

icare®

DRSplus



Instructions for Use

icare[®]

DOCUMENT INFORMATION

The information in this document is subject to change without prior notice and it is correct at revision date. 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 these Instructions for Use is English. Should a conflict situation arise concerning a translated document, the English language version shall prevail.

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1. General Information

1.1 Intended Purpose

DRSplus is an ophthalmology assessment and diagnosis instrument intended for the acquisition of retinal images with or without a mydriatic agent and for their review.

1.2 Indications for Use

DRSplus is indicated to provide retinal images used for the diagnosis and monitoring of several retinal pathologies.

There are no surgical or treatment decisions made solely on retinal images obtained by the devices.

The clinical interpretation of the exams acquired by DRSplus is restricted to eyecare professionals with training in the ophthalmology field (or equivalent) who retain the responsibility of the diagnosis.

1.3 Indications for Use (US FDA)

DRSplus is a confocal scanning ophthalmoscope indicated for color and infrared retinal imaging with or without the use of a mydriatic agent.

1.4 Clinical Benefit

DRSplus does not claim any clinical benefits, i.e. a positive impact on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome, as it does not provide any diagnostic outcome but provides information for the diagnosis.

The performance of the DRSplus – expressed as the ability of the device to achieve its intended purpose – is to capture, display and store various images to aid in diagnosing and monitoring a multitude of retinal diseases.

1.5 Contraindications

No contraindications nor side-effects have been found for fundus photography. There exist rare and discomforts limited in their timespan, as temporary glare, watery eyes, during and/or after the acquisition of the fundus image.

1.6 Ophthalmic Devices Compliance

DRSplus is compliant with ISO 10940:2009 and ISO 15004-1:2020.

1.7 Optical Safety

According to ISO 15004-2:2007 and ANSI Z80.36, DRSplus devices are classified as Group 1 – Ophthalmic instruments for which no potential light hazard exists.

1.8 RoHS Compliance

The product is RoHS-compliant according to Directive 2011/65/EU and Directive 2015/863/EU.

1.9 Electrical Safety

The devices are compliant with IEC 60601-1:2005+AMD1:2012+AMD2:2020. The devices are classified as Class I, type B applied part.

1.10 Reporting Serious Incidents (only for EU)

Report any serious incident related to the device, the operator, the patient, or anyone else to CENTERVUE S.P.A. and to the Competent Authority of the Country/State in which the user and/or patient is established.

1.11 Essential Performance

The clinical performance of the DRSplus is to capture, display and store images to aid in the diagnosis and monitoring of diseases and disorders occurring in the retina. Since there are no surgical or treatment decisions made solely on data obtained by the device, it was determined that DRSplus has no Essential Performance as defined in the IEC 60601-1 standard.

1.12 Use Environment

DRSplus is intended for use in

- professional healthcare facility environment:
 - Ophthalmic & Optometrist Offices
 - Ophthalmology Clinics
 - Hospitals
 - Research laboratories
 - Medical offices
- optical shops

The devices are suitable for use in domestic and home healthcare environments. Consult complete information about electromagnetic environment requirements in section §18 of this document.

1.13 Patient Profile

DRSplus can be used on any adult subject able to remain seated upright, to place the forehead on the forehead rest, alone or with the aid of another person. The decision to use the DRSplus on a vulnerable patient is under the responsibility of the eye care practitioner. The patient is not required to interact with the device, apart from keeping the eyelid open and staring at the fixation target. The patient population is NOT intended to be the end user of the device.

1.14 Intended user

The primary intended users of DRSplus are healthcare care professionals. The device is not intended for lay users.

User profile ROLE	Context of use	Characteristics
Operator user	Operating as per the medical intend purpose: Image acquisition and review Cleaning and disinfection Troubleshooting	Demographic trait: Healthcare professional with training in ophthalmology or equivalent: <ul style="list-style-type: none"> • Opticians • Ophthalmic photographers • Optometrists • Ophthalmologists • Clinical researchers • Medical assistants. Required knowledge, skills and abilities: <ul style="list-style-type: none"> • Experience with using medical imaging systems that have an embedded computer and software user interface • Basic computer knowledge • Qualified and experienced personnel, familiarized with the contents of the instructions for use.
Admin user	Configuration and set up	Demographic trait: System administrator. Required knowledge, skills and abilities: <ul style="list-style-type: none"> • Experience with desktop-based camera • Knowledge of operating systems, IT networks, user administration, and backup management • Qualified and experienced personnel, familiarized with the contents of the instructions for use.

1.15 Principle of operation

The acquisition of the retinal images is achieved by confocal illumination of the eye fundus by means of a scanning line, and simultaneous acquisition of the same portion of the illuminated retina. The device is able to compensate for eye movements by tracking in real-time the position of the pupil and adapting its position and focus accordingly.

1.16 Content of the device packaging

The device is provided with:

Parts
Lens cap (for shipping only)
Cables protection shell
Device Stand
Headrest with silicon cushion
External power supply
Country-specific power cable
USB extension cable
Packing straps

Documents
Unpacking, packing and setup manual
Leaflet and/or Instructions for Use
Climatic Preconditioning
Electrical Test Report
Optionals
External fixation light
Prismatic goggles

2. Introduction

Congratulations for choosing DRSplus and its confocal retinal imaging capabilities.

DRSplus is a fundus imaging device, based on a confocal scanning imaging system, which uses infrared and visible light to obtain confocal images of the retina.

DRSplus works with DRSplus Software, and it operates as a standalone unit.

DRSplus is intended for the acquisition of retinal images with or without¹ a mydriatic agent and their review. The intended End-users are health care professionals with training in the ophthalmology field (or equivalent).



The clinical interpretation of the images acquired by DRSplus is restricted to licensed eye care practitioners. The process of making a diagnosis using DRSplus results is the responsibility of the eye care practitioner.

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

¹ DRSplus works in a non-mydriatic condition for patients with minimum pupil size of 2.5 mm: the decision to use the mydriatic agent on patient's pupil eye is under the responsibility of the eye care practitioner.

3. Labels, Symbols and Definitions

3.1 Labels

Device information such as device model, serial number, manufacturing date and UDI barcode are reported in the label located on the back side of the display, as shown in Fig. 1: please do not remove it.

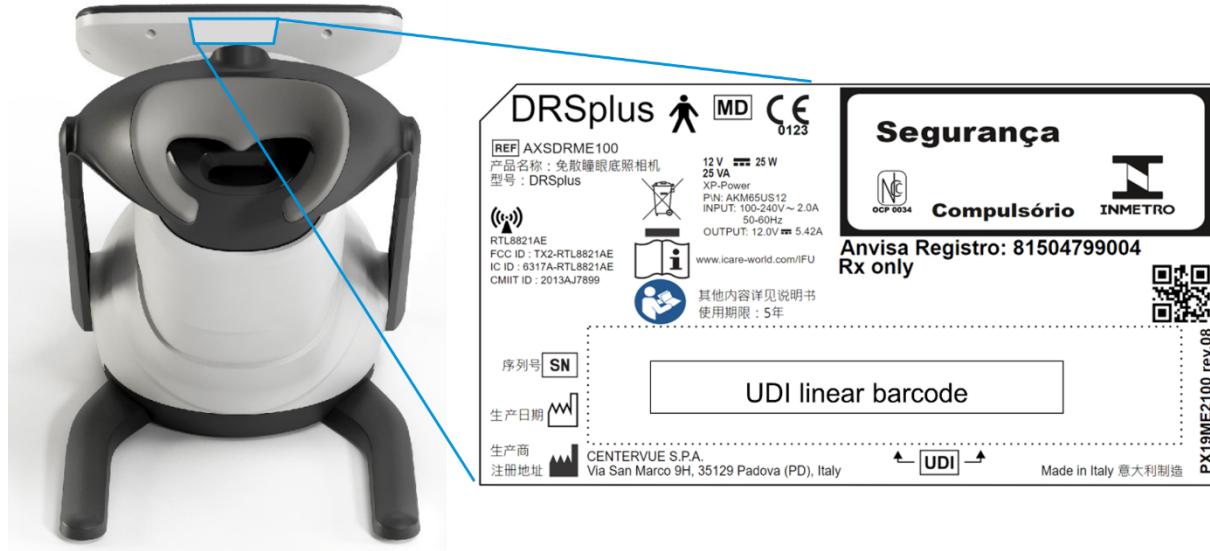


Fig. 1 – Device label²

² Labelling might be subject to changes depending on local regulatory requirements. The label QR Code does not contain information for the End-user and it is intended for internal use only.

3.2 Symbols used on the device

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

Symbol	Explanation
	Information about the Manufacturer.
	Manufacturing date (year-month, yyyy-mm).
	DRSplus identifier (catalogue number – product code).
	Indication of Medical Device.
	DRSplus Serial number.
	UDI number
	Electrical and electronic waste is destined for separate recycling.
	Please refer to the electronic Instructions For Use (eIFU)
	This instruction manual must be read Read this instruction manual before starting work or before operating equipment or machinery
	CE mark: the device complies with the general safety and performance requirements of the Regulation (EU) 2017/745. CE mark is followed by the Notified Body identifier.
	Type B Applied Part.
	Non-ionizing radiation - ME EQUIPMENT that includes RF transmitters.
	Device consumption
XP-Power PIN: AKM65US12 INPUT: 100-240V~ 2.0A 50-60Hz OUTPUT: 12.0V⎓ 5.42A	Power supply
	Direct current.
	Power button. See the device back panel (Fig. 8).

3.3 Other symbols found in the device packaging

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

Symbol	Explanation
	Information about the Manufacturer.
	Fragile. Handle with care.
	Kilogram stacking limit because of the nature of the device package.
	The Acceptable upper relative humidity for storage and transport.
	The maximum and minimum temperature limits for storage and transport.
	Correct the upright position of the transport package.
	Device package shall be kept away from rain and be kept in dry conditions.
	Stacking limit by number. Items shall not be vertically stacked beyond the specified number. The bottom package is not included in the stack.

3.4 Other symbols found in this manual

The meaning of the additional symbols adopted in the Instructions for Use is as follows:

Symbol	Explanation
	Important Information.
	General Warning, read carefully.

3.5 Definitions

Word	Explanation
Device	The synonym of DRSplus used in this User Manual.
Exam	Any image retinal acquisition session performed using the DRSplus for a certain patient on a certain date.
External eye examination	The examination mode involving the acquisition of images of the ocular surface instead of the retina.
Field	A 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	A 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.
Local interface	The application on the DRSplus device.
Picture	The synonym of the image acquired by DRSplus.
Pupil	The aperture 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.
Remote viewer	The web application running on an external PC.
Retina	The inner layer of the eyeball. It is the main area of interest in the images acquired by DRSplus.
Stereo exam	The 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.

4. Device description

DRSplus consists of:

- The device (with a lens cap for shipping only) (Fig. 2);
- Cables protection shell (Fig. 3);
- Device stand (Fig. 4);
- Headrest with silicone cushion (Fig. 5);
- External power supply (Fig. 6) which includes a country-specific power cable.



Fig. 2 – DRSplus device



Fig. 3 – Cables protection shell



Fig. 4 – Device stand



Fig. 5 – Headrest



Fig. 6 – External power supply



Fig. 7 – DRSplus

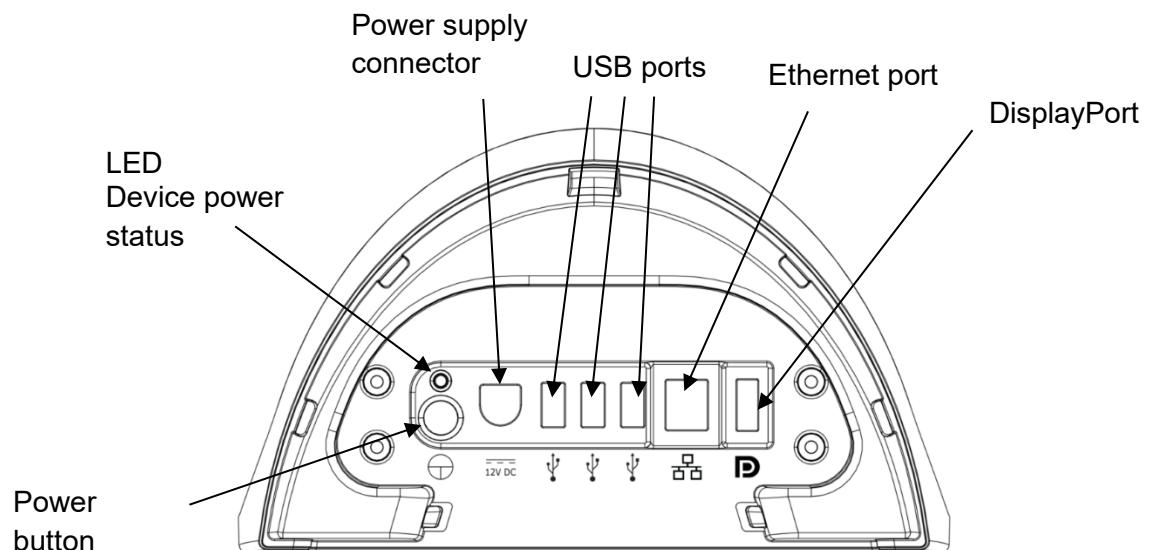


Fig. 8 – Back Panel

DRSplus can be optionally equipped³ with:

- External fixation target (Fig. 9);
- Prismatic goggles for stereo view (Fig. 10); see §8.6 to have more details on the stereo view functionality.



Fig. 9 – External fixation target



Fig. 10 – Prismatic stereoscopic goggles

³ For a list of all components included with DRSplus, refer to 1.16

5. Safety and security information

5.1 Safety information

Although great care and diligence have been taken during the design and development of this device to reduce as far as possible all risks related to the use of the devices, it is important to read and understand the following precautions to further mitigate all residual risks.

The following precautions and warnings are important to use the devices safely:

- The device is for professional use only
- The device needs to be installed and put into service by the Authorized Service Center
- Do not use DRSplus if the covers or other parts of the device have been removed.
- Avoid all contact with water: risk of fire or electric shock.
- Stand clear from moving parts during operation
- Do not open DRSplus: this could lead to electric shocks or damage to the device.
- No serviceable parts inside. Internal inspection is allowed to authorized personnel only.
- Do not use the device when there are visible signs of materials degradation.
- DRSplus is supplied with an earth ground using a protection conductor contained inside the power supply cable. Before turning on the device, make sure the power supply socket is correctly grounded to avoid the risk of electric shock
- DRSplus power supply must be connected to a socket with a circuit breaker.
- The use of other cables and accessories on DRSplus than ones provided by CENTERVUE S.P.A. may negatively affect EMC performances
- The power cord shall be properly maintained during use. In case of damage, contact CENTERVUE S.P.A. for the replacement.
- It is recommended to power off the device according to instructions of section §15; removing the power cable could result in data loss.
- External device/s connected to DRSplus, into the patient environment, must comply with IEC 60601-1. That/those device/s that does/do not comply with the IEC 60601-1 must be kept out of the patient environment and must comply with IEC 60950-1. Any end-user who connects external devices to DRSplus creates a new Medical Electrical System as defined by IEC 60601-1 and is therefore responsible for 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.
- DRSplus must be used in a room with an electrical system that complies with applicable healthcare environment safety regulations.
- DRSplus must NOT be used in an oxygen-rich environment or presence of flammable anaesthetics.
- DRSplus must be used and must be placed in a room that is not exposed to adverse chemical-physical conditions, such as the presence of sulphur, 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.
- DRSplus needs to be operated in a semi-dark environment, to ease the natural dilation of the patient's pupil.
- DRSplus needs to be operated in the following environmental conditions:
 - Temperature: +10 °C to +35 °C (50 °F to 95 °F)
 - Humidity (max): 90% non-condensing
- DRSplus needs to be stored in the following environmental conditions:
 - Temperature: -10 °C to +55 °C (14 °F to 131 °F)
 - Humidity (max): 95% non-condensing
- Only technicians authorized by CENTERVUE S.P.A. may service DRSplus. CENTERVUE S.P.A. cannot be held responsible for the device's safety should DRSplus be opened,



repairs carried out (including using of not CENTERVUE S.P.A.'s genuine parts), third-party software installed, or parts replaced by an unauthorized person.

- Risks can arise in relation to the biological contamination caused by the environment the device is operated into, and by the user and the patients. Follow the cleaning and disinfection instructions provided below in this document.
- The device is not supplied sterile, nor is intended to be sterilized before or after use; nevertheless, the risks connected to the biocompatibility of the parts that come into contact with the patient are in relation to severe consequences, including allergic reactions. Contact materials used in DRSplus are biocompatible and safe for contact with intact skin for limited exposure.

The following precautions are important to use the device correctly:

- The clinical interpretation of the images acquired by DRSplus is restricted to licensed eye care practitioners. The process of making a diagnosis using DRSplus results is the responsibility of the eye care practitioner.
- Device-specific training is not required: it is recommended for the end-user (operator) to carefully read these Instructions for Use to be informed and trained before use.
- Use the device in dim light, or at least away from direct light to facilitate the natural dilation of the pupil.
- Provide explanations to patients before placing them in front of the device: refer to §6.4.
- The minimum pupil diameter required to obtain good-quality images is 2.5 mm.
- DRSplus works in a non-mydriatic condition for patients with a minimum pupil size of 2.5 mm: the decision to use the mydriatic agent on a patient's pupil eye is under the responsibility of the eye care practitioner.
- Report any serious incident to CENTERVUE S.P.A. and to the competent authority of the Member State in which the user and/or patient is established.

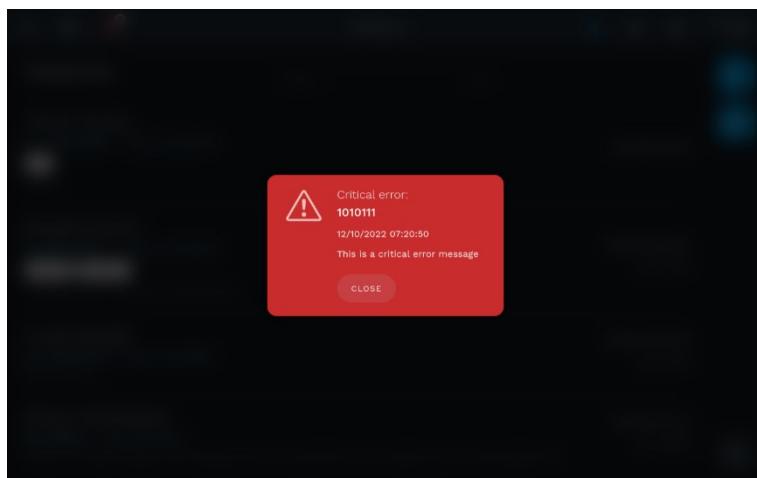


Fig. 11 – Error popup

5.2 Security Information

The following precautions for the End-users and the Responsible Organization are important to control the risks related to network interfaces, data protection and cybersecurity.

- When in operation DRSplus contains Personal Data. Transfer data using secure infrastructures to avoid compromising patient privacy.
- It is the end user's responsibility to keep and maintain an updated copy of the data generated by DRSplus through regular use of the backup facility, thus preventing the risk of accidental loss of data.
- To protect your devices against unauthorized access and manipulation, make sure that only authorized personnel have physical access to the device.
- The device offers a Wired Network Connection (via Ethernet cable) and a Wireless Connection. It is the responsibility of the IT department of your organization to maintain proper security practices.
- When setting your credentials in the device, it is strongly recommended to use complex passwords; refer to your infrastructure's policies to create an effective password. If your infrastructure does not enforce any password policy, we recommend for example:
 - use a password at least 8 characters long;
 - avoid using any of your personal information, like your real name, username or your company name;
 - select a password different from your previously used passwords;
 - avoid using any word spelled completely;
 - use a password containing different types of characters, including uppercase letters, lowercase letters, numbers and characters;
 - don't write down your password on notes;
 - don't share your password with other people;
 - change your password from time to time.
- The Remote Viewer browser runs on your PC/Laptop and allows you to locally download exam reports and patient images; reports and images stored in the Remote Shared Folder can be available also on your PC/Laptop. Refer to your infrastructure's policies to protect your equipment with complex passwords, updated browsers and other security policies, as an example:
 - apply physical security measures (locks, security alarms, monitoring, etc.) to prevent unauthorized persons from accessing your computer that stores patients' personal data files;
 - use full disk encryption (for example Bitlocker) with a strong password to render data unreadable even if an unauthorized person were to gain access to your computer;
 - use firewall and antivirus software to prevent intrusion and to detect infected files that might compromise the security of your computer, and thereby enable unauthorized file access;
 - install security patches and updates in a timely manner;
 - protect access to your Windows account with a strong password (see indications above);
 - log off or power off when leaving your computer unattended.
- When sending DICOM files to a configured PACS or receiving data from a Worklist server, please remember that the DICOM protocol does not encrypt patients' personal data: It is the responsibility of the IT department of your organization to maintain proper security practices for the IT infrastructure.
- Precautions for the security of your devices must be maintained at the State of the Art.

6. First usage

This section explains how to set up DRSplus for use.

6.1 Preparation of the device



Carefully read 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 on a suitable table;
- Install the device on the device stand and firmly secure it with the screw;
- Install the headrest (included in the package) on the device (see Fig. 12);
- Connect the power supply to the back panel, and the wall socket;
- (Optional) Connect a printer to one of the USB ports located in the back panel of the device;
- Install the cable's protective shell.



Fig. 12 – Headrest

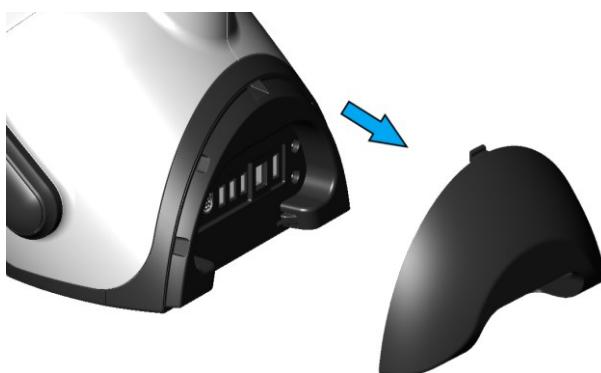


Fig. 13 – Back panel with the cables protection shell

6.2 Configuration wizard

Turn on the device by pressing the **power switch** button: upon the first power-on of the device, the *Configuration Wizard* will appear (Fig. 14).

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 can be resumed anytime afterwards.

To proceed with the *Configuration Wizard*,

1. Press the **START** button. In any of the wizard steps, it is possible to browse back to the previous step by pressing the **PREVIOUS** button.

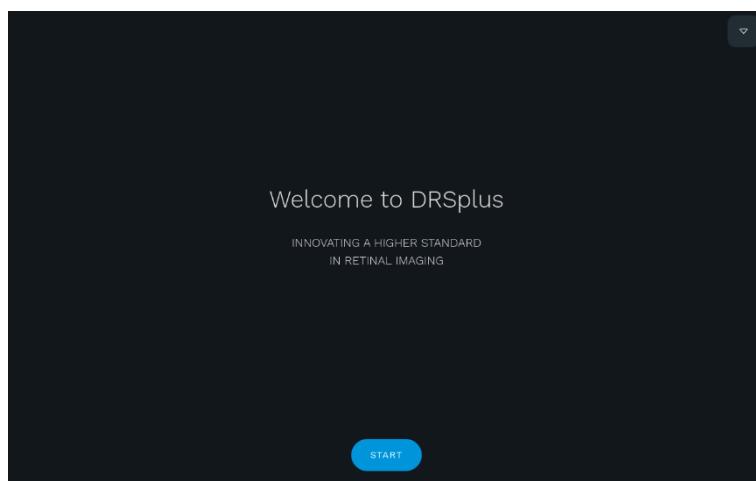


Fig. 14 – Beginning of the Configuration Wizard

2. Select the country in which you use the device.

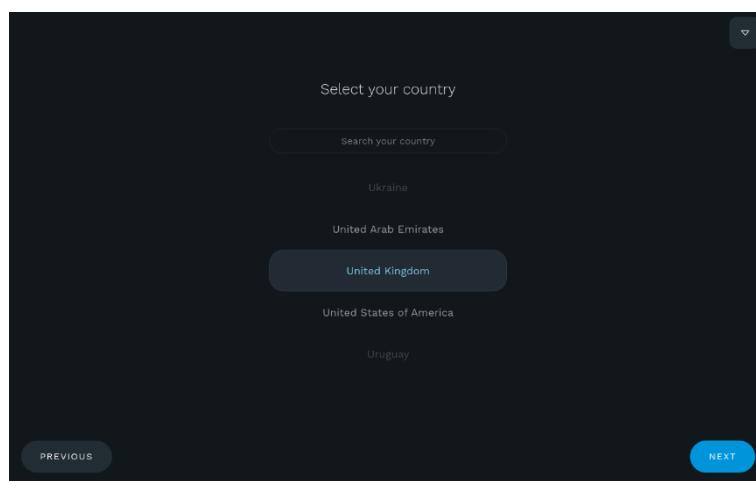


Fig. 15 - Country selection

3. Read and approve the End-user License Agreement (EULA) (Fig. 16). The EULA language changes according to the selected Country. Different types of EULA are defined for EU and EFTA, USA or Other Countries.

You must approve the EULA to continue the configuration and use the DRSpplus.



Fig. 16 End-user License Agreement

- Set the language. A language is suggested according to the selected country (Fig. 17).

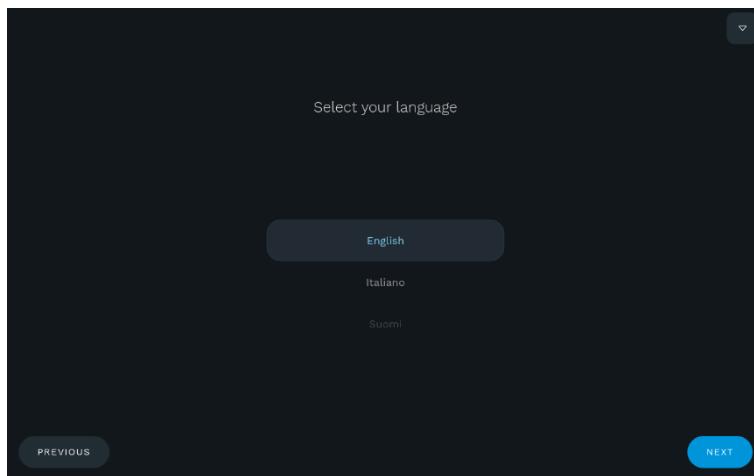


Fig. 17 - Language selection

- Set the current time zone (Fig. 18). An initial time zone is suggested according to the selected country.

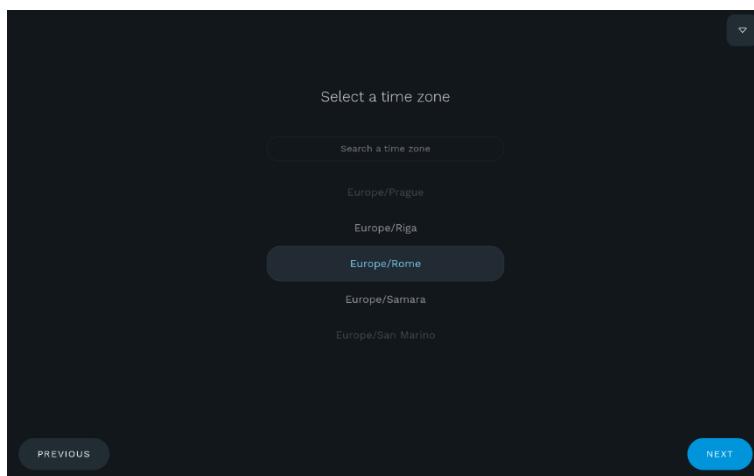


Fig. 18 – Time zone

- Set the current date and time and configure their format (Fig. 19).

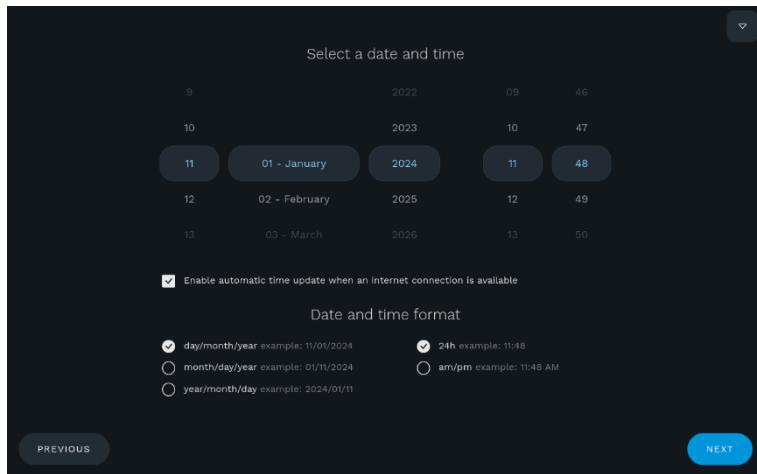


Fig. 19 –Date and time selection

7. Create the local **Administrator** account by selecting username and password (Fig. 20). The username must contain at least 4 characters⁴. The password must contain at least 6 characters. You can select the interface Language for such a user.

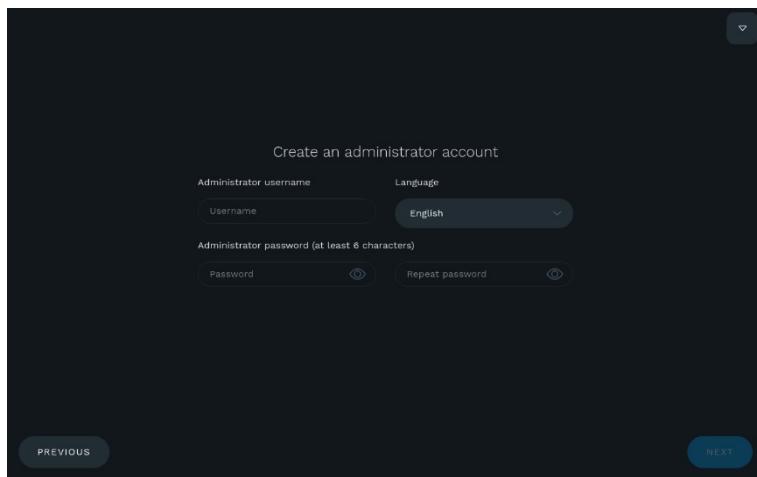


Fig. 20 – Administrator account creation

8. Optionally create an **Operator** account (Fig. 21) by following the same rules and constraints described for the Administration account. Tick the box *Use the administrator account also as the device operator* to use a unique account. To create different accounts, refer to §13.2.

⁴ Moreover, “service” and “production” cannot be used as usernames.

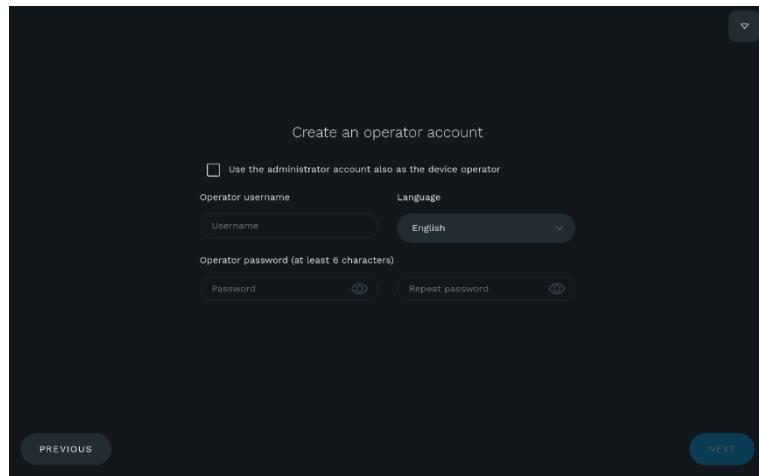


Fig. 21 – Creation of user accounts

9. Select the Online services configuration (Fig. 22). Select among the options. It is strongly recommended to enable the *Periodically check for online software updates* option to receive the security updates.

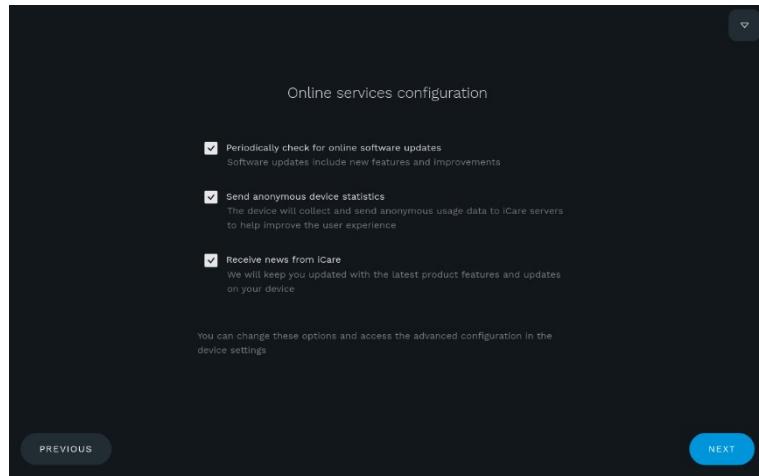


Fig. 22 - Online services configuration

10. Save the configuration (Fig. 23).

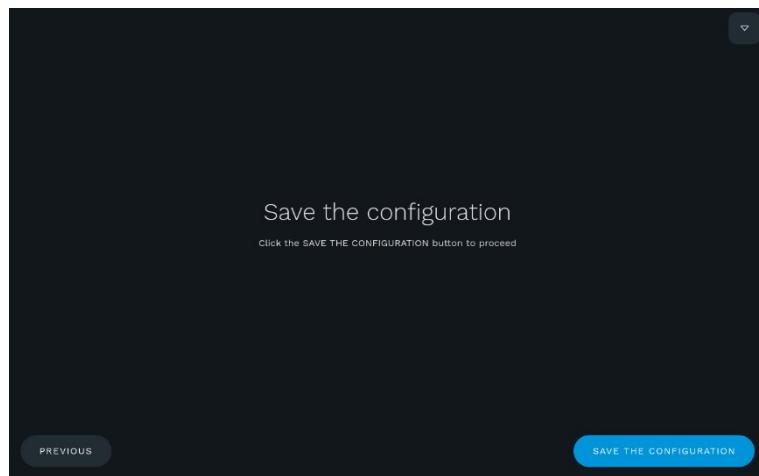


Fig. 23 - Save configuration

11. Wait for the device configuration (Fig. 24).

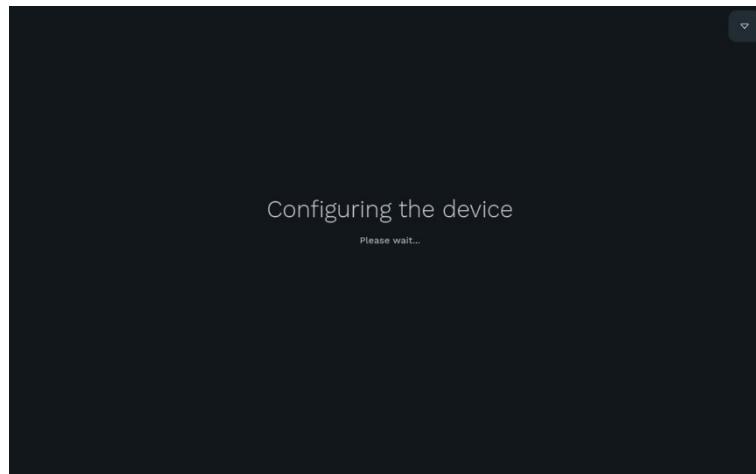


Fig. 24 - Device configuration

12. See an overview of the basic functions of the device and the improvement introduced by the actual software version (Fig. 25). Click **NEXT** to go through the different pages, click **SKIP** to proceed with the configuration.

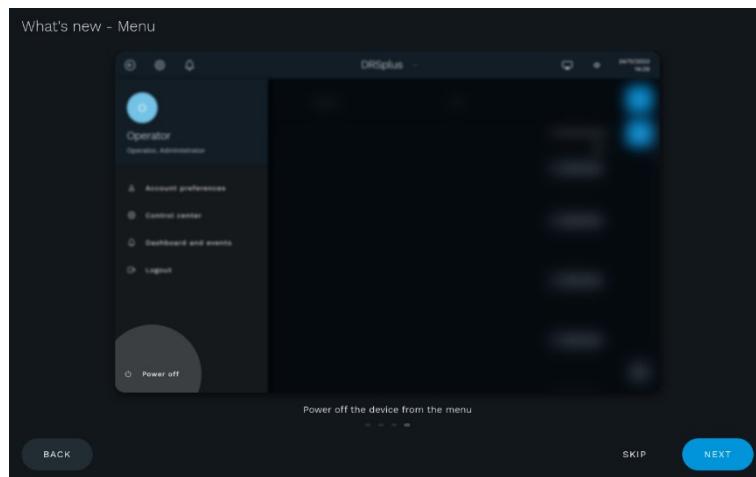


Fig. 25 - What's new

13. Start using the device (Fig. 26)

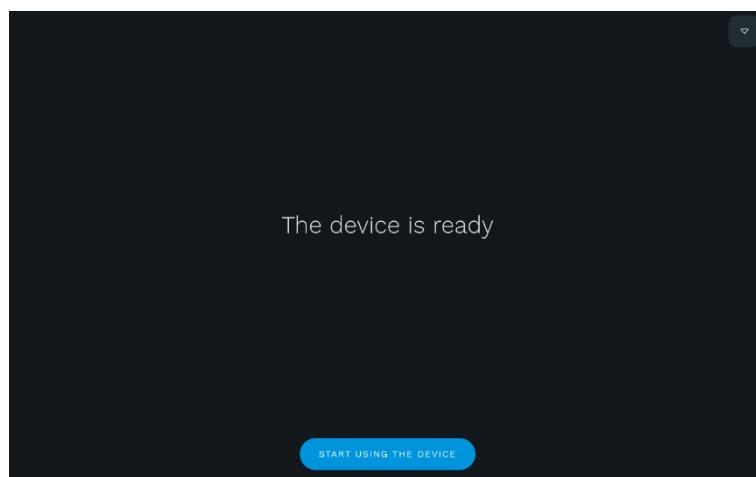


Fig. 26 - End of the Configuration Wizard

6.3 Login Screen

Turn on the device by pressing the power switch button (Fig. 8). When the boot is completed, the *Login* Screen will appear (Fig. 27).

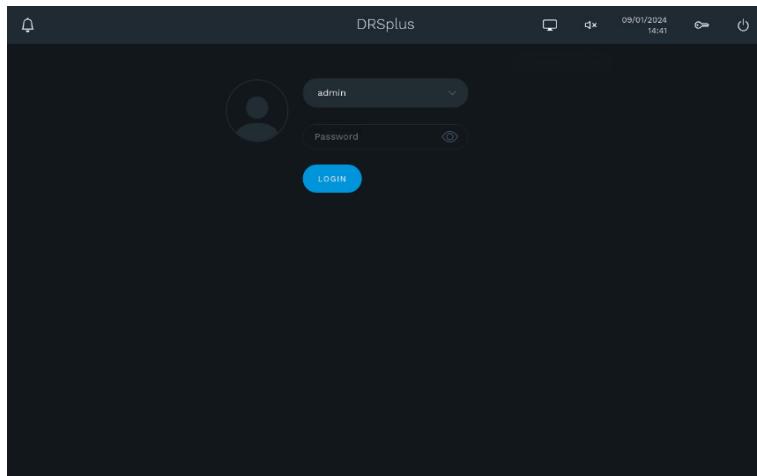


Fig. 27 – Login screen.

Select the desired user from the dropdown menu, input the user password and press **LOGIN**. DRSplus can now be operated.



To modify the password, see §13.1.

Push the **Dashboard** button to access the basic information of the device and consult the Instructions for Use (see §12.2).



The **Service** button is used for service activities only.



6.4 Preparation of the patient

This paragraph is dedicated to patient preparation before taking retinal images with DRSplus.

There are no specific restrictions based on the type of patients that can be examined with DRSplus. The acquisition of retinal images⁵ with DRSplus does not involve any risk, because DRSplus will never touch the patient's eye and the only effect perceived by the patient is a flashlight when the device acquires a retinal image.

If the patient does not fixate correctly and steadily on the green light during the exam, the images acquired may relate to portions of the retina that are not as expected.

⁵ DRSplus works in a non-mydriatic condition for patients with minimum pupil size of 2.5 mm: the decision to use the mydriatic agent on patient's pupil eye of under the responsibility of the eye care practitioner.



Provide the patient with the following instructions and explanations about the device's operation before placing the patient on the device:

1. Please find a comfortable position, keeping the forehead well placed on the device headrest;
2. Once you have found a good position, please do not move and do not talk;
3. Open your eyes wide;
4. Please keep looking forward while the device moves. The movement is necessary for the device to find your eye;
5. When a small light appears, please look at such light and avoid blinking.

6.5 Acquisition of retinal images

After the login, the *Patient List* Screen will appear as in Fig. 28.

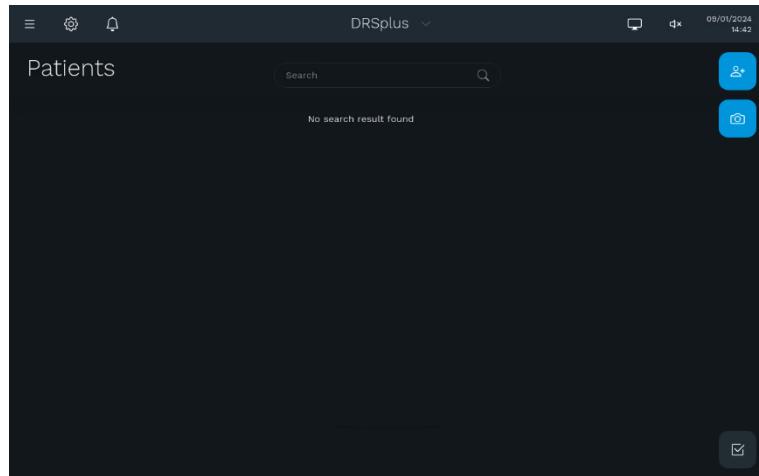


Fig. 28 - Patient List screen

Push the **new patient** button to open the *New patient* Screen (see Fig. 29).



Push the **Fast exam** button to access the *Exam Configuration* Screen (see Fig. 30).

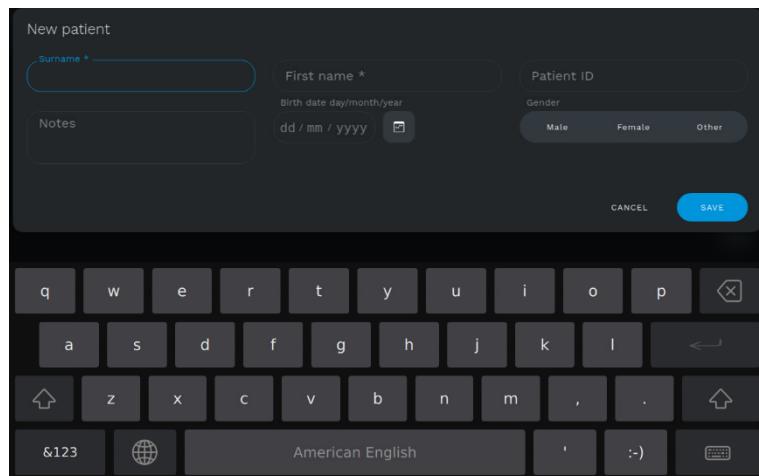


Fig. 29 - New Patient screen

Fill in the mandatory and optional fields and **SAVE** the new patient.

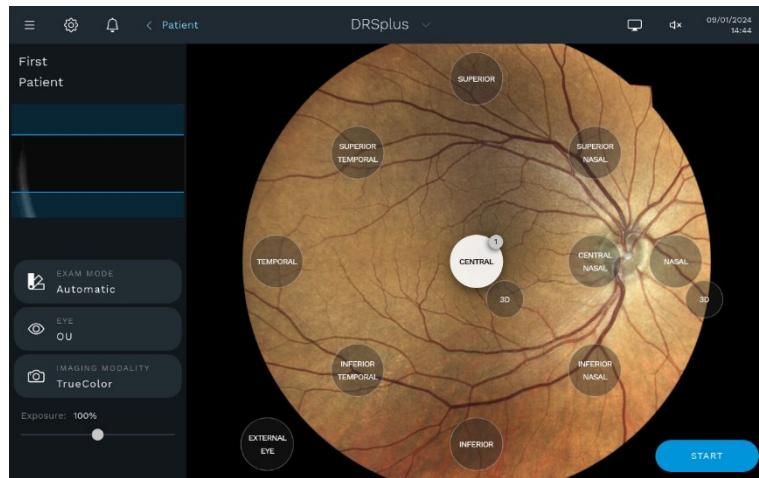


Fig. 30 - Exam Configuration screen

Push **START** to acquire the retinal images according to the default options shown on the screen.

Alternatively, configure any of the following parameters

- the **fields** you want to acquire by pushing the related locations on the reference image;
- the **exam mode** (automatic, manual);
- the **eye** (left, right, both);
- the **imaging modality** (TrueColor, IR, both).

Use the live view on the top-left corner to visualize the position of the patient's pupil. To ensure the correctness of the image acquisitions, make sure that the pupil falls inside the two blue lines before starting the exam.



Select **automatic** to make the device automatically align on the eye and perform the exam. Select **manual** to manually control the alignment, the focusing and the acquisition of the images.

Push **START** to conduct the examination.

The device emits a brief sequence of sounds immediately before acquiring an image, and a confirmation sound after its successful acquisition.

During the exam acquisition, press **STOP EXAM** if you need to interrupt the acquisition. All the already acquired images will be saved.

For more information about the exam configuration and execution, refer to §8.

6.6 Review of the acquired exam

After the acquisition, the *Patient details* Screen appears (see Fig. 31).



Fig. 31 - Patient details screen

From this screen, you can immediately review the exam with all the acquired retinal images.

Function	Command
New exam (§9.3.2)	
New mosaic (§9.4)	
Export patient (§10)	
Flicker (§9.3.2)	
Compare (§9.3.1)	
Select (§7.2)	
Retake	

Table 1 - Available functions of the Patient details

You can acquire a **New exam**, create a **New mosaic**, **Compare** or **Flicker** two images, **Export** the patient or **Select** items.

To retake an image, click the **retake** button in the bottom right corner. The image will be acquired with the same conditions as the previous one. Press **Patients** to access the *Patient List*.

7. Patient database

Upon login, the *Patient List* Screen appears, as shown in (Fig. 32). You will find the patients sorted from the last updated data. This is the entry point for each activity of the DRSplus: you can insert, review, export, merge, and delete patients from this Screen.

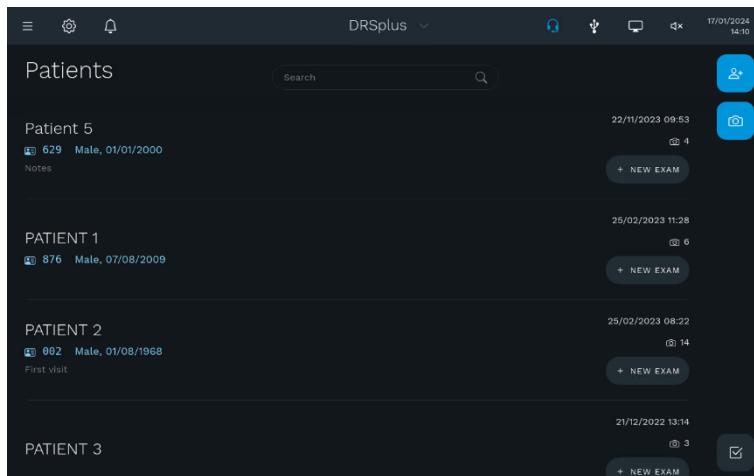


Fig. 32 – Patient List Screen

On the left side of the screen, you will find the patients' information:

- Surname and Name;
- Patient ID;
- Gender and Date of Birth;
- Notes.

On the right side, you will find the following exam information:

- Date of the last examination made with DRSplus;
- The number of acquired retinal images.

Use one finger to scroll the list back and forth.

Press **New exam** to directly start the acquisition for the relative patient (see §8.1.4)

Press on a patient's box to access the *Patient details* Screen and review the exams (see §7.6).

Use the **search** box above the patient list to retrieve a given patient or group of patients whose data contains the text you input. (see Fig. 33). This functionality is especially useful when you need to select and export a specific group of patients.

+ NEW EXAM

PATIENT 2
Male, 01/08/1968
First visit

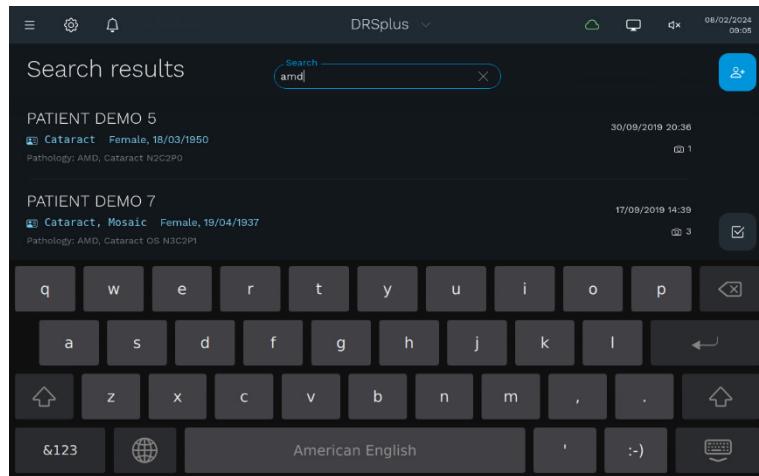


Fig. 33 - Search functionality



In the settings, activate **Privacy Mode** (see §7.6 for details) to hide patients' Surname and Name. They will be replaced by their first letters followed by asterisks.

On the right side of the screen, the following buttons appear:

Function	Command
New patient (§7.1)	
Fast exam (§8.1.3)	
Select (§7.2)	
New exam (§8.1.4)	

Table 2 - Available functions of the Patient List

7.1 Insert a New Patient

Push **New patient** to insert data of a new patient in the *New patient Screen* (see Fig. 34). Enter the Mandatory fields, that are marked by (*).⁶ You can either fill in or leave blank the additional fields.

⁶ For more information about the mandatory fields, refer to §13.6.

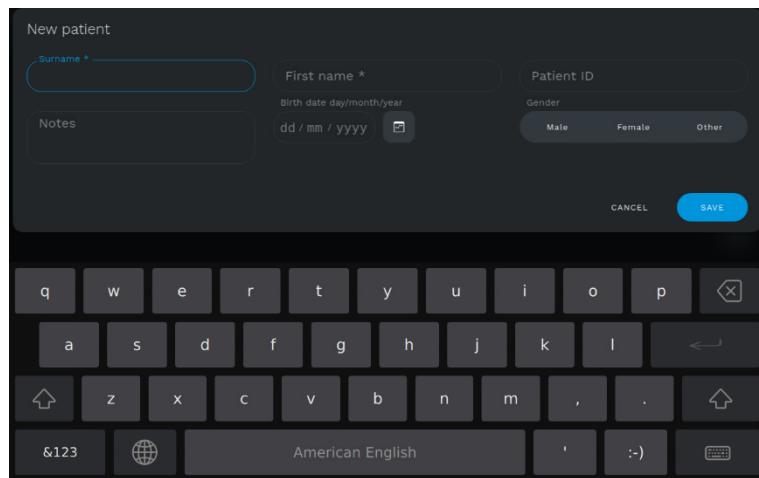


Fig. 34 - New patient Screen

Type on the keyboard to fill in *Surname*, *First name*, *Patient ID* and *Notes*. Use the numeric pad or push the **calendar** icon to insert the *Birth date*. Push **MALE**, **FEMALE**, **OTHER** to select the *Gender*. Press **SAVE** to save the new patient or **CANCEL** to cancel the operation.



To browse back to the *Patient List*, press the **Patients** icon located on the top left side of the screen

Patients

Whenever patient data are similar to those of an existing patient, the *Duplicate record* pop-up (Fig. 35) appears to warn about a possible duplication. Press **OPEN THIS RECORD** to use the existing patient, **SAVE ANYWAY** to create a new patient or **CANCEL** to cancel the operation.

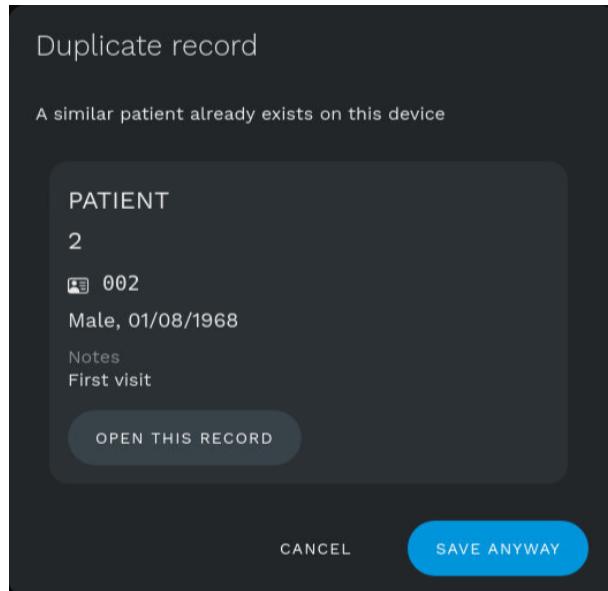


Fig. 35 – Duplicate record pop-up

7.2 Select patients

Press **Select**, or keep pressing the patient's info, to activate the *Select* functionality.

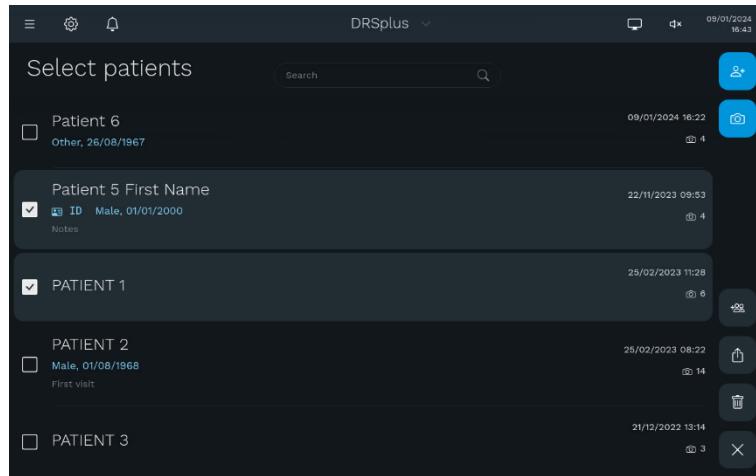


Fig. 36 - Select functionality

A box appears at the left of each patient's thumbnail (see Fig. 36). After ticking at least one box, you can **Merge**, **Export** or **Delete** the selected patients. Click **Cancel** to close the selection.

Function	Command
Merge (§7.6) Select two patients to enable the Merge button.	
Export (§7.4)	
Delete (§7.3)	
Cancel	

Table 3 - Available options of the Select screen

7.3 Delete patients

Select the patients to delete and click the **Delete** button on the right panel.

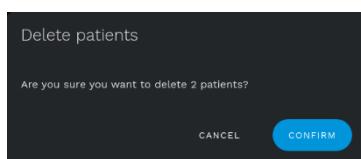
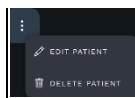


Fig. 37 – Deletion Confirmation Pop-up

Alternatively, open the *Patient details* screen (see §9), press the **ellipsis** and then the **Delete** button.



Press **CONFIRM** to delete the patient or **CANCEL** to return to the *Patient List Screen*, where your selection remains active.

7.4 Export patients

Select the patients to export and click the **Export** button on the right panel.



The *Export Screen* will appear (see Fig. 38).

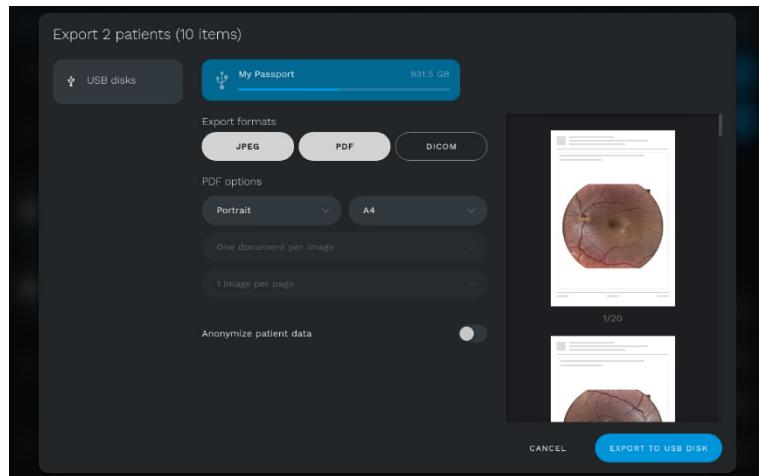


Fig. 38 - Export screen

Connect a USB drive or configure an Export destination.

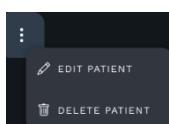
Select the export destination among the possible options.

Configure the export options and click **EXPORT TO USB DISK** to begin the export, or **CANCEL** to skip and revert to the previous screen.

Refer to §10 for more information about the export functionality.

7.5 Editing an existing patient

To modify the information of an existing patient, open the *Patient details* Screen (see §9), press the **ellipsis** at the right of the patient's name and then the **EDIT PATIENT** button.



This will open the *Edit Patient Panel* (Fig. 39).



Fig. 39 – Edit Patient Panel

If the edited patient data are similar to those of already existing patients, the *Duplicate Patient Panel* will warn you about a possible duplication (see Fig. 40).

Press **MERGE WITH THIS RECORD** to merge the edited patient with an existing one.
 Press **OPEN THIS RECORD** to exit the *Duplicate Patient Panel* box and open the related *Patient details* Screen.
 Press **SAVE ANYWAY** to create a new patient or **CANCEL** to cancel the operation.

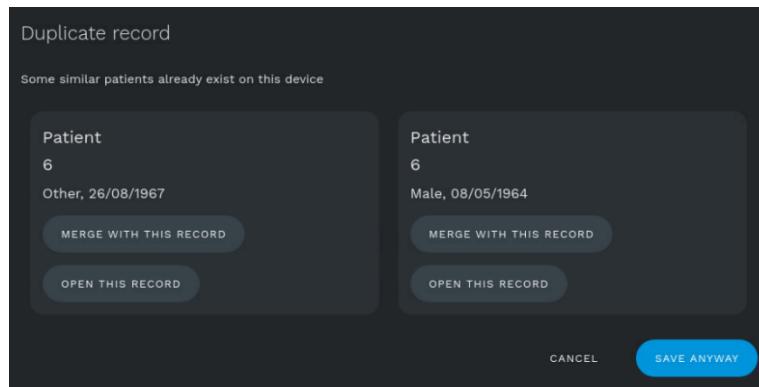


Fig. 40 – Duplicate Patient Panel

7.6 Patient Merge

To merge two patients, from the *Select* screen (Fig. 36) select two patients and click the **Merge** button on the right panel. The *Merge patients* Panel appears (Fig. 41).

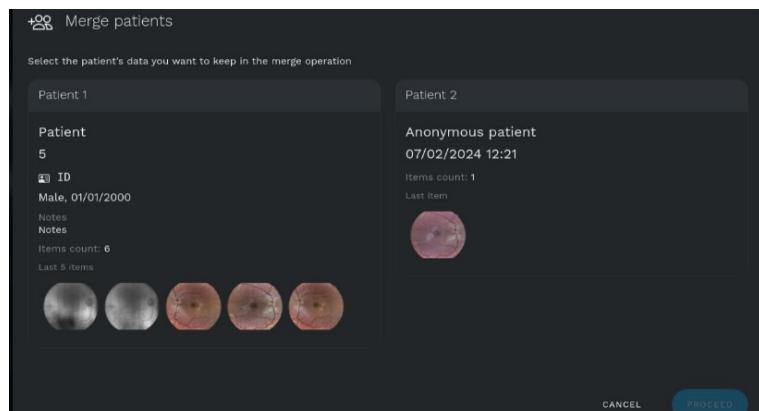


Fig. 41 – Merge patients Panel

Select which patient you want to keep by clicking the patient's box. The highlighted patient receives the data of the non-highlighted one (see Fig. 42).

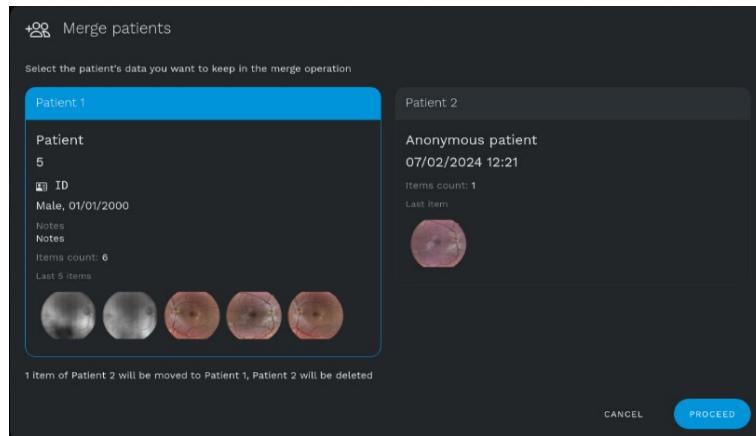
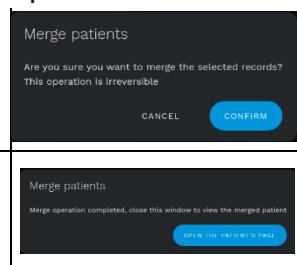


Fig. 42 – Merge patients Panel, selected patient

Click **CANCEL** to abort the operation, or click **PROCEED** to merge the patients.

To complete the merge, which is an irreversible operation, click **CONFIRM** on the *Merge patients* pop-up.

At the end of the operation, a pop-up warns you that the operation is completed. Click **OPEN THE PATIENT'S PAGE** to view the *Patient details* Screen of the merged patient.



7.7 Privacy mode

Activate the Privacy Mode in the *Settings|Patient data* Screen (see §13.6) to hide the Surname and Name of the patients. They will be replaced by their first letters followed by asterisks (see Fig. 43).

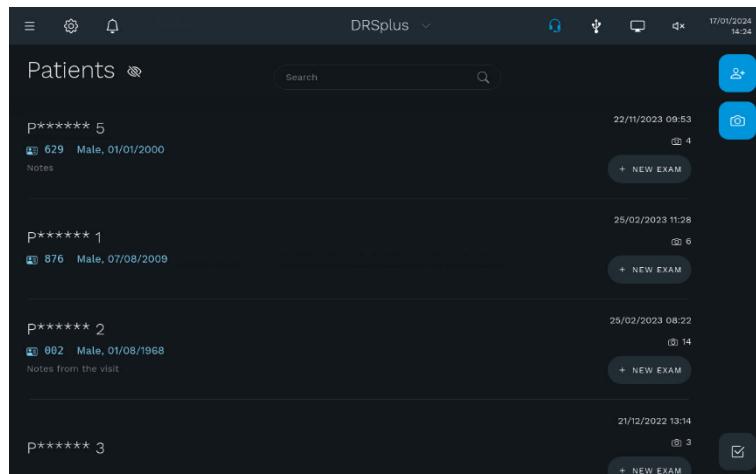


Fig. 43 - Patients database in privacy mode

Press the **privacy mode ON/OFF** button to hide/unhide the patients' information.



8. Acquisition of retinal images

This section explains how to acquire high-quality retinal images using DRSplus.

8.1 Start of the acquisition

To start the acquisition process, open the *Patient List* Screen and then you can:

- select an existing patient (§8.1.1);
- insert a new patient (§8.1.2);
- start a Fast Exam (§8.1.3);
- start an exam for an existing patient (§8.1.4).

8.1.1 Select an existing patient

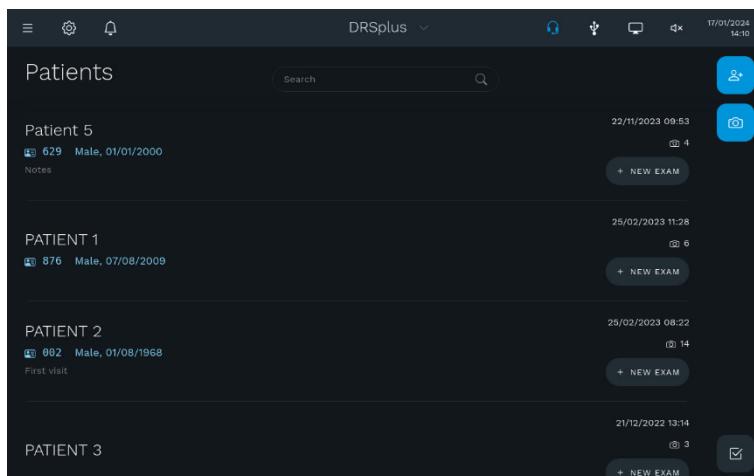


Fig. 44 – Patient List Screen

Scroll the *Patient List* screen, or enter the initial characters of the patient's name, surname or code in the search box to retrieve an existing patient.

Press on the patient's data to open the *Patient details* Screen.

Push the **New exam** button to access the *Exam Configuration* Screen.

8.1.2 Insert a new patient

Press the **New patient** button to create a new patient record (see §7.1). Fill in the data and **SAVE**.



Push the **New exam** button to access the *Exam Configuration Screen* and configure the exam (see §8.2).

+ NEW EXAM

8.1.3 Fast exam

Push the **Fast exam** button in the *Patient List* Screen to directly start an examination and postpone the insertion of the patient data.



The application automatically creates a patient, whose *Surname* temporarily is “Patient” and *First name* is the visit date and time.

After the acquisition of the images, the *Patient Detail* Screen will be shown, where you can edit any of the patient information and fill in all the mandatory fields.

8.1.4 New exam for patient

Push the **New exam** button in the *Patient List* Screen to directly start an examination for the selected patient.

+ NEW EXAM

8.2 Configuration of Exam Parameters

Enter the *Exam Configuration Screen* (see Fig. 45)

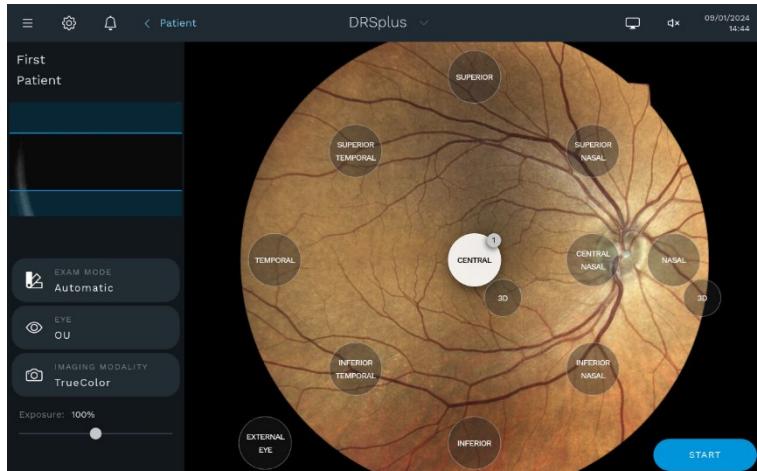


Fig. 45 – Exam configuration screen

Push the **START** button to acquire the exam according to the default configuration. Refer to §13.5.2 for more information regarding the default configuration.

You can modify the default exam parameters to change the acquisition.

8.2.1 Exam mode

Find the default **Exam mode** option in the **Exam mode** box. To change it, push the **Exam mode** button.



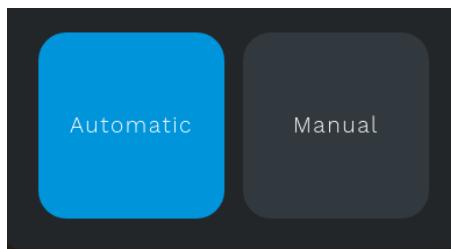


Fig. 46 – Exam mode selection

Select the **Automatic** mode to make DRSplus automatically perform the examination according to the exam settings (§8.3).

Select the **Manual** mode to directly control the movement of the device in front of the eye, adjust the focus and select the fields and the imaging modality (§8.4).

8.2.2 Eye selection

The **Eye** box shows the default option. To change it, press the **Eye** button.

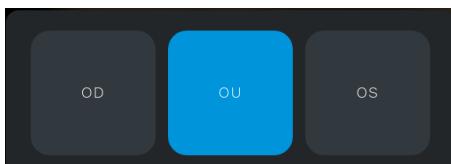


Fig. 47 – Eye selection

Select **OD** for the right eye, **OU** for both eyes or **OS** for the left eye.

8.2.3 Imaging modality

The **Imaging modality** box shows the default option. Push **imaging modality** to override the default.

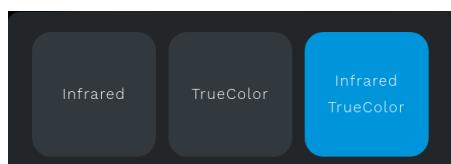
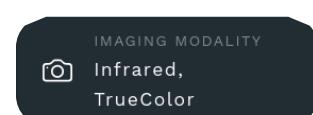


Fig. 48 – Imaging modality selection

Select **Infrared** to acquire only an Infrared retinal image, **TrueColor** for a color retinal image, **Infrared TrueColor** for both.

In the *Settings|Exam* Screen (§13.5), a default **imaging modality** can be set and will be used for each exam. Select a different modality in the *Exam Configuration* Screen to override the default modality previously defined.



The IR functionality is **not available** for devices with a **serial number** starting with **K**.

8.2.4 Exposure

The control of the **Exposure** is available for the **TrueColor** images.

Find the default **Exposure** percentage value in the **Exposure** box. The default value is 100%. Use the **Exposure** slider to decrease or increase the exposure level to get a darker or brighter image, respectively.

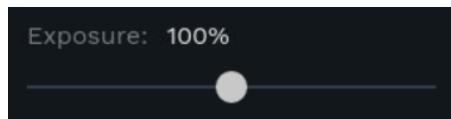


Fig. 49 – Exposure slider

When you change the exposure value, the image information shows (see the red box in Fig. 50) the value of exposure you have selected in the exam.



Fig. 50 – Image information

In the *Settings|Exam* Screen (§13.5), 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 the Settings screen. This value doesn't influence external eye acquisition.

8.2.5 Retinal fields

Find the default acquisition fields marked by a white-filled circle in the retina map (see as an example Fig. 51). In the example, **CENTRAL** and **CENTRAL NASAL** are selected, and **3D** and **INFERIOR NASAL** are deselected.



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

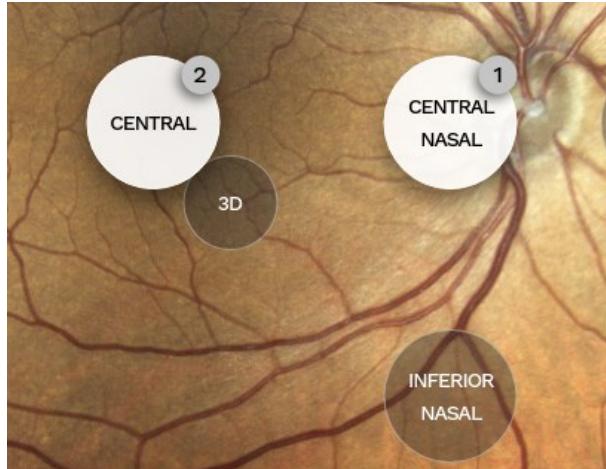


Fig. 51 – Example of the field configuration

Select the fields you want to acquire (see Fig. 45):

- **CENTRAL**: centered on the foveal pit;
- **3D**: a couple of retinal images for stereo review (see §8.6);
- **NASAL**: centered about 19° nasally to the foveal pit;
- **TEMPORAL**: centered about 19° temporally to the foveal pit;
- **CENTRAL-NASAL**: centered about 7° nasally to the foveal pit;
- **SUPERIOR**: centered about 19° superiorly to the foveal pit;
- **INFERIOR**: centered about 19° inferiorly to the foveal pit;
- **SUPERIOR-TEMPORAL**: centered about 12° superiorly and 7° temporally to the foveal pit;
- **SUPERIOR-NASAL**: centered about 12° superiorly and 7° nasally to the foveal pit;
- **INFERIOR-TEMPORAL**: centered about 12° inferiorly and 7° temporally to the foveal pit;
- **INFERIOR-NASAL**: centered about 12° inferiorly and 7° nasally to the foveal pit;
- **EXTERNAL EYE**: image of the external eye surface (see §8.5).

The device will acquire the fields in the order in which they are selected during the exam configuration.

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



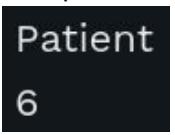
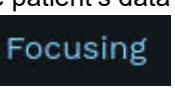
- The configuration of many fields ends in different portions of the retina being acquired. Such fields can be stitched together using the **Mosaic** feature⁷ (See §9.4).
- Use the live view on the top left box to visualize the position of the patient's pupil. To ensure the correctness and speed of the image acquisition, make sure that the pupil falls inside the two blue lines before starting the exam.



8.3 Automatic acquisition of images

After you click **START**, DRSplus automatically:

- Aligns the frontal lens toward the patient's pupil;
- Performs the autofocus of the retina to correct spherical errors;
- Flashes the patient's retina and acquires one or more images according to the number of selected fields;
- Saves the images in the local storage for a later review.

Information	Position on the screen
Patient data	Top left text 
Exam phase (aligning, focusing, waiting, waiting for picture)	Under the patient's data 
Current image acquisition information (OD or OS; TrueColor or Infrared; progressive image number for the exam)	top left corner of the image box 
Position of the eye on the headrest	Graphics 

⁷ Mosaic feature is available under license only: please refer to your local Authorized Distributor for detailed information.

Information	Position on the screen
<p>Estimated pupil size. The yellow box indicates that the pupil size is below the minimum suggested value. When the eye blinks or when the patient is away, a red box indicates that the eye is not found.</p>	<p>Under the graphics of the eye position</p>
<p>Acquisition status of every set field for the current examination (<i>in progress, processing, completed</i>)</p>	<p>Under the estimated pupil size</p>
<p>Live image of the retina, acquired using infrared light</p>	<p>At the center of the screen</p>
<p>Position of the internal fixation target for the patient</p>	<p>Green dot</p>
<p>The retinal field under acquisition, including useful instructions for the patient.</p>	<p>Top right text</p>

Table 4 – Information shown during the acquisition process

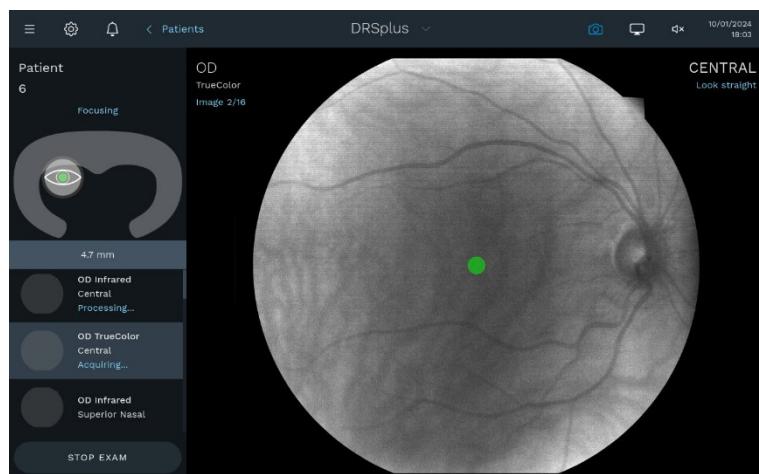


Fig. 52 – Running examination screen in automatic mode



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

8.4 Manual mode

Press the **Manual Mode** button to be able to manually adjust the automatic control of the device.

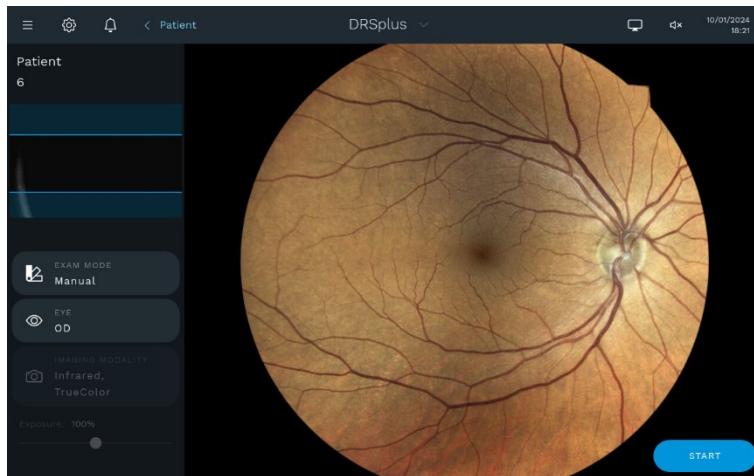


Fig. 53 – Manual mode configuration Screen

The *Manual mode configuration* Screen will appear (see Fig. 53).

Select **OD** to start the acquisition from the right eye, **OS** for the left eye.

Push **START**.

The *Manual mode* Screen appears. (see Fig. 54).

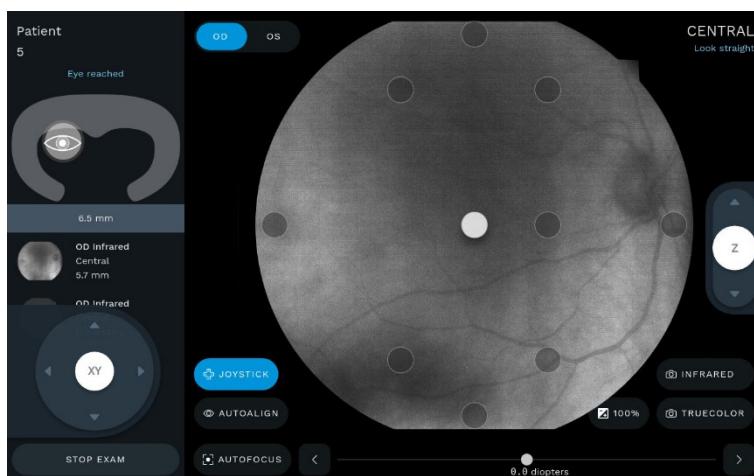
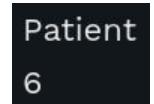
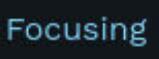
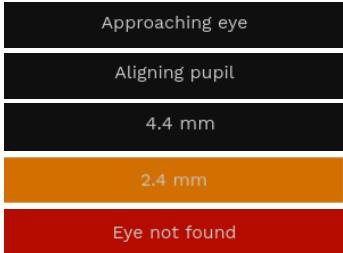


Fig. 54 – Manual mode Screen

You can exploit the device automatism and then manually refine the position of the optical head, the focusing condition, the exposure and the fixation position. You can then acquire as many images as you deserve by pushing the **TrueColor** or the **Infrared** buttons.

Push **STOP EXAM** to save the images and revert to the *Patient details* Screen for reviewing the exam.

A detailed description of the screen and the controls follows in the next table.

Information	Position on the screen
Patient data	Top left text 
Exam phase (aligning, focusing, waiting, waiting for picture)	Under the patient's data 
Position of the eye on the headrest	Graphics: 
Estimated pupil size. The yellow box indicates that the pupil size is below the minimum suggested value. When the eye blinks or when the patient is away, a red box indicates that the eye is not found.	Under the graphics of the eye position 
Acquisition status of every set field for the current examination (<i>in progress, processing, completed</i>)	Under the estimated pupil size 
Eye selection The currently selected eye is marked with a blue color. Push OD / OS to switch eyes.	
Autoexposure Push the Exposure button to get darker or brighter images, as explained in §8.3. A change in the Exposure value affects only TrueColor retinal images.	
Activate Autoalign to enable the Auto-alignment	

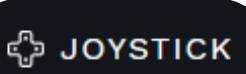
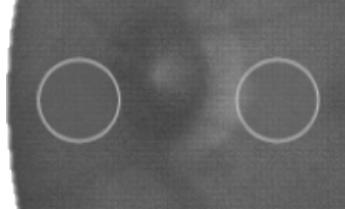
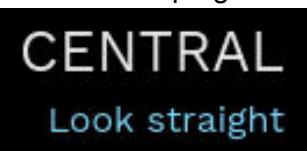
Information	Position on the screen
<p>Disable Autoalign or enable Joystick to manually control the alignment.</p> <p>Move the XY cursor up, down, left or right to move the optical head consequently.</p> <p>Move Z upwards or downwards to approach or recede from the patient's eye.</p>	 
<p>Push Joystick to make the XY and Z controls disappear. The auto-alignment remains disabled.</p>	
<p>Push Autofocus to activate the autofocusing procedure.</p>	
<p>Move the slider close to the Autofocus button to manually change the diopter corrections.</p>	
<p>Find the actual Diopter correction value at the right of the Focusing slider.</p>	-8.0 diopters
<p>Push TrueColor to acquire a color fundus image</p>	
<p>Push Infrared to acquire an Infrared fundus image</p>	
<p>Push any Circle in the retinal image to move the fixation accordingly</p>	
<p>See your selected fixation field</p>	
<p>Find the position of the internal fixation target from the patient's point of view</p>	
<p>See the retinal field under acquisition, including useful instructions for the patient.</p>	Top right text 

Table 5 – Information and controls of the Manual mode Screen

8.5 External eye examination

Set **External Eye** modality to automatically acquire a TrueColor image of the external surface of the eye (see Fig. 55).



Fig. 55 – Image of the external surface of the eye

8.6 Stereo modality

Select the **3D** modality to automatically acquire a couple of **TrueColor** retinal images using either the **nasal** or **central** fixation target.

The two acquisitions differ just by a small transverse displacement of the fixation to create the stereoscopic effect. See the stereo images using the prismatic stereoscopic goggles (see Fig. 10).

The stereo modality is available only for color images and under license⁸.

If the imaging modality is set to **Infrared**, the 3D option is disabled.

To review a stereo images acquisition see §9.5

⁸ Stereo modality is available under license only: please refer to your local Authorized Distributor for detailed information.

9. Review the patient visits

Click on a patient's data to enter the *Patient details Screen*, as in Fig. 56.



Fig. 56 – Patient details screen

On the left side, you find the patients' information for each visit. Exams are grouped by visit date.

Press a visit thumbnail to bring on top of the screen the corresponding exams.

Each image preview contains:

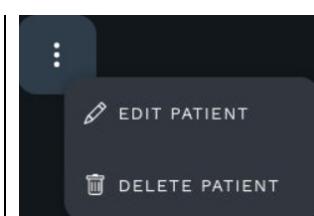
- Acquired eye: OS/OD for left and right eye, respectively
- Image modality: TrueColor, Infrared, Channel (see §9.3.2)
- Field: Field type, Mosaic, External Eye
- Visit date
- Image acquisition time
- Estimated pupil size



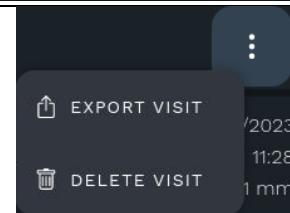
If an image is part of a **stereo** modality, a **3D** rounded button appears on the top right corner of the image.



Touch the **ellipsis (⋮)** button on the right of the *patient information* box to edit the patient data (see §7.5) or delete the patient (see §7.3).



Touch the **ellipsis (⋮)** button on the right of the visit date box to export (see §7.4) or delete the visit.



Function	Command
New exam (§8.2)	
New mosaic (§9.4)	
Export patient (§10)	
Flicker (§9.3.2)	
Compare (§9.3.1)	
Select (§7.2)	
3D Stereo review (§9.5)	
Retake	

Table 6 – Available functions of the Patient details



The **Export queue** button shows the status of the Export. This button appears only when the selected patient has items in the network export queue or when the PACS DICOM server is configured. Refer to §13.10 for more information.



9.1 Image review

Click on an image to open the *Image Review Screen* (see Fig. 57).

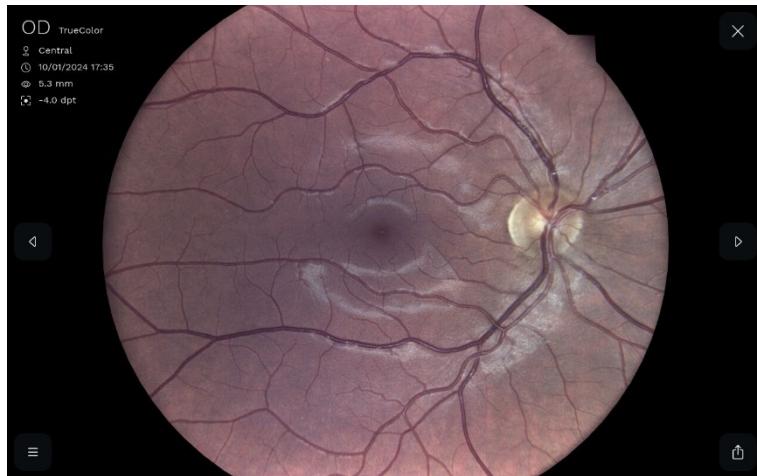


Fig. 57 – Image review

The top left corner shows the information on the acquisition conditions:

- Eye and image modality
- Field/Mosaic/External Eye
- Visit date and acquisition time
- Estimated pupil size
- Filter settings (only in case of a filtered image)
- Exposure value (only in case of a modified exposure)
- Estimated diopter correction

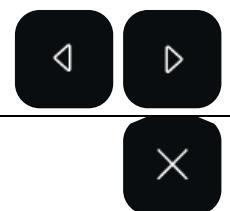
Double-click or use two fingers to zoom the image in and out (see Fig. 58). Drag the image with a finger to navigate around the image.



Fig. 58 – Zoomed region

Use the **left** and **right** arrows to switch to a following or previous image, respectively. The navigation spans across all the patient visits.

Press the **close** button to exit the *Image Review Screen* and revert to the *Patient details* screen.



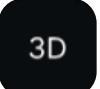
Function	Command
open sidebar Open the image adjustment screen (§9.2) and the comparison tools (§9.3)	
3D stereo review Show the images acquired with the 3D modality for a stereo review (see §8.6)	
export Export the current view of the image. See §10 for more information.	

Table 7 – Available functions of the Image Review

9.2 Image adjustment

Press the **open sidebar** button to adjust the image parameters. The *Filters* Panel will appear (see Fig. 59).



Press the **close sidebar** button to close the panel and see the image full-screen

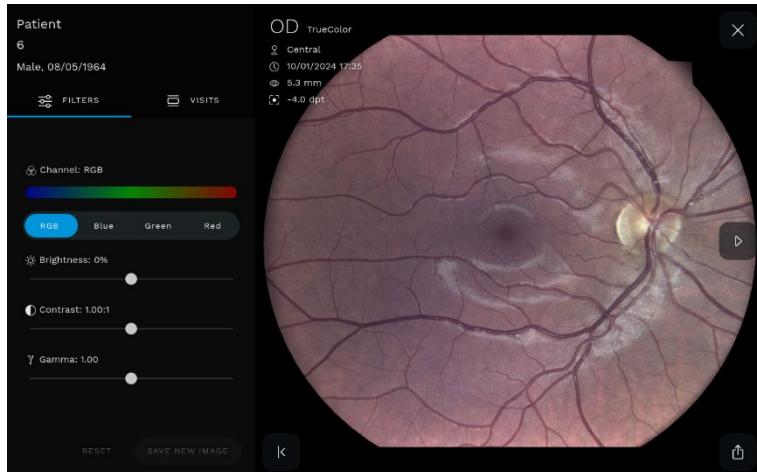
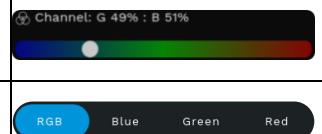


Fig. 59 – Filters panel

You can modify the **Brightness**, **Contrast**, and **Gamma** of the image. Move the Slider to view the effect on the full image.

Select **RGB** to apply a filter to the **TrueColor** image. The image adjustment applied to the image remains after closing the filtering option. You can **RESET** the image filters at any time.

Move the **Channel** slider to mix **BLUE** and **GREEN** or **GREEN** and **RED** channels



Select one of the **BLUE**, **GREEN** or **RED** channels to selectively filter a single color channel.

Click the **export** button to export the currently filtered image.



Click **SAVE NEW IMAGE** to a filtered image to save it in the *Patient details*. **SAVE NEW IMAGE** applies only to a TrueColor channel-filtered image.



Click **RESET** at any time to restore the image at the original acquisition condition.



9.3 Comparison of two exams

To compare the currently shown exam with another one:

- Push the **open sidebar** button on the *Image Review* Screen to open the *Sidebar* panel, and select the **VISITS** tab, as in Fig. 60.

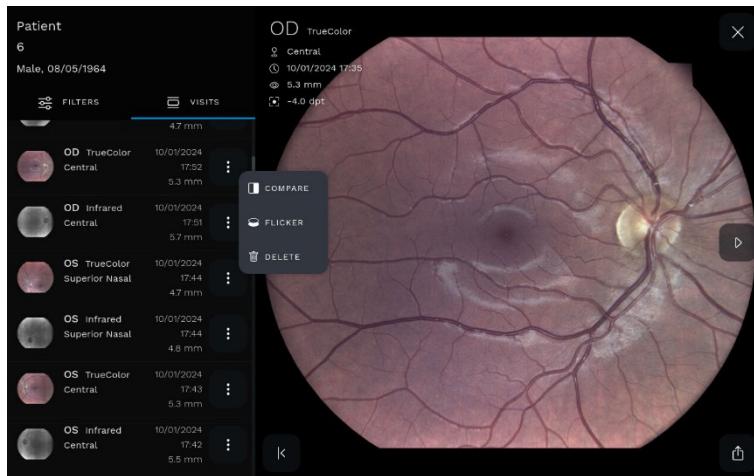


Fig. 60 – sidebar items screen

- Select an exam and press the **ellipsis**  to open the menu.

To compare two images from the *Patient details* screen:

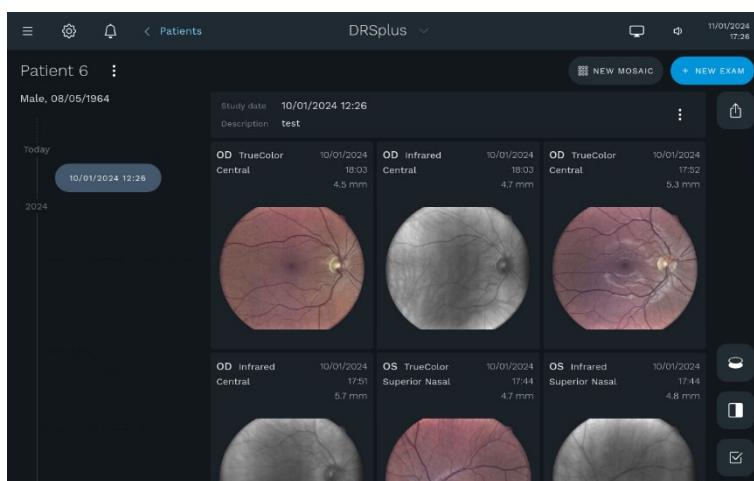


Fig. 61 – Patient details screen

Press the **FLICKER** button to select the images to be flickered.
 Flicker is available on images of the same eye. Flickering is not available for Mosaics.

Press the **COMPARE** button to select the images to be compared.



9.3.1 Side-by-side Image review

Click **COMPARE** to review any couple of patient images side-by-side (see Fig. 62).



Fig. 62 – Side-by-side comparison

The box on the corner of each image contains the information on the image acquisition, as in the *Image Review* panel. Double-click on a picture to zoom in, press and drag to pan the zoomed picture. Activate the **sync items** to apply the same operations to both images and deactivate the **sync items** to independently operate on the two images.

Press **switch items** to swap the images.



Press **sync items** to synchronously zoom and pan the two images.



Press **unsync items** to independently zoom and pan the two images.



Press **close compare** to interrupt the side-by-side view and revert to the previous Screen.



Press **flicker** to activate the flickering review modality. (§9.3.2)
Flicker is available on images of the same eye. Flickering is not available for Mosaics.



Press the **open sidebar** button on the bottom left and right side of the screen to independently filter the left or right image, respectively.



Press the **close sidebar** button to close the *Sidebar* panel.



Press **export** to export the current view of the two images (see §10).



9.3.2 Visual flickering of the images

Click **FLICKER** to alternatively visualize the two images superimposed on the *Flicker Screen* (see Fig. 63). The second image will be automatically registered on the first to overlap the retinal features and ease your reviewing analysis. The first image acts as a reference and only the overlapping part of the second image appears.



Fig. 63 – Flickering review of the images

The top left corner shows the information on the two images: imaging modality, fixation, and exam date. A grey line informs you what image is currently shown.

Press **play** to start the flickering and use the **slider** to slow down or increase the toggling frequency.

At any moment, with the flickering active or in pause, you can zoom, pan and de-zoom the images.

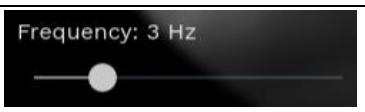
Function	Command
play Press play to start flickering	
pause Press pause to stop the flickering	
next frame Press next frame to toggle the images.	
Press along the slider or drag the circle to change the toggling frequency, that is shown in the box	 Frequency: 3 Hz
close flickering Press close flickering to revert to the <i>Image Review</i> .	

Table 8 – Available options of the *Flicker*

9.4 Mosaic creation

DRSplus includes a special software algorithm, called **mosaic**, that stitches together two or more photos of a retina to obtain an image with a wider field of view (Fig. 66).



The mosaic function is available only under license.

To create a mosaic, open the *Patient details* Screen.

Click the **New mosaic** button to open the *Mosaic Composition* Screen (see Fig. 64).

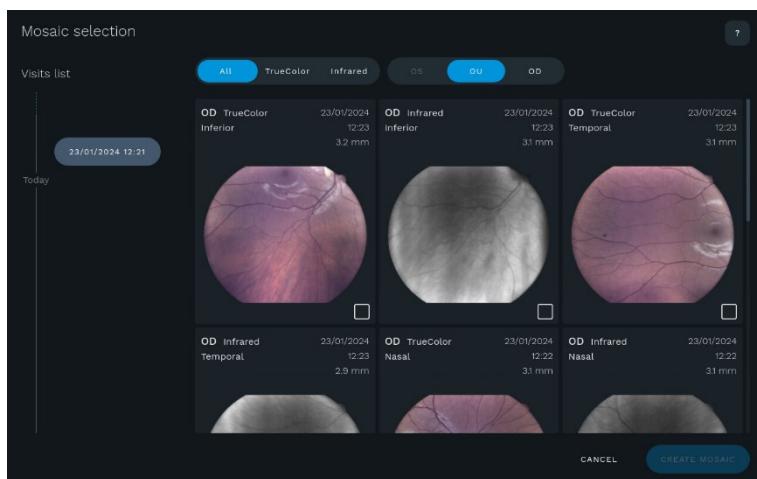
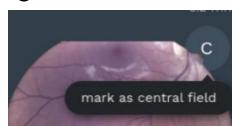


Fig. 64 – Mosaic Composition Screen

If you need to, filter the images by pushing **TrueColor** or **Infrared**, **OD** or **OS** on top of the images.

Select the fields you want to stitch together. While you select the fields, the device will automatically enable the additional stitchable fields and disable all the remaining ones.

Mark the field you want to address as a central field by pushing the **mark as central field** button on the top right corner of the image.



Press the **CREATE MOSAIC** button to start the stitching, press **CANCEL** to abort the Mosaic and return to the *Patient details* Screen.

Once you have pushed **CREATE MOSAIC**, DRSplus will generate the mosaic automatically and will save it as a new image, available in the Patient Details screen.

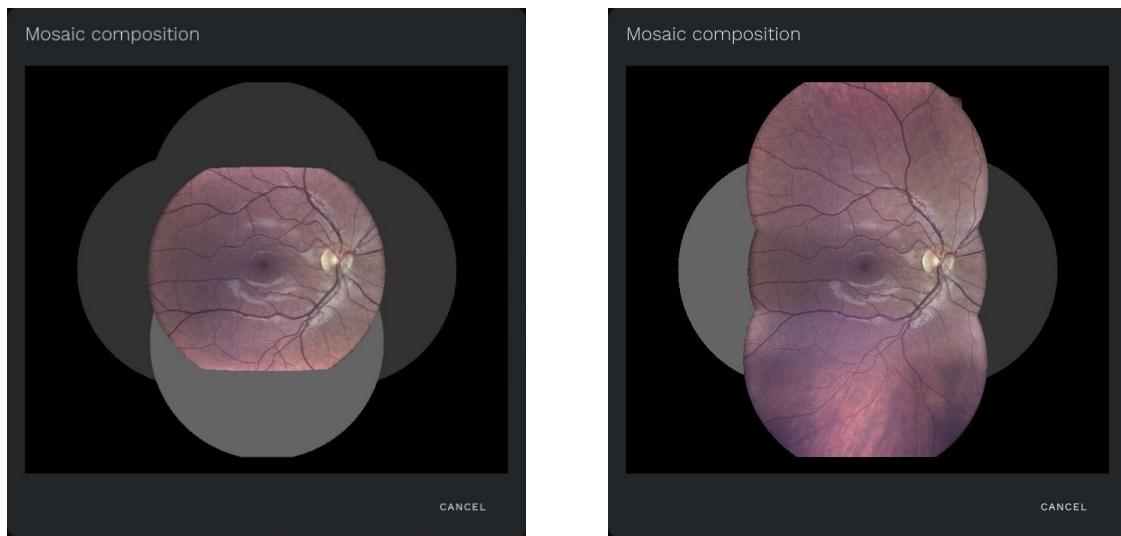


Fig. 65 – Mosaic elaboration in-progress



Fig. 66 – Final mosaic

The central field is automatically detected by the device, but you can manually mark another field as central in case of unstable patient fixation or external fixation.



Mark the field you want to address as a central field by pushing the **mark as central field** button on the top right corner of the image.



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

DRSplus cannot be used to acquire images, during a mosaic creation. The creation of a mosaic with 9 images takes about a minute.



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

9.5 Stereo review

Press **3D Stereo review** to open the *Stereo Review Screen* (see Fig. 67).

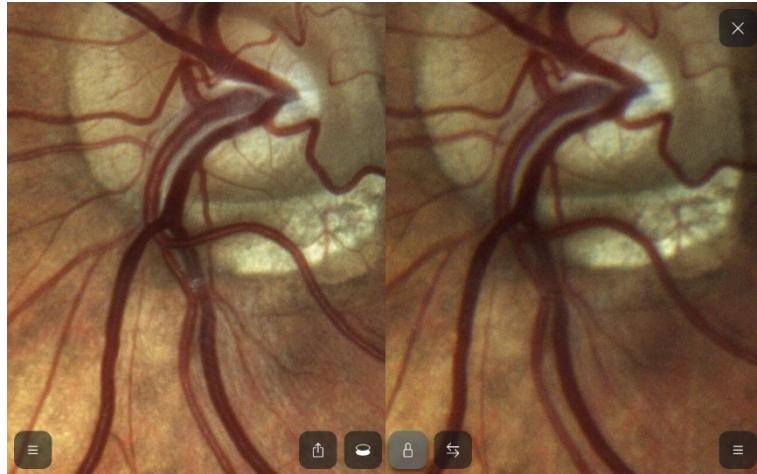


Fig. 67 – Stereo Review Screen

Two zoomed regions of the two views appear on the screen. Wear the prismatic goggles (refer to Fig. 10) and move forward or backward until you see a single 3D retinal image.

If you see elevations instead of cavities, press the **switch items** button.



Use a finger to pan the image. Use two fingers to increase or reduce the magnification. Double-click on the screen to zoom in or zoom out.

10. Exporting images

DRSplus offers extreme flexibility in exporting images. From the *Export* Screen, in detail, you can:

- simultaneously export all images of one or more patients (§7.4, 9.2);
- export or print a single image (§9.1);
- configure (§13.8) one or more destinations, including USB and network drives;
- Print all the images of a single patient.

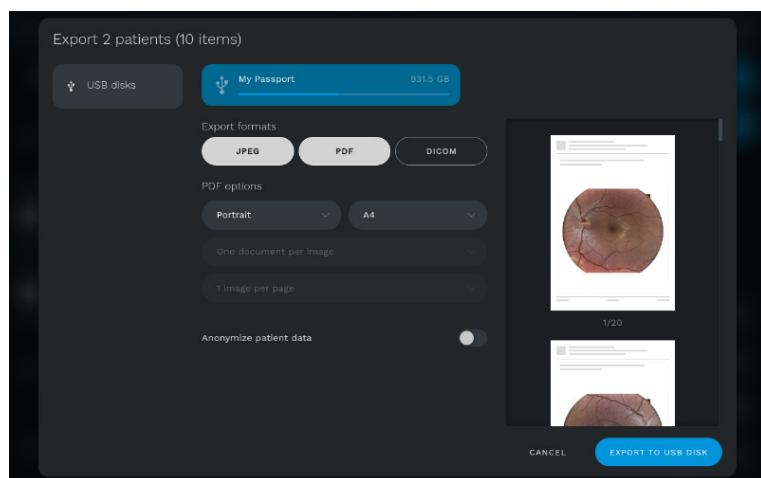


Fig. 68 – Export Screen

Connect one or more destinations.



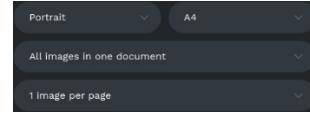
Select the export destination (*USB disks*, *Network disks*, *Printers*). Printing is available for a single patient only.



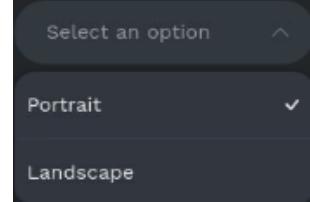
Select one or more of the following *Export formats*: **JPEG**, **PDF**, **DICOM**. Light grey buttons are enabled, and dark grey buttons are disabled. For printing, only the **PDF** option is available.



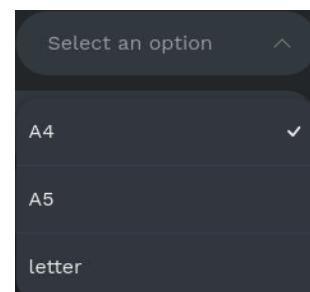
Customize the *PDF options* as follows



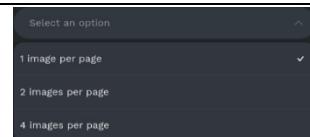
Layout: **Portrait** or **Landscape**



Paper Size: **A4, A5, letter**



Number of images per page: **1, 2, 4, 6, 9**



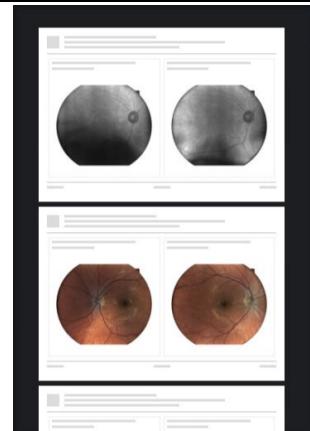
Enable **Anonymize patient data** to export all the patients with masked information:



Disable **Anonymize patient data** to export the patients with their information.



See the *PDF preview* on the right side of the screen. You can scroll through all the generated pages.



Click **EXPORT** to proceed, or click **CANCEL** to abort the Export. For printing, click **SEND TO PRINTER**.

See the progress of the export activity and its completion in the pop-up (see Fig. 69). Click **CANCEL** to interrupt the export or wait until the export is completed. Click **CLOSE** to return to the previous Screen.

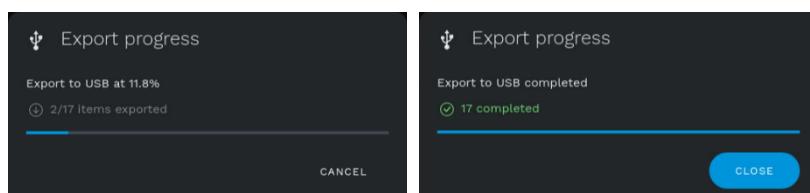


Fig. 69 – Export progress pop-up

In case of completion with errors (e.g.: for lack of space), a pop-up indicates the error. Click **CANCEL** to close the pop-up and interrupt the export. Select different support or empty the currently selected one to complete the export operation.

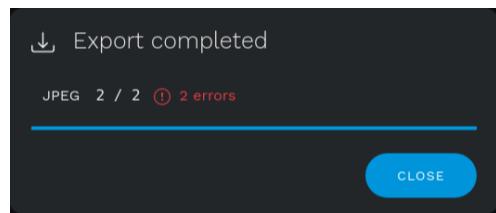


Fig. 70 – Error during export

10.1 Export a zoomed image

When you zoom on an image during the review (see §9.1) and you want to export the zoomed view, click the **EXPORT** button and the *Export Cropped View* Screen appears.

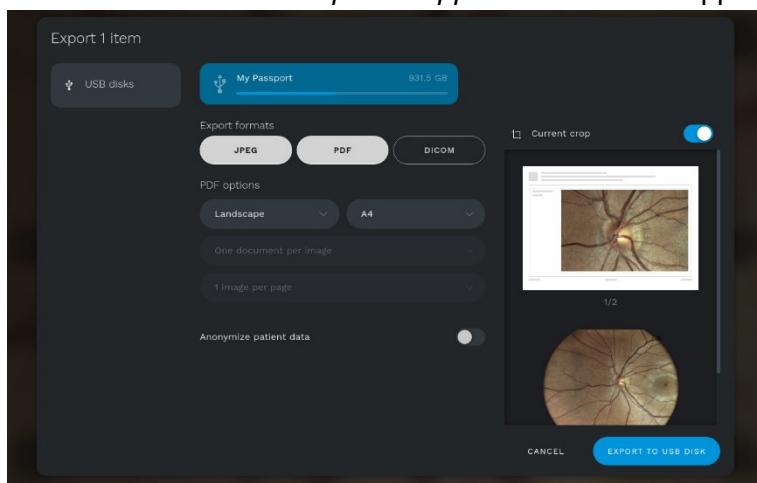


Fig. 71 – Export Cropped View Export Cropped View Screen

Enable **Current crop** to export the magnified, cropped image, as shown in the preview.



Disable **Current crop** to export the whole image, as shown in the preview.



10.2 Review exported images

Review the exported images on your device. See an example of an exported PDF report in Fig. 72, where two images per page have been exported. The headings contain the patient data and notes.



Fig. 72 — Example of pdf report of an exam

The following figure shows the PDF report of an anonymized export of a cropped, filtered image. The width of the image corresponds to the zoomed view of the image at the moment of export. The information on the color channel filter is indicated in the bottom left box of the report. The header contains an example of a custom logo and text. To customize your header, see §13.8.



Fig. 73 – PDF report of a cropped, filtered image

You can see in the top left corner that patient's data are replaced as follows:

- Patient's Surname -> **Anonymous**
- Patient's Name -> Universally Unique Identifier (UUID)
- Date of birth and age (DD/MM/YYYY, if present) (YY) -> 01/01/YYYY (YY)
- Gender -> Gender
- Operator

The **patient ID** is removed.

You can always retrieve the patient's visits starting from an anonymized export. Input the complete UUID in the **search** box of the *Patient List Screen*, as shown in Fig. 74.

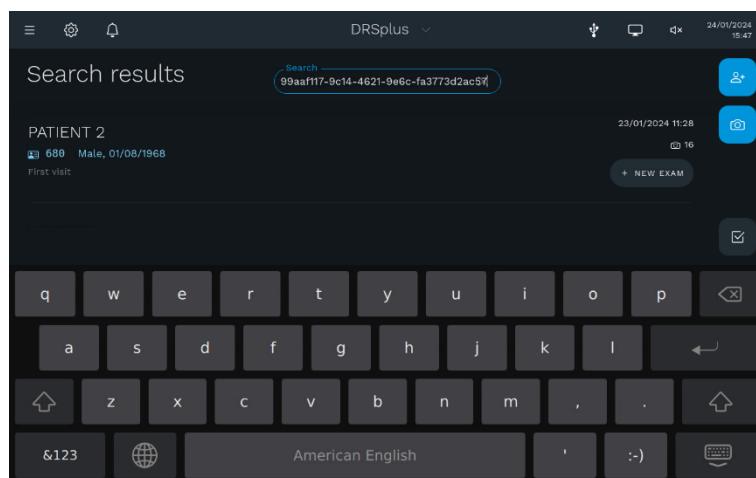


Fig. 74 – Search via UUID

11. Remote Viewer

Remotely review the whole patient database and all the images stored in DRSplus memory employing any standard PC connected to the same Local Area Network of the DRSplus.

In the Remote Viewer, you retrieve all the same screens and functionalities available in the local interface, plus some additional features.



In the Remote Viewer *Navigation Bar*, the **MENU** does not show the **Power off** button.



11.1 Remote viewer enabling

To enable the Remote Viewer, DRSplus must be connected to the Local Area Network using an Ethernet or Wireless connection (Fig. 8). 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).

Remote Viewer access (HTTP or HTTPS) must be enabled in the *Settings|Device access Screen* (§13.7)

By default, the remote viewer is disabled.

Once the connection is up and running, open a browser on 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 that compose the serial number of the DRSplus, as reported in the device label.



The Remote Viewer functionality is available only under license⁹. The license can be provided as a single license or a 5-license pack. Every single license will give access to DRSplus 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.

⁹ Remote Viewer functionality is available under license only: please refer to your local Authorized Distributor for detailed information.

- The Remote Viewer is tested on the latest release of the following browsers¹⁰: 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 to the local user interface.
- Every Remote Viewer session is automatically closed after the period specified in the *Settings|Device access* menu (§13.7). To continue using the Remote Viewer, a new login is required.
- The use of the HTTP protocol exposes to higher cybersecurity vulnerabilities.

11.2 Remote exam

From the Remote Viewer, the configuration and execution of a new exam are permitted only after Remote Exam activation.

DRSplus Remote Exam functionality¹¹ through DRSplus Remote Viewer provides the capability of executing a patient remote acquisition with DRSplus.

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 DRSplus to set up and control the exam.

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

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

For Remote Exam activation for a specific user, see §13.2.

From the computer, log in with the proper use of the **Remote Viewer**.

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

A pop-up appears and the **Remote Activation Code** is requested.

The Remote Activation Code will be shown on the display of the DRSplus.

¹⁰ As of February 2024.

¹¹ The Remote Exam Feature Viewer functionality is available under license only and needs as a pre-requisite a Remote Viewer license installed: please refer to your local Authorized Distributor for detailed information.

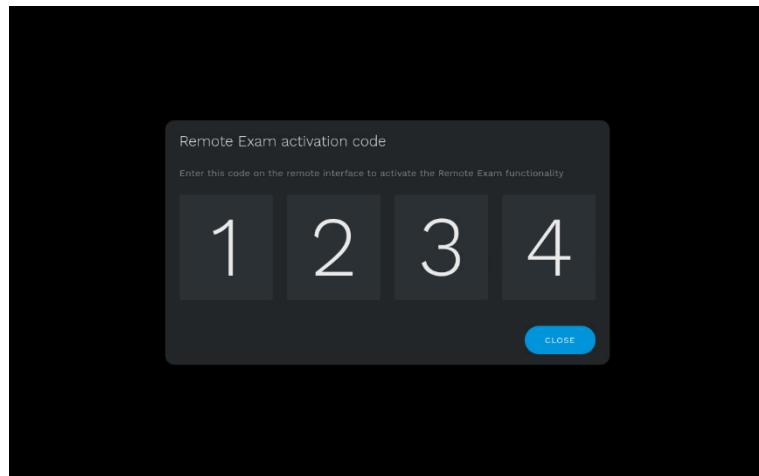


Fig. 75 – Remote Activation Code showed on DRSplus display

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.

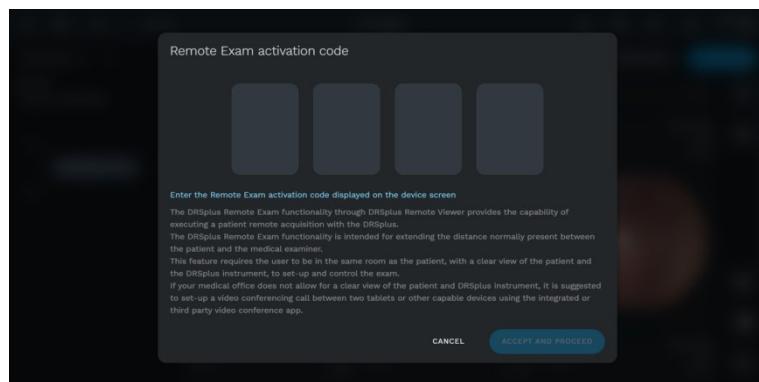


Fig. 76 – Remote Activation Code fill on Remote Viewer Interface

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

Verify the seat of the patients and instruct them to place their foreheads 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.

11.3 Export and print from the browser

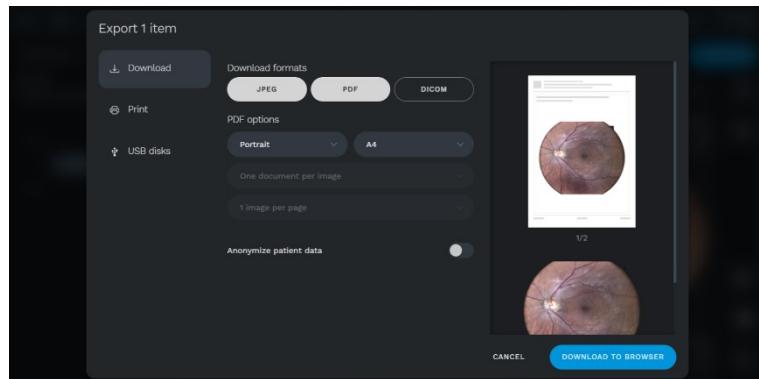


Fig. 77 – Remote viewer export

From the Remote Viewer, in the **Export** Panel, you can download it on your PC or print it through a printer connected to your PC.

Select **Download to browser** and then push **DOWNLOAD TO BROWSER** to export the selection on your PC.

DOWNLOAD TO BROWSER

Select **Send to printer** and then **OPEN PRINT WINDOW** to open the printing interface of your browser.

OPEN PRINT WINDOW

11.4 Remote Image review

11.4.1 Cup to disc

From the Remote Viewer, you can use the **cup to disc** function. Push the **cup to disc** button to activate the measurement function.

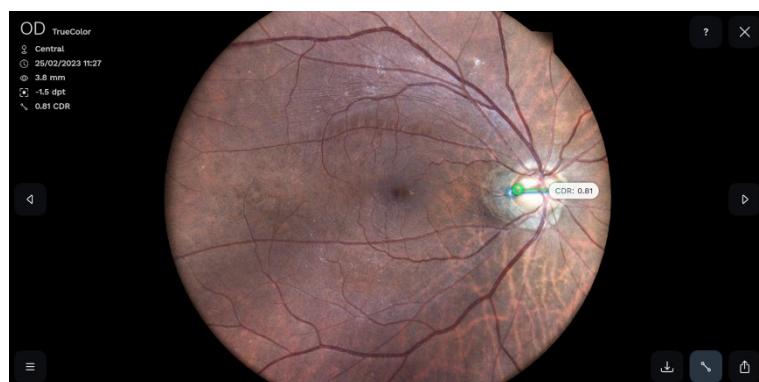
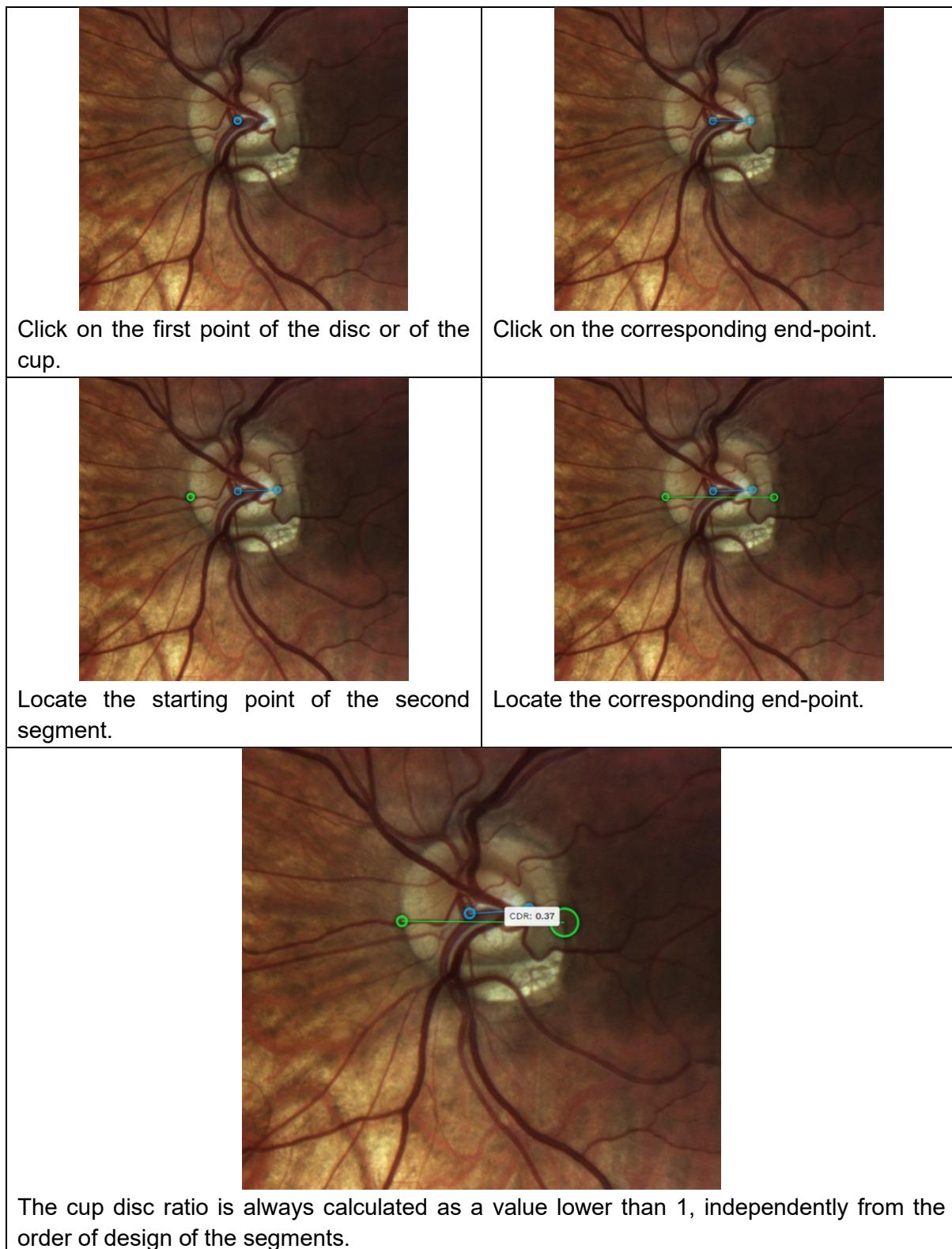


Fig. 78 –Image Review Screen, cup to disc



The cup to disc ratio is reported on the top left side of the image (see Fig. 78). Note that you can anytime edit the selected points and the CDR will correspondingly be updated.

11.4.2 Shortcuts

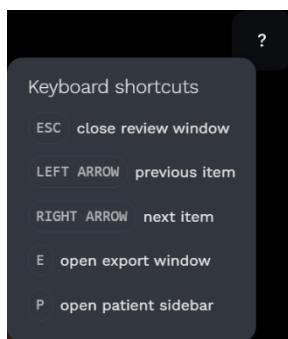


Fig. 79 – Shortcuts in the remote Image Review Screen

In the *Image Review* Screen of the *Remote viewer* push the question mark to discover the Keyboard shortcuts.

11.5 Privacy mode



Fig. 80 – Patients list in privacy mode

In the Remote Viewer, hover a patient box with the cursor to make the Surname and the First Name fully visible.

Press the **privacy mode ON/OFF** button to hide/unhide the patients' information.



12. Device controls

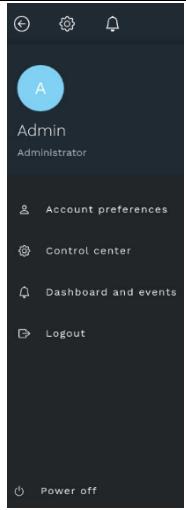
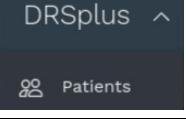
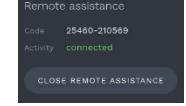
12.1 Navigation Bar

Upon login, the *Navigation Bar* shown in Fig. 81 appears on all the screens.



Fig. 81 – Navigation Bar

The Navigation Bar functionalities follow:

Function	Command
Menu Browse the main device management options: preferences, Control center, Dashboard, Logout, and Power off. The Power off button does not appear in the Remote Viewer.	 
Control center Open the <i>Control center</i> Screen including Configuration (§12.2) and Utilities tools (§13.11.3)	 
Open the Dashboard	
Patients Go back to the patient detail or patient screen	
Open the Patient List	 
Show the Remote assistance information This icon appears when you request remote assistance.	 
Show the iCare Cloud services status (see §13.11.3)	

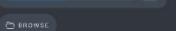
Function	Command
Show the DICOM automatic delete policy status	 Patient auto deletion Status enabled PAUSE
Announcements Show the announcements published by iCare server, like online software updates or availability of new features.	
View the USB disks connected for image export, if any. This icon disappears if no USB device is plugged in.	 USB disks My Passport 831.6 GB 
Connectivity View the current status of ethernet and wireless connections.	 Connectivity Ethernet Connected 10.220.6.121 Wi-Fi Disconnected
Speakers volume Set the volume of the audio notifications.	 Speakers volume
Date and time View the date and time of the DRSplus	29/01/2024 12:06

Table 9 – Navigation bar options

12.2 Dashboard

To access the *Dashboard* Screen, click the **Dashboard** button on the *Navigation Bar*.

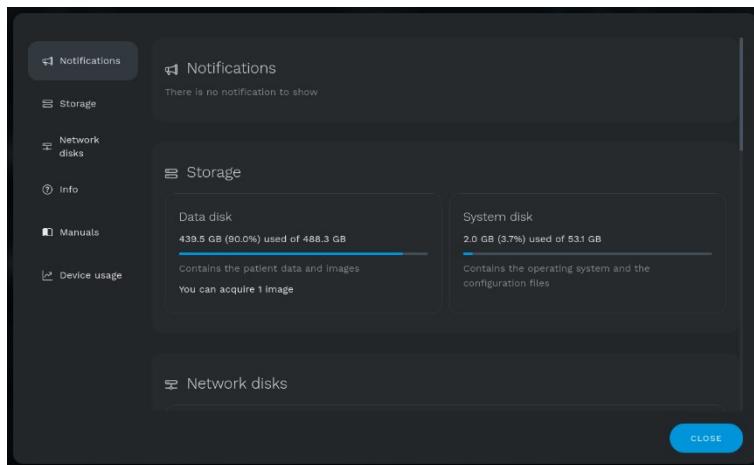


Fig. 82 –Dashboard Screen

The *Dashboard* contains a comprehensive review of the *Notifications* (§12.2.1), the storage on the device, the configured services like Backup destinations, Network disks and iCare Cloud, the *Info* of the device, the *Manuals*, and the usage statistics, to show at a glance all the information regarding the device operativity. For details refer to the *About* Screen (§12.5).

12.2.1 Notifications

The *Notifications* are all the information regarding an event, a warning or an error.

Within its operation activity, the device can generate notifications that are displayed to the operator through pop-ups and toasts (see Fig. 83). When such an event happens, the color of the **Dashboard** icon changes and becomes grey for an event, orange for a warning or red for an error. A number on the top right of the icon tells how many unseen notifications are present.

Click the **Dashboard** icon in the *Navigation Bar* to view the last notifications

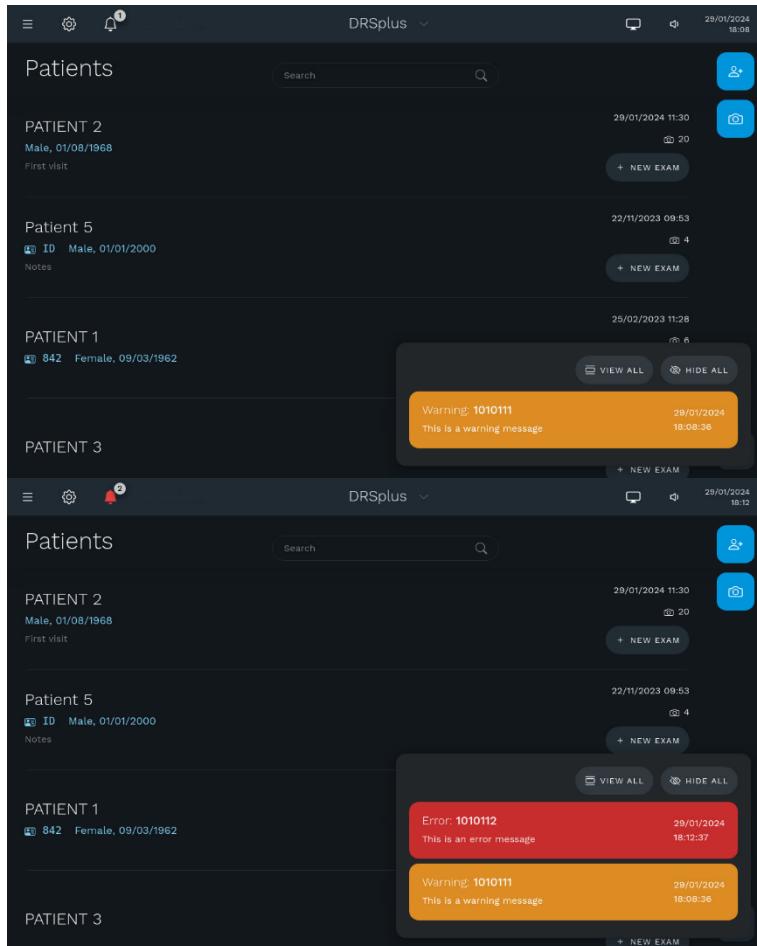


Fig. 83 – Examples of toasts for warning and error categories

Click **HIDE ALL** to close the toast. 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:

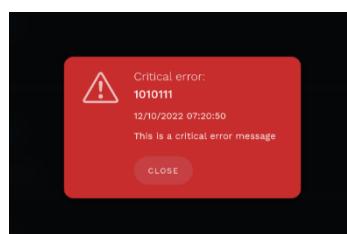


Fig. 84 – Example of a critical error blocking pop-up

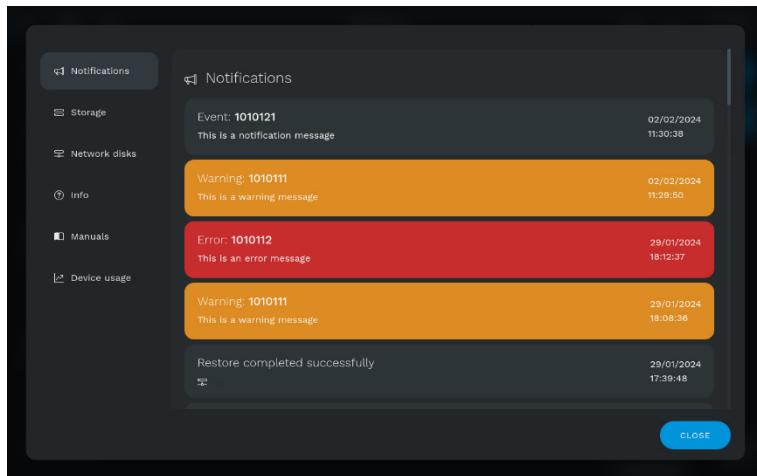


Fig. 85 – Notifications list Panel

After a critical notification, the dashboard icon remains highlighted. From this panel, all the notifications can be marked as viewed.

12.3 Control Center

To access the *Control center* Screen, click on the **Control center** icon in the *Navigation Bar*.

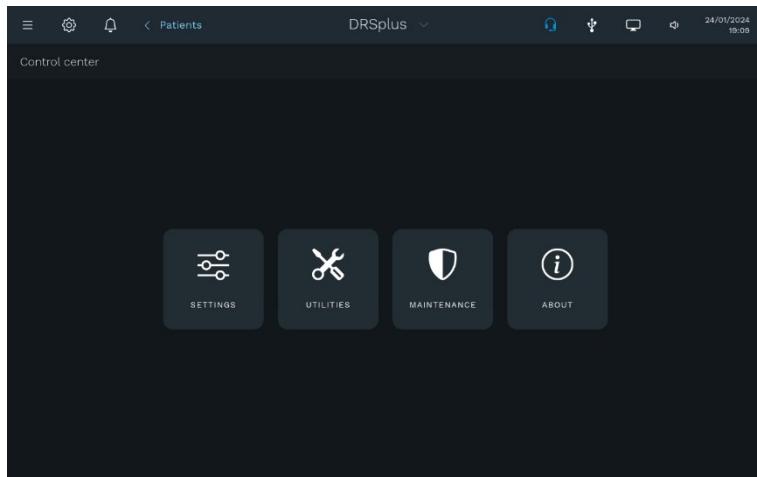


Fig. 86 – Control Center Screen

From the Control Center, you can access the following Screens:

- *Settings* (§12.5.1)
- *Utilities* (§14)
- *Maintenance* (§12.4)
- *About* (§12.5).

The first three screens will be described in dedicated paragraphs.

12.4 Maintenance

The *Maintenance* Screen contains two logs viewers, the System and the Audit logs (see Fig. 87), which are useful for *service* purposes.

To access the *Maintenance* Screen, click the **MAINTENANCE** button on the *Control center* Screen.

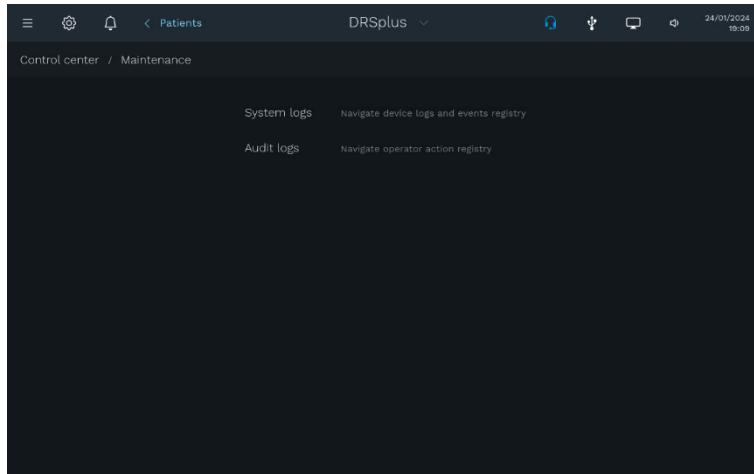


Fig. 87 – Maintenance Panel

12.4.1 System logs

The *System Logs* Screen shows the logs generated by either the operating system or the application software. They are divided into the following categories:

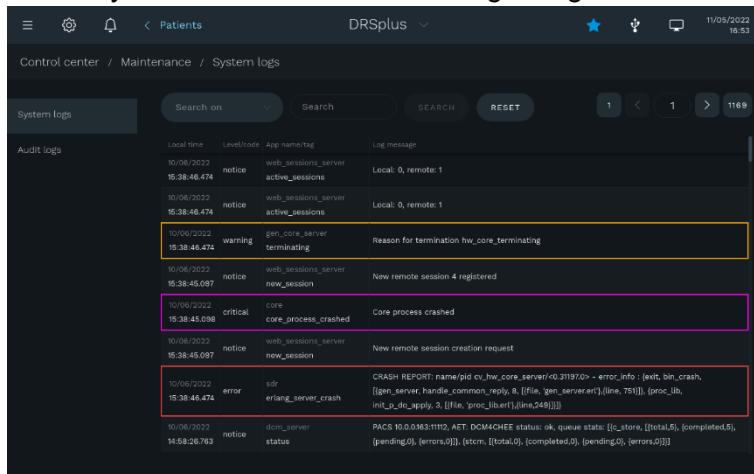


Fig. 88 – System logs Screen

Notice: messages informing that a run-time event, such as startup or shutdown, has occurred.

10/06/2022 15:38:46.474 notice web_sessions_server active_sessions Local: 0, remote: 1

Warning: message informing about situations that might have an adverse performance implication.

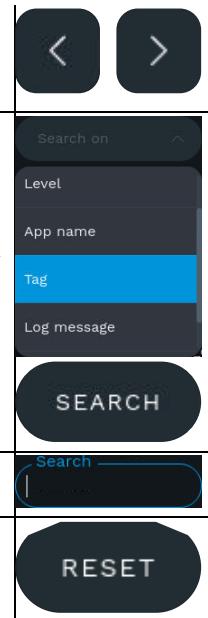
10/06/2022 15:38:46.474 warning gen_core_server terminating Reason for termination hw_core_terminating

Error: messages that inform about serious errors that anyway might allow the application to continue running.

10/06/2022 15:38:46.474	error	sdr erlang_server_crash	CRASH REPORT: name/pid cv_hw_core_server/<0.31197.0> - error_info : {exit, bin_crash, [{gen_server, handle_common_reply, 8, [{file, 'gen_server.erl'}, {line, 751}]}, {proc_lib, init_p_do_apply, 3, [{file, 'proc_lib.erl'}, {line, 249}]}}}
Critical: messages that inform about severe errors that can cause the application to terminate.			
10/06/2022 15:38:45.098	critical	core core_process_crashed	Core process crashed

By default, messages appear in chronological order (the newest at the top of the list) grouped in pages.

Use the **arrows** to change the page.



Press **Search on** to change the grouping option.

Select among: Local time, Level, App name, Tag, Log message and Error code.

Press **SEARCH** to refresh the page according to your selection.

Input a specific text in the **Search** field and then press **SEARCH** to find it.

Press **RESET** to restore the default view.

Click on a specific record to open a pop-up showing the related details (see Fig. 89). Push **CLOSE** to revert to the *System Logs* Screen.

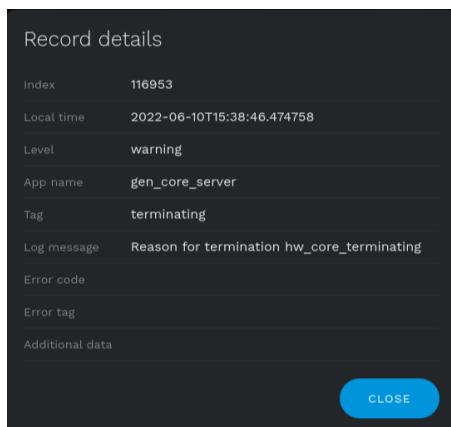


Fig. 89 – System Logs Record Details Dialog

12.4.2 Audit logs

The *Audit logs* Screen shows the activities performed on the device's interface (see Fig. 90).

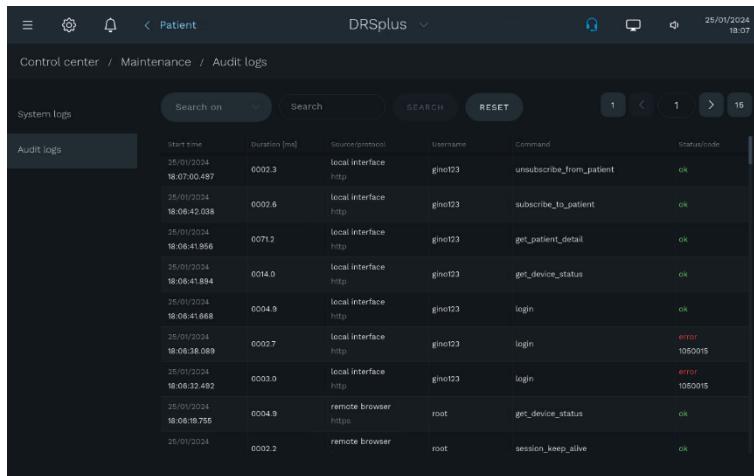
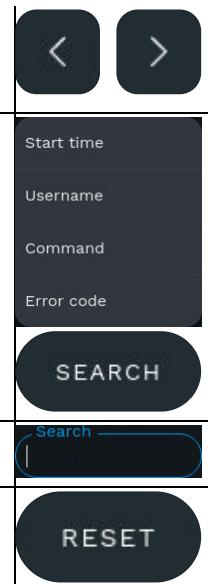


Fig. 90 – Audit Logs Panel

For each activity, the *Status code* shows the operation result, which can be either *ok* or *error*. By default, messages appear in chronological order (the newest at the top of the list) grouped in pages.

Use the **arrows** to change the page.



Press **Search on** to change the grouping option.

Select among: Start time, Username, Command and Error code.

Press **SEARCH** to refresh the page according to your selection.

Input a specific text in the **Search** field and then press **SEARCH** to find it.

Press **RESET** to restore the default view.

Click on a specific record, to open a pop-up showing the related details (see Fig. 91). Push **CLOSE** to revert to the *Audit logs* Screen.

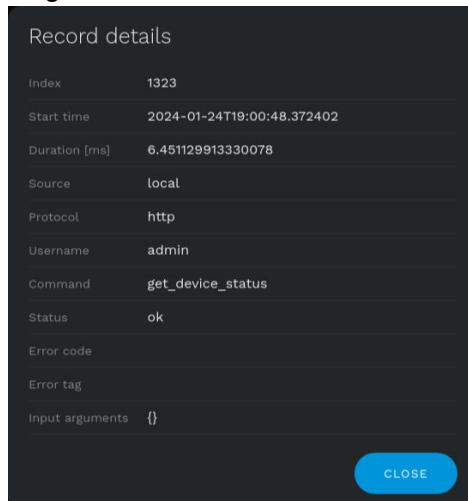


Fig. 91 – Audit Logs Record Details Dialog

12.5 About Screen

The *About* Screen contains general information regarding the device.

To access the *About* Screen, click the **ABOUT** button on the *Control center* Screen.



The *About* Screen shows:

- The *Info* section containing the installed software version, the device's serial number and the status of the *End User Licence Agreement* (EULA). Push the button to review the EULA on the language of the Country configured on the *Configuration Wizard* Screen (see §6.2)
- The *Storage* section with the size and the amount of free space for the *Data disk* and the *System disk*
- The *Manuals* section containing all the available Manuals (see §12.5.1)
- The *Device Usage*, in terms of Patient records, Item records and graphical information of the number of exams performed in the last 180 days.

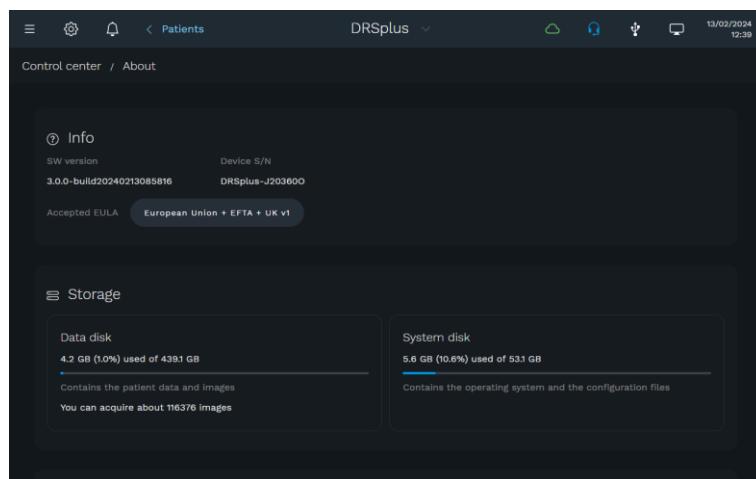


Fig. 92 – About Screen, About and Storage

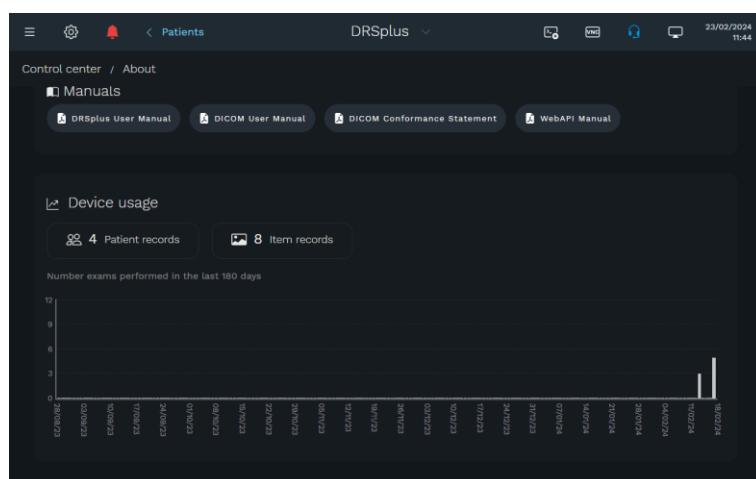


Fig. 93 – About Screen, Device usage

12.5.1 Manuals

The **Manuals** tab contains the Instructions for Use of the DRSpplus. The Instructions for Use are available in the following languages: English, Italian, French, German, Spanish, Portuguese, Czech, Danish, Estonian, Greek, Hungarian, Lithuanian, Romanian, Slovak, Norwegian, Swedish, Finnish, Latvian.

Push **DRSpplus User Manual** to make the Instructions for Use appear on the screen in the language corresponding to the Country selected during the Wizard. If your device has DICOM or WebAPI active licences, their Manuals will be available in the *About* Screen (see Fig. 93). Push **SELECT A LANGUAGE** (see Fig. 94) to change the language of the Instructions for Use, push **CLOSE** to close the Manual.

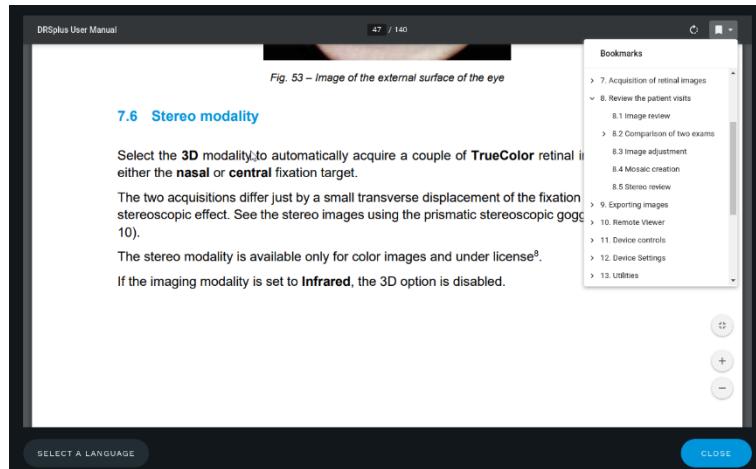
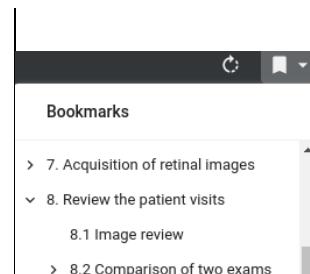


Fig. 94 – Manuals screen

Push **Bookmarks** to navigate the Manual Headings.



Push **Fit to width / Fit to page** to adjust the zoom of the Manual to the width or to the height of the screen, respectively



Push **Zoom in / Zoom out** to adjust the increase or decrease the zoom of the Manual, respectively.



The Manuals section is not available if during the configuration Wizard you have selected China as Country.

13. Device Settings

To access the *Settings* Screen, click the **Settings** button in the *Control center* Screen.



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.

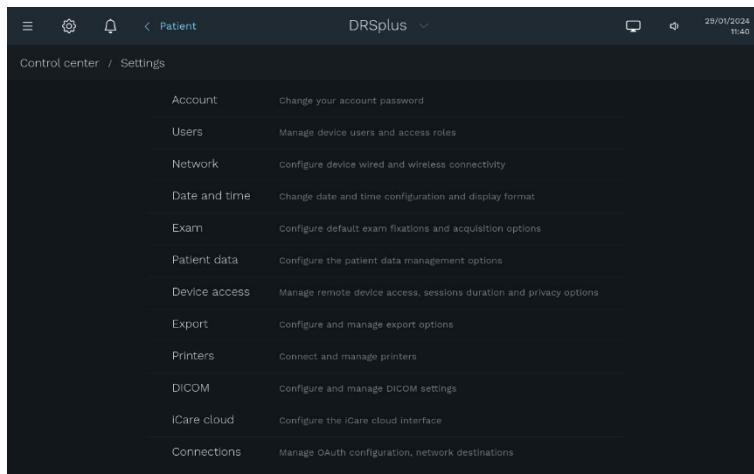


Fig. 95 – Settings Screen

13.1 Account

The *Settings|Account* Screen (Fig. 96) allows users to change their passwords.

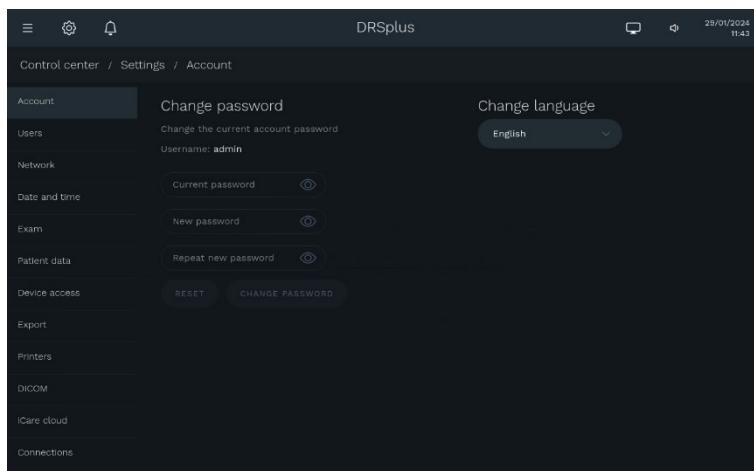


Fig. 96 – Settings|Account Screen



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

You can change the interface language of the current user via a dropdown menu. Supported languages are English, Spanish, Italian, French, German, Portuguese, Japanese, Chinese, Korean, Russian, Czech, Swedish and Finnish.

13.2 Users

The *Settings|Users* Screen (Fig. 97) manages (creation, modification and deletion) the user accounts. It is accessible only by the Administrator.

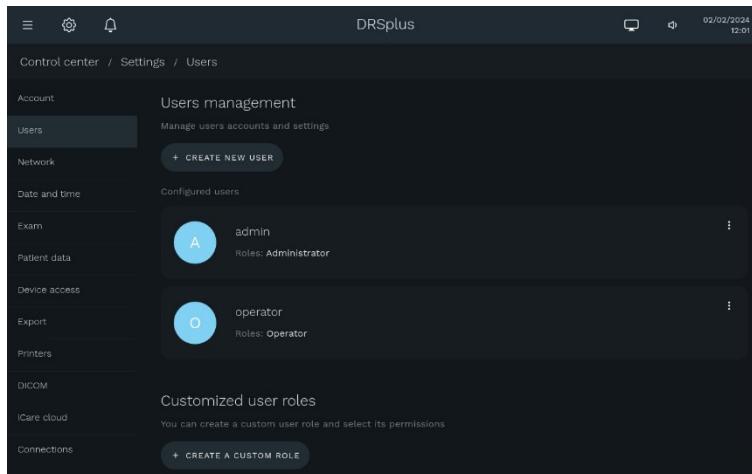


Fig. 97 – *Settings|Users* Screen



- 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.

Push the **CREATE NEW USER** button to create a new user.

+ CREATE NEW USER

In the *Create new user* Panel (Fig. 98), define Username and Password, Roles, and Language and enable or disable the Remote Exam functionality (see §11.2). Click **SAVE** to maintain the changes, click **CANCEL** to abort the creation of the new user.

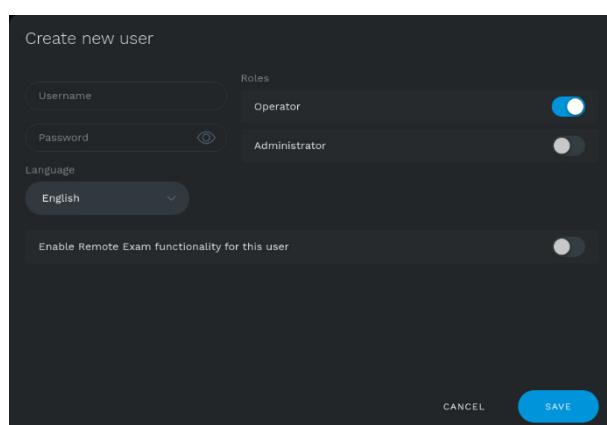
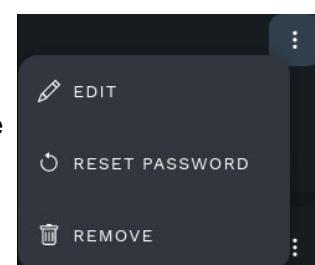


Fig. 98 – *Create New User*

To modify an existing user, press the **ellipsis (⋮)** at the right of the user's box.



Click **EDIT** to open the *Edit the user* Panel (Fig. 99).

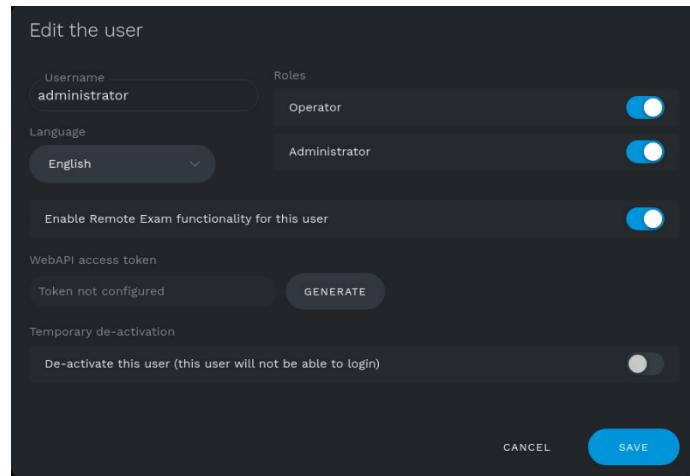


Fig. 99 – Edit the user Panel

You can change the Username, the Roles, and the Language, Enable or Disable the Remote Exam Functionality and Deactivate the user.

If a WebAPI license is active, you can generate an access token (refer to the *DRSplus webAPI Manual* for more information).

Click **SAVE** to save the changes, click **CANCEL** to abort the editing operation.

Click **RESET PASSWORD** to open the *Reset user password* Panel (Fig. 100).

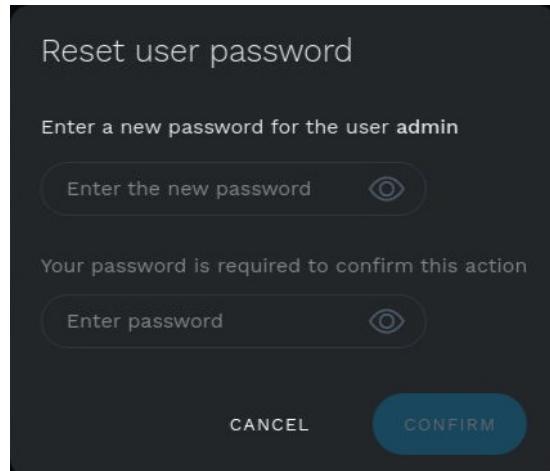


Fig. 100 - Reset user password Panel

You can modify the new password. Click **CONFIRM** to save the new password, click **CANCEL** to abort the operation.

Push the **CREATE A CUSTOM ROLE** button to create a new role with limited permissions.

Select a name to describe the custom role in the *Custom role description* box. Enable or disable the permissions, according to your needs. Click **SAVE** to create the role, click **CANCEL** to abort.

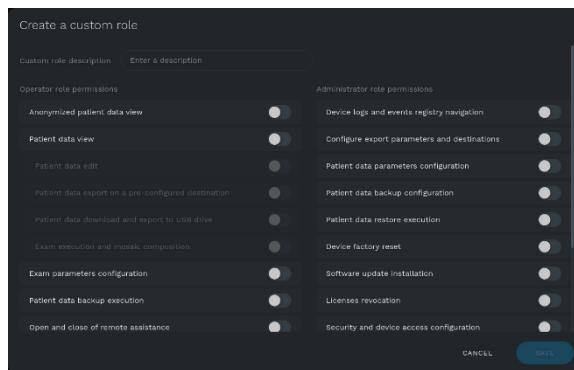


Fig. 101 - Creation of a custom role Panel

The two preset users **Administrator** and **Operator** have the permissions indicated in the next table.

Permission	admin	operator
Anonymized patient data view	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Patient data view	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Patient data edit	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Exam parameters configuration	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Exam execution and mosaic composition	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Patient data export on a pre-configured destination	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Patient data download and export to a USB drive	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Patient data backup execution	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Open and close the remote assistance	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Networking configuration	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Licenses installation	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Enable and disable demo images	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Date and time configuration	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Device logs and events registry navigation	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Configure export parameters and destinations	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Patient data parameters configuration	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Patient data backup configuration	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Patient data restore execution	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Device factory reset	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Software update installation	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Licenses revocation	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Security and device access configuration	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Device configuration restore	<input checked="" type="radio"/>	<input checked="" type="radio"/>

Table 10 – Permissions of the admin and operator users.

13.3 Network

Open the *Settings/Network* Screen (Fig. 102) to configure the network connection. Specify the primary network interface between Ethernet and Wi-Fi.

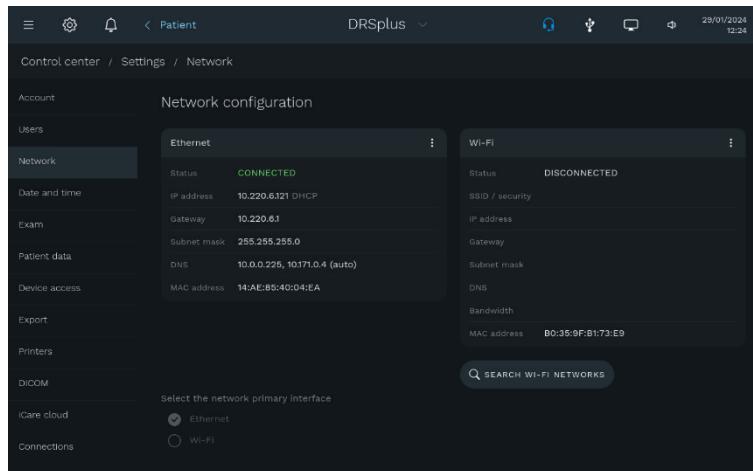
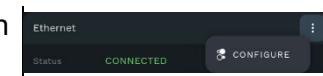


Fig. 102 – Settings/Network Screen

Press the **ellipsis (⋮)** at the right of the Ethernet box and then **CONFIGURE**.



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

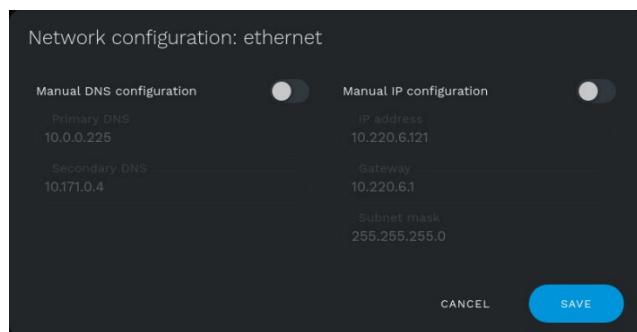
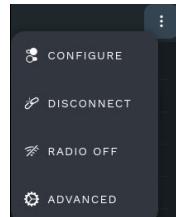


Fig. 103 – Ethernet connection settings

Wi-Fi connection

The network parameters can be configured as per the Ethernet. DRSplus supports the Wi-Fi authentication with WPA1/WPA2, WPA2 802.1X, WEP standard protocols.

Press the **ellipsis (⋮)** at the right of the Wi-Fi box. Click **CONFIGURE** to edit the standard Wi-Fi properties, **DISCONNECT** to remove the device from the current Wi-Fi network, **RADIO ON/RADIO OFF** to enable or disable the Wi-Fi, **ADVANCED** to edit the advanced Wi-Fi properties (see Fig. 104)



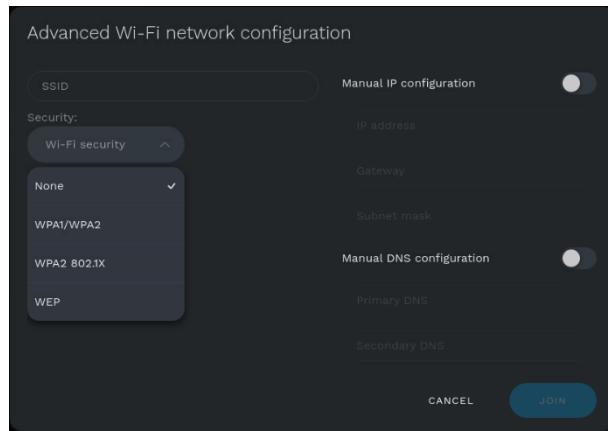
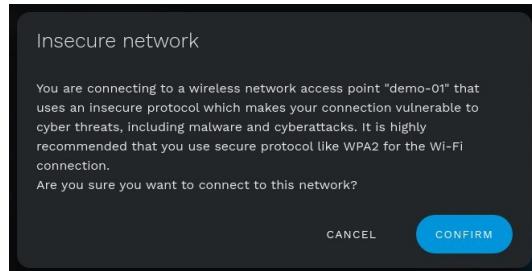


Fig. 104 - Advanced Wi-Fi panel

Push **SEARCH WI-FI NETWORKS** to scan for available Wi-Fi networks.

Wi-Fi network that use a protocol WPA1 and WEP are considered unsecure connections. A warning will appear if you select one of those protocols.



Select the network primary interface between *Ethernet* and *Wi-Fi*.

Push **RESET NETWORK** to revert to the factory defaults.

Push **PING TEST** to verify the connection status in the *Ping* panel (Fig. 105).

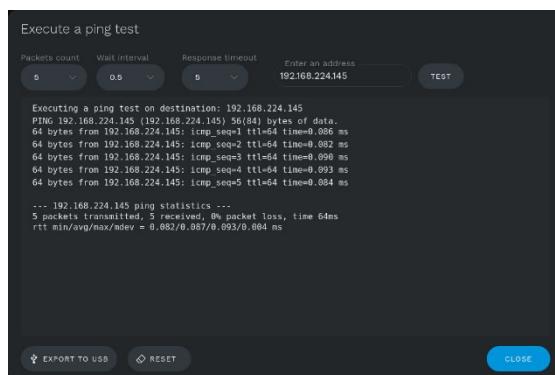


Fig. 105 – Ping Panel

Enter the **Address** and push **PING TEST** to verify. Click **RESET** to interrupt the test, click **CLOSE** to revert to the *Settings/Network* panel.

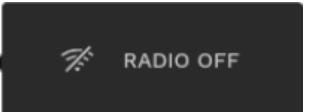
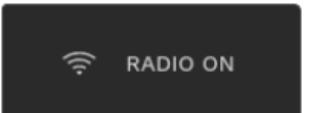
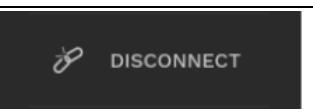
Function	Command
Enable/disable the Wi-Fi interface from the Wi-Fi ellipsis (⋮).	 RADIO OFF  RADIO ON
Disconnect the device from the current Wi-Fi network	 DISCONNECT
Scan for available Wi-Fi networks	 SEARCH WI-FI NETWORKS

Table 11 - Available functionalities

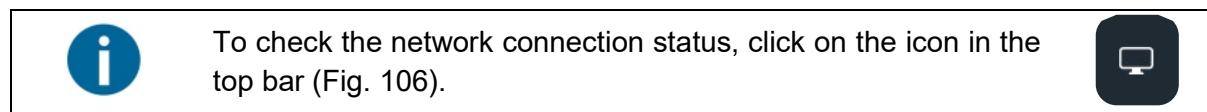


Fig. 106 – Example of wired and Wi-Fi network connection status

13.4 Date and time

Access the *Settings|Date and time* Screen (Fig. 107) to configure the date and time formats.

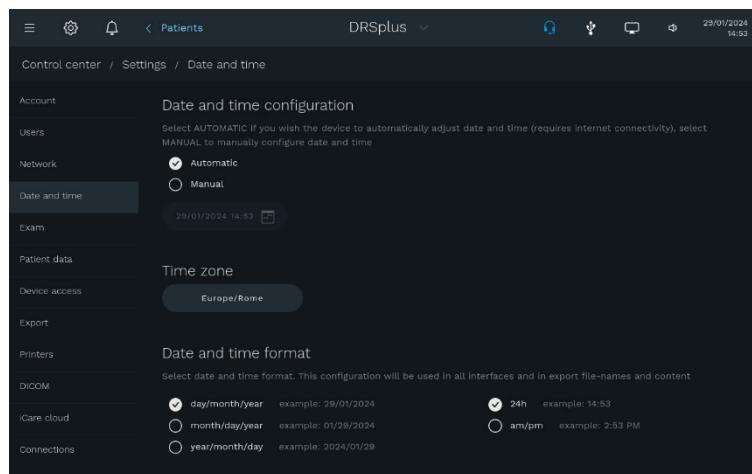


Fig. 107 – Settings|Date and time panel

In the *Date and time configuration* section, select between **Automatic** (requires Internet connection) or **Manual** date and time settings.

In the *Time zone* section, click on the currently selected one to set a time zone from the *Select a time zone* panel.

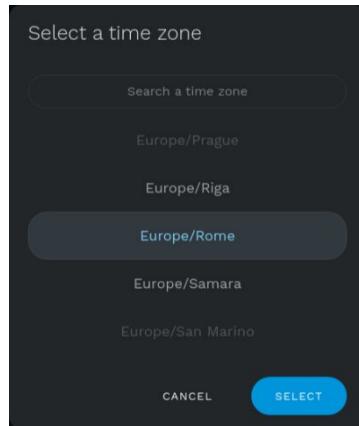


Fig. 108 - Select a time zone Panel

In the Date and time format section, set your preferred formats.

To provide the date and time to the device via an NTP server, push the **CONFIGURE** button in the Local NTP server section and insert the NTP server address.

13.5 Exam

Access the *Settings|Exam* Screen (Fig. 109) to select the exam default configurations for the *Exam Configuration* Screen. You will be able to override any of the preset configurations before starting the exam, as explained in §8.2.

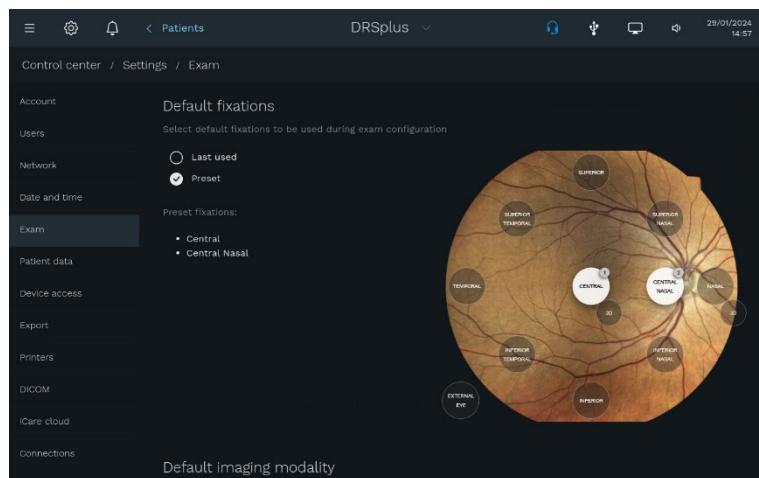


Fig. 109 – Settings|Exam Screen fixations

13.5.1 Fixations

Select between:

- Last used: last used fixation configuration becomes preset for the next exam;
- Preset: in the interface, touch the fixation positions you want to preset for all the exams. The list of the selected fixations is shown in the *Preset fixations* box, as well as in the configuration's picture.

13.5.2 Default imaging modality

It appears only if the IR imaging modality is enabled.

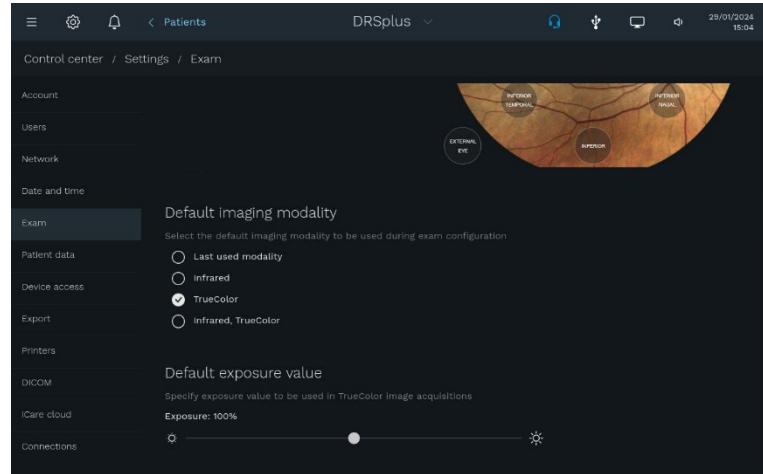


Fig. 110 – Settings|Exam Screen Imaging modality and exposure

Possible options are:

- last used modality: last used imaging modality will be preset for the next exam;
- Infrared: the default imaging modality is Infrared only;
- TrueColor: the default imaging modality is TrueColor only. This option is the initial **default**;
- Infrared, TrueColor: the default imaging modality is to acquire both Infrared and TrueColor images.

13.5.3 Default exposure value

Set the value (percentage) which defines the brightness of the TrueColor acquired image.

13.6 Patient data

Access the *Settings|Patient data* Screen to configure the patient data management options (Fig. 111).

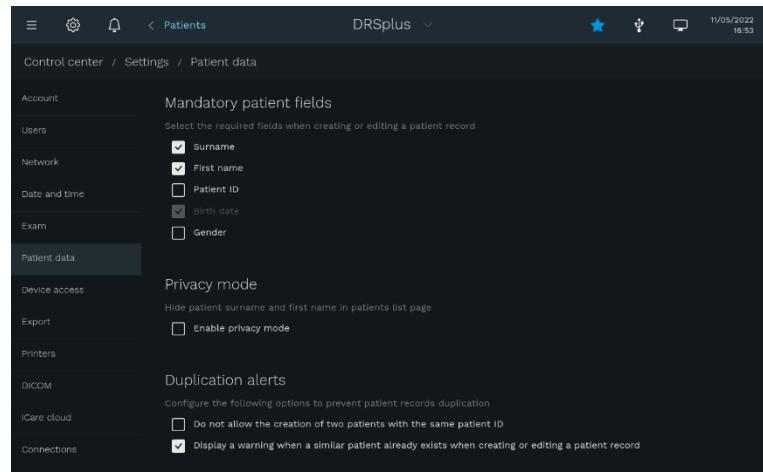


Fig. 111 – Settings|Patient data Screen Imaging modality and exposure

Set the **Mandatory** patient fields to fill when creating or editing a patient record. **At least one** field among Surname, First name, and patient ID must be selected.

An error message appears if you attempt to disable all the possible mandatory fields.

Error: Please select at least one among surname, first name or patient ID

12/10/2022
07:20:50

The *Privacy mode* setting allows enabling the privacy mode. As explained in section 7.7, if the Privacy Mode is activated, the Surname and Name of the patients are replaced by the initials followed by asterisks.

The *Duplication alerts* setting offers two options to prevent record duplication:

- Prevent the creation of multiple patients with the same patient ID by clicking on the upper box.
- Display a warning whenever a created or edited patient record is similar to an existing one with the inferior box.

13.7 Device Access

The *Settings|Device access* Screen (Fig. 112) allows you to configure the security options of the Remote Viewer, including the communication protocol and the session duration.

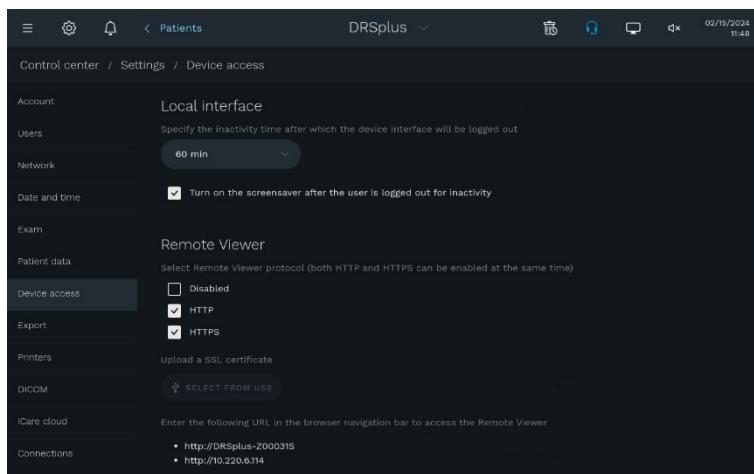


Fig. 112 - Settings|Device access Screen

For the *Local Interface*, select the inactivity time on the dropdown menu after which the device will log out the user. Activate or deactivate a screensaver when the inactivity time has expired. To resume work, you have to log in again.

For the *Remote Viewer*, select the communication protocol.

Select Disabled to temporarily disable the Remote Viewer for the device.

Select the HTTP and or the HTTPS protocol for the remote connection.

When you enable the “HTTPS” protocol, the device will use a self-signed HTTPS certificate. On your browser, accept the certificate once to dismiss the standard warning issued by all browsers.

You can however upload a custom certificate instead of the default one: to install it, store it into a USB device and plug it into the device, then press **SELECT FROM USB** and select the proper file. To remove an installed custom certificate, press the **REMOVE** button to uninstall it and revert back to the default device certificate.

A custom certificate must fulfill the following conditions to be installed on the Device:

- It must be an SSL certificate generated in PEM format
- The private key must not be protected by a passphrase
- It must contain the private key within the certificate file, like in the example file below:



```
-----BEGIN RSA PRIVATE KEY-----  
MIIEogIBAAKCAQEAvmKAUWO/Z0YJu8PMqOOOn1zTp9xHsJp4IRyytS9eMsTIJdxR  
[...]  
sfJw7OZ5bFPCBU+OfSEs24W4W/0Zad8xBveLSMt1jO45sfOPATTI=-----  
END RSA PRIVATE KEY-----  
-----BEGIN CERTIFICATE-----  
MIID1tCCAn2gAwIBAgIJAM9S1YMXAf/RMA0GCSqGSIb3DQEBCwUAMGExCzAJBgNV  
[...]  
3F5jTQf4s6+C-----  
END CERTIFICATE-----
```

Specify the inactivity time for the session running on the Remote Viewer.

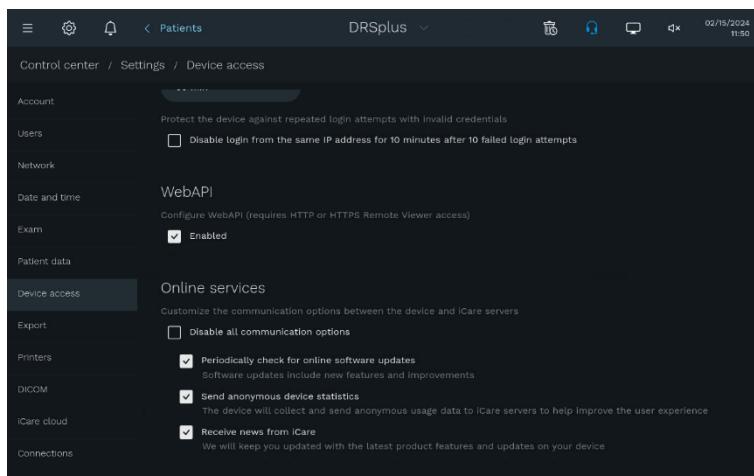


Fig. 113 - Settings|Device access Screen

As an additional security option, you can disable the login from a given IP address for 10 minutes after 10 attempts with invalid credentials.

The *Online services* customize the communication options between the device and the iCare servers. Enable or disable them according to your preferences. It is strongly recommended for security reasons to keep the *Periodically check for online software updates* always enabled.

13.7.1 WebAPI

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

WebAPIs allow:

- Patient data retrieval and management:
 - Retrieval of a patient list (and search)
 - Retrieval of visits list
 - Retrieval of single patient record
 - Retrieval of patient visits and images
 - Patient creation

- Patient editing
- Patient deletion
- Visit deletion
- Image data retrieval and management:
 - Image filters management
 - Download of images in JPG, DICOM or PDF formats
 - Image deletion

For WebAPI functionality refer to DRSplus WebAPI Manual.



The WebAPI functionalities are available only under license.

13.8 Export

Open the *Settings|Export* Screen (Fig. 114) to configure the parameters of the export function.

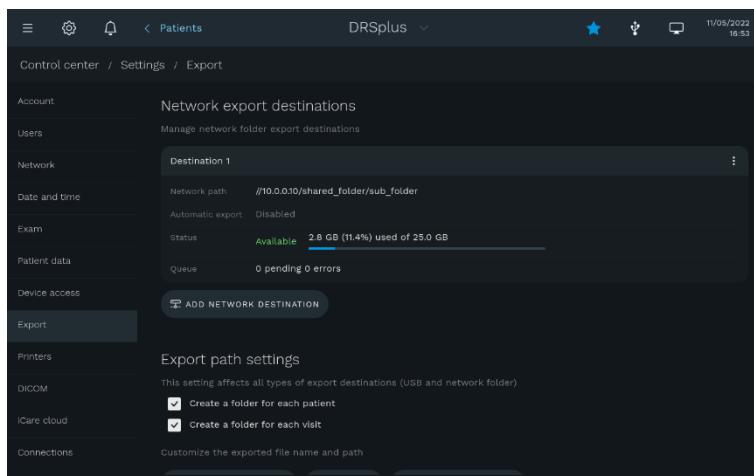


Fig. 114 - Settings|Export Screen, Network Export destination section

Push **ADD NETWORK DESTINATION** to open the *Add new network export destination* Panel and define the shared folder.

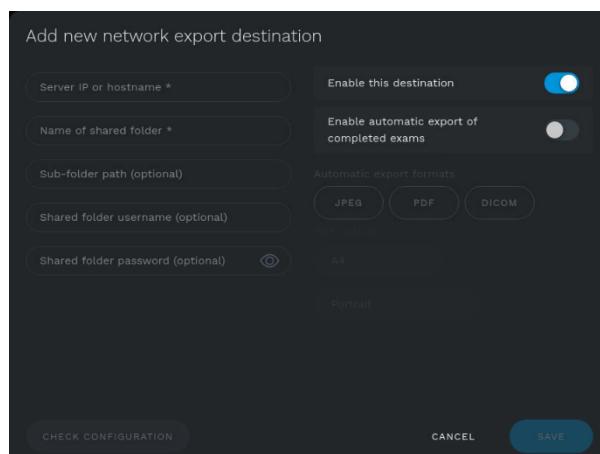
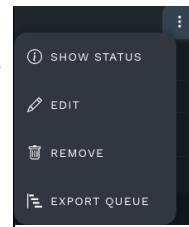


Fig. 115 - Add new network export destination panel

Insert the *Server IP or hostname* and the *Shared folder*, optionally fill the other fields. You can enable or disable the destination and the automatic export of completed exams.

Push **CHECK CONFIGURATION** to verify the connection, **SAVE** to complete the configuration, **CANCEL** to abort.

Press the **ellipsis** at the right of the *Destination* box to **SHOW STATUS** of the network and **PING**, **EDIT** to modify the network parameters, **REMOVE** the network and see the **EXPORT QUEUE** status.



In the *Export path settings* section, select how to group the exported data (with or without a patient folder, with or without a visit folder).

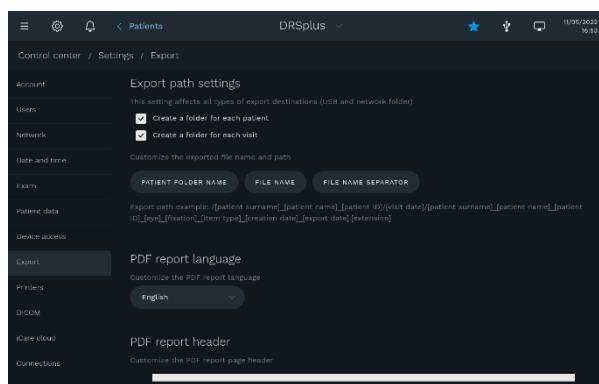


Fig. 116 - Settings|Export Screen, the Export path settings section

Separately customize the **PATIENT FOLDER NAME**, the **FILE NAME** and the **FILE NAME SEPARATOR**.

Default Filename formats are:

Single-image file name

The default file name is composed as follows:

[Surname]_[FirstName]_[PatientID]_[Eye]_[Field]_[ImageType]_[ImageDate]_[ExportingDate]_[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's 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
- ImageType: Type of image acquired, color or infrared
- 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 default filename

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

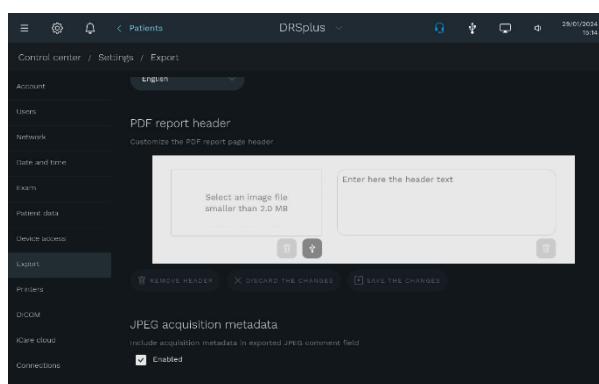
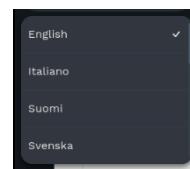


Fig. 117 - Settings|Export Screen, PDF report header section



Select the language for the PDF report from the *PDF report language* dropdown menu. By default, the PDF report language is the language selected during the initial configuration (see Fig. 17).

You can customize the PDF report by adding an image (JPEG, PNG and SVG formats are accepted) and some text. The image size must be smaller than 2.0 MB and the text must not exceed 5 rows.

Enable *JPEG acquisition metadata* to store the metadata of the exam in the JPEG comment section. This information may be useful for troubleshooting purposes if requested by the assistance personnel. Setting this option to "disabled" will improve JPEG export performances.

13.9 Printers

Access the *Settings|Printers* Screen (Fig. 118) to configure the printing subsystem.

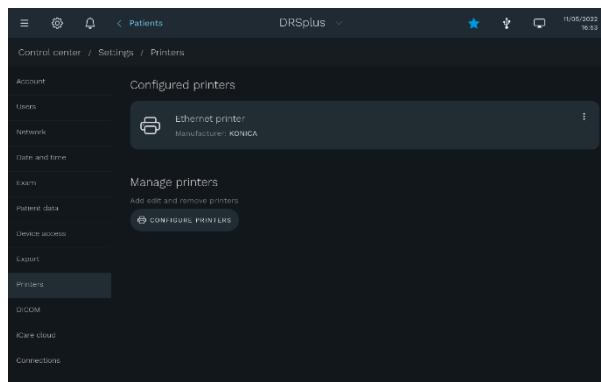


Fig. 118 - *Settings|Printers* Screen

The *Configured printers* section shows the already set printers. Click on the **ellipsis** at the right of this box to **REMOVE** or **CONFIGURE** the printer.

Click **CONFIGURE PRINTERS** to add, edit and remove printers.

You can access two main panels selectable using tabs:

- *Administration* (Fig. 119)
- *Printers* (Fig. 129 – “Printers” panel)

In the *Administration* Panel is possible to

- Add a printer
- Find new printers
- Manage Printers

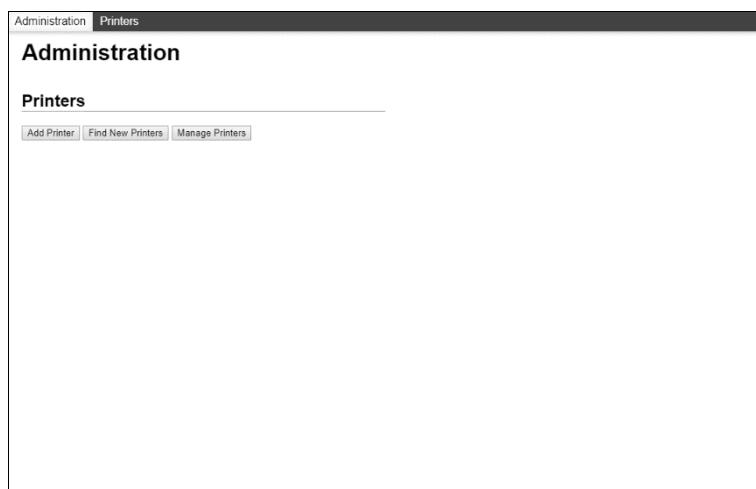


Fig. 119 - *Administration* panel

Press the **Add Printer** button in the *Administration* Panel shown in Fig. 119: 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 to 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

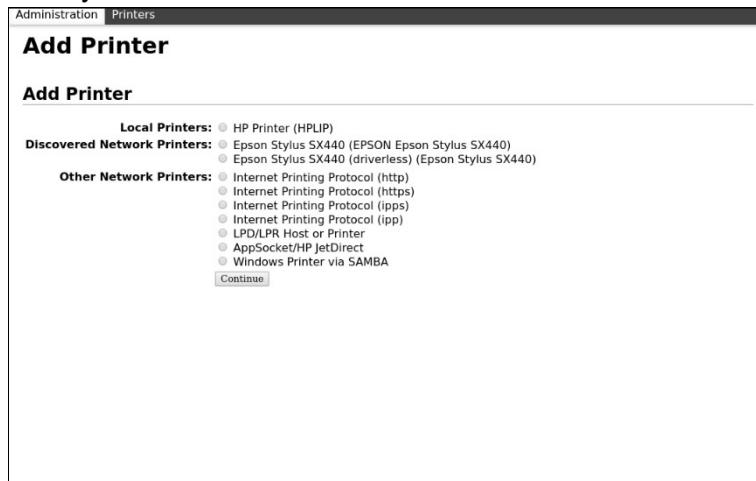


Fig. 120 – “Add Printer” panel

In the Printers panel, the printers configured for the device are listed and can be managed. WiFi Direct connection with printers is not available.

13.9.1 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. 121).

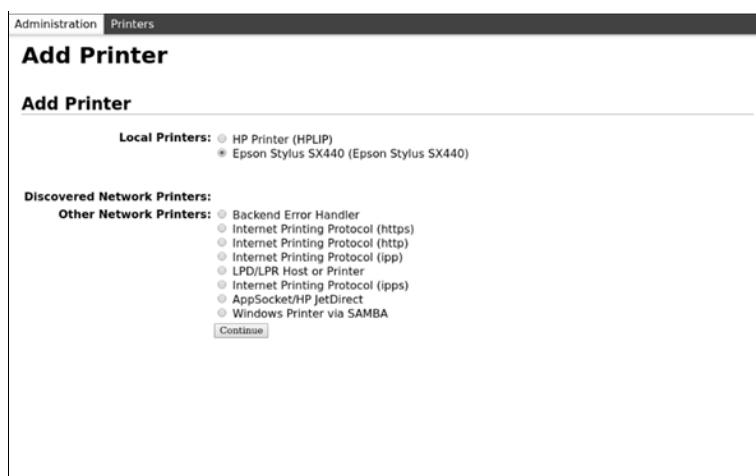




Fig. 121 – “Printer Identification” panel pre-set with automatic detection information

In this panel can be set the Name, which is used in printer selection dialogue during image 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 the 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 using the Choose File button.

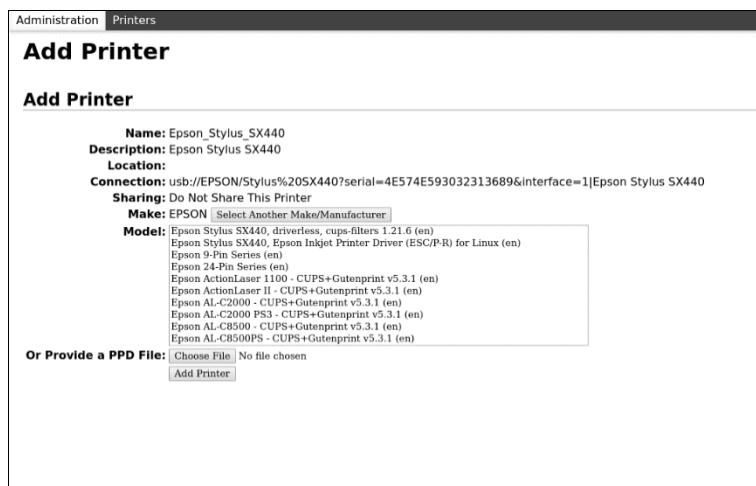
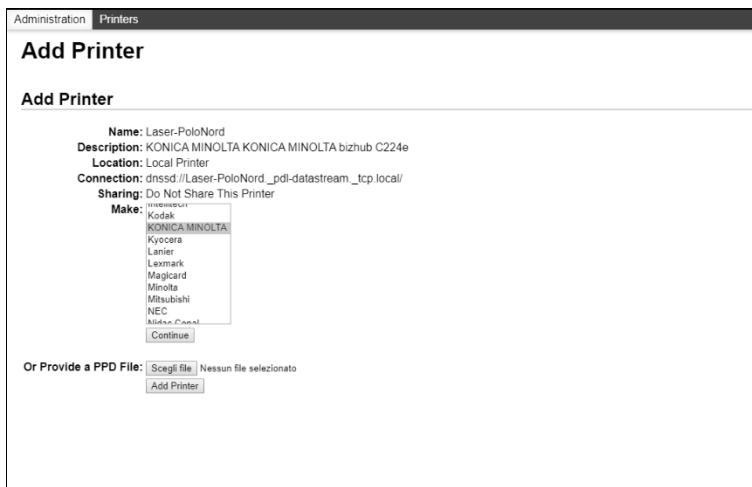


Fig. 122 – “Printer Model Selection” panel

In case the producer of the printer is not shown automatically, it can be selected in the 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 shown¹² (Fig. 123).

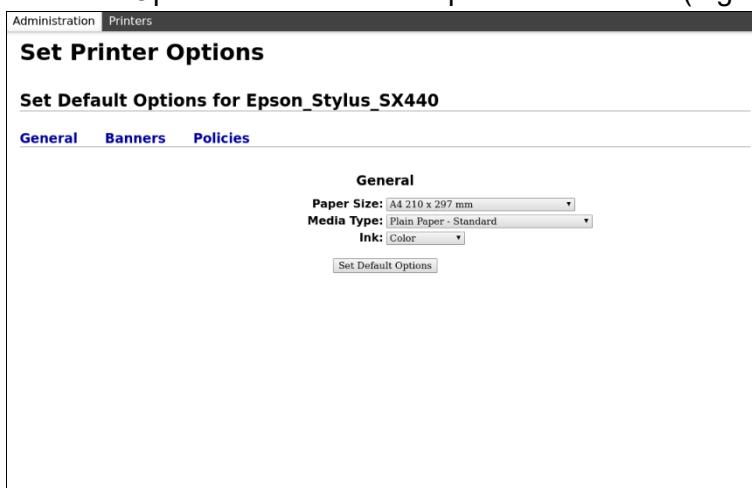


Fig. 123 – “Default Options Setting” panel, Banners tab

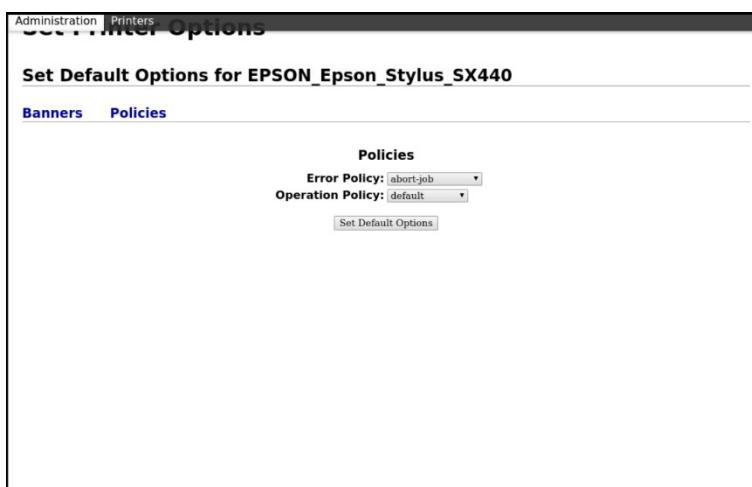


Fig. 124 – “Default Options Setting” panel, Policies tab

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.

¹² The Set Default Options doesn't influence the selection of the paper format set in Print Configuration pop-up shown in §10.

The Default Options Setting panel depends on the printer's characteristics. In the case of a multifunction printer, a panel like Fig. 125 can be presented.

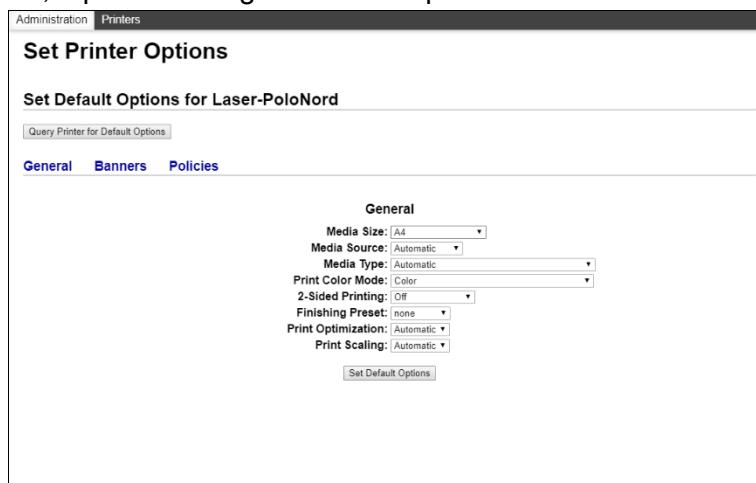


Fig. 125 – Set Default Options for a multifunction printer

With the Banners tab, it 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, the access control can be defined.

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

13.9.2 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. 126).

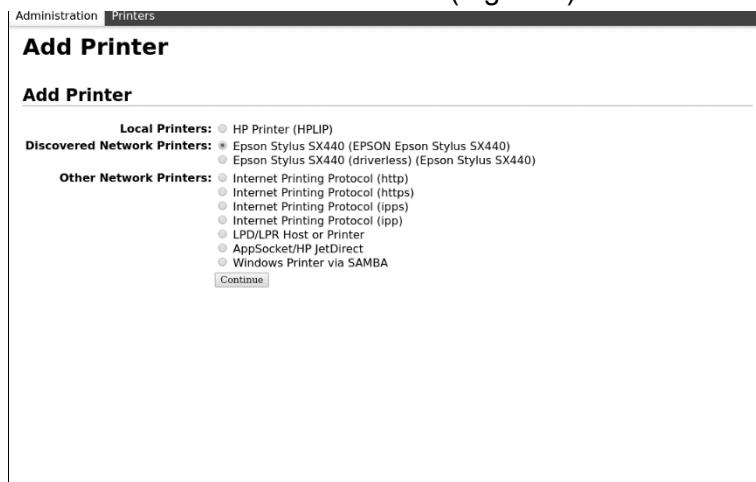


Fig. 126 – “Network Printers Selection” panel

Selecting the desired network printer, in this case, Epson Stylus SX440, and pressing Continue, the same printer identification panel shown in Fig. 121 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. 122, and it can be configured as explained in §13.9.1. Also, in this case, press the Add Printer button to see the Set Default Options for the selected printer (Fig. 123) as in §13.9.1.

13.9.3 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 using 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. 127).

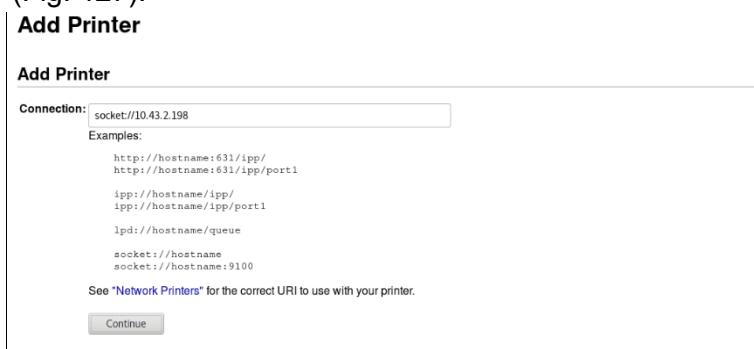


Fig. 127 – URI Printer Configuration

AppSocket Protocol

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

Device URLs 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 URLs 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 the 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 URLs 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

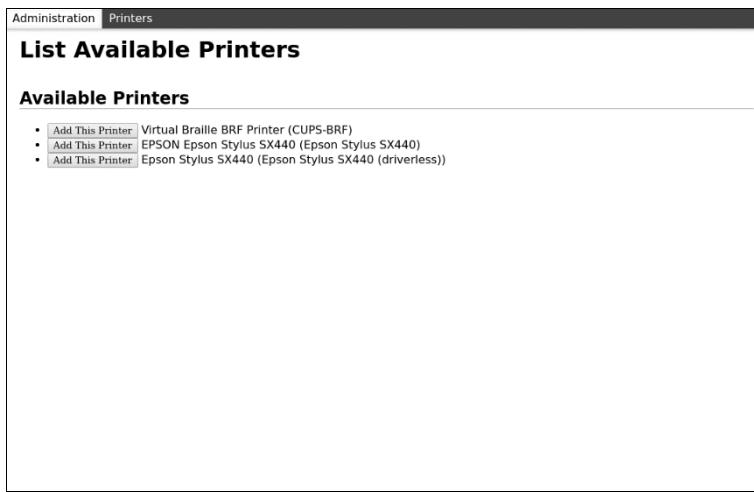
The following table summarizes the options supported.

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.
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.

Option	Description
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).

13.9.4 Find New Printers

Pushing the Find Printers button in the Administration panel, the Available Printers panel is shown (Fig. 128).



The screenshot shows a web-based administration interface. The top navigation bar has tabs for 'Administration' and 'Printers', with 'Printers' being the active tab. Below the navigation is a title 'List Available Printers'. Under this title is a section header 'Available Printers'. A list of three printers is displayed, each with an 'Add This Printer' button to its left:

- Virtual Braille BRF Printer (CUPS-BRF)
- EPSON Epson Stylus SX440 (Epson Stylus SX440)
- Epson Stylus SX440 (Epson Stylus SX440 (driverless))

Fig. 128 – “Available Printers” panel

If the desired printer is listed, push 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 §13.9.1, to configure it.

13.9.5 Printers panel

In the *Printers* panel, all the configured printers are listed (Fig. 129).



The screenshot shows the 'Printers' panel of the administration interface. The top navigation bar has tabs for 'Administration' and 'Printers', with 'Printers' being the active tab. Below the navigation is a title 'Printers'. Under this title is a search bar with 'Search in Printers:' and buttons for 'Search' and 'Clear'. Below the search bar is a message 'Showing 1 of 1 printer.' A table lists the configured printer:

Queue Name	Description	Location	Make and Model	Status
Laser-PoloNord	KONICA MINOLTA KONICA MINOLTA bizhub C224e	Local Printer	KONICA MINOLTA bizhub C258, driverless, cups-filters 1.21.6	idle

Fig. 129 – “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. 130).

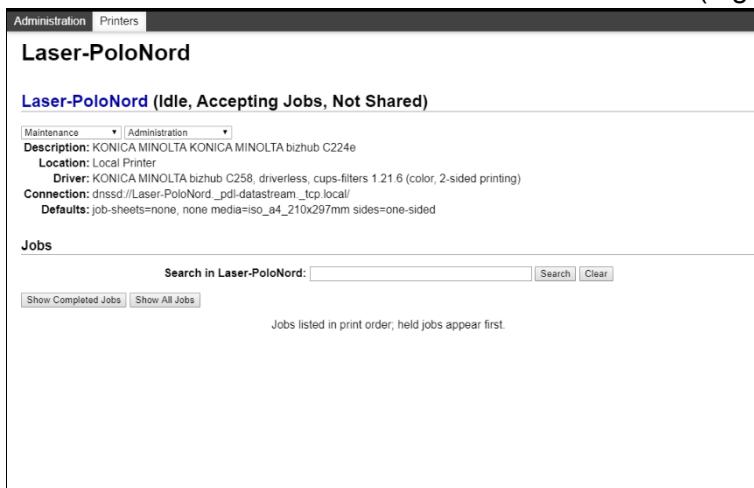


Fig. 130 – “Printer” panel

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

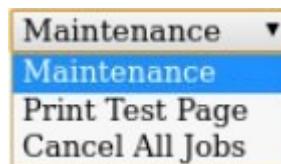


Fig. 131 – Maintenance Activities list

- 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

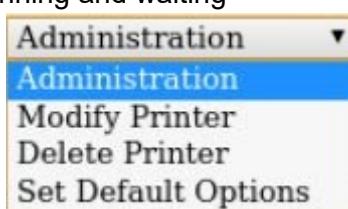


Fig. 132 – Administration Activities list

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
 - The printer can be deleted, after confirmation (Fig. 133)

- Set default options
 - Can modify the Default Options using the panel in Fig. 123 and Fig. 125

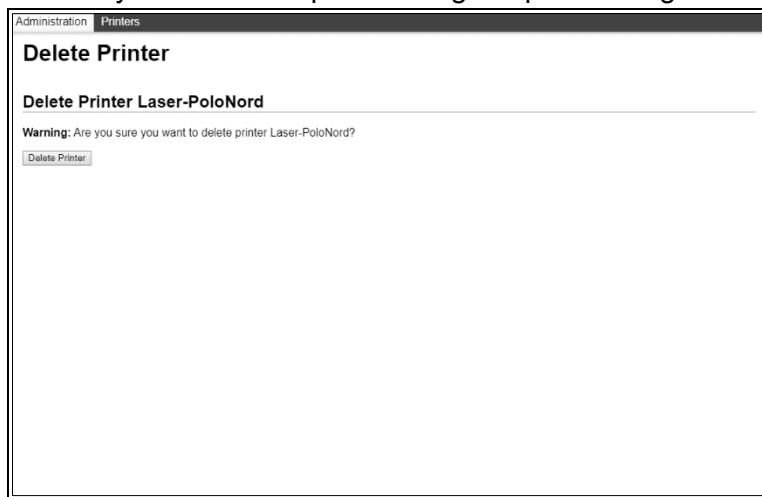


Fig. 133 – “Delete Printer” panel

13.10 DICOM Functionality

Access the *Settings|DICOM* Screen (Fig. 134) to set the DICOM configuration.

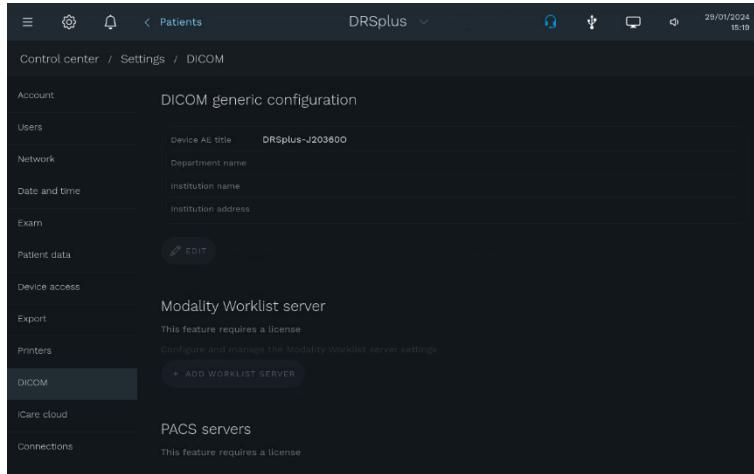


Fig. 134 - *Settings|DICOM* Screen

DICOM is an international standard for distributing and viewing medical images and related information. DRSplus supports DICOM¹³ and DICOMweb¹⁴ communications as specified in the **DICOM Conformance Statement document**¹⁵. For more information, refer to DRSplus *DICOM User Manual*.

¹³ The DICOM Feature for DRSplus is available under license only: please refer to your local Authorized Distributor for detailed information.

¹⁴ The DICOMweb Feature for DRSplus is available under license only: please refer to your local Authorized Distributor for detailed information.

¹⁵ Please refer to your local Authorized Distributor for the DRSplus DICOM conformance statement.

13.11 iCare Cloud

Access the *Settings|ICARE CLOUD* Screen (Fig. 135) to set the iCare Cloud Interface.

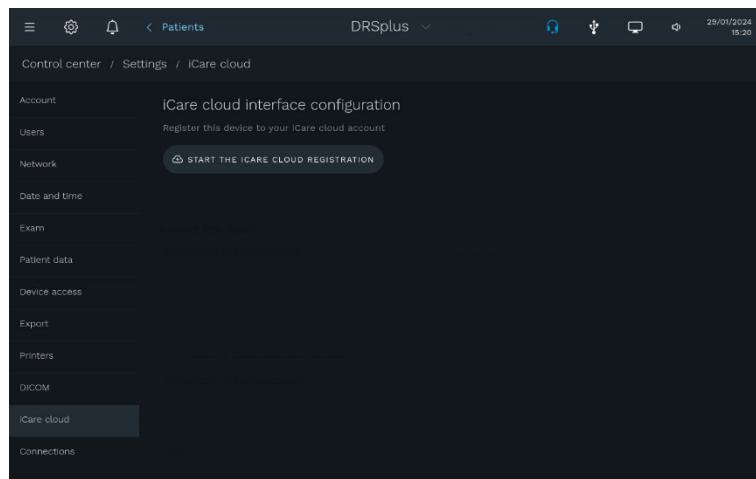


Fig. 135 - *Settings|ICARE CLOUD* Screen

The iCare Cloud Interface is a service that allows a DRSplus to connect to the iCare Cloud platforms. It enables the connection to iCare ILLUME and iCare ALTIUS platforms¹⁶.

Verify that

1. the device is connected to the Network, via Ethernet or WiFi.
2. the device reaches the following domains and their relative sub-domains via https:

Domain	Protocol	Port
*.icare-world.cloud	HTTPS	443
*.eu-north-1.amazonaws.com	HTTPS	443
api.centervue.net	HTTPS	443
*.cloudfront.net	HTTPS	443

Please note that at this stage we do not support connecting to our services using an HTTP Proxy.



The iCare ILLUME and iCare ALTIUS functionalities are available only under license.

¹⁶ Please refer to your local Authorized Distributor for detailed information about the ILLUME product and license.

13.11.1 iCare Cloud Registration

Click the **START THE ICARE CLOUD REGISTRATION** button to start the registration of the device.

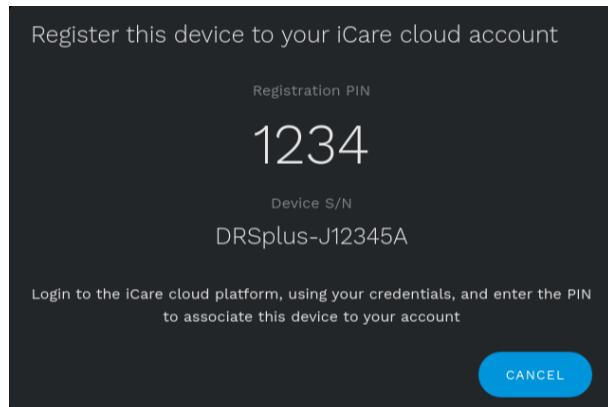


Fig. 136 - Registration PIN Screen

Push the **START THE REGISTRATION** button to confirm, push **CANCEL** to abort. Register the device on the iCare ILLUME or iCare ALTIUS platforms using the Registration PIN shown on the device (Fig. 136).

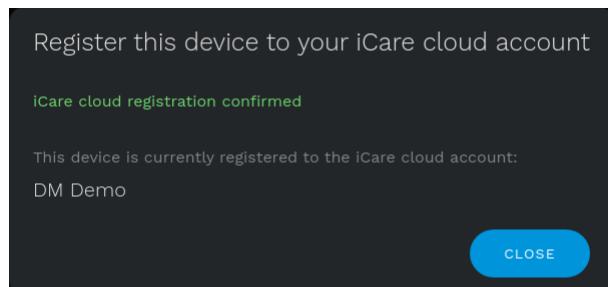


Fig. 137 Registration panel on the ILLUME platform

Push **CLOSE** on the *Registration PIN* screen to go back to the ICARE CLOUD screen.

When the iCare Cloud service is registered, a new icon appears on the Topbar of the screen (see §12.1)



13.11.2 iCare Cloud options

When the iCare Cloud services are enabled, the ICARE CLOUD shows the name of the iCare Cloud account connected, the upload status, the number of exams uploaded, and the status of the service (see Fig. 138).

Function	Command
Push START UPLOADER to start the upload of the exams to the iCare cloud service	START UPLOADER
Push PAUSE UPLOADER to stop the upload of the exams to the iCare cloud service.	PAUSE UPLOADER

Function	Command
Push VIEW THE UPLOAD QUEUE to open the <i>iCare cloud upload queue</i> window (See Fig. 139).	
Push UPLOAD HISTORICAL EXAMS to upload the exams acquired before the activation of the iCare Cloud service (available only for iCare ALTIUS).	

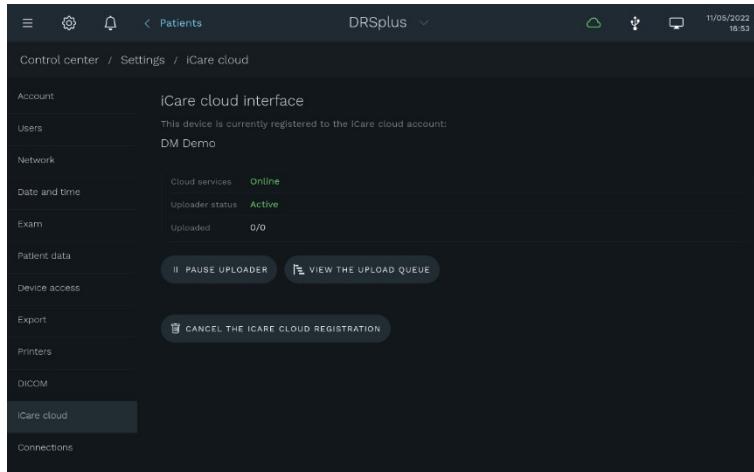


Fig. 138 Registered

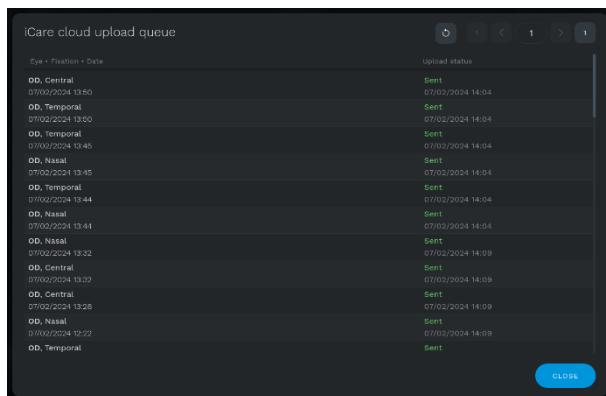


Fig. 139 Export queue

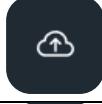
13.11.3 iCare Cloud status icon

If the iCare Cloud Service is enabled on the device, the iCare Cloud icon on the top bar of the screen shows the status of the service.

The device is registered to a cloud account, and all the items in the cloud queue have been synced.

The device is processing the upload queue and sending the pending items to the cloud.

The upload process is paused. The new exams will be in the queue and will be uploaded as soon as the operator starts the upload.



The device is unable to contact the cloud server. No item is pending upload.



The device is unable to contact the cloud server. At least one item is pending upload.

13.11.4 iCare Cloud de-registration

The device can be associated with a unique account. Before connecting the device to another iCare Cloud account, you shall de-register the device.

Push **CANCEL THE ICARE CLOUD REGISTRATION** to de-register the device from the iCare Cloud account. Push **CONFIRM** to deactivate the connection, push **CANCEL** to abort the operation.

13.12 Connections

Access the *Settings|Connections* Screen (Fig. 140) to configure the external connection services.

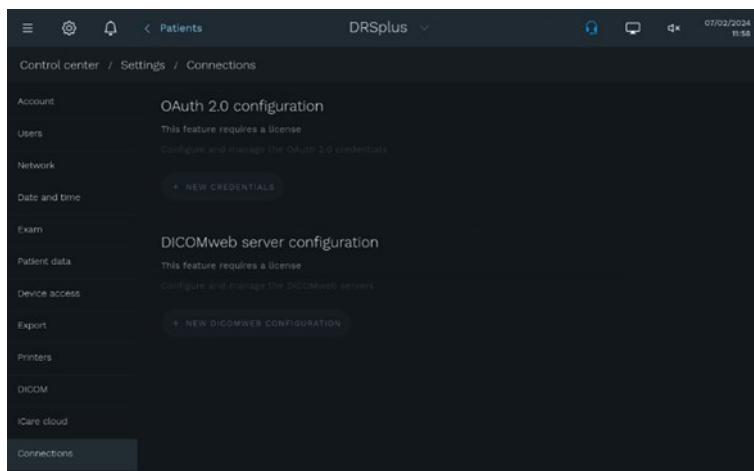


Fig. 140 – *Settings|Connections* Screen

The connection Screen is a comprehensive way to see and edit the connection of the device to third-party internet services. For OAuth 2.0 and DICOMweb refer to DRSplus DICOM Manual.



The *Connections* tab appears when a DICOMweb license is active on the device.

14. Utilities

The *Utilities* Screen contains a set of functionalities to keep the device updated, manage the data backup and ask for assistance (see Fig. 141).

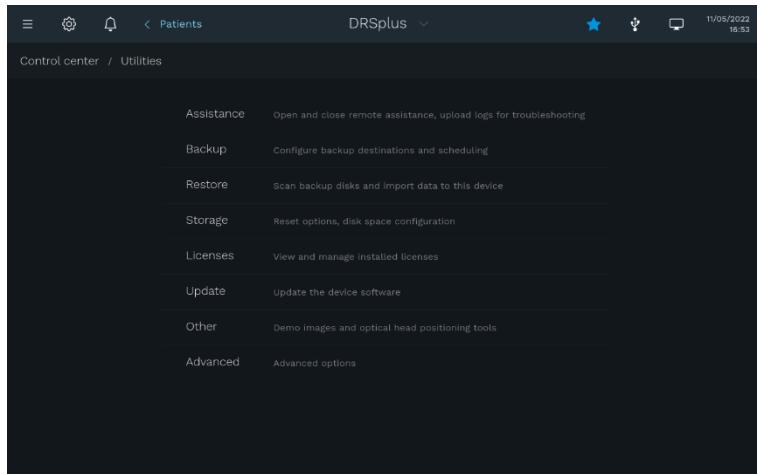


Fig. 141 - Utilities Screen

To access the system *Utilities* Screen, click the **UTILITIES** button on the *Control center* Screen.



14.1 Assistance

Access the *Utilities|Assistance* Screen (Fig. 142) to open a Remote Assistance (R.A.) session or to export diagnostic data for technical troubleshooting purposes.

14.1.1 Remote assistance

The Remote Assistance allows an iCare/CenterVue operator to connect to the device.

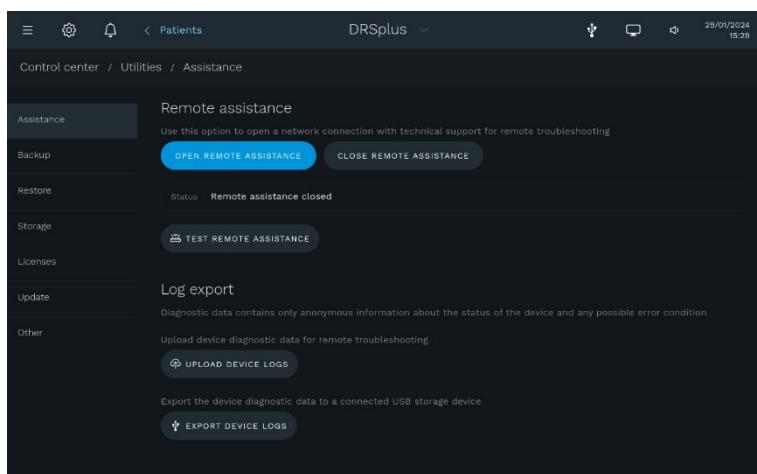


Fig. 142 – Utilities|Assistance Screen

Push **OPEN REMOTE ASSISTANCE** to open the *Authorize remote assistance by your own action* pop-up (see Fig. 143).

OPEN REMOTE ASSISTANCE

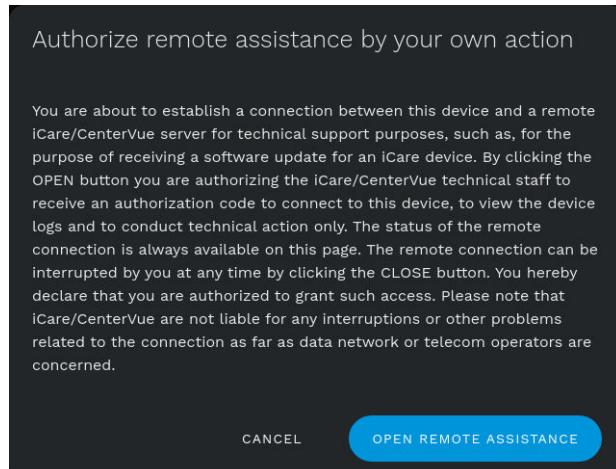


Fig. 143 –Authorize remote assistance by your own action pop-up

Push **OPEN REMOTE ASSISTANCE** to open the *Authorize remote assistance by your own action* pop-up.

OPEN REMOTE ASSISTANCE

A pop-up warns you that Remote assistance is available and shows the *Authorization code*. Click **OK** to close the pop-up.

Remote assistance available

This device can now be controlled remotely.
Authorization code: 25620-232317

OK

Communicate the *Authorization Code* to the remote operator for allowing him to connect to the device.

Only after the remote operator has confirmed that the assistance activity is completed, you can close the R.A.

Push **CLOSE REMOTE ASSISTANCE** to open the *Close remote assistance* pop-up (see Fig. 144).

CLOSE REMOTE ASSISTANCE

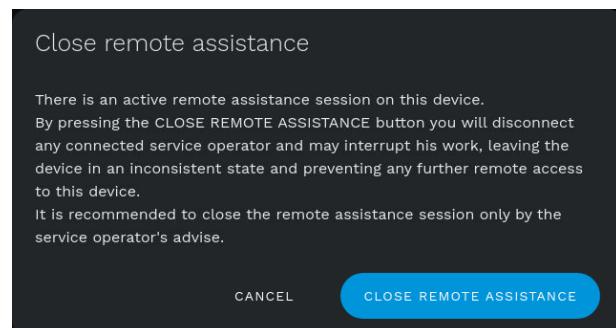


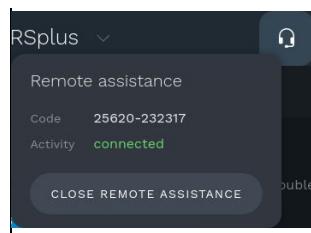
Fig. 144 - Close remote assistance pop-up



Remote Assistance always requires an internet connection.

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.



14.1.2 Log Export

In the *Log Export* section, you can extract diagnostic data of the device for service purposes.

UPLOAD DEVICE LOGS exports diagnostic data to an iCare/CenterVue server. **It requires an internet connection.**

Push **UPLOAD DEVICE LOGS** to open the *Upload diagnostic or statistic data* pop-up (see Fig. 145).

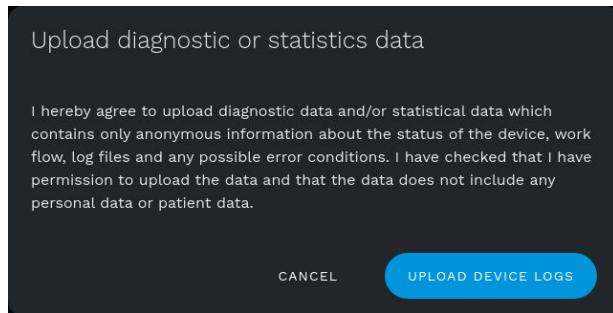


Fig. 145 – *Upload Device Logs* pop-up

Push **UPLOAD DEVICE LOGS** to start the logs transfer.

EXPORT DEVICE LOGS saves the diagnostic data of the device into a connected USB storage device. Connect a USB storage device in the rear of DRSplus (see Fig. 13).

Push **EXPORT DEVICE LOGS** to select the *USB disks* (see Fig. 145).

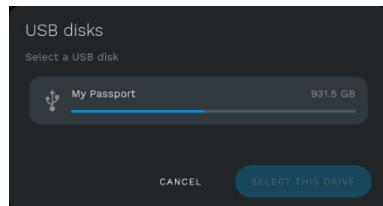


Fig. 146 – *Upload Device Logs* pop-up

Touch the box of the **USB DISK** you want to use to highlight it (see Fig. 147) and then push **SELECT THIS DRIVE** to start the logs export.

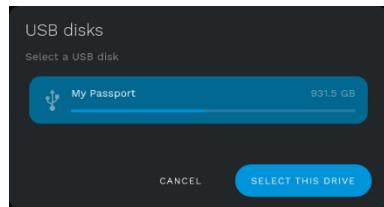


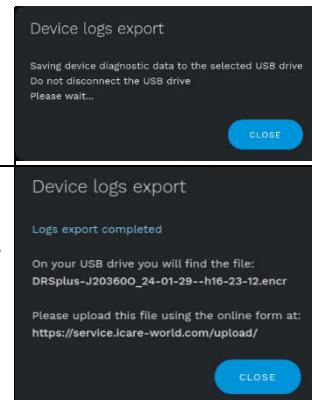
Fig. 147 – Upload Device Logs pop-up, USB DISK selected

A pop-up informs you that the export is in progress. Wait until it is completed, or push **CLOSE** to abort the operation.

When the export is completed, the pop-up informs you about the name of the export file *DRSplus-<SerialNumber>_<Date and time>.tar.gz*.

Push **CLOSE** to return to the *Utilities|Assistance* Screen.

Extract the USB storage data, plug it into a PC. Open the <https://service.icare-world.com/upload/> link in a browser and upload the file through the form you will find.



14.2 Backup

Access the *Utilities|Backup* Screen (Fig. 148) to backup the patient data stored in the onboard disk. Data can be backed up on a remote *Network backup* through an IP connection or into an external, *USB backup* through a connected memory device (flash memory or disk).

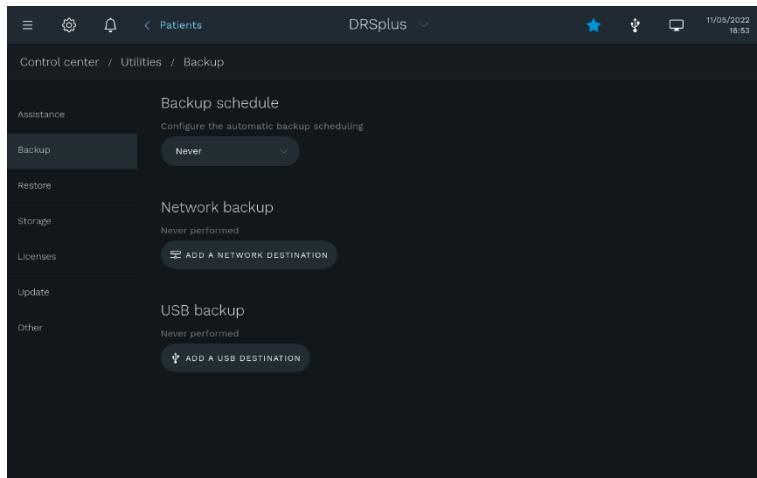


Fig. 148 – Utilities|Backup Screen

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

From the *Backup Schedule* dropdown menu, you can configure the automatic backup.

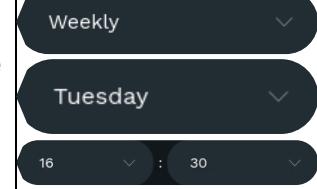
Select **Never** to perform the backup manually.



Select **Daily** to enable the automatic backup once a day. Configure the **time** from the hours and minutes dropdown menus.



Select **Weekly** to enable the backup once a week. Configure the backup **Day** from the dropdown menu. Configure the **time** from the hours and minutes dropdown menus.



To set up a *network backup*, push the **ADD A NETWORK DESTINATION** button. The *Add new network backup destination* panel appears.



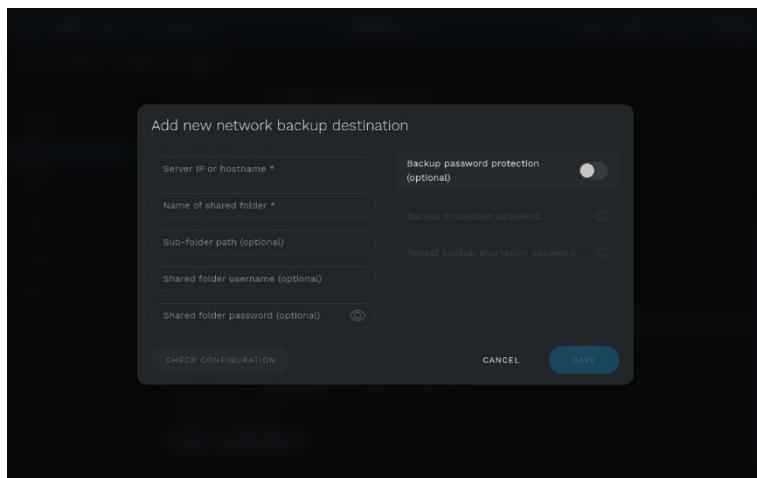


Fig. 149 – Add new network backup destination panel

Configure the mandatory parameters.

To encrypt the backup data, enable **Backup password protection**. Be careful to avoid losing the backup password.

Once the password is set, the backup can be performed by any user without knowing the password, but **the backup can be restored only with the backup password**. Without the password, the data cannot be restored, not even by iCare/CenterVue service personnel.



PASSWORD-PROTECTED BACKUPS CAN NOT BE RESTORED OR RECOVERED IF THE PASSWORD IS LOST.

Click **CANCEL** to abort the operation, **CHECK CONFIGURATION** to test the added backup network destination, **SAVE** to complete the configuration and revert to the *Utilities|Backup* Screen.

To set up backup on a USB storage device, push the **ADD A USB DESTINATION** button. The *USB disks* pop-up appears.

ADD A USB DESTINATION

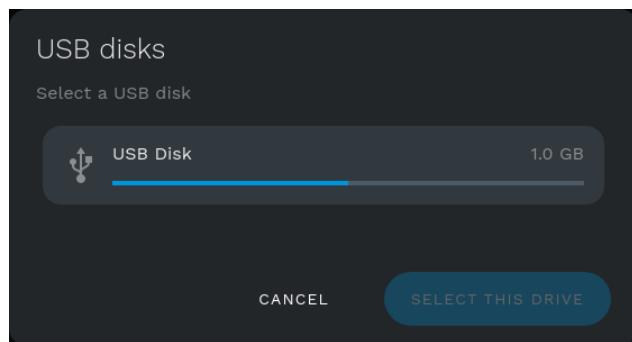


Fig. 150 - USB disks pop-up

Select the *USB DISK* to use for the backup. Push **CANCEL** to abort the operation, push **SELECT THIS DRIVE** to complete the set-up.

The first time you configure an **automatic** Backup on a valid location (Network or USB), a backup automatically starts, as you can see in the *Backup progress* pop-up (Fig. 151).

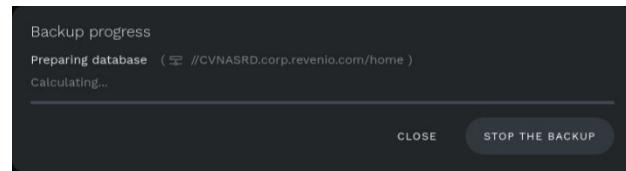


Fig. 151 - Backup progress pop-up

Click **STOP THE BACKUP** to abort the operation. To complete the backup, you can either wait until the end of the process or click **CLOSE**. When you click **CLOSE**, you will revert to the *Utilities|Backup* Screen while the backup operation will continue (see Fig. 152).

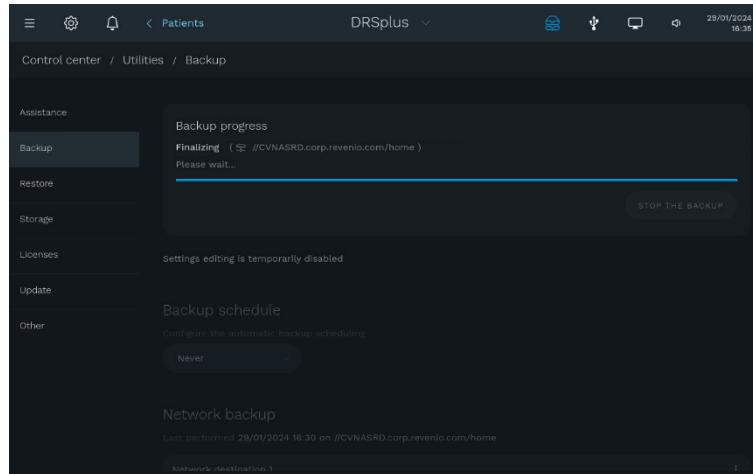


Fig. 152 – Utilities|Backup Screen, Backup progress

When the backup is completed, a pop-up appears. Click **CLOSE** to revert to the *Utilities|Backup* Screen, in which you will find the information about the date and time of the *Last performed* backup (see Fig. 153).

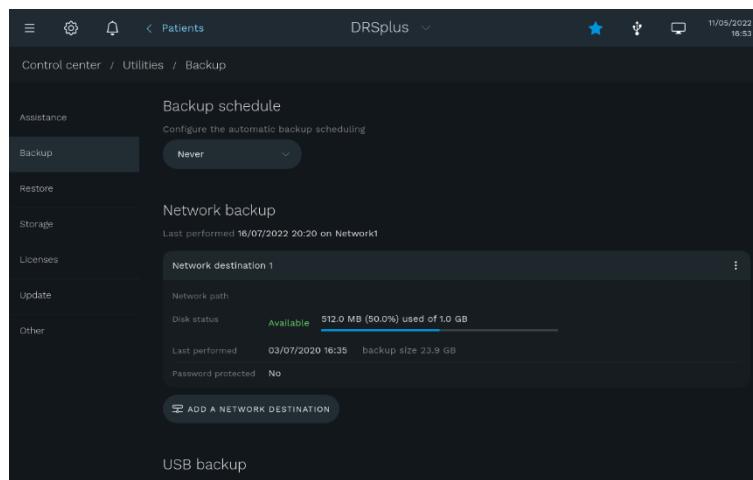
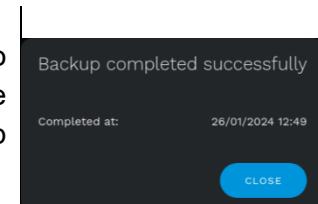


Fig. 153 – Utilities|Backup Screen, Last performed backup

You can find here the *Network path*, the *Disk status*, the date and time of the *last performed* backup, the backup size and the *Password protected* option.

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

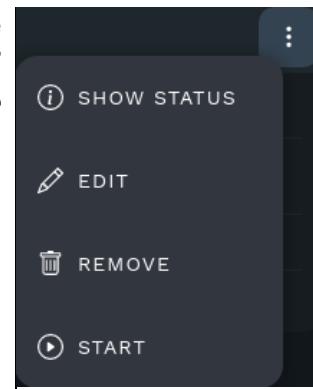
It is the end user's responsibility to keep an updated backup of the data generated by DRSplus through regular use of the backup utility



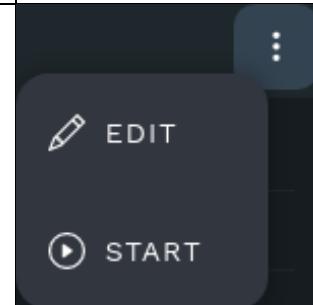
The Manufacturer declines all liability for loss of data due to hard disk failures.

Manual alterations of the files generated by the backup utility may affect the recovery of data

Click on the **ellipsis** at the right of the *Network destination*. In the menu, click **SHOW STATUS** to check the *Network disk status*, **EDIT** to *Edit the network backup destination*, **REMOVE** to *Remove the backup destination* or **START** to manually start a backup operation.



Click on the **ellipsis** at the right of the *USB destination*. In the menu, click **EDIT** to *Edit the USB backup destination* and add a backup password, or click **START** to manually start a backup operation.



14.3 Restore

The *Utilities|Restore* Screen (Fig. 154) provides the utility to restore from a backup. The Screen 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 DRS. Only backup images created by DRS devices running software 2.5.0 or greater can be imported into DRSplus.

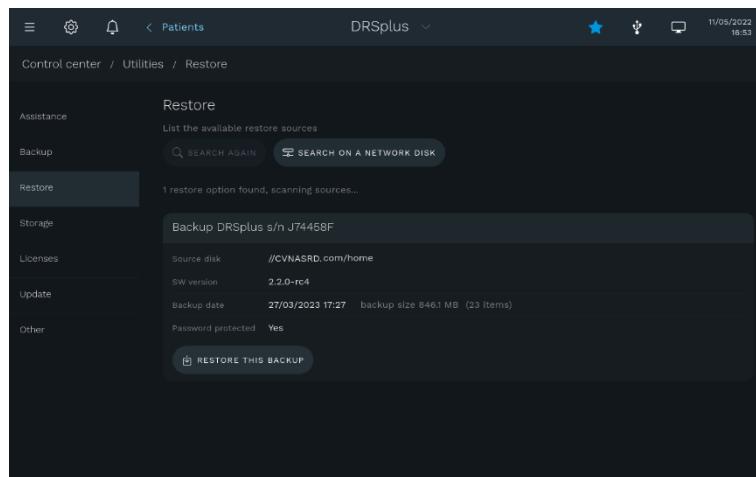


Fig. 154 – Utilities|Restore Screen

Click **SEARCH AGAIN** to scan the available restore sources.



Click **SEARCH ON A NETWORK DISK** to open the *Search on a network disk* panel (Fig. 155).



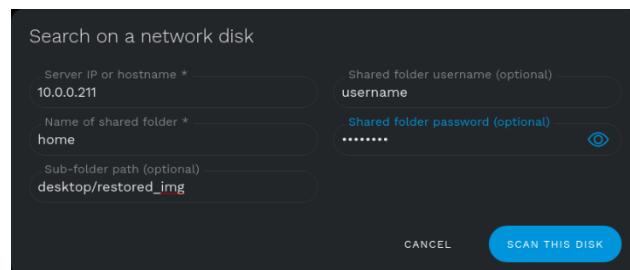


Fig. 155 - Search on a network disk panel

Manually insert the address of the restore position. Click **CANCEL** to abort the operation, click **SCAN THIS DISK** to proceed

Click **RESTORE THIS BACKUP** to start the restore process. The *Confirm the restore* pop-up appears (Fig. 156).



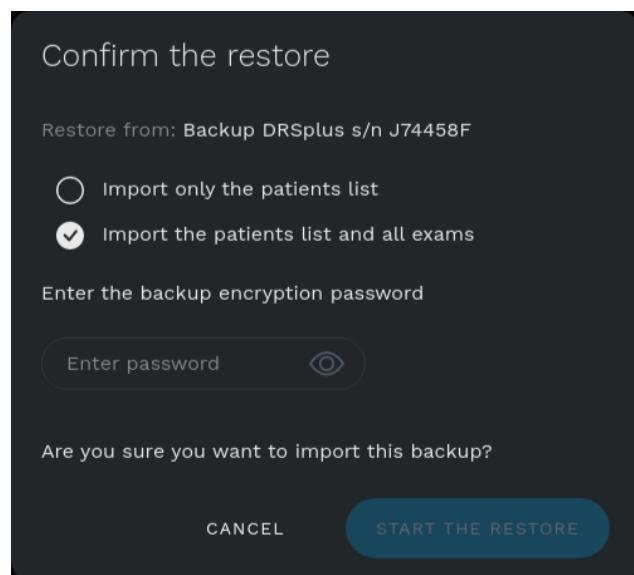
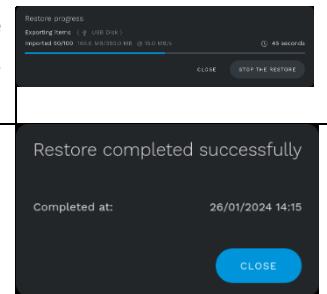


Fig. 156 - Confirm the restore pop-up

Alternatively, select to *Import only the patients list* or *Import the patients list and all exams*. Click **CANCEL** to abort the operation, click **START THE RESTORE** to complete it. The box of the encryption password appears when a password has been previously set for the backup (see §14.2). Input the backup password to proceed.

When the restore starts, a pop-up appears. You can **CLOSE** the pop-up to revert to the *Utilities|Restore* Screen while the restore is in progress. Click **STOP THE RESTORE** to interrupt the process.

A pop-up appears at the end of the restore process. Click **CLOSE** to revert to the *Utilities|Restore* Screen.



14.4 Storage

The **Utilities|Storage** Screen (Fig. 157) allows resetting the device and configuring a threshold for the data storage memory. Only an **Administrator account** has the permission to modify the configurations.

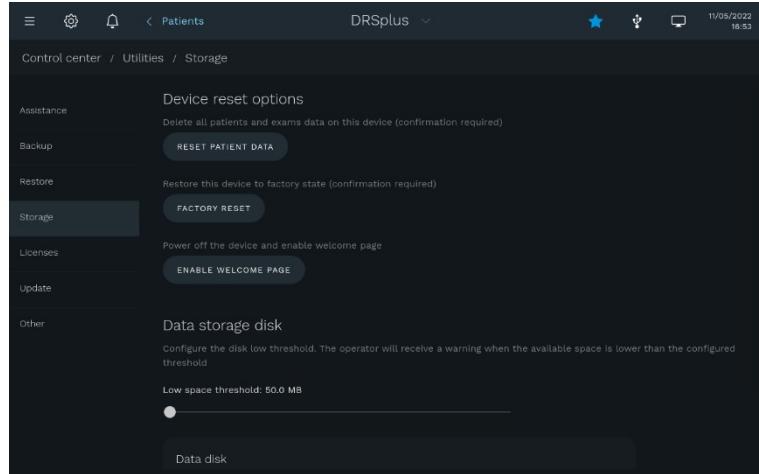


Fig. 157 – Utilities|Storage Screen

Click **RESET PATIENT DATA** to delete all patients and exams data from the device. The *Reset patient data* pop-up appears (Fig. 158).

RESET PATIENT DATA

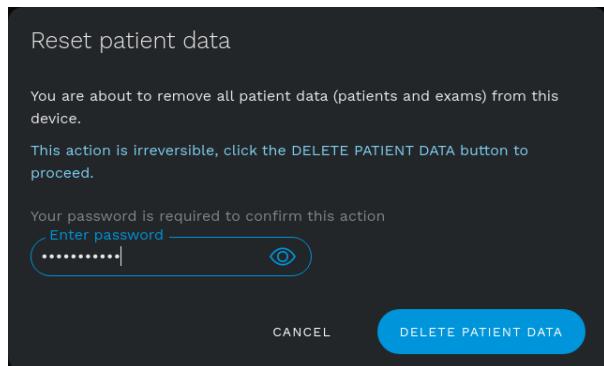


Fig. 158 - Reset patient data pop-up

Enter the Administrator password. Click **DELETE PATIENT DATA** to proceed with the reset, click **CANCEL** to abort. **The reset is an irreversible process.**

A pop-up warns you that the reset is in progress. At the completion, the pop-up is automatically closed and you will return to the **Utilities|Storage** Screen.

Click **FACTORY RESET** to bring back the device to the factory configuration. The *Factory reset* pop-up appears (Fig. 159).

Reset patient data

Reset in progress, please wait...

FACTORY RESET

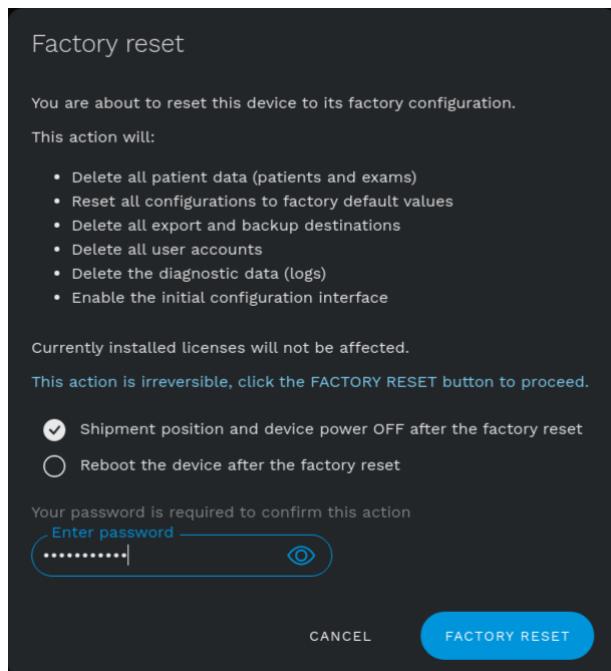


Fig. 159 – Factory reset pop-up

To enable the *Factory reset*, insert the Administrator password. Alternatively, select to put the device in the Shipment position, or to Reboot the device after the reset. Click **CANCEL** to abort the operation, click **FACTORY RESET** to proceed. **The factory reset does not alter or erase the installed licences.**

Click **ENABLE WELCOME PAGE** to bring back the device to the welcome page. The *Enable welcome page* pop-up appears (Fig. 160).

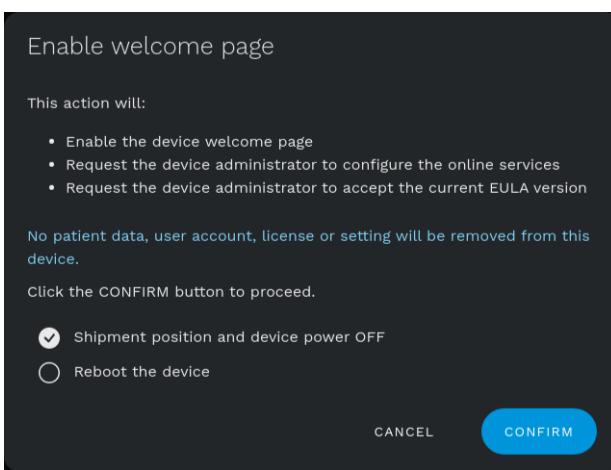


Fig. 160 – Enable welcome page pop-up

At the reboot, the acceptance of the End-user Licence Agreement and the online services will be again requested. Alternatively, select to bring the device to the shipment position or simply reboot the device.

The *Data storage disk* section provides information about the Data disk usage inside the device (see Fig. 161).

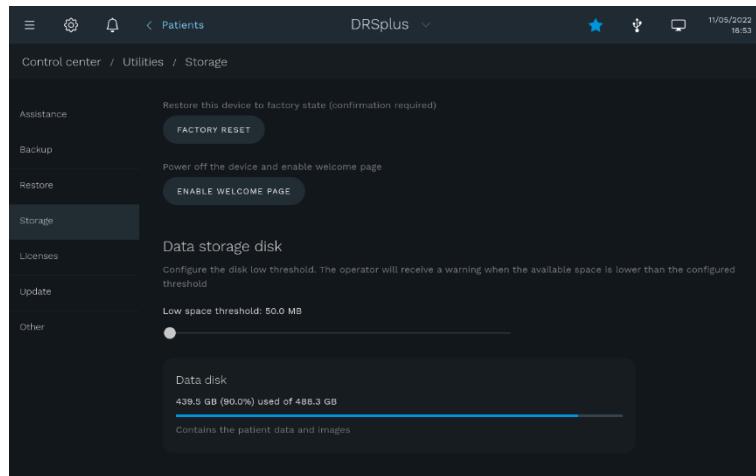


Fig. 161 - Data storage disk

In the *Low space threshold*, select with the slider the threshold of free space under which a warning pop-up appears (Fig. 162).

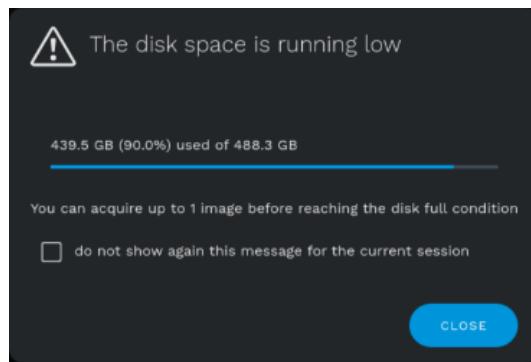
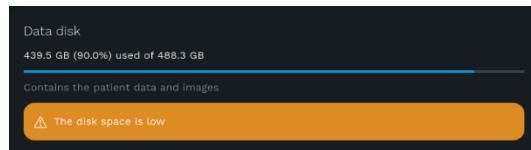


Fig. 162 - Disk space running low pop-up

The warning remains at the bottom of the *Utilities|Storage* Screen.



When the remaining memory does not allow acquiring additional exams, a *Disk full* pop-up appears (Fig. 163) and the image acquisition is disabled.

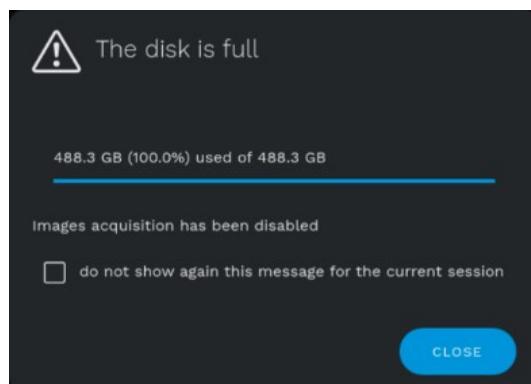
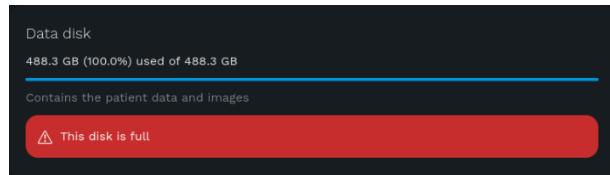


Fig. 163 - Disk full pop-up

Push **CLOSE** to close the pop-up. After closing the pop-up, the error message remains at the bottom of the *Utilities|Storage* Screen. Contact the iCare/CenterVue service for troubleshooting.



14.5 Licenses

Access the *Utilities|Licenses* Screen (Fig. 164) to manage optional licenses. It shows the installed licenses on the device and allows to either revoke a license or to install a new one¹⁷.

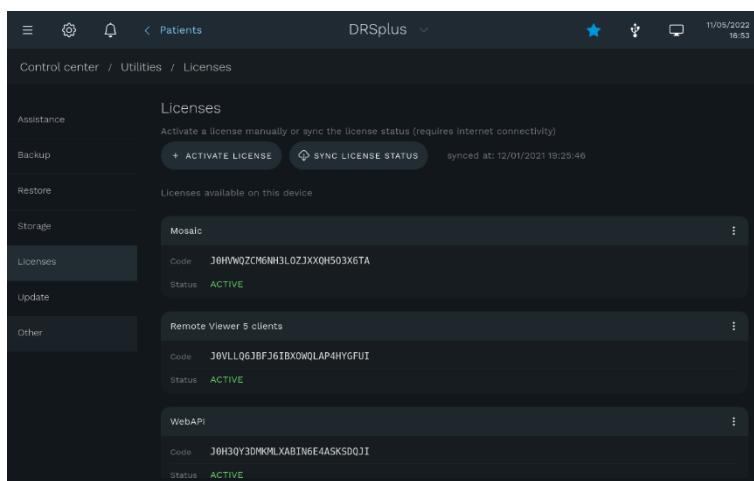


Fig. 164 - Utilities|Licenses Screen

DRSplus will automatically download any assigned license when connected to the iCare/CenterVue License Server. A suitable network configuration and internet connection are required.

Push **SYNC LICENSE STATUS** to immediately synchronize the status of the device licences from the iCare/CenterVue server. At the right of the button, the information about the last synchronization appears (see Fig. 164).

 SYNC LICENSE STATUS

Click **ACTIVATE LICENSE** to manually activate a license. In the *Activate licence* pop-up (Fig. 165). Insert the license code and push **ACTIVATE**, or click **CANCEL** to abort the operation.

 + ACTIVATE LICENSE

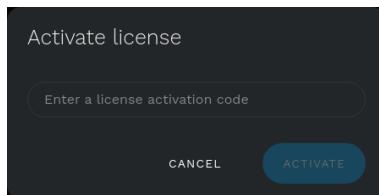


Fig. 165 – Activate License pop-up

¹⁷ Please refer to your local Authorized Distributor for requiring licenses

Possible licenses are:

Remote viewer 1 client	Stereo acquisition
Remote viewer 5 clients	DICOM workflow
Remote exam	DICOMweb workflow
Mosaic	WebAPI

To **remove** a license, click on the **ellipsis** at the right of the licence box, and then push **REVOKE**. The *Revoke the license* pop-up appears.

Insert the administrator password and push **CONFIRM** to remove the license, or click **CANCEL** to abort the operation. When you proceed with the revocation, the *License revoked* pop-up appears (Fig. 166).

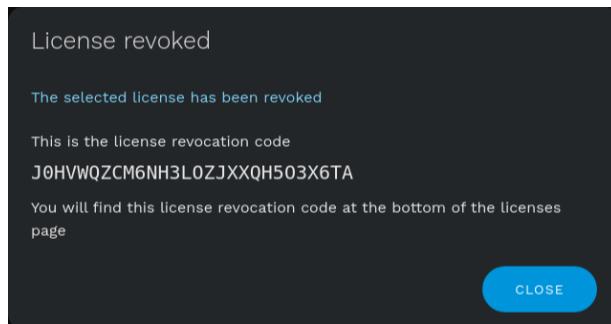
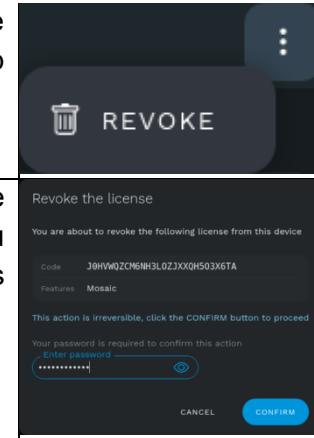


Fig. 166 – License revoked pop-up

The revoke of a license is an irreversible operation. To activate a revoked functionality, ask the iCare/CenterVue service for a new valid license.

To retrieve the list of the revoked licenses of the device, toggle the **HIDE/SHOW REVOKED LICENSES** at the bottom of the *Utilities|Licenses* Screen.

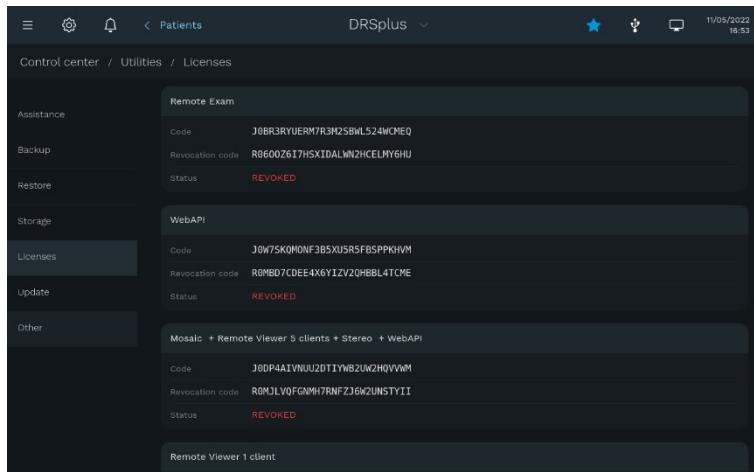


Fig. 167 - Utilities|Licenses Screen, license revoked

14.6 Update

Access the *Utilities|Update* Screen (Fig. 168) to install software updates and upgrades. The access to this panel is limited to the Administrator user. Software updates can be obtained either online or through a USB flash drive. All your configurations will be preserved.

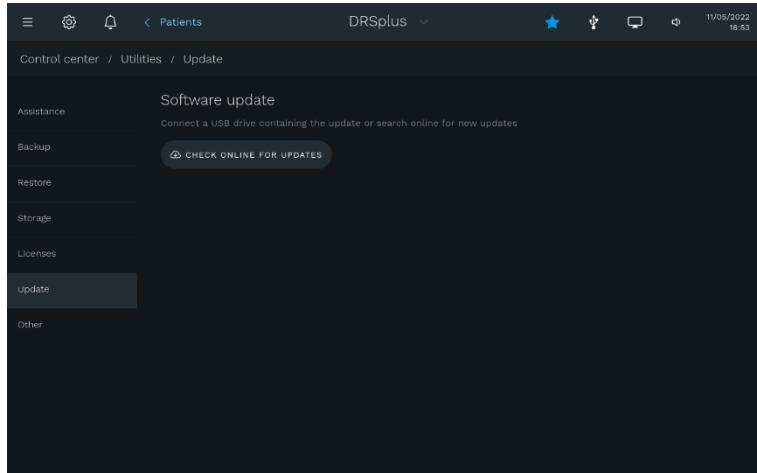


Fig. 168 - Utilities|Update Screen

14.7 Online updates

Push **CHECK ONLINE FOR UPDATES**. The *Search for online software updates* pop-up appears (see Fig. 169). Push **CHECK ONLINE FOR UPDATES** to allow the connection to the iCare/CenterVue servers or click **CANCEL** to abort the operation.

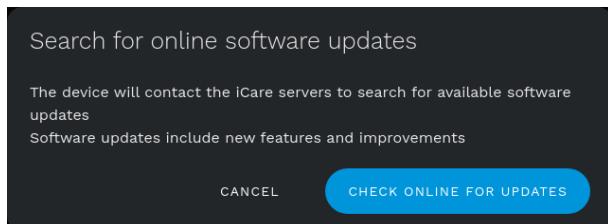


Fig. 169 - Search for online software updates pop-up

When an update is found, in the *Online Software Updates panel* push **DOWNLOAD THE SOFTWARE UPDATE** to receive the update or click **CLOSE** to abort (see Fig. 170).

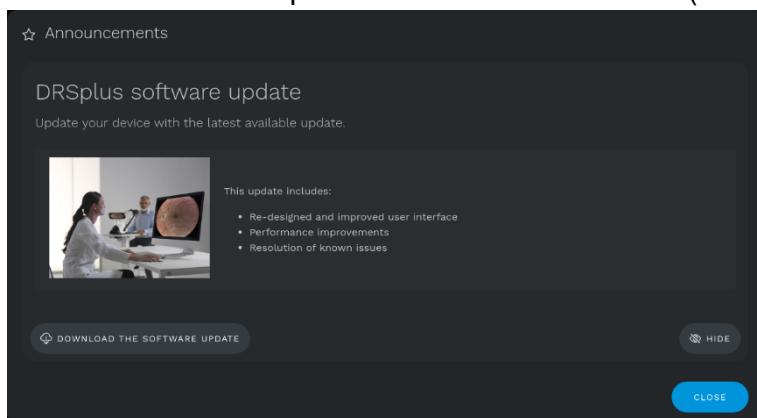


Fig. 170 - Online software updates panel

Wait for the download, then push **VIEW AND INSTALL THE DOWNLOADED UPDATE** to proceed, or push **CLOSE** to abort the operation.

In the *Utilities|Update* Screen, push **INSTALL THIS UPDATE**.

The Screen will now show the update file in the *1 update found* box, as shown in Fig. 171.

14.7.1 USB updates

Save the installation package on the top folder of a USB flash memory. Plug the USB drive into one of the three USB ports. The device will detect the installation package automatically, and the *1 update found* box will appear, as in Fig. 171.

14.7.2 Installation of the updates

The procedure is the same for the online and the USB updates.

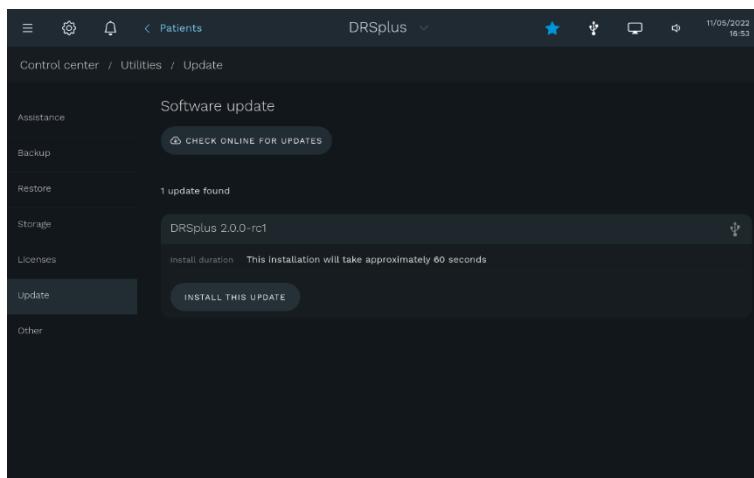


Fig. 171 - Utilities|Update Screen, *1 update found*

In the *Utilities|Update* Screen, push **INSTALL THIS UPDATE**.

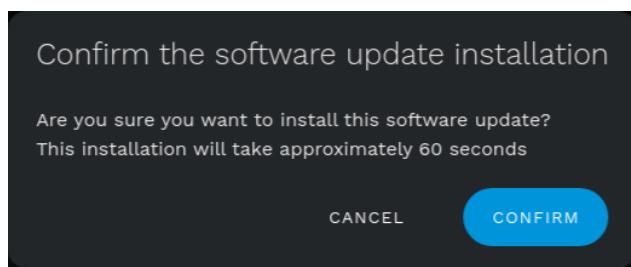


Fig. 172 - Installation confirmation pop-up

In the *Confirm the software update installation* pop-up (see Fig. 172), click **CONFIRM** to proceed with the installation or click **CANCEL** to abort the operation.

The *Software update appears* (Fig. 173). Wait until the end of the update or click **CANCEL INSTALLATION** to abort the operation.

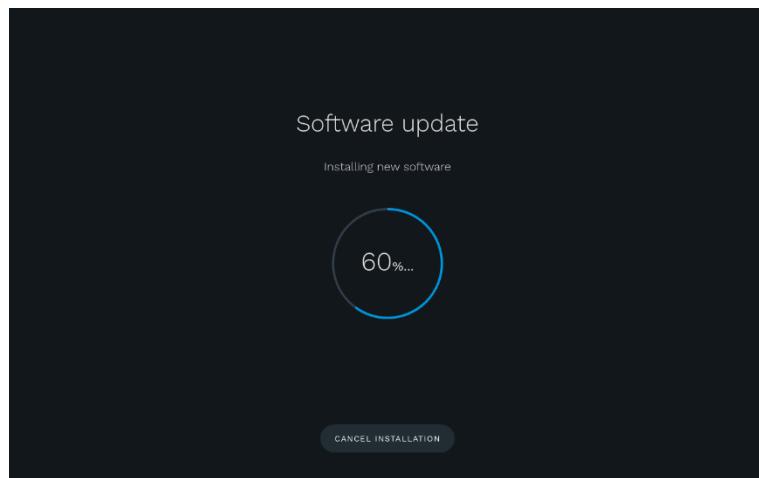


Fig. 173 - Software update Screen

At the end of the update, the *Device Updated* Screen appears (Fig. 174). Push **START** to verify the setup configuration described in §6.2 and start using the device.

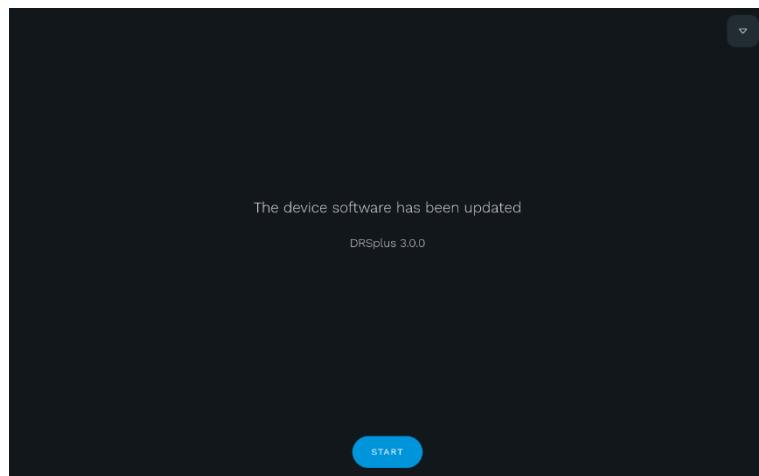


Fig. 174 – Device Updated screen

14.8 Other

The *Utilities|Other* Screen (Fig. 175) 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.

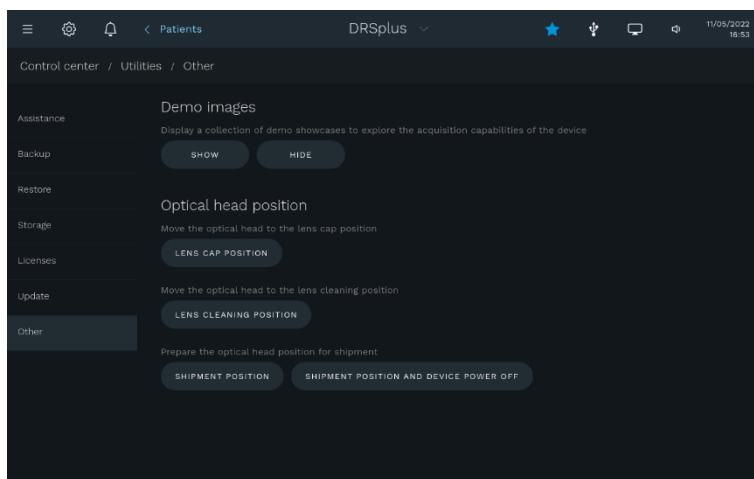


Fig. 175 - Utilities|Other Screen

14.8.1 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.

14.8.2 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.

Before 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

You can turn off the device **only via software** in the local interface. The remote connection does not show the **POWER OFF** button.

Push the **Menu** button in the *Navigation Bar*.

Push **Power off**



The *Power off* pop-up appears.

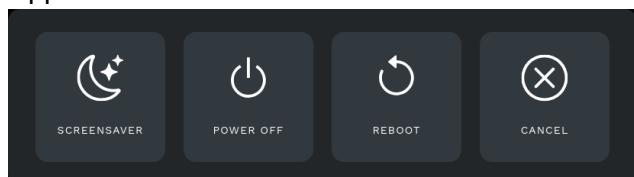


Fig. 176 - Power off pop-up

Click **SCREENSAVER** to close the current session and pause the device. The *Screensaver* Screen appears (Fig. 177). Push anywhere on the Screen to open the *Login Screen* (§6.3).

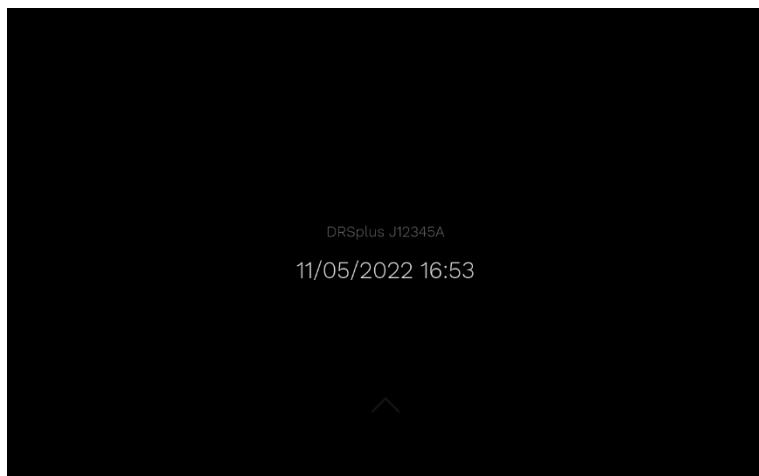


Fig. 177 - Screensaver Screen

Click **POWER OFF** to turn off the device.

Click **RESTART** to restart the device.

Click **CANCEL** to close the *Power off* pop-up.



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

16. Cleaning and disinfection

This section explains how to clean and disinfect the device.

The cleaning process is described as follows:

1. Clean the Touchscreen display and the device's exteriors: use a clean lint-free microfiber tissue dampened with small amount of water (i.e. tap-water).
2. Clean the headrest silicone cushion with a clean lint-free microfiber tissue dampened with small amount of water after each use. The cushion can also be removed and washed with water and/or a mild hand detergent.
3. Clean the other possible contact parts of the device with the user or patient (e.g. plastic covers, display and any optional components) using a clean lint-free microfiber tissue dampened with small amount of water or a mild hand detergent.
4. Clean the front lens (only if really needed) using a clean lint-free microfiber tissue or photographic cleaning paper dampened with a standard lens cleaning solution. Start from the center of the lens, wipe it with a circular movement, very slowly, only for one complete rotation. The exiting movement (i.e. moving away from the lens) has to be made radially, towards the border. Do not reuse the same wiping cloth area after one pass.
5. Allow all surfaces to dry before starting another exam.

The disinfection process should be done after each use and is described as follows:

1. Clean the headrest silicone cushion with a disinfecting wipe with 70% isopropyl alcohol (IPA).
2. Disinfect all the other contact parts using a disinfecting wipe with 70% IPA (or a soft clean disposable tissue damped with 70% IPA solution): plastic covers, frame and back panel of the touchscreen display, and optional components if present.
3. Clean the front lens: use a disinfecting wipe with 70% IPA (or a soft clean disposable tissue damped with 70% IPA solution). Starting from the centre of the lens, wipe it with a circular movement, very slowly, only for one complete rotation. The exiting movement (i.e. moving away from the lens) has to be made radially, towards the border. Do not reuse the same wipe area after one pass.
4. Allow all surfaces to dry before starting a new exam.



- Do not reuse the same area of the wiping tissue after one pass.
- Do not use disinfectant wipes containing bleach.
- Do not allow the liquid from the disinfecting wipe to sit or pool on the area being disinfected for a long amount of time.
- Do not use rough towels or cloths to dry the area.

17. Maintenance

The Manufacturer recommends the periodic maintenance of the device once a year. Only properly qualified Authorized Service Technicians can perform maintenance activities¹⁸ (for example cable checking, motor greasing, SW updates). Contact the Authorized Service Center for the maintenance.

To clean the front lens in case of dirt, refer to §16. To check the disk space, refer to §14.4, to check for Software updates, refer to §14.7.

¹⁸ DRSplus has no user serviceable internal parts. Only technicians authorized by CENTERVUE S.P.A may perform maintenance or repair procedures other than those described in these Instructions for Use.

18. Electromagnetic Compatibility

DRSplus complies with the requirements of Class B as defined by the IEC 60601-1-2 standards. DRSplus has been tested and found to comply with the limits for medical devices contained in IEC60601-1-2. These limits are intended to provide reasonable protection against harmful interference in a typical medical installation. DRSplus 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 device 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.

DRSplus 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 IEC 60601-1-2

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



DRSplus is intended for use in the electromagnetic environment specified in the below tables. The customer or the End-user of DRSplus should ensure that it is used in such an environment. Other cables and accessories not provided with the devices may negatively affect EMC performance.

IEC 60601-1-2 EMISSION TEST			
Test Requirements	Test Result	Compliance	Electromagnetic environment - Guidance
Class A or B	B	Yes	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.
Group	1	Yes	DRSplus is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes, providing the following warning is heeded:
CISPR 11, 14-1, 32 or ISO 7137	CISPR 11	Yes	
Conducted RF emissions	CISPR 11 Class B	Yes	
Radiated RF emissions	CISPR 11 Class B	Yes	
Disturbance Power (if applicable)	N/A	N/A	
Harmonic Distortion IEC 61000-3-2 (Class A, B, C, D)	Class A	Yes	
Voltage Fluctuations and Flicker IEC 61000-3-3	Passed	Yes	

Table 12 – Electromagnetic Emissions

18.2 Guidance and manufacturer declaration – electromagnetic immunity

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

Table 13 – Electromagnetic Immunity (IEC 60601-1-2:2014) of the DRSplus

18.3 Immunity pass criteria

IMMUNITY	
Function	IMMUNITY pass criteria
System functioning – main unit	During the applied testing stimulus, temporary cessation or interruption of any intended operation is acceptable

Table 14 – Electromagnetic Immunity (IEC 60601-1-2) criteria

DRSplus is indicated for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the end-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.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of DRSplus, including cables specified by the manufacturer (CENTERVUE S.P.A.). Otherwise, degradation of the performance of this equipment could result.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz d = 1.17√P	80 MHz to 800 MHz d = 1.17√P	800MHz to 2.5 GHz d = 1.17√P
0,01	0.12	0.12	0.12
0,1	0.37	0.37	0.37
1	1.17	1.17	1.17
10	3.70	3.70	3.70
100	11.70	11.70	11.70

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum power rating of the transmitter in (W) according to the transmitter manufacturer.

NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.

Table 15 – Recommended Separation Distances

18.4 Wi-Fi specifications

Wi-Fi specifications	
Model Name	AW-CB161H
Main Chipset	RTL8821AE
Product Description	IEEE 802.11 a/b/g/n/ac Wi-Fi with Bluetooth 4.0 class I Combo
Radio ON/OFF Control	Supported in both hardware and software
IEEE WLAN Standard	IEEE 802.11abgn, 802.11ac, 802.11d, 802.11e, 802.11i, 802.11h, 802.11w
Frequency Range	Wi-Fi: 2.4 GHz ISM Bands 2.412-2.472 GHz, 2.484 GHz / • 5.15-5.25 GHz (FCC UNII-low band) for US/Canada, Japan and Europe • 5.25-5.35 GHz (FCC UNII-middle band) for US/Canada and Europe • 5.47-5.725 GHz for Europe • 5.725-5.825 GHz (FCC UNII-high band) for US/Canada BT: 2402MHz~2483MHz
Host Interface	Wi-Fi PCI-E , BT : USB
Operation Voltage	3.3V +/-9%
Operating Range	Wi-Fi Open Space (300 m) / Indoor (100 m) (The transmission speed may vary according to the environment) BT: 10m~20m (depending on environment and NB model)
Authentication	WEP, WPA, WPA2, WPA2 802.1X
Encryption	64-bit and 128-bit WEP, AES-CCMP, TKIP

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

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

- FCC ID: TX2-RTL8821AE
- IC ID: 6317A- RTL8821AE
- CMIIT ID: 2013AJ7899

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Operation is subject to the following 2 conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

19. Technical Specifications



Technical specifications are reported in the next table¹⁹.

Fundus Imaging Features	
Field of view:	45° (H) x 40° (V) as captured with a single exposure
Mosaic (up to 9 fields):	83°
Light sources:	White LED (420-675 nm) Infrared LED (825-870 nm)
Imaging modalities:	TrueColor, Infrared, Red-Free*, Blue*, Red*, Stereo**, Mosaic**
Autofocus adjustment range:	-15 D to +15 D
Automatic operation:	Auto-alignment, Auto-focus, Auto-exposure, Auto-capture
Minimum pupil size:	Non-mydiatic 2.5 mm
Minimum Working distance:	25 mm
Pixel pitch on the retina:	4.3 micron
Image size:	10 Megapixels
Resolution:	77 pixel/degree
Fixation target:	Internal / External**
Dynamic Programmable Internal Target:	Central, Nasal, Temporal, Central-Nasal, Superior, Inferior, Superior-Temporal, Superior-Nasal, Inferior-Temporal, Inferior-Nasal
External Eye:	Yes

Other features and characteristics	
Display:	Integrated 10.1" (1280 x 800) Color, Capacitive, Multi-touch
Hard Drive:	SSD ≥ 480 GB
Interfaces	USB port 2.0 x 3, Gigabit Ethernet Port x 1
Export / Import:	jpeg, pdf, DICOM**, Web API**
Remote Viewer**:	Up to a maximum of 5 remote stations
Acoustic emission:	<80 dBA
Size:	300 mm x 450 mm x 650 mm / 11.8" x 17.7" x 25.6"
Weight:	11 Kg (24.3 lbs)
Device Power supply and consumption:	Voltage 12V DC Device Power Consumption 25W 25VA
External power supply:	Input: Related voltage 100-240V ~ Frequency 50-60 Hz 2A Output: 12.0V DC 5.42A
Class and type of applied part:	Class I, Type B (according to IEC 60601-1).
IP classification:	IPX0 (according to the degree of protection provided by the enclosure to harmful penetration of particulate matter or water).

* digital filters

**optional

¹⁹ Specifications are subject to change without notice for improvement, as a result of ongoing technical development.

20. Disposal

DRSplus is made of different materials, such as plastics, aluminium, and electronic parts. In the case of DRSplus 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 of electrical and electronic equipment

The European Directive 2012/19/EU establishes separate collections 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 an authorized company can recycle the WEEE. Please refer to the public administration about the 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 the water system.



Lead: damages the nervous system of humans, and affects the endocrine system, the cardiovascular system and the 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, and 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).

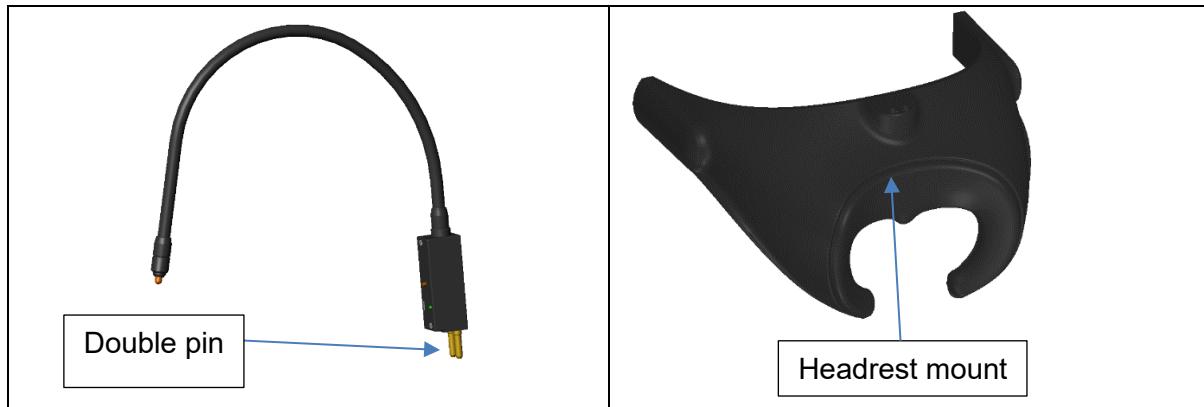
21. Log of Document Changes

IFU version	Description	IFU Release date	Software version
14.01	Fixed Minor Bugs	09-07-2024	3.0.1
14	Change of the UI appearance, introduction of DICOMweb, introduction of the support to WPA2 802.1x authentication, introduction of the electronic Instructions for Use	24-02-2024	3.0.0

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 this component, 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. 178). 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 DRSplus is required.



Fig. 178 – 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, DRSplus will mirror the onboard display.

Important

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

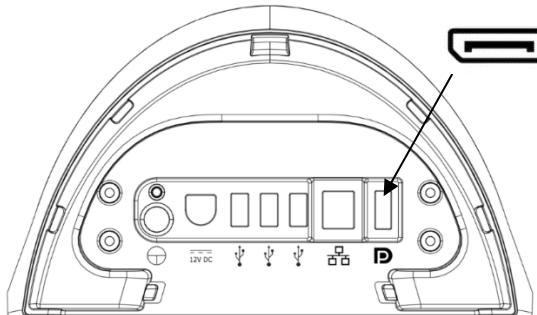
Requirements

- The external display must support “DisplayPort 1.0” standard
- The external display must support 1920x1080 resolution

DRSplus can be connected to a TV set via HDMI using an **active converter**.



Passive converters **are not supported**.



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