HD Analyzer™

An OQAS product by
Visiometrics

USER'S MANUAL
Version 2.4

English

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CE
0318

MODEL: OQAS – HDA
               Optical Quality Analysis System – High Definition Analyzer
BRAND: HD Analyzer

APPLICABLE PARTS:
Chin guard (Type B)

CODE: 2
REVIEW: 1
2017/08
PRINTED IN SPAIN

Table of Contents

WARNINGS

PLEASE, THOROUGHLY READ THIS COMPLETE USER'S MANUAL BEFORE CARRYING OUT ANY OPERATION WITH THE EQUIPMENT.

THIS EQUIPMENT MUST BE OPERATED BY PEOPLE WHO ARE FAMILIAR WITH THE USE OF OPHTHALMOLOGICAL DIAGNOSIS AND MONITORING INSTRUMENTS (OPHTHALMOLOGISTS, OPTOMETRISTS, NURSING STAFF, ASSISTANTS, ETC.).

THIS EQUIPMENT MUST BE OPERATED USING A POWER SUPPLY APPROVED BY VISIOMETRICS.

THE EQUIPMENT MUST NOT BE POSITIONED IN A WAY THAT HINDERS ACCESS TO EQUIPMENT'S POWER CONNECTION TO THE ELECTRICAL NETWORK.

TURN OFF OR UNPLUG THE DEVICE WHEN NOT IN USE.

TO AVOID THE RISK OF FIRE AND ELECTRIC SHOCK, DO NOT EXPOSE THE HD Analyzer ™ UNIT TO RAIN OR MOISTURE.

THIS DEVICE IS NOT WATER OR SPLASHPROOF. IF ANY LIQUID, WATER, OR MOISTURE GETS INSIDE THE INSTRUMENT, UNPLUG IT IMMEDIATELY AND CONTACT TECHNICAL SERVICES BEFORE USING THE DEVICE AGAIN.

KEEP THIS DEVICE DRY.

FOR INDOOR USE ONLY. IT IS NOT DESIGNED FOR OUTDOOR USE.

ANY ATTEMPT TO REMOVE THE CASING OF THE UNIT AND/OR ALTER THE UNIT WIL VOID THE WARRANTY.

TO GUARANTEE PROPER FUNCTIONING OF THE EQUIPMENT, IT SHOULD BE CALIBRATED ANNUALLY.

NOT SUITABLE FOR USE IN FLAMMABLE ENVIRONMENTS.

THERE ARE NO PARTS INSIDE THE DEVICE THAT CAN BE REPAIRED BY THE USER. CONTACT YOUR SUPPLIER OR TECHNICAL SERVICE.

IN CASE OF BROKEN OR DAMAGED EXTERNAL PARTS, PLEASE, CONTACT TECHNICAL SERVICES BEFORE USING THE DEVICE AGAIN.

DO NOT TOUCH THE GLASS OF THE EQUIPMENT'S OUTPUT WINDOW.

PRECAUTIONS

Do not attempt to disassemble, alter, or repair the HD Analyzer™ instrument. The instrument contains a class 3R laser product. Avoid direct eye exposure.

Do not expose the instrument to bright light such as sunlight for extended periods. Do not operate at temperatures above or below the recommended range.

This equipment must be connected to the electrical network. Take domestic precautions upon connecting it to the network.

If the equipment stops working normally, error messages will appear on the computer screen. In this case, do not try to repair it. Refer to your supplier or technical service.

If the equipment stops working or stops working normally (error messages appear on the computer screen) due to exposure, in reasonably predictable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or pressure variations, acceleration, thermal sources of ignition, or other causes, do not try to repair it. Refer to your supplier or technical service.

Contact VISIOMETRICS to ask for help.

1 INTRODUCTION

1.1 GENERAL DESCRIPTION

Due to the pressing need to measure visual quality in an objective way, VISIOMETRICS has developed the HD Analyzer™, an instrument based on the double-pass technique that provides an objective clinical evaluation of the optical quality of the eye.

It originated from an isolated light source produced by a laser beam whose image is formed on the retina of the eye. Upon reflecting on the retina, the light crosses the ocular medium twice. The HD Analyzer™ analyzes the size and shape of the reflected light source.

HD Analyzer™ images contain all the information about the optical quality of the eye, including high order aberrations and diffuse light, which are not usually taken into account by most aberrometric techniques. These higher-order aberrations can have a major impact on refractive surgery in the same way as diffuse light in the senile eye.

The HD Analyzer™ allows you to perform measurements in a variety of clinical situations. One of the most promising areas of application for the HD Analyzer™ is cataract detection and classification, as well as refractive surgery. Also, its functionalities for the evaluation of the pseudoaccommodation and for the evaluation of the degradation of the tear film over time are useful tools for the study of presbyopia and dry-eye syndrome.

The HD Analyzer™ has a measurement control and acquisition program that provides additional benefits: easy operation, intuitive working environment, and real-time control.

1.1.1 Double-pass technique

The Figure 1 sample shows a schematic diagram of a double-pass system similar to that of the HD Analyzer™.

The light source consists of a laser diode that is 780 nm in wavelength. The beam is spatially filtered and collimated. After the beam is reflected in a dividing film, it is transmitted by the L2 and L3 lenses that form a Badal system in the patient's eye. Through the FC moving head, to which two mirrors are attached, the correction of the spherical refraction of the eye to be measured is produced. This is achieved by modifying the optical paths between lenses L2 and L3.

Figure 1. Double-pass diagram
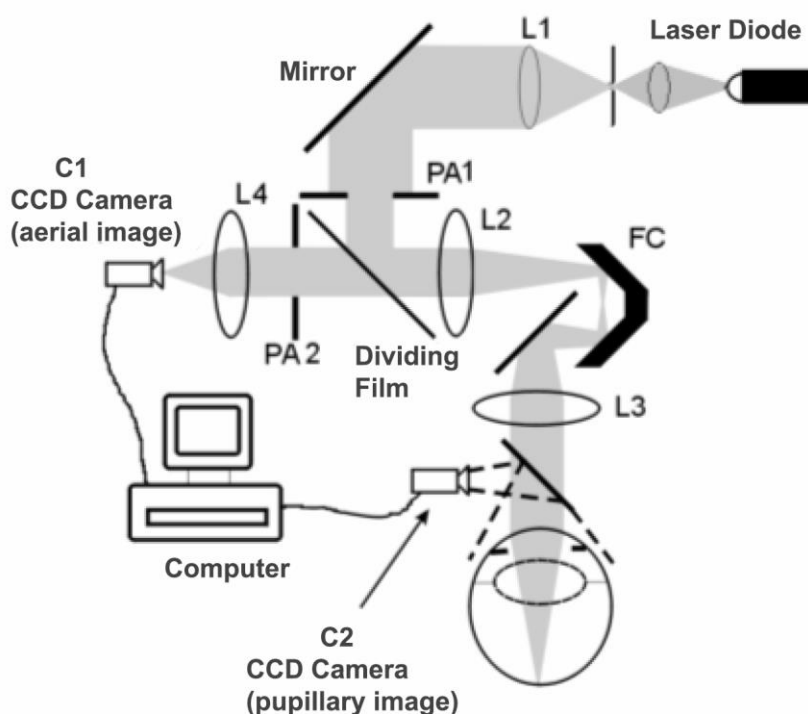
The eye forms the image of the isolated source on the retina. The optical path described so far constitutes the first step of the system.

The second step is that which the light determines in its path from the retina to the CCD camera (aerial or double-pass image). This path starts with the light that is reflected in the retina with a certain pattern due to the diffusive behavior of this

surface. The reflected light passes through the ocular optics, from the Badal system to the beam splitter. The transmitted light finds in its path the second artificial pupil (PA2) that is combined with the pupillary plane of the eye. This pupil is variable and acts as the effective exit pupil when the natural pupil of the eye has a diameter greater than PA2. The effective pupil will always be the smaller of the two. A lens focuses the aerial image on the CCD camera. Measurements can be made with different pupillary outlet diameters (PA2).

1.1.2 What is OSI?

OSI = Objective Scattering Index

OSI is a parameter that allows the objective evaluation of intraocular scattering. It is calculated from the assessment of the amount of light that is on the outside of the patient's double-pass image, relative to the amount of light in its central part. Accordingly, the higher the OSI value, the greater the level of intraocular scattering.

It is the only objective parameter that allows the objective quantification of intraocular scattering. It is of interest in all clinical situations where there may be diffuse light: cataract development and surgery, refractive surgery, intraocular lenses, age, dry-eye syndrome, etc.

The OSI has proven its validity for a new objective classification of cataract development, more robust and precise than the subjective ones that have existed up to now. For eyes with a normal scattering level (young) the OSI value is less than 1.0. For eyes in which a cataract is developing, the OSI value is between 1.5 and 4. For eyes with mature cataract the OSI value is greater than 4.

1.1.3 What is MTF?

MTF = Modulation Transfer Function

The MTF of an optical system is a function that allows for the evaluation of the degree of detail that the system is able to distinguish, or similarly, it evaluates the relation between the contrast of the **real scene** and the contrast of the **image** that forms the system. Our eye is an optical system, so it also has an associated MTF, and it indicates how much the contrast decreases in the image formed in the retina with respect to the real scene.

In any optical system, the contrast reduction is greater for high spatial frequencies (fine details and contours in the image). Therefore, in our case, of the following bar codes, the codes on the right are perceived as grayer (lower contrast) than those on the left, despite them all having the same definition. This agrees with the fact that the more details and contours (greater spatial frequency) there are in the **real scene**, the more the contrast between those details and contours is reduced in the **image** formed in our retina.

Figure 2. Bar patterns with different spatial frequencies

Therefore, MTF is a function that relates the spatial frequencies, measured in cycles per degree, with the decrease in contrast obtained for each of them in the image of the system, in our case, the image formed in the retina.

In the following figure we have symbolized, with a key, a distance that we will assimilate to a degree. We can observe that the number of complete space cycles (pattern formed by one black and one white stripe) that fall in a degree, varies according to the frequency. For the first bar code, the spatial frequency is 1, while for the following it is 2, 4, 8 and 16, respectively. In fact, the higher the spatial frequency, the lower the contrast in the image formed in the retina.

Figure 3. Bar patterns with different spatial frequencies and reference mark symbolizing a degree.

If the contrast in the system image were the same as the contrast in the **real scene**, the MTF value would be 1, the maximum possible. As the frequency increases, the MTF decreases because the contrast in the **system image** is increasingly less than the **real scene** contrast. This relationship, expressed mathematically, is the following:

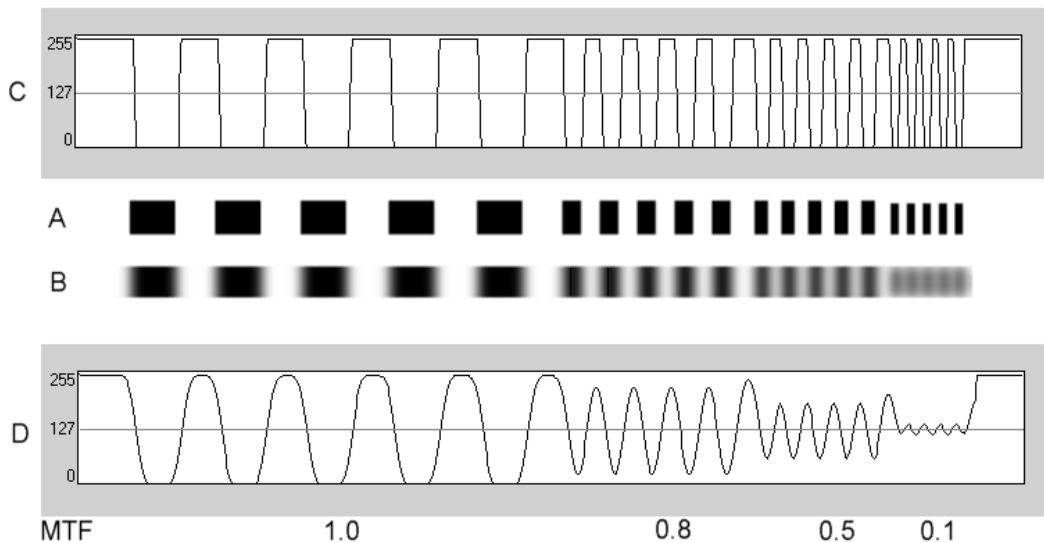$$\frac{Contrast\ of\ system\ image}{Contrast\ of\ real\ scene}$$

Figure 4. Comparison of the contrast (C) of the real scene (A) with respect to the contrast (D) of the image formed by the optical system (B).

And finally, if we represent the curve of the MTF in a graph, we get something similar to the following:
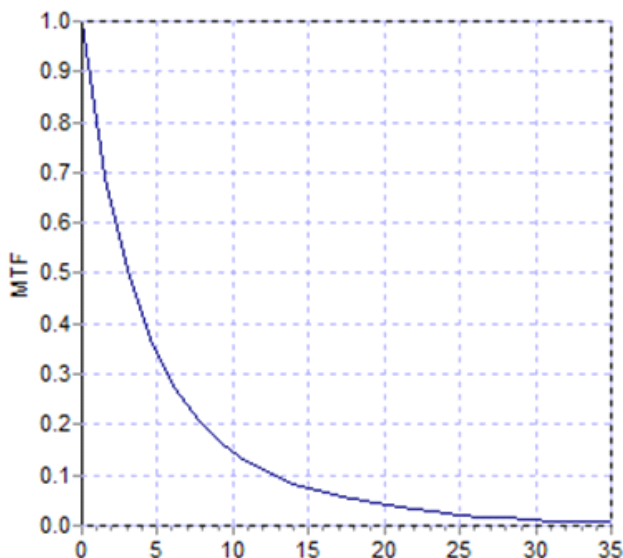
Figure 5. MTF graph: in the Y axis, the frequencies, in the X the MTF associated with each one.

The MFT also varies with the size of the pupil. It is therefore important to look at the pupil's diameter with which different measurements were taken before comparing them. This value will be the one we chose as an artificial pupil before the acquisition, provided that it is smaller than the actual pupil diameter of the patient. Since the patient's pupil dilates and contracts consistently, we recommend performing the measurement with an artificial pupil diameter that is less than the natural pupil diameter, so that the measurement conditions are reproducible.

1.2 CHARACTERISTICS

- Quantitative and objective assessment of intraocular scattering.
- Quantitative and objective assessment of the optical quality of the eye.
- Quantitative and objective assessment of optical quality loss due to tear film degradation.
- Quantitative and objective assessment of pseudo accommodation.
- Qualitative assessment of the quality of the eye through two-dimensional and three-dimensional maps of the double-pass retinal image, as well as the simulation of the image of a scene projected onto the retina.
- Assessment of the position of the optical axis with respect to the center of the pupil.

- In case an inlay KAMRA™ is implanted, assessment of the position of the implanted inlay with respect to the center of the pupil and with respect to the optical axis.
- Tools for optimal visualization and quantification of images, such as zoom, rotation, profiles, and measurements on the image.
- Patient database useful and easy to use.
- Print reports with the results and measurement data.
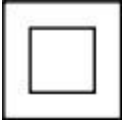- Easy acquisition and manipulation of images.

1.3 APPLICATIONS

- Assessment of intraocular scattering degree (OSI) for the early detection of cataracts or to determine their degree of maturity. Objective measurement of halos and glare.
- Comparison of pre- and post-surgery cataract and refractive surgery.
- Assessment of the quality of the tear film, especially in patients suffering from dry eye.
- Objective measurement of the pseudoaccommodation range.
- Diagnosis of pathologies.
- Precise measurement of the ocular MTF (Modulation Transfer Function) in all situations. The aberrometers overestimate the MTF when there is scattering produced, for example, by cataracts.
- It shows the effect of ocular aberrations on visual acuity (including higher order aberrations, which are not usually taken into account by most standard aberrometers).
- It shows the effect of lacrimal film degradation on the quality of the retinal image.
- Assessment of the Purkinje image of an eye without an implanted KAMRA™ inlay, detecting the exact position of its optical axis with respect to the center of its pupil, and allowing one to see the position required for the correct implantation of the KAMRA™ inlay.
- Assessment of the Purkinje image of an eye with an implanted KAMRA™ inlay, detecting the exact position of the implanted inlay with respect to its optical axis, allowing one to quantify how close the implanted inlay has been positioned with respect to its optimal position (the optical axis).

1.4 TECHNICAL SPECIFICATIONS OF THE HD ANALYZER™

1.4.1 Hardware specifications

	Type B	
Scope of measurements:	Between +5 D and -8 D E.E. (upper ametropias, including astigmatism, must be neutralized with an additional lens) • Reproducibility: +/- 0.25 D • Precision: +/- 0.25 D	
Repeatability of the diopter value with the best focus:	± 0.125 D of the middle point	
Measurement of the natural diameter of the pupil:	Automatic • Precision: +/- 0.5mm (for a pupillary diameter of 8mm)	
Artificial diameter of the pupil:	From 2 to 7 mm	
Image capture time:	240 ms	
Laser diode wavelength:	780 nm	
Selection of laser power:	Automatic	
Maximum laser power in pupil plane:	45.39 µW	
Best focus position:	Automatic	
Fixation target:	Landscape with house	
XY Movement:	Joystick	
Size:	415 (L) x 350 (An) x 530 (Al) mm	
Recommended work space:	2.5 m²	
Weight:	20 kg	
External power supply:	Entrance: 100-240 VAC, 50-60 Hz, max. 1 A Exit: 12 V DC, 3.5 A, 42 W	
Environmental conditions	Temperature	Relative humidity
Functioning	+10 ºC to +35 ºC	30% to 90%
Storage	-10 ºC to +55 ºC	10% to 95%.
Transport	-40 ºC to +70 ºC	10% to 95%
Regarding the Purkinje measurement:		
Selection of laser power:	Automatic	
Purkinje detection:	Error less than 142 µm in more than 95% of the measurements.	
Detection of offset Purkinje - inlay KAMRA™		
Detection of offset Pupil - inlay KAMRA™		

Class II	*This symbol indicates that the degree of electrical insulation of the HD Analyzer™ with respect to the power feed parts is Class II. This means that there is double electrical insulation, so a safety grounding point is not necessary.*

1.4.2 Program specifications

CPU:	Compatible with Pentium 1.6 MHz or higher
RAM:	512 MB minimum
Screen resolution:	Minimum 1280 x 768; recommended 1366 x 768
Operating system:	Windows XP, Windows Vista, and Windows 7 (32 bits)
Minimum USB ports	1 USB 2.0 port

1.4.3 Accessories

1.4.3.1 Computer (PC or laptop).

Used to run the instrument control program. Must meet the following minimum specifications:

Processor:	2.10 Ghz, 3 MB
Screen resolution:	Minimum 1280 x 768; recommended 1366 x 768
Memory:	4 GB 1600 MHz DDR3
Hard drive:	320 GB
Operating system:	Windows XP, Windows Vista, and Windows 7 (32 and 64 bits)
Minimum USB ports	1 USB 2.0 port (2 recommended)

1.5 PRODUCT SERVICE LIFE

The power supply delivered with the HD Analyzer™ equipment has a 3-year service life and must be replaced after this time.

⚠	*This equipment must be operated by using a power supply approved by Visiometrics.*

VISIOMETRICS estimates that the useful life of the equipment, having properly replaced the power supply, is 5 years. Regular use of the HD Analyzer™ over a 5-year period places the dynamic elements of the equipment below 15% of their service lives.

1.6   ACCURACY OF THE MANUAL

It is possible that some of the screens shown in the various images in this manual do not match the visible screens of your program with total accuracy.

In any case, the possible differences will be due to different setup options.

2 HD ANALYZER™ HARDWARE INSTALLATION AND MAINTENANCE

2.1 HD ANALYZER™ INSTALLATION

Installation of the HD Analyzer™ equipment must be carried out by an authorized installer.

The equipment is not designed to be portable. Once installed, moving it to another location is discouraged. If it is necessary to move it to a nearby location, we recommend that two people move it, lifting the instrument by its base, each person on one side of the instrument.

> ⚠️ ***Never seize the HD Analyzer™ except from its base. The moving part is very fragile and could damage the interior elements.***

If transport to a distant location is necessary, you should contact your local distributor or the manufacturer to carry out the packaging process correctly and the subsequent installation at the new destination.

2.2 MAINTENANCE AND CALIBRATION

Calibration

It is recommended that you contact your distributor to perform a calibration once a year. The user must not carry out any calibration work on this equipment, as this must be carried out by specialized personnel.

The unit label contains the date of the next recommended calibration. In addition, the program itself, in its setup, stores that date, so it will notify you 30 days before that date, or when it detects that date has already passed.

Cleaning

The only maintenance operation to be performed on the equipment by the user is cleaning, which must be performed as explained below.

Always unplug the HD Analyzer™ before cleaning. Wipe the plastic surfaces with a soft cloth slightly moistened with water. Do not use solvents or abrasive cleaners.

Disinfection

The HD Analyzer™ has a risk of infection derived from its use since the patient is in contact with the instrument through the skin via the chin and forehead that rest on the chin rest, and through the hands with which they can grasp the chin rest.

This risk, which can be classified as Non-Critical, and as a consequence will only require a low level of disinfection, is further minimized by the use of protective paper for the chin area (the instrument comes with an initial pack of 100 papers).

The patient is in contact with the instrument through intact skin via the chin and forehead that rest on the chin rest, and through the hands with which they can grasp the chin rest. These contact areas can be periodically disinfected using a disinfectant with a low disinfection level such as quaternary ammonium compounds.

It is recommended that this maintenance work be carried out on a quarterly basis.

- *Keep this device dry.*
- *For indoor use only. It is not designed to be used outdoors. Only for professional use.*
- *Turn off or unplug the device when it is not in use.*
- *This device is not water or splash proof. If moisture, water, or liquid gets inside, immediately unplug it and contact technical services or your provider before using the device again.*
- *In case of technical problems, never remove the side covers as there are no parts inside that can be repaired by the user. Refer to your supplier or technical assistance services.*

3   FUNCTIONING OF THE HD ANALYZER™

3.1   USING THE PROGRAM WITHOUT THE HD ANALYZER™

The program allows you to view saved data without the need to connect to or turn on the HD Analyzer™. All operations that the database allows you to perform (see section 3.4) can be performed without the instrument.

3.2   USING THE PROGRAM WITH THE HD ANALYZER™

3.2.1   User guidelines

The HD Analyzer™ allows you to perform eye measurements with or without correction. The program itself, when indicating the subjective refraction of the patient, will show you the different ways in which each of the patient's eyes can be corrected, and will indicate which ones are advisable. At this point, you can select the mode chosen for correction from all those available.

It is important to emphasize the following:

- Purkinje measurements do not require any external correction. Therefore, when performing a Purkinje measurement, do not use...
  - o   any type of astigmatic lens,
  - o   the patient's own glasses, or test glasses,
  - o   or contact lenses.
- Progressive lenses could impact the results. When correcting with progressive lenses, pay particular attention to the position of the head and glasses in order to try to have all measurements taken through the same area of the lens.
- The use of contact lenses can affect the tear, so it is recommended not to take "Tear" measurements while wearing contact lenses.
- Avoid the use of multifocal contact lenses.

In addition to the correction applied, the behavior of the patient during measurements is also very important. Inappropriate patient behavior may lead to inaccurate results.

> ⚠️ *It is recommended that all measurements be taken in rooms with low and constant luminosity, to facilitate the dilation of the pupil.*
>
> *It is also recommended to avoid direct airflow to the patient, so as not to affect the patient's blinking rate.*

To minimize these situations, you should be clearly aware of the behavior that the patient should follow, and appropriately transmit that to the patient.

Below, you can find a detailed account of expected patient behavior during the different measurements.

3.2.2 Patient guidelines

3.2.2.1 General guidelines

Before beginning the measurements, it's important to place the patient correctly and in a comfortable position.

To do this, make sure that the hygienic guards are correctly positioned in the chinstrap of the HD Analyzer™, and move the mobile part of the device to the position that is farthest from the patient. In addition, it is recommended that all measurements be taken in rooms with low and constant brightness, in order to facilitate the dilation of the pupil. Additionally, avoid direct airflow to the patient, so as not to affect the patient's blinking rhythm.

The patient must place his/her chin on the hygienic protector of the chin rest. With the aid of the instrument's joystick, move the headpiece towards the patient while keeping the patient's pupil centered on the image until the pupil appears to be focused on the image. Ask the patient to try to relax and feel comfortable.

3.2.2.2 Instructions to the patient during the "Best Focus" measurement

When initiating the sequence to determine the objective refraction (*Best Focus*), let the patient know that the stimulus will appear unfocused at times, and that he/she

should not try to focus it, but rather simply look at the focus point in a relaxed manner throughout the sequence.

3.2.2.3 Instructions to the patient during the "OSI" and "Light Condition" measurements

When initiating the sequences to determine the optical quality (OSI and Light Condition), ask the patient to try to focus on the focus point at all times.

3.2.2.4 Instructions to the patient during the "Tear Film" measurement

At the start of the tear film analysis sequence, ask the patient to look at the focus point in a relaxed manner.

If the measurement is performed following sound patterns, ask the patient to blink only when he/she hears the sounds.

If no sound pattern is followed, have the patient try not to blink, or blink as little as possible, during the entire process (20 seconds).

Also, advise the patient to close the eye not being analyzed to avoid stimulating the lacrimal glands and producing "extra" tears.

3.2.2.5 Instructions to the patient during "Depth of Focus" measurement

The pseudoaccommodation sequence (Depth of Focus) is solely indicated for those patients that have, to a great extent or even totally, lost their ability to accommodate. Regardless, at the start of the sequence, the patient is asked to try to focus on the stimulus at all times.

3.2.2.6 Instructions to the patient during the Purkinje sequence

At the start of the Purkinje sequence, the patient is asked to center his/her vision on the red dot. The patient is also asked to try not to blink while the software captures the images.

3.3   START MENU

The first time the program is opened, a notification pops up advising one to the read the user manual before using the program.

After accepting, the program will display the usual home screen as well as the days remaining until the next recommended calibration. If there are fewer than 30 days left, it will clearly state this at the bottom part of the screen. When this occurs, contact your distributor to schedule a calibration.

Figure 6. Home screen (*Home*)

Most times when running the program, after the home screen you head to the Database. To save time, the program automates this step, and after briefly displaying the usual home screen, it brings up the Database screen.

With the buttons on screen, you can access the following options:

- • *Database*: Allows access to the patient database in order to edit, view, compare, print, and delete previously saved results. You can always access the database through this button, even though the software runs it without having the equipment connected.

- *No hardware - Restart*: This is only visible if the program could not detect the hardware on startup. It allows you to restart the program and redetect the hardware quickly.

- *Backup*: Allows you to make a backup copy of the patient database and related images into the desired directory.

- *Setup*: This button displays the setup screen where some of the system parameters can be modified. Each parameter is detailed in later chapters.

3.4   DATABASE

The software contains an easy-to-use database, accessible via the *Database* button.

3.4.1   General description

From this screen you can add new patients and modify or delete existing ones. You can also select a patient to begin performing the measurements.

Figure 7. Patient database

The *Patient* field allows searching patients by name, surname, patient ID, and a range of dates (date of birth, last measurement, or any other measurement).

Figure 8. Patient searcher, no filter applied

By applying the various filters, the list of patients narrows down.
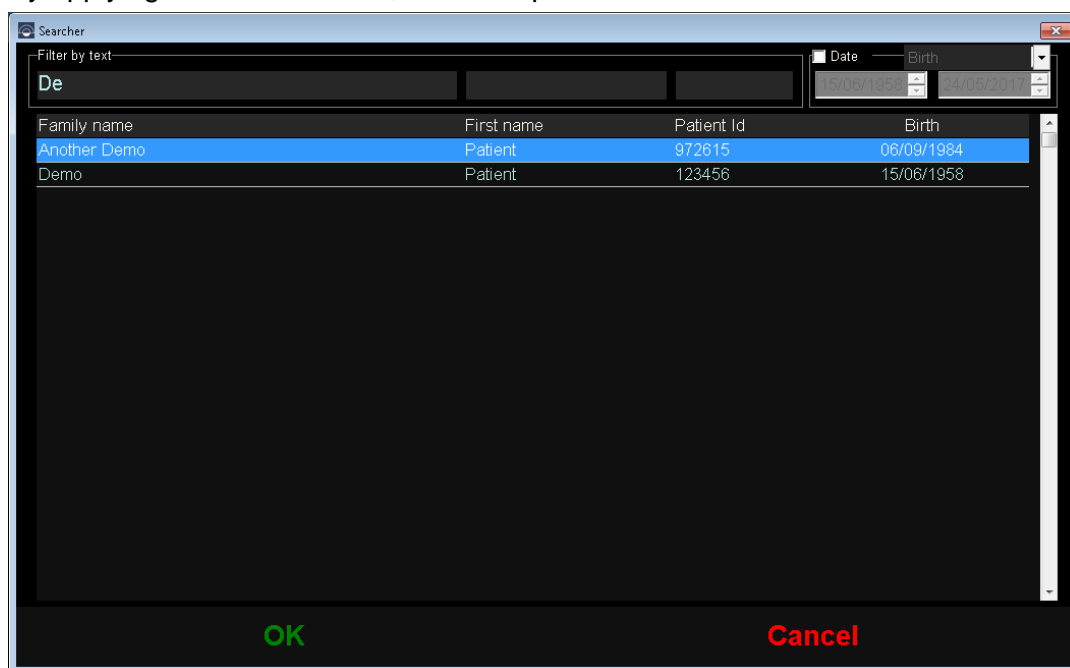
Figure 9. Patient searcher, filter applied

Once the desired patient is displayed, select it and press Enter, or double-click it, to load it onto the Database screen.

Now the Database displays all the details for this patient, and you can perform new measurements, or load and analyze existing data.

3.4.2 Working with patients

3.4.2.1 Add data on a new patient

To add data on a new patient to the database, click on *New* and all fields will now become editable. *Patient ID* (patient's identification number), *Name, Surnames*, and *Date of birth* are required fields. The rest of the fields are optional.

Click *OK* to register the new patient, or *Cancel* to return to the previous screen.

3.4.2.2   Modify data on an existing patient.

Select the patient whose data you wish to modify and click *Modify.*

Make the changes needed and click *OK* to register the new data. A dialog box asking to confirm the changes will be displayed. If confirmed, the changes will be saved. If not confirmed, it will bring you back to the data modification screen. Click *Cancel* to cancel the changes made.

Figure 10. Modifying data

3.4.2.3   Delete a patient's data

Select a patient whose data you wish to delete and clickon *Delete*.

You will be asked to confirm before deleting the patient's data.
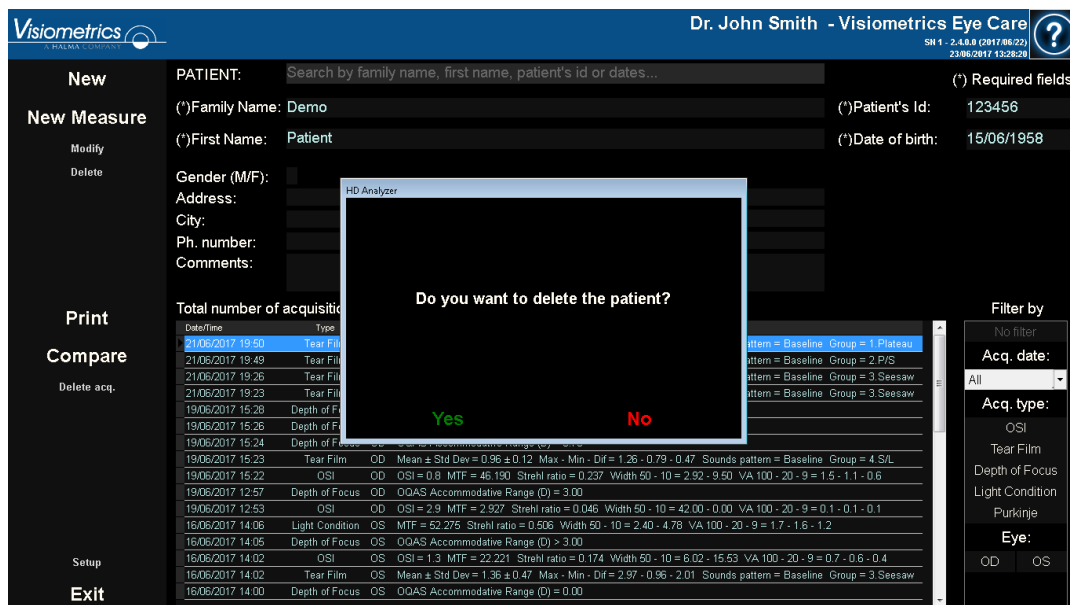
Figure 11. Confirming the deletion of a patient's data

> ⚠️ ***By deleting a patient's data, you will have erased all information and images associated with that patient. Make sure that you are deleting the correct patient's data.***
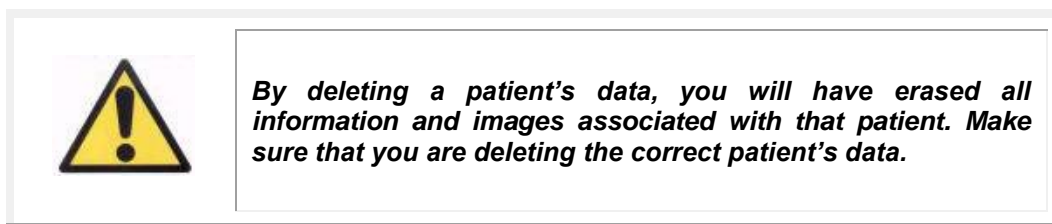
3.4.3   Working with measurements

3.4.3.1   Loading a specific measurement

Once the patient is selected, their previously saved measurements will be displayed. Here they can be retrieved for analysis, printing, comparison, etc. By default, the entire list is shown, but you can apply different filters using the buttons to the right of the list. You can also order the list through any of the existing columns by clicking on the title of said column. The following information is displayed for each acquisition:

- *Date/Time:* Date/Time of acquisition
- *Type*: Type of acquisition.
- *Eye*: OS for left eye, OD for right eye.

- *Information:* A summary of the most relevant numeric indicators from the measurement. If the measurement has notes associated with it, this will be shown in these values.

To load a measurement and see its results in detail, simply double-click it, or select it and press Enter.

3.4.3.2 Printing various measurements

This option allows you to print a series of measurements at the same time, avoiding the need to load each separate measurement manually.

Simply select those which you would like to print by holding Control and click. Once selected, click *Print*.
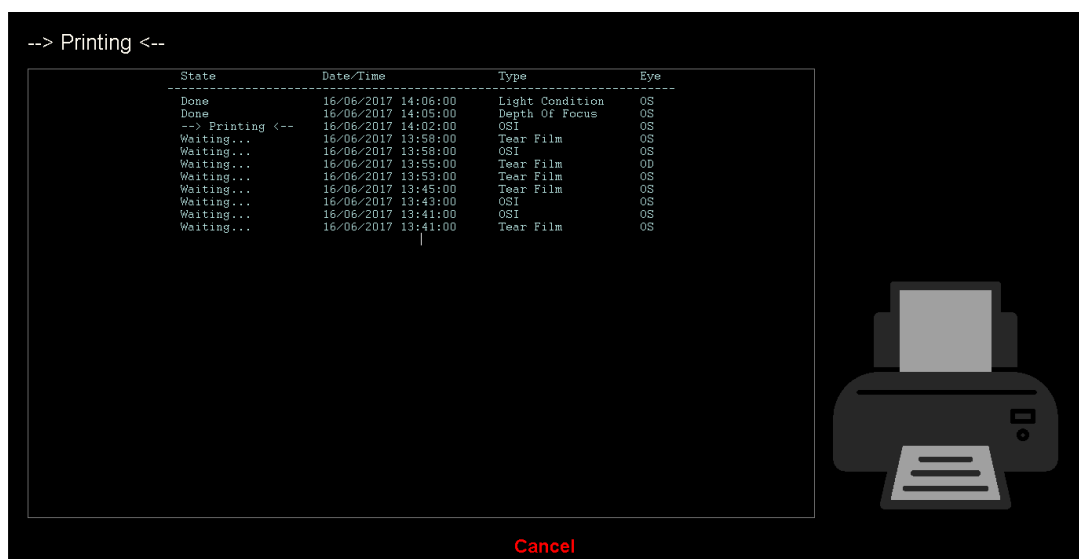
Figure 12. Printing process

The program will use the computer's default printer.

3.4.3.3 Comparing various measurements

This option allows you to load two different measurements simultaneously and compare their results. To do this, click *Compare*. The program will ask you to select the first measurement to be compared. Select it and click *OK*. Then select the

second measurement. It may be from the same patient or not, but it must be of the same type. Click *OK.*

It must be noted that you cannot load and compare different Purkinje measurements.

See section "3.5.4.4 Result comparison screens" for more information on comparison screens.

3.4.3.4 Deleting measurements

To delete an acquisition in the patient's history, select it and click *Delete Acq.* You will be asked to confirm before deleting.

3.5 MEASUREMENTS

To access the measurements screen, you must first access the Database screen. Next, select the patient you wish to take measurements from, and finally click on *Measure.*

You will be then asked to enter the subjective refraction values for the patient.

This information is needed for the instrument to search for the best spherical refraction correction around a determined range, thus obtaining more reliable, accurate, and faster results. *Sph* (sphere), *Cyl* (cylinder) and *Axis* (axis) are required fields for both eyes.

If the patient has never been studied previously, the window to enter the subjective refraction will appear empty.

Figure 13. Entering the refraction, without information

If the patient has been studied before, the program will fill in the sphere, cylinder, and axis fields with the last accepted values for that patient.

Figure 14. Entering the refraction, with information already entered

The instrument is able to correct automatically the equivalent refractions (spherical refraction + cylindrical refraction/2) within the range of +5D to -8D, as long as the astigmatism is less than or equal to 0.5D. In any other situation, the instrument requires external assistance. This may be:

- Cylindrical corrective lenses, located in the head of the unit.
- Glasses or trial frames.
- Contact lenses.

The program itself, depending on the information entered, will display how both patient's eyes can be corrected, hiding the corrective modes that do not apply, and highlighting the most recommended mode.

Depending on the selected correction modes, the program may display some warnings to keep in mind while the measurements are being taken.

You may also enter the best corrected visual acuity (BCVA) and the uncorrected visual acuity (UCVA) as additional information to be included in the printed results report, via the "..." button, located under the warning dialog box.

Figure 15. Subjective refraction (enlarged view)

Once you have entered the values, click *OK* to access the main measurement screen.

3.5.1 How to perform an acquisition

The screen is divided in six different parts (see Figure 16):
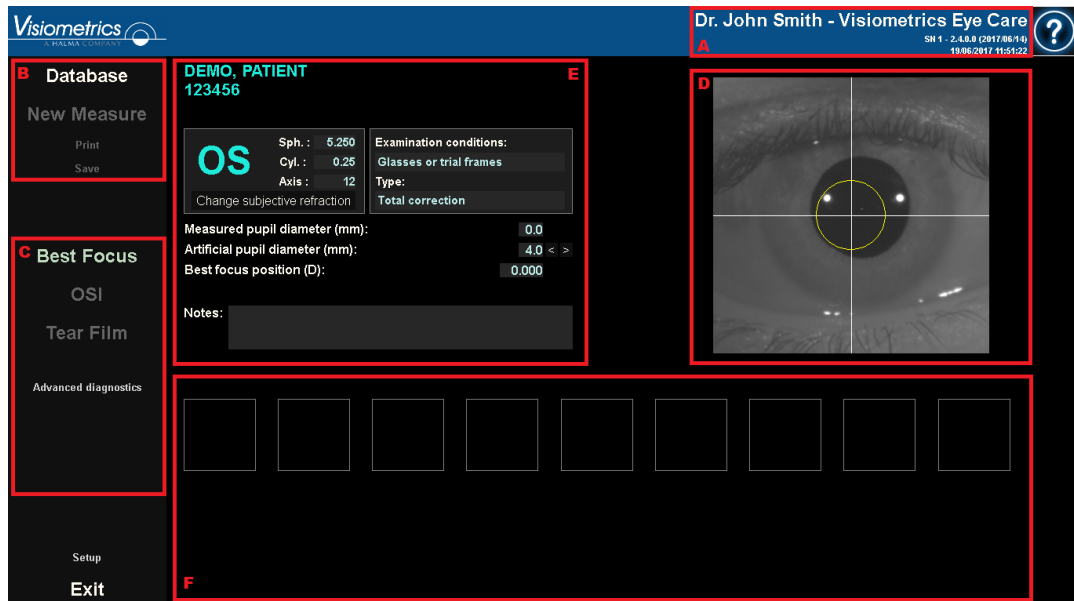
Figure 16. Main measurement screen

A. **General information:** In the top part of the screen, you will see the name of the doctor and medical center. This can be modified by means of the *Setup* screen. It also shows the unit's serial number and software version being run.

B. **Main functions:** Using these buttons you can carry out the various operations related to data processing, such as accessing the database (see section 3.4), and saving or printing results.

C. **Types of measurement:** Although some measurement buttons may be inactive at first, they later become active after running the Best Focus sequence. All the available types of measurement are detailed in later sections of the manual.

D. **Live image:** This window displays the patient's eye in real time, allowing the user to center and focus on the image of the pupil.

      E. **Input data:** Aside from displaying the selected patient's data, this section also allows you to enter or correct the values taken into the measurement (to be further explained in this section).

      F. Two types of information can be shown in this section:
- ○ *Best Focus* **view:** View of the status and search results of the best spherical refraction correction.
- ○ **Acquisition results:** Once the measurement has been taken, you can see all numeric results obtained for measurements relating to OSI, Light Condition, Depth of Focus, Tear Film, and Purkinje, as well as the parameters entered by the user (3.5.3.3).

Data on the selected patient also appears on the main screen alongside the eye to be measured, which is automatically detected by the instrument. Spherical refraction (*Sph.*)*,* cylindrical refraction (*Cyl.*), and the axis (*Axis*) are shown in their respective fields, as well as the conditions under which the measurement was taken. Please ensure that these values are correct. If they are incorrect, you can modify them by clicking *Change subjective refraction*, highlighted with a red box in the following screenshot.

Figure 17. Data relating to the patient's eye and refraction

It is important to enter correct values for the subjective refraction of the patient since, when performing the Best Focus sequence, the system searches for the best correction of the patient's spherical refraction within a ±3D range around the spherical equivalent of the subjective refraction entered by the user. If the values entered are incorrect, the system will produce an erroneous spherical correction, in turn making the rest of results incorrect as well.

> *The patient's subjective refraction is needed to carry out the Best Focus sequence. If the patient's refraction is ±3D over the indicated results, said sequence may give out an erroneous result.*

3.5.2 Best Focus

See the indications relating to the patient in section 3.2.

Click on *Best Focus* to begin determining the optimal correction of spherical refraction.

This process is necessary to avoid the presence of blurring on the double-pass images, which may hide other underlying problems. Consequently, the optimal spherical correction must be determined before performing any other measurement. Using the 5-mm artificial pupil, HD Analyzer™ searches for the best image of the point projected on the retina, making a sweep for different spherical refraction corrections in order to correct the focus.

While this process is taking place, the user can see the double-pass images that the program records. Once finished, the program automatically selects the double-pass image it considers to most in focus and displays the corresponding refraction in the *Best focus position* field.

By default, the refraction associated with the *Best focus position* will be applied to all other measurements. If you wish to apply a different refraction, click on the corresponding image. The image will be highlighted in yellow and will appear in the *Select best focus position* with the corresponding value. You can also select other refractions via the tool in this field.

> *Note that modifying the selected focus position parameter may retrieve an incorrect or unexpected measurement. Modify the value of this parameter only if you are complete sure that it should be changed.*

Figure 18. Best Focus *sequence*

Now the HD Analyzer™ is ready to begin the sequencing of any measurement, activating the corresponding buttons. It also possible at this point to have the program automatically begin the OSI measurement sequence.

3.5.3 Types of measurement

3.5.3.1 OSI and Light Condition
See the indications relating to the patient in section 3.2.

The OSI measurement (index of scattering or diffuse light), by defining the OSI parameter, can be carried out using the 4-mm artificial pupil, regardless of the value being entered. Entering this diameter is therefore not necessary.

Light Condition (assessment of optical quality for distance vision) can be established in the artificial pupil diameter you wish to use in the measurement. Select the desired value in the *Artificial pupil diameter.*

In both cases, if the program detects that the patient's pupil is inferior to that of the artificial pupil being used in the double-pass image capture, a warning will display at the end of the sequence.

Click on either of the two buttons to begin the corresponding sequence. These sequences basically consist in the capture of six double-pass images within the selected conditions of best spherical correction (distance vision), and its processing.

Depending on its settings, the program will jump to the next screen after capturing the six double-pass images. This may be:

- *The screen to validate each of the six double-pass images captured before processing them.*
- *The screen of the results selected in the user's options via the setup screen. In this case, it may also show the six double-pass images captured if set up this way.*

In either case, the double-pass images are marked in green when the program considers them to be correct. It also allows you to delete the ones you do not consider to be valid by selecting them with the mouse. The unwanted images will be marked in red. The images are then processed and analyzed by clicking on *Results*, displaying the results with different viewing options (see section 3.5.4.1 OSI and Light Condition).
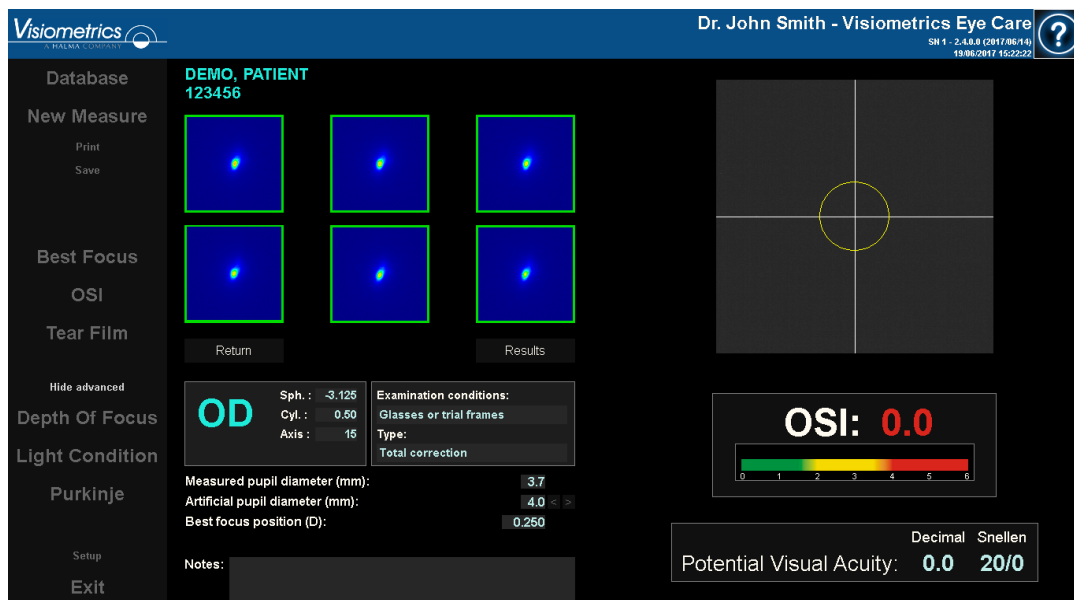
Figure 19. Diffusion *measurement*

3.5.3.2 Tear Film

See the indications relating to the patient in section 3.2.

With *Tear Film,* you don't need to establish an artificial pupil diameter when running the sequence. In order to ensure that any tear degradation is detected, including the periphery of the patient's pupil, this process is performed using the maximum possible artificial pupil size (7 mm) regardless of the value entered.

The *Tear Film* sequence can be guided, or if not, through a pattern of sounds. The results will display different information depending on whether or not it was guided or through a pattern of sounds. To configure the default mode that carries out the tear film sequences, access the *Setup* screen (see chapter 3.6.2).

To begin the sequence using the pattern by default, click on *Tear Film.* If you want to run a specific sequence using a different pattern, you can do so by clicking the same button while holding down the *Control* key. Doing it this way also allows you to change the default pattern without having to access the *Setup* screen.

In any case, this process consists of recording double-pass images every 0.5 seconds until completing a 20-second capture. This way the program records 40

double-pass images, reflecting the evolution of the optic quality during those 20 seconds. The images are always shown as they are being recorded.

At all times, try to keep the patient's eye centered in the coordinate axis of the visor, thus guaranteeing that any variation among the double-pass images is exclusively due to a change in the tear film.

The Figure 20 shows how the *Tear Film* images are being recorded.

Figure 20. *Tear Film* measurement

3.5.3.3 Depth of Focus

See the indications relating to the patient in section 3.2.

With *Depth of Focus* it's necessary to establish the artificial pupil diameter to be used in the measurement. Select the desired value in the *Artificial pupil diameter*. Click *Depth of Focus* to begin the pseudoaccommodation range sequence. This process is based on a sweep of four diopters [+1D, -3D] around the selected value, usually of the best spherical correction.

The system carries out increments of 0.5 D, taking double-pass images in each position until reaching the final position. The recorded images are shown on screen at all times.

Figure 21. *Depth of Focus* **measurement**

> ⚠️ ***Ask the patient to try to focus on the stimulus during the Depth of Focus process. Otherwise the results may come out incorrect.***
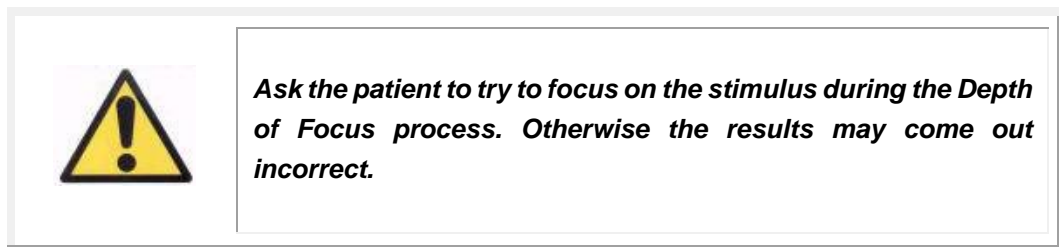
Keep in mind that, at times, the patient will not be able to see the stimulus clearly no matter how much it is accommodated. This happens when measurements are taken with refractions higher than the patient's best correction.

3.5.4 Monitoring of results

The screens with the results of the various types of measurement are presented in a common area (bottom left) which includes the parameters used in the measurement. These parameters are:

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

Sph., Cyl., and Axis: The subjective refraction values entered by the user before taking the measurement.

Examination conditions: Method used to correct the eye being measured.

Artificial pupil diameter: Artificial pupil diameter used in the measurement, entered by the user.

Measured pupil diameter: Patient's pupil diameter measured by the instrument. A value of 0.0 indicates that said diameter cannot be measured.

Best focus position: Best spherical correction found via the Best Focus sequence.

Selected focus position: Spherical correction used in the measurement. Only visible if it is different from the best focus position.

Acquisition notes: Notes related to the acquisition carried out and entered by the user. These notes can be later edited by the user.

The numerical results and the different available visualizations will depend on the particular type of measurement being used. Next, the various elements in each of the measurement types will be explained.

3.5.4.1   OSI and Light Condition

The results of these two measurements are shown in Figure 22 and Figure 23 respectively.
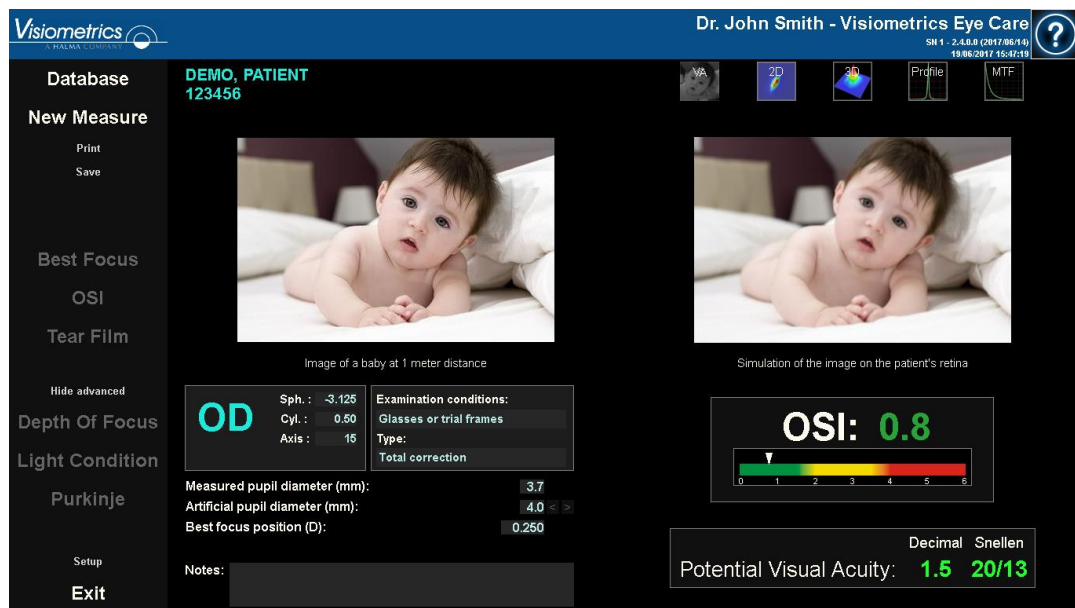
Figure 22. *OSI* **results**
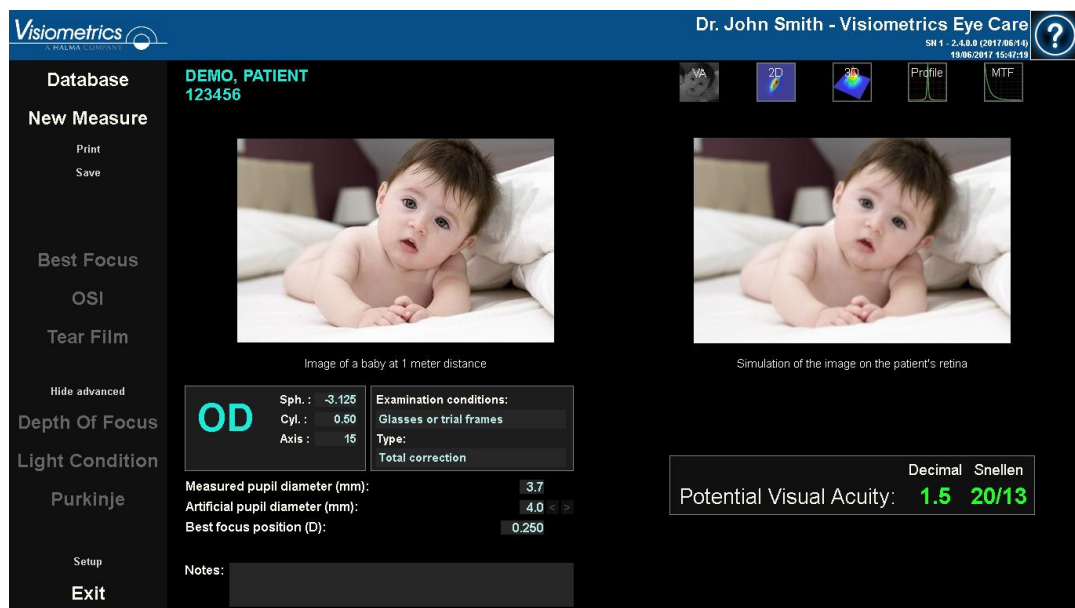
Figure 23. *Light Condition* **results**

The results given by the program in both measurement types are basically the same, with the exception of the OSI parameter (*Objective Scatter Index*), which is provided in the case of *OSI* (see section 1.1.2).

The screen displaying the results are divided into three clearly defined areas in Figure 24:
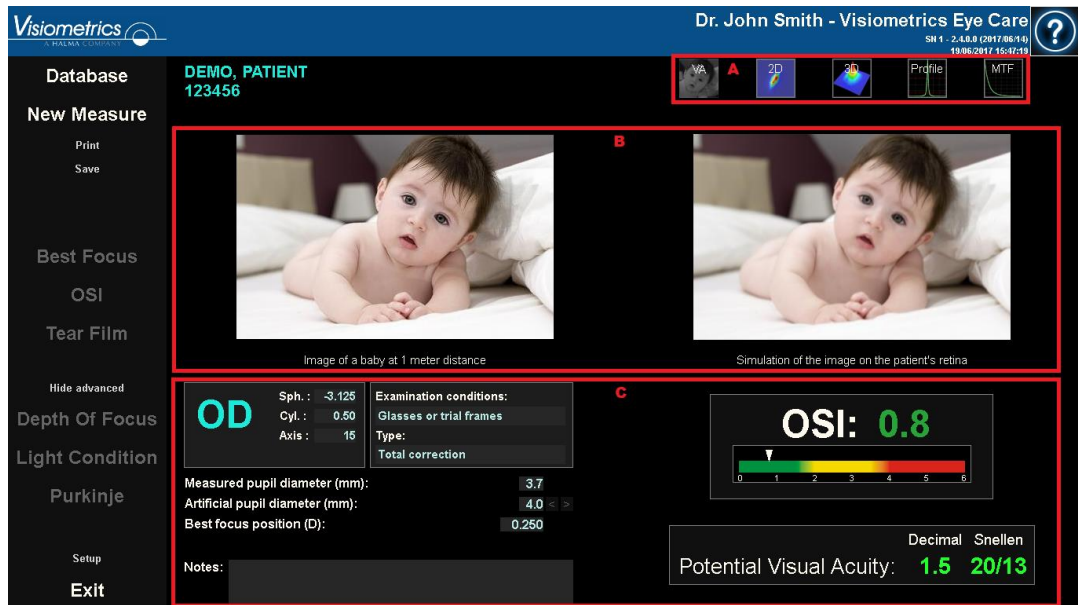
Figure 24. Areas of the result screen

A. **Button area:** These buttons give access to the different viewing options for the measurement results.

B. **Image view area:** Depending on what selection was made in section C, this area displays the images. Further detailed in this section.

C. **Input/output data:** This section contains the parameters used in the measurement and the most significant numeric results. The most representative results of the measurement are:

OSI: Only in the case of *OSI*. It is the *Objective Scatter Index*, which quantifies the degree of intraocular diffusion of the eye. For clarity, the value of OSI obtained on a color scale is also represented. This visually shows whether the value corresponds to a low, medium, or high degree of diffusion. Values in green represent eyes with little diffusion. Values in yellow represents eyes where the diffusion begins to be important (the beginnings of a cataract, onset of opacification of a lens, etc.). Values in red represent eyes with a significant degree of diffusion (mature cataract, etc.). The OSI value is colored according to the visible color scale under the value itself.

Potential Visual Acuity: It is the value of visual acuity that is estimated from the optical quality presented by the eye (*MTF*). It can be understood as the monocular visual acuity that the patient would present if it only depended on optical factors without taking into account the retina or the posterior neuronal processing. The result is shown in decimal and Snellen scales. The visual acuity value is colored according to a color scale that appears when you click on the value itself.
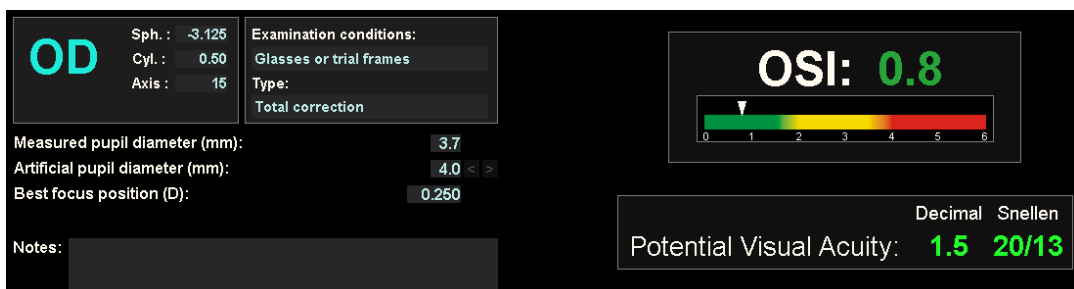
Figure 25. Input/output data

Next, each viewing option is further explained.

AV Simulation **view**

Click on the AV button in the buttons area of results to show the *AV Simulation* screen. This option is shown as default in processing the results.

The objective of this screen (Figure 26) is to show what the image of a daily scene would be like being formed in the retina of the patient. Specifically, it shows the image of a baby located 1 meter away from the observer.
On the left the original scene is shown, while on the right the image that would form on the retina is simulated. This simulation is carried out by means of the convolution of the PSF obtained in the measure with the original image of the scene. It is a sample of how aberrations and diffusion of the patient's optical system affect the formation of the image on the retina. The patient does not have to see as the screen shows, since only the optical quality of the eye is taken into account, not the subsequent neural treatment made to the retinal image.

Image of a baby at 1 meter distance   Simulation of the image on the patient's retina
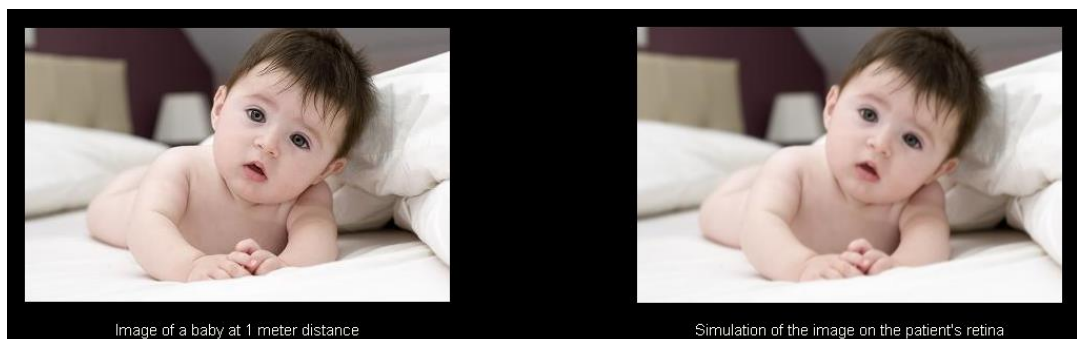
Figure 26. *AV Simulation* view

Both images (original and retinal) would appear very similar to a healthy eye without problems. For aberrated eyes, a blur of the image will be seen, making it harder to distinguish the details of the image. For eyes with high intraocular diffusion, there will be a clear loss of global contrast in the image.

It should be noted that other effects such as the appearance of halos or glare are not simulated in this image, so their presence should not be expected.

You can export the images by double-clicking with the left side of the mouse and specifying the desired directory. You can save them in either *jpg* or *bmp* format.

2D Display

Click on the *2D* button in the results button area to display the *2D* screen.

The Figure 27 shows the two representations of the retinal image. The left side of the screen shows the retinal image in 2D and the right-side zooms. The *zoom* allows you to zoom in and out of the image by pressing the *More* or *Less* buttons (the maximum magnification factor is 16 and the minimum is 2). The different levels of energy are represented by a color scale.

By clicking and dragging the mouse over the image on the left, you can select the area of the image that will be displayed on the right side, where you can apply the desired *zoom*. The scale of the images is displayed at all times at the bottom in minutes of arc.
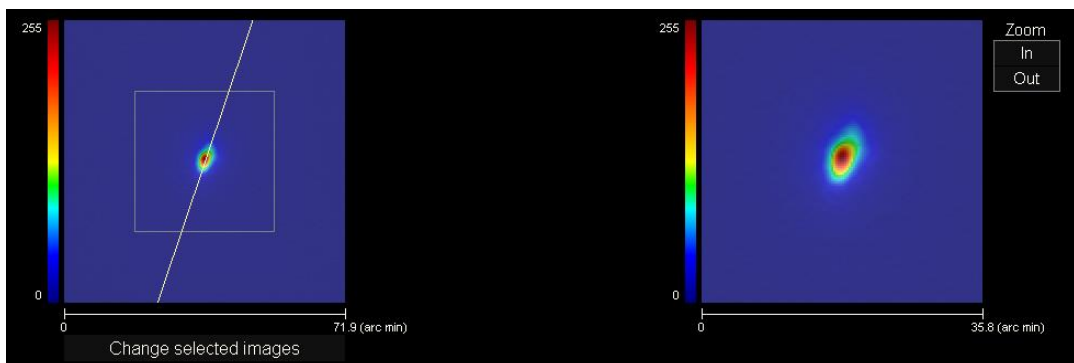
Figure 27. *2D* Display

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

You can export the images by double-clicking with the left side of the mouse and specifying the desired directory. You can save them in either *jpg* or *bmp* format.

3D Display

Click on the *3D* button in the results button area to display the *3D* screen.
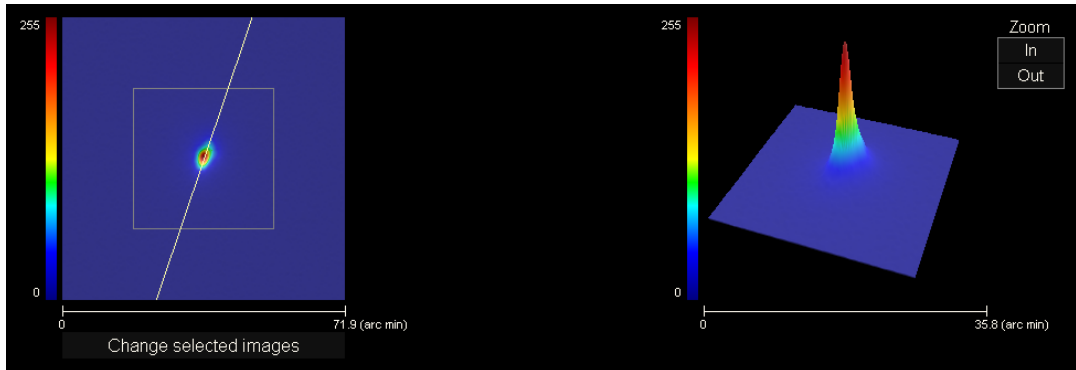
Figure 28. *3D* Display

The three-dimensional representation of the retinal image (Figure 28) is shown on the right side of the screen. The *zoom* allows you to zoom in and out of the image by pressing the *More* or *Less* buttons.

You can rotate the 3D image by simply dragging the mouse over it.

You can export the images by double-clicking with the left side of the mouse and specifying the desired directory. You can save them in either *jpg* or *bmp* format.

Profile Display

Click the on the *Profile* button in the results button area to display the *Profile* screen.
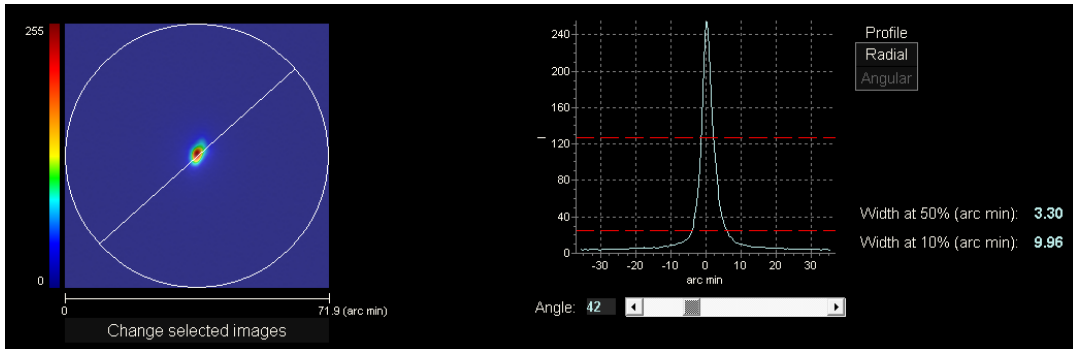
Figure 29. *Profile* Display

The right side of the screen shows the profile of the intensity distribution in the retinal image. By selecting a specific area of the graph with the mouse cursor, you can zoom in on that section. The zoom is increased starting from the top left, and decreases starting from the bottom right.

The radial profile shows the median profile. Choose the *Angular* display to view the profile at a particular angle. Move the cursor in the bar that opens under the image to change the angle.

The profile width values are also displayed at 50% and 10% of their maximum, respectively. Using these values, you can get an idea of the shape of the image profile.

To export the representation graph of the profile, double-click on the graph with the left side of the mouse and specify the desired directory. You can export it as an image (*bmp* or *jpg* format), or directly save the graphic data to a text file (*txt*).

MTF Display

Click on the *MTF* button in the results button area to show the *MFT* screen.

The MTF fully characterizes the response of an optical system. The MTF values give the quotient between the contrast in the image and the contrast in the object for each spatial frequency (see section 1.1.3). From this modulation transfer function, the visual acuity imposed by the optics of the eye is estimated for different contrasts (*AV Predicted 100%, 20%,* and *9%*). In this respect, it should be emphasized that this information, although similar to that obtained in subjective studies, such as the reading of Snellen's letter, is determined exclusively by the limitations imposed on the measurements by optical constraints, whereas in the subjective cases, neuronal processing aspects are largely involved. This visual acuity is shown on both decimal and Snellen scales.

The value of the cut-off frequency (*MTF* cut) is also displayed. The higher the cutoff frequency, the better the retinal image (see section 1.1.3). The value of the frequency is colored according to a color scale that appears when clicking on the value itself.

Another parameter provided by the system is the *Strehl ratio.* The Strehl ratio is a quantitative measure of the patient's eye quality and can be calculated as the MTF quotient of the eye and the MTF of a diffraction-limited system. Therefore, it will be a value between 0 and 1 and the greater it is, the greater the optical quality will be. For reference, for a normal young eye with a pupillary diameter of 4 mm, the value of the Strehl index is approximately 0.3.
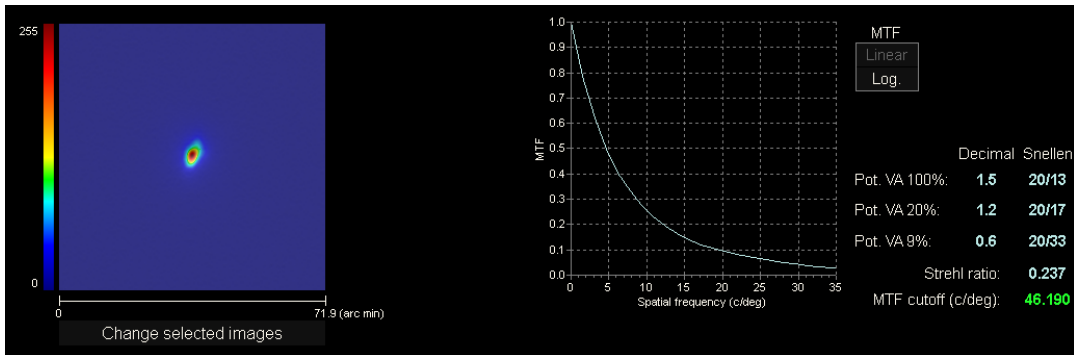
Figure 30. *MTF* **Display**

There are two representation methods for the MTF chart:

- The linear representation (*Lineal*), selected by default when the MTF graph is displayed for the first time, in which the MTF values are displayed in a linear scale.

- The logarithmic representation (*Log*), in which the MTF values are shown in logarithmic scale, which allows a clearer appreciation of the cut-off frequency (*MTF* cut-off).

This chart is displayed on the right side of the screen. By selecting a specific area of the graph with the mouse cursor, you can zoom in on that section. The zoom is increased starting from the top left, and decreases starting from the bottom right.

To export the MTF representation chart, double-click on the chart with the left side of the mouse and specify the desired directory. You can either export it as an image (*bmp* or *jpg* format), or directly save the graphic data to a text file (*txt*).

3.5.4.2   Tear Film

Depending on whether the sequence has followed a sound pattern or not, the information displayed in the results screen will be one or the other.

3.5.4.2.1   Results screen without sound pattern

Its appearance is shown in the following figure:

Figure 31. *Tear Film* result screen without sound pattern

The 40 double-pass images recorded during the sequence (see section "3.5.3.2 Tear Film") are shown. Two numerical values can be found at the top of each of them. The one on the left represents the moment the image was recorded. The one on the right represents the calculated OSI value for that image.

Also displayed, at the bottom right of the screen, is a chart representing the evolution of the OSI over time. An increase in the OSI value implies a degradation of the double-pass image that could be caused by rupture of the tear film. By selecting a specific area of the graph with the mouse cursor, you can zoom in on that section. Zoom in, starting from top left, and zoom out starting from bottom right.

At the top of this chart, the OSI average, along with its standard deviation, its maximum, its minimum, and the difference between the latter two are shown.

If the program detects any blinking during the measurement, it marks the corresponding image as "*Blink*" and removes the associated point from the chart. If you want to change the cataloging of any of the images, select it by clicking on it to tell the program how to catalog it. In doing so, you will have the possibility to select other images before commanding the program to recalculate the results taking into account the corrections provided.
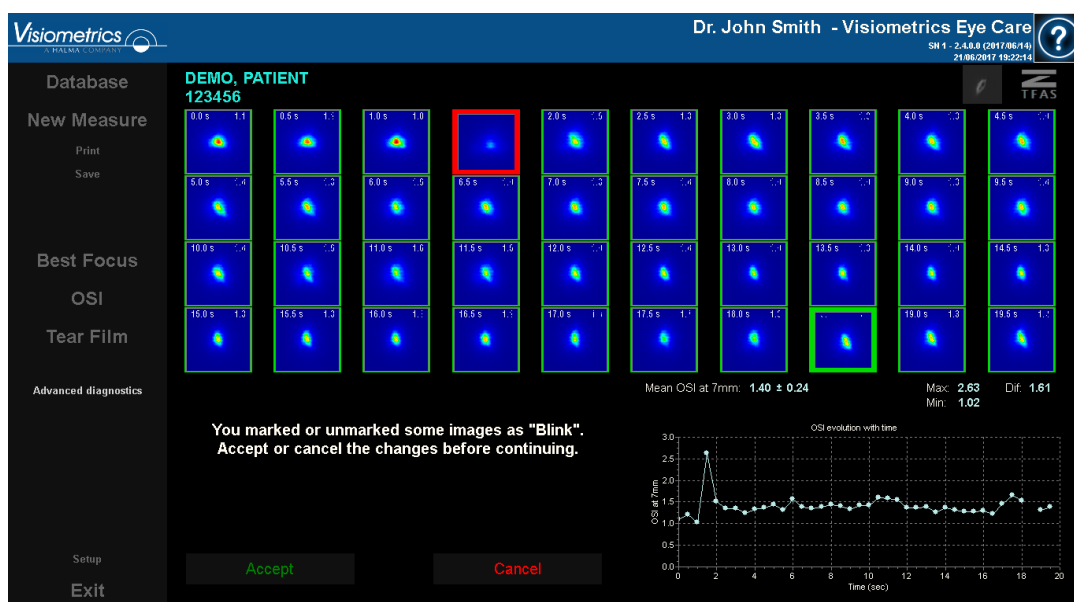
Figure 32. Modification in the cataloging of images

You can export the images by double-clicking with the left side of the mouse and specifying the desired directory. You can save them in either *jpg* or *bmp* format.

To export the chart, double-click on it with the left side of the mouse and specify the desired directory. You can export it as an image (*bmp* or *jpg* formats), or directly save your data in a text file (*txt*). These data will be exported in several columns, the most representative being the first three: time, OSI value, and whether or not there has been a blink. Note that even if a dot has been removed from the chart because there has been a blink, the corresponding OSI value will not be removed from the exported data.

3.5.4.2.2 Result screen with sound pattern

This screen is divided into 3 different areas, as shown in the following figure:

Figure 33. *Tear film* result screen with sound pattern

A. Patient History

Each time a measurement is guided by a sound pattern, it is classified into one of the following 5 groups, conveniently defined and identified by a number and an associated color:

- o   1 --- Plateau --- Bright green
- o   2 --- Plateau/Seesaw --- Olive green
- o   3 --- Seesaw --- Yellow
- o   4 --- Seesaw/Ladder --- Orange
- o   5 --- Ladder --- Red

Measurements whose characteristics do not allow a definite classification are associated to a sixth group, identified with zero and black.

The aim of this chart is to show the evolution of a particular eye over time. You can scroll horizontally by dragging the mouse by right-clicking on the mouse. By clicking on any marker in the chart, you can access the details of the associated measurement.

B. Details of a concrete measurement
In the upper left, the chart representing the OSI evolution over the 20 seconds of a specific measurement is shown, assigning it the color associated to the group to which the measurement belongs, according to its characteristics.

In the upper right, the group to which the measurement studied belongs is clearly shown, as well as the studied eye.

At the bottom right, the notes assigned to the displayed measurement are shown, as well as the date on which it was performed. You can modify the notes at the end of the measurement, or during any subsequent viewing.

C. Button area
Made up of the buttons that allow you to change the information seen between:
- The double-pass images, explained in point 3.5.4.2.1.
- The classification in groups, explained in points A and B of this section.

3.5.4.3 Depth of Focus

The results of this measurement are displayed as shown in the following figure:

Figure 34. *Depth of Focus* Results

The nine double-pass images recorded during the sequence are displayed. Each of these double-pass images has the following related information.

- Outside the image, above, the accommodative demand requested to the patient during the capture of that image is shown, taking into account the best focus position detected during the measurement itself. That is why the best double-pass image detected shows 0.0 D, and is marked as "Distance vision". The image marked "Near Vision" corresponds to an accommodative demand of 2.0 D.
- Inside the image, in the upper left part, a number is shown that corresponds to the value, in minutes of arc, of the width of the profile at 50%. The lower that width is, the better focused the image is considered to be.
- Outside the image, at the bottom, a simulation of how the image projected onto the retina of an optotype (Snellen letter E) is shown. Remember that the patient does not have to see it as it is shown on the screen since only the optical quality of the eye is taken into account, not the subsequent neural treatment made to the retinal image.

- Under the optotype simulation, the focus position corresponding to that position is displayed. The third image will always correspond to the focus position selected in the "Best Focus" measurement results at the time the measurement was started.

In addition, at the bottom right of the screen, a chart of an image quality index is displayed in accordance with the focus position. These image-quality values are normalized, so a unit value is associated with the best focus position. By selecting a specific area of the graph with the mouse cursor, you can zoom in on that section. You can zoom in by selecting from the top left, and zoom out by selecting from the bottom right.

The OQAS *Accommodative Range* (OAR) is considered to be the dioptric range between the BF and the point at which the quality chart decreases to 50%.

In the event that the program considers that it is possible to obtain the accommodative range more precisely by modifying the *selected Focus Position value*, either because the quality graph does not decrease below 50% or because the best spherical refraction is the first of those studied, it will report this through a visible warning at the top of the result screen just below the numerical result.

You can export the images by double-clicking with the left side of the mouse and specifying the desired directory. You can save them in either *jpg* or *bmp* format.

To export the chart, double-click on it with the left side of the mouse and specify the desired directory. You can export it as an image (*bmp* or *jpg* formats), or directly save your data in a text file (*txt*).

3.5.4.4 Result comparison screens

As indicated in section 3.4.3.3 Comparing, the program has result comparison screens for each of the measurement types with the exception of Purkinje measurements.

The following figures show an example of each of these screens. They all have a similar structure. In the lower part, the parameters used in each measurement are detailed, while in the upper part, the results obtained are shown. You will find the same numerical results as you would if you were consulting each measurement individually. On the *OSI* and *Light Condition* screens, use the *More Options* button to view the information related to MTF and profiles.
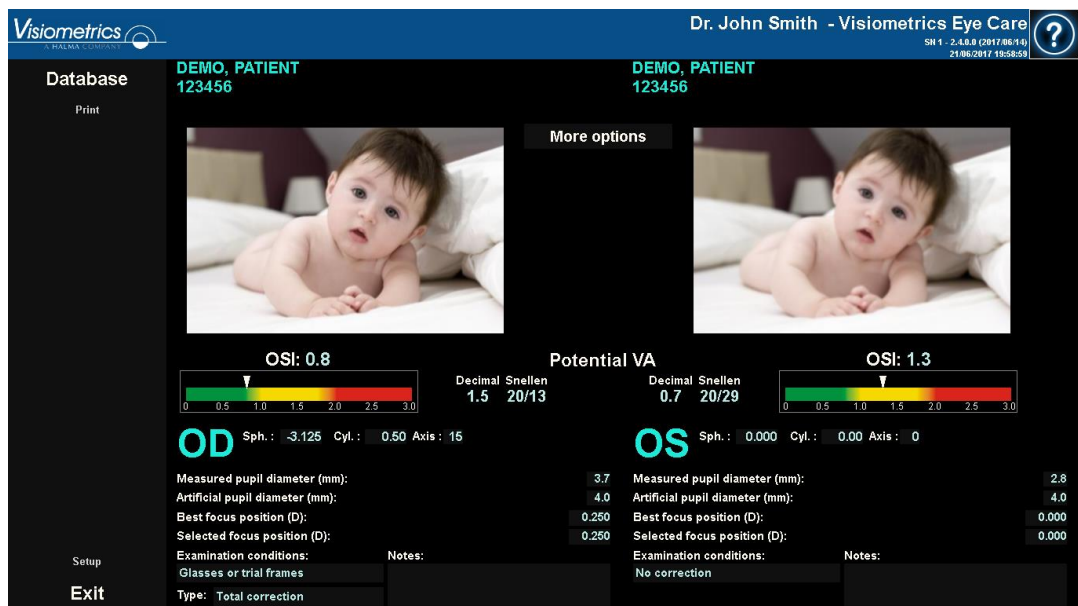
Figure 35. *OSI* **measurements comparison**

Figure 36. Comparison of profiles in *Light Condition* measurements
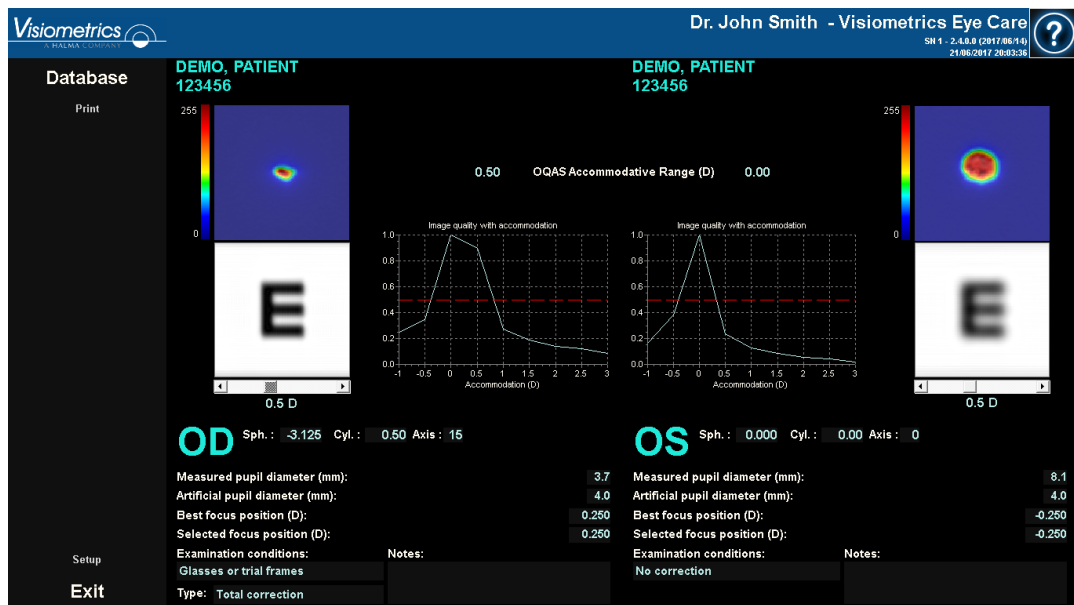
Figure 37. *Depth of Focus* measurement comparison
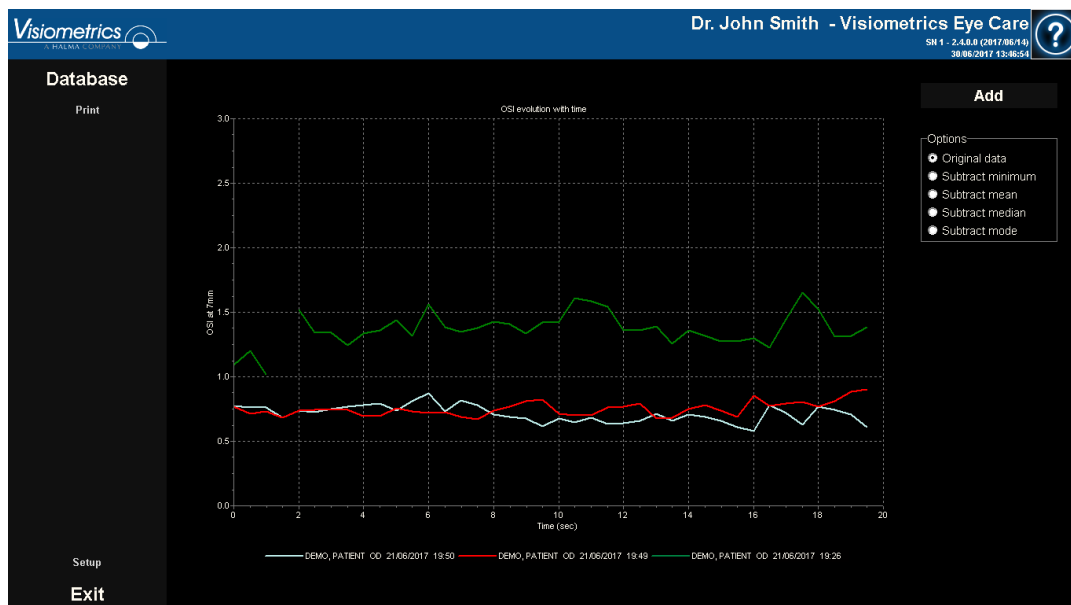
Figure 38. *Tear Film* **measurement comparison**

You can print a comparison report. To do this, simply click *Print*. See section 3.5.6 for more detailed information.

You can export any image displayed on these screens by double-clicking with the left side of the mouse and specifying the desired directory. You can save them in either *jpg* or *bmp* format. You can export the images by double-clicking on them with the left side of the mouse and specifying the desired directory. You can export it as an image (*bmp* or *jpg* format), or directly save your data in a text file (*txt*).

3.5.5 Purkinje Measurement

3.5.5.1 Introducing the subjective refraction
To perform a *Purkinje* measurement, it is not necessary to have made a *Best Focus* measurement. However, it is necessary to have introduced the subjective refraction of the patient.

It is important to emphasize that, at the time of measurement, the patient:
- Should not be corrected in any way: without their own or test glasses, without cylindrical lenses in the head of the machine or contact lenses.
- Must look at the laser whenever it is visible.

> ⚠ *The patient must perform the measurement without correcting their visual impairments. Therefore, neither test glasses nor the patient's own glasses will be used.*

Figure 39. Subjective refraction

Therefore, the data introduced here, in terms of the Purkinje measurement, is only used to place the stimulus at the appropriate distance from the patient's eye, which will allow them to see the stimulus clearly and comfortably.

3.5.5.2 Selecting the Purkinje option

Once the subjective refraction is introduced, select the *Purkinje* option.
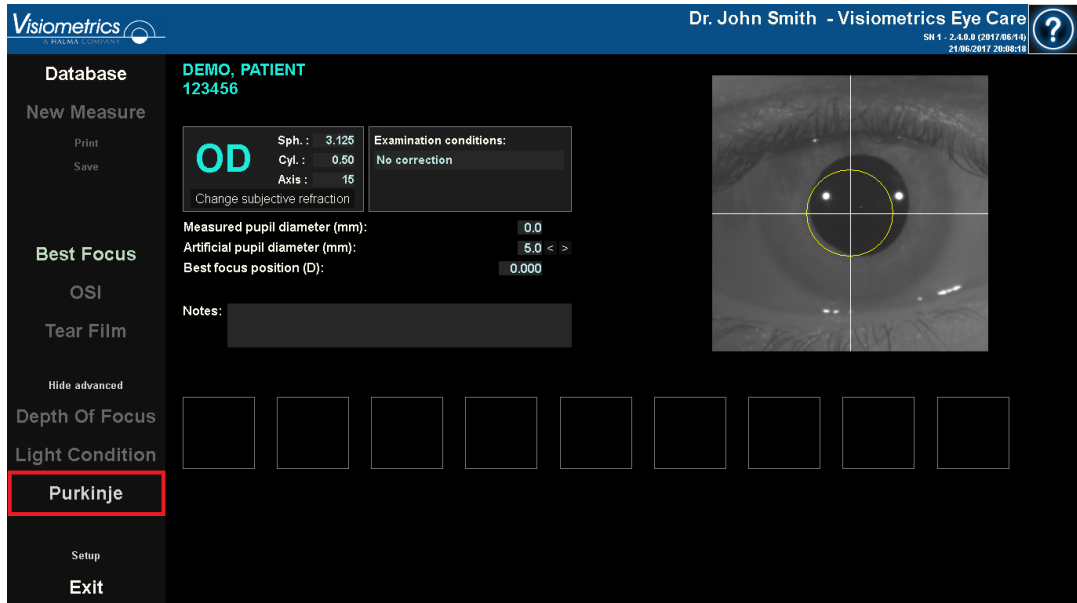
Figure 40. Position of the *Purkinje* option

3.5.5.3 Move the machine away from the patient and focus the eye

Now, while the patient is looking at the center of the house in the stimulus, move the machine as far as possible from the patient's eye and try, as best as possible, to center the pupil on the coordinate axis superimposed on the live image.

During this step:

- Do not pay attention to whether or not the eye appears focused on the live image.

- Let the patient know that they can blink as many times as they want, since no measurement is being captured yet.

Figure 41. Live eye centered, but out of focus.

3.5.5.4 Select the appropriate option

Once the machine is as far away as possible from the patient, and the patient's eye is moderately centered on the axis, select the appropriate option according to the type of study to be carried out:

- *Pre-Without inlay* for those patients who do not have the KAMRA™ "inlay" implanted.

- *Post-With inlay* for those patients who have the KAMRA™ "inlay" implanted.

At the moment you select one of the 2 options, the laser will be activated and the patient will be able to see it. From here on out, the patient should always try to look at the laser.

The *Automatic* and *Manual* options indicate to the program whether the image has to be studied automatically, or if you will be the one who marks one of the following situations on it once the image has been acquired:

- In *Pre-Without inlay* acquisitions, the pupil.

- In *Post-With inlay* acquisitions, the KAMRA™ "inlay".

The patient, in this step, can still blink as much as needed to feel comfortable.

3.5.5.5 Focus with the help of the directional arrows

During this step the program will use 2 arrows: one blue pointing to the patient's eye, and one yellow pointing to you, which will guide your movements. Note that these indications will only be displayed when the eye is correctly centered on the image.

Initially, the blue arrow will tell you to bring the machine closer to the patient. This approach must be carried out at a constant speed and always keeping the patient's eye centered on the screen.
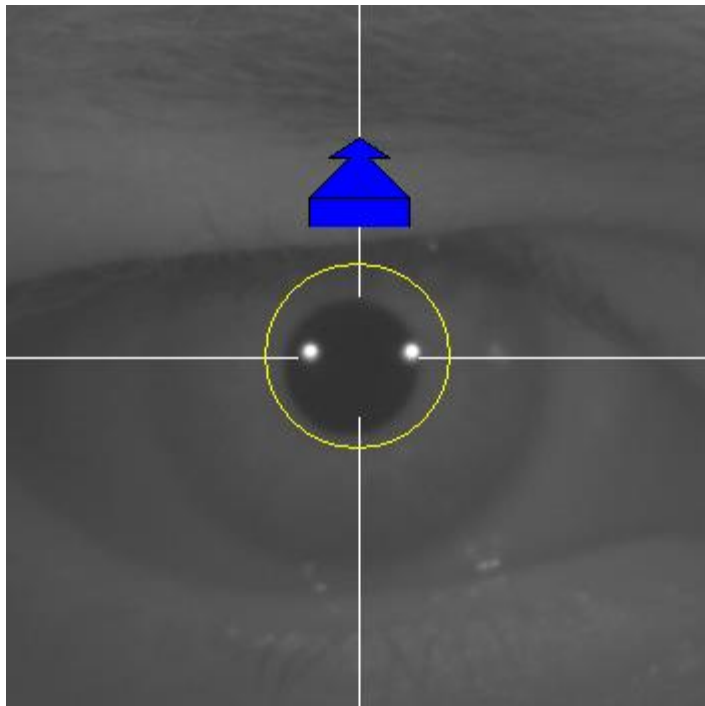
Figure 42. Blue arrow at the beginning of the sequence.

At some point of this process, a green circle will appear around the Purkinje image of the laser, in a very central area of the image. Continue moving at a constant speed, keeping that green circle as centered as possible, reaching the point of best focus and passing beyond it.
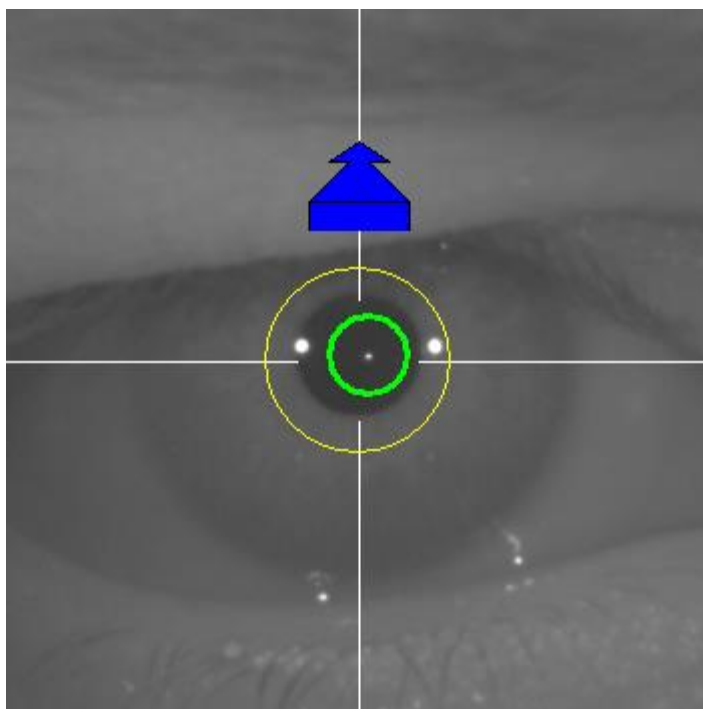
Figure 43. Blue arrow with green circle around the laser reflection.

Shortly after surpassing it, the program will recognize that it has passed beyond the point of best focus, and will replace the blue arrow with a yellow arrow pointing in the opposite direction. Reverse the direction of movement of the machine, moving it away from the patient.
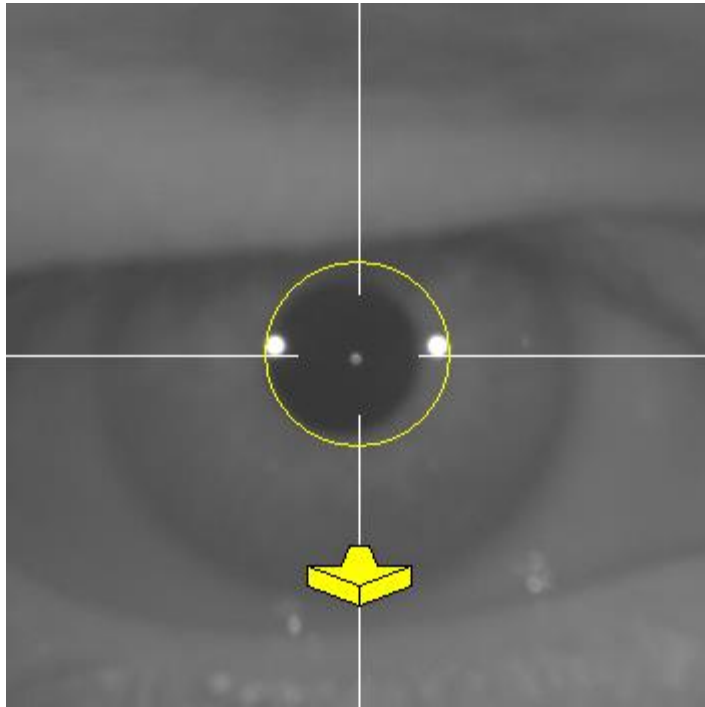
Figure 44. Yellow arrow just after losing the detection of the laser reflex.

At this point, the program will continue to use the arrows, and their size, to indicate which direction the machine should move to reach the point of best focus, and how far it is from that point of best focus (the larger the arrow, the farther away the machine is from the point of best focus).
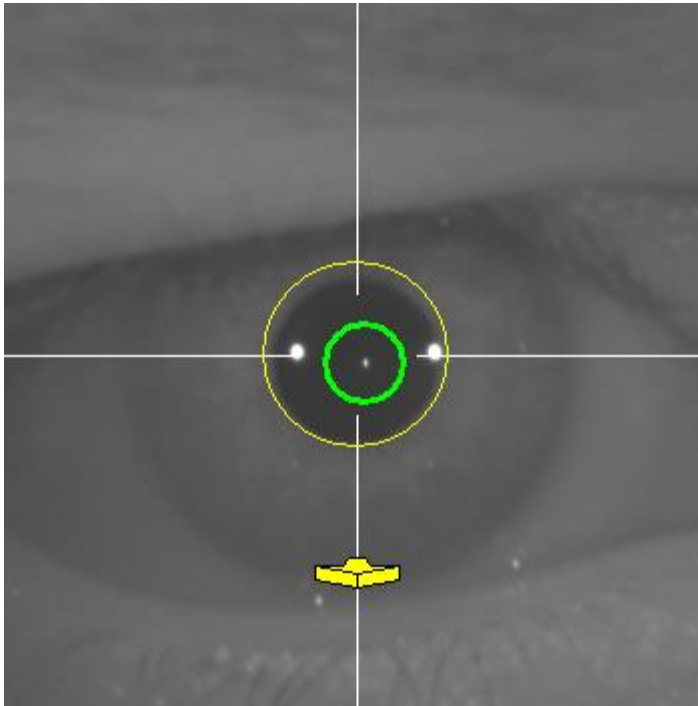
Figure 45. Yellow arrow at a point very close to the best focus

Once the point of best focus has been reached, the arrows will be replaced by a green mark, indicating that the machine is already at the optimum distance, so you should not move the machine any more.
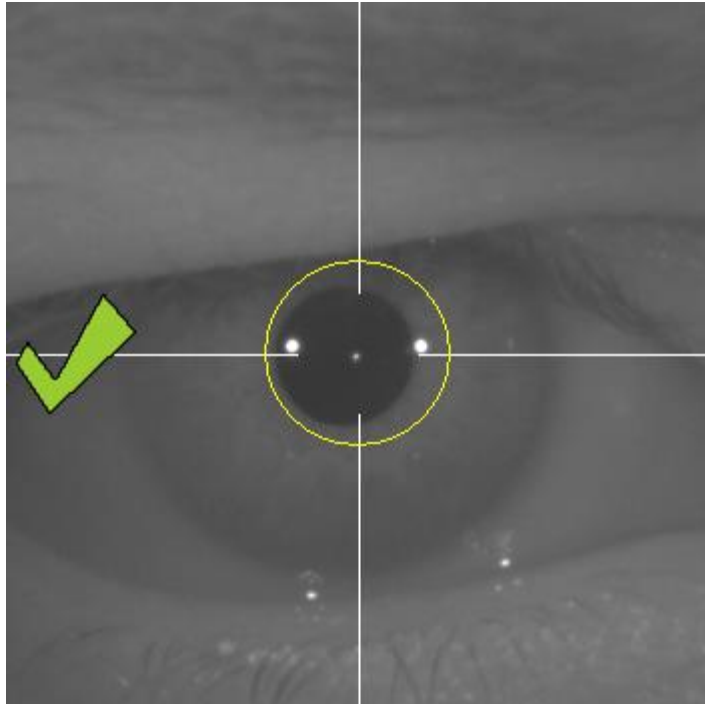
Figure 46. Green mark indicating the position of best focus.

It is advisable, during this focusing process, that the patient, although he/she can blink, should avoid doing so excessively, since blinking may confuse the program.

If at any time during the focusing process the program stops showing the directional arrows, cancel the operation completely, and start the measurement again.

3.5.5.6   **Automatic capture of images and detection of searched items**

Once arrived at this point, the program will begin to capture images automatically, and behave in the following ways:

- *Automatic* Mode: the program will try to detect, in the images:

    - o   In *Pre-Without inlay* acquisitions: the Purkinje image of the laser and the pupil.

    - o   In *Post-With inlay* acquisitions: the Purkinje image of the laser and the KAMRA™ "inlay". It will also try to detect the pupil, but that is not mandatory.

- *Manual* Mode: the program will simply try to detect the Purkinje image of the laser in the images. You will be the one who will later indicate where the important elements are.

If at any time, while the eye is centered, the best focus detected in the previous step is lost, either because the patient has involuntarily moved the head or you have involuntarily moved the machine, the indicating arrows will show you how to reach the best focus point again.

Similarly, if at any time the eye becomes decentered, the green mark that indicates the correct focus will disappear, as well as the green circle around the Purkinje image of the laser. You must center the patient's eye to get the appropriate indications again.

It is advisable, during this automatic image capture process, that the patient blinks as little as possible.

3.5.5.6.1 *Automatic* **Mode**

The program will try to capture 3 consecutive and sufficiently similar images from among them. Once this is done, the program will automatically decide the best of those 3 images, and will present it on the screen.

3.5.5.6.2 *Manual* **Mode**

Once the program captures an image in which it is able to detect the laser, the patient can again blink comfortably, since the image has already been captured. The captured image is shown enlarged and with exaggerated contrasts:
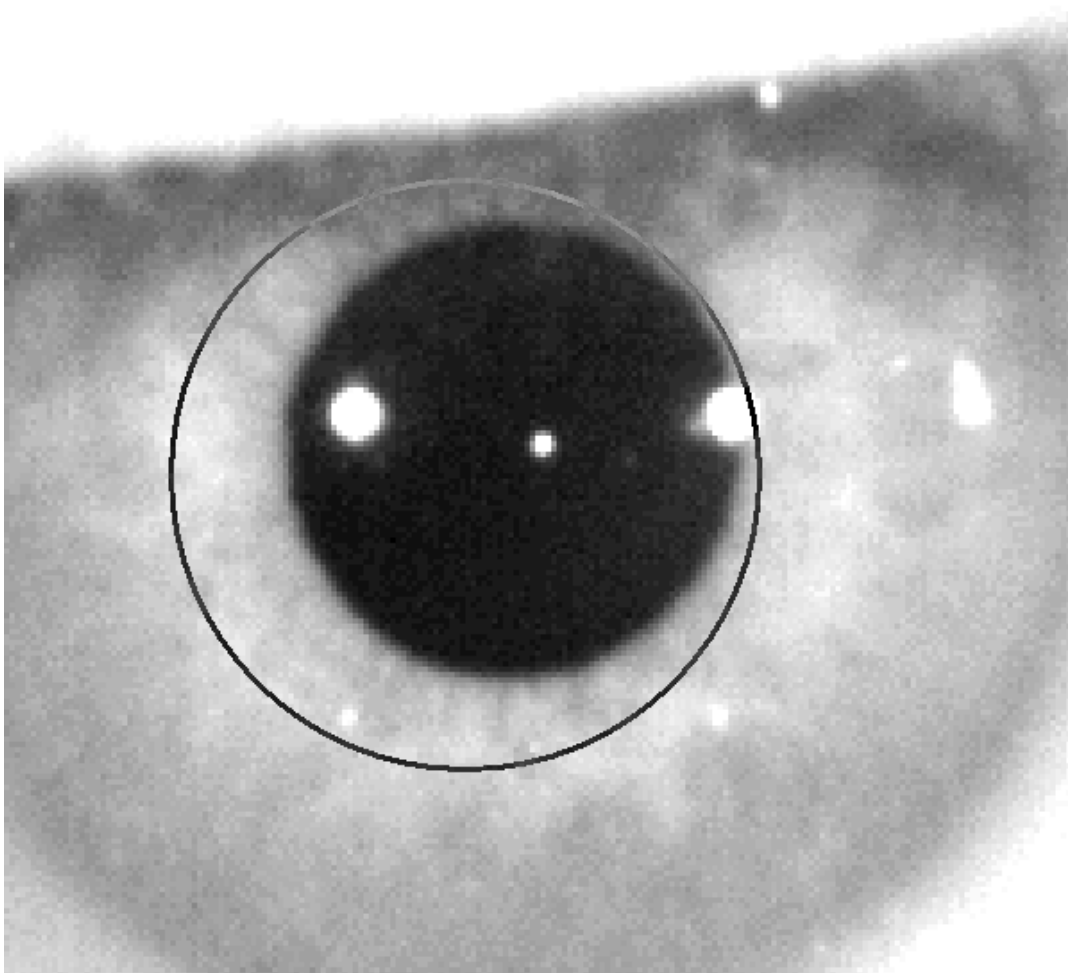
Figure 47. Enlargement in which the pupil and the indicated center are not correct.

On the enlarged image, locate:

- In *Pre-Without inlay* acquisitions: the center and the edge of the pupil.

- In *Post-With inlay* acquisitions: the center and edges of the KAMRA™ "inlay".

To locate the center, simply move the mouse to the ideal place. To adjust the diameter, use the mouse wheel, or the "+" and "-" keys.
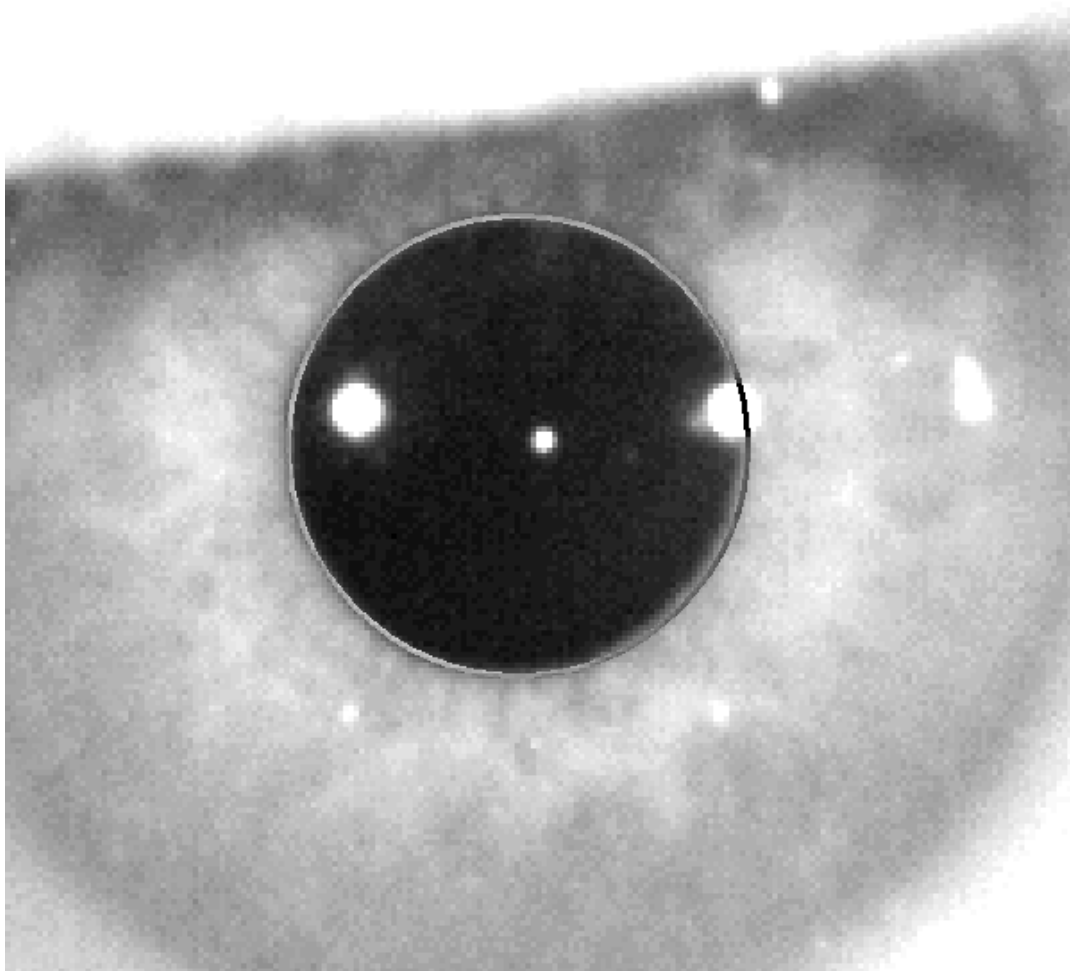
Figure 48. Enlargement in which the indicated pupil and center are correct.

Once you have located the correct center and diameter, click the mouse, and the program will show the partial results of the acquisition.

3.5.5.7   Validating a partial image

Evaluate how good the image captured and proposed by the program is, assessing how well the borders and points detected and displayed are adjusted to the image.

While making the decision, the patient can again blink comfortably, since the image has already been captured.

3.5.5.7.1 Incorrect partial image

If you consider that the detection of the pupil, or the optical axis, or the lens in case of post-operative measurements, is not good enough, select the *Discard image* button, and the program will return to the point again "3.5.5.63.5.5.6 Automatic capture of images and detection of searched items".

Figure 49. Incorrect detection of the pupil in pre-operative partial measurement.

3.5.5.7.2 Correct partial image

If you think the image is good enough, select the *Valid image!* button. The program will save the image as valid and go to the next point.

Figure 50. Correct detection of the pupil in pre-operative partial measurement.

3.5.5.8 Acquire and validate the remaining partial images

In *Manual* mode, this point is not necessary, so the program will jump directly to the next point (3.5.5.9 Final results).

In contrast, in *Automatic* mode, once you've reached this point, you have already captured and validated a complete partial image. But, due to the precision that is demanded of the program, one image is not sufficient enough to guarantee the accuracy of the resulting data, regardless of being validated by the user.

As a result, the program requires four more images to capture and validate, staying with the one that statistically best represents the reality of the patient's eye.

Therefore, when validating an image, the program returns to point "03.5.5.6 Automatic capture of images and detection of searched items", in order to capture and validate the remaining images until reaching a total of five validated images.

When returning to point "03.5.5.6 Automatic capture of images and detection of searched items", keep in mind that since neither the position of patient nor camera has moved, the eye should be in focus by now. Nevertheless, since the eye is in a state of constant change, it is possible that it has "lost" its best focus.

For the second image onward, the program automatically discards those that stray too far from the image previously validated by the doctor, so that as a whole the five images would be very similar.

Once the fifth image is validated, the program automatically jumps to the next step.

Figure 51. Fifth partial measurement belonging to a pre-operative measurement.

3.5.5.9 Final results

At this point, the patient can leave the machine as the measurement process is now complete.

Once the final image is validated, the program displays the final result. The program automatically selects the final result image among all the captured and validated images (1 in *Manual* mode or 5 in *Automatic*). Statistically speaking, they are the images closest to the reality of the patient.

For image results of pre-operative measurements, it shows:

- Yellow: Pupil and its center.

- Green: Optic eye.

- Red: Position where the KAMRA™ inlay should be implanted .
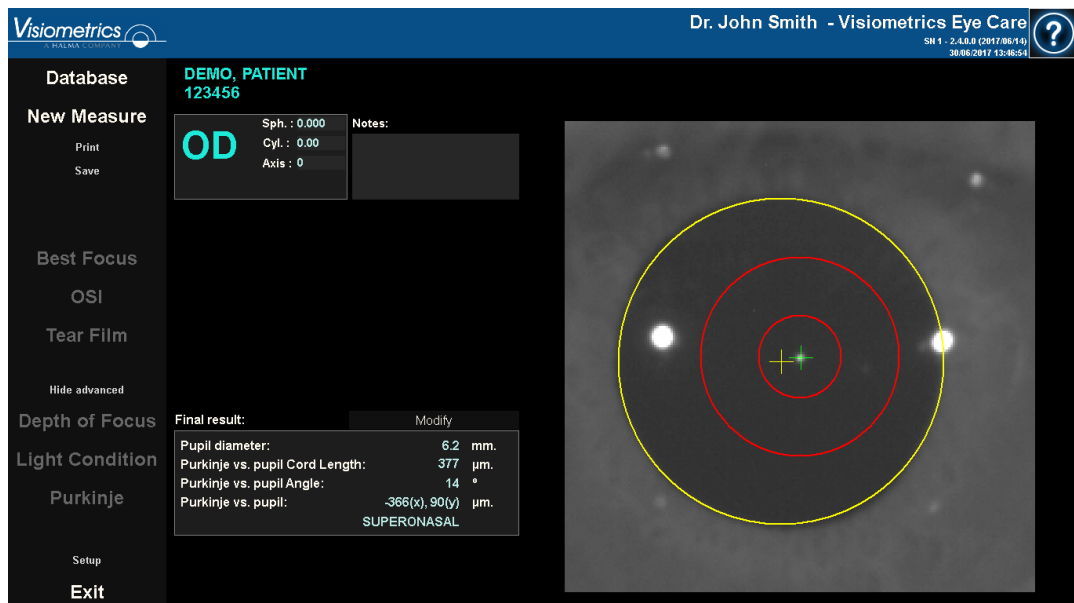
Figure 52. Final result of a pre-operative measurement.

For image results of post-operative measurement, it shows:

- Green: Optic eye.

- Red: KAMRA™ lens and its center.
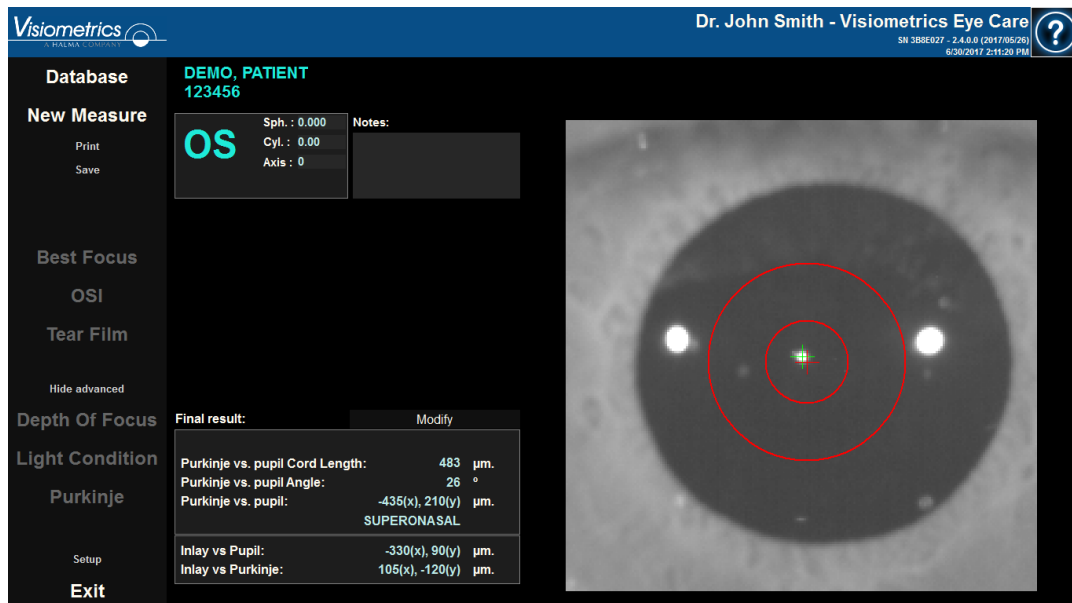
Figure 53. Final result of a post-operative measurement.

3.5.6 Printing and exporting a report of the results

In any measurement type, click the *Print* button to print out a full report of the results and parameters of the measurement.

There are two types of reports for *OSI* and *Light Condition.* One or the other may be printed, depending on the view option being used when clicking *Print.*

When printing, you are given the option to either print the report, view a print preview, or export the report as a file. The report can be exported as *bmp, jpeg,* and *pdf.* You can also export from the print preview (clicking on *Save as*).

The Figure 54 and the following show an example of printing a report for each type of measurement. Each report includes the measurement's most relevant information, including the parameters used and results obtained.

Figure 54. Example of a printed *OSI* report
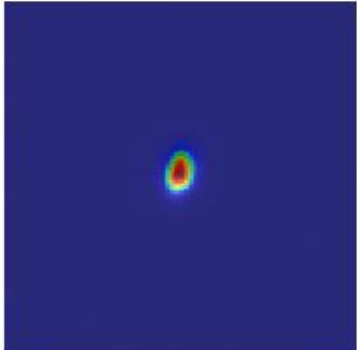
DEMO, PATIENT
123456

Dr. John Smith – Visiometrics Eye Care
16/06/2017 14:06

OS

		Sph:	Cyl:	Axis:
Manifest Refraction		0.000	0.00	0
			BCVA:	UCVA:

Artificial pupil diameter: 7.0   Measured pupil diameter: 2.8
Best focus position: 0.000   Notes:
Selected focus position: 0.000
No correction.

Original Image

Image of a baby at 1 meter distance

Retinal Image

Simulation of the image on the patient's retina

Double-pass Image

Potential VA:

Decimal	Snellen
1.7	20/12

Figure 55. Example of a printed *Light Condition* report

DEMO, PATIENT
123456

Dr. John Smith - Visiometrics Eye Care
19/06/2017 15:24

OD

		Sph:	Cyl:	Axis:
Manifest Refraction		-3.125	0.50	15
		BCVA:		UCVA:

Artificial pupil diameter: 4.0 Measured pupil diameter: 3.7
Objective spherical refraction: 0.250 Notes:
Measurement sph refraction: 0.250
Total correction.Glasses or trial frames.

Objective refraction images:

1.000	0.750	0.500	0.250	0.000	-0.250	-0.500	-0.750	-1.000

-0.5 D	Far Vision 0.0 D	0.5 D	1.0 D	1.5 D	Near Vision 2.0 D	2.5 D	3.0 D	3.5 D
6.47	2.49	2.91	6.75	8.79	13.60	15.60	7.43	8.95

1.250	0.750	0.250	-0.250	-0.750	-1.250	-1.750	-2.250	-2.750

Image quality with accommodation

Accommodation (D)

OQAS Accommodative Range (D):   0.75

Figure 56. Example of a printed *Depth of Focus* report
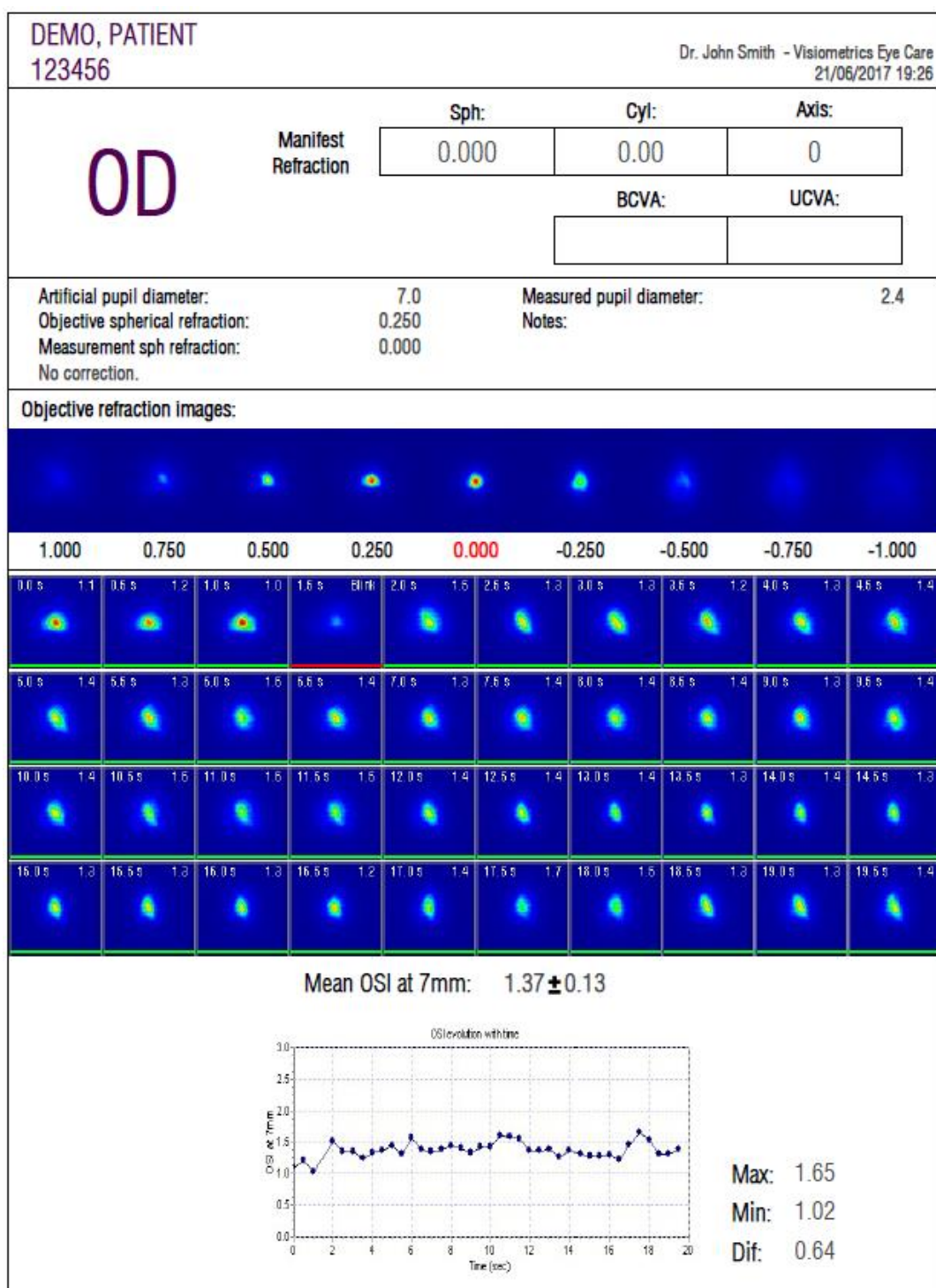
Figure 57. Example of a printed *Tear Film* report (double-pass images)
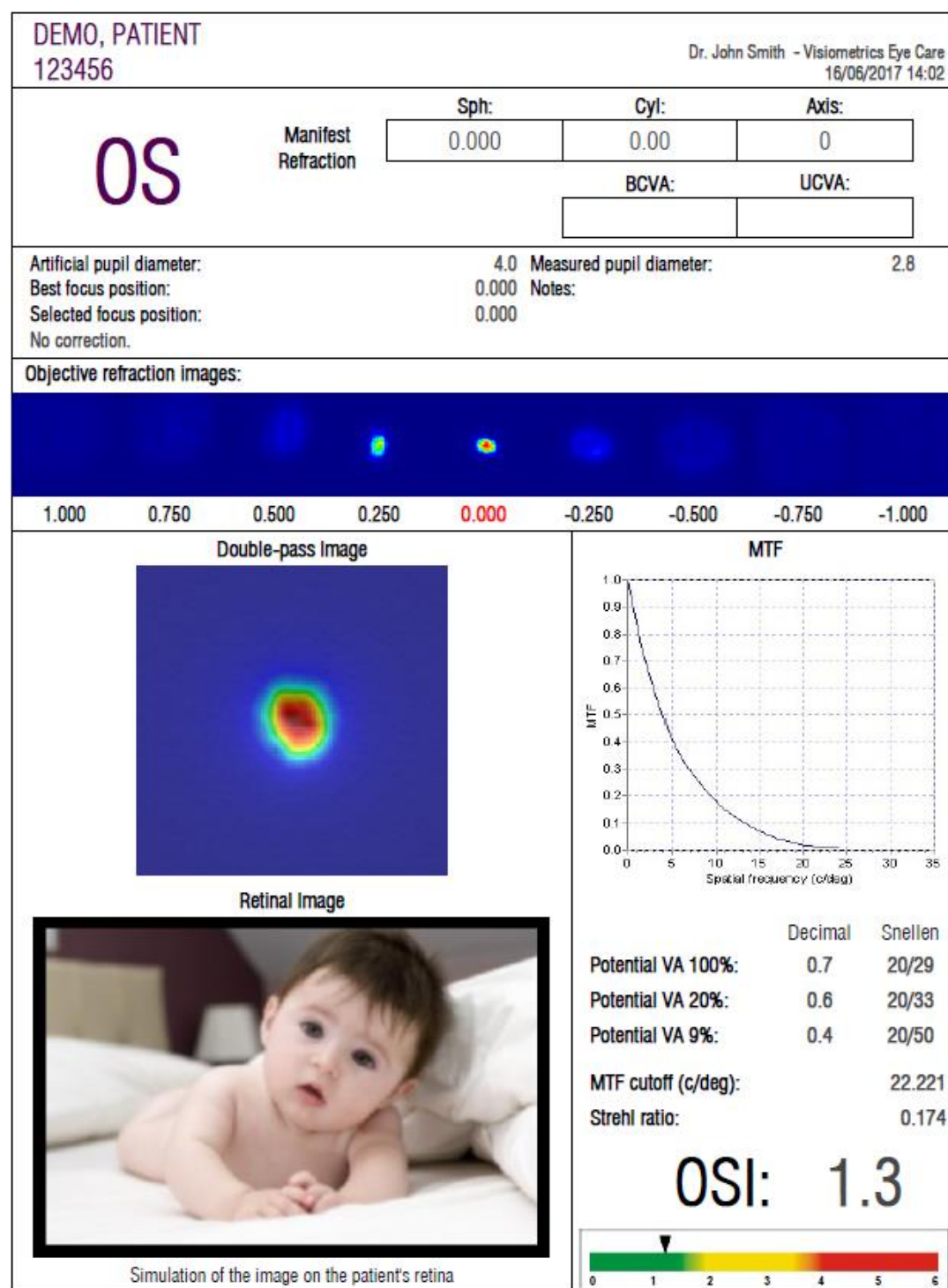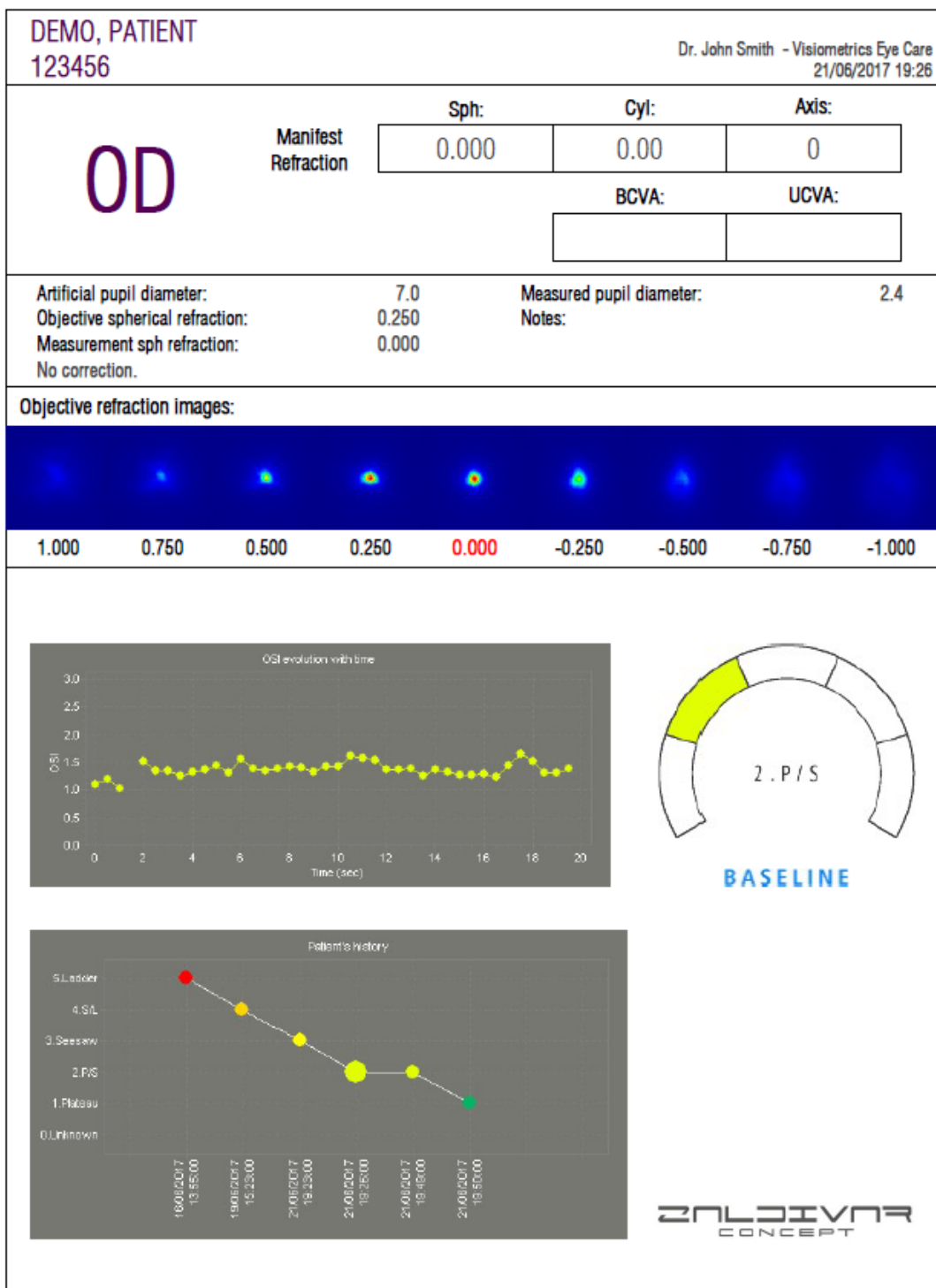
Figure 58. Example of a printed *Tear Film* report (sound patterns)
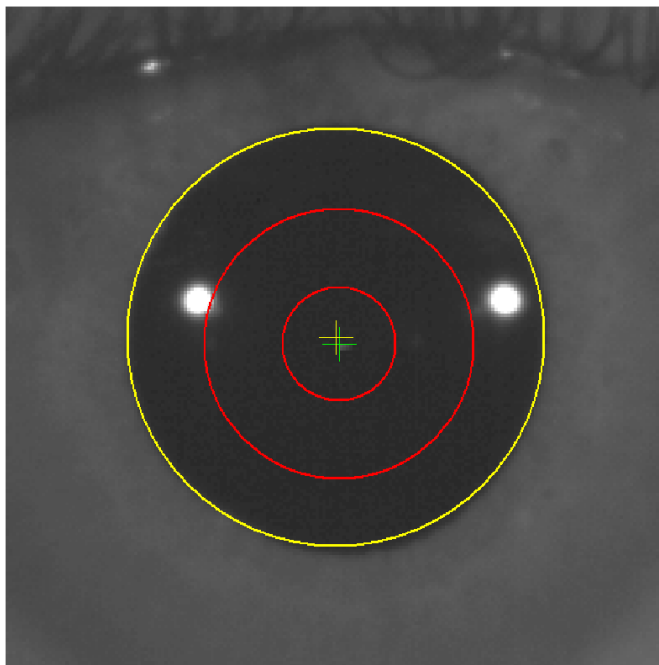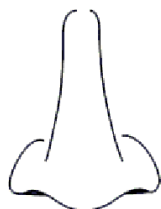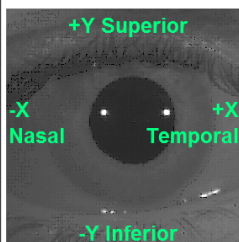
Figure 59. Example of a printed pre-operative *Purkinje* report
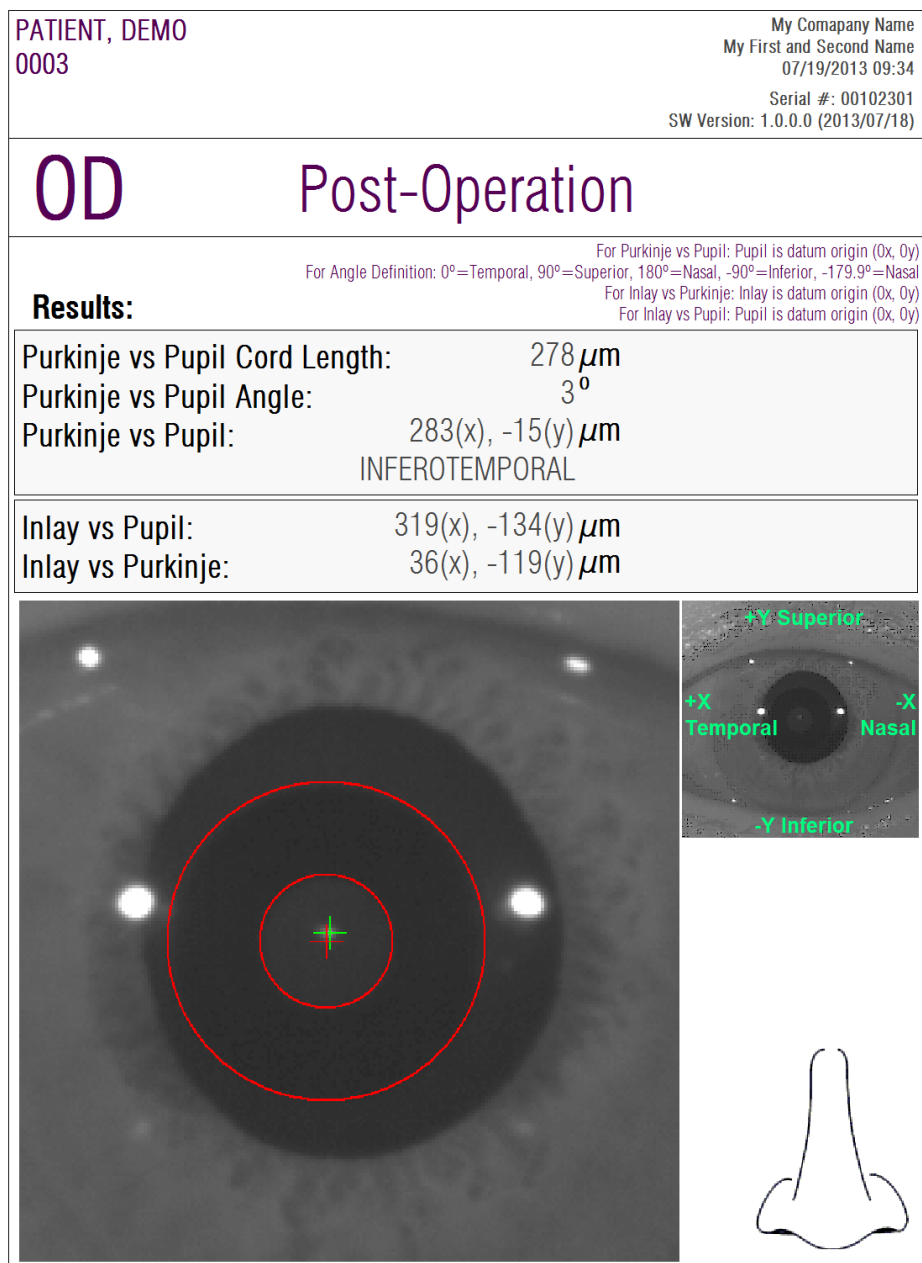
Figure 60. Example of a printed post-operative *Purkinje* report

Finally, you can also generate a report for each of result comparison screens (via the *Compare* option in *Database*). Click *Print* in these screens to obtain the reports.

3.6   SETUP

Clicking on *Setup*, visible on practically every screen in the program, gives you access to the system settings.

Figure 61 shows the settings screen. It can be divided into clearly defined areas.
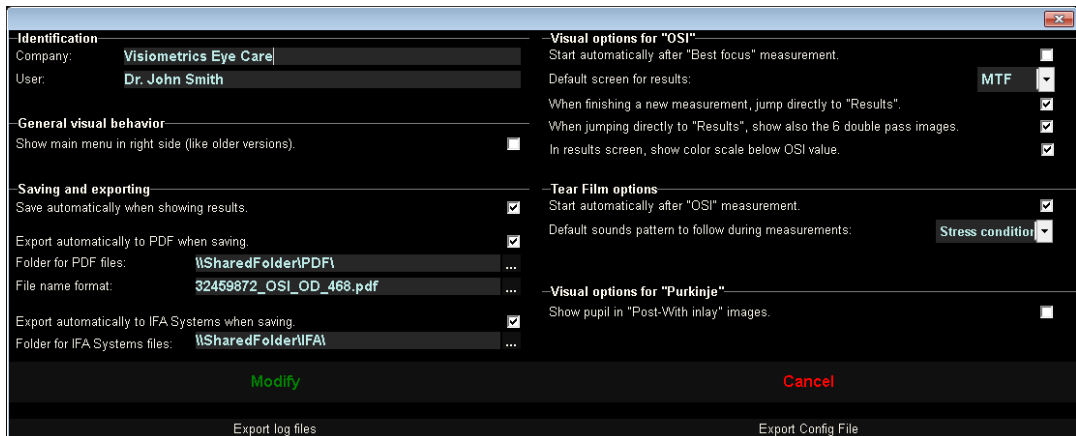
Figure 61. *Setup* screen

3.6.1   Identification

Company refers to the name of the clinic or hospital where the equipment is installed. *User* refers to the name of the doctor or person in charge.

The information entered is displayed in the top part of the screen, though no field is required and therefore can be left blank.

3.6.2   General visual behavior

Allows you to have main menus to the left, like normal, or to the right, like in older versions of the program.

3.6.3 Save and export

The first option allows you to save automatically when showing results.

The second option allows you to export automatically the results even when saving as a *pdf* file. The destination folder for exporting is set in the third option, and the file name in the fourth option.
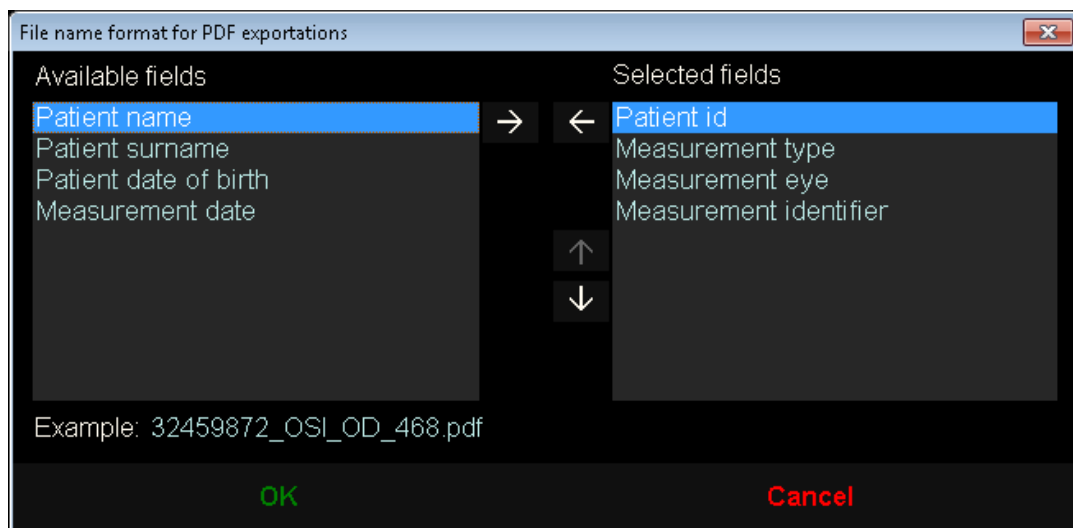
Figure 62. Screen to set the name format

The fifth and sixth options allow automatic exportation to an *xml* file, used by IFA Systems AG® servers.

3.6.4 Visual options for "OSI"

The first option allows you to start an "OSI" measurement automatically after performing a "Best Focus" measurement.

The second option allows you to calculate and display results without having to revise the six double-pass images.

The third option allows you to show the color scale under OSI value in the results screen.

The fourth option allows you to choose the default results screen to be displayed after the calculations have been made. All screens are available, but the program will show the one selected here by default.

The fifth option allows you to display the six double-pass images together with the results in the event that the program is set to calculate and show results without revising the six double-pass images.

3.6.5 Tear Film options

The first option allows you to start a "Best Focus" measurement automatically after performing an "OSI" measurement.

The second option selects the default sound patterns to follow when performing the Tear Film measurement.

3.6.6 Visual options for Purkinje

Indicates whether the program should show the pupil in the "Post-With inlay" measurements.

3.6.7 Modify and Cancel buttons

Once you have set the way you want the program to behave, click the *Modify* button to apply the changes made. If, on the other hand, you wish to discard the changes made, simply click *Cancel.*

3.6.8 Additional buttons

The *Export logs* button is useful to resolve possible technical problems or unexpected behavior from the program. The program internally records logs that, via this button, can be compressed into a single file and emailed to Visiometrics Technical Support if needed.

The *Export config.* button allows exportation of the program setup as a file. Like the previous button, it is useful to resolve possible technical problems or unexpected behavior.

3.7 BACKUP

Clicking on the *Backup* button on the main screen will create a backup copy of the database. To do this, select the location where the copy should be made.

The backup is of all files related to patient data and measurements taken. This includes the Microsoft Access™ database file, as well as all recorded images.

If you've chosen a location where a backup copy already exists, the program will overwrite the existing backup.

It is recommended to back up data on a regular basis. Keep in mind that a backup can take up a large amount of disk space, up to several gigabytes. Therefore, it is recommended to make sure there is enough space in the folder when making a copy.

4 MEASUREMENT EXAMPLES

4.1 NORMAL EYE

The Figure 63 is an example of a report of the measurement results of a young patient's healthy eye.
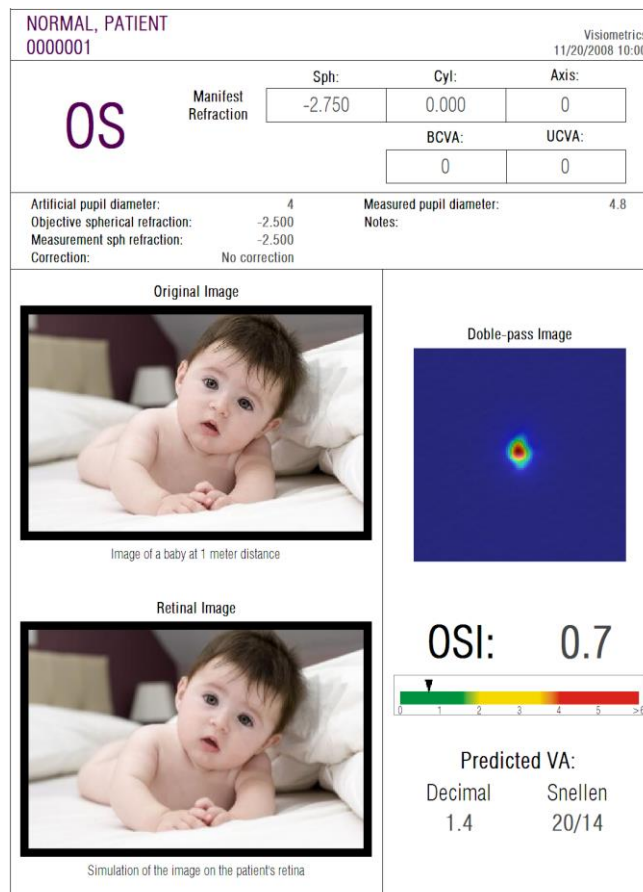
Figure 63. Normal eye

You can see that the double-pass image is very small and rounded, that is, the degradation of the retinal image due to both aberrations and intraocular diffusion is very small. This can be verified with the very high value of the AV Potential (few aberrations) and the very low value of OSI (little diffusion), as would be expected.

As for the simulation of the projected image on the retina, you can see there is no significant degradation with the original image.

4.2 EYE WITH CATARACT

The Figure 64 is an example of a report of the results of an eye with cataract.
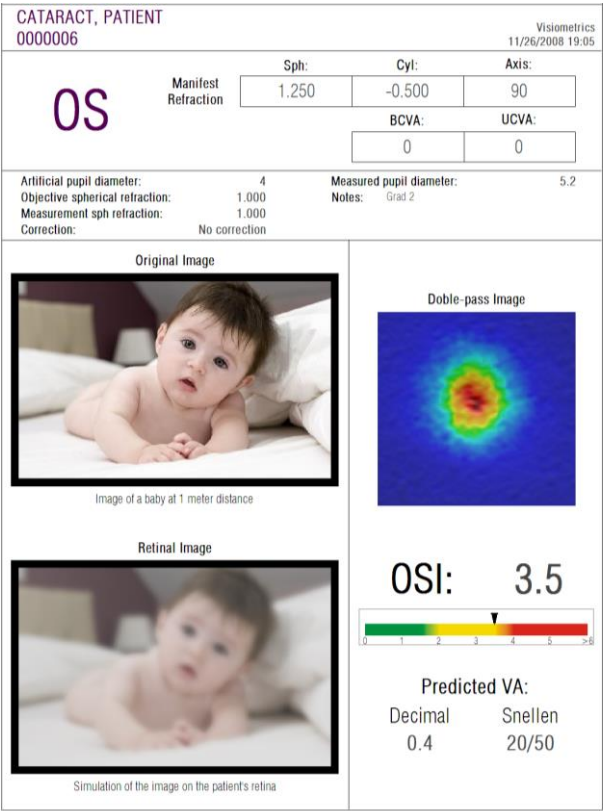
Figure 64. Eye with cataract

As you can see, the double-pass image is much larger than that of a normal eye. This means that the energy (light) that reaches the retina is very disperse. This is precisely the effect of intraocular diffusion (light that spreads in all directions). As a result, a high OSI value can be expected, as it is. At the same time, the AV Potential would be low.

Taking note of the simulation of the projected image on the retina, you can verify that the degradation entered by ocular means is important, in comparison with the original image. The diffusion generates a drop in the overall contrast of the image. This is the well-known veil effect caused by cataracts. It should be noted that other effects such as the appearance of halos or glare are not simulated in this image, so their presence should not be expected.

4.3 POST-LASIK EYE

After a LASIK operation, there is some uncertainty about the actual state of the eye because even if the patient sees correctly it is possible that new aberrations or a certain degree of diffusion in the cornea may appear. Carry out a measurement on the patient to verify that the operation has been a success. Figure 65 is an example of a report of the measurement results of an eye after LASIK surgery. You can see how the quality of vision is very satisfactory since the double-pass image is rounded and of acceptable size. The *OSI* value is low and the *AV Potential* is high, corresponding to a successful operation.
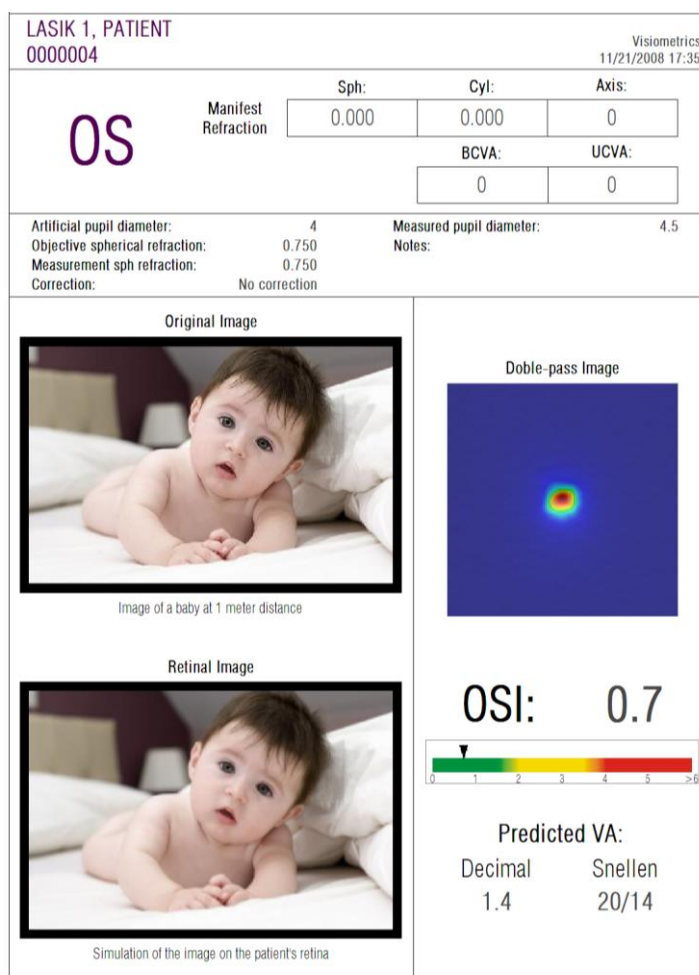
Figure 65. Post-LASIK eye after successful surgery

However, in Figure 66 you can see an example of where the surgery did not reach the expected results. The double-pass image is more extensive, due to the

presence of both aberrations and certain diffusion. The *OSI* value is more significant than in the previous case (major diffusion), and the *AV Potential* is minor.

In the simulations of the projected image on the retina, you can also see a more noticeable blurring in the second case.

Figure 66. Post-LASIK eye after unsuccessful surgery

5 TROUBLESHOOTING

When an error occurs, the program displays a message detailing the type of error that has occurred. These are the possible messages shown to the user:

5.1 ERROR MESSAGES

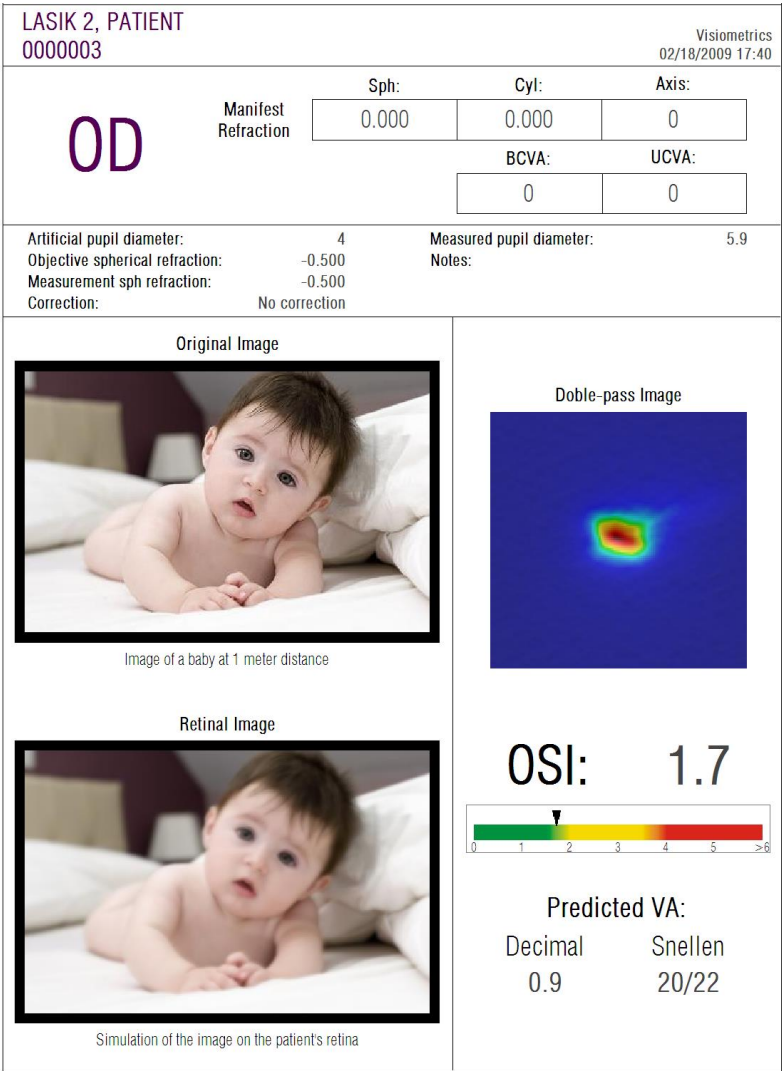| Code	Error message	Cause
5	The program requires a screen resolution of 1366x768, 1366x800, 1280x768, or 1280x800. The current resolution is different and that program must shut down. Try changing your screen resolution.	The program must be run using one of the following screen resolutions: 1366x768, 1366x800, 1280x768, 1280x800. The message is displayed if the resolution is none of these. The user must change the screen resolution.
6	Program startup has failed. The program will shut down.	For some reason (lack of memory or disk space, ...) the program could not start up. Contact Visiometrics.
21	Acquisition has failed.	For some reason, the measurement could not be completed. Try again.
22	The auto-focus process has failed. Please check the subjective refraction and correction entered and try again.	For some reason, the *Objective refraction* sequence could not be completed. Check the subjective refraction entered and try again.
25, 26, 27, 28, 29, 30	The program has detected a problem with the hardware.	A hardware error has occurred in the internal spherical refraction compensation system, in the artificial pupil, in the shutter, in the laser, in the vibrator, or in the LED lighting. The user should restart the instrument to check if it's a repetitive error. If it is, contact Visiometrics.
32	Error in the video signal.	Signal coming from the system cameras has been lost. The user should restart the instrument to check if it's a repetitive error. If it is, contact Visiometrics.
33	The images cannot be read from the disk.	The images from the selected measurement were not found on the disk. Contact Visiometrics if this error is repetitive.
34	Error processing the images.	There was an error when processing the images. Contact Visiometrics if this error is repetitive.
36	The program has not registered enough images for processing. Please try again.	For some reason, the measurement was not completed (not enough images were registered). Try again.
39	No patient was selected.	No patient was selected to view the measurement's results. Select one.
40	No acquisition was selected.	No measurement was selected to view its results. Select one.

Code	Error message	Cause
41	More than one acquisition was selected.	More than one measurement was selected to view its results. Select only one.
46	System cameras could not be detected. Check the connections.	The program could not detect the instrument's cameras. The user must check the connection between computer and instrument, making sure it's correct.
47	One of the system cameras could not be detected. Check the connections.	The program could not detect one of the instrument's cameras. The user should restart the instrument to check if it's a repetitive error. If it is, contact Visiometrics.
49	Communication failure with camera.	A communication error has occurred with the system cameras. The user should restart the instrument to check if it's a repetitive error. If it is, contact Visiometrics.
50	Not enough energy reaches the camera. The images could not be taken.	The system has reached the maximum emission of the laser, but it is not enough to measure the patient. Check the patient's correction.
54	Error in updating credit count. The program will shut down.	Unable to discount measurement credit. Contact Visiometrics.

5.2 WARNING MESSAGES

Message	Cause
The device has not been detected. The software will run in "read only" mode. To run in normal mode, check the connection cables and restart the software.	The hardware is not connected or is not working. Unable to take new measurements. To take new measurements, make sure the device is properly connected to the power source and computer. Once checked, restart the program.
The program has detected a problem with the hardware and will shut down.	There was an error in the hardware and the program will shut down. The user should restart the instrument to check if it's a repetitive error. If it is, contact Visiometrics.
The MTF could not be calculated.	The quality of the images is too low for the MTF function to process. Contact Visiometrics if this error is repetitive.
Unable to measure the patient's pupil during the process. By default, the value will be null.	The lighting conditions are not optimal. Unable to determine pupillary diameter of the patient. Try again.
At least one spherical refraction is out of range. If measuring this eye, please correct its refraction with test lenses and choose the "Total correction" option in the "Correction" field of the measurement screen.	The spherical refraction entered is out of range. It must be externally compensated with test lenses.

Apart from the on-screen message, the error and warning messages will be recorded in the file

C*:/Program Files (x86)/Visiometrics/HD_Analyzer/log/error.log.*

> *If an error occurs, please exit the program, turn off the instrument, and restart them both again. If the error persists, check the connections between the computer and hardware, and contact VISIOMETRICS detailing the source of the error.*

If the error persists, contact Visiometrics technical support.

6 MANUFACTURER

VISIOMETRICS, S.L.
C/Argenters, 8. Edifici 3.
Parc Tecnològic del Vallès
E-08290 Cerdanyola del Vallès
Barcelona (Spain)
Tel.: (+34) 935 824 501

Manufacturer number: 5.122-PS

Our website: www.visiometrics.com

Commercial information: customerservice@visiometrics.com
Technical Support: technicalservice@visiometrics.com

7 REGULATORY INFORMATION

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

8 SYMBOLS

Warning

Recycling electrical products. Do not throw out as miscellaneous urban waste, but rather dispose of it at a recycling point destined for electrical and electronic equipment.
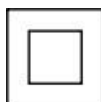
CE Brand

SN   Serial number

Applicable part

Laser radiation

Class II equipment

Fragile

Keep dry

Keep in vertical position

User's Manual

9 ELECTROMAGNETIC IMMUNITY

Guide and declaration from the manufacturer - ELECTROMAGNETIC IMMUNITY			
The HD Analyzer is intended for use in an electromagnetic environment, as specified below. The client or user of the HD Analyze equipment should ensure that it is used in such an environment.			
Immunity test	**Test level of the IEC 60601 standard**	**Level of conformity**	**Electromagnetic environment - Guide**
			Mobile and portable RF communications equipment should not be used closer to any part of the HD Analyzer equipment, including cables, than the recommended separation distance at the transmitter frequency. **Recommended separation distance:**
RF conducted IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside the ICM[a] bands	3 Vrms	$d= 1.17 (P)^{1/2}$
	10 Vrms 150 kHz to 80 MHz outside the ICM[a] bands	3 Vrms	$d= 4 (P)^{1/2}$
RF radiated IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	3 V/m	$d= 4 (P)^{1/2}$ 80 MHz a 800MHz
			$d=7.67 (P)^{1/2}$ 800 MHz a 2.5 GHz where P is the maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] The field strengths from the fixed transmitter of R, as determined by an on-site electromagnetic[c], should be less than the level of compliance in each frequency range.[d] Interference could occur in the vicinity of the equipment marked the following symbol:
NOTE 1: The highest range of frequencies is applied to 80 MHz and 800 MHz. NOTE 2: These guidelines cannot 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 at 27,283 MHz; and 40.66 MHz to 40.70 MHz. [b] Conformance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference, if introduced into patient areas inadvertently. For this reason, an additional factor of 10/3 is used in the calculation of the separation distance for the transmitters in these frequency ranges. [c] The field strengths of fixed transmitters, such as base stations for radio telephones (cellular/wireless) and land mobile radios, amateur radio stations, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To evaluate the electromagnetic environment due to the fixed RF transmitters, a study of the electromagnetic site should be considered. If the measurement of the field strength in the location in which the HD Analyzer equipment is used exceeds the applicable prior RF compliance level, the HD Analyzer equipment should be observed to verify normal operation. If an abnormal performance is observed, additional measures may be needed, such as reorienting and repositioning the HD Analyzer equipment. [d] Over the frequency range of 150kHz to 80MHz, the field strength should be less than 3 V/m			

Recommended separation distances between portable and mobile RF communications equipment and the HD Analyzer

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

Maximum assigned output power of the transmitter W	Separation distance according to transmitter frequency m			
	150 kHz to 80 MHz outside the ICM bands $d = 1{,}17\sqrt{P}$	150 kHz to 80 MHz within the ICM bands $d = 4\sqrt{P}$	80 MHz to 800MHz $d = 4\sqrt{P}$	800 MHz to 2.5GHz $d = 7{,}67\sqrt{P}$
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 assigned transmitters with a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the transmitter frequency, where P is the maximum rated output power in watts (W) according to the manufacturer of the transmitter.

NOTE 1. At 80 MHz and 800 MHz, the separation distance for the highest frequency range is applied.

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 at 27,283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3. An additional factor of 10/3 is used in the calculation of the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz to 2.5 GHz, to decrease the probability that mobile/portable communications equipment may cause interference if it is inadvertently introduced into patient areas.

NOTE 4. These guidelines cannot apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.