drsplus

Operating Manual

MANUAL INFORMATION

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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 are correct at the date of issue of the manual. The device configuration can change as product improvement are incorporated and this manual may not exactly depict your device. Please contact the customer service if you have any questions about differences.

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1. Introduction

Congratulations for choosing drsplus and its color confocal retinal imaging capabilities.

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

The clinical interpretation of images acquired by the drsplus must be carried out exclusively by ophthalmologists.

The ophthalmologist is responsible for any diagnosis based on drsplus results.

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

2. Symbols

2.1 Symbols used on the device

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

Symbol	Explanation
	Information about the Manufacturer.
	Manufacturing date (year/week).
	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/EC.
	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 drsplus consists of:

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

Fig. 1 – drsplus device

Fig. 2 – Cables protection shell

Fig. 3 – Device stand

Fig. 4 – Headrest

Fig. 5 – External power supply

Fig. 6 – drsplus

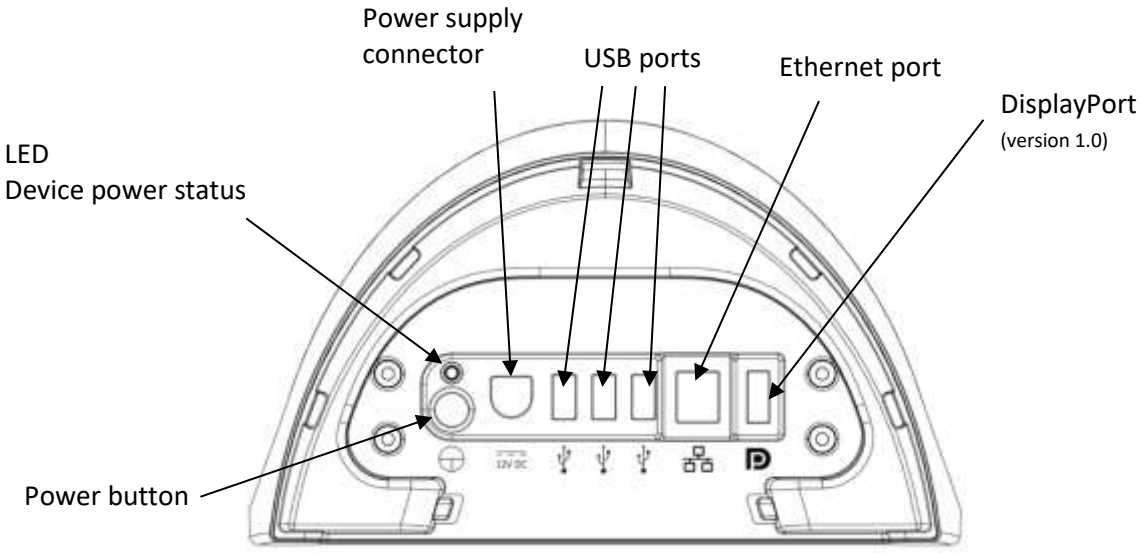


Fig. 7 – Back Panel

The DRSplus can be equipped with:

- External fixation light (Fig. 8);
- Prismatic goggles for stereo view (Fig. 9).

Fig. 8 – External fixation light

Fig. 9 - Stereo goggles

The DRSplus 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

5. WARNINGS AND PRECAUTIONS

The following precautions are important for the device safety:

- **The clinical interpretation of the images acquired by the drsplus is restricted to licensed eye care practitioners.**
- **Use of the device is restricted to operators who have undergone the necessary training.**
- **Do not open the device in order to prevent the risk of electrocution and damage to the device itself.**
- **Do not use the device if the covers or other parts of the device have been removed.**
- **Only technicians authorized by CenterVue may service the drsplus. CenterVue cannot be held responsible for the device safety should drsplus 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 device 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 drsplus must be used in a room with an electrical system that complies with applicable healthcare environment safety regulations.**
- **The drsplus power supply must be connected to a socket with a circuit breaker.**
- **The drsplus must NOT be used in an oxygen-rich environment or in presence of flammable anesthetics.**
- **External devices connected to the drsplus, 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. Any operator who connects external devices to drsplus 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 OPERATOR'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.

- drsplus **needs to be operated in the following environmental conditions:**
  - **Temperature: +10 °C to +35 °C**
  - **Humidity (max): 90% not condensing**
- drsplus **needs to be stored in the following environmental conditions:**
  - **Temperature: -10 °C to +60 °C**
  - **Humidity (max): 90% not condensing**
- **The device must be placed in a room which is not exposed to adverse chemical-physical conditions, such as the presence of sulfur, salt, dust, direct sunlight, lack of ventilation, high humidity, sudden temperature drops or peaks. The safety and/or effectiveness of the instrument cannot be guaranteed if these conditions are not 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 operators. No specific skills are required to use the drsplus. However, operators 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 OPERATOR'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

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: the central circular opening on the ocular surface, through which light enters the eye. The pupil naturally contracts when struck by light. If the pupil is too small the image quality may be impaired.

Retina: the posterior pole of the ocular bulb. 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 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.

7. Preparation of device

This section explains how to set up the drsplus for use.

7.1 First usage

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

To prepare drsplus 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.

drsplus needs to be operated in a semi dark environment, to ease the natural dilation of the 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 user name 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.

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

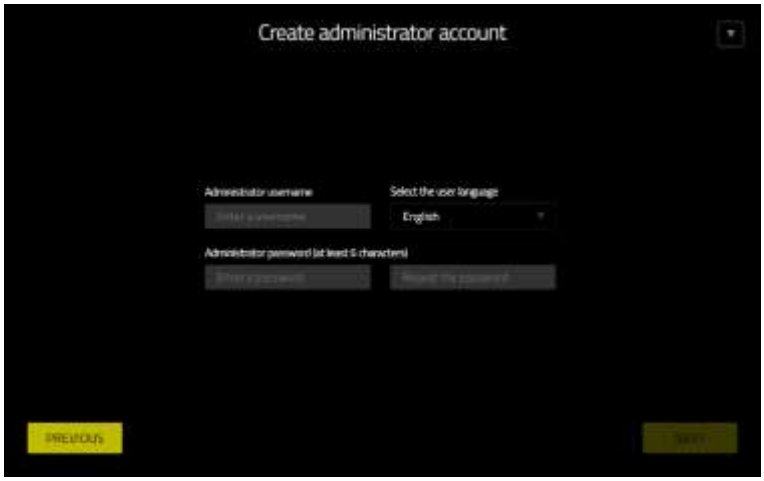


Fig. 16 – Configuration Wizard: creation of the System Administrator account

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.

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 §13.1.

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 two 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;
- Code;
- Date of Birth;
- Gender;
- Date of the last examination made with drsplus.

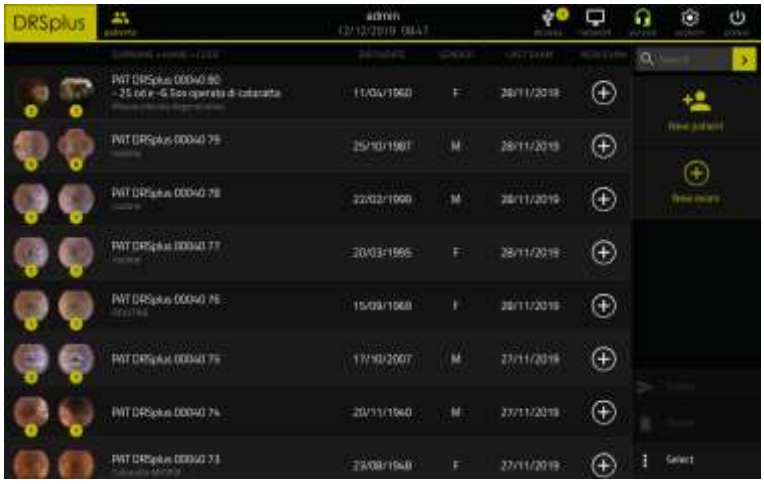


Fig. 19 – Patient List

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.

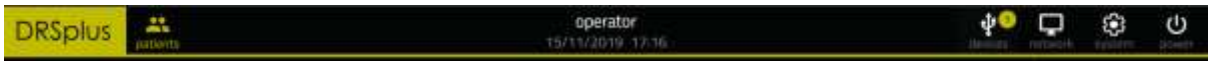
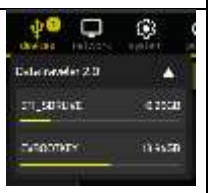
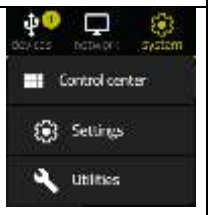


Fig. 20 – Navigation Bar

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 (§14)		
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 patients before taking pictures.

It is recommended to give the patient the following instructions:

1) The acquisition of retinal images with drsplus does not involve any risk, in particular 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 head-rest.;
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 head-rest of drsplus.

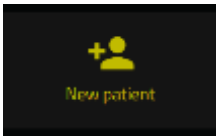
- Give the patient detailed information about the device operation before placing the patient on the device.
- The minimum pupil diameter which ensures high quality of the images is 2.5 mm.

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.

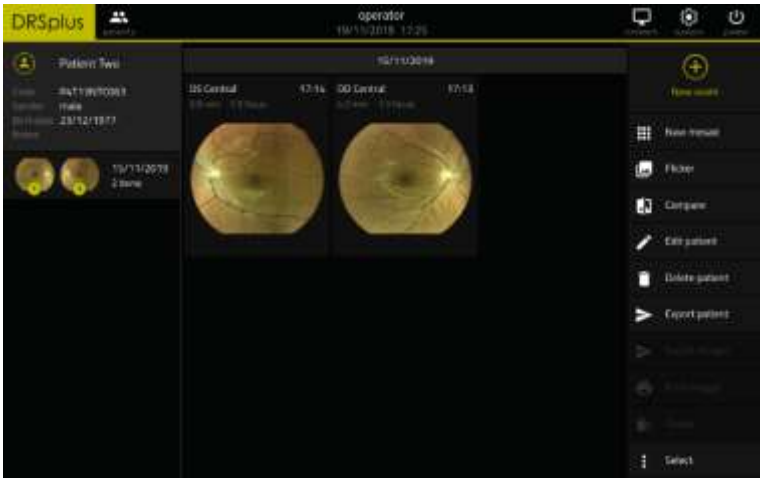


Fig. 21 – Patient Details screen

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 §0),
  - STEREO = acquire a couple of retinal images for stereo review (see §9.5);
- Retinal fields to acquire: the available options follow.

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

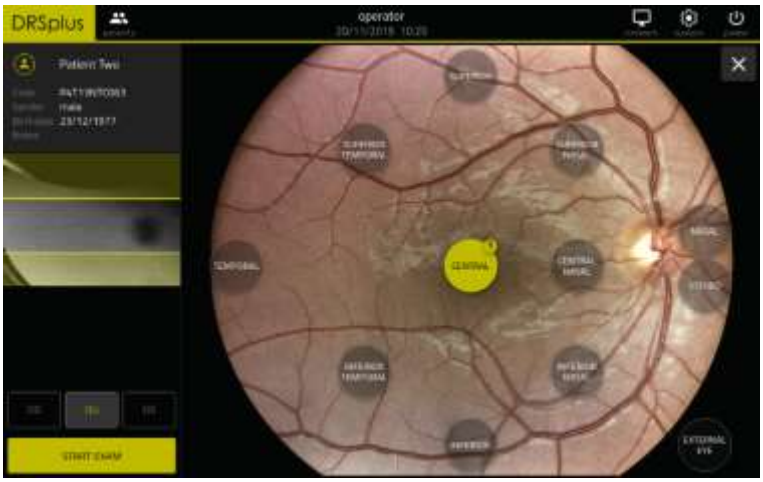


Fig. 22 – Exam configuration screen

The following fields can be selected:

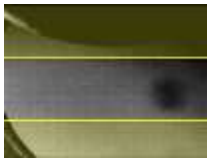
a. CENTRAL: centered on the foveal pit;
b. NASAL: centered approx. 19° nasally to the foveal pit;
c. TEMPORAL: centered approx. 19° temporally to the foveal pit;
d. CENTRAL-NASAL: centered approx. 7° nasally to the foveal pit;
e. SUPERIOR: centered approx. 19° superiorly to the foveal pit;
f. INFERIOR: 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 §33 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.



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

drsplus automatically:

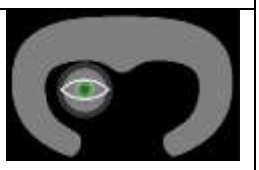
a. Aligns the frontal lens toward the patient's pupil;

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: 

Information	Position on the screen
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

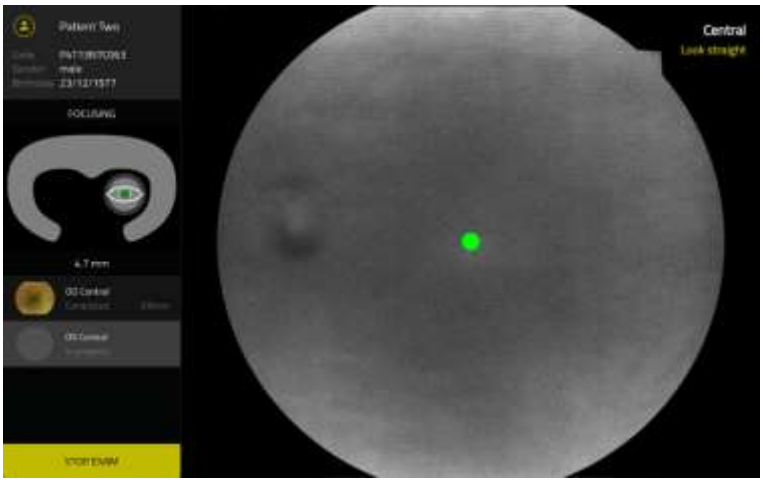


Fig. 23 – Running examination screen in automatic mode

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.

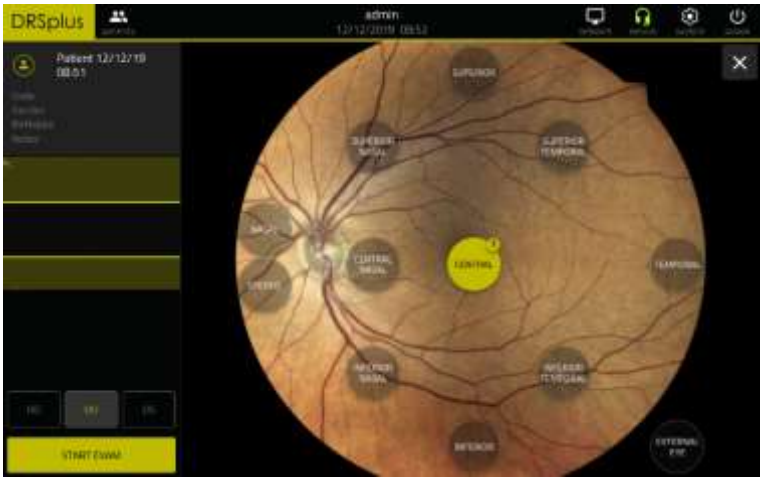


Fig. 24 – Exam configuration screen (“Fast exam” mode)

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).

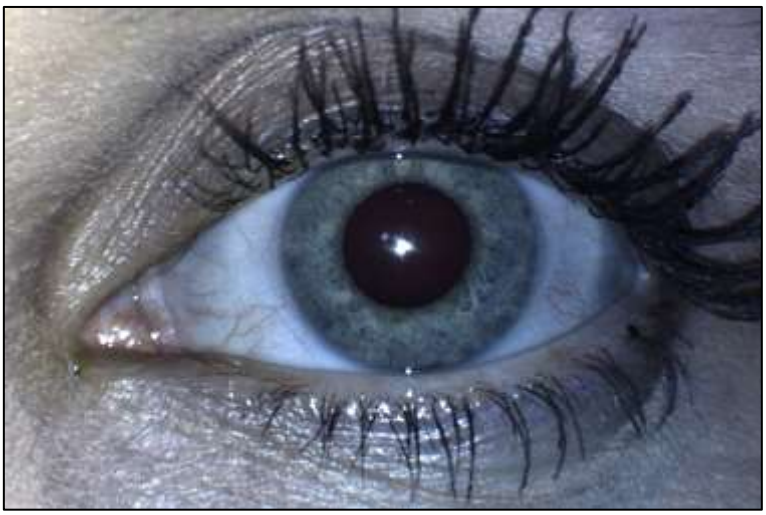


Fig. 25 – Image of the external surface of the eye (zoom)

9.5 Stereo modality (available under license only)

When this modality is set, drsplus will automatically acquire a couple of retinal images using the **nasal** 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 goggles, as shown in §3.

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: ID, Birthdate, Gender and Notes. Press **SAVE** to save the new patient or **CANCEL** to cancel the operation.

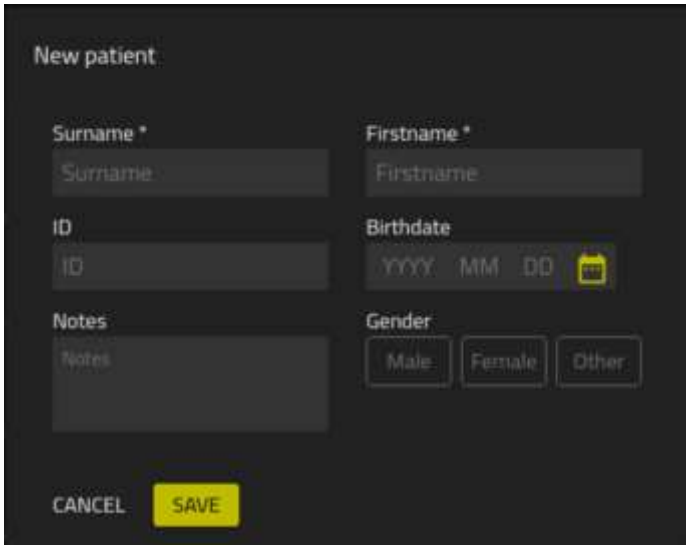
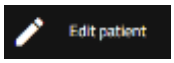


Fig. 26 – New Patient dialog

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).

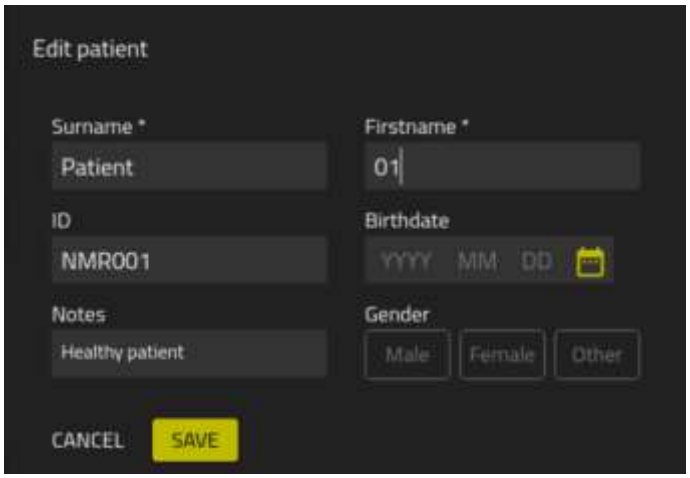
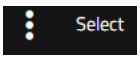


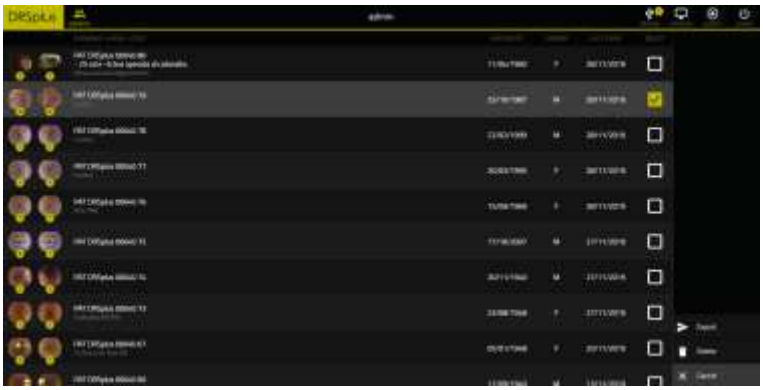
Fig. 27 – Edit Patient dialog

10.3 Single and multiple selection of patients

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

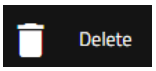


or keep pressed the patient row until the selection appears.



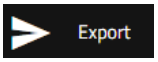
10.4 Deletion of patients

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



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, DRSplus will show the Patient Details screen (Fig. 28), which includes patient information and all of the images acquired.

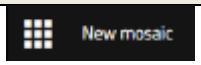
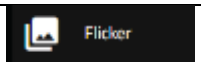
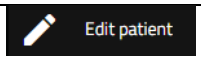
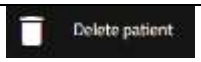
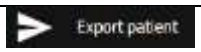
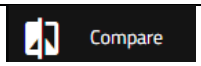
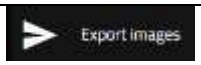
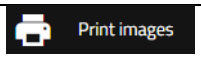
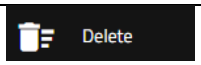
Patient information shown:

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. 28 – 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
New image acquisition	

Function	Command
Creation of a new mosaic[2]	
Flicker images[2]	
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[3]	
Export of all of the patient's images[3]	
Print images[3]	
Delete images[3, 4]	
Fullscreen review of a single image	Click on the image thumbnail
Retake an image[5]	Press the  icon on the bottom right corner

[2] Available under license only

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

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

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

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

11.2 Image review

The image review screen (Fig. 29) is used to review a single image at full resolution.

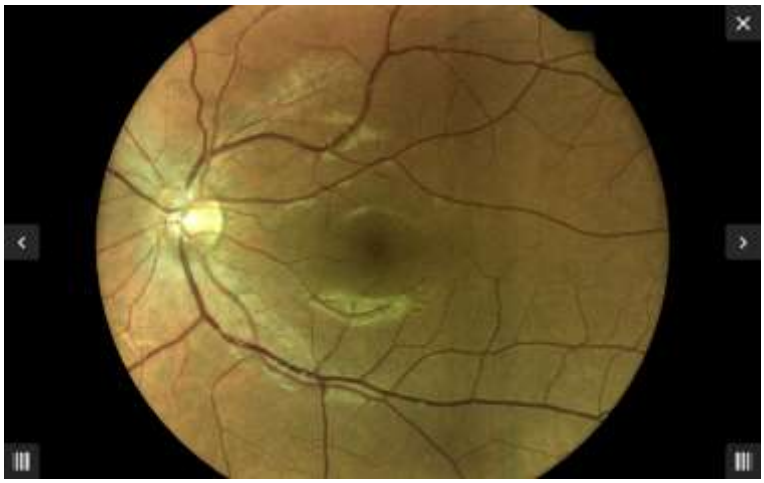


Fig. 29 – Single image review screen

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. 30)	button, bottom left
Open the toolbar that includes: image adjustment, export, print and deletion.	button, bottom right

Fig. 30 – Image review screen. Here the list of images for quick access is shown on the left panel, and the toolbar is shown on the right panel.

11.3 Side-by-side image review

The “side-by-side” screen (Fig. 31) permits the operator to quickly compare any couple of images selected from the Patient details screen. Images are shown next to each other.

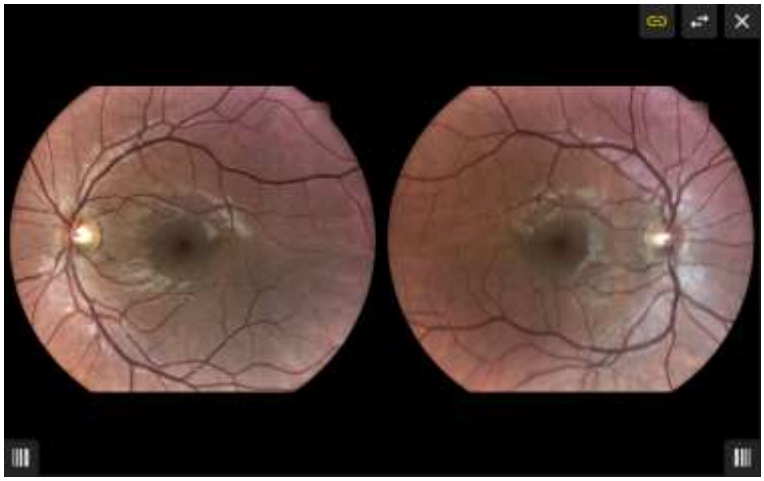


Fig. 31 – Side-by-side screen

Available functionalities

Function	Command
Enable / Disable the zoom and pan synchronization (any zoom and pan operation done on an image will immediately will replicated on the fellow image)	
Swap the images	
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. 32 – Side-by-side image review with toolbars

11.4 Visual flickering of images

The flickering screen (Fig. 33) 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 of the image features accurately overlapped. The registration of images is performed by means of a special algorithm included in the drsplus software.

Fig. 33 – Visual flickering screen

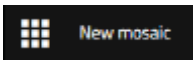
Available functionalities

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 drsplus 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. 35).

ⓘ	The mosaic function is available only under license.

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

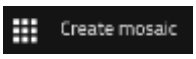
Then, select the fields that can be stitched together and press the “Create Mosaic” button. 

Fig. 34 – 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.

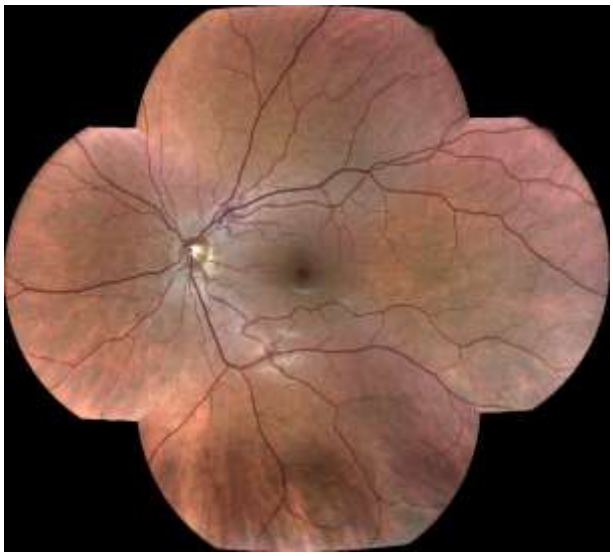


Fig. 35 – A mosaic

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. There are however several differences between the local user interface and the Remote Viewer: The configuration and execution of a new exam is not permitted.

To enable the Remote Viewer, the drsplus must be connected to the Local Area Network by means of a 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 (§13.3). Once the connection is up and running, open a browser in the remote PC and insert the address of the device:

http://*nnnnn.domain*

into the address bar. Here:

- *nnnnn* are the 7 characters which compose the serial number of the drsplus, as reported in the device label;
- *domain* is the network domain, if present (optional).

- The Remote Viewer functionality is available only under license.
- 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 supports the following browsers: Microsoft Edge, Mozilla Firefox (version 60 or higher), Apple Safari (version 6.2.8 or higher), Google Chrome (version 70 or higher).
- 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.
- Every Remote Viewer session is automatically closed after 20 minutes of inactivity. 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 (§0);
- configure (§13.6) one or more destinations, including USB and network drives;
- choose export parameters (Fig. 36):
  - select one or more of the following export formats: JPEG, PDF, DICOM;
  - 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.

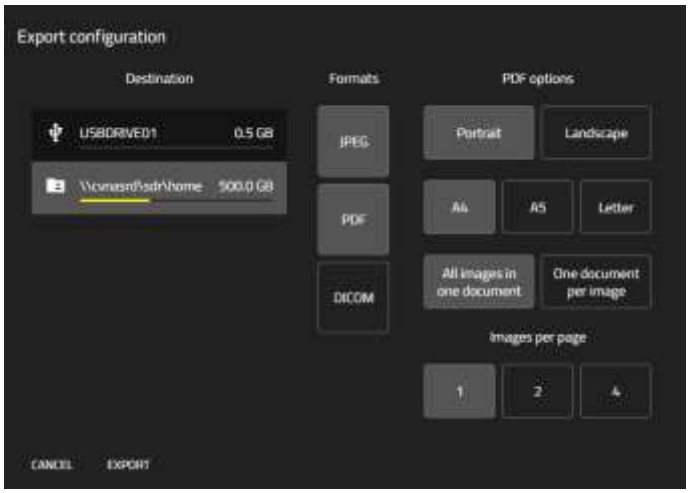


Fig. 36 – Export panel

13. Configuring the device

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.

13.1 Account

The “Account” panel (Fig. 37) allows users to change their password.

Fig. 37 – “Account” panel

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

13.2 Users

This panel (Fig. 38) is only accessible to the Administrator and enables management (creation, modification and deletion) of user accounts.

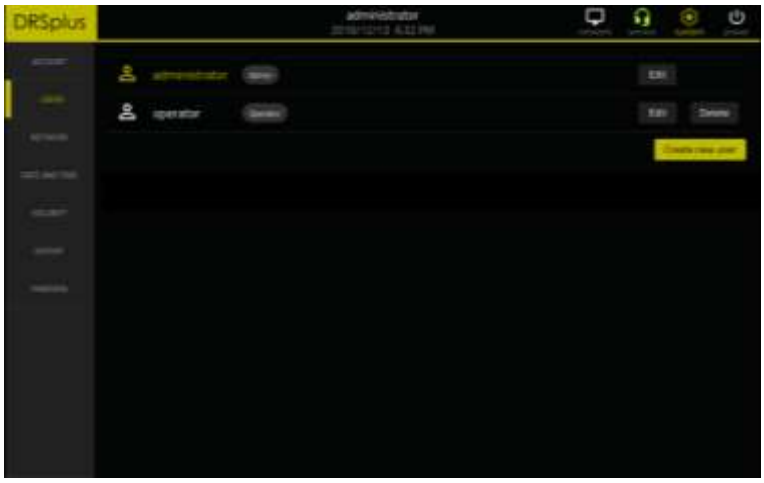


Fig. 38 - “Users” panel

- ❖ The user name must contain at least 4 characters
- ❖ The password must contain at least 6 characters

13.3 Network

This panel (Fig. 39) makes it possible to configure the parameters required for the network connection and specify the primary network using the ETHERNET | WIFI selector.

Fig. 39 – “Network” panel

Ethernet connection (wired)

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

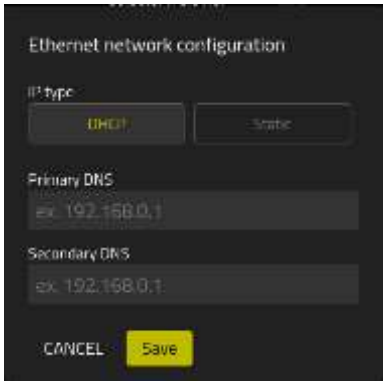


Fig. 40 – Ethernet connection settings

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

To check the network connection status, click on the icon in the top bar (Fig. 41).

Fig. 41 – Example of wired and Wi-Fi network connection status

13.4 Date and time

This panel (Fig. 42) 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. 42 – "Date & Time" panel

13.5 Security

This panel (Fig. 43) allows you to configure the security options of the Remote Viewer, or to disable the feature entirely.

When enabling “HTTPS” 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.

Fig. 43 - "Security" panel

13.6 Export

This panel (Fig. 44, Fig. 45) allows you to configure the parameters relating to the export function.

Fig. 44 - "Export" panel

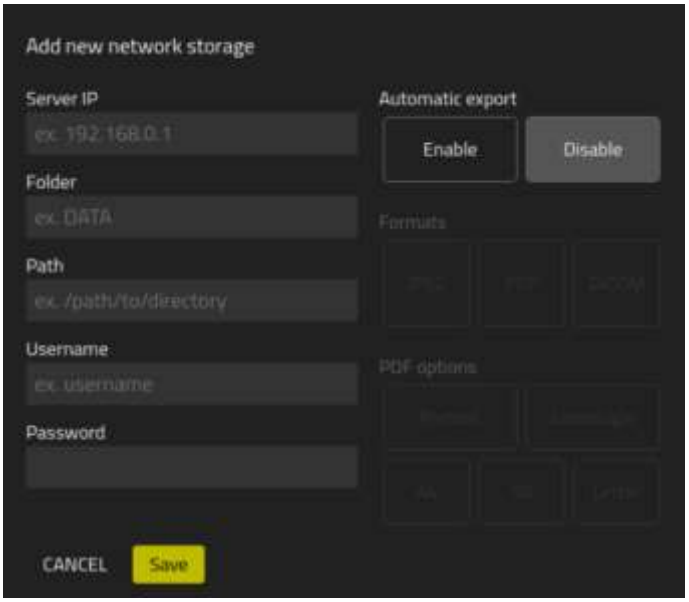


Fig. 45 – Configuration of export destination

13.7 Printers

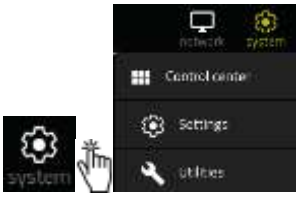
This panel (Fig. 46) allows you to configure the printing subsystem. Refer to the on-line documentation for details of how to configure the CUPS printing system.

Fig. 46 - "Printers" panel

14. Utilities

To access system utilities, click on the icon →

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



14.1 Assistance

This panel (Fig. 47) can be used to open a Remote Assistance (R.A.) session or to export diagnostic data for technical troubleshooting purposes.

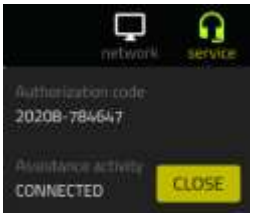
Once the R.A. session is established, the panel will show the Authorization Code that the remote operator will need in order to connect to the device.

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

Fig. 47 – Assistance Utilities

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.



14.2 Backup

This panel (Fig. 48) provides the utility to perform the backup of the patient data stored in the on-board disk.

Fig. 48 – "Backup" panel

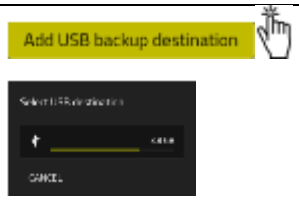
Data can be backed up on an external, USB-connected memory device (flash memory or disk) or a remote network destination.

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 OPERATOR'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**

Function	Command
Activation of automatic backup utility and setting of frequency, day and time of execution	 
Configuration of storage units in networks on which backup is performed automatically (= destination)	
Configuration of external storage units (USB keys and discs) on which backup is performed automatically (= destination)	

14.3 Restore

This panel (Fig. 49) 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.

Fig. 49 – “Restore” panel

14.4 Reset

This panel (Fig. 50) can only be accessed by an Administrator and allows to reset the device.

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

Fig. 50 – “Reset” panel

14.5 Licenses

This panel (Fig. 51) 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.

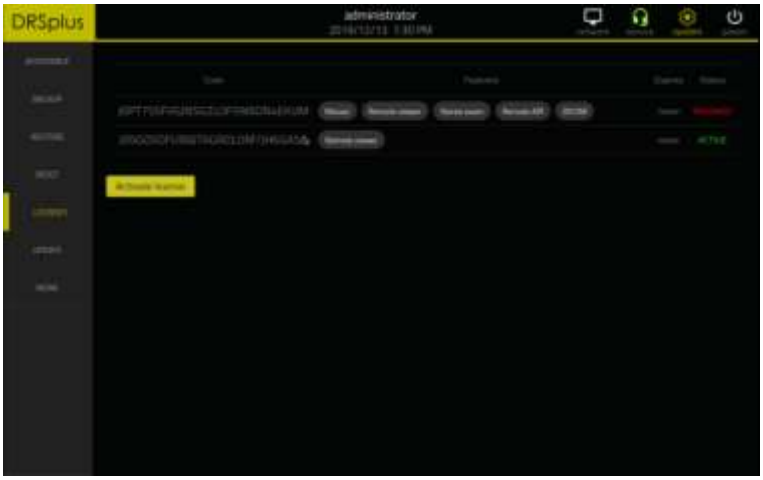


Fig. 51 - "License" panel

14.6 Update

This panel (Fig. 52) 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. 52 - "Update" panel

14.7 More

This panel (Fig. 53) 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 performing the exam.

Fig. 53 - "More" panel

14.8 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.

14.9 Optical head position

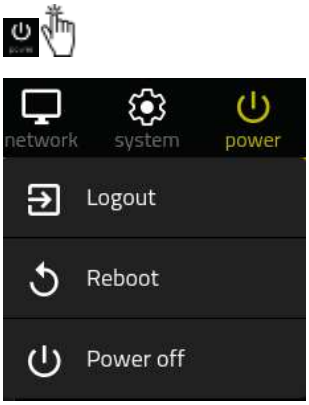
Except during startup and when an exam is in progress, the optical head is always positioned in the “lens cap position”, where the back of the headrest protects the front lens.

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.

15. 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).

16. 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 silicon cushion is the only part in direct contact with the patient: it should be sanitized 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 silicon 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.

17. 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.

18. 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.

18.1 Manufacturers EMC Declaration according to ISO 60601-1-2

The following tables provide specific information regarding compliance of the drsplus.

drsplus is intended for use in the electromagnetic environment specified below. The customer or the user of the drsplus 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.

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	

18.2 Guidance and manufacturer declaration – electromagnetic immunity

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

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

	for 5s	U_T) for 5s intervals.	
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 (ISO 60601-1-2:2007 5.2.2.2)

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 drsplus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80MHz to 800MHz $d = 1.17\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic sight survey[a], should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1: At 80MHz and 800MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which drsplus is used exceeds the applicable RF compliance level above, drsplus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating drsplus. [b] Over the frequency range 150Khz to 80MHz, field strengths should be less than 3V/m.			

18.3 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.			

18.4 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)

18.5 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.

20. 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.

20.1 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)