icare®

COMPASS

Instructions for Use

DOCUMENT INFORMATION

The information in this instruction for use is subject to change without prior notice and it is correct at revision date. Device configuration can change as products improvements are incorporated and this instruction for use may not exactly depict your device: please contact the local distributor if you have any questions about differences.
The original language of these instructions for use is English. Should a conflict situation arise concerning a translated document, the English language version shall prevail.
Please refer to §23 for information on the Software versions these Instructions For Use refers to.

Date of release:	July 15th, 2024
Revision number:	25
Software Version:	4.0.3
Reference device:	COMPASS (REF: AMGSDME001)

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CONTENTS

1. INTRODUCTION

1.1 Intended purpose

COMPASS is a peripheral vision analyser, intended for measuring retinal sensitivity, fixation stability and locus fixation as well as for the acquisition of retinal images with or without[1] a mydriatic agent and for their review.

1.2 Indications for Use

COMPASS is indicated to perform Visual Field tests to measure retinal sensitivity, and to provide retinal images used for diagnosis and monitoring of several retinal pathologies.

There are no surgical or treatment decisions made solely on retinal images and results obtained by the device. The clinical interpretation of the exams acquired with COMPASS is restricted to eyecare professionals with training in the ophthalmology field (or equivalent) that hold the responsibility of the diagnosis.

1.3 Indications for use (for FDA only)

COMPASS is intended for taking digital images of a human retina without the use of a mydriatic agent and for measuring retinal sensitivity, fixation stability and the locus of fixation. It contains a reference database that is a quantitative tool for the comparison of retinal sensitivity to a database of known normal subjects.

1.4 Clinical benefit

COMPASS does not claim any clinical benefits, i.e. a positive impact on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome, as it does not provide any diagnostic outcome but provide information for the diagnosis only.
The performance of COMPASS expressed as the ability of the device to achieve its intended purpose is to measure retinal sensitivity and to capture, display and store images to aid in the diagnosis and monitoring of diseases and disorders occurring in the retina.

1.5 Contraindications

No contraindications and side-effects have been found for fundus perimetry. No contraindications nor side-effects have been found for fundus photography. There exist rare and discomforts limited in their timespan, as temporary glare, watery eyes, during and/or during and after performing the exam.

1.6 Ophthalmic Devices Compliance

COMPASS is fully compliant with ISO 15004-1:2020 and ISO 12866:1999 /AMD:2008.

1.7 Optical Safety

According to ISO 15004-2:2007 and ANSI Z80.36, COMPASS is classified as: *Group 1 - Ophthalmic instruments for which no potential light hazard exists*.

[1] *COMPASS works in a non-mydriatic condition for patients with minimum pupil size of 3.0 mm: the decision to use the mydriatic agent on patient's pupil eye is under the responsibility of the eye care practitioner.*

1.8 RoHS Compliance

The product is RoHS-compliant according to Directive 2011/65/EU and to Directive 2015/863/EU.

1.9 Electrical Safety

The product is compliant with IEC 60601-1:2005+AMD1:2012+AMD2:2020.
The device is classified as Class II, type B applied part.

1.10 Reporting Serious Incidents (only for EU)

Report any serious incident related to the device, the operator, the patient, or anyone else to CENTERVUE S.P.A. and to the Competent Authority of the Country/State in which the user and/or patient is established.

1.11 Essential Performance

The clinical performance of COMPASS is to measure retinal sensitivity and to capture, display and store images to aid in the diagnosis and monitoring of diseases and disorders occurring in the retina.
Since there are no surgical or treatment decisions made solely on data obtained by the device, it was determined that COMPASS does not provide Essential Performance as defined in the IEC 60601-1 standard.

1.12 Use Environment

COMPASS is intended for use in professional healthcare facility environment:

- Ophthalmic & Optometrist Offices
- Ophthalmology Clinics
- Hospitals
- Research laboratories
- Medical offices

The device is suitable for use in domestic and home healthcare environment. Consult complete information about electromagnetic environment requirements in section §0 of this Instruction for Use.

1.13 Patient Profile

The execution of a Visual Field test requires active interaction between the device and the patient, via the dedicated push-button.
Consequently, COMPASS can be used by clinicians on any adult person that:

- is able to remain seated, with the forehead placed on the forehead rest, alone or with the aid of another person;
- has the psychophysical capabilities to understand how the exam works and accomplish the tasks required by the test, i.e. staring at the fixation target and pressing the dedicated pushbutton whenever the subject is able to detect a circular luminous stimulus.

The decision to use COMPASS on a vulnerable patient is under the responsibility of the eye care practitioner.

1.14 Intended users

The primary intended users of COMPASS device is healthcare professionals.
The device is not intended for lay users.
Patient's interaction with the device is limited to clicking on the patient response button following clinician's instructions.
Three different user profiles (Roles) are defined in COMPASS:

ROLE and User profile	Context of use	Characteristics
Operator user (Healthcare professionals)	Operating as per the medical intended purpose: Image acquisition and review Cleaning and disinfection Troubleshooting	Demographic trait: Healthcare professional with training in ophthalmology or equivalent: - Opticians - Ophthalmic photographers - Optometrists - Ophthalmologists - Clinical researchers - Medical assistants. Required knowledge, skills and abilities: - Experience with using medical imaging system that have an embedded computer and software user interface - Basic computer knowledge Qualified and experienced personnel, familiarized with the contents of the Instruction for Use.
Admin User	Configuration and set up	Demographic trait: System administrator. Required knowledge, skills and abilities: - Experience with desktop-based camera - Knowledge of operating systems, IT network, user administration, backup management Qualified and experienced personnel, familiarized with the contents of the Instruction for Use.
Patient	Operating as per the medical intend purpose: press the pushbutton whenever he/she perceives a luminous stimulus during the visual field test	Adult subject having the psycho-physical capabilities to undergo the eye test following the operator's instruction for the duration of the exam. The decision to use COMPASS on a vulnerable patient is under the responsibility of the eye care practitioner.

1.15 Principles of operation

The device achieves its intended purpose by projecting light stimuli of different intensities together with a uniform light background and recording the pressures of the pushbutton by the tested patient when he detects such stimuli, as in standard Visual Field tests. It also acquires confocal retinal images illuminating the retina of the patient's eye, with visible light for imaging purposes and with infrared light for imaging purposes, focusing and retinal tracking.

1.16 Temperature of applied parts

The applied parts of the devices are the forehead rest and the chin rest. When the device is operated at the upper limit of its operating temperature range (i.e. close to 40°C/104 °F), the temperature of these parts can, in extreme conditions, reach 46°C/115°C. It is recommended to not exceed the maximum intended duration of contact of 10 minutes between these parts and the patient skin. It is recommended to advise the patients to report to you any possible temperature-related discomfort he/she may perceive.

1.17 Content of the device packaging

The device is provided with:

Custom Control Interface with multi-touch display	Prismatic stereoscopic goggles
Support bracket for Control Interface with mounting kit	COMPASS front lens cap
External power supply with power cord	Light shield with magnets
Forehead and chin rest silicone cushions	This Instruction for Use (or Leaflet, in case of electronic Instruction for Use)
Dust cover	Mini-HDMI-to-HDMI adapter
Patient Push button	USB Extension cable

2. OVERVIEW

Congratulations for choosing COMPASS and its fundus perimetry and confocal retinal imaging capabilities.

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 an automatic perimeter[2] with fundus imaging capabilities (Fundus Perimeter), that measures retinal sensitivity, fixation stability and locus of fixation, and allows the acquisition of confocal images of the retina, thanks to its confocal scanning imaging system which uses infrared and visible light.

COMPASS works with COMPASS Software, and it operates as standalone units.

Each device integrates a Control Interface with multi-touch display and an external power supply.

As automatic perimeter, COMPASS offers full compatibility with standard 24-2, 30-2 and 10-2 visual field-testing choosing one of the projection strategies available (ex. 4-2, ZEST, ZEST Fast).

COMPASS SupraThreshold testing is used to perform fast screening for visual field loss.

COMPASS contains age-matched databases of retinal sensitivity in normal subjects.

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.

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.

Federal laws (US) restrict this device to sale by or on the order of a physician or a properly licensed practitioner. The clinical interpretation of the images is restricted to licensed eye care practitioners.

[2] *ISO 12866: 1999 Ophthalmic instruments — Perimeters*

3. COMPASS

3.1 Device description

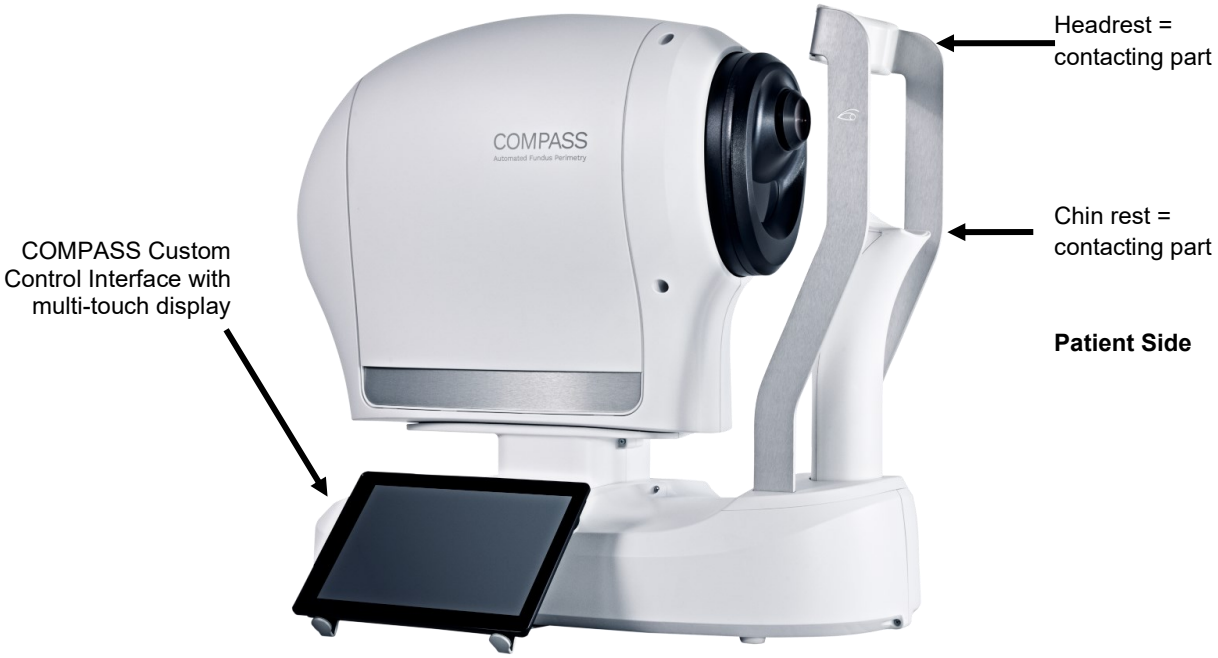


Fig. 1 – COMPASS

The main parts[3] of COMPASS consist of:

- COMPASS Custom Control Interface with multi-touch display
- External Power Supply[4]
- Patient Push Button[5]

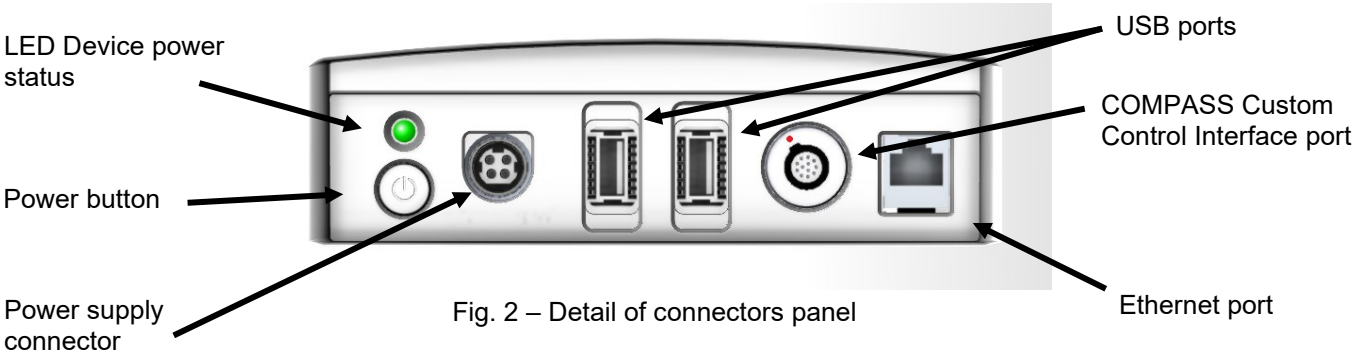


Fig. 2 – Detail of connectors panel

[3] *For a list of all components included with the COMPASS device, see the section "Content of the device packaging" of this Instruction for Use.*

[4] *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.*

[5] *The Patient Push Button is a device component, manufactured by CENTERVUE S.P.A.*

Fig. 3 – Patient Push Button (contacting part)

3.2 The COMPASS Custom Control Interface

The COMPASS Custom Control Interface with color multi-touch display (see Fig. 4) is an integral part of the device and COMPASS cannot operate without it.
The COMPASS Custom Control Interface must be connected to COMPASS using the supplied cable[6]: if the connection is not working an error message will appear on the screen (see § 19 for details). The Mini-HDMI-to-HDMI adapter allows the user to connect the tablet to an external monitor to display the image on a larger screen.

Patient data and images are not stored on the COMPASS Custom Control Interface

Fig. 4 – COMPASS Custom Control Interface with multi-touch display supplied with each COMPASS

The COMPASS Custom Control Interface with multi-touch display must be used only together with COMPASS and in accordance with the instructions provided in this Instruction for Use. Use of the COMPASS Custom Control Interface for other purposes than the one intended by the Manufacturer, as well as any modifications or misuses are exclusively under end-user responsibility.

To protect your device against unauthorized access and manipulation, make sure that only authorized personnel have physical access to the device

[6] *The COMPASS Custom Control Interface with multi-touch display is equipped with a custom cable permanently connected to it.*

4. LABELS, SYMBOLS AND DEFINITIONS

4.1 Labels

Device information such as device identifier (REF), serial number, manufacturing date and UDI barcode are reported in the labels fixed on the right[7] side of each device as shown in the following figure. Please do not remove them.

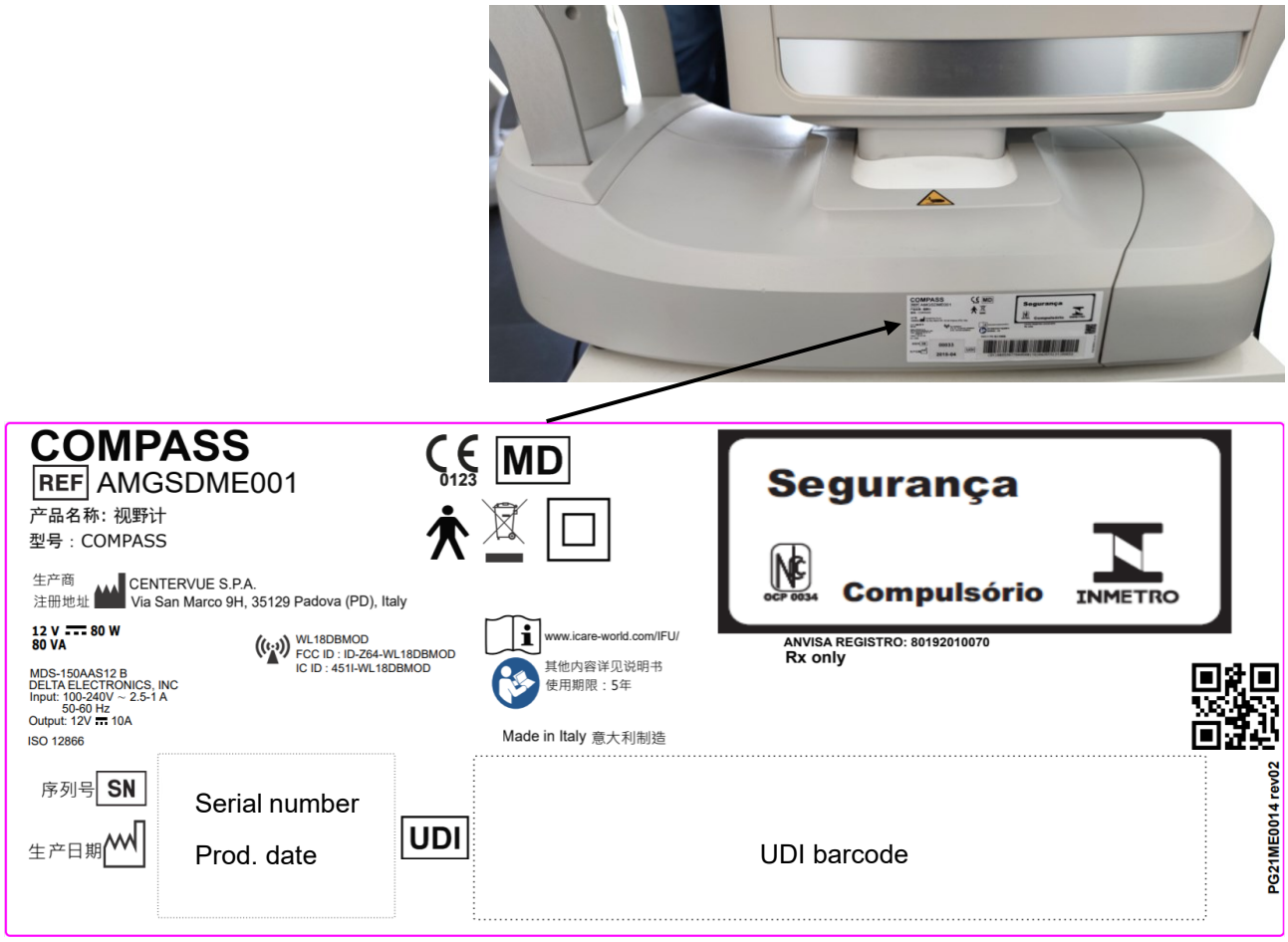


Fig. 5 – Device and warning labels[8]

[7] *Right and left sides are determined considering patient's point of view during exam.*

[8] *Labelling might be subject to changes depending on local regulatory requirements. The label QR Code does not contain information for the end-user, and it is intended for internal use only.*

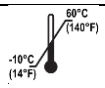
4.2 Symbols used on the device

The meaning of the symbols adopted in the device label is as follows:

Symbol	Explanation
	Information about the Manufacturer.
	Manufacturing date (YYYY-MM).
	Device identifier (catalogue number–product code).
	COMPASS is a Medical Device.
	COMPASS Serial number.
	UDI number.
	Electrical and electronic waste is destined for separate recycling.
	Class II device, according to IEC 60601-1.
	Please refer to the eIFU.
	This instructions for use must be read. Read this instruction for use before starting work or before operating equipment or machinery.
CE 0123	CE mark: the device complies with the general safety and performance requirements of the Regulation (EU) 2017/745. CE mark is followed by Notified Body identifier.
	Type B Applied Part.
	Non-ionizing radiation - ME EQUIPMENT that includes RF transmitters.
12 V ⎓ 80 W 80 VA	Device consumption.
DELTA ELECTRONICS, INC MDS.150AAS12 B INPUT: 100-240V ~ 2.5-1 A 50-60Hz OUTPUT: 12V ⎓ 10A	Power supply.
	Warning, closing motion of mechanical parts of equipment. Take care to avoid injury to hands.

4.3 Other symbols found on the device packaging

The meaning of the symbols adopted on the device packaging is as follows:

Symbol	Explanation
	Information about the Manufacturer.
	Fragile. Handle with care.
	Kilogram stacking limit because of the nature of the device package.
	The acceptable maximum relative humidity for storage and transport.
	The maximum and minimum temperatures limits for storage and transport.
	Correct upright position of the transport package.
	Device package shall be kept away from rain and be kept in dry conditions.

4.4 Other symbols found in this Instruction for Use

The meaning of the additional symbols adopted in this Instruction for Use is as follows:

Symbol	Explanation
	Important Information.
	General Warning, read carefully.

4.5 Definitions

The meaning of the specific words adopted in this Instruction for Use are as follows:

Word	Explanation
Alignment	The action of moving the top part of the device so that its optics are aligned with a patient's pupil.
Customer	COMPASS owner (it can be different from the COMPASS device's end-user)
Device	The synonym of COMPASS device used in this Instruction for Use.
Exam	Any Visual Field or Fundus acquisition session performed using the COMPASS device for a certain patient on a certain date. In this instru, the terms "test" and "exam" are used as synonyms.
Field	A portion of the retina visible in a specific image.
Fixation / Fixating	The ability of a patient to fix his/her view on a specific point, for example the internal fixation target.
Fixation target	A small bright green circle visible when looking into the front lens of the COMPASS device, used to move the gaze of the patient and capture different fields.
Focusing	The compensation, by means of internal optics, of a patient's spherical defect (myopia, hyperopia).
IFU	Acronym of Instruction for Use
Operator	COMPASS device' end-user
Optic disk	A specific portion of the retina characterized by a roughly circular shape and by outgoing / incoming vessels and fibers.
Picture	The synonym of the image acquired by COMPASS device used in these Instructions for Use.
Pupil	The aperture located in the center 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.
Remote viewer	The web application running on an external PC.
Retina	The inner layer of the eyeball. It is the main area of interest in the exams acquired by COMPASS device.
Sensitivity threshold	The minimum intensity of a light stimulus that is reliably perceived by a patient as emerging from the background.
Stereo exam	The examination mode that involves the acquisition of two images of the retina taken from different angles, providing a three-dimensional view using suitable prismatic glasses.
Stimulus	A spot of light, projected for a limited amount of time on a randomly selected retinal area overlapped on a uniform light background. Analysing the patient's responses to multiple projections of stimuli of varying intensity on the same area allows to determine the Sensitivity threshold (see definition above) for the tested area.

COMPASS provides capabilities for a fully automated test process. Specific training is not required: it is recommended for the end user (operator) to carefully read this Instruction for Use to be informed and trained before the use.

In particular, the end user (operator) shall be acquainted with the above concepts.

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

5. SAFETY INFORMATION

Although great care and diligence has been taken during the design and development of this device to reduce as far as possible all risks related to the use of the devices, it is important to read and understand the following precautions to further mitigate all residual risks.
The following precautions are important to use the device in safety:

- The device is for professional use only.
- The device needs to be installed and put into service by Authorized Service Center.
- Do not use COMPASS device if the covers or other parts of the device have been removed.
- Avoid all contact with water: risk of fire or electric shock.
- Stand clear from moving parts during operation.
- Do not open COMPASS device: this could lead to electric shocks or damage to the device.
- No serviceable parts inside. Internal inspection is allowed to authorized personnel only.
- Closing motion of mechanical parts of equipment, take care to avoid injury to hands and finger.
- Do not use the device when there are visible signs of materials degradation.
- COMPASS device is supplied with an earth ground by means of a protection conductor contained inside the power supply cable. Before turning on the system, make sure the power supply socket is correctly grounded to avoid the risk of electric shock.
- COMPASS device power supply must be connected to a socket with a circuit breaker.
- COMPASS' power supply allows to isolate the device from the supply mains on all poles simultaneously: when positioning the device, place it in a way that does not make it difficult to disconnect the power supply when needed.
- The use of other cables and accessories on COMPASS device than ones provided by the Manufacturer may negatively affect EMC performances.
- The power cable shall be properly maintained during use. In case of damage, contact CENTERVUE S.P.A. for the replacement.

- It is recommended to power off the device according to instructions of section §16; removing the power cable could result in data loss.
- External device/s connected to COMPASS device, into the patient environment, must comply with IEC 60601-1. Those device/s that do not comply/complies with the IEC 60601-1 must be kept out of the patient environment and must comply with IEC 60950-1. Any end-user who connects external devices COMPASS device 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.
- COMPASS device must be used in a room with an electrical system that complies with applicable healthcare environment safety regulations.
- COMPASS device must NOT be used in an oxygen-rich environment or presence of flammable anaesthetics.
- COMPASS device must be placed in a room that is not exposed to adverse chemical-physical conditions, such as the presence of sulphur, salt, dust, direct sunlight, lack of ventilation, high humidity, sudden temperature drops or peaks. The safety and/or effectiveness of the device cannot be guaranteed if these conditions are not met.
- COMPASS device needs to be operated in a semi-dark environment, to ease the natural dilation of the patient's pupil.
- The only applied parts of COMPASS device are the chinrest and forehead rest (see Fig. 1) and the Patient Push Button (see Fig. 3).
- COMPASS device need to be operated in the following environmental conditions:
    - Temperature: +10 °C to +40°C (50°F to 104° F)
    - Humidity (max): 90% not condensing
- COMPASS device need to be stored in the following environmental conditions:
    - Temperature: -10 °C to +60°C (14° F to 140° F)
    - Humidity (max): 95% not condensing

- Applied parts surface temperature (i.e. head and chin rests) can exceed the value of 41°C/105°F (i.e. maximum 46°C/115°F) when the device is operated at the upper limit of its use temperature range. Touch time of applied parts when the device is operated is < 10 min.
- Only technicians authorized by the CENTERVUE S.P.A. may service COMPASS device. The Manufacturer cannot be held responsible for the device safety should COMPASS device be opened, repairs carried out (included using of not Manufacturer's genuine parts), third-parties software installed, or parts replaced by an unauthorized person.
- Do not modify the device without authorization of the manufacturer: if this device is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- The Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist authorized Service technicians to repair those parts of the COMPASS device that are designated by the Manufacturer as repairable by Service personnel.
- In case an unexpected hardware condition occurs during use, an error message may appear (see for example Fig. 6) and the device may become temporarily locked. It is possible to reset this condition by letting the device re-initialize: refer to §15.2 for the complete procedure. If the error persists, please contact an Authorized Service Center.
- Risks can arise in relation to the biological contamination caused by the environment the device is operated into, and by the user and the patients. Follow the cleaning and disinfection instructions provided below in this Instruction for Use.
- The device is not supplied sterile, nor is intended to be sterilized prior or after use; nevertheless, the risks connected to the biocompatibility of the parts that come into contact with the patient are in relation to severe consequences, including allergic reactions. Contact material used in COMPASS is biocompatible and safe for the contact with intact skin for limited exposure.

The following precautions are important to use the device correctly:

- The clinical interpretation of the images acquired by COMPASS is restricted to licensed eye care practitioners. The process of making a diagnosis using COMPASS device results is the responsibility of the eye care practitioner.
- Device-specific training is not required: it is recommended for the end-user (operator) to carefully read this Instruction for Use to be informed before use.
- Use the device in dim light, or at least away from direct light to facilitate the natural dilation of the pupil.
- Provide explanations to patients before placing them in front of the device: refer to § 7.
- The minimum pupil diameter required to obtain good quality images is 3.0 mm.
- COMPASS device works in a non-mydriatic condition for patients with a minimum pupil size of 3.0 mm: the decision to use the mydriatic agent on a patient's pupil eye is under the responsibility of the eye care practitioner.
- Report any serious incident to the Manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

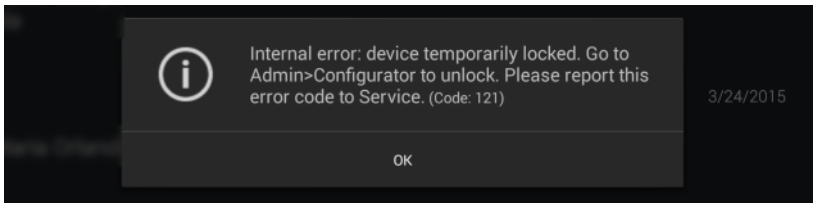


Fig. 6 – Example of error message

5.1 Security Information

The following precautions for the End-users and the Responsible Organization are important to control the risks related to network interfaces, data protection and cybersecurity.

- When in operation, COMPASS device contains Personal Data. Transferring data via USB ports (USB export) or via Ethernet (Shared Remote Folder) may result in compromised patient privacy.
- It is the end user's responsibility to keep and maintain an updated copy of the data generated by COMPASS device through regular use of the backup facility, thus preventing the risk of accidental loss of data.
- To protect your device against unauthorized access and manipulation, make sure that only authorized personnel have physical access to the device.
- The COMPASS Custom Control interface offers Wi-Fi connection (used for remote printing): it is strongly recommended to connect only to trusted networks protected by an encryption system, like for example WPA2, and refrain from connecting to unsecured Wi-Fi networks.
- The device offers a Wired Network Connection (via Ethernet cable), used to connect to a Remote Viewer (accessible with device credentials) and to store and/or backup data on a Remote Shared Folder (accessible with infrastructure credentials).
- Connecting the device increases its vulnerability to security risks that could disable your system. The Responsible Organization should maintain proper IT security practices like up-to-date virus protection, firewall and data protection in the systems where the device is used.
- When setting your credentials in the device and in any connected PC/Laptop/server, it is strongly recommended to use complex passwords; refer to your infrastructure's policies to create an effective password. If your infrastructure does not enforce any password policy, we recommend the following:
    - a strong password must be at least 8 characters long;
    - it should not contain any of your personal information, like your real name, username or your company name;
    - it must be different from your previously used passwords;
    - it should not contain any word spelled completely;
    - a strong password should contain different types of characters, including uppercase letters, lowercase letters, numbers and characters;
    - don't write down your password on notes;
    - don't share your password with other people;
    - change your password from time to time.
- The Remote Viewer browser runs on your PC/Laptop and allows to locally download exams reports and patient's images; reports and images stored in the Remote Shared Folder can be available also in your PC/Laptop. It is strongly recommended to protect your computer by:
    - applying physical security measures (locks, security alarms, monitoring, etc.) to prevent unauthorized persons from accessing your computer that stores patients' personal data files;

- using full disk encryption (Bitlocker) with a strong password to render data unreadable even if an unauthorized person were to gain access to your computer;
- using firewall and antivirus software to prevent intrusion and to detect infected files that might compromise the security of your computer, and thereby enable unauthorized file access;
- installing security patches and updates in a timely manner;
- protect access to your Windows account with a strong password (see indication above);
- log off or power off when leaving your computer unattended.

- DICOM files usually include very sensitive information about the patient (name, age, ID number, birth date, weight, etc.) and contain the medical images, which itself are of an extremely sensitive nature. Special care must be taken to ensure that this information stays private and is not susceptible to unauthorized access. Before taking any further actions, make sure that you are authorized to view and store specific DICOM files on your machine.

- DICOM related interfaces (Physical Interfaces used to export DICOM Data) are: Shared Remote Folder via Ethernet and USB Export via USB ports.

- When saving, exporting, or sending DICOM files, please remember that the DICOM protocol does not encrypt patients' personal data; for this reason, it is strongly recommended to delete the DICOM files from your computer when they are no longer necessary.

6. FIRST USAGE

6.1 Preparation of the device

> We recommend reading carefully and thoroughly §5 before proceeding with the first use.

To make COMPASS functional for the first use:

- extract the device from its box;
- place it on a suitable electrical table[9];
- insert the Headrest silicone cushion on the metal support (see Fig. 7);
- mount the support bracket provided for the COMPASS Custom Control Interface (see §6.2 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 its dedicated port (see Fig. 2);
- plug the power supply to the wall socket.

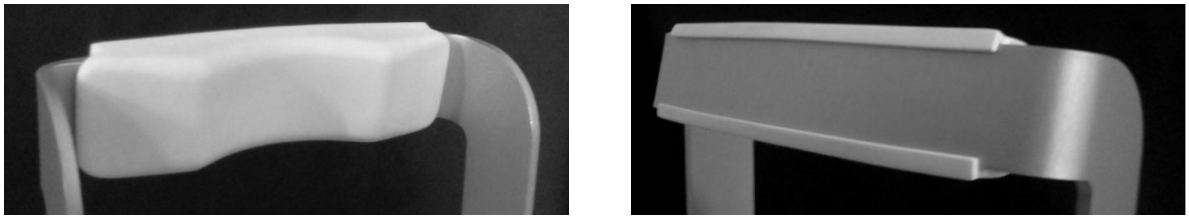


Fig. 7 - Headrest silicone cushion mounted on metal support

6.2 Assembling the tablet support bracket

Fasten the COMPASS Custom Control Interface to its support bracket using the two dedicated screws.
As an example, Fig. 10 shows the holes to be used for the left-side mount depicted in Fig. 8: to fix the support bracket use holes marked 1 and 2. Other configurations can be chosen, based on the user's preferences.

Fig. 8 – COMPASS Custom Control Interface mounted on the left side of the device

[9] *Not provided with the device. For a list of all components included with COMPASS, see the section "Content of the device packaging" of this Instruction for Use.*

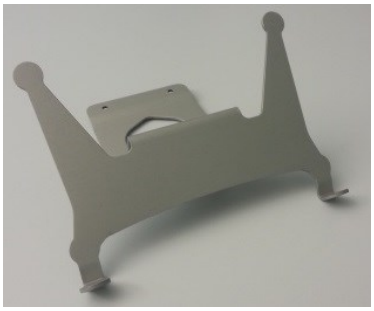


Fig. 9 – COMPASS Control Interface support bracket

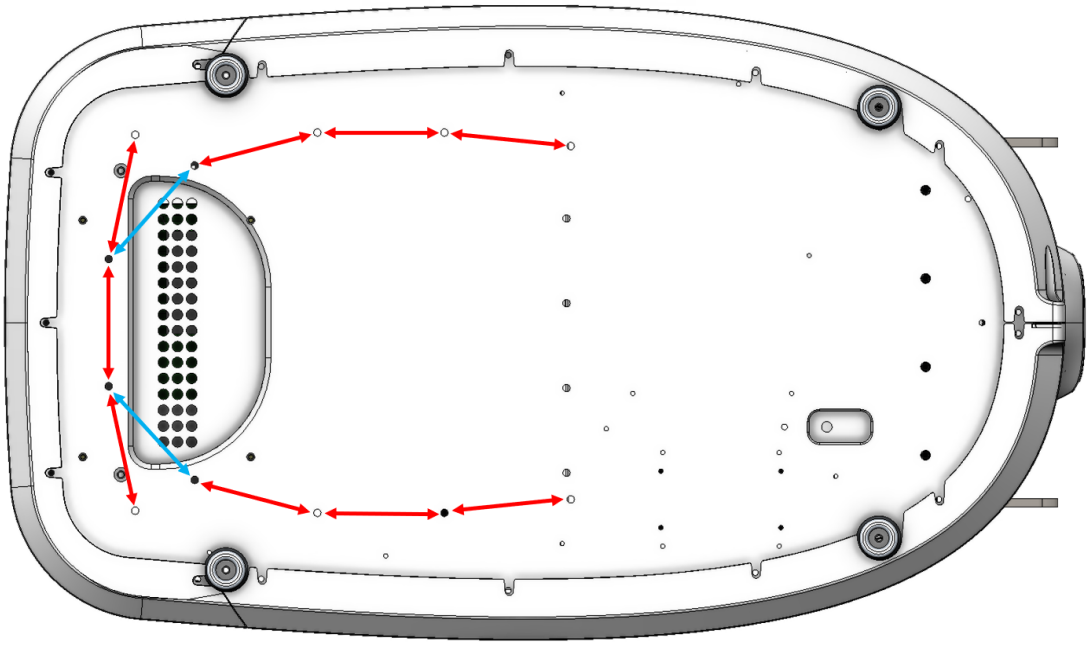


Fig. 10 – Device bottom with holes for the control Interface. Only **RED** positions can be used.

Mounting the support bracket on the back of the device will make access to USB ports difficult: in such case, use a USB extension cable[10] to make one of the USB ports readily accessible.

6.3 Removing the front lens cap

Unscrew the device's front lens cap to remove it, before turning on the device.

[10] *It is provided with the device. For a list of all components included with COMPASS, see the section "Content of the device packaging" of this Instruction for Use.*

6.4 Attaching the Magnetic Light Shield

The Magnetic Light Shield is a device component[11] 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. 11).

Fig. 11 – Magnetic Light Shield mounted on COMPASS

[11] *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.*

6.5 Turning on the Device

Turn on the Device by pressing the **power button** (see Fig. 2), the device will emit a single beep, the **LED Power Status** will power on and the **Custom control Interface** will power on. Then wait for the boot process to complete, until the **Login** screen appears (see Fig. 12).
During the power-on, the **LED Power Status** performs a red/green/blue cycle to test its LEDs functioning. After two second **LED Power Status** turns off, then becomes steady green. The device is turned on.

In addition, the following information are important to understand device messages emitted from the color **LED Power Status** (see Fig. 2):

- steady green light means “power on”
- Fast flashing red light means “Reboot”
- Fast flashing red/green light means “Reboot – Over Voltage Protection/Under Voltage Protection”
- Single red flashlight means “start of error code reporting”
- Single white flashlight means “start of version code reporting”
- Flashing blue light (code reporting) is proportional at tens in the numerical code
- Flashing green light (code reporting) is proportional at units in the numerical code

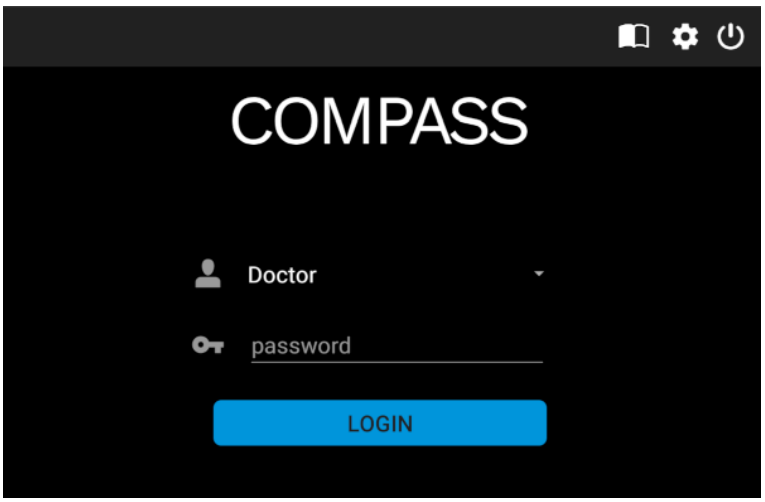


Fig. 12 – Login screen

The  button on the top allows to display the electronic Instruction for Use (this Instruction for Use) with the internal PDF viewer. Pressing the button will display a list of this Instruction for Use translated in all the languages supported: select the most suitable for your Country to open it.

From the drop-down menu you can select your user profile choosing between Doctor or Admin:

- **Doctor** User have only the access to perform exam (§ 11) and review exams (§ 12).
- **Admin** User have the access to the Doctor User function and the device’s setting (§ 15).

Type the password[12] and click on **Login** button. If login is successful, the **Home** screen opens (see Fig. 12).

The session is automatically closed after 10 minutes of inactivity, which means that the user has to perform the login again.

To modify the login password, see §15.4.
To modify the standby time, please see §15.12

[12] *Please ask an Authorized iCare representative for the factory password*

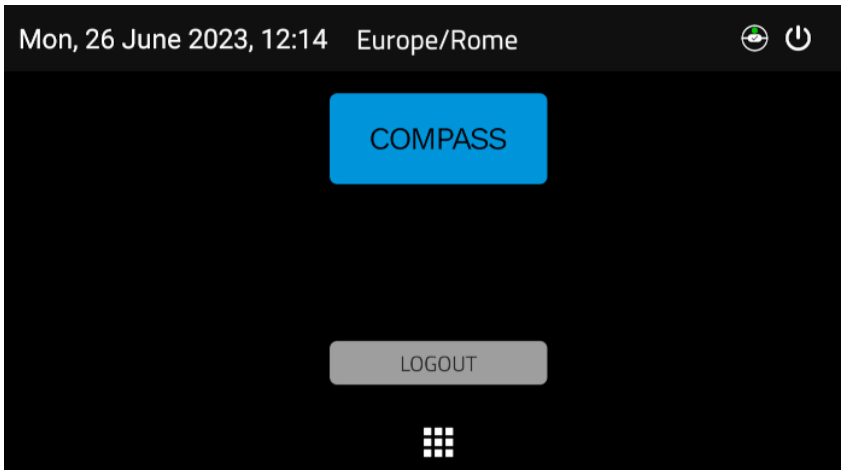


Fig. 13 - Home screen

6.6 Unlock function

When unlock button appears insert password to exit the standby to come back to the latest used page.

7. PREPARING THE PATIENT

This paragraph explains how to prepare a patient for the COMPASS exam (in this Instruction for Use is used as “test”).
COMPASS is a non-mydriatic device[12]: there is no need to dilate the patient’s pupil unless the pupil is smaller than 3 mm. The eye which is not examined should be patched.

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.

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 with the eye mark found on the sides of the metal frame (see Fig. 14). If this is not the case the chin rest height needs to be adjusted with the on-screen controls (see § 11.11)

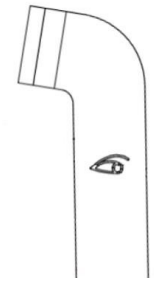


Fig. 14 - Sketch of the eye mark on the metal frame

Before the exam, the end-user should 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, in particular the device will never touch your eye, and 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 normal that you do not see many of the spots.

8. OPTIONAL FEATURES AVAILABLE UNDER LICENSE

The following optional features of COMPASS' software can be enabled by purchasing and installing a dedicated license[13]:

- Full **DICOM** communication (MWL and PACS): see also § 9
- Additional concurrent **Clients for the Remote Viewer**, for units manufactured with a SW version equal to or later than 4.0: for more details see § 13
- **SmartMosaic** (mosaic of 3 Fundus images): see § 11.14
- **LDAP** (Lightwight Directory Access Protocol) support: refer to the **COMPASS LDAP User Manual**
- **OPI** (Open Perimetry Interface): refer to the **COMPASS OPI User Manual**.

9. DICOM SUPPORT

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

COMPASS can export DICOM files natively.

Purchasing an additional license, COMPASS also supports full DICOM communication, as specified in the **COMPASS DICOM Conformance Statement document**[14]. For info about how to use COMPASS with DICOM, refer to the **COMPASS DICOM Operating Manual**.

DICOM support is available only for wired connections.

DICOM communication and ***LDAP support*** licenses are not compatible: it is not possible to install both licenses on the same device.

[13] Contact your local distributor for information about how to purchase and install any of the above software features.

[14] 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. 15).

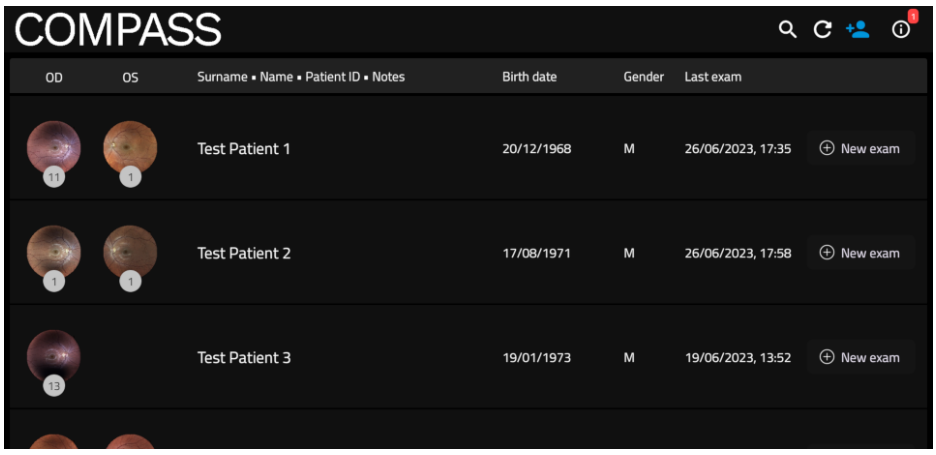


Fig. 15 – Patient list screen

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 patient's gender
- the date of the last exam performed
- a button that allows to start a new exam for that patient directly from the Patient List

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

- access the Information Center screen (see § 10.1)
- refresh the Patient List
- adding a new patient (see § 10.2)
- deleting a patient (see § 10.3)
- searching for an existing patient (see § 10.4)
- selecting an existing patient (see § 10.5)

10.1 Information Center

The **Information Center** 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 five tabs: **Backup, Shared folder**, **Data Storage, Data Security** and **About**.
Each tab title could display a red badge indicating the number of unread notifications related to that tab.

Backup tab

From the **Backup** tab, it is possible to check the backup progression status, stop a running backup or start a manual backup. This screen also includes information on the last backup performed, with its status (completed, cancelled, failed with reason explanation). For more information on Backup, see § 15.8.

Fig. 16 – Information Center screen – Backup status

Shared Folder tab

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 § 15.10. See § 19 for information about possible error conditions during the export process.

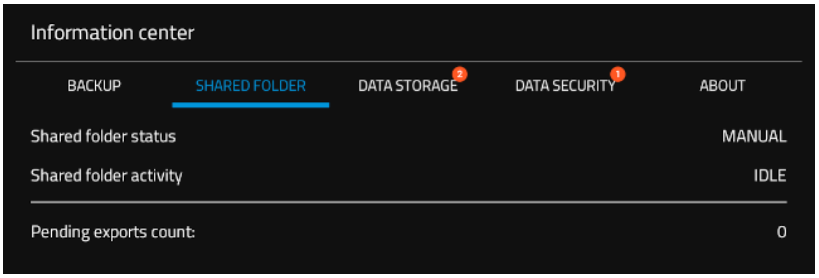


Fig. 17 – Information Center screen – Shared folder status

Data Storage tab

The Data Storage tab contains information about the capacity and the amount of space available of the internal data storage, and detects whether the installed storage media (both the memory module for the operating system and the disk for the exam data) are genuine parts authorized by the Manufacturer.

⚠	In case of storage media failure, it is recommended to replace it with a genuine part authorized by the Manufacturer, to ensure its compatibility and reliability. Contact your Authorized Service Center in case you need to replace the storage media.

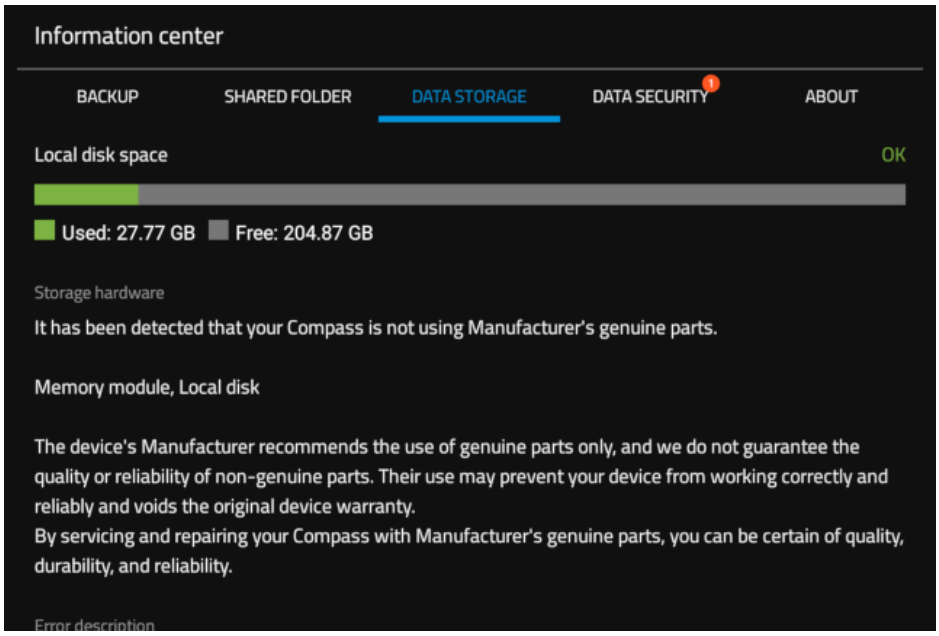


Fig. 18 – Information Center screen – Data Storage tab

Data Security tab

The Data Security tab lists any unsecure settings detected in the device configuration, and suggests how to solve them.

Unlike what happens with the other tabs, the notifications displayed on the Data Security tab title badge are permanent and are not dismissed after being read: the only way to make them disappear is to solve the detected security threats.

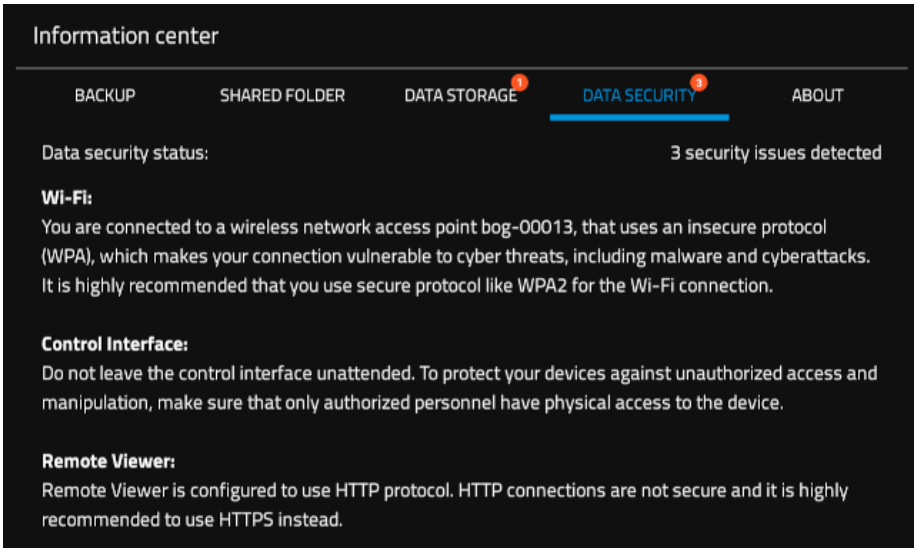


Fig. 19 - Information Center screen - Data Security Center tab, with 3 security issues detected

In detail, the following settings can be detected as insecure:

Wi-Fi: the tablet is connected via Wi-Fi (using the Android settings) to an access point that uses an insecure protocol (such as WEP, WPA or open connection), which is a potential cybersecurity threat. Configure the Wi-Fi access point to use the WPA2 protocol to solve this issue.

Control Interface: COMPASS units equipped with legacy ASUS and Nexus tablets as Control Interface could be compromised by a malicious user with advanced hacking knowledge and physical access to the tablet. It is recommended to never leave the Control Interface unattended.

Remote Viewer: the Remote Viewer is configured to use HTTP protocol, which is a potential cybersecurity threat. Configure the Remote Viewer to use HTTPS (see § 15.6), which prevents man-in-the-middle attacks.

About tab

The About tab contains information about the software release version installed.

It also contains the  button that allows to open the electronic Instruction for Use (this Instruction for Use), similarly to the Login page (see Fig. 12).

Press the More button to display information on the unit serial number, the device configuration, the status of optional licenses installed (see § 8) and the maximum number clients that can connect simultaneously to the Remote Viewer (see § 13 for more details).

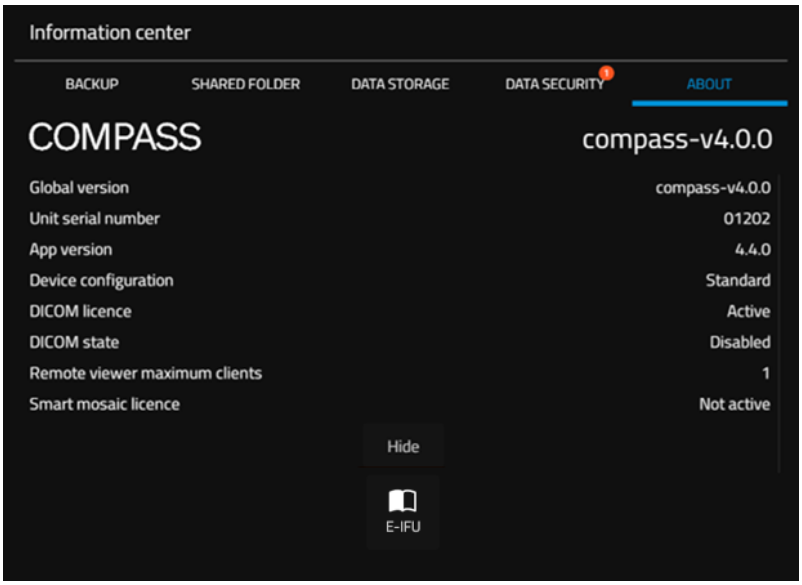


Fig. 20 – Information Center screen – About tab expanded

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. **21**). 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, to avoid undesired patient duplications.

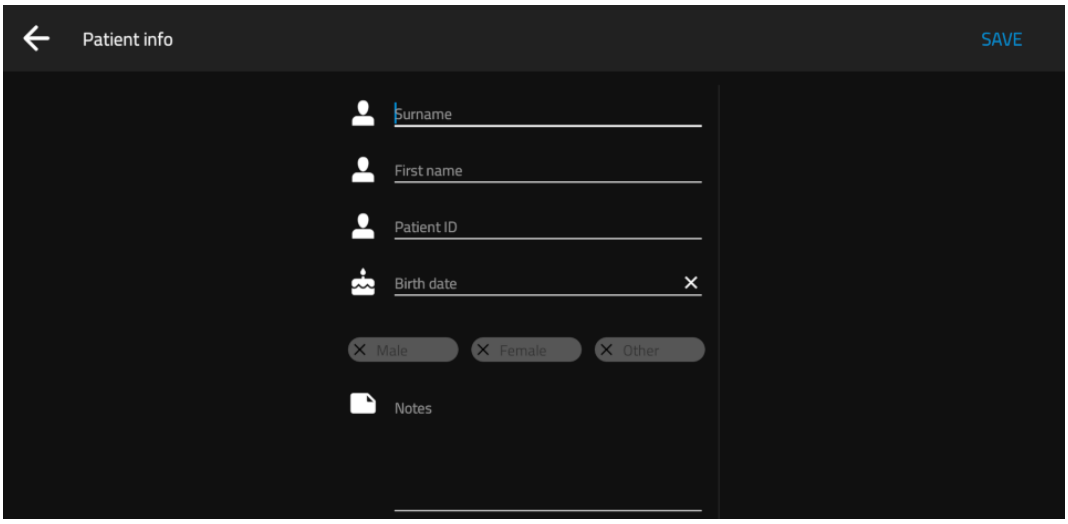


Fig. 21 – Patient editing screen

10.3 Deleting patients

To delete one or more patient, long-press on the corresponding row. The patient will be marked as selected and the  button will appear on the top bar. It is now possible to select/deselect more patients to be deleted at the same time. Press the trash bin button and confirm to delete the selected patients.

Alternatively, you can press the trash bin button in the Patient Record page of the desired patient (see Fig. 22) and confirm to delete it.

10.4 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  .

10.5 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.

Once a patient has been selected in any of the above ways, the **Patient Record** screen opens (see Fig. 22) and provides information on the selected patient, whose name is shown at the top-left corner of the screen. Press the icon next to the patient's name to edit the patient's details.
On the left side of the screen the Visit List is present, displaying the exams grouped by visit (i.e., by date). Select any visit to access the exams taken on that date.
On the central part of the screen the exams taken on the selected visit are listed: the list can be scrolled by dragging it. Click on the desired exam to review it.
Press the **Select** button or long-press any exam to select multiple exams to delete or export: a checkbox will appear next to each exam of the current visit to allow to add or remove the exam to the selection; then, press the button to export the selected exams or the button and confirm to delete them. If no exam is selected, press the button and confirm to delete the entire patient.
On the right side of the screen the sequences of Visual Field exams are displayed, grouped by eye and by grid used. Click on a sequence to expand it as in Fig. 23: this will display a scrollable list containing all the exams included in the sequence, and a button to start a new Follow-up exam to be added to the sequence.
See § 12 for full details on how to review an exam. Click on the **New Exam** button to initiate a new Root test (see § 11.1 for details).

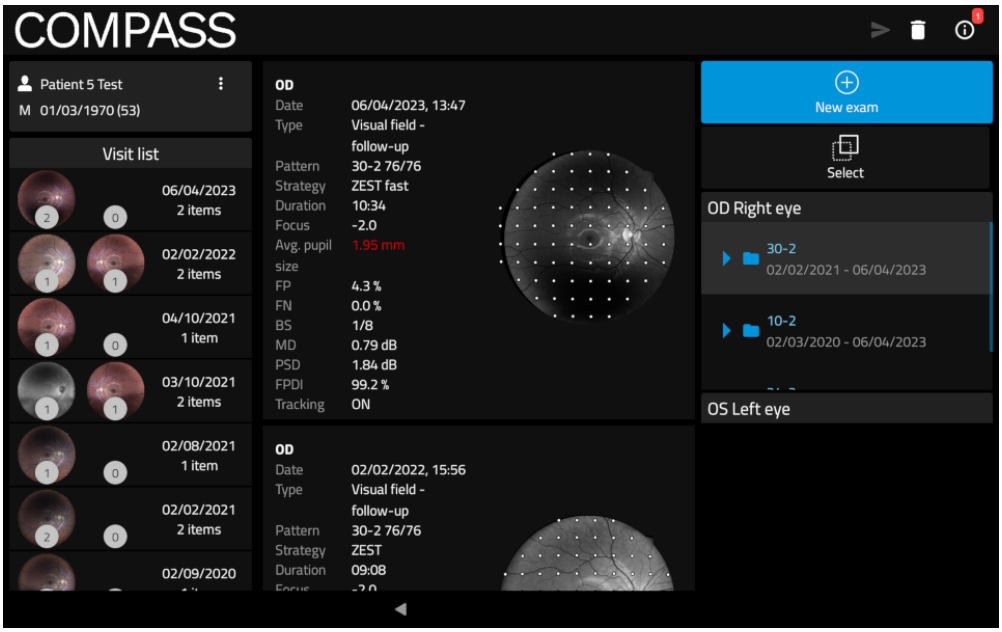


Fig. 22 – Patient Record screen

Fig. 23 – Exam sequence expanded

11. PERFORMING THE EXAM

This paragraph explains how to operate COMPASS to perform the test (in this instruction for use 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).

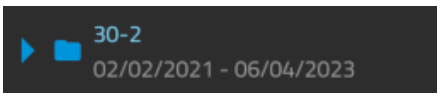
COMPASS provides four different test modalities:

- 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, ZEST and ZEST Fast 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. 33), 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**
- **an exam sequence (composed of a root test and its related follow-up tests) is identified by this graphics, displaying the grid used and the dates of the first and last exam of the sequence:**



- **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**

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 ***Exam Mode*** selector.
Then, select the desired projection strategy using the ***Visual Field Strategy*** 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 ***Exam Mode*** selector. For a description of the exam flow of the SupraThreshold test, refer to § 11.12.

11.5 Initiating a new Fundus/Fundus Stereo/SmartMosaic test

To initiate a new **Fundus** test, click on the **New Exam** button, and select **Fundus** using the ***Exam Mode*** selector.
Then, select the desired mode (among SmartMosaic, Fundus and Fundus Stereo) using the ***Visual Field Strategy*** selector
Finally, in case of a Single Field Fundus test, select the desired imaging mode (among IR, COLOR and IR+COLOR) using the ***Imaging Modality*** selector.
For a description of the exam flow of the fundus tests, refer to § 11.13.

11.6 Choosing test parameters

When the **New Exam** command is pressed the **Test parameters selection** screen opens (see Fig. 24), allowing review and modification of the test parameters.
The following commands / options are available:

1. **Exam mode** selection: ***Visual field, SupraThreshold, Quick SupraThreshold, Fundus***
2. **Eye** selection: ***OD (right eye), OS (left eye), OU (both eyes)***
3. Selection of:
   - **Visual Field strategy** (for Visual Field tests only): ***ZEST, ZEST Fast*** or ***"4-2"***
   - **Acquisition Modality** (for Fundus tests only): ***SmartMosaic, Single field*** or ***Stereo***
   - **Imaging Modality** (for Single field Fundus tests only): ***IR, COLOR*** or ***IR+COLOR***
4. For perimetric tests only, 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

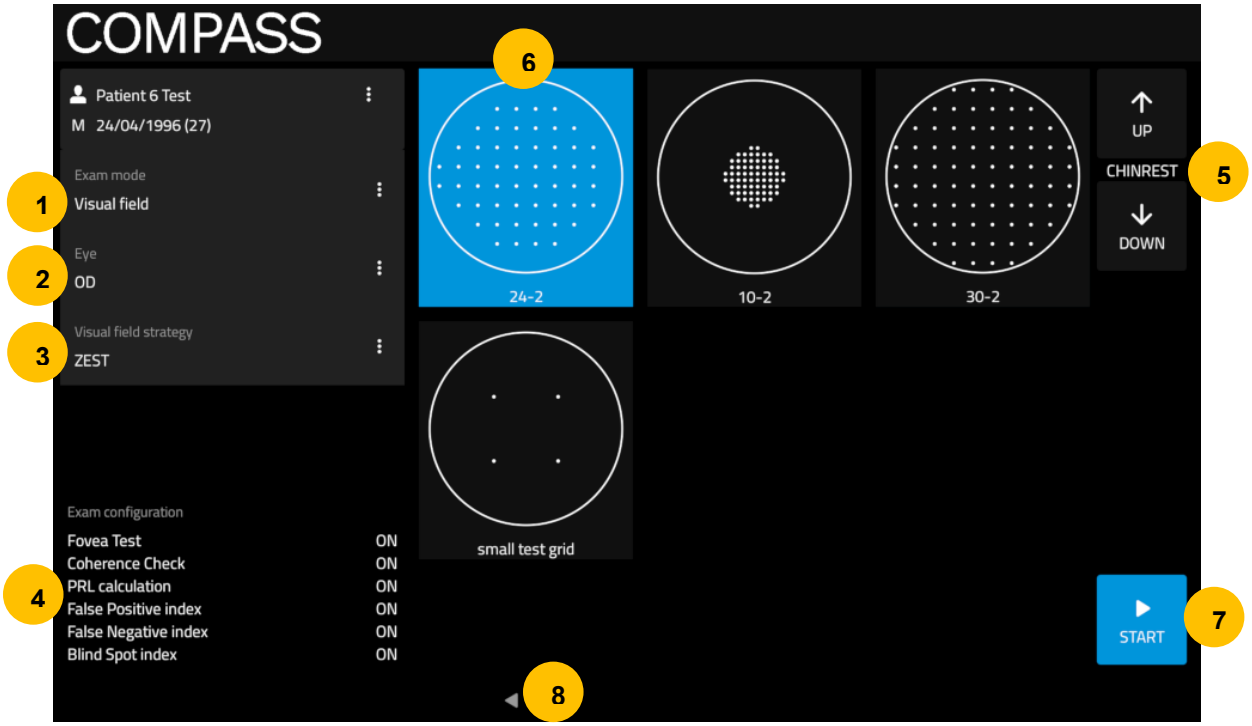


Fig. 24 – Test parameters selection screen

ZEST vs. 4-2 vs. ZEST Fast

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 ZEST Fast strategy adds an advanced projection algorithm to the ZEST strategy, allowing to reduce the examination time, resulting in a test approximately 30-40% shorter than a regular ZEST test with the Coherence Check option disabled.
ZEST and ZEST Fast strategies are equivalent, which means that it is possible to perform a Follow-up of a ZEST root test using the ZEST Fast strategy, and viceversa.

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 § 12.3. For the settings configuration, refer to §15.5.

Setting	Visual Field	SupraThreshold	Quick SupraThreshold
Coherence Check (CC)	Configurable, for ZEST strategy only	Not available	Not available
PRL calculation	ON	ON	OFF
Foveal threshold	ON	ON	Configurable
Blind Spot test (BS)	Configurable	ON	OFF
False Positives (FP)	ON	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 with 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 with 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 **Prev** button on the left of the screen to retake the reference image if its quality is not satisfactory (see for example Fig. 26). Click on the **Next** button to proceed. ⚠: **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 on the **Next** button to proceed (see Fig. 27) ⚠: **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 § 14).**
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 on **Next** to proceed with the 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 on **Next** to proceed with the 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 **Prev** button on the left 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. 28). 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 § 14). Once the image is satisfying, click on **Next** to finish the exam and store its results

VISUAL FIELD EXAMS WITH <u>30-2</u> 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. 25, 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. 25, 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. 25, 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.

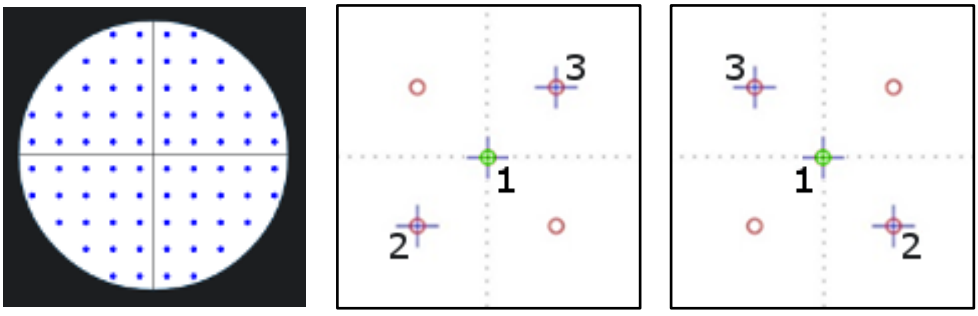


Fig. 25 – **"30-2"** grid test locations (left)

and fixation target positions used for OD (center) and OS (right)

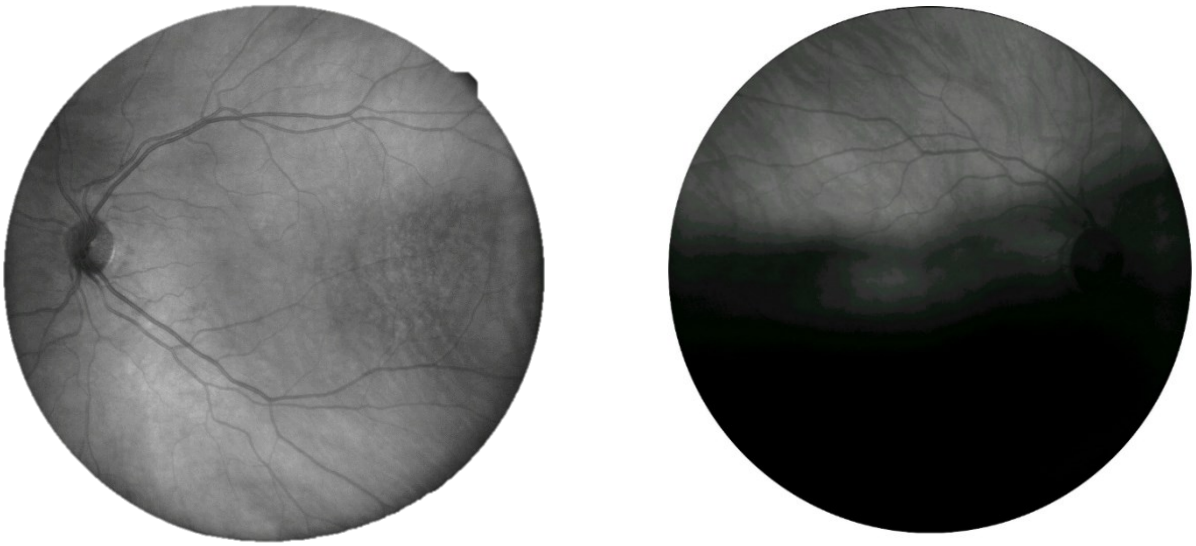


Fig. 26 – Good (left) and poor quality (right) reference image

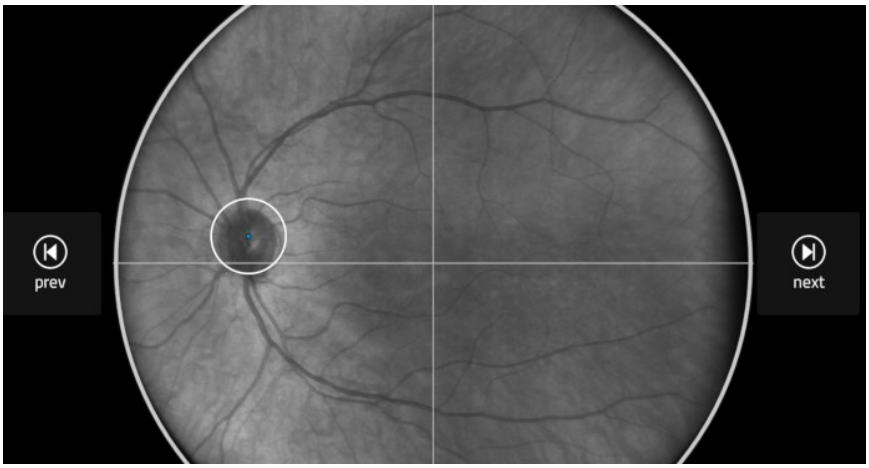


Fig. 27 – Marker for optic disc location in Exam screen

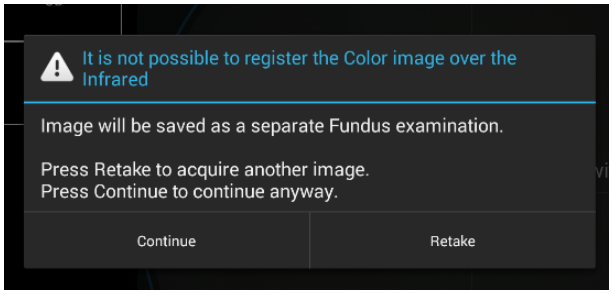


Fig. 28 – Message shown in case of a Color image registration failure

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. 29). **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 causes for this situation might be wrong patient head position (e.g. far from forehead rest), difficulties in fixation, closing eyes or falling eyelids.

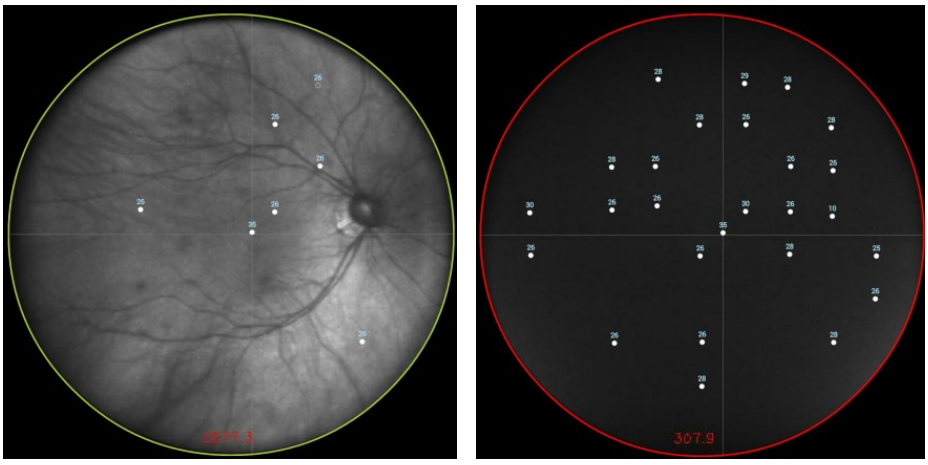


Fig. 29 – Tracking active (left) and on hold (right)

11.11 Monitoring test progress

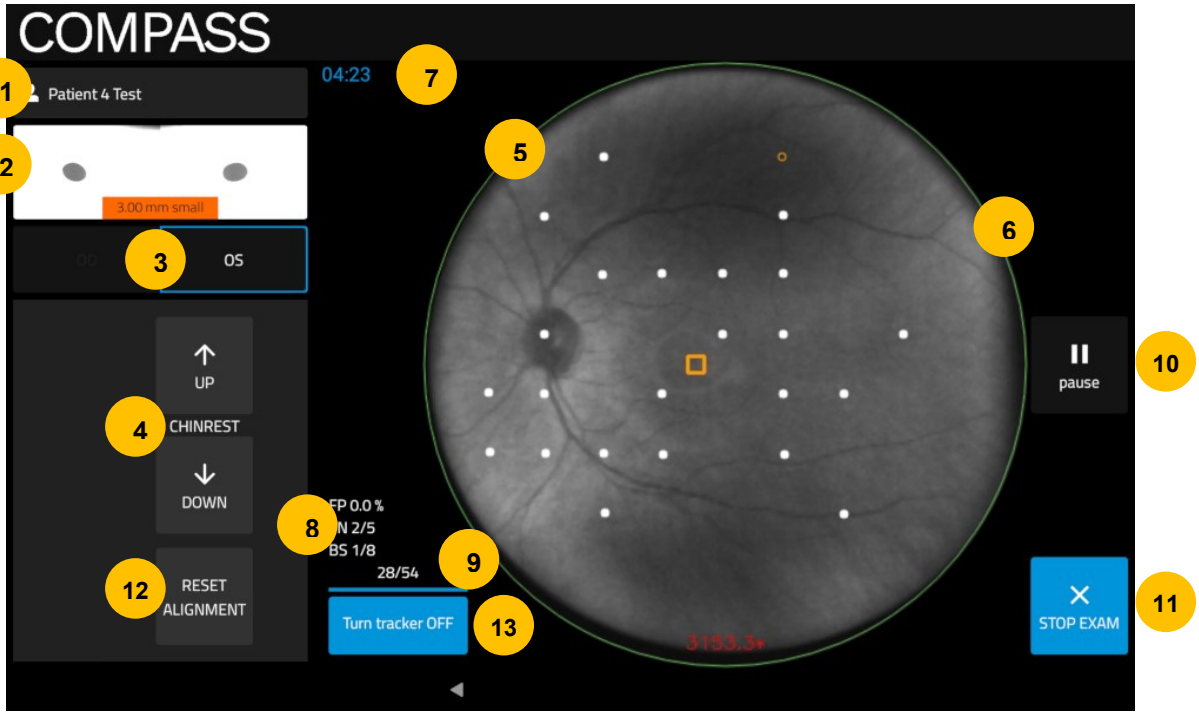


Fig. 30 – Exam screen while test is in progress

The following information and functions are available:

1. Patient name.
2. Pupil images from alignment cameras that allow the end user (operator) to check if patient's eyes are open, overlapped with a live measurement of the pupil size: if smaller than 3 mm a "small" label is displayed, and its color turns to orange. Pupil size may oscillate during the test due to accommodation.
3. Eye under examination (**OD / OS**)
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 with the centre of the fixation target at every moment). Completed stimuli are shown as white, filled dots. The stimulus being projected is shown as an empty orange circle, that turns to filled if the patient presses the pushbutton in time.
6. Tracking status (circular coloured frame).
7. Elapsed test time.
8. Reliability indices (False Positives, False Negatives and Blind Spot, see § 12.3) 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. Button that allows to pause the test at any time.
11. Button that allows to stop the exam: the exam will be saved as a partial test, containing the data of the completed stimuli only.
12. Button to reset the automatic alignment, if the motors' limits were reached.
13. 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. 31). <u>It is not possible to re-enable the tracking for the current exam once it has been disabled.</u> 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.

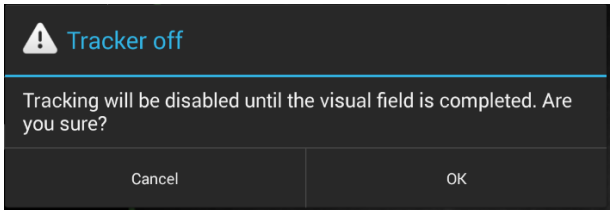


Fig. 31 – Confirmation request to disable tracking

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 outcomes: "*seen at lower intensity*", "*seen at higher intensity*", "*not seen at higher intensity*" (see Fig. 32). 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.

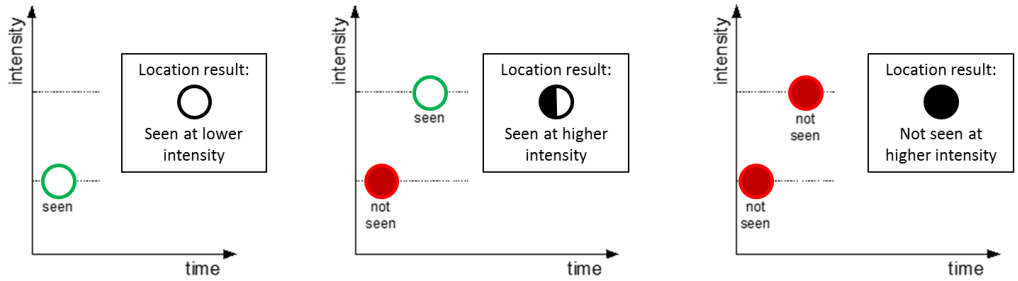


Fig. 32 – SupraThreshold test projection logic

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 § 12.5.

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. 33).

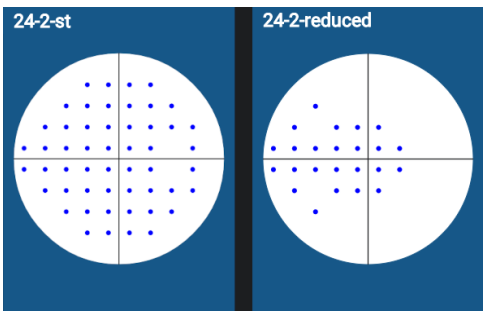


Fig. 33 – ***24-2-st*** (standard SupraThreshold) grid compared to ***24-2-reduced*** (Quick SupraThreshold)

11.13 Other exam types: FUNDUS and FUNDUS STEREO test

The **Fundus** test allows to acquire a TrueColor or Infrared photo of the fundus. With respect to the exam flow described at § 11.8, only steps 1, 2 and 8 take place, i.e. automatic alignment and focus. During the test, the fixation target is placed at the center of the visual field, to provide an image of the central field of the retina.
If the IR+COLOR option is selected, the two images are acquired in sequence and will be stored as two different exams.

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. For more information about the stereo feature, refer to § 12.6.

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.

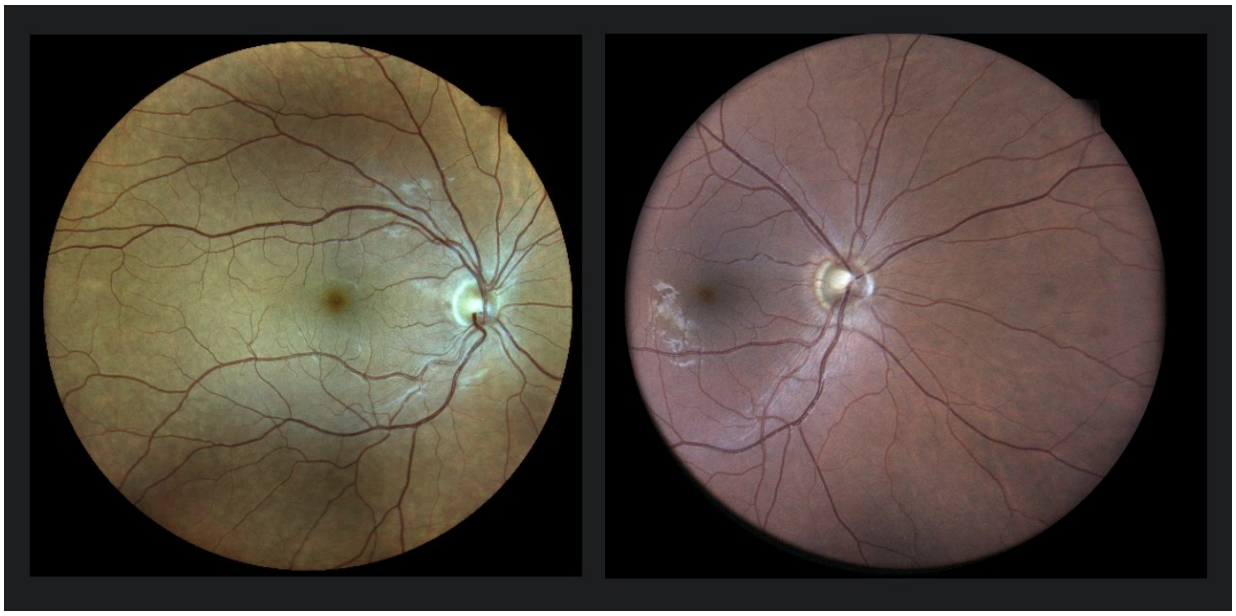


Fig. 34 – Example of a Fundus image (left) and of one of a Fundus Stereo image (one of the pair) (right)

11.13.1 Retaking an image

If the image quality is not satisfying, any Fundus image can be retaken, only within the current day. This can be done by pressing the button next to the desired image in the Patient Page (see Fig. 35): the device will acquire a new image and then the dialog in Fig. 36 will appear, allowing to compare the old and the new image and to decide whether to keep the old photo, replace it with the new one, or keep both.

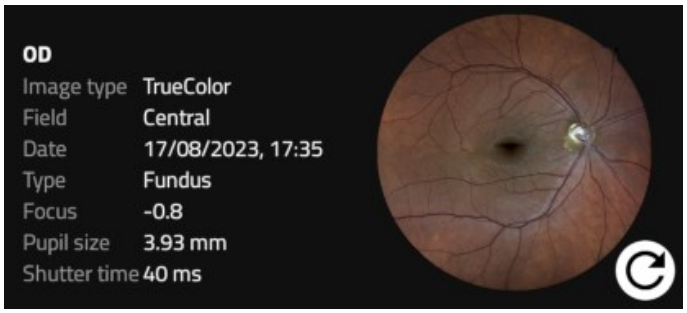


Fig. 35 – Fundus exam, with the retake button available

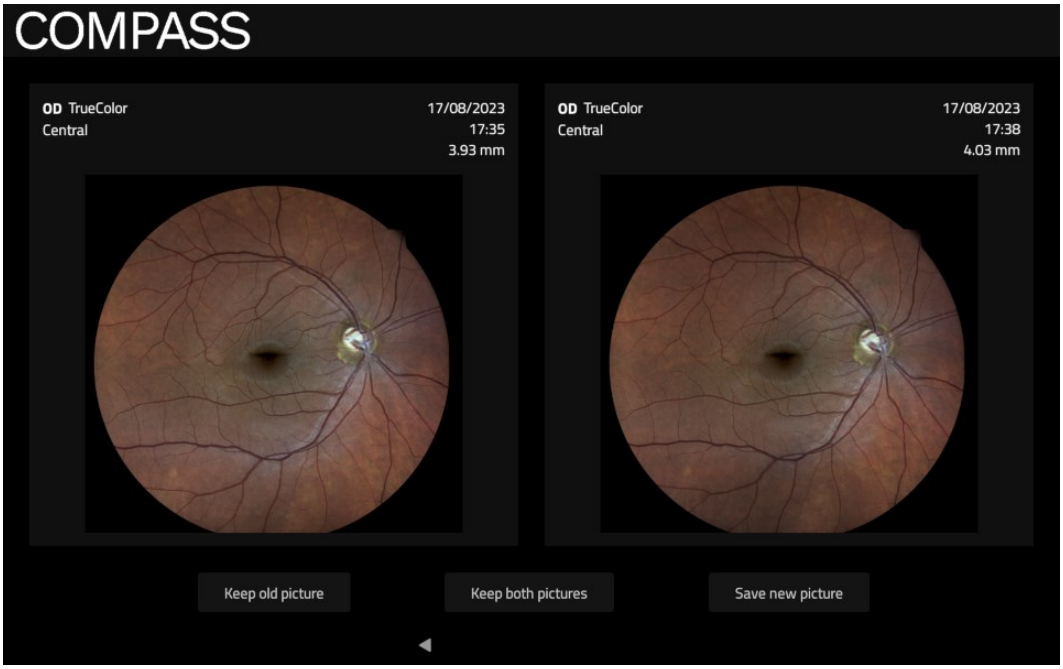


Fig. 36 – Image Retake: choosing which image(s) to keep

11.14 Other exam types: SMART MOSAIC test

The **SmartMosaic** is an optional feature that can be activated purchasing a dedicated license: see § 8 for details.
A SmartMosaic test consists of acquiring up to three Fundus TrueColor images of three pre-determined fields (Central, Nasal and Temporal), and to merge them into a single, wide-field image sized approximately 100°x60°.

As for the Fundus Stereo test, a delay between the shots is applied to let the pupil partially recover. After each shot, the fixation target will start blinking and gradually moving to the next position, to help the patient follow it. After all the images have been acquired, the interface in Fig. 37 will show up, allowing to retake any of the images that might have been acquired with low quality (typically due to pupil not recovered yet, bad alignment or blinking). Select the images that you want to re-acquire and press the **Retake Images** button. This procedure can be repeated as many times as needed. Press the **Create Mosaic** button to complete the test and start the mosaic generation.

After the mosaic has been generated, four Fundus exams will be stored: the three single fields that can be reviewed individually, and the Mosaic (see § 12.6 for details on reviewing Fundus images).
It will be possible to retake the single fields' images individually within the day, but not to re-generate the mosaic after it has been generated.

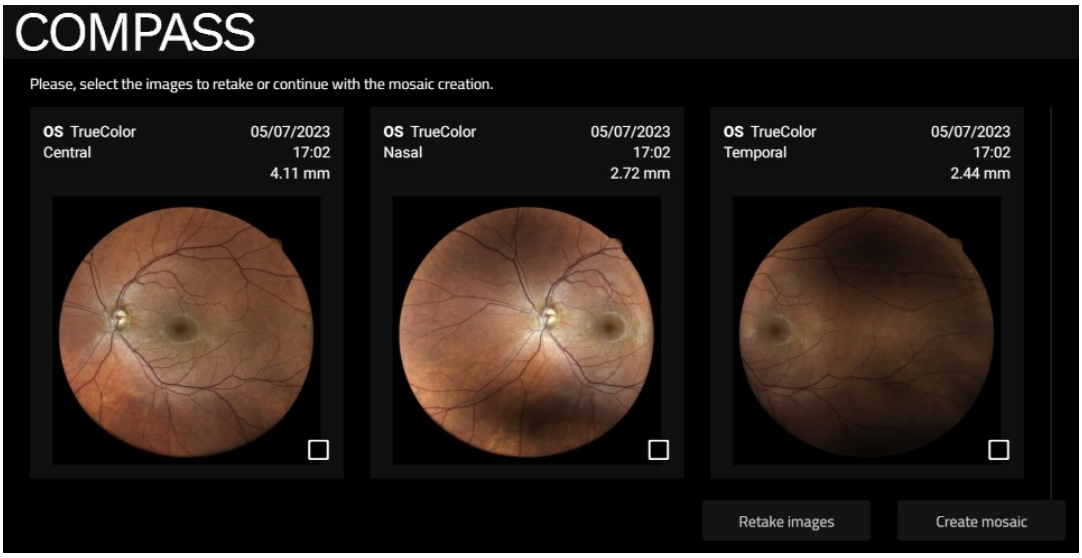


Fig. 37 - SmartMosaic: retaking the images

The images resulting from the mosaic process may contain artifacts (such as duplicated or disconnected vessels) that are generated at the transition between two adjacent fields and that are not present in the original images. Such artifacts can be easily ruled out by comparing the mosaic image with the original single-field images.

12. REVIEWING RESULTS

Once a test is completed, the system will open the **Patient Record** screen (Fig. 22) for the selected patient and display a thumbnail view (Fig. 38) of all exams taken on the selected date. Press on the desired exam to open the **Test Results Review** screen (see § 12.1).

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, ZEST Fast** 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**);
- Sate 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);
- If the exam was taken in the current day, the  button that allows to retake the photo (see § 11.13.1).

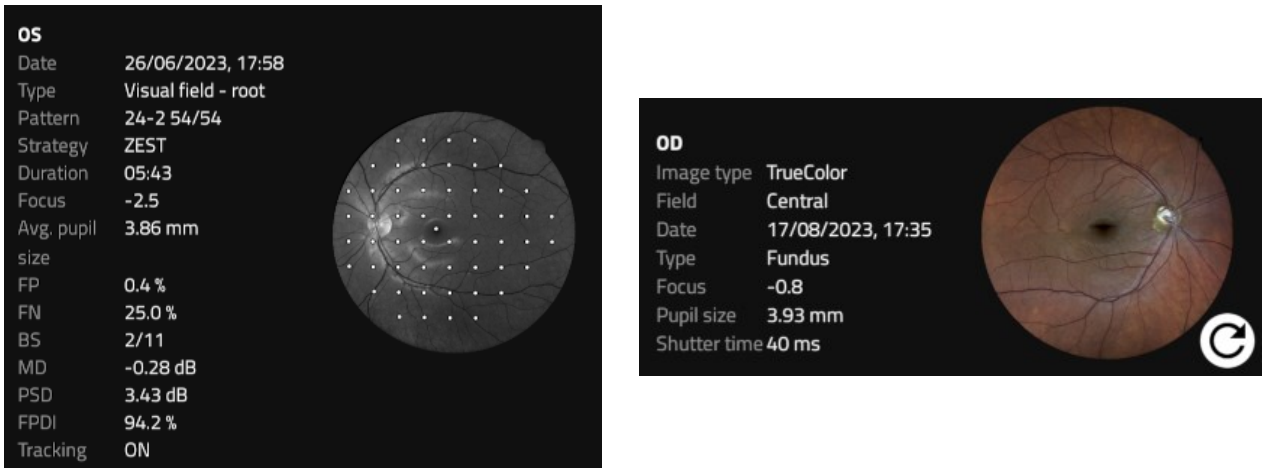


Fig. 38 – Example of thumbnails for **Visual Field** (left) and **Fundus** (right) exams

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.

12.1 Individual test results review

The **Exam Review** screen (Fig. 39) provides the following information and functions:

1. Patient name
2. Selector for image modality (**color, infrared** or **red-free**)
3. Retinal image and visual field data, depending on selected modality (default: red-free, infrared and red-free images are shown with overlaid VF data). Click on image to open a full screen view and zoom / pan the image. 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. Image tools including **blue, green, red filters** used to display individual color channels (for TrueColor image only) and **brightness, contrast and gamma**, used to enhance image brightness (see details explained in Table 3 below)
8. Commands for Single Test Report and Progression Report generation and sharing (see details explained in Table 3 below)
9. Command to go back to Patient record screen.

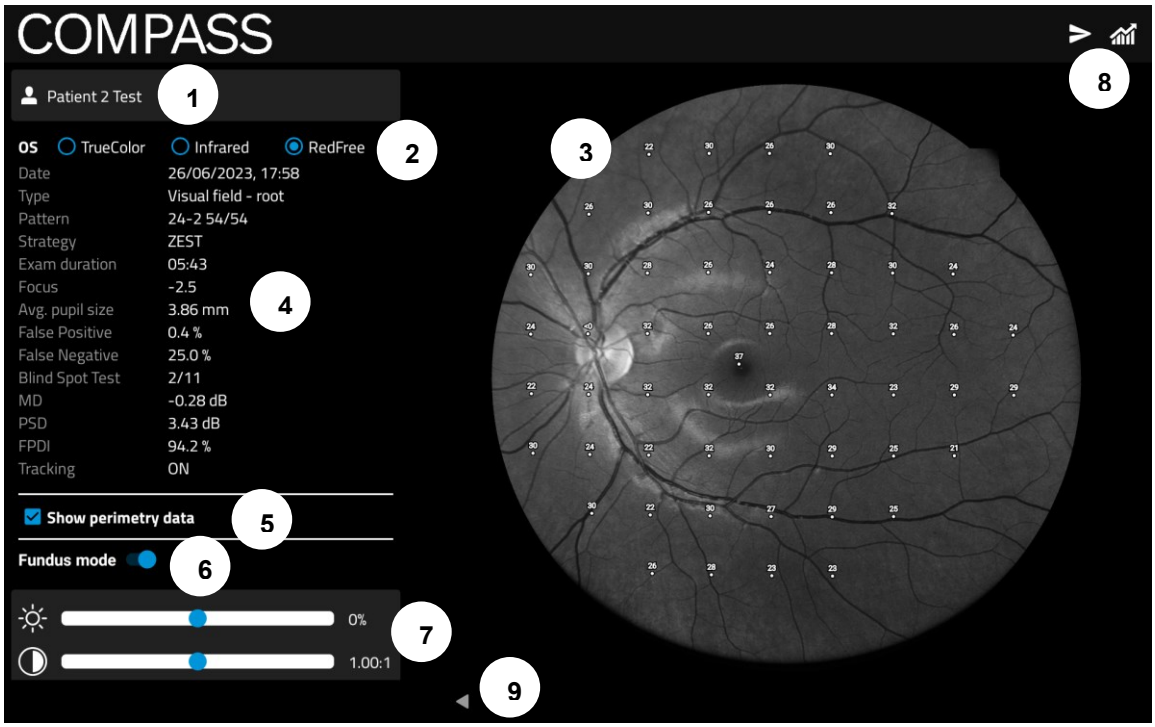


Fig. 39 – Exam review screen, red-free display modality

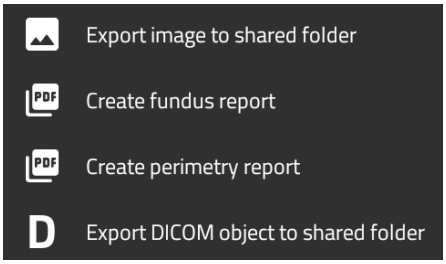
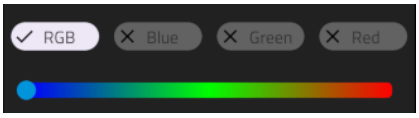
Top bar buttons	Description
	The following options will appear:  - **Export image to shared folder**: will send the displayed image to the shared folder (only available if the shared folder is set up) - **Export DICOM object to shared folder**: will send the displayed image as a DICOM object to the shared folder (only available if the shared folder is set up) - **Create fundus/perimetry report**: opens the interface for the report destination: see § 12.2 below.
	Generate the progression report (see § 12.4).
Image tools buttons	**Description**
 	Used to display individual colour channels (for TrueColor images). **The green channel provides the red-free image.**
 	Used to enhance image appearance by adjusting brightness, contrast and gamma. Each image type (Infrared, TrueColor, RedFree) has an independent set of these parameters. **These settings do not alter the original images, but are applied to that when opened.**
 	**The brightness, contrast and gamma settings are persistent**, which means that they are re-applied when the exam review is re-opened (also in the Remote Viewer) or when generating the exam report. Use this button to reset the brightness/contrast/gamma parameters to their default values.

Table 3 – Exam Review buttons and related commands

12.2 PDF report destination

When generating a Perimetry/Fundus/Progression PDF report, the dialog in Fig. 40 will show up. The buttons on the top bar allow to choose the destination for the generated report.

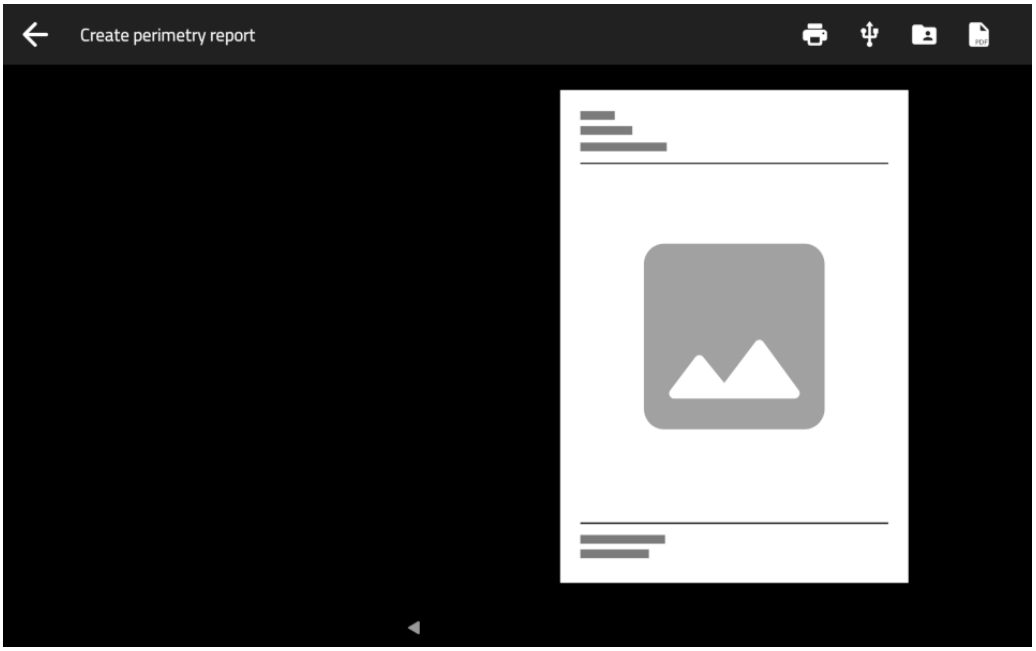


Fig. 40 - Dialog for the PDF report destination selection

Top bar button	Description
	Send the report directly to the printer.
	Store the report on the attached USB device. This button is only available when a USB device is plugged in.
	Send the report to the shared folder. This button is only available when a shared folder is set up (see § 15.10).
	Display the report in the onboard PDF viewer app.

12.3 Reliability indices

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

- **False Positives (FP)**: this value represents the occurrences in which the patient has pressed the pushbutton when no stimulus had been projected, and therefore he was 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 § 15.5.

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.

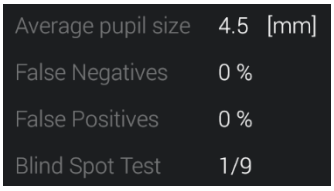


Fig. 41 – Detail of Exam review screen with reliability indices

Fixation plot / Area

Differently than in non-retinal tracked perimeters, the COMPASS fixation plot shown in a test report (see § 14.2 and Fig. 42 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 § 11.10), but these movements are considered and compensated at the time of projection of the stimuli, therefore they do not necessarily degrade a test reliability.

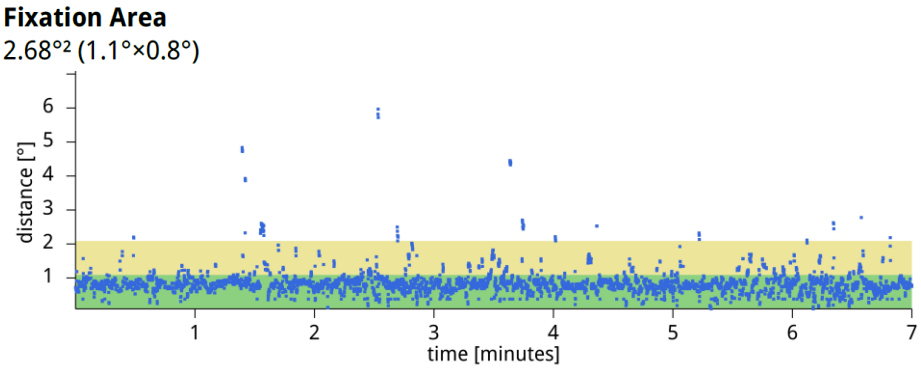


Fig. 42 – Fixation plot and Area

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.

12.4 Creating a Progression Report

To create a **Progression Report**, select and open any test belonging to the desired series (root or follow-up), then click the  button to generate the Progression Report.
SupraThreshold and Quick SupraThreshold tests cannot generate a Progression Report.

The **Progression report exam selection screen** will open (see Fig. 43), 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 of FP, FN, or BS indices).

Two different types of Progression Reports are available:

1) the **Comparison Report** (see § 14.6), that allows to compare any two exams, or a series of exams with 4-2 strategy.
2) the **Smart Progression Analysis Report** (see § 14.7), that provides the output of the **Smart Progression Analysis** on a series of exams taken with the ***ZEST*** or ***ZEST Fast*** strategy.

The Smart Progression Analysis Report is available for the ZEST and ZEST Fast strategies only.
The selected series can contain a mix of exams performed with any of the two strategies, which are considered equivalent. In detail, also the Baseline exams can be taken both with the same strategy or with different strategies (i.e., one ZEST and one ZEST Fast).

Exams where the FP index is higher than 15% are marked as Unreliable.
Note 1: unreliable exams are de-selected by default but can be selected on operator's choice (even to be used as Baseline exams). In both report types, they appear in the **Global Trend Analysis** graph with a different marker (grey instead of black) to identify them.
Note 2: incomplete tests are not selectable and will not be displayed in the Progression Report.

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 complete tests shall be included.
- If only two complete tests are selected, a **Comparison Report** is generated.
- If three or more ZEST/ZEST Fast tests are selected, a **Smart Progression Analysis Report** is generated: the two oldest complete tests selected will be marked as BASELINE (see Fig. 43), and they will constitute the base for the **Smart Progression Analysis**.

It is important to select two Baseline exams with similar results and close in time to produce a robust Smart Progression Analysis. To aid in this selection, two parameters are calculated:

1) the ***Baseline Similarity Index*** (***BSI***): this index quantifies how similar the results of the selected exams are, in percentage. It is advised to select two exams with more than 52.5% of BSI.
2) the ***Time Interval***: this value represents how distant in time the two exams are. It is advised to select two exams with less than 6 months of Time Interval.

It is possible to select two Baseline exams that do not fulfill these two conditions and proceed anyway; however, this situation will be highlighted both during the selection (with a  marker next to the related parameter, displayed in orange) and in the Smart Progression Report, where it will be printed in orange color (see § 14.7).

The **Progression Report Exams Selection** screen provides the following functions:

1. Checkboxes to select/deselect each exam, and one at the top to select/deselect all.
2. The Date column header allows to order the exams by date in ascending or descending order.
3. When two or more exams are selected, the two oldest are identified as BASELINE, and at the top right their ***Similarity Index*** and ***Time Interval*** values are displayed.
4. A checkbox that allows to hide/show Incomplete exams, that in any case cannot be selected.
5. A toggle button that allows to choose whether to use the MD or FPDI for the Global Trend Analysis chart in the Progression Report; the FPDI index is not available for 10-2 series.
6. A text comment will suggest how to proceed with the exam selection and which type of Report is going to be generated.
7. Press **GENERATE** to proceed with the Report creation or cancel to go back.

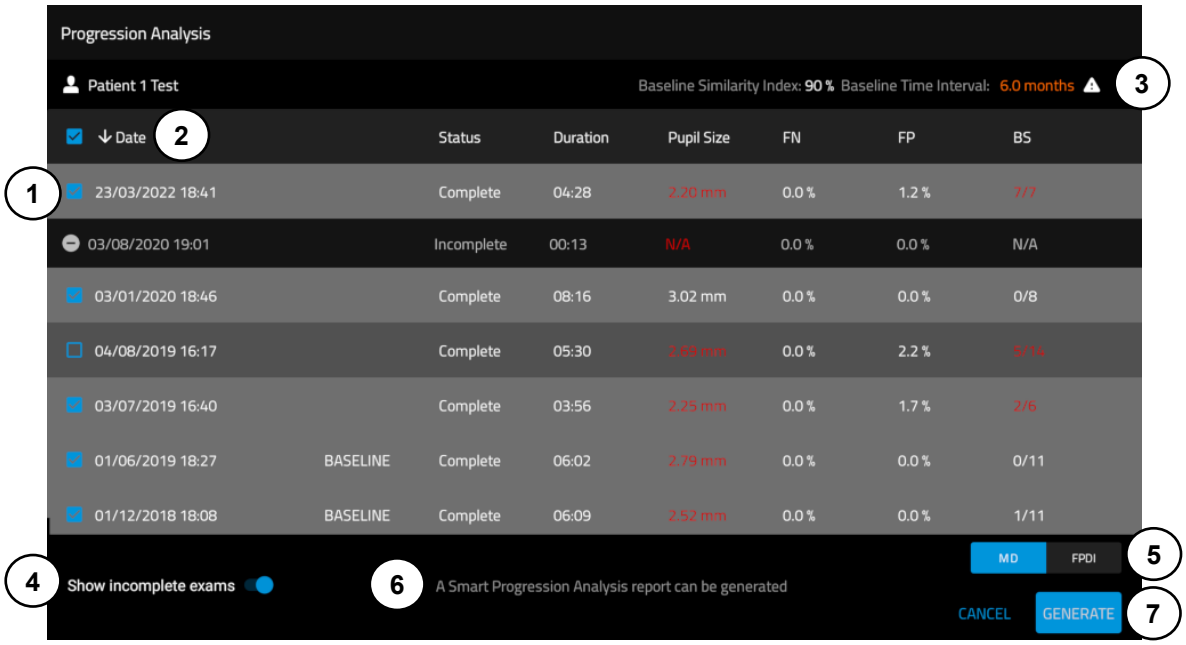


Fig. 43 – Progression Report exams selection screen

After pressing the **GENERATE** button, the report is created and the **Progression Report destination selection** screen appears (see Fig. 44), that allows to select whether to print the report directly, store it on a USB drive (if already plugged in), send it to the Shared Folder (if configured) or opened with the internal PDF Viewer.

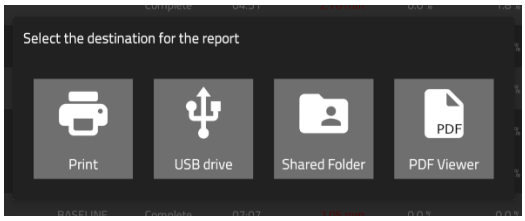


Fig. 44 – Progression Report destination selection screen

12.5 SupraThreshold exams review

The review window of a **SupraThreshold** test (Fig. 46 and Fig. 47) 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:

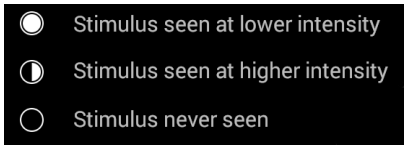


Fig. 45 – SupraThreshold responses

The MD, PSD and FPDI 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.

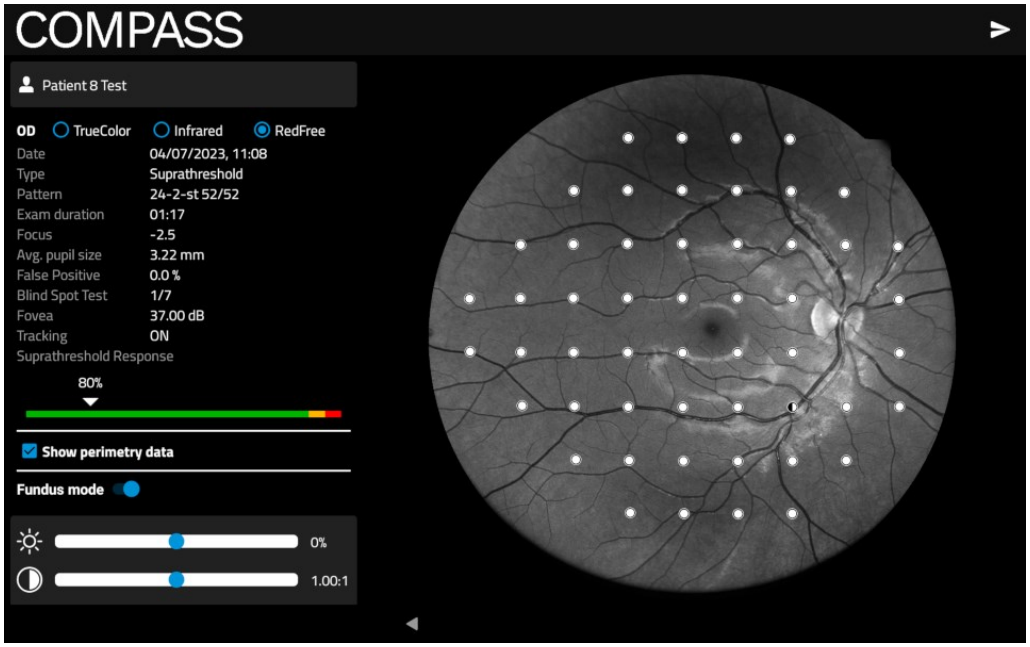


Fig. 46 – SupraThreshold exam review window

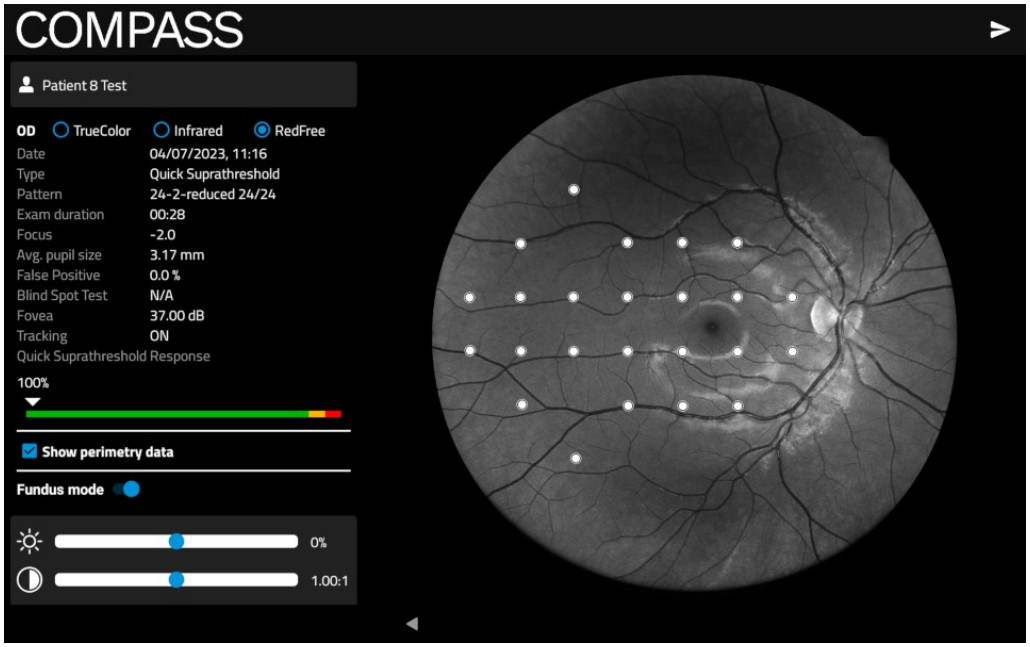


Fig. 47 – Quick SupraThreshold exam review window

12.6 Fundus exam review and Stereo 3D Viewer

The review window for **Fundus, SmartMosaic** 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. 48 and Fig. 49).
It is possible to zoom and move the image by pinching and dragging it as desired.
On the left side, the Image tools are available to adjust the image display parameters (brightness, contrast, channels, etc.).

Stereo images are stored and displayed as two single Fundus exams.

If the image is part of a Stereo pair of images, the 3D button allows to enter the **Stereo 3D Viewer** window to review the stereo pair it belongs to.

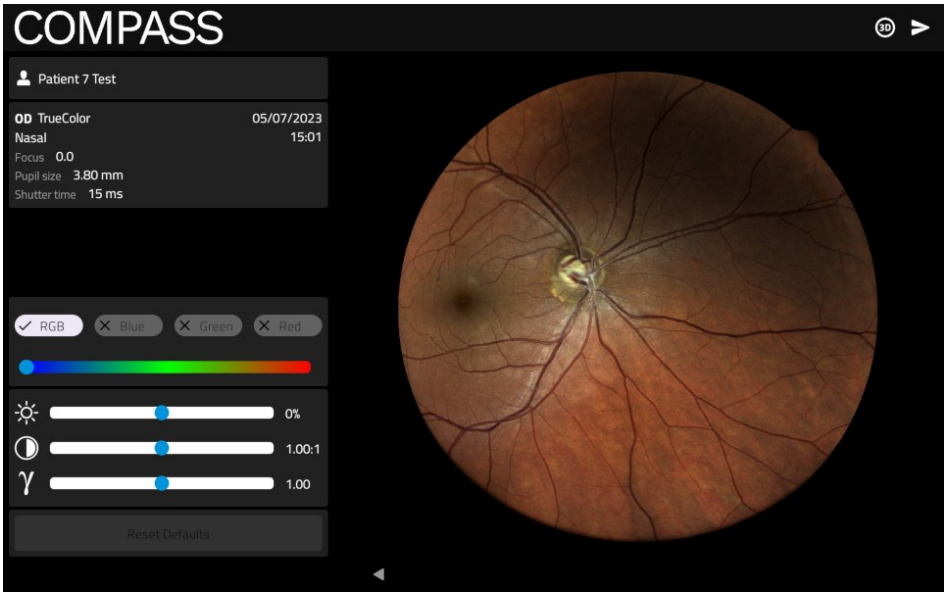


Fig. 48 – Fundus exam review window

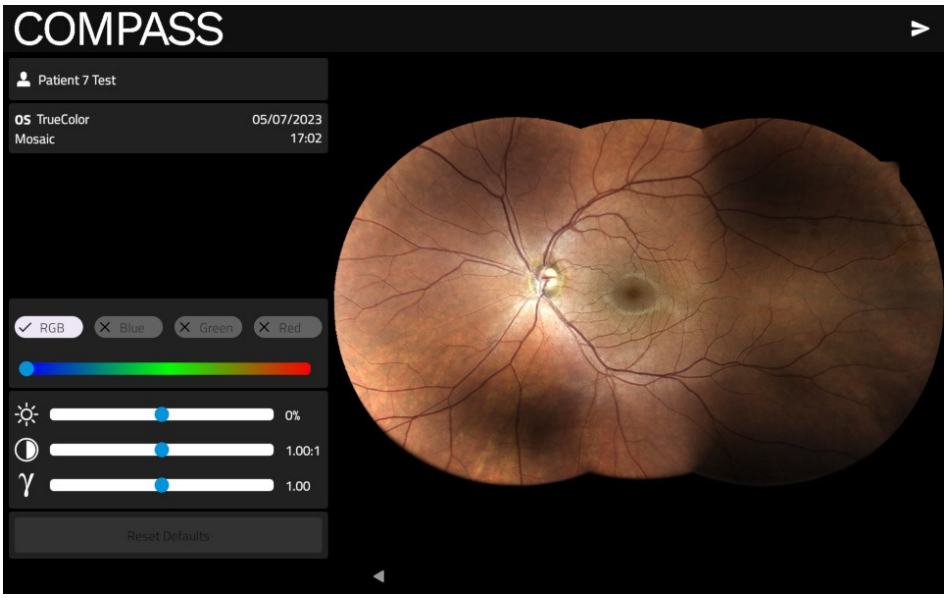


Fig. 49 – SmartMosaic exam review window

The **Stereo 3D Viewer** window (Fig. 50) 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.
To review stereo images, the end user (operator) should use specific 3D Prismatic stereoscopic goggles[15], 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.

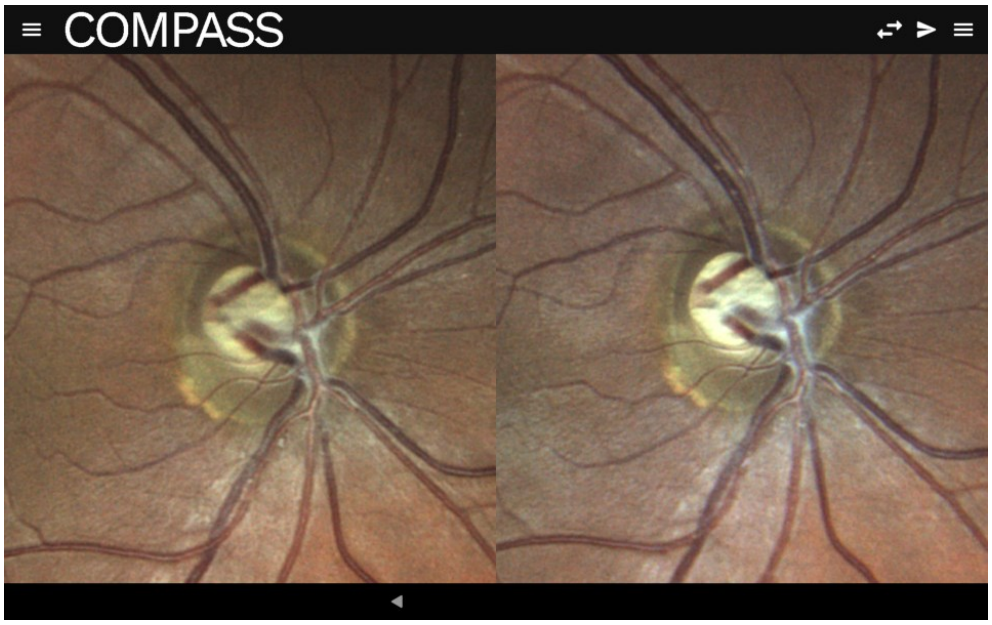


Fig. 50 – Stereo 3D Viewer

On the top bar, the following buttons are available:

Top bar button	Description
	Allows to view, print or export on USB or Shared Folder the report for the selected image (Fundus review) or pair of images (Stereo 3D Viewer).
	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.
	Displays the Image Tools interface to change the display parameters for the related image, such as brightness, contrast, etc. (see Table 3).

[15] *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.*

13. REMOTE VIEWER

The Remote Viewer is a browser-based software that allows the review of test results on any computer connected to COMPASS via a local area network.
The Remote Viewer provides access to the Patient List, individual Patient records, Exam Review screen and PDF printout.
To use the Remote Viewer, the device needs to be connected to the local area network via **Ethernet** connection.

The Remote Viewer is available for wired connections only.
Compatible browsers include Google Chrome™, Microsoft Edge™, Mozilla Firefox™ and Apple Safari™. Make sure you are accessing the Remote Viewer with the most up-to-date version of your browser.

Starting from the COMPASS serial number 03000, by default only one client can connect to the Remote Viewer. Additional concurrent clients can be added by purchasing a licence: contact your local distributor for more info on how to purchase such license.
Units with serial number below 03000 can have up to 11 clients simultaneously connected, instead.

13.1 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 (see Fig. 2).

To start using the Remote Viewer it must be enabled by selecting the desired protocol and setting an access password: see § 15.6 for instructions on how to setup the Remote Viewer.

13.2 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 the selected protocol is HTTPS, the https://gsd-*sssss.domain* address must be used. In case the device is not part of a domain, the http(s)://gsd-sssss.local address might work as well.

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 § 15.1);
- click on the “NETWORK” tab;
- click on the  icon of the “Wired” network;
- retrieve the IP;
- type http://IP (or https://IP if using HTTPS) in the address bar

Type the password and press **Login**: this will open the **Patient List** screen (Fig. **51**), which resembles the corresponding screen in the on-board software.

The user is automatically logged out after 20 minutes of inactivity.

13.3 Patient List screen

The left-most column shows the patient's name, gender and date of birth. The right-most column shows the date of the last exam and two icons representing the number of Visual Field and Fundus exams.
Patients in the list are sorted by the date of their last exam.
Patient **Search** function is available at the top of the screen, as well as the function to add a new patient clicking on the icon.
Click on the desired patient's row to enter the **Patient Record** screen (see Fig. 52). Click on and then **Logout** to exit the Remote Viewer.

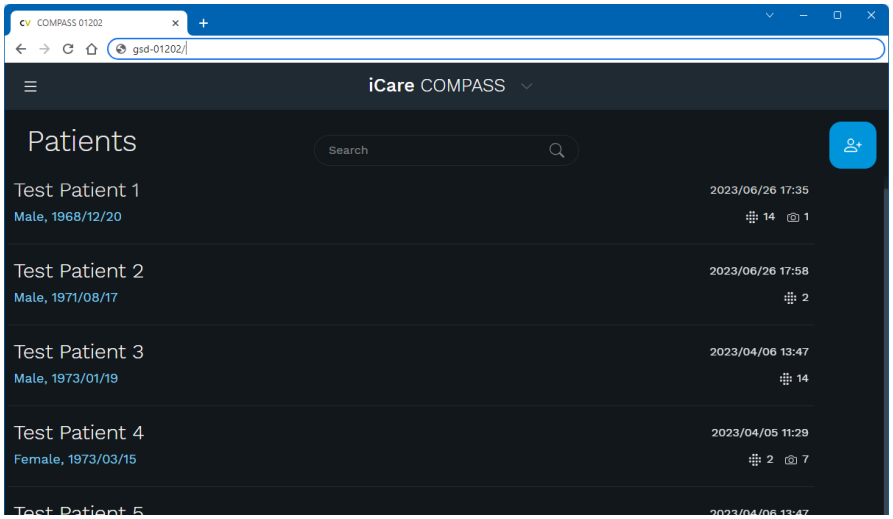


Fig. 51 – Patient List in Remote Viewer

13.4 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 button beside the patient name allows to enter the interface to edit the patient's details.

On the right side of the screen, the following additional buttons are available:

Command	Description
	Select: start the multiple selection of exams, to be exported using the button below.
	Export: opens the export options interface (see Fig. 53) to export all the patient's exams, or the selected exams if the multiple selection was initiated. The buttons on the left allow to choose whether to download the files or print directly. It is possible to choose whether to export the Perimetry report and/or the Fundus report of the exams. For the Fundus reports, it is possible to select the output format (JPEG or PDF), page orientation and how to regroup the images.
	Compare: opens the image selection screen for the Dual Image review screen (see § 13.8).
	Flicker: opens the image selection screen for the Flickering review screen (see § 0).

Click on the desired exam's box to enter the **Exam review** screen (see Fig. 54).

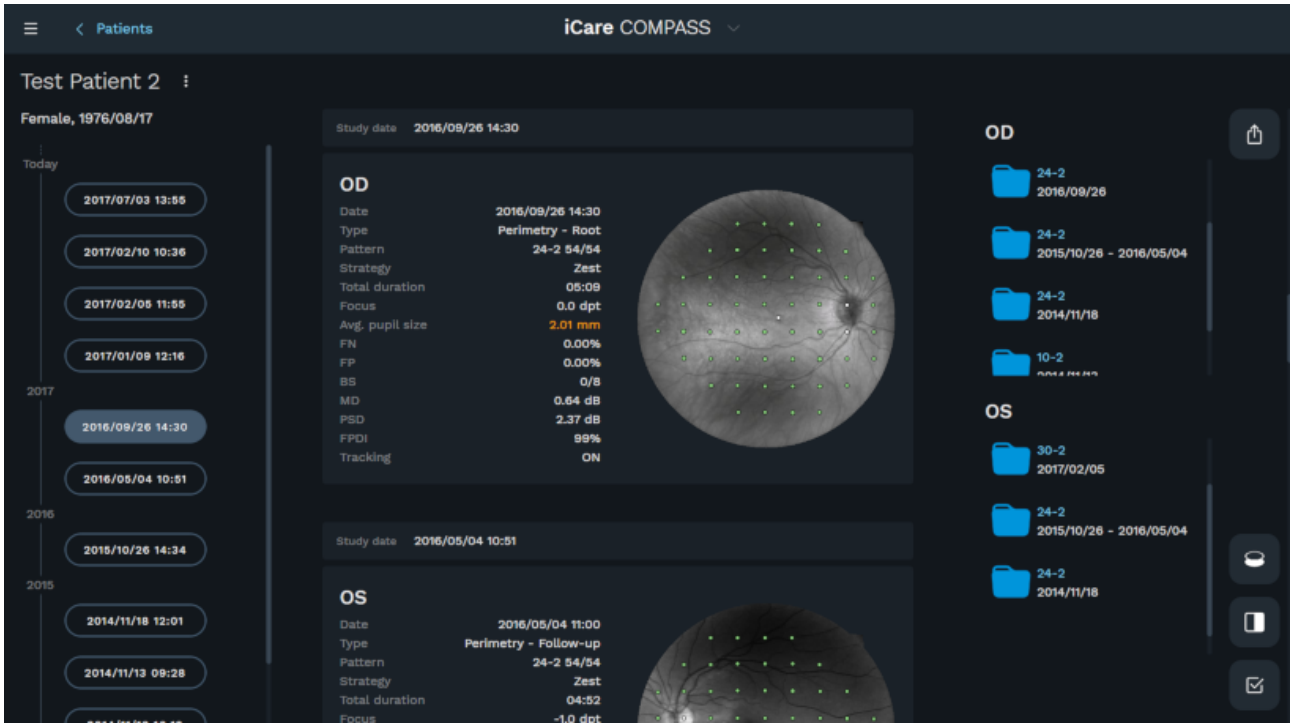


Fig. 52 – Patient Record screen in Remote Viewer

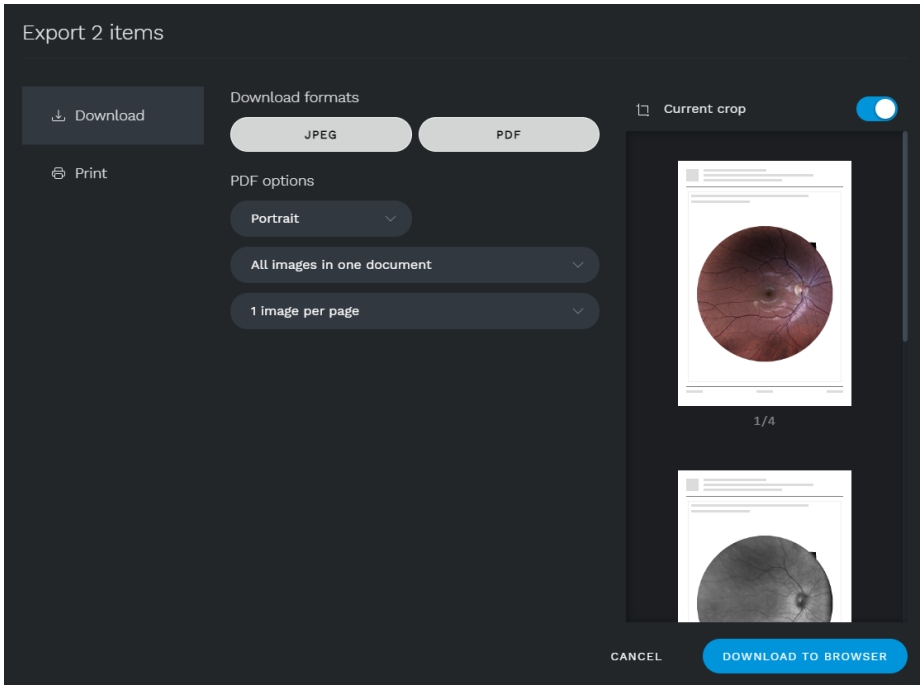


Fig. 53 – Export Options interface in Remote Viewer

When exporting a single or dual images being zoomed using the mouse scroll, the Current crop button allows to choose whether to export the current zoomed view or the full image in the PDF report.

13.5 Exam review screen

Entering the **Exam review** screen of a VF exam opens the interface shown in Fig. 54.

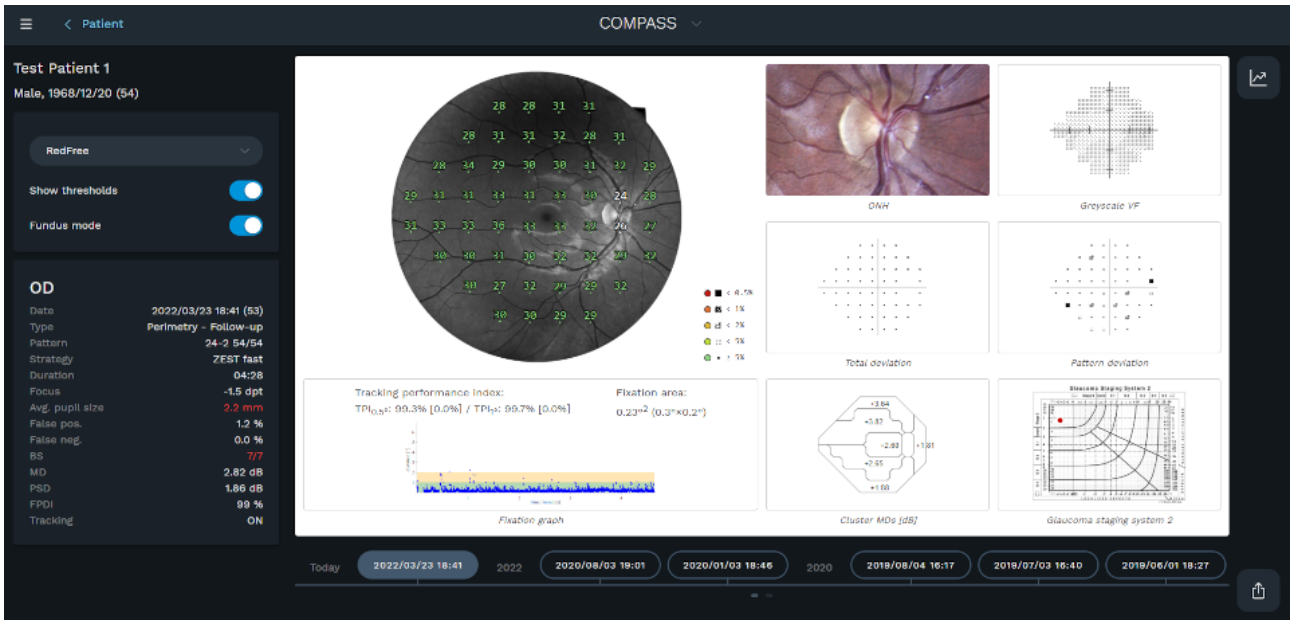


Fig. 54 – Exam Review screen in Remote Viewer

On the left side of the screen the patient's details, the exam details and the main results of the Visual Field test are displayed.
The dates buttons on the bottom allow to quickly open other exams of the same Baseline – Follow-up series.
In the middle of the screen, all the graphs present also in the exam PDF report are displayed. Clicking on any graph will display it in a magnified view.
Clicking on the retinal image with the thresholds overlapped will open the Perimetry Mode Review screen (see § 13.6).

The following functions are available in this screen:

Command	Description
	Allows to choose which retinal image to display with the thresholds overlapped. Among RedFree, Infrared and TrueColor.
	Hides/shows the thresholds overlapped to the retinal image.
	Allows to display the retinal image in Fundus (default) or Perimetry convention.
	**Export:** opens the export options interface (see Fig. 53) for the Perimetry report of this exam.
	**Progression analysis:** open the exams selection window for the generation of a Progression or Comparison report.

13.6 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. The image can be zoomed scrolling with the mouse and then panned dragging it with the mouse.

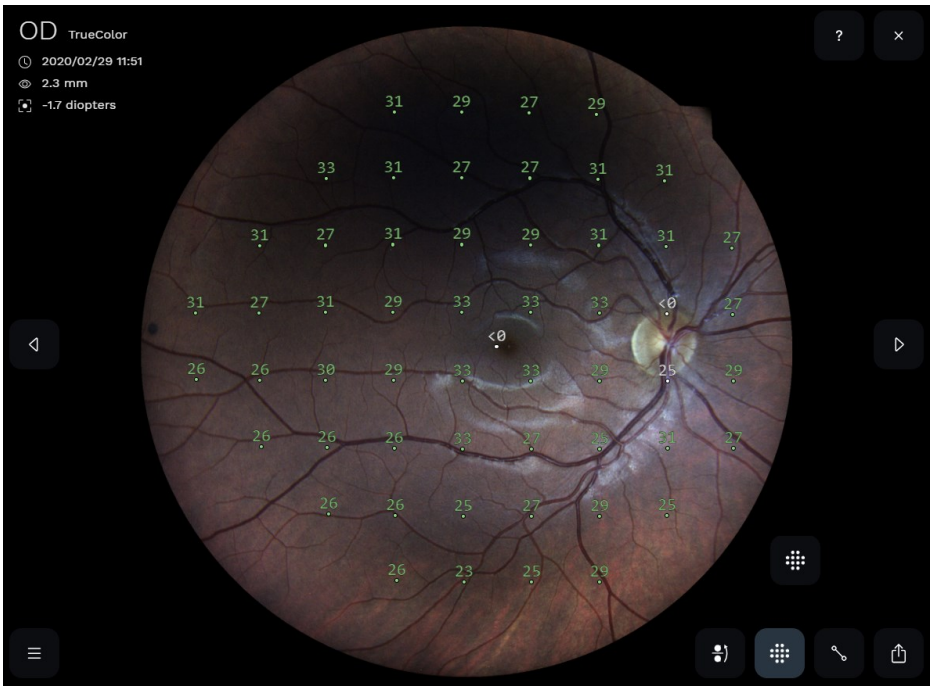


Fig. 55 – Perimetry Mode Review screen in Remote Viewer

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

Function	Command	Description
Close		Back to the **Exam** review screen.
Previous/next item		Switch to the Infrared/TrueColor image of the same exam, or to the previous/next exam.
Image tools		Displays the Image tools to adjust the image display parameters (see § 13.7).
Export		Opens the export options interface (see Fig. 53) for the Fundus report of this image.
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 image and results vertically (see § 12.1)
Cup-to-disc evaluation		Allows to set the markers for the cup-to-disc ratio evaluation (see § 13.10). Hides/shows the markers once they've been set.

13.7 Image tools/Visits dialog

This dialog has 2 tabs: **Filters** and **Visits** (see Fig. 56).

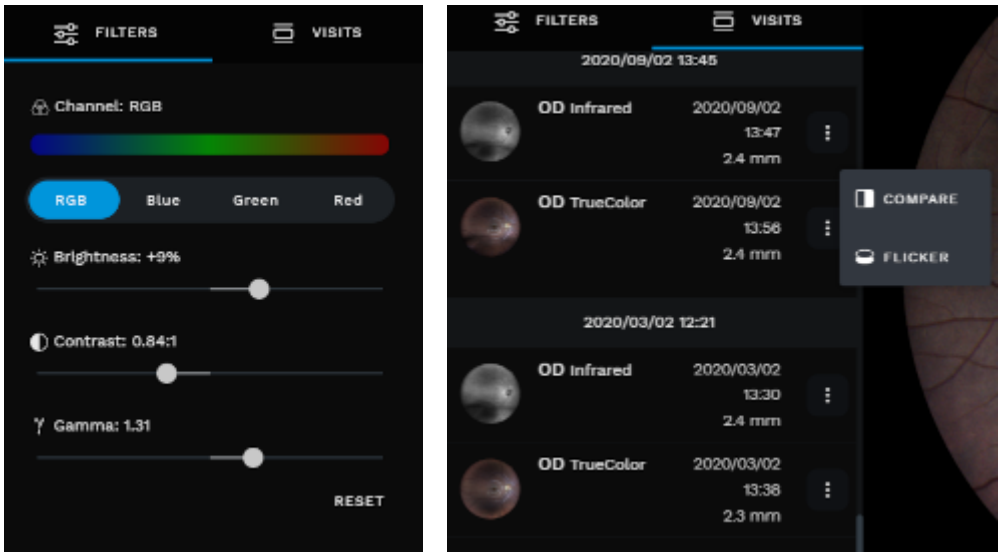


Fig. 56 – Image tools dialog: Filters (left) and Visits (right) tabs

The **Filters** tab allows to adjust the display parameters for the image, to enhance its appearance and/or to select the desired color channel, in the same way as can be done on the onboard application (see § 12.1). The RESET button reverts all the parameters to their default values.

The Filters do not alter the original image.
Once set, the visualization parameters are stored on the device, and are shared with the onboard application. This means that the most recent parameters applied are used both on the onboard application and on the Remote Viewer.

The **Visits** tab allows to view all the images of the patient (regardless whether they are included in a Visual Field or Fundus exam), and to select one to be used for comparison in the Dual Image review (see § 13.8) using the ⋮ button and clicking on COMPARE, or in the Flickering view (see § 0) clicking on FLICKER (available only if the two images are related to the same eye).

13.8 Dual Image review / Stereo 3D Viewer screen

The Dual Image review screen (Fig. 57) allows comparison of any pair of images of the selected patient (color and infrared, left and right eye, same or different dates), and can also be used as a Stereo 3D Viewer.

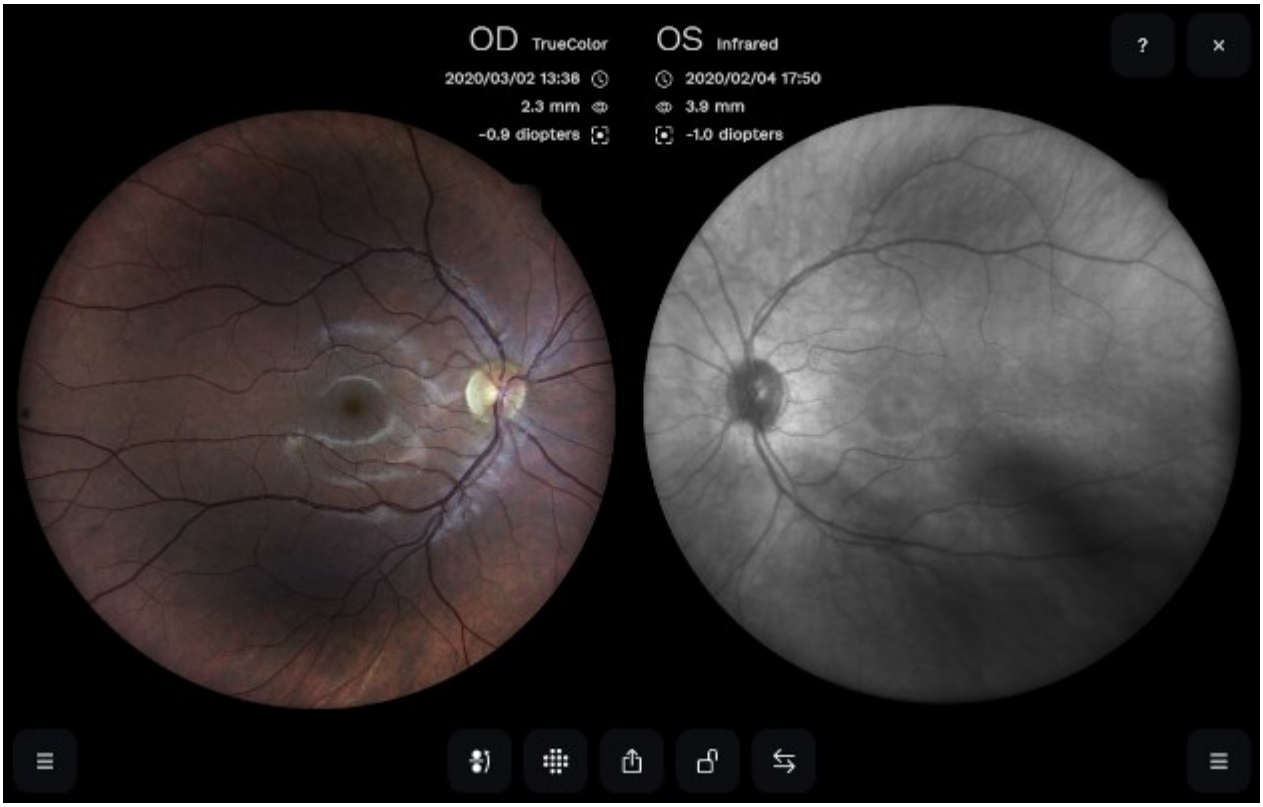


Fig. 57 – Dual Image Review screen in Remote Viewer

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

Function	Command	Description
Image tools		Displays the Image tools to adjust the related image display parameters, which can be done for each image independently (see § 13.7).
Lock		Allows to “lock”/”unlock” the two images so that the same region gets zoomed and panned in both images.
Swap images		Swaps left and right image.
Export		Opens the export options interface (see Fig. 53) for the Fundus report of this image.

13.9 Flickering view

COMPASS allows to compare two images one by one, by switching manually or automatically between the two. This feature is called **flickering**, and allows to compare any two images (Color or IR) of the same patient and same eye. It is possible to access the flickering window from the Patient record screen (see § 13.4) or from the Visits tab of the Image tools dialog (see § 13.7).

The software automatically registers the two images to overlap them (compensating shift, rotation and Color/IR distortion).

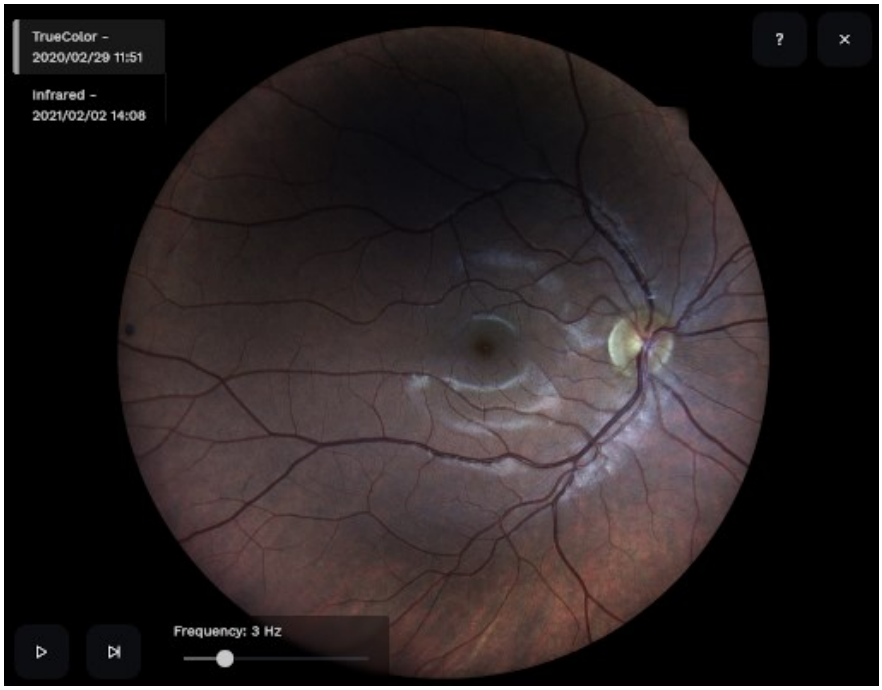
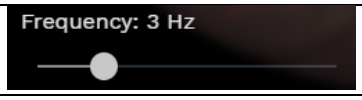


Fig. 58 – Flickering review window

On the left side of the image the date and time of the 2 selected pictures are displayed. The bar on the left indicates which image is currently displayed.

Fig. 59 – Currently active picture: “2020-02-29 11:51”

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 10 Hz).

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

13.10 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.

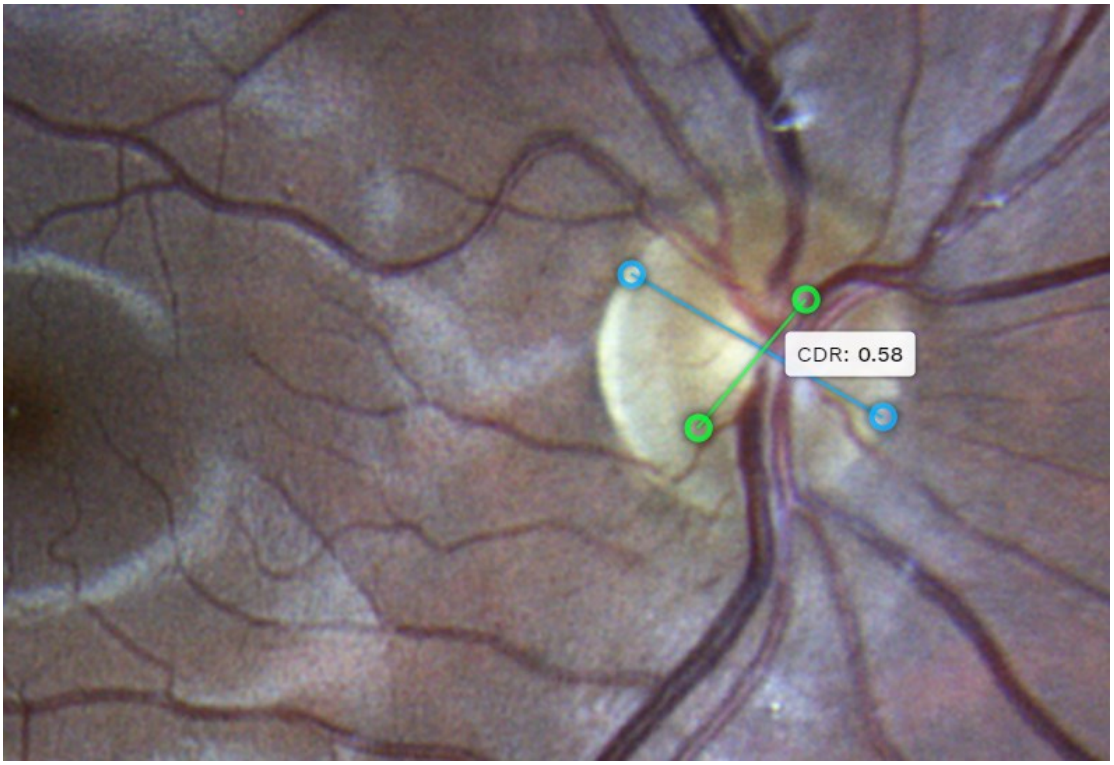


Fig. 60 – Cup-to-disc ratio evaluation

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.

14. PRINTING

14.1 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.

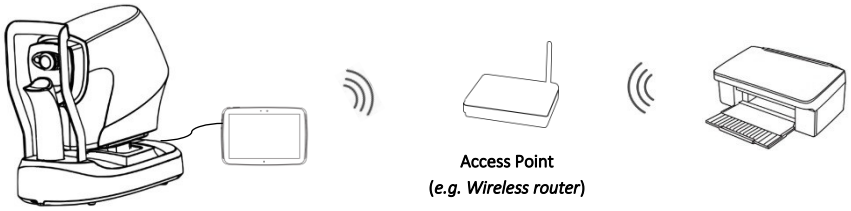
Brand	Description
Mopria	Multi-brand printer app
HP	HP Android ePrint
Samsung	Samsung Mobile Print App
Lexmark	Lexmark Mobile Printing
Canon	Canon Mobile Printing, Canon Easy-PhotoPrint, PIXMA/MAXIFY PrintingSolutions
Epson	Epson iPrint, Seiko Epson Corporation
Konica Minolta	Konica Minolta Printers,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

Table 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.

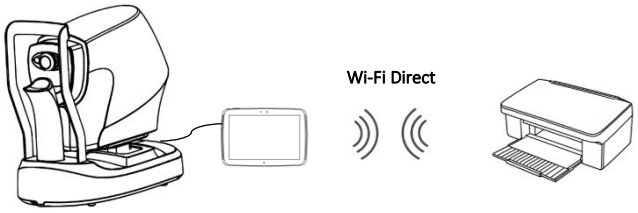
Infrastructure Mode

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. 61), and proceed with pairing with the printer following the instructions provided by producer.

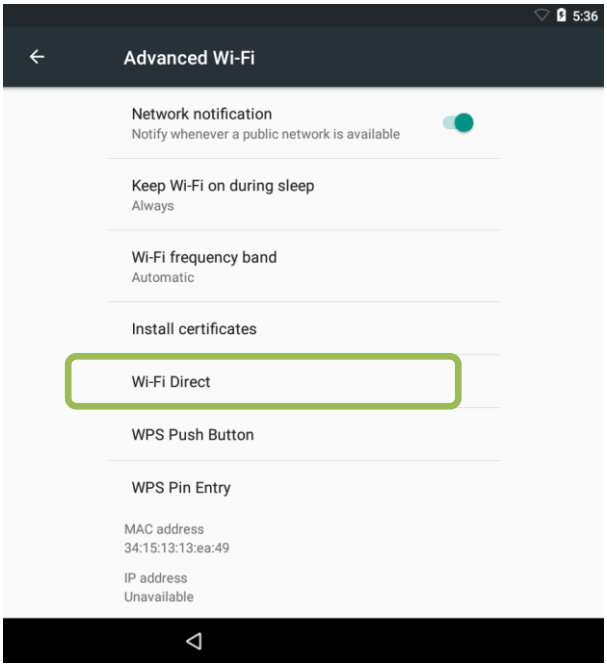


Fig. 61 – Item “Wi-Fi Direct” within “Advanced Wi-Fi” menu

Alternatively, it is possible to pair with the printer directly within the Adobe Acrobat Reader app, using the Mopria Print Service (see Fig. 62).

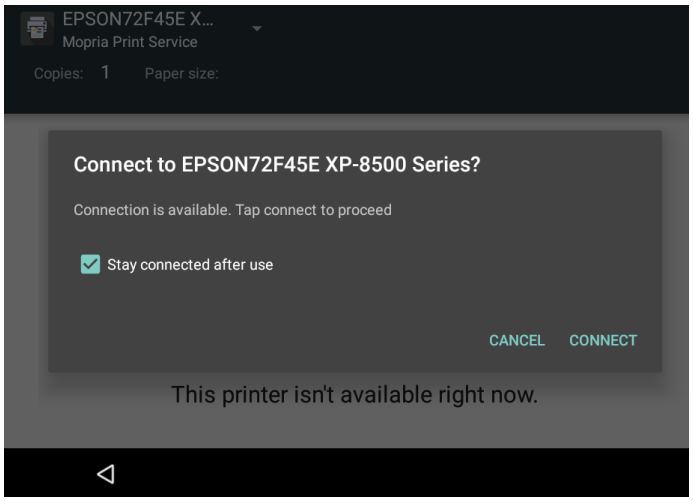


Fig. 62 – Connection to the printer in Wi-Fi Direct mode via Mopria Print Service

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.

14.2 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. 64):

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. 65);
8. Grayscale VF map (see Fig. 66 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. Serial number of the unit that generated the report, software version used to generate the report, and the version of the normative DB
15. Custom printout header (see § 15.11 for how to configure it).

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

Fig. 63 – 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 ≥ 0.5%
- light orange is used for points having a total deviation with p < 2% and ≥ 1%
- lime is used for points having a total deviation with p < 5% and ≥ 2%
- green is used for points having a total deviation with p ≥ 5%
- white is used for the foveal and optic disc locations

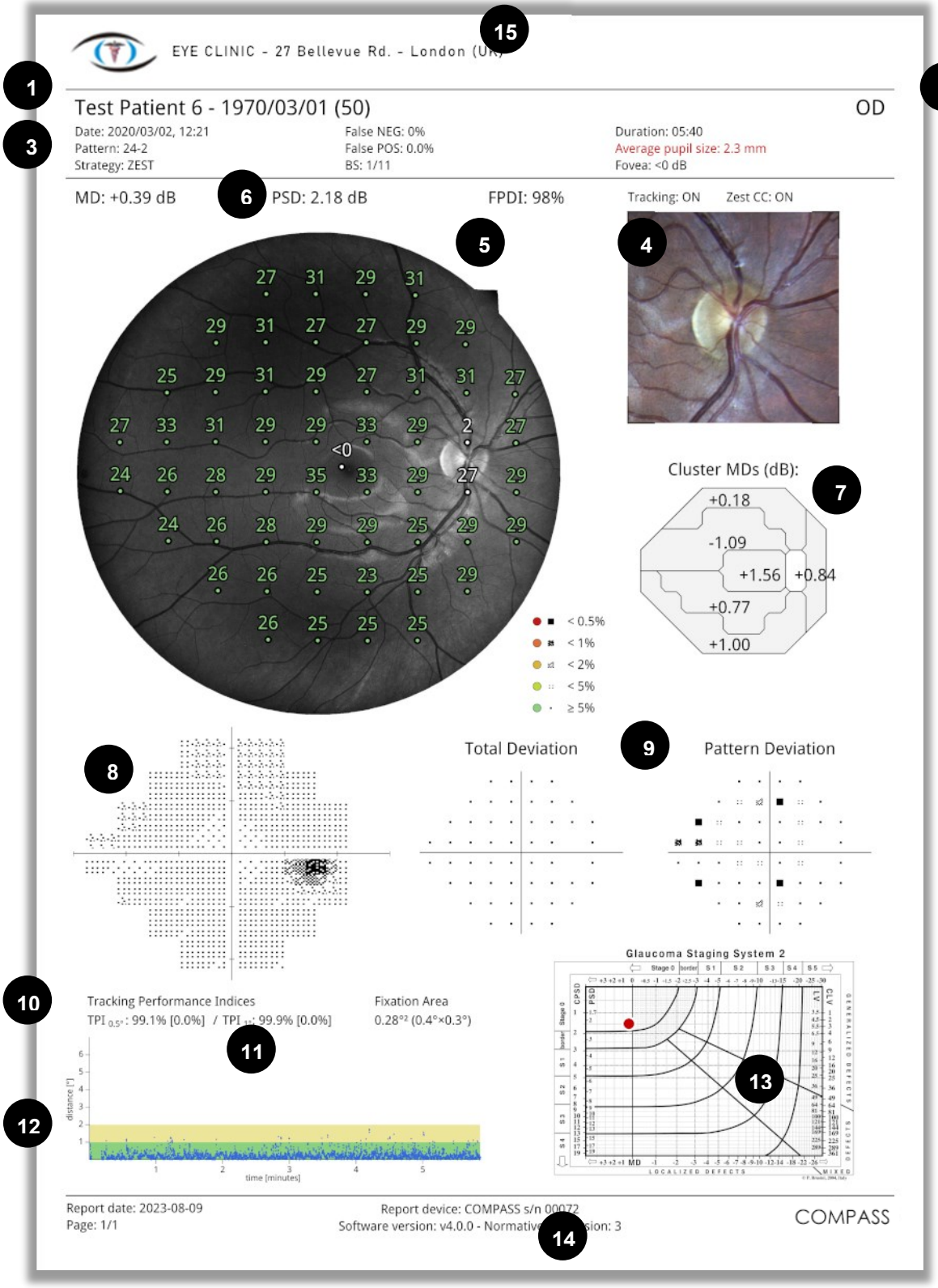


Fig. 64 – COMPASS report for a test with 24-2 grid

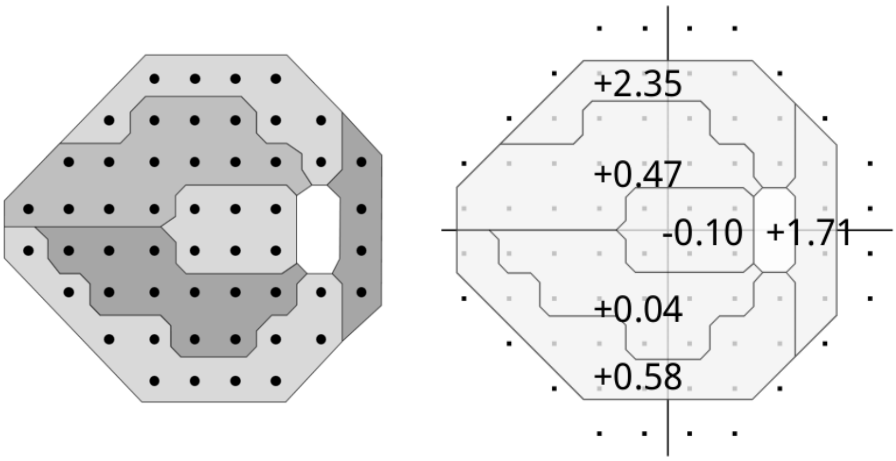


Fig. 65 – Stimuli of the 24-2 pattern (left) and 30-2 pattern (right) grouped in clusters[16]

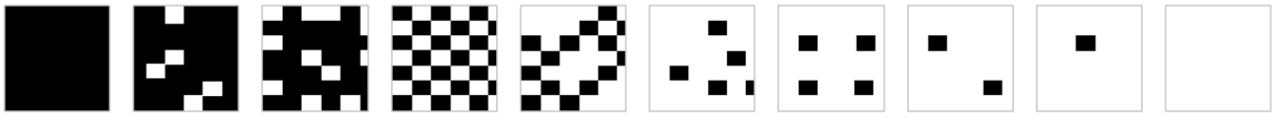


Fig. 66 – Symbols used for the grayscale map and related dB intervals

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

14.3 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. 67):

- The cluster analysis (7) is not available;
- The Glaucoma Staging System (13) is not available and is replaced by the TrueColor retinal image;
- 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.

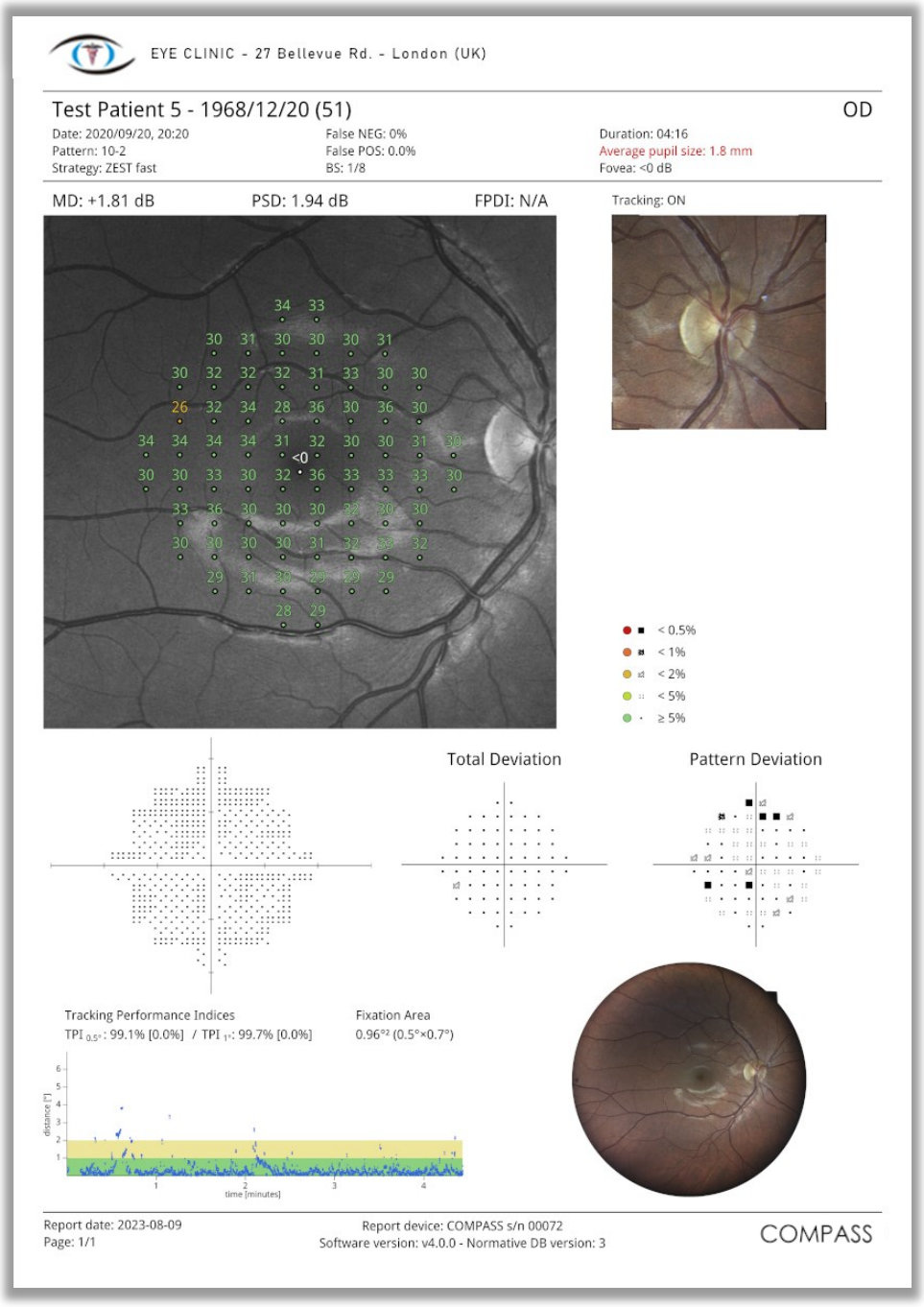


Fig. 67 – COMPASS report for a test with 10-2 grid

14.4 Report for 30-2 test

The printout for a test performed with the 30-2 grid (Fig. 68) 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. 65).

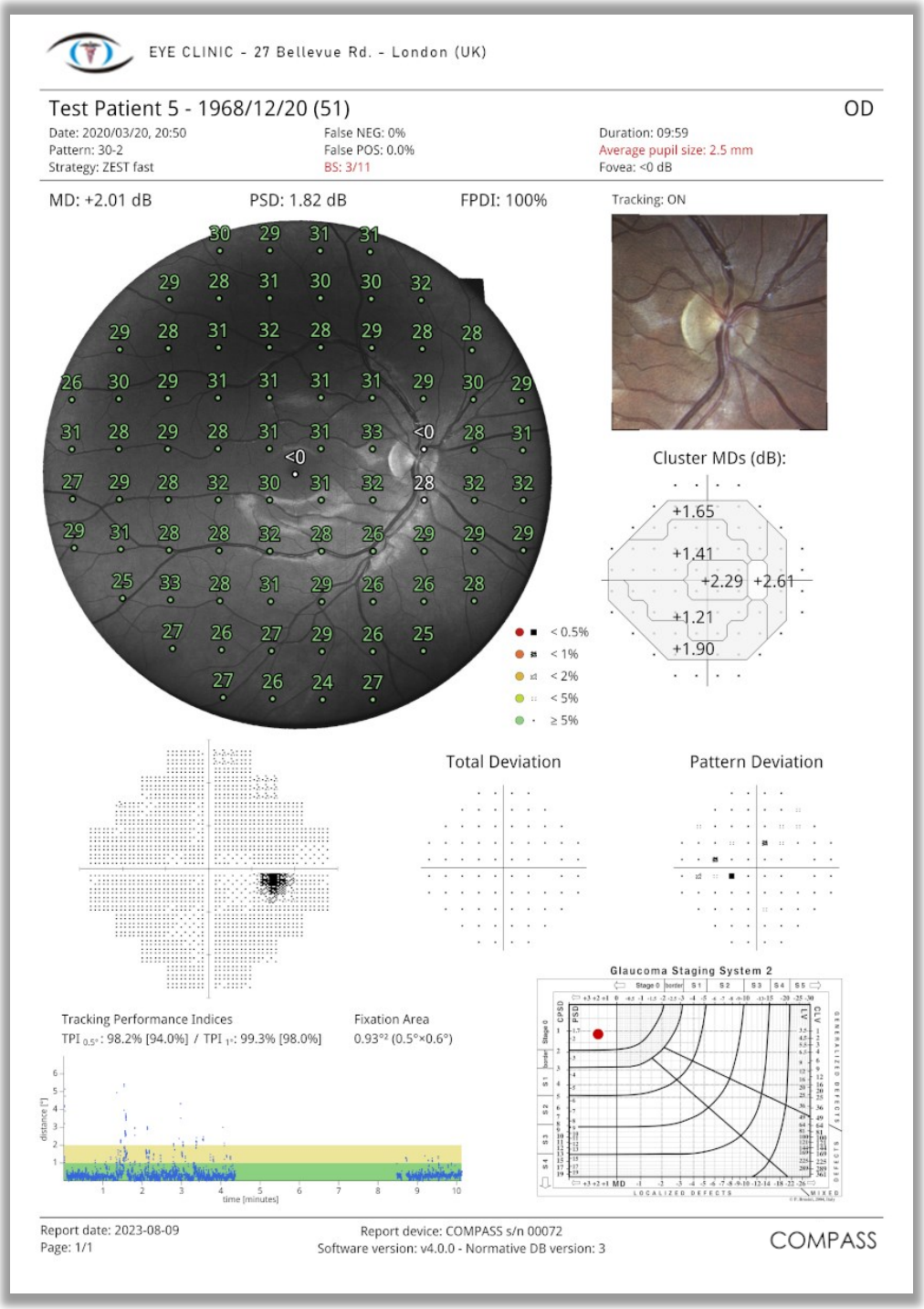


Fig. 68 – COMPASS report for a test with 30-2 grid

14.5 Reports for the SupraThreshold exams

The printout for a **SupraThreshold** exam displays the following information (see Fig. 69):

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

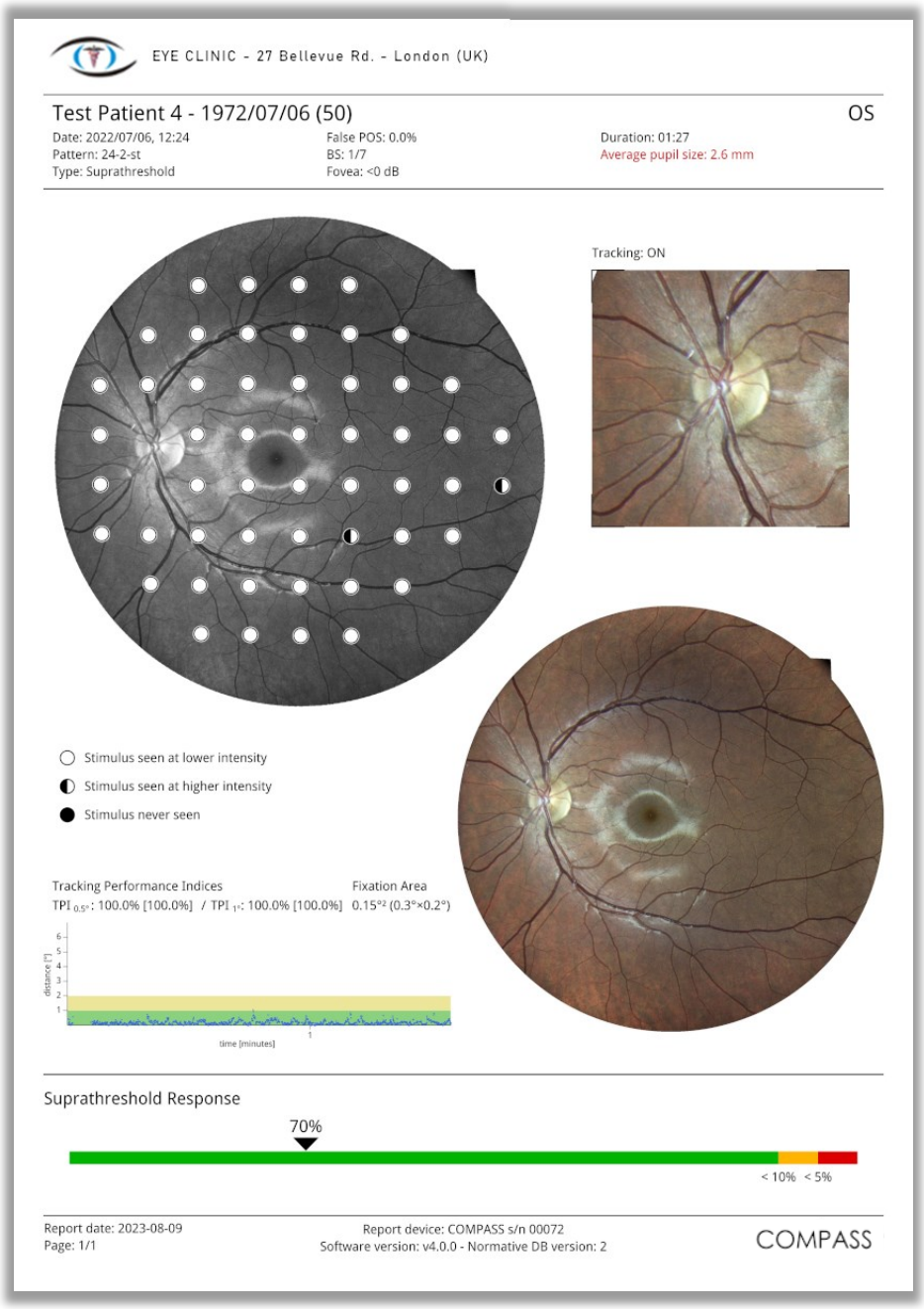


Fig. 69 – COMPASS report for a SupraThreshold test

The printout for a **Quick SupraThreshold** exam contains the same information (Fig. 70). The only differences are:

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

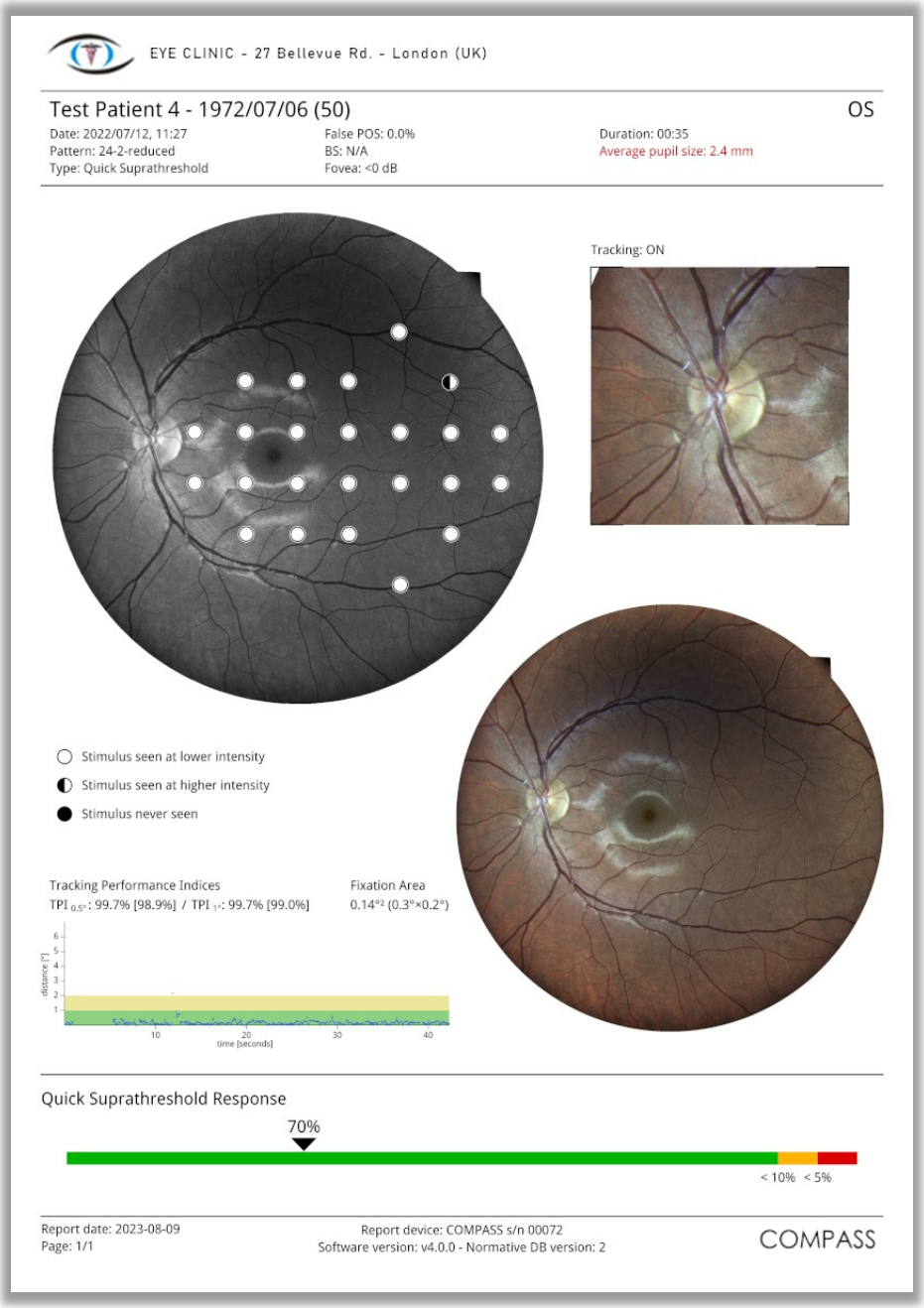


Fig. 70 – COMPASS report for a Quick SupraThreshold test

14.6 Comparison Report

The Comparison Report provides information on a Baseline-Follow-up pair 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. 71):

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 Follow-up and Baseline
11. Differences in cluster MDs between Follow-up and Baseline (for 24-2 and 30-2 tests only)
12. MD progression plot for all included tests
13. FPDI 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 § 15.11 for how to configure it).

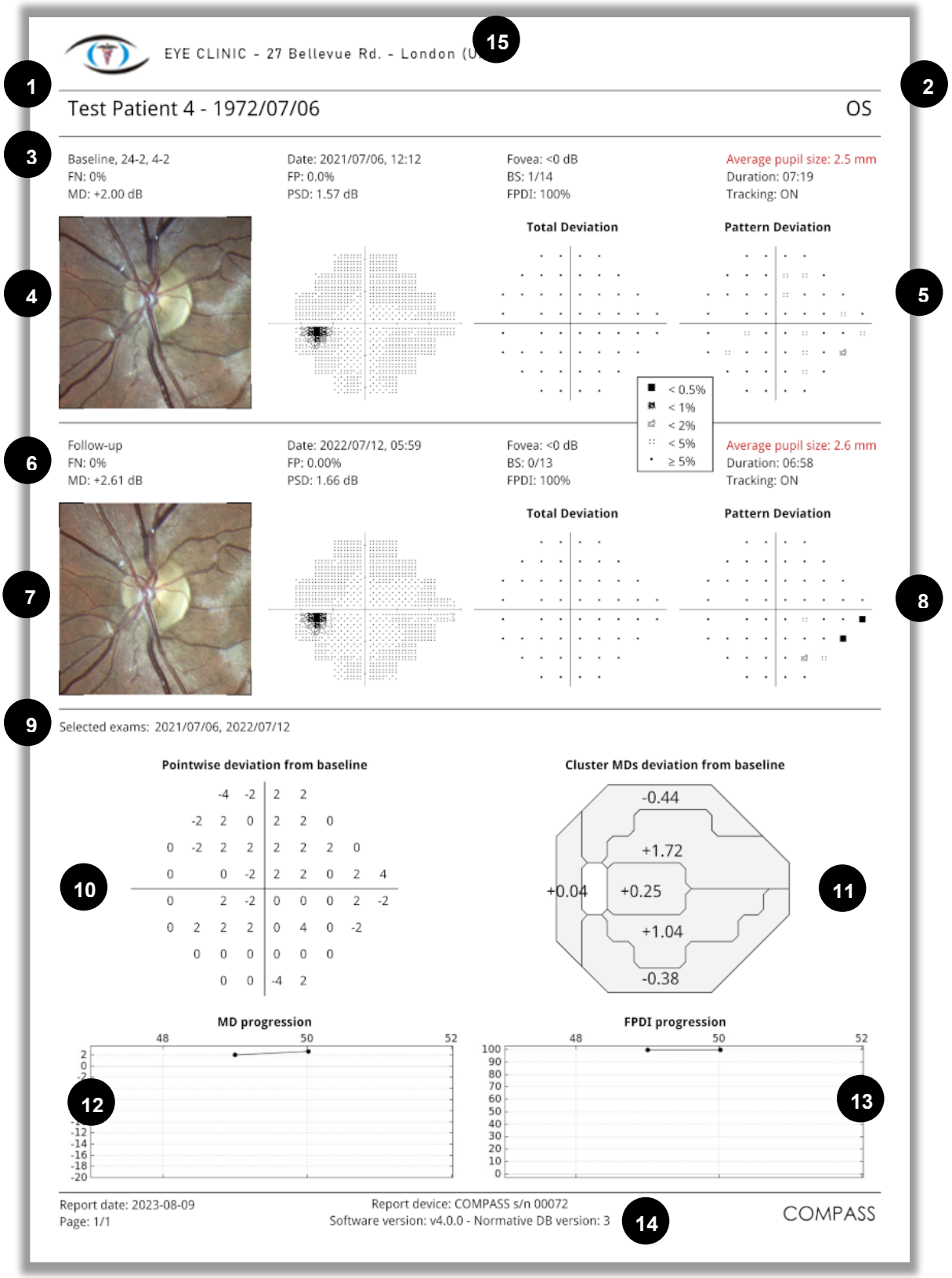


Fig. 71 – Comparison report for 24-2 exams

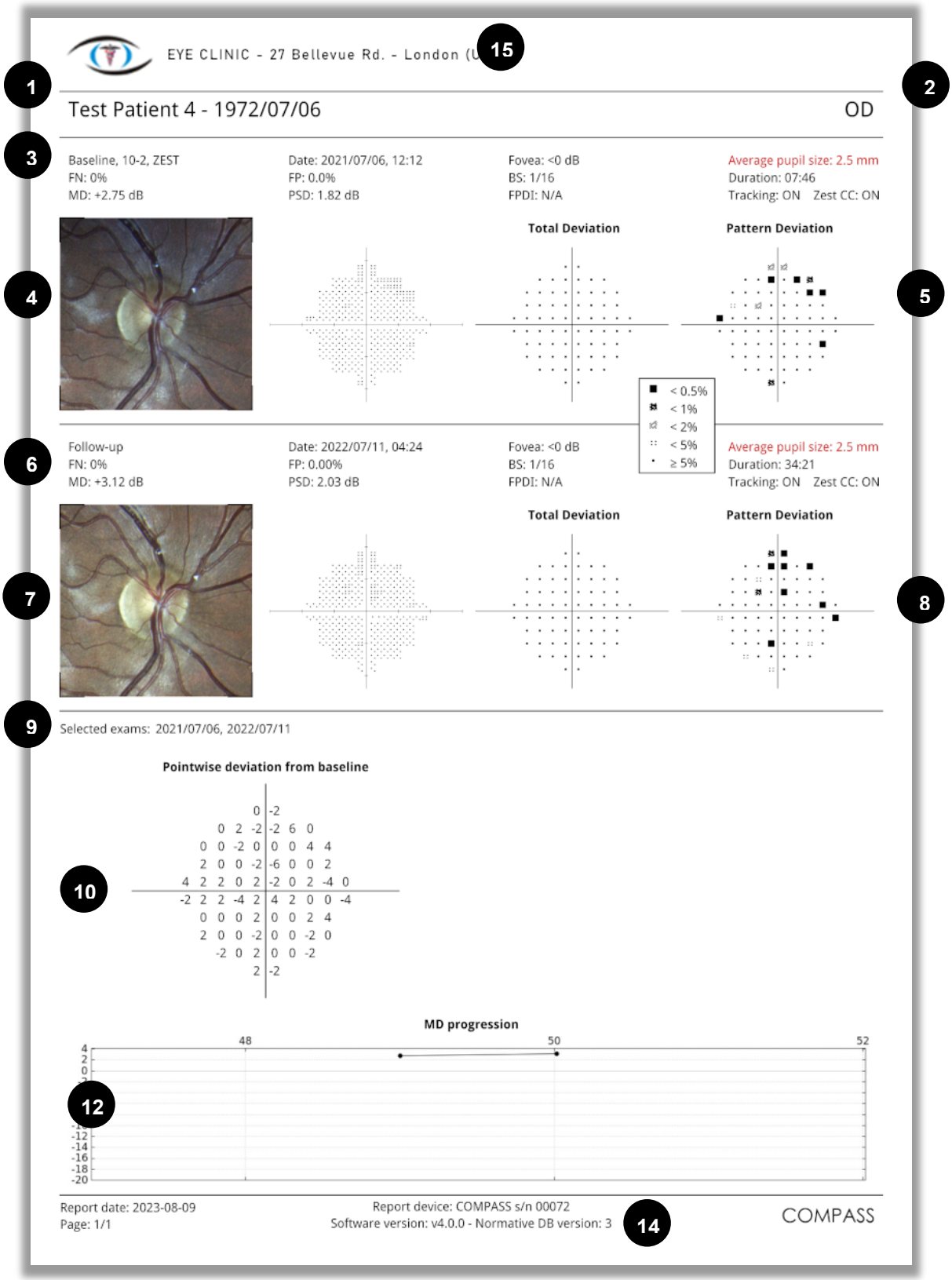


Fig. 72 – Comparison report for 10-2 exams

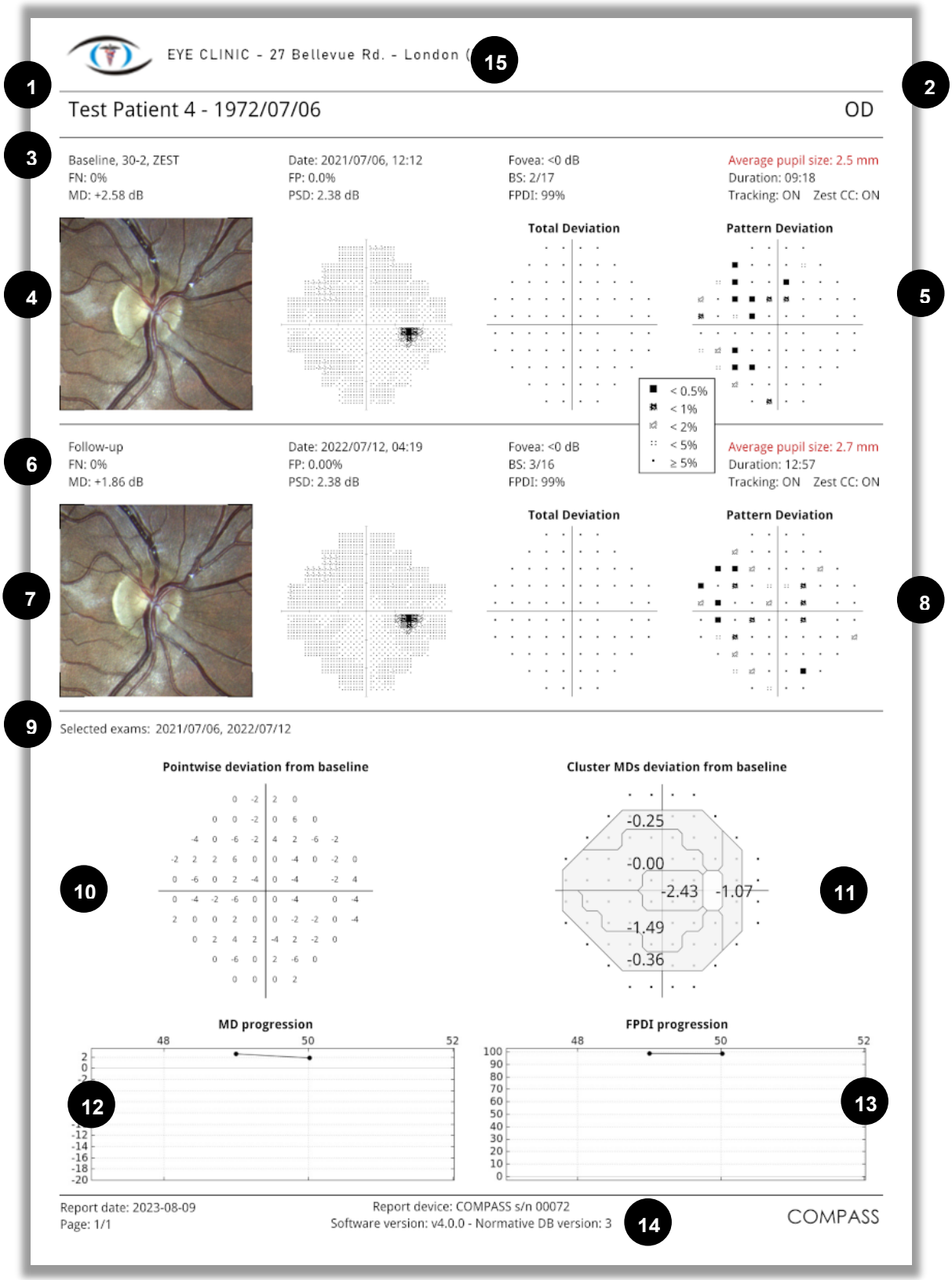


Fig. 73 – Comparison report for 30-2 exams

14.7 Smart Progression Analysis Report

The **Smart Progression Analysis** (also called “SPA”) analyzes a series of Root-FollowUp COMPASS exams to detect whether a retinal damage is progressing, locally or globally. It provides a detailed report, showing a comparison between two initial exams (identified as Baseline exams) and the last Follow-up of the series, and the outcomes of two analysis: the ***Event Analysis*** and the ***Trend Analysis***.

The ***Progression Event Analysis*** detects whether single or consecutive progressing events have occurred in each single tested location, also providing a global Event assessment. The detection of the Events is based on test-retest variability levels obtained from patients followed over relatively short periods of time, in whom there is reasonable assurance that the disease has not progressed.

The ***Global Trend Analysis*** allows to assess whether there is a progression of the damage (both locally and globally), it calculates the rates of Visual Field progression over time (i.e., the speed of progression) and, if enough data is available, extrapolates the progression from 3 to 5 years in the future.

Finally, the comparison of the TrueColor image of the ONH of the Baseline and last Follow-up exams allows qualified eye care practitioners to qualitatively appreciate whether structural changes have occurred over time and their relationship with sensitivity loss at corresponding regions of the visual field.

The Smart Progression Analysis Report is available for the ZEST and ZEST Fast strategies only.
The selected series can contain a mix of exams performed with any of the two strategies, which are considered equivalent. In detail, also the Baseline exams can be taken both with the same strategy or with different strategies (i.e., one ZEST and one ZEST Fast).

The ***SPA Report*** (see Fig. 74) is divided into 6 sections:

1) the Report header
2) the Baseline exams analysis
3) the Last Follow-up analysis
4) the Progression Event Analysis
5) the Trend Analysis
6) the Report footer

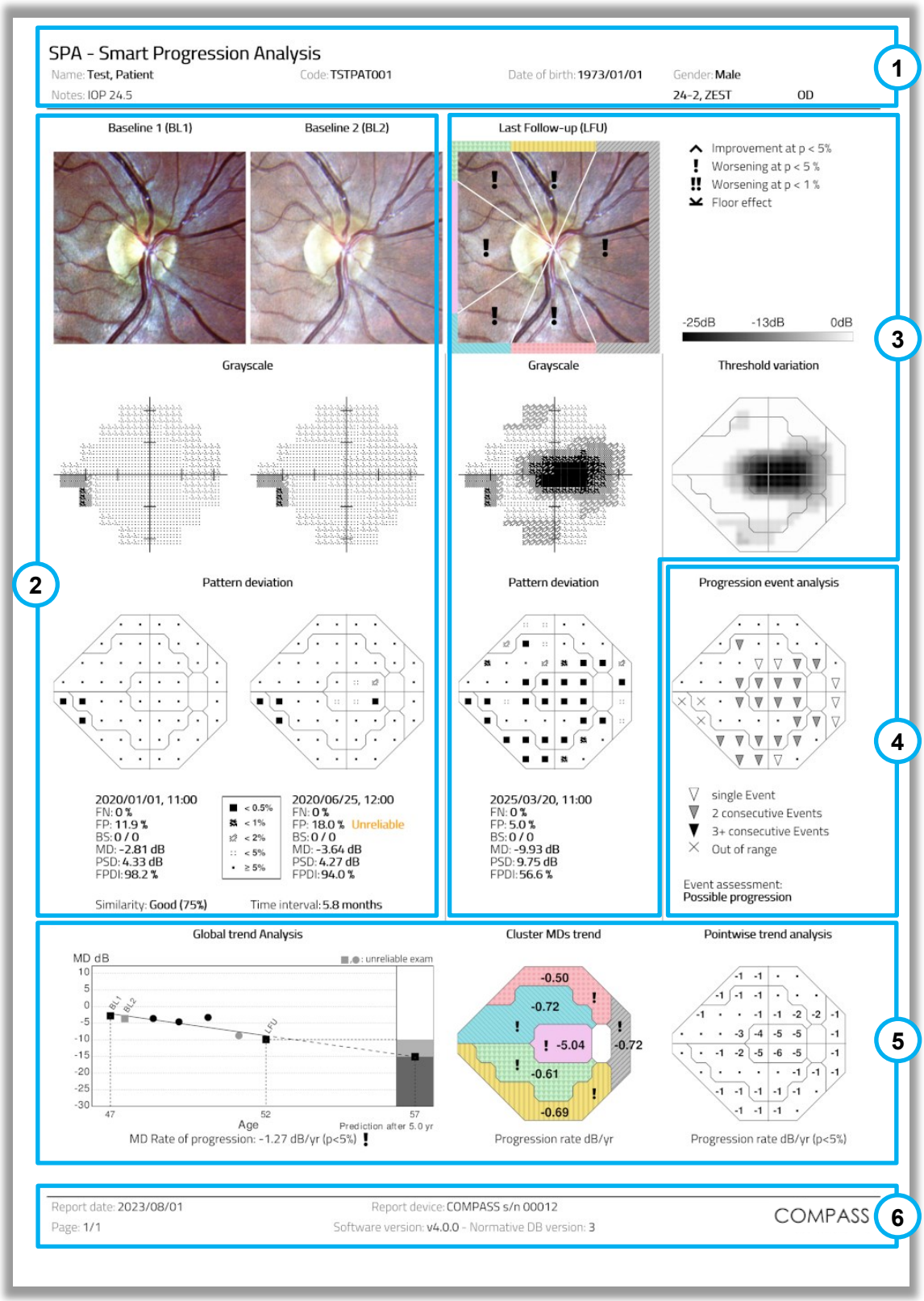


Fig. 74 – Smart Progression Analysis Report for a 24-2 series of exams

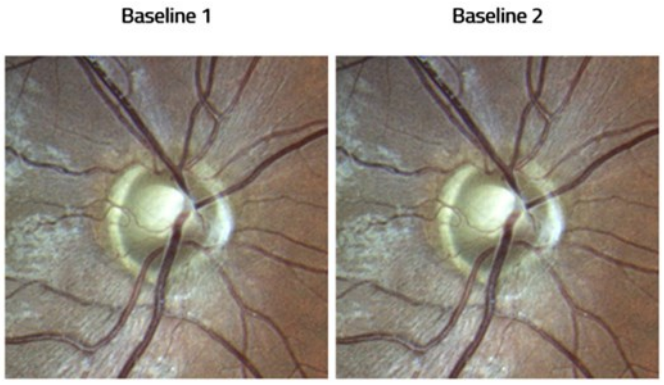
14.7.1 Report header

This section contains info about the Patient (name, code, date of birth, gender, notes) and the exam series (eye, grid and strategy used).

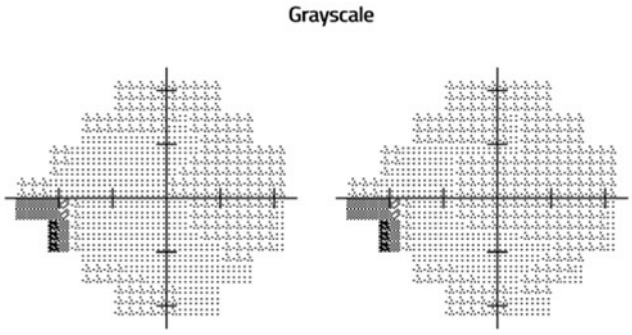
The ***Custom header*** is also present at the top (see § 15.11 to learn how to setup the Custom header).

14.7.2 Baseline exams analysis

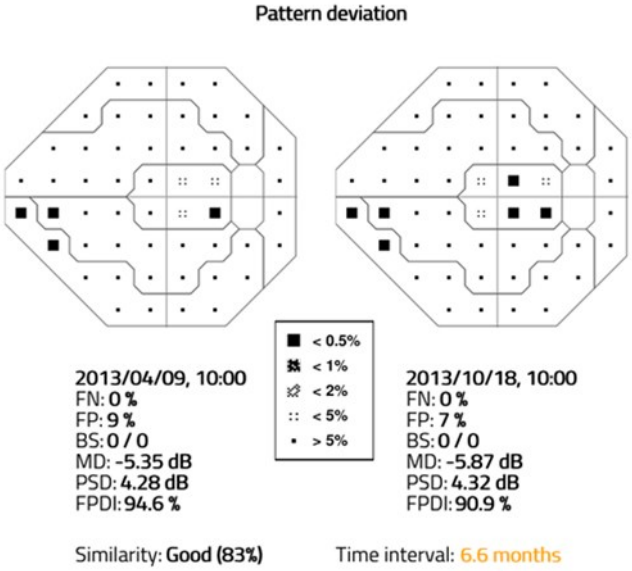
This section shows a side-by-side comparison of the two Baseline exams. From top to bottom, the following data are displayed:



TrueColor images of the ONH of the two exams



Grayscale VF maps, representing the measured thresholds.



Pattern Deviation charts, with separation of the locations in clusters

Exam data (date and time, FN, FP, BS, MD, PSD, FPDI indices)

The ***Baseline Similarity*** index (marked in orange if below 52.5%) and the ***Time Interval*** (marked in orange if higher than 6 months)

14.7.3 Last Follow-up exam analysis

This section shows the same data as the Baseline exams (excluding the Baseline Similarity index and the Time Interval), but related to the last Follow-up.

Moreover, the ONH color image is divided into 6 sectors, indicated with different colored patterns on the image frame. These colored patterns allow to relate each sector (and its RNFL bundles, see note below) to the correspondent cluster in the ***Cluster MDs*** chart in the Trend Analysis at the bottom of the page (see § 14.7.5). Note that the corresponding clusters appear vertically swapped because the ***Cluster MDs*** chart is represented in Standard perimetry convention (see § 12.3). A symbol on any image sector/cluster shows its trend in terms of MD, i.e., whether the cluster is improving, worsening or whether the worsening cannot be assessed due to floor effect (too low values for the MD).

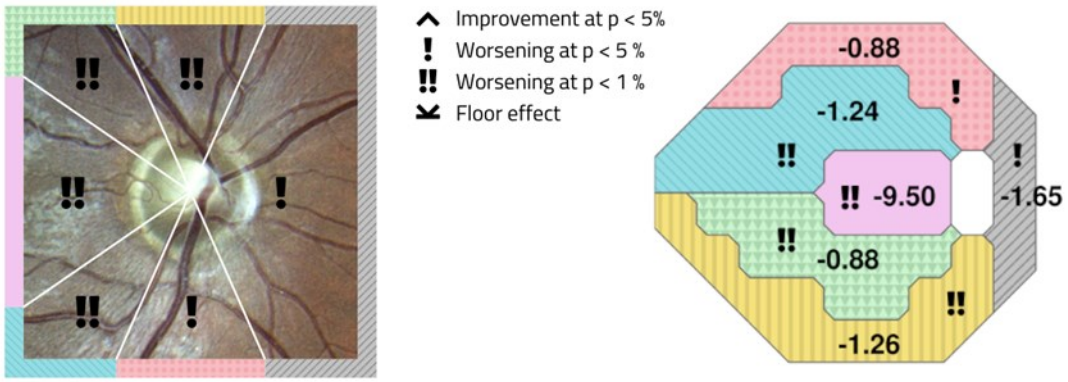


Fig. 75 - ONH sectors (left) and their related clusters (right), with the symbols legend (center)

The RNFL (Retinal Nerve Fiber Layer) is formed by bundles of nerve fibres coming out from the ONH and spreading below the retinal surface. An increased intra-ocular pressure (IOP) can damage some of these bundles resulting in reduced sensitivity in the VF test outcomes in the related areas identified by the clusters. This damage can also be visible as a reduced translucency of the fibres and/or an increase of optic nerve head cupping in the TrueColor image.

The division of the locations in clusters is available for the 24-2 and 30-2 grids only.
The report for the 10-2 grid does not provide this grouping, nor the related division in sectors for the ONH (see Fig. 67).

Furthermore, this section includes the Threshold variation graph: a grayscale VF map, representing the difference between the last Follow-up thresholds and the average of the Baseline exams. Only negative differences (i.e., only the points where the VF is worse in the Follow-up) are displayed, as shown in the legend above the chart.

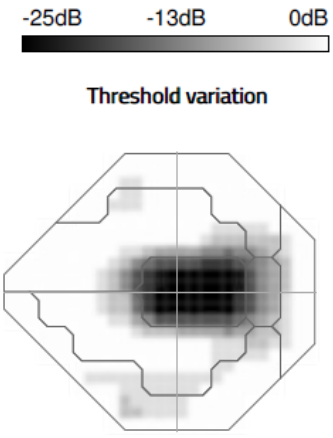
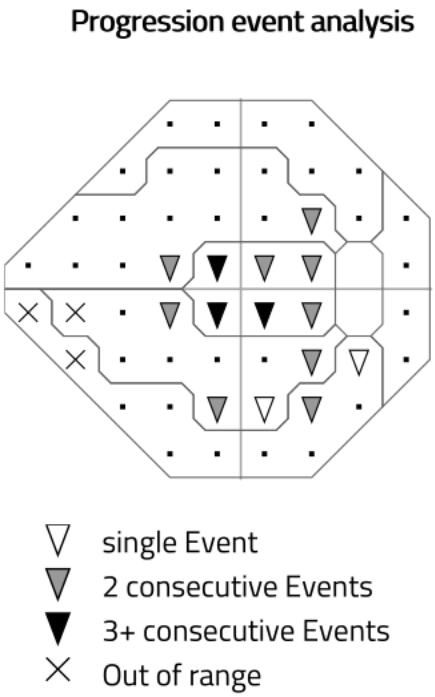


Fig. 76 – Threshold variation chart, with its grayscale above

14.7.4 Progression Event Analysis

The Progression Event Analysis detects the number of consecutive, significant progression Events that have occurred in each location within the exam series, based on COMPASS test-retest clinical database of a population of stable glaucoma patients. A progression Event is a decrease in sensitivity for a certain exam, that is below the 5th percentile of expected test-retest variability in such a population ($p < 5\%$). This section reports the following outcome data:



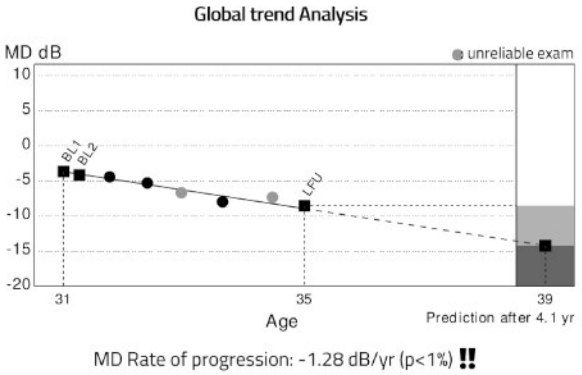
Progression Event analysis: for each location, a triangular symbol represents whether an Event has occurred in the last Follow-up. A black dot means that no Event has occurred in that location, because the change does not exceed the test-retest variability observed in the reference population.

Legend: the triangles have different filling depending on the number of consecutive exams (including the last) that have detected an Event If the average Baseline threshold for a location is lower than 15 dB, no Events are detectable for that location and it is marked as ***Out of range***.

Event assessment: based on the number and type of detected events, an overall Event assessment is reported among ***Likely/Possible/Suspect/No Progression***, or ***No Event Analysis Possible*** (if all locations are marked as Out of range).

14.7.5 Trend Analysis

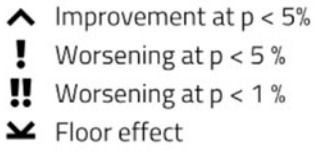
This section provides an analysis on the trend for the progression, which represents the speed (expressed as the Rate in ***dB/yr*** for MD, or ***%/yr*** for FPDI) at which the sensitivity is decreasing in time.



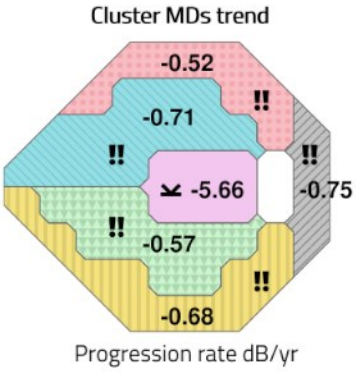
Global trend Analysis: a chart representing the linear trend of the MD or FPDI (depending on what was selected, see Fig. 43) over time. Unreliable exams are represented using a grey dot instead of a black dot.

If enough exams are available (at least 5 exams within 3 years), the progression is linearly extrapolated from 3 to 5 years into the future (see the column "Prediction after ***N*** yr").

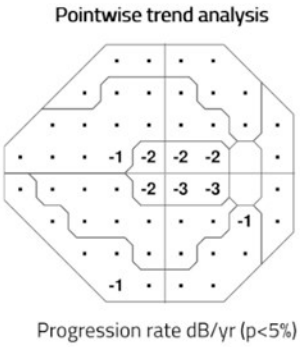
At the bottom of the chart, the linear progression rate is displayed, in dB/year.



The symbol possibly present beside the Rate of progression represents the degree of significance of the variation, according to this ***legend***. For example, a double exclamation mark means that the worsening is highly significant (p-value < 0.01). The ***Floor effect*** symbol is displayed when the MD difference between the Last Follow-up and the Baseline average exceeds 20 dB.



Cluster MDs trend: this chart (available for 24-2 and 30-2 grids only) displays the linear variation rate of the MD in each cluster, in dB/year. In case of significant variation, a symbol is present within the cluster, according to the same legend above.



Pointwise trend analysis: this chart displays the linear variation rate of the sensitivity thresholds in each location of the grid, in dB/year (rounded to integer values). Only statistically significant variations (p-value < 0.05) are displayed: a dot instead of the value means that the variation is positive or non-significant.

In the Global trend Analysis chart, the Progression Prediction requires the following conditions to be met for the calculation:

- At least 5 exams selected
- A minimum span of 3 years between the first Baseline and the last Follow-up exam
- The MD of the average of the two Baseline exams shall be > -20dB, to avoid floor effects

If any of the above conditions is not met, the Progression Prediction is not displayed, and a banner above the Global Trend Analysis chart will provide an explanation, such as:

Progression prediction cannot be calculated because less than 5 exams were selected, and their time span is less than 3 years.

Progression prediction cannot be calculated because the average MD of the two baselines is <-20 dB.

Similarly, in case the time span between the first Baseline and the last Follow-up exam is less than 6 months, the following banner will inform that the Progression rate values might be affected by such a short interval; therefore, the resulting values must be evaluated carefully:

Progression rate results might be affected by the short time interval between the first and the last exam.

14.7.6 Report footer

This section provides info about the report generation date, the COMPASS serial number that generated it and the SW version installed, together with the version of the Normative Database.

14.7.7 30-2 and 10-2 reports

Below are report samples for series of exams taken with the 10-2 grid (see Fig. 77) and with the 30-2 grid (see Fig. 78).

In the 10-2 report, note that the clusters are not displayed, the ***Cluster MDs*** chart is missing and that the FPDI values are not available:

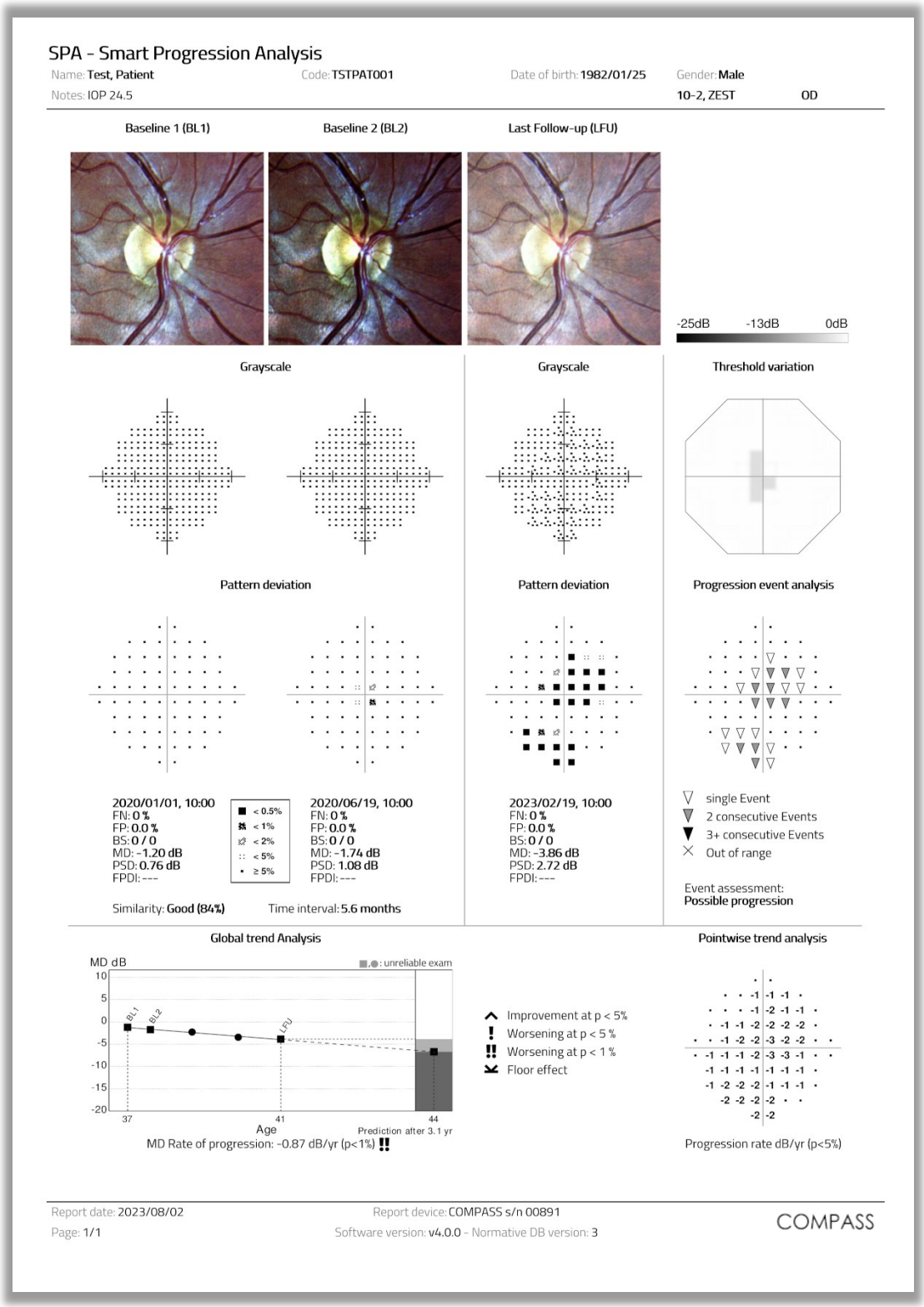


Fig. 77 – Smart Progression Analysis Report for a series of exams with the 10-2 grid

In the 30-2 report, note that the clusters contain only the points in common with the 24-2 grid, as for the single Exam printout (see § 14.4).

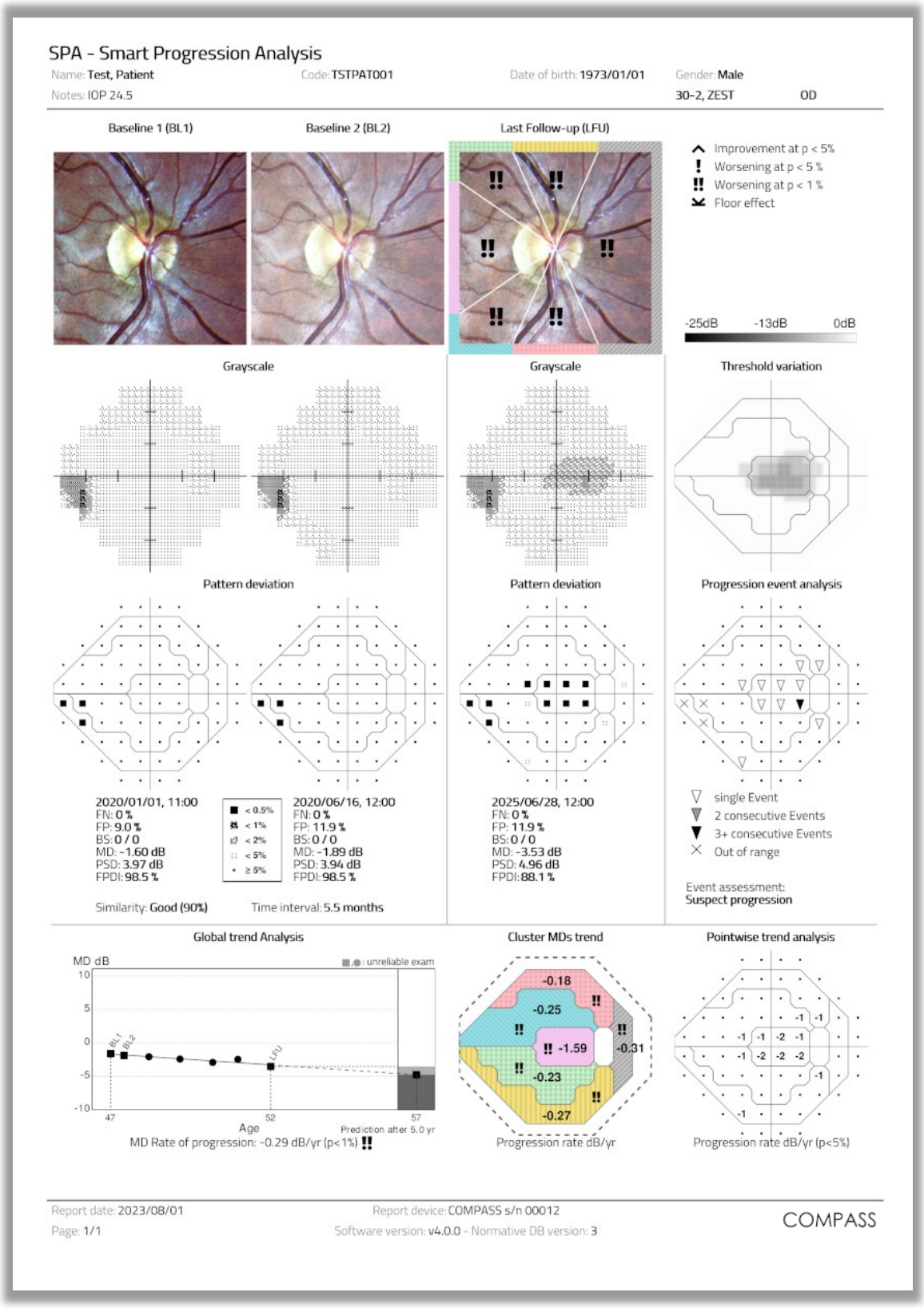


Fig. 78 – Smart Progression Analysis Report for a series of exams with the 30-2 grid

14.8 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. 79):

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).

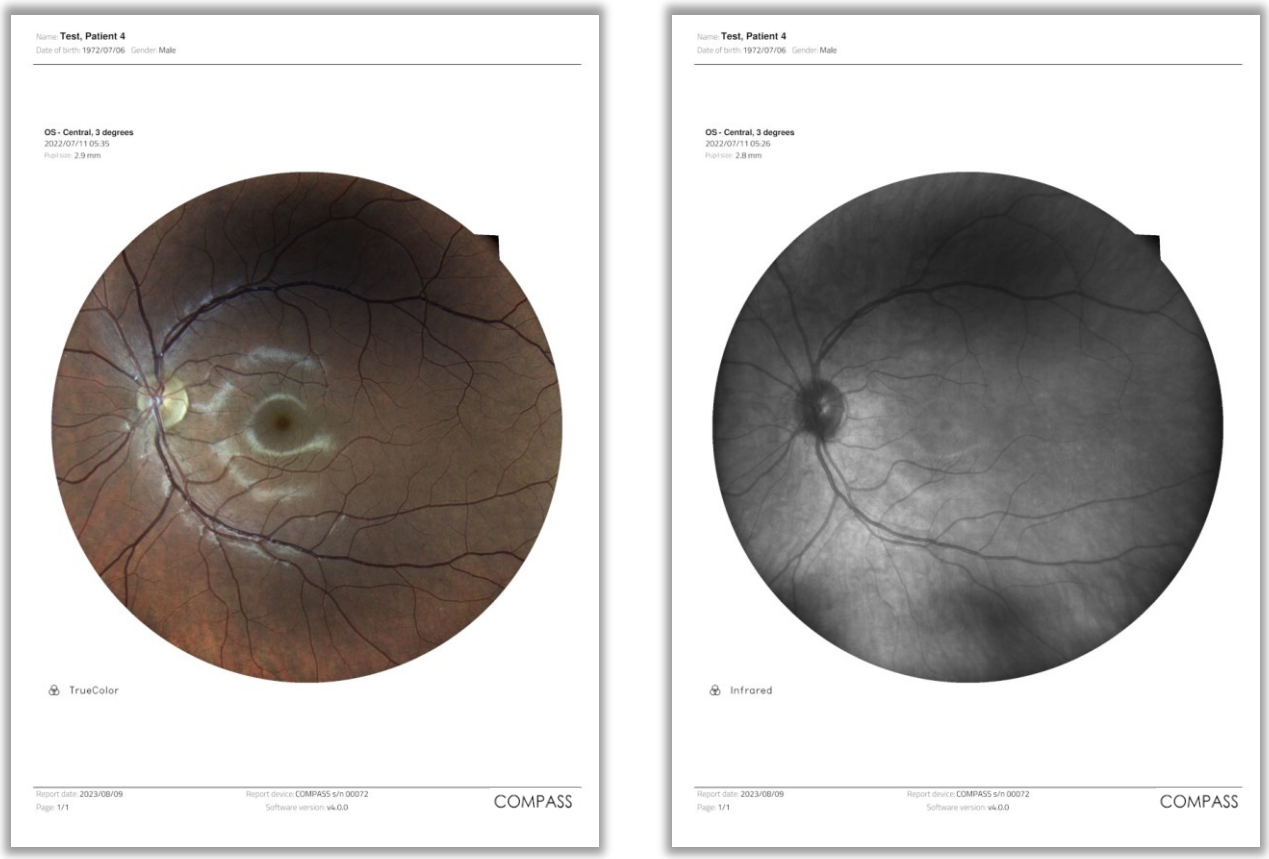


Fig. 79 – Fundus report examples: for a Color Image (left) and for an Infrared Image (right)

14.9 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).

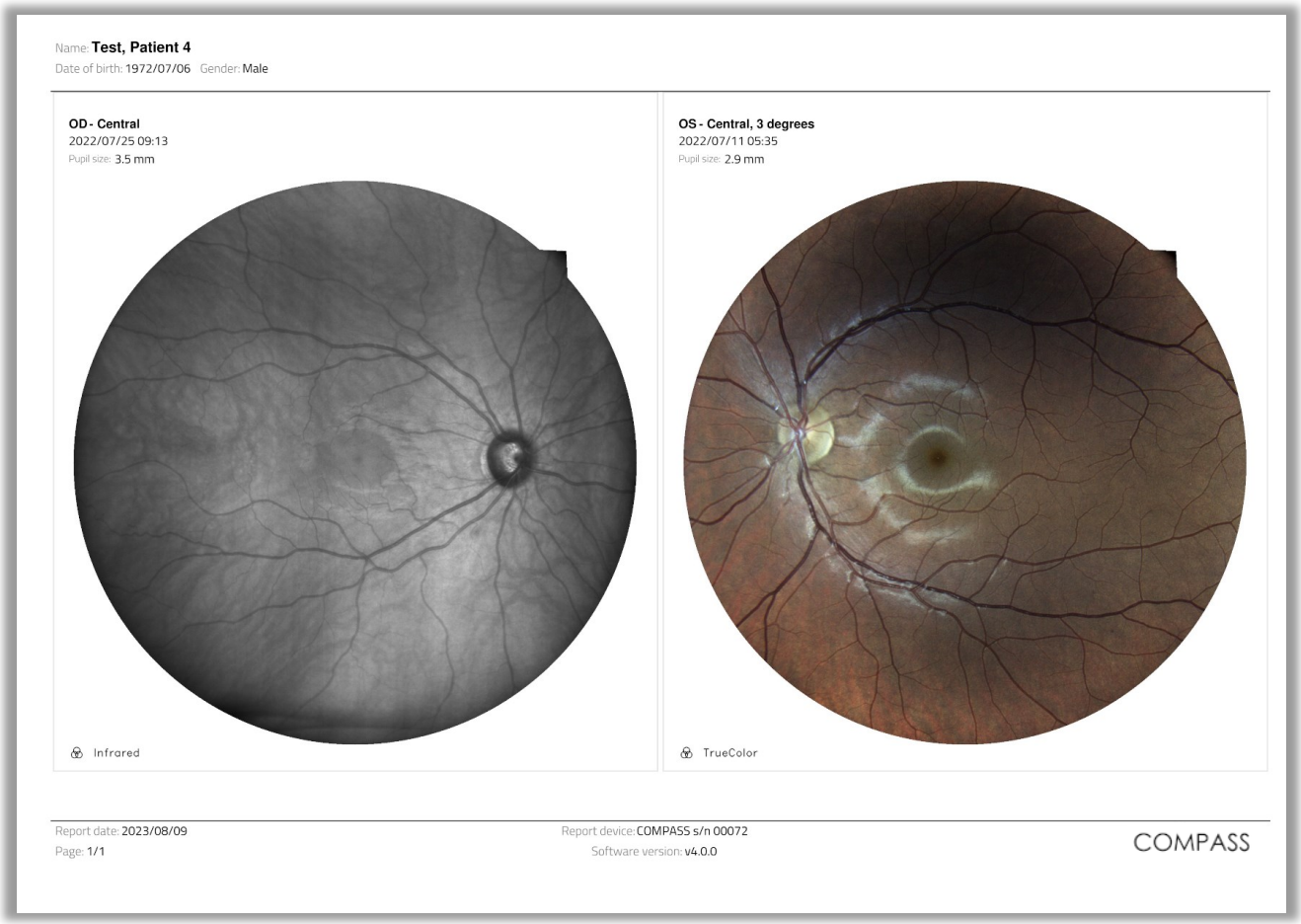


Fig. 80 – Example of a Dual printout Report

15. SETTINGS

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

> The Configurator app can be accessed by the Admin user only.

15.1 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 

.

15.2 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.

15.3 Date and time

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. 81): device will request to power off in order to apply the new settings.

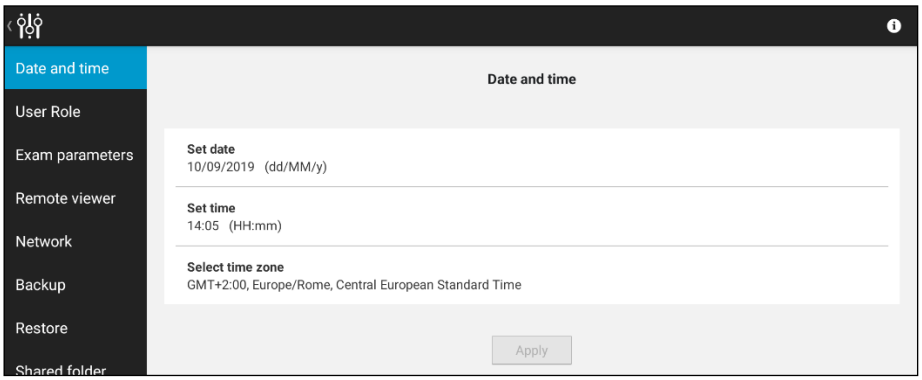


Fig. 81 – Configurator – DATE/TIME settings

15.4 Users

Passwords for both the “**Admin**” and “**Doctor**” **users** can be changed in the “**Users**” tab of the Configurator by clicking on the desired user (see Fig. 82). Shutdown and restart the device to make the new passwords effective.

- **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 Authorized Service Center for support.**

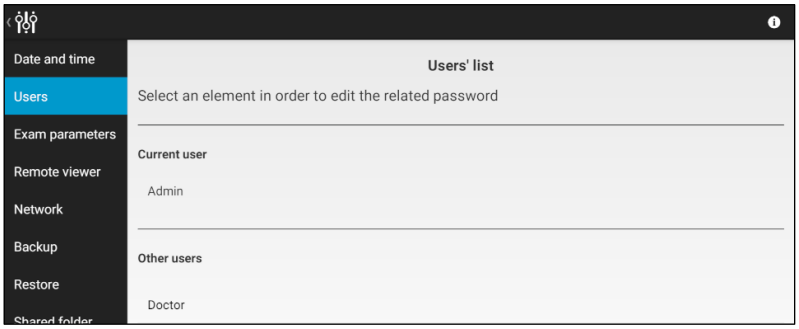


Fig. 82 – Configurator – USERS tab

15.5 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. 83). All the tests are enabled by default. For a detailed description of the reliability indices, see § 12.3.
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).

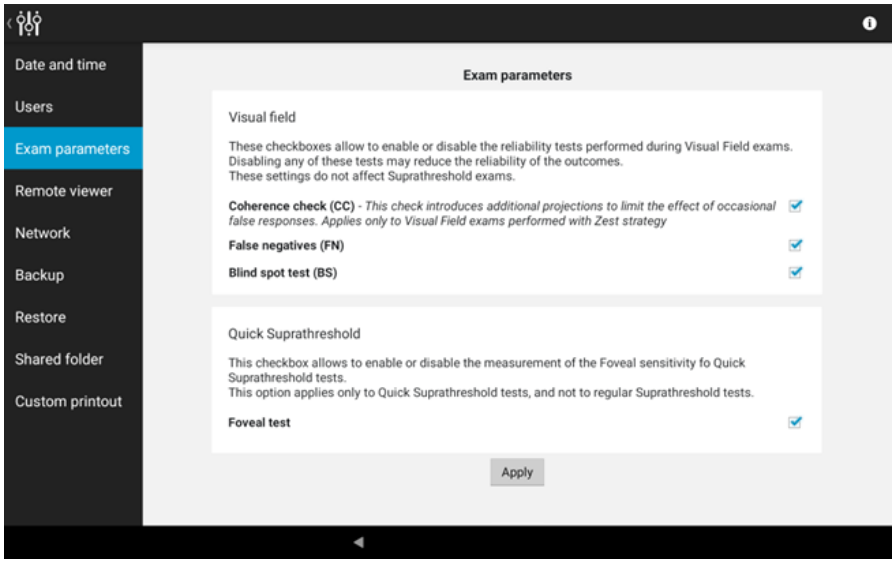


Fig. 83 – Configurator – EXAM PARAMETERS tab

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 SupraThreshold exams, instead, only FP and BS tests are performed (FN is disabled, and CC is not applicable, since ZEST strategy is not used).

15.6 Remote Viewer

This tab allows to enable the Remote Viewer and configure its parameters.

To change the password used to access the Remote Viewer, type the new password and press **Apply**.

It is possible to select the protocol used by the Remote Viewer web server (HTTP, HTTPS, or both) or to completely disable the Remote Viewer functionality.

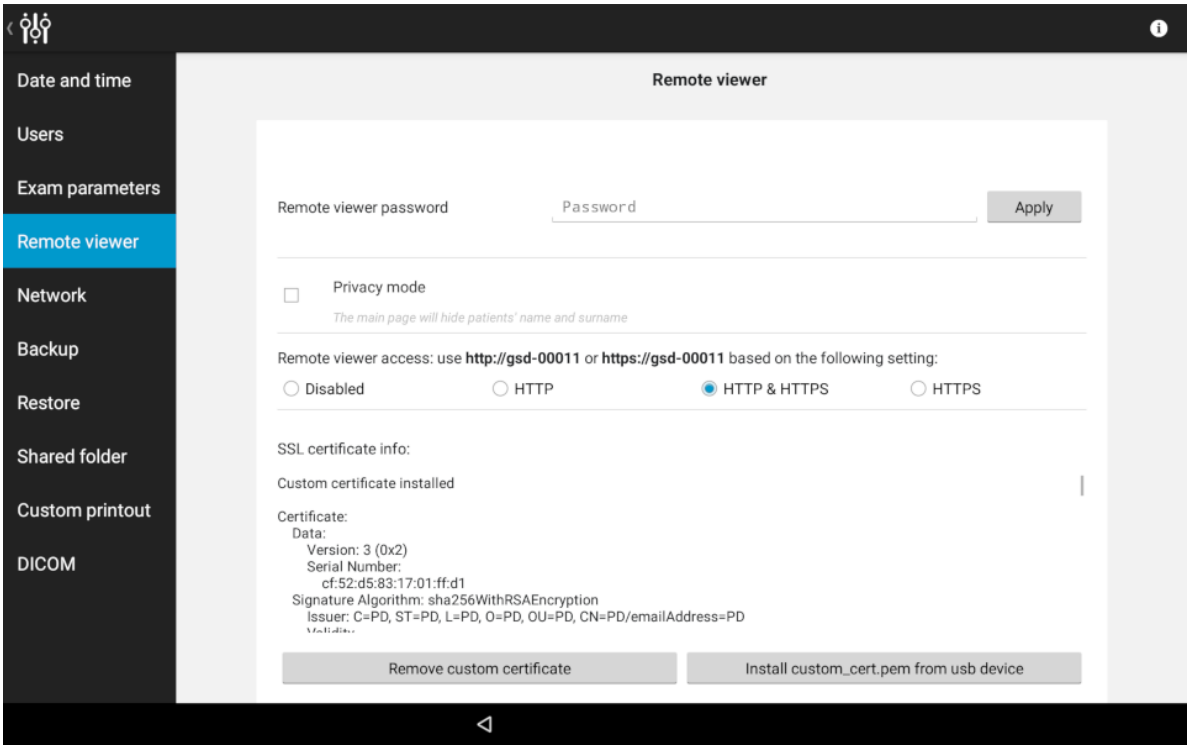


Fig. 84 – Configurator - REMOTE VIEWER screen

For cybersecurity reasons, it is recommended to configure the Remote Viewer to use HTTPS.

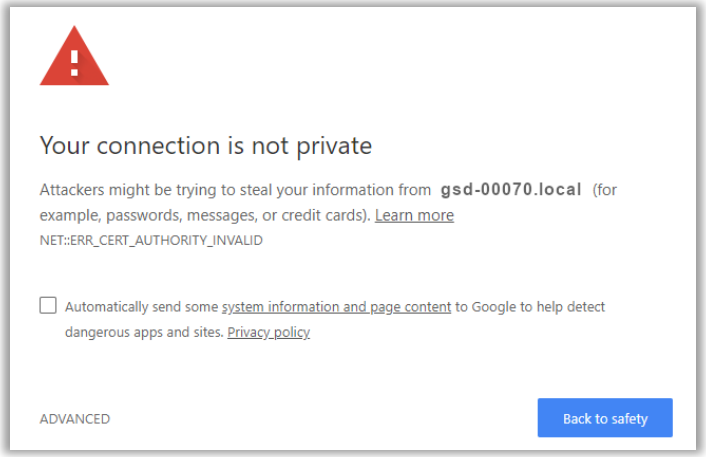
When using HTTPS protocol, the server authentication is carried on by means of an SSL certificate. COMPASS provides a default, self-signed built-in certificate for such authentication. It is however possible to generate and use a custom certificate instead of the default one: to install it, rename it to ***custom_cert.pem*** and store it into a USB device and plug it into COMPASS, then press the **Install custom_cert.pem from USB device** button.
When a custom certificate has been installed, press the **Remove custom certificate** button to uninstall it and revert back to the default COMPASS certificate.

A custom certificate must fulfill the following conditions to be installed on COMPASS:

- It must be an SSL certificate generated in PEM format
- The private key must not be protected by a passphrase
- It must contain the private key within the certificate file, like in the example file below:

```
-----BEGIN RSA PRIVATE KEY-----
MIIEogIBAAKCAQEAvmKAUWO/Z0YJu8PMqOOOn1zTp9xHsJp4IRyytS9eMsTIJdxR
[...]
sfJw7OZ5bFPCBU+OfSEs24W4W/0Zad8xBveLSMt1jO45sfOPATI=
-----END RSA PRIVATE KEY-----
-----BEGIN CERTIFICATE-----
MIIDlTCCAn2gAwIBAgIJAM9S1YMXAf/RMA0GCSqGSIb3DQEBCwUAMGExCzAJBgNV
[...]
3F5jTQf4s6+C
-----END CERTIFICATE-----
```

If the HTTPS protocol is selected, a warning message like the following one might appear on the browser when connecting. This is due to the browser not being able to verify COMPASS' self-signed certificate, but it is not a real security threat. Click on "Advanced" and then on "Proceed to gsd-sssss (unsafe)" to access the Remote Viewer.



The **Privacy mode** checkbox allows to hide all patient names from the **Patient List** view of the **Remote Viewer**. To find a patient, enter part of its name or code in the Search box: only the patient names that match the search criteria will be shown.

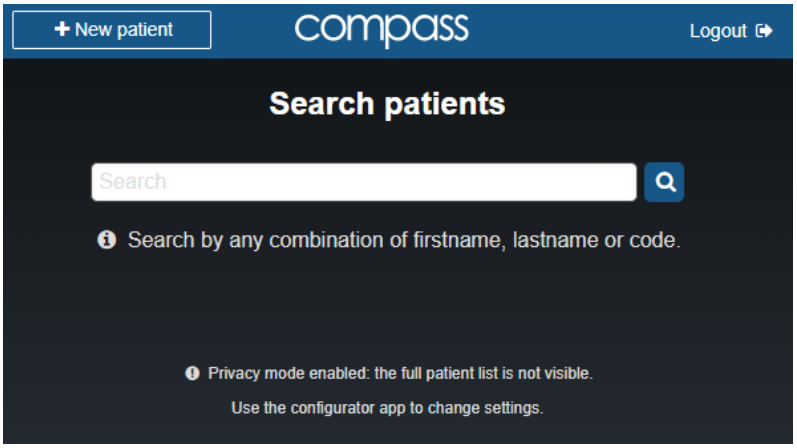


Fig. 85 - Remote Viewer's search interface if Privacy Mode is enabled

15.7 Network configuration

COMPASS supports either Ethernet connection or wireless connection. However, Remote Viewer, Shared Folder export, DICOM and service access are available only through wired network connection.
The wireless connection is available only through the Control Interface and is intended only for printing and service access.

Required characteristics and peripheric of the IT-network are:

- **Printers**: compatible printers are listed in section §14.1
- **Compatible browsers for Remote Viewer**: Google Chrome, Microsoft Edge, Mozilla Firefox, Apple Safari
- **Supported wireless protocols**: Open, WEP, WPA, WPA2
- **Supported Shared Folder protocols**: SMB/CIFS protocol, up to ver. SMBv3, connecting to hosts running the following operating systems: Windows 7, 8, 10, 11, Server 2012, and Linux.
- **DICOM**: DICOM compatibility is described in the COMPASS - DICOM IFU and DICOM Conformance Statement
- **LDAP**: LDAP compatibility is described in COMPASS - LDAP Instruction for Use

The Intended Information Flows from the device to the IT infrastructure are:

- Printing of exam reports via a compatible printer
- Storing exams' and patients' data to an external USB Data Storage
- Exporting exams' and patients' data to a configured remote Shared Folder
- Remote Viewer: view and export exams' and patients' data from a personal computer connecting to the device via a web browser
- DICOM

The responsible organization is strongly recommended to keep virus protection up to date on the computers used. The responsible organization is also recommended to install security updates to the used web browsers and computers when available.

It is strongly recommended to connect only to trusted networks protected by an encryption system, like for example WPA2, and refrain from connecting to unsecured Wi-Fi networks.

The responsible organization should identify, analyze, evaluate, and control any additional risks resulting from the EIDON device connected to IT networks including other equipment.

Changes to the IT network could introduce new risks requiring additional analysis by the responsible organization. The changes include:

- changes in the IT-network configuration
- connection of additional items to the IT-network
- disconnecting items from the IT-network
- update or upgrade of equipment connected to the IT-network

Potential Hazardous situations resulting from the failure of the IT-network

If the connection is lost during data transfer, no data is lost from the device. The images are still stored in the device and can be transferred once the connection is re-established.

Failure or misconfiguration of the IT-network may result in data not being transferred causing inconvenience to the operators.

The Ethernet port is located on the back of the system (see Fig. 2).

The COMPASS Custom Control Interface Wi-Fi must be enabled to connect the COMPASS to a wireless network.

Click on the “**Network**” tab in the Configurator app to access the Network configuration window.

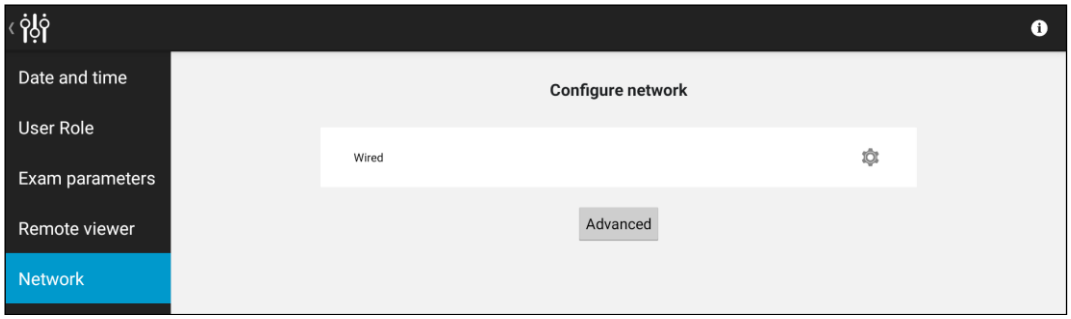


Fig. 86 – Configurator - NETWORK screen

The wireless network parameters are set directly using the tablet’s Android Wi-Fi Settings panel, while the Ethernet network is configured by clicking on the icon, near the “Wired” label.

Fig. 87 – Configurator - Network configuration screen

The COMPASS wired interface supports either DHCP or static profiles: to use DHCP, switch ON the DHCP button. Otherwise, type the IP, Network Mask, Gateway, and DNS: you may need to contact your system administrator to obtain these details.

After configuration, press **OK** button to store the parameters.

To switch between Ethernet and wireless connection, click on the **Advanced** button on the Network configuration window (Fig. 86): the following window appears.

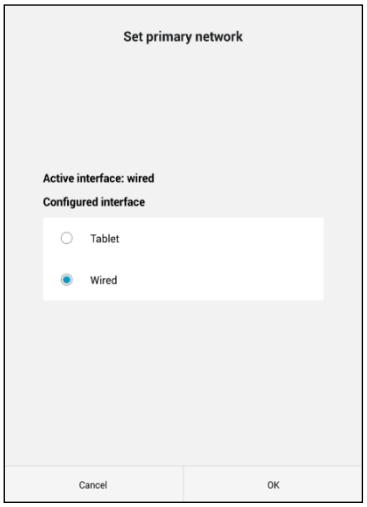


Fig. 88 – Primary Network settings

The window shows the current configured network interface, called **active interface**, and allows to select the connection to be used as network connection. By pressing **OK**, the Control Interface prompts a message if the configured interface was modified.

15.8 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.
To access the Backup window, press *Backup* on the Configuration app. The backup configurator contains three screens: **Device**, **Schedule**, **Execute**.

⚠	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.

⚠	Use a media formatted with the NTFS filesystem. External media formatted with different filesystems might lead to data loss.

15.8.1 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

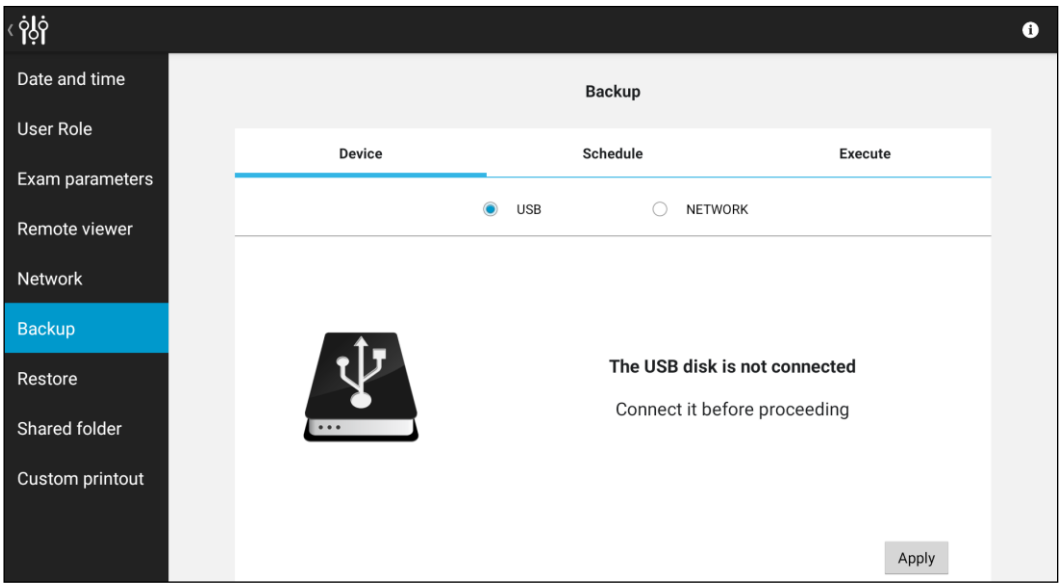


Fig. 89 – Configurator - BACKUP screen - USB-media backup selected

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

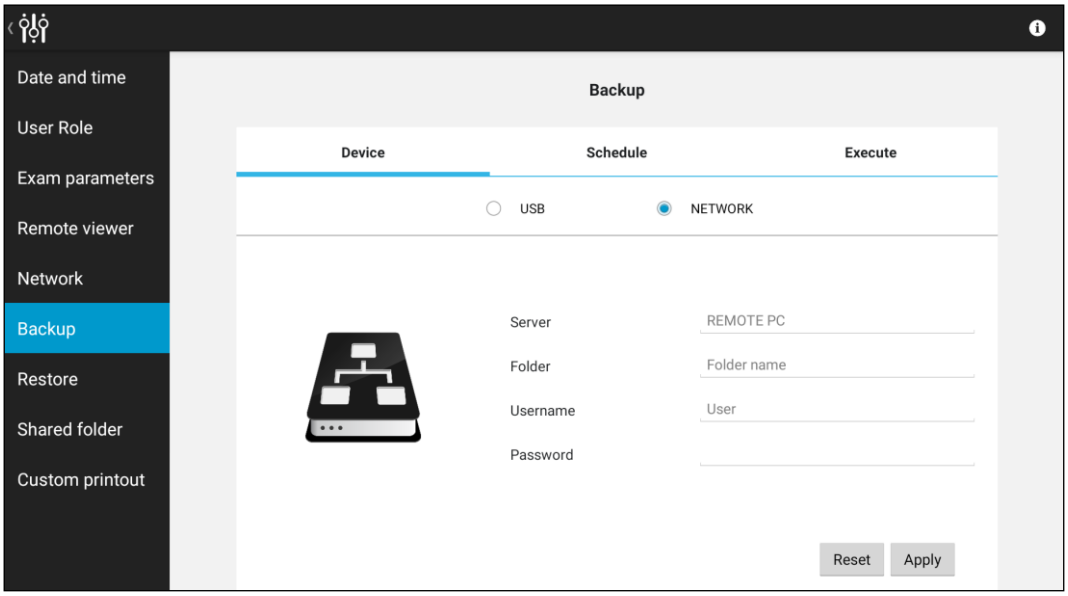


Fig. 90 – Configurator - BACKUP screen - Network backup selected

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: *DOMAIN\USERNAME*
- *Password*: this field contains the password used by the user in the remote server

All these fields are mandatory.

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

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

15.8.2 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.

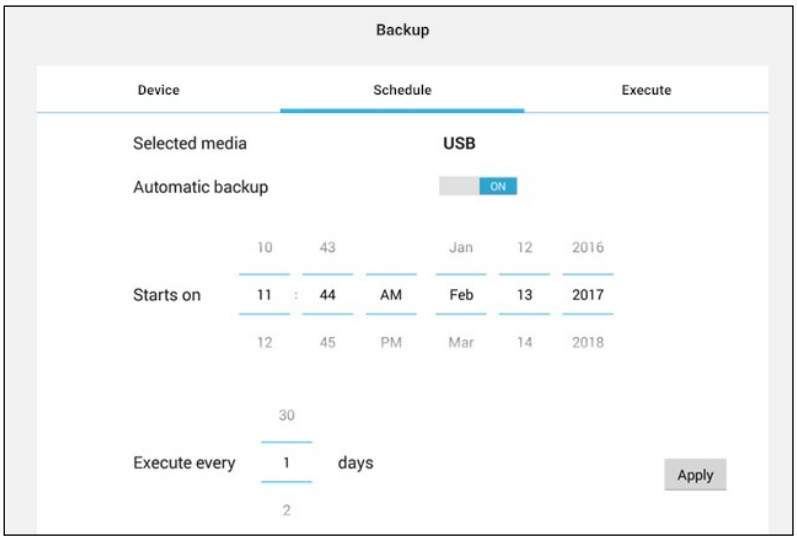


Fig. 91 – Configurator – BACKUP screen – Schedule tab with automatic backup enabled

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.

15.8.3 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.

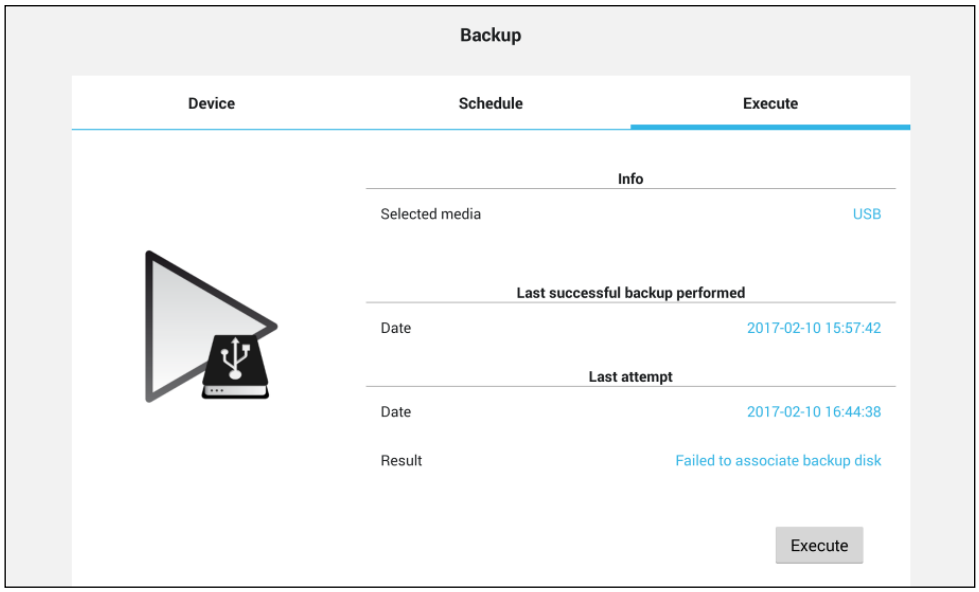


Fig. 92 – Configurator - BACKUP screen - Execute tab

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

15.9 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**.

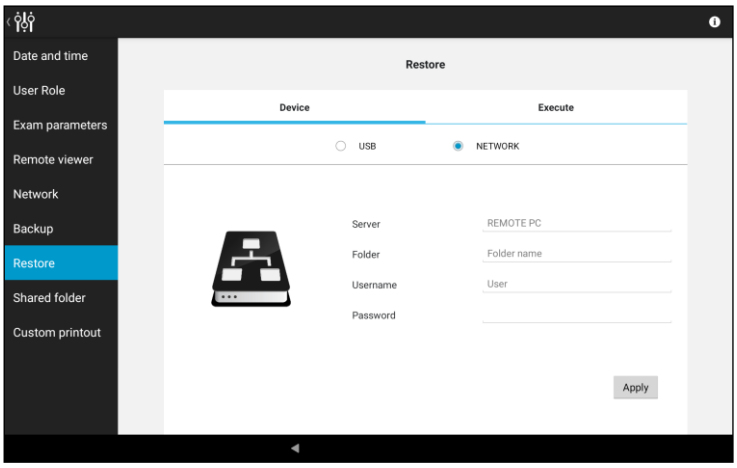


Fig. 93 – Configurator - RESTORE screen - Network folder selected

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

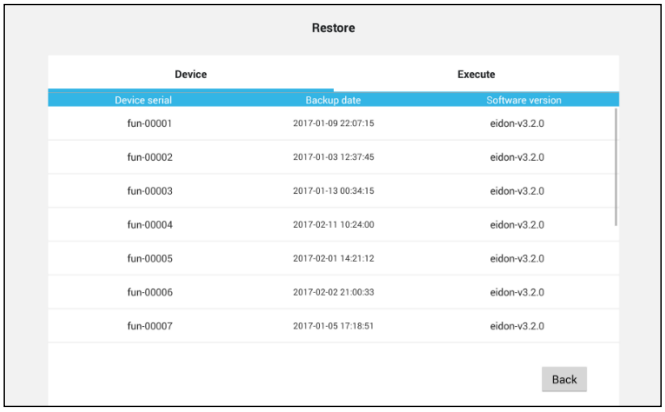


Fig. 94 – Configurator - RESTORE screen - List of available archives to be restored

- 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.

15.10 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 § 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.

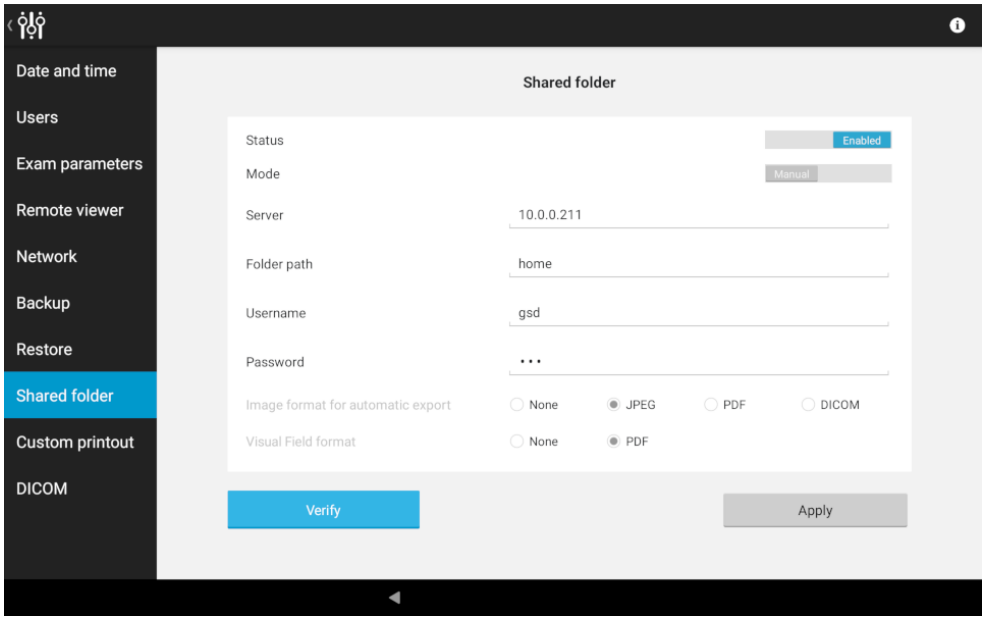


Fig. 95 – Configurator - SHARED FOLDER configuration

To check the Shared Folder connection status, check the Information Center (see § 10.1).

See § 19 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.

15.11 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.

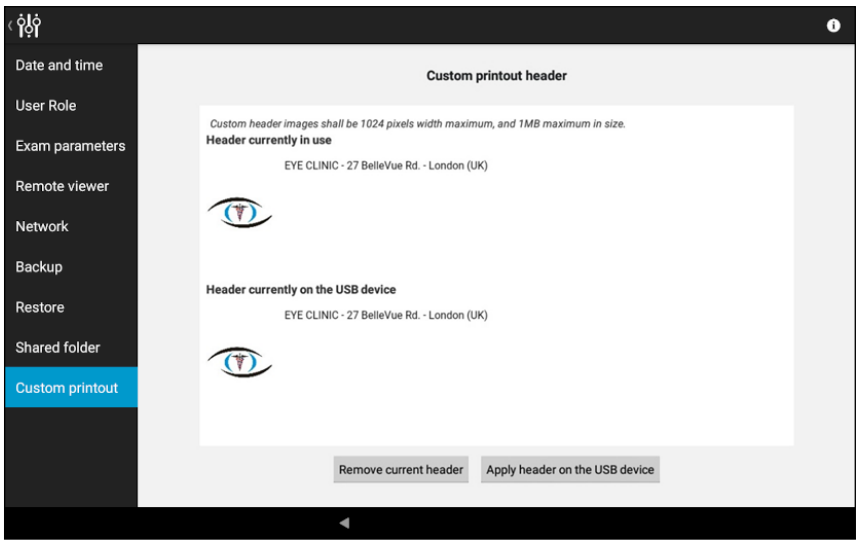


Fig. 96 – Configurator - CUSTOM PRINTOUT header configuration

15.12 Custom control interface setting

From the Home screen of Fig. **13** press  to enter the menu. Click on the Settings Icon to enter the menu and select the desired standby time for the Custom Control Interface Display.

Extending the display standby time, the patient data will be more exposed to unwanted visualization.

16. DEVICE SHUTDOWN

To shut down the device, go back to the **Home** screen and press the power off icon  : the device beeps twice and then turns off.

17. TECHNICAL SPECIFICATIONS

CE 0123

Fundus Automated Perimetry Features

Projection field:	30° (radius)
Background luminance and color:	31.4 asb, white
Maximum luminance:	10000 asb
Dynamic range:	0 - 50 dB
Stimulus size, shape and color:	Goldmann III, round, white
Stimulus duration:	200 ms
Test strategies:	ZEST, ZEST Fast
	4-2
	SupraThreshold testing
	Quick SupraThreshold testing
Test patterns:	24-2, 30-2, 10-2
Fixation control:	25 Hz automated retinal tracking

Fundus Imaging Features

Field of view:	60° (diameter)
Sensor resolution:	5 Mpixel (2592x1944)
Light sources:	infrared (825-870 nm) and white LED (440-650 nm)
Imaging modalities:	color, infrared, red-free, stereoscopic, SmartMosaic
Resolution:	17 µm
Minimum pupil size:	3 mm
Working distance:	28 mm

Other features and characteristics

Class and type of applied part:	Class II, Type B according to IEC 60601-1
IP classification:	IPX0 according to the degree of protection provided by the enclosure with respect to harmful penetration of particulate matter or water
Automatic operation:	Automatic pupil size measurement auto-alignment, auto-focus, auto-exposure, auto-capture
Auto-focusing adjustment range:	- 12 D to + 15 D
COMPASS Control Interface:	10.1” multi-touch, color display control interface
Connectivity:	Wi-Fi and Ethernet connection
Hard disk:	SSD, 480 GB or higher
DICOM[17]:	DICOM support, modality worklist
Size:	360 mm x 590 mm x 620 mm (14.2” x 23.2” x 24.4”)
Weight:	25 kg (55 lb)
Power supply:	Rated voltage 100-240VAC, Frequency 50-60 Hz Power Consumption 80W
Service life (lifetime):	The service life (lifetime) of the devices is five (5) years from the date of manufacturing.
COMPASS is equipped with[18]:	• Custom Control Interface with multi-touch display • Support bracket for Control Interface with mounting kit • External power supply with power cord • Forehead and chin rest silicone cushions • Dust cover • Patient push button • Prismatic stereoscopic goggles • COMPASS front lens cap • Light shield with magnets • This Instruction for Use (or Leaflet, in case of electronic Instruction for Use) • Mini-HDMI-to-HDMI adapter • USB Extension cable
Accessories:[19]	No Accessories

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

[17] Available under additional license only: please refers to your local distributor for further and detailed information including for DICOM Conformance Statatement

[18] COMPASS is always equipped with all the device components (definition = any raw material, substance, piece, part, software, firmware, labelling, or assembly which is intended to be included as part of the finished, packaged, and labelled device

[19] Accessory = a finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices.

18. CLEANING AND DISINFECTION

This section explains how to clean and disinfect the device.

The cleaning process is described as follows:

1. Turn off the device and disconnect the power cord from mains.
2. Clean the Custom Control Interface display and the device's exteriors: use a clean lint-free microfiber tissue dampened with small amount of water (i.e. tap-water);
3. Clean the headrest and chinrest silicone cushions with a clean lint-free microfiber tissue dampened with small amount of water after each use. Both cushions can also be removed and washed with water and/or a mild hand detergent;
4. Clean the other possible contact parts of the device with the user or patient (e.g. plastic covers, frame, any aluminum parts, Patient Push-button, Custom control Interface display and any other components) using a clean lint-free microfiber tissue dampened with small amount of water or a mild hand detergent
5. Clean the front lens (only if really needed) using a clean lint-free microfiber tissue or photographic cleaning paper dampened with a standard lens cleaning solution. Start from the center of the lens, wipe it with a circular movement, very slowly, only for one complete rotation. The exiting movement (i.e. moving away from the lens) has to be made radially, towards the border. Do not reuse the same wiping cloth area after one pass;
6. Allow all surfaces to dry for 5 minutes before turning on the device.

The disinfection process should be done after each use and is described as follows:

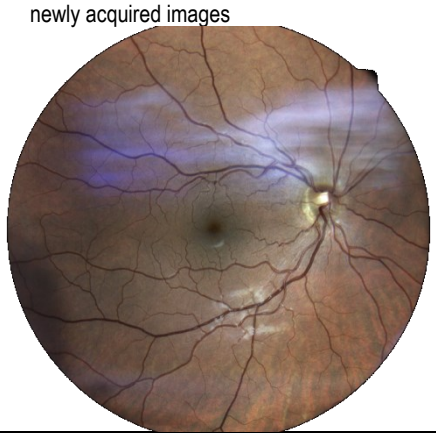
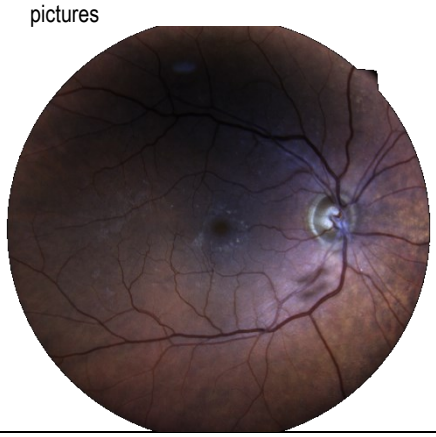
1. Turn off the device and disconnect the power cord from mains;
2. Clean the headrest and chinrest silicone cushions with a disinfecting wipe with 70% isopropyl alcohol (IPA);
3. Disinfect all the other contact parts using a disinfecting wipe with 70% IPA (or a soft clean disposable tissue damped with 70% IPA solution): plastic covers, frame and back panel of the tablet, any aluminum parts, touch screen and components if present.
4. Clean the front lens: use a disinfecting wipe with 70% IPA (or a soft clean disposable tissue damped with 70% IPA solution). Starting from the centre of the lens, wipe it with a circular movement, very slowly, only for one complete rotation. The exiting movement (i.e. moving away from the lens) has to be made radially, towards the border. Do not reuse the same wipe area after one pass.
5. Allow all surfaces to dry for 5 minutes before turning on the device.

Fig. 97 - Removal of the chin rest silicone pad

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

Do not reuse the same area of the wiping tissue after one pass.
Do not use disinfectant wipes containing bleach.
Do not allow the liquid from the disinfecting wipe to sit or pool on the area being disinfected for a long amount of time.
Do not use rough towels or cloths to dry the area.

19. 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 § 18)
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 §15.2 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
10. One or more dark areas appear in color and/or IR pictures 	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”	• Network connection to the remote shared folder not working • Write access to the selected remote folder not granted host computer is not reachable	• 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 Service representative.

19.1 REMOTE ASSISTANCE

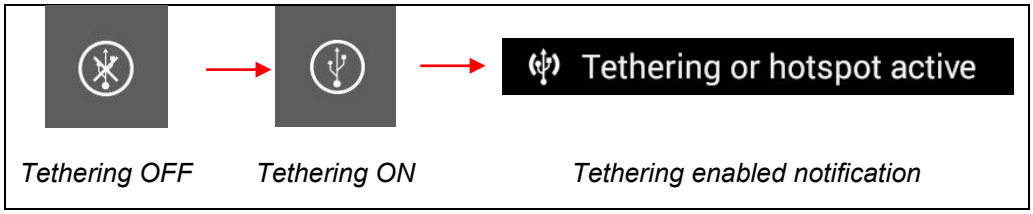
If an issue cannot be solved with the basic troubleshooting, please contact an Authorized Service representative explaining the problem.
The Service technician might require a remote connection to the unit to perform a thorough analysis: COMPASS includes a Remote Assistance feature by means of a separate 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

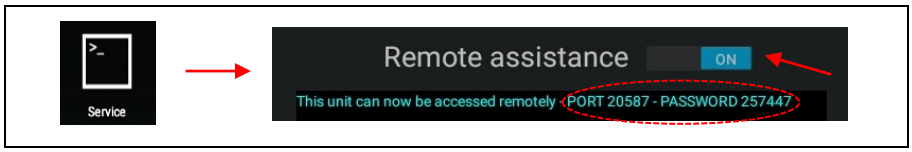
The following steps should be performed to establish a Remote Assistance session:

- 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 the Authorized Service personnel to allow them to connect remotely to the unit.

20. MAINTENANCE

The Manufacturer recommends the periodic maintenance of the device once per year.
Only properly qualified Authorized Service Technicians can perform maintenance activities [20]. Contact your local Authorized Service Center if you think your COMPASS requires maintenance.
To clean the front lens in case of dirt, refer to §19. To check the disk space, refer to §10.1.

20 Note: COMPASS has no user-serviceable internal parts.
Only CENTERVUE S.P.A. authorized personnel may perform maintenance or repair procedures other than those described in this manual.

21. ELECTROMAGNETIC COMPATIBILITY

COMPASS device has been tested and found to comply with the limits for medical devices contained in IEC 60601-1-2. These limits are intended to provide reasonable protection against harmful interference in a typical medical installation. COMPASS device 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 COMPASS device does cause harmful interference to other devices, which can be determined by turning the COMPASS device 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.

COMPASS 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 COMPASS device.

21.1 Manufacturers EMC Declaration to IEC 60601-1-2

The following tables provide specific information regarding compliance of COMPASS device.

COMPASS device is intended for use in the electromagnetic environment specified in the below tables. The customer or the end-user of COMPASS Device should ensure that it is used in such an environment. Other cables and accessories not provided with the devices may negatively affect EMC performance.

IEC 60601-1-2 EMISSION TEST for COMPASS models			
Test Requirements	**Test Result**	**Compliance**	**Electromagnetic environment - Guidance**
Class A or B	B	Yes	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. COMPASS is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes, providing the following warning is heeded:  COMPASS is intended for use by healthcare professionals only. COMPASS 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.
Group	1	Yes	
CISPR 11, 14-1, 32 or ISO 7137	CISPR 11	Yes	
Conducted RF emissions	CISPR 11 Class B	Yes	
Radiated RF emissions	CISPR 11 Class B	Yes	
Disturbance Power (if applicable)	N/A	N/A	
Harmonic Distortion IEC 61000-3-2 (Class A, B, C, D)	Class A	Yes	
Voltage Fluctuations and Flicker IEC61000-3-3	Passed	Yes	

Table 5 - Electromagnetic Emissions for COMPASS

21.2 Guidance and manufacturers declaration – Electromagnetic Immunity COMPASS device

IEC 60601-1-2 ELECTROMAGNETIC IMMUNITY FOR COMPASS		
Compliance		
Electrostatic Discharges	Passed	Yes
Radiated RF EM Fields and Proximity Wireless field	Professional Healthcare Facility Environment (IEC 60601-1-2)	Yes
Electrical Fast Transients and bursts	Passed	Yes
Surges Conducted Disturbances, induced by RF fields	Passed	Yes
Voltage Dips and Interruptions	Passed	Yes
Rated Power-frequency Magnetic Field	Passed	Yes

Table 6 - Electromagnetic Immunity (IEC 60601-1-2:2014) for COMPASS

21.3 Immunity pass criteria

IMMUNITY	
Function	**IMMUNITY pass criteria**
System functioning – main unit	During the applied testing stimulus, temporary cessation or interruption of any intended operation is acceptable
System functioning – connection between Control Interface and main unit	During the applied testing stimulus, temporary cessation or interruption of any intended operation is acceptable

Table 7 - Electromagnetic Immunity (IEC 60601-1-2)

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

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the COMPASS device, including cables specified by the Manufacturer. Otherwise, degradation of the performance of this equipment could result.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800MHz to 2.5 GHz** $d = 1.17\sqrt{P}$
0,01	0.12	0.12	0.12
0,1	0.37	0.37	0.37
1	1.17	1.17	1.17
10	3.70	3.70	3.70
100	11.70	11.70	11.70
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum power rating of the transmitter in (W) according to the transmitter manufacturer. *NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.* *NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.*			

Table 8 - Recommended Separation Distances

21.4 Wi-Fi Specifications

Model name:	WL18MODGI (Texas Instruments Incorporated)
Main Chipset:	WL1807MODGIMOC (Texas Instruments Incorporated)
Tx/Rx:	20- and 40-MHz SISO
Standard Conformance:	IEEE 802.11 b/g/n IEEE 802.11 a/n Dual-Band (2.4 and 5 GHz)
Interface:	4-Bit SDIO Host Interface Support
Operation Voltage:	DC 1.8V ±8%
Maximum RF Power:	According to EMF Exposure Evaluation Report: 2.4GHz Avg power: 17.5dbm (56.2mW) 5GHz Avg power: 19.5dbm (89.1mW)
Security:	Hardware-based encryption-decryption using 64-, 128-, and 256-bit WEP, TKIP, or AES keys Requirements for Wi-Fi-protected access (WPA and WPA2.0) and IEEE Std 802.11i (includes hardware-accelerated Advanced Encryption Standard AES)

FCC (USA) radio certification

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

FCC ID:	ID-Z64-WL18DBMOD
IC ID:	451I- WL18DBMOD

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.

22. 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).

23. LOG OF DOCUMENT CHANGES

IFU version	Description	IFU Release date	Software version
23	Introduction of new features: SPA ZEST, Smart Progression, SmartMosaic.	2023-10-10	4.0.1
24	Introduction of electronic IFU, added 12 languages for IFU, bugfixes.	2024-04-03	4.0.2
25	Updated for SW v.4.0.3. Added a couple of warnings in §5.	2024-07-15	4.0.3

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