

HD AnalyzerTM

An OQAS product by
Visiometrics 



USER MANUAL

Version 2.2

English

Português

اللغة العربية

Deutsch

日本語

Nederlands

한국어

Türkçe

Español

Français

Italiano

CE
0318

MODEL: OQAS – HDA
Optical Quality Analysis System – High Definition Analyzer
TRADE MARK: HD Analyzer™

APPLICABLE PARTS:
Chin rest (Type B)

CODE: 2
REVISION: 6
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Table of Contents

Warnings.....	5
Precautions.....	7
1 INTRODUCTION	8
1.1 GENERAL DESCRIPTION	8
1.1.1 Double-pass technique	8
1.1.2 What is OSI?	10
1.1.3 What is MTF?	10
1.2 FEATURES	13
1.3 APPLICATIONS	13
1.4 HD ANALYZER™ SPECIFICATIONS	14
1.4.1 Hardware Specifications	14
1.4.2 Software Specifications.....	16
1.4.3 Accessories	16
1.4.3.1 Computer (PC or laptop).....	16
1.4.4 Manufacturing compliance	16
1.5 PRODUCT LIFESPAN	17
1.6 USER MANUAL'S ACCURACY	17
2 HD Analyzer™ installation and maintenance	18
2.1 HD ANALYZER™ INSTALLATION.....	18
2.2 MAINTENANCE	18
3 HD Analyzer™ Functions	20
3.1 USING THE SOFTWARE WITHOUT THE HARDWARE	20
3.2 PAY-PER-PATIENT MODE	20
3.3 GETTING STARTED.....	21
3.4 HOME MENU	23
3.5 DATABASE	25
3.5.1 New	26
3.5.2 Modify.....	27
3.5.3 Delete: patient/acquisition	27
3.5.4 Results	28
3.5.5 Compare	29
3.6 MEASUREMENTS	29
3.6.1 How to carry out an acquisition	32
3.6.2 Objective Refraction.....	35
3.6.3 Types of measurement	36
3.6.3.1 Scatter Meter and Optical Quality.....	36
3.6.3.2 Pseudo Accommodation	38
3.6.3.3 Tear Film Analysis	40

3.6.4	Monitoring results	42
3.6.4.1	Scatter Meter and Optical Quality	43
3.6.4.2	Pseudo Accommodation	52
3.6.4.3	Tear Film Analysis.....	53
3.6.4.4	Result comparison screens.....	57
3.6.5	Purkinje Measurement	60
3.6.5.1	Typing in subjective refraction	60
3.6.5.2	Selecting the Purkinje option	61
3.6.5.3	Positioning the device	61
3.6.5.4	Select desired option	62
3.6.5.5	Focus using indicator arrows	63
3.6.5.6	Automatic capture of images	68
3.6.5.7	Validating an image	71
3.6.5.8	Acquiring and validating four more images.....	73
3.6.5.9	Validating final results	74
3.6.6	Printing and exporting a results' report	75
3.7	LICENSE MANAGER	83
3.8	SETUP.....	86
3.8.1	Tear Film Options.....	86
3.8.2	User visible parameters	87
3.8.3	Setup buttons	87
3.8.4	Hardware setup	88
3.9	BACKUP.....	88
4	Examples of measurements.....	89
4.1	NORMAL EYE	89
4.2	CATARACT EYE	90
4.3	POST-LASIK EYE	91
5	Error solving.....	93
5.1	ERROR MESSAGES	93
5.2	WARNING MESSAGES.....	94
6	Manufacturer	96
7	Regulatory information.....	97
8	Appendix A.....	98
8.1	PATIENTS_TABLE	98
8.2	ACQUISITIONS_TABLE	99
8.3	STRUCT	103
8.4	SYMBOLS	103
9	Electromagnetic immunity	104

WARNINGS

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

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

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

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

SWITCH OFF AND UNPLUG THE INSTRUMENT WHILE NOT USING IT.

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

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

KEEP THIS INSTRUMENT DRY.

FOR INDOOR USE ONLY. NOT INTENDED FOR OUTDOOR USE.

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

THIS INSTRUMENT REQUIRES ANNUAL CALIBRATION TO GUARANTEE PROPER PERFORMANCE.

NOT SUITABLE FOR USE IN FLAMMABLE ENVIRONMENTS.

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

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

DO NOT TOUCH THE LENS ON THE OUTPUT WINDOW OF THE DEVICE.

PRECAUTIONS

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

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

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

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

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

Contact VISIOMETRICS if you require any help.

1 INTRODUCTION

1.1 GENERAL DESCRIPTION

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

A single light source is sent from the HD Analyzer™ and is imaged on the retina. Light then passes back through ocular media. HD Analyzer™ then analyses the size and the shape of the reflected light spot.

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

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

HD Analyzer™ provides a control and acquisition software. Additional advantages are that it is easy to work with, provides an intuitive user interface and has real-time control.

1.1.1 Double-pass technique

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

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

by modifying the optical paths between L2 and L3.

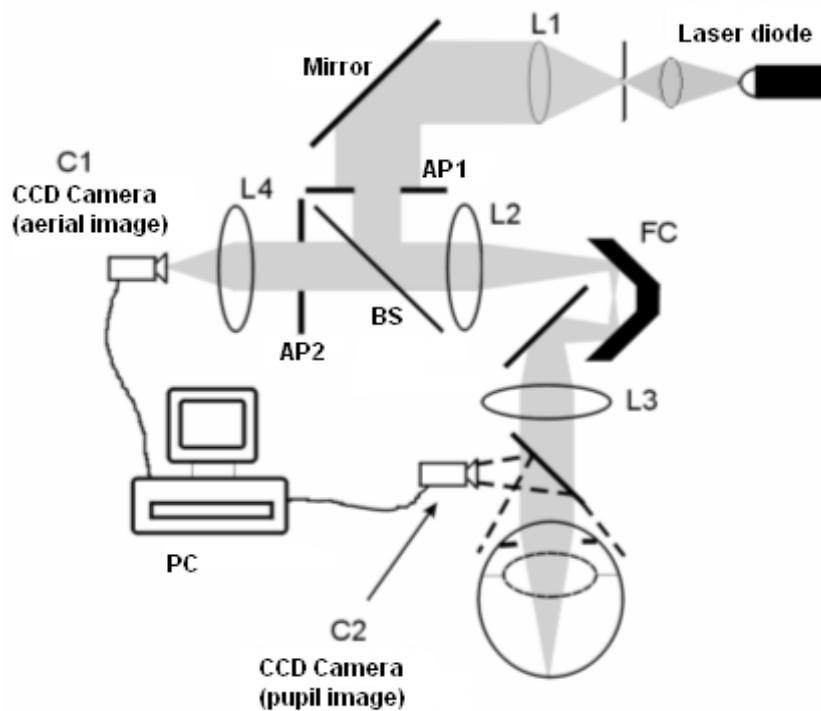


Figure 1. Scheme of the double-pass

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

The double-pass is determined by the light traveling from the retina to the CCD camera (aerial image or double-pass). This pathway begins with light being reflected on the retina in a set pattern due to the retina's diffusing behavior. The reflected light passes through the two doublet lenses and through the BS. Light transmitted through the BS encounters the second artificial pupil (AP2), which is conjugated with the eye's pupil plane. This pupil is variable and works as an effective exit pupil when AP2 is smaller than the natural pupil. The effective exit pupil will be whichever is smaller; AP2 or the natural pupil. Since the natural pupil is not static—it dilates and contracts—it is advised to set AP2 slightly smaller than the natural pupil. An optical objective focuses the aerial image on a CCD camera. Measurements may be taken using different AP2 diameters.

1.1.2 What is OSI?

OSI = Objective Scatter Index

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

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

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

1.1.3 What is MTF?

MTF = Modulation Transfer Function

The MTF of an optical system is a function which allows us to evaluate the degree of image detail that the system is able to distinguish, i.e. it evaluates the ratio between the contrast in the original scene and the contrast in the image formed by the system. As the eye is an optical system, it too has a MTF, which represents the loss of contrast of the image formed in the retina in relation to the real scene.

In any optical system, contrast reduction is higher for high spatial frequencies (fine details and contours on an image). In the following example of barcodes, the codes on the right are seen as greyer (less contrast) than those on the left, although all have the same definition. This is consistent with the fact that the more details and contours (greater spatial frequency) are found, the lower the contrast between these

details and contours in the image formed in the retina will be.



Figure 2. Bar patterns with distinct spatial frequencies.

Thus, MTF is a function that relates spatial frequency (measured in cycles per degree) to the contrast loss observed at each frequency on the image in the optical system—in this particular case, the image formed in the retina.

In the figure below, each bracket represents a distance that corresponds to one degree. The number of complete spatial cycles (the pattern formed by one black bar and one white bar) within the space of one degree varies as a function of frequency. The first bar code has a spatial frequency of 1, whereas the subsequent patterns have frequencies of 2, 4, 8, and 16, respectively. The higher the spatial frequency, the lower the contrast of the image formed in the retina.



Figure 3. Bar patterns with distinct spatial frequencies. Each bracket representing one degree.

If the contrast of the image in the optical system were the same as in the real scene, MTF would equal 1 (the highest possible value). As the frequency increases, MTF decreases because the contrast in the system image is lower and lower than in the real scene. This ratio can be expressed mathematically as follows:

$$\frac{\text{Contrast of image in optical system}}{\text{Contrast of real scene}}$$

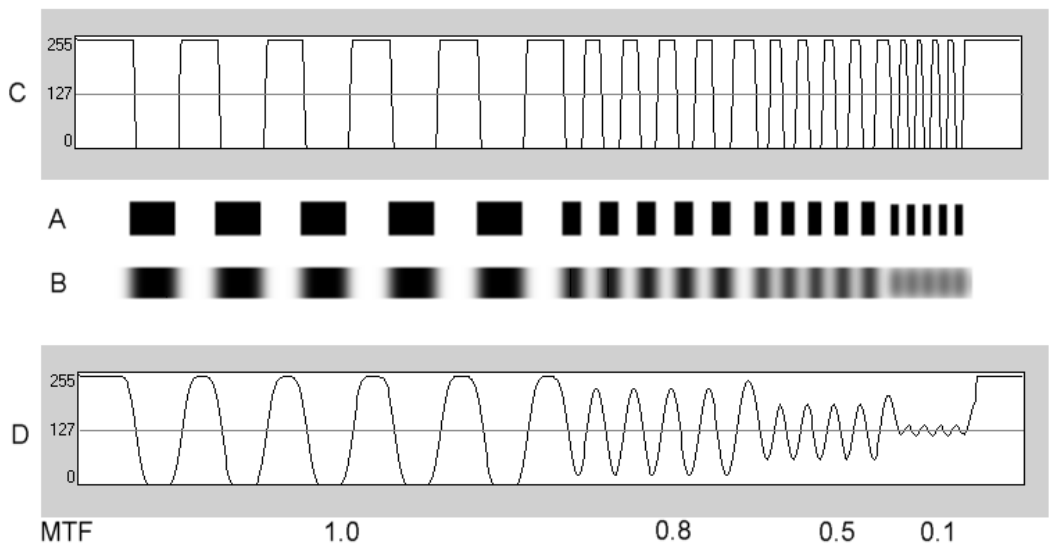


Figure 4. Comparison of contrast (C) in a real scene (A) and contrast (D) in the resulting image formed by an optical system (B).

Finally, plotting the MTF curve will yield a graph that resembles the following:

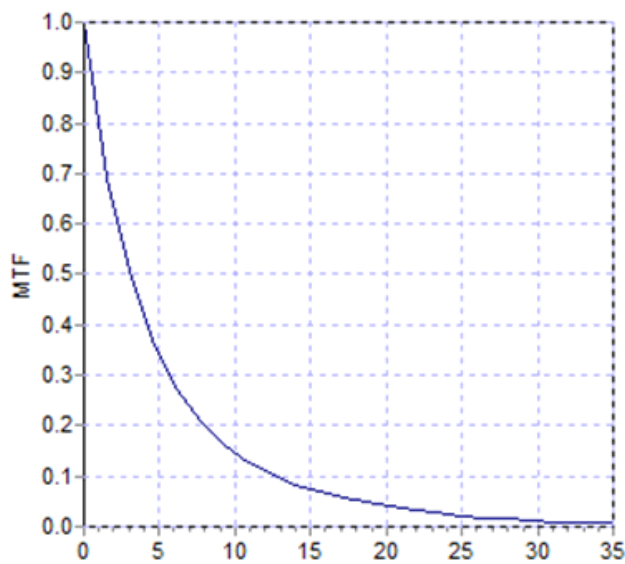


Figure 5. MTF plot. The X-axis corresponds to frequencies, and the Y-axis, the MTF associated with each frequency.

MTF also changes with pupil diameter. In this way, it is important to consider the pupil diameter of a measurement before comparing it to another measurement. This

value will be the one set as artificial pupil before performing the measurement, if it is smaller than the patient's pupil. Since a patient's pupil dilates and contracts, we advise the user to carry out measurements with a set artificial pupil slightly smaller than the natural pupil, so that measurements can be reproduced.

1.2 FEATURES

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

1.3 APPLICATIONS

- Evaluation of the level of intraocular objective scatter index (OSI) for early detection of cataracts or for the determination of its degree of maturity. Objective measurement of halos and glare.
- Comparing pre and post cataract and refractive surgery measurements.
- Evaluation of tear film quality, especially on patients suffering from dry eye.

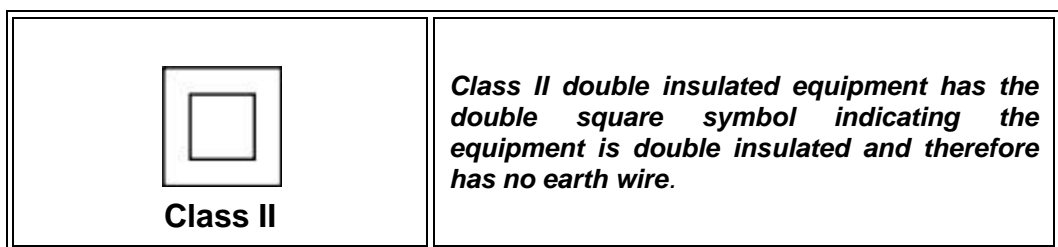
- Objective measurement of the amplitude of pseudo accommodation range.
- Diagnosis of pathologies.
- Precise measurements of the ocular MTF (Modulation Transfer Function) in all situations (overestimated by aberrometers when scattering exists, like in cataract patients).
- Showing the effect of ocular aberrations in visual acuity (including higher order aberrations, which are not usually measured by standard aberrometers).
- Showing the effect of the tear film degradation on the quality of the retinal image.
- Purkinje image assessment of an eye with no KAMRA™ inlay implanted, detecting exact position of its optical axis with respect to the pupil center and allowing the required correct position for KAMRA™ inlay implantation.
- Purkinje image assessment of an eye with a KAMRA™ inlay implanted, detecting exact position of implanted inlay with respect to the eye's optical axis, allowing the user to quantify how close the inlay is from its optimal position (eye's optical axis).

1.4 HD ANALYZER™ SPECIFICATIONS

1.4.1 Hardware Specifications

- Type B
- Measurement range: Min. +5 D to -8 D S.E. (higher ametropias including astigmatism can be neutralized with an additional lens)
 - Reproducibility: +/- 0.25 D
 - Accuracy: +/- 0.25 D
- Best focus dioptric value: ± 0.125 D of average
- Natural pupil diameter measurement: Automatic
 - Accuracy: +/- 0.5 mm (for an 8 mm pupil)
- Artificial pupil diameter: 2 to 7 mm
- Image capture time: 240 ms

- Laser diode wavelength: 780 nm
- Laser power selection: Automatic
- Maximum laser power at the pupil plane: 45.39μW
- Best focus position: Automatic
- Fixation target: Landscape with house
- XY translation: Joystick
- Size: 415 (L) x 350 (W) x 530 (H) mm
- Recommended working space: 2.5 m²
- Weight: 20 Kg
- External Power supply:
 - Input: 100-240 VAC, 50-60 Hz, max. 0.9 A
 - Output: 12 V DC, 3.0 A, 40 W
- Operating temperature and relative humidity: +10 °C to +35 °C (50°F to 95°F), and 30% to 90%.
- Storage temperature and relative humidity: -10 °C to +55 °C (14°F to 131°F), and 10% to 95%.
- Transport temperature and relative humidity: -40 °C to +70 °C (-40°F to 158°F), and 10% to 95%.



With respect to Purkinje measurement:

- Optimal distance between the patient's eye and HD Analyzer™ is achieved by following the arrow directions shown by the software when starting the measurement.
- Purkinje detection
 - Error below 142μm in more than 95% of measurements.

- Purkinje offset detection – KAMRA™ inlay
 - Error below 142µm in more than 95% of measurements.
- Pupil offset detection – KAMRA™ inlay
 - Error below 142µm in more than 95% of measurements.

1.4.2 Software Specifications

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

1.4.3 Accessories

1.4.3.1 Computer (PC or laptop)

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

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

1.4.4 Manufacturing compliance

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

1.5 PRODUCT LIFESPAN

The power source supplied with the HD Analyzer™ equipment has a useful life of 3 years and should be replaced after such time has passed.



This equipment must be operated with the power supply unit provided.

VISIOMETRICS estimates that the useful life of the equipment, having duly replaced the power supply, is 5 years. Habitual use of the HD Analyzer™ over 5 years places the useful life of the dynamic elements of the equipment at 15% below its useful life.

1.6 USER MANUAL'S ACCURACY

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

Small differences will be due only to different setup options.

2 HD ANALYZER™ INSTALLATION AND MAINTENANCE

2.1 HD ANALYZER™ INSTALLATION

The HD Analyzer™ system should only be installed by authorized personnel.

This equipment is not designed to be portable. Once the system has been installed, moving it to another location is discouraged. If transport to a nearby location is unavoidable, we recommend that two people lift and move the instrument by securely holding it from its base, with one person on each side of the instrument.



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

If the equipment is to be moved to a remote location, contact the distributor or manufacturer to schedule proper repackaging of the instrument and installation at its new location.

2.2 MAINTENANCE

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

Cleaning

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

The HD Analyzer™ has a low infection risk derived from its usage, which can be classified as non-critical and therefore will need a low level of disinfection. The

patient comes in contact with the instrument through intact skin of the chin and front areas, which rest on the chinrest, and with their hands, which they may use to hold the chinrest.

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



- ***Keep this device dry.***
- ***For indoor use only. Not designed for outdoor use. Professional use only.***
- ***Turn off or unplug when not in use.***
- ***This machine is not water or splash-proof. If moisture, water, or liquid gets inside the housing, immediately unplug the unit and contact a service technician or your dealer before using it again.***
- ***In case of technical issues, do not attempt to remove the side unit covers. There are no user-serviceable parts inside. Refer to your dealer or other accredited service personnel***

Calibration

User must not carry out any calibration tasks on the equipment.

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

3 HD ANALYZER™ FUNCTIONS

3.1 USING THE SOFTWARE WITHOUT THE HARDWARE

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

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

3.2 PAY-PER-PATIENT MODE

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

In free mode, you can perform unlimited measurements, with no limitation.

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

In order to get new measurement credits, you have to purchase them at Visiometrics' website (www.visiometrics.com). Once you have entered the web site, click on *Client Access*, and enter your username and password. This will allow you to access your private account, where you can check your personal data (*User Profile*) and a list of your previous purchases. In the section *Buy measurements*, select the center where the HD Analyzer™ is installed, its serial number, and the number of credits you would like to buy. After clicking on *Buy*, type in all of the required data in order to complete the purchase process. The result of this process

will be a 16-character code (activation code) with this format:

XXXX – XXXX – XXXX – XXXX

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

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

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

NOTES:

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

If you have any questions, please contact Visiometrics.

3.3 GETTING STARTED

Instructions for use

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

instead, which is already tilted.

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

General directions to patients

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

To do this, make sure that the hygienic protectors are correctly placed on the chinrest of the HD Analyzer™ instrument. The patient will be requested to sit down and place his chin on the hygienic protector, on the chin rest. In addition, it is also recommended that all measurements are taken in rooms with low and constant lighting, to aid the dilation of the pupils and to avoid direct air currents to the patient, so as not to affect the patient's blinking rhythm.

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

Directions to the patient during the objective refraction

During the objective refraction sequence, the patient should be warned that during the sequence, the target will appear, at times, unfocused, and that they should not attempt to focus on it, but to casually look at the target throughout the whole sequence.

Directions to the patient during the measurement of scattering and optical quality

During the scattering or optical quality sequence, the patient should be requested to try to focus on the target as much as possible during the process.

Directions to the patient during pseudoaccommodation

The pseudoaccommodation sequence (*Pseudo Accommodation*) is intended only for those patients who have, to a great extent or even completely, lost their accommodation ability. Nonetheless, the patient should be instructed to try to focus on the target as much as possible during the process.

Directions to the patient during Tear Film Analysis

During the tear film analysis sequence (*Tear Film Analysis*), the patient should be requested to casually look at the target. If the measurement is carried out following a sound pattern, patient should be requested to only blink when hearing the sound signals. If no sound pattern is followed, patient should be requested to try hard not to blink during the entire process (20 seconds).

Directions to the patient during the Purkinje sequence

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

3.4 HOME MENU

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

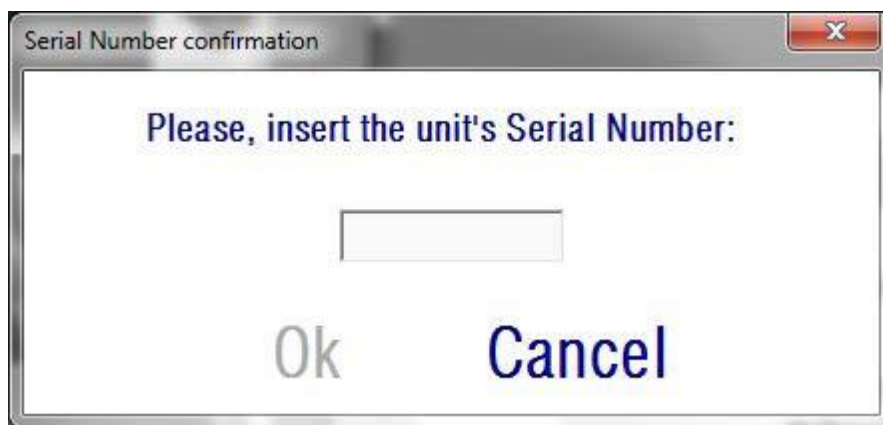


Figure 6. Serial number confirmation

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

After providing the unit's Serial Number and clicking OK, the *Home* screen will appear, as shown below.

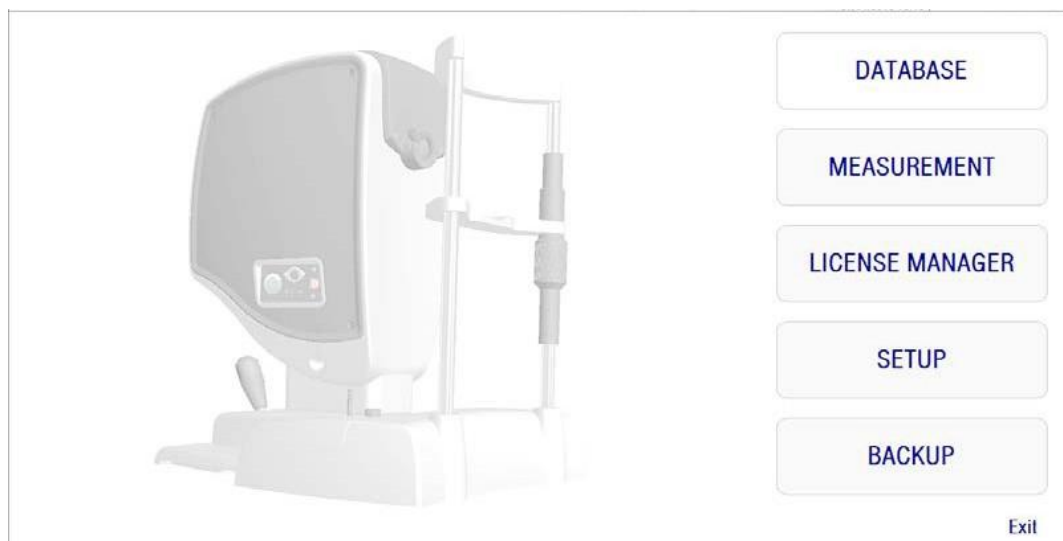


Figure 7. *Home* screen

This screen gives access to the following sections:

- *Database*: Gives access to the patient database in order to edit, view, compare, print or delete previously saved results. The database will always be accessible through this button; even when running the software without having the HD Analyzer™ instrument connected, or if there are no available measurement credits in pay-per-patient mode.
- *Measurement*: When the HD Analyzer™ instrument is connected to the computer, switched on and the serial number is correct, this button will be enabled and will activate the screen which allows measurements to be taken. In pay-per-patient mode, this option will be enabled only if there are measurement credits available.
- *License Manager*: Gives access to the application for the system's license management. In that application, the user will be able to enter the purchase codes obtained from his account from the Visiometrics web page. This will allow the new measurement credits bought by the user to be activated.
- *Setup*: This button activates the setup screen. The user will be able to modify some of the parameters of the system. The rest of parameters are

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

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

3.5 DATABASE

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

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

Database

You can either take a measurement first and select a patient later or select the patient first and then carry out the measurements. In this case, enter the database screen by clicking the *Database* button.

In this screen, you can add new patients and modify or delete the existing ones. You can also select a patient for performing new measurements.

PATIENT: P

Aaaaaa Aaaaaa, Aaaa

0001

Name(*):

Bbbbb Bbbbb, Bbbb

0002

Surname(*):

Patient, Demo

0003

Date of birth:

11/11/11, 11

0004

Address:

City:

Zip code:

Ph. number:

Country:

E-mail:

Comments:

Patient's Id(*) 0003

(*) Required fields

New

Modify

Delete

Measure

Total number of acquisitions: 13

Date/Time	Type	OD/OS	Pat. Refrac.	Sph. Refrac. Con.	NP	AP	NOTES
03/08/2013 18:36	SCT	S	-3.75 -0.5 x 135	-3.5	5.3	4	
02/08/2013 16:53	Opt. Qlt.	D	0 0 x 0	0.5	6	4	
02/08/2013 16:53	SCT	D	0 0 x 0	0.5	6	4	
02/08/2013 16:54	Pseudo Acc.	D	0 0 x 0	0.5	6	4	
02/08/2013 16:55	Tear Film	D	0 0 x 0	0.5	6	7	
02/08/2013 17:13	Opt. Qlt.	D	0 0 x 0	-0.5	6.4	4	
02/08/2013 17:13	SCT	D	0 0 x 0	-0.5	6.4	4	
02/08/2013 17:14	Pseudo Acc.	D	0 0 x 0	-0.5	6.4	4	
02/08/2013 17:17	Tear Film	D	0 0 x 0	-0.5	6.4	7	
07/19/2013 09:34	PKU	D	0 0 x 0	0	0	4	
07/19/2013 09:36	PKU	S	0 0 x 0	0	0	4	
07/30/2013 11:14	PKU	S	0 0 x 0	0	0	4	
07/30/2013 12:20	PKU	S	0 0 x 0	0	0	0	

Filter by

No filter

Acq. date:

All

Acq. type:

Scattering

Opt. Quality

Pseudo Acc.

Tear Film

Purkinje

Eye:

OD OS

Results

Compare

Delete acq.

Home

Exit

Figure 8. Patient database

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

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

3.5.1 New

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

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

3.5.2 Modify

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

PATIENT: PATIENT, DEMO		0003	New Modify Delete Measure																																																																																																																
Name(*):	Demo	Patient's Id(*) 0003																																																																																																																	
Surname(*):	Patient																																																																																																																		
Date of birth(mm/dd/yyyy): Gender (M/F): Address: City: Zip code: Ph. number: Country: E-mail: Comments:																																																																																																																			
Total number of acquisitions: 13 <table border="1"> <thead> <tr> <th>Date/Time</th> <th>Type</th> <th>OD/OS</th> <th>Pat. Refrac.</th> <th>Sph. Refrac. Corr.</th> <th>NP</th> <th>AP</th> <th>NOTES</th> </tr> </thead> <tbody> <tr><td>03/08/2012 18:36</td><td>SCT</td><td>S</td><td>-3.75 -0.5 x 135</td><td>-3.5</td><td>5.3</td><td>4</td><td></td></tr> <tr><td>02/28/2013 16:53</td><td>Opt. Qlt.</td><td>D</td><td>0 0 x 0</td><td>0.5</td><td>6</td><td>4</td><td></td></tr> <tr><td>02/28/2013 16:53</td><td>SCT</td><td>D</td><td>0 0 x 0</td><td>0.5</td><td>6</td><td>4</td><td></td></tr> <tr><td>02/28/2013 16:54</td><td>Pseudo Acc.</td><td>D</td><td>0 0 x 0</td><td>0.5</td><td>6</td><td>4</td><td></td></tr> <tr><td>02/28/2013 16:55</td><td>Tear Film</td><td>D</td><td>0 0 x 0</td><td>0.5</td><td>6</td><td>7</td><td></td></tr> <tr><td>02/28/2013 17:13</td><td>Opt. Qlt.</td><td>D</td><td>0 0 x 0</td><td>-0.5</td><td>6.4</td><td>4</td><td></td></tr> <tr><td>02/28/2013 17:13</td><td>SCT</td><td>D</td><td>0 0 x 0</td><td>-0.5</td><td>6.4</td><td>4</td><td></td></tr> <tr><td>02/28/2013 17:14</td><td>Pseudo Acc.</td><td>D</td><td>0 0 x 0</td><td>-0.5</td><td>6.4</td><td>4</td><td></td></tr> <tr><td>02/28/2013 17:17</td><td>Tear Film</td><td>D</td><td>0 0 x 0</td><td>-0.5</td><td>6.4</td><td>7</td><td></td></tr> <tr><td>07/19/2013 09:34</td><td>PKJ</td><td>D</td><td>0 0 x 0</td><td>0</td><td>0</td><td>4</td><td></td></tr> <tr><td>07/19/2013 09:38</td><td>PKJ</td><td>S</td><td>0 0 x 0</td><td>0</td><td>0</td><td>4</td><td></td></tr> <tr><td>07/30/2013 11:14</td><td>PKJ</td><td>S</td><td>0 0 x 0</td><td>0</td><td>0</td><td>4</td><td></td></tr> <tr><td>07/30/2013 12:20</td><td>PKJ</td><td>S</td><td>0 0 x 0</td><td>0</td><td>0</td><td>0</td><td></td></tr> </tbody> </table>			Date/Time	Type	OD/OS	Pat. Refrac.	Sph. Refrac. Corr.	NP	AP	NOTES	03/08/2012 18:36	SCT	S	-3.75 -0.5 x 135	-3.5	5.3	4		02/28/2013 16:53	Opt. Qlt.	D	0 0 x 0	0.5	6	4		02/28/2013 16:53	SCT	D	0 0 x 0	0.5	6	4		02/28/2013 16:54	Pseudo Acc.	D	0 0 x 0	0.5	6	4		02/28/2013 16:55	Tear Film	D	0 0 x 0	0.5	6	7		02/28/2013 17:13	Opt. Qlt.	D	0 0 x 0	-0.5	6.4	4		02/28/2013 17:13	SCT	D	0 0 x 0	-0.5	6.4	4		02/28/2013 17:14	Pseudo Acc.	D	0 0 x 0	-0.5	6.4	4		02/28/2013 17:17	Tear Film	D	0 0 x 0	-0.5	6.4	7		07/19/2013 09:34	PKJ	D	0 0 x 0	0	0	4		07/19/2013 09:38	PKJ	S	0 0 x 0	0	0	4		07/30/2013 11:14	PKJ	S	0 0 x 0	0	0	4		07/30/2013 12:20	PKJ	S	0 0 x 0	0	0	0		Filter by No filter Acq. date: All Acq. type: Scattering Opt. Quality Pseudo Acc. Tear Film Purkinje Eye: OD OS
Date/Time	Type	OD/OS	Pat. Refrac.	Sph. Refrac. Corr.	NP	AP	NOTES																																																																																																												
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02/28/2013 17:13	SCT	D	0 0 x 0	-0.5	6.4	4																																																																																																													
02/28/2013 17:14	Pseudo Acc.	D	0 0 x 0	-0.5	6.4	4																																																																																																													
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07/30/2013 12:20	PKJ	S	0 0 x 0	0	0	0																																																																																																													
			Results Compare Delete acq. Home Exit																																																																																																																

Figure 9 Data modification

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

3.5.3 Delete: patient/acquisition

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

Confirmation is required before deleting a patient record.



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

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

3.5.4 Results

Once the patient has been selected, all of the measurements performed on him are shown in the list below (see Figure 10), and are now available for analysis, printing, comparison, etc. The full list is shown by default. Different types of filters can be applied, using the buttons at the right of the list. The list can also be sorted by any of the available columns, by clicking on the column title.

PATIENT: PATIENT, DEMO		0003					
Name(*): Demo		Patient's Id(*) 0003					
Surname(*): Patient							
Date of birth(mm/dd/yyyy):		Gender (M/F):					
Address:							
City:		Zip code:					
Ph. number:		Country:					
E-mail:							
Comments:							
(*) Required fields							
Total number of acquisitions: 13							
Date/Time	Type	OD/OS	Pat. Refrac.	Sph. Refrac. Cor.	NP	AP	NOTES
03/08/2012 18:36	SCT	S	-3.75 -0.5 x 135	-3.5	5.3	4	
02/28/2013 16:53	Opt. Qlt.	D	0 0 x 0	0.5	6	4	
02/28/2013 16:53	SCT	D	0 0 x 0	0.5	6	4	
02/28/2013 16:54	Pseudo Acc.	D	0 0 x 0	0.5	6	4	
02/28/2013 16:55	Tear Film	D	0 0 x 0	0.5	6	7	
02/28/2013 17:13	Opt. Qlt.	D	0 0 x 0	-0.5	6.4	4	
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07/19/2013 09:34	PKJ	D	0 0 x 0	0	0	4	
07/19/2013 09:38	PKJ	S	0 0 x 0	0	0	4	
07/30/2013 11:14	PKJ	S	0 0 x 0	0	0	4	
07/30/2013 12:20	PKJ	S	0 0 x 0	0	0	0	

Filter by

No filter

Acq. date:

All

Acq. type:

Scattering

Opt. Quality

Pseudo Acc.

Tear Film

Purkinje

Eye:

OD OS

Figure 10. Open a measurement

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

- **Date/Time**
- **Type:** *SCT* (Scatter Meter), *Opt. Qlt.* (Optical Quality), *Pseudo Acc.* (Pseudo Accommodation), *Tear Film* (Tear Film Analysis) and *PKJ* (Purkinje). Some of these features may not be available in your system.
- **OS/OD:** Left/Right eye
- **Pat. Refrac.** Subjective patient's refraction (*Sph*, *Cyl* and *Axis* values), typed by the user before performing the measurement.

- Sph. Refrac. Corr.: Defocus (spherical refraction) correction applied by the instrument during the measurement.
- NP.: Natural pupil diameter (in mm) determined by the instrument while performing the measurement. A 0 value indicates that this diameter was not measured.
- AP.: Artificial pupil diameter (in mm) used for performing the measurement.
- Notes: Acquisition notes, if any.

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

3.5.5 Compare

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

See section 3.6.4.4 for more information about the comparison screens.

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

3.6 MEASUREMENTS

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

In both cases, the user will be required to enter the values of the subjective refraction of the patient (see Figure 11). This information is needed by the HD Analyzer™ instrument to look for the best spherical correction around a dioptric range, thus resulting in a more reliable and exact measurement and will require less time. The fields *Sph* (sphere), *Cyl* (cylinder) and *Axis* (axis) are required, for both eyes. The

instrument is able to perform measurements in the range of spherical refractions between +5 D a -8 D, and the range of astigmatism between +0.5 D and -0.5 D. Out of these ranges, the refraction of the patient must be corrected by means of trial lenses (only for the astigmatism, or for both sphere and cylinder).

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



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

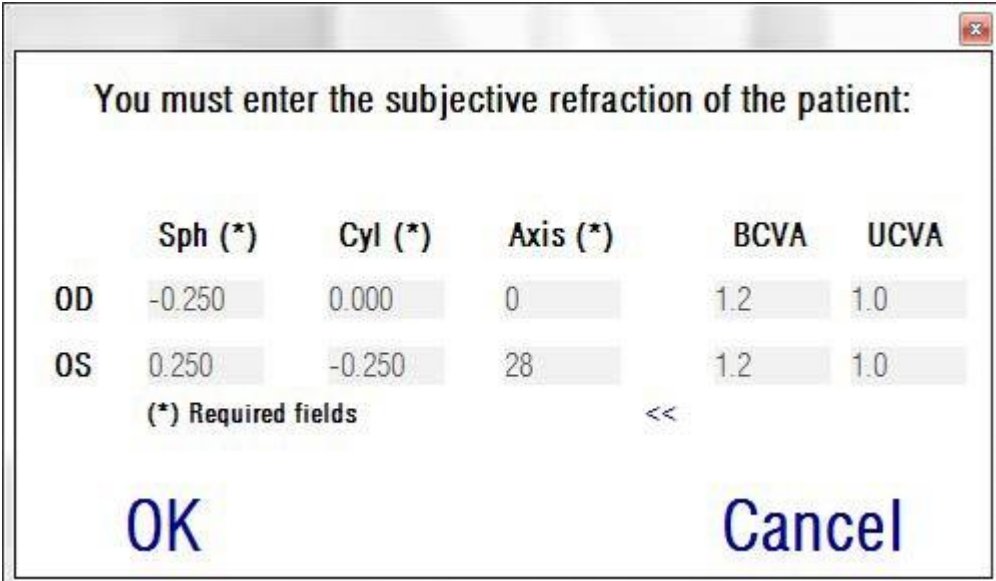
	Sph (*)	Cyl (*)	Axis (*)
OD	-0.250	0.000	0
OS	0.250	-0.250	28

(*) Required fields >>

OK Cancel

Figure 11. Subjective refraction (compacted view)

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



A dialog box titled "You must enter the subjective refraction of the patient:" with a close button in the top right corner. It contains a table for entering refraction data for OD and OS eyes. The table has columns for Sph (*), Cyl (*), Axis (*), BCVA, and UCVA. Below the table, there is a note "(*) Required fields" and a double arrow button "<<". At the bottom are "OK" and "Cancel" buttons.

	Sph (*)	Cyl (*)	Axis (*)	BCVA	UCVA
OD	-0.250	0.000	0	1.2	1.0
OS	0.250	-0.250	28	1.2	1.0

(*) Required fields <<

OK Cancel

Figure 12. Subjective refraction (enlarged view)

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

3.6.1 How to carry out an acquisition

The measurement's main screen is divided into six areas (see Figure 13):

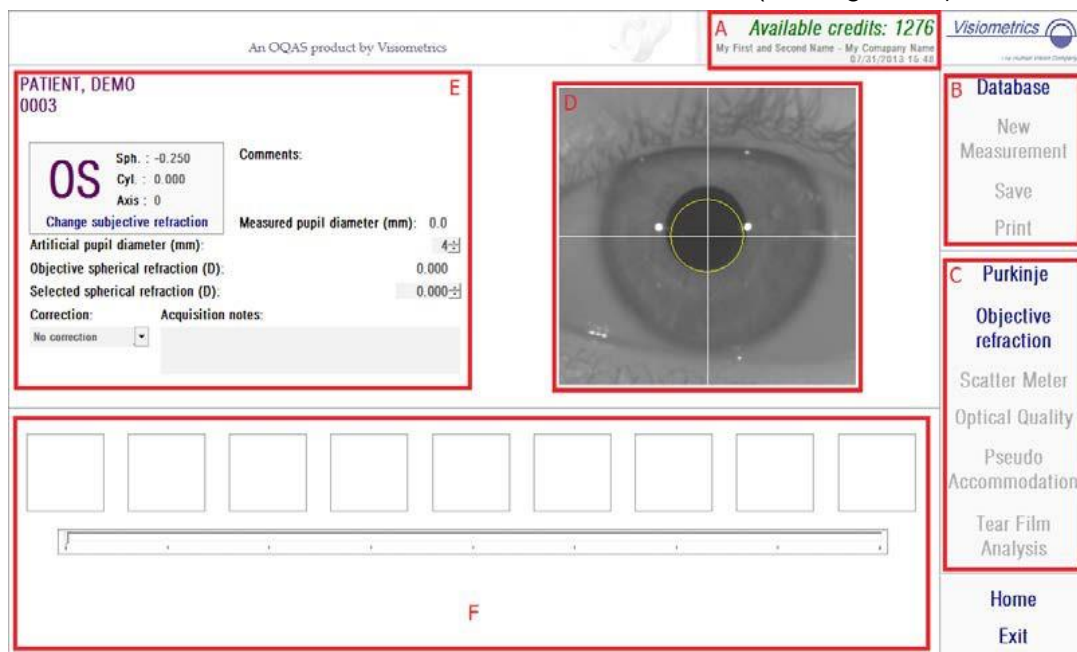


Figure 13. Measurements main screen

- A. System information:** The information shown at the top of the screen can be customized to include the name of the center and person who operates the HD Analyzer™ instrument. This information can be accessed and modified through the Setup button at the Home menu (see section 3.8). If the software is running in pay-per-patient mode, the system also shows the number of available measurement credits.
- B. Main functions:** These buttons allow the user to perform common actions with the data, such as accessing the database (see section 3.5), and saving or printing the results.
- C. Measurement processes:** Some of the buttons become available only when Objective Refraction has been carried out. See the following sections for more information. (Note: not all of the measurement options may be available in your system)
- D. Live image:** This window shows the patient eye in real time, allowing the user to center and focus the image.

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

F. This section shows two different types of information:

- Visualization of the Objective Refraction process: This section shows the progress and results of the process for the determination of the best spherical refraction correction.
- Measurement Results: Once the measurement process has finished, results are shown for: Scatter Meter, Optical Quality, Pseudo Accommodation and Tear Film Analysis, as well as parameters typed in by the user (see section 3.6.4)

If a patient has been selected, his data appears on the main screen. The eye that is going to be measured OD/OS (Right Eye / Left Eye respectively) is automatically detected by the instrument. The eye's spherical refraction (*Sph*), Cylinder (*Cyl*) and astigmatism axis (*Axis*) that have been entered previously are shown in the corresponding fields. Please check if those values are correct. If they are not, change the values by clicking on *Change subjective refraction*, as seen in red on Figure 14.

The screenshot displays the HD Analyzer software interface. On the left, under 'PATIENT, DEMO 0003', there is a section for 'OS' (Left Eye) with a red box highlighting the 'Change subjective refraction' button. Below this, fields show 'Sph.: -0.250', 'Cyl.: 0.000', and 'Axis: 0'. To the right of these fields is a 'Comments:' section. Further right, 'Measured pupil diameter (mm): 0.0' is displayed. Below the pupil diameter, there are fields for 'Artificial pupil diameter (mm): 4.0', 'Objective spherical refraction (D): 0.000', and 'Selected spherical refraction (D): 0.000'. A 'Correction:' dropdown menu is set to 'No correction'. An 'Acquisition notes:' text area is also present. In the center, there is a grayscale image of an eye with a green circle indicating the measurement area. On the right side, a vertical menu contains options: 'Database', 'New Measurement', 'Save', 'Print', 'Purkinje', 'Objective refraction', 'Scatter Meter', 'Optical Quality', 'Pseudo Accommodation', 'Tear Film Analysis', 'Home', and 'Exit'.

Figure 14. Eye and refraction data

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



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

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

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

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

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

- *Total correction*: The user has corrected both the patient's spherical refraction and astigmatism by means of trial lenses.

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



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

3.6.2 Objective Refraction

See section 3.3 for patients' directions.

Click *Objective Refraction* to begin the process of determination of the optimal spherical refraction correction. This process is necessary in order to avoid the presence of defocus on the registered images, which effect may hide other underlying problems. Consequently, the optimal spherical correction must be determined before performing any other measurement. The HD Analyzer™, using a 5-mm artificial pupil, performs a sweep looking for the best double-pass image at different spherical corrections, so as to compensate for defocus. While this process is running, the user can see the images that the HD Analyzer™ stores. When this process is completed, the system automatically selects the best correction.

HD Analyzer™ will show this value as *Objective spherical refraction* and *Selected spherical refraction*. This last value can be modified, if wanted, by clicking on the desired image. It should be taken into account that the measurements will be carried out considering the *Selected spherical refraction* value.



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

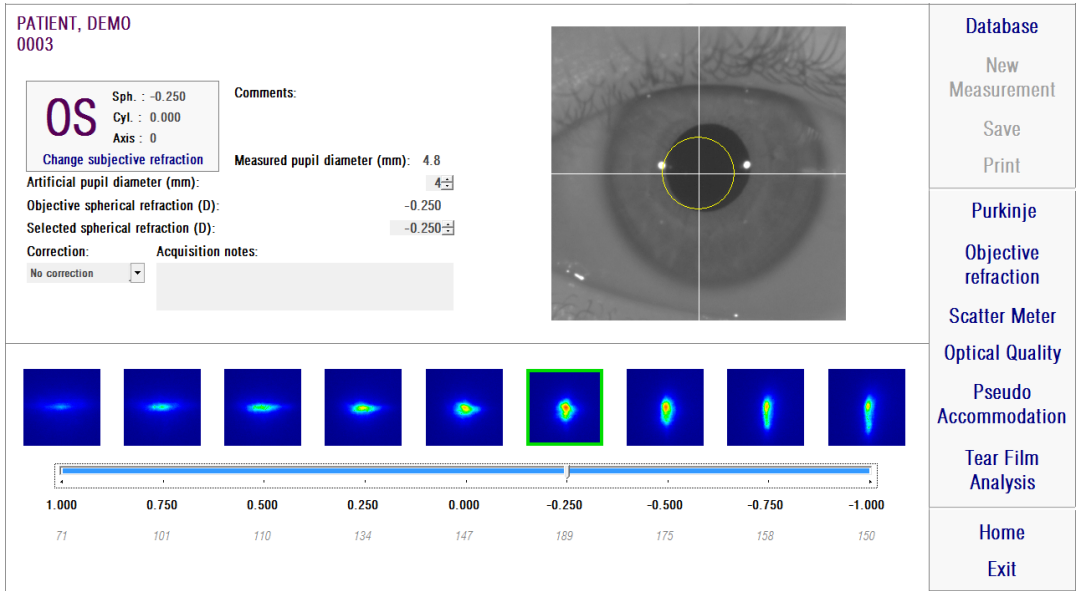


Figure 15. Objective Refraction process

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

3.6.3 Types of measurement

3.6.3.1 Scatter Meter and Optical Quality

See section 3.3 for patients' directions.

Once the *Objective Refraction* process has been carried out, measurements may begin. In the case of *Optical Quality*, you must establish the artificial pupil diameter that will be used for the measurement. Select the desired value in the field *Artificial pupil diameter*. In the case of *Scatter Meter*, there is no need for setting the parameter. According to the definition of OSI parameter, the measurement will be performed using a 4-mm artificial pupil, no matter what the entered value may be. If, when capturing the images, the software detects that the patient's pupil is inferior to the artificial pupil used, a warning will be shown at the end of the process.

Click *Scatter Meter* or *Optical Quality* to begin the corresponding measurement process (intraocular scattered light quantification, or optical quality evaluation for far

vision). Both processes consist of capturing six double-pass images in conditions of best spherical correction (far vision), and their processing. The system outlines in green the images considered to be correct. Once the capture has finished, the user can select any undesired image by clicking it with the mouse. Checked out images will appear outlined in red and will be excluded from the processing and analysis. Images outlined in green are processed and analyzed by clicking *Results*, and results are shown with different visualization options (see section 3.6.4.1).

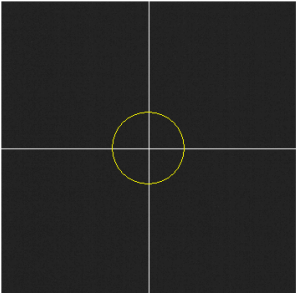
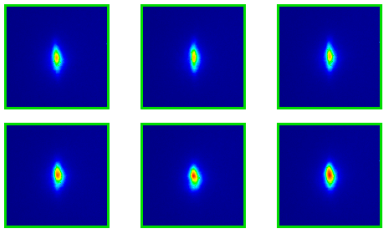
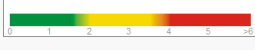
PATIENT, DEMO 0003			Database New Measurement Save Print
<div style="display: flex; justify-content: space-around;">  </div> <div style="display: flex; justify-content: center; gap: 20px;"> Return Results </div>			Purkinje Objective refraction Scatter Meter Optical Quality Pseudo Accommodation Tear Film Analysis
<div style="display: flex;"> <div style="flex: 1;"> <p>OS</p> <p>Sph. : -0.250 Cyl. : 0.000 Axis : 0</p> <p>Change subjective refraction</p> <p>Artificial pupil diameter (mm): 4.7</p> <p>Objective spherical refraction (D): -0.250</p> <p>Selected spherical refraction (D): -0.250</p> <p>Correction: No correction</p> <p>Acquisition notes:</p> </div> <div style="flex: 1;"> <p>Comments:</p> <p>Measured pupil diameter (mm): 4.7</p> </div> </div>		<div style="text-align: center;"> <p>OSI: 0.0</p>  </div> <div style="text-align: center;"> <p>Decimal Snellen</p> <p>Predicted Visual Acuity: 0.0 20/0</p> </div>	
		Home Exit	

Figure 16. Scatter Meter measurement

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



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

3.6.3.2 Pseudo Accommodation

See section 3.3 for patients' directions.

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

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

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

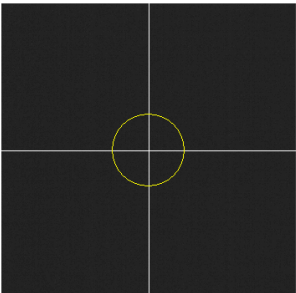
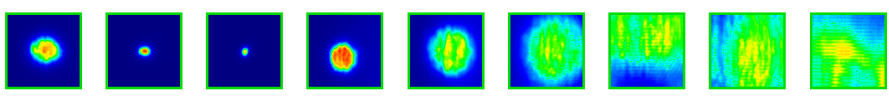
PATIENT, DEMO 0003			Database New Measurement Save Print
OD Sph. : -0.250 Cyl. : 0.000 Axis : 0 Change subjective refraction	Comments: Measured pupil diameter (mm): 8.3 Artificial pupil diameter (mm): 4.0 Objective spherical refraction (D): 1.250 Selected spherical refraction (D): 1.250 Correction: No correction Acquisition notes:		
			Home Exit
-1.0 D -0.5 D 0.0 D 0.5 D 1.0 D 1.5 D 2.0 D 2.5 D 3.0 D			Return Results

Figure 17. Pseudo Accommodation measurement

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



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

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



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

3.6.3.3 Tear Film Analysis

See section 3.3 for patients' directions.

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

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

The Tear Film Analysis sequence can be guided, or not, by a sound pattern. The results obtained will show different information according to whether it has been guided, or not, by a sound pattern. To configure the default mode in which the Tear Film Analysis sequences will be carried out, go to the Setup screen (see chapter 3.8.1).

To begin the Tear Film Analysis sequence, following the default setup, click on ***Tear Film Analysis***. If you want to occasionally carry out a sequence using a different pattern, you can do it by clicking on the button ***Tear Film Analysis*** while holding down the Control key. In addition, doing it this way will allow you to quickly change the default pattern used without having to go to the ***Setup*** screen.

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

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

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

Figure 18 shows the result of a Tear Film Analysis process.

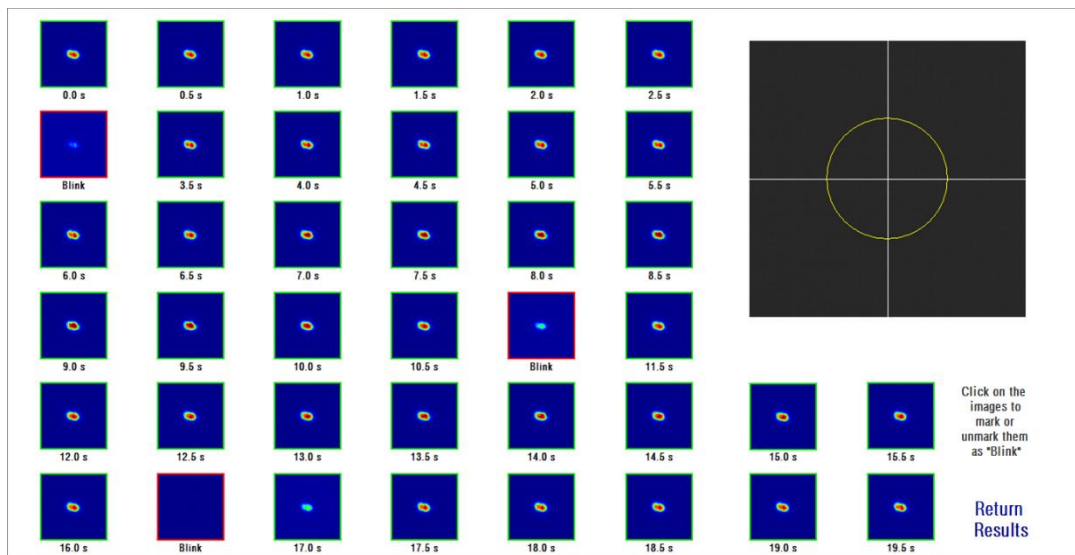


Figure 18. Tear Film Analysis measurement

At the end of the 20 seconds, you can see all 40 captured images. Below each one, you can find the exact second when the image was captured. Some of them may be labeled as “Blink”. In addition, those considered as blinks will be marked with a red square, whereas the rest will be marked with a green square. You can change the state of any image, from “Blink” to normal, or from normal to “Blink”, by clicking on the image.

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



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

3.6.4 Monitoring results

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

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

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

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

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

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

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

Selected spherical refraction: Spherical correction used in the measurement.

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

Acquisition notes: Comments related to the measurement, entered by the user. These notes can be modified by the user in any subsequent viewing.

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

3.6.4.1 Scatter Meter and Optical Quality

Once the *Scatter Meter* or *Optical Quality* measurement processes have finished, click on *Results*. Results are shown as per Figure 19 and Figure 20 respectively.

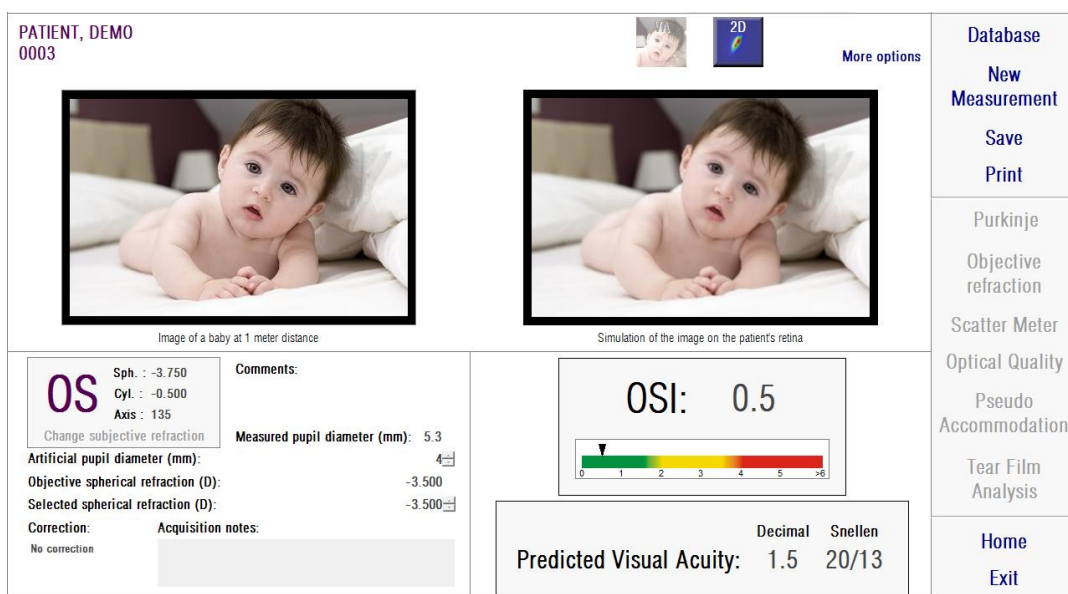


Figure 19. Scatter Meter results.

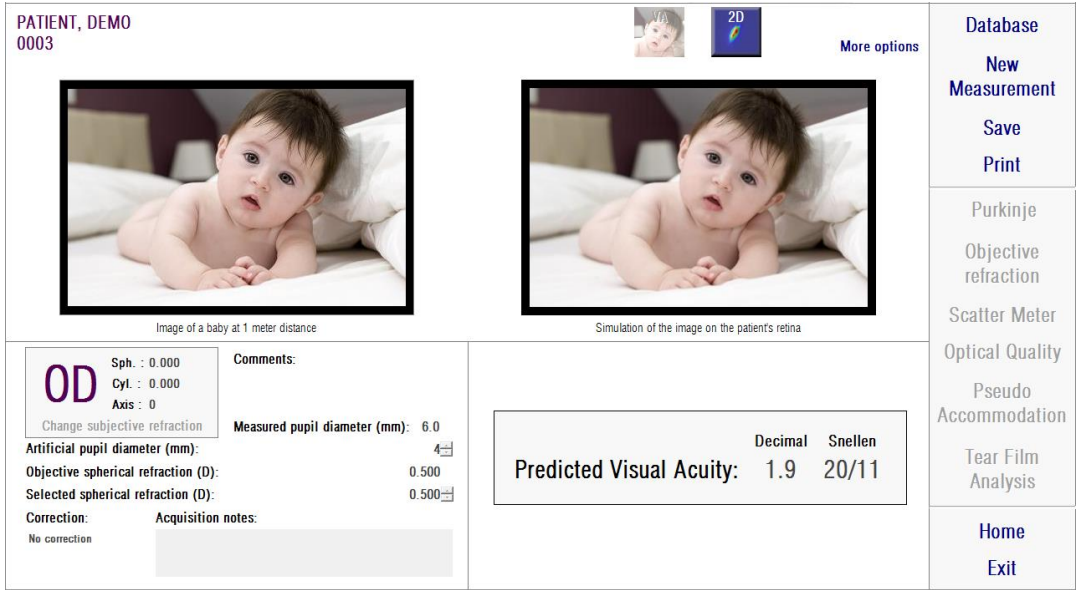


Figure 20. Optical Quality results

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

The results' screen is divided into three areas, clearly separated, as seen below:

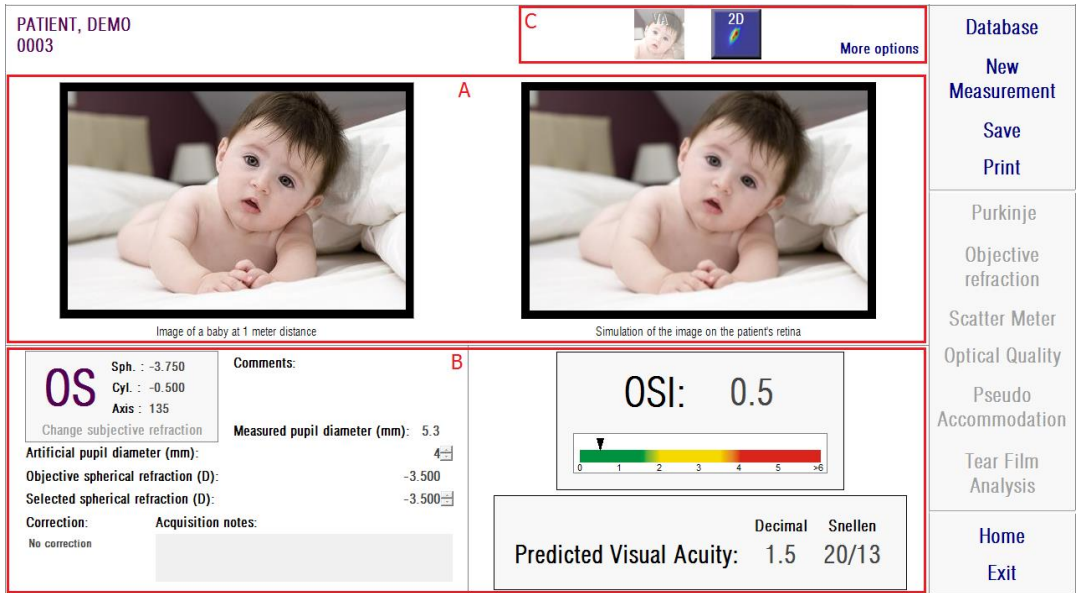


Figure 21. Areas of the results' screen

- A. Image visualization area:** Depending on selection made using buttons in section C, this area will show one of the visualization options available in normal mode (VA simulation, 2D) or for expert users (3D, Profile, MTF). (See below for more information).
- B. Input/Output data:** This section shows the most representative numerical results obtained in the measurement, as well as the input parameter values. The most representative results are:

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

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

<p>OD Sph. : -0.250 Cyl. : 0.000 Axis : 0</p> <p>Change subjective refraction</p> <p>Artificial pupil diameter (mm): 4</p> <p>Objective spherical refraction (D): -0.250</p> <p>Selected spherical refraction (D): -0.250</p> <p>Correction: No correction</p> <p>Acquisition notes:</p>	<p>Comments:</p> <p>Measured pupil diameter (mm): 5.9</p>	<p>OSI: 0.6</p>
		<p>Decimal Snellen</p> <p>Predicted Visual Acuity: 1.4 20/14</p>

Figure 22. Input / Output data

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

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

VA Simulation visualization

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

The goal of this screen (Figure 23) is to show what an image of a common scene looks like projected on to the retina of the patient. In particular, the software shows the image of a baby placed at a distance of 1 meter from the viewer.

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

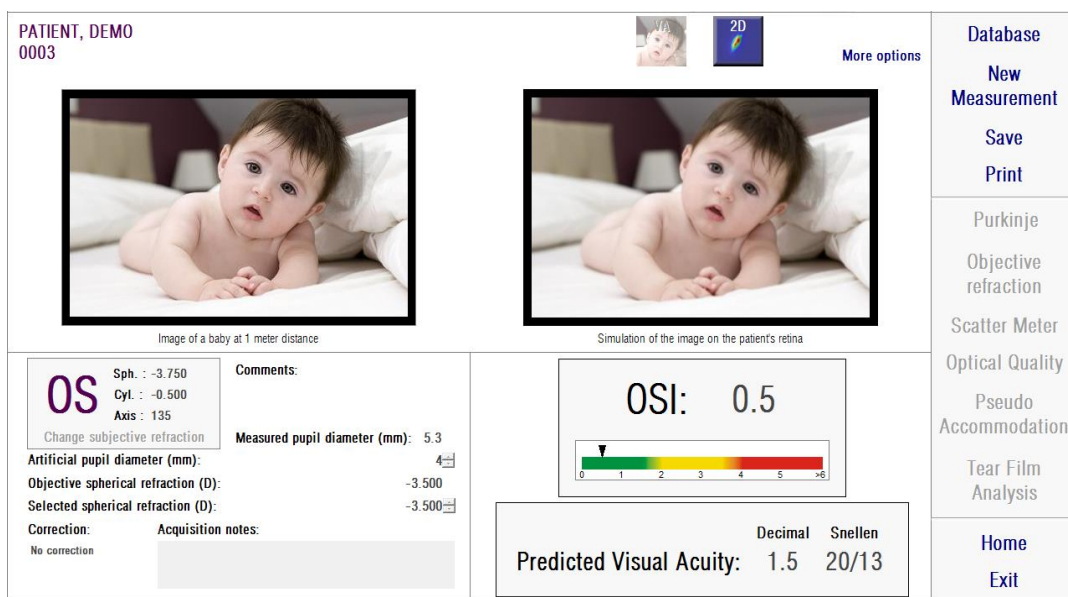


Figure 23 VA Simulation visualization

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

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

2D visualization

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

Two retinal image representations are shown in this screen, as seen in Figure 24. The 2D retinal image is displayed, on the left side of the screen with its original size while on the right side it is zoomed. Zoom in and zoom out can be performed by clicking the *In* or *Out* buttons (the maximum zoom in factor is 16 and the minimum zoom factor is 2). The different energy levels are represented with a color scale.

You can select a particular area of the image by clicking and dragging the mouse

over the left image. That area will be shown with the corresponding zoom in the right image. The scale of both images is shown below each one, in minutes of arc.

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

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

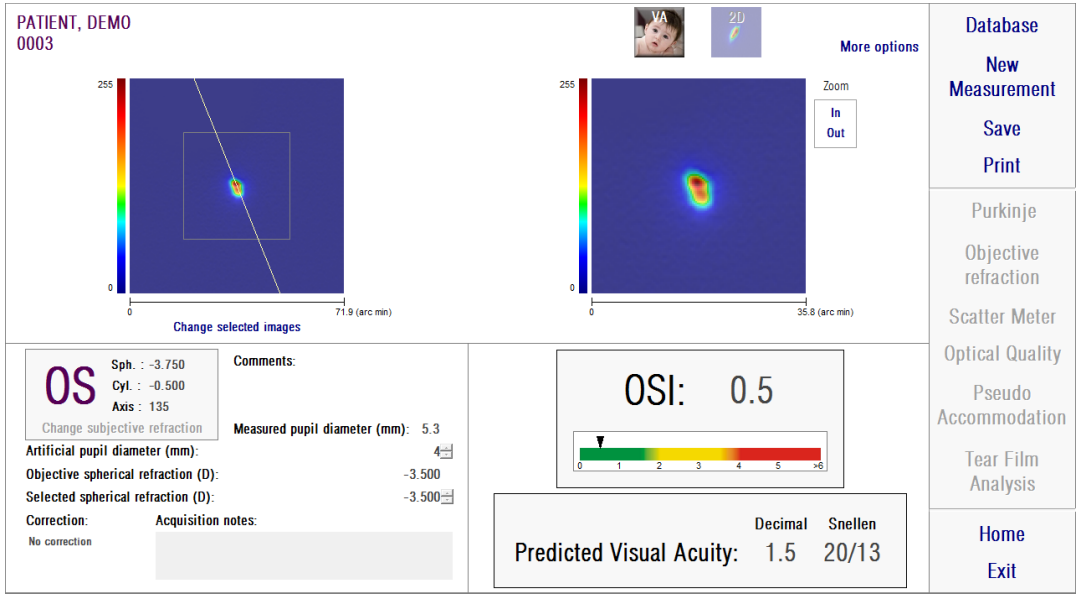


Figure 24. 2D visualization

3D visualization

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

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

The 3D retinal image representation is displayed on the right side of the screen (Figure 25). Zoom in and zoom out can be performed by clicking the *In* or *Out* buttons.

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

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

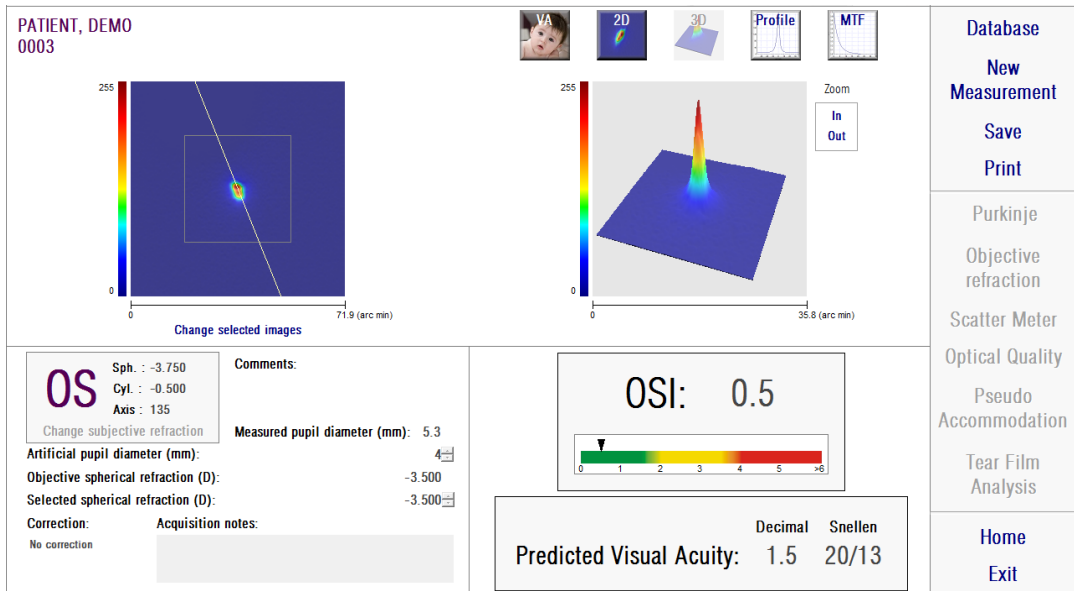


Figure 25. 3D visualization

Profile visualization

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

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

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

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

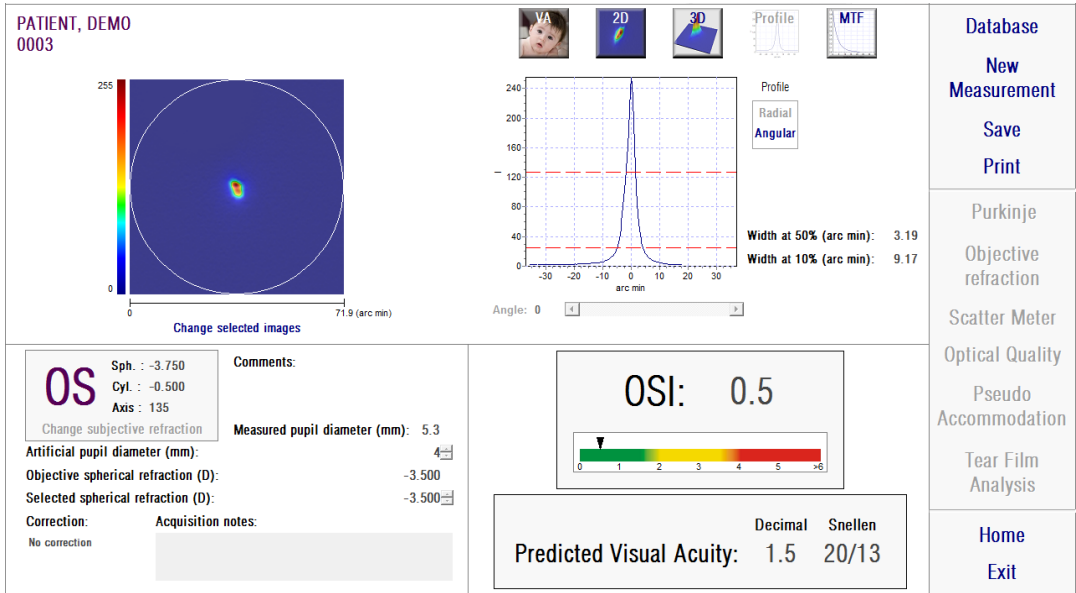


Figure 26. Profile visualization

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

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

MTF visualization

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

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

The MTF describes the performance of an optical system. MTF values represent the quotient between the image's contrast and the object's contrast for each spatial frequency (see section 1.1.3). From this function, the system can estimate visual acuity due to the optics of the eye, for different contrasts (*Predicted VA 100%, 20%*

and 9%). This information shows similar measurements of those obtained with subjective techniques, such as Snellen chart exams. It is important to note that this information is only affected by optical defects, while in subjective measurements it is greatly affected by neural processing tasks. The estimated visual acuity is shown in both decimal and Snellen scales.

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

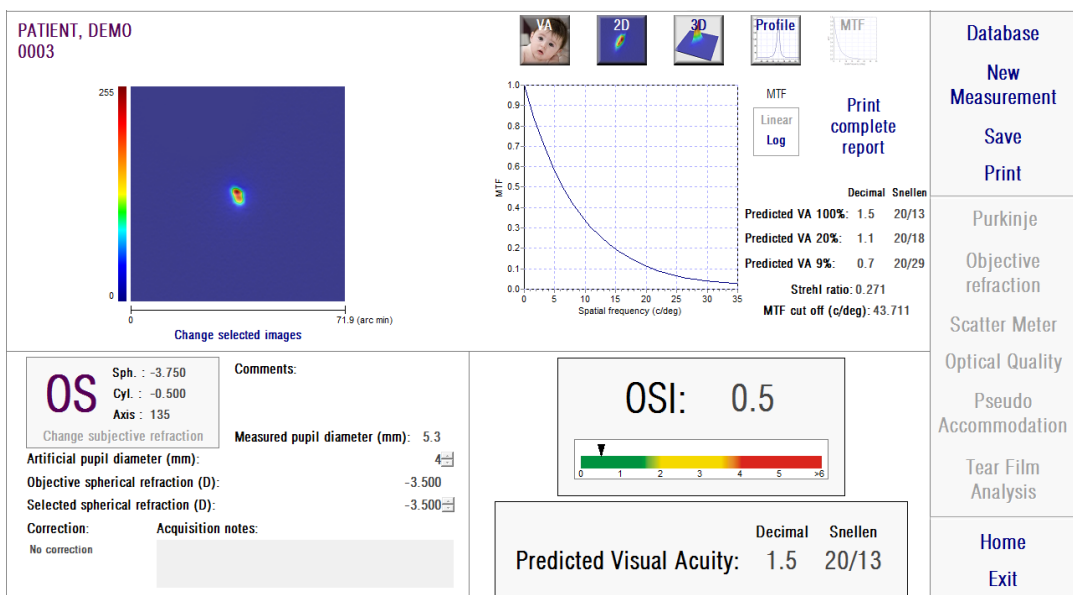


Figure 27. MTF visualization

Two representations of MTF are provided:

- Linear (*Linear*) is the default option when you select the MTF plot for the first time. Spatial frequency is shown in a lineal scale.
- Logarithmic (*Log*) is where the spatial frequency axis is shown in a logarithmic scale, which allows the user to clearly appreciate the cut off frequency (*MTF Cut off*).

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

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

3.6.4.2 Pseudo Accommodation

Once the user has finished the *Pseudo Accommodation* measurement process, the user may click on *Results*, and will obtain the results as shown in Figure 28.

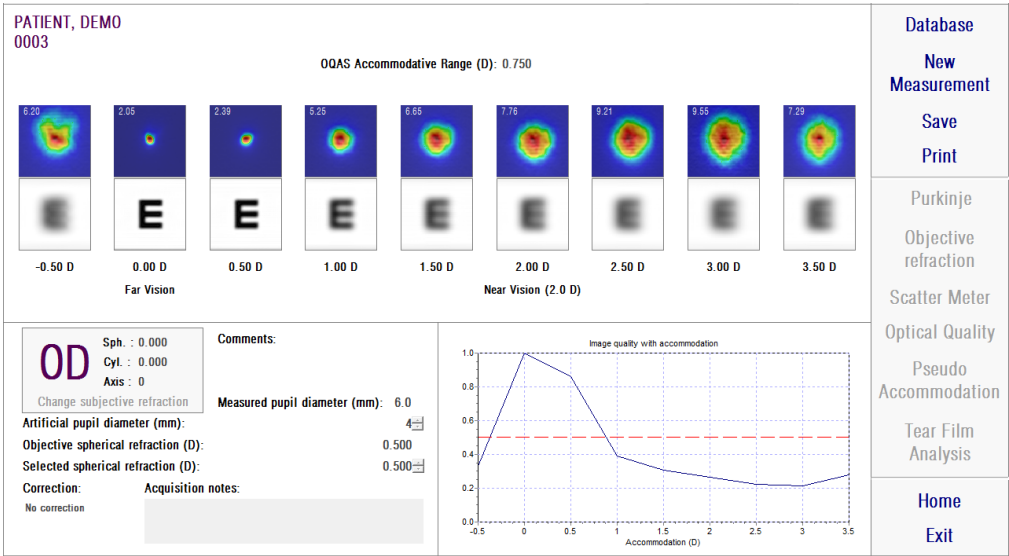


Figure 28. Pseudo Accommodation results

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

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

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

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

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

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

3.6.4.3 Tear Film Analysis

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

Once the *Tear Film Analysis* measurement process is complete, the user may click on *Results*, and will obtain the results as shown on Figure 29. According to whether the sequence has followed a sound pattern or not, the information shown on the results screen will be different.

3.6.4.3.1 Results screen without sound pattern

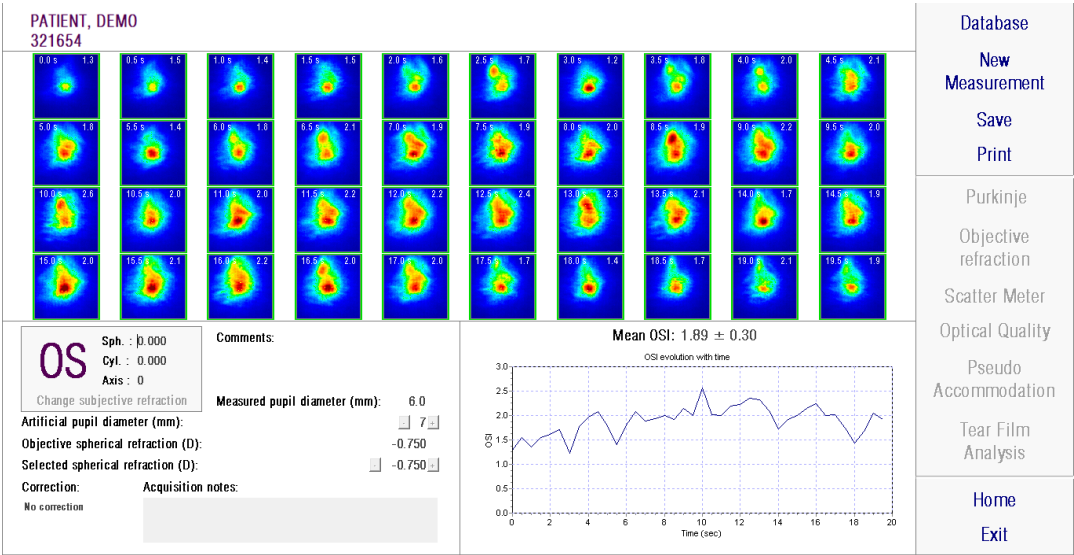


Figure 29. Tear Film Analysis without sound pattern results

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

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

If any blink has been detected during the measurement, the corresponding image will be labeled as 'Blink' and the point in the graph will be missed. If you want to modify the category of any of the images, select it by clicking on it to show the software how it should be categorized. By doing this you will be able to select other images before showing the software to recalculate to results considering the corrections made.

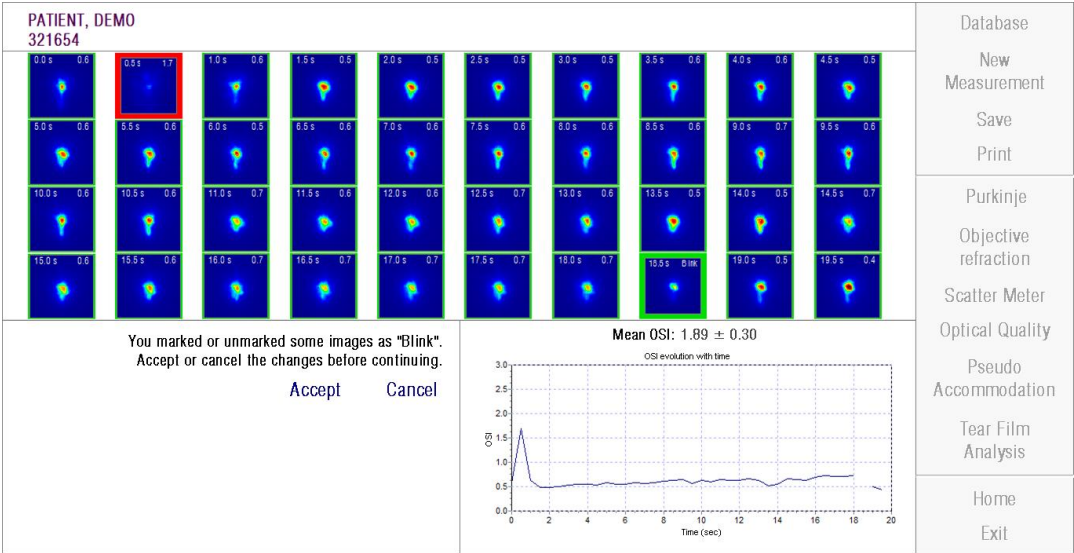


Figure 30. Modifying the categorization of the images

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

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

3.6.4.3.2 Results screen with sound pattern

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

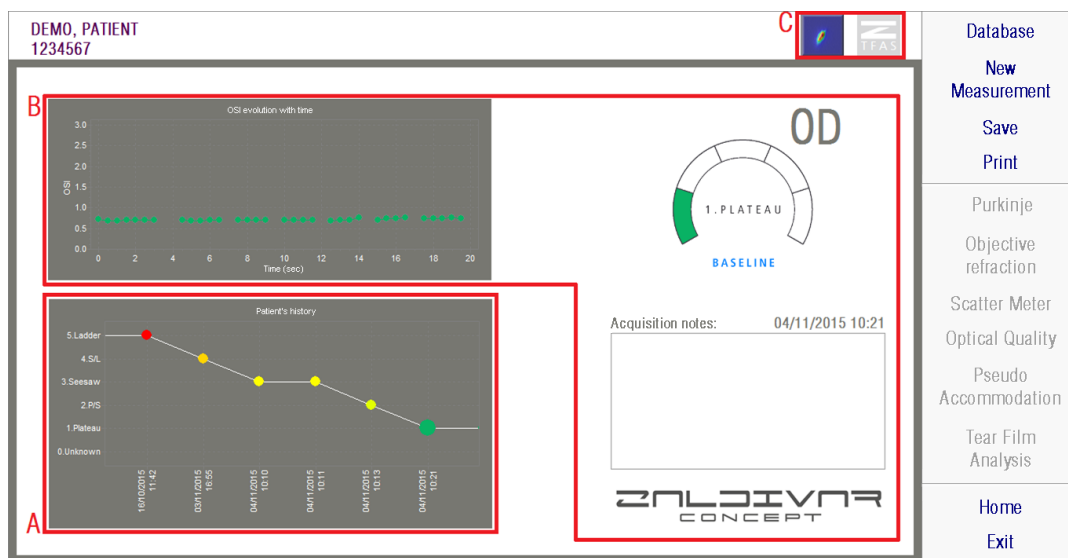


Figure 31. Results screen for Tear Film Analysis with sound pattern

A. Patient history

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

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

Some measurements, whose characteristics do not permit an accurate classification are associated to a sixth group, and identified with a zero and the color black.

The aim of this graph is to show the evolution of a specific eye over time. You can move horizontally across it by dragging the mouse while holding the right button. By clicking on any marker on the graph, you will be taken to the associated measurement details.

B. Detail of a specific measurement

In the upper left portion of the screen you will see the graph that shows the evolution of the OSI in the 20 seconds that a specific measurement is taken, giving it the color associated to the group that the measurement belongs to, according to its characteristics.

On the upper right portion of the screen, you will clearly see the group to which the studied measurement belongs, as well as the studied eye.

On the lower right portion of the screen, you will see the notes assigned to the measurement, as well as the date it was made. These notes can be modified by the user when finalizing the measurement, or during any subsequent viewing.

C. Button area

Formed by the buttons that change the information shown between:

- The double-pass images, explained in section 0.
- The classification in groups, explained in A & B of this section

3.6.4.4 Result comparison screens

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

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

Figure 32. Comparison of Scatter Meter measurements

Figure 33. Comparison of *Optical Quality* measurements

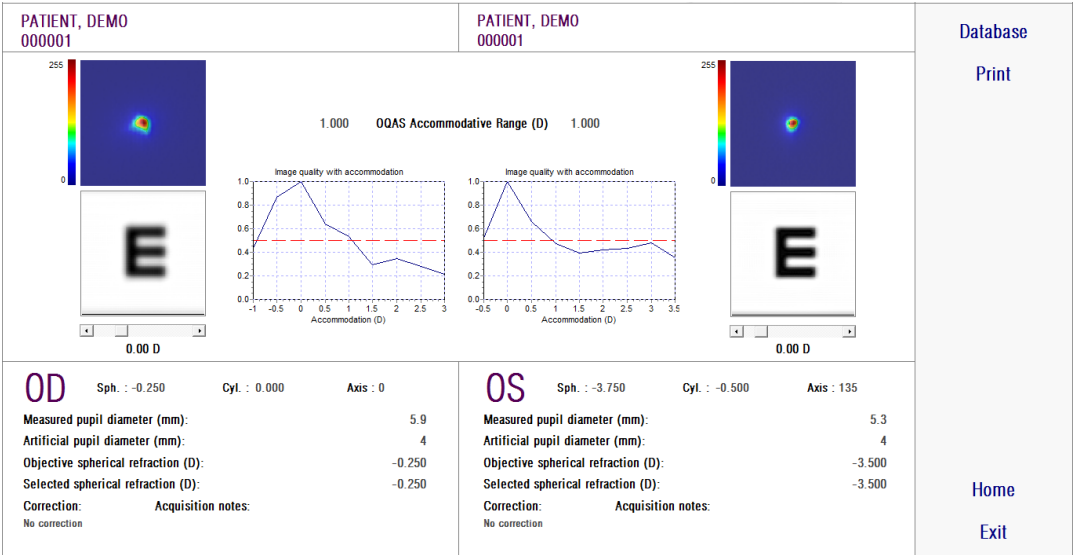


Figure 34. Comparison of Pseudo Accommodation measurements

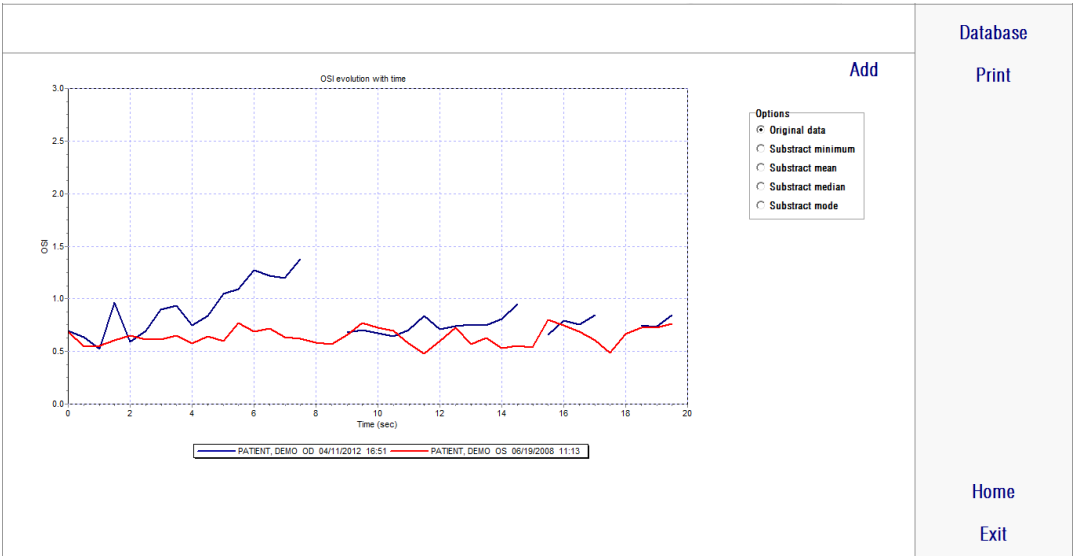


Figure 35. Comparison of Tear Film Analysis measurements

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

For any of the screens, all of the images can be exported by double-clicking over them and selecting the desired destination. You can export them as *bmp* or *jpeg* image files. You can also export the plots by double-clicking over them and selecting

the desired destination. You can export them as an image file (*bmp* or *jpeg*), or save the plot data as a text file (*txt*).

3.6.5 Purkinje Measurement

3.6.5.1 Typing in subjective refraction

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



Patient must remain uncorrected for this measurement. You must not use trial lenses nor the patient's own correction means.

	Sph (*)	Cyl (*)	Axis (*)	BCVA	UCVA
OD	-0.250	0.000	0	1.2	1.0
OS	0.250	-0.250	28	1.2	1.0

(*) Required fields <<

OK Cancel

Figure 36. Subjective refraction (enlarged view)

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

3.6.5.2 Selecting the Purkinje option

Once you have typed in the patient's subjective refraction, click on *Purkinje*.

The screenshot displays the HD Analyzer software interface. On the left, the patient information is 'PATIENT, DEMO 0003'. Below this, there are input fields for 'Sph. : 0.000', 'Cyl. : 0.000', and 'Axis : 0'. A 'Change subjective refraction' button is present. To the right of these fields are 'Comments:' and 'Measured pupil diameter (mm): 0.0'. Further right, there are fields for 'Artificial pupil diameter (mm): 4.0', 'Objective spherical refraction (D): 0.000', and 'Selected spherical refraction (D): 0.000±'. Below these is a 'Correction:' dropdown menu set to 'No correction' and an 'Acquisition notes:' text area. In the center, there is a live image of an eye with a yellow circle centered on the pupil. On the right side, there is a vertical menu with options: 'Database', 'New Measurement', 'Save', 'Print', 'Purkinje' (highlighted with a red border), 'Objective refraction', 'Scatter Meter', 'Optical Quality', 'Pseudo Accommodation', 'Tear Film Analysis', 'Home', and 'Exit'.

Figure 37. Purkinje option

3.6.5.3 Positioning the device

While the patient is looking at the target, use the joystick to bring the device to the furthest distance from the patient's eye, while centering the patient's pupil in the coordinate axis overprinted on the live image.

While doing this:

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



Figure 38. Live image showing centered eye, not well focused.

3.6.5.4 Select desired option

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

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

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

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

- In Pre-Without inlay acquisitions, the pupil.
- In Post-With inlay acquisition, the KAMRA™ inlay.

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

3.6.5.5 Focus using indicator arrows

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

At the beginning, the blue arrow indicates that the operator must move the instrument closer to the patient.

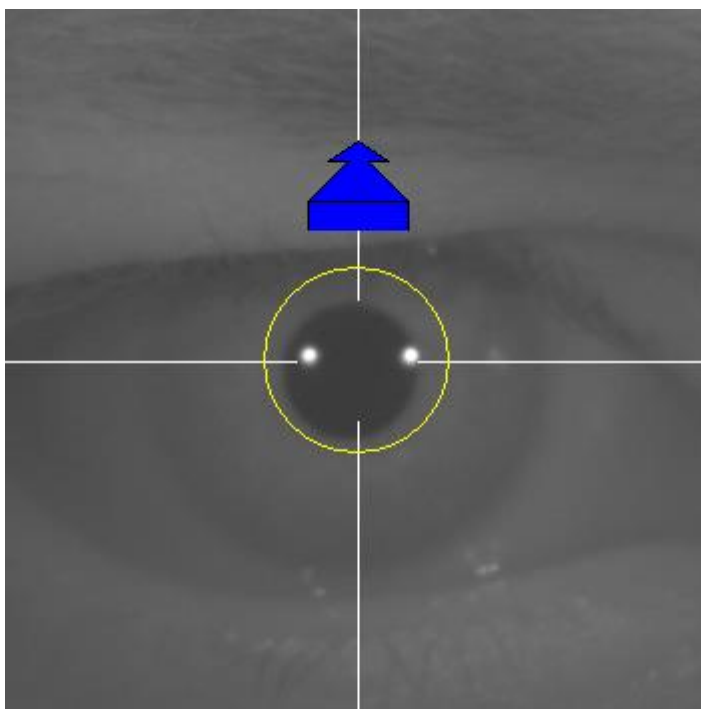


Figure 39. Blue arrow when beginning

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

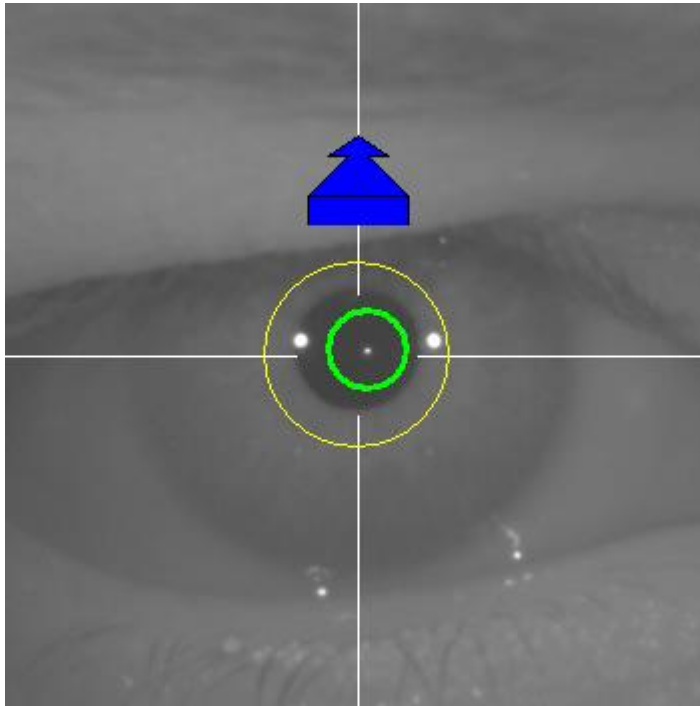


Figure 40. Blue arrow with green circle near laser reflection.

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

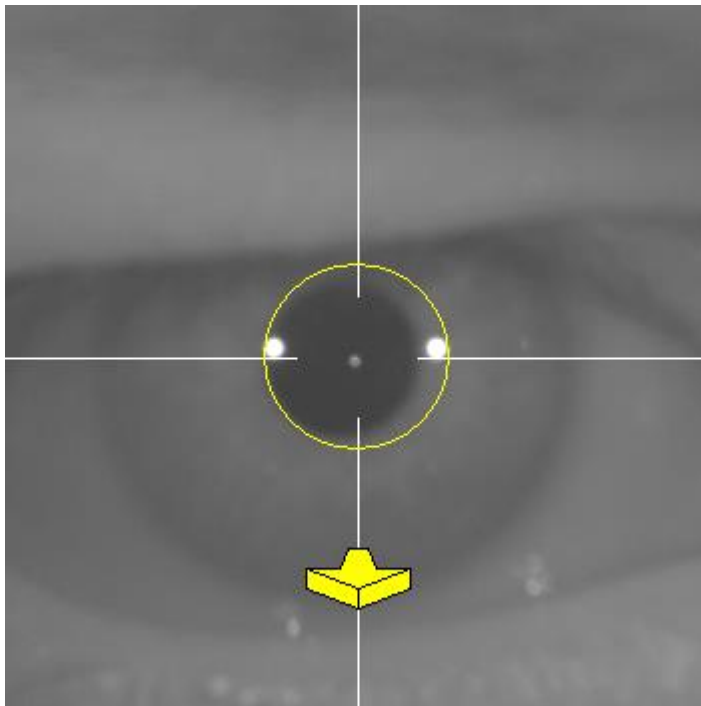


Figure 41. Yellow arrow just before losing the detection of laser reflection.

At this point, the software will continue using the arrows to indicate the correct direction the user should be moving in to reach the best focus point. Furthermore, the sizes of the arrows will fluctuate, to indicate how far the instrument is to the correct point (the larger the arrow, the farther it is to the best focus point).

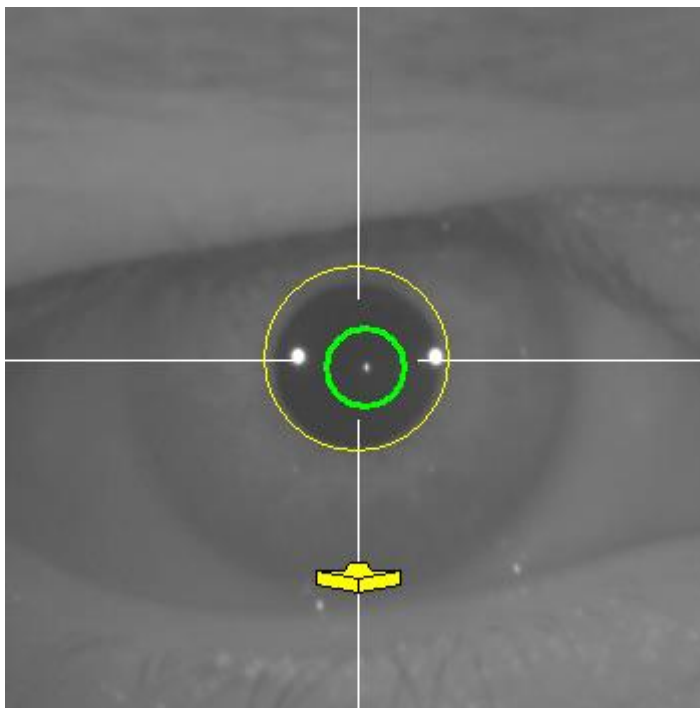


Figure 42. Yellow arrow when getting close to the best focus point.

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

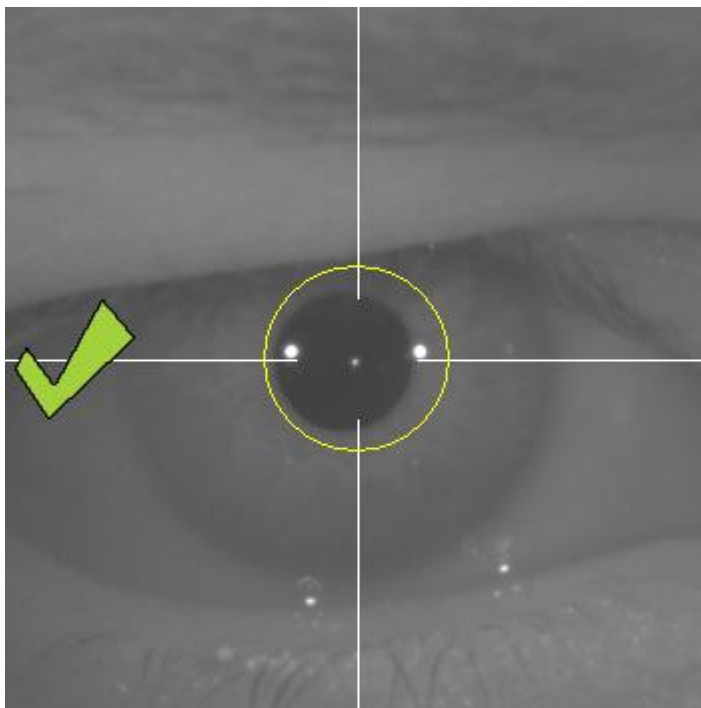


Figure 43. Green tick indicating the best focus point has been reached.

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

3.6.5.6 Automatic capture of images

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

- *Automatic* mode: software will try to detect:
 - In Pre-Without inlay acquisitions: the laser reflection, and the pupil.
 - In Post-With inlay acquisitions: the laser reflection and the KAMRA™ inlay. In some cases, the pupil parameters may also be detected.
- *Manual* mode: The software will try to detect the laser reflection and the operator will manually mark the location of the pupil (pre-op) or the inlay (post-op).

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

It is recommended that the patient blinks as little as possible during this step of automatic capture of images.

3.6.5.6.1 Automatic mode

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

3.6.5.6.2 Manual mode

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

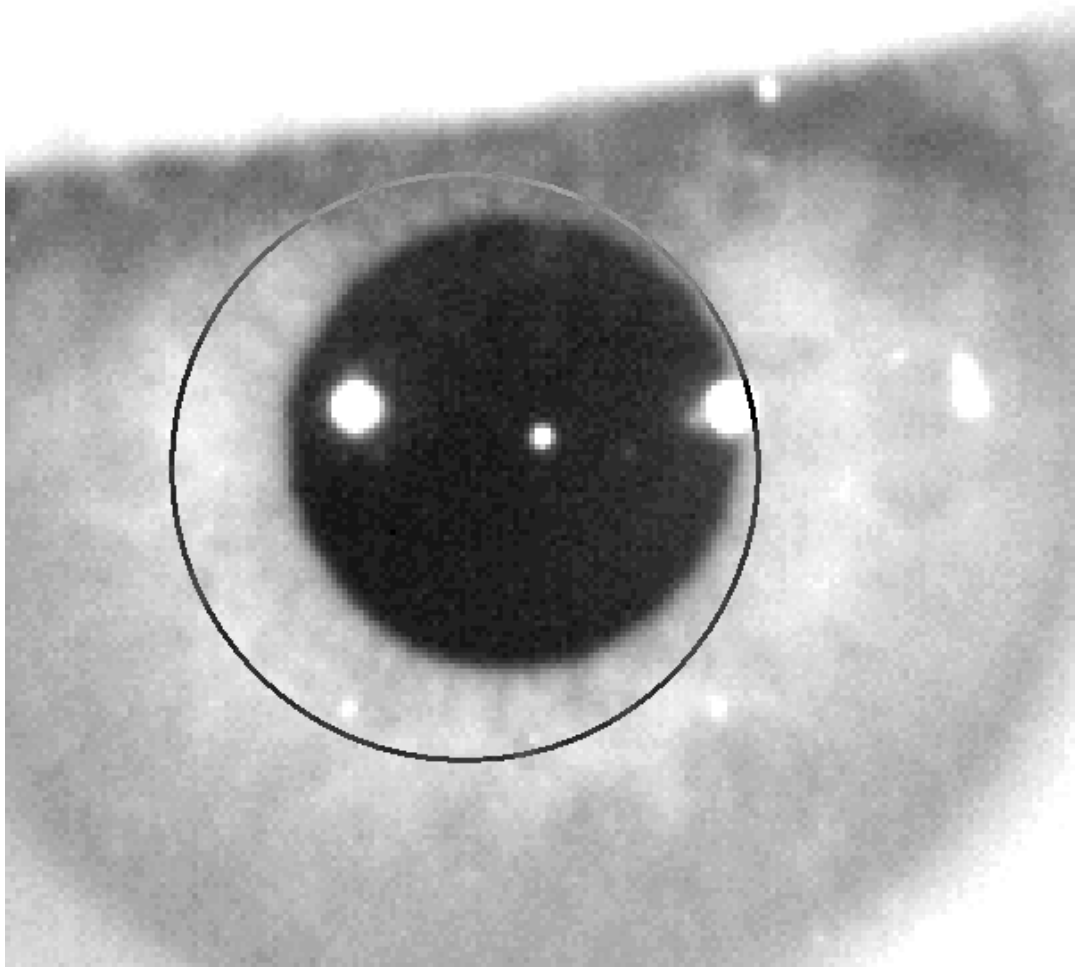


Figure 44. Zoomed and contrasted image, with a wrong mark for center and diameter pupil.

On the zoomed image, the operator must mark:

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

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

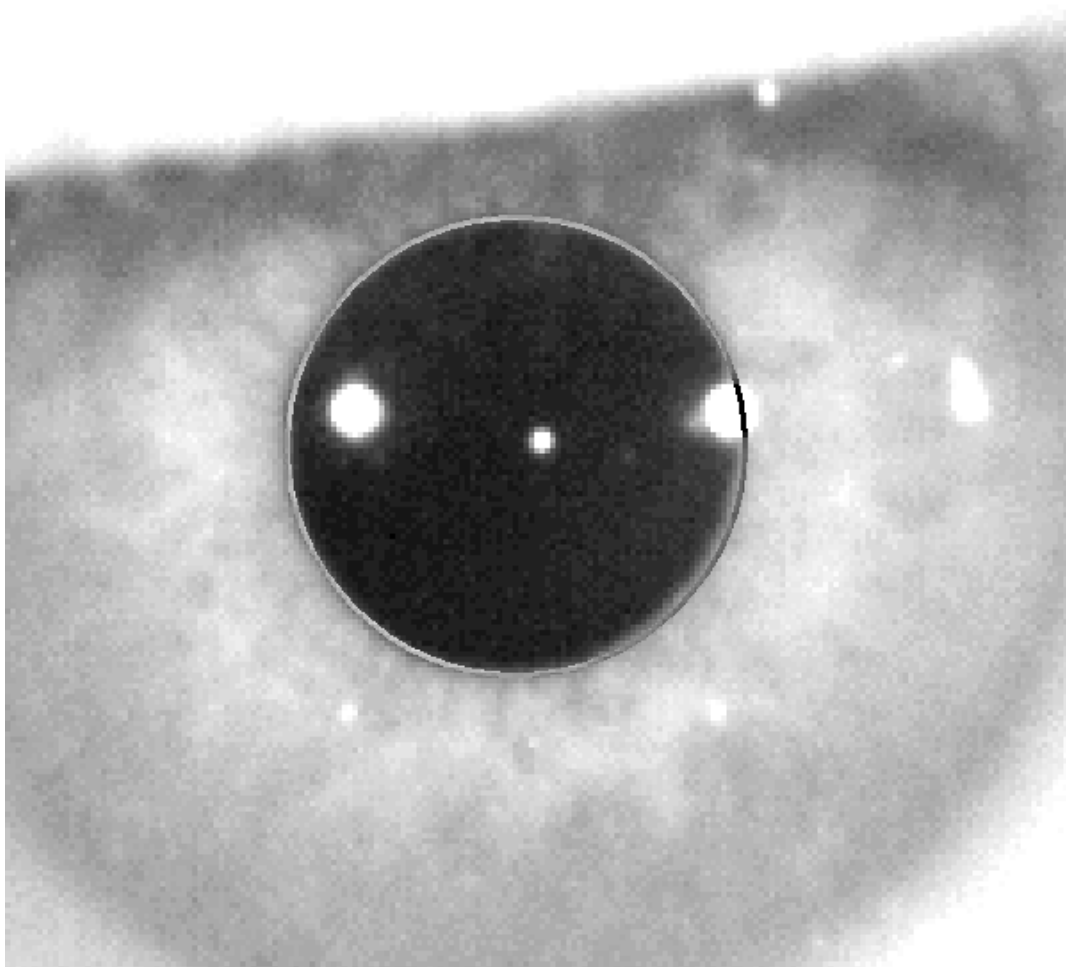


Figure 45. Zoomed and contrasted image with correct mark for center and diameter pupil.

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

3.6.5.7 Validating an image

The user should then assess how good the suggested image is based on how well borders and detected points adjust to patient's eye reality.

While the decision is made, the patient may again blink comfortably, since the image has already been captured.

3.6.5.7.1 Invalid image

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

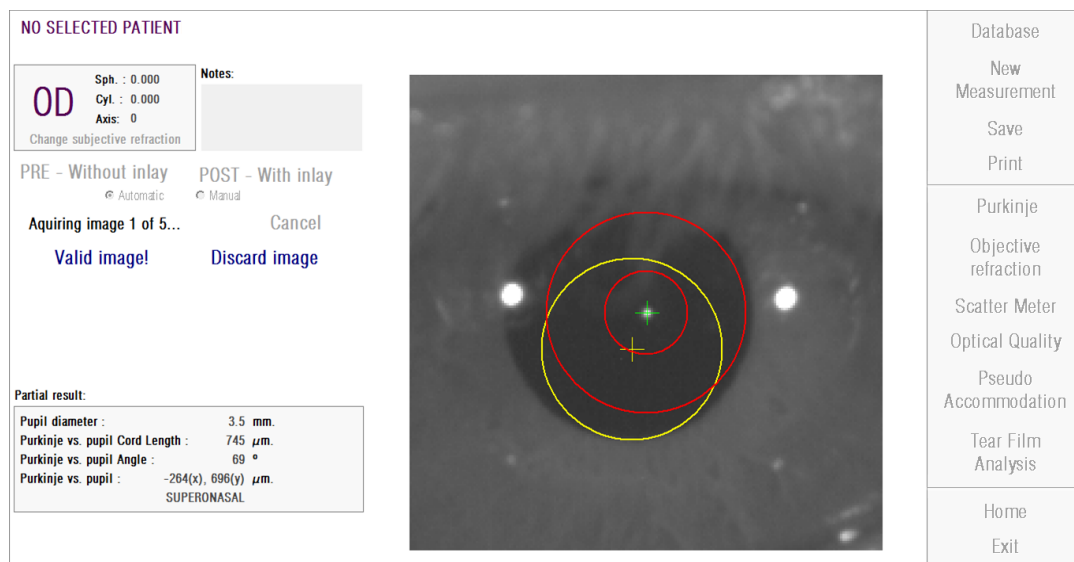


Figure 46. Wrong pupil detection on pre-op image

3.6.5.7.2 Valid image

If you consider the suggested image to be sufficient, you should then click on the *Valid image!* button. The program will keep the image and proceed to the next step.

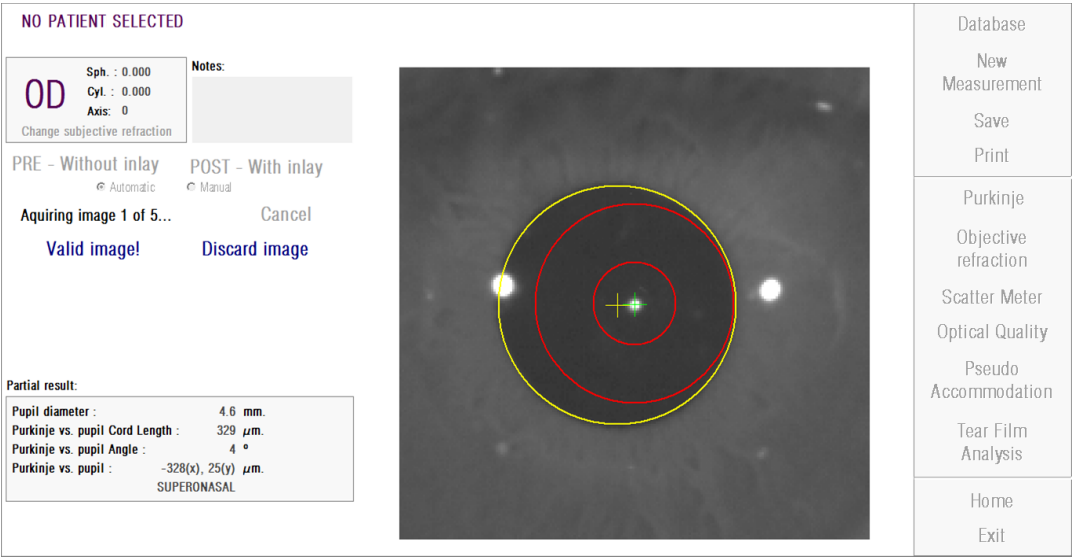


Figure 47. Valid pupil detection on pre-op image

3.6.5.8 Acquiring and validating four more images

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

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

Therefore, once you have validated one image, the program will take you back to section 3.6.5.6, in order to continue with the process of acquiring and validating images until reaching five valid images.

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

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

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

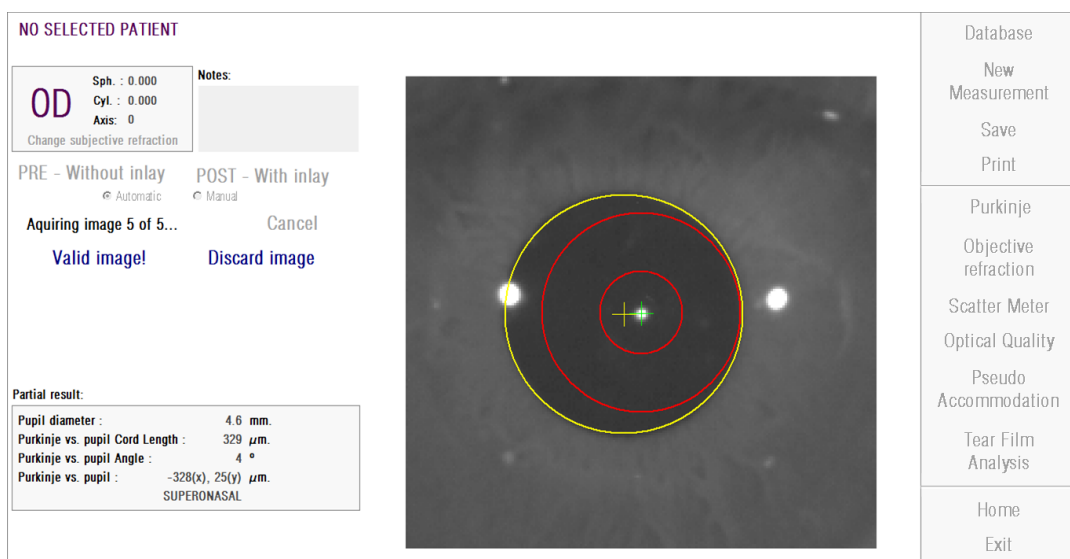


Figure 48. Fifth pre-op measurement.

3.6.5.9 Validating final results

At this stage, the patient can move away from the device since the measurement process has finalized.

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

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

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



Figure 49. Final result of a pre-op measurement

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

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



Figure 50. Final result of a post-op measurement

3.6.6 Printing and exporting a results' report

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

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

Figure 51 and the following figures provide an example of a report for each type of measurement. They include the most relevant information of the measurement, including the parameters that were used and the results that were obtained.


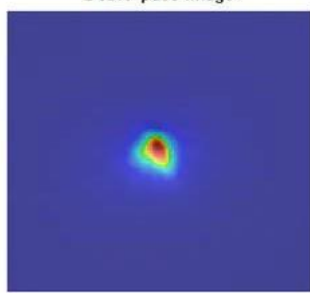


PATIENT, DEMO 000001		Technician - Visiometrics 04/11/2012 16:39		
OD	Manifest Refraction	Sph: -0.250	Cyl: 0.000	Axis: 0
		BCVA:		UCVA:
		<div style="border: 1px solid black; width: 100px; height: 20px;"></div>		<div style="border: 1px solid black; width: 100px; height: 20px;"></div>
Artificial pupil diameter: 4 Objective spherical refraction: -0.250 Measurement sph refraction: -0.250 Correction: No correction		Measured pupil diameter: 5.9 Notes:		
Original Image		Doble-pass Image		
				
Retinal Image		OSI: 0.6		
				
Simulation of the image on the patient's retina		Predicted VA: Decimal 1.4 Snellen 20/14		

Figure 51 Example of a report for *Scatter Meter*


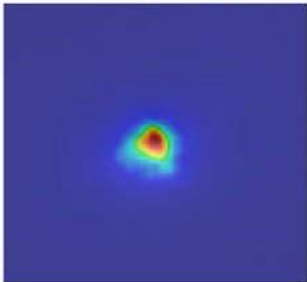

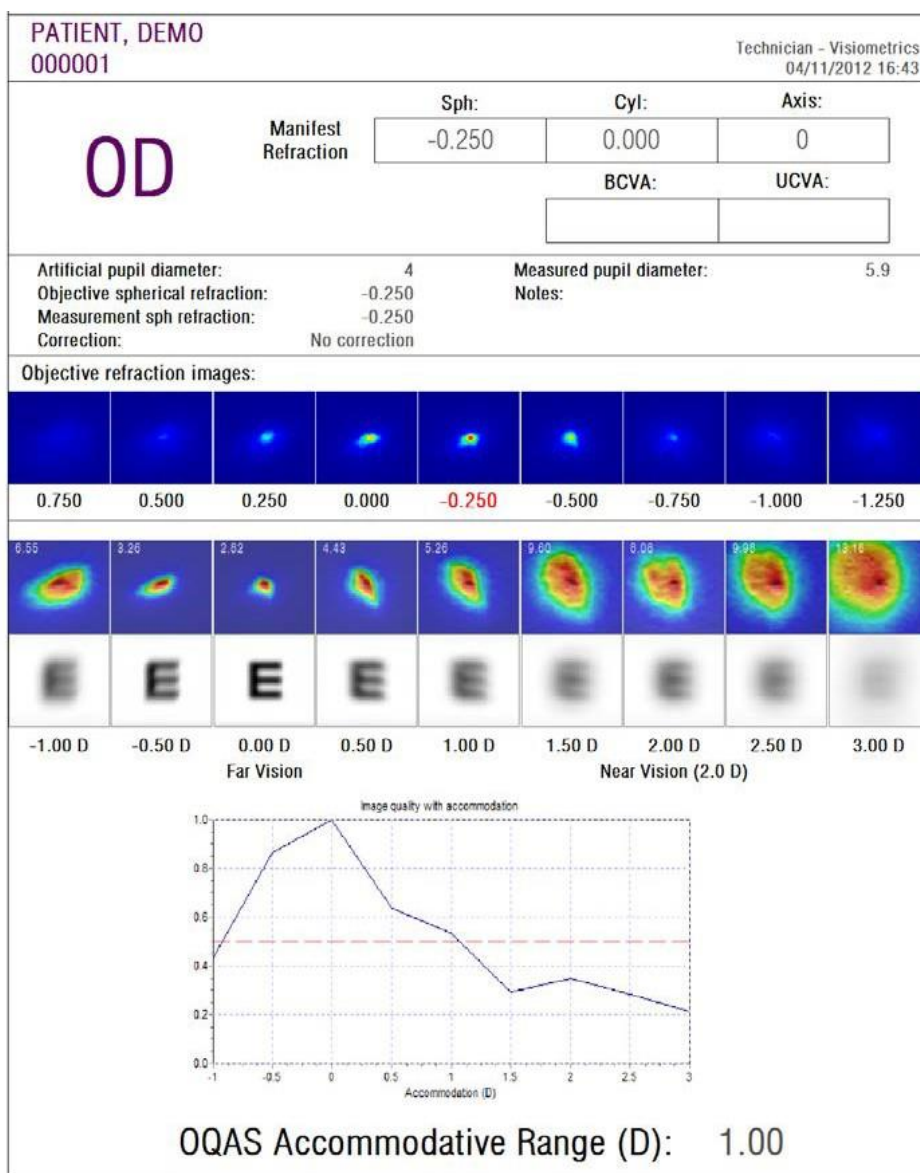
PATIENT, DEMO 000001		Technician - Visiometrics 04/11/2012 16:40	
OD	Manifest Refraction	Sph:	Cyl:
		-0.250	0.000
		Axis:	0
		BCVA:	UCVA:
Artificial pupil diameter: 5		Measured pupil diameter: 5.9	
Objective spherical refraction: -0.250		Notes:	
Measurement sph refraction: -0.250			
Correction: No correction			
Original Image		Doble-pass Image	
			
Image of a baby at 1 meter distance			
Retinal Image		Predicted VA:	
		Decimal Snellen	
Simulation of the image on the patient's retina		1.2 20/17	

Figure 52. Example of a report for *Optical Quality*

Figure 53. Example of a report for *Pseudo Accommodation*

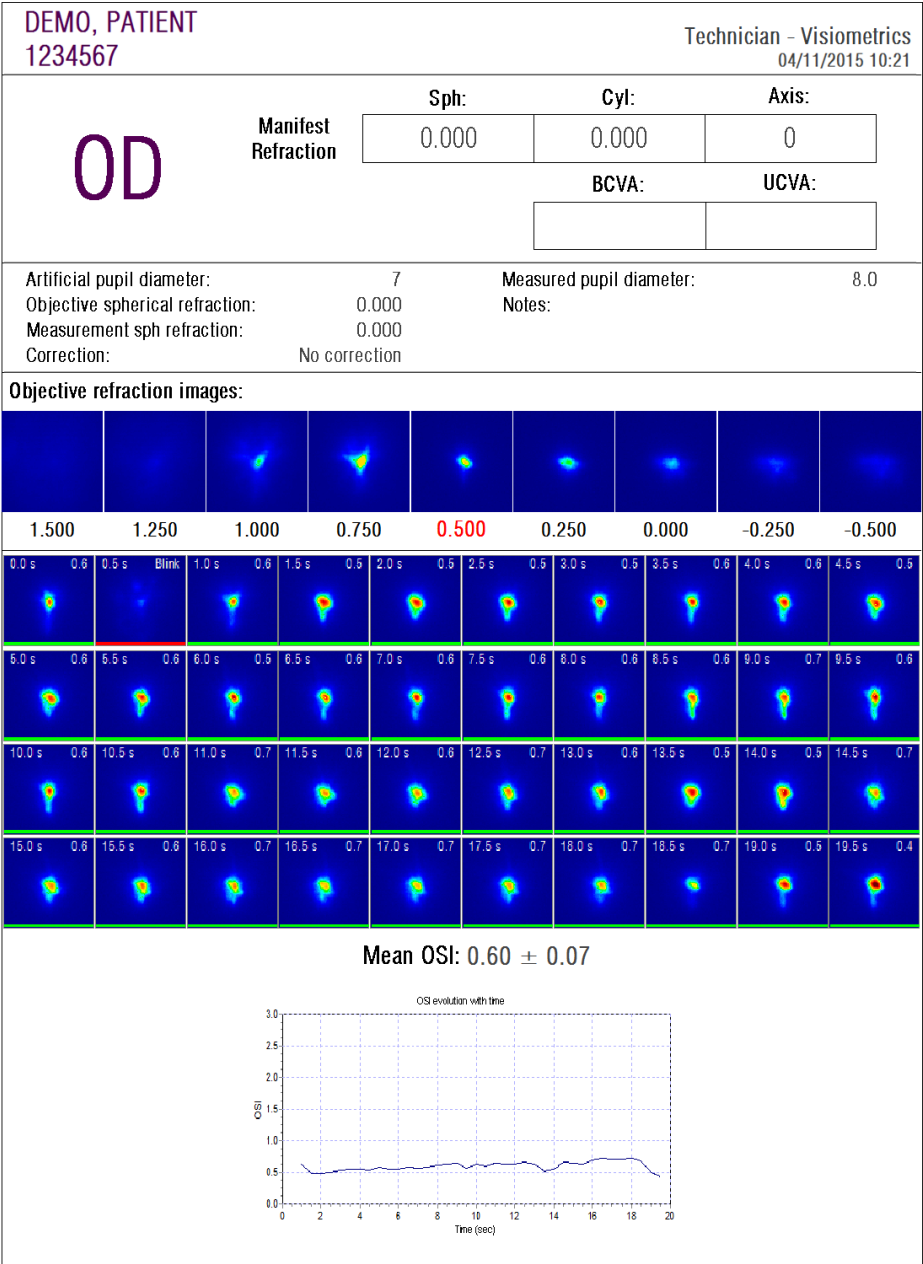


Figure 54. Example of a report for *Tear Film Analysis*

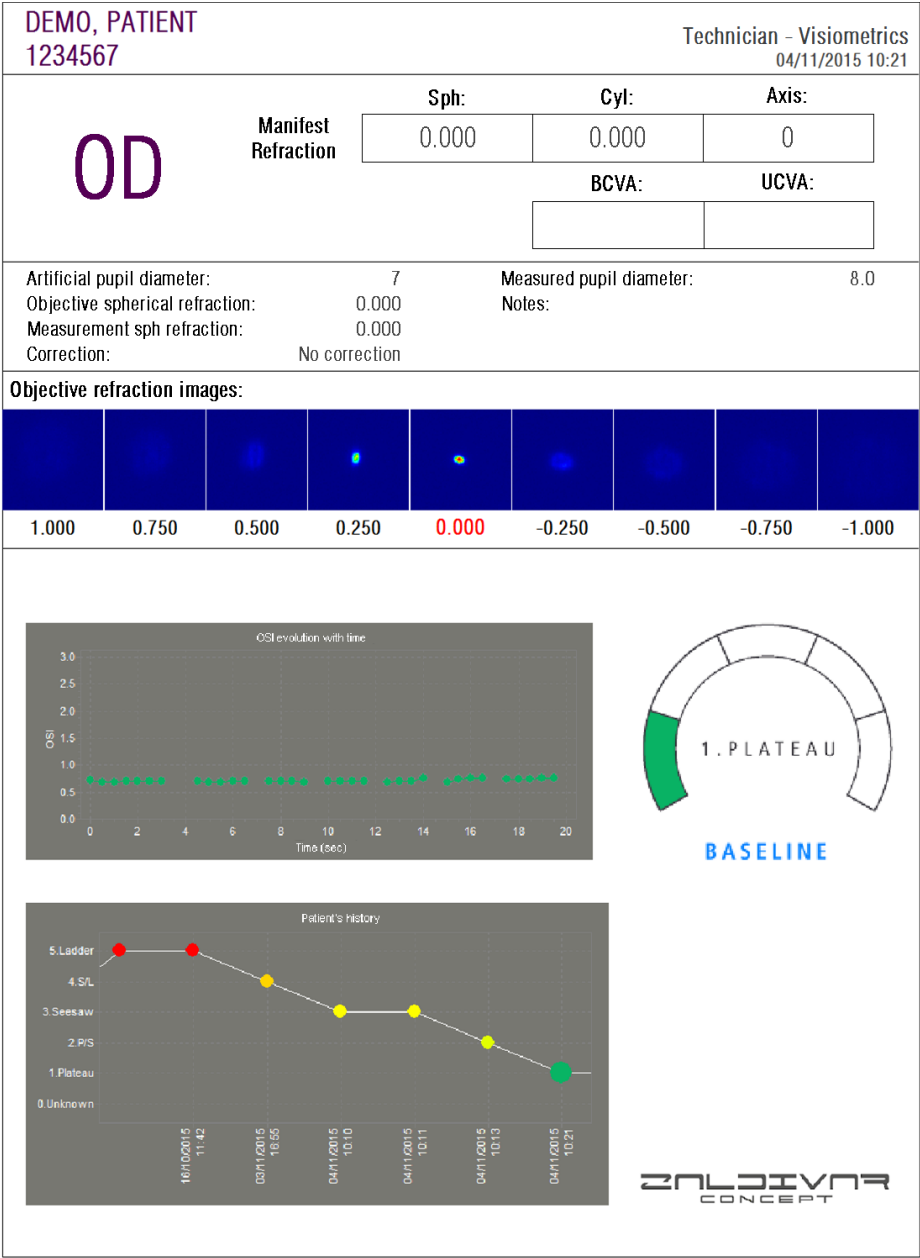
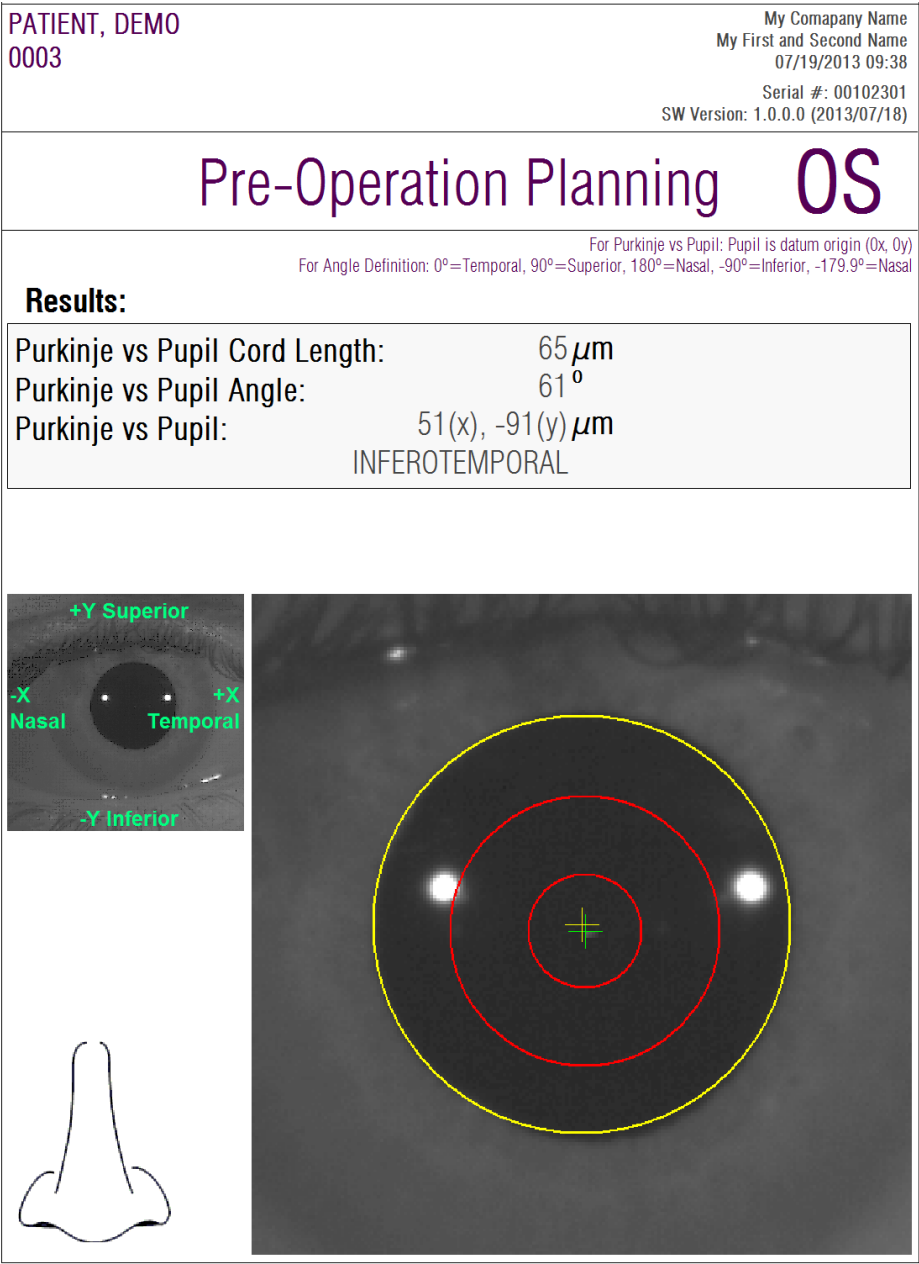


Figure 55. Example of a print report for Tear Film Analysis (sound pattern)



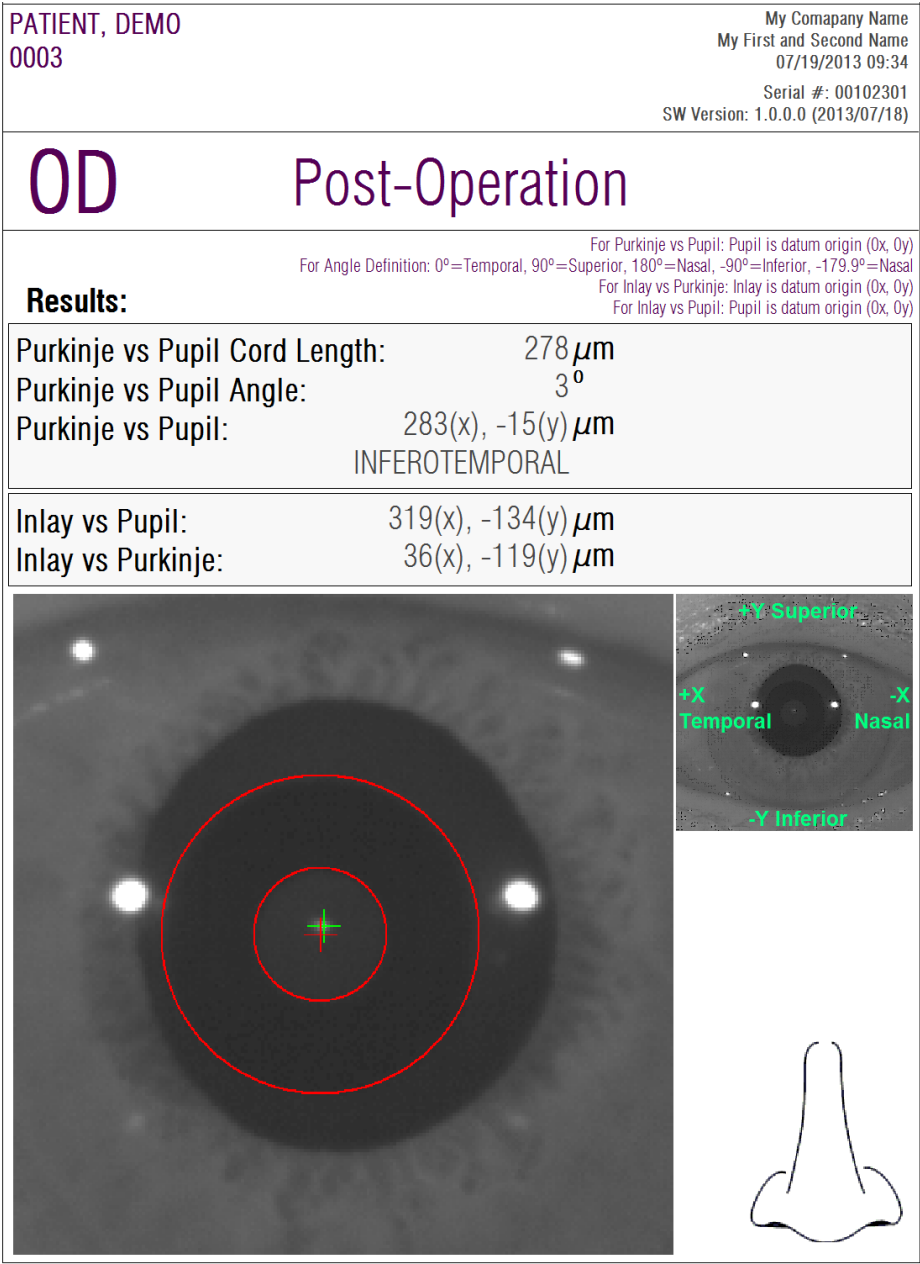


Figure 57. Example of a report for a post-op *Purkinje*

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

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

3.7 LICENSE MANAGER

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

Carefully read section 3.2 for more information about the different operation modes of the software.

After clicking on the *License Manager* button, the HD Analyzer™ software shuts down, after user confirmation. The license managing application will run immediately.

Figure 58 shows the home screen of that application.



Figure 58. *License Manager* Home menu

The field *Running mode* indicates the HD Analyzer™ software running mode. It can be in *Pay-Per-Patient* or *Free mode*. The field *Available credits* indicates the number of available measurement credits in pay-per-patient mode.

If you have purchased new credits and you want to activate them in the device, click on *Enter New Code*. You will be shown the screen represented in Figure 59.



Visiometrics License Manager X

The Human Vision Company 04/03/2012 16:29

CODE VALIDATION

ABCD - 1234 - 567a - lkjh

Validate Code

Home

Figure 59. Validation of the activation code

You must type in the activation code you obtained after your purchase at the Visiometrics web page (see section 3.2). In the example, the code ABCD-1234-567a-lkjh has been typed. Then click on *Validate Code*. If the code you have entered is not valid, you will be asked to check if the 16 digits have been typed correctly. If the code you have entered is valid, the new credits will be added to the previously available ones, and a summary screen will be shown (Figure 60).

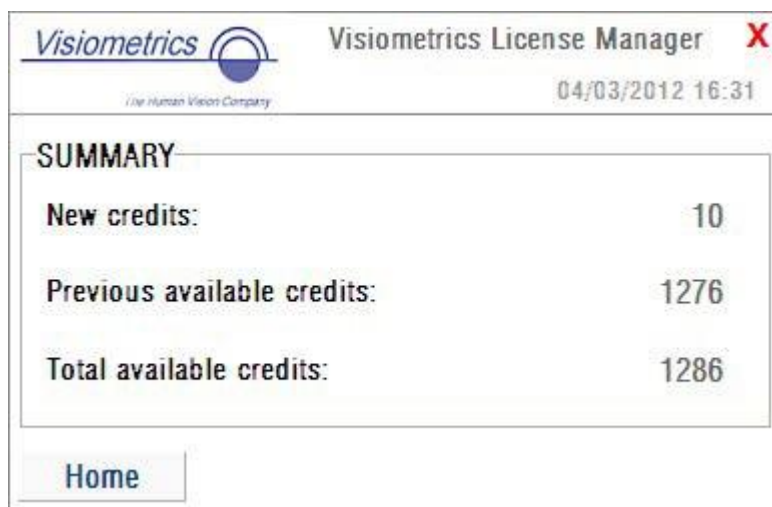


Figure 60. Summary of the activation code validation

In the home menu of the application (Figure 58), there is also an *Options* button. That button gives access to the option screen, as seen in Figure 61. The only parameter that can be modified by the user is the language of the license managing application (English and Spanish are available). The button *Administrative tools* activates a section of administrative parameters, which cannot be accessed by the user. In this way, this section is protected with a password that is not provided to the user.



Figure 61. License Manager options

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

3.8 SETUP

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

Figure 62 shows an example of the setup screen. It is clearly divided into four sections:

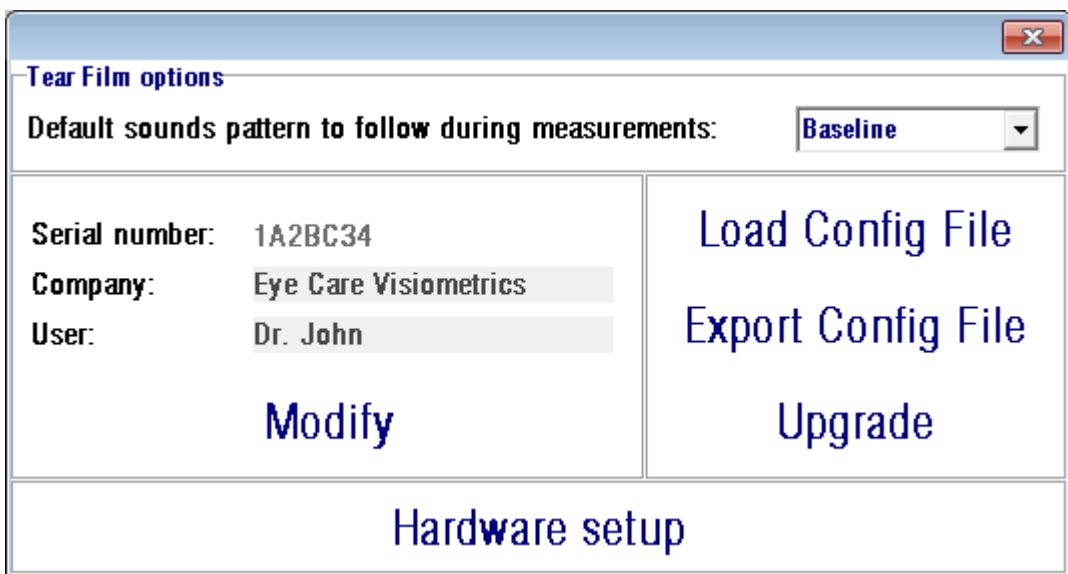


Figure 62. Setup screen

3.8.1 Tear Film Options

This refers to the sound pattern that will be used by default to carry out the Tear Film Analysis sequences. Click on *Modify* to apply changes. The program will restart with the new values, with prior confirmation from the user.

3.8.2 User visible parameters

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

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

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

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

3.8.3 Setup buttons

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



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

The other button that is included, *Upgrade*, is used for performing upgrades of the software version of the HD Analyzer™. In case that an upgrade is available for the equipment, Visiometrics will send the user the setup file, along with proper instructions. Please, follow those instructions carefully. In general, the upgrade is

performed by clicking on *Upgrade* and choosing the upgrade file in its location. A password will be required, which will be previously provided by Visiometrics. After password validation, the upgrade is performed. You must always follow the instructions that are provided with the upgrade file.

3.8.4 Hardware setup

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



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

3.9 BACKUP

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

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

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

4 EXAMPLES OF MEASUREMENTS

4.1 NORMAL EYE

Figure 63 shows a report of the results for a young and healthy eye measurement.

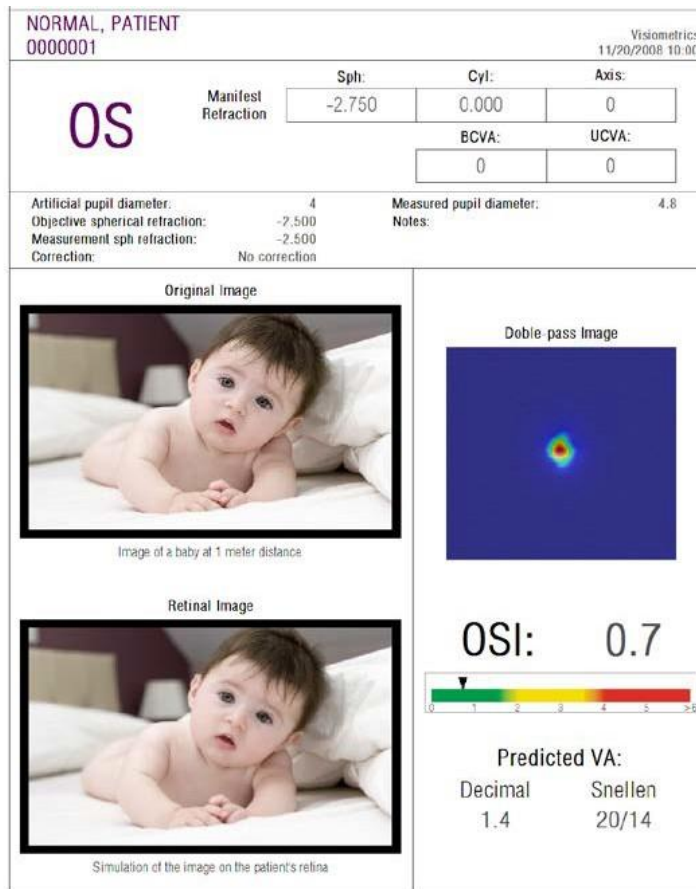


Figure 63. Normal eye

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

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

4.2 CATARACT EYE

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

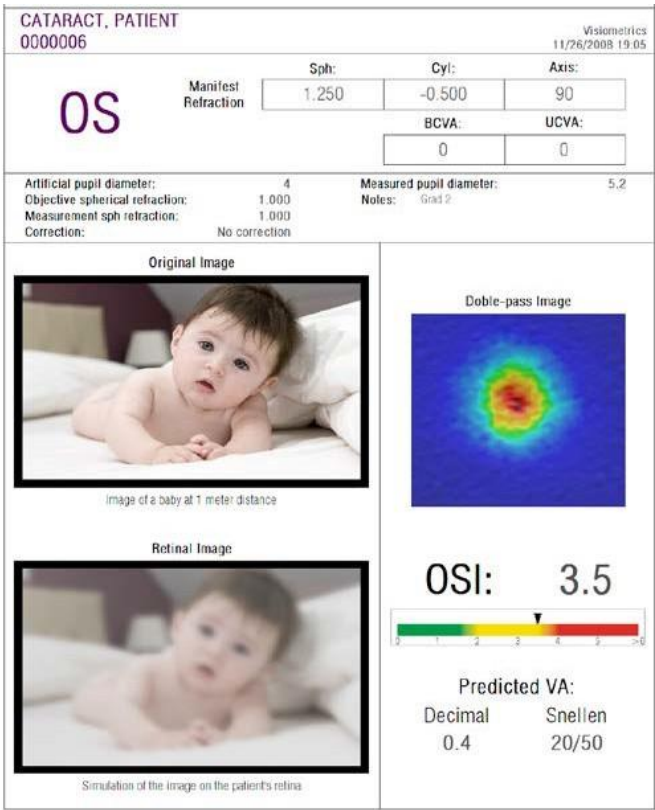


Figure 64. Eye with a cataract

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

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

4.3 POST-LASIK EYE

After a LASIK procedure, there is some uncertainty about the real state of the eye. Although the patient sees properly, new aberrations or a slight level of scatter on the cornea may appear. To verify the success of the procedure, the user may take a measurement on the patient. Figure 65 shows an example of a report of the results of an eye after LASIK surgery. In this case, quality of vision is very satisfactory, since the double-pass image is round and its size is acceptable. The *OSI* value is low and the *Predicted VA* value is high, as it should be for a successful procedure.

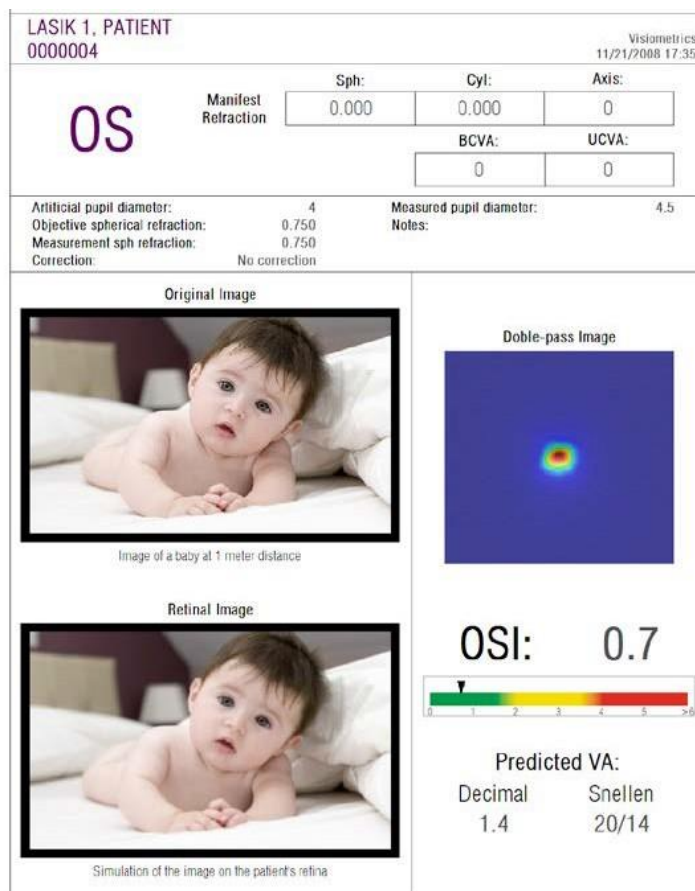


Figure 65. Eye after a successful LASIK surgery

On the other hand, Figure 66 shows an example of a surgery where the expected results have not been achieved. The double-pass image is larger, due to the presence of aberrations and a certain level of scatter. The *OSI* value is larger than in the previous case (more scatter), and *Predicted VA* is lower.

Lastly, the simulations of the image projected on to the retina show a more noticeable blurring in the second case.

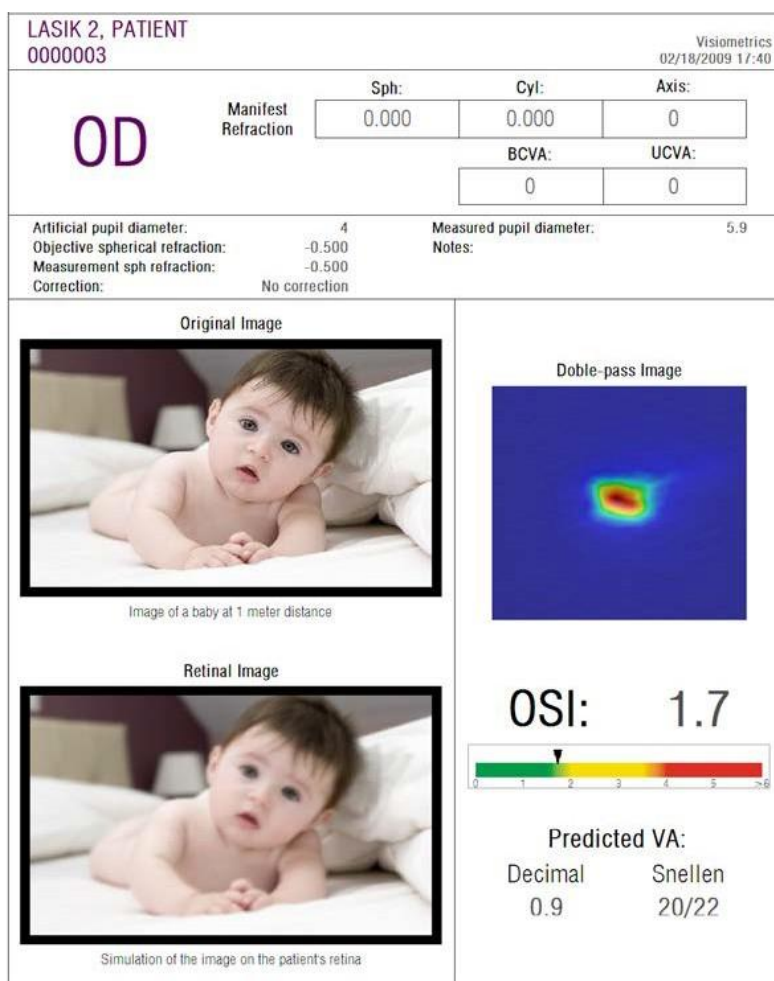


Figure 66. Eye after a non-successful LASIK surgery

5 ERROR SOLVING

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

5.1 ERROR MESSAGES

Code	Error message	Cause
5	The program requires a screen resolution of 1366x768, 1366x800, 1280x768 or 1280x800. The current resolution is not valid, so the program must shut down. Try to change your screen resolution.	The program requires a screen resolution of 1366x768, 1366x800, 1280x768 or 1280x800. This error shows up when a different screen resolution is being used. User should change screen resolution.
6	The program initialization has failed. The program will shut down.	For some reason (memory shortage, not enough free space on disk, etc.) software cannot initialize. Contact Visiometrics.
21	The acquisition has failed	Measurement could not be completed. Try again.
22	The self-focusing process has failed. Please check if the subjective refraction you have entered is correct and try again	The Objective Refraction process could not be completed. Check subjective refraction typed in and try again
25, 26, 27, 28, 29, 30		A hardware error has occurred in the spherical refraction compensation internal system, in the artificial pupil internal system, in the system's shutter, in the system's laser, in the vibration internal system or in the system's LEDs User should switch the device off and then on again to check if the error happens again. If it does, contact Visiometrics
32	Error in the video signal	Signal coming from the system cameras has been lost. User should switch the device off and then on again to check if error happens again. If it does, contact Visiometrics.
33	The images could not be opened	Images for that selected acquisition were not found in disk. Contact Visiometrics if this error becomes repetitive.
34	Error while processing the images	An error has occurred when processing the images. Contact Visiometrics if this error becomes repetitive.
36	The program has not captured enough images for their process. Please try again.	For some reason, measurement could not be completed. (Some images were not registered). Try again.
39	There is no patient selected.	No patient was selected. Select one.
40	There is no acquisition selected	No acquisition was selected. Select one.

Code	Error message	Cause
41	There is more than one acquisition selected.	Too many acquisitions have been selected. Select only one.
46	The system's cameras could not be detected. Check the connections.	Software is not detecting the device's cameras. User should check the connection between computer and device.
47	One of the system's cameras could not be detected. Check the connections.	Software is not detecting one of the device's cameras. User should switch the device off and then on again in order to check if the error occurs again. If it does, contact Visiometrics.
49	Communication failure with camera	A communication problem has occurred with the system cameras. User should switch the device off and then on again to check if error occurs again. If it does, contact Visiometrics.
50	There is not enough energy reaching the camera. The images could not be recorded.	The system has reached the maximum laser power, but it is still not enough to measure patent. Try again.
54	Error while updating the credit count. The program will shut down.	Credit could not be deducted. Contact Visiometrics.
56	The License Manager software was not found.	The License Manager software could not be found. Contact Visiometrics.

5.2 WARNING MESSAGES

Message	Cause
<p>The device has not been detected so the software will run in "read only" mode.</p> <p>To run it in normal mode, check the connection cables and restart the software.</p>	<p>Hardware is not connected or is not working. It will not be possible to take any new measurements.</p> <p>To take new measurements make sure that the device is correctly plugged into the main power source and to the computer. Once everything is checked, restart the software.</p>
The program has detected a problem with the hardware and will shut down.	A hardware error has occurred and the program shuts down. User should switch the device off and then on again to check if error occurs again. If it does, contact Visiometrics.
You can't perform new measurements. Visit our website www.visiometrics.com if you want to get more credits.	User does not have any credits left. User must buy and activate new credits through the License Manager tool.

Message	Cause
The MTF could not be computed.	Images have such poor quality that MTF function could not be processed. Contact Visiometrics if this error becomes repetitive.
The pupil diameter of the patient could not be measured during the process. This value will be set to zero.	Because of lighting conditions not being optimal, the patient's pupil diameter could not be measured. Try again.
At least one of the spherical refractions is out of range. In case of measuring that eye, please correct it with trial lenses and choose 'Total correction' in the Correction field in the measurement screen.	Spherical refraction typed in is out of range. It must be compensated by means of trial lenses or patients' own correction devices (contact lenses or glasses).
At least one of the cylindrical refractions is out of range. In case of measuring that eye, please correct it with trial lenses and choose 'Astig. correction' or 'Total correction' in the Correction field in the measurement screen.	Cylindrical refraction typed in is out of range. It must be compensated by means of trial lenses or patients' own correction devices (contact lenses or glasses).
You have typed an incorrect password	A wrong password has been typed in to enter setup. Try again.

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



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

If error persists, please contact Visiometrics technical support.

6 MANUFACTURER

VISIOMETRICS, S.L.

c/ Argenters, 8 - Edifici nº 3 Parc Tecnològic del Vallès

08290 Cerdanyola del Vallès

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Tel.: (+34) 935 824 501

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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
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8 APPENDIX A

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

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

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

- Patients_Table
- Acquisitions_Table
- Struct

8.1 PATIENTS_TABLE

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

These are the available fields:

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

OBSERVATIONS: Comments

OD_Sph, OD_Cyl, OD_Axis, OS_Sph, OS_Cyl, OS_Axis: Unused obsolete fields

8.2 ACQUISITIONS_TABLE

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

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

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

DATE, HOUR: When the measurement was taken

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

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

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

REFERENCE_SPH_REFRAC: Spherical refraction correction applied during the measurement.

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

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

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

WIDTH_PROFILE_1/2: Profile width at half height.

WIDTH_PROFILE_1/10: Profile width at 10% height.

MTF_CUT_OFF: MTF cut off frequency.

STREHL RATIO: Calculated Strehl Ratio.

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

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

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

Type: Measurement type

- 1 = Opt. Qlt (Optical Quality)
- 2 = SCT (Scatter Meter)
- 3 = Pseudo Acc (Pseudo Accommodation)
- 4 = Not in use
- 5 = Tear Film (Tear Film Analysis)
- 6 = Purkinje

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

Corr_Type: Indicates the correction type applied during the measurement.

- 0 = No correction
- 1 = Astig. correction
- 2 = Total correction

NImag: Number of captured images.

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

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

OAR: OQAS™ Accommodative Range.

OSI: Objective Scatter Index.

Refrac_Acc_Per_1: Not in use.

Refrac_Acc_Per_2: Not in use.

AR: Not in use.

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

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

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

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

TearFilm_Peripheral_Energy: Stores the energy at the periphery of each

image that was recorded in the Tear Film Analysis process.

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

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

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

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

PKJ_IsPreOperation: It only applies for Purkinje acquisitions. It stores if the acquisition is pre-operation or post-operation.

PKJ_MicrasPerPixel: It only applies for Purkinje acquisitions. It stores the relation pixel-microns in the associated image.

PKJ_PupilDiameter: It only applies for Purkinje acquisitions. It stores the pupil's diameter.

PKJ_PkjVsPupil_Length: It only applies for Purkinje acquisitions. It stores the distance, in pixels, between the Purkinje and the pupil's center.

PKJ_PkjVsPupil_Angle: It only applies for Purkinje acquisitions. It stores the angle between Purkinje and pupil's center.

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

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

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

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

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

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

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

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

PKJ_Pupil_PixelRadio: It only applies for Purkinje acquisitions. It stores the pupil's radius, in pixels.

PKJ_Laser_PixelCentroX: It only applies for Purkinje acquisitions. It stores the pixel, on X axis, where the Purkinje's center is.

PKJ_Laser_PixelCentroY: It only applies for Purkinje acquisitions. It stores the pixel, on Y axis, where the Purkinje's center is.

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

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

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

TearFilm_Pattern: Only applies in measuring Tear Film, and indicates the following sound pattern:

- 0: Without sound pattern
- 1: Baseline pattern
- 2: Stress Condition pattern

TearFilm_Group: Only applies in measuring Tear Film that has followed a type of sound pattern, and indicated the group to which the measurement belongs:

- 0: Not possible to determine a specific group
- 1: Plateau
- 2: Plateau/Seesaw
- 3: Seesaw
- 4: Seesaw/Ladder
- 5: Ladder

8.3 STRUCT

The fields of this table contain no useful information for the final user.

8.4 SYMBOLS



Warning



Electrical products recycling. Do not dispose of this product with your other household waste. It must go to a designated collection point for the recycling of electrical and electronic equipment waste.



CE Mark



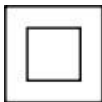
Serial number



Applicable part



Laser radiation



Class II device



Fragile



Keep dry




Keep in upright position



Read user manual

9 ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY			
The HD Analyzer™ is intended for use in the electromagnetic environment specified below. The customer or the user of the HD Analyzer™ should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF emissions IEC 61000-4-6	3Vrms 150 kHz to 80MHz outside ISM bands ^a	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the HD Analyzer™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,17 (P)^{1/2}$ $d = 4 (P)^{1/2}$
	10 Vrms 150 kHz to 80MHz In ISM bands ^a	3 Vrms	
Radiated RF emissions IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 4 (P)^{1/2}$ 80 MHz to 800MHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). ^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level for each frequency ^d range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 Mhz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. ^b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges. ^c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the HD Analyzer™ is used exceeds the above applicable RF compliance level, the HD Analyzer™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the device. ^d Over the frequency ranges 150 kHz to 80 MHz field strength should be less than 10 V/m.			

Recommended safety distances between portable and mobile RF-communication equipment and the HD Analyzer™				
<p>The HD Analyzer™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HD Analyzer™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HD Analyzer™ as recommended below, according to the maximum output power of the communications equipment.</p>				
Rated maximum output power of the transmitter in watts (W)	Separation distance according to the frequency of the transmitter in meters (m)			
	150 kHz to 80MHz outside ISM bands $d = 1,17\sqrt{P}$	150 kHz to 80MHz In ISM bands $d = 4\sqrt{P}$	80 MHz to 800 MHz $d = 4\sqrt{P}$	800 MHz to 2,5 GHz $d = 7,67\sqrt{P}$
0,01	0,17	0,4	0,4	0,77
0,1	0,37	1,26	1,26	2,43
1	1,17	4	4	7,67
10	3,70	12,6	12,6	24,25
100	11,7	40	40	76,7
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>Note 2: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.</p> <p>Note 3: An additional factor of 10/3 is used in calculating the recommended separation distances for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.</p> <p>Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>				