Operating Manual

MANUAL INFORMATION

Date of release:	June 10th, 2020
Revision number:	12
Reference software version:	2.0
Manufacturer:	CenterVue S.p.A. Via San Marco 9h, 35129 Padova – ITALY Tel. +39 049 501 8399 Fax +39 049 501 8398 centervue

CONTENTS

1. INTRODUCTION

Congratulations for choosing EIDON FA and its confocal retinal imaging capabilities.

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

In particular, EIDON FA uses:

- infrared light to obtain infrared-reflectance images (Fig. 1)
- white light to obtain color images (Fig. 2)
- blue light to obtain autofluorescence (Fig. 3) and fluorescence images (Fig. 4)

Fig. 1 – IR reflectance image

Fig. 2 – Color image

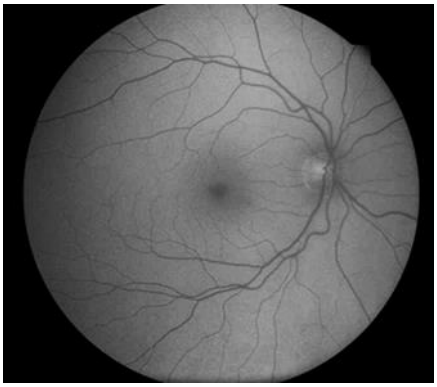


Fig. 3 – Autofluorescence image

Fig. 4 – Fluorescence image

The device integrates a tablet and is provided with an external power supply. The device works with a dedicated software application and operates as a standalone unit.

The clinical interpretation of the images acquired by EIDON FA is restricted to licensed eye care practitioners. The process of making a diagnosis using EIDON FA results is the responsibility of the eye care practitioner. A device specific training is required for any operator to become able to use the system.

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

2. SYSTEM

2.1 The device

Fig. 5 – **EIDON FA**

Fig. 6 – Detail of connectors side

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

2.2 The tablet

The tablet (see Fig. 7) is an integral part of the system and EIDON FA cannot operate without it. The tablet must be connected to EIDON FA using the supplied cable. The tablet is equipped with a color, multi-touch display. The 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 tablet.

Fig. 7 – Tablet supplied with EIDON FA

The tablet must be used only together with EIDON FA and in accordance with the instructions provided in this manual. Use of the tablet for other purposes, as well as any modifications of the tablet settings other than indicated in this manual may result in the EIDON FA becoming unusable.

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 FA is a confocal system that uses **white LED light** instead of monochromatic lasers, hence it provides **true color confocal** images and offers high image fidelity, no need for dilation, high resolution and contrast, high quality even in presence of media opacities.

3. LABELS

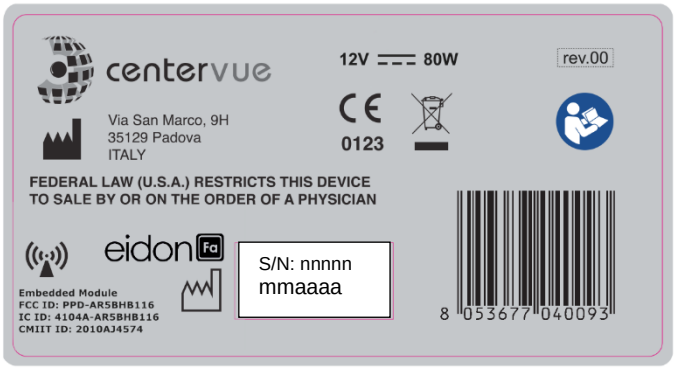


Fig. 8 – EIDON FA main label

Fig. 9 – EIDON FA UDI label

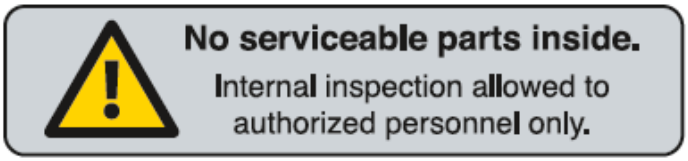
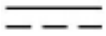


Fig. 10 – Other labels attached to the device

4. SYMBOLS

The meaning of the symbols adopted in the 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. 18 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
	Important information

5. PREPARING THE SYSTEM

We recommend reading carefully and thoroughly par. 6 before proceeding with first use.

To make EIDON FA functional for the first use:

- extract the system from its box;
- place it on a suitable electrical table[1];
- insert the forehead rest on the metal support (see Fig. 11);
- mount the support provided for the tablet and the joystick (see par. 5.1);
- connect the power supply provided with the unit to the power inlet (see Fig. 6);
- place the tablet on its support and connect it using the cable to the dedicated port;
- place the joystick on its support, connect it using the cable to any of the free USB ports and check for its correct orientation;
- optionally mount the external fixation light (see par. 5.2);
- plug the power supply to the wall socket.

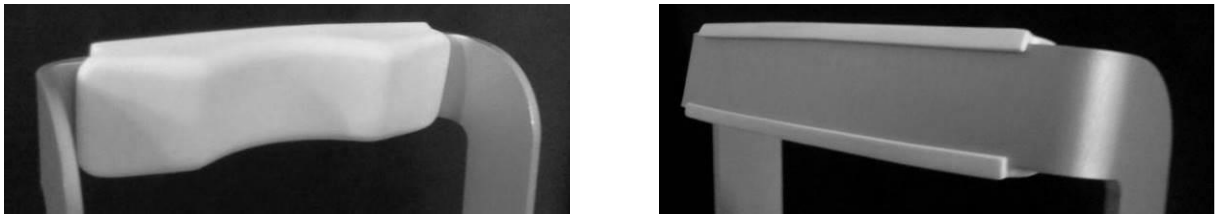


Fig. 11 – Forehead rest mounted on metal support

5.1 Assembling the tablet and joystick supports

The tablet and the joystick should be mounted towards the posterior part of the device: with the included support it is possible to choose their position on any side (see Fig. 13). The joystick should be placed close to the tablet 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. 14 shows the holes to be used for the left-side mount depicted in Fig. 12: to fix the supports use the holes marked 1 and 2 for the tablet and those marked 3 and 4 for the joystick. Other configurations can be chosen, based on the user's preferences.

Fig. 12 – Tablet and joystick mounted on the left side of the device

[1] Not provided with the system

Fig. 13 – Support for tablet (left) and for joystick (right)

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

Fig. 14 – Instrument bottom with holes for tablet and joystick supports

5.2 Assembling the external fixation light

The internal fixation light allows to frame fields that are centered within 20° from the fovea: the external fixation light can be used to image more peripheral areas.
Fasten the light to the forehead rest using the supplied screws and the spacer plate; connect it to any USB port to power it on.

Fig. 15 – External fixation light

5.3 Remove the front lens cap

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

5.4 Turning on the Device

Turn on the Device by pressing the main switch (see Fig. 6), this will also turn on the tablet: 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. 16).

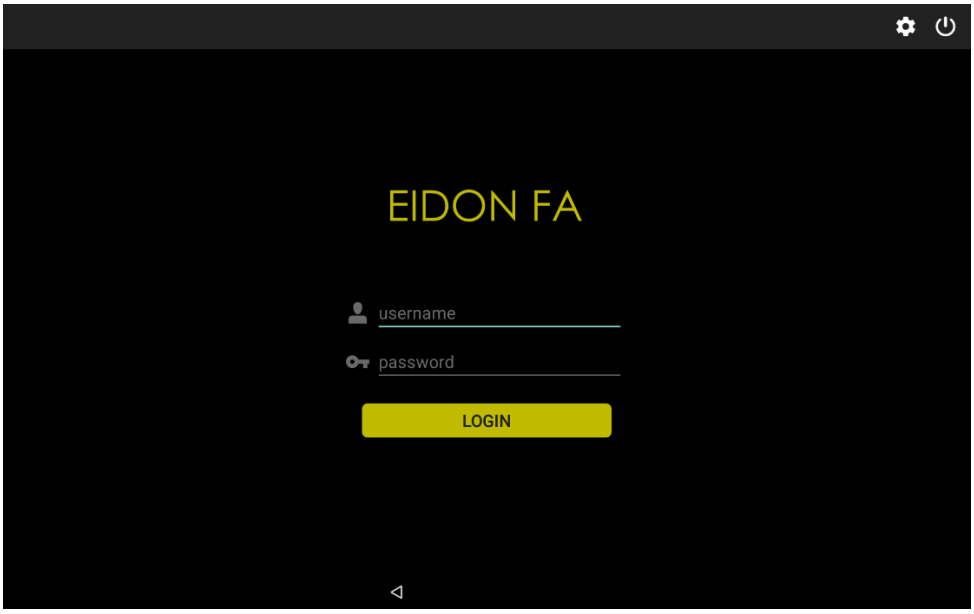


Fig. 16 – Login screen

From the drop-down menu select “Doctor”, type the password[2] and click on **login**. If login is successful, the **Home** screen opens (see Fig. 17).

To modify the password, see par. 12.4

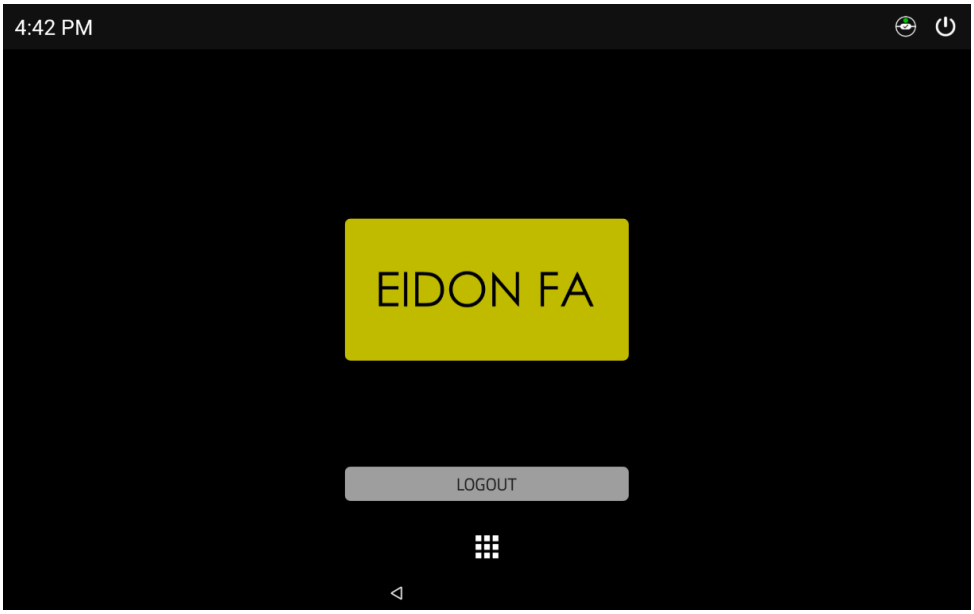


Fig. 17 – Home screen

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

5.5 Unlock function

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

6. WARNINGS AND PRECAUTIONS

EIDON FA is intended for use by healthcare professionals only.

The following precautions are important for the device 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.
- Device specific training is required for any operator to become able to use the system.
- Do not open the device: this could lead to electric shocks or damage to the system.
- Do not use the device if the cover or other parts of the device have been removed.
- Only technicians authorized by CenterVue may service EIDON FA. CenterVue cannot be held responsible for system safety should EIDON FA be opened, repairs carried out, third-parties' software be installed, or parts be replaced by un authorized persons.
- Do not expose the device to water: this could lead to fire or electric shock.
- Stand clear from moving parts during operation.
- The device is supplied with an earth ground by means of a protection conductor contained inside the power supply cable. Before turning on the system, make sure the power supply socket is correctly grounded to avoid the risk of electric shock.
- EIDON FA must NOT be used in an oxygen rich environment or in presence of flammable anesthetics.
- 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 the scope of this manual.

The following precautions are important to prevent use errors:

- The device must be placed in a room which is not exposed to adverse chemical-physical conditions, such as the presence of sulfur, salt, dust, direct sunlight, lack of ventilation, high humidity, sudden temperature drops or peaks. The safety and/or effectiveness of the instrument cannot be guaranteed if these conditions are not fulfilled.
- EIDON FA needs to be operated in a semi dark environment.
- EIDON FA needs to be operated under the following environmental conditions: temperature: 10 to 35 C° (50 to 95 F°); humidity (max): 90% not condensing.
- EIDON FA needs to be stored under the following environmental conditions: temperature: -10 to 60 C° (14 to 131 F°); humidity (max): 90% not condensing.

7. PREPARING THE SUBJECT

This paragraph explains how to prepare a subject for the test.

EIDON FA is a non-mydriatic device (minimum pupil diameter 2.5 mm), so there is no need to dilate the subject, except when fluorescein angiography is being performed. For preparation of the subject for this modality please refer to par. 8.13.

EIDON FA compensates for a subject's spherical refractive error in the range -12 to +15 diopters: testing a subject presenting a spherical error out of the above range may result in poor quality images. EIDON FA does not compensate for a subject's astigmatism.

The subject 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 test, please check the following:

- subject 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 subject can comfortably place her/his chin on the corresponding rest;
- the subject's head should be vertical (not tilted forward/backward);
- chin rest should be positioned so that the subject's eye is aligned to the mark found on the left side of the metal frame (see Fig. 18). If this is not the case the chin rest height needs to be adjusted (see 8.6).

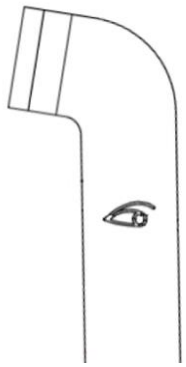


Fig. 18 – Sketch of the eye mark on the metal frame

Before the test inform the subject about the following:

- EIDON FA will take photos of the back of your eyes;
- the test 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 test, the unit will move around to find your pupil: this is absolutely normal;
- always keep your eyes wide open, so that eyelids do not interfere;
- when the test starts look straight in front of you and when a small green, circular spot appears anywhere, look at it;
- do not move, nor speak during the test;
- try to not blink when instructed.

8. PERFORMING THE TEST

This paragraph explains how to operate EIDON FA to perform the image acquisition process (in this manual the terms “test” and “exam” are synonyms). Once the Device has been turned on, click on the EIDON FA button to open the **Patient List** screen (see Fig. 19). The “New exam” button in the each patient record is a shortcut that links to the “exam configuration screen”, bypassing the “patient screen”.

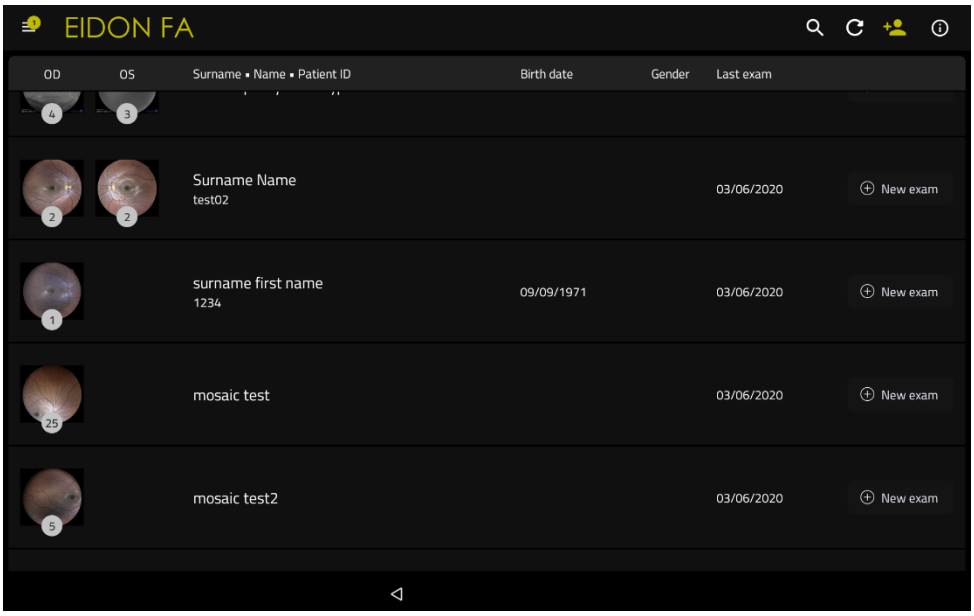


Fig. 19 – Patient list screen

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;
- If a FA session is open instead of “New exam” 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;
- deleting a patient;
- selecting an existing patient;
- searching for an existing patient.

To get more information on the device, click on  and the **Device** status screen will appear.

8.1 Device status

The **Device status** screen contains additional information on the EIDON FA status. This window includes four tabs: backup status, shared folder status, data storage and about.

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.

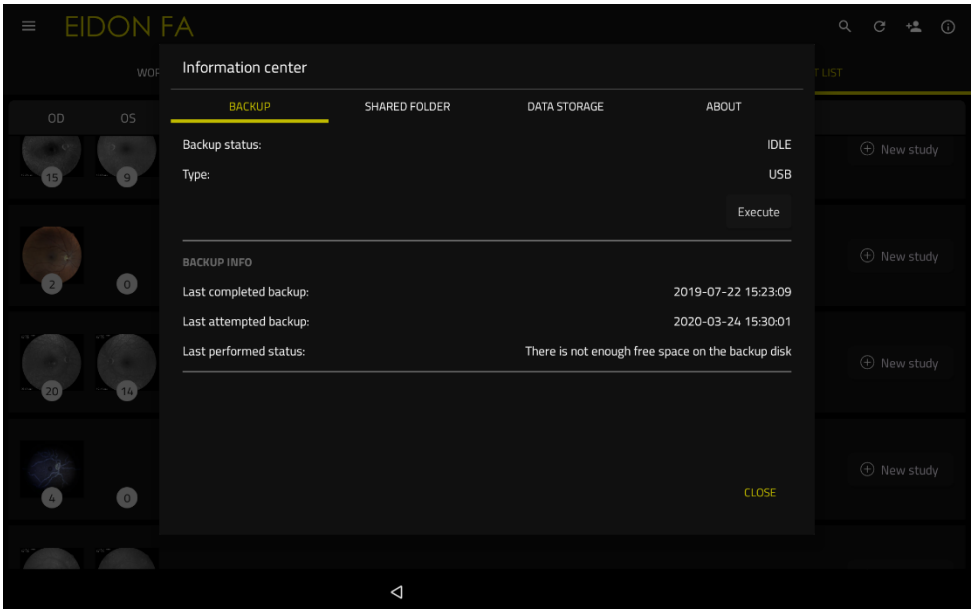


Fig. 20 – Device status screen – Backup status

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.

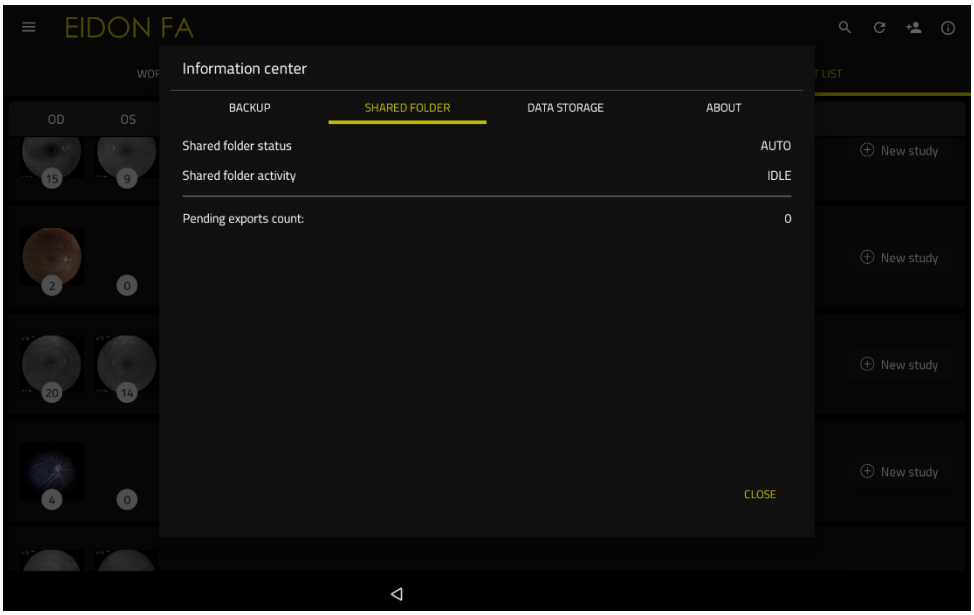


Fig. 21 – Device status screen – Shared folder status

8.1.3 Data storage status

In this tab it's possible to see some information about the storage available in the internal disk (*Local disk space*).

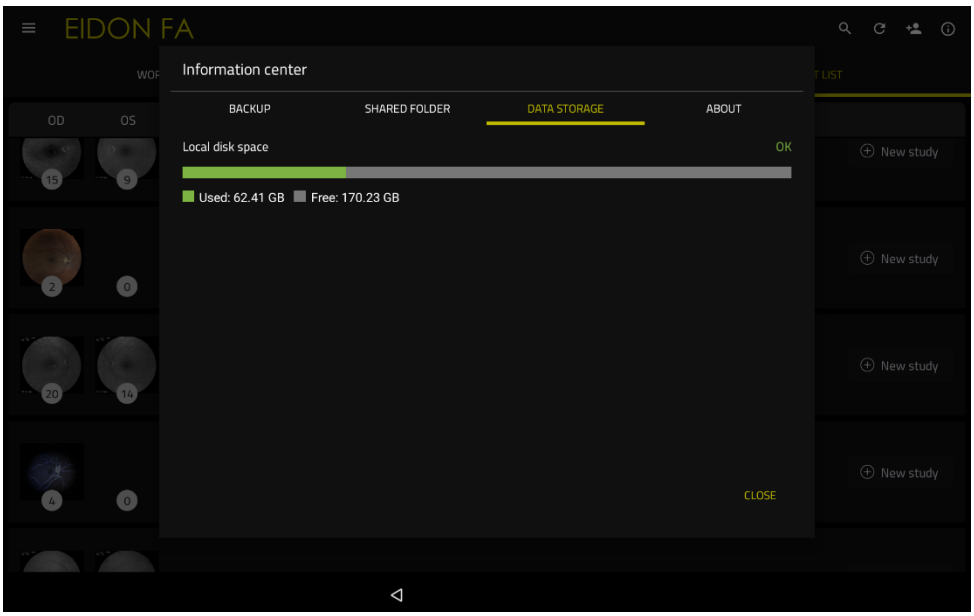


Fig. 22 – Device status screen – Data Storage status

8.1.4 About tab

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

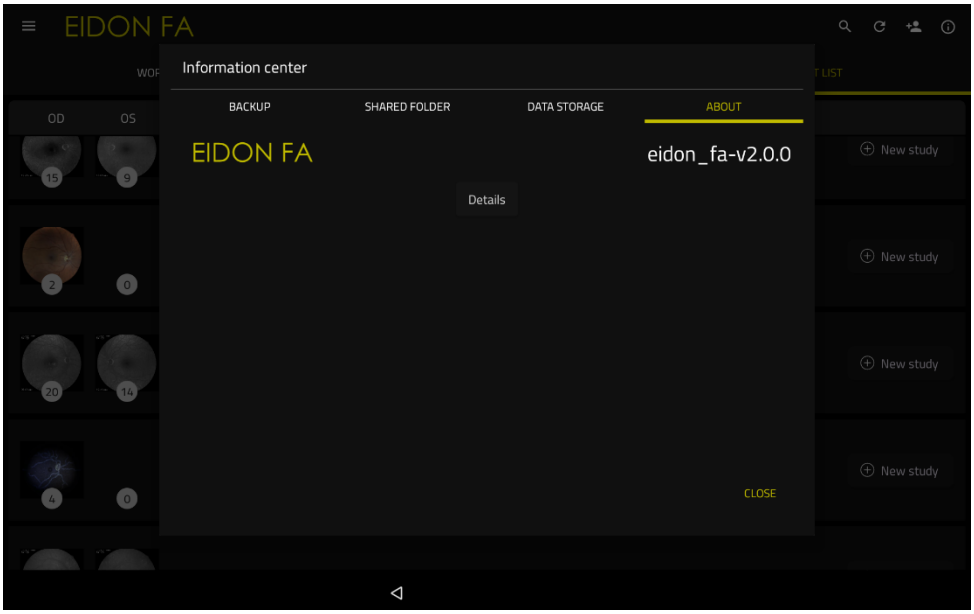


Fig. 23 – Device status screen – About tab

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. 24). 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 to save or Cancel to abort. When the operator enters a new patient with same Name and Surname, or same Patient ID of and already created patient, a warning message will inform that another patient with the same data already exist in the database.

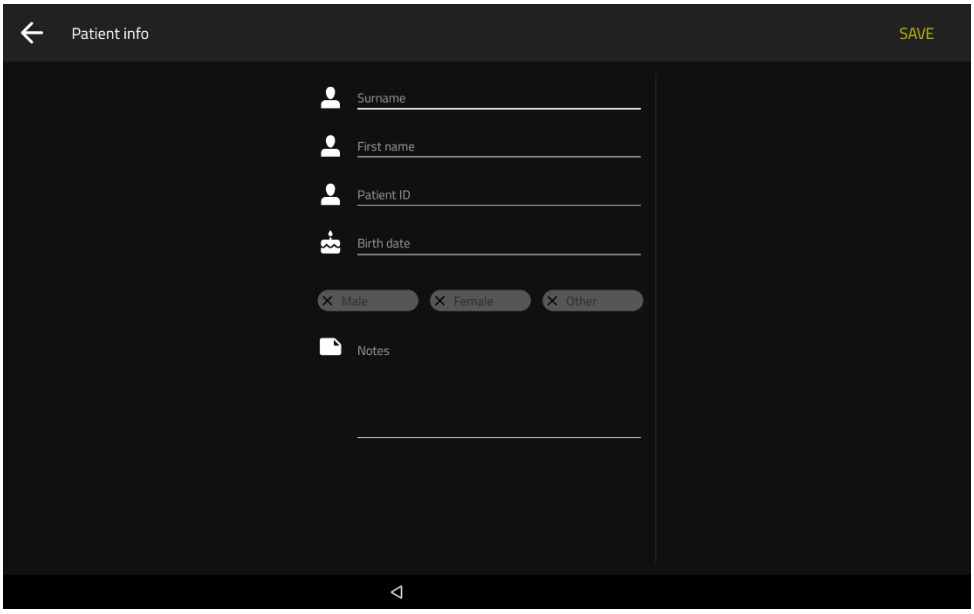


Fig. 24 – Patient editing screen

8.3 Deleting patients

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

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

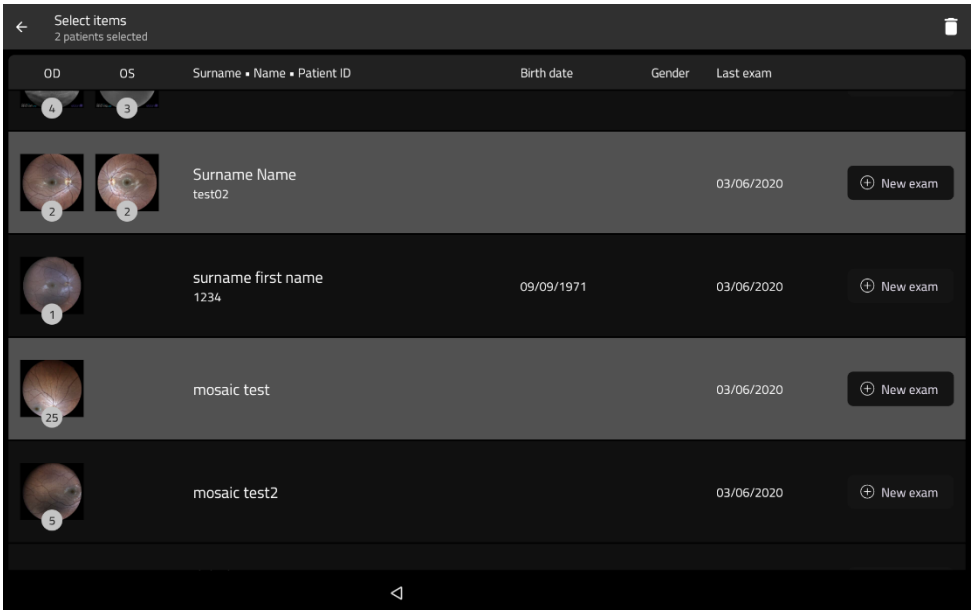


Fig. 25 – Multi selection

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 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. 26) 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** to start a new test for the selected patient.

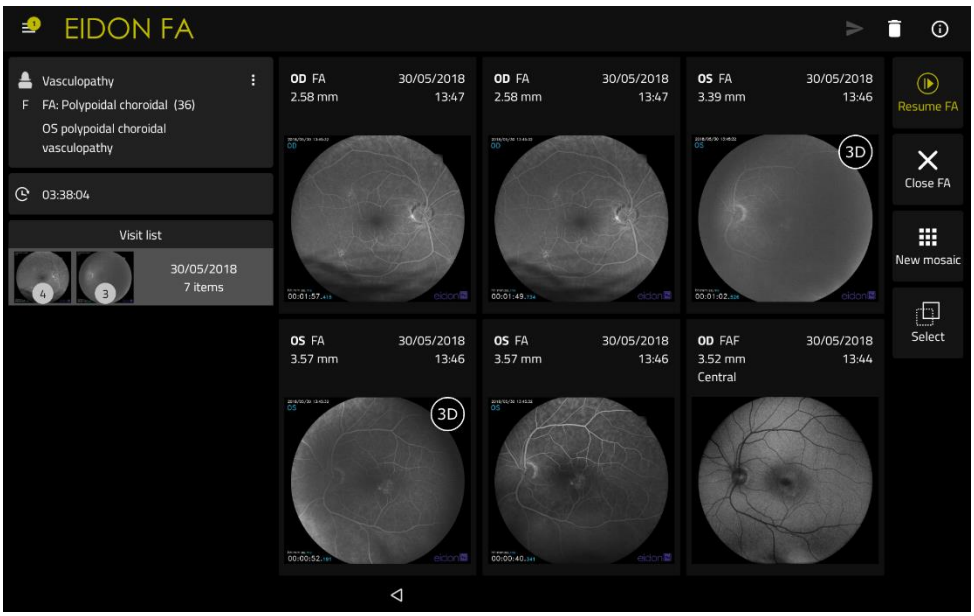


Fig. 26 – Patient Record screen

8.6 Setting up test parameters

When the New Exam button is clicked, the **New Exam** screen opens (see Fig. 27). This screen allows review and modification of the test parameters and triggers the acquisition process.

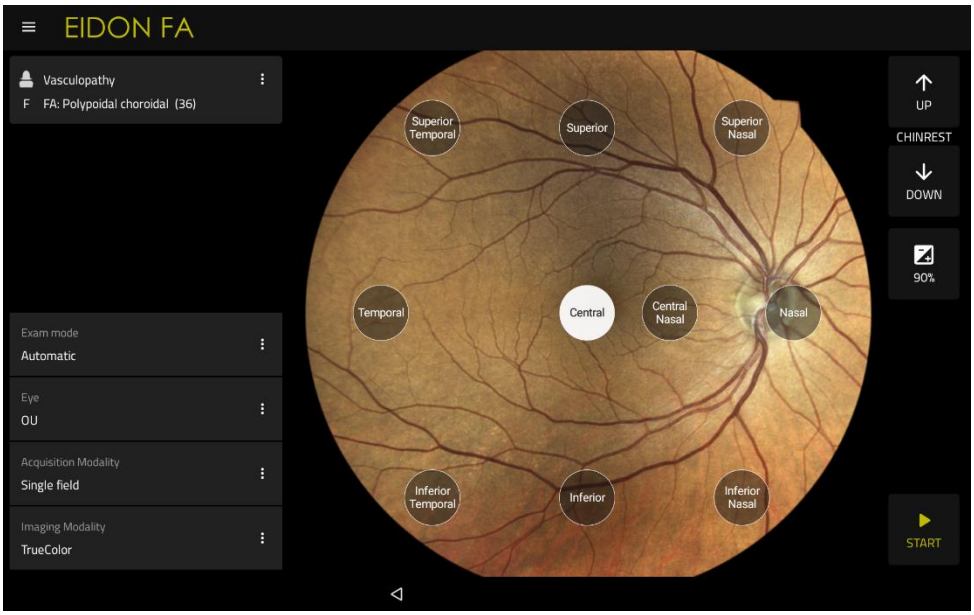
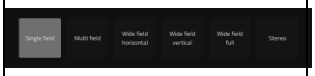
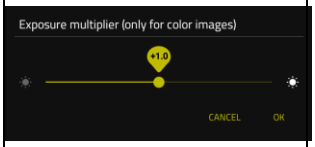
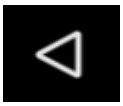


Fig. 27 – New Exam screen

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 fields for the automatic wide field mode		Select the automatic wide field acquisition fields (horizontal, vertical, full). **Default: WF horizontal** (Visible only if *Wide field* is selected)
Manual mode exam types		Manual mode exam types, available only if “Manual” mode is selected. 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 test

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 subject’s eye is aligned to the eye mark on the metal frame;
2. during the whole process the subject 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 subject 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.
- *Wide field*: allows, in combination with the *wide field mode* button, to select the wide field mode (see details below).
- *Stereo*: allows to acquire a stereo pair of the nasal field and produce a stereoscopic view of the optic disc (see details below).

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 Wide field

EIDON FA allows to merge multiple, partially overlapping, fields of the same retina, to obtain a wider image. The new picture generated is called **mosaic**.

To perform a fully-automated wide field capture (i.e. automatic multi-field acquisition and image composition), select the *Wide field* mode: EIDON FA will acquire 3 or 5 pre-defined different fields (color pictures) 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 operator can select between the following types of wide field:

- *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 software will ask to select the fields to be retaken before the mosaic elaboration.

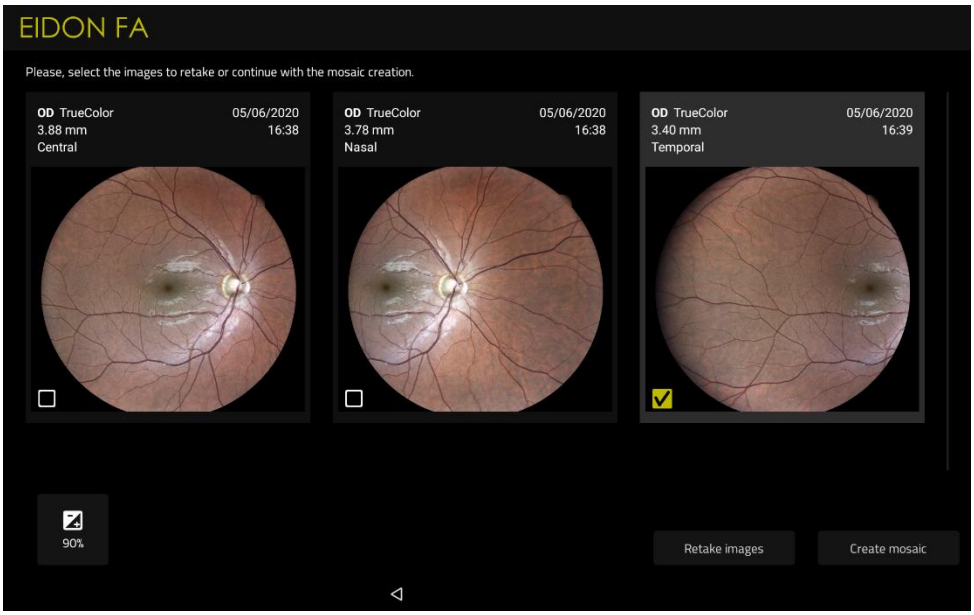


Fig. 28 – Image retake after horizontal wide field acquisition

Select the fields to be retaken then press the **Retake** button to acquire new pictures: the new pictures acquired will replace the old pictures.
If the button **Continue** is pressed, the software will generate the mosaic.

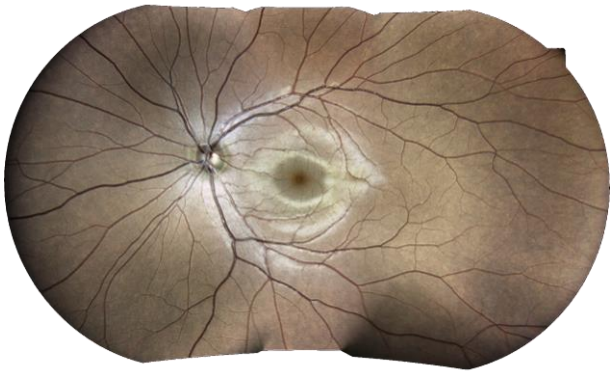


Fig. 29 – Example of *horizontal* wide-field

Fig. 30 – Example of *vertical* wide-field

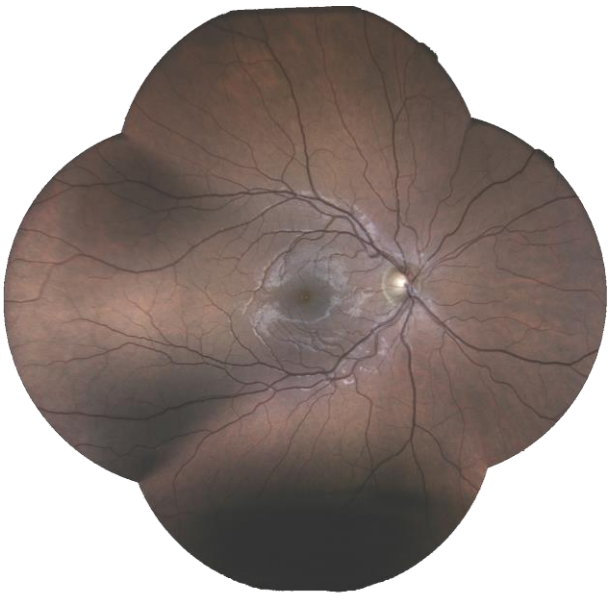


Fig. 31 – Example of *full* wide field

While the resolution of individual EIDON FA fields is 60 pixel/degree, the resolution of the resulting mosaic images is limited to 30 pixel/deg.

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 images, you should use specific prismatic goggles, such as those provided with EIDON FA. The retake function for stereo pictures 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 FA every time the pictures 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's possible to modify the target brightness of the acquired images.
See the par. 12.5 to modify the default exposure value.

8.11 Automatic mode

In this mode EIDON FA 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 (see Fig. 32):

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

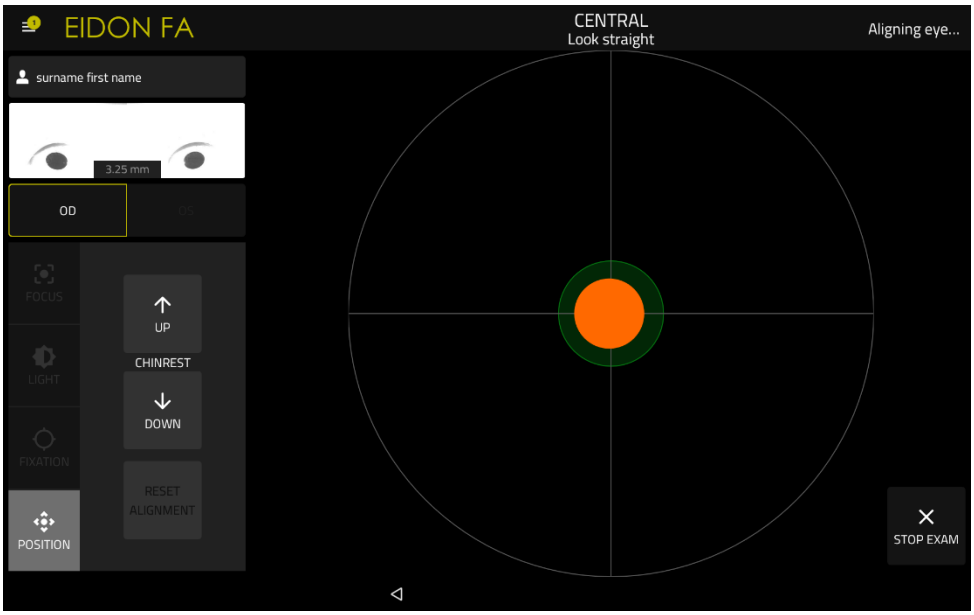


Fig. 32 – Exam screen in auto mode during auto-alignment

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 test parameter window

HINTS TO OPERATOR FOR BEST USE OF THE AUTOMATIC MODE

- Subject should sit in a comfortable position, with the forehead and chin in firm contact with the corresponding rests. Subject'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 subject 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 system to help the operator correct a subject's position (see Table 2)
- There is a delay between capture of the infrared, color image or, in AF devices, AF images, due to a focus adjustment between the two shots: subject 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, right
	Inferior-temporal	Down, left
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: System hints during auto-alignment

If the auto alignment algorithm fails during the alignment process (e.g. for eye not wide open), the software will give the option to switch to full manual mode: switching to the full manual mode will stops the Stereo or Wide Field acquisition.

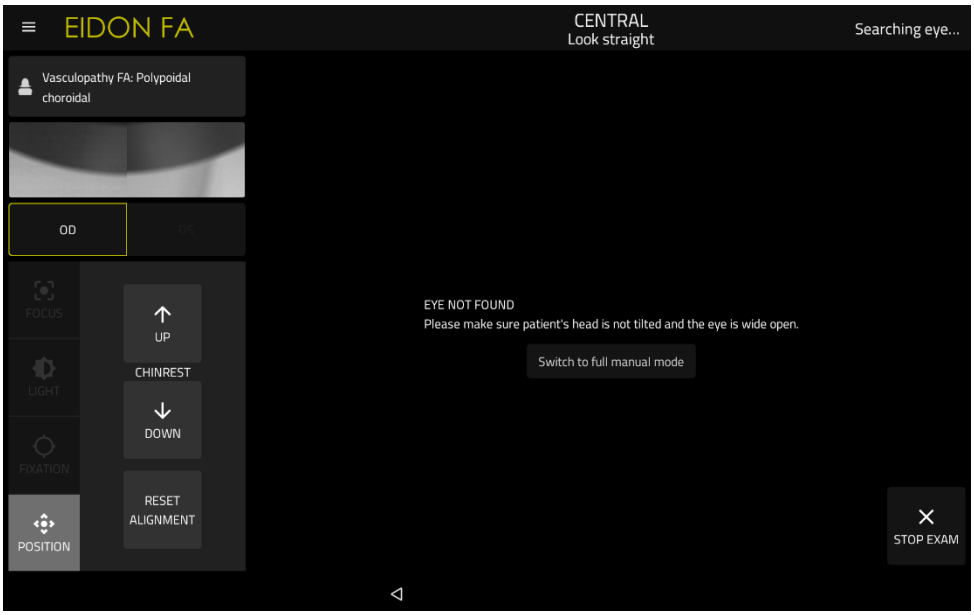


Fig. 33 – Eye not found during alignment phase in automatic mode exam

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.

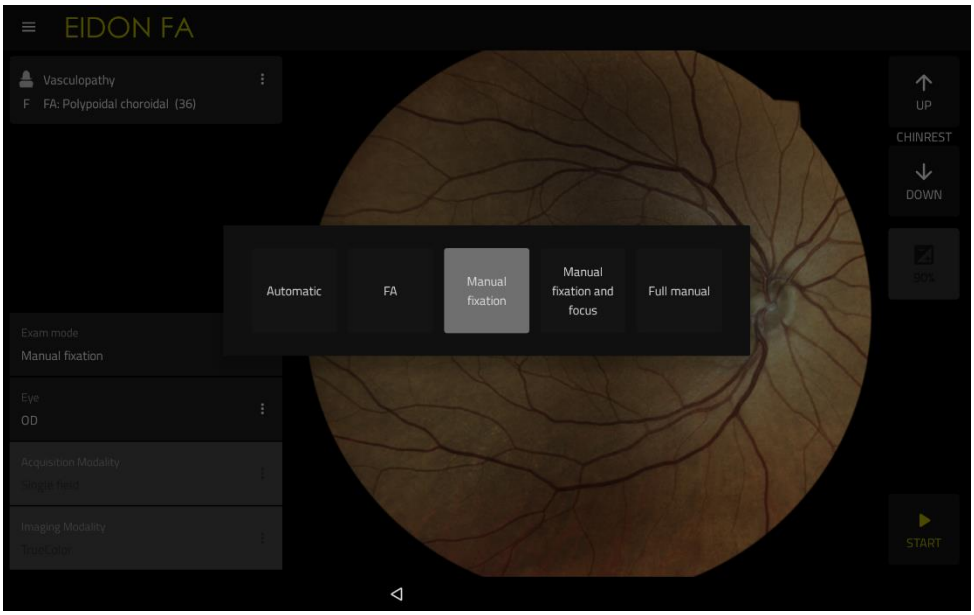


Fig. 34 – Manual mode options

In every type of manual mode the operator 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 external fixation light is used.

When manual placement of the fixation target is selected, EIDON FA 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. 35), waiting for operator's intervention.
Move the target by dragging it on the image. Different areas of the retina are framed depending on the fixation target position[3]: 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.

Click on the 

icon to stop the test at any time. Images are saved on the internal memory as soon as captured.
Is it always possible to exchange from internal to external fixation:

- Internal: fixation appears overimposed 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 external fixation

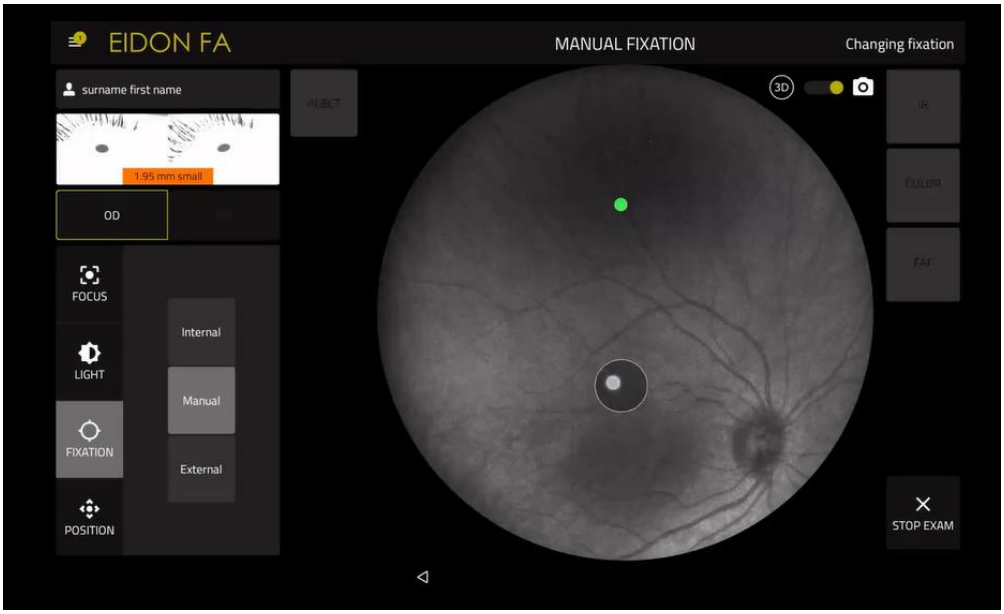


Fig. 35 – Exam screen in manual mode with displaced fixation target

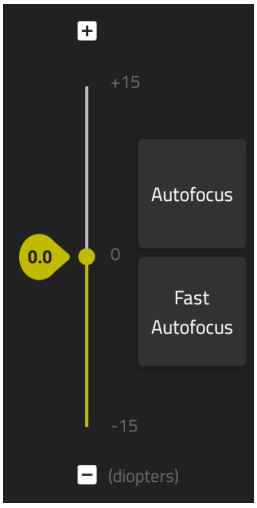
8.12.2 Manual Fixation and Focus

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 FA will stop after

[3] Provided the subject is able to fixate

completing step a described at par. 8.11 and display a live infrared image of the retina and the fixation target, waiting for operator'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)

The panel includes also a slider to set the exposure value, as described in the previous chapters.

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 digital joystick provided with the system. This mode is the most complex to use and requires some experience in the use of manually controlled imaging systems.

EIDON FA 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 operator's intervention (see Fig. 38). First bring the retinal blob to the center, using the joystick for alignment in the vertical and horizontal directions as explained in Fig. 37. Once the retina is centered, rotate the 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. 36 – Joystick

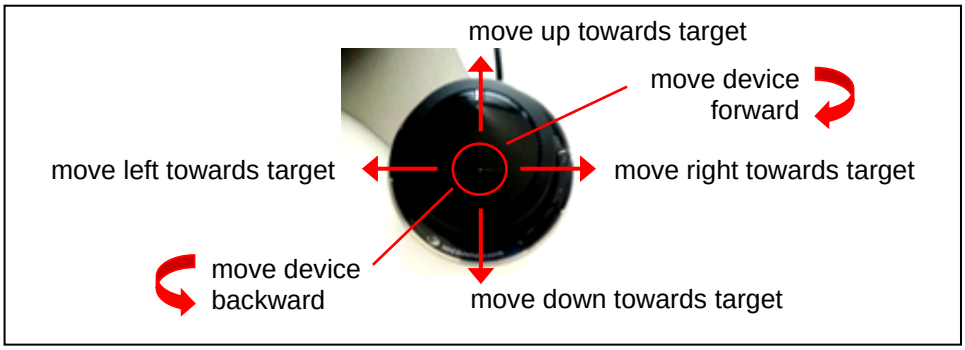


Fig. 37 – Joystick, top view

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.

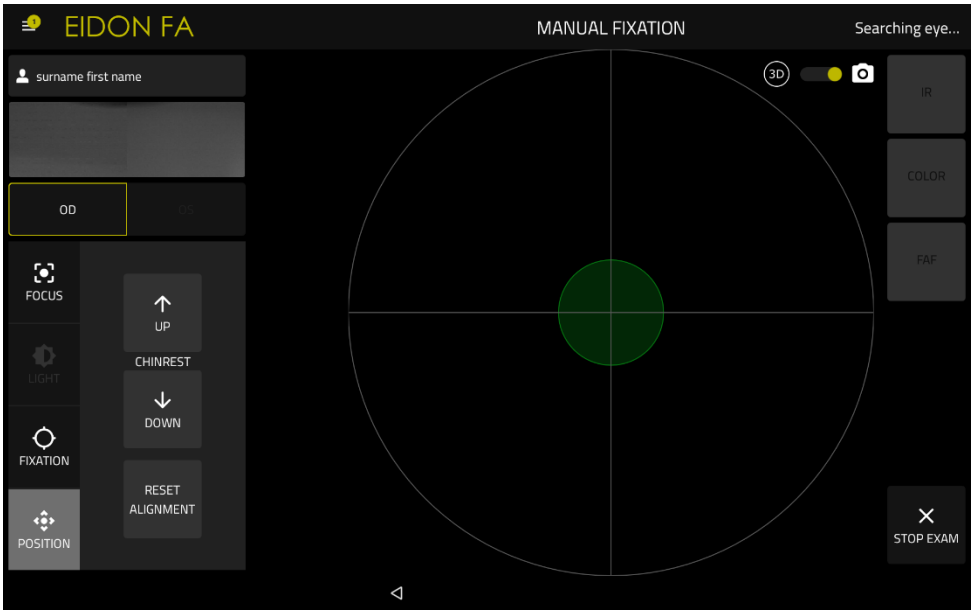


Fig. 38 – Exam screen in manual mode when approaching eye

8.13 Fluorescein angiography (FA)

EIDON FA allows to perform fluorescein angiography, i.e. to capture images and videos of the retina, following intravenous injection of fluorescein.

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 the scope of this manual.

Any fluorescein angiography session involves the following steps:

- patient preparation
- pre-injection phase
- fluorescein injection / recording of early, intermediate and late phase.

There are no specific requirements for use of EIDON FA following 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 ophthalmologist 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 subject 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. 39) and select the target eye.

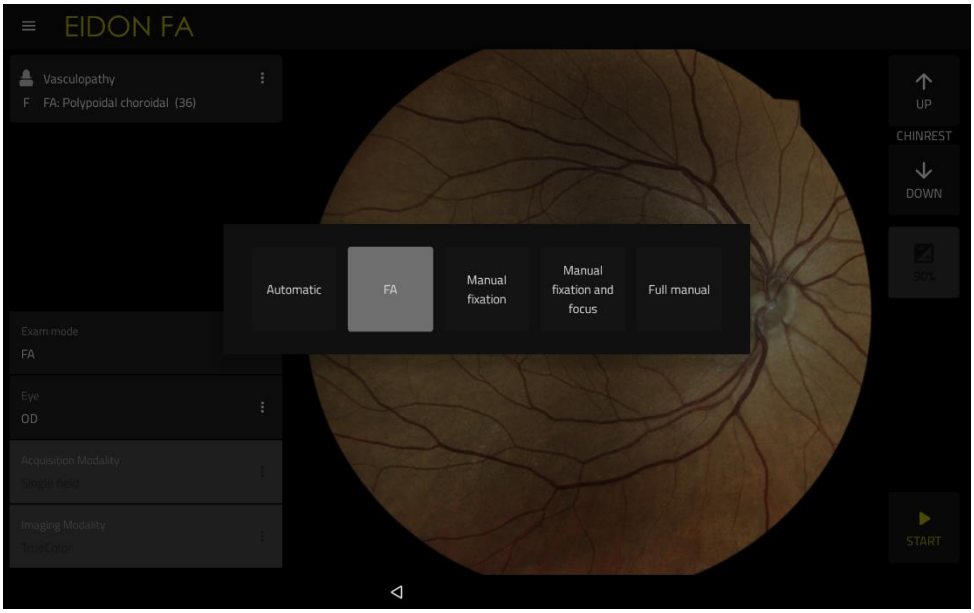


Fig. 39 – FA modality, selection in the new exam screen

Click on the right arrow to start the exam: the system will enter the pre-injection phase (see Fig. 40).

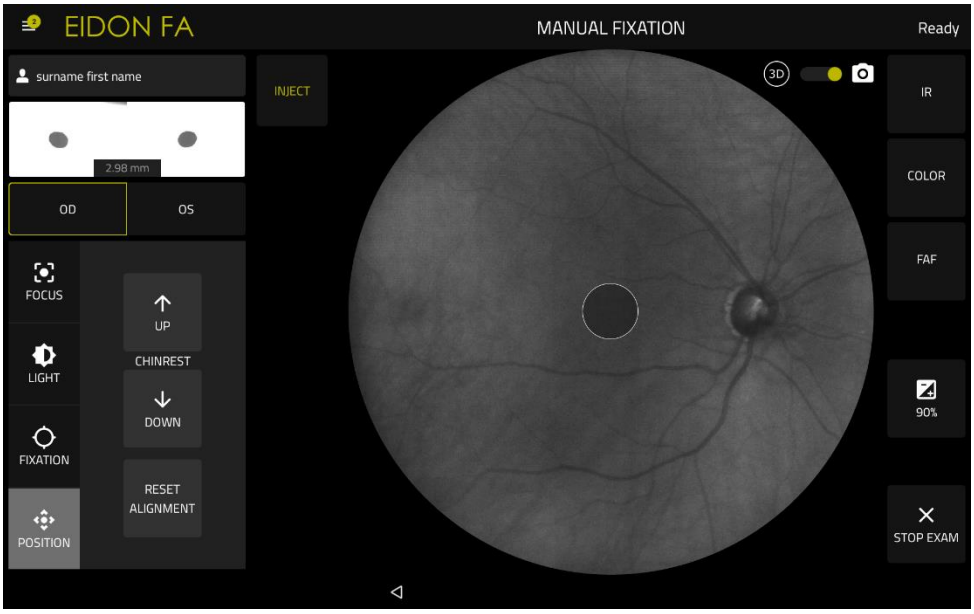
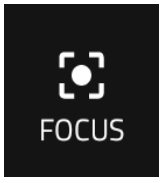
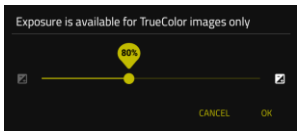
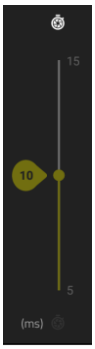


Fig. 40 – FA modality, pre-injection phase

The device aligns and focuses using the focus position calculated in the last picture acquired in the same day. If no picture 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 picture of the day for the patient selected (“N/A” in case no pictures 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)

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 (default changes in the different phases)
Raise chin rest		Adjust the height of the chin rest
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 front rest). In these cases, if message "eye not found" or "pupils not reachable" appears: •Press Reset Alignment •The device automatically returns to 'Search eye position' •In this moment, 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 color images

Function	Command	Description
Capture Autofluorescence		Capture single or stereo autofluorescence images
Interrupt the FA session		Interrupt the FA session and go back to the patient page: 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 picture just acquired will be shown in the bottom left part of the picture. 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. 41).

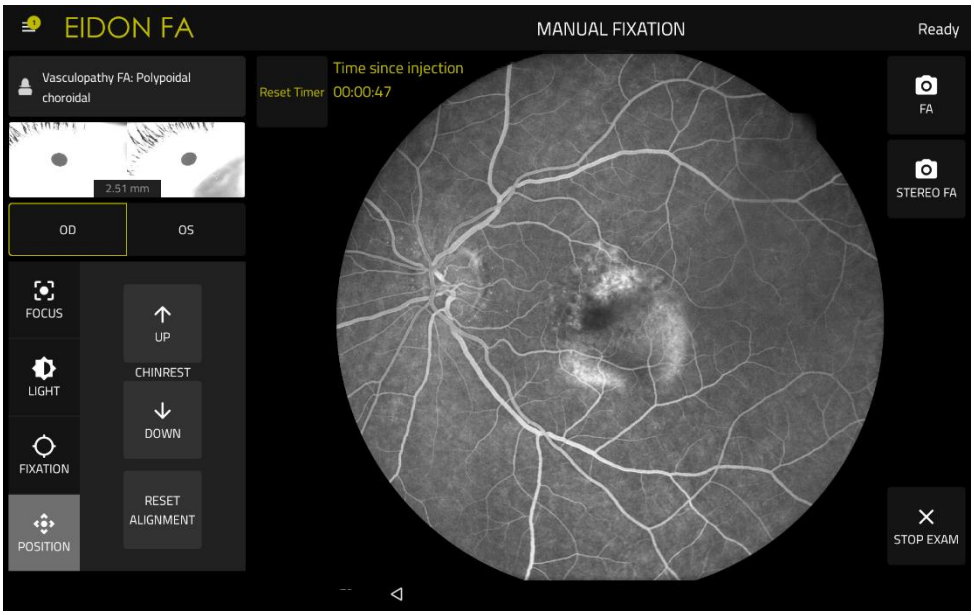
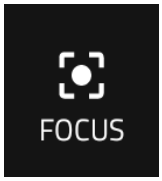
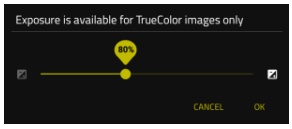
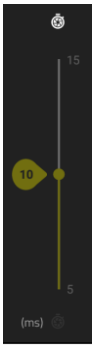


Fig. 41 – FA mode, post-injection phase

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 picture of the day for the patient selected (“N/A” if no pictures acquired).
Switch eye		Align to the other eye, then autofocus. If the patient hasn’t any focus position stored for the new eye, the device performs an autofocus.
Switch live illumination		Toggle among: • live infrared (IR) imaging, 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, 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
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
Lower chin rest		

Function	Command	Description
Move fixation		Slide the inner circle to move the internal fixation target / change the framed field
Start video acquisition		Start FA video capture[4]. 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 picture		Manually trigger single FA image acquisition or FA stereo pair[5] (only available when no FA video is being recorded)
Capture AF picture		Manually trigger single AF image acquisition or AF stereo pair[5] (only available in live infrared)
Capture IR picture		Manually trigger single IR image acquisition or IR stereo pair[5] (only available in live infrared)
Capture Color picture		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. 19), identify and select the patient for whom you want to resume the FA session and click on “resume FA session” (see Fig. 42).

[4] Image resolution 1840 x 1644 @ 5 frames per second

[5] Image resolution 3680 x 3288

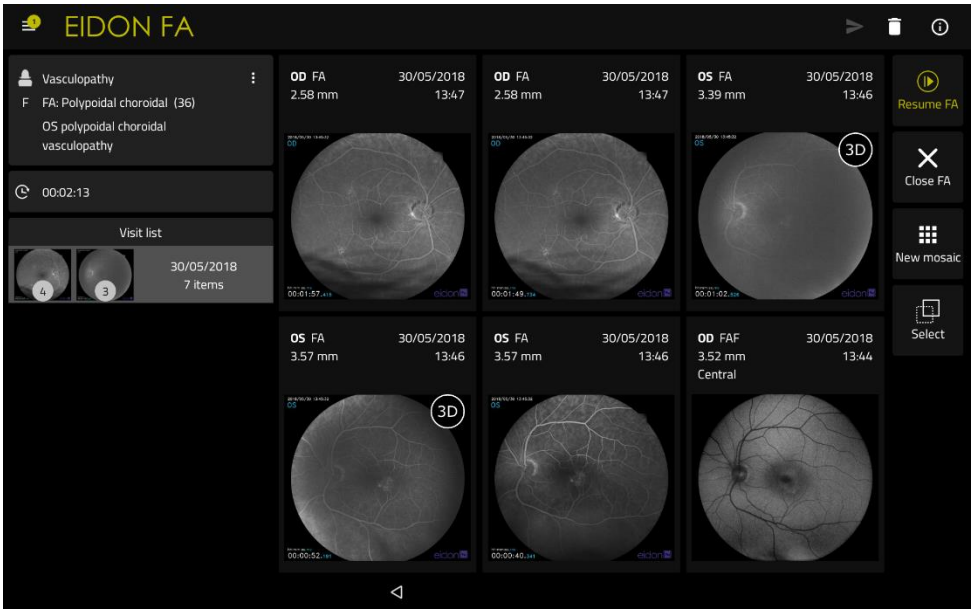


Fig. 42 – Patient Record screen for patient with an active FA session

8.13.5 Active FA sessions list

The patient list screen (see Fig. 19) 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” logo 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.

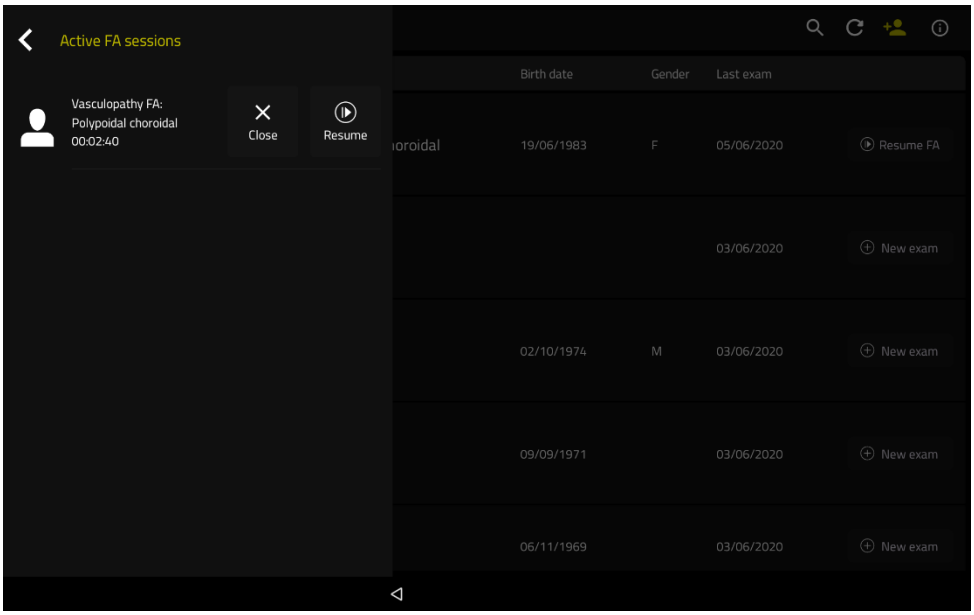


Fig. 43 – FA session bar

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”.

The panel is available when in the patients list or in the patient details pages.

8.14 Image retake

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

To retake a picture, 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. By clicking on this button, an automatic exam starts, with the same parameters as the picture to be retaken (same eye, same field). After retaking, the software will ask to keep the old picture , replace it with the new one or keep both.

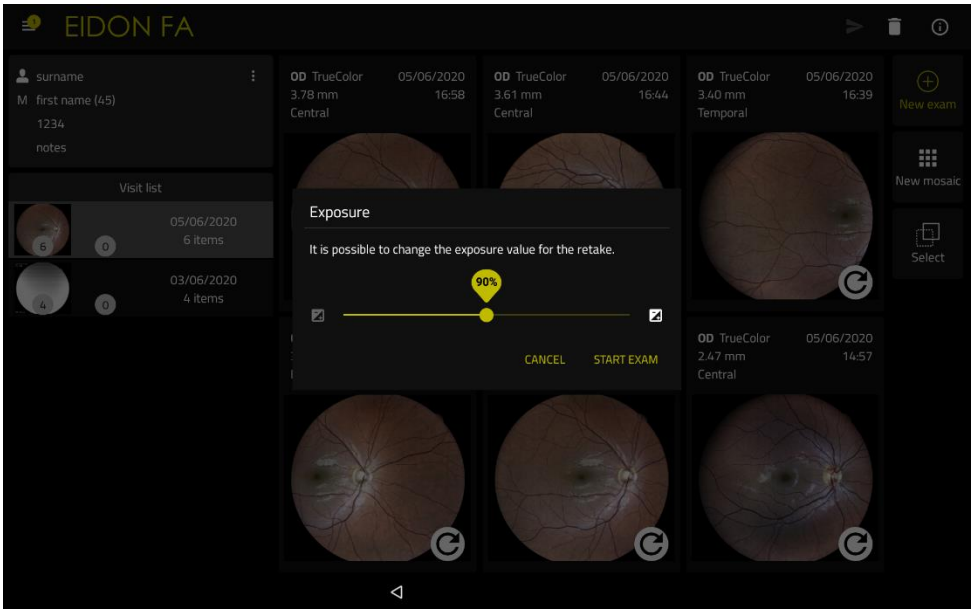


Fig. 44 – Image ready to be retaken

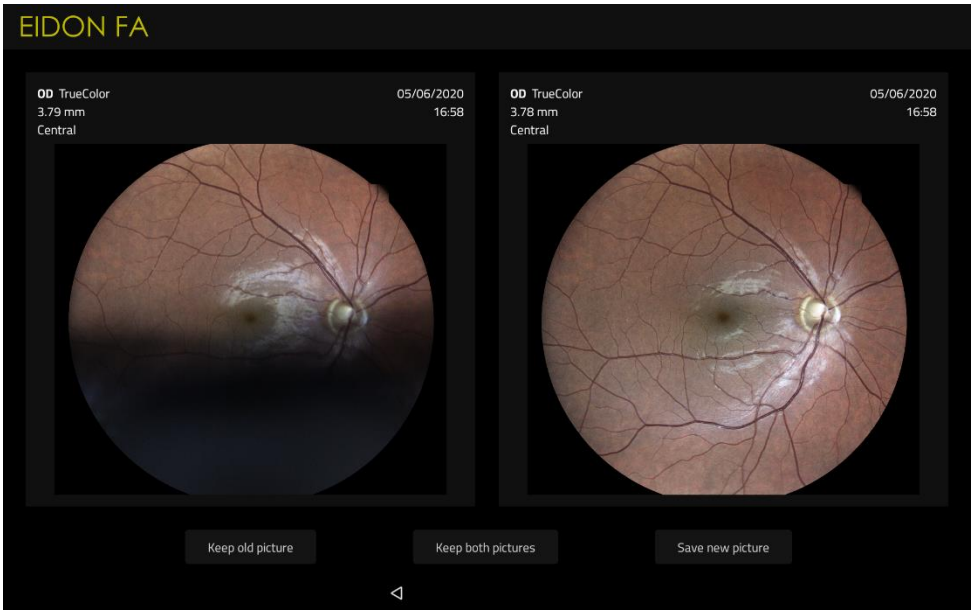
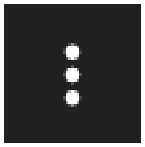
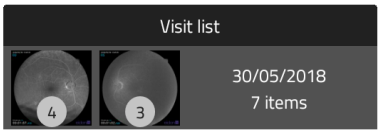


Fig. 45 – Image retaken: choose which picture to keep

9. REVIEWING IMAGES

The **Patient Record** screen (see Fig. 26) presents all patient related information and a thumbnail view of all 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 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 of 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.

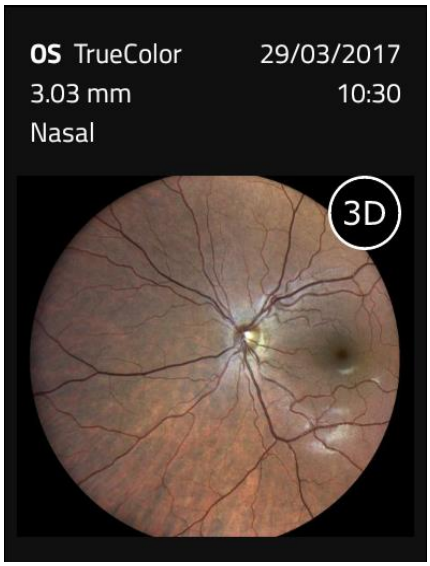


Fig. 46 – Example of thumbnail with 3D logo

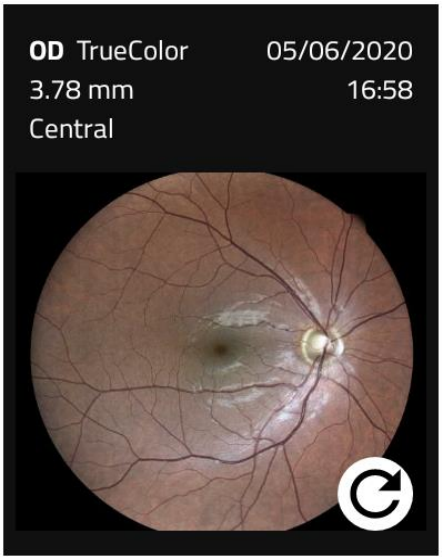


Fig. 47 – Example of thumbnail with retake logo

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. 48 and Fig. 49).

EIDON FA acquires and stores True Color images. Nevertheless, every operator can choose to modify the acquired 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 pictures by applying one of *the Red, Red+, Red++ color filters: press the button with the name of current setting (True Color in Fig. 48) 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 app 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 picture is available by selecting the Green channel

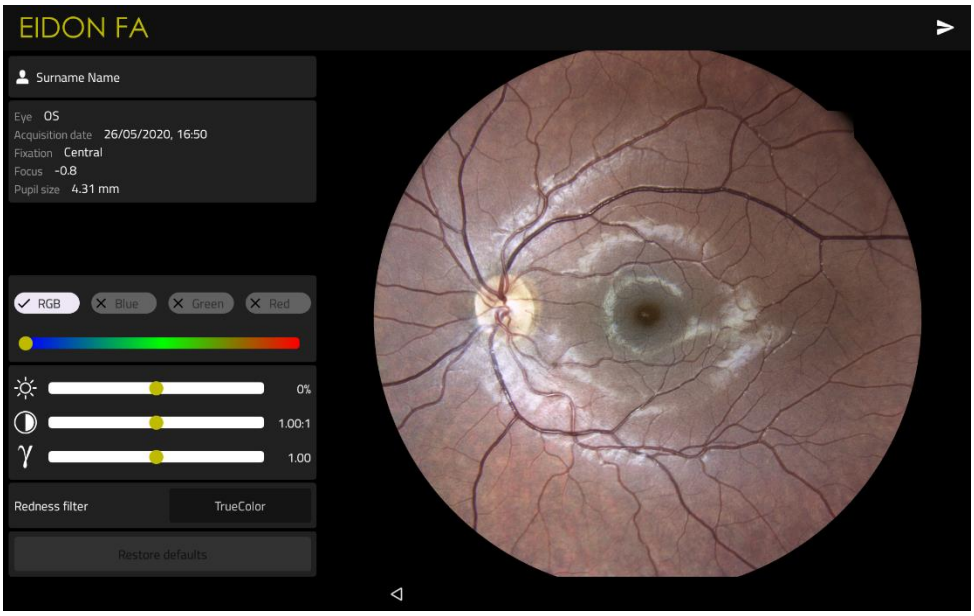


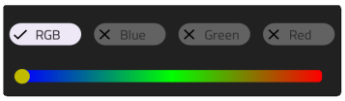
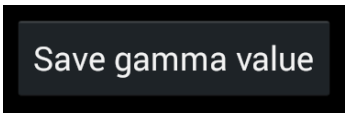
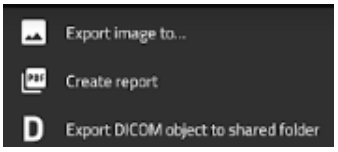
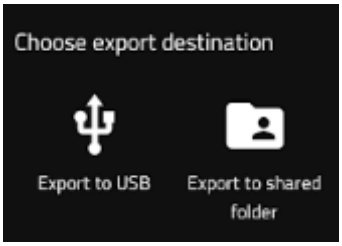
Fig. 48 – Exam review screen, color image

Fig. 49 – Exam review screen, FA image

The screen displays the following information:

Fig. 50 – Picture information

The following functions / commands are available:

Function	Command	Description
Open full screen view, zoom, pan	Click on the 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 **Error! Reference source not found.** for more information)
~~Save gamma value~~		~~Store the image's gamma in the database.~~ ~~**This correction does not alter the original image**~~
Export icon		Allows to export your data. The button open the export menu where operator 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 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 pairs
Back		Used to return to the Patient Record screen

EIDON FA 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 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. 51 – 3D review window

Wear the prismatic goggles and move forward or backward to the image until you see a single 3D picture. If you see elevations instead of cavities, press the  logo on the window top right corner.

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. 26). Click on the thumbnail to review the video (see Fig. 52).

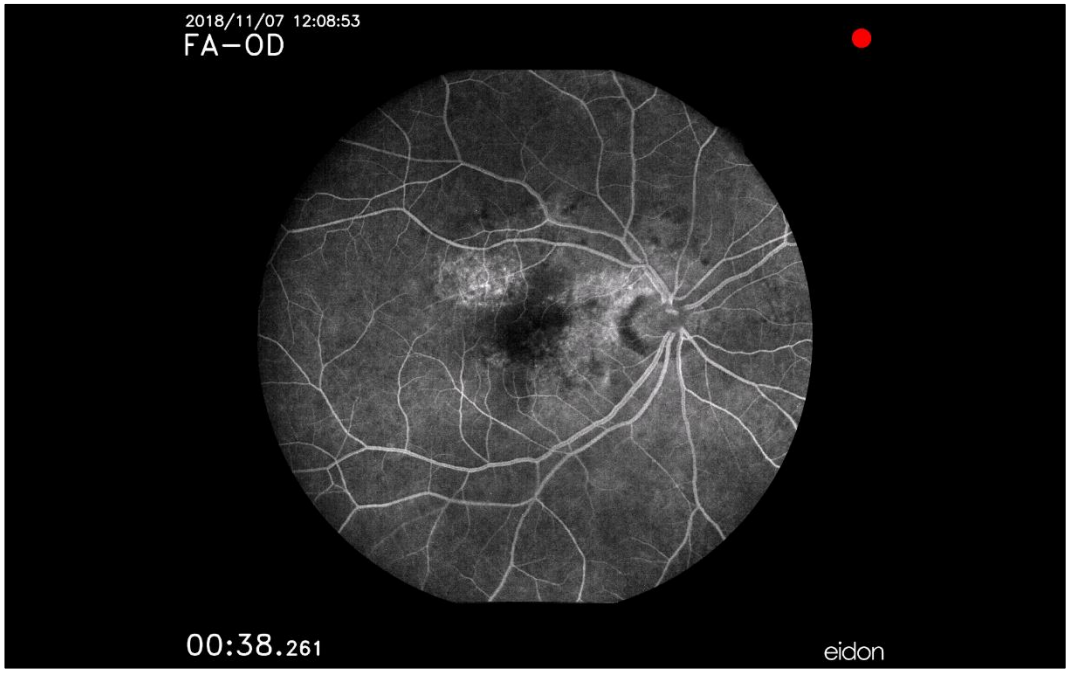


Fig. 52 – FA Video review screen

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 FA allows to merge multiple, partially overlapping, fields of the same retina, to obtain a wider image. The new picture generated is called **mosaic**.

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

Fig. 53 – Example of a 3-fields mosaic image generated by EIDON FA

Clicking on the **mosaic** button in the **Patient Record** screen (see Fig. 26), the **Field selection** screen opens (Fig. 54). Press on the images to be composed into a mosaic; when all fields are selected, click on the **Create Mosaic** button.

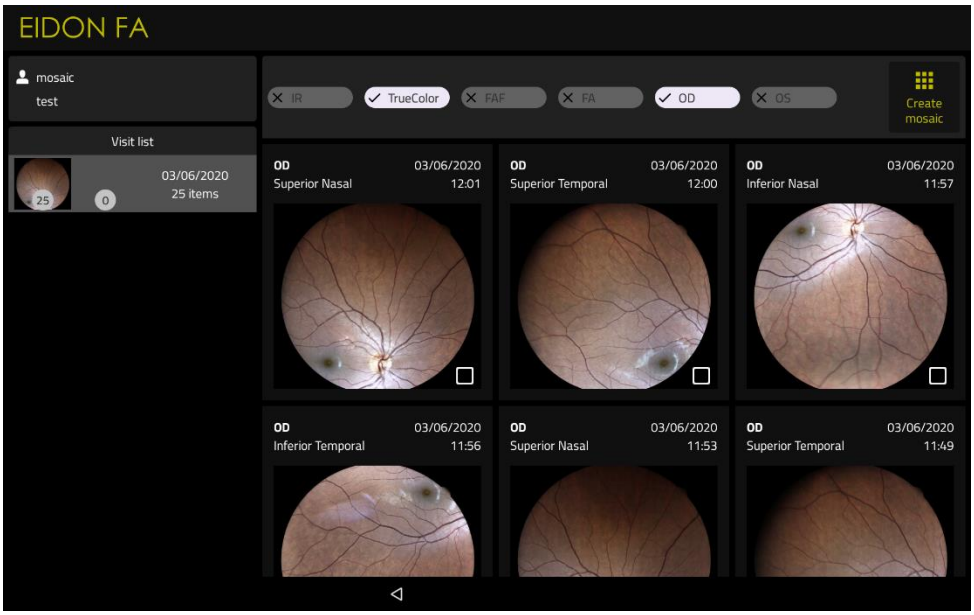


Fig. 54 – Field selection screen

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 FA cannot be used while mosaic generation is in progress.

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

Deleting an 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.

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[6] side by side, press and hold on the thumbnail of the first image until the image is selected (highlighted border); do the same for the second image.

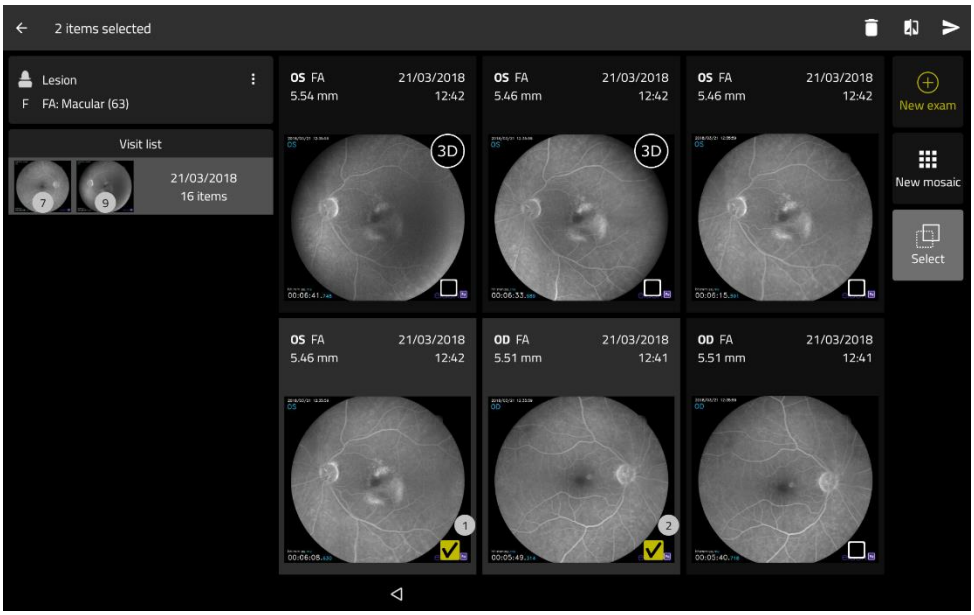


Fig. 55 – Dual image selection

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. 56).
To use image enhancement filters, swipe from the left of the screen or click the EIDON FA logo (see Fig. 57).

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

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

Fig. 57 – 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 on the top right screen corner.

9.6 HypoAF Boost feature

EIDON FA includes a feature called **HypoAF Boost** which enhances the low autofluorescence signals from the image. The HypoAF Boost shall be applied only to autofluorescence images.

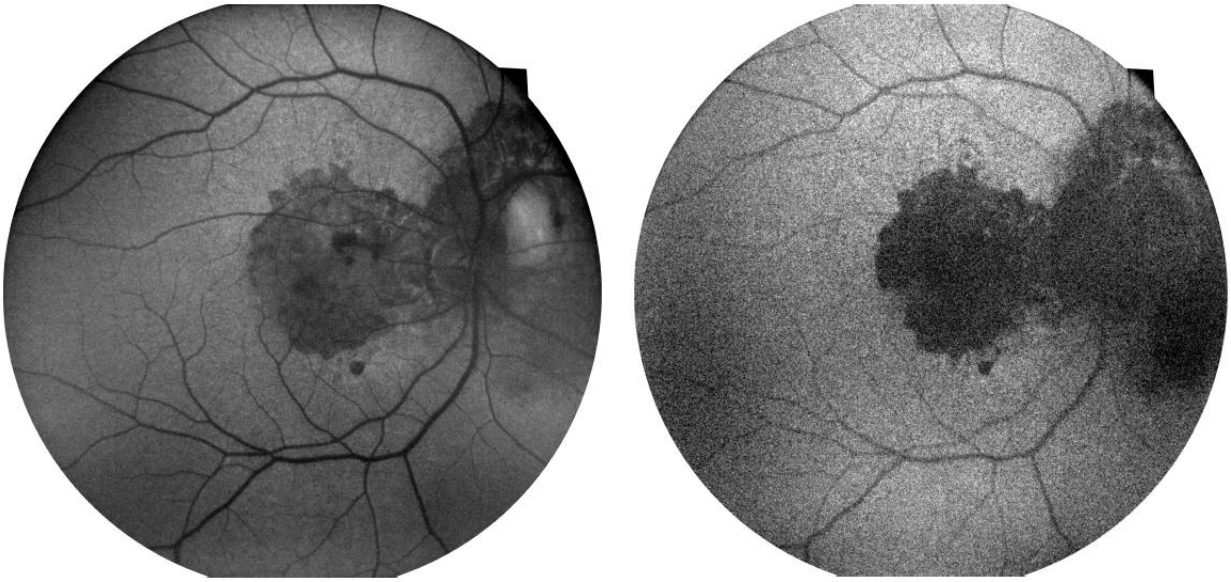


Fig. 58 – Example of AF picture before (left) and after (right) the application of HypoAF Boost

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 FA 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 EIDON FA 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 status** screen. For additional information on the Device status screen, 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 FA 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

The Remote Viewer is a browser-based software that allows the review of EIDON FA images on any computer connected to EIDON FA 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, EIDON FA 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 EIDON FA to the local network by plugging the network cable to the Ethernet port located on the back of the system (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 EIDON FA unit
- *domain* is the local network domain name (or ".local")

This will open the login screen.

If you cannot retrieve the network domain name or if the network is using static IPs and not DHCP, you can retrieve the EIDON FA IP as follows:
- launch the Configurator application (see par.12.1);
- click on the "NETWORK" tab (see Fig. 78);
- 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. 59), which resembles the corresponding screen in the EIDON FA on-board software.

The Remote Viewer session is automatically closed after 20 minutes of inactivity (no browsing, no downloading of pictures 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.

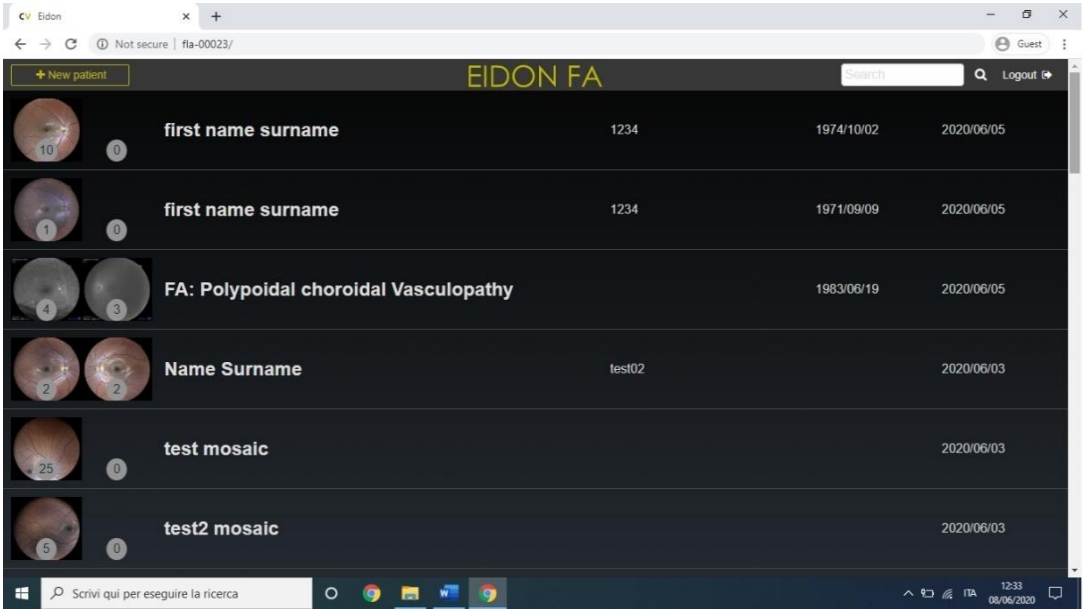


Fig. 59 – Patient List in Remote Viewer

Click on the desired patient to enter the **Patient Record** screen (see Fig. 60), which resembles the corresponding screen in the EIDON FA 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 on-board software. Click on **Dual Printout** to select two images to be printed in a single sheet (Fig. 61). Click on the desired image to enter the **Single Image review** screen (see Fig. 62).

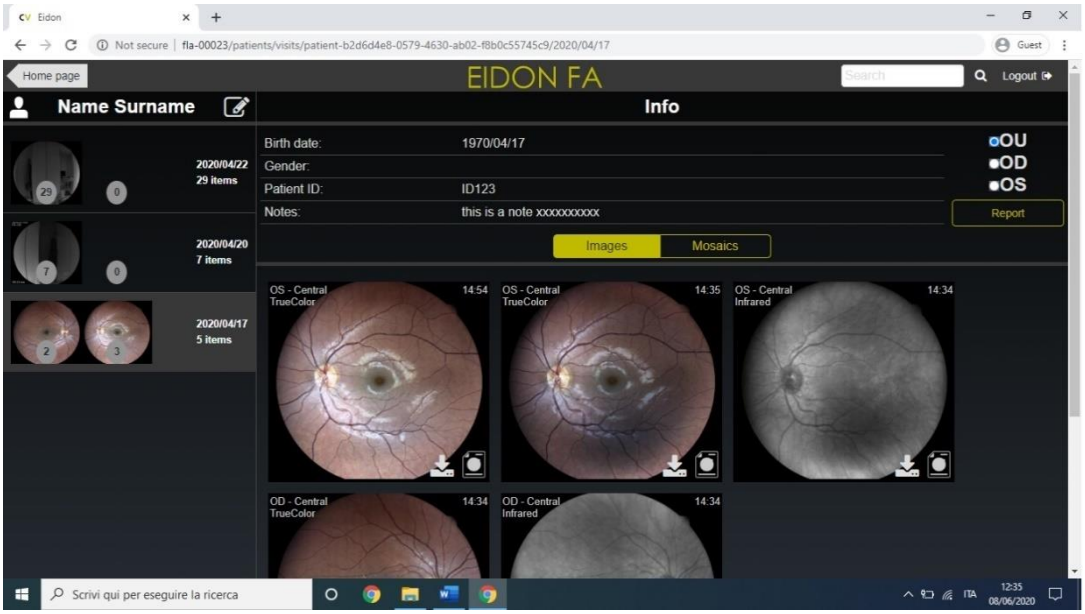


Fig. 60 – Patient Record screen in Remote Viewer

Fig. 61 – Dual printout image selection

9.8.5 Single Image review screen

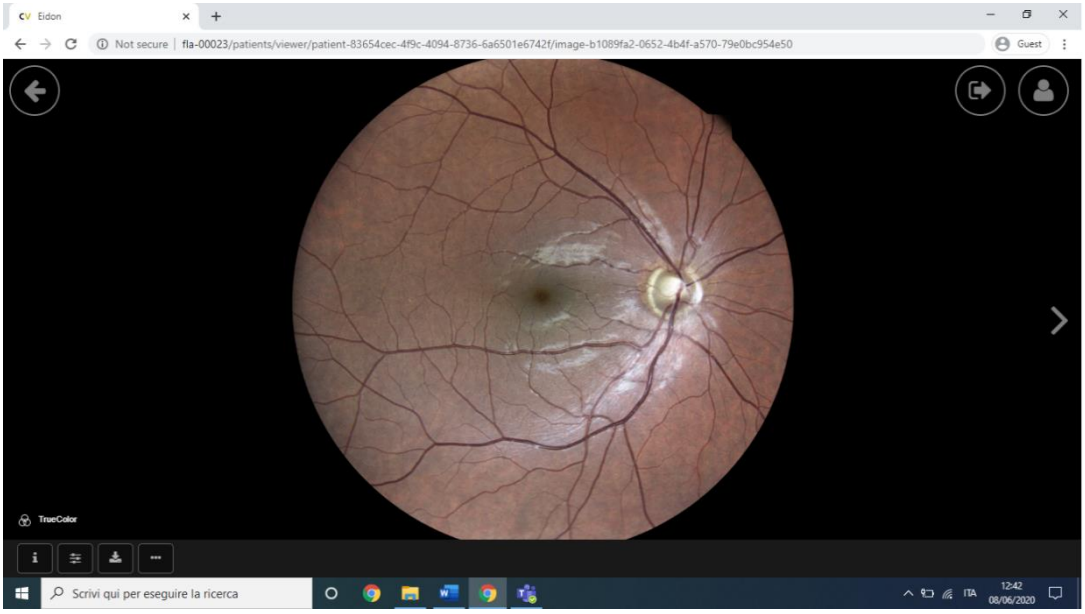


Fig. 62 – Single Image Review screen in Remote Viewer

The following functions are available in this screen:

Function	Command	Description
Previous / Next		Shows previous / next image
Back		Back to Patient Record Screen
Logout		Logout from the Remote Viewer

Function	Command	Description
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. 66).
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. 64): - 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. 64) or dual printout (a new window opens when selecting dual printout: see Fig. 65).
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

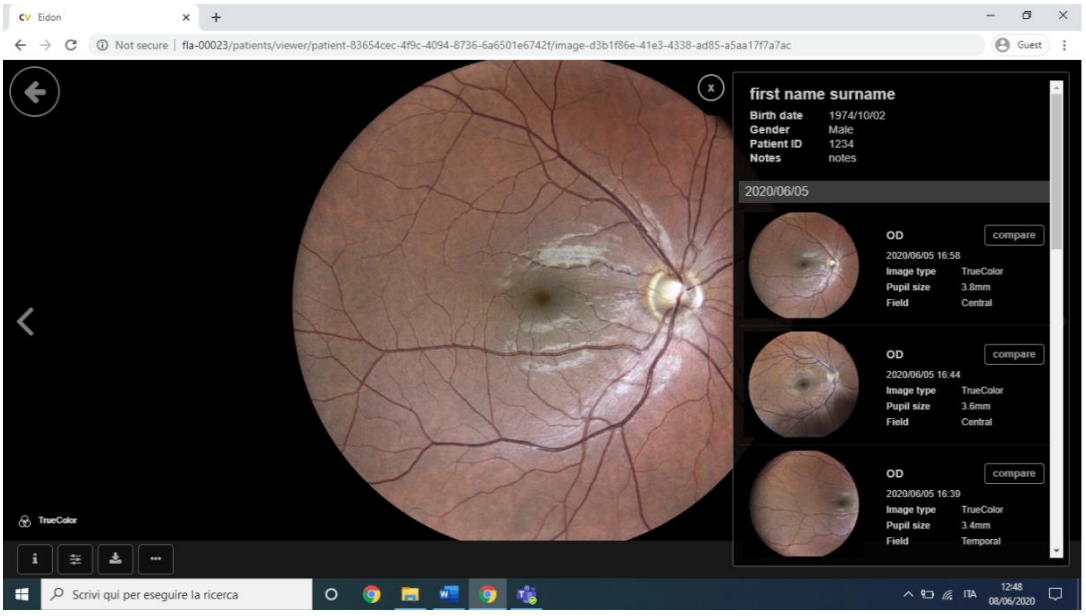


Fig. 63 – Patient Info window

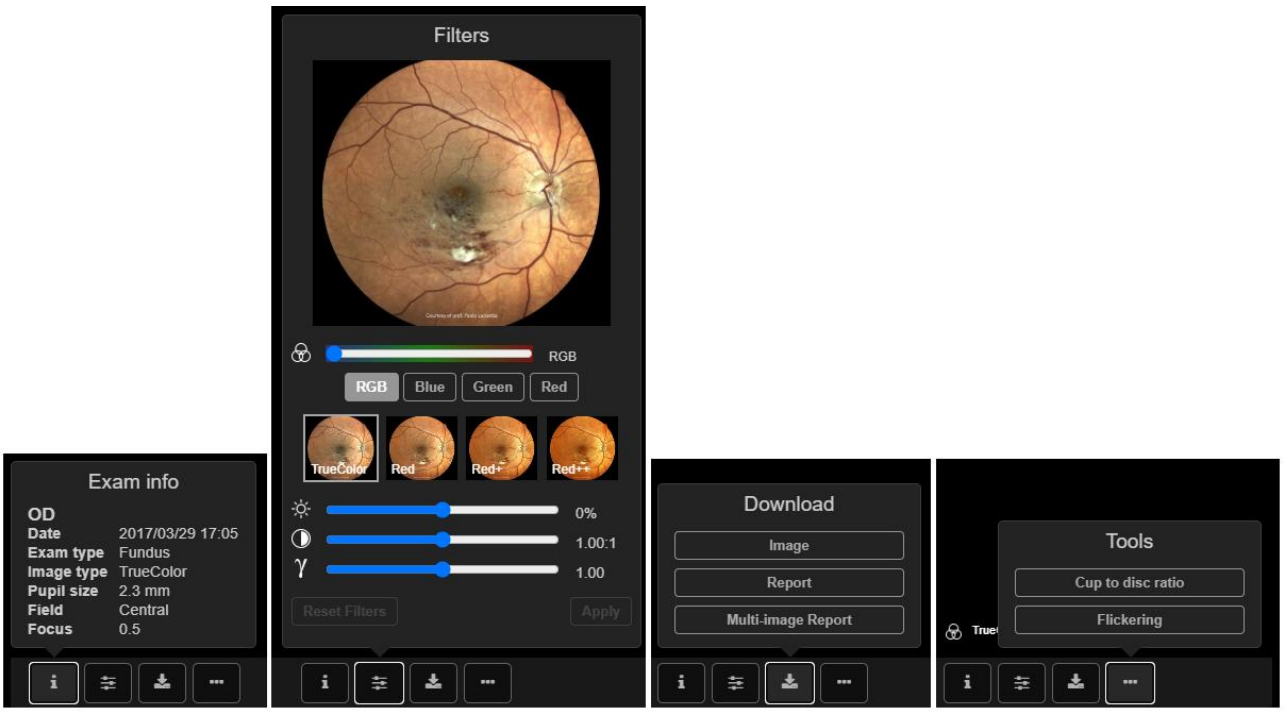


Fig. 64 – *Image Filters*, *Download* options and *More Tools* in Remote Viewer

The image tools do not alter the original image.

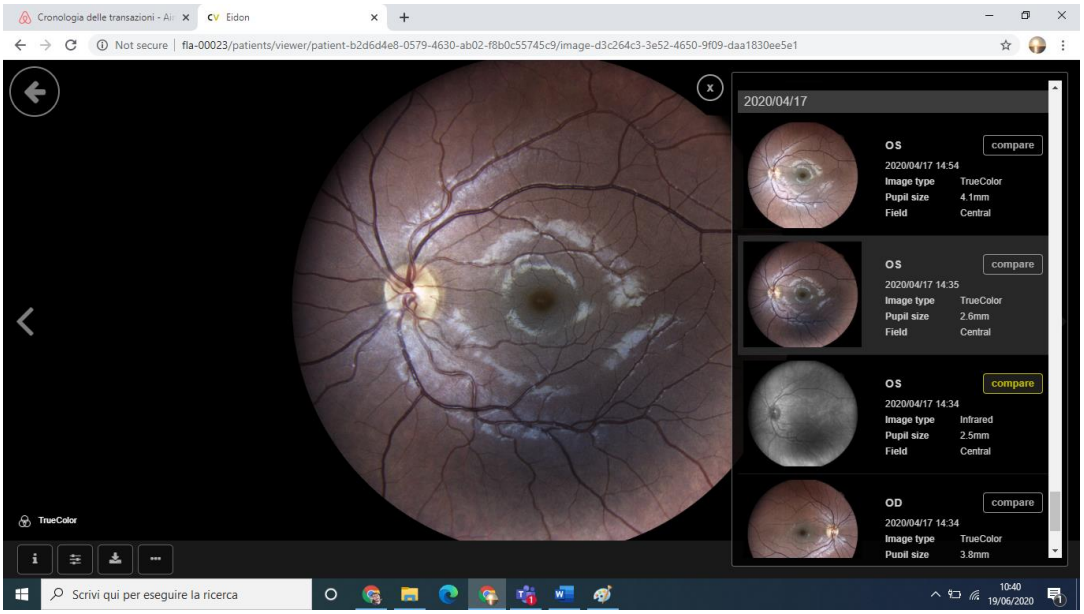


Fig. 65 – Image selection for dual printout, from the single review screen

9.8.6 Dual Image review screen

As for the EIDON FA on-board 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.

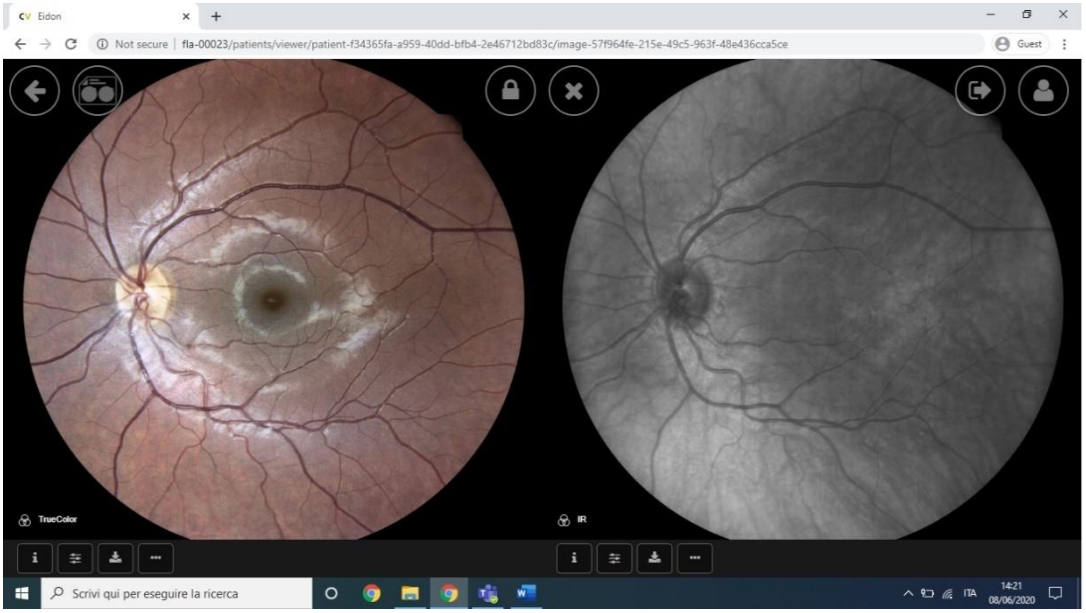


Fig. 66 – Dual Image Review screen in Remote Viewer

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.

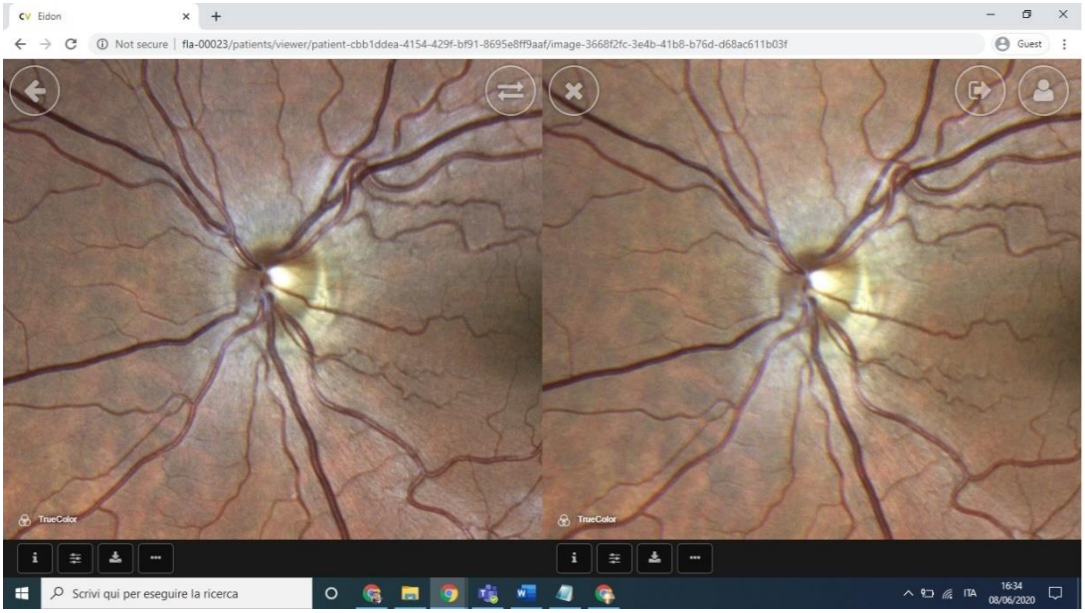


Fig. 67 – Stereo review window

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 FA allows to compare two images one by one, by manually or automatically toggling between them. This feature is called **flickering** (Chiang, et al., 2011) (Syed, et al., 2012) (VanderBeek, Smith, & Radcliffe, 2010). 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 FA software will show a window with all the pictures available for flickering (i.e. all of the Color, IR or AF pictures, of the same patient and same eye).

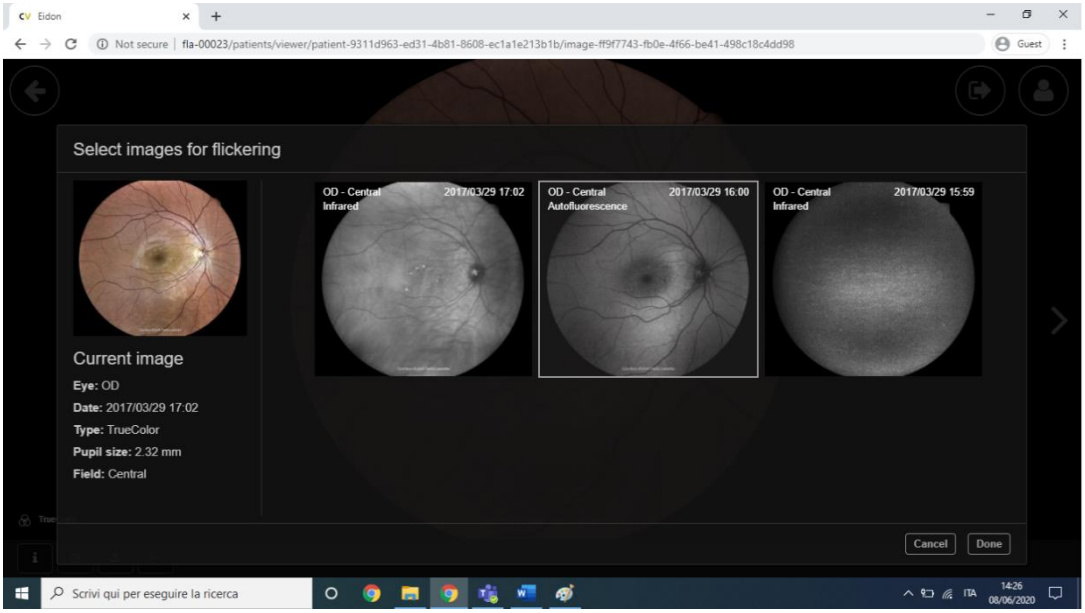


Fig. 68 – Flickering image selection

Select the image to flicker with, then click Done.

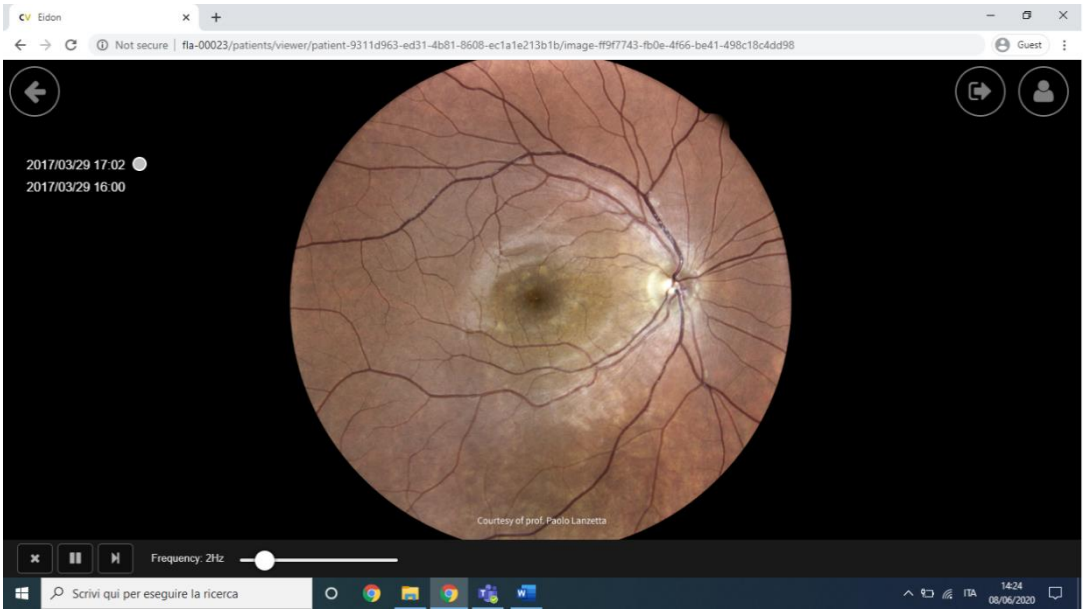
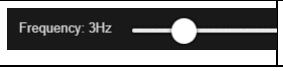


Fig. 69 – Flickering review window

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

The following features 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 picture to start the first segment drawing, then click to define the end. Do the same for the second diameter. The segments can be modified by clicking and dragging the segment endpoints.

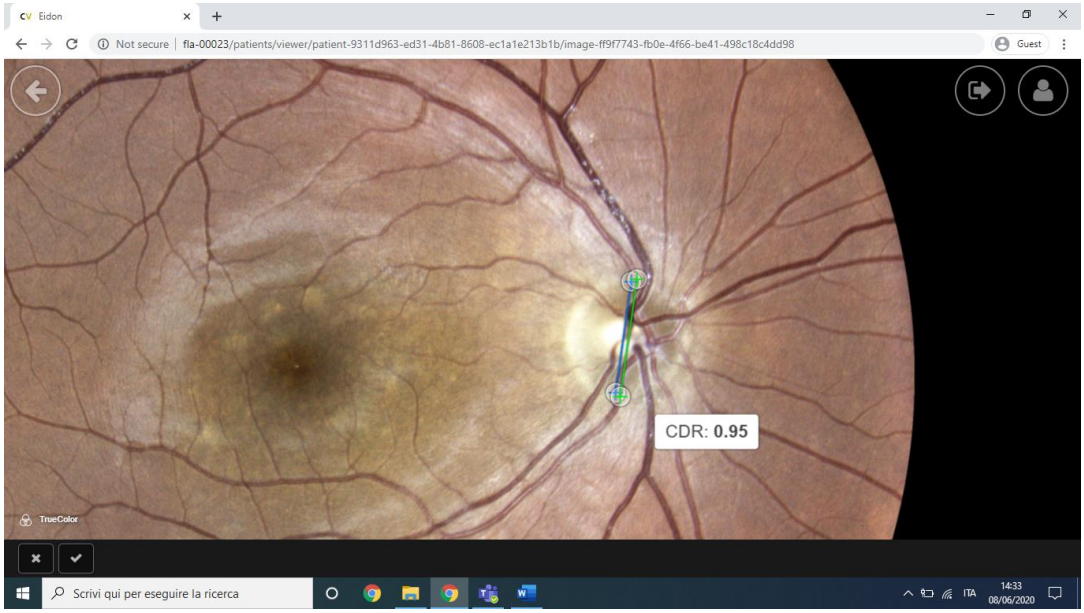


Fig. 70 – Flickering review window

The following buttons 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 FA 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 operator. The clinical interpretation of the CDR obtained with EIDON FA is the responsibility of the eye care practitioner.

9.8.10 Video Review

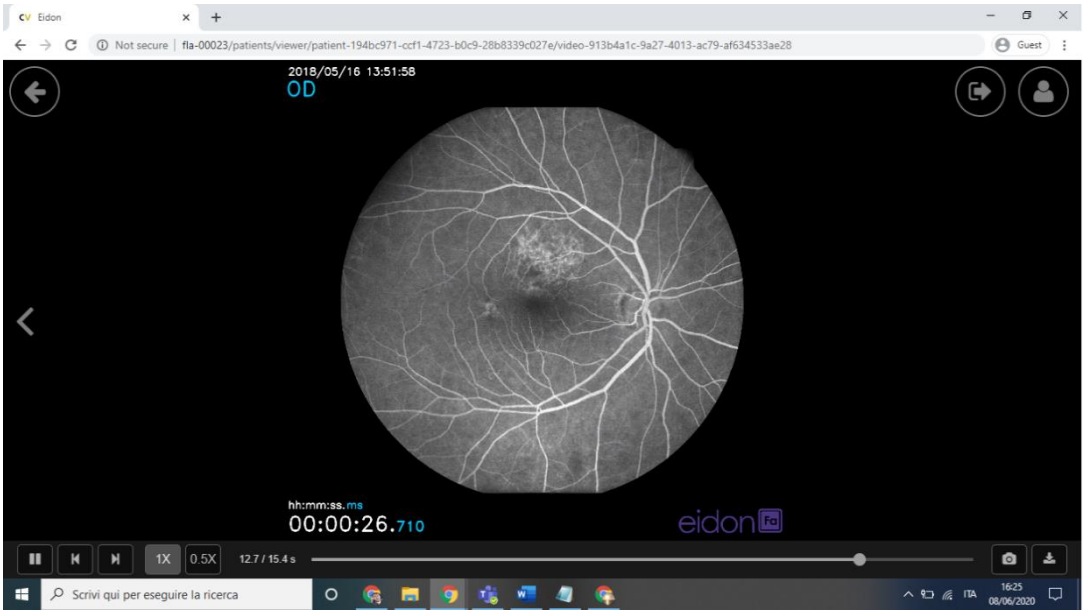
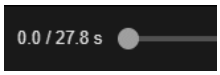


Fig. 71 – Video review window

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

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 FA supports full DICOM communication, as specified in the **EIDON FA DICOM Conformance Statement** document. This feature requires dedicated license.

For information about DICOM modality worklist and C-Store, see the **EIDON FA DICOM Operating Manual**.

11. PRINTING

11.1 Printer setup

EIDON FA supports wireless connection to most Android-compatible printers. Printing apps from the most common manufacturers come pre-installed into the EIDON FA tablet (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.

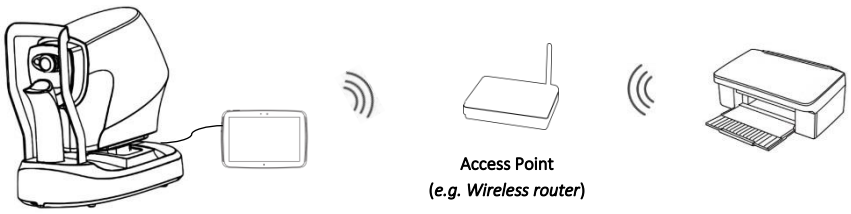
Brand	Description
HP	HP Android ePrint
Samsung	Samsung Mobile Print App
Lexmark	Lexmark Mobile Printing
Canon	Canon Mobile Printing, Canon Easy-PhotoPrint, PIXMA/MAXIFY PrintingSolutions
Epson	Epson iPrint, Seiko Epson Corporation
Konica Minolta	Konica Minolta Printers, Page Scope Mobile

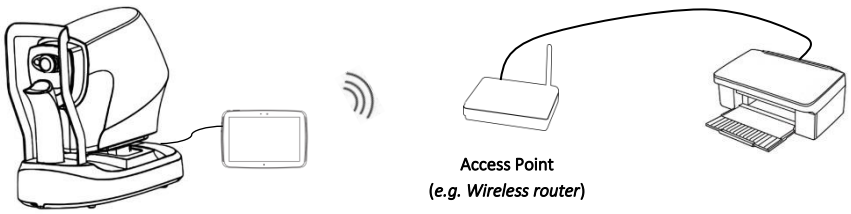
Table 3: Printing apps

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

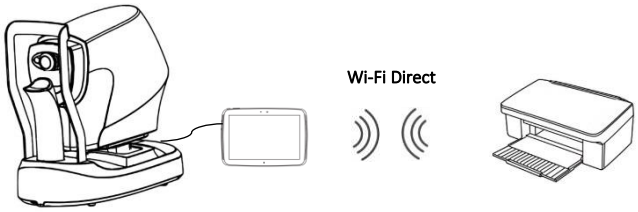
In this configuration, both the EIDON FA tablet and the printer are connected to an Access Point, such as a wireless router: the printer should be connected to the Access Point either by cable or wireless.





10.1.2 Ad-hoc Mode

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



11.2 Printout

The EIDON FA printout (Fig. 72) 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 FA 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 figure XX allows to choose page orientation (portrait or landscape) and number of images per page. First Selected Image is displayed in the Top Left. The following selections are order to Right and Down. Each image contains the following data:

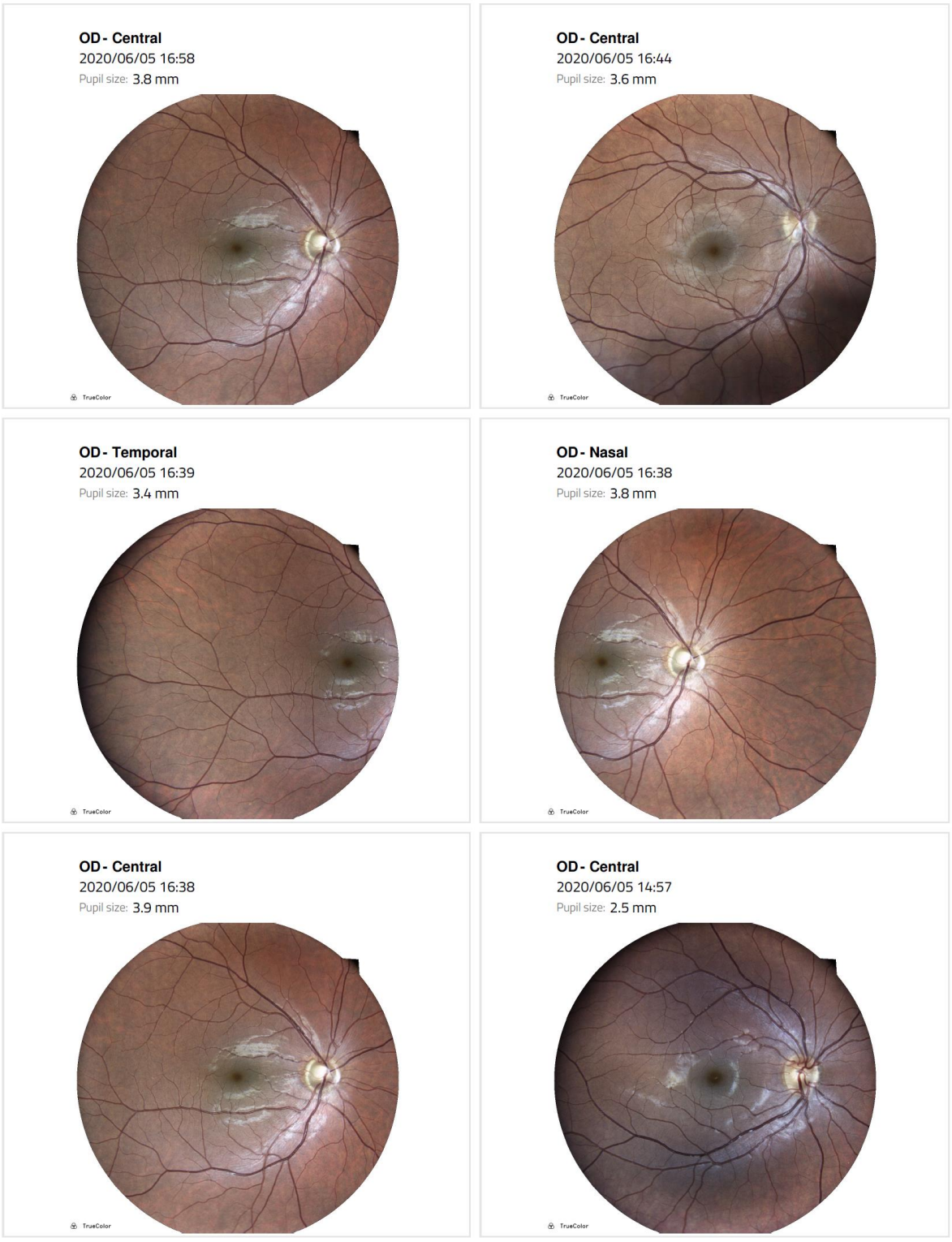
1. Examined eye (OD, OS)
2. Exam information (date, time)
3. Pupil size
4. Gamma, contrast and brightness correction (if applied)
5. Filtering values of the R, G, B channels (if filtering applied)
6. Captured field position (N.A. for pictures acquired in manual mode)
7. Cup-to-disc (if applied)

Icons description

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

Name: **surname, first name**
ID: 1234
Date of birth: 1974/10/02 Gender: Male

Notes: notes



Report date: 2020/06/08
Page: 1/1

Report device: EIDON s/n 00023
Software version: v2.0.0

centervue

Fig. 72 – Multi image printout with custom header

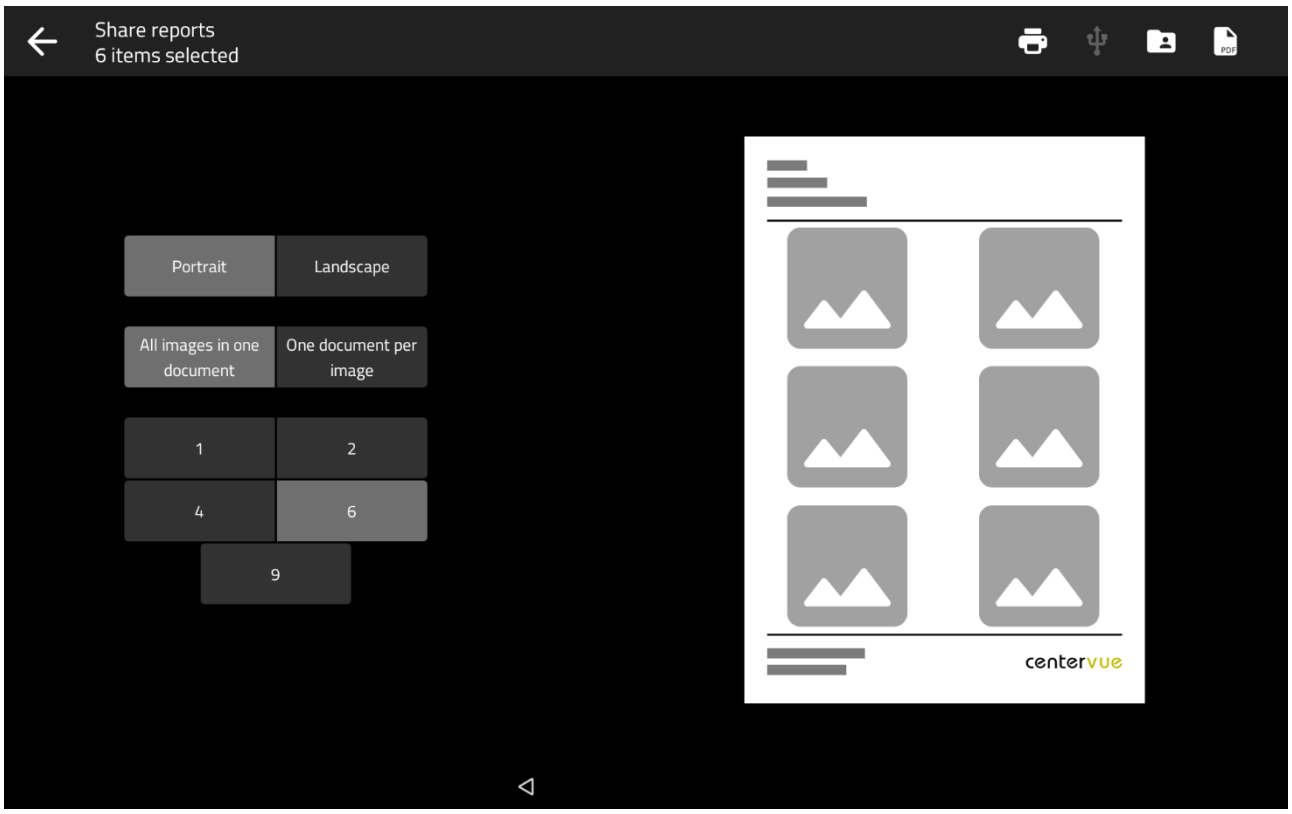


Fig. 73 – Report Configuration window

12. SETTINGS

EIDON FA 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 FA 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 FA will re-initialize. Upon completion of the re-initialization procedure it is possible to restart using EIDON FA 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.

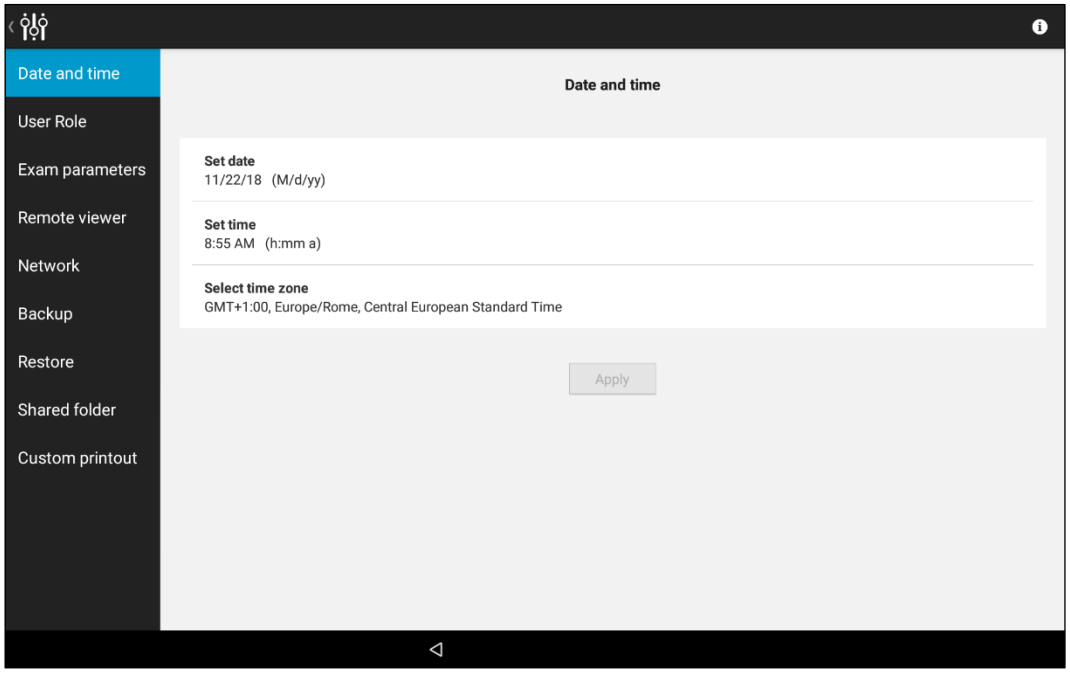


Fig. 74 – Configurator – Date time set

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. 75). 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 EIDON FA if the passwords are lost
- If both passwords are lost, or to reset the “Admin” password, contact your CenterVue Authorized Service Center for support.

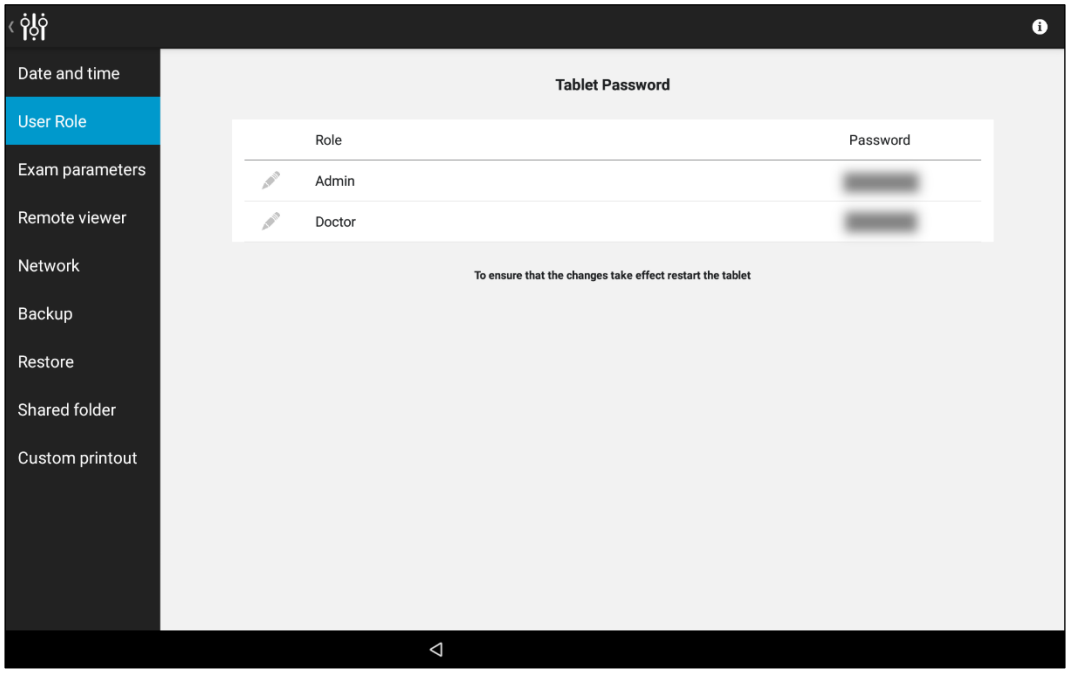


Fig. 75 – Configurator – USER ROLE screen

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 picture

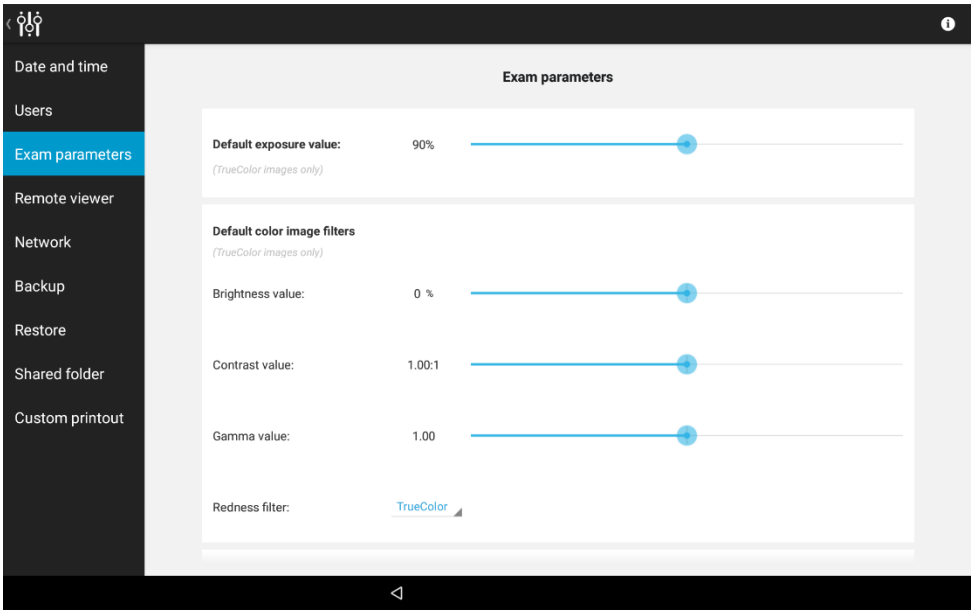


Fig. 76 – Configurator – EXAM PARAMETERS screen

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**.

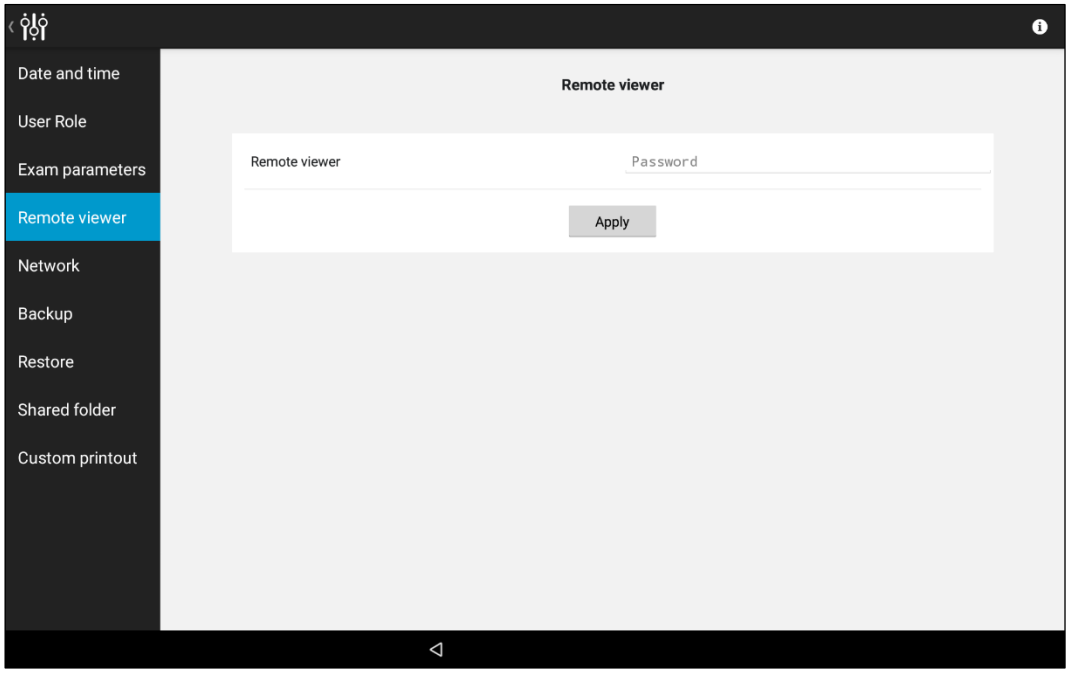


Fig. 77 – Configurator – REMOTE VIEWER screen

12.7 Network configuration

EIDON FA 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.

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

ℹ	The tablet Wi-Fi should be enabled to connect the EIDON FA to a wireless network.

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

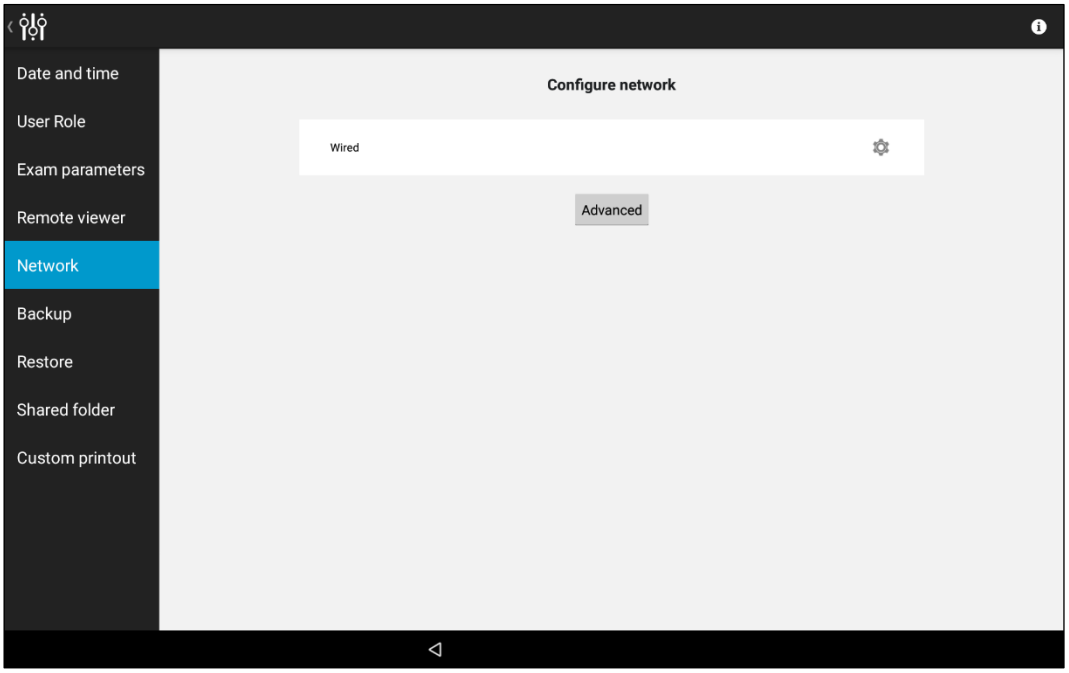


Fig. 78 – Configurator – NETWORK screen

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.

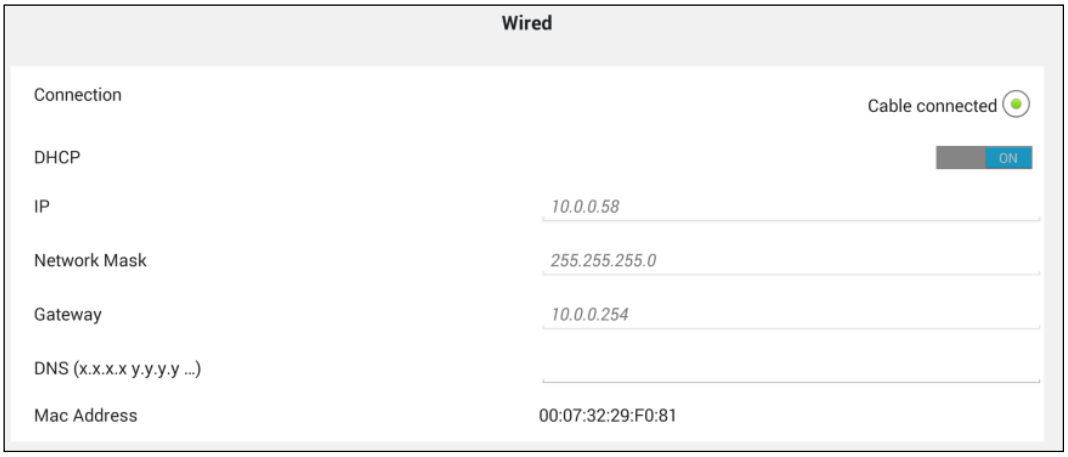


Fig. 79 – Configurator –Network configuration screen

The EIDON FA 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. 78): the following window appears.

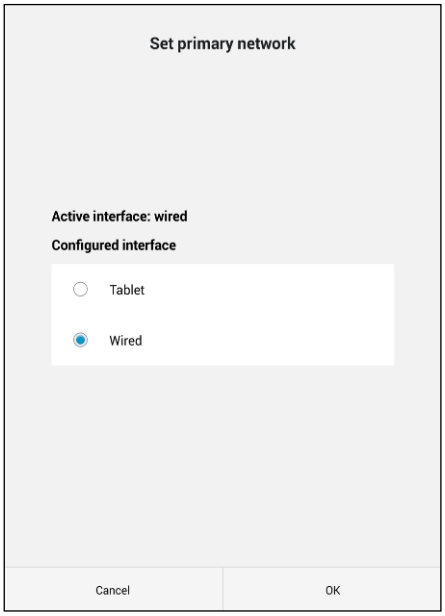


Fig. 80 – Primary Network settings

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 FA 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 FA will back up only the data added or modified since the last completed backup.
EIDON FA supports backup to more than one device media. Moreover, the same device media can be used as backup for different EIDON FAs.

	Although EIDON FA 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

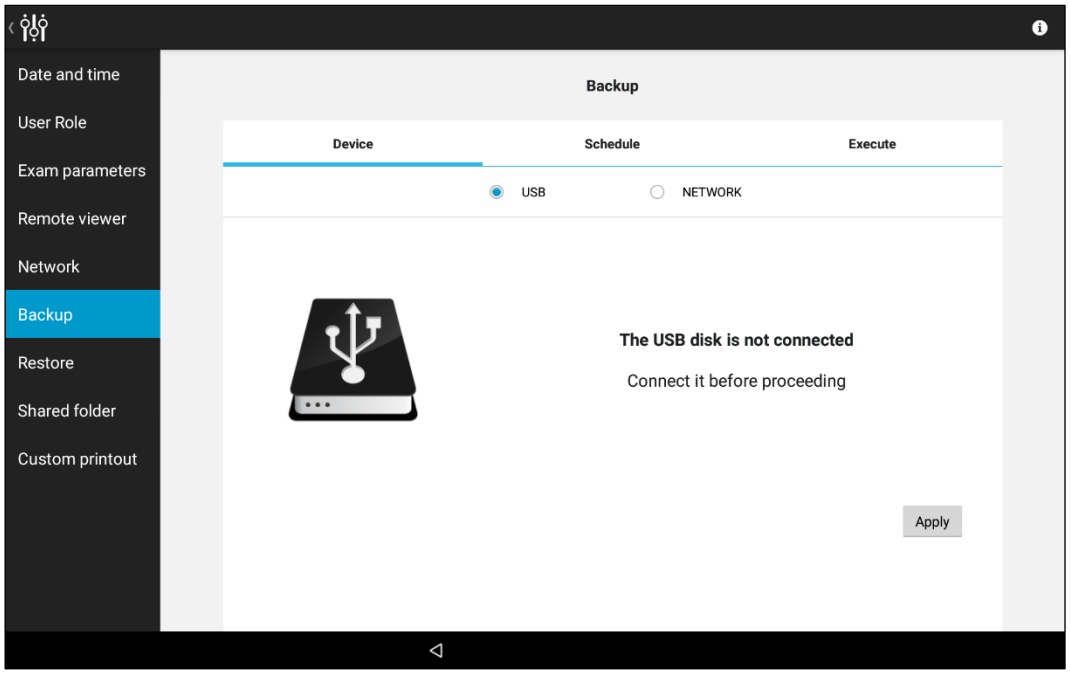


Fig. 81 – Configurator – BACKUP screen – USB-media backup selected

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

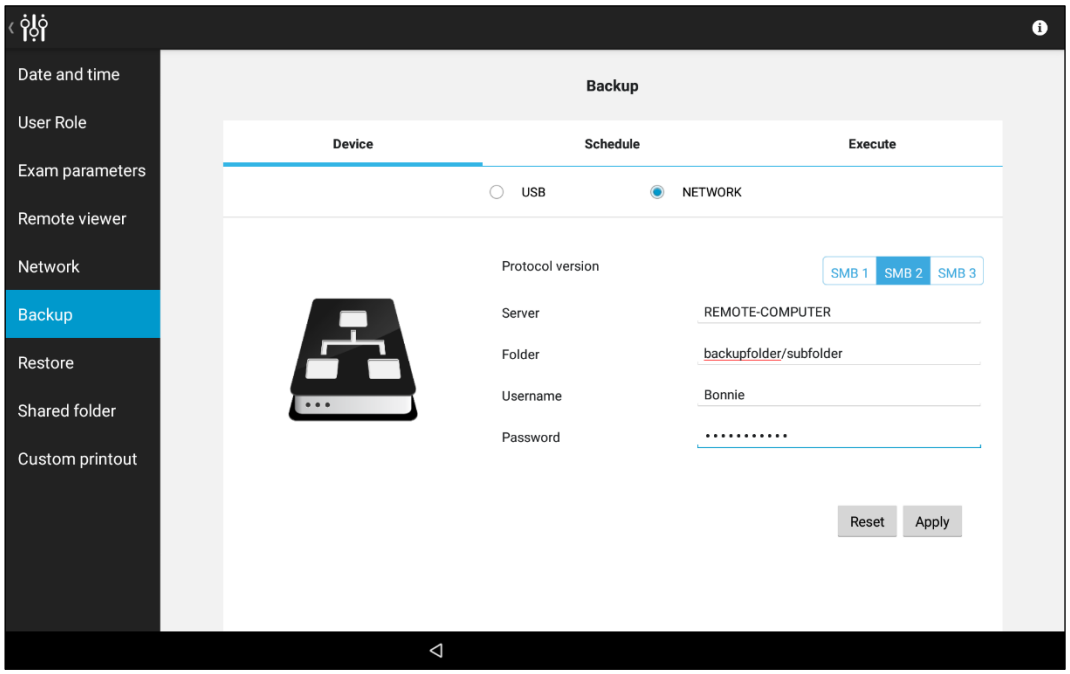


Fig. 82 – Configurator – BACKUP screen – Network backup selected

The network parameters to be set are the following:

- *Protocol version*: version of SMB protocol used in the network.
- *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 FA will try to contact the selected media. If the media is not ready (e.g. network disk not available or USB not connected), EIDON FA 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.

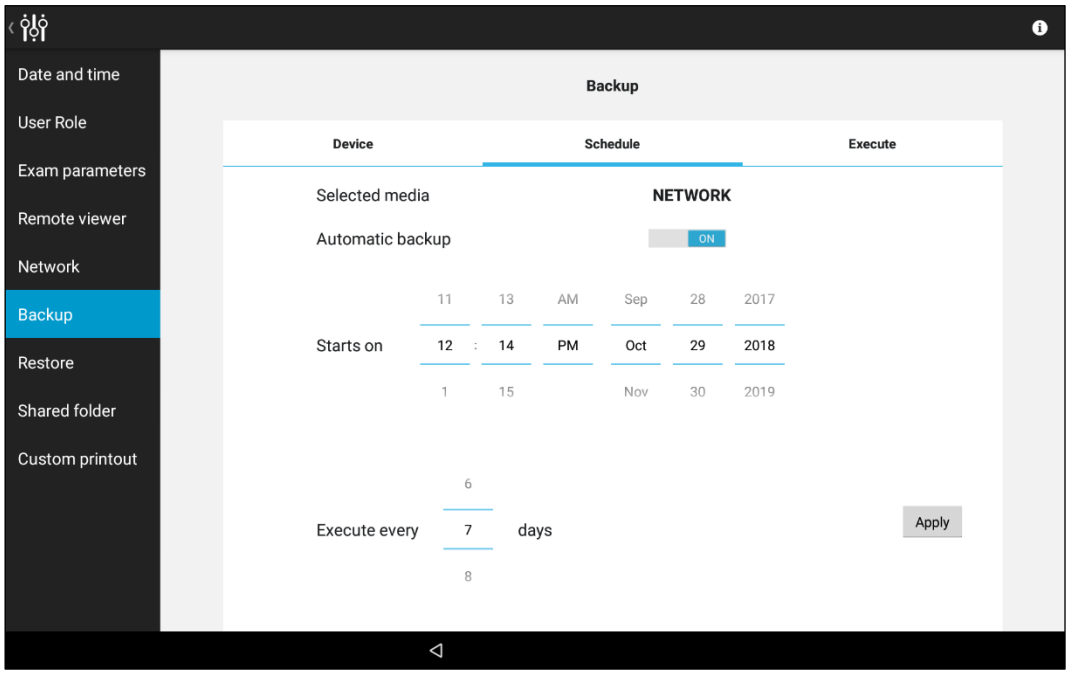


Fig. 83 – Configurator – BACKUP screen – *Schedule* tab with automatic backup enabled

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

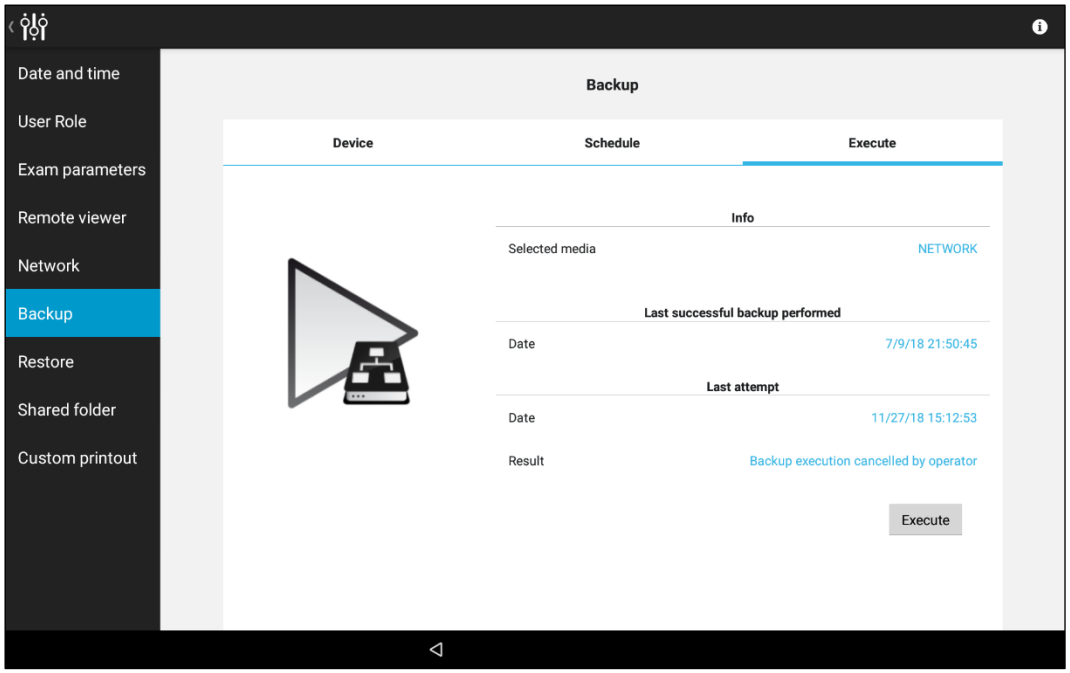


Fig. 84 – Configurator – BACKUP screen – *Execute* tab

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 FA or from another EIDON FA: 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**.

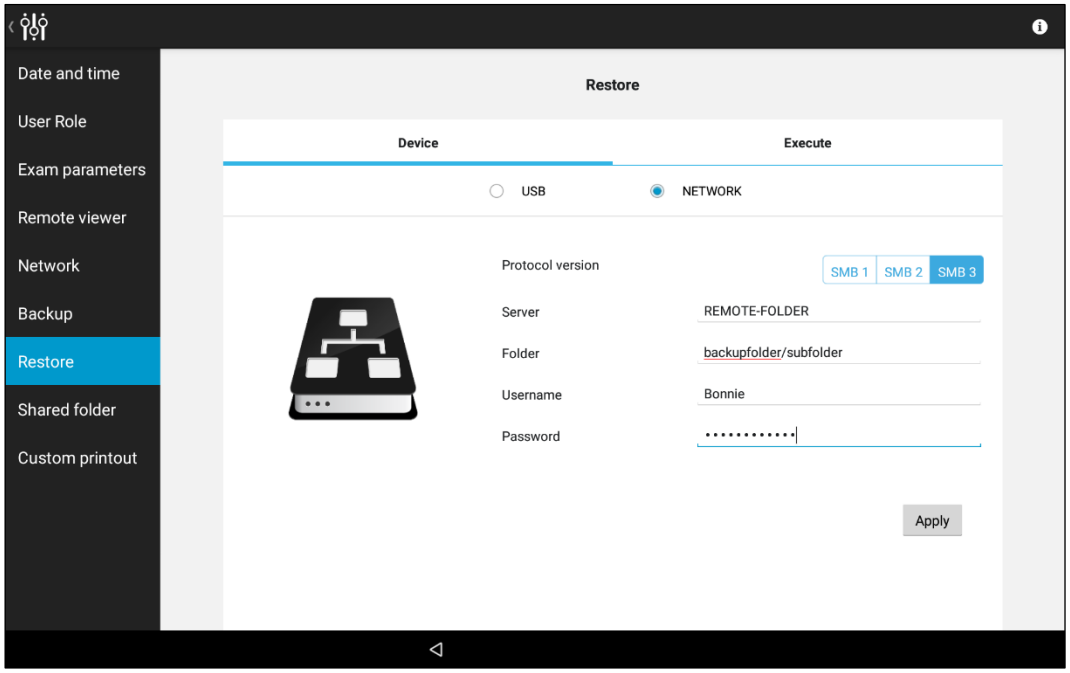


Fig. 85 – Configurator – RESTORE screen – Network folder selected

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

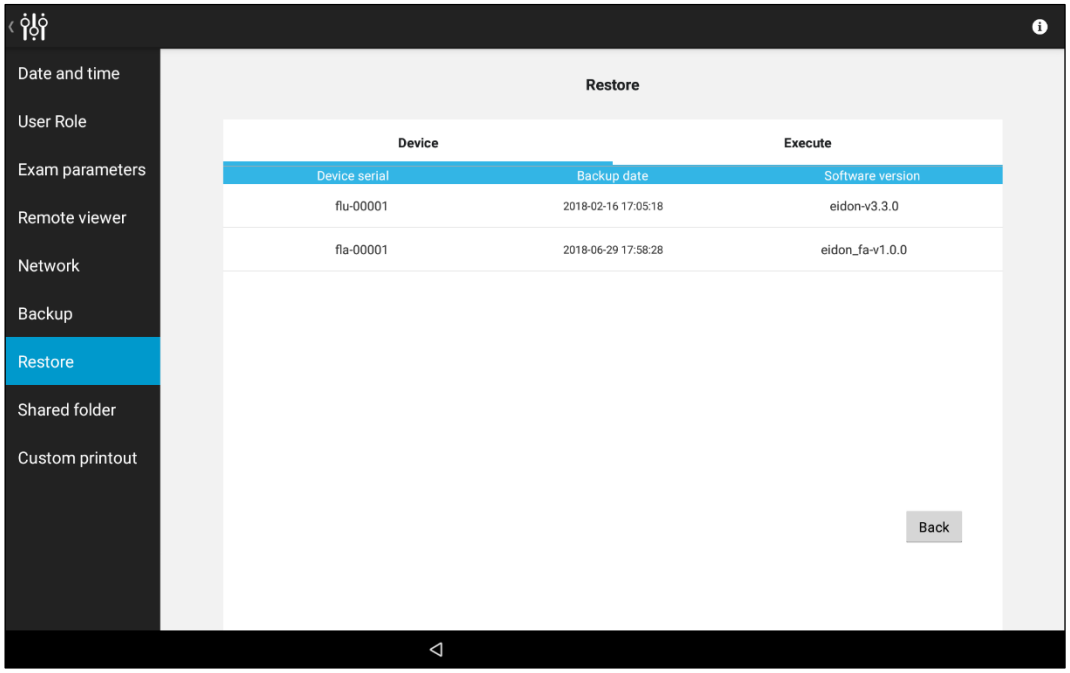


Fig. 86 – Configurator – RESTORE screen – List of available archives to be restored

- 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 FA database: patient data will be appended.

12.10 Shared folder configuration

EIDON FA images and video 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.

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 FA 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 pictures.
- `ImageType`: Type of image acquired. Possible values: `visible` for color images, `infrared` for infrared images, `AF` for AF images, `fa` for FA images, `favideo` for FA video, `favideoframes` for pictures extracted from FA videos.
- `ImageDate`: 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 pictures 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. 87 as an example of remote shared folder configured for network without domains, and Fig. 88 in the case of Windows Domain network.

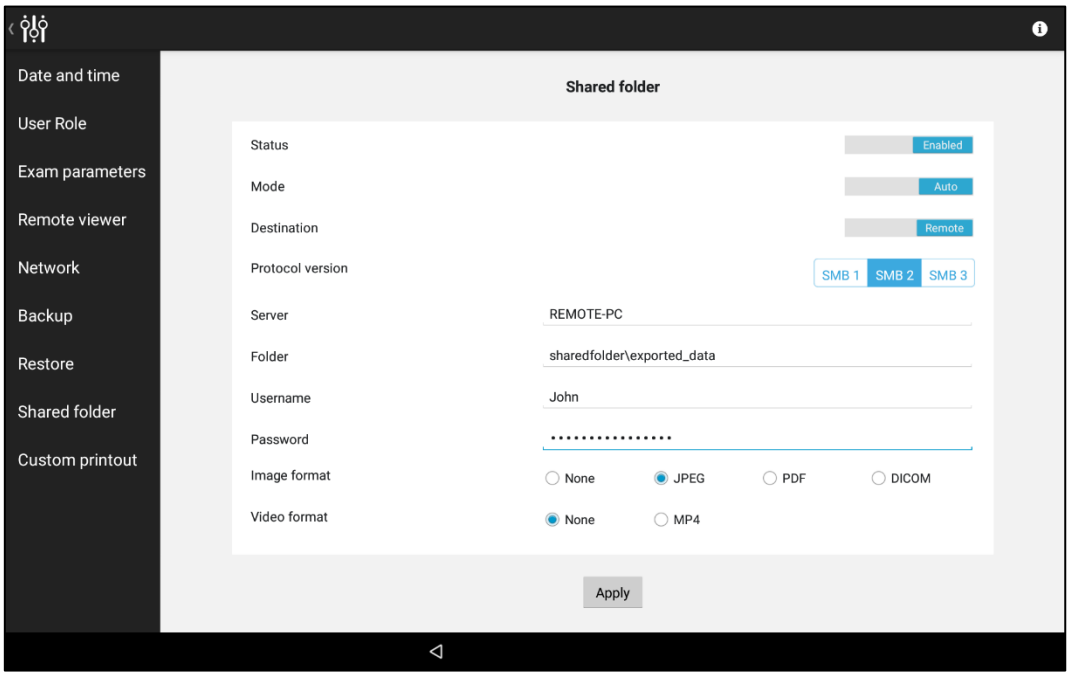


Fig. 87 – Configurator – SHARED FOLDER configuration example: automatic export of JPEG images and MP4 videos to a remote folder *exported_data* (subfolder of *sharedfolder*), located in the server *REMOTE-PC*, with *John* as server username

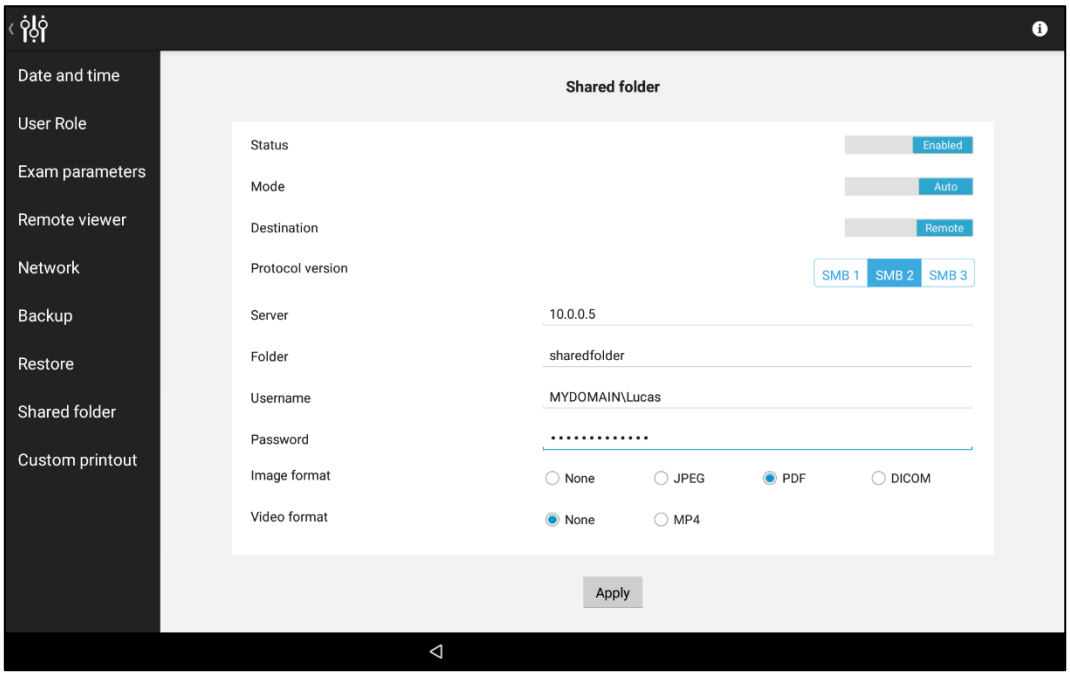


Fig. 88 – Configurator – SHARED FOLDER configuration example, in Windows Domain Networks: automatic export of PDF printouts to a remote folder *sharedfolder*, located in the server with IP *10.0.0.5*, with *Lucas* as domain username and *MYDOMAIN* as domain name

12.11 Custom Printout

EIDON FA 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 picture 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 EIDON FA when the configurator is in the Custom Printout tab: the tablet 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 EIDON FA and contains valid custom header files, the software will preview the custom header at the bottom of the window.

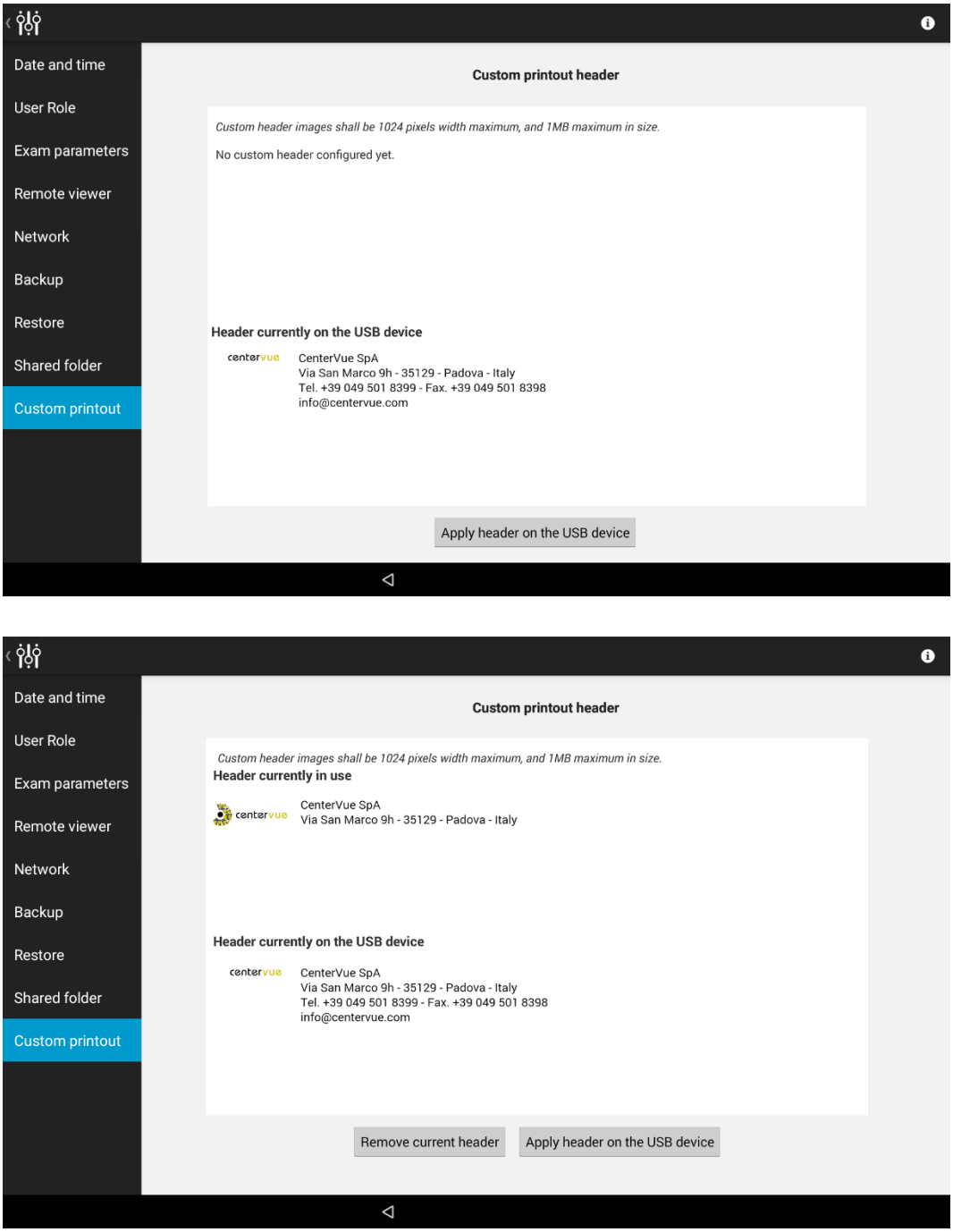


Fig. 89 – Configurator – CUSTOM PRINTOUT configuration

13. SYSTEM SHUTDOWN

To shut down the system, go back to the Home screen and press the power off icon  : EIDON FA beeps twice then turns off.
The tablet will shut down and power off automatically.

14. TECHNICAL SPECIFICATIONS

CE 0123

Class and type of applied part:
1, B (according to EN 60601-1).

Classification according to ISO 15004-2:
Group 2

IP classification:
IPX0 (according to the degree of protection provided by the enclosure with respect to harmful penetration of particulate matter or water).

Image acquisition:

- Minimum pupil size: 2.5 mm
- Field of individual image: 60° (H) x 55° (V) captured in a single exposure
- Sensor resolution: 14 Mpixel (4608x3288 pixels)
- Light sources: infrared LED (825-870 nm), white LED (440-650 nm), blue LED (440-475 nm)
- Imaging modalities: color, red-free, IR reflectance, autofluorescence (AF), fluorescein angiography (FA)
- Working distance: 28 mm
- Resolution: 60 pixels / deg
- Resolution on retina: 15 µm
- Pixel pitch: 4.9 µm
- FA video resolution: 1840x1644 pixels
- FA video acquisition rate: 5 fps

Other features:

- Automatic operation: auto-alignment, auto-focus, auto-exposure, auto-capture
- Focus adjustment range: -12 D to +15 D
- Internal fixation target: dynamic, programmable
- Display: 10.1” multi-touch, color tablet
- Hard disk: SSD, 2 TB

Dimensions:

- Weight: 25 Kg (55 lb)
- Size (W x H x D): 360 mm x 590 mm x 620 mm (14.2” x 23.2” x 24.4”)

Power supply:

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

Specifications are subject to change without notice for improvement

15. CLEANING

This paragraph explains how to clean the system.
The chin rest and the forehead rest should be wiped with an antiseptic wipe before each use and allowed to dry prior to reuse.

Fig. 90 – 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 FA 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 is dirty	Clean the front lens
4. Captured image is totally white	Subject blinked during image capture	Repeat capture and ask subject not to blink
5. One or more dark areas appear in color and/or IR pictures 	Pupil is too small (< 2.5 mm)	Dark adapt subject. Otherwise dilate subject
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

Symptom	Possible cause(s)	Solution
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

This device has 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. This instrument generates, uses and can radiate radio frequency energies and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If the system does cause harmful interference to other devices, which can be determined by turning the system off and on, try to eliminate the interference by adopting one or more of the following measures:

- reorient and/or relocate the receiving device;
- increase the distance between the devices;
- connect the system to an outlet on a different circuit than that to which the other devices are connected;
- contact the manufacturer or field service technician for help.

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

17.1 Manufacturers EMC Declaration to ISO 60601-1-2

The following tables provide specific information regarding compliance of EIDON FA:

EIDON FA is intended for use in the electromagnetic environment specified below. The customer or the user of EIDON FA should ensure that it is used in such an environment.
Warning: other cables and accessories not provided with the Device may negatively affect EMC performance.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	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.
RF emissions CISPR 11	Class A	**Warning**: The EMISSIONS characteristics of this equipment 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) this equipment 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 4: Electromagnetic Emissions

17.2 Guidance and manufacturers declaration – electromagnetic immunity

Immunity Test	IEC60601 test level	Compliance Level	Electromagnetic environment guidance
Electro-static discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Avoid touching the exposed conductive parts of connectors when handling the device or connecting cables.
Electrical fast transient burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle <5% U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in UT) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	<5% U_T (>95% dip in U_T) for 0,5 cycle <5% U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s intervals.	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Table 5: Electromagnetic Immunity (ISO 60601-1-2:2007 5.2.2.1f)

Immunity Test	IEC60601 test level	Compliance Level	Electromagnetic environment guidance
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3 Vrms 150KHz to 80MHz 3V/m 80MHz to 2.7GHz	3Vrms 3V/m	Portable and mobile RF equipment should be used no closer to any part of EIDON FA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80MHz to 800MHz $d = 1.17\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic sight survey[a], should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol. 
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.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which EIDON FA is used exceeds the applicable RF compliance level above, EIDON FA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating EIDON FA. [b] Over the frequency range 150Khz to 80MHz, field strengths should be less than 3V/m.			

Table 6: Electromagnetic Immunity (ISO 60601-1-2:2007 5.2.2.2)

17.3 Immunity pass criteria

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 (ISO 60601-1-2)

EIDON FA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of EIDON FA can help prevent electromagnetic interference

by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and EIDON FA 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 FA, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

Table 8: Recommended Separation Distances

17.4 Wi-Fi Specifications

- Model name: WL18MODGI (Texas Instruments Incorporated)
- Main Chipset WL1807MOD
- 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 FA contains a radio module that complies with regulations of the USA and Canada.

- FCC ID: ID-Z64-WL18DBMOD

- IC ID: 451I- WL18DBMOD These devices comply with part 15 of the FCC rules.

Changes or modifications not expressly approved by the party responsible for compliance could void user's authority to operate the equipment.
Operation is subject to the following 2 conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

18. DISPOSAL

EIDON FA is made of different materials, such as plastics, aluminum, electronic parts. In case of instrument disposal, please separate the various materials and follow the laws and regulations regarding disposal or recycling for each material effective in your own country.

Separate collection for electrical and electronic equipment

The European Directive 2012/19/EU establishes separate collection for Waste of Electrical and Electronic Equipment (WEEE). Users of Electric and Electronic Equipment (EEE) must not dispose of WEEE as unsorted municipal waste, but collect such WEEE separately. The available return and collection system is defined by the local public administration, or alternatively an authorized company can recycle the WEEE. Please refer to public administration about separate collection, if this information is not available, contact the equipment manufacturer. Users play a major role in contributing to the reuse, recycling and recovery of WEEE. The potentially dangerous substances contained in WEEE can pollute the environment and produce harmful effects on human health. Below is a list of specific hazards related to some substances, which may leach in the environment and in the water system.

Lead: damages the nervous system of humans, affects the endocrine system, the cardiovascular system and kidneys. It accumulates and is very toxic for animals, plants and micro-organisms.

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

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

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

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

19. INFORMATION ABOUT THE OPTICAL RADIATION HAZARD

It is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis.
The longer the duration of exposure and the greater the number of photos, the greater the risk of ocular damage.

19.1 ISO 15004-2

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:

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

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 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**.

19.2 ANSI Z80.36

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.