



Operating Manual

MANUAL INFORMATION

Date of release: August 26th, 2016
Revision number: 22
Reference software version: v2.5
Manufacturer:

CenterVue SpA
Via San Marco 9h, 35129 Padova – ITALY
Tel. +39 049 739 6147
Fax +39 049 739 6148



SUMMARY

1. INTRODUCTION	4
2. SYSTEM	5
3. LABELING	6
4. SYMBOLS.....	7
4.1 Symbols adopted on the device	7
4.2 Symbols adopted in this manual.....	7
5. PREPARING THE DRS.....	8
6. PREPARING THE PATIENT	9
7. WARNINGS AND PRECAUTIONS	10
8. NOTES TO OPERATOR	11
9. PERFORMING THE TEST	12
9.1 Adding a new patient	12
9.2 Selecting an existing patient.....	12
9.3 Starting the image acquisition process.....	13
9.4 Automated acquisition	14
9.5 Manual alignment	15
9.6 Anterior Eye	16
9.7 Stereo exams.....	17
9.8 Warning messages	17
10. REVIEWING THE IMAGES	19
10.1 Patient record screen.....	19
10.2 Full image screen	20
11. REMOTE VIEWER	23
12. PRINTOUT.....	24
12.1 Single image printout	24
12.2 Dual image printout.....	24
13. RETINAL FIELDS	26
14. BACKUP	27
14.1 First-time, total, backup	28
14.2 Incremental backups.....	30
14.3 Removing a backup disk.....	31
14.4 Partial backups	31
14.5 Restore	32
15. SETTINGS	34
15.1 Fields	34
15.2 Exam.....	34
15.3 Network.....	36
15.4 System	40
15.5 EKN.....	45
15.6 About.....	45
16. AUTOMATIC SOFTWARE UPDATE	46

17. SYSTEM SHUTDOWN.....	46
18. CLEANING.....	47
18.1 Front lens.....	47
18.2 Patient cushions	48
18.3 Touch screen panel	49
18.4 Plastic shells	49
19. MAINTENANCE.....	49
20. ELECTROMAGNETIC COMPATIBILITY	50
21. FCC (USA) and IC (Canada) radio certification.....	50
22. TECHNICAL SPECIFICATIONS	51
23. DISPOSAL	52
24. TROUBLESHOOTING AND ERROR MESSAGES.....	53
APPENDIX A - DICOM Statement	55
APPENDIX B – AUTOMATED MOSAIC FUNCTION	57
APPENDIX C – EYE KNOWLEDGE NETWORK (EKN).....	59
Enabling the EKN service	59
Data upload status	60
Multi-unit patient list	61
Retrieving the patient list from EKN	62

1. **INTRODUCTION**

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°, in a fully automatic mode. 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



Figure 1 - DRS left side view

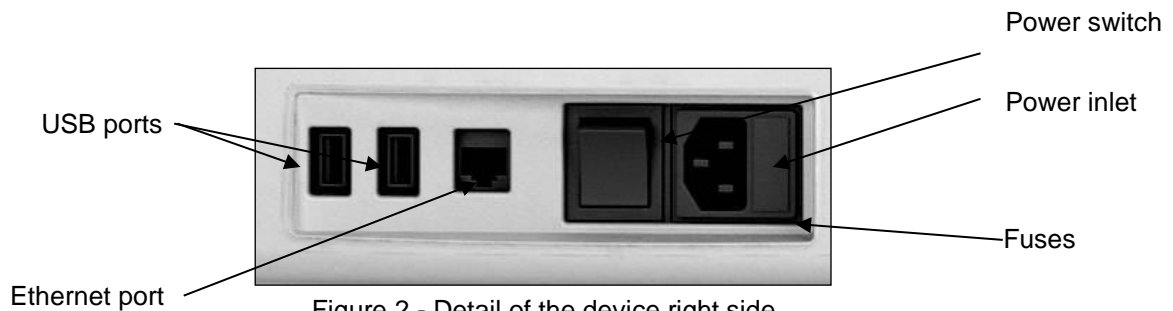


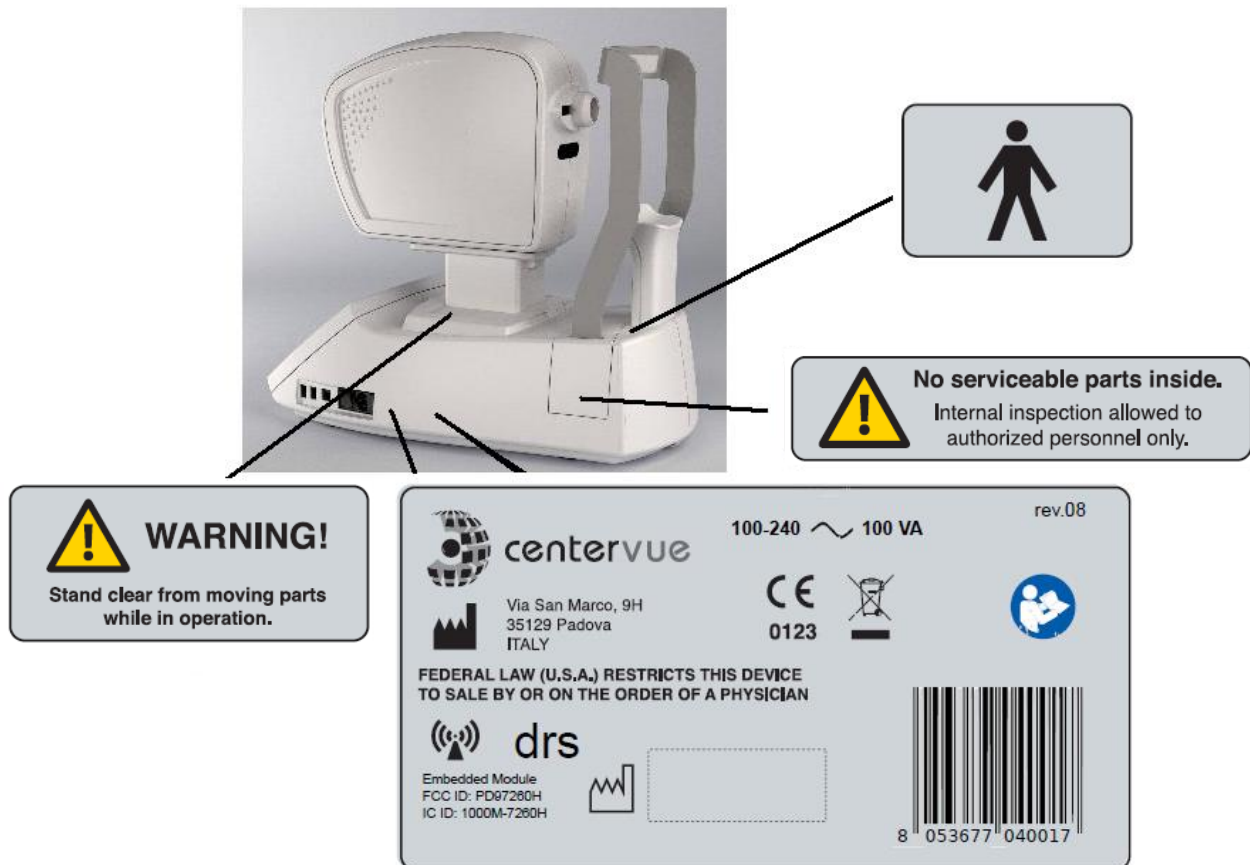
Figure 2 - Detail of the device right side

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





4. **SYMBOLS**

4.1 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 Symbols adopted in this manual

	Note
	Warning

5. PREPARING THE DRS

Read carefully and thoroughly paragraph 7 WARNINGS AND PRECAUTIONS before proceeding with first use.



The test should be performed in conditions of semi-darkness to facilitate natural dilation of the pupil.

To set up your DRS follow these steps:

- extract the system from its box;
- place the DRS on a suitable electrical table¹;
- connect the power cord provided with the unit to the power inlet (see Figure 2);
- optionally connect a compatible printer¹ 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);

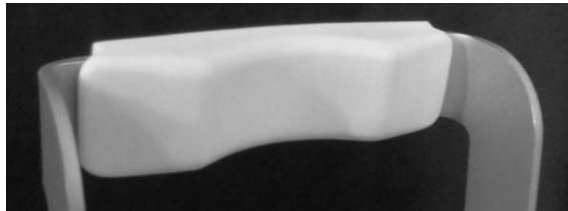


Figure 3 - Forehead rest patient side

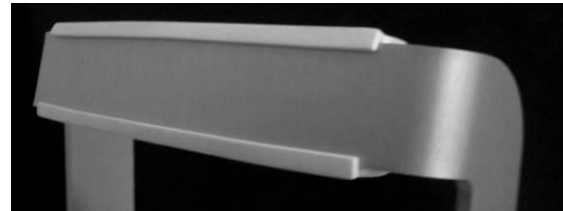


Figure 4 - Forehead rest rear side

Time zone configuration

The first time the DRS is powered on, the operator is requested to set the time zone. The configuration request (Figure 5) will appear every time the DRS is started, until the time zone is set (see §14.4).

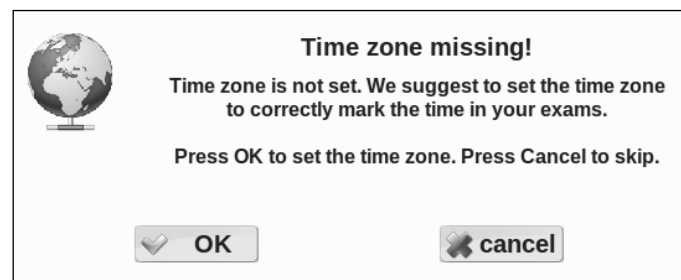


Figure 5 – Request to configure time zone

Request for camera auto-tuning

After a software upgrade to the latest version a message as in Figure 6 may appear. Such message appears only once when a new software is started for the first time: please apply the lens cap and press ok, then wait until the completion message (Figure 7) appears.

¹ Not provided with the DRS

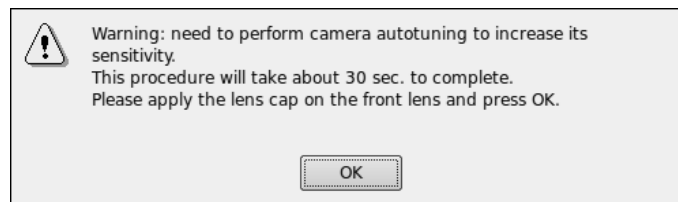


Figure 6 – Request to perform camera auto-tuning

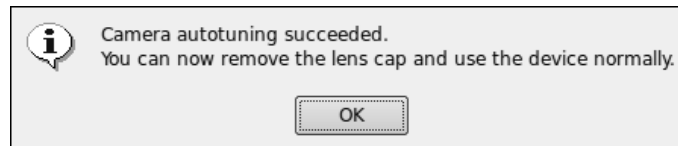
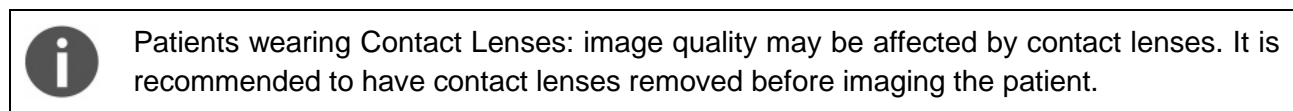


Figure 7 – Camera auto-tuning completion message

6. **PREPARING 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-mydratic device (minimum pupil diameter 3.8 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 steadily 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.
- 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 to 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: the DRS contains Patient Health Information. IT IS A RESPONSIBILITY OF THE OPERATOR TO KEEP AN UPDATED COPY OF THE DATA GENERATED BY THE DRS, BY PERIODICALLY USING THE BACKUP UTILITY IN ORDER TO BE PROTECTED AGAINST UNPREDICTABLE DATA LOSS. See par.14.4.3

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: from 10 °C to 40 °C (50 °F to 104 °F) / Humidity (max): 90% not condensing

- The DRS needs to be stored under the following environmental conditions: Temperature: from -10 °C to 60 °C (14 °F to 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.

Note on auto-alignment:



The auto-alignment process may fail in some circumstances such as:

- long eye-lashes;
- presence of make-up;
- room too bright;
- direct light on a patient's face;
- very big pupil.

Under such circumstances the exam should be repeated after removing the cause of the failure.

8. NOTES TO OPERATOR

No specific skills are required to operate the DRS.

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.



ITI IS A RESPONSIBILITY OF THE OPERATOR TO KEEP AN UPDATED COPY OF THE DATA GENERATED BY THE DRS, BY PERIODICALLY USING THE BACKUP UTILITY, IN ORDER TO BE PROTECTED AGAINST UNPREDICTABLE DATA LOSS.

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 8).

Figure 8 - 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 and any patient related notes. 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 9).

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 fields (the list can be sorted by last name, date of birth 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 or code in the **search** box.

Once the desired patient has been identified in the list, click on the corresponding line to select and open the **Patient Record** screen (see Figure 23).

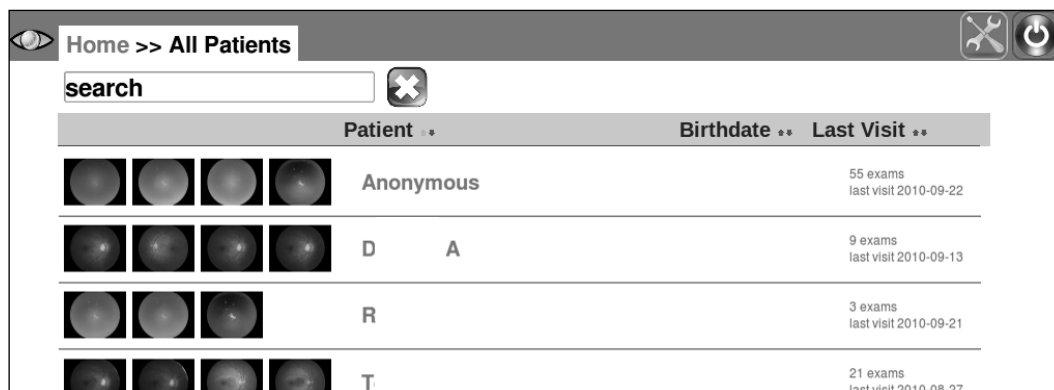


Figure 9 - Patient list screen

9.3 Starting the image acquisition process

When 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. 6 above.

Then choose among the different options / parameters:

- Click OU to acquire images from both eyes (default), OD for the right eye and OS for the left eye;
- Select SINGLE FIELD to acquire one 45° image of the retina (default);
- Select MULTI FIELD to acquire multiple 45° fields. See par. 14.1 for details on how to configure the fields acquired in each of the above two options;
- Select ANTERIOR EYE to acquire the external part of the eye;
- Select STEREO to acquire a stereo pair of the nasal field and produce a stereoscopic view of the optic disc (see details below);
- 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.

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:

- Move the optical head to locate the patient's pupil (see Figure 10);
- Move the optical head to center the patient's pupil to the front lens (see Figure 11); the system will also display the pupil current diameter and which eye is being acquired; the red circle in Figure 11 represents the pupil and becomes green when proper centering is achieved.
- Perform auto-focus (see Figure 12);
- Capture an image, by flashing the retina. This step involves also automatic tuning of the flash level;
- Store the image in the local hard drive (see Figure 13);
- 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. In case the auto-alignment process fails, manual alignment is possible: see par. 9.5 below for details.



The DRS stores any images and data on the local hard disk. If the hard disk capacity is reached, no more images can be saved and a warning message is displayed saying "Hard disk full".

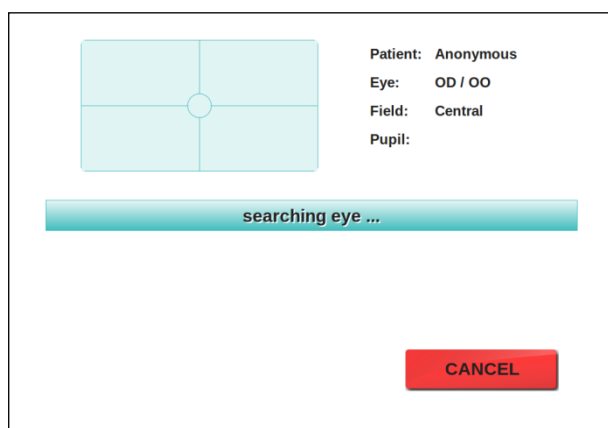


Figure 10 - Eye search in progress

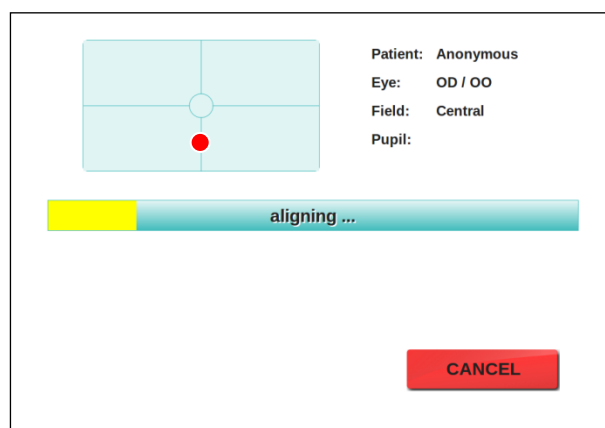


Figure 11 – Auto-alignment in progress

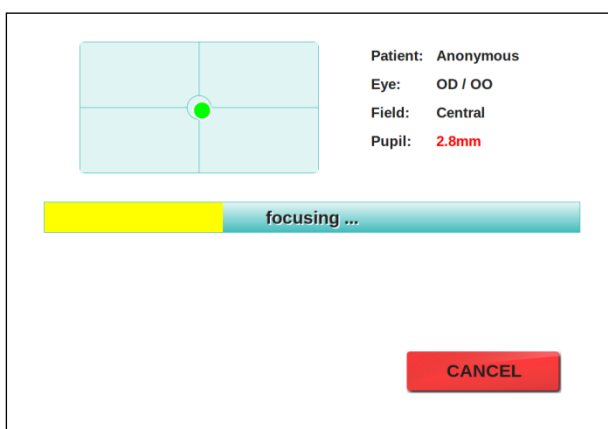


Figure 12 - Auto-focus in progress

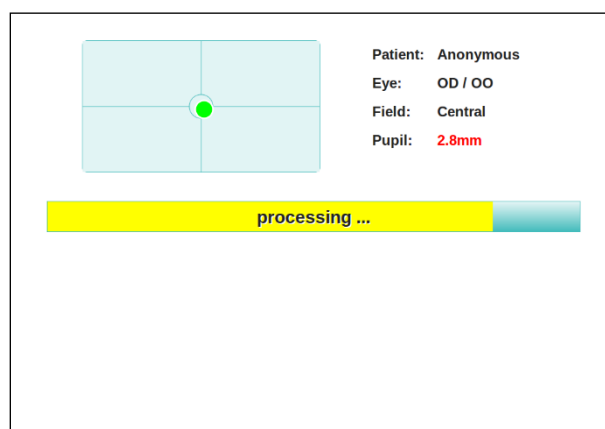


Figure 13 - Image processing and saving in progress

9.5 Manual alignment

If, for some reasons, the automated eye search fails, a message as in **Figure 14** 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 the target and/or to not move) before proceeding with 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.

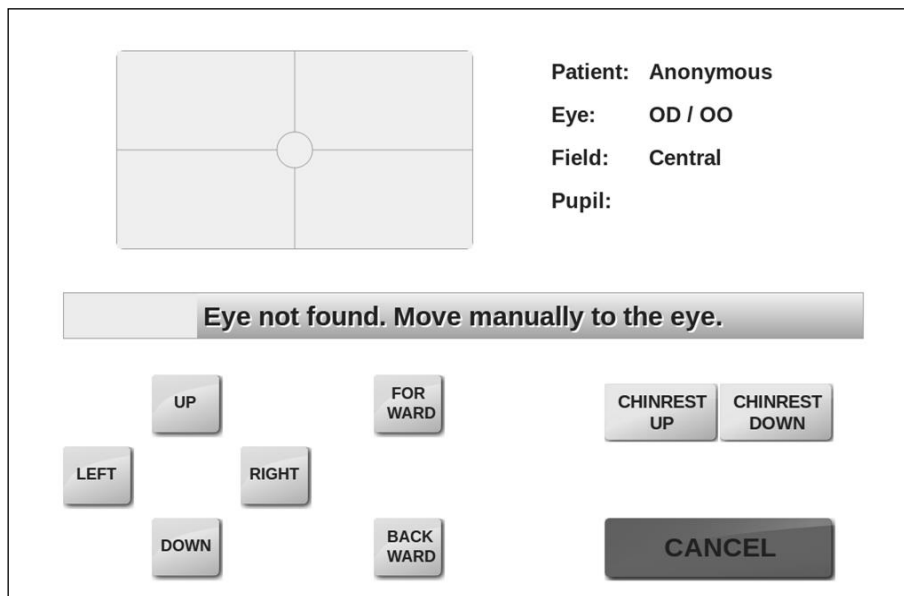


Figure 14 – Message indicating failure of automatic eye search

The result of the acquisition process is one or more retinal images as the one shown in Figure 15.



Figure 15 – Example of retinal image captured by the DRS

9.6 Anterior Eye



In order to capture a focused image of the anterior part of the eye, the patient's forehead must be placed on the chinrest at a distance of 3-5 cm (1-2 inches) from the instrument forehead rest. The patient's chin should be placed near the edge of the chin rest (see Figure 16).

The room must be sufficiently lit in order to take an anterior eye image.

Once the process is started, the optical head moves in front of the selected eye and performs a rough alignment. When it reaches the optimal position, a live color view of the eye is displayed (Figure 17) so that manual alignment and focus can be performed using the on-screen buttons.

Manual adjustment of alignment and focus may be necessary to capture a good quality picture. Click on the live image to toggle a full-screen view (Figure 18). Once satisfied with alignment and focus, press **SHOOT** to acquire the image.



Figure 16 - Anterior eye: correct patient position

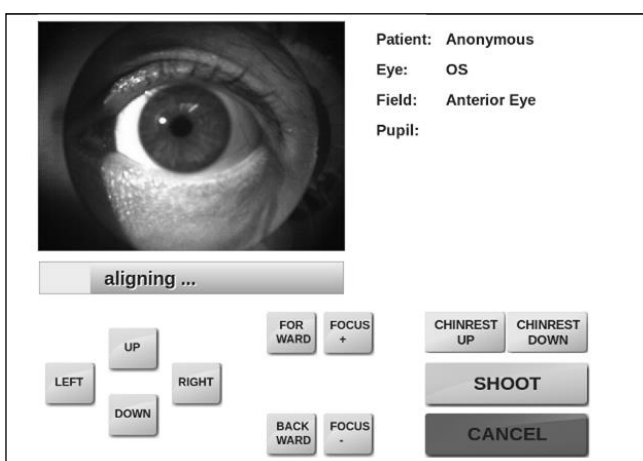


Figure 17 - Anterior eye acquisition



Figure 18 - Full screen view of the anterior eye

9.7 Stereo exams

If Stereo is selected before starting the exam, two slightly offset images of the central-nasal field will be captured with automatic alignment and focus. A delay between the shots is applied in order to let the pupil recover. The delay amount can be set in the Settings page (see par. 14). At the end of the acquisition process the resulting two images will appear in the **Patient Record** screen (Figure 19). See par. 10 for details on how to review stereo pairs.

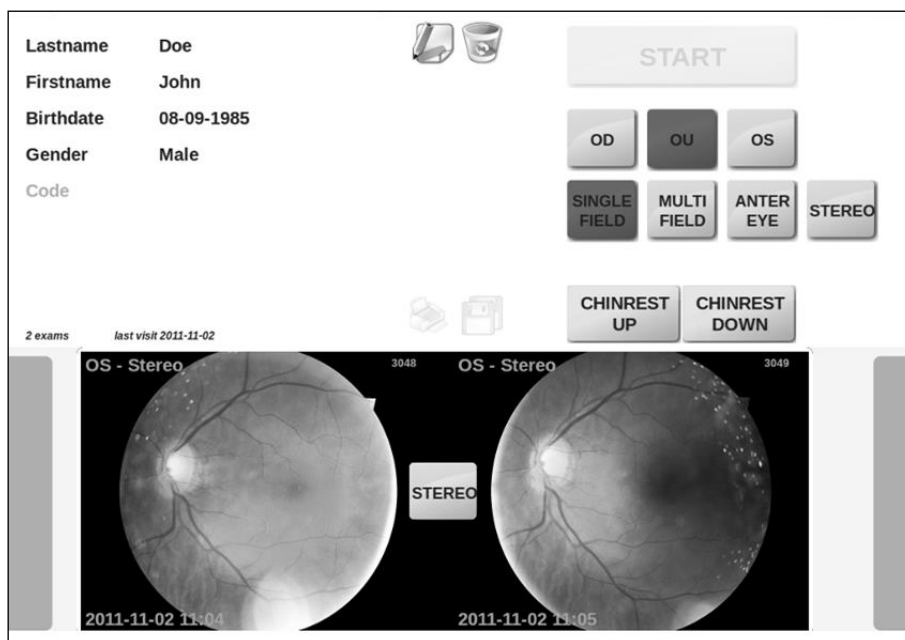


Figure 19 - Patient record with stereo pair

9.8 Warning messages

If the lens cap is placed on the front lens when an exam is started, the message shown in Figure 20 will appear (unless “check lens cap presence” is off, see 14.2). Press **OK** to exit and restart the exam after removing the lens cap.



Figure 20 - Message when lens cap is detected

If 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 degradation of image quality (see Figure 21).

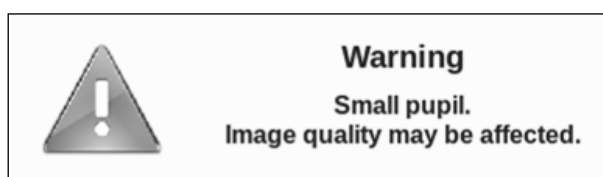


Figure 21 - Warning due to small pupil

When the auto-focus process is not able to find an optimal focus, a warning message is shown to inform the operator about the possible occurrence of poor focusing conditions (see Figure 22).

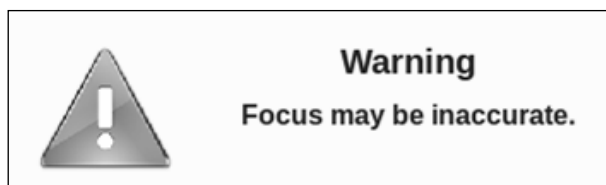


Figure 22 - Warning due to incorrect focusing

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 23).

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.

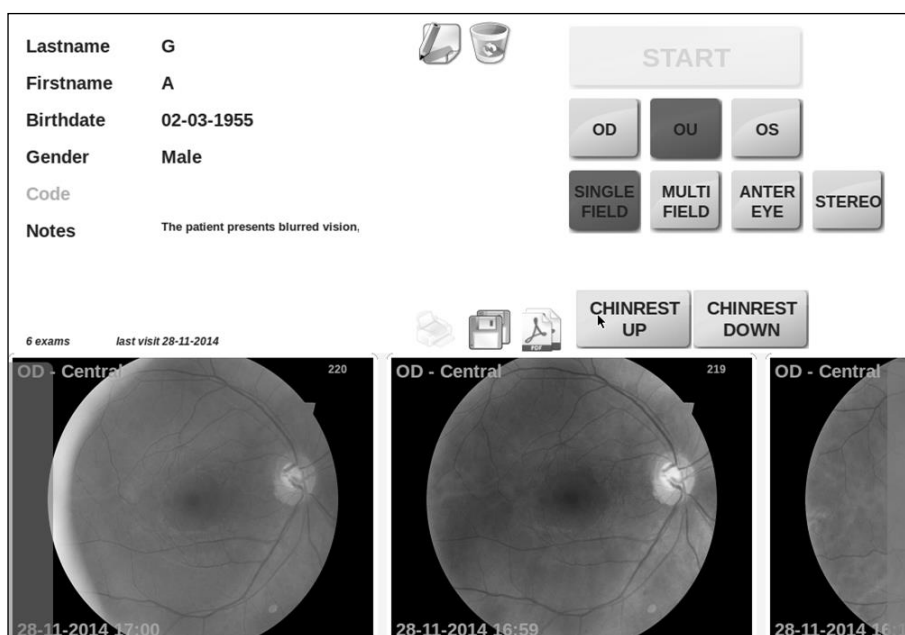





Figure 23 - Patient record screen

Available functions include:

Function	Icon	Command
Image scroll	-	Point on any thumbnail and drag to the left / right or press the left / right buttons located at the bottom on the sides
Edit patient record		Click on this icon to enter the edit mode and correct any mistyped information or provide additional details
Delete patient record		Click on this icon to permanently delete the current patient and all related exams. A confirmation is required.
Batch image export		Click on this icon to export all images of the selected patient as JPG files on a USB key (only available if a USB key is plugged in any of the USB ports)
Retake images		Click on this icon to select one or more images to be retaken. When all images have been selected, click on RETAKE . Images can be retaken within 5 minutes after they have been captured.
Open full image screen	-	Click on the corresponding thumbnail to open the full image screen
Open 3D image view		Click on the STEREO button between the two thumbnails of a stereo couple thumbnail: this command will open the 3D viewer. Only available for stereo pairs.

Function	Icon	Command
Print		Click on the printer icon to print two images in a single sheet. Icon is enabled when a supported printer is connected.
Export to pdf		Click on the Acrobat icon to generate and export a dual image printout (available if a USB key is connected, see par. 12.2 for further details).
Automated mosaic		Click on this icon to start generation of a mosaic (a composition) of multiple retinal fields. This icon is only available if the related license is installed. See Appendix B for explanations on how to use this function. Please contact your CenterVue representative for information on how to obtain the license.

10.2 Full image screen

The Full Image screen (see Figure 24) is used to review individual images at full screen. The information available in this screen includes the eye (OD, OS), pupil size at capture, date and time when the image was captured and any image related notes.

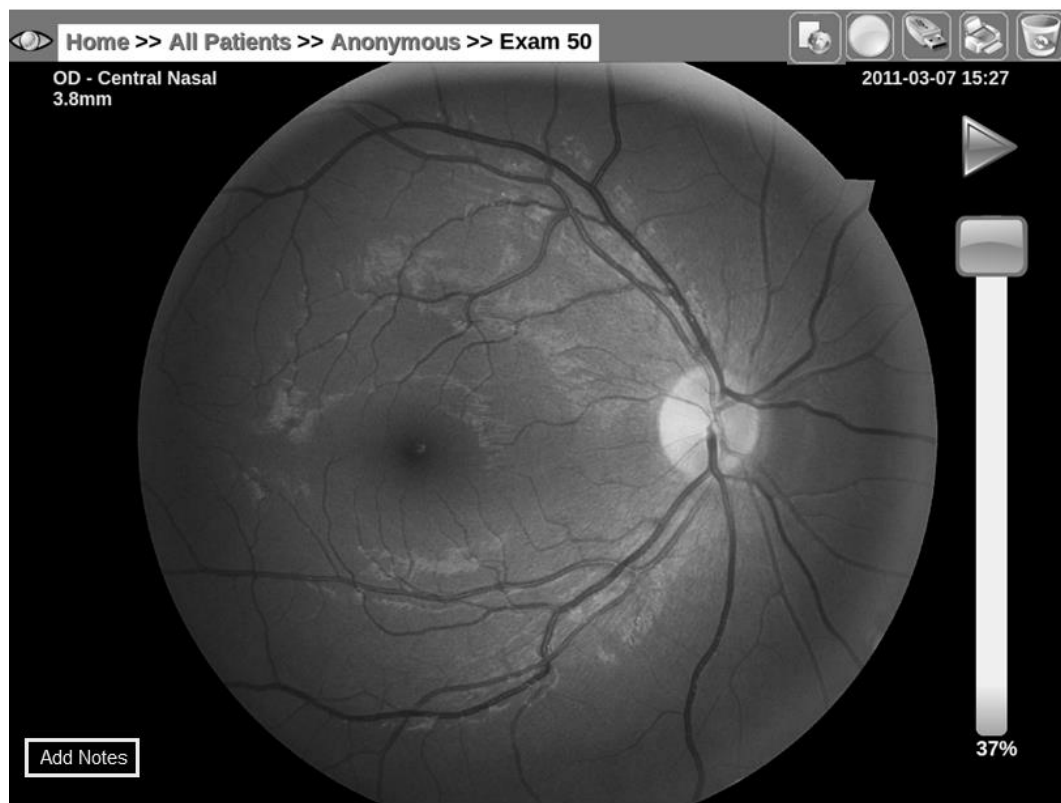





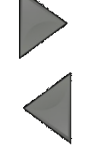





Figure 24 - Full image screen

Functions available in this screen include:

Function	Icon	Command
Zoom image	-	The slider on the right side of the screen allows zooming
Pan image	-	Click on the image and drag it around to frame the desired area
Red-free filter		Click on this icon to display a black and white image corresponding to the green component of the image

Export image to shared folder		Click on this icon to export the selected image to a shared folder (see Settings >> Network >> Shared folder)
Export image file to USB		Click on this icon to export the selected image as a jpg file on any USB key (only available if a USB key is connected)
Image print		Click on this icon to print the current image (only available if a compatible USB printer is connected)
Image delete		Click on this icon to permanently delete the selected image
Move to next / previous image		Click on these icons to move to the next/previous image of the current patient
3D viewer		Click on this icon to toggle between normal and 3D viewer for the stereo images. Only available when showing a stereo pair.
Swap stereo images		Click on this icon to swap right and left image of a stereo pair ("crossed-eye" format). Only available when showing a stereo pair.
Add image notes	Add Notes	Click on Add Notes to add / edit image specific comments (see Figure 25)



Edit notes

Insert the notes for this exam:

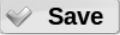
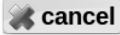
 Save
  cancel

Figure 25 – Notes editing screen



Figure 26 - Stereo Images 3D viewer



To obtain a three dimensional view, images must be looked at with appropriate prismatic goggles (see Figure 27). A crossed-eye format is also supported.



Figure 27 – Example of prismatic goggles for three-dimensional viewing

11. REMOTE VIEWER

There are two ways to review DRS data and images from a remote PC, a tablet or a smart-phone. 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 *private network* modes².



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 (version 8 or later), Mozilla Firefox (version 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 and configure the remote PC with a different IP;
4. Retrieve the DRS IP, as explained in Settings >> Network (see par. 14.3, Figure 36);
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 smart-phone (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. Type <http://drs> in the URL box of the remote PC's Internet browser.

Once the connection is established, the DRS patient list will show up on the remote PC, tablet or smart-phone (please consider that not all devices support the *private network*). You might be required to type a password depending on whether password protection was enabled in the DRS settings (see 14.3). Available functions include:

- Patient list (same as Figure 9);
- Patient record screen (same as Figure 23)
- Access to individual images
- Possibility to download this Operating Manual in pdf format in About page

Patient	Birthdate	Last Visit
anonymous	2016-08-25	0 exams
Ch 68001-187	Vi 1966-10-07	2016-08-26 1 exams

Figure 28 - DRS patient list in remote viewer

² some Wi-Fi network cards may fail to establish connection with the DRS when using the *private network* mode. In such case an external router is required to successfully connect via Wi-Fi

12. PRINTOUT

12.1 Single image printout

When a compatible USB printer is connected, any acquired image can be printed by clicking on the printer icon in the **Full Image** screen. Also red-free images (see par. 10) can be printed using the same procedure. In the same way a pdf file containing the single printout can be generated if a USB key is connected.

12.2 Dual image printout

By clicking on the printer icon in the **Patient Record** screen it is possible to print two images on the same sheet. Once the button is pressed a dialog box appears prompting for the selection of two images. The list can be scrolled to select the images to be printed by clicking on the printer icon that is placed on the top right corner of each image. Once two images are selected, click the **Print** button. In the same way, a pdf file containing the dual printout can be generated if a USB key is connected.



The single image printout uses portrait format, while the dual image printout uses landscape format.

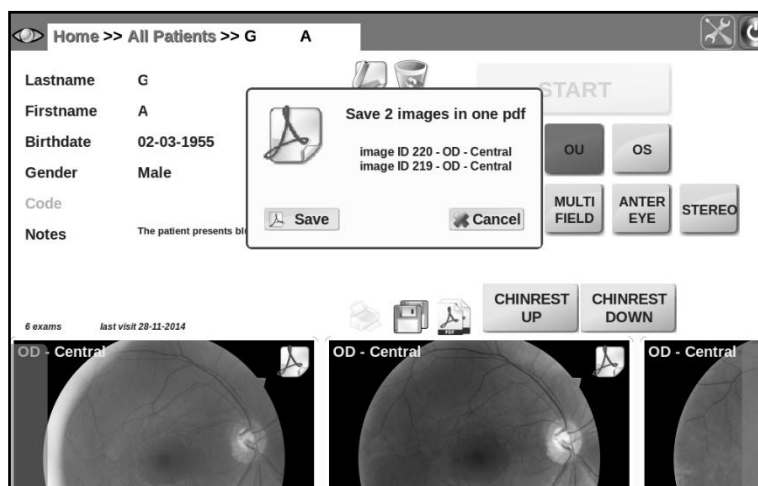


Figure 29 – image selection screen for dual image printout



Figure 30 - Single and dual image printout

13. RETINAL FIELDS

The following fields can be acquired (see Figure 31 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;

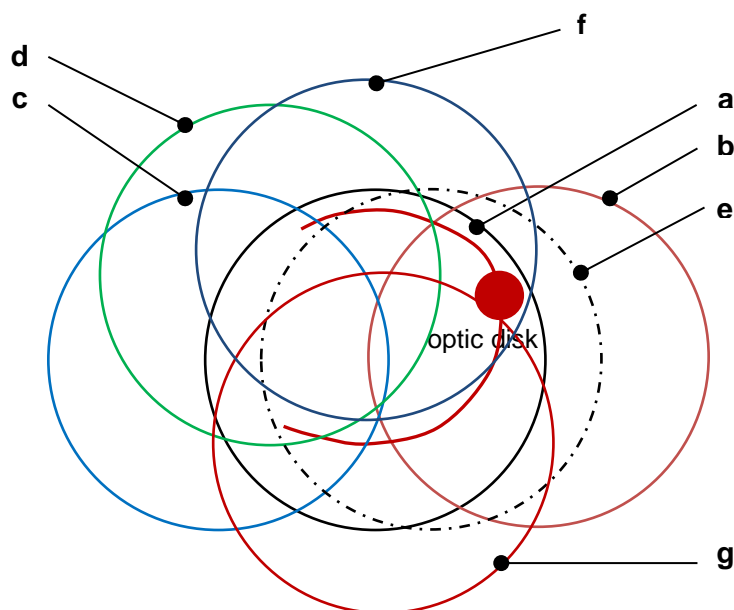


Figure 31 - DRS retinal fields

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

14. BACKUP

The Backup utility allows to perform the backup of DRS data and can be found in the Settings, under the “System” tab (see Figure 46).



The backup utility is based on the concept of **incremental backup**. The following paragraphs explain: i) how to perform the first-time backup and ii) how to perform any subsequent incremental backups. The backup utility is structured as a wizard and will guide you through the process.



- IT IS A RESPONSIBILITY OF THE OPERATOR TO KEEP AN UPDATED BACKUP COPY OF THE DATA GENERATED BY THE DRS, BY PERIODICALLY USING THE BACKUP UTILITY, IN ORDER TO BE PROTECTED AGAINST UNPREDICTABLE FAILURES RESULTING IN DATA LOSS
- THE MANUFACTURER CANNOT BE HELD RESPONSIBLE FOR LOSS OF DATA DUE TO UNPREDICTABLE FAILURES
- IN CASE OF A FAILURE RESULTING IN DATA LOSS, THE DATA CAN BE RESTORED FROM THE LAST PERFORMED BACKUP
- MANUAL MODIFICATION OF BACKUP FILES STORED ON THE BACKUP MEDIA MAY PREVENT THE ABILITY TO RESTORE THE DATA: DO NOT EVER ALTER THOSE FILES



Figure 32 - **System >> BACKUP** tab in Settings when no backup was ever performed

14.1 First-time, total, backup

To perform the first-time backup, insert a USB drive in any of the DRS USB ports. The USB drive should preferably be a hard disk and its capacity should exceed 320 GB (although initially the data size is much smaller).

The first-time backup process involves two steps:

1. initializing the USB drive;
2. creating the backup file.



- A BACKUP IS ONLY EFFECTIVE WHEN THE “BACKUP COMPLETED” MESSAGE IS DISPLAYED (SEE Figure 36)
- IF THE BACKUP PROCESS IS INTERRUPTED USING THE “STOP BACKUP” COMMAND THE BACKUP IS NOT EFFECTIVE, DATA CANNOT BE RESTORED AND THE PROCESS SHALL BE REPEATED
- IF DURING THE BACKUP PROCESS AN ERROR MESSAGE IS DISPLAYED (SEE Figure 37) THE RESULTING BACKUP IS NOT EFFECTIVE, DATA CANNOT BE RESTORED AND THE PROCESS SHALL BE REPEATED
- A BACKUP CANNOT BE SPLIT INTO DIFFERENT USB DRIVES



The duration of the backup process depends on the amount of data stored in the DRS and on the speed of the USB drive used. Typically, first time backups may take longer than subsequent incremental backups.

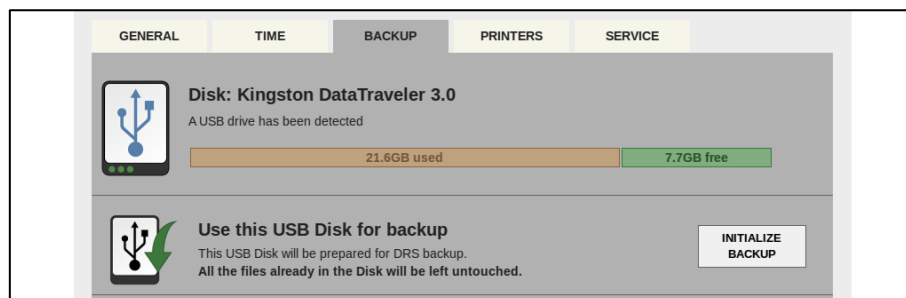


Figure 33 – Backup process, step 1

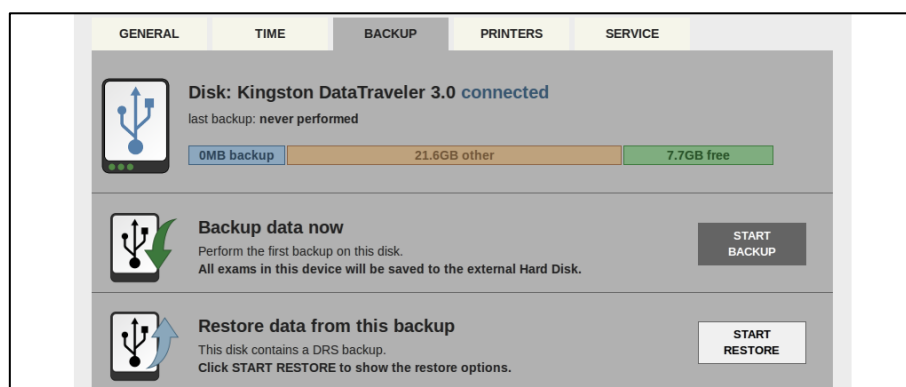


Figure 34 – Backup process, step 2

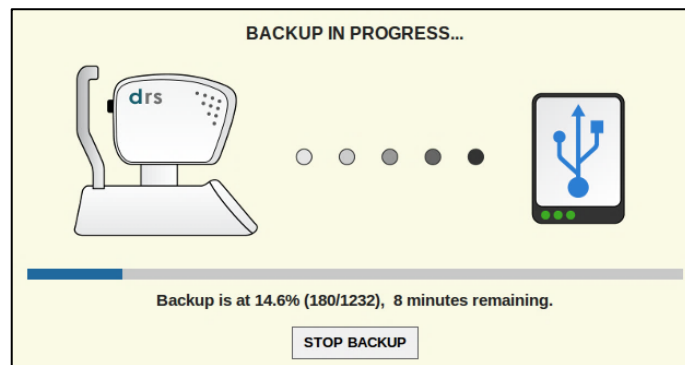


Figure 35 – Backup in progress message

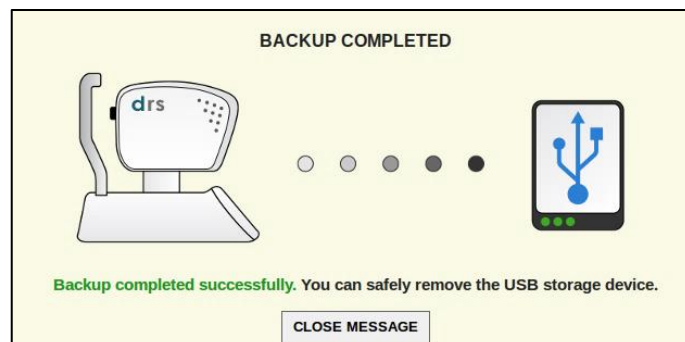


Figure 36 – Backup completed message

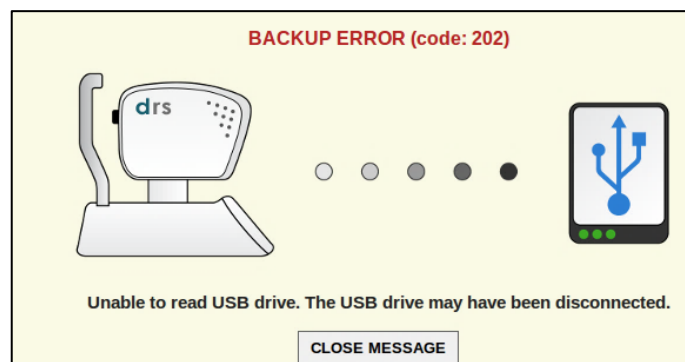


Figure 37 – Error message during backup

14.2 Incremental backups

To perform an incremental backup, click on Settings and select the BACKUP tab: information about the USB drive used for previous backups will be displayed (see Figure 38). Retrieve the same USB drive, insert it in any of the DRS USB ports and click on START BACKUP (see Figure 39): information on progress will be displayed.



If you use a different USB drive than indicated above you will actually be performing again a first-time, total, backup

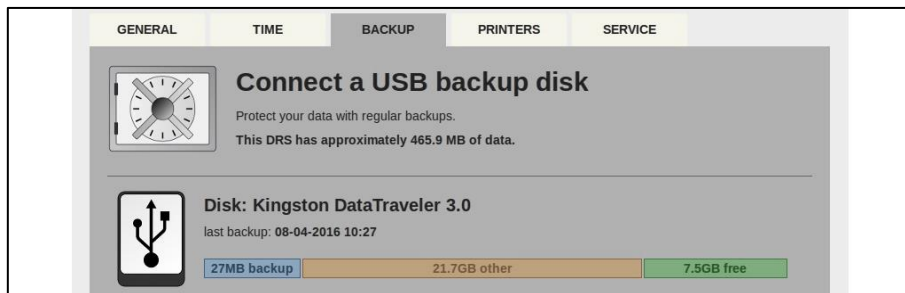


Figure 38 – **System >> BACKUP** tab in Settings when a previous backup had already been performed

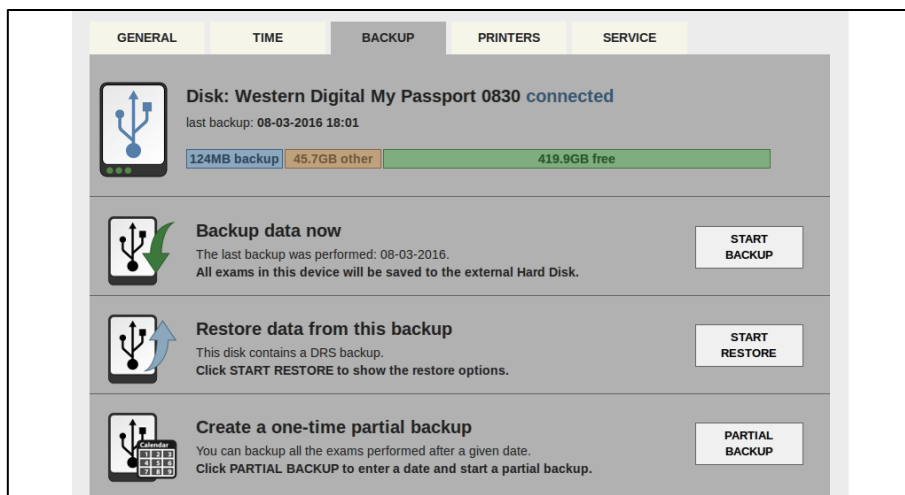


Figure 39 – **System >> BACKUP** tab in Settings when the USB drive containing the previous backup is connected

14.3 Removing a backup disk

If you do not use a backup disk anymore and wish to remove it from the DRS list, click on Settings, select the BACKUP tab and click on the icon corresponding to the disk you want to remove, then click on “REMOVE BACKUP” (see Figure 40).



Figure 40 – Removing a backup disk from the list



- Backup files are not altered by this operation and remain on the disk
- It is still possible to perform a Restore using the data on the disk
- It is no longer possible to perform an incremental backup on the disk

14.4 Partial backups

Using the backup utility, you can also **create a one-time partial backup** (see Figure 39): this option allows to create a backup copy of all exams performed **after a specified date**. Such partial backups can be restored as any other backup.



PARTIAL BACKUPS SHALL BE USED ONLY IN THOSE SITUATIONS WHERE NOT ALL PATIENTS / EXAMS ARE OF INTEREST, AS PARTIAL BACKUPS DO NOT ALLOW TO RESTORE EXAMS THAT WERE PERFORMED BEFORE THE SELECTED DATE

14.5 Restore

To restore data from an existing backup, click on Settings and select the BACKUP tab: information about the USB drive used for previous backups will be displayed. Retrieve the same USB drive, insert it in any of the DRS USB ports and click on START RESTORE (see Figure 39).

The restore process involves two steps:

1. selecting the backup file from which data shall be restored (if more than one is available);
2. selecting the restore method (erase & restore or restore new data).



- DO NOT DISCONNECT THE USB DRIVE WHILE THE RESTORE PROCESS IS IN PROGRESS
- THE “ERASE & RESTORE” METHOD WILL **PERMANENTLY ERASE** ALL DATA STORED ON THE DRS BEFORE RESTORING THAT PRESENT IN THE BACKUP: USE THIS METHOD WITH CARE
- THE “RESTORE NEW DATA” METHOD WILL PRESERVE EXISTING DATA AND ADD THE PATIENTS CONTAINED IN THE BACKUP. THIS METHOD MAY RESULT IN DUPLICATED PATIENTS
- THE RESTORE PROCESS CANNOT BE INTERRUPTED
- IF THE HARD DISK CAPACITY IS REACHED, NO DATA CAN BE RESTORED AND A WARNING MESSAGE IS DISPLAYED



Figure 41 – Restore process, step 1

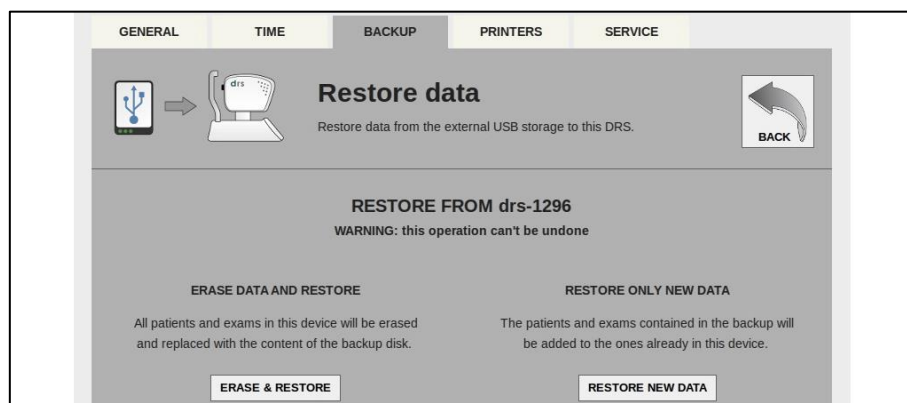


Figure 42 – Restore process, step 2



Figure 43 – Restore in progress



Figure 44 – Restore completed

15. **SETTINGS**



To access the settings screen click on the button.

In the Settings screen several different tabs as described in the following pages are available.

15.1 **Fields**

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.

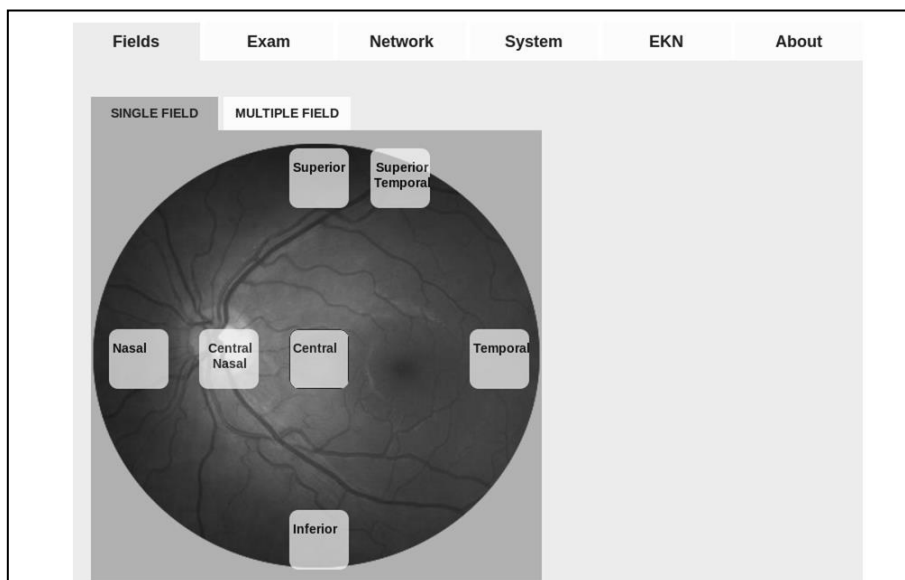


Figure 45 - **Fields >> SINGLE FILED** tab in Settings

15.2 **Exam**

The Exam tab has three sub-tabs, namely EXAM, SAVING and ADVANCED.

15.2.1 **EXAM**

Use this tab (see Figure 33) to:

- set a time delay in seconds (default 0) between subsequent snapshots;
- set a time delay between stereo images;
- set the fixation target to be permanent or blinking at 3 different speeds;
- enable automatic chin rest adjustment;
- select UNIFORMITY or CONTRAST image processing strategy (see note below).

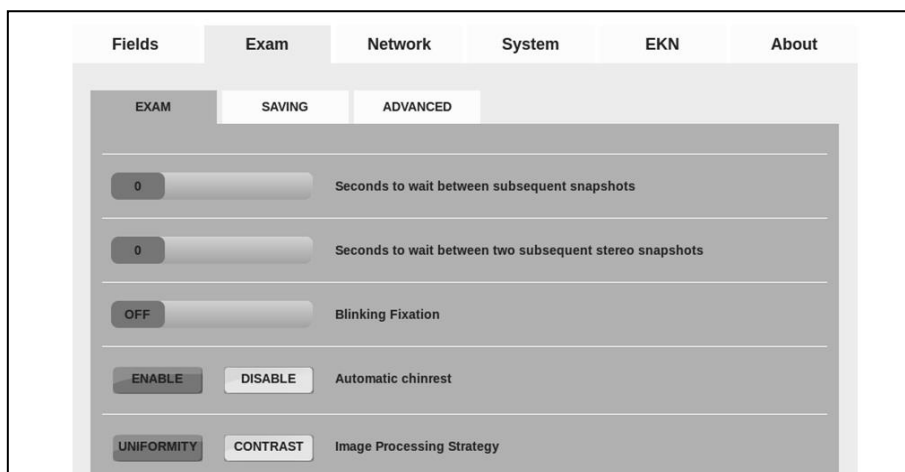


Figure 46 - **Exam >> EXAM** tab in Settings

Image Processing Strategy.

It is possible to select between two different image processing strategies: 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.

UNIFORMITY: with this setting the image appears very uniform in color, with mild shades. Micro aneurisms and macula details may appear more visible with this setting.
CONTRAST: with this setting the image will show higher contrast. Details may appear more evident but image has a grainier aspect.

15.2.2 SAVING

Use this tab (see Figure 34) to:

- 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*).
- choose to automatically create a folder for each patient name and/or a folder for each exam ID when saving on USB key.
- enable 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., see Appendix A).

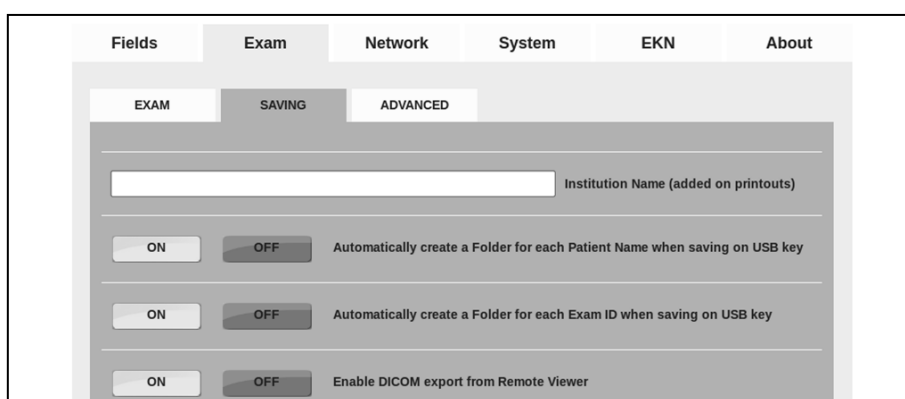


Figure 47 - **Exam >> SAVING** tab in settings

15.2.3 ADVANCED

Use this tab (see Figure 35) to:

- 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.
- set 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).

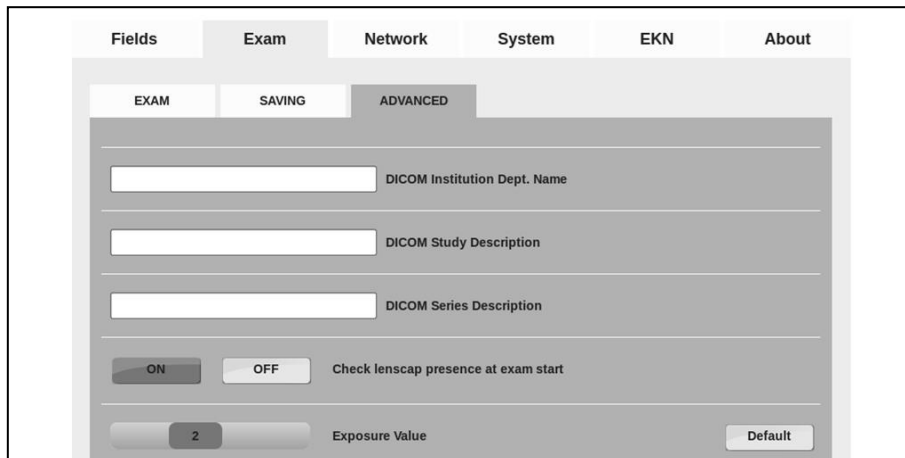


Figure 48 - **Exam >> ADVANCED** tab in Settings

15.3 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 36):

- *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, see Settings >> EKN).
- *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.

The Network tab has 4 sub-tabs: GENERAL, WIRELESS, SHARED-FOLDER and LAN ACCESS.

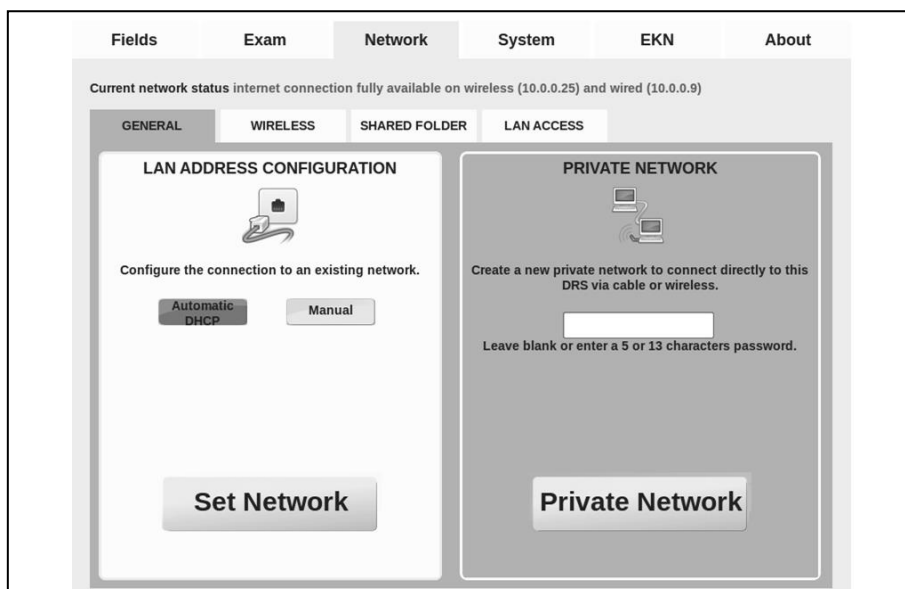


Figure 49 – **Network >> GENERAL** tab in Settings

15.3.1 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 37).

To allow the DRS to create a private network click on Private Network button (see Figure 37). 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.

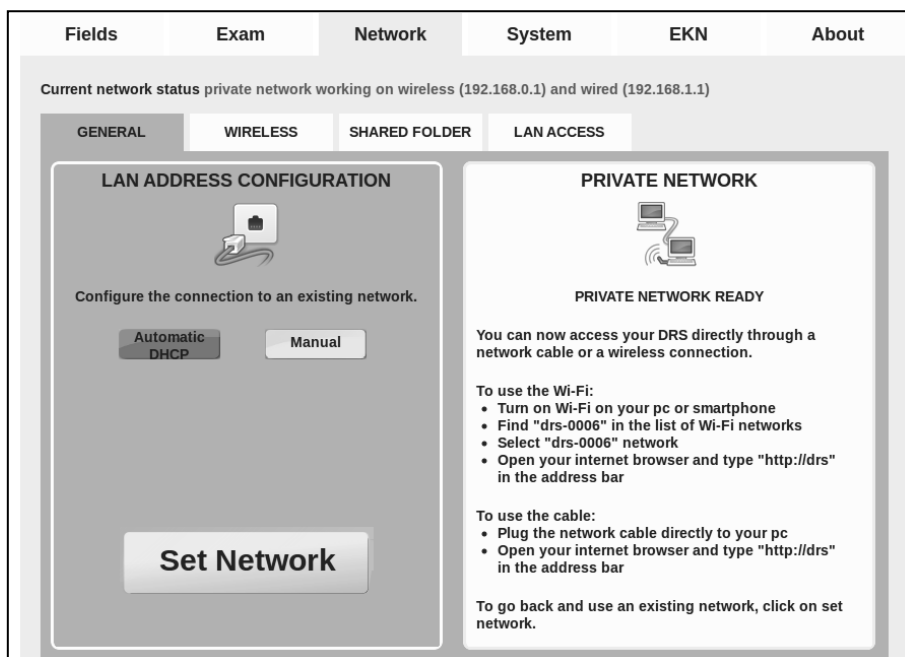


Figure 50 – Network tab in Settings when a private network has been set-up

15.3.2 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 you want to connect to. Enter the WiFi password/key and click “Connect” to establish the wireless connection. See example in Figure 38.

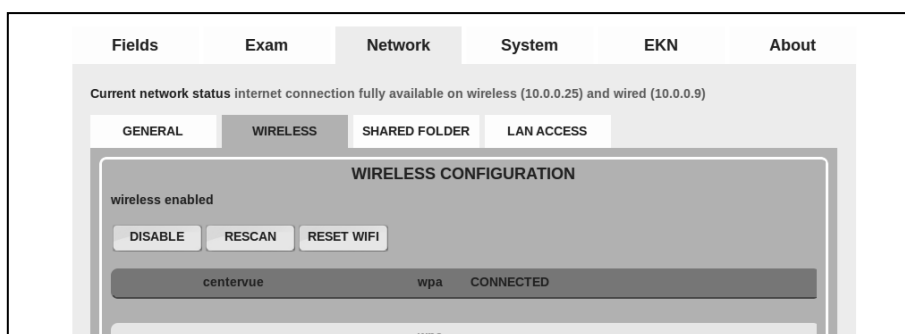


Figure 51 – Network >> WIRELESS tab in Settings

15.3.3 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 39).

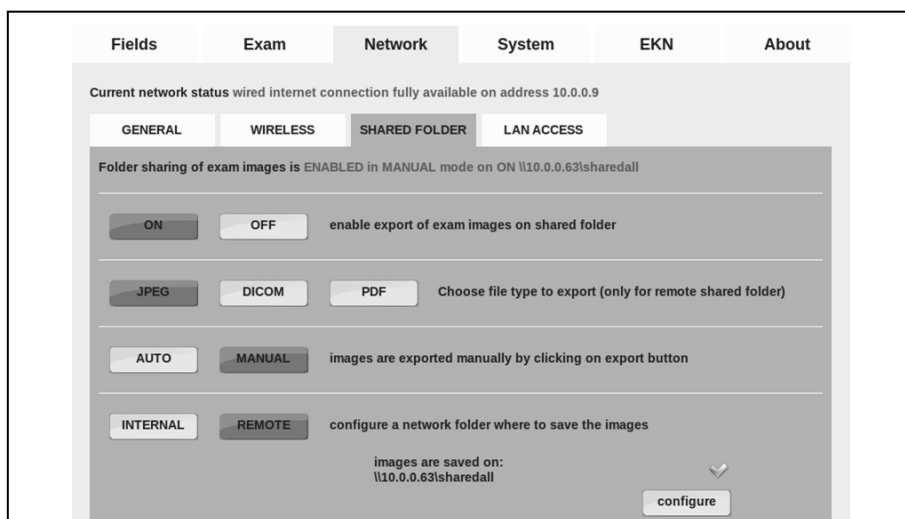


Figure 52 – **Network >> SHARED FOLDER** tab in Settings

As shown in Figure 39, 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 40, Figure 41) show the messages that will be displayed to the operator.

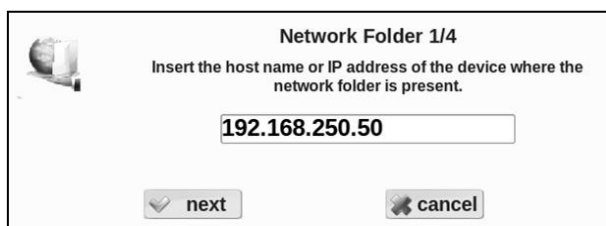


Figure 53 - Remote Folder Configuration – step 1



Figure 54 - Remote Folder Configuration – step 2

A third step may require you to insert username and password on the remote folder. In case of correct setting a dialog box like the one in Figure 42 will appear. Press OK to confirm and save the network folder setup.



Figure 55 - Remote Folder Configuration – Connection Successful

The most important difference between the two types of shared folder (internal and remote) is where the data is stored and 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.

15.3.4 LAN ACCESS

The **LAN ACCESS** sub-tab lets you set a password for the Remote Viewer access to the DRS, to prevent access to the data by unauthorized persons.

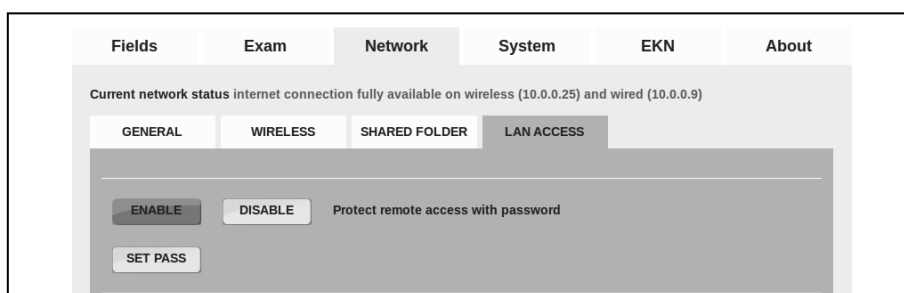


Figure 56 – **Network >> LAN ACCESS** tab in Settings

15.4 System

The System tab has five sub-tabs: GENERAL, TIME, BACKUP, PRINTERS and SERVICE.

15.4.1 GENERAL

Use this tab to:

- Enable, disable and configure the screensaver: the delay can be between 5 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;
- Enable third party EMR systems to interface the DRS using their 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.

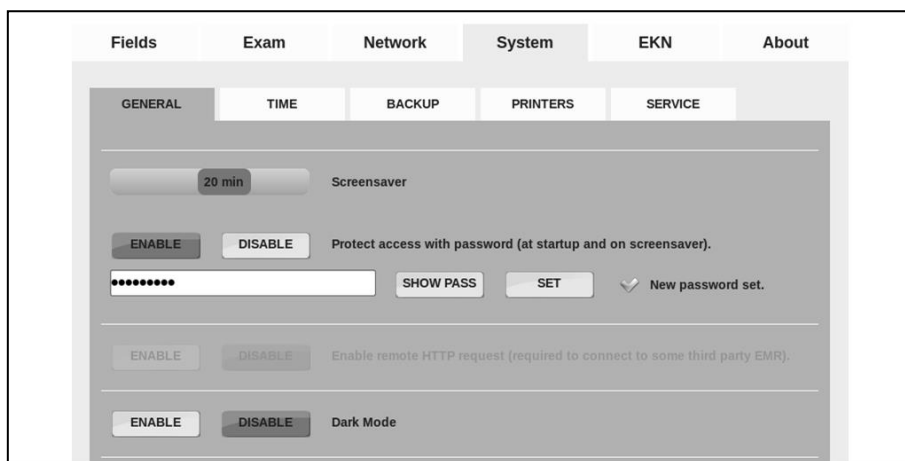


Figure 57– **System >> GENERAL** tab in Settings

15.4.2 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, the date and time format

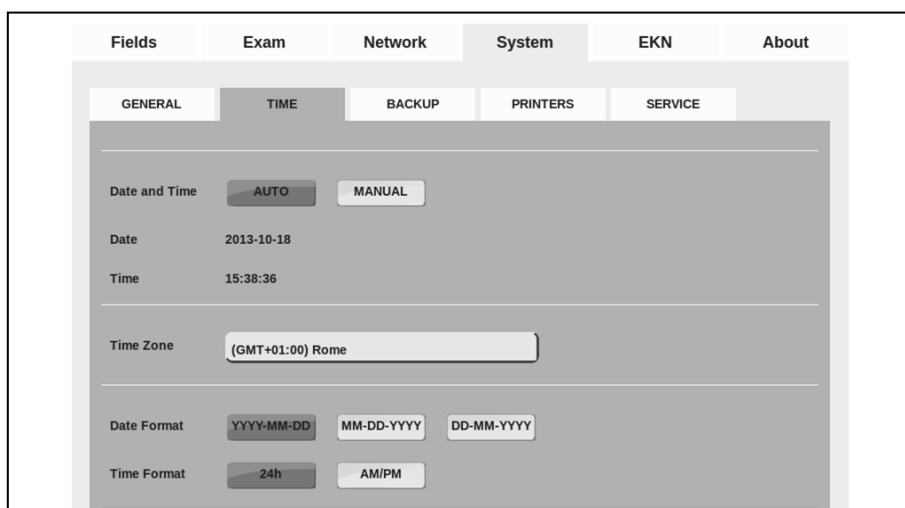


Figure 58 - **System >> TIME** tab in Settings

15.4.3 PRINTERS

Use this tab to:

- choose among different printer drivers (built-in drivers or generic postscript driver);
- adjust image brightness on the printout;
- optionally enable the “Automatic fit to page” for printouts.

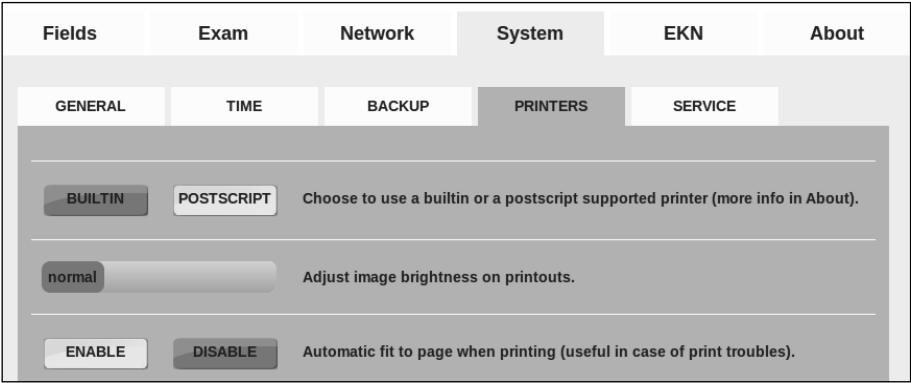


Figure 59 – **System >> PRINTERS** tab in Settings

15.4.4 SERVICE

This tab provides access to various functionalities and tools, in particular:

- **Reset Head** this tool resets the position of the optical head (same procedure performed at unit startup);
- **Lens cleaning assistant**: this tool helps check the cleaning condition of the front lens. See below for additional information.
- **Service** gives access to a special password-protected panel available for authorized personnel only.
- **Remote assistance** opens a remote connection that allows authorized service technicians to connect to the DRS. Once pressed, the disclaimer shown in Figure 54 appears, informing the operator that he/she is authorizing access to all data present on the device, for servicing purposes. Once confirmed with the **OK** button, the DRS 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. The connection can be closed by clicking the **Close Remote Assistance** button. Please note that, as stated in the disclaimer (see Figure 54), the remote assistance is closed automatically if the machine is restarted.
- **Save log files to USB** allows to export the log file of your DRS unit onto a USB key, for troubleshooting purposes.
- **Image rebuild** allows to regenerate image thumbnails, in case some are missing following a data restore from backup;
- **Reset Parameters** erases all device settings to Factory defaults (selected fields, network configuration, shared folder, preferences, etc.).
- **Reset Patients** erases all stored patient data and images. This function is disabled when the DRS is connected to the EKN.



RESET PATIENTS ERASES THE WHOLE DATABASE CONTENT. ONCE THE OPERATION HAS BEEN CONFIRMED THERE IS NO WAY TO RESTORE THE DATA. USE THIS FUNCTION WITH CAUTION.

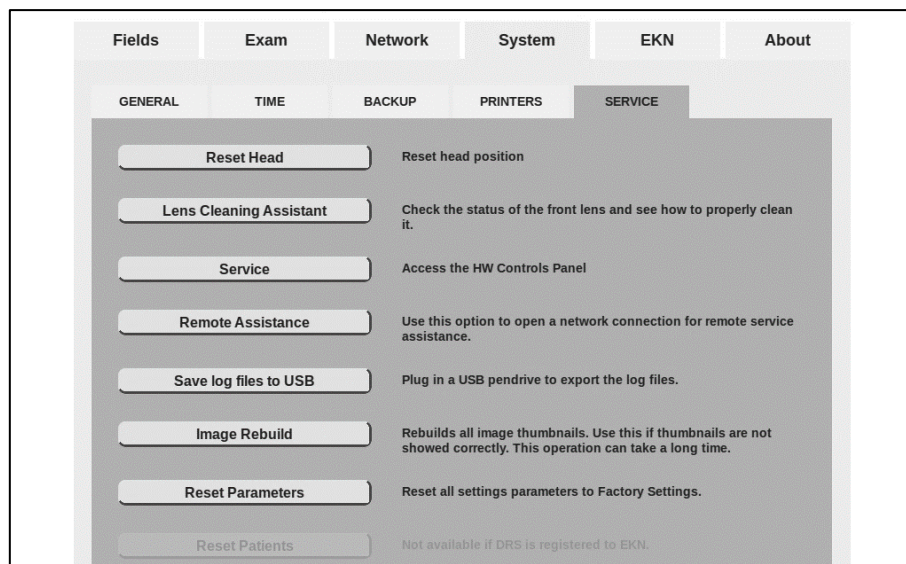


Figure 60 - **System >> SERVICE** tab in Settings

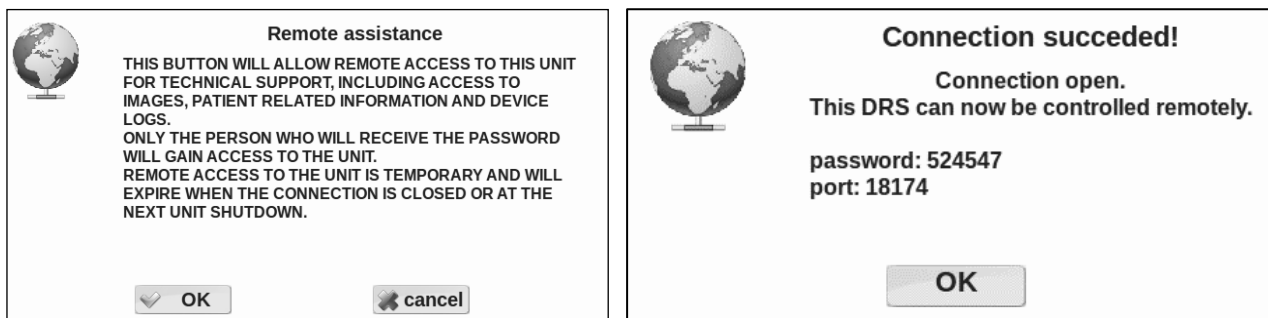


Figure 61 - Remote Assistance, steps 1 and 2

Lens cleaning assistant

Clicking the **Lens Cleaning Assistant** button opens the box shown in Figure 55.

Clicking on **Instructions** opens the instructions box shown in Figure 56.

Clicking on **Tools** opens a box describing the tools to be used for cleaning the lens.

Clicking on **SHOOT** captures an image which should be mostly black: white particles indicate presence of residual dirt on the outer surface of the lens.

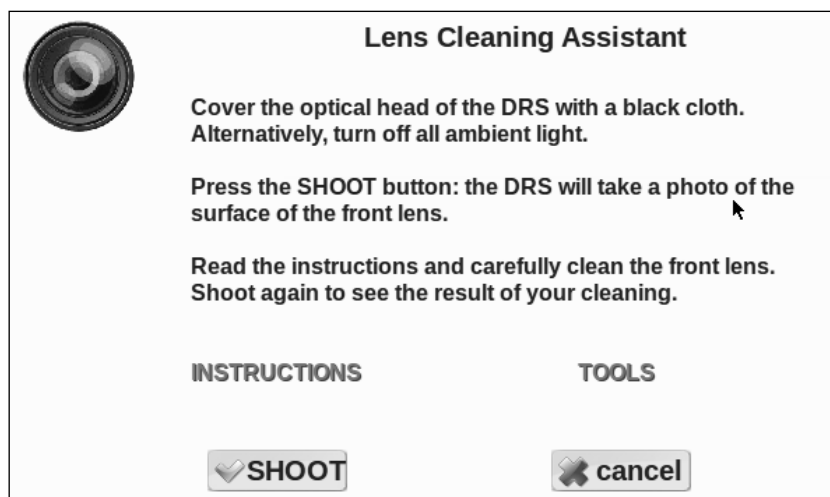


Figure 62 – Lens cleaning Assistant information dialog

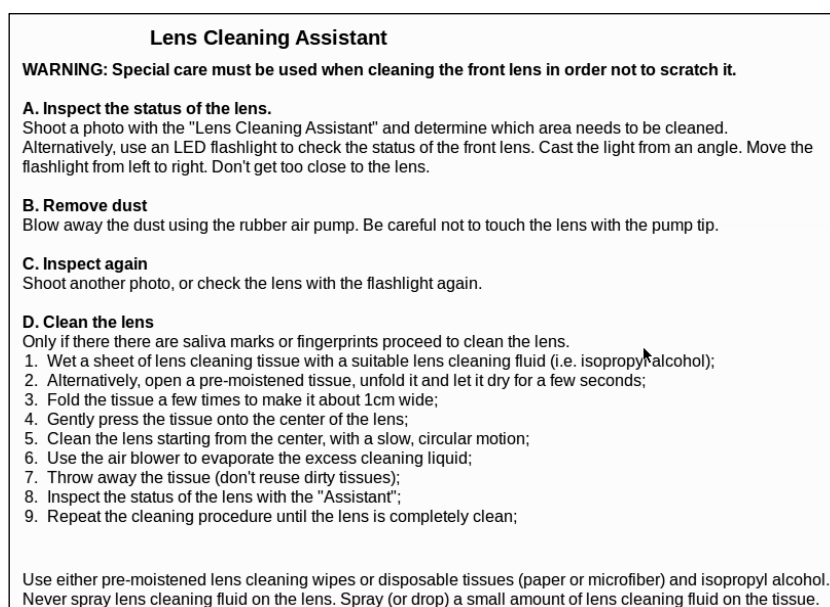


Figure 63 – Lens cleaning instructions

15.5 EKN

The EKN tab in the Settings is used to activate and manage the connection of the DRS to the **Eye Knowledge Network** (EKN). See Appendix C and www.eyeknowledge.net for additional information about this optional feature.

15.6 About

This screen shows the DRS serial number, the software and firmware version, the OS version, the Ethernet and WiFi MAC address, the total number of patients and exams stored, the space left on the hard disk, the presence of any optional licenses and the list of compatible printers. It also allows to download this Operating Manual on a USB key, in pdf format.


Fields	Exam	Network	System	EKN	About
Serial number	drs-1296				
SW version	2.5.0				
FW version	0.53				
OS version	3.2				
Calibrator version	1.1.5				
Production id	1296				
Eth MAC address	00:03:2d:1c:85:e6				
WiFi MAC address	00:34:f1:80:02:00 (8712u)				
Records	6 patients, 1 exams				
Space left on disk	144G				
Installed licenses:					
 centervue					
CenterVue SpA Via San Marco, 9h - 35129 Padova - ITALY Office: +39 049 7396 147 - info@centervue.com					
		DRS OPERATING MANUAL Connect a USB drive and click the button below to download the operating manual DOWNLOAD DRS MANUAL TO USB			
		PRINTER SUPPORT To enable support for printers listed here below, choose "BUILTIN" under the System/Printers tab. BUILTIN SUPPORTED PRINTERS Brother DCP-195C Canon IP 4600 Canon IP 100 Canon IP 2700 Canon IP 4800 HP Photosmart C4600 HP Deskjet 1000 J110 HP Deskjet 1518 HP Deskjet 3000 J310 HP Deskjet 6980 HP Deskjet 6940 HP Officejet 6500 HP Deskjet D5560 HP Officejet Pro 8000 HP Officejet Pro 8100 Xerox ColorQube 8570N Sony UP-DR80MD No supported printer is currently connected. Postscript (non-emulated) printers can work directly using a generic driver. To enable Postscript support choose "POSTSCRIPT" under the System/Printers tab.			

Figure 64 - **About** tab in Settings


16. AUTOMATIC SOFTWARE UPDATE

When a new software update is released by the manufacturer and the DRS is connected to the internet, a new icon in the Home screen top bar, notifies availability of the update. Clicking on the icon, the message shown in Figure 59 will appear. To download and install the new software version click **Install**, otherwise click **Cancel**.



Figure 65 - Message to confirm the installation of the new software version

17. SYSTEM SHUTDOWN

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.



18. CLEANING

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



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

18.1 Front lens

The front lens should be cleaned by using a small hand pump air blower (e.g. *Kaiser Typhoon 6316*), to blow away dust.

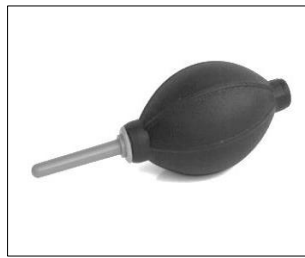


Figure 66 – Hand air blower

Only if really needed, for instance due to the presence of a fingerprint, the front lens should be cleaned using photographic cleaning paper (e.g. *Edmund Optics NT53-984*) and a suitable lens cleaning fluid (e.g. *Edmund Optics P57-727*) as illustrated in Figure 61.



**Do not attempt to clean the front lens with a dry cloth.
This could lead to scratching its surface.**

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



Figure 67 – Cleaning liquid and wipes



Figure 68 – Spray the wipes



Figure 69 – Clean the lens

Use the Lens cleaning assistant tool in order to check the cleaning status of the front lens. Please note that some small white dots will always appear due to dust (see Figure 65), but they do not affect image quality.

See *Lens cleaning assistant* at par.14.4.5, for a detailed assisted procedure.

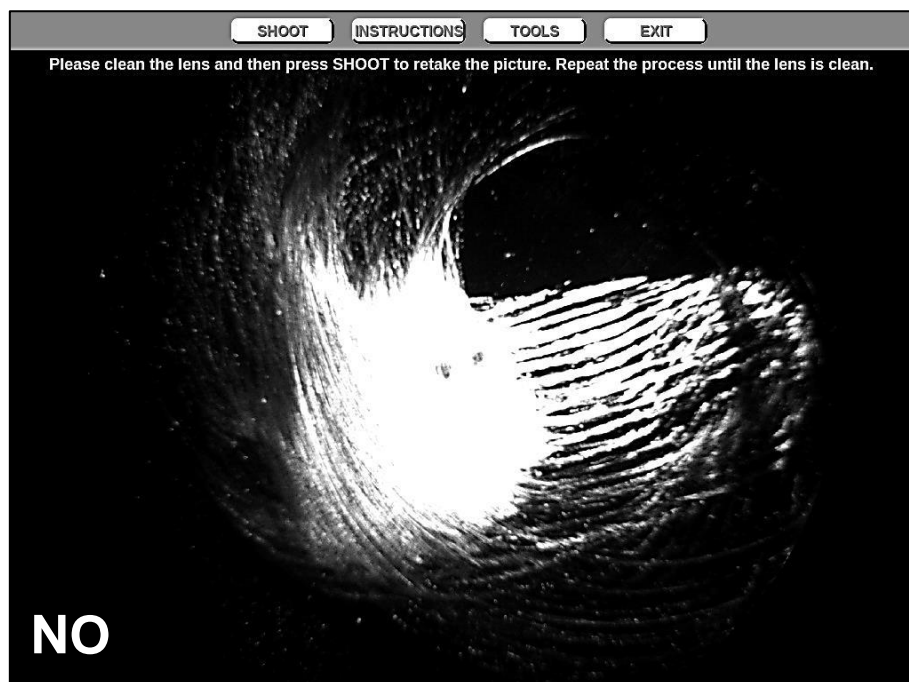


Figure 70 – Sample picture of a very dirty front lens



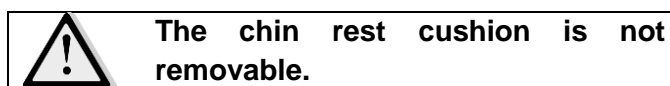
Figure 71 – Sample picture of a clean front lens

18.2 Patient cushions

The chin rest and the forehead rest are the only parts in direct contact with the patient: they should be wiped with an antiseptic wipe, before each use and allowed to dry prior to reuse.

Take care not to sprinkle parts not belonging to the patient rest.

If the unit is equipped with silicon cushions, it is possible to remove the forehead rest, and rinse it with warm water and a mild hand detergent.



18.3 Touch screen panel

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



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

18.4 Plastic shells

If needed, the external covers of the unit can be cleaned by means of a cloth slightly dampened in water.



Do not use alcohol or detergents to clean the plastic shells, as they might erase labels or indications.

19. MAINTENANCE

The only operation the operator can do on the device is the replacement of the fuses.

Following is the relevant procedure:

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



All service interventions other than the above should be carried out by authorized CenterVue personnel.

CenterVue recommends requiring a service to the instrument in order to:

- check the electrical safety (IEC 60601-1) every year.
- check the general functionality every 5 years.

Upon request, CenterVue and its authorized personnel can provide specific maintenance contracts.

20. 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 are connected;
- consult the manufacturer or field service technician for help.

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

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

22. TECHNICAL SPECIFICATIONS



Class and type of applied part

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

IP classification

IPX0 (according to IEC 60529, related 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-mydratic operation (3.8 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 x 55 x 33 cm (22 x 22 x 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

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) must not dispose of WEEE as unsorted municipal waste, but 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 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 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 AND ERROR MESSAGES

If any problem occurs, check the following table and try to apply the proposed solution. If the problem persists, please contact CenterVue Service representative.

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 sends a connection error saying: "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 USB key is not appropriate	Use the USB extension cord that comes with the DRS (inside the accessories box) to connect the USB key.
<p>The database is experiencing problems</p>  <p>The database of this unit was found in a corrupted state and has been deactivated to prevent further damage.</p> <p>You can attempt an automatic recovery of the data. Click the proceed button and wait. The screen will turn black and the interface will restart after a few moments.</p> <p>IMPORTANT: do not shut down the unit until the data recovery is completed.</p> <p>PROCEED WITH DATA RECOVERY CLOSE THIS MESSAGE</p>		<p>The database got corrupted because of a hard shutdown</p> <p>Click on "proceed with data recovery"</p>
<p>This unit was not shutdown correctly</p>  <p>Incorrect shutdown can cause damage to the device and can lead to data loss. Please follow the correct shutdown procedure.</p> <p>Please wait while data integrity is restored. Data integrity check in progress...</p>		<p>The unit underwent a hard shutdown</p> <p>None needed, the units will check data integrity and restart</p>

Issue	Possible cause	Solution
<p data-bbox="280 197 756 224">Save diagnostic logs to USB pendrive</p> <div data-bbox="188 246 293 389">  </div> <p data-bbox="351 259 826 362">ERROR: no USB detected. Please connect a USB pendrive with at least 100MB of free space and press the Retry button. If this problem persists please try another USB pendrive.</p> <div data-bbox="418 430 619 465"> Retry Cancel </div>	<p data-bbox="896 309 1126 362">No valid USB drive is connected</p>	<p data-bbox="1184 309 1401 362">Use a different USB drive</p>

APPENDIX A - 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
(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
(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

Tag	Description	VR	Len	Value
(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

APPENDIX B – AUTOMATED MOSAIC FUNCTION

A mosaic is the composition of multiple, partially overlapping, fields of the same retina and it is used to obtain a wider view. Mosaic images are permanently stored on the local memory and can be reviewed at any time as individual fields. Typical examples of fields used are: central, temporal and nasal or central, temporal, nasal, superior and inferior.



This function is not active by default on the DRS system and requires installation of a dedicated license. Please contact your CenterVue representative for further information on how to activate the mosaic function.

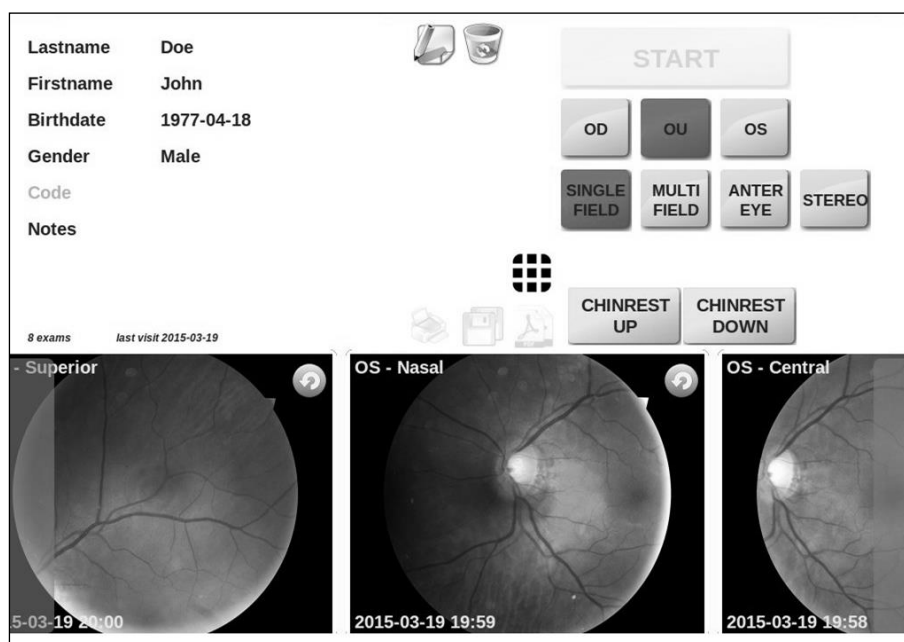



Figure 72 – Patient Record screen when mosaic function is enabled

To create a mosaic, check that the fields of interest have been captured, then click on the mosaic button in the **Patient Record** screen (see Figure 66) to open the **image selection** screen: the first step requires selection of the eye, the second one requires selection of the fields to be composed. 



Presence of a central field is always required for mosaic generation. 2 to 6 fields can be used. Only images of the same eye captured on the same day can be used. Only one eye at a time can be selected.

Once field selection is completed click on the **Create Mosaic** button to start mosaic generation, or click on **Cancel** to abort (see Figure 68).



Once the mosaic is started it cannot be interrupted before its completion. Generation of a mosaic image may take from 2 to 6 minutes, depending on how many fields are used. The DRS cannot be used while mosaic generation is in progress.

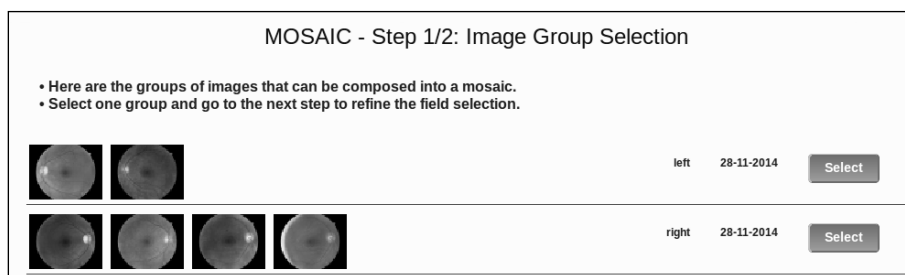


Figure 73 – Mosaic function, eye selection screen

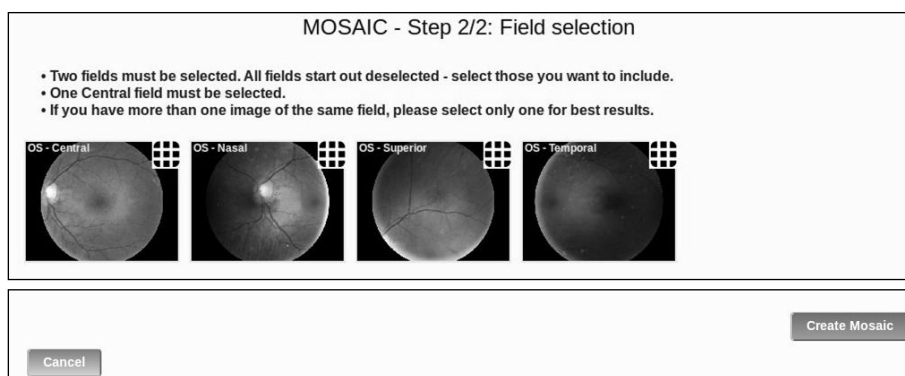


Figure 74 – Mosaic function, field selection screen

During mosaic generation a message will inform that the mosaic is still in progress and eventually that it has completed. Click on **Ok** to go back to the **Patient Record** screen and review the mosaic image (see Figure 69).



Images resulting from the mosaic process may contain artifacts (such as duplicated or disconnected vessels) that are generated at the transition between two adjacent fields and that are not present in the original images. Such artifacts can be easily ruled out by comparing the mosaic image with the original single-field images.



Figure 75 – Example of a 3-fields mosaic image

APPENDIX C – EYE KNOWLEDGE NETWORK (EKN)

Introduction

The Eye Knowledge Network is CenterVue Cloud solution for data management. EKN is used to transfer, store and display DRS images and textual information to a remote server and make them available for online consultation, using the web browser, to authorized users.



- the EKN service is not active by default on the DRS and requires the purchase and activation of a dedicated license. Please visit www.eyeknowledge.net or contact us at www.eyeknowledge.net/contact for further information on how to activate the EKN.
- This section of the manual explains some features of the DRS when used in connection with the EKN service. Please refer to the EKN Operating Manual for specific information on the use of EKN service.

Enabling the EKN service

To enable the EKN service and start accessing DRS data online, you need to first register as a User on EKN and then register the DRS on EKN:

- Make sure that you have a valid EKN license;
- press the SHOW button to show the “One Time Secret Key”;
- press ENABLE to activate DRS synchronization with the EKN server;
- setup a new user account on www.eyeknowledge.net by clicking on the “Sign Up” button (refer to the EKN Operating Manual for additional details);
- once the account is active, login with your credentials, click on “Admin”, then on “Register new DRS”, type the serial number of your DRS (e.g. drs-0123), use lowercase characters. Then type the One Time Secret Key shown on your DRS (this step is required only once);
- make sure the DRS is connected to the internet. After maximum half an hour the DRS status as displayed in Settings >> EKN >> GENERAL should read "REGISTERED" (see Figure 76) and any existing patients and exams will start being uploaded on the EKN.

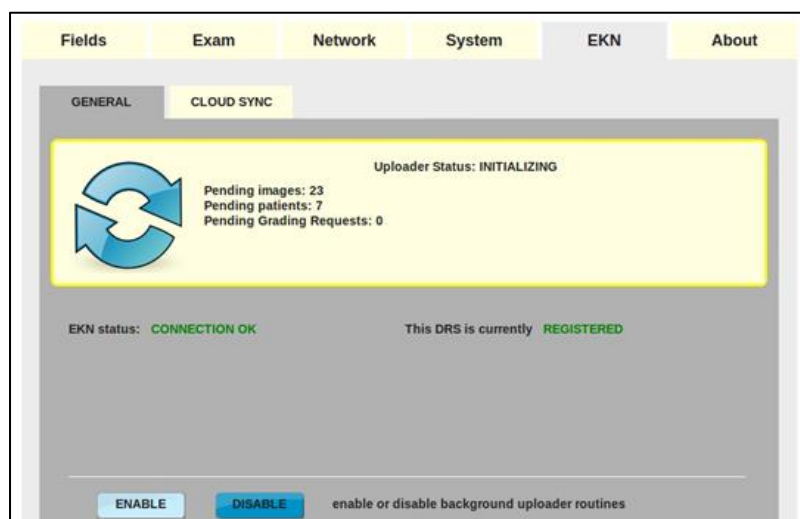


Figure 76 - EKN tab in Settings







- The upload time depends on the number of patients and images stored in the DRS and on the available bandwidth.
- Use Ethernet (wired) connection to maximize performance.

Data upload status

When the DRS is enabled for data transmission to EKN, the Settings >> EKN >> GENERAL tab provides status information on the upload process (see Figure 76). Furthermore, a new icon appears on the top bar of the home screen, besides the settings icon.

Icons have the following meaning:

Icon	Meaning
	Upload in progress (3 images missing)
	Upload is complete.
	EKN problem: the EKN license may be expired or there is a temporary problem with the EKN server. Please click the status icon to go to Settings >> EKN >> GENERAL and check the error code.
	Network problem: EKN server is not reachable, please check your Internet connection.

Multi-unit patient list

If your DRS is part of a group of units connected to EKN, you can combine the patient lists of all units belonging to the group.

Patients retrieved from the EKN (including those who were not generated by your DRS) will be listed in the patient list screen (see Figure 9) and can be searched for, exactly like local patients.



- the multi-unit patient list has no value if your DRS is not part of a group of units connected to EKN
- all patients of the EKN device group to which the DRS belongs will be downloaded
- only the patient anagraphics is retrieved, not the exams and images, in particular exams and images generated on a different DRS unit will not be accessible
- exams and images that are not available locally can only be accessed on the EKN
- all retrieved patients can be selected, new exams captured, stored locally and then uploaded on EKN

To enable this multi-unit mode, click on Settings, select the EKN >> CLOUD SYNC tab, click on “enter your EKN account credentials”, type your EKN credentials, click on login and then click on “sync enabled” in the “Sync EKN remote patient list with local list” box (see Figure 77). When the synchronization is enabled, the DRS will periodically retrieve from the EKN the updated patient list, as resulting from the activity of all DRS units belonging to the group.

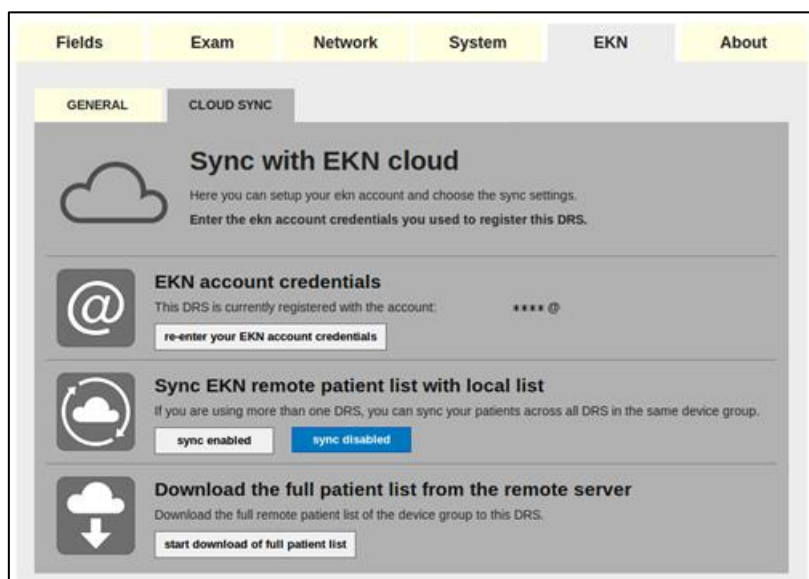


Figure 77 - EKN >> CLOUD SYNC tab in Settings

Retrieving the patient list from EKN

In several situations you may want to retrieve the patient list from the EKN server. This can be useful, for example, if you are periodically erasing part of the data from the DRS following its upload on EKN (see next paragraph).

To retrieve the patient list from the EKN server at any time, click on Settings, select the EKN >> CLOUD SYNC tab, click on “enter your EKN account credentials”, type your EKN credentials, click on login, then click on “start download of full patient list” (see Figure 77) and eventually click on “proceed”. A progress bar will display and a message will acknowledge completion.



- all patients of the EKN device group to which the DRS belongs will be downloaded
- only the patient anagraphics is retrieved, not the exams and images
- exams and images that are not available locally can only be accessed on the EKN
- all retrieved patients can be selected, new exams captured, stored locally and then uploaded on EKN
- data contained in the DRS unit will be preserved

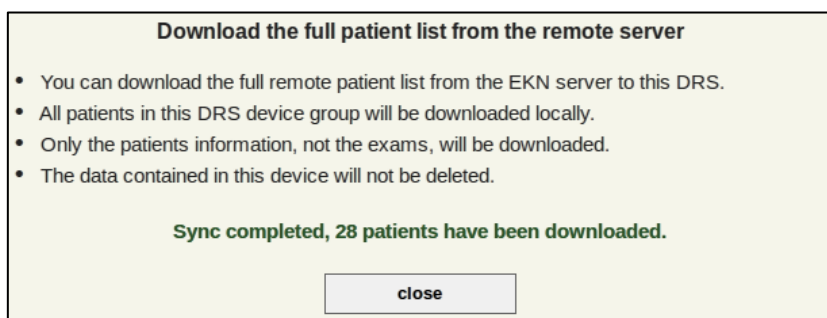


Figure 78 – Patient list retrieval completed message