

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



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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-mydratic 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 mydratic 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.

COMPASS is NOT intended to be used in a HOME HEALTHCARE ENVIRONMENT as defined in the standard IEC 60601-1-11, but in a professional healthcare facility environments where OPERATORS with medical training are continually available when PATIENTS are present.

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
- this operating manual
- removable forehead rest
- patient push button
- front lens cap
- the Magnetic Hood ¹
- prismatic glasses for stereoscopic vision ¹

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. 18 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 when COMPASS is switched off.

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 becoming unusable.

¹ The Magnetic Hood and the stereoscopic prismatic glasses will be delivered with Compass from September 2017. For information about how to purchase these accessories, please refer to your CenterVue Sales representative.

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.

If the battery level decreases under 15%, check the connection between the tablet and the device: the tablet must be connected to the left-most USB port. To save battery reduce the display brightness and turn off the Wi-Fi.

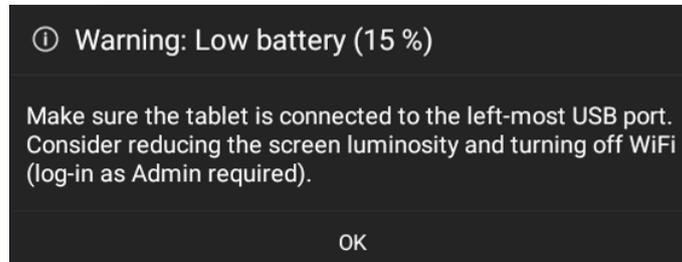


Fig. 4 – Warning message when the battery charge decreases to 15%

The tablet automatically powers off when the battery is lower than 5%, to prevent total discharge. Verify that the tablet is connected to the device through the left-most USB port or connect it to a wall charger. The following message will appear:

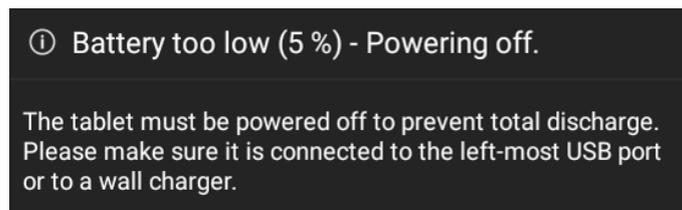


Fig. 5 – Warning message when the battery charge decreases to 5%

	<p>To maximize the duration of the charge:</p> <ul style="list-style-type: none">• Set the screen brightness to “Auto” or anyway not to maximum;• Plug the tablet in the left-most USB port (see Fig. 2), 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.
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3. LABELS



Fig. 6 – Warning labels

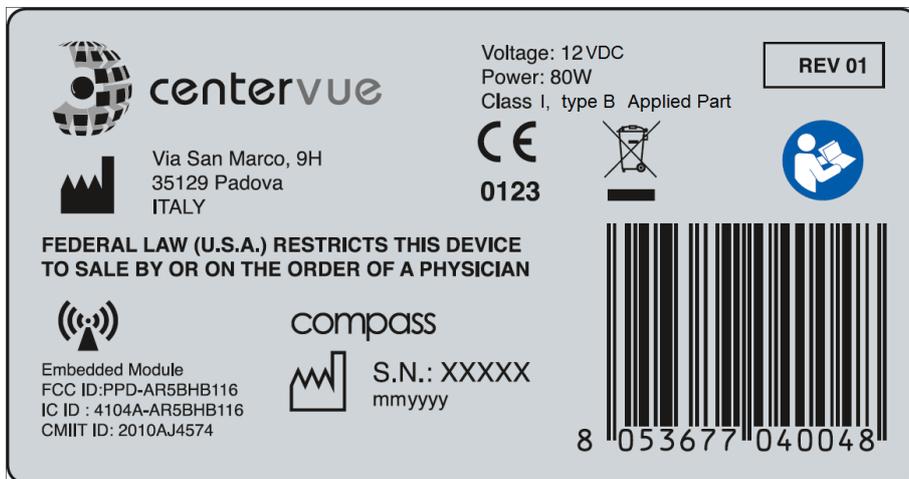


Fig. 7 – Compass main label

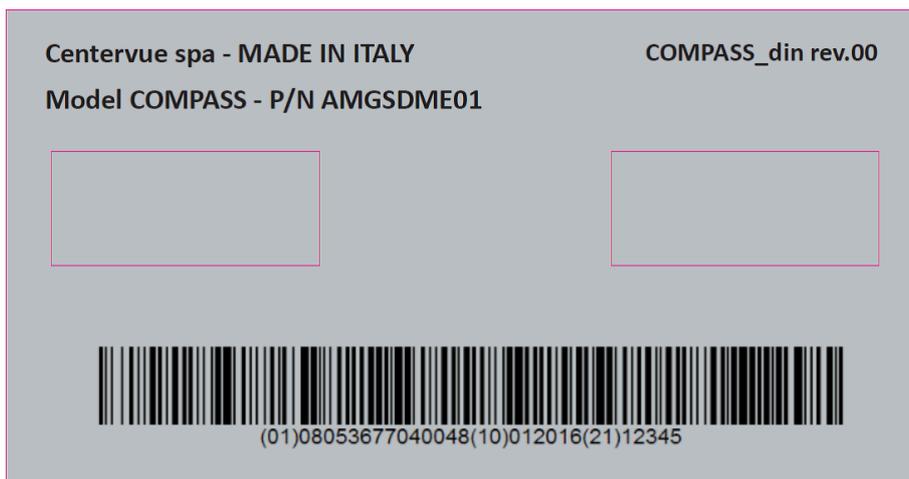


Fig. 8 – Compass UDI label

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

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

Symbol	Explanation
	General warning, read carefully
	Important information

5. PREPARING THE SYSTEM



We recommend reading 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 table²;
- insert the soft forehead rest on the metal support (see Fig. 9);
- mount the support provided for the tablet (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;
- plug the power supply to the wall socket.

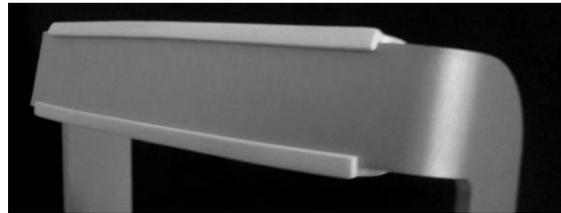
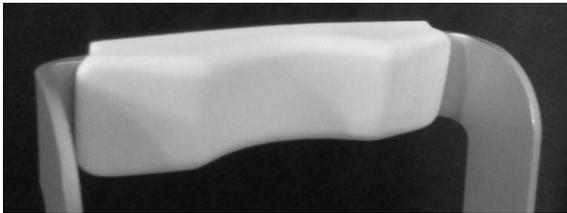


Fig. 9 - Forehead rest mounted on metal support

5.1 Assembling the tablet support

The tablet is mounted, using the included support (see Fig. 11), towards the posterior part the device, on any side. The support is fixed with screws to the bottom of the device.

As an example, Fig. 12 shows the holes to be used for the left-side mount depicted in Fig. 10: to fix the supports use holes marked 1 and 2. Other configurations can be chosen, based on the user's preferences.



Fig. 10 – Tablet mounted on the left side of the device

² Not provided with the system



Fig. 11 – Tablet support



Fig. 12 – Instrument bottom with holes for tablet support

5.2 Attaching the Magnetic Hood

The Magnetic Hood is a device that shields the patient's eyes from external sources of light, as a non-invasive alternative to an eye-patch and to improve patient's comfort during the test. To attach it, apply it on the front lens frame: the Magnetic Hood will adhere magnetically to the frame (see Fig. 13).



Fig. 13 - Magnetic Hood mounted on Compass

5.3 Turning on the Device

Turn on the Device by keeping the main switch (see Fig. 2) pressed for approximately 2 seconds, then turn on the tablet by keeping its switch pressed for approximately 3 secs: wait for the boot process to complete, and the **Login** screen to appear (see Fig. 14).



When the tablet is off do not keep pressed the main switch together with the volume switch, as this combination activates factory reset mode. Factory reset erases all the data and software and cannot be undone.



Pressing the tablet power button does not take effect when the tablet is showing a gray battery image over a black screen.

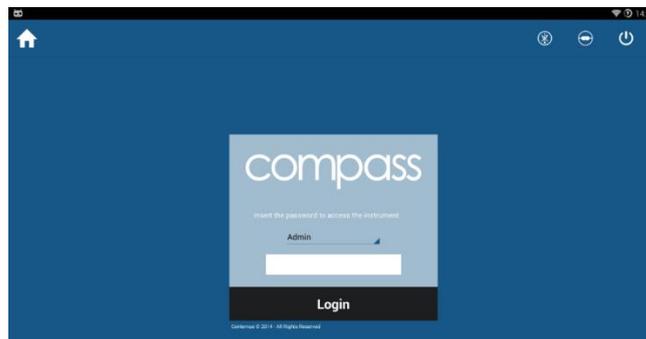


Fig. 14 – Login screen

From the drop-down menu select “Doctor”, type the password³ and click on **Login**. If login is successful, the **Home** screen opens (see Fig. 15).



Use of user “Admin” requires manual activation of the tethering by clicking the corresponding icon at the top.



To modify the password, see par. 14.3.

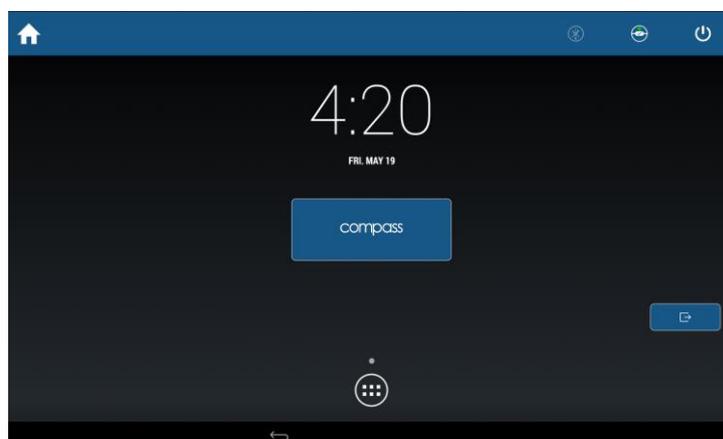


Fig. 15 - Home screen

³ To find out the default 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-mydratic 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.
- 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 if 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. 16) 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 usage of other cables and accessories may negatively affect EMC performances

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.

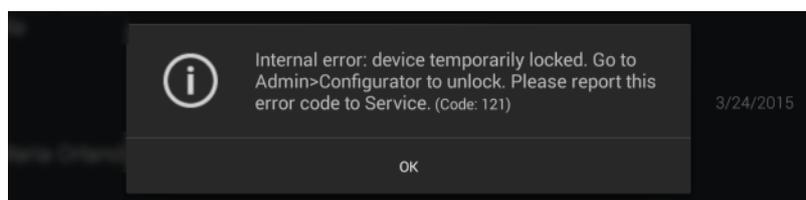


Fig. 16 – Example of error message

8. NOTES FOR THE OPERATOR

COMPASS provides capabilities for a fully automated test process. No specific skills are required to operate the Device and 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. DICOM SUPPORT

DICOM is a standard for distributing and viewing medical images and related information.

Compass can export DICOM files. With an additional license Compass also supports full DICOM communication, as specified in the **COMPASS DICOM Conformance Statement document⁴**. For info about how to use Compass with DICOM, refer to the **COMPASS DICOM Operating Manual**.



DICOM support is available only for wired connections.

⁴ Ask to your local distributor for the **COMPASS DICOM manual** and **Conformance Statement**.

10. PATIENT LIST AND PATIENT RECORD

Once the Device has been turned on click on the **compass** button to open the **Patient List** screen (see Fig. 17).

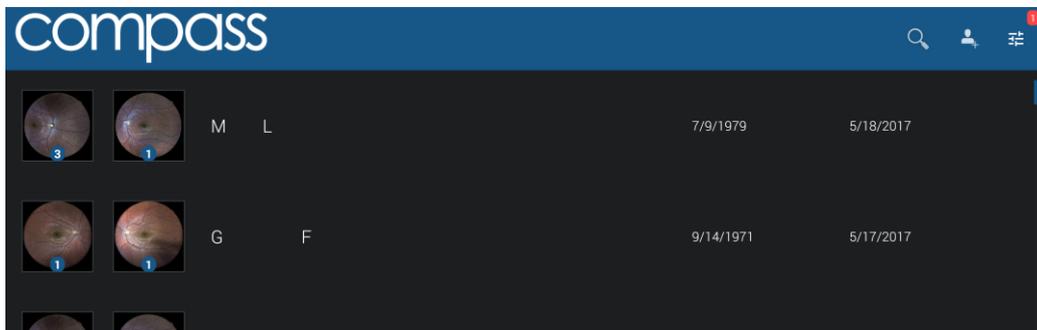


Fig. 17 – Patient list screen

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.

The following functions and commands are available in the Patient List screen:

- adding a new patient;
- deleting a patient;
- selecting an existing patient;
- searching for an existing patient.
- checking the Device Status

10.1 Device status

The **Device status** screen contains additional information on the COMPASS status and can be accessed tapping on the  icon. A change in the status will be signaled with a red number on the top right of the icon, representing the number of new notifications.

This window includes three tabs: Backup status, Shared folder status and About.

Backup status

From the **Backup** tab, it is possible to see the backup progression status, stop a running backup or start a manual backup. This screen also includes information on the backup media and on the last backup, with its status (completed, cancelled, failed with reason explanation). For more information on Backup, see par. 14.6.

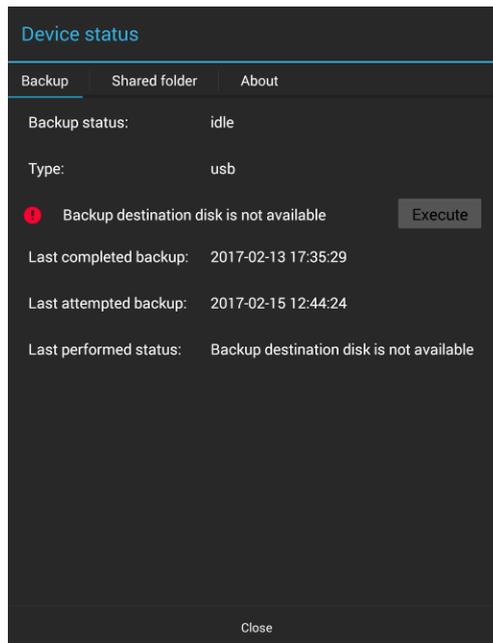


Fig. 18 – Device status screen – Backup status

Shared folder status

From the Shared Folder tab it is possible to monitor the progression and see the error messages of the Shared Folder processes. For more information on the Shared Folder see par. 14.8. See par. 18 for information about possible error conditions during the export process.

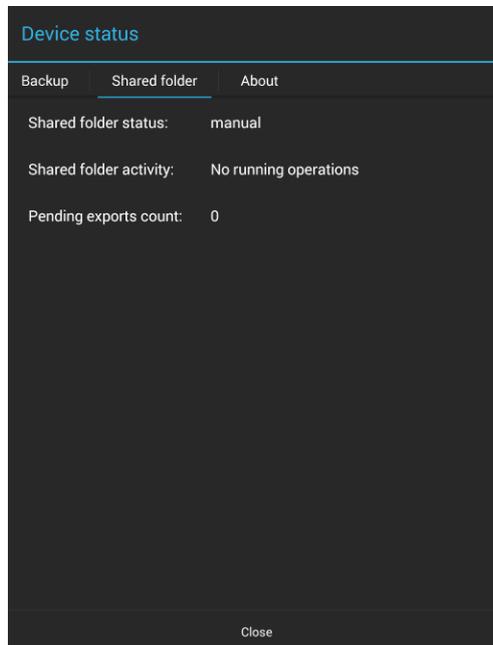


Fig. 19 – Device status screen – Shared folder status

About tab

The About tab contains information about the software release version installed, the total disk capacity and the amount of space available.

10.2 Adding a new patient

To create a record for a new patient, click on  and the **Patient Editing** screen will open (see Fig. 20). 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.

10.3 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 .

10.4 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.

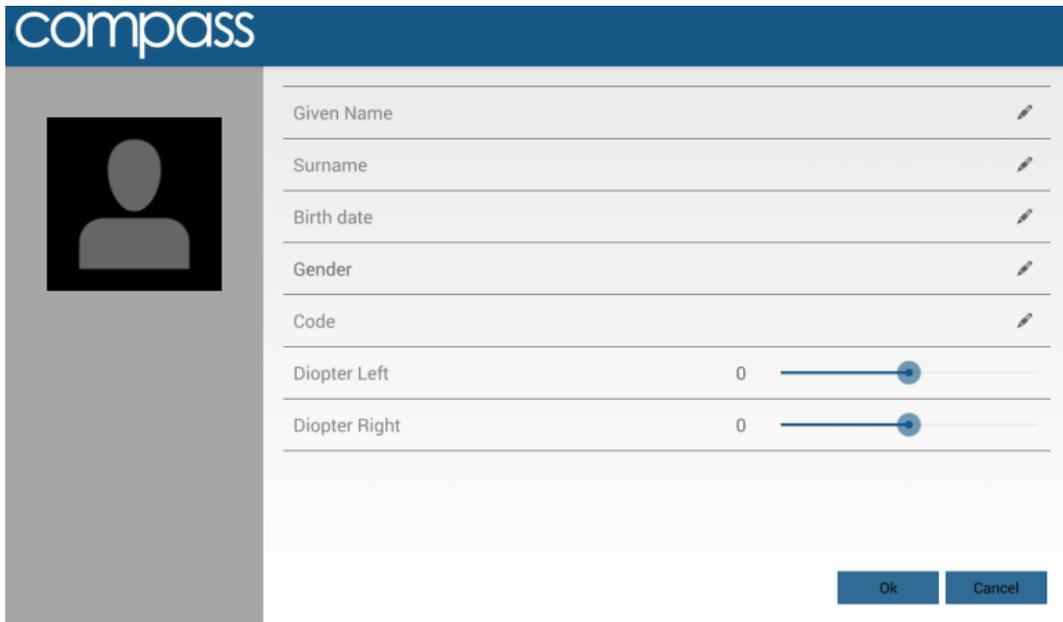


Fig. 20 – Patient editing screen

Once a patient has been selected in any of the above ways, the **Patient Record** screen opens (see Fig. 21) and provides information on the selected patient, whose name is shown at the top-left corner of the screen. See par. 12 for full details on how to review a patient's data. Click on the **New Exam** button to initiate a new test.

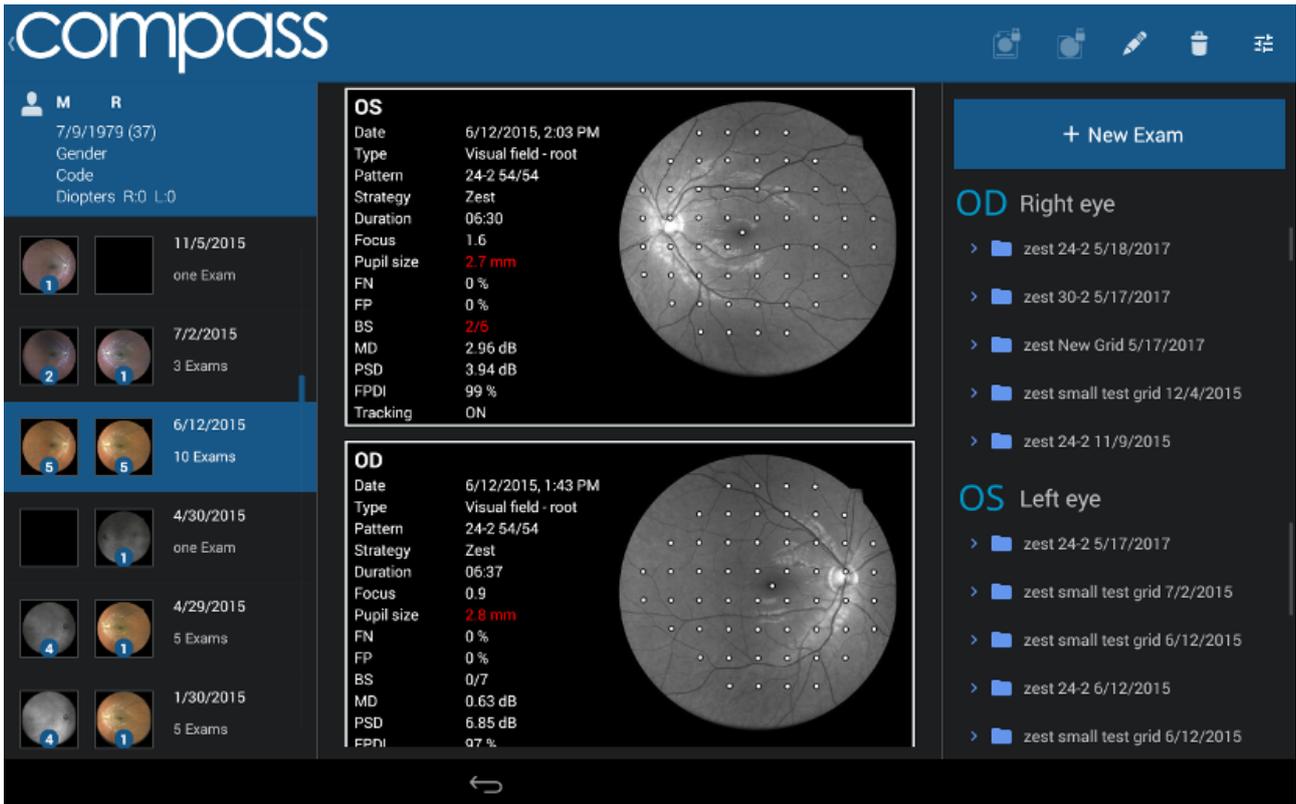


Fig. 21 – Patient Record screen

11. 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).

11.1 Compass test modalities

COMPASS allows to measure a subject’s visual field in time, hence creating a sequence of tests. It also provides a true color confocal image of the retinal fundus (see below).

COMPASS provides four 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;
- a **supra-threshold test** allows to perform a quick assessment of the retinal sensitivity;
- a **fundus/fundus stereo** test allows to acquire only the fundus color image.



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 should 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:**



>  zest 24-2 02/15/2015

- **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**

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.

11.2 Initiating a new root test

To initiate a new **root** test, click on the **New Exam** button, and select **Visual Field** using the test type selector.

11.3 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.

11.4 Initiating a supra-threshold test

To initiate a new **supra-threshold** test, click on the **New Exam** button, and select **SupraThreshold** using the test type selector. For a description of the exam flow of the supra-threshold test, refer to par. 11.12.

11.5 Initiating a new fundus test

To initiate a new **fundus** test, click on the **New Exam** button, and select **Fundus/Fundus Stereo** using the test type selector. For a description of the exam flow of the fundus tests, refer to par. 11.13.

11.6 Choosing test parameters

When the New Exam command is pressed the **Test parameters selection** screen opens (see Fig. 22), allowing review and modification of a test parameters.

The following commands / functions are available:

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

⁵ Total deviation and Pattern deviation maps and related indices are only available when using the 24-2 grid

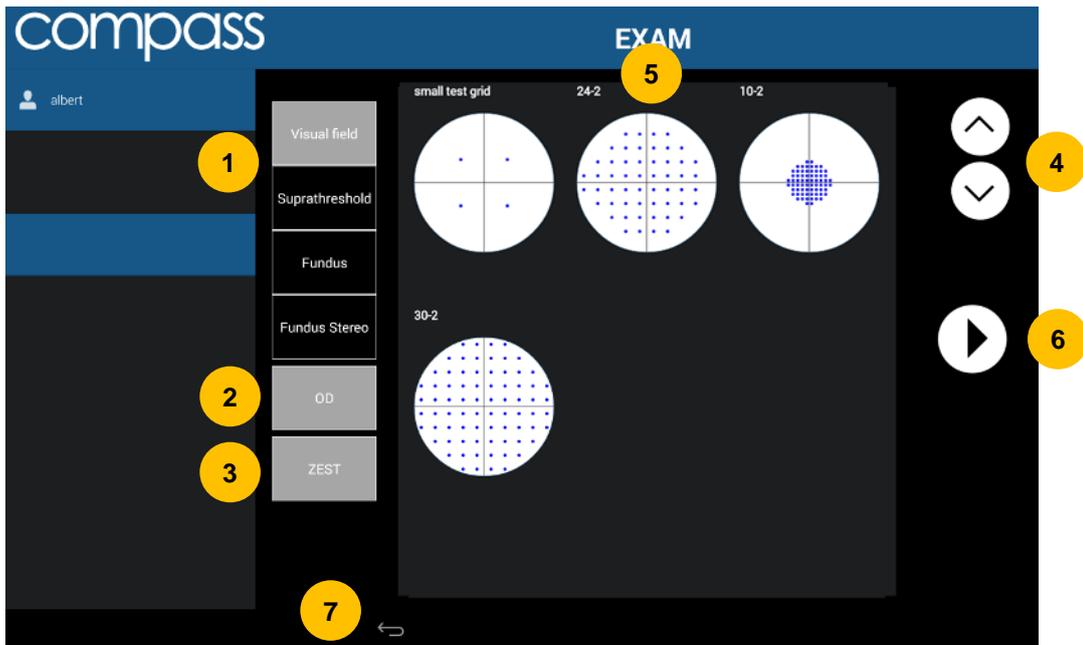


Fig. 22 – Test parameters selection screen

ZEST vs. 4-2



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.



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



Fixation Target

The standard projection grid used in Compass is the “24-2”. This grid has an asymmetric shape which extends to the temporal peripheral area. In order to project

stimuli in the extreme positions, Compass will show a fixation target shifted 3 degrees right when testing OD, and left when testing OS. For homogeneity, the same happens for any other test grid, except for the “30-2” grid.

11.7 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

11.8 During the test

The following table describes the test process flow for a Visual Field exam.

#	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 IR image	Capture reference infrared 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. 24).  : 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 location	Identify location of blind spot	Drag and center circle over optic disc, then click the forward arrow (see Fig. 25)  : a wrong or imprecise placement of the optic disc marker results in failure of the BS test, and in a wrong display of the ONH in the results printout (see par. 13).
5	Detect fixation	Locate center of fixation	Subject should look steadily at fixation target.  : once this step is 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 is 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 is 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.  : the system will try to register (i.e. to match) the acquired Color image over the Reference IR image. Should the registration fail due to bad quality of either of the two images, the operator will be prompted to Retake the image, or to Continue (see Fig. 26). In the latter case, the Color image will be saved as a separate Fundus exam, and the Reference IR image will be used for the results printout (see par. 13).

VISUAL FIELD EXAMS WITH 30-2 GRID

Due to test locations of the 30-2 grid being close to the edges of the field, the exam flow with the 30-2 grid has the following variations:

- Steps 1 to 6 take place as described above, with the IR image and foveal test being performed with a fixation target in the central position with respect to the field (see Fig. 23, position 1);
- Step 7 is split in two parts: at the end of the foveal test the fixation target changes from the central position to a position at about 4° from the center in lower-nasal direction (see Fig. 23, position 2). Allow the patient to locate the fixation target and to start fixating it before clicking the arrow to proceed;
- The projection takes place only on a subset containing half of the total grid locations (38 out of 76), until all the corresponding thresholds are measured;
- Then, the fixation target changes to a position at about 4° from the center in upper-temporal direction (see Fig. 23, position 3). Allow the patient to locate the fixation target and to start fixating it before clicking the arrow to proceed; the remaining 38 locations are then measured;
- Step 8 finally takes place using the central fixation target, in order to make it possible to register the color image over the IR image.

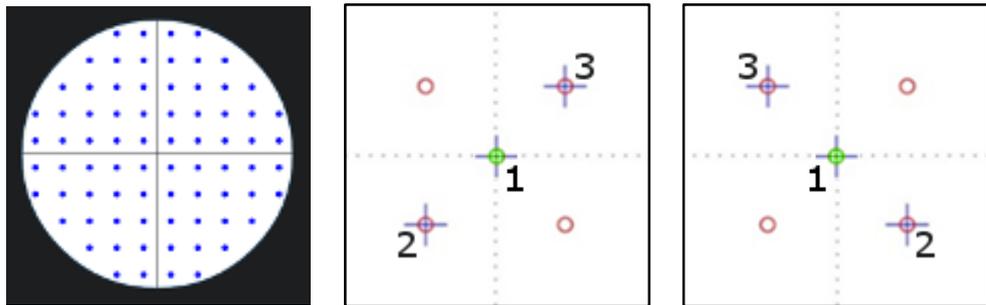


Fig. 23: “30-2” grid test locations (left)
and fixation target positions used for OD (center) and OS (right)

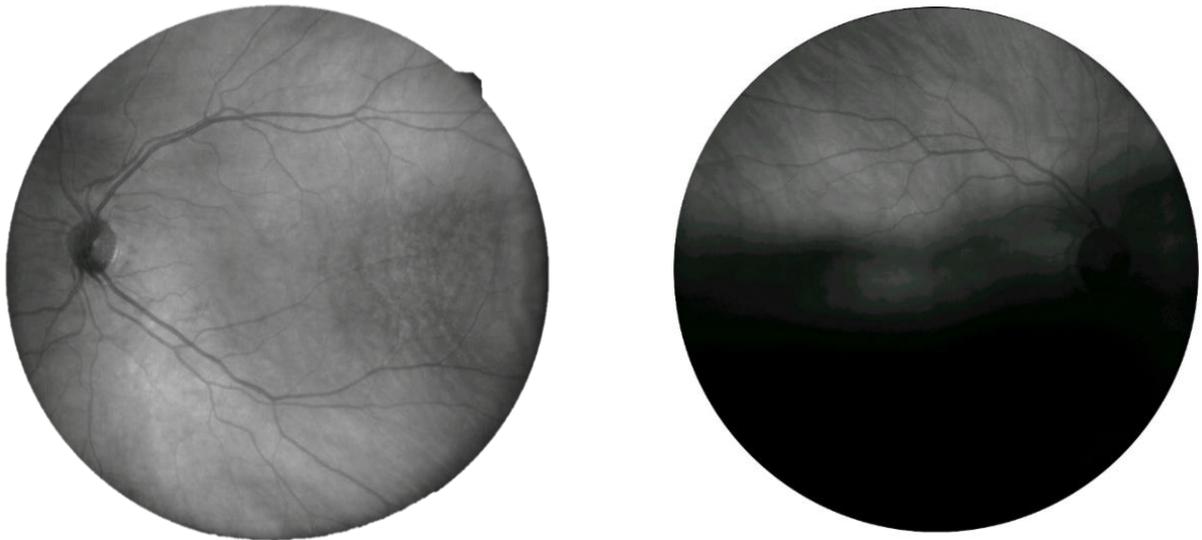


Fig. 24 – Good (left) and poor quality (right) reference image

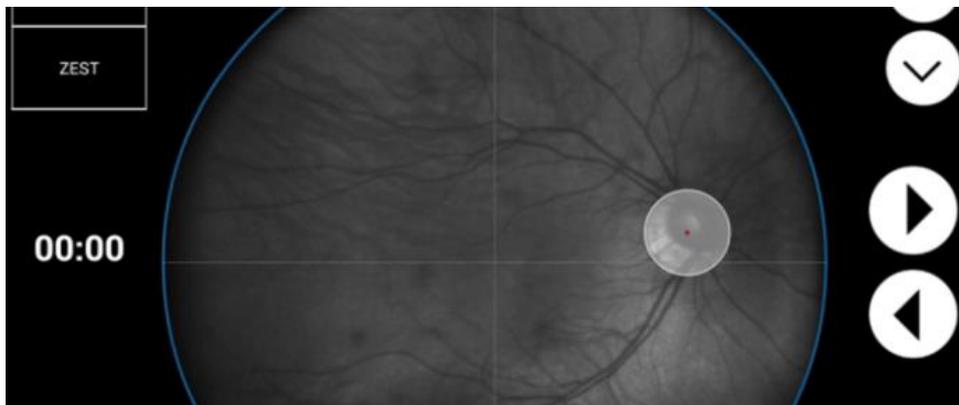


Fig. 25 – Marker for optic disc location in Exam screen

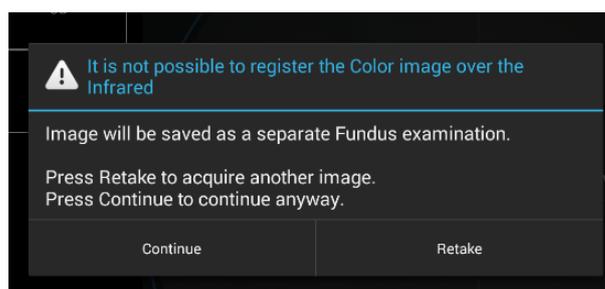


Fig. 26 – Message shown in case of Color image registration failure

11.9 Auto-alignment

Several hints may be presented on screen by the system to help the operator correct a subject's position: see Table 1 - System hints during auto-alignment 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

11.10 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. 27). **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).

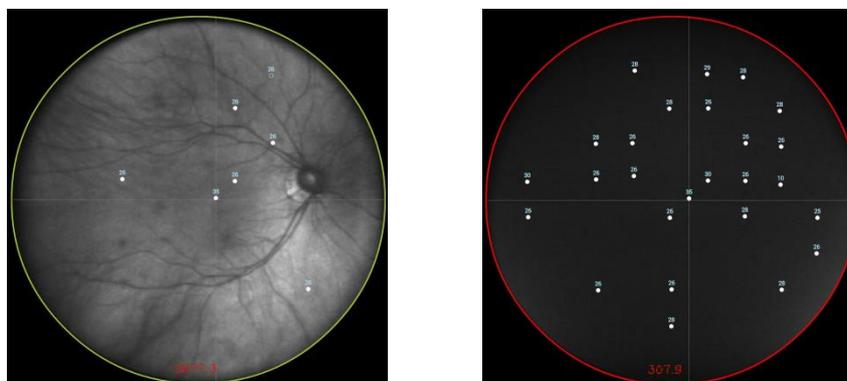


Fig. 27 - Tracking active (left) and on hold (right)

11.11 Monitoring test progress

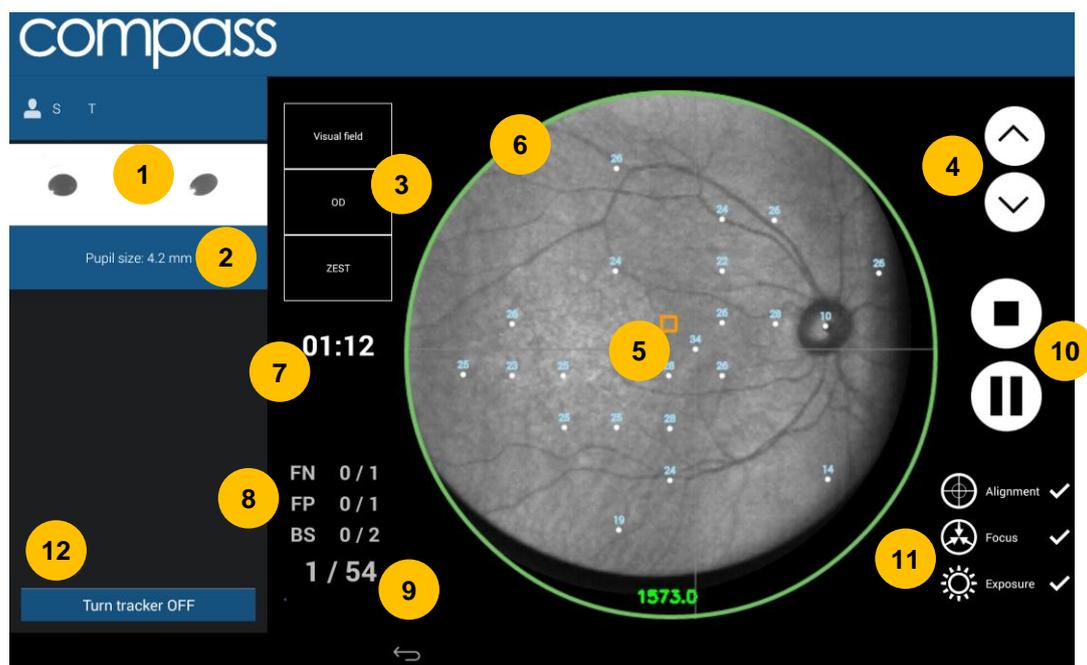


Fig. 28 – Exam screen while test is in progress

The following information and functions 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. Information about the selected exam parameters: type (**Visual Field / SupraThreshold / Fundus**), eye (OD/OS) and strategy (**Zest / 4-2**)
4. Buttons to adjust the height of the chin rest
5. Live stabilized retinal image (i.e. shifted using the information coming from the eye-tracking) with stimuli allows the operator to monitor progress. The center of the small orange square displayed on the stabilized image represents the current fixation point (the point of the retina which is aligned to the center of the fixation target at every moment). Seen stimuli are shown as filled dots. The stimulus being projected is shown as an empty circle.
6. Tracking status (circular colored frame)
7. Elapsed test time
8. Reliability indices (False Negatives, False Positives and Blind Spot) updated live (caught occurrences over catch trials)
9. Completed stimuli over total being projected: test proceeds slow at the beginning and turns progressively faster
10. Buttons that allow to stop (top) or to pause (bottom) the test at any time
11. Information about the exam phases completed (Alignment, Autofocus, Auto-exposure)
12. Button that allows to turn OFF the retinal Tracking



Patients with little experience of Compass might take some time to understand how the test works. If the reliability indices reach high values, it is advised to train the patient better and stop the test because the current one will result unreliable.



The Pause button allows to suspend the exam for some time in order to let the patient rest if he/she is experiencing some fatigue. When resuming from the pause, the projection will restart after 3s of delay in order to avoid missing the first stimuli.



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



It is possible to turn OFF the retinal Tracking, if the test is taking too long due to highly unstable fixation or poor image quality. However, the stimuli positioning correction will no longer take place and this will result in the exam being considered unreliable. The system will ask for confirmation when pressing the “Turn Tracker OFF” button (see Fig. 29). It is not possible to re-enable the tracking for the current exam once it has been disabled. The fact that the retinal Tracking has been disabled during the exam will be displayed both in the *Exam review* screen and in the *report Printout*.

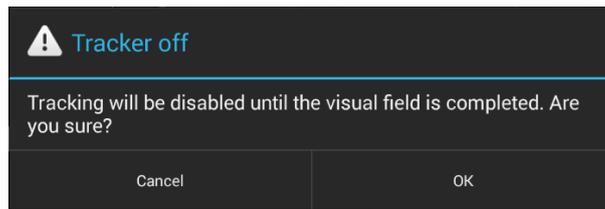


Fig. 29 – Confirmation request to disable tracking

11.12 Other exam types: SUPRA-THRESHOLD test

The Supra-Threshold Test has been developed to provide a quick assessment of the retinal sensitivity compared to normality values in a reduced examination time, as in supra-threshold perimetric tests. Only two intensities are tested: first at a lower intensity and then, if not seen, at a higher intensity, hence this test does not measure the actual threshold but rather a supra-threshold response consisting of one of the following options: “*seen at lower intensity*”, “*seen at higher intensity*”, “*not seen at higher intensity*” (see Fig. 30). The two intensities used are determined on the basis of average and standard deviation values from Compass normality database and are dependent on the point location and on the subject’s age.

The Supra-Threshold Test follows the same exam flow of the Visual Field Test and takes approximately 2 to 3 minutes per eye and it is designed to quickly determine whether the retinal sensitivity falls below or above the 90th and 95th percentile of a reference group of normals, without determining the actual threshold. The Supra-Threshold Test Test also analyzes the fixation stability and the full foveal sensitivity threshold using Zest strategy.

For a complete description of the outcomes of the Supra-Threshold Test see par. 11.12.

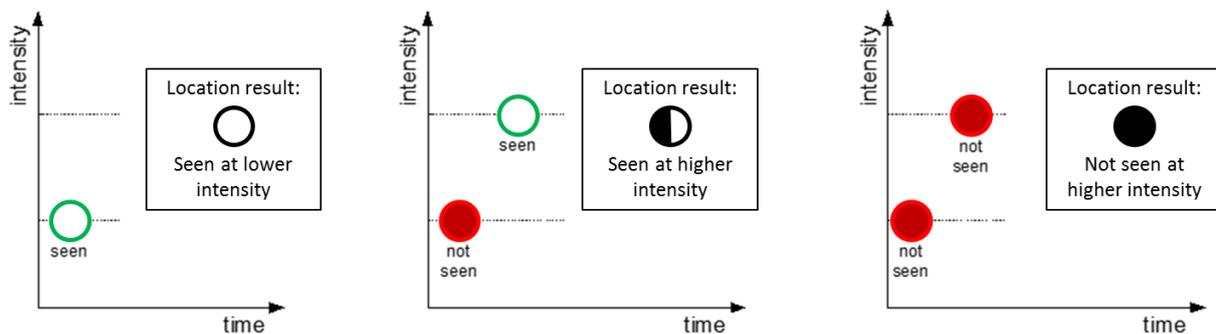


Fig. 30 – Supra-threshold test projection logic



The only grid available for the Supra-Threshold test is the “24-2”.

11.13 Other exam types: FUNDUS and FUNDUS STEREO test

The **Fundus** test allows to acquire the color photo of the fundus. With respect to the exam flow described at par. 11.8, only steps 1, 2 and 8 take place, i.e. automatic alignment and focus. During the test the fixation target is at the same position as in the Visual Field test, in order to provide an image of the central field of the retina.

The **Fundus Stereo** test allows to acquire two images of the nasal field with a slight lateral displacement of the unit's head position. A delay between the shots is applied in order to let the pupil partially recover. To review stereo images, the operator should use specific 3D prismatic glasses, such as the model provided with Compass starting from September 2017: in this way it will be possible to have a 3D representation of the optic nerve head. For more information about the stereo feature, refer to par. 11.13.



The Fundus Stereo test takes images of the nasal field, so the fixation target will be positioned at the far nasal end of the visual field: before starting the test, instruct the patient where to search in order to locate the target.



Fig. 31: example of a Fundus image (left) and of one of a Fundus Stereo image (one of the pair) (right)

12. REVIEWING RESULTS

Once a test is completed, the system will open the **Patient Record** screen (Fig. 33) for the selected patient and present a thumbnail view (Fig. 32) of all tests made on the selected date.

The **Visual Field** exam thumbnail presents the following information:

- red-free retinal image (with overlaid actual test locations) if the Color Image registration was successful, otherwise the IR retinal image is displayed;
- 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);
- Fundus Perimetry Deviation Index (FPDI);
- Tracking **ON/OFF** indicator (will display **OFF** if the tracking has been disabled during the exam)

The **Fundus** and **Fundus Stereo** exam thumbnails present the following information:

- color retinal image;
- examined eye (OD / OS);
- date and time the test was performed;
- type (**Fundus / Fundus Stereo**);
- focus index;
- pupil size at time of shooting;
- field;
- shutter Time (photo exposition in ms)

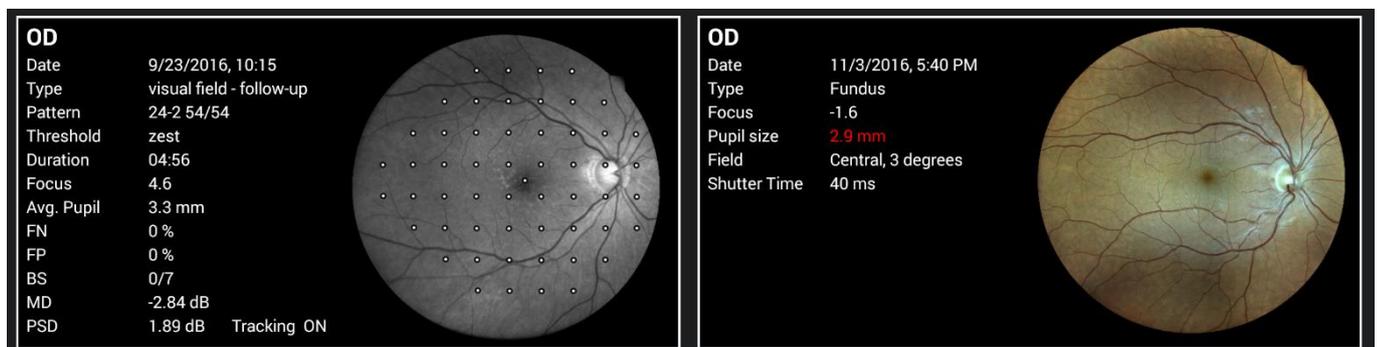


Fig. 32 – Example of thumbnails for **Visual Field** (left) and **Fundus** (right) exams



The **Fundus Perimetry Deviation Index (FPDI)** is a global index that assigns a value between 1% and 100% based on an aggregate percentage of visual function, with 100% being a perfect age-adjusted visual field. Central visual field points are more heavily weighted, and the percentage of visual field loss is calculated based on pattern or total deviations depending on the depth of loss.

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. shows the Device Status window (see par. 10.1)
4. display the tests performed at a specific date
5. display the tests performed within a certain sequence identified by a root test
6. open Exam Review screen (see Fig. 34)
7. start a new root test (do not use this button if you wish to start a follow-up)
8. start a follow-up test within the specified sequence of tests
9. go back to patient list screen

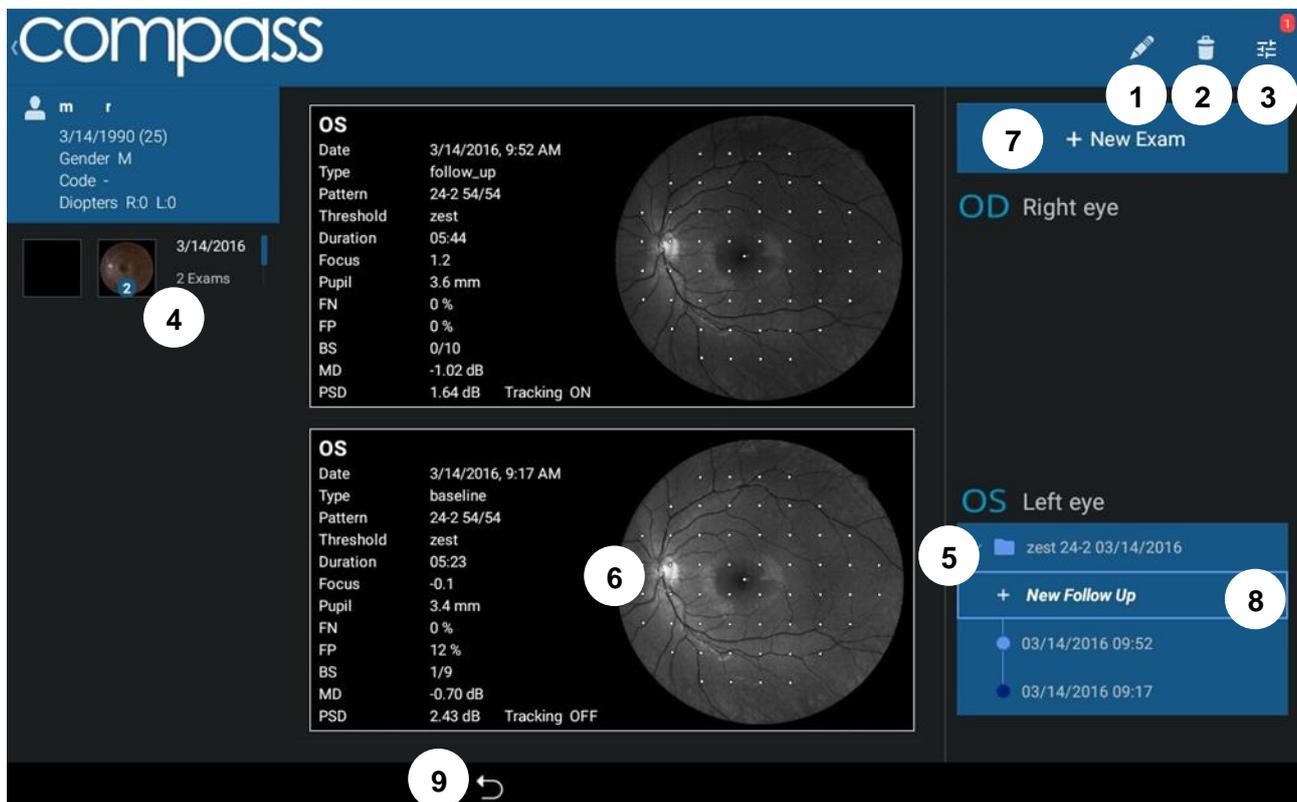


Fig. 33 – Patient Record screen

12.1 Individual test results review

The **Exam Review** screen (Fig. 34) provides the following information and functions:

1. Patient name and info
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. Swiping left and right allows to switch to the other image types (same as selector 2.);
4. Perimetric test parameters
5. Option to enable / disable display of perimetric results over retinal image (default: yes). Note: this option is not available on Color images.
6. Option to switch ON / OFF fundus mode convention (default: on). See the information box below for more details.
7. (scroll down to see these) Image tools including **blue, green, red filters** used to display individual color channels and **gamma correction**, used to enhance image brightness (see details explained in *Table 2* below).
8. Commands for report generation, storage and printout (see details explained in *Table 2* below)
9. Command to go back to Patient record screen

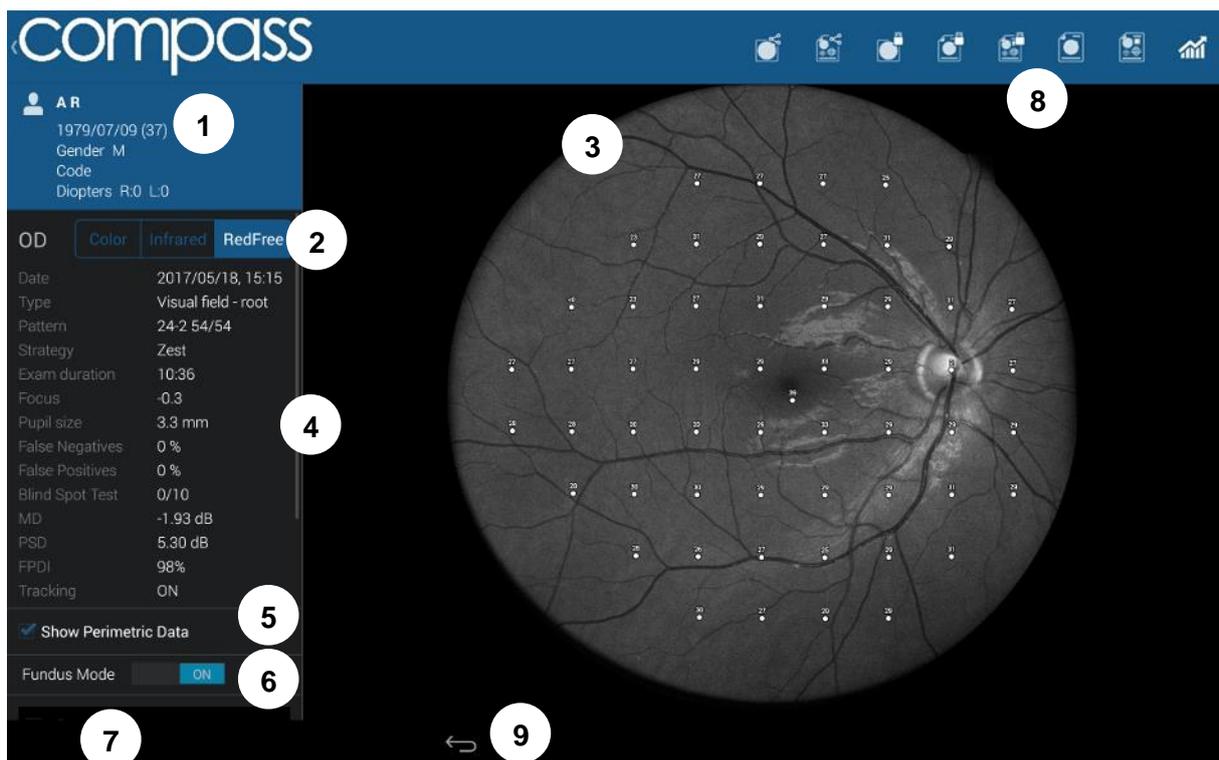


Fig. 34 – Exam review screen, red-free display modality

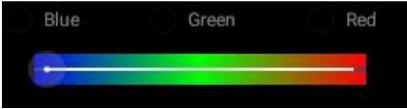
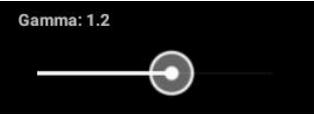
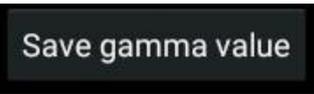
Top bar button	Description
	Export image in JPG format (first icon), fundus report in PDF format (second icon), image in DICOM format (third icon) or perimetric test report in PDF format (last icon) to a shared folder (see par. 14.8). These buttons are enabled only if the shared folder has been previously configured.
	Export image (left icon), fundus report in PDF format (center icon) or perimetric test report (right icon) to USB. These buttons are enabled only if a USB storage device is plugged in.
	Open the fundus report in PDF format (left icon) or the perimetric test report PDF (right icon) for viewing in a PDF viewer or printout.
	Generate the progression report (see par. 12.3).
Image tools button	Description
	Toggles between original image and the filtered image (i.e. the image with the below filters applied).
	Used to display individual color channels (for color images). The green channel provides the red-free image.
	Used to enhance image brightness by adjusting gamma, from 0.5 to 1.8. This correction does not alter the original image.
	Store the selected gamma value in the database. When re-opening the image in the future this value, will be applied by default. This correction does not alter the original image, which can always be accessed with the “filtered” button.

Table 2 - Exam Review buttons and related commands

12.2 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. 35 – 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. 13.2 and Fig. 36 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. 11.10), 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.

Fixation Area

2.68°² (1.1°×0.8°)

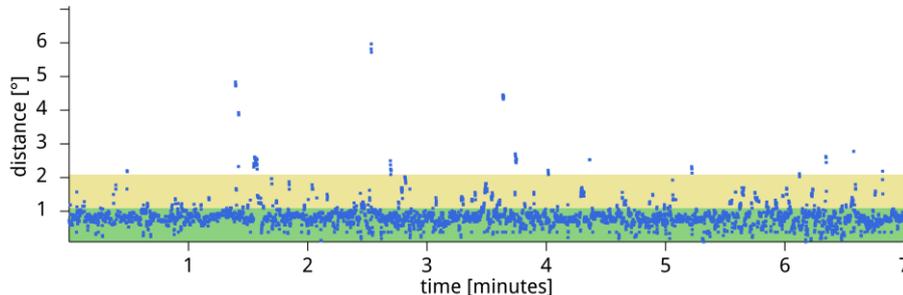


Fig. 36 – Fixation plot and Area

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.

12.3 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. 37), 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. 13.7 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

Navigation buttons: **5** CANCEL, **3** SAVE PROGRESSION TO USB, **4** SAVE PROGRESSION TO SHARED FOLDER, **2** SHOW PROGRESSION ANALYSIS

Fig. 37 – Progression Report test selection screen

12.4 Supra-Threshold exam review

The review window of a Supra-Threshold test (Fig. 39) is similar to the one of the Visual Field test, except that the stimuli do not have a numeric representation but an icon whose meaning is as follows:

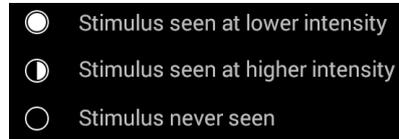


Fig. 38 - SupraThreshold responses

The MD, PSD and FPDJ indices cannot be determined for a supra-threshold test, instead, the responses at individual points (seen at lower intensity, seen at higher intensity, not seen) are summed into one global index called **SupraThreshold Response**. The foveal threshold is not considered in the calculation of this index but is displayed on the left panel.

Based on the reference database from approximately 400 normal eyes included in Compass, the **SupraThreshold Response** index represents the percentage of normal subjects having the same result as the one being reviewed, and the colors in the underlying bar indicate whether the value of this index is:

- above the 10th percentile of normals (GREEN) or
- between the 10th and 5th percentile (YELLOW) or
- below the 5th percentile (RED).

A RED outcome indicates in other words that results lower than or equal to the present were found in only 5% of the reference normals. A YELLOW outcome indicates that results lower than or equal to the present were found in only 10% of the reference normals. Conversely, a GREEN outcome indicates that results equal to or higher than the present were found in 90% of the reference normals.

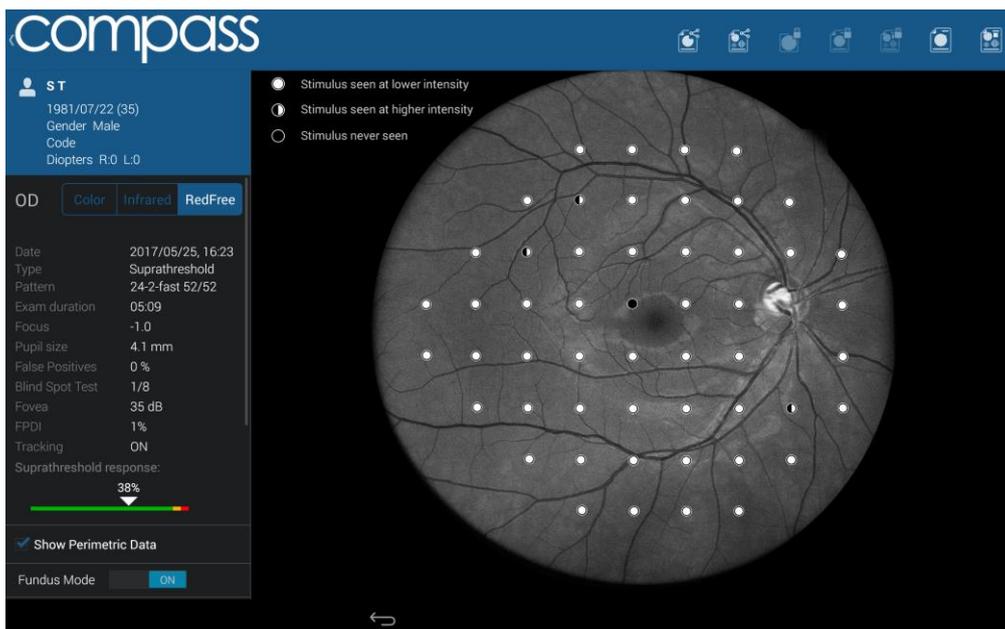


Fig. 39 - SupraThreshold exam review window

12.5 Fundus exam review and Stereo 3D Viewer

The review window for Fundus and Fundus Stereo exams is similar to the one for Visual Field exams. Instead of the Visual Field parameters, image-related information is shown on the left panel (Exam Type, Focus position, Pupil size, Field and Shutter Time, see Fig. 40).

If the image is part of a Stereo pair of images, a selector on the left panel (see point 1. in Fig. 40) or swiping left/right on the image allows to switch between the two images of the pair. Moreover, the  button allows to enter the Stereo 3D Viewer window. It is possible to enter this window also by clicking on the  button present on the bottom right of Stereo images in the Patient Record screen (see Fig. 33).

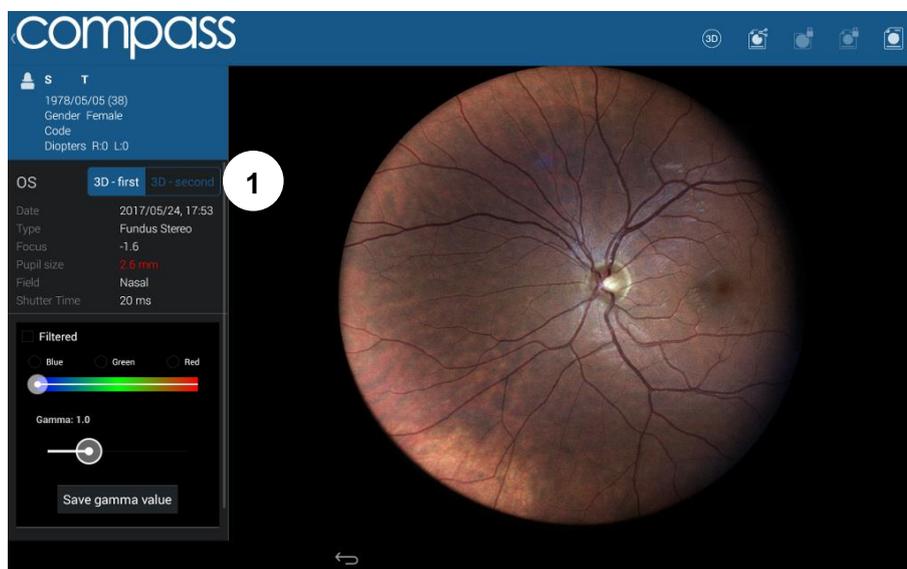


Fig. 40 - Fundus Stereo exam review window

The Stereo 3D Viewer window (Fig. 41) displays images of the Stereo pair side by side; the images info are displayed on the top, and the pan and zoom of the two images is linked so they can be adjusted together. In order to view the 3D reconstruction of the images a pair of prismatic stereoscopic goggles has to be used.

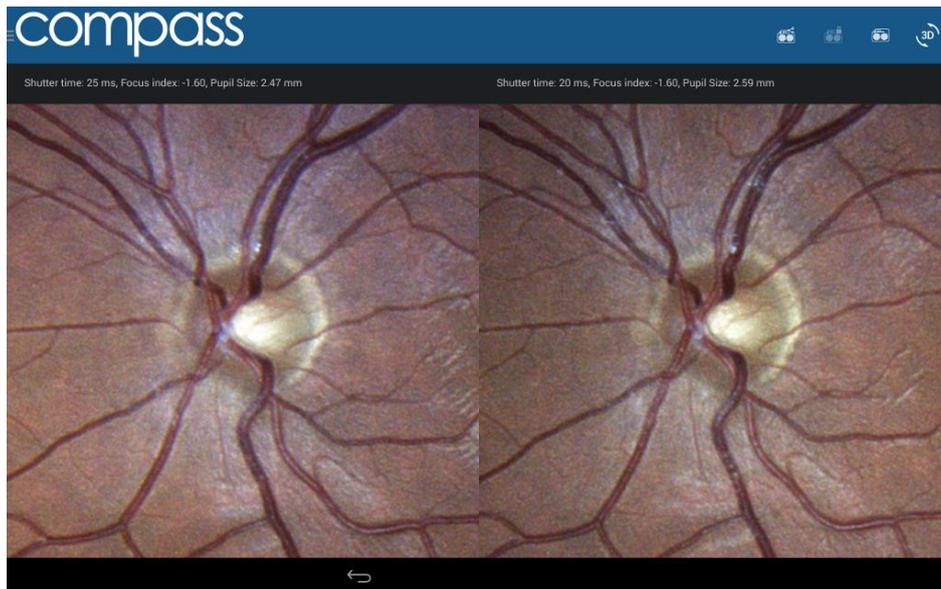


Fig. 41 - Stereo 3D Viewer

On the top bar, the following buttons are available:

Top bar button	Description
	<p>Open (first icon), export to USB (second icon) or export to Shared Folder (last icon) the dual printout of the images of the Stereo pair. For more info on the dual printout, see par. 13.8.</p>
	<p>Swaps left and right image: this function can be used when using a different method for 3D reconstruction (like crossing eyes), or if the optic nerve head is perceived as an elevation instead of a cavity.</p>

12.6 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 only allows to display the data and does not have any patient data editing function.

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).



Since use of the Remote Viewer depletes some computational resources, no more than two clients can be connected to the unit at the same time.

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. 6214.4

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. 14.1);
- 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 user is automatically logged out 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. 43). Click on **Logout** to exit the Remote Viewer.

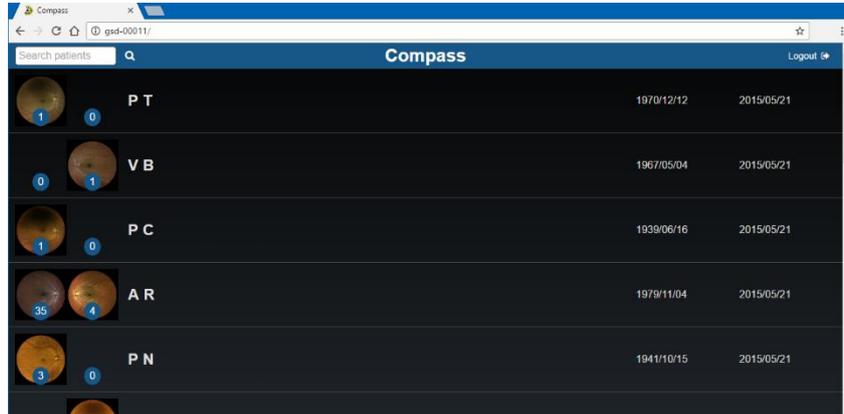


Fig. 42 – Patient List in Remote Viewer

Patient Record screen

This screen allows access to all exams, and displays the same info present in the Patient Record screen in the on-board software. The **edit/delete patient** and **New Exam** commands are not available in the Remote Viewer.

In each exam box the following additional buttons are available:

	Generate the progression report (see par. 12.3).
	Download the perimetric report in PDF format (see par. 13).
	Download the fundus report of the Color Image in PDF format. <u>Fundus exams provide only this button.</u>
	Download the fundus report of the Infrared Image in PDF format.
	(Fundus Stereo exams only) Downloads the stereo report in PDF format.

Click on the desired image to enter the **Exam review** screen (see Fig. 44).

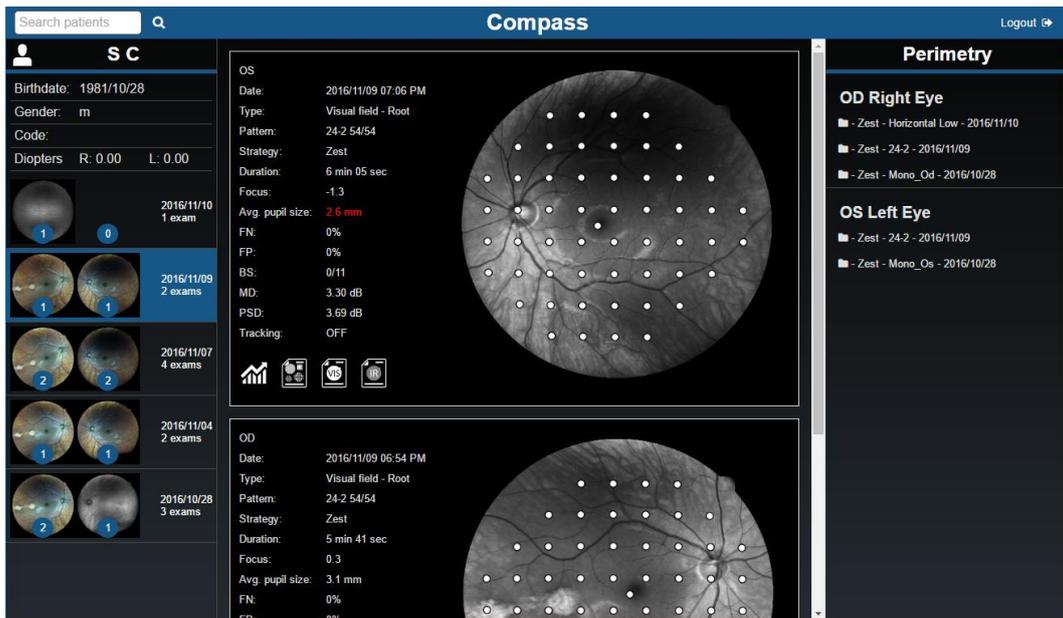


Fig. 43 – Patient Record screen in Remote Viewer

Exam review screen

Entering the **Exam review** screen shows the Color image of the selected Exam (or the IR image if the Color image is not available):



Fig. 44 – Exam Review screen in Remote Viewer

The following functions are available in this screen:

Function	Command	Description
Back		Back to Patient Record Screen

Logout		Logout from the Remote Viewer
Patient Info		Displays all patient related information (full name, date of birth, gender, code) and gives access to a thumbnail view of all the images available for this patient. Also used to compare the currently displayed image with any other image in the list click on the corresponding Compare button: this will open the Dual Image Review screen (see Fig. 47).
Exam Info		Displays all exam related information (date and time of capture, eye, pupil size, field, exposure, focus)
Image Filters		Provides access to the red, green (i.e. red-free), blue filters and gamma adjustment (see Fig. 45).
Download		Allows to download the Perimetry report (PDF), the Progression analysis (PDF) original image (JPG), the Fundus report of the image (PDF), the Filtered image (JPG), the Fundus report of the Filtered image (PDF) or the Dual printout Report (PDF) on local PC (see Fig. 45)
Stereo 3D Viewer		Enters the Stereo 3D Viewer
Perimetry Mode		Provides access to the Perimetry Mode window, showing stimuli thresholds overlay on retinal image (available only for Visual Field exams) [see below for details]
Additional Tools		Provide access to additional tools like flickering and cup-to-disc evaluation (see below for details)
Zoom	Mouse wheel	Zooms in or out
Pan	Mouse left-click and drag	Moves the image around to frame different regions

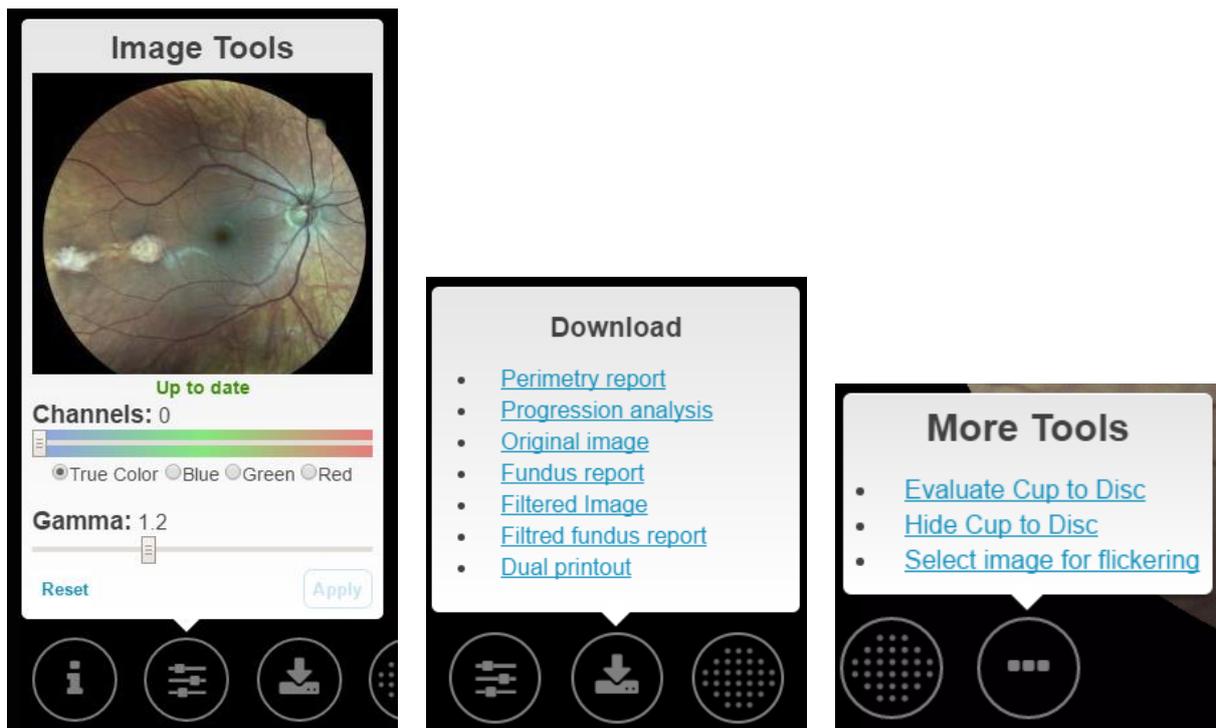


Fig. 45 – Image Filters, Download options and More Tools in Remote Viewer

i **The image tools do not alter the original image.**
When applying a Gamma value from the Remote Viewer, the same value will be stored and used also in the on-board software interface, and viceversa.

Perimetry Mode review screen

This screen allows the review of the perimetric data of a Visual Field exam. When accessing this interface the stimuli thresholds are superposed over the red-free (or IR if not available) retinal image. The results of the Visual Field test are displayed on the left side of the screen.

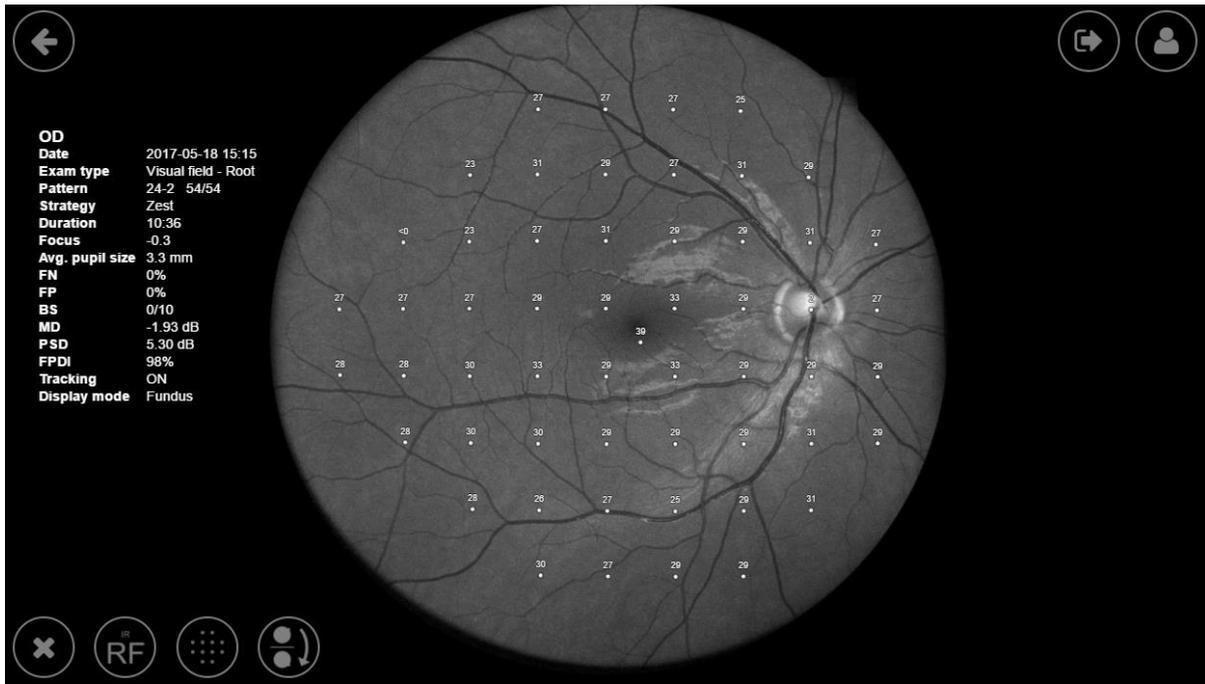


Fig. 46 – Perimetry Mode Review screen in Remote Viewer

The following additional functions are available in the bottom-left side of this screen:

Function	Command	Description
Close		Back to Fundus (image only) review screen.
Image Type		Switch between the red-free and the IR retinal image for the stimuli overlay.
Hide/Show Thresholds		Hide or show the stimuli threshold overlay over the retinal image.
Fundus/Standard perimetry display convention		Switch between Fundus Perimetry and the Standard Perimetry display conventions, i.e. flips the results vertically (see par. 12.1)

Dual Image review / Stereo 3D Viewer screen

The Dual Image review screen (Fig. 47) allows comparison of any pair of images of the selected patient (color and infrared, left and right eye, same or different dates). The Stereo 3D Viewer screen has a very similar interface, except that the **Lock** button is missing (pan and zoom are kept locked), and it is replaced by the **Swap images** button.

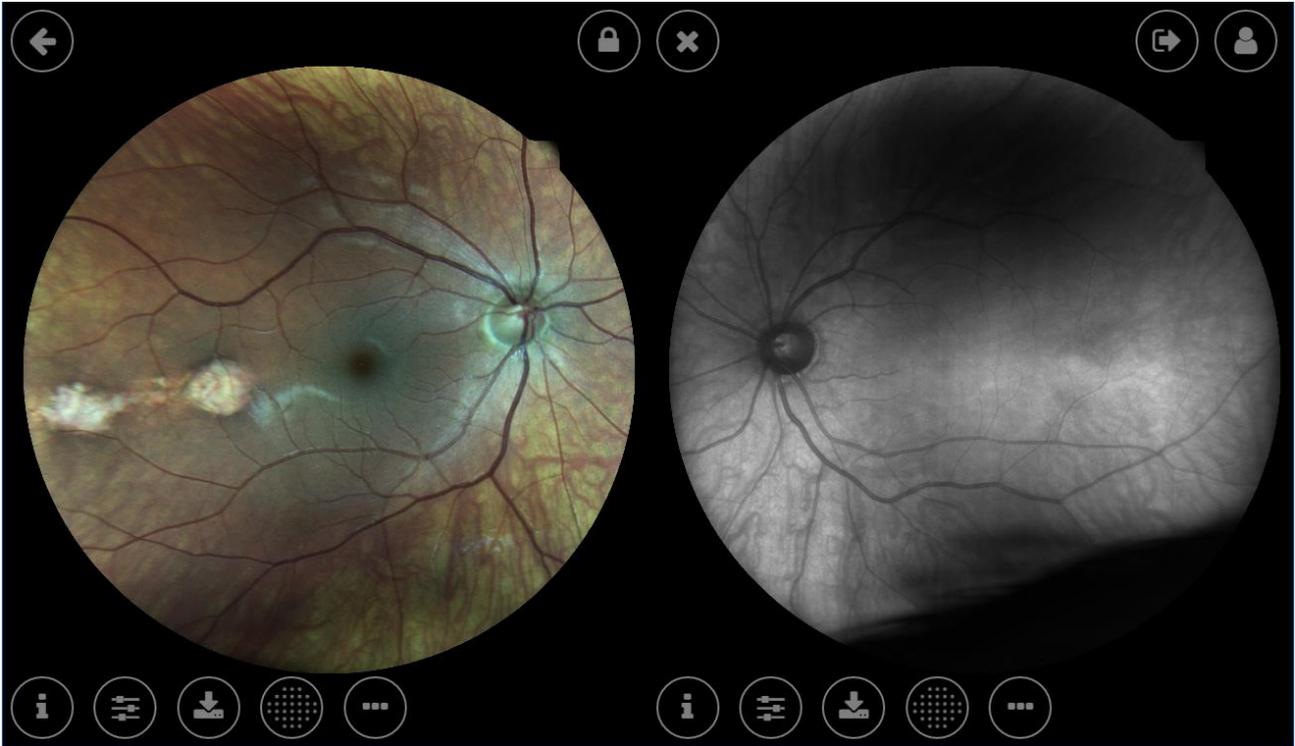


Fig. 47 – Dual Image Review screen in Remote Viewer

The following additional functions are available in this screen, in addition to those described above for the Single Image review screen:

Function	Command	Description
Lock	 	(Dual Image review only) Allows to “lock”/“unlock” the two images so that the same region gets zoomed and panned in both images.
Swap images		(Stereo 3D Viewer only) Swaps left and right image, to be used if the optic nerve head is perceived as an elevation instead of a cavity.
Close		Goes back to the Exam Review screen.

Flickering view

Compass allows to compare two images one by one, by switching manually or automatically between the two. This feature is called **flickering**. To access the flickering window, press the Additional Tools button in the Single Image review screen, then click on **Select image for flickering**: the remote viewer will show a window (see Fig. 48) with all the pictures available for flickering (i.e. all of the Color and IR images of the same patient and same eye). The software automatically registers the two images in order to overlap them (compensating shift, rotation and Color/IR distortion).

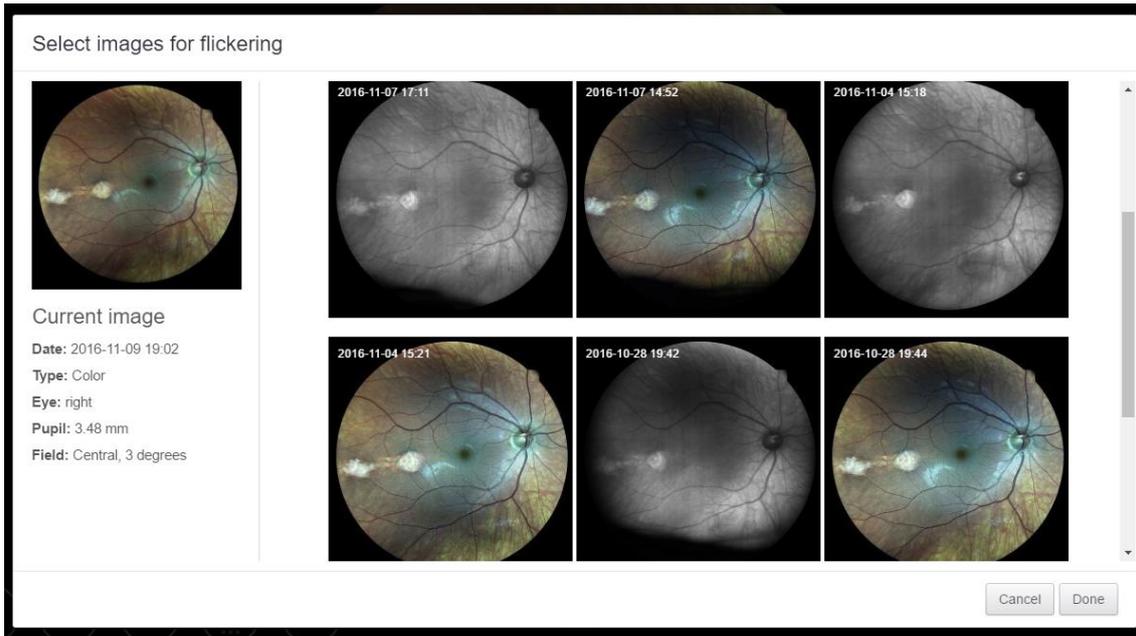


Fig. 48 – Flickering image selection

Select the image to flicker with, then click Done.

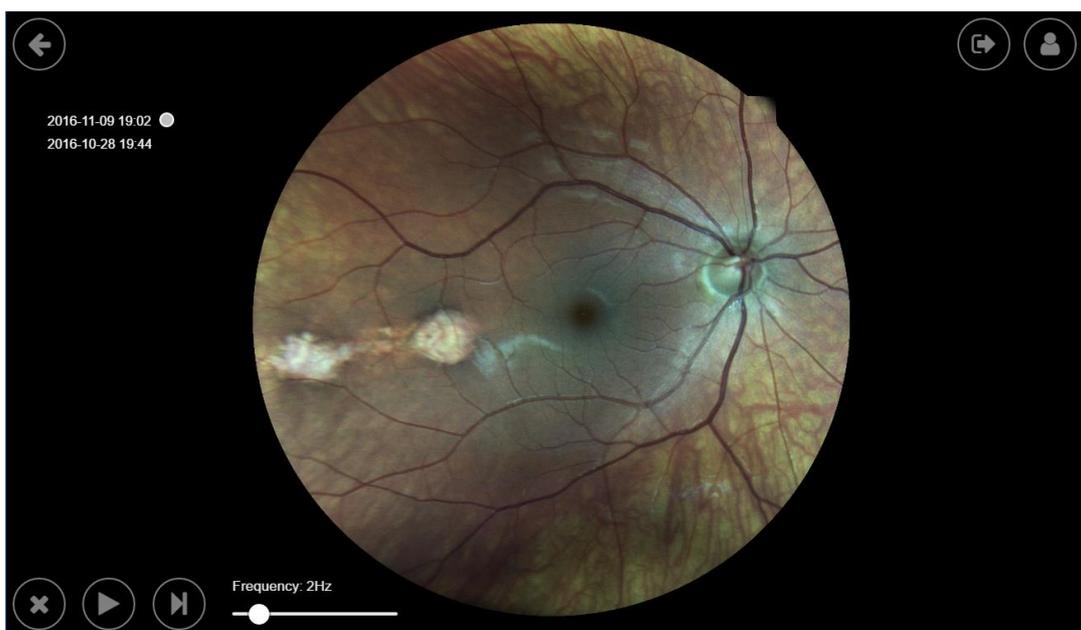


Fig. 49 – Flickering review window

On the left side of the image the date and time of the 2 selected pictures are displayed. The small circle indicates the date and time of the currently displayed image.



Fig. 50 – Currently active picture: “2016-09-09 17:28”

The following features are available in this screen:

Function	Command	Description
Close		Goes back to the Exam Review screen.
Play/Pause		Play/pause the automatic flickering.
Next image		Toggle manually between the two images.
Animation speed		Flickering frequency selection (from 1 to 10Hz).

The 2 images are “locked”: zooming and dragging will act on both images.

Cup-to-disc evaluation

The cup-to-disc ratio (CDR) is the ratio between the optic cup and the neuroretinal rim diameters. To evaluate it, draw the two diameters: click over the picture to start the first segment drawing, then click to define the end. Do the same for the second diameter. The segments can be modified by clicking and dragging the segment endpoints.

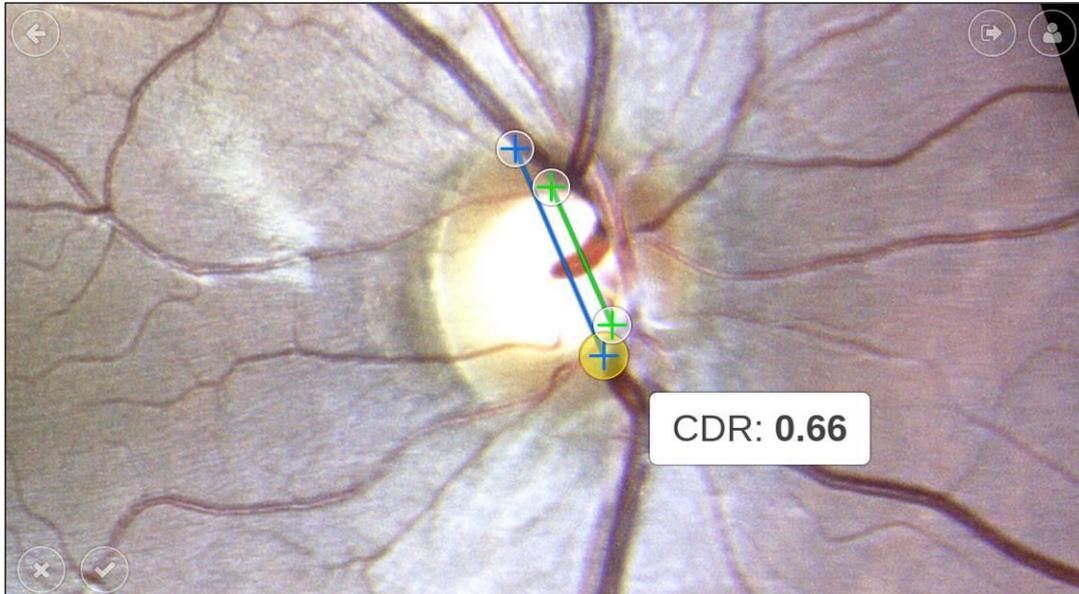


Fig. 51 – Flickering review window

The following buttons are available in this screen:

Function	Command	Description
Cancel		Discard drawings and return back to the Exam review window.
Accept		Save cup-to-disc drawings and return back to the Exam review window.



Compass is not a cup-to-disc ratio measurement equipment.

Its calculation is determined by how the diameters are drawn by the user and so it is subject to the error introduced by the operator: the CDR in Compass shall be considered as a qualitative indication only.

Moreover, Compass does not provide CDR values comparison with normative data, so the clinical interpretation of the CDR measurements obtained with Compass is the sole responsibility of the eye care practitioner.

13. PRINTING

13.1 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 3). Before choosing a printer, please check if the model is included in the compatibility list issued by the printer manufacturer for every app.

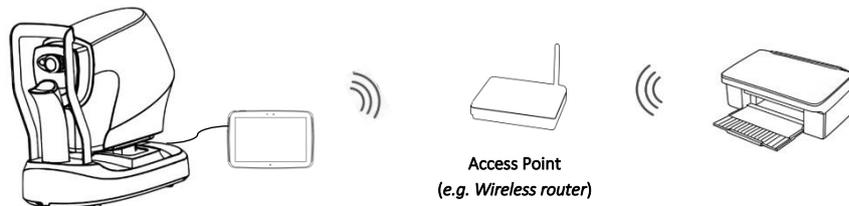
Brand	Description
HP	HP Android ePrint
Samsung	Samsung Mobile Print App
Lexmark	Lexmark Mobile Printing
Canon	Canon Mobile Printing, Canon Easy-PhotoPrint, PIXMA/MAXIFY Printing Solutions
Epson	Epson iPrint, Seiko Epson Corporation
Konica Minolta	Konica Minolta Printers, Page Scope Mobile

Table 3: 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.

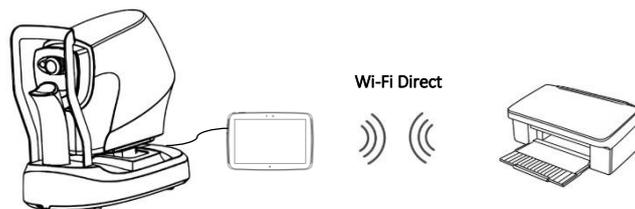
Infrastructure Mode

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.



13.2 Report for 24-2 test

The printout for an exam performed with the 24-2 grid is a one-page layout presenting the following information (see Fig. 53):

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), Pattern Standard Deviation (PSD) and Fundus Perimetry Deviation (FPDI) indices, plus information if the Tracking was enabled during the entire exam
7. Cluster MDs (dB) (see clusters identification in Fig. 54)
8. Grayscale VF map (see Fig. 55 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 $MD < -8$ 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
15. Custom printout header (see Par. 14.9 for how to configure it)

$TPI_{0.5^\circ}$: 94.4% [74.1%] / TPI_{1° : 96.9% [89.1%]

Fig. 52 – 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

13.3 Report for 10-2 test

The printout for an exam performed with the 10-2 grid is similar to the one of a 24-2 grid, 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;

- as the projection grid is smaller, the retinal image shows a zoomed view of the projected area.

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

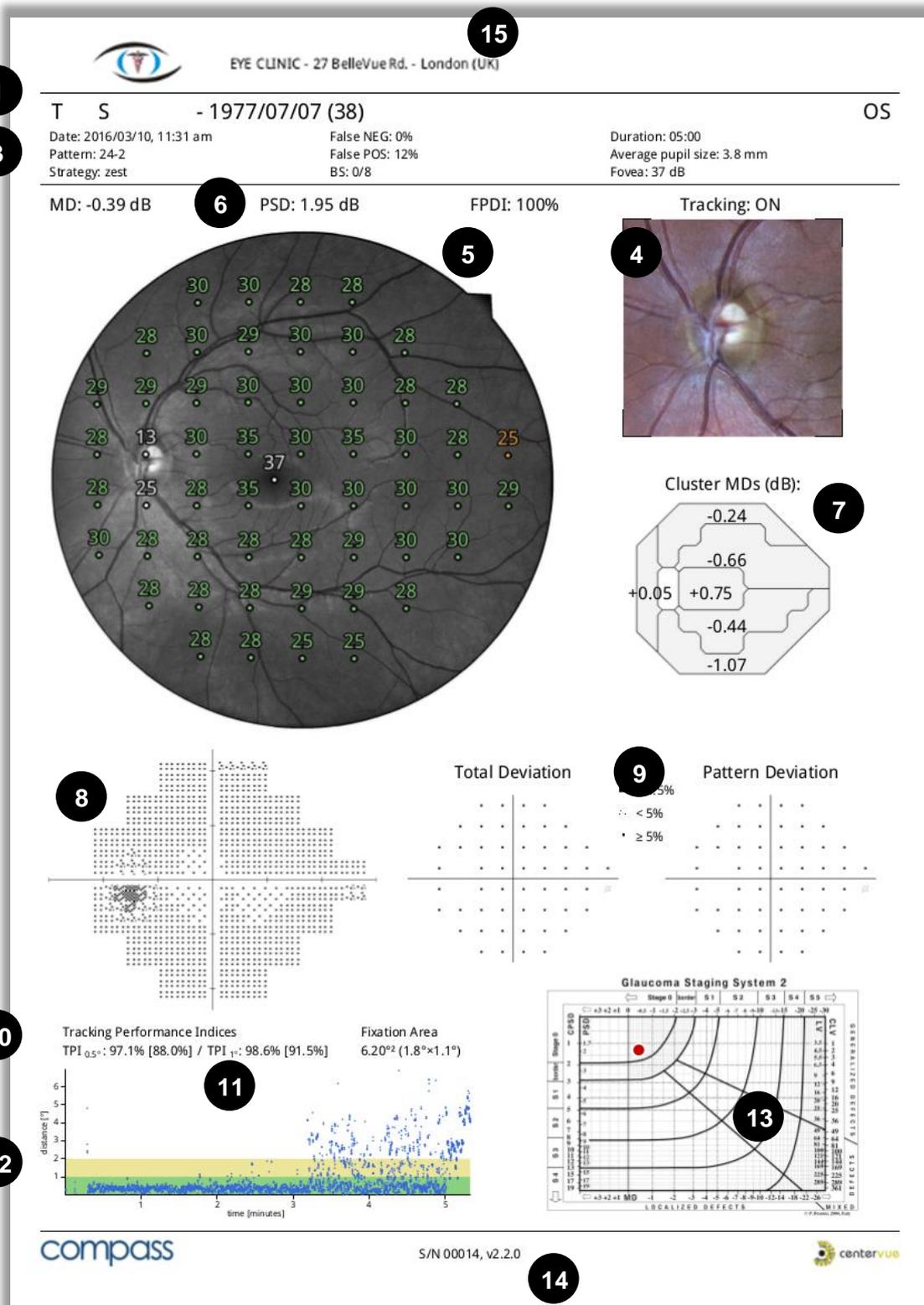


Fig. 53 – COMPASS report for a test with 24-2 grid

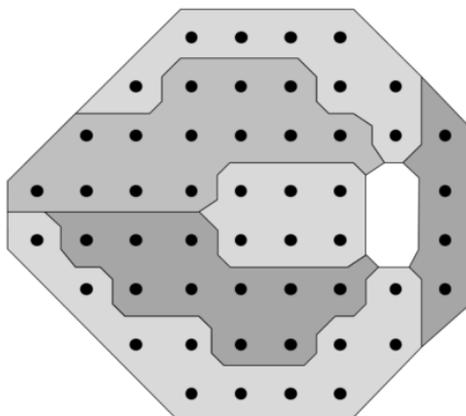


Fig. 54 – Stimuli of the 24-2 pattern grouped in clusters⁶

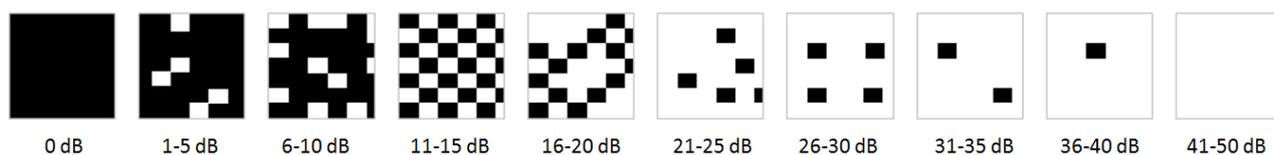


Fig. 55 – Symbols used for the grayscale map and related dB intervals

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

13.4 Report for 30-2 test

The printout for a test performed with the 30-2 grid (Fig. 56) is similar to the one of a 24-2 grid, with the following differences:

- the MD, PSD and FPD values (6) are not available;
- the cluster analysis (7), Total and Pattern Deviation maps (9) are not available;
- the Glaucoma Staging System (13) is not available and is replaced by the color photo.

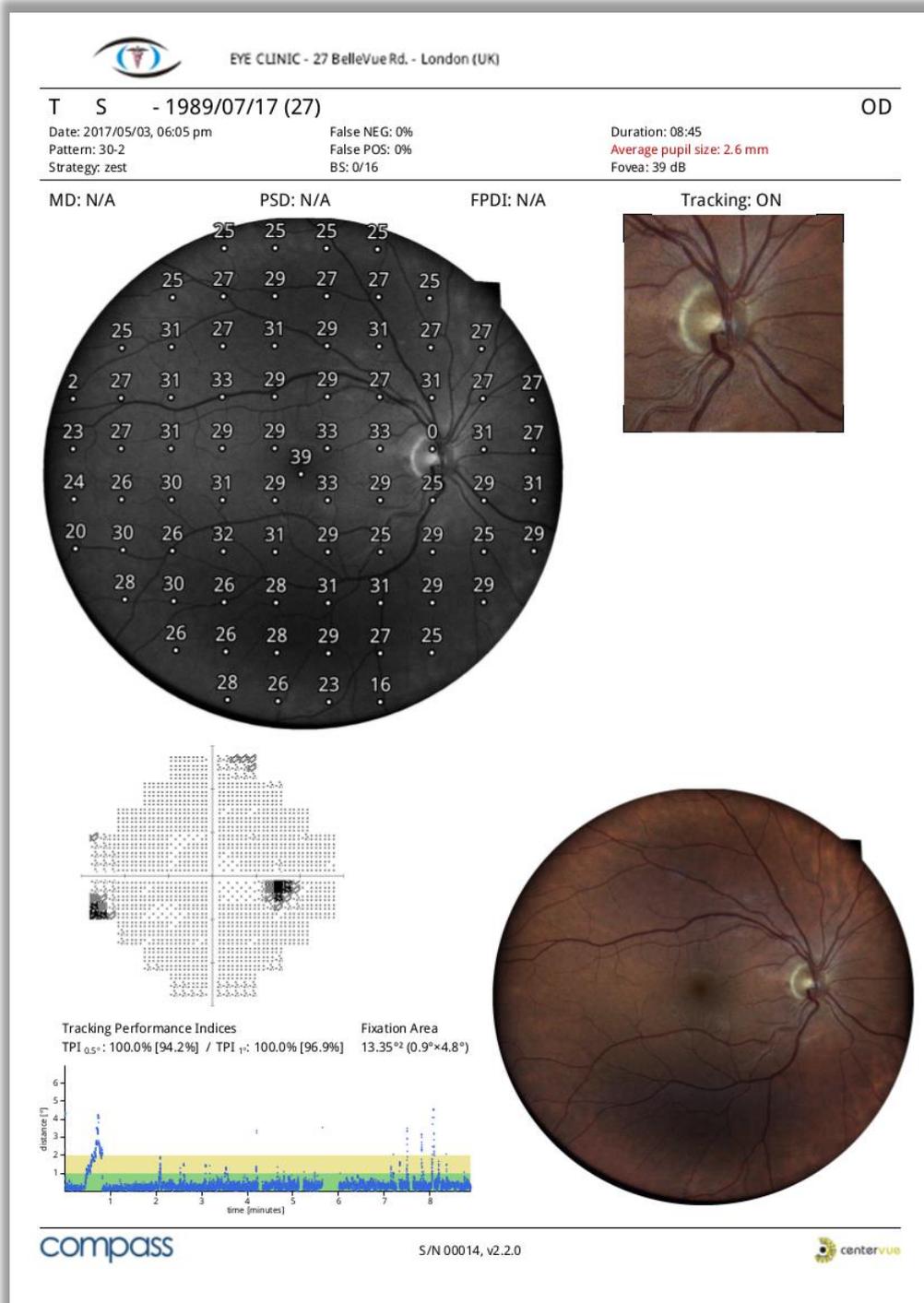


Fig. 56 – COMPASS report for a test with 30-2 grid

13.5 Report for the SupraThreshold exam

The printout for a SupraThreshold exam displays the following information (see Fig. 57):

1. Patient information and exam data, among which the foveal threshold measurement
2. Red-free retinal image with overlapped 3 symbols representation (seen at lower intensity, seen at higher intensity, not seen)
3. Color image of the ONH detail
4. Tracking performance indices and Fixation plot
5. Color image of the entire retina
6. *Suprathreshold Response* index, with reference to delimiting percentiles

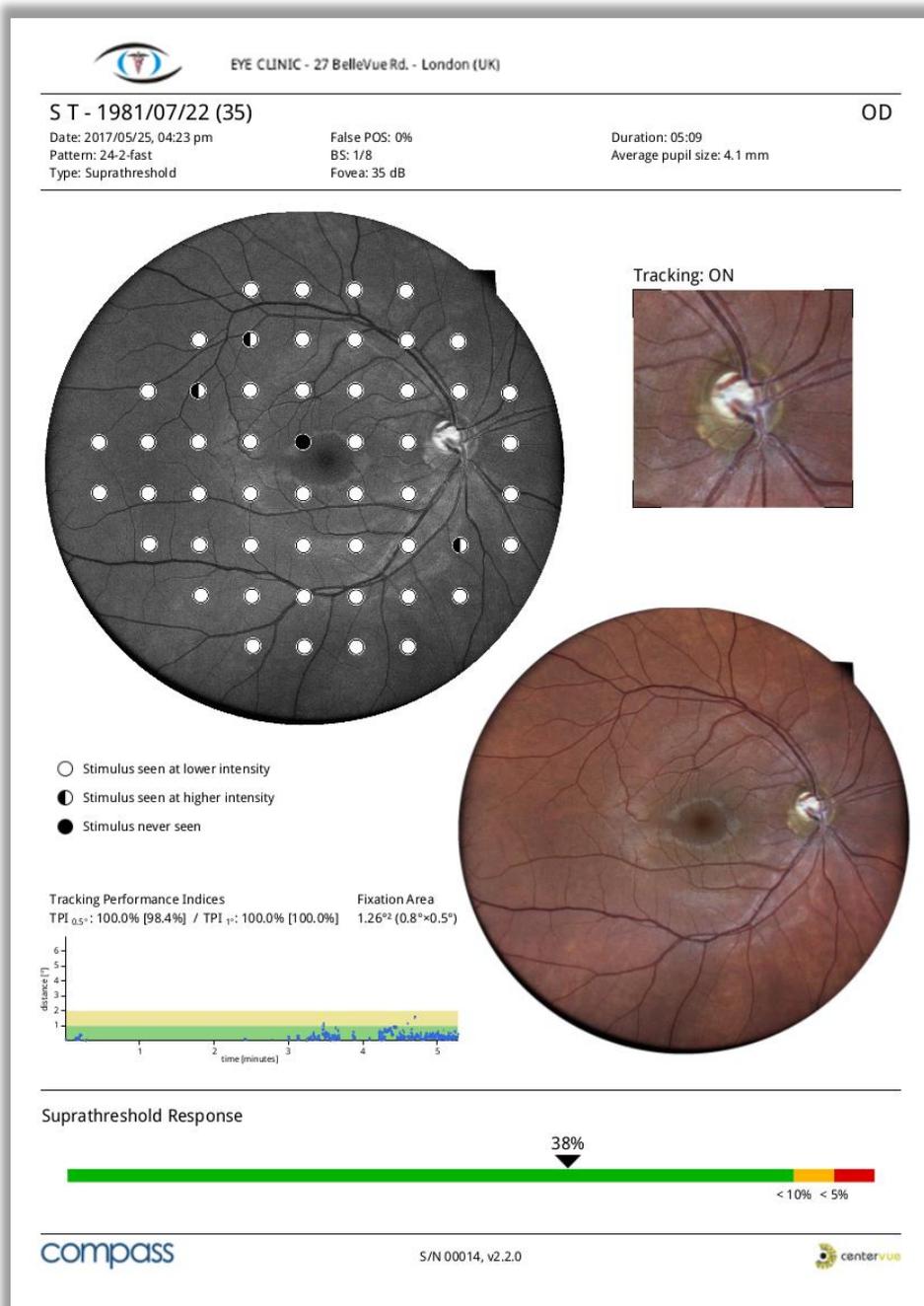


Fig. 57 – COMPASS report for a SupraThreshold test

13.6 Fundus Report

The Fundus Report printout can be generated and exported for both **Fundus/Fundus Stereo** and **Visual Field/SupraThreshold** tests (both Color and Infrared image).

It is a one-page layout presenting the following information (see Fig. 58):

1. Patient information (name, date of birth, age when test was performed)
2. Exam date and time
3. Examined eye (OD, OS)
4. Pupil size during photo shoot
5. Type of image (**Color / Infrared**)
6. Cup-to-disc ratio (if previously set by the operator)

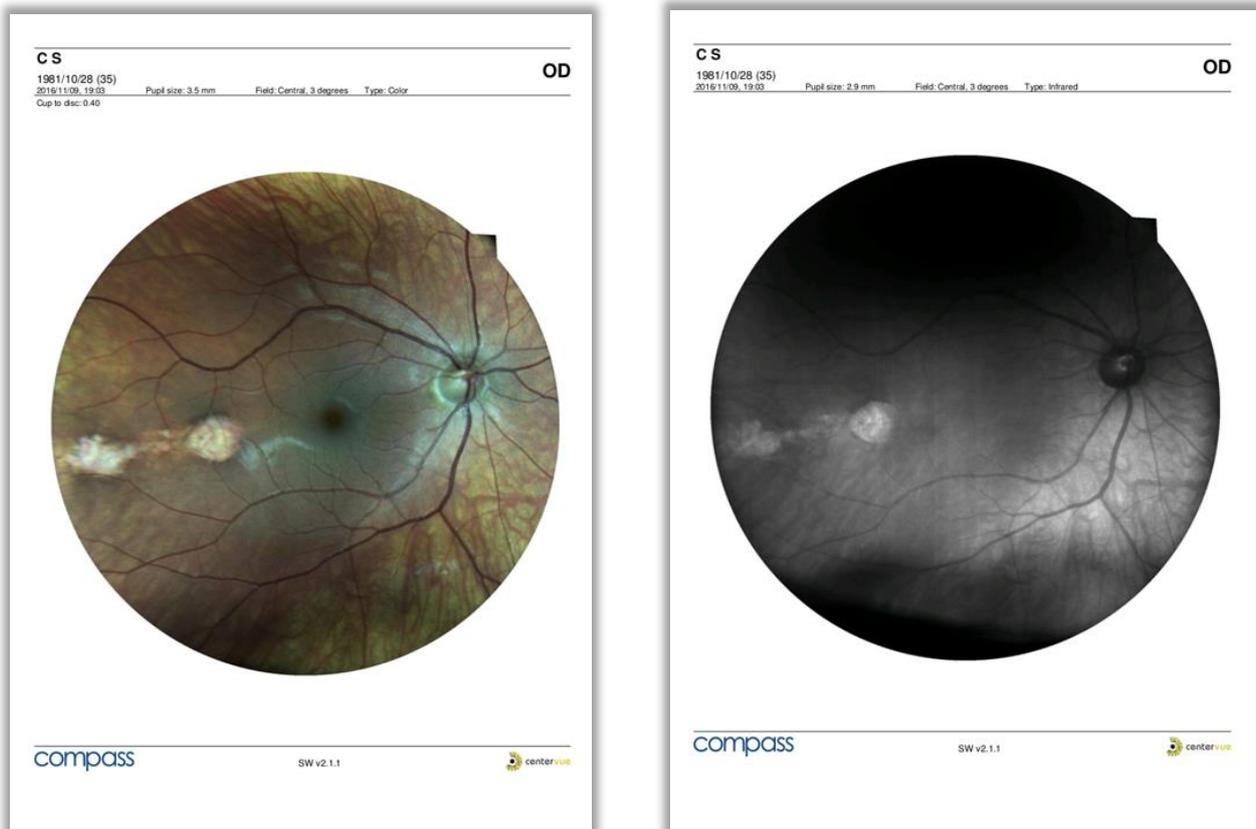


Fig. 58 – Fundus report examples: for Color Image (left) and for Infrared Image (right)

13.7 Progression report

The Progression Report provides information on a series of tests (24-2, 10-2 or 30-2) pertaining to the same subject and eye.

It is a one-page layout presenting the following information (see Fig. 59):

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. Point-wise 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. FPGI progression plot for all included tests
14. Software version used to generate report
15. Custom printout header (see Par. 14.9 for how to configure it)

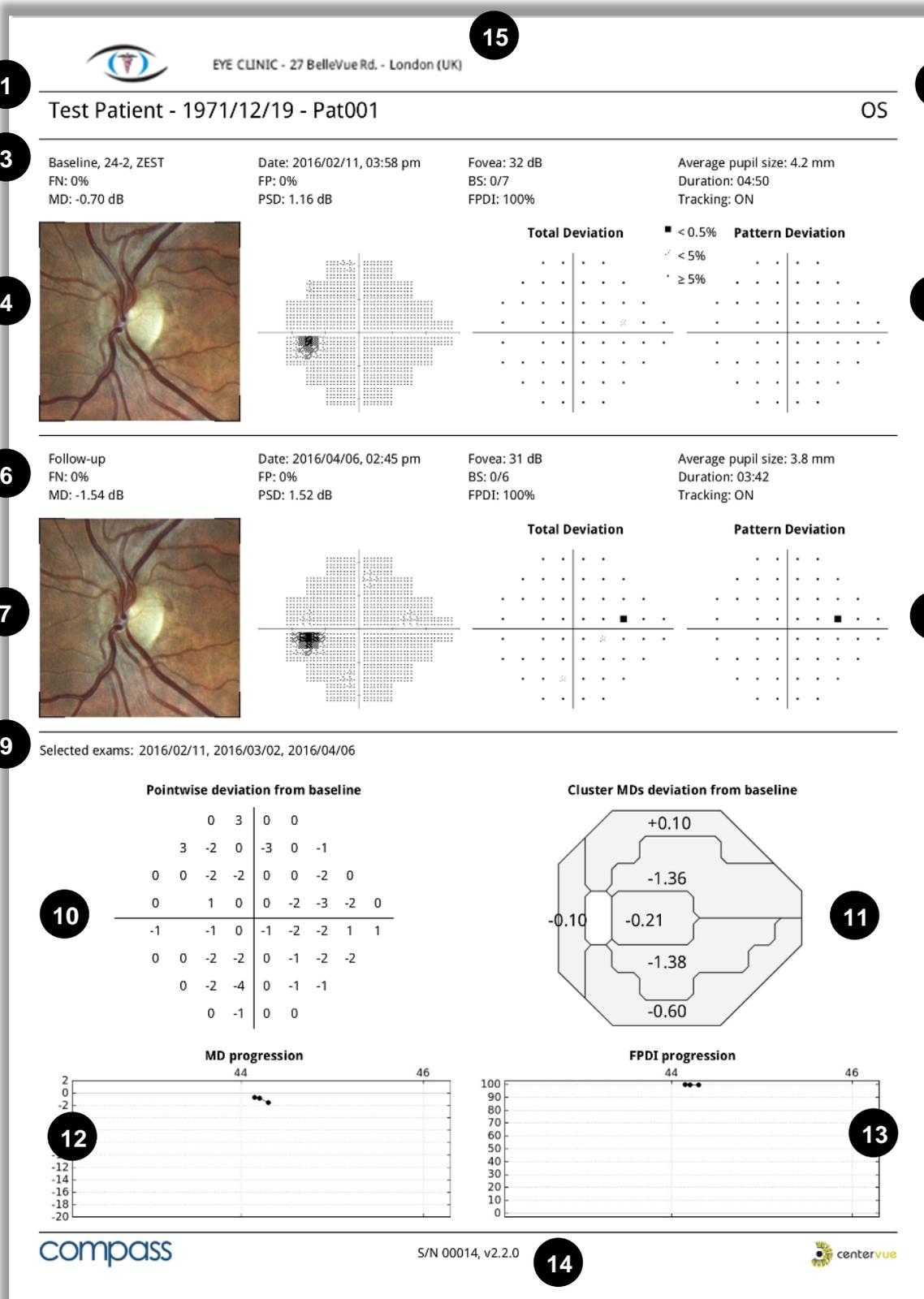


Fig. 59 – Progression report for 24-2 series

13.8 Dual printout / Stereo report

The Dual printout and the Stereo report have the same layout and they display the two images selected (or the pair of Stereo images) on a single page, in landscape format. The header displays info of the patient (Name, code and date of birth) and of each image (date/time, Pupil size, field and Image Type).

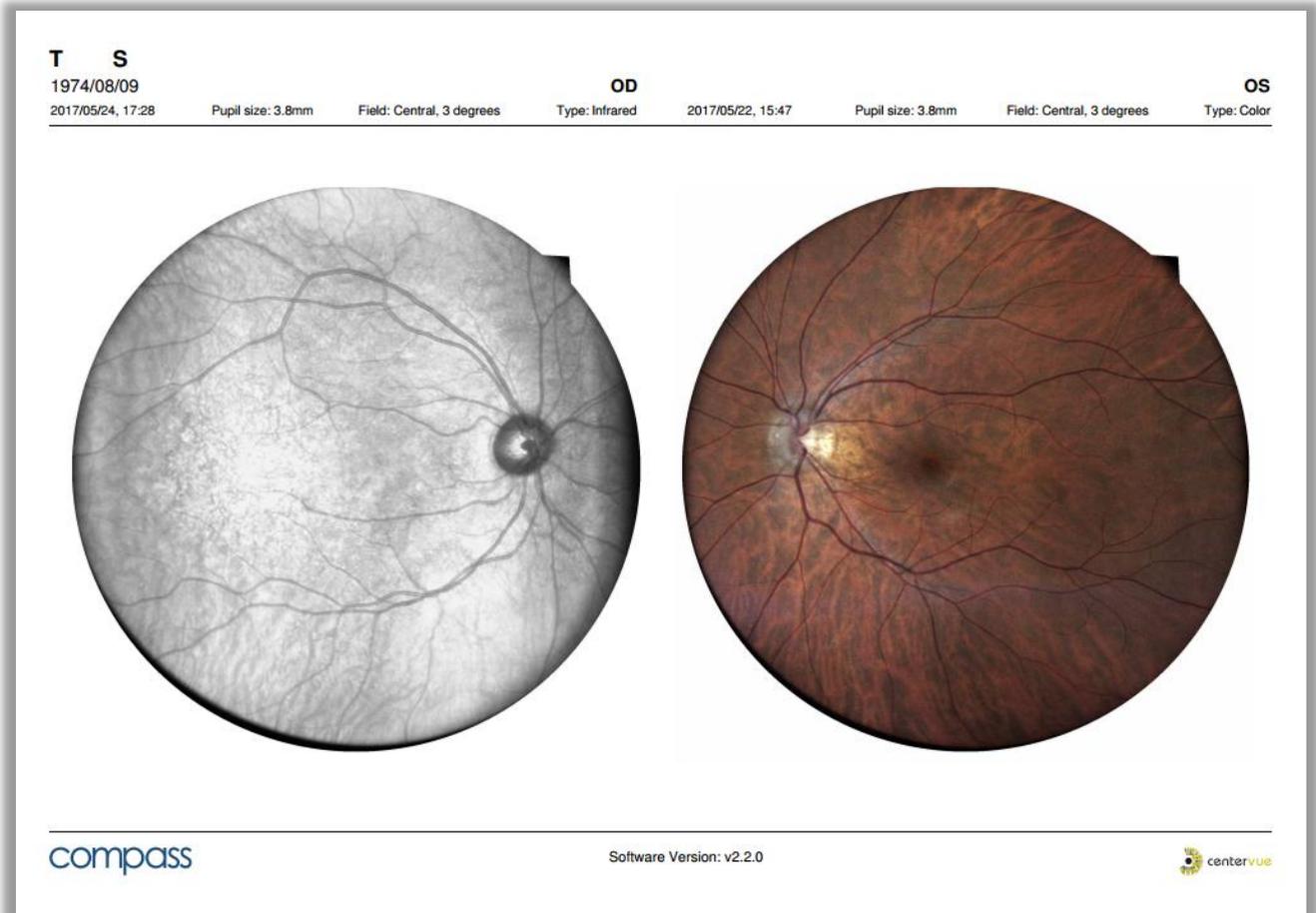


Fig. 60 – Example of a Dual printout Report

14. SETTINGS

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

14.1 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



14.2 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 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.

14.3 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. 61). 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**

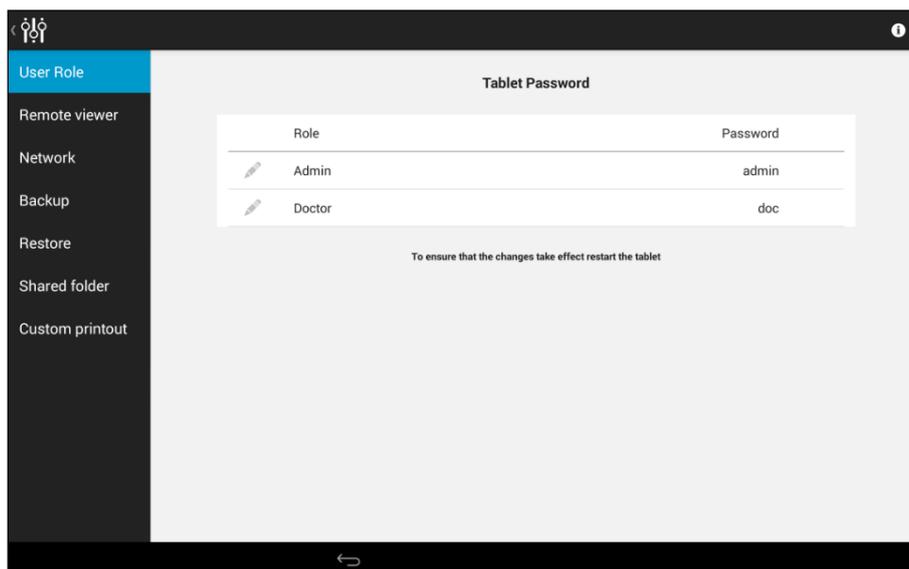


Fig. 61 – Configurator – User Role screen

14.4 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**.

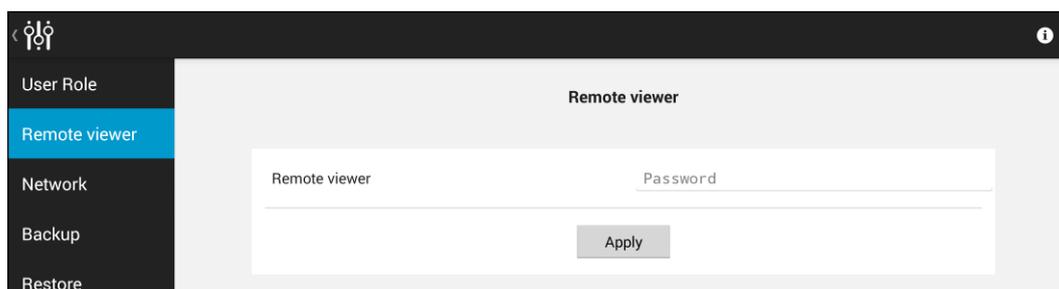


Fig. 62 – Configurator – Remote Viewer screen

14.5 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.

To select the primary network, click on Advanced. To configure the selected network, click on the  icon.

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.

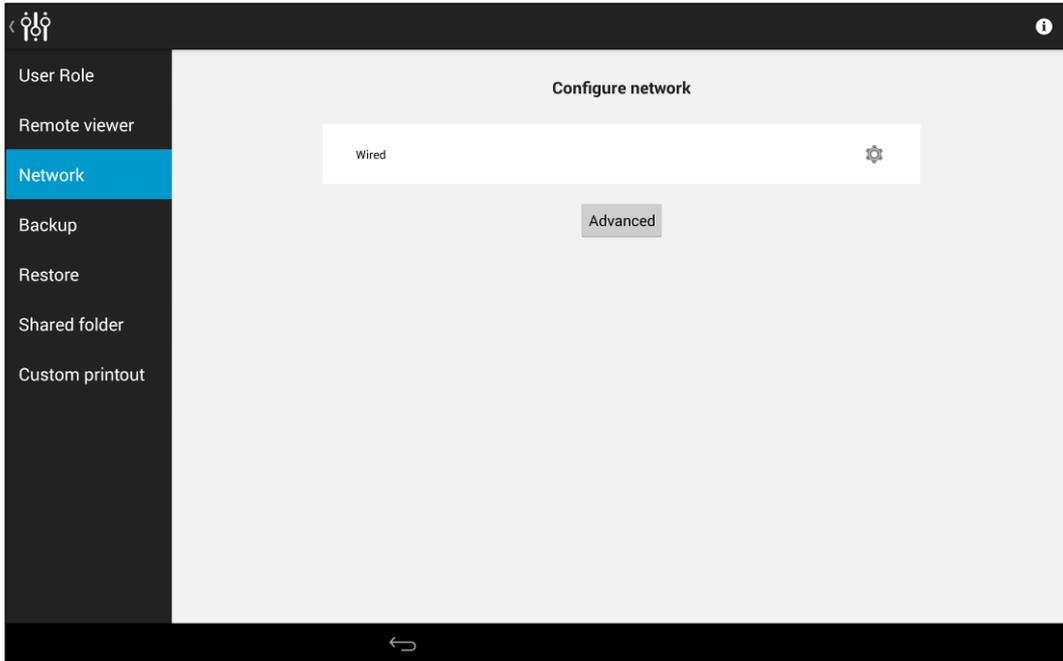


Fig. 63 – Configurator – NETWORK screen



Fig. 64 – Configurator – Specific network configuration screen (in this case: wired network configuration)

14.6 Backup

COMPASS allows the backup of data to a USB media or to a Network folder. The backup can be automatic (i.e. periodically scheduled) or manual.

The backup is an incremental backup and will be saved in a subfolder called `cv_backup`: this means that Compass will backup only the data added or modified since the last completed backup. Compass supports backup to more than one device media. Moreover, the same device media can be used as backup for different Compass units.



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



Manual modifications to the backup folders will damage the backup data.

To access the Backup window, press *Backup* on the Configuration app. The backup configurator contains three screens: **Device**, **Schedule**, **Execute**.

Device tab

This screen allows to select the device used for backup. The backup can be performed to a USB media or to a network folder: select the desired backup device by clicking on **USB** or **NETWORK** at the top of the screen.

When all the parameters are defined for the selected device, press *Apply* to store the device parameters and move to the **Schedule** screen.

Backup to USB

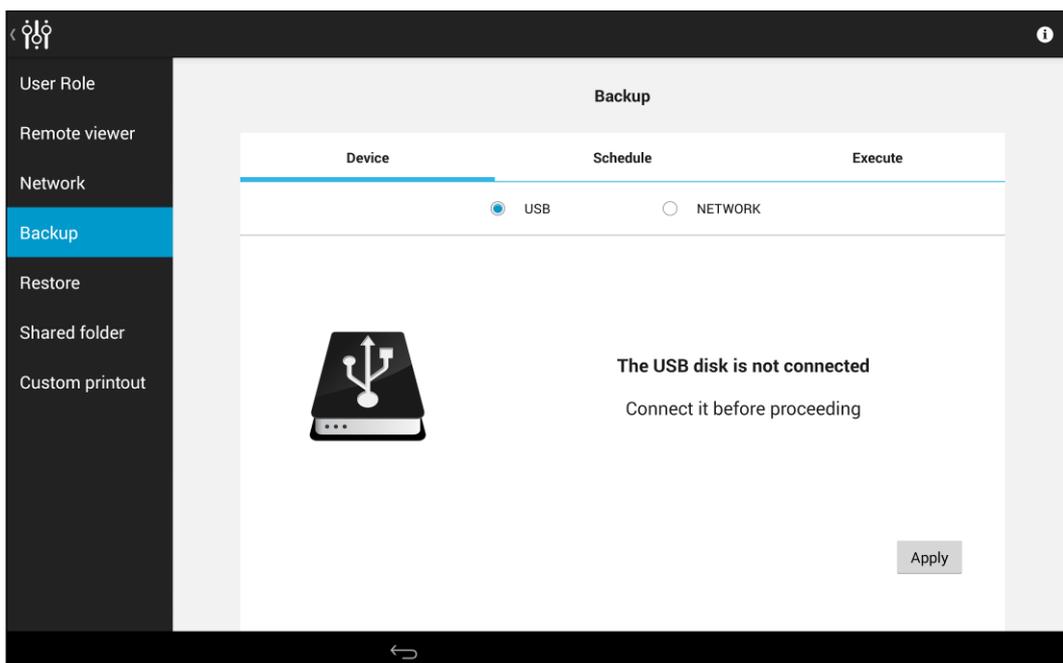


Fig. 65 – Configurator – BACKUP screen – USB-media backup selected



When the device is connected and ready for backup, the  icon changes to green. The USB media used for backup should be **formatted as NTFS, with enough free space to store the backup file.**



USB sticks are less reliable than USB disks: in case of backup to USB media, consider using USB disks instead of USB sticks.

Backup to Network

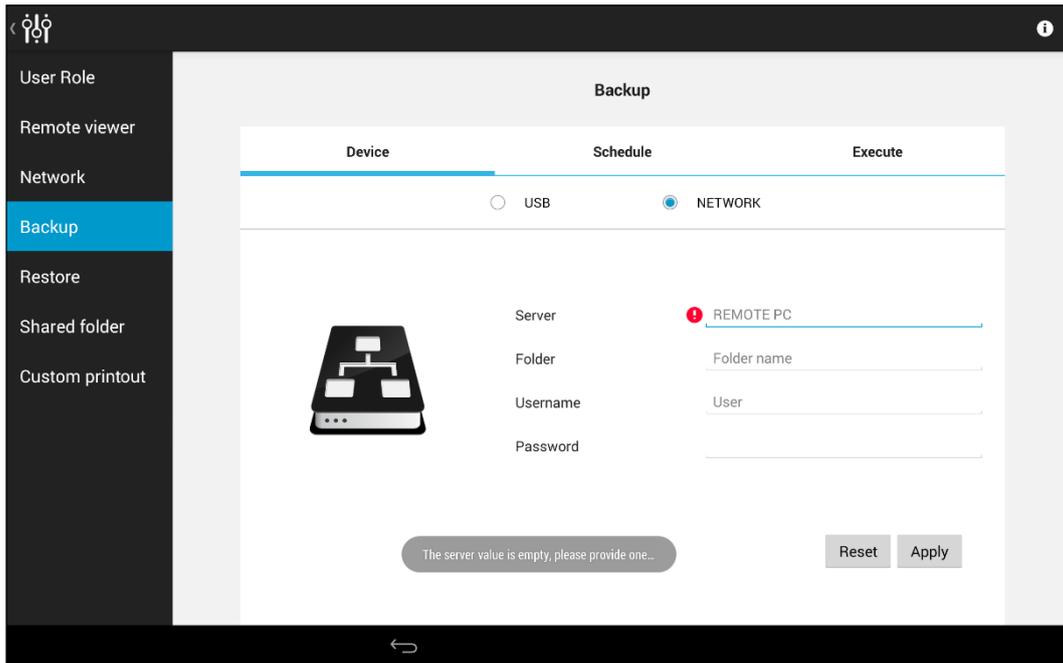


Fig. 66 – Configurator – BACKUP screen – Network backup selected

The network parameters to be set are the following:

- *Server*: network name or IP address of the remote host.
- *Folder*: name of the shared folder in the server.
- *Username*: if you're not in a Windows Domain network, this field contains the user name used in the remote server; if you're in a Windows Domain network, the format of this field is: *DOMAIN\USERNAME*
- *Password*: this field contains the password used by the user in the remote server

All these fields are mandatory.



Empty passwords (e.g. guest accounts) are not supported.



If a Windows-based system is used as backup destination, the *Username* should be different from Guest, because of Windows Guest user restrictions.

Schedule tab

Turn **ON** the **Automatic backup** button in the **Schedule** tab to allow periodic backup.

At the scheduled time, Compass will try to contact the selected media. If the media is not ready (e.g. network disk not available or USB not connected), Compass will temporary suspend the backup procedure and will keep retrying for one hour.

The backup will be performed regularly on the next scheduled occurrence even if the last backup attempt failed.

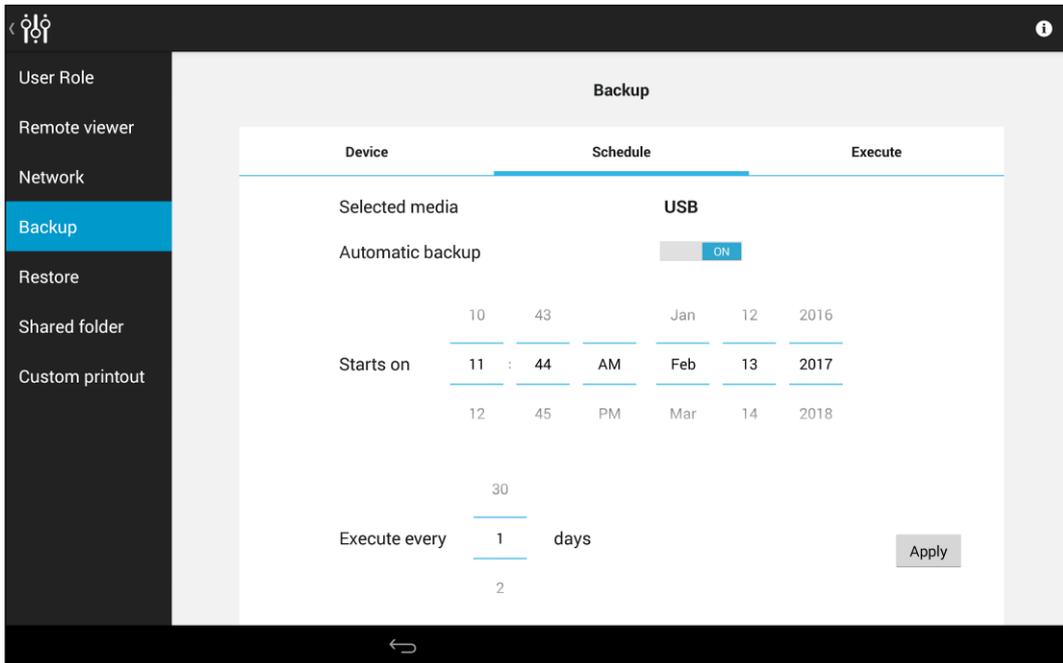


Fig. 67 – Configurator – BACKUP screen – Schedule tab with automatic backup enabled

The backup will be performed starting on the date set in the **Starts on** field with the frequency configured in the **Execute every** field.

By pressing the **Apply** button, COMPASS stores the backup configuration.

Execute tab

This screen shows the backup status and allows to perform a manual backup. To perform a backup, press on the **Execute** button.



Once the backup has started, Compass can be used regularly except for the impossibility to delete images.

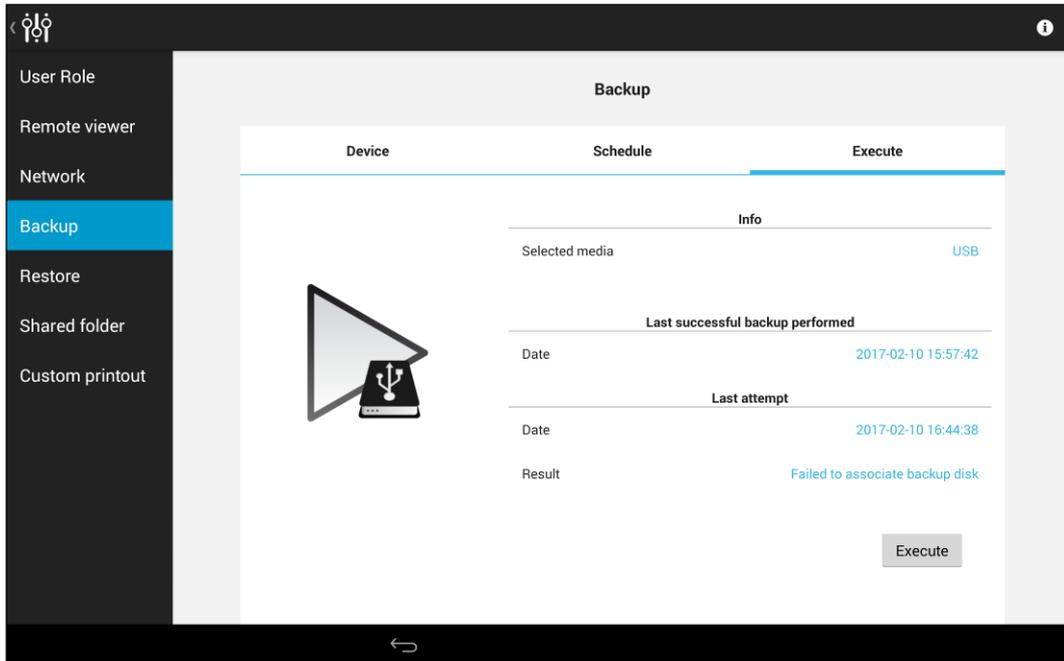


Fig. 68 – Configurator – BACKUP screen – Execute tab

If a manual or automatic backup is in execution, this screen shows the progression status with an estimation of the remaining time.

14.7 Restore

This feature allows to restore a backup from the selected media.

The backup to be restored can come from the same unit or from another Compass: the **Restore** window will show a list of available backups.

To restore a database:

- Be sure that the USB media or the Network folder used as backup are available, then select the right device in the **Device** tab and press **Apply**.

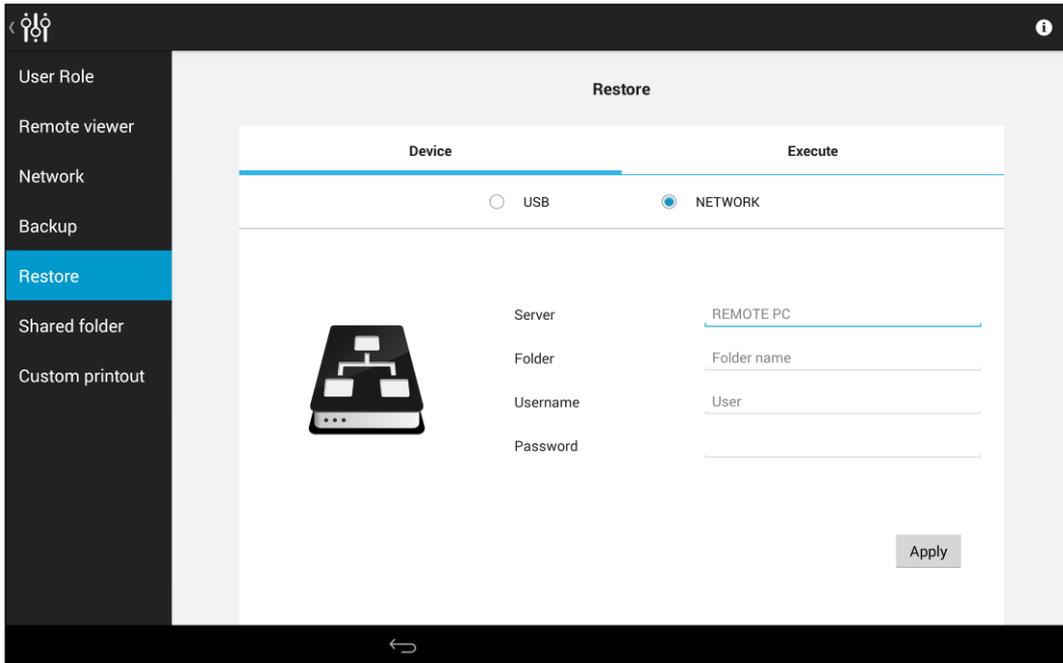


Fig. 69 – Configurator – RESTORE screen – Network folder selected

- Click **Apply**: the screen shows the list of available backups in the selected media.

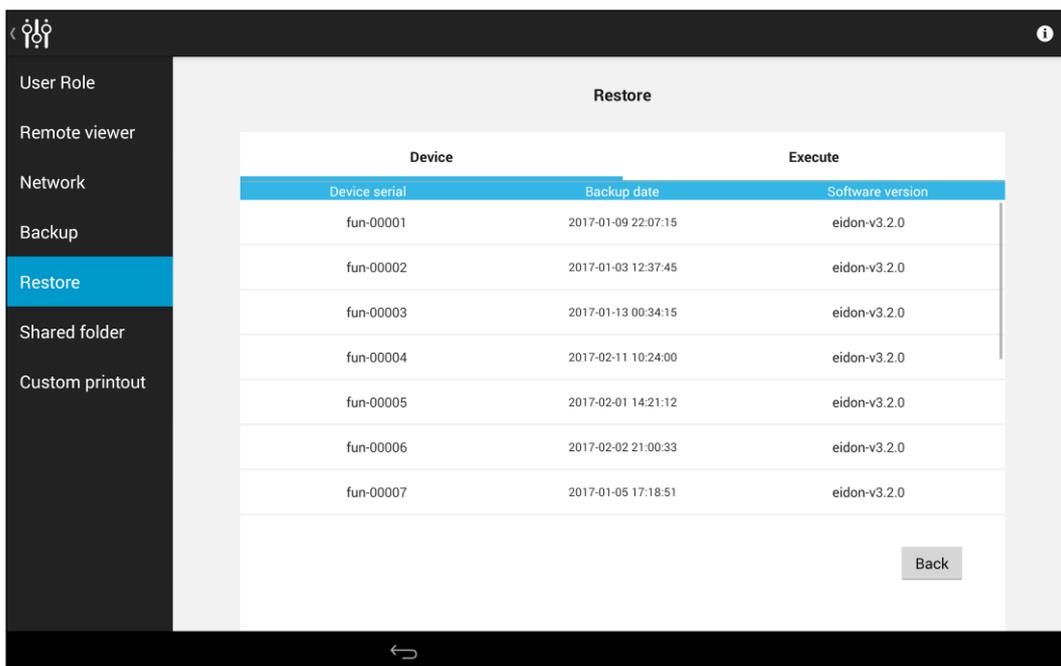


Fig. 70 – Configurator – RESTORE screen – List of available archives to be restored

- Tap on the backup to be restored to select the backup. The screen switches to the **Execute** tab. Press the **Execute** button: all the data contained in the backup media will be uploaded to the device.
- Wait until the message “Restore completed successfully” is displayed.



The restore function will not erase the Compass database: patient data will be appended.



The backup/restore system is **NOT** compatible with backup archives generated with versions older than 2.2.0. So, after upgrading from a version older than 2.2.0, it is strongly advised to perform a new full backup of the unit data right after the software upgrade in order to prevent any loss of data in case of any unpredictable hardware failure.

14.8 Shared folder configuration

Compass exams can be exported to a network shared folder, in different formats. The Shared Folder configuration tab in the Configurator app allows to edit the export parameters. Press **Apply** when the modification process has been completed.

Status

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 (see Par. 12.1, *Table 2*). If “**Auto**” is selected, data is exported automatically to the selected shared folder upon acquisition and can also be exported manually.

Connection parameters

- **SERVER:** network name of the remote host shall be inserted. The IP of the server may also be used in this field, if the network does not have a DNS.
- **FOLDER:** this field shall contain the name of the shared folder in the server.
- **USERNAME:** if you are not in a Windows Domain network, this field contains the user name used in the remote server; if you are in a Windows Domain network, the format of this field shall be: *DOMAINUSERNAME*
- **PASSWORD:** this field contains the password used by the user in the remote server

Image/Visual Field Format

Select the file format desired for the export. Images can be exported in JPG, PDF or DICOM format; Visual Field report only in PDF format.

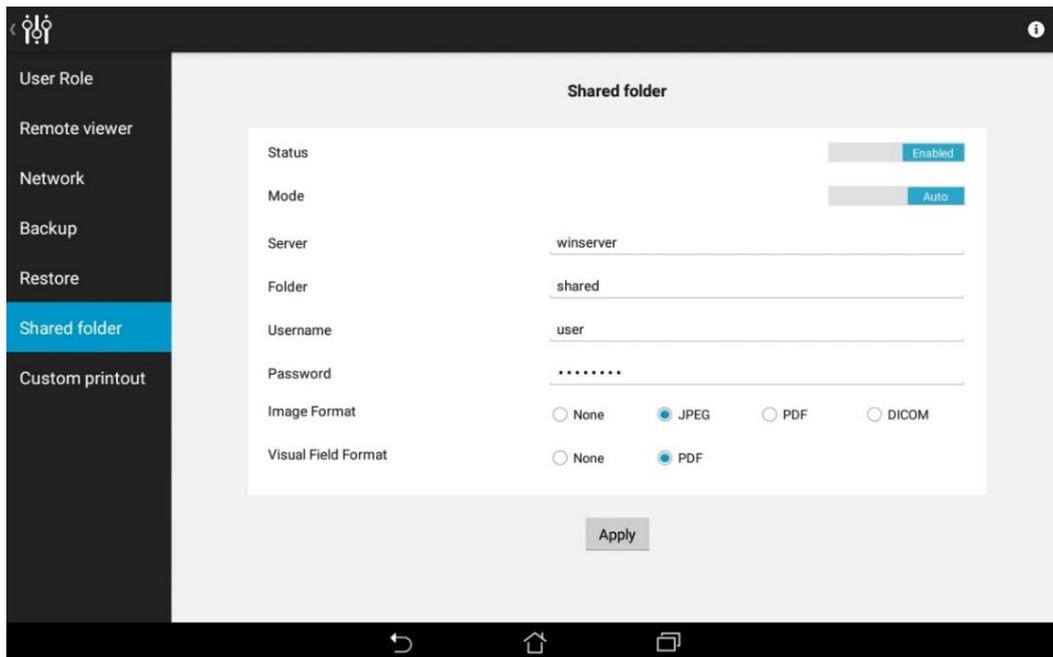


Fig. 71 – Configurator – SHARED FOLDER configuration

To check the Shared Folder connection status, check the Device Status window from the Patient List or the Patient Page interfaces (see par. 10.1).

See par. 18 for information about possible error conditions during the export process.

i COMPASS Shared Folder connectivity uses Samba protocol. Compass supports Samba connection to hosts running the following operating systems: Windows 7, 8, 10, Server 2012, and Linux.

i COMPASS natively stores all images using jpg compression. A 95% quality factor is used. **Exported images are identical to those stored in the device**, i.e. they retain the same resolution, quality factor and size.

14.9 Custom Printout Header

Compass report printouts can be customized with personal information: it is possible to add a custom logo and custom text to the header.

The logo must be a JPG or PNG image, up to 1024x1024 pixels size, and must be named `custom_header_image.jpg` (or `.png` in case of a PNG image).

The text information must be up to 5 lines and must be stored in a file named `custom_header.txt`.

To set the custom header, save the two files above in a USB storage device and plug it into Compass when the configurator is in the Custom Printout tab: the tablet will recognize the presence of the above files in the USB and it will be possible to import the new header with the button “**Apply header on the USB device**”.

If a custom header has been previously imported, the header is shown in the upper part of the screen. The custom header can be removed from the printouts using the “**Remove current header**” button.

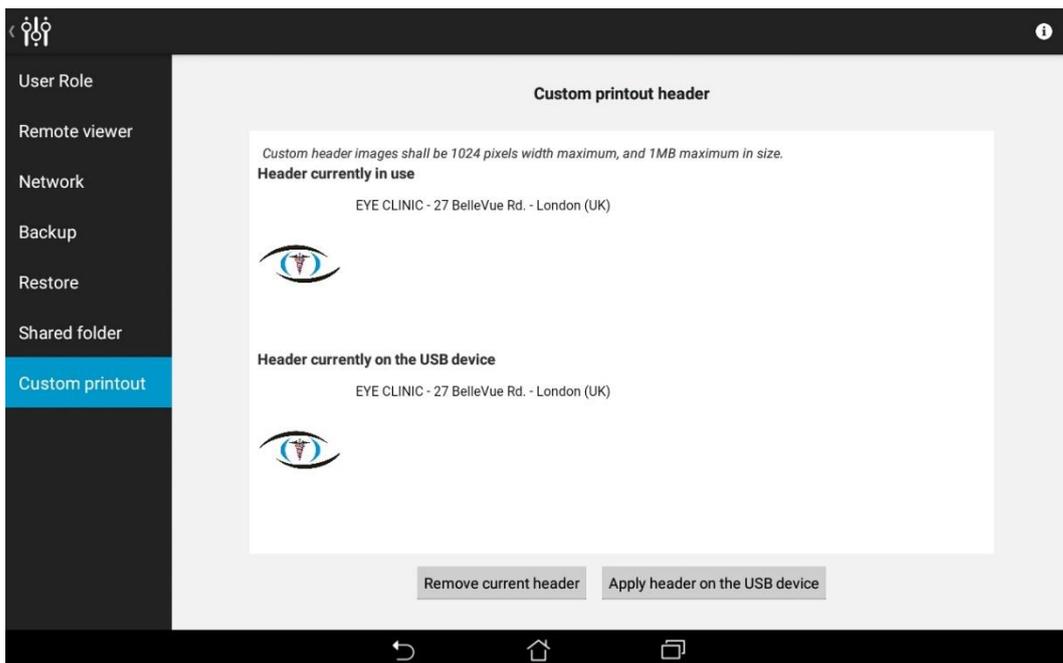


Fig. 72 – Configurator – Custom printout header configuration

15. 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.

16. TECHNICAL SPECIFICATIONS



Class and type of applied part:

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

IP classification:

IPX0 (according to 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-mydratric operation: minimum pupil size 3 mm
- Working distance: 28 mm
- Auto-focus range: -12D to +15D
- Fixation target: programmable, internal
- User interface: 10.1" multi-touch screen tablet
- 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 improvement changes without notice

17. 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. 73 - Removal of the chin rest silicon pad



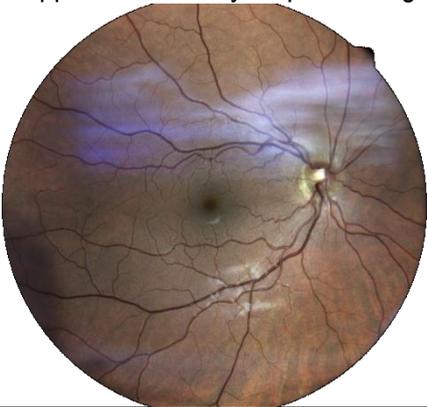
Gently pull up and slide the chin rest pad to avoid breaking the retaining peg.

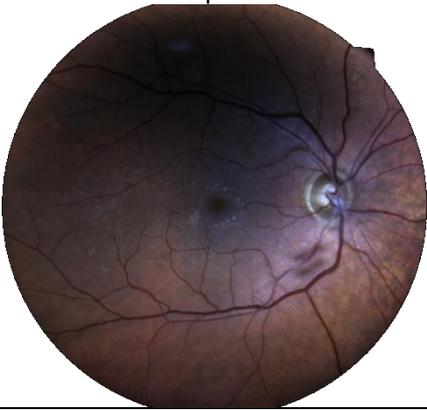
The front lens should be cleaned using a small hand pump air blower, to blow away dust. Only if really needed, for instance due to the presence of a fingerprint, the objective lens can be cleaned by means of photographic cleaning paper and a suitable lens cleaning fluid.

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

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

18. 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: machine turned off or not responding" appears when trying to access the instrument	COMPASS is off	Turn COMPASS on and login again
4. Message "Disconnected: cable not connected" appears when trying to access the instrument	USB cable is disconnected from tablet and/or from device	Connect USB cable and login again
5. 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
6. Bluish artifacts as in this example appear in all newly acquired images 	Front lens is dirty	Clean the front lens (see par. 17)
7. Captured image is totally white	Subject blinked during image capture	Repeat capture and ask subject not to blink
8. 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 occurs frequently, contact authorized service center
9. 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

Symptom	Possible cause(s)	Solution
<p>10. One or more dark areas appear in color and/or IR pictures</p> 	Pupil is too small (< 2.5 mm)	Dark adapt or dilate subject
<p>11. The fixation target appears de-centered approx. 3 degrees to the left/right</p>	<p>This is normal, and is due to the asymmetric shape of the “24-2” grid, which extends to the temporal peripheral area. In order to project stimuli in the extreme positions, the fixation target is shifted 3 degrees right when testing OD, and left when testing OS. The same happens for any other test grid.</p>	<p>This condition is normal.</p>
<p>12. Export to the remote shared folder fails with message “The selected host is not reachable” or “Timeout”</p>	<ul style="list-style-type: none"> • Network connection to the remote shared folder not working • write access to the selected remote folder not granted • host computer is not reachable 	<ul style="list-style-type: none"> • Check that the network cable is correctly plugged • Check that the local area network is available • Check that the remote folder is shared with write permissions <p>Check that the computer hosting the shared folder is reachable</p>
<p>13. Export to the remote shared folder fails with message “Unknown error”</p>	<p>The remote export folder was renamed after the export destination was configured</p>	<p>Re-configure the export destination</p>
<p>14. Export to the remote shared folder fails with message “The shared disk is full.”</p>	<p>The computer hosting the shared folder has a full hard disk</p>	<p>Empty some space on the host computer or change the export destination to another computer</p>

19. ELECTROMAGNETIC COMPATIBILITY

This device has been tested and found to comply with the limits for medical devices contained in IEC60601-1-2: Ed. 04 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 are connected;
- contact 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: Ed. 04

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.

Warning: other cables and accessories not provided with the Device may negatively affect EMC performance.

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, provided the following warning is heeded: 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 4: 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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	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 <5% UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	<5% UT (>95% dip in UT) for 0,5 cycle <5% UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s 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	30A/m	30A/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 5: 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> <p>$d = 1.17\sqrt{P}$</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</p>
Radiated RF IEC61000-4-3	See TABLE 9 of IEC 60601- 1-2	See TABLE 9 of IEC 60601-1-2	<p>frequency range^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p>  <p>In any case portable RF communications equipment, including antennas, can effect medical electrical equipment. They should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer.</p>
<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 6: Electromagnetic Immunity (ISO 60601-1-2:2007 5.2.2.2)

IMMUNITY pass criteria

#	Function	IMMUNITY pass criteria
1	Images display	During the applied testing stimulus artefact or distortion in the image are acceptable
2	USB3.0 connection between PC and control board	During and after the applied testing stimulus - for field > 20 V/m, lost connection between USB3 and PC is accepted if service error is displayed
3	System functioning	During the applied testing stimulus, temporary cessation or interruption of any intended operation is acceptable

Table 7: Electromagnetic Immunity (ISO 60601-1-2)

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 8: Recommended Separation Distances

Wi-Fi Module Advantech EWM-W135F01E:

Specifications

Main Chipset	Atheros AR9382
Tx/Rx	2Tx/ 2Rx MIMO
Standard Conformance	IEEE 802.11 a/b/g/n dual-band (2.4 and 5 GHz) standard
Interface	PCI Express mini-card rev. 1.2
Operation Voltage	DC 3.3V \pm 5%
Power Consumption	Continue TX: 1815 mW (Avg.) (802.11 a)
Security	64/128/152 bit WEP, WPA, WPA2, 802.1x, AES-CCM & TKIP

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.

20. 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 2012/19/EU establishes separate collection for Waste Electrical and Electronic Equipment (WEEE). Users of Electrical and Electronic Equipment (EEE) must not dispose of WEEE as unsorted municipal waste, but collect such WEEE separately. The available return and collection system is defined by the local public administration, or alternatively an authorized company can recycle the WEEE. Please refer to public administration about separate collection; if this information is not available, contact the equipment manufacturer. Users play a major role in contributing to the reuse, recycling and recovery of WEEE. The potentially dangerous substances contained in WEEE can pollute the environment and produce harmful effects on human health. Below is a list of specific hazards related to 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).

