MAIA

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 this instructions for use is English. Should a conflict situation arise concerning a translated document, the English language version shall prevail.
Please refer to §26 for information on the Software versions these Instructions For Use refer to.

Date of release:	2026-04-01
Revision number:	07.00
Software Version:	1.3
Reference device:	MAIA (REF: AHMACME001)

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CONTENTS

1 INTRODUCTION

1.1 Intended purpose

MAIA is a peripheral vision analyzer, 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

MAIA is indicated to perform Microperimetry 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 MAIA is restricted to eyecare professionals with training in the ophthalmology field (or equivalent) that hold the responsibility of the diagnosis.

1.3 Clinical benefit

MAIA 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 MAIA 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.

1.4 Contraindications

No contraindications and side-effects have been found for Fundus Perimetry. No contraindications nor side-effects have been found for Fundus Photography. Rare and time-limited discomforts might arise, as temporary glare, watery eyes, during and/or during and after performing the exam.

1.5 Ophthalmic Devices Compliance

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

1.6 Optical Safety

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

1.7 RoHS Compliance

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

1.8 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.
The device is suitable for continuous operation.

1.9 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.

1.10 Essential Performance

The clinical performance of MAIA 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 MAIA does not provide Essential Performance as defined in the IEC 60601-1 standard.

1.11 Use Environment

MAIA 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 §24 of these Instructions for Use.

[1] *MAIA 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.*

1.12 Patient Profile

The execution of a Perimetry test requires active interaction between the device and the patient, via the dedicated push-button.
Consequently, MAIA 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 MAIA on a vulnerable patient is under the responsibility of the eye care practitioner.

1.13 Intended users

The primary intended users of MAIA device are 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 MAIA:

ROLE and User profile	Context of use	Characteristics
Operator user (Healthcare professionals)	Operating as per the medical intended purpose: Microperimetry tests and Imaging 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 Instructions 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 Instructions for Use.
Patient	Operating as per the medical intend purpose: press the pushbutton whenever he/she perceives a luminous stimulus during the Perimetry 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 MAIA on a vulnerable patient is under the responsibility of the eye care practitioner.

1.14 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/she detects such stimuli, as in standard Perimetry 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.

1.15 Temperature of applied parts

The applied parts of the devices are the forehead rest, the chin rest and the Patient Push Button. 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. In this case, 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.

1.16 Content of the device packaging

The device is provided with:

Parts
Multi-touch Embedded display
Display support with mounting kit
External power supply with power cord
Forehead and chin rest silicone cushions
Dust cover
Patient Push button
Straps for packing
Front lens cap (already installed, only for shipping)
Magnetic Light shield
USB extension cable
Documents
These Instructions for Use (or Leaflet, in case of electronic Instructions for Use)
Electric Test Report
Unpacking, Packing and Installation Guide

2 OVERVIEW

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

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

MAIA 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.

MAIA works with MAIA Software, and it operates as a standalone unit.

Each device integrates a multi-touch embedded display and an external power supply.

MAIA uses a confocal optical design to capture color and infrared images of superior quality. In addition, a high-resolution live image of the retina obtained using infrared illumination is available throughout the test.

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 MAIA

3.1 Device description

Fig. 1 – MAIA

1	15'' Embedded display
2	Optical head
3	Forehead rest = Applied part / contacting part
4	Chin rest = Applied part / contacting part
5	Base
6	Patient pushbutton = Applied part / contacting part

The main parts[3] of MAIA consist of:

- MAIA's multi-touch Embedded display
- External Power Supply[4]
- Patient Push Button[5]

[3] *For a list of all components included with the MAIA 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.*

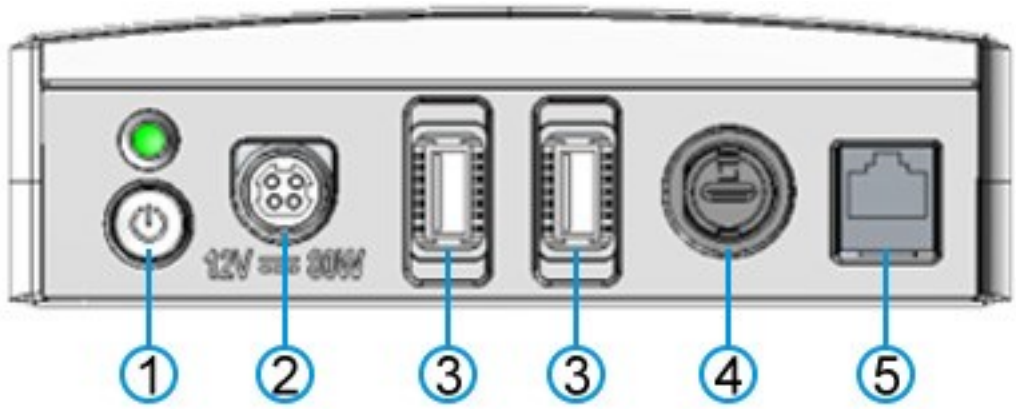


Fig. 2 – Detail of connectors panel

1 Power button and status LED

2 Power supply connector

3 USB ports

4 MAIA Display Port

5 Ethernet port

3.2 MAIA's embedded display

MAIA's embedded display (see Fig. 1) is an integral part of the device and MAIA cannot operate without it.

MAIA's embedded display must be connected to MAIA using the supplied cable[6]: if the connection is not working or the cable is connected the wrong way, the system will boot but the display will not switch on, even after restoring the corrected cable orientation. In this case, the system must be switched off pressing the power button, and restarted to have the display working.

MAIA's multi-touch Embedded display must be used only together with MAIA and in accordance with the instructions provided in these Instructions for Use. Use of MAIA's Embedded display 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 MAIA Embedded Display is equipped with a custom cable.*

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.

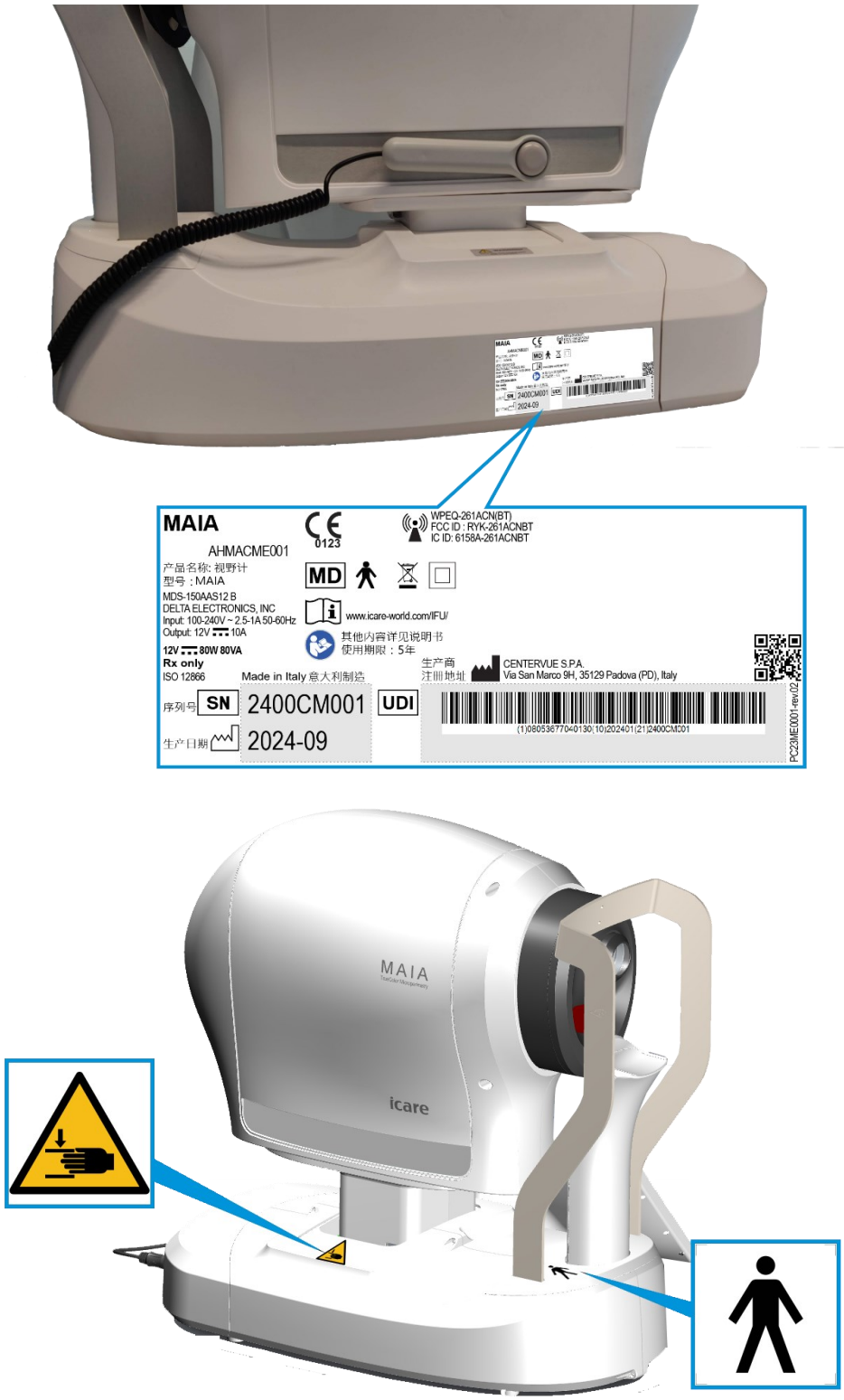


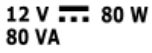
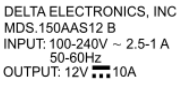
Fig. 3 – Device and warning labels[8]

[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.*

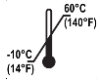
4.2 Symbols used on the device

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).
	MAIA is a Medical Device.
	MAIA 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.
	These instructions for use must be read. Read these instructions for use before starting work or before operating equipment or machinery.
	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.
	Device consumption.
	Power supply.
ISO 12866	Device complies to ISO 12866
	Warning, closing motion of mechanical parts of equipment. Take care to avoid injury to hands.
Rx Only	Caution: US Federal law restricts this device to sale by or on the order of a physician or a properly licensed practitioner

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 these Instructions for Use

The meaning of the additional symbols adopted in these Instructions for Use is as follows:

Symbol	Explanation
	Important Information.
	General Warning, read carefully.

4.5 Definitions

The meaning of the specific words adopted in these Instructions 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	MAIA owner (it can be different from MAIA device's end-user)
Device	The synonym of MAIA device used in these Instructions for Use.
Exam	Any Perimetry or Fundus acquisition session performed using MAIA device for a certain patient on a certain date. In these instructions for use, 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 red circle visible when looking into the front lens of MAIA 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 Instructions for Use
Macula	The central portion of the retina
Operator	MAIA device end-user
Optic disc	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 MAIA device used in these Instructions for Use.

Word	Explanation
PRL (Preferred Retinal Locus)	Portion of the retina preferably used by the subject for fixating. On healthy subjects it coincides or is in the proximity of the fovea. Subjects affected by retinal pathologies might have it located on a more eccentric position, or present more than one PRL.
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 MAIA device.
Sensitivity threshold	The minimum intensity of a light stimulus that is reliably perceived by a patient as emerging from the background.
Stimulus	A spot of light, projected for a limited amount of time on a randomly selected retinal area overlapped on a uniform light background. Analyzing 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.

MAIA provides capabilities for a fully automated test process.

Specific training is not required: it is recommended for the end user (operator) to carefully read these Instructions 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 microperimetry is helpful for an effective use of some of the features of the Device and for the interpretation of its results.

5 SAFETY AND SECURITY INFORMATION

5.1 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 and warnings to further mitigate all residual risks.
Residual risks are also reported.

The following precautions and warnings are important to use the device safely:

- The device is for professional use only. The clinical interpretation of the images acquired by MAIA is restricted to licensed eye care practitioners. The process of making a diagnosis using MAIA results is the responsibility of the eye care practitioner.
- The device needs to be installed and put into service by Authorized Service Center.
- Do not use MAIA device if the covers or other parts of the device have been removed. Risk of electrical shock.
- Do not open MAIA cover: risk of electrical shocks or damage to the device.
- Avoid all contact with water: risk of fire or electrical shock.
- Stand clear from moving parts during operation. Risk of body injuries
- 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. Risks deriving from malfunctioning of the device.
- MAIA 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 electrical shock.
- MAIA's power supply must be connected to a socket with a circuit breaker.
- MAIA's 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 MAIA device than ones provided by the Manufacturer may negatively affect EMC performances. Risks of electromagnetic interference.
- Power cable shall be properly maintained during use. In case of damage, contact CENTERVUE S.P.A. for the replacement. Risk of electrical shock.
- It is recommended to power off the device according to instructions of section §15.
- External device/s connected to MAIA device, into the patient environment, must comply with IEC 60601-1. That/Those device/s that does/do not comply 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 to MAIA 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.
- MAIA device must be used in a room with an electrical system that complies with applicable healthcare environment safety regulations. Risks deriving from malfunctioning of the device.
- MAIA device must NOT be used in an oxygen-rich environment or presence of flammable anesthetics. Risk of fire.
- In case of Wireless unavailability and/or signal degradation, issues can be resolved using wired network connections.
- MAIA is not intended to be wirelessly powered, nor used in close proximity to wireless charging devices.
- MAIA device is not suitable to be used in proximity to strong EM emitters, as for example MRI device, Diathermy machines, electrocautery; refer to section §24 of this IFU for details.
- In the event of a self-recoverable condition caused by electromagnetic disturbances, the device will automatically recover within approximately 1 minute after the disturbances cease.
- MAIA device must be placed in a room that is not exposed to adverse chemical-physical conditions, such as the presence of sulfur, salt, dust, direct sunlight, lack of ventilation, high humidity, sudden temperature drops or peaks. The safety and/or effectiveness of the device cannot be guaranteed if these conditions are not met. Risks deriving from malfunctioning of the device.
- MAIA device needs to be operated in a semi-dark environment, to ease the natural dilation of the patient's pupil. Use the device in dim light, or at least away from direct light to facilitate the natural dilation of the pupil. Risk of acquiring non-gradable images.
- The only applied parts of MAIA device are the chinrest, forehead rest and the Patient Push Button (see Fig. 1).
- MAIA needs to be operated in the following environmental conditions:
    - Temperature: +10 °C to +40°C (50°F to 104° F);
    - Humidity (max): 90% not condensing.

- MAIA needs to be stored in the following environmental conditions:
  - Temperature: -10 °C to +60°C (14° F to 140° F);
  - Humidity (max): 95% not condensing.

  Deviating from the above conditions may cause malfunctioning of the device.
- 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. In this case, it is recommended not to 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 he/she may perceive. Risk of temperature-related discomfort for the patient.
- Only technicians authorized by the CENTERVUE S.P.A. may service MAIA device. The Manufacturer cannot be held responsible for the device safety should MAIA device be opened, repairs carried out (included use of parts different from Manufacturer's genuine parts), third-parties software installed, or parts replaced by an unauthorized person.
- Modifications to the device are strictly prohibited. Such actions may result in harm to the user, the patient, or the device itself.
- 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 MAIA 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. 4) and the device may become temporarily locked. It is possible to reset this condition by letting the device re-initialize: refer to §17.2.1 for the complete procedure. If the error persists, please contact an Authorized Service Center.
- Follow the cleaning and disinfection instructions provided below in these Instructions for Use. Risk of damaging labels and risk deriving from malfunctioning of the device if the recommended cleaning methods are not followed.
- The device is not supplied sterile, nor is intended to be sterilized prior or after use; contact material used in MAIA is biocompatible and safe for the contact with intact skin for limited exposure. 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.
- Device-specific training is not required: it is recommended for the end-user (operator) to carefully read these Instructions for Use to be informed before use. Risk deriving from wrong use of the device
- 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 mm.
- MAIA device works in non-mydriatic conditions for patients with a minimum pupil size of 3 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 CENTERVUE S.P.A. and to the competent authority of the Member State in which the user and/or patient is established.

Fig. 4 – Example of error message due to device hardware lock

5.2 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, MAIA device contains Personal Data. Transfer data using secure infrastructures to avoid compromising patient privacy.
- It is the end user's responsibility to keep and maintain an updated copy of the data generated by MAIA 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 device provides 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, 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 for example:
  - use a password at least 8 characters long;
  - avoid using any of your personal information, like your real name, username;
  - or your company name;
  - select a password different from your previously used passwords;
  - avoid using any word spelled completely;
  - use a password containing 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. Refer to your infrastructure's policies to protect your equipment with complex passwords, updated browsers and other security policies, as an example:
  - 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.
- When sending DICOM files to a configured PACS or receiving data from a Worklist server, please remember that the DICOM protocol does not encrypt patients' personal data: it is the responsibility of the IT department of your organization to maintain proper security practices for the IT infrastructure. Precautions for the security of your devices must be maintained at the State-of-the-Art. It is strongly recommended to configure username and password for the network export destination.

- The device exposes the following services:

Protocol	Port(s)	Usage	State
TCP	443	HTTPS Remote Viewer and WebAPIs traffic	Default: closed. Active only when these functionalities are enabled
TCP	80	HTTP Remote Viewer and WebAPIs traffic	Default: closed. Active only when these functionalities are enabled
TCP	22	SSH daemon	Default: closed. Active only when a Local Remote Assistance session is active
TCP	104, 11112, 1238	DICOM Storage Commitment listener	Default: closed. Active only when this functionality are enabled
TCP	50001	OPI server	Default: closed. Active only when an OPI exam is being performed on the device
UDP	5353	avahi-daemon for Zeroconf network configuration protocol	Default: open

6 FIRST USAGE

6.1 Preparation of the device

> We recommend careful and in-depth reading of §5 before proceeding with the first use.

To make MAIA functional for the first use:

- extract the device from its box, lifting the device from the base and side bars. Do not lift it from the optical head or embedded display, as they might get damaged;
- place it on a suitable electrical table[9];
- insert the Headrest silicone cushion on the metal support (see Fig. 5);
- mount the support bracket provided for MAIA's display (see §6.2 below);
- connect the Patient Push Button cable to the connector located underneath the device (see Fig. 6);
- connect the External power supply provided with the unit to the power inlet (see Fig. 2);
- place the display 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.

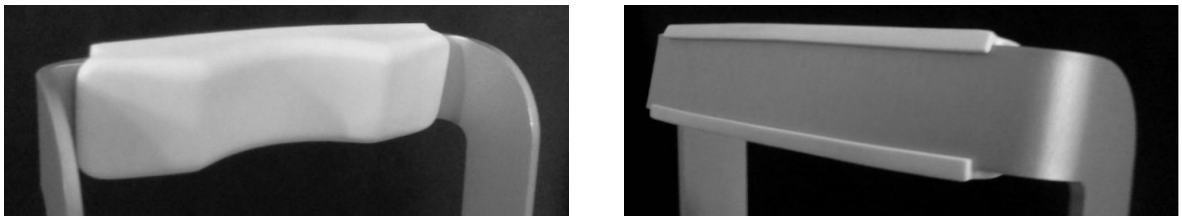


Fig. 5 - Headrest silicone cushion mounted on metal support

Fig. 6 – Patient Push Button plug (left) and with the cable plugged in (right)

6.2 Assembling and connecting the embedded display

MAIA's embedded display comes as partially pre-assembled from the production line. The embedded display must be attached to the support bracket plate using the four hex screws provided. Then, the resulting assembly must be fixed under the device by screwing the other two hexagonal screws provided into one of the 5 pairs of holes indicated in Fig. 9, according to the user's preferences. As an example, Fig. 7 shows the embedded display positioned on the right side of the device.

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

Fig. 7 – MAIA's embedded display mounted on the right side of the device

Fig. 8 – The embedded display fixed to its support bracket plate

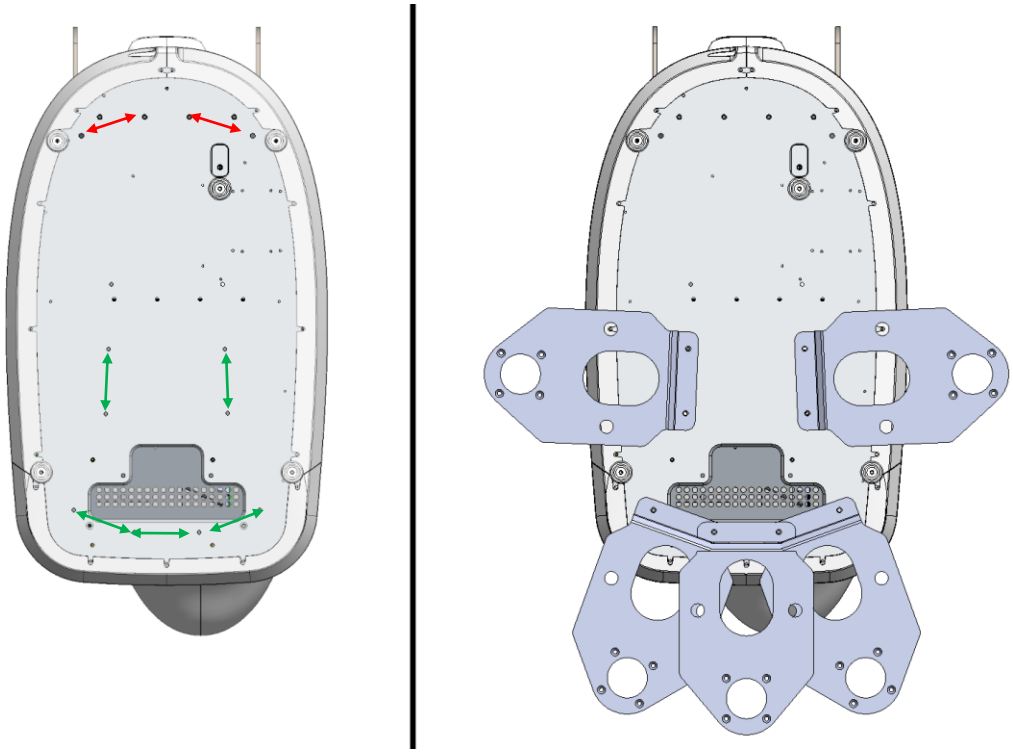


Fig. 9 – Device bottom with holes for the Embedded display bracket. Only the pairs of holes indicated by the green arrows (left image) can be used. The right image shows all the resulting possible positions for the embedded display's support bracket plate

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.

The embedded display can rotate around its vertical axis of approximately 7° in both directions, to provide further positioning flexibility.

Finally, connect the embedded display cable to the MAIA custom display port on the back of the device (see Fig. 2), with the ▲ symbol facing up (see Fig. 10):

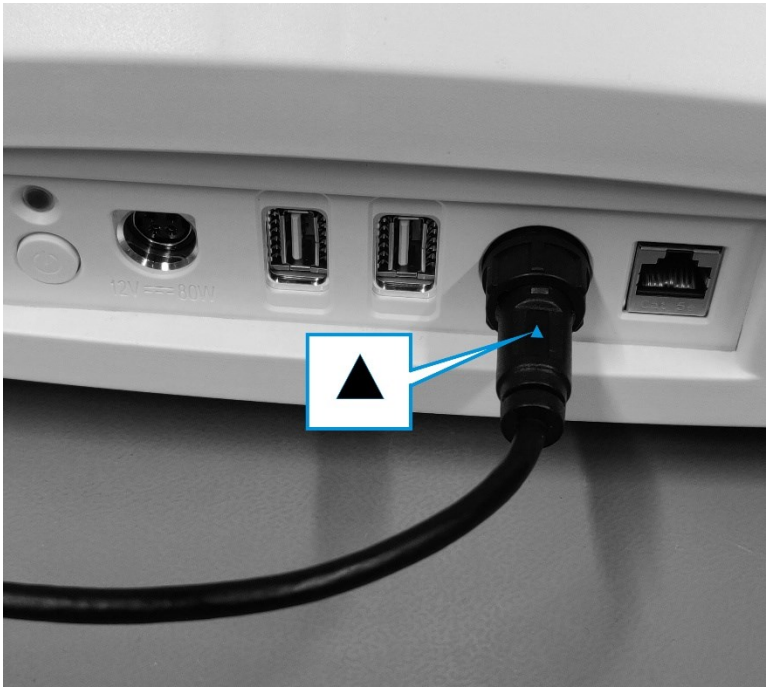


Fig. 10 – Embedded display cable correctly plugged in

MAIA's display cable must be plugged in with the ▲ symbol facing up **before** switching on the device, otherwise the display will not be detected. Reversing the connector with the device powered on will not let the embedded display recover its state. Consequently, in case the device is powered on with the display connected the wrong way, it is necessary to switch it off (refer to §6.5), connect the cable with the ▲ symbol facing up and then switch it on again.

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 MAIA, see the section "Content of the device packaging" in these Instructions for Use.*

6.4 Attaching the Magnetic Light Shield

The Magnetic Light Shield is a device component that shields the patient's eyes from external sources of light, as a non-invasive alternative to an eye-patch and to improve the 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 MAIA

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 **Embedded display** will power on. Then wait for the boot process to complete, until the **Login** screen appears (see §6.7).
During the power-on, the **LED Power Status** performs a red/green/blue cycle to test its LEDs functioning.
After 2 seconds **LED Power Status** turns off, then becomes steady green for approx. 90 seconds. 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

Approx. 30 seconds after the system has booted, the green LED will turn off: this behavior is intended, and designed to eliminate all undesired lights generated by the device.

- if the power button is pressed when the device is on and the LED is off, the green LED will turn on for 30 seconds more and then will turn off again
- if the power button is pressed when the device is on and the LED is on, a dialog on the display will request for confirmation to shut down the system; if the display is not connected, the soft-shutdown procedure will start
- if the power button is kept pressed for more than 10 seconds, the system will undergo a hard-shutdown, cutting the power to the device (not recommended: to be used in exceptional cases only)
- if any error condition occurs at the power board, the related error code reporting sequence described in the table above will take place, regardless of the current status of the LED

6.6 *Configuration wizard*

Turn on the device by pressing the **power switch** button: upon the first power-on of the device, the *Configuration Wizard* will appear (Fig. 12).

Use the down-arrow (▽) button at the top-right corner of the screen to temporarily skip the Configuration Wizard and go straight to the login screen. The Configuration Wizard can be resumed anytime afterwards.

To proceed with the *Configuration Wizard*,

1. Press the **START** button. In any of the wizard steps, it is possible to browse back to the previous step by pressing the **PREVIOUS** button.

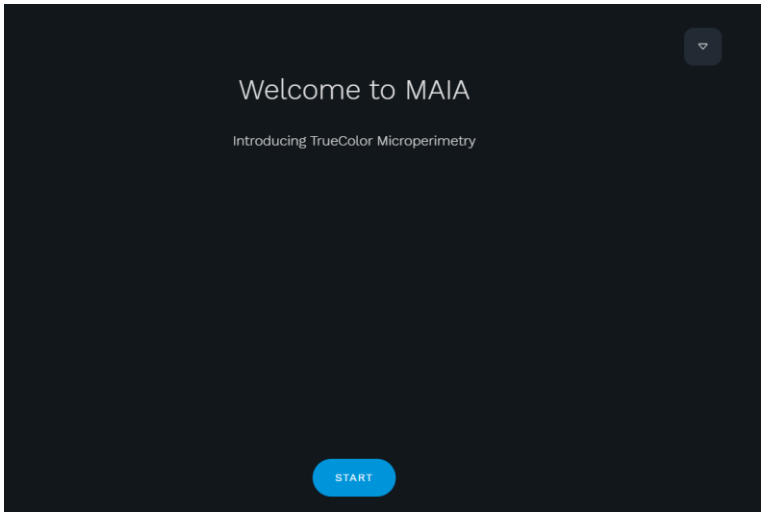


Fig. 12 – Beginning of the Configuration Wizard

2. Select the country where the device will be used.

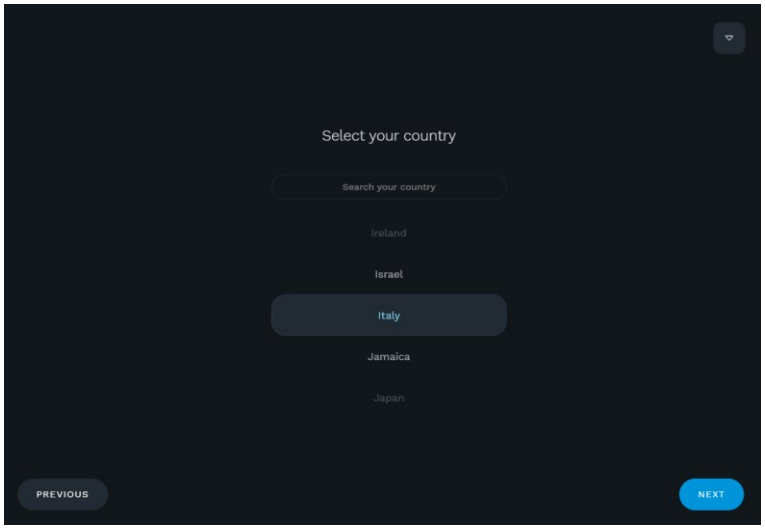


Fig. 13 - Country selection

3. Read and approve the End-user License Agreement (EULA) (Fig. 14). The EULA language changes according to the selected Country. Different types of EULA are defined for EU and EFTA, USA or Other Countries.

You must approve the EULA to continue the configuration and use MAIA.

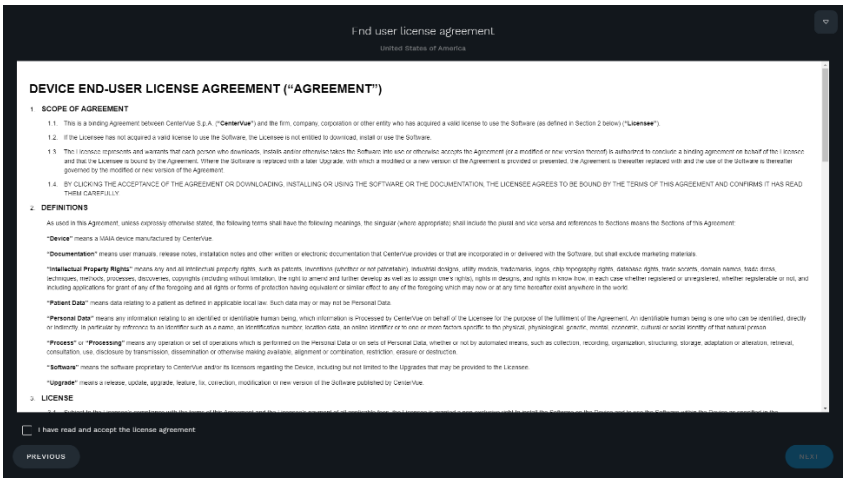


Fig. 14 End-user License Agreement

4. Set the language. A language is suggested according to the selected country (Fig. 15).

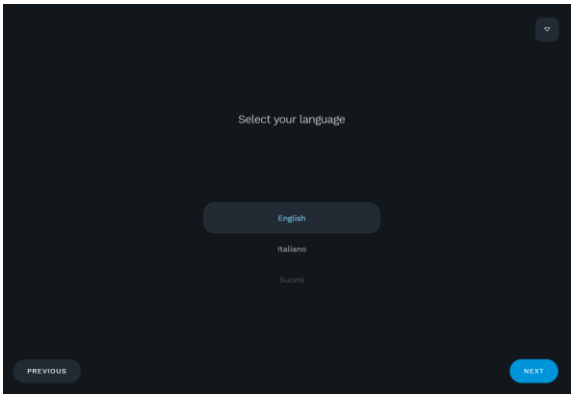


Fig. 15 - Language selection

5. Set the current time zone (Fig. 16). An initial time zone is suggested according to the selected country.

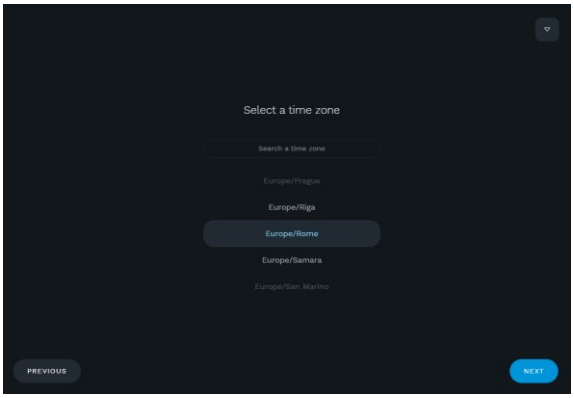


Fig. 16 – Time zone

6. Set the current date and time and configure their format (Fig. 17).

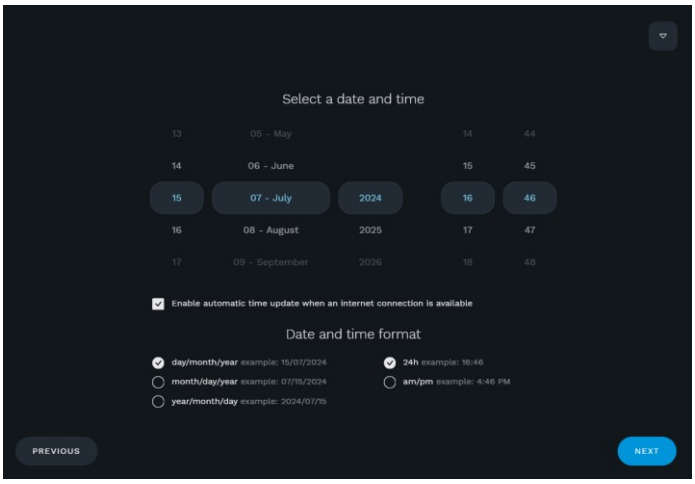


Fig. 17 –Date and time selection

7. Create the local **Administrator** account by selecting username and password (Fig. 18). The username must be at least 4 characters long[11]. The password must be at least 8 characters long, and fulfill the constraints indicated on the bottom of the page. You can select the interface Language for such a user.

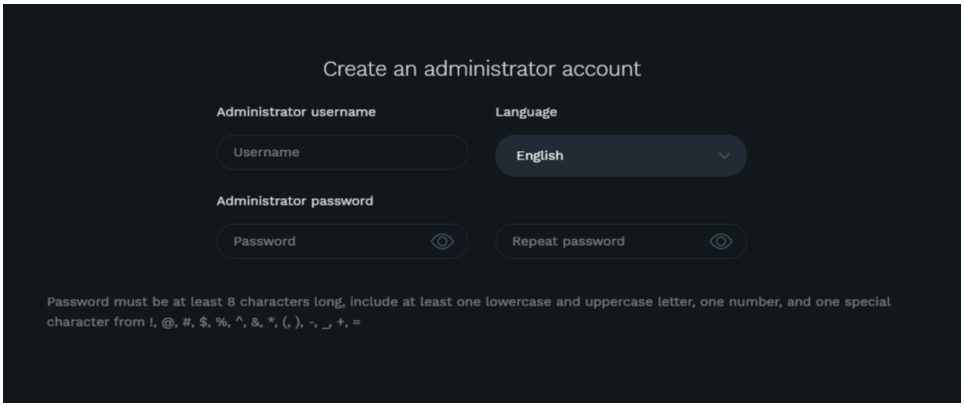


Fig. 18 – Administrator account creation

8. Optionally create an **Operator** account (Fig. 19) by following the same rules and constraints described for the Administration account. Tick the box *Use the administrator account also as the device operator* to use a unique account. To create different accounts, refer to §18.2.

Fig. 19 – Creation of user accounts

9. Select the Online services configuration (Fig. 20). Select among the options. It is strongly recommended to enable the *Periodically check for online software updates* option to receive the security updates.

[11] *Moreover, "service" and "production" cannot be used as usernames.*

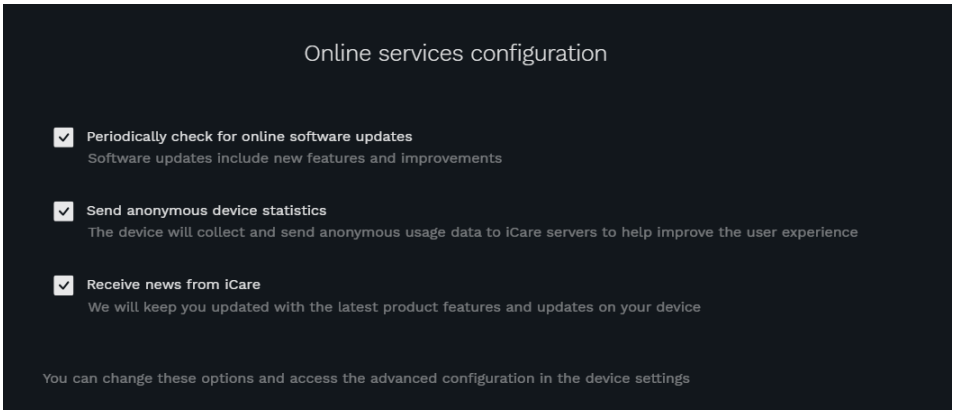


Fig. 20 - Online services configuration

10. Save the configuration (Fig. 21).

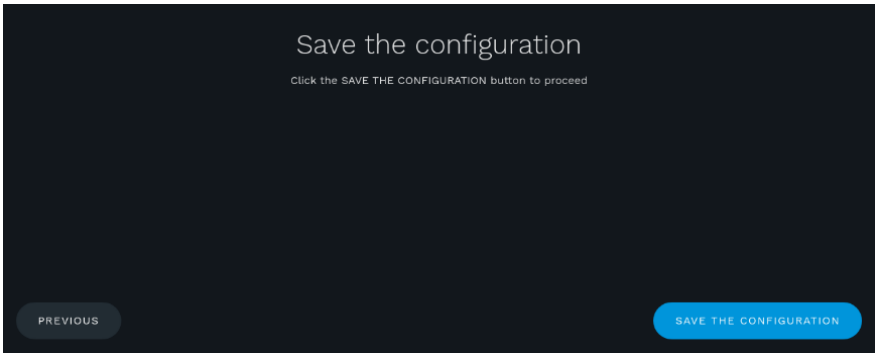


Fig. 21 - Save configuration

11. Wait for the device configuration (Fig. 22).

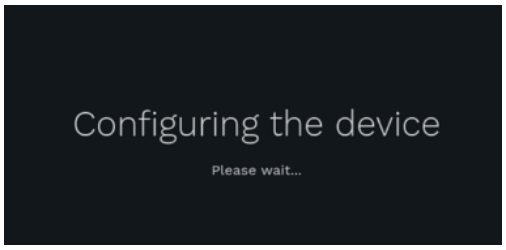


Fig. 22 - Device configuration

12. See an overview of the basic functions of the device and the improvement introduced by the current software version (Fig. 23). Click **NEXT** to go through the different pages, click **SKIP** to proceed with the configuration.

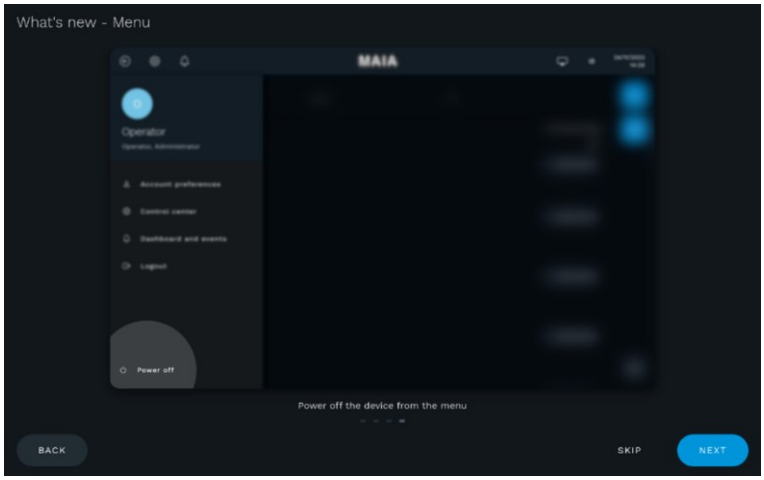


Fig. 23 - What's new

13. The device is ready (Fig. 24): after pressing the **START USING THE DEVICE** button, the *Login screen* will appear (see §6.7).

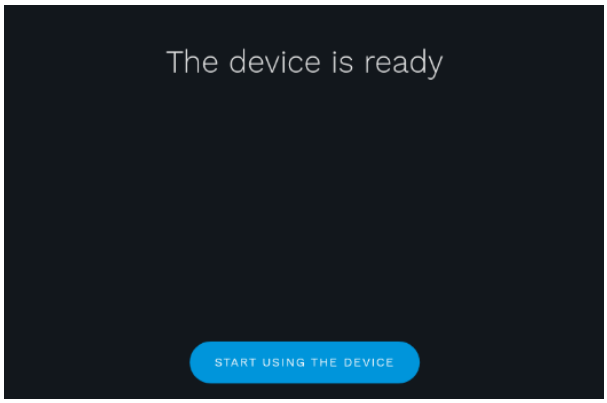


Fig. 24 - End of the Configuration Wizard

6.7 Login Screen

Turn on the device by pressing the power switch button (Fig. 2). When the boot is completed, the *Login* Screen will appear (Fig. 25).

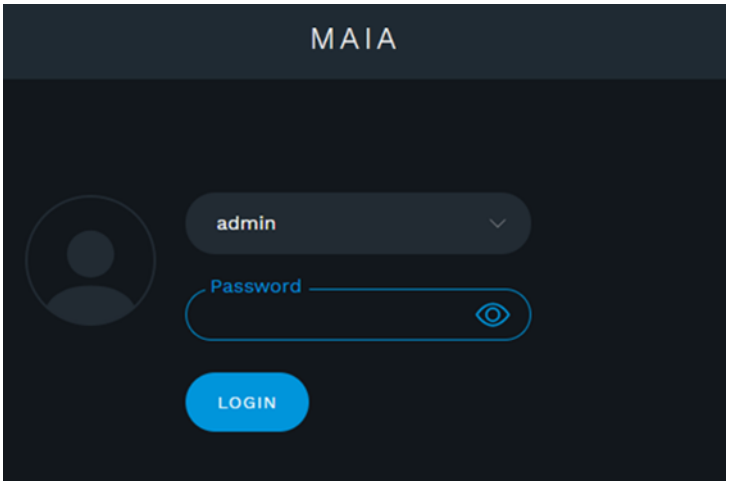


Fig. 25 – Login screen

From the drop-down menu you can select one of the available users. Different users can be assigned with different user profiles with different privileges and allowed capabilities. On a blank device only the user ***admin*** is available, which has full administrative rights and can create other users. For instructions about user management, see §18.2.

Type the password[12] and click on the **Login** button. If the login is successful, the **Patient list** screen or the **Control Center** appears, depending on the user role (see Fig. **27**).

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 §18.1.
To modify the standby time, please see §18.7.

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

7 PREPARING THE PATIENT

This paragraph explains how to prepare a patient for MAIA exam (in these Instructions for Use is used as “test”).
MAIA is a non-mydriatic device: 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.

MAIA 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.

MAIA 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. 26). If this is not the case the chin rest height needs to be adjusted with the on-screen controls (see §11.14)

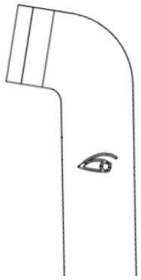


Fig. 26 - Sketch of the eye mark on the metal frame

Before the exam, the End User should inform the patient about the following:

- MAIA 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 red, 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 MAIA's software can be enabled by purchasing and installing a dedicated license[13]:

- **Clients for the Remote Viewer**: see §13
- **Remote Exam** functionality: see §13.2
- **OPI** (Open Perimetry Interface): refer to ***MAIA OPI User Manual***
- ***Targeted Microperimetry****: see §15*
- ***Custom Strategies****: see §18.11*

For details on the available licenses and how to install/revoke them, refer to §19.5.

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

9 DICOM SUPPORT

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

MAIA can export DICOM files natively.

10 PATIENT LIST AND PATIENT RECORD

When a user with operator role logs in, the **Patient List** screen appears (see Fig. 27).

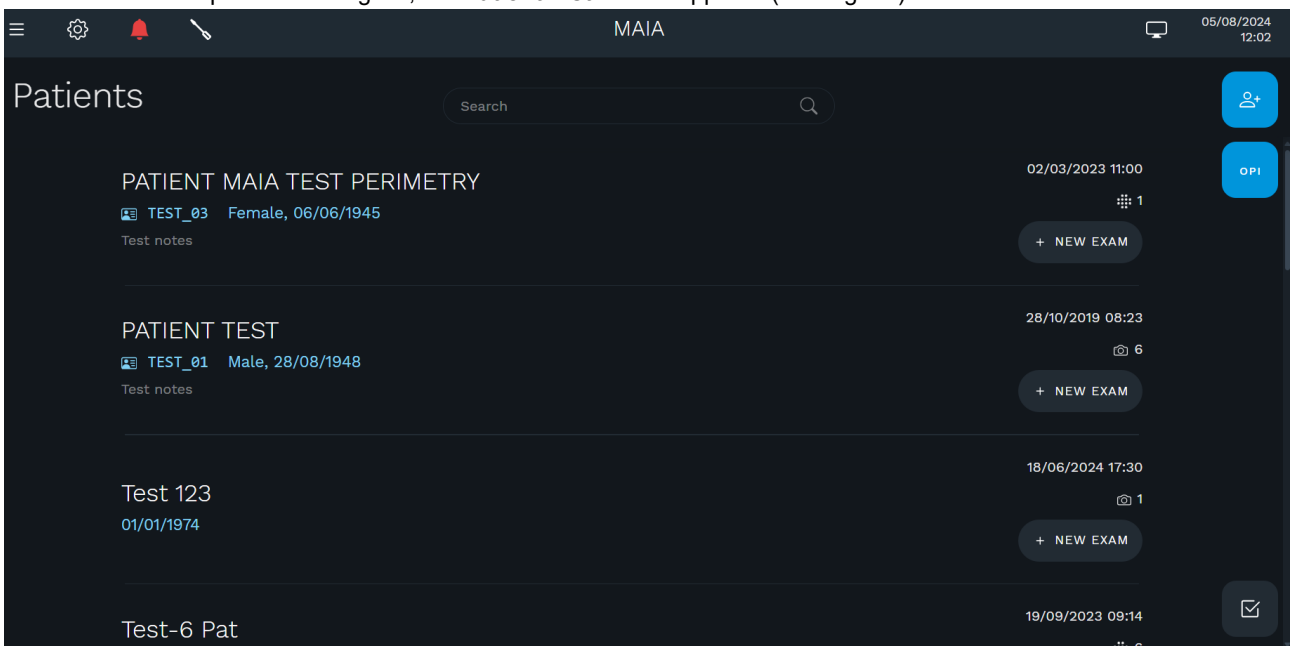
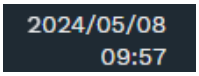


Fig. 27 – Patient list screen

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

Command	Function
	Access the Account settings (see §18.1)
	Access the Control Center (see §17.3).
	Access the Dashboard (see §10.1); the icon provides a badge with the number of unread notifications.
	Access the Network Configuration
	Current system date and time

For each patient, these data are displayed:
On the left side of the screen:

- the patient's full name
- the Patient ID (if set)
- the patient's gender (if set)
- the patient's date of birth

On the right side of the screen:

- the date of the last exam performed
- the presence and number of microperimetry exams (represented by the grid icons) and fundus exams (represented by the pic icon) stored for a certain patient
- a shortcut button "**+ New Exam**" that allows to start a new exam for that patient directly from the Patient List

10.1 Dashboard

The **Dashboard** screen contains additional information on MAIA status and can be accessed tapping on the  icon. A change in the status will be signalled with a numeric badge on the top right of the icon, representing the number of new notifications.
This window includes five tabs: **Notifications, Storage, Info, Manuals,** and **Device Usage**.
Each tab title could display a red badge indicating the number of unread notifications related to that tab.

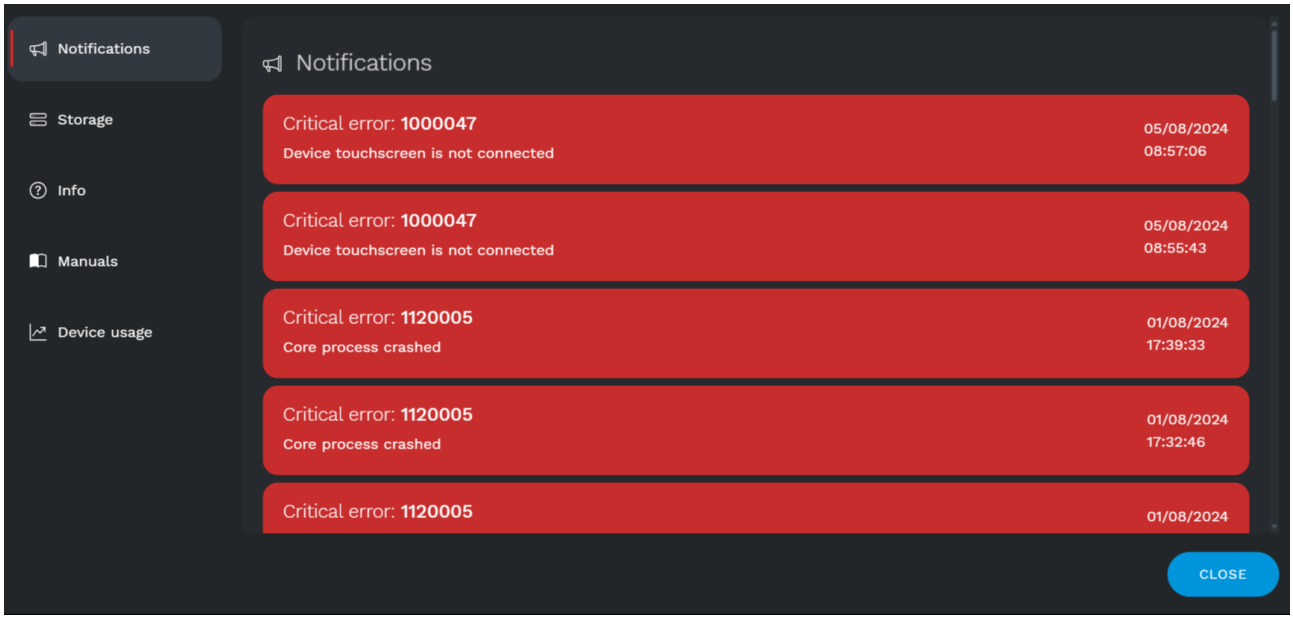


Fig. 28 – Dashboard screen: **Notifications** tab

10.1.1 Notifications

Displays a list of the system notifications: each event displays an unique ID, a description, a timestamp of the last occurrence.

10.1.2 Storage

The 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 ***System disk*** – the memory module for the operating system – and the ***Data disk*** - 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.

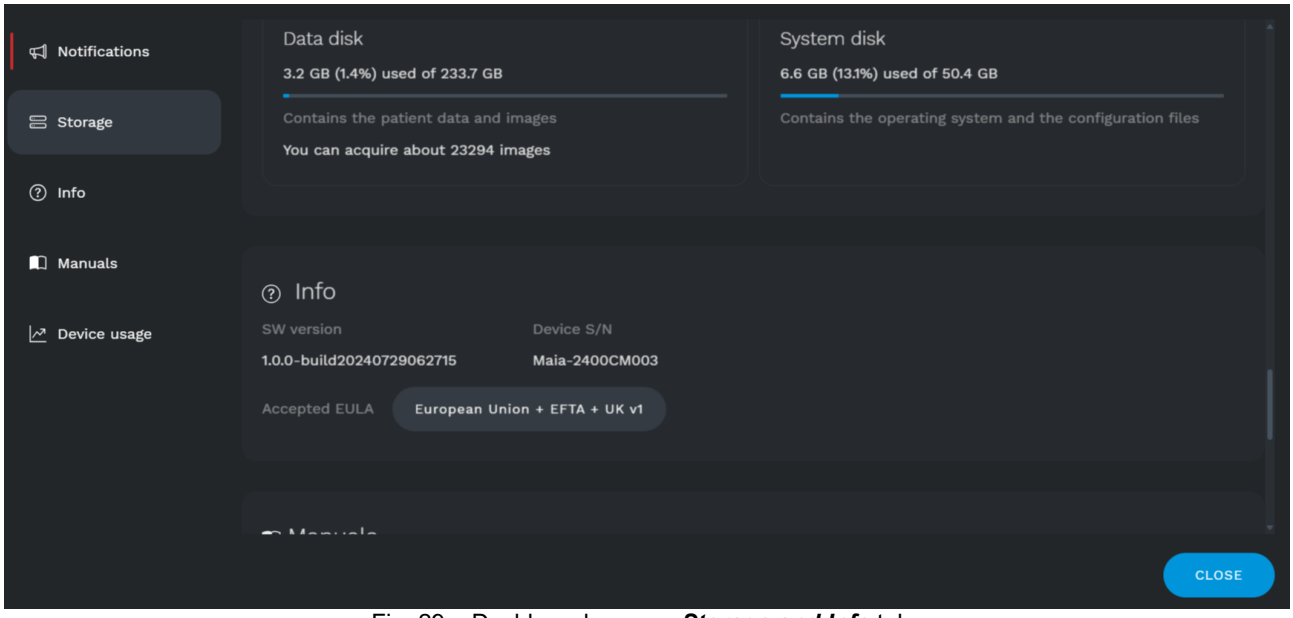


Fig. 29 – Dashboard screen: ***Storage and Info*** tabs

10.1.3 Info tab

The ***Info*** tab displays the following information:

- SW version installed;
- Device S/N (text and bar code);
- Accepted End User License Agreement (EULA).

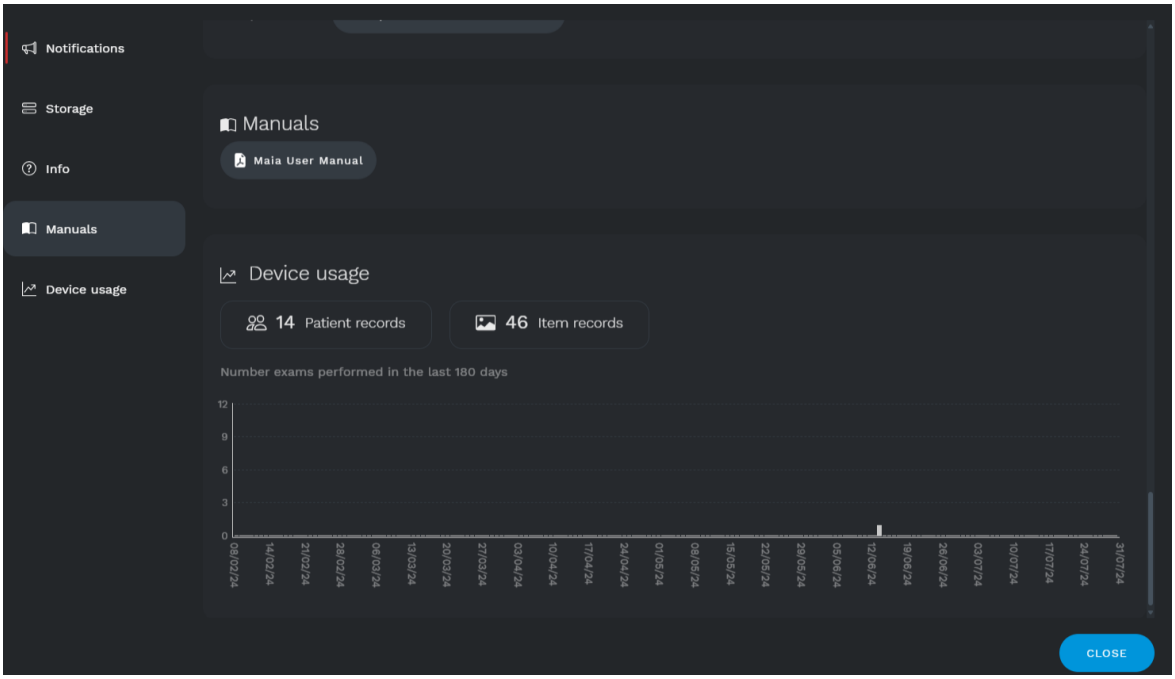


Fig. 30 - Dashboard screen: ***Manuals*** and ***Device Usage*** tabs

10.1.4 Manuals

Within the ***Manuals*** tab (

Fig. 30) the ***MAIA User Manual*** button allows to display these Instructions for Use, for the main usage in all supported languages, and for other installed licenses. Once the Instructions for Use are displayed, the ***Change Language*** button will display a list of the available languages: select the most suitable for your Country.

10.1.5 Device Usage tab

The ***Device Usage*** tab (

Fig. 30) provides statistics on the number of patients and exams stored in the internal database, and an histogram of the number of exams performed in the last 6 months, regrouped by week .

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. **31**). Type the surname, first name and select the date of birth (mandatory fields), optionally select the gender and type a unique code (Patient ID) of your choice. It is also possible to type free text in the Notes field. Then click **SAVE** to save or **Cancel** to abort.

If a patient with the same surname, 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.

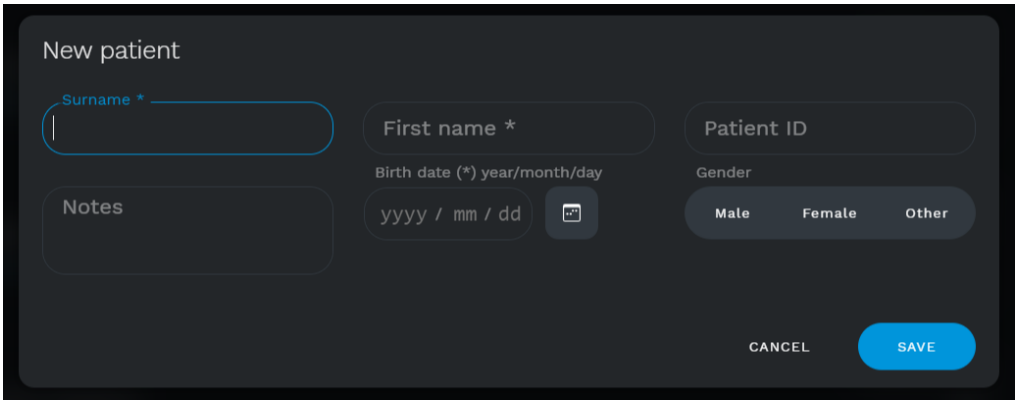


Fig. 31 – Patient editing screen

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 side 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 select the “Delete Patient” function available when pressing the 3 dots button beside the patient’s name in the Patient Record page of the desired patient (see Fig. 32) and confirm to delete it.

10.4 Searching for an existing patient

To search for an existing patient, click on the Search field and type a portion of the name, surname or code of the patient you are looking for: the list is automatically filtered as you type. Clicking on the symbol will reset the filtering. When the desired patient is shown in the list, click on it to select it.

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.

10.6 The Patient Record screen

Once a patient has been selected in any of the above ways, the **Patient Record** screen opens (see Fig. 32) 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, to delete the patient or to create a backup of the individual patient on a USB drive connected to the device (single patient backup).
On the left side of the screen the ***Visit List*** is shown, displaying each date in which exams for the selected patient are present.
On the central part of the screen all the exams of the selected patients are shown, in chronological order (newer exams first) and grouped by visit: the list can be scrolled by dragging it. Select any visit on the left to quickly jump to the exams taken on that date. Click on the desired exam to review it.
Long-press on any exam or press the button to select multiple exams to delete or export: a checkbox will appear next to each exam to allow to add or remove the exam to the selection; then, press the button to export the selected exams (see §12.6) or the button and confirm to delete them.
Note: it is not possible to delete a Root exam if it has one or more Follow-up exams associated with it.
On the right side of the screen the sequences of Perimetry exams are displayed, grouped by eye and by grid used. Click on a sequence to expand it as in Fig. 33: 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).

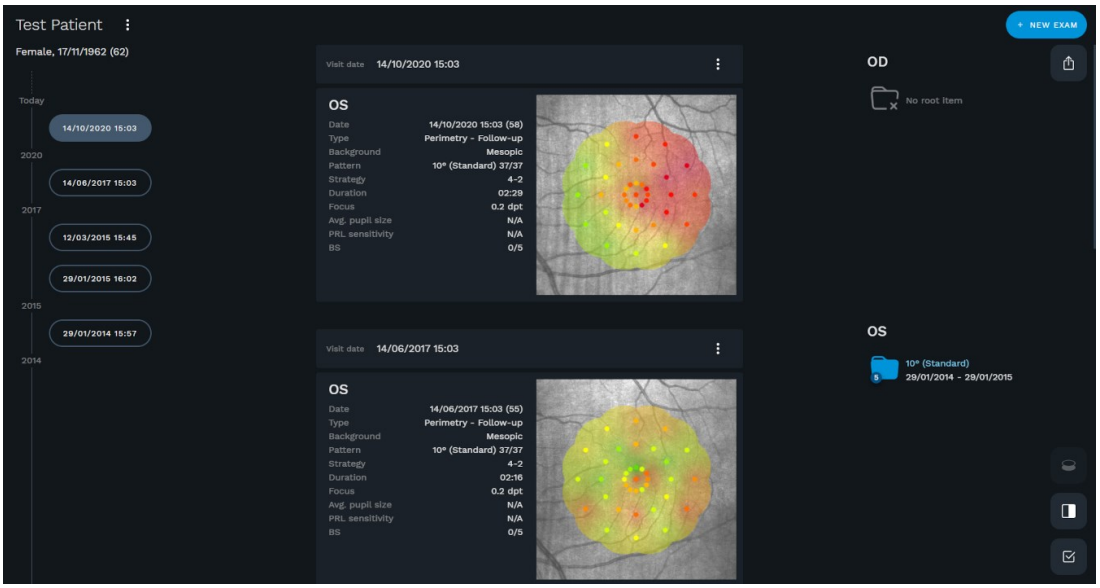


Fig. 32 – Patient Record screen

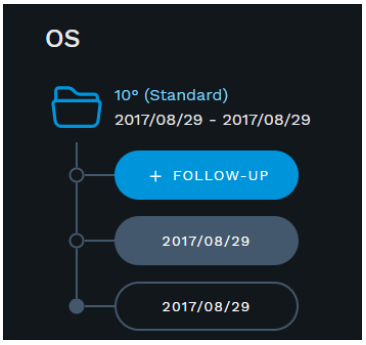


Fig. 33 – Exam sequence expanded

11 PERFORMING THE EXAM

This paragraph explains how to operate MAIA to perform the test (in these Instructions for Use the terms “test” and “exam” are used as synonyms).

11.1 MAIA test modalities

MAIA allows to measure a patient’s retinal sensitivity in time, hence creating a sequence of tests. It also provides a TrueColor confocal image of the retinal fundus (see below).

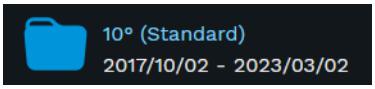
MAIA provides two different test modalities:

- a **Perimetry test** allows to determine the sensitivity thresholds for each location identified by the selected test grid, using the selected projection strategy. Perimetry 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 performed with the same strategy and the same test grid
- a **Fundus** test allows to acquire only the fundus color and/or infrared 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 MAIA:

- **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:**



11.2 Initiating a new Perimetry root test

To initiate a new **root** test, click on the **New Exam** button on the top right of the ***Patient Record*** screen (see Fig. 32). The ***Test Parameters selection*** screen will appear (see Fig. 34), which allows to configure the exam.

- select **Perimetry** using the ***Exam Mode*** selector
- select the eye to be tested using the ***Eye*** selector
- select the desired projection strategy using the ***Exam Type*** selector
- select the desired stimuli pattern (projection grid) among the ones displayed on the right
- tap **START** to start the exam

11.3 Initiating a Perimetry 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 **Perimetry** using the ***Exam Mode*** selector. Then, select the desired projection strategy using the ***Exam type*** selector. For a description of the exam flow of the SupraThreshold test, refer to §11.6.1.

11.5 Initiating a new Fundus test

To initiate a new **Fundus** test, click on the **New Exam** button, and select **Automatic Fundus** using the ***Exam Mode*** selector.
Then, select the desired imaging mode (among **Infrared, TrueColor** and **Infrared+TrueColor**) using the ***Imaging Modality*** selector. Only the Central field is available for Fundus imaging.
For a description of the exam flow of the Fundus tests, refer to §11.16.

11.6 Choosing test parameters

When the **New Exam** command is pressed the **Test parameters selection** screen opens (see Fig. 34), allowing review and modification of the test parameters.
The following commands / options are available:

1. **Exam mode** selection: ***Perimetry / Automatic Fundus***
2. **Eye** selection: ***OD (right eye) / OS (left eye) / OU (both eyes)***
3. In case of Perimetry exam:
   - **3a. Exam Type** selection: 4-2 / 4 Levels Fixed / Scotoma Finder / Fixation Only / Custom strategy (optional – see §18.11)

   In case of Fundus exam:
   - **3b. Imaging Modality** selection: Infrared / TrueColor / Both
4. Live display of the pupil cameras for auto-alignment
5. Chin-rest height adjustment
6. For perimetric tests only, selection of the test grid (or pattern); groups are divided into Standard and Custom (created by the user or imported, see §18.10). The grid can also be changed before starting the stimuli projection (see §11.10)
7. Test start: starts the exam
8. Back to Patient Record screen

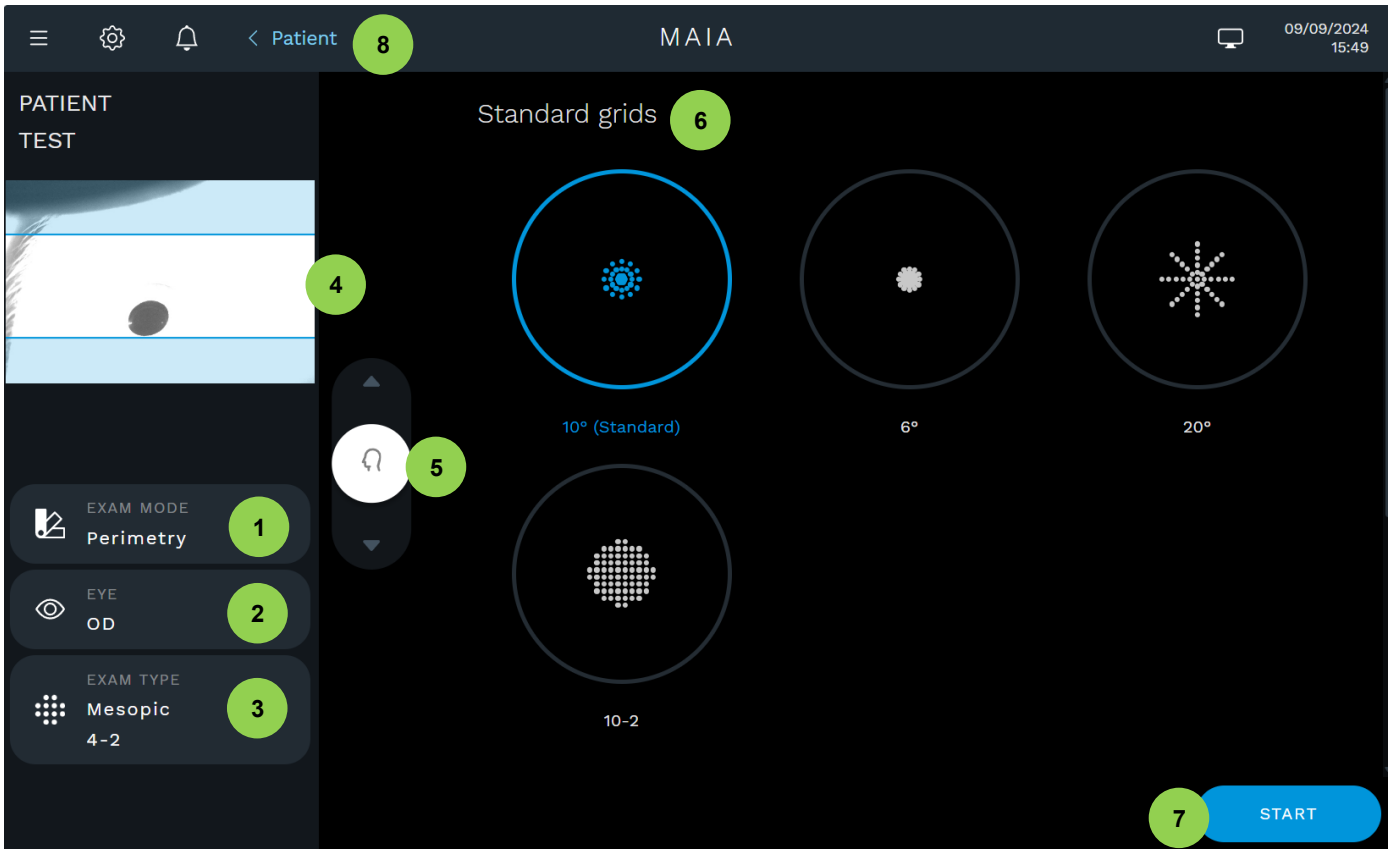


Fig. 34 – Test parameters selection screen

The following perimetric parameters are used and cannot be modified:

- background luminance: 4 asb
- maximum luminance (0 dB): 1000 asb
- stimulus duration: 200 ms
- stimulus size: Goldmann III
- fixation target for foveal stimulus: 2 red circles in vertical configuration
- fixation target for non-foveal stimuli: single red circle

11.6.1 Exam strategies: “4-2” (Full Threshold)

The 4-2 staircase projection is a full-threshold strategy used to measure retinal sensitivity. It involves presenting light stimuli of varying intensities to the retina and adjusting the intensity based on the patient's responses. Here's a brief explanation of how it works:

1. **Initial Stimulus**: The test begins with a light stimulus of a defined intensity.
2. **4 dB step phase**: If the patient sees the stimulus, the intensity is decreased by 4 dB. If the patient does not see the light, the intensity is increased by 4 dB. This process keeps repeating until the response changes (from seen to not-seen, or vice-versa)
3. **2 dB step phase**: Now the intensity increases by 2 dB if the patient does not see the stimulus, and decreases by 2 dB if the patient sees the stimulus. This process keeps repeating until the response changes again (from seen to not-seen, or vice-versa)
4. **Threshold determination:** the resulting sensitivity threshold is defined as the last intensity seen by the patient. If in any step the patient is not able to see the highest intensity (0 dB), the resulting threshold will be “<0” (which means: 0 dB not seen).

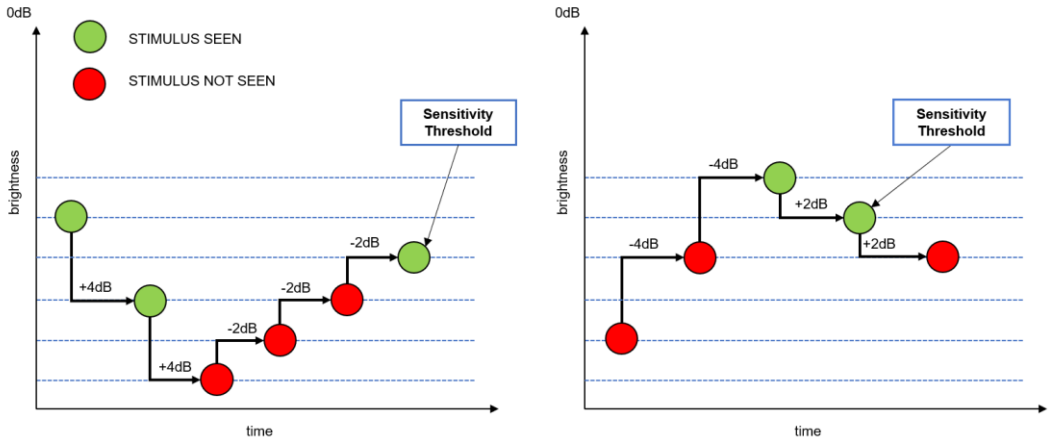


Fig. 35 – “4-2” strategy projection logic

11.6.2 Exam strategies: 4 Levels Fixed and Scotoma Finder

These tests are **SupraThreshold** tests and 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 a limited number of intensities are tested (depending on the selected strategy): 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 intensity 1*”, “*seen at intensity 2*”, “*not seen at highest intensity*”, etc. (see Fig. 36). All SupraThreshold strategies are designed to quickly determine a rough range of retinal sensitivity for each location, without determining the actual threshold.

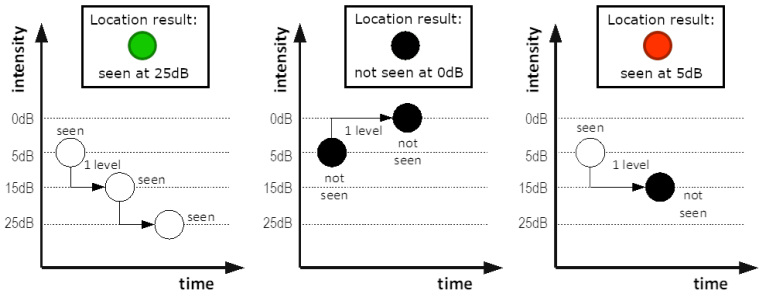


Fig. 36 – 4 Levels Fixed strategy projection logic

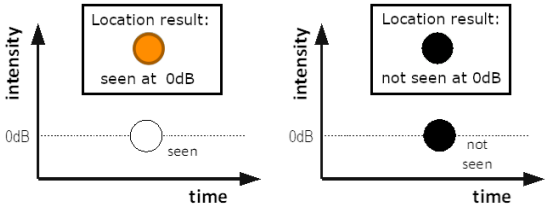


Fig. 37 – Scotoma Finder strategy projection logic

The **SupraThreshold** tests use the following intensities:

- ***4 Levels Fixed***: 0, 5, 15, 25dB

- ***Scotoma Finder***: 0dB only

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 (i.e., start an exam and with any grid and stop it once the patient has got acquainted to the test) on patients that never had a perimetry test before.

11.8 During the test

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

#	STEP	PURPOSE	INSTRUCTIONS
1	Auto-alignment	Align instrument with patient's eye	The patient should not move and should look for the red fixation target. For additional details, see next paragraph.
2	Auto-focus	Correct for patient's spherical refraction	The patient should refrain from blinking and should look at the fixation target.
3	Fixation target selection	Select the Fixation target to be used during the exam	Some patients with specific retinal damage or with eccentric PRL might have difficulties fixating the fixation target. MAIA can switch on several patterns of fixation targets to help the patient identify them, and allow the operator to select the most suitable one for the patient. The patient should try to identify the Fixation targets and follow the instructions of the operator, communicating whether she/he is able to detect the targets or not. Refer to §11.9 for further details.
4a	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 **Retake** button on the bottom right corner of the screen to retake the reference image if its quality is not satisfactory (see for example Fig. 38). ⚠: **a poor-quality reference image may compromise the test, increase its duration, prevent retinal tracking or make follow-up testing impossible.**
4b	Matching with baseline (Follow-up exams only)	Check and confirm IR image matching with the baseline exam's one	*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 **Retake** button on the bottom right corner of the screen to retake the reference image if its quality is not satisfactory (see for example Fig. 38). A preview of the automatic registration of the follow-up image over the baseline one is displayed for check. In case of an inaccurate matching, the image can be retaken or it is possible to adjust the registration manually (see §11.11).* ⚠***: an inaccurate registration between the follow-up and the baseline exam IR images will result in different locations being tested, with consequent inaccurate monitoring of the progression of the sensitivity.***
5	Blind spot location	Identify location of the blind spot	Drag and place the circle over the optic nerve head (ONH) disc, then click on the **Continue** button to proceed (see Fig. 39). This step will not take place in follow-up tests because the information of the ONH is automatically derived from the baseline exam. ⚠**: a wrong or inaccurate placement of the optic disc marker results in an unreliable exam due to high values of the BS index (see §12.1.1)**
6	PRL acquisition	Locate the Preferred Retinal Locus (PRL), i.e. the center of fixation	The patient should look steadily at fixation target. ℹ: once this step is completed the system will stop and wait for confirmation: click the **Continue** button to proceed with next step

#	STEP	PURPOSE	INSTRUCTIONS
7	Grid editing	Change, move or edit the projection grid	This step is optional. After examining the acquired IR image, the operator might be interested in choosing a different grid, moving it over a specific area to be tested, or to add or delete some of the tested points. Refer to §11.10 for further details. This step will not take place in follow-up tests because the projection grid will be exactly the same used in the baseline test, and the same exact locations will be tested. While the operator edits the grid, the patient can move away from the chinrest and get some rest.
8	PRL sensitivity	Measure sensitivity at the PRL	The patient should look between the 2 red dots and press the button when she/he is able to perceive 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 the **Continue** button to proceed with the next step
9	Grid projection	Measure sensitivity at all grid locations using the selected fixation target	The patient should look steadily at the red 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 the **Continue** button to proceed with the next step
10	Color image	Capture color photo of posterior pole	The patient should refrain from blinking and should look at the red fixation dot until a light is flashed. 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 Manual mode will be enabled in the Image Registration interface, and it will be possible to manually adjust the position and rotation parameters to achieve a better matching. Once the image registration is satisfying, click on the **CONTINUE** button to finish the exam and store its results. If the **STOP EXAM** button is pressed at this step, the exam will be stored without the TrueColor image. ⓘ: click on the **RETAKE** button on the bottom right corner to retake the image if of poor quality or in case of a failed registration.

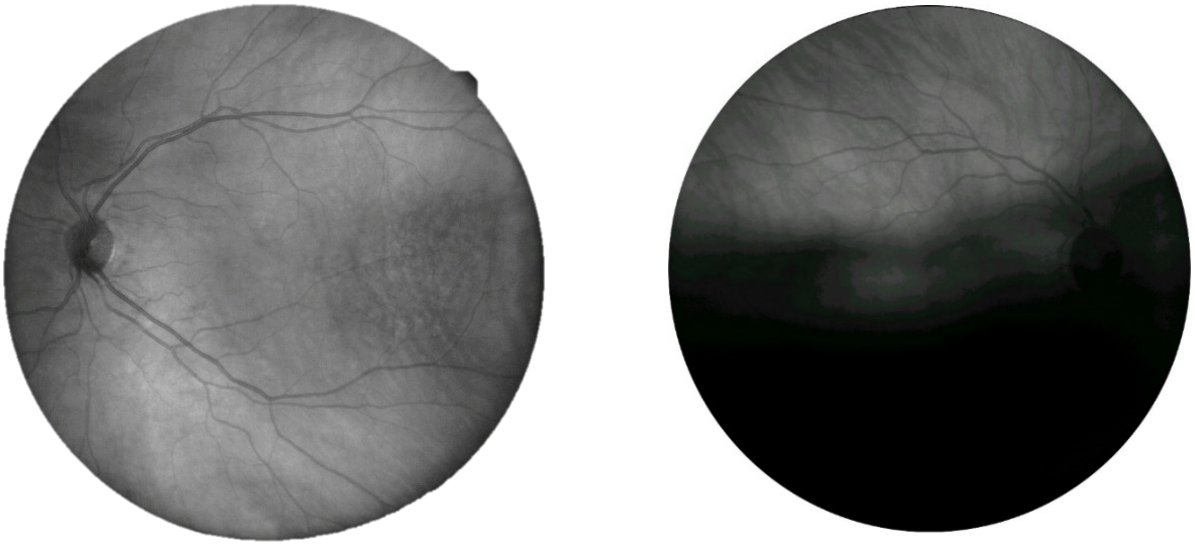


Fig. 38 – Good (left) and poor quality (right) reference image

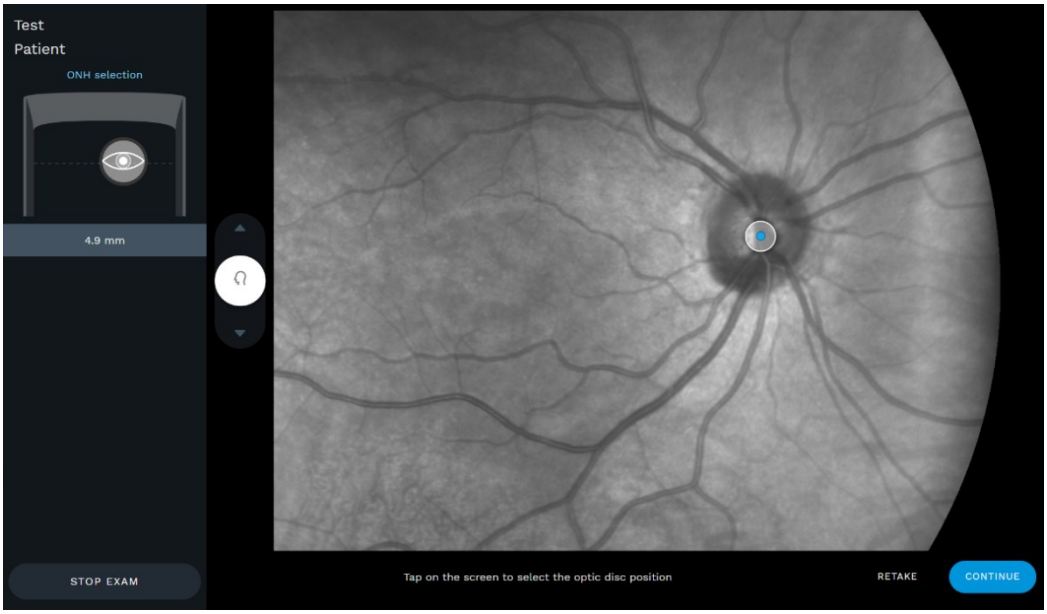


Fig. 39 – Marker for optic disc location in Exam screen

11.9 Fixation target selection

MAIA provides the possibility to change the fixation target position, in a 5x5 grid separated by approx. 2.4° (see Fig. 40). In cases of large central scotoma, patients may have difficulties to see the central fixation target; in such cases, the operator may choose to select an eccentric target. Tapping over any of the red circles allows to toggle that target.

The lightbulb icon on the top-right corner indicates the intensity of the fixation target. The arrows can be used to adjust the level. The buttons on the right allow to switch on pre-selected patterns of targets (single target, cross, all targets).

The operator can switch on multiple targets at once to help the patients identify them, but before proceeding only one fixation target can be switched on.

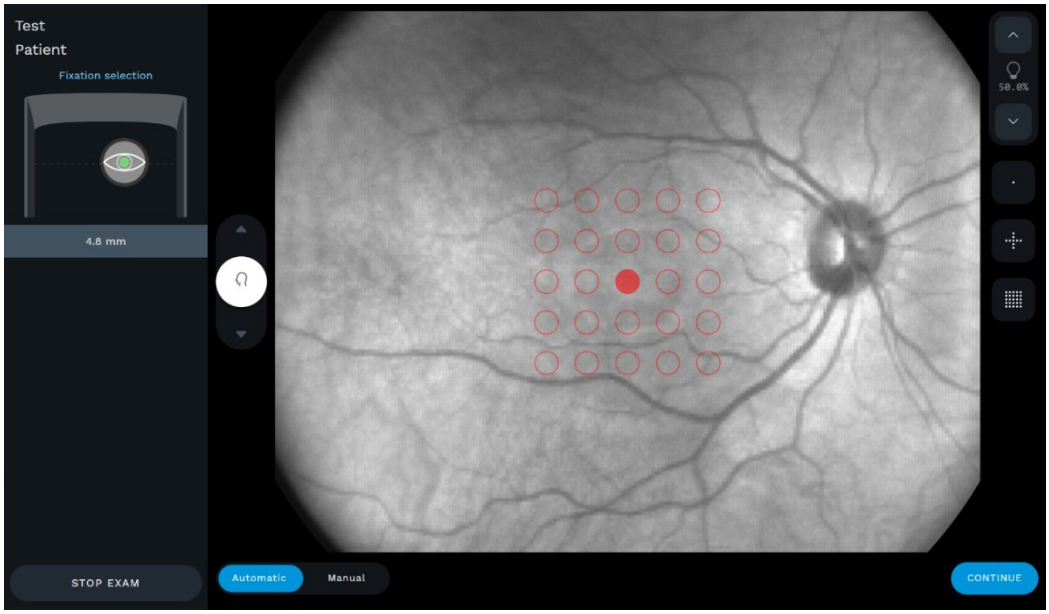


Fig. 40 – Fixation target selection interface

The fixation target choice has no direct impact on the microperimetry test results. The only impact is related to the resulting position of the retina (and of the optic disc) on the exam images.

11.10 Grid editing

Once the IR image is acquired and before starting the test, it is possible to change or customize the stimuli pattern (grid) to be projected (see Fig. 41). A preview of where the grid is expected to be projected is displayed. Using the available commands, it is possible to select a different grid, edit it or create an eye-specific pattern to measure the sensitivity of desired areas.

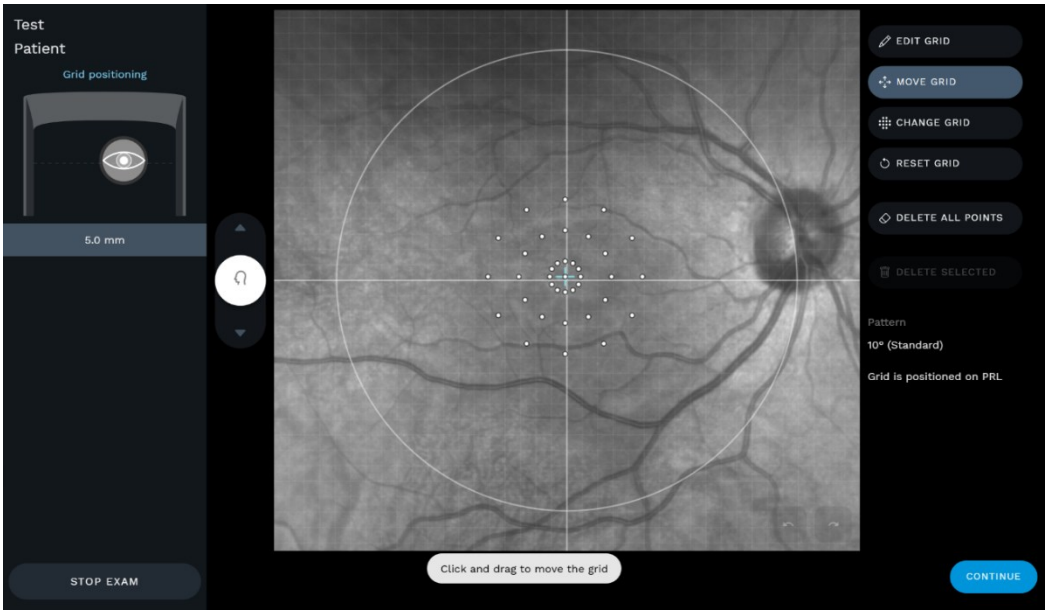


Fig. 41 – Grid editing interface

	The white circle displayed in Fig. 34 represents the limit of the projection field (15° of diameter). Adding and dragging the stimuli or the entire grid is limited by this circle, so that it is not possible to place or drag any point outside of it. If, looking at the image, the operator is interested in testing locations outside the circle, it is necessary to use a different fixation target (see §11.9) to shift the retinal image and have the desired area to be tested fall inside the projection field circle.

The available commands and information are:

Info: displays the name of the selected grid.	Pattern 10° (Standard)
Allows to change the selected grid, among those available (see Fig. 34).	CHANGE GRID
Info: tells where the grid will be positioned. In detail: - If the grid was moved or edited, it will be positioned where it is currently displayed over the retinal image - If the grid was not altered in any way, it will be centered on the PRL	Grid has been moved or Grid is positioned on PRL
Enables ***Moving*** mode: allows to position the grid by dragging it where desired on the retinal image. The positioning range is limited by the projection field, so that none of the stimuli can fall outside the projection field circle displayed.	MOVE GRID
Allows to reset the grid to its initial state: - all actions like moving/adding/deleting stimuli are canceled - the positioning turns back to “being centered on the PRL”.	RESET GRID
Enables ***Editing*** mode, which allows to: - add more stimuli where desired by tapping directly on the retinal image - select any stimulus (pre-existing or added) to be dragged where desired, or deleted with the “Delete selected” button	EDIT GRID
In ***Editing*** mode, deletes the currently selected point from the grid.	DELETE SELECTED
Deletes all points in the grid, allowing to create a fully custom grid over the retinal image.	DELETE ALL POINTS

11.11 Image registration

This step is used to register the TrueColor image over the IR image, or to register the Follow-up IR image over the Baseline IR image.

Once the image is acquired, MAIA will automatically try to match (register) the follow-up image with the baseline exam's one, by determining its rotation, scaling and shift parameters. Then, a preview of the registration is displayed using a 3x3 checkboard overlapping portions of the follow-up image over the baseline one, allowing to evaluate the outcome of the registration (see Fig. 42). On the top-right, an automatic evaluation of the registration is displayed (***Automatic registration successful*** or ***Registration below threshold***).

The **Flickering OFF/ON** button on the bottom allows to alternate hiding and showing the overlapping image. In case of a bad quality image (due to blinking, image darkness or bad focusing), the **RETAKE** button allows to acquire a new one and retry the matching.

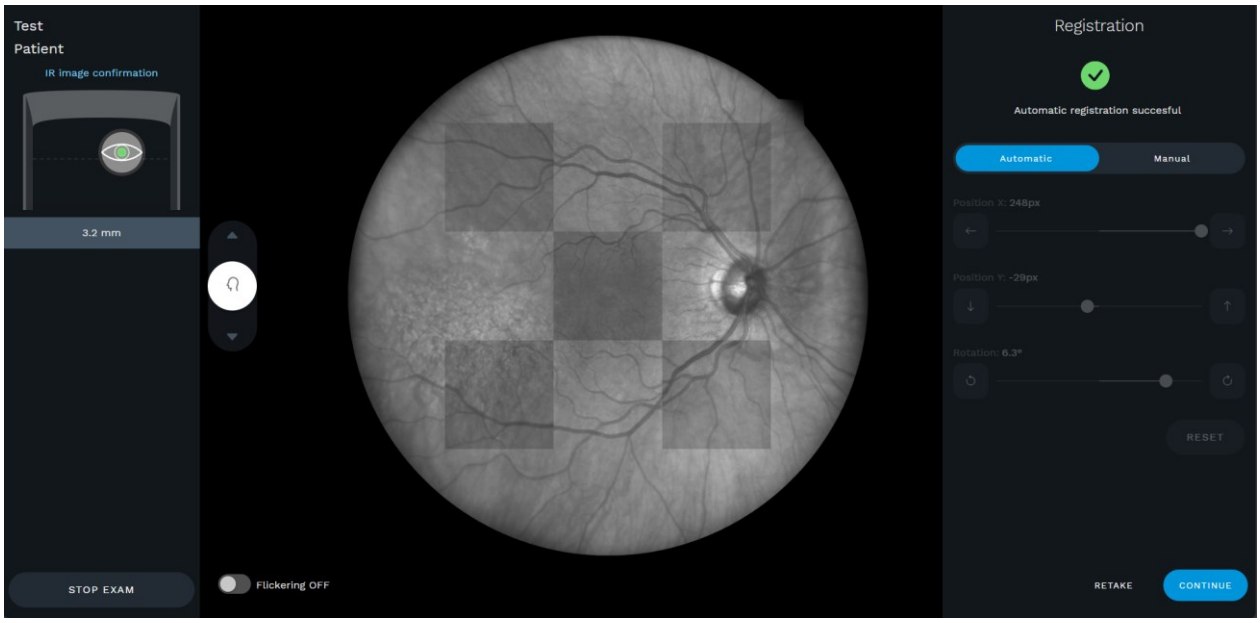


Fig. 42 - Automatic registration of the follow-up image over the baseline

Since the retina can undergo relevant changes in time due to the progression of diseases, the automatic registration might end up not being accurate enough. This could also happen when performing follow-up of exams taken with previous MAIA models, due to the different imaging technology. In such cases, the Manual button allows to switch to a manual matching phase (see Fig. 43), where it is possible to manually adjust the parameters determined by the automatic registration and obtain a better overlapping of the images.

Each parameter can be adjusted either using the related slider, or fine-tuned with the buttons located beside it: the registration preview will be updated live whenever a parameter is changed, but the evaluation message will not.

When the operator is satisfied with the registration, the exam can proceed pressing the **CONTINUE** button.

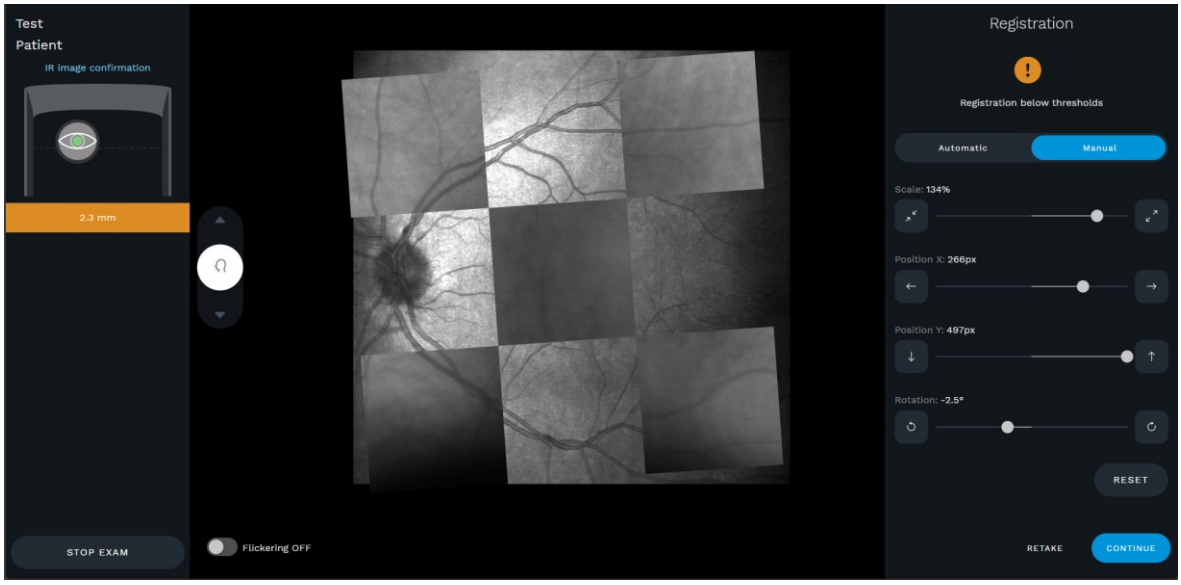


Fig. 43 - Manual registration of the follow-up image over a baseline exam acquired with a previous MAIA model

The outcome of the Registration step is stored within the exam parameters, and can have the following values:

- Automatic, if the Automatic registration was successful
- Auto (below threshold), if the Automatic registration was below threshold but the user proceeded without adjusting the detected parameters
- Manual, if the user needed to adjust the parameters manually

Due to the different imaging technology, the Scale parameter for the manual registration is only available when performing a follow-up of a baseline exam acquired with a previous model of MAIA.

An inaccurate registration between the follow-up and the baseline exam IR images will result in different locations being tested, with consequent inaccurate monitoring of the progression of the sensitivity.

11.12 Auto-alignment

Several hints may be presented on screen by the system to help the end user correct a patient's position: see Table 1 below.

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 the forehead rest

Table 1 – System hints during auto-alignment

The graphical representation in the upper left of the screen shows the alignment status. If the pupil is green (like in Fig. 44), the eye has been identified and aligned correctly; if it is white, the alignment is in progress. In case of difficulty finding the pupil, reposition the patient acting on the chinrest. It is possible to check the pupil cameras' live stream by tapping on the alignment graphical representation (see Fig. 44).

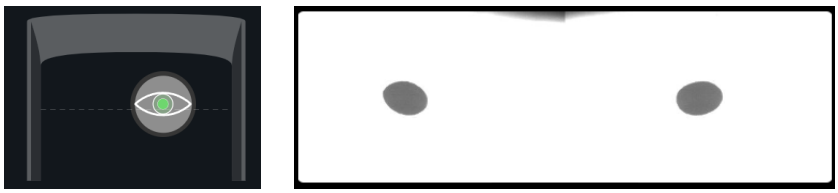


Fig. 44 – Alignment graphical representation with the eye aligned (left) and pupil cameras' live stream (right)

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

11.13 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 Perimetry results.

Regular operation of the eye tracking is indicated by a GREEN “Tracking OK” label next to the stabilized retinal image (see Fig. 45). **A RED “Tracking Unreliable” label 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.

11.14 Monitoring the stimuli projection

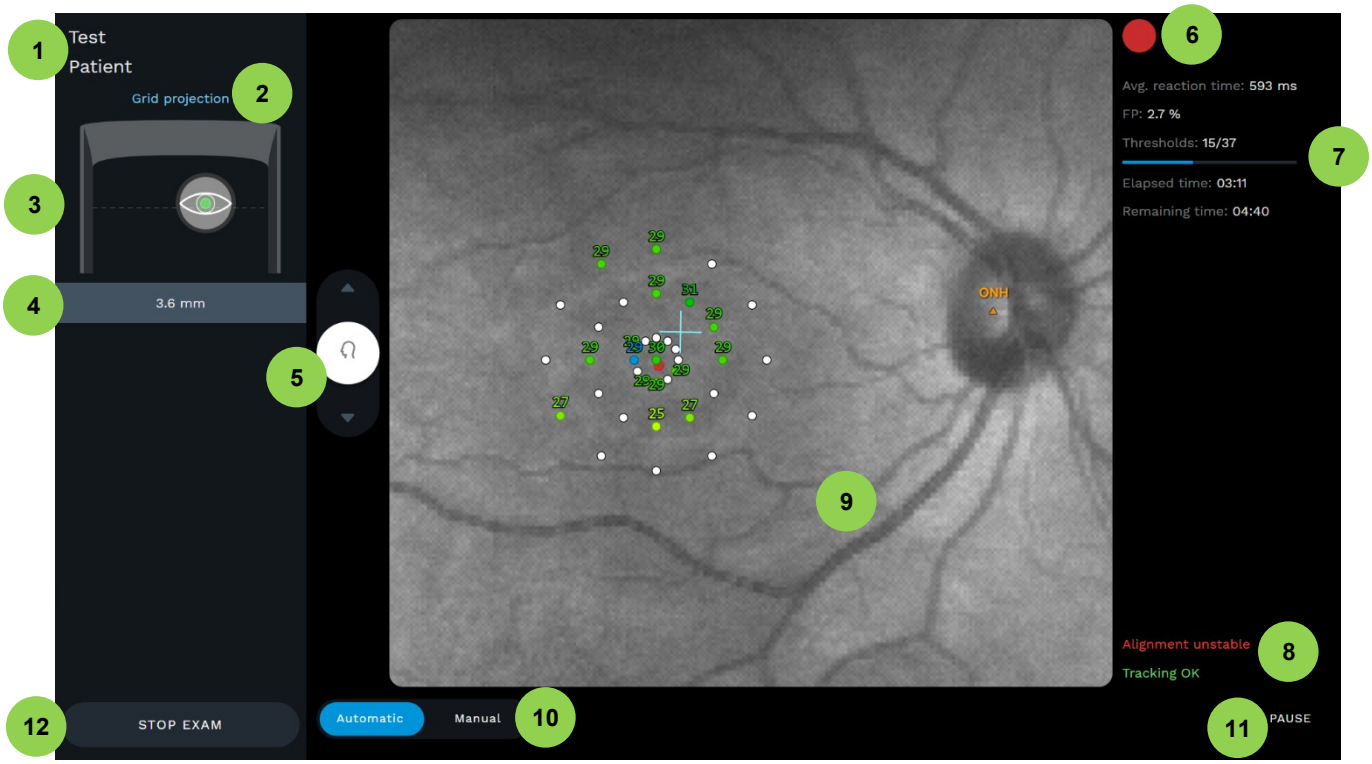


Fig. 45 – Exam screen while the test is in progress

The following information and functions are available during the exam:

1. Patient full name
2. Exam stage (for example, Aligning and Focusing, PRL acquisition, Grid projection…)
3. Auto-alignment indicator: the eye symbol moves according to the detected position of the eye. The pupil inside the symbol is white while the head is trying to reach the eye, and will turn green when the eye is correctly aligned. Tapping on this indicator will switch the visualization to the live stream coming from the pupil alignment cameras
4. Live estimation 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. If the eye cannot be detected, this frame turns red and the measurement is replaced by an “Eye not found” message
5. Buttons to adjust the height of the chinrest.
6. Pushbutton status: red if it is not pressed, turns green when pressed, orange in case of random pressure (false positive)
7. Exam parameters, updated live during the exam, such as Average reaction time, FP index, FN index (if enabled), BS index, number of measured thresholds over the total stimuli of the grid, Elapsed time, estimated Remaining time to the end of the exam
8. Live status of the Auto-alignment and Retinal Tracking
9. Live stabilized retinal image (i.e. shifted using the information coming from the eye-tracking) with stimuli allows the operator to monitor progress. The image can be panned and zoomed by dragging and pinching it. The center of the blue cross displayed on the stabilized image represents the current fixation point (the point of the retina which is aligned with the center of the fixation target at every moment). An orange triangle with the ONH label indicates the position of the selected ONH marker. Completed stimuli are displayed with the color representing their measured threshold, which is also displayed as a label next to them. The stimulus being projected is displayed in blue color, with the tested intensity also displayed as a label next to it. All the other stimuli (not yet finalized) of the grid are displayed as white circles.
10. Buttons to switch from Automatic to Manual alignment
11. Button that allows to pause the test at any time, in case the patient is tired. Pausing the exam will suspend the tracking, and pause the Elapsed Time counter (and consequently, the exam duration)
12. Button that allows to stop the exam: the exam will be saved as a partial test, containing the data of the completed stimuli only

Patients with little experience of MAIA 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.

The projection sequence is randomized, so that the patient does not know where to expect each stimulus to be presented.

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

11.15 Projection System check

MAIA is equipped with an automatic tool to verify the correct functioning of the Projection System.

An automatic check of the Projection System is performed at the device startup and at the end of each Perimetry exam, to verify the positioning of the stimulus before and after the test. In case an anomaly is detected, the device attempts to solve it by re-initializing the Projection system and checks it again.

If the anomaly is solved, the warning in Fig. 46 is displayed, and the exam is flagged as “Projection System unreliable” to keep track of the event.

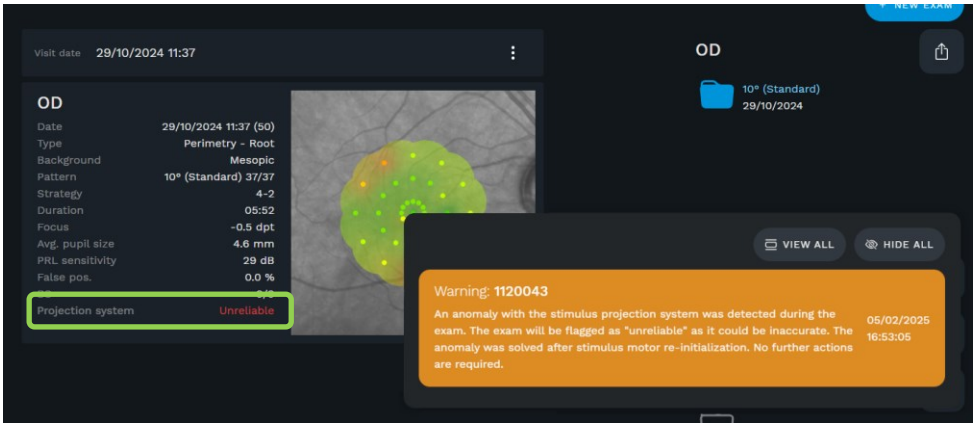


Fig. 46 – Projection System warning in case of a solved anomaly (right), and Unreliable flag for the exam (left)

If the anomaly cannot be solved with the re-initialization, the exam is still flagged as “Projection System unreliable” and the warning in Fig. 47 is displayed, suggesting to contact an Authorized Service Representative as the device is not able to self-recover. The same message is displayed if this condition is met at the device startup.

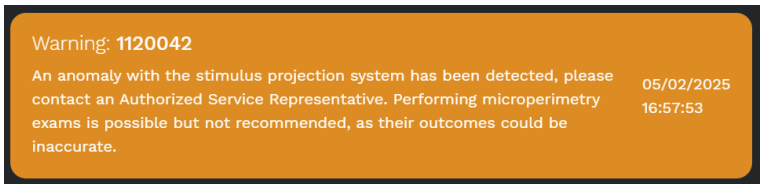


Fig. 47 – Projection System warning in case of an unsolved anomaly

If the Projection System is in an unrecoverable anomaly state, when the user attempts to start a new Perimetry exam the message in Fig. 48 will show up, warning that the positioning of the stimuli might be inaccurate and asking for confirmation to proceed: the CLOSE button will cancel the exam start, while the CONTINUE button allows to proceed anyway and start the test.

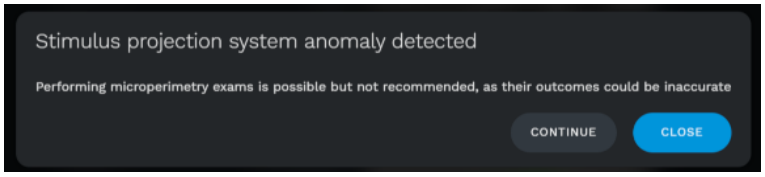


Fig. 48 – Warning message when attempting to start an exam in case of an unsolved anomaly of the Projection System

In all of these cases, it is possible to have a visual check of the status of the Projection System, by accessing the Maintenance menu in the settings (see §17.4.4).

11.16 Other exam types: FUNDUS test

The **Fundus** test allows to acquire photos of the Central field of the retinal fundus, in TrueColor or Infrared or both. 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 Perimetry, to provide an image of the central field of the retina.

If the Infrared+TrueColor option is selected, the two images are acquired in sequence and will be stored as two different exams (see Fig. 49).

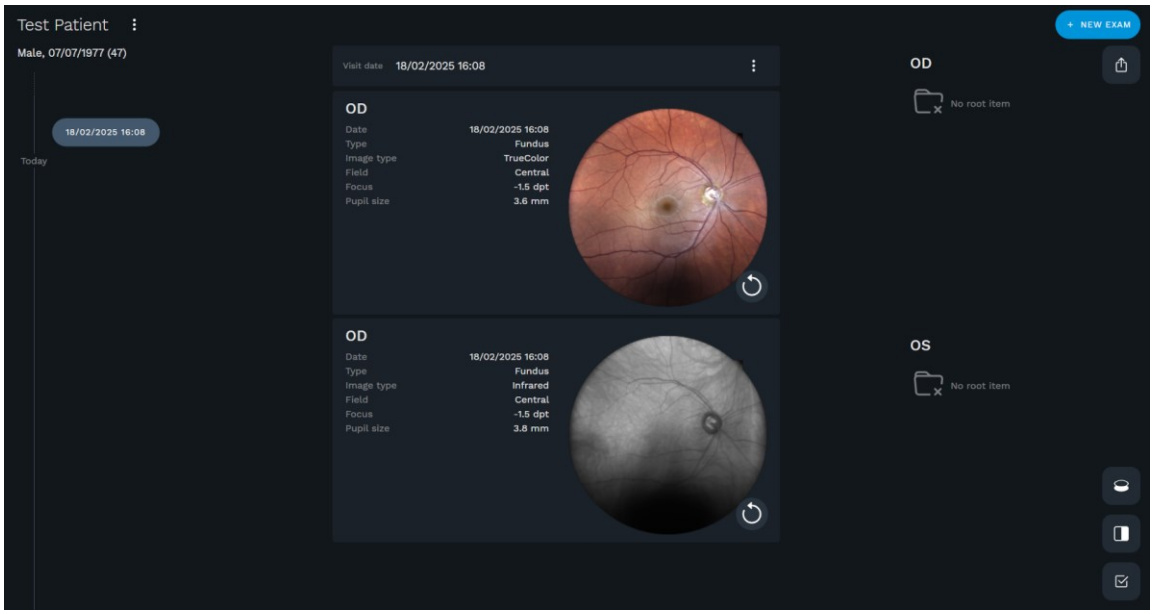


Fig. 49 – Patient Record screen, after acquiring an Infrared+TrueColor exam

11.16.1 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. 50): the device will acquire a new image and then the dialog in Fig. 51 will appear, allowing to compare the old and the new image and to decide whether to retake the image again, keep the old photo, replace it with the new one, or keep both (see Fig. 51).

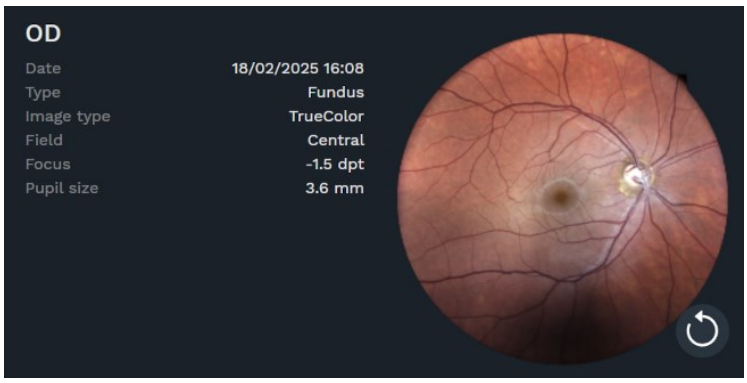


Fig. 50 – Fundus exam, with the retake button available

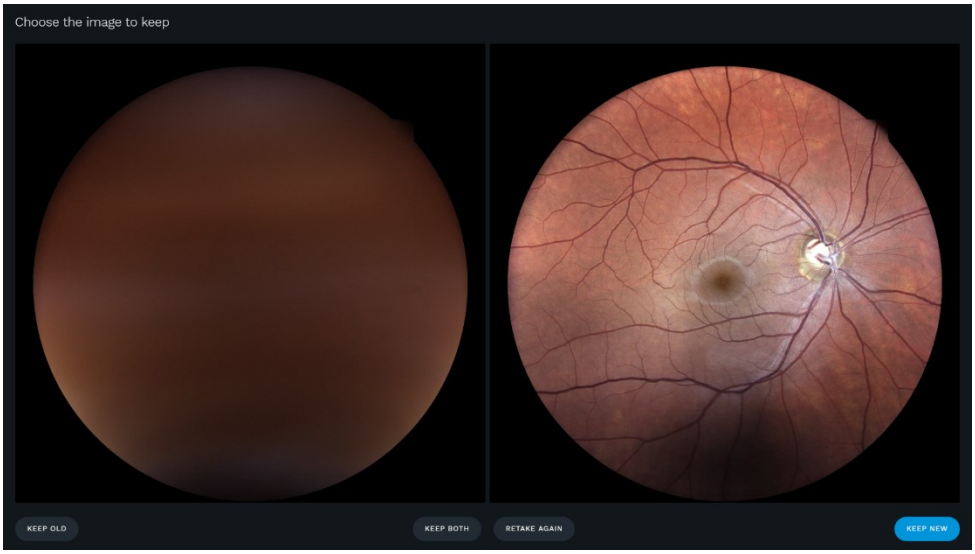


Fig. 51 – Image Retake: choosing which image(s) to keep

12 REVIEWING RESULTS

Once a test is completed, the system will open the **Patient Record** screen (Fig. 32) for the selected patient and display a thumbnail view (Fig. 52) of all exams taken on the selected date. Press on the desired exam's thumbnail to open the **Test Results Review** screen (see §12.1 and §12.3).

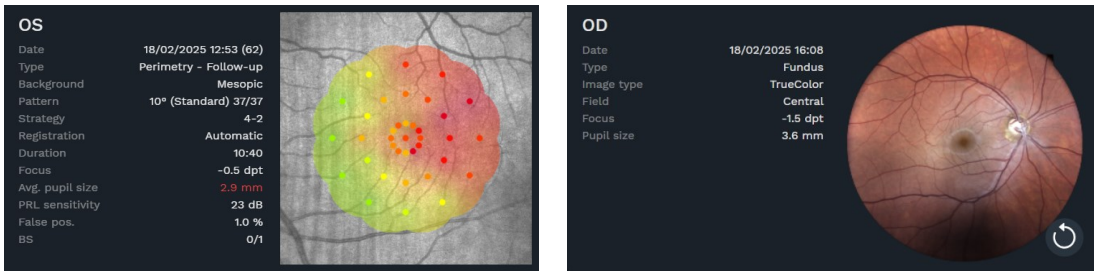


Fig. 52 – Example of thumbnails for **Perimetry** (left) and **Fundus** (right) exams

The **Perimetry** exam thumbnail provides the following information:

- Examined eye (**OD** / **OS**);
- Date and time the test was performed, and patient's age at that time;
- Type (**Root** / **Follow-up**);
- Pattern used and number of test locations actually completed;
- Projection Strategy (**4-2, 4 Levels Fixed, Scotoma Finder, custom**);
- Registration outcome of the TrueColor image (**Automatic, Auto below threshold, Manual**) (see §11.11)
- Duration (minutes: seconds);
- Focus index;
- Average pupil size during test;
- False Positives index (FP);
- False Negatives index (FN);
- Blind Spot index (BS);
- Infrared retinal image with overlaid test locations and interpolated color map;

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

- Examined eye (**OD** / **OS**);
- Date and time the test was performed;
- Type (**Fundus**);
- Image Type (**TrueColor** / **Infrared**);
- Field (only **Central** is available)
- Focus index;
- Pupil size at time of shooting;
- Thumbnail of the retinal image;

If the exam was taken in the current day, the button that allows to retake the photo (see §11.16.1).

12.1 Perimetry test results review

The **Exam Review** screen (Fig. 53) provides the following information and functions:

1. Patient name, gender and date of birth
2. Test strategy
3. Selector for image modality to be displayed (**TrueColor, Infrared, Red-free**) (NB: exams imported from previous MAIA Editions only provide Infrared image)
4. Selector for the Fixation points representation: ***All fixation points***, ***Filtered fixation points*** (i.e., points acquired only during stimuli presentations), ***None***
5. Buttons to enable different layers to be displayed over the retinal image: ***Fixation target, PRLs, Stimuli, Threshold values, Interpolated map***
6. Perimetric test parameters
7. Scrollable and zoomable retinal image, overlayed with the layers activated using the buttons listed at point 5. Clicking on the image opens the Image Review screen (see §12.3)
8. Average Threshold slider. The slider might be color-coded if the exam is imported from a previous MAIA Edition device. For exams taken with MAIA 2025 edition, the slider is grayed since no normative database is currently available
9. The button to open the Time Analysis interface for the sequence of exams that the current exam belongs to (see §12.5)
10. The histogram chart of the measured Thresholds
11. Percent Reduced Thresholds slider, if available. The slider might be color-coded if the exam is imported from a previous MAIA Edition device. For exams taken with MAIA 2025 edition, the slider is grayed since no normative database is currently available
12. Fixation Stability slider
13. Bivariate Contour Ellipse Area values and Fixation Graph (see §12.1.2)
14. Exams of the same Baseline-FollowUp sequence represented on a chronological timeline, to quickly jump to the review of other exams
15. Button to start a new Follow-up exam within the current sequence
16. Button to export the exam (see §12.6)
17. Command to go back to the Patient record screen

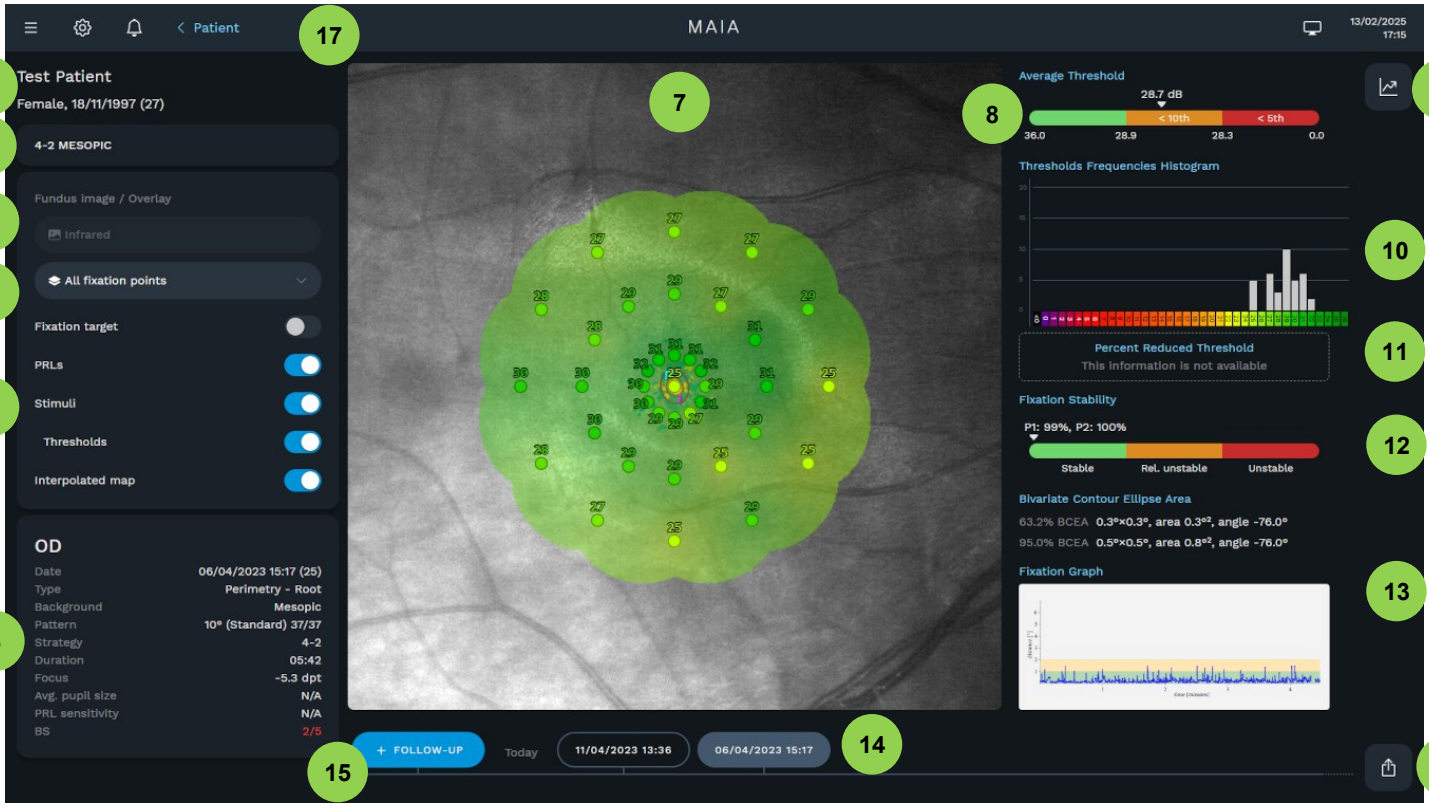


Fig. 53 – Exam review screen

12.1.1 Reliability Indices

MAIA provides standard methods to assess the reliability of a patient in performing the Perimetry test:

- **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. This test is disabled by default and can be disabled within the settings (see §18.5.2).
- **False Positives (False pos.)**: 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.
- **False Negatives (False neg.)**: this value represents the occurrences in which the patient did not press the pushbutton when a stimulus 10 dB higher than the determined threshold had been projected on a specific location, and therefore he was expected to respond. This test is disabled by default and can be enabled within the settings (see §18.5.2).

MAIA displays the Reliability Indices in red when they exceed 25%. This is an arbitrarily set value: each professional can independently decide the threshold beyond which an exam should be considered unreliable, or evaluate it on a case-by-case basis.

MAIA 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.

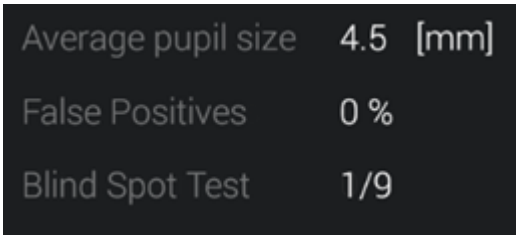
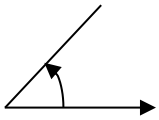


Fig. 54 – Detail of Exam review screen with reliability indices

12.1.2 Fixation Analysis

MAIA exploits the data collected by its retinal tracker to provide indexes that allow to assess the patient's fixation stability. At 25 Hz, the retinal tracker allows to determine the "fixation point", that is, the point of the retina that at a certain moment is aligned with the center of the fixation target, and which is therefore the point used by the patient to fixate at that specific moment. The analysis of all collected fixation points results in the following output indexes and data:

- **PRL-i** (initial) and **PRL-f** (final): the PRL (Preferred Retinal Locus) is the statistical point used by the patient in a given period of time to fixate, calculated as the average of the fixation points collected during that period of time. The PRL-i marker represents the PRL calculated in the first 10 seconds of the exam and used to center the grid in a Root test (unless the Move Grid option is used); the PRL-f marker, instead, represents the PRL calculated during the rest of the exam, during the stimuli projection phase;
- **P1** and **P2**: these indexes represent the percentage of fixation points collected during the stimuli projection phase that are included within 1° and 2° of distance from the PRL-f, respectively. The slider displays the marker in the Stable range if P1 is 75% or higher, in the Relatively Unstable range if P1 is lower than 75% and P2 is 75% or higher, and in the Unstable range if both values are below 75%
- **BCEA (Bivariate Contour Ellipse Area):** the 63% and 95% BCEA represent the ellipses describing the statistical distribution of 63% and 95% of all fixation points, respectively. The ellipses are described as the size of their semiaxes (in retinal degrees), their area (in squared retinal degrees) and the angle between the major axis and the horizontal axis (measured counter-clockwise, as in figure below)



- **Fixation graph**: this chart plots the absolute distance between each collected fixation point and the PRL-f, over time. It is useful both to assess the patient's fixation stability (together with the above other indexes) and to check how it changes with time/fatigue

Fixation graph
Differently from non-retinal tracked perimeters, MAIA fixation plot shown in a test report (see §14.1 and Fig. 55 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 §11.13), but these movements are considered and compensated at the time of projection of the stimuli, therefore they do not necessarily degrade a test reliability.

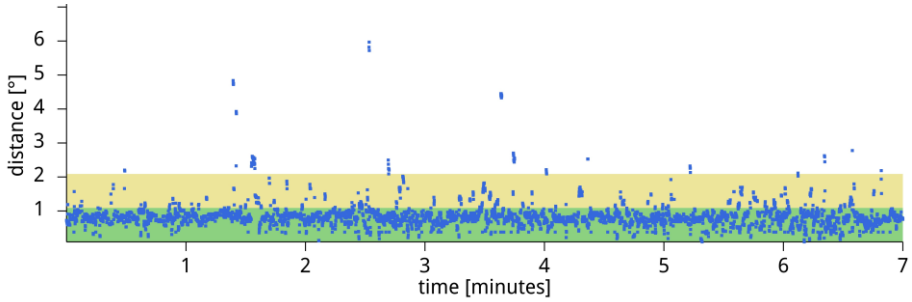


Fig. 55 – Fixation graph

12.2 SupraThreshold exams review

The review window of a **SupraThreshold** test (Fig. 56) is similar to the one of the **Perimetry** test, except that the stimuli do not have a numeric value. As a consequence, the following buttons/information are missing:

- Thresholds button
- Average Threshold index slider

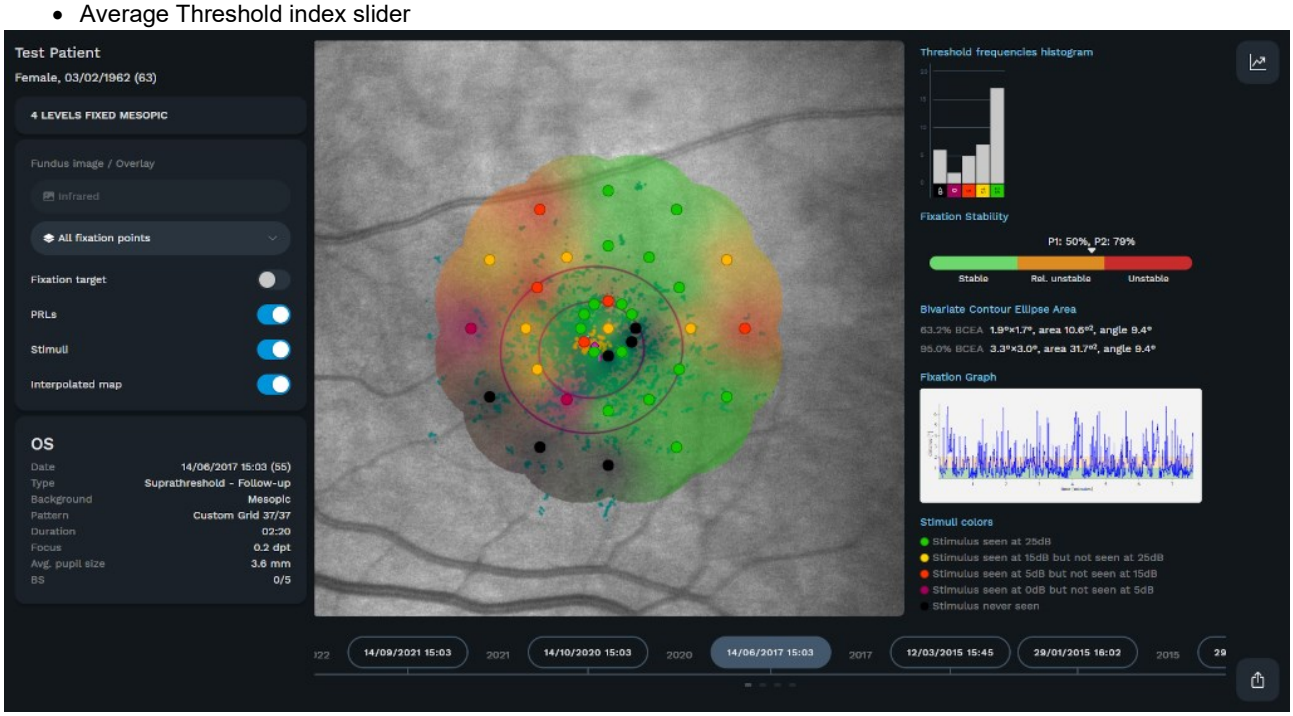


Fig. 56 – SupraThreshold exam review window

As displayed in the ***Stimuli colors*** legend on the bottom right, the colors for the stimuli have the following meaning:

- For the 4 Levels Fixed strategy:

  Stimulus seen at 25dB
  Stimulus seen at 15dB but not seen at 25dB
  Stimulus seen at 5dB but not seen at 15dB
  Stimulus seen at 0dB but not seen at 5dB
  Stimulus never seen

- For the Scotoma Finder strategy:

  Stimulus seen at 0dB
  Stimulus never seen

12.3 Image Review screen

When an image is clicked on a Perimetry or Fundus exam review screen, the *Image Review* screen opens (see Fig. 57).

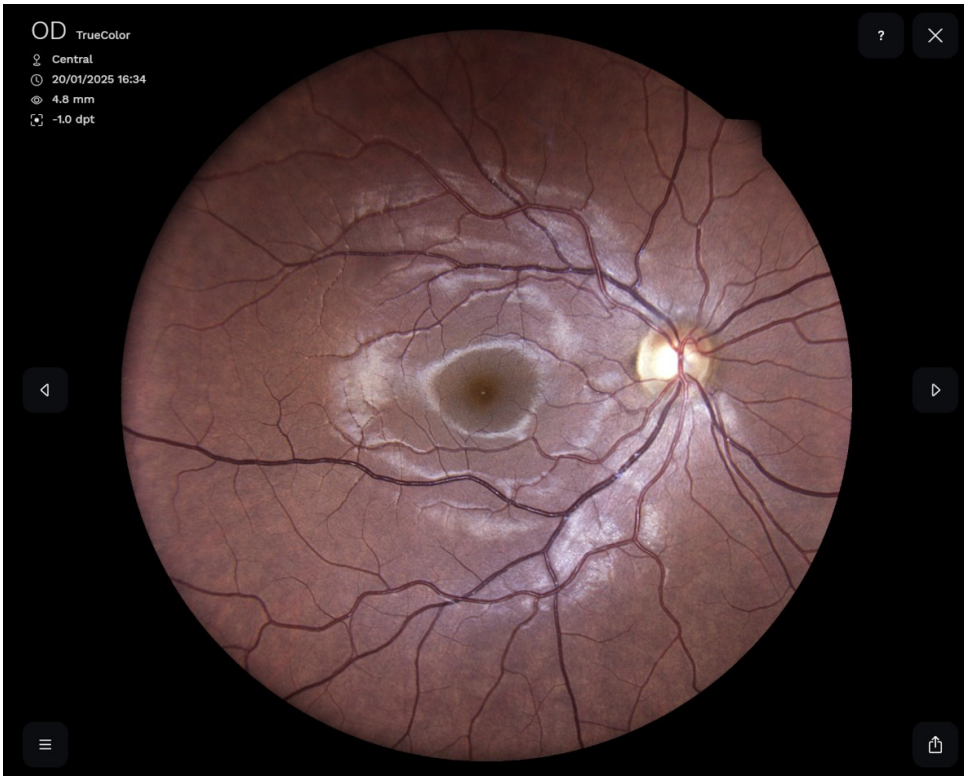


Fig. 57 – Image review screen

The top left corner shows the information on the acquisition conditions:

- Eye and image modality
- Field (only Central is available)
- Exam date and time
- Estimated pupil size
- Device's diopter correction

Use two fingers to zoom the image in and out, drag the image with a finger to navigate around the image.

Functions available in the *Image Review* screen:

Function	Command
navigation Use the **left** and **right** arrows to switch to a following or previous image, respectively. The navigation spans across all the patient visits.	
close Press the **close** button to exit the ***Image Review*** screen and revert to the ***Patient Record*** screen.	
open the sidebar Open the *Image Adjustment* screen (§12.4.1)	
export Export the current view of the image. See §12.6 for more information.	

12.4 Perimetry Mode Review screen

This screen allows the review of the Image acquired as part of a Perimetry exam. When accessing this interface, the stimuli thresholds are displayed over the retinal image. The image can be zoomed scrolling with the mouse and then panned dragging it with the mouse.

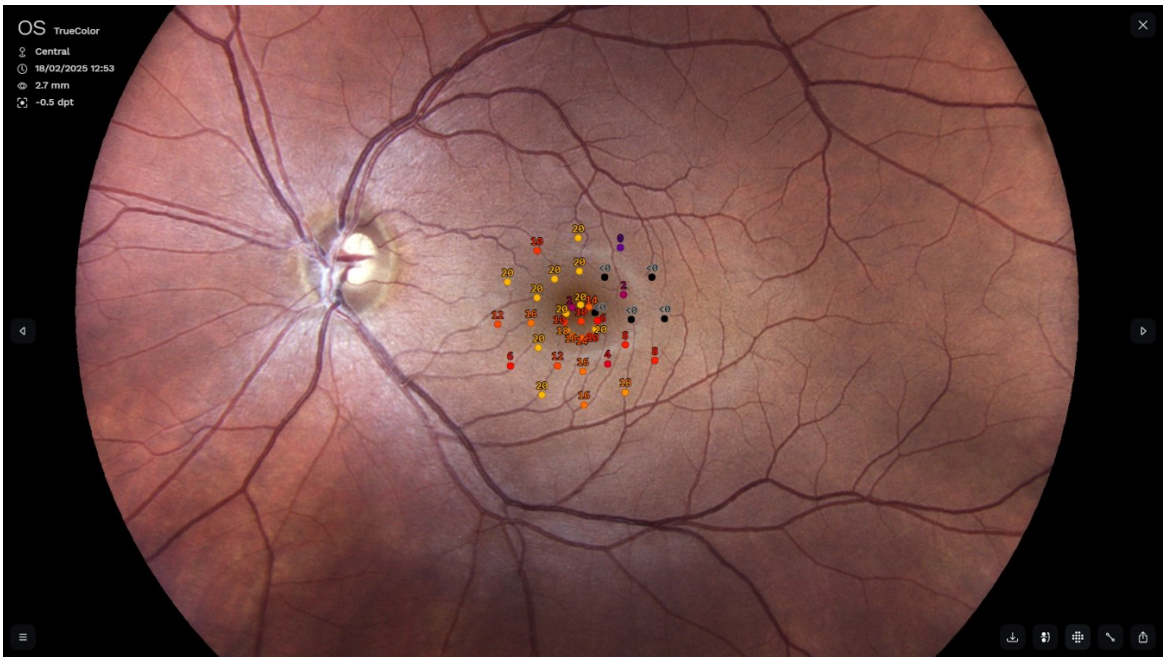


Fig. 58 – Perimetry mode Review screen

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 §12.4.1).
Export		Opens the export options (see §12.6) interface 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 **Perimetry mode** and **Fundus mode** display conventions, i.e. flips the image and thresholds vertically (see below)
Cup-to-disc evaluation		Available only on the Remote Viewer. Allows to set the markers for the cup-to-disc ratio evaluation (see §13.4.1). Hides/shows the markers once they've been set.

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**. Values from the superior field, corresponding to the inferior retina, are displayed at the top and vice versa: this convention is used in the Exam Review screen when the Fundus Mode selector is set to OFF ("***Perimetry mode***" 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 mode***" convention). Values from the superior field, corresponding to the inferior retina, are displayed at the bottom, and vice versa. This is the default convention in MAIA to display retinal images. This is the convention used in the Perimetry exams printout, too.

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

12.4.1 Image Adjustment dialog

This dialog provides 2 tabs: **Filters** and **Visits** (see Fig. 59).

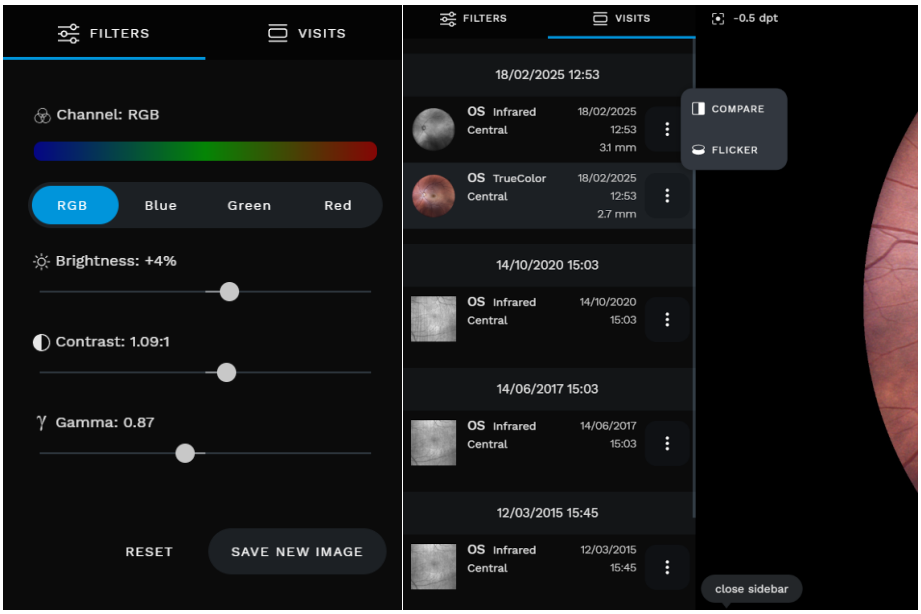


Fig. 59 – Image tools dialog: Filters (left) and Visits (right) tabs

The **Filters** tab allows to adjust the display parameters for the image, to enhance its appearance and/or to select the desired color channel.

The **RESET** button reverts all the parameters to their default values.

Click **SAVE NEW IMAGE** when applying filters to save the filtered image as a new Fundus exam within the ***Patient Record***. **SAVE NEW IMAGE** applies only to a TrueColor channel-filtered image.

The Filters do not alter the original image.
Once set, the visualization parameters are stored on the device, and are shared between the onboard application and the Remote Viewer. 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 Perimetry or Fundus exam), and to select one to be used for comparison in the *Dual Image Review* screen (see §12.4.2) using the ⋮ button and clicking on COMPARE, or in the Flickering view (see §12.4.3) clicking on FLICKER (available only if the two images are related to the same eye), or to delete a single image by clicking on DELETE.

12.4.2 Dual Image Review screen

The Dual Image review screen (Fig. 60) allows a side-by-side comparison of any pair of images of the selected patient (color and infrared, left and right eye, same or different visits).

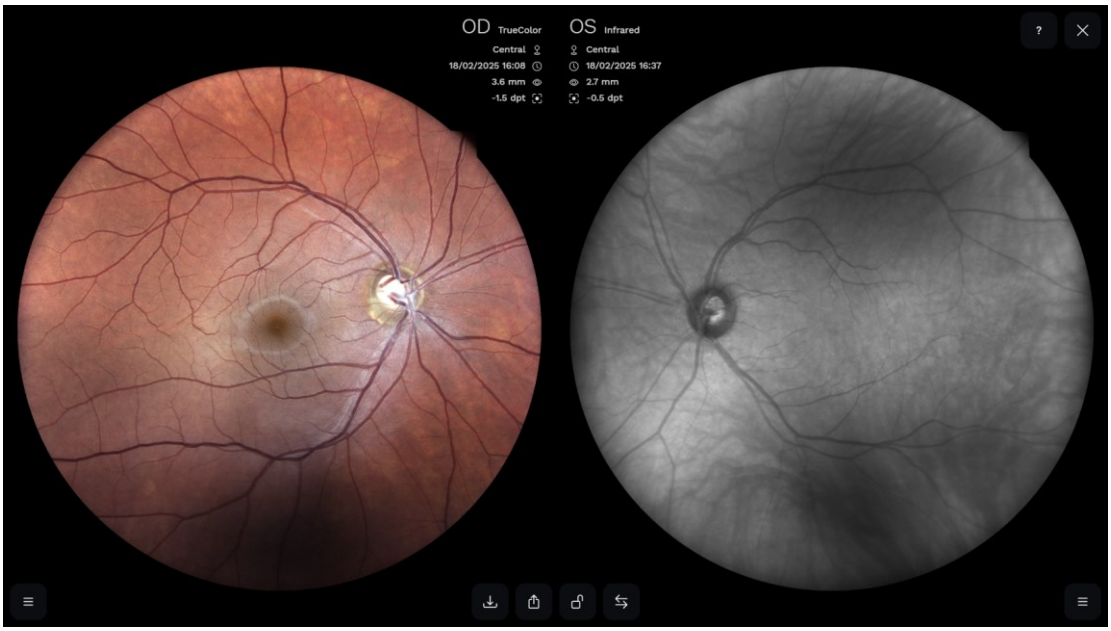


Fig. 60 – Dual Image Review screen

The box on the corner of each image contains the information on the image acquisition, as in the *Image Review* panel. Double-click on a picture to zoom in, press and drag to pan the zoomed picture.

The following additional functions are available in this screen, in addition to those described above for the *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 §12.4.1).
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 §12.6) for the Fundus report of this image.
Flicker		Open the pair of images in the *Flickering Review* screen (see §12.4.3). Only available if the two images belong to the same eye and field.

12.4.3 Flickering view screen

MAIA 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 §10.6), or from Visits tab of the *Image Adjustment* dialog (see §12.4.1), or from the *Dual Image Review* screen (see §12.4.2).

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

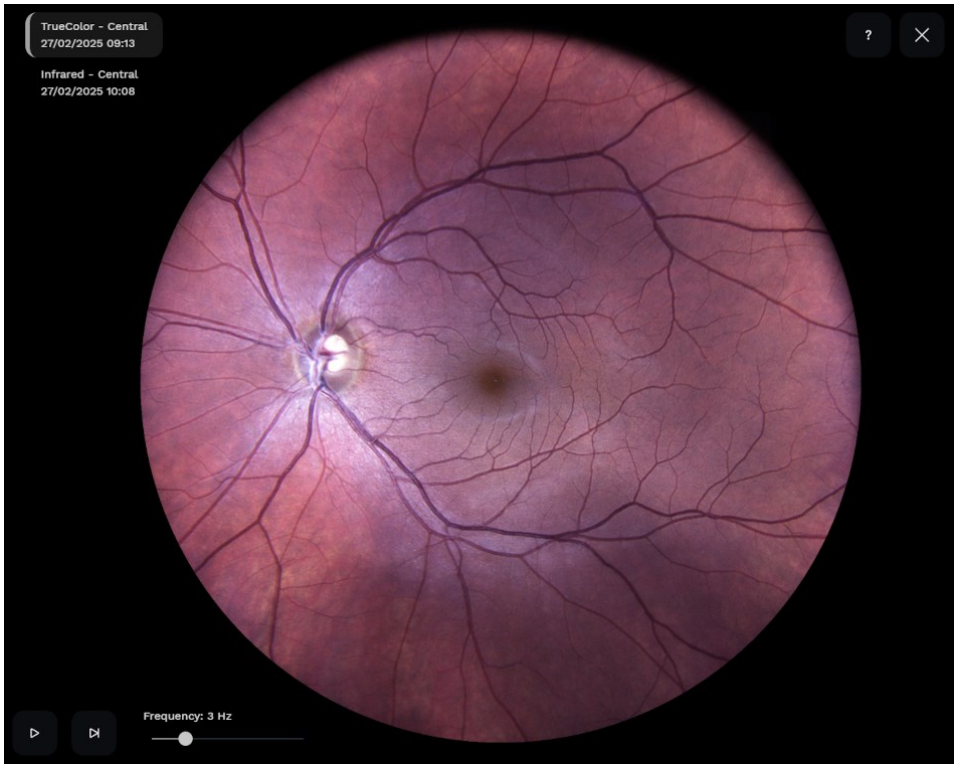


Fig. 61 – Flickering review window

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.

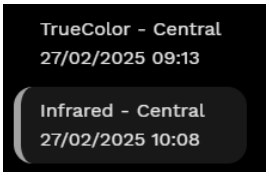
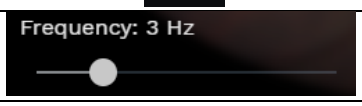


Fig. 62 – Currently active picture: “Infrared – 27/02/2025 10:08”

The following features are available in this screen:

Function	Command	Description
Close		Goes back to the ***Image 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).

In the *Flickering Review* screen, the second image is automatically registered on the first to overlap the retinal features, making the reviewing analysis easier. The first image acts as a reference and only the overlapping parts of the second image appear. Consequently, the 2 images are “locked”: zooming and dragging will act on both images.

12.5 Time Analysis

The Time Analysis screen allows to monitor the progression of perimetry and fixation parameters over time.

To access the **Time Analysis** screen, select and open any test belonging to the desired sequence of exams (Root or Follow-up), then click the  button.

The **Time Analysis Exams Selection screen** will open (see Fig. 63), which allows to select / deselect the tests to be considered for the analysis. For example, some tests may be excluded because of poor reliability (excess of FP, FN, or BS indices, refer to §12.1.1).

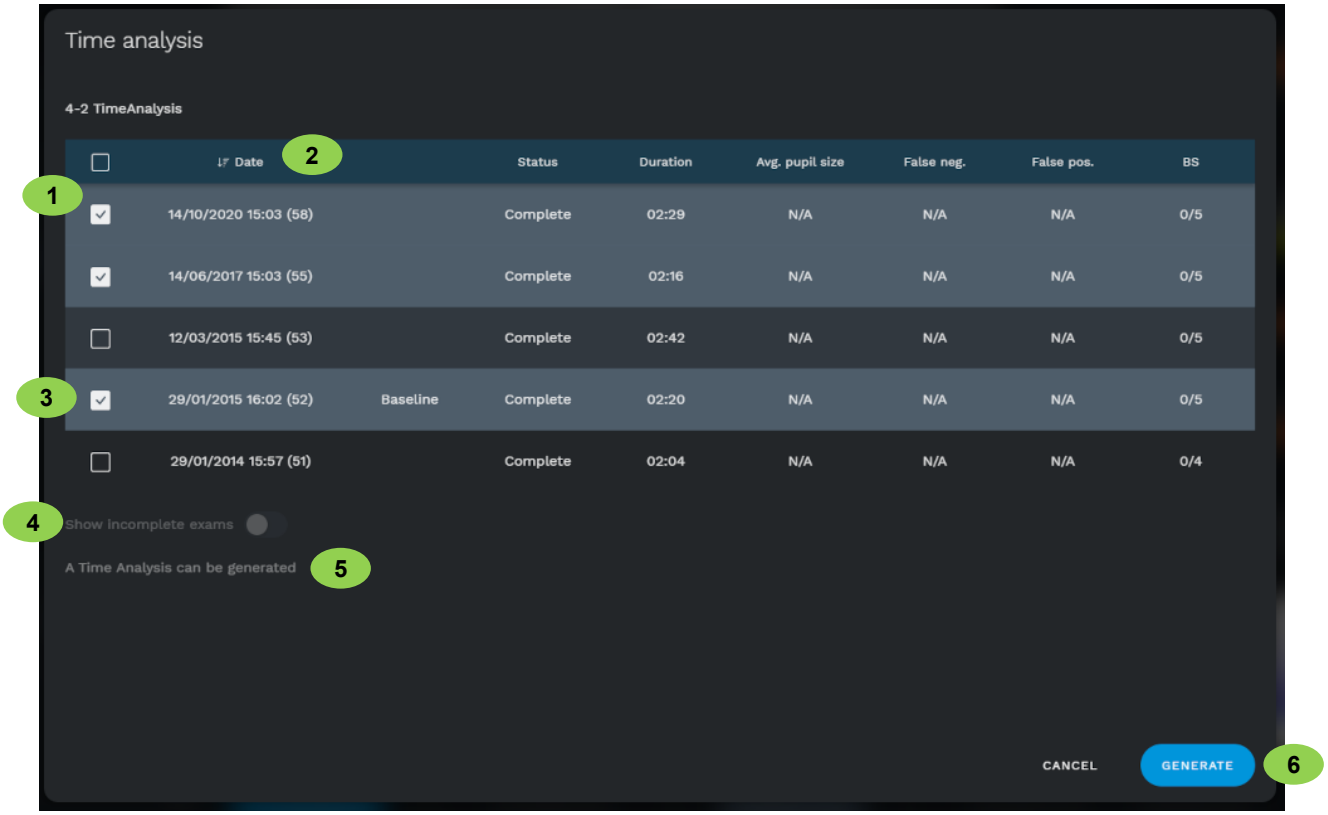


Fig. 63 – Time Analysis Exams Selection screen

The **Time Analysis Exams Selection** screen provides the following information and 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 oldest is identified as the Baseline, and will be the starting point for the analysis.
4. A checkbox that allows to hide/show Incomplete exams, that in any case cannot be selected for the Time Analysis.
5. A text comment will inform whether it is possible to generate the Time Analysis.
6. Press **GENERATE** to proceed to the Time Analysis screen (Fig. 64) or CANCEL to go back.

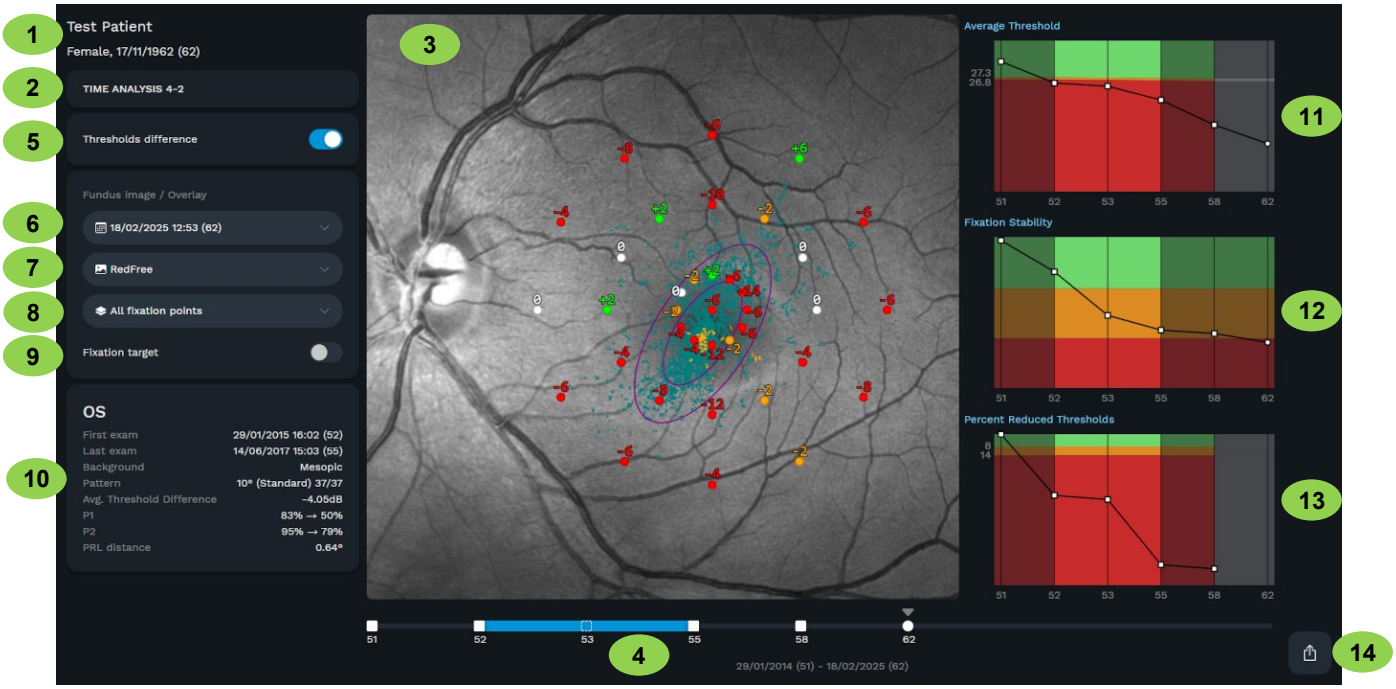


Fig. 64 – Time Analysis screen for a **4-2 Strategy** exam sequence

The **Time Analysis** screen provides the following information and functions:

1. Patient name, gender and date of birth
2. Test strategy
3. Differential Map: displays the difference in the thresholds (or in the levels, for SupraThreshold exams, see Fig. 65) between the pair of exams selected with the selector at the bottom of the screen. Positive differences are displayed in green, no difference in white, negative differences up to -2 in orange, differences below -2 in red. The differential map is overlapped to the image of a selected exam (that can be chosen with the selector at point 6), which may not be part of the selected pair of exams
4. Selector for the exams interval. Square markers represent exams taken with previous MAIA Edition devices, circle markers represent exams taken with MAIA 2025 Edition devices; this applies also to the charts displayed on the right side. The range of the blue line identify the exams being compared in the differential map. By default, the first and the last exam are selected for comparison: drag the limits of the blue line to select a different pair of exams. The triangle identifies the exam used for the underlying image and fixation plot
5. Toggle button to display or hide the stimuli grid and thresholds
6. Selector for the exam to be used for the underlying image and fixation chart. The triangle in the bottom selector (see 4) identifies which exam is selected for the underlying image
7. Allows to select the image to be displayed underneath the Differential Map: ***Infrared***, ***TrueColor*** or ***RedFree*** (if available)
8. Selector for the Fixation points representation: **All fixation points**, **Filtered fixation points** (i.e., points acquired only during stimuli presentations), **None**
9. Toggle button to display or hide the Fixation Target marker
10. Information about the selected pair of exams: examined eye, date and time of the two exams, background and projection grid used, average threshold difference, variation of P1 and P2, and distance between the PRL-i of the two exams
11. Average Threshold: chart representing the variation of the Average Threshold over time. The selected interval for the comparison is highlighted. The colored ranges are the same displayed in the Exam Review screen for each exam (see §12.1), and are currently missing for exams taken with MAIA 2025 Edition
12. Fixation Stability: chart representing the variation of the Fixation Stability over time. The colored ranges are the same displayed in the Exam Review screen for each exam
13. Percent Reduced Thresholds: chart representing the variation of the Percent Reduced Thresholds over time. The colored ranges are the same displayed in the Exam Review screen for each exam, and the values are currently missing for exams taken with MAIA 2025 Edition
14. Button to export the Time Analysis report printout (see 12.6)

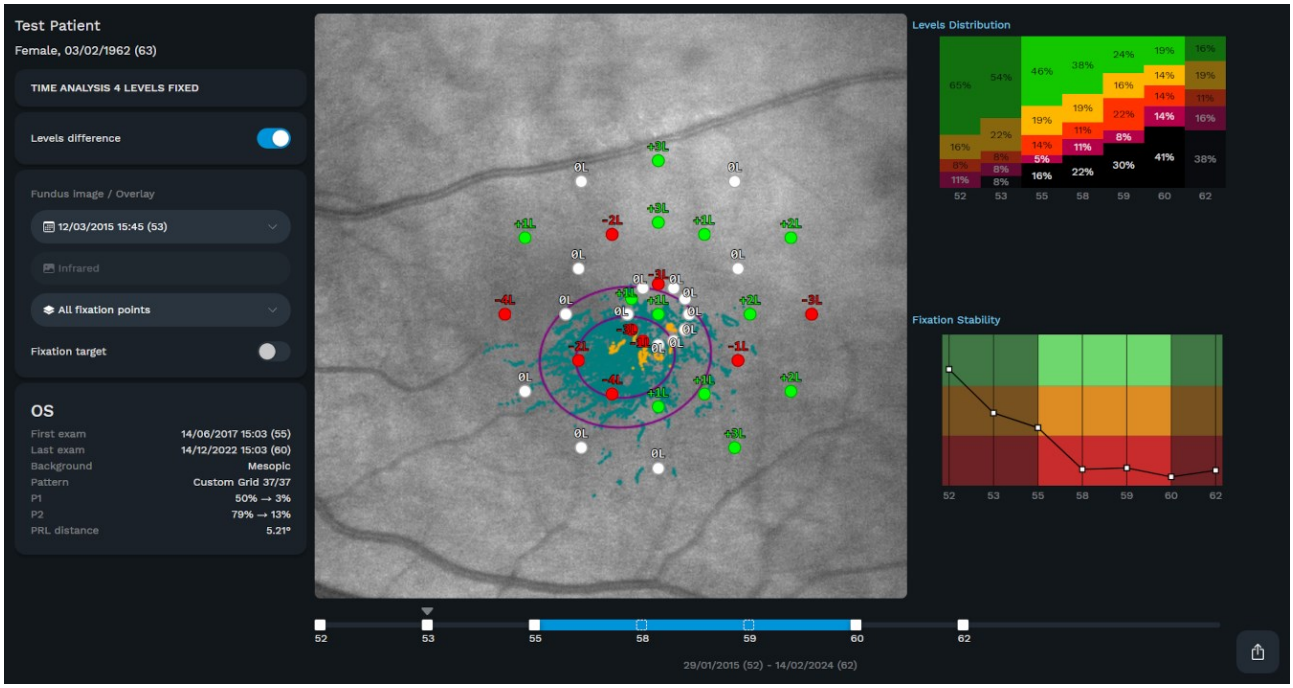


Fig. 65 – Time Analysis screen for a **4 Levels Fixed Strategy** exam sequence

The **Time Analysis** for a SupraThreshold Strategy sequence of exams (such as the one in Fig. 65) is similar to the one for a 4-2 Strategy, with the following differences:

- The Differential Map expresses the difference in Levels, using the suffix “L” (such as +1L, -2L, etc.). Positive differences are displayed in green, no difference in white, negative differences in red
- The Average Threshold graph is replaced by the Levels Distribution chart, representing the variation of the levels histograms over time (each exam’s distribution is represented vertically)
- The Percent Reduced Thresholds graph is missing

12.6 Exporting exams

MAIA offers extreme flexibility in exporting exams and images. From the *Export* Screen, in detail, you can:

- simultaneously export all exams/images of one or more patients (§10.6);
- export or print a single exam/image (§12.1, §12.3);
- Print all the images of a single patient.

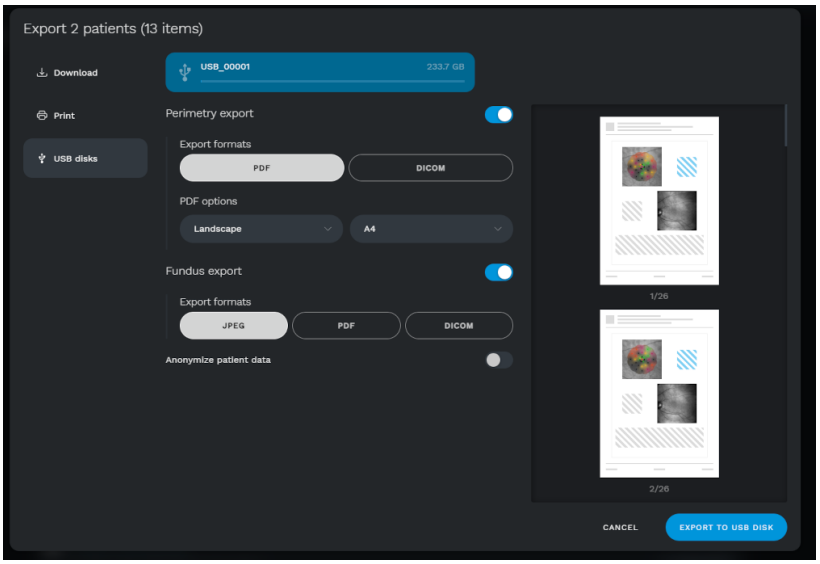
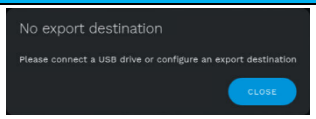
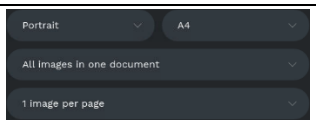
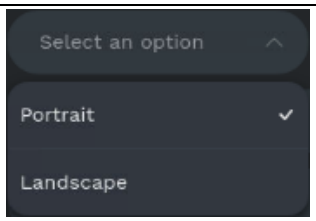
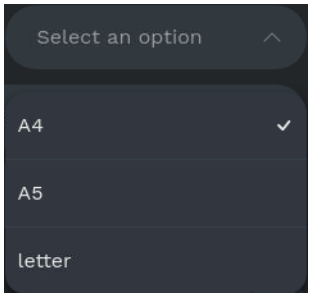
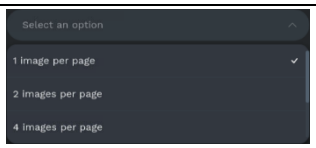


Fig. 66 –Export Screen

Function	Command
Connect one or more destinations.	
Select the export destination (*USB disks, Network disks, Printers*). Printing is available for a single patient only.	
Select one or more of the following *Export formats*: **JPEG**, **PDF**, **DICOM**. Light grey buttons are enabled, and dark grey buttons are disabled. For printing, only the **PDF** option is available.	
Customize the *PDF options* as follows	
Layout: **Portrait** or **Landscape**	
Paper Size: **A4**, **A5**, **letter**	
Number of images per page: **1, 2, 4, 6, 9**	
Enable/disable **Anonymize patient data** to export all the patients with masked information	
See the *PDF preview* on the right side of the screen. You can scroll through all the pages to generate.	

Click **EXPORT** to proceed, or click **CANCEL** to abort the Export. For printing, click **SEND TO PRINTER**.

See the progress of the export activity and its completion in the pop-up (see Fig. 67). Click **CANCEL** to interrupt the export or wait until the export process is complete. Click **CLOSE** to return to the previous Screen.

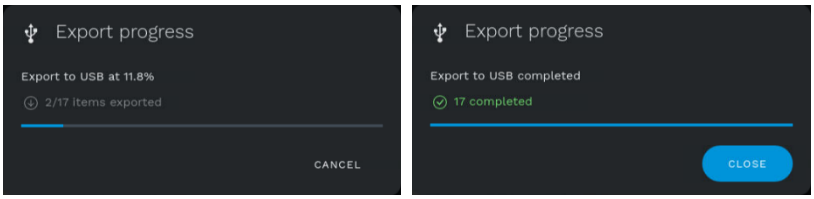


Fig. 67 – Export progress pop-up

In case of completion with errors (e.g.: for lack of space), a pop-up indicates the error. Click **CANCEL** to close the pop-up and interrupt the export process. Select a different support or empty the currently selected one to complete the export process.

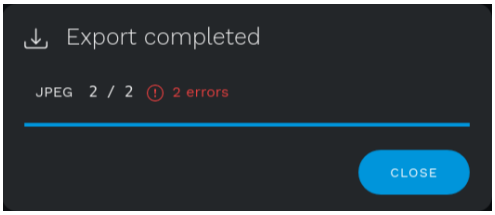


Fig. 68 – Error during export

13 REMOTE VIEWER

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

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** or **WiFi** connection.

In the Remote Viewer some commands/icon are not available: for example, the **MENU** does not show the **Power off** button.

13.1 Enabling the Remote Viewer

To enable the Remote Viewer, MAIA must be connected to the Local Area Network using an Ethernet (Fig. 2) or Wireless connection. After the connection of the ethernet cable to the Ethernet port located on the back panel of the device, the network connection might require additional configuration (§18.3).

Remote Viewer access (HTTP or HTTPS) must be enabled in the *Settings|Device access* Screen (§18.7)

By default, the remote viewer is disabled.

Once the connection is up and running, open a browser on the remote PC and insert the address of the device:

https://MAIA-*nnnnnnnnn*

or

https://MAIA-*nnnnnnnnn*.local

into the address bar. Here: *nnnnnnnnn* are the 9 characters that compose the serial number of your MAIA, as reported in the device label.

The Remote Viewer functionality is available only under license[14]. The license can be provided as a ***single license*** or a ***5-license*** pack. Every ***single license*** will give access to MAIA from one remote station at a time, while the ***5-license*** pack will give access to the device from up to 5 remote stations at a time. Refer to §19.5 for info about the available licenses and how to install and revoke them.

- The Remote Viewer requires a standard Web Browser and does not require any additional third-party software to be installed in the remote computer.
- The Remote Viewer is tested on the latest releases of the following browsers[15]: Google Chrome, Mozilla Firefox, Microsoft Edge (Chromium-based), Apple Safari
- The Remote Viewer requires the user to log in using the same user credentials (username and password) used to log in to the local user interface.
- Every Remote Viewer session is automatically closed after the period specified in the *Settings|Device access* menu (§18.7). To continue using the Remote Viewer, a new login is required.
- The use of the HTTP protocol exposes to higher cybersecurity vulnerabilities.

[14] *Remote Viewer functionality is available under license only: please refer to your local Authorized Distributor for detailed information.*
[15] *As of September 2024.*

13.2 Remote Exam

From the Remote Viewer, the configuration and execution of a new exam are permitted only after Remote Exam activation.

MAIA Remote Exam functionality[16] through MAIA Remote Viewer provides the capability of executing a patient remote acquisition with MAIA.

MAIA Remote Exam functionality is intended for extending the distance normally present between the patient and the medical examiner.

This feature requires the user to be in the same room as the patient, with a clear view of the patient and of MAIA to set up and control the exam.

If your medical office does not allow for a clear view of the patient and MAIA, it is suggested to set up a video conferencing call between two tablets or other capable devices (not provided by the Manufacturer) using the integrated or third-party video conference app.

Note that some patients may have difficulty following a remote exam set-up: patients who may have a poor fixation or a very small pupil, need a standard testing approach. In those cases, remember to protect yourself and the patient against the spread of pathogens.

For Remote Exam activation for a specific user, see §18.2.

From the computer, log in with the proper use of the **Remote Viewer**.

Select or Create a **New Patient** and start a **New Exam**.

A pop-up appears and the **Remote Activation Code** is requested.

The Remote Activation Code will be shown on the display of MAIA (see Fig. 69).

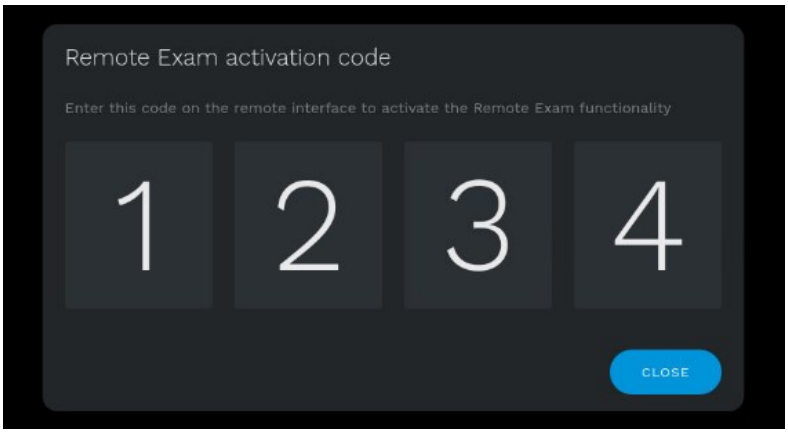


Fig. 69 – Remote Activation Code showed on MAIA display

Insert the Remote Activation Code on the Remote Exam interface (see Fig. 70).

[16] *The Remote Exam Feature functionality is available under license only and needs as a pre-requisite a Remote Viewer license installed: please refer to your local Authorized Distributor for detailed information.*

The Remote Exam activation code is requested only the first time the operator starts an exam from a Remote Viewer station. The code will not be requested again for the same operator account and the same review station. The code is requested once more after 4 hours of inactivity.

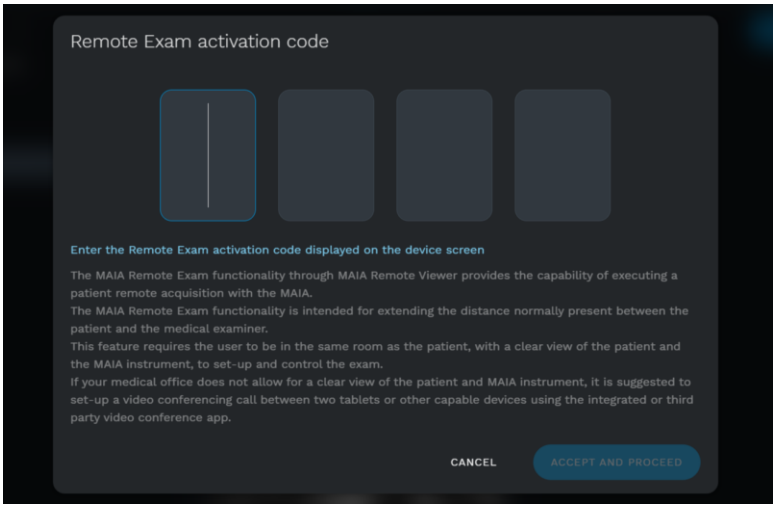


Fig. 70 – Remote Activation Code fill on Remote Viewer Interface

Perform the exam steps the same way as if you were next to the patient.

Verify the seat of the patients and instruct them to place their foreheads in the proper position.

Use the eye position view to make sure that the patient is well aligned.

Perform the exam sequence just as you would normally, instructing the patient remotely when the test has begun.

During the exam, it is always possible to control and stop the exam from the display of MAIA. When the exam has been completed, you can review the results and download the report directly from the Remote Viewer.

13.3 Export and print from the browser

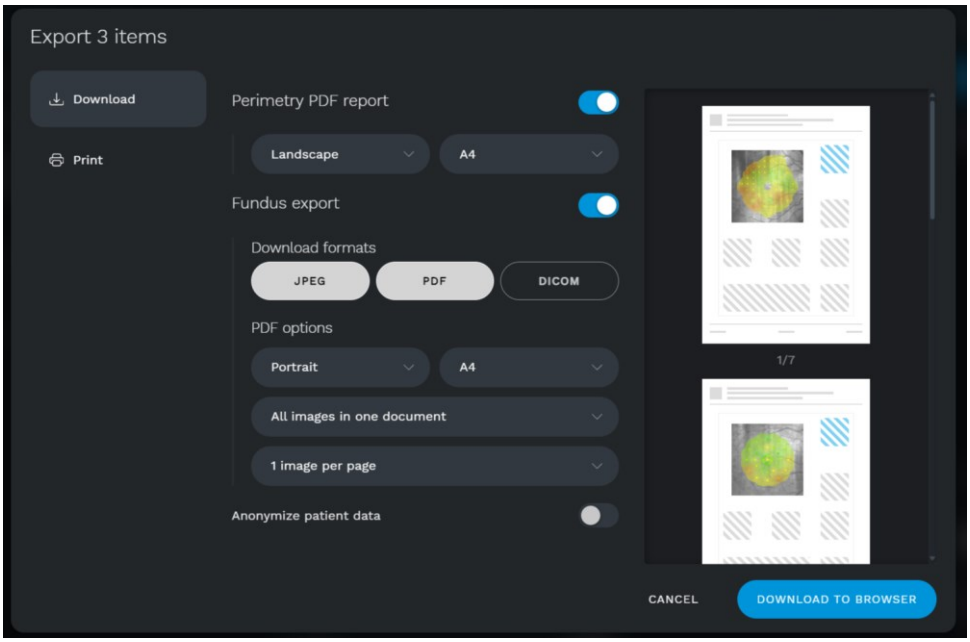


Fig. 71 – Remote viewer export

From the Remote Viewer, in the *Export* Panel, it is possible download the report printouts on the PC.

Configure the desired export options as described in §12.6, then push **DOWNLOAD TO BROWSER** to export the selection on your PC.

13.4 Remote Image review

13.4.1 Cup-to-disc evaluation

From the Remote Viewer, you can use the **cup to disc** function.

Push the **cup to disc** button to activate the measurement function.

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 and the CDR will correspondingly be updated.

The cup disc ratio is always calculated as a value lower than 1, regardless on the order of design of the segments.

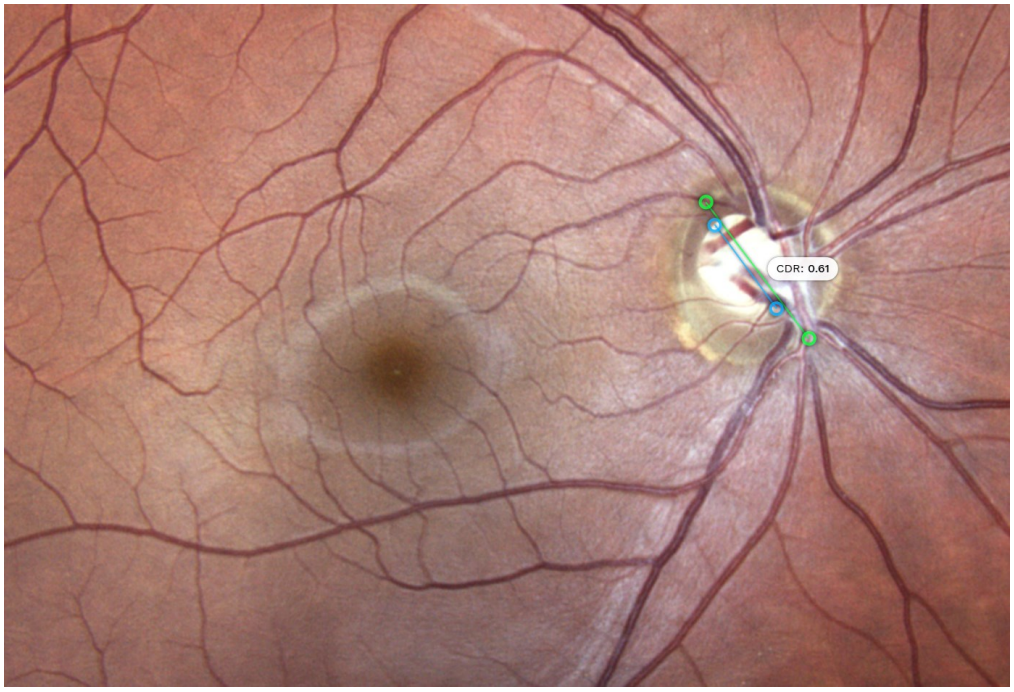


Fig. 72 – Cup-to-disc ratio evaluation

MAIA 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 MAIA shall be considered as a qualitative indication only. Moreover, MAIA does not provide CDR values comparison with normative data, so the clinical interpretation of the CDR measurements obtained with MAIA is the sole responsibility of the eye care practitioner.

The cup to disc ratio is reported on the top left side of the image. Note that you can anytime edit the selected points and the CDR will correspondingly be updated.

13.4.2 Shortcuts

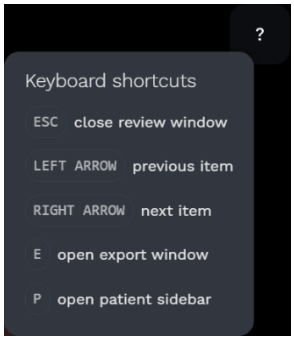


Fig. 73 – Shortcuts in the remote Image Review Screen

In the Image Review Screen of the *Remote viewer* push the question mark to discover the Keyboard shortcuts.

13.5 Privacy mode

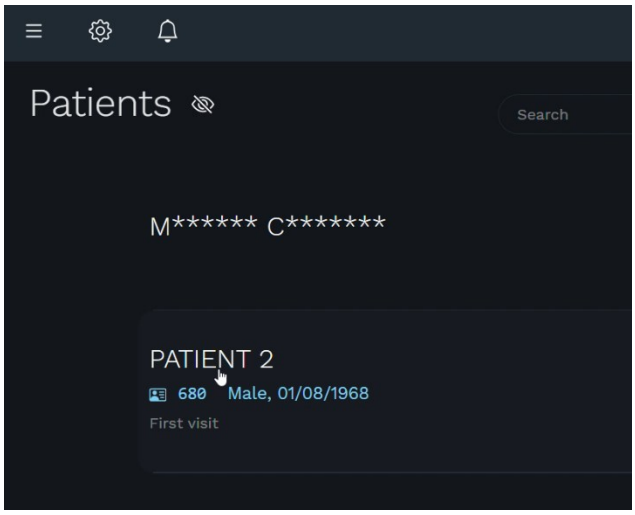


Fig. 74 – Patients list in privacy mode

When the *Privacy Mode* is enabled, In the Remote Viewer you can hover a patient box with the cursor to make the Surname and the First Name fully visible.

Press the **privacy mode ON/OFF** button to hide/unhide the patients' information.	

14 PRINTING

14.1 Printout report of a Perimetry exam

The printout report for a Perimetry exam is a one-page layout presenting the following information (see Fig. 75):

1. Patient information (name, date of birth, age when test was performed, gender, operator who executed the test)
2. Exam notes
3. Custom header (logo and text)
4. Test parameters (date, time, threshold strategy and test pattern, number of completed locations, average pupil size, exam duration, FP and BS indexes)
5. Examined eye (OD, OS) and exam type (Baseline, Follow-up)
6. TrueColor image of the retina
7. Zoomed view of the test pattern with threshold values (dB) over the fundus image, using the Fundus mode convention. The type of image (infrared, TrueColor, red-free) printed is the same used for the overlay on the Exam Review screen when the printout was generated.
8. Zoomed view of the interpolated map over the fundus image
9. Average Threshold and Histogram of threshold frequencies
10. Fixation plot, representing the fixation points used to determine the PRL-I (in orange) and the PRL-F (in blue) and the BCEA ellipses over the fundus image
11. Fixation stability indexes (P1 and P2), and Bivariate Contour Ellipse Areas: this index reports the area (and its semi-axis between brackets) of the 63 th and 95th percentile fitting ellipses of the fixation points recorded during the test: the higher this index the more dispersed fixation and the wider eye movements
12. Graph, describing the amplitude of eye movements in time, relative to the PRL-F
13. Footer: report generation date, serial number of the unit that generated the report, SW version used to generate the report, MAIA logo

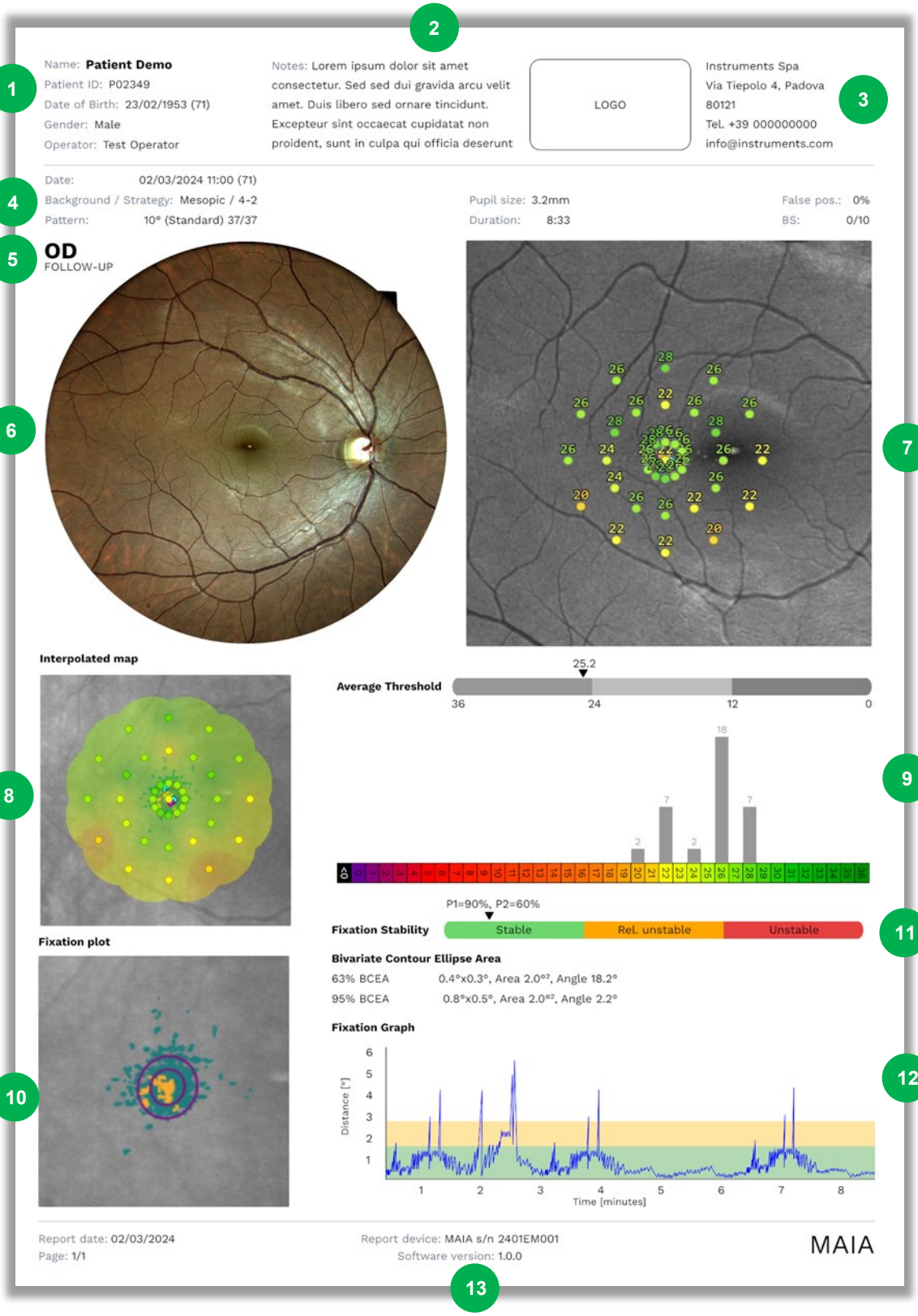


Fig. 75 – MAIA report for a test with 10° grid

15 TARGETED MICROPERIMETRY

Targeted Microperimetry is an optional MAIA software feature that allows clinicians to perform microperimetry examinations using a custom set of stimulus locations defined on a reference retinal image imported from an external source (e.g. OCT en face images or fundus camera images).

Targeted Microperimetry enables examinations to focus on specific retinal areas of clinical interest, such as lesions, regions of structural change, or areas previously identified using other imaging modalities.

This feature relies on MAIA's eye tracking system to ensure that each stimulus is projected at the intended retinal location, compensating for eye movements in real time. Targeted Microperimetry is particularly suitable for follow up examinations, structure–function correlation, and research or advanced clinical applications.

The Targeted Microperimetry feature requires a dedicated license to be enabled.
Please contact an authorized iCare Service representative to purchase and activate the license.

15.1 Principle of Operation

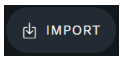
In Targeted Microperimetry, the examination is based on a reference retinal image imported by the user together with a JSON file defining the desired test point locations. Test point positions are provided in a structured data format and are expressed relative to the imported reference image.

When the examination is started, MAIA acquires an infrared (IR) retinal image of the patient's eye. The system then performs an automatic image matching process between the imported reference image and the acquired MAIA IR image. During this process, MAIA calculates the optimal scaling, rotation, and translation parameters required to align the two images.

Once image alignment is complete, the predefined test points are mapped onto the patient's retina using the calculated transformation parameters. During stimulus presentation, MAIA continuously tracks eye movements and compensates in real time to ensure that each stimulus is projected at the intended retinal location.

After completion of the examination, the measured sensitivity values and associated spatial information are stored. Results can be reviewed overlaid either on the MAIA acquired retinal image or on the imported reference image, allowing direct correlation between functional results and retinal anatomy.

15.2 Importing an external image with test points

When a valid Targeted Microperimetry license is installed on the device, an 

button is available in the top right corner of the Patient Record screen. Pressing this button allows the user to import an external image and the corresponding pattern of test points. This operation can be performed either directly on the MAIA device (Local Interface) or using the Remote Viewer.

15.3 Accepted file formats

15.3.1 Image file formats

Supported image formats are JPG and PNG only. Imported images may be fundus photographs, autofluorescence images, infrared images, or OCT en face images, and may be monochrome or color.

The image file size must not exceed 12 MB. The maximum supported resolution is 7500 × 6000 pixels (width × height), and the minimum resolution is 300 × 260 pixels.

15.3.2 Test Locations file format

Test locations must be specified in a separate JSON file following the structure defined by the JSON Schema provided in the par. 15.10. Here is a short example for such a JSON file:

```
{
  "label": "Grid ONH",
  "points": [
    {"id": 1, "x_perc": 0.54296875, "y_perc": 0.298828125, "starting_intensity": 20},
    {"id": 2, "x_perc": 0.599609375, "y_perc": 0.651041667, "starting_intensity": 22},
    [...]
    {"id": 42, "x_perc": 0.951171875, "y_perc": 0.324869792},
    {"id": 43, "x_perc": 0.961588542, "y_perc": 0.371744792, "starting_intensity": 20}
  ]
}
```

In the above example, the optional ***label*** field contains the name of the grid (see Fig. 79). If not provided, the grid name can be defined onboard MAIA when importing the file (see Fig. 77).

The coordinates **(x_perc, y_perc)** represent the relative position of each test point as a ratio (0–1) of the image width and height, starting from the top-left corner of the image. For example, if the image size is 1920x1080 pixels, the point expressed as **{"x_perc": 0.54270833, "y_perc": 0.323148148}** corresponds to the pixel [1042, 349]. A precision of at least five decimal places is recommended.

The **id** field is optional and, if used, must be provided for all points. IDs must be unique positive integers. If omitted, IDs are automatically generated by the device.

The optional ***starting_intensity*** field defines the starting stimulus intensity (in dB) for 4 2 strategies. If a Suprathreshold strategy is used, the closest test intensity lower than the specified starting_intensity is used. It is not necessary to provide a starting_intensity for all test locations: if not specified, the default value for the selected strategy and patient age is used.

15.3.3 Using a ZIP archive

Image and JSON files may be imported separately or included in a ZIP archive for convenience. A ZIP archive may contain files for one eye or for both eyes. Each eye requires a complete set of image + locations file.

When including files for both eyes, filenames must follow this convention:

- **[name]_od.[jpg/png/json]** for the right eye (OD)
- **[name]_os.[jpg/png/json]** for the left eye (OS)

For single eye archives, filenames may be arbitrary; however, using the same convention is strongly recommended to avoid importing files for the wrong eye.

15.4 Importing data using the Local Interface

After pressing the **IMPORT** button, the ***External Files Import interface*** will appear (Fig. 76) allowing to upload the files. The interface allows to select the file for the OD (left side) and OS (right side). The **Select from USB** buttons will only be enabled if a USB device is inserted into the system.

Fig. 76 – External Files Import local interface

After pressing one of the **Select from USB** buttons you will be able to navigate the file system of the USB device to select the desired file(s). Once the pair of image + locations files is selected, a preview will be displayed for the selected eye (see Fig. 77). The imported grid name can be overwritten in this phase, by editing the text shown in the **Grid label** field.

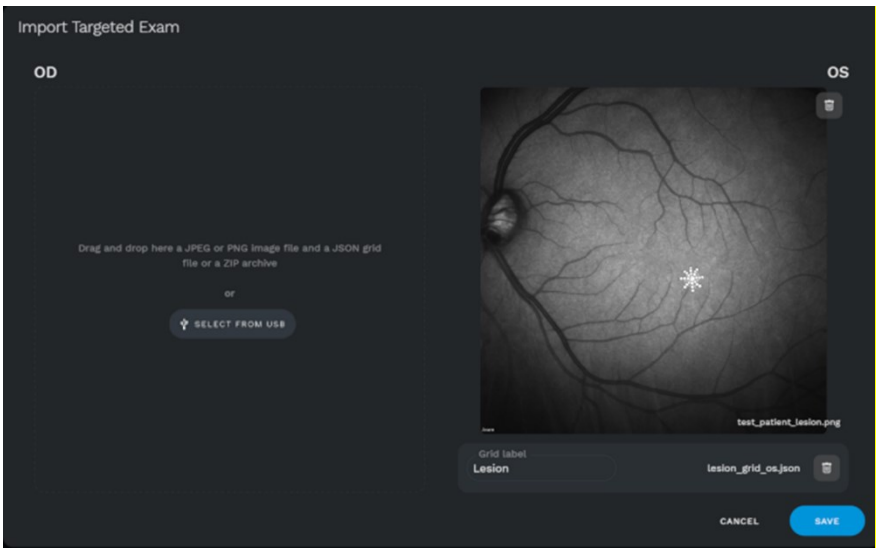


Fig. 77 - Preview of the imported data for the OD

It is possible to import data for both eyes at once, or for one eye only. If a ZIP archive is imported, the eyeside is automatically assigned based on the name of files included in the archive. If individual files are imported, the filename is ignored, and the eyeside is assigned based on the used **Select from USB** button. To store the imported data and proceed, press the **SAVE** button. If the dataset for any of the eyes is incomplete (image or JSON file missing) the **SAVE** button will be disabled.

The trash bin  buttons beside the image and the JSON filename allow to remove the related imported file, and select a new one.

15.5 Importing data using the Remote Viewer

The Remote Viewer facilitates the import of external image and locations data. Other than the import from USB, which remains available, the External Files Import interface in the Remote Viewer (Fig. 78) also allows to drag-and-drop the files directly in the OD and OS frames, or to press the **BROWSE FILES** button, to navigate the filesystem of the PC running the Remote Viewer and select the desired files. If a ZIP archive is imported, the eye side is automatically assigned based on the name of files included in the archive. If individual files are imported, the filename is ignored, and the eye side is assigned based on the used **BROWSE FILES** button or the frame used for drag-and-drop.

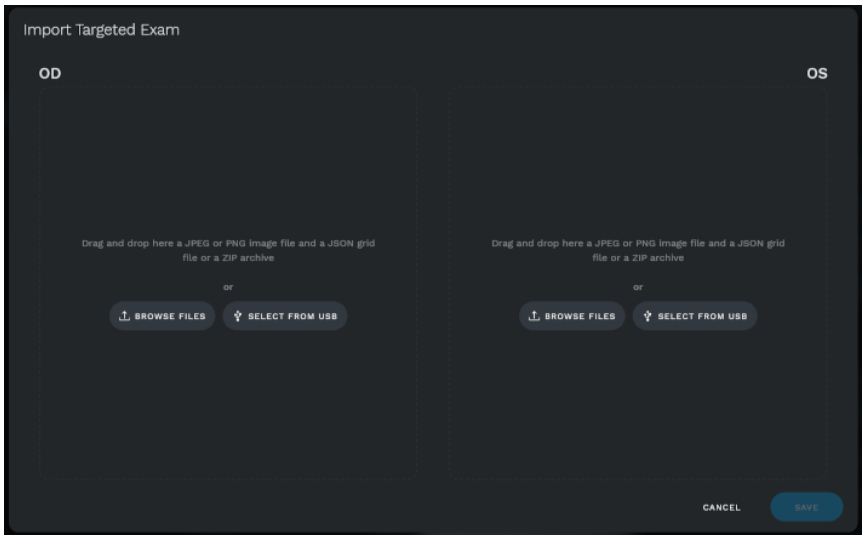


Fig. 78 - External Files Import interface in the Remote Viewer

15.6 Imported data in the Patient Record window

After pressing **SAVE**, each imported “image+locations” pair is stored in the device and is represented as a special exam type, called “**Targeted Exam**” (see Fig. 79), whose Pattern field displays the name of the test pattern as identified in the imported JSON using the ***label*** field (see §15.3.2). This serves as a reference to perform microperimetry tests at the locations identified in the imported JSON file. It is possible to select the Targeted Exam to display a preview of the imported image, with the overlaid test points.

The **DUPLICATE** button can be used at any time, to duplicate the imported data into a new Targeted Exam, for example to use it as a baseline for a microperimetry exam using a different Strategy, without needing to re-import the data.

To start a microperimetry test using the Targeted Exam as a baseline, press the **START** button below it, or the **START** button available in the related folder on the right side after expanding it.

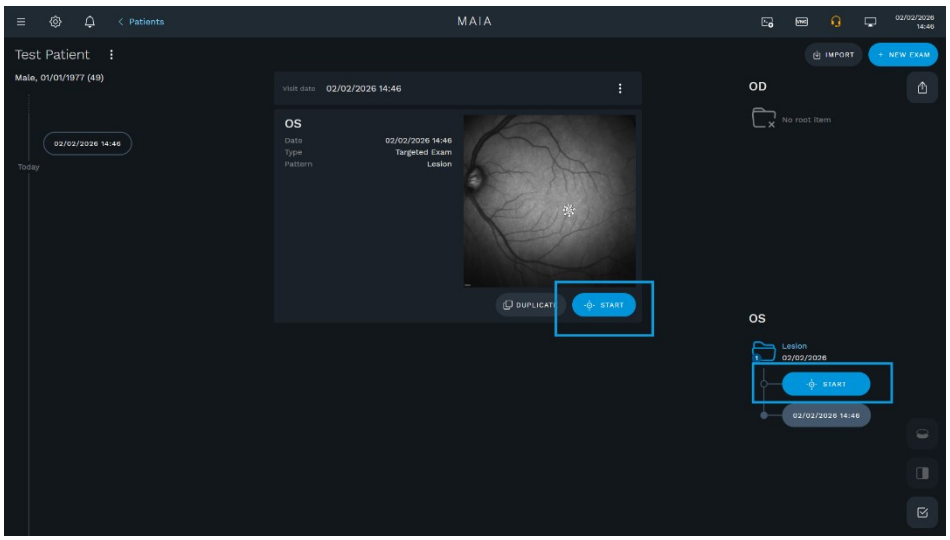


Fig. 79 - **START** buttons available for Targeted exams in the Patient Record window

15.7 Performing a microperimetry exam on a Targeted Exam

Once the **START** button is pressed, the device begins to align the optical head with the patient's eye. During the alignment, a preview of the grid of points to be tested is displayed in the center of the screen, overlapped to the live retinal image. Before proceeding, it is possible to choose which strategy to use for the exam among those available (4-2, 4 Levels Fixed, Scotoma Finder…) by pressing the **EXAM TYPE** button on the bottom left. Once the strategy has been selected, press **START** on the bottom right to start the microperimetry exam.

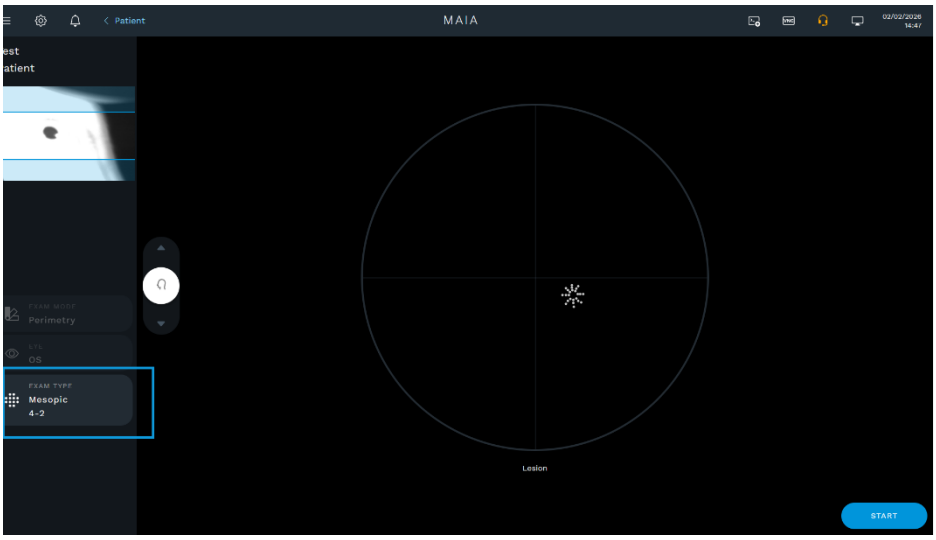


Fig. 80 - Starting a Targeted exam: it is possible to select the Strategy using the enlightened button

The examination then proceeds with the same steps as for a Follow-up exam:

- Selection of the Fixation target
- Acquisition of the IR reference image
- Registration of the imported image over the IR reference image. The procedure is the same as for the registration of the Follow-up IR image over the baseline IR image and described in §11.11 (see Fig. 81): the parameters are calculated automatically, but can then be overridden/fine-tuned manually
- Identification of the Optic Disc location
- PRL identification
- Preview of the imported grid locations over the acquired IR reference image: this will display where the test points are located on the IR reference image, and allows to retake the IR image or continue
- Stimuli projection and thresholds assessment
- TrueColor photo acquisition

For more info on the exam steps mentioned above, refer to §11.

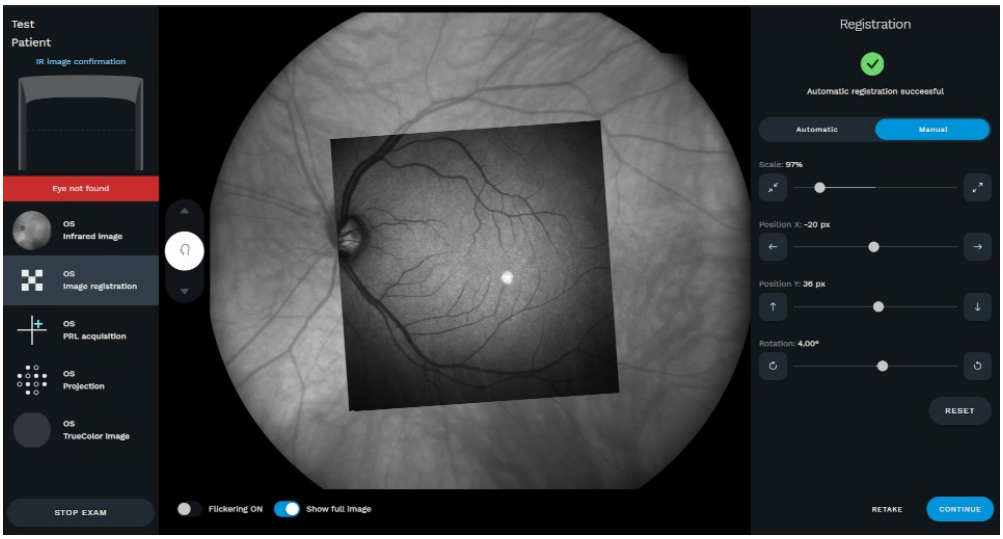


Fig. 81 - Targeted Exam: registration of the imported image over the IR reference image

The image registration process is based on a rigid roto-translation and scaling of the two images. Higher order distortions, e.g. due to a different optical system between MAIA and the device used to acquire the imported image, cannot be managed. In such cases, or in case one or both the images are of bad quality, perfect registration cannot be guaranteed.

It is the operator's responsibility to verify whether the registration is satisfactory.

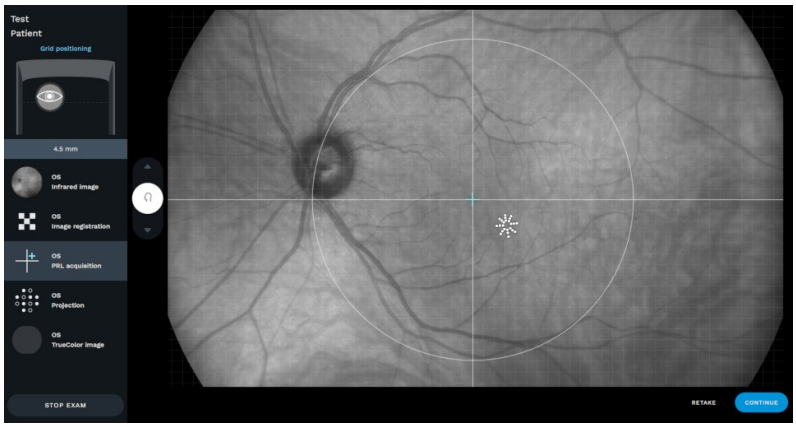


Fig. 82: Targeted Exam: preview of the test locations over the IR reference image

Once the exam is completed, the results are stored as a new exam in a sequence originated by the initial, blank "Targeted Exam" (see Fig. 83). Press on the exam thumbnail to review the exam results (see §15.10).

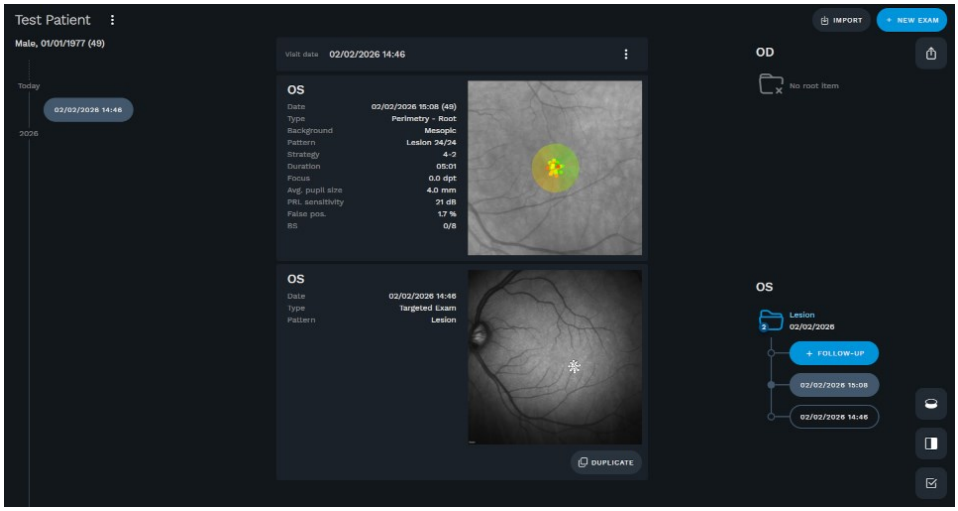


Fig. 83 - Patient Record screen: ***Microperimetry - Root*** exam (above) started from a ***Targeted Exam*** (below)

15.8 Reviewing the results

The **Exam Review** screen for a Targeted Exam (see Fig. 84) provides the same information and functions as for other exam types:

- on the left side: Patient data, Test Strategy, review screen selectors and buttons, and exam data on the left side
- at the center: scrollable and zoomable retinal image, overlaid with the layers activated using the selectors and buttons available on the left side
- on the right side: Average Threshold, Threshold Frequencies Histogram, Percent Reduced Thresholds, Fixation Stability, BCEA and Fixation Graph sliders and charts, together with the buttons to open the Time Analysis, delete and export the exam
- at the bottom of the screen: a list of buttons representing the exams of the same sequence represented on a chronological timeline, to quickly jump to the review of other exams, together with the button to start a new Follow-up exam for this sequence

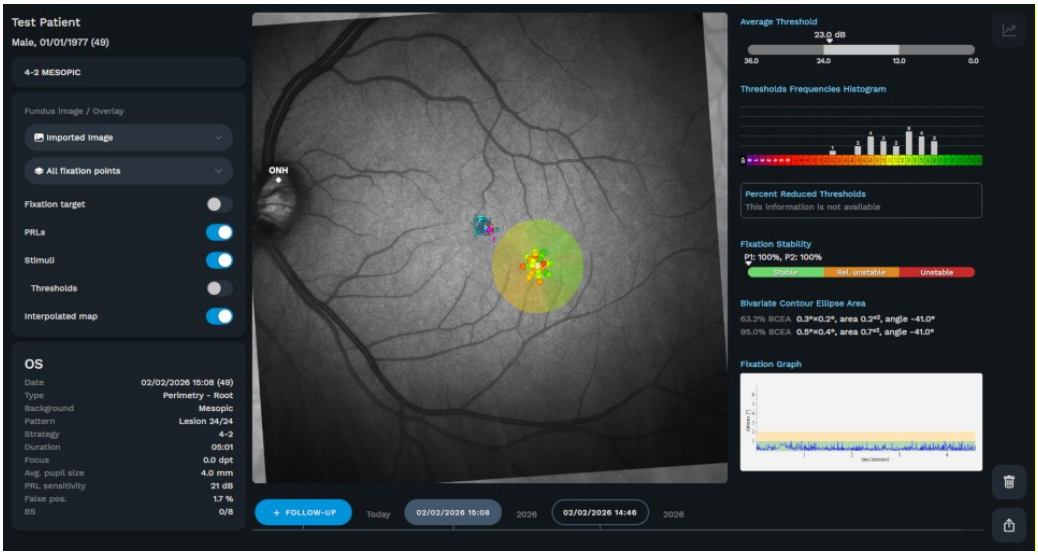


Fig. 84: Exam Review screen for a Targeted Exam

For more details about these information and functions, refer to §12.

The only difference in the Exam Review screen compared to other types of exams is in the **Fundus Image / Overlay** selector, which now adds the ***Imported Image*** to the available images to be displayed for the review (see Fig. 85).

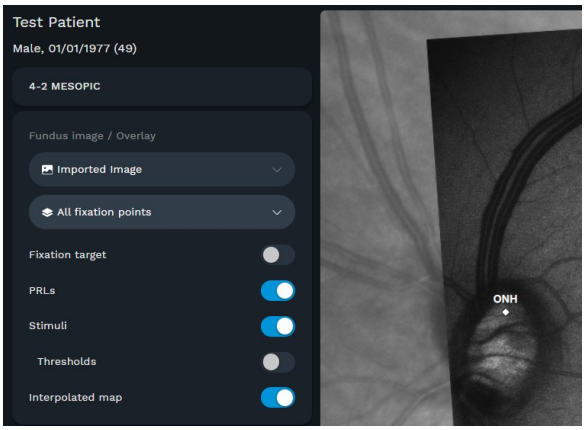


Fig. 85 Exam Review screen for a Targeted Exam: selection of which image to display

15.8.1 Image Review and Perimetry Review screens for Targeted Exams

The Image Review and Perimetry Review screens for Targeted exams provide the same information and functionalities as for the other exam types (for more details about these information and functions, refer to §12.3 and §12.4).

When displaying the IR or TrueColor images, it is possible to display the imported image registered and overlaid by activating the  button, as shown in Fig. 86 below:

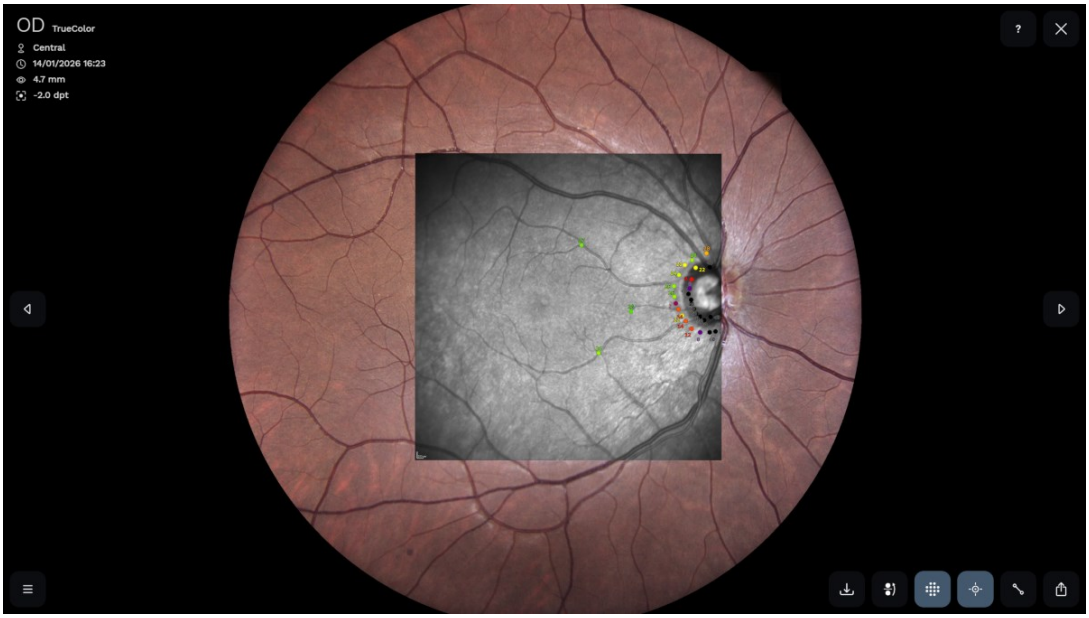


Fig. 86 - Exam Review screen for a Targeted Exam, with the imported image overlaid

When applying image filters to a MAIA image with the imported image overlaid, the filters are applied to MAIA's image only, while the imported image remains unaltered.

15.8.2 Dual Image review

It is possible to display the imported image also within the Dual Image Review screen, both in the original form or overlaid over MAIA's IR or TrueColor image (see Fig. 87).

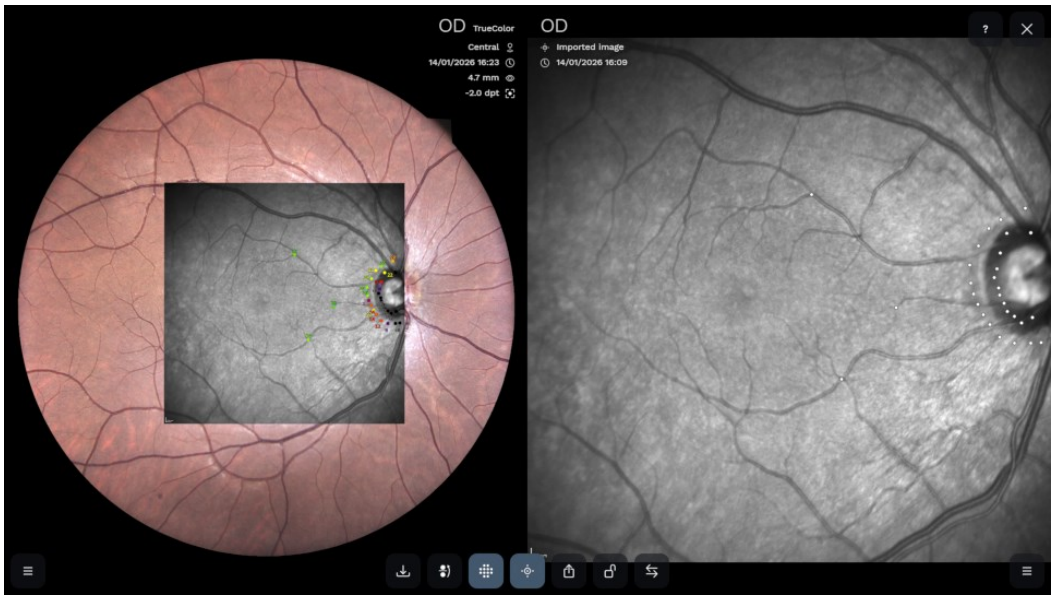


Fig. 87 - Dual Image Review screen for a Targeted Exam,
with the imported image overlaid (left) or in the original form (right)

The imported image can be selected and used within the Dual Image Review screen, but cannot be selected or displayed within the Image Flickering screen.

15.9 Exporting the results

The exam results of a Targeted Exam can be exported using the  button, as per the other exam types. For more details about the export interface and options, refer to §12.6. In this chapter, only the differences introduced in the Targeted Exams exported results are described.

15.9.1 PDF Printout

The PDF report printout displays the same information as all the other exam types. For more details about the information provided in the report printout, refer to §14.

If the imported image is selected for display in the Exam Results viewer, the zoomed view of the test pattern with thresholds, the Interpolated Map and the Fixation plot will display the imported image overlapped over MAIA's IR reference image (see Fig. 88).

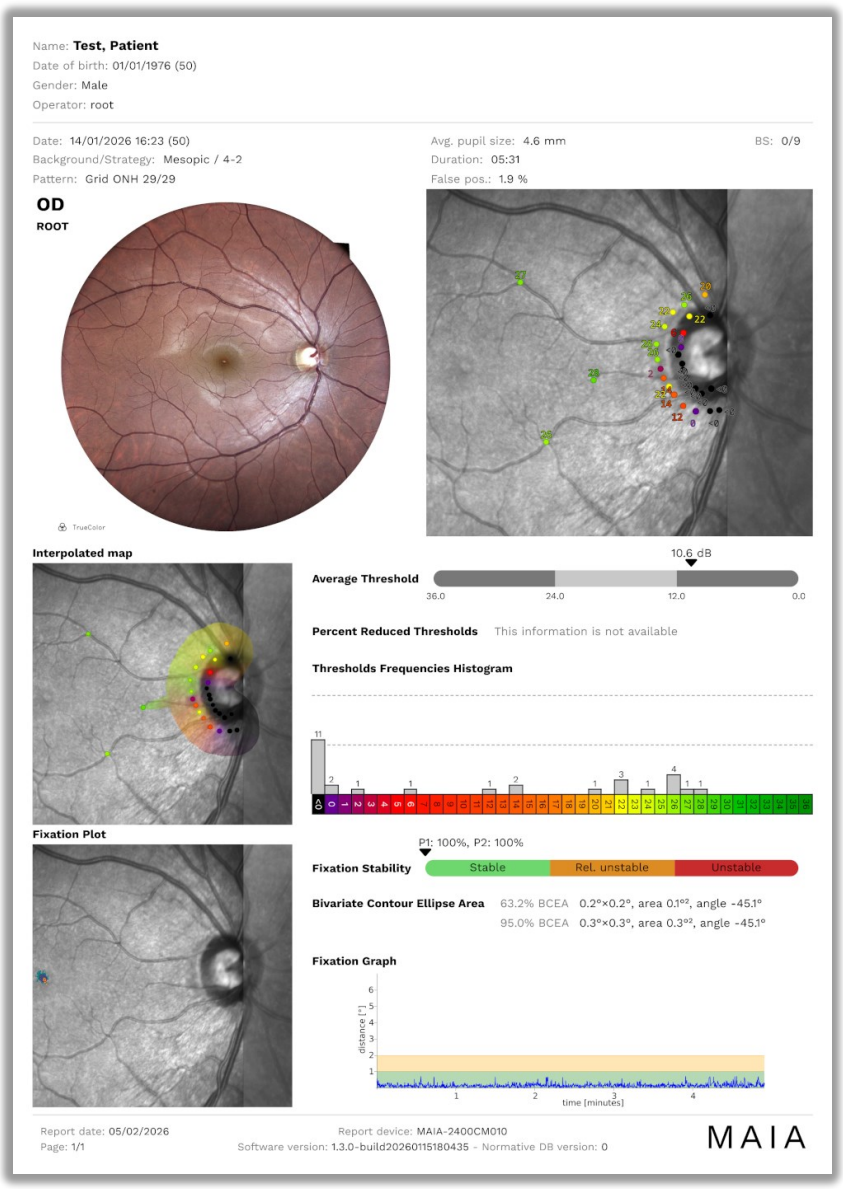


Fig. 88: Exam report printout for a Targeted Exam, when the imported image is displayed in the viewer

15.9.2 DICOM format

When a perimetry report for a Targeted Exam is exported in DICOM format, the data structure of the resulting file is the same as for any other MAIA exam, with the addition of the imported image included in the file.
Specifically, the imported image (edited to be registered over MAIA's IR reference image) is stored within the DICOM perimetry object, in the private tag (9001, 1006).

15.10 Targeted Grid JSON Schema

The JSON containing the list of locations to be tested shall validate against the following JSON Schema:

```
{
  "$schema": "https://json-schema.org/draft/2020-12/schema",
  "description": "The grid associated to a Targeted Exam",
  "type": "object",
  "properties": {
    "label": {
      "type": "string",
      "description": "Optional label for the Targeted Exam grid (max length 20 characters)",
      "minLength": 1,
      "maxLength": 20
    },
    "points": {
      "type": "array",
      "description": "List of points in the Targeted Exam grid",
      "items": {
        "description": "Targeted Exam Point",
        "type": "object",
        "properties": {
          "id": {
            "description": "Optional unique identifier for the point in the grid. This identifier
should be unique within the grid and be a positive integer. Either all points have an ID or none of
them do.",
            "oneOf": [
              {
                "type": "integer",
                "minimum": 1
              },
              {
                "type": "null"
              }
            ]
          },
          "x_perc": {
            "description": "X coordinate of the grid point as a percentage of the image width (0 to
1). The coordinate system has its origin at the top-left corner. A precision of 5 decimal places is
recommended for accurate representation of the point location.",
            "type": "number",
            "minimum": 0,
            "maximum": 1
          },
          "y_perc": {
            "description": "Y coordinate of the grid point as a percentage of the image height (0 to
1). The coordinate system has its origin at the top-left corner. A precision of 5 decimal places is
recommended for accurate representation of the point location.",
            "type": "number",
            "minimum": 0,
            "maximum": 1
          },
          "starting_intensity": {
            "description": "Optional starting intensity for the point (in dB). This option is
compatible only with a 4-2 staircase strategy. This value will be bounded by the strategy's minimum
and maximum intensity limits.",
            "oneOf": [
              {
                "type": "integer",
                "minimum": 0
              },
              {
                "type": "null"
              }
            ]
          }
        },
        "required": [
          "x_perc",
          "y_perc"
        ]
      }
    }
  },
```

```
  "required": [
    "points"
  ],
  "examples": [
    {
      "points": [
        {
          "x_perc": 0.235,
          "y_perc": 0.789
        },
        {
          "x_perc": 0.584,
          "y_perc": 0.345
        }
      ]
    },
    {
      "label": "Targeted Grid 1",
      "points": [
        {
          "id": 1,
          "x_perc": 0.235,
          "y_perc": 0.789,
          "starting_intensity": 20
        },
        {
          "id": 2,
          "x_perc": 0.584,
          "y_perc": 0.345,
          "starting_intensity": 22
        }
      ]
    }
  ]
}
```

16 DEVICE SHUTDOWN

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

It is also possible to switch off by pressing the Power button on the back of the device (see Fig. 2): the green power status LED will switch on; pressing it again will make a confirmation dialog appear on the display: press ok to start the shutdown procedure. If no actions are performed after pressing the power button, the device shuts down automatically after 10 seconds.

17 DEVICE CONTROLS

17.1 Navigation Bar

Upon login, the *Navigation Bar* shown in Fig. 89 appears on all the screens.

Fig. 89 – Navigation Bar

The Navigation Bar functionalities follow:

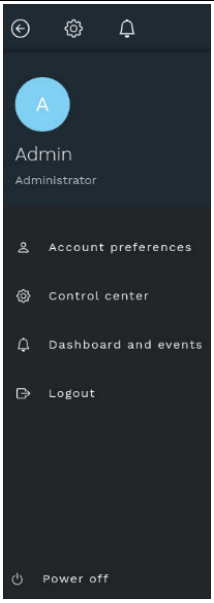
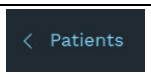
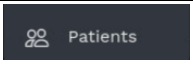
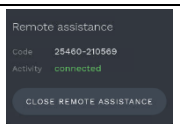
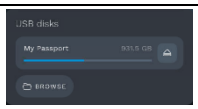
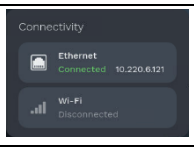
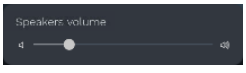
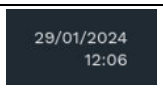
Function	Command	
Menu Browse the main device management options: preferences, Control center, Dashboard, Logout, and Power off. The **Power off** button does not appear in the Remote Viewer.		
Control center Open the *Control center* Screen (§17.3), allowing access to Settings, Utilities, Maintenance and About screens.		
Open the **Dashboard**		
Patients Go back to the patient detail or patient screen		
Open the **Patient List**		
Show the **Remote assistance** information This icon appears when you request remote assistance.		
Announcements Show the announcements published by iCare server, like online software updates or availability of new features.		
View the **USB disks** connected for image export, if any. This icon disappears if no USB device is plugged in.		
Connectivity View the current status of ethernet and wireless connections.		
Speakers volume Set the volume of the audio notifications.		
Date and time View the date and time of MAIA		

Table 2 – Navigation bar options

17.2 Dashboard

To access the *Dashboard* Screen, click the **Dashboard** button on the *Navigation Bar*.	

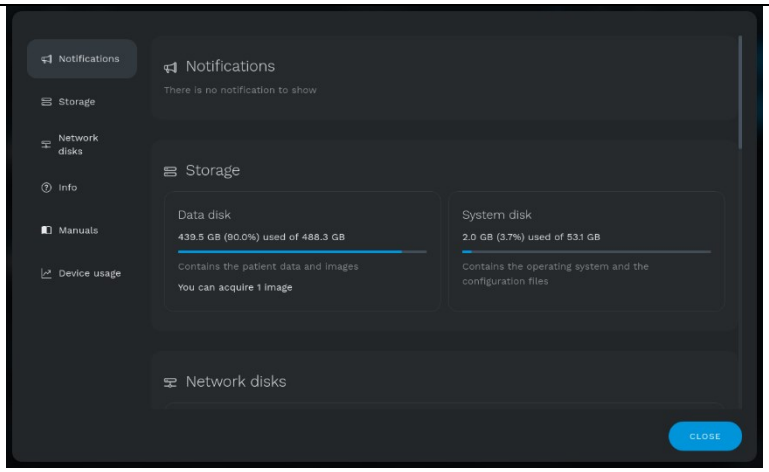


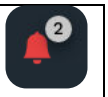
Fig. 90 – Dashboard Screen

The *Dashboard* contains a comprehensive review of the *Notifications* (§17.2.1), the storage on the device, the configured services like Backup destinations, Network disks and iCare Cloud, the Info of the device, the Manuals, and the usage statistics, to show at a glance all the information regarding the device operativity. For details refer to the *About* Screen (§17.5).

17.2.1 Notifications

The *Notifications* are all the information regarding an event, a warning or an error.

Within its operation activity, the device can generate notifications that are displayed to the operator through pop-ups and toasts (see Fig. 91). When such an event happens, the color of the **Dashboard** icon changes and becomes grey for an event, orange for a warning or red for an error. A number on the top right of the icon tells how many unseen notifications are present.

Click the **Dashboard** icon in the *Navigation Bar* to view the last notifications	

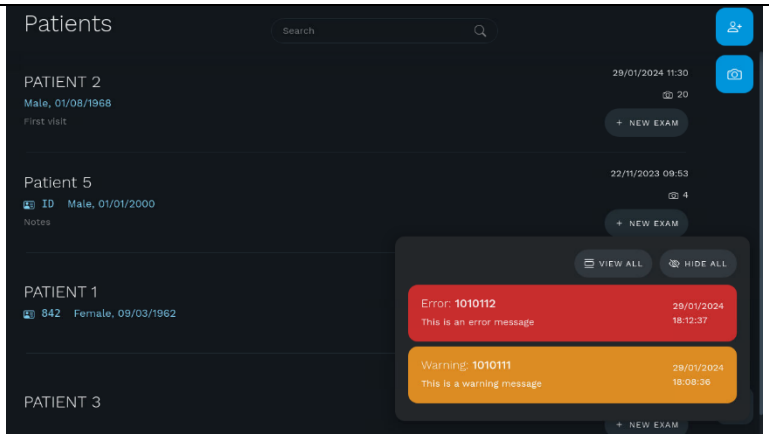


Fig. 91 – Examples of toasts for warning and error categories

Click **HIDE ALL** to close the toast. In this case, the notification is marked as viewed.

In case of critical errors, the notification is displayed as a blocking pop-up like the following:

Fig. 92 – Example of a critical error blocking pop-up

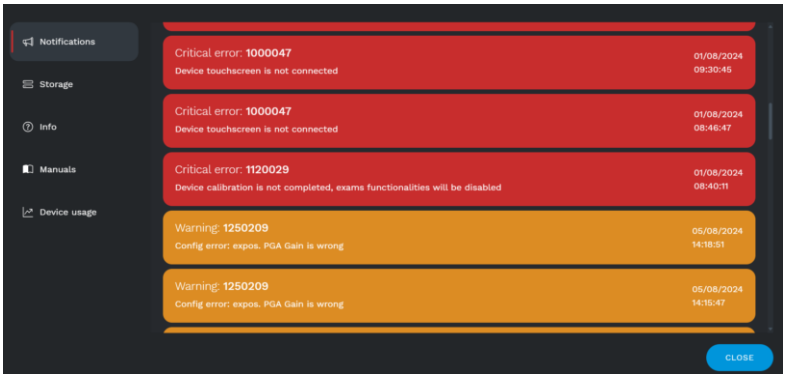


Fig. 93 – Notifications list Panel

After a critical notification, the dashboard icon remains highlighted.

From this panel, all the notifications can be marked as viewed.

In case of critical malfunctions, the hardware module might enter a “locked” condition which prevents from performing exams, and the message in Fig. 94 appears. If this happens, it is necessary to press the UNLOCK HARDWARE button to restore the functionality: the hardware will re-initialize. If the problem persists after unlocking or occurs frequently, contact an Authorized Service Center to receive assistance.

Fig. 94 – Critical error, requiring to unlock the hardware

17.3 Control Center

To access the *Control center* Screen, click on the **Control center** icon in the *Navigation Bar*.	

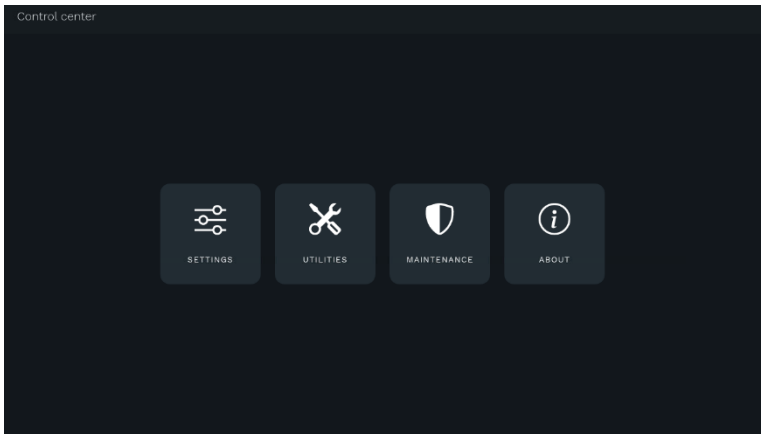


Fig. 95 – Control Center Screen

From the Control Center, you can access the following Screens:

- *Settings* (§17.5.1)
- *Utilities* (§19)
- *Maintenance* (§17.4)
- *About* (§17.5).

The first three screens will be described in dedicated paragraphs.

17.4 Maintenance

The *Maintenance* Screen provides (see Fig. 96):

- two logs viewers (the System and the Audit logs) which are useful for *service* purposes
- the registry of the exported patient data (Export registry)
- an interface to manually check the status of the Projection System

To access the *Maintenance* Screen, click the **MAINTENANCE** button on the *Control center* Screen.	

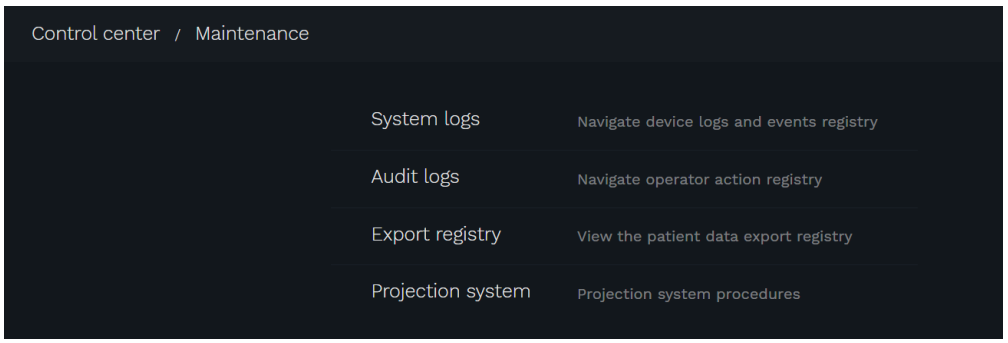


Fig. 96 – Maintenance Panel

17.4.1 System logs

The *System Logs* Screen shows the logs generated by either the operating system or the application software. They are divided into the following categories:

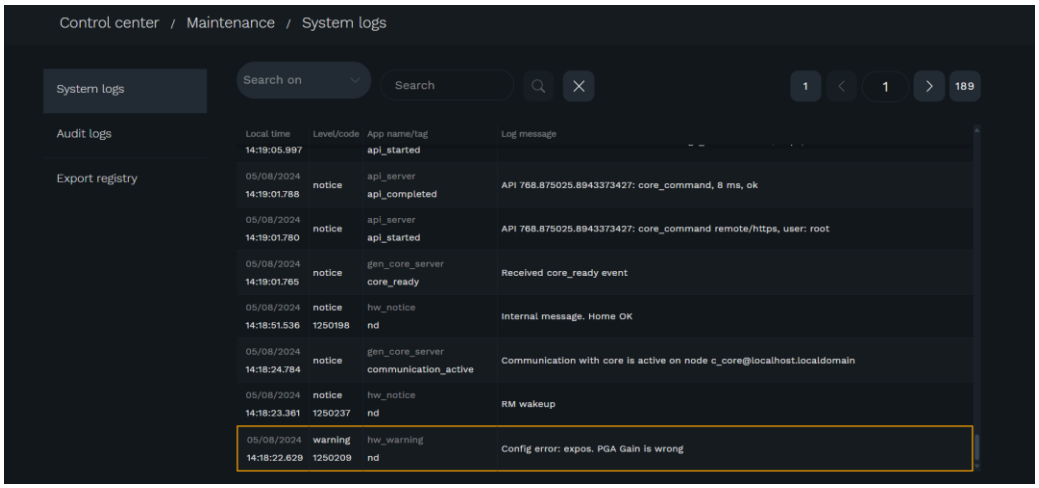
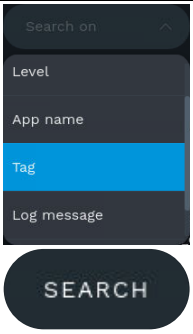


Fig. 97 – System logs Screen

Notice: messages informing that a run-time event, such as startup or shutdown, has occurred. 10/06/2022 15:38:46.474 notice web_sessions_server active_sessions Local: 0, remote: 1
Warning: message informing about situations that might have an adverse performance implication. 10/06/2022 15:38:46.474 warning gen_core_server terminating Reason for termination hw_core_terminating
Error: messages that inform about serious errors that anyway might allow the application to continue running. 10/06/2022 15:38:46.474 error sdr erlang_server_crash CRASH REPORT: name/pid cv_hw_core_server/<0.31197.0> - error_info : {exit, bin_crash, [{gen_server, handle_common_reply, 8, [{file, 'gen_server.erl'},{line, 751}]}, {proc_lib, init_p_do_apply, 3, [{file, 'proc_lib.erl'},{line,249}]}]}
Critical: messages that inform about severe errors that can cause the application to terminate. 10/06/2022 15:38:45.098 critical core core_process_crashed Core process crashed

By default, messages appear in chronological order (the newest at the top of the list) grouped in pages.

Use the **arrows** to change the page.	
Press **Search on** to change the grouping option. Select among: Local time, Level, App name, Tag, Log message and Error code. Press **SEARCH** to refresh the page according to your selection.	
Input a specific text in the **Search** field and then press **SEARCH** to find it.	
Press **RESET** to restore the default view.	

Click on a specific record to open a pop-up showing the related details (see Fig. 98). Push **CLOSE** to revert to the *System Logs* Screen.

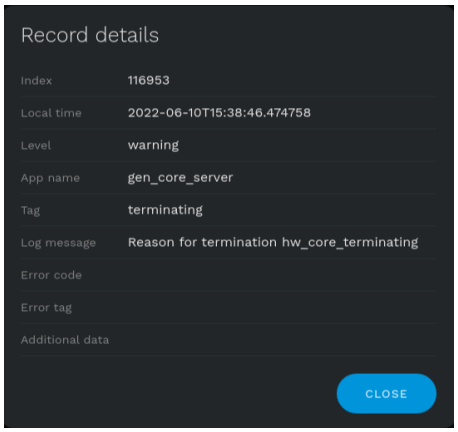


Fig. 98 – System Logs Record Details Dialog

17.4.2 Audit logs

The *Audit logs* Screen shows the activities performed on the device's interface (see Fig. 99).

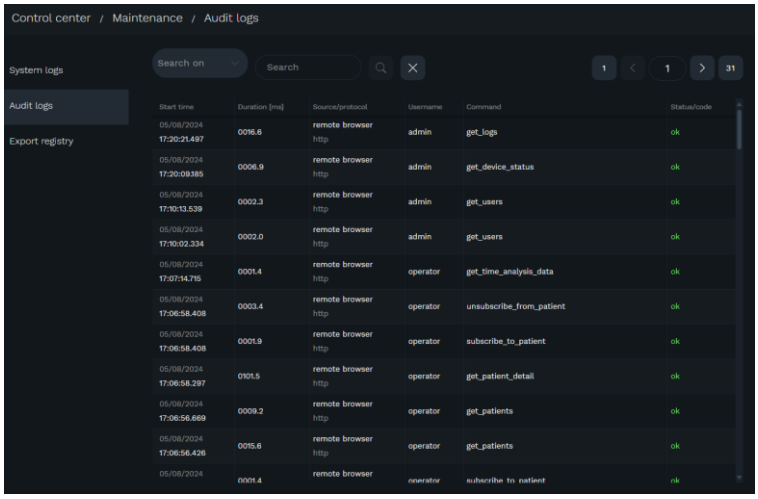
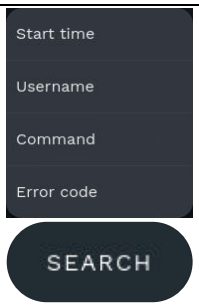
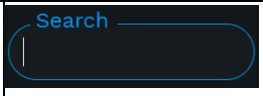


Fig. 99 – Audit Logs Panel

For each activity, the *Status code* shows the operation result, which can be either *ok* or *error*.

By default, messages appear in chronological order (the newest at the top of the list) grouped in pages.

Use the **arrows** to change the page.	
Press **Search on** to change the grouping option. Select among: Start time, Username, Command and Error code. Press **SEARCH** to refresh the page according to your selection.	
Input a specific text in the **Search** field and then press **SEARCH** to find it.	
Press **RESET** to restore the default view.	

Click on a specific record, to open a pop-up showing the related details (see Fig. 100). Push **CLOSE** to revert to the *Audit Logs* Screen.

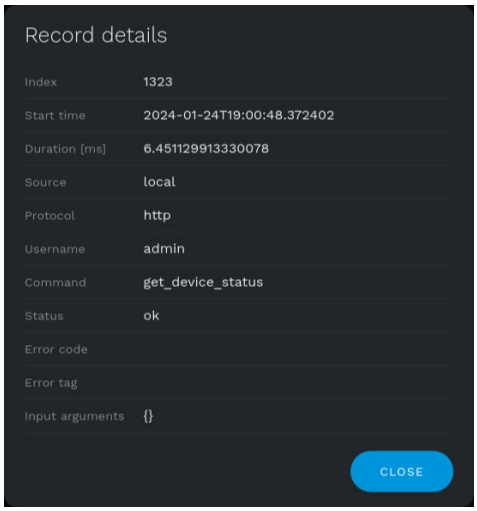
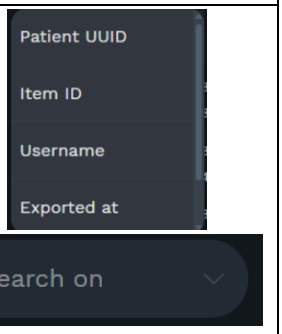
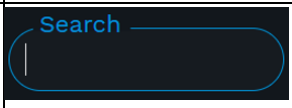
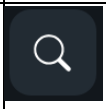
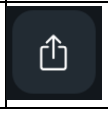


Fig. 100 – Audit Logs Record Details Dialog

17.4.3 Export Registry

The *Export Registry* shows the history of the exported date (Fig. 101).

By default, data appear in chronological order (the newest at the top of the list).

Use the **arrows** to change the page.	
Press **Search on** to change the grouping option. Select among: PaitientUUID; Item ID; Username; Patient; Exported date; Destination.	
Input a specific text in the **Search** field and then press **SEARCH** to find it.	
Press **SEARCH** to refresh the page according to your selection.	
Press **RESET** to restore the default view.	
Press **EXPORT** to export all the data in a connected USB drive as .csv file.	

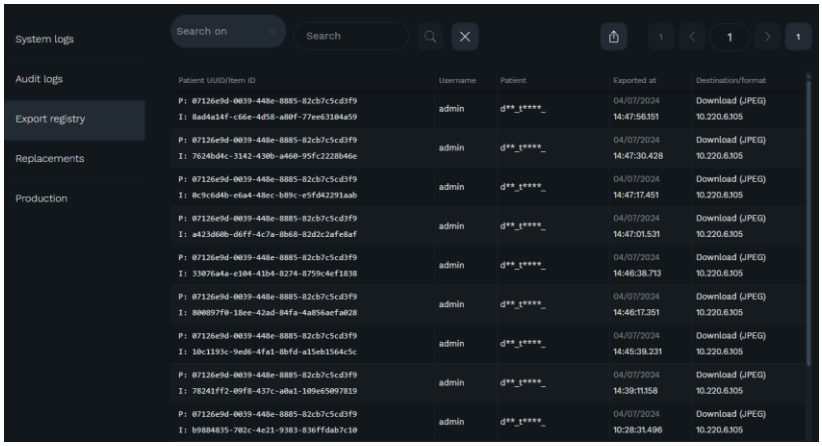


Fig. 101 – Export Registry

17.4.4 Projection System

The *Projection System* page allows to have a visual check of the status of the stimuli Projection System, by inspecting directly the position of the stimulus with respect to the fixation target. Press the START VERIFICATION button to start the verification process (Fig. 102).

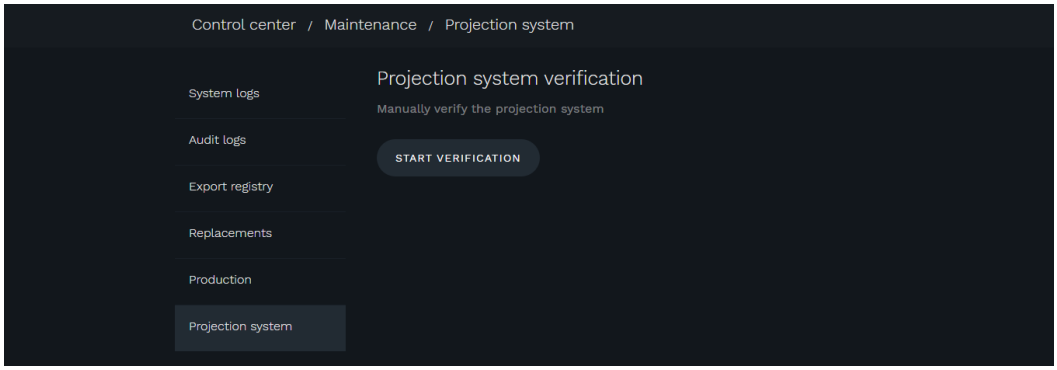


Fig. 102 – Projection System check page in the Maintenance menu

The optical head will move towards the right eye, the fixation target will switch on and the stimulus will start blinking to allow to estimate its position and its distance from the fixation target: if the Projection System is working properly, they should overlap at least partially.

Some examples of correct and incorrect positioning are displayed on the page (Fig. 103). Press on the image that represents best the stimulus condition and press PROCEED: the outcome of the procedure will be stored in the device's internal logs. If any of the NOT OK conditions are met, contact an Authorized Service Center to have your unit checked.

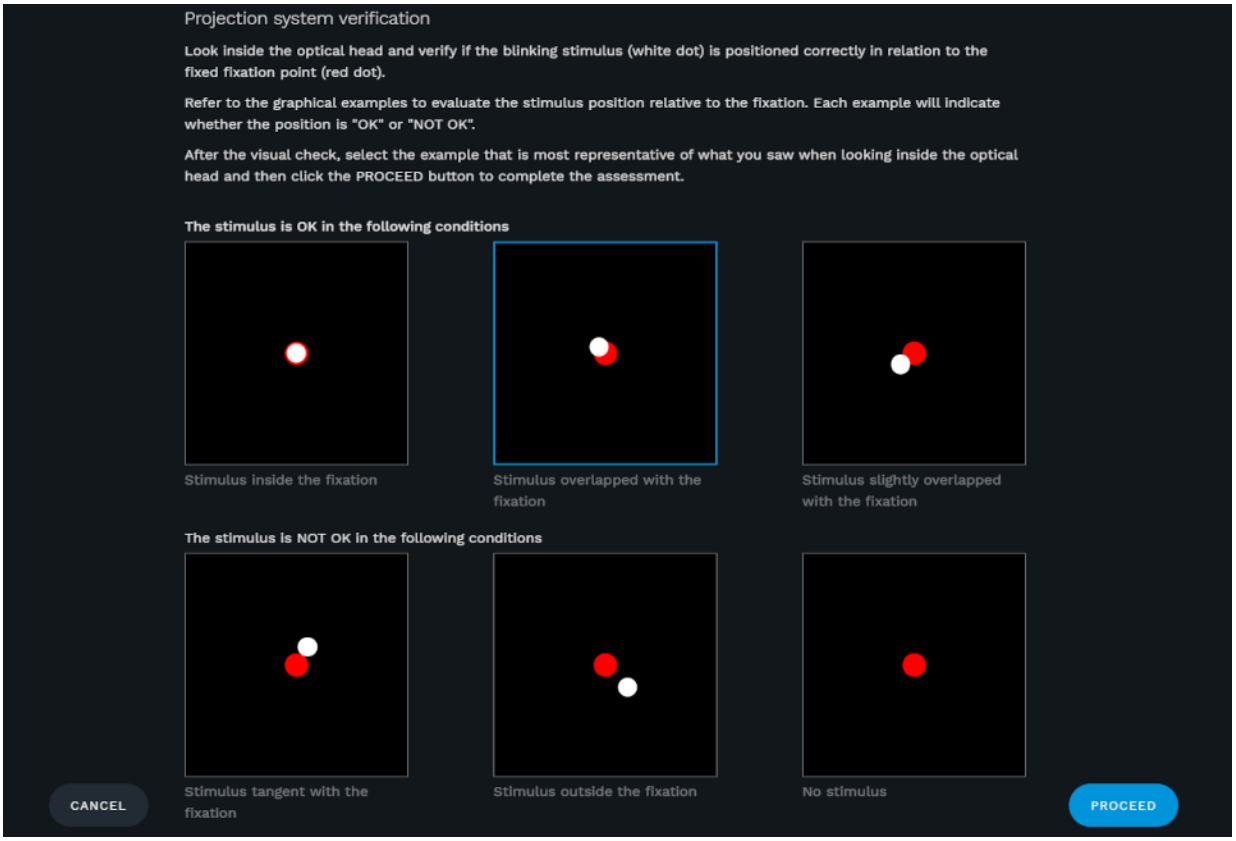


Fig. 103 – Projection System check page in the Maintenance menu

17.5 About Screen

The *About* Screen contains general information regarding the device.

To access the *About* Screen, click the **ABOUT** button on the *Control Center* Screen.	

The *About* Screen shows:

- The *Info* section containing the installed software version, the device's serial number and the status of the *End User Licence Agreement* (EULA). Push the button to review the EULA on the language of the Country configured on the **Configuration Wizard** Screen (see §**6.6**)
- The *Storage* section with the size and the amount of free space for the *Data disk* and the *System disk*
- The *Manuals* section containing all the available Manuals (see §17.5.1)
- The *Device Usage*, in terms of Patient records, Item records and graphical information of the number of exams performed in the last 180 days.

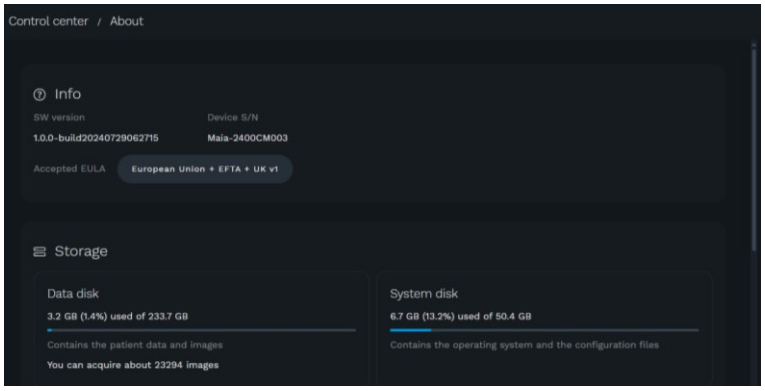


Fig. 104 – About Screen, About and Storage

The Manuals section is not available if during the configuration Wizard you have selected China as Country.

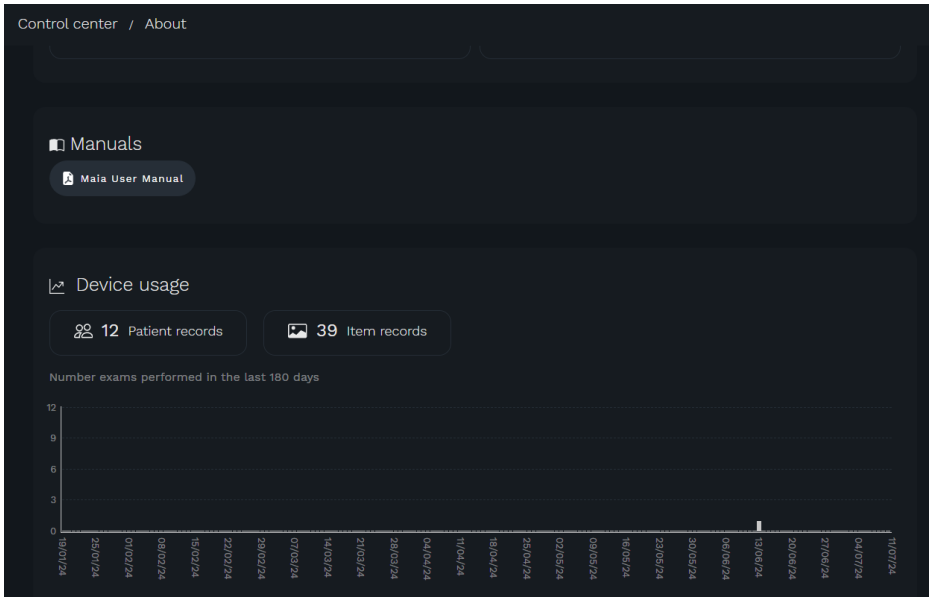


Fig. 105 – About Screen, Device usage

17.5.1 Manuals

The *Manuals* tab contains the Instructions for Use of MAIA. The Instructions for Use are available in the following languages: English, Italian, French, German, Spanish, Portuguese, Czech, Danish, Estonian, Greek, Hungarian, Lithuanian, Romanian, Slovak, Norwegian, Swedish, Finnish, Latvian.

Push **MAIA User Manual** to make the Instructions for Use appear on the screen in the language corresponding to the Country selected during the Wizard.

Push **SELECT A LANGUAGE** (see Fig. 106) to change the language of the Instructions for Use, push **CLOSE** to close the Manual.

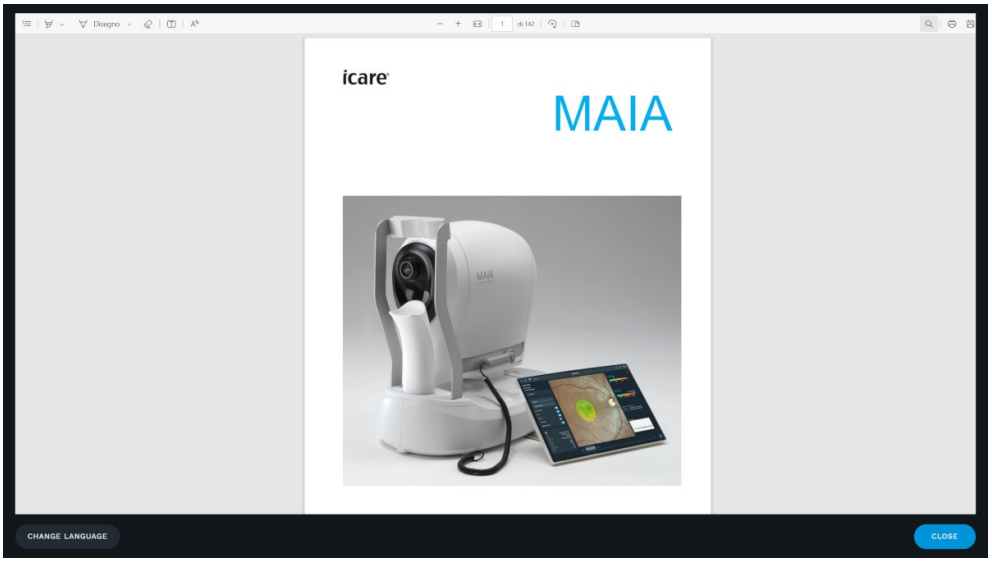
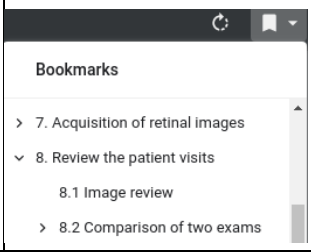


Fig. 106 – Manuals screen

Push **Bookmarks** to navigate the Manual Headings.	
Push **Fit to width / Fit to page** to adjust the zoom of the Manual to the width or to the height of the screen, respectively	
Push **Zoom in / Zoom out** to adjust the increase or decrease the zoom of the Manual, respectively.	

18 DEVICE SETTINGS

To access the *Settings* Screen, click the **Settings** button in the *Control Center* Screen.	

The menu on the left allows access to various configuration panels, described below. Some configuration panels are accessible or restricted, according to the user level.

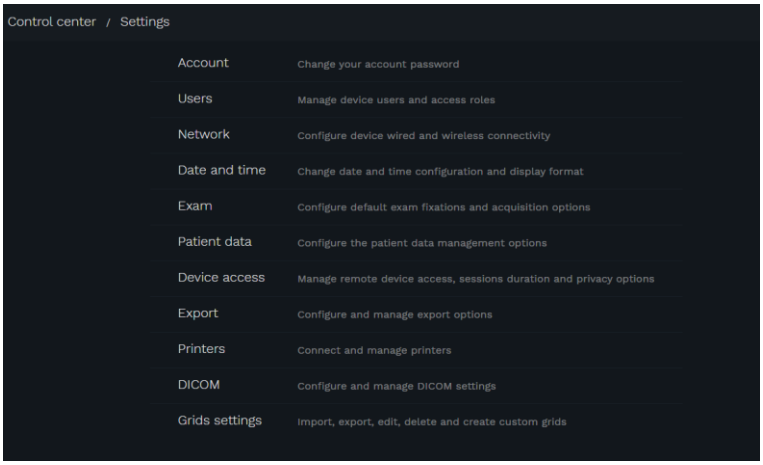


Fig. 107 – Settings Screen

18.1 Account

The *Settings|Account* Screen (Fig. 108) allows users to change their passwords.

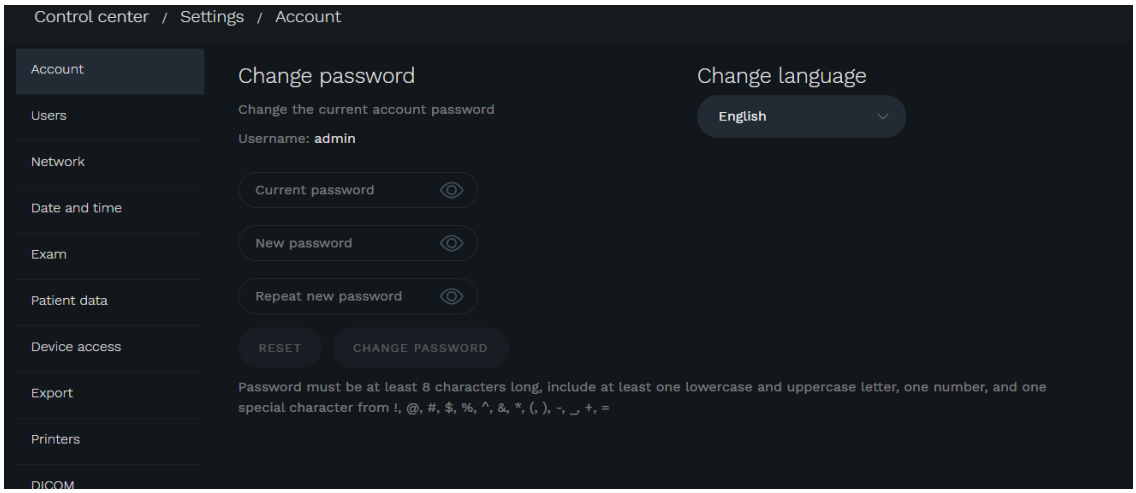


Fig. 108 – Settings|Account Screen

	You must know the current password to be able to change it.

You can change the interface language of the current user via a dropdown menu. Supported languages are English, Spanish, Italian, French, German, Portuguese, Japanese, Chinese, Korean, Russian, Czech, Swedish and Finnish.

18.2 Users

The *Settings*|*Users* Screen (Fig. 109) manages (creation, modification and deletion) the user accounts. It is accessible only by the Administrator.

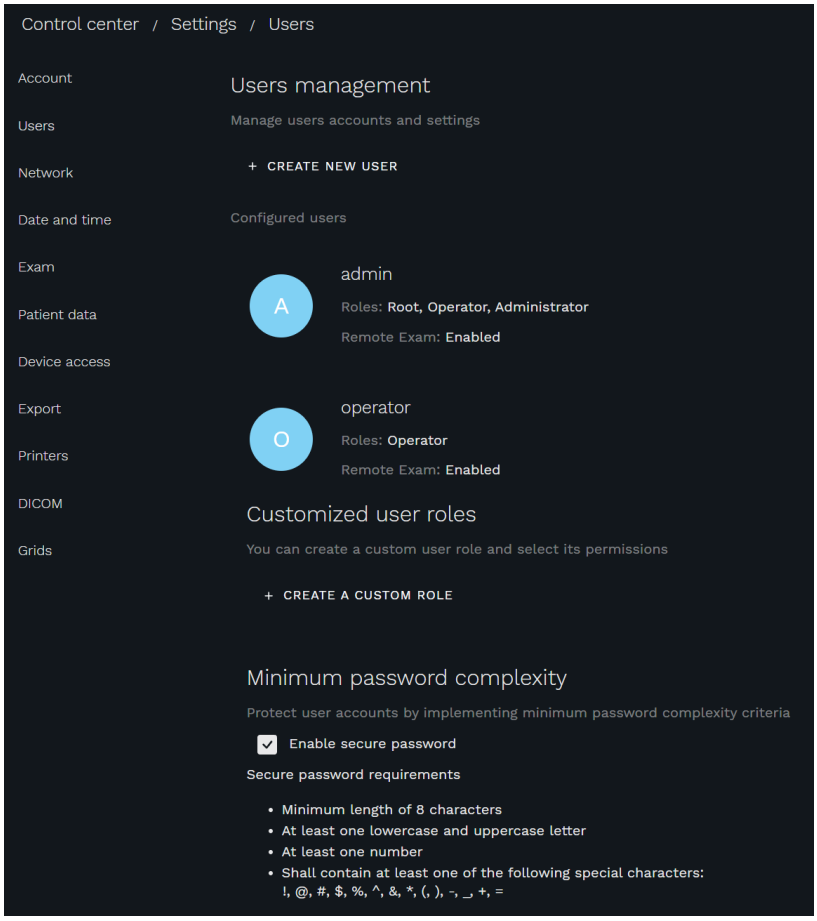


Fig. 109 – Settings|Users Screen

- The username must contain at least 4 characters
- The password must contain at least 6 characters; if the “Enable secure password” checkbox at the bottom of the page is ticked, the minimum length turns to 8 characters, and it must fulfill the mentioned constraints: at least one lowercase char, one uppercase char, one number and one special symbol

Push the **CREATE NEW USER** button to create a new user.	

In the *Create new user* Panel (Fig. 110), define Username and Password, Roles, and Language. Click **SAVE** to maintain the changes, click **CANCEL** to abort the creation of the new user.

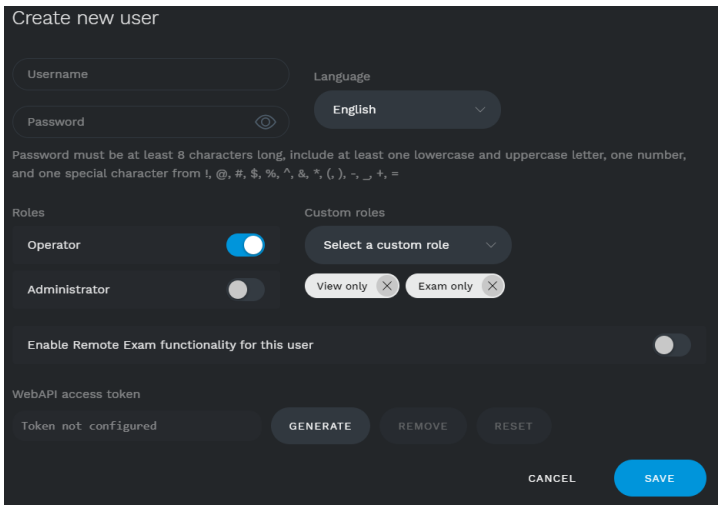
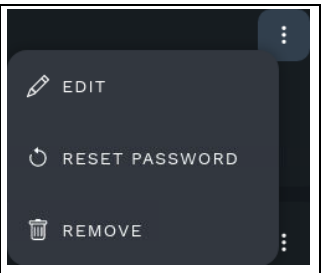


Fig. 110 – Create New User

To modify an existing user, pre ss the **ellipsis** (⋮) at the right of the user's box.	

Click **EDIT** to open the *Edit the user* Panel (Fig. 111).

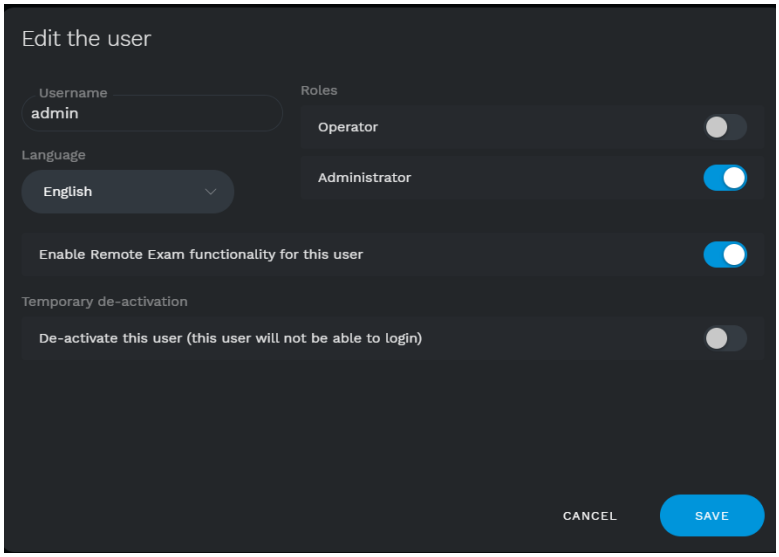


Fig. 111 – Edit the user Panel

You can change the Username, the Roles, and the Language, Enable or Disable the Remote Exam Functionality and Deactivate the user.

Click **SAVE** to save the changes, click **CANCEL** to abort the editing operation.

Click **RESET PASSWORD** to open the *Reset user password* Panel (Fig. 112).

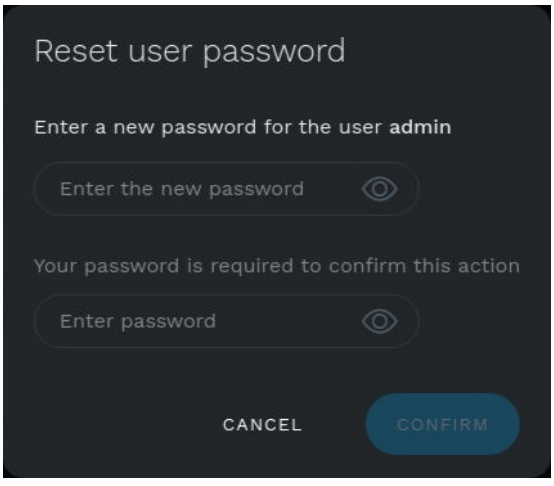
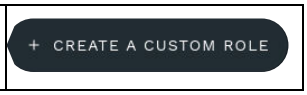


Fig. 112 - Reset user password Panel

You can modify the new password. Click **CONFIRM** to save the new password, click **CANCEL** to abort the operation.

Push the **CREATE A CUSTOM ROLE** button to create a new role with limited permissions.	

Select a name to describe the custom role in the *Custom role description* box. Enable or disable the permissions, according to your needs. Click **SAVE** to create the role, click **CANCEL** to abort.

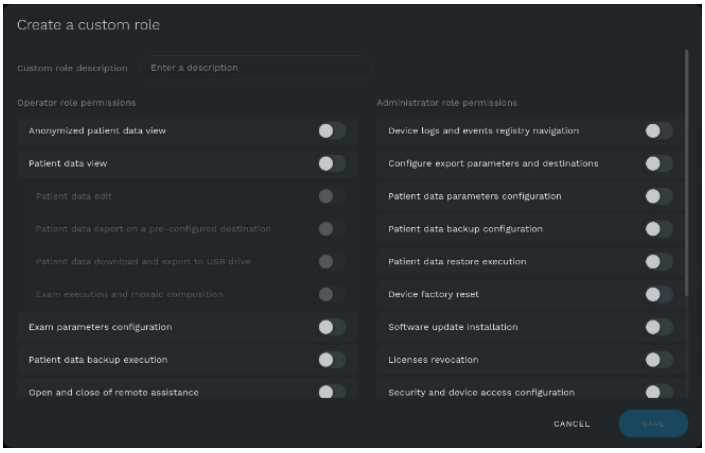


Fig. 113 - Creation of a custom role Panel

The two preset users **Administrator** and **Operator** have the permissions indicated in the next table.

Permission	admin	operator
Anonymized patient data view		
Patient data view		
Patient data edit		
Exam parameters configuration		
Exam execution		
Patient data export on a pre-configured destination		
Patient data download and export to a USB drive		
Patient data backup execution		
Open and close the remote assistance		
Networking configuration		
Licenses installation		
Enable and disable demo images		
Date and time configuration		
Device logs and events registry navigation		
Configure export parameters and destinations		
Patient data parameters configuration		
Patient data backup configuration		
Patient data restore execution		
Device factory reset		
Software update installation		
Licenses revocation		
Security and device access configuration		
Device configuration restore		

Table 3 – Permissions of the admin and operator users.

18.3 Network

To export and remotely review retinal images acquired by the device must be connected to responsible organization's IT Network. MAIA is designed such that network failures will not prevent the device from working normally.

MAIA supports both Ethernet connection and wireless connection.

Required characteristics and peripheric of the IT-network are:

- Printers: Configured printers as described in §14
- Compatible browsers for Remote Viewer: Google Chrome, Microsoft Edge, Mozilla Firefox, Apple Safari
- Supported wireless protocols: WEP, WPA, WPA2, WPA2 802.1X.
- Supported Shared Folder protocols: SMB/CIFS protocol, up to ver. SMBv3
- DICOM: DICOM compatibility is described in the DICOM Conformance

Statement

- The Intended Information Flows from the device to the IT infrastructure are:
- Printing of exam reports via a connected 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 exam and patient data from a personal computer connecting
- to the device via a web browser

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 MAIA 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.

Open the *Settings/Network* Screen (Fig. 114) to configure the network connection. Specify the primary network interface between Ethernet and Wi-Fi.

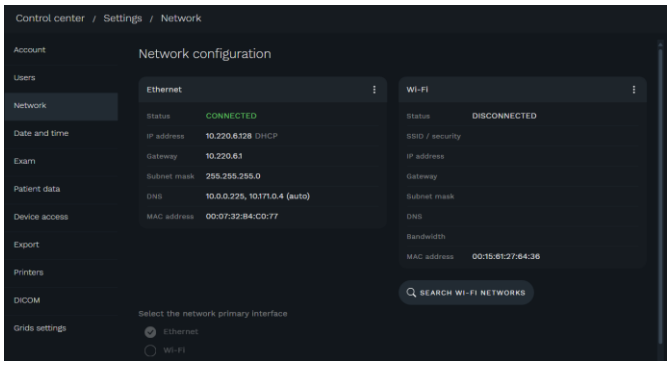
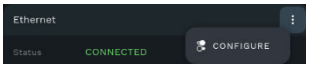


Fig. 114 – Settings/Network Screen

Press the **ellipsis** (⋮) at the right of the Ethernet box and then **CONFIGURE**.	

DHCP auto / manual settings can be configured. In this latter case, the IP address and DNS must be configured manually.

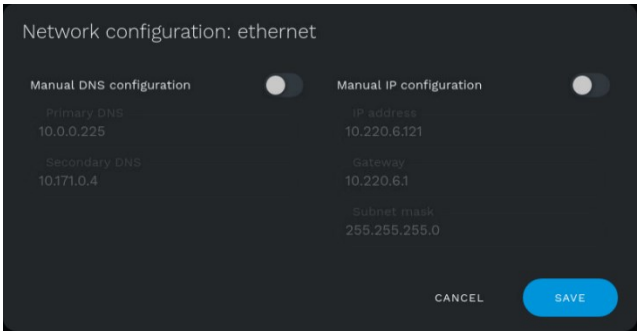
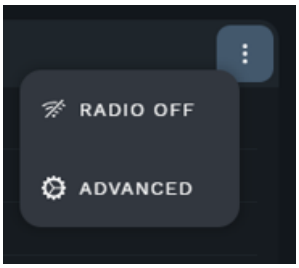


Fig. 115 – Ethernet connection settings

Wi-Fi connection

The network parameters (DHCP/manual, IP address and DNS) can be configured as per the Ethernet. MAIA supports the Wi-Fi authentication with WPA1/WPA2, WPA2 802.1X, WEP standard protocols.

Press the **ellipsis** (⋮) at the right of the Wi-Fi box. Click **RADIO ON/RADIO OFF** to enable or disable the Wi-Fi, **ADVANCED** to edit the advanced Wi-Fi properties (see Fig. 116)	

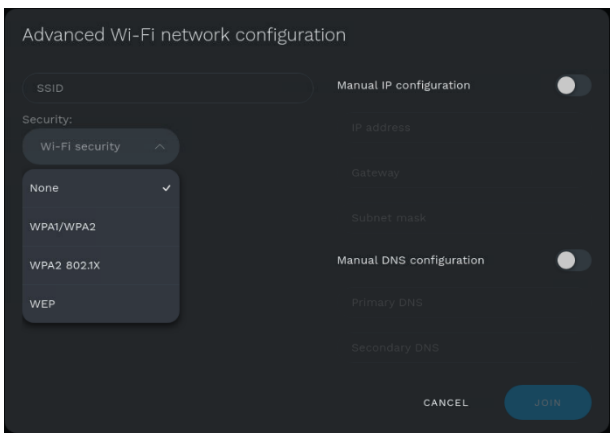
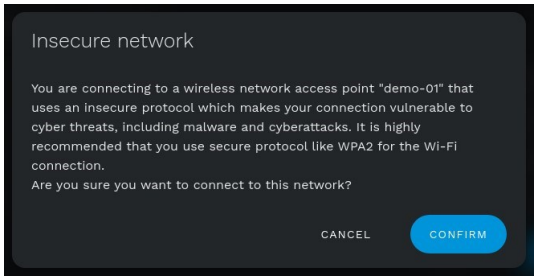


Fig. 116 - Advanced Wi-Fi panel

Push **SEARCH WI-FI NETWORKS** to scan for available Wi-Fi networks.	

Wi-Fi network that use a protocol WPA1 and WEP are considered unsecure connections. A warning will appear if you select one of those protocols.



Select the network primary interface between *Ethernet* and *Wi-Fi.*

Push **RESET NETWORK** to revert to the factory defaults.

Push **PING TEST** to verify the connection status in the *Ping* panel (Fig. 117).

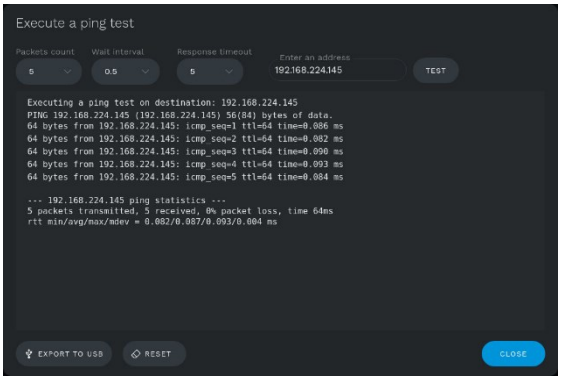


Fig. 117 – Ping Panel

Enter the *Address* and push **PING TEST** to verify. Click **RESET** to interrupt the test, click **CLOSE** to revert to the *Settings/Network* panel.

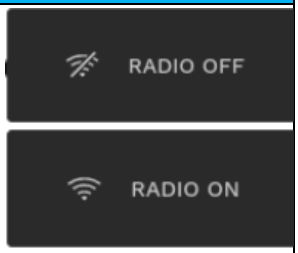
Function	Command
Enable/disable the Wi-Fi interface from the Wi-Fi **ellipsis** (⋮).	
Scan for available Wi-Fi networks	

Table 4 - Available functionalities

To check the network connection status, click on the icon in the top bar (Fig. 118). 

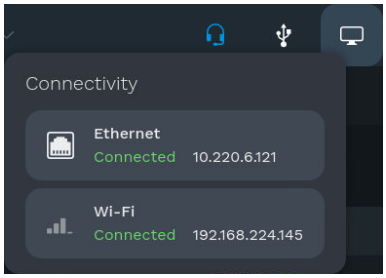


Fig. 118 – Example of wired and Wi-Fi network connection status

18.4 Date and time

Access the *Settings|Date and time* Screen (Fig. 119) to configure the date and time formats.

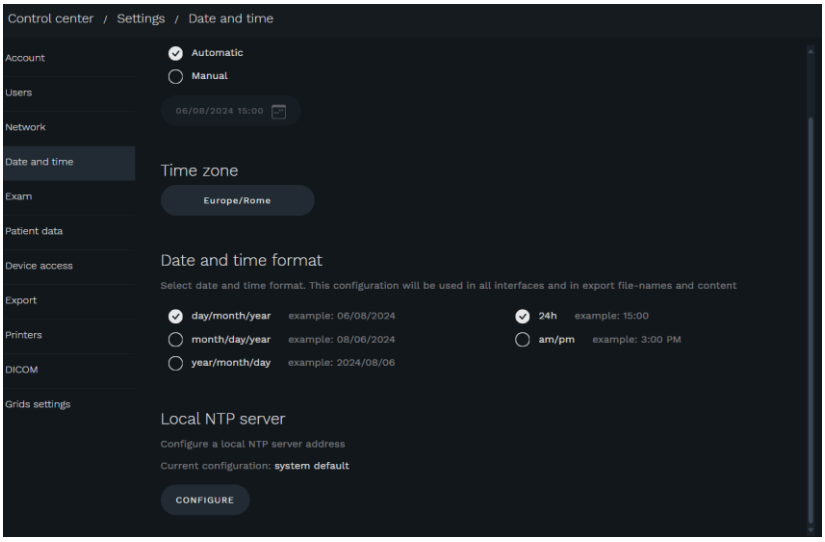


Fig. 119 – Settings|Date and time panel

In the *Date and time configuration* section, select between **Automatic** (requires Internet connection) or **Manual** date and time settings.

In the *Time zone* section, click on the currently selected one to set a time zone from the *Select a time zone* panel.

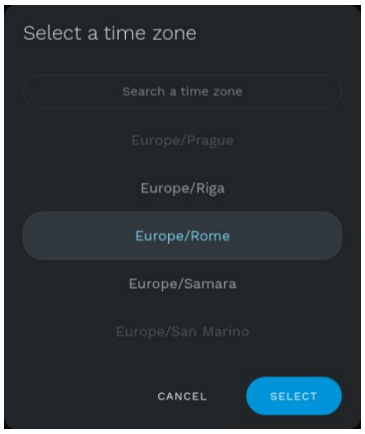


Fig. 120 - Select a time zone Panel

In the Date and time format section, set your preferred formats.

To provide the date and time to the device via an NTP server, push the **CONFIGURE** button in the Local NTP server section and insert the NTP server address.

18.5 Exam

Access the *Settings|Exam* Screen (Fig. 121) to select the exam default configurations for the Exam Configuration Screen. You will be able to override any of the preset configurations before starting the exam, as explained in §11.6.

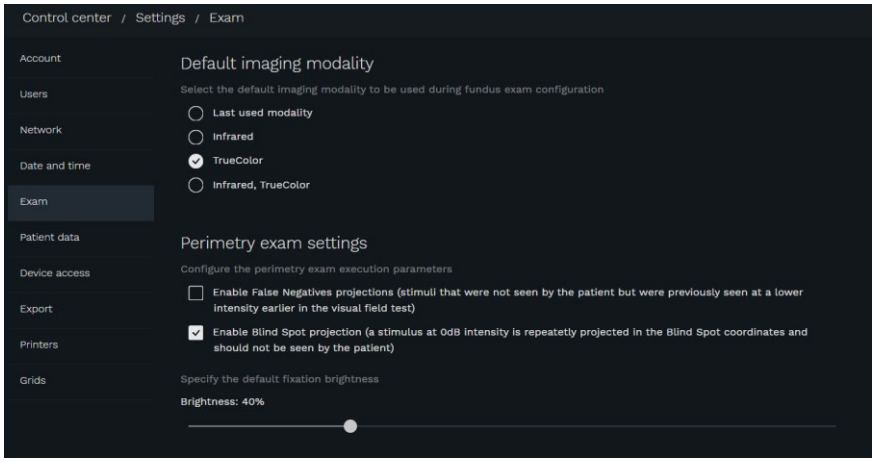


Fig. 121 – Settings|Exam

18.5.1 Default imaging modality

This option defines the modality selected by default when configuring a Fundus exam. Possible options are:

- Last used modality: last used imaging modality will be preset for the next exam;
- Infrared: the pre-set imaging modality is Infrared only;
- TrueColor: the pre-set imaging modality is TrueColor only. This option is the initial **default**;
- Infrared, TrueColor: the pre-set imaging modality is to acquire both Infrared and TrueColor

18.5.2 Perimetry exam settings

These options allow to enable or disable the False Negatives and Blind Spot projections used as reliability tests during the during the exams (refer to §12.1.1). By **default**, False Negatives projections are **disabled** and Blind Spot projections are **enabled**.

18.6 Patient data

Access the *Settings|Patient data* Screen to configure the patient data management options (Fig. 122).

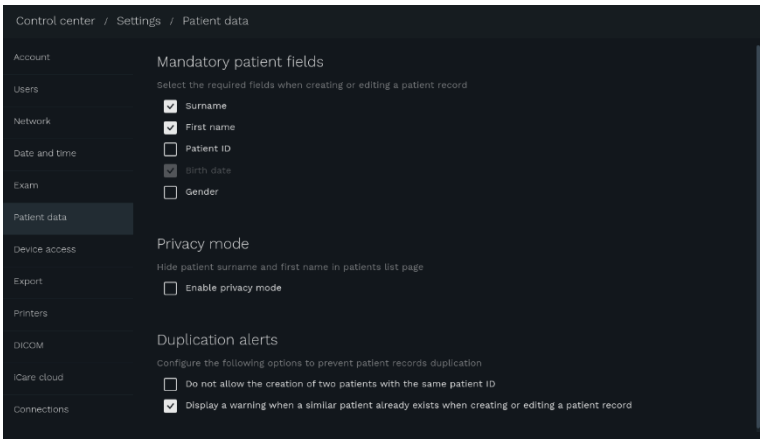
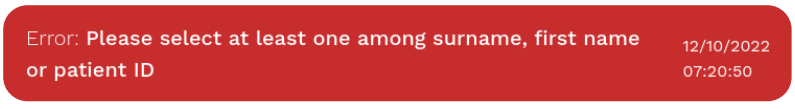


Fig. 122 – Settings|Patient data Screen Imaging modality and exposure

Set the **Mandatory** patient fields to fill when creating or editing a patient record. **At least one** field among Surname, First name, and patient ID must be selected.

An error message appears if you attempt to disable all the possible mandatory fields.



The *Privacy mode* setting allows enabling the privacy mode. When the Privacy Mode is activated, the Surname and Name of the patients are replaced by their initials followed by asterisks.

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

• 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-----
```

The *Duplication alerts* setting offers two options to prevent record duplication:

- Prevent the creation of multiple patients with the same patient ID by clicking on the upper box.
- Display a warning whenever a created or edited patient record is similar to an existing one with the inferior box.

18.7 Device Access

The *Settings|Device access* Screen (Fig. 123) allows you to configure the security options of the Remote Viewer, including the communication protocol and the session duration.

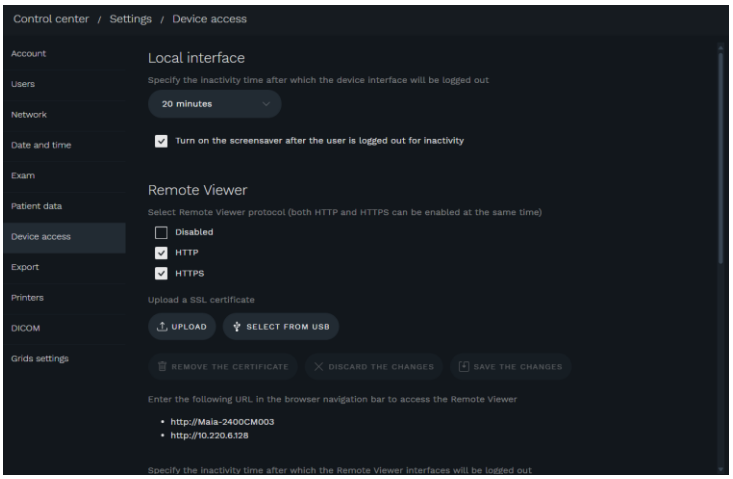


Fig. 123 - Settings|Device access Screen

For the *Local Interface*, select the inactivity time on the dropdown menu after which the device will log out the user. Activate or deactivate a screensaver when the inactivity time has expired. To resume work, you have to log in again.

For the *Remote Viewer*, select the communication protocol.

Select Disabled to temporarily disable the Remote Viewer for the device.

Select the HTTP and or the HTTPS protocol for the remote connection.

When you enable the “HTTPS” protocol, the device will use a self-signed HTTPS certificate. On your browser, accept the certificate once to dismiss the standard warning issued by all browsers.

You can however upload a custom certificate instead of the default one: to install it, store it into a USB device and plug it into the device, then press **SELECT FROM USB** and select the proper file.To remove an installed custome certificate, press the **REMOVE** button to uninstall it and revert back to the default device certificate.

Specify the inactivity time for the session running on the Remote Viewer.

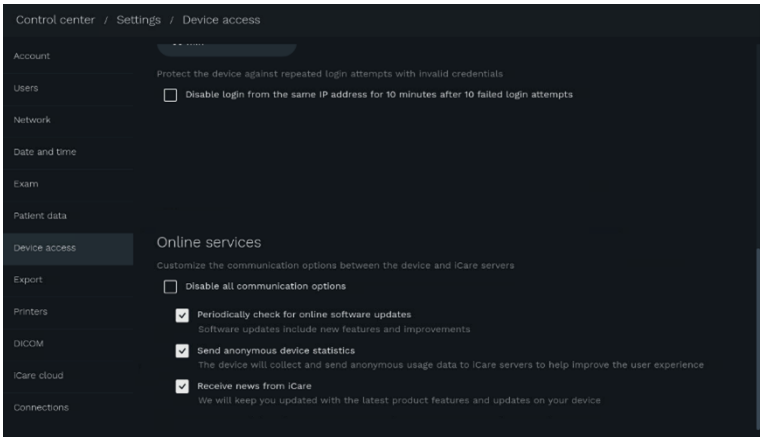


Fig. 124 - Settings|Device access Screen

As an additional security option, you can disable the login from a given IP address for 10 minutes after 10 attempts with invalid credentials.

The *Online services* customize the communication options between the device and the iCare servers. Enable or disable them according to your preferences. It is strongly recommended for security reasons to keep the *Periodically check for online software updates* always enabled.

18.8 Export

Open the *Settings*|*Export* Screen (Fig. 125) to configure the parameters of the export function.

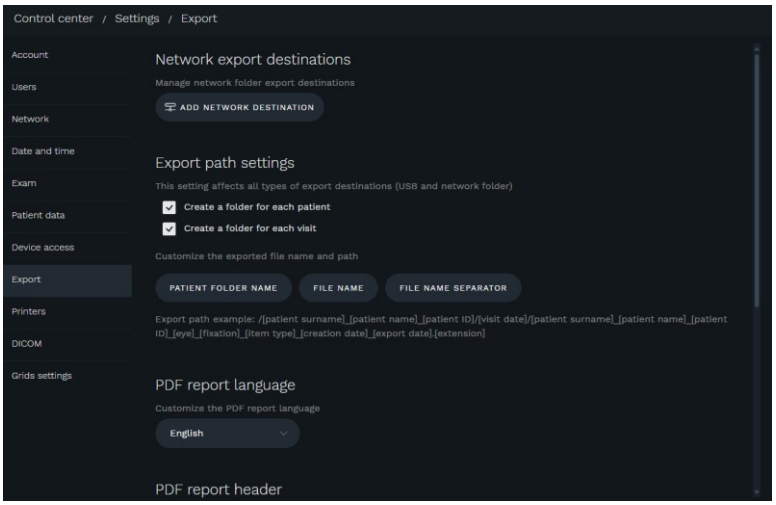


Fig. 125 - Settings|Export Screen, Network Export destination section

Push **ADD NETWORK DESTINATION** to open the *Add new network export destination* Panel and define the shared folder.

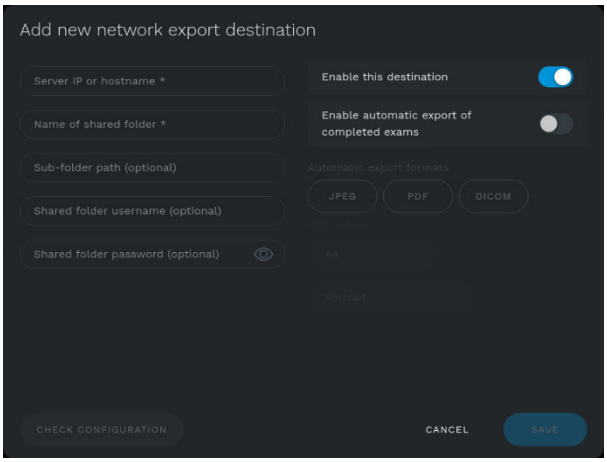


Fig. 126 - Add new network export destination panel

Insert the *Server IP or hostname* and the *Shared folder*, optionally fill the other fields. You can enable or disable the destination and the automatic export of completed exams.

Push **CHECK CONFIGURATION** to verify the connection, **SAVE** to complete the configuration, **CANCEL** to abort.

In the *Export path settings* section, select how to group the exported data (with or without a patient folder, with or without a visit folder).

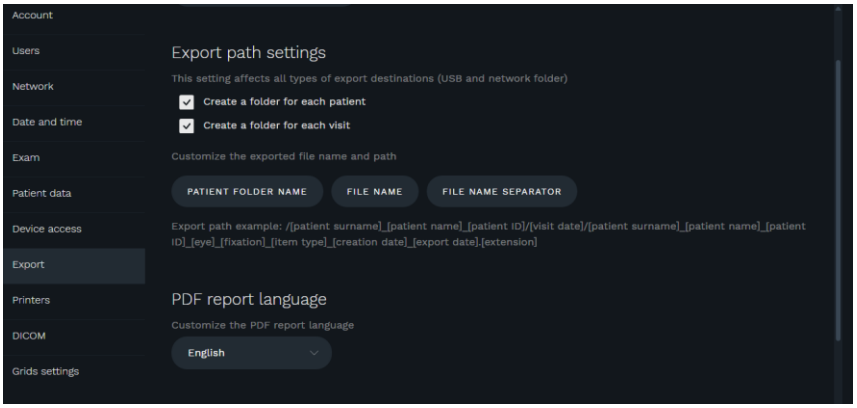


Fig. 127 - Settings|Export Screen, the Export path settings section

Separately customize the **PATIENT FOLDER NAME**, the **FILE NAME** and the **FILE NAME SEPARATOR**.

Default Filename formats are:

18.8.1.1 Single-image file name

The default file name is composed as follows:

[Surname]_[FirstName]_[PatientID]_[Eye]_[Field]_[ImageType]_[ImageDate]_[ExportingDate]_[ExportingDateMicroseconds].[FileExtension]

Example:

Doe_John_ABC123_OD_central_color_2020-09-23_175010_2020-11-02_143741_264527.jpg

Where:

- Surname: the patient surname, as in the surname field.
- FirstName: the patient's first name, as in the given name field.
- PatientID: the patient ID, as in the patient id field.
- Eye: Side of the Eye. Possible values: OD, OS.
- Field: Index representing the field acquired:
  - central, nasal, temporal, superior, inferior, central_nasal, superior_nasal, inferior_nasal, superior_temporal, inferior_temporal, external, anterior_eye, stereo1, stereo2
- ImageType: Type of image acquired, color or infrared
- ImageDate: Image acquisition date and time. Formatted as per-user configuration (i.e.: mm-dd-yyyy_hhiiss AM/PM)
- ExportingDate: Exporting Date/Time of the image, same format as ImageDate
- ExportingDateMicroseconds: Microseconds of the ExportingDate
- FileExtension: File extension, according to the selected format. Possible values: .jpg for JPEG images, .pdf for PDF files, .dcm for DICOM files.

18.8.1.2 Multi-image default filename

When more than one image is to be included in a single file (this is the case for multi-image PDF reports) the file name is stripped of the image parameters while all patient parameters are preserved. The trailing elements of the file name show the number of images included in the exported file:

[Surname]_[FirstName]_[PatientID]_[ItemsNumber]-images_[ExportingDate]_[ExportingDateMicroseconds].[FileExtension]

Example:

Doe_John_ABC123_4-images_11-04-2019_121315_981247.pdf

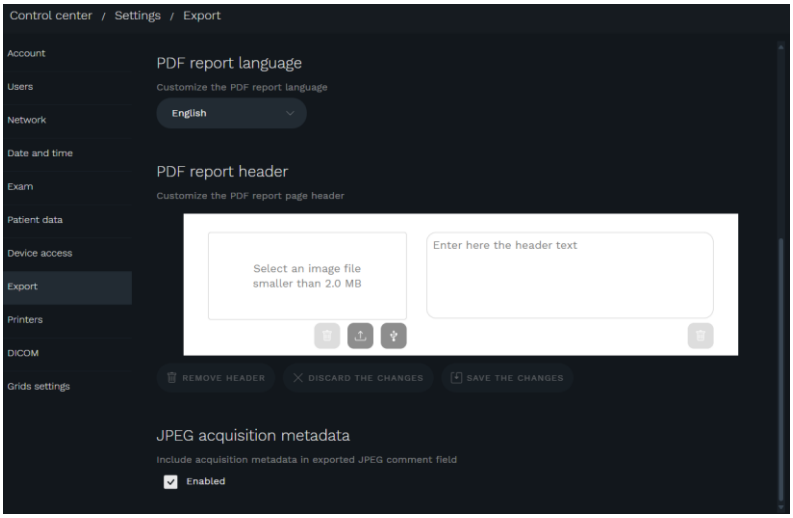
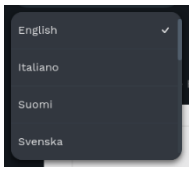


Fig. 128 - Settings|Export Screen, PDF report header section

Select the language for the PDF report from the *PDF report language* dropdown menu. By default, the PDF report language is the language selected during the initial configuration (see **Fig. 15**).	

You can customize the PDF report by adding an image (JPEG, PNG and SVG formats are accepted) and some text. The image size must be smaller than 2.0 MB and the text must not exceed 5 rows.

Enable *JPEG acquisition metadata* to store the metadata of the exam in the JPEG comment section. This information may be useful for troubleshooting purposes if requested by the assistance personnel. Setting this option to "disabled" will improve JPEG export performances.

18.9 Printers

Access the *Settings|Printers* Screen (Fig. 129) to configure the printing subsystem.

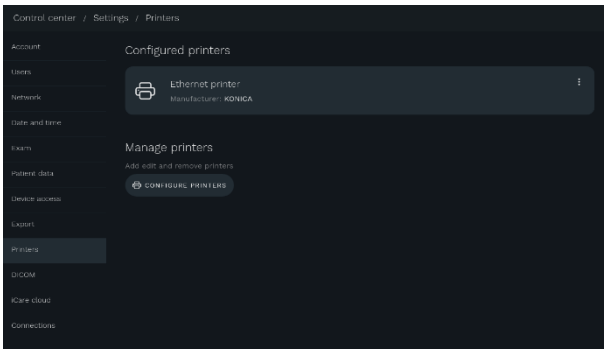


Fig. 129 - Settings|Printers Screen

The *Configured printers* section shows the already set printers. Click on the **ellipsis** at the right of this box to **REMOVE** or **CONFIGURE** the printer.

Click **CONFIGURE PRINTERS** to add, edit and remove printers.

You can access two main panels selectable using tabs:

- *Administration* (Fig. 130)
- *Printers* (Fig. 140 – “Printers” panel)

In the *Administration* Panel is possible to :

- Add a printer
- Find new printers
- Manage Printers

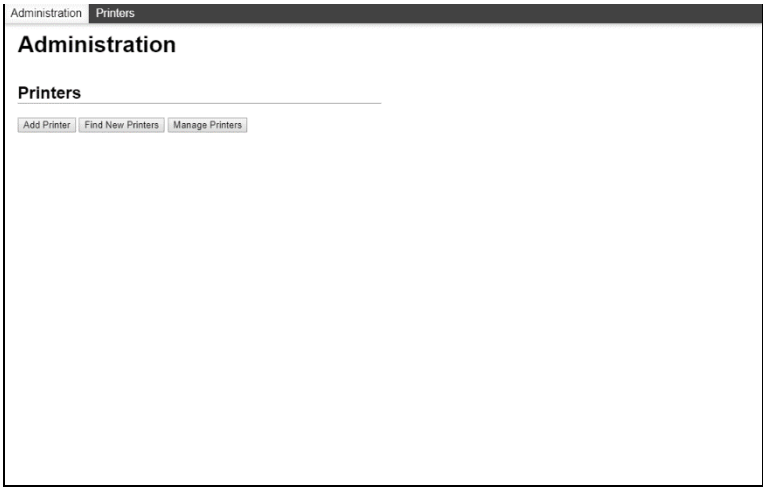


Fig. 130 - Administration panel

Press the Add Printer button in the Administration Panel shown in Fig. 130: after a while, the panel Add Printer appears. In this panel, there are three sections:

- Local printers
  - In this section printers connected directly via USB will be shown, if correctly detected. In this example, the printer Epson Stylus SX440 has been detected automatically by the system once connected to one of the USB ports.
- Discovered Network Printers
  - In this section will be shown the printers available on the network, if correctly detected.
- Other Network Printers
  - In this section network printers not automatically detected can be configured manually

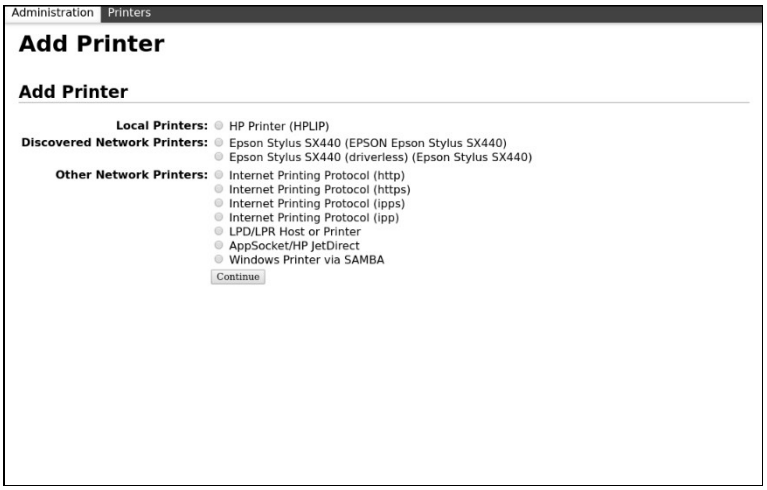


Fig. 131 – “Add Printer” panel

In the Printers panel, the printers configured for the device are listed and can be managed.

WiFi Direct connection with printers is not available.

18.9.1 Add Printer – Local Printer

Selecting the radio button related to the local printer automatically detected, in this case, Epson Stylus SX440, and pressing Continue, the panel for printer identification is shown (Fig. 132).

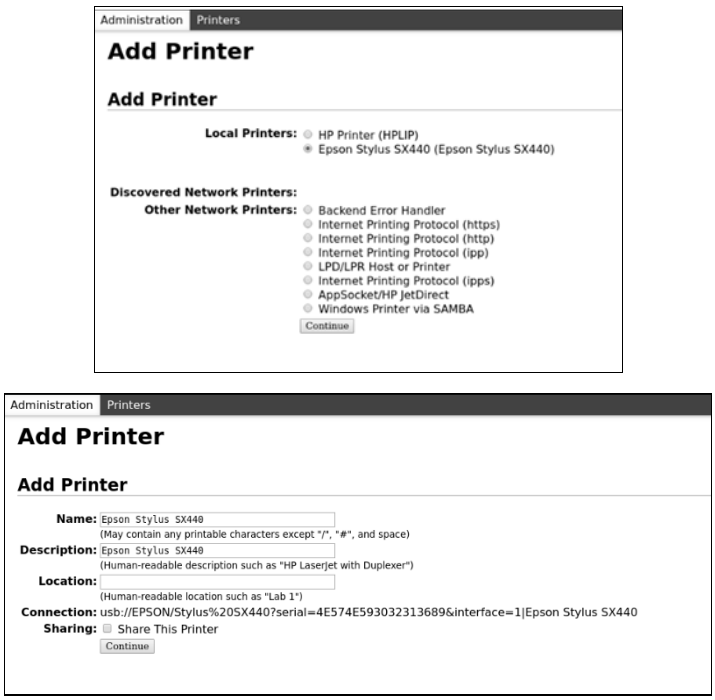


Fig. 132 – “Printer Identification” panel pre-set with automatic detection information

In this panel can be set the Name, which is used in printer selection dialogue during image printing, a Description, the location of the printer (in this case can be Local Printer) and a check box to set if this printer can be shared in the network with other devices.

Pressing Continue the panel with the selection of the model of the printer is shown. Scrolling the Model section, the correct model of printer in use can be selected. In case a “.ppd” file is available, which is a file that serves as a driver for a PostScript printer, it can be uploaded using the Choose File button.

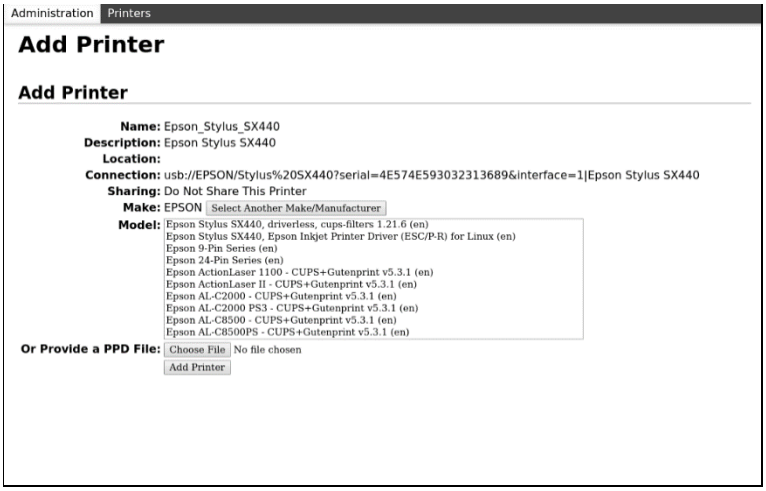


Fig. 133 – “Printer Model Selection” panel

In case the producer of the printer is not shown automatically, it can be selected in the Make section, scrolling the list, as shown in the following figure.

Once the printer model has been selected, pushing the Add Printer button the configuration is saved and the Set Default Options for the selected printer is shown[17] (Fig. 134).

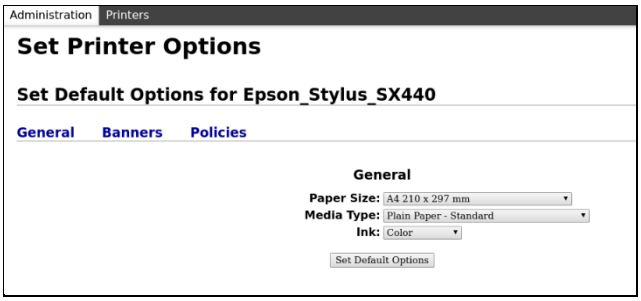


Fig. 134 – “Default Options Setting” panel, Banners tab

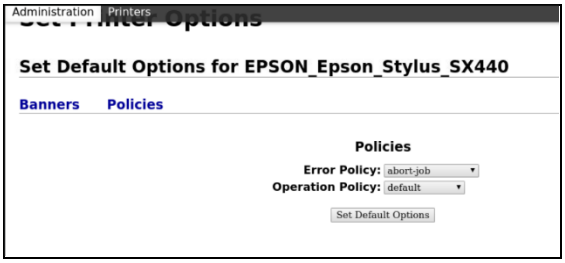


Fig. 135 – “Default Options Setting” panel, Policies tab

In this panel, three tabs are present: General, Banners and Policies.

With the General tab, the Paper Size, Media Type and Ink can be set.

The Default Options Setting panel depends on the printer’s characteristics. In the case of a multifunction printer, a panel like Fig. 136 can be presented.

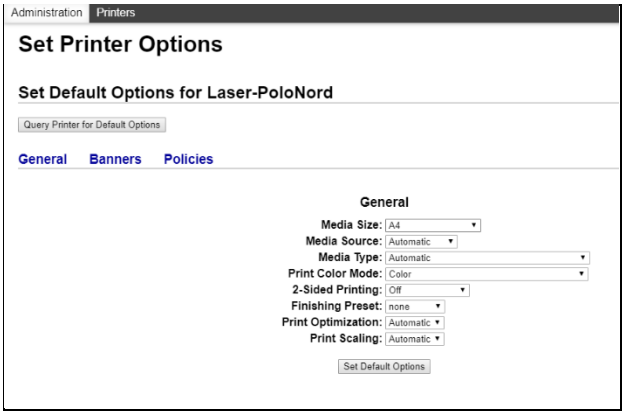


Fig. 136 – Set Default Options for a multifunction printer

[17] *The Set Default Options doesn’t influence the selection of the paper format set in Print Configuration pop-up shown in §.*

With the Banners tab, it is possible to select starting or ending banners from a top-down list (classified, confidential, …). With the tab Policies, the rules for each operation can be configured, like abort the job or retry in case of error. In this tab, the access control can be defined.

Pushing the Set Default Options the configuration procedure is completed and the printer can be found in the printer selection list when trying to print an image.

18.9.2 Add Printer – Network Printer

In case a printer connected to the network can be detected, the system shows it in the Add Printer panel, Discovered Network Printers section (Fig. 137).

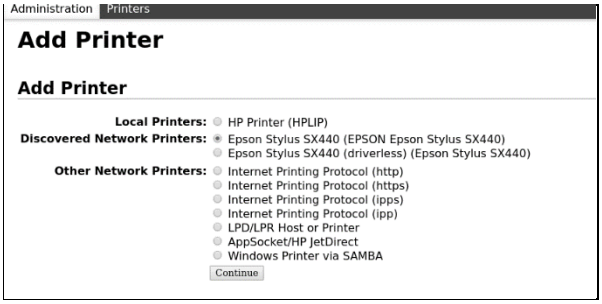


Fig. 137 – “Network Printers Selection” panel

Selecting the desired network printer, in this case, Epson Stylus SX440, and pressing Continue, the same printer identification panel shown in Fig. 132 appears. In this case, a name indicating that this is a network printer and the Location indicating the physical position of the printer are suggested.

The following panel is the Printer model selection panel shown in Fig. 133, and it can be configured as explained in §18.9.1. Also, in this case, press the Add Printer button to see the Set Default Options for the selected printer (Fig. 134) as in §18.9.1.

18.9.3 Add Printer – Other Network Printers

In case the network printer has not been automatically detected, it can be configured manually.

The printer can be configured using one of three TCP/IP-based protocols:

- AppSocket
- Internet Printing Protocol
- Line Printer Daemon.

Printers are referred by using a Uniform Resource Identifier (URI) which is an addressing technology for identifying resources on the Internet or a private intranet.

Selecting the protocol in the list and pressing Continue, the printer address can be set in the following window (Fig. 138).

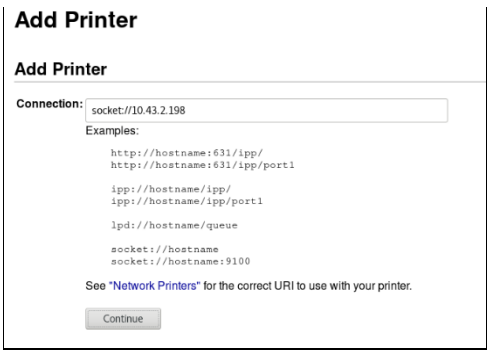


Fig. 138 – URI Printer Configuration

AppSocket Protocol

The AppSocket protocol is the simplest and fastest network protocol used for printers.

Device URIs for the printer have the following structures:

socket://ip-address

socket://ip-address/?contimeout=30

socket://ip-address/?waiteof=false

socket://ip-address/?contimeout=30&waiteof=false

socket://ip-address:port-number/?...

The “contimeout” option controls the number of seconds that the backend will wait to obtain a connection to the printer. The default is 1 week or 604800 seconds.

The “waiteof” option controls whether the socket backend waits for the printer to complete the printing of the job. The default is to wait (waiteof=true). Add waiteof=false to the URI to tell the backend not to wait.

Internet Printing Protocol (IPP)

For this protocol, the device URIs have the following structures:

http://ip-address-or-hostname:port-number/printers/name/.printer

ipp://ip-address/ipp/print

ipp://ip-address-or-hostname/printers/name

ipps://ip-address/ipp/print

ipps://ip-address:443/ipp/print

ipps://ip-address-or-hostname/printers/name

The protocol supports many options, which are summarized in the following table.

IPP URI Options

Option	Description
contimeout=seconds	Specifies the number of seconds to wait for the connection to the printer to complete (default 1 week or 604800 seconds).
encryption=always	Specifies that the connection to the IPP printer should be encrypted using SSL.
encryption=ifrequested	Specifies that the connection to the IPP printer should only be encrypted if the printer requests it.
encryption=never	Specifies that the connection to the IPP printer should not be encrypted.
encryption=required	Specifies that the connection to the IPP printer should be encrypted using TLS.
version=1.0	Specifies that version 1.0 of the IPP protocol should be used instead of the default version 2.0.
version=1.1	Specifies that version 1.1 of the IPP protocol should be used instead of the default version 2.0.
version=2.1	Specifies that version 2.1 of the IPP protocol should be used instead of the default version 2.0.
waitjob=false	Specifies that the IPP backend should not wait for the job to complete.
waitprinter=false	Specifies that the IPP backend should not wait for the printer to become idle before sending the print job.

Line Printer Daemon (LPD) Protocol

LPD is the original network printing protocol.

Device URIs for the printer have the following structures:

lpd://ip-address/queue

lpd://ip-address/queue?format=l

lpd://ip-address/queue?format=l&reserve=rfc1179

The following table summarizes the options supported.

Option	Description
banner=on	Specifies that a banner page should be printed by the printer.
contimeout=seconds	Specifies the number of seconds to wait for the connection to the printer to complete (default 1 week or 604800 seconds).
format=f	Specifies that the print data is a plain text file.
format=o	Specifies that the print data is a PostScript file.
format=p	Specifies that the print data is a plain text file that should be “pretty” printed with a header and footer.
mode=stream	Specifies that the backend should stream print data to the printer and not wait for confirmation that the job has been successfully printed.
order=data,control	Specifies that the print data files should be sent before the control file.
reserve=none	Specifies that the backend should not reserve a source port.
reserve=rfc1179	Specifies that the backend should reserve a source port from 721 to 731 as required by RFC 1179.
sanitize_title=no	Specifies that the job title string should not be restricted to ASCII alphanumeric and space characters.
sanitize_title=yes	Specifies that the job title string should be restricted to ASCII alphanumeric and space characters.
timeout=seconds	Specifies the number of seconds to wait for LPD commands to complete (default 5 minutes or 300 seconds).

18.9.4 Find New Printers

Pushing the Find Printers button in the Administration panel, the Available Printers panel is shown (Fig. 139).

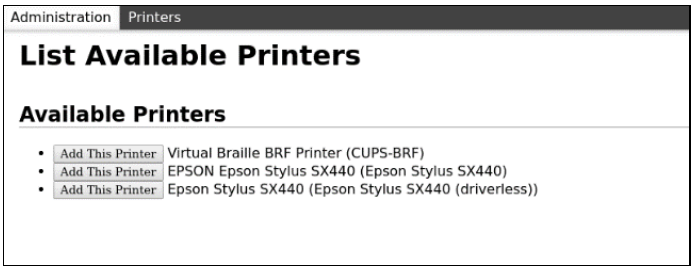


Fig. 139 – “Available Printers” panel

If the desired printer is listed, push the Add This Printer button: the Printer Identification panel, Printer Model selection panel and Default Options Setting panel are shown in sequence as explained in §18.9.1, to configure it.

18.9.5 Printers panel

In the *Printers* panel, all the configured printers are listed (Fig. 140).

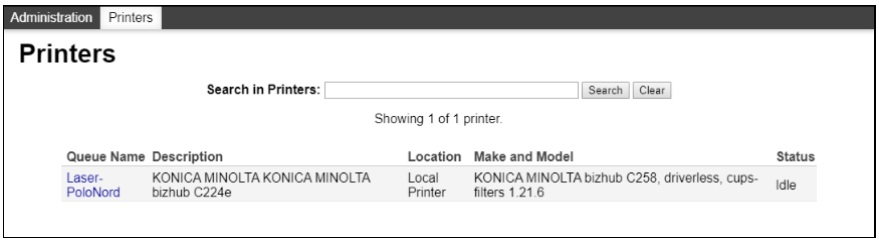


Fig. 140 – “Printers” panel

Touching the name of the printer, a panel showing two sections is shown. The first section presents the main information of the printer, with two buttons:

Maintenance

Administration

The second section lists all the jobs for this printer, with the possibility to show all jobs or just the completed jobs and to search in the list with the dedicated buttons (Fig. 141).

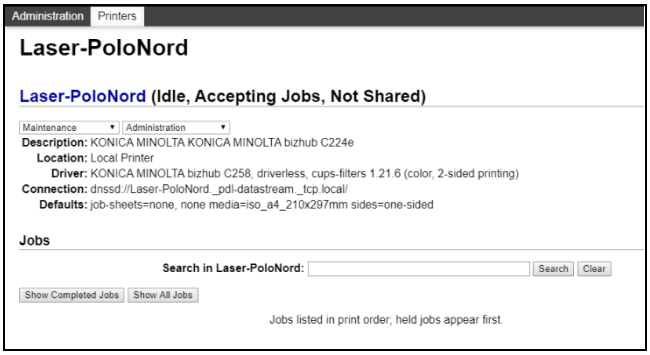


Fig. 141 – “Printer” panel

Pushing the Maintenance button, a list of activities that can be done on the printer is shown.

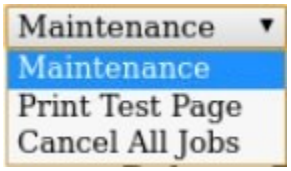


Fig. 142 – Maintenance Activities list

Print test page

- With this command, a test page is sent to the printer to check the communication and printing capability

Clean Print Heads

- With this command, the procedure to clean the print heads is launched in the printer (this command can be present or not depending on the printer model)

Cancel all jobs

- Cancel all jobs running and waiting

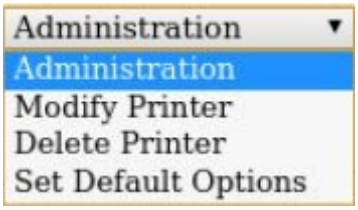


Fig. 143 – Administration Activities list

Pushing the Administration button, a list of activities that can be done on the printer is shown.

Modify printer

- The Configuration of the printer can be modified

Delete printer

- The printer can be deleted, after confirmation (Fig. 144)

Set default options

- Can modify the Default Options using the panel in Fig. 134 and Fig. 136

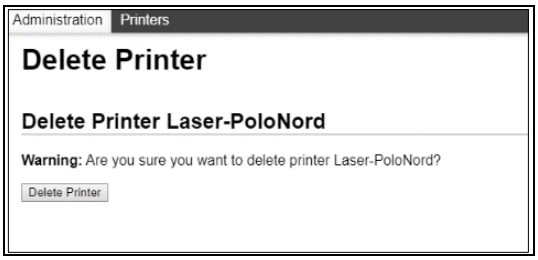


Fig. 144 – "Delete Printer" panel

18.10 Grids settings

Access the *Settings*|*Grids settings* screen (see Fig. 145) to see the available grids or to add a new one.

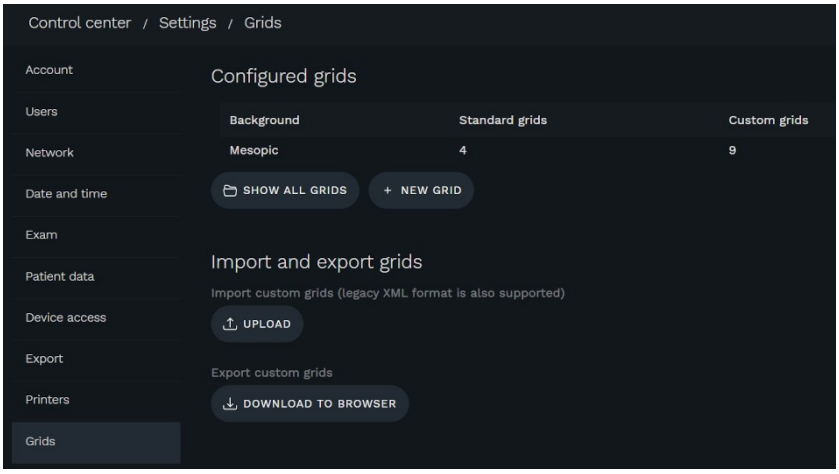


Fig. 145 - Settings|Grids settings screen

The Configured grids table shows the number of available grids divided in Standard grids and Custom grids (see Fig. 146).

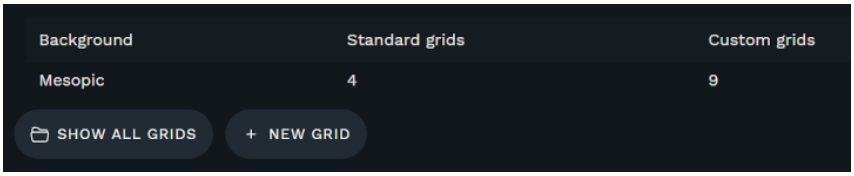


Fig. 146 – Configured grids

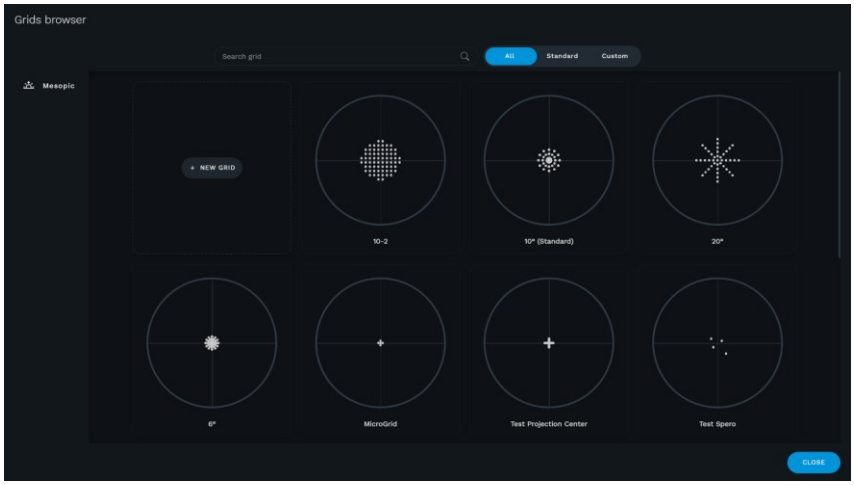
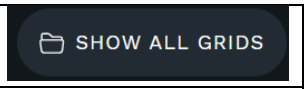
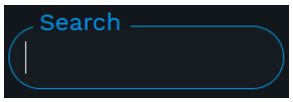
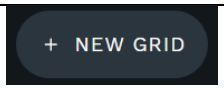


Fig. 147 – Grids Browser

The **SHOW ALL GRIDS** button allows to open the Grid browser to see the image previews of all the available grids (see Fig. 147).	
Input a specific text in the **Search** field to find it.	
Select **All, Standard** or **Custom** tabs to see the grids belonging to the specific category selected (see Fig. 147).	
The **NEW GRID** button allows to add a custom grid using the Grid editor (see Fig. 145 and Fig. 148).	

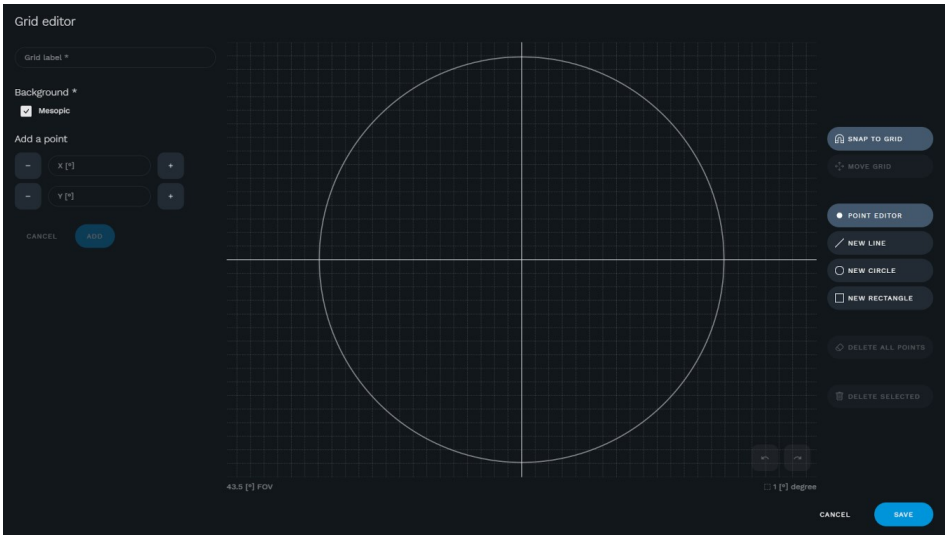


Fig. 148 – Grid editor

It is possible also import and export the grids using the functionality at the bottom page (see *Fig. 149*).

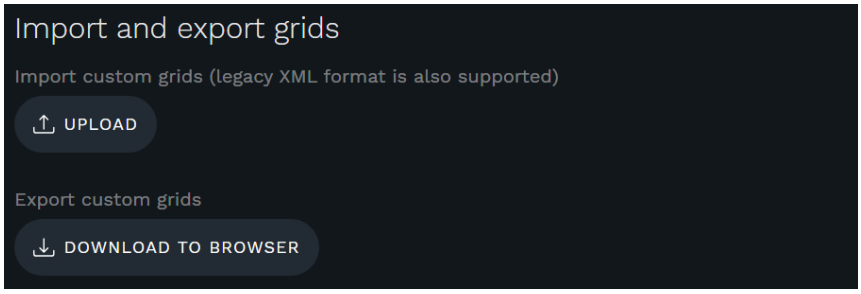
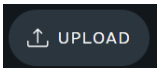
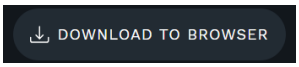


Fig. 149 – Import and export grid functionality

Push on **UPLOAD** button to add new custom grids. The format supported are: .xml, .XML (for grids used with the previous editions of MAIA), .json, or .JSON (for grids created with MAIA 2025 Edition).	

Push on **DOWLOAD TO BROWSER** button to export custom grids.	

18.10.1 Grid editor

The Grid editor allows to create a new custom Grid and add it on the grid library. In the center of the page it is possible to see a grid preview before saving the new edited grid.

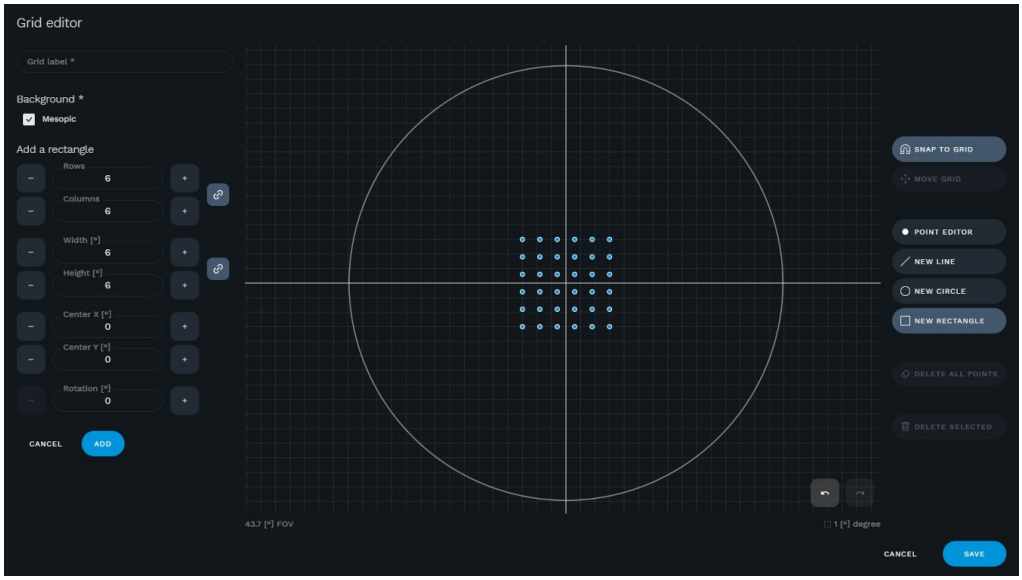
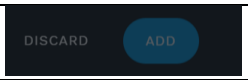
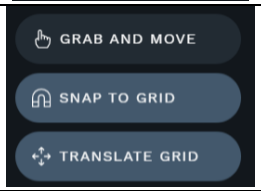


Fig. 150 – Grid preview

Input a specific label for the new custom grid.	
Insert specific coordinate (X[°] and Y[°]) to add a specific point in the grid.	
Push on **ADD** to confirm and add a new point in the grid or **DISCARD** to delete the point.	
Push on **GRAB AND MOVE** button to select and move an existing point into the grid. The **SNAP TO GRID** option allows to force the positioning of the stimuli on integer values of the degrees coordinates when dragging the stimuli. Push on **TRANSLATE GRID** button to translate all points into the grid at the same time.	
Push on **POINT EDITOR** button to add into the grid only a point or push on **NEW LINE**, **NEW CIRCLE**, or **NEW RECTANGLE**, to add a pre-selected pattern.	
Press **DELETE ALL POINTS** to eliminate all points in the grid.	
Push on **SAVE** to store the newly created grid, or **CANCEL** to go back to the grid setting page.	
Click on the left arrow to undo the last action or on the right arrow to repeat it (see *Fig. 150*).	

18.11 Custom Strategies settings

The Custom Thresholding Strategy functionality requires a dedicated license and allows users to define custom projection strategies (i.e., the sequence of stimulus intensities) to be used during microperimetry examinations. Consequently, the Strategies menu will be visible only if the dedicated license is installed on the device.

Access the *Settings*|*Strategies* screen (Fig. 151) to view available custom strategies or to create a new one.

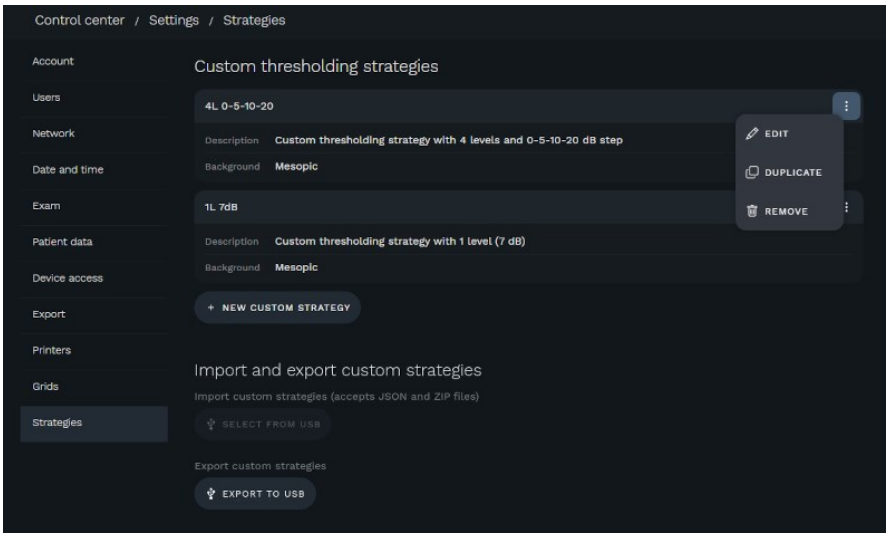


Fig. 151 - Settings|Strategies settings screen

Each custom strategy is identified by its Name, Description and the Background type for which it is available (currently, only Mesopic is supported). Selecting the three-dot menu next to a strategy allows the user to Edit, Duplicate or Remove it.

A custom strategy can be created in two ways:

1) Using the **+ NEW CUSTOM STRATEGY** button in the User Interface (UI).

   The dialog in Fig. 152 appears, allowing to choose whether to create the strategy using:

   - The N-Levels simplified UI (see §18.11.1), or
   - The fully customizable Projection tree UI (see §18.11.2)

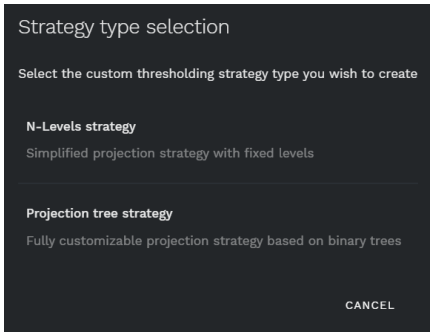


Fig. 152 - *Settings*|*Custom Strategy* creation type selection

2) Importing a JSON file that describes the structure of the strategy (see §18.11.3)

18.11.1 Editing a custom strategy using the N-Levels simplified UI

The N-Levels simplified UI (Fig. 153) is suitable for creating a multi-level SupraThreshold strategy when the initial intensity is not age-dependent.

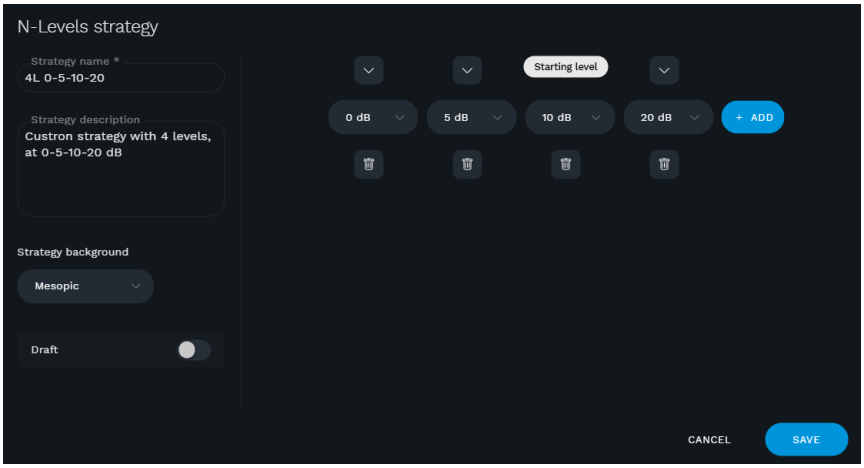


Fig. 153 – Creating a Custom Strategy from scratch using the simplified UI

On the left side, the user can define the strategy's Name, a Description and select the Background type (currently Mesopic only is supported). If the **Draft** option is enabled, the strategy will be saved as a draft and will not be available for use in new examinations.
On the right side, the user can define any number of levels for the SupraThreshold strategy. Levels can be added using the **+ ADD** button, can be edited by selecting the desired projection intensity, and can be deleted using the trash bin buttons below each level. The down-arrow button allows selection of the starting intensity level for the examination, identified with the "Starting level" label.
When editing is complete, press **SAVE** to store the strategy and make it available for examinations (unless it is marked as Draft).

18.11.2 Editing a custom strategy using the projection tree UI

The fully customizable Projection trees UI (Fig. 154) allows the creation of more complex projection strategies based on binary trees, depending on the patient's response to stimulus presentations. It is also suitable for SupraThreshold strategies with age-dependent initial intensities.

As in the simplified UI, the fields on the left allow the user to define its Name, a Description and to select the Background type (currently Mesopic only is supported). If the **Draft** option is enabled, the strategy will be saved as a draft and will not be available for use in new examinations.

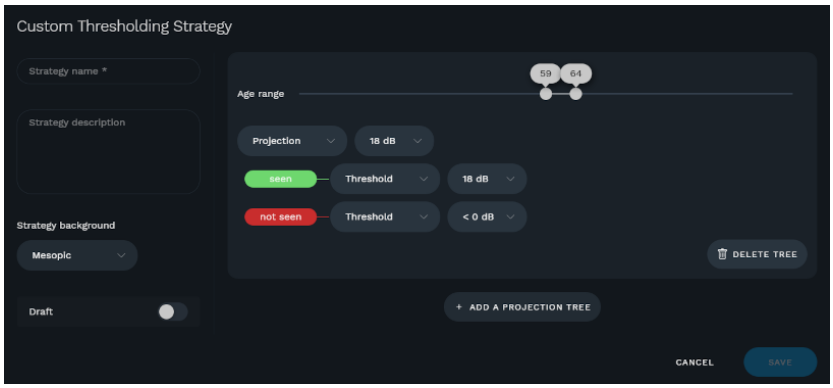


Fig. 154 – Creating a Custom Strategy from scratch using the Projection trees UI

A strategy may consist of multiple Projection Trees, each associated with a specific age range. This allows different initial projection intensities to be defined for different age groups.

When creating a new strategy, a minimal Projection Tree is initially generated.

- The associated age range can be set using the slider at the top.
- A drop-down menu allows selection of the initial projection intensity.
- Below this, the user defines the behavior based on whether the stimulus is seen or not seen by the patient. For each outcome, the drop-down menu allows selection between:
  - ***Threshold***: the projection sequence for that location is completed, and the threshold value set on drop-down list next to the button is assigned to the tested location
  - ***Projection***: a new nested binary tree is created, allowing the definition of a new projection intensity and subsequent behavior depending on whether the stimulus is seen or not seen. Projection trees can be nested without limitation

As an example, Fig. 155 shows the same strategy defined using the simplified N-Levels UI in Fig. 153, but represented using the Projection Trees UI.

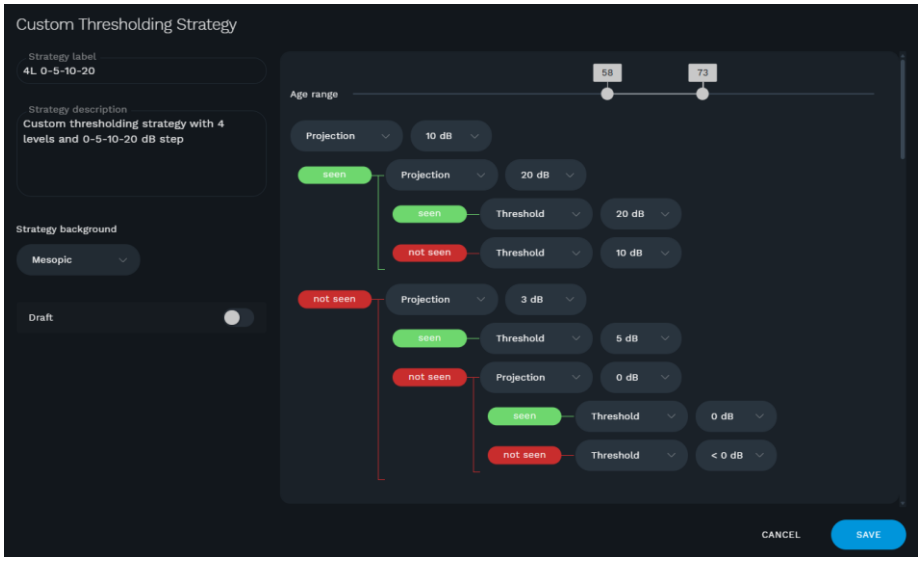


Fig. 155 – Creating a Custom Strategy using the Projection trees UI: a sample SupraThreshold strategy

To add another Projection Tree associated with a different age range, press **+ ADD A PROJECTION TREE**.

Age ranges must be:

- Continuous (e.g., 18–50, 51–80)
- Non-overlapping

If these conditions are not met, the **SAVE** button will be disabled.

If a patient's age falls outside the defined ranges, the nearest age range will be applied. For example, if the highest defined range is 45–80, that Projection Tree will also apply to patients older than 80 years.

Fig. 156 shows a custom strategy made up of two different age ranges (18-57 and 58-73).

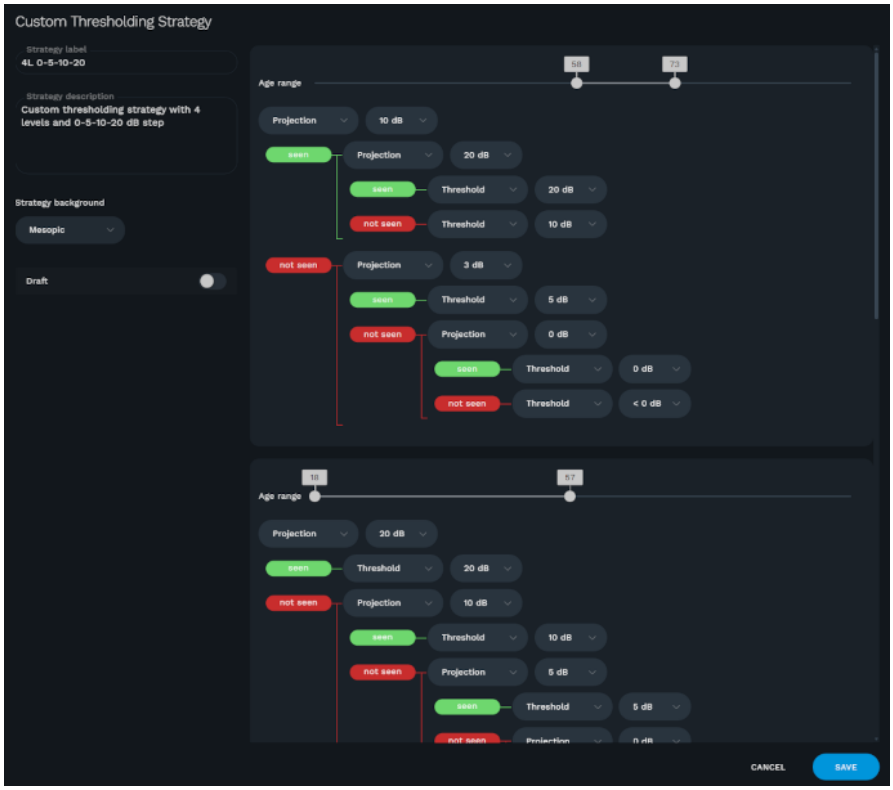


Fig. 156 – Projection trees UI: defining two Projection trees associated with different age ranges (18-57 and 58-73)

When editing is complete, press **SAVE** to store the strategy and make it available for examinations (unless it is marked as Draft).

18.11.3 Importing a custom strategy in JSON format

A custom strategy may also be defined by uploading a JSON file.

The example below represents a 3-level SupraThreshold strategy with different initial intensities for patients aged 18–57 and 58–73:

```
{
        "label": "3L 0-10-20",
        "description": "Custom thresholding strategy with 3 levels and 0-10-20 dB step",
        "background": "mesopic",
        "age_related_initial_value": {
                "18-57": 20,
                "58-73": 10
        },
        "thresholding_strategy": {
                "10": {
                        "seen": {
                                "20": {
                                        "seen": 20,
                                        "not_seen": 10
                                }
                        },
                        "not_seen": {
                                "0": {
                                        "seen": 0,
                                        "not_seen": -1
                                }
                        }
                },
                "20": {
                        "seen": 20,
                        "not_seen": {
                                "10": {
                                        "seen": 10,
                                        "not_seen": {
                                                "0": {
                                                        "seen": 0,
                                                        "not_seen": -1
                                                }
                                        }
                                }
                        }
                }
        }
}
```

These are the meanings of the JSON fields:

- **active**: Boolean value indicating whether the strategy is available (i.e., not a Draft).
- **label**: Strategy name.
- **description**: Description of the strategy.
- **background**: Background type for which the strategy is valid (“mesopic” only).
- **age_related_initial_value**: Dictionary defining age ranges and corresponding initial projection intensities.
- **thresholding_strategy**: Nested dictionary describing the binary projection tree structure. Keys represent projection intensities, and nested “seen” and “not_seen” objects define subsequent behavior.

The custom strategies currently installed on the device can be exported in JSON format using the **EXPORT TO USB** button (on the Local Interface) or the **DOWNLOAD TO BROWSER** button (on the Remote Viewer). This action generates a ZIP file containing one .json file for each custom strategy.

The JSON file can be edited using a text editor, and imported on the device using the **SELECT FROM USB** button (on the Local Interface) or the **UPLOAD** button (on the Remote Viewer).

The JSON file defining the custom strategy must comply with the provided JSON Schema:

```
{
  "$schema": "https://json-schema.org/draft/2020-12/schema",
  "description": "Custom Thresholding Strategy",
  "type": "object",
  "properties": {
```

```
    "label": {
      "type": "string",
      "description": "Label for the Custom Thresholding Strategy (max length 20 chars)",
      "minLength": 1,
      "maxLength": 20
    },
    "description": {
      "type": "string",
      "description": "Description for the Custom Thresholding Strategy (max length 400 chars)",
      "maxLength": 400
    },
    "background": {
      "type": "string",
      "description": "Background type for the Custom Thresholding Strategy (only 'mesopic' is allowed for this
schema)",
      "const": "mesopic"
    },
    "age_related_initial_value": {
      "description": "This object contains the patient's age ranges in format 'X-Y' where X and Y are integers
between 0 and 100, and the corresponding initial projection intensity for that age range (integer between 0 and 36).
The age ranges should be non-overlapping and continuous. If the patient's age is outside of the provided age ranges,
the initial projection intensity of the closest age range will be used.",
      "type": "object",
      "patternProperties": {
        "^\\d{1,3}-\\d{1,3}$": {
          "type": "integer",
          "minimum": 0,
          "maximum": 36
        }
      },
      "minProperties": 1,
      "additionalProperties": false
    },
    "thresholding_strategy": {
      "description": "This object contains a set of keys (integers between 0 and 36) representing the projection
intensity, and the corresponding value is projection node.",
      "type": "object",
      "minProperties": 1,
      "additionalProperties": false,
      "patternProperties": {

"^(0|1|2|3|4|5|6|7|8|9|10|11|12|13|14|15|16|17|18|19|20|21|22|23|24|25|26|27|28|29|30|31|32|33|34|35|36)$": {
          "$ref": "#/$defs/cts_node_mesopic"
        }
      }
    }
  },
  "required": [
    "label",
    "background",
    "age_related_initial_value",
    "thresholding_strategy"
  ],
  "$defs": {
    "cts_node_mesopic": {
      "type": "object",
      "properties": {
        "seen": {
          "oneOf": [
            {
              "description": "Threshold value",
              "type": "integer",
              "minimum": -1,
              "maximum": 36
            },
            {
              "description": "Object containing a single key (the next projection intensity) and the corresponding
value is the projection node.",
              "type": "object",
              "patternProperties": {

"^(0|1|2|3|4|5|6|7|8|9|10|11|12|13|14|15|16|17|18|19|20|21|22|23|24|25|26|27|28|29|30|31|32|33|34|35|36)$": {
                  "$ref": "#/$defs/cts_node_mesopic"
                }
              },
              "additionalProperties": false
            }
          ]
        },
        "not_seen": {
          "oneOf": [
            {
              "description": "Threshold value",
```

```
              "type": "integer",
              "minimum": -1,
              "maximum": 36
            },
            {
              "description": "Object containing a single key (the next projection intensity) and the corresponding
value is the projection node.",
              "type": "object",
              "patternProperties": {

"^(0|1|2|3|4|5|6|7|8|9|10|11|12|13|14|15|16|17|18|19|20|21|22|23|24|25|26|27|28|29|30|31|32|33|34|35|36)$": {
                  "$ref": "#/$defs/cts_node_mesopic"
                }
              },
              "additionalProperties": false
            }
          ]
        }
      },
      "required": [
        "seen",
        "not_seen"
      ],
      "additionalProperties": false
    }
  }
}
```

19 UTILITIES

The *Utilities* Screen contains a set of functionalities to keep the device updated, manage the data backup and ask for assistance (see Fig. 157).

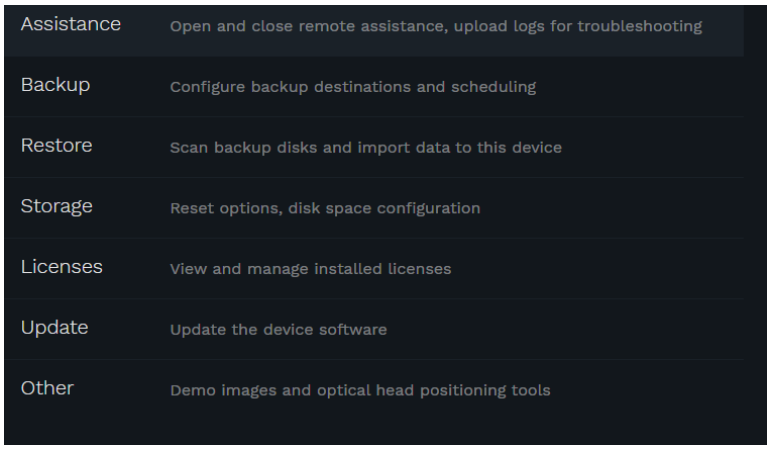


Fig. 157 - Utilities Screen

To access the system *Utilities* Screen, click the **UTILITIES** button on the *Control center* Screen.	

19.1 Assistance

Access the *Utilities*|*Assistance* Screen (Fig. 158) to open a Remote Assistance (R.A.) session or to export diagnostic data for technical troubleshooting purposes.

19.1.1 Remote assistance

The Remote Assistance allows an iCare/CenterVue operator to connect to the device.

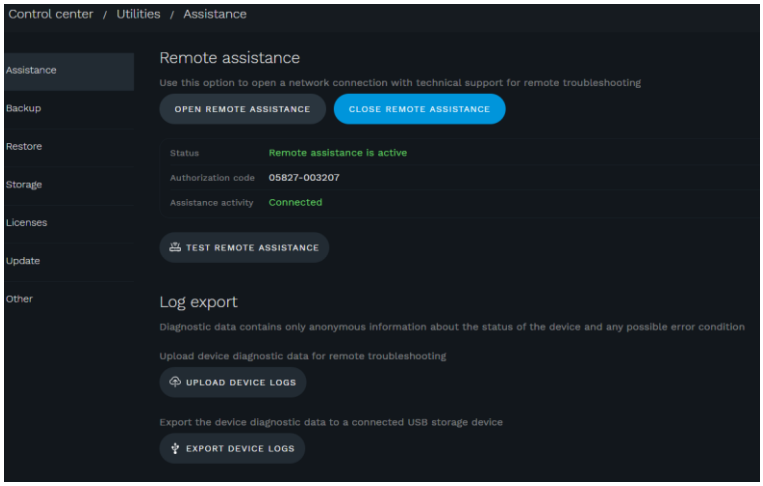
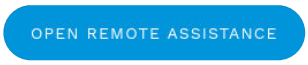


Fig. 158 – Utilities|Assistance Screen

Push **OPEN REMOTE ASSISTANCE** to open the *Authorize remote assistance by your own action* pop-up (see Fig. 159).	

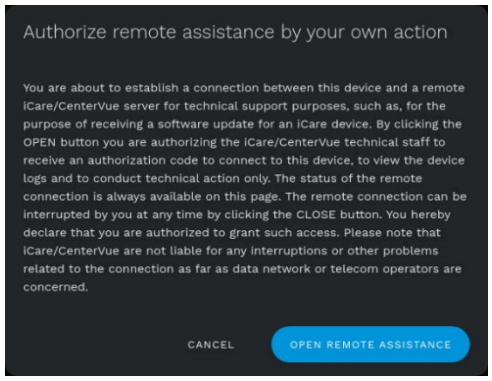
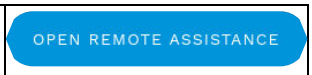
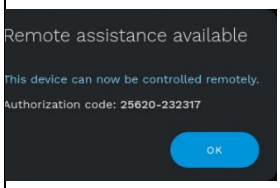
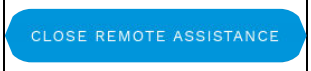
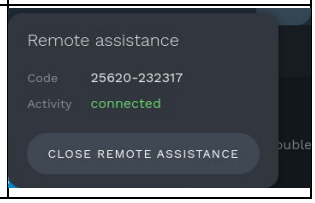


Fig. 159 – Authorize remote assistance by your own action pop-up

Push **OPEN REMOTE ASSISTANCE** to open the *Authorize remote assistance by your own action* pop-up.	
A pop-up warns you that Remote assistance is available and shows the *Authorization code*. Click **OK** to close the pop-up. Communicate the *Authorization Code* to the remote operator to allow him to connect to the device. Only after the remote operator has confirmed that the assistance activity is completed, you can close the R.A.	
Push **CLOSE REMOTE ASSISTANCE** to open the *Close remote assistance* pop-up (see Fig. 160), then confirm to close the currently active remote assistance session.	
The current status of the Remote Assistance session is always available through the “service” icon on the top bar. Pressing the button will open a menu that will show the current authorization code and a button that can be used to close the session.	

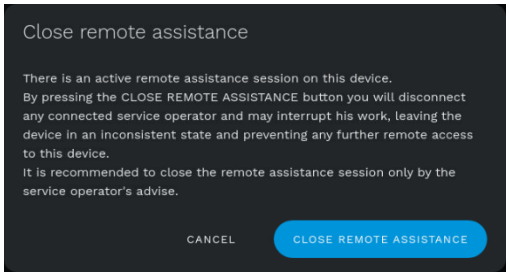


Fig. 160 - Close remote assistance pop-up

The Remote Assistance always requires an internet connection.

19.1.2 Log Export

In the *Log Export* section, you can extract diagnostic data of the device for service purposes.

UPLOAD DEVICE LOGS exports diagnostic data to an iCare/CenterVue server. **It requires an internet connection.**

Push **UPLOAD DEVICE LOGS** to open the *Upload diagnostic or statistic data* pop-up (see Fig. 161).	

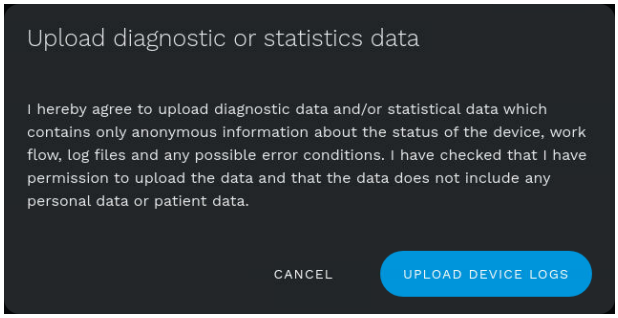


Fig. 161 – Upload Device Logs pop-up

Push **UPLOAD DEVICE LOGS** to start the logs transfer.

EXPORT DEVICE LOGS saves the diagnostic data of the device into a connected USB storage device. Plug a USB storage device into one of the ports in the rear connector panel of MAIA (see Fig. 2).

Push **EXPORT DEVICE LOGS** to select the *USB disks* (see Fig. 161).	

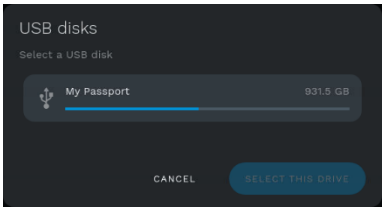


Fig. 162 – Upload Device Logs pop-up

Touch the box of the **USB DISK** you want to use to highlight it (see Fig. 163) and then push **SELECT THIS DRIVE** to start the logs export.

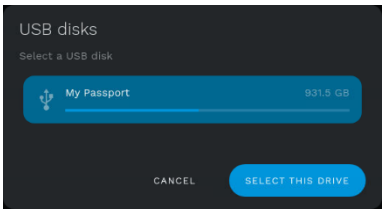
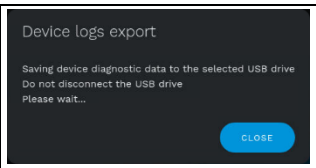
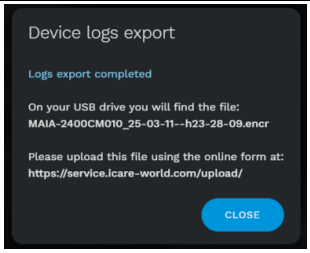


Fig. 163 – Upload Device Logs pop-up, USB DISK selected

A pop-up informs you that the export is in progress. Wait until it is completed, or push **CLOSE** to abort the operation.	
When the export is completed, the pop-up informs you about the name of the export file *MAIA-<SerialNumber>_<Date and time>-.tar.gz*. Push **CLOSE** to return to the *Utilities|Assistance* Screen.	

Extract the USB storage data, plug it into a PC. Open the https://service.icare-world.com/upload/ link in a browser and upload the file through the form you will find.

19.2 Backup

Access the *Utilities|Backup* Screen (Fig. 164) to backup the patient data stored in the onboard disk. Data can be backed up on a remote *Network backup* through an IP connection or into an external, *USB backup* through a connected memory device (flash memory or disk).

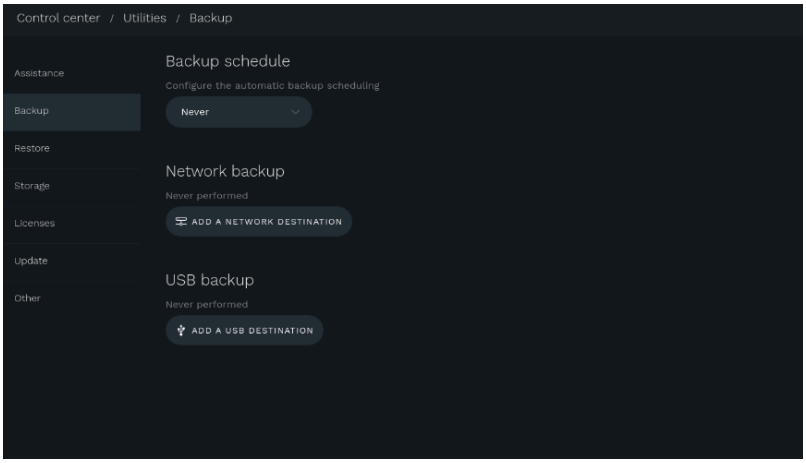
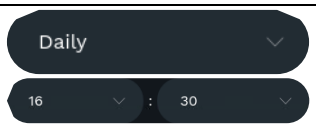
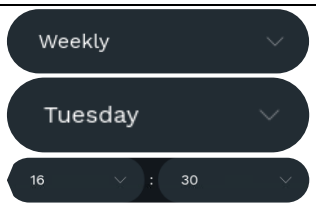


Fig. 164 – Utilities|Backup Screen

Only the Administrator user can create a backup configuration. The Operator user can only execute an already-configured backup job.

From the *Backup Schedule* dropdown menu, you can configure the automatic backup.

Select **Never** to perform the backup manually.	
Select **Daily** to enable the automatic backup once a day. Configure the **time** from the hours and minutes dropdown menus.	
Select **Weekly** to enable the backup once a week. Configure the backup **Day** from the dropdown menu. Configure the **time** from the hours and minutes dropdown menus.	
To set up a *network backup*, push the **ADD A NETWORK DESTINATION** button. The *Add new network backup destination* panel appears.	

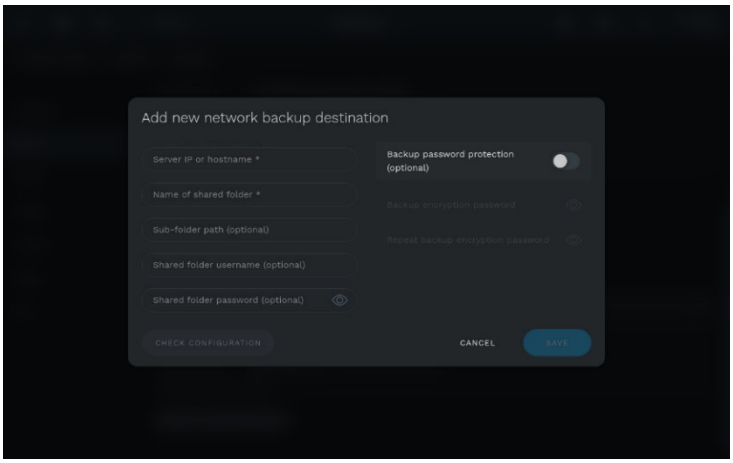


Fig. 165 – Add new network backup destination panel

Configure the mandatory parameters.

To encrypt the backup data, enable **Backup password protection**. Be careful to avoid losing the backup password.

Once the password is set, the backup can be performed by any user without knowing the password, but **the backup can be restored only with the backup password**. Without the password, the data cannot be restored, not even by iCare/CenterVue service personnel.

PASSWORD-PROTECTED BACKUPS CAN NOT BE RESTORED OR RECOVERED IF THE PASSWORD IS LOST.

Click **CANCEL** to abort the operation, **CHECK CONFIGURATION** to test the added backup network destination, **SAVE** to complete the configuration and revert to the *Utilities*|*Backup* Screen.

To set up backup on a USB storage device, push the **ADD A USB DESTINATION** button. The *USB disks* pop-up appears.	

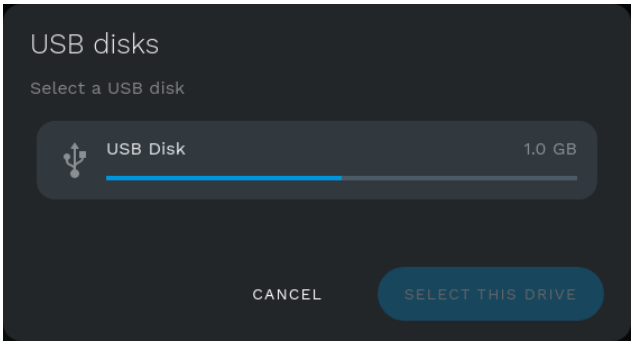


Fig. 166 - USB disks pop-up

Select the *USB DISK* to use for the backup. Push **CANCEL** to abort the operation, push **SELECT THIS DRIVE** to complete the set-up.

The first time you configure an **automatic** Backup on a valid location (Network of USB), a backup automatically starts, as you can see in the *Backup progress* pop-up (Fig. 167).

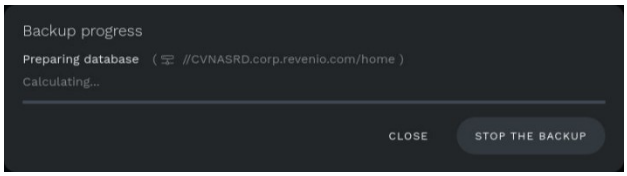


Fig. 167 - Backup progress pop-up

Click **STOP THE BACKUP** to abort the operation. To complete the backup, you can either wait until the end of the process or click **CLOSE**. When you click **CLOSE**, you will revert to the *Utilities|Backup* Screen while the backup operation will continue (see Fig. 168).

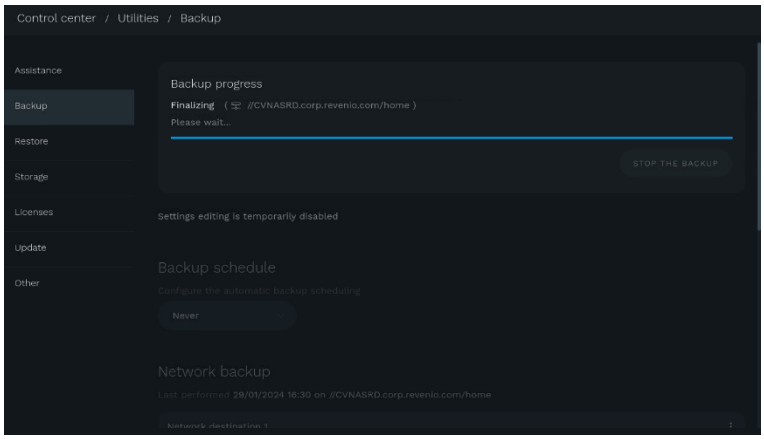
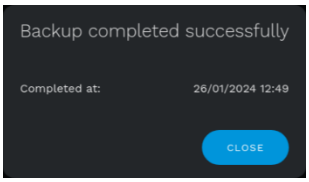


Fig. 168 – Utilities|Backup Screen, Backup progress

When the backup is completed, a pop-up appears. Click **CLOSE** to revert to the *Utilities|Backup* Screen, in which you will find the information about the date and time of the *Last performed* backup (see Fig. **169**).



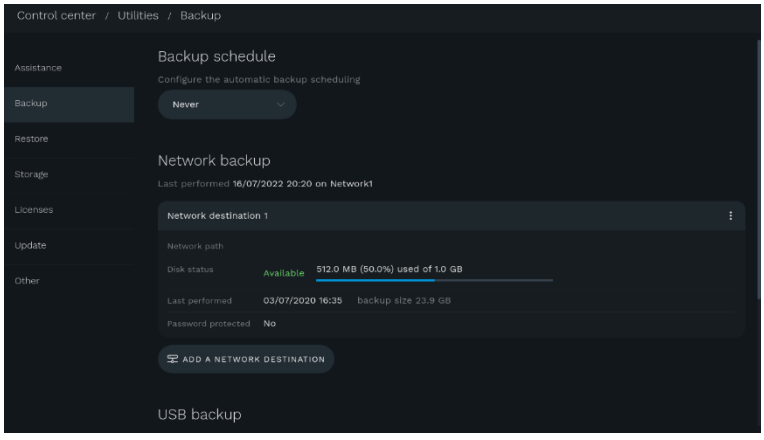


Fig. 169 –Utilities|Backup Screen, Last performed backup

You can find here the *Network path*, the *Disk* status, the date and time of the *last performed* backup, the backup size and the *Password protected* option.

The backup system is **incremental**, which means that if the destination media already contains an older backup archive of the device, only the new and modified items are transferred, to optimize and reduce the backup process time.

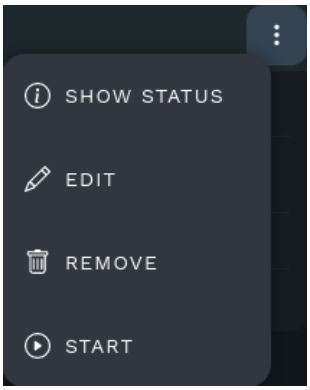
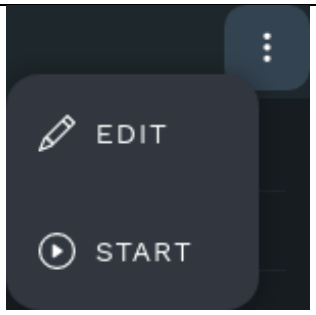
Hard disk failures are unpredictable and may cause irreversible loss of data

In the event of loss of data, it can be easily recovered from the last backup performed

It is the end user's responsibility to keep an updated backup of the data generated by MAIA through regular use of the backup utility

The Manufacturer declines all liability for loss of data due to hard disk failures.

Manual alterations of the files generated by the backup utility may affect the recovery of data

Click on the **ellipsis** at the right of the *Network destination.* In the menu, click **SHOW STATUS** to check the *Network disk status*, **EDIT** to *Edit the network backup destination,* **REMOVE** to *Remove the backup destination* or **START** to manually start a backup operation.	
Click on the **ellipsis** at the right of the *USB destination.* In the menu, click **EDIT** to *Edit the USB backup destination* and add a backup password, or click **START** to manually start a backup operation.	

19.3 Restore

The *Utilities*|*Restore* Screen (Fig. 170) provides the utility to restore from a backup. The Screen displays a list of available destinations that contain a compatible backup image that can be restored. Only the Administrator user is allowed to perform a restore operation.

MAIA can restore backup images generated by previous MAIA generations (2009 and 2013 Editions), with no restrictions on the SW versions used to generate the backup archives.

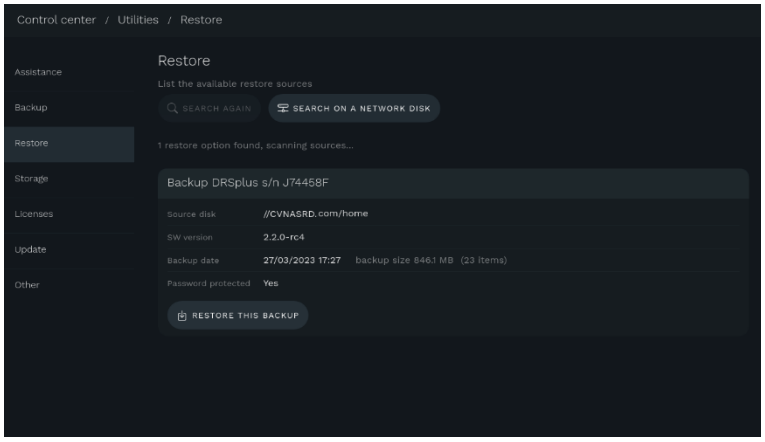


Fig. 170 – Utilities|Restore Screen

Click **SEARCH AGAIN** to scan the available restore sources.	
Click **SEARCH ON A NETWORK DISK** to open the *Search on a network disk* panel (Fig. 171).	

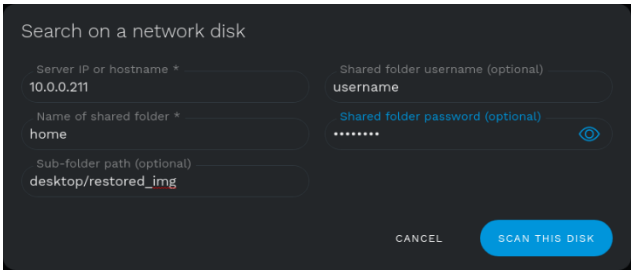


Fig. 171 - Search on a network disk panel

Manually insert the address of the restore position. Click **CANCEL** to abort the operation, click **SCAN THIS DISK** to proceed

Click **RESTORE THIS BACKUP** to start the restore process. The *Confirm the restore* pop-up appears (Fig. 172).	

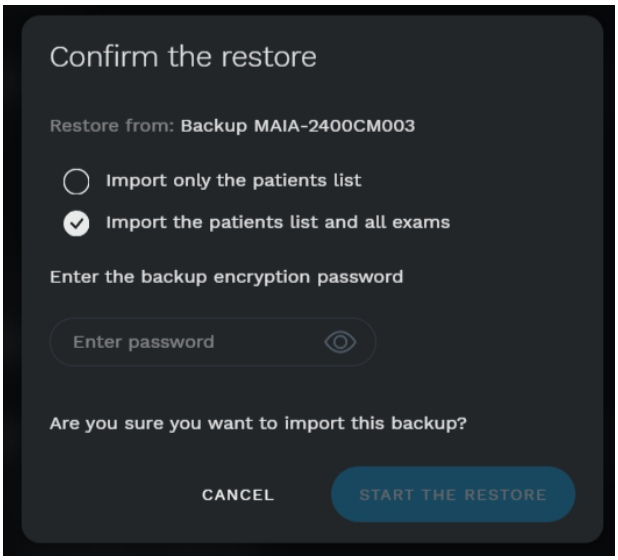
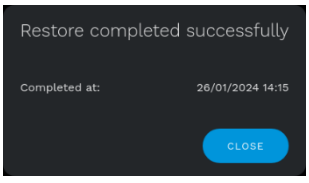


Fig. 172 - Confirm the restore pop-up

Alternatively, select to *Import only the patients list* or *Import the patients list and all exams*. Click **CANCEL** to abort the operation, click **START THE RESTORE** to complete it. The box of the encryption password appears when a password has been previously set for the backup (see §19.2). Input the backup password to proceed.

When the restore starts, a pop-up appears. You can **CLOSE** the pop-up to revert to the *Utilities*|*Restore* Screen while the restore is in progress. Click **STOP THE RESTORE** to interrupt the process.	
A pop-up appears at the end of the restore process. Click **CLOSE** to revert to the *Utilities*|*Restore* Screen.	

19.4 Storage

The *Utilities*|*Storage* Screen (Fig. 173) allows resetting the device and configuring a threshold for the data storage memory. Only an **Administrator account** has the permission to modify the configurations.

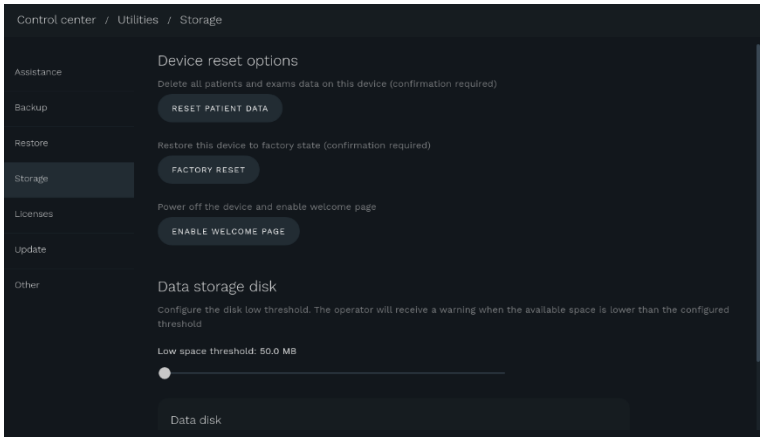


Fig. 173 – Utilities|Storage Screen

Click **RESET PATIENT DATA** to delete all patients and exams data from the device. The *Reset patient data* pop-up appears (Fig. 174).	

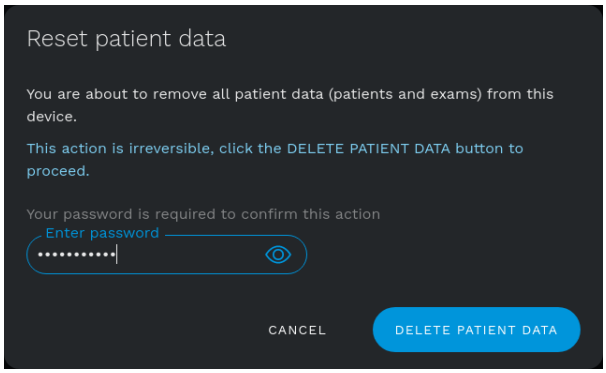
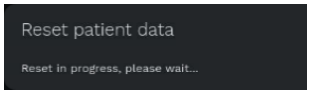


Fig. 174 - Reset patient data pop-up

Enter the Administrator password. Click **DELETE PATIENT DATA** to proceed with the reset, click **CANCEL** to abort. **The reset is an irreversible process.**

A pop-up warns you that the reset is in progress. At the completion, the pop-up is automatically closed and you will return to the *Utilities*|*Storage* Screen.	
Click **FACTORY RESET** to bring back the device to the factory configuration. The *Factory reset* pop-up appears (Fig. 175).	

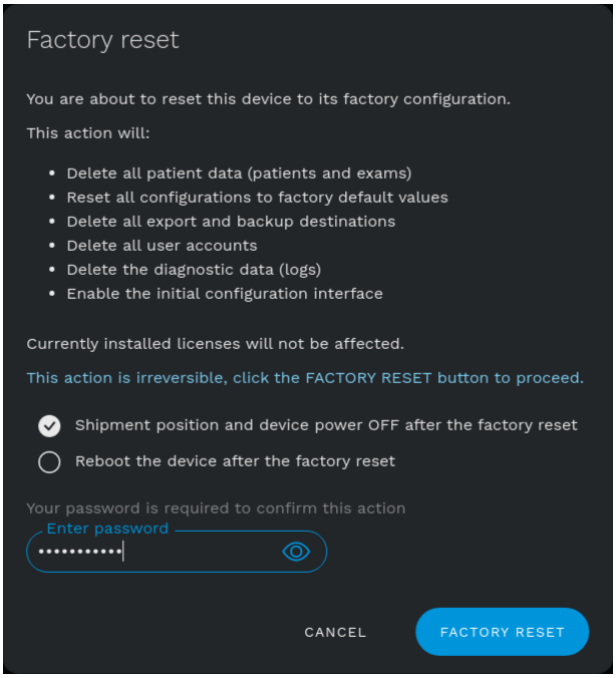


Fig. 175 – Factory reset pop-up

To enable the *Factory reset*, insert the Administrator password. Alternatively, select to put the device in the Shipment position, or to Reboot the device after the reset. Click **CANCEL** to abort the operation, click **FACTORY RESET** to proceed. **The factory reset does not alter or erase the installed licences.**

Click **ENABLE WELCOME PAGE** to bring back the device to the welcome page. The *Enable welcome page* pop-up appears (Fig. 176).	ENABLE WELCOME PAGE

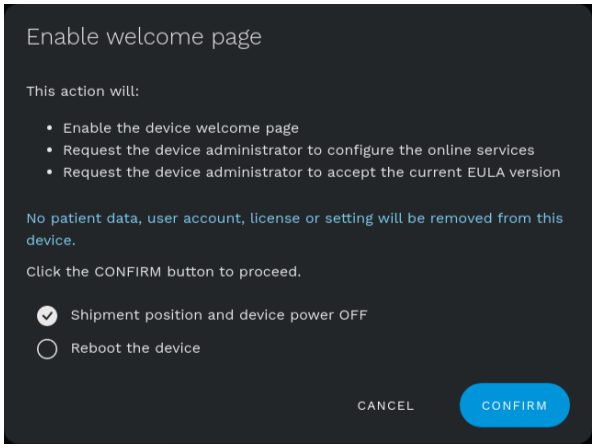


Fig. 176 – Enable welcome page pop-up

At the reboot, the acceptance of the End-user Licence Agreement and the online services will be again requested. Alternatively, select whether to power off or to reboot the device.

The *Data storage disk* section provides information about the Data disk usage inside the device (see Fig. 177).

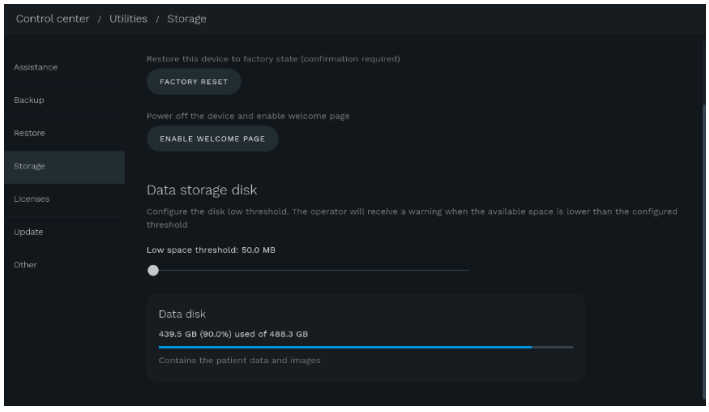


Fig. 177 - Data storage disk

In the *Low space threshold,* select with the slider the threshold of free space under which a warning pop-up appears (Fig. 178).

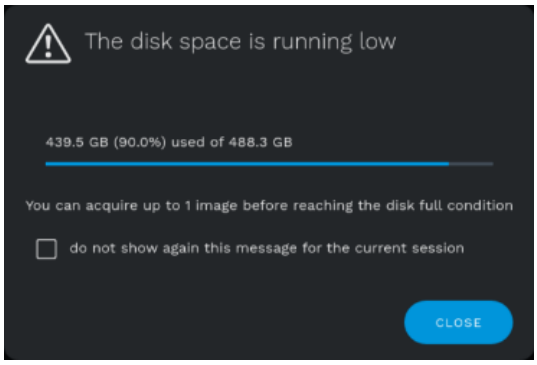
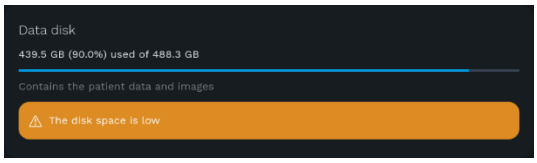


Fig. 178 - Disk space running low pop-up

The warning remains at the bottom of the *Utilities*|*Storage* Screen.



When the remaining memory does not allow acquiring additional exams, a *Disk full* pop-up appears (Fig. 179) and the image acquisition is disabled.

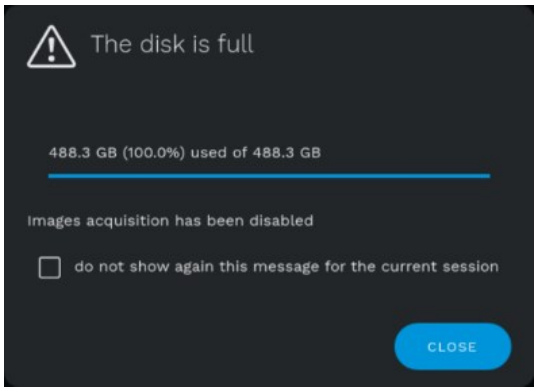
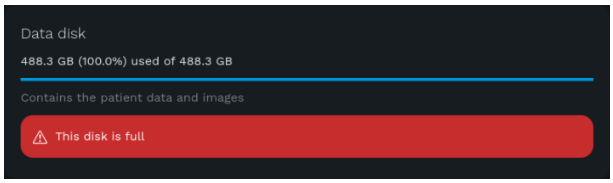


Fig. 179 - Disk full pop-up

Push **CLOSE** to close the pop-up. After closing the pop-up, the error message remains at the bottom of the *Utilities*|*Storage* Screen. Contact the iCare/CenterVue service for troubleshooting.



19.5 Licenses

The available licenses are those mentioned at § 8.
Access the *Utilities|Licenses* Screen (Fig. 180) to manage optional licenses. It shows the installed licenses on the device and allows to either revoke a license or to install a new one[18].

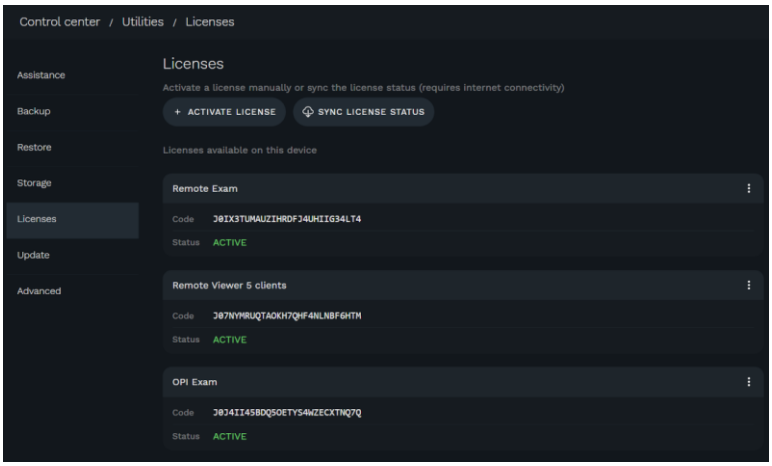
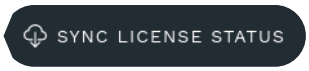


Fig. 180 - Utilities|Licenses Screen

MAIA will automatically download any assigned license when connected to the iCare/CenterVue License Server. A suitable network configuration and internet connection are required.

Push **SYNC LICENSE STATUS** to immediately synchronize the status of the device licences from the iCare/CenterVue server. At the right of the button, the information about the last synchronization appears (see Fig. 180).	
Click **ACTIVATE LICENSE** to manually activate a license. In the *Activate licence pop-up (*Fig. 181). Insert the license code and push **ACTIVATE**, or click **CANCEL** to abort the operation.	

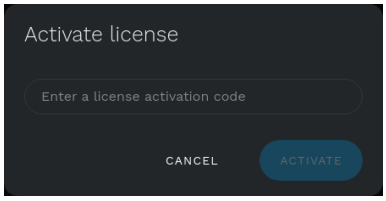
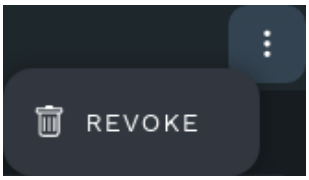
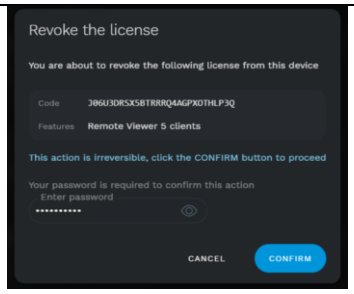


Fig. 181 – Activate License pop-up

To **remove** a license, click on the **ellipsis** at the right of the licence box, and then push **REVOKE**. The *Revoke the license* pop-up appears.	
Insert the administrator password and push **CONFIRM** to remove the license, or click **CANCEL** to abort the operation. When you proceed with the revocation, the *License revoked* pop-up appears (Fig. 182).	

[18] *Please refer to your local Authorized Distributor for requiring licenses*

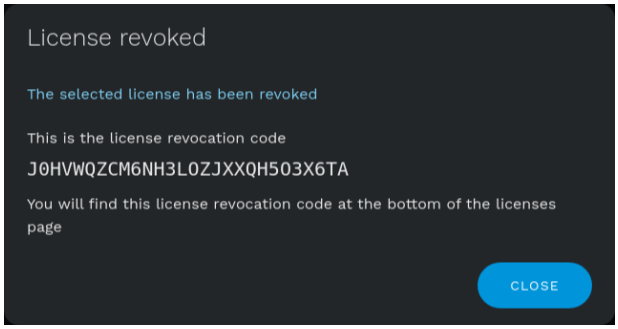
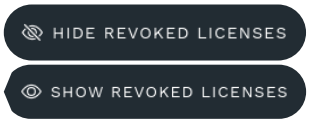


Fig. 182 – License revoked pop-up

The revoke of a license is an irreversible operation. To activate a revoked functionality, ask the iCare/CenterVue service for a new valid license.

To retrieve the list of the revoked licenses of the device, toggle the **HIDE/SHOW REVOKED LICENSES** at the bottom of the *Utilities*|*Licenses* Screen.	

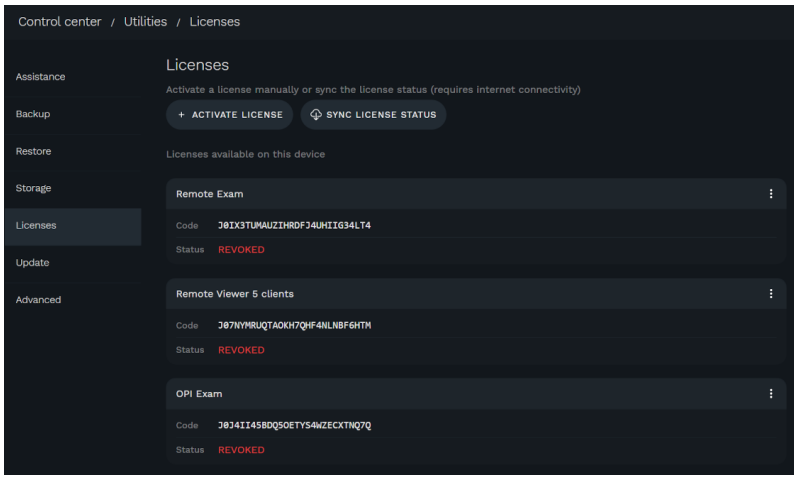


Fig. 183 - Utilities|Licenses Screen, license revoked

19.6 Update

Access the *Utilities*|*Update* Screen (Fig. 184) to install software updates and upgrades. The access to this panel is limited to the Administrator user. Software updates can be obtained either online or through a USB flash drive. All your configurations will be preserved.

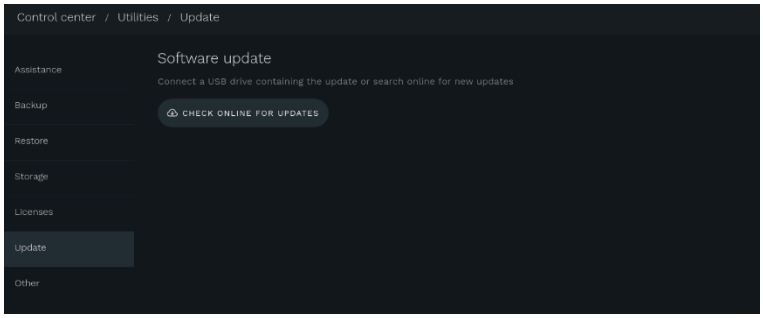


Fig. 184 - Utilities|Update Screen

19.6.1 Online updates

Push **CHECK ONLINE FOR UPDATES**. The *Search for online software updates* pop-up appears (see Fig. 185).	

Push **CHECK ONLINE FOR UPDATES** to allow the connection to the iCare/CenterVue servers or click **CANCEL** to abort the operation.

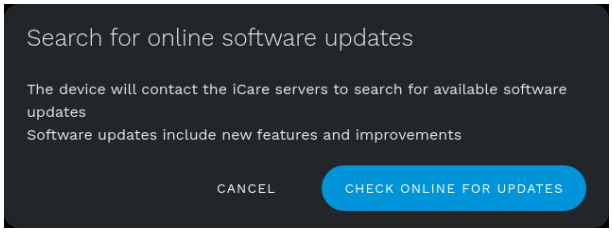


Fig. 185 - Search for online software updates pop-up

When an update is found, in the *Online Software Updates panel* push ***DOWNLOAD THE SOFTWARE UPDATE*** to receive the update or click **CLOSE** to abort (see Fig. 186).

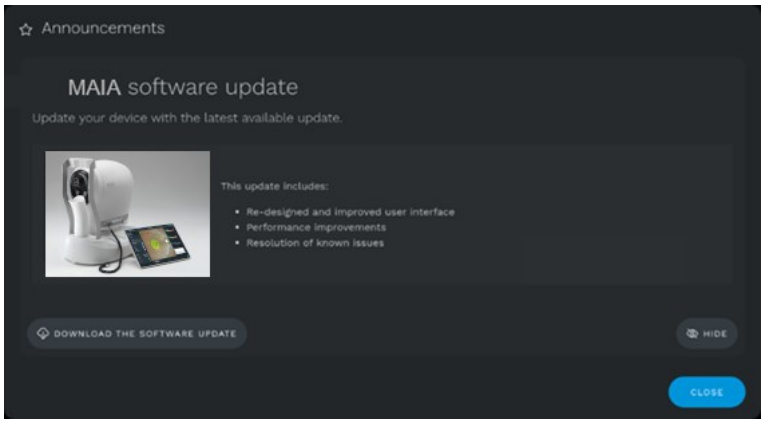
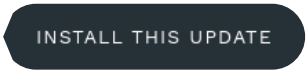


Fig. 186 - Online software updates panel

Wait for the download, then push **VIEW AND INSTALL THE DOWNLOADED UPDATE** to proceed, or push **CLOSE** to abort the operation.	
In the *Utilities*|*Update* Screen, push **INSTALL THIS UPDATE**.	

The Screen will now show the update file in the *1 update found* box, as shown in Fig. 187.

19.6.2 USB updates

Save the installation package on the top folder of a USB flash memory. Plug the USB drive into one of the three USB ports. The device will detect the installation package automatically, and the *1 update found* box will appear, as in Fig. 187.

19.6.3 Installation of the updates

The procedure is the same for the online and the USB updates.

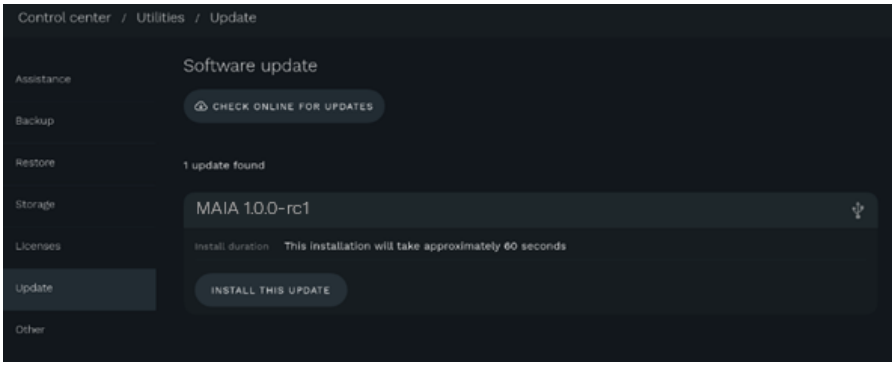
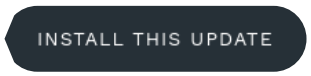


Fig. 187 - Utilities|Update Screen**, 1 update found**

In the *Utilities*|*Update* Screen, push **INSTALL THIS UPDATE**.	

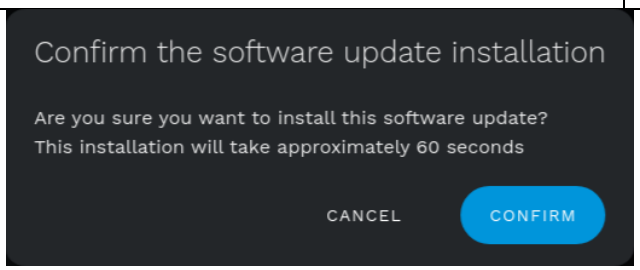


Fig. 188 - Installation confirmation pop-up

In the *Confirm the software update installation* pop-up (see Fig. 188), click **CONFIRM** to proceed with the installation or click **CANCEL** to abort the operation.

The *Software update appears (*Fig. 189*).* Wait until the end of the update or click **CANCEL INSTALLATION** to abort the operation.

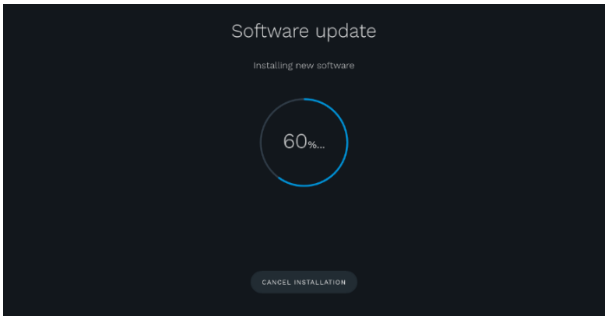


Fig. 189 - Software update Screen

At the end of the update, the *Device Updated* Screen appears (Fig. 190). Push **START** to verify the setup configuration described in §**6.6** and start using the device.

Fig. 190 – Device Updated screen

20 TECHNICAL SPECIFICATIONS

Microperimetry Features

Projection field:	30° (diameter)
Background luminance and color:	4 asb, white
Maximum luminance:	1000 asb
Dynamic range:	0 - 36 dB
Stimulus size, shape and color:	Goldmann III, round, white
Stimulus duration:	200 ms
Test strategies:	4-2 (Full threshold), 4 Levels Fixed, Scotoma Finder, Fixation Only, custom strategies (optional)
Test patterns:	Standard 10° (10° area, pattern of 3 rings, 37 points), circular 6° (6° area, pattern of 3 rings, 37 points), circular 20° (20° area, pattern of 4 equidistant diagonals, 41 points), 10-2 (20° area, 68 points), custom grids, Targeted Grids (optional)
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:	TrueColor, infrared
Resolution:	17 µm

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
Minimum pupil size:	3 mm
Working Distance:	28 mm
Auto-focusing adjustment range:	-12 D to +15 D
MAIA Control interface:	15” multi-touch, color, embedded display
Connectivity:	Wi-Fi and Ethernet connection
Hard disk:	SSD, 480 GB or higher
Size (WxHxD):	Device: 360 x 590 x 620 mm (14.2" x 23.2" x 24.4") Display: 390 x 180 x 190 mm (15.4" x 7.1" x 7.5")
Weight:	27 kg (59 lbs)
Power supply:	Rated voltage 100-240VAC, Frequency 50-60 Hz Power Consumption 80W
Service life (lifetime):	The service life (lifetime) of the device is five (5) years from the date of manufacturing.
MAIA is equipped with[19]:	• 15’’ multi-touch display • Support bracket for display with mounting kit • External power supply with power cord • Forehead and chin rest silicone cushions • Dust cover • Patient push button • Front lens cap • Magnetic light shield • USB extension cable
Accessories:[20]	No Accessories

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

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

21 CLEANING AND DISINFECTION

This section explains how to clean and disinfect the device.

a. Cleaning

The cleaning process, to remove the dust or visible dirt and visible signs from the device, especially from the lens, is described as follows:

1. Turn off the device and disconnect the power cord from mains.
2. Carefully clean the embedded display and the device's exteriors: use a clean lint-free microfiber tissue dampened with small amount of water (i.e. tap-water);
3. Carefully 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. Carefully 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, embedded display and any other components) using a clean lint-free microfiber tissue dampened with small amount of water or a mild hand detergent.
5. Carefully clean the front lens (only if visible dust or signs are present) 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.

b. Disinfection

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. Carefully 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 display, any aluminum parts, touch screen and components if present.
4. Carefully 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 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 wipe area after one pass.
5. Allow all surfaces to dry for 5 minutes before turning on the device.

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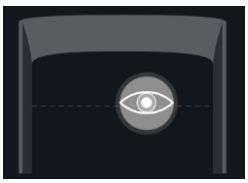
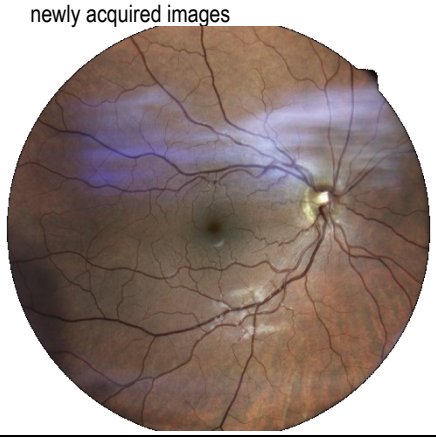
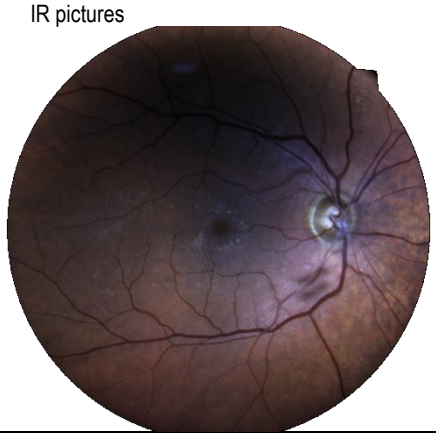
Fig. 191 - Removal of the chin rest silicone pad

⚠	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. Risk of damaging labels and risk deriving from malfunctioning of the device if the recommended cleaning methods are not followed.

22 TROUBLESHOOTING

Symptom	Possible cause(s)	Solution
1. MAIA does not power on (no green LED)	MAIA is not powered	Plug the power supply into a properly working socket then press the power button for at least 3 seconds
2. The green LED is off even though the device is powered	This behavior is intentional	Press the power button to switch on the green led for 30 seconds, then it will turn off again. Refer to §6.5
3. The display does not turn on	The cable was plugged the wrong way (▲ facing down).	Power off the device, connect the display cable correctly, and then switch on the device again (see §6.2).
4. System keeps failing alignment with message “Eye not found”	Difficulty finding the pupil	Reposition the patient acting on the chinrest. It is possible to check the pupil cameras’ live stream by tapping on the alignment graphical representation (see §11.12): 
5. Bluish artifacts as in this example appear in all newly acquired images 	Front lens is dirty	Clean the front lens (see §21)
6. The captured image is totally white or black	Patient blinked during image capture	Repeat the capture and ask the patient to refrain from blinking.
7. System is not usable and the “Critical error 1120021” shows up, reporting a message such as “Critical hardware failure. Exam functionalities will be permanently disabled”	Malfunction of the rotating mirror or of the infrared LED board for pupil illumination or other non-self-recoverable critical condition	Press the UNLOCK HARDWARE button on the notification message to reset the lock condition (see §17.2.1). If the condition persists or occurs frequently, contact an Authorized Service representative to receive assistance.
8. 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.
9. The “Warning 1120043” message shows up at the end of an exam.	Self-recovered anomaly in the Projection System	The device was able to autonomously solve the anomaly in the Projection System: no action needed from the operator (see §11.15).
10. The “Warning 1120042” message shows up at the device startup, or at end of an exam	Unrecoverable anomaly in the Projection System	Contact an Authorized Service representative and report the error (see §11.15).

23 MAINTENANCE

The Manufacturer recommends the periodic maintenance of the device once per year.

Only properly qualified Authorized Service Technicians can perform maintenance activities[21].

Contact your local Authorized Service Center if you think your MAIA requires maintenance.

To clean the front lens in case of dirt, refer to §22. To check the disk space, refer to §17.5.

24 ELECTROMAGNETIC COMPATIBILITY

MAIA Device had 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. MAIA 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 MAIA Device do cause harmful interference to other devices, which can be determined by turning MAIA 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.

MAIA 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 operations of MAIA Device. Strong EM emitters like MRI devices, diathermy machines and electrocautery could affect the MAIA functions.

24.1 Manufacturers EMC Declaration to IEC 60601-1-2

The following tables provide specific information regarding compliance of MAIA.

MAIA is intended for use in the electromagnetic environment specified in the below tables.
The customer or the end-user of MAIA 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 MAIA			
Test Requirements	**Test Result**	**Compliance**	**Electromagnetic environment - Guidance**
Class A or B	B	Yes	MAIA use RF energy for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. MAIA 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: ⚠ MAIA is intended for use by healthcare professionals only. MAIA 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 MAIA 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 IEC 61000-3-3	Passed	Yes	

Table 5 - Electromagnetic Emissions for MAIA device

21 Note: MAIA 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.

24.2 Guidance and manufacturers declaration – Electromagnetic Immunity for MAIA devices

IEC 60601-1-2 ELECTROMAGNETIC IMMUNITY FOR MAIA device			
Immunity Test	**Immunity test level**	**Test result**	**Compliance**
Electrostatic Discharges IEC 61000-4-2	• ±8 kV (contact direct discharge) • ±8 kV (contact indirect discharge) • ±2 kV ±4 kV ±8 kV ±15 kV (air discharge)	Passed	Yes
Electrical fast transients/bursts IEC 61000-4-4	• ±2 kV (A.C. power port input) • ±1 kV (Telecom port Ethernet)	Passed	Yes
Surge IEC 61000 4-5	• ±0,5 ±1 kV ±2 kV common mode (A.C. power port) • ±0.5 ±1 kV differential mode (A.C. power port) • ±2 kV common mode (Ethernet)	Passed	Yes
Voltage dips, short interruptions and voltage variations IEC 61000-4-11	*Voltage dips:* • 0% UT, 0,5 cycle with applied voltage dips at 0°,45°,90°,135°,180° 225°, 270° and 315° of the supply voltage • 0% UT, 1 cycle at 0° of the supply voltage • 70% UT, 25 cycles at 0° of the supply voltage *Interruptions: 0% UT, 250 cycles at 0° of the supply voltage* *UT 110V and 230V*	Passed	Yes
Power frequency magnetic field IEC 61000-4-8	• 30 A/m, 50/60 Hz	Passed	Yes
Immunity to conducted disturbances, induced by radio-frequency fields IEC 61000-4-6	*Test made on AC input, Ethernet, display port* *Amplitude (range)* • 3 V (0.15 MHz – 80 MHz) outside ISM and amateur radio bands • 6 V (0.15 MHz – 80 MHz) in ISM and amateur radio bands *Modulation AM, Modulating signal 1 kHz, Amplitude modulation 80%*	Passed	Yes
Radiated RF EM Fields and Proximity Fields from Wireless Communications IEC 61000-4-3	*Amplitude – frequency – modulation* • 10 V/m – from 80 MHz to 2.7 GHz – 1kHz, 80% AM • 27 V/m – 385 MHz – 18 Hz, 50% PM • 28 V/m – 450 MHz – 18 Hz, 50% PM • 9 V/m – 710 MHz, 745 MHz, 780 MHz – 217 Hz, 50% PM • 28 V/m – 810 MHz, 870 MHz, 930 MHz – 18 Hz, 50% PM • 28 V/m – 1.720 GHz, 1.845 GHz, 1.970 GHz – 217 Hz, 50% PM • 28 V/m – 2.450 GHz – 217 Hz, 50% PM • 9 V/m – 5.240 GHz, 5.500 GHz, 5.785 GHz – 217 Hz, 50% PM	Passed	Yes
Radiated Fields in close proximity IEC 61000-4-39	*Amplitude – frequency – modulation* • 8 A/m – 30 kHz – CW • 65 A/m – 134.2 kHz – 2.1 kHz, 50% PM • 7.5 A/m – 13.56 MHz – 50 kHz, 50% PM	Passed	Yes

Table 6 - Electromagnetic Immunity (IEC 60601-1-2) for MAIA Device

24.3 Immunity pass criteria

IMMUNITY	
Function	**IMMUNITY pass criteria**
Primary Functions (device available for exams, taking retinal pictures, performing perimetry tests)	Under EMC disturbances, primary functions shall operate as intended, or shall reach a self-recoverable state
Ancillary Functions (network functionalities, backup and restore, use of remote viewer, export and printouts)	Under EMC disturbances, ancillary functions can operate as intended, be temporarily lost, be self-recoverable, or requiring intervention from user or operator

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

The MAIA device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the end-user of MAIA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MAIA 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 MAIA device, including cables specified by the Manufacturer. Otherwise, degradation of the performance of this equipment could result.

In the event of a self-recoverable condition caused by electromagnetic disturbances, the device will automatically recover within approximately 1 minute after the disturbances cease.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz d = 1.17√P	80 MHz to 800 MHz d = 1.17√P	800MHz to 2.5 GHz d = 1.17√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

24.4 Wi-Fi Specifications

Model Name	WPEQ-261ACN(BT)
Main Chipset	QCA6174A-5
Product Description	802.11ac/a/b/g/n Wi-Fi+BT Combo Half Mini PCIe Module (Bluetooth is disabled)
Tx/Rx	MU-MIMO
Standard conformance	802.11ac/a/b/g/n (2T2R) Dual-Band (2.4 and 5 GHz)
Frequency Range	2.4 GHz ISM Bands 2.412 - 2.484 GHz 5.15 - 5.85 GHz (subject to local regulations)
Interface	Wi-Fi: PCIe
Operation Voltage	DC 3.3V
Maximum RF power	2.4GHz Max power: 19dBm 5GHz Max power: 13dBm
Security	64-bit and 128-bit WEP, WPA, WPA2, WPA2 802.1X

FCC (USA) radio certification

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

FCC ID: RYK-261ACNBT

IC ID: 6158A-261ACNBT

MAIA complies 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.

25 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).

26 LOG OF DOCUMENT CHANGES

IFU version	Description	IFU Release date	Software version
07.00	Introduced Targeted Microperimetry and Custom Strategies.	2026-04-01	1.3.0
06.00	Fixed Bugs	2025-07-21	1.2.1
05.00	Fixed Minor Bugs	2025-05-20	1.2.0
04	Introduced Grid Editing, Image Registration, Time Analysis and Projection System check paragraphs. Updated screenshots.	2025-02-18	1.1.0
03	Updated main label. Updated section §5 and §23.3 with additional warnings and information on EM compliance, and specifying the self-recovery time. Updated table in §24.2. Reviewed §24.4 (Wi-Fi Specifications).	2025-01-20	1.0.0
02	First version validated for EU (MDR), USA (FDA) markets (SW 1.0).	2024-10-24	1.0.0

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