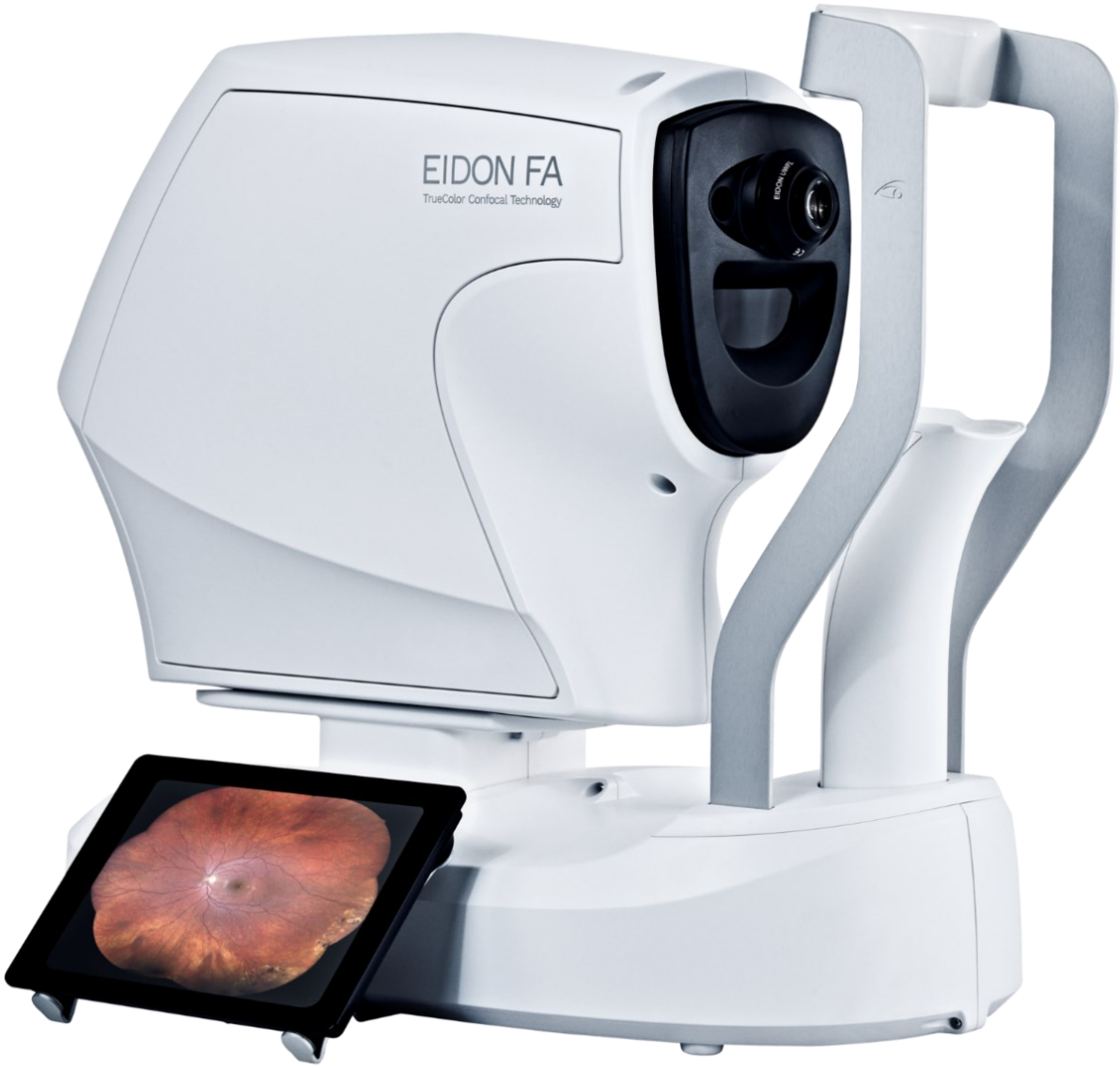
EIDON Family



Instructions for Use

DOCUMENT INFORMATION

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

Date of release:	2025-10-27	
Revision number:	33.00	
Software Version:	4.4	
Devices:	**EIDON Family devices:**	**REF:**
	EIDON	AMFUNME001
	EIDON AF	AIFLUME001
	EIDON FA	AIFLAME001

CENTERVUE S.P.A.
Via San Marco 9h, 35129 Padova – ITALY
www.icare-world.com

CE 0123

icare

CONTENTS

1. GENERAL INFORMATION

1.1 Intended Purpose

EIDON, EIDON AF and EIDON FA are ophthalmology assessments and diagnosis instruments, intended for the acquisition of retinal images with or without a mydriatic agent, and for their review.

1.2 Indications for Use

EIDON, EIDON AF and EIDON FA are indicated 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 obtained by the devices.
The clinical interpretation of the exams acquired by EIDON, EIDON AF and EIDON FA is restricted to eyecare professionals with training in the ophthalmology field (or equivalent) that retain the responsibility of the diagnosis.

1.3 Indications for Use (US FDA)

EIDON, EIDON AF and EIDON FA are confocal scanning ophthalmoscopes indicated for color, infrared and autofluorescence imaging and fluorescein angiography of a human retina with or without the use of a mydriatic agent.

1.4 Clinical benefit

The EIDON Family devices do 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 they do not provide any diagnostic outcome but provide information for the diagnosis.
The performance of the EIDON Family expressed as the ability of the device to achieve its intended purpose is to capture, display and store various images to aid in diagnosing and monitoring of a multitude of retinal diseases.

1.5 Contraindications

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

1.6 Contraindications for Angiography

Injected dye can have side effects for some patients. Read dye manufacturer’s documentation carefully regarding dye side effects and contraindications.

Because there is a possibility of adverse effects of dye injections, only perform fluorescein angiography at the direction and under the supervision of a licensed physician.

1.7 Ophthalmic Devices Compliance

EIDON, EIDON AF and EIDON FA are compliant with ISO 10940:2009 and ISO 15004-1:2020.

When the devices are used with the accessory EIDON UWF Module, the combination is no longer fully compliant with ISO 10940:2009.

1.8 Optical Safety

According to ISO 15004-2:2007 and ANSI Z80.36, EIDON Family devices are a classified as:

- EIDON and EIDON AF: Group 1 - Ophthalmic instruments for which no potential light hazard exists.
- EIDON FA: Group 2 - Ophthalmic instruments for which a potential light hazard exists; consult complete information in section 20 of this document.

The use of the device with the accessory EIDON UWF Module does not change the Group of the devices.

1.9 RoHS Compliance

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

1.10 Electrical Safety

The devices are compliant with IEC 60601-1:2005+AMD1:2012+AMD2:2020.
The devices are classified as Class II, type B applied part.
The devices are suitable for continuous operation.

1.11 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.

1.12 Essential Performance

The clinical performance of the EIDON Family devices is 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 EIDON, EIDON AF and EIDON FA have no Essential Performance as defined in the IEC 60601-1 standard.

1.13 Use Environment

EIDON Family Devices are intended for use in professional healthcare facility environment:

- Ophthalmic & Optometrist Offices
- Ophthalmology Clinics
- Hospitals
- Research laboratories
- Medical offices
- Optical Shops, where a medical office is available

The devices are suitable for use in domestic and home healthcare environment. Consult complete information about electromagnetic environment requirements in section 19 of this document.

1.14 Patient Profile

EIDON, EIDON AF and EIDON FA can be used on any adult subject able to remain seated upright, to place the chin rested on the chinrest and the forehead placed on the forehead rest, alone or with the aid of another person.

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

The patient is not required to interact with the devices, apart keeping the eyelid open and staring at the fixation target.

Patient population is NOT intended to be the end user of the devices.

1.15 Intended user

The primary intended users of EIDON Family devices are healthcare professionals.
The devices are not intended for lay users.
The primary user profiles have been identified and described as follows:

User profile ROLE	Context of use	Characteristics
Operator user	Operating as per the medical intended purpose: Image acquisition and review Cleaning and disinfection Troubleshooting	Demographic trait: Healthcare professional with training in ophthalmology or equivalent: - Opticians - Ophthalmic photographers - Optometrists - Ophthalmologists - Clinical researchers - Medical assistants. Required knowledge, skills and abilities: - Experience with using medical imaging system that have an embedded computer and software user interface - Basic computer knowledge - Qualified and experienced personnel, familiarized with the contents of the 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.

1.16 Principle of operation

The acquisition of the retinal images is achieved by confocal illumination of the eye fundus by means of a scanning line, and simultaneous acquisition of the same portion of the illuminated retina. The devices are able compensate for eye movements by tracking in real-time the position of the pupil and adapting its position and focus accordingly.

1.17 Temperature of applied parts

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

1.18 Content of the device packaging

Each device is provided with:

Front lens cap
Custom Control Interface with multi-touch display
Support bracket for User Control Interface
USB extension cable
External Power supply
Power cable
Forehead and chin rest silicone cushions
Dust cover
3D Joystick with support bracket
External fixation target
Prismatic stereoscopic goggles
Packing straps
Mini-HDMI-to-HDMI adapter
Mounting kit: screws, washers and hex key
This Instruction for Use (or Leaflet in case of electronic Instruction for Use)

2. OVERVIEW

EIDON Family devices are fundus imaging devices which are based on confocal scanning imaging system.
EIDON Family devices are intended for taking images of a human retina with or without[1] the use of a mydriatic agent.
In particular, EIDON Family imaging modalities depend on the chosen device model as follow:

- infrared light to obtain infrared-reflectance images (Fig. 1) (available for all EIDON models);
- white light to obtain color and red-free images (Fig. 2) (available for all EIDON models);
- blue light to obtain autofluorescence images (Fig. 3) (available for EIDON AF and EIDON FA);
- blue light to obtain fluorescein angiography images (Fig. 4) (available for EIDON FA only).

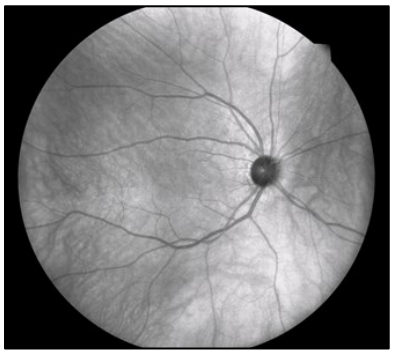


Fig. 1 – IR retinal reflectance image

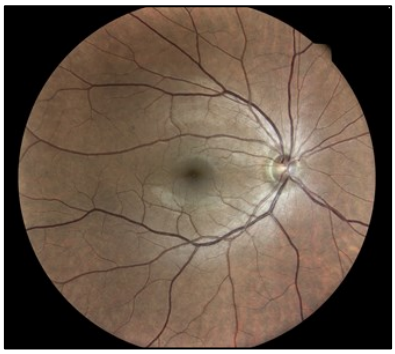


Fig. 2 – Color retinal image

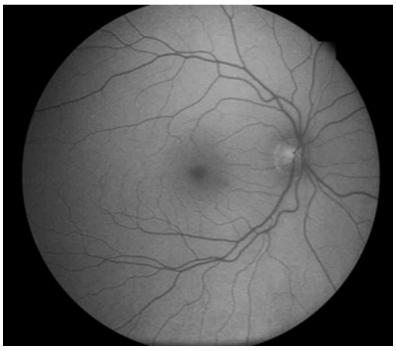


Fig. 3 – Autofluorescence retinal image

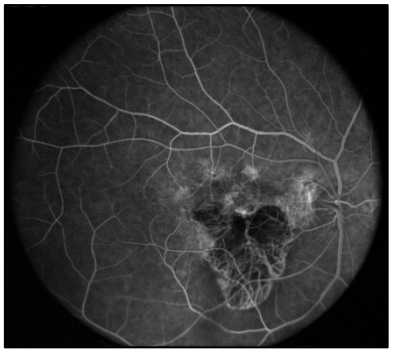


Fig. 4 – Fluorescence angiography retinal image

The clinical interpretation of the images acquired by the EIDON Family devices is restricted to licensed eye-care practitioners: the process of making a diagnosis is the responsibility of the eye care practitioner.

Each device integrates a EIDON Custom Control Interface with multi-touch display, a 3D joystick and an external power supply. All EIDON Family devices work with the same EIDON Family software and they operate as standalone units.

Federal laws (US) restrict these devices to sale by or on the order of a physician or a properly licensed practitioner.

[1] *EIDON Family devices work in a non-mydriatic condition for patients with minimum pupil size of 2.5 mm: the decision to use the mydriatic agent on patient's pupil eye is under the responsibility of the eye care practitioner.*

3. EIDON Family devices

3.1 Devices description

Fig. 5 – EIDON FA as representative example of the EIDON Family devices

1 Device Logo (EIDON or EIDON AF or EIDON FA)

2 Headrest (applied/contacting part)

3 Chin rest (applied/contacting part)

4 Connectors panel

5 EIDON Custom Control Interface with multi-touch display

6 Patient side

The main parts[2] of each EIDON Family device consists of:

- Custom Control Interface with multi-touch display;
- External Power supply[3];
- 3D Joystick[4].

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

[3] *Model MDS-150AAS12-B manufactured by Delta Electronics. It features 100-240 VAC, 50-60 Hz and a consumption of 80 W.*

[4] *Model 3DX-700059 manufactured by 3DConnexion. It features the possibility to adjust focus by using the left (focus +) and right (focus -) buttons of the joystick, using the retinal image as feedback.*

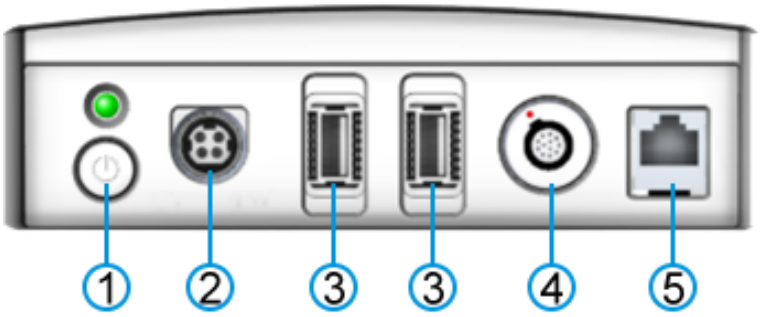


Fig. 6 – Detail of connectors panel

1 Power button and status LED

2 Power supply connector

3 USB ports

4 EIDON Custom Control Interface port

5 Ethernet port

3.2 The EIDON Custom Control Interface

The EIDON Custom Control Interface with color multi-touch display (see Fig. 7) is an integral part of the EIDON Family device that cannot operate without it. The EIDON Custom Control Interface must be connected to EIDON device using the supplied cable[5]. The Mini-HDMI-to-HDMI adapter allows the user to connect the Custom control Interface to an external monitor in order to display the image on a larger screen.

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

Fig. 7 – EIDON Custom Control Interface with multi-touch display supplied with each EIDON Family device

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

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

[5] *EIDON Custom Control Interface has to be connected to EIDON with the cable provided. The cable is permanently connected to the Control Interface.*

4. LABELS, SYMBOLS AND DEFINITIONS

4.1 Labels

Device information such as device model, serial number, manufacturing date and UDI barcode are reported in the labels fixed on the right[6] side of each device as shown in the following figure from EIDON FA which is a representative example for EIDON Family devices: please do not remove them.

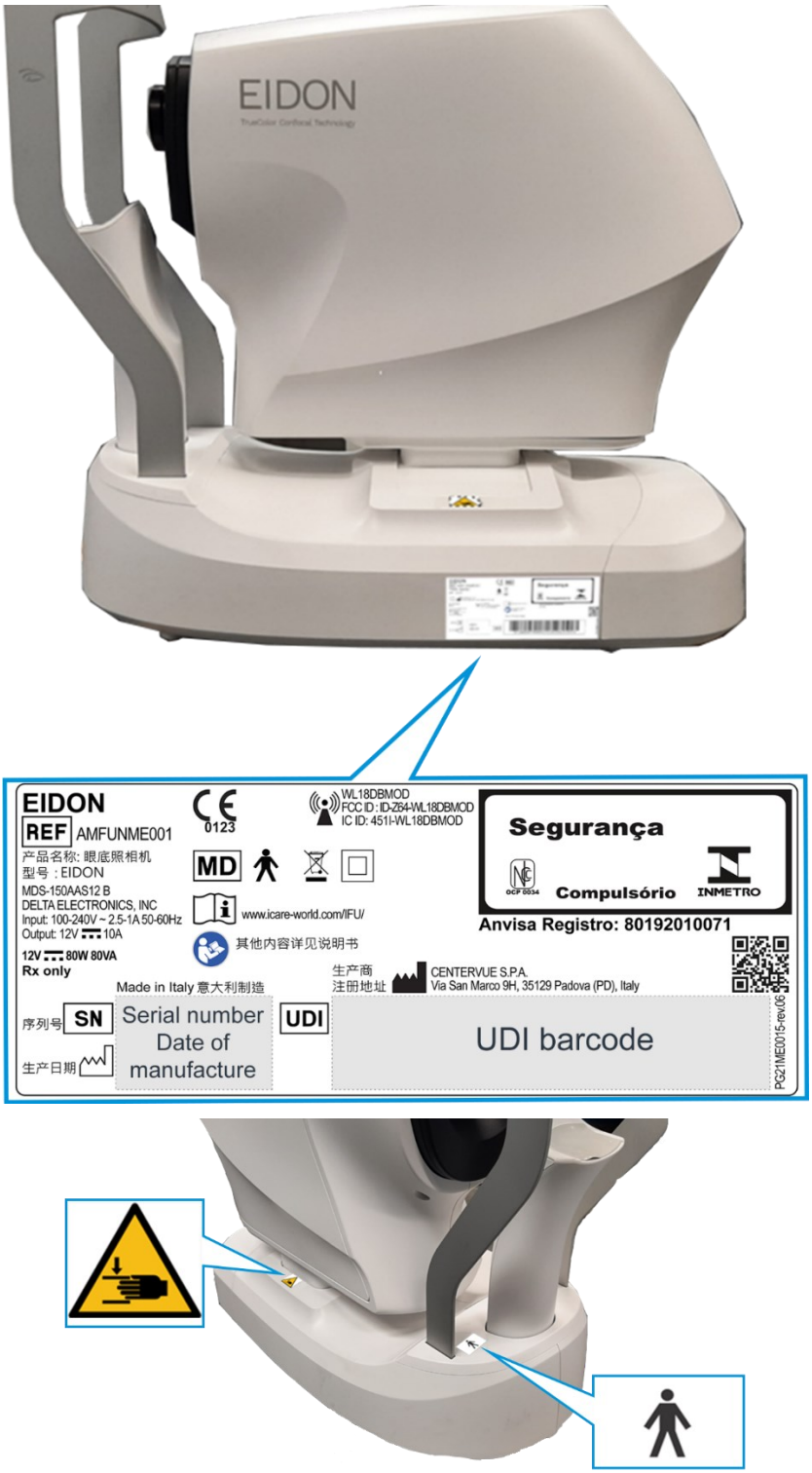


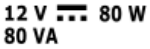
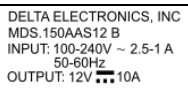
Fig. 8 – Device and warning labels[7] on a EIDON FA model as representative example of the EIDON Family devices

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

[7] *Label might be subject to changes depending on local regulatory requirements. The QR Code label 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 labels is as follows:

Symbol	Explanation
	Information about the Manufacturer.
	Manufacturing date (YYYY-MM).
	Device identifier (catalogue number–product code).
	EIDON / EIDON AF / EIDON FA is a Medical Device.
	EIDON / EIDON AF / EIDON FA Serial number.
	UDI number.
	Electrical and electronic waste is destined for separate recycling.
	Please refer to the eIFU.
	This Instruction for Use must be read Read this Instruction 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.
	Warning, closing motion of mechanical parts of equipment. Take care to avoid injury to hands.
	Applicable for EIDON FA only Warning, Optical radiation. Please carefully read section 20.1

4.3 Other symbols found in the device packaging

The meaning of the symbols adopted in 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 upper relative humidity for storage and transport.
	The maximum and minimum temperatures limits for storage and transport.
	Correct upright position of the transport package.
	Device package shall be kept away from rain and be kept in dry conditions.

4.4 Other symbols found in this Instruction for Use

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

Symbol	Explanation
	Important Information.
	Warning, read carefully.

4.5 Definitions

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

Word	Explanation
Customer	EIDON Family devices' owner (it can be different from EIDON Family devices' end-user).
Device/s	The synonym of EIDON Family device/s used in the Instructions for Use.
Exam	Any retinal image acquisition session performed using the EIDON Family device for a certain patient on a certain date.
External eye examination	The examination mode involving the acquisition of images of the ocular surface instead of the retina.
Field	A portion of the retina visible in a specific image.
Fixation	The ability of a patient to fix his/her view on a specific point, for example the internal fixation target or the external fixation target.
Fixation target	A small bright green circle visible when looking into the front lens of the EIDON Family device, used to move the gaze of the patient and capture different fields.
IFU	Acronym of Instruction for Use.
Operator	EIDON Family devices' end-user
Picture	The synonym of the image acquired by EIDON Family device used in this Instruction for Use.
Pupil	The aperture located in the center of the iris, of variable diameter, which allows light to enter the eyeball. The pupil naturally is open (dilated) and contracts when struck by light. If the pupil is too small the image quality may be impaired.
Remote viewer	The web application running on an external PC.
Retina	The inner layer of the eyeball. It is the main area of interest in the images acquired by EIDON Family devices.
Stereo exam	The examination mode that involves the acquisition of two images of the retina taken from different angles, providing a three-dimensional view using suitable prismatic glasses.

5. SAFETY INFORMATION

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

The following precautions and warnings are important to use the devices in safety:

- The device is for professional use only.
- The device needs to be installed and put into service by Authorized Service Center.
- The power supply of EIDON Family devices 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.
- Do not use EIDON Family devices if the covers or other parts of the device have been removed. Risk of electrical shock
- Do not modify the device without authorization of the manufacturer: if this device is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- Avoid all contact with water: risk of fire or electric shock.
- Stand clear from moving parts during operation. Risk of body injuries.
- Do not open EIDON Family devices: this could lead to electric shocks or damage to the device.
- No serviceable parts inside. Internal inspection is allowed to authorized personnel only.
- Closing motion of mechanical parts of equipment, take care to avoid injury to hands and finger.
- Do not use the device when there are visible signs of materials degradation. Risks deriving from malfunctioning of the device.
- The power supply of the EIDON Family devices is provided with an earth ground by means of a protection conductor contained inside the power supply cable. Before turning on the device, make sure the power supply socket is correctly grounded to avoid the risk of electric shock.
- The power supply of the EIDON Family device works as all pole disconnection from the electric grid.
- EIDON Family devices are supplied with an earth ground by means of a protection conductor contained inside the power supply cable. Before turning on the system, make sure the power supply socket is correctly grounded to avoid the risk of electric shock.
- EIDON Family devices power supply must be connected to a socket with a circuit breaker.
- The use of other cables and accessories on EIDON Family devices than ones provided by CENTERVUE S.P.A., 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; removing the power cable could result in data loss.
- The use of the EIDON Family devices for other purposes than the one intended by the Manufacturer (see section 1.1), as well as any modifications or misuses, are exclusively under end-user responsibility.
- EIDON Family devices are suitable for continuous use operation in accordance with IEC 60601-1.
- External device/s connected to EIDON Family devices, 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 EIDON Family 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.

- EIDON Family devices 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.
- EIDON Family devices must NOT be used in an oxygen-rich environment or presence of flammable anaesthetics. Risk of fire.
- EIDON Family devices must be used and must be placed in a room that is not exposed to adverse chemical-physical conditions, such as the presence of sulphur, salt, dust, direct sunlight, lack of ventilation, high humidity, sudden temperature drops or peaks. The safety and/or effectiveness of the device cannot be guaranteed if these conditions are not met. Risks deriving from malfunctioning of the device.
- EIDON Family devices need 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.
- EIDON Family devices 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
- EIDON Family devices 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
- 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 CENTERVUE S.P.A. shall service EIDON Family devices. CENTERVUE S.P.A. cannot be held responsible for the devices safety should EIDON Family devices be opened, repairs carried out (included using of not CENTERVUE S.P.A.'s genuine parts), third-parties software installed, or parts replaced by an unauthorized person.
- In case an unexpected hardware condition occurs during use, an error message may appear (see for example Fig. 9) and the device may become temporarily locked. It is possible to reset this condition by letting the device re-initialize: refer to § 14.2 for the complete procedure. If the error persists, please contact an Authorized Service Center.

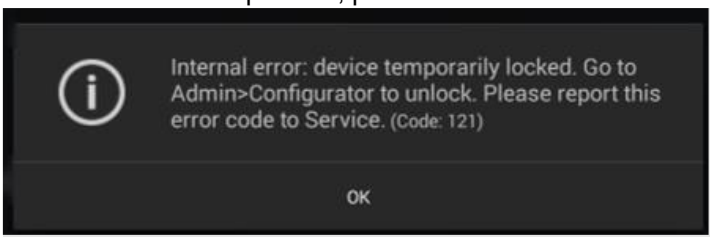


Fig. 9 - Example of error message

- Risks can arise in relation to the biological contamination caused by the environment the device is operated into, and by the user and the patients. Follow the cleaning and disinfection instructions provided below in this document.
- The device is not supplied sterile, nor is intended to be sterilized prior or after use; nevertheless, the risks connected to the biocompatibility of the parts that come into contact with the patient are in relation to severe consequences, including allergic reactions. Contact material used in EIDON Family devices are biocompatible and safe for the contact with intact skin for limited exposure.

The following precautions are important to use the device correctly:

- The clinical interpretation of the images acquired by EIDON Family is restricted to licensed eye care practitioners. The process of making a diagnosis using EIDON Family devices results is the responsibility of the eye care practitioner.
- Device-specific training is not required: it is recommended for the end-user (operator) to carefully read the Instructions for Use to be informed and trained before use. Risk deriving from wrong use of the device.
- Use the device in dim light, or at least away from direct light to facilitate the natural dilation of the pupil.
- Provide explanations to patients before placing them in front of the device: refer to par 7.
- The minimum pupil diameter required to obtain good quality images is 2.5 mm.
- EIDON Family devices work in a non-mydriatic condition for patients with a minimum pupil size of 2.5 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.

5.1 Security Information

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

- When in operation, EIDON Family devices contain Personal Data. Transferring data via USB ports (USB export) or via Ethernet (Shared Remote Folder) may result in compromised patient privacy.
- It is the end user’s responsibility to keep and maintain an updated copy of the data generated by EIDON Family devices through regular use of the backup facility, thus preventing the risk of accidental loss of data.
- To protect your devices against unauthorized access and manipulation, make sure that only authorized personnel have physical access to the device.
- The Custom Control interface offers Wi-Fi connection (used for remote printing): it is strongly recommended to connect only to trusted networks protected by an encryption system, like for example WPA2, and refrain from connecting to unsecured Wi-Fi networks.
- The device offers a Wired Network Connection (via Ethernet cable), used to connect to a Remote Viewer (accessible with device credentials) and to store and/or backup data on a Remote Shared Folder (accessible with infrastructure credentials) in any computer connected to the device via a local area network (wired LAN).

Connecting the instrument 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 or and PC/Laptop/server it is strongly recommended to use complex passwords; refer to your infrastructure's policies to create an effective password. If your infrastructure does not enforce any password policy, we recommend the following:

- a strong password must be at least 8 characters long;
- it should not contain any of your personal information, like your real name, username or your company name;
- it must be different from your previously used passwords;
- it should not contain any word spelled completely;
- a strong password should contain different types of characters, including uppercase letters, lowercase letters, numbers and characters;
- don't write down your password on notes;
- don't share your password with other people;
- change your password from time to time.

- The Remote Viewer browser runs on your PC/Laptop and allows to locally download exams reports and patient's images; reports and images stored in the Remote Shared Folder can be available also in your PC/Laptop. It is strongly recommended to protect your computer by:
  - applying physical security measures (locks, security alarms, monitoring, etc.) to prevent unauthorized persons from accessing your computer that stores patients' personal data files;
  - using full disk encryption (BitLocker) with a strong password to render data unreadable even if an unauthorized person were to gain access to your computer;
  - using firewall and antivirus software to prevent intrusion and to detect infected files that might compromise the security of your computer, and thereby enable unauthorized file access;
  - installing security patches and updates in a timely manner;
  - protect access to your Windows account with a strong password (see indication above);
  - log off or power off when leaving your computer unattended.
- DICOM files usually include very sensitive information about the patient (name, age, ID number, birth date, weight, etc.) and contain the medical images, which itself is of an extremely sensitive nature. Special care must be taken to ensure that this information stays private and is not susceptible to unauthorized access. Before taking any further actions, make sure that you are authorized to view and store specific DICOM files on your machine.
- DICOM related interfaces (Physical Interfaces used to export DICOM Data) are: Shared Remote Folder via Ethernet and USB Export via USB ports.

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

6. FIRST USAGE

6.1 Preparation of the device

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

To make EIDON Family device functional for the first use:

- extract the device from its box;
- place it on a suitable electrical table[8];
- mount the headrest on the metal support (see Fig. 10);
- place the EIDON Custom Control Interface and the 3D Joystick on their supports, screw it with the dedicated screws (§ 6.2);
- connect the power supply provided with the unit to the power inlet (see Fig. 6);
- mount the EIDON Family External Fixation Target (see § 6.3);
- plug the power supply to the wall socket.

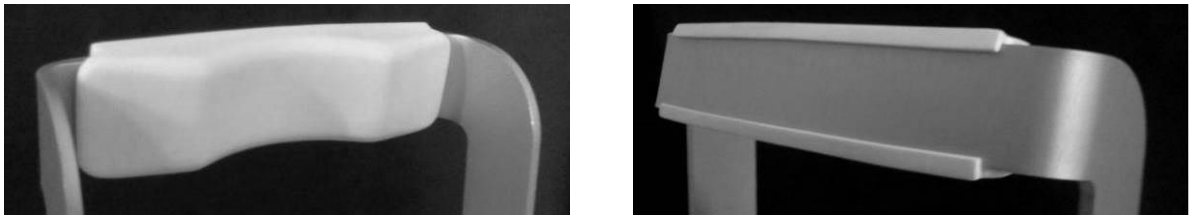


Fig. 10 – Headrest mounted on metal support

6.2 Assembling the EIDON Custom Control Interface and 3D Joystick supports

Fasten the Custom Control Interface to is support bracket using the two dedicated screws.
For the 3D Joystick, first fasten its support bracket to the device and then place the 3D Joystick on it.
The 3D Joystick should be placed close to the EIDON Custom Control Interface. Both supports need to be fixed with screws to the bottom of the device according with the schematic showed on Fig. 13.
Connect the Custom Control Interface to the proper socket and the 3D Joystick to one of the USB ports (see Fig. 6).

Fig. 11 – EIDON Custom Control Interface and 3D Joystick mounted on the left side of the device

Fig. 12 – Support bracket for EIDON Custom Control Interface (left) and for 3D Joystick (right)

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[9] to make one of the USB ports readily accessible.

[8] *It is not provided with the device. For a list of all components included with EIDON family device, see the section "Content of the device packaging" of this Instruction for Use.*
[9] *It is provided with the device. For a list of all components included with EIDON family device, see , see the section "Content of the device packaging" of this Instruction for Use.*

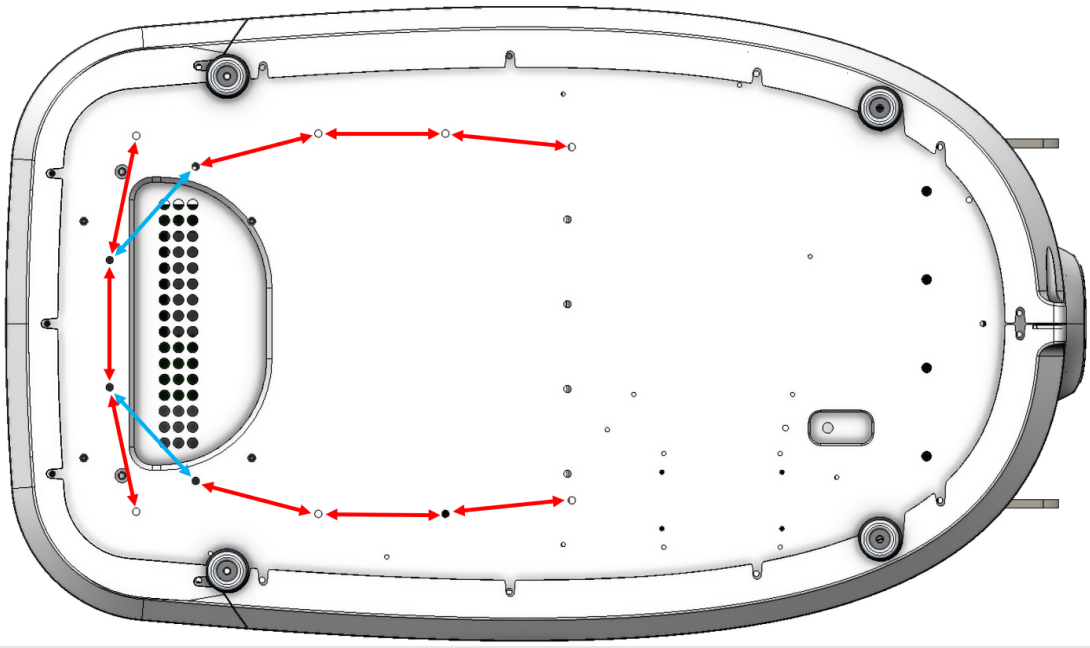


Fig. 13 – Device bottom with holes for Custom control Interface and 3D Joystick supports **RED** positions for both Custom Control Interface and 3D Joystick, **Blue** only for 3D Joystick.

6.3 Assembling the EIDON Family External Fixation Target

The EIDON Family External Fixation Target[10]is an external light that can be used for all EIDON Family devices. Fasten the external fixation target to the headrest using the supplied screws (see Fig. 14); connect it to one of the device USB ports to power it on (see Fig. 6).

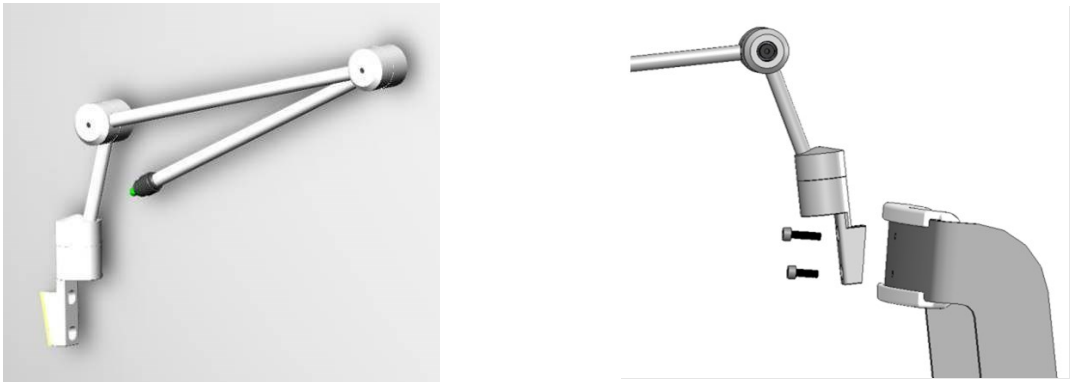


Fig. 14 – EIDON Family External Fixation Target

6.4 Removing the front lens cap

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

6.5 Turning on the Device

Turn on the device by pressing the **Power button** (see Fig. 6), the device will emit a single beep, the **LED Power Status** will power on and the **Custom control Interface** will power on. Then wait for the boot process to complete, until the **Login** screen appears (see Fig. 15).
All the next screens from EIDON FA are representative for the EIDON Family Software used for all EIDON Family devices: EIDON Family Software will show the related name of the specific EIDON Family model used.
During the power-on, the **LED Power Status** performs a red/green/blue pre-boot sequence to test its LEDs functioning.
After two second **LED Power Status** turns off, then becomes steady green. The device is turned on.

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

The following information are important to understand device messages emitted from the color **LED Power Status** (see Fig. 6):

- Steady green light indicates the device is turned on
- Short fast flashing red light indicates the device is rebooting, wait for the device to turn on.
- Single red flashlight followed by blinking blue and green light indicates an error has occurred. Contact an authorized service center and communicate the sequence of blinking lights.
- Fast flashing red/green light means the device is in Protection mode. Wait for the device to turn off before turning it back on. If the error persists, contact an authorized service center.

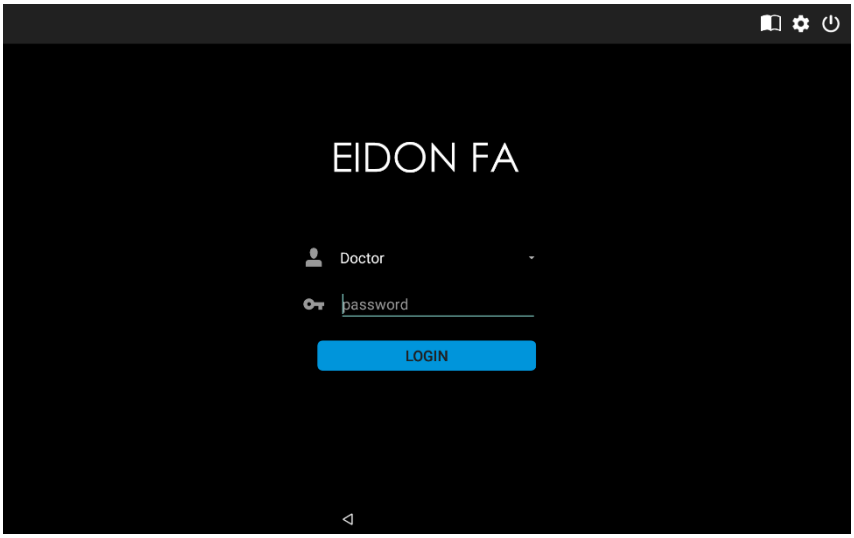


Fig. 15 – Login screen of a EIDON FA as an example

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

- **Doctor** User have only the access to perform exam (§ 8) and review images (§ 9).
- **Admin** User have the access to the Doctor User function and the device's setting (§ 13).

Type the password[11] and click on **Login** button. If login is successful, the **Home** screen opens (see Fig. 16). 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 § 0.
To modify the standby time please, see § 14.12.

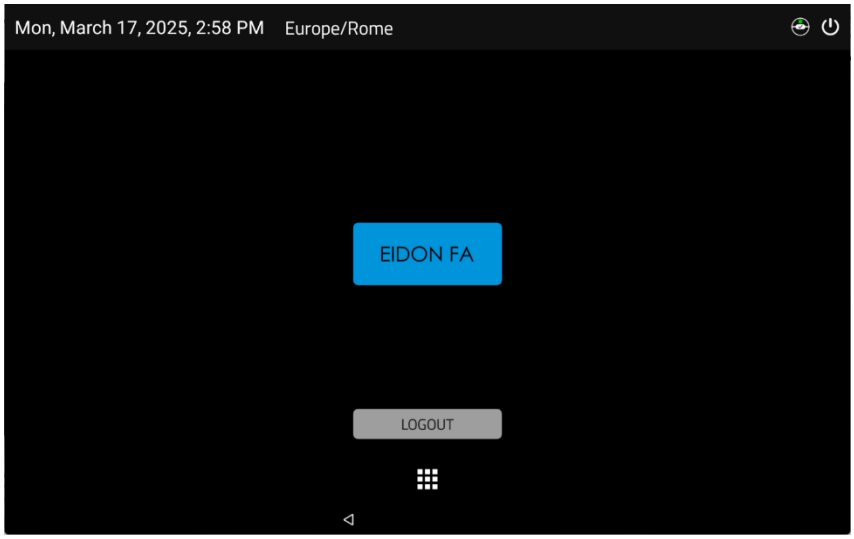


Fig. 16 – Home screen

6.6 Unlock function

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

[11] *Please ask an authorized CENTERVUE S.P.A. representative for the factory password*

7. PREPARING THE PATIENT

This paragraph explains how to prepare a patient for the exam.

The acquisition of retinal images[12] with EIDON Family devices does not involve any risk, because EIDON Family devices will never touch the patient's eye and the only effect perceived by the patient is a flashlight when the device acquires a retinal image.

EIDON Family devices are non-mydriatic[12] devices (minimum pupil diameter 2.5 mm), so there is no need to dilate the pupil's patient, except when fluorescein angiography is being performed. For preparation of the patient for this modality please refer to § 8.11.

EIDON Family devices compensate for a patient's spherical refractive error in the range -15 to +15 diopters: testing a patient presenting a spherical error out of the above range may result in poor quality images. EIDON Family devices do not compensate for a patient's astigmatism.

The patient may wear spectacles or contact lenses while being examined, although this may occasionally cause reflection artifacts in the retinal image.

Patient contacting parts are indicated in Fig. 5.

Before starting the exam, the operator should check the following:

- patient should sit in a comfortable position, with the forehead and chin in firm contact with the rests;
- height of table and chair should be adjusted so that the patient can comfortably place her/his chin on the corresponding rest;
- the patient's head should be vertical (not tilted forward/backward);
- chin rest should be positioned so that the patient's eye is aligned to the mark found on the left side of the metal frame (see Fig. 17). If this is not the case the chin rest height needs to be adjusted (see § 8.6).

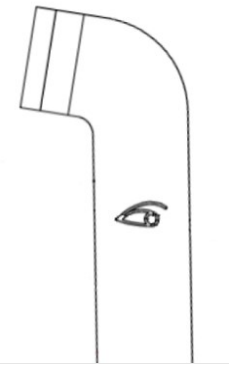


Fig. 17 – Sketch of the eye mark on the metal frame

Before the exam, the operator should inform the patient about the following:

- EIDON Family devices will take photos of the fundus of the eyes;
- the exam is non-invasive, in particular the system will never touch your eye and you will only see a flash of light when a photo is taken;
- find a comfortable position, keeping the chin and forehead firmly pressed against the rests;
- at the beginning of each exam, the device 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 exam starts, look straight in front of you and when a small green, circular spot appears anywhere, look at it;
- do not move, nor speak during the exam:
- try to not blink when instructed.

[12] *EIDON Family devices work in a non-mydriatic condition for patients with minimum pupil size of 2.5 mm: the decision to use the mydriatic agent on patient's pupil eye of under the responsibility of the eye care practitioner.*

8. PERFORMING THE EXAM

This paragraph explains how to operate EIDON Family Software to perform the image acquisition process. Once the Device has been turned on (see § 6.5), click on the device' name button (EIDON or EIDON AF or EIDON FA) to open the **Patient List** screen (see Fig. 18). The **New exam** button in each Patient record is a shortcut that links to the **Exam configuration** screen, bypassing the **Patient** screen.

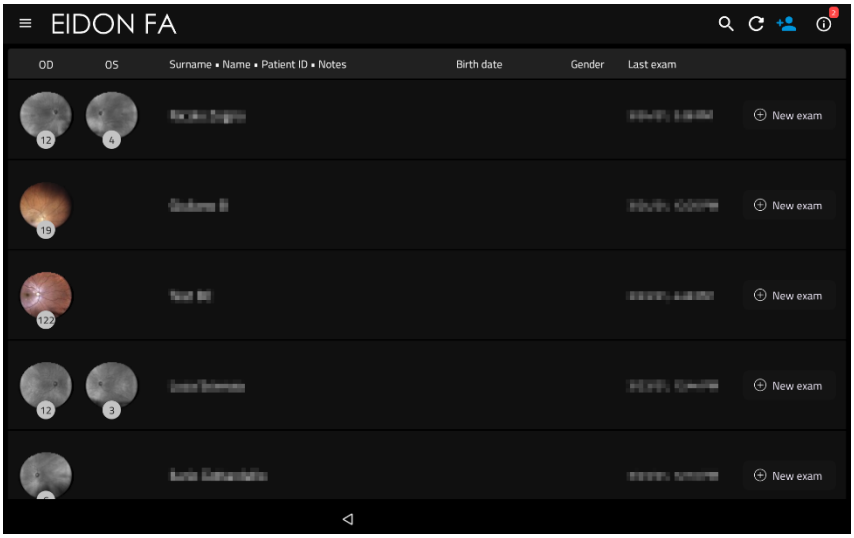


Fig. 18 – Patient list screen as an example from EIDON FA device

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

- presence and number of images (represented by the retinal images) stored for a certain patient (right and left eye);
- patient's Surname and Name, Patient ID, Birth date, patient gender;
- date of last exam, formatted as month/day/year;
- for EIDON FA only, if an FA session is open, instead of **New exam** button will appear the **Resume FA** button that allow to resume the FA session already in progress.

The following commands are available on the upper part of the **Patient List** screen:

Position on the screen	Information
	**Active sessions:** Only available on EIDON FA, shows the FA session already active (see § 8.11.5).
	**Search:** Search for an existing patient (see § 8.3).
	**Refresh:** Refresh of the patient list.
	**New Patient:** Create a new patient (see § 8.1).
	**Information Center:** Show relevant information about the device (see § 13).

8.1 Adding a new patient

To create a record for a new patient, click on and the **Patient Editing** screen will open (see Fig. 19). Type the First Name and Surname (mandatory fields), optionally select the date of birth, gender, patient notes and a code of your choice to identify the patient (patient ID). Then click **Save** button to save or **Cancel** button to abort. When the operator enters a new patient with same Name and Surname, or same Patient ID of and already created patient, a warning message will inform that another patient with the same data already exist in the database.

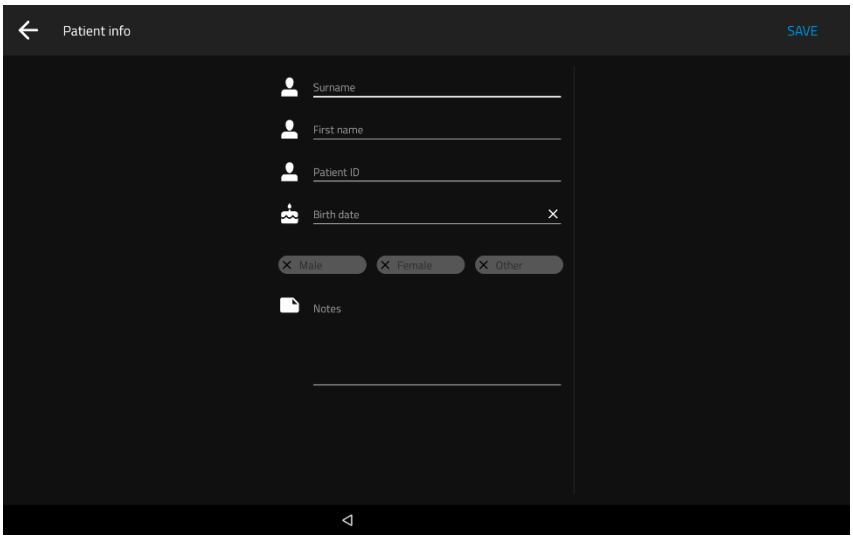


Fig. 19 – Patient editing screen

8.2 Deleting patients

From the **Patient List** screen, press and hold the patient to be deleted: the EIDON Family Software enters a *patient **multi-selection*** mode.

Select other patients to perform a simultaneous delete, then press the icon.

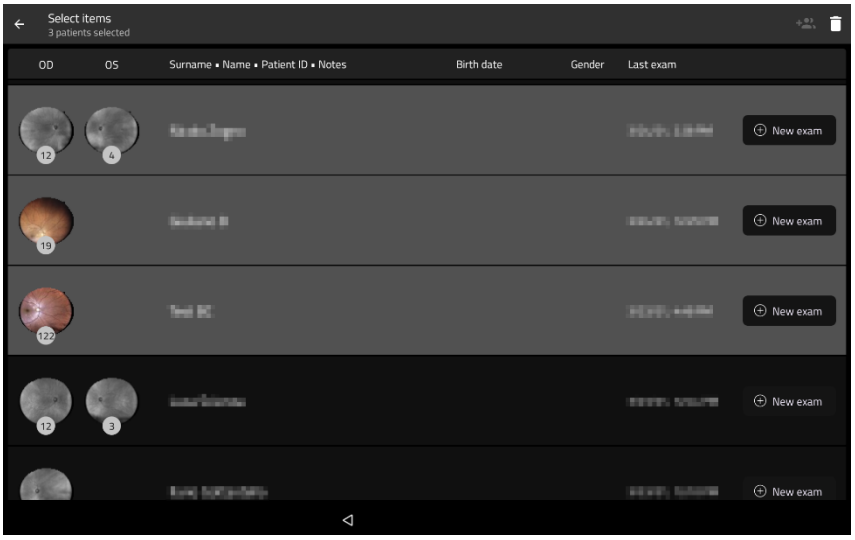


Fig. 20 – Multi selection for patient deleting.

8.3 Searching for an existing patient

To search for an existing patient, click on and type the initial letters of the patient you are looking for. This function will search on **Surname**, **Name**, **Patient ID** and **Notes** fields.

To exit the search, click on to hide the keyboard and then on .

8.4 Patient Merge

Patient merge function allows to select and unify two patients by selecting the records to be merged. Following the instruction (see Fig. 21 and Fig. 22):

- Select the duplicated patient (e.g., merge of Smith Jon with Smith John)
- Select the patient's personal data you want to keep (e.g., Keep data of Patient 2)
- Press **Proceed** to confirm the operation
- Once the merge is completed the Patient will result as the sum previous two patients images.

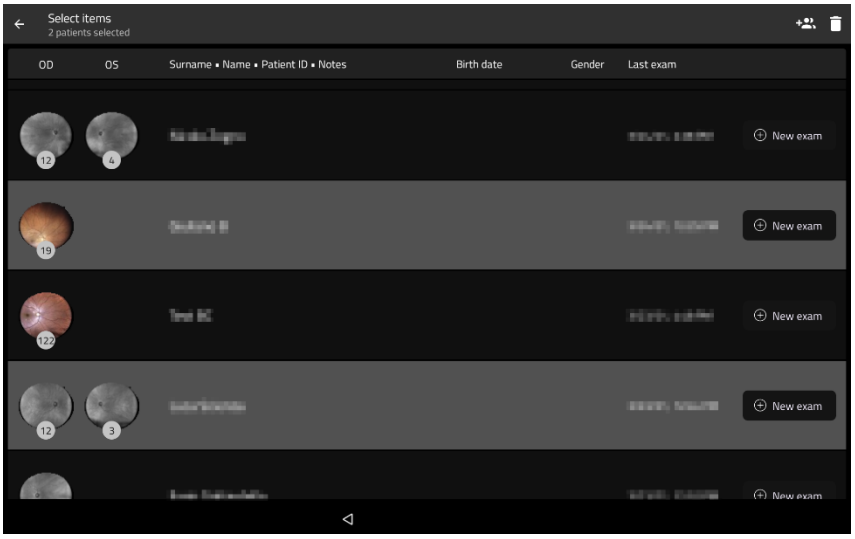


Fig. 21 – Selection of patients for Patient Merge

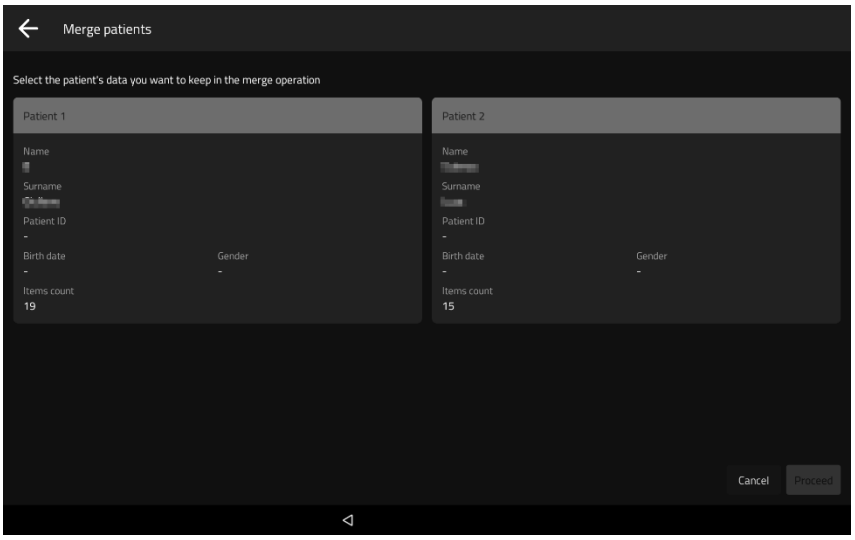


Fig. 22 – Selection of patient to keep.
Images will be transferred from Patient 1 to Patient 2

8.5 Selecting an existing patient

To select a specific patient in the **Patient list**, click on it. The list is sorted by the date and time of the last exam and can be scrolled up and down.
Once a patient has been selected, the **Patient Record** screen opens (see Fig. 23) and provides information on the selected patient (See § 9 for additional details).
Click on **New Exam** button to start a new exam for the selected patient.

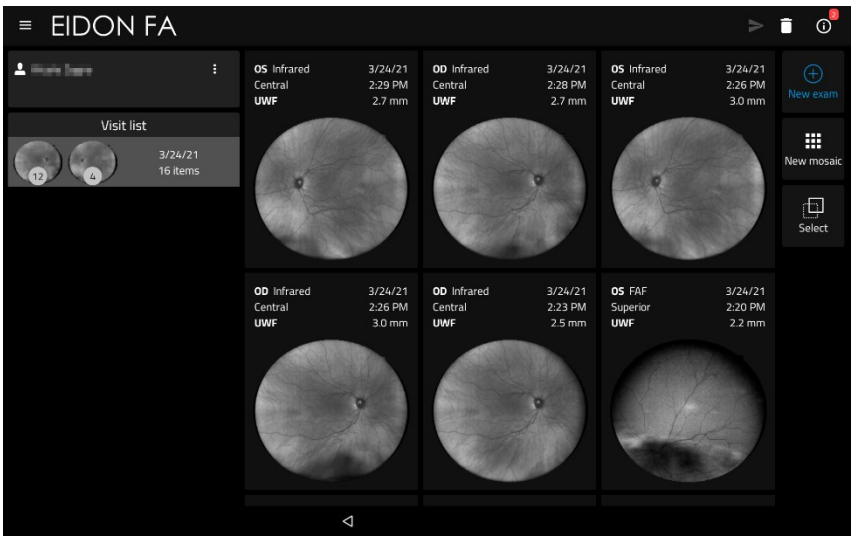


Fig. 23 – Patient Record screen

8.6 Setting up exam parameters

When the New Exam button is clicked, the **New Exam** screen opens (see Fig. 24). This screen allows to set the exam parameters and trigger the acquisition process.

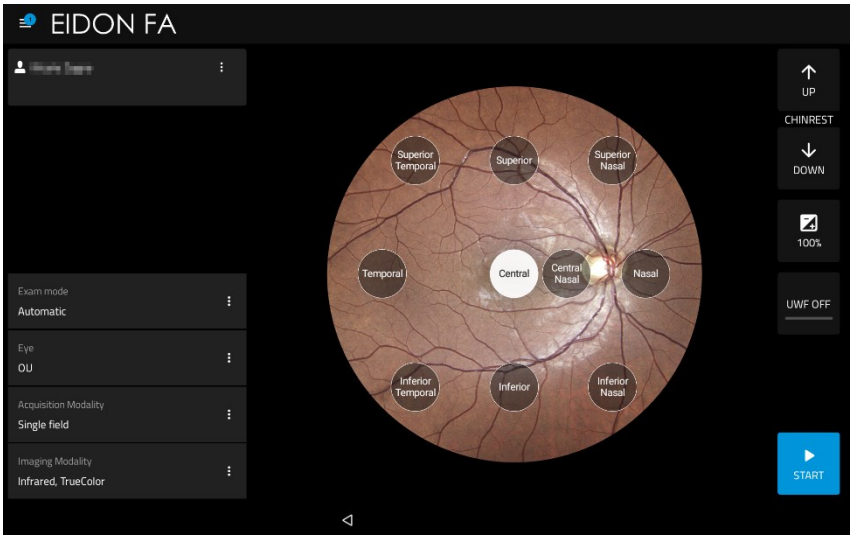
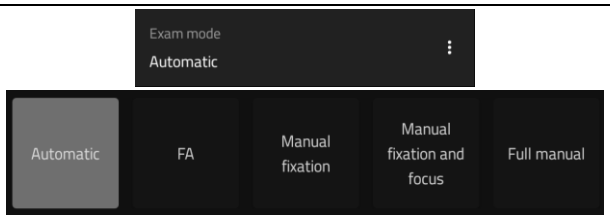
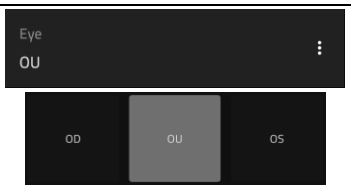
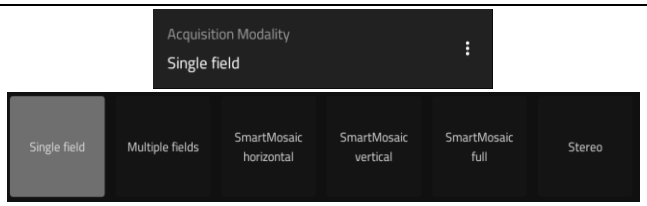
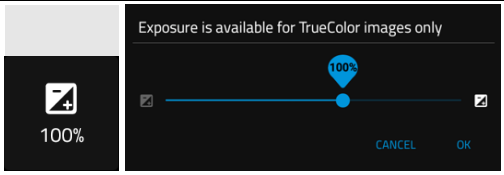
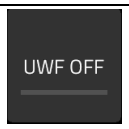
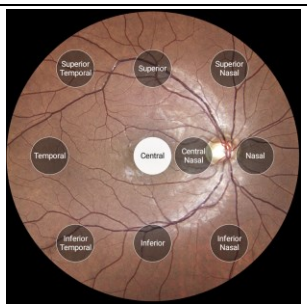
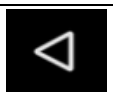


Fig. 24 – New Exam screen

The following commands are available:

Position on the screen	Information
	Edit patient's personal data
	Select the **Exam Mode**: - Automatic (see § 8.9), - FA (only available on EIDON FA see § 8.11). Manual mode (see § 8.10)
	Select the **Eye**(s) to be captured: - OD: Right eye - OU: Both eyes - OS: Left eye.
	Select the **Acquisition Modality**: - Single Field (see § 8.9.1) - Multiple fields (see § 8.9.2) - SmartMosaic (see § 8.9.3) - Stereo (see §8.9.4)
	Adjust the height of the chin-rest: **UP** or **DOWN**
	**Exposure** value: Adjust the exposure value (see § 8.8)
	**UWF** Status button: Available only with the EIDON UWF Module activated (see §8.12)
	**Start** Button: Start the acquisition process
	**Fields Selection map**: To select the field(s) to be acquired (see § 8.7).
	Go back to the **Patient Record** screen

8.7 Selecting the field(s) to be captured

The following fields can be selected:

- **Central**: centered on the foveal pit;
- **Central-Nasal**: centered 5° nasally to the foveal pit;
- **Nasal:** centered approx. 20° nasally to the foveal pit;
- **Temporal**: centered approx. 20° temporally to the foveal pit;
- **Superior-Temporal**: centered approx. 12° superiorly and 12° temporally to the foveal pit;
- **Inferior:** centered approx. 20° inferiorly to the foveal pit;
- **Superior:** centered approx. 20° superiorly to the foveal pit.
- **Superior-nasal:** centered approx. 12° superiorly and 12° nasally to the foveal pit
- **Inferior-nasal:** centered approx. 12° inferiorly and 12° nasally to the foveal pit;
- **Inferior-Temporal**: centered approx. 12° inferiorly and 12° temporally to the foveal pit.

8.8 Exposure Value

The exposure is the total amount of light reaching the retina of the patient. In order to have images with the right brightness value, the exposure is automatically adjusted by EIDON Family Software every time the retinal images are acquired.
Some kinds of retinas, due to their reflecting properties, require an adjustment of the default target brightness, i.e. they need to be more or less exposed. With the **Exposure Value** slider, it is possible to modify the target brightness of the acquired images.
See the § 14.5 to adjust the default exposure value.

8.9 Automatic mode

In this **Exam Mode**, EIDON Family Software will automatically perform all steps involved in the exam process, namely:

a. align the instrument to the selected eye;
b. set the fixation target to the location corresponding to the desired field;
c. perform auto-focusing, while maintaining alignment;
d. capture image of the selected field(s);
e. repeat steps b., c and d. for any additional fields or move to next eye and repeat a. through e.

The following information are available on screen during the automatic exam process (see Fig. 25):

A. Patient name and surname
B. Live view from IR pupil cameras and an evaluation of the current pupil size;
C. Eye currently being captured;
D. Field currently being captured and the indication of where the patient should look;
E. Current step of the exam process;

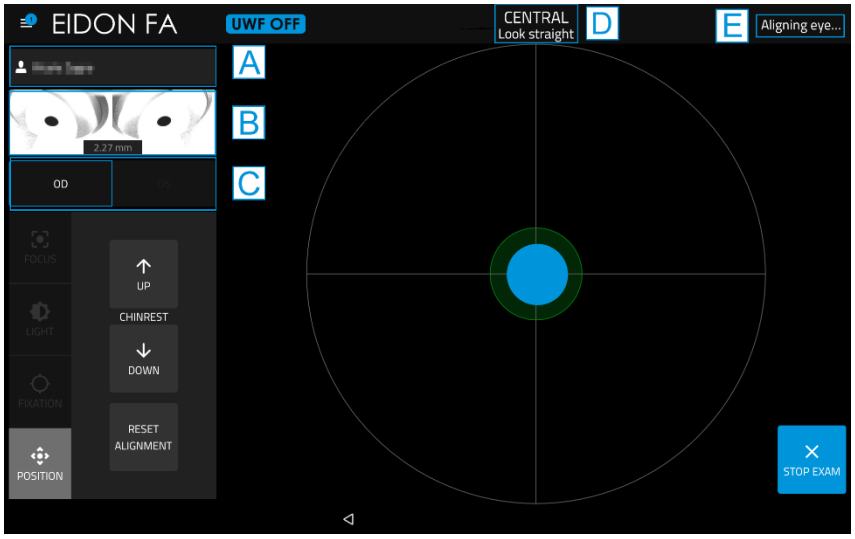
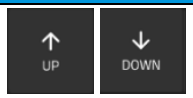


Fig. 25 – Exam screen in auto mode during auto-alignment

The following commands are available during the automatic exam process:

Position on the screen	Information
	Adjust the height of the chin-rest: **UP** or **DOWN**
	Reset Alignment: Restart the Alignment process
	**Stop** the acquisition process and go back to the exam **Patient Record** screen

EYE	FIELD	GAZE DIRECTION
OD or OS	Central	Straight
	Superior	Up
	Inferior	Down
OD	Nasal	Left
	Central nasal	Left
	Temporal	Right
	Superior temporal	Up, right
	Superior-nasal	Up, left
	Inferior-nasal	Down, left
	Inferior-temporal	Down, right
OS	Nasal	Right
	Central nasal	Right
	Temporal	Left
	Superior temporal	Up, left
	Superior-nasal	Up, right
	Inferior-nasal	Down, right
	Inferior-Temporal	Down, left

Table 1 – Gaze directions corresponding to the various fields

If the auto alignment fails, the EIDON Family Software will give the option to switch to full manual mode.

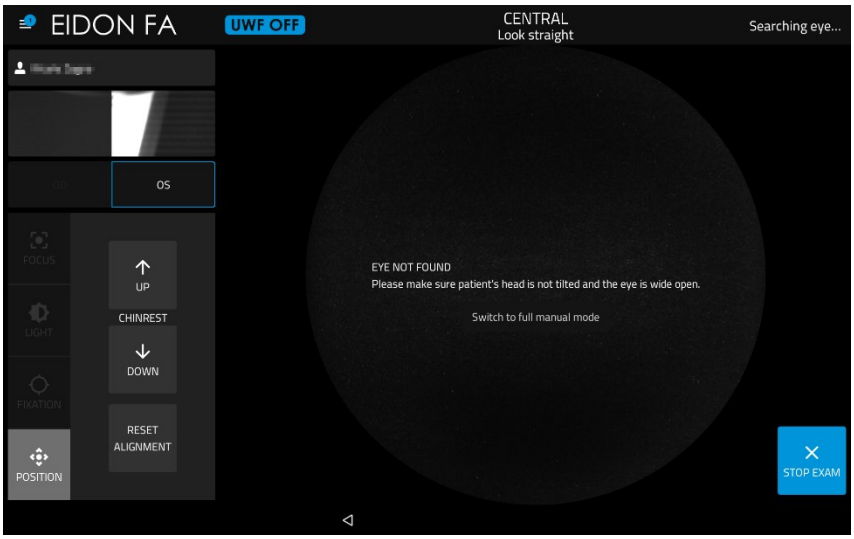


Fig. 26 – Eye not found during alignment phase in automatic mode exam

EYE NOT FOUND	Make sure patient's head is not tilted, eye is open wide
EYE TOO FAR LEFT	Make sure patient's head is well centered in front rest and not tilted
EYE TOO FAR RIGHT	Make sure patient's head is well centered in front rest and not tilted
EYE TOO LOW	Please raise the chin rest until alignment process restarts
EYE TOO HIGH	Please lower the chin rest until alignment process restarts
PATIENT TOO FAR	Make sure patient's head is not tilted, or detached from front rest

Table 2 – EIDON Family Software hints during auto-alignment

8.9.1 Single field

Allows, in combination with the **Field Selection map** on the center of the screen, to select which field (1) will be captured.

8.9.2 Multiple fields

Allows, in combination with the **Field Selection map**, to select which fields (2 to 10) will be captured.

8.9.3 Smart mosaic

Allows to acquire automatically 3 or 5 fields as multiple fields acquisition modality of color images and directly proceed with the Mosaic creation.
The operator can select between the following types of smart mosaic:

- *Horizontal:* automatic acquisition of Central, Nasal and Temporal fields.
- *Vertical:* automatic acquisition of Central, Superior and Inferior fields.
- *Full:* automatic acquisition of Central, Superior, Inferior, Nasal and Temporal fields.

After the fields' acquisition, the EIDON Family Software will ask to select the fields to be retaken before the mosaic elaboration.

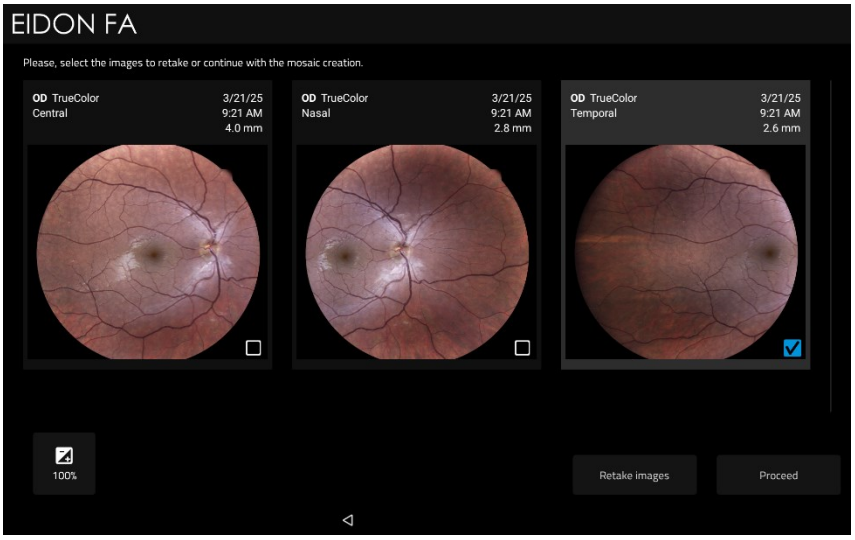


Fig. 27 – Image retake after horizontal smart mosaic acquisition

Select the fields to be retaken then press the **Retake** button to acquire new retinal images: the new retinal image acquired will replace the old retinal images.
If the **Proceed** button is pressed, or if no button interaction is done for 10 seconds, the EIDON Family Software will generate a retinal mosaic image.

If a SmartMosaic OU is performed, the creation of the two mosaic will be done at the end of the exam.

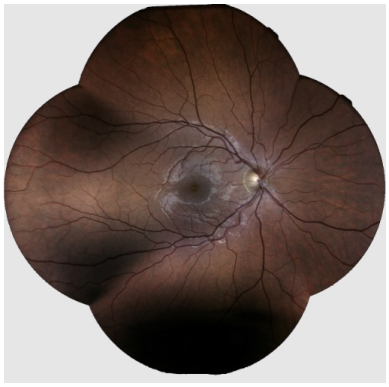


Fig. 28 – Example of full smart mosaic smart mosaic acquisition

Typically, the generation of a 3-fields mosaic image takes around 20 seconds, while a 5-fields mosaic takes up to 1 minute. Mosaic images are permanently stored on the local memory and can be reviewed at any time as individual fields.

8.9.4 Stereo

Stereo functionality in automatic mode is available for nasal and central fixation target to acquire stereo images of ONH and Macula respectively. If a Stereo exam is selected, two slightly offset images of the selected field will be captured with automatic alignment and focus. A delay between the acquisitions is applied in order to let the pupil recover. To review stereo retinal images, please use specific prismatic stereoscopic goggles, such as those provided with EIDON Family Devices. The retake function for stereo retinal images is disabled.

8.10 Manual mode

Partial or full override of automated controls is possible by selecting one of the manual mode options in the **New Exam** screen. This paragraph explains how the different available options work.

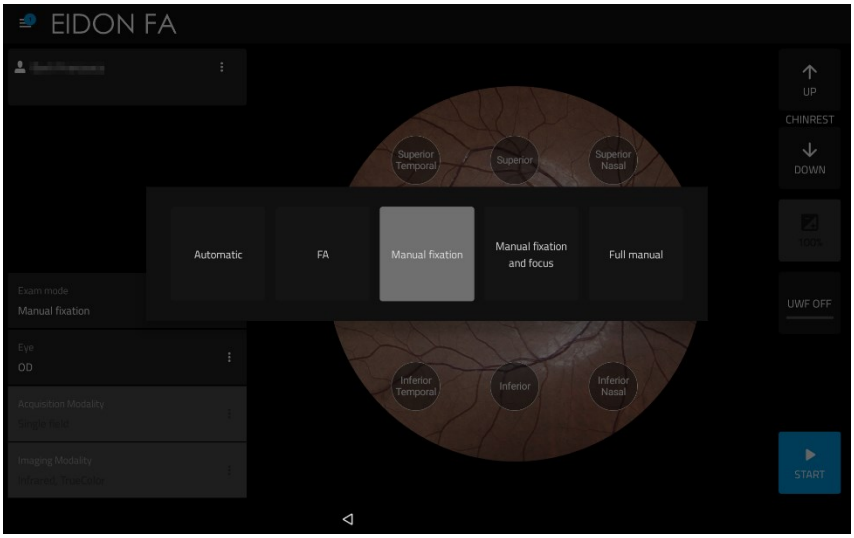


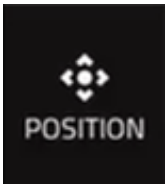
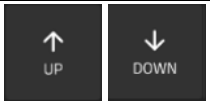
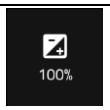
Fig. 29 – Manual mode options (FA option available only in the EIDON FA)

8.10.1 Manual fixation

In this Exam Mode, the EIDON Family software allows the operator to manually adjust the fixation target and acquire images in the different modality.
The device will automatically perform the following steps:

a. align the instrument to the selected eye;
b. perform auto-focusing, while maintaining alignment;

The following commands are available on screen:

Main Tab on the screen	Position on the screen	Information
		Adjust the height of the chin-rest: **UP** or **DOWN**
		**Reset Alignment**: Restart the Alignment process
		**Stop** the acquisition process and go back to the exam **Patient Record** screen
		**Internal fixation:** Allows the standard selection of fixation that appeared superimposed to the live infrared image retina.
		**Manual fixation:** Allows the operator to move freely the fixation on the live infrared image, using the white semi-transparent circle.
		**External fixation:** Allows the operator to use the external fixation powering off the internal fixation.
No Tab		**Switch eye**: Align to the contralateral eye
		**3D switch:** Allows to switch between standard and 3D acquisition.
		**IR:** Acquire a fundus infrared image
		**COLOR:** Acquire a fundus color image
		**FAF:** Acquire a fundus Autofluorescence image
		**Exposure** value: Adjust the exposure value
		**Stop** the acquisition process and go back to the exam **Patient Record** screen

In order to help the Patient, during the Fixation positioning, which could be both Internal or Manual, it appears a green dot that is the position of the fixation target from the patient point of view.

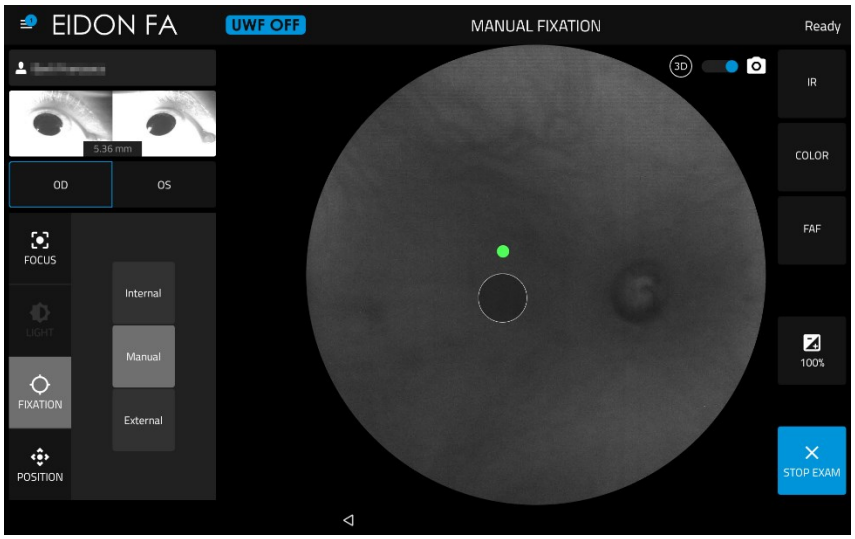
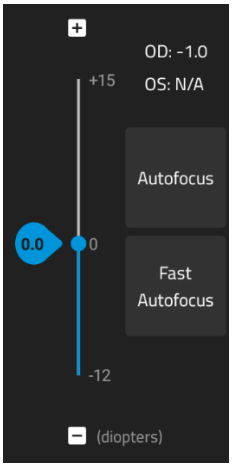
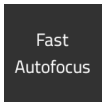


Fig. 30 – Exam screen in manual mode with displaced fixation target

8.10.2 Manual Fixation and Focus

In this Exam Mode, the EIDON Family software allows the operator to manually adjust the fixation target, set the focus position and acquire images in the different modality.
The device will automatically align the instrument to the selected eye and maintaining the alignment.

The following commands are available on screen in addition to the ones explained in the previous § 0 :

Main Tab on the screen	Position on the screen	Information
		Manual **Focus** Adjustment: Allows the manual focus adjustment, by moving the vertical slider or pressing “+” or “-“ Buttons.
		**Autofocus:** Allows to perform the automatic focus adjustment.
		**Fast Autofocus:** Allows to perform a short automatic focus adjustment, on the range of ±2 Diopters from the current focusing position.

8.10.3 Full Manual

This option requires use of the **3D Joystick** provided with the EIDON Family devices.
In this Exam Mode, the EIDON Family software allows the operator to manually align the instrument to the selected eye, adjust the fixation target, set the focus position and acquire images in the different modality.
The device will perform a preliminary alignment to the patient's eye, so that part of the retina is visible on the screen and then the operator can adjust the position using the 3D Joystick as explained on the Fig. 31. Using the 3D Joystick for alignment in the vertical and horizontal directions, bring the retinal reflection to the center of the infrared retina live image.
Once the retina is centered, rotate the 3D Joystick clockwise to move the optical head towards the patient until the retina is fully framed. Once you reach a proper distance adjust focusing as explained for the manual focusing option. Once alignment and focusing are satisfactory proceed as explained for the manual fixation option for displacing the fixation target and capturing images.

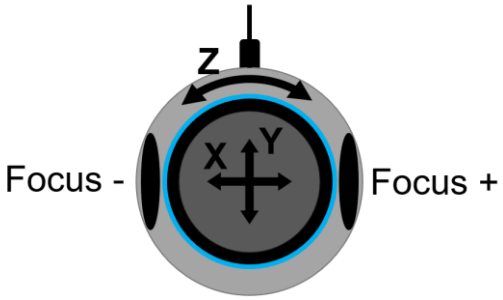


Fig. 31 – 3D Joystick, top view

If at any time while focusing or when displacing the fixation target, the retinal image disappears from view, rotate the Joystick **counter-clockwise** to "zoom out" and re-center as explained above.

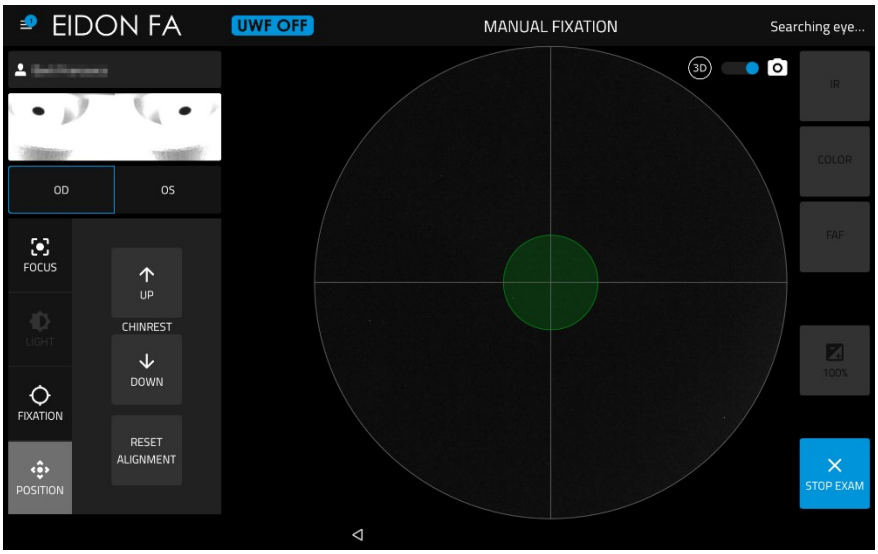


Fig. 32 – Exam screen in manual mode when approaching eye

8.11 Fluorescein Angiography Imaging (FA)

Only EIDON FA model includes additional EIDON Family Software features that allow fluorescein angiography images and videos acquisition, following intravenous injection of fluorescein.

> The decision on whether to perform fluorescein angiography must be made by end-user. It is end-user's responsibility to be properly skilled to perform such procedure, which is outside the scope of the Instructions for Use and of the products.

Any fluorescein angiography session involves the following steps:

- Patient preparation;
- Pre-injection phase;
- Fluorescein injection / recording of early, intermediate and late phase.

> It is outside the scope of the Instructions for Use to provide specific indications about injection of fluorescein dye to perform angiography. In particular, the type and dosage of the fluorescein dye, as well as the injection device (syringe) and administration method shall be decided by the prescribing clinicals and are independent from the use of EIDON FA.

8.11.1 Patient preparation

In addition to what has been described at § 7, the preparation for a fluorescein angiography session involves explaining the entire procedure to the patient, dilating the patient's pupil and, after the pre-injection phase, administering an intravenous injection of fluorescein.
To improve the patient fixation during the FA examination, the internal fixation color is orange, and its size is larger.

> Pharmacological dilation is required during fluorescein angiography exams in order to guarantee that the pupil of the patient remains above the minimum allowed for good quality imaging during the whole exam (2.5 mm in diameter).

> After administration of a mydriatic agent, patient's pupils are dilated, therefore patients may experience glaring or blurred vision. Instruct the patient to be careful when they walk or move around and refrain from driving.

8.11.2 Pre-injection phase

To start a new FA session, select the **FA option** in the **Exam Mode** options (see Fig. 33) and select the target eye.

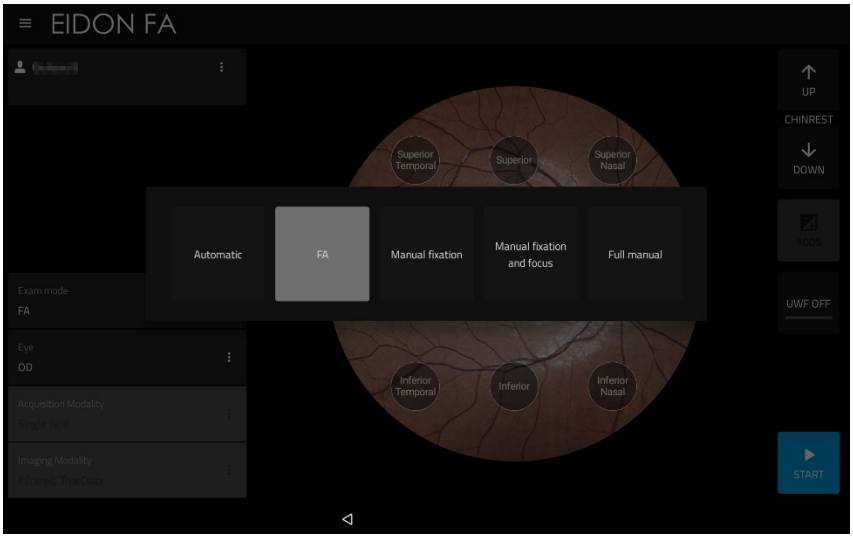


Fig. 33 – FA mode, selection in the new exam screen

Click on the **START** button to start the exam: EIDON Family Software will enter the pre-injection phase (see Fig. 34).

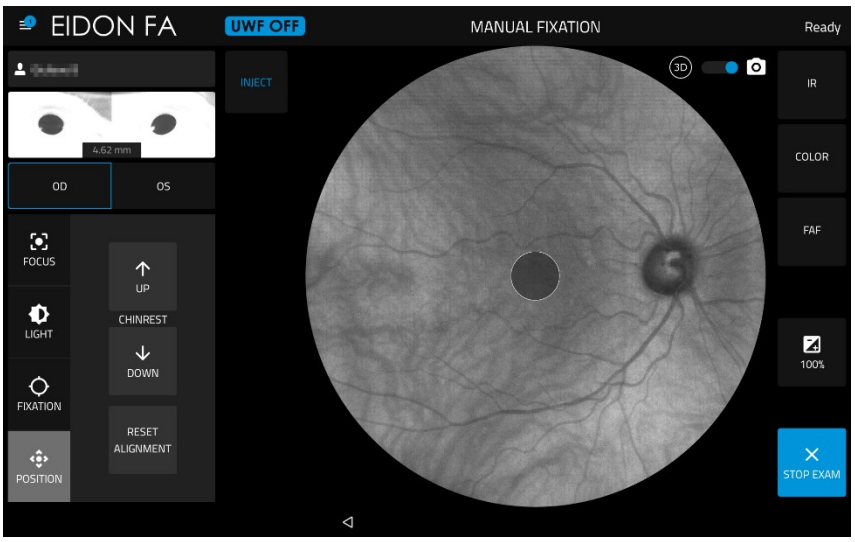
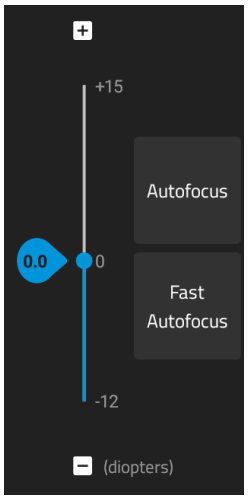
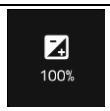
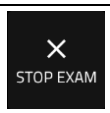


Fig. 34 – FA modality, pre-injection phase

The device aligns and focuses using the focus position calculated in the last retinal image acquired in the same day. If no retinal image was acquired yet, the device performs automatic focusing.

The following commands are available at this time:

Main Tab on the screen	Position on the screen	Information
POSITION	UP / DOWN	Adjust the height of the chin-rest: **UP** or **DOWN**
	RESET ALIGNMENT	**Reset Alignment**: Restart the Alignment process
	STOP EXAM	**Stop** the acquisition process and go back to the exam **Patient Record** screen
FIXATION	Internal	**Internal fixation:** Allows the standard selection of fixation that appeared superimposed to the live infrared image retina.
	Manual	**Manual fixation:** Allows the operator to move freely the fixation on the live infrared image, using the white semi-transparent circle.
	External	**External fixation:** Allows the operator to use the external fixation powering off the internal one.

Main Tab on the screen	Position on the screen	Information
		Manual **Focus** Adjustment: Allows the manual focus adjustment, by moving the vertical slider or pressing “+” or “-“ Buttons.
		**Autofocus:** Allows to perform the automatic focus adjustment.
		**Fast Autofocus:** Allows to perform a short automatic focus adjustment, on the range of ±2 Diopters from the current focusing position.
No Tab		**Switch eye**: Align to the contralateral eye, then autofocus. If the patient has no focusing information for the new eye, the device performs autofocus.
		**Inject: Start the FA session.** The timer and the blue light are activated for the post injection phase.
		**3D switch:** Allows to switch between standard and 3D acquisition.
		**IR:** Acquire a fundus infrared image
		**COLOR:** Acquire a fundus color image
		**FAF:** Acquire a fundus Autofluorescence image
		**Exposure** value: Adjust the exposure value
		**Stop Exam:** Interrupt the FA session and go back to the patient screen: This allows to resume session later.

The light used for FA is a pulsed blue flash, with a 5 Hz repetition frequency. Each pulse of the flash has a certain duration, which can be adjusted. Reducing flash duration will make the exam more comfortable to the patient, but the images may become noisier.

It is recommended to perform at least one acquisition per eye before every FA session: in this way EIDON FA records the eyes position and focus. During the FA session, these positions and focuses are taken as a starting point for alignment and focusing operations, to speed up the switching between eyes. For more information see Post-injection phase.

A preview of the retinal image just acquired will be shown in the bottom left part of the retinal image. Click on it to enlarge it.

8.11.3 Post-injection phase

As soon as the **Inject** button is pressed the device switch to the FA acquisition.
The time elapsed since the injection is prominently displayed at the top of the screen (see Fig. 35).

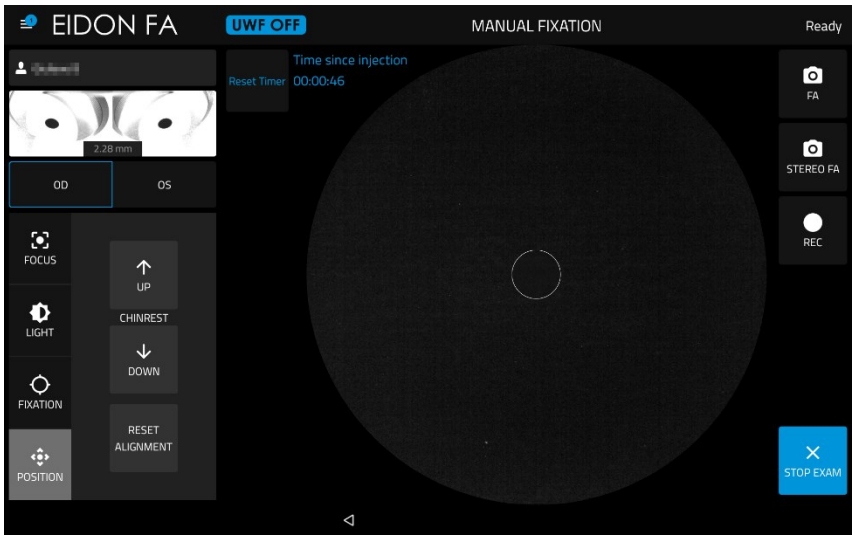
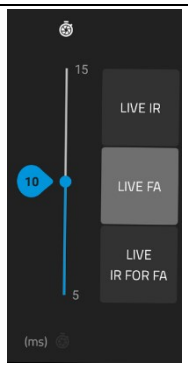


Fig. 35 – FA mode, post-injection phase

The following commands are available on screen in addition to the ones explained in the previous § 8.11.2:

Main Tab on the screen	Position on the screen	Information
		**Live IR:** Allows to switch the light source to IR and enable the IR, Color and AF Imaging Modalities, in the case that the operator need to acquire these images during FA session.
		**Live FA:** Allows to switch to the FA acquisition, to see the live FA view. It's the standard during the Early phase or for the Video acquisition.
		**Live IR for FA:** Allows to switch the light source to IR, but the device remains ready for FA acquisition (this may result in a blurred IR image). This in mainly to reduce the stress for the patient.
		**Flash duration:** Allows to adjust the FA flash duration between 5, 10 or 15 ms.
No Tab		**Reset timer:** Allows to reset the inject timer and revert to pre-injection phase
		**Rec:** Allows to Start FA video capture[13]. Recording stops automatically after 35 seconds. The actual start of the video recording precedes by 5 seconds the click of this button
		**Stop Rec:** Stops FA video capture before its automatic termination
		**FA:** Acquire a Fundus Fluorescein Angiography image
		**Stereo FA:** Acquire a pair of stereo Fundus Fluorescein Angiography images

[13] *Image resolution 1840 x 1644 @ 5 fps*

8.11.4 Resuming an active FA session

Active FA sessions are kept on hold, with the timer running, and can be resumed at any time. To do that, go back to the **Patient List** screen (see Fig. 18), identify and select the patient for whom you want to resume the FA session and click on **Resume FA session** button (see Fig. 36).

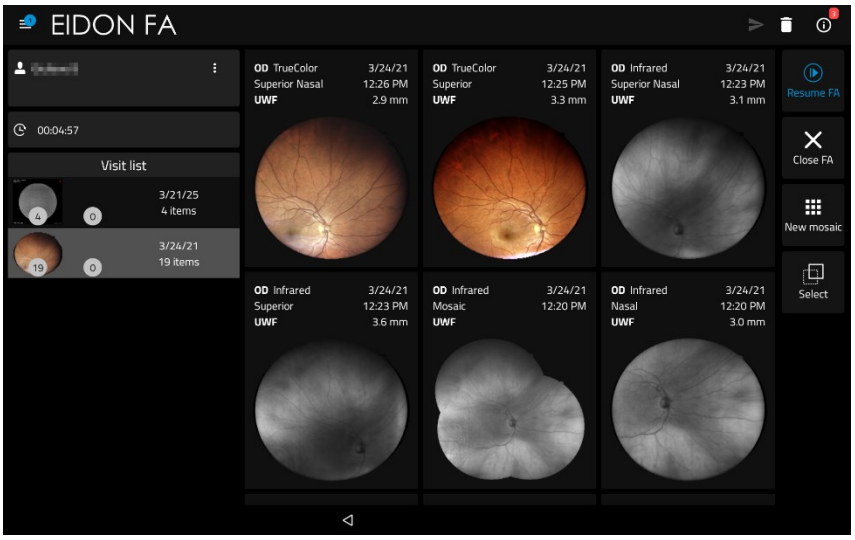


Fig. 36 – Patient Record screen for patient with an active FA session

8.11.5 Active FA sessions list

The **Patient List** screen (see Fig. 18) includes a column that indicates which patients have an active FA session. The list of all active FA sessions is available in a swipe-in side panel that can be opened in the patients list or patient details pages. The panel can also be opened by clicking the ☰ icon on the top-left corner of the screen. The panel is also available during image acquisition although in that case the **Close FA session** buttons are not available.

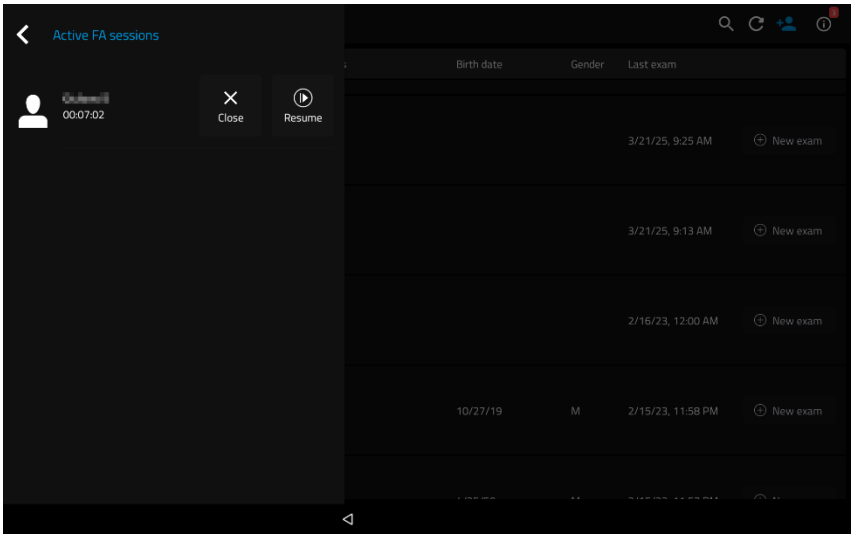


Fig. 37 – FA session tab

8.11.6 Terminating an active FA session

To terminate an active FA session, open the swipe-in panel listing the active FA sessions and click “**Close FA session”** button.

8.12 Ultra-Widefield Imaging modality (only with accessory EIDON UWF Module)

The EIDON UWF Module[14] is compatible with all the EIDON Family devices imaging modalities (color, infrared, autofluorescence imaging and fluorescein angiography) and is intended for extending the field of view of EIDON Family devices[15].

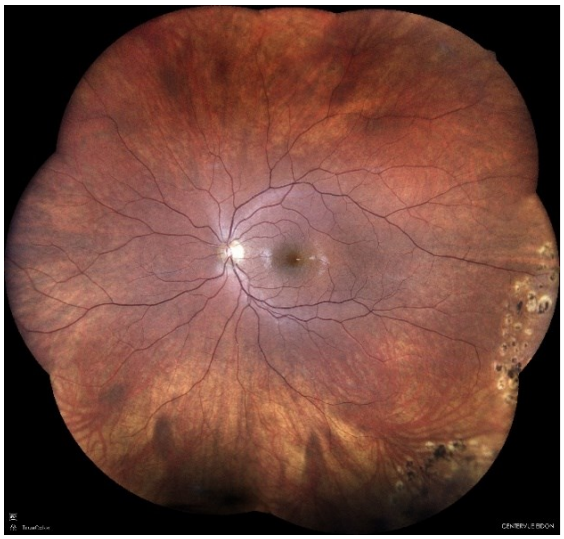


Fig. 38 – Color retinal image with Ultra-Widefield Modality

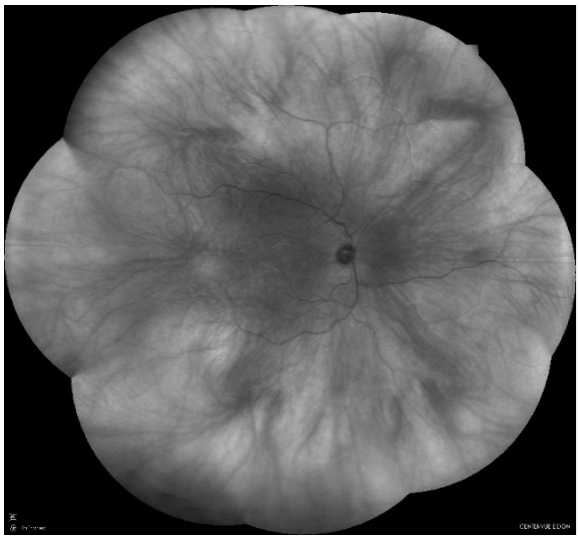


Fig. 39 – IR retinal image with Ultra-Widefield Modality

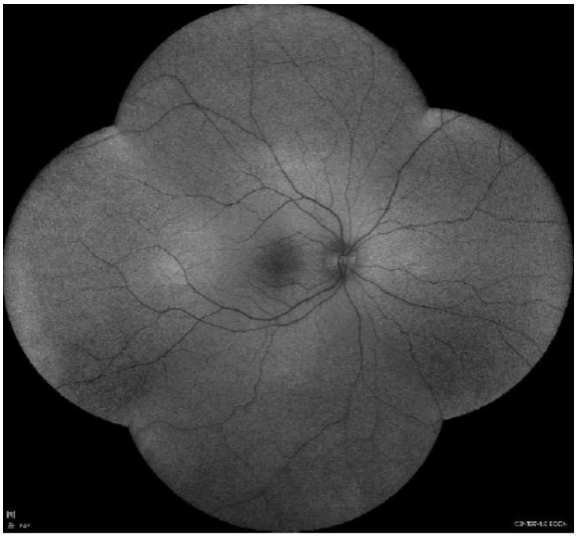


Fig. 40 – Autofluorescence retinal image with Ultra-Widefield Modality

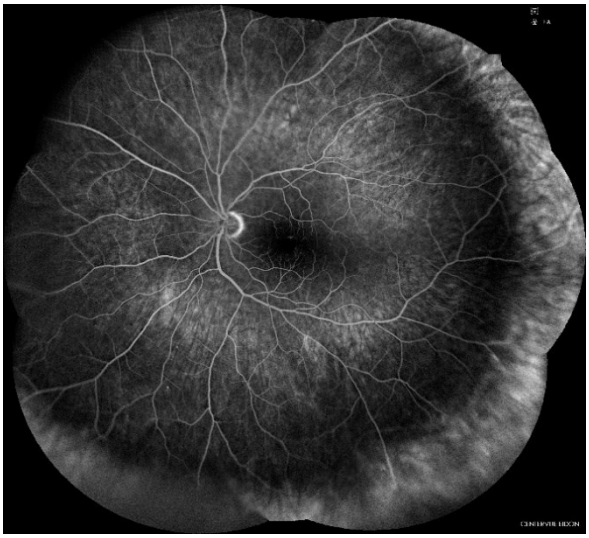


Fig. 41 – Fluorescence angiography retinal image with Ultra-Widefield Modality

Please refers to the EIDON UWF Module Instruction for Use for:

- Instruction for preparing the patient for exam with EIDON UWF Module;
- Instruction for first installation and for mounting and removing the EIDON UWF Module;
- Warning and precaution information including details about the Optical radiation hazard
- Other information (disposal, cleaning, labelling, technical specifications…).

[14] It is an optional accessory to EIDON Family devices and it is sold separately: please, refers to your local distributor for further details and information about this product.
[15] Please, refer to EIDON UWF Instruction for Use for further details and information (technical specification included).

On EIDON Custom Control Interface, press **New Exam** and chose the desired imaging mode with the button **UWF ON // UWF OFF** (see Fig. 42).

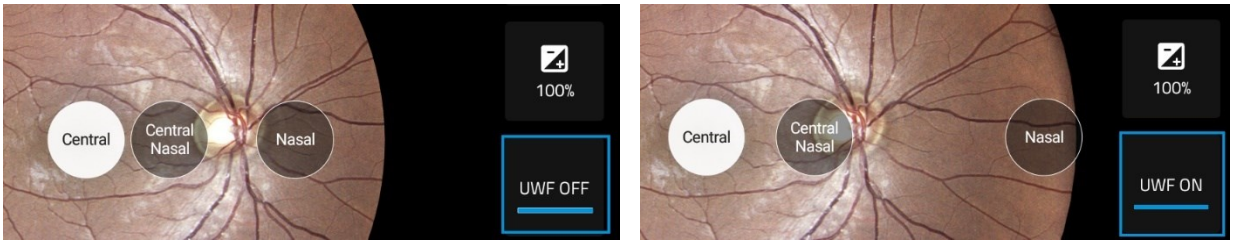


Fig. 42 – UWF ON and UWF OFF button

To perform an Ultra-Widefield (UWF) acquisition, mount the EIDON UWF Module and switch status button to **UWF ON:** exam will progress as usual. To return to standard acquisition modality, remove the EIDON UWFL and switch the status button to **UWF OFF**. During acquisition, a tag (see Fig.43) is always visible to inform the operator on the current selected imaging mode.

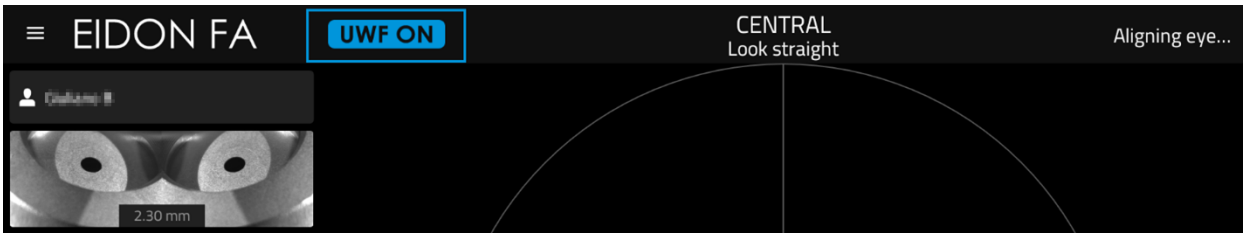


Fig. 43 – EIDO UWF Tag

The EIDON Family Software preserve the last chosen modality (**UWF ON** or **UWF OFF**, see Fig. 42): verify that the current acquisition modality is the desired one, by looking at the **UWF Status** on the top of the screen (see Fig. 43).

Review of retinal image acquired with EIDON UWF Module is made as per standard images review used on EIDON Family device without the EIDON UWF Module installed: please, refers to § 9 for further details and information.

8.13 Image retake

It is possible to retake every retinal image acquired in automatic mode during the current day, except for FA and stereo retinal images.

To retake a retinal image, press the retake icon on the bottom right thumbnail corner: the exposure information panel will appear to set exposure value if necessary before pressing **start exam** button. By clicking on this button, an automatic exam starts, with the same parameters as the retinal image to be retaken (same eye, same field). After the acquisition, the software will ask to keep the old retinal image, replace it with the new one or keep both.

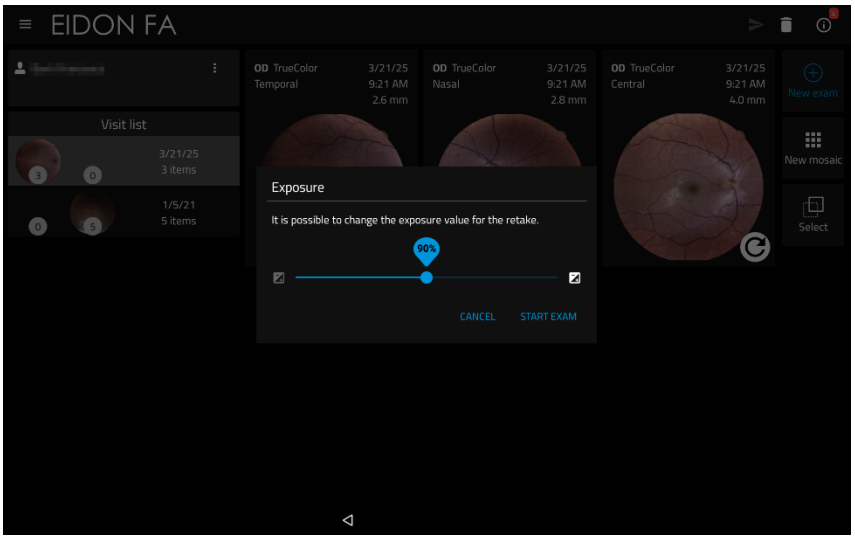


Fig. 44 – Image ready to be retaken

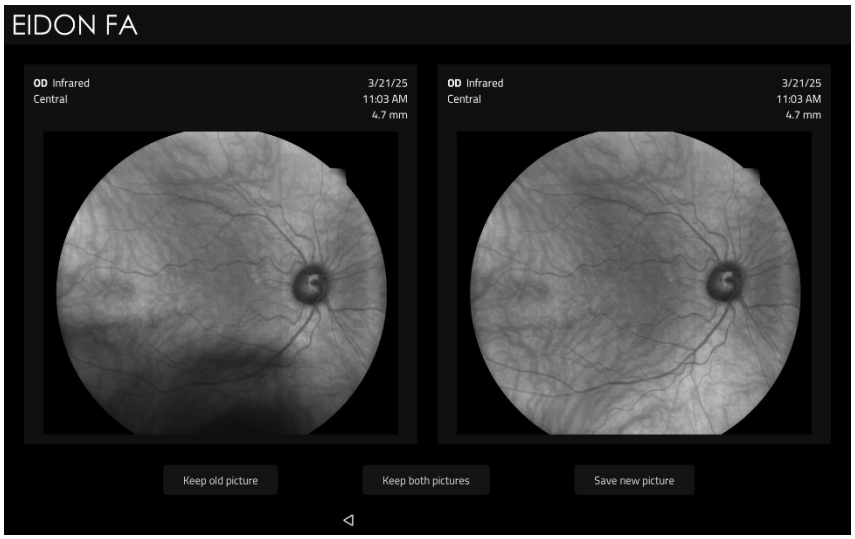


Fig. 45 – Image retaken choose which retinal image to keep

9. REVIEWING IMAGES

This paragraph explains how to navigate on the EIDON Family Software to review and manage from the Custom control interface the images acquired.

9.1 Patient list

Once the Device has been turned on, click on the device' name button (EIDON or EIDON AF or EIDON FA) to open the **Patient List** screen (see Fig. 46).

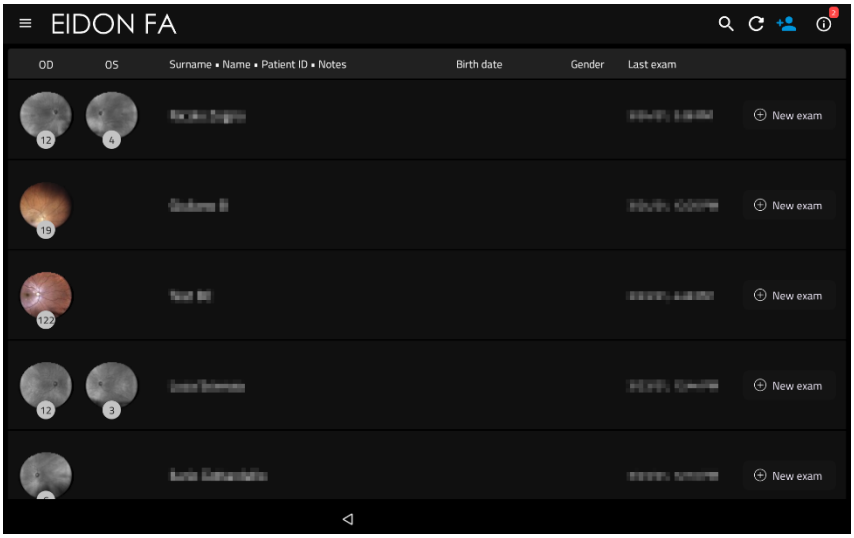


Fig. 46 – Patient list screen

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

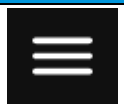
- presence and number of images (represented by the retinal images) stored for a certain patient (right and left eye);
- patient's Surname and Name, Patient ID, Birth date, patient gender;
- date of last exam, formatted as month/day/year;
- for EIDON FA only, if an FA session is open, instead of **New exam** button will appear the **Resume FA** button that allow to resume the FA session already in progress.

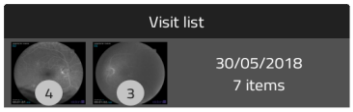
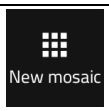
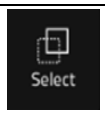
Further information about the **Patient List** screen is available at § 8.

9.2 Patient Record

The **Patient Record** screen (see Fig. 23) presents all patients' related information and a thumbnail view of all retinal images captured at any selected date.

The following commands are available for the review and manage of the patient:

Position on the screen	Information
	**Active FA session List:** Shows the list of the Active FA sessions (See § 8.11.5)
	**Export Button:** Allows to export the images to: • USB (if an USB drive is connected) • Remote shared folder (if it is properly set) When both USB and RSF are active a Pop-up appears asking the user to choose the desired export destination (see § 9.9).
	**Delete:** Used to permanently delete all data pertaining to the current patient. To delete individual retinal images, select the thumbnail by pressing and holding on it, click on other thumbnails (if needed), then press the delete button

Position on the screen	Information
	**Edit patient data:** Used to add or modify a patient's data
	**Edit patient data:** Used to add or modify a patient's data
	**Visit list:** Allows to select different Patient Visit.
	**New Mosaic:** Allows to create a new mosaic (see § 9.5)
	**Select:** Allows to select multiple images in order to delete, export or create a PDF report.
	**Back:** Allows to return to the Patient List screen.

Each thumbnail displays the following information:

- examined eye (**OD**/**OS**);
- imaging modality **(IR**, **Color**, **FAF** or **FA**)
- time and date at which the image was acquired;
- field information (not available when image is acquired in manual mode);
- **3D logo**, when the image has been acquired in stereo mode;
- player icon, when the "image" is actually a fluorescein angiography video;
- **retake** logo, when it is possible to retake the image.

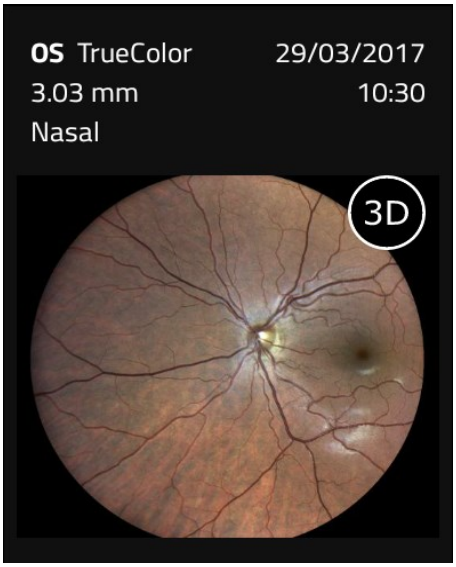


Fig. 47 – Example of thumbnail with 3D logo

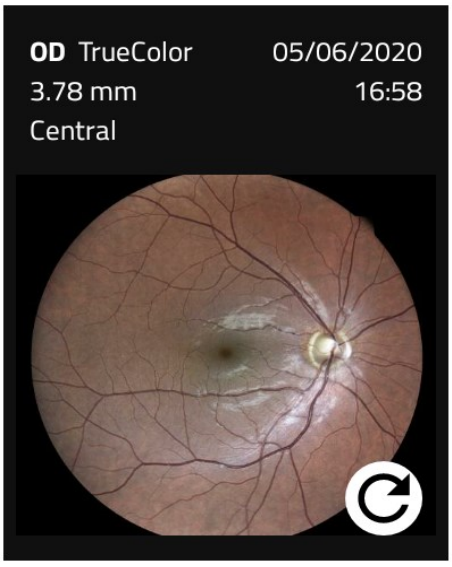


Fig. 48 – Example of thumbnail with retake logo

9.3 Single image review

To review any of the available images click on the corresponding thumbnail: this will open the **Exam review** screen (see Fig. 49).

EIDON Family Device acquires and stores TrueColor images. Nevertheless, the operator can adjust the acquired retinal image according to his own preferences.

Every adjustment to the image is reversible because the original image will never be altered.

It is possible to filter the color component of the image (Blue, Green and Red).

Images can be modified in brightness, contrast and gamma by moving the related slider.

In addition, for color images, it is possible to enhance the red component of the retinal images by applying one of the **Red, Red+, Red++ color filters**: press the button with the name of current setting (True Color in Fig. 49) to select the desired filter.

Red color enhancement can be used together with brightness, contrast and gamma: the adjustments will be applied to every exported image, thumbnail and printout, except for the images stored in the internal shared folder (see § 9.9).

From the **Configurator**, it is possible to change the default settings for brightness, contrast, gamma and red enhancement filters: see the § 14.5 for more information.

To revert to the default settings (i.e. the settings seen in Configurator) press the **Restore defaults** button.

The red-free retinal image is available by selecting the Green channel

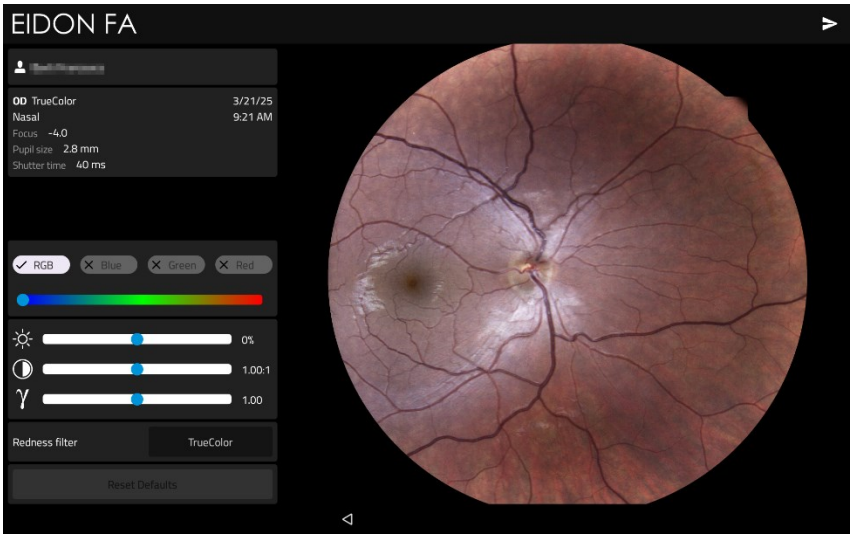
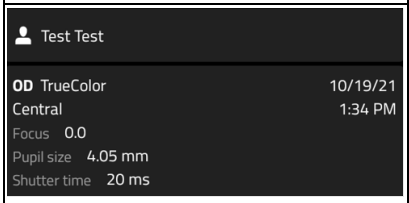
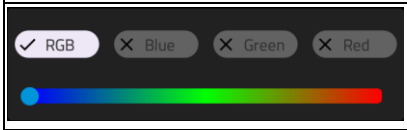
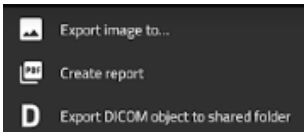
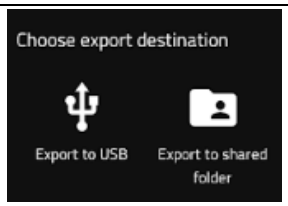
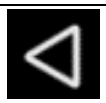


Fig. 49 – Exam review screen, color image

The following commands and information are available:

Position on the screen	Information
Click on the retinal image	Allows to open a full screen view, also allowing **zoom** and **pan**
	**Patient and image information**
	**RGB filters:** Allows to display individual color channels (for color images) and the IR image (if available).
	**Image Adjustment:** Allows to adjust the image acquired. Every parameter will be stored internally but **the correction does not alter the original image**
	**Export:** Allows to export your data. The button open the export menu where operator can choose the format
	**Export Details** Allows to: - **Export image to.. :** export a jpg image to USB or shared folder(§ 9.9). - **Create report:** Create a PDF report - **Export DICOM object to shared folder**
	**Export image to..** : Allows to export the jpg image to USB or shared folder. This menu shows only the export properly configured (Shared folder and USB)
	**3D:** Allows to open the **3D** viewer when the image is part of a stereo acquisition.
	**Back:** Allows to return to the **Patient Record** screen

9.4 3D Stereo Review

When the retinal image is part of a stereo pair, a 3D logo will be shown at the top of the review window: when clicking on this logo, the 3D reviewing window will be opened.

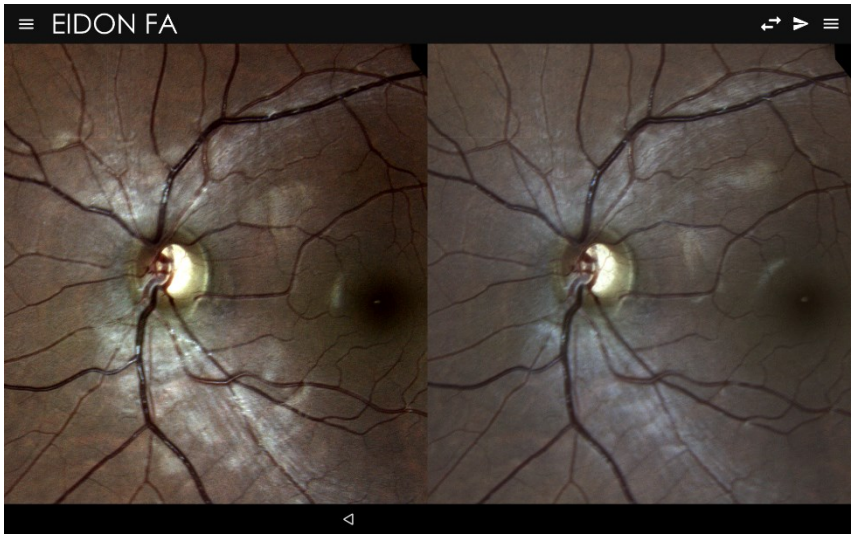


Fig. 50 – 3D review window

Wear the prismatic stereoscopic goggles[16], and move forward or backward to the retinal image until you see a single 3D retinal image. If you see elevations instead of cavities, press the logo on the top right corner of the screen.

9.5 Mosaic

EIDON Family Software allows to merge multiple fields of the same retina, to obtain a wider retinal image. The new retinal image generated is called **mosaic**.

> Two to nine images can be used to generate a mosaic.
> A central field is always required.

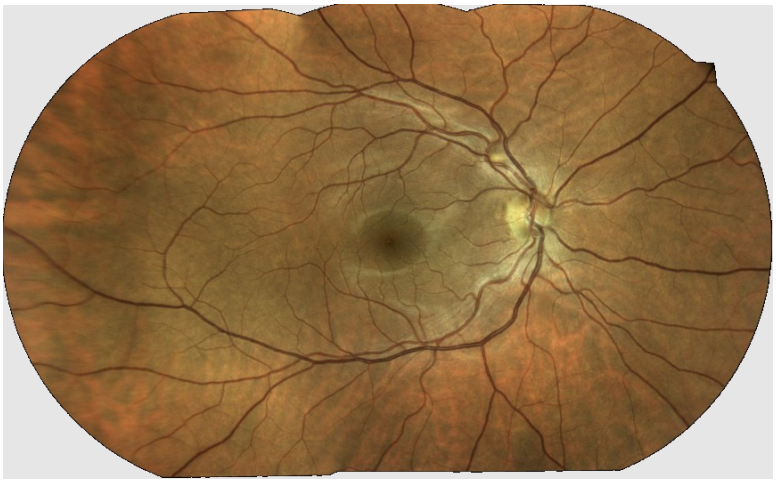


Fig. 51 – Example of a 3-fields mosaic image generated by EIDON Family device

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

Clicking on the **Mosaic** button in the **Patient Record** screen, the **Field selection** screen opens (see Fig. 52).

Select the **retinal images** to be composed into a mosaic; select the icon to identify the central field.
When all fields are selected, click on the **Create Mosaic** button.

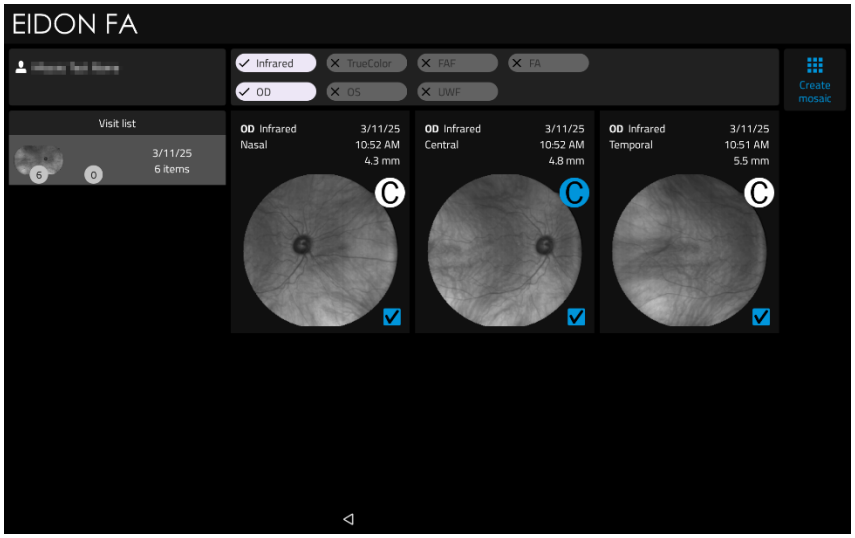


Fig. 52 – Field selection screen

Once mosaic generation is initiated, a dialog box on screen provides progress indications.
Press “HIDE” button to move the mosaic creation to the background and continue the exam review.

EIDON Family Device cannot perform acquisition while mosaic generation is in progress.

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

Only EIDON FA also allows to create mosaics of FA images.
FA images acquired at very different times from injection may present significant differences in fluorescein perfusion, especially during the early perfusion phase, which may prevent proper functioning of the algorithm.
In general, a mosaic of FA images may be misleading as it mixes information captured at different times during a dynamic process (dye perfusion).

9.6 Compare Images

To review or print a pair of images side by side, press and hold on the thumbnail of the first retinal image until the image is selected (highlighted border); do the same for the second image.

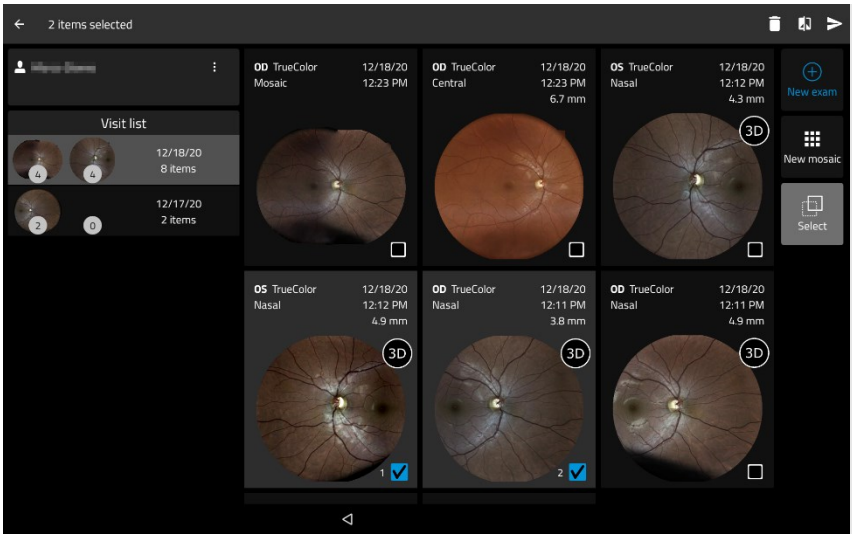


Fig. 53 – Dual image selection

To review the images, click the button at the top-right corner of the screen: this will open the **Dual image review** screen (see Fig. 54).

To use image enhancement filters, click on the icon and swipe the slider corresponding to , , (see Fig. 55).

If the images are taken from different eyes (left and right), the right eye will be displayed on the left, while the left will be shown on the right. Otherwise, the most recent image is displayed on the left.

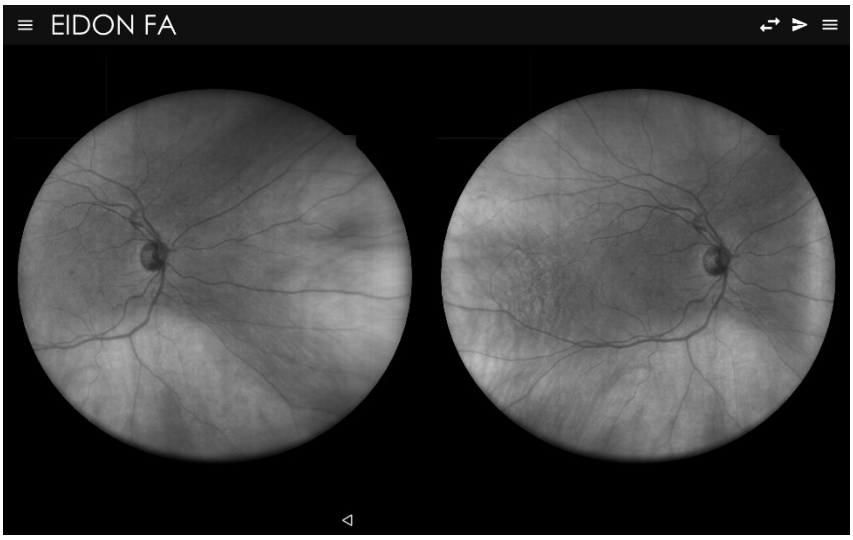


Fig. 54 – Dual image review screen.

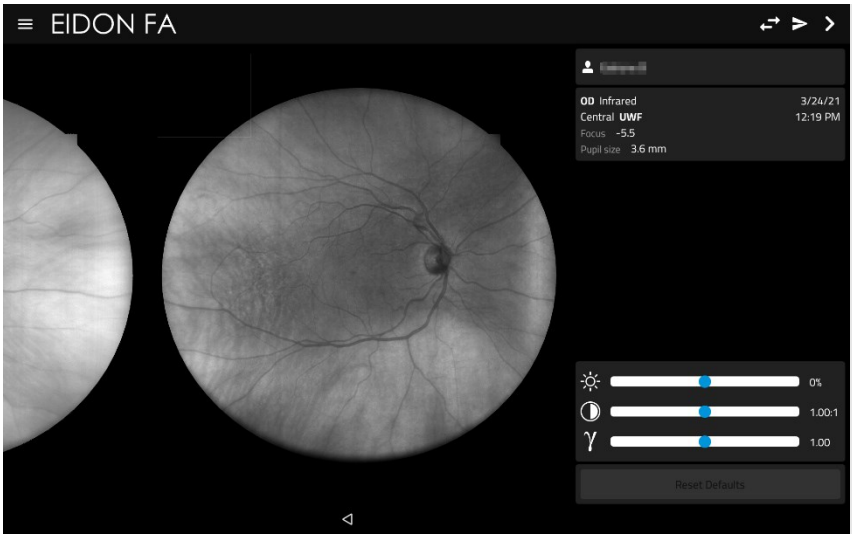


Fig. 55 – Dual image review screen with image enhancements filters

To export the two images, press  from the **dual image review** screen: the two images will be saved in a landscape page, using the same page template as described in 9.10.

9.7 HypoAF Boost

EIDON AF and EIDON FA models include an additional feature called **HypoAF Boost** which enhances low autofluorescence signals on the retinal image. The HypoAF Boost can be applied only to autofluorescence images.

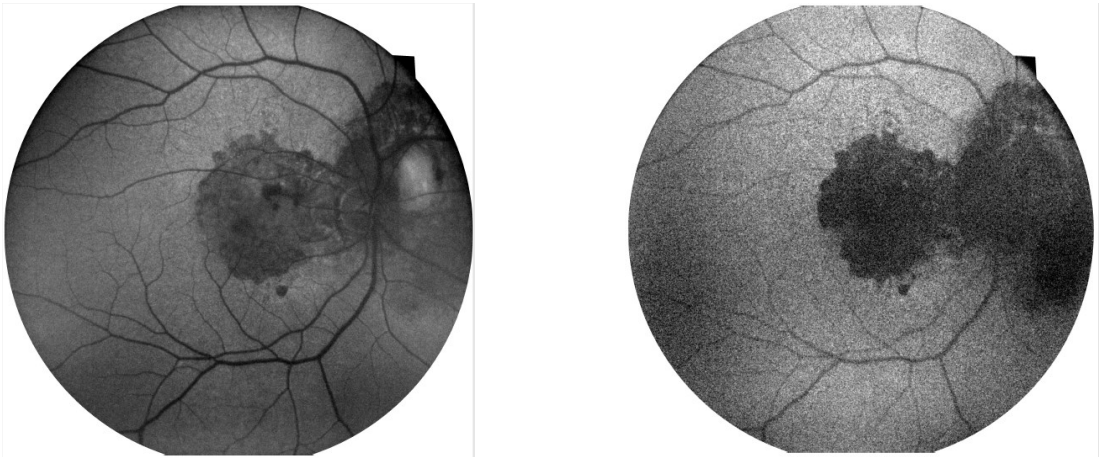


Fig. 56 – Example of AF retinal image before (left) and after (right) the application of HypoAF Boost

> A secondary effect of the HypoAF Boost feature is a grainy image. Disabling the HypoAF Boost will restore the original AF image preserving the image quality.

9.8 Video review

During FA sessions videos can be captured. In such case a video-camera icon appears as a thumbnail in the patient record screen. Click on the thumbnail to review the video (see Fig. 57).

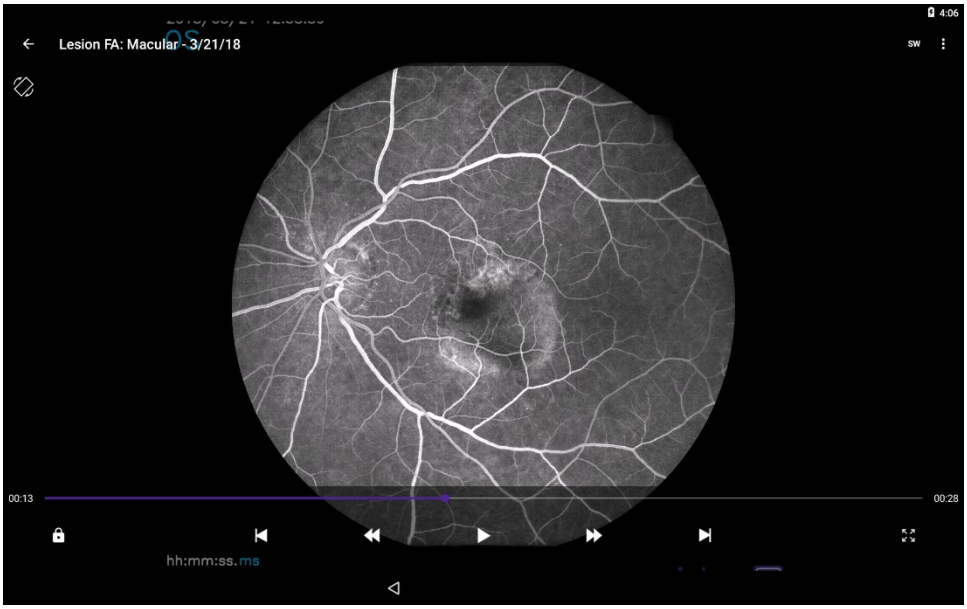
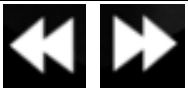


Fig. 57 – FA Video review screen

The following commands are available:

Position on the screen	Information
	Play and Pause
	Step forward or backward by 10 seconds

The video shows the information on acquisition, like the eye, date/time of injection and time from injection.

9.9 Export functions

EIDON Family Software allows to export the patient images and videos to three different locations:

- JPG images, videos and PDF printouts, to a USB storage connected to the back panel of the device.
- JPG images and videos, to an internal folder called *Local shared folder*
- JPG images, videos, PDF printouts and DICOM files, to a network folder called *Remote Shared Folder (RSF)*

All of the information about the shared folder status are included in the **Device Information Center** screen. For additional information on the Device Information Center, see § 13.

For additional information on the shared folder and how to configure the export to shared folder (i.e. shared folder type, location, username, etc.) see § 14.10.

EIDON Family Software: press and hold on the thumbnail (first item only) to enter the selection mode for images and videos (highlighted border), choose other elements for export, then press on the export icon.

When both USB key and RSF are active a Pop-up appears asking the user to choose the desired export destination.

	Transferring data may result in compromised patient privacy

9.10 Printout

EIDON Family Software allows to create multi-images and multi-pages PDF printout presenting the following information:

1. Clinic information header (only if the header has been uploaded by the Configurator app. For additional information, see par 14.11)
2. Patient information (name, date of birth, age)
3. Patient notes
4. EIDON Family Device Software version and Device number

Depending on the selection, the printout can include up to 9 retinal images per page. The interface allows to choose page orientation (portrait or landscape) and number of images per page (see Fig. 59). First Selected Image is displayed in the Top Left. he following selections are order to Right and Down. Each retinal image contains the following data:

1. Examined eye (OD, OS)
2. Exam information (date, time)
3. Pupil size
4. Gamma, contrast and brightness correction (when applied)
5. Filtering values of the R, G, B channels (when applied)
6. Captured field position (N.A. for retinal images acquired in manual mode)
7. Cup-to-disc (when applied)

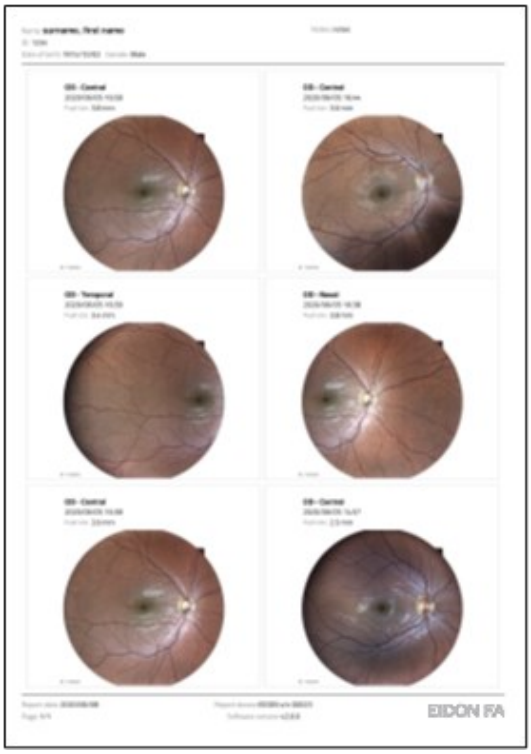


Fig. 58 – Multi image printout with custom header

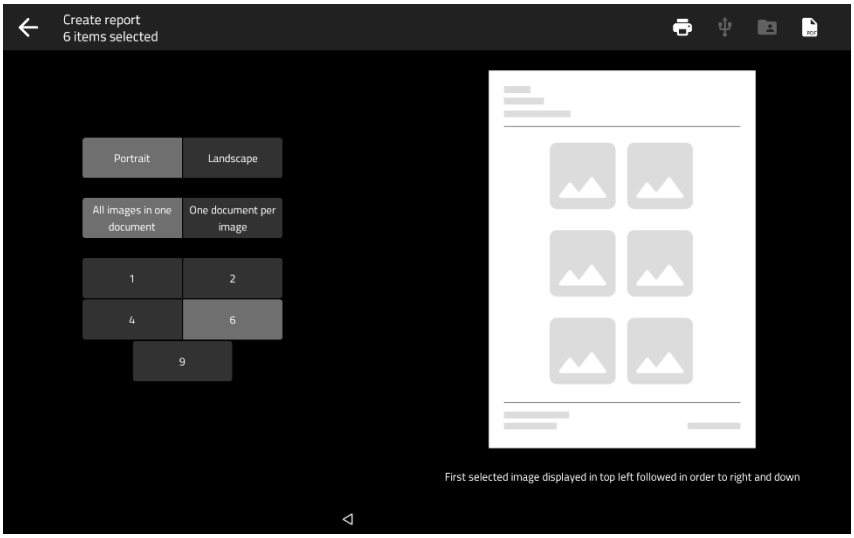


Fig. 59 – Report Configuration window

The following functions are available in this screen:

Position on the screen	Information
	**Report preview:** It allows to generate the preview of the Printout.
	**Export report to remote shared folder:** It allows to export the printout to the remote shared folder.
	**Export report to USB:** It allows to export the report to the USB drive. Functionality is available if USB is plugged otherwise the icon is greyed out
	**Report Printing:** It allows to print the report

10. REMOTE VIEWER[17]

The Remote Viewer is a browser-based software that allows the review of retinal images taken with EIDON Family Device on any computer connected to EIDON Family Device via a local area network.
The Remote Viewer provides access to the patient list, individual patient records, single and dual image review screen and pdf printout.
Compatible browsers include Google Chrome™, Microsoft Edge™, Mozilla Firefox™ and Apple Safari™.
To use the Remote Viewer, the device needs to be connected to the local area network via **Ethernet** connection.

Remote viewer is available only for wired connections.

10.1 Setting up the Remote Viewer

To enable the Remote Viewer, connect the device to the local network by plugging the network cable to the Ethernet port located on the back of the device (see Fig. 6)

To start using the Remote Viewer it must be enabled by selecting the desired protocol and setting and access password from configurator: see § 14.6 for instructions on how to setup the Remote Viewer

10.2 Using the Remote Viewer

Open the browser and type https://*xxx-nnnnn.domain* in the address bar, where:

- *xxx* is the EIDON Family identification name:
  - EIDON = fun
  - EIDON AF = flu
  - EIDON FA = fla
- *nnnnn* is the five digits' serial number of the Device unit
- *domain* is the local network domain name (or ".local")

This will open the **Login** screen.

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

- launch the Configurator application (see §14.1);
- click on the "NETWORK" tab (see Fig. 79);
- click on the  icon of the "Wired" network;
- retrieve the IP (e.g. 10.0.0.19);
- type https://IP in the browser address bar (e.g. https://10.0.0.19)

Type the password and press **Login**: this will open the **Patient List** screen (see Fig. 60), which resembles the corresponding screen in the EIDON Family on-board software.

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

If needed, press F5 to update the data displayed.

[17] *Starting from EIDON Family manufactured Software v.4.0, the multiple concurrent access to the Remote Viewer on the EIDON Family devices is available under license. One Remote Viewer access is always included by default with the device: please, refer to your local distributor for detailed information.*

10.3 Patient List

Right and left eye image thumbnails are shown in the first columns, followed by the patient full name, patient code, gender and date of birth. The right-most column shows the date of the last exam and the number of images stored.
Patients in the list are sorted by the date of their last exam.
Patient **Search** function is available in the top of the screen. From the top right side of the window, the **New Patient** button allows to add new patients to the device database.
Click on the desired patient to enter the **Patient Record** screen. Click on **Logout** to exit the Remote Viewer.

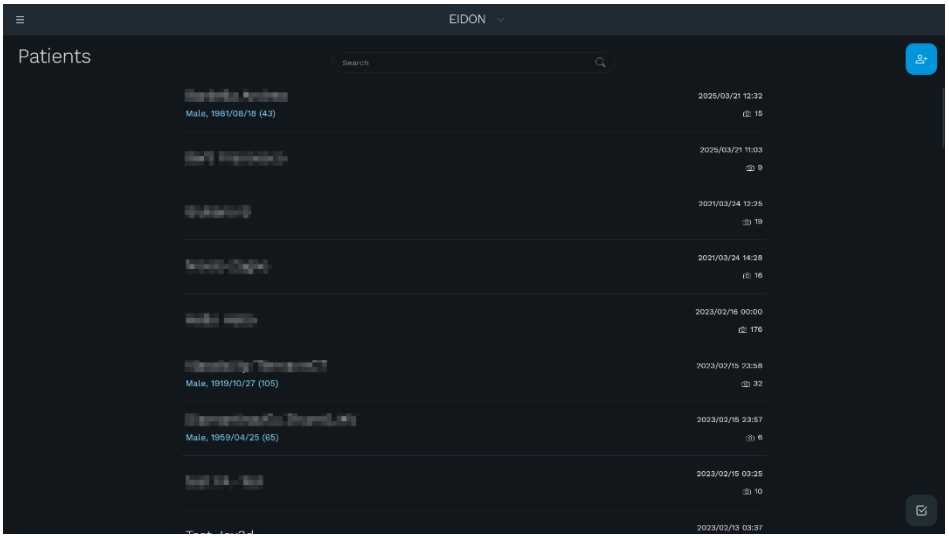
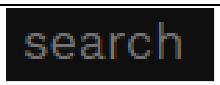


Fig. 60 – Patient List in Remote Viewer

The following functions are available in this screen:

Position on the screen	Information
	Remote viewer Information.
	**EIDON:** Allows to return to the Patient list screen.
	**Search:** Allows to search for an existing patient.
	**New Patient:** Allows to create a new patient.
	**Select:** Allows to select multiple patients.
	**Export of selection:** After Select multiple patients, allows to export the selected patient images (see § 10.13).
	**Delete of selection:** After Select multiple patients, allows to delete them.
	**Close of selection:** After Select multiple patients, allows to cancel the selection and go back.

10.4 Patient Record

This screen allows access to individual images as well as mosaic images.
Click on the desired image to enter the **Single Image review** screen.

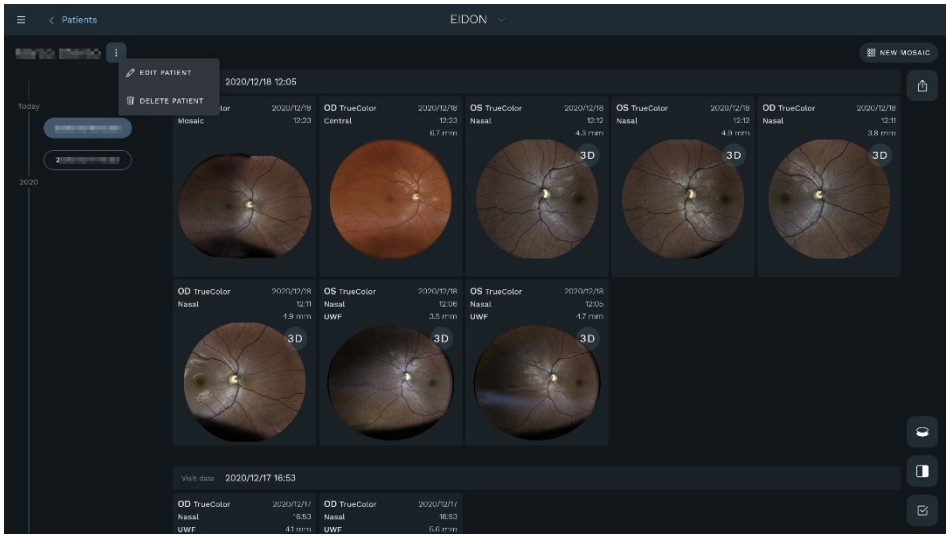
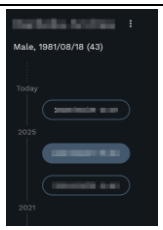
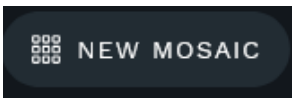
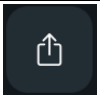


Fig. 61 – Patient Record screen in Remote Viewer

The following functions are available in this screen:

Position on the screen	Information
	Remote viewer Information.
	**EIDON:** Allows to return to the Patient list screen.
	**Patient Data and visits information.**
	**Edit Patient Data:** Allows to edit or delete the patient.
	**New Mosaic:** Allows to create a new Mosaic (see § 10.7).
	**Export:** allows to export or create a printout of the current visit images (see § 10.13).
	**Flicker:** Allow the flicker between the two images selected.
	**Compare:** Allows to enable the compare images function (see § 0)
	**Select:** Allows to select multiple images.
	**Export of selection:** After select multiple images, allows to export or create a printout of them (see § 10.13).

Position on the screen	Information
	**Delete of selection:** After Select multiple images, allows to delete them.
	**Close of selection:** After Select multiple images, allows to cancel the selection and go back.

10.5 Single Image review

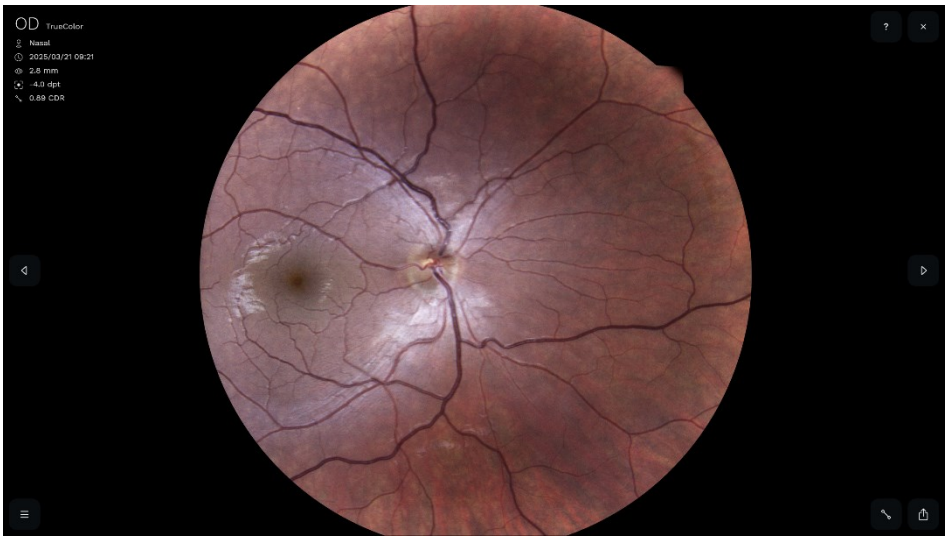
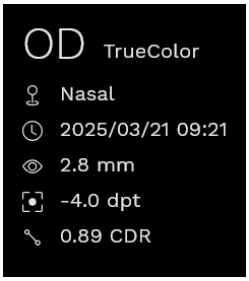
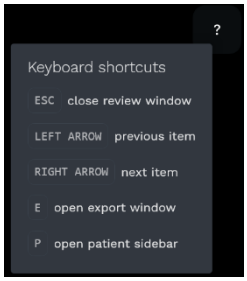
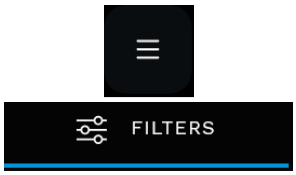
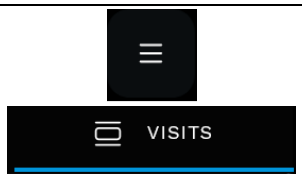
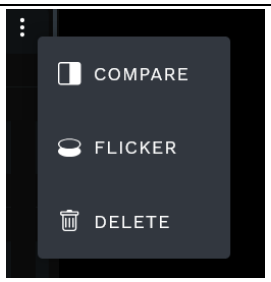
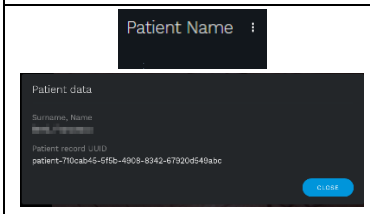


Fig. 62 – Single Image Review screen in Remote Viewer

The following functions are available in this screen:

Position on the screen	Information
	**Image Data**
	**Previous / Next:** Allows to move between previous and next images.
	**Keyboard shortcuts:** Allows to know the shortcuts instruction.
	**Close:** Back to Patient Record Screen.

Position on the screen	Information
	**Image Adjustment:** Allows to adjust the image acquired. Every parameter will be stored internally but the correction does not alter the original image
	**Visits:** Allows to open the patient panel on the side of the image. It shows Patient Data and the other images acquired for the same patient. Also allows access to the Image options.
	**Image options:** Allows to compare or delete or flicker the selected image from the **Patient data Panel**.
	**Patient Data:** Allows to open the popup with Patient Data.
	**Cup-to-disc:** Allows the cup-to-disc ratio evaluation (see par 10.10).
	**Export: Export:** Allows to export the image (see §10.13).
	**3D Stereo Mode:** Allows to access to the **stereo** mode window when image is part of stereo pairs (see § 10.6).
Double click or Mouse wheel	Zooms in or out.
Mouse left-click and drag	Moves the image to frame different regions.

10.6 3D Stereo Review

By clicking on the 3D button, the software display the 3D Stereo Images. Zoom and Pan are available as per the **Single Image Review Screen**. For more information about the stereo feature, see § 8.9.4.

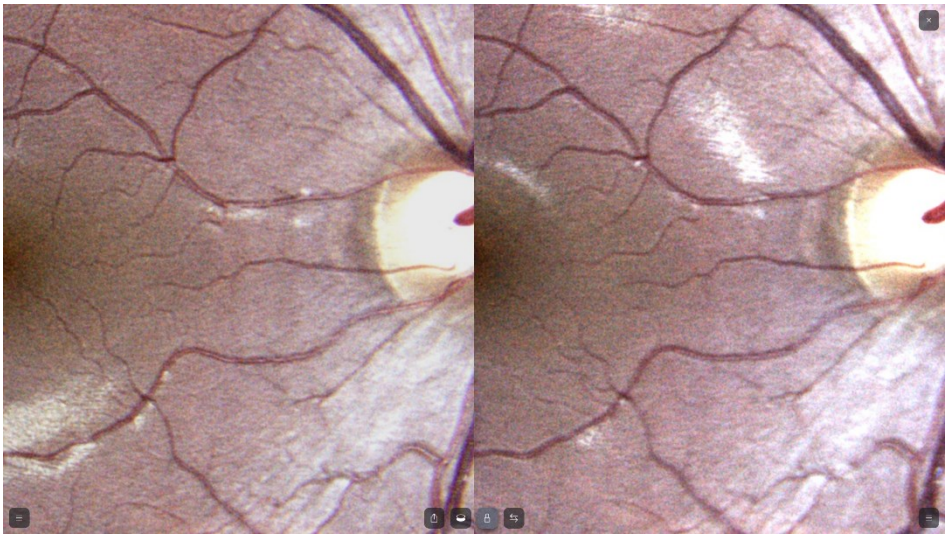
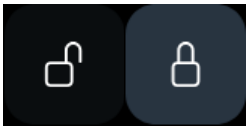
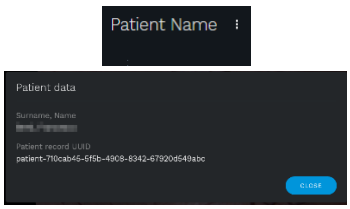
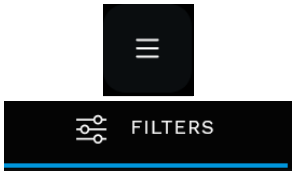
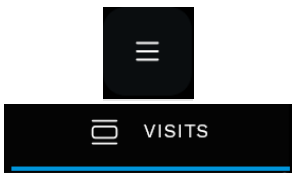


Fig. 63 – 3D Stereo Review Image Screen

The following functions are available in this screen:

Position on the screen	Information
	**Switch:** Allows to switch the two images
	**Sync/Unsync:** Allows to Sync or Unsync the zoom and pan of the two images.
	**Close the side bar.**
	**Close:** Back to Patient Record Screen.
	**Patient Data:** Allows to open the popup with Patient Data.
	**Image options:** Allows to compare or delete or flicker the selected image from the **Patient data Panel**
	**Image Adjustment:** Allows to adjust the selected image. Every parameter will be stored internally but the correction does not alter the original image
	**Visits:** Allows to open the patient panel on the side of the image. It shows Patient Data and the other images acquired for the same patient. Also allows access to the Image options.

Position on the screen	Information
	**Export:** Allows to export and create the printout of the current view, the images will be exported on the printout with the same zoom and pan set in this window (see §10.13)
	**Flicker:** Allow the flicker between the two images selected.
Double click or Mouse wheel	Zooms in or out
Mouse left-click and drag	Moves the image to frame different regions

10.7 Mosaic

By clicking on the New Mosaic Button is possible to create a new mosaic.

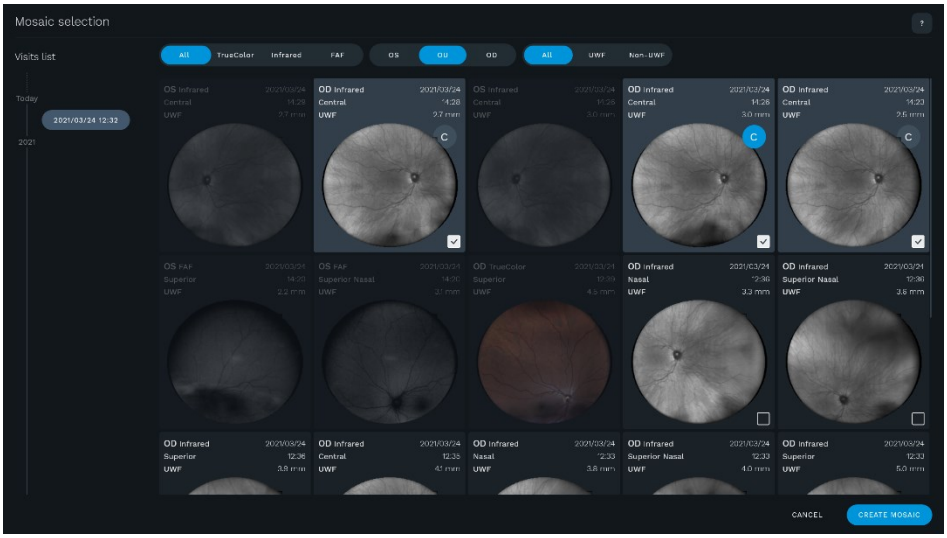


Fig. 64 – Field selection screen in Remote viewer

Select the **retinal images** to be composed into a mosaic; select the  icon to identify the central field.
When all fields are selected, click on the **Create Mosaic** button.
Once mosaic generation is initiated, a dialog box on screen provides progress indications, including which field is being processed and the estimated time to complete.

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

Only EIDON FA also allows to create mosaics of FA images.
FA images acquired at very different times from injection may present significant differences in fluorescein perfusion, especially during the early perfusion phase, which may prevent proper functioning of the algorithm.
In general, a mosaic of FA images may be misleading as it mixes information captured at different times during a dynamic process (dye perfusion).

10.8 Compare Images

This screen allows comparison of any pair of images of the same patient (color, infrared or AF images, left and right eye, same or different dates, same or different fields). This window allows also to compare two copies of the same image, e.g. to simultaneously see the original image versus the red-free version. When the two images are “synced”: zooming and panning will act on both images.

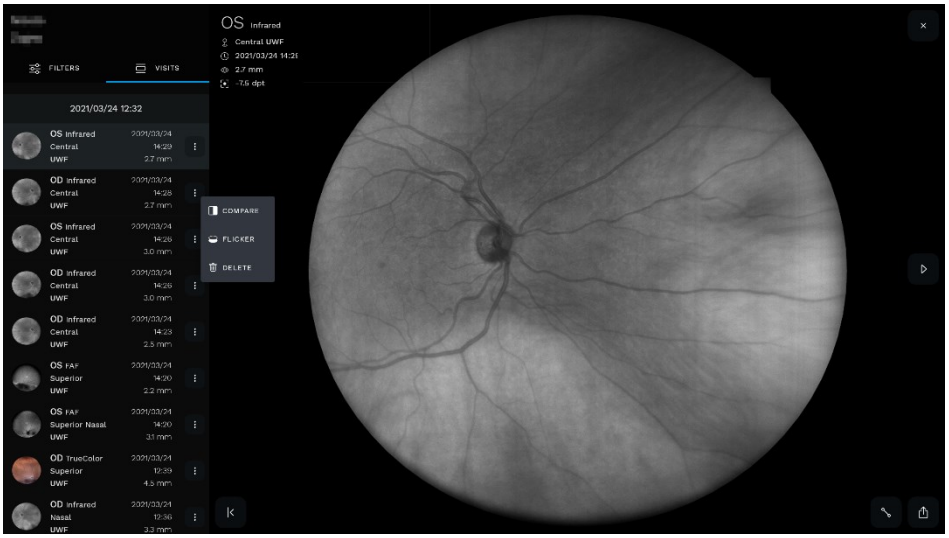


Fig. 65 – Image selection for **compare** function, from the single review screen

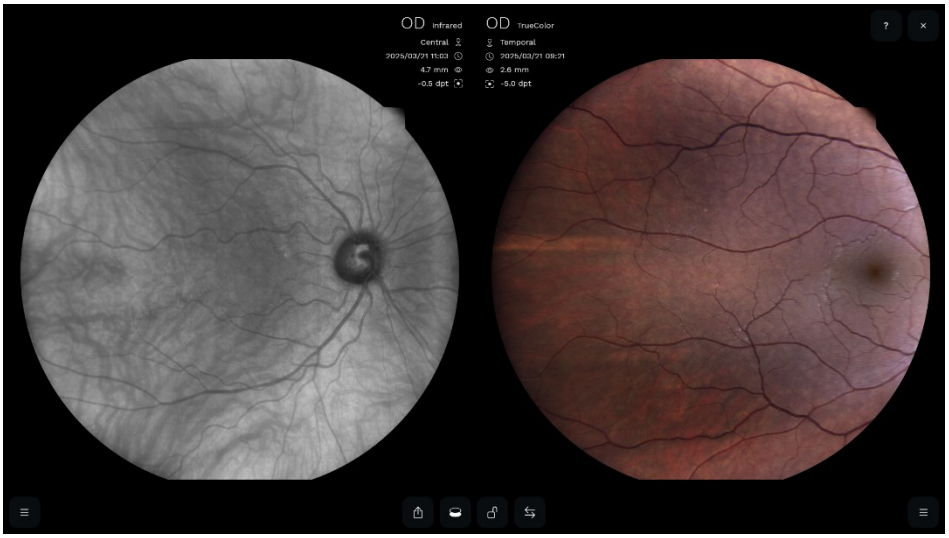
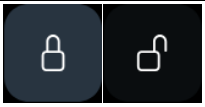
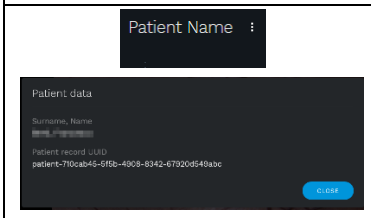
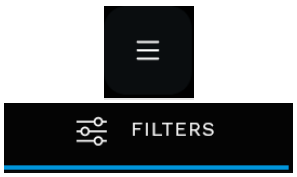
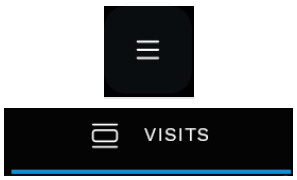


Fig. 66 – Dual Image Review screen in Remote Viewer

It is also possible to compare two identical images and zooming one or both to different details and export the selected view.

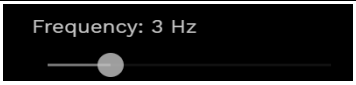
The following functions are available in addition to the function described in the **Single Image Review**:

Position on the screen	Information
	**Switch:** Allows to switch the two images.
	**Sync/Unsync:** Allows to Sync or Unsync the zoom and pan of the two images.
	**Close the sidebar.**

Position on the screen	Information
	**Close:** Back to Patient Record Screen.
	**Patient Data:** Allows to open the popup with Patient Data.
	**Export:** Allows to export and create the printout of the current view, the images will be exported on the printout with the same zoom and pan set in this window (see §10.13).
	**Flicker:** Allow the flicker between the two images selected.
	**Image Adjustment:** Allows to adjust the selected image. Every parameter will be stored internally but it does not alter the original image
	**Visits:** Allows to open the patient panel on the side of the image. It shows Patient Data and the other images acquired for the same patient. Also allows access to the Image options.

10.9 Flickering view

EIDON Family Software allows to overlap two images and manually or automatically toggling between them. This feature is called **flickering** and is accessible both from the Single Image review screen (click on the icon **all patient items** then click on settings an than on **compare** button or **flickering** button) or form the compare view (from the dedicated icon  , see § 0). During Flickering, patient details are listed and highlighted on right side of each image. Zooming and panning are available.
The following functions are available in this screen:

Position on the screen	Information
	**Close:** Allows to go back to the Single Image Screen.
	**Play/pause** flickering.
	**Next Frame:** Allows to manually flicker between images.
	**Animation speed:** Allows to adjust the flicker frequency from 1 to 10Hz.

 Flickering is not available during the execution of an exam or the creation of a mosaic

10.10 Cup-to-disc evaluation

The cup-to-disc ratio (CDR) is the ratio between the optic cup diameter and the neuroretinal rim diameter. To evaluate it, draw the two diameters: click over the retinal image 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. In the flickering review Screen are still available the **Export** and **Filter** functions.

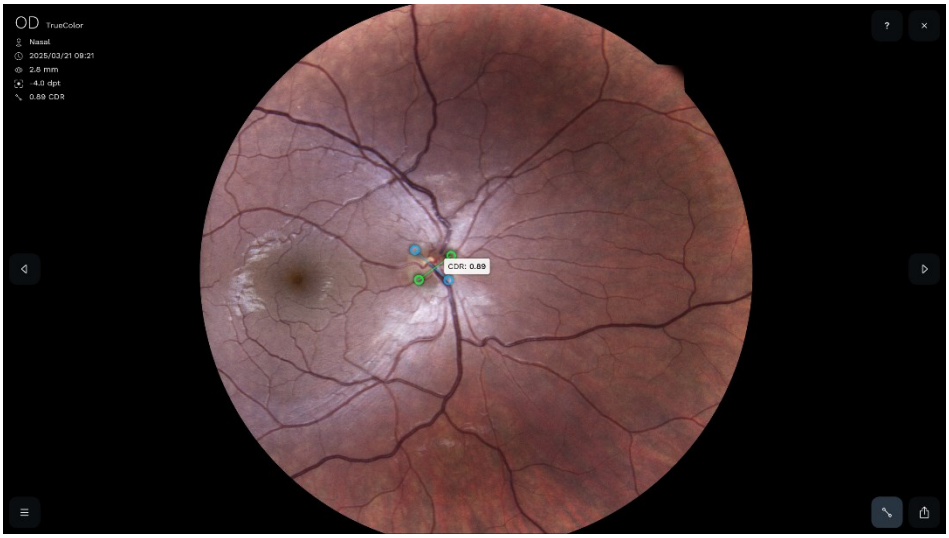


Fig. 67 – Cup-to-disc view

> The cup-to-disk ratio (CDR) in EIDON Family Device is a qualitative indication to be used as an aid for the detection of diseases: its accuracy depends on how the diameters are drawn by the operator. The clinical interpretation of the CDR obtained with EIDON Family device is the responsibility of the eye care practitioner.

10.11 HypoAF Boost

HypoAF Boost is available in the FILTERS icon of AF images (for more info see §9.7)

10.12 Video Review

Video Review is available in the EIDON FA model only.
In the video review window, it is possible to view the video acquisitions and extract and save frames into the patient details screen. The video shows the information on acquisition, like the eye, date/time of injection and time since injection.

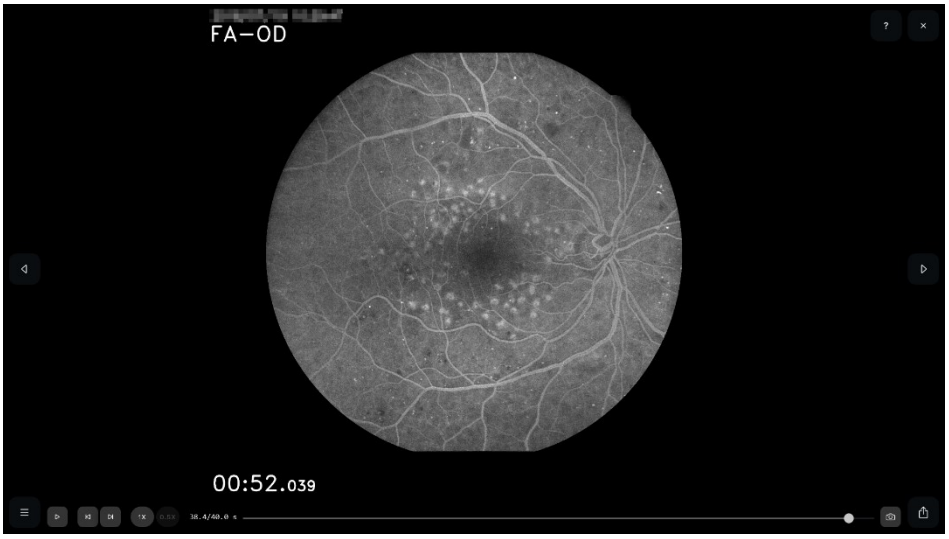


Fig. 68 – Video review window

The following functions are available in this screen:

Position on the screen	Information
	**Play or pause** the video.
	**previous/next:** Allows to move between previous and next video frame.
	**Speed:** Allows to adjust the speed of video reproduction.
	**Video timer and frame navigation.**
	Save the current frame of the video inside the device.
	Export the full video to the local computer.

The “Extract and save” functionality is not working on videos acquired on EIDON FA with software version previous the v2.0.0

Browser required for video review:

- Google Chrome
- Microsoft Edge

Otherwise, the video can be viewed from VLC players, by enabling the video HW acceleration feature from the VLC options.

10.13 Export Functions

By pressing the  icon, the Remote Viewer allows to export the images to the Local computer.

With this function is possible to download the selected images, create the pdf printout or send (both images or/and printout) to the local printer installed on the local computer.

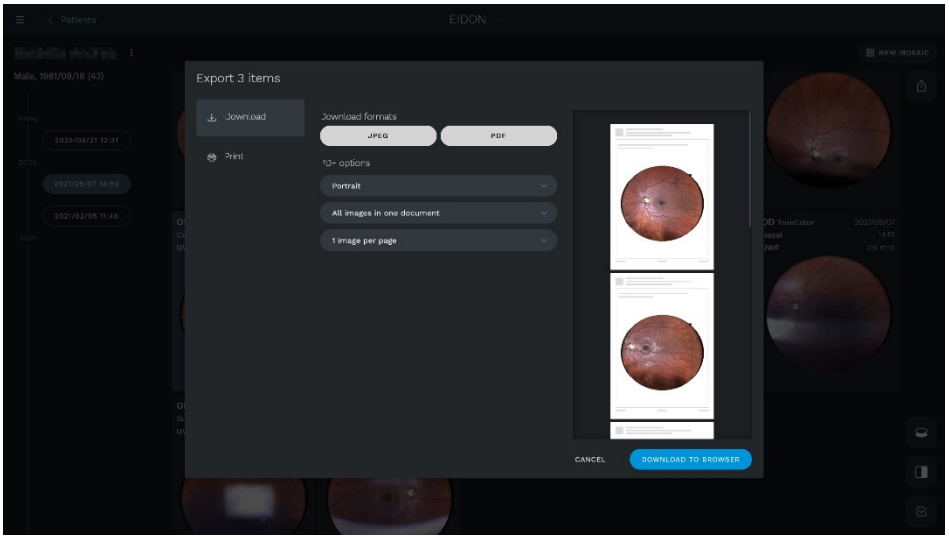
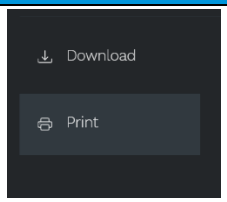
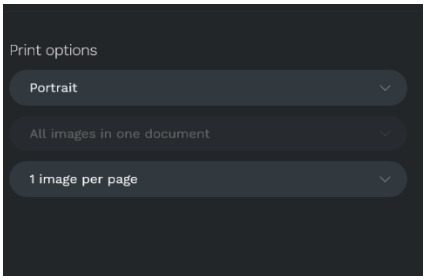
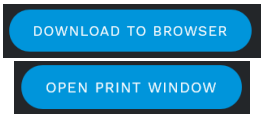
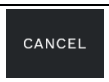


Fig. 69 – Export function in Remote Viewer

The following functions are available in this screen:

Position on the screen	Information
	**Destination:** Allows to choose the export destination between: - Download. - Send to Printer.
	**Export Format:** Allows to choose the export format between Jpeg or/and PDF.
	**PDF options:** - Page orientation. - All images in one document or One document per image. - Number of images per page.
	Allows to proceed with the action selected.
	**Cancel:** go back to the previous screen.

11. DICOM

DICOM[18] is a standard for distributing and viewing medical images and related information.

EIDON Family Device supports full DICOM communication, as specified in the **EIDON Family Device DICOM Conformance Statement**[19] document. This feature requires dedicated license.

For information about DICOM modality worklist and C-Store, see the **EIDON Family device DICOM Instruction for Use**.

[18] The DICOM Feature for is available under license only: please refer to your local CENTERVUE S.P.A.'s Authorized Distributor for detailed information

[19] Please refer to your local CENTERVUE S.P.A.'s Authorized Distributor for the EIDON Family device DICOM conformance statement.

12. LDAP

LDAP (Lightweight Directory Access Protocol) is a software protocol provide a central place for authentication.

LDAP is used in Microsoft's Active Directory, but can also be used in other tools such as Open LDAP, Red Hat Directory Servers and IBM Tivoli Directory Servers for example

EIDON Family device supports the LDAP authentication, as specified in the EIDON Family - LDAP Instruction for Use document. This feature requires dedicated license.

13. INFORMATION CENTER

The **Information Center** contains additional information on the EIDON Family device status. This window includes four tabs:

- **Backup status** (for further details, see § 13.1);
- **Shared folder status** (for further details, see § 13.2);
- **Data storage** (for further details, see § 13.3);
- **Data Security** (for further details, see § 13.4);
- **About** (for further details, see § 13.5)

13.1 Backup status

From the **Backup** tab, it is possible to see the status of the backup process, execute or stop a backup. This screen also includes information on the backup media and on the last backup. For more information on Backup and to see how to initialize a new media, see § 14.8.

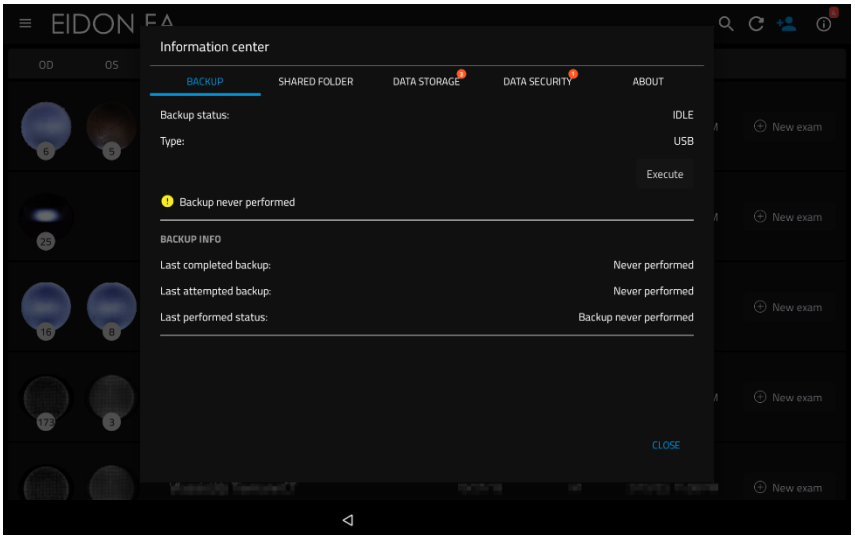


Fig. 70 – Device Information Center – Backup status

13.2 Shared folder status

From the **Shared Folder** tab, it is possible to monitor the status, the activity and errors of the Shared Folder export process. For more information on Shared Folder see § 9.9. See § 18 for information about possible error conditions during the export process.

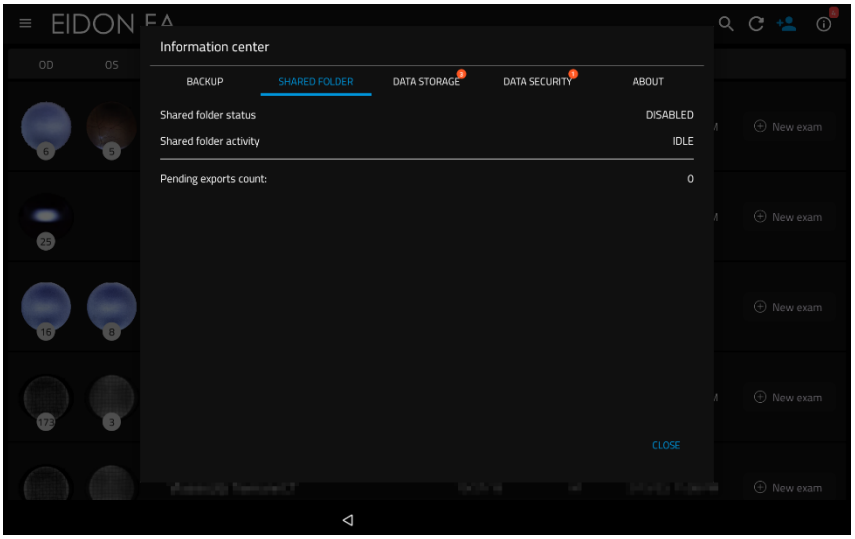


Fig. 71 – Device Information Center – Shared folder status

13.3 Data storage status

From the **Data Storage** tab, it is possible to see some information about the storage available in the internal disk (*Local disk space*).

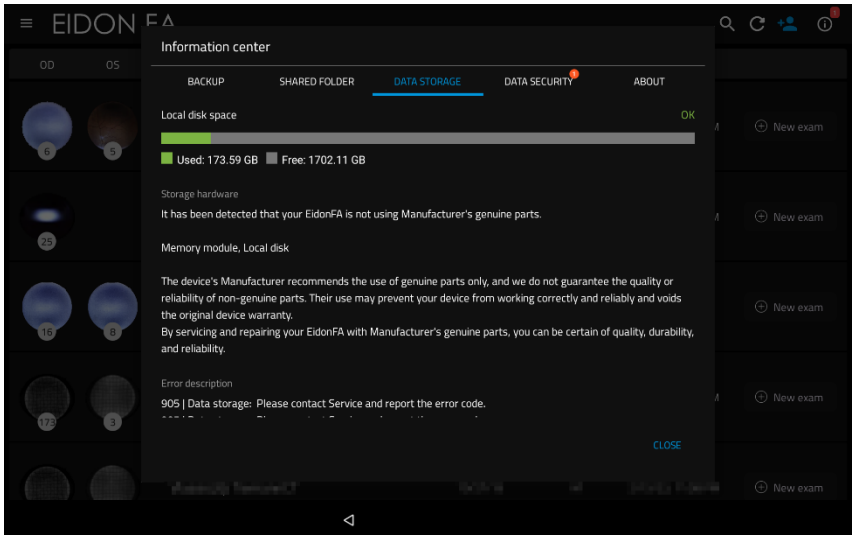


Fig. 72 – Device Information Center – Data Storage status

13.4 Data Security

The **Data Security** tab lists any unsecure settings detected in the device configuration and suggests how to solve them. Unlike what happens with the other tabs, the notifications displayed on the Data Security tab title badge are permanent and are not dismissed after being read: the only way to make them disappear is to solve the detected security threats. If Remote Viewer is disabled, the tab doesn't show any security message.

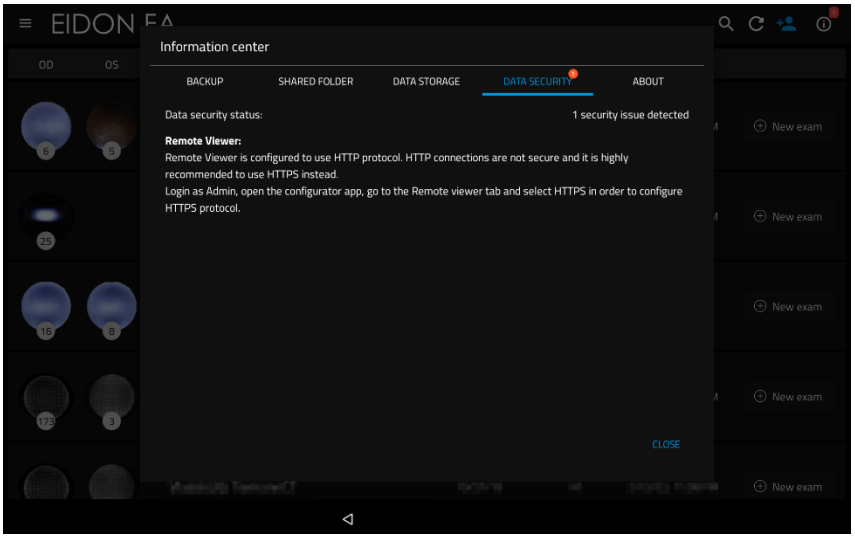


Fig. 73: Device Information Center - Data security tab

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

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

Control Interface: EIDON units equipped with consumer tablet[20] as Control Interface could be compromised by a malicious user with advanced hacking knowledge and physical access to the Custom Control Interface. It is recommended to never leave the Control Interface unattended.

Remote Viewer: the Remote Viewer is configured to use HTTP protocol, which is a potential cybersecurity threat. Configure the Remote Viewer to use HTTPS (see § 14.6), which prevents man-in-the-middle attacks.

13.5 About tab

The **About** tab contains the software release version. Additional information appears after pressing the *Details* button. From this tab it's possible to consult this Instruction for Use.

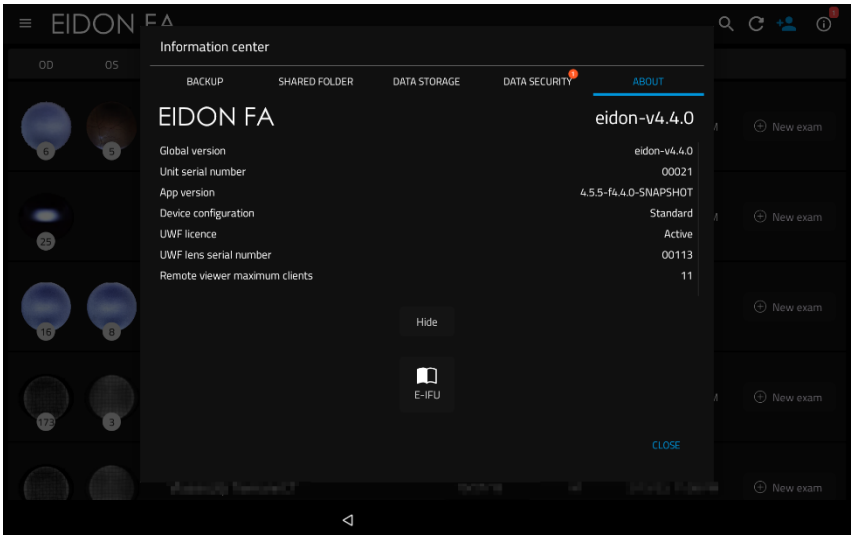


Fig. 74 – Device Information Center – About tab

[20] *The consumer tablet is no longer in use on the current configuration of the EIDON Family devices and it is replaced by the Custom Control Interface with multi-touch display.*

14. SETTINGS

EIDON Family Software provides access to settings by means of a separate application called “Configurator”.

The Configurator app is available only for the Admin user.

14.1 Launching the Configurator

To access the Configurator:

- Press the “back” icon at the bottom of the screen to go to the Home screen (see Fig. 16);
- Press the logout icon;
- Select “Admin” user from the drop-down menu;
- Type the corresponding password and click login;
- Click the App icon ;
- Start the Configurator by clicking the icon Configurator.

14.2 Device lock reset procedure

In case EIDON Family Software raises error codes ranging from “117” to “121”, or from “124” to “130”, entering a locked state, the Configurator can be used to reset this condition. In such cases a warning icon is shown on the top right bar of the Configurator.

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

14.3 Date and time

To modify the device date and time, go to the “Date and time” tab on the Configurator: modify the time and date, then press **apply**.

The device will be turned on after applying the date and time modifications.

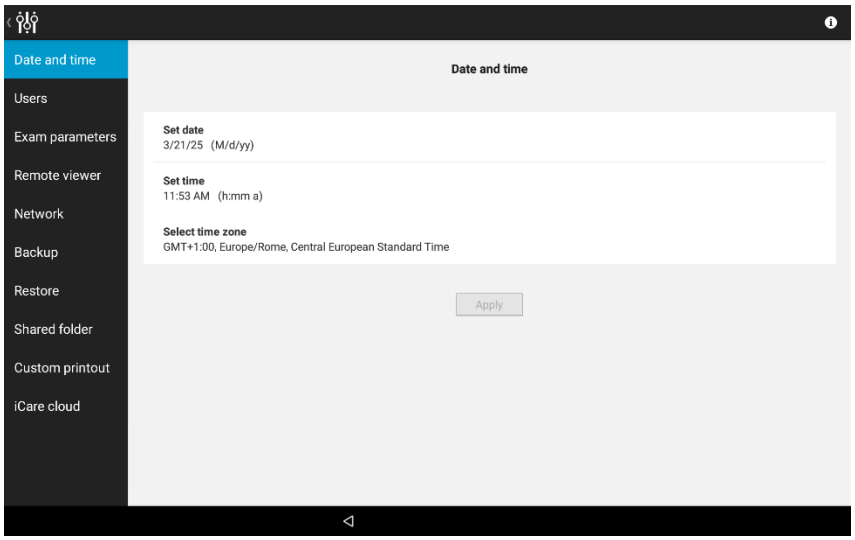


Fig. 75 – Configurator – Date time set

14.4 Password change

Passwords for both the “Admin” and “Doctor” users can be changed in the “User Role” tab of the Configurator by clicking the pencil icon (see Fig. 76). Shut down and restart the device to make the new passwords effective.

- Always keep passwords in a safe place
- It is not possible to operate if the EIDON Family Device passwords are lost
- If both passwords are lost, or to reset the “Admin” password, contact your CENTERVUE S.P.A. Authorized Service Center for support.

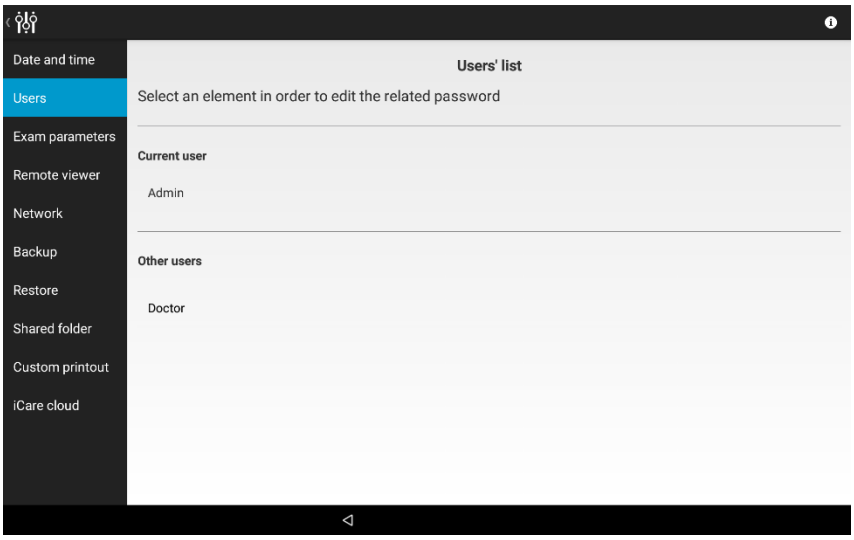


Fig. 76 – Configurator – USER ROLE screen

14.5 Exam parameters

From the **Exam parameters** tab it is possible to:

- Set the default value for exposure parameter when acquiring color images either in full-automatic or manual mode (see section 8.8);
- Set the default brightness, contrast, gamma and redness filter applied to the acquired color images;
- Select the default imaging modality (see section 9.3);
- Enable the pupil size detection in full-automatic exams. When enabled, the pupil size shall be selected between 2.0 and 3.0mm and the maximum waiting time to reach the selected pupil size dimension can be chosen between 5 and 40s.

These parameters will be applied starting from the next acquired retinal image.

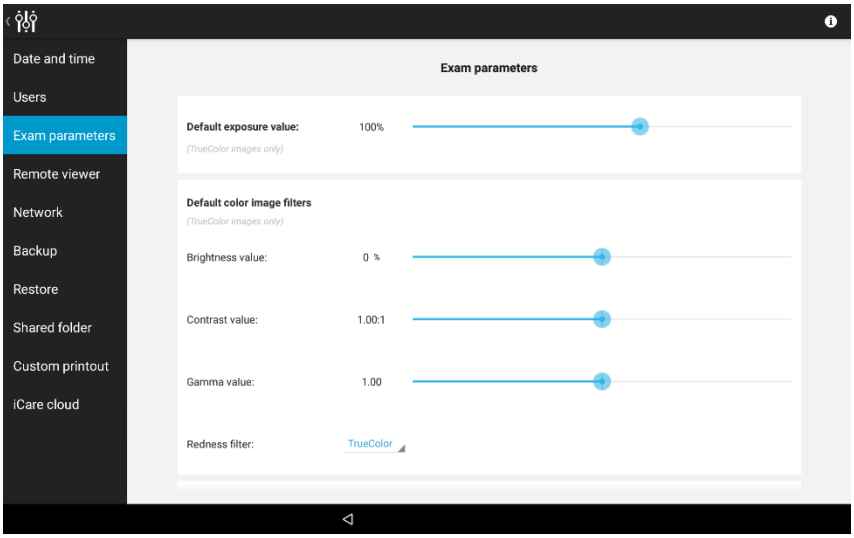


Fig. 77 – Configurator – EXAM PARAMETERS screen

14.6 Remote Viewer

To set or change the password used to access the Remote Viewer click on the **Remote viewer** tab of the Configurator, type the new password and press **Apply**. It is possible to select the protocol used by the **Remote Viewer** web server (HTTPS, HTTP, or both) or to completely disable the **Remote Viewer** functionality.
It is also possible to set the **Privacy mode** that will hide the patient name and surname from the patient list of the remote viewer.

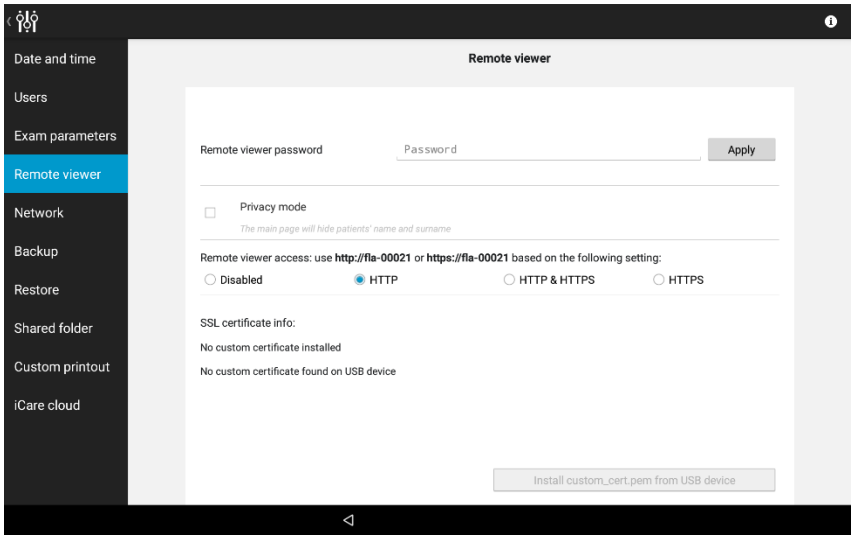


Fig. 78 – Configurator – REMOTE VIEWER screen

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

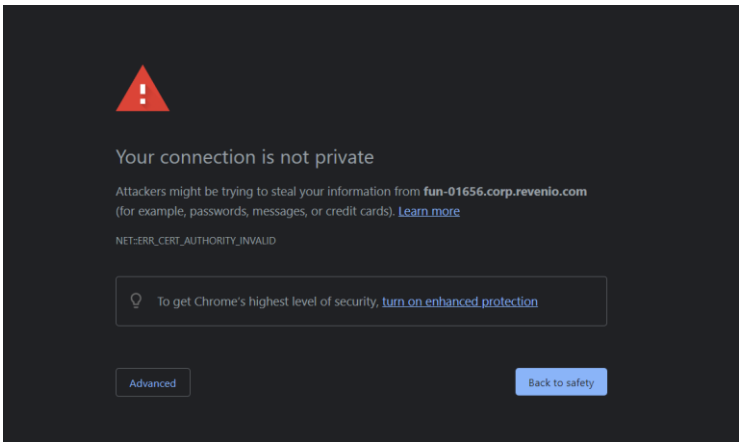
When using HTTPS protocol, the server authentication is carried on by means of an SSL certificate. EIDON Family provide a default, self-signed built-in certificate for such authentication. It is however possible to generate and use a custom certificate instead of the default one: to install it, rename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

A custom certificate must fulfil the following conditions to be installed on EIDON Family:

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

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

If the HTTPS protocol is selected, a warning message like the following one might appear on the browser when connecting. This is due to the browser not being able to verify EIDON self-signed certificate but is not a real security thread. To access the Remote Viewer click on “Advanced” and then “Proceed to fun-sssss (unsafe)” for EIDON, “Proceed to flu-sssss (unsafe)” for EIDON AF, “Proceed to fla-sssss (unsafe)” for EIDON FA.



14.7 Network configuration

To export and remotely review retinal images (and video for EIDON FA only) acquired by EIDON Family device must be connected to responsible organization’s IT Network. The EIDON Family device is designed such that network failures will not prevent the EIDON Family device from working normally.
EIDON Family Device supports either Ethernet connection or wireless connection. However, **Remote Viewer**, **Shared Folder Export**, **DICOM** and service access are available only through wired network connection.
The wireless connection is available only through the **Custom Control Interface** and is intended only for printing and service access.
Required characteristics and peripheric of the IT-network are:

- Printers: compatible printers are listed in section 14.14
- Compatible browsers for Remote Viewer: Google Chrome, Microsoft Edge, Mozilla Firefox, Apple Safari
- Supported wireless protocols: Open, WEP, WPA, WPA2
- Supported Shared Folder protocols: SMB/CIFS protocol, up to ver. SMBv3, connecting to hosts running the following operating systems: Windows 7, 8, 10, 11, Server 2012, and Linux.
- DICOM: DICOM compatibility is described in the DICOM IFU and DICOM Conformance Statement
- LDAP: LDAP compatibility is described in 2.2.3 - EIDON Family - LDAP Instruction for Use

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

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

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

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

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

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

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

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

If the connection is lost during data transfer, no data is lost from the device. The images are still stored in the device and can be transferred once the connection is re-established.
Failure or misconfiguration of the IT-network may result in data not being transferred causing inconvenience to the operators.

The Ethernet port is located on the back of the system (see Fig. 6).

The Custom Control Interface Wi-Fi should be enabled to connect the EIDON Family Device to a wireless network.

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

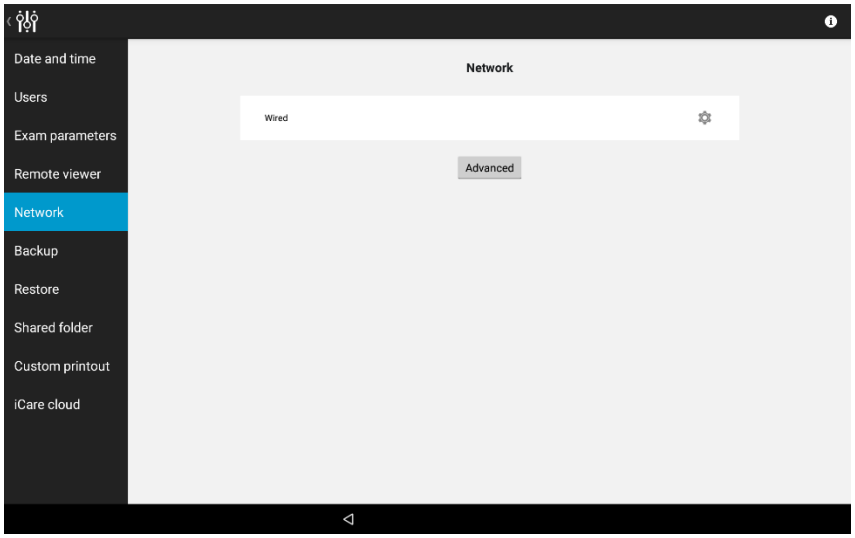


Fig. 79 – Configurator – NETWORK screen

The wireless network parameters are set directly using the Custom Control Interface's Android Wi-Fi Settings panel, while the Ethernet network is configured by clicking on the icon, near the **Wired** label.

Fig. 80 – Configurator –Network configuration screen

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

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

To switch between Ethernet and wireless connection, click on the **Advanced** button on the Network configuration window (Fig. 79): the following window appears.

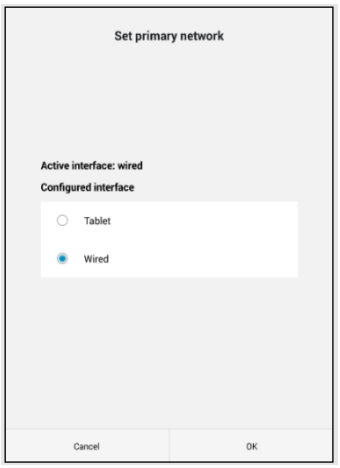


Fig. 81 – Primary Network settings

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

14.8 Backup

EIDON Family device allows the backup of data to a USB media or to a Network folder. The backup can be automatic (i.e., periodically scheduled) or manual.
The backup is an incremental backup and will be saved in a subfolder called `cv_backup`: this means that EIDON Family Device will back up only the data added or modified since the last completed backup.
EIDON Family Device supports backup to more than one device media but it is recommended to use a media formatted with the NTFS filesystem to avoid data loss. Moreover, the same device media can be used as backup for different EIDON devices.
To access the Backup window, press *Backup* on the Configuration app. The backup configurator contains three screens: **Device**, **Schedule**, **Execute**.

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

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

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

14.8.1 Device tab

This screen allows to select the device used for backup. The backup can be performed to a USB media or to a network folder: select the desired backup device by clicking on **USB** or **NETWORK** at the top of the screen. When all the parameters are defined for the selected device, press **Apply** to store the device parameters and move to the **Schedule** screen.

Backup to USB

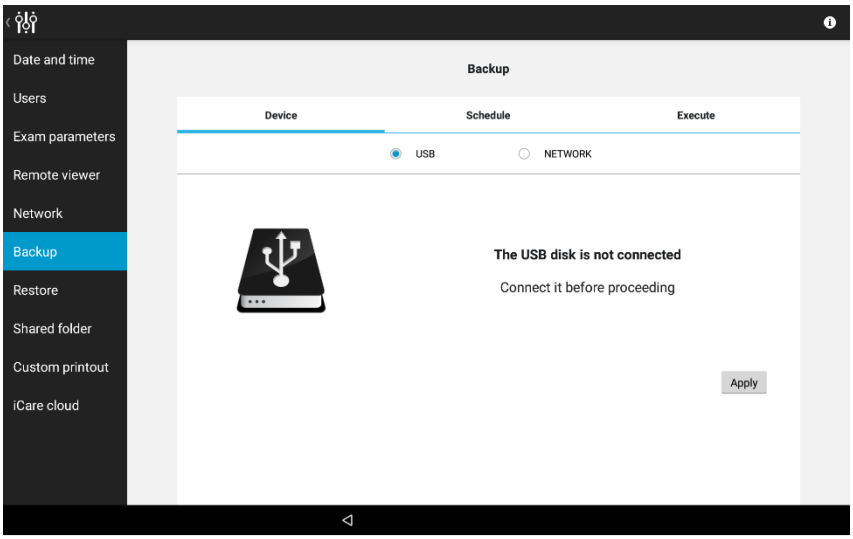


Fig. 82 – Configurator – BACKUP screen – USB-media backup selected

When the device is connected and ready for backup, the  icon changes to green.

The USB media used for backup should be **formatted as NTFS, with enough free space to store the backup file**.

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

Backup to Network

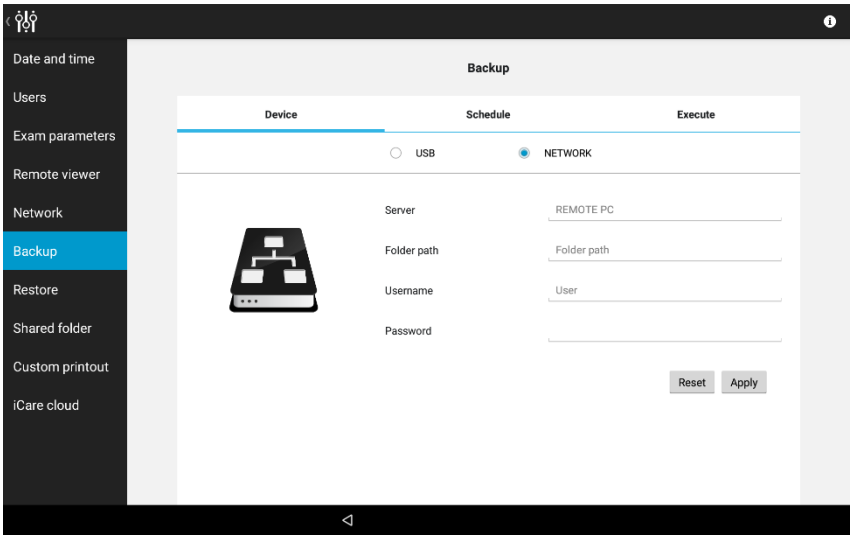


Fig. 83 – Configurator – BACKUP screen – Network backup selected

The network parameters to be set are the following:

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

All these fields are mandatory.

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

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

14.8.2 Schedule tab

Turn **ON** the **Automatic backup** button in the **Schedule** tab to allow periodic backup.
At the scheduled time, EIDON Family Device will try to contact the selected media. If the media is not ready (e.g. network disk not available or USB not connected), EIDON Family Device will temporary suspend the backup procedure and will keep retrying for one hour.
The backup will be performed regularly on the next scheduled occurrence even if the last backup attempt failed.

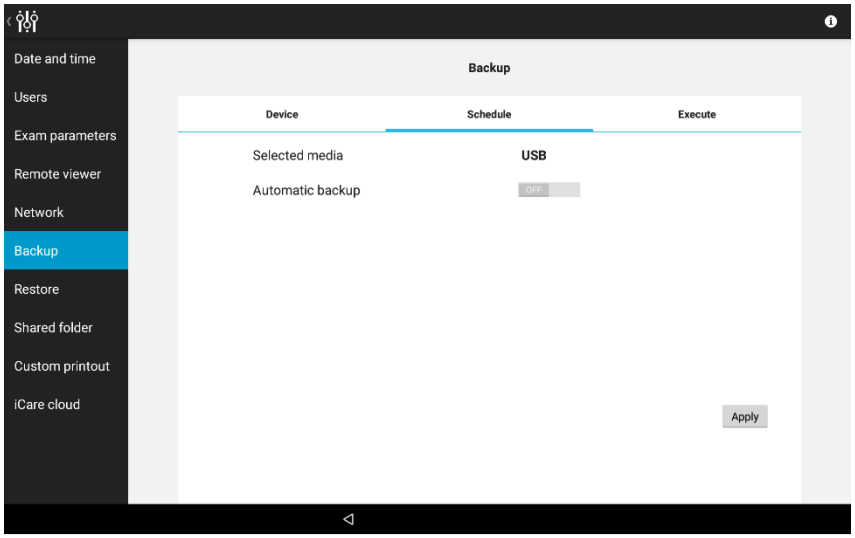


Fig. 84 – Configurator – BACKUP screen – *Schedule* tab with automatic backup enabled

The backup will be performed starting on the date set in the **Starts on** field with the frequency configured in the **Execute every** field.
By pressing the **Apply** button, EIDON Family Device stores the backup configuration.

14.8.3 Execute tab

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

> Once the backup has started, EIDON Family Devices can be used regularly except for the impossibility to delete images.

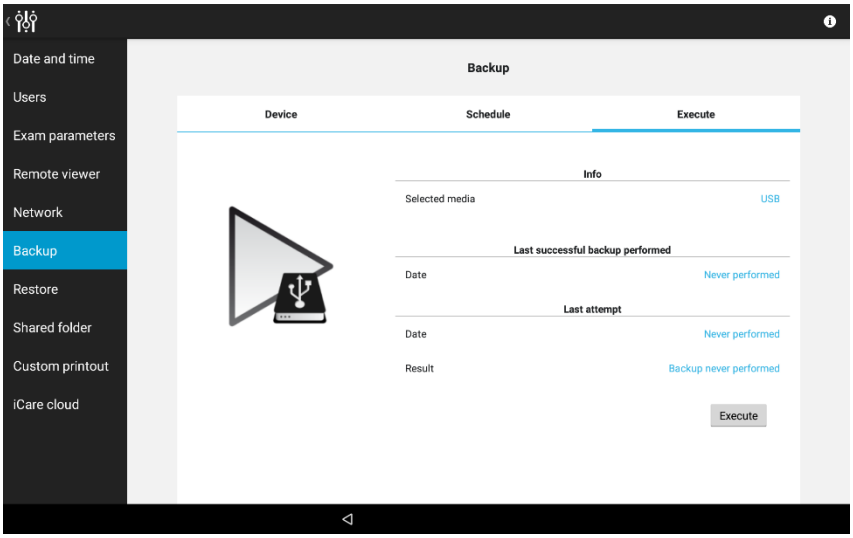


Fig. 85 – Configurator – BACKUP screen – *Execute* tab

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

14.9 Restore

This feature allows to restore a backup from the selected media.
The backup to be restored can come from the same EIDON Family Device or from another EIDON Family device with an exception[21]: the **Restore** window will show a list of available backups.
To restore a database:
Be sure that the USB media or the Network folder used as backup are available, then select the right device in the **Device** tab and press **Apply**.

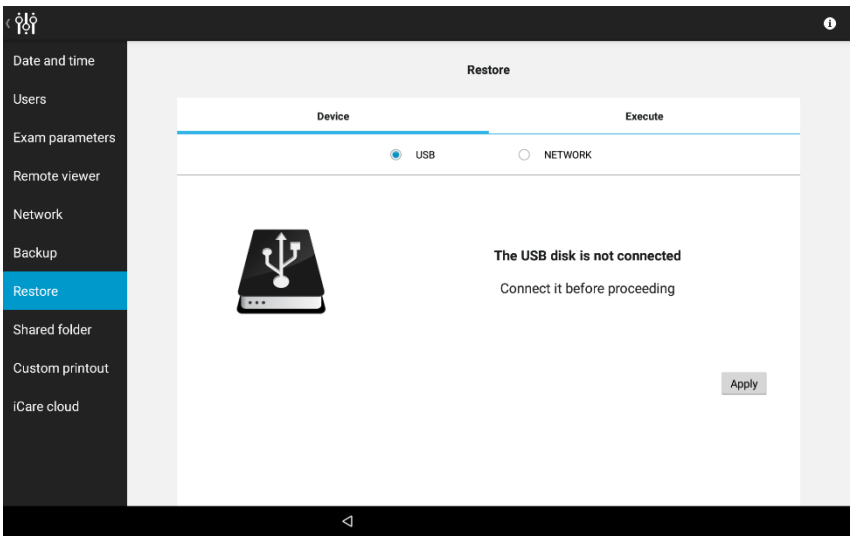


Fig. 86 – Configurator – RESTORE screen – Network folder selected

[21] *EIDON FA accepts restore also from EIDON and EIDON AF. It is not possible to restore EIDON FA backup on EIDON or EIDON AF device.*

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

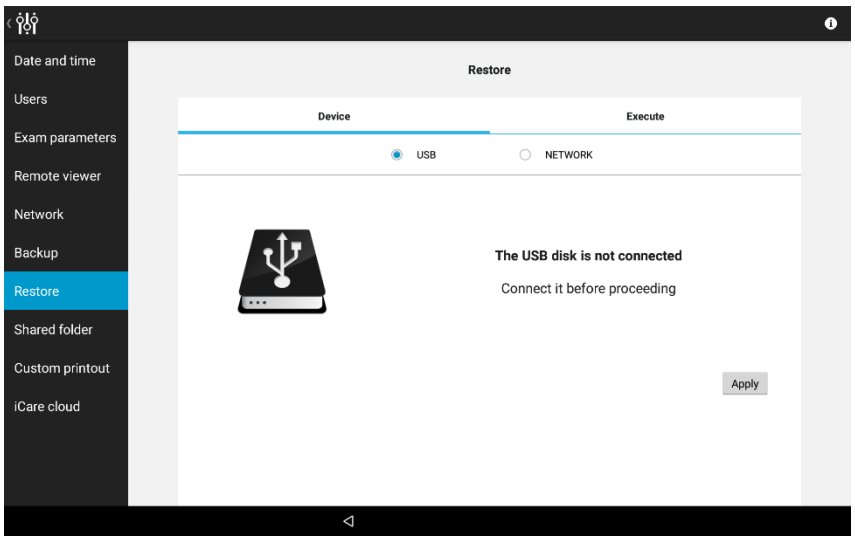


Fig. 87 – Configurator – RESTORE screen – List of available archives to be restored

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

> The restore function will not erase the EIDON Family Device database: patient data will be appended.
> EIDON and EIDON AF cannot restore backups from EIDON FA, while EIDON FA can restore backups from EIDON and EIDON AF.

14.10 Shared folder configuration

Retinal images (and video for EIDON FA only) acquired by EIDON Family Software can be automatically copied to a folder, called **shared folder**. The Shared Folder configuration tab in the Configurator app allows to edit the export parameters. Press **Apply** when the modification process has been completed.

14.10.1 Status

Switch to "Enabled" to activate data export to a shared folder and configure the relevant options, including server, destination folder, username and password.

14.10.2 Mode

If the **"Manual"** option is selected, data is exported using the export icon located in the exam review screen (see § 9.9). If **"Auto"** is selected, data is exported automatically to the selected shared folder upon acquisition and can also be exported manually.

14.10.3 Destination

Both **"Local"** and **"Remote"** shared folders can be selected as the export destination:

- Local shared folder is a folder located in the device;
- Remote shared folder is a folder located in another computer connected to the EIDON Family Device through a network.

> Export to a **remote** destination requires an active network connection.

<u>Local shared folder</u>
No additional parameters can be defined for the **local** shared folder: the shared folder address will be shown at the top of the screen.

Remote shared folder

If the remote shared folder is selected, *Server*, *Folder*, *Username* and *Password* fields are required: for additional information on them, please see the chapter 14.8 (Backup configuration).
When the administrator clicks on the apply button and a remote shared folder is selected, the device checks for the configuration and displays the check result.

14.10.4 File type

If the local option is used, only one export format is available for images (**JPEG**) and one for video (**MP4**). Otherwise, JPEG, PDF and DICOM formats are available for images and it is possible to avoid video export.

14.10.5 Filenames

The filename of a single exported image or video is as follows:
`Surname-FirstName-PatientID-ExamDate-SerialNumber-Eye-Field-ImageType-ImageDate-ExportingDate-Options.FileExtension`
where:
Surname: the patient surname, as in the surname field.

FirstName: the patient given name, as in the given name field.

PatientID: the patient ID, as in the patient id field

ExamDate: Date/Time of the exam in ISO8601 format: yyyy-mm-ddThh_mm_ssZ where yyyy mm dd are respectively year, month, and day, T is the separator between date and time, hh mm ss are respectively hours, minutes and seconds and Z indicates that the exported file time zone is UTC.

SerialNumber: Device serial number, including a prefix eidon_.

Eye: Side of the Eye. Possible values: right or left.

Field: Index representing the field acquired. Possible values: 0 central, 1 central nasal, 3 nasal, 4 temporal, 5 superior, 6 inferior, 8 superior temporal and undefined in case of manual pictures.

ImageType: Type of image acquired. Possible values: visible for color images, infrared for infrared images, af for AF images, fa for FA images, favideo for FA video, favideoframes for pictures extracted from FA videos.

ImageDate: Acquisition Date/Time of the image, in the same format as exam date.

ExportingDate: Exporting Date/Time of the image, formatted as yyyy-mm-dd_hhmmss, where yyyy mm dd are respectively year, month and day, hh mm ss are respectively hours, minutes and seconds.

Options: this is an optional parameter:

report if the exported file is a report (i.e. not an image).

image if the exported file is an image.

mosaic if the exported file is a mosaic.

(null) in case of DICOM files.

FileExtension: File extension, according to the selected format. Possible values: JPG for JPEG images, PDF for PDF files, dcm for DICOM files.

Example: John-Smith-123456789-2020-10-16T13_47_11Z-eidon_00045-right-0-visible-2020-10-16T13_46_48Z-2020-11-02_171549-image.jpg

The filename of a dual exported image is as follows:
`Surname-GivenName-SerialNumber-dual-Eye1-Field1-ImageType1-ImageDate1-Eye2-Field2-ImageType2-ImageDate2-Options.FileExtension`
with the same parameters as for the single image (`1` and `2` identify respectively the left and the right image in the printout), except for the constant string `dual` and the extension (only `pdf` allowed).

14.10.6 Shared Folder Configuration examples

See Fig. 88 as an example of remote shared folder configured for network without domains, and Fig. 89 in the case of Windows Domain network.

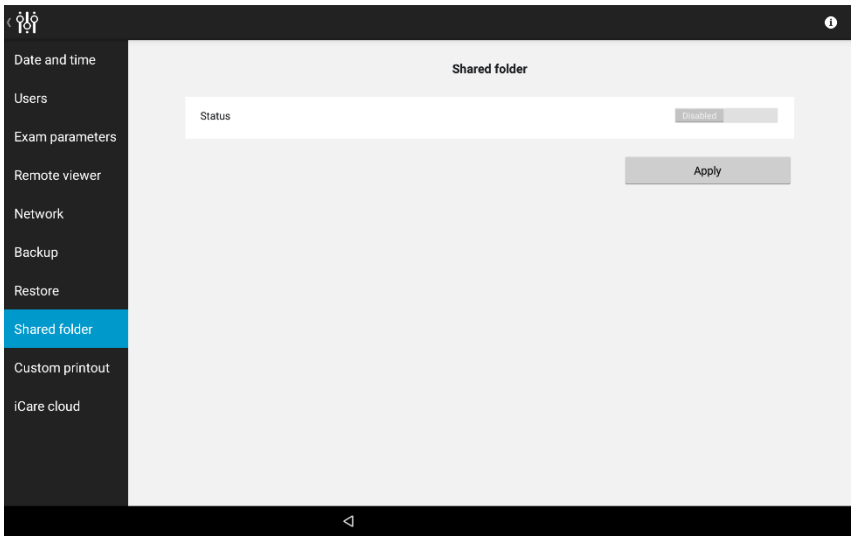


Fig. 88 – Configurator – SHARED FOLDER configuration example:
automatic export of JPEG images and MP4 videos to a remote folder *exported_data* (subfolder of *shared folder*), located in the server *REMOTE-PC*, with *John* as server username

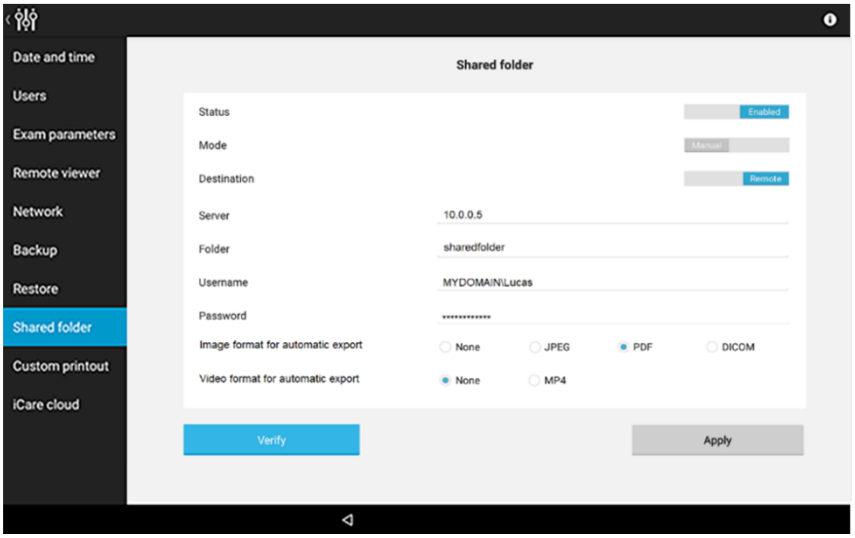


Fig. 89 – Configurator – SHARED FOLDER configuration example, in Windows Domain Networks:
automatic export of PDF printouts to a remote folder *shared folder*, located in the server with IP *10.0.0.5*, with *Lucas* as domain username and *MYDOMAIN* as domain name

14.11 Custom Printout

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

To add the logo, store a JPG or PNG image, up to 1024x1024 pixels, in a USB key. The retinal image filename must be `custom_header_image.jpg` in case a JPG image is used as logo, or `custom_header_image.png` in the case of a PNG image.
To add custom information to the header, write a text up to 5 lines in a file named `custom_header.txt`, and store it in a USB key.

> The file extension (“.jpg”, “.png”, “.txt”) is added automatically by the software used to create the files.
> By default, Windows hides the “known extensions” (like “.png”, “.jpg” and “.txt”) therefore the file will have the correct extension even if you don’t see it.
> **Do not add** an extra extension otherwise the configurator will not recognize the file.

Plug the USB key to the device when the configurator is in the Custom Printout tab: device recognizes the presence of the above files in the USB.

If a custom header has been previously uploaded, the header is shown in the upper part of the screen. With “Remove current header” it is possible to remove the custom header from the printouts.

If a USB key is plugged to the device and contains valid custom header files, the software will preview the custom header at the bottom of the window.

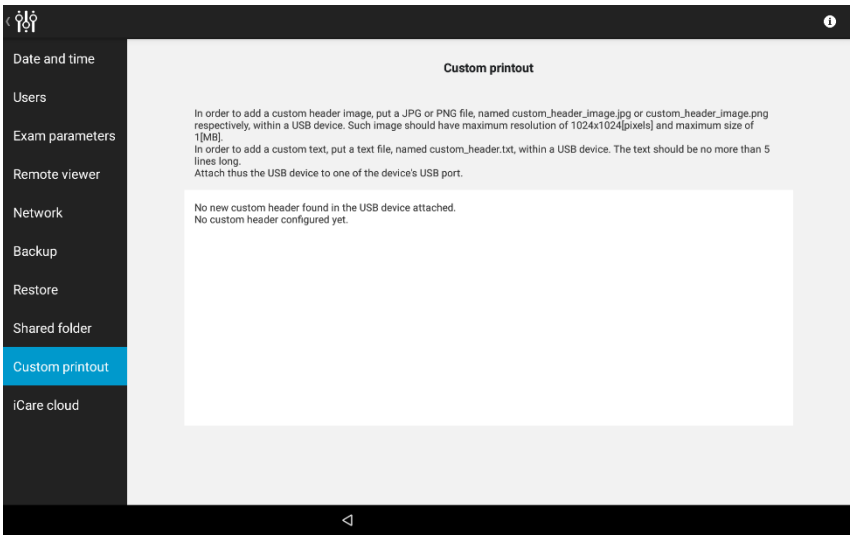


Fig. 90 – Configurator – CUSTOM PRINTOUT configuration

14.12 iCare cloud

The iCare cloud Interface is a service that allows a EIDON Family to connect to the iCare cloud platforms.

Verify that

1. the device is connected to the Network, via Ethernet.
2. the device reaches the following domains and their relative sub-domains via https:

Domain	Protocol	Port
*.icare-world.cloud	HTTPS	443
*.eu-north-1.amazonaws.com	HTTPS	443
api.centervue.net	HTTPS	443

Please note that at this stage we do not support connecting to our services using an HTTP Proxy.

> The iCare ALTIUS functionalities are available only under license.

14.12.1 iCare cloud Registration

To perform the registration of the device, proceed as follows:

1. Access the ***iCare cloud*** Screen (Fig. 91).

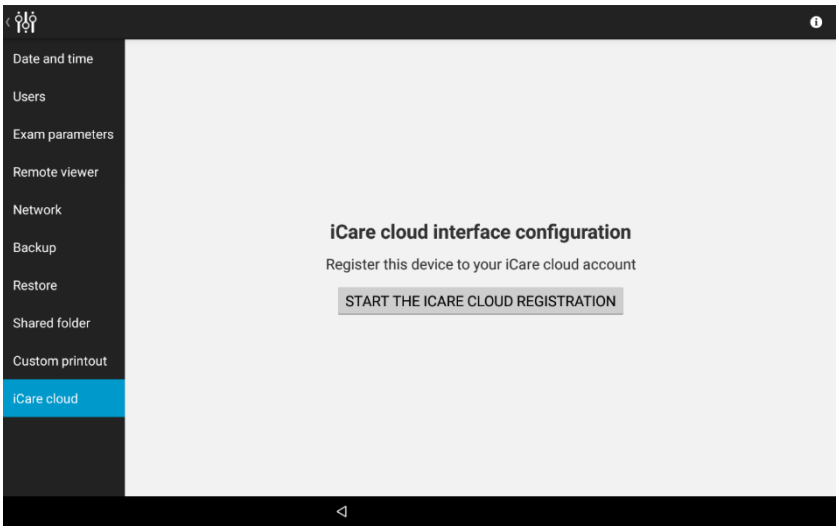


Fig. 91 – iCare cloud screen

2. Click the **START THE ICARE CLOUD REGISTRATION** button (Fig. 91) to start the registration of the device.
3. Push **start registration** button to confirm, push **dismiss** to abort.

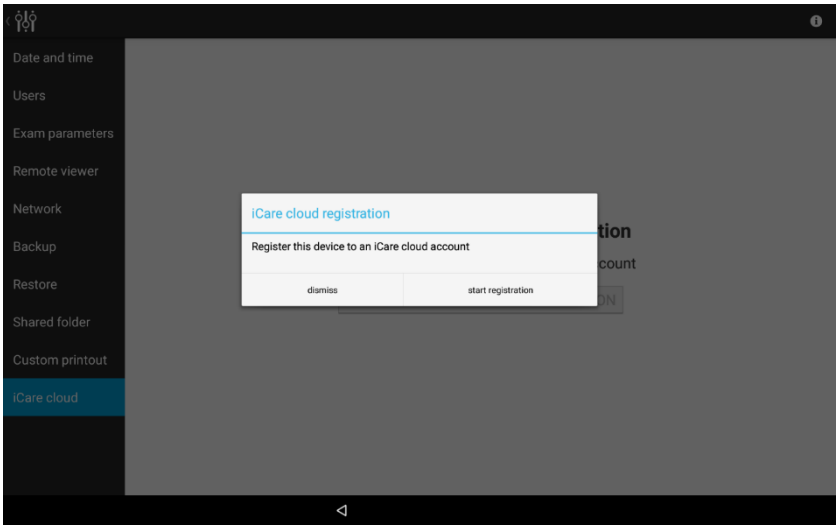


Fig. 92 Registration panel on the iCare cloud platform

4. Register the device on the iCare platform using the Registration PIN shown on the device (Fig. 93).

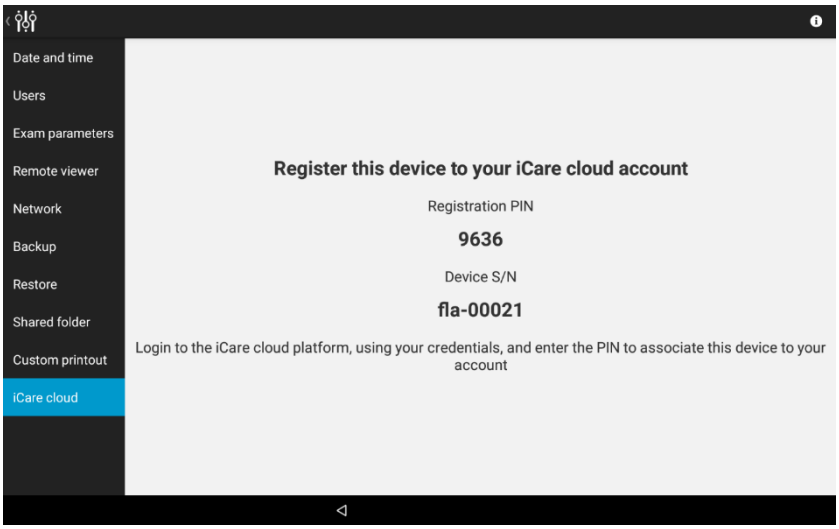


Fig. 93 - Registration PIN Screen

5. When the iCare cloud service is properly registered the iCare cloud interface page shows the status of the service (Fig. 4). On the top bar of the screen appears the icon shown in (Fig. 95).

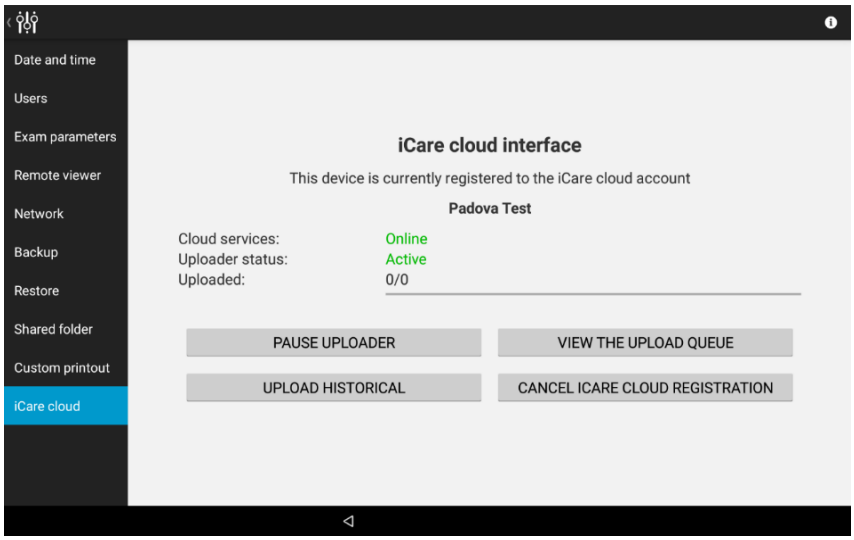


Fig. 94 iCare cloud interface

Fig. 95 iCare cloud icon: device registered

14.12.2 iCare cloud options

When the iCare cloud services are enabled, the iCare cloud interface shows the name of the iCare cloud account connected, the upload status, the number of exams uploaded, and the status of the service (see Fig. 4).

Function	Command
Push **PAUSE UPLOADER** to stop the upload of the exams to the iCare cloud service.	PAUSE UPLOADER
Push **RESUME UPLOADER** to start the upload of the exams to the iCare cloud service	RESUME UPLOADER
Push **VIEW THE UPLOAD QUEUE** to open the *iCare cloud upload queue* window (See Fig. 96).	VIEW THE UPLOAD QUEUE
Push **UPLOAD HISTORICAL** to upload the exams acquired before the activation of the iCare cloud service.	UPLOAD HISTORICAL
Push **CANCEL ICARE CLOUD REGISTRATION** to de-register the device from the iCare cloud account	CANCEL ICARE CLOUD REGISTRATION

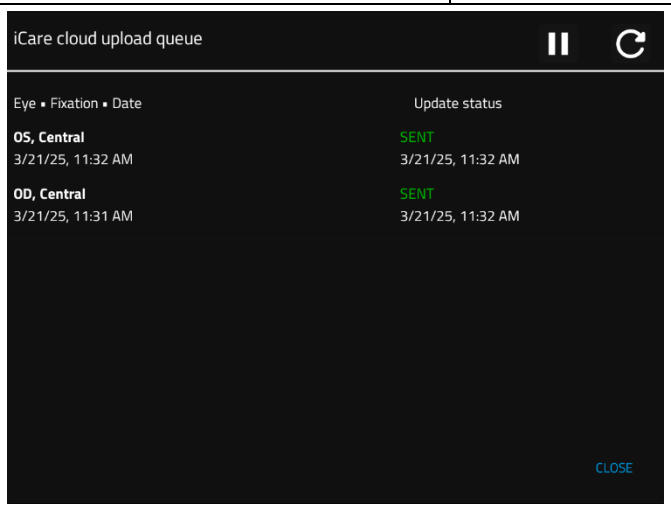


Fig. 96 Export queue

14.12.3 iCare cloud status icon

If the iCare cloud service is enabled on the device, the iCare cloud icon on the top bar of the screen shows the status of the service.

The device is registered to the iCare cloud account, and all the items in the cloud queue have been synced.	
The device is processing the upload queue and sending the pending items to the cloud.	
The upload process is paused. The new exams will be in the queue and will be uploaded as soon as the operator starts the upload.	
The device is unable to contact the cloud server. No item is pending upload.	
The device is unable to contact the cloud server. At least one item is pending upload.	

14.12.4 iCare cloud de-registration

The device can be associated with a unique account. Before connecting the device to another iCare cloud account, you shall de-register the device.

On the iCare cloud interface (Fig. 94) push **CANCEL ICARE CLOUD REGISTRATION** to de-register the device from the iCare cloud account.
Push **deregister** to deactivate the connection, push **dismiss** to abort the operation.

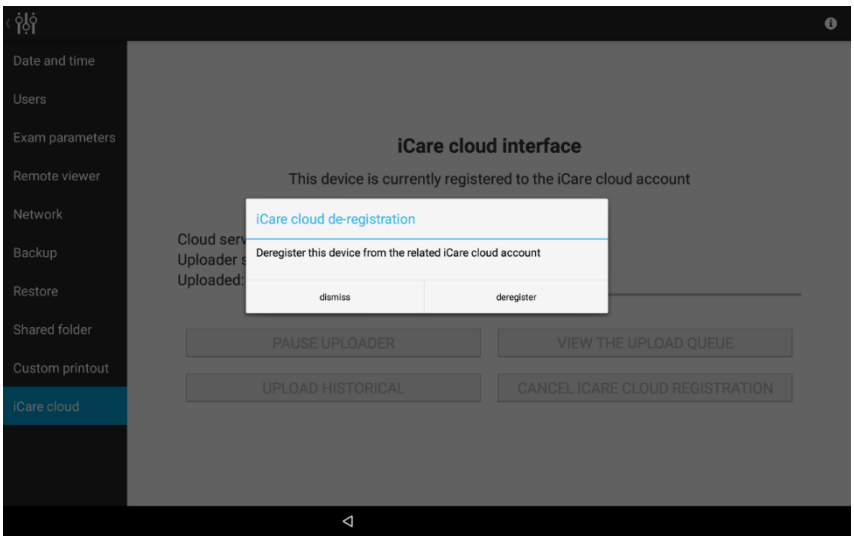


Fig. 97 De-registration

14.13 Custom control interface setting

From Home screen of Fig. 16 press  to enter into the menu. Click on the Settings Icon to enter the menu and select the desired standby time for the Custom Control Interface Display.

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

14.14 Printer setup

EIDON Family Device supports wireless connection to most Android-compatible printers. Printing apps from the most common manufacturers come pre-installed into the EIDON Custom Control Interface. Before choosing a printer, please check if the model is included in the compatibility list issued by the printer Manufacturer for every app.

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

Table 3 - Printing apps

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

14.14.1 Infrastructure Mode

In this configuration, both the EIDON Custom Control Interface and the printer are connected to an Access Point, such as a wireless router: the printer should be connected to the Access Point either by cable or wireless.

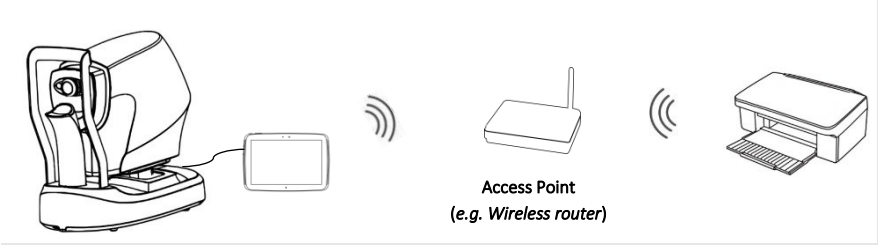


Fig. 98: EIDON Family device's connection to the printer via Access point (wireless)

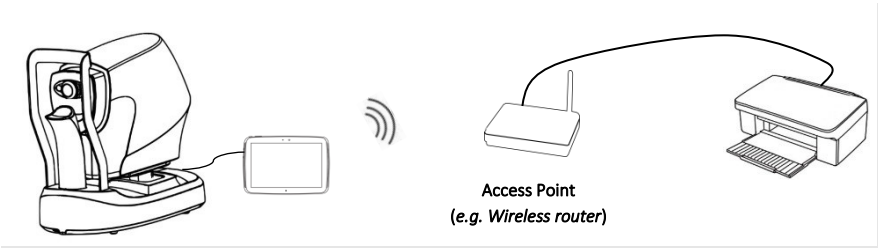


Fig. 99: EIDON Family device's connection to the printer via Access point (cable)

14.14.2 Wi-Fi Direct Mode

The EIDON Family device connects directly to the printer via wireless (**Wi-Fi Direct** Mode), without the need of an Access Point: please note that, in order to set up this configuration, the printer must support **Wi-Fi Direct**.

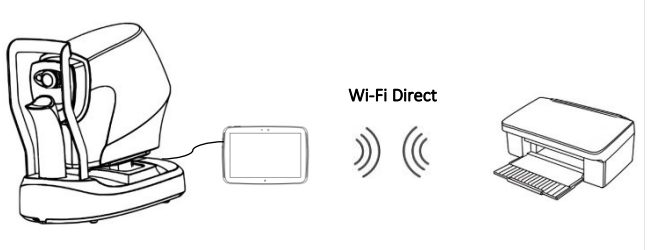


Fig. 100 – EIDON Family device's connection to the printer via **Wi-Fi Direct**

To connect the printer in Wi-Fi Direct mode, enter the “**Advanced Wi-Fi**” from settings and select the “**Wi-Fi Direct**” item (see Fig. 101 – Item “Wi-Fi Direct” within “Advanced Wi-Fi” menu), and proceed with pairing with the printer following the instructions provided by producer.

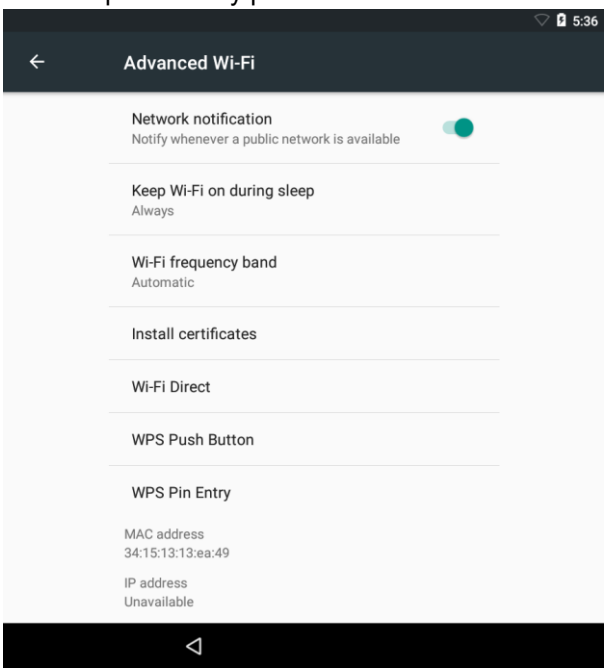


Fig. 101 – Item “Wi-Fi Direct” within “Advanced Wi-Fi” menu

Alternatively, it is possible to pair with the printer directly within the Adobe Acrobat Reader app, using the Mopria Print Service (see Fig. 102).

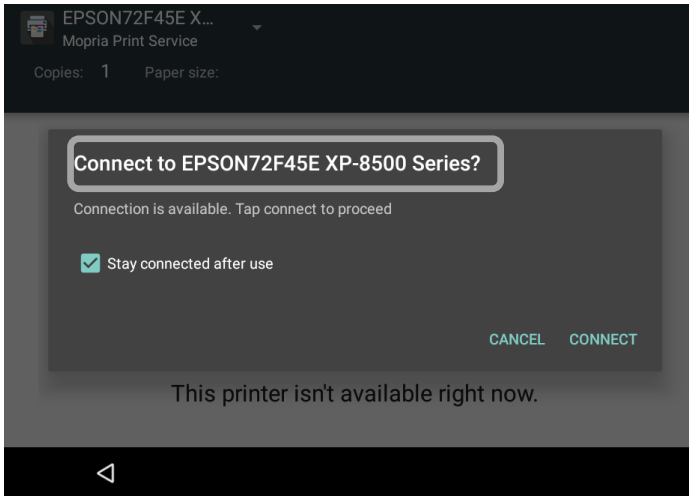


Fig. 102 – Connection to the printer in Wi-Fi Direct mode via Mopria Print Service

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

15. DEVICE SHUTDOWN

To shut down the device, go back to the **Home** screen and press the power off icon  : device beeps twice then turns off. Is it also possible to press the on/off button on the rear connectors panel (see Fig. 6).
The EIDON Custom Control Interface will shut down and power off automatically.

16. TECHNICAL SPECIFICATIONS

Fundus Imaging Features

Field of view for Single image:	60°(H) x 55°(V) captured in a single exposure (external eye notation) 90°(H) x 85°(V) captured in a single exposure (center of the eye notation) 80°(H) x 75°(V) captured in a single exposure (external eye notation) – with EIDON UWF Module[22] 120°(H) x 110°(V) captured in a single exposure (center of the eye notation) –with EIDON UWF Module[22]
Field of Mosaic[23] image: (three images)	110° (H) captured with 3 images horizontally (external eye notation) 160° (H) captured with 3 images horizontally (center of the eye notation)
Sensor resolution:	14 Mpixel (4608 x 3288 pixels)
Light sources:	White LED (440-650 nm) - for all models Infrared LED (825-870 nm) - for all models Blue LED (440-475 nm) - for EIDON AF and EIDON FA model only)
Imaging modalities:	Color, Infrared, RGB channel separation[24] - for all models Autofluorescence - for EIDON AF and EIDON FA model only Fluoresceine Angiography Imaging - for EIDON FA model only
Working distance:	28 mm 16 mm – with EIDON UWF Module[22]
Resolution:	60 pixels / deg
Optical resolution on retina:	15 µm
Pixel pitch:	4.9 µm 6.34 µm - with EIDON UWF Module[22]
Minimum pupil size	2.5 mm
FA Video resolution: *(EIDON FA model only)*	1840x1644 pixels
FA Video acquisition rate: *(EIDON FA model only)*	5 fps

Other features and characteristics

Automatic operation:	auto-alignment, auto-focus, auto-exposure, auto-capture, auto-mosaic
Auto-focusing adjustment range:	- 15 D to + 15 D
Fixation targets:	internal / external
Dynamic programmable internal Fixation target:	Central, Nasal, Temporal, Central-Nasal, Superior, Inferior, Superior-Temporal, Superior-Nasal, Inferior-Temporal, Inferior-Nasal
EIDON Custom Control Interface:	10.1” multi-touch, color display custom control interface
Wi-Fi connectivity:	through EIDON Custom Control interface
Hard disk:	SSD, at least 480 Gb for - EIDON and EIDON AF models SSD, at least 2 TB - for EIDON FA model only
DICOM[25]:	Compatibility - DICOM version 3.0

22 Ultra-Widefield Imaging is avaible with the optional accessory EIDON UWF Module only. For further information and technical specifications about the EIDON Family devices used with the EIDON UWF module, see EIDON UWF Module Instruction for Use: please, refers to your local distributor for further and detailed information.

23 Up to nine retinal images.

24 Digital filters.

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

Other features and characteristics

Size:	360 mm x 590 mm x 620 mm (14.2” x 23.2” x 24.4”)
Weight:	25 kg (55 lb)
Power supply:	Related voltage 100-240VAC Frequency 50-60 Hz Power Consumption 80W
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).
Service life (lifetime):	The service life (lifetime) of the devices is five (5) years from the date of manufacturing.
Content of the device packaging:	Front lens cap Custom Control Interface with multi-touch display Support bracket for User Control Interface USB extension cable External Power supply Power cable Headrest silicone cushion Chinrest cushion Dust cover 3D Joystick with support bracket External fixation target Prismatic stereoscopic goggles Packing straps Mini-HDMI-to-HDMI adapter Mounting kit: screws, washers and hex key This Instruction for Use (or Leaflet in case of electronic Instruction for Use)
Accessory: *(Optionally equipped with EIDON Family devices)*	EIDON UWF Module[22]

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

17. CLEANING AND DISINFECTION

This section explains how to clean and disinfect the device.

The cleaning process is described as follows:

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

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

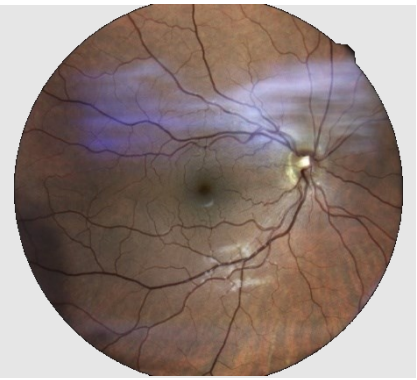
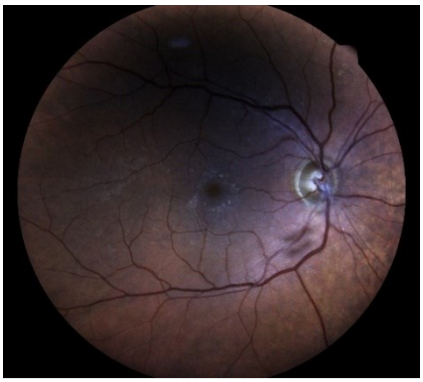
1. Turn off the device and disconnect the power cord from mains
2. Clean the headrest and chinrest silicone cushions with a disinfecting wipe with 70% isopropyl alcohol (IPA)
3. Disinfect all the other contact parts using a disinfecting wipe with 70% IPA (or a soft clean disposable tissue damped with 70% IPA solution): plastic covers, frame and back panel of the Custom Control Interface, any aluminum parts, touch screen and optional components if present
4. Clean the front lens: use a disinfecting wipe with 70% IPA (or a soft clean disposable tissue damped with 70% IPA solution). Starting from the 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.

Fig. 103 – 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.
Do not use the device when there are permanent signs (e.g. scratches) on the lens. In this case contact the authorized service.

18. TROUBLESHOOTING

Symptom	Possible cause(s)	Solution
1. EIDON Family Device does not power on (no green LED)	Unit is not powered	Plug the power supply into a properly working socket then press the power button for at least 2 seconds
2. System keeps failing alignment with message “Eye not found”	Front lens cap is in place	Remove front lens cap
3. Bluish artifacts as in this example appear in all newly acquired images 	Front lens or EIDON UWF Module is dirty	Clean the front lens or the EIDON UWF Module
4. Captured image is totally white	Patient blinked during image capture	Repeat capture and ask patient not to blink
5. One or more dark areas appear in color and/or IR retinal images 	Pupil is too small (< 2.5 mm)	Dark adapt patient. Otherwise dilate patient’s pupils.
6. Export to the remote shared folder fails with message “The selected host is not reachable” or “Timeout”	• Network connection to the remote shared folder not working • Write access to the selected remote folder not granted host computer is not reachable	• Check that the network cable is correctly plugged • Check that the local area network is available • Check that the remote folder is shared with write permission • Check that the computer hosting the shared folder is reachable
7. Export to the remote shared folder fails with message “Unknown error”	The remote export folder was renamed after the export destination was configured	Re-configure the export destination
8. Export to the remote shared folder fails with message “The shared disk is full.”	The computer hosting the shared folder has a full hard disk	Empty some space on the host computer or change the export destination to another computer

19. ELECTROMAGNETIC COMPATIBILITY

EIDON Family Devices have 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. EIDON Family Devices generates, uses and can radiate radio frequency energies and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If the EIDON Family Devices does cause harmful interference to other devices, which can be determined by turning the EIDON Family Devices 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.

EIDON Family Devices need special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided within this document. Portable and mobile RF communications equipment can affect the readings made by these EIDON Family Devices.

19.1 Manufacturers EMC Declaration to IEC 60601-1-2

The following tables provide specific information regarding compliance of EIDON Family Devices

EIDON Family Device is intended for use in the electromagnetic environment specified in the below tables. The customer or the end-user of EIDON Family 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 EIDON, EIDON AF, EIDON FA			
Test Requirements	**Test Result**	**Compliance**	**Electromagnetic environment - Guidance**
Class A or B	B	Yes	EIDON Family 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. EIDON 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:  EIDON Family are intended for use by healthcare professionals only. EIDON and EIDON AF 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 EIDON /EIDON AF 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 4 - Electromagnetic Emissions for EIDON Family devices

19.2 Electromagnetic Immunity Tests

IEC 60601-1-2 ELECTROMAGNETIC IMMUNITY FOR EIDON Family devices			
Immunity testing	**Test level IEC 60601-1-2**	**Test result**	**Compliance**
Electrostatic Discharges (ESD) IEC 61000-4-2	• ±8 kV (contact) • ±2 kV ±4 kV ±8 kV ±15 kV (air)	Pass	Yes
Electrical Fast Transients and bursts IEC 61000-4-4	• ±2 kV power lines • ±1 kV signal lines	Pass	Yes
Surge Immunity IEC 61000 4-5	• ±0,5 ±1 kV differential mode • ±0,5 ±1 kV ±2 kV common mode	Pass	Yes
Voltage Dips and Interruptions IEC 61000-4-11	• 0% Ut; for 0.5 cycle at 0°,45°,90°,135°,180°, 225°,270°, 315° • 0% Ut; 1 cycle • 70% Ut; 25/30 cycles monophase: 0°	Pass	Yes
Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	• 30 A/m	Pass	Yes
Surges Conducted Disturbances induced by RF IEC 61000-4-6	• 3 Vrms from 150kHz to 80 MHz outside ISM and amateur radio bands. • 6 Vrms from 6MHz to 80MHz outside amateur radio bands.	Pass	Yes
Radiated RF EM Fields and Proximity Wireless field IEC 61000-4-3	• 10 V/m from 80 MHz to 2,7 GHz • 27 V/m, 18 Hz PM 50%, 385 MHz • 28 V/m, 18 Hz PM 50%, 450 MHz • 9 V/m, 217 Hz PM 50%, 710 MHz, 745 MHz, 780 MHz • 28 V/m, 18 Hz PM 50%, 810 MHz, 870 MHz, 930 MHz • 28 V/m, 217 Hz PM 50%, 1720 MHz, 1845 MHz, 1970 MHz • 28 V/m, 217 Hz PM 50%, 2450 MHz, • 9 V/m, 217 Hz PM 50%, 5240 MHz, 5500 MHz, 5785 MHz	Pass	Yes
Radiated fields in close proximity IEC 61000-4-39	• Test frequency: 30 kHz, 134.2 kHz, 13.56 MHz	Pass	Yes

Table 5 - Electromagnetic Immunity (IEC 60601-1-2) for EIDON Family Devices

19.3 Electromagnetic Immunity Criteria

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

Table 6 - Electromagnetic Immunity criteria (IEC 60601-1-2)

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

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

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz d = 1.17√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 7 - Recommended Separation Distances

19.4 Wi-Fi Specifications

Model name: WL18MODGI (Texas Instruments Incorporated)

Main Chipset: WL1807MODGIMOC (Texas Instruments Incorporated)

Tx/Rx: 20- and 40-MHz SISO

Standard Conformance: IEEE 802.11 b/g/n
IEEE 802.11 a/n
Dual-Band (2.4 and 5 GHz)

Interface: 4-Bit SDIO Host Interface Support

Operation Voltage: DC 1.8V ±8%

Maximum RF Power: According to EMF Exposure Evaluation Report:
2.4GHz Avg power: 17.5dbm (56.2mW)
5GHz Avg power: 19.5dbm (89.1mW)

Security: Hardware-based encryption-decryption using 64-, 128-, and 256-bit WEP, TKIP, or AES keys
Requirements for Wi-Fi-protected access (WPA and WPA2.0) and IEEE Std 802.11i (includes hardware-accelerated Advanced Encryption Standard AES)

FCC (USA) radio certification
The EIDON Family devices contain a radio module that complies with regulations of the USA and Canada.

FCC ID: ID-Z64-WL18DBMOD

IC ID: 451I- WL18DBMOD

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

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

20. INFORMATION ABOUT THE OPTICAL RADIATION HAZARD

According to ISO 15004-2:2024 and ANSI Z80.36, EIDON Family devices are classified as:

- EIDON and EIDON AF: group 1
- EIDON FA: group 2

The use of the device with the EIDON UWF Module does not change the class of the device.

20.1 Information required by ISO 15004-2 valid for EIDON FA model only

EIDON FA is marked with optical radiation hazard warning label:

CAUTION!
The light emitted from EIDON FA is potentially hazardous.

Continuous wave output
Exposure to light from EIDON FA when all sources are operated at maximum intensity will potentially exceed Group 1 exposure limit of 2,2 J/cm2 after:

- 16 minutes illumination during dynamic fluorescein angiography (FA video)
- 124 hours illumination of green Fixation light
- 1502 hours illumination of yellow Fixation light

Although the risk of retinal injury at an exposure just exceeding 2,2 J/cm2 is low, caution is advised, as some patients may be more susceptible than others.
Exposures exceeding the recommended maximum exposure (RME) of 10 J/cm2 (cumulative exposure duration exceeding 4,5 times the Group 1 limits) entail a significant risk of injury.
The exposure from all light sources is cumulative and additive.

Pulsed wave output
Exposure to light of spatially overlapping pulsed light sources from EIDON FA when operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2 J/cm2 after, e.g. 110 pulses for color image, 110 pulses for autofluorescence image.
Although the risk of retinal injury at an exposure just exceeding 2,2 J/cm2 is low, caution is advised, as some patients may be more susceptible than others.
Exposures exceeding the recommended maximum exposure (RME) of 10 J/cm2 (cumulative exposures from all sources exceeding 4,5 times the Group 1 limit) entail a significant risk of injury.
The exposure from all light sources is cumulative and additive.

Patient exposure to lights emitted from EIDON FA is, for each source:

- for color images the exposure for 1 photo is $0{,}00026\ {}^{J}/_{cm^2}$
- for autofluorescence image the exposure for 1 photo is $0{,}0015\ {}^{J}/_{cm^2}$
- for illumination light during dynamic fluorescein angiography the exposure for 1 minute is $0{,}133\ {}^{J}/_{cm^2}$
- for fluorescein angiography image the exposure for 1 photo is $0{,}0015\ {}^{J}/_{cm^2}$
- for green fixation light the exposure for 1 minute is $0.0000134\ {}^{J}/_{cm^2}$
- for yellow fixation light the exposure for 1 minute is $0.00000034\ {}^{J}/_{cm^2}$

Since the exposure from all light sources is cumulative, and all imaging modalities, including fluorescein angiography, and the fixation light can be used in combination, the exposure given by each source shall be added in order not to exceed the safety guidelines.

Therefore, the following formula is used to determine the patient's total exposure.

$$Total\ exposure = (n_{VIS} \times 0.00026) + (n_{AF} \times 0.0015) + (n_{FA} \times 0.0015) + (t_{FA} \times 0.133) + (t_{FIXgreen} \times 0.0000134) + (t_{FIXyellow} \times 0.00000034) < 10 \left[{}^{J}/_{cm^2} \right]$$

Where:

- n_{VIS} is the number of color images captured during an exam
- n_{AF} is the number of autofluorescence images captured during an exam
- n_{FA} is the number of fluorescein angiography images captured during an exam
- t_{VIS} is the time, in minutes, that the illumination light for fluorescein angiography is on
- $t_{FIXgreen}$ is the time, in minutes, that the fixation light is on during all exams
- $t_{FIXyellow}$ is the time, in minutes, that the fixation light is on during all exams

Example 1
If 100 color photos, 100 autofluorescence photos, 100 fluorescein angiography photos are captured, together with 60 minutes of continued fluorescein angiography illumination and 120 minutes of green fixation, the resulting exposure will be about **8.3 J/cm²**, which is still below the safety guideline.

Example 2
If 6 color photos, 4 autofluorescence photos and 50 fluorescein angiography photos are captured, together with 2 minutes of continued fluorescein angiography illumination and 20 minutes of green fixation, the resulting exposure is **0.35 J/cm²**.

To request a graph showing the relative spectral output, please send an email to IFU@icare-world.com.

20.2 Information required by ANSI Z80.36 for EIDON FA model only

The light emitted from this instrument is potentially hazardous. The greater the number of pulses, the greater is the risk of ocular damage. Exposure to light from this instrument when it operates at maximum intensity will exceed the recommended maximum exposure (RME) of $2.2\,J/cm^2$, unless additional action is taken by the user to minimize exposure, after 10185 color fundus images taken alone, 1467 autofluorescence images taken alone, 17 minutes for illumination light during FA exam operating alone, 1467 FA images taken alone, 1892 hours for green fixation used alone, 24154 hours for yellow fixation used alone.
The risk of retinal injury at an exposure of $2.2\,J/cm^2$ is not high but, because some patients may be more susceptible than others, caution is advised if this radiant exposure value is exceeded. However, because of a significant risk of injury at exposures exceeding $10\,J/cm^2$, the user should avoid exposures longer than 46300 color images or 6666 autofluorescence images or 75 minutes of continued fluorescein angiography video or 6666 fluorescein angiography images or 14467 hours of continued green fixation light or 8600 hours of continued yellow fixation light.

Patient exposure to light from the EIDON FA can be calculated as follows:

- For color images the exposure for 1 photo is $0.0002157\,J/cm^2$.
- For autofluorescence image the exposure for 1 photo is $0.0015\,J/cm^2$.
- For illumination light during dynamic fluorescein angiography the exposure for 1 minute is $0.133\,J/cm^2$.
- For fluorescein angiography image the exposure for 1 photo is $0.0015\,J/cm^2$.
- For green fixation light the exposure for 1 minute is $0.00001938\,J/cm^2$.
- For yellow fixation light the exposure for 1 minute is $0.0000015\,J/cm^2$.

Since the exposure from all light sources is cumulative and all the images type, the FA exam and the fixation can be used in combination, the exposure given by each source shall be summed in order not to exceed the safety guidelines in the following way:

$$Total\ exposure = (n_{VIS} \times 0.0002157) + (n_{AF} \times 0.0015) + (n_{FA} \times 0.0015) + (t_{FA} \times 0.133) + (t_{FIXgreen} \times 0.00001938) + (t_{FIXyellow} \times 0.0000015) < 10[J/cm^2]$$

where:

- n_{VIS} is the number of color images captured during an exam,
- n_{AF} is the number of autofluorescence images captured during an exam,
- n_{FA} is the number of fluorescein angiography images captured during an exam,
- t_{VIS} is the time, in minutes, that the illumination light for fluorescein angiography is on,
- $t_{FIXgreen}$ is the time, in minutes, that the green fixation light is on during all exams,
- $t_{FIXyellow}$ is the time, in minutes, that the yellow fixation light is on during all exams.

Example: if 100 color photos, 100 autofluorescence photos and 100 fluorescein angiography photos are performed in combination with 60 minutes of fluorescein angiography illumination light and 120 minutes of green fixation the exposure will be about 8,3 J/cm².

21. DISPOSAL

EIDON Family Device are made of different materials, such as plastics, aluminum, electronic parts. In case of device 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 of Electrical and Electronic Equipment (WEEE). Users of Electric 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, affects the endocrine system, the cardiovascular system and kidneys. It accumulates and is very toxic for animals, plants and micro-organisms.

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

Mercury: is easily accumulated in organisms and concentrates through the food chain. It has chronic effects and can cause brain damage.

Chromium (Hexavalent): easily absorbed into cells with toxic effects. The results can be allergic reactions, asthma and it is considered to be genotoxic (damages the DNA). Especially dangerous when incinerated.

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

22. MAINTENANCE

The Manufacturer recommends the periodic maintenance of the device once a year. Only properly qualified Authorized Service Technicians can perform maintenance activities (for example cable checking, motor greasing, SW updates). EIDON models have no user serviceable internal parts. Only technicians authorized by manufacturer may perform maintenance or repair procedures other than those described in these Instructions for Use. Contact the Authorized Service Center for the maintenance.

To clean the front lens in case of dirt, refer to §17. To check the disk space, refer to §13.3.

23. LOG OF DOCUMENT CHANGES

IFU version	Description	IFU Release date	Software version
33.00	Revision sections "Symbols used on the devices" and "Information required by ISO 15004-2 valid for EIDON FA model only" for ISO 15004-2: 2024 compliance. Introduced SW bugfixes.	2025-10-27	4.4.2
32.01	Introduced SW bugfixes	2025-09-08	4.4.1
32.00	New graphic interface, added iCare cloud paragraph, minor improvements	2025-04-01	4.4.0
31	Introduced SW bugfixes	2024-11-08	4.3.2
30	Introduced SW bugfixes and update of section “Manufacturers EMC Declaration to IEC 60601-1-2”	2024-07-08	4.3.1
29	Introduction of electronic IFU	2023-12-14	4.3.0

CENTERVUE S.P.A.
Via San Marco 9h, 35129 Padova – ITALY
Ph.: +39 049 5018399
Fax: +39 049 5018398
info@icare-world.com

www.icare-world.com

For better perception