natus®

RetCam envision™

User Manual

Publisher's Notice

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RetCam Envision™ User Manual
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To request a hard copy of the RetCam Envision User Manual, contact Natus Technical Support via phone or email, or contact your local representative. Natus Technical Support is available 24 hours a day, 7 days a week. See "Technical Support".

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1. Introduction

The RetCam Envision™ ophthalmic imaging system enables quick, easy capture of wide-field, high-resolution digital images and videos of the eye. This manual describes how to use the system to record, annotate, store, review, and transfer such images, along with related patient data, in a secure healthcare network environment.

Indications for Use

- General ophthalmic imaging including retinal, corneal, and external imaging.
- Photodocumentation of pediatric ocular diseases, including retinopathy of prematurity (ROP).
- Screening for Type 2 pre-threshold retinopathy of prematurity (ROP) (zone 1, stage 1 or 2, without plus disease, or zone 2, stage 3, without plus disease), or treatment-requiring ROP, defined as Type 1 ROP (zone 1, any stage, with plus disease; zone 1, stage 3 without plus disease; or zone 2, stage 2 or 3, with plus disease), or threshold ROP (at least 5 contiguous or 8 non-contiguous clock hours of stage 3 in zone 1 or 2, with plus disease) * in 35-37 week postmenstrual infants.

*References:

1. Cryotherapy for Retinopathy of Prematurity Cooperative Group. Multicenter trial of cryotherapy for retinopathy of prematurity: preliminary results. Archives of Ophthalmology 1988; 106(4):471-479.

2. Early Treatment for Retinopathy of Prematurity Cooperative Group. Revised indications for the treatment of retinopathy of prematurity: results of the Early Treatment for Retinopathy of Prematurity Randomized Trial. Archives of Ophthalmology 2003; 121(12):1684-1694.

Article Clinical Reference

Telemedical Retinopathy of Prematurity Diagnosis, Accuracy, Reliability, and Image Quality. Michael F. Chiang, MD; Lu Wang, MD, MS; Mihai Busuioc, OD, MD; et al. Arch Ophthalmol. 2007;125(11):1531-1538:

https://jamanetwork.com/journals/jamaophthalmology/fullarticle/419992

Contraindications

Any patient with a perforating injury to the globe must not be imaged with the RetCam Envision system using a contact technique until the wound is repaired. In the case of an eye infection, use of the RetCam Envision system must be delayed until treatment for the infection has been rendered. Any infant determined to be unstable by a neonatologist is not a candidate for imaging with the RetCam Envision system.

Qualified Use

Federal law (US) restricts this device to sale by or on the order of a physician or licensed medical practitioner. RetCam Envision is intended for use by individuals knowledgeable and skilled in the use of ophthalmology devices, including physicians, nurses, ophthalmic photographers, and ophthalmic technicians. Those individuals must be trained in proper clinical technique by personnel authorized by Natus Medical Incorporated before they use the equipment to acquire images of patient eyes.

The primary environments for use of the systems are clinics, doctors' offices, neonatal intensive care units, operating rooms, pediatric intensive care units, and research facilities. Only authorized Natus Medical Incorporated personnel install and service RetCam Envision systems, except for service that can be accomplished directly by the customer.

Essential Performance

- The system performs live video imaging.
- The system displays images free from consistent artifacts.
- Temporary disruption of the imaging function or temporary visibility of image artifacts has been assessed and determined not to affect patient safety.

Access Control and User Authorization

User accounts are assigned roles, which determine the degree of access and the tasks that can be performed on your RetCam Envision system. The RetCam Administrator role is assigned to a user by the patient-care or research facility. The RetCam Administrator has the highest level of access and controls who has permission to use the system. For information on configuring user permissions, see “User Roles and Permissions”.

Warnings and Precautions

This section provides information on safety warnings and precautions. It is important to read and understand this safety information before using the system.

Safety Conventions

WARNING

Indicates a hazardous situation which, if not avoided, could result in death or serious injury. WARNING consists of the following information:

The nature of the hazard, and the consequences of not avoiding the hazardous situation.

- Methods of avoiding a hazardous situation.

CAUTION

Indicates a hazardous situation which, if not avoided, could result in minor injury, material damage, or delay in use. CAUTION consists of the following information:

The nature of the hazard, and the consequences of not avoiding the hazardous situation.

- Methods of avoiding a hazardous situation.

Warning Statements

WARNING

Cross-contamination of microorganisms can lead to the spread of infections to the patient, particularly with vulnerable infants in the Neonatal Intensive Care Unit (NICU).

- To reduce the risk of cross-contamination:

  Follow hand washing procedures, and wear gloves.

  Disinfect the lens piece before each patient following, at a minimum, the Intermediate-Level Chemical Disinfection instructions.

WARNING

Use by unqualified personnel may lead to injury or delay in patient treatment.

- RetCam devices are intended for use by individuals knowledgeable and skilled in the use of ophthalmology devices including physicians, nurses, ophthalmic photographers, and ophthalmic technicians.

WARNING

Use by untrained personnel may lead to injury or delay in patient treatment.

- Before using this equipment to acquire images of patient eyes, users must be trained in proper clinical technique by personnel authorized by Natus Medical Incorporated.

WARNING

Unauthorized modifications could lead to injury, unexpected system performance, or failure of the system.

- Do not modify this equipment without authorization of the manufacturer.

WARNING

Using a contaminated or damaged lens piece may cause patient eye injury.

- Never clean the front of the lens piece with abrasive or sharp materials. Clean, disinfect, and inspect the lens piece for nicks, breaks, scratches, or rough surfaces prior to each use.

WARNING

Performing service or maintenance on the system while in use with patient may cause electrical shock to the user.

- Do not perform service or maintenance on the system while in use with a patient.

WARNING

The light emitted from this instrument is potentially hazardous to the eye.

The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 199 minutes (White light), and 15.7 minutes (Blue light).

- Start imaging at the lowest light intensity level and increase as necessary, using the least light exposure necessary**.**

WARNING

Application of excessive pressure during imaging may cause eye injury.

- Support the handpiece to avoid direct pressure and unnecessary movement on the cornea.

WARNING

Use of insufficient or noncompatible coupling gel may cause eye injury.

- Always ensure the lens piece is immersed in the recommended coupling gel to avoid direct contact of the lens piece with the eye.

WARNING

Excessive force when using the speculum, sclera depressor or lens piece against the patient eye may cause patient eye injury.

- Do not roughly manipulate the speculum, a sclera depressor, or a lens piece against the patient eye.

WARNING

Inadequate protective earth ground may cause electrical shock.

- Always connect the system to a supply mains with protective earth ground.

WARNING

Looking at the illuminated light source may cause eye injury.

- Do not look directly at the illuminated light source.

WARNING

Use of unapproved power cord may cause electrical shock.

- Always use power cord supplied by the manufacturer, or with the specified service part number.

WARNING

Use of damaged electric cord or cables may cause electrical shock.

- Inspect cables and electrical cords for damage prior to each use.

WARNING

System emits electromagnetic radiation that may interfere with the functioning or performance of another nearby device(s).

- To reduce interference the following control measures may be taken:

  Reorient or relocate the receiving device.

  Increase the separation between the equipment.

  Connect the equipment to an outlet on a circuit different from that to which the other device is connected.

  Consult the manufacturer or field service technician for help.

WARNING

Replacement of fuses with non-compliant part may cause fire.

- Always replace fuses with the specified service part number.

WARNING

Using a lens piece that has cleaning solution residue on it may result in compromising the cornea.

- Wipe the lens piece in accordance with the cleaning instructions.

WARNING

Immersing the entire lens piece or handpiece in liquid may cause electrical shock or damage.

- Do not immerse the entire lens piece or handpiece in any liquid.

WARNING

Use of unapproved cables, accessories or transducers may cause electromagnetic interference leading to unexpected system performance or failure of other nearby devices.

- Do not perform any unauthorized modifications or service on the system.

WARNING

Exceeding the chemical disinfection soak times may damage the lens piece and lead to patient eye injury.

- Do not exceed the recommended soak times during disinfection.

WARNING

Improper storage of handpiece may cause damage.

- Always return the handpiece to the holster when not in use.

WARNING

Using a damaged lens piece may lead to patient eye injury.

- Do not drop or mishandle the handpiece and/or lens piece.

WARNING

Support failure of the cart when overweight may cause injury to the user and the patient.

- Do not place objects on the adjustable cart top that would add more than 10 kg (22 lbs) load.

Caution Statements

CAUTION

Improperly sized speculum used on neonates can cause patient discomfort.

- Ensure the lid speculum is appropriately sized for the neonate when imaging.

CAUTION

Electromagnetic interference may cause unexpected system performance or failure.

- Do not use portable RF communications equipment (including cables and external antennas) closer than the recommended separation distance specified in the RetCam Envision Electromagnetic Immunity Guidance.

CAUTION

Blocking of system vents may cause overheating of the system components leading to loss of function or damage.

- Do not block any system vents.

CAUTION

Battery backup failure may cause system shutdown and lead to loss of data.

- Service the battery when instructed by the system.

CAUTION

Operating with low battery charge may cause system shutdown and lead to loss of data.

- Do not start a new imaging session without AC power. If AC power fails, promptly complete the imaging session and save the media.

CAUTION

Autoclaving may cause irreparable system damage.

- Do not autoclave any part of the system.

CAUTION

Hard shutdown may cause data corruption and lead to delay in the diagnosis or treatment.

- Do not use the hard shutdown for system shutdown unless it is necessary.

CAUTION

Improper handling of the lens piece and handpiece while moving the system may cause damage.

- Store the lens piece in the system drawer and place the handpiece securely in the holster.

CAUTION

Improper handling of the fiber optic cable may cause damage.

- Do not wrap the fiber optic cable around the wrap post more than two (2) times.

CAUTION

Using, transporting or storing the system on steep slopes may lead to cart instability.

- Do not use, transport, or store on steep slopes.

CAUTION

Rough handling of the system may cause damage.

- Do not transport the system outdoors.

RetCam Envision System Components

The RetCam Envision system consists of modules mounted in a stable mobile cart. The cart is easy to set up, transport, and store.

Cart Components, Front View

Figure 1 shows the components of the cart, including the optional FA feature. For a description of each component, see the table below the figure.

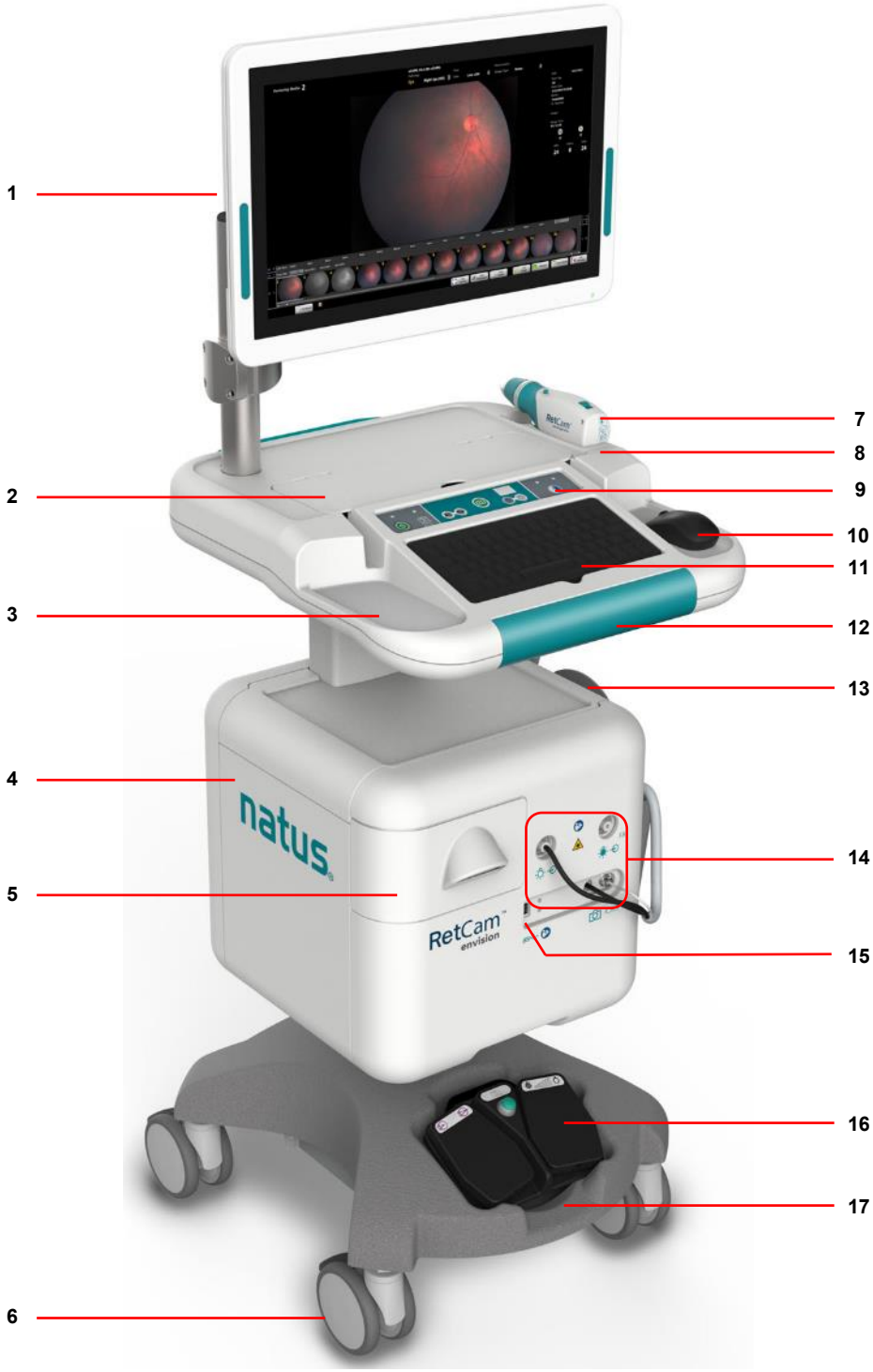


Figure 1. RetCam Envision System, Front View

NOTE: All illustrations in this user manual are representative and may be different from your actual setup.

1	Display monitor A high-resolution flat panel display monitor is standard. Teal-colored grips on both sides are provided for grasping the monitor while you adjust the height, angle, and vertical or horizontal orientation. The display screen is touch-sensitive. See “Monitor”.
2	Storage compartment (lens piece holder, lens piece storage box, mouse, and examination items)
3	Left-side mouse pad for left-hand use
4	Chassis. The chassis controls modular subsystems and connections: • The computer incorporates the system processor, which performs media acquisition, export, import, and storage. Additionally, it provides user data management. • The instrument control module directs camera I/O, including focus and illumination intensity. It also controls power for system functions. • The cybersecurity module protects the system from intrusions, malware, and unauthorized access to patient data.
5	Storage drawer (Quick Start Guide, lens piece storage box, service tool bag, and other items)
6	Four (4) wheels with locks facilitate tight maneuverability and positioning of the cart in confined spaces. To lock the wheels, press the lock tabs down with your foot. To unlock the wheels, pull the lock tabs up.
7	Handpiece/camera The handpiece contains the camera and the FA barrier filter. The long harness (shown in Figure 2) is flexible for convenient reach to patients. See “Handpiece”. Use the handpiece with the changeable lens pieces for patient imaging.
8	Handpiece holster
9	Control panel (see “Control Panel”).
10	Mouse and right-side mouse pad for right-hand use
11	Keyboard with backlighting for use in low-light environments
12	Teal-colored grip area for maneuvering the cart
13	Handpiece harness wrap post
14	Handpiece connections • White light and blue light (FA) LED modules • Camera controls See “Handpiece Connections”.
15	USB port (SuperSpeed USB)
16	Footswitch (see “Footswitch”).
17	Footswitch storage pocket

Cart Components, Rear View

Figure 2 shows the components on the rear of the cart. For a description of each component, see the table below the figure.

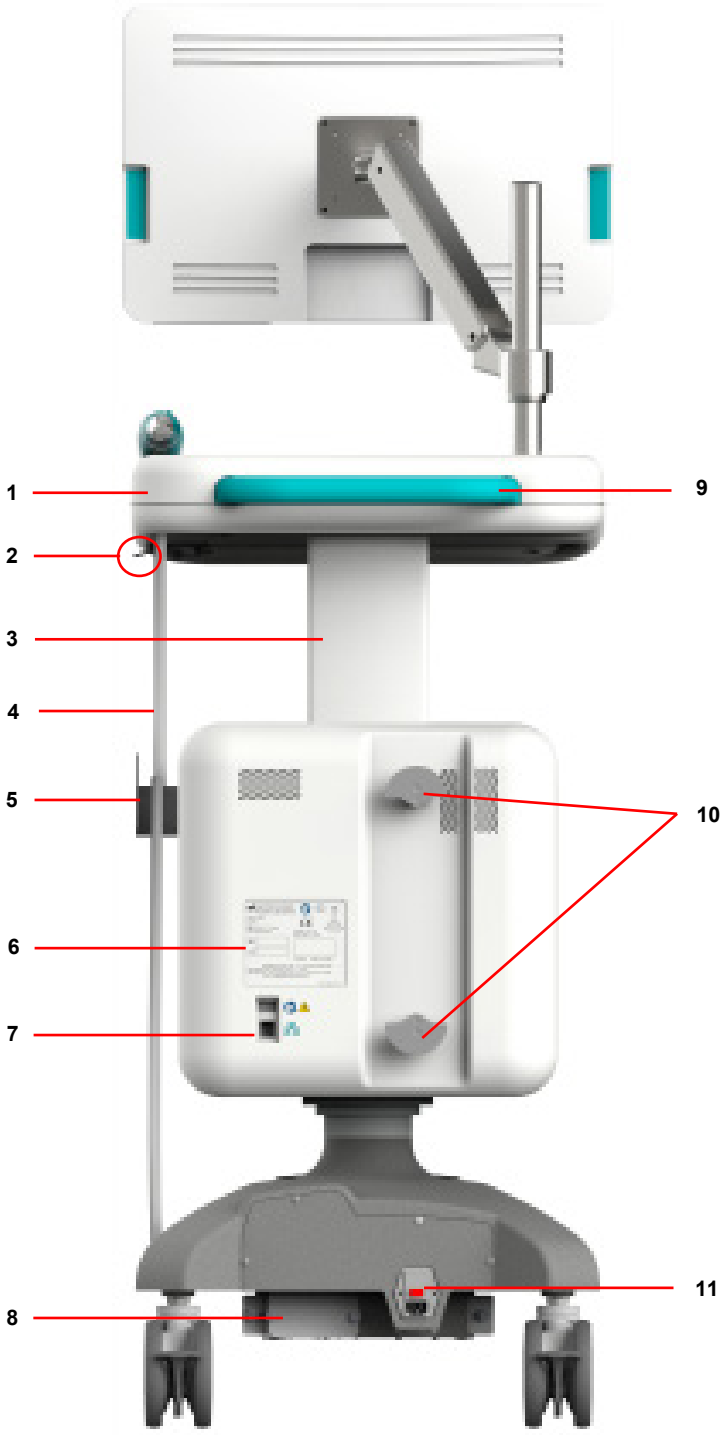


Figure 2. RetCam Envision System, Rear View

1	Adjustable cart top. The cart top can be raised and lowered as necessary for comfortable use.

2	Cart top height adjustment lever. To adjust the cart top height, grasp both sides of the cart top, squeeze the lever, and then slide the cart top up or down as necessary. Release the lever to lock the cart top in place.
3	Cart top support column
4	Handpiece harness (see “Handpiece”)
5	Handpiece harness wrap post (see “Handpiece”)
6	Device label (see “Labels and Symbols”)
7	Ethernet port
8	Battery compartment. Two (2) Lithium Ion batteries provide power when the AC supply is interrupted. **NOTE**: If the battery charge is very low (10% ±5%), a warning message appears and the system powers down. Batteries that are completely discharged must be charged for a minimum of five (5) hours.
9	Transport handle (see “System Transport”)
10	Power cord wrap posts
11	Main power switch and power cord connection. The power supply regulates AC and DC power to the system.

Monitor

The display screen is touch-sensitive (touch control must be enabled). To activate a UI control or screen feature, tap it with your gloved fingertip. Touch control can be disabled for screen cleaning.

NOTE: Some UI elements may be too small for touch control.

Figure 3 shows the monitor controls. The controls are active only when the monitor is on.

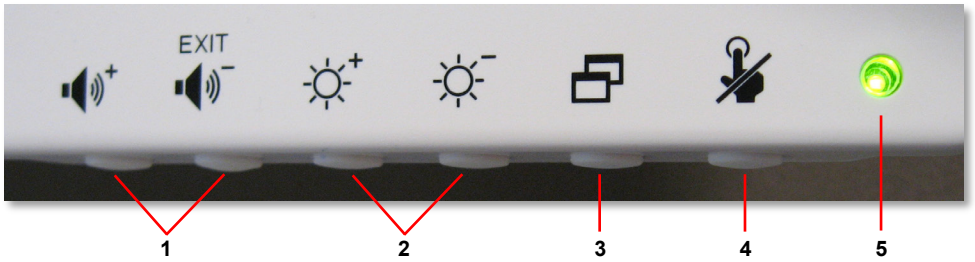


Figure 3. Monitor Controls

1	Turn on, increase volume, and decrease volume. The volume level is displayed on-screen while you make adjustments. **NOTE**: All audible tones come from the monitor. If you do not hear anything, the volume is off.
2	Increase brightness and decrease brightness. The brightness level is displayed on-screen while you make adjustments.
3	Display the on-screen Settings menu. Press EXIT (the Volume decrease button), and the menu disappears.
4	Disable and enable touch control (toggle). An on-screen message confirms your selection.
5	A green light indicates that the monitor is on. The light is off when the system is off.

Handpiece

The handpiece contains the camera and the FA barrier filter. Use the handpiece with the changeable lens pieces for patient imaging. See “Lens Pieces”.

Figure 4 shows the handpiece with the protective cap. The FA barrier filter switch is at the top of the handpiece.

Figure 4. Handpiece with Protective Cap

NOTE: Always return the handpiece to the holster when not in use. Wrap the handpiece harness in a loose coil around the wrap post. For proper handpiece placement in the holster, make sure the harness section closest to the handpiece rests against the back of the wrap post.

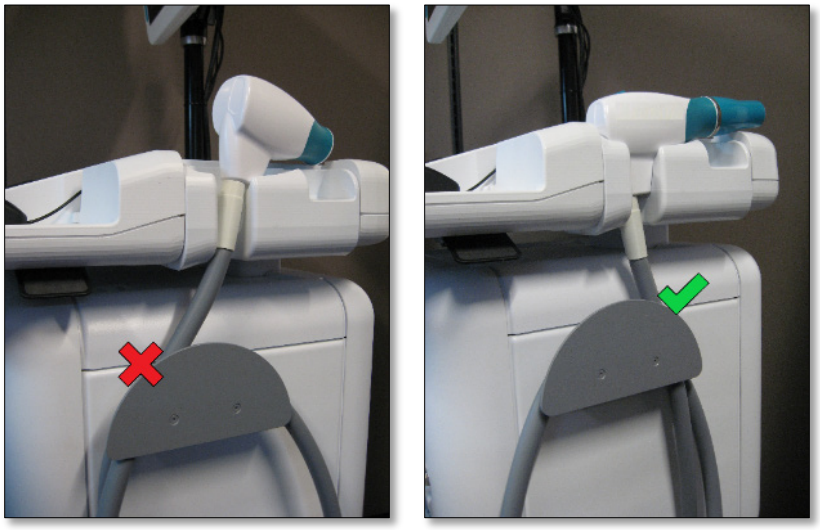


Figure 5. Handpiece and Harness Stowed Correctly

Handpiece Connections

NOTE: There are two (2) light ports in systems with the FA option.

The handpiece harness contains three (3) cables for illumination, camera, and focus control. Figure 6 shows the cables and connection ports.

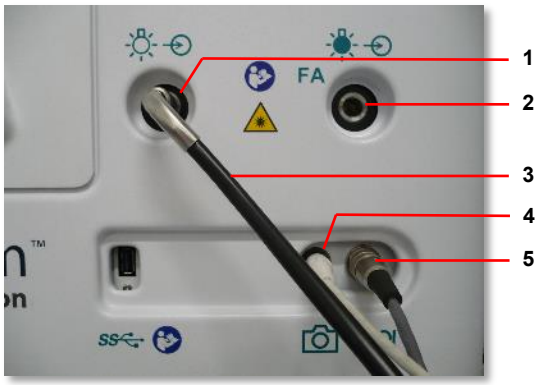


Figure 6. Handpiece Cable Connections

1	White light LED port (provides illumination for non-FA patient imaging)
2	FA (blue light) LED port (included only in systems with the FA option), which is a narrow-band blue light source that excites injected fluorescein dye in fundus vasculature. When excited by the blue light, the fluorescein emits green light. A barrier filter in the handpiece rejects the blue light reflected by the fundus such that the green emission is readily visible; this results in black and white images.
3	Fiber-optic cable
4	Camera cable (white) and port
5	Camera focus cable and port

NOTE: It is not necessary to remove any of the connectors for handpiece storage or system transportation.

To connect the fiber-optic cable (Figure 7), insert the plug into the appropriate LED port as far as it will go. When you remove the fiber-optic cable from the port, you will feel slight resistance; this is normal.

Figure 7. Illumination Ports and Fiber-optic Plug

Lens Pieces

NOTE: If you perceive that maximum light output is diminishing, contact Natus Technical Service. See “Technical Support”.

Following are the available lens pieces.

Lens Piece Model	Application	Common Field of View (FOV)
130 FOV (LP130)	Retinal imaging: Newborn, premature infant	130 degrees
Portrait (LPP01)	External eye and facial imaging	Not applicable

To attach a lens piece to the handpiece:

NOTE: When attaching and detaching a lens piece, work over a soft surface (if possible) to prevent damage in case the lens piece falls. At a minimum, ensure that you hold the handpiece close to you, and point it upward.

1. Hold the handpiece with one hand and the lens piece with the other hand, and align the tab (1) on the lens piece with the seam (2) along the top of the handpiece (Figure 8).

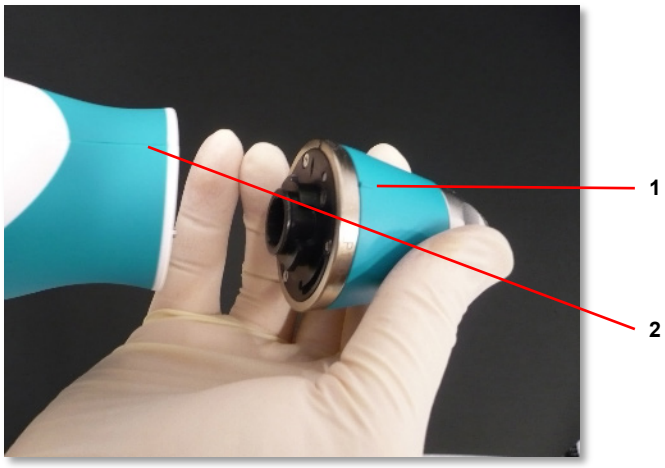


Figure 8. Lens Piece Alignment Tab and Handpiece Alignment Seam

2. Insert the lens piece into the handpiece, and turn the lens piece clockwise until you feel the detent engage. This indicates that the lens piece is securely locked in place. Verify that the tab and seam are in the indicated positions shown in Figure 9.

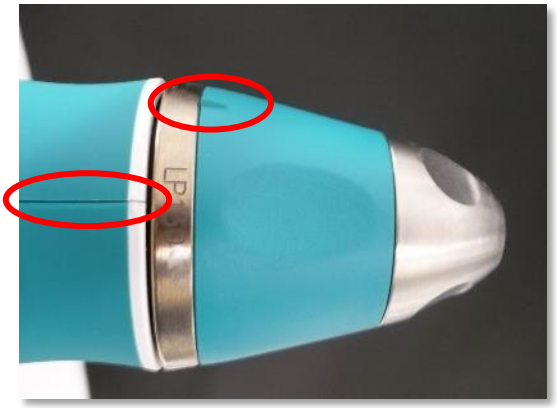


Figure 9. Lens Piece Locked

Lens Piece Holder

Use the lens piece holder to secure a lens piece when changing lens pieces during an exam. This prevents the lens piece from rolling off the cart or other surface.

Figure 10. Lens Piece Holder

Control Panel

The control panel (Figure 11) is located above the keyboard. The controls in the teal-colored center section are also available on the footswitch. See “Footswitch”.

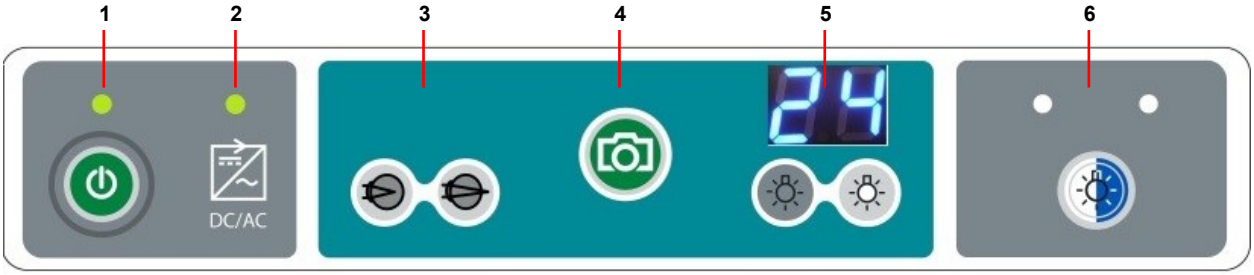


Figure 11. Control Panel

1	System Power button and green LED indicator
2	DC/AC power green LED indicator • When the system is supplied by AC power, the light is solid. • When the system is powered by the battery, the light flashes off and on.
3	Focus controls
4	Capture (or SNAP) button. Press to start, pause and restart video recording, and to capture a still image.
5	Illumination intensity controls and intensity value display
6	Illumination button and LED indicators • White indicates that the white light source (left LED) is in use. • Blue indicates that the blue light source for FA (right LED) is in use.

Footswitch

The footswitch is stored in the front pocket at the base of the cart. A handle is provided for holding or carrying the footswitch.

You can control focus (1), illumination intensity (2), and image or video capture (3) using the footswitch (Figure 12). These controls are duplicates of the same controls available on the control panel.

Figure 12. Footswitch Controls

Use the footswitch as follows:

- Illumination intensity, right pedal: Press the left side of the pedal down to decrease the intensity, and press the right side down to increase the intensity. You can press and hold until you reach the desired value, or you can press and release to adjust in small increments.
- Capture (or SNAP) button: Press to start, pause and restart video recording, and to capture a still image.
- Focus, left pedal: Press the left side of the pedal down to focus anteriorly far (away form the retina), and press the right side down to focus posteriorly (toward the retina). You can press and hold until you reach the desired focus, or you can press and release to adjust in small increments.
- You can rest your foot on the plastic divider between the pedals just below the Capture button.

System Transport and Storage

The RetCam Envision system is easily transportable within a healthcare facility.

NOTE: The RetCam Envision system is not intended to be transported outdoors. Contact Natus Technical Service for instructions on packaging and transporting the system to a location outside a healthcare facility.

To transport the system to another location when you are finished with an examination:

1. Ensure that the software is at the Patients and Exams window, and ensure that the handpiece is stored securely in the holster.
2. Adjust the monitor to provide a clear view in front of the cart. Make sure the monitor does not extend beyond the boundaries of the cart top (see Figure 13).
3. Stow the footswitch in the storage pocket at the base of the cart.
4. Unplug the power cord and wrap it around the cord posts on the back of the cart. You do not need to shut down the system. The batteries will sustain power.

5. Unlock the wheels.
6. To minimize vibration, move the cart slowly while transporting it. Exercise caution at floor transitions and when entering and exiting elevators.
7. At the new location, be sure to plug in the power cord, position the cart and adjust the monitor as necessary, and then lock the wheels.

To prepare the system for storage:

1. Ensure that the lens pieces have been properly cleaned and stored.
2. Shut down the system. Follow the instructions in “User Logout and System Shutdown”.
3. Stow the handpiece with its cap in the holster.
4. Position the monitor within the boundaries of the cart top (see Figure 13).
5. Stow the footswitch.
6. Turn off the power switch. Unplug the power cord and wrap it around the cord posts on the back of the cart.
7. Carefully transport the system to the storage location, and lock all wheels. Press the power switch to turn main power on.

Figure 13 shows the RetCam Envision system with all items stowed for storage.

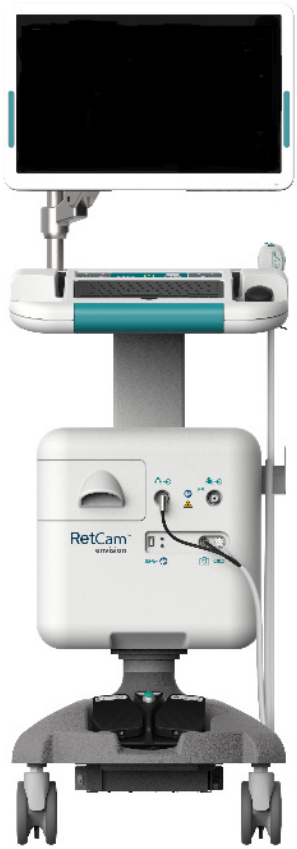
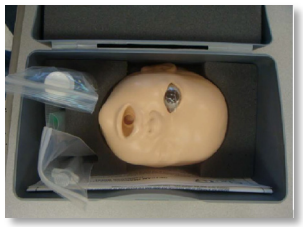


Figure 13. RetCam Envision System Storage Configuration

When the RetCam Envision system is not in use, conduct maintenance and store system components. For information on system maintenance, see “Maintenance, Cleaning, and Technical Support”.

Accessories

	Accessory	Part Number
	Lens piece, 130 FOV (LP130)	60-000090
(Shown in lens piece holder) 	Lens piece, Portrait (LPP01)	60-000092
	Handpiece protective cap	60-000188
  	Imaging Practice Kit	99-100048

Recommended Coupling Gels

In markets where available, the recommended coupling gel is:

GenTeal® Tears Gel (Severe Dry Eye Formulation)

In markets where GenTeal® Tears Gel is not available, either of the following (or equivalent formulations with indications for ophthalmic use) can be used:

- Viscotears® Liquid Gel
- Vidisic® Eye Gel

2. System Preparation and Operation

NOTES:

- New systems are installed by personnel trained by Natus Medical Incorporated. The installation includes the attachment and setup of the system components, the initial configuration of the software, and functional testing.
- The software is preinstalled on the system. If the software is reloaded, the database is cleared and all data will be deleted. Natus Medical Incorporated highly recommends that you back up the patient data in MLX format at the end of each imaging day.
- The RetCam Administrator must grant domain access before clinically-trained users can begin patient imaging.

For FA operation, see “Fluorescein Angiography (FA)”.

Start the System

1. Move the cart in position, and lock the wheels.
2. Plug the power cord into an outlet, and press the main power switch to turn on the main power.
3. Adjust the monitor height and angle as necessary for unobstructed direct viewing and to minimize glare.

   NOTE: Imaging can be performed sitting or standing.
4. Adjust the cart height for comfortable and ergonomic keyboard and mouse use.
5. Remove the footswitch from the storage pocket and set it in a comfortable and easy-to-reach location on the floor for use when imaging. Verify that it is plugged into the base of the cart.
6. Have all examination items, the lens piece holder, and the handpiece protective lens cap within reach.
7. Press the System Power button on the control panel. A green LED above the button will illuminate, the software boots up, and the User Login dialog appears on the screen. See “User Login”.

   NOTE: Connecting to the network may take 3-4 minutes. Network-enabled logins, printing, and data backup functions will be delayed until the network is available.

Prepare the System for a Patient Exam

1. Connect the lens piece to the handpiece. See “Lens Pieces”.
2. Verify that the handpiece is connected to the system. For more information, see “Handpiece Connections”.

   NOTE: Always return the handpiece to the holster when not in use. Wrap the handpiece harness in a loose coil around the wrap post. To prevent damage to the fiber-optic cable, do not wrap it around the post more than two (2) times.
3. If necessary, press the Illumination button on the control panel to turn on the light source.

User Login

1. When the system is powered on and the software boots up, the User Login dialog appears. There are two (2) login types, local and network-enabled. If you have questions about your network-enabled login, see your network or IT Administrator.

   - Local: Following is the RetCam Envision User dialog for local logins.

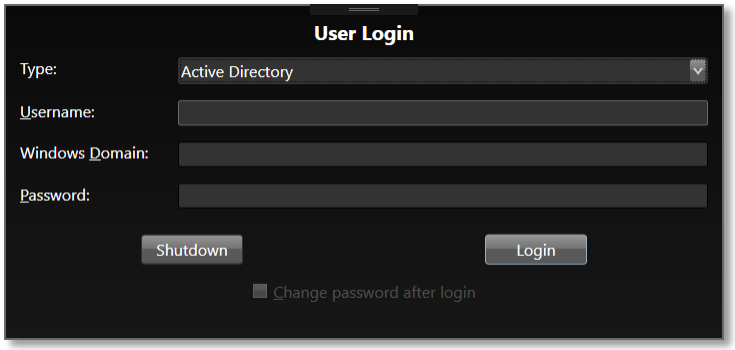
   First-time login: Passwords issued by your RetCam Administrator are temporary. When you log in for the first time, you will be required to change your password before you can continue.

   NOTES:

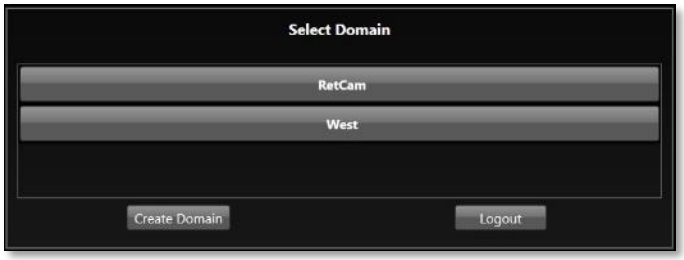
   - Your new password must be at least six (6) characters long, include at least one (1) numeric character, and it must be different from the old password.
   - After a period of inactivity, a logged-in user is logged out automatically. The default minimum is 15 minutes, and this value can be changed by your RetCam Administrator.

   - Network-enabled: If you are required to log in using your network-enabled (Active Directory) login, the Active Directory User Login dialog appears.

     NOTE: Before you can use your network-enabled login, the RetCam Envision system must be connected to the network.



2. Enter your username, Windows domain name (if applicable), and password.
3. Click **Login**. The Select Domain dialog appears.



4. Select the appropriate domain, and, after a momentary splash screen, the Patients and Exams window is displayed. See “Patients and Exams Window”.

   The basic steps of conducting a patient exam are described in “Conduct a Patient Exam”.

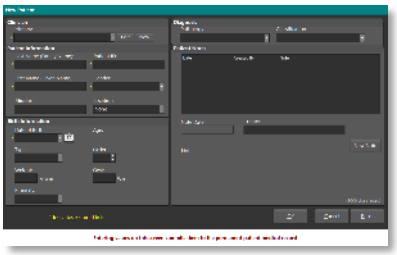
   If you need to create a domain, click **Create Domain**. See “Create a Domain”. Your user account must have permission to create a domain.

Conduct a Patient Exam

The following steps describe the typical patient exam workflow. If you require detailed information on a particular window or dialog, see “User Interface Windows and Dialogs”.

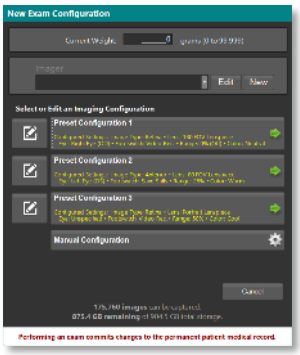
NOTES:

- For a list of recommended coupling gels, see “Recommended Coupling Gels”.
- Patient health information must remain strictly confidential and secure from unauthorized access, alteration, and use.
- The system delivers audible tones when you save a still image, start, stop, or pause video, extract still images from video, change filters, and when warning and error messages appear. Make sure the volume on your monitor is on and that you can hear the tones.
- To conduct a patient exam in FA mode, see “Fluorescein Angiography (FA)”. FA is available on RetCam Envision systems equipped with the FA option.
- If the system fails, contact Natus Technical Service. For more information, see “Technical Support”.

1. After you have logged in and selected a domain, the Patients and Exams window appears. • To load patient records for the selected domain, click **Show**. All records are displayed by default. • If necessary, use the Search function to find a specific patient record. For complete information, see “Patient Records Search”.	 See “Patients and Exams Window”.
2. In the Patients and Exams window: • For a first-time patient, create the patient record. Click . The New Patient dialog appears. • Complete the fields as necessary, and click **OK** to save the record and close the dialog.	 See “New Patient Record and Edit Patient Record Dialogs”.

3. In the Patients and Exams window, select the desired patient to start a new exam.
4. Click

. The New Exam Configuration dialog appears.



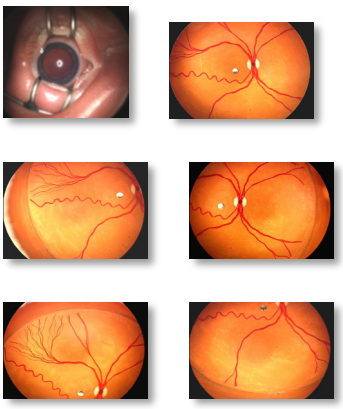
See “New Exam Configuration Dialog”.

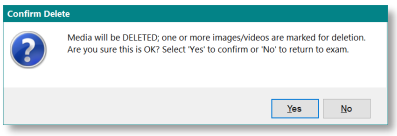
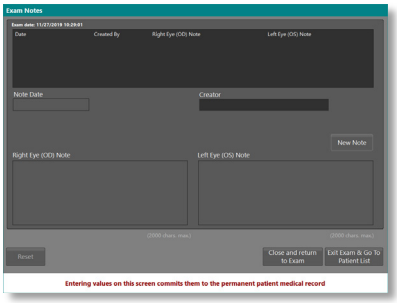
5. In the New Exam Configuration dialog, click next to the desired exam imaging configuration. The Live Image window appears.

See “Live Image Window”.

6. In the Live Image window, capture images of the patient’s eye(s). It is recommended that you start with the right eye (OD). If desired, capture an external image of the eye, and then capture 5 retinal fields of view (Posterior, Nasal, Temporal, Inferior, and Superior).

   Natus Medical Incorporated recommends recording a video of each eye, especially when imaging patients who are awake. You can capture still images from the videos before exiting the exam session, or you can save the videos and capture still images after exiting the exam session. For more information on the process, see “Image Extraction from Video”.



NOTES: • Do not image each eye for longer than 5 minutes. Maximum light exposure is no more than a total of 5 accumulated minutes per eye. • Use only recommended optical coupling gels that act as an optical bridge between the lens and the patient's eye. • An ample amount of gel should be applied to the patient's eye and reapplied frequently throughout the exam. • Do not directly contact or apply pressure to the patient's eye with the lens. The tip of the lens should be "floated" in the gel for capturing images and videos (this is called the immersion technique). • Restrict patient movement during imaging, and move the imaging lens piece away from the patient's eye if there are any signs of patient movement. • If necessary, gently manipulate the speculum to access the patient's eye. • If the RetCam Envision system fails, continue to examine the patient's eye(s) using an indirect ophthalmoscope.	
7. Exit the imaging session. Click in the Live Image window. If still images are selected for deletion, or if videos are automatically marked for deletion, a message appears to indicate that they will be deleted upon exam exit. Click **Yes** to confirm the deletion. The Exam Notes dialog appears. If no media are selected for removal, the Exam Notes dialog appears automatically.	  See "Exam Notes Dialog".
8. Add exam notes in the dialog. When you are finished, click **Exit Exam and Go to Patient List**. The Exam Notes dialog closes and the Patients and Exams window returns to view.	See "Patients and Exams Window".
9. Clean the lens piece.	See "Lens Piece Cleaning and Disinfection".

User Interface Windows and Dialogs

Patients and Exams Window

Upon login	From Live Image, Exam Notes	From Exam Review
Select a domain	Exit Exam/ Add Note → Exit Exam & Go To Patient List	Exit Review

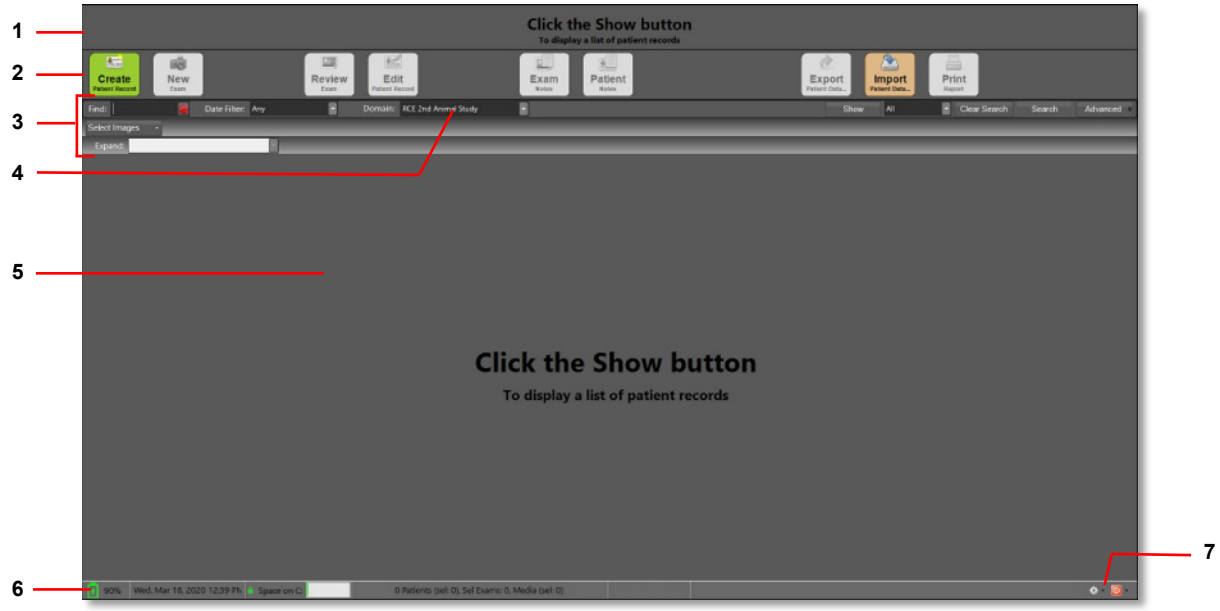


Figure 14. Patients and Exams Window (No Patient Records)

NOTE: When you log in and select a domain, the Patients and Exams window is always blank (no patient records are listed), as shown above. Patient records are displayed after you click **Show**. See the example in Figure 15.

1	When a patient record (row) is highlighted, a summary of the patient record is displayed at the top of the window.
2	Button bar. See “Patients and Exams Window Button Bar”.
3	Search and find patient and exam records fields. See “Patient Records Search” and “Advanced Search”.
4	Domain selection field
5	List of patients and exams records displayed in rows, one (1) row per patient • If no patient records are displayed, click **Show**. For more information, see “Patient Records Search”. • Patient records that are imported from a DICOM system are displayed in a different color initially. The color changes to white after an exam is created and saved. For information on importing patient records from a DICOM system, see “Import Ordered Exams”. • To perform an action on a patient record, click or tap the record. The row is highlighted, and a summary of the patient record is displayed at the top of the window. **NOTE**: You cannot highlight more than one (1) patient record at a time.

6	Status bar: • Battery status (green icon indicates that the battery is charging; yellow indicates that the system is running on battery power; red indicates that battery power is below 20%) • Current date and time • Available space on the C: drive. An icon of a lock indicates BitLocker status (locked = enabled; unlocked = disabled). • After a records search, the status bar shows the number of patients found, the number of patients selected, the number of media selected, and the number of media removed.
7	Utilities menu and system shutdown options. See “Utilities” and “User Logout and System Shutdown”.

Patients and Exams Window Button Bar

NOTE: A greyed-out button indicates that it is disabled. Most buttons are disabled until patient records are added and displayed in the Patients and Exams window. The color of the button changes to represent the corresponding function. A button may also be disabled because the user account does not have permission to use that function.

	Create a patient record. See “New Patient Record and Edit Patient Record Dialogs”.
	Start a new exam. See “New Exam Configuration Dialog”.
	Review exam images for a selected patient. See “Exam Review Window”.
 	Edit a selected patient record. See “New Patient Record and Edit Patient Record Dialogs”.
	Add notes to a patient record. This button is enabled only when you have selected a patient record. See “Exam Notes Dialog”.
	Export patient data. This button is enabled only when you have selected one (1) or more exam records. See “Export and Import Patient Data”.
	Import patient data from a USB drive or network. See “Export and Import Patient Data”.
	Print reports. For information on printing, see your RetCam Administrator.
	(DICOM only) Import the patient records for current-day ordered exams for the current RetCam Envision system. See “Import Ordered Exams”.

Navigation and Data Entry

- Mouse. Click to navigate among windows and fields and to initiate actions.
- Touchscreen. Using a gloved hand, tap or double-tap features on the touchscreen with your fingertip to navigate among windows and fields and to initiate actions. Note that some UI elements may not be large enough for touch control.
- Keyboard:
  - Navigate among windows and fields.
  - Enter data into fields.
  - Initiate actions.
  - To extract images from a video after video imaging, use the right arrow key to go forward or the left arrow key to go backward during video review. See “Image Extraction from Video”.
  - Use the S key on the keyboard to extract and save an image from video.
  - Keyboard shortcuts (also called “hotkeys”) are keys and key combinations used to accomplish various actions. See “Keyboard Shortcuts”.
- Icons. When patient records are listed in the Patients and Exams window, use the icons on the left of each row as follows:

	• Patient record: Expand the patient record to reveal exams and notes. • Exam record: Expand the exam to reveal image thumbnails of the saved still images and videos. Alternatively, click or tap one time on the row.
	Hide information (the row collapses). Alternatively, click or tap one time on the row.
	Start a new exam for the selected patient.

Keyboard Shortcuts

Shortcut	Description	Shortcut	Description
Patients and Exams Window			
Alt+C	Create patient	Alt+A	Patient notes
Alt+N	New exam	Alt+X	Export data
Alt+R	Review exam	Alt+I	Import data
Alt+E	Edit patient	Alt+P	Print
Alt+M	Exam notes	Alt+O	Ordered exams
New Exam Configuration Dialog			
Ctrl+1	Select Configuration 1	Ctrl+3	Select Configuration 3
Ctrl+2	Select Configuration 2	Ctrl+4	Select Manual Configuration
Live Image Window			
S	Save still image	Ctrl+F7	Reset timer
Spacebar	Start or pause video recording	Ctrl+F8	Restart timer

Shortcut	Description	Shortcut	Description
Enter	Either unfreeze image or stop recording	F11	Toggle full screen mode
N	Cycle through lens types	Ctrl+Insert	Toggle the flag icon on thumbnail
Ctrl+Y	Cycle through eye assignments	Delete	Toggle the delete status on thumbnail
R	Cycle through the range levels	Ctrl+F5	Start timer
C	Cycle through color levels	Ctrl+F6	Pause timer
F	Toggle FA (if FA light + FA filter are set), or Red-Free mode		
Exam Review Window			
Ctrl+, (comma)	Go to previous thumbnail	Ctrl+. (period)	Go to next thumbnail
F11	Toggle full screen mode		

Patient Records Search

NOTE: A basic search finds all patient records in a domain (**Show All**, described below). Although this approach is the most inclusive, it is the most time-consuming method of locating patient records and is not recommended. For sites with large volumes of records, it may take a few minutes for the records to load. You can narrow the search using the advanced search fields. See “Advanced Search”.

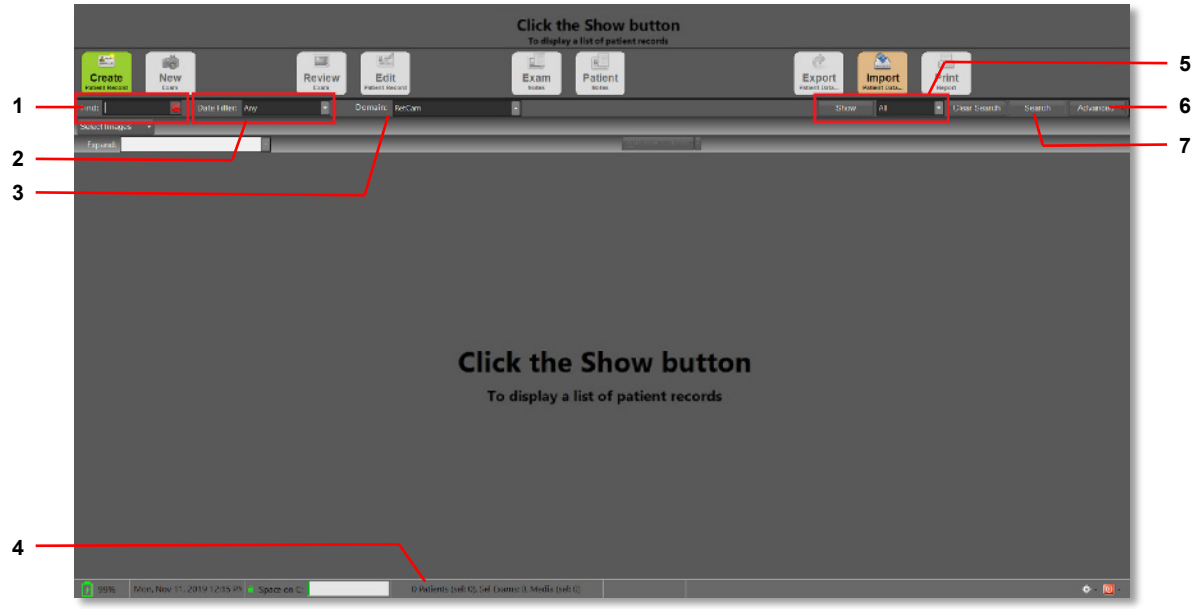


Figure 15. Patients and Exams Window Search Fields

1	Find field. Enter any part of a patient’s name. The system searches patients’ last names, first names, patient IDs, and primary clinician names for matches. Click on the red **X** to clear the field.
2	Date Filter. If you select **Any**, there are no date restrictions.
3	Domain. A search is always confined to the domain shown.

4	Search results summary. The status bar shows the number of patients found, the number of exams found, the number of media selected, and the number of media removed.
5	Show options. If you select **All**, all records in the selected domain are displayed on a single page when you click **Show**. To set a page limit of displayed records (for example, 20 records per page), use the **##/page** drop-down options.
6	Advanced search options. See “Advanced Search”.
7	To execute a search, click the **Show** button, the **Search** button, or press Enter on the keyboard. Search results appear in the Patients and Exams window (see “Search Results”). For information on refining the search, see “Expand the Search Results” and “Advanced Search”.

Search Results

Patient records are displayed in rows in the Patients and Exams window. The first record is highlighted (selected) by default, and a summary of that patient record is displayed at the top of the window. Patient notes, exams, and exam notes associated with a patient record are hidden from view. To see that information, expand the rows (see “Navigation and Data Entry” and “Expand the Search Results”).

From the search results, you can view patient records, create patient records, start exams, review exams, edit exam notes, and export and import patient data.

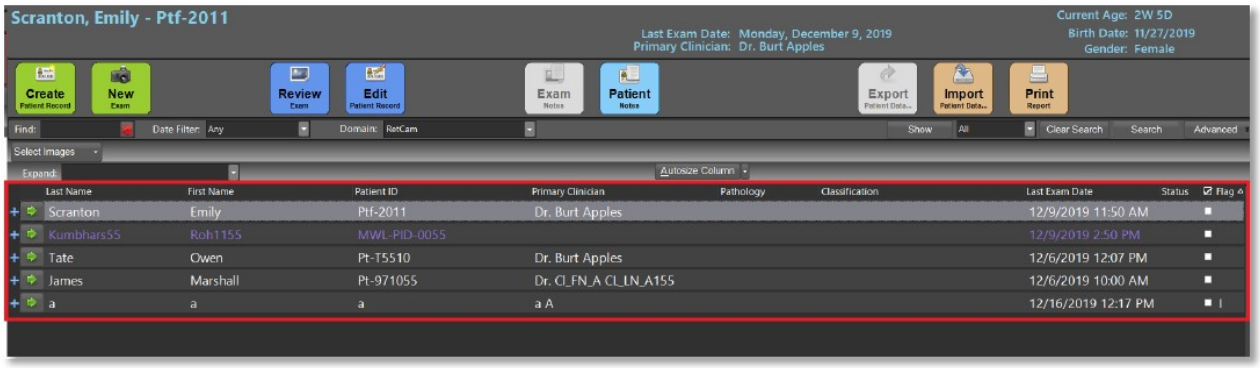


Figure 16. Search Results

The information in a patient record is organized into columns. Click on any column header to change the sort order.

The two (2) columns on the far right are:

- Checked (selected) records. A checkmark appears in the checkboxes next to the records that are selected for export.
- Archive status:
  - A capital “I” indicates that the record has been imported.
  - A capital “E” indicates that the record has been exported.
  - If the status is blank, the record has not been imported or exported.

If the list of records is long, use the scroll bar on the right to scroll up and down as necessary to bring more records into view.

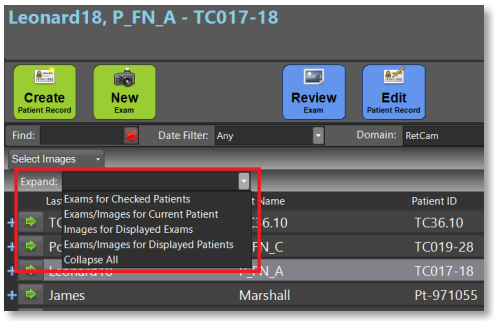
Expand the Search Results

To refine the search results, several options are available:

- Expand selected rows (described below).

- Select images in the patient records. This is used primarily for exporting patient data. For more information, see “Export and Import Patient Data”.
- Advanced search. See “Advanced Search”.

To expand search results, select the desired option from the Expand drop-down menu, which is located above the list of patients on the left.

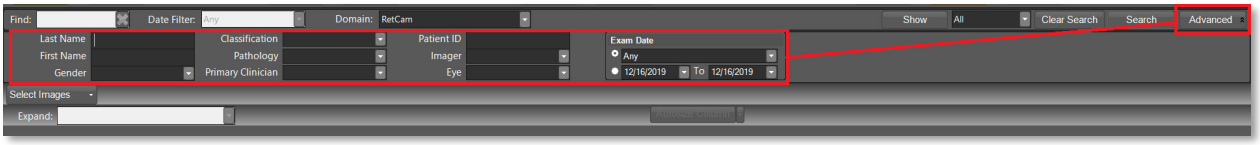


Exams for Checked Patients	Shows the exams for checked patient records (checkmark in the Checked column).
Exams/Images for Current Patient	Shows the exams and the exam image thumbnails of the current patient record (the row that is highlighted).
Images for Displayed Exams	Shows the exam image thumbnails for any exams that are displayed (patient records must be open).
Exams/Images for Displayed Patients	Shows the exams and the exam image thumbnails for all displayed patient records.
Collapse All	Closes all open rows, hiding all exams and notes. Only patient record rows are displayed.

Advanced Search

An advanced search allows you to enter criteria that narrow the search to meet your requirements. An advanced search is conducted on all patient records in the selected domain.

1. In the Patients and Exams window, select a domain.
2. Click **Advanced** on the upper right to reveal the advanced search fields.



Last Name	Classification	Patient ID	Exam Date
First Name	Pathology	Imager	• Date ranges
Gender	Primary Clinician	Eye	• Exam dates

3. Enter or select the desired information in any combination, and click **Search**. Records that contain the selected criteria are displayed.
4. To conduct a new search, click **Clear Search** and repeat the previous steps.
5. Click **Advanced** again to hide the fields.
6. To work with the search results, see “Search Results”.

New Patient Record and Edit Patient Record Dialogs

If your RetCam Envision system is employed as an examination device in a DICOM environment, most patient records are not created locally. For more information, see “Import Ordered Exams”.

Create, from Patients and Exams	Edit, from Patients and Exams, patient record selected
	or or

The New and Edit dialogs are the same, except that the fields in the New Patient dialog will be blank. Note that the Edit Patient dialog is also referred to as the Patient Notes dialog.

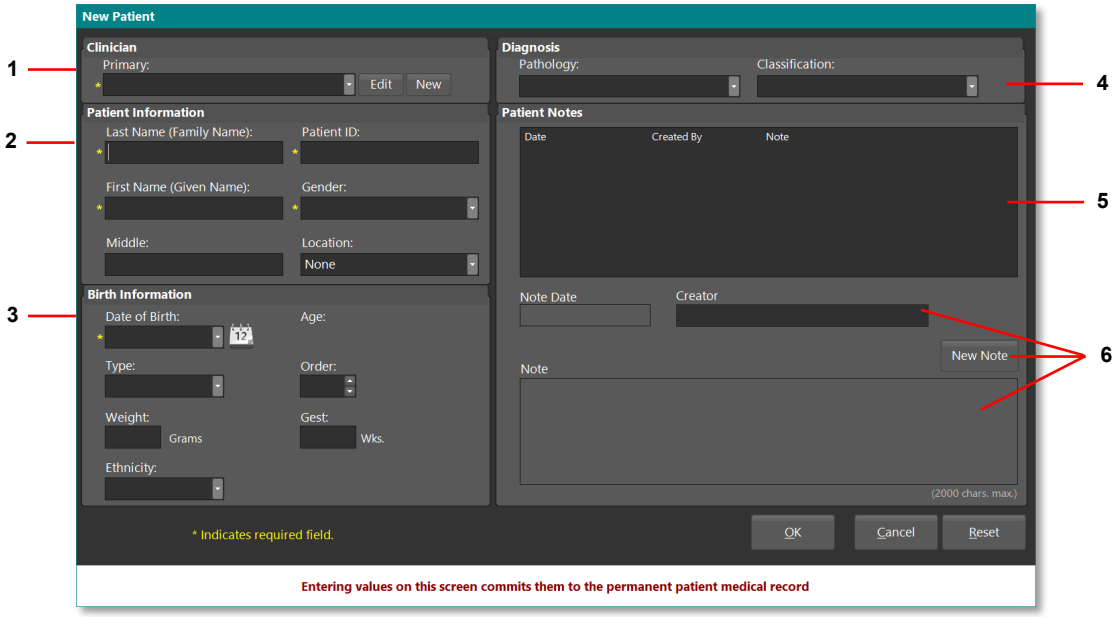


Figure 17. New Patient Record Dialog

1	Clinician (required). You can create a new clinician or edit a selected clinician. **NOTE**: Changes to clinician information are applied to all users and patients.
2	Patient Information (asterisks denote required fields)
3	Birth Information (required). Enter the patient’s date of birth (DOB), or use the pop-up calendar.
4	Diagnosis. Enter the type of exam to be performed or the expected pathology to be captured (for example, Screening for ROP).
5	Saved patient notes. Saved notes cannot be edited. Notes are stamped with the creation date and time.
6	• Creator is the name of the individual who creates a note. You can create a new Creator or edit a selected Creator. • Click **New Note** to select a Creator (required) and to enter notes in the Notes entry field. To save, click **Save Note**. If you cancel, a message appears to allow you to confirm, in which case all changes will be lost. • Notes entry field (2000 characters maximum)

NOTES:

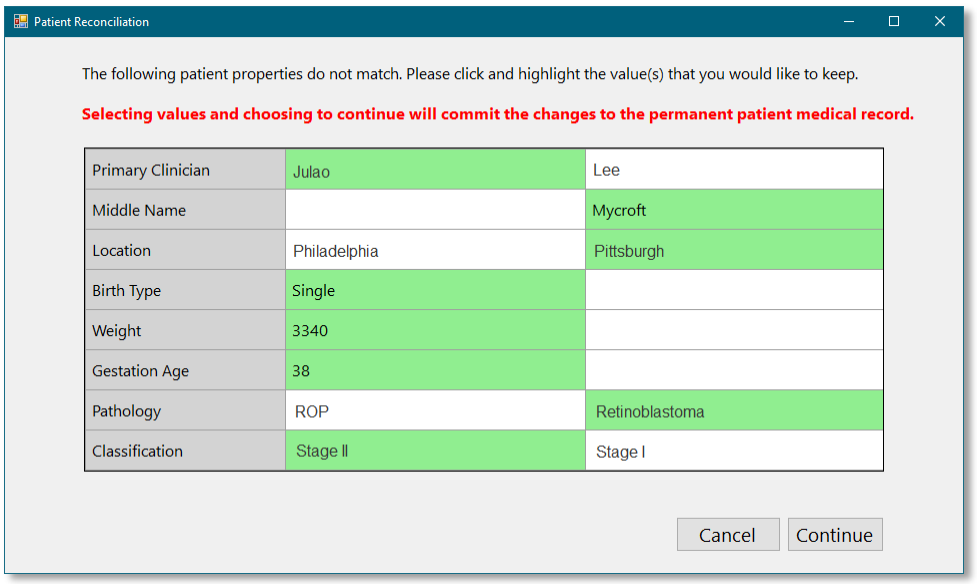
- If the patient record was not created locally, some fields in the Edit Patient dialog are not editable (the field titles appear grey). Those fields can be edited only on the EMR system.
- If you create a patient record that is identical to another record (same first name, last name, patient ID, and DOB), a message indicates that you are about to create a duplicate of an existing record. You can proceed to save the record or cancel.
- If you discover that a patient record has been duplicated, you can merge the records and eliminate the duplicate. See “Patient Records Merge”.
- Patient records cannot be deleted.

Patient Records Merge

You may have created two (2) identical patient records. To prevent confusion, it is recommended that you merge the records.

NOTE: Before merging the records, verify that the two (2) records you select show exactly the same First Name, Last Name, Patient ID, and DOB. The names do not have to be in the same case (lowercase, uppercase, and capitalization).

1. To merge the patient records, select both records in the Patients and Exams window. The **Merge Patients** button appears.
2. Click the **Merge Patients** button. The Patient Reconciliation dialog appears.



3. In each column, select the data you want to keep. The selections turn green.
4. Verify the information, and click **Continue**.

New Exam Configuration Dialog

From Patients and Exams, patient record selected

or

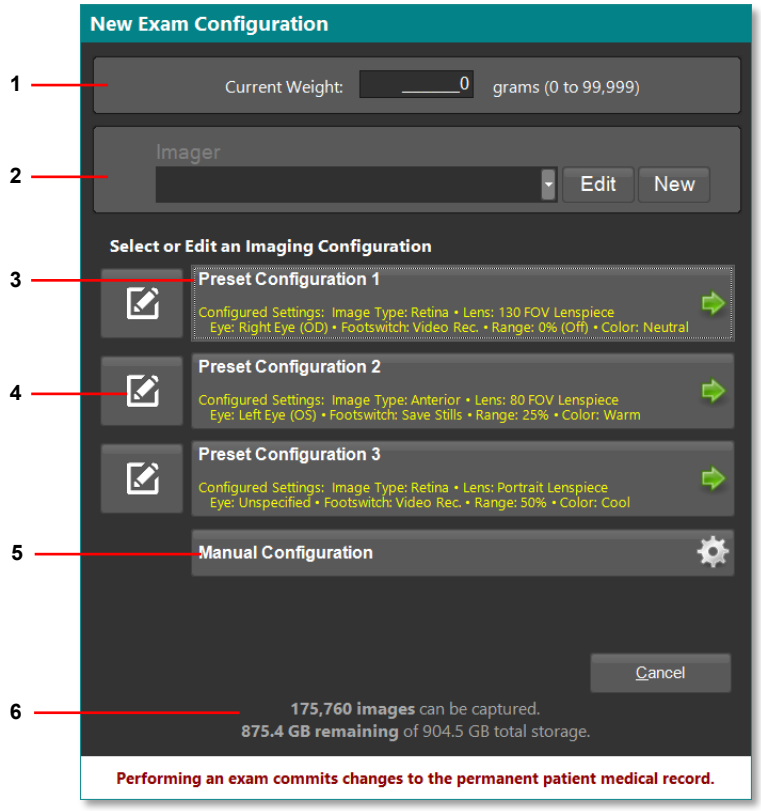


Figure 18. Exam Configuration Dialog

1	The Current Weight field appears for patients who are less than one (1) year old.
2	Imager is the name of the imaging technician. You can also create a new Imager, or you can edit the selected Imager information.
3	Three (3) preset exam imaging configurations are available. Click on the appropriate configuration to proceed directly to the Live Image window. See “Live Image Window”.
4	Edit a preset exam imaging configuration. See “Imaging Configuration Dialogs”.
5	Set up an exam imaging configuration using parameters that you specify. Opens the Manual Configuration dialog. See “Imaging Configuration Dialogs”.
6	Available system storage drive capacity. The approximate number of new images that can be saved depends on the quantity of videos and still images that have already been saved.

Imaging Configuration Dialogs

From New Exam Configuration

(Edit Preset) or (Edit Manual)

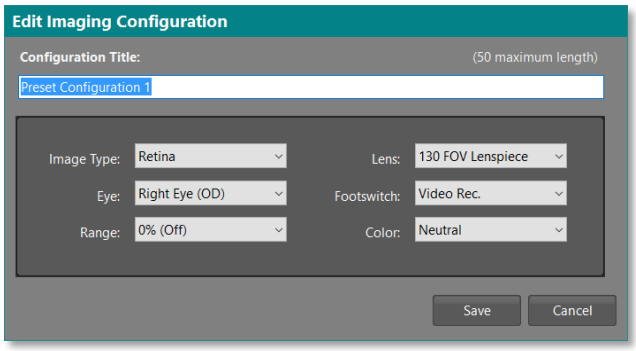


Figure 19. Edit Preset Imaging Configuration Dialog

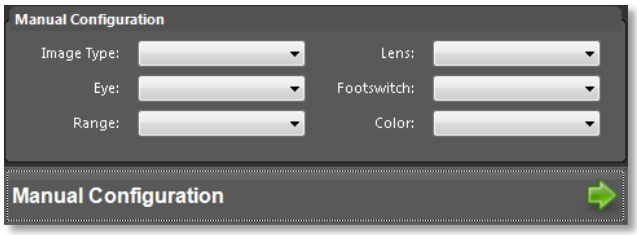


Figure 20. Edit Manual Imaging Configuration Dialog

Select the configuration options from the drop-down menus. If editing a preset configuration, click **Save** to save your changes.

Live Image Window

From Image Configuration

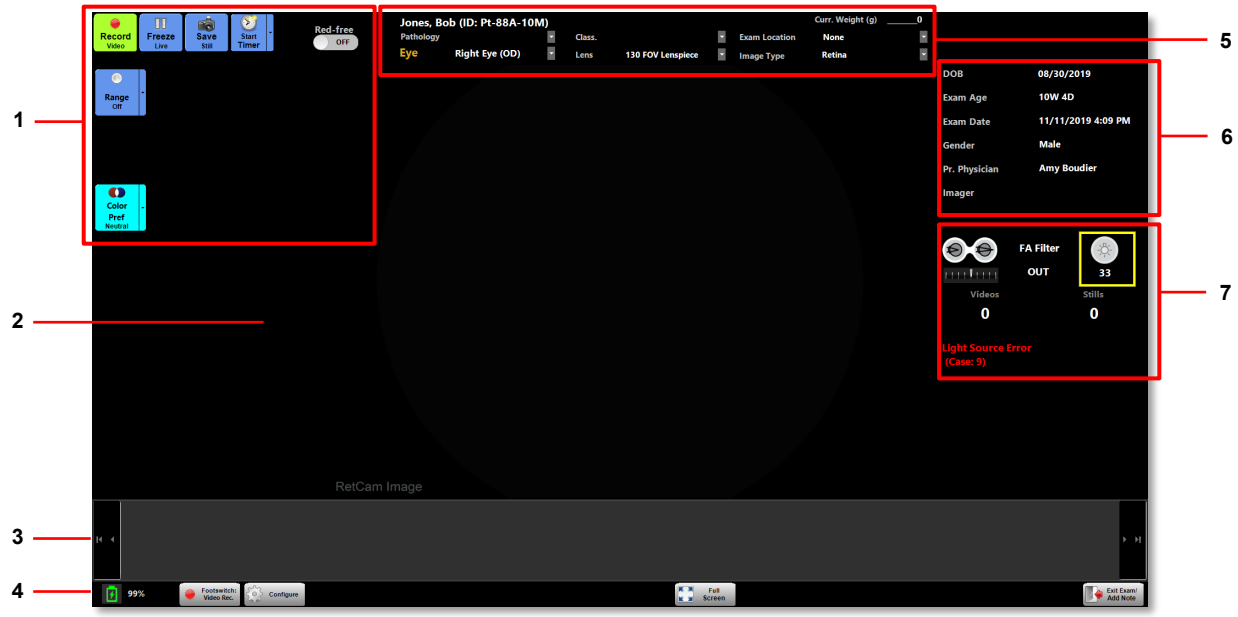
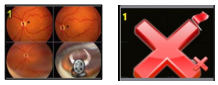


Figure 21. Live Image Window

1	Live video recording and image capture controls, timer, range, and color controls, Red-free mode control, and FA indicator. See “Live Image Controls”.
2	Live image display area. In addition to the live image, “RetCam Image” appears on the lower left, and any watermarks appear on the upper left, upper right, or lower right corner of the image.
3	The Thumbnail preview and selector bar shows thumbnail versions of still images and videos captured during an exam. • Use the arrows on the left and right of the thumbnail bar to bring additional thumbnails into view. • Captured videos are displayed in a square with four (4) sample images (first, last, and two (2) intermediate images from the video). A large red “X” on top of a video thumbnail indicates that the video is marked for deletion when you exit the exam. By default, videos are deleted when you exit an exam. To retain the video, click the small “x”. For more information, see “Image Extraction from Video”.  • Select an image or video thumbnail to show a large version of the image in the image display area. For a selected video clip, playback controls appear on the upper left of the window. • Flag an image for further review. To flag an image, place the cursor over the thumbnail and click the Flag icon . The flag appears on the thumbnail in all windows that show thumbnails.

4	Status and available actions:	
	 	When you start a new exam, the footswitch is enabled automatically. These controls accomplish the same actions as the on-screen Record Video and Save Still live image controls. Toggle record video and save still images. The corresponding on-screen controls change color. See “Live Image Controls”.
		Display live image configuration options. See “Live Image Configuration Options”.
	 	Toggle full-screen and normal-screen display of the live image.
		Exit the live image exam session and go to the Exam Notes dialog. See “Exam Notes Dialog”.
5	Exam image labels. See “Image Labels”.	
6	Display-only exam information: Patient DOB, exam date stamp, patient age and gender, physician name, and Imager name	
7	Other exam information: • FA filter status (in or out) • Illumination level • Number of videos and still images captured • Error messages (displayed in red text). For more information, see “Troubleshooting”.	

Live Image Controls

	Record, pause, and stop live video recording. During live video recording, a progress bar appears below the controls. The progress bar shows the total time available for video recording (in minutes) and the percentage used. This control is green when the footswitch is activated to record video.
	Pause and resume live video recording.
	Freeze live video recording to capture a still image. Unfreeze to return to live video recording.
	Save a still image to the storage drive. This control is green when the footswitch is activated to save still images.
	Return to the patient’s live exam. Show Live appears during save still capture review or video image extraction during a live exam.

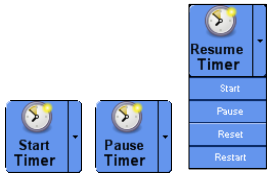
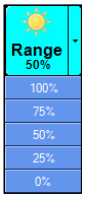
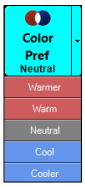
	• Start a new timer. • Pause the timer. • Reset the current timer to 0. • Reset the timer to 0 and automatically start the timer. **NOTE**: To configure the position of the timer display in the window, see “Live Image Configuration Options”. In FA/Red-free mode, the timer is controlled separately from the video.
	Remove or include the red component of images. In Red-free mode, images are in grey scale when imaging with the white light source. In Red-free mode for the FA exam process, images are monochromatic when imaging with the blue light source. During both video recording and freeze live recording, a lock symbol appears on the icon to indicate that the function cannot be changed until you stop or unfreeze live video recording.
	FA mode is activated when the blue light has been connected and the FA switch on the handpiece has been engaged. During both video recording and freeze live recording, a lock symbol appears on the icon to indicate that the function cannot be changed until you stop or unfreeze live video recording.
	Five (5) range settings each corresponds to a unique combination of adjustments that include gamma correction. The default setting is 50%; this setting changes based on user activity. Gamma correction, an industry standard effect, helps normalize the brightness across the entire image. Range is useful in imaging an object where highly reflective (bright) areas are close to less reflective (dark) areas and the illumination cannot be optimized for both. In these instances with range applied, the darker areas brighten with minimal change to existing bright areas, resulting in normalization of the overall brightness. **NOTE**: The last active range selection is retained until modified by the user; it does not reset to the default setting. **NOTE**: Range is automatically set to 0% (off) in FA mode and Red-free mode.
	Adjust camera color temperature in five (5) increments from warmer to neutral to cooler. This function can help distinguish features in patients with dark retinas. You can also adjust color based on personal preference. **NOTE**: Color preference does not apply to FA mode.

Image Labels

Use the drop-down menus at the top of the window to select or change information that is saved with both images and videos.

Figure 22. Image Label Selections

Pathology	Select or change pathology type (live imaging sessions only).
Eye	Select or change the eye designation during live imaging sessions or during exam review.

Classification	Select or change classification (live imaging sessions only).
Lens	Select or change lens type during live imaging sessions or during exam review.
Exam Location	Select or change exam location (live imaging sessions only).
Image Type	Select or change image type during live imaging sessions or during exam review.

Live Image Configuration Options

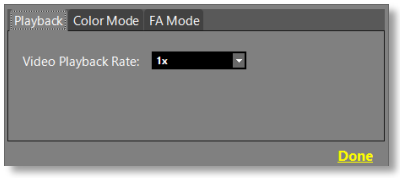
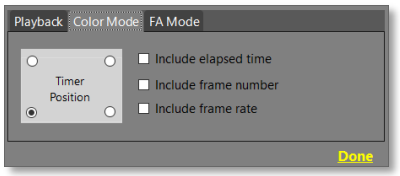
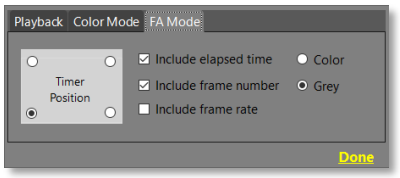
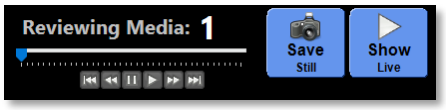
	Select the appropriate option. The selected rate is displayed in red next to the playback controls.
	Color mode applies to all image captures, except FA imaging by RetCam Envision systems equipped with the FA option. Images in Color mode are displayed in full color. Select the appropriate options. The timer is displayed prominently in yellow text in the selected position.
	FA mode applies only to FA imaging by RetCam Envision systems equipped with the FA option. Select the appropriate options. By default, images and videos are captured in greyscale.

Image Extraction from Video

NOTE: Saving video consumes a large amount of system storage space. For best performance, extract the images of interest from the video. By default, videos are marked for deletion.

1. Press the Capture button on the control panel or on the footswitch to start, pause, and restart video recording.
2. To stop video recording to extract individual images from the video, click

.
3. Click on the video thumbnail. Video playback controls appear on the upper-left.



4. Start from the beginning of the video. If necessary, use the rewind video playback controls or the left arrow keyboard key to return to the beginning.
5. Press the right arrow keyboard key to go forward incrementally through the video (or press and hold the right arrow to go forward faster). When a feature of interest appears, release the right arrow key to stop the playback.

6. To extract and save the desired image, press the S key on the keyboard (or click

).
7. Repeat until all desired images have been extracted. Thumbnails of the extracted images appear on the thumbnail bar.
8. If multiple videos have been captured, repeat these steps for each video.

Exam Notes Dialog

From Patients and Exams, exam selected	From Live Image	From Exam Review

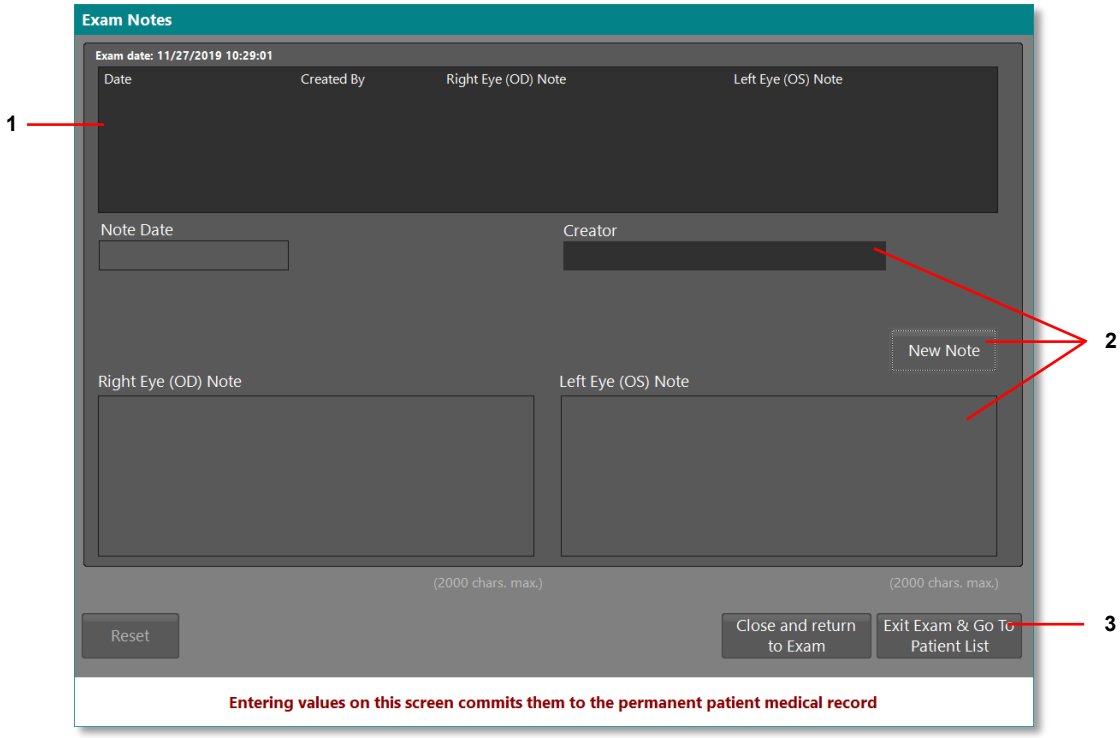
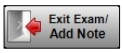
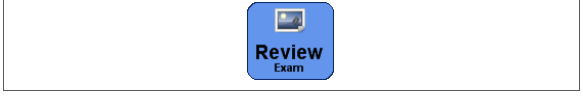


Figure 23. Exam Notes Dialog

1	Saved patient notes. Saved notes cannot be edited. Notes are stamped with the creation date and time.
2	• Creator is the name of the individual who creates a note. You can create a new Creator or edit a selected Creator. • Click **New Note** to select a Creator and to enter notes in the Notes entry fields. To save, click **Save Note**. If you cancel, a message appears to allow you to confirm, in which case all changes will be lost. • Right Eye and Left Eye notes entry fields (2000 character maximum per entry field).
3	From  : **Close and Return to Exam** **Exit Exam & Go to Patient List** From and : **OK** **Cancel**

Exam Review Window

From Patients and Exams, exam selected



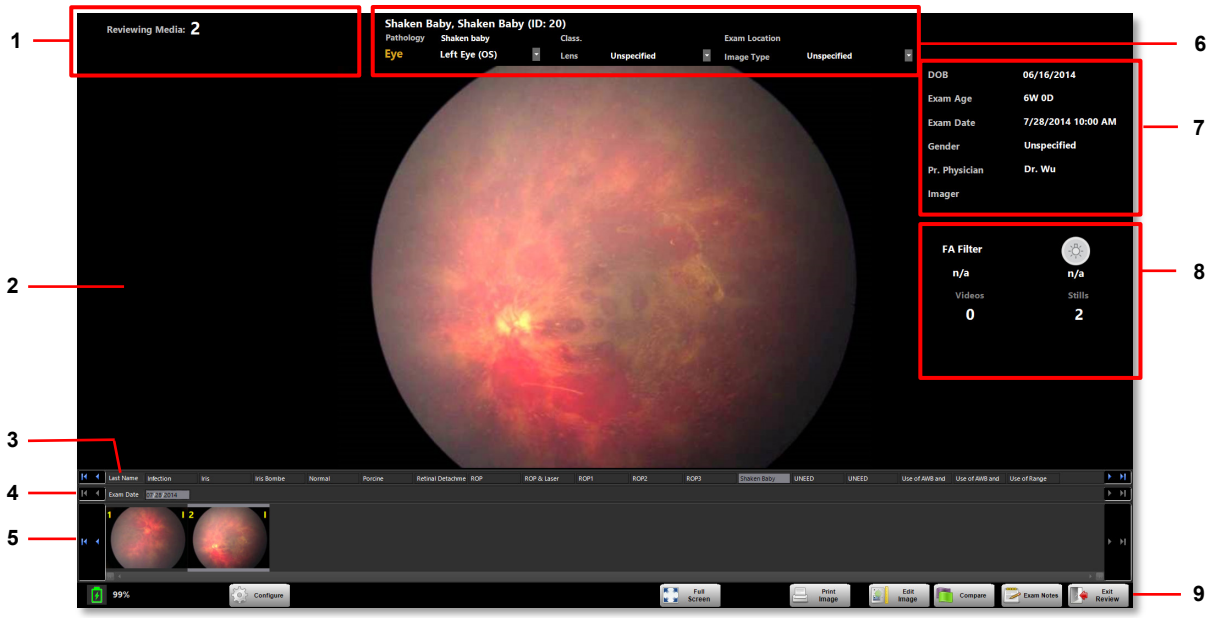
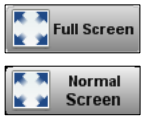


Figure 24. Exam Review Window

1	Reviewing Media shows the number of the thumbnail under review in the image display area. When a video clip is selected for review, playback controls appear. For information on video playback and capturing Still images from video, see “Image Extraction from Video”.
2	Image display area
3	The Patient selector bar displays the last names of patients in the current domain. The images, exam dates, and thumbnails associated with the selected patient appear. Use the arrows or click on a name to select another patient.
4	The Exam selector bar displays all exam dates for the selected patient. The images and thumbnails associated with the selected exam appear. Use the arrows or click on a date to select another exam date.
5	The Thumbnail preview and selector bar shows thumbnail versions of still images and videos captured during the selected exam. • Saved videos are displayed in a square with four (4) sample images: first, last, and two (2) intermediate images from the video. • Select an image or video thumbnail to show a large version of the image in the image display area. • Use the arrows to bring additional thumbnails into view. • Flag an image for further review. To flag an image, place the cursor over the thumbnail and click the Flag icon . The flag appears on the thumbnail in all windows that show thumbnails.
6	Patient and exam information. You can change the eye designation, lens preference, and image type using the drop-down menus.

7	Display fields: DOB, exam date stamp, patient age and gender, physician name, and Imager name, range, and color information	
8	Live imaging information: • FA filter status (in or out) • Illumination level • Number of videos and still images captured • Error messages (displayed in red text)	
9	Status and available actions:	
		Display exam review configuration options. See “Exam Review Configuration Options”.
		Toggle full-screen and normal-screen displays of the selected image or video.
		Print the selected image.
		Open the Image Adjustment toolbar. See “Image Adjustments”.
		Display two (2) images side-by-side for comparison. See “Image Comparison”. **NOTE**: Videos cannot be compared.
		Open the Exam Notes dialog. See “Exam Notes Dialog”.
		Exit the exam review session and return to the Patients and Exams window.

Exam Review Configuration Options

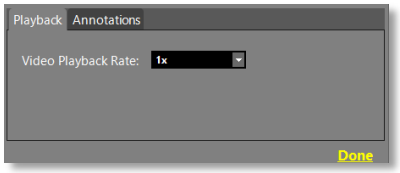
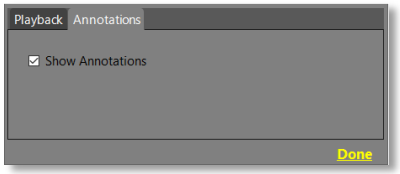
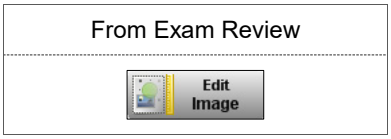
	Select the video playback rate. The selected rate is displayed in black next to the playback controls.
	Select whether to show annotations on an image. See “Image Annotations”.

Image Adjustments

NOTES:

- You can save adjusted images only outside the RetCam Envision database and in nonproprietary formats such as PNG or JPG (or JPEG). The saved images reflect any adjustments and changes you make, but the original images in the database are not changed.
- Videos cannot be edited.



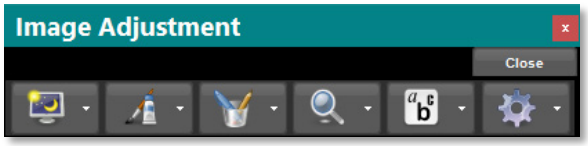


Figure 25. Image Adjustment Toolbar

	Adjust image brightness and contrast.
	Adjust image display colors.
	Annotate an image. See “Image Annotations”.
	Adjust image magnification.
	Add text overlays to an image. **NOTE**: Text overlays are not permanent. They can be turned on and off during Exam review. If they are turned on, they appear when you print the image and when you save the image (PNG or JPG format).
	• Load Preset. Adjustment values can be saved as a preset that can then be loaded as a group and applied to other images. • Save Preset • Reset the image adjustments to the system defaults. • Save As

Image Annotations

To superimpose information on an image, use the annotation tools. When an image contains annotations, the Annotation icon is displayed on the image thumbnail in all windows that show thumbnails.

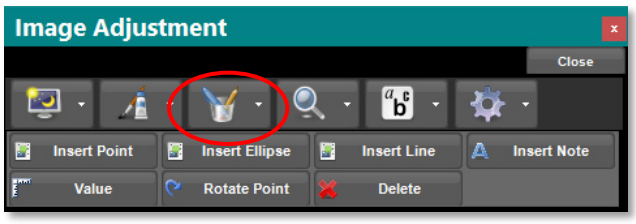
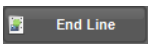
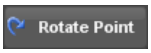
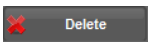


Figure 26. Image Annotation Tools

	Insert a point and add text.
	Insert an ellipse and add text.
	Insert a line and add text. To complete the line, click **End Line** or press the Esc key.
	Insert a note.
	Show (or hide) the measurements of a selected annotation (line, ellipse, point). The units of measurement are pixels based on the original size of the image. Point: X, Y location Ellipse: CP is the X, Y location of the center point; A is the area covered by the ellipse. Line: Total length of all line segments
	After you insert a point, select it and click **Rotate Point** to rotate the point 90 degrees clockwise. Repeat to continue rotating in 90-degree increments.
	Delete a selected annotation.

Annotation tips:

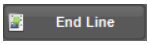
- To add an annotation, click the desired tool, move the cursor over the image, and click to set the annotation in place.
- You can create a line that has multiple segments. After you insert and click to set the first segment, move the cursor to create the next segment and click to set it. Repeat this action to create as many segments as desired. To complete the line, click  or press the Esc key.
- To move or resize an annotation, drag the square handles that appear when you move the cursor over the annotation.
- To edit the text associated with an annotation, double-click the text box labeled “{Type Here}” and type the desired text. Click outside the text box when you are finished.

Image Comparison

You can compare images from one or more exams for a single patient or from two (2) different patients. The options are the same for either type of comparison.

In Image Comparison, two (2) images are displayed side-by-side in two (2) Exam Review windows. Use the Image Comparison window the same way you use the Exam Review window. For more information, see “Exam Review Window”.

NOTE: The following functions are not available in image comparison:

- Flag image
- Full screen mode
- Video comparison
- Change: Eye designation, Lens preference, or Image type
- Exam notes

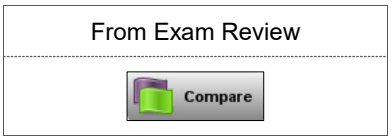


Figure 27. Image Comparison Window

NOTE: When you click

, the Image Adjustment toolbar appears and is expanded to allow independent adjustments to both images. For more information, see “Image Adjustments”.

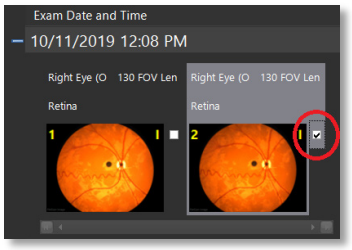
Figure 28. Image Adjustment Toolbar in Image Comparison

Remove Media

You can remove media (still images and video) from patient records in the Patients and Exams window. To ensure that only users with permission can remove media, any request for removal requires authentication.

NOTE: The availability of this option is based on the permissions assigned to your user account.

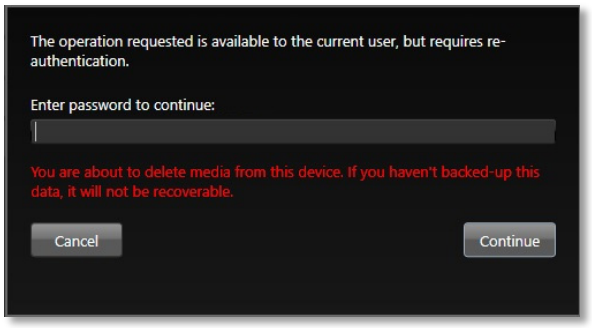
1. In the Patients and Exams window, search for and select the desired patient records.
2. Select the desired exams. Expand each exam to reveal image thumbnails of the saved still images and videos.
3. Check the still images and videos you want to remove. To do this, check the box next to each thumbnail image.



When the boxes are checked, the **Remove Selected Media** button appears above the patient list.

NOTE: If the entire patient record is selected (a checkmark is in the Checked column), all media in all exams are selected for removal automatically.

4. Click **Remove Selected Media**. If the media have not been backed up, a message appears to allow you to confirm your action.
5. To continue, click **Yes**. The password confirmation message appears.



6. Enter your password, and click **Continue**. After the media are removed, the corresponding thumbnails become placeholders overlaid with the word “Removed”. The thumbnails cannot be removed.

User Logout and System Shutdown

The RetCam Envision system offers both automatic and manual logout options. Logout closes the active user account on the RetCam Envision system in use. It is a separate step from shutting down, which turns the main power off.

NOTES:

- After a period of inactivity, a logged-in user is logged out automatically. The default minimum is 15 minutes. This value can be changed by your RetCam Administrator.
- Natus Medical Incorporated recommends that you back up and store your data before turning off the RetCam Envision system. See “Export and Import Patient Data”.

To log out and shut down the system, click on the Status bar, and select one of the following from the pop-up menu:

- To log out of your user account without shutting down the system, select **Log out**.
- To log out of your user account and shut down the system, select **Shutdown**.

If the system stops responding, wait at least 1 minute.

If the system does not respond after 1 minute, press the System Power button on the control panel once. All control panel indicators, except the DC/AC indicator, will turn off.

Hard Shutdown

Hard shutdown is recommended only if it is necessary. Data corruption may occur.

To perform a hard shutdown, press the System Power button on the control panel for at least 6 seconds.

3. Export and Import Patient Data

Export or import patient records, exams, and media to:

- Make RetCam Envision data available on other RetCam Envision systems. The data include the selected patient's information, exams for the patient(s), and all media in the exam(s).
- Make backup copies of the original media on the storage drive (both images and videos).
- View with standard image software.
- Use RetCam Envision images with third-party imaging systems.

Data Backup

The RetCam Envision system stores all images and videos in the internal storage drive. Natus Medical Incorporated highly recommends that you back up all data at the end of each day on which you acquire new images.

For long-term data retention, Natus Medical Incorporated recommends that you back up all data on another computer in your office network, preferably a server-class computer with large capacity and redundant storage capabilities (Redundant Array of Independent Disks, or RAID). For secondary backup in this environment, consider backing up to a removable USB mass-storage device.

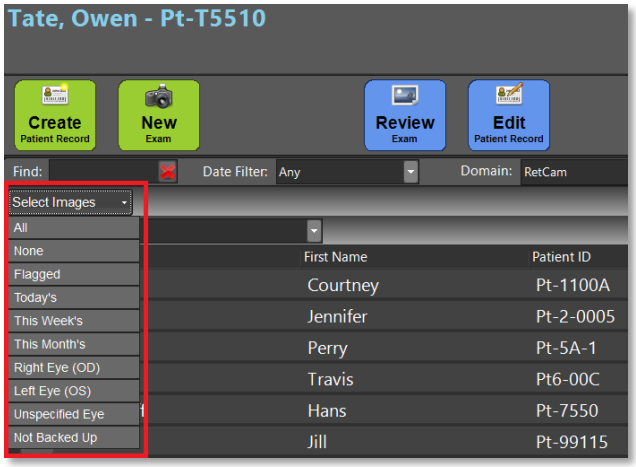
Export Data

You can export data to any accessible location. A copy of the data is exported, and the original data is intact on the system storage drive.

NOTE: Natus Medical Incorporated recommends limiting export to no more than 3000 images in one (1) batch to avoid an extended transfer time. Instead of exporting a large batch of data, export small batches.

To export data:

1. Verify that the destination device (such as a USB) is ready and has sufficient space.
2. In the Patients and Exams window, search for the desired records.
3. In the search results, select an option from the Select Images drop-down menu, which appears above the patient list.



All	Selects all records.
None	If any records have been selected, this option clears the selections.

Flagged	Selects all media (images and videos) that have been flagged.
Today's	Selects all media captured on the current date.
This Week's	Selects all media captured during the current week, from Sunday to Saturday.
This Month's	Selects all media captured during the current month.
Right Eye (OD)	Selects all media captured of the right eye.
Left Eye (OS)	Selects all media captured of the left eye.
Unspecified Eye	Selects all media labeled "Unspecified".
Not Backed Up	Selects media that have not been exported. This is especially helpful to verify whether data were backed up after a particular date if date criteria were used for the search.

4. Click

. This button is greyed out until records are selected.
5. Select the appropriate options in the Export dialog (Figure 29).
6. Click **Export**. When the export process has completed, a report shows the number of records that were copied successfully.

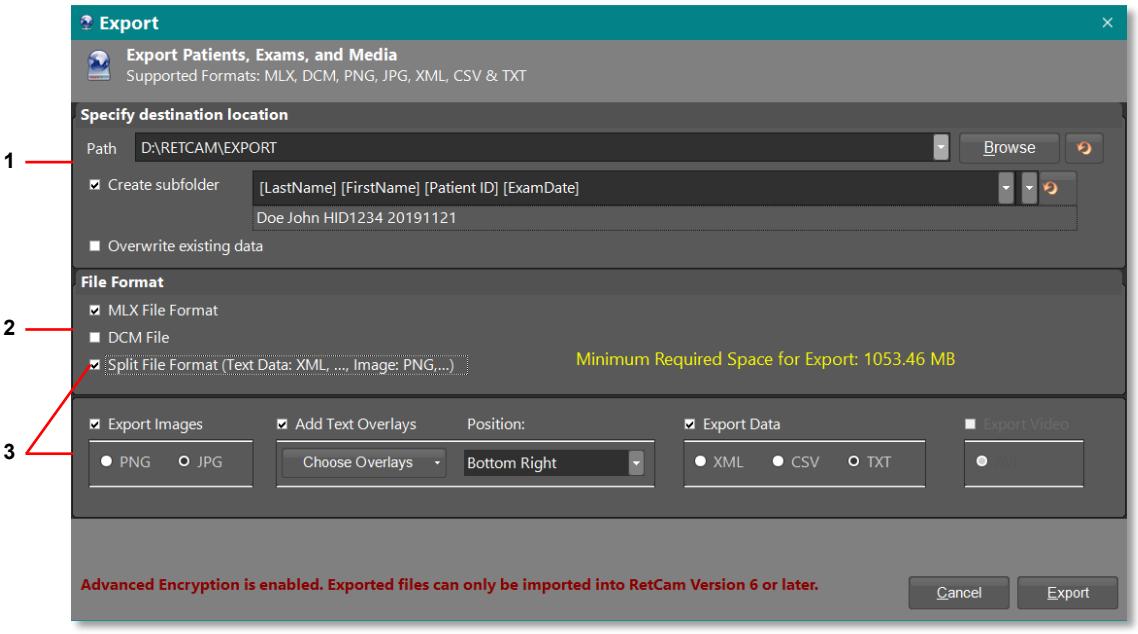


Figure 29. Export Dialog

1	Specify destination location • Select a previously used path from the Path drop-down menu, type a new path in the field, or click **Browse** to select another location. By default, the fields are populated with the options that were used for the last export. Click to reset the destination location to the default. • Create subfolder. Use the drop-down menus on the right to construct a subfolder name with existing data fields. • If you choose to overwrite existing data, a message appears to allow you to confirm.

2	File Format. Verify that the export destination has sufficient available space. • MLX is the RetCam Envision proprietary encrypted data format. • DCM is the filename extension for patient data files that are compatible with DICOM for ophthalmology. **NOTES**: ○ The DCM File option appears only if the DICOM option is included in your RetCam Envision system purchase. ○ Annotations on images are not transferred with DCM files. • Split File. If you select this format, the dialog expands and provides additional options (see below).
3	Split File Format options: • Export Images ○ Portable Network Graphic (PNG) 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. ○ JPG uses compression to reduce file size, which results in loss of resolution or quality in proportion to the amount of compression. • Add Text Overlays. Select the text overlays you want to include, and select the position of the overlays on the images. Note that text overlays apply to PNG and JPG image types only. • Export Data ○ Extensible markup language format (XML) ○ Comma separated values format (CSV) ○ Generic text format (TXT) • Export Video (AVI)

Import Data

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 Envision system, you must use the RetCam software to import the transferred images into the target system database.

NOTES:

- To ensure that exam date and time are displayed accurately, determine the time zone in which the patient data were originally captured. Create a domain with the location set to that time zone and import patient data into that domain.
- The Import operation can be time-consuming. The recommended maximum import per single batch is 3000 images. It is strongly recommended that you limit batch size by importing images from one patient at a time and by selecting only the images required for your immediate needs.
- Use the MLX format when importing images captured on another RetCam Envision system (or images from preceding RetCam systems using software version 6.3 and above).

To import data:

1. Verify that the drive from which to import is connected and ready.
2. In the Patients and Exams window, click

.
3. In the confirmation dialog, click **Yes**. Select the appropriate options in the Import Review dialog (Figure 29).
4. Click **Import**. This button is greyed out until files are selected. When the import process has completed, a report shows the number of records that were copied successfully.

NOTE: If any files were not imported, click **View Log** in the Import Report dialog for details. Click **OK** to close the report.

5. In the Patients and Exams window, click **Show All**, and confirm that the imported patient records are present.

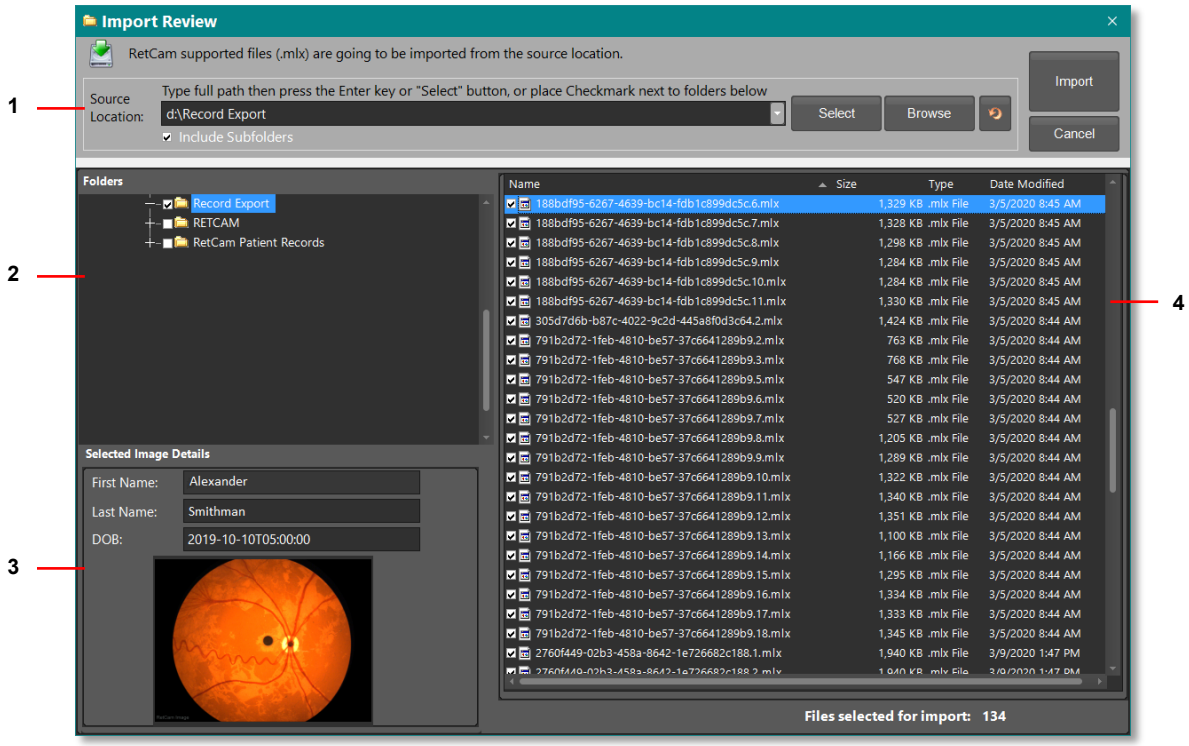


Figure 30. Import Review dialog

1	Source Location. By default, this field displays the source location used for the last import. • Type a new path in the field or click **Browse** to select another location. Check the Include subfolders checkbox if desired. • Click to reset the source location to the default. • Click **Select** to display the folders and files.
2	Folders. Use the checkboxes to select and deselect the folders that you want to import.
3	Selected Image Details. Select a file on the right to display details . If the file is a still image, a thumbnail of the image is displayed. If the file is a video, an image of a video reel is displayed.
4	List of files in a selected folder. Use the checkboxes to select and deselect the files that you want to import. The number of selected files is displayed at the bottom of the dialog.

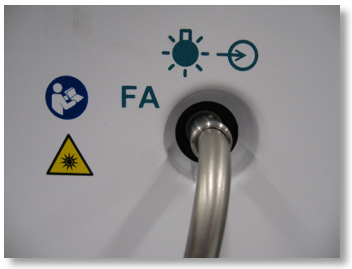
4. Fluorescein Angiography (FA)

NOTE: The FA light source is an option for the RetCam Envision system. Confirm that your system is equipped with the FA light source before scheduling an FA exam.

A narrow-band blue illumination source excites injected fluorescein circulating in the retinal vasculature. When exposed to the blue light, the fluorescein emits green light. A barrier filter in the handpiece rejects the blue light reflected by the retina; thus, the green emission is visible.

1. In the Patients and Exams window, start a new exam (click

).
2. Engage the FA barrier filter by sliding the FA switch on the handpiece toward the rear of the handpiece.
3. Plug the fiber-optic cable into the FA illumination port. If the blue LED above the Illumination button on the control panel does not illuminate, press the button to turn the FA lamp on. Blue light will emit from the handpiece.



4. In the Live Image window, ensure that Red-free/FA imaging is activated (the Red-free indicator is green and changes automatically to “ON”).
5. At the start of fluorescein dye injection, start the timer (click

), and simultaneously press the Capture button on the footswitch to capture one still image. At the end of the injection, capture another image to time-stamp the injection.
6. Capture still images as the dye circulates in the patient’s eye.

   NOTE:

   If using video capture:

   - In FA mode, the timer is controlled separately from the video. For example, when the video is paused or stopped, video capture is interrupted but the timer continues.
   - Pausing video capture does not save the video images. Stop video recording to extract and save images from the video.
7. If imaging the fellow eye, select the eye designation in the Eye field, and capture images of that eye.
8. When you are finished, pause the timer (click

), and exit the exam.

5. DICOM

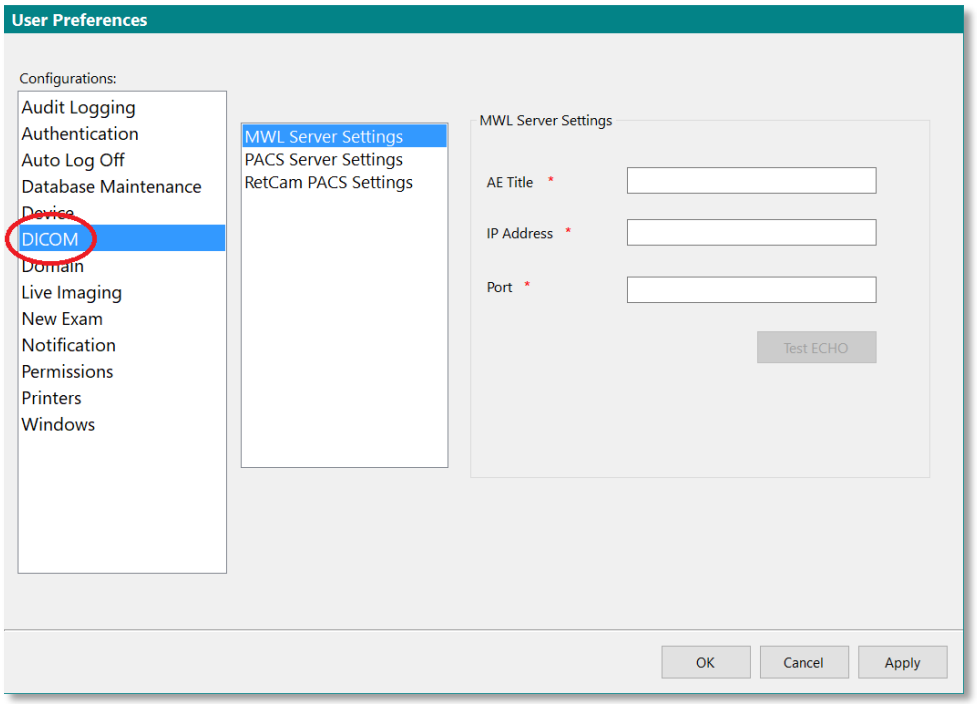
If the DICOM option is included in your RetCam Envision system purchase, you must have a license to configure and use DICOM on your RetCam Envision system.

Configure DICOM Settings

NOTE: Your user account must have permission to configure DICOM settings.

1. Verify that your RetCam Envision system is connected to the network and that the PACS server is accessible.
2. On your RetCam Envision system, copy the license key to the appropriate folder. Refer to the RetCam Envision DICOM License Configuration Work Instruction.
3. Shut down and then restart the system.
4. Log in.
5. Click on the Status bar, and select **User Preferences**.

   If DICOM is enabled and your user account has permission, the DICOM settings are available in the User Preferences dialog.



6. Select each group of settings and configure as appropriate.
7. When you are finished, click **OK**.

Import Ordered Exams

1. Verify that your RetCam Envision system is connected to the network.
2. To import the patient records for current-day ordered exams for the current RetCam Envision system, click

in the Patients and Exams window.

   If exams have been scheduled, the corresponding patient records are displayed.
3. Before conducting an exam, disconnect the system from the network.
4. Select a patient.
5. Start a new exam and capture images. Review and save the images as desired. For information on conducting an exam, see “Conduct a Patient Exam”.
6. Exit the exam. All saved images are automatically placed in a queue for transfer to the PACS server for archiving.
7. After exams have been concluded for the day, and before shutting down the system, connect the system to the network. All images will be transferred automatically.
8. To check the status of the transfer, open the Archive Queue. Click on the Status bar, and select **Archive Queue**. Note that this option is available to user accounts that have permission.

NOTES:

- Image annotations are not transferred to DICOM PACS.
- DICOM data cannot be imported.

6. Maintenance, Cleaning, and Technical Support

The RetCam Envision system has been delivered with firewall and antivirus services enabled and configured. Please contact Natus Technical Service for the latest revision of the RetCam Security Hardening Policy.

General Maintenance

The RetCam Envision system requires regular general maintenance to continue operating as designed.

General maintenance schedule:

- Between patients: Disinfect, clean, and inspect the lens piece.
- Weekly: Wipe down the system.
- Monthly: Inspect the cables and connections for wear.

For cleaning purposes, the RetCam Envision system is divided into two (2) categories:

- The lens piece (comes in contact with patients)
- The remainder of the system

Lens Piece Cleaning and Disinfection

Disinfect, clean, and inspect the lens piece between patients.

NOTE: To prevent the coupling gel from hardening on the lens piece, clean the patient contact area immediately after use.

Manual Cleaning

For manual cleaning using Super-Sani® Cloth wipes, CaviWipes™ Towelettes, neodisher® Mediclean Forte, or Prolystica® 2x Enzymatic Cleaner, follow these steps:

1. Use the prepared wipes or detergent prepared at the manufacturer's recommendation and lint-free cloths dampened with the prepared detergent solution.
2. Wipe to remove all visible soil.
3. Wipe to remove any chemical residue using a lint-free cloth dipped in tap water.
4. Dry using lint-free cloths, and then allow to air dry.

Intermediate-Level Chemical Disinfection

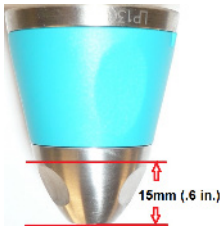
For intermediate-level chemical disinfection using CaviWipes™ Towelettes or Super-Sani® Cloth wipes, follow these steps:

1. Wipe and ensure that all surfaces remain visibly wet as follows: 4 minutes using Super-Sani® Cloth wipes or 3 minutes using CaviWipes™ Towelettes (use additional wipes if needed).
2. Wipe to remove any chemical residue using a sterile, lint-free cloth dampened with purified (PURW) water.
3. Dry using sterile, lint-free cloths, and then allow to air dry.

High-level Chemical Disinfection

For high-level chemical disinfection using Sporox® II Solution or Cidex® OPA Solution, follow these steps:

1. Equilibrate a bath of the disinfectant to 20°C.
2. Confirm the minimum effective concentration (MEC) of the disinfectant as indicated by the disinfectant manufacturer (several methods may be applicable).
3. Tilt the lens piece at a small angle and gradually immerse the front portion into the disinfectant (ensure that the lens piece is not lowered vertically, when the tip first enters the solution, to avoid trapping air at the tip).
4. Ensure that there is no air trapped between the concave surface of the optical window and the solution and that the liquid surface is not beyond the permitted immersion level (the surface of the disinfectant is not above the line between the stainless steel cap and the plastic housing). The immersion depth should be no more than 15 mm (0.6 in), as shown below.



5. When the front portion is immersed, the lens piece can sit vertically.
6. Soak as follows: 30 minutes in Sporox® II Solution or 12 minutes in Cidex® OPA Solution.
7. Rinse by immersing the front portion of the lens piece in purified (PURW) water, agitate, and allow it to set for a minimum of 1 minute.
8. Dry using sterile, lint-free cloths.

System Cleaning

As with any medical device, use good public health practices when handling the equipment, based on U.S. Centers for Disease Control (CDC) guidelines. In addition, gentle wiping with a cloth moistened with mild soap and water is recommended. Such cleaning must precede any service operations. Do not spray cleaning solutions on any part of the system.

Cables and Connections Inspection

Every month, verify that each cable and connection are properly attached to the RetCam Envision system. To eliminate the possibility of electric shock, replace cables or connections that show damage.

Disposal of Materials

Dispose of waste materials according to local and national requirements. Contact Natus Technical Service if you need additional assistance. See “Technical Support”.

WEEE Statement

Natus is committed to meeting the requirements of the European Union WEEE (Waste Electrical and Electronic Equipment) Regulations 2014. These regulations state that electrical and electronic waste must be separately collected for the proper treatment and recovery to ensure that WEEE is reused or recycled safely. In line with that commitment Natus may pass along the obligation for take back and recycling to the end user, unless other arrangements have been made. Please contact us for details on the collection and recovery systems available to you in your region at www.natus.com

Electrical and electronic equipment (EEE) contains materials, components and substances that may be hazardous and present a risk to human health and the environment when WEEE is not handled correctly. Therefore, end users also have a role to play in ensuring that WEEE is reused and recycled safely. Users of electrical and electronic equipment must not discard WEEE together with other wastes. Users must use the municipal collection schemes or the producer/importers take-back obligation or licensed waste carriers to reduce adverse environmental impacts in connection with disposal of waste electrical and electronic equipment and to increase opportunities for reuse, recycling and recovery of waste electrical and electronic equipment.

Equipment marked with the below crossed-out wheeled bin is electrical and electronic equipment. The crossed-out wheeled bin symbol indicates that waste electrical and electronic equipment should not be discarded together with unseparated waste but must be collected separately.

Technical Support

NOTE: The service life of the RetCam Envision system is at least 7 years.

When contacting Natus Medical Incorporated by telephone, please leave a message and provide the following information:

- Name
- Organization
- Contact information
- A description of the problem
- The system type (for example, RetCam Envision) and serial number

In addition, Natus Technical Service recommends that you send an e-mail message with the same information.

E-mail: service@retcam.com. Natus Technical Service responds to e-mails promptly. Our goal is to respond within 24 hours of receipt.

Telephone support is available Monday through Friday from 8 a.m. to 5 p.m., Pacific Time. If necessary, please leave a message. Natus Technical Service returns calls promptly.

Telephone: +1 650-802-0400

Toll-free: 1-888-496-2887 (U.S. and Canada only)

Mailing Address:

Natus Medical Incorporated
1183 Quarry Lane, Suite A
Pleasanton, CA 94566
USA

Service

For service questions, contact Natus Technical Service. See “Technical Support”.

Field Replacement Modules

For information on replacing a module, contact Natus Technical Service and provide the service part number. Refer to the list below.

Service Part Number	Description
18-000557-SERVICE	USB Hub
18-000572-SERVICE	Ethernet Isolator
18-000663-SERVICE	Fuse
60-000001-SERVICE	Handpiece
61-000090-SERVICE	CPU
61-000112-SERVICE	Instrument Control Module
61-000156-SERVICE	Power Supply Module
61-000005-SERVICE	Lithium Ion Battery
61-000010-SERVICE	Footswitch
61-000012-SERVICE	White LED Module
61-000033-SERVICE	Keyboard
61-000046-SERVICE	Blue LED Module
61-000056-SERVICE	Mouse
61-000069-SERVICE	Membrane
61-000091-SERVICE	Display Monitor
61-000166-SERVICE	Fortinet 30E Box
RETCAM-FA-UPGRADE	FA Upgrade Kit for RetCam Envision systems without FA
N/A	Power Cord – Must meet the following specifications: • Hospital grade • 305 cm (10 ft) maximum length • Rated at 10A (minimum) • UL/CSA listed • REACH, RoHS compliant

7. Troubleshooting

System Startup

Message	Condition or User Action	Corrective Action
BitLocker has not been enabled on the main data drive. Enabling BitLocker is recommended for improved security.	BitLocker was not enabled by an Administrator prior to a user's attempt to start the system.	See your RetCam Administrator.
Unable to connect to SQL server after 45 seconds.	The user attempted to start the system. The SQL service was installed but was turned off.	See your RetCam Administrator.
If the handpiece does not respond, it will not affect the functionality of the rest of the system. You may proceed, but the handpiece will not function. To regain use of the handpiece, reconnect it and then restart the system. If the issue persists, contact Natus Technical Service.	• The user disconnected the camera focus cable. • The handpiece or the camera focus cable is broken or has lost proper connection.	To regain use of the handpiece, reconnect it and then restart the system. If the issue persists, contact Natus Technical Service.

System Shutdown

Message	Condition or User Action	Corrective Action
This will shut down the system. Are you sure you want to continue?	The user attempted to shut down the system.	• Click **Yes** to shut down. • Click **No** to cancel shutdown.
The operating system could not be shut down.	A user who does not have permission attempted to shut down the system.	See your RetCam Administrator.

Patients and Exams

Message	Condition or User Action	Corrective Action
Warning: You might lose these media! <#> checked media item(s) have not been backed up. Do you want to continue?	The user attempted to remove selected media that have not been backed up.	• To cancel, click **No**. Back up the media and try again. • To continue without backing up the media, click **Yes**. Note that the removed media are not recoverable.

New Exam and Live Imaging

Message	Condition or User Action	Corrective Action
The following may be issues for Live Imaging: • System is running on battery, but it should be plugged in. Would you like to continue?	The user started a new exam while the system was running on battery power only.	Recommended action: Connect the system to AC power, and click **Yes**.
Light Source Error (Case: 1)	No fiber-optic cable is connected.	Reconnect the fiber-optic cable.
Light Source Error (Case: 2)	The FA switch is on, but no fiber-optic cable is connected.	Connect the fiber-optic cable to the FA light source, or turn the FA switch off and connect the fiber-optic cable to the white light source.
Light Source Error (Case: 9)	The light source was off, or the user turned the light source off.	Press the Illumination button on the control panel to turn on the light source.
Check FA cart connection (Case: 10)	The handpiece FA switch was on, and the camera was not connected to the FA light source.	Press the illumination button on the control panel to turn off the light source, and turn the handpiece FA switch off.
Check FA switch on HP (Case: 12)	FA mode was not activated: The handpiece FA switch was on, or the user turned the FA switch on.	Turn the handpiece FA switch off.
Check FA switch on HP, check control panel light indicator (Case: 17)	FA mode was activated: Both the handpiece FA switch and illumination were off.	• Turn the handpiece FA switch on. • Press the Illumination button on the control panel to turn on the light source.
Check control panel light indicator (Case: 18)	FA mode was activated: Illumination was off, or the user turned illumination off.	Press the Illumination button on the control panel to turn on the light source.
Check FA switch on HP (Case: 21)	FA mode was activated: The FA filter was off, or the user turned the FA switch off.	Turn the handpiece FA switch on.
There was an error while capturing media. Consult the log for details.	The user attempted to capture images.	See your RetCam Administrator.
Exam will NOT be saved; no images/videos have been captured. Are you sure this is OK? Select “Yes” to confirm or “No” to return to exam.	The user attempted to exit live imaging without capturing any images or videos.	• Click **Yes** to exit. • Click **No** to cancel and return to live imaging.
Exam will NOT be saved; the exam contains images/videos but none are set to be saved. Are you sure this is OK? Select “Yes” to confirm or “No” to return to exam.	The user attempted to exit live imaging with all captured media marked for deletion.	• Click **Yes** to exit. No media will be saved. • Click **No** to cancel and return to live imaging.
Please do not shut down the system due to possible data loss.	The user pressed the Shutdown button on the control panel.	Click **OK** to cancel shutdown and continue with live imaging.

Exam Review

Message	Condition or User Action	Corrective Action
Please do not shut down the system due to possible data loss.	The user pressed the Shutdown button on the control panel.	Click **OK** to cancel shutdown and continue with exam review.

Import

Message	Condition or User Action	Corrective Action
If you are importing from a removable drive, it must be connected before you begin the import process. Are all necessary drives ready?	The user attempted to import data from a removable drive.	Verify that the drive from which to import is connected and ready, and click **Yes**.

Print

Message	Condition or User Action	Corrective Action
There is no printer installed on the system.	The user attempted to print.	See your RetCam Administrator.
Printer appears to be off-line or disconnected. Please check and try again.	The user attempted to print.	See your RetCam Administrator.

User Preferences

Message	Condition or User Action	Corrective Action
Custom watermark cannot be larger than 640x100. Please use a smaller image.	Live Imaging configuration: The user attempted to load a watermark.	Load a smaller image.
Custom watermark cannot be smaller than 160x32. Please use a larger image.	Live Imaging configuration: The user attempted to load a watermark.	Load a larger image.
Error trying to load the custom watermark to verify: {exception message}.	Live Imaging configuration: The user attempted to load a watermark that is not an image file.	Load an image file.
Cannot load the custom watermark to verify.	Live Imaging configuration: The user attempted to load a watermark.	The file format may be wrong. Load an image file that is in the correct format.
No index with fragmentation level equal or higher than " + threshold + "% is being found.	Database Maintenance configuration: The user checked the statistics, and the fragmentation level was less than the specified level (default is 15).	This message is for informational purposes.

Message	Condition or User Action	Corrective Action
{0} of the audit log files could not be deleted. (**NOTE**: {0} indicates the number of files.)	Audit Logging configuration: The user attempted to delete audit logs.	This message is for informational purposes.

Other Error Conditions

Message	Corrective Action
User does not have permission to log in.	See your RetCam Administrator. The user account might be disabled.
Fatal error, could not write error to file.	See your RetCam Administrator.
There was an error while toggling freeze/stop recording. Consult the log for details.	See your RetCam Administrator.
Unable to play video, attempt number <#>.	See your RetCam Administrator. Possible causes: • The selected video file was deleted. • An old video was imported (for example, RetCam 4.1 or older).
captureGraphBuilder is null!	See your RetCam Administrator.

8. Utilities

NOTE: The options available in the Utilities pop-up menu are based on the permissions assigned to your user account. Figure 31 is an example, and the complete list of options is described in the table that follows.

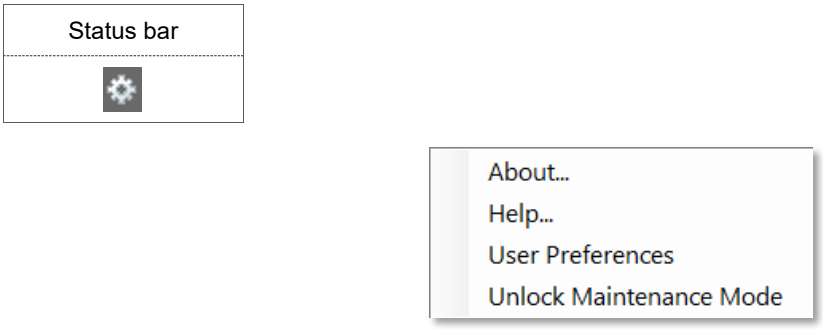


Figure 31. Utilities Menu

About	Displays the RetCam Envision system software version and other system information. For license information for third-party software used in RetCam Envision, click **Software Licenses** in the About dialog.
Help	Displays a PDF copy of the RetCam Envision User Manual.
Image Audit	For RetCam Administrator use only.
System Logs	For RetCam Administrator use only.
User Preferences	Opens the User Preferences window. See “Configure User Preferences”.
Manage Users	Create and modify user accounts, and reset passwords. For RetCam Administrator use only. See “Manage Users”.
Unlock Maintenance Mode	Provides access to system maintenance and other tasks. For RetCam Administrator use only. The system will prompt for the Maintenance Mode password. This option is greyed out if the system is in Maintenance Mode.

Configure User Preferences

NOTE: Your user account must have permission to configure user preferences. If your user account does not have permission, the configuration options are either not available or disabled.

Utilities menu
User Preferences

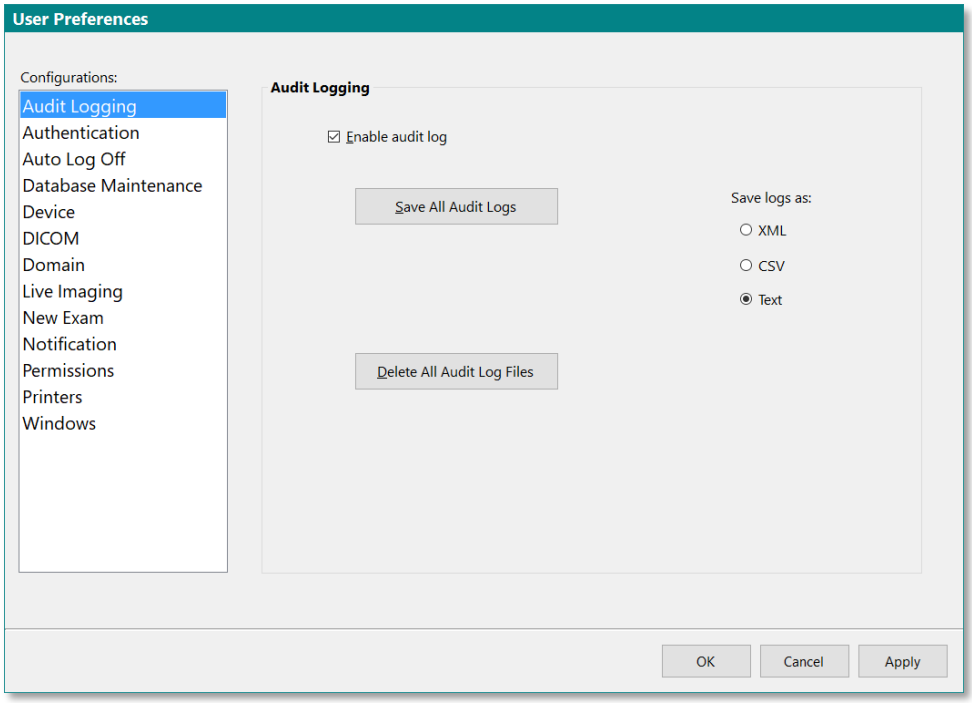


Figure 32. User Preferences Window

Audit Logging	Configure the system audit logs.
Authentication	Configure authentication for local devices and networks. Active Directory options are visible only to user accounts that have permission. For network authentication, you have the option to allow users to authenticate using Active Directory, and if so, you can optionally require it. To create a user with Active Directory authentication, see “Create a User Account”.
Auto Log Off	Configure automatic logoff. **NOTE**: Auto Log Off does not apply during an exam if certain dialogs are open or under other circumstances that would cause data loss.
Database Maintenance	Maintain database functions.
Device	Manage the device name and serial number.
DICOM	Configure DICOM (available only if DICOM is installed). For more information, see “DICOM”.
Domain	Configure domains. See “Configure Domains”.
Live Imaging	Configure camera device, live imaging file size, and custom watermarks.

New Exam	Configure the imaging configurations for new exams.
Notification	Manage messages for general use, import/export activities, imaging library, media removal, and hardware.
Permissions	Manage user roles and permissions. See “User Roles and Permissions”.
Printers	Set the default printers.
Windows	Provides access to Windows functions. Some functions are available only to user accounts that have permission, and some functions are available only in Administrator/Service/Maintenance mode.

Configure Domains

NOTE: The RetCam Envision system requires at least one (1) domain. A default domain called “RetCam” is included with your system.

From User Preferences
Domain

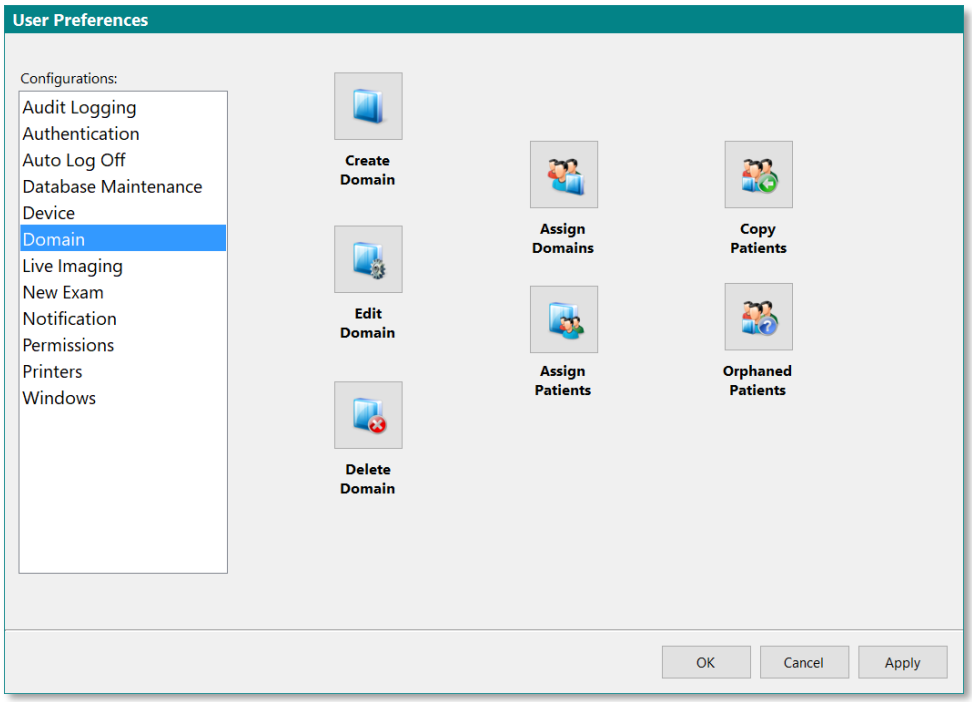


Figure 33. Domain Configuration Options

	Create a domain. See “Create a Domain”.
	Edit a domain. See “Edit a Domain”.
	Delete a domain. Only user accounts that have permission can delete domains.

	Assign domains to patients.
	Assign patients to domains.
	Copy patients to other domains.
	Assign orphaned patients to a domain.

Create a Domain

From Select Domain dialog	From User Preferences, **Domain** selected
Create Domain	

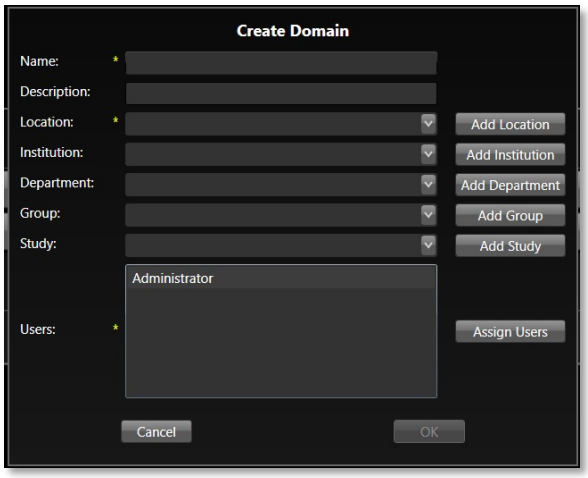


Figure 34. Create Domain dialog

Name	(Required) The domain name displays throughout the RetCam Envision system. Enter a name that is meaningful and recognizable to all users.
Description	Enter a description.
Location	(Required) Identifies the geographic location of the RetCam Envision system. Additionally, it defines the time zone of that system. Select the appropriate location from the drop-down menu. Add a new location, or create or change the time zone if necessary. The time zone setting is used to display the date and time of a patient exam in your local time zone.
Institution	Select the appropriate institution from the drop-down menu. Add an institution if necessary.
Department	Select the appropriate department from the drop-down menu. Add a department if necessary.
Group	Select the appropriate group from the drop-down menu. Add a group if necessary.
Study	Select the appropriate study from the drop-down menu. Add a new study if necessary.
Users	(Required) Displays a list of users who have access to this domain. Add users or modify assignments if necessary.

Edit a Domain

From User Preferences, **Domain** selected

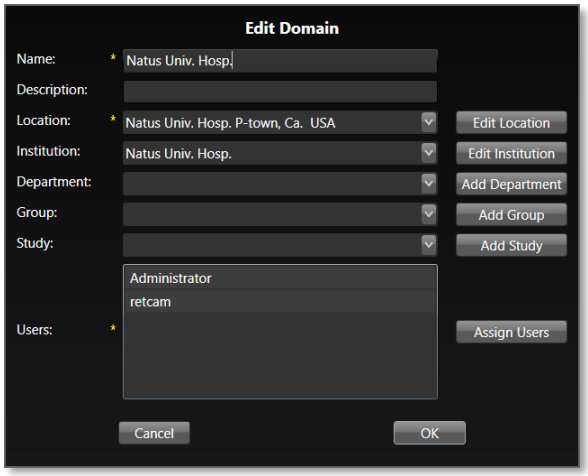


Figure 35. Edit Domain dialog

Name	(Required) Edit the domain name as desired.
Description	Enter a description.
Location	(Required) Select the appropriate location from the drop-down menu. Edit location information if necessary.
Institution	Select the appropriate institution from the drop-down menu. Add or edit an institution if necessary.
Department	Select the appropriate department from the drop-down menu. Add or edit a department if necessary.
Group	Select the appropriate group from the drop-down menu. Add or edit a group if necessary.
Study	Select the appropriate study from the drop-down menu. Add or edit a study if necessary.
Users	(Required) Displays the list of users who have access to this domain. Assign users to the domain if necessary.

Manage Users

NOTES:

- Only the RetCam Administrator account can be used to create and edit user accounts and passwords.
- User accounts cannot be deleted.
- To configure the permissions for a user account, see “Configure Roles and Permissions”.

Create a User Account

From Utilities menu
Manage Users > Create User

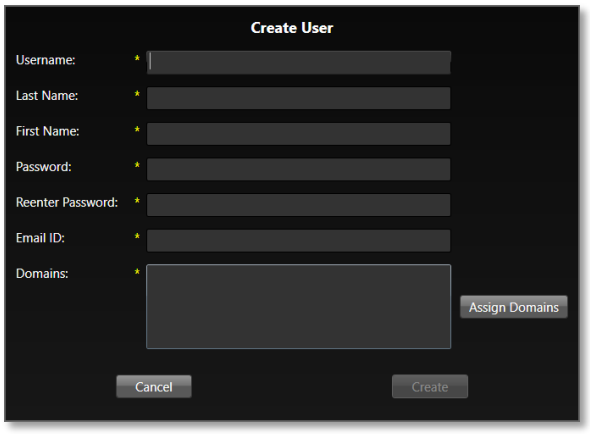


Figure 36. Create User Dialog

NOTE: All fields are required, unless the user will be authenticated using Active Directory only. See “Network Authentication”.

Username	Provide a unique identifier for the user. This name is displayed throughout the RetCam Envision system. Your healthcare facility should follow a defined system of assignment so that users can recognize one another easily. The username is not case-sensitive. **NOTE**: For Active Directory authentication, the username must already exist in the domain.
Last Name	User’s last name
First Name	User’s first name
Password Reenter Password	This is a temporary password. The password entered in both fields must match. The new password must be at least six (6) characters long and include at least one (1) numeric character. **NOTE**: For Active Directory authentication, the password is not used.
Email ID	User’s e-mail address for all RetCam system work. **NOTE**: For Active Directory authentication, the email address is not used.
Domains	Assign domains to the user account if necessary. See “Assign Domains to a User Account”.

Network Authentication

For Active Directory logins, you can either require authentication against Active Directory or give users the option to authenticate against Active Directory. See the available options in Figure 37.

From User Preferences
Authentication

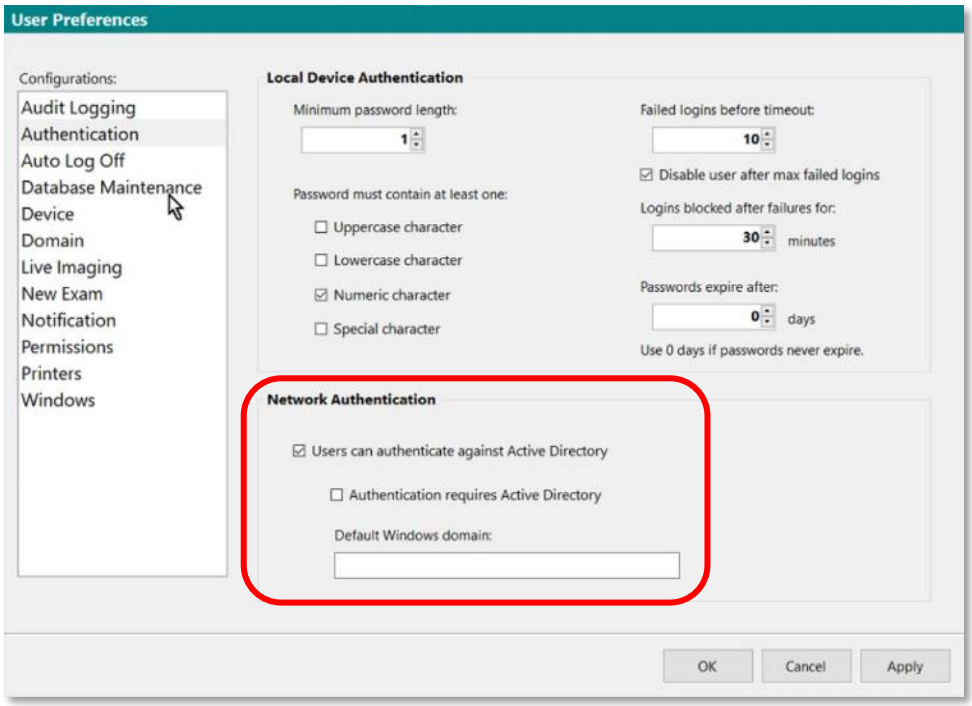


Figure 37. Network Authentication Options

Edit a User Account

From Utilities menu
Manage Users > Modify User, select user

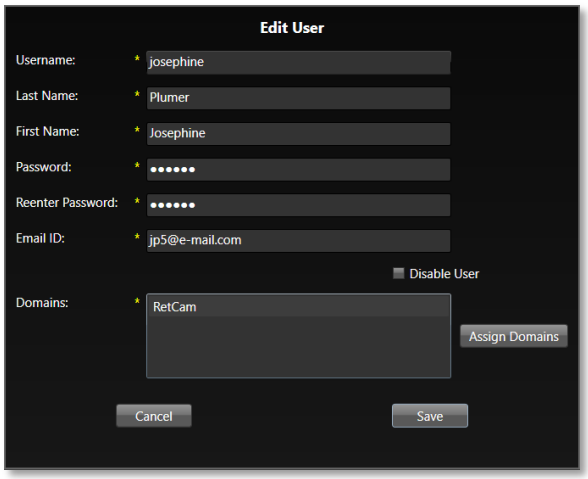


Figure 38. Edit User Dialog

NOTE: All fields are required.

Username	Provide a unique identifier for the user. This name is displayed throughout the RetCam Envision system. Your healthcare facility should follow a defined system of assignment so that users can recognize one another easily. The username is not case-sensitive.
Last Name	User's last name
First Name	User's first name
Password Reenter Password	**NOTE**: Do not select these fields, unless you want to change the user's password. Selecting either Password field clears the password. To preserve the user's password in case it was cleared by accident, press **Cancel** and start over. The password entered in both fields must match. The new password must be at least six (6) characters long, include at least one (1) numeric character, and it must be different from the old password.
Email ID	User's e-mail address for all RetCam system work
Disable User	Select this checkbox to disable the user account.
Domains	Assign domains to the user account if necessary. See "Assign Domains to a User Account".

Assign Domains to a User Account

From Create User dialog or Edit User dialog
Assign Domains

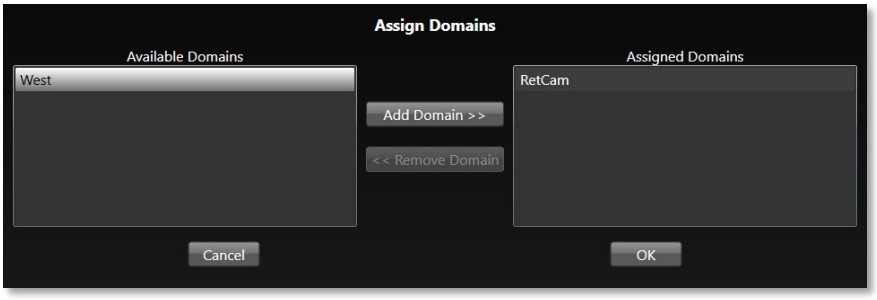


Figure 39. Assign Domains Dialog

You must assign at least one (1) domain to a user account.

Password Reset

NOTES:

- Only the RetCam Administrator account can be used to reset user passwords.
- The new password must be at least six (6) characters long, include at least one (1) numeric character, and it must be different from the old password. This password rule applies to all user roles.

From Utilities menu
Manage Users > Reset Password

Figure 40. Reset Password Dialog

Following a password reset, the user will be required to change the password upon first login.

User Roles and Permissions

User accounts are assigned roles, which determine the degree of access and the tasks that can be performed on your RetCam Envision system. The RetCam Administrator has the highest level of access and can modify roles, add roles, and assign permissions.

The standard roles are:

- General RetCam
- RC Imager
- RetCam Administrator

Roles are granted permissions in these categories:

- General
- Patient
- Exams
- Import/Export
- Special
- Administrative

Configure Roles and Permissions

From User Preferences

Permissions

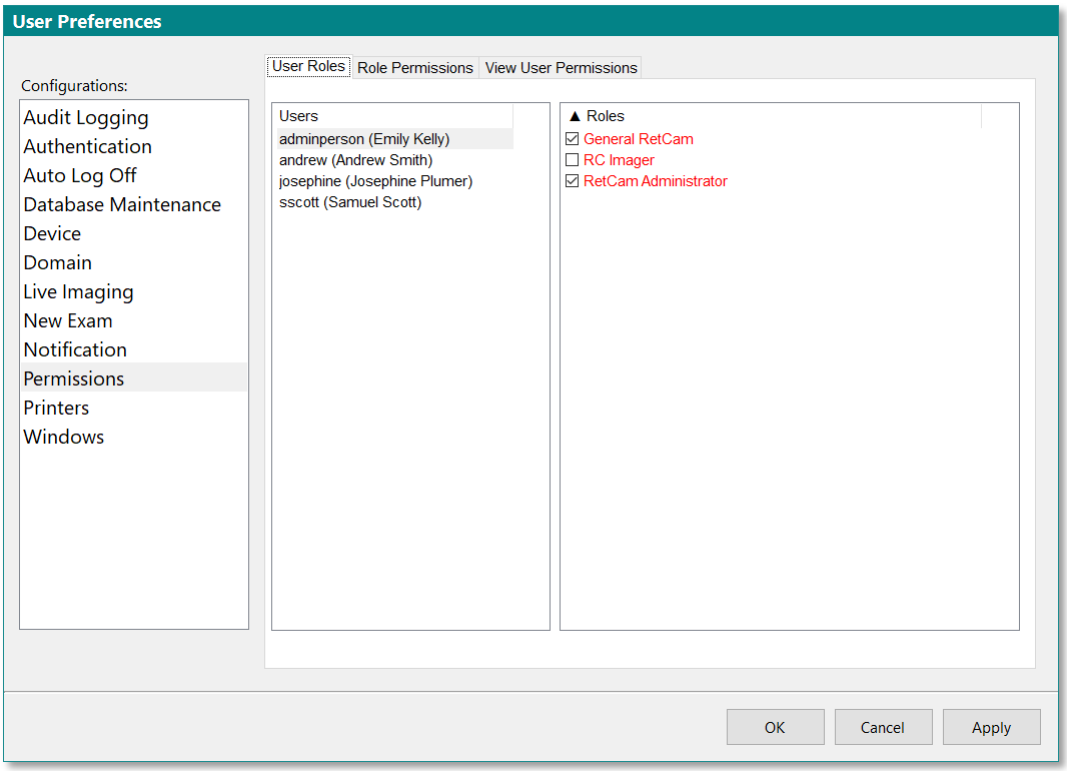


Figure 41. Permissions Configuration Options

In the User Roles tab, select the user and apply the desired roles. To view the permissions, select the Role Permissions and View User Permissions tabs.

9. Safety and Labeling

Electrical Safety

The system was designed, inspected, and tested to comply with the safety requirements of IEC 60601-1 with respect to fire, shock, and mechanical hazards only if used as intended.

Class I Type BF Electrical Equipment

Rated for Continuous Operation

IEC 60601-1: 2005 Corrigendum 1 + Corrigendum 2

Accessories equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e., IEC60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1 and 60601-1-2. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible to ensure the system complies with the requirements of the system standard IEC 60601-1 and 60601-1-2. If in doubt, contact Natus Technical Services.

RetCam Envision Electromagnetic Emissions		
Compliance Level: Group 1, Class A		
Test Type	**Compliance Level**	**Notes**
Radiated Emissions CISPR 11/ EN 55011	Group 1, Class A	The RetCam Envision system generates RF energy related only to internal function. System RF emissions are very low and unlikely to cause any interference in nearby electronic equipment. The RetCam Envision system is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following is heeded: **NOTE**: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Conducted Emissions CISPR 11/ EN 55011	Group 1, Class A	
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/flicker emissions EN 61000-3-3	Complies	
FCC Part 15B	Complies	

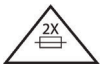
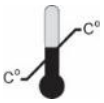
RetCam Envision Electromagnetic Immunity			
Test Type	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge (ESD) EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transients (AC Power) (I/O Lines) EN 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment. Electronic disturbances (transients) in AC power may cause the system display to scroll continuously. If this occurs, imaging should not proceed until the disturbance ceases.
Surges Line to Line and Surges Line to Earth (AC Power) (I/O Lines) EN 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Voltage Variations on Power Supply Input Lines, and Short Voltage Interruptions EN 61000-4-11	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	Mains power quality should be that of a typical commercial or hospital environment.
	0% U_T for 1 cycle and 70% U_T for 25/30 cycle, single phase at 0°	0% U_T for 1 cycle and 70% U_T for 25/30 cycle, single phase at 0°	
	0% U_T for 250/300 cycles	0% U_T for 250/300 cycles	
Power Frequency (50/60 Hz) magnetic field EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

RetCam Envision Electromagnetic Immunity			
Test Type	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Radiated Immunity EN 61000-4-3	80 MHz-2.7 GHz 3 V/m 80%@1 kHz Proximity Fields: 385 MHz, 18 Hz pulse mod, 27 V/m 450 MHz, FM mod, ±5 kHz dev, 1 kHz sine, 28 V/m 710 MHz, 745 MHz, and 780 MHz, 217 Hz pulse Mod, 9 V/m 810 MHz, 870 MHz, 930 MHz, 18 Hz pulse mod, 28 V/m 1720 MHz, 1845 MHz, and 1970 MHz, 217 Hz pulse mod, 28 V/m 2450 MHz, 217 Hz pulse mod, 28 V/m 5240 MHz, 5500 MHz, and 5783 MHz, 217 Hz pulse mod, 9 V/m	3 V/m 28 V/m 28 V/m 9 V/m 28 V/m 28 V/m 28 V/m 9 V/m	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 = 1.2 $\sqrt{P}$ d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz to 2.7 GHz where $\sqrt{P}$ 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).
Conducted Immunity EN 61000-4-6	0.15-80 MHz 3 Vrms 0.15-80 MHz 6 Vrms in ISM bands 80%@1 kHz	3 Vrms 6 Vrms 80%@1 kHz	

Labels and Symbols

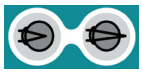
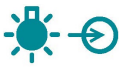
Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
Rx Only	21 CFR 801.109(b)(1)	Labeling-Prescription devices.	Prescription only	Indicates the product is authorized for sale by or on the order of a licensed healthcare practitioner
Medical Device	Not applicable	Not applicable	An indication of Medical Device	This product is a medical device.

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	Not applicable	Not applicable	No presence of natural Latex Rubber	Medical device does not contain natural rubber latex
	ISO-60601-1, Table D.2 #10	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Follow Instructions for Use	Refer to instruction manual/Booklet. NOTE on ME EQUIPMENT “Follow Instructions for use”
	ISO-15223-1, Symbol 5.4.3	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied.	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.
	ISO 60601-1 Table D.1 #11	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Operating instructions	
	ISO 7000/IEC-60417, Symbol 3500	Graphical symbols for use on equipment	Electronic Instructions For Use	To indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.
	IEC-60417; 2002-5194	Graphical symbols for use on equipment	AC/DC Power Indicator	To identify the system operates on DC or AC
	ISO-7000/IEC-60417, Symbol 5019	Graphical symbols for use on equipment	Protective earth; protective ground	To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	IEC-60601-1, Table D.1 #1	Medical electrical equipment — Part 1: General requirements for basic safety and Essential performance.	Alternating current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	IEC-60417: 2002-5016	Graphics symbols for use on equipment	To identify fuse	System contains 2 fuses of indicated type. Do not use any other type.
	IEC/TR 60878 Symbol 5988	Graphical system for electrical equipment in medical practice.	Computer network	To identify the computer network itself or to indicate the connecting terminal of the computer network.
	ISO-7000/IEC-60417 Symbol 5140	Graphical Symbols for use on equipment	Non-ionizing electromagnetic radiation	Indicates generally elevated, potentially hazardous, levels of non-ionizing radiation
	IEC 62471-2	Photobiological safety of lamps and lamp systems – Part 2: Guidance on manufacturing requirements relating to non-laser optical radiation safety.	Warning: Optical Radiation, do not look directly into light source.	Indicates not to look directly into the light source
	ISO-7000/IEC-60417 Symbol 0621	Graphical Symbols for use on equipment	Fragile, handle with care	Indicates that the contents of the transport package are fragile, and the package shall be handled with care.
	ISO-7000: 2014-0623	Graphical Symbols for use on equipment	This way up	To indicate correct upright position of the transport package.
	ISO 15223-1 Symbol 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Storage Temperature range	Indicates the (storage) temperature limits to which the medical device can be safely exposed

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	ISO 15223-1 Symbol 5.3.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Storage Humidity range	Indicates the range of (storage) humidity to which the medical device can be safely exposed
	ISO 15223-1 Symbol 5.3.9	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied.	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO-15223-1, Symbol 5.3.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO-15223-1 Symbol 5.1.7	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO-15223-1 Symbol 5.1.6	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied.	Catalogue or model number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Symbol 5.1.1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied.	Manufacturer	Indicates the medical device manufacturer
	ISO-15223-1 Symbol 5.1.3	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied.	Date of Manufacture	Indicates the date when the medical device was manufactured.
	ISO-15223-1 Symbol 5.1.2	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied.	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	MDR 2017/745	EU Medical Device Regulation	CE marking	Signifies European technical conformity

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	IEC-60529	Degrees of protection provided by enclosures (IP Code)	Degree of Ingress Protection Provided by Enclosure	Protected against the effects of continuous immersion in water.
	IEC-60529	Degrees of protection provided by enclosures (IP Code)	Protected against dripping water	Indicates that the device is protected against the effects of vertically falling water
	ISO-60601-1 Table D.2 #2	Medical electrical equipment — Part 1: General requirements for basic safety and Essential performance.	General warning sign	Indicates a hazard of potential personal injury to patient or operator
	ISO-15223-1, Symbol 5.4.4	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied.	Caution: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 60601-1 Table D.1 #10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.		
	2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)	Disposal at the end of operating life instructions	Indicates that electrical and electronic equipment waste should not be discarded together with unseparated waste but must be collected separately
	N/A	Test Mark	North American compliance certification	Indicates that product has been tested and certified by TUV Rheinland
	IEC/TR 60878 Symbol 5009	Graphical symbols for electrical equipment in medical practice,	System Power button	Standby – To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the standby condition

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	Not applicable	Not applicable	Focus controls	Buttons on the control panel for adjusting focus
	Not applicable	Not applicable	Lamp Illumination button	Buttons on the control panel and footswitch for turning the lamp on and off
	Not applicable	Not applicable	Illumination Intensity controls	Buttons on the control panel and footswitch for adjusting illumination intensity
	Not applicable	Not applicable	Capture (or SNAP)	Button on the control panel and footswitch for capturing still images and for starting and pausing video recording
	Not applicable	Not applicable	Illumination cable port	Indicates the location of the Illumination cable port
	Not applicable	Not applicable	FA Illumination cable port	Indicates the location of the FA Illumination cable port
	Not applicable	Not applicable	Handpiece camera port	Indicates the location of the handpiece camera port
	Not applicable	Not applicable	Camera control port	Indicates the location of the camera control port
	Not applicable	Not applicable	Fluorescein Angiography (FA)	Indicates FA
	IEC 62680-2-1	Universal Serial Bus interfaces for data and power Part 2-1: Universal Serial Bus Specification, Revision 2.0 (TA 14)	USB connector	To indicate that the device is plugged into a USB port or is compatible with a USB port
	IEC-62680-2-1	Universal Serial Bus interfaces for data and power Part 2-1: Universal Serial Bus Specification, Revision 2.0 (TA 14)	USB 3.0 connector	To indicate that the device is plugged into a USB 3.0 port or is compatible with a USB port

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	ISO-60601-1, Table D.1 #20	Medical electrical equipment — Part 1: General requirements for basic safety and Essential performance.	Type BF Applied Part	To identify a type BF applied part complying with IEC 60601-1.
	Not applicable	Not applicable	Store handpiece in holster when not in use	Indicates to store the handpiece in the holster to prevent damage to the lens piece
	Not applicable	Not applicable	Clean lens piece after use	Indicates to clean the lens piece after use

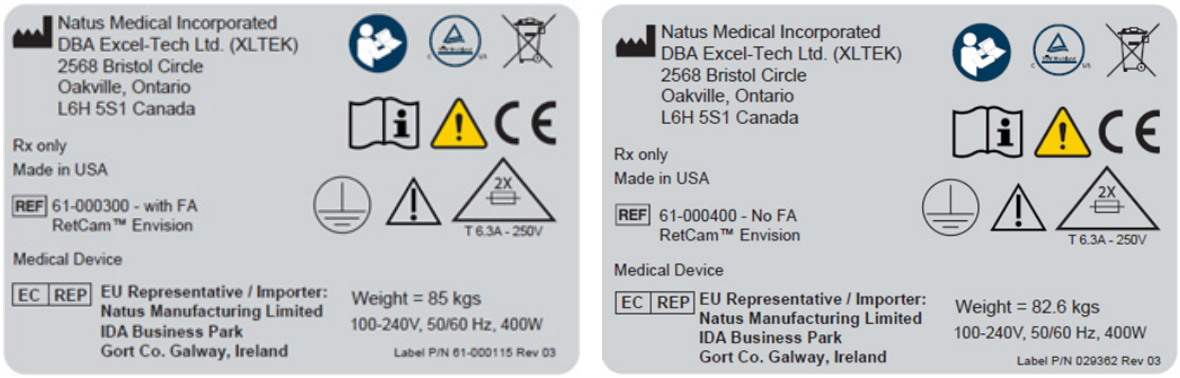


Figure 42. Device Label: With FA (left), No FA (right)

10. Technical Specifications

NOTE: Specifications are subject to change without notice.

Hardware and Software

Physical	Dimensions: 660 mm (26”) wide x 610 mm (24”) deep x 1372 mm (54”) minimum height Weight: • With FA: Approximately 85 kg (188 lbs) fully loaded • Without FA: Approximately 82.6 kg (182 lbs) fully loaded
Electrical	Ratings: 100-240 V~, 50/60 Hz, 400 VA Fuses: 3AG 6.3A 250V slo-blo 5 x 20 mm Power consumption: 400 W maximum with all options Detachable hospital-grade power cord
CPU and Storage	Intel® Core i7 16 GB Random Access Memory 1 TB Solid State Storage Drive
Operating System	Microsoft Windows® 10 operating system (OS) **NOTE**: For security purposes, the Task Manager for the Microsoft Windows OS is not available to most user accounts. Only the RetCam Administrator user account is granted access.

Environmental Conditions

The system as delivered is intended for use indoors, at normal room temperatures and humidity, and positioned upright on a level surface with the wheels locked.

Temperature	
Operating Storage (unboxed) Transport (in original shipping material)	50º F to 95º F (10º C to 35º C) 14º F to 131º F (-10º C to 55º C) -20º F to 122º F (-29º C to 50º C)
Relative Humidity	
Operating Storage (unboxed) Transport (in original shipping material)	30% to 90% noncondensing 30% to 90% noncondensing 10% to 85% noncondensing
Atmospheric Pressure	
Operating Storage (unboxed) Transport (in original shipping material)	70 to 106 kPa (20.7 to 31.3” Hg) 70 to 106 kPa (20.7 to 31.3” Hg) 50 to 106 kPa (14.7 to 31.3” Hg)
Altitude	
Operating Storage (unboxed) Transport (in original shipping material)	-382 to 3012 meters (-1255 to 9882 feet) -382 to 3012 meters (-1255 to 9882 feet) -382 to 5574 meters (-1255 to 18,288 feet)

Appendix A. RetCam Envision Unpacking and Setup

Unpack the System

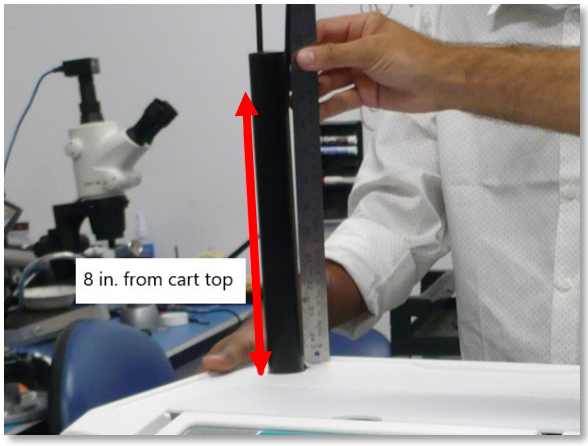
1. Remove the front panel of the crate and set it down to serve as a ramp.
2. Release the brakes on the wheels and carefully roll the cart out of the crate.
3. Remove all packing material from the system.
4. Unpack the box containing the monitor.
5. Unpack the accessories box.

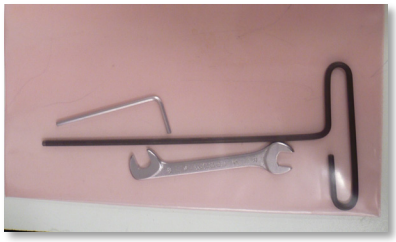
Set up the System

Install the monitor:

1. Mount the display monitor to the monitor arm using the 4 thumbscrews provided (thumbscrews are threaded into the back of the display monitor).
2. Install the monitor arm and attached monitor on the monitor arm pole with the supplied tools in the tool bag.

   Note: Verify that the position of the stop ring on the monitor pole is less than or equal to 20 cm (8 inches) above the cart top.





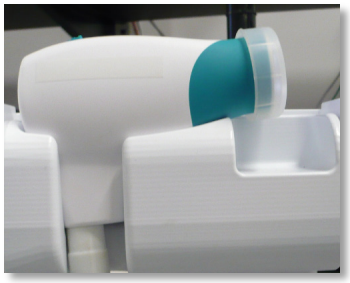
3. Ensure that the display power switch is in the on position, and then connect the monitor power cable, display-port cable, and USB cable to the back of the monitor.

   NOTE: You can rotate the monitor 90 degrees to facilitate connecting the cables. Return the monitor to the normal position.

Install the handpiece:

1. To provide access to the handpiece connectors, the drawer needs to be removed. Slide the drawer out from the front of the system until it stops.
2. Using two hands, lift the black plastic tab on the guides on both sides of the drawer to release the drawer from the side rails. Remove the drawer.

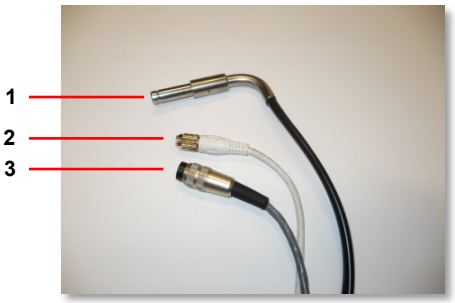
3. Carefully lift the handpiece and its harness from the packing foam and place the handpiece in the holster that is molded into the right side of the cart top.

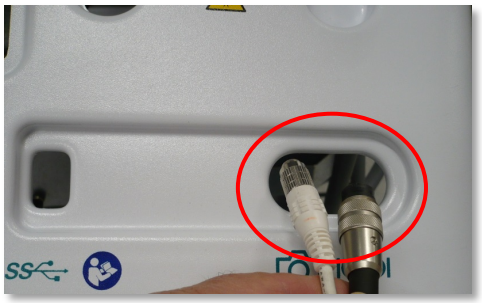


4. Wrap the handpiece harness in a loose coil around the wrap post.

5. Gently unsnap and remove the front cover from the system by prying along the cover edges and drawer opening using only fingertip pressure.

6. Before connecting the handpiece harness, ensure that the main power switch on the back of the cart is off.
7. Feed the connectors on the camera (2) and focus (3) cables through the opening in the front cover. The fiber optic cable (1) is connected separately into the illumination port.

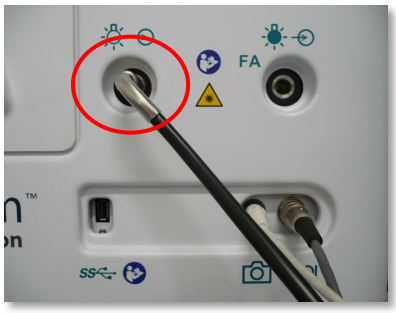




8. Connect the handpiece camera and focus cables to their corresponding ports in the instrument control module behind the front cover.
9. The threaded connector on the focus cable is indexed to the receptacle at the right front of the instrument control module by a tab at the top. Locate the tab in the cable connector, ensure it is in line with the slot in the receptacle, plug in the cable connector, and turn the threaded collar until the collar is fully engaged.

10. Connect the camera cable to the receptacle next to the focus cable on the instrument control module. The connector on the camera cable is indexed to its receptacle by a slot at the bottom of the connector. Make sure the slot aligns properly with the receptacle and carefully thread the connector into the receptacle until it is tight.

11. Reinstall the front cover.
12. Reinstall the drawer. Position the rails on the drawer guides, engage the plastic tabs, and close the drawer.
13. Plug the fiber-optic connector into the illumination port on the left. The illumination port on the right is available only in systems with the FA option.



NOTE: For complete information on the handpiece, see “Handpiece”.

Power on the System

1. Turn on the main power switch.
2. Press the Power button on the control panel.
3. Log in to the system using the Administrator account and password provided with the system.
4. Follow the on-screen prompts to change the password.
5. Create and select a domain as described in “Create a Domain”.
6. Add users or set up Active Directory users as described in “Manage Users”.
7. Create a test patient and operate the device for the first time as described in “System Preparation and Operation”.

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