drs
OPERATING MANUAL

MANUAL INFORMATION

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Reference software version: v2.3.x

Manufacturer:

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SUMMARY

1. <u>INTRODUCTION</u>

The Digital Retinography System (DRS) is a fundus camera for the acquisition of digital images of the retina without the use of a mydriatic agent.

In particular, the DRS allows to acquire color images of the retina over a field of view of 45° x 40°. Seven different retinal fields can be framed using multiple internal fixation targets.

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

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

2. SYSTEM

Operator side

Patient side

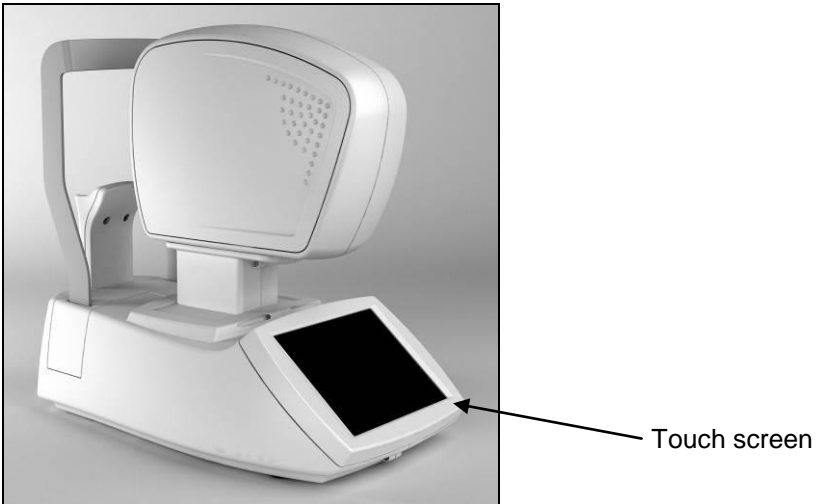Forehead rest = applied part

Chin rest = applied part
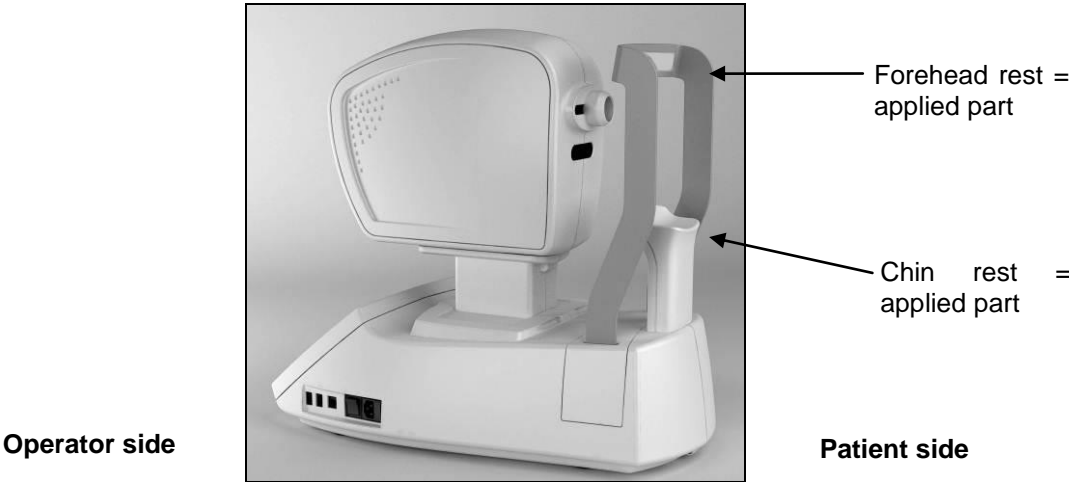
Touch screen

Figure 1 - DRS right side (top) and left side (bottom) views

USB ports

Ethernet port

Power switch

Power inlet
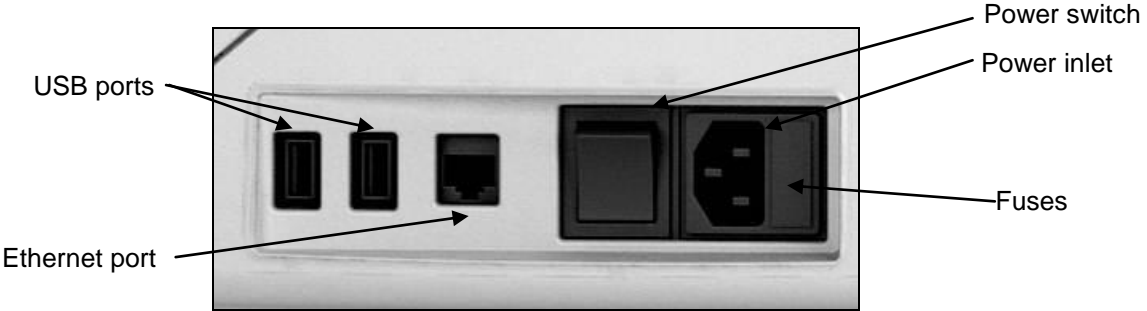
Fuses

Figure 2 - Detail of the device right side

The DRS system is supplied with:
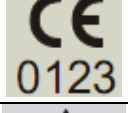
- Power cord;
- Spare fuses;
- This Operating Manual;
- Dust cover;
- Microfiber cleaning tissue for touch screen;
- Front lens photographic cleaning paper, pack of single-use sheets
- Silicone forehead rest;
- Hand blower;
- Glasses with adjustable prisms;
- USB 2.0 extension cord.

3. LABELING

WARNING!
Stand clear from moving parts while in operation.

No serviceable parts inside.
Internal inspection allowed to authorized personnel only.

centervue
at the centre of vision
Via San Marco, 9H
36129 Padova
ITALY

Voltage: 100 - 240 VAC
Freq.: 50 / 60 Hz
Power: 100 VA
Fuses: 5x20mm T 3.15A 250V

CE 0123

model
drs
s/n 0002
2010/04
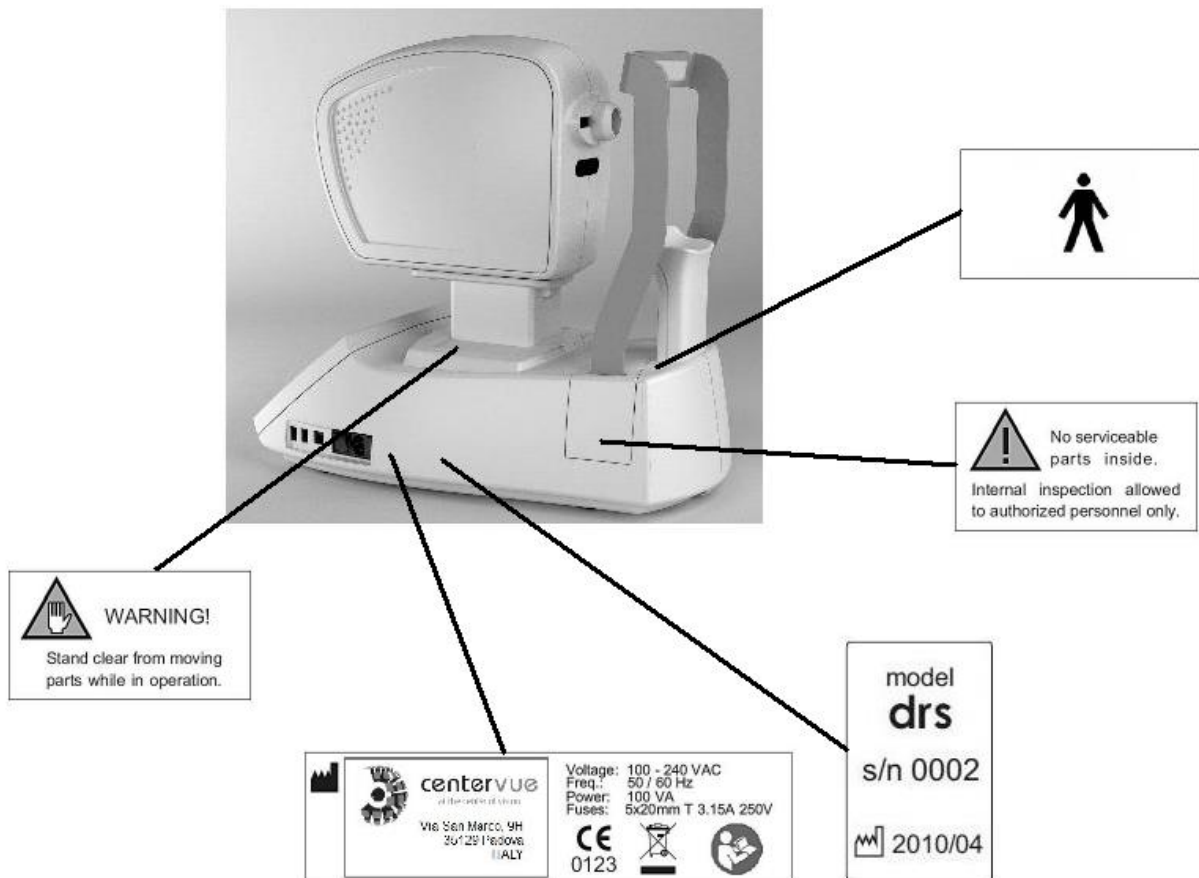
4. SYMBOLS

4.1 List of symbols adopted on the device

Symbol	Explanation
	Manufacturer Data
	Manufacturing Date (year/week of production)
	Electronic and electric devices must be recycled.
	Refer to Instruction Manual
	CE mark: the device complies with the essential requirements of the European Medical Devices Directive 93/42/EC
	Warning: Do Not Touch
	Type B Applied Part
	Generic Warning

4.2 List of symbols adopted in this manual

	Note
	Warning

5. PREPARING THE DRS

Carefully and thoroughly read paragraph 7 WARNINGS AND PRECAUTIONS before proceeding with first use.

The test should be performed in conditions of semi-obscurity to facilitate the dilation of the pupil

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To set up your DRS follow these steps:
- extract the system from its box;
- place the DRS on a suitable electrical table[1];
- connect the power cord provided with the unit to the power inlet (see Figure 2);
- optionally connect a compatible printer[1] to any of the USB ports (see Figure 2);
- attach the silicon forehead rest (included in the tool box) on the forehead rest frame as shown in the pictures below (Figure 3 and Figure 4);
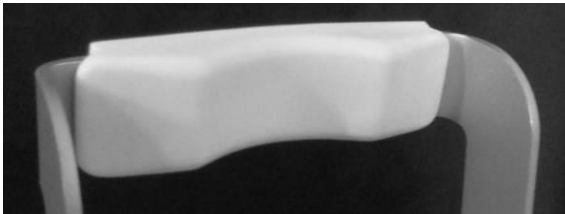
Figure 3 - Forehead rest patient side
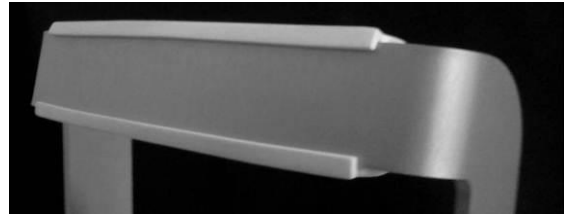
Figure 4 - Forehead rest rear side

5.1 TIME ZONE SETTING

The first time the DRS is powered on, the operator should set the Time zone: see § 14.4 – SYSTEM/TIME.

The configuration request will appear every time the DRS is started, until the time zone is set.

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[1] Not provided with the DRS

5.2 Camera autotuning message on first start

After upgrade to latest software version a message could appear:

> ⚠️ Warning: need to perform camera autotuning to increase its sensitivity.
> This procedure will take about 30 sec. to complete.
> Please apply the lens cap on the front lens and press OK.
>
> [OK]
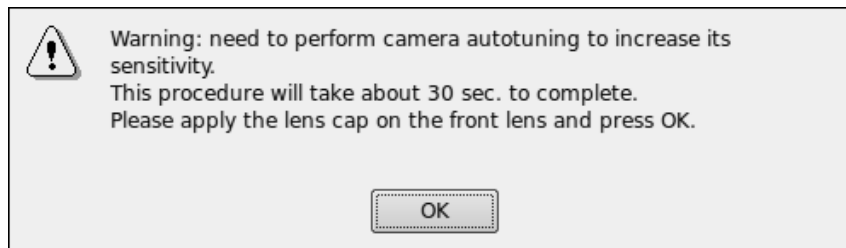
This message appears **ONLY ONCE** when recent software is started the first time.

PLEASE APPLY THE LENS CAP AND PRESS OK AND WAIT ABOUT 30 SECONDS UNTIL THE FOLLOWING MESSAGE APPEARS:

> ℹ️ Camera autotuning succeeded.
> You can now remove the lens cap and use the device normally.
>
> [OK]
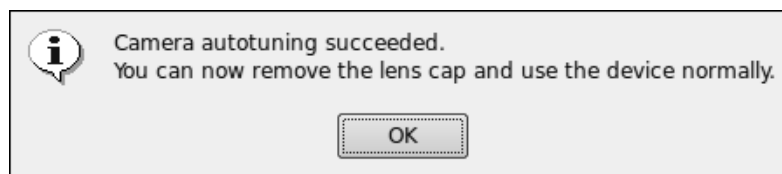
This procedure is not invasive and not essential: if the operator forgets to apply the Lens Cap and just presses ok, the image quality is not affected and no danger is possible to the patient anyway.

6. PREPARING THE PATIENT

Patients with Contact Lenses. Image quality may be affected by contact lenses. It is recommended to have contact lenses removed before imaging the patient.

This paragraph explains how to prepare a patient for the DRS test.

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

The DRS is a non-mydriatic device (minimum pupil diameter 4 mm), so there is no need to dilate the subject's pupil. Patient contacting parts are indicated in Figure 1.

Before the test inform the patient about the following:

1) *the test is non-invasive, in particular the system will never touch your eye and you will only see a flash of light when a photograph is taken;*
2) *find a comfortable position, keeping the chin and forehead firmly pressed against the rests;*
3) *at the beginning of each test, the unit will move around to find your pupil: this is absolutely normal;*
4) *when the test starts look straight in front of you and when a small green circle becomes visible anywhere within the field look steady at it;*
5) *open your eyes wide so that eyelids do not interfere and try to not blink during the test;*
6) *do not move during the test;*
7) *if you follow these instructions the acquisition of a single photo will take less than 30 seconds.*

7. WARNINGS AND PRECAUTIONS

The following precautions are particularly relevant to the device safety:

> ⚠
> - Federal laws (US) restrict this device to sale by or on the order of a physician or a properly licensed practitioner.
> - The clinical interpretation of DRS images is restricted to licensed eye care practitioners.
> - A device specific training is required for any operator to become able to use the system.
> - Do not open the device: this could lead to electric shocks or damage to the system.
> - Do not use the instrument in the event that the cover or other parts of the device have been removed.
> - Only technicians authorized by CenterVue may service the DRS. CenterVue cannot be held responsible for system safety should the DRS be opened, repairs carried out, third parties software be installed, or parts be replaced by unauthorized persons.
> - Do not expose the device to water: this could lead to fire or electric shock.
> - Stand clear from moving parts during operation.
> - All parts in contact with a patient's skin need to be disinfected after use (see par. 17).
> - The instrument is supplied with an earth ground by means of a protection conductor contained inside the power supply cable. Before turning on the system, make sure the power supply socket is correctly grounded to avoid the risk of electric shock.
> - The room where the DRS is operated must respect IEC or ISO safety standards relative to medical use of a room or area.
> - The DRS must NOT be used in an oxygen rich environment or in presence of flammable anesthetics.
> - External equipment connected to the DRS within the patient environment must be compliant with IEC 60601. Equipment not complying with IEC 60601-1 shall be kept outside the patient environment and complying with IEC 60950. Any person who connects external equipment to signal input, signal output or other connectors of the DRS has formed a Medical Electrical System according the definition of IEC 60601-1 and is therefore responsible for the system to comply with the requirements of IEC 60601-1, § 16. If in doubt, contact the local representative.
> - Data Backup: DRS contains Patient Health Information. It is strongly recommended the use of the "backup" utility as indicated at the Chapter "System".

The following precautions are particularly relevant to prevent use errors:

> ⚠
> - The device must be placed in a room which is not exposed to adverse chemical-physical conditions, such as the presence of sulfur, salt, dust, direct sunlight, lack of ventilation, high humidity, sudden temperature drops or peaks. The safety and/or effectiveness of the instrument cannot be guaranteed if these conditions are not fulfilled.
> - The DRS needs to be operated in a semi dark room (except when taking Anterior Eye photos).
> - The DRS needs to be operated under the following environmental conditions: Temperature: 10 - 40 C° (50 - 104 F°) / Humidity (max): 90% not condensing

- The DRS needs to be stored under the following environmental conditions: Temperature: -10 - 60 C° (14 - 140 F°) / Humidity (max): 90% not condensing
- A not optimal pupil alignment may cause the acquisition of an image of the retina that has a growing light crescent on a board. Such growing light should be considered an artifact and not a feature of the retina under examination.
- Do not leave the front lens uncovered while the system is not in use.

> The DRS display is a **touch screen panel**: wherever this manual says "click on ..." it means "point the finger on the display on ..."

Automatic alignment of the pupil:

> Automatic alignment of the pupil is a sophisticated computer algorithm procedure. The algorithm may fail in some circumstances such as:
> - long eyelashes;
> - make-up;
> - room too bright or presence of breaches of light on patient face;
> - very big pupil.
>
> Under these conditions the alignment may fail and the device could rest on the patient face.
> No safety issue is compromised, but the exam should be repeated under better conditions.

8. NOTES TO OPERATOR

No specific skills are required to operate the DRS.
A minimal, device specific, training is required to become able to use the system.
The operator needs to be acquainted with the following concepts:
- pupil: the central part of the external surface of the eye, through which light goes in;
- retina: the internal surface of the eye ball;
- fixation / fixating: the ability of a subject to stare at a specific point in space and specifically the DRS internal fixation targets.

9. PERFORMING THE TEST

This paragraph explains how to operate the DRS to perform a complete test.

When the unit is turned on and the boot process is over, the Home screen shows up (see Figure 5).
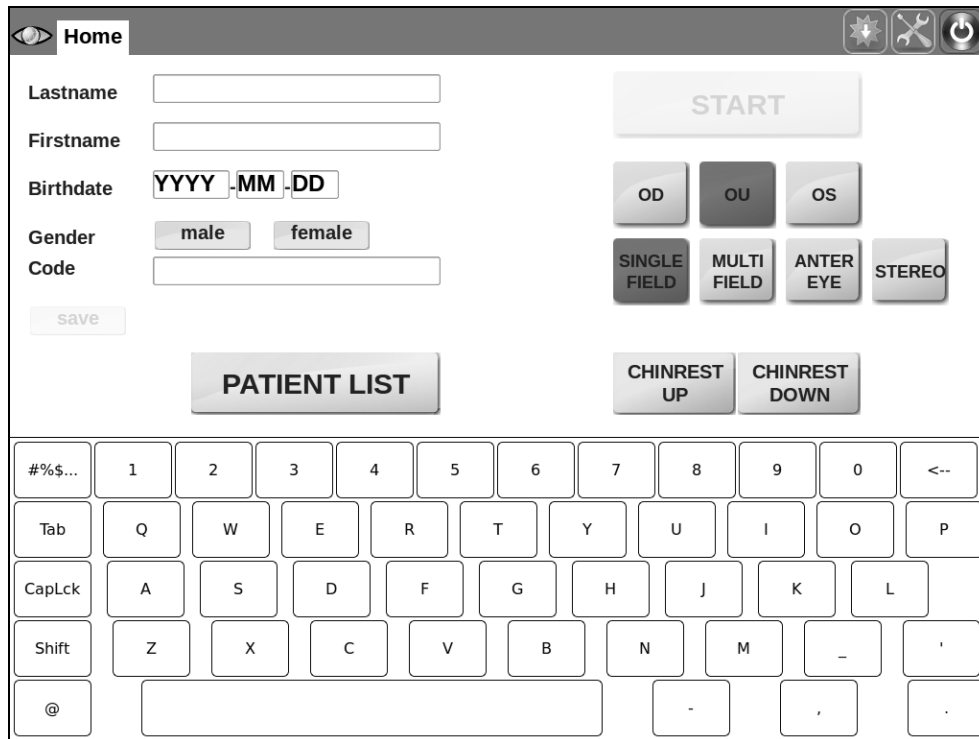
Figure 5 - "Home" screen

Several options are available at this point, such as:

- adding a new patient (see 9.1 below);
- selecting an existing patient from the list (see 9.2 below);
- starting the image acquisition process without identifying the patient (see 9.3 below).

9.1 Adding a new patient

To add a new patient to the list, type the last name (mandatory), first name and date of birth in the corresponding boxes. Optionally select the gender and type a Code of your choice. Then click on **save**.

9.2 Selecting an existing patient

To select an existing patient from the list, click on the **PATIENT LIST** button: the complete list of stored patients will show up (see Figure 6).

The following mechanisms are available to find a specific patient:
- scroll the list by dragging the screen up or down;
- sort the list by one of the available field (the list can be sorted by last name, age or date of last visit) by clicking on the corresponding arrows (↓ for descending, ↑ for ascending) located at the header of the list (by default patients are sorted by their numeric ID, in ascending order);
- search for a specific patient by typing the initials of the last name or first name in the **search** box.
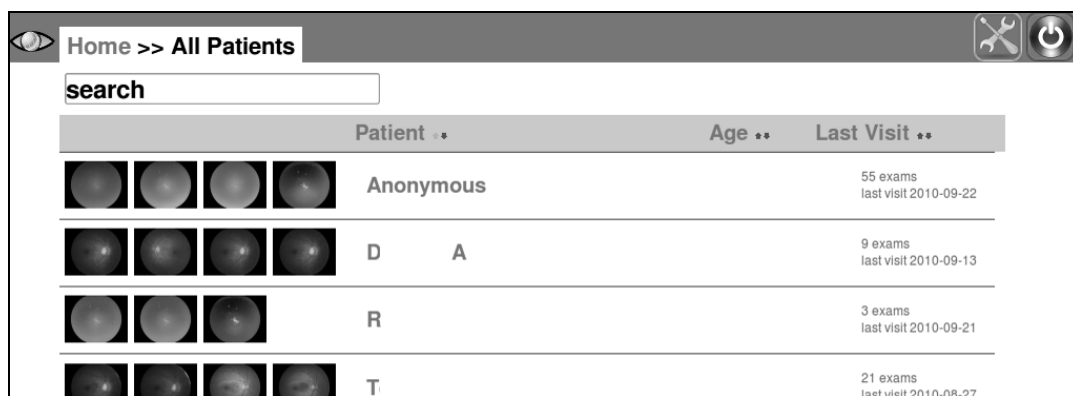

Figure 6 - Patient list screen

Once the desired patient has been identified in the list, click on the corresponding line to select.

9.3 Starting the image acquisition process

Whether a new patient has been created or an existing one selected or none of the above (anonymous), it is possible to start the image acquisition process.
Before proceeding, be sure that the patient received complete explanations concerning the test and what she/he is required to do, as explained at par.5.1.
Then proceed as follows:
   a. Select OU to acquire images from both eyes (default), OD for the right eye only and OS for the left eye only;
   b. Select SINGLE FIELD to acquire one 45° image of the retina (default) or MULTI FIELD to acquire multiple fields at 45° per photo. See par. 14.1 for details on how to configure the fields acquired in each of the above two options; you can also select ANTERIOR EYE to acquire the external part of the eye (useful to prove the presence of cataract in case of impossibility to acquire the retina) or STEREO to acquire a couple of Central Nasal field images with two different head displacement to produce a Stereoscopic vision of the optic disc (see details below);
   c. Position the patient on the chin rest and head rest and use the CHINREST UP and CHINREST DOWN buttons to adjust the chin rest position, if needed. When the AUTOMATIC CHIN REST flag is selected from the settings menu (see par. 14), the chin rest is automatically adapted to the patient head characteristics.
   d. Press the START button to start the acquisition procedure.

The START button is only enabled if the chin rest is engaged. If the patient is not properly positioned on the chin rest, the START button will not be enabled and it will not be possible to start the acquisition process.

9.4 Automated acquisition

Once the START button is pressed, the DRS will automatically perform the following steps:

a. Move the optical head to locate the patient's pupil (see Figure 7);
b. Move the optical head to center the patient's pupil to the front lens (see Figure 8); the system will also display the pupil current diameter and which eye is being acquired; the red circle in Figure 8 represents the pupil and becomes green when proper centering is achieved.

In case the auto-alignment module fails, manual alignment is possible: see par. 9.5 below for details.

c. Perform auto-focus (see Figure 9);
d. Capture an image, by flashing the retina. This step involves also automatic tuning of the flash level;
e. Store the image in the local hard drive (see Figure 10);
f. In case of acquisition of both eyes and/or multiple fields, the acquired images can be displayed before proceeding to the next one, depending on the settings (see par. 14.2).

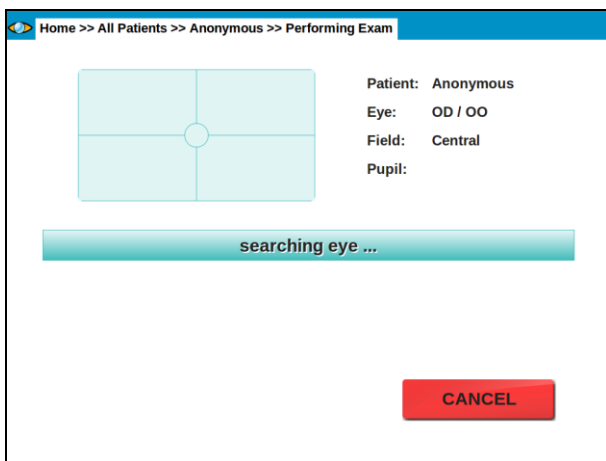At any time during the above sequence it is possible to stop the acquisition process by pressing the CANCEL button.
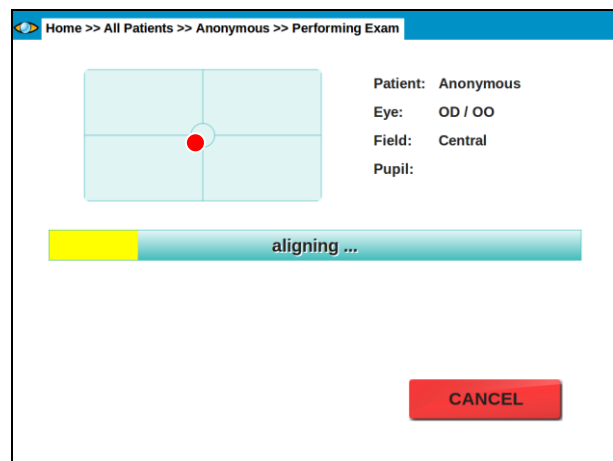

Figure 7 - Automatic eye search in progress

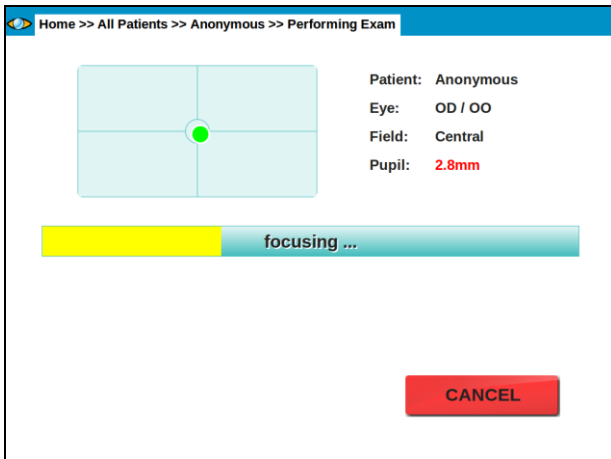**Figure 8 - Automatic alignment in progress**
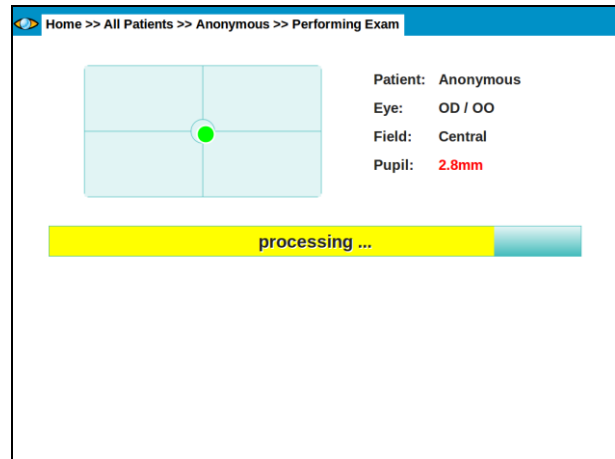
Figure 9 - Auto-focus in progress

Figure 10 - Image processing and storage in progress

9.5 Manual alignment

If, for some reasons, the automated eye search fails, a message as in 11 shows up. Reasons for failure include: improper patient positioning, patient not fixating steadily, patient moving the head and / or the gaze during eye search.

> If any of the above situations applies, try to fix the cause (re-position the patient, instruct her/him to steadily fixate at the target and/or to not move) before proceeding with the manual alignment.

Use the UP / DOWN / LEFT / RIGHT buttons to adjust the optical head position and align the patient's eye to the instrument front lens. As soon as the eye is detected the automated procedure will resume.
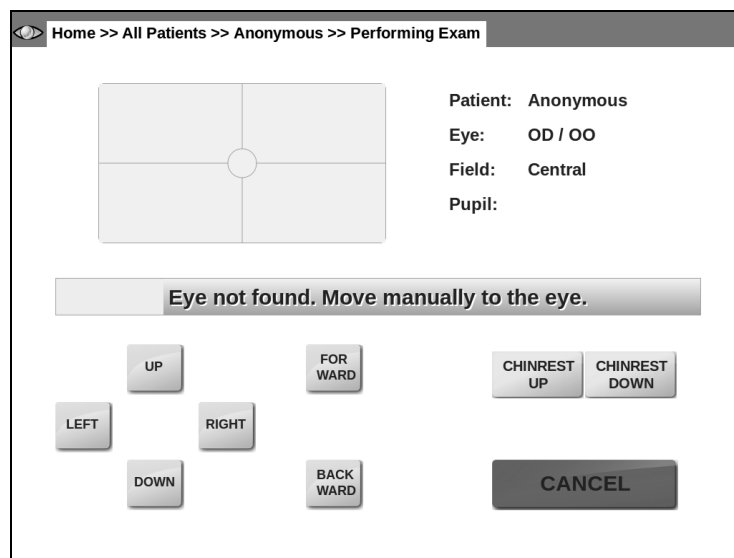

Figure 11 - Failure of automatic eye search

The result of the overall acquisition process is one or more retinal images as the one shown below.
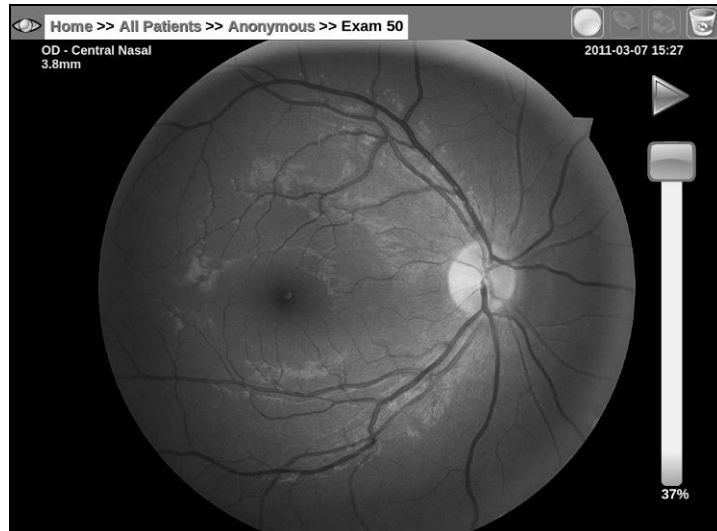
Figure 12 - Retinal image acquired by the DRS

9.6 Anterior Eye

In order to shoot a focused image of the anterior part of the eye, the patient's head must be placed on the chinrest but with a distance of 3-5cm (2-3 fingers) between the patient's forehead and the instrument forehead rest. The patient's chin should be placed near the edge of the chin rest (see Figure 13).

Once started, the optical head moves in front of the selected eye for a rough alignment. When it reaches the optimal position, a live color view of the eye is displayed so that manual alignment and focus can be performed using the on-screen buttons. The fine manual positioning and focus setting is necessary in order to take a good quality picture. The live view can be toggled to full-screen just by pressing it.

Once satisfied with the position and focus, press **SHOOT** to acquire the image.

Figure 13 - Anterior eye: correct patient position

The room must be sufficiently lit in order to be able to take an Anterior Eye photo.
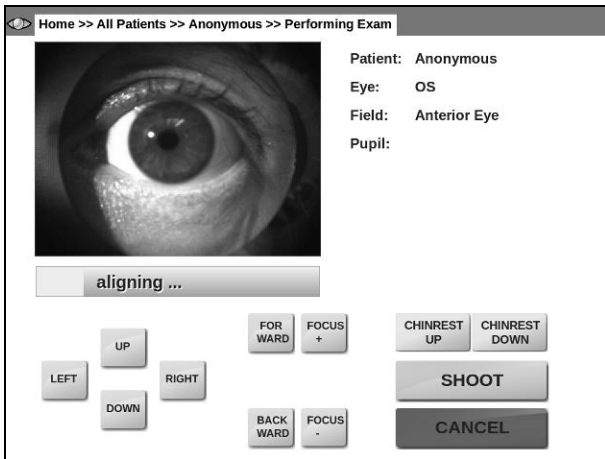
Figure 14 - Anterior eye acquisition

Figure 15 - Full screen of the anterior eye

9.7 Stereo exams

If Stereo is selected prior to start the exam, two images of the Central Nasal field will be shot one after the other, with automatic alignment and focus. A delay between the shots will be applied in order to let the pupil get back to its normal dimensions and have two images as much similar as possible in terms of brightness. The delay length can be set in the Settings page (Exam >> Saving).

Implementing a slight shift between one image and the other, the optical head of the DRS will capture a simulated stereoscopic view of the optical disc.

In order to perceive the 3D vision of the optic disk, the images must be watched with a couple of prismatic goggles that let each eye see only one of the two images. Alternatively, the "crossed-eye" format, which does not require goggles, can be toggled by clicking on the swap images button.

9.8 Warning messages

If the lens cap is placed on the front lens when an exam is started, the message reported in Figure 16 will be shown (unless "check lenscap presence" is off, see 14.2 - Exam | Advanced). Press **ok** to exit and restart the exam, after having removed the lenscap.

Warning!
Lens Cap detected.
Please remove the lens cap and restart the exam.

OK

Figure 16 - Message when lens cap is detected

When the pupil – measured immediately before the snapshot - is smaller than 3.8 mm, a warning message is shown to inform the operator about the possible low quality of the image (see Figure 17).
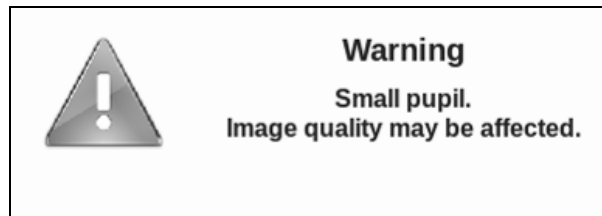
Warning
Small pupil.
Image quality may be affected.

Figure 17 - Warning due to small pupil

When the auto-focus process is not able to find an optical focus, a warning message is shown to inform the operator about the possible low quality of the image (see Figure 18).
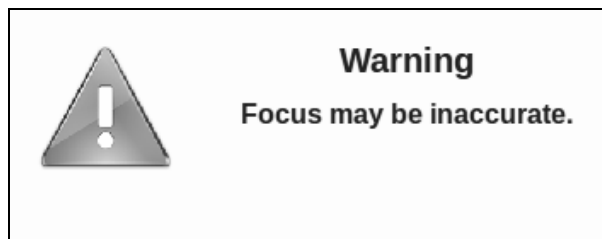
Warning
Focus may be inaccurate.

Figure 18 - Warning due to incorrect focusing

10. REVIEWING THE IMAGES

Once the image(s) has (have) been acquired, the system will open the patient's individual record and present a thumbnail view of all the available images (see Figure 19).

10.1 Patient record screen

For each image thumbnail, the following information is displayed:
- the eye (OD/OS) and field information, in the top-left corner;
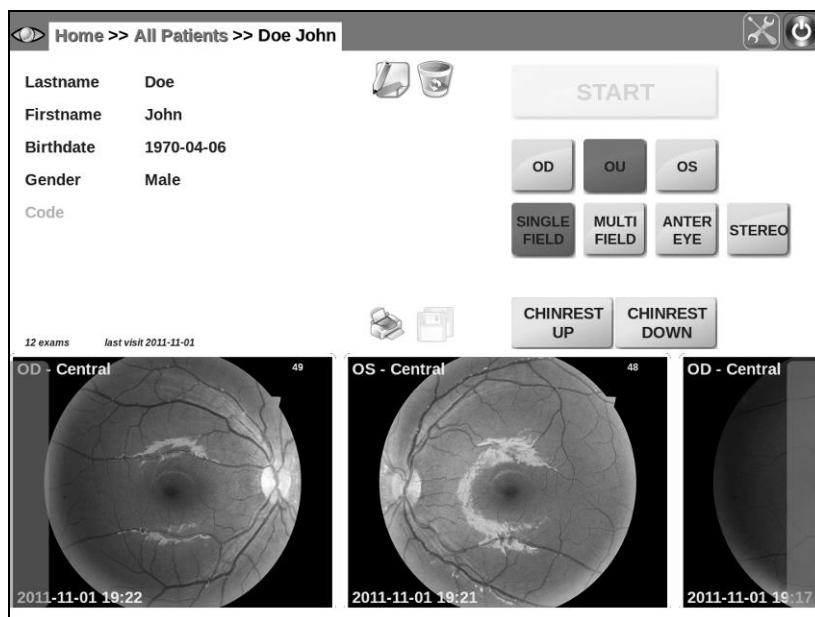- the image number, in the top-right corner;
- the acquisition date and time, in the bottom-right corner.
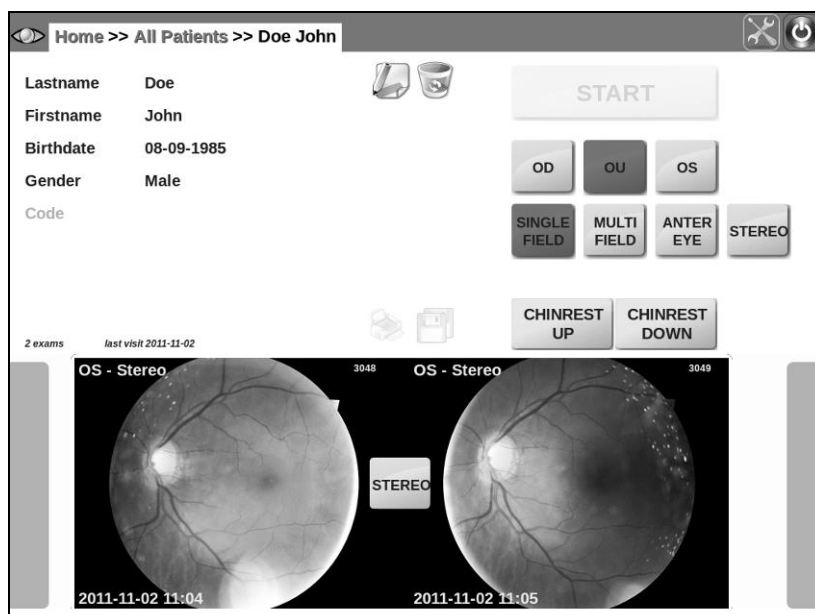

Figure 19 - Patient record screen

Figure 20 - Patient record with a stereo couple

Available functions include:

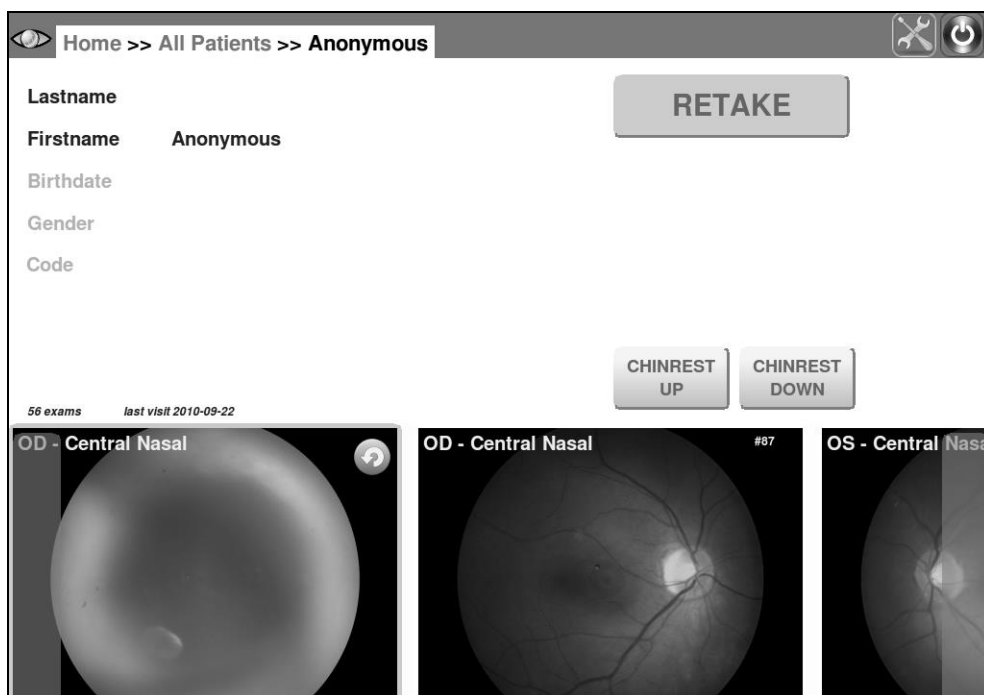| Function	Icon(s)	Command
Image scroll		Point on any thumbnail and drag to the left / right or press the left / right buttons
Edit patient's data		Clicking on this icon will enter the edit mode
Delete patient record		Clicking on this icon will permanently delete the current patient and all related exams. A confirmation is required.
Batch image export		Clicking on this icon will export all images of the selected patient as high quality JPG files on a USB key (only available if a USB key is plugged in any of the USB ports)
Retake images		Clicking on this icon will select one or more images to be retaken (see Figure 21). When all images have been selected, click on RETAKE . NOTE: images can be retaken within 5 minutes after they have been captured.
Open full image screen		Click on the corresponding thumbnail: this command will open the full image screen shown in Figure 22
Open 3D image view	STEREO	Click on the STEREO button between the two thumbnails of a stereo couple thumbnail: this command will open the 3D viewer
Print both eyes		Click on the printer icon to print two images on a single page. Icon is enabled when a supported printer is connected.

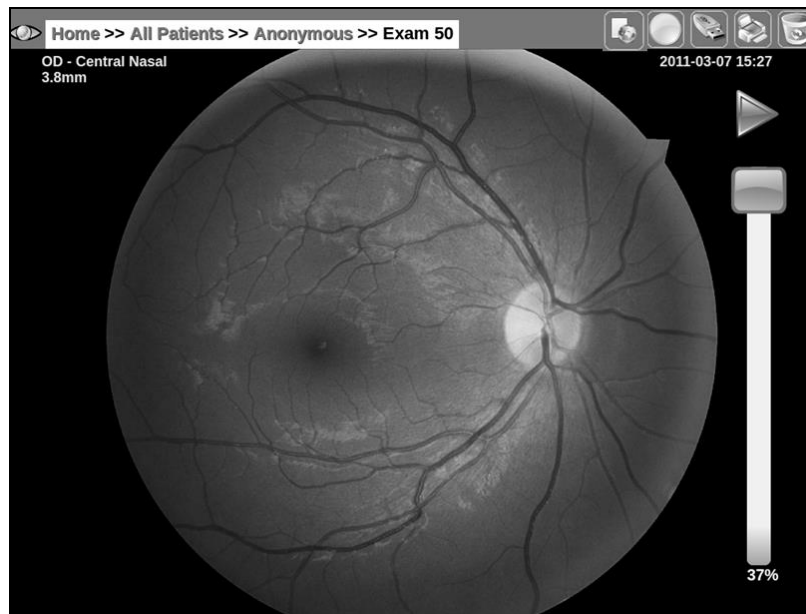**Figure 21 - Image retake function**

10.2   Full image screen

Figure 22 - Full image screen

Available functions include:

Function	Icon(s)	Command
Image zoom		A slider on the right side of the screen manages the image zooming
Image pan		Drag the image
Red-free filter		Clicking on this icon will display a black and white image corresponding to the green component of the image
Export to shared folder		Clicking on this icon will allow manual export of the selected image to a shared folder (only available if a shared folder has been configured)
Image export		Clicking on this icon will export the selected image as a high quality jpg file on any USB key (only available if a USB key is plugged in any of the USB ports)
Image print		Clicking on this icon will print the current image (only available if a compatible USB printer is connected)
Image delete		Clicking on this icon will permanently delete the selected image
Move to next / previous image		Clicking on these icons will move to the next/previous image of the current patient
3D viewer		Clicking on this icon will toggle between normal and 3D viewer for the stereo images. Only available when showing a stereo image.
Swap stereo images		Clicking on this icon will swap right and left image of a stereo pair ("crossed-eye" format). Only available when showing a stereo pair.
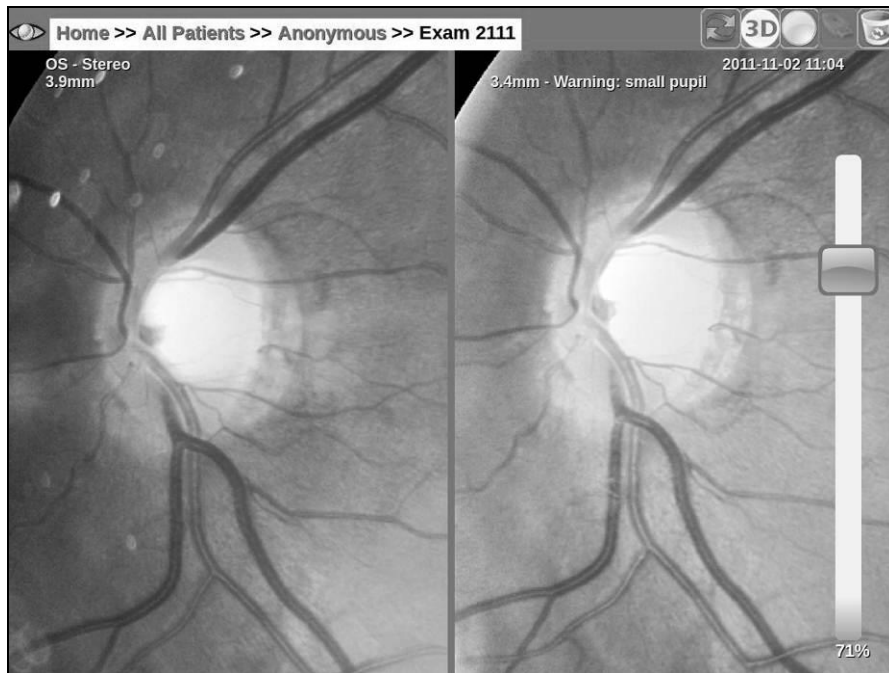
Figure 23 - Stereo Images 3D viewer.

Figure 24 - To perceive the 3D vision of the optic disk, the images must be watched with a couple of prismatic goggles that let each eye see only one of the two images. The photo shows an example of such goggles. "Crossed-eye" format is also supported.

11. REMOTE VIEWER

There are two ways to review DRS data and images remotely from a PC, a tablet or a smartphone. The first is by connecting to an existing network (LAN) and the second is by creating a *private network* even in absence of an existing network infrastructure. The DRS supports both wired and Wi-Fi connections in both the regular and the *private network* mode.

> The DRS remote viewer uses standard Internet browsers and does not require installation of any software application on the remote PC.
> Supported browsers include: Microsoft Internet Explorer 8 (or later), Mozilla Firefox 3 (or later), Apple Safari, Google Chrome.

Remote visualization through a LAN
To configure the DRS for LAN access see par. 14.3. In order to use the remote viewer with an existing LAN proceed as follows:
1. Connect the DRS to the LAN;
2. Connect the remote PC to the LAN;
3. In case the local area network does not provide automatic IP assignments, configure the DRS as explained at par. 14.3 (**Manual** configuration) and configure the remote PC with a different IP;
4. Retrieve the DRS IP, as displayed in the Settings – Network screen (see par. 14.3, Figure 33);
5. Type the DRS IP in the URL box of the remote PC's Internet browser.

Remote visualization through a private network
To configure the DRS for a private network access see par. 14.3.
To use the viewer in wireless mode proceed as follows:
1. Enable the wireless connection of your PC, tablet or smartphone (some restrictions apply: not all devices support *private network*);
2. Select the wireless network created by the DRS that will be called "drs-s/n";
3. Open the browser;
4. Digit `http://drs` in the browser

To use the viewer in wired mode proceed as follows:
1. Connect the DRS with a cable to your PC;
2. Open the browser;
3. Digit `http://drs` in the browser;

Once the connection is established, the DRS patient list will show up on the remote PC, tablet or smartphone (some restrictions apply: not all devices support *private network*). You might be required to type a password depending whether password protection was enabled in the DRS settings (see 14.3). Available functions include:
- Patient list (same as Figure 6);
- Patient record screen (same as Figure 19)
- Access to individual images (same as Figure 22).
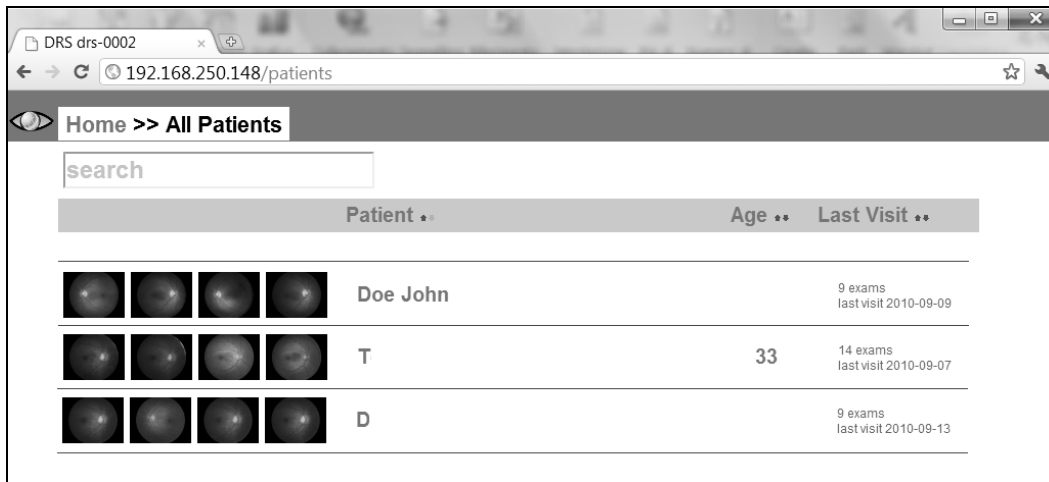
Figure 25 - DRS patient list displayed in remote viewer

12. PRINTOUT

12.1   Full image screen

When a compatible USB printer is connected a printout of any acquired image can be generated

by clicking on the [printer icon] button.

12.2   Patient record screen

By clicking on the [printer icon] button it is possible to print two images on the same printout. Once the button is pressed a dialog box appears prompting for the selection of two images. The image list can be scrolled in order to select the images to be printed, by clicking on the print icon that is placed on the top right corner of each image.
Once two images are selected the printout can be printed by clicking on the "Print" button.
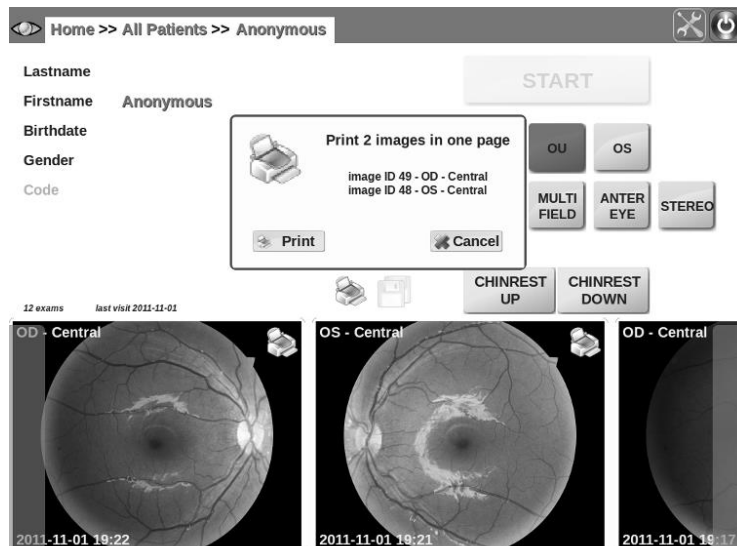
Figure 26 - Double printout images selection
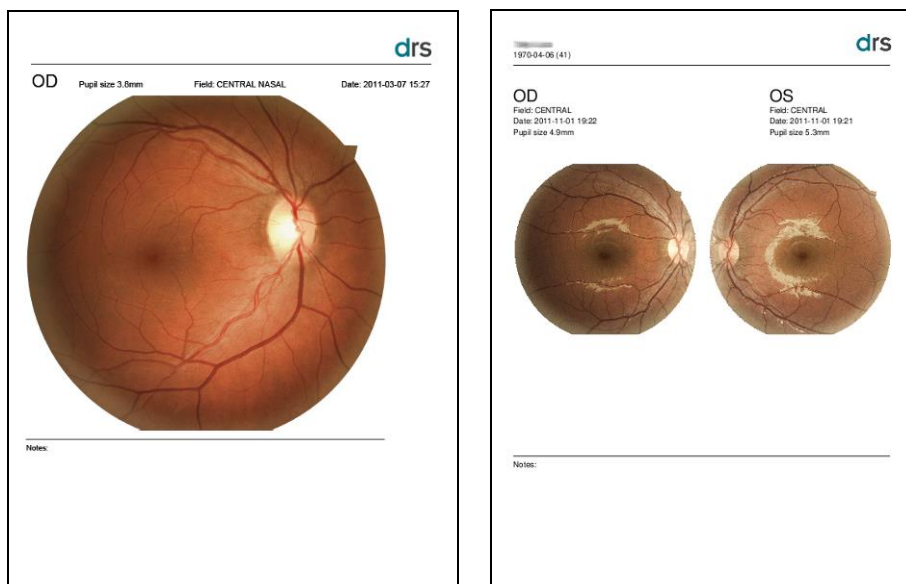
Figure 27 - Single and double images printout

13. RETINAL FIELDS

The following fields can be acquired (see Figure 28 for fields representation for the right eye):

a. CENTRAL: centered on the foveal pit;
b. NASAL: centered 17° nasally to the foveal pit ;
c. TEMPORAL: centered 17° temporally to the foveal pit ;
d. SUPERO-TEMPORAL: centered 12° superiorly and 12° temporally to the foveal pit;
e. PERI-CENTRAL: centered 5° nasally to the foveal pit ;
f. SUPERIOR: centered 17° superiorly to the foveal pit ;
g. INFERIOR: centered 17° inferiorly to the foveal pit;
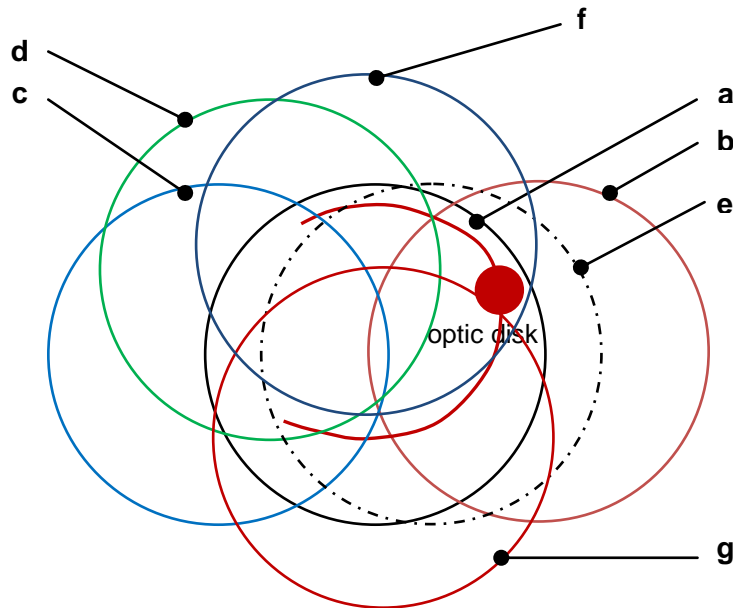
Figure 28 - DRS retinal fields

The field(s) acquired respectively when using the SINGLE FIELD or MULTI FIELD acquisition modes described previously can be configured in **Settings** (see par. 14).

14. <u>SETTINGS</u>

To access the settings screen click on the ⚒ button in the upper-left corner of the home screen, patient list or Patient record screen. Once in the settings page, the following tabs are available:

14.1   <u>Fields</u>

This page allows configuring the fields acquired by the SINGLE and MULTI acquisition modes: any 45° field, among the 7 available ones (see par. 13), can be associated to the SINGLE mode, while up to seven 45° fields can be associated to the MULTI mode.
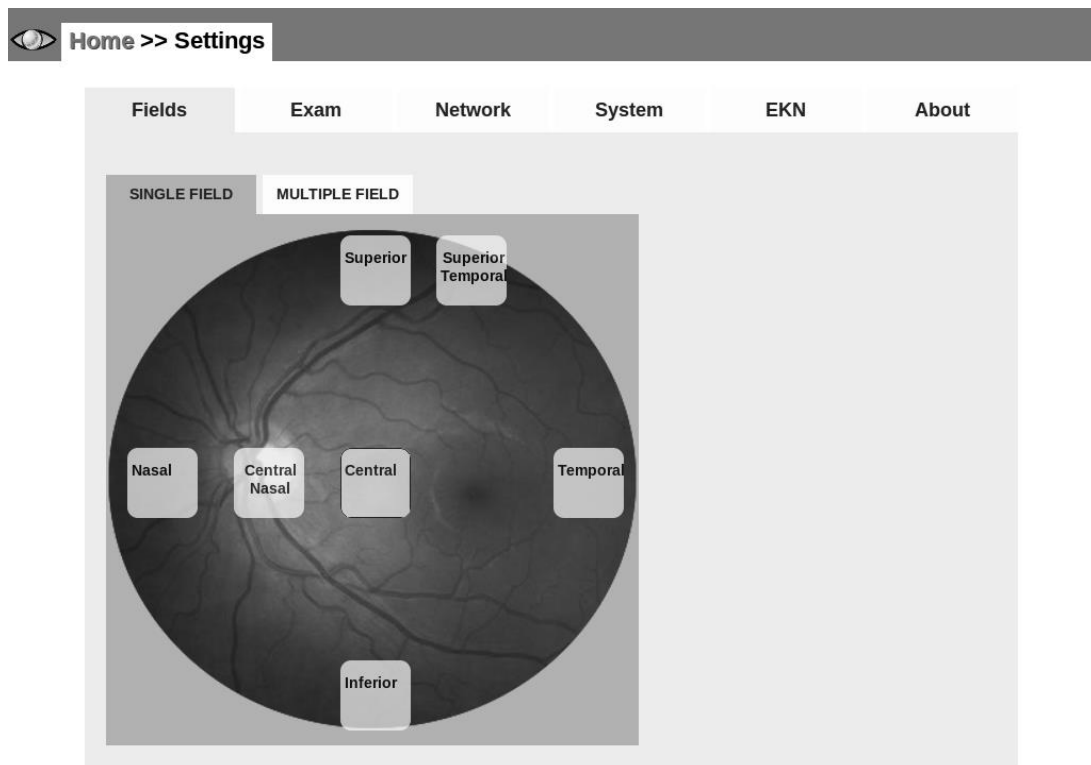
Figure 29 - Fields menu in settings page (single field)

14.2 Exam

Exam has three sub tabs which are: **Exam**, **Saving** and **Advanced**.

Exam
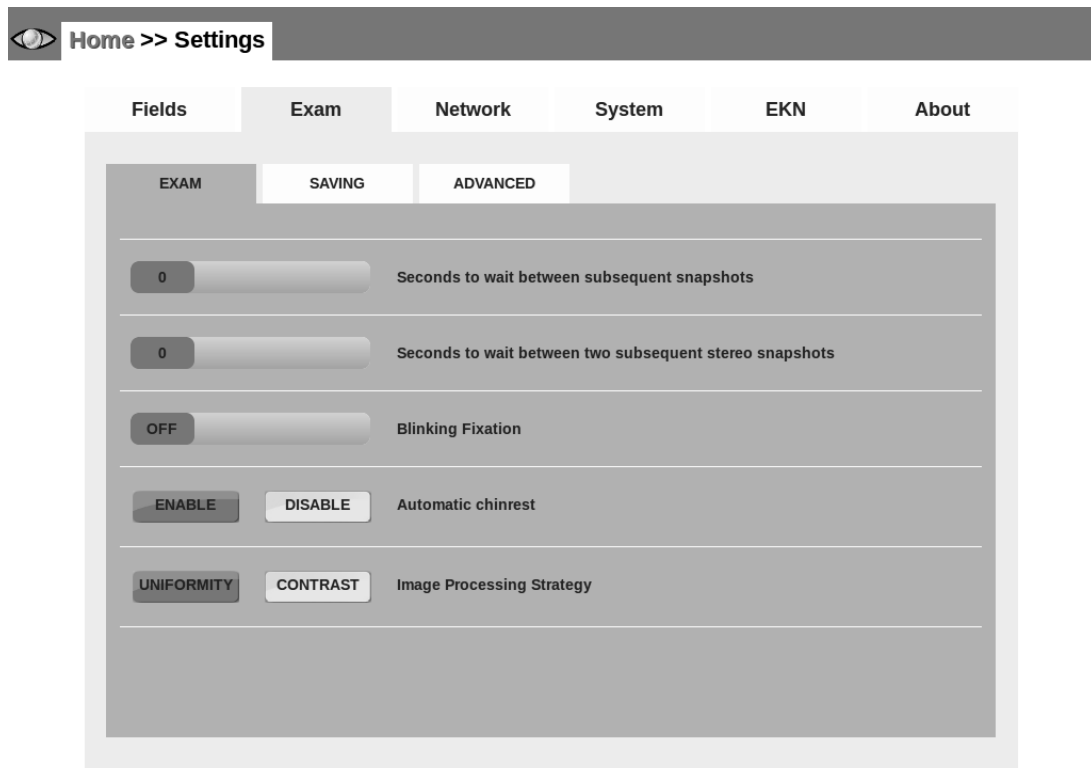
Figure 30 - Exam menu in settings page (Exam)

From **Exam** (see Figure 30):
- one can set a delay in seconds (default 0) between subsequent snapshots;
- A separate delay can be set between stereo pairs;
- Additionally the fixation target can be set to be permanent or blinking at 3 different speeds (slow, medium and fast);
- The chin rest can be set to automatically adjust its position by clicking on ENABLE.
- HIGH UNIFORMITY Image Processing Strategy

HIGH UNIFORMITY Image Processing Strategy.

It is possible to select between two different Image Processing Strategy: Uniformity and Contrast.
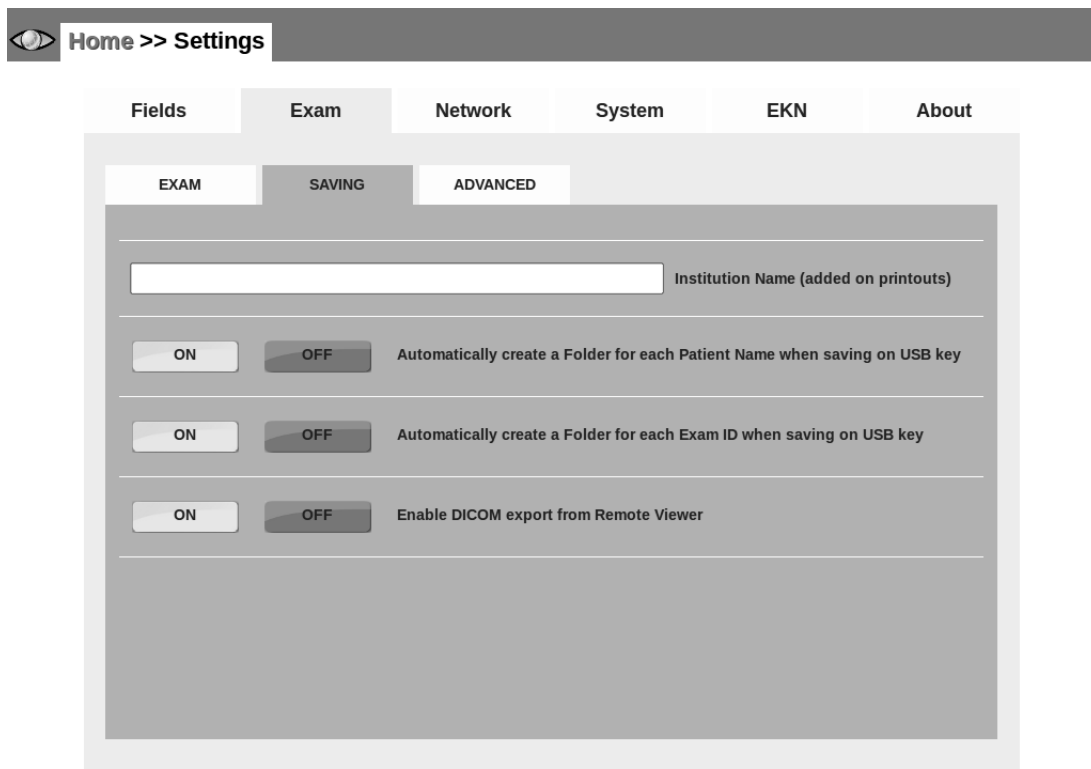
This setting affects the internal gains and color tunings of the Camera. The final retina image has different color balance and luminosity, but the original image details are the same.

One Strategy is not better than other and mostly depends on personal taste and habit.

UNIFORMITY strategy - with this selection the image appears very uniform in color, with mild shades. Micro aneurisms and macula details may appear more visible with this setting

CONTRAST strategy - this selection returns an image with more contrast and luminosity difference. Details may appear more evident but image has a more grainy aspect, especially at high zoom levels.

Saving

Figure 31 - Exam tab in settings page (Saving)

From **Saving** (see Figure 31) one can:
- Set the name of the Doctor or Clinic that will appear in the header of the printouts (this value is saved in the DICOM tag 0008, 0080 *Institution name*).
- It is also possible to choose to automatically create a folder for each patient name and/or a folder for each exam ID when saving on USB key.
- it is possible to enable the function for DICOM export of images from the Remote Viewer. (The DICOM file format contains both the retina image and some corollary field, for example: exam date/time, patient name, type of medical instrument, etc.)

Advanced

Figure 32 - Exam menu in Settings page (Advanced)

From **Advanced** (see Figure 32) one can:

- Enter the *Institution Dept. Name*: this value is saved in the DICOM tag 0008,1040;
- Enter the *Study Description*: this value is saved in the DICOM tag 0008,1030;
- Enter the *Series Description*: this value is saved in the DICOM tag 0008,103e;
- find the option to disable the lens cap detection at the start of the exams.
- control the threshold of the auto-exposure meter (Exposure Value box). The higher the value specified, the brighter the flash level. The value can be set from 0.5 to 5.0. The "default" button sets the value to the default level (2.0).

14.3   Network

Each time the "Network" tab is selected, a network test is performed. Once it completes, the result is displayed on the screen next to the Current network status label. The result can be any of the following (see Figure 33):

- *Internet connection fully available on address xxx.xxx.xxx.xxx*: the DRS is fully connected to the Internet (required for EKN connection and support purposes).
- *LAN working on IP xxx.xxx.xxx.xxx*: a valid network is set and the local network is ready.
- *No working connection*: the DRS is not connected to any network.
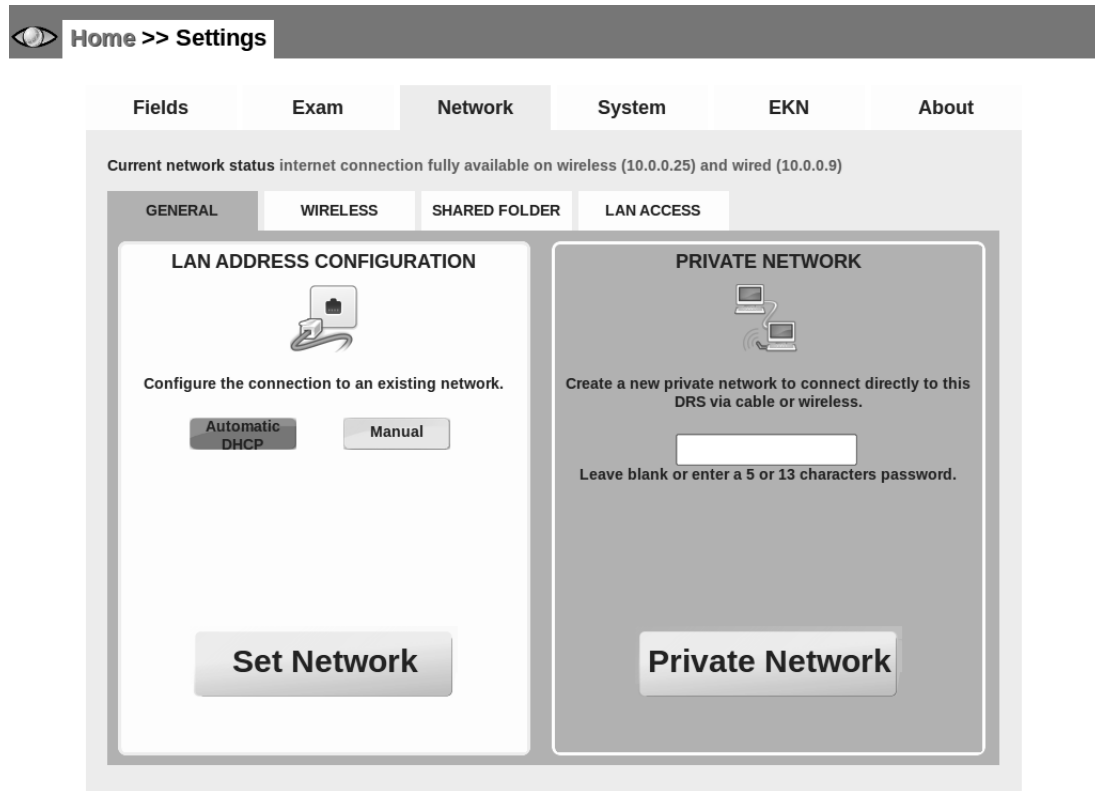
Figure 33 - Network/General tab in settings page

General

To enable a wired connection, plug a network cable into the DRS and wait a few seconds. Press "SET NETWORK" to refresh the network configuration. Most networks do not require the operator to set the IP address manually, but in case it's needed, click on the Manual button and enter the IP address (mandatory), netmask (mandatory), gateway (optional) and DNS (optional). Then select "SET NETWORK" (see Figure 34).
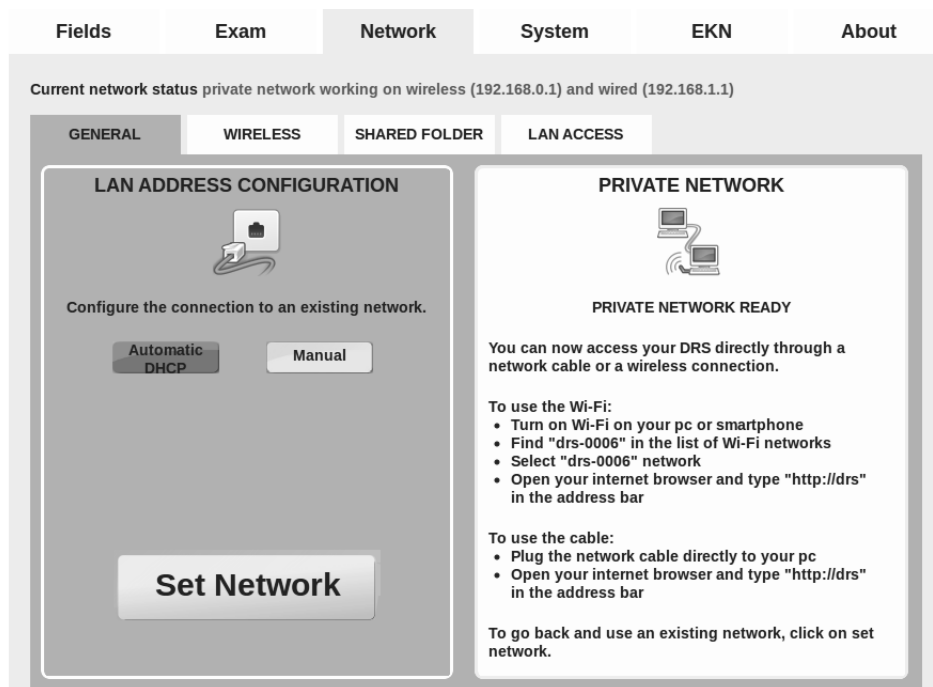
Figure 34 - Network/General tab when a private network has been set-up

To enable the DRS to create a private network click on **Private Network** button (see Figure 34). The Private Network allows the use of the DRS remote viewer without using existing networks. It can be used both in wired and wireless configuration. To go back and use an existing network click on **Set Network.**

	The Private Network always enables the wireless interface.
	If the DRS is plugged into an existing network (where another DHCP server is active), unplug the network cable before enabling the Private Network in order not to interfere with the existing DHCP server.

	The DRS wireless Private Network is compatible with Apple iPad and Microsoft Windows XP, 7, Vista and 8 (up to version 8.0). Android-based devices and Windows 8.1 have known limitations that prevent the correct use with the DRS wireless Private Network.

Wireless

To enable the wireless network select the **WIRELESS** tab and click the **ENABLE** button. Make sure that no cable is plugged into the Ethernet port: this could create problems in wireless connection. Press **RESCAN** to refresh the list of available networks, then select the network to which you want to connect to. Enter the WiFi password/key and click "Connect" to establish the wireless connection. In Figure 35 an example of a wireless networks found.
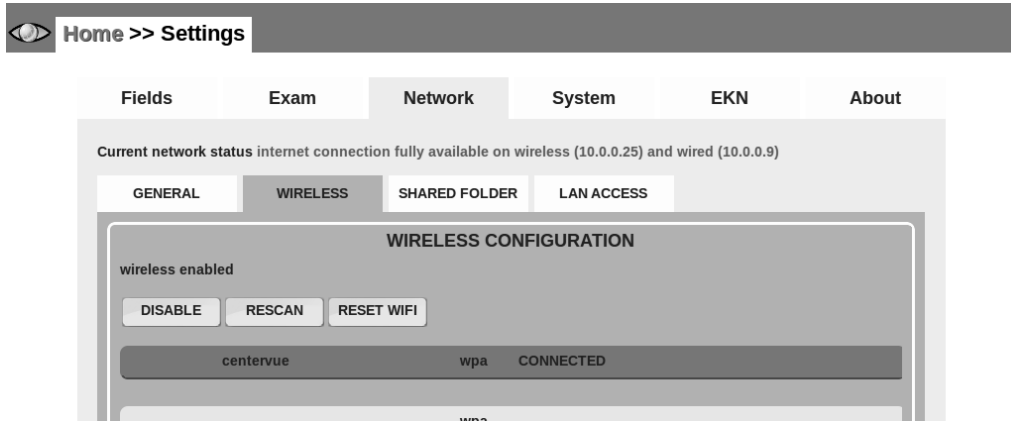
Figure 35 - Wireless menu when a wireless network is going to be set-up

Shared folder

The DRS can export images into a shared network folder. To enable exporting to shared folder select the **SHARED FOLDER** tab and then press **ON**.

Choose the format type to be exported (JPEG, DICOM or PDF) and the mode (MANUAL or AUTO). If the **AUTO** mode is chosen, at the end of each exam, a copy of the photo will be automatically saved to the shared network folder. The images in the shared folder can be deleted at any time by the operator or by a program without altering the database and files inside the DRS. The exported files are saved by creating a file whose name follows the following format:

patientID_lastname_firstname_date_time_drsNumber_eye_fieldNumber_examNumber.<ext>

If the **MANUAL** option is selected, a new button will be shown in the upper right corner of the Full image screen. This button allows you to save the exam in the shared folder (Figure 36).
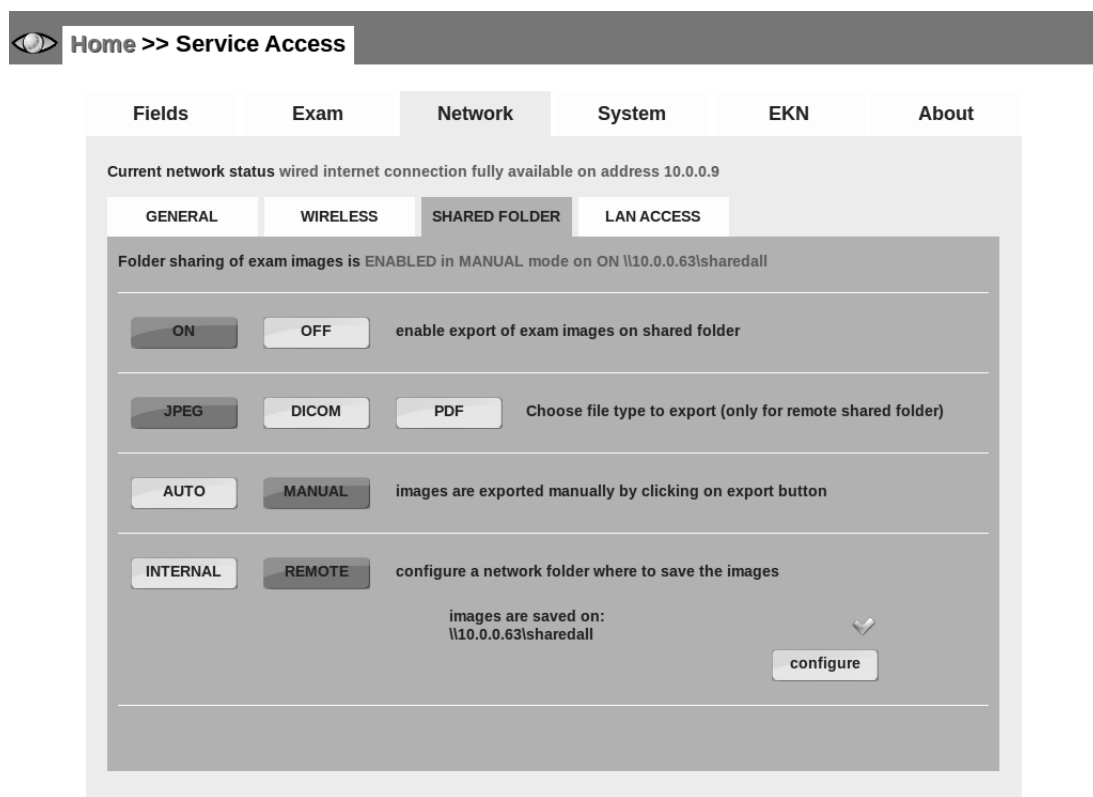
Figure 36 - Menu in Settings page (Shared Folder)

As shown in Figure 36 you can set the export function to save the images in a folder inside the DRS (by pressing the **INTERNAL** button) or in a remote folder (by pressing the **REMOTE** button).

When **INTERNAL** is selected, data is saved in a folder inside the DRS. This folder can be reached from a regular PC by searching a network resource named \\DRS-ID\shared (e.g. \\drs-0010\shared).

In case of complex networks, it may be necessary to insert the IP address of the DRS instead of its name (e.g. \\192.168.1.10\shared). In this case you might need to seek the support of your local IT staff.

When **REMOTE** is selected, the DRS needs to be configured with the name of the remote host, the name of the share, and the username (and its password) of a user that has the necessary rights to access the remote folder. The following figures (Figure 37, Figure 38) show the messages that will be displayed to the operator.
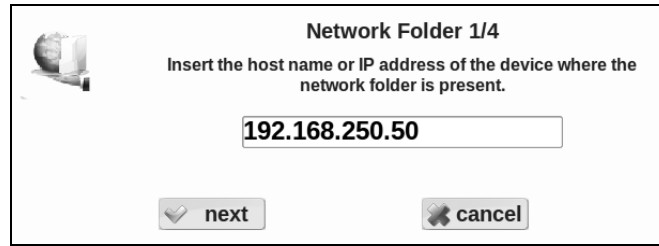
Figure 37 - Remote Folder Configuration – Dialog Window n°1

Figure 38 - Remote Folder Configuration – Dialog Window n°2

A third step may require you to insert your username and password on the remote folder, if required by the remote server.

In case of correct setting a dialog box like the one in Figure 39 will appear. When you press OK the setup will be validated and stored in your DRS configuration.

Figure 39 - Remote Folder Configuration – Connection Successful

The most important difference between the two type of shared folder (internal and remote) is where the data is store and therefore how it can be accessed. The Internal option is the easiest to set up, but the data is available only as long as the DRS is powered on and connected to the network. The Remote option might require additional information and special permissions (especially in complex networks) but the data is available even when the DRS is powered off or disconnected.
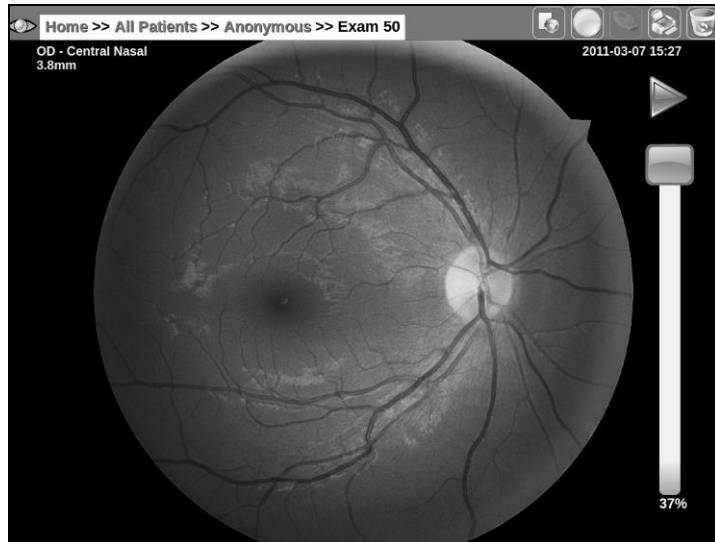
Figure 40 - Image Visualization when MANUAL shared folder is active

Password to protect access from the network
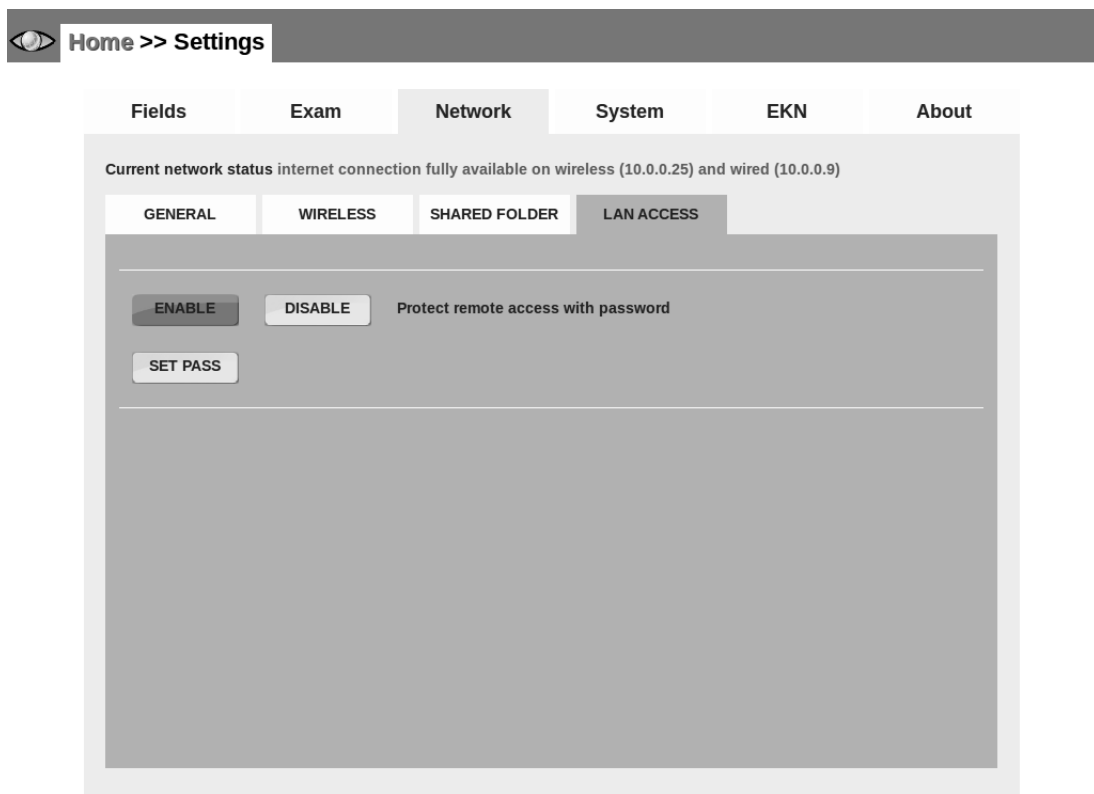
Figure 41 – LAN Access submenu in Settings page

The **LAN ACCESS** sub tab lets you set a password for the Remote Viewer access to the DRS, to prevent access to the exams data to unauthorized people in your local network.

14.4 System

From **System** one can access five other menus: **General, Time**, **Backup, Printer** and **Service.**

General
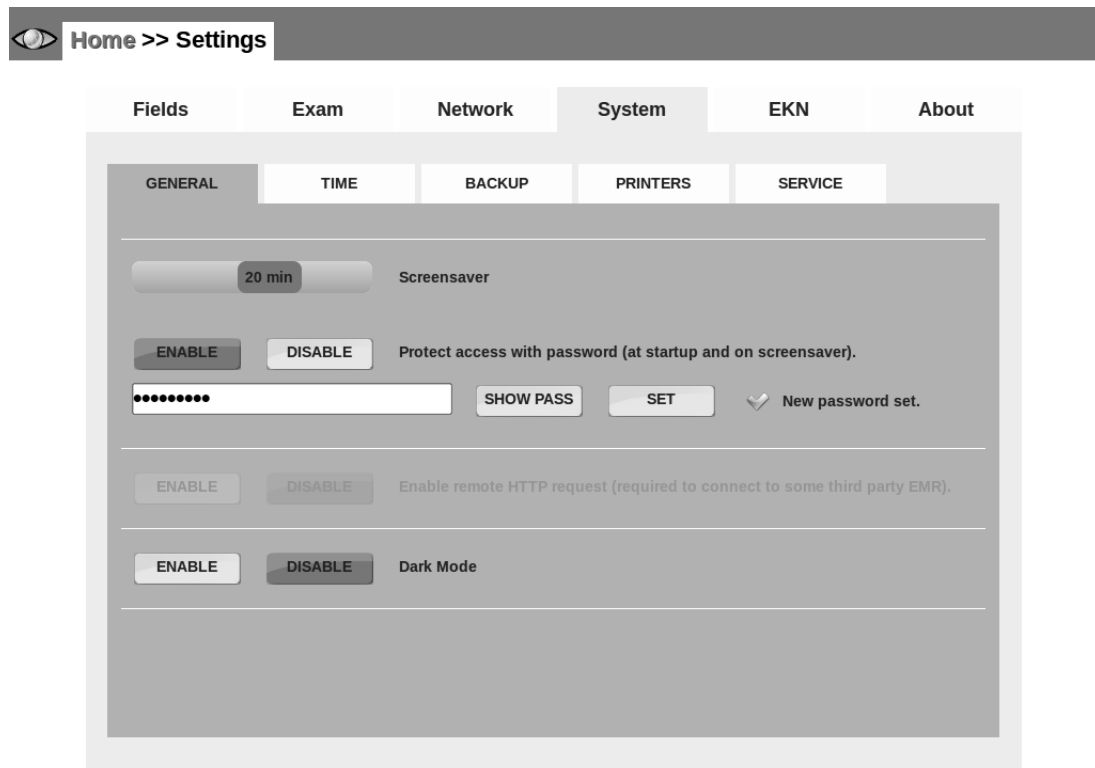
Figure 42– Submenu GENERAL of System

The **General** tab can be used to configure the following features:
- Enable, disable and configure the screensaver: the delay can be between 5 min and 60 min.
- If the screensaver is enabled it can be protected by a password: the operator will also be prompted for the password when the DRS starts;
- Third party EMR systems can interface to the DRS using its web programming interface. This feature can be enabled only if a valid license is installed.
- Enable or disable the "DARK MODE": a configuration that reduces the emission of light, useful when using the device in a dark room.
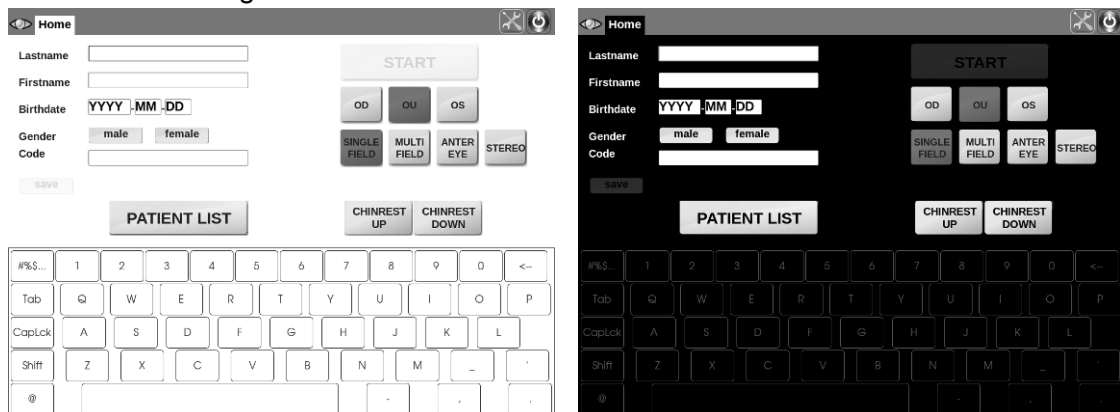
Time
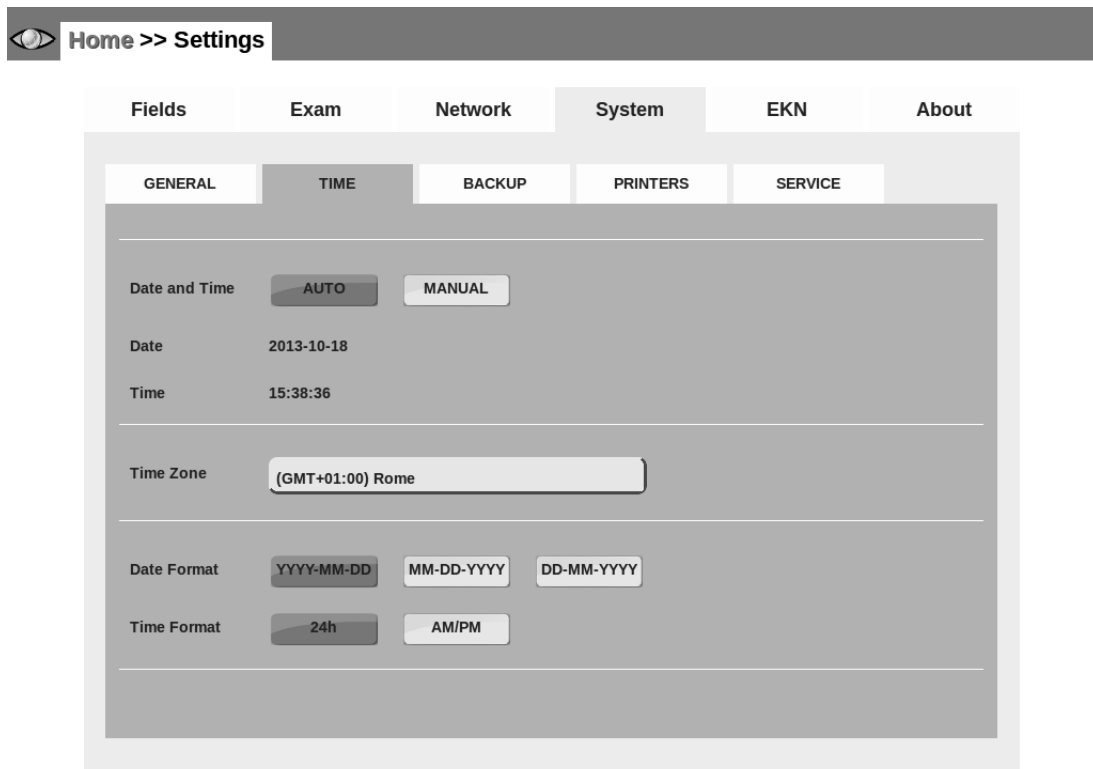
Figure 43 - System menu in settings page (Time)

The system date and time can be set-up:
- Automatically from Internet
- Manually from the pull-down menus

In this submenu, you can also set: the correct time zone, format the date and time

Backup

Backup tab allows full management of backup and restoration of the DRS entire database. To perform a data backup, simply connect a USB key or hard disk to the DRS and start the backup operation by pressing "Backup Data" button (see Figure 44).

To restore data from an existing backup, press the button "Restore Data" (see Figure 44). A wizard will let you choose between a full restore (existing data are replaced with the ones contained in the backup) or a fusion of the data (the imported data are merged with the ones present in the DRS). The restore has a "same patient" recognition, and in case of doubt the wizard asks for confirmation of duplicate patients handling.

> ⚠ **It is very important to frequently use the backup function to store the data on an external drive. In case of a hardware failure resulting in data loss, the data can be then restored from the last performed backup.**

Here below are some additional notes on the *backup* and *restore* procedures.
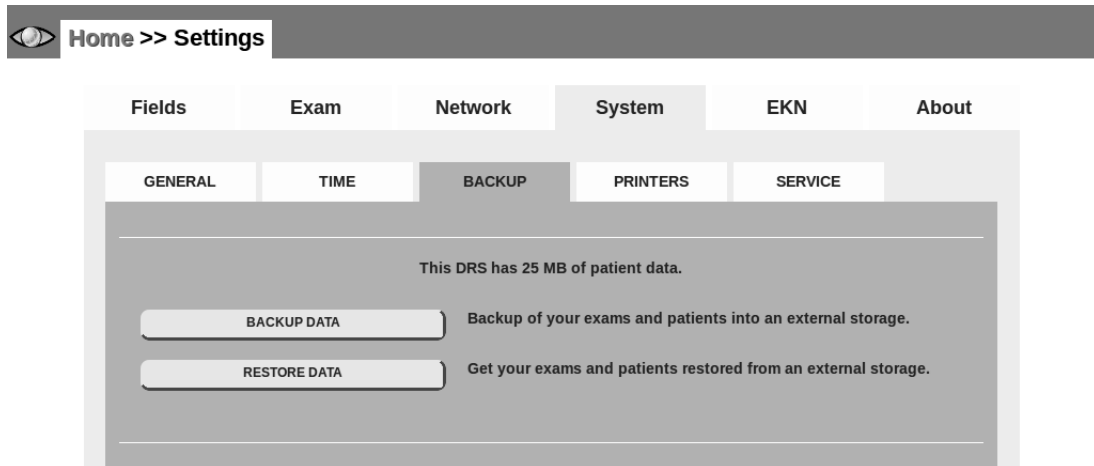
Figure 44 - System/Backup menu in Settings page (no USB key connected)

A further note on the backup process. If a backup of the same machine is found in the external device, the operator is warned of the number of exams and patients that would be lost by executing a new backup. This warning permit to cancel the operation by pressing the "Cancel" button (see the dialog boxes here below), and afterwards plug another external device and launch the backup operation again.

⚠ A manual modification of the backup data over your external device prevents the ability to restore that backup. Remember to never modify your exams when reviewing them.
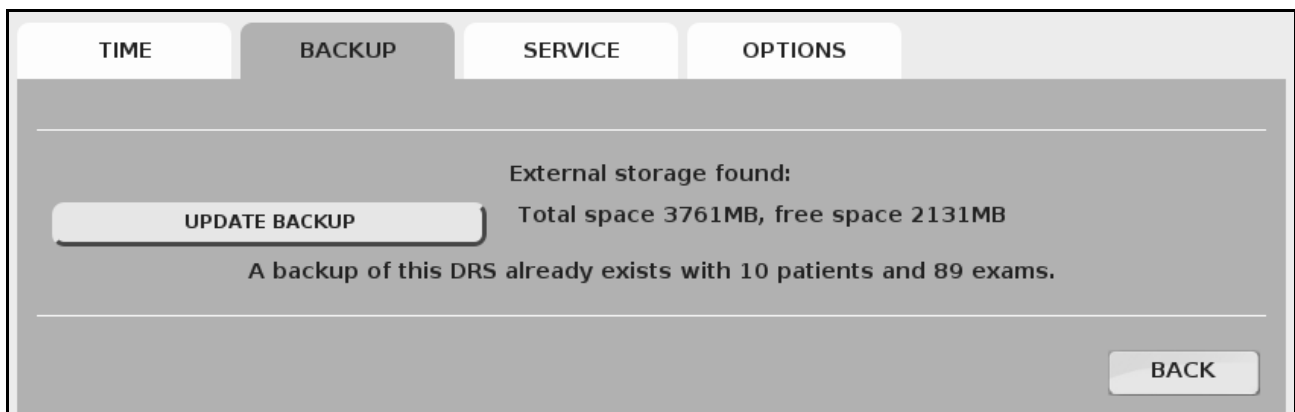
Figure 45 - This view is shown when a previously stored backup is found. Note how the button is labeled "UPDATE BACKUP" instead of "START BACKUP".
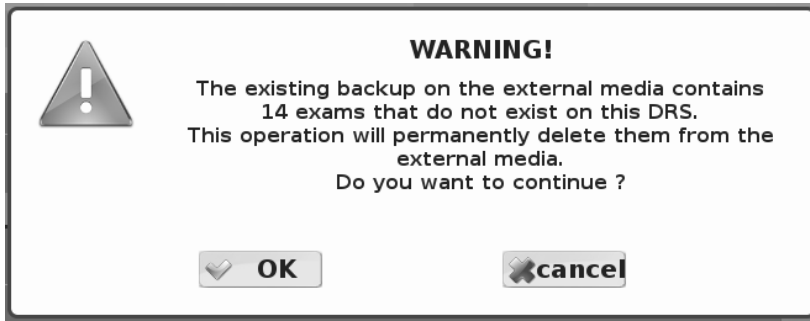
Figure 46 - Message shown when the operator presses "UPDATE BACKUP".

Figure 47 - Final confirmation that the backup completed successfully.

On the Restore process. Full operation compatibility is guaranteed with backups generated using previous software versions (whose backups were stored in a unique archive format). Here below you can see the restoration mode selection view.
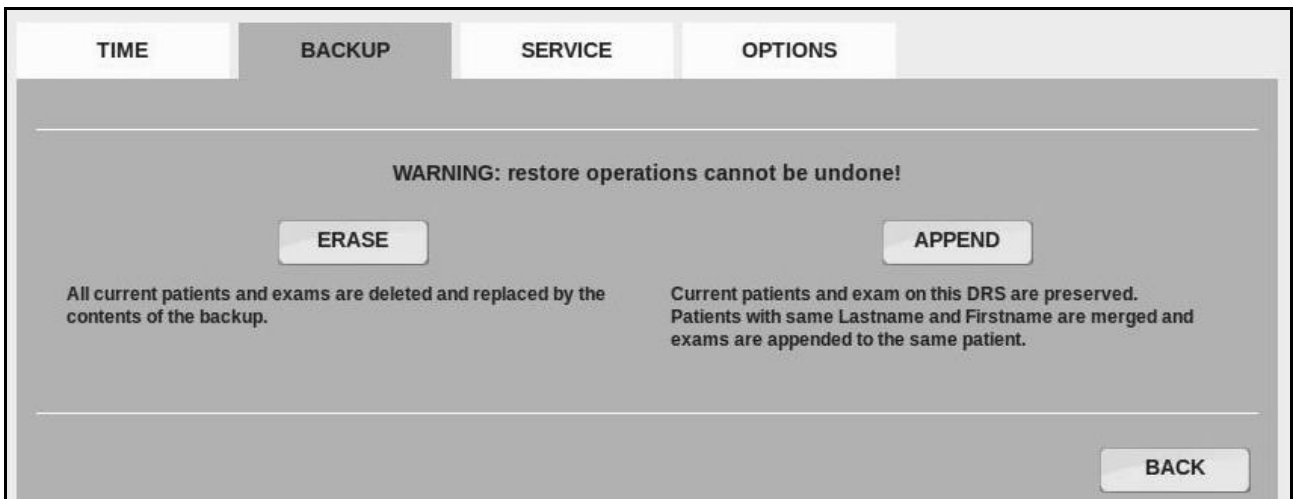
Figure 48 - Restore mode

Using the first mode (ERASE button) the current DRS exams and patient's data are overwritten by data of the selected backup source. In the second mode (APPEND button), the system properly recognizes identical patients and exams and executes a restoration into the DRS of the differences only. Only in case of ambiguity, the system asks the operator to select from a pool of "similar" patients into whom appending the exams (see Figure 49 - Duplicated patients , where patient John Doe is asked to be merged into a target patient with the same name or be duplicated).
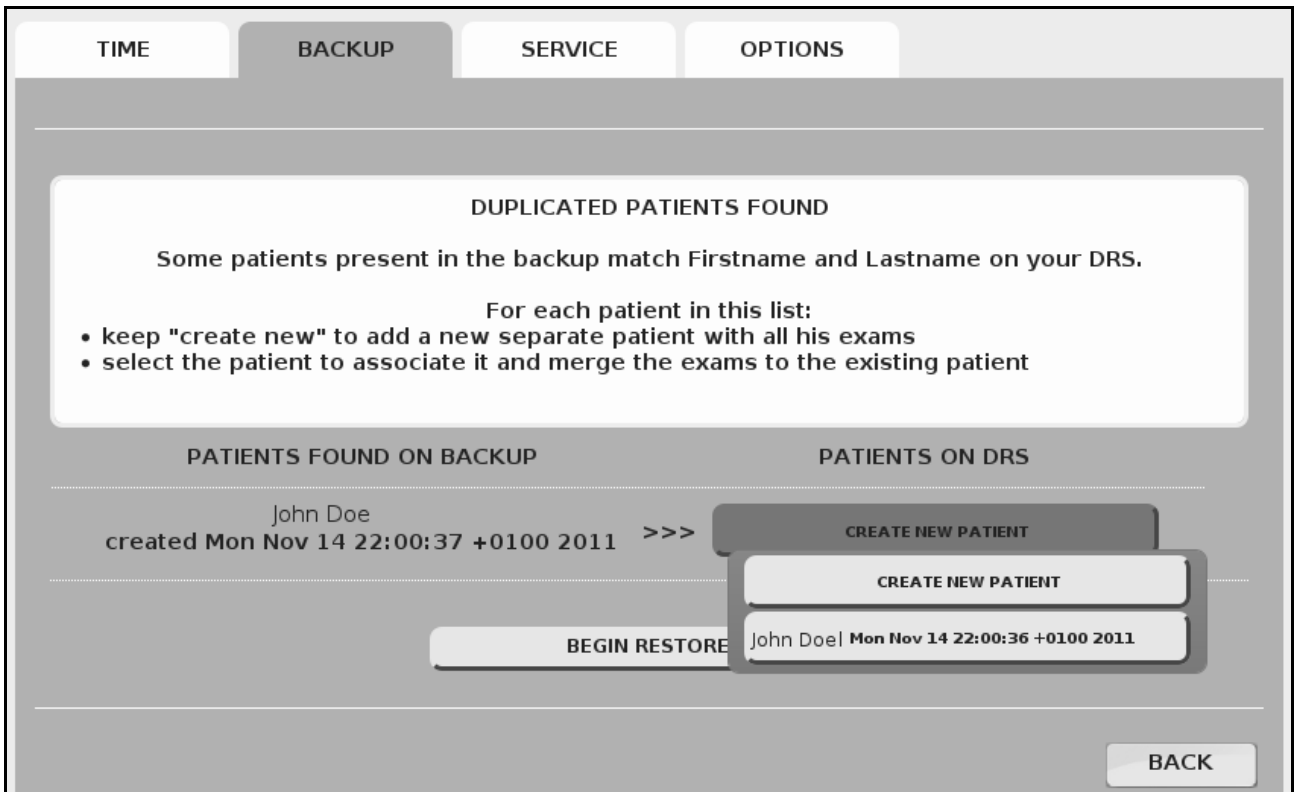
Figure 49 - Duplicated patients dialog

An ambiguity between patients arises when they have the same name, no other useful information (like birth date, etc.) and they do have different database creation dates.

For both backup and restore, a progress percentage informs the operator about the operation status.

Printers
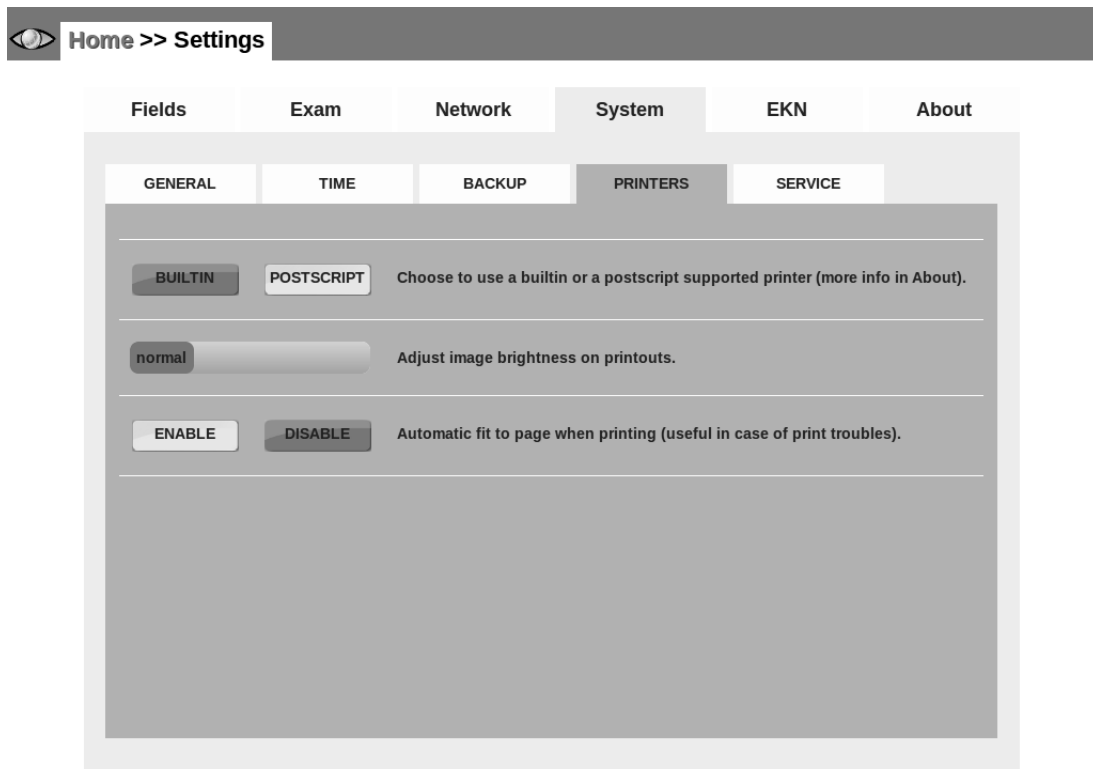
Figure 50 – System menu in Settings page (Printers)

The **Printers** tab can be used to configure the following features:
- Chose different kind of drivers for printer: use a built-in driver or a postscript version;
- Adjust image brightness on printout;
- Option to enable the "Automatic fit to page" for printouts, to be used if you are experiencing printing problems.

Service

The **Service** menu allows using some service functionalities. In particular, **Reset Robot** will force a reset of the robot motor positions (the same procedure is performed by the system at startup), **Service** will give access to a special password-protected panel available for authorized personnel only. **Image rebuild** allows rebuilding the images thumbnails, in case some of them have disappeared as a consequence of a data restore; **Reset Patients** will erase all the patients and their data exams, while **Reset Parameters** will erase all the settings to Factory defaults (selected fields, network configuration, shared folder, preferences, etc.).
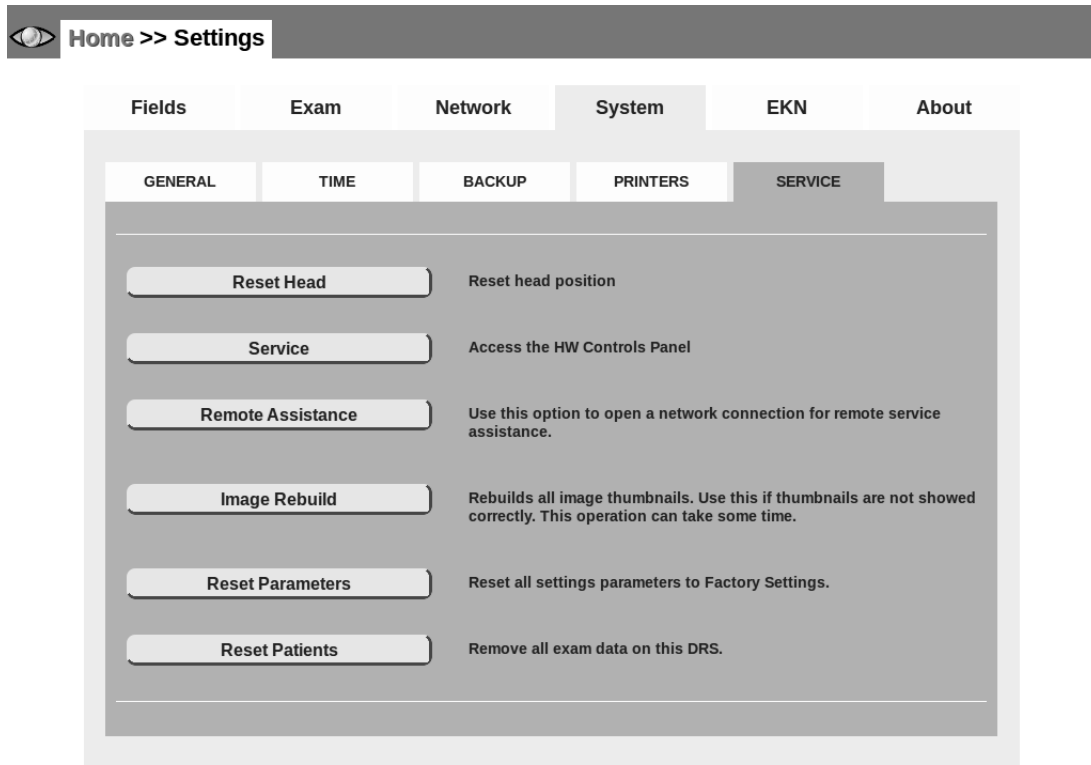
Figure 51 - System menu in Settings page (Service)

⚠	**Reset Patients will ERASE the whole database content. Once the operation has been confirmed there is NO WAY to restore the data. Use this function with caution.**

ⓘ	**The Reset Patients button is disabled when the DRS is connected to the EKN cloud.**

The **Remote assistance** button opens a remote connection that allows authorized service technicians to connect to the DRS. Once pressed, the following disclaimer appears informing the operator that he/she is authorizing the access to all the data present on the device, for servicing purposes:
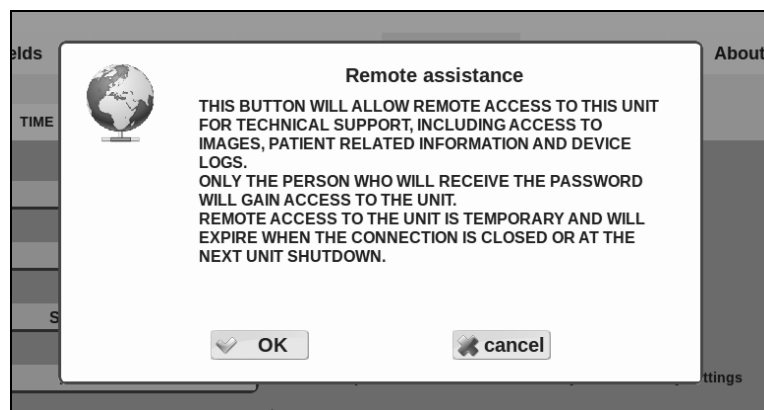
Figure 52 - Remote Assistance confirmation

Once confirmed with the **OK** button, the device contacts CenterVue servers and generates a random password and a port to connect to. These parameters must be sent to the service operator in order to connect.
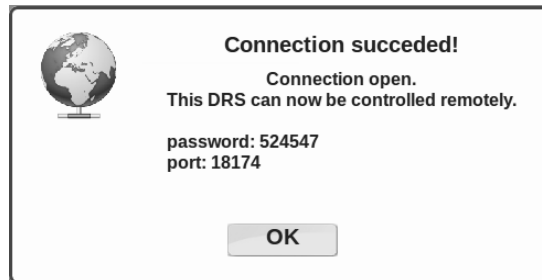
Figure 53 - Remote Assistance result

The connection can be closed using the same button, which now has changed to **Close Remote Assistance**. Please note that, as stated in the disclaimer, the remote assistance is closed automatically if the machine is restarted.
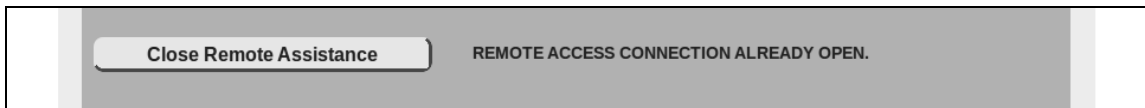
Figure 54 - Remote assistance status

14.5   EKN

The **EKN** tab lets you handle the remote synchronization of DRS data to the CenterVue Cloud solution (`https://www.eyeknowledge.net`): by enabling this feature, all exams data will be uploaded on the cloud using a secure, encrypted channel and stored encrypted using a proprietary encryption algorithm (patent pending).
The advantages of using this feature are several:
- It can be used as a form of backup of exams data;
- It is possible to review your images from any web browser, from anywhere in the world;
- It can be used as a system of telemedicine (the operator and the doctor can be situated in different places);
- It is possible to easily share some of the images with who you desire.

For more detailed information on this new feature, please refer to `https://www.eyeknowledge.net/about`
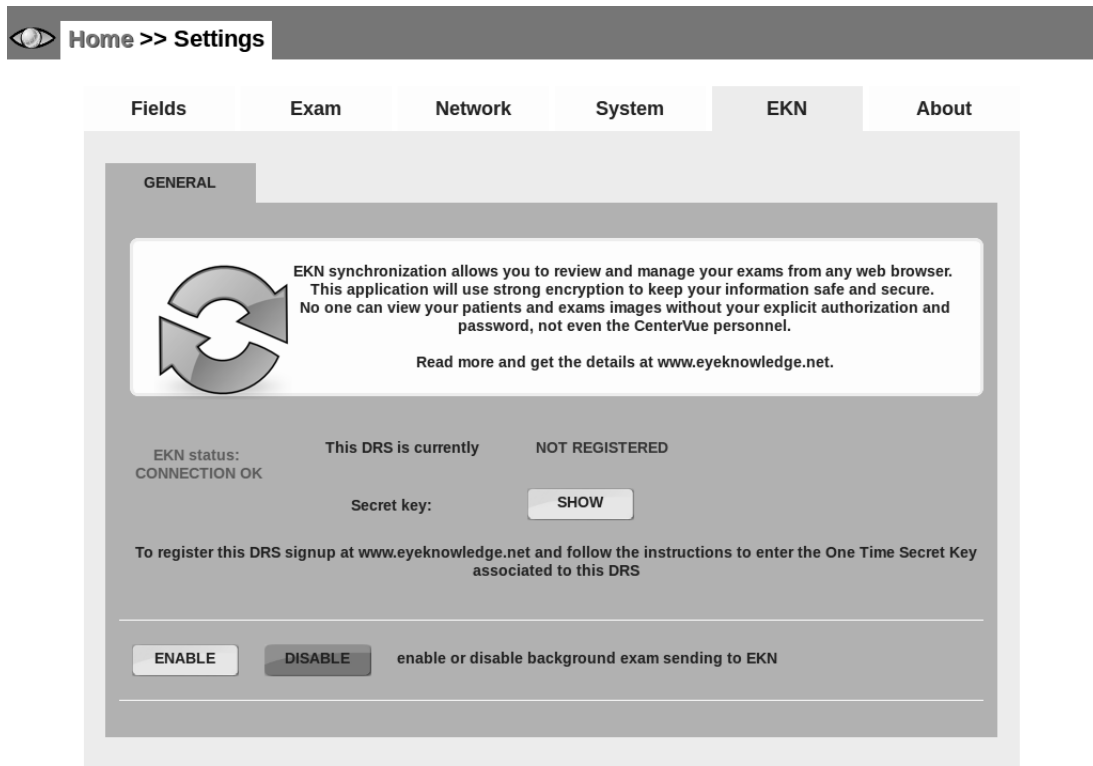
Figure 55 - EKN sync submenu in Settings page

HOW TO REGISTER YOUR DRS ON THE EKN CLOUD

To start browse your DRS through the EKN platform you need to first register the instrument on the EKN.

1. First time registration with the One Time Secret Key
Go to Settings, then EKN; press the SHOW button to show the Secret Key.
Press "ENABLE" to prepare your DRS to synchronize data with the EKN server.

2. Create an account on the Eye Knowledge Network
From your PC, navigate to `https://www.eyeknowledge.net/` and register a new account by clicking on the "Sign Up" button.

3. Register your DRS
On the `eyeknowledge.net` website click on "Register now" to open the registration page.
Insert the serial number of your DRS, such as drs-0123 or drs-9999. Remember to type the letters using lowercase characters. Then carefully type the One Time Secret Key shown on your DRS. You need to do this operation only once.
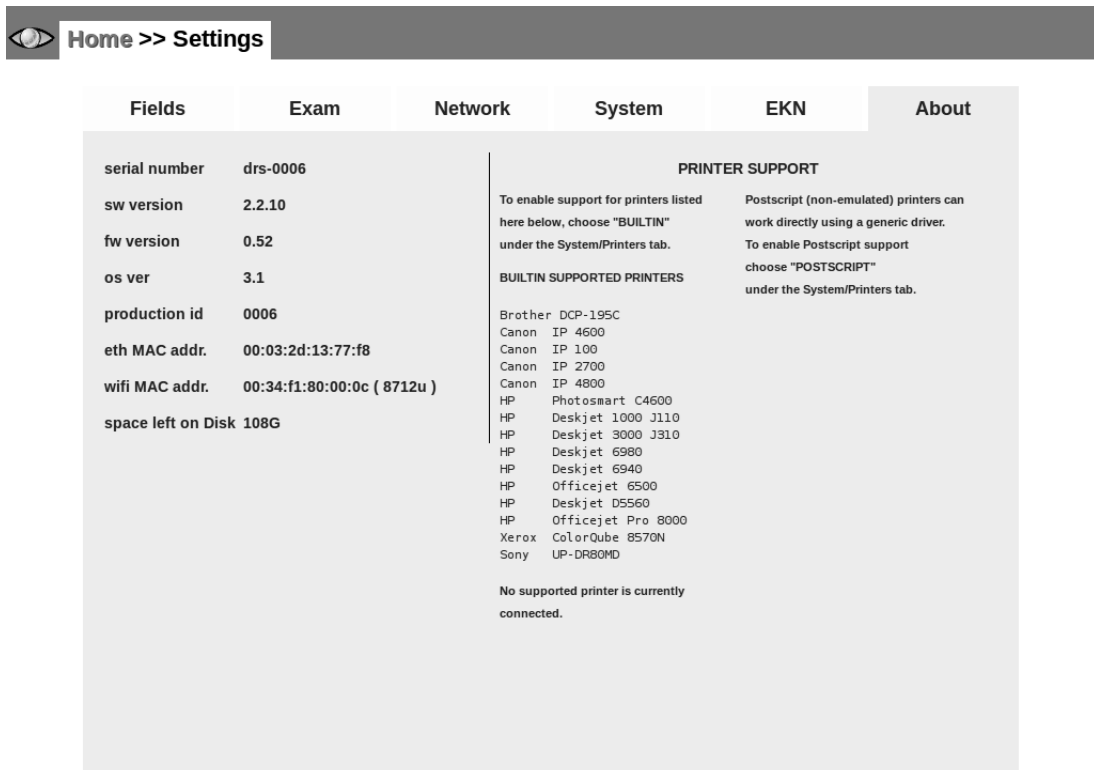
4. Start viewing
Go back to your DRS and keep it connected to the internet. After less than half an hour you can go back to Settings=>EKN and the device will display "registered".
After a while all the patients and the exams will be available on your EKN account.

The upload time depends on the number of patients and photos already stored in the DRS and on the available bandwidth. It is advised to configure the DRS with a wired connection in order to provide a stable connection with a high bandwidth.

14.6   About

This screen shows the DRS serial number, the software and firmware version, the OS version and the Ethernet / WiFi MAC address.

Figure 56 - About menu in Settings page

15. AUTOMATIC SOFTWARE UPDATE

When a new software update is released by the manufacturer and the DRS is connected to the internet, a new icon will appear [icon] on the Home screen at the top bar, notifying availability of the update. If you click on the icon, the message shown in Figure 57 will appear. To download and install the new software version click **Install**, otherwise to keep the current version click **Cancel.**
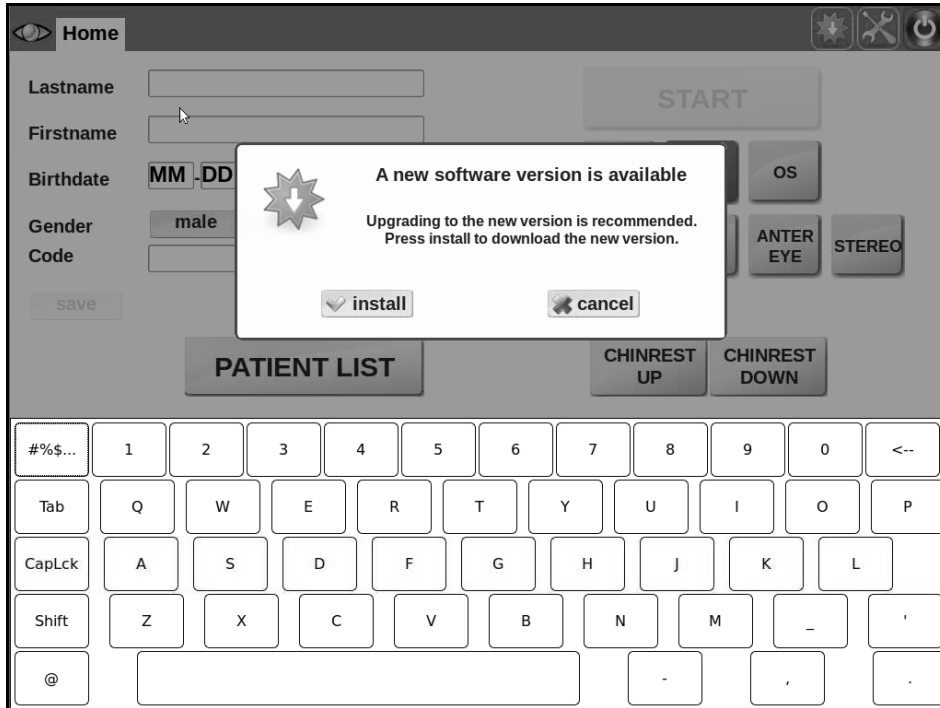
Figure 57 - Message to confirm the installation of the new software version

16. <u>SYSTEM SHUTDOWN</u>

To shut down the system go to the startup screen, patient list or Patient record screen and click on the power off button . Wait for the progress bar to completely roll back. A message on the screen will inform you when it is safe to turn off the **main switch**.

Always put back the cap on the front lens.

   Do not leave the front lens uncovered while the system is not in use.

17. <u>CLEANING</u>

This paragraph explains how to clean the system. The chin rest and the forehead rest shall be disinfected between one patient and the next. The disinfecting solution should be applied using a wipe, taking care not to sprinkle parts not belonging to the patient rest.

After each examination, between one patient and the next, the forehead rest and the chin rest shall be cleaned using isopropyl alcohol or another similar disinfectant solution, not containing oxidizing agents.

Extreme care should be given to always protect the front lens.

The front lens should be cleaned by using a small hand pump air blower, to blow away dust. Only if really needed, for instance due to the presence of a fingerprint, the front lens should be cleaned using photographic cleaning paper and a suitable lens cleaning fluid.

The touch screen panel should be cleaned only with a cloth damped in water.

⚠	Do not use alcohol or detergents to clean the touch screen as these may damage the film covering the panel

When cleaning the rest of device, the device must be powered off, and the power cord shall be disconnected from mains. If needed, the external covers of the unit can be cleaned by means of a slightly damp cloth.

18. <u>MAINTENANCE</u>

The only operation the operator can do on the device is the fuse substitution. Following is the procedure for performing this operation:

- •Disconnect power cord from mains
- •Remove fuse holder with the help of a small screwdriver
- •Remove and replace fuses (see section "Technical specifications")
- •Insert fuse holder
- •Connect power cord to mains.

All service interventions not included in this chapter should be carried out by authorized CenterVue personnel.

It is warmly recommended to provide a service to the instrument in order to check

- the electrical safety (IEC 60601-1) every year.
- the general functionality test and measurement tests every 5 years.

CenterVue and its authorized personnel can provide on demand specific maintenance contracts.

19. ELECTROMAGNETIC COMPATIBILITY

This device is classified in class B according to IEC 60601-1-2.

This device has been tested and found to comply with the limits for medical devices contained in IEC 60601-1-2 and Medical Device Directive 93/42/EEC. These limits are intended to provide reasonable protection against harmful interference in a typical medical installation. This instrument generates, uses and can radiate radio frequency energies and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If the system does cause harmful interference to other devices, which can be determined by turning the system off and on, try to eliminate the interference by adopting one or more of the following measures:

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

20. FCC (USA) and IC (Canada) radio certification

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

- FCC ID: K7T-WIFIHU-A ID
- IC: 2377A-WIFIHUA.

These devices comply with part 15 of the FCC rules.

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

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

21. TECHNICAL SPECIFICATIONS

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

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

Retinal Imaging
- Field of view: 45° x 40°
- Non-mydriatic operation (4 mm minimum pupil size)
- Fixation target: internal LEDs
- Operating distance: 37 mm.
- Sensor size: 5 MPixel (2592 x 1944)
- Resolution: 48 pixels/deg
- Resolution on retina: 15 µm
- Pixel pitch on retina: 6 µm

Other features:
- Patient presence sensor
- Motorized chin-rest
- Automatic alignment
- Auto-focus (adjustment range: from -15D to +15D)
- Auto-flash level adjustment
- Touch-screen color display
- Embedded PC
- Ethernet connectivity

Dimensions:
- Weight: 19 Kg (42 lbs.)
- Size: 55 × 55 × 33 cm (22 × 22 × 13 in)

Accessories:
- Power cord;
- Spare fuses;
- Operating Manual;
- Dust cover;
- Microfiber cleaning sheet for touch screen;
- Front lens photographic cleaning tissue, pack of single-use sheets;
- Silicone forehead rest;
- Hand blower;
- Glasses with adjustable prisms;
- USB 2.0 extension cord.

Power requirements:
- Voltage: 100-240 VAC, 50-60 Hz, fuse 3.15 A (T type)
- Power consumption: 100 VA

22. DICOM Statement

DRS can export a DICOM-compliant file format. Refer to the table below for the list of supported tags.

Tag	Description	VR	Len	Value
(0002,0000)	Group Length	UL	4	180
(0002,0001)	File Meta Information Version	OB	2	0
(0002,0002)	Media Storage SOP Class UID	UI	32	1.2.840.10008.5.1.4.1.1.77.1.5.2
(0002,0003)	Media Storage SOP Instance UID	UI	22	2.16.840.1.114496.6.4
(0002,0010)	Transfer Syntax UID	UI	20	1.2.840.10008.1.2.1
(0002,0012)	Implementation Class UID	UI	26	1.2.826.0.1.3680043.8.641
(0002,0013)	Implementation Version Name	SH	8	CVUEDRS
(0002,0016)	Source Application Entity Title	AE	10	RUBY_DICOM
(0008,0016)	SOP Class UID	UI	32	1.2.840.10008.5.1.4.1.1.77.1.5.2
(0008,0018)	SOP Instance UID	UI	22	CenterVue ANSI registration code (unique id number) plus machine id and actual exam id. Example: 2.16.840.1.114496.6.4
(0008,0020)	Study Date	DA	8	Exam date
(0008,0021)	Series Date	DA	8	Exam date
(0008,0022)	Acquisition Date	DA	8	Exam date
(0008,0023)	Image Date	DA	8	Exam date
(0008,002A)	Acquisition Datetime	DT	14	Exam datetime

Tag	Description	VR	Len	Value
(0008,0030)	Study Time	TM	14	Exam time
(0008,0031)	Series Time	TM	14	Exam time
(0008,0032)	Acquisition Time	TM	14	Exam time
(0008,0033)	Image Time	TM	14	Exam time
(0008,0050)	Accession Number	SH	0	This tag is always empty
(0008,0060)	Modality	CS	2	OP
(0008,0064)	Conversion Type	CS	2	DI
(0008,0070)	Manufacturer	LO	16	CenterVue S.p.A.
(0008,0090)	Referring Physician's Name	PN	0	This tag is always empty
(0008,0100)	Code Value	SH	8	R-1021A
(0008,0102)	Coding Scheme Designator	SH	4	SRT
(0008,0104)	Code Meaning	LO	14	Fundus Camera
(0008,1030)	Study Description	LO	2	Value entered in Settings | Exam | Advanced | Study Description
(0008,103E)	Series Description	LO	2	Value entered in Settings | Exam | Advanced | Series Description
(0010,0010)	Patient's Name	PN	10	Value entered in the patient's Last Name and First Name fields (last + first)
(0010,0020)	Patient ID	LO	2	Value entered in the patient's "code" field
(0010,0030)	Patient's Birth Date	DA	8	Value entered in the patient's date of birth fields
(0010,0040)	Patient's Sex	CS	2	Value entered in the patient's gender field
(0010,1000)	Other Patient IDs	LO	2	Value entered in the patient's "code" field
(0018,7004)	Detector Type	CS	4	CMOS

Tag	Description	VR	Len	Value
(0020,000D)	Study Instance UID	UI	22	2.16.840.1.114496.6.4
(0020,000E)	Series Instance UID	UI	22	2.16.840.1.114496.6.4
(0020,0010)	Study ID	SH	0	This tag is always empty
(0020,0011)	Series Number	IS	0	This tag is always empty
(0020,0013)	Instance Number	IS	0	This tag is always empty
(0020,0020)	Patient Orientation	CS	2	LF
(0020,0062)	Image Laterality	CS	2	R or L (left or right eye)
(0022,000C)	Horizontal Field of View	FL	4	45.000000
(0028,0002)	Samples per Pixel	US	2	3
(0028,0004)	Photometric Interpretation	CS	4	RGB
(0028,0006)	Planar Configuration	US	2	0
(0028,0010)	Rows	US	2	1944
(0028,0011)	Columns	US	2	2592
(0028,0030)	Pixel Spacing	DS	6	0.0064
(0028,0100)	Bits Allocated	US	2	8
(0028,0101)	Bits Stored	US	2	8
(0028,0102)	High Bit	US	2	7
(0028,0103)	Pixel Representation	US	2	0

23. DISPOSAL

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

Separate collection for electrical and electronic equipment

The European Directive 2002/96/EC establishes the separate collection for Waste of Electrical and Electronic Equipment (WEEE). The users of Electric and Electronic Equipment (EEE) have not to dispose of WEEE as unsorted municipal waste, they have to collect such WEEE separately. The available return and collection system is defined by the local public administration, or in alternative an authorized company can recycle the WEEE. Please refer to public administration about the separate collection, if this information is not available, contact the manufacturer of the equipment. Users have a fundamental role in contributing to reuse, recycling and recovery of WEEE. The potentially dangerous substances contained in the WEEE can pollute the environment and produce harmful effects to the human health. Below, there are a few indications of specific dangers of some substances, which may leach in the environment and in the water system.

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

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

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

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

24. TROUBLESHOOTING

If any problem occurs, check the following table and try to apply the proposed solution.

If this does not solve the problem, immediately stop the unit operation, switch off the main power, disconnect the power supply cord and contact CenterVue authorized personnel.

Issue	*Possible cause*	*Solution*
The unit does not turn on	Main fuses are blown up.	Replace main fuses according to the § "Maintenance"
After a period of functioning, the DRS computer becomes very slow	Overheating of the computer	Remove the objects under the DRS that are blocking the cooling air flow
After the system booting, the software application send a connection error with the control board: "Robot initialization error" or "Unable to connect to control board".	The control board is not powered with 12V, or there is no USB connection between the computer and the control board, or the BIOS of the embedded PC is set not to power control board logic	Contact an Authorized Service Center
The retinal image is blurred/defocused	The motor of the focus LED doesn't move. The motor of the camera lens doesn't move.	Try repeating the exam, possibly on a different eye. If still defocused, contact an Authorized Service Center
During the exam, the software application fails the auto-alignment.	One (or both) of the pupil LEDs is damaged or not powered	Contact an Authorized Service Center
The USB key does not work	The mechanical connection of the USK key is not appropriate	Use the USB extension cord that comes with the DRS (inside the accessories box) to connect the USB key.