

compass

Operating Manual

MANUAL INFORMATION

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Manufacturer: CenterVue S.p.A.
Via San Marco 9h, 35129 Padova – ITALY
Tel. +39 049 739 6147
Fax +39 049 739 6148



centervue

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1. INTRODUCTION

Fundus Perimetry is a technique that images the retina during visual field testing, enabling a correlation to be made between visual function and retinal structure.

COMPASS is a scanning ophthalmoscope combined with an automatic perimeter, also a **Fundus Perimeter**, that allows the acquisition of confocal images of the retina, simultaneously to the measurement of retinal threshold sensitivity and the analysis of fixation. The Device operates in non-mydriatic conditions, i.e. without the need of pharmacological dilation.

As a perimeter, the system offers full compatibility with standard 24-2 visual field testing and contains an age-matched database of retinal sensitivity in normal subjects.

As a retinal imager, COMPASS uses a confocal optical design, similarly to SLO systems, to capture color as well as red-free images of superior quality. In addition, a high resolution live image of the retina obtained using infrared illumination is available throughout the test.

COMPASS is intended for use as a diagnostic device to aid in the detection and management of glaucoma. The device is indicated for measuring retinal sensitivity, for a quantitative assessment of fixation characteristics, as well as to capture infrared and color images of the retina without the use of a mydriatic agent.

The Device integrates a tablet and is provided with an external power supply. The device works with a dedicated software application and operates as a standalone unit.

The clinical interpretation of the results obtained with COMPASS is restricted to licensed eye care practitioners. The process of making a diagnosis using COMPASS results is the responsibility of the eye care practitioner.

A device specific training is required for any operator to become able to use the system.

2. SYSTEM

2.1 The device



Fig. 1 - COMPASS

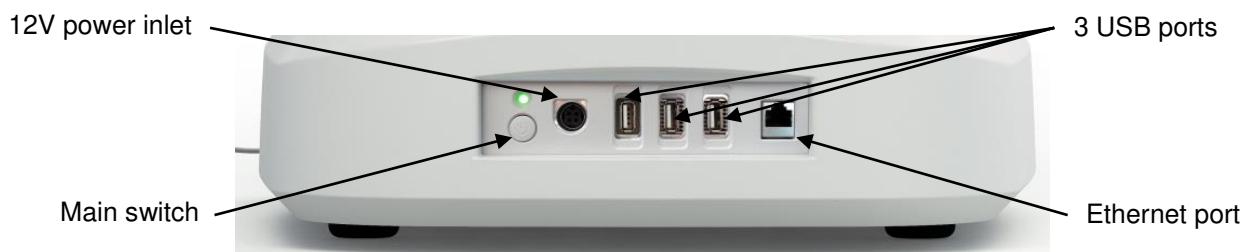


Fig. 2 – Detail of connectors side



Fig. 3 – Patient push button

COMPASS is provided with:

- dedicated tablet with USB cable and related support
- external power supply and related power cord
- digital, USB powered, joystick and related support
- this operating manual
- removable forehead rest
- patient push button
- front lens cap



2.2 The tablet

The tablet is an integral part of the system and COMPASS cannot operate without it.

The tablet must be connected to COMPASS using the supplied USB cable: if the connection is not working an error message will appear on the screen (see par. 16 for details).

Use the USB port next to the power inlet to connect the tablet: this is the only port that will also recharge the tablet.

The tablet is equipped with a color, multi-touch display.

More than one model is supported: the tablet power switch, volume control and USB port are located on the tablet frame and vary depending on the specific model.



Patient data and images are not stored on the tablet.



The tablet must be used only together with COMPASS and in accordance with the instructions provided in this manual. Use of the tablet for other purposes, as well as any modifications of the tablet settings other than indicated in this manual may result in the COMPASS to become unusable.

Charging the tablet

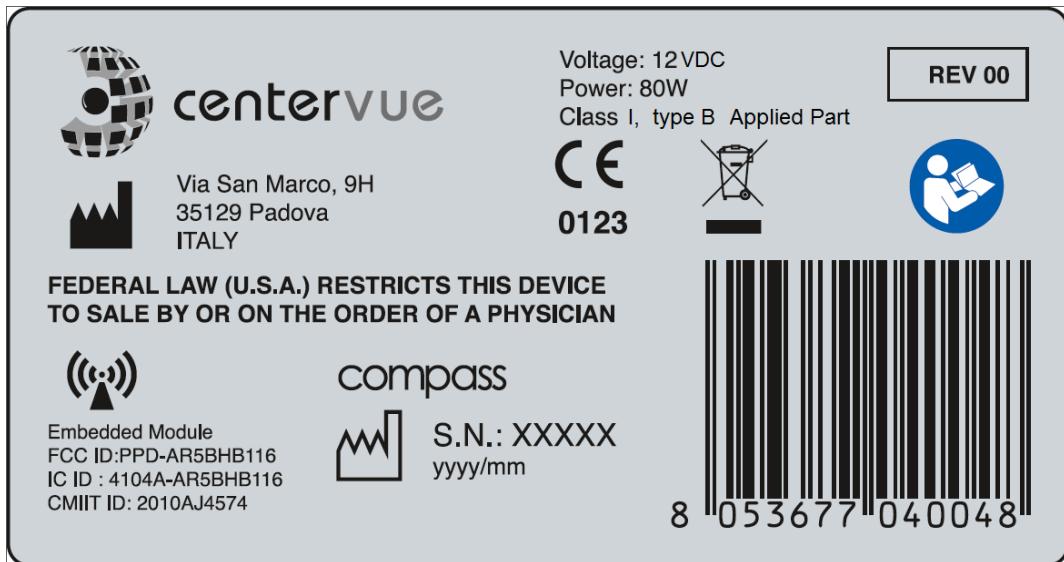
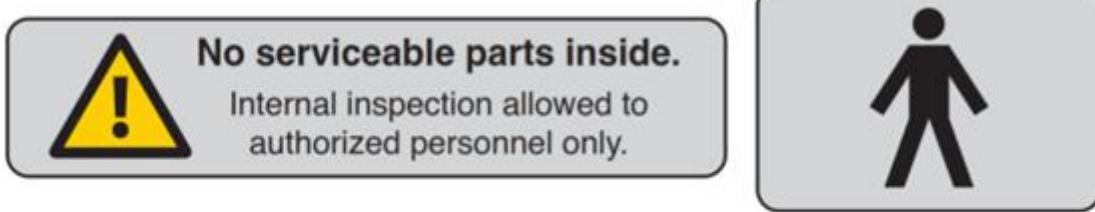
COMPASS cannot be used if the tablet is not sufficiently charged. The tablet is charged via the USB port of the device.

To maximize the duration of the charge:



- Set the screen brightness to "Auto" or anyway not to maximum;
- Plug the tablet in the left-most USB port, near the power switch;
- Keep COMPASS powered and the tablet connected when the device is off;
- Turn off the screen when the device is not in use.

3. LABELS



4. SYMBOLS

The meaning of the symbols adopted in this manual is as follows:

| Symbol | Explanation |
|---------------|---|
| | Manufacturer Data |
| | Manufacturing Date (year/month of production) |
| | Electronic and electric devices must be recycled. |
| | Refer to Instruction Manual |
| | CE mark: the device complies with the essential requirements of the European Medical Devices Directive 93/42/EC |
| | Type B Applied Part |
| | Non-ionizing radiation - ME EQUIPMENT that include RF transmitters |
| | Generic Warning |
| | Important information |

5. PREPARING THE SYSTEM



We recommend to read carefully and thoroughly par. 7 WARNINGS AND PRECAUTIONS before proceeding with first use.

To make COMPASS functional for the first use:

- extract the system from its box;
- place it on a suitable electrical table¹;
- insert the soft forehead rest on the metal support (see Fig. 4);
- mount the supports provided for the tablet and the joystick (see par. 5.1 below);
- connect the patient push button cable to the connector located underneath the device;
- connect the power supply provided with the unit to the power inlet (see Fig. 2);
- place the tablet on its support and connect it using the cable to the left-most USB port;
- place the joystick on its support, connect it using the cable to any of the free USB ports and check for its correct orientation;
- plug the power supply to the wall socket.

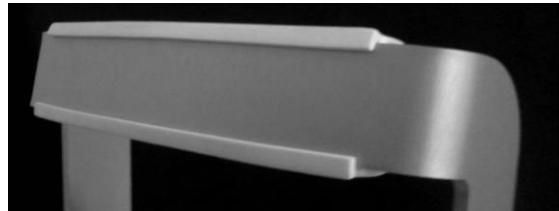
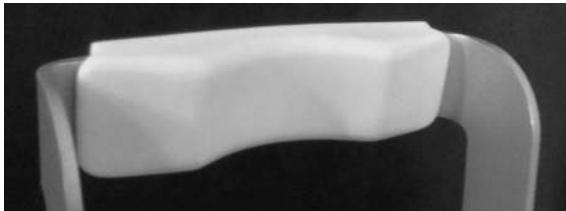


Fig. 4 - Forehead rest mounted on metal support

¹ Not provided with the system

5.1 Assembling the tablet and joystick supports

The tablet and joystick are mounted, using the included supports (see Fig. 6), towards the posterior part the device, on any side. Both supports are fixed with screws to the bottom of the device.

As an example, Fig. 7 shows the holes to be used for the left-side mount depicted in Fig. 5: to fix the supports use holes marked 1 and 2 for the tablet and those marked 3 and 4 for the joystick. Other configurations can be chosen, based on a user's preferences.



The joystick is not used in the current software version.



Fig. 5 – Tablet mounted on the left side of the device



Fig. 6 – Support for the tablet



Fig. 7 – Instrument bottom with holes for tablet and joystick supports

5.2 Turning on the Device

Turn on the Device by keeping the main switch **pressed for approximately 3 secs**, turn on the tablet by keeping its switch pressed for approximately 4 secs, wait for the boot process to complete and the **Login** screen to appear (see Fig. 8).

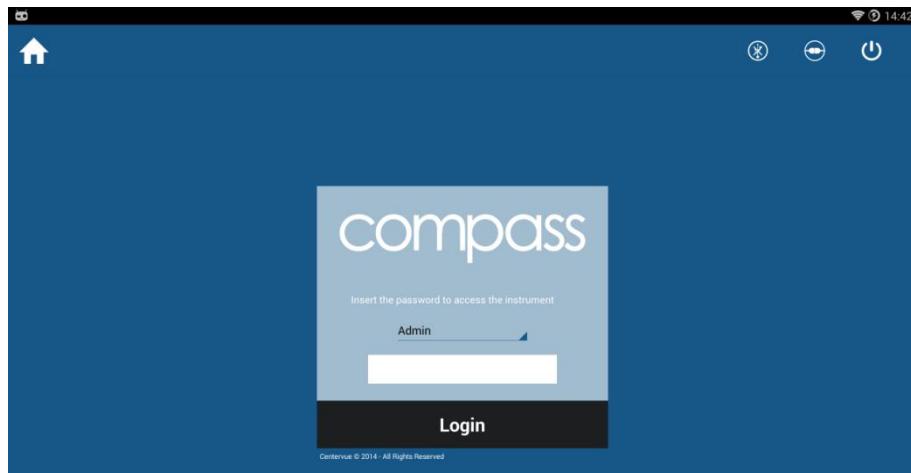


Fig. 8 – Login screen

From the drop-down menu select “Doctor”, type the password² and click on **Login**. If login is successful, the **Home** screen opens (see Fig. 9).



To modify the password, see par. 12.2.

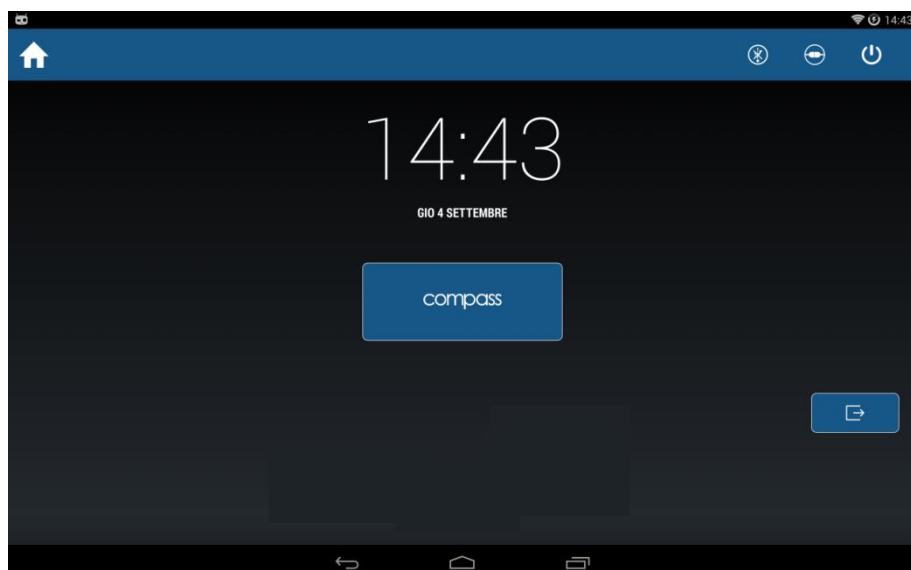


Fig. 9 - Home screen

² To find out the password please contact an authorized Centervue representative

6. PREPARING THE SUBJECT

This paragraph explains how to prepare a subject for the COMPASS test.

There are no restrictions as to the selection of the subjects undergoing testing, but since the test requires the subject to maintain concentration and to follow the below instructions for several minutes, very young subjects (before primary school), as well as mentally diseased persons may not be able to co-operate appropriately.

COMPASS compensates for a subject's spherical refractive error in the range -12 to +15 diopters: testing a subject presenting a spherical error out of the above range may result in inaccurate measurements.

COMPASS does not compensate for a subject's astigmatism. Subjects with astigmatism within ± 4 diopters can be tested normally. Testing a subject with astigmatism outside of the above range may result in inaccurate measurements.

The subject can wear contact lenses or spectacles while being examined, although in the latter case artifacts may appear in the retinal image.

Patient contacting parts are indicated in Fig. 1 and Fig. 3.

COMPASS is a non-mydriatic device: there is no need to dilate the subject unless if the pupil is smaller than 3 mm. The eye which is not examined should be patched.

Before starting the test, please check the following:



- subject should sit in a comfortable position, with the fore head and chin in firm contact with the rests;
- height of the table and chair should be adjusted so that the subject can comfortably place her/his chin on the corresponding rest;
- the subject's head should be vertical (not tilted forward / backward);
- chin rest should be positioned so that the subject's eye is aligned to the eye mark found on the sides of the metal frame. If this is not the case the chin rest height needs to be adjusted.

Before the test inform the subject about the following:



- COMPASS will test your ability to perceive light while looking at a steady target.
- the test is non-invasive, in particular you will only perceive some light.
- find a comfortable position and keep the chin and forehead firmly pressed against the rests;
- at the beginning of each test, the unit will move around to find your pupil: this is absolutely normal;
- always keep your eyes wide open, so that eyelids do not interfere;
- when the test starts, look straight in front of you and when a small green, circular spot appears anywhere, look at it;
- do not move, nor speak during the test;
- **you can blink whenever you feel necessary, unless instructed not to do so;**
- you will be given this push-button: press it when you see, or believe to see, a whitish small spot appearing anywhere;
- it is absolutely normal that you do not see many of the spots.

7. **WARNINGS AND PRECAUTIONS**

The following precautions are important for the device safety:

- Federal laws (US) restrict this device to sale by or on the order of a physician or a properly licensed practitioner.
- Clinical interpretation of the results is restricted to licensed eye care practitioners.
- A device specific training is required for any operator to become able to use the system.
- Do not open the Device: this could lead to electric shocks or damage to the system.
- Do not use the Device in the event that the cover or other parts of the device have been removed.
- Only technicians authorized by CenterVue may service the Device. Centervue cannot be held responsible for system safety should the device be opened, repairs carried out, third parties' software be installed, or parts be replaced by un authorized persons.
- Do not expose the Device to water: this could lead to fire or electric shock.
- Stand clear from moving parts during operation.
- The Device is supplied with an earth ground by means of a protection conductor contained inside the power supply cable. Before turning on the system, make sure the power supply socket is correctly grounded to avoid the risk of electric shock.
- The Device must NOT be used in an oxygen rich environment or in presence of flammable anesthetics.
- In case an unexpected hardware condition occurs during use, an error message may appear (see for example Fig. 10) and COMPASS may become temporarily locked. It is possible to reset this condition by letting the device re-initialize: refer to par. 12.4 for the complete procedure. If the error condition persists, please contact an authorized service center.



The following precautions are important to prevent use errors:

- The Device must be placed in a room which is not exposed to adverse chemical-physical conditions, such as the presence of sulfur, salt, dust, direct sunlight, lack of ventilation, high humidity, sudden temperature drops or peaks. The safety and/or effectiveness of the instrument cannot be guaranteed if these conditions are not fulfilled.
- Since the Device measures a light sensitivity at the threshold of perception, it needs to be operated in a dark environment.
- The Device needs to be operated under the following environmental conditions: temperature: 10 - 40 C° (50 – 104 F°); humidity (max): 90% not condensing.
- The Device needs to be stored under the following environmental conditions: temperature: 0 – 60 C° (32 - 140 F°); humidity (max): 90% not condensing.

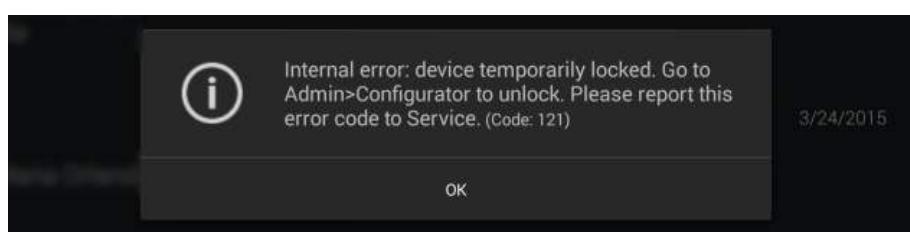


Fig. 10 – Example of error message

8. NOTES FOR THE OPERATOR

COMPASS provides capabilities for a fully automated test process. No specific skills are required to operate the Device and a minimal, device specific, training is required to become able to operate the system.

In particular, the operator shall be acquainted with the following concepts:

- pupil: the central part of the external surface of the eye, through which light goes in;
- retina: the internal surface of the eye ball;
- optic disk: a specific portion of the retina characterized by a roughly circular shape and by outgoing / incoming vessels;
- fixation / fixating: the ability of a subject to stare at a specific point in space and specifically the Device internal fixation target;
- alignment: the action of moving the top part of the system so that its optics are aligned with a subject's pupil;
- focusing: the compensation, by means of internal optics, of a subject's spherical defect (myopia, hyperopia);
- sensitivity threshold: the minimum intensity of a light stimulus that is perceived by a subject as emerging from the background.



Acquaintance with the basic concepts of standard automated perimetry is helpful for an effective use of some of the features of the Device and for interpretation of its results.

9. PERFORMING THE TEST

This paragraph explains how to operate COMPASS to perform the test (in this manual the terms “test” and “exam” are used as synonyms). Once the Device has been turned on click on the **compass** button to open the **Patient List** screen (see Fig. 11).

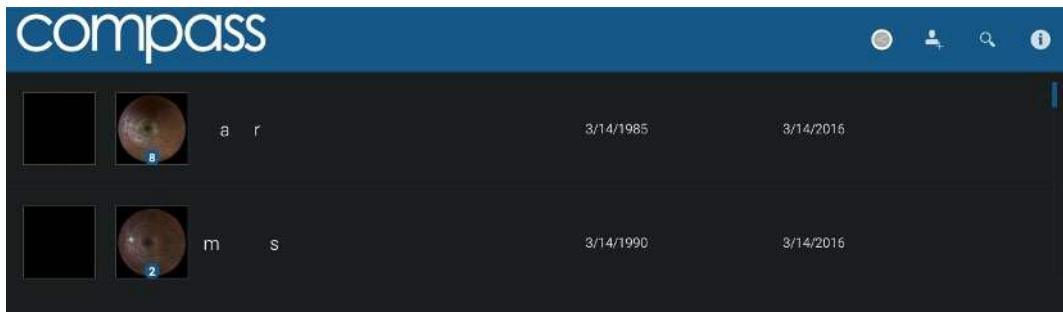


Fig. 11 – Patient list screen

The different columns in the list indicate respectively (left to right):

- the presence and number of exams (represented by the retinal images) stored for a certain patient (right and left eye);
- the patient's full name;
- the patient's date of birth;
- the date of the last exam performed.

9.1 Adding a new patient

To create a record for a new patient, click on and the **Patient Editing** screen will open (see Fig. 12). Type the last name, first name and select the date of birth (mandatory fields), optionally select the gender and type a unique code of your choice. Then click OK to save or Cancel to abort.

9.2 Searching for an existing patient

To search for an existing patient, click on and type the initial letters of the patient you are looking for, then click Ok. When the desired patient is shown in the list, click on it to select. To exit the search, click on to hide the keyboard and then on .

9.3 Selecting an existing patient

To select a specific patient in the list, click on it. The list is sorted by the date and time of the last exam and can be scrolled up and down.

Given Name

Surname

Birth date

Gender

Code

Diopter Left: 0

Diopter Right: 0

Ok Cancel

Fig. 12 – Patient editing screen

Once a patient has been selected in any of the above ways, the **Patient Record** screen opens (see Fig. 13) and provides information on the selected patient, whose name is shown at the top-left corner of the screen. See par. 10 for full details on how to review a patient's data.

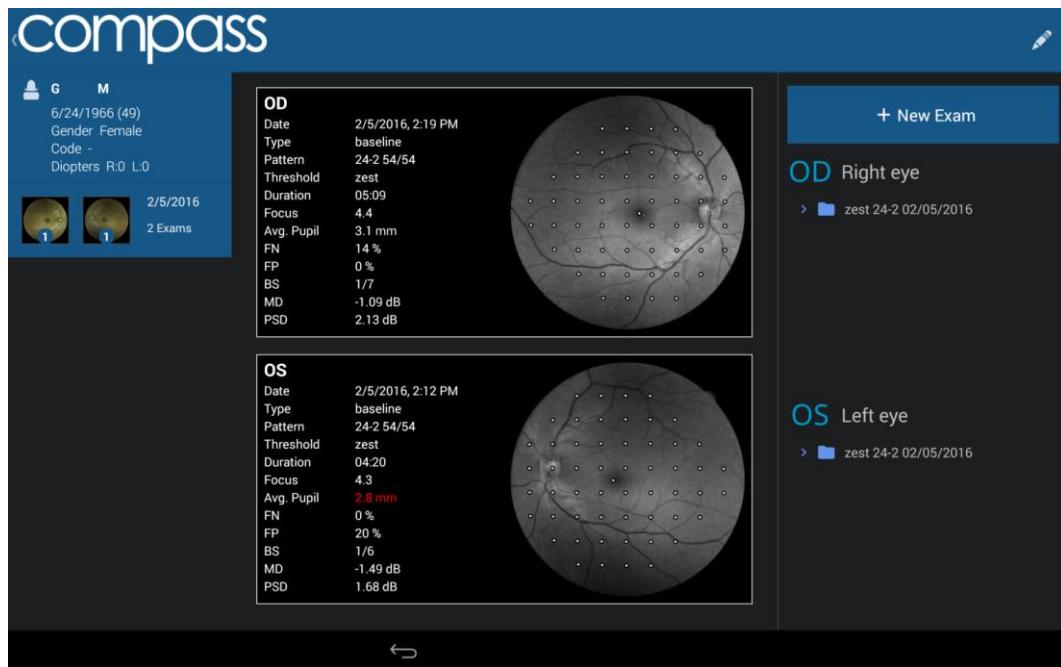


Fig. 13 – Patient Record screen

9.4 Root test vs. follow-up test

COMPASS allows to measure a subject's visual field in time, hence creating a sequence of tests.

COMPASS provides two different test modalities:

- a **root test** is the first performed on a certain subject and eye, thus it does not require the existence of a previous test;
- **follow-up tests** require a previous root test of the same eye.



The **follow-up modality exploits image registration techniques to accurately match stimuli locations in the follow-up test with their position in the corresponding root test and ensure high precision of the results.** Operators shall be fully aware of the difference between root tests and follow-up tests.

With COMPASS:

- any follow-up test is associated with its root test
- any root test is identified by this graphics:



- it is not possible to generate a progression report using only root tests
- it is only possible to generate a progression report using a root test and its follow-up tests

9.5 Initiating a new root test

To initiate a new root test, click on the **New Exam** button.

9.6 Initiating a new follow-up test

To initiate a new follow-up test, select the desired root test and click on the **New Follow Up** button.

9.7 Choosing test parameters

When the New Exam command is pressed the **Test parameters selection** screen opens (see Fig. 14), allowing review and modification of a test parameters.

The following commands / functions are available:

1. Eye selection (OD, OS)
2. Selection of the threshold strategy ("4-2" or ZEST)
3. Chin rest height adjustment
4. Selection of the test grid (or pattern)³
5. Test start
6. Back to Patient Record screen

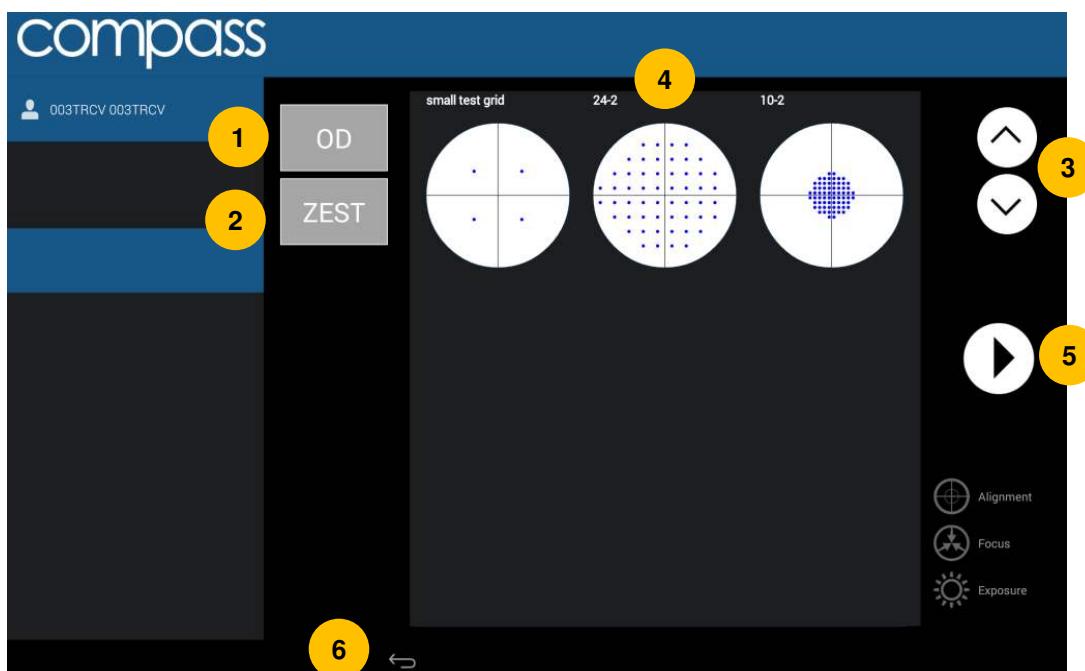


Fig. 14 – Test parameters selection screen

ZEST vs. 4-2

i Zippy Estimation by Sequential Testing (ZEST) is an adaptive Bayesian method for determining sensitivity measures. ZEST, similarly to SITA algorithms, allows to reduce examination time while maintaining accuracy.

In terms of threshold, ZEST estimates are on average 0.9 dB higher than those found with the 4-2 staircase (similarly to SITA algorithms vs. full threshold).

In terms of examination time, the average for a 24-2 test is approximately 40% shorter using ZEST than using 4-2.

³ Total deviation and Pattern deviation maps and related indices are only available when using the 24-2 grid

The following perimetric parameters are used and cannot be modified:

- background luminance: 31.4 asb
- maximum luminance (0 dB): 10000 asb
- stimulus duration: 200 ms
- stimulus size: Goldmann III
- blind spot test: ON
- foveal threshold: ON
- false Positives: ON
- false Negatives: ON
- fixation target for foveal stimulus: 4 green circles in diamond configuration
- fixation target for non-foveal stimuli: single green circle



9.8 Before starting

Following are some hints to maximize the effectiveness of the test:

- check that the lens cap has been removed
- check that the room is sufficiently dark
- subject should sit in a comfortable position, with the forehead and chin in firm contact with the corresponding rests. Subject's head should be vertical and not tilted. Chin rest should be positioned so that eye is aligned to the mark
- ask the subject to look at the fixation target throughout the test
- perform a quick training on subjects that never had perimetry before

9.9 During the test

The following table describes the test process flow.

| # | STEP | PURPOSE | INSTRUCTIONS |
|---|-----------------|---|---|
| 1 | Auto-alignment | Align instrument to subject's eye | Subject should not move and should look for the green fixation target. For additional details see next paragraph. |
| 2 | Auto-focus | Correct for subject's spherical refraction | Subject should not blink and should look at fixation target |
| 3 | Reference image | Capture reference retinal image to be used for eye tracking | The reference image should have good quality, in particular images that are too dark, or partially occluded by eye lashes or lids should be retaken. Click the back arrow to retake the reference image if its quality is not satisfactory (see for example Fig. 15).  : a poor quality reference image may compromise the VF test, increase its duration, prevent retinal tracking or make follow-up testing impossible. |
| 4 | Blind spot test | Identify location of blind spot | Drag and center circle over optic disc, then click the forward arrow (see Fig. 16)  : improper or missed placement of the optic disc marker results in failure of the BS test |
| 5 | Detect fixation | Locate center of fixation | Subject should look steadily at fixation target.  : once this step has completed the system will stop and wait for confirmation: click the forward arrow to proceed with next step |
| 6 | Fovea Test | Measure sensitivity at the fovea | Subject should look at the center of the 4 green dots and press the button when she/he sees a white spot.  : if not properly instructed subjects often miss clicking at this time.  : once this step has completed the system will stop and wait for confirmation: click the forward arrow to proceed with next step |
| 7 | Perimetry | Measure sensitivity at all grid locations using central fixation target | Subject should look steadily at the green dot and press the button when she/he sees a white spot. Subject can blink at any time. Periodically inform the subject of the progress. See note concerning eye tracking.  : if not properly instructed subjects sometimes get away from the forehead rest during the test.  : once this step has completed the system will stop and wait for confirmation: click the forward arrow to proceed with next step |
| 8 | Color image | Capture color photo of posterior pole | Subject should not blink and should look at the green fixation dot until a light is flashed.  : click on the back arrow to retake the image if of poor quality. |

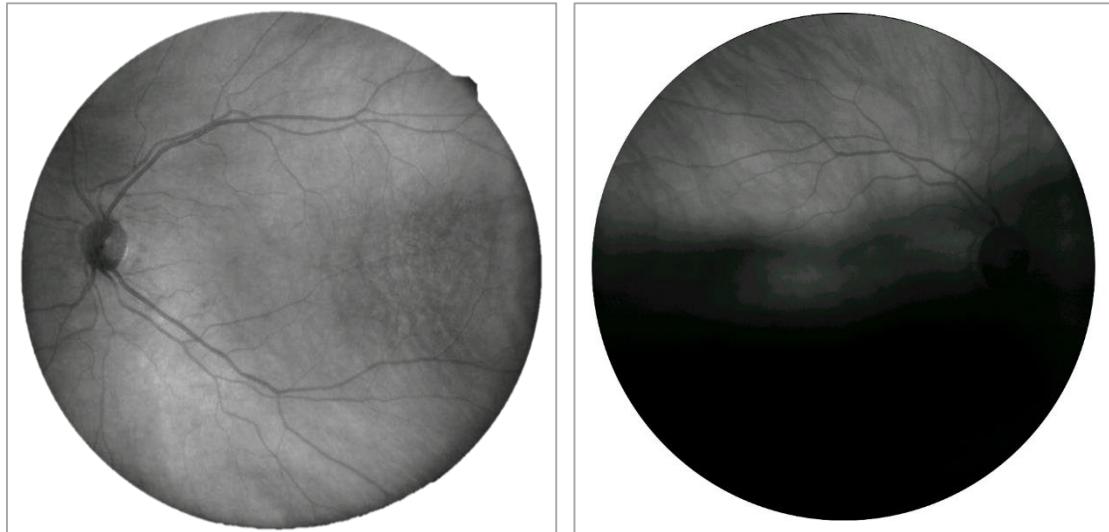


Fig. 15 – Good (left) and poor quality (right) reference image

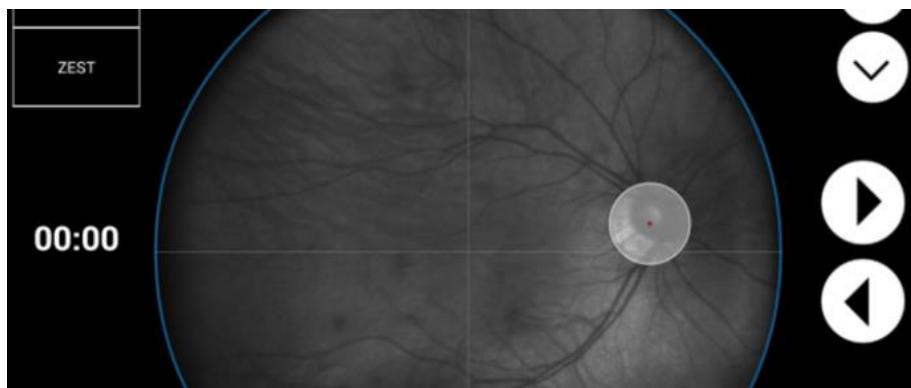


Fig. 16 – Marker for optic disc location in Exam screen

9.10 Auto-alignment

Several hints may be presented on screen by the system to help the operator correct a subject's position: see Table below.



Pupils smaller than the minimum required may trouble the auto-alignment and auto-focusing processes

EYE NOT FOUND: Please make sure patient head is not tilted, eye is open wide

EYE TOO FAR LEFT: Please make sure patient head is well centered in front rest and not tilted

EYE TOO FAR RIGHT: Please make sure patient head is well centered in front rest and not tilted

EYE TOO LOW: Please raise chin rest until alignment process restarts

EYE TOO HIGH: Please lower chin rest until alignment process restarts

PATIENT TOO FAR: Please make sure patient head is not tilted, or detached from front rest

Table 1 – System hints during auto-alignment

9.11 Retinal tracking

Eye tracking is a fundamental component of Fundus Perimetry.

Infrared retinal images, acquired at the rate of 25 images per second, allow for continuous, automated, tracking of **eye movements**. Determination of eye movements allows, in turn, **active compensation of fixation losses**, with perimetric stimuli being automatically re-positioned prior to and during projection based on the current eye position. This mechanism reduces test-retest variability and ensures accurate correlation between function (i.e. retinal threshold values) and structure (retinal appearance). Compensation of eye movements takes place before and during projection of a certain stimulus. In absence of this mechanism shifts in eye position occurring at the time of projection of a certain stimulus even in healthy subjects easily produce artifacts in VF results.

Regular operation of the eye tracking is indicated by a GREEN frame surrounding the retinal image (see Fig. 17). A RED frame indicates that eye tracking is NOT operational: in such case stimuli cannot be projected and **the test is paused until the retina can be tracked again**. Typical reasons for tracking failure include: blinking, small pupil (requires dilation), closed eye lids, incorrect subject position (e.g. far from forehead rest).

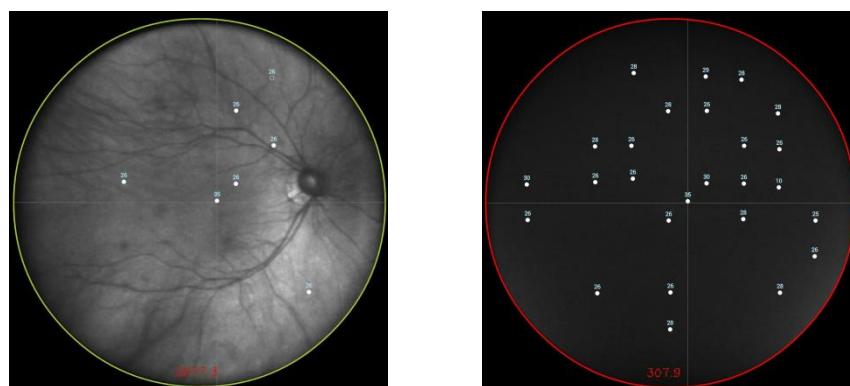


Fig. 17 - Tracking active (left) and on hold (right)

9.12 Monitoring test progress

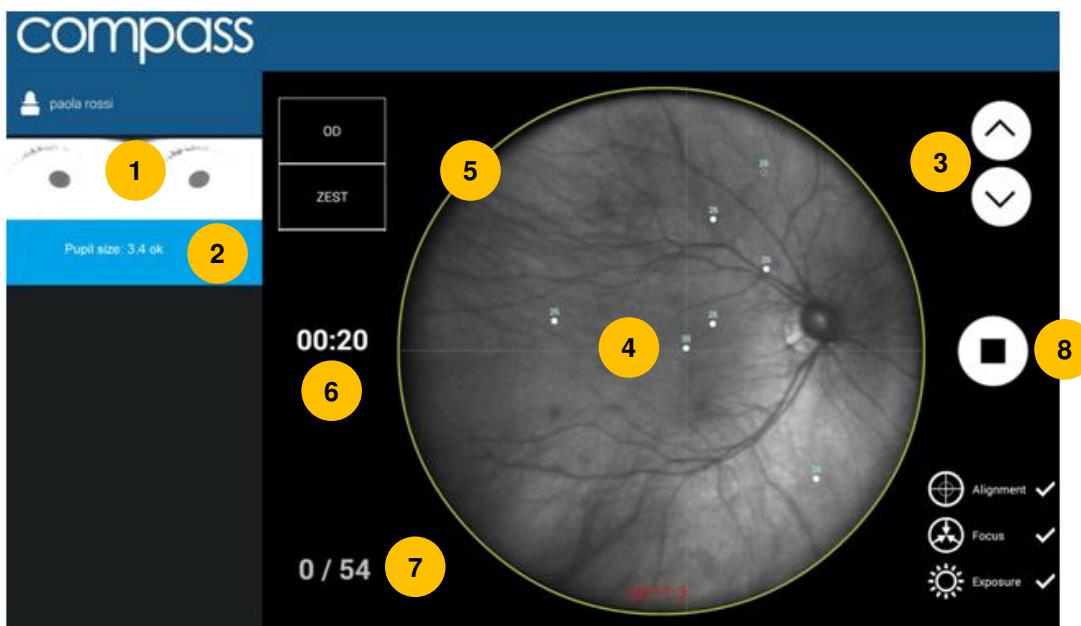


Fig. 18 – Exam screen while test is in progress

The following commands are available:

1. Pupil images from alignment cameras allow the operator to check if subject's eyes are open
2. Pupil size: if smaller than 3 mm a "small pupil" warning is displayed. Pupil size may oscillate during the test due to accommodation
3. Allows to adjust the height of the chin rest
4. Live retinal image with stimuli allows the operator to monitor progress. Fovea should stay at the center of the gray cross. Seen stimuli are shown as filled dots. The stimulus being projected is shown as an empty circle
5. Tracking status (circular colored frame, see par. 9.11)
6. Elapsed test time
7. Completed stimuli over total being projected: test proceeds slow at the beginning and turns progressively faster
8. Allows to stop the test at any time



COMPASS requires a minimum pupil of 3.0 mm: a test with average pupil size smaller than 3.0 mm may be unreliable.

10. REVIEWING RESULTS

Once a test is completed, the system will open the **Patient Record** screen (Fig. 20) for the selected patient and present a thumbnail view of all tests made on the selected date.

Each thumbnail presents the following information:

- red-free retinal image with overlaid actual test locations;
- examined eye (OD/OS);
- date and time the test was performed;
- type (root / follow-up);
- pattern used and number of test locations actually completed (incomplete tests will show in yellow);
- threshold algorithm (ZEST or 4-2 staircase);
- duration (minutes: seconds);
- focus index;
- average pupil size during test;
- False Negatives index (FN);
- False Positives index (FP);
- Blind Spot index (BS);
- Mean Deviation index (MD);
- Pattern Standard Deviation index (PSD);

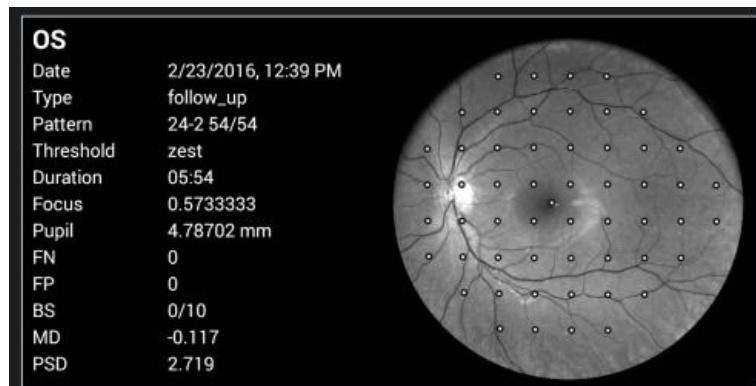


Fig. 19 – Example of thumbnail

The Patient Record screen provides the following commands:

1. modify the patient's name, birth date, gender and code
2. permanently delete the selected patient's record (any data)
3. display the tests performed at a specific date
4. display the tests performed within a certain sequence identified by a root test
5. open Exam Review screen (see Fig. 21)
6. start a new root test (do not use this button if you wish to start a follow-up)
7. start a follow-up test within the specified sequence of tests
8. go back to patient list screen

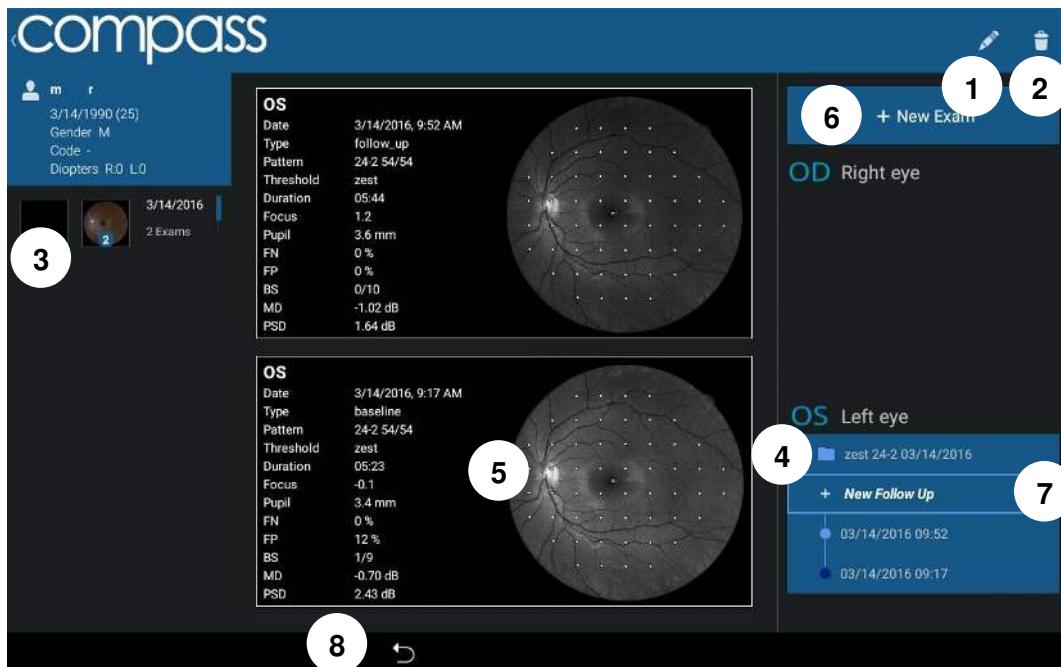


Fig. 20 – Patient Record screen

10.1 Individual test results review

The **Exam Review** screen (Fig. 21) provides the following information and functions:

1. Patient name
2. Selector for image modality (color, infrared or red-free)
3. Retinal image and visual field data, depending on selected modality (default: red-free, infrared and red-free images are shown with overlaid VF data). Click on image to open a full screen view and zoom / pan the image
4. Perimetric test parameters
5. Option to enable / disable display of perimetric results over retinal image (default: yes)
6. Option to switch ON / OFF fundus mode convention (default: on). See information box below at this regard
7. Image tools including **blue, green, red filters** used to display individual color channels and **gamma correction**, used to enhance image brightness. The green channel provides the red-free image. The red, green and blue filters are only available when reviewing color images. These tools do not alter the original image.
8. Command to create a test report and save it to USB
9. Command to export the selected image to USB
10. Command to view or print a test report
11. Command to view or print a progression report
12. Export results to shared folder (see par. 12.8)
13. Command to go back to Patient record screen

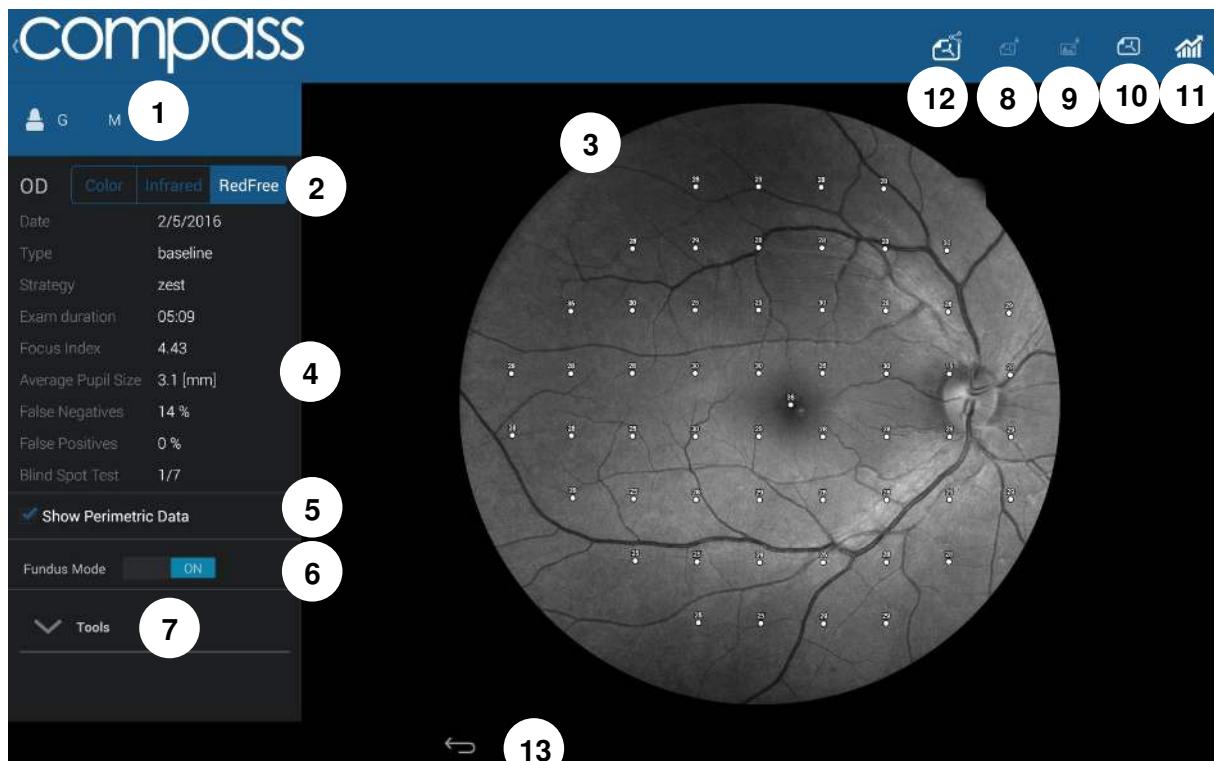


Fig. 21 – Exam review screen, red-free display modality

10.2 Reliability indices

COMPASS provides standard methods to assess the reliability of a subject in performing the visual field test:

- **False Positives:** these are trials in which no stimulus has been projected, therefore the subject is not expected to respond. If this index exceeds 25% the number will show in red, indicating possibly poor reliability.
- **False Negatives:** during the test, certain stimuli are randomly selected and retested at brighter level than has been previously seen. If the patient does not respond, a false negative instance is recorded. If this index exceeds 25%, the number will show in red, indicating possibly poor reliability.
- **Blind Spot Test:** during the test stimuli are projected with high luminance, at random times, at the blind spot location that has been selected prior to the start. Index shows the number of positive responses obtained over the total number of such BS projections. If this index exceeds 25%, the number will show in red, indicating possibly poor reliability.

COMPASS provides one additional parameter to be considered when assessing the reliability of a certain test:

- **Average pupil size:** shows the average pupil diameter throughout the test. If this index is below 3.0 mm, the number will show in red, indicating possibly poor reliability.

| | |
|--------------------|----------|
| Average pupil size | 4.5 [mm] |
| False Negatives | 0 % |
| False Positives | 0 % |
| Blind Spot Test | 1/9 |

Fig. 22 – Detail of Exam review screen with reliability indices

Fixation plot / Area

Differently than in non-retinal tracked perimeters, the COMPASS fixation plot shown in a test report (see par. 11.2 and Fig. 23 below) is not to be considered a way to assess the reliability of a subject / test.

In fact, the plot shows fixation losses, as determined by tracking eye movements (see par. 9.11), but these movements are taken into account and compensated at the time of projection of the stimuli, therefore they do not necessarily degrade a test reliability.

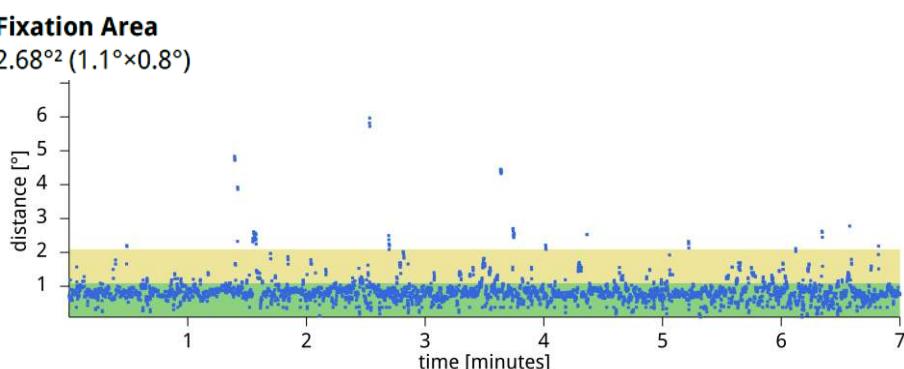


Fig. 23 – Fixation plot and Area

Fundus Perimetry vs. Standard Perimetry display conventions

In Standard Automated Perimetry, results are always displayed using the patient's perspective, i.e. they represent **visual field maps**, with superior field at the top and inferior field at the bottom: this convention is used in the Exam Review screen when the Fundus Mode selector is set to OFF ("Visual Field" convention).

In Fundus Perimetry, results are displayed using the doctor's perspective, i.e. they represent **retinal sensitivity maps** and show properly oriented retinal images: this convention is used when the Fundus Mode selector is set to ON ("Fundus" convention). Values from the superior field correspond to the inferior retina and viceversa.

Therefore, the two conventions differ in that they flip the results vertically.

COLOR CONFOCAL IMAGING

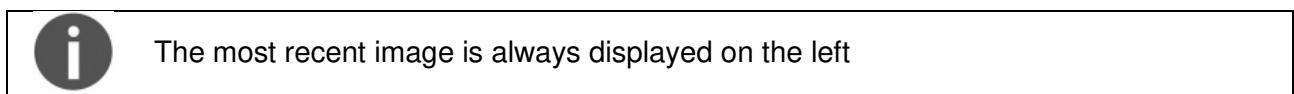
SLO systems are superior to conventional fundus cameras in many ways, as they exploit a confocal imaging principle, which limits the effect of backscattered light from deeper layers and provides enhanced image quality in terms of contrast and resolution. Another advantage of SLO systems is that they operate with smaller pupils than non-confocal imaging systems. At the same time, though, SLO systems do not provide color images, as they typically employ monochromatic laser sources, resulting in black and white or pseudo-color images.

COMPASS uses **white light** instead of monochromatic lasers, hence providing **true color** images and offering high image fidelity, no need for dilation down to 3 mm. pupil, excellent resolution and contrast, high quality even in presence of media opacities and optimized exposure of the ONH.



10.3 Dual image review

To review the images belonging to two different exams side by side, in the Patient Record Screen keep the thumbnail of the first exam pressed until the exam is selected (highlighted border); do the same for the second exam, then click the button found in the top-right corner of the screen: this will open the **Dual image review** screen (see Fig. 24).



To change the type of image being displayed (infrared, color or red-free) in both halves of the screen, click the button found in the top-right corner: this will open the panel shown in Fig. 25.



Fig. 24 – Dual Review screen

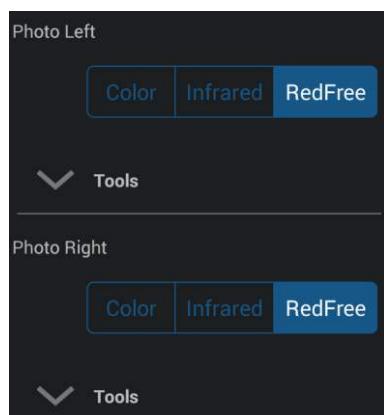


Fig. 25 – Image type selection panel

10.4 Creating a Progression Report

To create a progression report, select and open any test belonging to the desired series (root or follow-up), then click the button to view the progression report → 

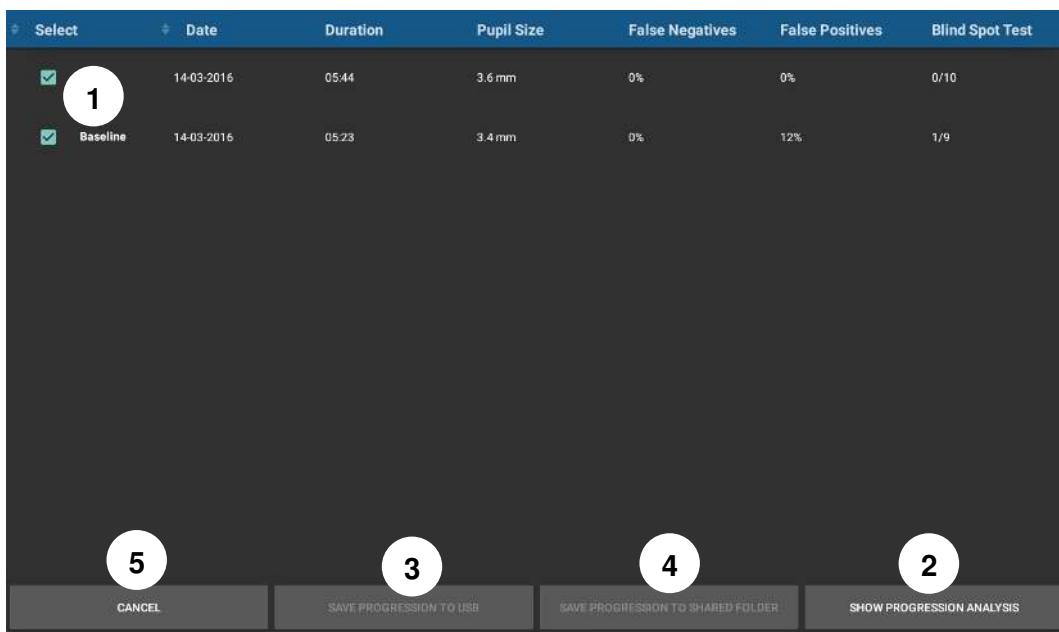
The **Progression report test selection screen** will open (see Fig. 26), which allows to select / deselect the tests to be considered to generate the report. For example, some tests may be excluded because of poor reliability (excess FP, FN or BS).

- **A progression report is created using a root test and its follow-up tests**
- Only tests that derive from the same root can be included
- At least two tests shall be included
- The earliest test included in the report acts as the **baseline**
- Either root or follow-up tests can act as baseline

This screen provides the following functions:

1. Include / exclude a certain test from the report
2. Show Progression Report
3. Save Progression Report to USB (requires USB drive)
4. Save Progression Report to shared folder
5. Cancel report generation and go back to Exam Review screen

See par. 11.4 for a description of the Progression report.



| Select | Date | Duration | Pupil Size | False Negatives | False Positives | Blind Spot Test |
|--|------------|----------|------------|-----------------|-----------------|-----------------|
| <input checked="" type="checkbox"/> 1 | 14-03-2016 | 05:44 | 3.6 mm | 0% | 0% | 0/10 |
| <input checked="" type="checkbox"/> Baseline | 14-03-2016 | 05:23 | 3.4 mm | 0% | 12% | 1/9 |

1
2
3
4
5

CANCEL SAVE PROGRESSION TO USB SAVE PROGRESSION TO SHARED FOLDER SHOW PROGRESSION ANALYSIS

Fig. 26 – Progression Report test selection screen

10.5 Remote Viewer

The Remote Viewer is a browser-based software that allows review of test results on any computer connected to the device via a local area network.



The Remote Viewer provides access to the patient list, individual patient records and image review screen.

The Remote Viewer does not allow to review Visual Field results, except by giving access to the pdf reports.

Compatible browsers include Chrome™, Firefox™ and Safari™.

To use the Remote Viewer, the device needs to be plugged in the local area network via **Ethernet** connection (Wi-Fi not supported).

Setting up the Remote Viewer

To enable the Remote Viewer, connect the device to the local network by plugging the network cable in the Ethernet port located on the back of the system.



To start using the Remote Viewer a password must be set: to set (or change) the Remote Viewer password see par. 12.6

Using the Remote Viewer

Open the browser and type <http://gsd-sssss.domain> in the address bar, where sssss is the five digits serial number of the unit and *domain* is the local network domain name: this will open the login screen.



If you cannot retrieve the network domain name or if the network is using static IPs and not DHCP, you can retrieve the device IP as follows:

- launch the Configurator application (see par. 12.1);
- click on the “NETWORK” tab;
- click on the icon of the “Wired” network;
- retrieve the IP;
- type <http://IP> in the address bar

Type the password and press **Login**: this will open the **Patient List** screen, which resembles the corresponding screen in the on-board software.

The Remote Viewer session is automatically closed after 20 minutes of inactivity.

Patient List screen

Right and left eye image thumbnails are shown in the first column, followed by the patient name and date of birth. The right-most column shows the date of the last exam.

Patients in the list are sorted by the date of their last exam.

Patient **Search** function is available in the top-left corner of the screen.

Click on the desired patient to enter the **Patient Record** screen (see Fig. 28), which resembles the corresponding screen in the on-board software. Click on **Logout** to exit the Remote Viewer.

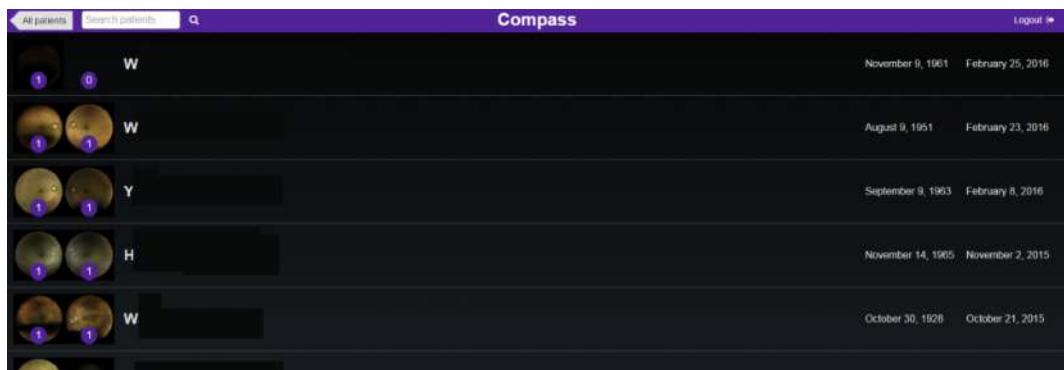


Fig. 27 – Patient List in Remote Viewer

Patient Record screen

This screen allows access to individual images.

Click on the desired image to enter the **Single Image review** screen (see Fig. 29).

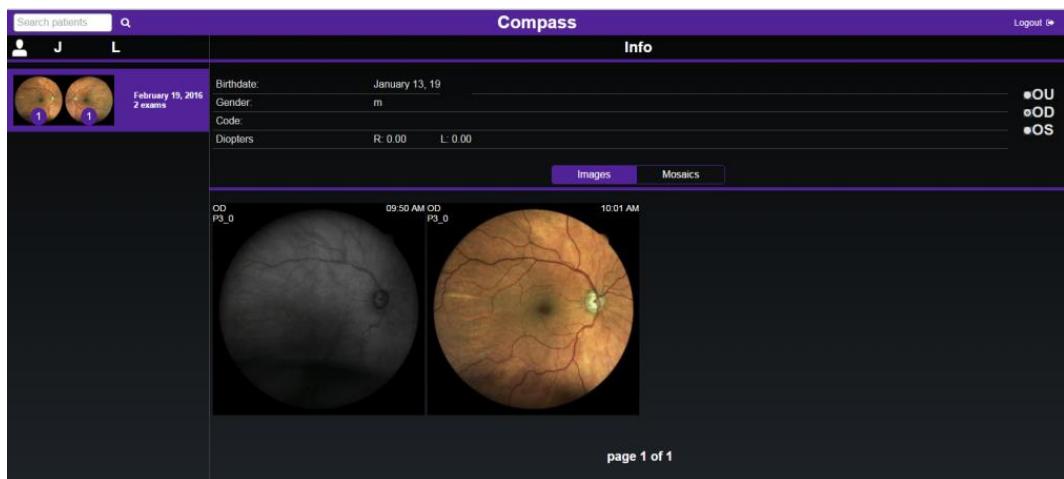


Fig. 28 – Patient Record screen in Remote Viewer

Exam review screen

The following commands are available in this screen:

1. Go back to Patient Record Screen
2. Logout
3. Displays patient related information (full name, date of birth, gender, code) and a thumbnail view of all exams available for this patient (date and time of acquisition, eye, average pupil size, exam type). Command is also used to compare the currently displayed image with any other image in the list click on the corresponding Compare button: see Dual Image Review screen (see Fig. 30)
4. Displays all exam related information (date and time of acquisition, eye, exam type, threshold strategy, focus index, average pupil size)
5. Shows red-free version of color image
6. Allows to save the corresponding image (jpg), or test report (pdf), or progression report (pdf, if available) on the local memory

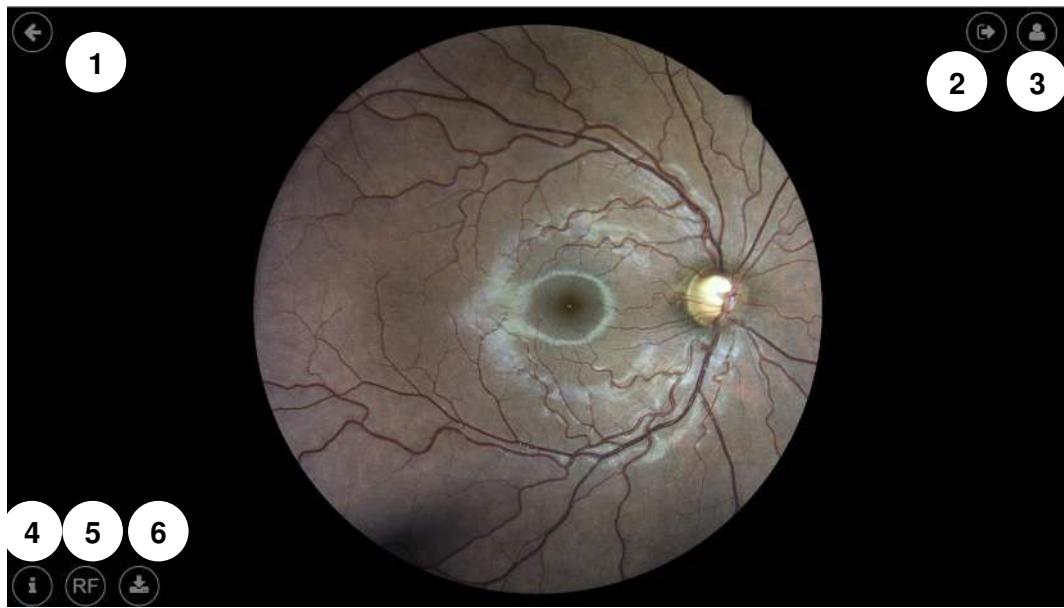


Fig. 29 – Exam Review screen in Remote Viewer

Dual Image review screen

This screen allows comparison of any pair of images (color and infrared, left and right eye, same or different dates).



Fig. 30 – Dual Image Review screen in Remote Viewer

11. PRINTING

11.1 Printer Setup

COMPASS supports wireless connection to most Android-compatible printer. Printing apps from the most common manufacturers come pre-installed into the COMPASS tablet (see Table 1). Before choosing a printer, please check if the model is included in the compatibility list issued by the printer manufacturer for every app.

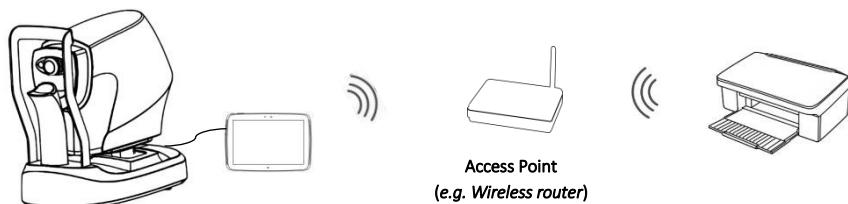
| Brand | Description |
|----------------|--|
| HP | HP Android ePrint |
| Samsung | Samsung Mobile Print App |
| Lexmark | Lexmark Mobile Printing |
| Canon | Canon Mobile Printing, Canon Easy-PhotoPrint, PIXMA/MAXIFY PrintingSolutions |
| Epson | Epson iPrint, Seiko Epson Corporation |
| Konica Minolta | Konica Minolta Printers, Page Scope Mobile |

Table 1: Printing apps

There are two possible network setups for printers, depending on whether a wireless Access Point (e.g. Wireless router) is available or not.

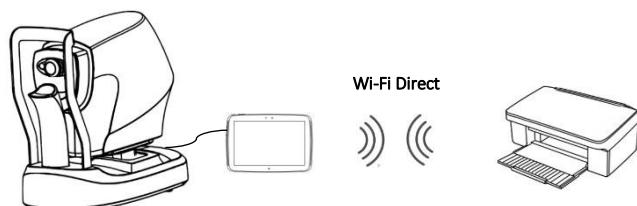
Infrastructure Mode

In this configuration, both the COMPASS tablet and the printer are connected to an Access Point, such as a wireless router.



Ad-hoc Mode

COMPASS connects directly to the printer via wireless, without the need of an Access Point: please note that, in order to setup this configuration, printer must support Wi-Fi Direct.



11.2 Report for 24-2 test

The printout for a 24-2 test is a one-page layout presenting the following information (see Fig. 32):

1. Patient information (name, date of birth, age when test was performed)
2. Examined eye (OD, OS)
3. Test parameters (date, time, duration, test pattern, threshold strategy, average pupil size during test, BS, FP, FN, foveal threshold)
4. Color image of the ONH
5. Threshold values (dB) over red-free image, using the Fundus Perimetry display convention (see info box below for information about the colors used and previous info box for details about the various display convention)
6. Mean Deviation (MD) and Pattern Standard Deviation (PSD) indices
7. Cluster MDs (dB) (see clusters identification in Fig. 33)
8. Grayscale VF map (see Fig. 34 for the gray tone symbols adopted), using the Standard Perimetry display convention
9. Total and Pattern deviation maps and related significance levels, using the Standard Perimetry display convention (the Pattern Deviation map is not shown if $MD < -8 \text{ dB}$)
10. Tracking Performance Indices: $TPI_{0.5^\circ}$ and TPI_{1° measure the rate of occurrence, during stimuli projections, of uncompensated eye movements exceeding respectively 0.5° and 1.0° in amplitude. The numbers between brackets report the corresponding values in (simulated) absence of retinal tracking, for comparison
11. Fixation Area: this index reports the area (and its semi-axis between brackets) of the 95th percentile fitting ellipse of the fixation points recorded during the test; the higher this index the more dispersed fixation and the wider eye movements
12. Fixation plot, describing the amplitude of eye movements in time, relative to the PRL
13. Glaucoma Staging System 2
14. Software version used to generate the report

TPI 0.5° : 94.4% [74.1%] / TPI 1° : 96.9% [89.1%]

Fig. 31 – Example of Tracking Performance Indices

The colors used in the Fundus Perimetry map (5) are derived from normative values:



- green is used for points having a total deviation with $p \geq 5\%$
- orange is used for points having a total deviation with $p < 5\%$ and $\geq 0.5\%$
- red is used for points having a total deviation with $p < 0.5\%$
- white is used for the foveal and optic disc locations

11.3 Report for 10-2 test

The printout for a 10-2 test is similar to the 24-2, with the following differences:

- the cluster analysis (7) is not available;
- the Glaucoma Staging System (13) is not available and is replaced by the color photo.



Tests performed with the “small test grid” are solely for training and not suitable for generating a report.

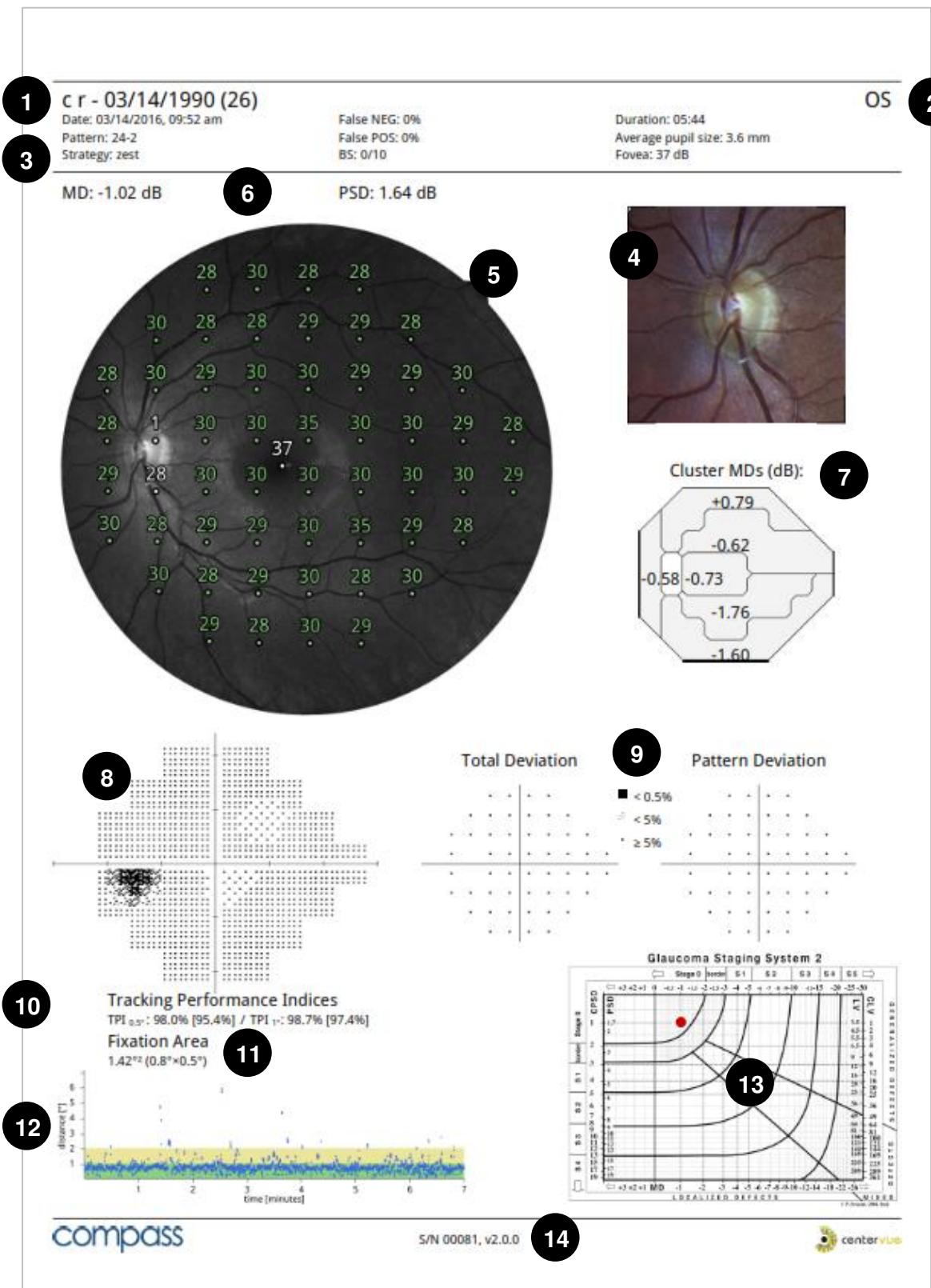


Fig. 32 – COMPASS report for 24-2 test

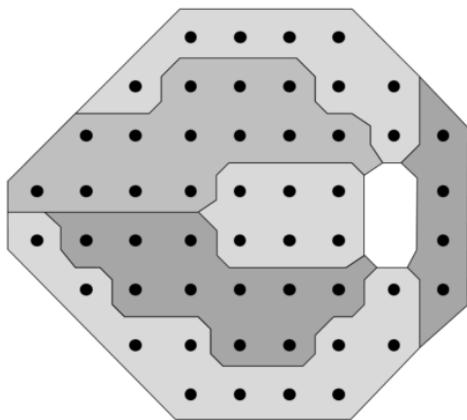


Fig. 33 – Stimuli of the 24-2 pattern grouped in clusters⁶

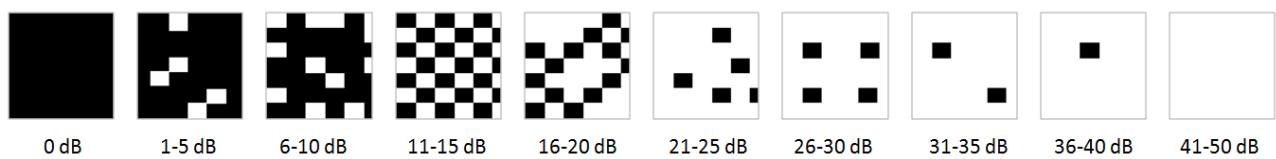


Fig. 34 – Symbols used for the grayscale map and related dB intervals

⁶ Garway-Heath et al; *Mapping the Visual Field to the Optic Disc*; Ophthalmology Volume 107, Number 10, October 2000

11.4 Progression report

The Progression Report provides information on a series of tests (24-2 or 10-2) pertaining to the same subject and eye.

It is a one-page layout presenting the following information (see Fig. 35):

1. Patient information (name, date of birth)
2. Examined eye (OD, OS)
3. Baseline Test parameters (date, time, duration, test pattern, threshold strategy, average pupil size during test, BS, FP, FN, foveal threshold, MD and PSD)
4. Color image of the ONH at baseline
5. Grayscale map, Total and Pattern deviation maps and related significance levels at baseline
6. Last follow-up parameters (date, time, duration, test pattern, threshold strategy, average pupil size during test, BS, FP, FN, foveal threshold, MD and PSD)
7. Color image of the ONH at last follow-up
8. Grayscale map, Total and Pattern deviation maps and related significance levels at last follow-up
9. Dates of intermediate follow-up tests included in the MD progression plot
10. Pointwise differences (dB) between last follow-up and baseline
11. Differences in cluster MDs between last follow-up and baseline
12. MD progression plot for all included tests
13. Software version used to generate report

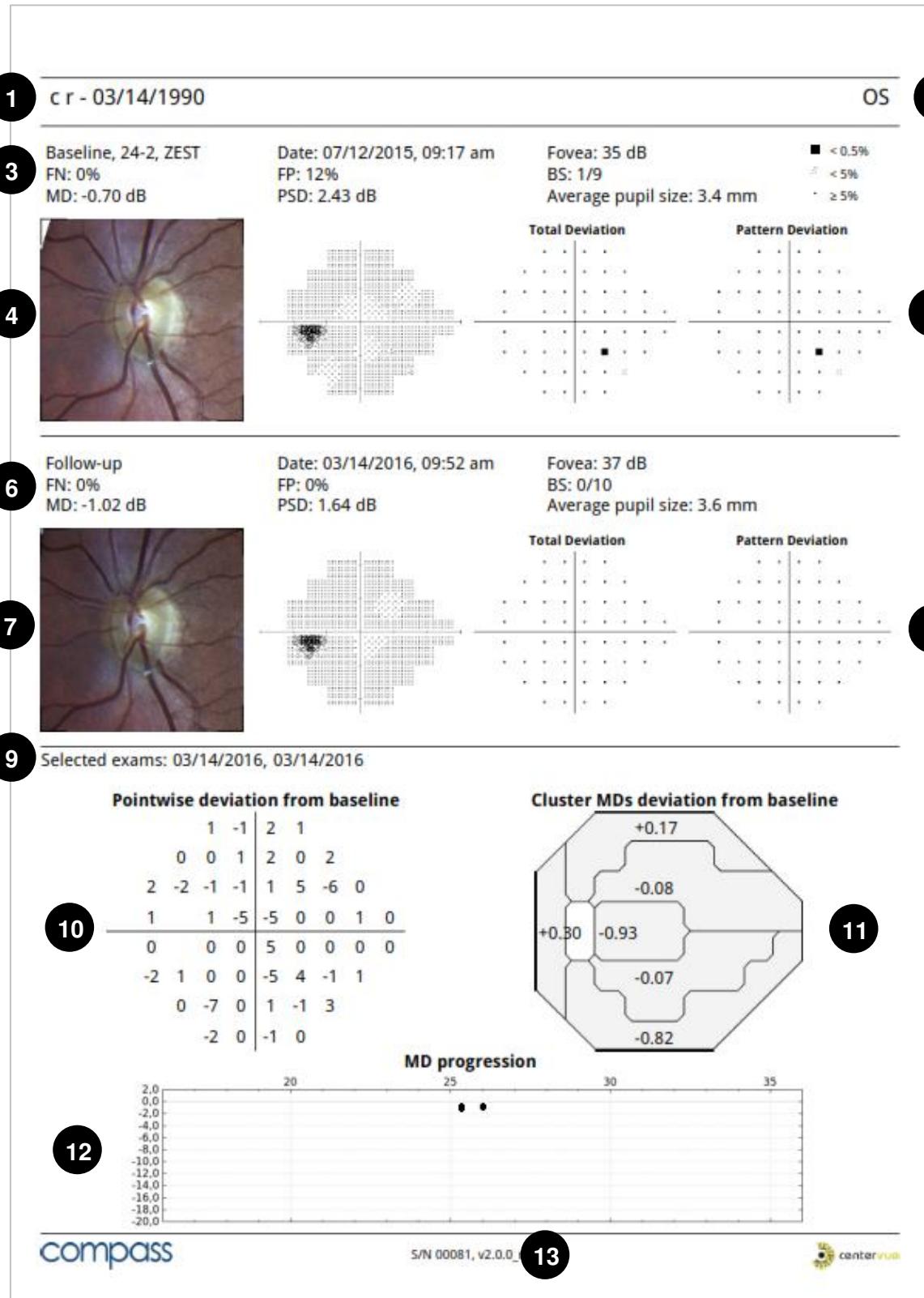


Fig. 35 – Progression report for 24-2 series

12. SETTINGS

COMPASS provides access to settings by means of a separate application called “Configurator”.

12.1 Launching the Configurator

To access the Configurator:

- Press the “back” icon at the bottom of the screen to go to the Home screen;
- Press the logout icon;
- Select user “Admin” from the drop down menu;
- Type the corresponding password and click **Login**;
- Enable tethering by clicking 
- Click the App icon 
- Start the Configurator by clicking 

12.2 Password change

Passwords for both the “Admin” and “Doctor” users can be changed in the “User role” tab of the Configurator by clicking the pencil icon (see Fig. 36). Shutdown and restart the device to make the new passwords effective.

- **Do not type special characters in the passwords as this may lead to locking the system**
- **Always keep passwords in a safe place**
- **It is not possible to operate COMPASS if the passwords are lost**
- **If both passwords are lost, or to reset the “Admin” password, contact your CenterVue Authorized Service Center for support**

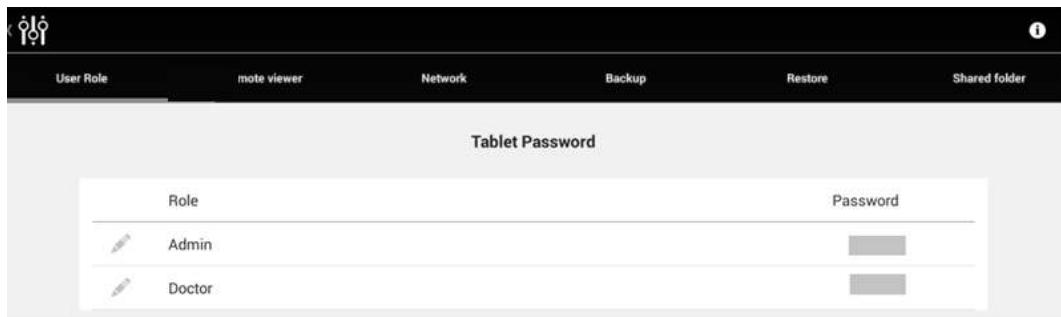


Fig. 36 – Configurator – User Role screen

12.3 Backup

COMPASS provides a USB-based data backup function. **Backup requires an external USB media (hard disk or memory stick), formatted as NTFS, with enough free space to store the backup file.**



Although COMPASS uses Solid State Drive (SSD) technology for data storage, performing periodic backups is critical for the safety of your data against unpredictable hardware failures.

Patient data (database and images) and calibration files can be backed up separately.

To perform a backup:

- Click on the “BACKUP” tab of the Configurator screen (see Fig. 37);
- Connect a pre-formatted USB disk to any available USB port (the icon on the top-right corner turns active when a USB device is detected). You might need to temporarily disconnect the external fixation to free up one USB port;
- To perform a backup of the patient data, click on the left-most **Backup** button (“Backup Db/Images”);
- To perform a backup of the device calibration files click on the right-most one (“Backup Calibration”);
- Wait until message “Backup completed” is displayed.

The name of the backup file contains the ID of the device and the date and time of the backup. It is possible to perform more than one backup on the same USB media, as long as there's enough available space.

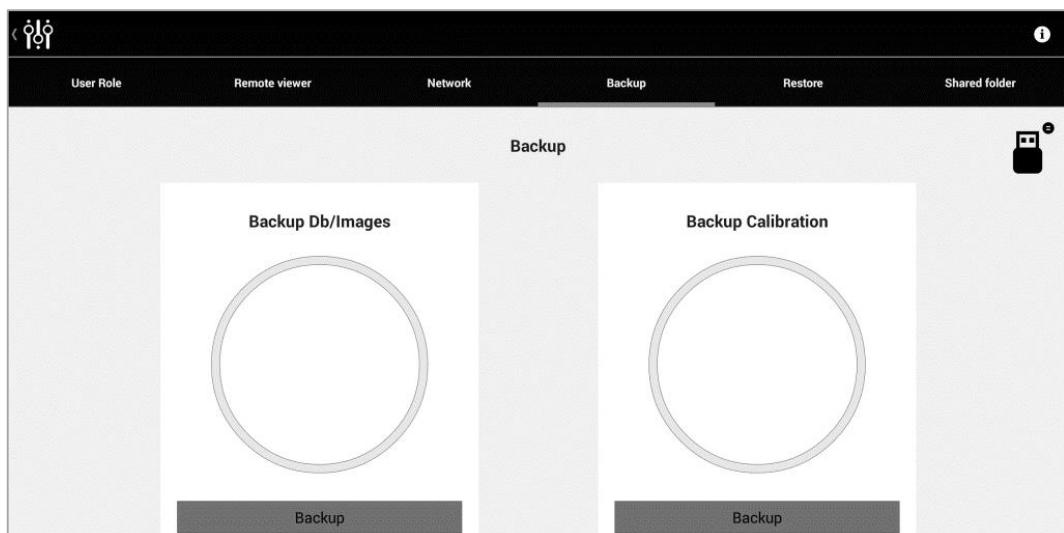


Fig. 37 – Configurator – Backup screen

12.4 Restore

To restore from the most recent backup saved on a USB media:

- Click on the Restore tab of the Configurator screen;
- Connect the USB disk containing the backup to any available USB port (you might need to temporarily disconnect the external fixation to free up one USB port);
- Click on the left-most **Restore** button for restoring the patient data (database and images) or on the right-most one for the calibration files;
- Wait until message “Restore completed” is displayed.



The restore function will permanently erase all patient data stored in the device and then restore the data and images that are stored on the USB flash drive!

To restore from a different backup file (not the latest), move all other backups into a subfolder, so that only the desired backup file is on the top-level folder of the USB media.

To restore from a backup file made on a different COMPASS, rename the backup file with the Serial Number of the COMPASS that should receive the data.

Example:

A backup of COMPASS SN 00001 exists and is named “gsd-**00001**_20150408-1028.backup”.

In order to transfer the content of this backup into COMPASS SN 12345, plug the USB media onto any PC and rename the backup file to “gsd-**12345**_20150408-1028.backup”.

Eject the USB media from the PC and follow the usual restore procedure.

12.5 Device lock reset procedure

In case COMPASS raises error codes ranging from “117” to “121”, or from “124” to “130”, entering in a locked state, the Configurator can be used to reset this condition. In such case a warning icon is shown on the top right bar of the Configurator (to start the Configurator please refer to the beginning of this chapter).

To reset the error condition, click on the warning icon: a confirmation message will appear. After clicking the Ok button COMPASS will re-initialize. Upon completion of the re-initialization procedure it is possible to restart using COMPASS normally. If the error condition keeps occurring, please contact an authorized service center.

12.6 Password change for Remote Viewer

To change the password used to access the Remote Viewer click on the “Remote viewer” tab of the Configurator, type the new password and press **Save**.

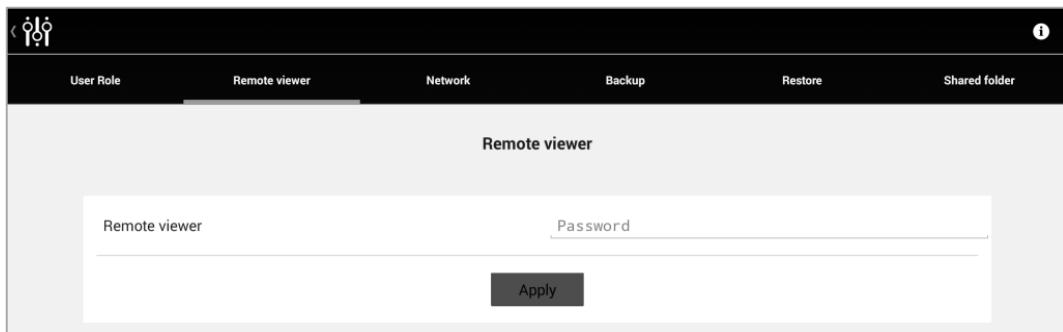


Fig. 38 – Configurator – Remote Viewer screen

12.7 Network configuration

COMPASS supports wired network connection.

To enable network connectivity, the device must be connected to the local network via Ethernet cable, using the port located on the back of the system. Then click on the “Network” tab to configure the network.

If the network is using static IPs and not DHCP, switch OFF the DHCP and type the IP, Network Mask, Gateway and optionally DNS: you may need to contact your system administrator to obtain these details.

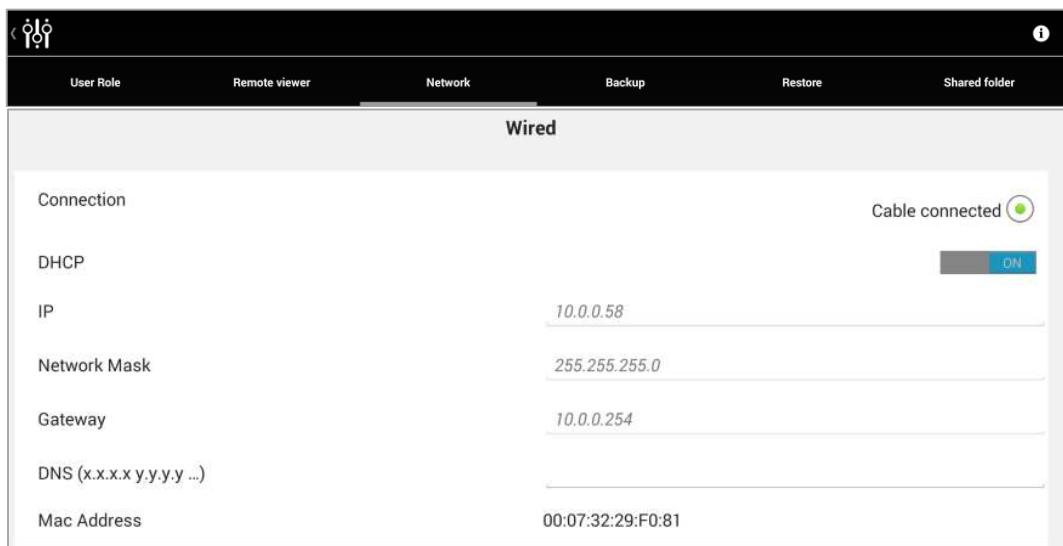


Fig. 39 – Configurator – Network screen

12.8 Shared folder configuration

This screen is used to enable/disable data export to a remote shared folder.

Status

Turn this switch to “Enabled” to activate data export to a shared folder and configure the relevant options, including server, destination folder, username and password.

Mode

If the “**Manual**” option is selected, data is exported using the export icon located in the exam review screen. If “**Auto**” is selected, data is exported automatically to the selected shared folder upon acquisition and can also be exported manually.

Format

Choose “PDF & IMAGES” to export both reports (pdf) and images (jpg), or “PDF” to export only the reports.

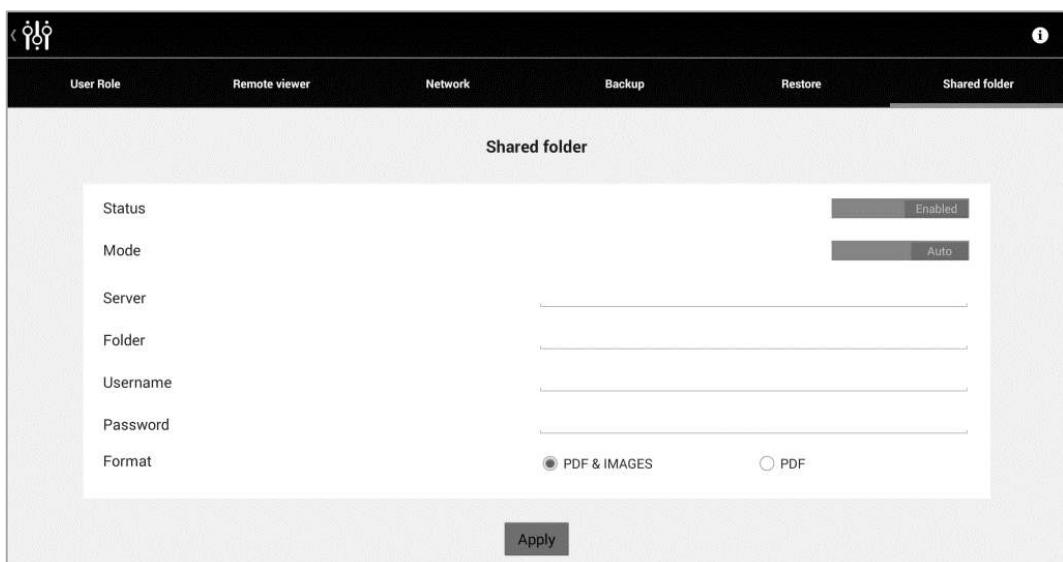


Fig. 40 – Configurator – Shared folder configuration – remote shared folder

13. SYSTEM SHUTDOWN

To shut down the system go back to the Home screen and press the power off icon:



COMPASS beeps twice when turned off.

14. TECHNICAL SPECIFICATIONS

CE 0123

Class and type of applied part:

Class I, Type B (according to EN 60601-1).

IP classification:

IPX0 (according IEC 60529, related to the degree of protection provided by the enclosure with respect to harmful penetration of particulate matter or water).

Fundus Perimetry:

- Projection field: 30° (radius)
- Background luminance: 31.4 asb
- Maximum luminance: 10000 asb
- Dynamic range: 0 - 50 dB
- Stimulus size: Goldmann III
- Stimulus duration: 200 ms
- Threshold tests: 24-2, 10-2
- Fixation control: 25 Hz automated retinal tracking

Fundus Imaging:

- Field of view: 60° (diameter)
- Sensor resolution: 5 Mpixel (2592x1944)
- Light source: infrared (825-870 nm) and white LED (440-650 nm)
- Imaging modalities: color, infrared, red-free

Other features:

- Non-mydriatic operation: minimum pupil size 3 mm
- Working distance: 28 mm
- Auto-focus range: -12D to +15D
- Fixation target: programmable, internal
- User interface: Tablet with 10.1" multi-touch screen
- Connectivity: Wi-Fi and Ethernet
- Printer: any printer compatible with Tablet
- Hard disk: SSD, 240 GB

Dimensions:

- Weight: 25 Kg
- Size: H 620 X W 590 X D 360 mm

Electrical requirements:

- Power: 100-240 VAC, 50-60 Hz
- Consumption: 80 W

Specifications are subject to change without notice for improvement

15. CLEANING

This paragraph explains how to clean the system.

The chin rest and the forehead rest should be wiped with an antiseptic wipe before each use and allowed to dry prior to reuse. Painted parts of the chin rest, such as the twist grip, should not be cleaned by means of aggressive solutions.



Fig. 41 - Removal of the chin rest silicon pad



Gently pull up and slide the chin rest pad to avoid breaking the retaining peg.

The front lens should be cleaned by using a small hand pump air blower, to blow away dust. Only if really needed, for instance due to the presence of a fingerprint, the objective lens can be cleaned by means of photographic cleaning paper and a suitable lens cleaning fluid.

The tablet display should be cleaned only with a cloth damped in water.

When cleaning the rest of device, the device must be off, and the power cord shall be disconnected from mains. If needed, the external covers of the unit can be cleaned by means of a slightly damp cloth.

16. TROUBLESHOOTING

| Symptom | Possible cause(s) | Solution |
|---|---|--|
| 1. COMPASS does not power on (no green LED) | System is not powered | Plug the power supply into a properly working socket then press the power button for at least 3 seconds |
| 2. System keeps failing alignment with message "Eye not found" | Front lens cap is in place | Remove front lens cap |
| 3. Message "Disconnected: cable not connected or machine turned off" appears when trying to access the instrument | USB cable is disconnected from tablet and/or from device or system is off | Turn system on and/or connect USB cable and login again |
| 4. Message "Disconnected: tethering not enabled" appears when trying to access the instrument | Login was made with "Admin" user and tethering was not enabled | Enable tethering or switch to "Doc" user and login again |
| 5. Bluish artifacts as in this example appear in all newly acquired images | Front lens is dirty | Clean the front lens (see par. 15) |
| 6. System is not usable with message "internal error: device temporarily locked" | Malfunction of the rotating mirror or of the infrared LED board for pupil illumination | See par. 12.5 to reset the lock condition. If the condition presents frequently, contact authorized service center |
| 7. Tablet does not turn on and does not recharge | Tablet is fully discharged and current from device is not sufficient to initiate recharge | Use the wall charger found in the accessory box to charge the tablet for at least one hour, then connect it normally to the system |
| 8. One or more dark areas appear in color and/or IR pictures | Pupil is too small (< 2.5 mm) | Dark adapt or dilate subject |

17. ELECTROMAGNETIC COMPATIBILITY

This device has been tested and found to comply with the limits for medical devices contained in IEC60601-1-2 and Medical Device Directive 93/42/EEC. These limits are intended to provide reasonable protection against harmful interference in a typical medical installation. This instrument generates, uses and can radiate radio frequency energies and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If the system does cause harmful interference to other devices, which can be determined by turning the system off and on, try to eliminate the interference by adopting one or more of the following measures:

- reorient and/or relocate the receiving device;
- increase the distance between the devices;
- connect the system to an outlet on a different circuit than that to which the other devices is connected;
- consult the manufacturer or field service technician for help.

This device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided within this document.

Portable and mobile RF communications equipment can affect the readings made by this device.

Manufacturers EMC Declaration to ISO 60601-1-2

The following tables provide specific information regarding compliance of COMPASS. COMPASS is intended for use in the electromagnetic environment specified below. The customer or the user of COMPASS should ensure that it is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment - guidance |
|---|------------|--|
| RF emissions CISPR 11 | Group 1 | COMPASS uses RF energy for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | COMPASS is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes, providing the following warning is heeded: |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orientating or re-locating COMPASS or shielding the location. |

Table 1: Electromagnetic Emissions

Guidance and manufacturers' declaration – electromagnetic immunity

| Immunity Test | IEC60601 test level | Compliance Level | Electromagnetic environment guidance |
|---|--|--|---|
| Electro-static discharge (ESD) IEC 61000-4-2 | ± 6 kV contact ± 8 kV air | ± 4 kV contact ± 4 kV air Note: ESD levels in excess of ± 4 kV applied to the sensor input connectors can damage the sensitive measurement electronics. | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Avoid touching the exposed conductive parts of connectors when handling the device or connecting cables.  |
| Electrical fast transient burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines N/A for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC61000-4-5 | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | ± 1 kV line(s) to line(s) N/A for lines to earth | Mains power quality should be that of a typical commercial hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11 | <5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s | AC Power Port Dips of: >95% for 0.5 cycle; 60% for 5 cycles; 30% for 25 cycles; 100% for 250 cycles of Vnom repeated 10 times at 10 second intervals. | Mains power quality should be that of a typical commercial or hospital environment. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3A/m | 3A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE UT is the a.c. mains voltage prior to application of the test level | | | |

Table 2: Electromagnetic Immunity (ISO 60601-1-2:2007 5.2.2.1f)

| Immunity Test | IEC60601 test level | Compliance Level | Electromagnetic environment guidance |
|------------------------------|------------------------------|-------------------------|---|
| Conducted RF IEC61000-4-6 | 3 Vrms 150KHz to 80MHz | 3Vrms | <p>Portable and mobile RF equipment should be used no closer to any part of COMPASS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.17\sqrt{P}$ <p>$d = 1.17\sqrt{P}$ 80MHz to 800MHz $d = 1.17\sqrt{P}$ 800MHz to 2.5GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic sight survey^a, should be less than the compliance level in each frequency range^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p>  |
| Radiated RF IEC61000-4-3 | 3V/m 80MHz to 2.5GHz | 3V/m | <p>NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.</p> <p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, Am and FM radio broadcasts and TV broadcasts 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 in the location in which COMPASS is used exceeds the applicable RF compliance level above, COMPASS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating COMPASS.</p> <p>^b Over the frequency range 150Khz to 80MHz, field strengths should be less than 3V/m.</p> |

Table 3: Electromagnetic Immunity (ISO 60601-1-2:2007 5.2.2.2)

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

| Rated maximum output power of transmitter | Separation distance according to frequency of transmitter | | |
|--|--|--|--|
| | 150 KHz to 80 MHz $d = 1.17\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.17\sqrt{P}$ | 800MHz to 2.5 GHz $d = 1.17\sqrt{P}$ |
| 0,01 | 0.12 | 0.12 | 0.12 |
| 0,1 | 0.37 | 0.37 | 0.37 |
| 1 | 1.17 | 1.17 | 1.17 |
| 10 | 3.70 | 3.70 | 3.70 |
| 100 | 11.70 | 11.70 | 11.70 |

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 power rating of the transmitter in (W) according to the transmitter manufacturer.

NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.

Table 4: Recommended Separation Distances

FCC (USA) and IC (Canada) radio certification

The COMPASS contains a radio module that complies with regulations of the USA and Canada.

- FCC ID: PPD-AR5BHB116
- IC ID: 4104A-AR5BHB116
- CMIIT ID: 2010AJ4574

These devices comply with part 15 of the FCC rules. Changes or modifications not expressly approved by the party responsible for compliance could void user's authority to operate the equipment.

Operation is subject to the following 2 conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

18. DISPOSAL

This device is made of different materials, such as plastics, aluminum, electronic parts. In case of instrument disposal, please separate the various materials and follow the laws and regulations regarding disposal or recycling for each material effective in your own country.

Separate collection for electrical and electronic equipment

The European Directive 2002/96/EC establishes the separate collection for Waste of Electrical and Electronic Equipment (WEEE). The users of Electric and Electronic Equipment (EEE) have not to dispose of WEEE as unsorted municipal waste, they have to collect such WEEE separately. The available return and collection system is defined by the local public administration, or in alternative an authorized company can recycle the WEEE. Please refer to public administration about the separate collection, if this information is not available, contact the manufacturer of the equipment. Users have a fundamental role in contributing to reuse, recycling and recovery of WEEE. The potentially dangerous substances contained in the WEEE can pollute the environment and produce harmful effects to the human health. Below, there are a few indications of specific dangers of some substances, which may leach in the environment and in the water system.

Lead: damages the nervous system of humans, it affects the endocrine system, the cardiovascular system and kidneys. It accumulates and is very toxic for animals, plants and micro-organisms.

Cadmium: accumulates with a half-life of 30 years and can damage the kidneys and cause cancer.

Mercury: is easily accumulated in organisms and concentrates through the food chain. It has chronic effects and can cause brain damage. Chromium (Hexavalent): easily absorbed into cells with toxic effects. The results can be allergic reactions, asthma and it is considered to be genotoxic (damages the DNA). Especially dangerous when incinerated.

Brominated Flame Retardants: widely used to reduce flammability (e.g. cables, connectors and plastic cases).

