RetCam 3

Ophthalmic Imaging System

International User Manual

PN 21-100375 Rev. A
For use with
software version 5.1

CE

Caution: Federal law (US) restricts this device to sale by or on the order of a physician or licensed medical practitioner.

Clarity medical systems

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1 Introduction

The **RetCam3 Ophthalmic Imaging System** (system) is designed to allow the quick and easy capture of wide field, high resolution, fully digital images and videos of the eye.

Indications for Use

For general ophthalmic imaging, including retinal, corneal, and external.

Warnings and Cautions

CAUTION: Federal law (US) restricts this device to sale by or on the order of a physician or licensed medical practitioner.

WARNING: Prior to using the system, read all user safety information.

WARNING: Before using this equipment to acquire images from patient eyes, users must be trained in proper clinical technique by personnel authorized by Clarity.

WARNING: The RetCam system is designed and tested as a system. Omission or substitution of RetCam components may adversely affect system performance and is strongly not recommended.

WARNING: Unauthorized modifications or additions to the RetCam system (including hardware and software, etc.) could adversely affect system function and will void the warranty.

WARNING: Carefully inspect and clean the lens piece before each use. DO NOT USE if the lens piece has nicks, breaks, scratches, or rough surfaces that may damage the eye.

WARNING: To mitigate the potential for excess light exposure, always start at the lowest light intensity level and increase if necessary. Use only the shortest amount of exposure time necessary; no greater than 5 minutes.

WARNING: Use care when contacting the eye; i.e., use the least amount of pressure and/or movement necessary.

WARNING: A risk/benefit ratio must be assessed before confirming a patient for RetCam imaging if they are: photosensitive, concomitantly exposed to photosensitizing agents, or aphakic.

WARNING: To avoid the risk of electric shock, the equipment must be connected to a supply mains with protective earth**.**

WARNING: To mitigate the potential for excess light exposure, the user should avoid looking directly at the illuminated light source**.**

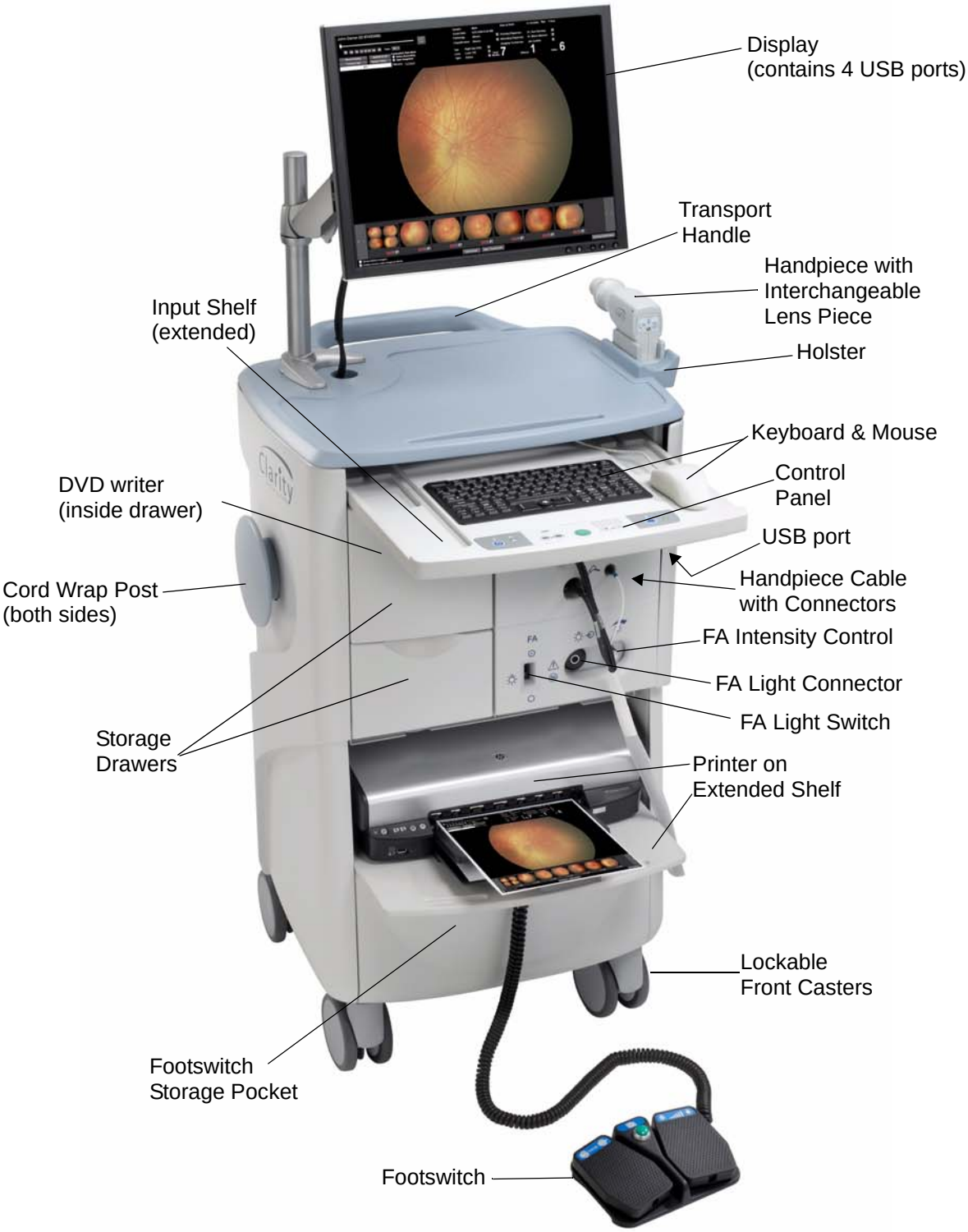


Figure 1 RetCam3 Ophthalmic Imaging System front view*

*Shown with optional FA (Fluorescein Angiography) feature

Figure 2 RetCam3 Ophthalmic Imaging System rear view

Main Hardware Components

- **Display:** A flat panel display is standard with the system.
- **Control Panel:** A membrane control panel turns the system on with one button, and has controls for illumination intensity, camera focus and snap (capture an image or start/stop video recording).
- **Handpiece:** Contains the camera. Lightweight and easy to position, it has a long cable for easy reach. Use with changeable lens pieces.

- **Chassis:** Contains the control systems and connections.
- **Footswitch:** Provides optional means to control illumination intensity, camera focus and snap.
- **Storage Drawers:** All units have two storage drawers for lens pieces, tools and supplies.
- **Fluorescein Angiography Module or FA (optional):** An optional blue exciter light source is available for FA digital photography. It comes complete with a yellow barrier filter for the handpiece. You can adjust illumination intensity only through the FA intensity control.
- **Printer:** Color images and reports can be printed.

Figure 3 Handpiece and Lens piece

Lens Model	Application	Common Field of View
D1300	Premature Infant	130 Degrees
B1200	Standard Baby	120 Degrees
E800	High Contrast Children's & Adults	80 Degrees
C300	High Magnification	30 Degrees
PL200	Portrait Lens	N/A

Electrical Safety Information

The system has been designed, inspected and tested to comply with the safety requirements of IEC60601-1 with respect to fire, shock and mechanical hazards only if used as intended.

Class I Type BF Electrical Equipment

Rated for Continuous Operation

Electromagnetic Emissions		
Compliance Level: Group 1, Class A		
Test Type	**Compliance Level**	**Notes**
Conducted Emissions CISPR 11/ EN 55011	Class A	The RetCam system uses RF energy for its internal function. Nearby electronic equipment may be affected.
Radiated Emissions CISPR 11/ EN 55011	Class A	
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	
FCC Part 15B	Complies	

Electromagnetic Immunity		
Test Type	**IEC 60601-1-2 test and compliance level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transients (AC Power) (I/O Lines) EN 61000-4-4	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment. AC Power electronic disturbances (transients) may cause the system's display to scroll continuously. If this occurs, imaging should not processed until the disturbance has ceased.
Surge Line to Line (AC Power) (I/O Lines) EN 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions EN 61000-4-11	>95% dip in Ut 0.5 cycle 60% dip in Ut 5 cycles 30% dip in Ut 25 cycles >95% dip in Ut 5 seconds	If the user of the RetCam system requires continued operation during power mains interruptions, it is recommended that the RetCam system be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated Immunity EN 61000-4-3	80MHz-2.5GHz 3V/m 80%@1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the RetCam system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 3.5 / E_1 \sqrt{P}$ 80 MHz to 800 MHz $d = 7 / E_1 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). E_1 is 3 V/m. Conducted Immunity: $d = (3.5 / V_1) \sqrt{P}$ where V_1 is 3 Vrms. Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol.
Conducted Immunity EN 61000-4-6	0.15-80MHz 3 Vrms 80%@1kHz AC Mains	

WARNING: Interference may occur in the vicinity of equipment marked with the following symbol.

This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

An error message may be displayed, which then may require a system reset. To perform a system reset, press the system power switch on the control panel for ~6 seconds until the system powers down, then press the switch again to power the system back on.

WARNING: This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the system or shielding the location.

WARNING: To avoid the risk of electric shock, this equipment must be connected to a supply mains with protective earth.

WARNING: For continued protection against risk of fire, replace only with same type and rating fuse.

Important User Safety Notices

1. Never contact the front of the lens piece with hard or sharp objects. This could damage the precision optics and sealing.
2. DO NOT AUTOCLAVE any part of the device.
3. Appropriately power down and unplug the unit and allow the light source bulb to cool before replacing it.
4. Always return the handpiece to the holster when not imaging. You can drape the handpiece cable over the cord wrap post, but do not wrap it tightly or damage to the fiber optic may result.
5. Do not block access to the holster.
6. The system is not intended to be transported outdoors.
7. Newly acquired data may be lost if power is interrupted during live imaging.

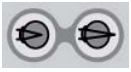
Note: backup battery power is available for at least 15 minutes after interrupt.

8. **The system comes protected from viruses, worms, and spyware with Microsoft's anti-malware. Please refer to your warranty prior to adding any additional software or contact Clarity Service.**

Labels and Symbols

System Power button

Focus



Focus Controls

Lamp Illumination button

Intensity Controls

SNAP (capture) switch or button

Warning or Caution

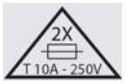
Warning:
Do not look directly into light source

Warning: Dangerous Voltage
(used in FA)

Chassis ground

Protective earth (ground)

Alternating current (AC)



System contains 2 fuses of indicated type.
Do not use any other type.

Backup battery

Computer network

Non-ionizing electromagnetic radiation

FA = Fluorescein Angiography

FA light Intensity, increase clockwise

FA light OFF

FA light ON

Light source (fiber optic) connector

Handpiece connector

USB connector

Read accompanying user documentation

Fragile contents

This side of carton up

Temperature limits

Authorized representative in the EU

Type BF equipment (applied part is handpiece)

To prevent damage to lens piece, carefully store handpiece in holster when not in use.

Clean lens piece after use

Separate collection of waste at end-of-life as required by European directives. Contact Clarity for equipment disposal instructions.

European conformity

North American compliance certification

Serial number

Date of Manufacture

Keep away from the rain

Go to next screen

Hide image

Delete image

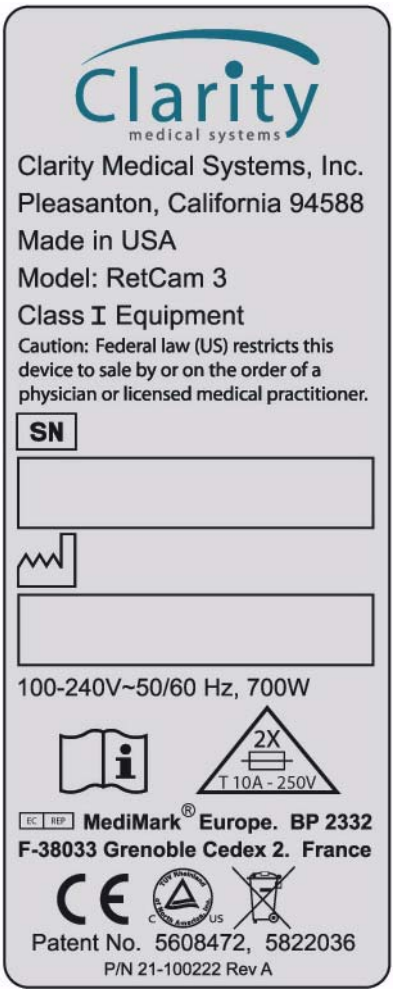
Flag or select item

Reset

View patient directory

Utilities

Product Label



2 Using the RetCam 3

This chapter explains how to use the RetCam 3 system, after it is properly installed at your site. The activities described include:

- Turning the System ON (from Stand-by Mode) on page 19
- Turning the System OFF (Stand-by Ready) on page 21
- Using Hard Shutdown on page 22
- Turning OFF the Main Power on page 23
- Managing Patient Records on page 23
- Performing Exams on page 26
- Using Helpful Features on page 30
- Adding Exam Notes on page 33

Turning the System ON (from Stand-by Mode)

New systems are installed by Clarity trained personnel. The installation includes installing main power, attaching the handpiece, and adjusting the monitor. Upon request, full installation instructions are available from the Clarity Service Department. The instructions in this chapter are for using an installed system, which has the main power, printer, and monitor turned ON, the monitor height adjusted, and software installed and configured for the site.

Note: After software is installed, the system requires an Authorization key to initiate the system. The key is available through Clarity MSI service.

CAUTION: Never block any RetCam 3 System vents.

CAUTION: Never block access to the handpiece holster.

To turn the system ON from the Stand-by mode:

1. Carefully pull out the input shelf until it is fully extended.
2. Depress the System Power (Stand-by) button (located on the Control Panel) to turn ON system power. The System Power (Stand-by) indicator light (solid green) should be illuminated. The software should initialize.

The membrane control panel is located at the front edge of the keyboard tray. It provides controls and indicators of system status.

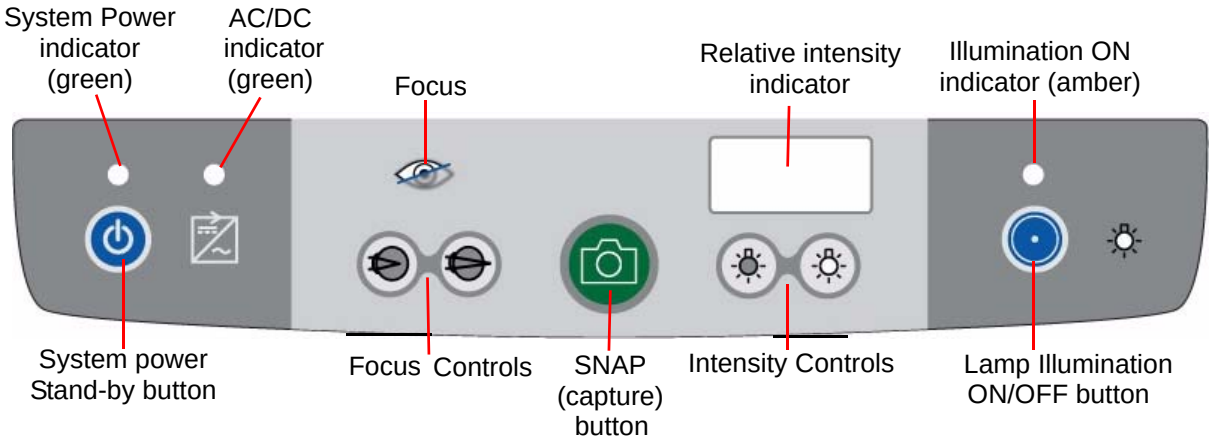


Figure 4 Control panel

3. Attach the desired lens piece to the Handpiece, as shown in Figure 5 and Installing Lens Pieces on page 21.

Figure 5 Installing a lens piece on the handpiece

Installing Lens Pieces

A. Fit the lens piece on the handpiece, aligning the 3 radial pins on the front of the handpiece with the spaces between the tabs of the spring ring on the lens piece.

B. Twist the lens piece clockwise (as shown in Figure 5) until you hear a click, indicating that the lens piece is locked in place.

4. Verify that the handpiece is connected to the system as shown in Figure 6.

Figure 6 Handpiece connections

Always return the handpiece to the holster when it is not in use. You can drape the handpiece cable over the cord wrap post, but do not wrap it tightly or damage to the fiber optics may result.

WARNING: Carefully inspect and clean the lens piece before each use. DO NOT use if the lens piece has nicks, breaks, scratches, or rough surfaces that may damage the eye.

5. PRINTER. Extend the printer shelf fully and verify that sufficient paper is installed in the printer. The shelf can be pushed back in.
6. When the software is ready, you will see the message “Not Displaying Patients.”
7. For FA operation (if available) see Chapter 6, Fluorescein Angiography Module for instructions.
8. If the illumination lamp is OFF, press the illumination lamp button located on the right side on the Control Panel to turn illumination ON. The amber indicator light is illuminated when the lamp is ON.

Turning the System OFF (Stand-by Ready)

Note: We strongly suggest that you backup and store your data prior to turning OFF the system. See Exporting Images on page 43 for details.

1. To turn OFF the system (leaving the Stand-by Ready) hover over the red **Shutdown** button at the bottom of the Patients and Exams screen.

Figure 7 Shutdown button

The shutdown options screen appears. Select **Shutdown Computer**.

2. If the system stops responding, wait at least one minute because it may be busy. If the system does not respond after one minute, depress the System Power button (on the Control Panel) once.
3. All Control Panel indicators except for the green AC/DC indicator will turn off.
4. If FA is available, verify that the FA light switch is OFF.
5. Remove the lens from the handpiece. Carefully inspect and clean the lens piece. Store the lens in the lens box.
6. Return the handpiece to the holster.
7. Return the footswitch to the footswitch pocket (See Figure 8).

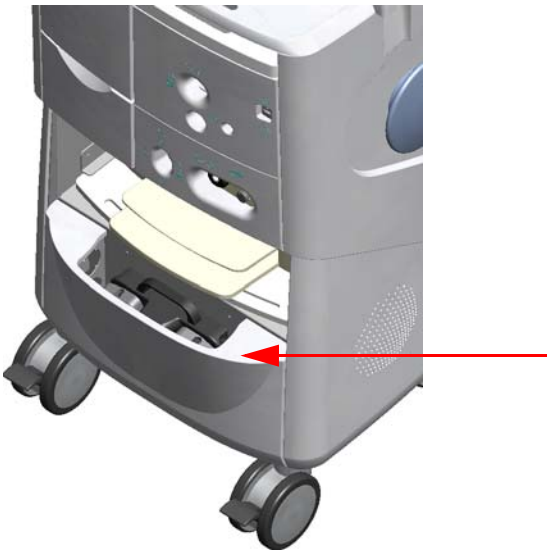


Figure 8 Footswitch pocket

Note: To re-start the system, see Turning the System ON (from Stand-by Mode) on page 19.

Using Hard Shutdown

WARNING: Do not use the hard shutdown method unless necessary because data corruption can occur.

In the event that hard shutdown is required, continuously press the System Power button on the control panel for at least 6 seconds to force the system, including the backup battery, to shut down.

Turning OFF the Main Power

Flip the main power switch (located on the rear of the system) to OFF. All Control Panel indicators will be OFF except the AC/DC indicator. The AC/DC indicator will flash green while the backup battery continues to supply power (at least 15 minutes).

Managing Patient Records

This section describes how to add a new patient and locate the records for an existing patient.

The software is ready to use when you see the start screen shown in Figure 9.

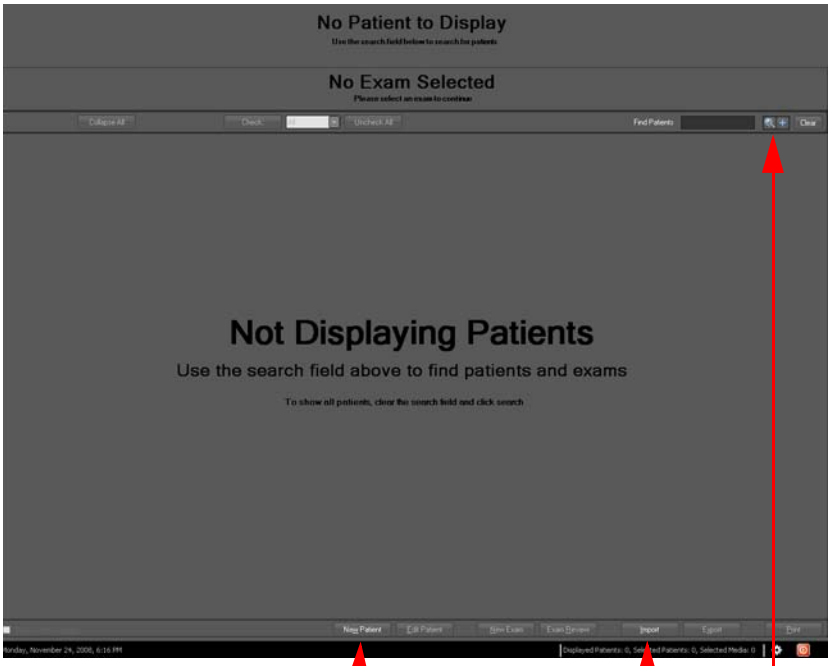


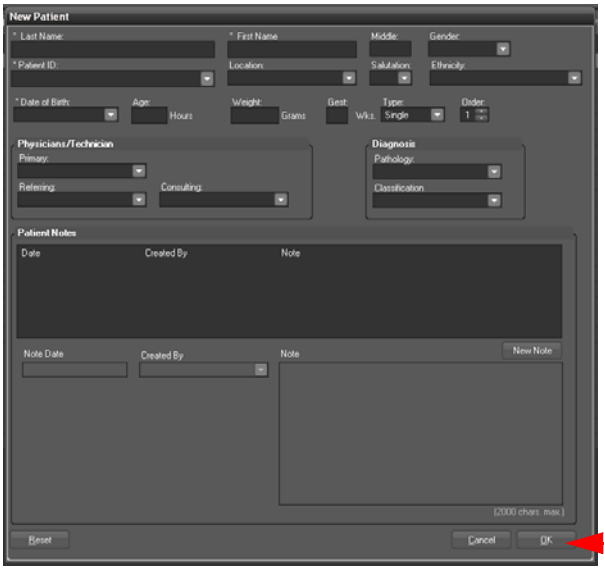
Figure 9 Start screen

Add a New Patient Record

To create a new patient record, the following information is required:

- First Name
- Last Name
- Date of Birth
- Patient ID

Patient information is repeated in several of the screens. The patient name and Patient ID are always shown in the upper left corner of every screen.



Select OK to proceed.

Enter information manually or use menus, where available.

Figure 10 Add new patient screen

Editing a Patient Record

Highlight the patient's record from the Patients and Exams screen.

Select Edit Patient.

You can edit the following information:

- First Name
- Last Name
- Gender (Male, Female, Other, or Unknown)
- Date of Birth
- Weight (in grams)

Note: Any fields on the Edit Patient Screen are editable.

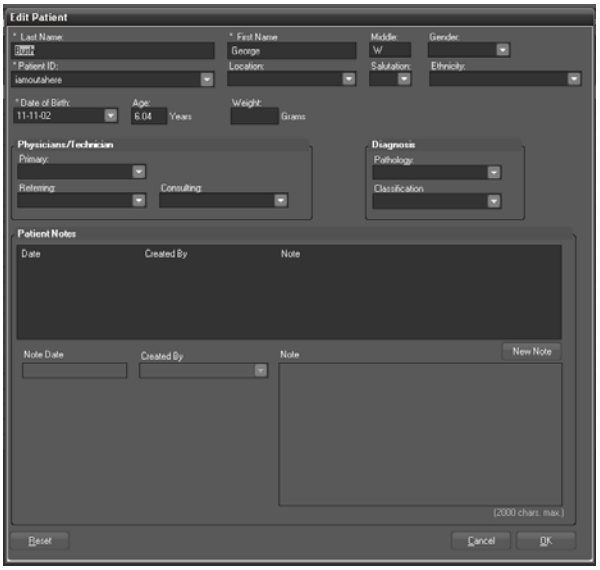


Figure 11 Edit Patient record screen

Finding Existing Patient Records

You can search the directory to locate specific patient records.

Figure 12 Search buttons

From the Start screen, select the icon to display the entire patient directory or select the plus sign to locate patient records using one or more of the search features (see Figure 13).

Figure 13 Patient search options

Select **Clear** to clear all search fields.

Search Results

When you select the to display the entire patient directory, the results are displayed as shown in Figure 14.

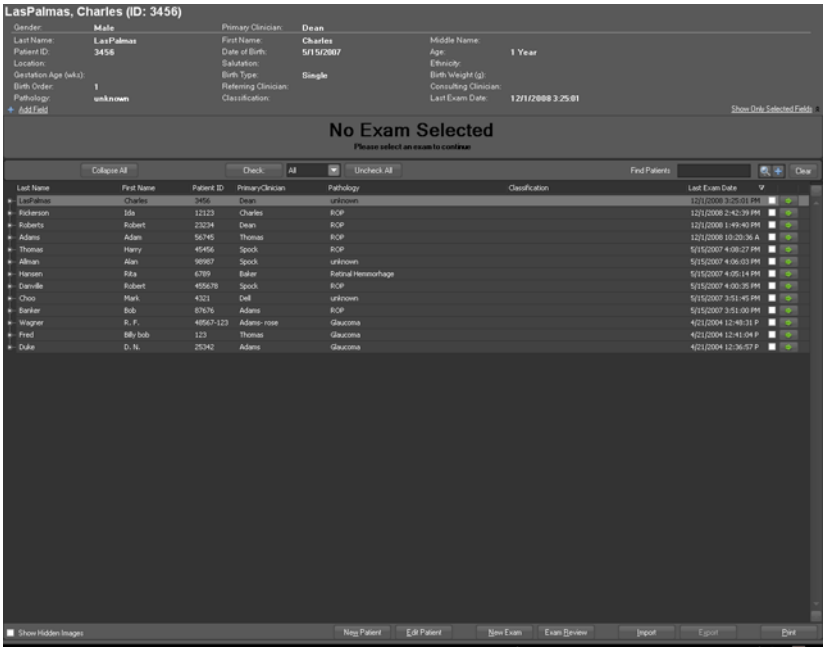


Figure 14 Patients and Exams Screen (Patient Directory)

From the Patients and Exams Screen, you can use the buttons shown in Figure 15 to sort the results.

Figure 15 Patients and Exams screen navigation buttons

Performing Exams

You can use the RetCam 3 to capture still images or video after selecting a patient.

Select the green arrow on the right side of a patient name, or select the New Exam button. To start an exam, you can select a Preset Configuration, which can be easily edited, or Manual Configuration.

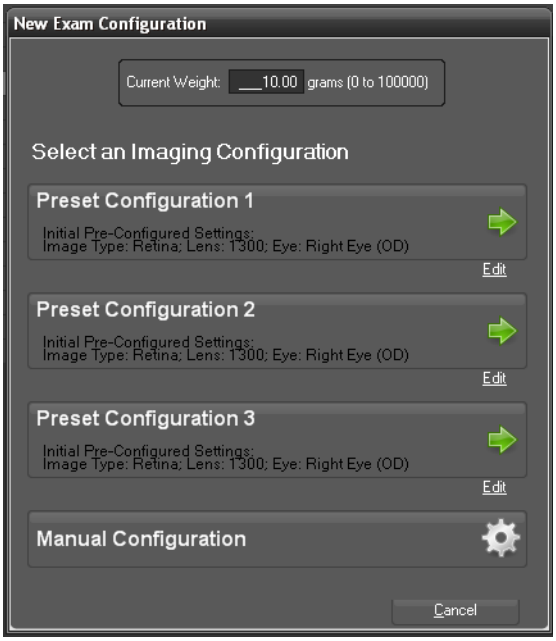


Figure 16 New Exam configuration screen

The following Information can be defined in the Preset or Manual Configuration:

Image Type	Lens	Eye
Retina	300	Right (OD)
Fluorescein Angiography	800	Left (OS)
Anterior Segment	1200	Unspecified
Unspecified	1300	
	Unspecified	

Once the new exam is configured, select the green arrow to enter the New Exam screen.

Select **Show Thumbnails** at the bottom of the Exam screen to maximize the available features.

Figure 17 Show Thumbnails button

0 The **Show Thumbnails** button toggles between **Show Thumbnails** and **Hide Thumbnails**.

Capturing Still Images

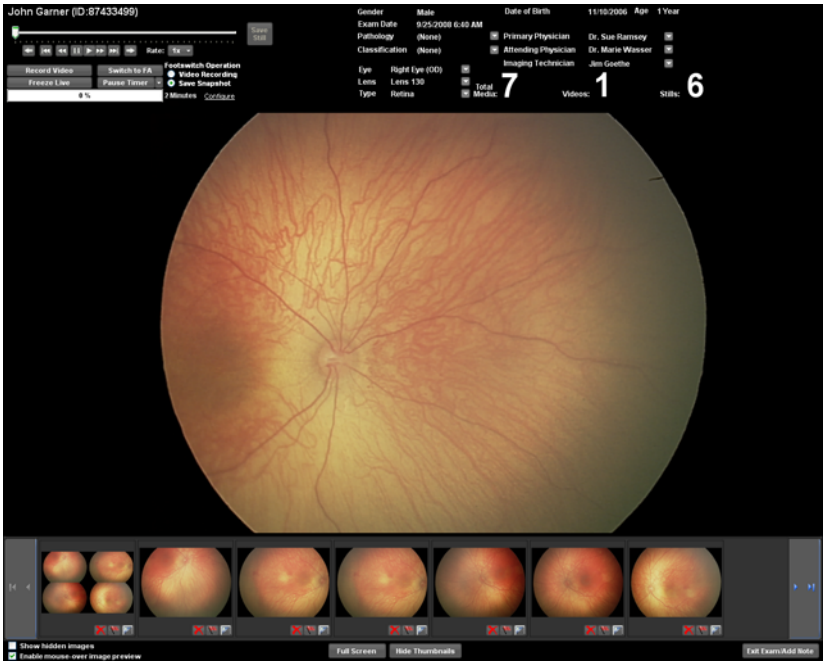


Figure 18 New Exam screen

The recommended procedure is to capture video of the entire exam, and grab still images from the video then delete the video prior to exiting the New Exam session. You can take still images from the New Exam screen using the following:

Keyboard and Mouse

Some utility buttons are displayed on the monitor; use the mouse to select them.

Figure 19 Onscreen capture controls

Use the “S” key to SNAP images.

Footswitch

Select **Save Snapshot** from the monitor display (see Figure 19 on page 28). Then use the footswitch button to SNAP images.

Control Panel

Press the button.

Note: Saving video can take significant time and consumes a great deal of disc space. To maintain optimal system performance, select the images of interest from the video then delete the video prior to exiting Image Capture.

Note: The storage capacity of the system hard drive is a maximum of approximately 250,000 still images. Saving a combination of videos and stills will affect the total number of each that can be saved. Saving images with annotations reduces the total number of images that can be saved.

Note: If the Control Panel (or keyboard) controls do not respond, check that the Footswitch Controls are not activated.

Capturing Video

Up to 2 minutes of Video capture is available per session. A progress bar is enabled each time video is started to let you know the percentage of time used.

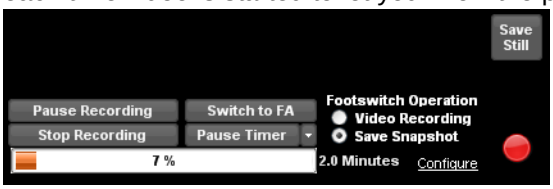


Figure 20 Video and image capture controls

Video is captured at full resolution, 30 frames per second.

The following controls are available on screen:

- **Record Video**—Starts recording video; to stop recording video, select **Stop Recording** or **Pause Recording**.
- **Freeze Live**—Freeze an image during image capture.
- **Switch to FA**—Change the image type to Fluorescein Angiography. See Chapter 6, Fluorescein Angiography Module.
- **Start Timer**—Start a timer to record the time elapsed during the exam.
- **Save Still**—Saves a still image to the hard drive
- Footswitch Operation options:
  - Use the button to pause and continue video recording.

Note: The storage capacity of the system hard drive is a maximum of 140 minutes of total video (for example, 70 videos of two minutes duration each, or 280 videos of 30 seconds each). Saving a combination of videos and stills

will affect the total number of each that can be saved. Saving images with annotations reduces the total number of images that can be saved.

Video Playback

When you stop live recording, the playback buttons are enabled.

Reverse, pause, and play

Fast forward

Go to the beginning of the recorded video

Go back one video

Advance one video

Go to the end of the recorded video

Control the rate of playback or search.

Tip: Using the left and right arrow keys on the keyboard will also move the video back or forward one frame at a time.

Deleting a Video

To delete a video, in the thumbnail view, select the **delete** icon at the bottom of the frame. This marks the video for deletion when you exit the exam. The **delete** icon toggles, that is, selecting it again before exiting the exam means the video is no longer marked for deletion.

Note: Images and video can be selected for deletion only during the imaging session. Once the session has been exited, the images will be saved for that session.

Using Helpful Features

The RetCam 3 software includes some useful features to streamline your work.

Shortcut Keys

An underlined letter indicates a quick key. To use a quick key, press ALT and the letter key simultaneously.

Note: Do not use Windows shortcut keys, for example Copy (Ctrl+C), Paste (Ctrl+V), Undo (Ctrl+Z), and others.

Still Images From Video

During video replay, you can identify and save still images from the exam. There are three ways to locate and save a still image.

1. Scroll through the thumbnails, using the arrows at the right and left ends of the strip at the bottom of the screen.

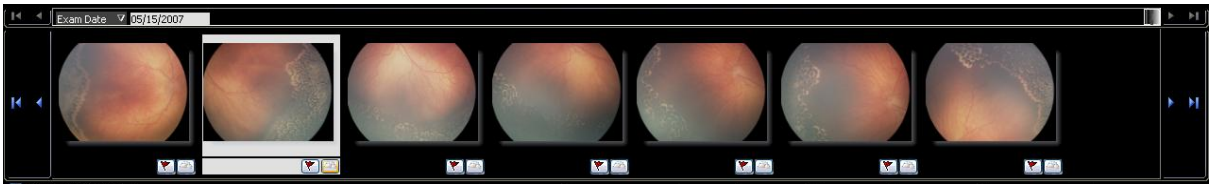


Figure 21 Video thumbnails

- Use the arrow at the right to scroll forward through the video and the arrow at the left to scroll back.
- Stop when the image you want to save is highlighted.
- With the image highlighted, select Save Still (or press **'S'** on the keyboard or press the button on the footswitch).

2. Use the scrollbar at the top of the video controls to scroll through the video, and find a frame.

Figure 22 Video scrollbar control

- Move the slider to the right or left to scroll forward or back through the video.
- Stop the slider when you see an image you want to save.
- Select Save Still (or press **'S'** on the keyboard or press the button on the footswitch).

3. Use the playback controls at the top of the screen to locate a still image:

- Start playback by selecting **Play** or **Reverse** .
- Select **Pause** when you see an image you want to save.
- Select Save Still (or press **'S'** on the keyboard or press the button on the footswitch).

Changing Image Capture Options During an Exam

Before you start imaging, verify that the options displayed for eye, image type and lens piece are correct. If necessary, you can edit options from the image capture screen.

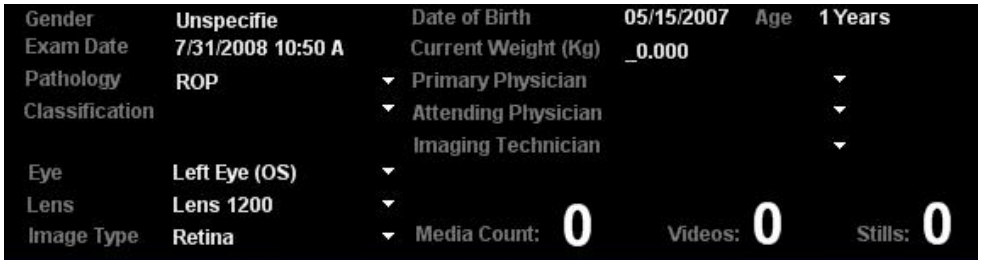


Figure 23 Select options for image capture

Eye Changing: Right Eye (OD) / Left Eye (OS)

To image the other eye in the same session, expand the **Eye** menu and select the other eye (**Right Eye (OD)** or **Left Eye (OS)**). The **Eye** selection is saved with the image.

Note: When using this option, be careful that you select the correct eye before you save the image. This is especially important when both eyes are captured in one video clip, and you save still images from the video. Make sure you select the correct eye before you save each still image from the video.

Note: Images and video can be selected for deletion only during the imaging session. Once the session has been exited, the images will be saved for that session.

Lens Changing Lens

You can also select a different lens piece during imaging. Expand the **Lens** menu to select **1300** (Premature Infant), **1200** (Standard Baby), **800** (Posterior), **300** (High Mag), or **Unspecified**. The lens piece selection is saved with the image.

Image Type Changing Image Type

Expand the **Image Type** menu to select **Retina, Anterior Segment,** or **Other** during an imaging session. All selections record the images in color. The Image type selection is saved with the image.

WARNING: System power from a fully-charged battery is available for at least 15 minutes after an AC (main) power loss. In the event of an AC power loss, we strongly suggest that you complete the imaging session and save images to prevent potential data loss. Start a new live imaging session only after reconnecting the AC power.

Enable mouse-over image preview: Check this box to see an existing image on screen during a live imaging session.

Figure 24 Enable mouse-over

Adding Exam Notes

When you select the **Exit Exam/Add Note** button at the bottom right corner of the image capture screen, the Exam Notes dialog appears. For each eye, it provides a field where you can type in notes.

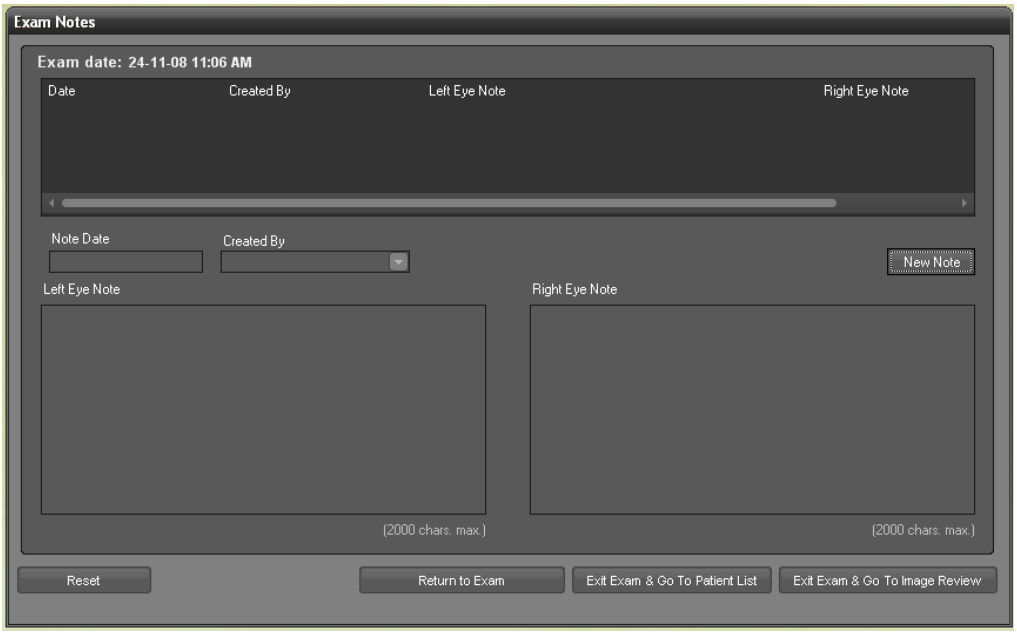


Figure 25 Exam Notes dialog

To add notes:

1. Select **New Note** to activate the notes fields.
2. Input **Created By** information.
3. Type new notes in the fields titled Left Eye Note and Right Eye Note.
4. Select **Save Note** to add notes you have typed to the notes above.

Note: You cannot change a note after you select Save Note.

- Select **Reset** to clear all fields.
- Select **Return to Exam** to save note and return to Live Imaging.
- Select **Exit Exam & Go to Patient List** to save note and return to the Patients and Exams screen.
- Select **Exit Exam & Go to Image Review** to save note and return to the image review screen.

You can add notes also from the Review screen. Once saved, the text cannot be modified. You can append text to notes from the Review, Compare, and Image Process screens by selecting **Exam Notes**. Notes are identified by date/time and person creating the note.

3 Image Review and Compare Mode

Having acquired images, they are available for review and comparison This section covers the following topics:

- Image Review Screen, below
- Compare Mode, page 37

Image Review Screen

The Image Review screen appears optionally when you exit live imaging. You can also access it by selecting the Exam Review button on the Patients and Exams screen.

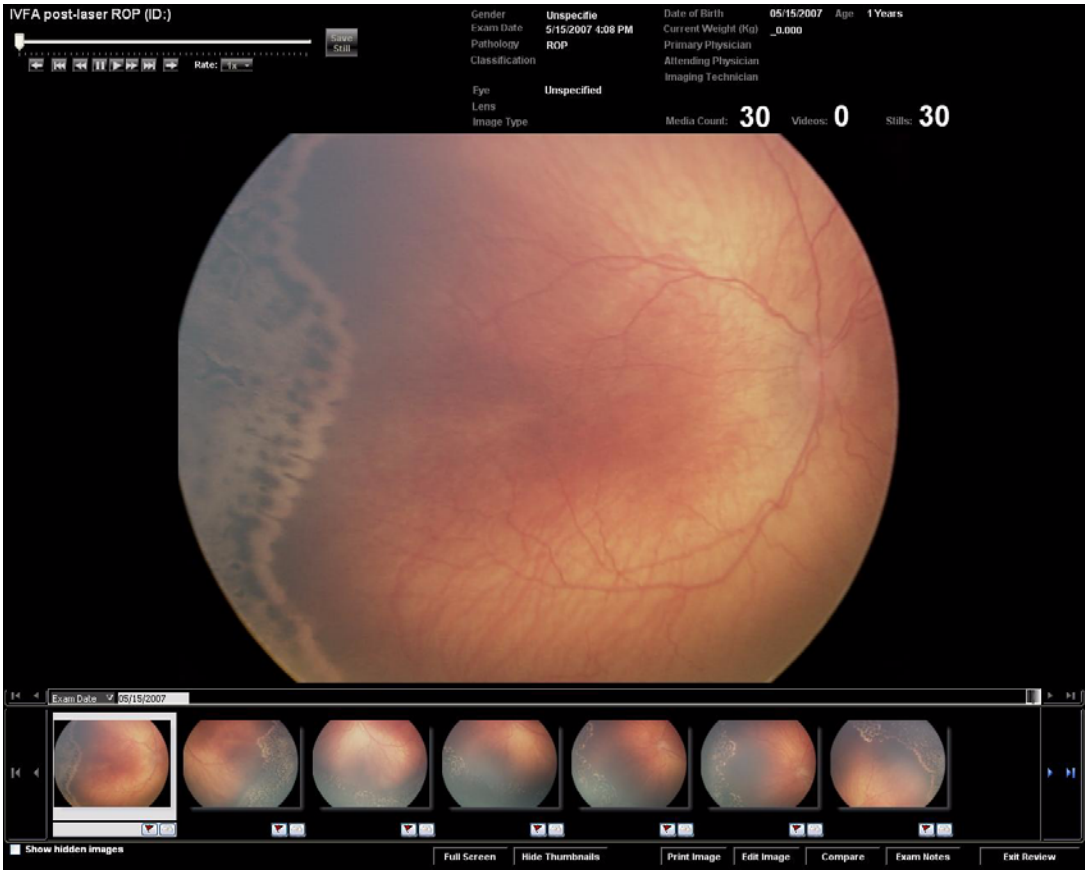


Figure 26 Image Review screen

The Image Review screen displays the images acquired in the session just completed. When you access the Image Review Screen by other means, it displays the images for the last patient and session you selected. To review exams for a different patient, exit to the Patients and Exams screen, and select another patient.

By default, thumbnails for all images acquired in the selected session appear along the bottom of the screen.

Video playback controls appear in the upper left corner of the screen.

The currently selected image (the first one by default) appears full size. Select a thumbnail to display the full resolution image. You can use the arrows at the left and right edges of the thumbnail strip or the up and down arrow keys on the keyboard to scroll through the thumbnails or select a thumbnail.

Thumbnails of video clips show four images (first, last, and two intermediate images in the video) in the quadrants of a square.

Click on the thumbnail to bring the video to the display area. Use the video playback buttons to control the video. The buttons have the same functions as for live imaging. Click **Play** to start playing video.

The following options are available on the Review Screen:

Exam Date

Select a different exam to review by clicking the arrow next to **Exam Date**.

Show Hidden Images

Default is unchecked, in which case only thumbnails of non-hidden images are displayed. When this box is checked, thumbnails for hidden images appear and are available for full size viewing.

Hide Image

Click the **Hide Image** icon below the highlighted thumbnail to hide the current image. You can click this icon beneath any thumbnail to hide that image. You can use the icon to toggle between hidden and unhidden . Hidden items are not deleted. Their thumbnails do not appear unless the **Show hidden images** box is checked.

Unhide Item

When **Show hidden images** is checked, select the **Hide Image** icon to unhide an image. The hidden image icon appears in the upper right corner of the thumbnail for a hidden image.

Flag Image

Click the **Flag Image** icon to flag the current image as an image of special interest. A small red flag appears at the top left corner of the thumbnail. To unflag an image, click the icon again. The icon toggles between flagged and unflagged.

Full Screen

Click **Full Screen** to display a full screen view of the current image, with no thumbnails visible.

Hide Thumbnails

Click **Hide Thumbnails** to remove the thumbnail display without changing the display of the current image.

Print Image

Click **Print Image** to print the current image displayed.

Edit Image

Click **Edit Image** to edit the current image.

Compare

Click **Compare** to view two images side-by-side on the screen. See Compare Mode for details.

Exam Notes

Click **Exam Notes** to review or append text to the session notes in the Review screen. You cannot alter saved notes. Notes are identified by date and created by.

Exit Review

Click **Exit Review** to exit the current review session and return to the Patients and Exams screen.

Compare Mode

The Compare screen appears when you click **Compare**. Use the Compare screen to compare any two images. You can compare images for one or more exams for a single patient.

.

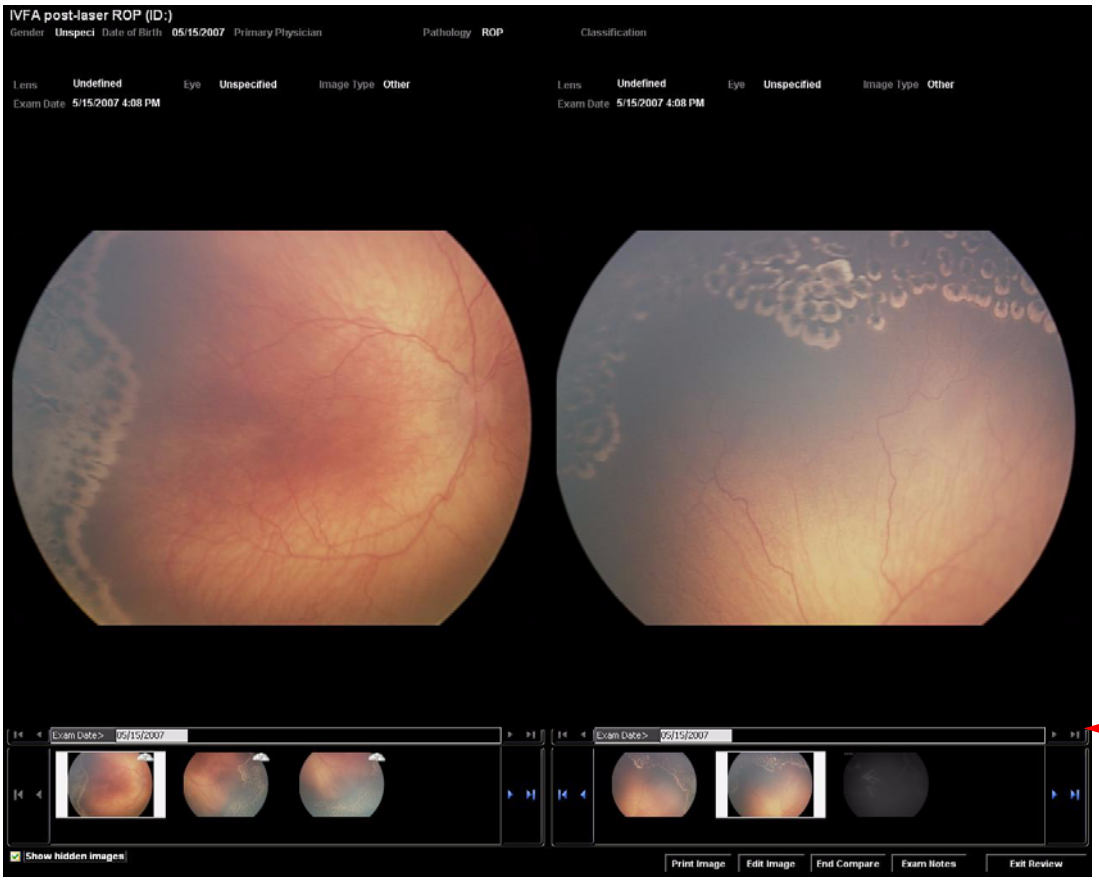


Figure 27 Compare [Images] screen

The last image displayed on the Image Review screen will appear on the left side of the Compare screen. On the right side, by default, the first image of the first session for the same patient appears. Identifying information for each image appears above it. Below each image at the bottom, thumbnails appear for all images in the same session. The Exam Selector displays the dates for all the current patient's exams above the thumbnails. The highlighted date is the exam date for the current thumbnails. To view images from a different exam, select another exam date from the Exam Selector.

The video playback controls are not displayed on this screen because It is not possible to compare videos.

The Compare screen provides a toolbar for the following options:

Show hidden images

The check box for displaying hidden images is available.

Print Image

Click **Print Image** to print the two images displayed on this screen, one above the other.

Edit Image

Click Edit Image to display the Image Adjustment window.

End Compare

Click **End Compare** to return to the display of a single image.

Exam Notes

Click **Exam Notes** to review or append text to the exam notes for that image. You cannot alter saved notes. Notes are identified by date/time and person creating the note.

Exit Review

Click **Exit Review** to return to the Patients and Exams screen.

Image Adjustment

To adjust an image, select the image from the Image Review screen and click **Edit Image**.

The Image Adjustment window appears. To exit the Image Adjustment window, click the “X” in the upper right corner of the window.

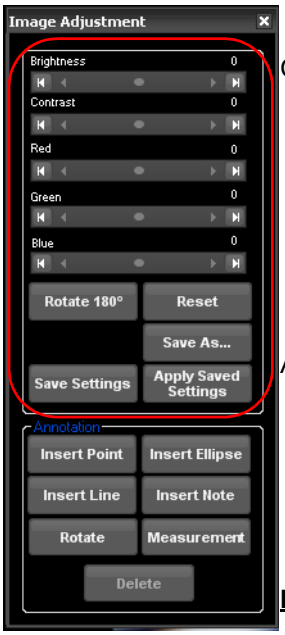


Image Adjustment Parameters

Controls to adjust the image display parameters are:

- **Brightness**
- **Contrast**
- **Red**
- **Green**
- **Blue**

All parameters have a default setting of zero (0), and range from -100 to +100.

- Each click on the right or left arrow at the end of the slider bar changes the parameter value by 1.
- Each click on the bar to the right or left of the slider changes the parameter to the end of the range.

Rotate 180º

Click this button to rotate the image 180º.

Reset Button

Click **Reset** to reset all display parameters to zero.

Save As

Select to export the image.

Save Settings

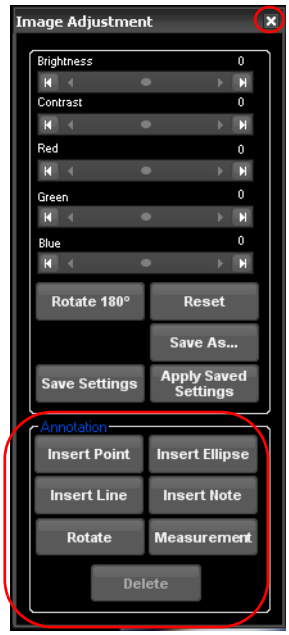
Click to save the current settings for **Brightness, Contrast** and **Red, Green** and **Blue**. The saved settings can be applied when you select **Apply Saved Settings**.

Apply Saved Settings

Click to apply the currently saved settings for **Brightness, Contrast** and **Red, Green and Blue**. Image display adjustments are applied to all images in the current image processing session, until you save new settings or click the **Reset** button, which resets all parameters to zero.

When you leave the current session, the display settings are reset to zero.

Note: Images you save from the Image Adjustment window will reflect image display adjustments (and all other changes) you make, but the original images in the database will not be changed.



Annotation

You can annotate an image by inserting graphic elements or text notes.

Click to select any of the following annotation features:

- Insert Point—Insert pointer and text on the image.
- Insert Ellipse—Draw an ellipse on the image.
- Insert Line—Draw a line on the image.
- Insert Note—Add text to the image.
- Rotate—Rotate the pointer.
- Measurement—Display the number of pixels between two points.
- Delete—Remove a selected annotation.

Select the “X” at the top right to close the screen.

Note: The original images in the database are never changed, even when you modify the image displayed on the screen. You can save processed images only outside the RetCam database and in a non-proprietary format.

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4 Import and Export Images

You can import or export images:

- To make RetCam data available on other RetCam stations, which include RetCam3, RetCam II and RetCam Shuttle systems, and PCs running RetCam Review Software.
- To make a backup copy of the original image data kept on the hard drive.
- To view with standard image software.
- To use RetCam images with third party imaging systems.

Backing Up Images

The RetCam system stores all images to the local hard drive. It is highly recommended to create a central repository on a network of all data from the RetCam device for long term data backup.

Recommended Backup Frequency: Each day you acquire new images.

Exporting Images

You can export data to any accessible location. There are three general steps to complete export. These are:

1. Select Images for Export, below
2. Select Export Options, page 45
3. Complete Export, page 47

Select Images for Export

1. Go to the Patients and Exams screen and highlight the desired patient. Click the arrow on the left side to show all the exams for the selected patient.

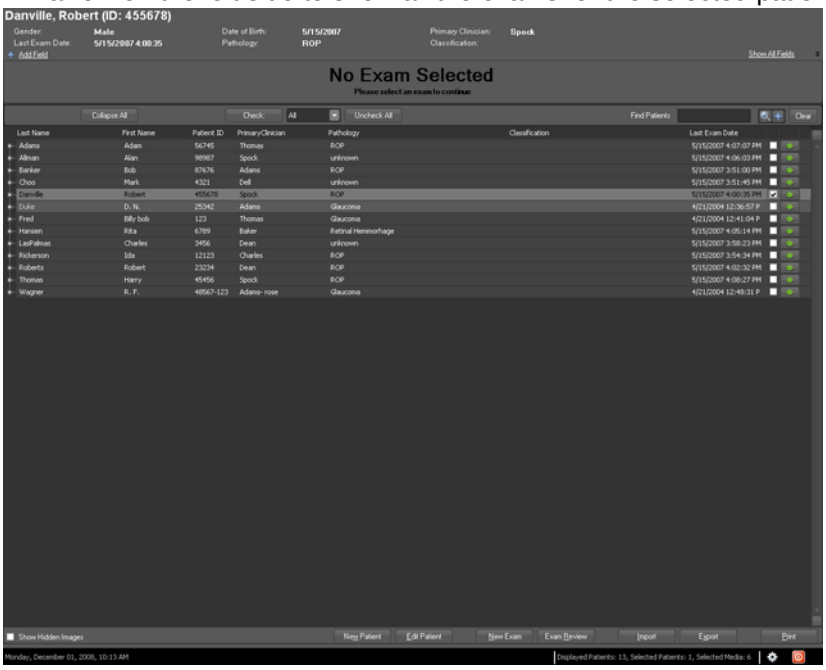

Figure 28 Select patients and exams for export

2. Check the white boxes on the right side of the display to select files for Export. You can select **Check All** to select all patients' records and exams.
3. Click the **Export** button at the bottom of the screen.
4. The **Export** dialog appears.

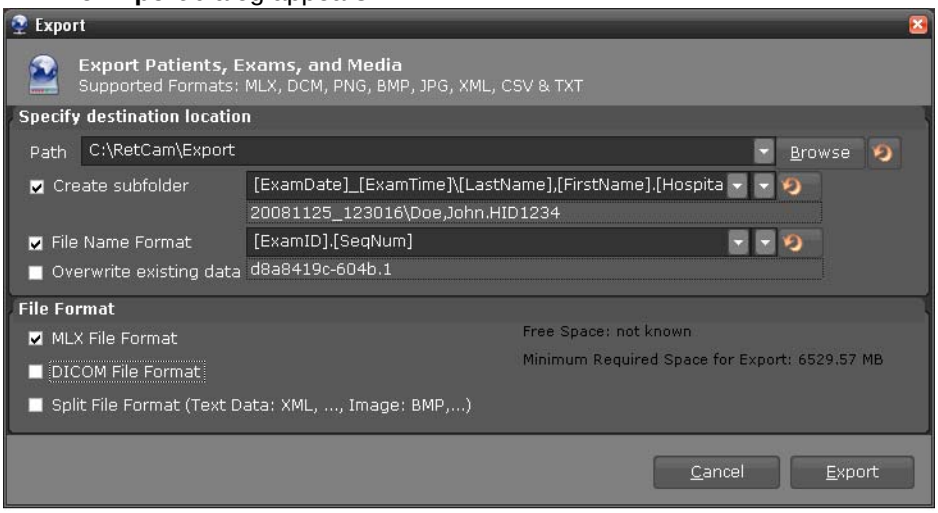

Figure 29 Export dialog

By default, the dialog shows the source location path and options used for the last export.

Note: The Minimum Required Space for Export is displayed. Verify that the export destination has sufficient free space to accept the exported files.

Note Regarding File Size Capacity: We recommend that you do not export more than 2000 images in one batch, because the export will take a long time. We recommend that multiple smaller transfers be executed.

Select Export Options

1. To change the destination location path, select the arrow to expand the path list or click **Browse**. Clicking the red reverse arrow resets the source location to the default setting.

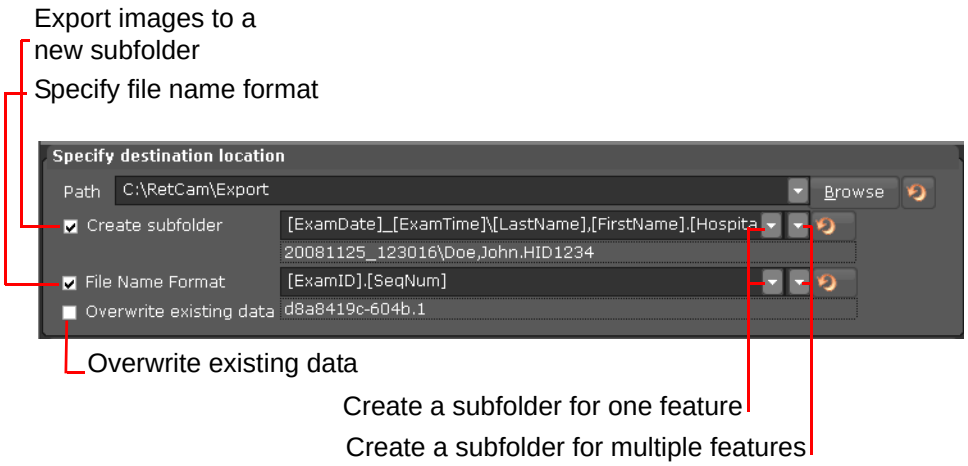

Figure 30 Export destination options

2. Select the destination options:
   - Export images to a new subfolder.
   - Create a subfolder for one feature, such as exam date, exam time, last name, etc.
   - Create a subfolder for multiple features.
   - Specify a file name format for the exported files.
   - Overwrite existing data.

Select the File Format

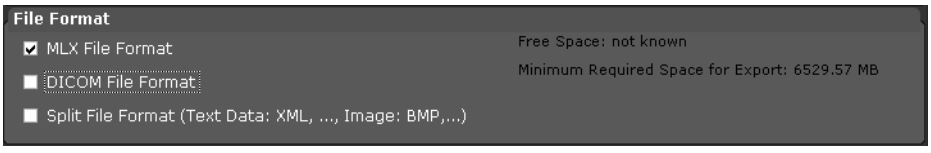

Figure 31 Select file format

Select MLX, DICOM, or Split File format.

MLX	Clarity's proprietary encrypted data format
DICOM (DCM)	DCM is the filename extension for patient data files that are compatible with the DICOM (Digital Imaging and Communications in Medicine) standards for ophthalmology.
Split File Format	If you select this format, you will have additional options for the Export Image and Export Data formats.

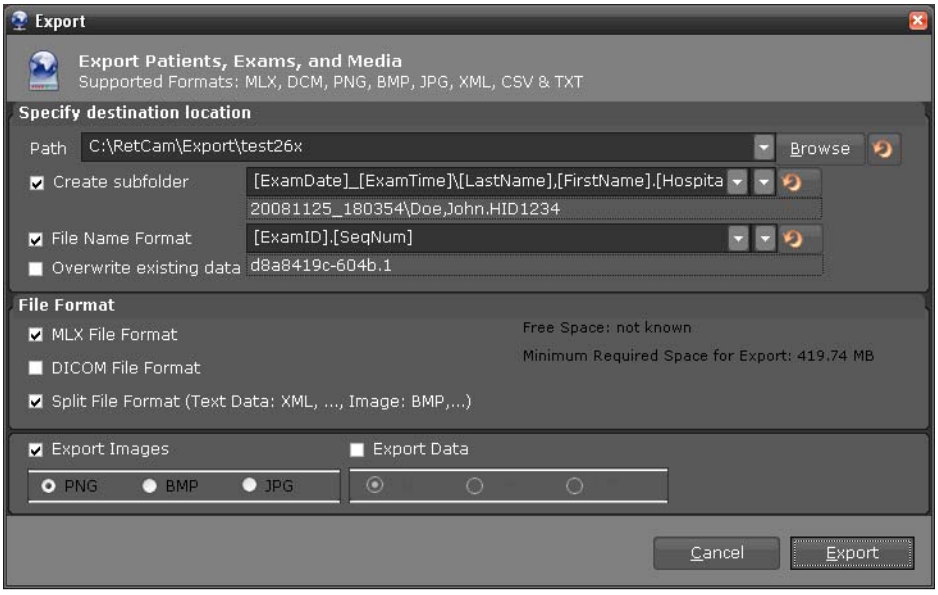

Figure 32 Select image and data format

Export Image Formats

PNG	Portable Network Graphic uses compression to reduce file size (about half the size of a bitmap file), but without loss in quality or resolution. It can be viewed in a standard web browser and used in image processing or viewing applications.
BMP	The bitmap format saves images at full resolution without any quality loss. It results in the largest files.
JPG	(or JPEG) This format uses compression to reduce file size, which results in loss of resolution or quality in proportion to the amount of compression. You can select the image quality before you save.

Export Data Formats

XML	Extensible markup language format
CSV	Comma separated values format
TXT	Generic text format

Complete Export

Select **Export** to initiate Exporting or **Cancel**. A dialog opens to show export progress.

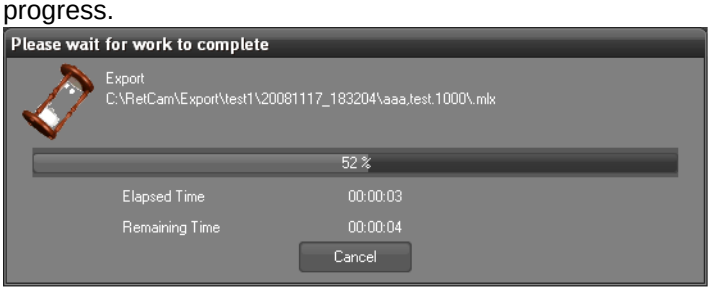

Figure 33 Export progress dialog

Importing Images

Except for data backup, the export destination on the network is an intermediate location. To complete the data transfer and make the images available for viewing on another RetCam system, you must use the RetCam software to import the transferred images into the target system database.

WARNING: Never connect the RetCam3 to a network or any externally powered devices or peripherals *during imaging*.

Note: We recommend that you do not import more than 2000 images in one batch, because the import will take a long time. One way to limit batch size is to import only the files from which you (or someone else) exported a limited number of images. In general, we recommend you import images from one patient at a time.

Follow these steps to import RetCam images:

1. Return to the start screen by selecting **Clear** from the Patients and Exams screen. Select **Import**.

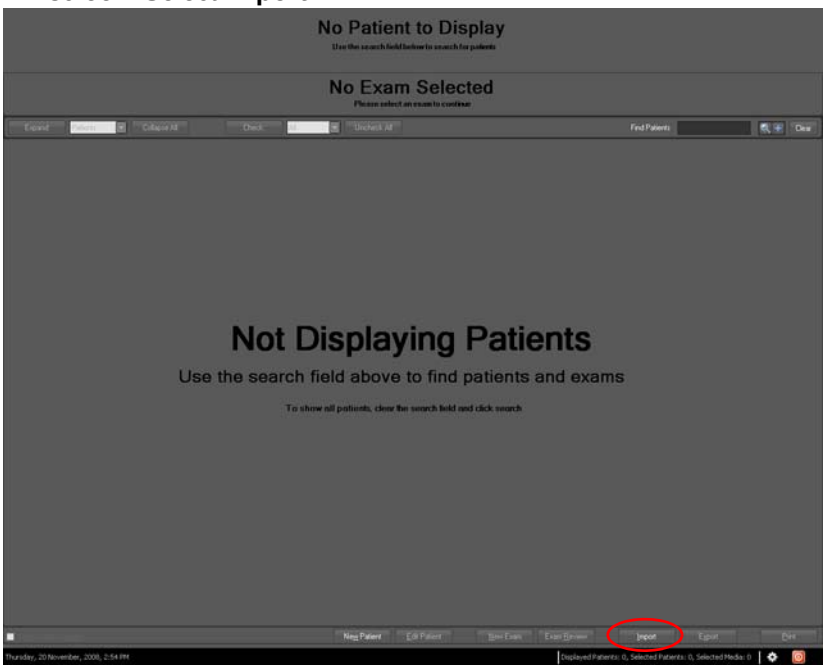

Figure 34 Start screen

The Import Folder dialog appears

.

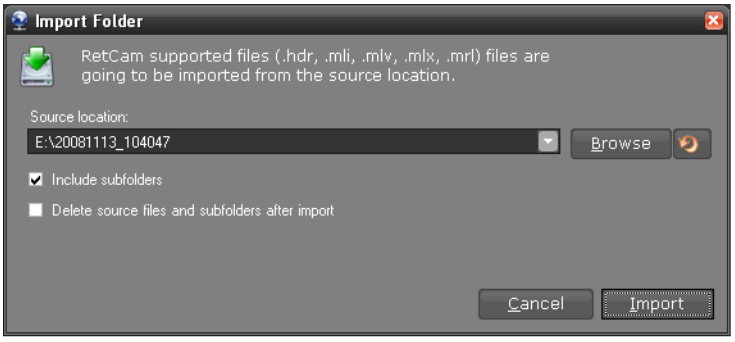

Figure 35 Import Folder dialog

By default, it shows the Source location path and all the options last used.

2. To change the source location, select the arrow to expand the path list or select **Browse**. Selecting the red reverse arrow resets the source location to the default setting.
3. Once the desired Source location is showing, you can select import options.

Include subfolders check box

Check if you want to import images in all subfolders of the source location. If not checked, you will import only the files found in the source location folder itself, and no images in its subfolders. If you want files from a specific (patient) subfolder only, select that subfolder as the Source location.

Delete source files and subfolders after import check box

To manage the size of the export destination, select this check box to delete the source files and subfolders after import is complete.

Note: Do not check if you or others want to import the same data to another RetCam station, which would be the case especially if you are importing from the backup repository.

Note: This does not affect any working RetCam database, but only the intermediate location where files are exported to and imported from.

4. Click **Import** to initiate importing, or **Cancel**. A dialog opens to show import progress.
5. A **Select Import Data to save** dialog will appear. If not all items were imported, you may select **Show Detailed Log** for the explanation. It could be because some files are duplicates (already in the destination database), or the file is not found, or it is corrupt, or the destination is write-protected.

View imported data and select thumbnails you need to save. Select **Import Selection**. You can also select **Import All** to save all images.

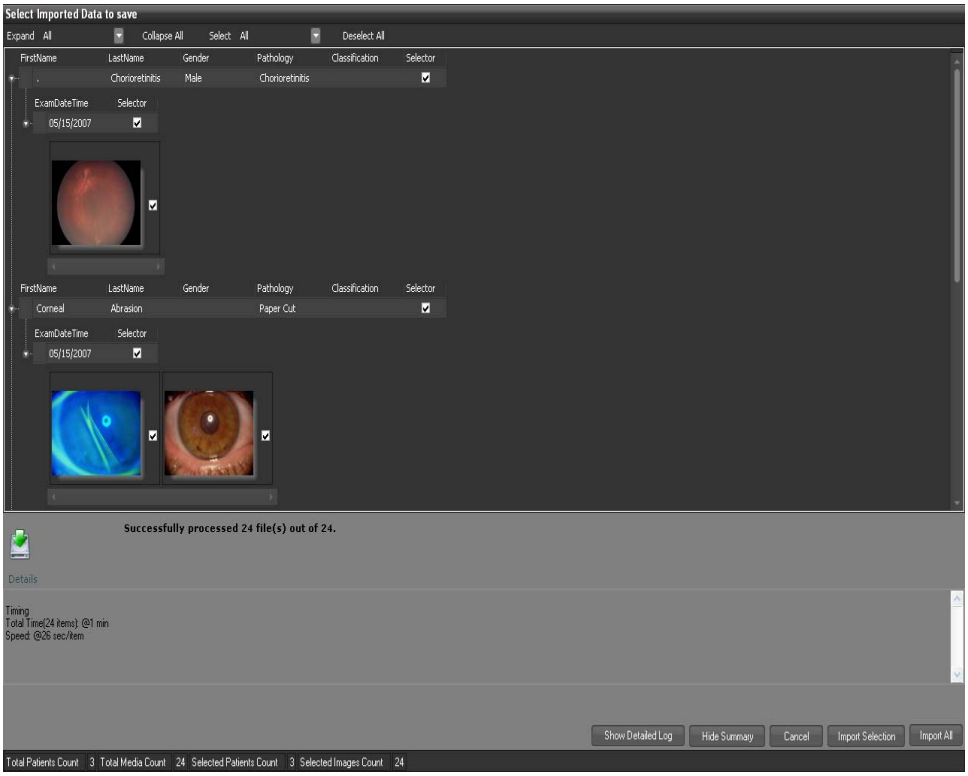

Figure 36 Import successful

The system will notify you when the import is completed successfully.

5 Printing Images

The **Print** button appears at the lower right of screens when printing is available.

Note: Print is only available if there is a printer attached to the system, either directly or through the network, if so connected.

WARNING: Never connect the RetCam3 to a network or any externally powered devices or peripherals *during imaging*.

You can **Print Images** from the:

- **Image Review Screen**
- **Compare Screen**
- **Patient list (or Patients and Exams screen):** Print images, reports, or both

The default image size is 5" x 7." For optimal resolution, Clarity recommends printing images 5" x 7" or smaller. This also avoids the rapid depletion of printer ink.

Printing Images and Reports

You can print both images and reports from the patient list (or Patients and Exams screen):

1. Select (or highlight) patient.
2. Check the desired session, patient, or image.
3. Select **Print**.

The following dialog appears:

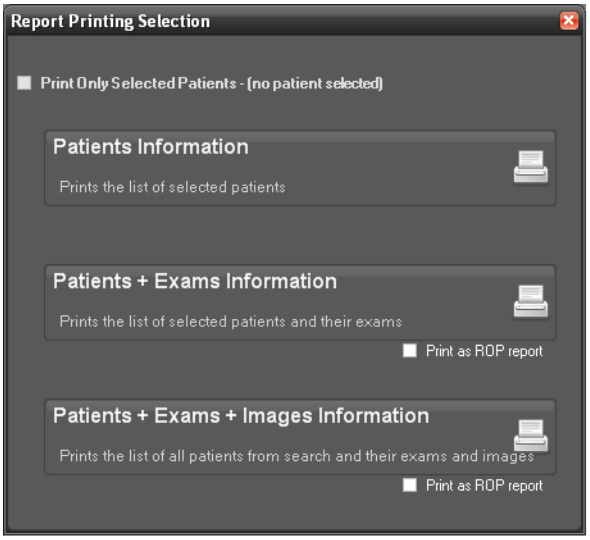

Figure 37 Print dialog

Select the desired option(s).

+ **Reports are formatted to fit on US letter size or A4 paper.**

Recommended Supplies

Clarity sells printer supplies - photo paper and ink - for the printer supplied with the system.

+ **Note: Network printers used with the system must have a printer driver supported by Windows XP.**

+ **Note: Be aware that you must change the paper in the printer when switching between printing images and reports.**

See the User Preferences section for information on setting printer defaults.

6 Fluorescein Angiography Module

This chapter covers acquisition of still or video images using the fluorescein angiography (FA module) option. These functions are provided through the Image Capture screen.

Theory of Operation

A narrow-band blue excitation light centered at approximately 470 nanometers is generated from the FA module. The barrier filter inserted in the handpiece has a cutoff wavelength at 510 nanometers or shorter. Fluorescein dye absorbs the blue light and emits green light longer than 510 nanometers, so the RetCam3 camera can image the green fluorescence without being overwhelmed by the blue excitation light.

Using Fluorescein Angiography (FA) Module

Note: The internal backup battery never powers the FA module. Therefore, the system must be plugged into wall power to operate the FA module.

1. Switch ON FA module power. The FA lamp requires a few minutes to stabilize.

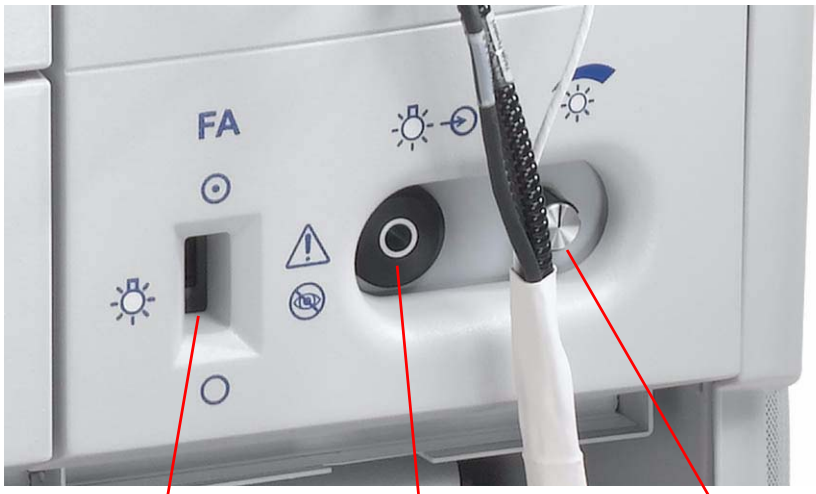

Figure 38 Front panel of FA Module

2. Carefully install the barrier filter into the handpiece:
   A. Remove the lens piece (if present).
   B. Insert the barrier filter into the cavity of the handpiece, observing the orientation as shown in Figure 39.
   C. Reattach the lens piece before moving the handpiece.

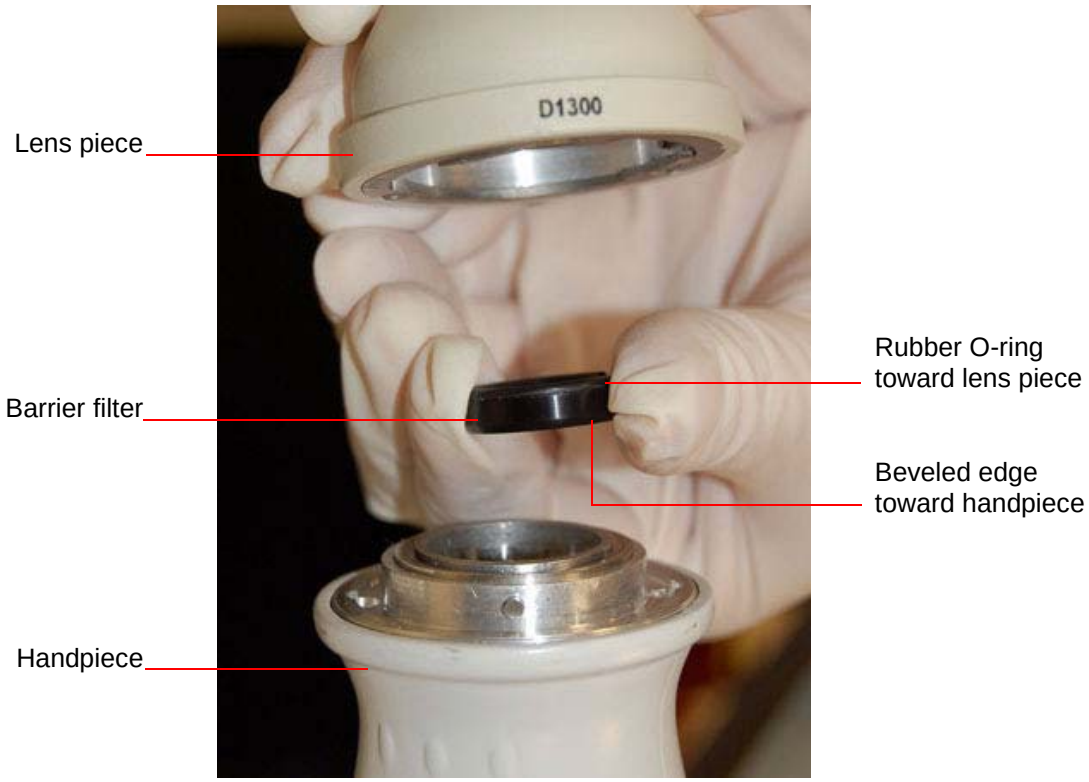

Figure 39 Barrier filter installation

Note: If lenses are exchanged during an FA imaging session, hold the camera upright to avoid having the barrier filter fall out during the exchange.

3. Select Switch to FA and SNAP a “red-free” image (recommended).
4. Attach the fiber optic lamp connector from the handpiece into the FA module fiber optic port. (See Figure 38.)
5. Select Start Timer. Dye can now be injected.

Note: The timer can be paused or stopped at any time.

6. Adjust FA light intensity using the FA light intensity knob shown in Figure 38.

Note: You cannot adjust the FA light intensity using the footswitch or control panel controls.

7. You can take still photos or video during the FA imaging session, and you can SNAP still photos during video replay.
8. When the FA imaging session is completed:
   A. Pause or Reset the timer.

.

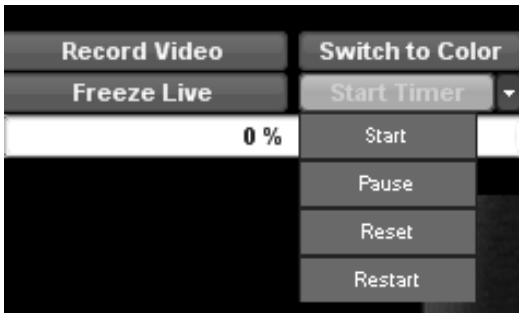

Figure 40 FA timer controls

The drop-down menu offers the following timer options:

- Start—Start the timer.
- Pause—Pause video capture, but keep the timer running.
- Restart—Restart the timer, following a stop or reset.
- Reset—Set the timer to zero again.

B. Move the fiber optic cable back to the white light port and switch OFF the FA module power.

C. Remove and store the barrier filter in the special clear plastic box provided, or in a manner that prevents damage. Clean the filter with compressed air and optical cleaner and tissue as required.

When the Image Type selected is Fluorescein, the video and images are displayed and stored in grayscale by default.

To view and store FA images and videos in color, select Fluorescein as the Image Type instead of using the Switch to FA button.

WARNING: To mitigate the potential for excess light exposure, always start at the lowest light intensity level and increase if necessary. Use only the shortest amount of light necessary; no greater than 5 minutes.

WARNING: Do not look directly at the fiber optic port.

WARNING: If the light from the illumination source is not blue DO NOT USE IT because there may be a filter failure.

WARNING: Do not attempt to override the interlock switches, or to operate in FA mode with the cover off. The FA module contains internal sources of high voltage, high current, heat, and moving parts. Only authorized technicians may attempt any service or repairs to the FA module. Failure to observe this warning could result in injury to operator or patient.

Configuring the FA Module Timer

To configure the FA timer, click **Configure** at the top left of the screen.

You can configure the following:

- Capture video and images in color or greyscale
- Set the frame rate
- Frame number
- Elapsed time
- Timer position
- Timer display (Frame numbers, etc.)

Note: You can use the timer when you are not in FA mode.

Tip: You can move the timer display to any location on the image capture window.

Tip: You can use the timer when you are not in FA mode.

Using Video Controls in FA Mode

When you are in FA mode, the timer is controlled separately from the video. For example, when you pause or stop the video, video capture is interrupted, but the timer continues uninterrupted.

When you pause video capture, the video images acquired up to that point are not yet saved to the hard drive.

Images are saved automatically to the hard drive when you stop video capture. The video display shows the percentage of the available 2GB hard drive space already used.

7 Maintenance and Support

This section addresses maintenance and support under the following topics:

- Recommended Maintenance Schedule, below
- Cleaning Procedures, below
- Fuse Replacement, page 59
- Replace Illumination Lamp/Bulb, page 61
- Key Validation, page 65
- Technical Support, page 66
- Service Information, page 67

Recommended Maintenance Schedule

Between patients: Clean and inspect lens piece.

Weekly: Wipe down the system.

Monthly: Inspect cables and connections for wear.

> System powered for at least 8 hours (AC powered - AC/DC indicator ON light solid) to assure backup battery is fully charged.

Burned out bulb: Replace illumination bulb.

Blown fuse: Replace system fuses.

Cleaning Procedures

For cleaning purposes, the RetCam3 is divided into two categories:

- The Lens Piece that contacts the patient
- The rest of the system

Cleaning the Lens Piece

The patient contact area lens should be cleaned immediately after use to prevent the coupling gel from hardening.

1. Wipe away debris from the front lens piece surface with a soft dry tissue, sterile water soaked tissue, or combination.
2. Then, using a clean soft cloth (such as sterile gauze) saturated in a fresh solution of 70% IPA (isopropyl alcohol), gently wipe the front of the lens piece, being sure to pay special attention to the concave contact lens area, to remove any remaining debris. Use at least 11 wipes with a clean saturated cloth.
3. Rinse surface thoroughly using sterile water.
4. Air dry.

5. Verify that the lens surface is free of debris and coupling gel. Repeat above steps if necessary.
6. Inspect the lens for damage and clarity. Do not use the lens if there are chips, cracks, or rough edges on the lens which may injure the patient's eye.

CAUTION: Do not autoclave any part of the system. Autoclaving causes irreparable damage and voids the warranty.

CAUTION: Never immerse the entire lens piece or handpiece in any liquid or solution. If necessary, only the distal 4 mm can be immersed. See Figure 41. It is important not to immerse the joint where the polished metal tip meets the painted housing, since it is susceptible to corrosion.

WARNING: If you clean or disinfect, rinse the lens with sterile water to avoid corneal de-epithelialization that may be caused by residual solution.

Note: For disinfection, the American Academy of Ophthalmology recommends 1:10 dilution of bleach soak for 5 minutes.

CAUTION: As disinfection solutions may cause corrosion of the lens piece, soak times that exceed the recommendation should be avoided.

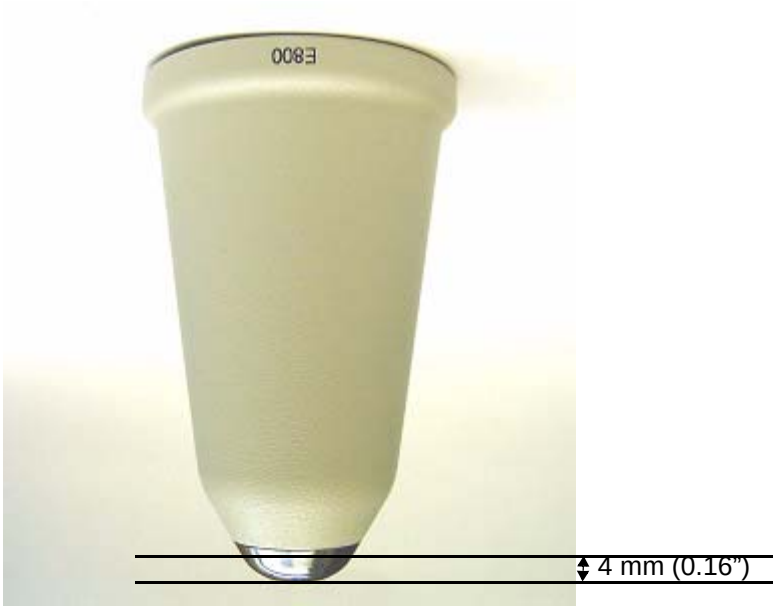

Figure 41 Inverted lens piece showing permissible depth of immersion

Cleaning the Rest of the System

As with any medical device, use good public health practices when handling the equipment, based on CDC guidelines. In addition, as with typical office equipment, a gentle wiping with a cloth moistened with mild soap and/or water is recommended. Do not spray cleaning solutions on any part of the system.

Disposal of Materials

Dispose of waste materials according to local and national requirements. Contact Clarity Service if additional assistance is required.

Fuse Replacement

Locate the power entry module on the lower right side of the rear of the cart. Make sure to remove the power cord before proceeding any further. (See Figure 42.)

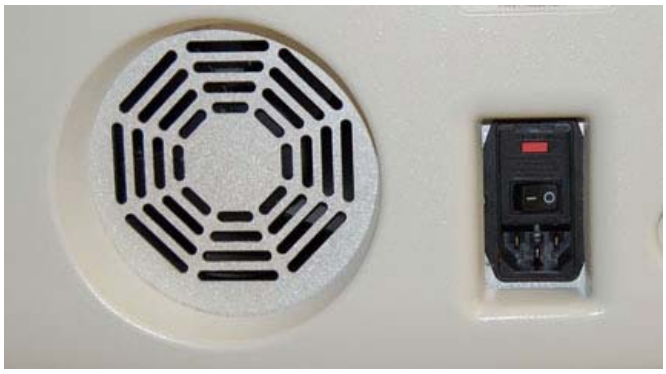

Figure 42 Power Entry Module

Using a flat blade screwdriver, gently pry open the cover of the fuse holder at the top of the power entry module. (See Figure 43.)

Figure 43 Opening the fuse holder cover

Remove the fuse holder. (See Figure 44.)

Figure 44 Removing the fuse holder

Remove the blown fuse or fuses from the fuse holder and replace it with a new fuse of same type and rating. (See Figure 45.) Re-insert the fuse holder.

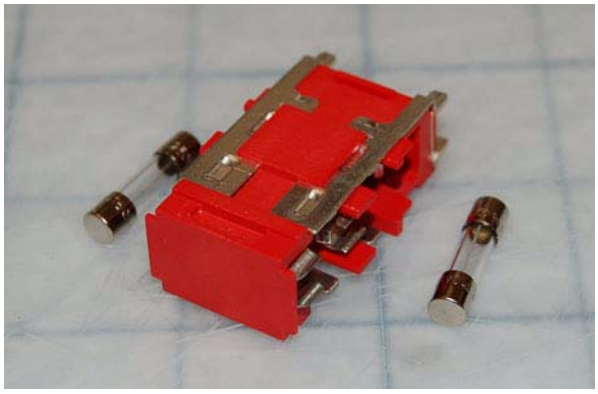

Figure 45 Fuses removed

CAUTION: For continued protection against risk of fire, replace only with same type and rating fuse.

Replacement fuses are available from Clarity Customer Service.

.

Figure 46 Fuse holder re-inserted

Replace Illumination Lamp/Bulb

WARNING: Appropriately power down and unplug the unit to allow the bulb to cool before replacing it.

Replacement bulbs are available from Clarity.

Follow these steps to replace the bulb:

1. If not already OFF, turn OFF the main power.
2. Disconnect the power cord from the wall.
3. Unplug the fiber optic cable from the front panel.

4. Remove the two screws from the lamp assembly drawer.

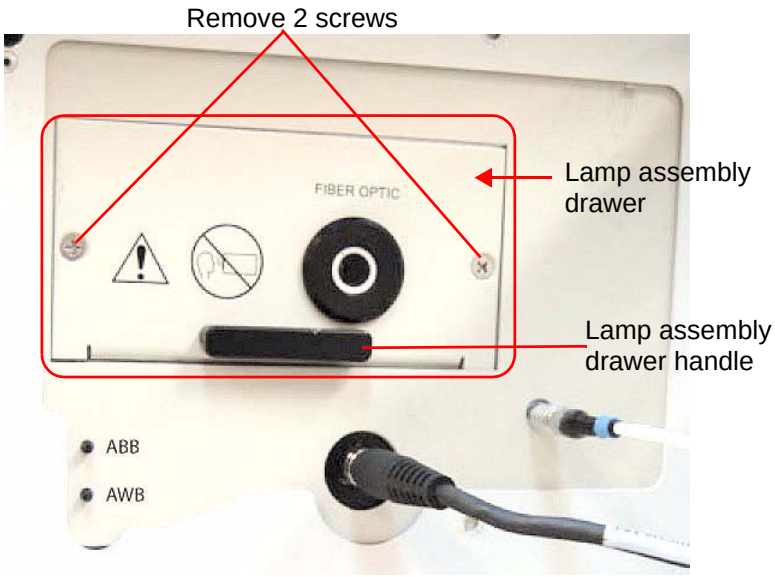

Figure 47 Front panel showing the lamp assembly drawer

5. Grip the handle on the lamp assembly drawer. Pull the drawer out slowly. Stop when the light bulb is fully exposed.

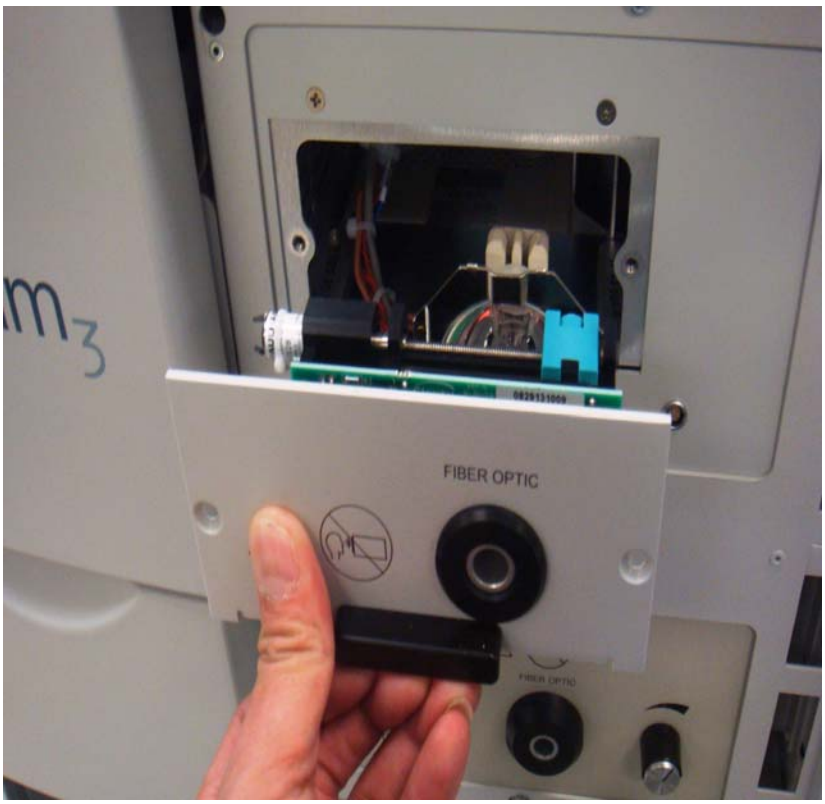

Figure 48 Open the drawer

6. Push the lamp ejector as shown.

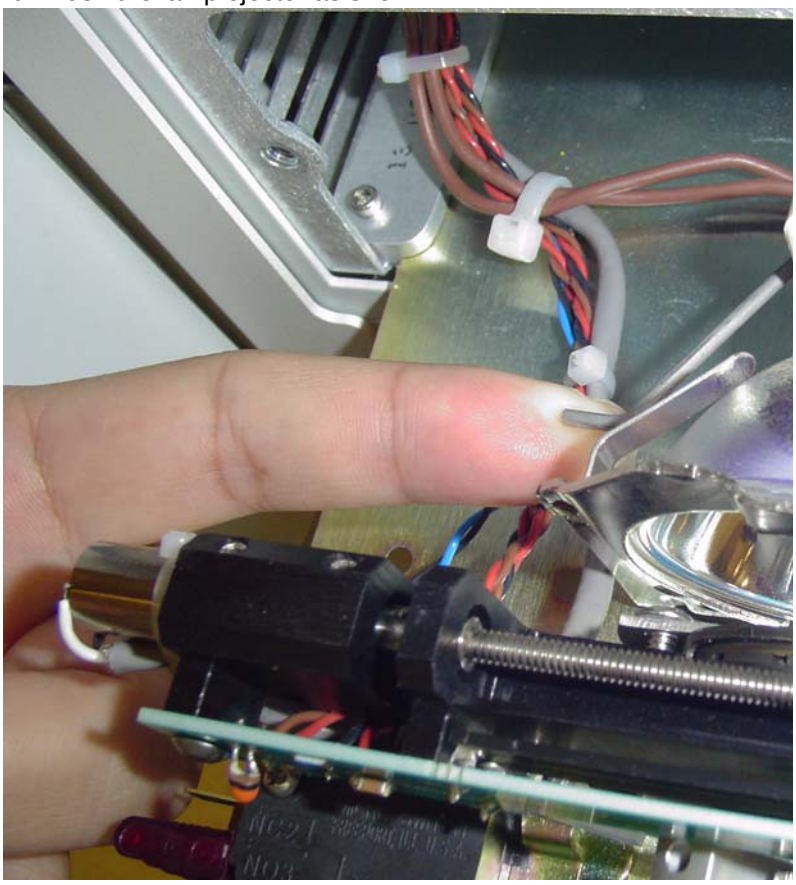

Figure 49 Removing the bulb

7. Carefully slide the bulb out of the socket slots.
8. Pick up the bulb.

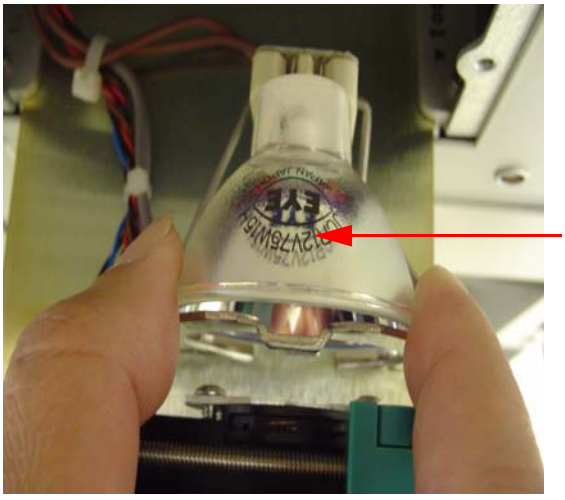

Figure 50 Catch the bulb

9. Holding the new bulb only on the outside, align the two pins of the bulb with the two slots in the socket. Push it all the way in.

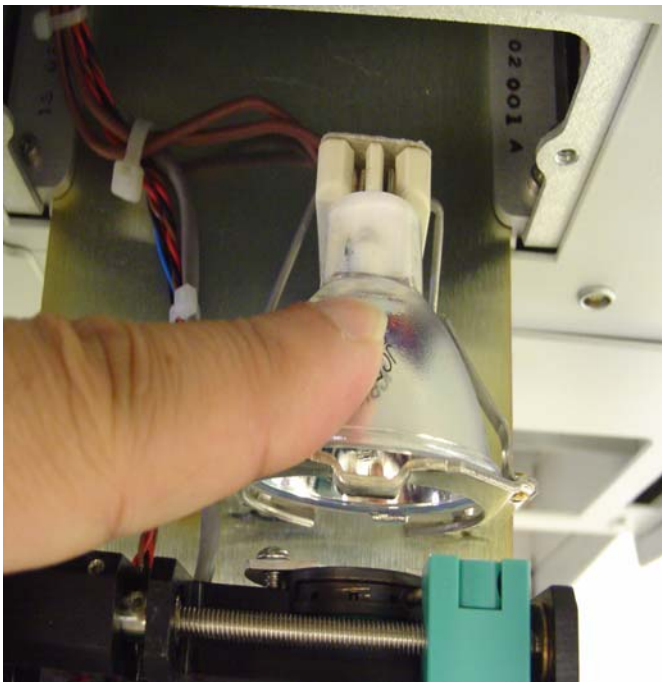

Figure 51 Place new bulb in socket

10. Carefully push the lamp assembly drawer back. Use caution to avoid pinching wires in the area.
11. Replace the two screws on the lamp assembly drawer and replace the fiber optic cable.

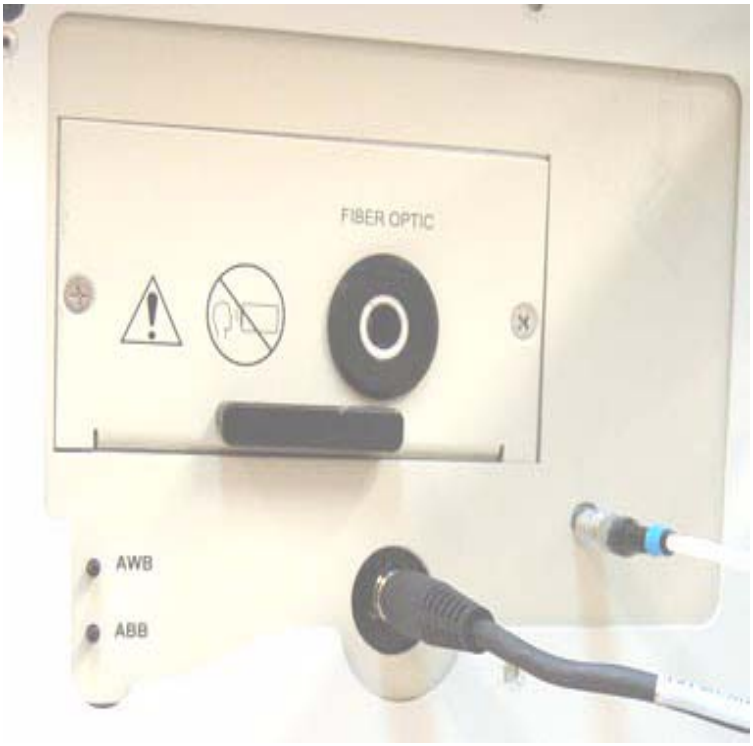

Figure 52 Close drawer and replace connections

CAUTION: Only touch the exterior surface of the illumination lamp. Do not touch the bulb, which is located in the center of the reflector, nor the inner (concave) surface of the reflector. Skin oils will adhere to the bulb and reflector, which reduces the cooling efficiency of the bulb and thereby creates a hot-spot leading to premature burnout. Handle by the outside of the lamp only, as shown.

Key Validation

Note: New RetCam3 systems ship with their license key already registered and validated. However, significant changes to the system hardware or a re-load of the system software for any reason (including software upgrade) may require you to perform the key validation process as described below. Key validation requires that you get a license key from Clarity to use the revamped system, and you cannot request this key until after installation is complete. Since it may take up to two (2) business days to obtain a license key after submitting a request, we recommend that you effect system or software upgrades when you can manage two business days without use of the system.

Note: To ensure the preservation of your patient data and images, we strongly recommend that you perform a complete backup of the system's images before you begin any software installation.

When key validation is necessary, the Key Validation dialog appears when you start the system (and each time thereafter until you complete this step), before the Site Awareness dialog.

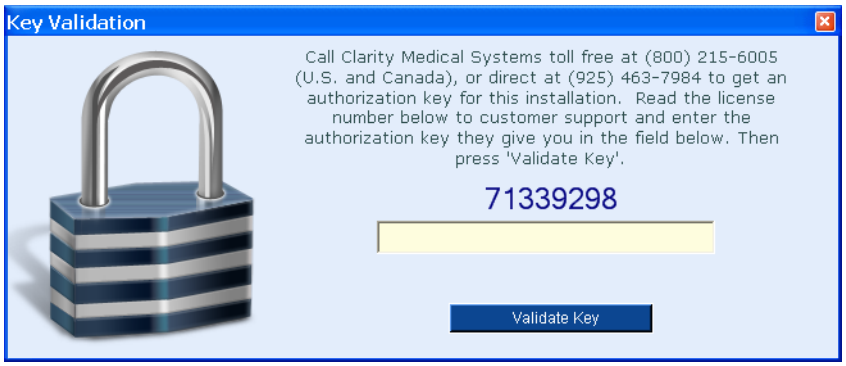

Figure 53 Key Validation dialog

Follow the instructions on screen: Call Clarity and provide to the customer support representative the large license number in the dialog (71339298 in the example above), which is unique for your system. You will be provided in turn a unique authorization key.

Tip: You may also send the license number via email to **service@retcam.com** and receive the authorization key by return email.

You must enter the authorization key in the field and click **Validate Key** to access the system software. If you call, to make sure you enter the number correctly, we recommend you do not hang up until the number is accepted.

Technical Support

Technical Support Contact Information

Customers outside the US, please contact your distributor for technical support.

In the US, you have the following options:

Telephone

Toll-free: (800) 215-6005

Fax: (925) 251-0078

Telephone support is typically available between the hours of 9am and 5pm Pacific Time.

After hours: Please leave a message as the messages are checked during the evening hours.

Send correspondence to:

Clarity Medical Systems, Inc.

5775 West Las Positas Blvd.

Pleasanton, CA 94588

USA

Email

service@retcam.com

Our US technical support staff will respond to your questions as soon as a staff member is available. In most cases, you should receive an answer within 48 hours. Complex questions that require testing or special research may take longer.

Note: Questions about products no longer under warranty and questions other than to explain ordinary use of the product may incur service charges. Please ask for an hourly quotation before incurring charges.

Service Information

Service information is available separately in the RetCam3 Service Manual.

RetCam3 components are typically return-to-factory components and can be repaired by only Clarity personnel and/or our qualified distributors. The Service Manual contains information on user-replaceable parts and/or instructions to remove components for return for factory repair.

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8 User Preferences

The section describes the User Preferences available, including:

- System Identification/Institution
- Setting Pre-configuration Imaging defaults for New Exams
- Changing Date/Time
- Changing Speaker Volume
- Setting Printer defaults
- Setting Network connections

Select the cog icon in the lower right hand corner to access the User Preferences.

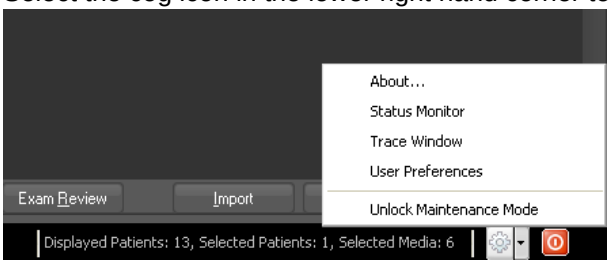

Figure 54 Access User Preferences

Click **About** to identify the RetCam software version. Click **OK** to exit.

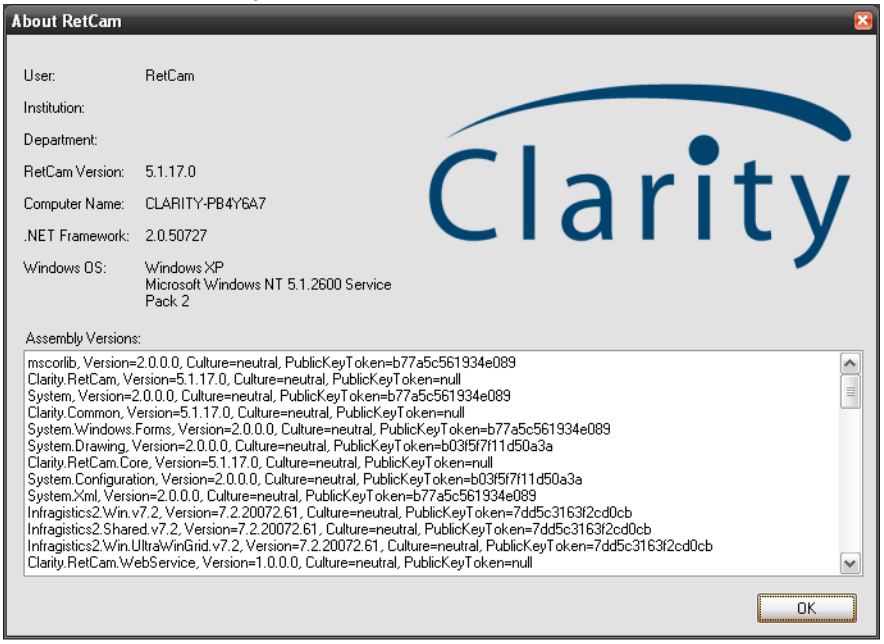

Figure 55 About Clarity software

Select **User Preferences**.

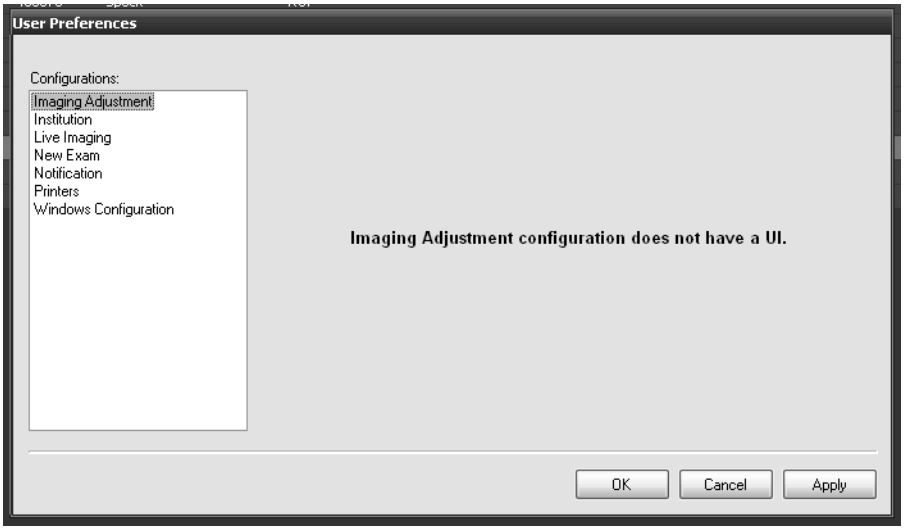

Figure 56 User Preferences screen

Select from the following options:

Imaging Adjustment	Not available
Institution	Add the name of the Institution, Department and Location.
Live Imaging	Not applicable
New Exam	Set the Pre-set Imaging Configurations for new exams.
Notification	Not applicable
Printers	Set the Default Image and Report Printer.
Windows Configuration	Set Date and Time, Display, Network Connections, Printers and Faxes, Region and Language, Security Center and Sound.

Institution

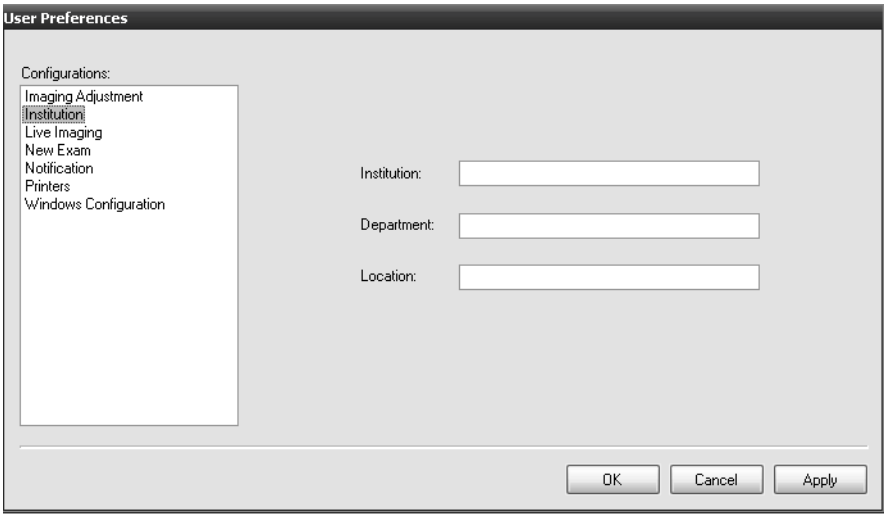

Figure 57 User Preferences: Institution

New Exam

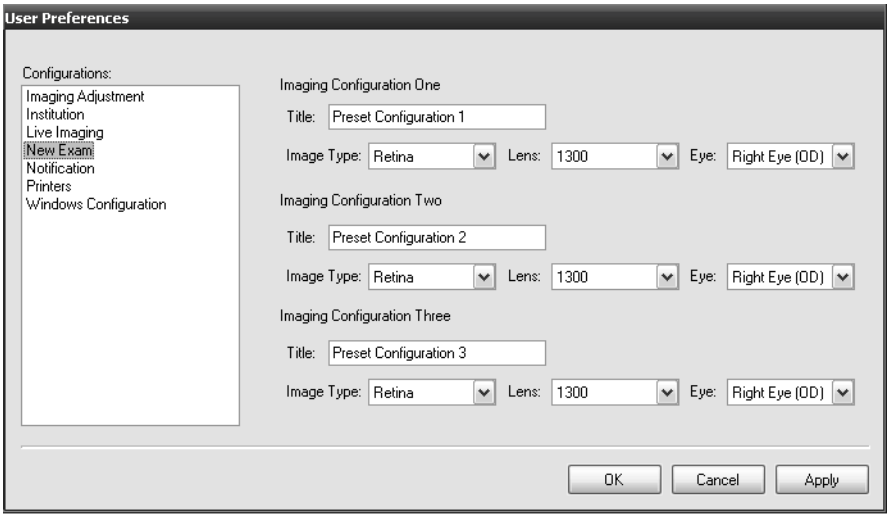

Figure 58 User Preferences: New Exam

Once the New Exam preset configurations are adjusted, click **Apply** to initiate the change or **Cancel**. Click **OK** to exit the screen.

Printers

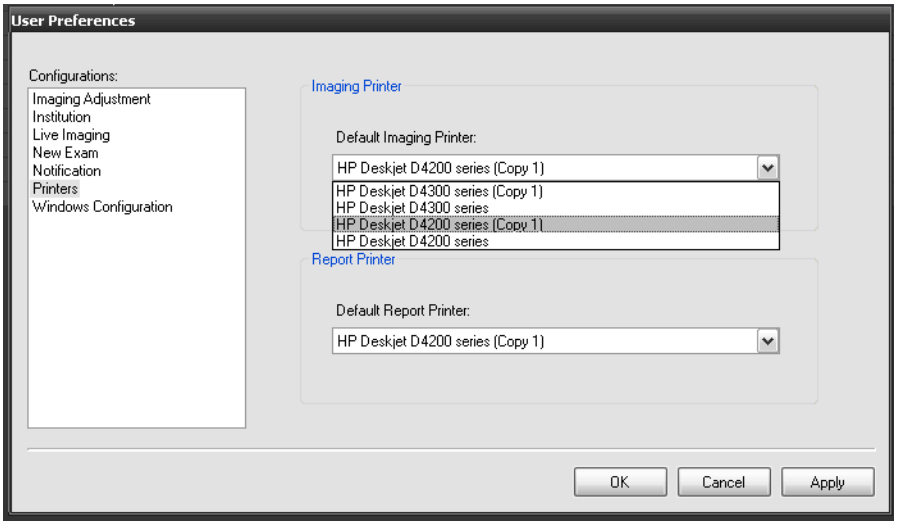

Figure 59 User Preferences: Printers

Select the default printers, then click **Apply** to initiate the change or **Cancel**. Click **OK** to exit the screen.

Windows Configuration

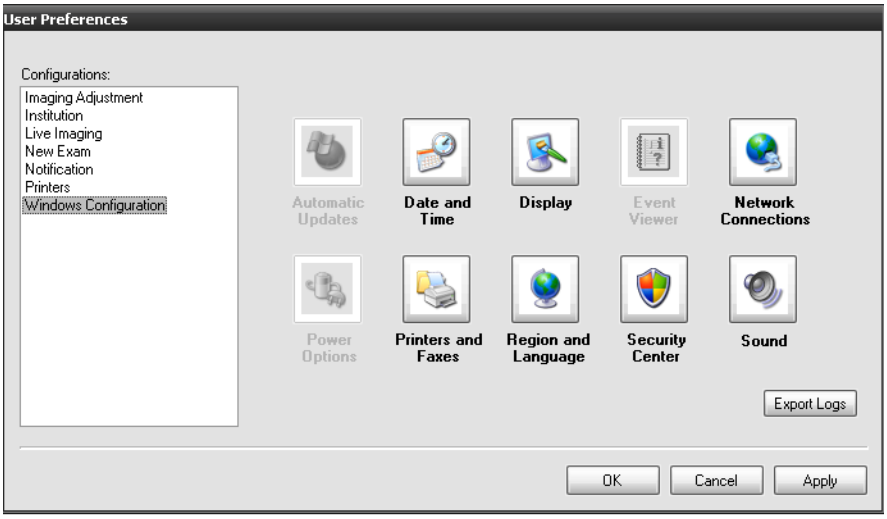

Figure 60 User Preferences: Windows Configuration

Select the desired Windows configuration icon and make changes where needed. Click **Apply** to initiate changes or **Cancel**. Click **OK** to exit the screen.

9 Technical Specifications

Hardware

Physical

- 26”(660 mm) wide x 24”(610 mm) deep x 54”(1372 mm) minimum height
- Approximately 200 lbs. (91 Kg) fully loaded

Electrical

- Ratings: 100-240 V~, 50/60 Hz, 700 VA
- Fuses: 3AG 10A 250V slo-blo 5 x 20 mm
- Power consumption: 700W with all options
- Detachable hospital grade power cord

Environmental Conditions

The system as delivered is intended for use indoors, at normal room temperatures and humidity, upright, on a level surface, with the brakes applied to the front casters.

Condition	Operating	Storage and Transport
Temperature	50º to 95º F (10º to 35º C)	-20º to 122º F (-29º to 50º C)
Relative Humidity	30% to 90% non-condensing	10% to 85% non-condensing
Atmospheric Pressure	20.7 to 31.3 inches Hg (70 to 106 kPa)	14.7 to 31.3 inches Hg (50 to 106 kPa)
Altitude	-1255 to 9882 feet (-382 to 3012 meters)	-1255 to 18288 feet (-382 to 5574 meters)

Note: Specifications subject to change without notice.

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