

compass

User Manual

MANUAL INFORMATION

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centervue

The information in this manual is correct at the date of issue. The device configuration can change as product improvements are incorporated and this manual may not exactly depict your device. Please contact the local distributor if you have any questions about differences. The original language of the COMPASS Operating Manual is English: in case of conflict of terms, the English version shall prevail.

CONTENTS

1. INTRODUCTION	4
2. DEVICE	5
2.1 COMPASS (p/n AMGSDME001)	5
2.2 The User Control Interface (tablet).....	6
3. LABELS	8
4. SYMBOLS	9
5. PREPARING THE DEVICE	10
5.1 Assembling the tablet support bracket	10
5.2 Attaching the Magnetic Light Shield	11
5.3 Turning on the Device	12
6. PREPARING THE PATIENT	13
7. WARNINGS AND PRECAUTIONS	14
8. NOTES FOR THE END USER	16
9. DICOM SUPPORT	16
10. PATIENT LIST AND PATIENT RECORD.....	17
10.1 Device status.....	17
10.2 Adding a new patient.....	19
10.3 Searching for an existing patient.....	19
10.4 Selecting an existing patient	19
11. PERFORMING THE TEST	21
11.1 COMPASS test modalities	21
11.2 Initiating a new Visual Field root test.....	22
11.3 Initiating a Visual Field follow-up test	22
11.4 Initiating a Supra-Threshold test	22
11.5 Initiating a new Fundus/Fundus Stereo test.....	22
11.6 Choosing test parameters	23
11.7 Before starting.....	24
11.8 During the test.....	25

11.9	Auto-alignment	28
11.10	Retinal tracking	28
11.11	Monitoring test progress.....	29
11.12	Other exam types: SUPRATHRESHOLD tests	31
11.13	Other exam types: FUNDUS and FUNDUS STEREO test.....	32
12.	REVIEWING RESULTS	33
12.1	Individual test results review	35
12.2	Reliability indices.....	36
12.3	Creating a Progression Report.....	38
12.4	SupraThreshold exams review.....	39
12.5	Fundus exam review and Stereo 3D Viewer	41
12.6	Remote Viewer.....	43
13.	PRINTING	52
13.1	Printer Setup	52
13.2	Report for 24-2 test	54
13.3	Report for 10-2 test	57
13.4	Report for 30-2 test	58
13.5	Reports for the SupraThreshold exams	59
13.6	Fundus Report	61
13.7	Progression report.....	62
13.8	Dual printout / Stereo report.....	66
14.	SETTINGS	67
14.1	Launching the Configurator	67
14.2	Device lock reset procedure.....	67
14.3	Date and time settings	67
14.4	Users Passwords	67
14.5	Exam parameters.....	68
14.6	Remote Viewer.....	69
14.7	Network configuration	70
14.8	Backup	71
14.9	Restore	75
14.10	Shared folder configuration	76
14.11	Custom Printout Header.....	78
15.	DEVICE SHUTDOWN	78
16.	TECHNICAL SPECIFICATIONS	79
17.	CLEANING	80
18.	TROUBLESHOOTING	81
18.1	REMOTE ASSISTANCE	83
19.	MAINTENANCE	84
20.	ELECTROMAGNETIC COMPATIBILITY	85
21.	DISPOSAL	91

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, COMPASS 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 environment where OPERATORS (end users) with medical training are continually available when patients are present.

Device-specific training is required for any end user (operator) to become able to use the device.

2. DEVICE

2.1 COMPASS (p/n AMGSDME001)



Fig. 1 - COMPASS



Fig. 2 – Detail of connectors side



Fig. 3 – Patient Push Button



The main parts of COMPASS consist of:

- Device with the COMPASS User Control Interface (tablet);
- External Power Supply¹;
- Patient Push Button²

For a list of all components included with COMPASS, see the Content list in the package.

2.2 The User Control Interface (tablet)

The COMPASS User Control Interface (from now on, the tablet) is an integral part of the device 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 It is a device component, model MDS-150AAS12-BA manufactured by Delta Electronics. It features 100-240 VAC, 50-60 Hz and a consumption of 80 W.

² The Patient PushButton is a device component, manufactured by CenterVue.

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.

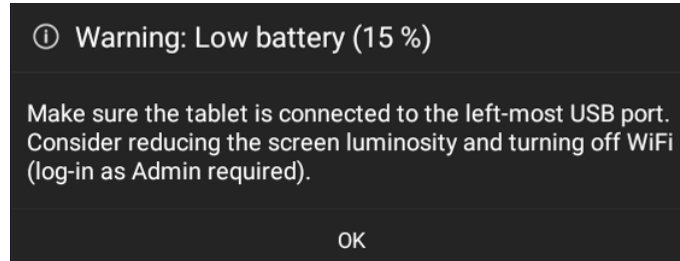


Fig. 4 – Warning message when the battery charge decreases to 15%

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:

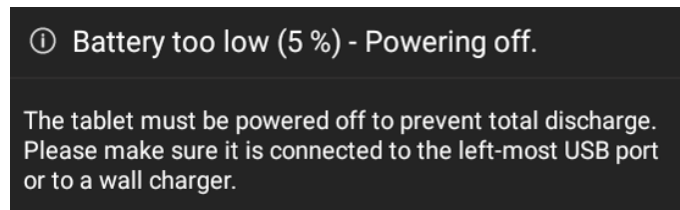


Fig. 5 – Warning message when the battery charge decreases to 5%

To maximize the duration of the charge:

- set the screen brightness to “Auto” or anyway not to maximum;
- plug the tablet in the left-most USB port (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.

3. LABELS

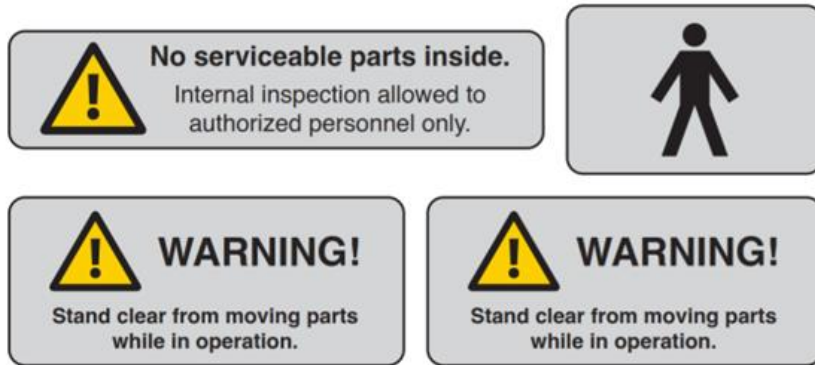


Fig. 6 – Warning labels

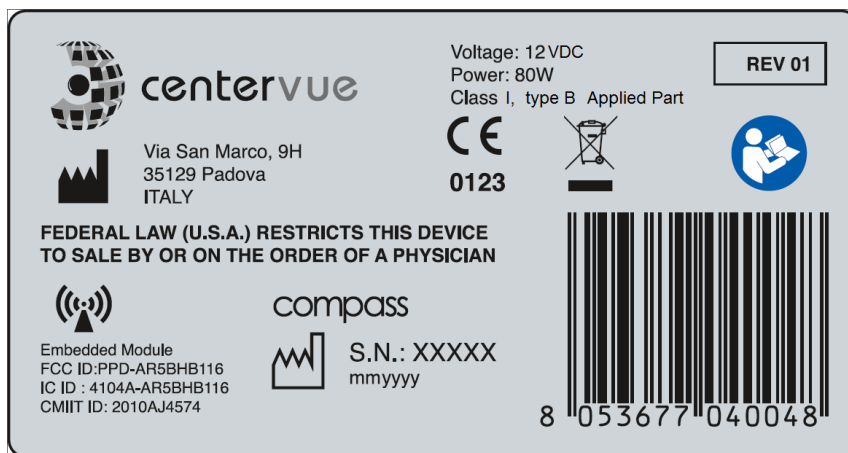


Fig. 7 – COMPASS main label











Fig. 8 – COMPASS UDI label



Labelling might be subject to changes depending on local regulatory requirements

4. **SYMBOLS**

The meaning of the symbols adopted in labels is as follows:

Symbol	Explanation
	Manufacturer Data
	Manufacturing Date (mmyyyy where mm is 2-digit month and yyyy is 4-digits year)
S/N	Device serial number (where nnnnn is 5-digit serial number)
	In Europe, electronic and electric devices must be recycled. See the par. 21 for device disposal.
	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
	General Warning Sign

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

Symbol	Explanation
	General warning, read carefully
	Important information

5. PREPARING THE DEVICE



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 device from its box;
- place it on a suitable electrical table³;
- insert the Headrest silicone cushion on the metal support (see Fig. 9);
- mount the support bracket provided for the tablet (see par. 5.1 below);
- connect the Patient Push Button cable to the connector located underneath the device;
- connect the External power supply provided with the unit to the power inlet (see Fig. 2);
- place the tablet on its support bracket and connect it using the cable to the left-most USB port;
- plug the power supply to the wall socket.

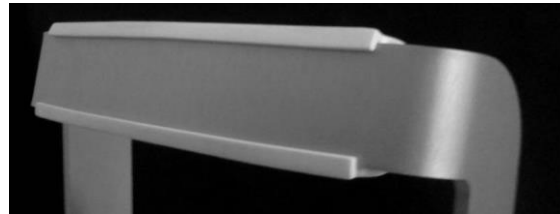
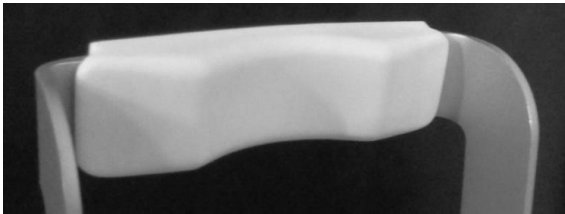


Fig. 9 - Headrest silicone cushion mounted on metal support

5.1 Assembling the tablet support bracket

The tablet is mounted, using the included support bracket (see Fig. 11), towards the posterior part of the device, on any side. The support bracket 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 support bracket use holes marked 1 and 2. Other configurations can be chosen, based on the user's preferences.



Fig. 10 – COMPASS tablet mounted on the left side of the device

³ Not provided with the device. For a list of all components included with COMPASS, see Content List in the package



Fig. 11 – COMPASS User Control Interface support bracket



Fig. 12 – Instrument bottom with holes for tablet support bracket

5.2 Attaching the Magnetic Light Shield

The Magnetic Light Shield is a device component⁴ 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 Light Shield will adhere magnetically to the frame (see Fig. 13).



Fig. 13 – Magnetic Light Shield mounted on COMPASS

⁴ The Magnetic Light Shield is delivered with COMPASS since September 2017. For information about how to purchase these components, please refer to your local distributor.

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.

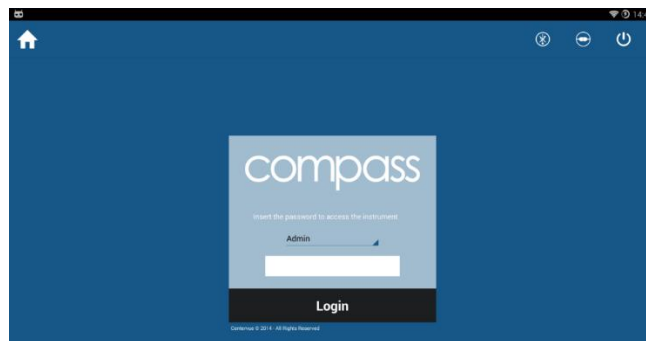


Fig. 14 – Login screen

From the drop-down menu select “Doctor”, type the password⁵ 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. 14.4.

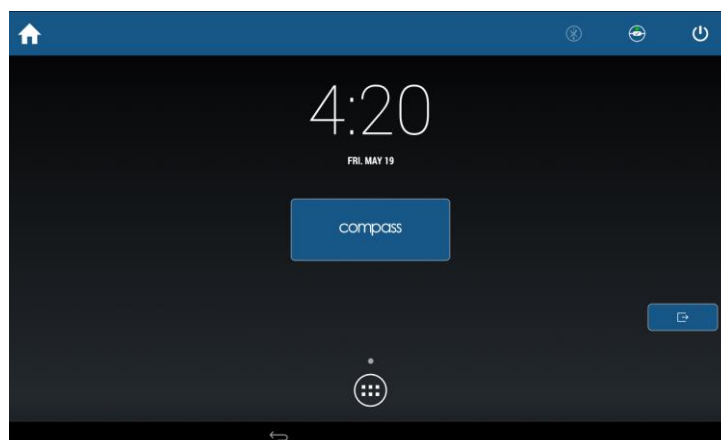


Fig. 15 - Home screen

⁵ To find out the default password please contact an authorized CenterVue representative

6. PREPARING THE PATIENT

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

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

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

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

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

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

COMPASS is a non-mydriatic device: there is no need to dilate the patient's pupil 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:



- patient should sit in a comfortable position, with the forehead and chin in firm contact with the rests;
- height of the table and chair should be adjusted so that the patient can comfortably place her/his chin on the corresponding rest;
- the patient's head should be vertical (not tilted forward / backward);
- chin rest should be positioned so that the patient'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 patient about the following:



- COMPASS will test your ability to perceive light while looking at a steady target.
- the test is non-invasive, 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 to use the device in 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 end user to become able to use COMPASS.
- Do not open COMPASS: this could lead to electric shocks or damage to the device.
- Do not use COMPASS if the cover or other parts of the device have been removed.
- Only technicians authorized by CenterVue may service COMPASS. CenterVue cannot be held responsible for device safety should COMPASS be opened, repairs carried out, third parties' software be installed, or parts be replaced by unauthorized people.
- Do not expose COMPASS to water: this could lead to fire or electric shock.
- Stand clear from moving parts during operation.
- COMPASS is supplied with an earth ground by means of a protection conductor contained inside the power supply cable. Before turning on the device, make sure the power supply socket is correctly grounded to avoid the risk of electric shock.
- COMPASS 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. 14.2 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
- External devices connected to COMPASS, into the patient environment, must comply with IEC 60601-1. Those devices that do not comply with the IEC 60601-1 must be kept out of the patient environment and must comply with IEC 60950-1. Any operator (end user) who connects external devices COMPASS creates a new Medical Electrical System as defined by IEC 60601-1 and is therefore responsible of the conformity of such system with the requirements defined in clause 16 of IEC 60601-1. Please contact the local distributor for any additional information.
- When in operation, COMPASS contains Personal Data. IT IS THE END USER'S RESPONSIBILITY TO KEEP AND MAINTAIN AN UPDATED COPY OF THE DATA GENERATED BY COMPASS THROUGH REGULAR USE OF THE BACKUP FACILITY (see par.14.8), THUS PREVENTING THE RISK OF ACCIDENTAL LOSS OF DATA.

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.

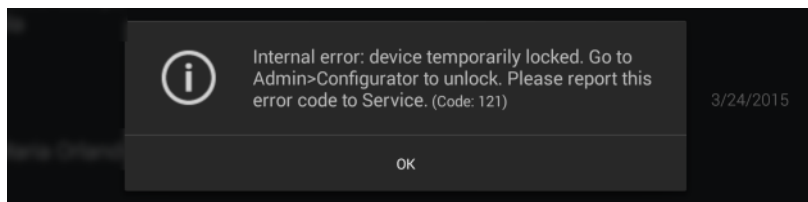


Fig. 16 – Example of error message

8. NOTES FOR THE END USER

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 device

In particular, the end user (operator) shall be acquainted with the following concepts:

- **Alignment:** the action of moving the top part of the device so that its optics are aligned with a patient's pupil
- **Exam:** any image/data acquisition performed using COMPASS for a certain patient on a certain date, in this manual the terms "test" and "exam" are used as synonyms;
- **Fixation / fixating:** the ability of a patient to stare at a specific point in space and specifically the COMPASS internal fixation target;
- **Focusing:** the compensation, by means of internal optics, of a patient's spherical defect (myopia, hyperopia);
- **Optic disk:** a specific portion of the retina characterized by a roughly circular shape and by outgoing / incoming vessels;
- **Pupil:** it is the opening located in the centre of the iris, of variable diameter, which allows light to enter the eyeball. The pupil naturally is open (dilated) and contracts when struck by light. If the pupil is too small the image quality may be impaired;
- **Retina:** the internal surface of the eyeball;
- **Sensitivity threshold:** the minimum intensity of a light stimulus that is perceived by a patient 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 natively.

Purchasing with an additional license, COMPASS also supports full DICOM communication, as specified in the **COMPASS DICOM Conformance Statement document**⁶. For info about how to use COMPASS with DICOM, refer to the **COMPASS DICOM Operating Manual**.



DICOM support is available only for wired connections.

⁶ Ask to your local distributor for purchasing a DICOM license, and 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. 14.8.

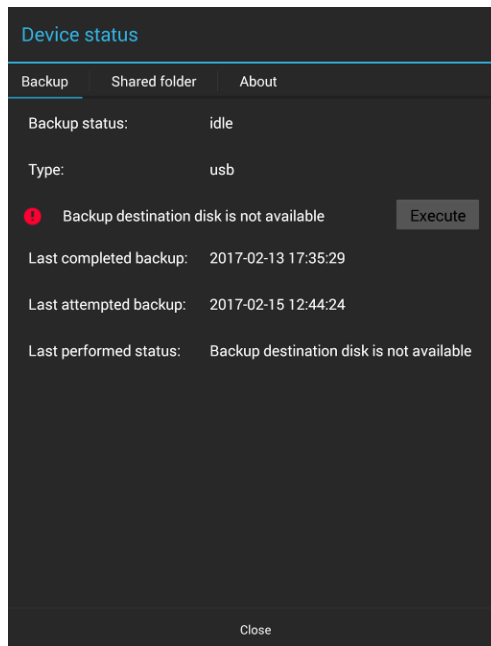


Fig. 18 – Device status screen – Backup status

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

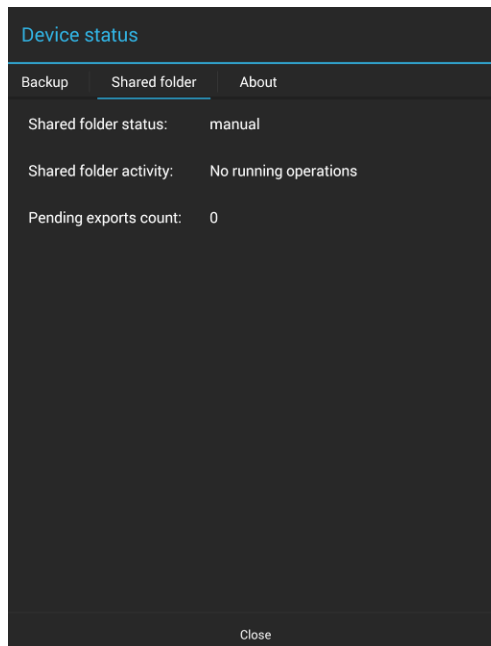



Fig. 19 – Device status screen – Shared folder status

About tab

The About tab contains information about the software release version installed, the unit serial number, 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.

If a patient with the same last name, first name and birth date already exists in the unit database, a warning message will pop-up suggesting to select the existing one instead of the new one, in order to avoid undesired patient duplications.

10.3 Searching for an existing patient

To search for an existing patient, click on  and type the initial letters of the name, surname or code 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.

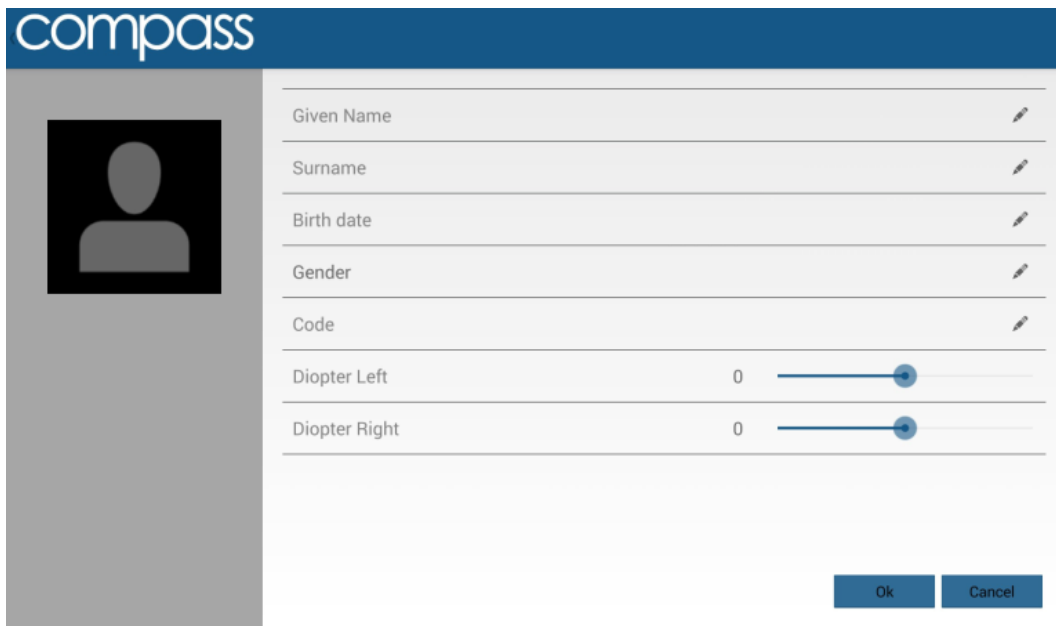


Fig. 20 – Patient editing screen

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.

M R

7/9/1979 (37)
 Gender
 Code
 Diopters R:0 L:0

11/5/2015
 one Exam

7/2/2015
 3 Exams

6/12/2015
 10 Exams

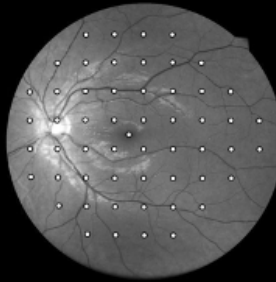
4/30/2015
 one Exam

4/29/2015
 5 Exams

1/30/2015
 5 Exams

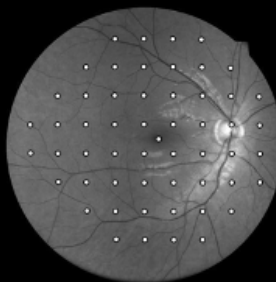
OS

Date 6/12/2015, 2:03 PM
 Type Visual field - root
 Pattern 24-2 54/54
 Strategy Zest
 Duration 06:30
 Focus 1.6
 Pupil size **2.7 mm**
 FN 0 %
 FP 0 %
 BS **2/6**
 MD 2.96 dB
 PSD 3.94 dB
 FPD1 99 %
 Tracking ON



OD

Date 6/12/2015, 1:43 PM
 Type Visual field - root
 Pattern 24-2 54/54
 Strategy Zest
 Duration 06:37
 Focus 0.9
 Pupil size **2.8 mm**
 FN 0 %
 FP 0 %
 BS 0/7
 MD 0.63 dB
 PSD 6.85 dB
 FPD1 97 %



+ New Exam

OD Right eye

- > zest 24-2 5/18/2017
- > zest 30-2 5/17/2017
- > zest New Grid 5/17/2017
- > zest small test grid 12/4/2015
- > zest 24-2 11/9/2015

OS Left eye

- > zest 24-2 5/17/2017
- > zest small test grid 7/2/2015
- > zest small test grid 6/12/2015
- > zest 24-2 6/12/2015
- > zest small test grid 6/12/2015



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 patient’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 **Visual Field test** allows to determine the sensitivity thresholds for each location identified by the selected test grid, using the selected projection strategy (4-2 and ZEST are available). Visual Field (VF) tests allow to monitor the progression of retinal sensitivity by performing follow-up sequences:
 - a **root test** is the first performed on a certain patient 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 **SupraThreshold test** allows to perform a quick assessment of the retinal sensitivity, without determining the threshold for each location;
- the **Quick SupraThreshold test** allows to perform an even faster assessment of retinal sensitivity, using the same projection strategy of the SupraThreshold test on a smaller grid (see Fig. 31), and with speed optimizations
- 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. End users 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 Visual Field 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 Visual Field 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 **SupraThreshold** test, click on the **New Exam** button, and select **SupraThreshold** or **Quick SupraThreshold** using the test type selector. For a description of the exam flow of the SupraThreshold test, refer to par. 11.12.

11.5 Initiating a new Fundus/Fundus Stereo 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 the test parameters.

The following commands / functions are available:

1. Test type selection (**Visual field**, **Suprathreshold**, **Quick SupraThreshold**, **Fundus** or **Fundus Stereo**);
2. Eye selection (**OD**, **OS**, **OU**). OU option is currently available for **Quick SupraThreshold** tests only;
3. For Visual Field tests only, selection of the threshold strategy (**ZEST** or “**4-2**”);
4. For perimetric tests, the current exam configuration as determined by fixed and configurable settings (see Table 1);
5. Chin-rest height adjustment;
6. For perimetric tests only, selection of the test grid (or pattern);
7. Test start;
8. Back to Patient Record screen.

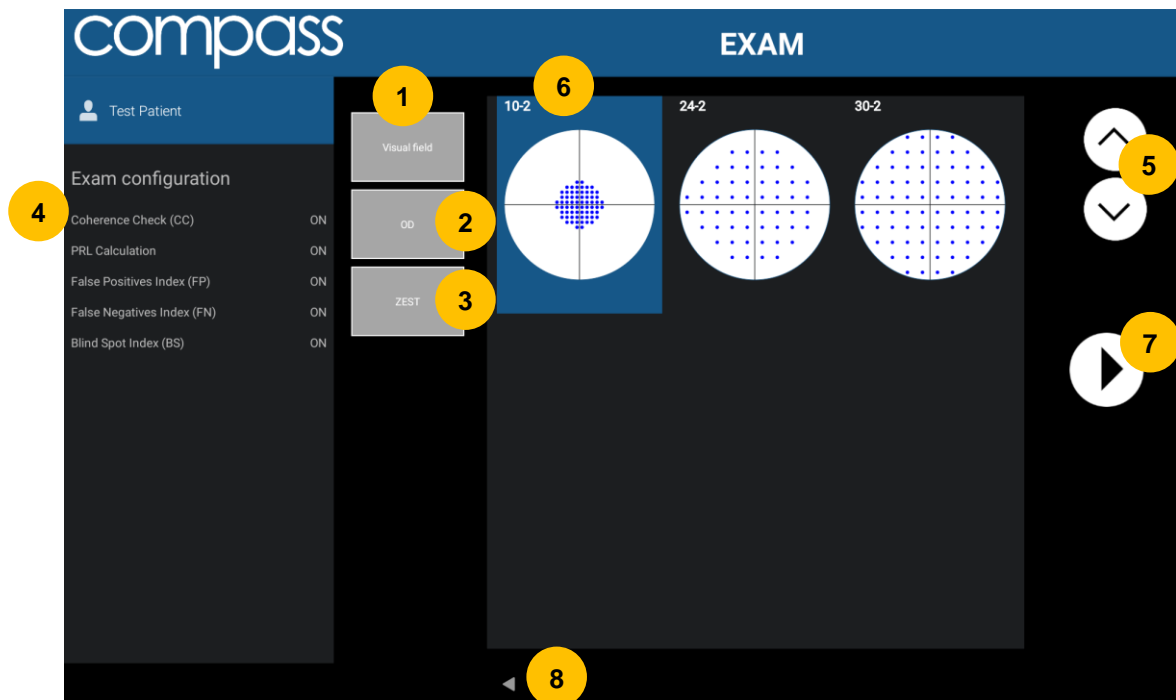



Fig. 22 – Test parameters selection screen

ZEST vs. 4-2

 Zippy Estimation by Sequential Testing (ZEST) is an adaptive Bayesian method for determining sensitivity measures. ZEST, that is similar 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
- 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.



The following settings may be fixed or configurable, depending on the selected test type. For a description of the Reliability indexes refer to par. 12.2. For the settings configuration, refer to par.14.5.

Setting	Visual Field	SupraThreshold	Quick SupraThreshold
Coherence Check (CC)	Configurable	Not available	Not available
PRL calculation	ON	ON	OFF
Foveal threshold	ON	ON	Configurable
Blind Spot test (BS)	Configurable	ON	OFF
False Positives (FP)	Configurable	ON	ON
False Negatives (FN)	Configurable	ON	OFF

Table 1 – Fixed and configurable Exam settings

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;
- patient should sit in a comfortable position, with the forehead and chin in firm contact with the corresponding rests. Patient’s head should be vertical and not tilted. Chin rest should be positioned so that eye is aligned to the mark;
- ask the patient to look at the fixation target throughout the test;
- perform a quick training on patients 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 patient's eye	Patient should not move and should look for the green fixation target. For additional details see next paragraph.
2	Auto-focus	Correct for patient's spherical refraction	Patient 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	Patient 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	Patient 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, patients 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	Patient should look steadily at the green dot and press the button when she/he sees a white spot. Patient can blink at any time. Periodically inform the patient of the progress. See note concerning eye tracking.  : if not properly instructed, patients 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	Patient 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 end user 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 tested;
- 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.

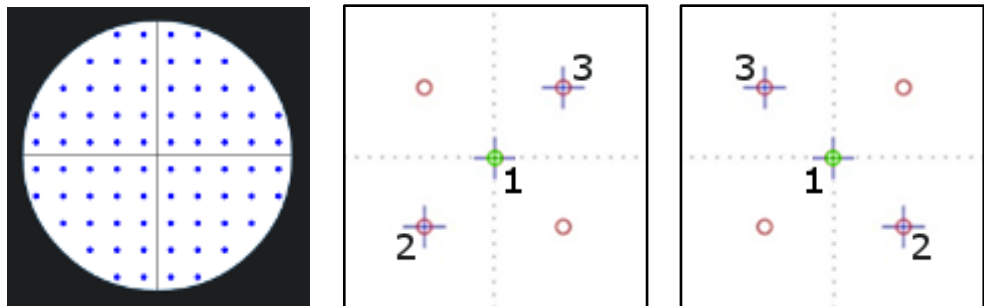


Fig. 23 – “30-2” grid test locations (left)
and fixation target positions used for OD (center) and OS (right)

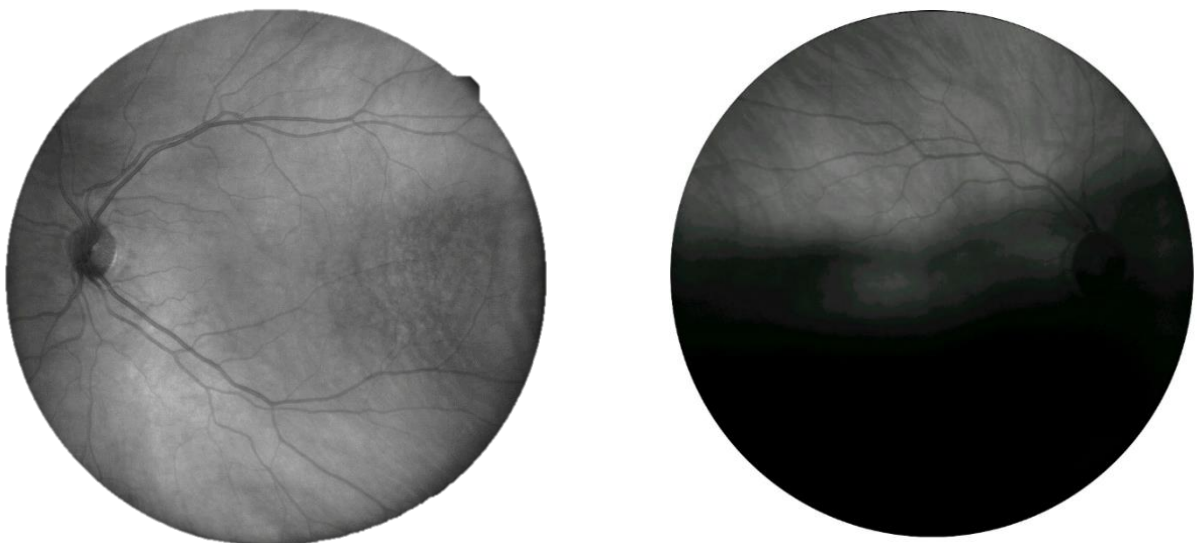


Fig. 24 – Good (left) and poor quality (right) reference image

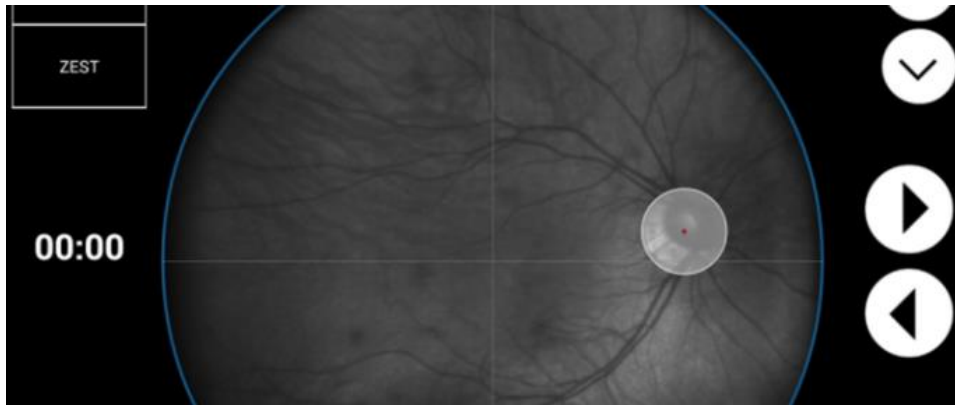


Fig. 25 – Marker for optic disc location in Exam screen

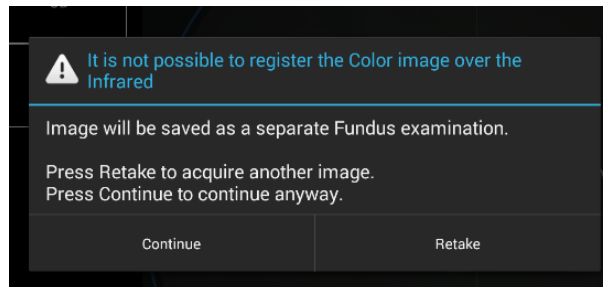


Fig. 26 – Message shown in case of Color image registration failure

11.9 Auto-alignment

Several hints may be presented on screen by the system to help the end user correct a patient's position: see Table 2 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 2 – 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 patients 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 patient position (e.g. far from forehead rest).

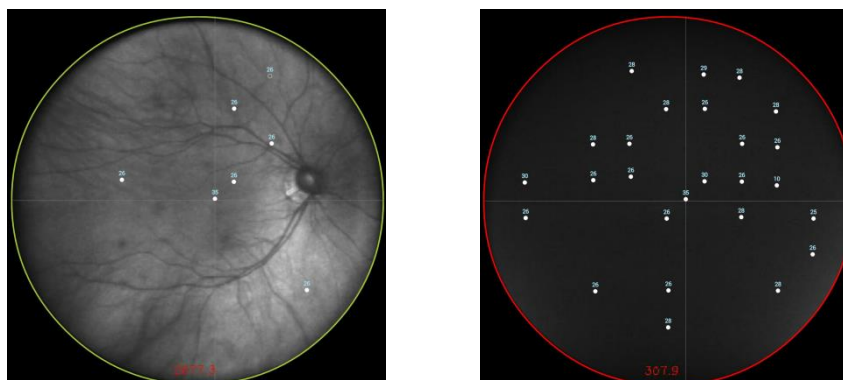


Fig. 27 – Tracking active (left) and on hold (right)

11.11 Monitoring test progress

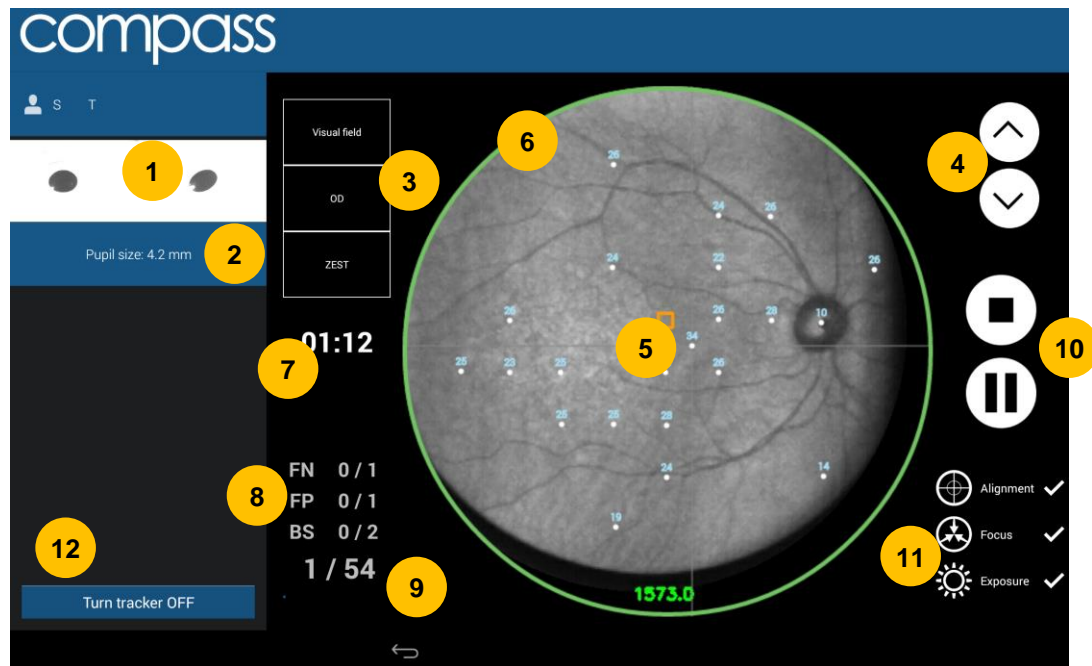


Fig. 28 – Exam screen while test is in progress

The following information and functions are available:

1. Pupil images from alignment cameras allow the end user (operator) to check if patient'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 / Quick SupraThreshold / Fundus**), eye (**OD / OS**) and strategy (**ZEST / 4-2**)
4. Buttons to adjust the height of the chinrest
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, see par. 12.2) 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 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 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.

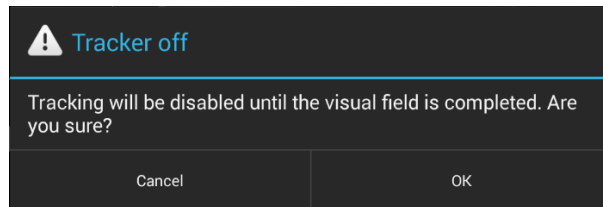


Fig. 29 – Confirmation request to disable tracking

11.12 Other exam types: SUPRATHRESHOLD tests

The **SupraThreshold** and **Quick SupraThreshold** tests have been developed to provide a quick assessment of the retinal sensitivity compared to normality values in a reduced examination time, as in SupraThreshold 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 SupraThreshold 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 based on average and standard deviation values from COMPASS normality database and are dependent on the point location and on the patient’s age. Both Suprathreshold tests are designed to quickly determine whether the retinal sensitivity falls below or above the 90th and 95th percentile of a reference population of normal subjects, without determining the actual threshold.

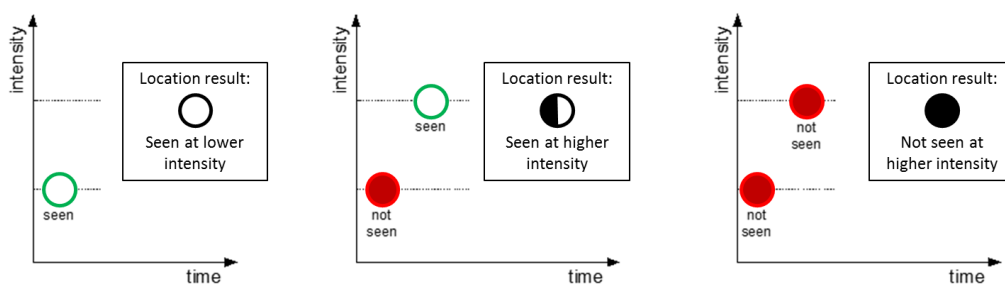


Fig. 30 – SupraThreshold test projection logic

The **SupraThreshold** test follows the same exam flow of the Visual Field Test and takes approximately 2 to 3 minutes per eye.

The **Quick Suprathreshold** test is designed to take 30 to 90 seconds per eye to complete, by means of the following optimizations:

- A reduced test grid: 24 locations instead of 52
- Possibility to select OU: OS test starts right after OD test has completed
- No PRL determination: the grid will not be centered on the PRL
- Reduced Reliability tests (only False Positives are tested)
- Possibility to disable the Fovea threshold measurement

For a complete description of the outcomes of the SupraThreshold and Quick SupraThreshold tests see par. 12.4.



The only grid available for the SupraThreshold test is the “**24-2-st**”.
The only grid available for the Quick SupraThreshold test is the “**24-2-reduced**”, which consists of a reduced subset (24 instead of 52) of the 24-2-st grid locations (see Fig. 31).

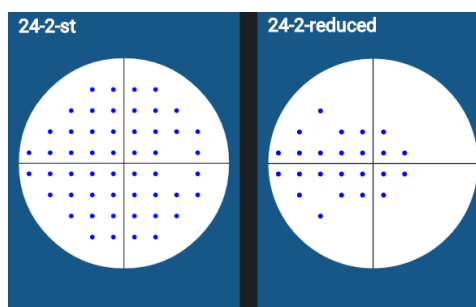


Fig. 31 – **24-2-st** (standard Suprathreshold) grid compared to **24-2-reduced** (Quick Suprathreshold)

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, 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 to let the pupil partially recover. To review stereo images, the end user (operator) should use specific 3D Prismatic stereoscopic goggles⁷, 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. 12.5.



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. 32 – Example of a Fundus image (left) and of one of a Fundus Stereo image (one of the pair) (right)

⁷ The Prismatic Stereoscopic Goggles are delivered with COMPASS since September 2017. For information about how to purchase these components, please refer to your local distributor.

12. REVIEWING RESULTS

Once a test is completed, the system will open the **Patient Record** screen (Fig. 34) for the selected patient and present a thumbnail view (Fig. 33) 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).

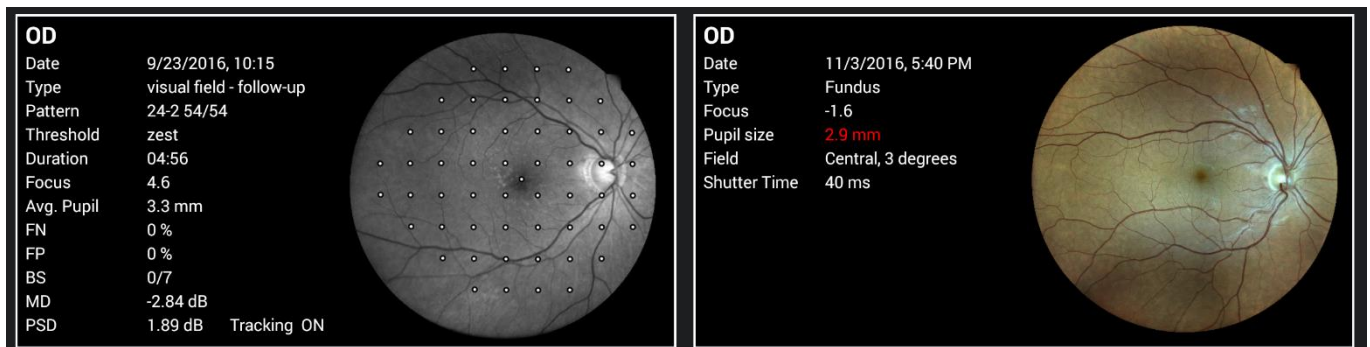


Fig. 33 – Example of thumbnails for **Visual Field** (left) and **Fundus** (right) exams



The **Fundus Perimetry Deviation Index (FPDI)** is a global index that assigns a value between 0% 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. 35);
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.

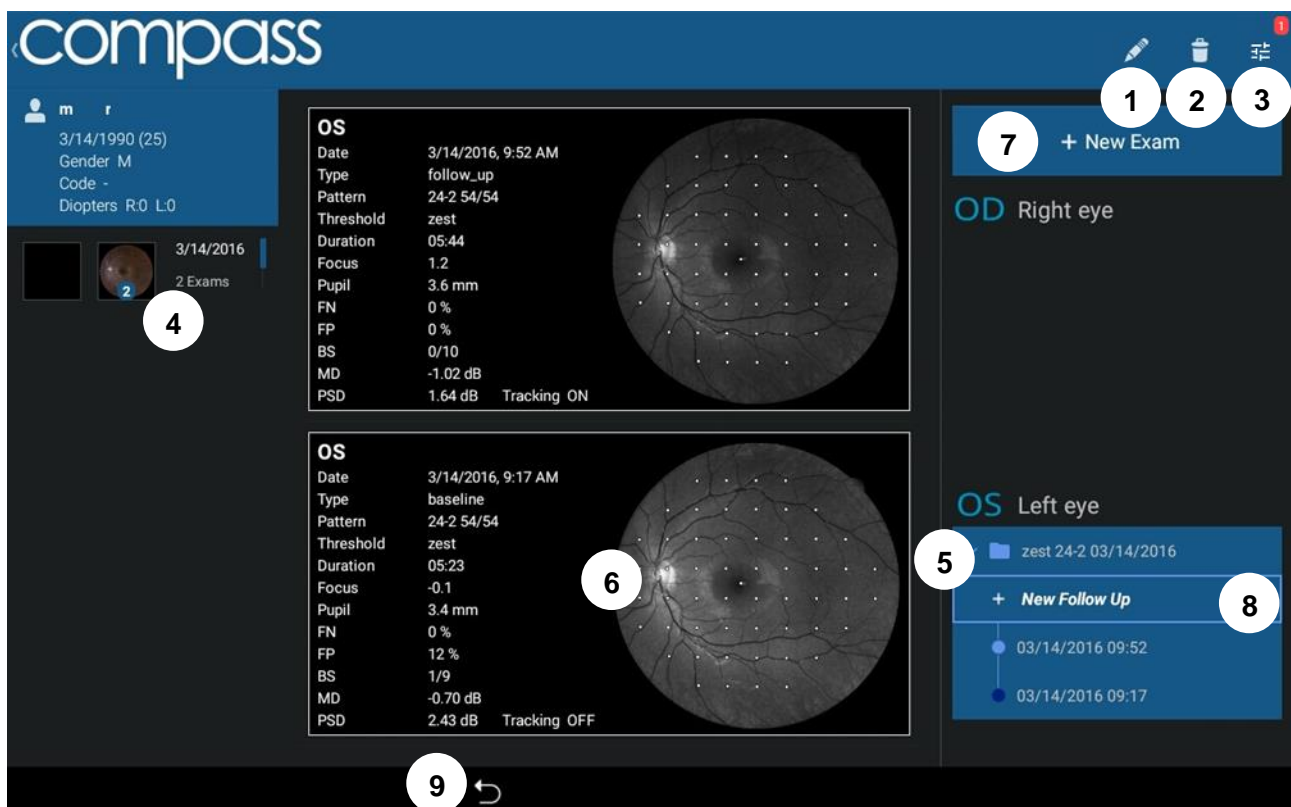


Fig. 34 – Patient Record screen

12.1 Individual test results review

The **Exam Review** screen (Fig. 35) 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 3 below)
8. Commands for report generation, storage and printout (see details explained in Table 3 below)
9. Command to go back to Patient record screen.

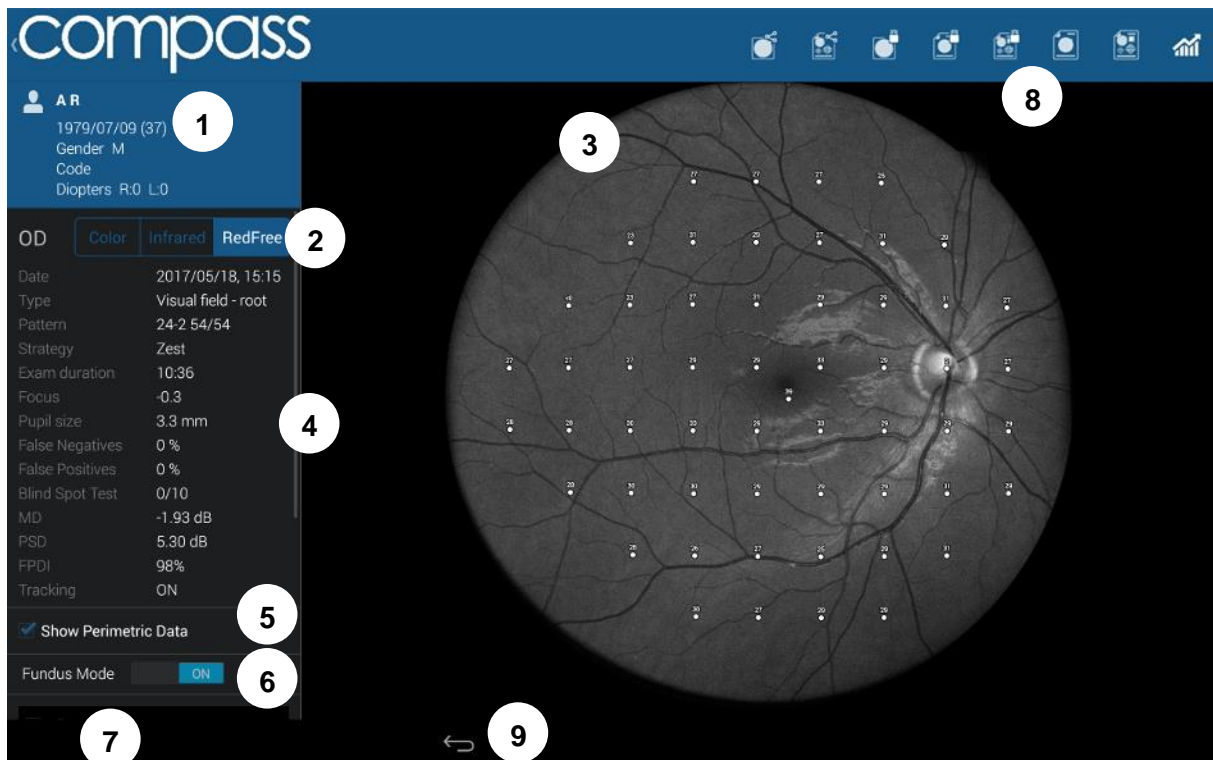


Fig. 35 – Exam review screen, red-free display modality






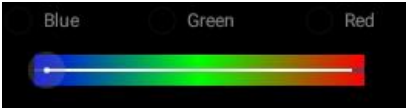
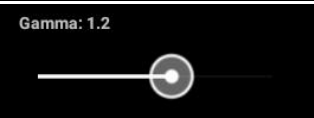
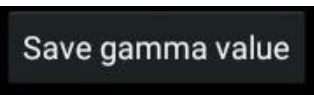
Top bar button	Description
	Export image in JPG format (first icon), fundus report in PDF format (second icon), image in DICOM format (third icon) or perimetric test report in PDF format (last icon) to a shared folder (see par. 14.10). These buttons are enabled only if the shared folder has been previously 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 3 - Exam Review buttons and related commands

12.2 Reliability indices

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

- **False Positives (FP):** these are trials in which no stimulus has been projected, therefore the patient is not expected to respond. If this index exceeds 25% the number will show in red, indicating possibly poor reliability.
- **False Negatives (FN):** 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 (BS):** 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.

Moreover, COMPASS introduces an additional test specific for Visual Field exams performed with **ZEST** strategy:

- **Coherence Check (CC)**: this test introduces additional projections (max. 1 per grid location point) to limit the effect of occasional false responses.

Depending on the selected exam type, the four above tests may be individually enabled or disabled in the Configurator app: see par. 14.5.

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. 36 – 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. 37 below) is not to be considered a way to assess the reliability of a patient / 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°)

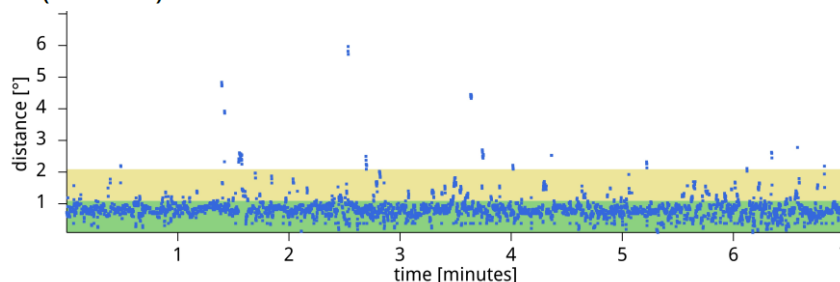


Fig. 37 – Fixation plot and Area

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 vice versa.

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. 38), 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

5 CANCEL 3 SAVE PROGRESSION TO USB 4 SAVE PROGRESSION TO SHARED FOLDER 2 SHOW PROGRESSION ANALYSIS

Fig. 38 – Progression Report test selection screen

12.4 SupraThreshold exams review

The review window of a **SupraThreshold** test (Fig. 40 and Fig. 41) 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:

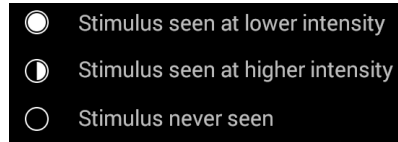


Fig. 39 - SupraThreshold responses

The MD, PSD and FPDl indices cannot be determined for a **SupraThreshold** test; instead, the responses at individual points (seen at lower intensity, seen at higher intensity, not seen) are merged 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 (if enabled).

Based on the reference database from approximately 400 eyes of normal subjects' population included in COMPASS, the **SupraThreshold Response** index represents the percentage of the population 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 normal subjects' population (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 population of normal subjects. A YELLOW outcome indicates that results lower than or equal to the present were found in only 10% of the reference of subjects of normal population. Conversely, a GREEN outcome indicates that results equal to or higher than the present were found in 90% of the reference population of normal subjects.

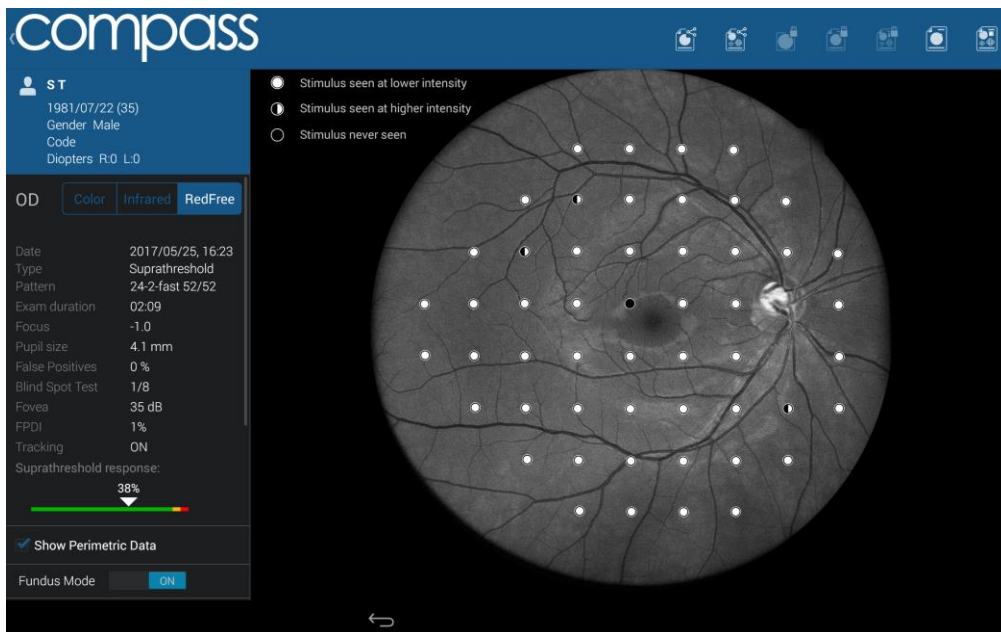


Fig. 40 - SupraThreshold exam review window

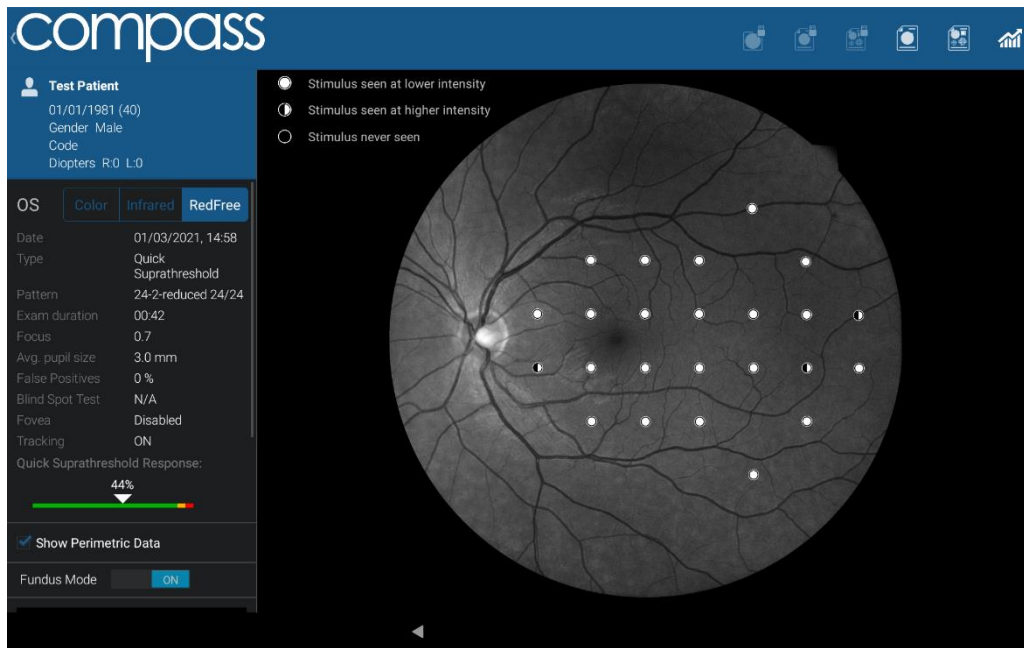




Fig. 41 – Quick SupraThreshold exam review window

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. 42).

If the image is part of a Stereo pair of images, a selector on the left panel (see point 1. in Fig. 42) 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. 34).

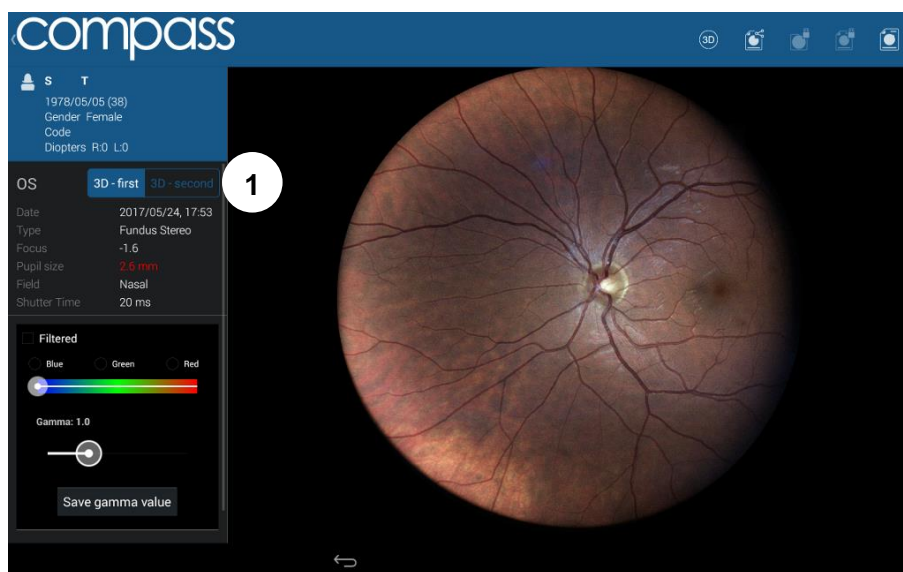


Fig. 42 - Fundus Stereo exam review window

The **Stereo 3D Viewer** window (Fig. 43) 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 goggles⁸ has to be used.

⁸ The Prismatic Stereoscopic Goggles are delivered with COMPASS since September 2017. For information about how to purchase these components, please refer to your local distributor.

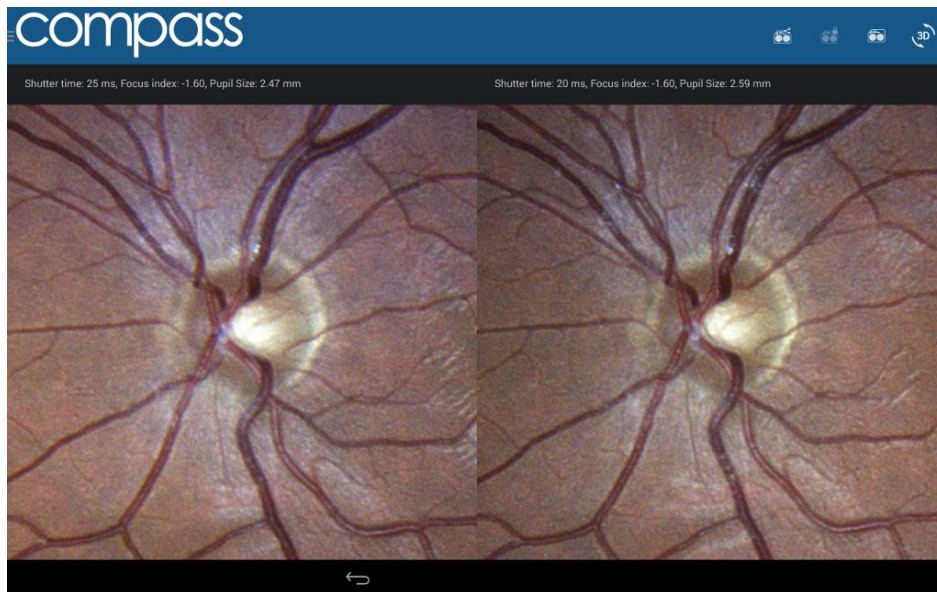




Fig. 43 - Stereo 3D Viewer

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. 6914.6

Using the Remote Viewer

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



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

- launch the Configurator application (see par. 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. 45). Click on **Logout** to exit the Remote Viewer.

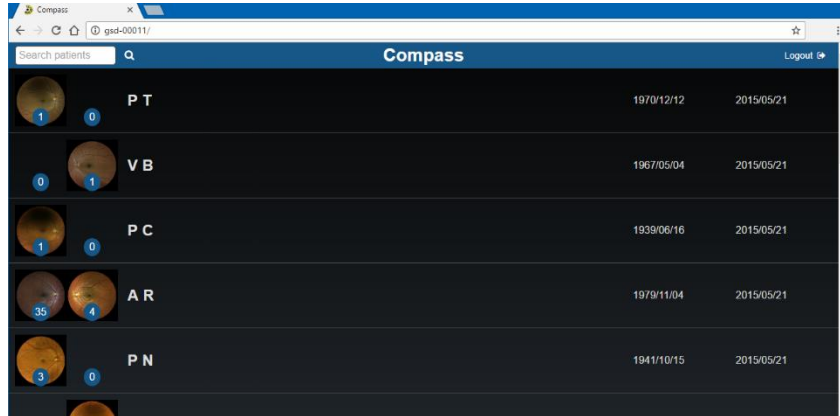






Fig. 44 – Patient List in Remote Viewer

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. Fundus exams provide only this button.
	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. 46).

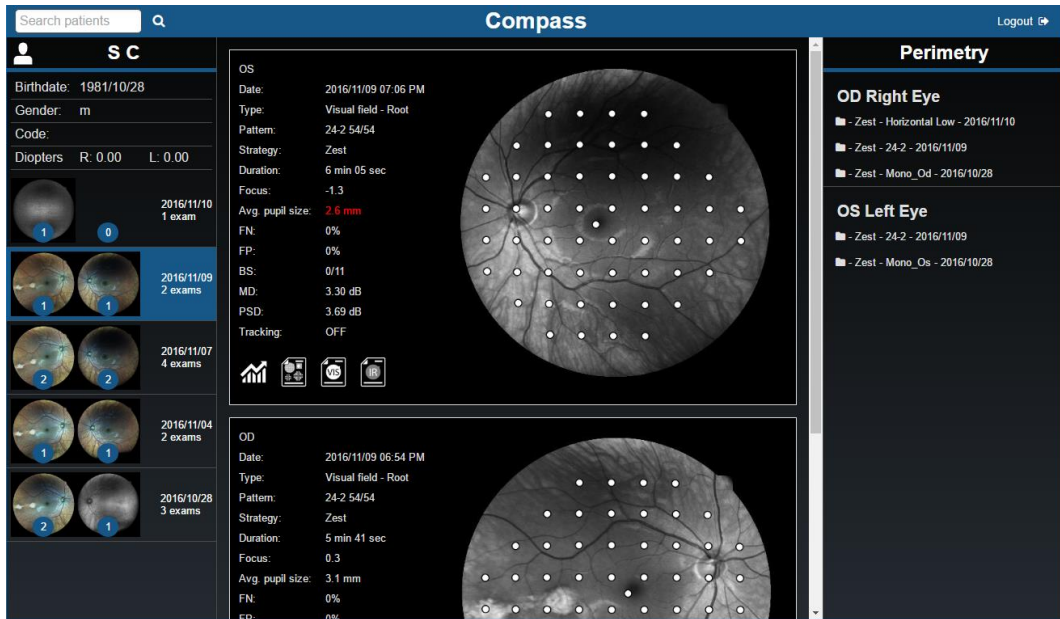


Fig. 45 – Patient Record screen in Remote Viewer

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).

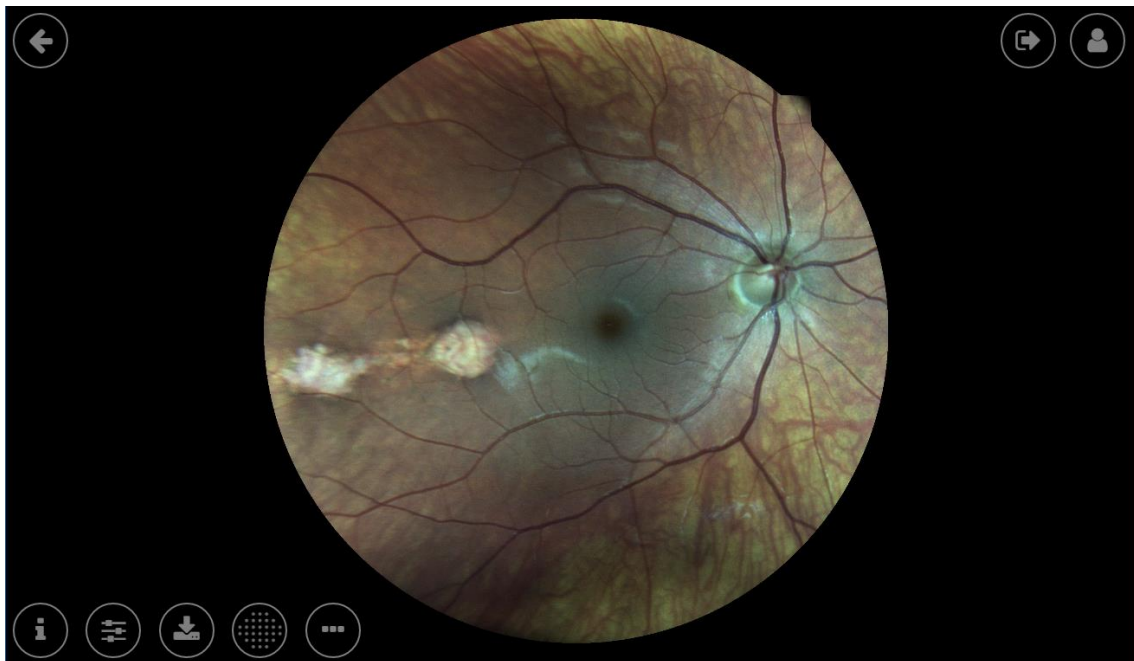











Fig. 46 – Exam Review screen in Remote Viewer

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. 49).
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. 47).
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. 47)
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

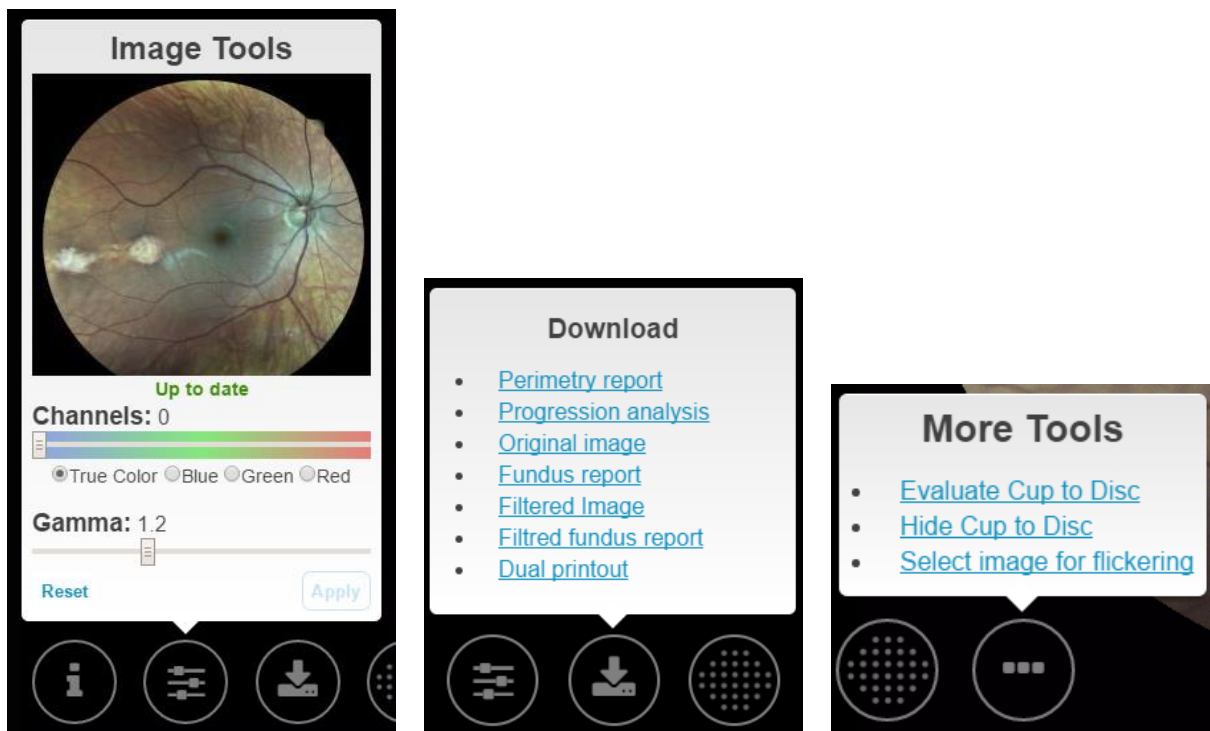


Fig. 47 – Image Filters, Download options and More Tools in Remote Viewer

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 vice versa.

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.

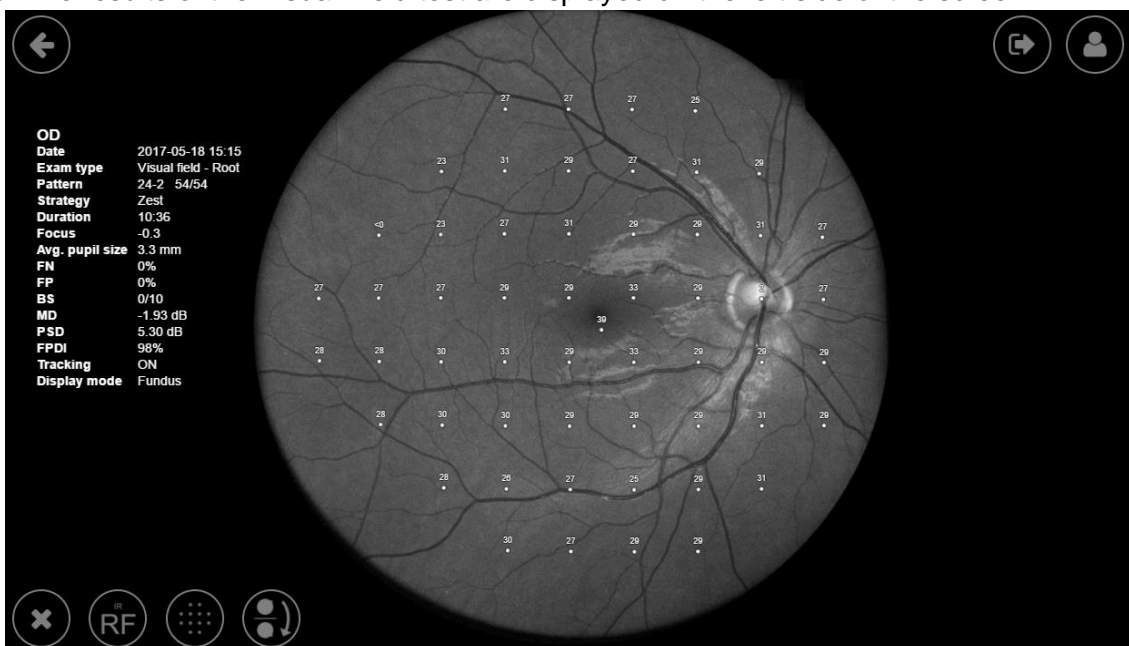









Fig. 48 – Perimetry Mode Review screen in Remote Viewer

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. 49) 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. 49 – 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. 50) 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 to overlap them (compensating shift, rotation and Color/IR distortion).

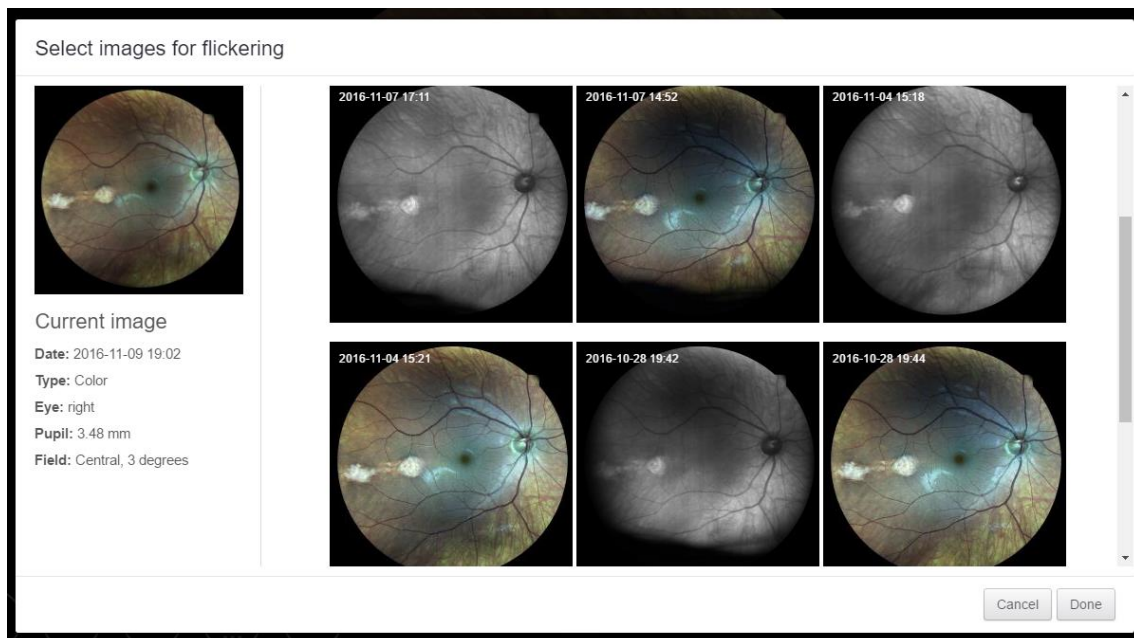


Fig. 50 – Flickering image selection

Select the image to flicker with, then click **Done**.

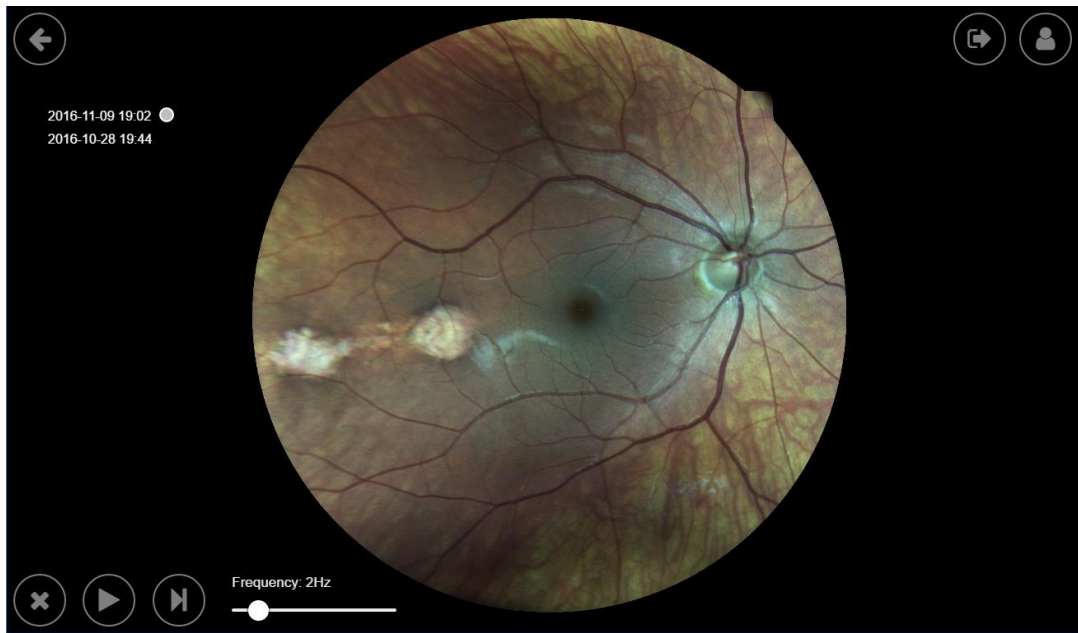


Fig. 51 – Flickering review window

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.

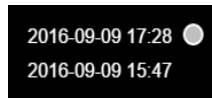


Fig. 52 – Currently active picture: “2016-09-09 17:28”

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.

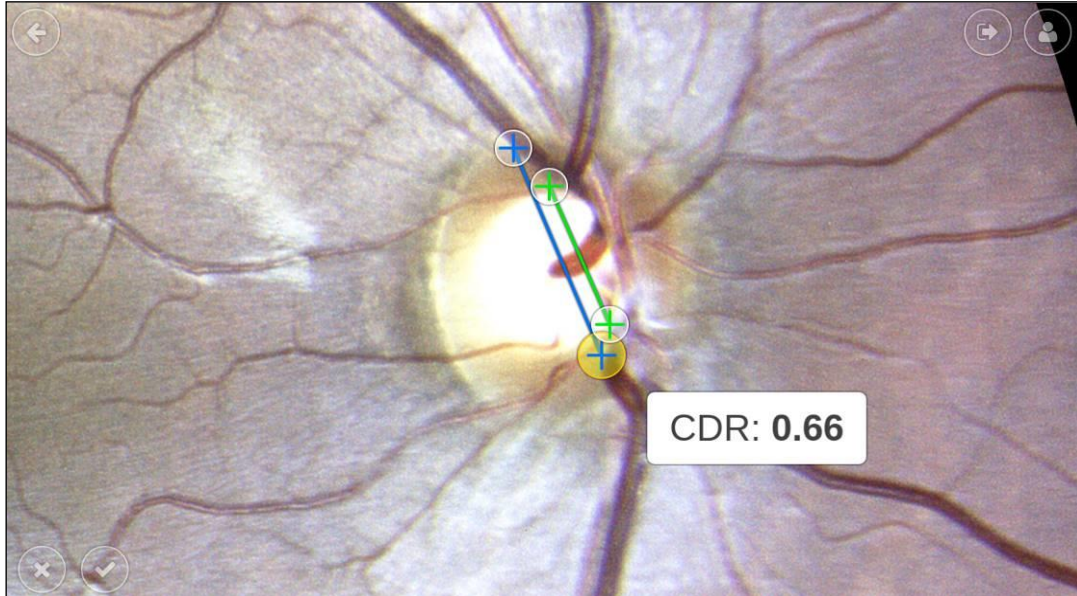


Fig. 53 – Flickering review window

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 end user (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 COMPASS tablet (see Table 4). Before choosing a printer, please check if the model is included in the compatibility list issued by the printer manufacturer for every app.

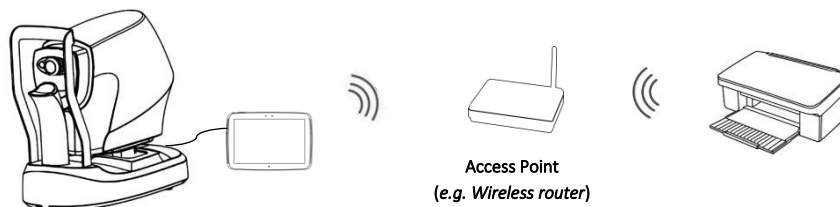
Brand	Description
HP	HP Android ePrint
Samsung	Samsung Mobile Print App
Lexmark	Lexmark Mobile Printing
Canon	Canon Mobile Printing, Canon Easy-PhotoPrint, PIXMA/MAXIFY Printing Solutions
Epson	Epson iPrint, Seiko Epson Corporation
Konica Minolta	Konica Minolta Printers, Page Scope Mobile

Table 4 – 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.

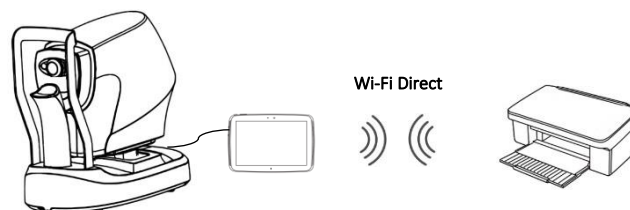
Infrastructure Mode

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



Wi-Fi Direct Mode

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



To connect the printer in Wi-Fi Direct mode, enter the "Advanced Wi-Fi" menu of the tablet settings and select the "Wi-Fi Direct" item (see Fig. 54), and proceed with pairing with the printer following the instructions provided by producer.

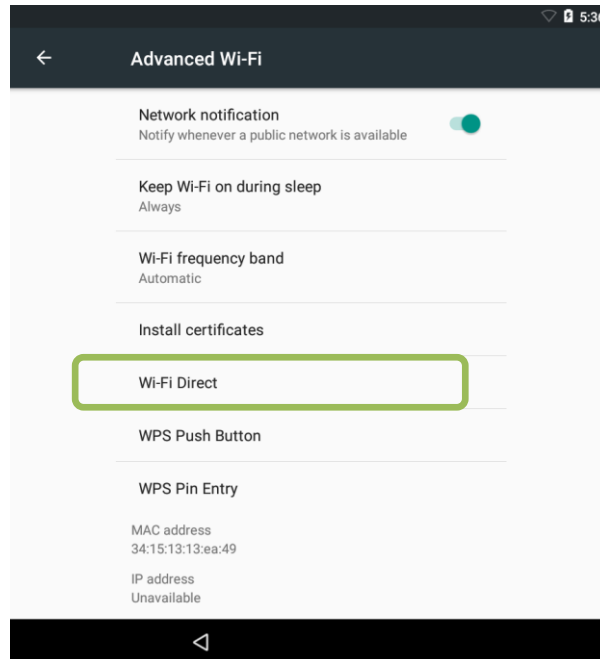


Fig. 54 – Item "Wi-Fi Direct" within "Advanced Wi-Fi" menu

Alternatively, it is possible to pair with the printer directly within the Adobe Acrobat Reader app, using the Mopria Print Service (see Fig. 55).

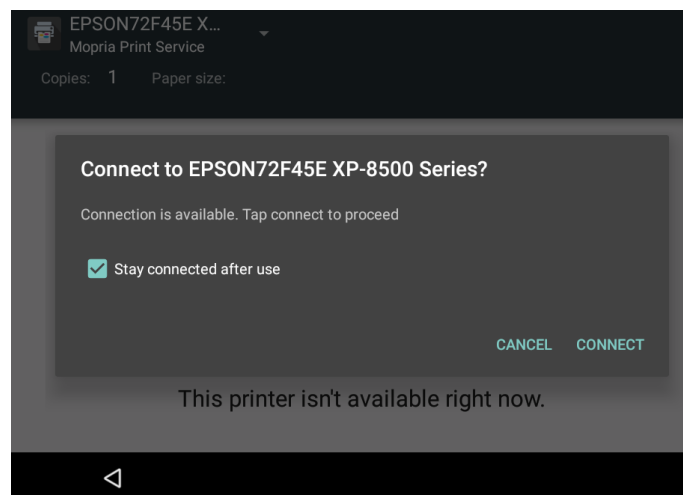


Fig. 55 – Connection to the printer in Wi-Fi Direct mode via Mopria Print Service



It is preferable to avoid connecting directly to the printer in Wi-Fi Infrastructure mode, as the tablet cannot be connected to another Wi-Fi data network at the same time. As a result, it will not automatically reconnect to the printer after reboot (as it does not provide internet access), so it is recommended to connect in Wi-Fi Direct mode instead of Wi-Fi Infrastructure.

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. 57):

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 and CC were enabled during the exam
7. Cluster MDs (dB) (see clusters identification in Fig. 58);
8. Grayscale VF map (see Fig. 59 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;
10. Tracking Performance Indices: TPI_{0.5°} and TPI_{1°} measure the rate of occurrence, during stimuli projections, of eye movements compensated by the tracking within 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. 14.11 for how to configure it).

TPI_{0.5°}: 94.4% [74.1%] / TPI_{1°}: 96.9% [89.1%]

Fig. 56 – Example of Tracking Performance Indices

The colors used in the Fundus Perimetry map (5) and symbols used in the Total and Pattern Deviation maps (9) are derived from normative values:

- ■ red is used for points having a total deviation with $p < 0.5\%$
- ✱ dark orange is used for points having a total deviation with $p < 1\%$ and $\geq 0.5\%$
- ✱ light orange is used for points having a total deviation with $p < 2\%$ and $\geq 1\%$
- ∴ lime is used for points having a total deviation with $p < 5\%$ and $\geq 2\%$
- · green is used for points having a total deviation with $p \geq 5\%$
- white is used for the foveal and optic disc locations

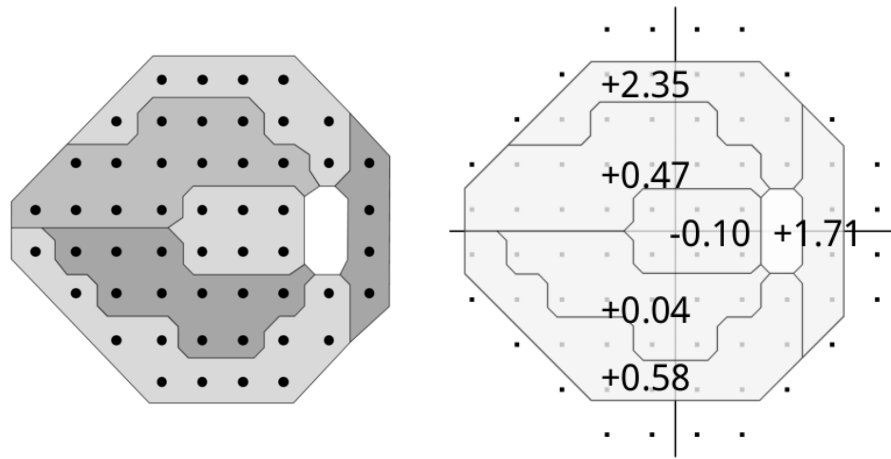


Fig. 58 – Stimuli of the 24-2 pattern (left) and 30-2 pattern (right) grouped in clusters⁹

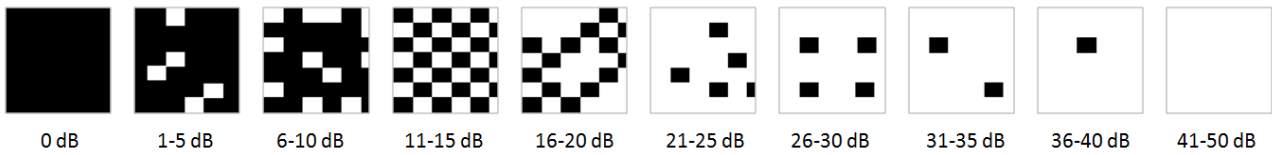


Fig. 59 – Symbols used for the grayscale map and related dB intervals

⁹ Garway-Heath et al; Mapping the Visual Field to the Optic Disc; Ophthalmology Volume 107, Number 10, October 2000

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 (see Fig. 60):

- 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.



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

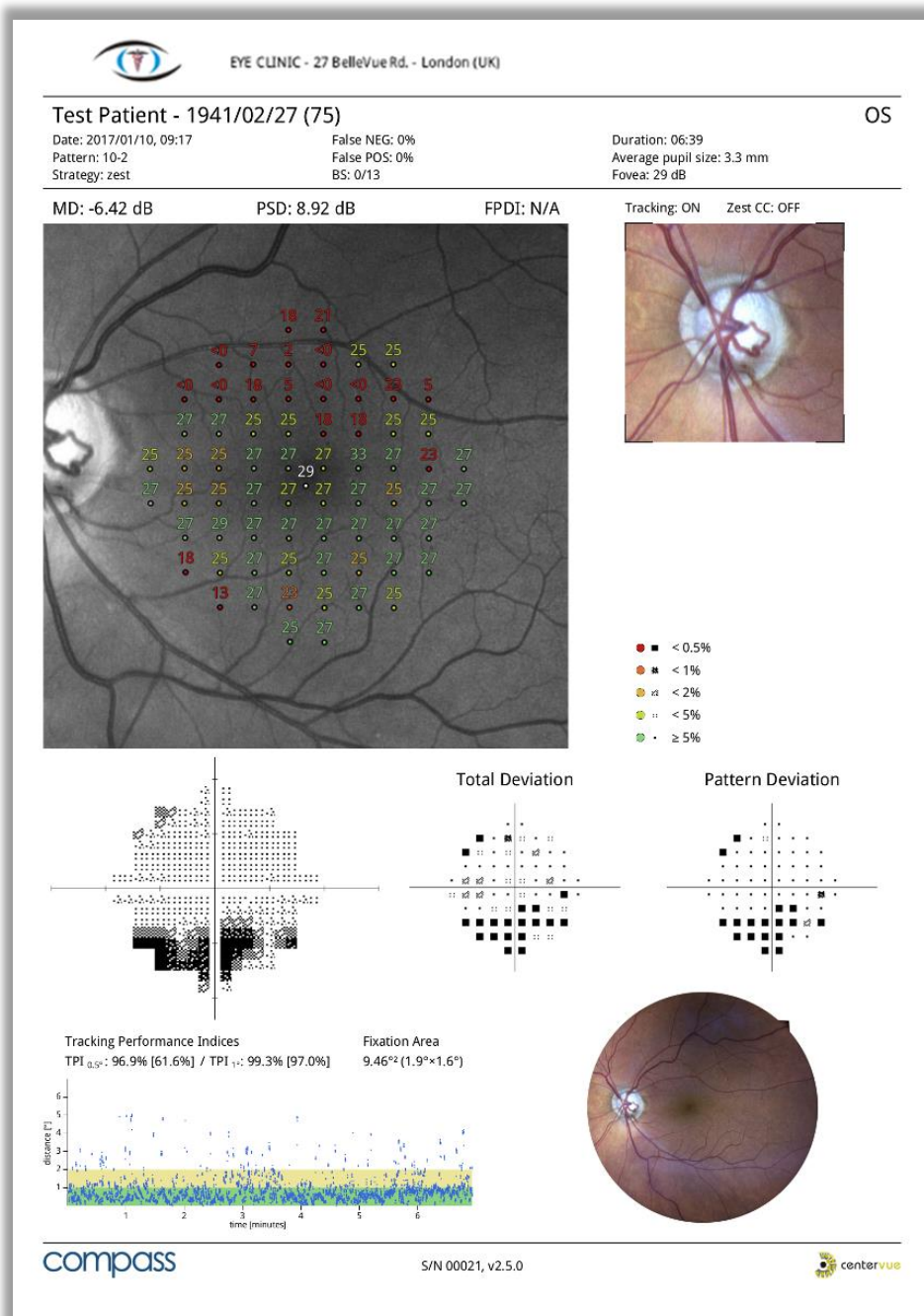


Fig. 60 – COMPASS report for a test with 10-2 grid

13.4 Report for 30-2 test

The printout for a test performed with the 30-2 grid (Fig. 61) is similar to the one of a 24-2 grid, with the following difference:

- the cluster analysis (7) displays the Cluster MDs only for the subset of locations that are in common with the 24-2 grid (see Fig. 58).

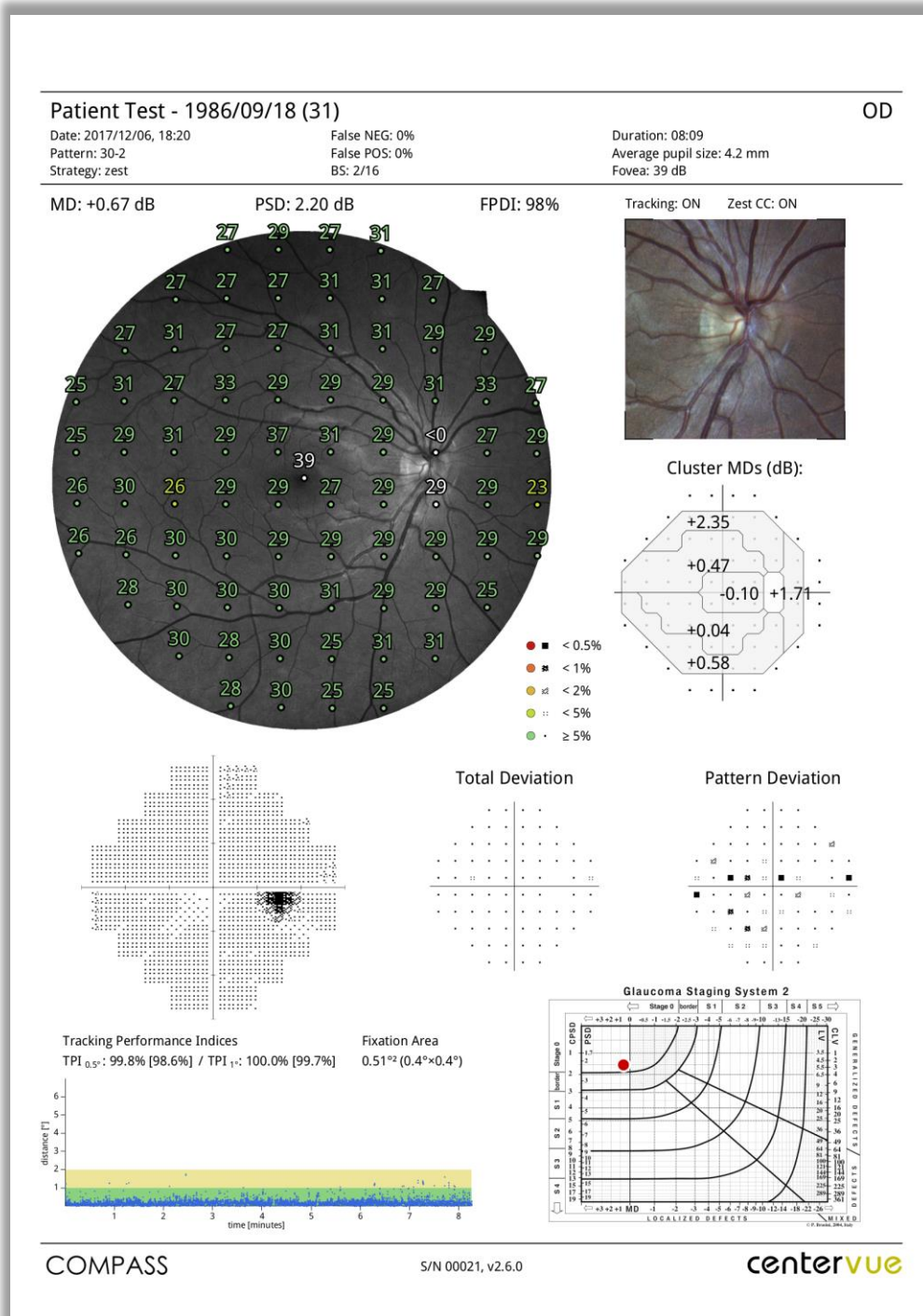


Fig. 61 – COMPASS report for a test with 30-2 grid

13.5 Reports for the SupraThreshold exams

The printout for a **SupraThreshold** exam displays the following information (see Fig. 62):

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

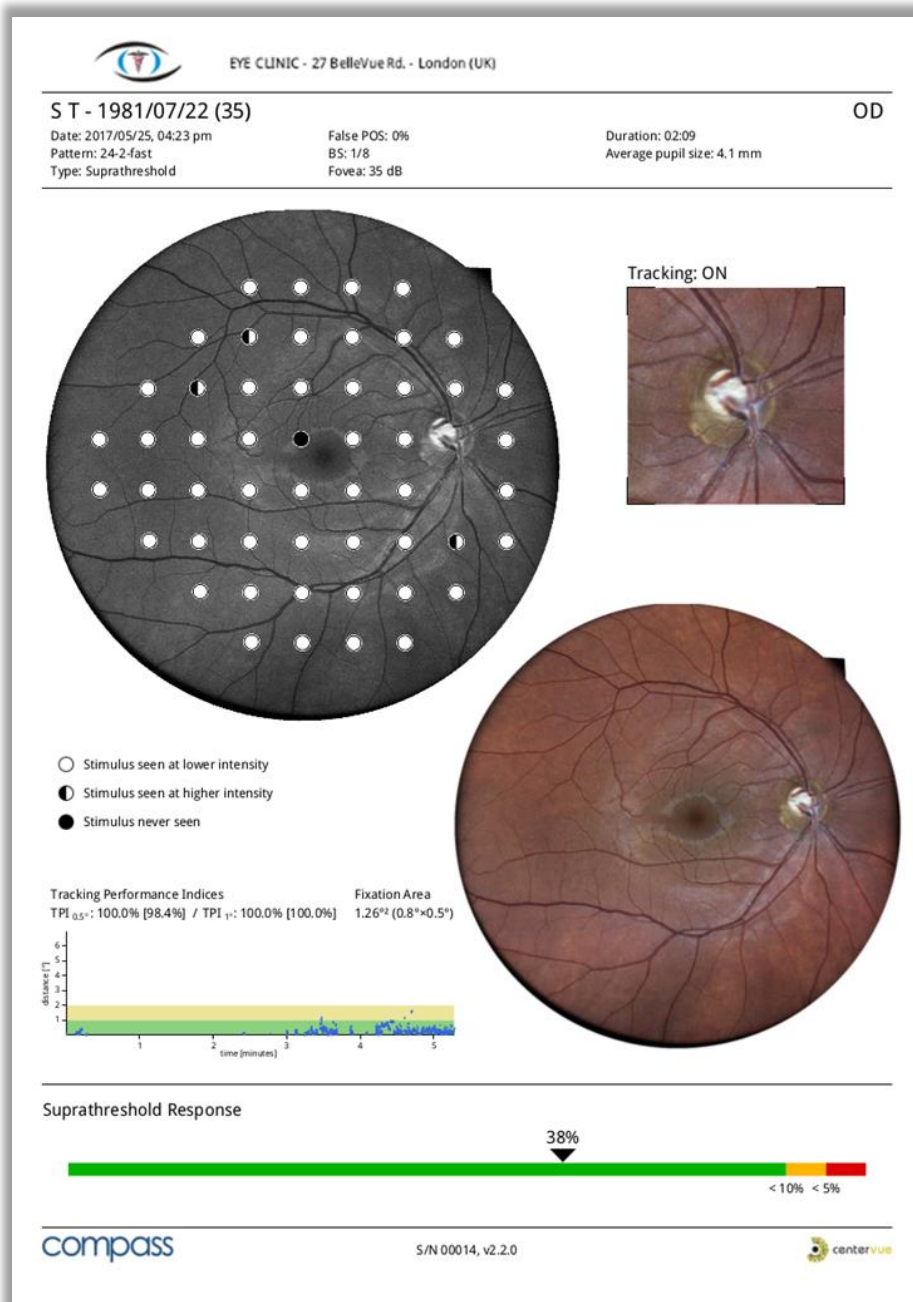


Fig. 62 – COMPASS report for a SupraThreshold test

The printout for a **Quick SupraThreshold** exam contains the same information (Fig. 63). The only differences are:

- a wider ONH detail image;
- the BS reliability index is N/A;
- the Fovea threshold might be Disabled.

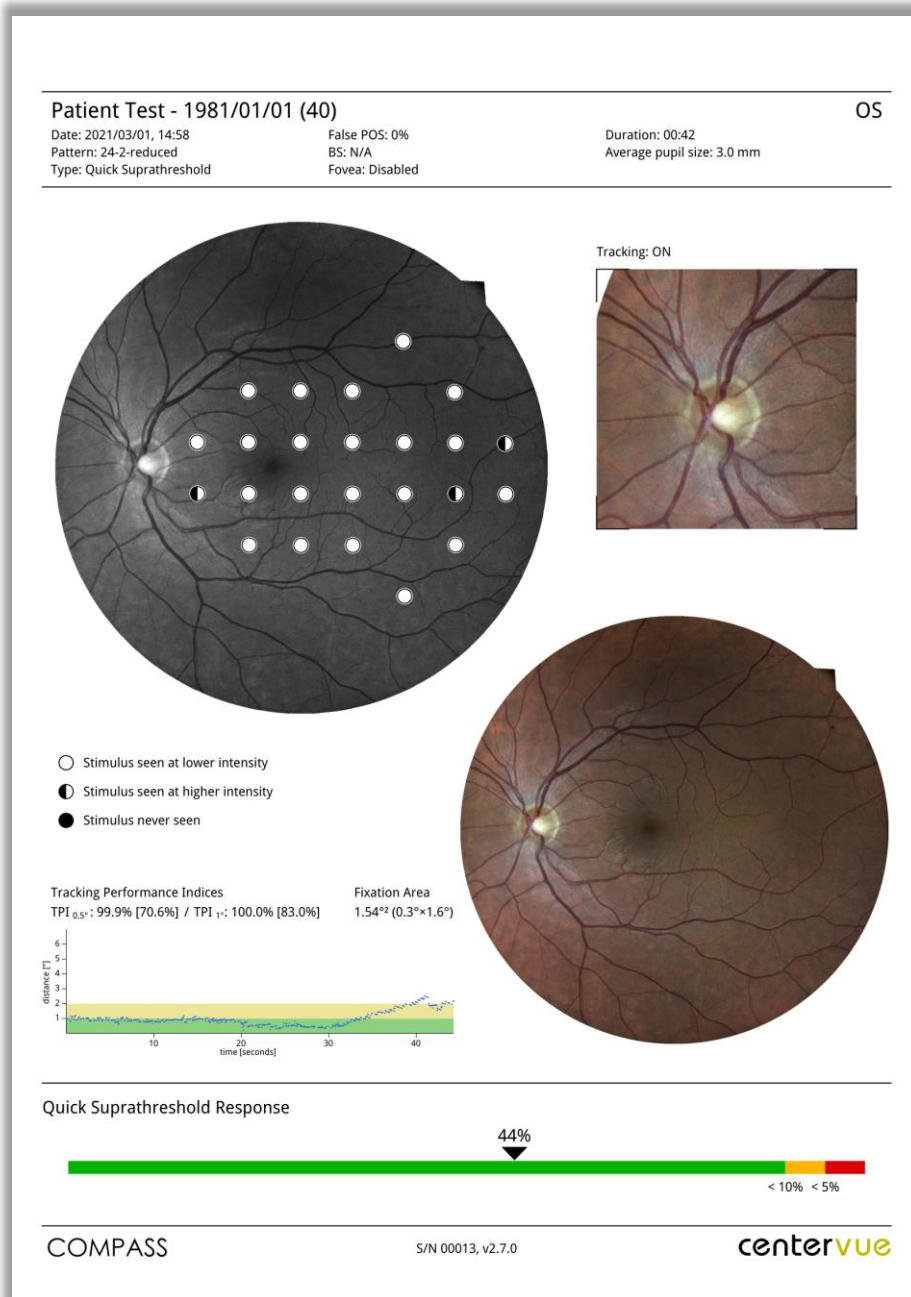


Fig. 63 – COMPASS report for a Quick SupraThreshold test

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. 64):

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 end user).

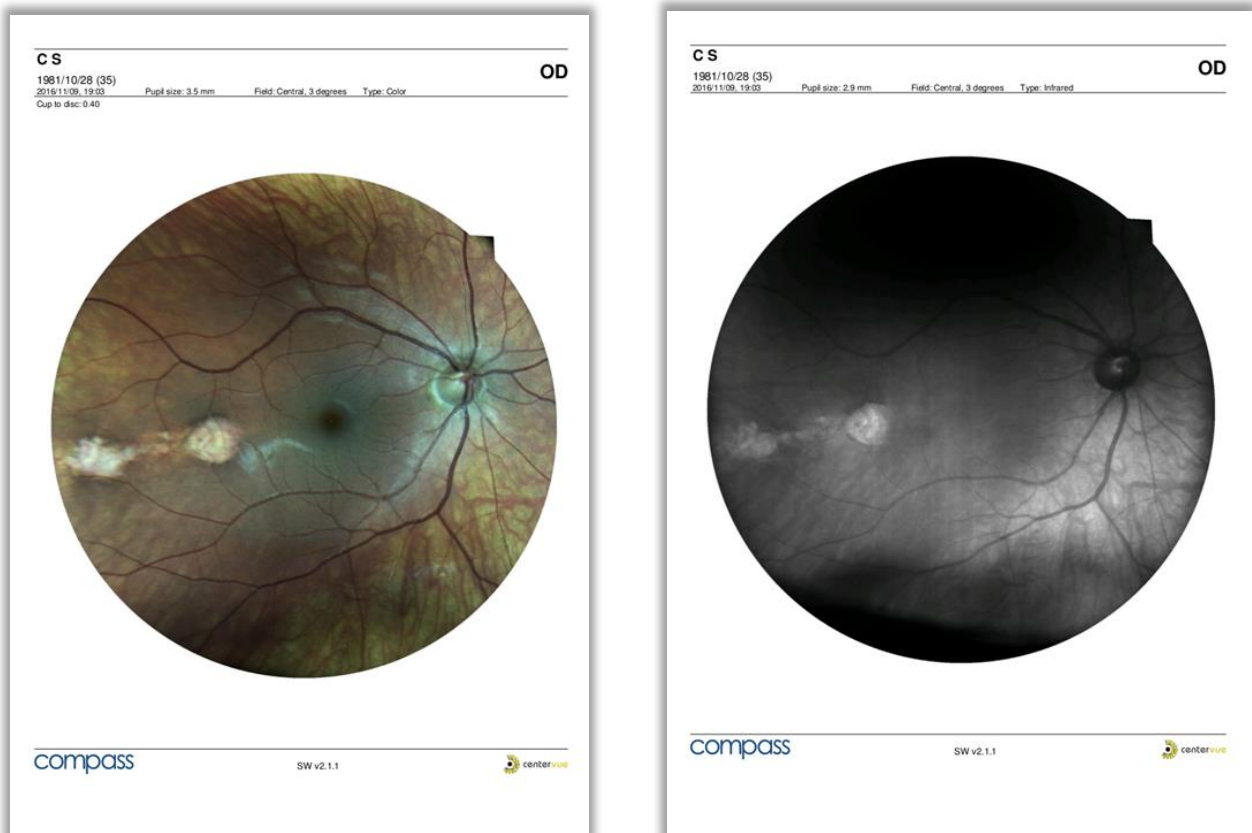


Fig. 64 – Fundus report examples: for Color Image (left) and for Infrared Image (right)

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 patient and eye.

It is a one-page layout presenting the following information (see Fig. 65):

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 (for 24-2 and 30-2 tests only)
12. MD progression plot for all included tests
13. FPGI progression plot for all included tests (for 24-2 and 30-2 tests only)
14. Software version used to generate report
15. Custom printout header (see Par. 14.11 for how to configure it).

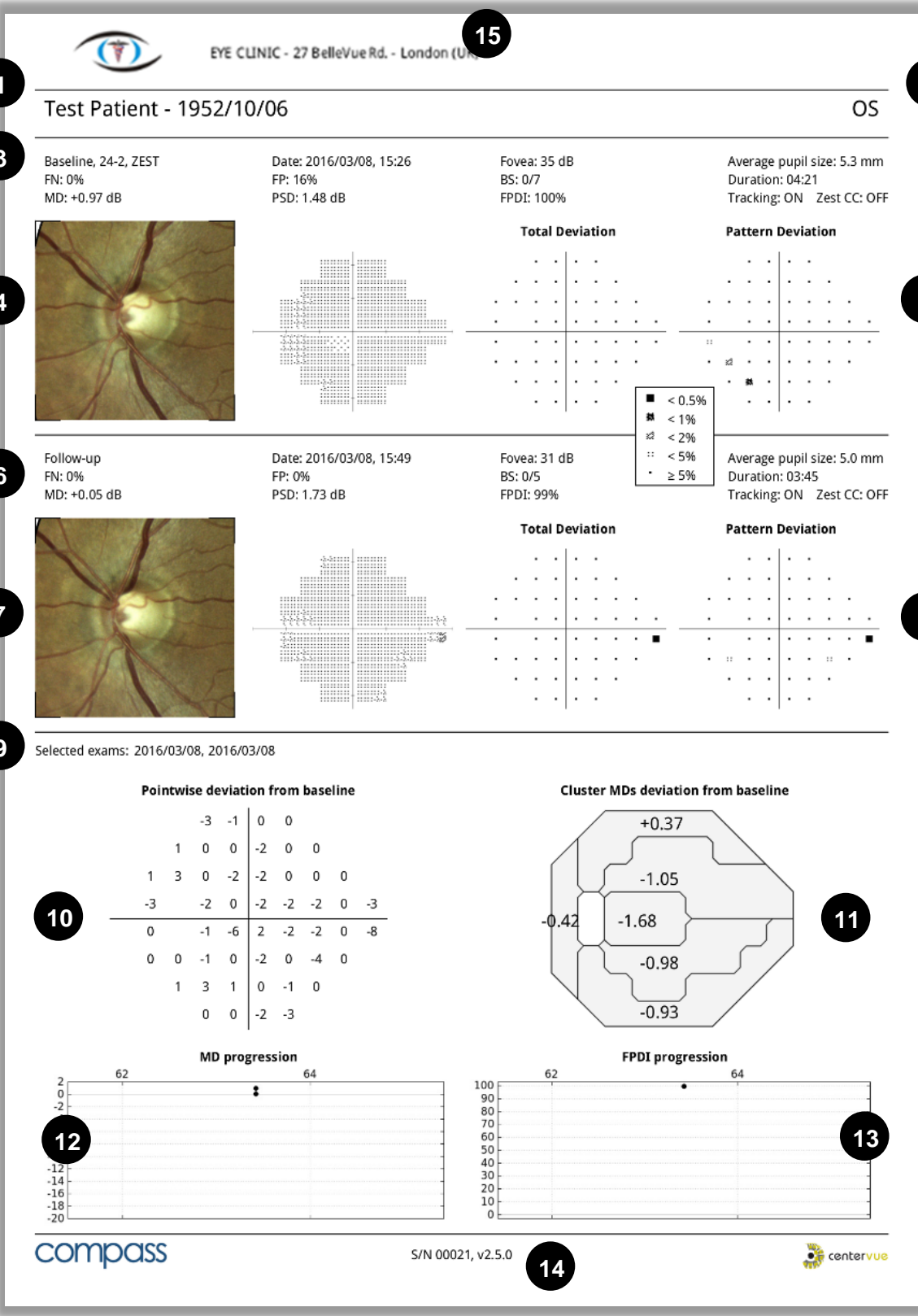


Fig. 65 – Progression report for 24-2 series



1

Test Patient - 1990/06/18

OS

2

3

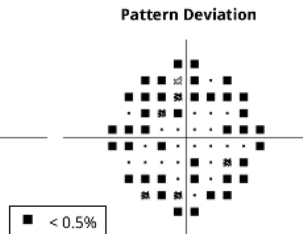
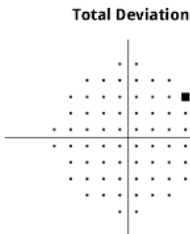
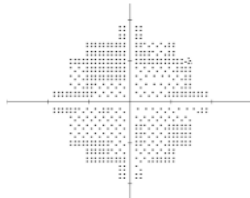
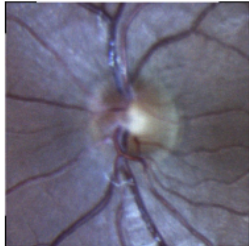
Baseline, 10-2, ZEST
FN: 0%
MD: +1.23 dB

Date: 2016/03/09, 11:56
FP: 0%
PSD: 2.69 dB

Fovea: 35 dB
BS: 0/13
FPDI: N/A

Average pupil size: 4.0 mm
Duration: 07:25
Tracking: ON Zest CC: OFF

4



5

6

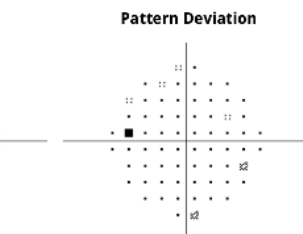
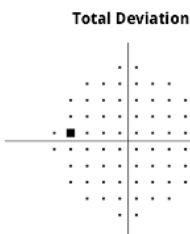
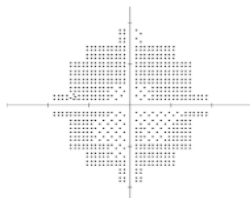
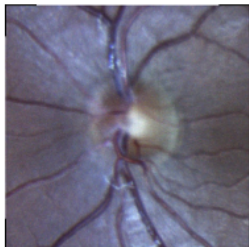
Follow-up
FN: 0%
MD: +0.16 dB

Date: 2016/03/10, 12:14
FP: 0%
PSD: 1.85 dB

Fovea: 37 dB
BS: 1/12
FPDI: N/A

Average pupil size: 3.2 mm
Duration: 07:10
Tracking: ON Zest CC: OFF

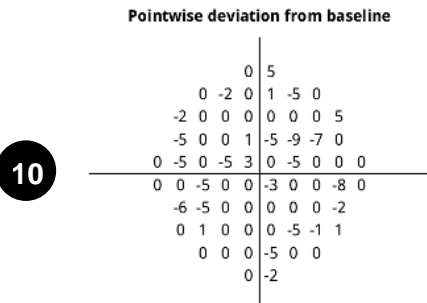
7



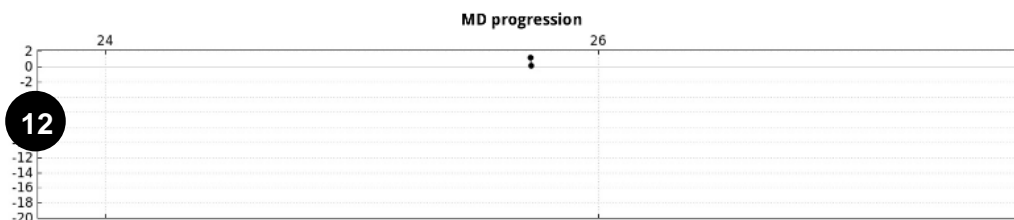
8

9

Selected exams: 2016/03/09, 2016/03/10



10



12

Fig. 66 – Progression report for 10-2 series

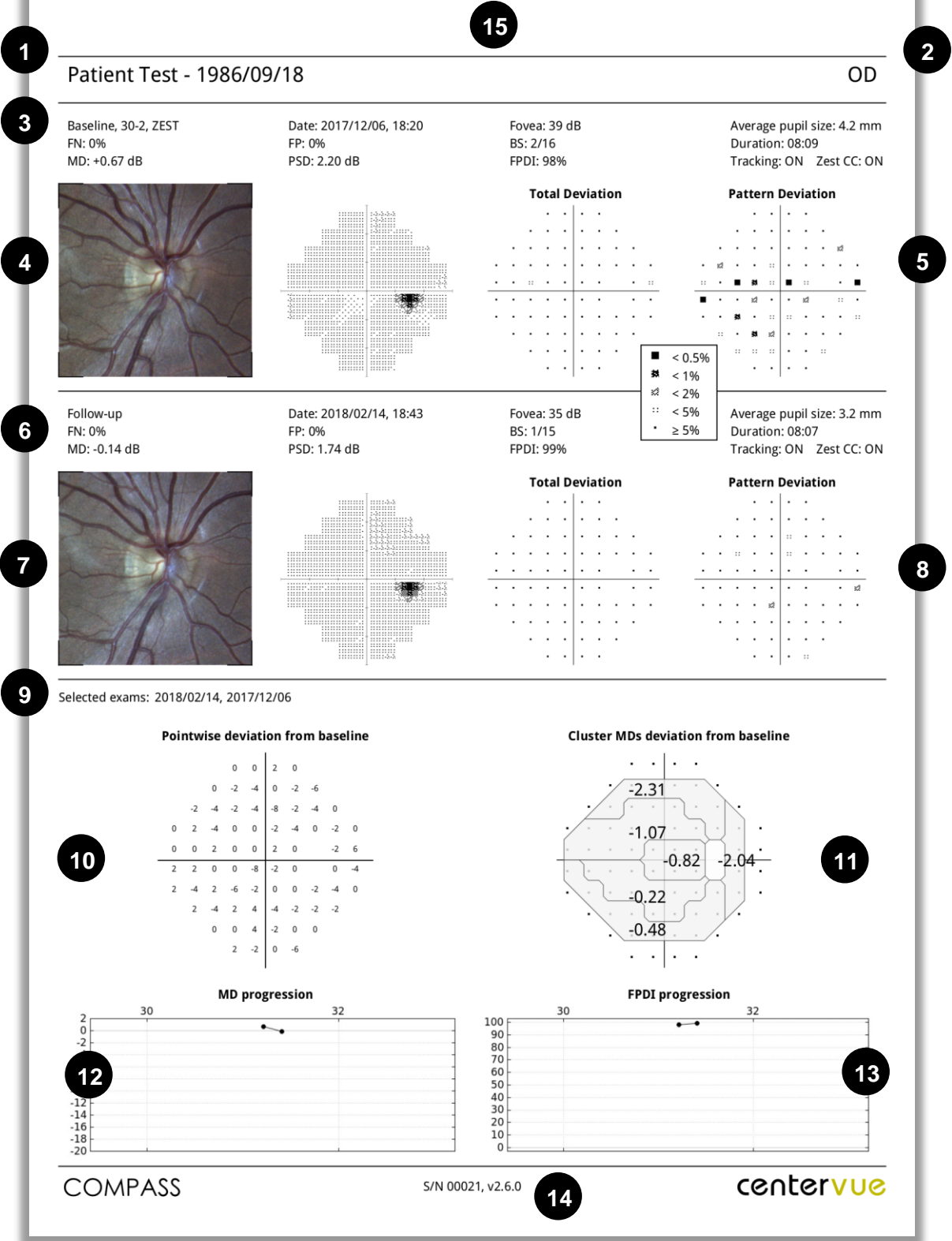


Fig. 67 – Progression report for a 30-2 series

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).

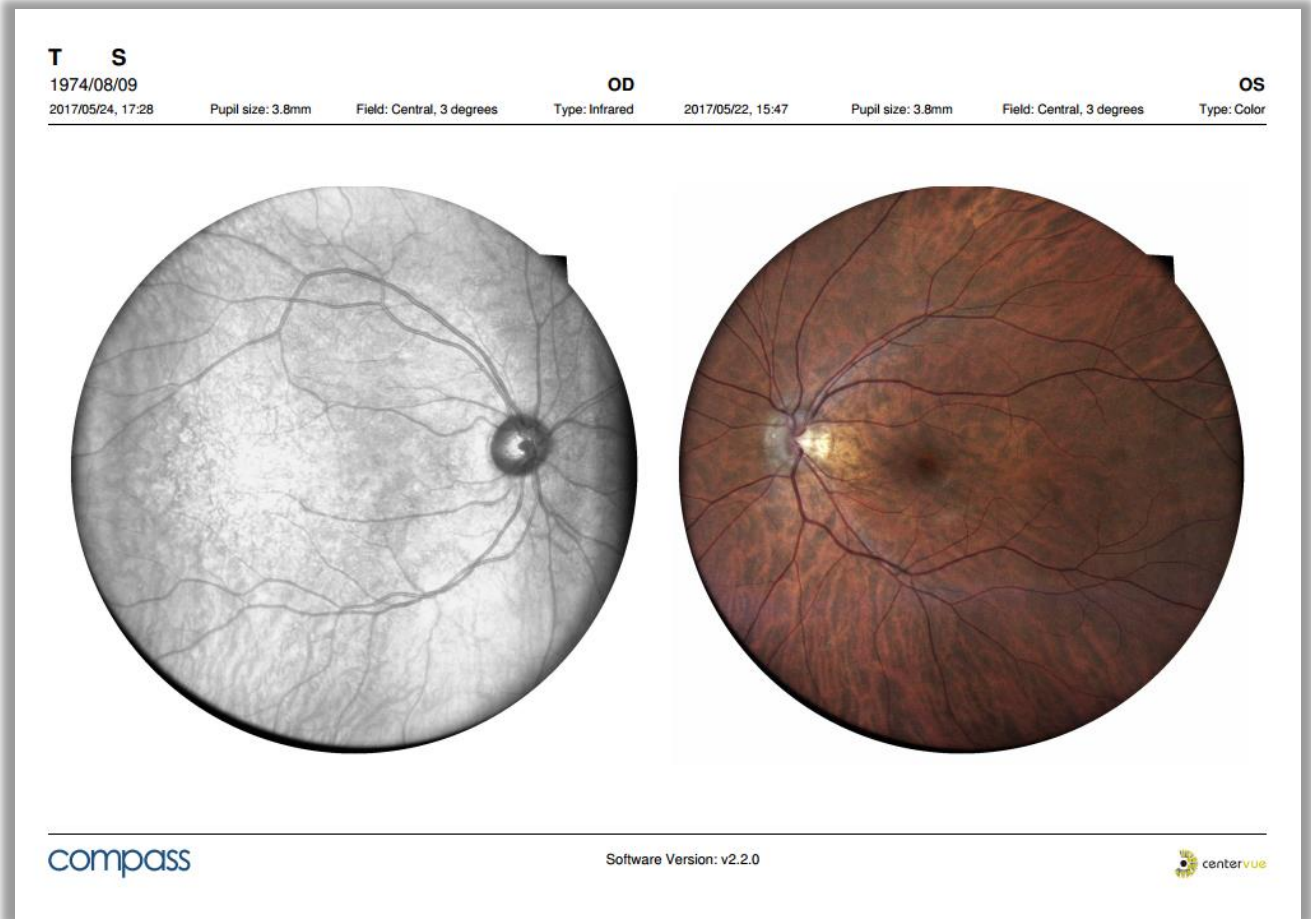





Fig. 68 – Example of a Dual printout Report

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 Date and time settings

This page allows to set the date, time, and time zone of the system. The setting will affect the date and time of the tablet and the main unit’s internal PC. In order to store the new setting, press the **Apply** button (see Fig. 69): device will request to power off in order to apply the new settings.

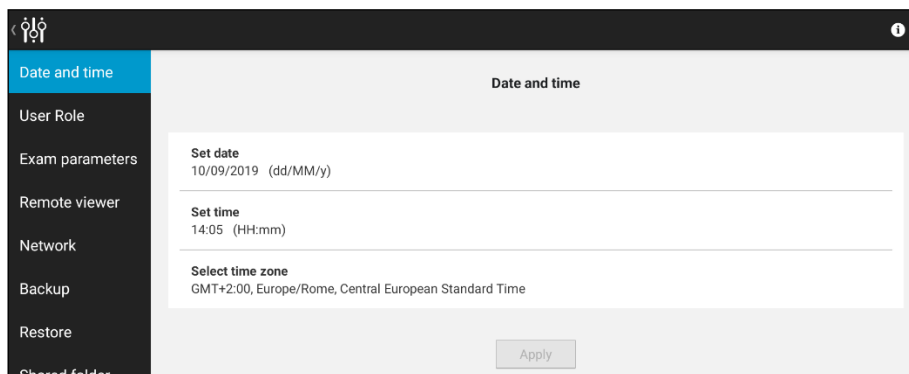



Fig. 69 - Configurator - Date/time settings

14.4 Users Passwords

Passwords for both the “**Admin**” and “**Doctor**” users can be changed in the “**User role**” tab of the Configurator by clicking the  icon (see Fig. 70). 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.

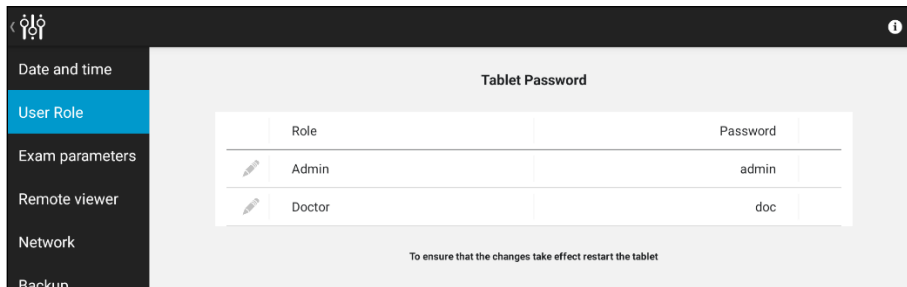


Fig. 70 – Configurator - User Role tab

14.5 Exam parameters

This tab is divided in two sections.

The top section allows to choose which reliability tests to perform during **Visual Field** exams (see Fig. 71). All the tests are enabled by default. For a detailed description of the reliability indices, see par. 12.2.

The bottom section allows to enable or disable the Fovea threshold measurements for **Quick Suprathreshold** tests. This option is disabled by default being of little interest for a Suprathreshold test, to reduce test time. This setting only applies to Quick Suprathreshold tests (and not to regular Suprathreshold tests).

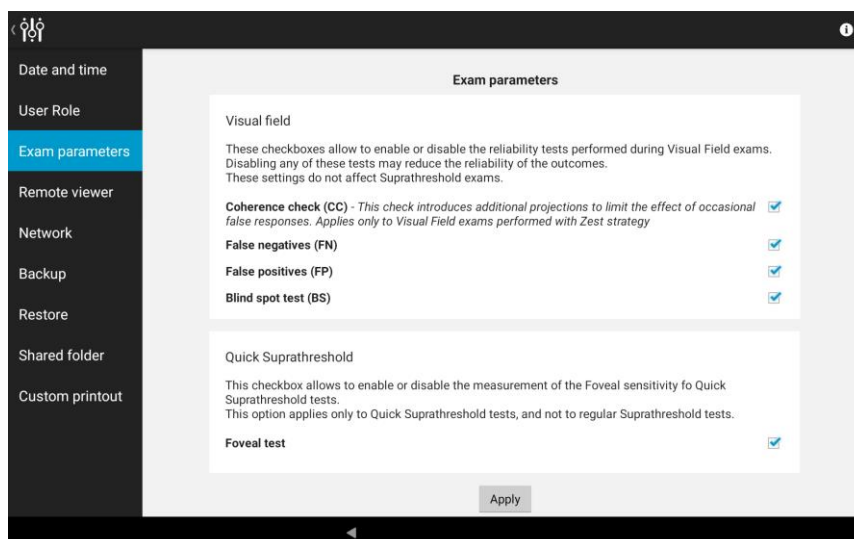


Fig. 71 – Configurator – Exam parameters tab



Disabling reliability tests reduces the examination time but it may also lead to less reliable results.

The reliability tests can be configured for Visual Field exams only. In Supra Threshold exams, instead, only FP and BS tests are performed (FN is disabled, and CC is not applicable, since ZEST strategy is not used).

14.6 Remote Viewer

This tab allows to change the password used to access the Remote Viewer: type the new password and press **Apply**. The **Privacy mode** checkbox allows to hide all the patients in the **Patient list** of the **Remote Viewer** and have them displayed only after searching for them.

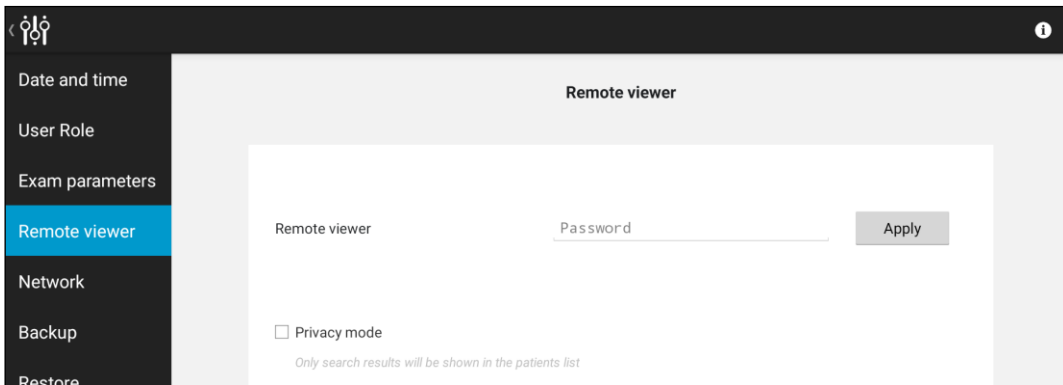



Fig. 72 – Configurator - Remote Viewer screen

14.7 Network configuration

COMPASS supports wired network connection.

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

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.

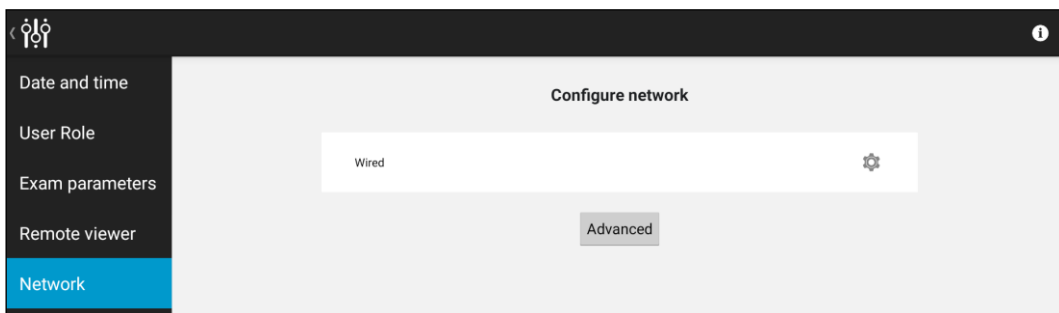


Fig. 73 – Configurator - NETWORK screen



Fig. 74 – Configurator - Specific network configuration screen (in this case: wired network configuration)

14.8 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 back up 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

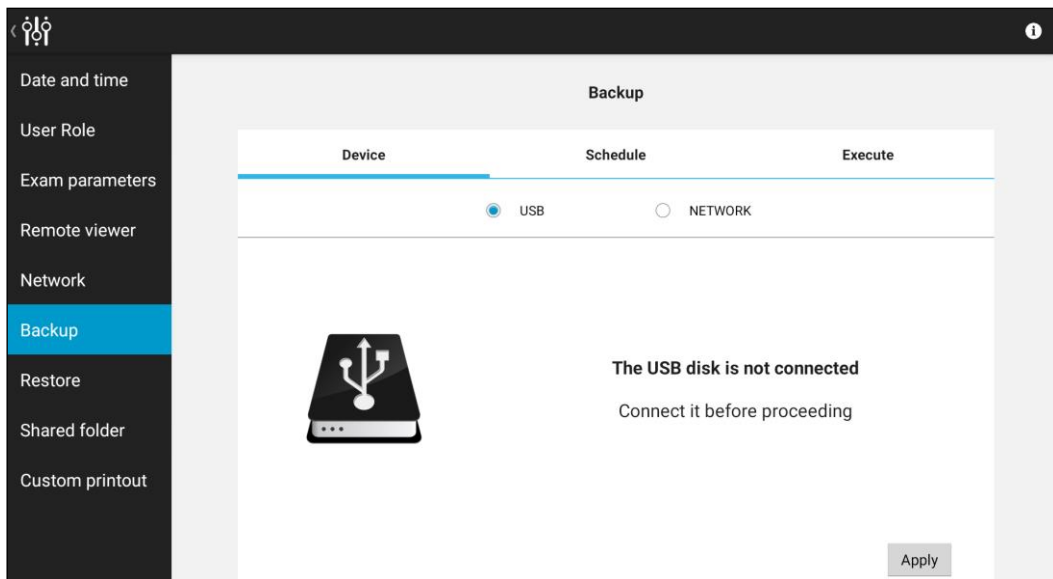



Fig. 75 – Configurator - BACKUP screen - USB-media backup selected



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

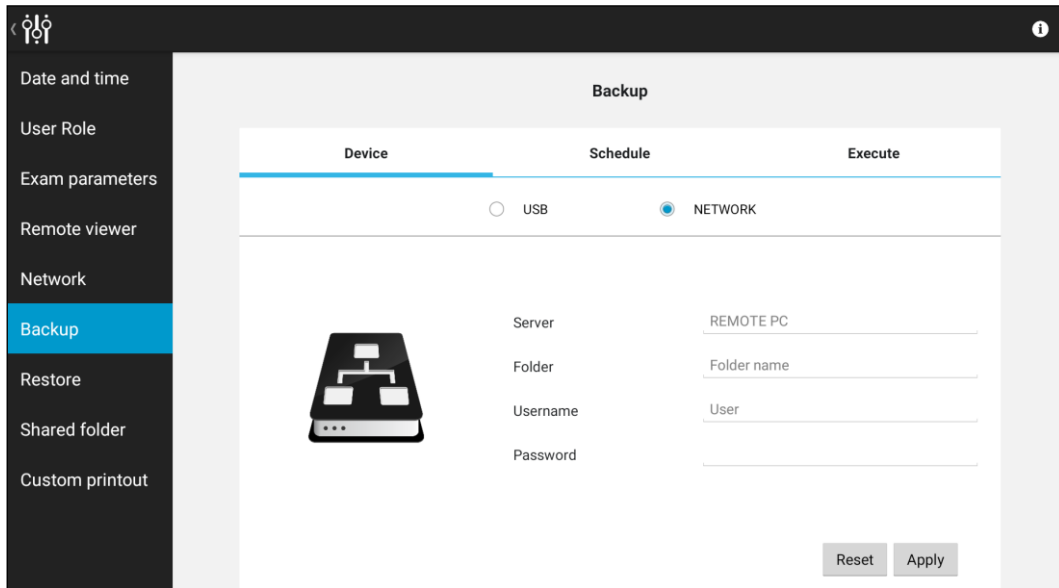


Fig. 76 – Configurator - BACKUP screen - Network backup selected

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 username used in the remote server; if you're in a Windows Domain network, the format of this field is: *DOMAINUSERNAME*
- *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 temporarily 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.

The screenshot shows the 'Backup' configuration screen with the 'Schedule' tab selected. The 'Device' section shows 'Selected media' as 'USB'. The 'Automatic backup' toggle is turned 'ON'. The 'Starts on' field is set to 11:44 AM on Feb 13, 2017. The 'Execute every' field is set to 1 day. An 'Apply' button is visible at the bottom right.

Fig. 77 – 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.

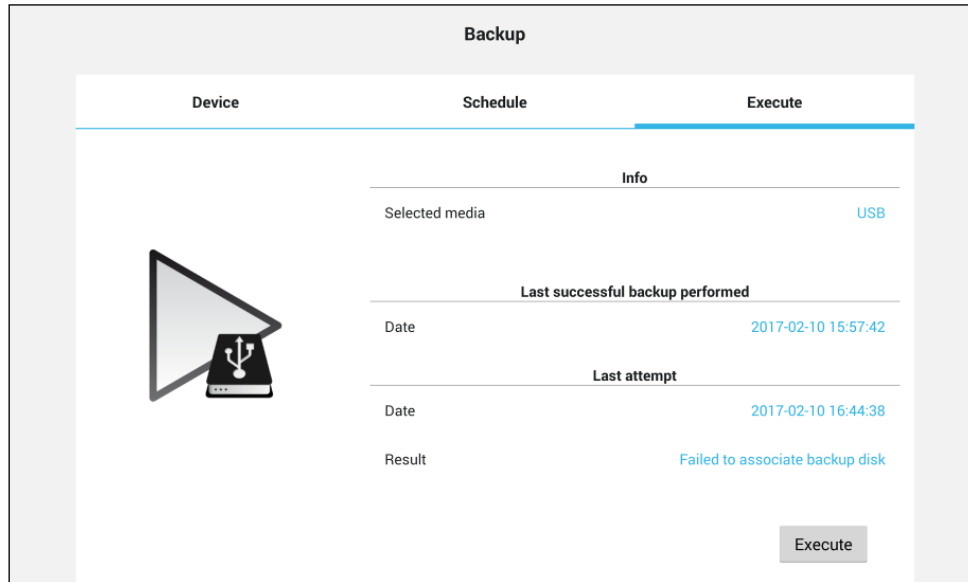


Fig. 78 – Configurator - BACKUP screen - Execute tab

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

14.9 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**.

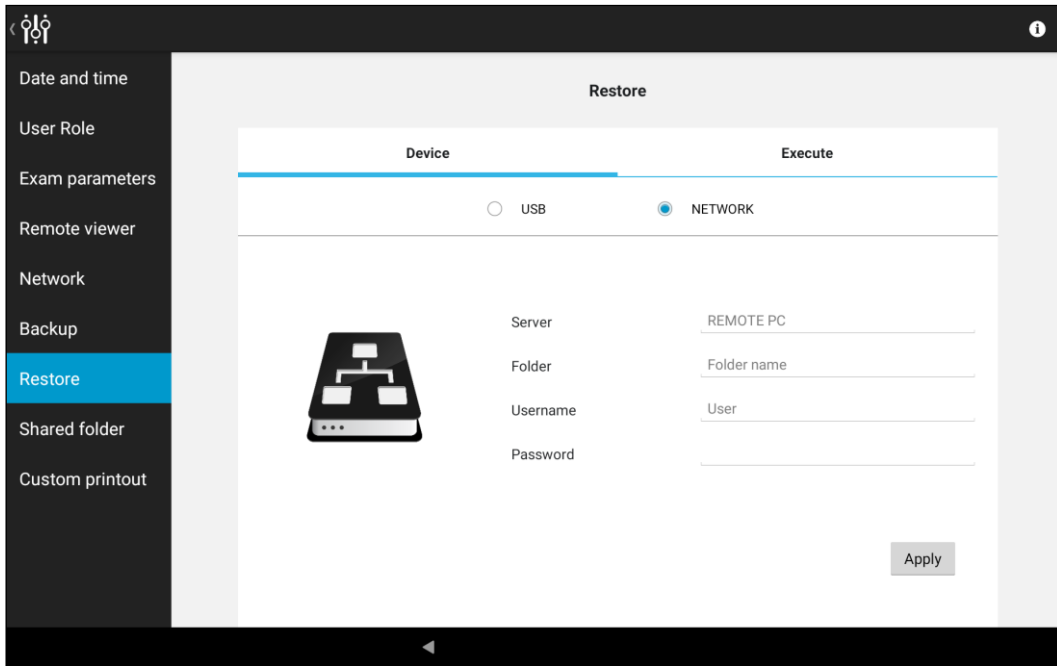


Fig. 79 – Configurator - RESTORE screen - Network folder selected

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

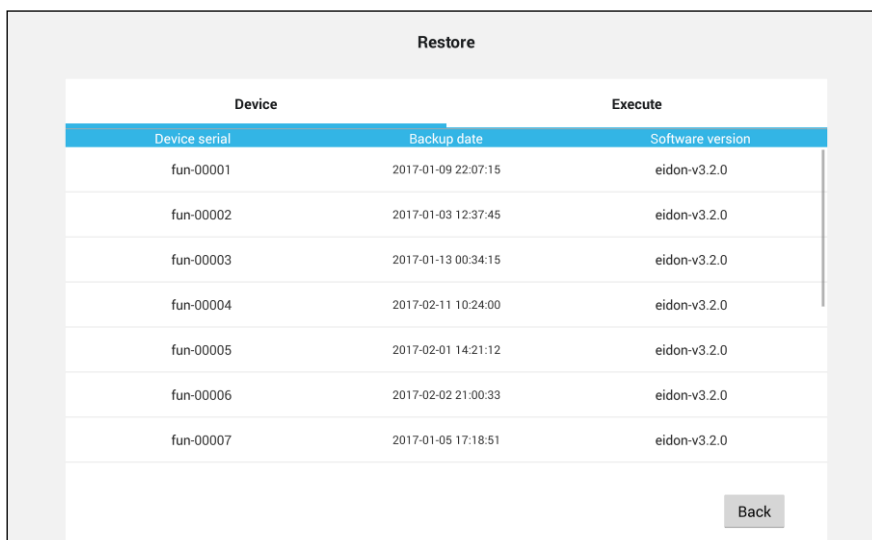


Fig. 80 – Configurator - RESTORE screen - List of available archives to be restored

- 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.

14.10 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 3). 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 username used in the remote server; if you are in a Windows Domain network, the format of this field shall be: *DOMAIN\USERNAME*
- **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.

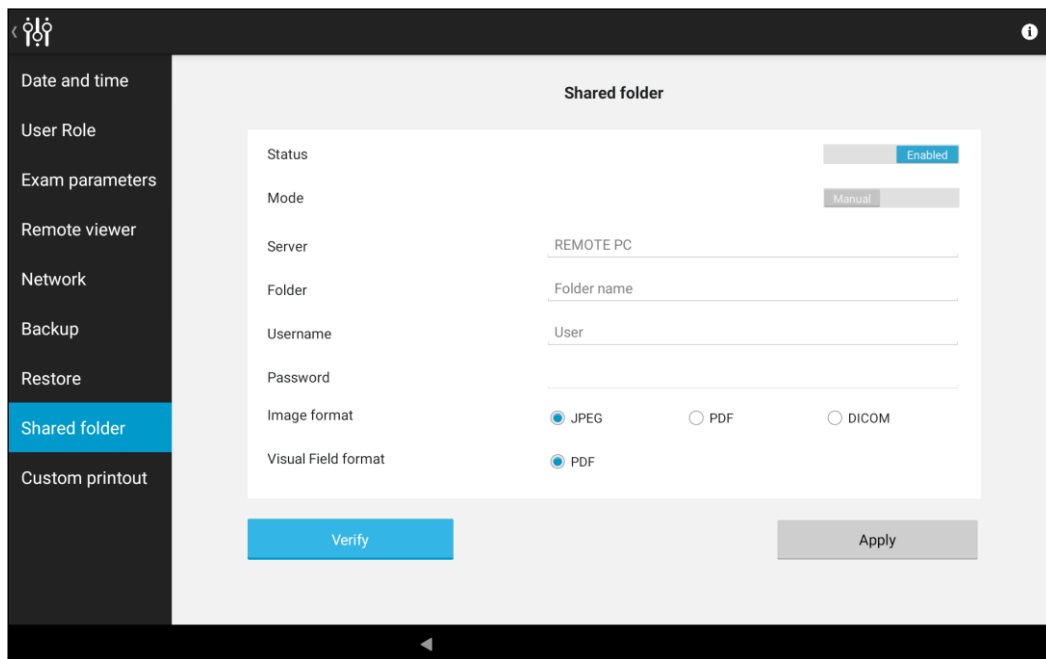


Fig. 81 – Configurator - SHARED FOLDER configuration

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.



COMPASS Shared Folder connectivity uses SMB/CIFS protocol, up to ver. SMBv3. COMPASS supports SMB/CIFS connection to hosts running the following operating systems: Windows 7, 8, 10, Server 2012, and Linux.



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.

14.11 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 device 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.

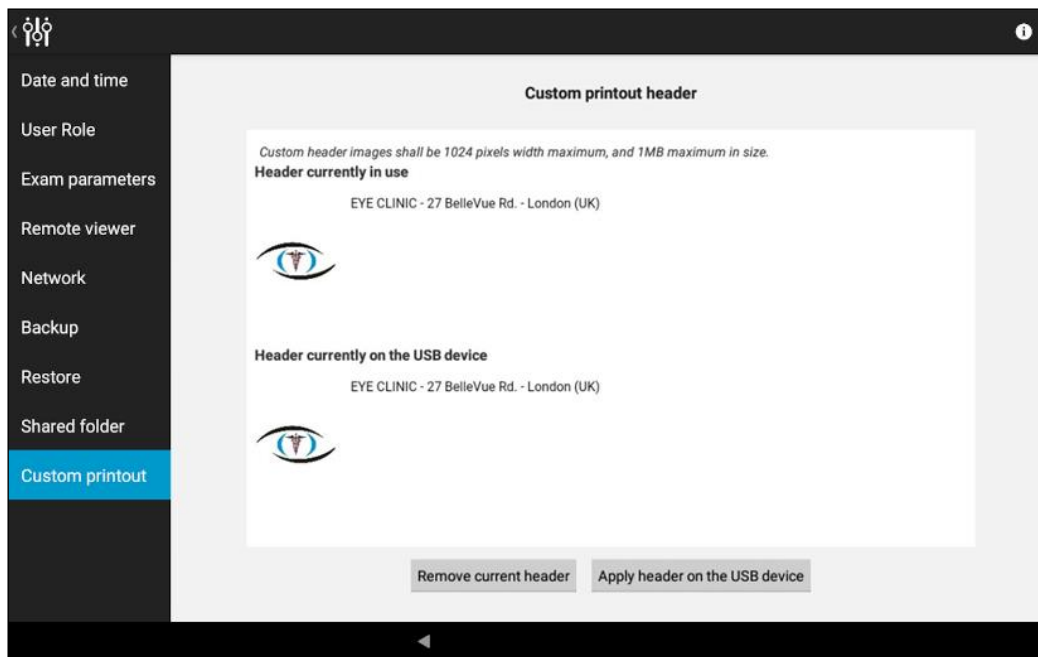



Fig. 82 – Configurator - Custom printout header configuration

15. DEVICE SHUTDOWN

To shut down COMPASS, 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 IEC 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
- Default test patterns: 24-2, 10-2, 30-2
- 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 Control Interface: 10.1" multi-touch screen User Control Interface (tablet)
- Connectivity: Wi-Fi and Ethernet
- Hard disk: SSD, 240 GB

Dimensions:

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

Electrical requirements:

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

Specifications are subject to change without notice for improvement, as the result of ongoing technical development.

17. CLEANING

This paragraph explains how to clean the device.

The chinrest and the Headrest silicone cushion should be wiped with an alcohol 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. 83 - Removal of the chin rest silicone pad



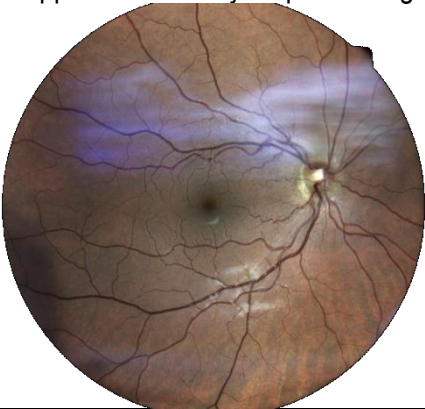
Gently pull up and slide the chin rest pad to avoid breaking the retaining peg.


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)	COMPASS 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	Patient blinked during image capture	Repeat capture and ask patient 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 components 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 (< 3.0 mm)	Dark adapt or dilate patient's pupils.
11. The fixation target appears de-centered approx. 3 degrees to the left/right	This is normal and is due to the asymmetric shape of the "24-2" grid, which extends to the temporal peripheral area. 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.	This condition is normal.
12. Export to the remote shared folder fails with message "The selected host is not reachable" or "Timeout"	<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 • Check that the computer hosting the shared folder is reachable
13. Export to the remote shared folder fails with message "Unknown error"	The remote export folder was renamed after the export destination was configured	Re-configure the export destination
14. Export to the remote shared folder fails with message "The shared disk is full."	The computer hosting the shared folder has a full hard disk	Empty some space on the host computer or change the export destination to another computer
15. The system reports the message "Unable to get feedback from stimulus" (Code 227)	The stimulus position check failed.	Contact an authorized CenterVue Service representative.

18.1 REMOTE ASSISTANCE

If an issue cannot be solved with the basic troubleshooting, please contact an authorized CenterVue Service representative explaining the problem.

The Service technician might require a remote connection to the unit to perform a thorough analysis: COMPASS includes a Remote Assistance feature by means of a separate application called “**Service**”.

Remote Assistance allows authorized service technicians to connect to the COMPASS.



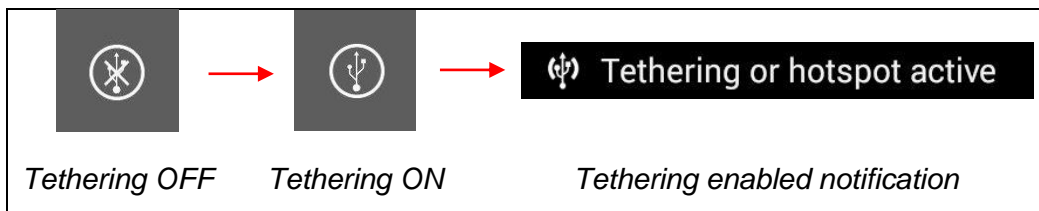
Establishing a Remote Assistance session will authorize the remote access to the unit, including access to images, patient-related information, and device logs. Remote access is temporary and will expire when the connection is closed or when the device is shut down.



Remote Assistance requires the unit to be connected to the Internet

The following steps should be performed to establish a Remote Assistance session:

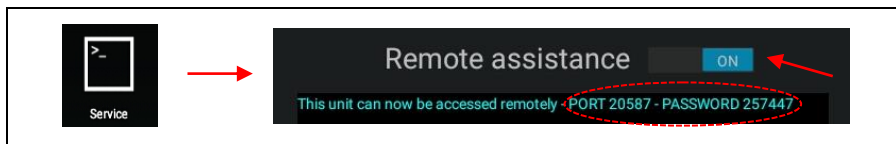
- press the “back” icon at the bottom of the screen to go to the Home screen;
- press the logout icon;
- select user “Admin” from the drop down menu;
- type the corresponding password and click **Login**
- enable Tethering by clicking its icon on the top bar:



- click the App icon:



- start the Service application and toggle the Remote Assistance button to “ON”



- Provide “PORT” and “PASSWORD” numbers to CenterVue Service personnel to allow them to connect remotely to the unit

19. MAINTENANCE

CenterVue recommends the periodic maintenance of the components listed in the following table. Only properly qualified CenterVue Authorized Service Technicians can perform calibration activities. Contact your local CenterVue distributor or CenterVue Service Center if you think your COMPASS requires calibration.

TEST ITEM	TEST DESCRIPTION	ACCEPTANCE CRITERIA	TEST FREQUENCY	IN CASE OF FAILURE
Patient Push Button	Press the Patient Push Button at least 10 times, moving the cable, once every 2 seconds.	A beep can be heard anytime the button is pressed	Before performing any test	Patient Push Button is not working and no patient response is detected. Test results are affected. Check proper insertion of the Patient Push Button connector in the COMPASS unit. If connection is OK and the problem persists, contact Technical Support.
Front lens	Visual check of front lens external surface.	No presence of dust or stains detected	Daily	Image quality is adversely affected. Clean the lens as explained at section 17 of this Manual.
Patient data	Backup the patient database on an external USB media.	The backup procedure completes successfully.	Weekly	External media could be corrupted (use a different media) or USB connection is faulty. If problem persists, contact Technical Support.

20. ELECTROMAGNETIC COMPATIBILITY

This device has been tested and found to comply with the limits for medical devices contained in IEC 60601-1-2: Ed. 04 and Medical Device Directive 93/42/EEC concerning Medical Devices. 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 IEC 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 end 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 5 - Electromagnetic Emissions

Guidance and Manufacturers' declaration – Electromagnetic Immunity


Immunity Test	IEC 60601 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 6 - Electromagnetic Immunity (IEC 60601-1-2: 2014)

Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	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 frequency range^b</p>
Radiated RF IEC61000-4-3	See TABLE 9 of IEC 60601-1-2	See TABLE 9 of IEC 60601-1-2	<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 affect 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>
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.			
<p>^a Field strength 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 7: Electromagnetic Immunity (IEC 60601-1-2: 2014)

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 8 - Electromagnetic Immunity (IEC 60601-1-2: 2014)

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 9 - 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.

21. **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 genotoxic (damages the DNA). Especially dangerous when incinerated.

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

