drsplus

Operating Manual

MANUAL INFORMATION

Date of release:	December 11th, 2020
Revision Number:	9
Reference software version:	1.5
Manufacturer:	CenterVue S.p.A. Via San Marco 9h, 35129 Padova – ITALY Tel. +39 049 501 8399 Fax +39 049 501 8398

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

CONTENTS

1. Introduction

Congratulations for choosing drs$_{plus}$ and its color confocal retinal imaging capabilities.

The drs$_{plus}$ is intended for the acquisition of colored images of the retina without the use of a mydriatic agent. More specifically, the drs$_{plus}$ provides colored images of the retina with a field of view of 45° x 40°, in fully automatic mode. The device includes an embedded software application and operates as a stand-alone unit.

The clinical interpretation of the images acquired by the drs$_{plus}$ is restricted to licensed eye care practitioners. The process of making a diagnosis using drs$_{plus}$ results is the responsibility of the eye care practitioner.

Use of the device is strictly limited to suitably trained operators.

Federal law (U.S.) restricts this device to sale by or on the order of a physician.

2. Symbols

2.1 Symbols used on the device

The meaning of the symbols adopted in the device labels and on the device back panel is as follows:

Symbol	Explanation
	Information about the Manufacturer.
	Manufacturing date (year-month).
	Electrical and electronic waste is destined for separate recycling.
	Refer to the Operating Manual.
CE 0123	CE mark: the device complies with the essential requirements of the European Medical Devices Directive 93/42/EEC.
	Type B Applied Part.
	Non-ionizing radiation - ME EQUIPMENT that includes RF transmitters.
	Direct current.
	Power button. See the device back panel (Fig. 7).

2.2 Other symbols found in this manual

Symbol	Explanation
	Important Information.
	General Warning, read carefully.

3. Product description

The drs$_{plus}$ consists of:

- The device (with a lens cap for shipping only) (Fig. 1);
- Cables protection shell (Fig. 2);
- Device stand (Fig. 3);
- Headrest with silicone cushion (Fig. 4);
- External power supply (Fig. 5) which includes a country-specific power cable.

Fig. 1 – drs$_{plus}$ device

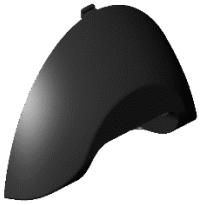


Fig. 2 – Cables protection shell

Fig. 3 – Device stand

Fig. 4 – Headrest

Fig. 5 – External power supply

Fig. 6 – drsplus

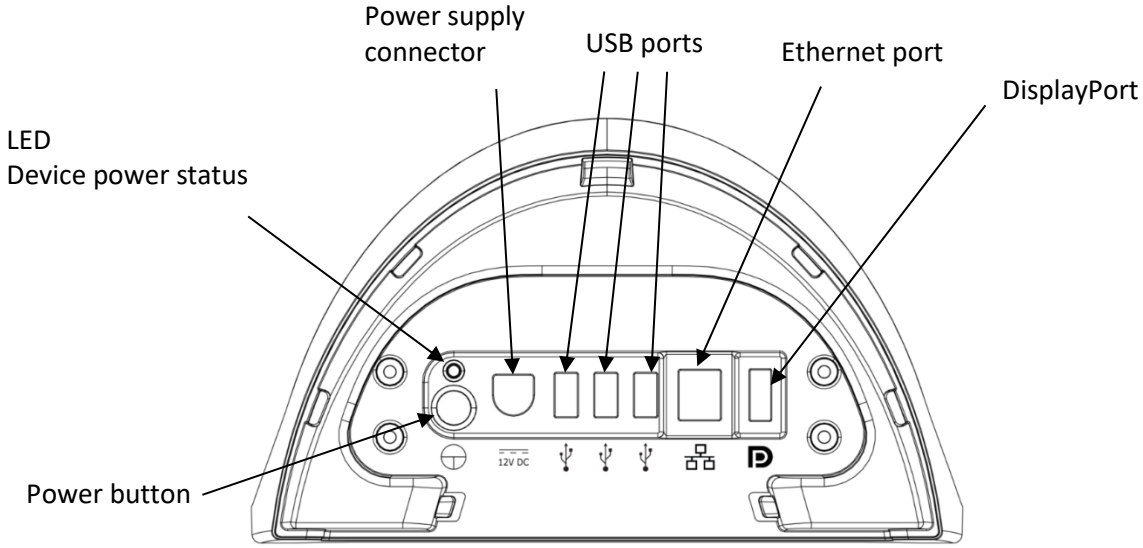


Fig. 7 – Back Panel

The drs$_{plus}$ can be optionally equipped with:

- External fixation target (Fig. 8);
- Prismatic goggles for stereo view (Fig. 9); see §9.5 to have more details on the stereo view functionality.

Fig. 8 – External fixation target

Fig. 9 – Prismatic stereoscopic goggles

The drs$_{plus}$ is provided with:

- This operating manual;
- Contents list;
- Unpacking, packing and setup manual;
- Climatic preconditioning instructions;
- Electrical test report.

4. Labels

The device label is located on the back side of the display, as shown in Fig. 10

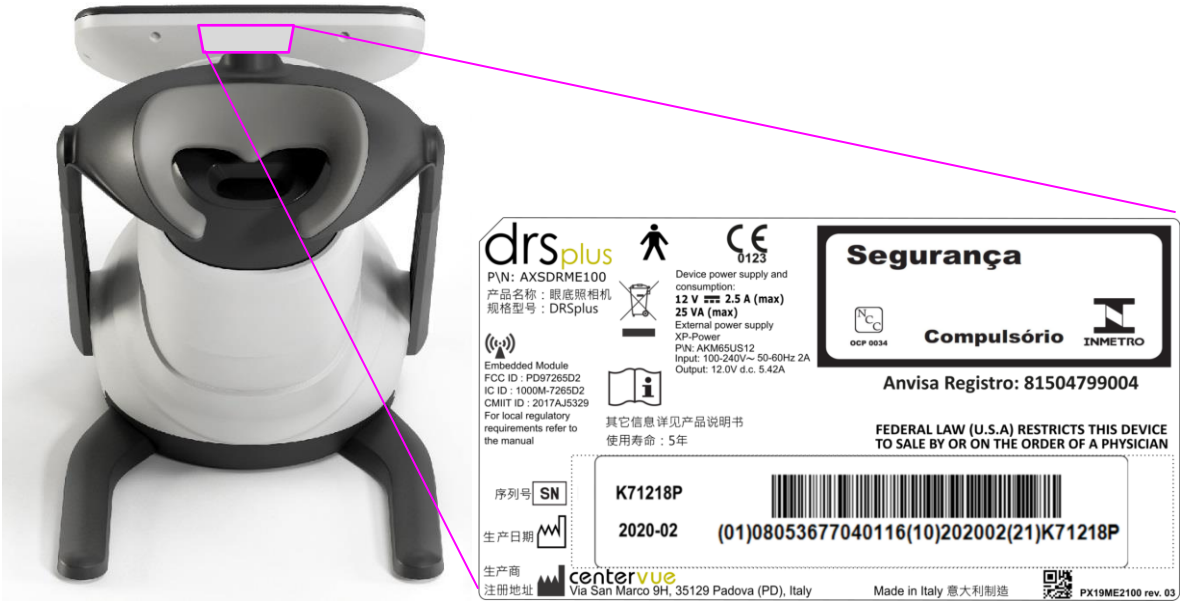


Fig. 10 – Device label[1]

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

5. WARNINGS AND PRECAUTIONS

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

- **The clinical interpretation of the images acquired by the drs$_{plus}$ is restricted to licensed eye care practitioners. The process of making a diagnosis using drs$_{plus}$ results is the responsibility of the eye care practitioner.**
- **Use of the drs$_{plus}$ is restricted to operators who have undergone the necessary training.**
- **Do not open the drs$_{plus}$ in order to prevent the risk of electrocution and damage to the device itself.**
- **Do not use the drs$_{plus}$ if the covers or other parts of the device have been removed.**
- **Only technicians authorized by CenterVue may service the drs$_{plus}$. CenterVue cannot be held responsible for the device safety should drs$_{plus}$ be opened, repairs carried out, third-parties' software be installed, or parts be replaced by an unauthorized person.**

- **Avoid all contact with water: risk of fire or electric shock.**
- **Stand clear from moving parts during operation.**
- **The drs$_{plus}$ is equipped with an earth connection by means of a protective conductor inside the power cable. Before switching on the device, check that the power outlet is correctly earthed to avoid the risk of electrocution.**
- **The drs$_{plus}$ must be used in a room with an electrical system that complies with applicable healthcare environment safety regulations.**
- **The drs$_{plus}$ power supply must be connected to a socket with a circuit breaker.**
- **The drs$_{plus}$ must NOT be used in an oxygen-rich environment or in presence of flammable anesthetics.**
- **External devices connected to the drs$_{plus}$, into the patient environment, must comply with IEC 60601-1. Those devices that do not comply with the IEC 60601-1 must be kept out of the patient environment and must comply with IEC 60950-1. Any operator who connects external devices to drs$_{plus}$ creates a new Medical**

Electrical System as defined by IEC 60601-1 and is therefore responsible of the conformity of such system with the requirements defined in clause 16 of IEC 60601-1. Please contact the local distributor for any additional information.

- **When in operation, drsplus contains Personal Data.**
  IT IS THE END USER'S RESPONSIBILITY TO KEEP AND MAINTAIN AN UPDATED COPY OF THE DATA GENERATED BY THE drsplus THROUGH REGULAR USE OF THE BACKUP FACILITY, THUS PREVENTING THE RISK OF ACCIDENTAL LOSS OF DATA.
- **The drsplus needs to be operated in the following environmental conditions:**
  - **Temperature: +10 °C to +35 °C (50°F to 95° F)**
  - **Humidity (max): 90% not condensing**
- **The drsplus needs to be stored in the following environmental conditions:**
  - **Temperature: -10 °C to +55 °C (14° F to 131° F)**
  - **Humidity (max): 95% not condensing**
- **The drsplus 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 device cannot be guaranteed if these conditions are not met.**

The following precautions are important to avoid incorrect use of the device:

- Provide explanations to patients before placing them in front of the device.
- Use the device in dim light, or at least away from direct light. This will facilitate the natural dilation of the pupil.
- The minimum pupil diameter required to obtain good quality images is 2.5 mm.
- If the patient does not fix correctly and steadily, the images acquired may relate to portions of retina that are not what is expected.

6. Notes for the operator

This section provides basic information for drsplus end users (operators). No specific skills are required to use the drsplus. However, end users must receive the minimum training in the use of the device. The acquisition of images using the drsplus does not involve any risks. This is because the device does not come into contact with the patient's eye and the only perceived effect will be a flash of light when each shot is taken. The device is controlled entirely by touchscreen. Once the acquisition sequence has started, the drsplus will perform the examination automatically.

IT IS THE END USER'S RESPONSIBILITY TO KEEP AND MAINTAIN AN UPDATED COPY OF THE DATA GENERATED BY THE drsplus THROUGH REGULAR USE OF THE BACKUP FACILITY, THUS PREVENTING THE RISK OF ACCIDENTAL LOSS OF DATA.

6.1 Definitions

Device: is the synonym of drsplus used in this operating manual.

Exam: any image acquisition session performed using the drsplus for a certain patient on a certain date.

External eye examination: examination mode involving the acquisition of images of the ocular surface instead of the retina.

Field: portion of the retina visible in a specific image.

Fixation: the ability of a patient to fix his/her view on a specific point, for example the internal fixation target of the drsplus.

Fixation target: small bright green circle visible when looking into the front lens of the drsplus, used to move the gaze of the patient and capture different fields.

Pupil: is the opening located in the center of the iris, of variable diameter, which allows light to enter the eyeball. The pupil naturally is open (dilated) and contracts when struck by light. If the pupil is too small the image quality may be impaired.

Retina: The inner layer of the eyeball. It is the main area of interest in the images acquired by drsplus

Stereo exam: examination mode that involves the acquisition of two images of the retina taken from different angles, providing a three-dimensional view using suitable prismatic glasses.

- If the patient does not fixate correctly and steadily the green light during the exam, the images acquired may relate to portions of retina that are not what is expected.
- Provide explanations to patients before placing them in front of the device (see §8).

7. Preparation of device

This section explains how to set up the drs$_{plus}$ for use.

7.1 First usage

Read carefully the chapter 5 before proceeding to the device operation.

To prepare drs$_{plus}$ for the first usage:

- Take the device out of its shipping box and place it onto a suitable table;
- Install the headrest (included in the package) on the device (Fig. 11);
- Connect the power supply to the back panel, and to the wall socket;
- (Optional) Connect a printer to one of the USB ports located in the back panel of the device;
- Install the cables protection shell.

drs$_{plus}$ needs to be operated in a semi dark environment, to ease the natural dilation of the patient's pupil.

Fig. 11 – Headrest

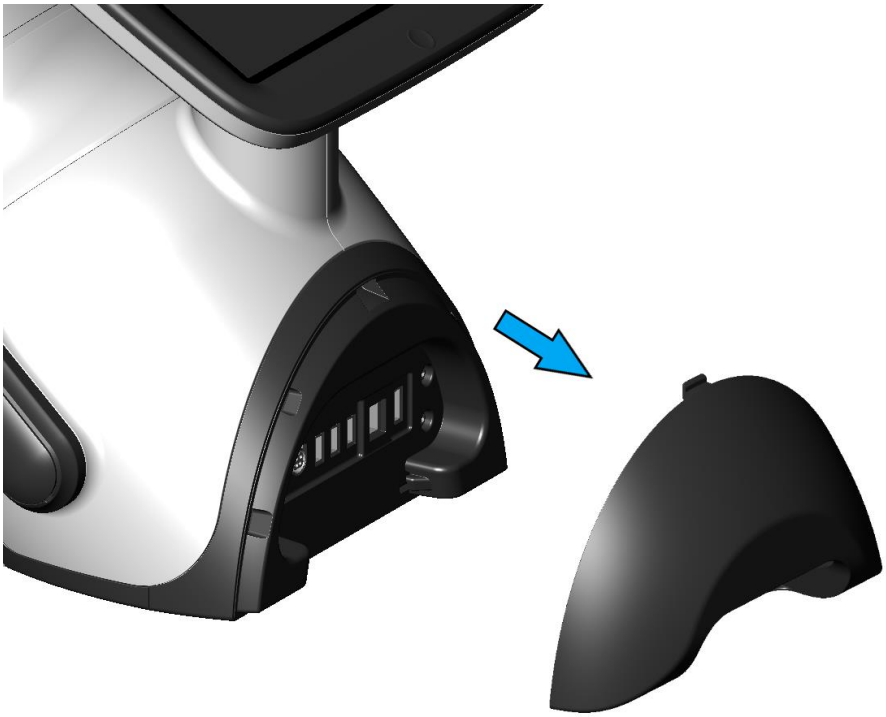


Fig. 12 – Back panel with cables protection shell

7.2 Initial configuration wizard

Turn on the device by pressing the power switch button: upon the first power on of the device, the initial Configuration Wizard will be (Fig. 13).

Use the button located near the top-right corner of the screen to temporarily skip the Configuration Wizard and go straight to the login screen. The Configuration Wizard will be shown the next time the device is started.

To proceed with the Configuration Wizard, press the **START** button. In any of the wizard steps, it is possible to browse back to the previous interface by pressing the **PREVIOUS** button.

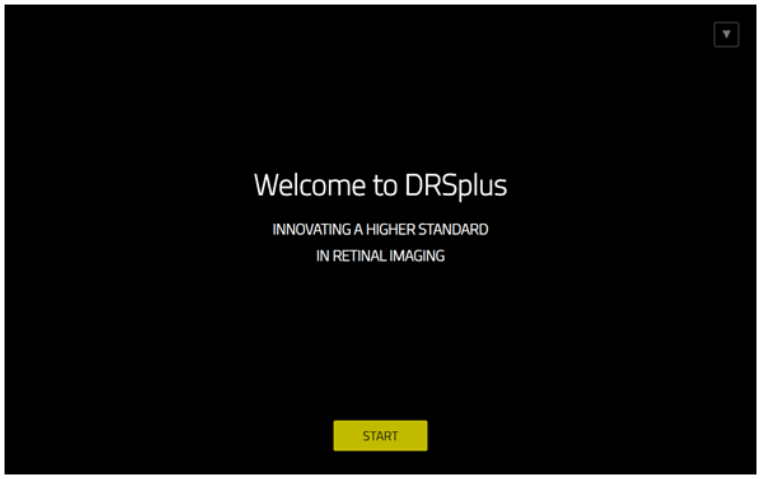


Fig. 13 – Beginning of the Configuration Wizard

In the following step it is possible to set the current time-zone (Fig. 14).

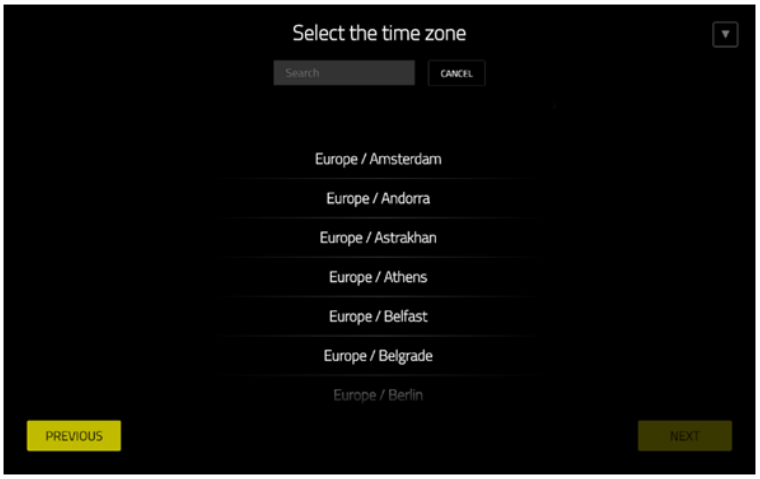


Fig. 14 – Configuration Wizard: setting of the local time-zone

In the following step it is possible to set the current date and time and configure their format (Fig. 15).

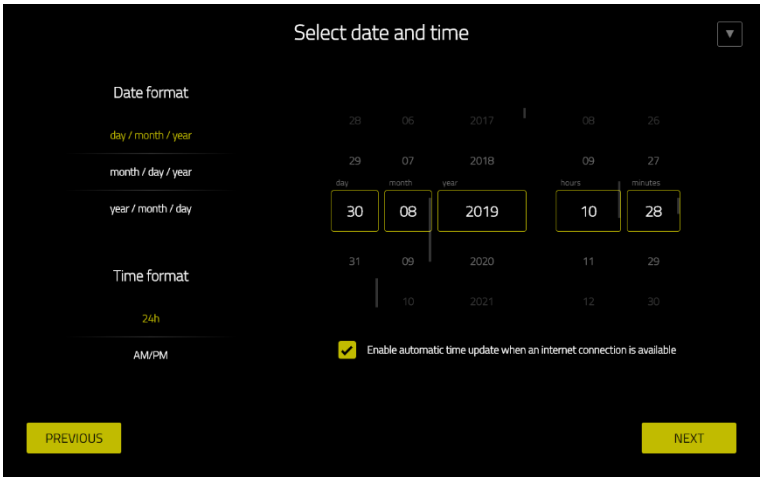


Fig. 15 – Configuration Wizard: date and time settings

In the following screen (Fig. 16) the local "System Administrator" user can be created by selecting user name and password. The username must contain at least 4 characters[1]. The password must contain at least 6 characters. It is possible to select for such user a different language than the one selected in the first step.

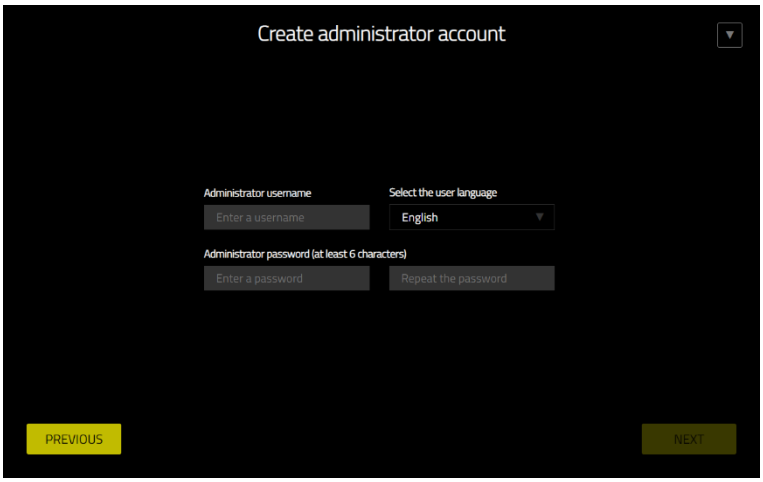


Fig. 16 – Configuration Wizard: creation of the System Administrator account

In the following screen (Fig. 17) it is possible to create another account (Operator account), by following the same rules and constraints described for the Administration account.

[1] Moreover, "service" and "production" cannot be used as user names.

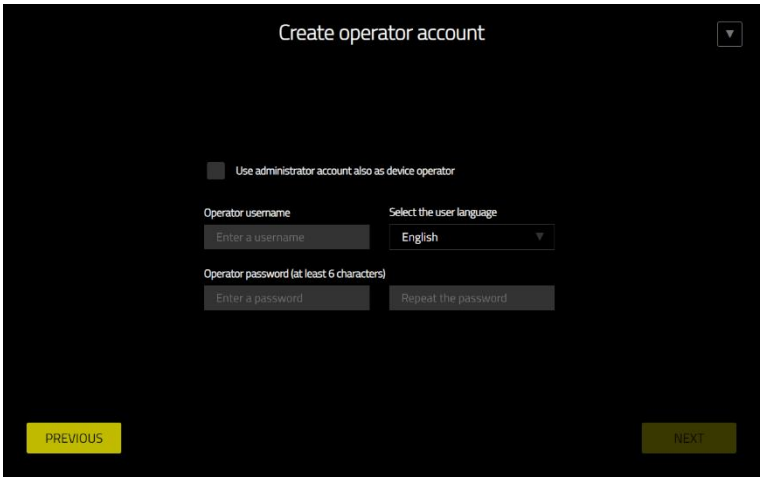


Fig. 17 – Configuration Wizard: creation of user accounts

7.3 Login

Turn on the device by pressing the power switch button (Fig. 7). When the boot is completed, the **Login** screen will be shown (Fig. **18**).

Select the desired user from the menu, input the user password and press the login button. 

The drsplus can now be operated.

	To modify the password, see §15.4.

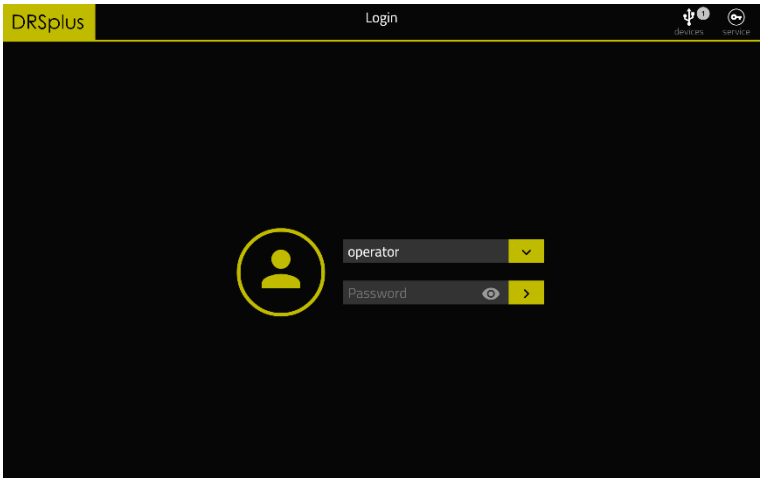


Fig. 18 – Login screen

7.4 Patient list

Upon the login, the Patient List will be shown (Fig. 19). It includes the following data, for each patient, from left to right:

- Thumbnails of the *last left and right images* acquired for that patient. The total number of images acquired for that patient is superimposed above the thumbnail, for the left and right eye respectively;
- Surname;
- Name;
- Patient ID;
- Date of Birth;
- Gender;
- Date of the last examination made with drsplus.

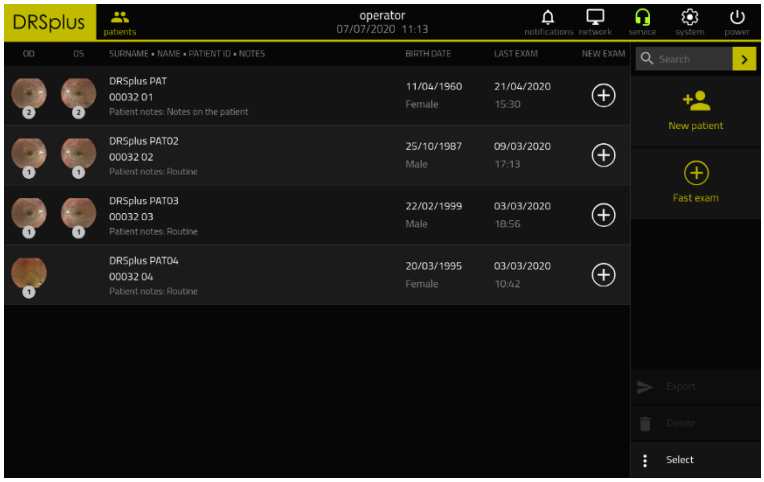


Fig. 19 – Patient List

To browse back to the Patient List, from any other screen, press the **Patients** icon locate on the top left side of the screen

7.5 Navigation Bar

Upon the login, the Navigation Bar shown in Fig. 20 is found on many screens. At the center of the Navigation Bar the current username, date and time are found.

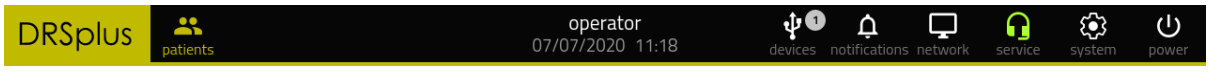
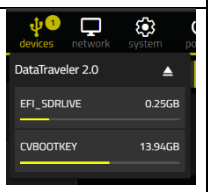
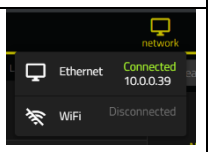
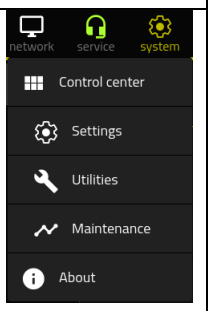
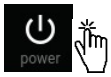
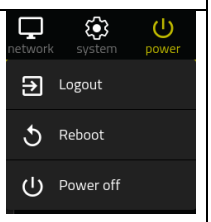


Fig. 20 – Navigation Bar

The Navigation Bar functionalities follows:

Function	Command	
Browse to the Patient List		
View the USB devices ready for images export, if any		
View the current status of ethernet and wireless connections.		
Open the panel including Configuration (§13) and Utilities tools (§16)		
Logout, Reboot and Shutdown menu		

8. Preparation of the patient

This paragraph is dedicated to the patient preparation before taking pictures with the drsplus.

There are no specific restrictions based on the typology-of patients that can be examined with drsplus. drsplus is a non-mydriatic medical device, therefore it is not mandatory to dilate patient's pupils before taking pictures.

It is recommended for the end users to give the patient the following instructions:

1) The acquisition of retinal images with drsplus does not involve any risk, because the device will never touch the patient's eye and the only effect perceived by the patient is a flash light when the device acquires a picture;
2) Please find a comfortable position, keeping the forehead well placed on the device headrest;
3) Once a good position is found, please do not move and do not talk;
4) Open your eyes wide;
5) At the beginning of the exam, the device will move to find your eye. Such movement is normal: when the device moves, please keep looking forward;
6) When a small green light appears, please look at such light and avoid blinking;
7) The acquisition of every picture will last less than 20 seconds.

After having given the instructions, place the patient in front of the device. Control the height of the medical table or the height of the chair so that the patient is comfortable to place his forehead on the headrest of drsplus.

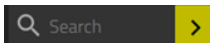
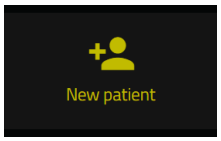
- ❖ Give the patient detailed information about the device operation before placing the patient on the device.
- ❖ The minimum pupil diameter which ensures high quality of the images is 2.5 mm.

9. Acquisition of retinal images

This paragraph explains how to acquire high quality retinal images using drsplus.

To start the acquisition process, it is necessary to select the desired patient in the Patient List.

To do so, in the **Patient List** screen:

❖ If the patient is already included in the local database, enter the initial characters of the patient's name, surname or code in the search box →	
❖ To add to the local database a new patient, press the "New Patient" button → Refer to §10.1 for additional details about the "New Patient" functionality.	

Upon having (saved and) located the patient in the **Patient List**, click on the corresponding line the new exam button to start a new examination after configuring acquisition parameters.

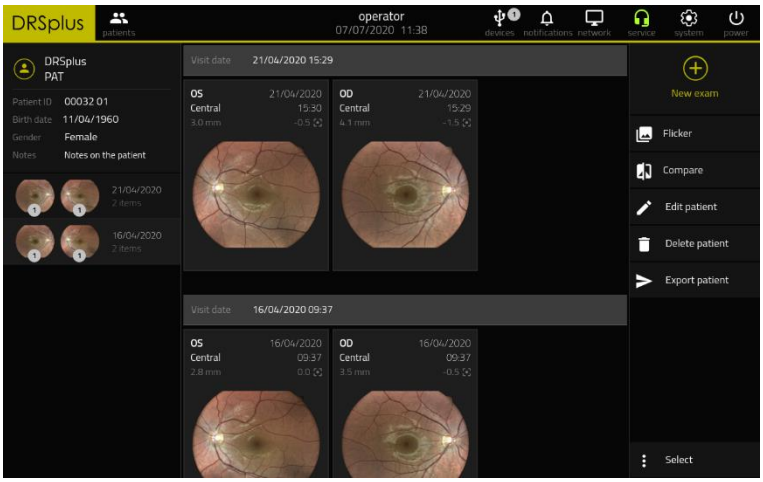
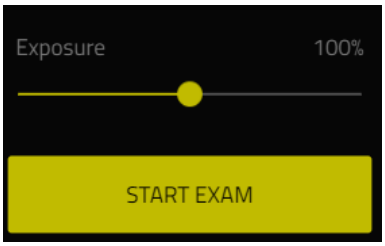


Fig. 21 – Patient Details screen

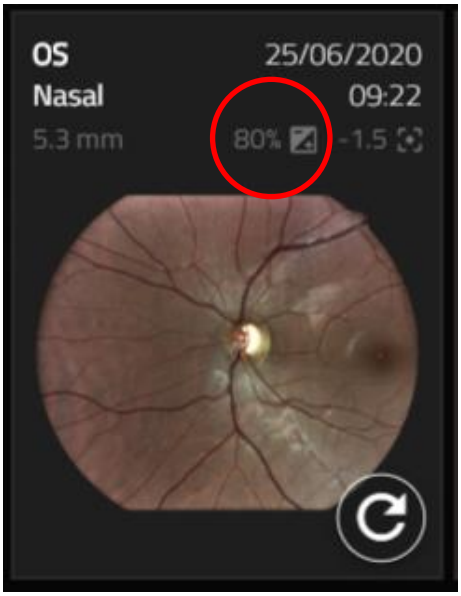
9.1 Configuration of Exam Parameters

To configure the examination, the following parameters can be set (see Fig. 22):

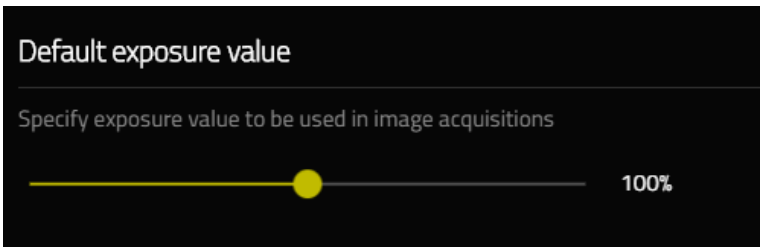
- Eye:
  - OD = right eye,
  - OS = left eye,
  - OU = both eyes (default option);
- Exam modality:
  - default = acquire a retinal picture,
  - EXTERNAL EYE = acquire a picture of the external eye surface (see §9.4),
  - 3D = acquire a couple of retinal images for stereo review (see §9.5);
- Exposure percentage: a value in percentage which defines the exposure of the acquired image.



The value set in exam configuration is shown in the image icon like in the following image (red circle).



In Settings screen a default value can be set that will be used for each acquisition. The value set in the Exam Configuration screen overrides the value defined in Settings screen. This value doesn't influence the external eye acquisition.



❖ Retinal fields to acquire: the available options follow.

	Every selected field corresponds to a specific position of the internal green fixation target.

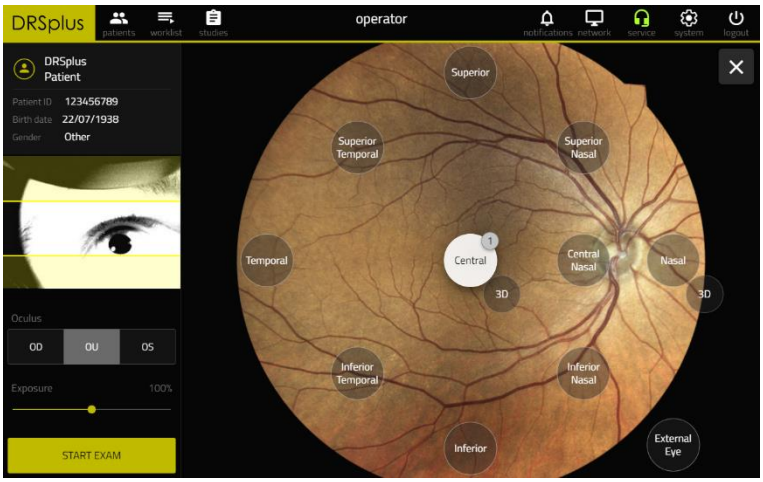


Fig. 22 – Exam configuration screen

The following fields can be selected:

a. CENTRAL: centered on the foveal pit;

b. NASAL: centered approx. 19° nasally to the foveal pit;

c. TEMPORAL: centered approx. 19° temporally to the foveal pit;

d. CENTRAL-NASAL: centered approx. 7° nasally to the foveal pit;

e. SUPERIOR: centered approx. 19° superiorly to the foveal pit;

f. INFERIOR: centered approx. 19° inferiorly to the foveal pit;

g. SUPERIOR-TEMPORAL: centered approx. 12° superiorly and 7° temporally to the foveal pit;

h. SUPERIOR-NASAL: centered approx. 12° superiorly and 7° nasally to the foveal pit;

i. INFERIOR-TEMPORAL: centered approx. 12° inferiorly and 7° temporally to the foveal pit;

j. INFERIOR-NASAL: centered approx. 12° inferiorly and 7° nasally to the foveal pit.

- Give the patient detailed information about the device operation before placing the patient on the device.
- The configuration of many fields ends in different portions of the retina being acquired. Such fields can be stitched together using the **Mosaic** feature (available under license). See §11.5.
- The live view on the left is used to visualize the position of the patient's pupil from the frontal lens. To ensure the correctness and speed of image acquisitions the pupil shall fall in the area delimited by yellow bands. Make sure that the pupil is inside the two lines before starting the exam.

When the patient is ready and the acquisition is configured, press the **START EXAM** button to begin the image acquisition procedure.

9.2 Automatic acquisition of images

drs plus automatically:

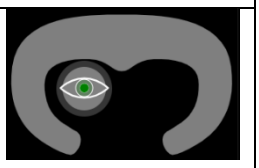
a. Aligns the frontal lens toward the patient's pupil;

b. performs the autofocus of the retina in order to correct spherical errors;

c. flashes the patient's retina and acquires one or more images according to the number of selected fields;

d. saves the images in the local storage for a later review.

Information shown during the acquisition process

Information	Position on the screen
Patient data	Top left text
Exam phase (aligning, focusing, waiting, waiting picture)	Under the patient's data
The position of the eye, with respect to the headrest	Graphics: 
Estimated pupil size: when yellow, indicates that the pupil size is below the minimum suggested value	Under the graphics of the eye position
Acquisition status of every field set for the current examination (*pending, acquiring, completed*)	Under the estimated pupil size
Live image of the retina, acquired using infrared light	At the center of the screen
Position of the internal fixation target	Green dot
The retinal field under acquisition, including useful instructions for the patient.	Top right text

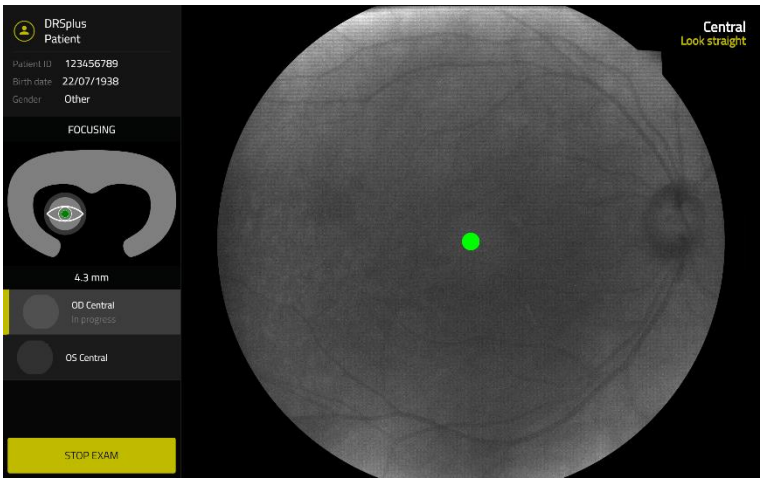


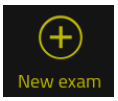
Fig. 23 – Running examination screen in automatic mode

The acquisition process can be interrupted at any moment by clicking the **STOP EXAM** button. Being the acquisition totally automated, this is the only available control.

9.3 "Fast" exam

This functionality (Fig. 24) permits to start an examination without the need to add a new patient first.

When a “Fast Exam” is started, a new patient will be automatically created by the drsplus. Surname and Name of the new patient are respectively “Patient”, and the date and time of acquisition. To start a “Fast Exam”, just press the button on the right panel →



The exam configuration screen will be shown (Fig. 24). To proceed, just configure the acquisition and press the **START EXAM** button.

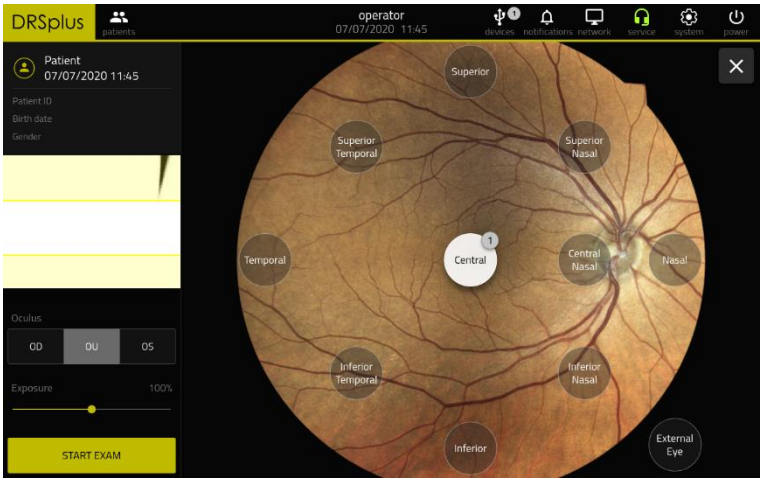


Fig. 24 – Exam configuration screen (“Fast exam” mode)

After the acquisition of the images, the Patient Detail screen will be shown, where the operator can edit any of the patient information.

9.4 “External eye” examination

When this modality is set, the drsplus will automatically acquire an image of the external surface of the eye (see Fig. 25).

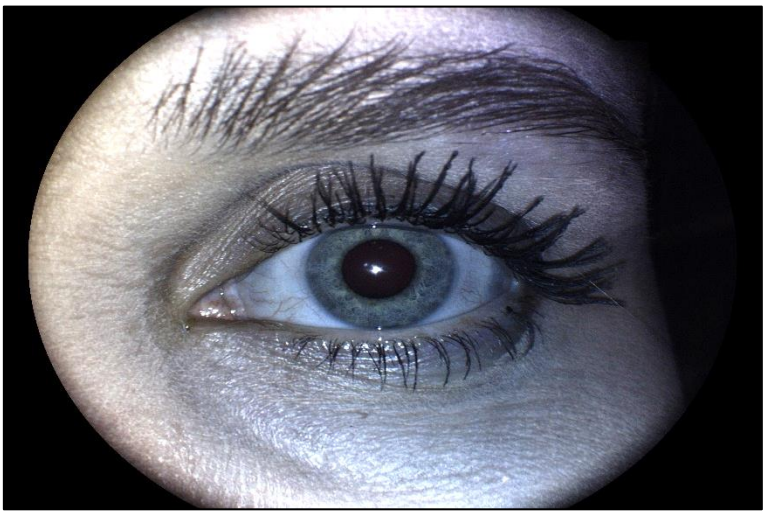


Fig. 25 – Image of the external surface of the eye (zoom)

9.5 Stereo modality

When this modality is set, drs$_{plus}$ will automatically acquire a couple of retinal images using the **nasal** or **central** fixation target. The two acquisitions differ just by a small transverse displacement acquired to add the stereoscopic effect when reviewing the two images using the prismatic stereoscopic goggles, as shown in §3.

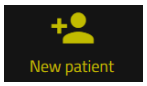
The stereo modality is available only under license[1]

[1]To request licenses, refer to local distributor

10. Patients Database

10.1 Adding a new patient

Open the “New Patient” dialog by pressing the button in the Patient List (Fig. 26). Enter Surname and Name (mandatory fields) for the new patient; enter additional fields if available: Patient ID, Birth date, Gender and Notes. Press **SAVE** to save the new patient or **CANCEL** to cancel the operation.



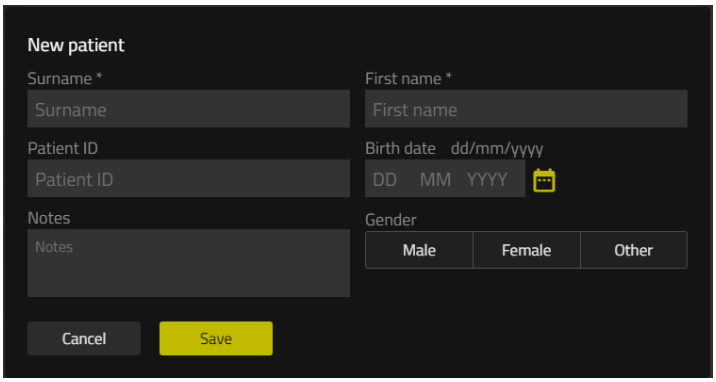
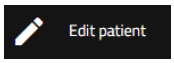


Fig. 26 – New Patient dialog

10.2 Editing an existing patient

To modify the information of an existing patient, open the Patient Details screen (see §11.1) and press the Edit Patient button. →



This will open the Edit Patient dialog (Fig. 27).

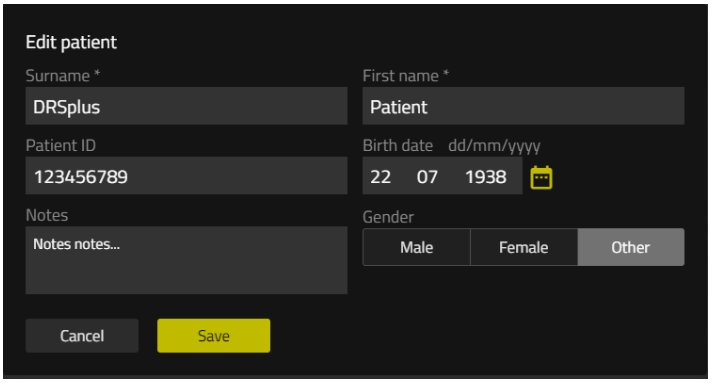
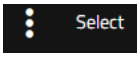


Fig. 27 – Edit Patient dialog

10.3 Single and multiple selection of patients

To select one or more patient, click the “Select” button on the right panel →



or keep pressed the patient row until the selection appears.

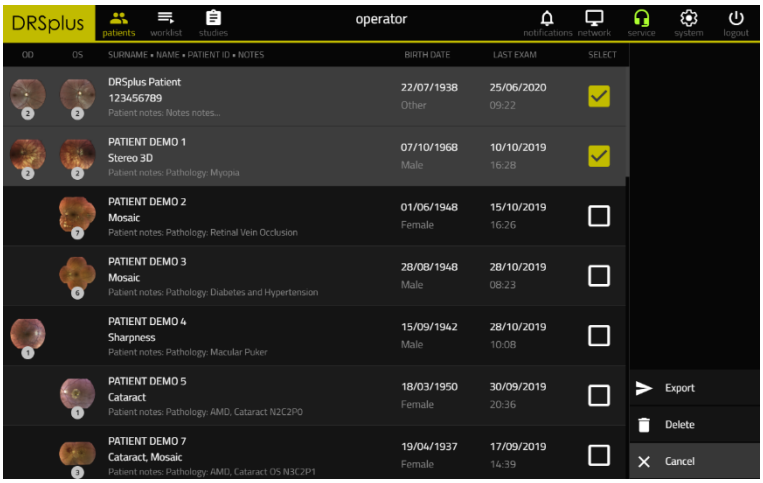
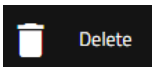


Fig. 28 – Selection of Patients

10.4 Deletion of patients

Select the patients to be deleted and click the “Delete” button on the right panel →



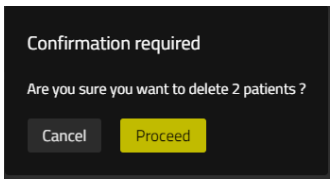
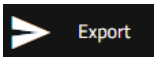


Fig. 29 – Deletion Confirmation Pop-up

10.5 Export of all patients’ images

Select the patients whose images are to be exported and click the “Export” button in the right panel →



Refer to §12 for additional information about this feature.

11. Image review

11.1 Patient Details screen

Upon the acquisition of images, drs$_{plus}$ will show the Patient Details screen (Fig. 30), which includes patient information and all the images acquired.

Patient information shown:

Information	Position on the screen
Patient information	Top left box
List of dates when the patient was examined. Each row includes the thumbnails of the last acquired images (both OD and OS) and the number of images for that date (OD and OS).	Left panel
Thumbnails of the images acquired in the selected date, including additional information: (eye, retinal field, estimated pupil size, acquisition date and time)	Center of the screen

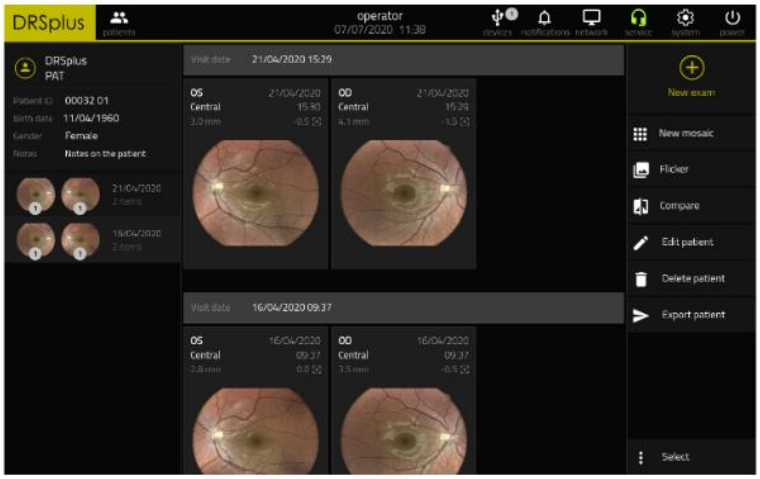
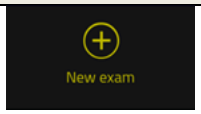
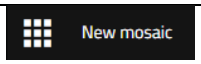
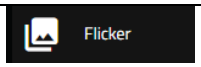
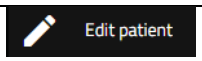
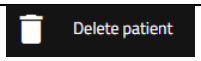
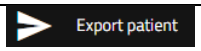
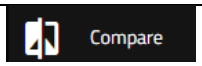
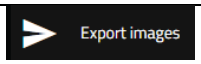
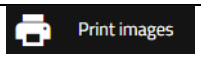
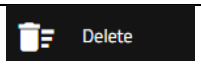


Fig. 30 – Patient Details screen

Available functionalities

Function	Command
Review of images acquired in a certain date	Click on the date of interest in the list located into the left panel

Function	Command
New image acquisition	
Creation of a new mosaic[1]	
Flicker images	
Modify patient's information	
Delete the current patient	
Export all of the images of the patient	
Multiple selection of images	
Side-by-side comparison of two images[2]	
Export of all of the patient's images[3]	
Print images	
Delete images[3]	
Fullscreen review of a single image	Click on the image thumbnail
Retake an image[4]	Press the  icon on the bottom right corner

[1] Available under license only; to request licenses, refer to local distributor.

[2] Function is active only upon selection of two images

[3] It is not possible to delete an image that has been mounted in a mosaic. Operator shall delete the mosaic before deleting its images.

[4] Only images acquired in the current date can be retaken.

11.2 Image review

The image review screen (Fig. 31) is used to review a single image at full resolution.

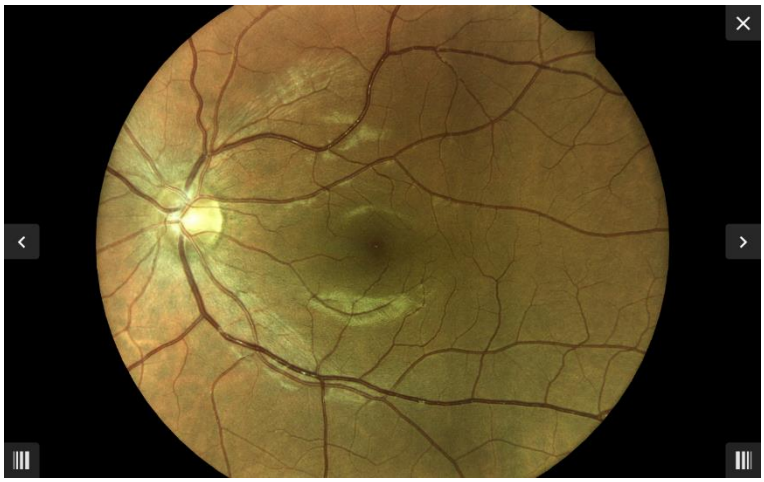


Fig. 31 – Single image review screen

Available functionalities

Function	Command
Browse to the previous / next image	< > buttons located on the left / right edge of the screen
Browse back to the patient details screen	× button, top right
Open the list of images for quick access (Fig. 32)	button, bottom left
Open the toolbar that includes: image adjustment, export, print and deletion.	button, bottom right

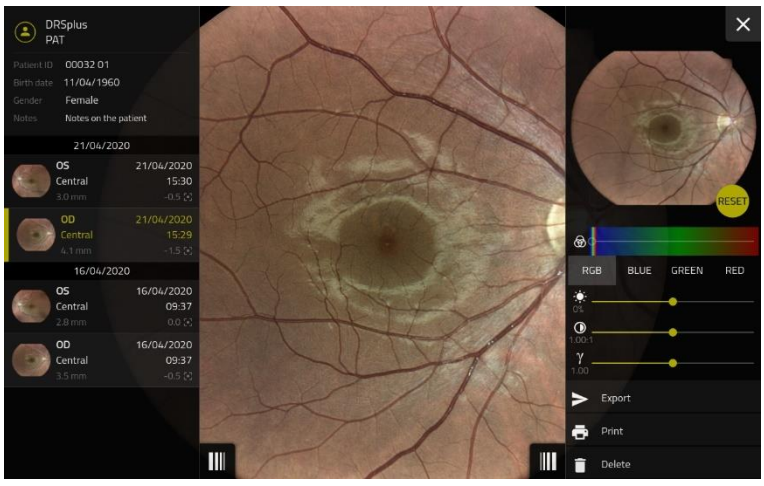


Fig. 32 – Image review screen

Pressing the Print icon, the Print Configuration pop-up is shown (Fig. 33), permitting the selection of the printer and the configuration of the orientation and format of the page.

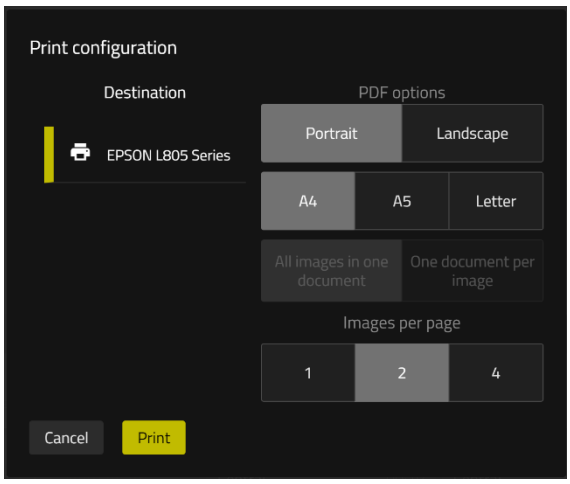


Fig. 33 – Print Configuration pop-up

11.3 Side-by-side image review

The "side-by-side" screen (Fig. 34) permits the operator to quickly compare any couple of images selected from the Patient details screen. Images are shown next to each other.

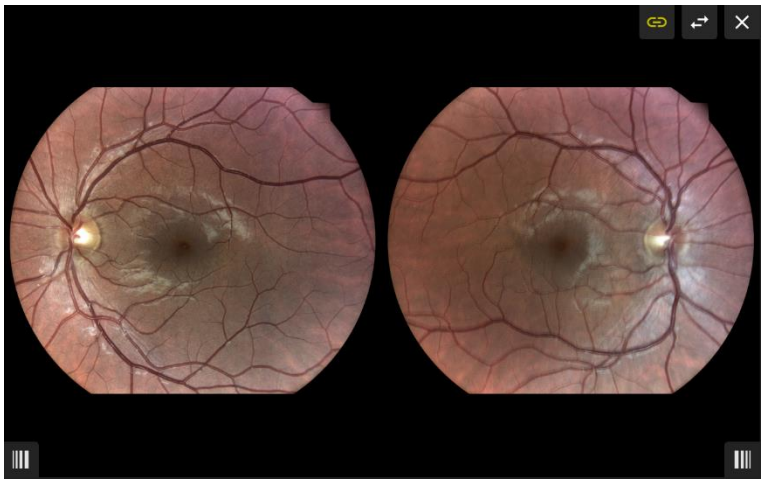


Fig. 34 – Side-by-side screen

Available functionalities

Function	**Command**
Enable / Disable the zoom and pan synchronization (any zoom and pan operation done on an image will be immediately replicated on the fellow image)	
Swap the images	

Function	Command
Close the side-by-side review screen	
Open the toolbar that includes: right image adjustments, export, print and deletion.	 button, bottom right
Open the toolbar that includes: left image adjustments, export, print and deletion.	 button, bottom left

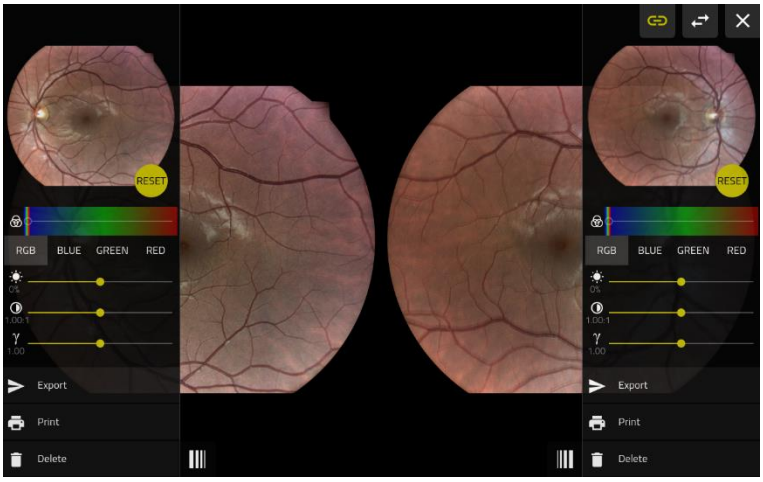


Fig. 35 – Side-by-side image review with toolbars

11.4 Visual flickering of images

The flickering screen (Fig. 36) gives the possibility to select any couple of images of the current patient, and shows the fast alternation of them. Prior the visualization, the images are registered one to the other in order to ease the clinician to review them having all the image features accurately overlapped. The registration of images is performed by means of a special algorithm included in the drs$_{plus}$ software.

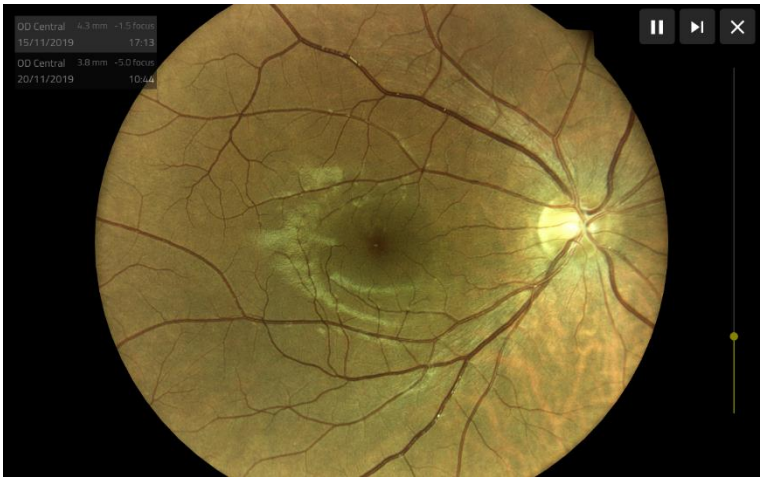


Fig. 36 – Visual flickering screen

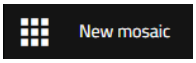
Available functionalities

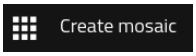
Function	Command
Start or pause the image flickering	▶ ⏸
Show the other image	⏭
Change the flickering speed	Cursor on the right side
Close the image flickering screen	✕

11.5 Mosaic

The drs$_{plus}$ includes a special software algorithm that stitches together two or more photos of a retina to obtain an image with wider field of view, called **mosaic** (Fig. 39).

> The mosaic function is available only under license.

To create a mosaic, in the Patient Detail screen click the “New Mosaic” button 

Then, select the fields that can be stitched together and press the “Create Mosaic” button. 

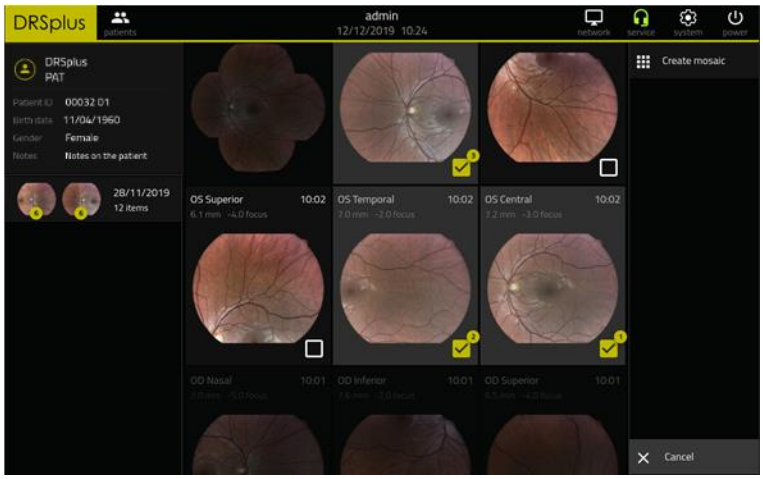


Fig. 37 – Selection of images for mosaic

The drsplus will generate the mosaic automatically and will save it as a new image, available in the Patient Details screen.

Fig. 38 – Mosaic elaboration in-progress

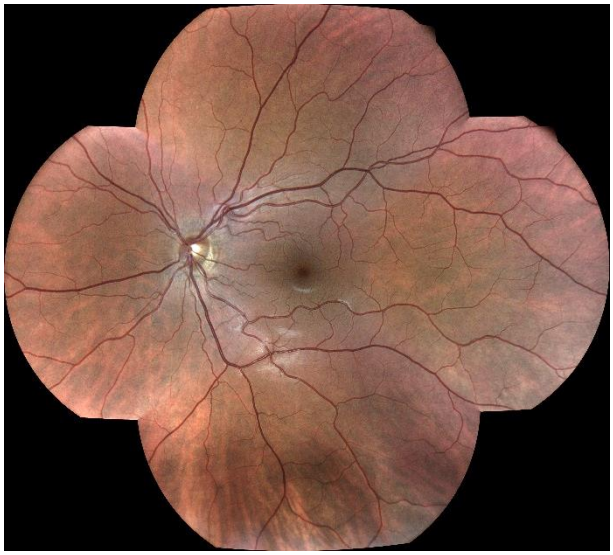


Fig. 39 – A mosaic

The creation of a new mosaic is possible only under certain conditions:

a) The selected retinal fields belong to the same eye;

b) The selected retinal fields have been acquired in the same date;

c) At least one CENTRAL field has been selected.

A maximum of 9 images can be stitched together into a mosaic.

The drsplus cannot be used to acquire images, during a mosaic creation. The creation of a mosaic with 9 images takes at maximum 40 seconds.

A mosaic of retinal images can show visual artifacts (e.g. duplicated retinal vessels or non-contiguous retinal vessels) in the areas where two images are stitched together. These artifacts can be easily recognized by looking at the original images.

11.6 Remote Viewer

All of the patient database and the images stored into the drsplus memory can be remotely reviewed by means of any standard PC connected in the same Local Area Network the drsplus is connected to.

In particular, the Remote Viewer presents to the operator the same screens and commands available in the local interface. From the Remote Viewer the configuration and execution of a new exam is permitted only after Remote Exam activation (see §17).

To enable the Remote Viewer:

- ❖ the drs$_{plus}$ must be connected to the Local Area Network by means of an Ethernet or Wireless connection (Fig. 7). After the connection of the ethernet cable to the Ethernet port located on the back panel of the device, the network connection might require additional configuration (§15.6)

- ❖ Remote Viewer access (HTTP or HTTPS) must be enabled in the Security menu (§15.9)

By default, the remote viewer is disabled.

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

http://drsplus-*nnnnnnn*
or
http://drsplus-*nnnnnnn*.local

into the address bar. Here:

- *nnnnnnn* are the 7 characters which compose the serial number of the drs$_{plus}$, as reported in the device label;

- ❖ The Remote Viewer functionality is available only under license[1]. The license can be provided as single license or 5 license pack. A single license will give access to the drs$_{plus}$ from one remote station at a time, while the 5 license pack will give access to the device from 5 remote stations at a time.
- ❖ The Remote Viewer requires a standard Web Browser and does not require any additional third-party software to be installed in the remote computer.
- ❖ The Remote Viewer is tested on the latest release of the following browsers[2]: Google Chrome, Mozilla Firefox, Microsoft Edge (Chromium-based), Apple Safari
- ❖ The Remote Viewer requires the user to log in using the same user credentials (username and password) used to log in into the local user interface.

[1] To request licenses, refer to local distributor.

[2] As of September 2020

- Every Remote Viewer session is automatically closed after the period specified in the Security menu (§15.8). To continue using the Remote Viewer, a new log in is required.

12. Exporting images

The drsplus offers extreme flexibility in exporting images. In detail, it is possible to:

- ❖ simultaneously export all images of one or more patients (§10.5, §11.1);
- ❖ export a single image (§11.2);
- ❖ configure (§15.10) one or more destinations, including USB and network drives;
- ❖ choose export parameters (Fig. 40):
  - o select one or more of the following export formats: JPEG, PDF, DICOM;
  - o in the case of the PDF format, various parameters can be selected, including the orientation of the paper (vertical, horizontal), sheet size (A4, A5, Letter) and number of images per page.
- ❖ Once the export parameters have been defined, click on EXPORT to proceed.

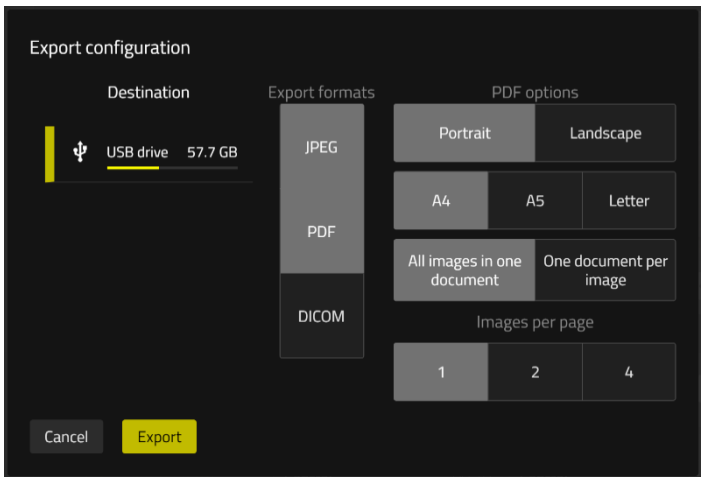
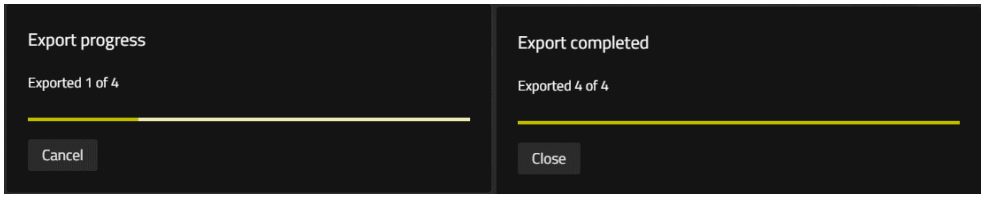
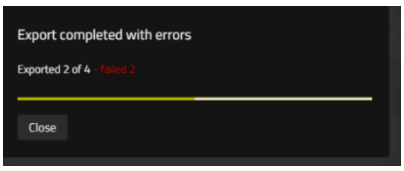


Fig. 40 – Export panel

The progress of the export activity and its completion is shown with a pop-up.



In case of completion with errors (e. g.: for lack of space), the pop-up indicates the error.



In Fig. 41 an example of pdf report of an exam is shown.

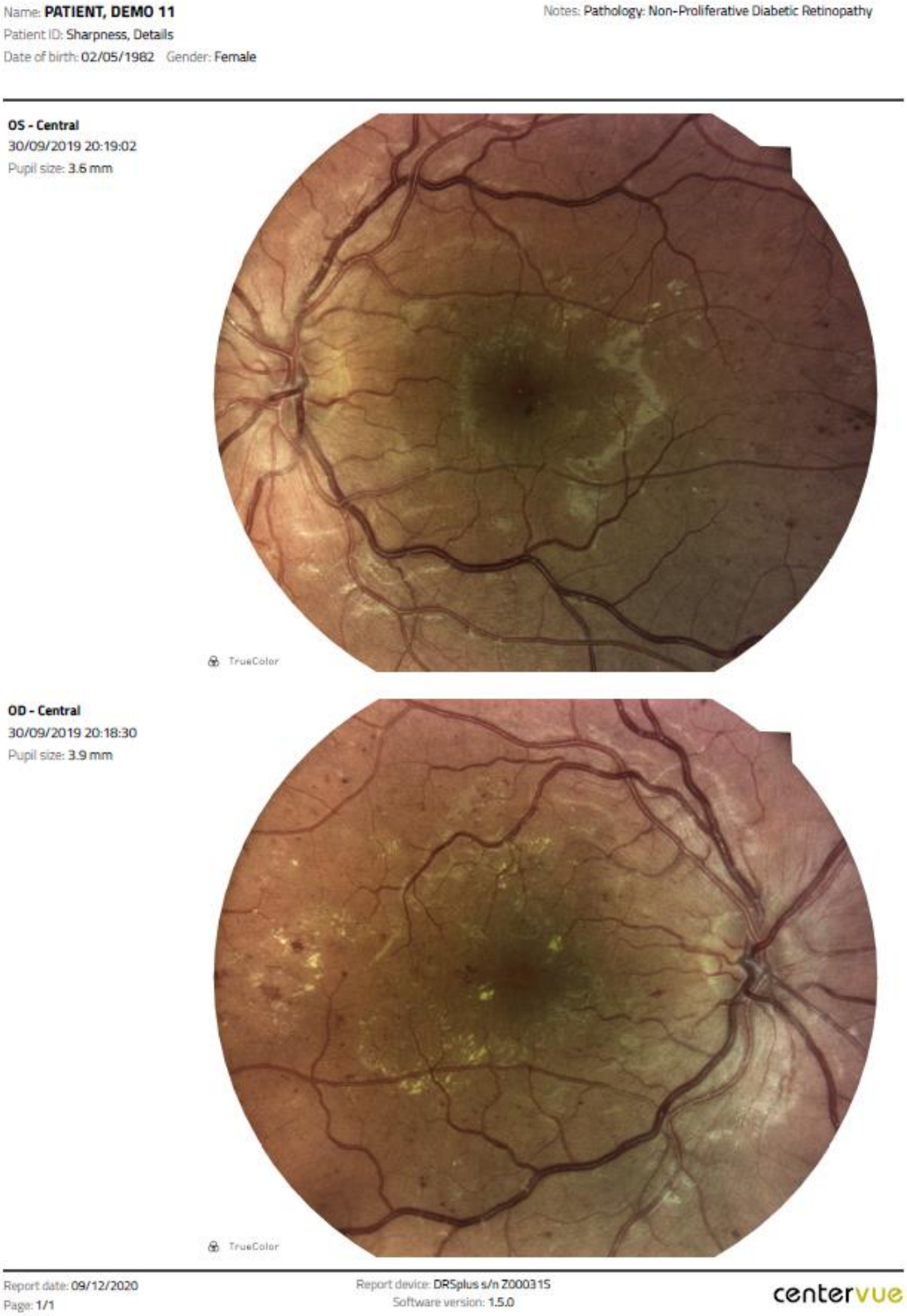
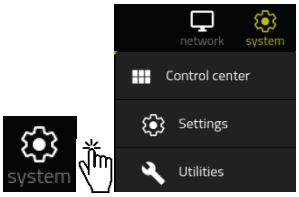


Fig. 41 — Example of pdf report of an exam

13. Control Center

To access the Control Center screen, click on the icon →

in the toolbar and then Control Center in the drop-down menu.



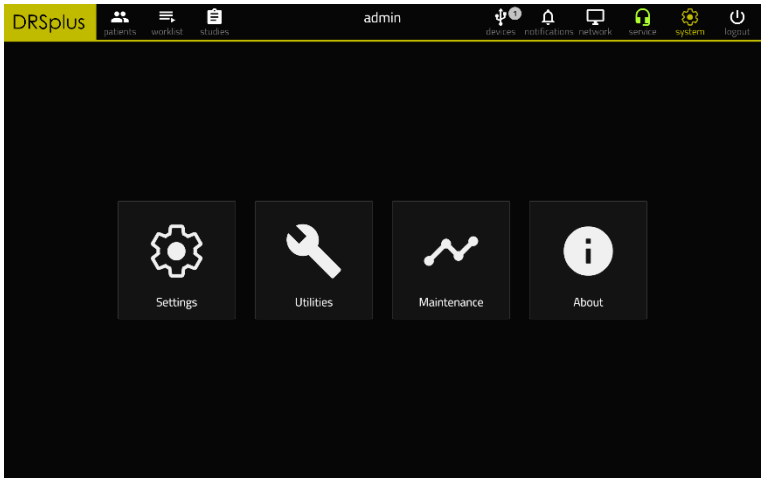


Fig. 42 – Control Center Screen

From the Control Center the following screens can be accessed:

- Settings
- Utilities
- Maintenance
- About.

The first three screens will be described in dedicated paragraphs.

13.1 About Screen

The About screen shows:

- The device serial number
- The installed software version
- The size and amount of free space for System and Data disks
- The barcode of the serial number

Fig. 43 – About Screen

13.2 Maintenance

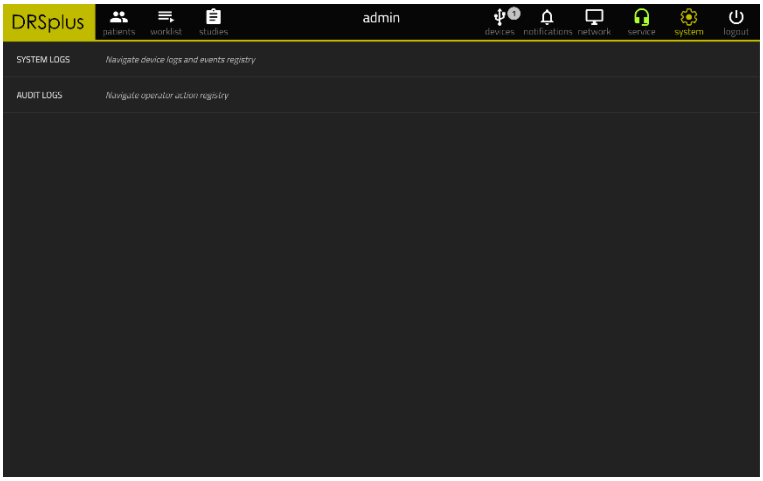


Fig. 44 – Maintenance Panel

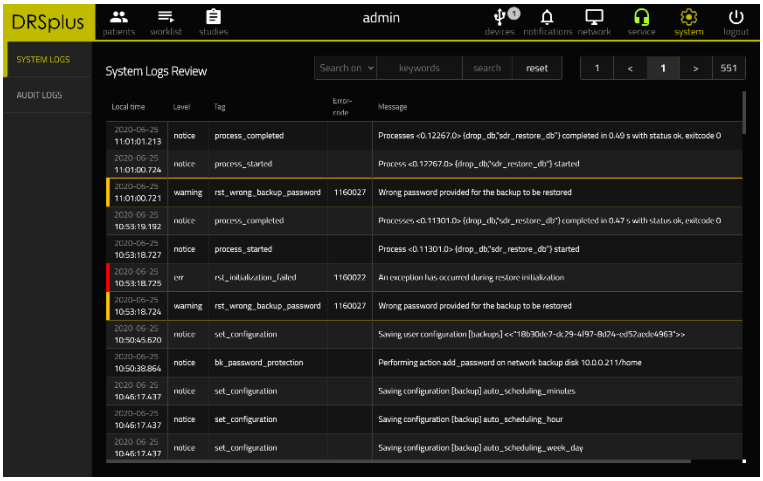
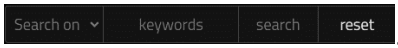


Fig. 45 – System Log Panel

The Maintenance panel permits to access two log viewers:

- SYSTEM LOGS: which shows the logs generated either the operating system or the application software. They are divided in the following categories
  - Notice: messages that inform that a run-time event, such as startup or shutdown, has occurred.
  - Warning: messages that inform about situations that might have an adverse performance implication.
  - Error: messages that inform about serious errors that anyway might allow the application to continue running.
  - Critical: messages that inform about severe errors that can cause the application to terminate.

  In this panel the messages are shown in time order (the last at the top of the list) and grouped in pages. At the top of the panel a navigation cursor 

permits to move to the pages. The messages can be searched using the search panel 

. With “Search on”, the column to be searched with “keyword” can be selected among:
  - Local Time,
  - Level,
  - Tag,
  - Error-code,
  - Message

  Clicking on a specific record, a dialog pops-up showing the details related to that record.

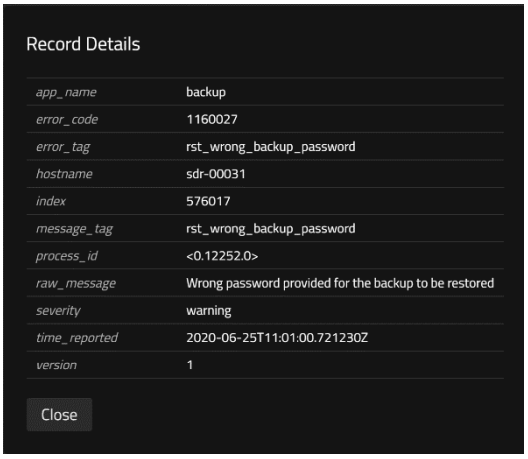


Fig. 46 – System Logs Record Details Dialog

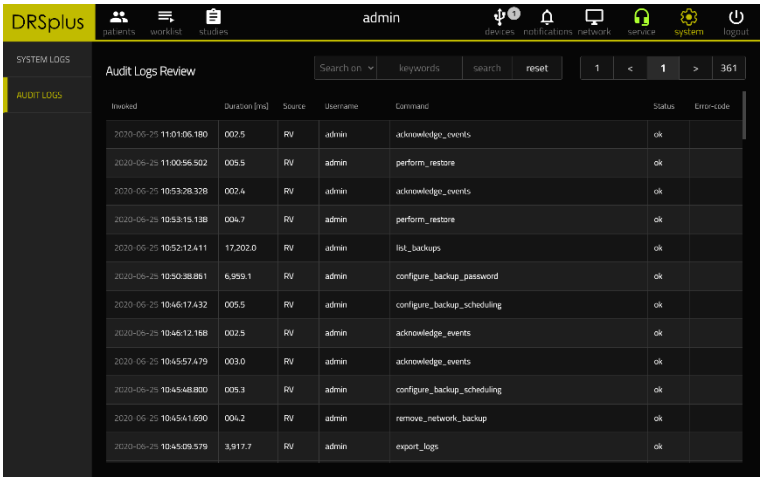
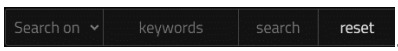


Fig. 47 – Audit Log Panel

- AUDIT LOGS: which shows the activities performed by the operator on the device's interface. In case the activity generates an error, it is reported in the last column "Error-code". In this panel the messages are shown in time order (the last at the top of the list) and grouped in pages. At the top of the panel a navigation cursor 

permits to move to the pages. The messages can be searched using the search panel 

. With "Search on", the column to be searched with "keyword" can be selected among:
  - Invoked (time stamp of the event),
  - username,
  - command,
  - Error-code,

Clicking on a specific record, a dialog pops-up showing the details related to that record.

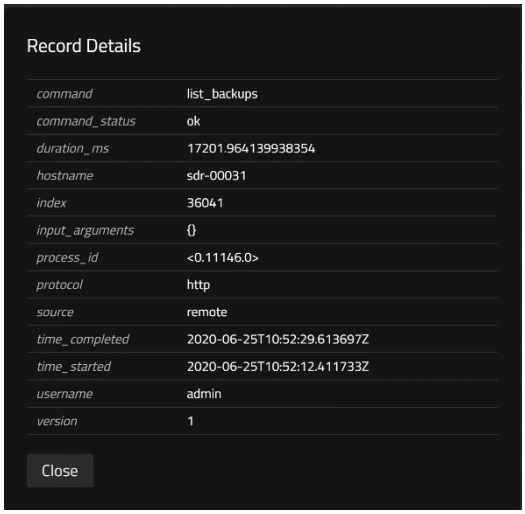


Fig. 48 – Audit Logs Record Details Dialog

14. Notification Center

Within its operation activity, the device can generate notifications that are displayed to the operator by means of pop-ups and toasts

The following are examples of the toasts shown in case of notification of an event, warning and error.

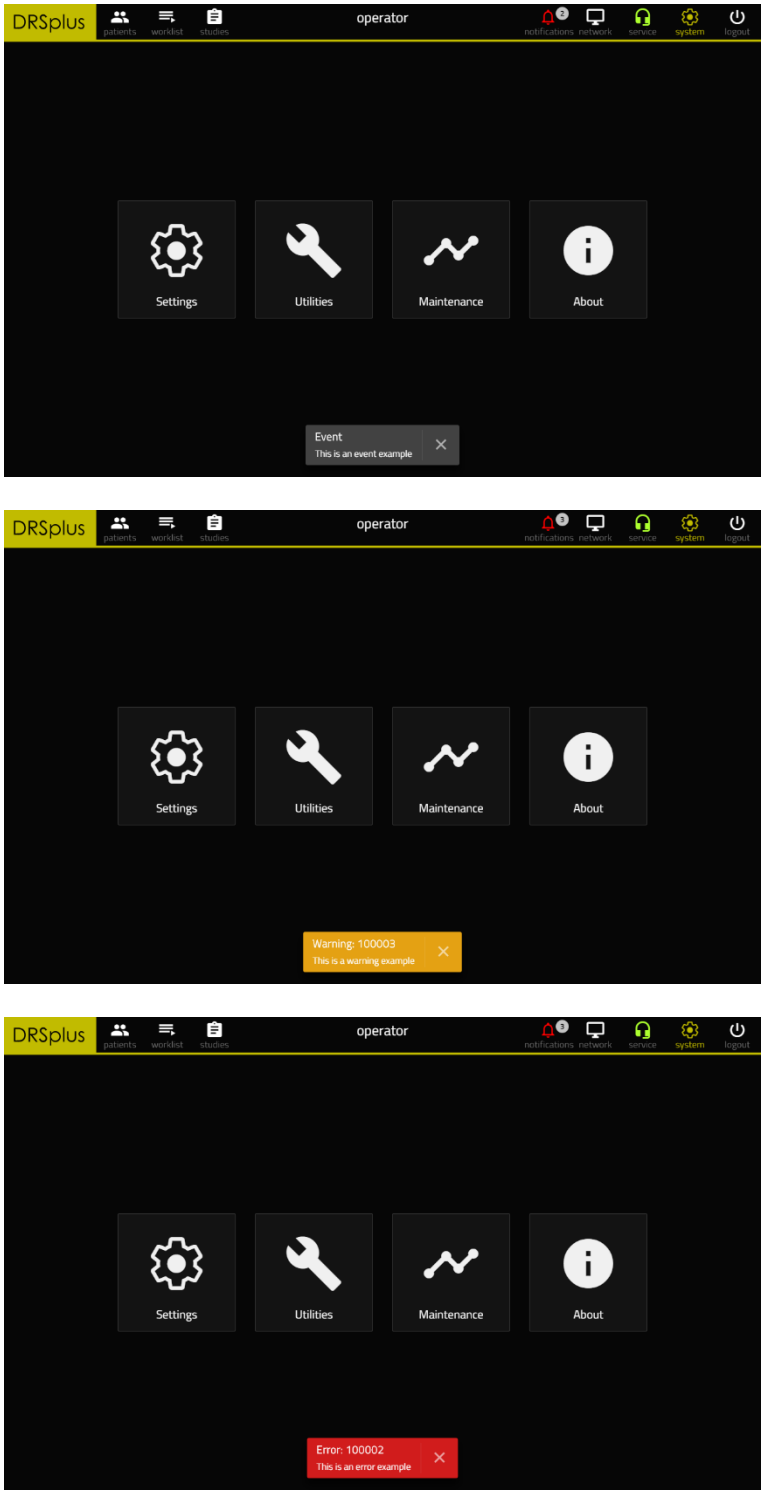


Fig. 49 – Examples of toasts for event, warning and error categories

The toasts will disappear automatically after some seconds, or if the cross on the right is pressed. In this case the notification is marked as viewed.

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

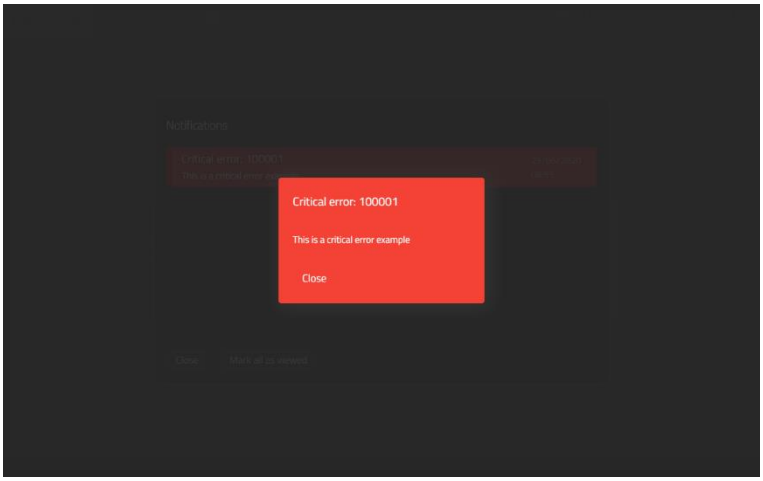


Fig. 50 – Example of a critical error blocking pop-up

Clicking on the Notifications icon in the Navigation Bar, the last notifications can be shown.

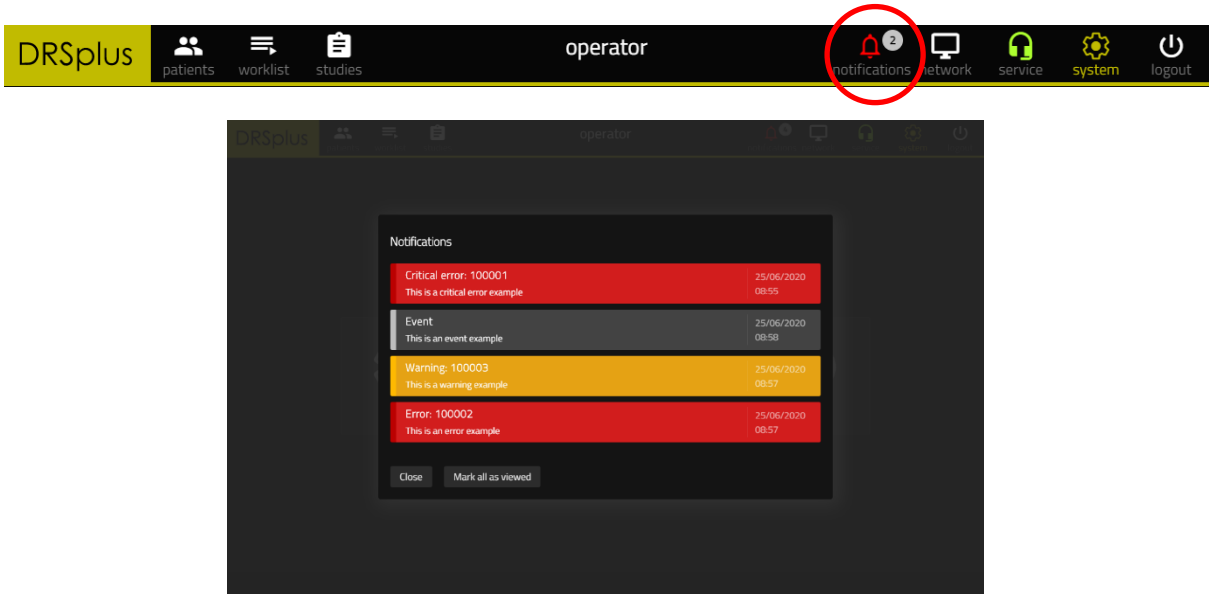


Fig. 51 – Notifications list

The notifications already viewed are shown greyed. With this dialog, all the notifications can be marked as viewed.

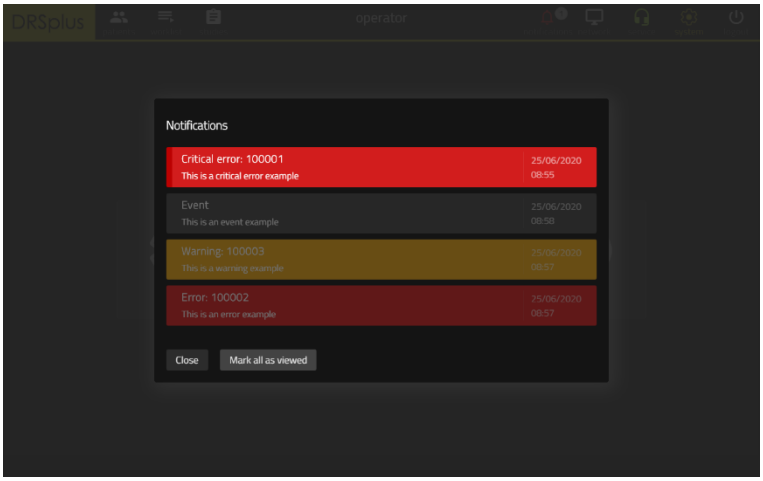


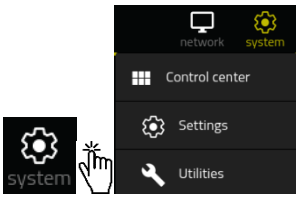
Fig. 52 – Notifications List with partially viewed events

15. Configuring the device

15.1 Settings

To access the configuration screen, click on the icon →

in the toolbar and then Settings in the drop-down menu.



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

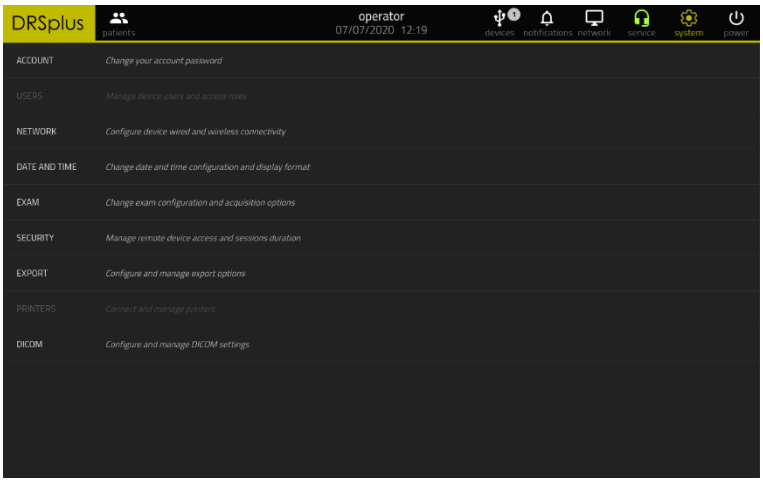


Fig. 53 – "Settings" panel

15.2 DICOM Functionality

DICOM is an international standard for distributing and viewing medical images and related information. drsplus supports DICOM[1] communication as specified in the **DICOM Conformance Statement document**[2].

For DICOM Functionality description refer to drsplus DICOM Operating Manual.

15.3 WebAPI

WebAPI are HTTP/HTTPS REST APIs that allow integration of the device with a third parties software.

WebAPIs allow:

[1] The DICOM feature for drsplus is activated with a license. Please contact your local CenterVue representative for more information.

[2] Ask to your local distributor for the drsplus DICOM conformance statement

- Patient data retrieve and management:
    - Retrieve of patient list (and search)
    - Retrieve of visits list
    - Retrieve of single patient record
    - Retrieve of patient visits and images
    - Patient creation
    - Patient editing
    - Patient deletion
    - Visit deletion
- Image data retrieve and management:
    - Image filters management
    - Download of images in JPG, DICOM or PDF formats
    - Image deletion
- For WebAPI functionality refer to drsplus WebAPI Manual.

15.4 Account

The “Account” panel (Fig. 54) allows users to change their password.

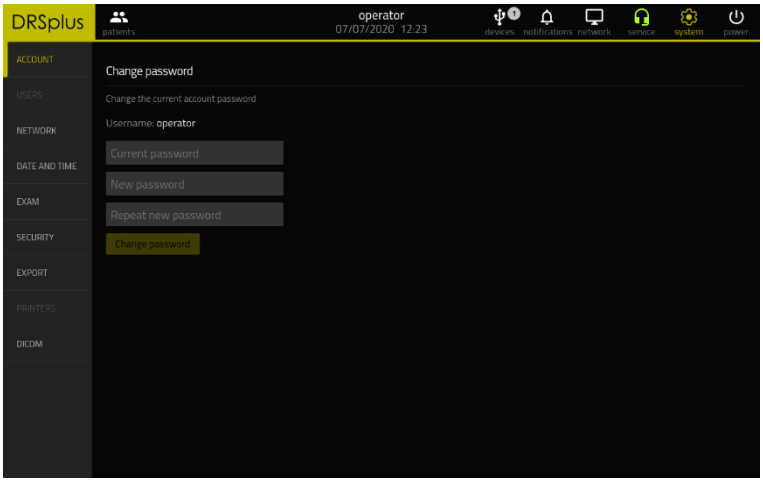


Fig. 54 – “Account” panel

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

15.5 Users

This panel (Fig. 55) is only accessible to the Administrator and enables management (creation, modification and deletion) of user accounts.

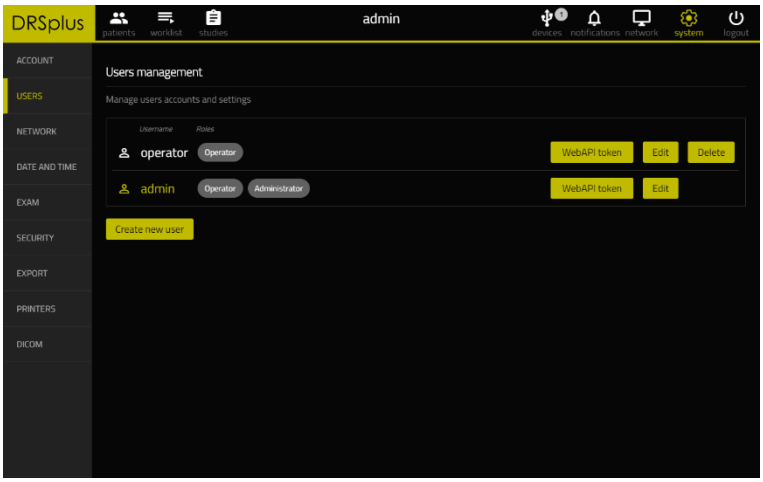


Fig. 55 - “Users” panel

- ❖ The username must contain at least 4 characters
- ❖ The password must contain at least 6 characters

For each user can be also generated the WebAPI token.

Creating or editing a user permits to define the username and password, to enable or disable him, to define its role and to set the capability to perform a Remote Exam (see §17)

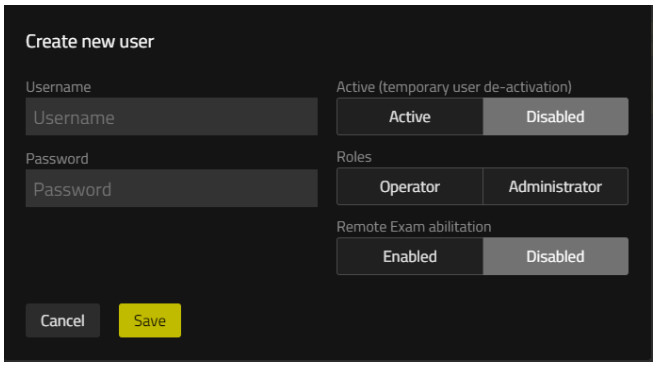


Fig. 56 – New User Dialog

15.6 Network

This panel (Fig. 57) makes it possible to configure the parameters required for the network connection and specify the primary network using the ETHERNET WIFI selector.

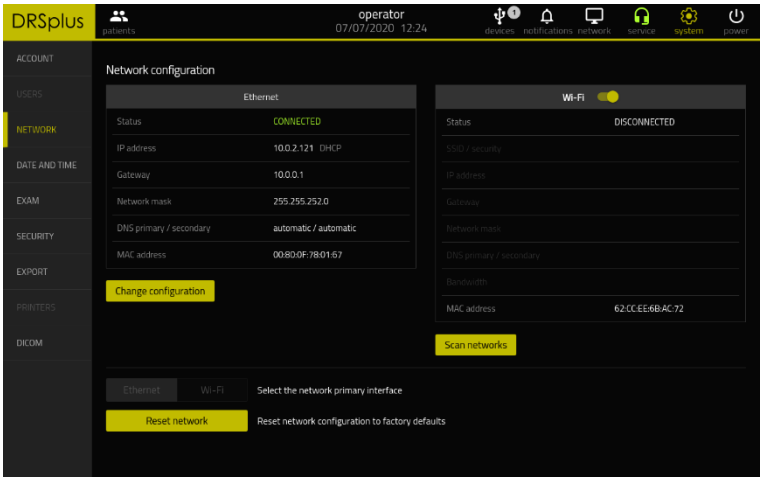


Fig. 57 – "Network" panel

Ethernet connection (wired)

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

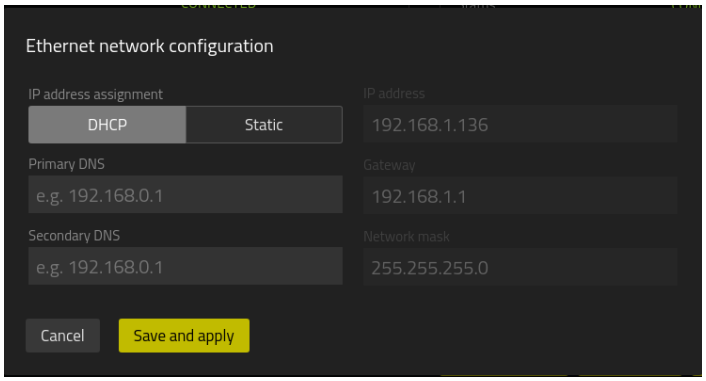


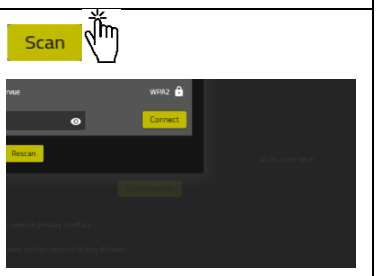
Fig. 58 – Ethernet connection settings

Wi-Fi connection

The network parameters can be configured as per the Ethernet.

The following functionalities are also available:

Function	Command
Enable / disable Wi-Fi interface	WiFi

Function	Command
Disconnect the device from the current Wi-Fi network	
Scan for available Wi-Fi networks	

To check the network connection status, click on the icon  in the top bar (Fig. 59).

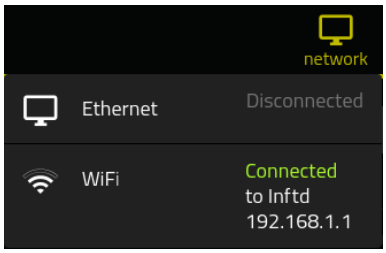


Fig. 59 – Example of wired and Wi-Fi network connection status

15.7 Date and time

This panel (Fig. 60) allows you to configure the parameters relating to the date and time formats, offering the following functions:

- Automatic (requires Internet connection) or manual date and time settings;
- Time-zone settings;
- Date and time format settings.

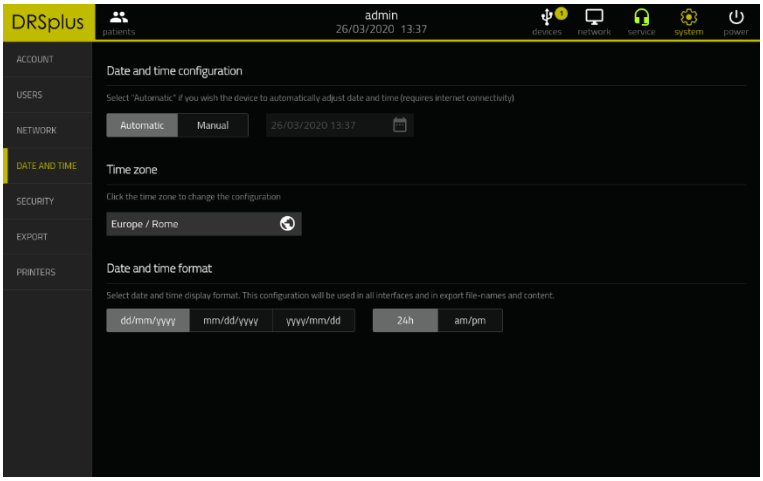
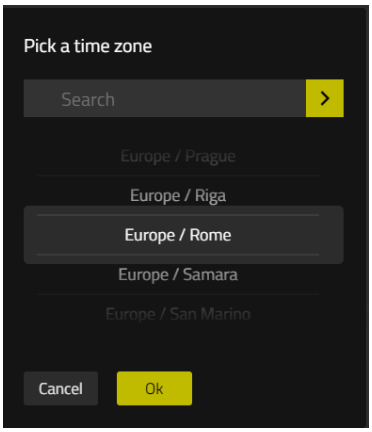


Fig. 60 – "Date & Time" panel

The time zone can be selected by means of the pop-up:



15.8 Exam

Using this panel (Fig. 61) the following configurations can be set:

- Fixations: can be selected between
  - Last used: for each exam, the fixation position used will be automatically set equal to the previous exam; Anyway, at the start of each exam, the operator can override the preset choosing a different configuration.
  - Preset: using the interface the fixation position for each exam can be set. The configuration defined in this section will be used as default in exam configuration screen (§9.1). Anyway, at the start of each exam, the operator can override the preset choosing a different configuration.

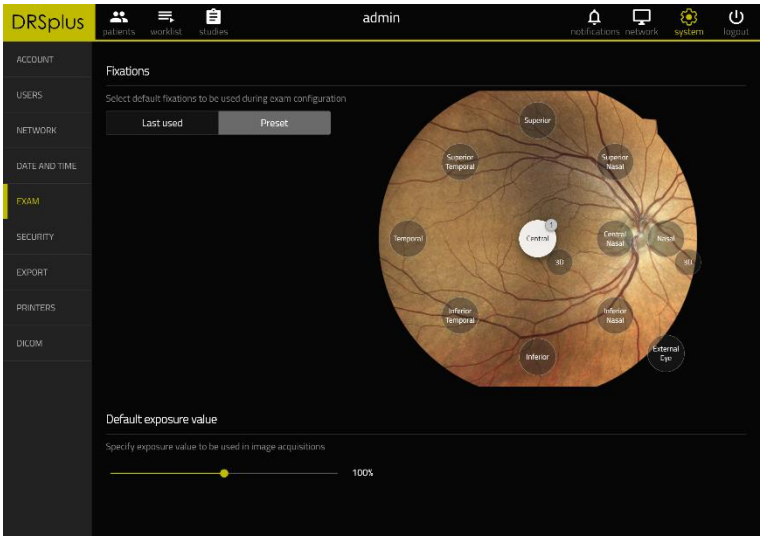


Fig. 61 – “Exam” panel

- Default exposure value: the value of the percentage which defines the brightness of the acquired image can be set for each exam. Anyway, at the start of each exam, the preset can be changed.

15.9 Security

This panel (Fig. 62) allows you to configure the security options of the Remote Viewer, including the communication protocol and the session duration.

When enabling “HTTPS” protocol, the device will use a self-signed HTTPS certificate that must be accepted into your browser in order to dismiss the standard warning issued by all browsers.

In addition to that, it is also possible to specify the duration for the session running on the on-board display.

For WebAPI functionality refer to drsplus WebAPI Manual.

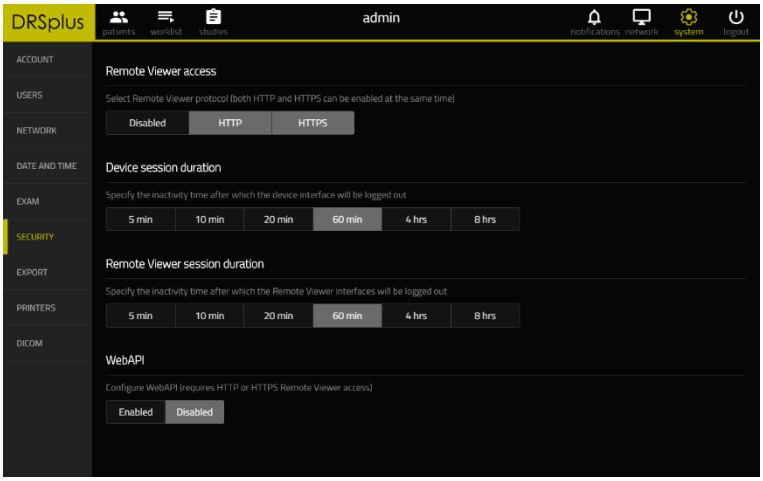


Fig. 62 - "Security" panel

15.10 Export

This panel (Fig. 63, Fig. 64) allows you to configure the parameters relating to the export function:

- Network export destinations: defines the shared folder network address;
- Export path settings: for each export destination (USB and shared folder), defines how the exported data will be grouped (with or without patient folder, with or without visit folder);
- JPEG acquisition metadata: when this option is enabled the exam acquisition metadata is stored in the JPEG comment section. This information may be useful for troubleshooting purposes if requested by CENTERVUE assistance personnel. Setting this option to "disabled" will improve JPEG export performances.

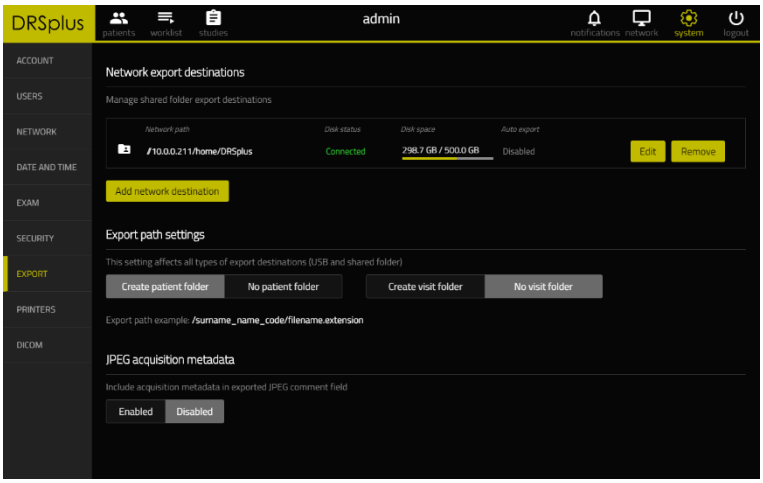


Fig. 63 - "Export" panel

Export destination can be set with the pop-up in Fig. 64.

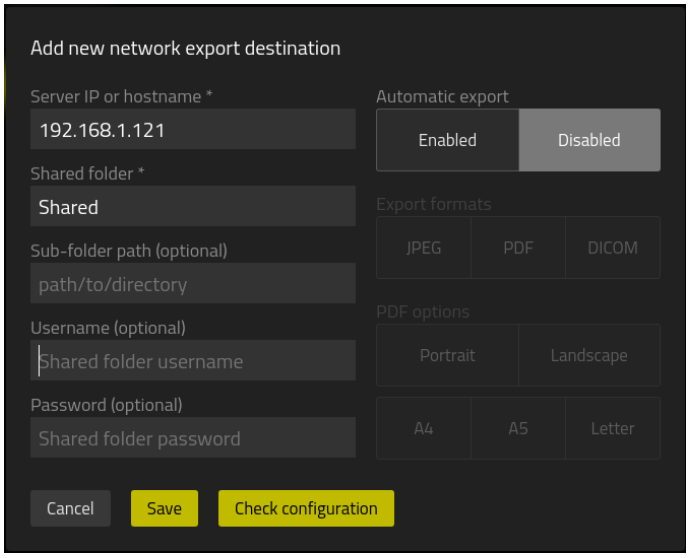


Fig. 64 – Configuration of export destination

15.10.1 Filename format[1]

Single-image file name

The default file name is composed as follows:

`[Surname]_[FirstName]_[PatientID]_[Eye]_[Field]_[ImageType]_[ImageDate]_[Exporting Date]_[ExportingDateMicroseconds].[FileExtension]`

Example:

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

Where:

- `Surname`: the patient surname, as in the surname field.
- `FirstName`: the patient first name, as in the given name field.
- `PatientID`: the patient ID, as in the patient id field.
- `Eye`: Side of the Eye. Possible values: OD, OS.
- `Field`: Index representing the field acquired:
    - central, nasal, temporal, superior, inferior, central_nasal, superior_nasal, inferior_nasal, superior_temporal, inferior_temporal, external. anterior_eye, stereo1, stereo2

[1] It is not guaranteed that future releases, due to development needs, will not alter the default composition of the exported filename

- `ImageType`: Type of image acquired, only color
- `ImageDate`: Image acquisition date and time. Formatted as per-user configuration (i.e.: mm-dd-yyyy_hhiiss AM/PM)
- `ExportingDate`: Exporting Date/Time of the image, same format as ImageDate
- `ExportingDateMicroseconds`: Microseconds of the ExportingDate
- `FileExtension`: File extension, according to the selected format. Possible values: JPG for JPEG images, PDF for PDF files, dcm for DICOM files.

Multi-image file name

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

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

Example:

`Rossi_Mario_ABC123_4-images_11-04-2019_121315_981247.pdf`

15.11 Printers

This panel (Fig. 65) allows you to configure the printing subsystem. Two main panels are selectable by means of tabs:

- Administration
- Printers

In Administration Panel is possible to

- Add a printer
- Find new printers
- Manage Printers

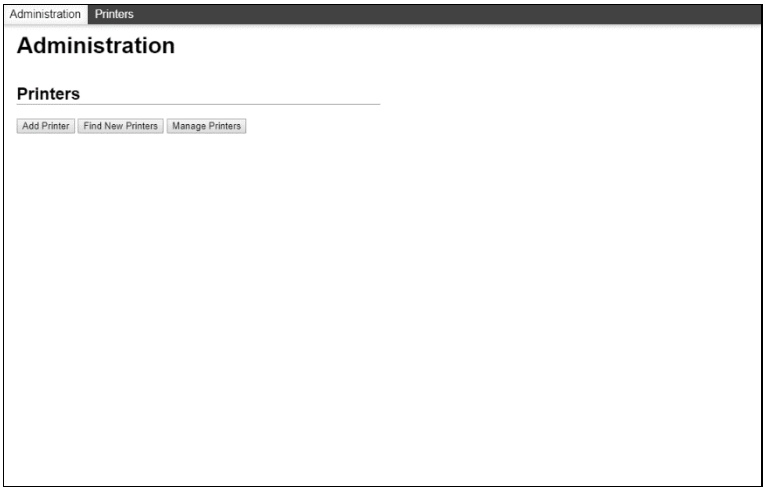


Fig. 65 - "Printers Administration" panel

Pressing the Add Printer button in Administration Panel shown in Fig. 65, after a while the panel Add Printer appears. In this panel there are three sections:

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

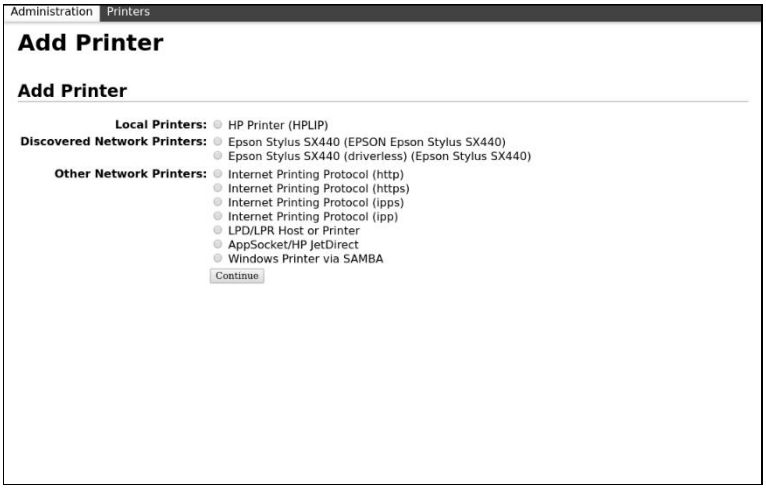


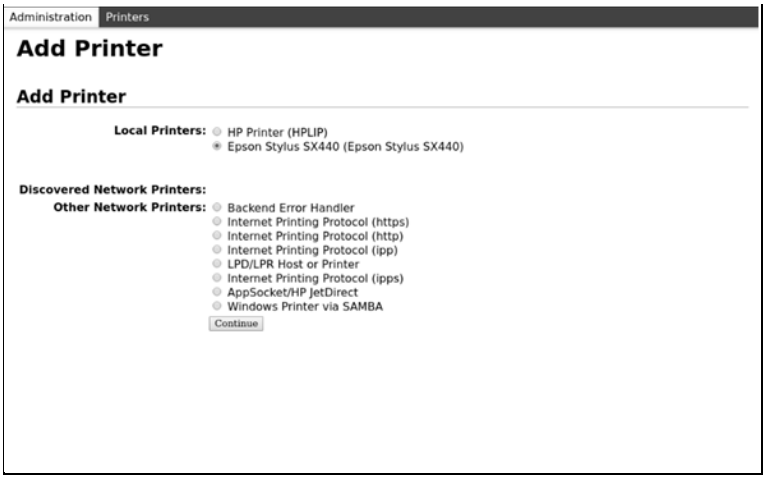
Fig. 66 – "Add Printer" panel

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

WiFi Direct connection with printers is not available.

15.11.1 Add Printer – Local Printer

Selecting the radio button related to the local printer automatically detected, in this case Epson Stylus SX440, and pressing Continue, the panel for printer identification is shown (Fig. 67).



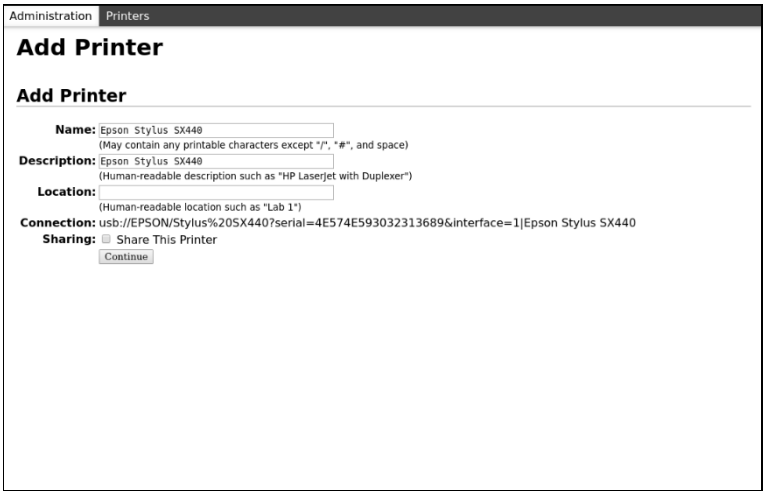


Fig. 67 – "Printer Identification" panel pre-set with automatic detection information

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

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

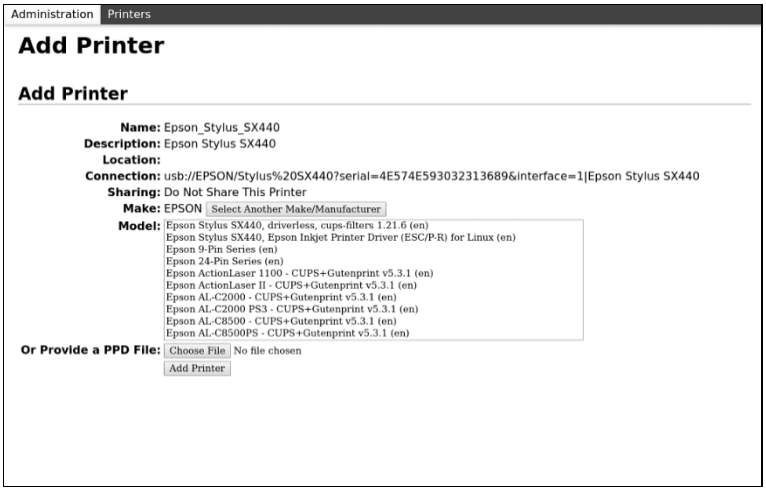
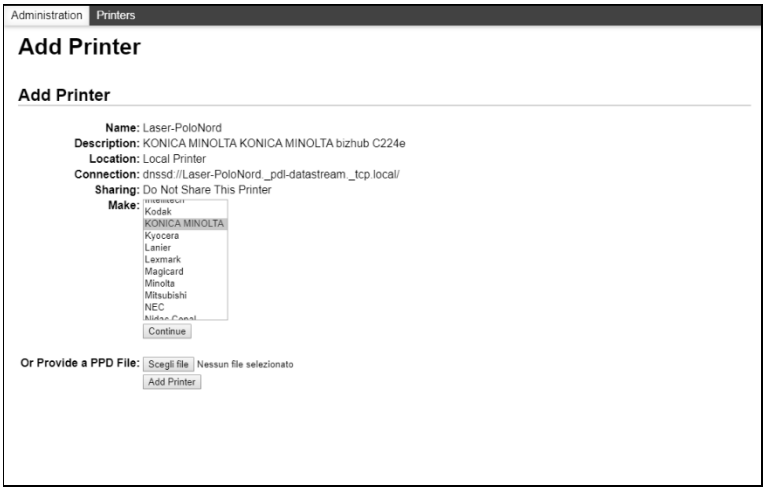


Fig. 68 – "Printer Model Selection" panel

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



Once the printer model has been selected, pushing the Add Printer button the configuration is saved and the Set Default Options for the selected printer is shown[1] (Fig. 69).

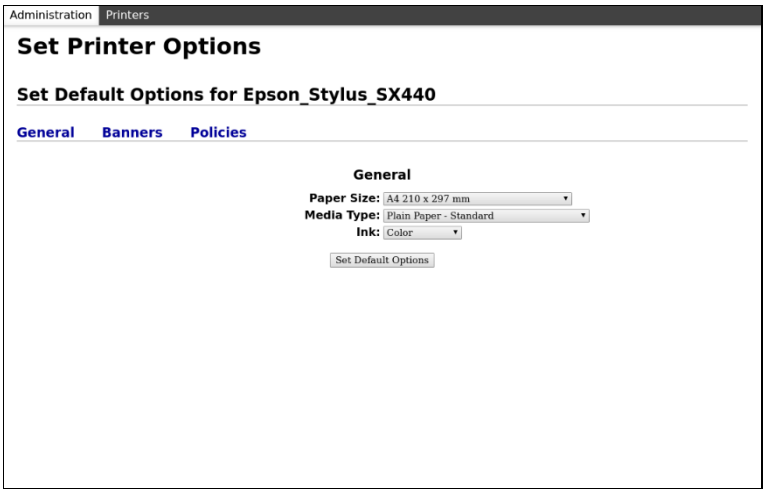


Fig. 69 – "Default Options Setting" panel, Banners tab

[1] The Set Default Options doesn't influence the selection of the paper format set in Print Configuration pop-up shown in §11.2

Fig. 70 – "Default Options Setting" panel, Policies tab

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

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

The Default Options Setting panel depends on the printer's characteristics. In case of a multifunction printer, a panel like Fig. 71 can be presented.

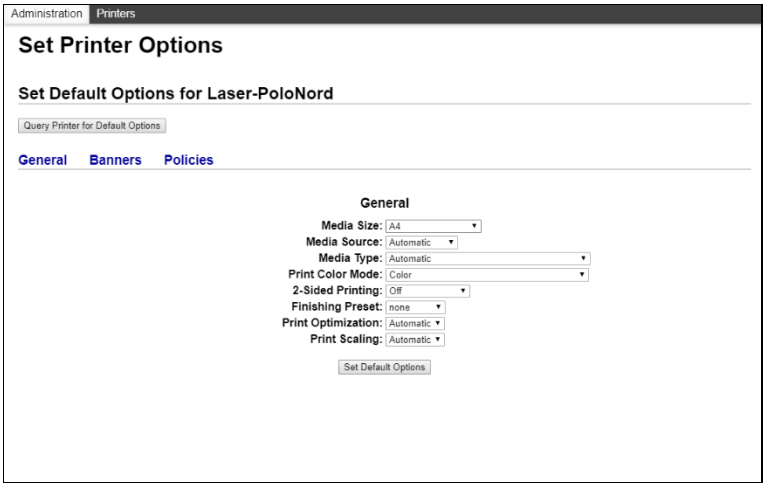


Fig. 71 – Set Default Options for a multifunction printer

With the tab Banners is possible to select starting or ending banners from a top-down list (classified, confidential, …).

With the tab Policies, the rules for each operation can be configured, like abort the job or retry in case of error. In this tab can be defined the access control as well.

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

15.11.2 Add Printer – Network Printer

In case a printer connected to the network can be detected, the system shows it in the Add Printer panel, Discovered Network Printers section (Fig. 72).

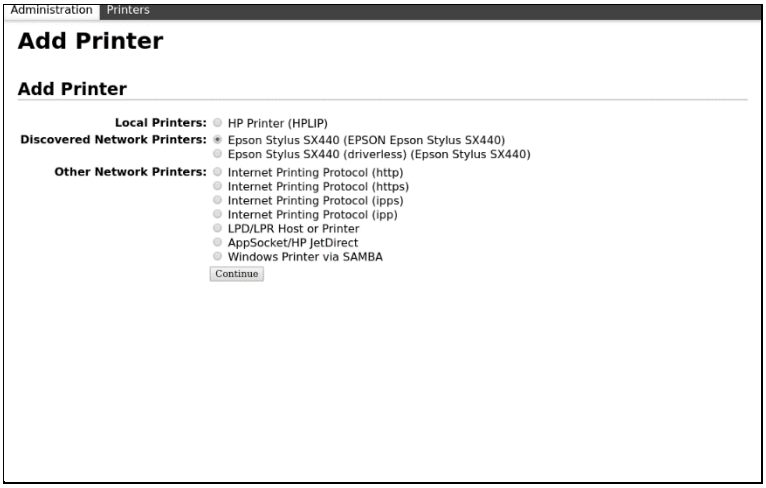


Fig. 72 – "Network Printers Selection" panel

Selecting the desired network printer, in this case Epson Stylus SX440, and pressing Continue, the same printer identification panel shown in Fig. 67 appears. In this case a name indicating that this is a network printer and the Location indicating the physical position of the printer are suggested.

The following panel is the Printer model selection panel shown in Fig. 68, and it can be configured as explained in §15.11.1. Also in this case, pressing the Add Printer button, the Set Default Options for the selected printer is shown (Fig. 69) as in §15.11.1.

15.11.3 Add Printer – Other Network Printers

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

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

- ❖ AppSocket
- ❖ Internet Printing Protocol
- ❖ Line Printer Daemon.

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

Selecting the protocol in the list and pressing Continue, the printer address can be set in the following window (Fig. 73).

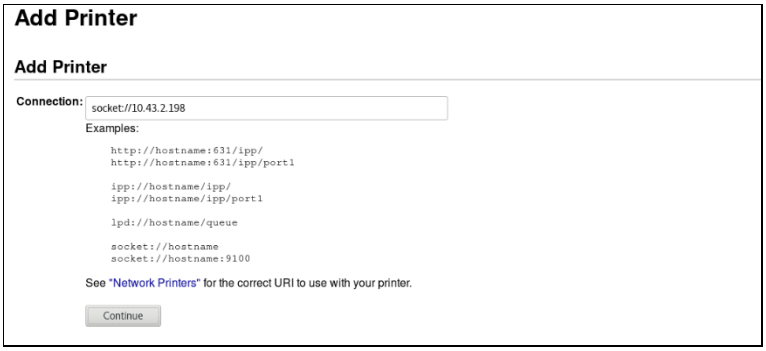


Fig. 73 – URI Printer Configuration

AppSocket Protocol

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

Device URIs for the printer have the following structures:

socket://ip-address

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

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

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

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

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

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

Internet Printing Protocol (IPP)

For this protocol the device URIs have the following structures:

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

ipp://ip-address/ipp/print

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

ipps://ip-address/ipp/print

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

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

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

IPP URI Options

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

Line Printer Daemon (LPD) Protocol

LPD is the original network printing protocol.

Device URIs for the printer have the following structures:

lpd://ip-address/queue

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

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

The following table summarizes the options supported.

Option	Description
banner=on	Specifies that a banner page should be printed by the printer.
contimeout=seconds	Specifies the number of seconds to wait for the connection to the printer to complete (default 1 week or 604800 seconds).
format=f	Specifies that the print data is a plain text file.

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

15.11.4 Find New Printers

Pushing the Find Printers button in Administration panel, the Available Printers panel is shown (Fig. 74).

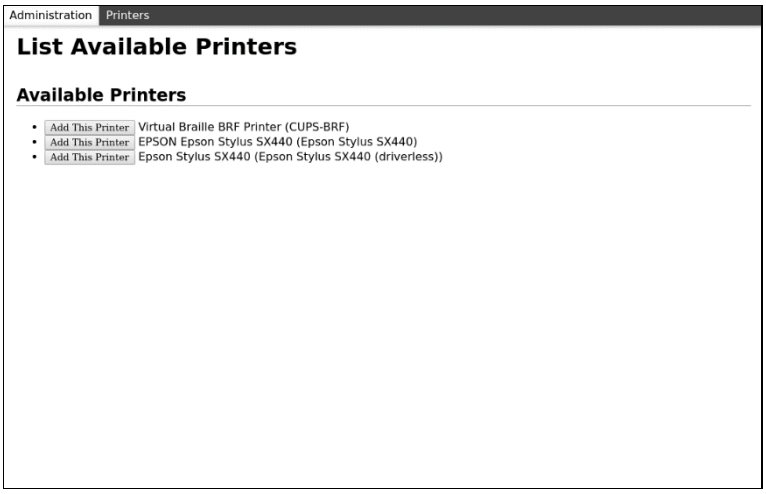


Fig. 74 – “Available Printers” panel

If the desired printer is listed, pushing the Add This Printer button, the Printer Identification panel, Printer Model selection panel and Default Options Setting panel are shown in sequence as explained in §15.11.1, to configure it.

15.11.5 Printers panel

In this panel all the configure printers are listed (Fig. 75).

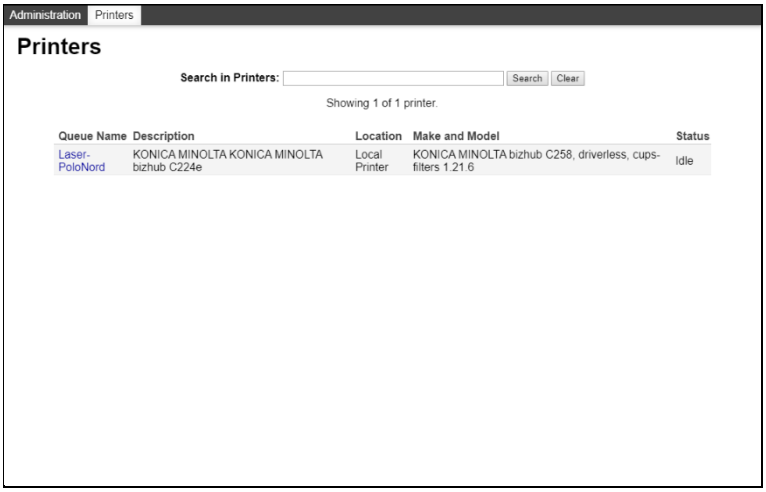


Fig. 75 – "Printers" panel

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

- Maintenance
- Administration

The second section lists all the jobs for this printer, with the possibility to show all jobs or just the completed jobs and to search in the list with the dedicated buttons (Fig. 76).

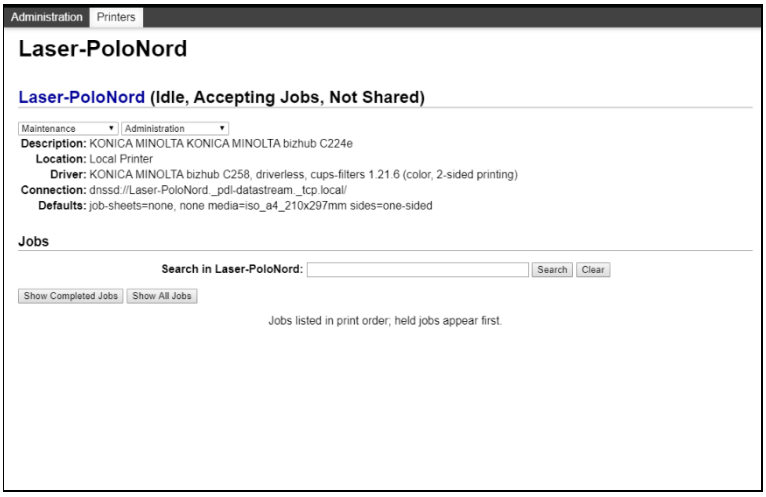


Fig. 76 – "Printer" panel

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

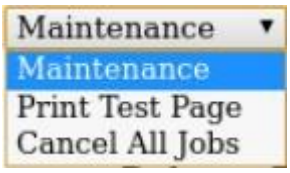


Fig. 77 – Maintenance Activities list

- Print test page
  - With this command a test page is sent to the printer to check the communication and printing capability
- Clean Print Heads
  - With this command the procedure to clean the print heads is launched in the printer (this command can be present or not depending on the printer model)
- Cancel all jobs
  - Cancel all jobs running and waiting

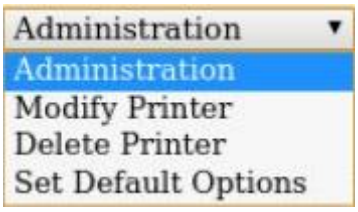


Fig. 78 – Administration Activities list

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

- Modify printer
  - The Configuration of the printer can be modified
- Delete printer
  - Printer can be deleted, after confirmation (Fig. 79)
- Set default options
  - Can modify the Default Options by means of the panel in Fig. 69 and Fig. 71

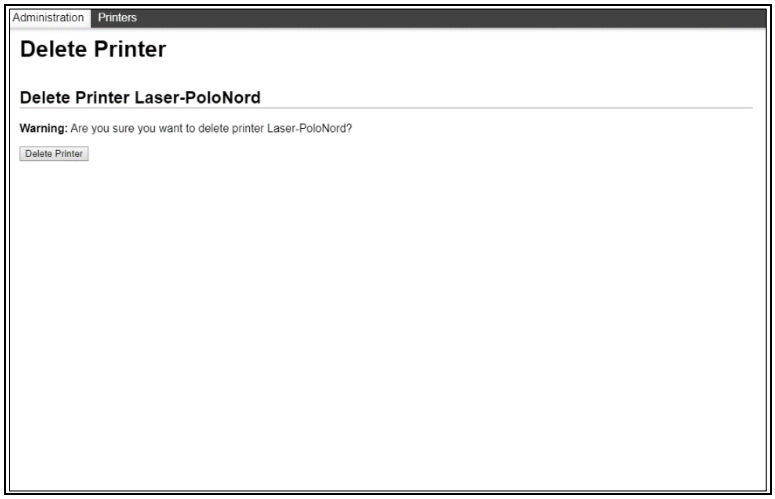
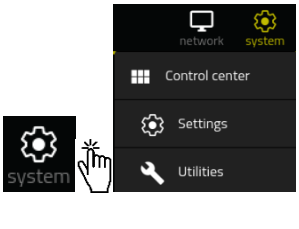


Fig. 79 – “Delete Printer” panel

16. Utilities

To access system utilities, click on the icon →

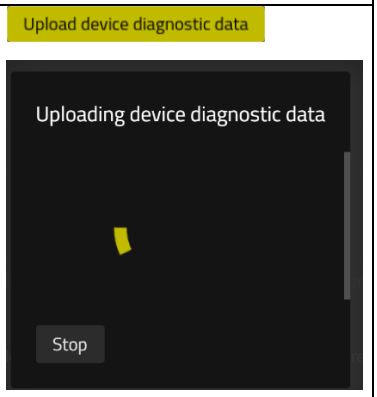
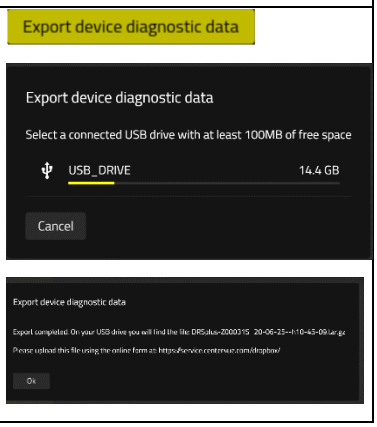
in the toolbar and then Utilities in the drop-down menu.



16.1 Assistance

This panel (Fig. 80) can be used to open a Remote Assistance (R.A.) session or to export diagnostic data for technical troubleshooting purposes.

Once the R.A. session is established, the panel will show the Authorization Code that the remote operator will need to connect to the device.

Function	Command
Open a Remote Assistance (RA) session	
Upload device diagnostic data to a CenterVue server	
Export diagnostic data to USB	

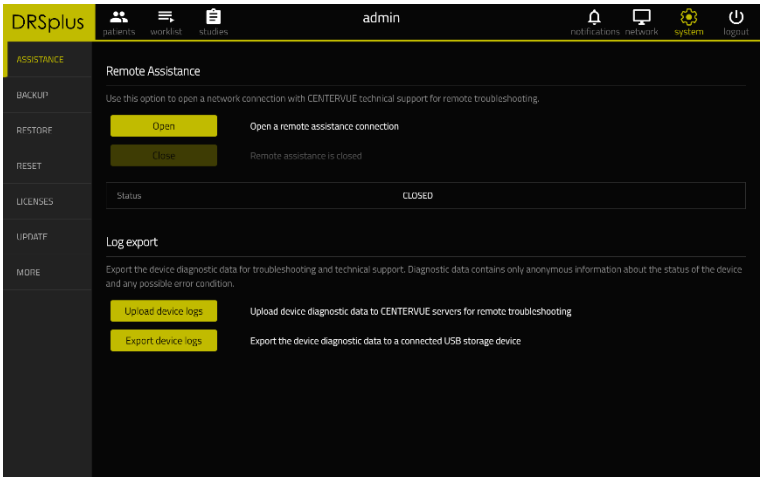
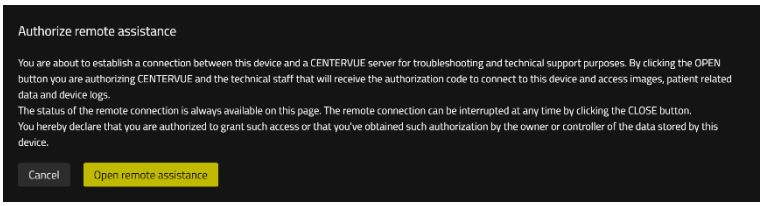
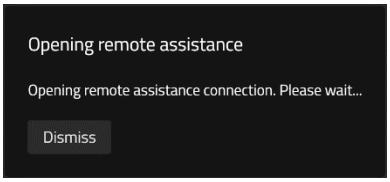


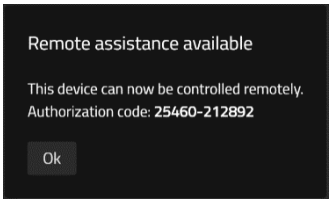
Fig. 80 – Assistance Utilities

Hitting the Open button in Remote Assistance, an authorization pop-up will be displayed.

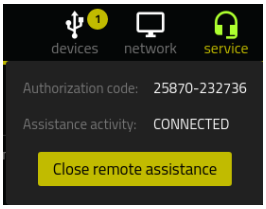


Once the Remote Assistance is open, the authorization code is displayed:





The current status of the Remote Assistance session is always available through the “service” icon on the top bar.



Pressing the button will open a menu that will show the current authorization code and a button that can be used to close the session.

16.2 Backup

This panel (Fig. 81) provides the utility to perform the backup of the patient data stored in the on-board disk.

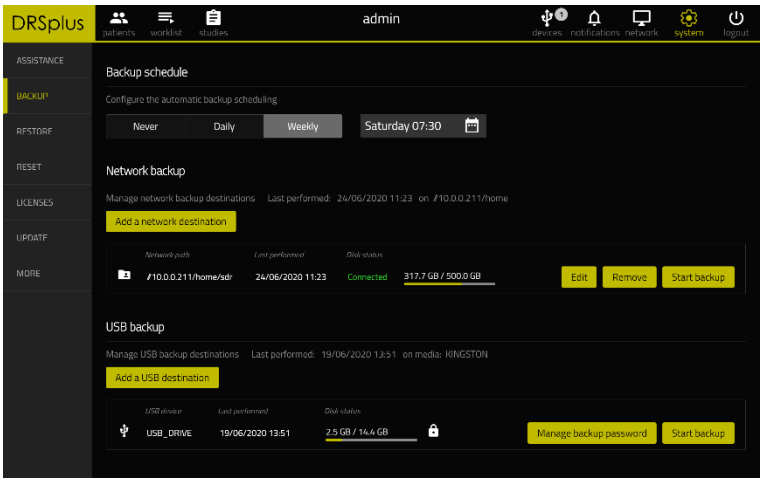


Fig. 81 – "Backup" panel

Data can be backed up on an external, USB-connected memory device (flash memory or disk) or a remote network destination.

Backup jobs can be run manually or scheduled to run automatically either once a day or once a week.

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

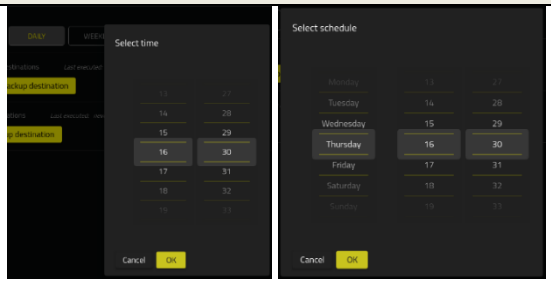
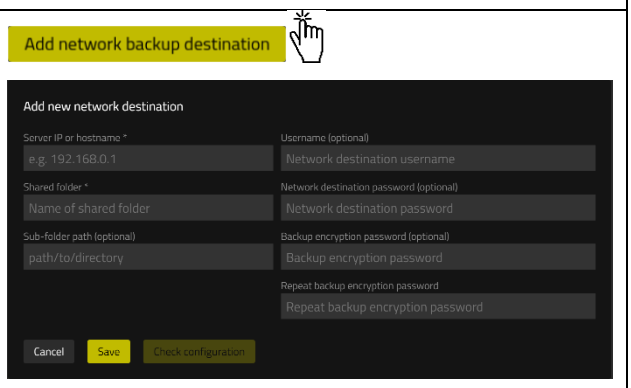
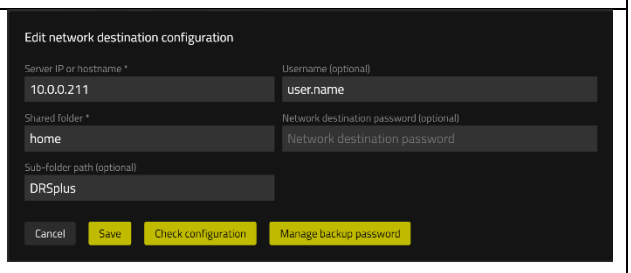
The panel displays the date and time of the last successful backup.

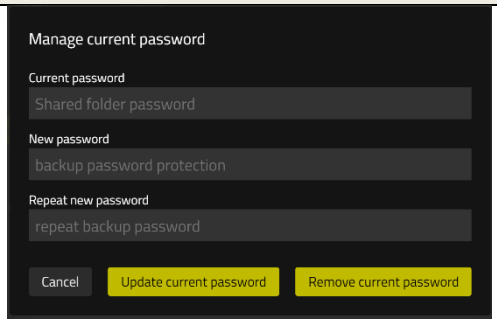
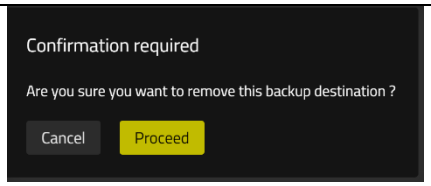
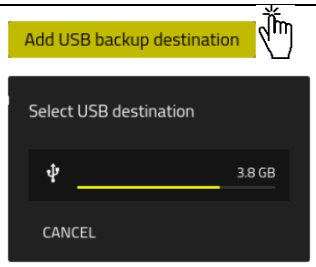
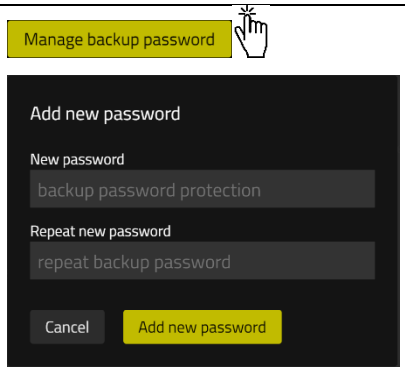
- **HARD DISK FAILURES ARE UNPREDICTABLE AND MAY CAUSE IRREVERSIBLE LOSS OF DATA**
- **IN THE EVENT OF LOSS OF DATA, IT CAN BE EASILY RECOVERED FROM THE LAST BACKUP PERFORMED**
- **IT IS THE END USER'S RESPONSIBILITY TO KEEP AN UPDATED BACKUP OF THE DATA GENERATED BY THE drsplus THROUGH REGULAR USE OF THE BACKUP UTILITY**
- **THE MANUFACTURER DECLINES ALL LIABILITY FOR LOSS OF DATA DUE TO HARD DISK FAILURES**

❖ **MANUAL ALTERATIONS OF THE FILES GENERATED BY THE BACKUP UTILITY MAY AFFECT THE RECOVERY OF DATA**

The device administrator may choose to protect the data in the backup with an encryption password. Data in password-protected backups is encrypted. This password will not be asked each time the operator performs the backup but is required during the restore procedure.

PASSWORD PROTECTED BACKUPS CANNOT BE RESTORED OR RECOVERED IF THE PASSWORD IS LOST.

Function	Command
Activation of automatic backup utility and setting of frequency, day and time of execution	
Configuration of storage units in network on which backup is performed automatically (= destination)	
Edit of storage units in network already configured	

Function	Command
Management of current shared folder password	
Remove storage units in network already configured	
Configuration of external storage units (USB keys and discs) on which backup is performed automatically (= destination)	
Configuration of a password for backup protection.	

16.3 Restore

This panel (Fig. 82) provides the utility to restore from a backup. The panel displays a list of available destinations that contain a compatible backup image that can be restored. Only the Administrator user is allowed to perform a restore operation.

drsplus can restore backup images made with the CenterVue drs. Only backup images created by drs devices running software 2.5.0 or greater can be imported into drsplus.

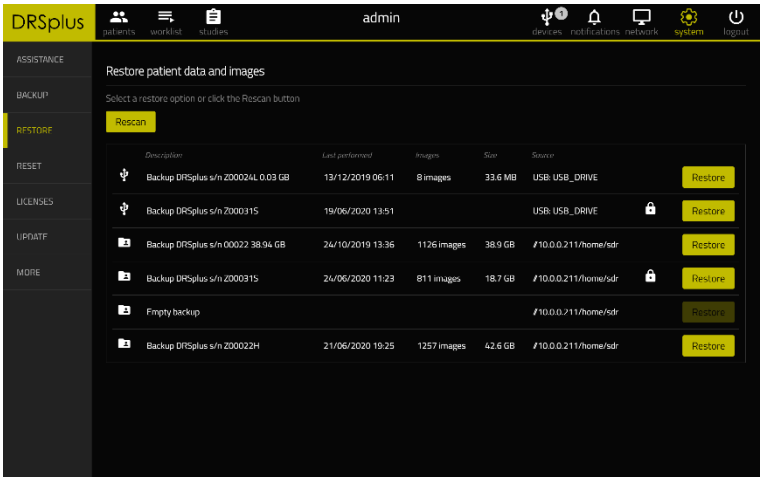
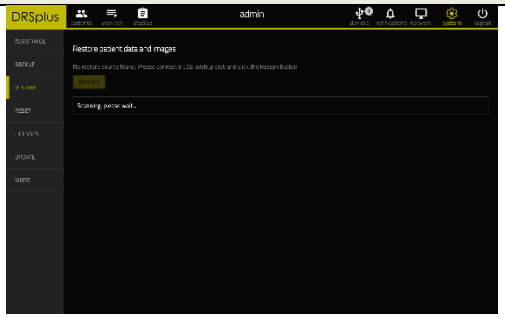
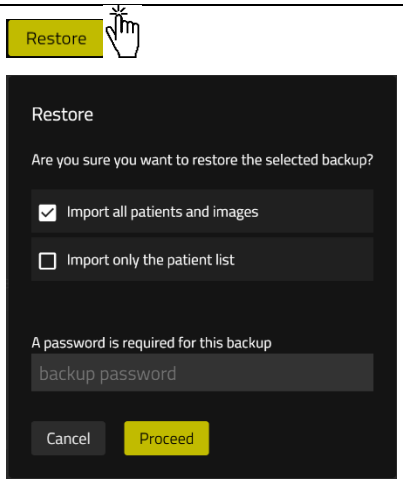
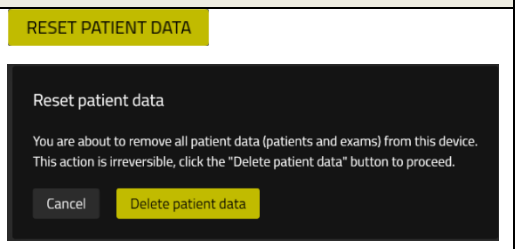
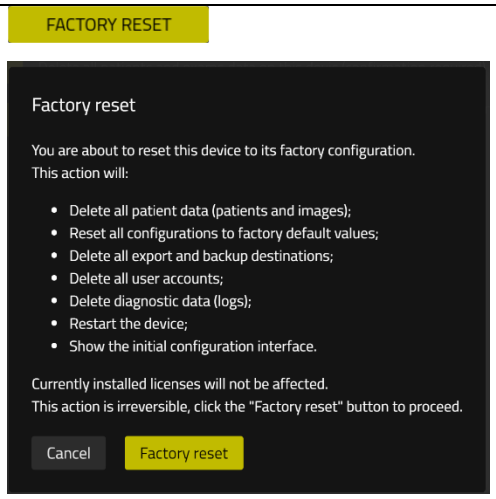


Fig. 82 – “Restore” panel

Function	Command
Scan of the restore sources	
Restore from the selected source. It is also possible to import only the list of patients (no exam data). If the backup image is password-protected, the encryption password must be entered.	

16.4 Reset

This panel (Fig. 83) can only be accessed by an Administrator and allows to reset the device.

Function	Command
Deletion of all patients and examination data	
On resetting to factory settings, all data will be erased, and all settings returned to initial values. Installed licenses are not affected.	

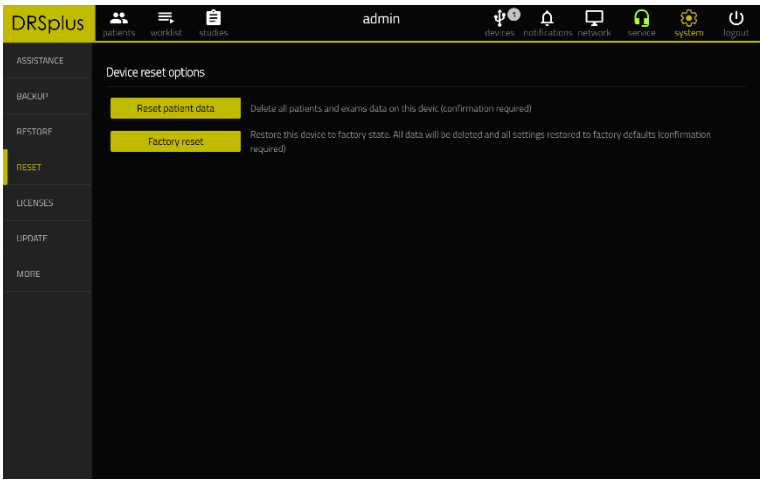


Fig. 83 – “Reset” panel

16.5 Licenses

This panel (Fig. 84) can be used to manage optional licenses. It shows the list of licenses installed on the device and allows to either revoke a license or to install a new one[1].

[1] To request licenses, refer to local distributor.

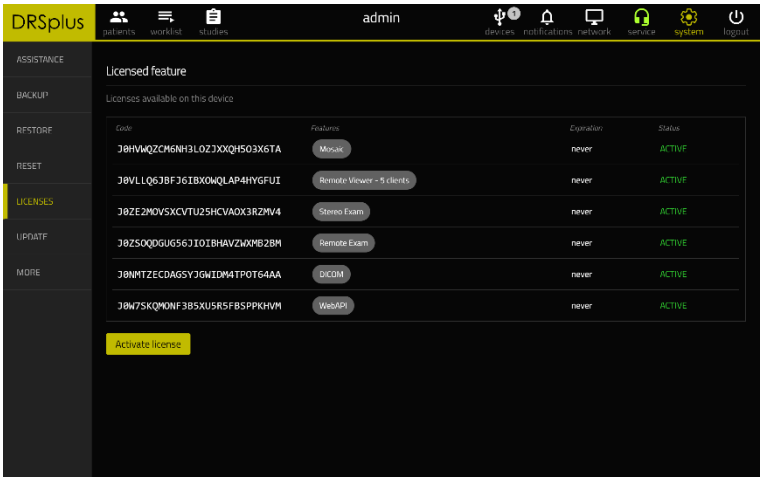


Fig. 84 - "License" panel

drsplus will automatically download any license assigned to it as soon as it is able to connect to the CenterVue License Server. A suitable network configuration and internet connection is required.

Licenses can be also activated manually introducing the code in the dedicated dialog.

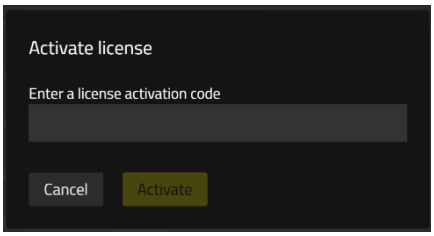


Fig. 85 – Activate License Dialog

16.6 Update

This panel (Fig. 86) provides the utility to install software updates and upgrades. Access to this panel is limited to the Administrator user.

The installation package should be saved on the top folder of a USB flash memory which then must be plugged into one of the three USB ports. The device will detect the installation package and prompt the operator for a confirmation before proceeding with the installation.

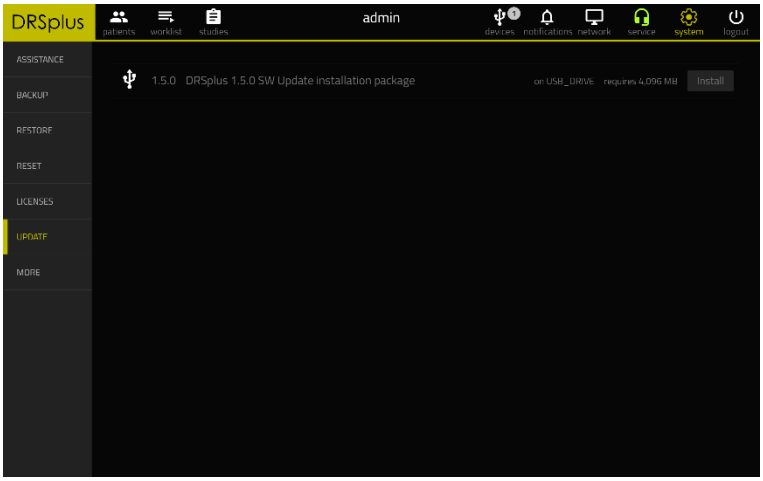


Fig. 86 - "Update" panel

Once the update is selected, the installation is done automatically while the progress of the activity is shown.

16.7 More

This panel (Fig. 87) provides a few utilities that can be used to

- Enable or disable the “demo” dataset

- Move the optical head to positions that are suitable for cleaning the lens, shipping or waiting for performing the exam.

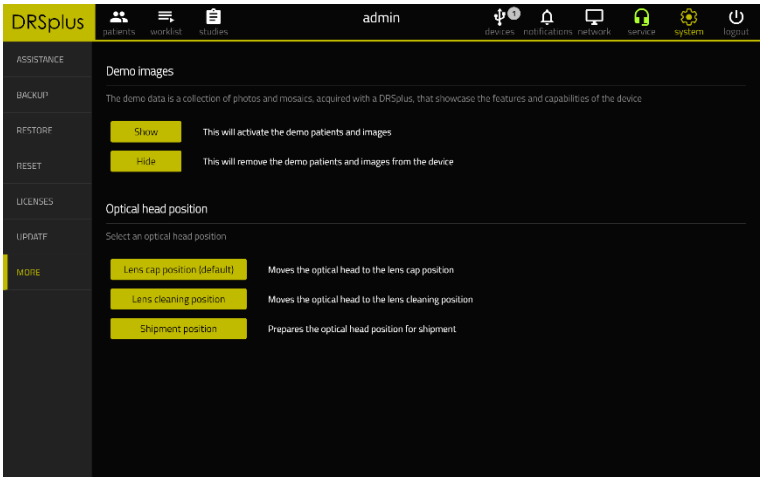


Fig. 87 - "More" panel

16.8 Demo dataset

Once the demo dataset is enabled, the patient list will be populated with a small number of dummy patient records each containing a few sample images intended to showcase the quality of the images that can be acquired with the drsplus.

The dummy patients cannot be edited. When reviewing the images of a dummy patient the “new exam” button is not available.

The demo dataset can be enabled and disabled with no restrictions by the Administrator.

16.9 Optical head position

Except during startup and when an exam is in progress, the optical head is always positioned in the “lens cap position”, where the back of the headrest protects the front lens.

To clean the front lens the operator can press the “Lens cleaning position” button to move the optical head to a position that exposes the front lens to the operator. Pressing the “Lens cap position” button will return the optical head to the default position.

Prior to shipment, the operator should press the “Shipment position” button to completely retract the optical head so that the device can fit the shipping container.

17. Remote Exam

The drsplus Remote Exam functionality[1] through drsplus Remote Viewer provides the capability of executing a patient remote acquisition with CENTERVUE drsplus.

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

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

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

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

For Remote Exam activation for a specific user, see §15.5.

From the computer, login with the proper user on the **Remote Viewer**.

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

A popup appears and the **Remote Activation Code** is requested.

The Remote Activation Code will be showed on the display of the drsplus.

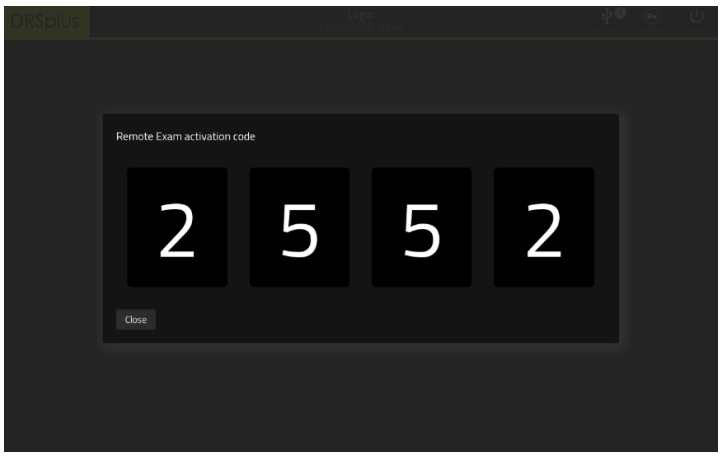


Fig. 88 – Remote Activation Code showed on drsplus display

[1] The Remote Exam Feature is licensed and needs as a pre-requisite a Remote Viewer license installed. Please request the license to your Official Local Distributor

Insert the Remote Activation Code on the remote exam interface.

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

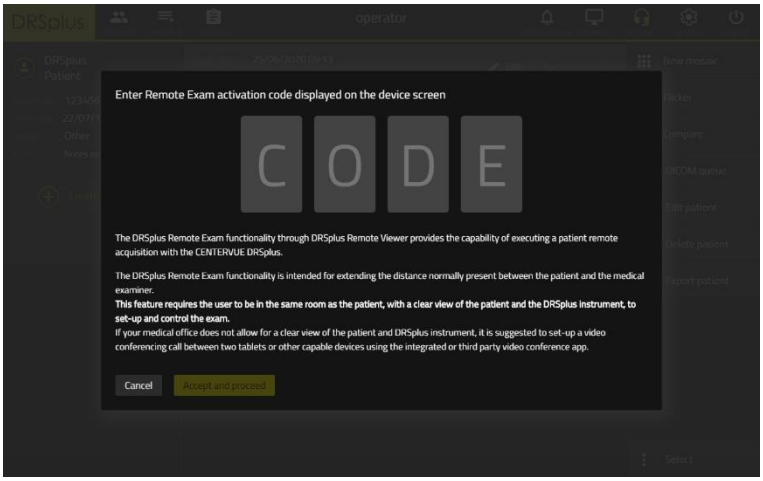


Fig. 89 – Remote Activation Code fill on Remote Viewer Interface

Conduct the exam steps the same way as if you are next to the patient.

Verify the seat of the patient and instruct to place their forehead in the proper position.

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

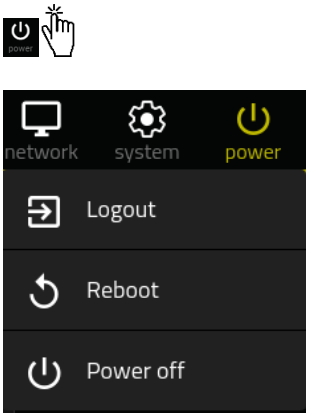
Perform the acquisition sequence just as you would normally, instructing the patient remotely when the acquisition has begun.

During the exam, it is always possible to control and stop the exam from the display of the drsplus.

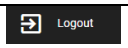
When the exam has been completed, you can review the images and download the report directly from the remote viewer.

18. Power-off

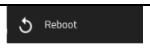
❖ To power off the device click on the “power” icon near the top-right corner of the screen →



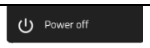
❖ A menu will open: select the “Logout” option to close the current session →



❖ or select “Reboot” to restart the device →



❖ or select “Power off” to initiate the shutdown procedure and power off the device →



Wait a few seconds after the on-board display goes dark before removing the power cord of switching off the power source (for example, by turning the main switch on the electric table).

19. Cleaning

This paragraph explains how to clean the device. The device must be powered off, and the power cord shall be disconnected from mains.

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

If the lens is very dirty, for instance due to the presence of fingerprints or other impurities, the front lens should be cleaned using photographic cleaning paper or a very clean microfiber cloth and a suitable lens cleaning fluid.

Pass a wet wipe on the front lens with a single circular motion: never reuse it after each pass. Several passes may be needed in order to achieve a good cleaning level.

Do not attempt to clean the front lens with a dry cloth as this may scratch the surface.

The headrest silicone cushion is the only part in direct contact with the patient: it is recommended to sanitize it with a disinfecting wipe after each use and allowed to dry prior to reuse.

Take care not to sprinkle parts not belonging to the patient rest. The headrest silicone cushion can also be removed and washed with lukewarm water and a mild detergent.

The touch screen panel should be cleaned using a soft, lint-free cloth dampened with a small amount of water.

Do not use alcohol or detergents to clean the touch screen, as these may damage the protective coating.

The plastic covers of the device can be cleaned using of a cloth dampened in a small amount of water.

Do not use alcohol or detergents to clean the plastic shells, as this could erase labelling and other indications.

20. Maintenance

All maintenance operations must be carried out exclusively by personnel authorized by CenterVue.

Maintenance frequency recommended by CenterVue:

- Safety electric tests (according to IEC 60601-1): once a year.
- Comprehensive system verification: every two years.

Inquire with your local distributor or Authorized Service Center for service contracts and warranty extensions.

21. Electromagnetic Compatibility

This device complies with the requirements of Class A as defined by the IEC 60601-1-2 standard.

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;
- 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.

21.1 Manufacturers EMC Declaration according to IEC 60601-1-2

The following tables provide specific information regarding compliance of the drs$_{plus}$.

drs$_{plus}$ is intended for use in the electromagnetic environment specified below. The customer or the user of the drs$_{plus}$ should ensure that it is used in such environment.

The device has radio disturbance characteristics that make it suitable for use in industrial and hospital environments (CISPR 11 class A). If used in a residential environment (for which CISPR 11 class B is normally required), this device may not offer adequate protection of radio-frequency communications. It may therefore be necessary to take steps to mitigate the problem, such as reorienting or moving the device.

In case the device is connected to an ethernet network, the cable shall be shielded and its length shall be lower than 5m.

Other cables and accessories not supplied with the drsplus could adversely affect the electromagnetic compatibility performance.

Table 1 – Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	drsplus 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	

21.2 Guidance and manufacturer declaration – electromagnetic immunity

Table 2 – 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	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	Mains power quality

IEC61000-4-5	±2 kV line(s) to earth	±2 kV line(s) to earth	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 3 – Electromagnetic Immunity

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 drs plus, 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 strength 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 drs plus is used exceeds the applicable RF compliance level above, drs plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating drs plus. [b] Over the frequency range 150Khz to 80MHz, field strengths should be less than 3V/m.			

Considering the device functionality, in case of presence of burst during the exam, some errors are tolerated. The recovery action in these cases, is the restart of the exam.

21.3 Immunity tests performance criteria

Function	Immunity tests performance criteria
Device operation - main unit	During application of the test stimulus, any temporary cessation or interruption of the intended operation remains within acceptable limits.

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

Do not use portable radio frequency (RF) communication devices (including peripheral devices such as antenna cables and external antennas) at distances of less than 30 cm from any component of the drsplus, including manufacturer recommended cables. Failure to observe this precaution may compromise the performance of the device

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.			

21.4 Wi-Fi specifications

Model:	Intel Dual Band Wireless-AC 7265 (Intel)
Main chipset:	7265D2W
Diversity	Supported
Radio ON/OFF Control	Supported in both hardware and software
Connector interface	M.2: PCIe, USB
IEEE WLAN Standard	IEEE 802.11abgn, 802.11ac, 802.11d, 802.11e, 802.11i, 802.11h, 802.11w
Authentication	WPA and WPA2, 802.1X (EAP-TLS, TTLS, PEAP, LEAP, EAP-FAST), EAP-SIM, EAP-AKA
Authentication Protocols	PAP, CHAP, TLS, GTC, MS-CHAP*, MS-CHAPv2
Encryption	64-bit and 128-bit WEP, AES-CCMP, TKIP
Wi-Fi Direct Encryption and Authentication	WPA2, AES-CCMP
Product Safety	UL, C-UL, CB (IEC 60950-1)
Management Frame Protection	802.11w (WFA- Protected Management Frames)

21.5 FCC (USA) and IC (Canada) radio certification

drsplus contains a radio module that complies with regulations of Canada and the USA and in particular with Part 15 of FCC regulation.

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.

22. Technical Specifications

CE 0123

93/42/EEC Directive

Class IIa

Class and type of applied part

Class I, Type B (according to IEC 60601-1).

IP Classification

IPX0 (according to IEC 60529, 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 View:	45° (H) x 40° (V) as captured with a single exposure
❖ Image size:	10 Mpixel
❖ Light sources:	Infrared LED (825-870 nm), white LED (420-675 nm)
❖ Imaging modalities:	TrueColor, External Eye
❖ Working distance:	25 mm
❖ Pixel pitch on the retina:	4.3 micron

Other characteristics

❖ Automatic operation:	auto-alignment, auto-focus, auto-exposure, auto-capture
❖ Auto-focusing adjustment range:	from -15 D to +15 D
❖ Fixation targets:	10 positions
❖ On-board display:	10.1” multi-touch, color
❖ Internal storage:	SSD, ≥480 GB
❖ Acoustic emission:	<80 dBA

Dimensions

❖ Weight:	11 Kg (24.3lb)
❖ Size (WxHxD):	300mm × 450mm × 650mm (11.8” × 17.7” × 25.5”)

Power supply

❖ Voltage:	12 V DC
❖ Consumption	60 W

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

23. Disposal

drsplus 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.

23.1 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.

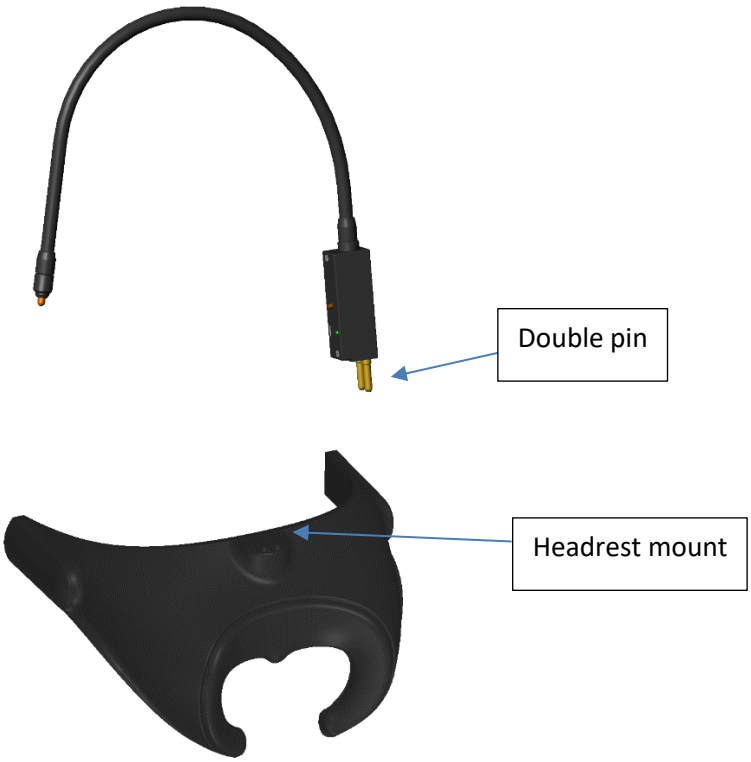
Mercury: is easily accumulated in organisms and concentrates through the food chain. It has chronic effects and can cause brain damage. Chromium (Hexavalent): easily absorbed into cells with toxic effects. The results can be allergic reactions, asthma and it is considered to be genotoxic (damages the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

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

Appendix A External Fixation Target Usage

The External Fixation Target consists of an orange LED light, whose position can be adjusted through a flexible tube.

To install the part, insert the double pin of the External Fixation Target into the corresponding mount on the Headrest: note that the button on the base of the External Fixation Target should be orientated towards the operator (i.e. towards the display).



Once the part is installed, the position of the fixation light can be adjusted as desired by flexing the tube (Fig. 90).

The base of the External Fixation Target includes: the power button, a green LED indicator, a Micro-USB port and an internal battery.

Press the button to power on the Fixation Light: it will automatically power off after 10 minutes.

To charge the internal battery, use a standard USB charger, connected to the Micro-USB port: the green LED indicator will turn on when the External Fixation Target is charging.

Since the External Fixation Target is battery powered, no electrical connection with the drs$_{plus}$ is required.

Fig. 90 – External Fixation Target positioning

Appendix B External Display Setup

drsplus can be connected to an external monitor using the DisplayPort socket placed at the back of the device.

When an external monitor is plugged in, the drsplus will mirror the on-board display.

Important

Native DisplayPort links are usually found in monitors, but they are rarely available on TV sets.

Requirements

- The external display must support “DisplayPort 1.0” standard
- The external display must support 1920x1080 resolution
- The drsplus can be connected to a TV set via HDMI using an **active converter**.

⚠	Passive converters **are not supported.**