


eidon

eidon  Af

True Color Confocal Scanner

Operating Manual

MANUAL INFORMATION

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CONTENTS

1. INTRODUCTION	4
1.1 EIDON and EIDON AF	4
2. SYSTEM	5
2.1 The device	5
2.2 The tablet	7
3. LABELS	9
4. SYMBOLS	11
5. PREPARING THE SYSTEM	12
5.1 Assembling the tablet and joystick supports	12
5.2 Assembling the external fixation light	13
5.3 Turning on the Device	14
6. PREPARING THE SUBJECT	16
7. WARNINGS AND PRECAUTIONS	17
8. NOTES FOR THE OPERATOR	18
9. DICOM SUPPORT	19
10. PERFORMING THE TEST	20
10.1 Adding a new patient	20
10.2 Deleting patients	21
10.3 Searching for an existing patient	21
10.4 Selecting an existing patient	21
10.5 Setting up the test parameters	22
10.6 Selecting the field(s) to be captured	23
10.7 Wide field	24
10.8 Stereo	26
10.9 Automatic mode	26
10.10 Manual mode	29
11. REVIEWING IMAGES	33
11.1 Single image review	34
11.2 3D Viewer	36

11.3 Image retake	36
11.4 Export functions	37
11.5 Mosaic.....	39
11.6 Dual image review	40
11.7 Remote Viewer	41
12. PRINTING.....	49
12.1 Printer setup.....	49
12.2 Printout.....	50
13. SETTINGS.....	51
13.1 Launching the Configurator	51
13.2 Password change	51
13.3 Password change for Remote Viewer	52
13.4 Network configuration	52
13.5 Backup	53
13.6 Restore	54
13.7 Device lock reset procedure	55
13.8 Shared folder configuration.....	56
13.9 Custom Printout	58
14. SYSTEM SHUTDOWN.....	60
15. TECHNICAL SPECIFICATIONS	61
16. CLEANING.....	62
17. TROUBLESHOOTING.....	63
18. ELECTROMAGNETIC COMPATIBILITY	65
19. DISPOSAL	69

1. INTRODUCTION

Congratulations for choosing EIDON and its color confocal retinal imaging capabilities

EIDON is intended for taking digital images of a human retina without the use of a mydriatic agent.

EIDON is a scanning ophthalmoscope which uses infrared and visible light to obtain confocal images of the retina. Multiple retinal fields can be captured using a programmable internal fixation target. 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 is restricted to licensed eye care practitioners. The process of making a diagnosis using EIDON 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.

1.1 EIDON and EIDON AF

EIDON AF is a variant derived from EIDON. In addition to the EIDON features, EIDON AF can take blue fundus autofluorescence retinal images.

The autofluorescence image is obtained by illuminating the eye with a blue light. The image reflected by the ocular fundus will be filtered to select only the fluorescent emission (i.e. wavelengths greater than 500nm).

In the below figure, the forth image is the autofluorescence image which can be taken only with EIDON AF. The first three images are present also in EIDON.

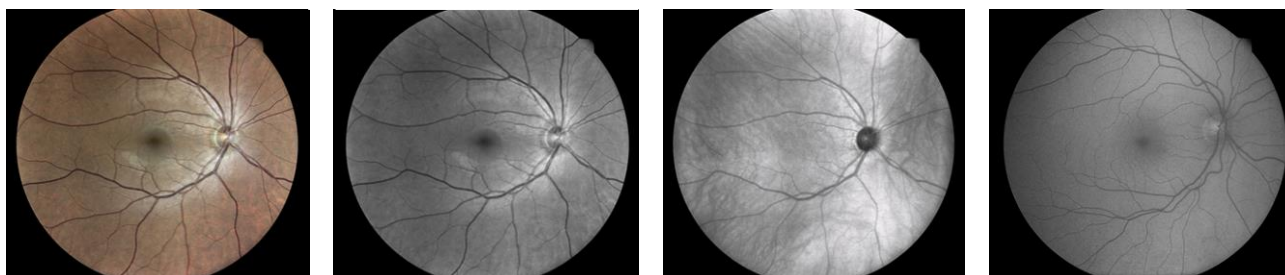


Fig. 1 – From the left: color fundus picture, red-free fundus picture, IR fundus picture, Autofluorescence fundus picture

In the following chapters we will refer to “EIDON” to describe features of both devices. Otherwise, we will specify “EIDON AF” o “EIDON without AF” feature.

2. SYSTEM

2.1 The device



Fig. 2 – EIDON without AF



Fig. 3 – EIDON AF



Fig. 4 – Detail of connectors side

EIDON is provided with:



- dedicated **tablet** with USB cable and related support
- external power supply and related power cord
- digital joystick, USB powered, and related support
- this operating manual
- removable forehead rest
- front lens cap
- external fixation light, USB powered

2.2 The tablet

The tablet (see Fig. 5) is an integral part of the system and EIDON cannot operate without it. The tablet must be connected to EIDON using the supplied USB cable. If the connection is not available, a warning appears on the screen (see Fig. 6).

Use the USB port next to the power inlet to connect the tablet: this is the only port that will also recharge the tablet.

The tablet is equipped with a color, multi-touch display.

Click the left-most button at the top of the tablet to turn it on or to turn the screen off/on.

Use the button in the left side to adjust the volume.



Patient data and images are not stored on the tablet.



Fig. 5 – Tablet supplied with EIDON

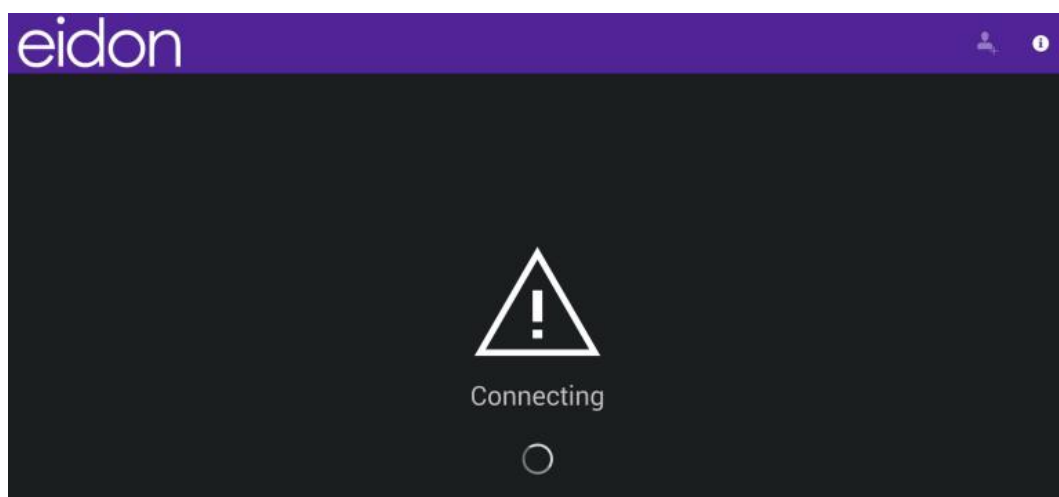


Fig. 6 – Message appearing when tablet attempts to connect to EIDON

Charging the tablet

EIDON cannot be used if the tablet is not sufficiently charged. The tablet is charged via the USB port of the device.

If the battery level decreases under 15%, check the connection between the tablet and the device: the tablet must be connected to the left-most USB port. To save battery reduce the display brightness and turn off the Wi-Fi.

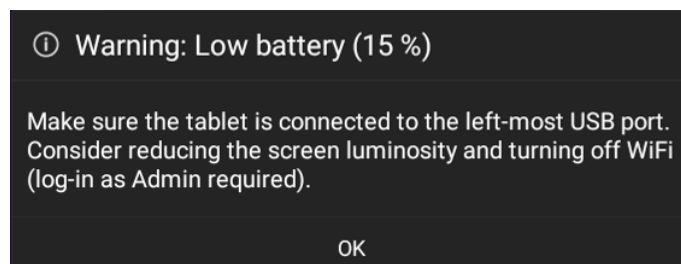


Fig. 7 – Warning message when the battery charge decreases to the 15%

The tablet automatically powers off when the battery lowers than 5%, to prevent the total discharge. Verify the tablet is connected to the device through the left-most USB port or connect it to a wall charger. The following message will appear:

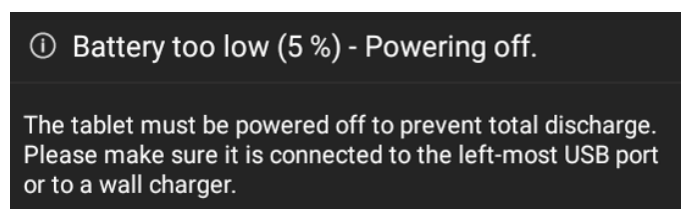


Fig. 8 – Warning message when the battery charge decreases to the 5%



To maximize the duration of the charge:

- Set the screen brightness to “Auto” or anyway not to maximum;
- Plug the tablet in the left-most USB port, near the power switch;
- Keep EIDON powered and the tablet connected when the device is off;
- Turn off the screen when the device is not in use.



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 is a confocal system that uses **white 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 and optimized exposure of the ONH.

3. LABELS

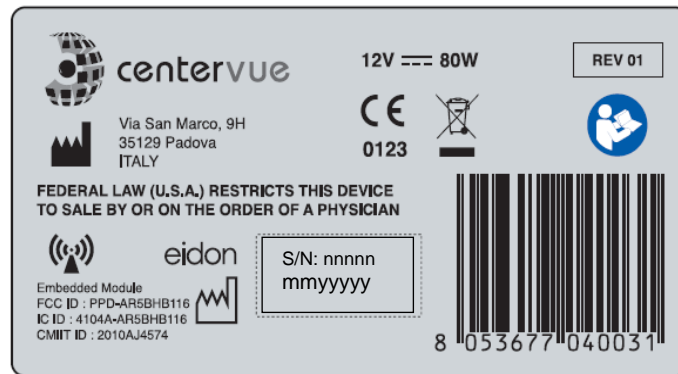


Fig. 9 – EIDON main label (non-AF version)

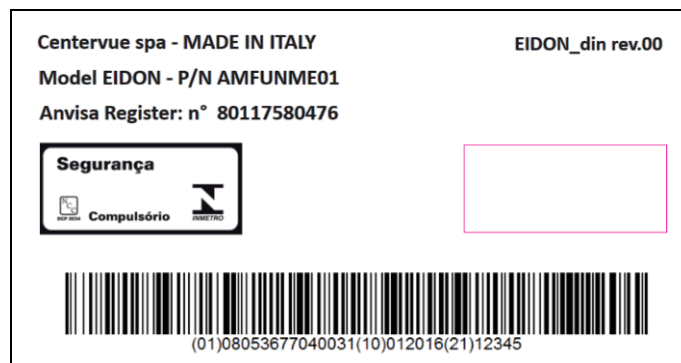


Fig. 10 – EIDON UDI label (non-AF version)

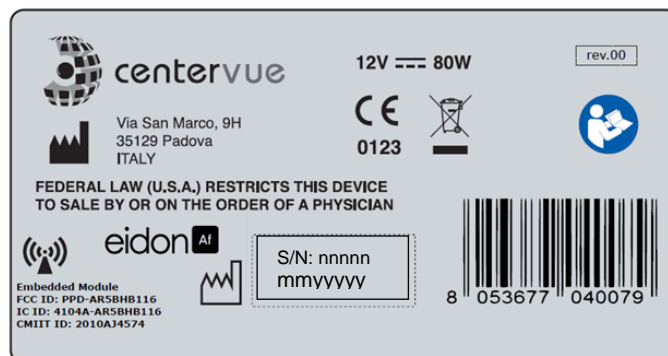


Fig. 11 – EIDON AF main label

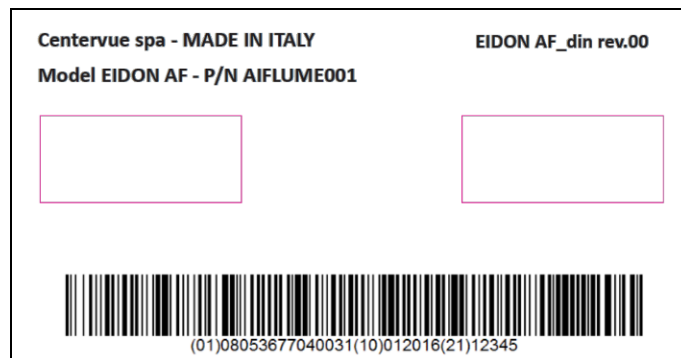










Fig. 12 – EIDON AF UDI label





Fig. 13 – Common labels for both EIDON models

4. **SYMBOLS**

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

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

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

Symbol	Explanation
	General warning, read carefully
	Important information

5. PREPARING THE SYSTEM



We recommend to read carefully and thoroughly par. 7 WARNINGS AND PRECAUTIONS before proceeding with first use.

To make EIDON functional for the first use:

- extract the system from its box;
- place it on a suitable electrical table¹;
- insert the forehead rest on the metal support (see Fig. 14);
- mount the supports 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. 4);
- place the tablet on its support and connect it using the cable to the left-most USB 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.

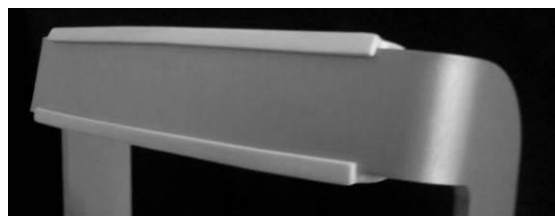


Fig. 14 – Forehead rest mounted on metal support

5.1 Assembling the tablet and joystick supports

The tablet and the joystick shall be mounted towards the posterior part of the device: with the included supports it is possible to choose their position among any side (see Fig. 16). The joystick should be placed closed to the tablet during the 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. 17 shows the holes to be used for the left-side mount depicted in Fig. 15: 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 a user's preferences.



Fig. 15 – Tablet and joystick mounted on the left side of the device

¹ Not provided with the system



Fig. 16 – Support for tablet (left) and for joystick (right)



Fig. 17 – 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.

Fix the light to the forehead rest using the supplied screws and the spacer plate; connect it to any USB port to power it on.

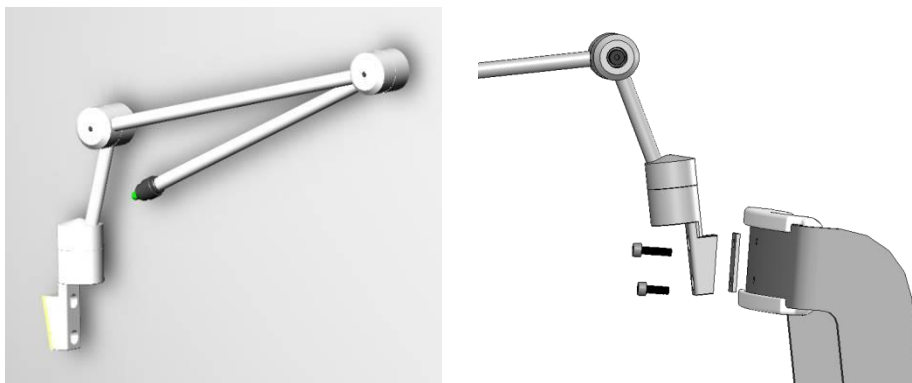


Fig. 18 – External fixation light

5.3 Turning on the Device

To turn on the Device, keep the main switch (see Fig. 4) pressed for 2 seconds, then turn on the tablet by keeping its switch pressed for approximately 3 secs: after the booting process, the **Login** screen appears (see Fig. 19).



When the tablet is off don't keep pressed the main switch together with the volume switch: with this combination you'll access to the "reset to factory default" menu that resets the tablet and can't be undone.



Pressing the tablet power button doesn't take effect when the tablet is showing a gray battery image over a black screen.

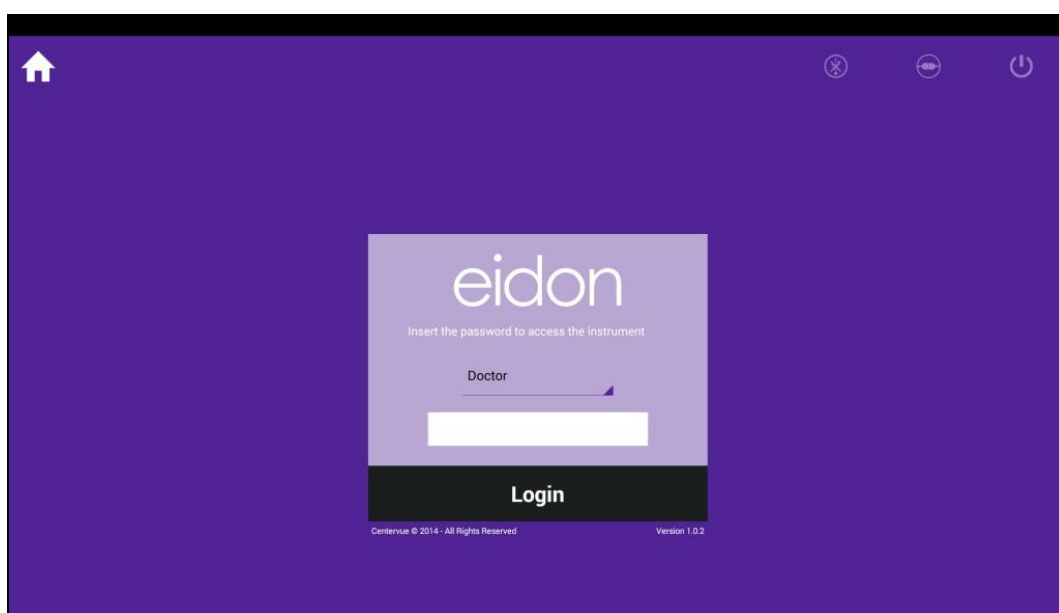


Fig. 19 – Login screen

From the drop-down menu select "Doctor", type the password² and click on **login**. If login is successful, the **Home** screen opens (see Fig. 20).



Use of user "Admin" requires manual activation of the tethering by clicking the corresponding icon at the top.



To modify the passwords, see par. 13.2

² To learn the factory password please ask an authorized CenterVue representative

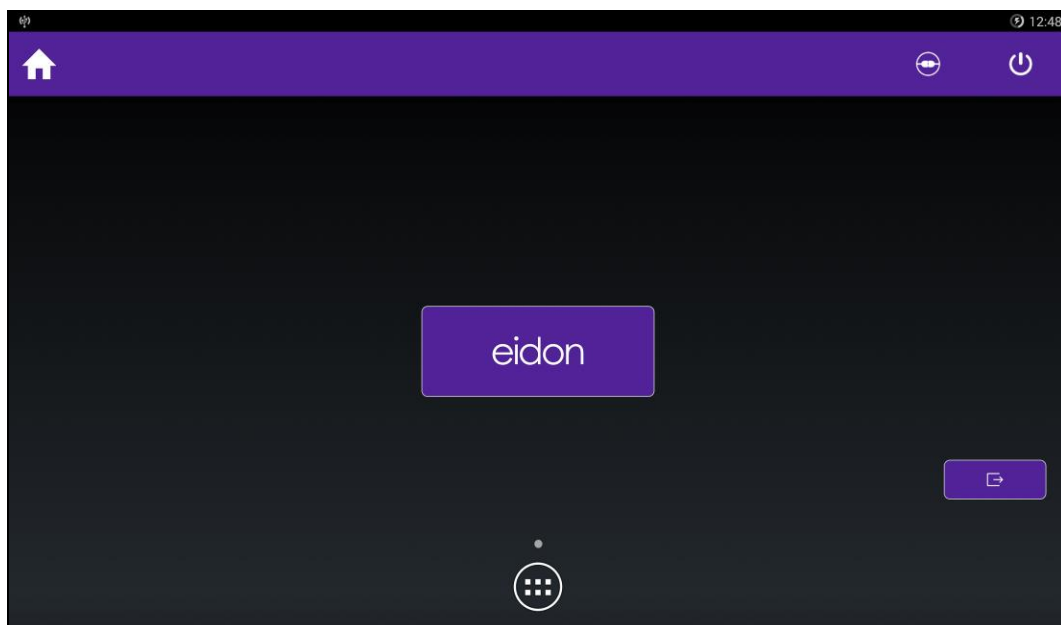


Fig. 20 – Home screen

6. **PREPARING THE SUBJECT**

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

There are no restrictions as to the selection of the subjects undergoing testing.

EIDON is a non-mydriatic device (minimum pupil diameter 2.5 mm), so there is no need to dilate the subject.

EIDON 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 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. 2 for EIDON and Fig. 3 for EIDON AF.

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. 21). If this is not the case the chin rest height needs to be adjusted (see par. 10.5).

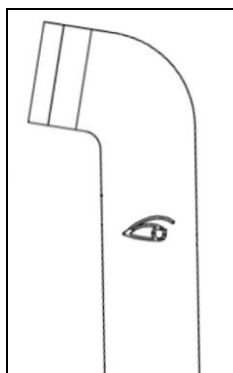


Fig. 21 – Sketch of the eye mark on the metal frame

Before the test inform the subject about the following:



- EIDON 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.

7. **WARNINGS AND PRECAUTIONS**

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.
- A 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 in the event that the cover or other parts of the device have been removed.
- Only technicians authorized by CenterVue may service EIDON. CenterVue cannot be held responsible for system safety should EIDON be opened, repairs carried out, third-party 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 must NOT be used in an oxygen rich environment or in presence of flammable anesthetics.
- In case an unexpected hardware condition occurs during use, an error message may appear (see for example Fig. 22) and the device may become temporarily locked. It is possible to reset this condition by letting the device re-initialize: refer to par. 13.7 for the complete procedure. If the error condition persists, please contact an authorized service center.

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 needs to be operated in a semi dark environment.
- EIDON needs to be operated under the following environmental conditions: temperature: 10 - 40 C° (50 – 104 F°); humidity (max): 90% not condensing.
- EIDON needs to be stored under the following environmental conditions: temperature: 0 – 60 C° (32 - 140 F°); humidity (max): 90% not condensing.

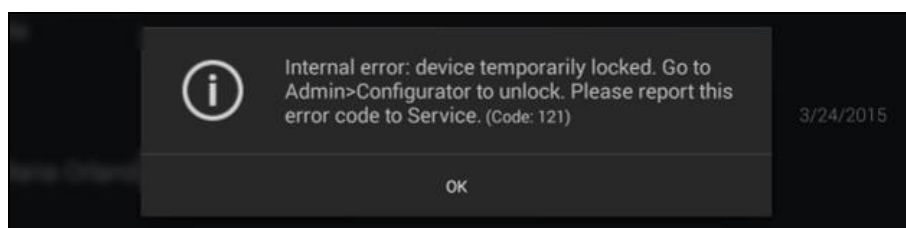


Fig. 22 – Example of error message

8. **NOTES FOR THE OPERATOR**

EIDON provides capabilities for fully automated image capture. No specific skills are required to operate EIDON and a minimal device specific training is required to become able to operate the system.

In particular the operator shall be familiar with the following concepts:

- pupil: the central part of the external surface of the eye, through which light goes in;
- retina: the internal surface of the eye ball;
- fixation/fixating: the ability of a subject to stare at a specific point in space and specifically the internal fixation targets;
- alignment: the action of moving the top part of the system so that its optics are aligned with a subject's pupil;
- focusing: the compensation, by means of internal optics, of a subject's spherical defect (myopia, hypermetropia).



EIDON also offers the possibility for manual image capture. To operate the system in manual mode, the operator should be familiar with joystick-based retinal imagers.

9. **DICOM SUPPORT**

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

Eidon can export DICOM files. With an additional license Eidon supports full DICOM communication too, as specified in the **EIDON DICOM Conformance Statement document³**.

³ Ask to your local distributor for the EIDON DICOM manual and conformance statement

10. PERFORMING THE TEST

This paragraph explains how to operate EIDON 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** button to open the **Patient List** screen (see Fig. 23).

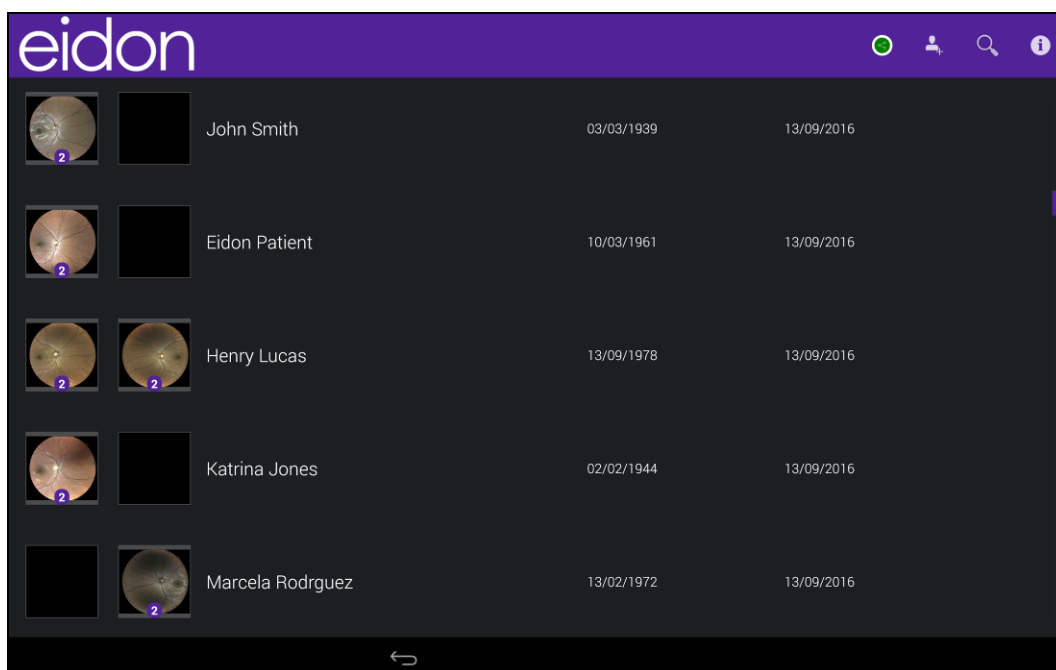




Fig. 23 - Patient list screen

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

- presence and number of images stored for a certain patient (right and left eye);
- patient's full name;
- patient's date of birth (when inserted);
- date of last exam.

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 the software version, press the  button. To see the shared folder exporting status, click on the  (for more information see par.11.4)

10.1 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 Given name and Surname (mandatory fields), optionally select the date of birth, gender and a unique code of your choice to identify the patient. Then click OK to save or Cancel to abort.




Fig. 24 – Patient editing screen

10.2 Deleting patients

To permanently delete a patient or patients from the Patient List screen, keep pressed on a patient: the software enters in a *patient multi-selection* mode: select the patient(s) to be deleted and press

the  icon.

10.3 Searching for an existing patient

To search for an existing patient, click on  and type the initial letters of the patient you are looking for: 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 .

10.4 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. 25) and provides information on the selected patient, whose name is shown at the top-left corner of the screen. See par. 11 for additional details about this screen.

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

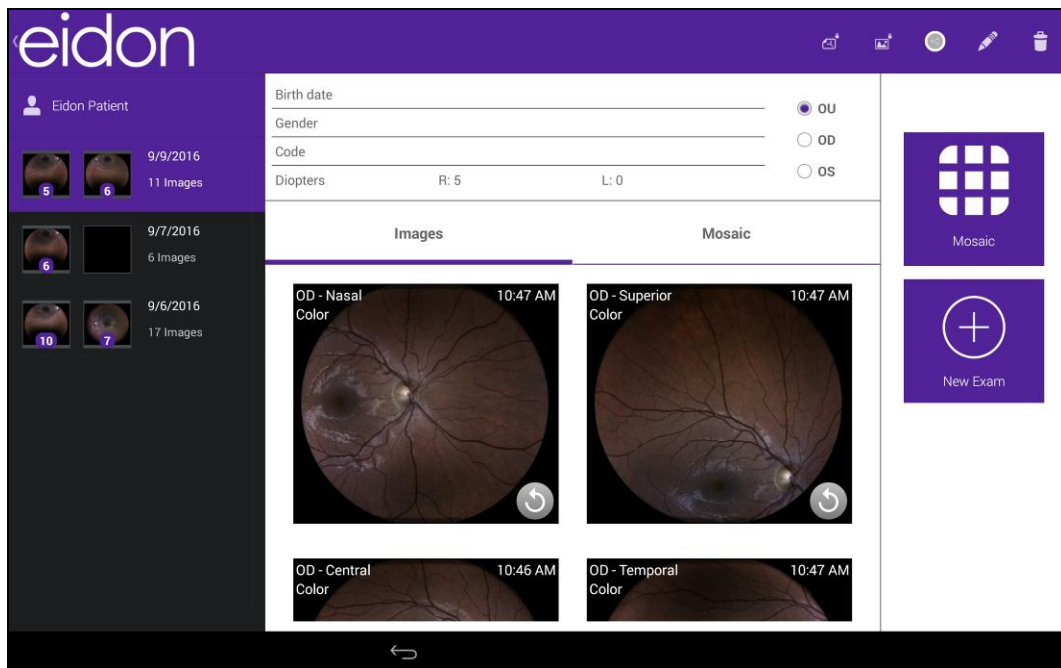


Fig. 25 – Patient Record screen

10.5 Setting up the test parameters

When the New Exam button is clicked, the **New Exam** screen opens (see Fig. 26). This screen allows review and modification of the test parameters and triggers the acquisition process.

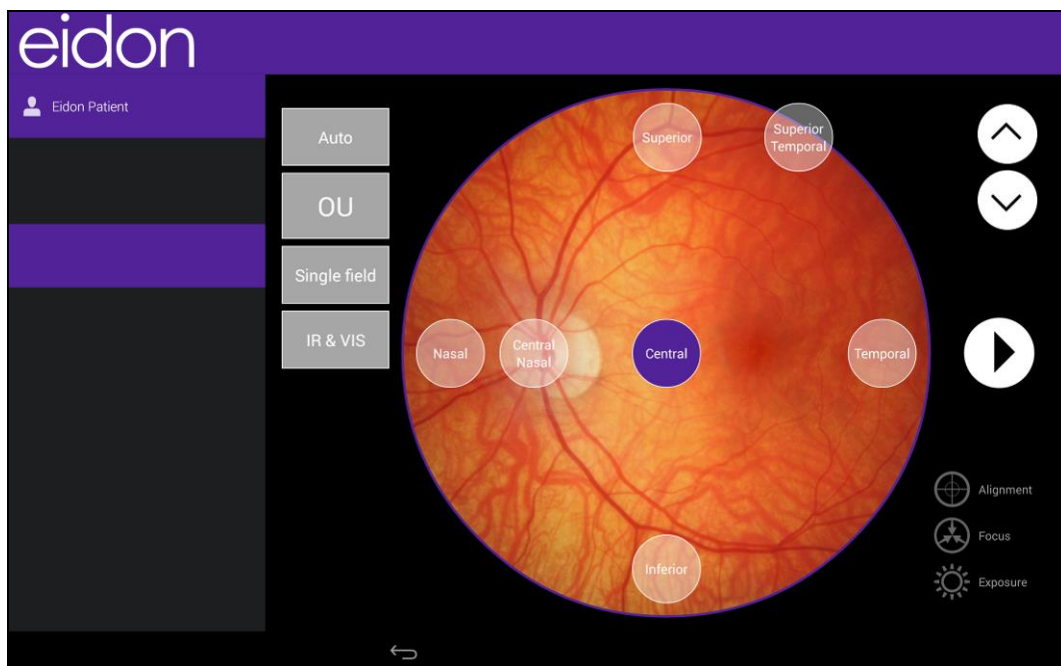


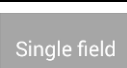








Fig. 26 – New Exam screen

The following functions/commands are available:

Function	Command	Description
Select Automatic / Manual modes		Used to select between automatic and manual mode. Default: Auto
Select eye(s) to be captured		Used to select the right eye (OD), left eye (OS), or both (OU). Default: OU
Select field(s) to be captured		See par. 10.6 for additional information. Default: single field, central
Select imaging modality in auto mode		Used to select infrared image (IR), color (VIS), AF images (only EIDON AF devices) or IR&VIS (Auto mode only). Default: IR & VIS
Select the fields for the automatic wide field mode		Used to select the automatic wide field acquisition fields (horizontal, vertical, full). Default: WF horizontal (Visible only if <i>Wide field</i> is selected)
Raise chin rest		Used to adjust the height of the chin rest
Lower chin rest		
Start acquisition process		Used to start the acquisition process
Exit		Used to 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.

10.6 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.



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

10.7 Wide field

If *Wide field* is selected, EIDON will acquire 3 or 5 pre-defined different fields (color pictures) like in multi filed mode, and then it will perform the mosaic.



The **mosaic** is the composition of multiple, partially overlapping, fields of the same retina and it is used to obtain a wider view. Typically, the generation of a 3-fields mosaic image takes around 20secs, 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 and, in AF devices, to AF images. (for more information about mosaic, see par. 11.5).

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.

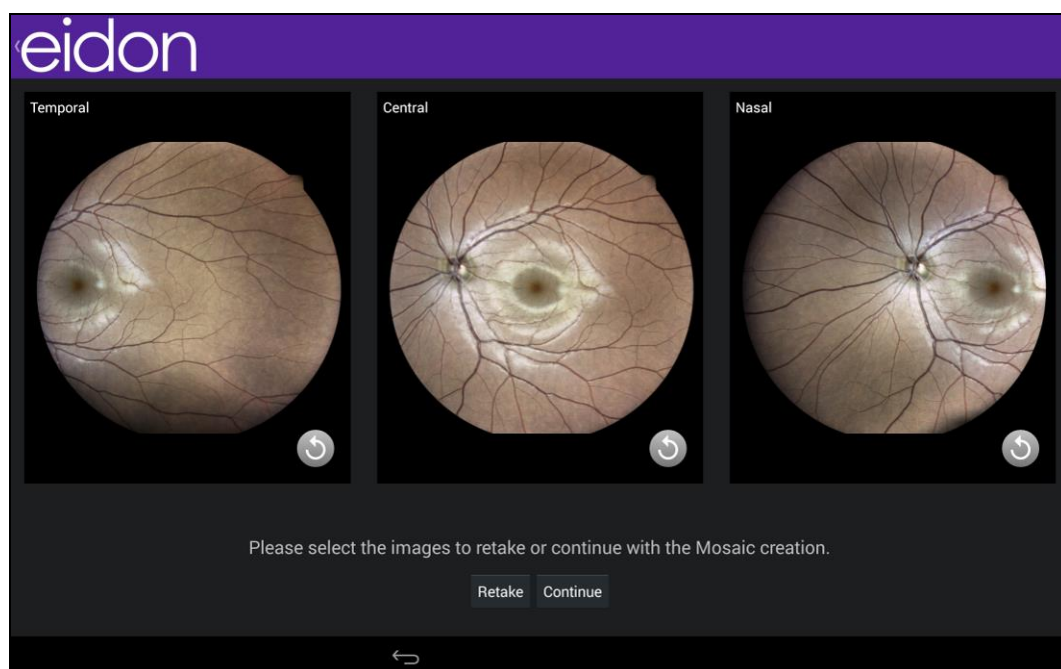


Fig. 27 – Image retake after horizontal wide field acquisition

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 elaborate the mosaic.

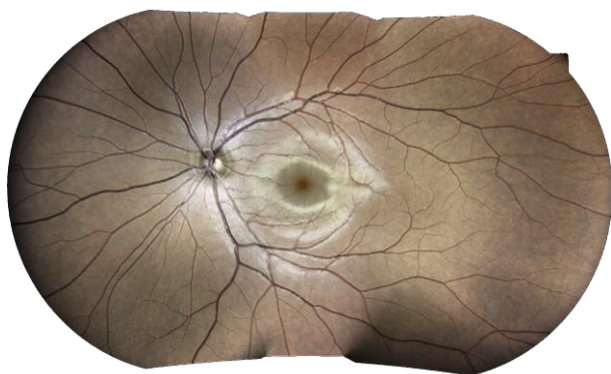


Fig. 28 – Example of *horizontal* wide-field

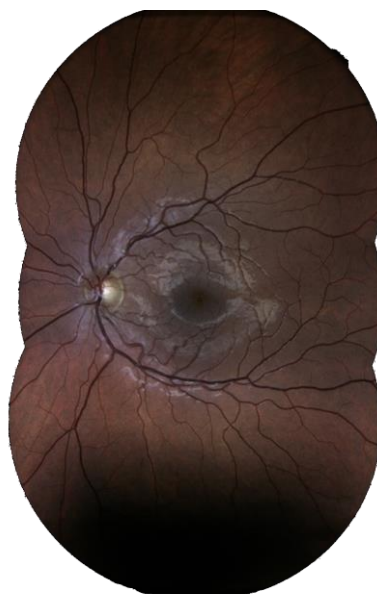


Fig. 29 – Example of *vertical* wide-field

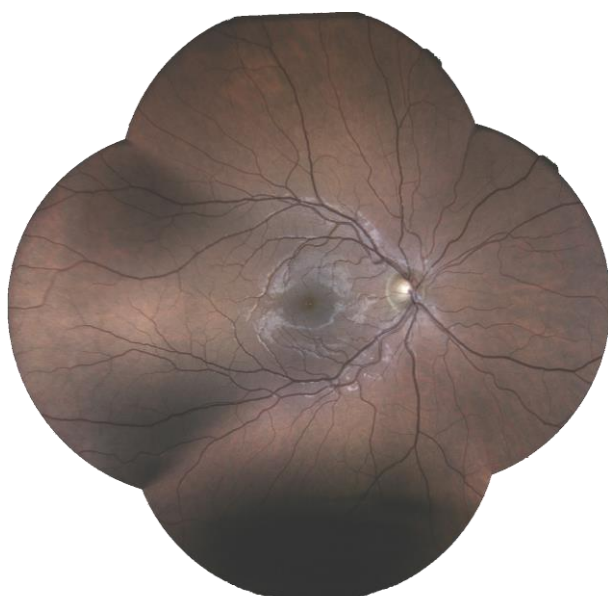


Fig. 30 – Example of *full* wide field



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

10.8 Stereo

If it is selected a **Stereo** exam, 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, the operator should use specific 3D prismatic glasses, not provided with EIDON. The retake for stereo pictures is disabled. For more information about the stereo feature, refer to the par. 11.2.

10.9 Automatic mode

In this mode EIDON 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 (in AF devices) 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. 31):

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

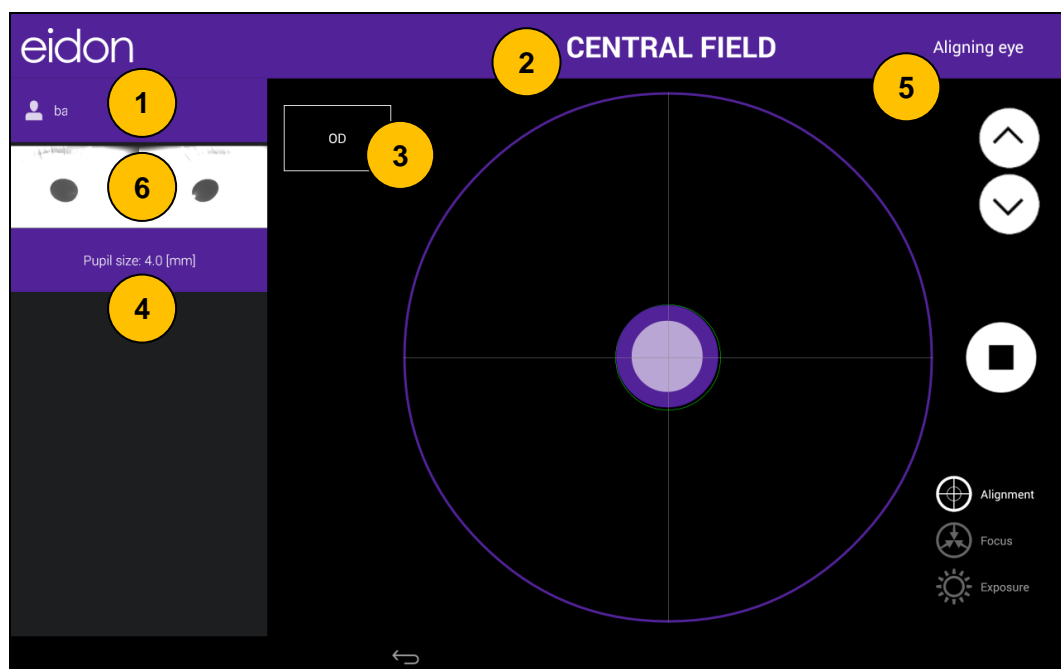





Fig. 31 – Exam screen in auto mode during auto-alignment

The following commands are available during the automatic exam process:

Function	Command	Description
Raise chin rest		Used to adjust the height of the chin rest
Lower chin rest		
Stop the process		Used to stop the acquisition process and return 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
- To disable vocal messages set the audio volume to zero by clicking on the right most buttons (+/-) on top of the tablet

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
OS	Nasal	Right
	Central nasal	Right
	Temporal	Left
	Superior temporal	Up, left

Table 1: Gaze directions corresponding to the various fields

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

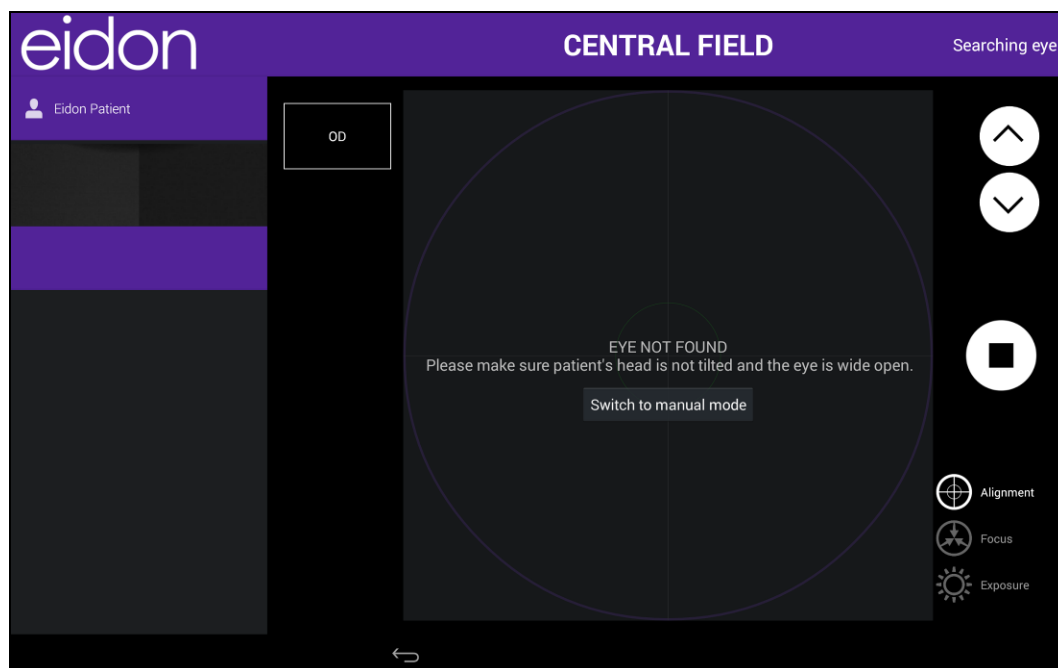


Fig. 32 – Eye not found during alignment phase in automatic mode exam

10.10 Manual mode

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

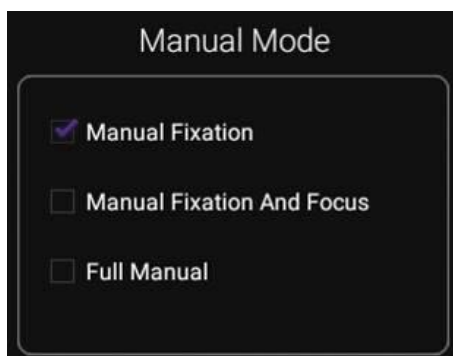



Fig. 33 – Manual mode options

Manual fixation

This option can be used to frame regions of the retina other than the fields described at par. 10.6 and also when the external fixation light is used.

When manual placement of the fixation target is selected, EIDON will stop after completing steps 1 and 2 described at par. 10.9 and display the live infrared image of the retina and the fixation target (the purple, semi-transparent circle in Fig. 34), 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 position⁴: moving the target in a certain direction should result in shifting the framed retina in the same direction.

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 infrared image (only AF devices) 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.

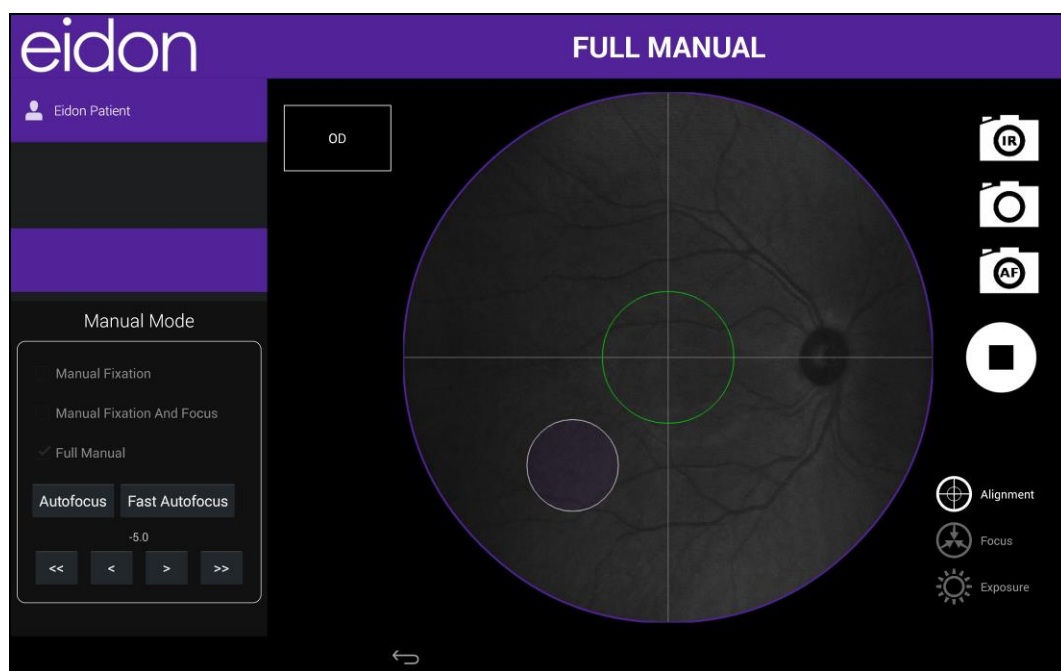


Fig. 34 – Exam screen in manual mode with displaced fixation target

Manual Fixation and Focusing

This option can be used in case auto-focusing fails for a certain patient or when certain specific regions of the retina need to be focused. This option requires use of the joystick provided with the system (see Fig. 35).

When this option is selected, EIDON will stop after completing step 1 described at par. 10.9 and display a live, unfocused, infrared image of the retina and the fixation target, waiting for operator's intervention.

Adjust focus by using the left (focus +) and right (focus -) buttons of the joystick, using the retinal image as feedback. Once focusing is ok, proceed as explained for the manual fixation option for further steps.



Fig. 35 – Joystick used for manual focusing

⁴ Provided the subject is able to fixate

The left panel features the focus adjust (same as joystick left and right keys) in steps of 0.5 or 3. Even if the focusing is manual in this exam mode, the left panel includes two buttons for autofocus: **Autofocus** or **Fast Autofocus**. In both cases the algorithm for the autofocus detection is the same, but in the fast autofocus the EIDON head movement range is reduced.

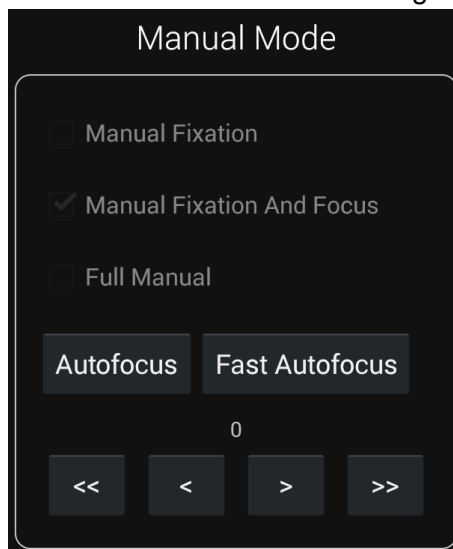


Fig. 36 – Manual mode panel during image acquisition

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 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 (see Fig. 39) 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.

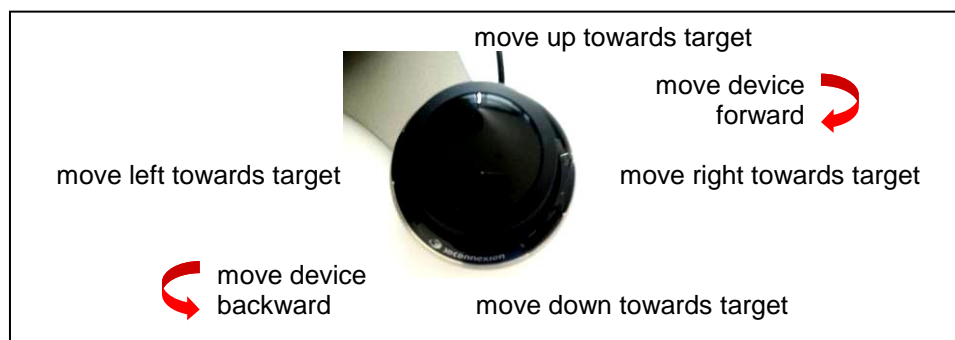


Fig. 37 – Joystick, top view



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.

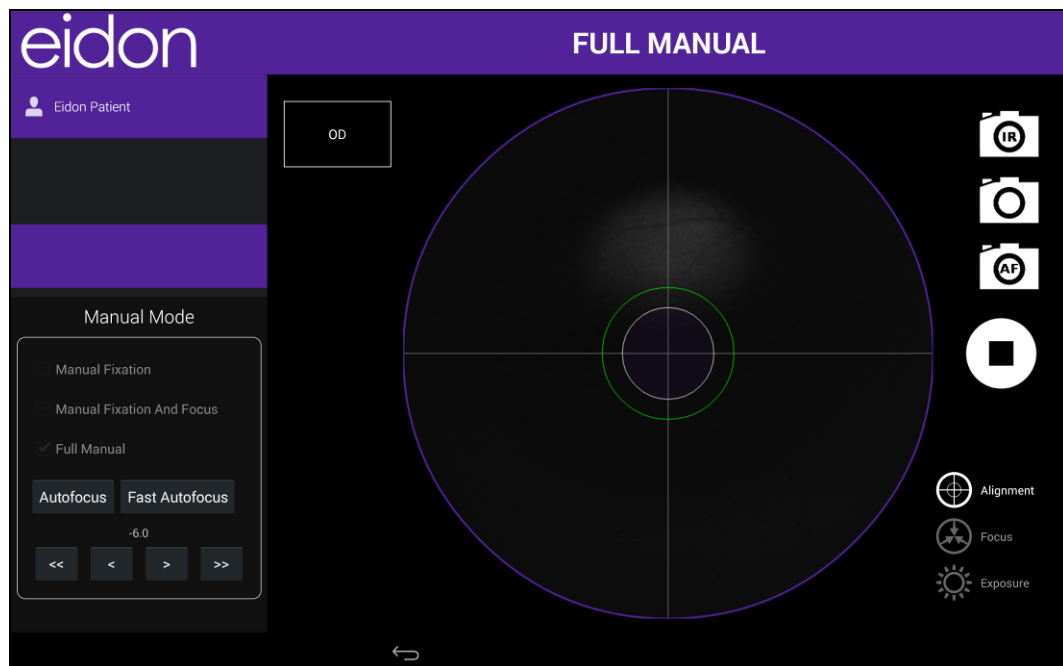


Fig. 38 – Exam screen in manual mode when approaching eye

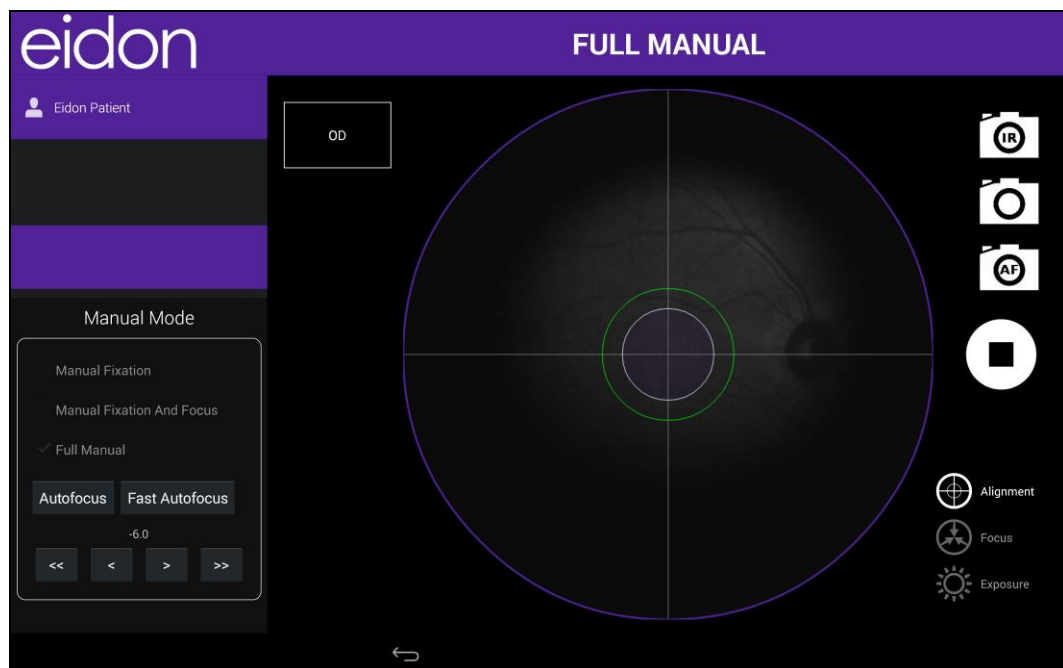



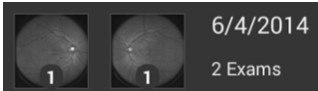

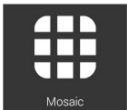





Fig. 39 – Exam screen in manual mode when retina is centered

11. REVIEWING IMAGES

The **Patient Record** screen (see Fig. 25) 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 keep pressing on it, click on other thumbnails (if requested), then press the delete button.
eye filter		Used to select display of both eyes (OU), just the right eye (OD) or just the left one (OS)
date selector		Used to open the exam images acquired in the selected date
start new exam		Used to start a new exam (see par. 9)
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
export patient printouts to USB		Used to export all of the patient printouts to USB, as pdf files
exit		Used to return to the Home screen

Each thumbnail displays the following information:

- the examined eye (OD/OS);
- the field information (for non-standard fields, the horizontal and vertical displacement of the target relative to the center, in degrees, is shown). This information is not displayed when the manual mode is used, see also par. 10.10;
- the time at which the image was acquired;
- the 3D logo, if the image has been acquired in stereo mode;
- the retake logo, if it is possible to retake the image.

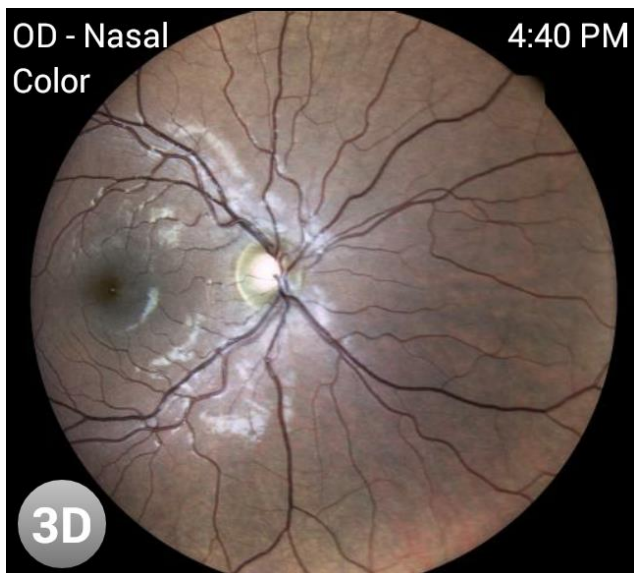


Fig. 40 – Example of thumbnail with the 3D logo

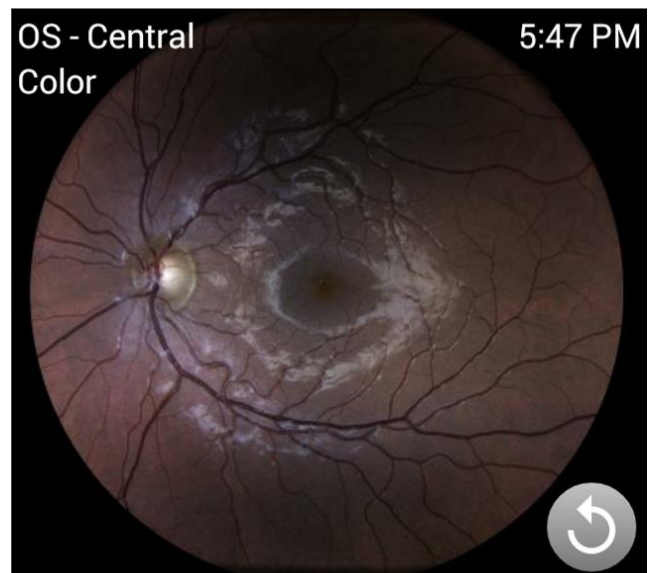



Fig. 41 – Example of thumbnail with the retake logo

For information about the meaning of the  optional icon, please see par. 11.2.

11.1 Single image review

To review any of the available images click on the corresponding thumbnail: this will open the **Exam review** screen (see Fig. 42). The screen displays the following information:

Patient name	→	 Eidon Patient
Eye	→	OD
Field	→	Nasal
Exposure time	→	Shutter Time 40 [ms]
Focus index	→	Focus Index -3.20
Pupil size	→	Average Pupil Size 4.10 [mm]

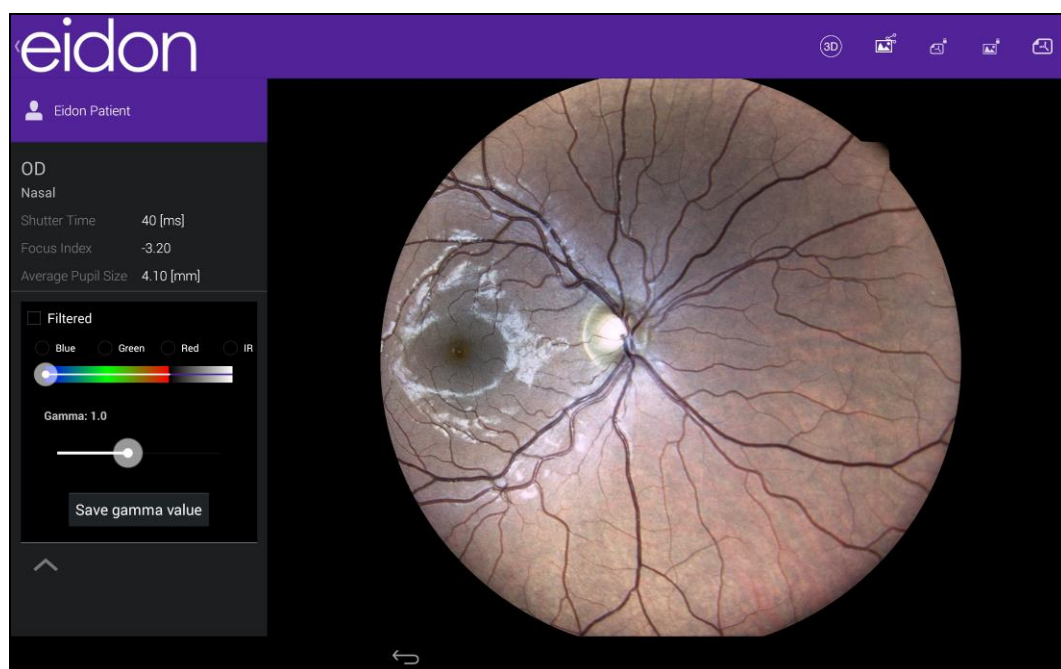


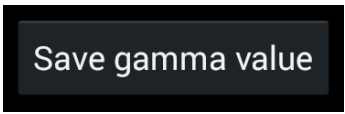









Fig. 42 – Exam review screen, color image

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.
Gamma correction		Used to enhance image brightness by adjusting gamma. This correction does not alter the original image.
Save gamma value		Store the image's gamma in the database. This correction does not alter the original image.
Export to shared folder		Used to manually export an image to a shared folder. File format, folder location and export modality depend on settings. See par. 0 for additional information.
Export image to USB		Used to export an image to USB as a jpg file
Export printout to USB		Used to export printout to USB as a pdf file
Open print preview		Used to open a print preview and/or print. See par. 12 for additional information on printout

Function	Command	Description
Back		Used to return to the Patient Record screen
3D viewer		Opens the 3D viewer. Only available for stereo pairs

11.2 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.

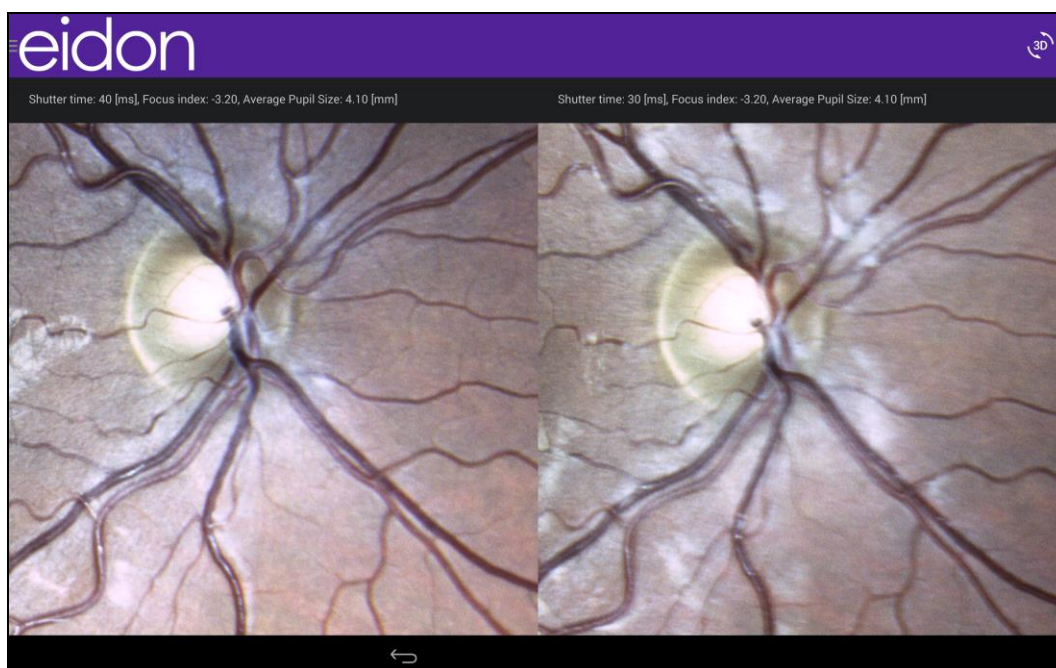




Fig. 43 – 3D review window

Wear your 3D stereo prism glasses and move forward or backward to the image until you see a single 3D picture. To switch between elevations or cavities, press the  logo on the window top right corner.

11.3 Image retake

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

To retake a picture, press the retake  logo on the bottom right thumbinal corner: the logo will turn to purple and the retake button appears on the right. By clicking on this button, an automatic exam with the same parameters starts. After retaking, the software will ask to keep the old picture or replace it with the new one.

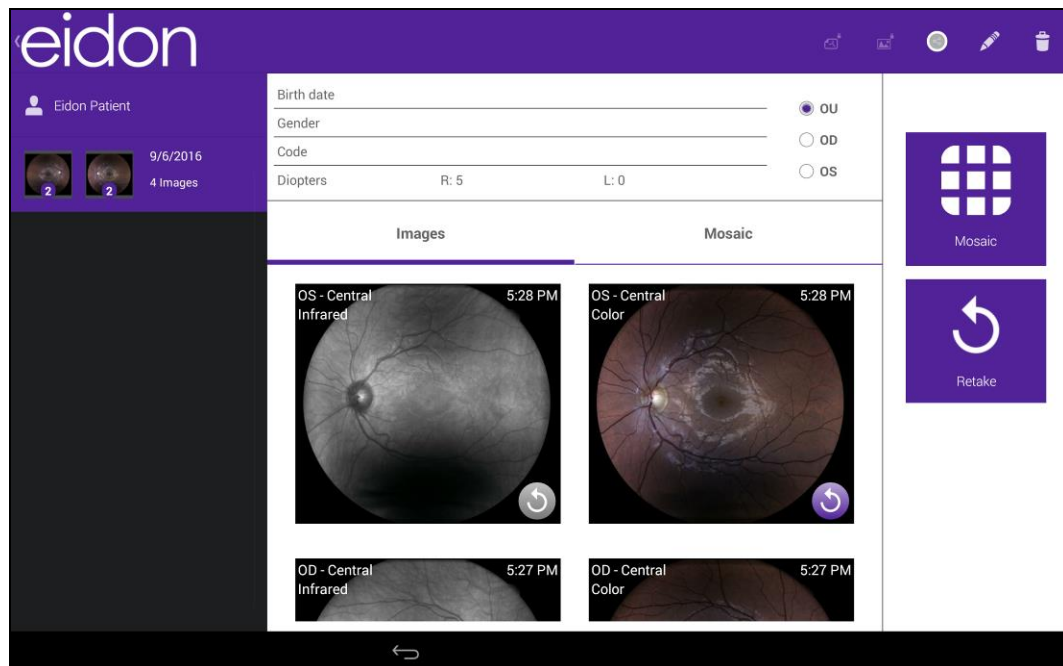


Fig. 44 – Image ready to be retaken

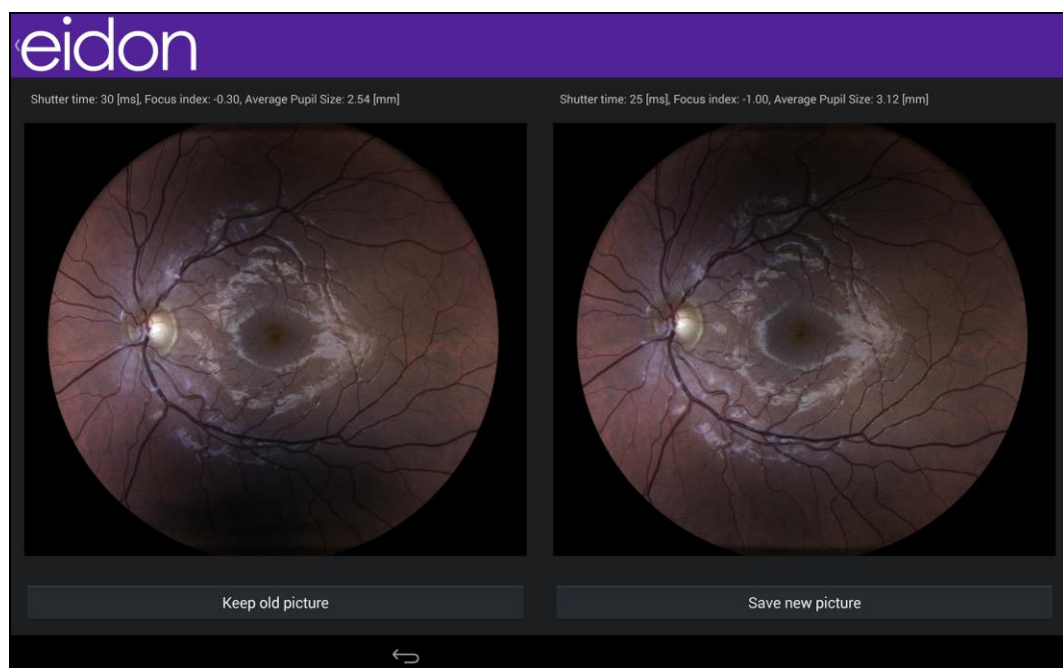


Fig. 45 – Image retaken: choose which picture to keep




11.4 Export functions

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

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


When the export to shared folder function is enabled, an icon at the top of the patient record screen and patient list screen provides information about the status of the export process.

Export-to-shared-folder status icons:

	The export process has completed
	An error prevented completion of the export process
	The export function is disabled

For additional information on how to configure the export to shared folder (i.e. shared folder type, location, username...) see par.13.8.

See par. 17 for information about possible error conditions during the export process.

	EIDON natively stores all images using jpg compression. A 95% quality factor is used. Exported images are identical to those stored in the device , i.e. they retain the same resolution, quality factor and size.
---	---

11.5 Mosaic



2 to 6 fields can be used to generate a mosaic.
A central field is always required.



Fig. 46 – Example of a 3-fields mosaic image generated by EIDON

To create a mosaic, check that the fields of interest have been captured then click on the mosaic button in the **Patient Record** screen (see Fig. 25) to open the **Field selection** screen (Fig. 47). Choose a thumbnail and keep it pressed until it highlights to select the corresponding field; when all fields are selected, click on the **Create Mosaic** button.

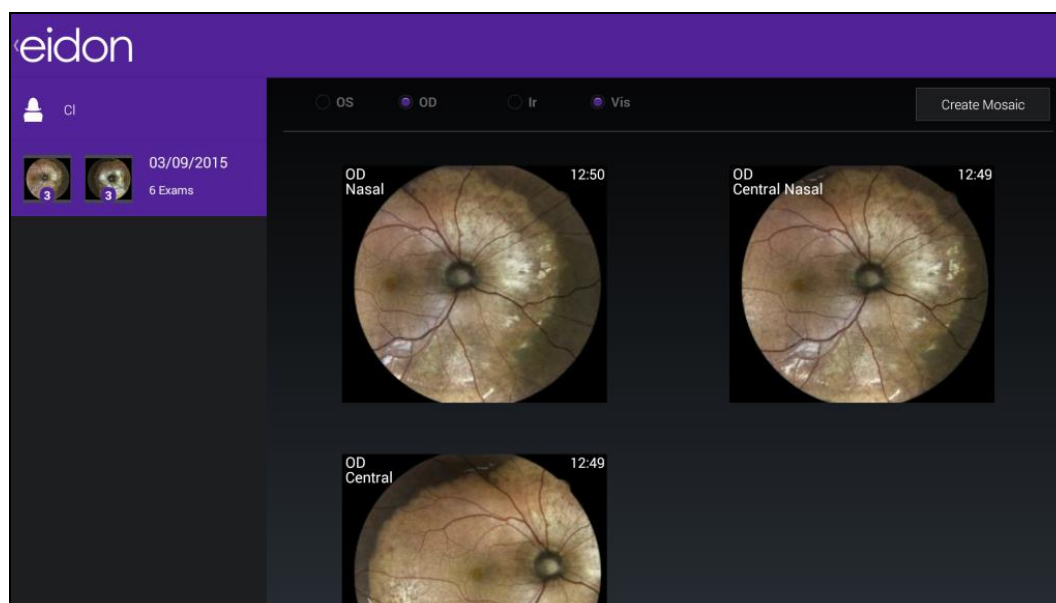


Fig. 47 – Field selection screen

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



EIDON 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 (see par. 11.1). Click on the **Images** tab to go back to single-field image display.



Deleting an image part of mosaic is not allowed: remove the relative 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.

11.6 Dual image review

To review any⁵ two images side by side, keep the thumbnail of the first image pressed until the image is selected (highlighted border); do the same for the second image, then click the button



at the top-right corner of the screen: this will open the **Dual image review** screen (see Fig. 48).

To delete the selected images, click on the recycle bin on the top right screen corner.

To use image enhancement filters, swipe from the right of the screen or click the EIDON logo (see Fig. 49).



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

⁵ Color, infrared and, in AF devices, AF images, left and right eye, same or different dates, same or different fields, etc...

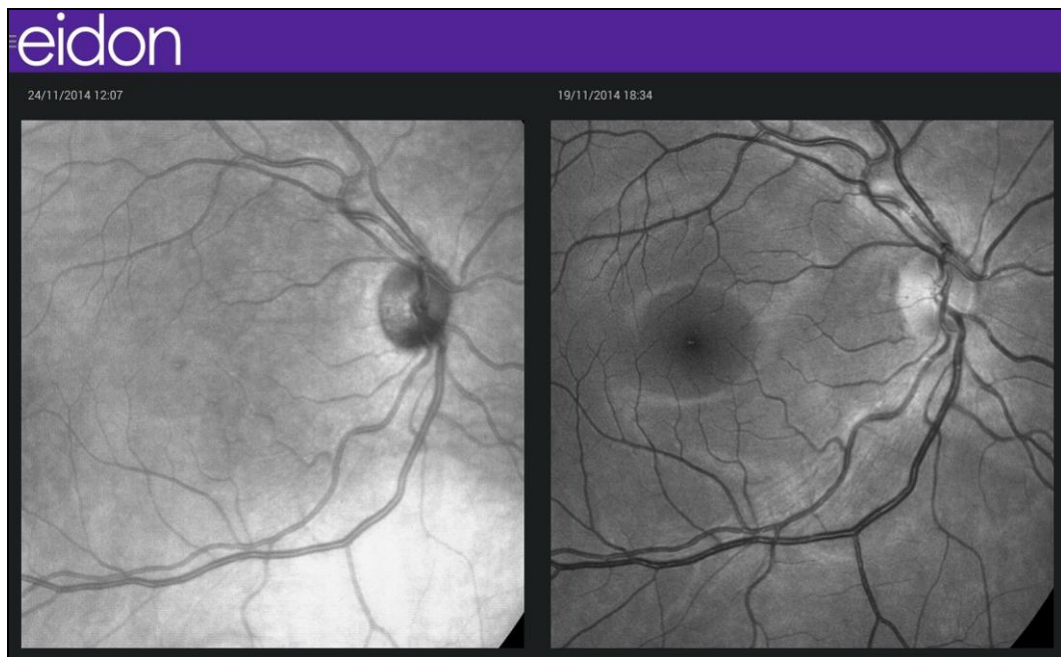


Fig. 48 – Dual image review screen, IR and Red-free images on different visit dates

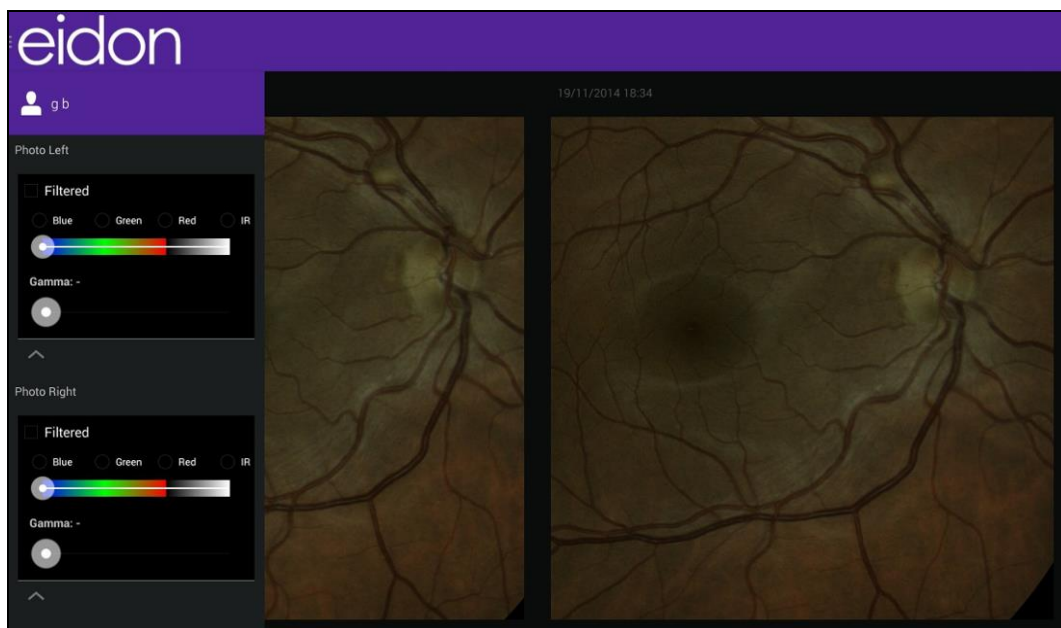


Fig. 49 – Dual image review screen with image enhancements filters

11.7 Remote Viewer

The Remote Viewer is a browser-based software that allows review of EIDON images on any computer connected to EIDON 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 Chrome™, Firefox™ and Safari™.

To use the Remote Viewer, EIDON needs to be connected to the local area network via **Ethernet** connection.



Wi-Fi connectivity is not currently supported.

Setting up the Remote Viewer

To enable the Remote Viewer, connect EIDON to the local network by plugging the network cable to the Ethernet port located on the back of the system (see Fig. 4).




To start using the Remote Viewer a password must be set: to set (or change) the Remote Viewer password see par. 13.1 and 13.3.

Using the Remote Viewer

Open the browser and type <http://fun-sssss.domain> in the address bar, where sssss is the five digits' serial number of the EIDON unit and *domain* is the local network domain name: 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 IP as follows:

- launch the Configurator application (see par. 13.1);
- click on the “NETWORK” tab (see Fig. 63);
- 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. 50), which resembles the corresponding screen in the EIDON on-board software.

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

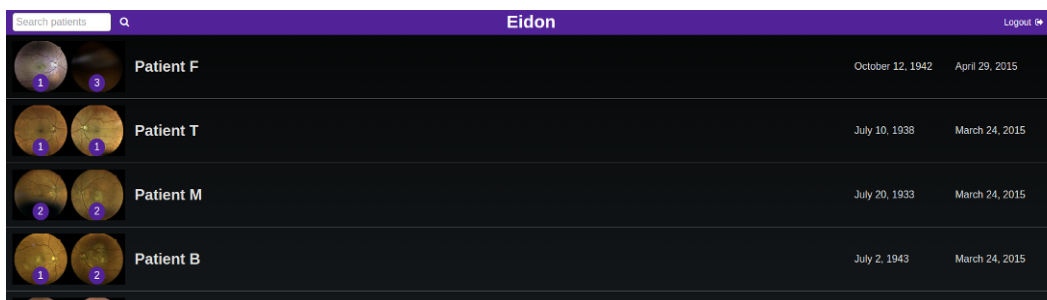
From every remote viewer window, pressing F5 updates the data displayed.

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.











Search patients		Eidon	Logout	
		Patient F	October 12, 1942	April 29, 2015
		Patient T	July 10, 1938	March 24, 2015
		Patient M	July 20, 1933	March 24, 2015
		Patient B	July 2, 1943	March 24, 2015

Fig. 50 – Patient List in Remote Viewer

Click on the desired patient to enter the **Patient Record** screen (see Fig. 51), which resembles the corresponding screen in the EIDON on-board software. Click on **Logout** to exit the Remote Viewer.

Patient Record screen

This screen allows access to individual images as well as mosaic images. Commands available and displayed information are the same of the homonymous screen in the EIDON on-board software. Click on the desired image to enter the **Single Image review** screen (see Fig. 52).

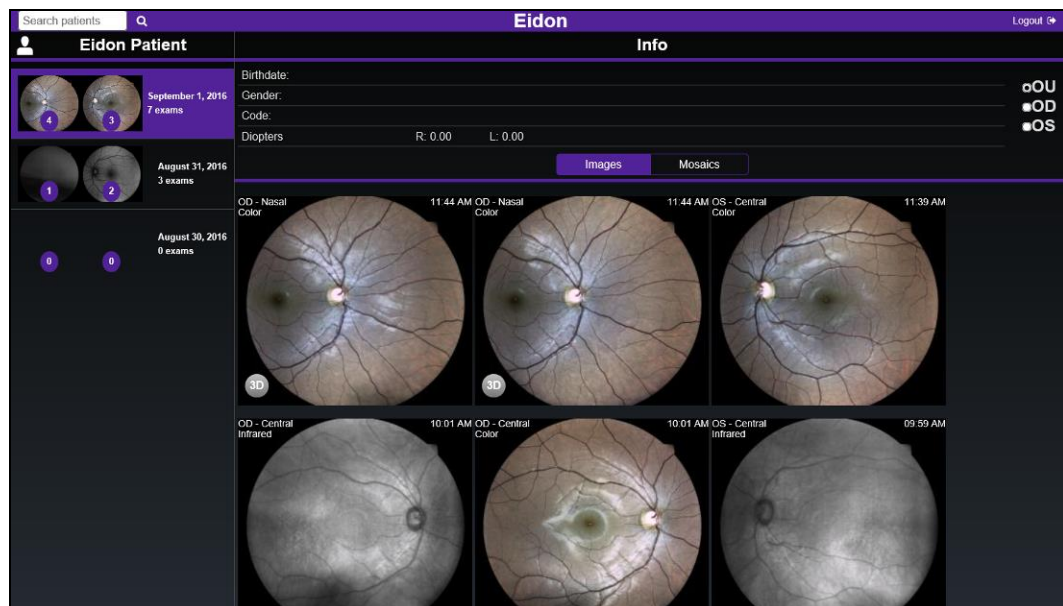


Fig. 51 – Patient Record screen in Remote Viewer

Single Image review screen

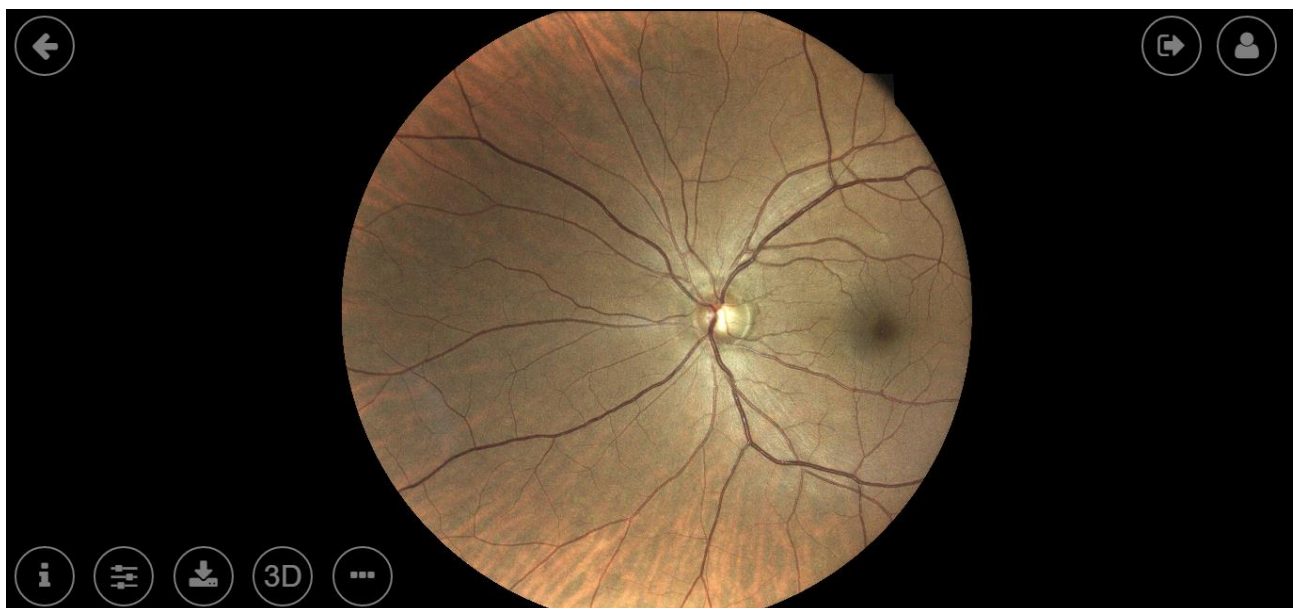










Fig. 52 – Single Image Review screen in Remote Viewer

The following functions are available in this screen:

Function	Command	Description
Back		Back to Patient Record Screen
Logout		Logout from the Remote Viewer
Patient Info		Displays all patient related information (full name, date of birth, gender, code) and gives access to a thumbnail view of all the images available for this patient. Is used also 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. 54).
Exam Info		Displays all exam related information (date and time of capture, eye, pupil size, field, exposure, focus)
Image Filters		Provides access to the red, green (i.e. red-free), blue filters and gamma adjustment (see Fig. 53)
Download		Allows to save original image (jpg), report with original image (pdf), processed image (jpg) or report with processed image (pdf) on local memory (see Fig. 53)
Stereo Mode		Provides access to the stereo mode window (available only for images part of stereo pairs)
Additional Tools		Provide 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

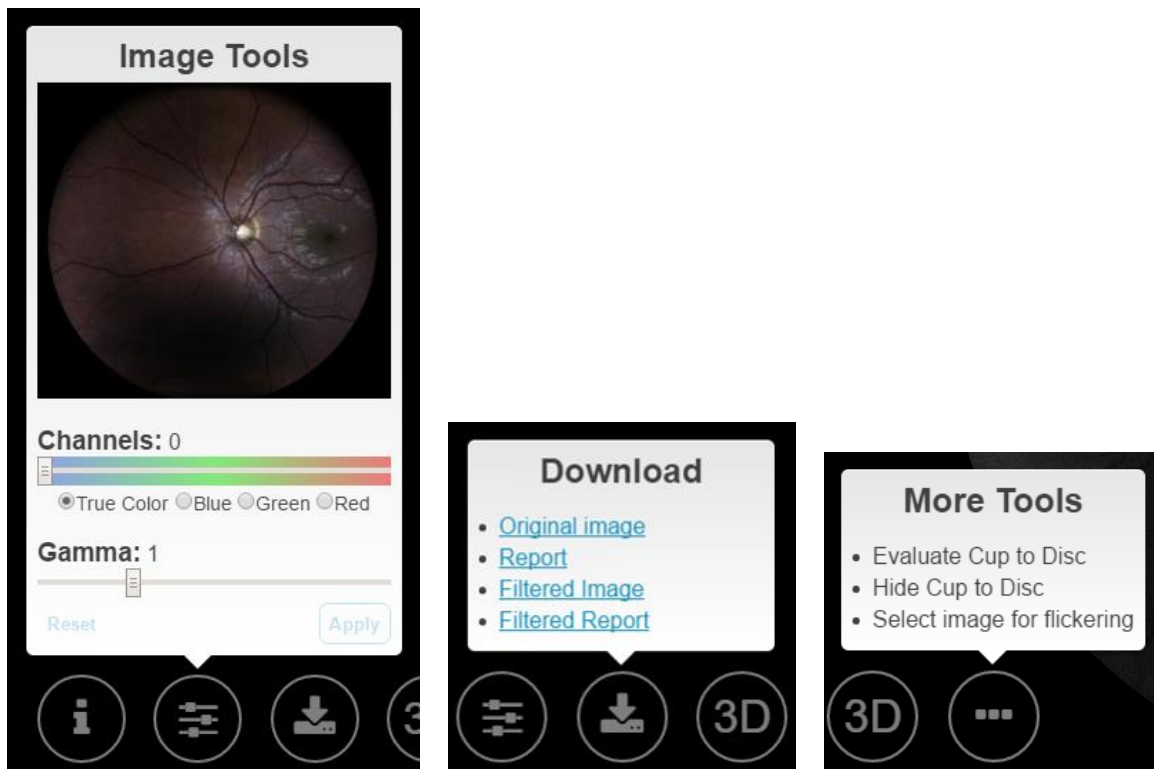


Fig. 53 – Image Filters, Download options and More Tools in Remote Viewer



The image tools do not alter the original image.

Dual Image review screen

As for the EIDON 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).

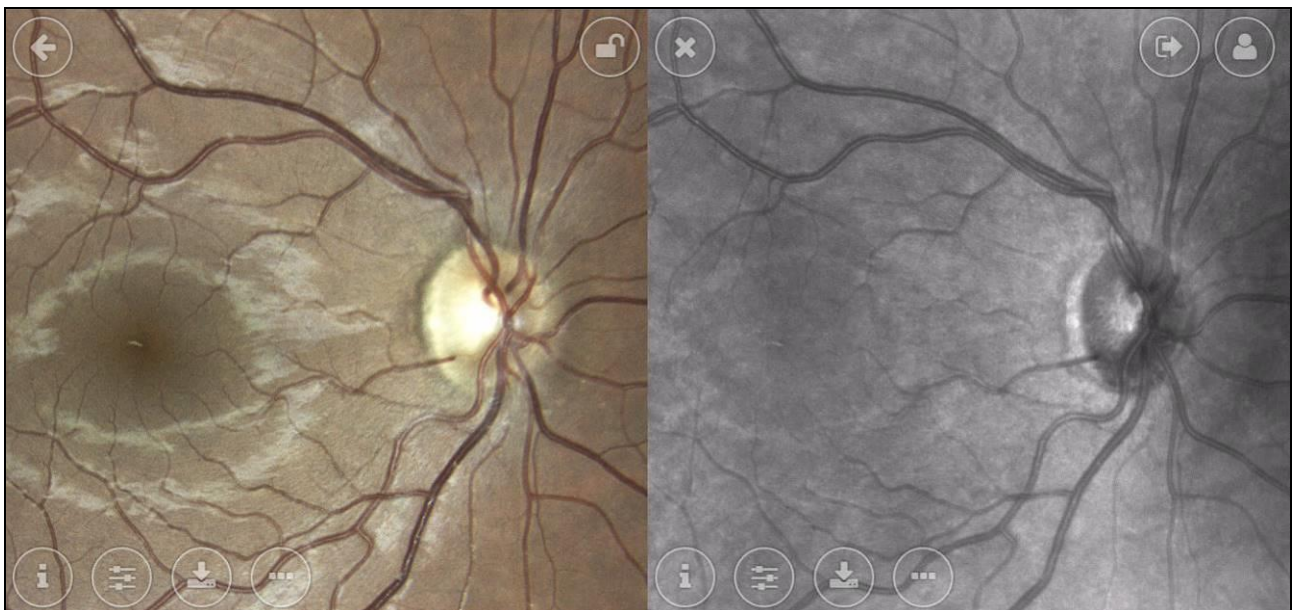




Fig. 54 – Dual Image Review screen in Remote Viewer

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 get zoomed and panned in both images.
Close		Goes back to the Single Image Review Screen.

Stereo image review screen

By clicking on the 3D button at the bottom, the software access to the stereo images review window. For many information about the stereo feature, see the par. 10.8.

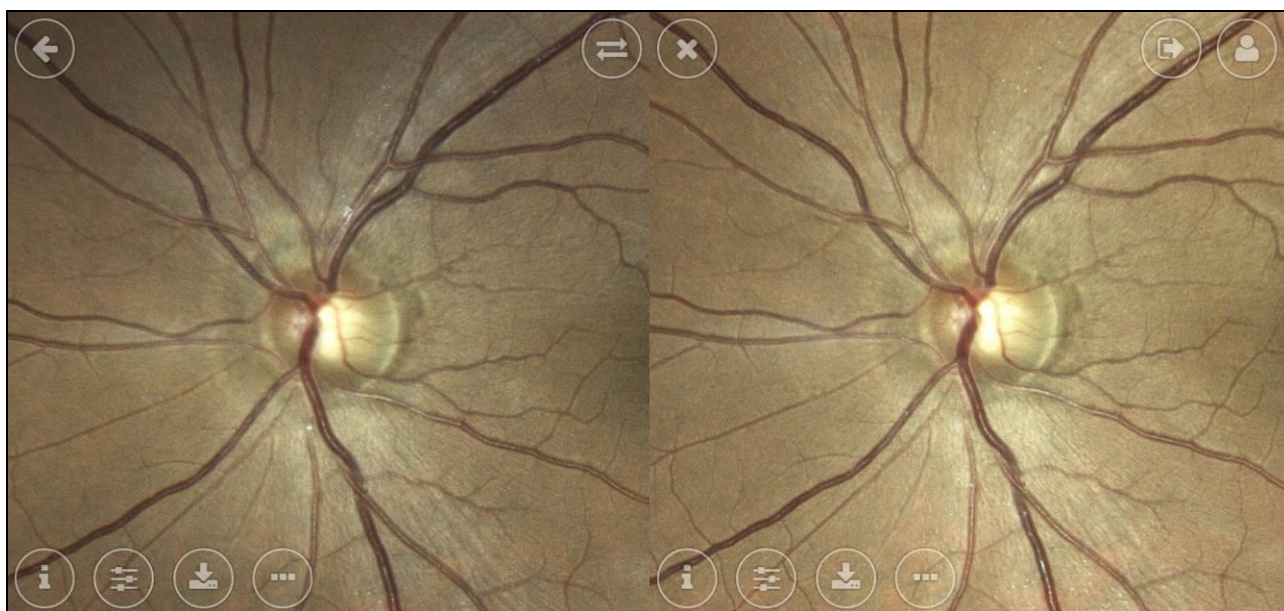




Fig. 55 – Stereo review window

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.

Flickering view

EIDON allows to compare two images one by one, by switching manually or automatically between each other. This feature is called **flickering**. To access to the flickering window, press the Additional Tools button in the Single Image review screen, then click on **Select image for flickering**: the EIDON 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. 56 – Flickering image selection

Select the image to flicker with, then click Done.

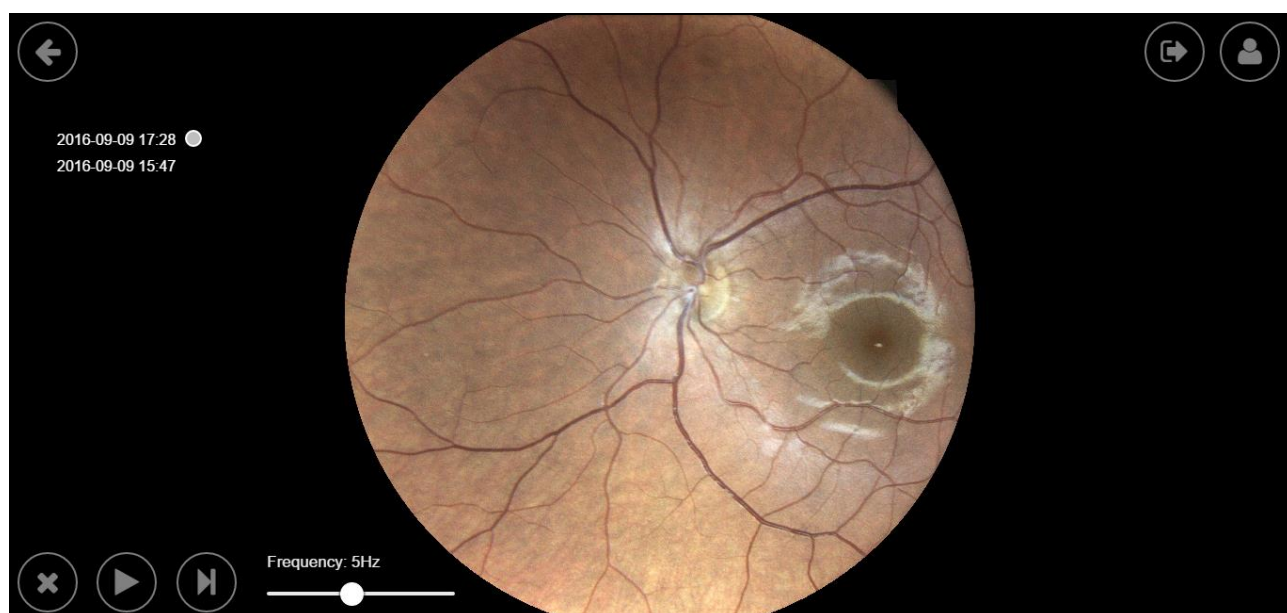


Fig. 57 – Flickering review window

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.

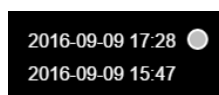



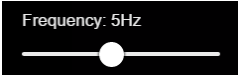


Fig. 58 – Currently active picture: “2016-09-09 17:28”

The following features are available in this screen:

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

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

Cup-to-disc evaluation

The cup-to-disc ratio is the ratio between the optic cup and the neuroretinal rim diameters. To evaluate it, draw the two diameters: click over the picture to start the first segment drawing, then click to define the end. Do the same for the second diameter. The segments can be modified by clicking and dragging the segment endpoints.

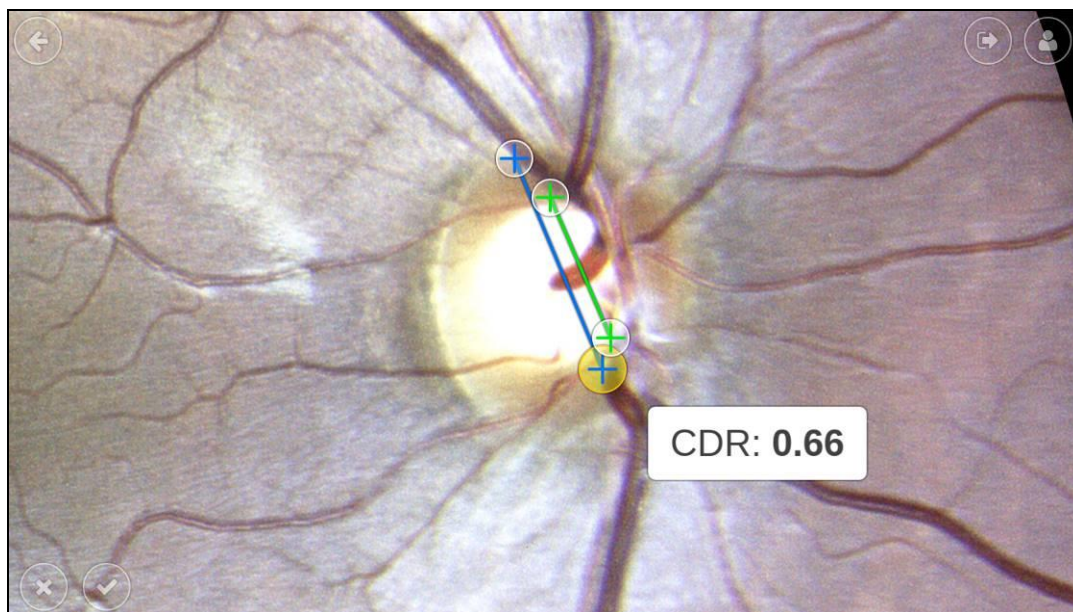




Fig. 59 – Flickering review window

The following buttons are available in this screen:

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

12. PRINTING

12.1 Printer setup

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

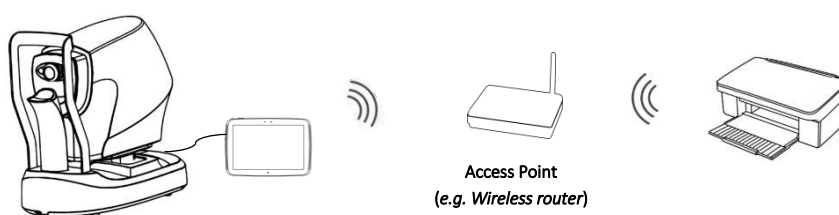
Brand	Description
HP	HP Android ePrint
Samsung	Samsung Mobile Print App
Lexmark	Lexmark Mobile Printing
Canon	Canon Mobile Printing, Canon Easy-PhotoPrint, PIXMA/MAXIFY PrintingSolutions
Epson	Epson iPrint, Seiko Epson Corporation
Konica Minolta	Konica Minolta Printers, Page Scope Mobile

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.

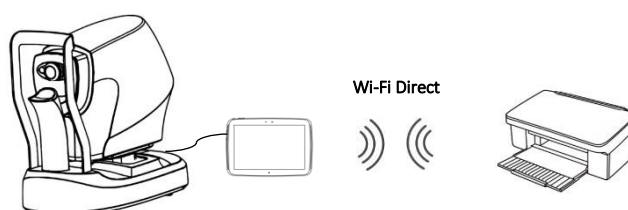
Infrastructure Mode

In this configuration, both the EIDON's tablet and the printer are connected to an Access Point, such as a wireless router.



Ad-hoc Mode

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



12.2 Printout

The EIDON printout (Fig. 60) 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. 13.9)
2. Patient information (name, date of birth, age)
3. Examined eye (OD, OS)
4. Exam information (date, time)
5. Pupil size
6. Captured field position
7. Color retinal image, infrared retinal image or, in AF devices, AF images






Fig. 60 – Print layout with custom header

13. **SETTINGS**

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

13.1 **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 user “Admin” from the drop down menu;
- Type the corresponding password and click login;
- If not enabled, enable tethering by clicking on the icon  (green icon means tethering enabled);
- Click the App icon ;
- Start the Configurator by clicking the icon .

If the DICOM license is activated, the configurator will also include a DICOM tab, to change the DICOM settings.

13.2 **Password change**

Passwords for both the “Admin” and “Doctor” users can be changed in the “Tablet Password” tab of the Configurator by clicking the pencil icon (see Fig. 61). 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 if the passwords are lost**
- **If both passwords are lost, or to reset the “Admin” password, contact your CenterVue Authorized Service Center for support.**

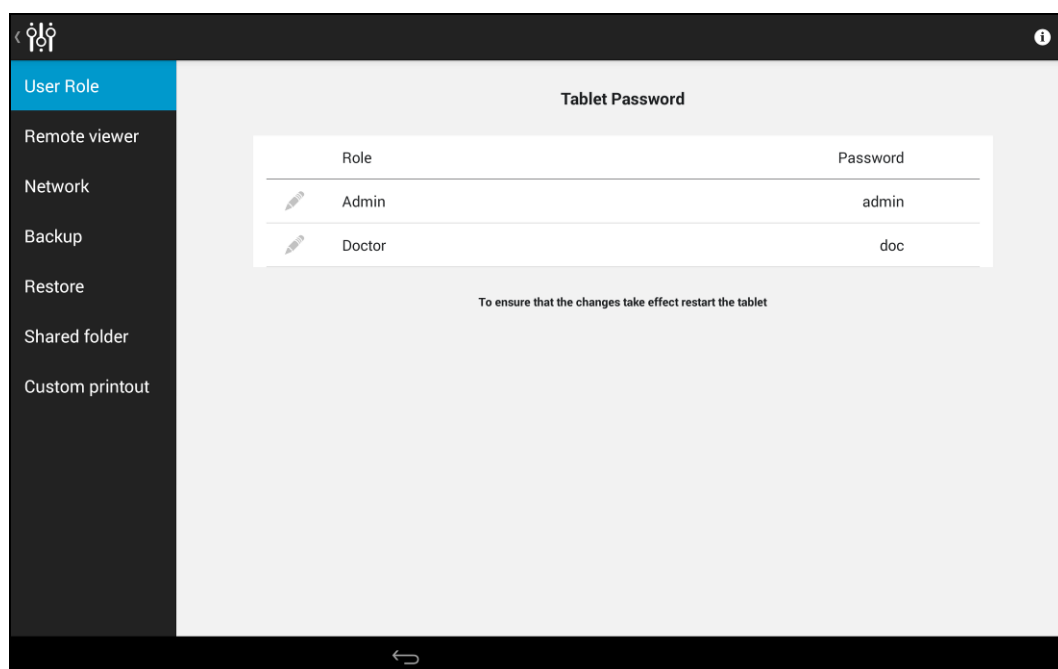


Fig. 61 – Configurator – TABLET PASSWORD screen

13.3 Password change for 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**.

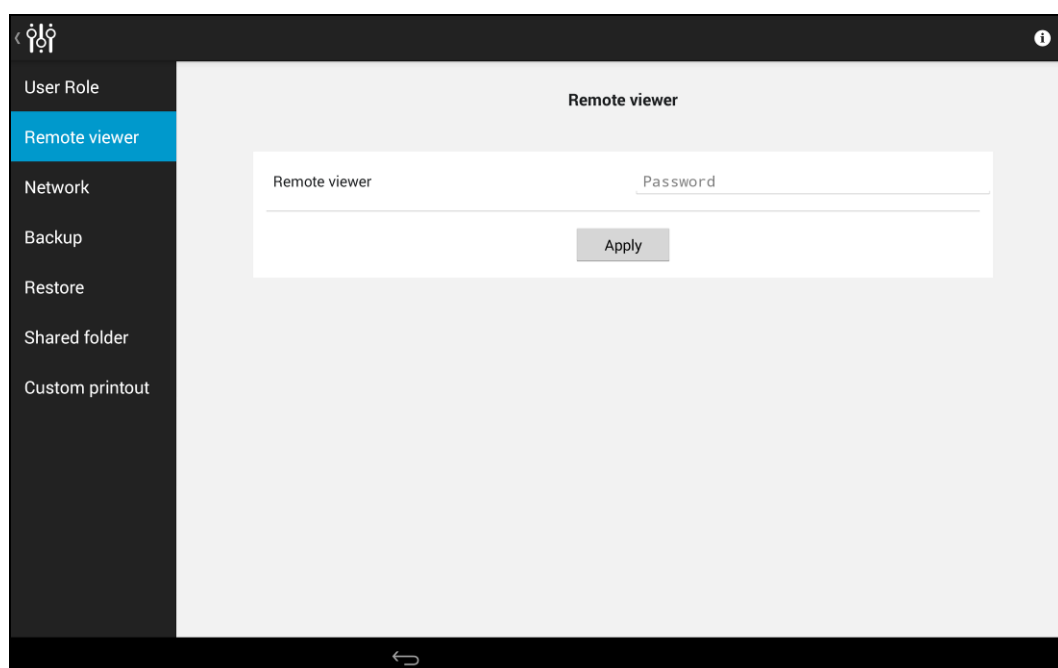



Fig. 62 – Configurator – REMOTE VIEWER screen

13.4 Network configuration

EIDON supports wired network connection.

To enable network connectivity, EIDON must be connected to the local network via Ethernet cable, using the port located on the back of the system. Then click on the “Network” tab to configure the network.

To select the primary network, click on Advanced. To configure the selected network, click on the  icon.

If the network is using static IPs and not DHCP, switch OFF the DHCP and type the IP, Network Mask, Gateway and optionally DNS: you may need to contact your system administrator to obtain these details.

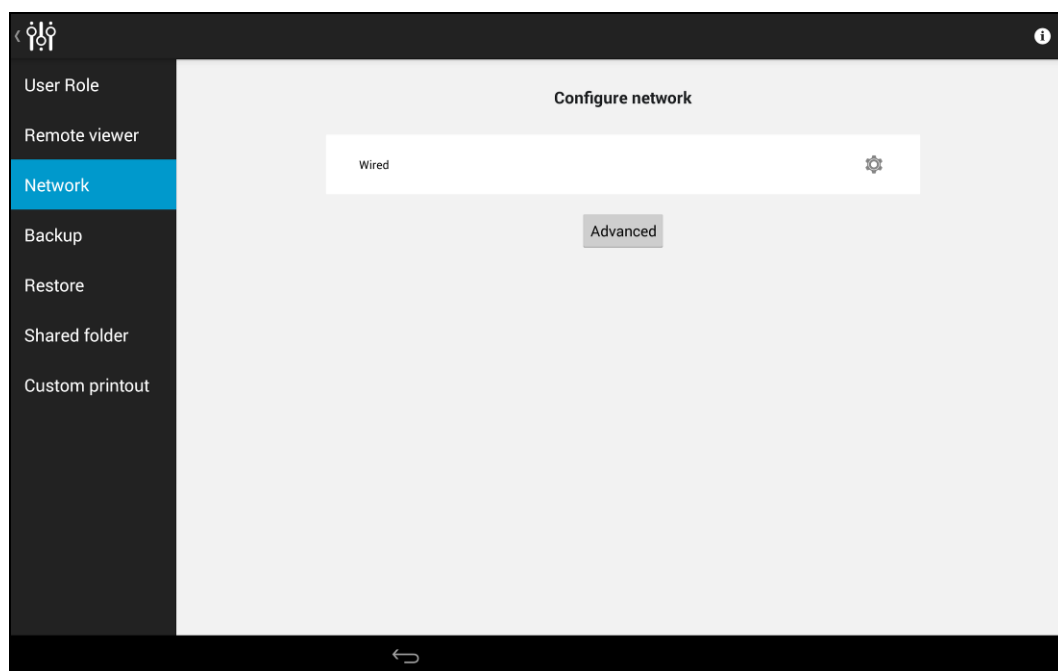


Fig. 63 – Configurator – NETWORK screen

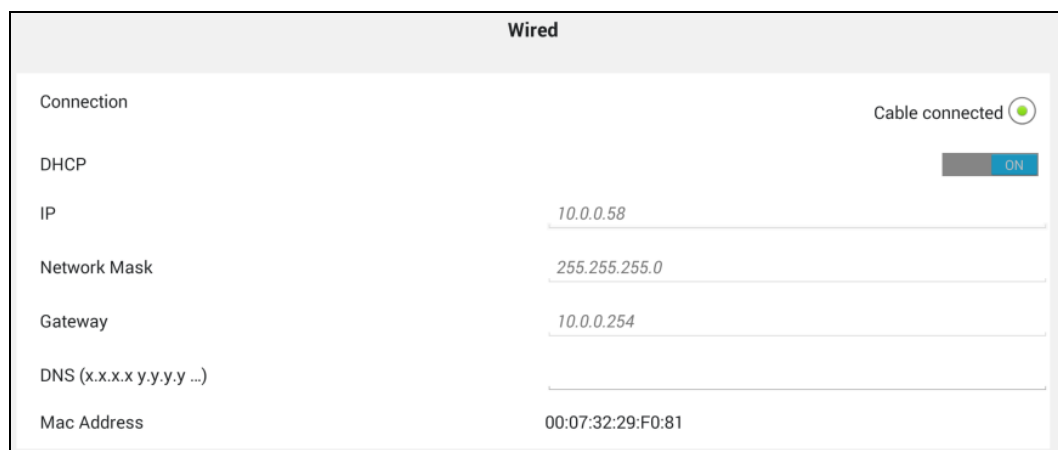


Fig. 64 – Configurator – Specific network configuration screen (in this case: wired network configuration)

13.5 Backup

EIDON provides a USB-based data backup function. **Backup requires an external USB media (hard disk or memory stick), formatted as NTFS, with enough free space to store the backup file.**



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

Patient data (database and images) and calibration files can be backed up separately.

To perform a backup:

- Click on the “Backup” tab of the Configurator screen (see Fig. 65);
- Connect a pre-formatted USB disk to any available USB port (the icon on the top-right corner turns active when a USB device is detected). You might need to temporarily disconnect the external fixation to free up one USB port;
- To perform a backup of the patient data, click on the left-most **Backup** button (“Backup Db/Images”);
- To perform a backup of the device calibration files, click on the right-most one (“Backup Calibration”);
- Wait until message “Backup completed” is displayed.

The name of the backup file contains the ID of the device and the date and time of the backup. It is possible to perform more than one backup on the same USB media, as long as there’s enough available space.

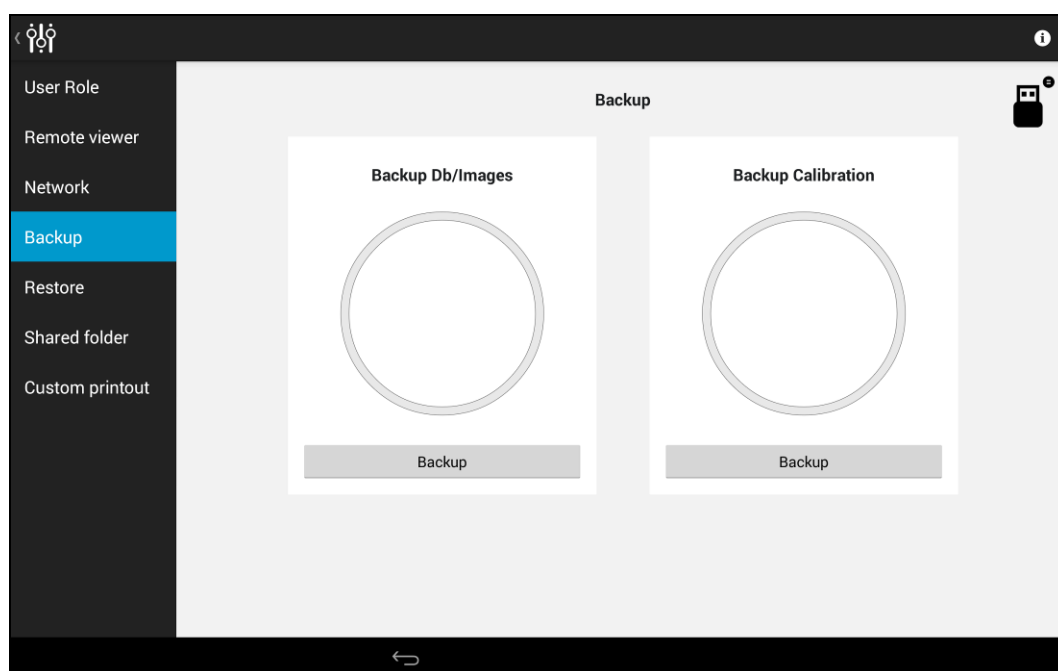


Fig. 65 – Configurator – BACKUP screen

13.6 Restore

To restore from the most recent backup saved on a USB media:

- Click on the “Restore” tab of the Configurator screen;
- Connect the USB disk containing the backup to any available USB port (you might need to temporarily disconnect the external fixation to free up one USB port);
- Click on the left-most **Restore** button for restoring the patient data (database and images) or on the right-most one for the calibration files;

- Wait until message “Restore completed” is displayed.



The restore function will permanently erase all patient data stored in the device and then restore the data and images that are stored on the USB flash drive

To restore from a different backup file (not the latest), move all other backups into a subfolder, so that only the desired backup file is on the top-level folder of the USB media.

To restore from a backup file made on a different EIDON, rename the backup file with the Serial Number of the EIDON that should receive the data.

Example:

A backup of EIDON SN 00001 exists and is named “fun-00001_20150408-1028.backup”.

In order to transfer the content of this backup into EIDON SN 12345, plug the USB media onto any PC and rename the backup file to “**fun-12345**_20150408-1028.backup”.

Eject the USB media from the PC and follow the usual restore procedure.

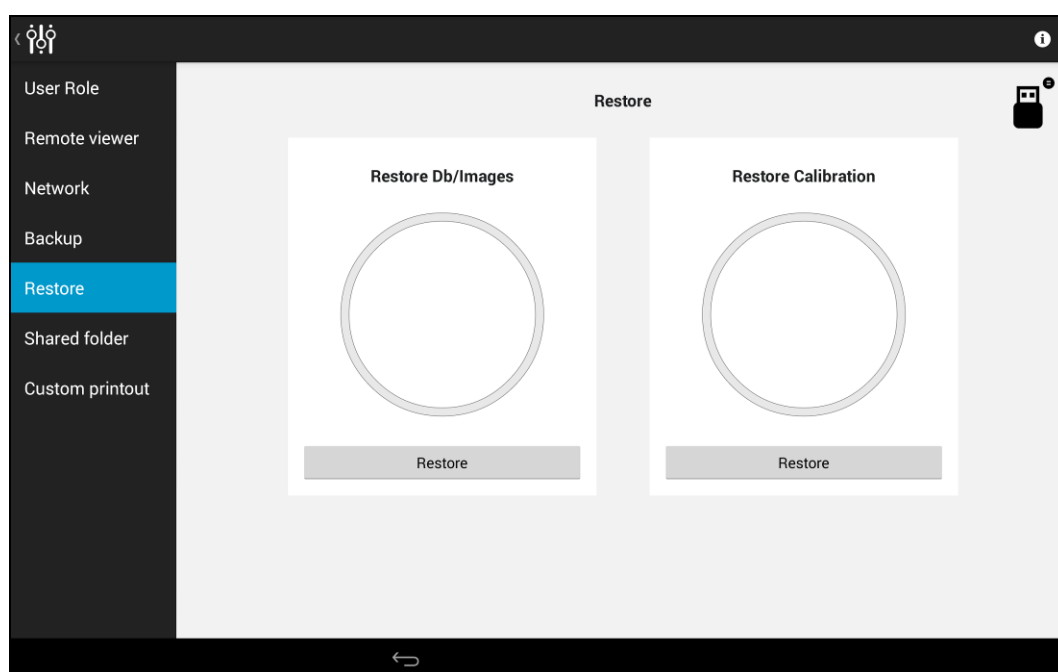


Fig. 66 – Configurator – RESTORE screen

13.7 Device lock reset procedure

In case EIDON raises error codes ranging from “117” to “121”, or from “124” to “130”, entering in a locked state, the Configurator can be used to reset this condition. In such case a warning icon is shown on the top right bar of the Configurator (to 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 will re-initialize. Upon completion of the re-initialization procedure it is possible to restart using EIDON normally. If the error condition keeps occurring, please contact an authorized service center.

13.8 Shared folder configuration

The shared folder configuration tab allows to edit the export parameters. Press **Apply** when the modification process has been completed.

Status

EIDON supports a function for exporting images to a shared folder: this screen is used to enable/disable this function and configure the relevant options.

Mode

When **manual** export is selected images are exported using the export icon located in the single image review screen (see par. 11.1). When **automatic** export is selected images are exported automatically to the selected shared folder upon capture 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 into the device;
- Remote shared folder is a folder located in another computer connected to the Eidon 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, additional information are required:

- **SERVER**: network name of the remote host shall be inserted. The IP of the server may also be used in this field, if the network does not have a DNS.
- **FOLDER**: this field shall contain the name of the shared folder in the server.
- **USERNAME**: if you'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 shall be: *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 remote shared folder destination, the username shall be different from Guest, because of Windows Guest user restrictions.

When the administrator clicks on the apply button and a remote shared folder is selected, the device checks for the configuration and prompt the check result.

File type

If the local option is used, only one export format is available (**JPEG**). Otherwise JPEG, PDF and DICOM formats are available.

Shared Folder Configuration examples

See Fig. 67 as an example of remote shared folder configured for network without domains, and Fig. 68 in case of windows domain network.

Fig. 67 – Configurator – SHARED FOLDER configuration example: automatic export of JPEG images to a remote folder *exported_data* (subfolder of *sharedfolder*), located in the server *REMOTE-PC*, with *John* as server username

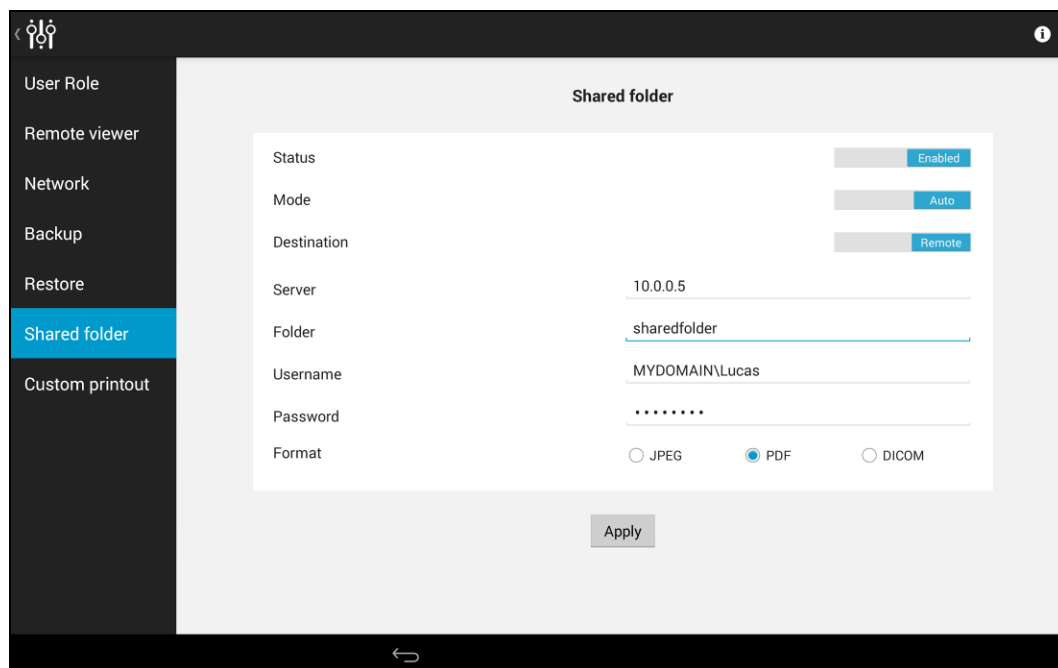


Fig. 68 – Configurator – SHARED FOLDER configuration example, in **Windows Domain Networks**: automatic export of PDF printouts to a remote folder *sharedfolder*, located in the server with IP *10.0.0.5*, with *John* as domain username and *MYDOMAIN* as domain name

13.9 Custom Printout

EIDON reporting can be customized with personal information: it is possible to add a custom logo and 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.png*, or *custom_header_image.png* in 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.

Plug the USB key to the EIDON 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 the “Remove current header” it is possible to remove the custom header from the printouts.

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

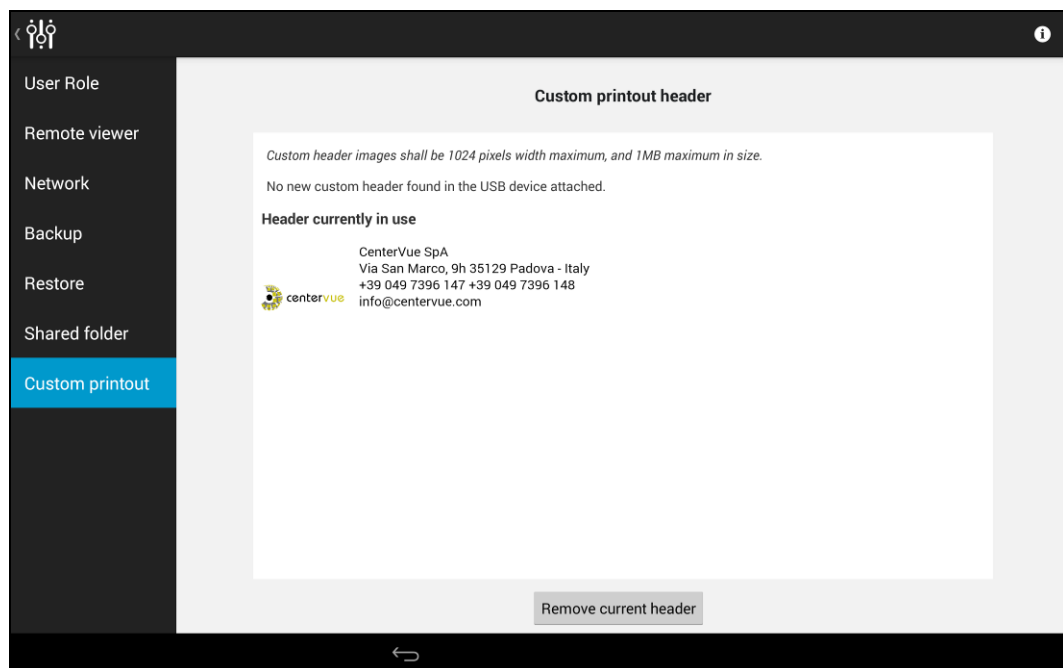



Fig. 69 – Configurator – CUSTOM PRINTOUT configuration

14. **SYSTEM SHUTDOWN**

To shutdown the system, go back to the Home screen and press the power off icon .

15. TECHNICAL SPECIFICATIONS



Class and type of applied part:

1, B (according to EN 60601-1).

IP classification:

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

Image acquisition:

- Non-mydratic (minimum pupil size 2.5mm)
- Field of individual image: 60° (H) x 55° (V) captured in a single exposure
- Sensor resolution: 14Mpixel (4608x3288)
- Light source: near infrared (825-870nm) and white LED (440-650nm). For AF devices, also blue LED (440-475nm)
- Working distance: 28mm
- Resolution: 60pixels/deg
- Resolution on retina: 15microns
- Pixel pitch: 4.9µm

DICOM⁶:

- Compatibility⁷: DICOM version 3.0

Other features:

- Imaging modalities: color, IR, red-free and, only in Eidon AF models, autofluorescence
- Automatic operation: auto-alignment, auto-focus, auto-exposure, auto-capture
- Auto-focusing adjustment range: -12D to +15D
- Dynamic, programmable internal fixation target
- Tablet operated, with 10.1" multi-touch, color display
- Wi-Fi connectivity through tablet
- Hard disk: SSD, 256GB

Dimensions:

- Weight: 25Kg (55lb)
- Size (WxHxD): 360mm x 590mm x 620mm (14.2" x 23.2" x 24.4")

Power supply:

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

Specifications are subject to change without notice for improvement

Service life (lifetime)

The service life (lifetime) of the device is five (5) years from the date of manufacturing.

⁶ Available under additional license.

⁷ Ask to your local distributor for the *DICOM conformance statement*.

16. **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. 70 – Removal of the chin rest silicone pad



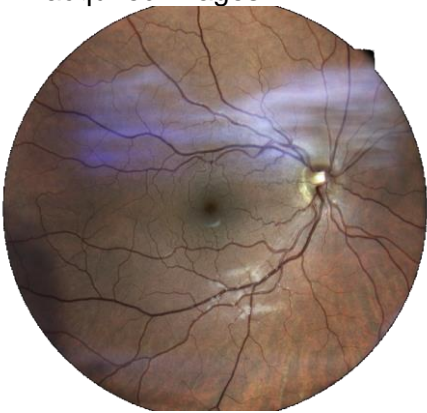
Gently pull up and slide the chin rest pad to avoid breaking the retaining peg.


The front lens should be cleaned by 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 device, the device must be off, and the power cord shall be disconnected from mains. If needed, the external covers of the unit can be cleaned by means of a slightly damp cloth.

17. TROUBLESHOOTING

Symptom	Possible cause(s)	Solution
1. EIDON 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. Message "Disconnected: machine turned off or not responding" appears when trying to access the instrument	EIDON is off	Turn EIDON on and login again
4. Message "Disconnected: cable not connected" appears when trying to access the instrument	USB cable is disconnected from tablet and/or from device	Connect USB cable and login again
5. Message "Disconnected: tethering not enabled" appears when trying to access the instrument	Login was made with "Admin" user and tethering was not enabled	Enable tethering or switch to "Doc" user and login again
6. Bluish artifacts as in this example appear in all newly acquired images 	Front lens is dirty	Clean the front lens
7. Captured image is totally white	Subject blinked during image capture	Repeat capture and ask subject not to blink
8. System is not usable with message "internal error: device temporarily locked"	Malfunction of the rotating mirror or of the infrared LED board for pupil illumination	See par. 13.7 to reset the lock condition. If the condition presents frequently, contact authorized service center
9. Tablet does not turn on and does not recharge	Tablet is fully discharged and current from device is not sufficient to initiate recharge	Use the wall charger found in the accessory box to charge the tablet for at least one hour, then connect it normally to EIDON

Symptom	Possible cause(s)	Solution
<p>10. One or more dark areas appear in color and/or IR pictures</p> 	<p>Pupil is too small (< 2.5 mm)</p>	<p>Dark adapt subject. Eventually dilate subject</p>
<p>11. Export to the remote shared folder fails with message “The selected host is not reachable” or “Timeout”</p>	<ul style="list-style-type: none"> • Network connection to the remote shared folder not working • write access to the selected remote folder not granted • host computer is not reachable 	<ul style="list-style-type: none"> • 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
<p>12. Export to the remote shared folder fails with message “Unknown error”</p>	<p>The remote export folder was renamed after the export destination was configured</p>	<p>Re-configure the export destination</p>
<p>13. Export to the remote shared folder fails with message “The shared disk is full.”</p>	<p>The computer hosting the shared folder has a full hard disk</p>	<p>Empty some space on the host computer or change the export destination to another computer</p>

18. ELECTROMAGNETIC COMPATIBILITY

This device has been tested and found to comply with the limits for medical devices contained in IEC60601-1-2 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;
- consult 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.

Manufacturers EMC Declaration to ISO 60601-1-2

The following tables provide specific information regarding compliance of EIDON:

EIDON is intended for use in the electromagnetic environment specified below. The customer or the user of EIDON should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	EIDON 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 B	EIDON is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes, providing the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orientating or re-locating EIDON or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 4: Electromagnetic Emissions

Guidance and manufacturers declaration – electromagnetic immunity


Immunity Test	IEC60601 test level	Compliance Level	Electromagnetic environment guidance
Electro-static discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±4 kV contact ±4 kV air Note: ESD levels in excess of ±4kV applied to the sensor input connectors can damage the sensitive measurement electronics.	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 N/A 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) N/A for lines 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% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	AC Power Port Dips of: >95% for 0.5 cycle; 60% for 5 cycles; 30% for 25 cycles; 100% for 250 cycles of Vnom repeated 10 times at 10 second 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	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the AC 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
<p>Conducted RF IEC61000-4-6</p> <p>Radiated RF IEC61000-4-3</p>	<p>3 Vrms 150KHz to 80MHz</p> <p>3V/m 80MHz to 2.5GHz</p>	<p>3Vrms 3V/m</p>	<p>Portable and mobile RF equipment should be used no closer to any part of EIDON, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1.17\sqrt{P}$</p> <p>$d = 1.17\sqrt{P}$ 80MHz to 800MHz $d = 1.17\sqrt{P}$ 800MHz to 2.5GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> 
<p>NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.</p>			
<p>^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 is used exceeds the applicable RF compliance level above, EIDON should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating EIDON.</p> <p>^b Over the frequency range 150Khz to 80MHz, field strengths should be less than 3V/m.</p>			

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

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

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
<p>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.</p> <p>NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.</p>			

Table 7: Recommended Separation Distances

FCC (USA) and IC (Canada) radio certification

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

- FCC ID: PPD-AR5BHB116
- IC ID: 4104A-AR5BHB116
- CMIIT ID: 2010AJ4574

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.

19. **DISPOSAL**

EIDON 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 the separate collection for Waste of Electrical and Electronic Equipment (WEEE). The users of Electric and Electronic Equipment (EEE) have not to dispose of WEEE as unsorted municipal waste, they have to collect such WEEE separately. The available return and collection system is defined by the local public administration, or in alternative an authorized company can recycle the WEEE. Please refer to public administration about the separate collection, if this information is not available, contact the manufacturer of the equipment. Users have a fundamental role in contributing to reuse, recycling and recovery of WEEE. The potentially dangerous substances contained in the WEEE can pollute the environment and produce harmful effects to the human health. Below, there are a few indications of specific dangers of some substances, which may leach in the environment and in the water system.

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

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

Mercury: is easily accumulated in organisms and concentrates through the food chain. It has chronic effects and can cause brain damage. Chromium (Hexavalent): easily absorbed into cells with toxic effects. The results can be allergic reactions, asthma and it is 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).

