eidon eidon Af eidon Fa

True Color Confocal Scanner

EIDON Family User Manual

USER MANUAL INFORMATION

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Revision number: 25
Reference software version: 4.0
Reference devices: EIDON Family devices [models: EIDON (REF: AMFUNME001), EIDON AF (REF: AIFLUME001) and EIDON FA (REF: AIFLAME001)]

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

CONTENTS

1. INTRODUCTION

Congratulations for choosing one of the EIDON Family devices (EIDON, EIDON AF, EIDON FA) and its confocal retinal imaging capabilities.

EIDON Family devices (EIDON, EIDON AF, EIDON FA) are fundus imaging devices which are based on confocal scanning imaging system (see detail at pag.6)
EIDON Family Devices are intended for taking color, infrared and autofluorescence and fluorescein angiography imaging of a human retina with or without 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 (Fig. 3) (additional feature for EIDON AF and EIDON FA)
- fluorescence images (Fig. 4) (additional feature for EIDON FA only)

Fig. 1 – IR retinal reflectance image

Fig. 2 – Color retinal image

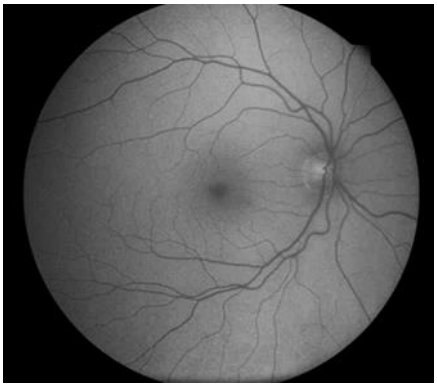


Fig. 3 – Autofluorescence retinal image

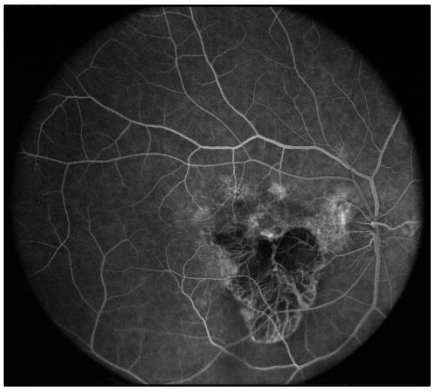


Fig. 4 – Fluorescence angiography retinal image

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. It is recommended for the end-user to carefully read this User Manual to be informed and trained before the use.

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 this device to sale by or on the order of a physician or a properly licensed practitioner.

COLOR CONFOCAL IMAGING

SLO systems are superior to conventional fundus cameras in many ways, as they exploit a **confocal imaging principle** which limits the backscattered light effect from deeper layers and provides enhanced image quality, in terms of contrast and resolution. Another advantage of SLO systems is that they operate with smaller pupils than non-confocal imaging systems. However, SLO systems do not provide color images, as they employ monochromatic laser sources, resulting in black and white or pseudo-color images.

EIDON Family devices are based on a confocal system that uses **white LED light** instead of monochromatic lasers, hence it provides **TrueColor** C**onfocal** images and offers high image fidelity, no need for dilation, high resolution and contrast, high quality even in presence of media opacities.

2. EIDON Family devices

2.1 Devices

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

The main parts of each EIDON Family device consists of:

- Device (EIDON or EIDON AF or EIDON FA);
- EIDON Custom Control Interface with multi-touch display (same for all models of EIDON Family devices);
- External Power supply[1];
- 3D Joystick[2];
- EIDON UWF Module[3].

For a list of all components included with device see Content List in the device package.

[1] *It is a EIDON device component, model MDS-150AAS12-BA manufactured by Delta Electronics. It features 100-240 VAC, 50-60 Hz and a consumption of 80 W.*

[2] *It is a EIDON device component, 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.*

[3] *It is not a EIDON device component but an EIDON family accessory (sold as a EIDON Family's optional and shipped with a dedicated box). The EIDON UWF Module is manufactured by CenterVue and it features the possibility to increase the EIDON field of view (see EIDON UWF Module User Manual for details) when mounted on the EIDON frontal lens. The EIDON UWFL module is available only under license: to request license, please refer to your local distributor.*

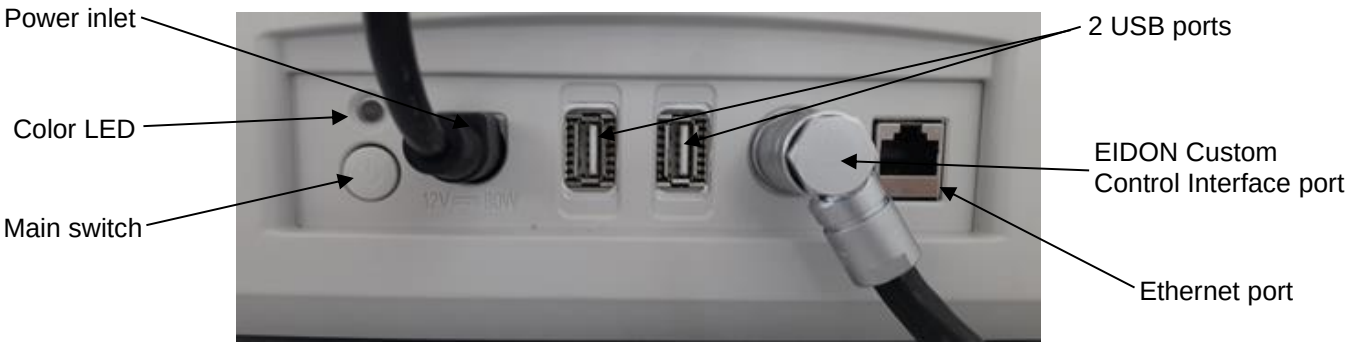


Fig. 6 – Detail of connectors side

The following precautions are important to understand device light messages emitted from the color LED close to the stand-by button (see Fig. 6):

- Steady Red light means “waiting”
- Steady Green light means “power on”
- Flashing Blu light means POST (DEBUG = 1)
- Fast flashing green light means “Power on sequence (DEBUG = 1)”
- Fast flashing red light means “Reboot”
- Fast flashing red/blue light means “Reboot – feedback absent”
- Fast flashing red/green light means “Reboot – OVP/UVP)
- Single red flashlight means “start of error code reporting”
- Single white flashlight means “start of version code reporting”
- Flashing blue light (code reporting) is proportional at tens in the numerical code
- Flashing green light (code reporting) is proportional at units in the numerical code

2.2 EIDON User Custom Control Interface

The EIDON User 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 User Custom Control Interface must be connected to EIDON device using the supplied custom cable[4] only. The Mini-HDMI-to-HDMI adapter allows the user to connect the tablet PC to the monitor in order to display the image on a larger screen.

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

Fig. 7 – EIDON User 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 user manual. Use of the EIDON Custom Control Interface for other purposes than the one intended by the Manufacturer (CenterVue), as well as any modifications or misuses are exclusively under end-user responsibility.

[4] EIDON Custom Control Interface with multi-touch display is equipped with a custom cable permanently connected to the same EIDON Custom Control Interface.

3. LABELS

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

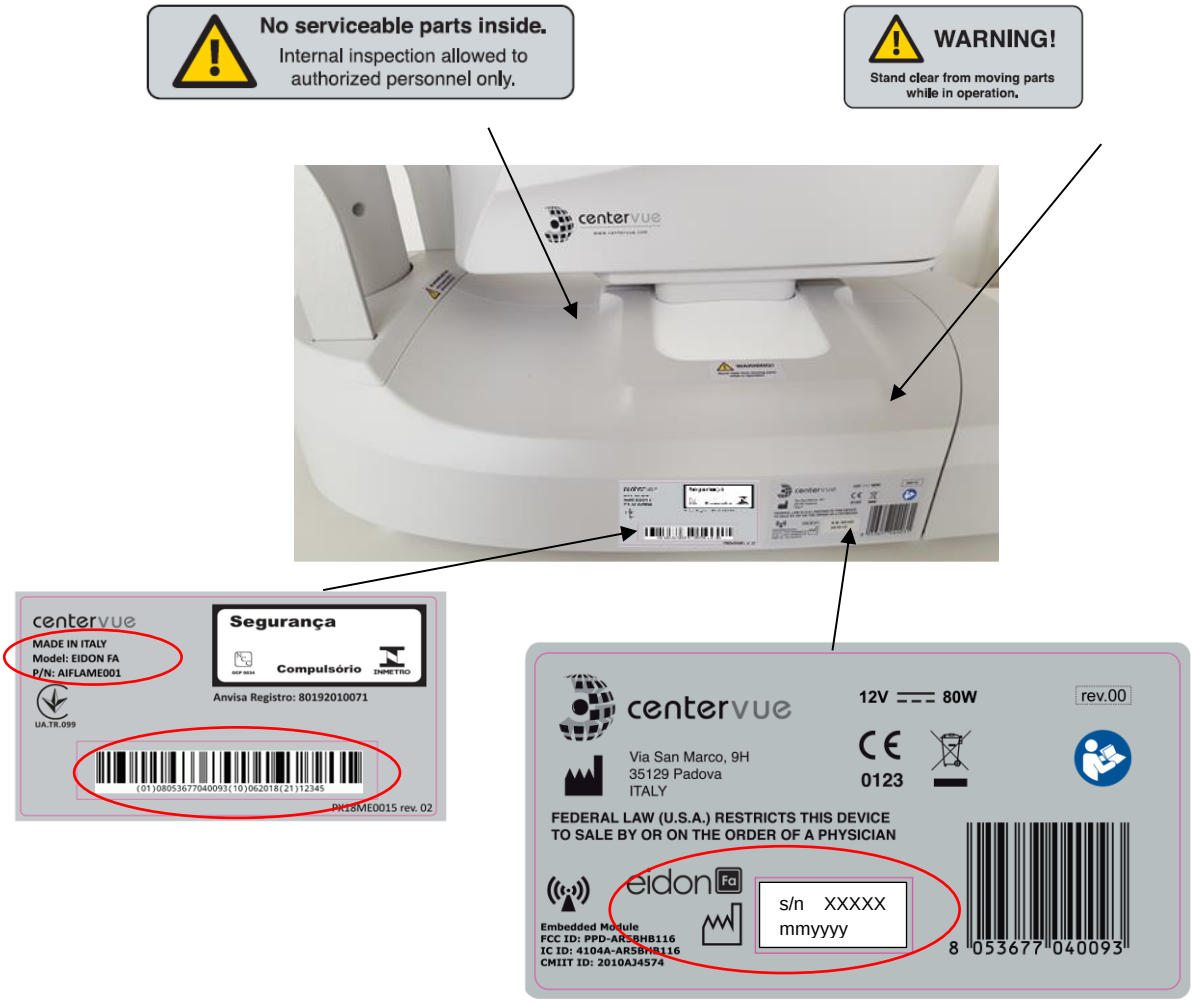


Fig. 8 – Device identification and warning labels on a EIDON FA model as representative example of the EIDON Product Family devices

Fig. 9 – Other warning labels on the EIDON Family devices

Labelling might be subject to changes depending on local regulatory requirements.

4. SYMBOLS AND DEFINITIONS

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

Symbol	Explanation
	Manufacturer Data
	Manufacturing Date (*mmyyyy* where *mm* is 2-digit month and *yyyy* is 4-digits year)
S/N	Device serial number (where *nnnnn* is 5-digit serial number)
	In Europe, electronic and electric devices must be recycled. See par. 19 for device disposal.
	Refer to Instruction Manual
CE 0123	CE mark: the device complies with the essential requirements of the European Medical Devices Directive 93/42/EC
	Type B Applied Part
	Direct current
	Non-ionizing radiation - ME EQUIPMENT that include RF transmitters
	General Warning Sign

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

Symbol	Explanation
	General warning, read carefully
	Important information

The meaning of the specific words adopted in this user manual are as follows:

- **Customer:** EIDON Family devices' owner (it can be different from EIDON Family devices' end-user);
- **Device:** is the synonym of EIDON Family device/s used in this user manual
- **Exam:** any retinal image acquisition session performed using the drsplus for a certain patient on a certain date.
- **Field:** portion of the retina visible in a specific retinal 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**: small bright green circle visible when looking into the front lens of the drsplus, used to move the gaze of the patient and capture different fields.
- **Operator:** EIDON Family devices' end-user
- **Pupil:** is the opening 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.
- **Retina:** The inner layer of the eyeball. It is the main area of interest in the images acquired by EIDON Family devices.

5. PREPARING THE DEVICE

We recommend reading carefully and thoroughly par. 6 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[5];
- insert the headrest on the metal support (see Fig. 12);
- mount the support provided for the EIDON User Custom Control Interface and the 3D Joystick (see par. 5.1)
- connect the power supply provided with the unit to the power inlet (see Fig. 6);
- place the EIDON User Custom Control Interface on its support (support bracket) and connect it using the cable to the dedicated port (see Fig. 10);
- place the 3D Joystick on its support, connect it using the cable to any of the free USB ports and check for its correct orientation (see Fig. 11);
- optionally mount the EIDON Family External Fixation Target (see par. 5.2);
- plug the power supply to the wall socket.

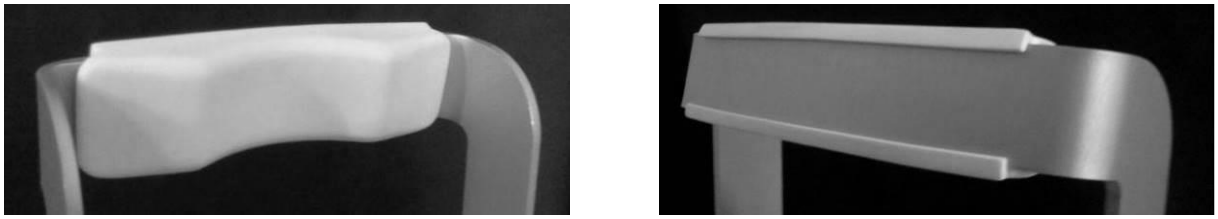


Fig. 12 – Headrest mounted on metal support

5.1 Assembling the EIDON User Custom Control Interface and 3D Joystick supports

The EIDON User Custom Control Interface and the 3D Joystick should be mounted towards the posterior part of the device with the included support bracket and it is possible to choose their position on any side (see Fig. 14). The 3D Joystick should be placed close to the EIDON User Custom Control Interface during use, on its left or on its right. Both supports need to be fixed with screws to the bottom of the device.

As an example, Fig. 15 shows the holes to be used for the left-side mount depicted in Fig. 13: to fix the supports use the holes marked 1 and 2 for the tablet and those marked 3 and 4 for the joystick.

Other position for EIDON User Custom Control Interface and for 3D Joystick than the two suggested above can be chosen as per end-user's preferences taking care about connection cables and connectors.

Fig. 13 – EIDON User Custom Control Interface and 3D Joystick mounted on the left side of the device

Fig. 14 – Support bracket for EIDON User Custom Control Interface (left) and for 3D Joystick (right)

[5] *It is not provided with the device. For a list of all components included with EIDON family device, see Content List in the device package*

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

Fig. 15 – Device bottom with holes for tablet and 3D Joystick supports

5.2 Assembling the EIDON Family External Fixation Target

The EIDON Family External Fixation Target[7] is an external light that can be used for all EIDON Family devices. It allows to frame fields that are centered within 20° from the fovea: the EIDON Family External Fixation Target can be used to image more peripheral areas.
Fasten the light to the headrest using the supplied screws and the spacer plate; connect it to one of the device USB port to power it on (see fig 6).

Do not use EIDON Family External Fixation Target in combination with the accessory EIDON UWF Module since collision may occur

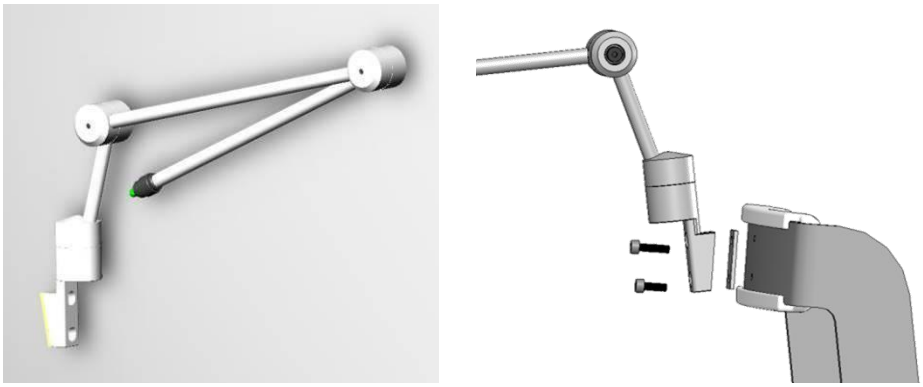


Fig. 16 – EIDON Family External Fixation Target

5.3 Remove the front lens cap

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

[6] *It is provided with the device. For a list of all components included with EIDON family device, see Content List in the device package*

[7] *It is provided with the device. For a list of all components included with EIDON family device, see Content List in the device package*

5.4 Turning on the Device

Turn on the device by pressing the main switch (see Fig. 6), the device will emit a single beep during the power-on sequence. Then wait for the boot process to complete, until the **Login** screen appears (see Fig. 17). 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 (EIDON or EIDON AF or EIDON FA)

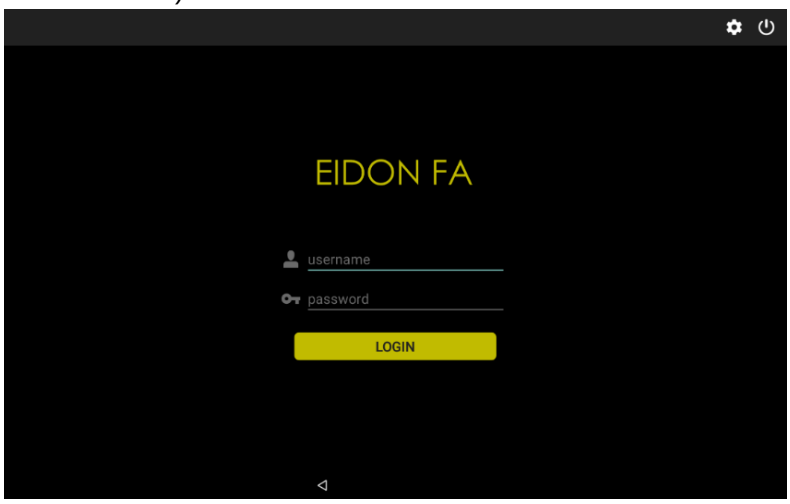


Fig. 17 – Login screen of a EIDON FA as an example

From the drop-down menu select **Doctor**, type the password[8] and click on **Login** button. If login is successful, the **Home** screen opens (see Fig. 18).
The session is automatically closed after 10 minutes of inactivity, which means that the user has to perform again the login to modify the standby time please (see Section 12.12).

	To modify the password, see par. 12.4

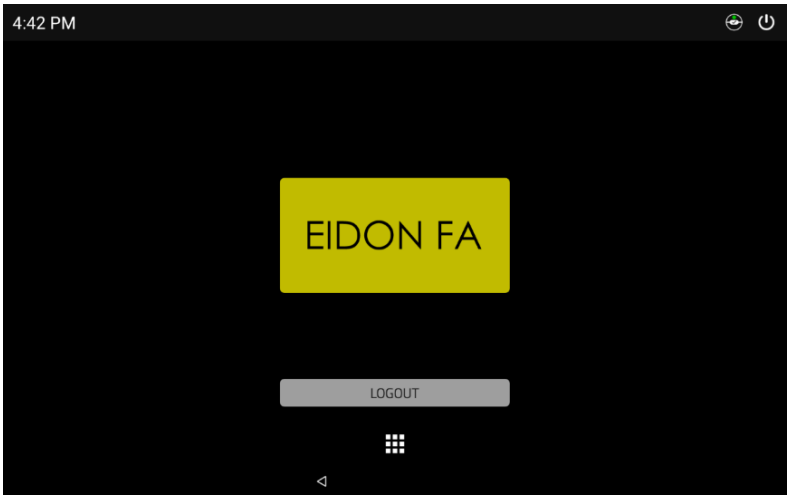


Fig. 18 – Home screen

5.5 Unlock function

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

[8] Please ask an authorized CenterVue representative for the factory password

6. WARNINGS AND PRECAUTIONS

The following precautions are important for use the device in safety:

- Federal laws (US) restrict this device to sale by or on the order of a physician or a properly licensed practitioner. The clinical interpretation of the images is restricted to licensed eye care practitioners.
- It is recommended for the end-user to carefully read this User Manual to be informed and trained before the use.
- Do not open the EIDON Family devices: this could lead to electric shocks or damage to the system.
- Do not use the EIDON Family devices if the cover or other parts of the device have been removed.
- Only technicians authorized by CenterVue may service an EIDON Family devices. CenterVue cannot be held responsible for device safety should EIDON Family devices be opened, repairs carried out, third-parties' software be installed, or parts be replaced by unauthorized people.
- Do not expose the EIDON Family devices to water: this could lead to fire or electric shock.
- Stand clear from moving parts during operation.
- The 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.
- The EIDON Family devices must NOT be used in an oxygen rich environment or in presence of flammable anesthetics.
- In case an unexpected hardware condition occurs during use, an error message may appear (see for example Fig. 19) and the device may become temporarily locked. It is possible to reset this condition by letting the device re-initialize: refer to par. 12.2 for the complete procedure. If the error condition persists, please contact an Authorized Service Center.
- To avoid the risk of electric shock, the EIDON Family devices must only be connected to a supply main with protective earth.
- The decision on whether to perform fluorescein angiography must be made by a licensed eye care practitioner. Specific medical knowledge is required to perform such procedure, which is beyond and out the scope of this User manual.
- The use of other cables and accessories on EIDON Family devices than ones provided by CenterVue may negatively affect EMC performances
- External device/s connected to EIDON Family devices, into the patient environment, must comply with IEC 60601-1. Those device/s that do not comply/complies with the IEC 60601-1 must be kept out of the patient environment and must comply with IEC 60950-1. Any end-user who connects external devices 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.
- When in operation, EIDON Family Device contains personal data (patient data and images are not stored on the EIDON User Custom Control Interface). It is the end-user's responsibility to keep and maintain an updated copy of the data generated by compass through regular use of the backup facility, thus preventing the risk of accidental loss of data.
- Report any serious incident to CenterVue and to the competent authority of the Member State in which the user and / or patient is established.

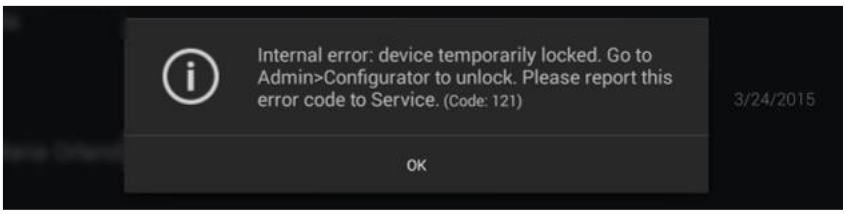


Fig. 19 - Example of error message

The following precautions are important to prevent use errors:

- The EIDON Family devices must be placed in a room which is not exposed to adverse chemical-physical conditions, such as the presence of sulfur, salt, dust, direct sunlight, lack of ventilation, high humidity, sudden temperature drops or peaks. The safety and/or effectiveness of the instrument cannot be guaranteed if these conditions are not fulfilled.
- EIDON Family devices need to be operated in a semi dark environment.
- EIDON Family devices need to be operated under the following environmental conditions: temperature: 10 to 40 C° (50 to 95 F°); humidity (max): 90% not condensing.
- EIDON Family devices need to be stored under the following environmental conditions: temperature: 0 to 60 C° (32 to 131 F°); humidity (max): 90% not condensing.

7. PREPARING THE PATIENT

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

EIDON Family devices are a non-mydriatic 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 par. 8.13.

EIDON Family device compensate for a patient's spherical refractive error in the range -12 to +15 diopters: testing a patient presenting a spherical error out of the above range may result in 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, end-user 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 's eye is aligned to the mark found on the left side of the metal frame (see Fig. 20). If this is not the case the chin rest height needs to be adjusted (see 8.6).

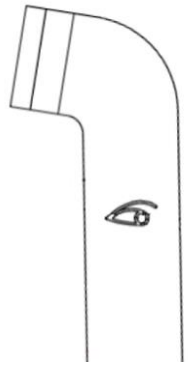


Fig. 20 – Sketch of the eye mark on the metal frame

Before the exam, the end-user should inform the patient about the following:

- EIDON Family devices will take photos of the back of your 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 unit will move around to find your pupil: this is absolutely normal;
- always keep your eyes wide open, so that eyelids do not interfere;
- when the 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.

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 par 6.4), click on the device' name button (EIDON or EIDON AF or EIDON FA) to open the **Patient List** screen (see Fig. 21). The **New exam** button in each Patient record is a shortcut that links to the **Exam configuration** screen, bypassing the **Patient** screen.

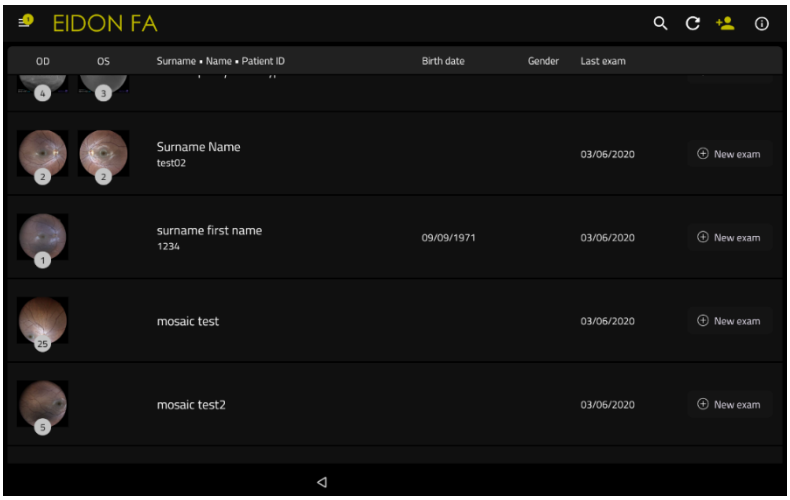


Fig. 21 – Patient list screen as an example from EIDON FA device

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

- presence and number of exams (represented by the retinal images) stored for a certain patient (right and left eye);
- patient's first name and surname, birthday, patient ID, patient gender;
- for EIDON FA only, if a FA session is open, instead of **New exam** button will appear the **Resume FA** button that allow to start again the FA session;
- date of last exam, formatted as month/day/year.

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

- **adding a new patient** (for further details, see par. 8.2);
- **deleting a patient** (for further details, see par. 8.3);
- **searching for an existing patient** (for further details, see par. 8.4);
- **selecting an existing patient** (for further details, see par. 8.5).

To get more information on the device, click on  and the **Information Center** will appear.

8.1 Device Information Center

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

- **backup status** (for further details, see par. 9.1.1);
- **shared folder status** (for further details, see par. 9.1.2);
- **data storage** (for further details, see par. 9.1.3);
- **about** (for further details, see par. 9.1.4).

8.1.1 Backup status

From the **Backup** tab, it is possible to see backup progression, stop a running backup or start a manual backup. This screen also includes information on the backup media and on the last backup. For more information on Backup, see par. 12.8.

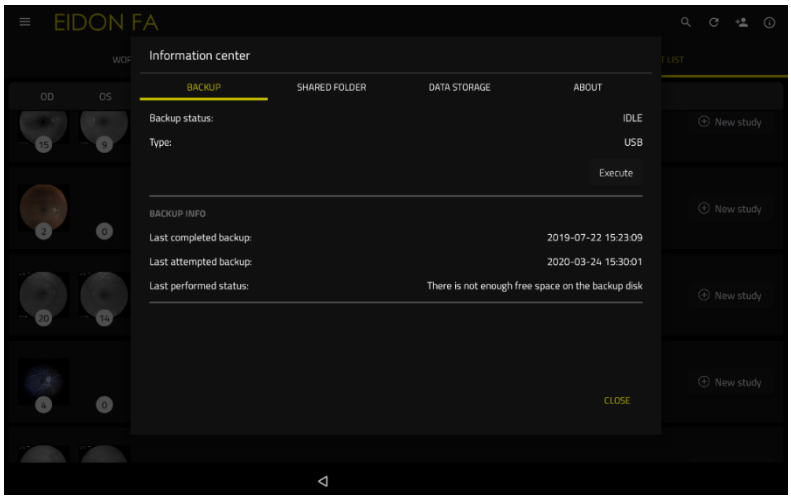


Fig. 22 – Device Information Center – Backup status

8.1.2 Shared folder status

From the **Shared Folder** tab, it is possible to monitor the progression and see the error messages of the Shared Folder processes. For more information on Shared Folder see par. 9.6. See par. 16 for information about possible error conditions during the export process.

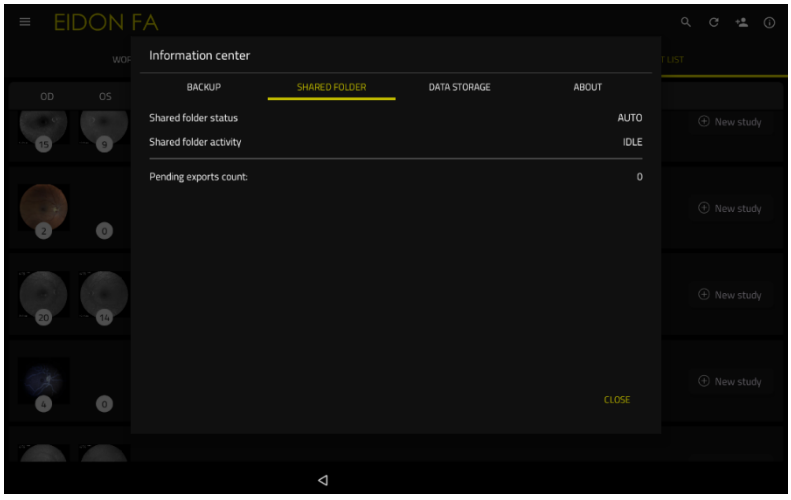


Fig. 23 – Device Information Center – Shared folder status

8.1.3 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*).

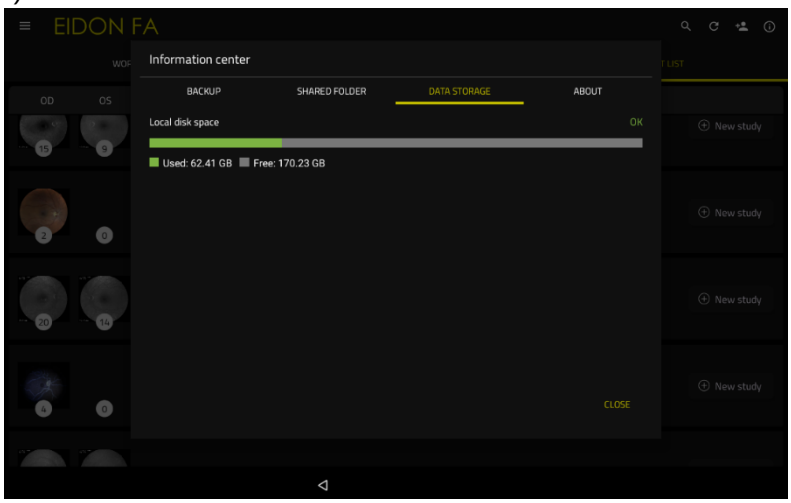


Fig. 24 – Device Information Center – Data Storage status

8.1.4 About tab

The **About** tab contains the software release version. Additional information appears after pressing the *Details* button.

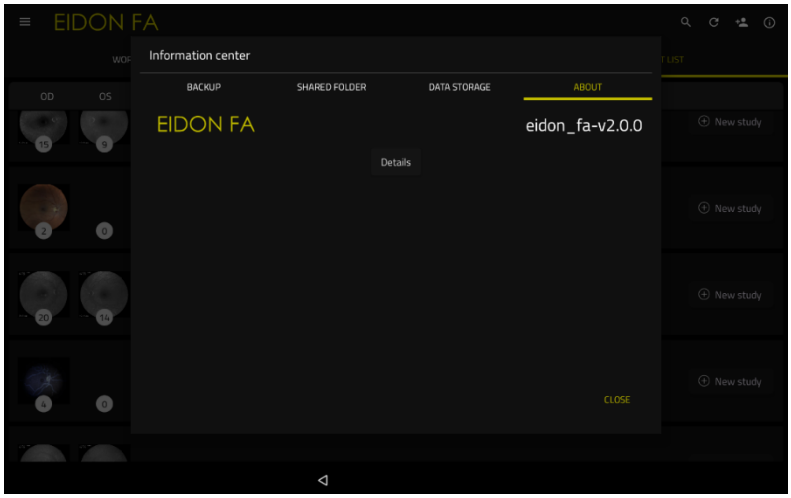


Fig. 25 – Device Information Center – About tab

8.2 Adding a new patient

To create a record for a new patient, click on  and the **Patient Editing** screen will open (see Fig. 26). Type the First Name and Surname (mandatory fields), optionally select the date of birth, gender, patient notes and a unique code of your choice to identify the patient (patient ID). Then click **Save** button to save or **Cancel** button to abort. When the end-user 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.

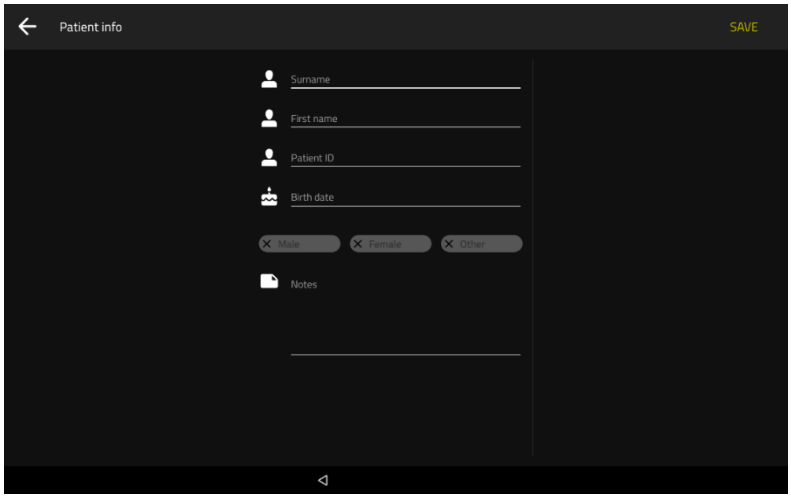


Fig. 26 – Patient editing screen

8.3 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.

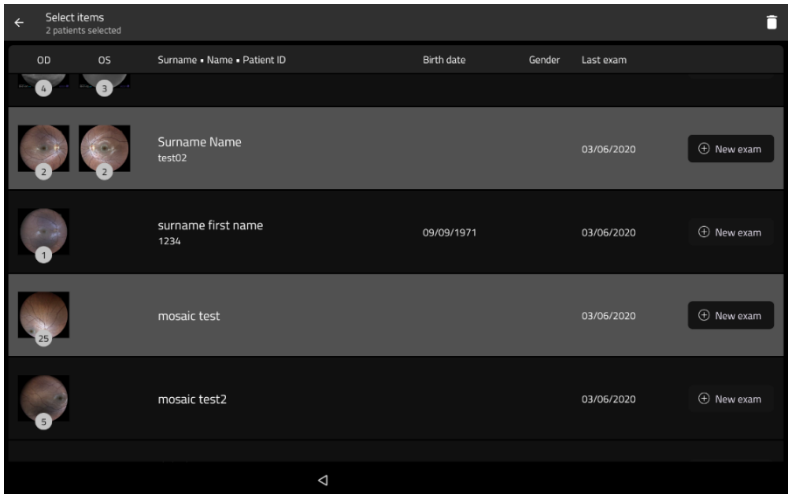


Fig. 27 – Multi selection for patient deleting.

8.4 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: the **Patient list** will only show patients whose name contains the typed letters.

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

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. 28) and provides information on the selected patient, whose name is shown at the top-left corner of the screen. See par. 9 for additional details about this screen.

Click on **New Exam** button to start a new exam for the selected patient.

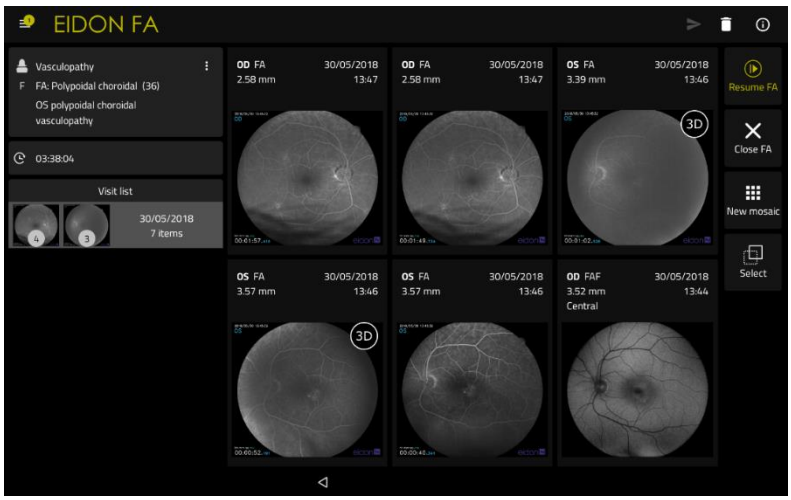


Fig. 28 – Patient Record screen

8.6 Setting up exam parameters

When the New Exam button is clicked, the **New Exam** screen opens (see Fig. 29). This screen allows review and modification of the exam parameters and triggers the acquisition process.

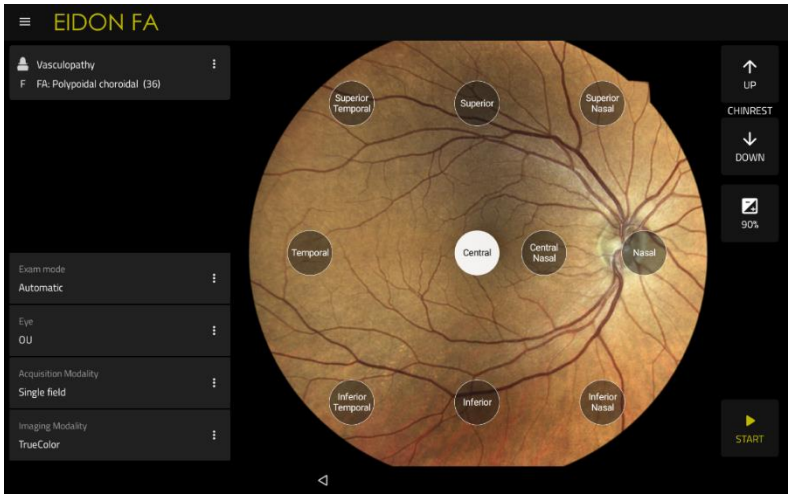
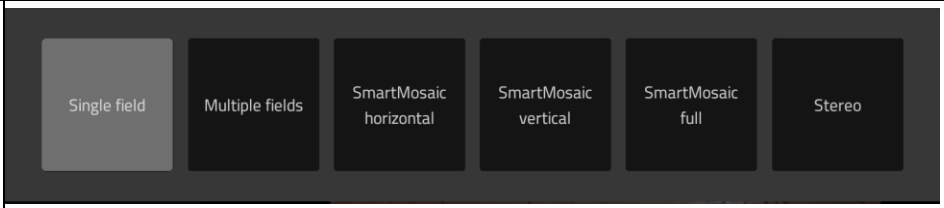
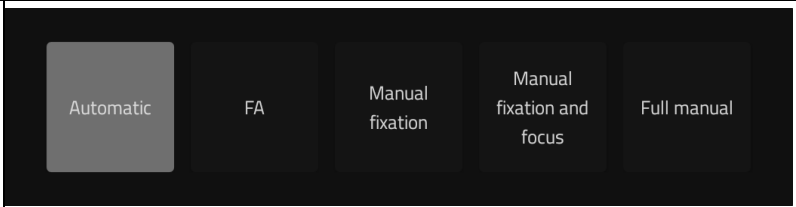
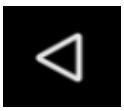


Fig. 29 – New Exam screen

The following functions/commands are available:

Function	Command	Description
Select Automatic / Manual modes		Toggle between automatic, manual or FA mode. **Default: Auto**
Select eye(s) to be captured		Select the right eye (OD), left eye (OS), or both (OU). **Default: OU**
Select field(s) to be captured		See par. 8.7 for additional information. **Default: single field, central**
Select imaging modality in auto mode		Options include: (IR), color (COLOR), IR&COLOR, autofluorescence (FAF) images, fluorescein angiography (FA), COLOR & AF and IR & COLOR & AF. **Default: IR & COLOR**
Select the Exam mode	 Select the single field, multiple fields or SmartMosaic modes and Stereo from the exam mode menu.	
Select Acquisition modalities	 Five Acquisition modalities are available. See par. 8.12 for additional information	

Exposure value		Adjust the exposure value (**the default exposure value is set in the configurator,** see par 8.10)
Raise chin rest		Adjust the height of the chin rest
Lower chin rest		
Start acquisition process		Start the acquisition process
Exit		Go back to the **Patient Record** screen and abort the exam

Hints to maximize effectiveness of the exam and the quality of the resulting images:

1. pre-adjust the height of the chinrest so that the patient's eye is aligned to the eye mark on the metal frame;
2. during the whole process the patient should (try to) steadily look at the fixation target: pre-instruct the patient to do so and inform her/him where the fixation target will appear, especially when it is not central to capture peripheral fields;
3. blinking during the auto-focus process may result in a poorly focused image: ask the patient to not blink while the system is auto-focusing.

8.7 Selecting the field(s) to be captured

The following options are available for this setting:

- Single field: allows, in combination with the field selectors on the right of the screen, to select which field (1) will be captured. See below for available options.
- **Multiple field:** allows, in combination with the field selectors, to select which fields (2 to 7) will be captured. See below for available options.
- **Smart Mosaic:** allows, in combination with the **Smart mosaic mode** button, to select the **smart mosaic mode**.
- **Stereo:** allows to acquire a stereo pair of the nasal field and produce a stereoscopic view of the optic disc.

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;

Use of the manual mode will disable field selection and display of field information in thumbnails.

8.8 Smart mosaic

EIDON Family Software allows to merge multiple, partially overlapping, fields of the same retina, to obtain a wider image. The new retinal image generated is called **mosaic**.
To perform a fully-automated wide field capture (i.e. automatic multi-field acquisition and image composition), select the **Smart mosaic** mode: EIDON Family Software will acquire 3 or 5 pre-defined different fields (color retinal images) like in multi-field mode, and then it will create the mosaic.

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. The mosaic function can also be applied to infrared images, to AF images and to FA images (for more information about mosaic, see par. 9.4).

The end-user 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.

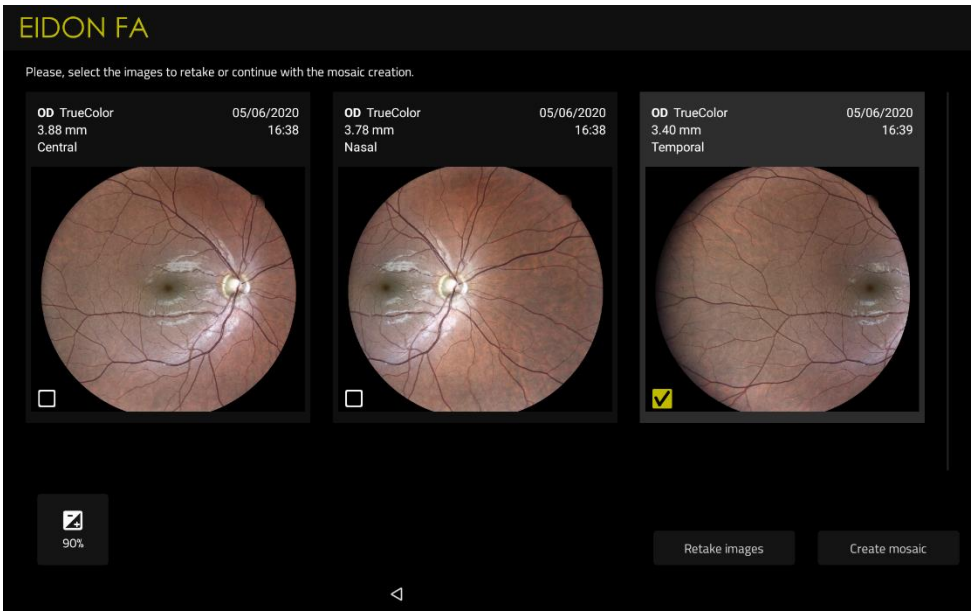


Fig. 30 – Image retake after horizontal smart mosaic acquisition

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 **Continue** button is pressed, the EIDON Family Software will generate a retinal mosaic image.

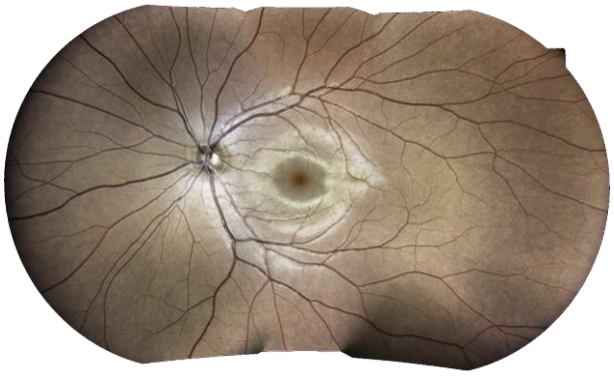


Fig. 31 – Example of horizontal wide-field

Fig. 32 – Example of vertical wide-field

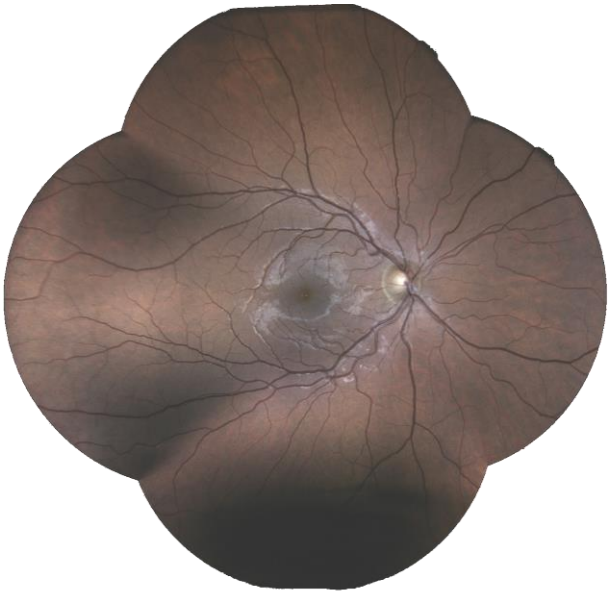


Fig. 33 – Example of full smart mosaic

8.9 Stereo

Stereo functionality in automatic mode is available for nasal fixation target and central fixation to acquire stereo images of ONH and Macula respectively. If a **Stereo exam** is selected, two slightly offset images of the central-nasal field will be captured with automatic alignment and focus. A delay between the shots is applied in order to let the pupil recover. To review stereo retinal images, please use specific prismatic stereoscopic goggles[9], such as those provided with EIDON Family Devices. The retake function for stereo retinal images is disabled.

8.10 Exposure Value

The exposure is the total amount of light reaching the retina of the patient. The exposure is automatically adjusted by EIDON Family Software every time the retinal images are acquired, to have images with the right brightness value.

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 par. 12.5 to modify the default exposure value.

[9] [9] It is provided with the device. For a list of all components included with EIDON family device, see Content List in the device package

8.11 Automatic mode

In this 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 infrared and/or color image and/or AF image of the first selected field;
e. repeat steps b. and d. for any additional fields or move to next eye and repeat a. through e.

The following information is available on screen during the automatic exam process (seeFig. 34):

1. Patient name;
2. Field currently being captured;
3. Eye currently being captured;
4. Current pupil size;
5. Current step of the exam process;
6. Images of the examined eye as seen by both pupil cameras.

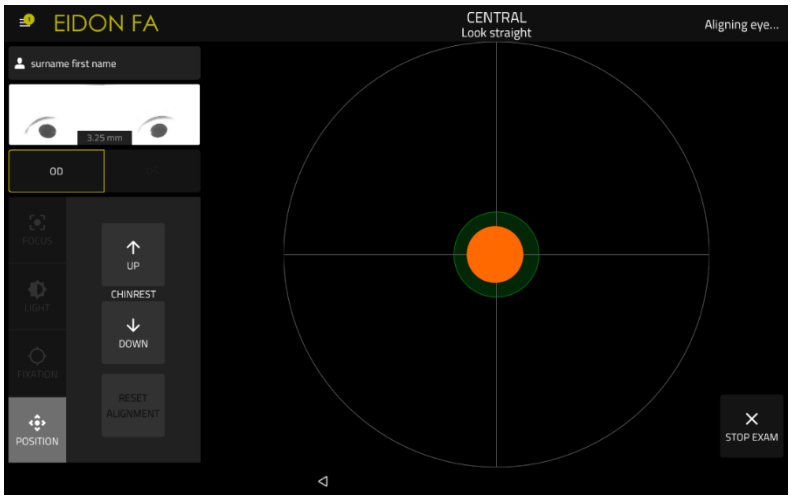


Fig. 34 – Exam screen in auto mode during auto-alignment

The following commands are available during the automatic exam process:

Function	Command	Description
Raise chin rest		Adjust the height of the chin rest
Lower chin rest		
Stop the process		Stop the acquisition process and go back to the exam parameter window

HINTS TO END-USER FOR BEST USE OF THE AUTOMATIC MODE

- Patient should sit in a comfortable position, with the headrest and chin in firm contact with the corresponding rests. Patient's head should be vertical and not tilted. Chin rest should be positioned so that eye is aligned to the mark.
- The field information on screen can be used to help the patient locate the fixation target (see Table 1).
- Information about which step is currently in progress can be used to prevent blinking during the auto-focusing step.
- Pupils smaller than the minimum required (2.5 mm) may trouble the auto-alignment and auto-focusing processes.
- Several hints may be presented on screen by the device to help the end-user correct a patient's position (see Table 2).
- There is a delay between capture of the infrared, color image or, in EIDON AF devices, AF images, due to a focus adjustment between the two shots: patient should not move, nor blink during such time interval.

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

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

If the auto alignment fails (e.g., for eye not wide open), the EIDON Family Software will give the option to switch to full manual mode.

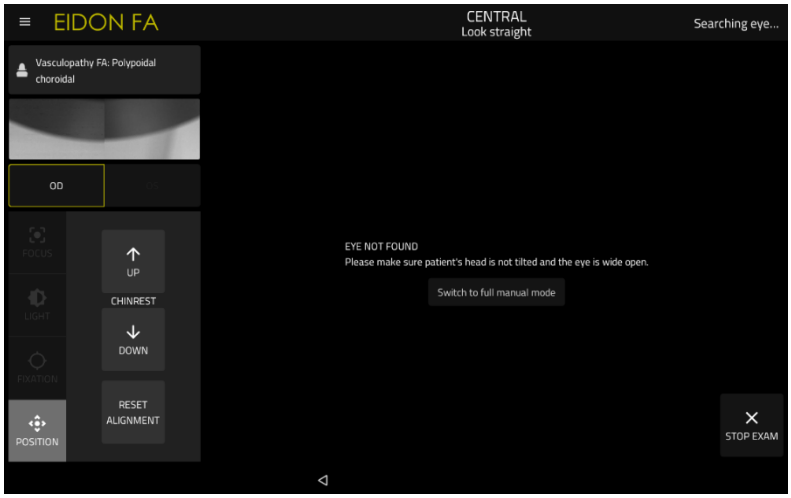


Fig. 35 – Eye not found during alignment phase in automatic mode exam

8.12 Manual mode

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

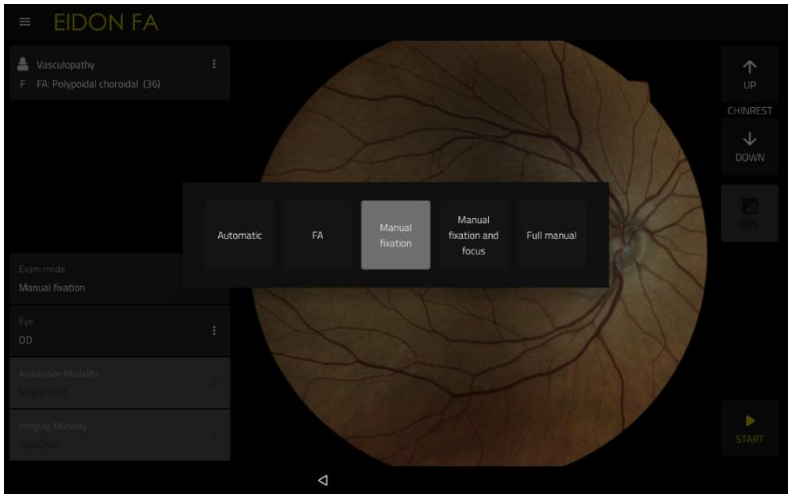


Fig. 36 – Manual mode options (FA option available only in the EIDON FA)

In each manual mode option, the end-user can adjust the chinrest by acting on the  and  buttons.

8.12.1 Manual fixation

This option can be used to frame regions of the retina other than the fields described at par. 8.7 and also when the EIDON External fixation target light is used.

When manual placement of the fixation target is selected, the EIDON Family Software will stop after completing steps a. and b. described at par. 8.11 and display the live infrared image of the retina and the fixation target (the white, semi-transparent circle in Fig. 37), waiting for end-user's intervention.
Move the target by dragging it on the image. Different areas of the retina are framed depending on the fixation target position[10]: moving the target in a certain direction should result in shifting the framed retina in the same direction. Refers to the position of the green dot on the display, to help the patient with correct advice about where to look to find fixation target.

Once the fixation target position is set, click on the camera icon labeled **IR** to capture an infrared image, on the camera icon labeled **AF** to capture an autofluorescence image or on the lower camera icon to capture a color image. Repeat to capture additional images.

[10] *Provided the patient is able to fixate*

Click on the 

icon to stop the exam at any time. Images are saved on the internal memory of the EIDON Family device (and not on EIDON Custom Control Interface) as soon as captured.
Is it always possible to switch from the above-described manual fixation management internal to the following options:

- **Internal:** fixation appears superimposed to the retina showing all standard fixation targets;
- **External**: it turns off the internal fixation target to avoid the patient confusion while looking at the EIDON Family external fixation target.

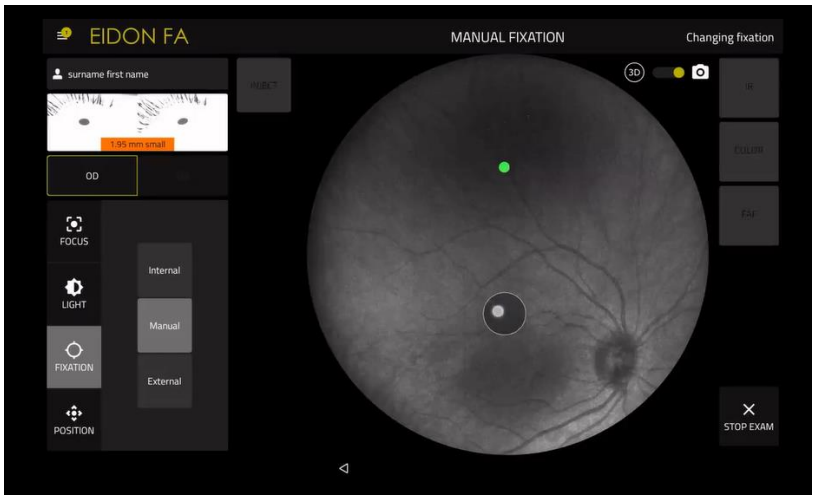
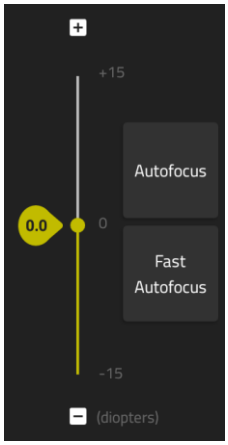


Fig. 37 – Exam screen in manual mode with displaced fixation target

8.12.2 Manual Fixation and Focus

This option can be used in case the auto-focusing fails for a certain patient or when certain specific regions of the retina need to be focused. When this option is selected, EIDON Family Software will stop after completing step a described at par. 8.11 and display a live infrared image of the retina and the fixation target, waiting for end-user's intervention.

Available functions/commands include:

Function	Command	Description
Focus shift		Shifts focus by +0.5D (>) or -0.5D (<)
Fast focus shift		Shifts focus by +3D (≫) or -3D (≪)
Autofocus		Runs auto-focusing process
Fast Autofocus		Runs partial auto-focusing process (±2D around current focusing position)

8.12.3 Full Manual mode

This option can be used in case auto-alignment fails for a certain patient. This option requires use of the 3D Joystick provided with the EIDON Family devices.

It is recommended for the end-user to carefully read this section to be informed and trained before the use of EIDON Family devices in a full manual mode.

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 stop, waiting for end-user's intervention (see Fig. 40). First bring the retinal blob to the center, using the 3D Joystick for alignment in the vertical and horizontal directions as explained in Fig. 39.

Once the retina is centered, rotate the 3D Joystick clockwise (without shifting) to move towards the patient and "zoom in" until the retina is fully framed and fills the purple circle but no corneal reflections appear. 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 (if needed) and capturing images.

Fig. 38 – 3D Joystick

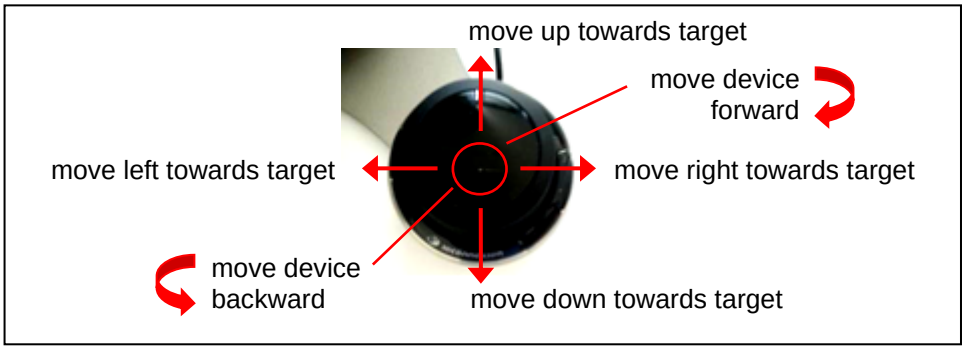


Fig. 39 – 3D Joystick, top view

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.

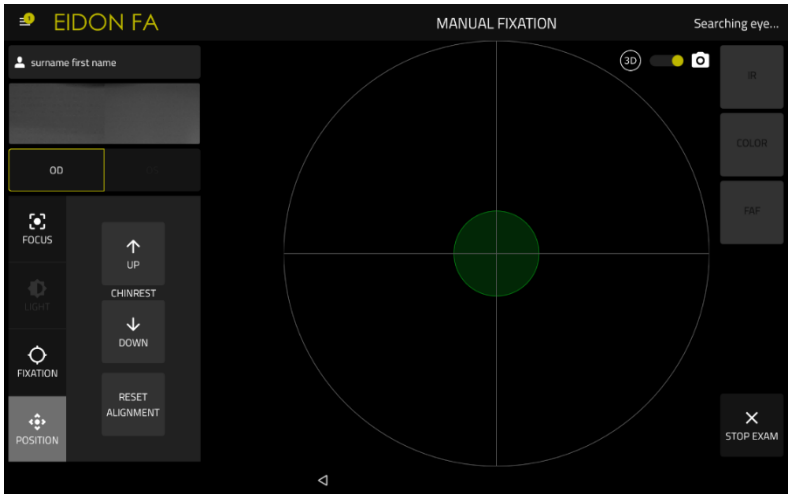


Fig. 40 – Exam screen in manual mode when approaching eye

8.13 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.

It is recommended for the end-user to carefully read this section to be informed and trained before the use of EIDON Family devices in a full manual mode

> 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 this user manual 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 this user manual and of the products providing specific about injection of fluorescein sodium 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 on EIDON FA.

8.13.1 Patient preparation

In addition to what has been described at par. 7, 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.

> 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.

8.13.2 Pre-injection phase

To start a new FA session, select the **FA option** in the new exam screen (see Fig. 41) and select the target eye.

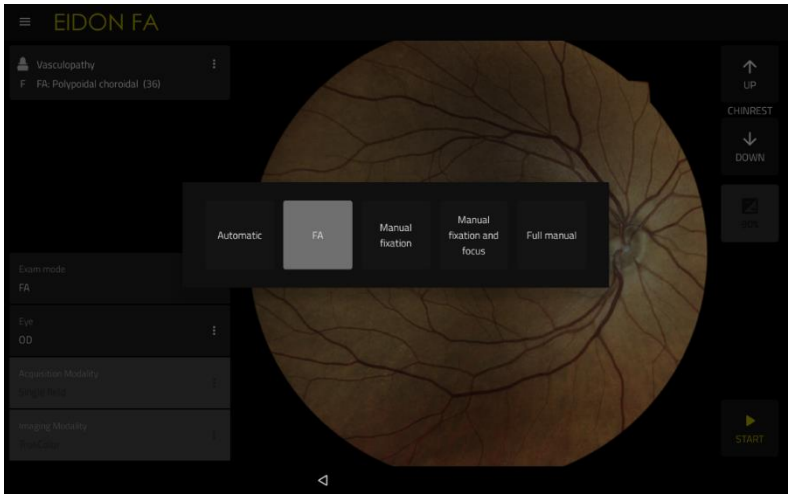


Fig. 41 – FA modality, selection in the new exam screen

Click on the right arrow to start the exam: EIDON Family Software will enter the pre-injection phase (see Fig. 42).

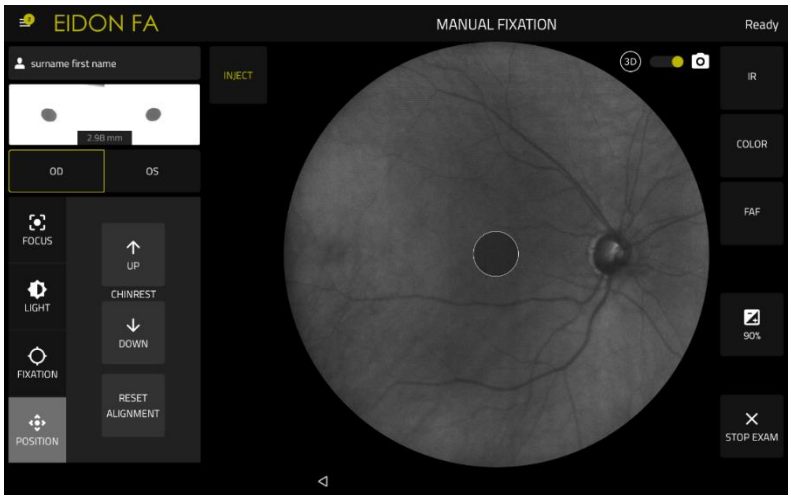
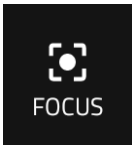
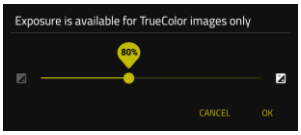
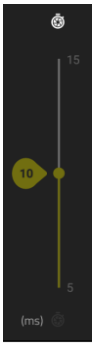


Fig. 42 – FA modality, pre-injection phase

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 functions / commands are available at this time:

Function	Command	Description
Focusing		Focusing modification and information: in addition to what described at 8.12.2 Manual Fixation and Focus, this panel contains also information on the current focus position (Current) and the stored focusing position for right (OD) and left eye (OS): the stored focus position is taken from the last acquired retinal image of the day for the patient selected (“N/A” in case no retinal image were acquired).
Switch eye		Align to the other eye, then autofocus. If the patient has no focusing information for the new eye, the device performs autofocus.
Start injection timer		**Start the timer and activate blue light for FA video recording** (post-injection phase)
Exposure value		Adjust the exposure value (The default exposure value is set in the configurator, see par 12.5.)
Flash duration		Reduce flash duration (default changes in the different phases)
Raise chin rest		Adjust the height of the chin rest

Function	Command	Description
Lower chin rest		
Reset alignment		**Reset Alignment** button is intended to reset alignment when device can't find the eye properly. This button is useful in extreme cases, during very long exams (especially FA), when the patient is tired and moves away from the right position (forehead detached from the headrest). In these cases, if message "eye not found" or "pupils not reachable" appears: • Press **Reset Alignment** button • The device automatically returns to '**Search eye position' screen** • Put the patient's head in the proper position • The device automatically re-aligns properly to the eye.
Move fixation		Slide the inner circle to move the internal fixation target / change the framed field
Capture IR		Capture single or stereo IR-reflectance images
Capture color		Capture single or stereo TrueColor images.
Capture Autofluorescence		Capture single or stereo autofluorescence images
Interrupt the FA session		Interrupt the FA session and go back to the patient screen: the FA session timer remains in a "not injected yet" (active) state. 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 eyes position and focus. During the FA session, these position and focus are taken as a starting point for alignment and focusing operations, to speed up the switching between eyes. For more information see 8.13.3 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.

8.13.3 Post-injection phase

The time elapsed since the injection is prominently displayed at the top of the screen (see Fig. 43).

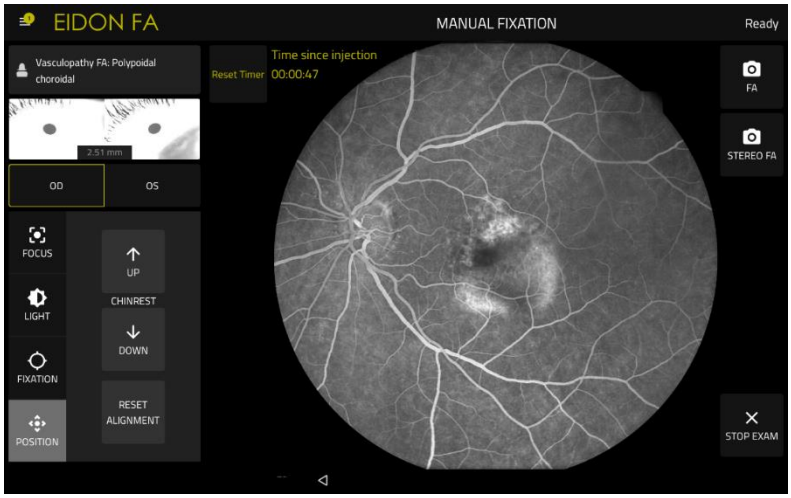
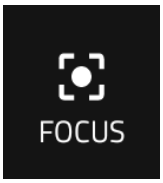
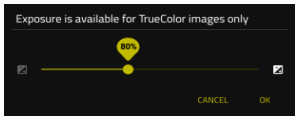
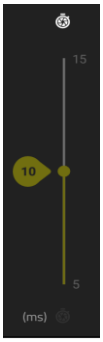
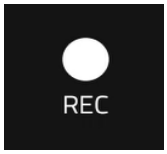


Fig. 43 – FA mode, post-injection phase

The following functions / commands are available at this time:

Function	Command	Description
Focusing		Focusing modification and information: in addition to what described in the 8.12.2 Manual Fixation and *Focus* chapter, this panel contains also information on the current focus position (**Current**) and the stored focusing position for right ("**OD**") and left eye ("**OS**"): the stored focus position is taken from the last acquired retinal image of the day for the patient selected ("**N/A**" if no retinal image acquired).
Switch eye		Align to the other eye, then autofocus. If the patient has not any focus position stored for the new eye, the device performs an autofocus.
Switch live illumination		Toggle among: • live infrared imaging (Live **IR button**), which employs infrared light and is more comfortable for the patient but switches focus to deeper structures; • live FA imaging (**default**), which employs a pulsed blue flash; • IR for FA (**Live IR for FA** button), which employs infrared illumination but maintains focus on the vascular plexus (this may result in a blurred IR image), so that no delay is experienced when capturing FA images
Reset Timer		Reset timer and revert to pre-injection phase

Function	Command	Description
Exposure value		Adjust the exposure value (the default exposure value is set in the configurator, see par 12.5).
Flash duration		Reduce flash duration
Raise chin rest		Adjust the height of the chin rest
Lower chin rest		
Move fixation		Slide the inner circle to move the internal fixation target / change the framed field
Start video acquisition		Start FA video capture[11]. Recording stops automatically 35 seconds later. The actual start of the video recording precedes by 5 seconds the click of this button
Stop video acquisition		Stops FA video capture before its automatic termination
Interrupt FA session		Interrupt FA session (without resetting timer): this allows to resume session later (active session)
Capture FA retinal image		Manually trigger single FA image acquisition or FA stereo pair[12] (only available when no FA video is being recorded)
Capture AF retinal image		Manually trigger single AF image acquisition or AF stereo pair[5] (only available in live infrared)
Capture IR retinal image		Manually trigger single IR image acquisition or IR stereo pair[5] (only available in live infrared)

[11] Image resolution 1840 x 1644 @ 5 frames per second
[12] Image resolution 3680 x 3288

Function	Command	Description
Capture Color retinal image		Manually trigger single color image acquisition or color stereo pair[5] (only available in live infrared)

8.13.4 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. 21), identify and select the patient for whom you want to resume the FA session and click on **Resume FA session** button (see Fig. 44).

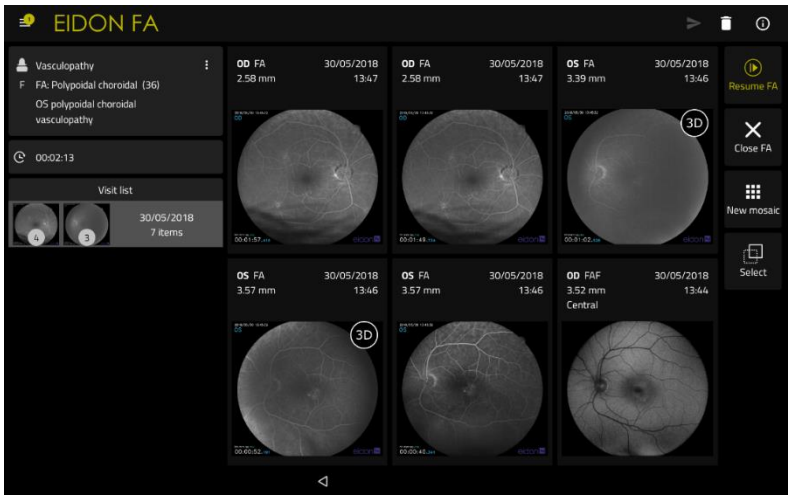


Fig. 44 – Patient Record screen for patient with an active FA session

8.13.5 Active FA sessions list

The **Patient List** screen (see Fig. 21) includes a column with 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 when in the patients list or patient details pages. The panel can also be opened by clicking the **"EIDON FA**" logo button 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.

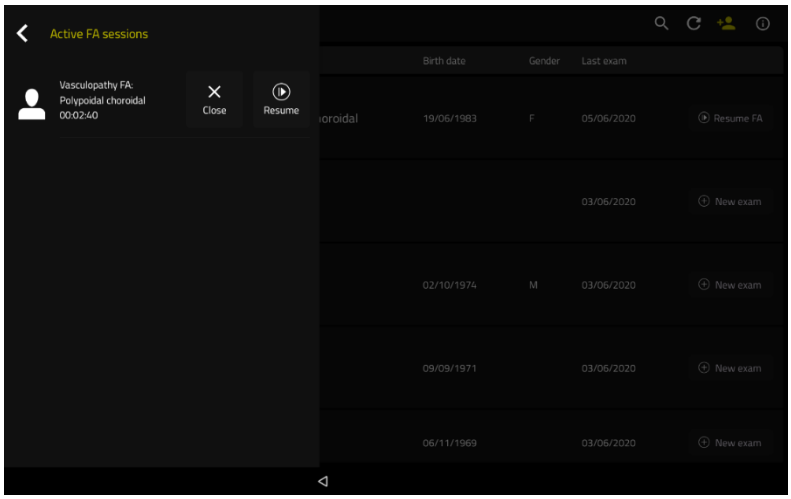


Fig. 45 – FA session bar

8.13.6 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.

8.14 Image retake

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

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 retaking, the software will ask to keep the old retinal image, replace it with the new one or keep both.

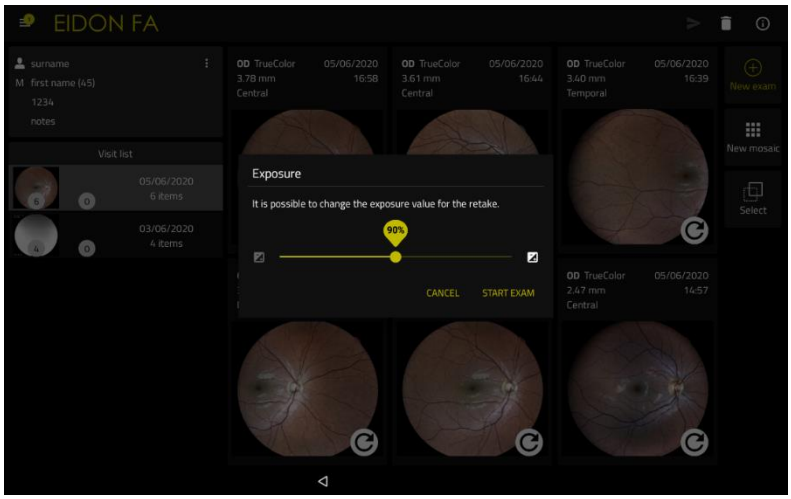


Fig. 46 – Image ready to be retaken

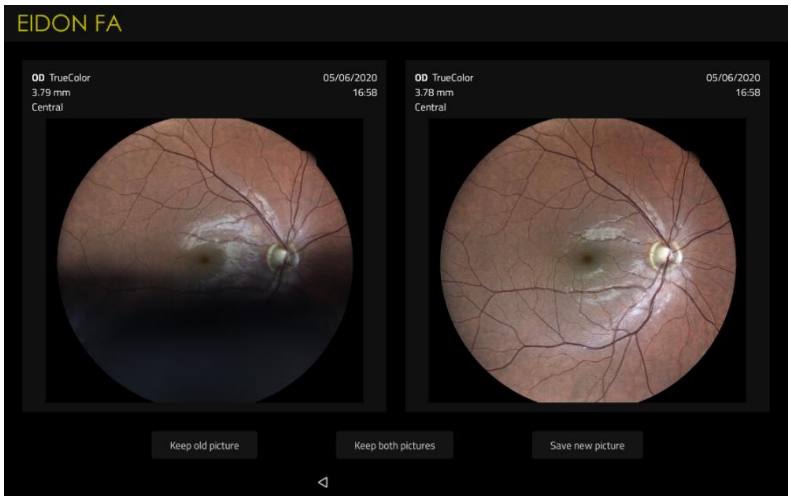


Fig. 47 – Image retaken choose which retinal image to keep

8.15 Ultra-Widefield Imaging modality

EIDON UWF Module[13] is compatibles 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[14].

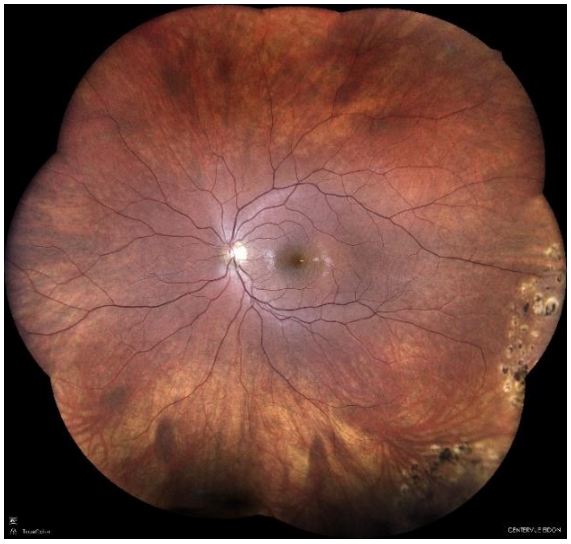


Fig. 48 – Color retinal image with Ultra-Widefield Modality

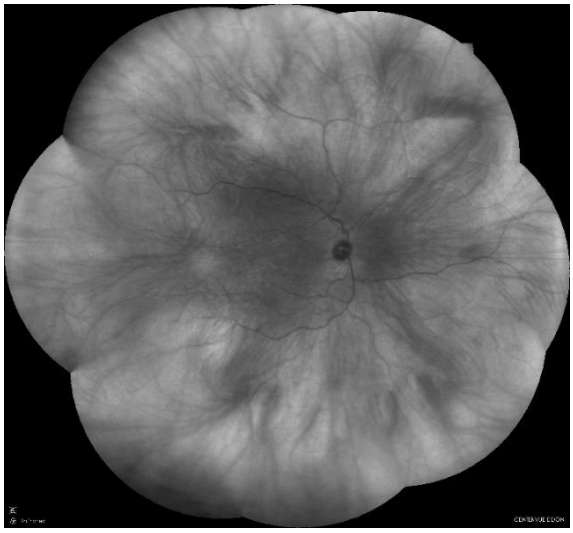


Fig. 49 – IR retinal image with Ultra-Widefield Modality

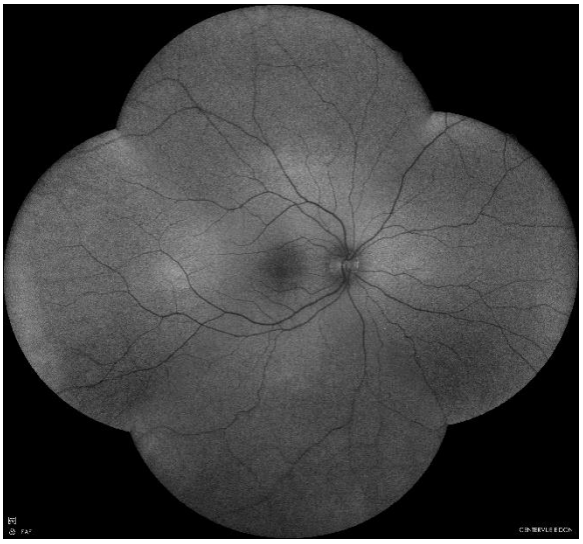


Fig. 50 – Autofluorescence retinal image with Ultra-Widefield Modality

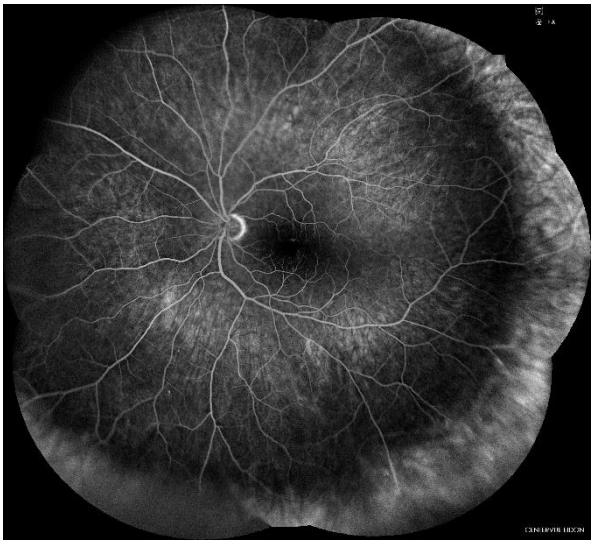


Fig. 51 – Fluorescence angiography retinal image with Ultra-Widefield Modality

Please refers to the EIDON UWF Module User Manual for:

- Instruction for preparing the patient for exam with EIDON UWF Module;
- Instruction for first installation and for mounting and removing the EIDON Ultra-Widefield Lens[15];
- Warning and precaution information including information about the Optical radiation hazard
- Other information (disposal, cleaning, labelling, technical specifications…).

[13] It is an optional accessory to EIDON Family devices: please, refers to your local distributor for further details and information about this product.

[14] Please, refer to EIDON UWF Manual User Manual for further details and information (technical specification included).

[15] The key functional element of the EIDON UWF Module is EIDON Ultra-Widefield Lens (EIDON UWFL). It is compatible with all the EIDON Family devices' imaging modalities (color, infrared, autofluorescence and fluorescein angiography imaging).

On EIDON Custom User Control Interface, press **New Exam** and chose the desired imaging mode with the button **UWF ON // UWF OFF** (see Fig. 52).

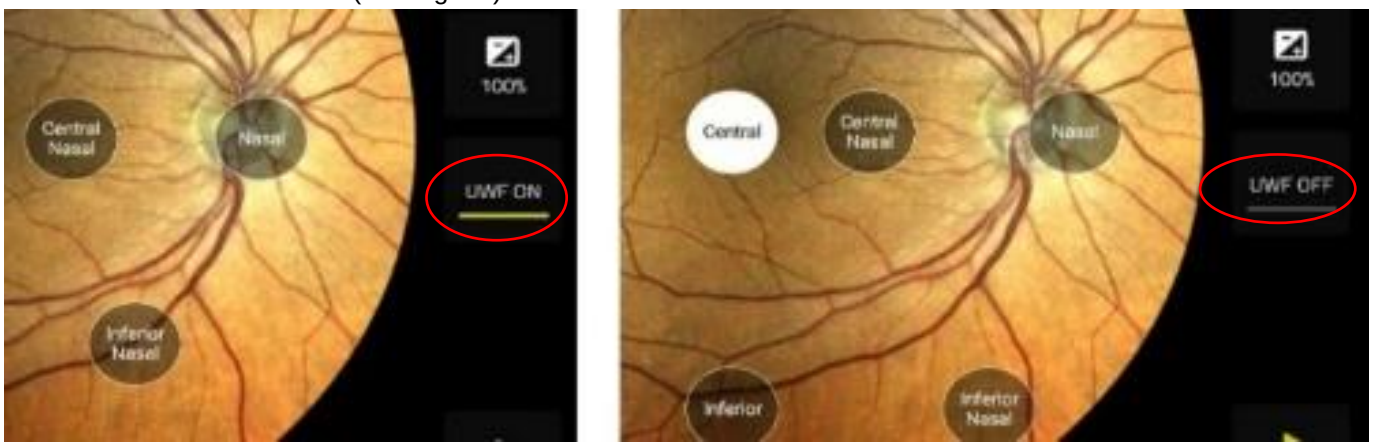


Fig. 52 – UWF ON and UWF OFF button

To perform a Ultra-Widefield (UWF) acquisition, press the button **UWF ON:** exam will progress as usual. To return to standard acquisition modality, remove the EIDON UWFL and press the button **UFW OFF**. During acquisition, a tag (see Fig. 53) is always visible to inform the end-user on the current selected imaging mode.

Fig. 53 – EIDON UWF Tag (example from EIDON FA model)

EIDON Family devices preserve after stand-by or shutdown the last chosen modality (**UWF ON** or **UWF OFF Buttons**, see Fig. 52): verify that the current acquisition modality is the desired one, by checking the **UWF Tag** on the top of the screen (see Fig. 53).

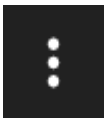
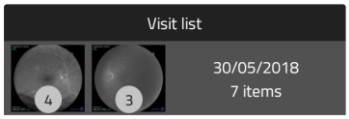
Review of retinal images acquired with EIDON UWF Module is made as per standard images review used on EIDON Family devices without the EIDON UWF Module installed: please, refers to section 9 for further details and information.

There are no special ad/or additional settings related EIDON UWF than the EIDON Family devices' ones: please, refers to section 12.

9. REVIEWING IMAGES

The **Patient Record** screen (see Fig. 28) presents all patients' related information and a thumbnail view of all retinal images captured at any selected date.

The following functions / commands are available:

Function	Command	Description
edit patient data		Used to add or modify a patient's name, birth date, gender and code
delete patient record		Used to permanently delete all data pertaining to the current patient. To delete individual retinal images, select a thumbnail by pressing and holding on it, click on other thumbnails (if requested), then press the delete button
Status		Shows information on the status of the device (par. 8.1)
date selector		Used to open the exam images acquired in the selected date
start new exam		Used to start a new exam
Resume active FA session		Used to resume an active FA session
mosaic		Used to generate a mosaic of multiple fields pertaining to the same eye and captured on the same date
export patient images to USB		Used to export all the patient images to USB, as jpg files and videos as mp4 files to USB
export patient printouts to USB		Press "create PDF" option This will open the report configuration panel, where you can configure the report and export it with dedicated icon
exit		Used to return to the Home screen

Each thumbnail displays the following information:

- the examined eye (**OD**/**OS**);
- field information. This information is not displayed when the manual mode is used, see also par. 8.12;
- time at which the image was acquired;
- the imaging modality **(IR**, **Color**, **FAF** or **FA**)
- the **3D logo**, if the image has been acquired in stereo mode;
- the videocamera icon, if the "image" is actually a fluorescein angiography video;
- the **retake** logo, if it is possible to retake the image.

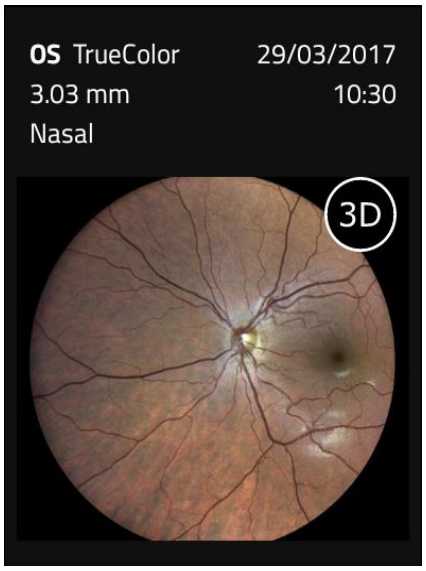


Fig. 54 – Example of thumbnail with 3D logo

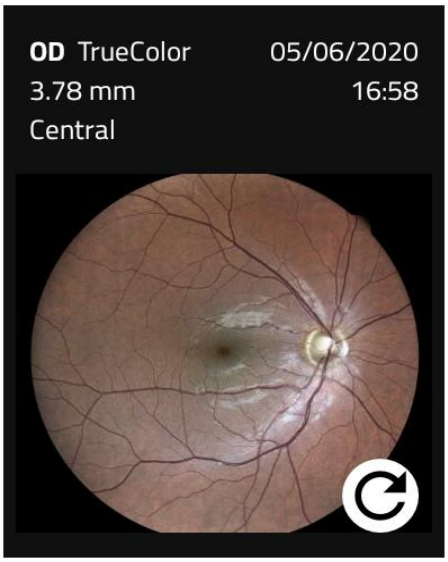


Fig. 55 – Example of thumbnail with retake logo

9.1 Single image review

To review any of the available images click on the corresponding thumbnail: this will open the **Exam review** screen (see Fig. 56 and Fig. 57).

EIDON Family Device acquires and stores TrueColor images. Nevertheless, every end-user can choose to modify the acquired retinal image according to his own preferences.

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

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. 56) 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 par. 9.7).

From the **Configurator** screen, it is possible to change the default settings for brightness, contrast, gamma and red enhancement filters: see the par. 12.5 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

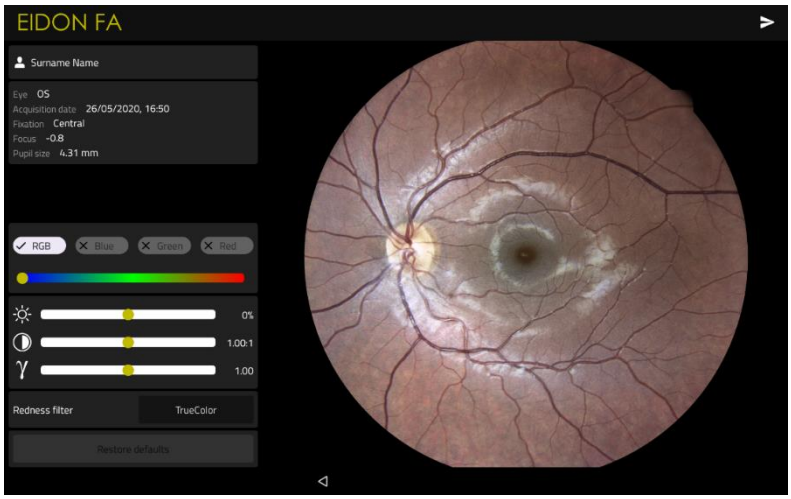


Fig. 56 – Exam review screen, color image

Fig. 57 – Exam review screen, FA image

The screen displays the following information:

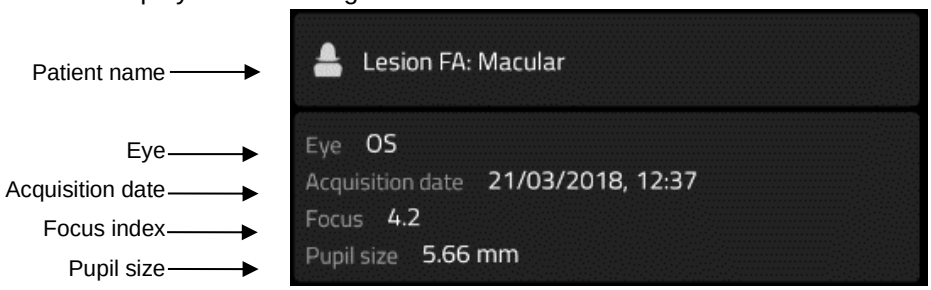
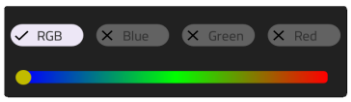
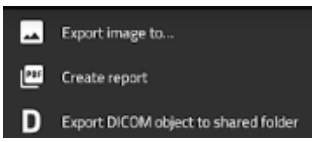
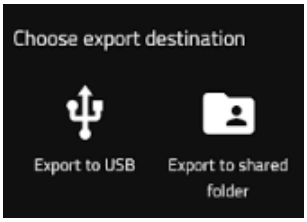
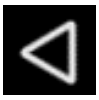


Fig. 58 – Retinal image information

The following functions / commands are available:

Function	Command	Description
Open full screen view, zoom, pan	Click on the retinal image	Used to open a full screen view, also allowing **zoom** and **pan**
Red, Green, Blue channels		Used to display individual color channels (for color images) and the IR image (if available). **The green channel provides the red-free image**
Image adjustments		Allows to adjust the image acquired. Every parameter will be stored internally but **the correction does not alter the original image** (see paragraph 9.1 and 12.5)

Function	Command	Description
Export icon		Allows to export your data. The button open the export menu where end-user can choose Data format
Export image type		Used to export an image: - to USB or shared folder. - as a report - to DICOM
Export image to		Allows to export data to USB or shared folder if configured. If USB is not plugged or shared folder is not configured, the menu shows the other option if available.
Open print preview		Used to open a print preview and/or print
3D viewer		Opens the 3D viewer. Only available for stereo view
Back		Used to return to the **Patient Record** screen

EIDON Family Software also allows to review and print two images at the same time. For more information on dual image review and printing, see par. 9.5.

9.2 3D Viewer

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

Fig. 59 – 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 window top right corner.

[16] It is provided with the device. For a list of all components included with EIDON family device, see Content List in the device package

9.3 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 (see Fig. 28). Click on the thumbnail to review the video (see Fig. 60).

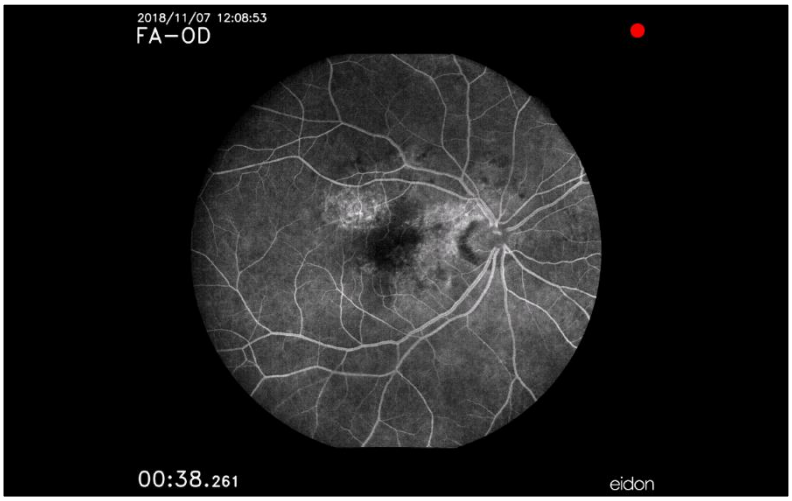
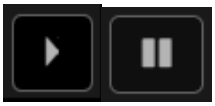


Fig. 60 – FA Video review screen

The following functions / commands are available:

Function	Command
Play (stop)	
Step forward or backward by 1 sec	

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

9.4 Mosaic

EIDON Family Software allows to merge multiple, partially overlapping, 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. 61 – Example of a 3-fields mosaic image generated by EIDON Family device

Clicking on the **Mosaic** button in the **Patient Record** screen (see Fig. 28), the **Field selection** screen opens (Fig. 62). Press on the **retinal images** to be composed into a mosaic; when all fields are selected, click on the **Create Mosaic** button.

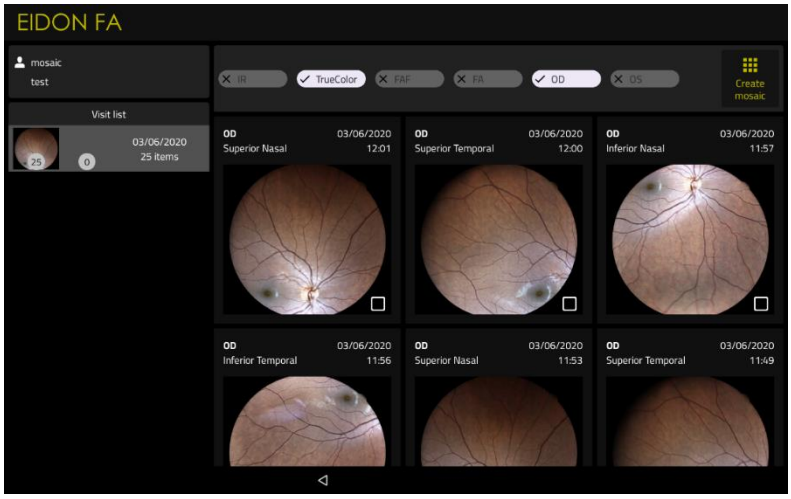


Fig. 62 – Field selection screen

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. To stop mosaic generation at any time, click on the **Cancel Mosaic** button at the bottom of the dialog box.

EIDON Family Device cannot be used while mosaic generation is in progress.

Click on the **Mosaic** tab in the **Patient Record** screen to review any existing retinal mosaic image, as done for single-field images. Click on the **Images** tab to go back to single-field image display.

Deleting a retinal image part of a mosaic is not allowed: remove the relevant mosaic and then you can delete the single field images.

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

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).

9.5 Dual image review and dual image printing

To review or print a pair of images[17] 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.

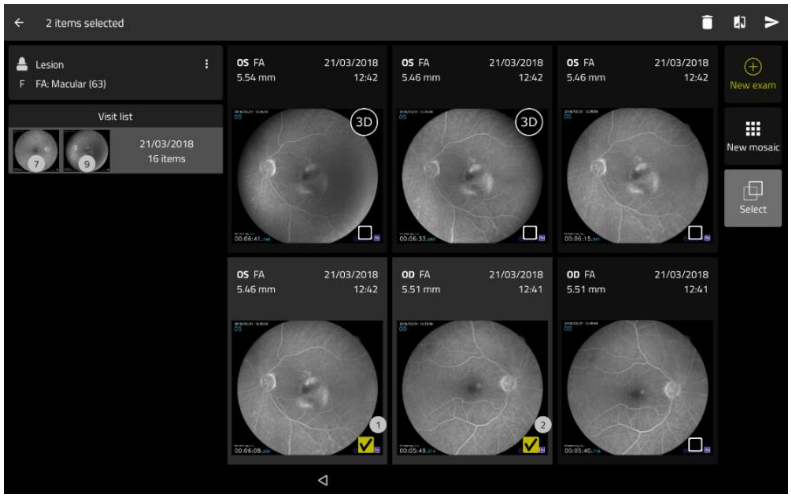


Fig. 63 – Dual image selection

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. 64).

To use image enhancement filters, click on the icon and swipe the slider corresponding to , , (see Fig. 65).

> 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. 64 – Dual image review screen, IR and Red-free images.

[17] *Color, infrared and, in AF devices, AF images, left and right eye, same or different dates, same or different fields, etc...*

Fig. 65 – Dual image review screen with image enhancements filters

To open a print preview and/or print to PDF two images, press  from the **dual image review** screen or from the patient screen: the two images will be saved in a landscape page, using the same page template as described in par. 11.2. The same PDF printout can be exported to USB pressing on the  button, or to the shared folder pressing on the  button.
To delete the selected images, click on the **recycle bin** button on the top right screen corner.

9.6 HypoAF Boost feature

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

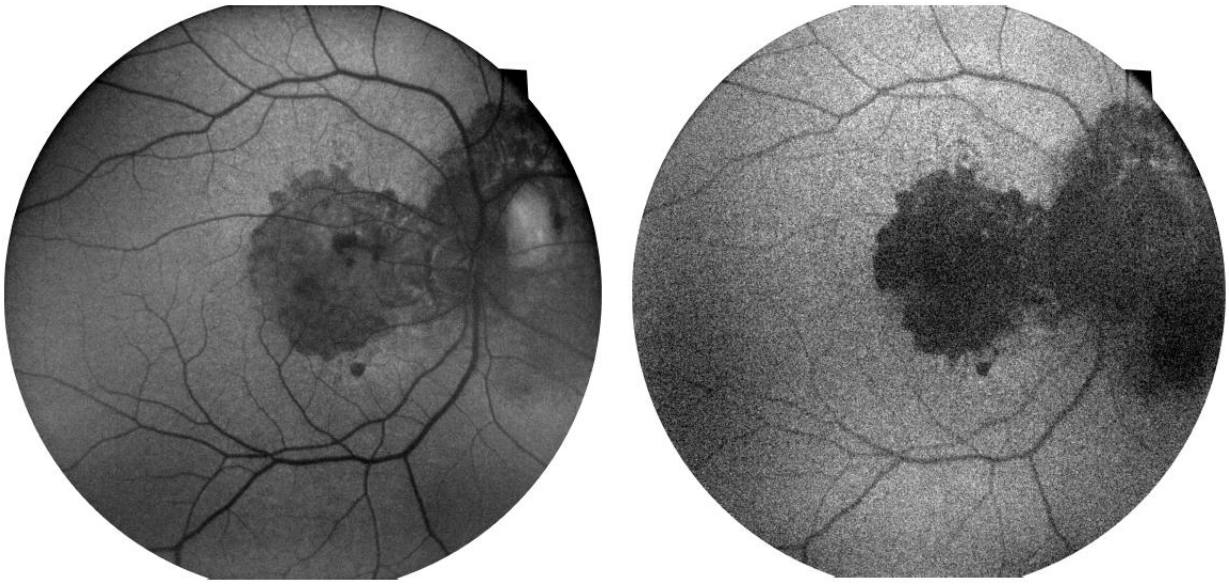


Fig. 66 – Example of AF retinal image before (left) and after (right) the application of HypoAF Boost

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.

9.7 Export functions

EIDON Family Software allows to export either a single image or all of the patient images and videos to three different locations:

- JPG images, videos and PDF printouts, to a USB support connected to the device through the back USB sockets
- JPG images and videos, to an internal folder called *Internal shared folder*
- JPG images, videos, PDF printouts and DICOM files, to a network folder called *External shared folder*

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 par. 8.1.
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 par. 12.10.

Exported images are identical to those stored in the device

EIDON Family Software allows to export to USB multiple objects at the same type: press and hold on the thumbnail of the first image or video until it is selected (highlighted border), then press on the other thumbnails to be exported; at the end, press on the export to USB icon.

9.8 Remote Viewer[18]

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 t needs to be connected to the local area network via **Ethernet** connection.

Remote viewer is available only for wired connections.

9.8.1 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 a password must be set: to set (or change) the Remote Viewer password see par. 12.1 and 12.6.

9.8.2 Using the Remote Viewer

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

- *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.

[18] *Starting from EIDON Family 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.*

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

- launch the Configurator application (see par.12.1);
- click on the “NETWORK” tab (see Fig. 89);
- click on the icon of the “Wired” network;
- retrieve the IP (e.g. 10.0.0.19);
- type http://IP in the browser address bar

Type the password and press **Login**: this will open the **Patient List** screen (see Fig. 67), which resembles the corresponding screen in the EIDON Family Device on-board software.

The Remote Viewer session is automatically closed after 20 minutes of inactivity (no browsing, no downloading of retinal images or PDF printouts).

From every remote viewer window, press F5 to update the data displayed.

9.8.3 Patient List screen

Right and left eye image thumbnails are shown in the first columns, followed by the patient full name and date of birth. The right-most column shows the date of the last exam.
Patients in the list are sorted by the date of their last exam.
Patient **Search** function is available in the top-left corner of the screen. From the top left side of the window, the **New Patient** button allows to add new patients to the device database.

Fig. 67 – Patient List in Remote Viewer

Click on the desired patient to enter the **Patient Record** screen (see Fig. 68), which resembles the corresponding screen in the Device on-board software. Click on **Logout** to exit the Remote Viewer.

9.8.4 Patient Record screen

This screen allows access to individual images as well as mosaic images.
Available commands and displayed information are the same as the homonymous screen in the EIDON Family Software. Click on **Dual Printout** to select two images to be printed in a single sheet (Fig. 69). Click on the desired image to enter the **Single Image review** screen (see Fig. 70).

Fig. 68 – Patient Record screen in Remote Viewer

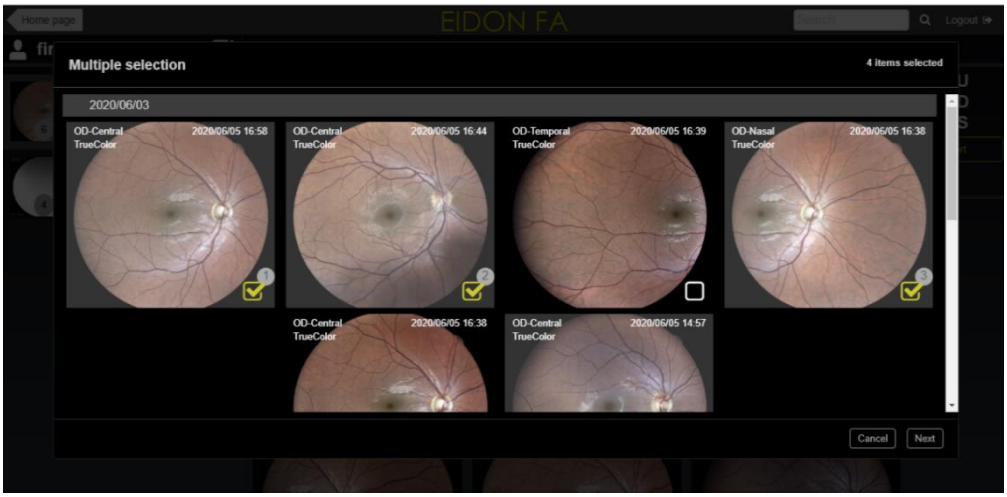


Fig. 69 – Dual printout image selection

9.8.5 Single Image review screen

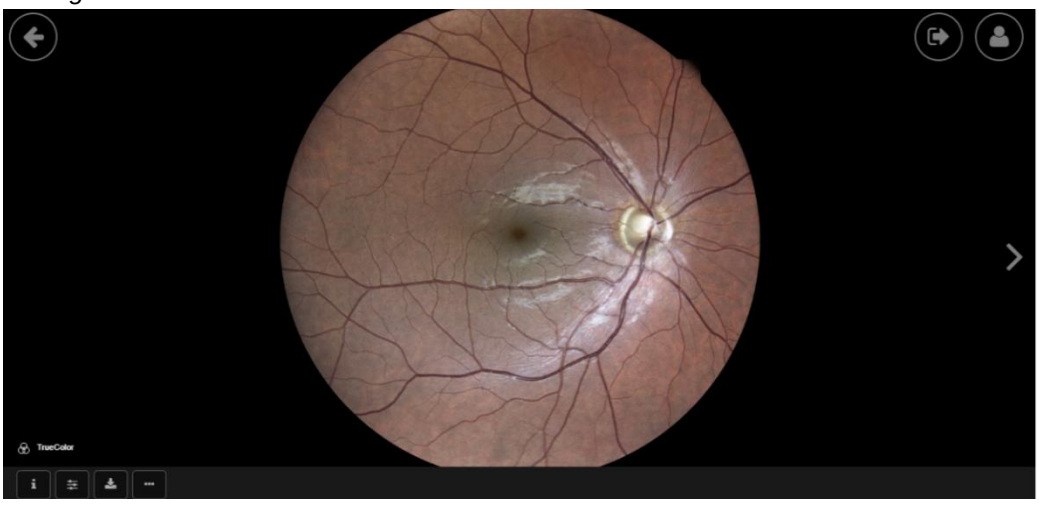


Fig. 70 – Single Image Review screen in Remote Viewer

The following functions are available in this screen:

Function	Command	Description
Previous / Next		Shows previous / next image
Back		Back to Patient Record Screen

Function	Command	Description
Logout		Logout from the Remote Viewer
Patient Info		Displays all patient related information (full name, date of birth, gender, code) and gives access to a thumbnail view of all the images available for this patient. It is also used to compare the currently displayed image with any other image in the list. Click on the corresponding **Compare** button: this will open the **Dual Image Review** screen (see Fig. 74).
Exam Info		Displays all exam related information (eye, date and time of capture, type of exam, type of image, pupil size, field, exposure, focus)
Image Filters		Provides access to the filters (see Fig. 72): - Gamma adjustment - Only for color images: Red, green (i.e. red-free), blue filters - Only for AF images: HypoAF Boost (more information on par. 9.6)
Download		Allows to save original image (jpg), report with original image (pdf), processed image (jpg), report with processed image (pdf) on local memory (see Fig. 72) or dual printout (a new window opens when selecting dual printout: see Fig. 73).
Stereo Mode		Provides access to the **stereo** mode window (available only for images part of stereo pairs)
Additional Tools		Provides access to additional tools like **flickering** and **cup-to-disc evaluation**
Zoom	Mouse wheel	Zooms in or out
Pan	Mouse left-click and drag	Moves the image around to frame different regions

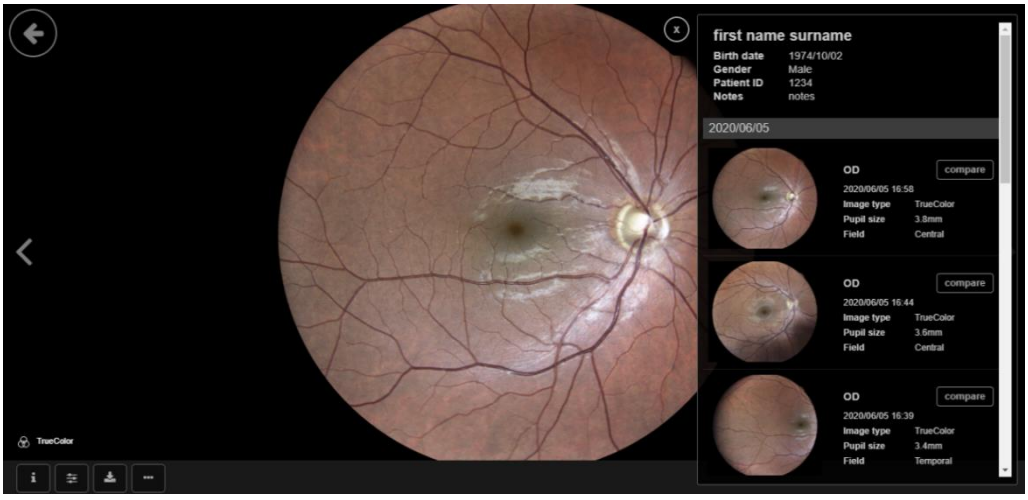


Fig. 71 – Patient Info window

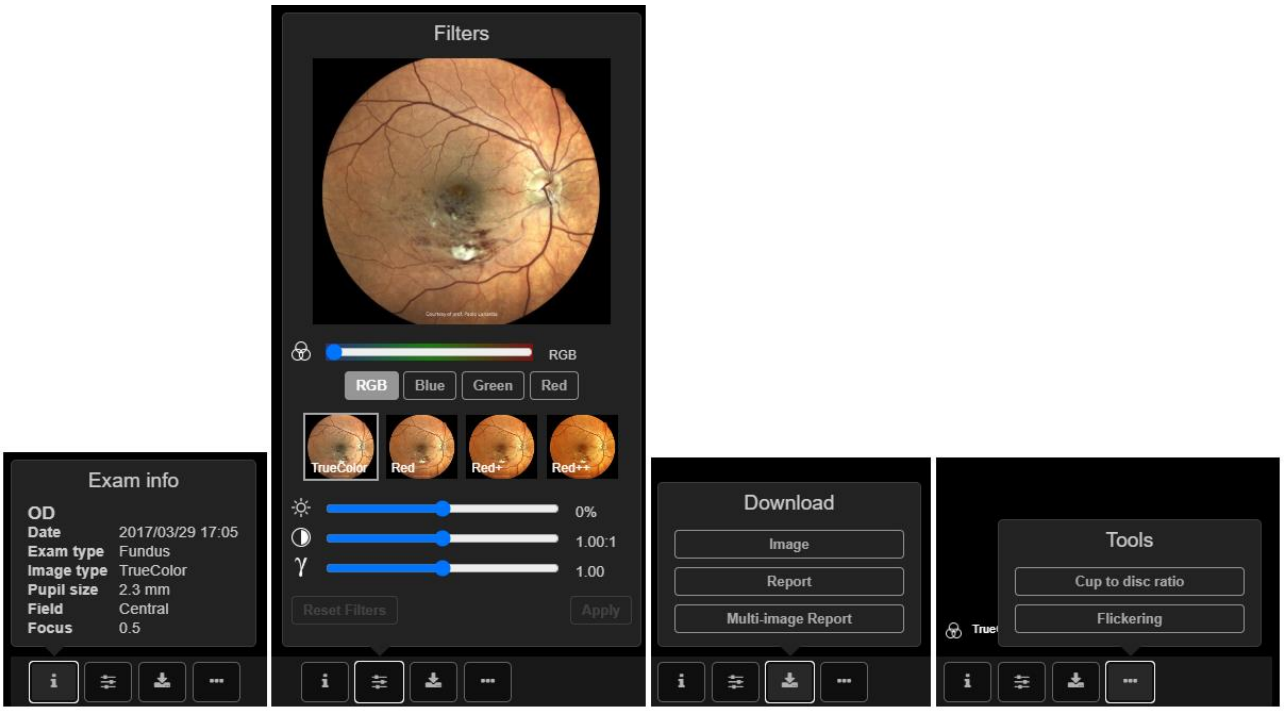


Fig. 72 – Image Filters, Download options and More Tools in Remote Viewer

The image tools do not alter the original image.

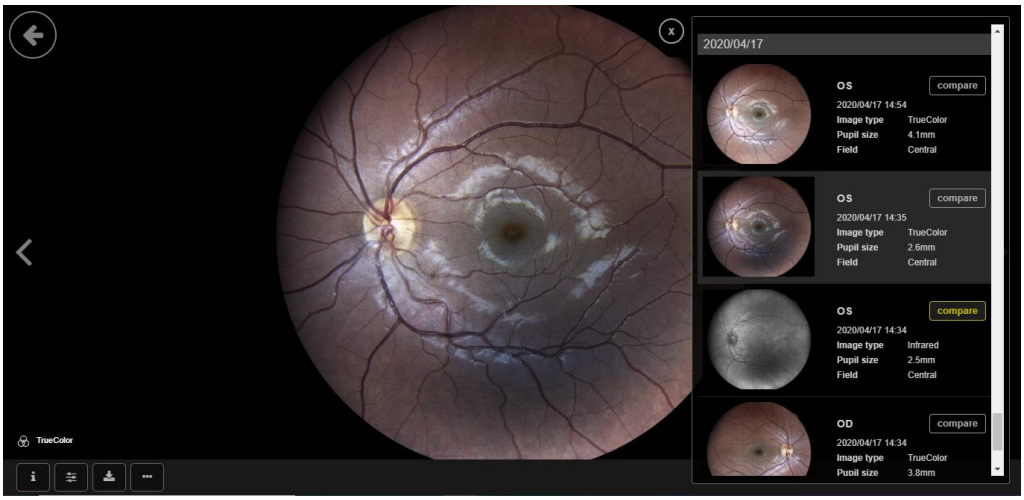


Fig. 73 – Image selection for dual printout, from the single review screen

9.8.6 Dual Image review screen

As for the EIDON Family Software, this screen allows comparison of any pair of images (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.

Fig. 74 – Dual Image Review screen in Remote Viewer

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

Function	Command	Description
Lock		Allows to “lock” the two images so that the same region gets zoomed and panned in both images.
Dual image printing		Exports the pair printout.
Close		Goes back to the Single Image Review Screen.

9.8.7 Stereo image review screen

By clicking on the 3D button at the bottom, the software accesses the stereo images review window. For more information about the stereo feature, see par.8.9.

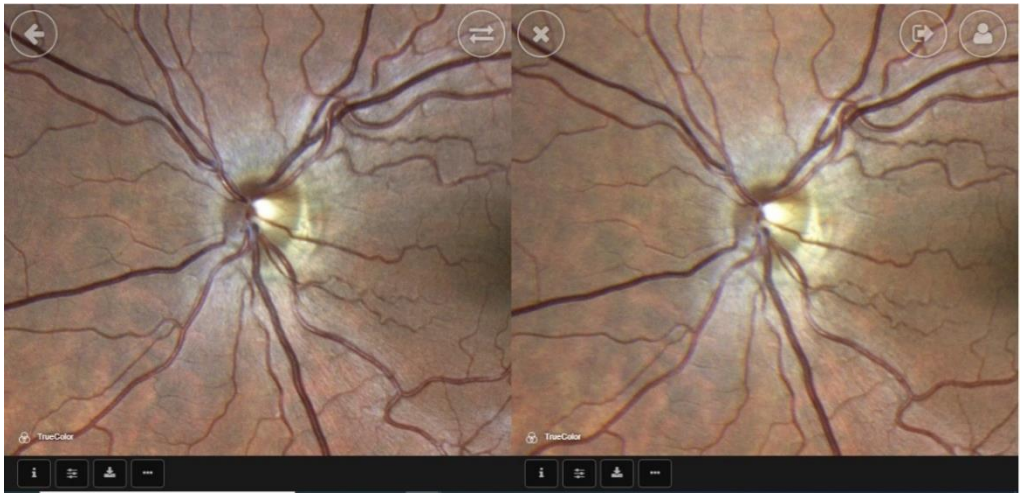


Fig. 75 – Stereo review window

The following functions are available in this screen:

Function	Command	Description
Swap images		Allows to swap the two images to switch between cavities view to elevation view.
Close		Goes back to the Single Image Review Screen.

9.8.8 Flickering view

EIDON Family Software allows to compare two images one by one, by manually or automatically toggling between them. This feature is called **flickering.** To access the flickering window, press the Additional Tools button in the Single Image review screen, then click on **Select image for flickering**: the EIDON Family Software will show a window with all the retinal images available for flickering (i.e. all of the Color, IR or AF retinal images, of the same patient and same eye).

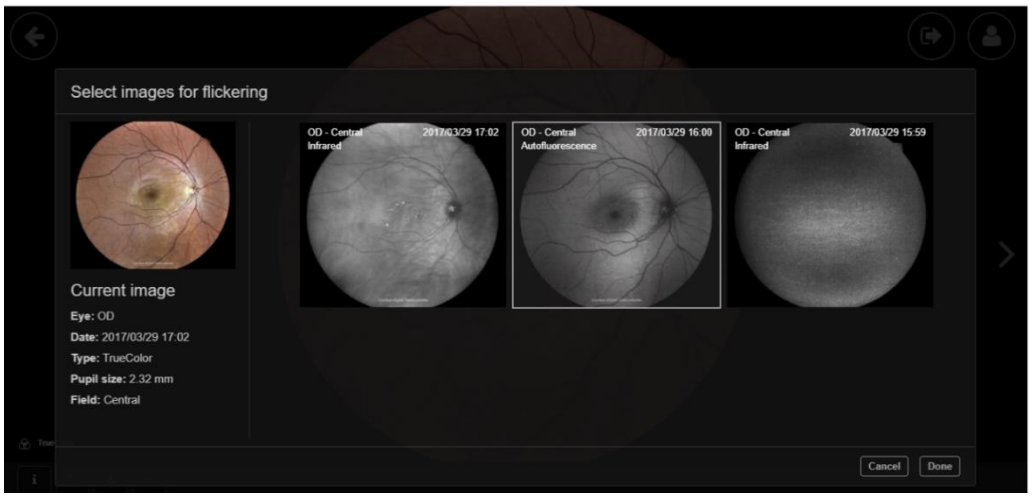


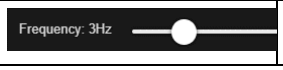
Fig. 76 – Flickering image selection

Select the image to flicker with, then click Done.

Fig. 77 – Flickering review window

On the left of the image there are the date and time of the 2 retinal images selected. The retinal image currently active is the one with the circle near the date and time.

The following functions are available in this screen:

Function	Command	Description
Close		Goes back to the Single Image Review Screen.
Play/Pause		Play/pause automatic flickering.
Next image		Change image.
Animation speed		Flickering frequency selection (from 1 to 10Hz).

Zooming and panning are available during flickering. The two images are “locked”: zooming and panning will act on both images.

9.8.9 Cup-to-disc evaluation

The cup-to-disc (CDR) ratio 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.

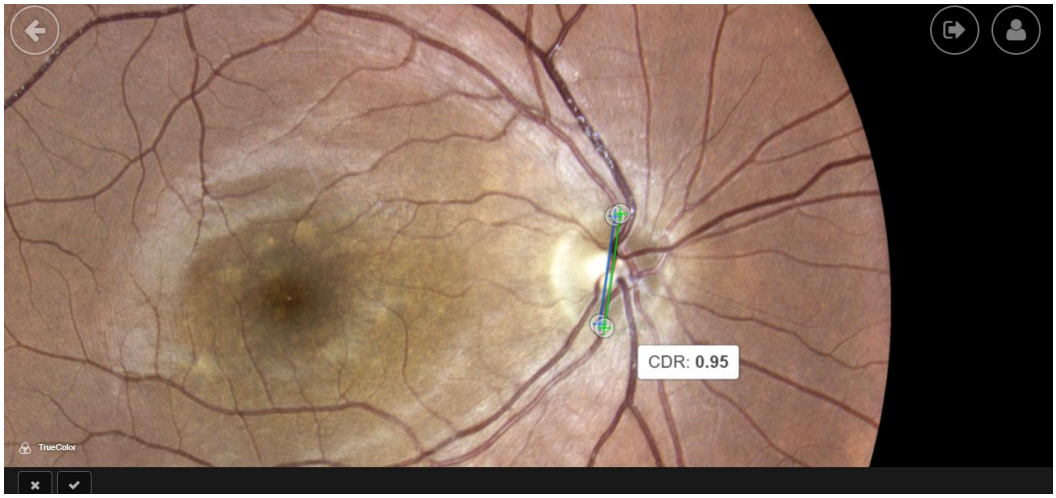


Fig. 78 – Flickering review window

The following function are available in this screen:

Function	Command	Description
Cancel		Discard drawings and go back to the single image review window.
Accept		Save cup-to-disk drawings and go back to the single image review window.

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 user. In particular, the CDR is subject to errors introduced by the end-user.
The clinical interpretation of the CDR obtained with EIDON Family device is the responsibility of the eye care practitioner.

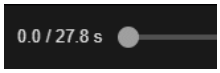
9.8.10 Video Review

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 field, date/time of injection and time since injection

Fig. 79 – Video review window

The following functions are available in this screen:

Function	Command	Description
Video play/pause		Play or pause the video
Previous/next frame		View previous/next video frame
Reproduction speed		Speed of video reproduction
Navigation bar		Video timer and frame navigation
Extract and save current frame		Extract the frame from the video and save it on the patient details screen. Once extracted, the frames are saved in the patient details screen, respecting the time since injection order.
Download full video		Download the full video with the same file format described for export to USB or shared folder

The “Extract and save” functionality is not working on videos acquired 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. DICOM

DICOM 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** document[19]. This feature requires dedicated license.

For information about DICOM modality worklist and C-Store, see the **EIDON Family device DICOM User Manual**.

[19] *Ask to your local distributor for purchasing a DICOM license, and for the EIDON Family DICOM User Manual or EIDON Family Conformance Statement.*

11. PRINTING

11.1 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 User Custom Control Interface (see Table 3). Before choosing a printer, please check if the model is included in the compatibility list issued by the printer manufacturer for every app.

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

Table 3 - Printing apps

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

10.1.1 Infrastructure Mode

In this configuration, both the EIDON User 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.

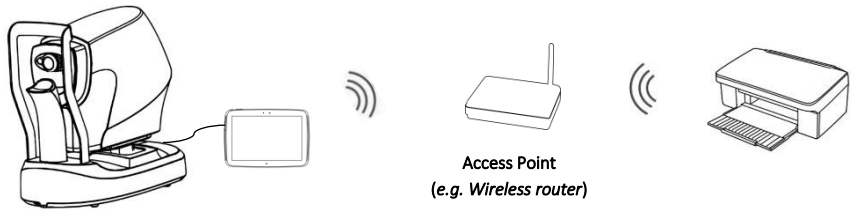


Fig. 80 - EIDON Family device's connection to the printer via Access point (wireless)

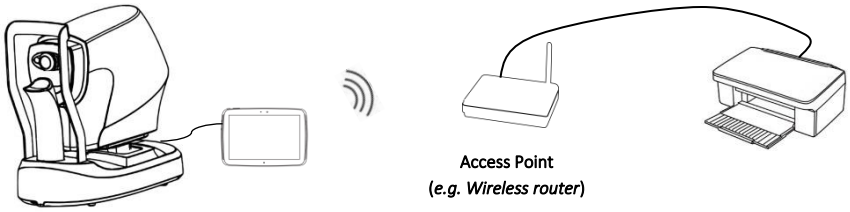


Fig. 81- EIDON Family device's connection to the printer via Access point (cable)

10.1.2 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.

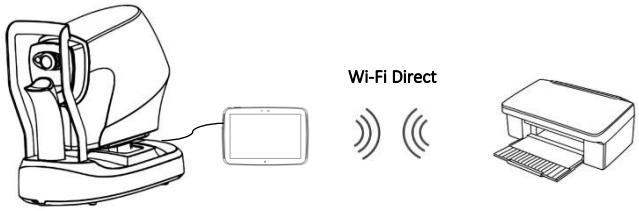


Fig. 82 – EIDON Family device's connection to the printer via Wi-Fi Direct

11.2 Printout

The printout (Fig. 83) is a **one-page layout** presenting the following information:

1. Custom header (only if the header has been uploaded by the configurator app. For additional information, see par. 12.11)
2. Patient information (name, date of birth, age)
3. Patient notes
4. EIDON Family Device Software version

Depending on the selection, the printout can include up to 9 retinal images per page without the black background area. The interface in Fig. 84 allows to choose page orientation (portrait or landscape) and number of images per page. 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 (if applied)
5. Filtering values of the R, G, B channels (if filtering applied)
6. Captured field position (N.A. for retinal images acquired in manual mode)
7. Cup-to-disc (if applied)

The following functions are available in this screen:

Function	Command	Description
Report preview		It generates the preview of the PDF report
Report export to remote shared folder		It allows single or multiple images print out manual export to shared folder. Functionality is available if remote shared folder is configured otherwise the icon is greyed out
Report export to USB drive		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

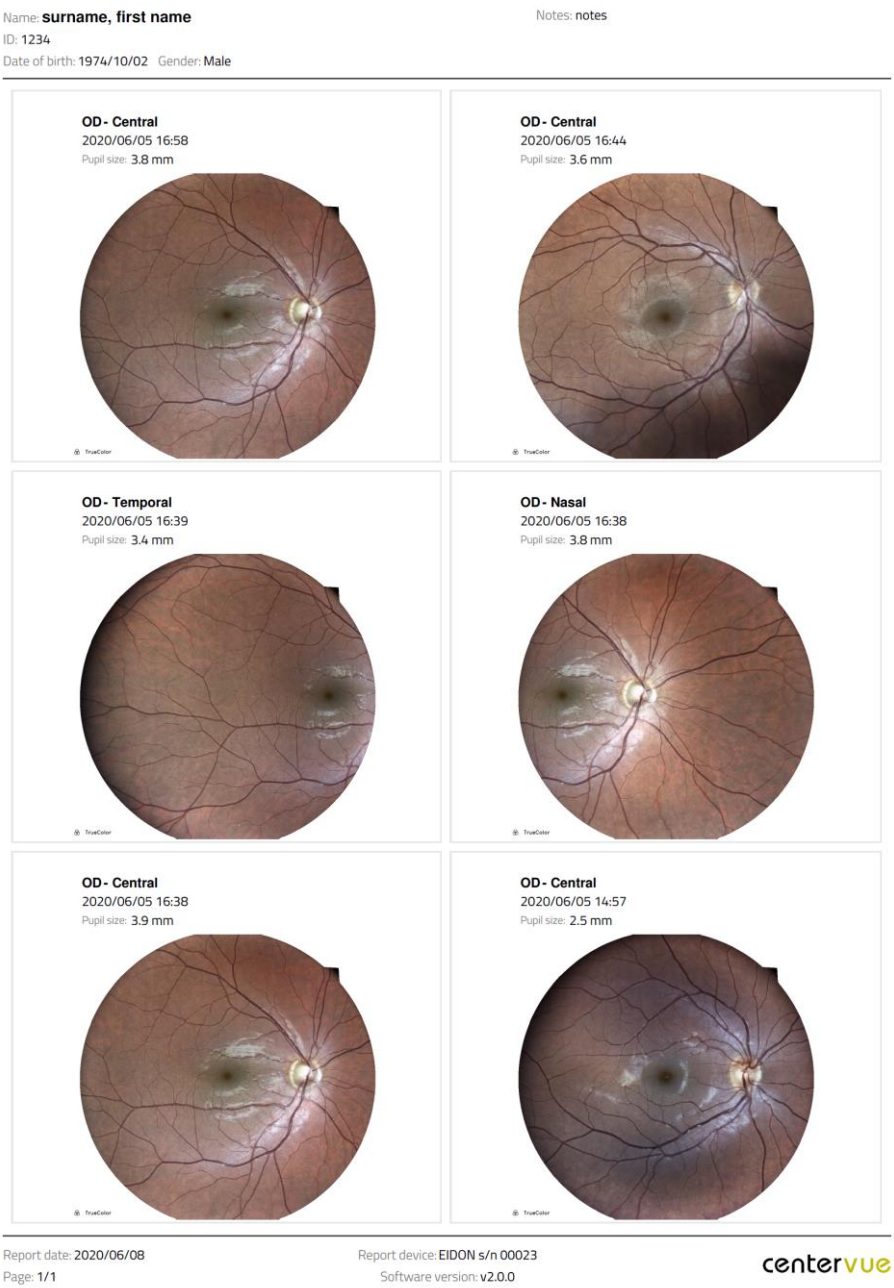


Fig. 83 – Multi image printout with custom header

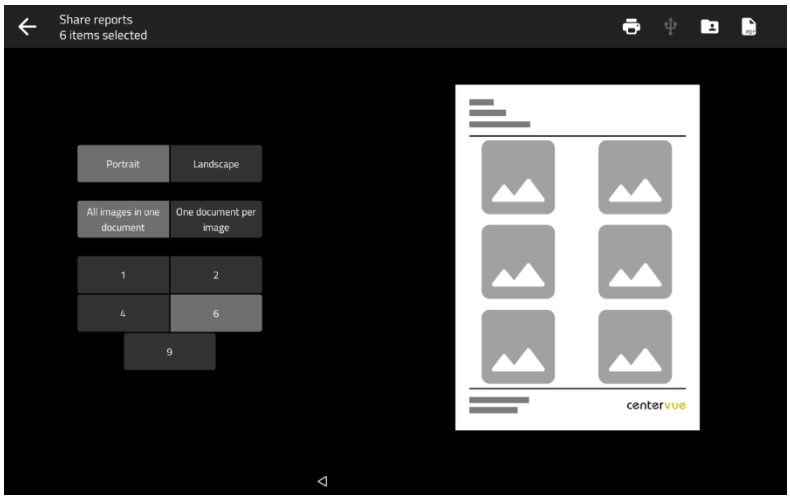


Fig. 84 – Report Configuration window

12. 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.

12.1 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. 18);
- 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.

12.2 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 start the Configurator please refer to the beginning of this chapter).

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.

12.3 Date and time set

To modify date and time, access 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.

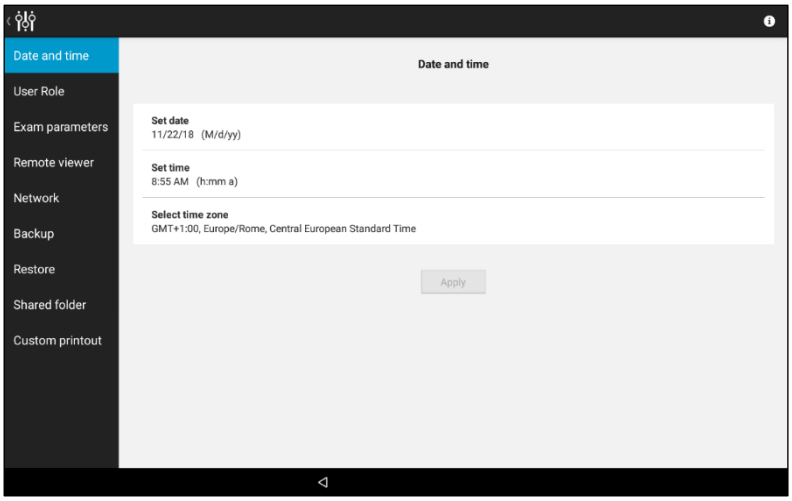


Fig. 85 – Configurator – Date time set

12.4 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. 86). 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 Authorized Service Center for support.

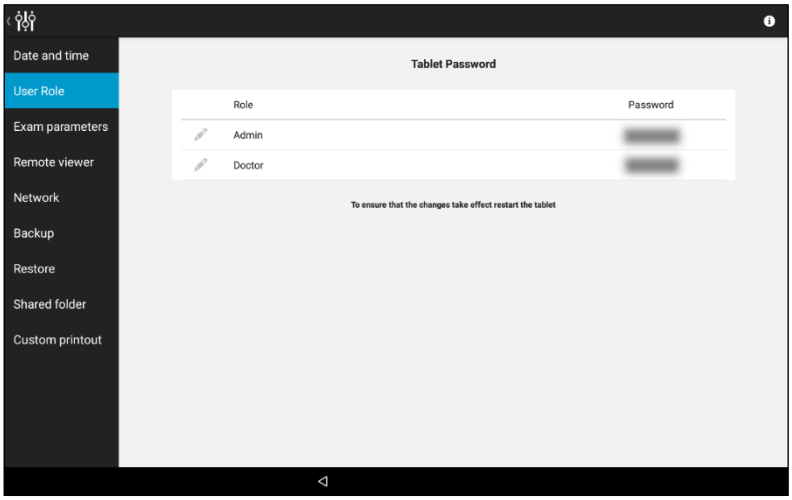


Fig. 86 – Configurator – USER ROLE screen

12.5 Exam parameters

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

- Set the default value for exposure meter when acquiring color images either in full-automatic or manual mode;
- Set the default brightness, contrast, gamma and redness filter applied to the acquired color images;
- Select the default imaging modality;
- 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.

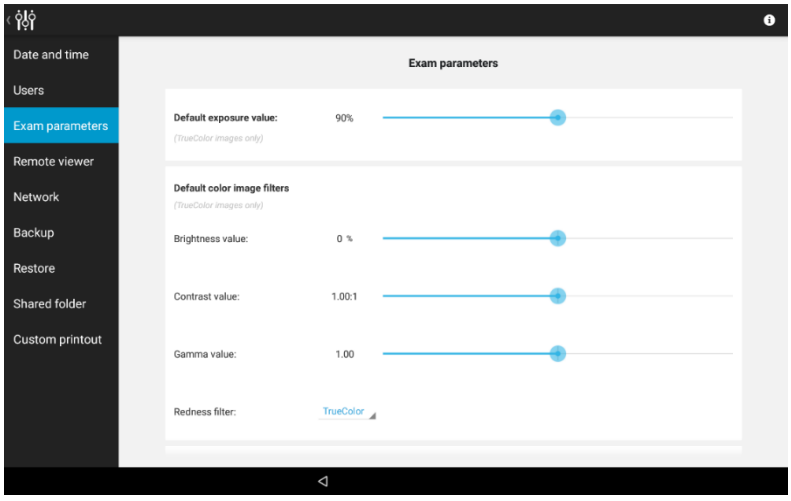


Fig. 87 – Configurator – EXAM PARAMETERS screen

12.6 Remote Viewer

To change the password used to access the Remote Viewer click on the **Remote viewer** tab of the Configurator, type the new password and press **Apply**.

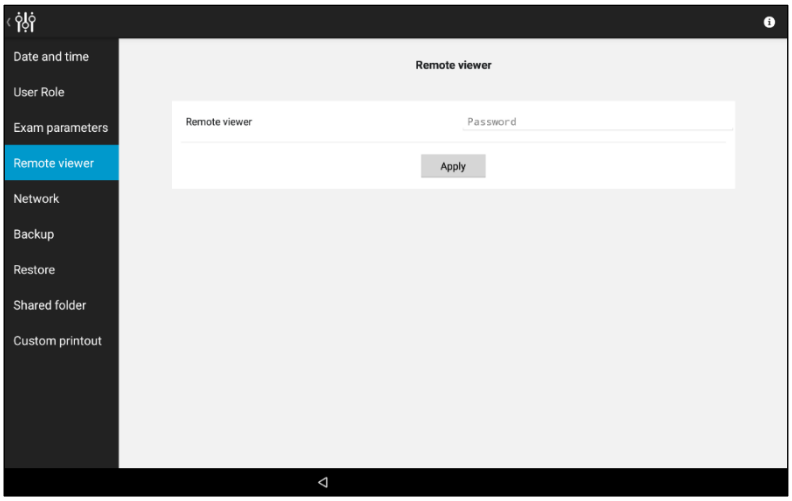


Fig. 88 – Configurator – REMOTE VIEWER screen

12.7 Network configuration

EIDON Family Device supports either Ethernet network connection or wireless network connection. However, remote viewer, shared folder export and full DICOM support are available only through wired network connection.

The Ethernet port is located on the back of the system (see

Fig. 6).

The User Custom Control Interface (tablet) 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.

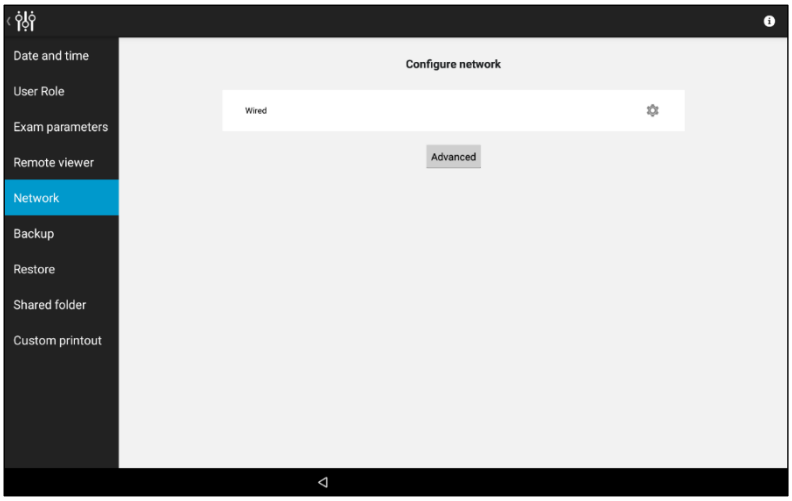


Fig. 89 – Configurator – NETWORK screen

The wireless network parameters are set directly by the Android Wi-Fi configurator, while the Ethernet network is configured by clicking on the  icon, near the “Wired” label.

Fig. 90 – 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. 89): the following window appears.

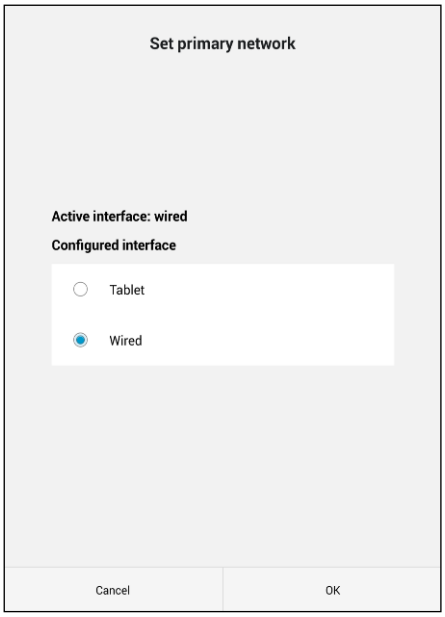


Fig. 91 – Primary Network settings

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 tablet prompts a message if the configured interface was modified.

12.8 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. Moreover, the same device media can be used as backup for different EIDON FAs.

⚠	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.

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

Device tab

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

Backup to USB

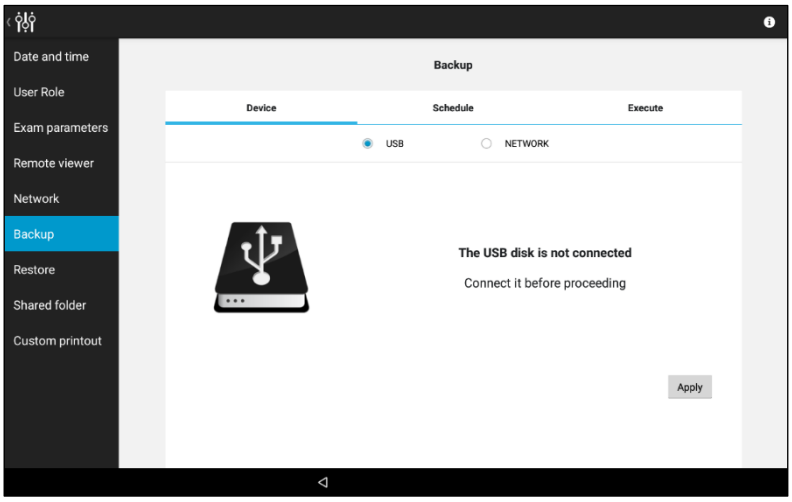


Fig. 92 – Configurator – BACKUP screen – USB-media backup selected

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

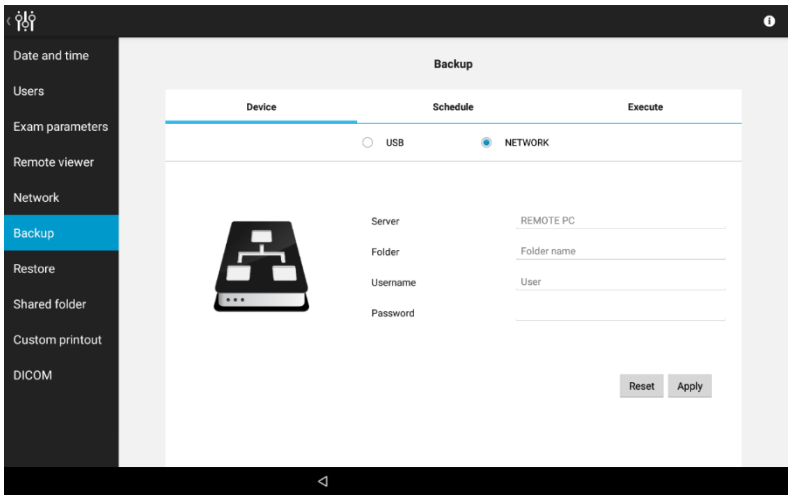


Fig. 93 – Configurator – BACKUP screen – Network backup selected

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

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

Schedule tab

Turn **ON** the **Automatic backup** button in the **Schedule** tab to allow periodic backup.
At the scheduled time, 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.

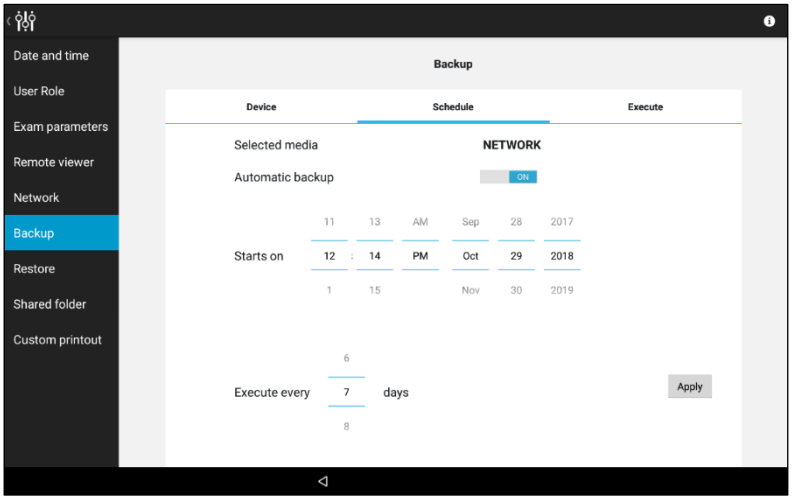


Fig. 94 – Configurator – BACKUP screen – *Schedule* tab with automatic backup enabled

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.

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 DEVICE can be used regularly except for the impossibility to delete images.

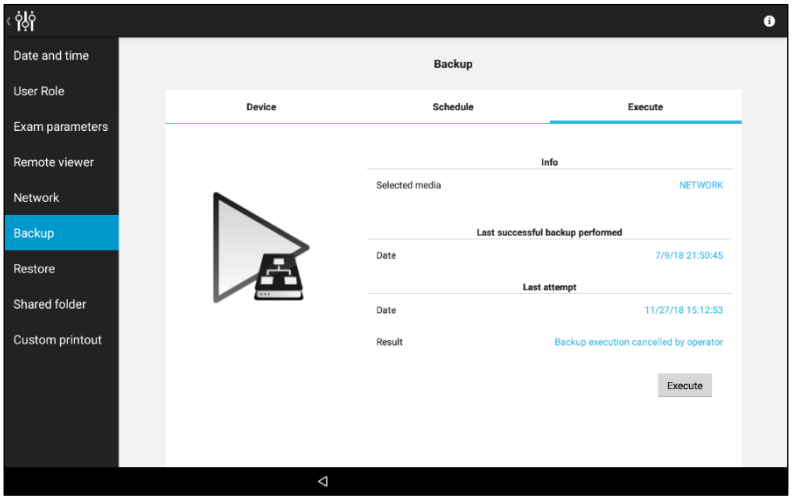


Fig. 95 – Configurator – BACKUP screen – *Execute* tab

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

12.9 Restore

This feature tries 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[20]: 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**.

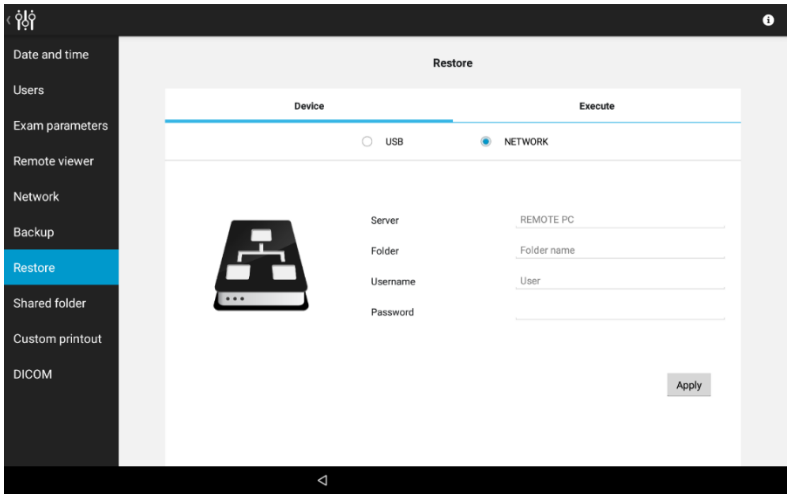


Fig. 96 – Configurator – RESTORE screen – Network folder selected

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

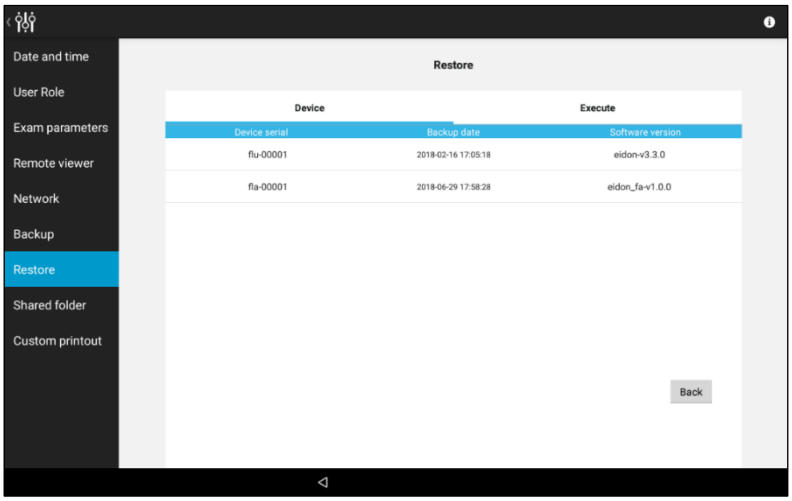


Fig. 97 – Configurator – RESTORE screen – List of available archives to be restored

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.

12.10 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.

[20] *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.*

Status

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

Mode

If the **“Manual”** option is selected, data is exported using the export icon located in the exam review screen (see par. 9.7). If **“Auto”** is selected, data is exported automatically to the selected shared folder upon acquisition and can also be exported manually.

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.

Local shared folder

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 12.8 (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.

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.

Filenames

The filename of a single exported image or video is as follows:
`Surname-GivenName-ExamDate-SerialNumber-Eye-Field-ImageType-ImageDate-Options.FileExtension`
where:

- `Surname`: the patient surname, as in the surname field.
- `GivenName`: the patient given name, as in the given name 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 the hour, minutes and seconds and `Z` indicates that the exported file time zone is UTC.
- `SerialNumber`: Device serial number, including a prefix `EIDON FA_`.
- `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, `11` for mosaic retinal images.
- `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 retinal images extracted from FA videos.
- `ImageDate`: Date/Time of the image or video, in the same format as exam date.
- `Options`: this is an optional parameter used to add more information:
    - `Filtered` in case of printout of filtered images
    - `Report` if the printout is a report (i.e. not an image)
    - Time since injection in milliseconds for FA images and FA retinal image exported from FA video
- `FileExtension`: File extension, according to the selected format. Possible values: `jpg` for JPEG images, `pdf` for PDF files, `dcm` for DICOM files, `mp4` for videos.

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).

Shared Folder Configuration examples

See Fig. 98 as an example of remote shared folder configured for network without domains, and Fig. 99 in the case of Windows Domain network.

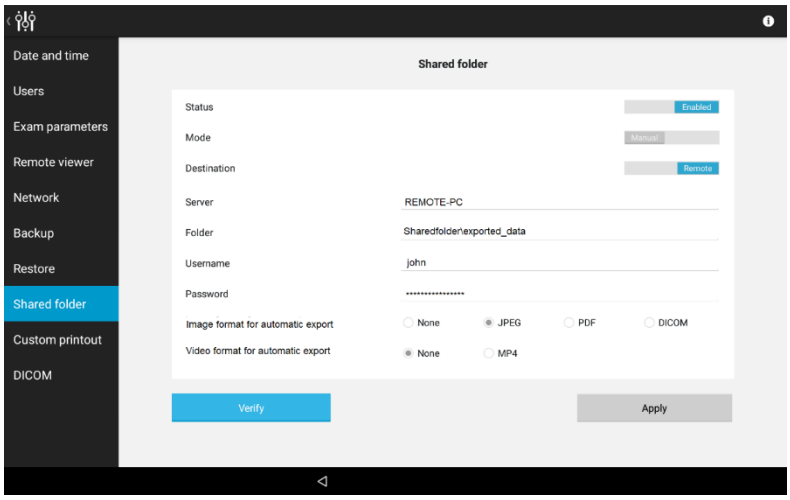


Fig. 98 – Configurator – SHARED FOLDER configuration example: automatic export of JPEG images and MP4 videos to a remote folder *exported_data* (subfolder of *sharedfolder*), located in the server *REMOTE-PC*, with *John* as server username

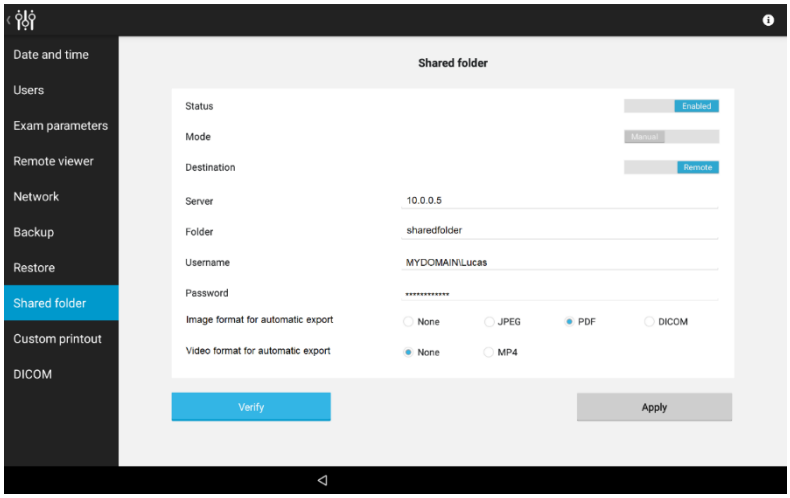


Fig. 99 – Configurator – SHARED FOLDER configuration example, in Windows Domain Networks: automatic export of PDF printouts to a remote folder *sharedfolder*, located in the server with IP *10.0.0.5*, with *Lucas* as domain username and *MYDOMAIN* as domain name

12.11 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 (see Fig.6 for detail on connectors side) 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.

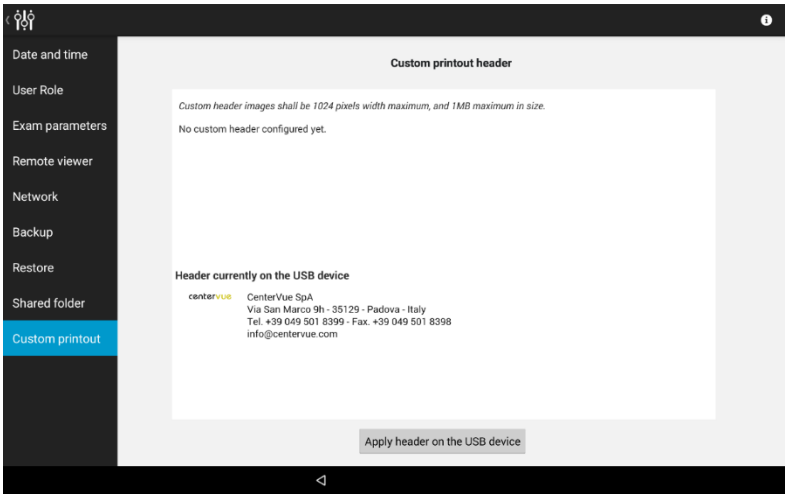


Fig. 100 – Configurator – CUSTOM PRINTOUT configuration

12.12 Settings and standby time

From Home screen of Fig. 18 press  to enter into the menu. Click non 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.

13. 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.

The EIDON Custom Control Interface will shut down and power off automatically.

14. TECHNICAL SPECIFICATIONS

CE 0123

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 UWFL[21]
	120°(H) x 110°(V) captured in a single exposure (center of the eye notation) – with EIDON UWFL[21]
Field of Mosaic[22] 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[23] - 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 UWFL[21]
Resolution:	60 pixels / deg
Optical resolution on retina:	15 µm
Pixel pitch:	4.9 µm
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:	- 12 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, 480 Gb for - EIDON and EIDON AF models SSD, 2 TB - for EIDON FA model only
DICOM[24]:	Compatibility - DICOM version 3.0

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

22 Up to nine retinal images.

23 Red-Free digital filters.

[24] 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 I, 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.

EIDON Family devices are equipped with:

- Support bracket for Control Interface with mounting kit for 3 different positioning
- 3D Joystick with support bracket
- Prismatic stereoscopic goggles
- Headrest and chin rest silicone cushion
- Dust cover
- EIDON Family front lens cap
- This User manual
- EIDON Family External Fixation Target
- Mini-HDMI-to-HDMI adapter
- USB Extension cable

Accessory: EIDON UWF Module[21]

(Optionally equipped with EIDON Family devices)

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

15. CLEANING

This paragraph explains how to clean the device.

The chin rest and the headrest should be wiped with an alcohol wipe before each use and allowed to dry prior to reuse.

Fig. 101 – Removal of the chin rest silicone pad

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

The front lens should be cleaned using a small hand pump air blower, to blow away dust.

Only if really needed, for instance due to the presence of a fingerprint, the objective lens can be cleaned by means of photographic cleaning paper and a suitable lens cleaning fluid.

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

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

16. 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 UWFL is dirty	Clean the front lens or the UWFL
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 permissions • 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

17. ELECTROMAGNETIC COMPATIBILITY

EIDON Family Devices have been tested and found to comply with the limits for medical devices contained in IEC 60601-1-2 and Medical Device Directive 93/42/EEC. 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

17.1 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 and EIDON AF models			
Test Requirements	**Test Result**	**Compliance**	**Electromagnetic environment - Guidance**
Class A or B	B	Yes	EIDON and EIDON AF uses RF energy for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. 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 and EIDON AF 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 IEC61000-3-3	Passed	Yes	

Table 4 - Electromagnetic Emissions for EIDON and EIDON AF models

IEC 60601-1-2 EMISSION TEST for EIDON FA			
Test Requirements	**Test Result**	**Compliance**	**Electromagnetic environment - Guidance**
Class A or B	A	Yes	EIDON FA uses RF energy for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. The EMISSIONS characteristics of EIDON FA make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), EIDON FA might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Group	1	Yes	
CISPR 11, 14-1, 32 or ISO 7137	CISPR 11	Yes	
Conducted RF emissions	CISPR 11 Class A	Yes	
Radiated RF emissions	CISPR 11 Class A	Yes	
Disturbance Power (if applicable)	N/A	N/A	
Harmonic Distortion IEC 61000-3-2 (Class A, B, C, D)	Class A	Yes	
Voltage Fluctuations and Flicker IEC61000-3-3	Passed	Yes	

Table 5 - Electromagnetic Emissions for EIDON FA model

17.2 Guidance and manufacturers declaration – Electromagnetic Immunity EIDON Family devices

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

Table 6 - Electromagnetic Immunity (IEC 60601-1-2:2014) for EIDON Family Devices

17.3 Immunity pass criteria

IMMUNIT	
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 tablet and main unit	During the applied testing stimulus, temporary cessation or interruption of any intended operation is acceptable

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

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 (CenterVue). 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 8 - Recommended Separation Distances

17.4 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.

18. INFORMATION ABOUT THE OPTICAL RADIATION HAZARD

EIDON Family devices are a classified[25] as:

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

according to ISO 15004-2 and ANSI Z80.36.

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

The light emitted from this instrument is potentially hazardous. The longer the duration of exposure and the greater the number of pulses, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum output will exceed the safety guideline after 46300 color images or 6666 autofluorescence images or 75 minutes of continued fluorescein angiography video or 6666 fluorescein angiography images or 8600 hours of continued green fixation light or 109793 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 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, calculation of total exposure is as follows:

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

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 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**.

[25] *EIDON Family devices used with EIDON Ultra-Widefield Lens (EIDON UWFL) remain in the same class.*

18.2 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/cm^2.

19. 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 (eg. cables, connectors and plastic cases).