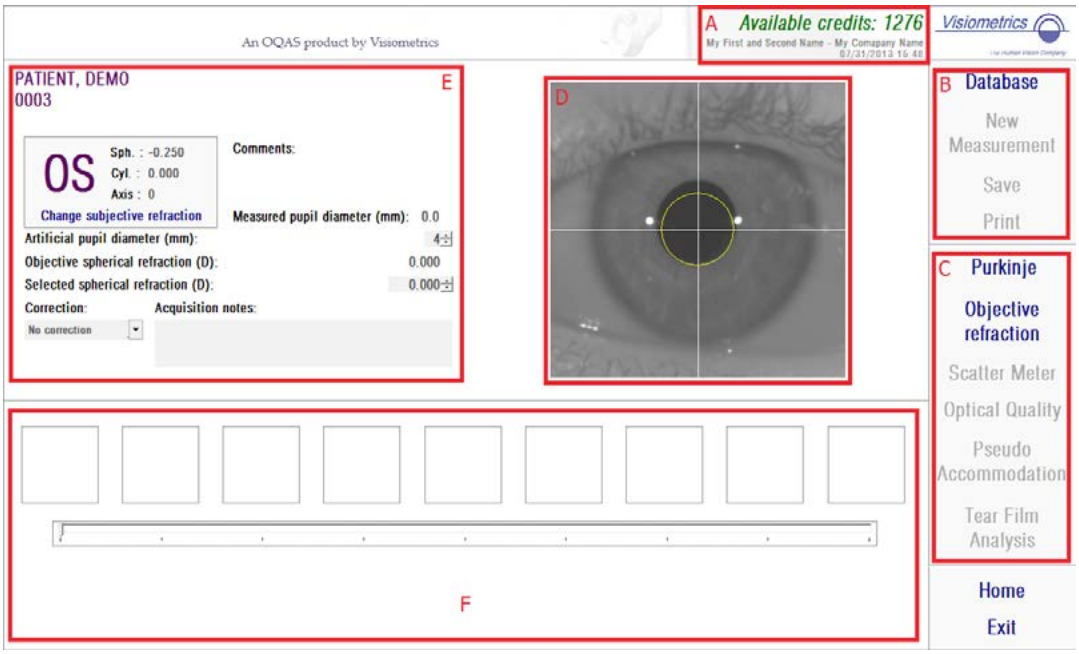


Figure 10. Measurements main screen

If a patient has been selected, his data appears on the main screen. The eye that is going to be measured *OD/OS* (Right Eye / Left Eye respectively) is automatically detected by the instrument. The eye's spherical refraction (*Sph*), Cylinder (*Cyl*) and astigmatism axis (*Axis*) that have been entered previously are shown in the corresponding fields. Please check if those values are correct. If they aren't, change the values by clicking on *Change subjective refraction*, as seen in red on Figure 11.

Figure 11. Eye and refraction data

It is important to enter correct values for the subjective refraction of the patient. In the *Objective Refraction* process (the determination of the best spherical correction for the patient), the HD Analyzer™ searches for corrections within a ± 3D range around the spherical equivalent of the subjective refraction typed in by the user. If the entered values are not correct, the instrument will find a wrong spherical correction, and so the rest of results may be wrong too.

The subjective refraction is needed for the process of determination of the best spherical correction to be applied in the measurements. If patient's refraction is ± 3D over the input values, this process will come out with a wrong result.

Remember also that the instrument is able to perform measurements in the range of spherical refractions between +5 D a -8 D. If the eye to be measured is out of that range, the subject's refraction must be corrected externally by means of trial lenses. Regarding patient's astigmatism, the system is able to perform measurements in the range between +0.5 D y -0.5 D. Larger astigmatisms affect seriously the retinal image registered by the instrument, so any underlying problem may be hidden by this effect. Furthermore, the results of OSI can be affected by the astigmatism presence. In consequence, cylindrical refractions out of that range must be corrected by means of trial lenses. In these out of range cases, the software will remind you to enter the proper external correction.

The instrument has a trial lens holder placed in its front part. We strongly recommend using this holder, although it is possible to use a trial frame or even the patient's spectacles (see section 3.3).

In case of correcting externally the spherical and/or cylindrical refractions, that must be indicated to the instrument. In this way, select the proper option in the drop down list of the field *Correction*. The different options are:

- *No correction*: The user has not corrected the patient's refraction by means of trial lenses.
- *Astig. correction*: The user has corrected the patient's astigmatism by means of a trial lens.
- *Total correction*: The user has corrected both the patient's spherical refraction and astigmatism by means of trial lenses.

Again, it is important to select the correct option of the field *Correction*. The spherical equivalent used for the *Objective Refraction* process may depend strongly on the applied correction. If an incorrect option is selected, the instrument will find a wrong spherical correction, and so the rest of results may be wrong too.

You must select the correct option in the field Correction. If an incorrect option is selected, the process of determination of the best spherical correction may come out with a wrong result.

3.6.2. Objective Refraction

See section 3.3 for patients' directions.

Click *Objective Refraction* to begin the process of determination of the optimal spherical refraction correction. That process is necessary in order to avoid the presence of defocus on the registered images, which effect may hide other underlying problems. Consequently, the optimal spherical correction must be determined before performing any other measurement. HD Analyzer™ makes a sweep looking for the best double-pass image at different spherical corrections, so as to compensate defocus. While this process is taking place, the user can see the images that are being recorded by HD Analyzer™. Once finished, the system automatically chooses the best correction. This selection can be modified by clicking on the desired image, but only if you are really sure that it is a better correction.

Once the best correction has been set, HD Analyzer™ will show this value as *Objective spherical refraction* and *Selected spherical refraction*. This last value can be modified, if wanted. It should be taken into account that the measurements will be carried out considering the *Selected spherical refraction* value.

It should be taken into account that modifying the value Selected spherical correction, may cause obtaining a wrong or unexpected result. Only change this value when you are absolutely sure.

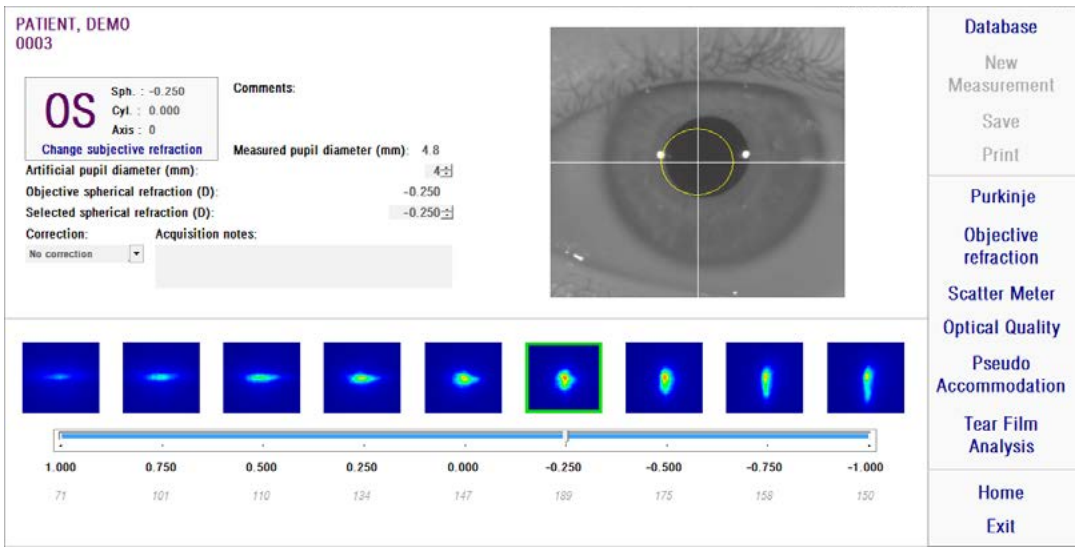


Figure 12. ***Objective Refraction*** **process**

HD Analyzer™ is now ready to start the measurement processes, and buttons *Scatter Meter, Optical Quality*, *Pseudo Accommodation and Tear Film Analysis* are enabled now. (Note: not all the measurement options may be available in your system)

3.6.3. Types of measurement

3.6.3.1. Scatter Meter and Optical Quality

See section 3.3 for patients' directions.

Once the *Objective Refraction* process has been carried out, measurements may begin. In the case of *Optical Quality*, you have to establish the artificial pupil diameter that will be used for the measurement. Just select the desired value in the field *Artificial pupil diameter*. In the case of *Scatter Meter*, there's no need for setting that parameter. According to the definition of OSI parameter, the measurement will be performed using a 4 mm artificial pupil, no matter what the entered value may be.

Click *Scatter Meter* or *Optical Quality* to begin the corresponding measurement process (intraocular scattered light quantification, or optical quality evaluation for far vision). Both processes consist on capturing six double-pass images in conditions of best spherical correction (far vision), and their processing. The system outlines in green those images considered to be correct. Once the capture has finished, the user can check out from calculations any desired image by clicking it with the mouse. Checked out images will appear outlined in red. Images are processed and analyzed by clicking *Results*, and results are shown with different visualization options (see section 3.6.4.1).

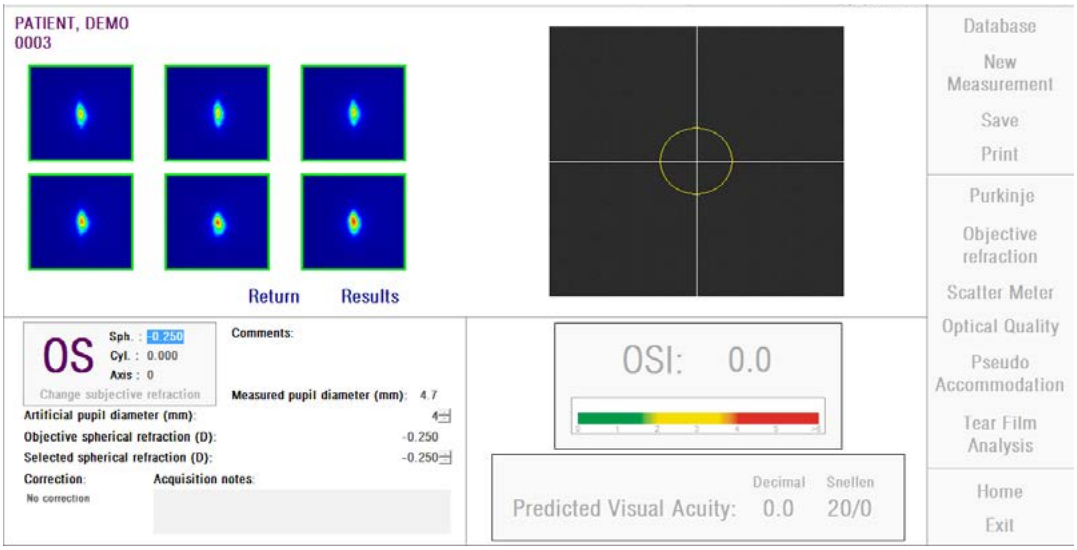


Figure 13. ***Scatter Meter*** **measurement**

If measurement does not satisfy you, it can be repeated it by clicking *Return.*

If you are running the software in pay-per-patient mode and you click on Results, the system will consider that you have completed the measurement. A measurement credit allows you to complete two consecutive measurements on the same patient. So, a measurement credit will be subtracted from your counter as you complete the first measurement on a patient, but you won't be charged if you perform a second measurement just after the first one. If you perform a third measurement you will be charged again and the fourth one would be free, and so on. Please, take into account that if you access the database and select a patient, it will always be considered as a new patient, no matter if you have selected the same one.

3.6.3.2. Pseudo Accommodation

See section 3.3 for patients' directions.

Once the *Objective Refraction* process has been carried out, measurements may begin. In the case of *Pseudo Accommodation*, you have to establish the artificial pupil diameter that will be used for the measurement. Just select the desired value in the field *Artificial pupil diameter*.

Click *Pseudo Accommodation* to begin the measurement process of pseudo accommodative range. This process makes a sweep of 4 diopters [BF + 1 diopters, BF - 3 diopters] from the best correction (BF) value measured during the *Objective Refraction* process or that one designated by the user.

The system makes -0.5 D steps, registering images at each vergence, until reaching the final position. The recorded images are shown in real time.

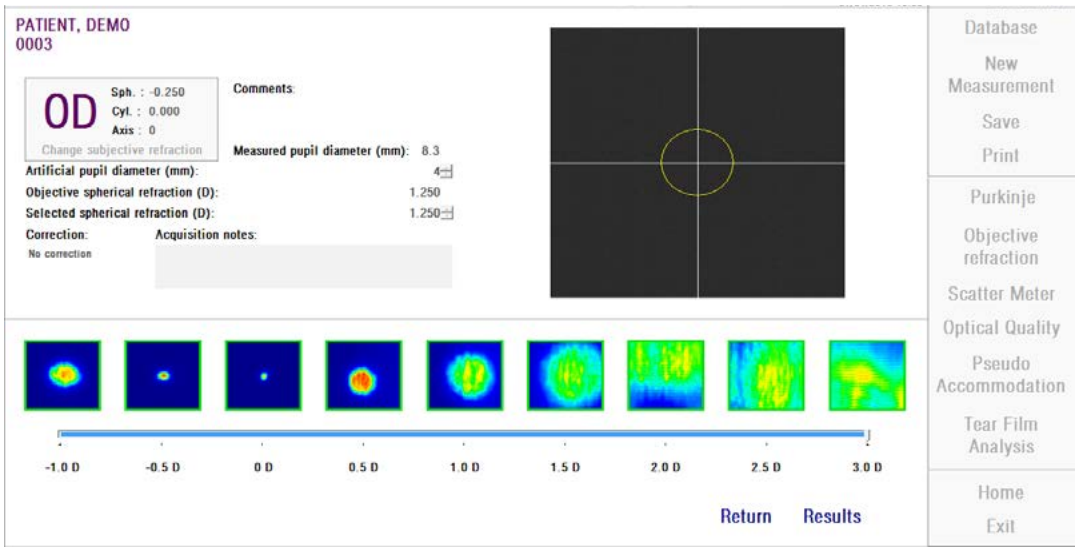


Figure 14. ***Pseudo Accommodation*** **measurement**

It must be taken into account that, when measuring at BF + 1 D and BF + 0.5 D, patient will not be able to see the target clearly, no matter how much he tries to accommodate. In the range between BF and BF - 3 D, patient should always try to accommodate with the purpose of seeing the target clearly.

When carrying out a Pseudo Accommodation sequence, patient will be requested to try and focus on the target, through all the process. Otherwise, the measurement may come out with a wrong result.

If you consider the process to be correct, click *Results* to view the final calculations. Otherwise, you can repeat the test by clicking *Return*.

If you are running the software in pay-per-patient mode and you click on Results, the system will consider that you have completed the measurement. A measurement credit allows you to complete two consecutive measurements on the same patient. So, a measurement credit will be subtracted from your counter as you complete the first measurement on a patient, but you won't be charged if you perform a second measurement just after the first one. If you perform a third measurement you will be charged again and the fourth one would be free, and so on. Please, take into account that if you access the database and select a patient, it will always be considered as a new patient, no matter if you have selected the same one.

3.6.3.3. Tear Film Analysis

See section 3.3 for patients' directions.

Note: This measurement type may not be available in your system.

Once the *Objective Refraction* process has been carried out, measurements may begin. In the case of *Tear Film Analysis*, you don't need to set the artificial pupil diameter. In order to assure that any tear degradation is detected, including the periphery of the patient's pupil, this process is performed using the maximum size of the artificial pupil (7 mm) , no matter what the entered value may be.

Click *Tear Film Analysis* to begin the process of evaluation of tear film dynamics. It consists on recording double-pass images every 0.5 seconds, until a 20 seconds capture has been completed. In this way, the system records 40 images, showing the optical quality evolution during those 20 seconds. These images are shown in real time.

It is strongly recommended to keep closed the eye that is not being measured, in order to avoid the stimulation of the tear glands and the production of "extra" tear.

The user should try to keep the patient's eye centered on the image in order to assure that any variation between images is due to a tear film change. If the patient blinks during the process, a red frame will be shown around the live image of the eye, and the corresponding image will be labeled as 'Blink'.

Figure 15 shows the result of a Tear Film Analysis process.

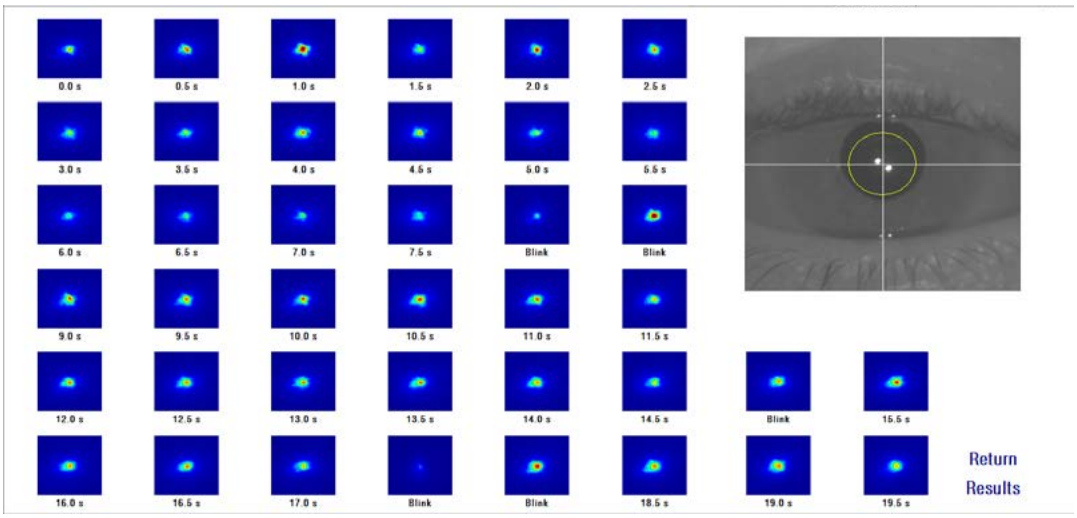


Figure 15. ***Tear Film Analysis*** **measurement**

At the end of the 20 seconds, you can see all 40 captured images. Below each one, you can find the exact second when the image was captured. But, some of them may be labeled as "Blink". You can change the state of any image, from "Blink" to normal, or from normal to "Blink", by clicking on the image.

If you consider the process to be correct, click *Results* to view the final calculations. Otherwise, you can repeat the test by clicking *Return*.

If you are running the software in pay-per-patient mode and you click on Results, the system will consider that you have completed the measurement. A measurement credit allows you to complete two consecutive measurements on the same patient. So, a measurement credit will be subtracted from your counter as you complete the first measurement on a patient, but you won't be charged if you perform a second measurement just after the first one. If you perform a third measurement you will be charged again and the fourth one would be free, and so on. Please, take into account that if you access the database and select a patient, it will always be considered as a new patient, no matter if you have selected the same one.

3.6.4. Monitoring results

The results' screens for the different types of measurement have a common area, which includes the parameters used during the measurement. Those parameters are:

OD/OS: Measured eye (Right / Left).

Sph, Cyl, Axis: Subjective refraction values entered by the user before performing the measurement.

Comments: Comments related to the patient typed in by the user in the patient's data on *Database*.

Artificial pupil diameter: Artificial pupil diameter used to take measurements, entered by the user.

Measured pupil diameter: Patient's pupil diameter measured by the instrument. A value of 0.0 will indicate that the patient's pupil size could not be measured.

Objective spherical refraction: Best spherical correction obtained during the *Objective Refraction* process.

Selected spherical refraction: Spherical correction used in the measurement.

Correction: Shows if the measurement was performed without external refraction correction, with astigmatism correction or with total correction, as entered by the user.

Acquisition notes: Comments related to the measurement, entered by the user.

The numerical results and the different available visualizations will depend on the particular type of measurement. In the next pages, you will find the description of the different elements shown for each type.

3.6.4.1. Scatter Meter and Optical Quality

Once the *Scatter Meter* or *Optical Quality* measurement processes have finished, click on *Results.* Results are shown as per Figure 16 and Figure 17 respectively.

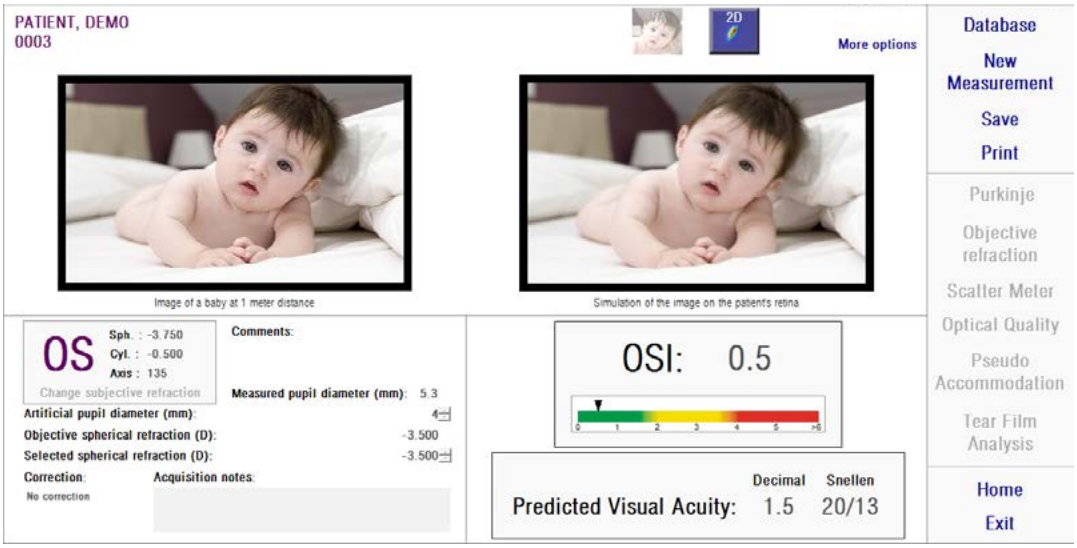


Figure 16. ***Scatter Meter*** **results**

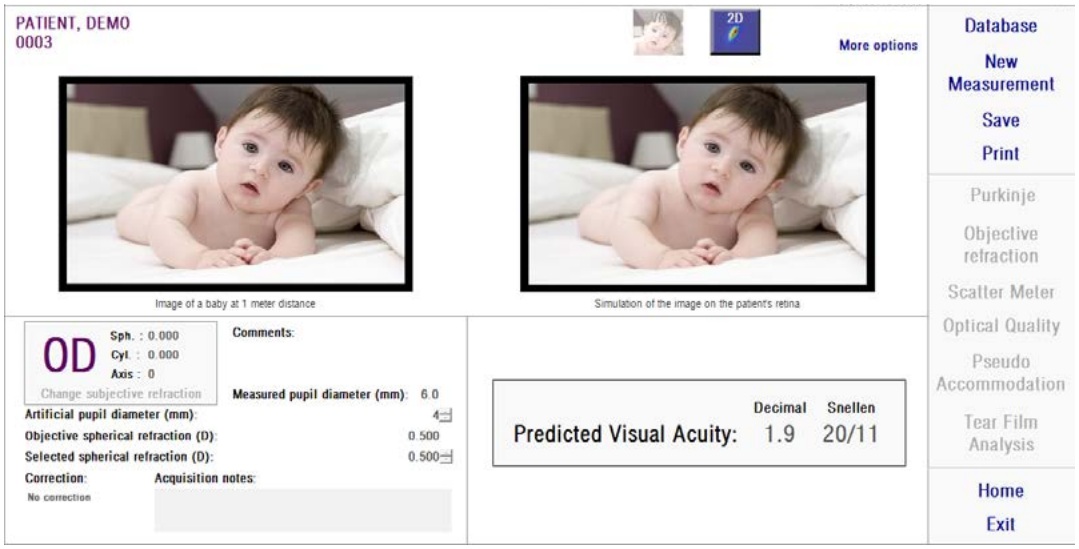


Figure 17. ***Optical Quality*** **results**

The results given by the system for both types of measurement are basically the same, excepting the parameter OSI (*Objective Scattering Index*) computed only for *Scatter Meter* (see section 1.1.2).

The results' screen is divided into three areas, clearly separated, as seen on Figure 18:

A. **Image visualization area:** Depending on selection made using buttons in section C, this area will show one of the visualization options available in normal mode (VA simulation, 2D) or for expert users (3D, Profile, MTF). (See below for more information).

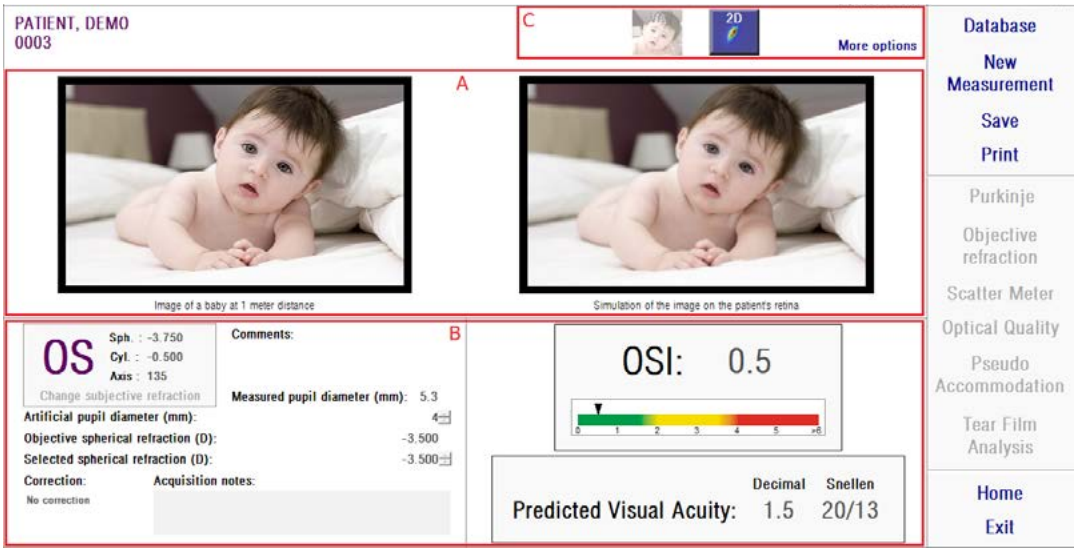


Figure 18. Areas of the results' screen

B. Input/Output data: This section shows the most representative numerical results obtained in the measurement, as well as the input parameter values.

The most representative results are:

OSI: Only for *Scatter Meter*. It is the *Objective Scattering Index*, that quantifies the level of intraocular scattering of the eye. For more clarity, the OSI value is also represented in a color scale. This shows in a graphical way if that value corresponds to a low, medium or high level of scattering. Values within the green range of the scale represent eyes with low scattering level. Values within the yellow range of the scale represent cases where scattering begins to be remarkable (first stages of a cataract, lens starting to get opacified, etc). Values within the red range of the scale represent eyes with an important scattering level (mature cataract, etc).

Predicted Visual Acuity: It is the value of the visual acuity estimated from the actual eye's optical quality (*MTF*). It can be understood as the monocular visual acuity that the patient would have, if that magnitude depended only on optical factors. It doesn't take into account the retinal sampling and the neural processing performed afterwards. The result is shown in both decimal and Snellen notations.

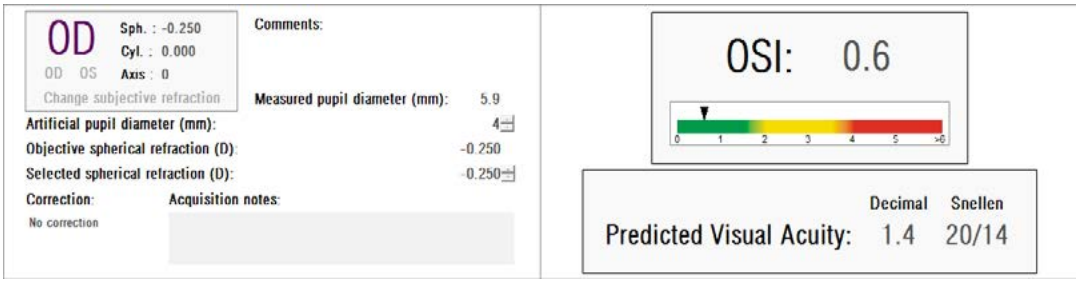


Figure 19. Input / Output data

C. **Buttons area:** It consists on the buttons which give access to the different visualization options of the results obtained for the measurements. By default, two options are shown (VA simulation y 2D). By means of the button More options, it is possible to access the visualizations for expert users (3D, Profile y MTF, apart from the two default ones).

We will now describe what the user can find in each of the different visualization options.

VA Simulation visualization

Click on the button *VA* of the results' button area in order to access the *VA Simulation* screen. It is the default option that is shown just after the results are processed.

The goal of this screen (Figure 20) is to show how it looks like the image of a common scene, projected on to the retina of the patient. In particular, the software shows the image of a baby placed at a distance of 1 meter from the viewer.

In the left side of the screen, you can see the original scene. In the right side you can find a simulation of how that scene would be imaged on the retina. That simulation is achieved by means of the convolution of the original scene with the eye's PSF measured by the instrument. In this way, it will show how aberrations and intraocular scattering of the patient's optical system are affecting the image formation. This doesn't mean that the patient is seeing in the way that is shown on the screen, because the only factor that is being considered is the optical quality, not the neural processing performed to the retinal image.

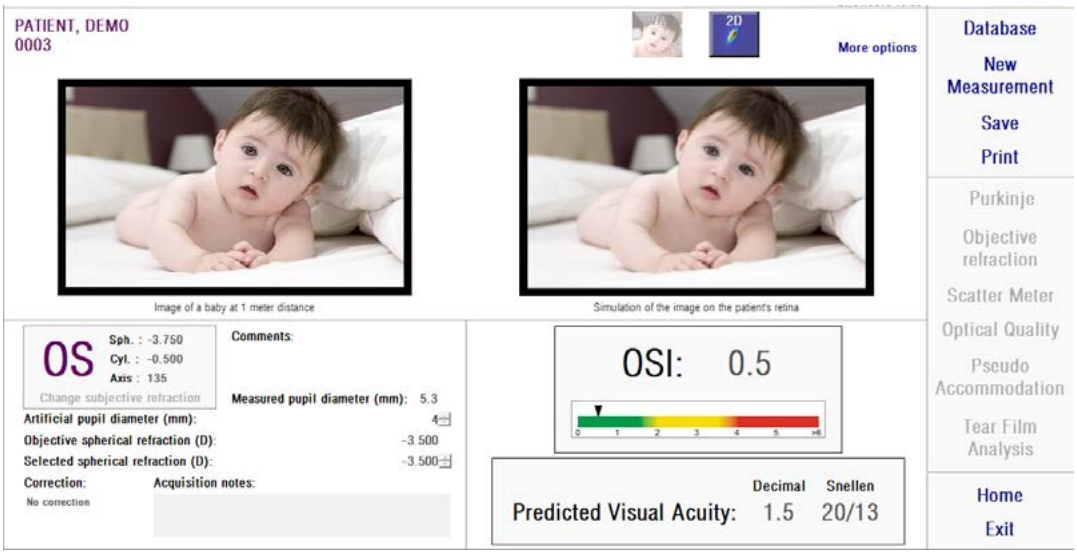


Figure 20. ***VA Simulation*** **visualization**

For a normal and healthy eye, both images (original and retinal) will be very similar. For aberrated eyes, you will notice a blurring of the image, so it will be harder to distinguish its details. For eyes with a high level of intraocular scattering, you will notice a clear overall loss of contrast on the image. It should be taken into account that other effects such as glare or halos are not simulated on this image, so their presence must not be expected.

The images can be exported by double-clicking over them and selecting the desired destination. You can export them as *bmp* or *jpeg* image files.

2D visualization

Click on the *2D* button in the results' button area in order to access the *2D* screen.

Two retinal image representations are shown in this screen, as seen on Figure 21. The 2D retinal image is displayed, in the left side of the screen with its original size while in the right side it is zoomed. Zoom in and zoom out can be performed by clicking *In* or *Out* buttons (maximum zoom in factor is 16 and minimum zoom factor is 2). The different energy levels are represented with a color scale.

You can select a particular area of the image by clicking and dragging the mouse over the left image. That area will be shown with the corresponding zoom in the right image. The scale of both images is shown bellow each one, in minutes of arc.

You can measure distances on the retinal image by right clicking and dragging the mouse over any of both images. The measured distance appears over the cursor of the mouse.

The images can be exported by double-clicking over them and selecting the desired destination. You can export them as *bmp* or *jpeg* image files.

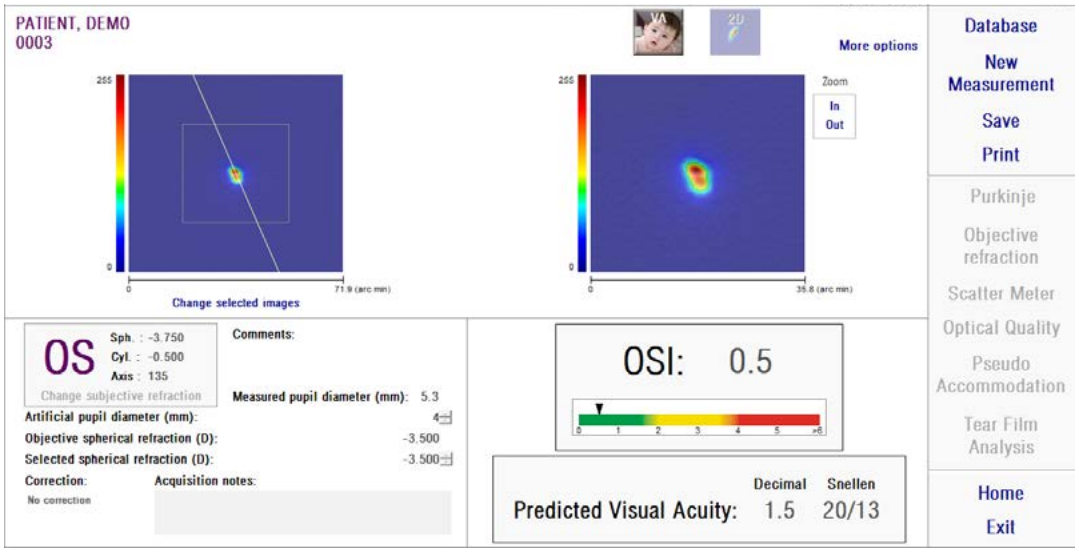


Figure 21. *2D* visualization

3D visualization

This option is only available after clicking on the button *More options*. It is intended for expert users.

Click on the button *3D* of the results' button area in order to access the *3D* screen.

The 3D retinal image representation is displayed in the right side of the screen (Figure 22). Zoom in and zoom out can be performed by clicking *In* or *Out* buttons.

The retinal image can be rotated, moved and scaled just dragging the mouse over it.

The images can be exported by double-clicking over them and selecting the desired destination. You can export them as *bmp* or *jpeg* image files.

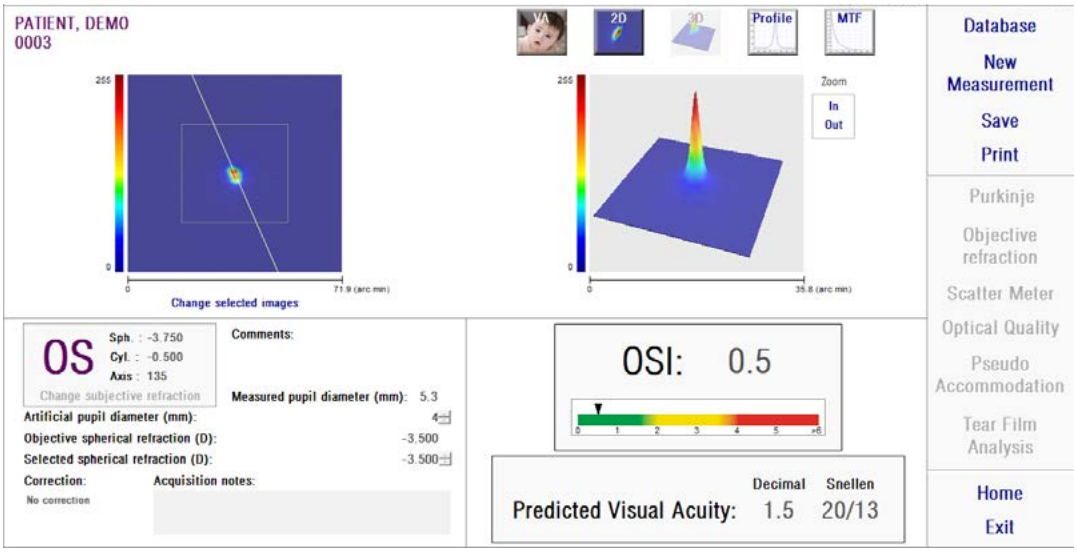


Figure 22. *3D* visualization

Profile visualization

This option is only available after clicking on the button *More options*. It is intended for expert users.

Click on the button *Profile* of the results' button area in order to access the *Profile* screen.

The right side of screen shows the retinal image intensity distribution profile. You can select a specific area with the mouse and then zoom in and out. To zoom in, you must start selecting the desired area from the left top. To zoom out, you must start selecting the desired area from right bottom.

The radial profile shows the average profile. To see the profile at a desired angle, choose *Angular*. Slide the bar that will appear below the image in order to modify the desired angle.

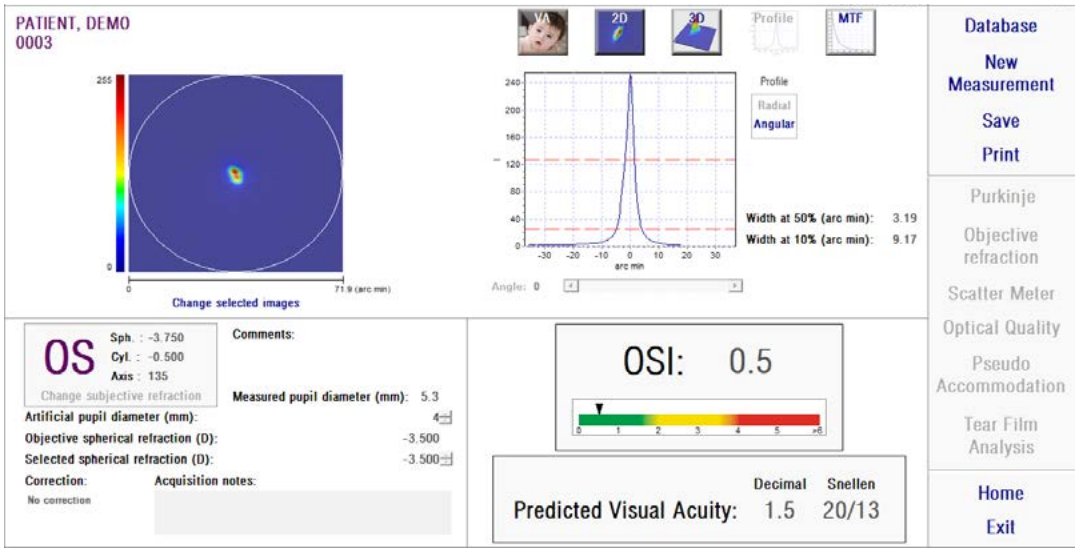


Figure 23. *Profile* visualization

The software also shows the values of the widths of the profile at 50% and 10% of its maximum value. With these values the user can obtain information about the size and shape of the image profile.

The profile plot can be exported by double-clicking over it and selecting the desired destination. You can export it as an image file (*bmp* or *jpeg*), or save the plot data as a text file (*txt*).

MTF visualization

This option is only available after clicking on the button *More options*. It is intended for expert users.

Click on the button *MTF* of the results' button area in order to access the *MTF* screen.

The MTF completely describes the performance of an optical system. MTF values represent the quotient between the image's contrast and the object's contrast for each spatial frequency (see section 1.1.3). From this function, the system can estimate visual acuity due to the optics of the eye, for different contrasts (*Predicted VA 100%*, *20%* and *9%*). This information has a similar meaning of that obtained with subjective techniques, as Snellen chart exams. But we must point out that this information is only affected by optical defects, while in subjective measurements it is greatly affected by neural processing tasks. The estimated visual acuity is shown in both decimal and Snellen scales.

The *MTF cut off* value is also provided. The higher cut off values, the better the retinal image (see section 1.1.3). Another parameter given by the system is the *Strehl ratio*. This ratio is a qualitative measurement of the optical quality of the eye and can be calculated as the ratio of the eye's MTF and that of a system limited by diffraction. Thus, it will be a figure between 0 and 1. Again, the higher it's value, the better optical quality. As a reference, a normal young eye with a pupil diameter of 4 mm will have a Strehl ratio around 0.3.

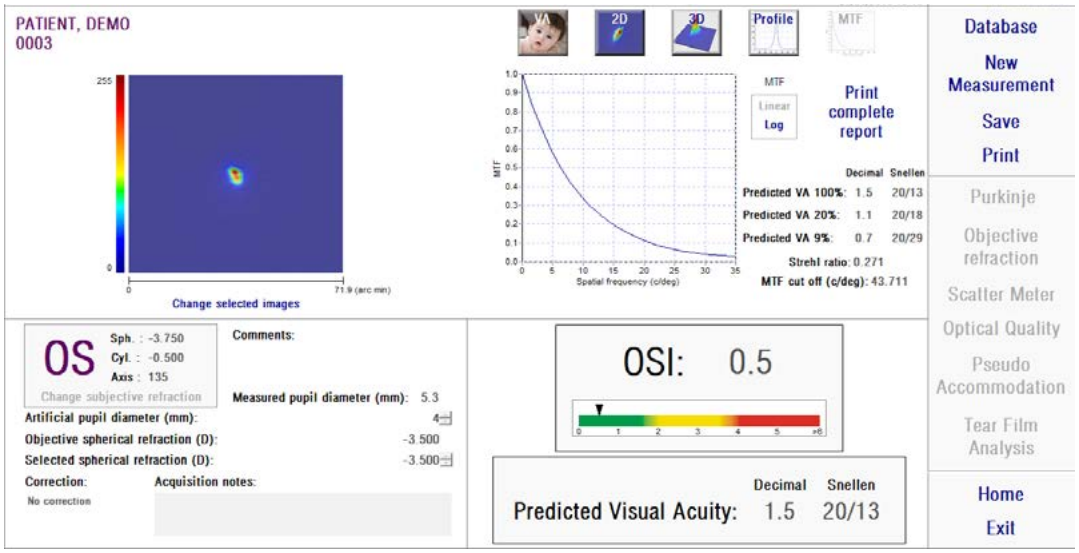


Figure 24. ***MTF*** **visualization**

Two representations of MTF are provided:

- Linear (*Linear*) is the default option when you select the MTF plot for the first time. Spatial frequency is shown in a lineal scale.

- Logarithmic (*Log*), where the spatial frequency axis is shown in a logarithmic scale, which allows to clearly appreciate the cut off frequency (*MTF Cut off*).

That plot is shown on the right side of screen. You can select a specific area with the mouse and then zoom in and out. To zoom in, you must start selecting the desired area from the left top. To zoom out, you must start selecting the desired area from right bottom.

The MTF plot can be exported by double-clicking over it and selecting the desired destination. You can export it as an image file (*bmp* or *jpeg*), or save the plot data as a text file (*txt*).

3.6.4.2. Pseudo Accommodation

Once finished the *Pseudo Accommodation* measurement process, and clicking on *Results*, you will obtain the results as shown on Figure 25.

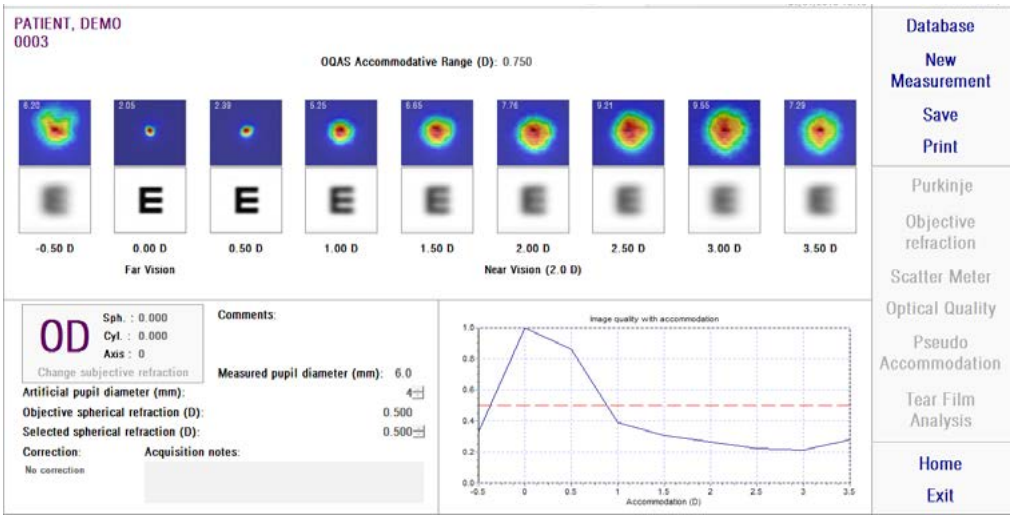


Figure 25. ***Pseudo Accommodation*** **results**

The results' screen shows all nine images recorded during the process (see section 3.6.3.2). In addition, it includes a plot of an image quality index for each vergence. These image quality values are normalized. Thus, for the best spherical correction (BF), it should have a value of 1. That plot is shown on the right bottom side of screen. You can select a specific area with the mouse and then zoom in and out. To zoom in, you must start selecting the desired area from the left top. To zoom out, you must start selecting the desired area from right bottom.

OQAS™ Accommodative Range is considered to be the dioptric range between BF and the point at which quality decreases to a 50% of its maximum.

The value on the top left corner of each image corresponds to the profile width at 50% in minutes of arch.

The system also provides a simulation of the image projected on to the retina of an optotype (Snellen E letter), for each vergence, as in *VA simulation* visualization for *Scatter Meter* y *Optical Quality*. We remind you that this doesn't mean that the patient is seeing in the way that is shown on the screen, because the only factor that is being considered is the optical quality, not the neural processing performed to the retinal image.

The images can be exported by double-clicking over them and selecting the desired destination. You can export them as *bmp* or *jpeg* image files.

The plot can be exported by double-clicking over it and selecting the desired destination. You can export it as an image file (*bmp* or *jpeg*), or save the plot data as a text file (*txt*).

3.6.4.3. Tear Film Analysis

Note: This measurement type may not be available in your system.

Once finished the *Tear Film Analysis* measurement process, and clicking on *Results*, you will obtain the results as shown on Figure 26.

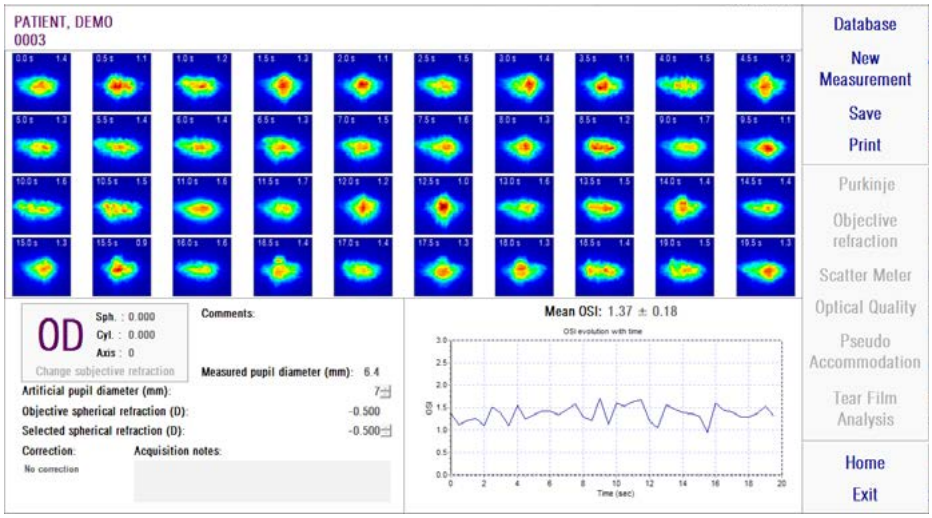


Figure 26. ***Tear Film Analysis*** **results**

The results' screen shows all the 40 images recorded during the process (see section 3.6.3.3). In the top of each image you will find two numbers. The left one corresponds with the moment when the image was recorded. The right one corresponds to the OSI value for that image.

A plot is also provided, representing the evolution of the OSI with time. An increment in the OSI may suppose an image degradation caused by the tear film break-up. That plot is shown on the right bottom side of screen. You can select a specific area with the mouse and then zoom in and out. To zoom in, you must start selecting the desired area from the left top. To zoom out, you must start selecting the desired area from right bottom.

If any blink has been detected during the measurement, the corresponding image will be labeled as 'Blink' and the point in the graph will be missed.

The images can be exported by double-clicking over them and selecting the desired destination. You can export them as *bmp* or *jpeg* image files.

The plot can be exported by double-clicking over it and selecting the desired destination. You can export it as an image file (*bmp* or *jpeg*), or save the plot data as a text file (*txt*). These data will be exported in several columns, being the most representative the 3 first: time, OSI values and whether there has been a blink or not. Notice that, even if the point is missed in the graph because of a blink, the corresponding OSI value will not be missed in the exported data.

3.6.4.4. Result comparison screens

As explained in section 3.5.5, the system provides a results comparison screen for each type of measurement, except for Purkinje measurements.

The next figures show an example of each of these comparison screens. All of them have the same structure. The bottom part corresponds with the parameters used for each of the measurements, while in the upper part you can find the results that were obtained. You will find the same numerical results as if you viewed each measurement individually. In the same way, as in the results' screens that were explained previously, for *Scatter Meter* and *Optical Quality* you can click on *More*

options in order to access the results intended for expert users (as well as *MTF* and *Profile* views).

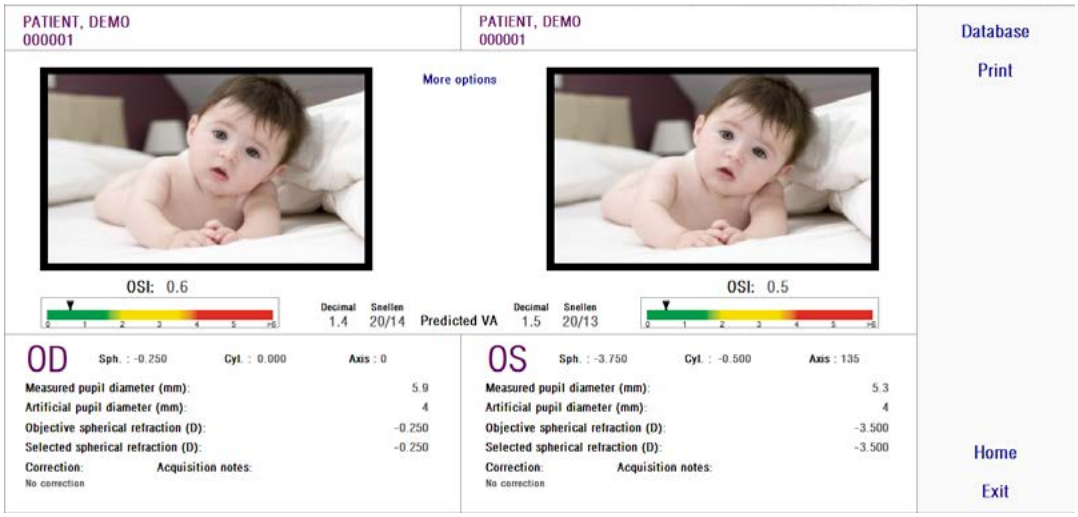


Figure 27. Comparison of *Scatter Meter* measurements

Figure 28. Comparison of *Optical Quality* measurements

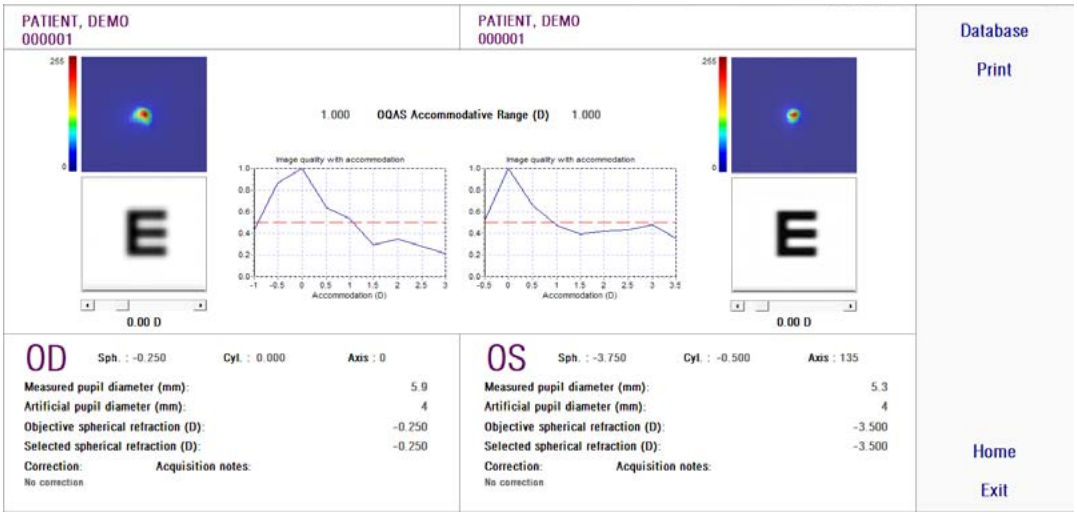


Figure 29. Comparison of *Pseudo Accommodation* measurements

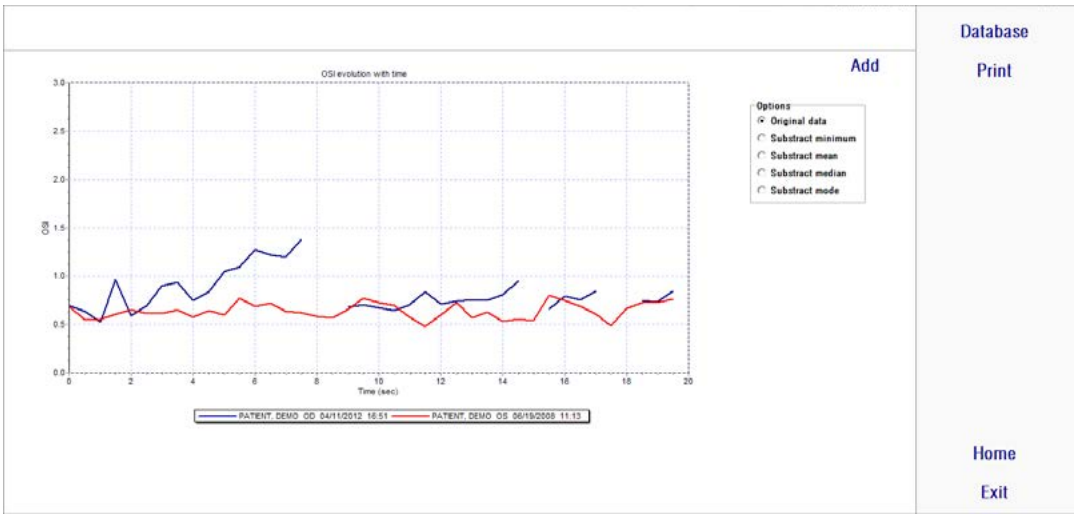


Figure 30. Comparison of *Tear Film Analysis* measurements

A report of the comparison can be printed out. Just click on *Print* to access that report. See section 3.6.6 for more information.

For any of the screens, all the images can be exported by double-clicking over them and selecting the desired destination. You can export them as *bmp* or *jpeg* image files. You can also export the plots by double-clicking over them and selecting the desired destination. You can export them as an image file (*bmp* or *jpeg*), or save the plot data as a text file (*txt*).

3.6.5. Purkinje Measurement

3.6.5.1. Typing in subjective refraction

To access the Purkinje measurement screen, you have to select *Measurement* and type in patient's subjective refraction.

Patient has to go uncorrected. You must not use trial lenses nor patient's own correction means.

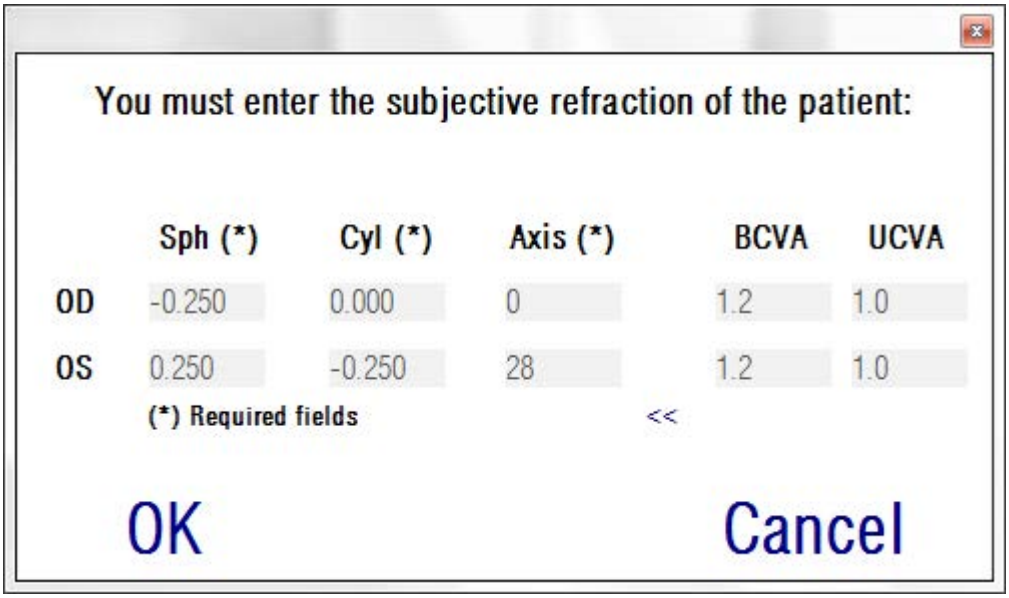


Figure 31. Subjective refraction (enlarged view)

Typed in subjective refraction will be used, with respect to Purkinje measurement, to place the target at the proper distance from patient's eye, allowing patient to clearly and comfortably see the target.

3.6.5.2. Selecting the Purkinje option

When you have typed in patient's subjective refraction, you should click on *Purkinje*.

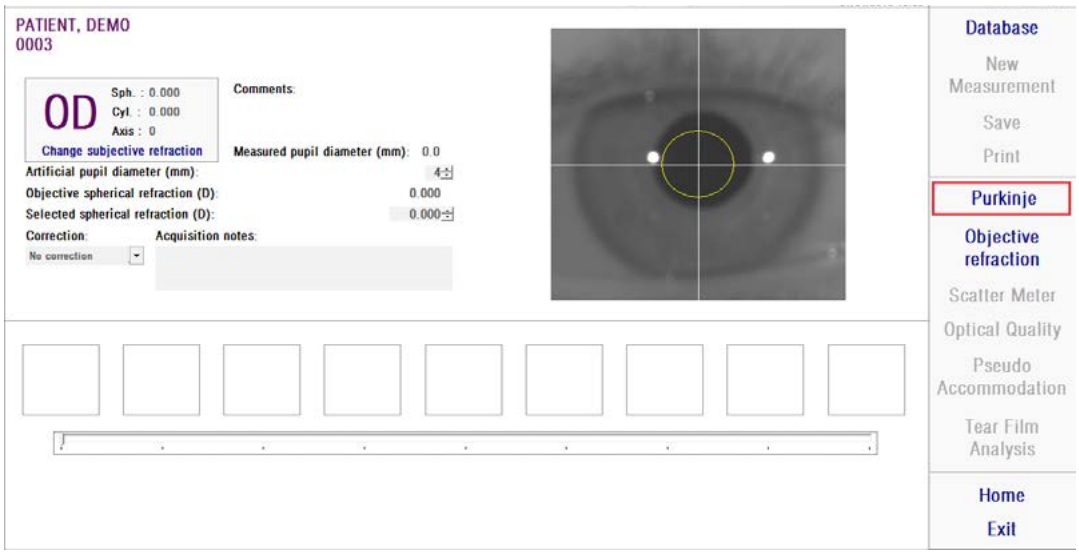


Figure 32. *Purkinje* option

3.6.5.3. Move far and centering patient's eye

While patient is looking at the target and by means of the device's joystick, you should start with the device at the furthest distance from the patient's eye and try to center patient's pupil in the overprint coordinate axis overprinted on the live image.

While doing this:

- You should not take into account whether patient's eye appears well focused or not on the live image.
- Patient can blink as often as they like, since no image is being captured.

Figure 33. Live image showing centered eye, not well focused.

3.6.5.4. Select desired option

Once the device is as far as possible from patient's eye and patient's eye is centered on the axis, you should select the desired option according to the kind of study you want to carry out:

- *Pre-Without inlay* for those patients who do not have a KAMRA™ inlay implanted.
- *Post-With inlay* for those patients who already have a KAMRA™ inlay implanted.

When you select one of both options, the laser diode will be activated and it will be visible to the patient. The patient must look at the laser beam (red light).

Automatic and *Manual* options specify if the acquired images have to be studied automatically by the software, or if the operator must manually select the exact location and size of

- In Pre-Without inlay acquirements, the pupil.
- In Post-With inlay acquirement, the KAMRA™ inlay.

At this stage, patient can still blink as much as needed in order to feel comfortable.

3.6.5.5. Focus using indicator arrows

During this step, the software will use 2 arrows, a blue one pointing at the patient's eye, and another yellow pointing at the operator. These arrows will guide the movements of the operator. Keep in mind that the indicator arrows will be shown only when the eye is well centered in the crosshairs.

At the beginning, the blue arrow indicates that the operator has to move the instrument close to the patient.

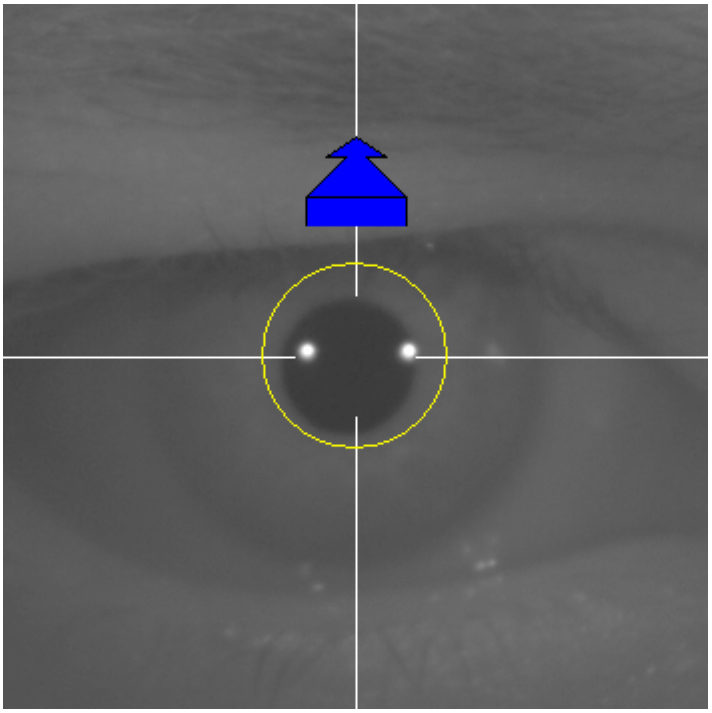


Figure 34. Blue arrow when beginning

When approaching the patient it is important to always keep the eye well centered. During this process, a green circle will appear around the laser reflection. The operator must keep the green circle as centered as possible, until he has reached the best focus point. The operator should slightly surpass this point.

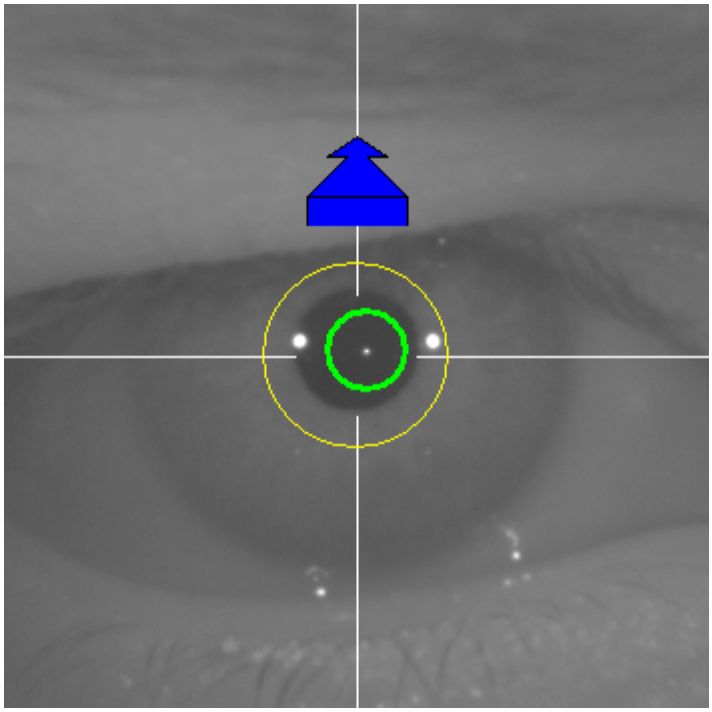


Figure 35. Blue arrow with green circle near laser reflection.

After surpassing it, the software will recognize that the best focus point has been reached and surpassed, and blue arrow will be substituted by the yellow arrow, pointing in the opposite direction. The operator must change direction of the instrument, moving it away from the patient.

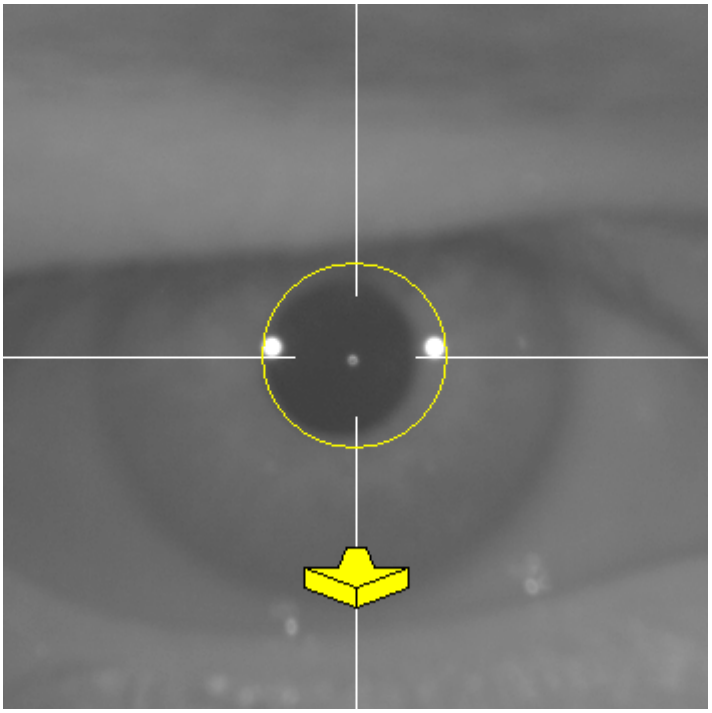


Figure 36. Yellow arrow just before losing the detection of laser reflection.

At this point, the software will continue using the arrows to indicate the correct direction to reach the best focus point. But also their sizes, to indicate how far of that point the instrument is (is the bigger the arrow, the farther it is to the best focus point).

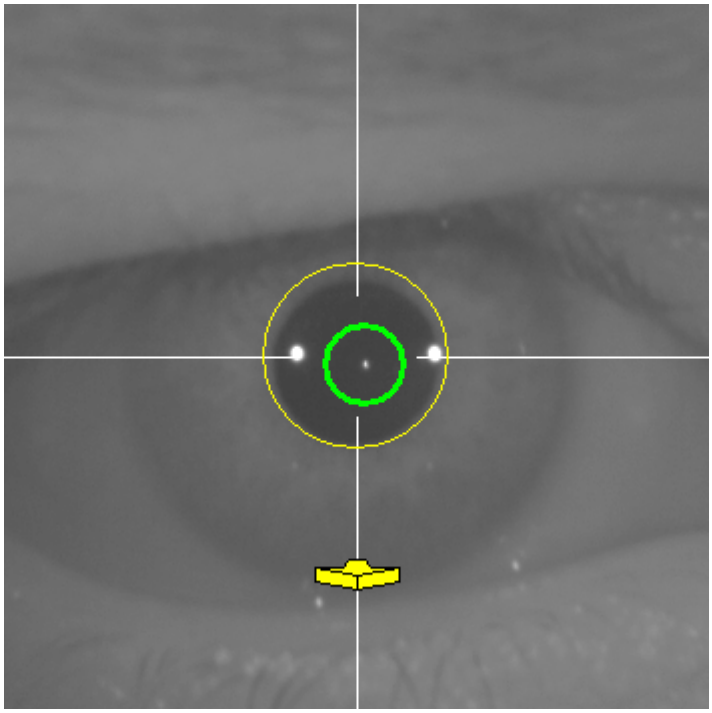


Figure 37. Yellow arrow when getting close to the best focus point.

Once the best focus is reached, the arrows will be replaced by a green tick mark (check mark). Once this position has been reached, do not move the instrument.

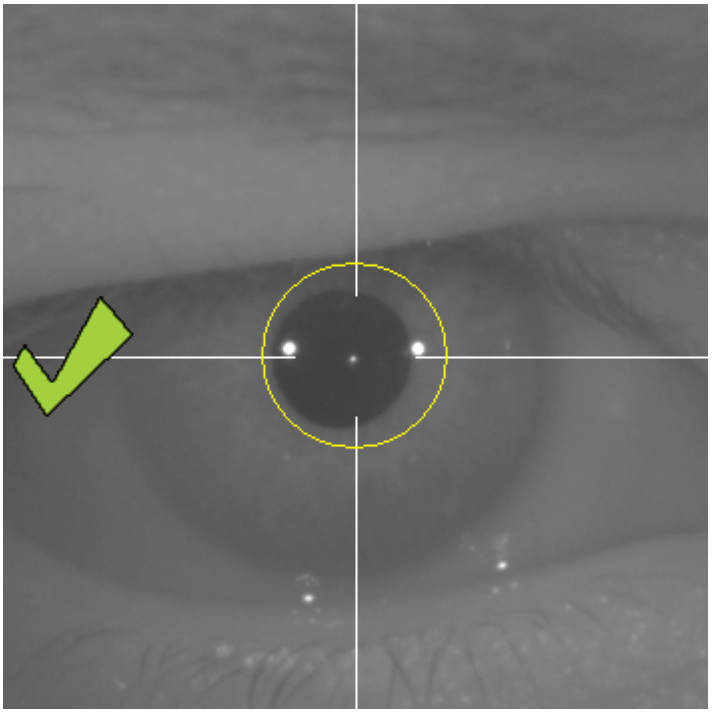


Figure 38. Green tick indicating the best focus point has been reached.

The patient can now blink freely at this point. During the focus process it is recommended to ask the patient NOT to blink. Blinking can cause the software to restart calculating the result.

3.6.5.6. Automatic capture of images

Once at this point, the software will begin capture images automatically. There are two modes of image capture and below are the parameters they detect:

- *Automatically* mode: software will try to detect:
  - In Pre-Without inlay acquirements: the laser reflection, and the pupil.
  - In Post-Without inlay acquirements: the laser reflection and the KAMRA™ inlay. In some cases the pupil parameters may also be detected.

- *Manual* mode: Software will try to detect the laser reflection and the operator will manually mark the location of the pupil (pre-op) or the inlay (post-op).

If for some reason the best focus point is lost (tick/check mark and green circle disappear) move the instrument again in the direction of the indicator arrows to center and obtain best focus. This can happen due to involuntary movement of the instrument by the operator or movement of the patient's head.

It is recommended, during this step of automatic capture of images that the patients blink as little as possible.

3.6.5.6.1. Automatic mode

The software will try to capture 3 consecutive and similar images. Once done, the software will decide automatically the best of these 3 images, and will display it on the screen to the operator.

3.6.5.6.2. Manual mode

Once the software captures an image where the laser reflection is detected, patient can blink normally again. The captured image is displayed to the operator, zoomed and with incremented contrasts.

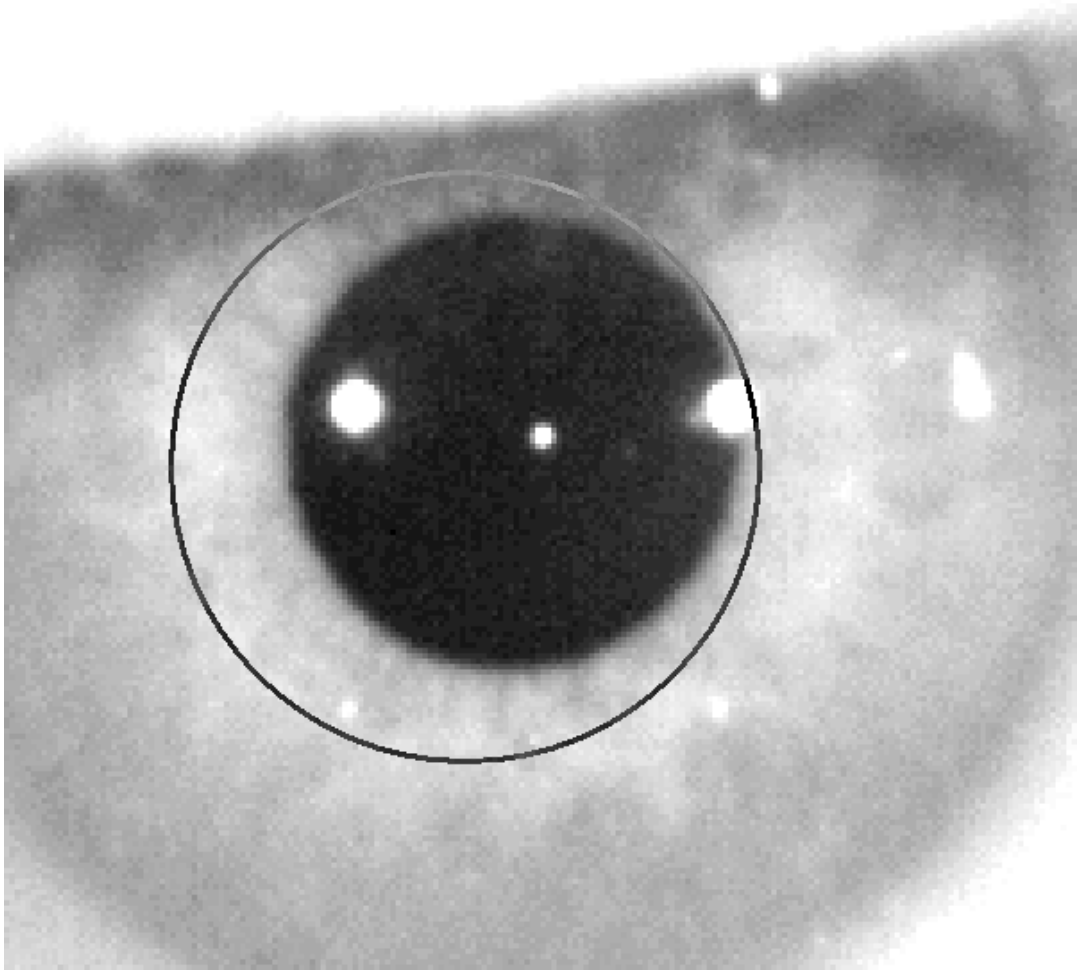


Figure 39. Zoomed and contrasted image, with wrong mark for center and diameter pupil.

On the zoomed image, the operator must mark:

- *Pre-Without inlay* acquirements: pupil's center and border.
- *Post-With inlay* acquirements: KAMRA™ inlay's center and borders.

In order to mark the center, simply move the mouse to the center the circle over the pupil (pre-op) or inlay (post-op). To adjust the diameter, simply use the mouse wheel, or keys "+" and "-".

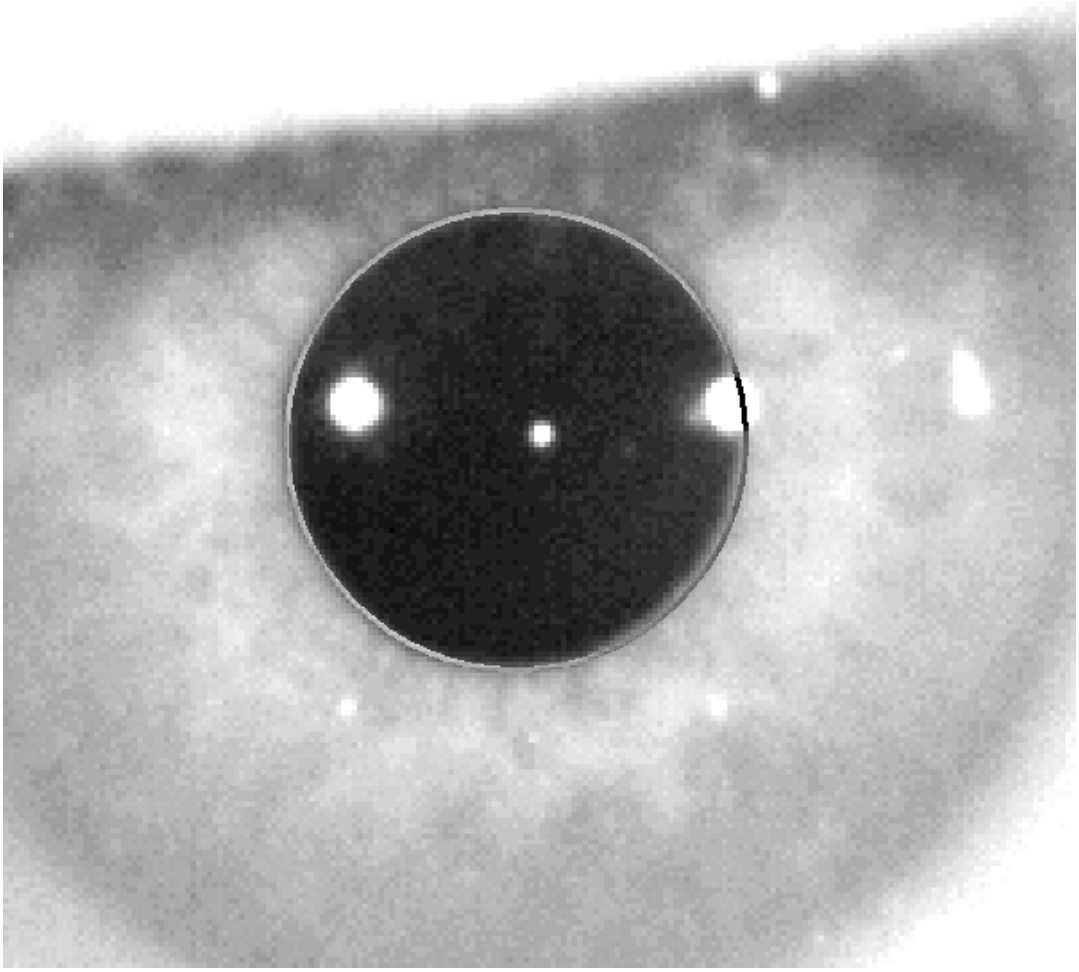


Figure 40. Zoomed and contrasted image with correct mark for center and diameter pupil.

Once the operator finds the correct center and diameter, he must click, and the software will show the results of this partial acquirement.

3.6.5.7. Validating an image

User has to assess how good the suggested image is based on how well borders and detected points adjust to patient's eye reality.

3.6.5.7.1. Invalid image

If you consider that the pupil border has not been properly detected, you should click on *Discard image* and the program will take you back to section 3.6.5.6.

Figure 41. Wrong pupil detection on pre-op image

3.6.5.7.2. Valid image

If you consider the suggested image to be good enough, you must click on the *Valid image!* button.

The program will keep the image and proceed to the next step.

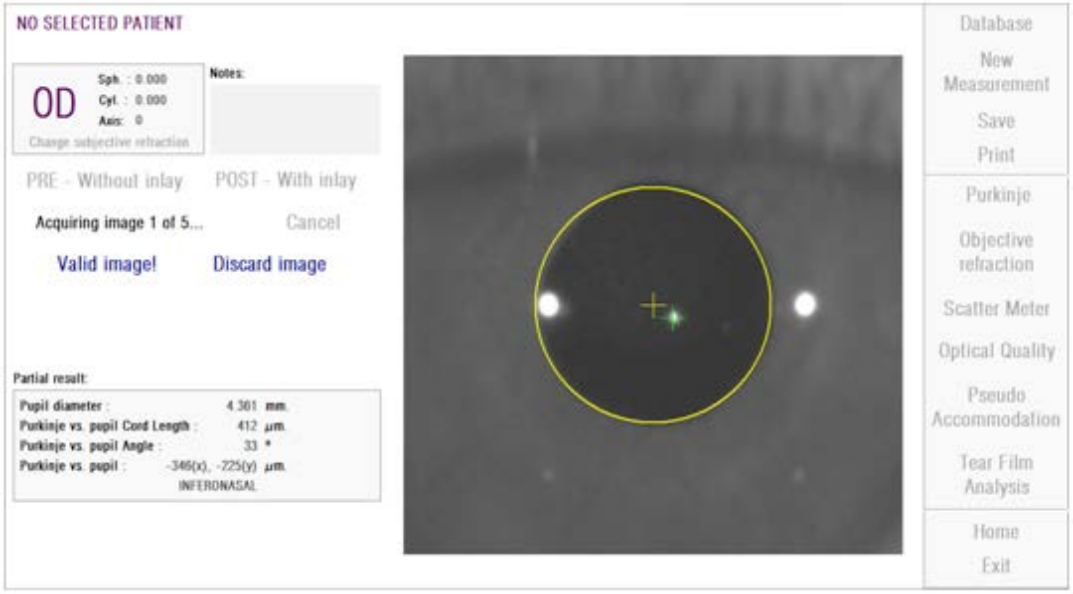


Figure 42. Valid pupil detection on pre-op image

3.6.5.8. Acquiring and validating four more images

In *Manual* mode, this step is not required and therefore the software will move on to next step (section 3.6.5.9).

Otherwise, in *Automatic* mode, at this stage, you have managed to acquire and validate one image but in order to guarantee accurate results, the program requires five images and, it will choose the one which best reflects the patient's eye reality.

Therefore, once you have validated one image, the program takes you back to section 3.6.5.6, in order to carry on with the process of acquiring and validating images until reaching five valid images

When going back to section 3.6.5.6 you should take into account that, since patient position should not have changed (nor the device's position), patient's eye should still be well focused, but maybe small corrections of the position machine will be needed.

For second and successive images, the program will automatically discard those images that are far from the initially validated image. In this way, the five validated images will be very similar from one another.

Once you validate the fifth image, the program takes you to the next step.

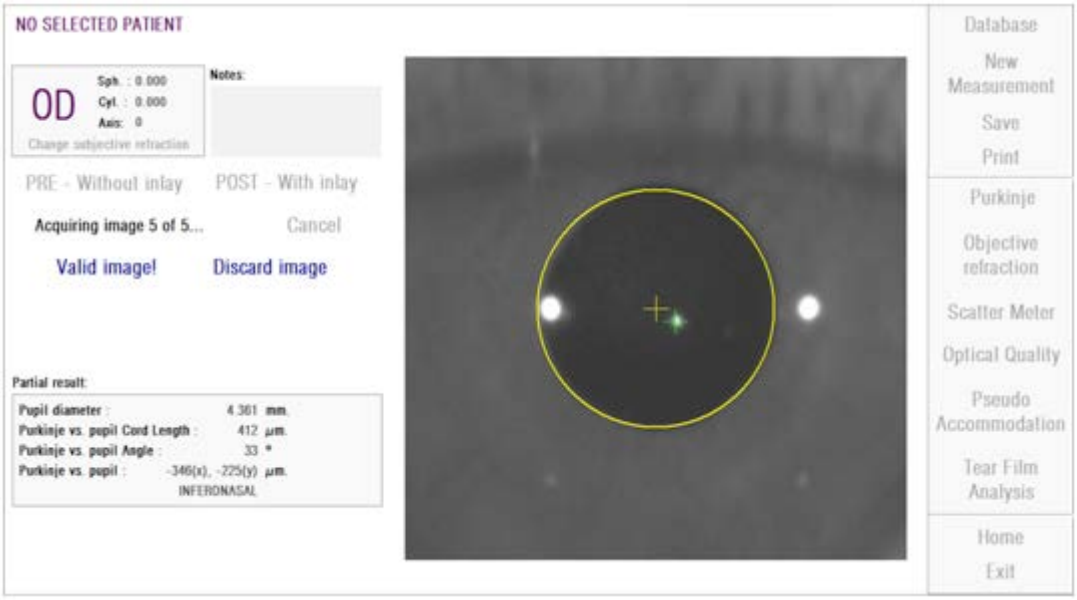


Figure 43. Fifth pre-op measurement.

3.6.5.9. Validating final results

At this stage, patient can draw apart from the device and sit at ease since the measurement process has finalized.

Once you validate the last captured image, the program will show you the final result image. This final result image is automatically chosen by the program from the set of previously validated and accepted images by the operator (1 in *Manual* mode, or 5 in *Automatic* mode), and it is, statistically, the one closest to reality.

For result images of pre-op measurements the following parameters are shown:

- Yellow: Pupil and pupil center.
- Green: Optical axis.
- Red: Position where the KAMRA™ inlay should be implanted.

Figure 44. Final result of a pre-op measurement

For result images of post-op measurements the following parameters are shown

- Green: Optical axis.
- Red: KAMRA™ inlay and its centre.

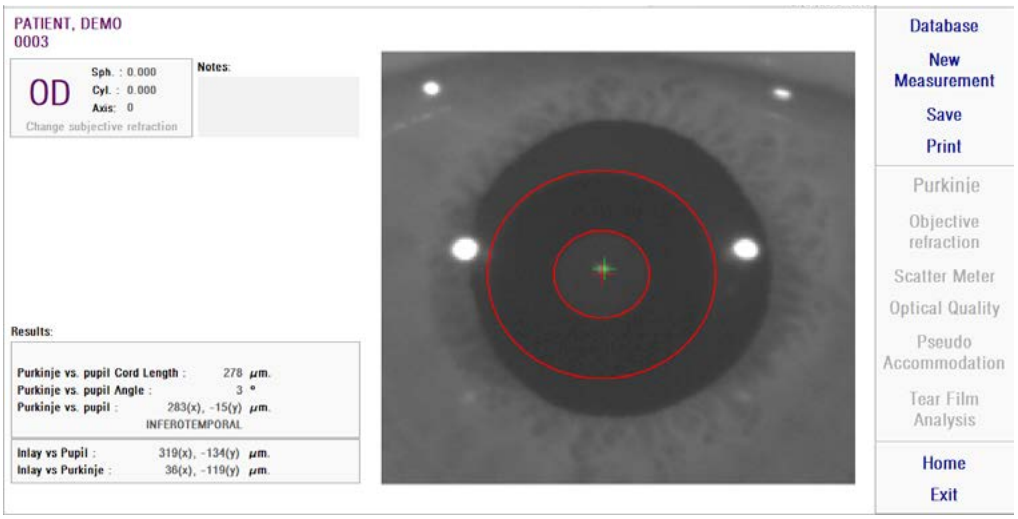


Figure 45. Final result of a post-op measurement

3.6.6. Printing and exporting a results' report

For any of the measurement types, click *Print* button to print a complete report of the measurement results and parameters.

You will be shown a menu where you can choose to print the report, access a preview or export the report to a file. The report can be exported to *bmp*, *jpeg* and *pdf* files. It can also be exported from the preview screen (click on *Save as*).

Figure 46 and following figures provide an example of a report for each type of measurement. They include the most relevant information of the measurement, including the parameters that were used and the results that were obtained.

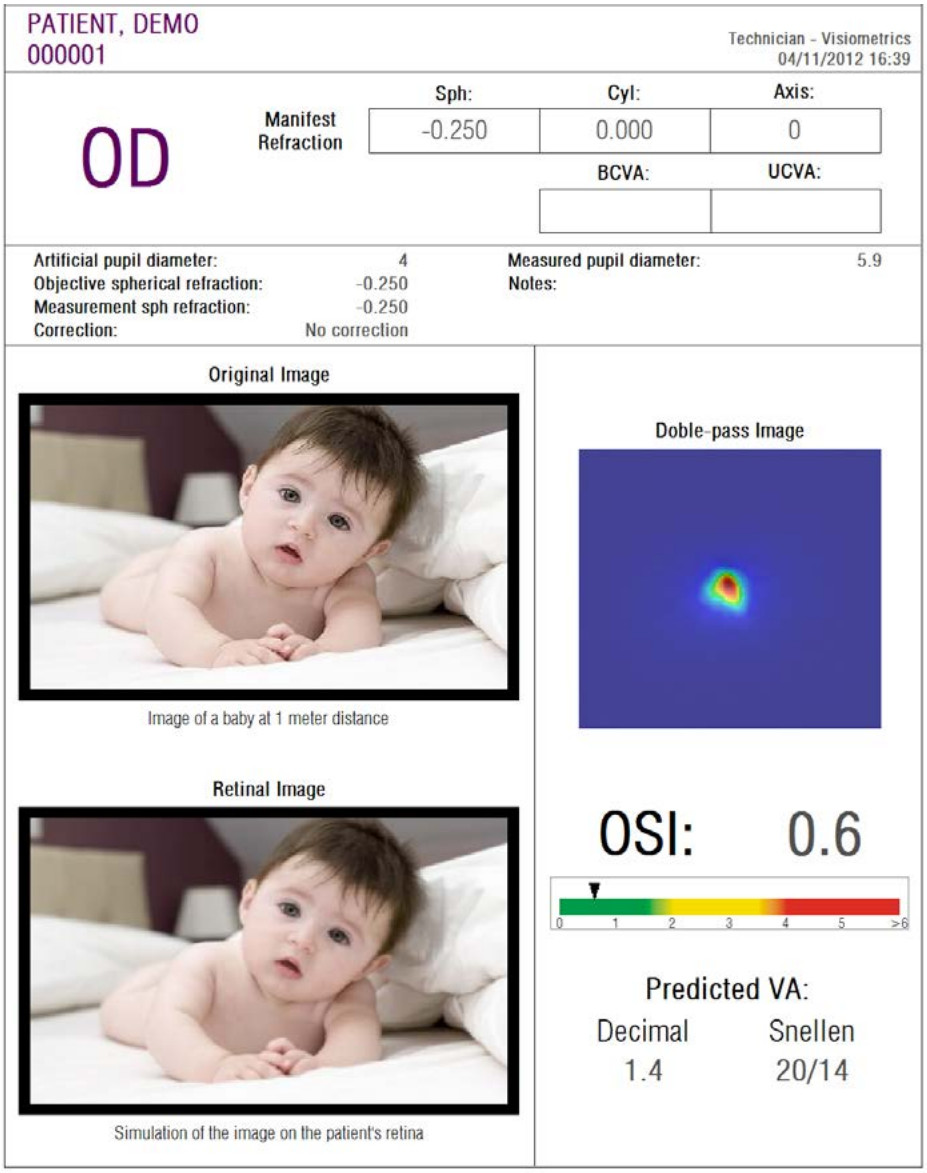
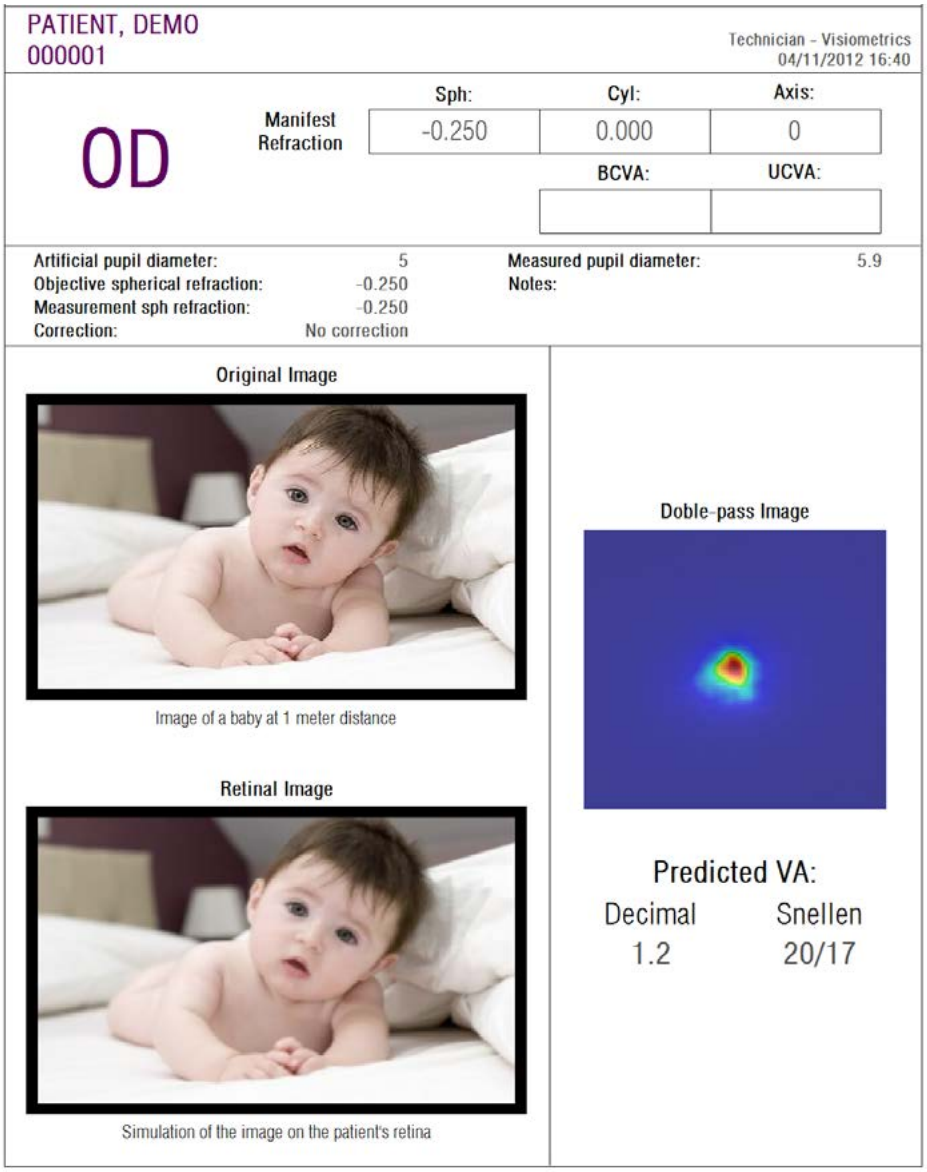


Figure 46. Example of a report for *Scatter Meter*



PATIENT, DEMO
000001

Technician - Visiometrics
04/11/2012 16:40

OD

	Sph:	Cyl:	Axis:
Manifest Refraction	-0.250	0.000	0
		BCVA:	UCVA:

Artificial pupil diameter: 5
Objective spherical refraction: -0.250
Measurement sph refraction: -0.250
Correction: No correction

Measured pupil diameter: 5.9
Notes:

Original Image

Image of a baby at 1 meter distance

Retinal Image

Simulation of the image on the patient's retina

Doble-pass Image

Predicted VA:

Decimal	Snellen
1.2	20/17

Figure 47. Example of a report for *Optical Quality*

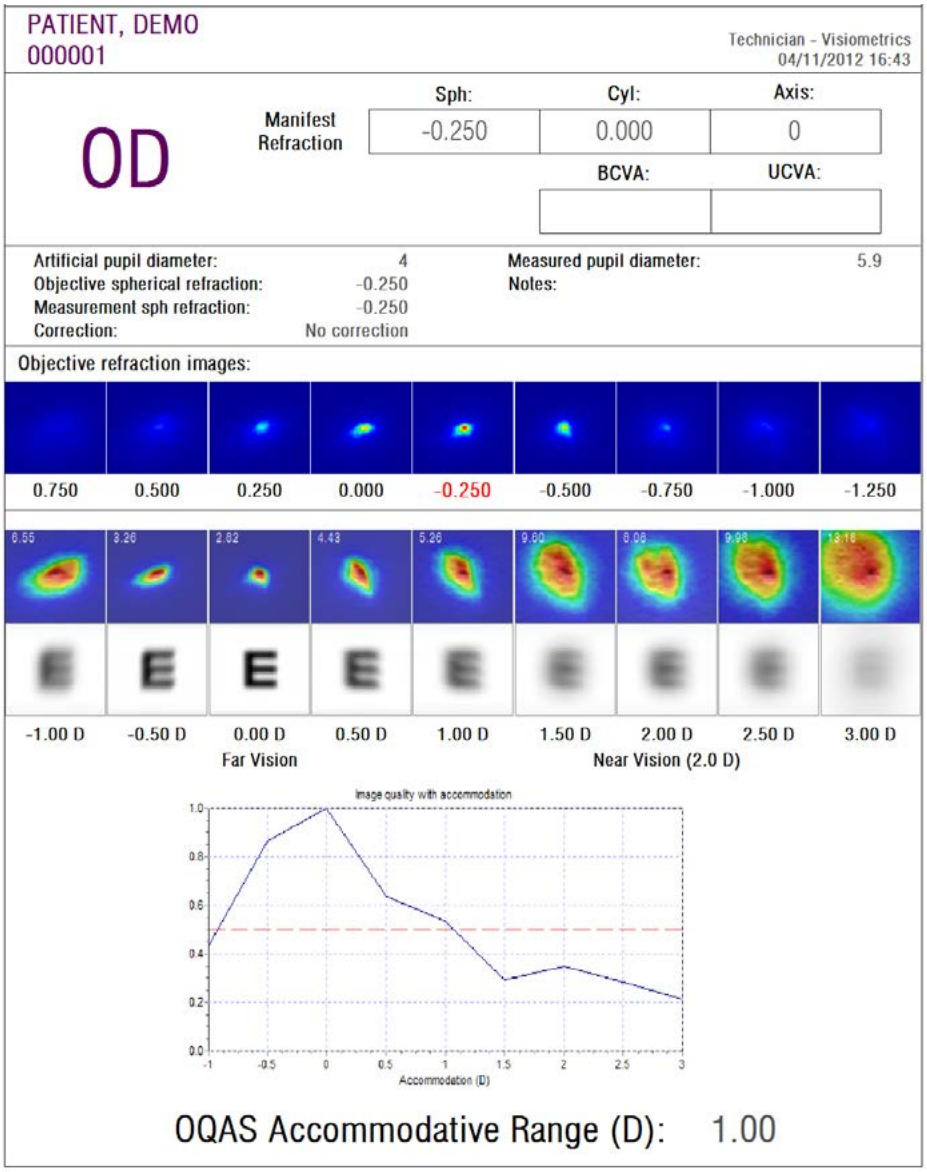


Figure 48. Example of a report for *Pseudo Accommodation*

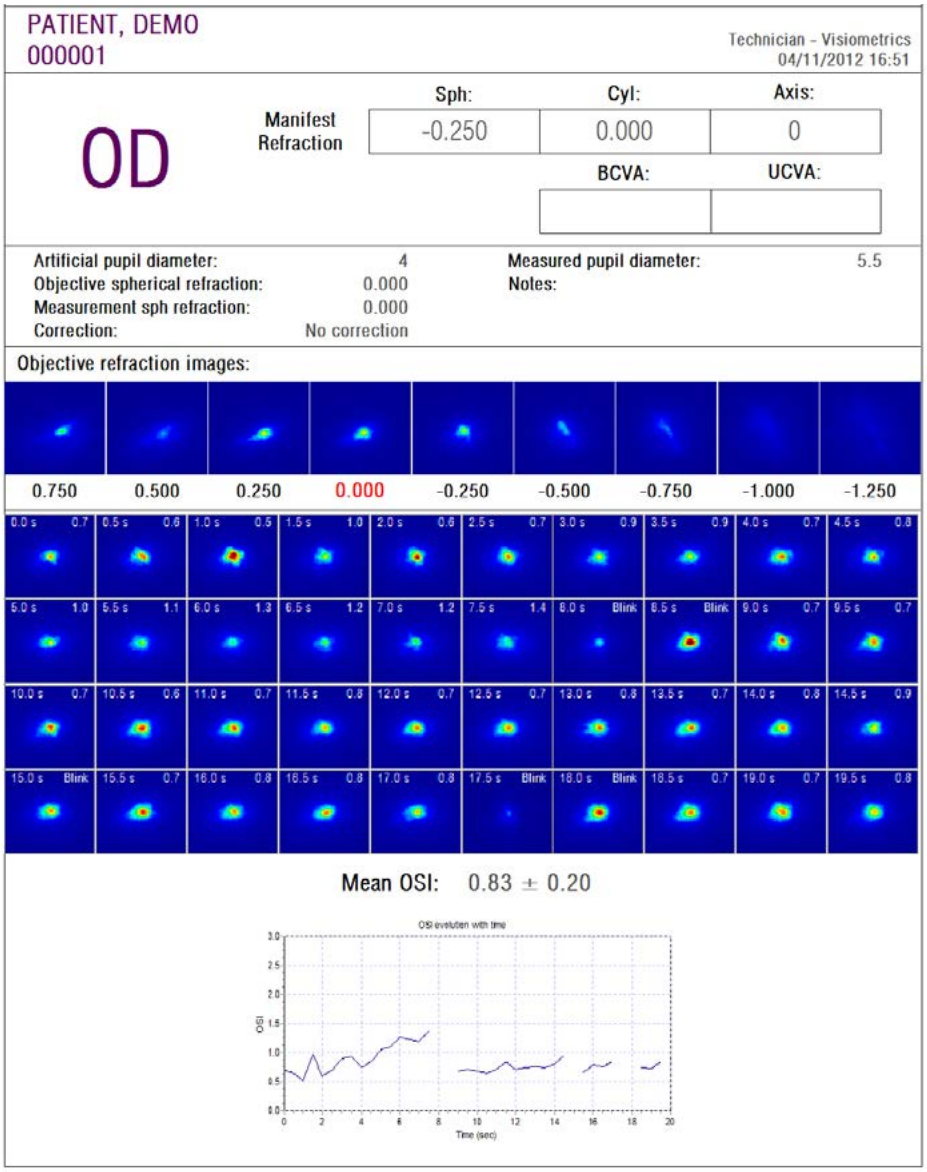


Figure 49. Example of a report for *Tear Film Analysis*

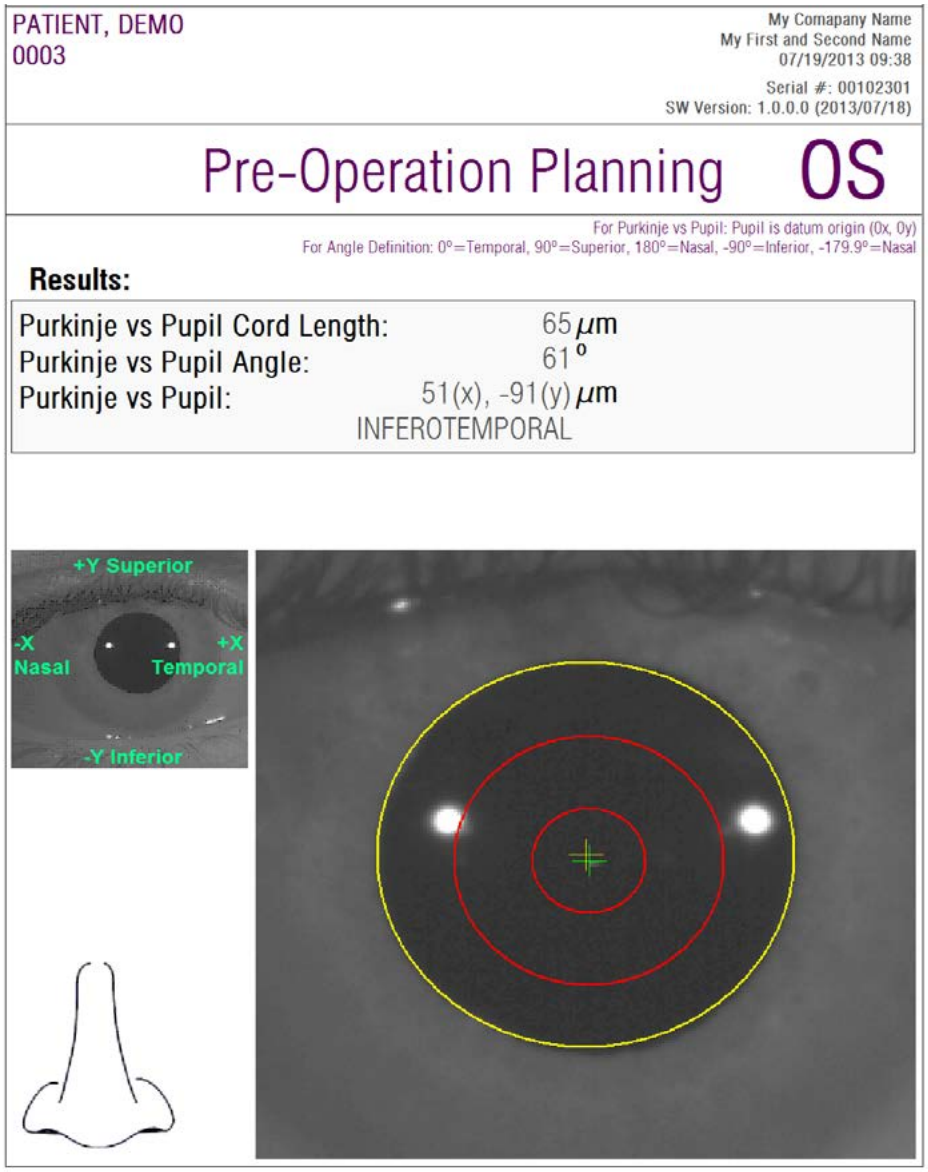


Figure 50. Example of a report for a pre-op Purkinje

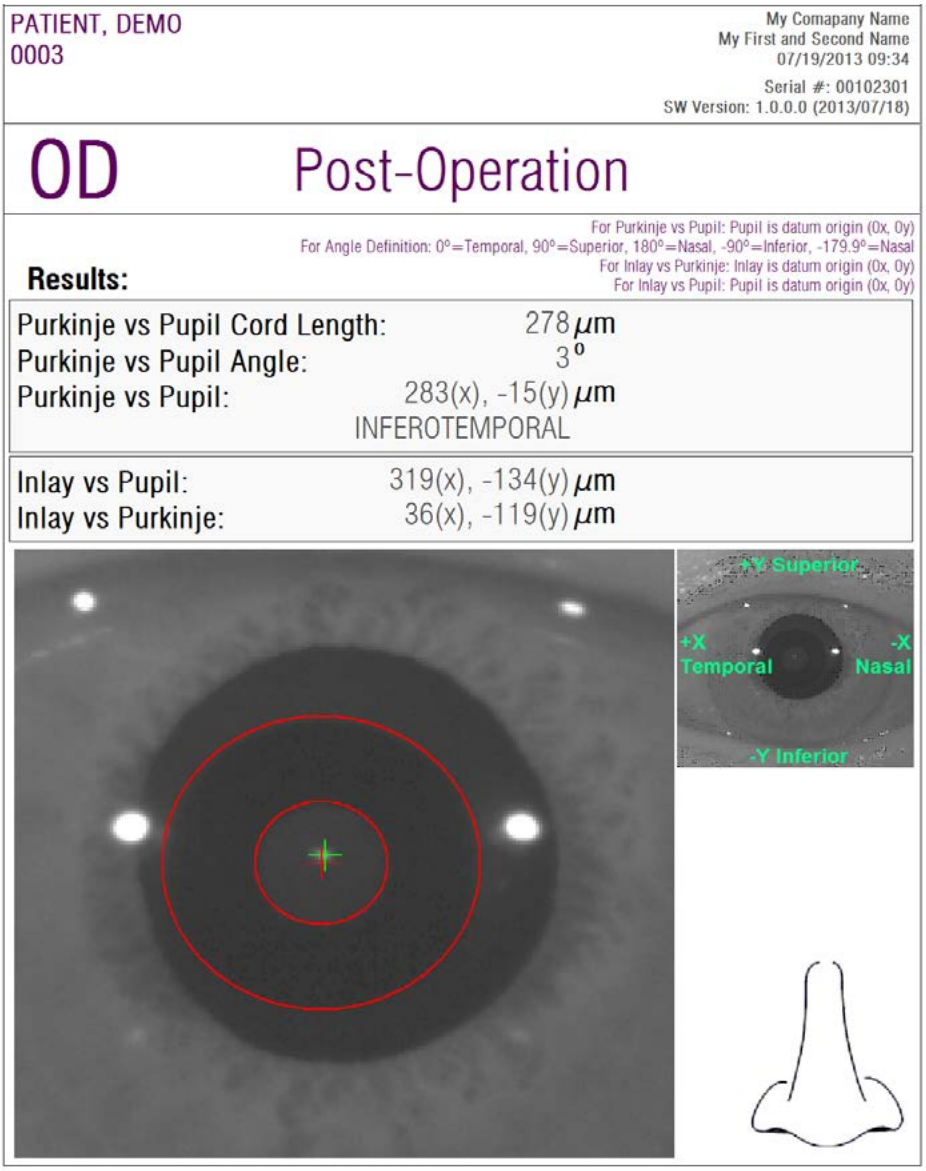


Figure 51. Example of a report for a post-op *Purkinje*

For *Scatter Meter* and *Optical Quality*, more complete reports are also available, which include all the results (also those intended for expert users). These reports are only accessible after clicking the *More options* button of the visualization options, in the *MTF* visualization in particular. Click on *Print complete report* in order to get those reports.

Finally, you can also generate reports for each of the result comparison screens (accessible from the option *Compare* in *Database*). Click on *Print complete report* in order to get those reports.

3.7. LICENSE MANAGER

Click on the *License Manager* button in the home menu (*Home*) in order to access the application for the system's license management. That application manages the measurement credits that are available for the HD Analyzer™ user, when the software runs in pay-per-patient mode.

Please, read carefully section 3.2 for more information about the different operation modes of the software.

Having clicked on the *License Manager* button, the HD Analyzer™ software shuts down, after user confirmation. The license managing application runs immediately.

Figure 52 shows the home screen of that application.

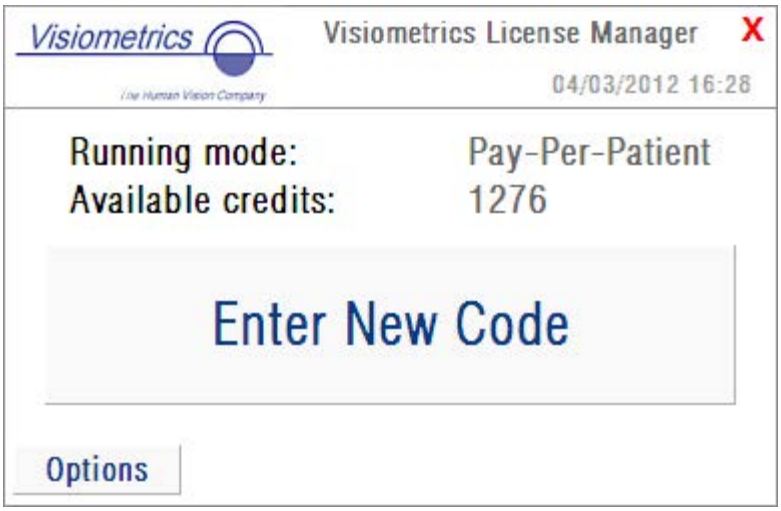


Figure 52. ***License Manager*** **Home menu**

The field *Running mode* indicates the HD Analyzer™ software running mode. It

can be *Pay-Per-Patient* or *Free mode*. The field *Available credits* indicates the number of available measurement credits in pay-per-patient mode.

If you have purchased new credits and you want to activate them in the device, click on *Enter New Code*. You will be shown the screen represented in Figure 53.

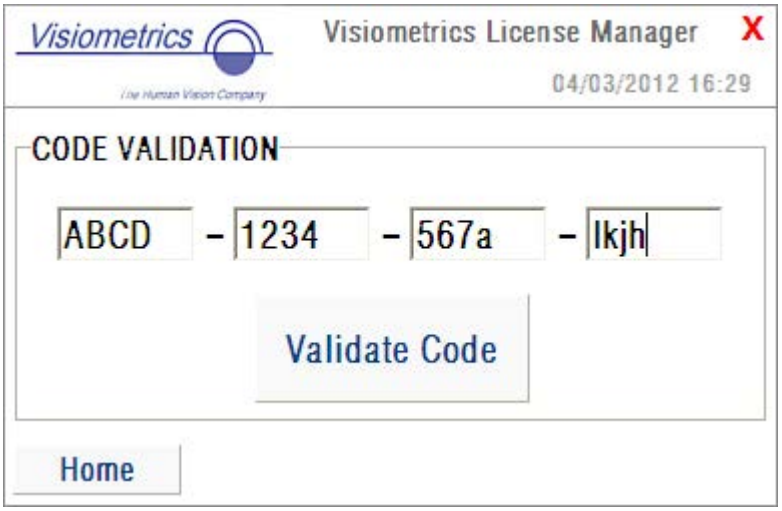


Figure 53. Validation of the activation code

You must type in the activation code you obtained after your purchase at Visiometrics web page (see section 3.2). In the example, the code ABCD-1234-567a-lkjh has been typed. Click then on *Validate Code*. If the code you have entered is not valid, you will be asked to please check if the 16 digits have been typed correctly. If the code you have entered is valid, the new credits will be added to the previously available ones, and a summary screen will be shown (Figure 54).

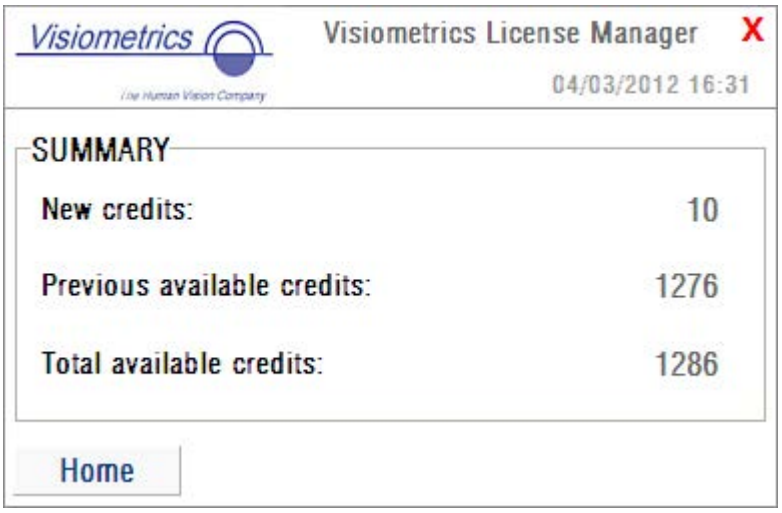


Figure 54. Summary of the activation code validation

In the home menu of the application (Figure 52), there is also a button named *Options*. That button gives access to the option screen, as seen on Figure 55. The only parameter that can be modified by the user is the language of the license managing application (English and Spanish available). The button *Administrative tools* activates a section of administrative parameters, which can't be accessed by the user. In this way, this section is protected with a password that is not provided to customer.

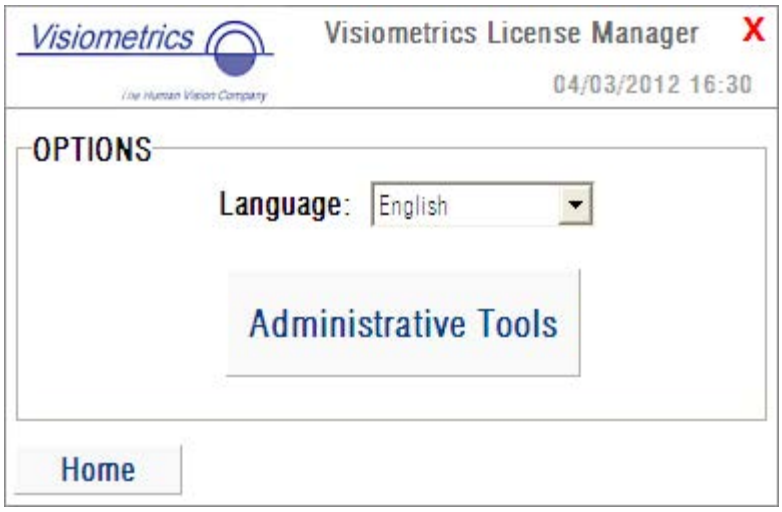


Figure 55. *License Manager* options

The application can be closed at any moment by clicking on the red cross on the right top corner of the screen. The license managing application will be shut down. The HD Analyzer™ software will restart then with the updated number of available measurement credits (if it has been modified).

3.8. SETUP

Click on the *Setup* button in the home menu (*Home*) in order to access the system's setup screen.

Figure 56 shows that setup screen. It can be clearly divided in three different sections:

Figure 56. Setup screen

3.8.1. User visible parameters

There are three data fields that are visible for the user:

- *Serial number* refers to the serial number of the HD Analyzer™ unit that is being operated and cannot be modified by user.
- *Company* refers to the name of the clinic, hospital, company, etc where the equipment is installed, and it can be modified by user.
- *User* refers to the user's name that operates the HD Analyzer™, and it can be modified by user.

The data entered in the fields *Company* and *User* is shown in the header of all software screens. None of the editable fields is mandatory and can be left blank, if desired.

By clicking on *Modify*, the software will restart with the new values, after user's confirmation.

3.8.2. Setup buttons

In this section you will find three buttons. The actual configuration is stored in a file, which can be imported/exported by means of the buttons *Load Config File* and *Export Config File*, respectively. Both actions are only necessary in case of an error in the system or due to maintenance tasks. The user must never manipulate the configuration file unless proper instructions were given by Visiometrics or an

authorized person. An incorrect manipulation of that file will result on a system malfunctioning.

The user must never perform import/export operations of the configuration file of HD Analyzer™ (Load Config File / Export Config File), unless having the express consent of Visiometrics. An incorrect manipulation of that file will result on a system malfunctioning.

The other button that is included, *Upgrade*, is used for performing upgrades of the software version of HD Analyzer™. In case that an upgrade is available for the equipment, Visiometrics will send the user the setup file, along with proper instructions. Please, follow carefully those instructions. In general, the upgrade is performed by clicking on *Upgrade* and choosing the upgrade file in its location. A password will be requested, which would be previously provided by Visiometrics. After password validation, the upgrade is performed. In any case, remember that you must always follow the instructions that you've got along with the upgrade file.

3.8.3. "Quick check" process

"Quick check" process must be carried out after the first installation has taken place and after any transfer to a new work site.

If detected values during this process differ significantly from factory values, software will show a warning. In this case, a specialized technician trained by Visiometrics must carry out a complete calibration using specific equipment.

"Quick check" process allows the user to check focus values and laser alignment. An auxiliary tool, delivered with the unit, is needed (section 1.4.3.2).

During the "Quick check" process, light conditioning must be similar to those used in normal situations.

The process consists of 3 steps:

- Focusing…
- Searching new focus value…
- Laser centering…

3.8.3.1. Focusing…

First of all, user should:

- Place the auxiliary tool in the chinrest bars, as showed in following picture:

Figure 57. Auxiliary tool in the chinrest.

- Place the instrument as close as possible to the chinrest.
- Click on "Quick check".
- Center the pattern in the image:
  - It doesn't matter if the pattern's image looks blurry.
  - It doesn't matter if the external rectangle is red.
- Move the instrument's head far from the chinrest:
  - The pattern's image will become clearer.
  - At some point, the red rectangle will change to green (maybe unstable, changing between red and green).
- Continue moving the instrument's head far from the chinrest, slowly:
  - At some point, the red rectangle will be stable.
- Then, invert the direction, moving the instrument's head close to the chinrest, also very slowly:
  - When you get a stable green rectangle, don't move the instrument anymore.
  - Click on "Focused" button and go to next step.

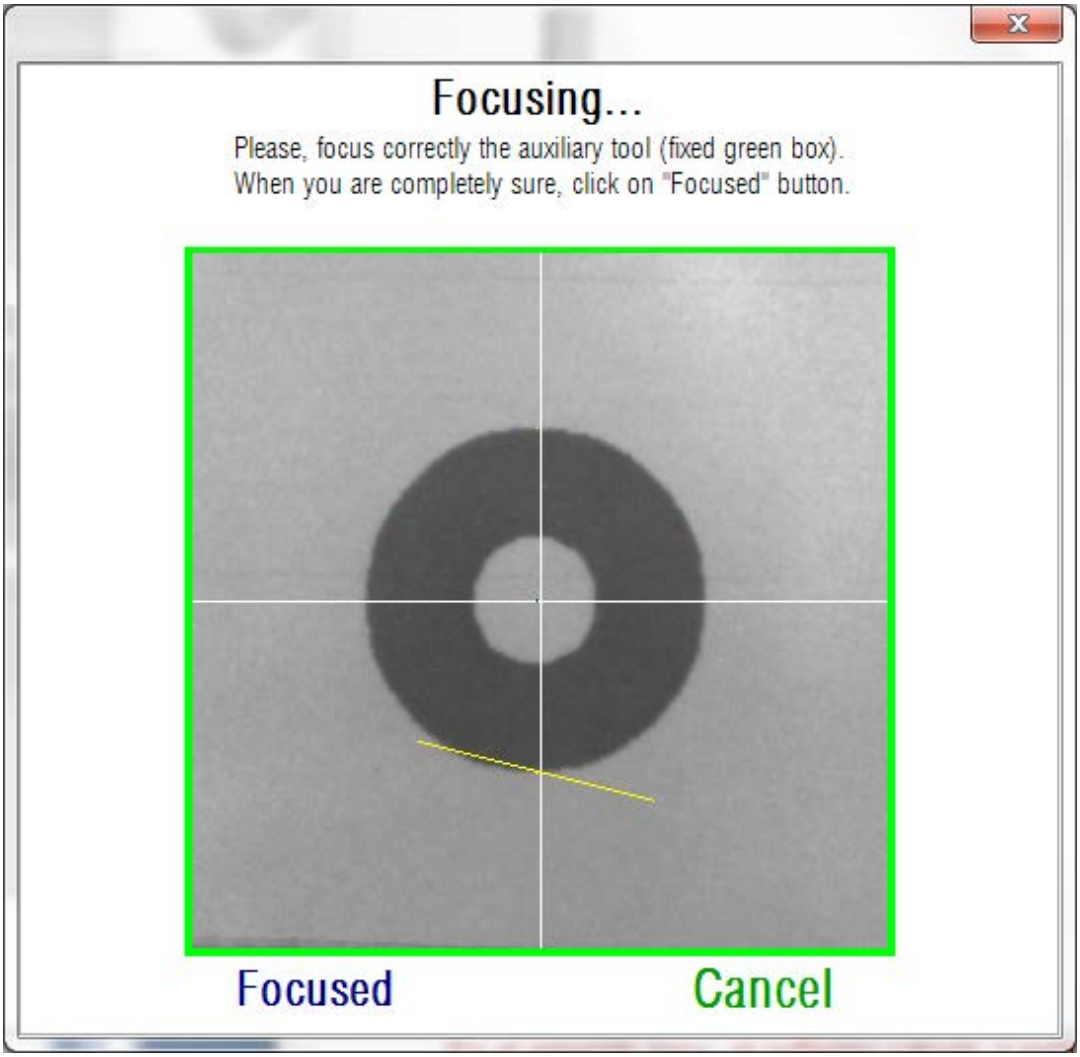


Figure 58. Pattern in the auxiliary tool well focused.

3.8.3.2. Searching new focus values…

In the second step, software will calculate, using 100 captured pattern images, an internal parameter.

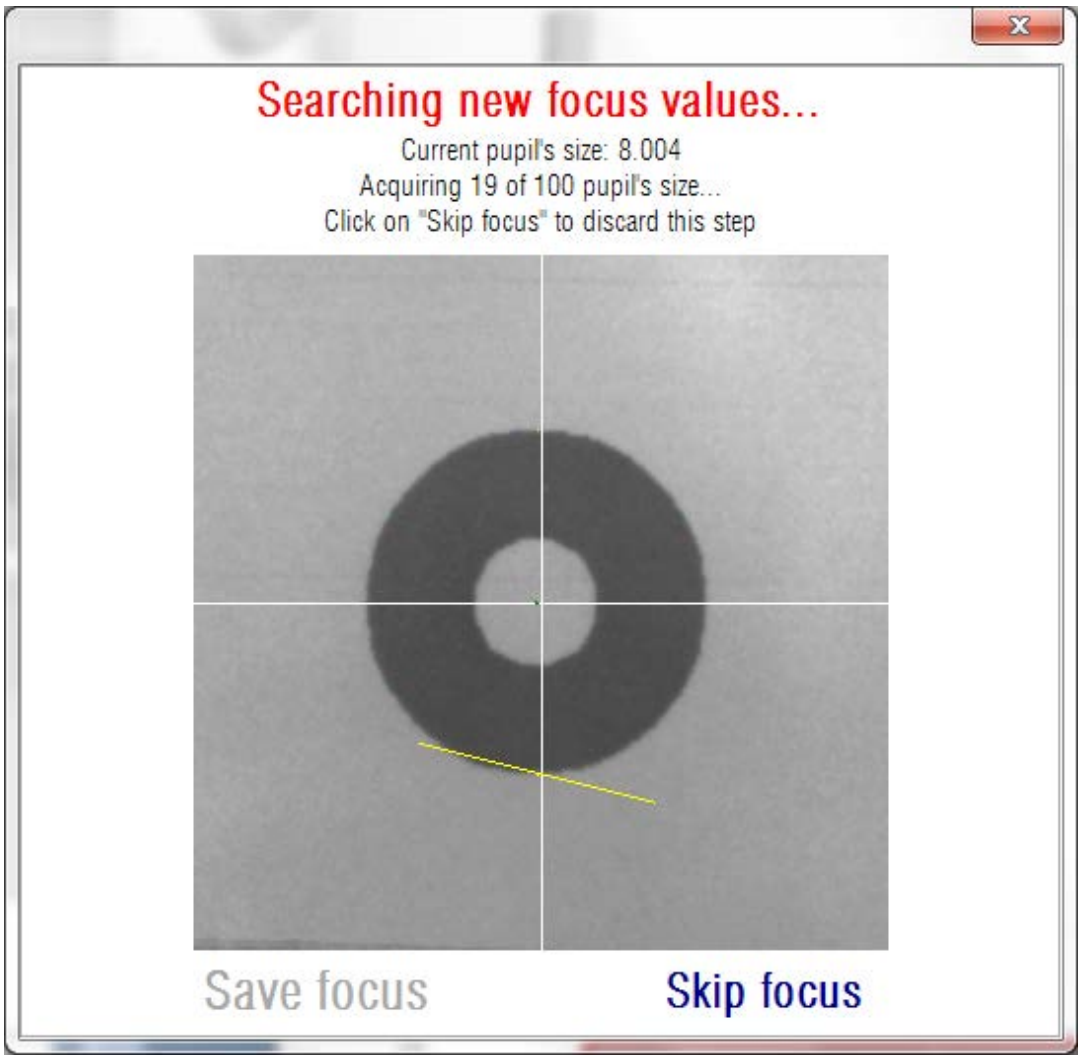


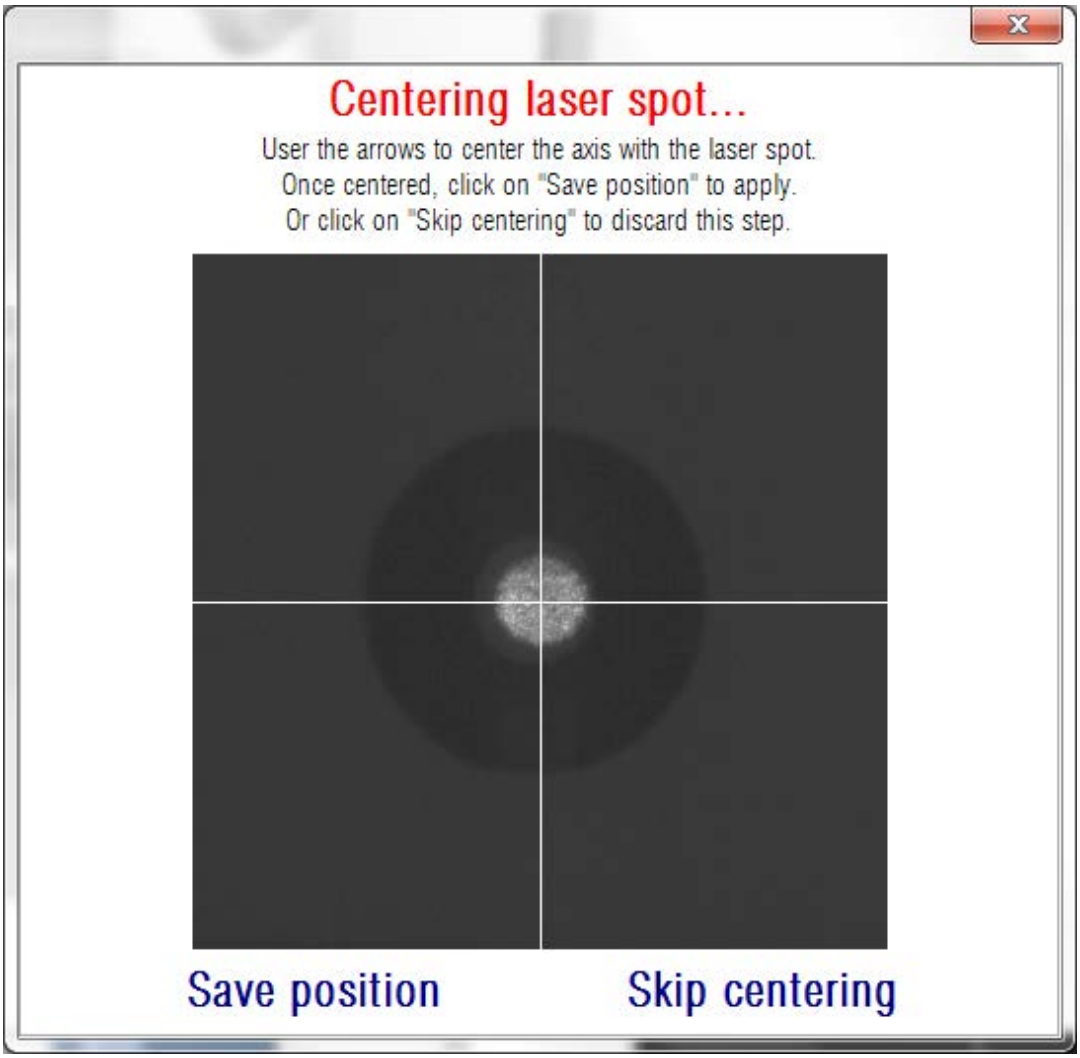
Figure 59. Software calculating pupil size.

Once 100 images have been captured, if the image was well focused, the pupil's size detected in pattern should be very close to 8mm, but do not worry if it is not. What really matters is that the pattern has been correctly focused during the previous step.

Wait until the process is complete and click on "Save focus" to save the results. Bear in mind that changing this parameter will not affect previous ones already calculated. But, it will affect the precision of futures acquirements. If you don't want to accept the results, click on "Skip focus" button. In any case, you will access to the next step.

3.8.3.3. Centering laser spot…

In the third step, the software will turn off the infrared LEDs and it will turn on the laser. Then, you will be able to see how the laser spot impacts on the auxiliary tool.



You should move the crosshair, using the arrow keys, to center the axis with the laser spot. During this step, you must ignore completely the pattern of the auxiliary tool.

Once done, click on "Save position". Or click on "Skip centering" if you do not want to modify the laser position.

At this point, software will inform about the changes on the configuration (none, focus values and/or laser position). You must confirm again if you agree with the changes, if any.

3.8.4. Hardware setup

This section is protected with a password, which the manufacturer will provide only in case that the device needs some maintenance task. The password is not provided by default, in order to avoid any unintended modification of the configuration parameters of the instrument.

Access to the Hardware setup section is restricted to qualified staff. Some parameters, if changed, can cause the equipment malfunction.

3.9. BACKUP

Click on the *Backup* button in the home menu (*Home*) in order to perform a backup copy of the database. You must select the desired location and name of the folder where the copy of the data will be stored.

The system backups all the files related with patients' data and the measurements performed to them. This includes the Microsoft Access™ database file, as well as all the registered images.

You should make a backup copy regularly. Please, take into account that the copy may take up a great amount of disk space (it could reach up to several gigabytes). So, before performing the backup, verify that there is enough free disk space in the folder where the copy will be stored.

4. Examples of measurements

4.1. NORMAL EYE

Figure 60 shows a report of the results for a young and healthy eye measurement.

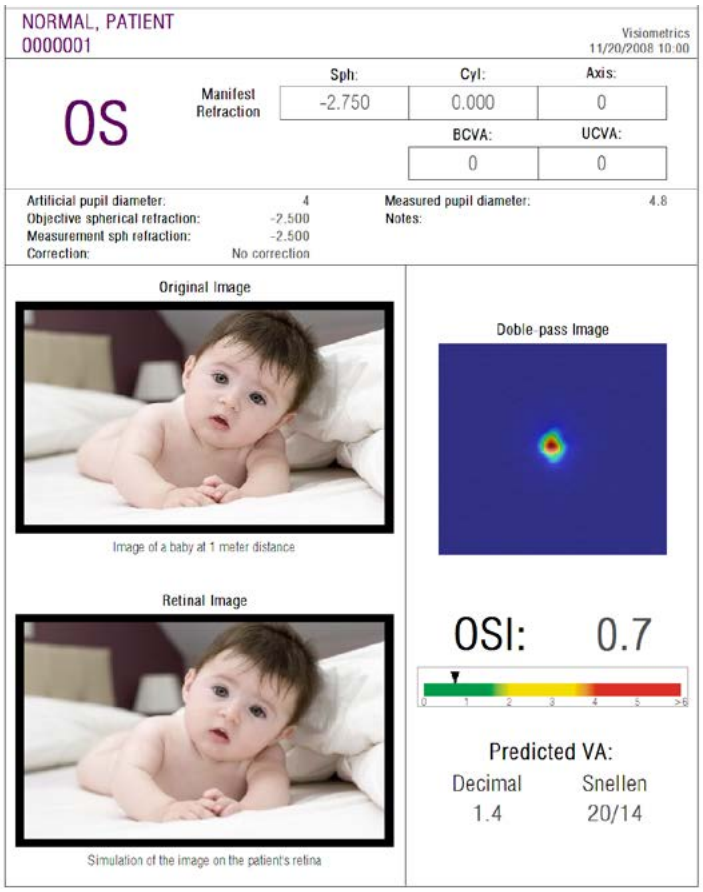


Figure 60. Normal eye

Notice that the double-pass image is sharp and round. This means that the optical degradation, due to both aberrations and intraocular scattering, is very small. This is also confirmed with the high value of *Predicted VA* (few aberrations) and the low value of *OSI* (low level of scattering), as expected.

Regarding the simulation of the image projected on to the retina, it can be seen that there is no remarkable degradation compared with the original image.

4.2. CATARACT EYE

Figure 61 is an example of a report of the results of an eye with a cataract.

It can be noticed that the double-pass image is much larger than in the case of a normal eye. This means that the energy (light) is spread on the retina. That's the effect of the intraocular scattering (light spreading in all directions). In this way, a high value of *OSI* should be expected, as it actually is. Furthermore, the *Predicted VA* value must be low.

The simulation of the image projected on to the retina shows an important degradation caused by the ocular media, comparing it with the original image. The scattering generates an overall loss of contrast in the retinal image. This is the well known veil effect caused by cataracts. It should be taken into account that other effects such as glare or halos are not simulated on this image, so their presence must not be expected.

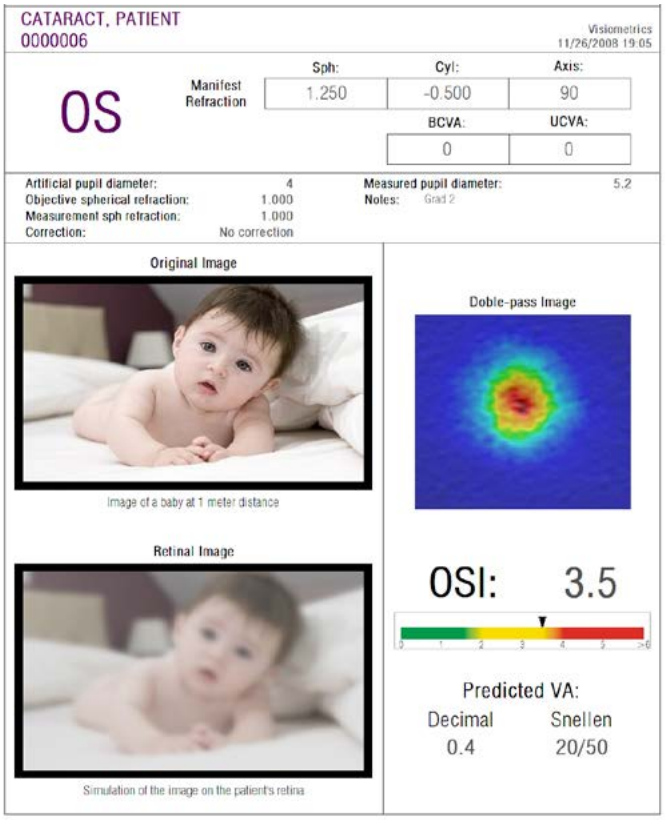


Figure 61. Eye with a cataract

4.3. POST-LASIK EYE

After a LASIK procedure there is some uncertainty about the real state of the eye. Although the patient sees properly, new aberrations or a slight level of scattering on the cornea may appear. To verify the success of the procedure, take a measurement to the patient. Figure 62 shows an example of a report of the results of an eye after a LASIK surgery. In this case, it can be seen that quality of vision is very satisfactory, since the double-pass image is round and its size is acceptable. The *OSI* value is low and the *Predicted VA* value is high, as it should be for a successful procedure.

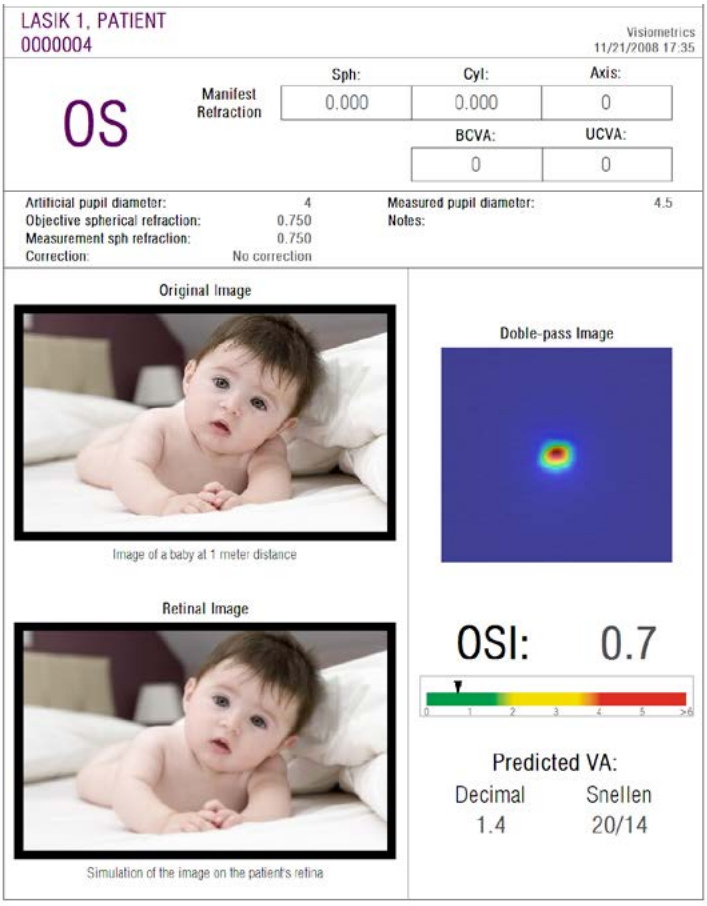


Figure 62. Eye after a successful LASIK surgery

On the other hand, Figure 63 shows an example of a surgery where the expected results have not been reached. The double-pass image is larger, due to the presence of aberrations and a certain level of scattering. The *OSI* values is more significant than in the previous case (more scattering), and *Predicted VA* is lower.

The simulations of the image projected on to the retina show as well a more noticeable blurring in the second case.

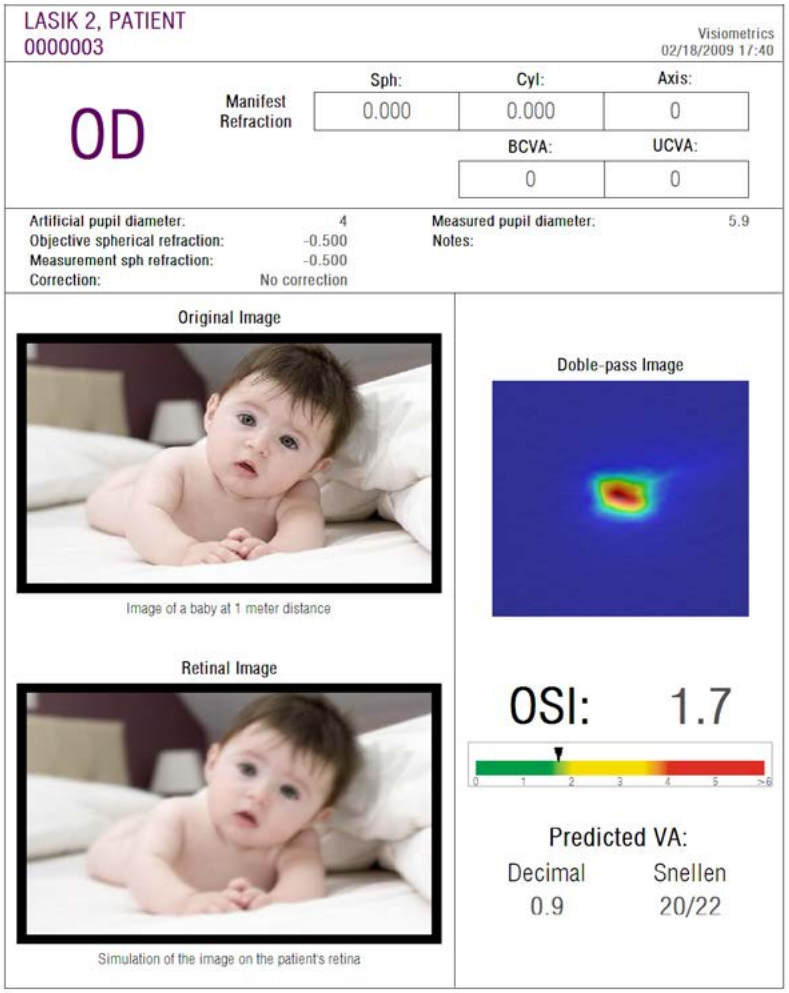


Figure 63. Eye after a non successful LASIK surgery

5. ERROR SOLVING

HD Analyzer™ software shows several error messages when an error occurs. These are the possible messages the system can show:

5.1. ERROR MESSAGES

Code	Message	Cause
5	The program requires a screen resolution of 1366x768, 1366x800, 1280x768 or 1280x800. The current resolution is not valid, so the program must shut down. Try to change your screen resolution.	The program requires a screen resolution of 1366x768, 1366x800, 1280x768 or 1280x800. This error shows up when a different screen resolution is being used. User should change screen resolution.
6	The program initialization has failed. The program will shut down.	For some reason (memory shortage, not enough free space on disk, etc.) software cannot initialize. Contact Visiometrics.
21	The acquisition has failed	For some reason, measurement could not be completed. Try again.
22	The selffocusing process has failed. Please check if the subjective refraction you have entered is correct and try again	For some reason, the Objective Refraction process could not be completed. Check subjective refraction typed in and try again
25	A Thorner movement has failed	A hardware error has occurred in the spherical refraction compensation internal system. User should switch the device off and then on again to check if error happens again. If it does, contact Visiometrics.
26	The pupil motor has failed	A hardware error has occurred in the artificial pupil internal system. User should switch the device off and then on again to check if error happens again. If it does, contact Visiometrics.
27	The shutter motor has failed	A hardware error has occurred in the system's shutter. User should switch the device off and then on again to check if error happens again. If it does, contact Visiometrics.
28	The laser has failed	A hardware error has occurred in the system's laser. User should switch the device off and then on again to check if error happens again. If it does, contact Visiometrics.
29	The anti-speckle system has failed	A hardware error has occurred in the vibration internal system. User should switch the device off and then on again to check if error happens again. If it does, contact Visiometrics.
30	The LEDS have failed	A hardware error has occurred in the system LED. User should switch the device off and then on again to check if error happens again. If it does, contact Visiometrics.
32	Error in the video signal	Signal coming from the system cameras has been lost. User should switch the device off and then on again to check if error happens again. If it does, contact Visiometrics.
33	The images could not be opened	Images for that selected acquisition were not found in disk. Contact Visiometrics if this error becomes repetitive

Code	Message	Cause
34	Error while processing the images	An error has occurred when processing the images. Contact Visiometrics if this error becomes repetitive.
36	The program has not captured enough images for their process. Please try again.	For some reason, measurement could not be completed. (Some images were not registered). Try again.
39	There is no patient selected.	No patient was selected. Select one.
40	There is no acquisition selected	No acquisition was selected. Select one.
41	There is more than one acquisition selected.	Too many acquisitions have been selected. Select only one.
46	The system's cameras could not be detected. Check the connections.	Software is not detecting the device's cameras. User should check the connection between computer and device.
47	One of the system's cameras could not be detected. Check the connections.	Software is not detecting one of the device's cameras. User should switch the device off and then on again in order to check if error happens again. If it does, please contact Visiometrics.
49	Communication failure with camera	A communication problem has occurred with the system cameras. User should switch the device off and then on again to check if error happens again. If it does, contact Visiometrics.
50	There is not enough energy reaching the camera. The images could not be recorded.	The system has reached the maximum laser power, but still it is not enough to measure patent. Try again.
54	Error while updating the credit count. The program will shut down.	Credit could not be deducted. Contact Visiometrics.
56	The License Manager software was not found.	The License Manager software could not be found. Contact Visiometrics.

5.2. WARNING MESSAGES

Message	Cause
The program will run without hardware	Hardware is not connected or is not working.
The program has detected a problem with the hardware and will shut down.	A hardware error has occurred and the program shuts down. User should switch the device off and then on again to check if error happens again. If it does, contact Visiometrics.
You can't perform new measurements. Visit our website www.visiometrics.com if you want to get more credits.	User does not have any credits left. User must buy and activate new credits through the License Manager tool.
The MTF could not be computed	Images have such poor quality that MTF function could not be processed. Contact Visiometrics if this error becomes repetitive.
The pupil diameter of the patient could not be measured during the process. This value will be set to zero.	Because of lighting conditions not being optimal, patient's pupil diameter could not be measured. Try again.
At least one of the spherical refractions is out of range. In case of measuring that eye, please correct it with trial lenses and choose 'Total correction' in the Correction field in the measurement screen.	Spherical refraction typed in is out of range. It must be compensated by means of trial lenses or patients' own correction devices (contact lenses or glasses).
At least one of the cylindrical refractions is out of range. In case of measuring that eye, please correct it with trial lenses and choose 'Astig. correction' or 'Total correction' in the Correction field in the measurement screen.	Cylindrical refraction typed in is out of range. It must be compensated by means of trial lenses or patients' own correction devices (contact lenses or glasses).
You have typed an incorrect password	A wrong password has been typed in to enter setup. Try again.

Error listing is registered in the file *C:/Program Files (x86)/Visiometrics/HD_Analyzer/log/error.log*.

If an error occurs, please, exit the application; switch off the instrument and restart PC and HD Analyzer™. If repetitive error occurs, please verify connexions between computer and hardware and contact VISIOMETRICS.

If error persists, please contact Visiometrics technical support.

6. Manufacturer

VISIOMETRICS, S.L.
c/ Argenters, 8 - Edifici nº 3
Parc Tecnològic del Vallès
08290 Cerdanyola del Vallès
Barcelona (Spain)

Tel.: (+34) 935 824 501

Manufacturer nr: 5.122-PS

Our Website: www.visiometrics.com

Sales Inquiries: customerservice@visiometrics.com
Technical Support: technicalservice@visiometrics.com

This symbol on the product or on its packaging indicates that this product must not be disposed of with your other household waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office or your household waste disposal service or the distributor where you purchased the product.

7. Regulatory information

Australian Sponsor	Emergo Australia Level 20 Tower II, Darling Park 201 Sussex Street Sydney, NSW 2000 Australia

8. APPENDIX A

If MS Access™ is installed in your computer, you can access the HD Analyzer™ database directly.

You will find a copy of the database file in this folder *C:/Program Files (x86)/ Visiometrics/HD_Analyzer / PATIENTS BD*. In this way, there is no danger of harming or deleting existing data. This copy of the database file (*BD_PATIENTS. mdb*) is regenerated every time the HD Analyzer™ software is closed. We strongly recommend not accessing it while running the software.

When you open *BD_PATIENTS.mdb* you will find two tables:

Patients_Table
Acquisitions_Table

8.1. PATIENTS_TABLE

This table shows patients' personal data, which was typed in at the time of adding a new patient file.

These are the available fields:

Id:	Automatically generated exclusive identifier for each patient. For internal use of the system.
NAME:	Patient's name.
SURNAME1:	Patient's surname.
REFERENCE:	It stands for Patient's Id number on patient's file. It is a compulsory field.
DATE_OF_BIRTH	
SEX	
ADDRESS	
CITY	
ZIP	
COUNTRY	

PHONE

E_MAIL

OBSERVATIONS: Comments

OD_Sph: Right eye spherical refraction

OD_Cyl: Right eye cylindrical refraction

OD_Axis: Right eye axis

OS_Sph: Left eye spherical refraction

OS_Cyl: Left eye cylindrical refraction

OS_Axis: Left eye axis

These last six fields are not calculated measurements, but data typed by the user when filling in patient's file.

8.2. ACQUISITIONS_TABLE

Fields on this table are related to acquisitions. Each register corresponds to one measurement of any of the available types (Purkinje, *Scatter Meter*, *Optical Quality, Pseudo Accommodation* or *Tear Film Analysis*).

Id_Acq: Automatically generated exclusive identifier for each measurement. For internal use of the system.

FK_Id_Patient: Patient's identifier to whom the measurement belongs to. It is the same value as "Id" on the Patients_Table and it allows us to relate this table to the patients' table.

DATE, HOUR: when the measurement was taken

OS, OD: left eye, right eye, respectively.

SPH, CYL, AXIS: These are spherical and cylindrical refraction values and astigmatic axis introduced by user in the "Sph", "Cyl" and "Axis" fields on the main screen, before carrying out the measurement.

BCVA, UCVA: These are the visual acuities for best correction (*Best Corrected Visual Acuity*) and no correction (*Uncorrected Visual Acuity*), respectively. They were introduced by the user before carrying out the measurement.

REFERENCE_SPH_REFRAC: Spherical refraction correction applied during the measurement.

AP, NP: diameter in millimetres of the artificial (diaphragm) and natural pupil, respectively.

NOTES: These are the comments written under the field "Acquisition notes" on the results' screen.

BESTFOCUS: It is the value of optimal spherical correction obtained in the *Objective Refraction* process.

WIDTH_PROFILE_1/2: Profile width at half height.

WIDTH_PROFILE_1/10: Profile width at 10% height.

MTF_CUT_OFF: MTF cut off frequency.

STREHL RATIO: Calculated Strehl Ratio.

VA_100, VA_20 and VA_9: Estimated decimal VA at different contrast situations, 100%, 20% y 9%.

OQAS_Value_100, OQAS_Value_20 and OQAS_Value_9: *OQAS value* at different contrast situations, 100%, 20% y 9%.

Type_Num: 1, 2, 3, 4 or 5. It relates to the following field.

Type: Measurement type

1 = Opt. Qlt (*Optical Quality*)

2 = SCT (*Scatter Meter*)

3 = Pseudo Acc (*Pseudo Accommodation*)

4 = Not in use

5 = Tear Film (*Tear Film Analysis*)

Corr_Type_Num: 0, 1 or 2. It relates to the following field

Corr_Type: Indicates the correction type applied during the measurement.

0 = No correction

1 = Astig. correction

2 = Total correction

NImag: Number of captured images.

NImag_Acc_Each: Number of images processed for each pseudo accommodative stage (*Pseudo Accommodation*).

COMPUTED_IMAGES: It records which of the six available images were used to carry out calculations the last time that acquisition was shown.

OAR: OQAS™ Accommodative Range.

OSI: Objective Scattering Index.

Refrac_Acc_Per_1: Not in use.

Refrac_Acc_Per_2: Not in use.

AR: Not in use.

Time_Each_Image_TearFilm: Time between images for the *Tear Film Analysis* process.

TearFilm_Time: Stores the moment when each image was recorded in the *Tear Film Analysis* process.

TearFilm_OSI: Stores the OSI value for each image that was recorded in the *Tear Film Analysis* process.

TearFilm_Central_Energy: Stores the energy at the centre of each image that was recorded in the *Tear Film Analysis* process.

TearFilm_Peripheral_Energy: Stores the energy at the periphery of each image that was recorded in the *Tear Film Analysis* process.

TearFilm_VA: Stores the estimated VA for each image that was recorded in the *Tear Film Analysis* process.

TearFilm_MTFCutoff: Stores the MTF cut off frequency for each image that was recorded in the *Tear Film Analysis* process.

TearFilm_MeanOSI: Stores the mean OSI value for the *Tear Film Analysis* process.

TearFilm_StdevOSI: Stores the standard deviation of the OSI for the *Tear Film Analysis* process.

PKJ_IsPreOperation: It only makes sense for Purkinje acquirements. It stores if the acquirement is pre-operation or post-operation.

PKJ_MicrasPerPixel: It only makes sense for Purkinje acquirements. It stores the relation pixel-microns in the associated image.

PKJ_PupilDiameter: It only makes sense for Purkinje acquirements. It stores the pupil's diameter.

PKJ_PkjVsPupil_Length: It only makes sense for Purkinje acquirements. It stores the distance, in pixels, between the Purkinje and the pupil's center.

PKJ_PkjVsPupil_Angle: It only makes sense for Purkinje acquirements. It stores the angle between Purkinje and pupil's center.

PKJ_PkjVsPupil_X: It only makes sense for Purkinje acquirements. It stores the existent distance, in microns, on X axis, between Purkinje and pupil's center.

PKJ_PkjVsPupil_Y: It only makes sense for Purkinje acquirements. It stores the existent distance, in microns, on Y axis, between Purkinje and pupil's center.

PKJ_InlayVsPupil_X: It only makes sense for Purkinje post-operations acquirements. It stores the existent distance, in microns, on X axis, between inlay KAMRA™'s center and pupil's center.

PKJ_InlayVsPupil_Y: It only makes sense for Purkinje post-operations acquirements. It stores the existent distance, in microns, on Y axis, between inlay KAMRA™'s center and pupil's center.

PKJ_InlayVsPkj_X: It only makes sense for Purkinje post-operations acquirements. It stores the existent distance, in microns, on X axis, between inlay KAMRA™'s center and Purkinje.

PKJ_InlayVsPkj_Y: It only makes sense for Purkinje post-operations acquirements. It stores the existent distance, in microns, on Y axis, between inlay KAMRA™'s center and Purkinje.

PKJ_Pupil_PixelCentroX: It only makes sense for Purkinje acquirements. It stores the pixel, on X axis, where the pupil's center is.

PKJ_Pupil_PixelCentroY: It only makes sense for Purkinje acquirements. It stores the pixel, on Y axis, where the pupil's center is.

PKJ_Pupil_PixelRadio: It only makes sense for Purkinje acquirements. It stores the pupil's radius, in pixels.

PKJ_Laser_PixelCentroX: It only makes sense for Purkinje acquirements. It stores the pixel, on X axis, where the purkinje's center is.

PKJ_Laser_PixelCentroY: It only makes sense for Purkinje acquirements. It stores the pixel, on Y axis, where the purkinje's center is.

PKJ_Inlay_PixelCentroX: It only makes sense for Purkinje post-operation acquirements. It stores the pixel, on X axis, where the inlay KAMRA™'s center is.

PKJ_Inlay_PixelCentroY: It only makes sense for Purkinje post-operation acquirements. It stores the pixel, on Y axis, where the inlay KAMRA™'s center is.

PKJ_Inlay_PixelRadio: It only makes sense for Purkinje post-operation acquirements. It stores the inlay KAMRA™'s radius in pixels.

8.3. SYMBOLS

	Warning
	Electrical products recycling
	CE Mark
SN	Serial number
	Applicable part
	Class II device
	Laser radiation
	Fragile
	Keep dry
	Keep in vertical position
	Read user manual

9. ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY			
The HD Analyzer™ is intended for use in the electromagnetic environment specified below. The customer or the user of the HD Analyzer™ should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the HD Analyzer™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF emissions IEC 61000-4-6	3Vrms 150 kHz to 80MHz outside ISM bands[a]	3 Vrms	$d = 1,17\ (P)^{1/2}$
	10 Vrms 150 kHz to 80MHz In ISM bands[a]	3 Vrms	$d = 4\ (P)^{1/2}$
Radiated RF emissions IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 4\ (P)^{1/2}$ 80 MHz to 800MHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level for each frequency[d] range. Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1: At 80 Mhz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the HD Analyzer™ is used exceeds the above applicable RF compliance level, the HD Analyzer™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the device.

[d] Over the frequency ranges 150 kHz to 80 MHz field strength should be less than 3 V/m.

Recommended safety distances between portable and mobile RF-communication equipment and the HD Analyzer™

The HD Analyzer™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HD Analyzer™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HD Analyzer™ as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter in watts (W)	Separation distance according to the frequency of the transmitter in meters (m)			
	150 kHz to 80MHz outside ISM bands $d = 1,17\sqrt{P}$	150 kHz to 80MHz In ISM bands $d = 4\sqrt{P}$	80 MHz to 800 MHz $d = 4\sqrt{P}$	800 MHz to 2,5 GHz $d=7,67\sqrt{P}$
0,01	0,17	0,4	0,4	0,77
0,1	0,37	1,26	1,26	2,43
1	1,17	4	4	7,67
10	3,70	12,6	12,6	24,25
100	11,7	40	40	76,7

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distances for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.