phoenix | ICON™

# Instructions for Use

OPL-0016-19

How to use the Instructions for Use:

This manual is divided into four sections with a table of contents at the start of each one.

Section headers are as follows:

**Section 1:** System Hardware

**Section 2:** Using the Phoenix ICON™ Hand Piece and Phoenix ICON™ Software

**Section 3:** Phoenix ICON™ System Cleaning Procedures

**Section 4:** Phoenix ICON™ Quick Start Guides

# User's Guide

## Section 1: Phoenix ICON Cart

**Caution: Federal law restricts this device to sale by or on the order of a physician.**

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Pleasanton, CA 94588, USA
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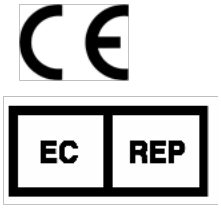


**MDSS GmbH**
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30175 Hannover, Germany

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# 1. Indications for Use

The Phoenix Technology Group, LLC. Phoenix ICON™ system is indicated for general ophthalmic imaging including retinal, corneal, and external structures of the eye.

# 2. Device Description

The Phoenix ICON™ imaging system is equipped with optics designed to capture images and videos of the retina, cornea, and external eye through contact methods. Captured media may be saved and exported.

The Phoenix ICON™ consists of a camera within a handpiece that uses a low power light emitting diode (LED) light source to illuminate the retina. The camera utilizes the very latest in sensitive CMOS sensor technology, allowing for low light levels, which reduces stress on sensitive patients.

The Phoenix ICON™ (Model Number: PCI 40-1000) comprises of several components:

- Cart housing a Computer, Monitor, Keyboard and Control Box (Model Number: PCI 40-1001)
- Handpiece (Model Number: PCI 40-1002)
- White Light LED Module (Model Number: PCI 40-1005)
- Blue Light LED Module (Model Number: PCI 40-1004 option for fluorescein angiography)
- Foot pedal (Model Number: PCI 30-1000, not sold separately)
- Diffuser (Model Number: PCI 40-1017)

The handpiece has two detachable LED modules. One is white light for general color imaging; the other is a blue LED for fluorescein angiography. A barrier filter is moved in place using a lever on the handpiece, depending on the LED module being used.

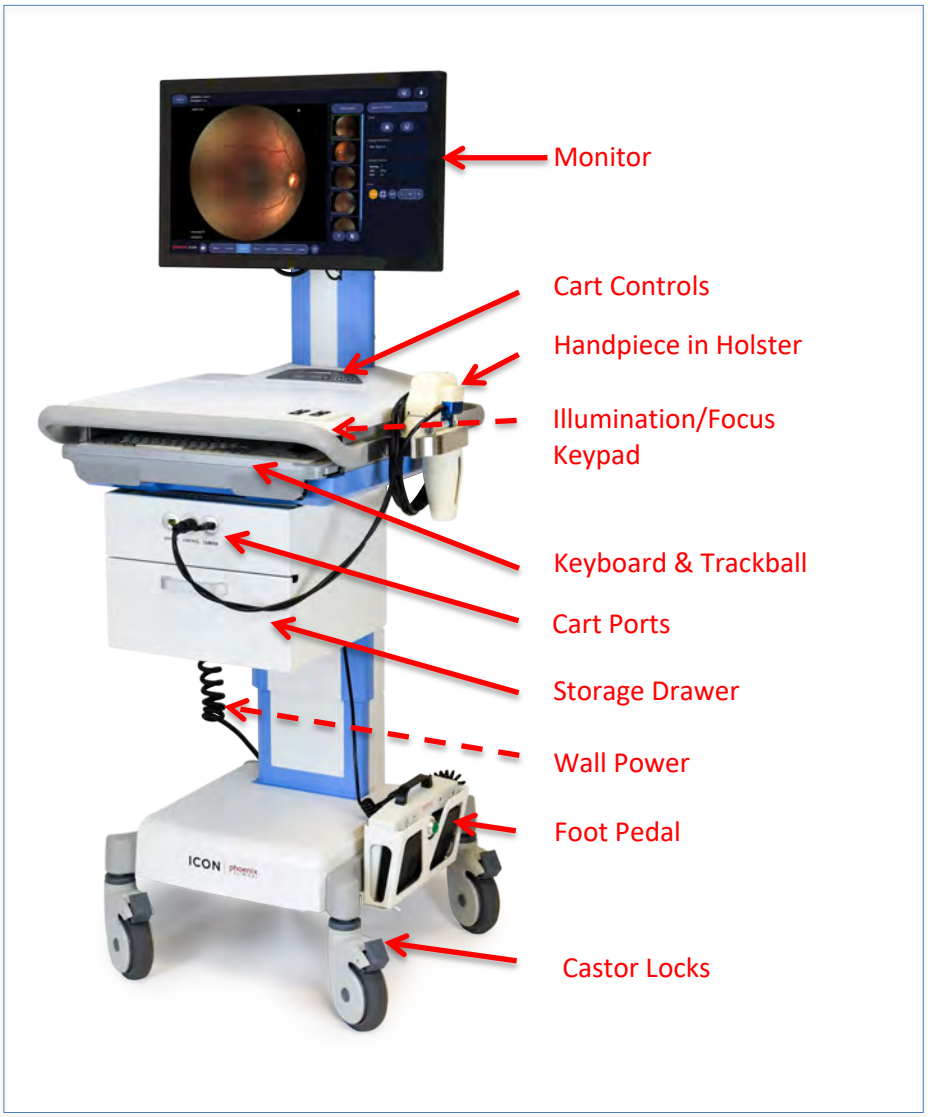
The lightweight, easy to move cart with motorized up/down controls, is on four lockable castor wheels. The cart houses the computer, keyboard, focus/illumination keypad, trackball mouse, touch screen monitor, illumination control box, and a battery backup to maintain portability of the system. The control box has a foot pedal attachment used to modify the illumination and to focus the image.

The system runs on Windows 7 or Windows 10 IoT Enterprise. Stronger ransomware, malware and cyber security tools are part of Windows IoT Enterprise to combat other potential future threats. Additionally, password protected encrypted logins are possible for Users and Administrators with encryption of the database including

- All patient information
- All user information
- All association of images to a specific patient

## User Accessible Parts

**Monitor**: On/Off and positioning
**Cart Controls**: System power and height adjustment
**Keypad:** Handpiece illumination and focus control
**Trackball:** Pointing, selecting and clicking actions
**Foot pedal:** Handpiece illumination and focus control
**Keyboard:** Software data entry
**Cart Ports:** Handpiece connections
**Drawers:** Storage of supplies
**Wall Power:** Battery charge and power supply to system
**Caster Locks:** Immobilize cart




*User Accessible Parts*

# 3. Cart Controls and Buttons

## Cart Control Panel

**Cart Power**: Press and hold this button for 5 seconds to turn cart power on/off.

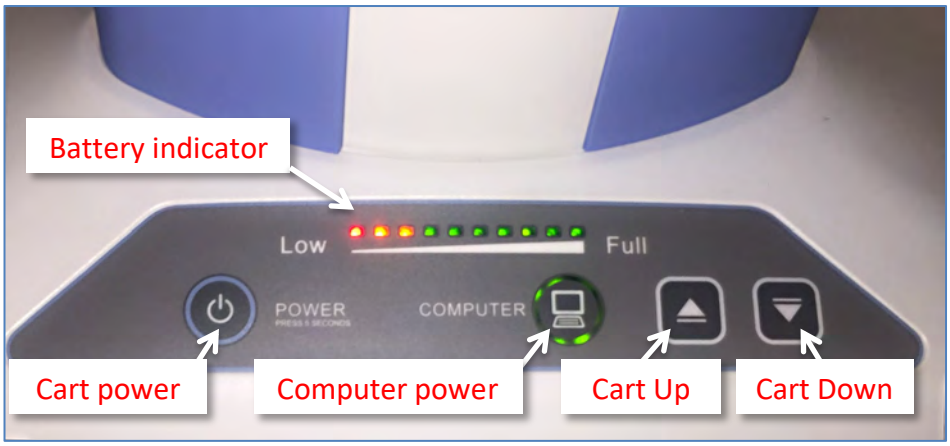
**Battery Indicator**: The lights indicate the charge status of the cart batteries. As the cart is charging, the lights will blink from Low to Full status.

> **Caution:** When only the red LED is on, **immediately** plug the unit into an AC socket to maintain power to the cart and computer.

**Computer**: A single press of this button turns the computer on or off.

**Up**: The cart lift motor will raise the operating height of the cart.

**Down**: The cart lift motor will lower the operating height of the cart.




*Cart Control Panel*

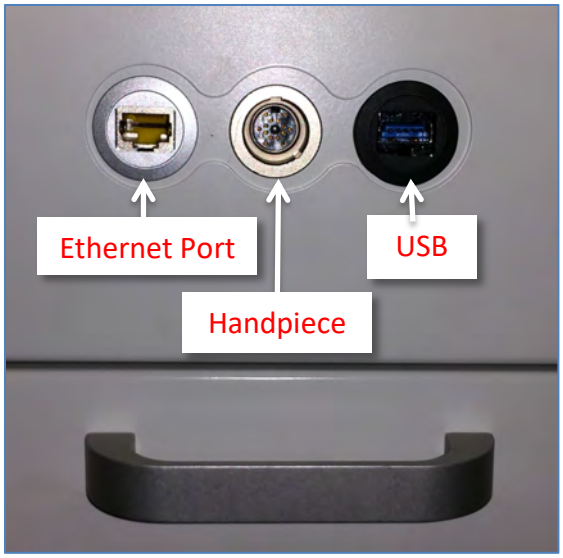
## Cart Ports

There are three ports on the front of the Phoenix ICON™ cart assembly:

**Maintenance**:
The Ethernet port is for system maintenance use only, including maintaining data integrity by exporting data to a server. The Ethernet port must not be used during an active imaging session and may NOT be used in an operating theater after an imaging session.

**Handpiece**:
Main control port for the system handpiece

**USB**:
Camera data from the system handpiece




*Cart Ports*

## Keyboard

The keyboard is mounted within a drawer assembly for convenient access and storage when not in use. Being medical grade, with a spill resistant covering, it may be wiped or cleaned using disinfectant wipes. There is a small keyboard light that can be turned on and off located in the center, just under the cart top.


*Keyboard*

## System Battery

The cart has a battery backup that is intended for short transport only. The battery will also mitigate data loss by keeping the computer powered on if the cart is inadvertently unplugged from the wall power supply. Do not rely on the battery for normal operation. Instead, always keep the system plugged into the wall when in use.

## Cart Keypad

The keypad on the cart controls the camera focus and light intensity of the handpiece. (Focus and light intensity may also be controlled using the foot pedal.)

**User Note:** The foot pedal deployed on the floor should be the primary method for capturing images. If the user needs assistance, a helper may operate the keypad controls, **not** the person holding the Phoenix ICON™ camera. This will allow the Phoenix ICON™ user, to concentrate on image alignment and positioning of the camera on the eye and not inadvertently shift their position by trying to access the keypad.

**Focus**: (+/-) These move the focus motor in either direction

**Light Intensity**: When the handpiece LED is on, these controls increase or decrease the projected brightness

**WARNING: Do not place objects on keypad**

## Focus

- Push the up arrow to drive the focus towards the back of the eye
- Push the down arrow to drive the focus to the front of the eye

## Light Intensity

Increase or decrease the projected light from the handpiece LED.

- Push the up arrow to increase illumination
- Push the down arrow to decrease illumination


*Keypad*

# 4. Foot Pedal

The foot pedal may be used instead of the keypad to operate the LED light intensity and camera focus. This allows the user to operate the Phoenix ICON™ independently without needing an assistant on the focus/illumination controls. The foot pedal is placed on the floor within comfortable reach of the user's foot.

## Focus

This rocker pedal is depressed from side to side.

Depress the rocker to the right to drive the focus towards the retina
Depress the rocker to the left to drive the focus towards the lens or front of the eye

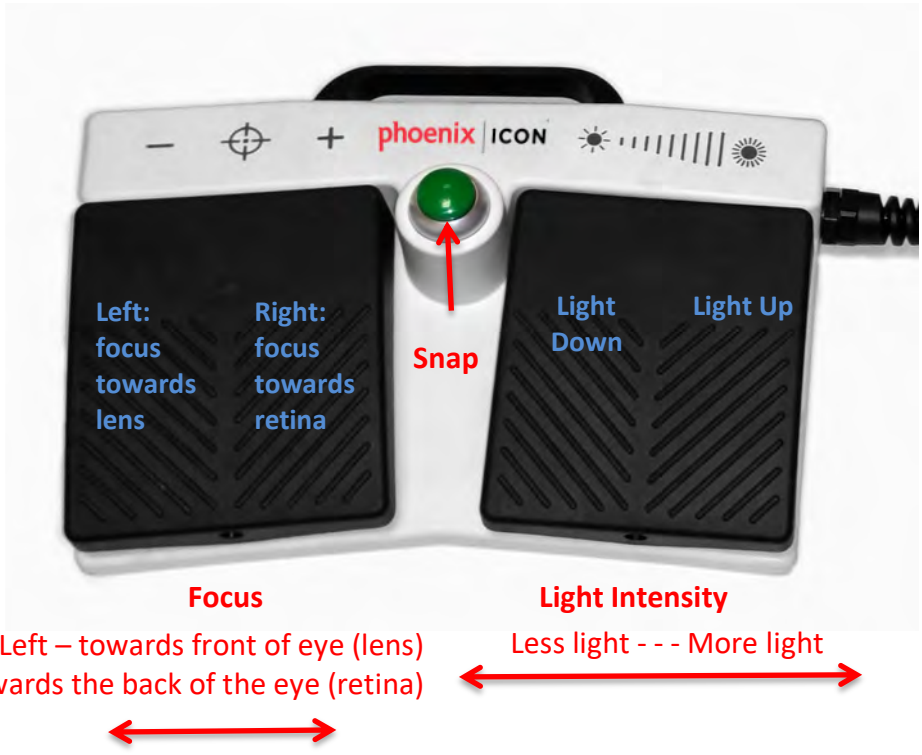
## Light Intensity

This rocker pedal duplicates the Light Intensity buttons on the control box to increase or decrease the projected light from the handpiece LED.

Depress the rocker to the right to increase illumination
Depress the rocker to the left to decrease illumination

## Snap

This green button has two modes. Depending on the option selected in software it will either take a picture or starts/stop the acquisition of a video.




*Foot pedal*

## 5. Cart Hardware Maintenance Procedure

Wipe down the keyboard, computer trackball, platform, holster, etc. in between patients with disinfectant wipes. Ensure that any gel or particulates are removed.

## 6. Startup Procedure

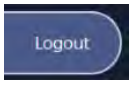
Plug in the Phoenix ICON™ cart using the main power cable. Remove the camera handpiece from the drawer and place it in the side holster on the cart. Deploy the foot pedal and place it nearby on the floor.

Turn on the cart power by pressing the power button for 5 seconds. Depress the button for the computer power. The computer software will start up at the "Login" screen.

## 7. Shutdown Procedure

a. Clean the handpiece tip as recommended in **Section 3: Phoenix ICON System Cleaning Procedures Handpiece**.

b. Shut down the software by clicking the **Log Out** button on any of the screens. This will take you to the Welcome/Login page.




c. Click the Shutdown icon.

d. To shut down the system, press and hold the Cart Power button on the Cart Controls for 5 seconds until the battery light indicator turns off.

e. Disconnect the handpiece from the cart and store safely in the provided cart drawer.

f. Disconnect the cart from the wall if connected.
Note: The cart may also be plugged into the wall while off to charge.

## 8. Servicing the Phoenix ICON™ System

There are no serviceable parts in the Phoenix ICON™ system. If it is suspected that something is not operating correctly, contact Customer Support at +1.877.839.0080 or iconhelp@phoenixtech.com.

## 9. System Accessories and Cables

The following is a list of all detachable parts and materials for use with the Phoenix ICON™ system:

- Handpiece (Phoenix Technology Group Part # PCI 40-1002) can be detached from the control box
- The Phoenix ICON™ White Light Module can be detached from the handpiece
- The Phoenix ICON™ Blue Light Module (Phoenix Technology Group Part # PCI 40-1004) is an accessory that can be added to the handpiece
- Camera holster can be detached from the cart

Cables:

- The handpiece cable can be up to 3 meters long
- The cart AC cable (Advantech AMiS-50) is less than 3 meters long

**Caution: Only use the AC Cable supplied with the Phoenix ICON™ system**

## 10. Ethernet Port

- The Ethernet port is available for maintenance only. Maintenance is defined as: *Retrieving a modality worklist *Storing images to a PACS *Exporting or backing up patient and image information *Downloading system security patches".

## 11. Transporting the System

### For short transport of just a few yards:

- The system has a backup battery to keep the system operational during short transports
- Using the Cart Controls, lower the cart to the **LOWEST** position
- Check that the battery is fully charged prior to unplugging the system
- Once the system is fully charged, unplug the unit from the wall causing the unit to revert to battery power
- Unlock the caster wheels
- Push the system to the new location
- Position the system and lock the caster wheels
- Plug the system back into the wall
- Raise the car to the desired operating height

**WARNING**: The system must remain plugged into the wall. The battery is intended for short transport periods only.

### For long transport:

- Use the cart controls to lower the cart to the LOWEST position
- Detach the handpiece and carefully package in the cart drawer
- Unplug the cart power cable and hang it from the little cart power cable hanger
- Make sure the entire cart system is powered OFF
- Put the system in the approved transportation packaging prior to transporting

## 12. Environmental Protection

- The Phoenix ICON™ system does not utilize any disposables
- Please use your organization's disposal procedures for effective discarding of all cleaning supplies used with the system
- **NOTE: All disposals must comply with local regulations**
- For disposal of the Phoenix ICON™ system, do not throw cart and handpiece into the waste bin. Contact Customer Support for disposal options

# 13. System Technical Specifications

| Parameter | Specification |
|---|---|
| Electrical ratings | 100 – 240 VAC, 50 – 60 Hz, Max 4.5A |
| Battery Type | Lithium-Iron Phosphate (LFP) |
| Battery Charge Time | < 3 hr. DOD 100% |
| Battery Capacity | 420 Wh |
| Battery Runtime<br>(Depends on system configuration and use) | ~ 6 hours |
| Environment | Operating Room, Medical Exam Room |
| Environmental condition of use | Temperature: +10°C to +30°C<br>Relative Humidity: 30% to 90%<br>Atmospheric Pressure: 800 hPA to 1060 hPA |
| Environmental transport conditions | Temperature: -40°C to +70°C<br>Relative Humidity: 10% to 95%<br>Atmospheric Pressure: 500 hPA to 1060 hPA |
| Environmental storage conditions | Temperature: -10°C to +55°C<br>Relative Humidity: 10% to 95%<br>Atmospheric Pressure: 700 hPA to 1060 hPA |

| Observation Light Source | White Module | Blue Module |
|---|---|---|
| Light source type, wavelength | 10W White light LED, filtered 450-675nm | 10W Blue light LED, 450-460nm, filtered 450-500nm. |
| Maximum Light source output power | 4 mW/cm^2 | 25 mW/cm^2 |
| Light intensity control | Zero to maximum | Zero to maximum |
| External fixation light (if any) | None | None |
| **Camera** | | |
| Field of View | 100 degrees | 100 degrees* |
| Resolution | Single lens at 12 microns | Single lens at 12 microns |
| Frame Rate | 30 frames per second | 30 frames per second |

| Other Accessories | White Module | Blue Module |
|---|---|---|
| Insert filter | No insert filter needed. | Used with the blue LED module. Use switch on the handpiece to put filter into place. Filter blocks band at 500nm, edge wavelength 515nm |
| Imaging lens | Flat field external camera | N/A |
| Eye Contact Materials | Goniosol or GenTeal Gel | Goniosol or GenTeal Gel |
| **Performance** | | |
| Imaging Format | .TIF/.JPEG/.AVI | .TIF/.JPEG/.AVI |
| Imaging Resolution | Single lens at 12 microns | Single lens at 12 microns |

| **Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| The EQUIPMENT is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the EQUIPMENT should assure that it is used in such an environment. | | |
| Emissions Test | Compliance | Electromagnetic environment – guidance |
| RF emissions<br>CISPR 11 | Group 1 | The EQUIPMENT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class B<br>150 kHz to 30 | The EQUIPMENT is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | Class B<br>150 kHz to 30 | |
| Voltage Fluctuations/<br>Flicker emissions<br>IEC 61000-3-3 | Complies | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The EQUIPMENT is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the EQUIPMENT should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | 8 kV<br>contact discharge<br>2, 4, 8 &15kV<br>air discharge | 8 kV<br>contact discharge<br>2, 4, 8 &15kV<br>air discharge | 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 transient/burst<br>IEC 61000-4-4 | 2 kV AC Mains<br>1 kV I/O Lines<br>5/50<br>100 kHz | 2 kV AC Mains<br>1 kV I/O Lines<br>5/50<br>100 kHz | Mains power quality should be that of a typical domestic, commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | 1 kV<br>Line to Line<br>2 kV<br>Line to Ground | 1 kV<br>Line to Line<br>2 kV<br>Line to Ground | Mains power quality should be that of a typical domestic, commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | 0% UT .5 cycle<br>0% UT 1 cycle<br>70% UT 25 cycles<br>0% UT5 Sec | 0% UT .5 cycle<br>0% UT 1 cycle<br>70% UT 25 cycles<br>0% UT5 Sec | Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the<br>EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT be powered from an uninterruptible power supply or a battery. |
| (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment. |
| NOTE *U*T is the a.c. mains voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The EQUIPMENT is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the EQUIPMENT should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 Test Level** | **Compliance level** | **Electromagnetic environment – guidance** |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance** |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms | $d = 1.2\sqrt{P}$ |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br><br>where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br>  |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| [a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EQUIPMENT is used exceeds the applicable RF compliance level above, the EQUIPMENT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EQUIPMENT.<br>[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | | |

| Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT | | | |
|---|---|---|---|
| The EQUIPMENT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EQUIPMENT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EQUIPMENT as recommended below, according to the maximum output power of the communications equipment. | | | |
| **Rated maximum output power of transmitter** W | **Separation distance according to frequency of transmitter** m | | |
| | 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.<br>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and<br>reflection from structures, objects and people. | | | |

# 14. Manufacturer's Declaration

The Phoenix ICON™ has been tested and is compliant to the following safety and performance standards:

- EN/IEC 60601-1 Medical Electrical Equipment—Part 1: General Requirements for Safety
- EN/IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests

# 15. Troubleshooting Guide

| Issue | Potential Solutions |
|---|---|
| Lost Password | - If there is no user password, you can use the Admin password to gain functional access to the system.<br>- If there is no Admin available to login, please contact Customer Support for password recovery and system access. |
| No Image | - Ensure the camera is plugged in and the system is correctly powered on.<br>- Inspect all cables for damage. Damage can include excessive kinks or visible damage to the insulation surrounding the cable.<br>- If all connections are correctly plugged in, there is power to the system, and there is no visible damage, please contact Customer Support |
| System shuts down | - Possible battery failure. Contact Customer Support. |

List of Software pop ups and warnings and possible solutions

| Issue | Potential Solutions |
|---|---|
| Camera disconnected | - The system cannot see a connected camera. Ensure that the handpiece USB plug is seated into the USB port on the controller box. If the system is correctly plugged in but no camera appears, contact Customer Support. |
| WARNING: Failed to connect to controller board | - The system cannot find the main controller board for controlling the handpiece functions. Select “Abort” to cancel the software start. Or select “Ignore” to continue booting the software even though some system functions will not be accessible.<br>- To regain connection to the controller board, reboot the system. If the error message comes up again, contact Customer Support. |
| The following files already exist | - You are attempting to export or archive files which have already been exported to that location. Choose from the provided options to continue. |
| RetinalImagingSystem.exe has stopped working | - The software has crashed. Reboot the system and if the problem persists, contact Customer Support. |

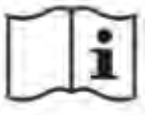
| | |
|---|---|
| Failed to archive/export images | - The system indicates which images failed to export. You may try to export/archive them again. Also try switching locations of export/archive. If the problem persists, contact Customer Support. |

| | |
|---|---|
| Incorrect Password | - Use the correct password. Check to see if you have inadvertently typed the password with the caps lock on or contact a system Admin to gain access to the system. |
| Safe to Remove Hardware | - This indicates that the Phoenix Removable Drive has been safely disconnected from the system and can be physically removed. |
| Archiving will create a copy of the images and videos and delete the local copies | - This is the intended functionality of the Archive function to free up hard disk space. |

For other concerns, please contact Customer Support and have the following information available:

- Site location (i.e. hospital name, department, etc.)
- System Station ID (located on the Login screen)
- System Serial Number (the top label located at the back of the cart)

## 16. Symbols Used in Product Labeling

| Symbol | Meaning |
|---|---|
|   | Part/Catalogue # |
|   | Serial Number |
|  | Do not throw away |
|  | Fragile |
|   | TUV Rheinland (3rd party electrical safety and EMC compliance testing mark) |
| Y | Attention consult accompanying documents |
| p | Keep dry |
| U | This side up |
|  | This is a blue man with a book which means user must read the manual before using the equipment. |
|  | Caution |
|  | Consult Instructions for Use |
|  | Type B Applied part |
|  | Alternating Current |
|   | European Authorized Representative |

| Symbol | Meaning |
|---|---|
|  | Manufacturer |
|  | Manufacture date |

# 17. Service and Warranty Statement

Phoenix Technology Group, LLC. warrants your Phoenix ICON™ system to be free from defects in materials and workmanship for two years. Phoenix Technology Group, LLC. will repair or replace such product or part thereof which, upon inspection by Phoenix Technology Group, LLC. is found to be defective in materials or workmanship. As a condition to the obligation of Phoenix Technology Group, LLC. to repair or replace such product, the product must be returned to Phoenix Technology Group, LLC. together with proof-of-purchase satisfactory to Phoenix Technology Group, LLC.

The proper Return Authorization Number (RMA) must be obtained from Phoenix Technology Group, LLC. in advance of return. Call Phoenix Technology Group, LLC. at +1.877.839.0080 to receive the number to be displayed on the outside of your shipping container.

All returns must be accompanied by a written statement setting forth the name, address, and daytime telephone number of the owner, together with a brief description of any claimed defects. Parts or products for which replacement is made shall become the property of Phoenix Technology Group, LLC.

The customer shall be responsible for all costs of transportation and insurance, to the factory of Phoenix Technology Group, LLC. and shall be required to prepay such costs. Phoenix Technology Group, LLC. shall use reasonable efforts to repair or replace any Phoenix ICON™ covered by this warranty within fifteen days of receipt. In the event repair or replacement shall require more than fifteen days, Phoenix Technology Group, LLC. shall notify the customer accordingly.

Phoenix Technology Group, LLC. reserves the right to replace any product which has been discontinued from its product line with a new product of comparable value and function.

This warranty shall be void and of no force of effect in the event a covered product has been modified in design or function, or subjected to abuse, misuse, mishandling or unauthorized repair. Further, product malfunction or deterioration due to normal wear is not covered by this warranty.

PHOENIX TECHNOLOGY GROUP, LLC. DISCLAIMS ANY WARRANTIES, EXPRESS OR IMPLIED, WHETHER OF MERCHANTABILITY OF FITNESS FOR A PARTICULAR USE, EXCEPT AS EXPRESSLY SET FORTH HERIN. THE SOLE OBLIGATION OF PHOENIX TECHNOLOGY GROUP, LLC. UNDER THIS LIMITED WARRANTY SHALL BE TO REPAIR OR REPLACE THE COVERED PRODUCT, IN ACCORDANCE WITH THE TERMS SET FORTH HERIN. PHOENIX TECHNOLOGY GROUP, LLC. EXPRESSLY DISCLAIMS ANY LIABILITY FOR LOST PROFITS, GENERAL, SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES WHICH MAY RESULT FROM BREACH OF ANY WARRANTY, OR ARISING OUT OF THE USE OF INABILITY TO USE ANY PHOENIX TECHNOLOGY GROUP, LLC. PRODUCT. ANY WARRANTIES WHICH ARE IMPLIED AND WHICH CANNOT BE DISCLAIMED SHALL BE LIMITED IN DURATION TO A TERM OF TWO YEARS FROM THE DATE OF ORIGINAL RETAIL PURCHASE.

Some states do not allow the exclusion or limitation of incidental or consequential damages or limitation on how long an implied warranty lasts, so the above limitations and exclusions may not apply to you.
This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

Phoenix Technology Group, LLC. reserves the right to modify or discontinue, without prior notice to you, any model or style Phoenix ICON™.

If warranty problems arise, or if you need assistance in using your Phoenix ICON™, please contact: Phoenix Technology Group, LLC. dealer in the U.S.A. or Canada. Warranty outside the U.S.A. and Canada is valid only to customers who purchased from a Phoenix Technology Group, LLC. International Distributor or Authorized Phoenix Technology Group, LLC. Dealer in the specific country. Please contact them for any warranty questions.

Phoenix Technology Group, LLC

# Section 2

# Using the Phoenix ICON™ Hand Piece and

# Phoenix ICON™ Software

(Applies to both the cart-based Phoenix ICON and the portable Phoenix ICON GO systems)

**v1.23**

# Table of Contents

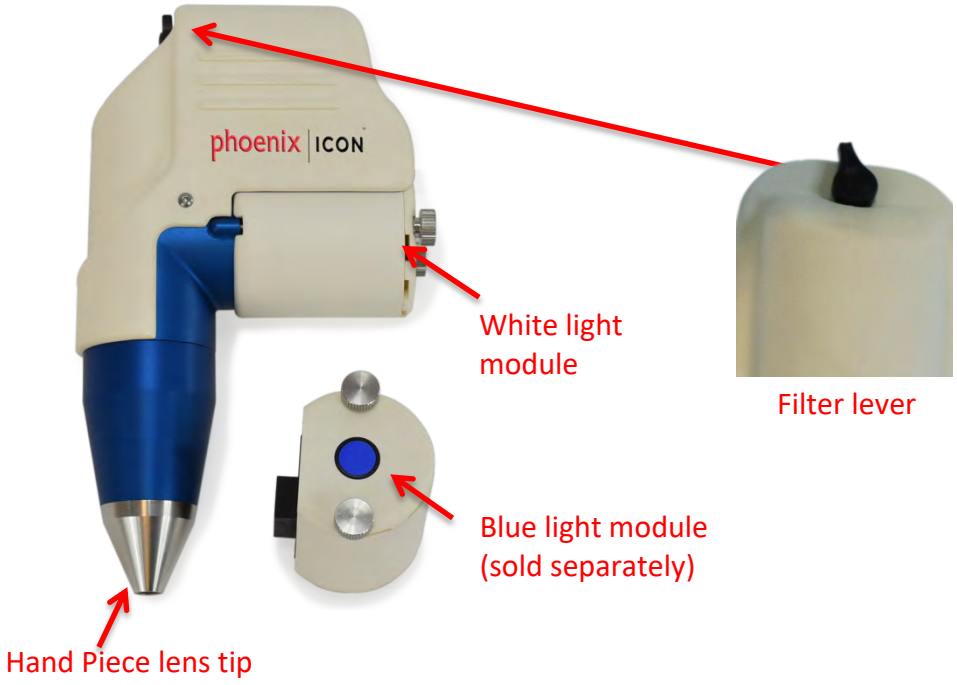
# 1. The Phoenix ICON™ Camera Hand Piece

Phoenix ICON imaging systems capture videos and images using the Phoenix ICON camera hand piece. The camera hand piece consists of optics, a digital sensor, and an interchangeable LED light module. The contact lens on the tip of the camera hand piece has a smooth concave surface, which will come in contact with coupling gel and gently contact with the patient's eye. Note that the patient-contacting lens must be cleaned according to appropriate infection control procedures after use and between patients.

An interchangeable LED light module generates and emits the light for the camera. The hand piece has two detachable light modules: one is white light for general color imaging; the other is a blue LED for fluorescein angiography.

***Note:*** *Support for fluorescein angiography is available in selected geographies. Please see the indications for use for your specific region.*

For fluorescein angiography, the white LED module is removed. The blue LED module is attached and the filter lever on the hand piece is moved to the barrier filter position (blue dot) allowing the wavelength (yellow/green color) of the emitted excited light to reach the camera.




*Phoenix ICON Hand Piece*

## 2. Operator and Camera Positioning During Imaging

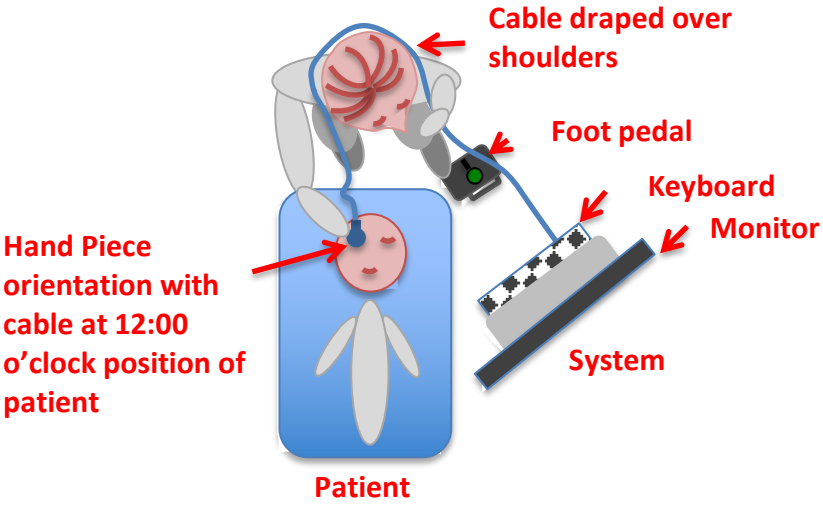
During normal use the system the operator should be situated with adequate access to the patient, in a position comfortably holding the hand piece, able to operate the foot pedal focus/capture controls, and able to easily see the monitor.

The operator should be positioned at the top of the head of a supine patient, with the patient's feet directed away from the operator.

The viewing angle of the screen will make a difference to the operator's perception of illumination brightness of the retinal image. For imaging consistency, the operator should position the system so that they are looking straight at zero degrees to the center of the monitor.

Before bringing the camera hand piece into contact with the patient's eye, the operator should deploy the foot pedal on the floor and have their foot positioned to operate the focus/capture controls.

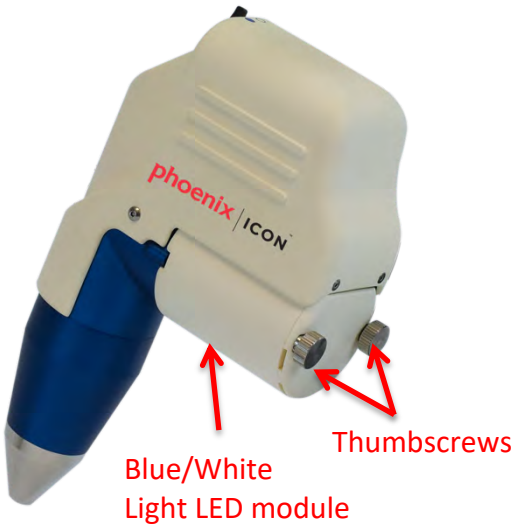
The operator should align the camera hand piece so that the cable is at the 12:00 o'clock position of the forehead of the patient with the cable coming towards the operator. This will ensure the image is correctly oriented on the screen.




*Basic schematic of orientation of patient, hand piece and Phoenix ICON*

## 3. Changing the Light Module

To switch between color imaging and fluorescein angiography, the operator must change the light module. The white light module is used for color imaging. The blue light module is used for fluorescein angiography.




*Phoenix ICON Hand Piece*

To change the light module:

1) Fully loosen the two thumbscrews on the back of the LED module; pull back the module and remove.

2) Align the new module and insert into the bottom of the hand piece. Carefully tighten the two thumbscrews one at a time to ensure proper seating of the module.

# 4. Using the Phoenix ICON™ Diffuser

The Phoenix ICON™ Diffuser is an accessory for the Phoenix ICON hand piece that is intended for use when capturing images of the external structures of the eye. The unmodified illumination scheme used in the Phoenix ICON hand piece is designed for high-contrast, high-resolution images of the retina. When used without the Diffuser, artifacts may appear in the center of the image. The Diffuser removes these artifacts allowing the operator to capture high-quality external images.

**To use the Phoenix ICON™ Diffuser**

1. Prepare the Phoenix ICON™ camera system for imaging, as noted earlier in this manual:
    a. Power on the Phoenix ICON™ cart
    b. Login into the Phoenix ICON™ software

2. Properly clean and prepare the Phoenix ICON™ hand piece, as noted in Section 4 of this manual

3. Ensure that the light is off on the Phoenix ICON™ hand piece by pointing the tip of the hand piece at a surface facing away from the operator and observing that there is no light coming from the hand piece

4. Slide the Phoenix ICON™ Diffuser on to the nose of the Phoenix ICON™ hand piece


*Phoenix ICON™ hand piece with diffuser*

5. Prepare the patient for imaging of the external structures of the eye

6. Capture one or more images of the external structures of the eye:
    a. From the Patient screen in the Phoenix ICON™ software, select an existing patient or enter a new patient
    b. Click Acquire to move to the image acquisition screen
    c. Select an existing study or select "Create new study"
    d. Select which eye is being imaged
    e. Turn on the light by clicking the light on/off control button on the software
    f. Set the initial intensity and gain, or select the preset for Anterior segment
    g. Position the Phoenix ICON™ hand piece so that the desired external structures of the patient's eye are visible in the camera's field of view as seen on the Phoenix ICON™ screen.
    h. Focus so that the structures are clearly in view
    i. Capture images and/or video of the external structures of the eye
    j. Turn off the light on the hand piece

7. When imaging is complete, slide the Phoenix ICON™ Diffuser off the nose of the Phoenix ICON™ hand piece and store it in the box provided with the Phoenix ICON™ Diffuser

**NOTE:** The Phoenix ICON™ Diffuser is intended for non-contact imaging only. The tip of the Diffuser should never come in contact with the patient's eye.

# 5. Feature Summary

The Phoenix ICON™ Software supports the following camera and system features and frequently used functions:

## 5.1. Software Interface

- Patient and study data Input
- User-specific User Names and Passwords
- User-specific permissions for access to key features
- Encryption of database including
- - All patient information
- - All user information
- - All association of images to a specific patient
- Multiple clinic or department locations
- Built-in soak timer and audit log for disinfection
- Security event logging in an audit log that is available to device administrators

## 5.2. Live Capture

- Snap single images stored in .TIFF format
- Record videos up to 2 minutes in length in Standard mode or 10 seconds in Flashback
- Toggle still or video recording with the keyboard, foot pedal or touch screen software controls
- Control focus and illumination using on-screen controls, the foot pedal (and on a control pad on the cart-based ICON system)
- Adjust Automatic White Balance and Gain using integrated camera control functions
- Use Gain as a tool to brighten an image instead of increasing light intensity
- Create 4 presets for Exposure/Gain preferences
- Apply a time stamp on the live and saved images and videos
- Enter/edit study notes on a visit or individual image frame
- Apply a timer to images for time-based studies such as fluorescein angiography
- Capture images in color or monochrome
- Capture 4 simultaneous images of varying gain settings for later HDR blending

## 5.3. Image and Video Review

- Review images captured during an imaging Study
- Review a single image
- Compare up to 4 images from one or multiple visits

- Playback video
- Extract a single frame from a video file
- Save zoomed-in magnified image
- Save image comparisons
- Enter, edit and review study and image notes

## 5.4. Image Export

- Export images with patient data to a DICOM image file
- Export images as .TIFF or .JPEG, with or without patient data in a companion .csv file
- Still images and images captured from video are both 1240 x 1240 pixels and approximately 6 MB .TIFF files.
- DICOM files are approximately 4 MB
- 1 second video is approximately 69 MB
- JPEG files are approximately 600 kb MB
- Archive data

## 5.5. DICOM Connectivity

- Download a modality worklist from a DICOM-compliant PACS or RIS (C-FIND)
- Present the day's worklist to the operator as a "to do list"
- Export images to a DICOM-compliant PACS (C-STORE)
- Carry the accession number forward to the PACS when imaging was initiated from a modality worklist
- Log DICOM activity

## 5.6. Reporting

- Creation of a patient report, including demographic data and selected images
- Export of the report to a PDF file

# 6. Main ICON Software Concepts

This section presents some of the main concepts that will be referred to throughout the Software documentation.

## 6.1. Users, Permissions, and Clinics

Each operator that uses the Phoenix ICON™ Software must login under as a User. A User has a unique User Name.

Each User is granted a set of permission that determine the operations that the User can perform in the Software. This includes operations such as whether the User can export images, whether the User can export to a USB thumb drive, and whether the User can access the Settings screen.

Each User is associated with one or more Clinics. A Clinic is a logical grouping of patients. When a User logs in, they select a Clinic, and can only see the patients associated with that Clinic. This approach is used when the Phoenix ICON™ system will be moved between locations to ensure that the system is complying with the data privacy guidelines of each site. Note that it is acceptable to define one master Clinic for all users in situations where this delineation is not useful.

## 6.2. Patients and Imaging Studies

A Patient represents one person that will be imaged using the Phoenix ICON™ camera system. Information such as name, patient ID, MRN, and birth date may be entered in the system for each Patient. A Patient is associated with one Clinic and may be moved in the ICON Software from one Clinic to another.

An Imaging Study corresponds to one imaging session for one patient. An Imaging Study has a date and time, and a collection of images and videos that were captured during that imaging session.

## 6.3. Imaging Modes

When capturing images and videos, the Phoenix ICON™ system displays a real-time view of the field that is viewable to the camera sensor. This is displayed to the operator on the system's touch screen to allow for easy focusing, exposure, and image capture.

The Phoenix ICON™ system is capable of imaging in three modes:

- **Still image capture**. In this mode, the operator is capturing single images with each capture operation.

- **Video**. In this mode, the operator is recording a video from the camera. The operator can toggle between record and pause to save up to two minutes of video per file.

- **Flashback Video**. In this mode, the Phoenix ICON™ system is constantly buffering the prior few seconds of video. When the operator sees the perfect frame, they can initiate a capture which will save the current frame and the prior few seconds to help ensure that the best frame is available upon review.

## 6.4. General Software Workflow

In general, the operator will perform the following operations when imaging a patient:

- Login to the Phoenix ICON™ Software under their User Name and select the Clinic (if multiple Clinics are configured).

- Enter the patient information for all new patients that will be imaged during this session so that patient data entry isn't done bedside. (Note that, optionally, patient information can be downloaded from a modality worklist server)

- Select the patient that is being imaged

- Move to the Acquire screen and capture images and/or videos of the right and left patient eyes

- Repeat for each additional patient that is to be imaged during the same imaging session

- Move to the Review screen and move through each imaged patient. For patients that were imaged on video, the operator will select and save video frames as still images. Once any video has been processed, the operator will tag each still image that is to be used for further patient assessment.

- Move to the Export screen and export the selected images to a shared network folder, a PACS, or a thumb drive for long-term patient data storage and access by the clinical care team.

# 7. Standard Operating Procedures

## 7.1. Important Notes

- Training on the use of the Phoenix ICON™ camera system must be performed by Phoenix Technology Group or an authorized representative.
- The Phoenix ICON™ Software and the Phoenix ICON™ hardware have built-in timeouts that automatically turn off the LED light module. The expected duty cycle is maximum continuous patient illumination of 3 minutes with a 50% duty cycle.
- The maximum patient exposure to blue light is 60 minutes
- The maximum patient exposure to white light is 6 hours.

## 7.2. Recommended patient preparation

Prior to imaging, prepare the patient for ophthalmic imaging according to individual hospital or clinic procedures and protocols for ophthalmic procedures.

## 7.3. Required device preparation

- Check the Phoenix ICON™ system for any damage, especially for damage to the patient contacting surface of the camera hand piece tip.
- Clean and disinfect the hand piece tip according to the maintenance procedure of this document.
- Turn on the Phoenix ICON™ system, login as a user, select a clinic, and either a) enter patient data, b) select a patient from the Phoenix ICON™ patient directory, or c) select a procedure from the modality worklist.
- Dress the handset cables so they are away from the patient and do not interfere when acquiring images.
- Enter the Acquire screen and test the light module on/off, focus, intensity, gain and capture mechanisms to ensure the Phoenix ICON™ system is functioning as expected prior to beginning an imaging session.

## 7.4. Recommended Procedure Setup

### 7.4.1. Fundus Imaging

- Ensure that the white LED light module is inserted in the Phoenix ICON™ camera hand piece
- Position the Phoenix ICON™ system and foot pedal close to the examination table at a comfortable viewing distance for the examiner.
- Position the monitor at eye level. Deploy the foot pedal on the floor close to the examiner's foot.
- Reduce the ambient light of the room and minimize glare and reflections on the monitor.
- Before retinal imaging, pre-focus the camera at infinity by pointing the tip of the camera hand piece at an object across the room, or by turning the hand piece sideways and focusing on the Phoenix ICON™ monitor. Sharpen the image you see by adjusting the focus using the foot pedal. This will set the focusing plane near the correct range for retinal imaging.
- Either select a preset from dropdown for the type of imaging session or adjust the illumination to low by adjusting the intensity with the foot pedal.
- Administer topical anesthetic to the eyes.
- Insert a lid speculum in the eyes being imaged, ensuring that the size of the speculum is appropriate for the age of the patient.
- Apply coupling gel (as needed per procedure) to the camera lens tip and/or onto the cornea of the patient, taking care to minimize bubbles.
- Hold the camera hand piece close to the tip of the lens with the light module positioned over the hand between the index finger and thumb.
- Gently place the tip of the camera in the gel on the eye while supporting the camera.
- The hand piece cable should be placed at the patient's 12:00 o'clock position of the forehead to maintain the correct image orientation.

- Adjust the intensity and focus as necessary with the foot pedal or have an assistant use the software controls. Pivot the camera to visualize the peripheral areas of the retina.

> Note: Throughout the imaging session, visually monitor the central retinal arterial and venous branches for pulsation, indicative of excessive pressure to the eye. If pulsations occur, bring the camera away from the eye slightly until they cease, or remove the camera from the eye entirely and reposition it to continue imaging.

### 7.4.2. Fluorescein Angiography

- Ensure that the blue LED light module is inserted in the Phoenix ICON™ camera hand piece.

- Position the Phoenix ICON™ system and foot pedal close to the examination table at a comfortable viewing distance for the examiner.

- Perform the procedure seated, if possible. Position the monitor at eye level. Deploy the foot pedal on the floor close to the examiner's foot.

- Decide if you will do the angiogram in Video or Still mode as the procedures differ slightly.

- Click Greyscale to capture the photos in black and white if this is not selected by default in Settings.

- Select Video or Still mode for the foot pedal operation.

- **If video is chosen** for the foot pedal, select the Sync Start check box. This will start the timer when the foot pedal is depressed. **You must be in Video mode for the timer to sync with the foot pedal.**

- Instill topical anesthetic in both eyes. If the patient is under anesthesia, insert a lid speculum in both eyes after and apply coupling gel to keep the corneas hydrated. (Placing a lid speculum in both eyes allows the efficient capture of the early phase for both eyes without losing time.)

- Hold the camera hand piece close to the tip of the lens with the light module positioned over the hand between the index finger and thumb.

- Gently place the tip of the camera in the gel on the eye while supporting the camera.
- The hand piece cable should be placed at the patient's 12:00 o'clock position of the head to maintain the correct image orientation.
- Place the camera on the eye and Increase the Gain setting so that the fundus vessels are visible.
- Alternatively, select a Preset for Fluorescein with the Gain at 20 and the Intensity at 100. Be prepared to reduce the Gain during mid phase.
- Select the eye of interest to start the imaging.
- Modify focus so the vessels are sharp.
- Important: Position the handpiece filter lever to the blue dot to move the barrier filter in place without moving the camera on the eye. The filter will permit only light emitted from the fluorescein to pass through to the camera, therefore the image will be dark until dye fills the vessels.

  Have an assistant inject fluorescein intravenously while the camera is held steadily on the eye. Instruct them to wait for the clinical team to be ready with the camera on the eye before administering the fluorescein injection.

  It can be useful to perform a countdown of 3-2-1 Start at which time the injection is started, the timer on the system and the first photograph/video is taken.
- Depress the green capture foot pedal button at the start of the injection. This will begin the video capture and record as dye enters the eye vessels. Stop the video using the controls on the software at the end of the early phase and save the video. Continue with another video as time passes into the mid phase.
- During video capture, you may also click the green foot pedal button to toggle pause and record.
- The video must be saved before changing eyes.

  Note: Throughout the imaging session, visually monitor the central retinal arterial and venous branches for pulsation, indicative of excessive pressure to the eye. If pulsations occur,

bring the camera away from the eye slightly until they cease, or remove the camera from the eye entirely and reposition it to continue imaging.

- **If Still mode is chosen** for the foot pedal operation, have the assistant press the timer arrow at the start of the injection. The timer will be running on the lower right of the screen.

- Still mode may be used to capture snapshots in a rapid progression 1 – 2 seconds apart as the dye enters the eye and fills the vessels.

- Apply additional coupling gel (as needed per procedure) to the camera lens tip and/or onto the cornea of the patient, taking care to minimize bubbles.

- Change the R/L eye designation using the touch screen when moving to the contralateral eye during the image series.

- Adjust the illumination and focus as necessary with the foot pedal or have an assistant use the software controls.

## 7.5. Required Final Steps

- Clean and disinfect the hand piece tip according to maintenance procedure section of this document at the end of each patient imaging session.

- When all imaging sessions are complete properly stow the Phoenix ICON™ system according to the instructions in this document.

# 8. Login Screen

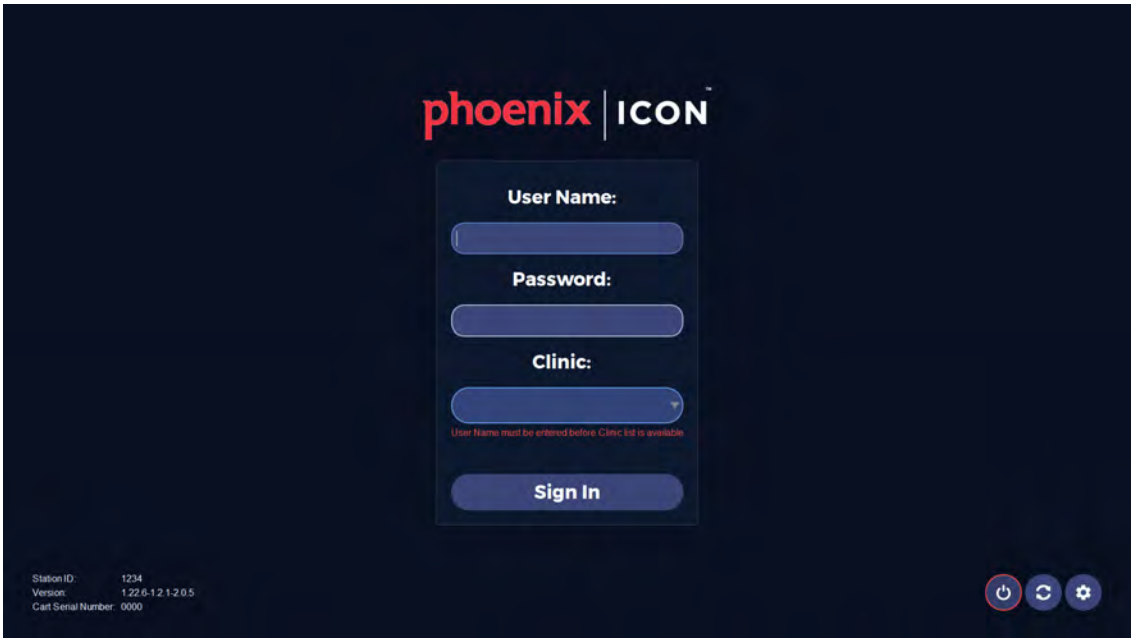
Users gain access to the Phoenix ICON™ Software and use of the Phoenix ICON™ system via the Login screen, which is the first screen displayed when the Phoenix ICON™ system is started.

## 8.1. Login Screen Overview

The Phoenix ICON™ system operates as a dedicated medical device. After powering on the system, the Phoenix ICON™ Software will display the Login screen. The system ships initially configured with one user account ("ADMIN") with the password "5678". User accounts can be setup for multiple users of the Phoenix ICON™ system (see the administration section below).

Note that on the Login screen you will find key system information in the lower left corner:

- The Station ID
- Software and firmware version
- Cart Serial Number




*Login Screen*

System Shutdown is located at the bottom right of the screen.

Reset Connections is used when troubleshooting the connection of the camera.

## 8.2. Logging in to the Phoenix ICON™ Software

To login to the Phoenix ICON™ Software:

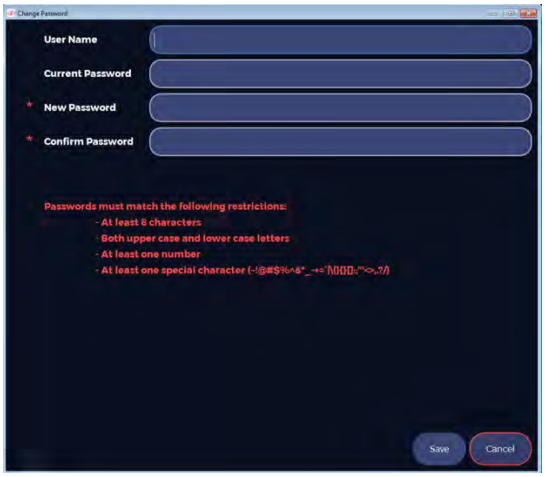
- Enter your User Name
- Select the Clinic from the dropdown list
- Enter your Password
- Click ***Sign In***

## 8.3. Logging In the First Time

Each new Phoenix ICON system is shipped with one administrative user pre-configured. The User Name is “ADMIN” and the password is “5678”. This user account can be used to login the first time and setup other User accounts (see the administration section below). Note that this password should be changed during system setup for security.

## 8.4. Resetting Your Password

Reset Password may be initiated from the Login screen and is used to change the password for a User. It may also be performed from the Settings/User screen described further on.

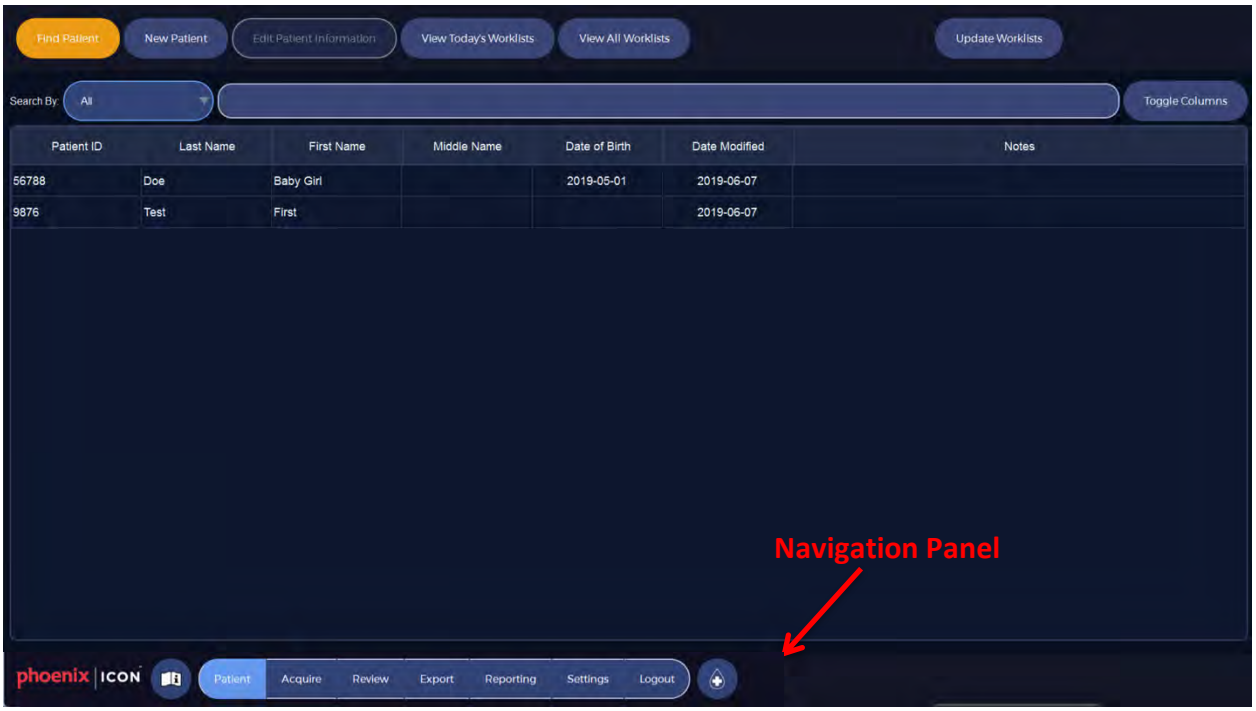



To change your Password:

- Enter your User Name
- Enter your current Password
- Enter a new Password and enter it a second time in the Confirm Password field. Note that the Password must meet the Password guidelines set by the device administrator.
- Click Save

# 9. Navigation Panel

Users navigate between main functions of the Phoenix ICON™ Software via the Navigation Panel that is found at the bottom of each screen, as shown below.




Use the Navigation Panel to access eight sets of functions:

- **Patient**: Find, enter, and edit information about Patients. This screen also provides the ability to move a Patient from one Clinic to another.

- **Acquire**: Capture images and videos for the currently selected Patient, which are grouped together in an imaging study

- **Review**: Review images and videos that have been captured for the selected Patient. Access is provided to all imaging studies for the Patient. This screen also provides access to the Compare function, allowing two to four images to be presented side-by-side for comparison.

- **Export**: Export images associated with the currently selected Patient to one of the export locations that have been defined (through the Settings screen). Export locations can include a shared network folder, a thumb drive, or a PACS.

- **Reporting**: Generate and export a report related to the currently selected Patient that includes patient demographic information, imaging study information, and selected images.

- **Settings**: Adjust the settings of the Phoenix ICON™ software. This screen is only available to administrators of the Phoenix ICON™ Software. This includes creating and changing user permissions, configuration export locations, creating imaging presets, setting up the DICOM connectors, and more.

- **Logout**: Logs out the current user.

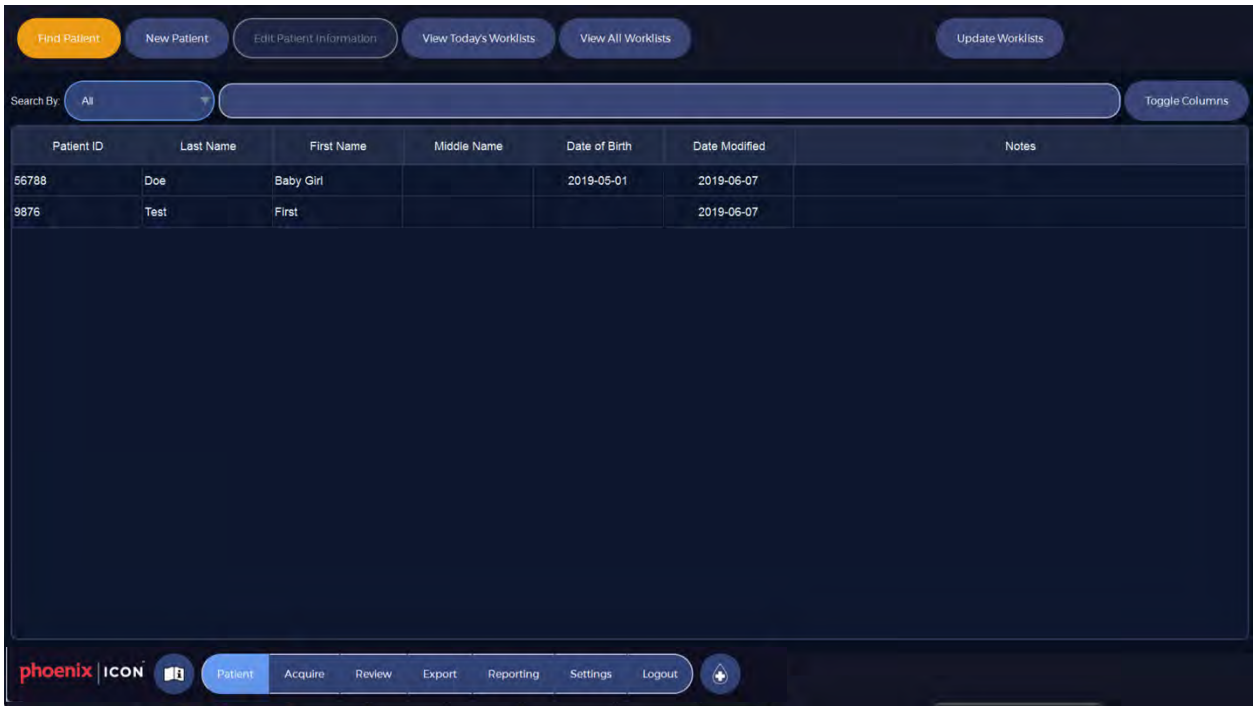
- **Instructions for Use**: Presents a PDF of this user manual. 

- **Soaking Timer**: Brings up a timer that can be used to time disinfection soaking of the Phoenix ICON™ camera hand piece. Using the timer creates an audit log of all disinfection actions. 

# 10. Patient Screen

The Patient Screen provides the ability to find, add, and edit patient information. The Patient Screen also provides access to a Modality Worklist.

There are three primary buttons at the top of the screen: **Find Patient**, **New Patient**, and **Edit Patient Information.** In addition, there are three buttons related to working with modality worklists: **View Today's Worklists, View All Worklists,** and **Update Worklists.**



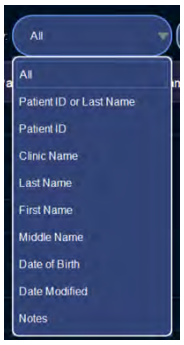

These operations are described in the following sections.

## 10.1. Find Patient

To access a previously entered patient, click the orange **Find Patient** button.

Enter search criteria in the search box. Matching Patients will dynamically appear in the Patient list.

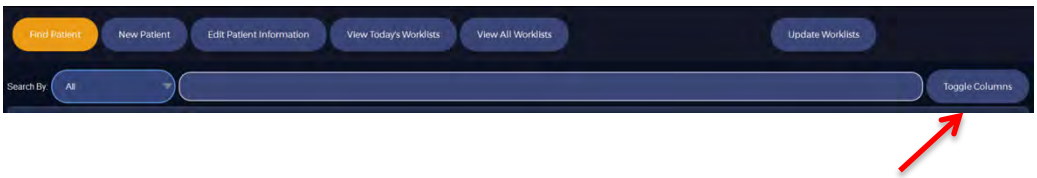
To control which Patient data fields are included in the search, click the down arrows next to "All" and select the columns to include in the search.

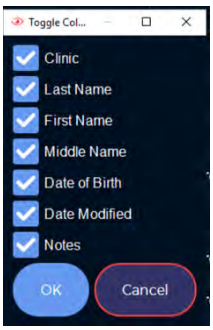



> ***Quicktip***: The Patient list can be sorted in ascending or descending order by any of the columns. Click on the column header once to make it the sort column (ascending). Click on the column again to change to descending sort.

## 10.2. Toggling Columns Shown on the Patient List

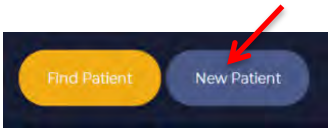
The set of columns shown on the Patient List can be changed. Click Toggle Columns and check the box next to each column that should be visible in the list.

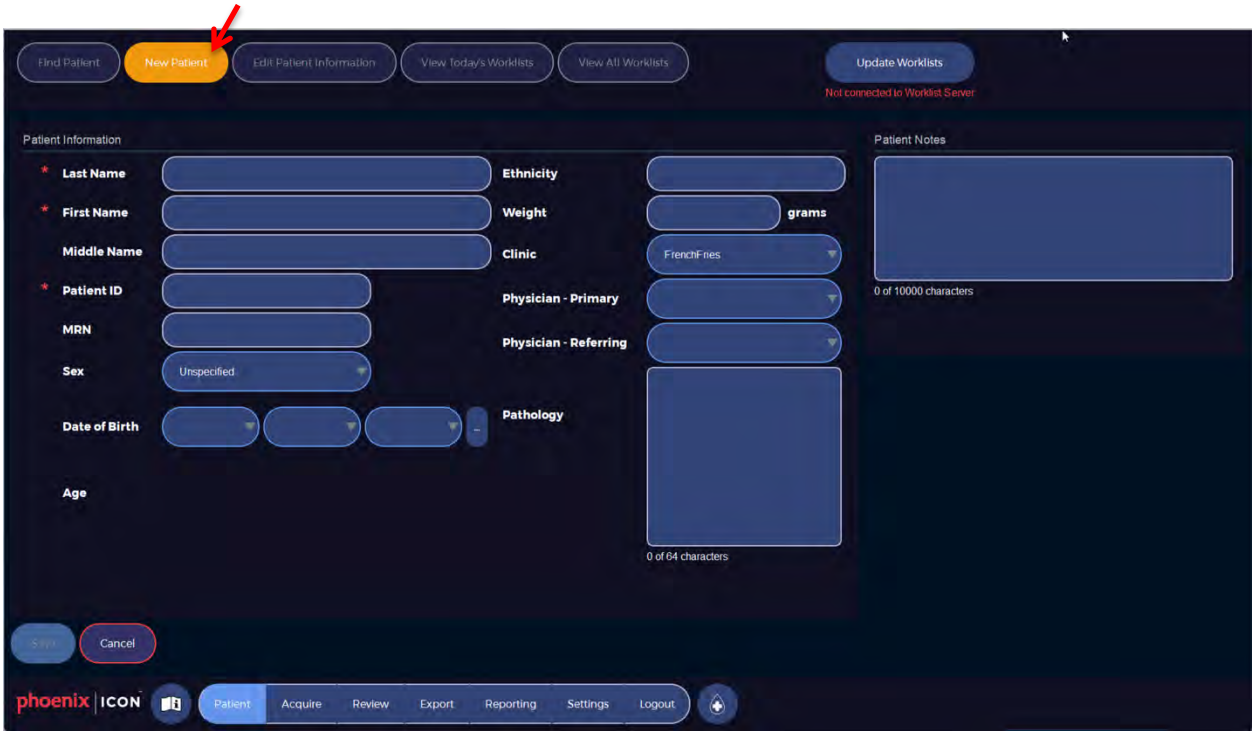


## 10.3. Enter New Patient

To enter data for a new Patient, click the ***New Patient*** button on the Patient screen. Once selected it will turn yellow.

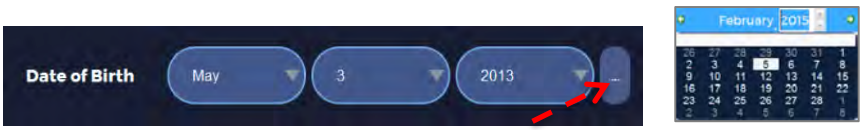



*New Patient Data Input*

- Two fields are always required: **Last Name**, and **First Name**. A **Patient ID** may also be required if the corresponding setting is enabled on the Settings screen. The Patient ID must be unique across all patients. Mandatory fields are marked with a red asterisk (*).

- Select the Month, Day and Year of birth using the dropdown menus. The date can also be set by using the calendar selector, available by clicking the "**…**" button as shown below.




***Quicktip***: Click the Month on the calendar header, to display a dropdown menu, or use the up/down arrows on the year to select other dates. The age of the patient will be automatically displayed below the date of birth.

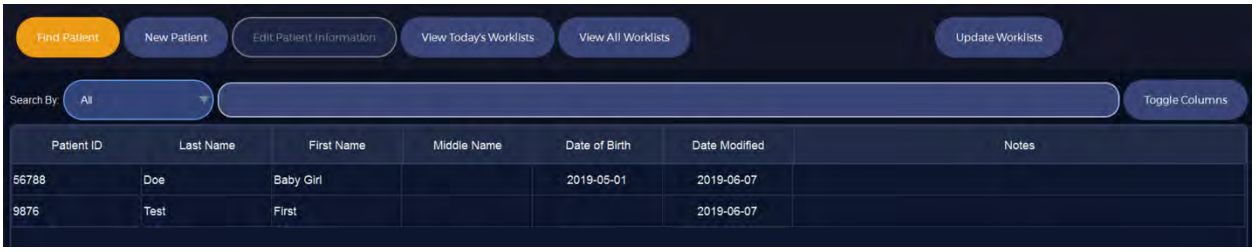
When using the Month/Day/Year dropdowns, click on a menu and start typing the date information. This will make a selection from the menu. Then click "enter" on the keyboard. For example, a date of birth in February, start typing "F" and that month will be selected. Do the same with the number date fields.

- Enter any of the remaining patient data that should be tracked for the Patient, including any notes.
- Click ***Save***

## 10.4. View Patient Information

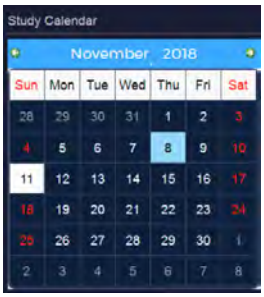
Click on a name in the Patient list and select the ***Edit Patient Information*** button at the top of the Patient screen.

Information for the selected Patient will be displayed.



## 10.5. Jump to Imaging Study

A Study Calendar is shown on the Patient information screen. Dates that are highlighted are those days when imaging has occurred. Click on any highlighted date to jump to Review screen for the corresponding imaging study. If there is more than one imaging study on the date, a pop-up window will appear allowing you to choose which study to select.




## 10.6. Edit Patient Information

Select a Patient by double clicking on a name in the Patient list or by selecting the Patient in the list and clicking the ***Edit Patient Information*** button at the top of the Patient screen.

Click ***Edit,*** and correct or change Patient data fields on the Patient information screen.

After all edits have been made click the ***Save*** at the bottom of the screen.

## 10.7. Working with Modality Worklists

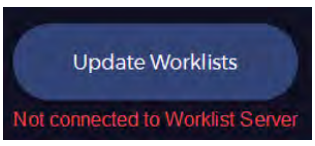
The Phoenix ICON™ system includes support for downloading a modality worklist (MWL) from a DICOM-compliant server on the network. Using the modality worklist feature can eliminate the need for patient and study data entry on the Phoenix ICON™ camera and improve the integration with hospital and clinic information systems.

The modality worklist feature is configured on the Settings screen. See Section 3: Setting – ICONnect MWL.

### 10.7.1. Updating the Worklist

Clicking the ***Update Worklist*** button on the top of the Patient screen causes the Phoenix ICON™ software to send a request to the configured modality worklist server and download a new worklist of available.

If the worklist server is unavailable, if the Phoenix ICON™ camera is not connected to the network, or if the ICONnect MWL connector is improperly setup, an error will be displayed indicating that the modality worklist server could not be reached.



The Phoenix ICON™ camera stores the worklists that have been received from the worklist server.

### 10.7.2. Viewing Today's Worklist

Click ***View Today's Worklist*** to list the imaging procedures to be performed today.

Each procedure is associated with one and only one patient.

Each worklist procedure is clickable.

When you click on a procedure, the following actions are taken:

1. If the associated patient is new to the ICON Software, the patient record is automatically created in the Phoenix ICON™ Software database

2. If the associated patient is already known to the Phoenix ICON™ Software, the patient record is updated to match the data provided by the worklist server (we always assume that the data on the server is the most current, and this is particularly useful when the patient's name has changed since it was first loaded in the Phoenix ICON™ Software)

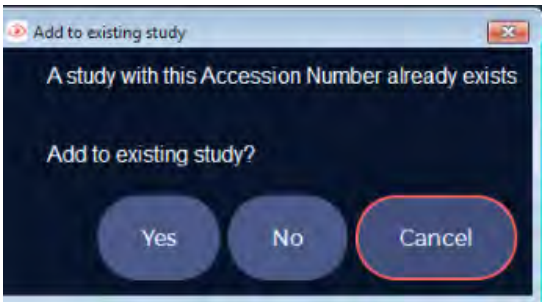
3. A new study is created for today. The study is associated with the given patient, and the accession number provided by the modality worklist server is stored with the study.

4. The Acquire screen is opened to begin capturing images for the patient

A few important points as it relates to data integrity and which system (the Phoenix ICON™ Software or the modality worklist server) controls the data:

- When a new worklist is received, the Phoenix ICON™ Software searches its database for a patient with a matching Patient ID. If a patient with the same patient ID already exists, the patient fields in the Phoenix ICON™ database are overwritten with the data provided by the modality worklist server. This includes overwriting the patient name, as the Phoenix ICON™ Software assumes that the modality worklist server is attached to the system of record for patient information.

- If an imaging study with the same accession number already exists, the operator is asked if images should be added to the existing study or if a new study should be created with the same accession number.



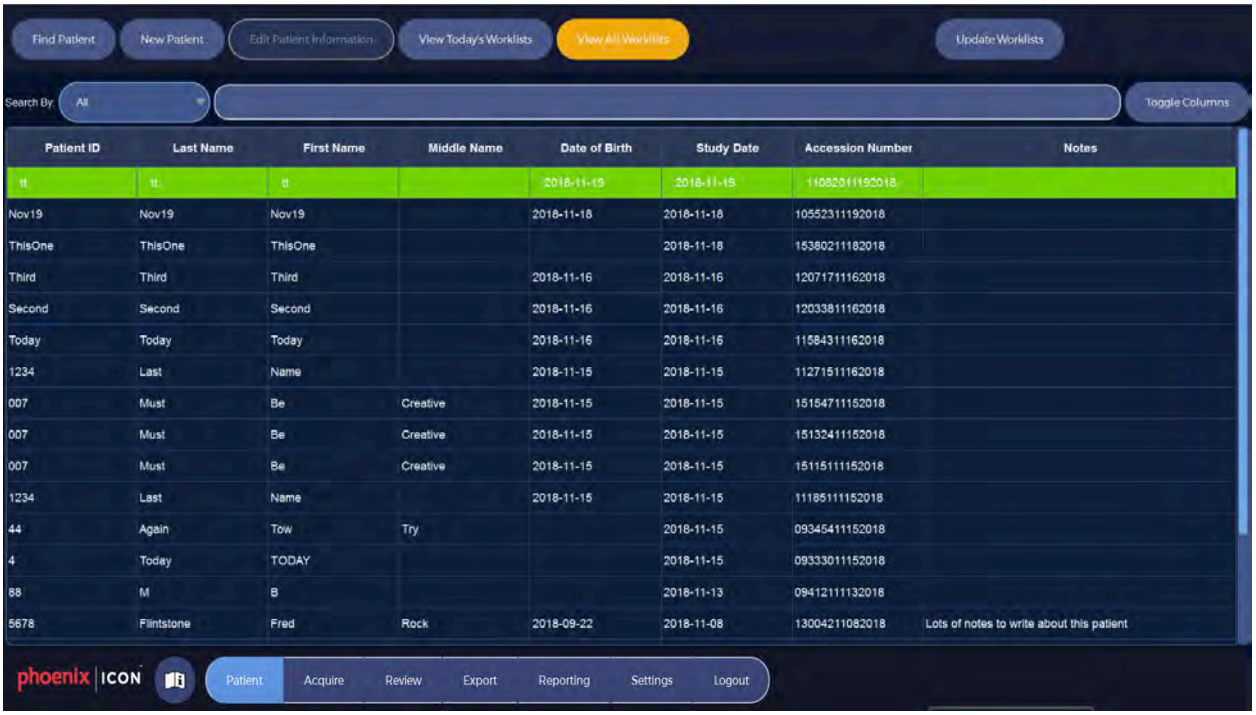

*Add to Existing Study*

- Today, the Phoenix ICON™ software only processes the first scheduled procedure step in a returned modality worklist. Additional scheduled procedure steps are ignored in the current release.

### 10.7.3. Initiating Imaging from the Worklist

Double clicking on a worklist entry launches the Acquire screen to all the operator to capture images and videos of the corresponding Patient.

After one or more images have been captured in the study, the worklist entry will be marked as green on the next visit to the Patient -> View Worklist screen. All worklist procedures that have associated images (associated studies) will be highlighted in green. This provides a means of using the worklist as a "task list" while imaging patients, to help ensure that all scheduled studies have been completed.



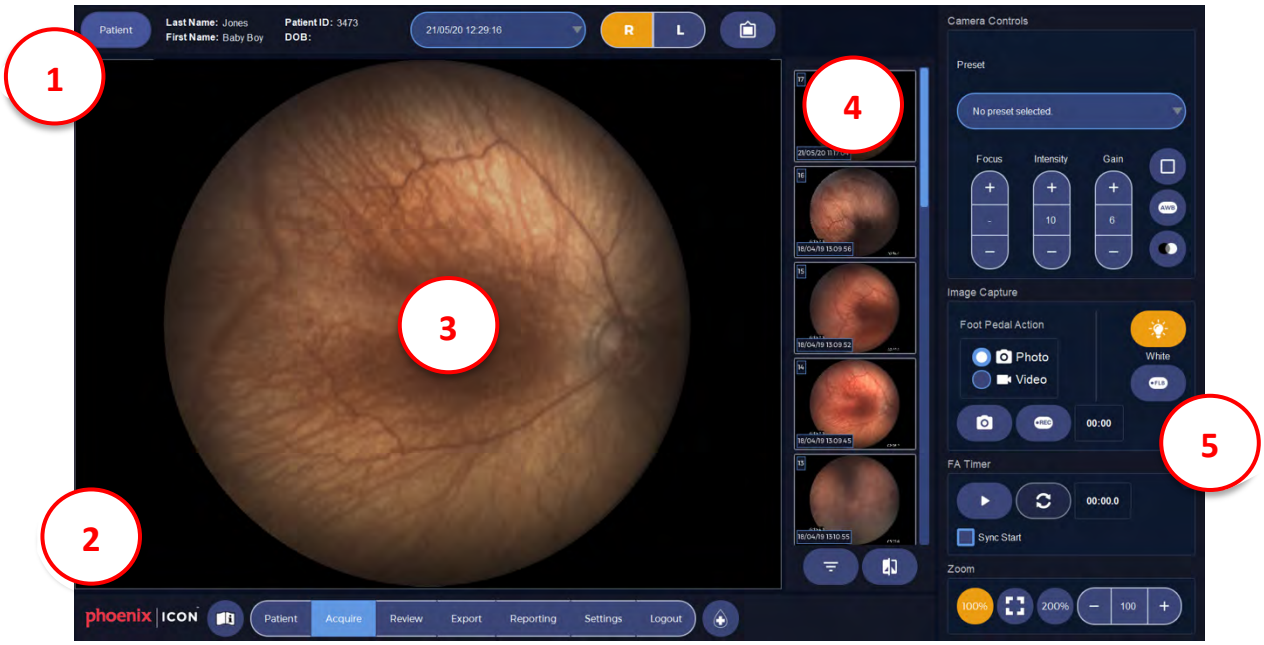
By initiating the image acquisition process from the View Worklist screen, you are associating the study with the procedure step by recording the provided accession number. When these images are later in DICOM format, or sent to a PACS using the ICONnect PACS connector, the accession number will be present, and this can be used by the IT systems to connect the images to the patient record.

### 10.7.4. View All Worklists

The "View Today's..." shows a list of worklists that have a study date matching the current computer date. From this list you can select a patient which will then be copied over to the imaging database and the system will take you to the Acquire screen ready for imaging.
The "View All Worklists" is for information only. It will show all entries currently in the local worklist database, but you cannot select them.

# 11. Acquire Screen

The Acquire screen presents the image and video capture interface for the Phoenix ICON™ camera. The screen is divided into five zones:



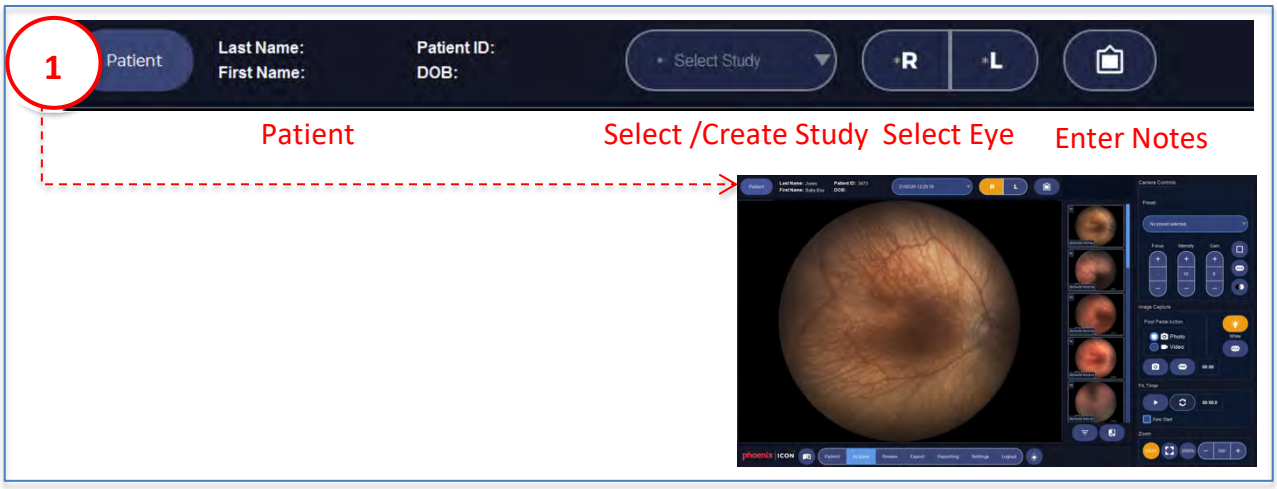

*Acquire Screen*

**1** - Patient/Study Information: Name, Study Date, Eye, Study Notes
**2** - Navigation Panel
**3** - Image Display Window
**4** - Thumbnail Tray, showing captured images/videos, with the most recent at the top
**5** - System Controls: Camera, Image, FA Timer and Zoom controls

All panels are described in detail on the following pages.

## 11.1. Section1: Patient / Study Information

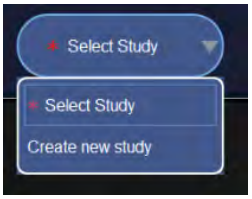
You must select a Patient, the Study date, and the Eye being imaged before you are able to capture images or videos. Prompts within the imaging frame will indicate this. If a patient is not selected, you are not able to select a Study or Eye**.**




### 11.1.1. Select Study

To being imaging, either create a new study, or select an existing study.

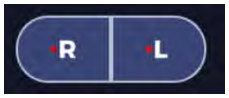
To create a new study, click the ***Select Study*** drop down, and click ***Create new study***




To add images to a study that you started today, select today's date and continue imaging. The new images will be added to the previous images in the thumbnail panel.

### 11.1.2. Select Eye

The Right Eye or Left Eye must be selected prior to imaging. Click ***R*** or ***L*** to select the eye being imaged.

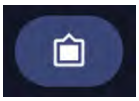



***Note: If an image is captured with the wrong eye selected, it is not possible to change it to the correct eye after capture.***

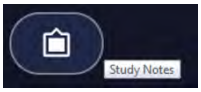
***QuickTip*** – Go to ***Settings -> User*** to select whether the eye designation appears as R/L or L/R.

### 11.1.3. Study Notes

Click the ***Study Notes*** button to enter text associated with the current imaging study. This can be entered and edited on both the Acquire and Review screens.



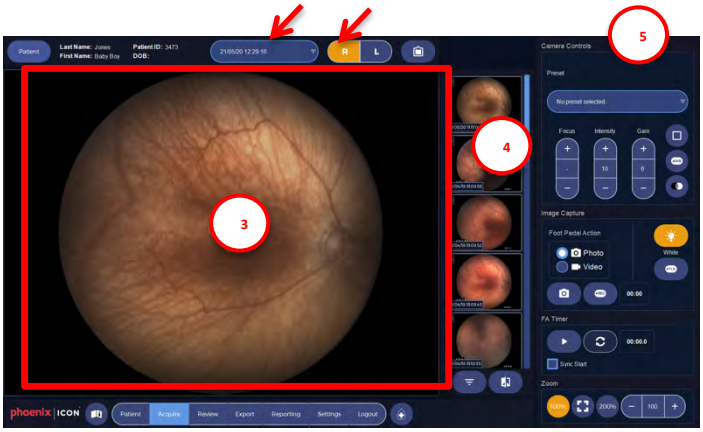
***QuickTip*** – Hover your mouse over any icon to reveal the tool tip description of its function.




## 11.2. Section 3: Image Display Window

The large area in the center of the Acquire screen presents a live view of the Phoenix ICON™ camera. This allows the operator to clearly see the area being imaged to facilitate focus, exposure and capture.

Messages will appear in the center of the screen if a Patient, study date, and right/left eye have not been selected.




Message will also appear in the screen if the Software is connecting to the camera hand piece, or if communication to the camera has been disrupted or the hand piece is not connected to the system.

Although there may be a live image on the screen, the **Study Date** and **Eye** must be selected before the software will allow the acquisition of images or videos.

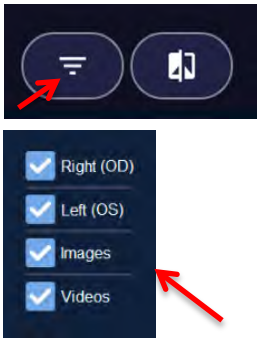
## 11.3. Section 4: Thumbnail Tray

Thumbnails of still images and videos are displayed vertically down the **Thumbnail Tray** as they are captured, with the most recent images/videos appearing at the top.

Thumbnails are numbered sequentially at the top left corner. A date and time stamp is visible on the bottom left of each thumbnail.

Click once on an image to view it larger in the **Review** screen.

The Thumbnail Tray can be filtered to show only the Right or Left eye, and to show only images or videos. Click the ***Filter*** button, shown on the right, to open the filter menu, and click all items that should appear in the Thumbnail Tray.




Click the ***Compare Images*** button to open the Review screen to compare images from the same or different studies of the same patient.

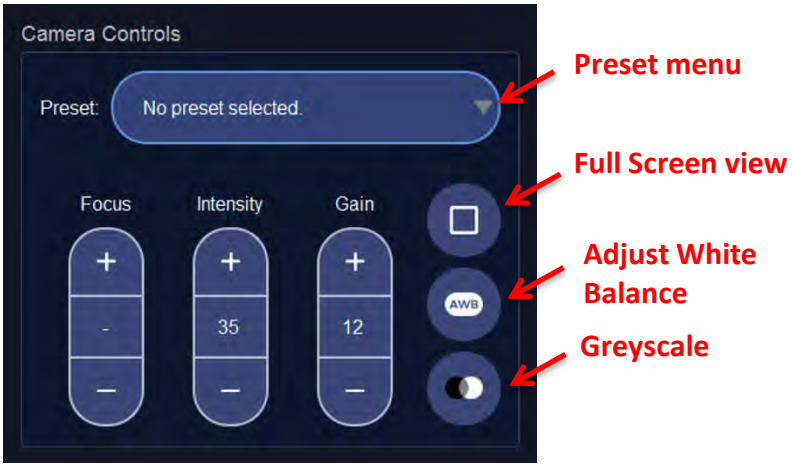
## 11.4. Section 5: System Controls

Operation of the camera is controlled through the System Controls panel, which includes controls for imaging mode, focus and exposure, image zoom, and more. These controls are described below.

### 11.4.1. Camera Controls

The Phoenix ICON™ camera provides two controls to adjust image exposure: intensity and gain. Intensity controls the brighness of the camera imllumination. Gain controls digital amplification of the signal. Intensity and gain can be combined to achieve properly exposed images, even on darkly pigmented retina, with a small amount of light injected into the patient's eye.

The operator can adjust focus, intensity, and gain in the camera control section of the System Controls. The controls are greyed out until the White LED is turned on by clicking the lightbulb icon further down the panel.




**Focus**

Click the + and – buttons on the **Focus** adjustment to make the image clear and sharp so that features are in focus.

On cart-based Phoenix ICON™ systems, the focus can also be adjusted using the keypad on the cart (see the hardware section of the manual). For both portable and cart-based Phoenix ICON™ systems, the focus can be adjusted using the foot pedal (see the hardware section of the manual).

**Intensity**

The **Intensity** control allows the operator to increase or decrease the amount of light emitted from the Phoenix ICON™ camera hand piece. A reference number on the control shows the intensity, which can also be displayed or watermarked on to the image in Settings -> Camera.

On cart-based Phoenix ICON™ systems, the intensity can also be adjusted using the keypad on the cart (see the hardware section of the manual). For both portable and cart-based Phoenix

ICON™ systems, the intensity can be adjusted using the foot pedal (see the hardware section of the manual).

**Gain**

Gain adjusts the Phoenix ICON™ sensor's sensitivity to light. This means the brightness of the image can be altered without changing the light intensity. Use the + or - buttons to increase or decrease the Gain. The amount of Gain is displayed from -3 dB to 38 dB. Normal is considered zero (0 dB). The gain can be controlled from the software or with a user-defined keyboard shortcut.

> ***Quick Tip:***
> *Increase the Gain to get a brighter image without increasing the illumination. Be aware that an extremely high level of gain may result in an overall grainy appearance to the video or image, however this may be a reasonable tradeoff to get the information needed if the patient is particularly sensitive to light.*

**Preset**

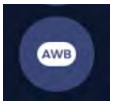
A dropdown menu contains four user-definable **Presets** for **Intensity** and **Gain**. These may be configured in the Settings screen. The light must be on to select a Preset. After a Preset is selected, the Camera Controls can then be adjusted manually using the + and – buttons in the software (or using the available hardware controls).

**Full Screen**

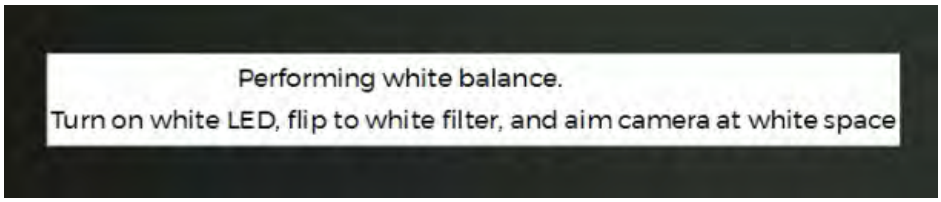
The Phoenix ICON™ Software supports a full-screen mode in which only the live view of the camera image is displayed. In this view, all of the controls need to be accessed via keyboard shortcuts (set up on the Settings > Shortcuts screen) or the hardware controls (food pedal, cart keypad).

Press the ***Full Screen*** button to display only the camera image. Click the Escape key on the keyboard to go back to the standard view.

**AWB (Adjust White Balance)**




The white balance of the Phoenix ICON™ camera can be adjusted using the Adjust White Balance button. Turn on the camera light, point the lens towards a white surface or white piece of paper so that it completely fills the live image on



the screen, and press the ***AWB*** button. The dialogue box below will appear in the image display area during AWB.

> ***Quick Tip***: *The white balance will not work if the barrier filter is in position on the hand piece. If the image looks abnormally yellow, and the white balance does not function, ensure the yellow barrier filter is not engaged.*

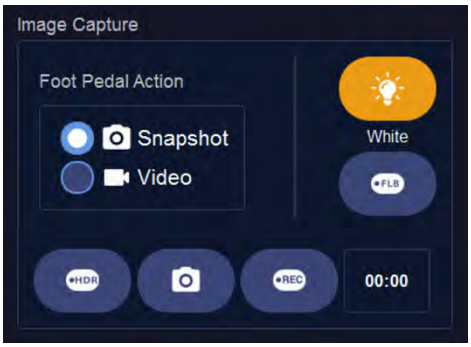
**Greyscale**

Click the **Greyscale button** to display switch from color imaging to greyscale imaging. This may be useful for fluorescein angiography where it is common to see the images of the transit of dye in black-and-white.

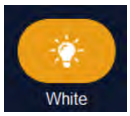
Note: A Greyscale by default option is available in the **Settings** screen should you want all fluorescein imaging to be captured in this mode.

### 11.4.2. Image Capture

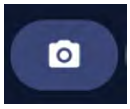
The Image Capture section of the System Controls is used to turn on the camera light, control the capture mode (video, still, Flashback), determine which action is taken when the foot pedal capture button is pressed, and provide an on-screen means of capturing images.



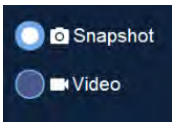

Each of the operations is described below.



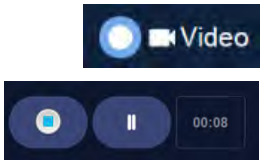

**Turn the LED illumination on**, by clicking the light bulb button. The color of the LED inserted in the hand piece (white or blue) is labeled underneath. The illumination button also powers camera focusing. If it is off, there may be a live view on the screen however the camera won't focus.



Click the ***Camera*** button to capture a still image.



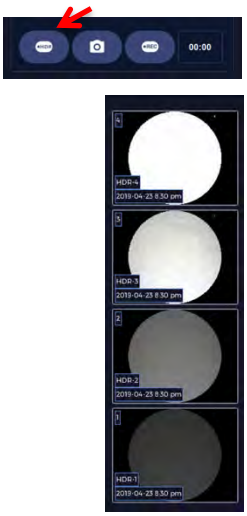

**Control Foot Pedal Action.** The selections on this panel indicate whether the **Foot Pedal** will capture a Snapshot or Video when the Foot pedal snap button is depressed.




When the **Video** mode is selected, each time the **Snap** button on the foot pedal is depressed it will toggle between capture mode and pause mode. This enables you to pause the video capture if the view is not ideal, or you are no longer on the eye but have more areas to image. (Note that it is recommended that still frames be exported from a video, and then the video be deleted to prevent filling the Phoenix ICON™ system hard drive.)

When you are finished capturing, click the **Stop** button on the software. This will prompt you to save your video. Still images may be captured from the video at a later time and the video may be deleted to save hard disc space.

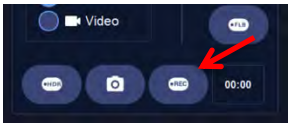

**Record video** using the software by clicking the **Rec** button. The duration of the video as it captures is displayed. Videos will be recorded using the Foot pedal if the Video capture mode is enabled. The maximum video length is two minutes which can be reduced in the Settings screen.




**Capture HDR**. Click the ***HDR*** button to set a mode that will simultaneously capture four images of the same region of interest each with different gain values. (Gain adjusts the sensitivity of the camera, not the intensity of the illumination for the patient.) As a result, images will be of varying brightness, from dark to light. They may be exported and worked with in third-party software to create an image of high dynamic range.

### 11.4.3. Video Recording Modes

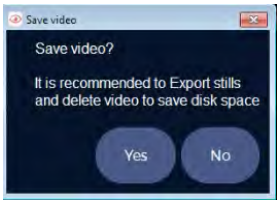
There are two options for recording video: Normal video recording (REC) and Flashback mode (FLB). Still images may be captured from the video at a later time and the video may be deleted to save hard disc space. The resolution of images captured in still mode or captured from videos are the same.



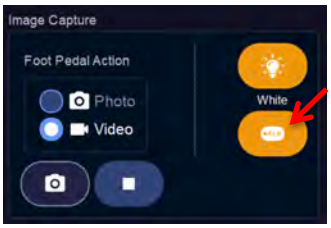

**Normal Video Recording Mode (REC)**: When the REC video recording mode is selected, each time the Snap button on the foot pedal is depressed it will toggle between capture mode and pause mode. This enables video capture to be paused if the view is not ideal, the camera is no longer on the eye but there are more areas to image.


A red pulsing circle will appear around the **Stop** button when the camera is recording. The red circle will be visible but not pulsing when the video is in pause mode.

When video capture is complete, click the square **Stop** button.



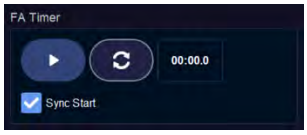

This will display a prompt to save the video. Click **Yes** to save the video. Clicking **No** will present an "are you sure" dialog.




**Flashback Mode (FLB)**: In this mode, the system is always buffering video. When the foot pedal is clicked, the system will save the last user-defined number of seconds. The duration can be set on the Settings/Camera screen to a maximum duration of 10 seconds. In other words, when the foot pedal or software is clicked, it saves a recording of what has already happened for a set period of time. Recording 1-2 seconds in FLB mode is recommended. FLB videos will automatically save after the defined number of seconds of video recording are complete.

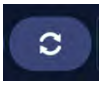
### 11.4.4. Fluorescein Angiography

To perform fluorescein angiography, an accessory blue light module is required for the Phoenix ICON hand piece. Fluorescein angiography in only in certain regions.




Because fluorescein angiography is a time sensitive series of images you can add a timer to the bottom right of the image using **FA Timer** controls. Timing of the test is also visible on the FA Timer controls.

**Manual timer start:** Click the arrow to manually start the timer at the beginning of the injection of fluorescein dye.

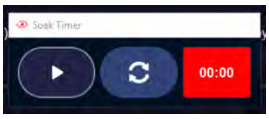


**Reset FA Timer**: Each stop of the **Start Video** button provides the option to save a video. During the next video capture, the timer will continue from the last stopped time unless the **Reset** button is clicked to return the timer to 00.00.0

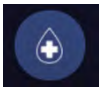
**Sync Start:** Select the check box for **Sync Start** to initiate the timer when **video** recording begins using the record button or the foot pedal. **Sync start** is **not** enabled when using the Snapshot capture mode.

### 11.4.5. Soak Timer

The Phoenix ICON™ Software includes a ***Soak Timer*** that can be used to time soaking of the Phoenix ICON camera hand piece in disinfection solution. Newer models of the Phoenix ICON™ camera also include a hand piece holster with a removable soaking cup so that the hand piece can be soaked when placed in the holster.




Once the camera has been placed in the cleaning or rinse fluid, click the Soak Timer button on the task bar. A floating window will open. Click the ***Start*** button (play arrow) to start the countdown. The timer will flash red when the soaking duration is complete.



The Soak timer button is available and visible from any screen and the pop-up timer can be repositioned once activated.

The default number of minutes can be set in Settings -> Camera up to a maximum of 30 minutes.

To close the window, click the Soak Timer button on the task bar again.

Each start / stop of the Soaking Timer create an entry in the audit log which includes the current User Name and the date and time. These entries form an infection control cleaning log.

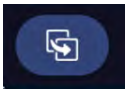
### 11.4.6. Zoom the Image

Use the software controls to zoom into the image during live imaging or when reviewing images. The percentage of the zoom is indicated for reference.


Quickly zoom to 100% or 200% zoom using the shortcut buttons.

A 100% zoom will fill the frame vertically.

Click the button with the white corners to reset the image to fill the viewing area horizontally. When on the Acquire screen, Zoom will allow you to see the live image magnified however the native image size is captured without zoom.

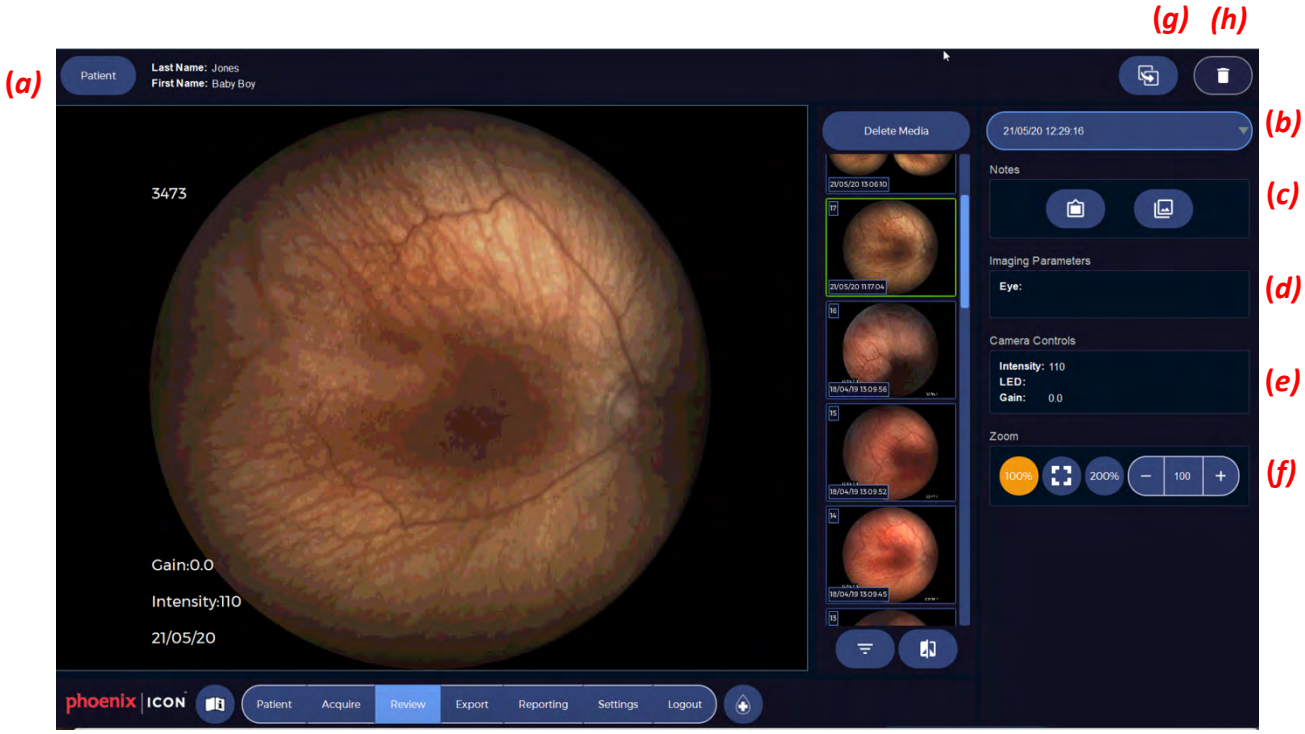


**Quick Tip:** It is possible to zoom captured images in **Review** mode. These zoomed areas may be saved as separate images by clicking **Save Image as Copy**.

**Quick Tip**: Each time the operator enters and leaves the Acquire screen, the system creates a database backup which can be useful to recover from unexpected failures.

# 12. Review Screen

When image acquisition is complete, media may be assessed on the **Review** screen.




The following operations can be performed on the review screen:

- **Patient Name**: The name of the Patient is visible at the top left of the Review screen ***(a)***. Click the ***Patient*** button to return to the Patient Screen to select a different patient to review.

- **Selected Study**: Click the dropdown list at the upper right of the Review screen ***(b)*** to select a study that has been captured for the selected Patient. Once the study has been selected the images and videos from that study will be displayed in the thumbnail panel.

- **Viewing and Editing Notes**: Information relevant to the selected study or the currently viewed image may be added to the **Study Notes** and **Image Notes** ***(c).***

- **Image Capture Details**: Details about the currently selected image are shown on the right of the Review screen, showing the laterality (right or left) ***(d)*** , and the exposure settings (intensity, gain, and whether the white or blue light module was used ***(e)***.

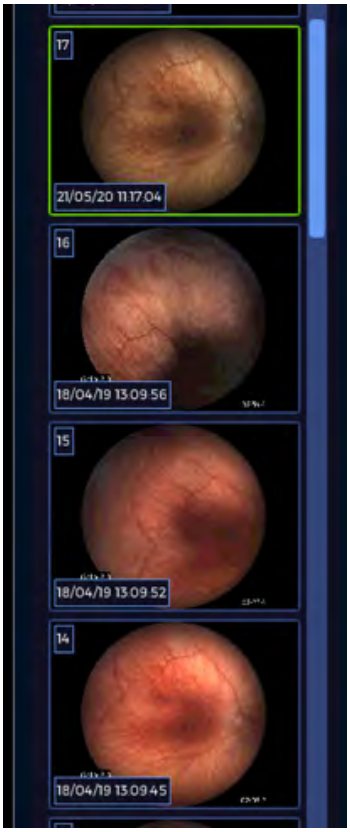
- **Zoom:** Zoom controls ***(f)*** allow the operator to zoom the view of the currently selected image in or out. The operation of the Zoom feature is described in section 11.4.5.

- **Save a Magnified Image Copy:** Click the "save a copy" button in the upper right of the Review screen ***(g)*** to save the current view of the selected image as a copy. This allows the operator to zoom in to an area of interest and save the zoomed view. A magnifying glass and the percentage of zoom will appear on the thumbnail of the save image in the thumbnail tray.

- **Delete Empty Study:** Once all the images and views in an imaging study have been deleted, the imaging study can be deleted by clicking the "delete study" button in the upper right ***(h)***.

### 12.1.1. Interacting with Thumbnails on the Review Screen

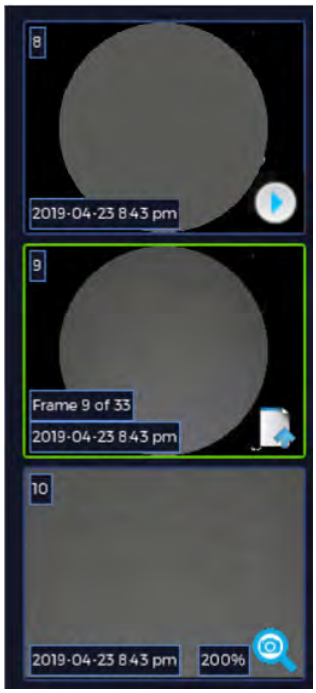
Similar to the Acquire screen, thumbnails of still images and videos are displayed in the Thumbnail Tray of the Review screen with the most recent images appearing at the top of the column.




Click once on an image to view it in the viewing area of the screen.

The capture date and time are visible on the bottom left of each thumbnail.

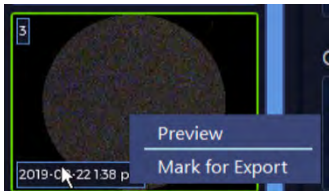
The thumbnail of the image being reviewed is outlined in with a light green border.



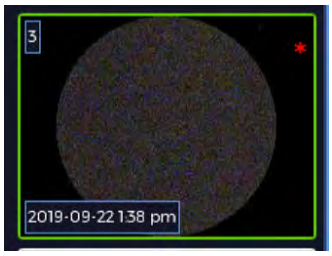

**Videos**: A thumbnail displaying a forward-facing blue arrow or "play" icon indicates a video has been captured.

**Frame from Video**: A frame saved from a video is marked with an arrowed document in the lower right corner, amd the frame number as a watermark. The frame number is included as part of the file name when exported.

**Copy of Zoomed Image**: A blue magnifying glass icon on the bottom right of a thumbnail indicates that a zoomed version of the image has been saved. The degree of magnification is also displayed.
This feature can be performed in the Review screen.

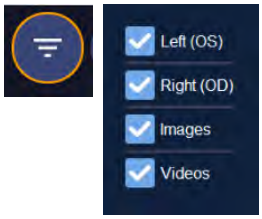

**Mark for Export**: Thumbnails may be preselected for export on the Review screen by right clicking the image and choosing "Mark for Export". This will place a red asterisk on the image. The image will be pre-selected on the Export screen.




The "Mark for Export" tags are removed after exporting or when navigating to a screen other than the Export screen.

### 12.1.2. Filtering the Thumbnail Tray

The Thumbnail Tray can be filtered to display only images or only videos, and to show only images for the right or left eye.




Click the ***Filter*** button found at the bottom of the thumbnail tray, and the select the items to be shown. The Thumbnail Tray will refresh to show thumbnails of only matching images.

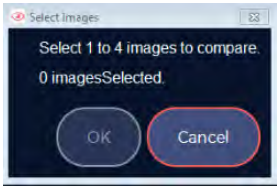
> **Quick Tip**: When viewing the Thumbnail Tray, if some captured images appear to be missing, check the Filter to ensure all images are being shown.

### 12.1.3. Comparing Images

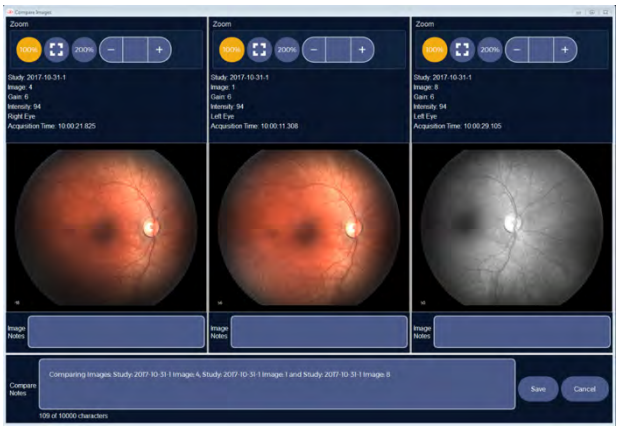
Two to four images can be presented side-by-side for comparison. This can be launched from the Acquire screen, or from the Review screen. The selected images must all be from the same patient and can be from multiple imaging studies.

To initiate the comparison, click the ***Compare*** button found at the bottom of the thumbnail tray.

A dialog will appear prompting the operator to select from one to four images. These can be selected from the current imaging study or a different imaging study for the same patient. To change imaging studies, select a new study date/time from the dropdown in the upper right. Click ***OK*** to display the comparison.



The Compare screen will be displayed.

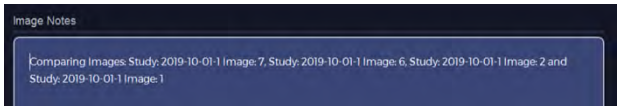


Each image is presented with Zoom Controls, allowing the operator to zoom in to areas of interested. Once zoomed in, the image may be panned to move to other areas of the frame The size of the windows in the compare mode can be adjusted so that all images don't have to be the same zoomed magnification. Notes that have been entered are visible below each image, as well as a general note for the compared series.

Click the Save button to save an image of the comparison series for later reference. The comparison series image will be added to the most recent imaging study that was active when the ***Compare*** button was clicked (and will show up in the Thumbnail Tray on the Acquire, Review, and Export screens).


The dates of the comparisons may be viewed under *Image Notes*

**Note:** It is not possible to compare videos or still images of compared frames.




### 12.1.4. Reviewing Videos

Both standard and Flashback videos can be replayed on the Review Screen, and any single video frame can be saved as a still image. A video is indicated in the Thumbnail Tray with a forward-facing blue arrow or "play" icon.

***Video scrub bar***. When the thumbnail of a video is selected in the Thumbnail Panel, a Video Scrub bar with playback controls becomes active on the top of the Review screen:


The Video Scrub Bar provides playback controls, shows the current frame in the video, provides a control to move forward and backward in the video (called "scrubbing"), and provides a button to save the current frame as a still image (at the same resolution and size as would have been used if the image was captured in still image mode).

***Playback controls***

 First Frame - jump to the first frame of a displayed video

 Play - play the video at normal speed. To pause, tap the arrow again.

 Last Frame - jump to the last frame at the end of a displayed video

 Save a frame from a video as a TIFF image

Note that when the video is paused, the left and right arrow keys on the keyboard can be used to move backward and forward through the video a frame at a time.

To capture a still image frame, advance the video to the desired frame and click the **Save a Frame** button. The new image will appear in the Thumbnail Tray.

### 12.1.5. Deleting Images and Videos

Images and videos may be deleted from an imaging study. The user must have the permission to delete. (Note that images and videos may also be archived, archives images/videos to an external storage location and will delete them from the imaging study. Archiving is performed on the Export screen).

To delete individual images or video:

1. Click the ***Delete Media*** button ***(h)*** found on the upper right corner of the Review screen.

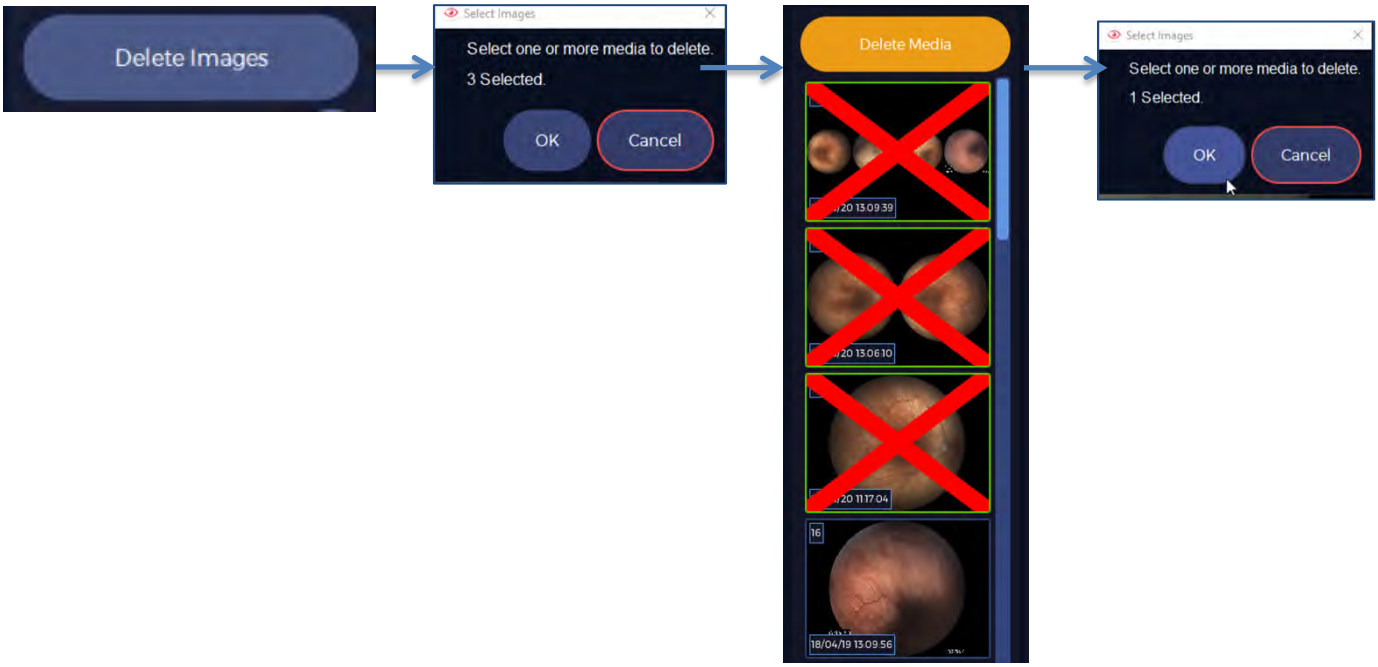
2. If the option to require a password on Delete is set, a password dialog box will appear requiring the operator to enter their password and click ***OK***.

3. A dialogue box will appear asking the operator to select 1 or more images to delete.

4. Select thumbnails (videos or frames). As the thumbnails are selected, they will be marked with a red X indicating they are selected (but have not yet been deleted)

5. Click the ***OK*** button in the select images dialog and the videos or stills will be deleted.

**Note:** Be aware that once you select "OK" there is no possibility to undo the action, and whatever media were selected will be deleted permanently.

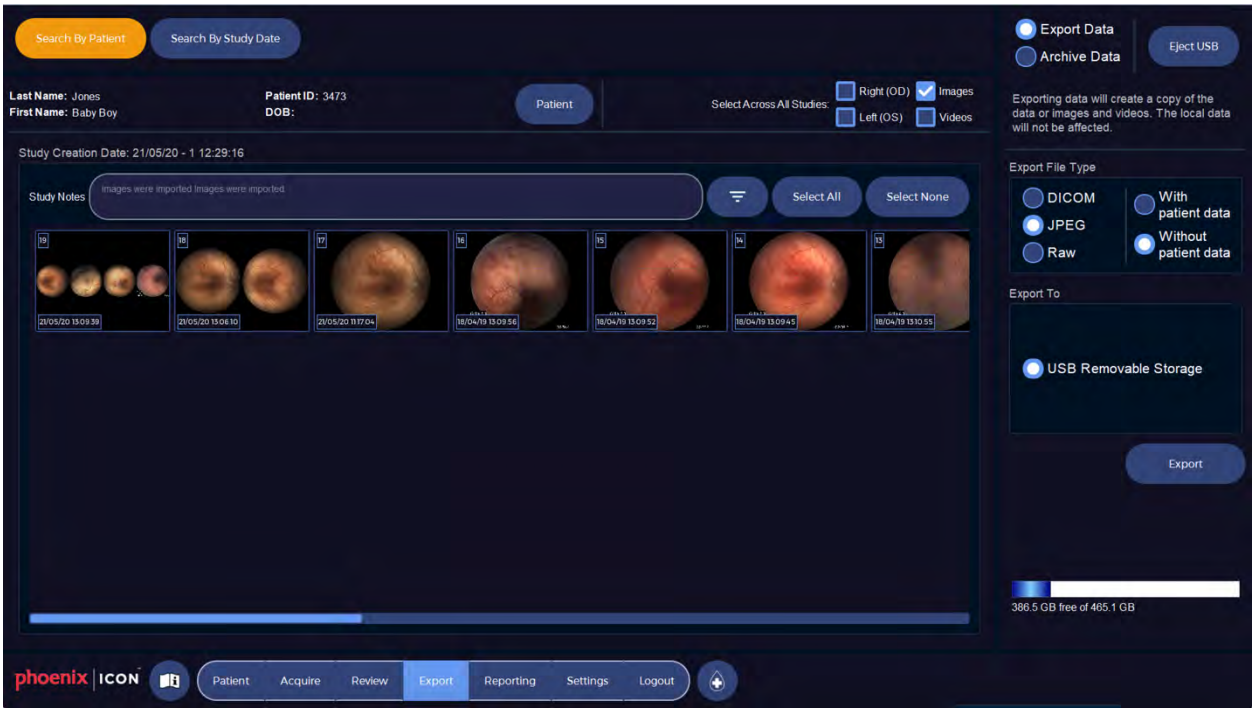


# 13. Export Screen

The Export screen provides tools to export and archive images to external storage locations.

Images may be exported in DICOM format, which includes patient and study metadata. Images may also be exported in Raw (TIFF) or JPEG format. When selecting Raw or JPEG, patient and study meta data can be optionally exported to a companion CSV (comma separated value) file.

Export locations are configured on the Settings screen by an administrator and should be configured before starting to export images.




## 13.1. Export vs. Archive


Exporting images makes a copy of the images at the selected external storage location. Archiving images copies the images to the selected external storage location and **DELETES** them from the ICON database. Export and Archive mode is controlled by clicking the desired mode in the upper right corner of the Review screen. Note that archiving data requires that the user be granted that permission and will require the user to enter their password to complete the operation.

## 13.2. Selecting Data to Export/Archive

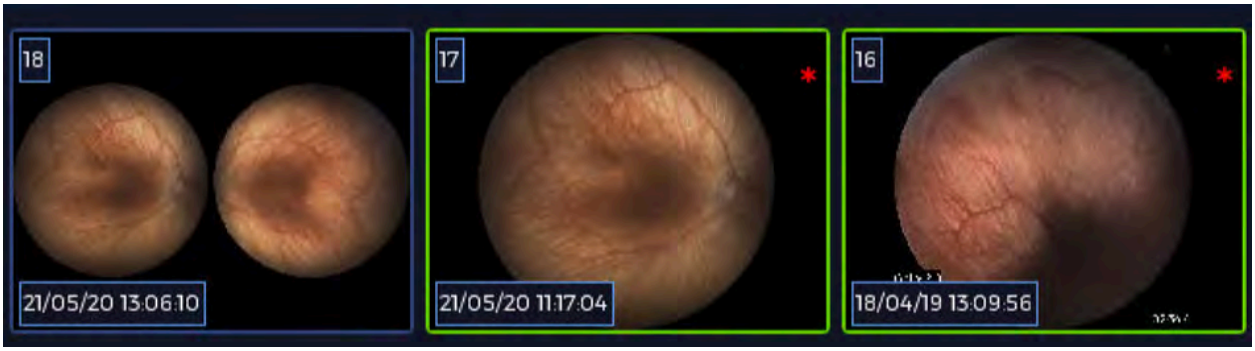
Two buttons at the top of the screen allow the operator to ***Search by Patient*** or ***Search by Study Date***:

- Click ***Search by Patient*** to see all of the imaging studies captured for a specific patient.
- Click ***Search By Study Date*** to see all of the images captured on a specific date or within a date range.

To **preview** an image before deciding to export it, hover over the thumbnail and right click the image. A larger preview of the image will display including any image notes.

To select the images to export:

- Click an image to select it for inclusion in the set of images to export. Selected images will have a green outline and a red asterisk indicating they have been selected
- To unselect an image, click the image a second time.



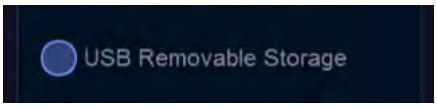

- Click the ***Select All*** button on an imaging study to select all of the images in that imaging study
- Click the ***Select None*** button to unselect all of the images in that imaging study

Next, select the ***Export File Type*** from the list.


- DICOM, JPEG or Raw images
  (Raw images are .TIFF file format)
- When exporting to Raw or JPEG, select with or without patient data

Note: images may only be archived in DICOM or Raw (TIFF) format.

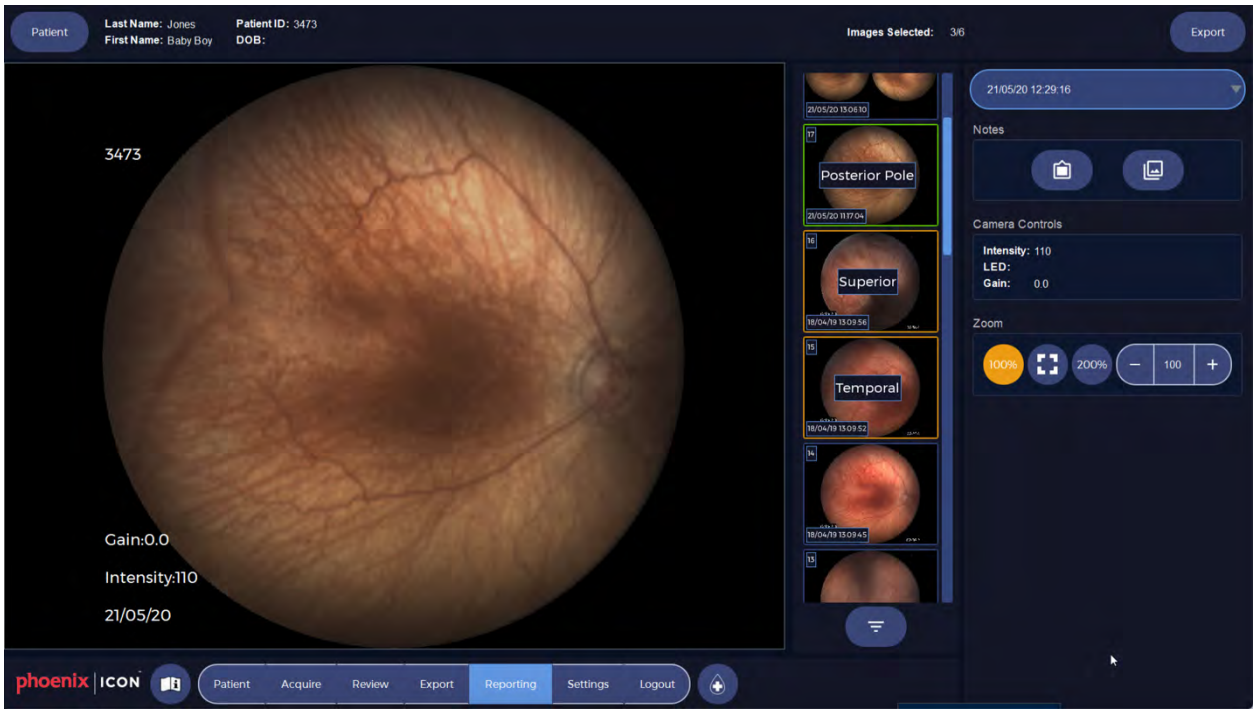
Once all of the images to be exported or archived have been selected, select one of the destinations from the list of ***Export To*** locations.




Finally, click the **Export** button to initiate the export or archive operation. A progress dialog box will be displayed while the images are copied.

# 14. Reporting

The Phoenix ICON™ Software supports the generation of a report from an imaging study. Reports are created from the **Reporting** screen. A report contains patient and study information as well as up to 6 images from the imaging study. Reports are generated as a PDF file and can be exported to one of the configured Export locations.




Click the ***Patient*** button, found on the upper left-hand corner of the Reporting screen, to select a different patient for the report.

Click the ***Study Dropdown***, found on the upper right-hand corner of the Reporting screen, to select an imaging study for the report.

Select the images to be included on the Report by right-clicking on an image in the Thumbnail Tray and selecting the retina quadrant. A selection counter at the top of the screen indicates how many of the six images have been selected.

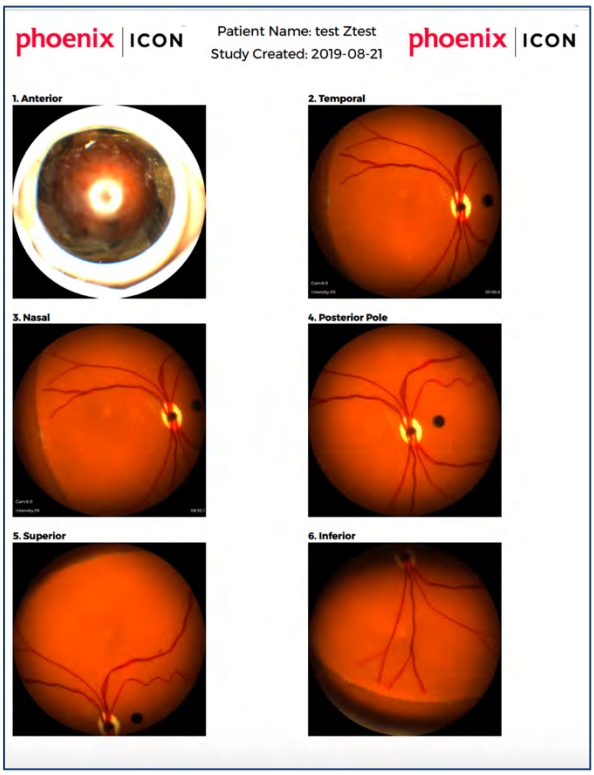

The **Filter** button at the bottom of the thumbnails allows you to limit the images shown in the Thumbnail Tray to images from only the right eye or the left eye individually.

Once at least one image has been selected, the ***Export*** button becomes enabled. If more than six images are selected, the Export button will become disabled until the number of selected images is six or less.

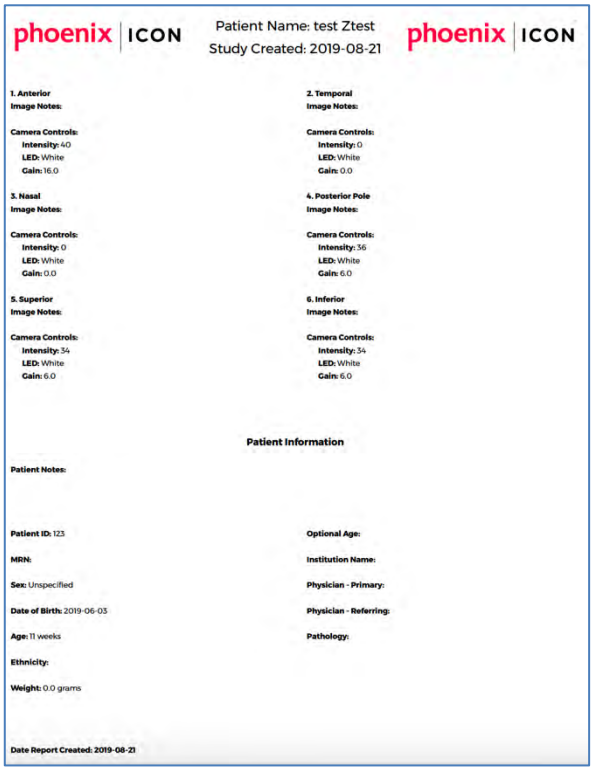
> **Quick Tip**: Export locations may be configured in the **Settings** menu under Export/Archive – Network Locations. In **Settings > Patient Report** options can be selected to automatically launch a PDF viewer and/or automatically launch a printer dialog.

Click the ***Export*** button to create the report. A sub folder will be created in the selected export folder containing copies for the selected images and the PDF report. The PDF report will open in a PDF reader to review. Click the X at the top-right of the PDF viewer to return to the Phoenix ICON software.

A sample report is shown below:


phoenix | ICON Patient Name: test Ztest Study Created: 2019-08-21 phoenix | ICON

1. Anterior
2. Temporal
3. Nasal
4. Posterior Pole
5. Superior
6. Inferior


phoenix | ICON Patient Name: test Ztest Study Created: 2019-08-21 phoenix | ICON

**1. Anterior**
**Image Notes:**

**Camera Controls:**
**Intensity:** 40
**LED:** White
**Gain:** 16.0

**2. Temporal**
**Image Notes:**

**Camera Controls:**
**Intensity:** 0
**LED:** White
**Gain:** 0.0

**3. Nasal**
**Image Notes:**

**Camera Controls:**
**Intensity:** 0
**LED:** White
**Gain:** 0.0

**4. Posterior Pole**
**Image Notes:**

**Camera Controls:**
**Intensity:** 36
**LED:** White
**Gain:** 6.0

**5. Superior**
**Image Notes:**

**Camera Controls:**
**Intensity:** 34
**LED:** White
**Gain:** 6.0

**6. Inferior**
**Image Notes:**

**Camera Controls:**
**Intensity:** 34
**LED:** White
**Gain:** 6.0

**Patient Information**

**Patient Notes:**

**Patient ID:** 123
**MRN:**
**Sex:** Unspecified
**Date of Birth:** 2019-06-03
**Age:** 11 weeks
**Ethnicity:**
**Weight:** 0.0 grams

**Optional Age:**
**Institution Name:**
**Physician - Primary:**
**Physician - Referring:**
**Pathology:**

**Date Report Created: 2019-08-21**

# 15. Software Administration (Settings Screen)

The Phoenix ICON Software can be configured on the ***Settings*** screen. Only users with permission to access the Settings screen can access and adjust the configuration options listed in this section.

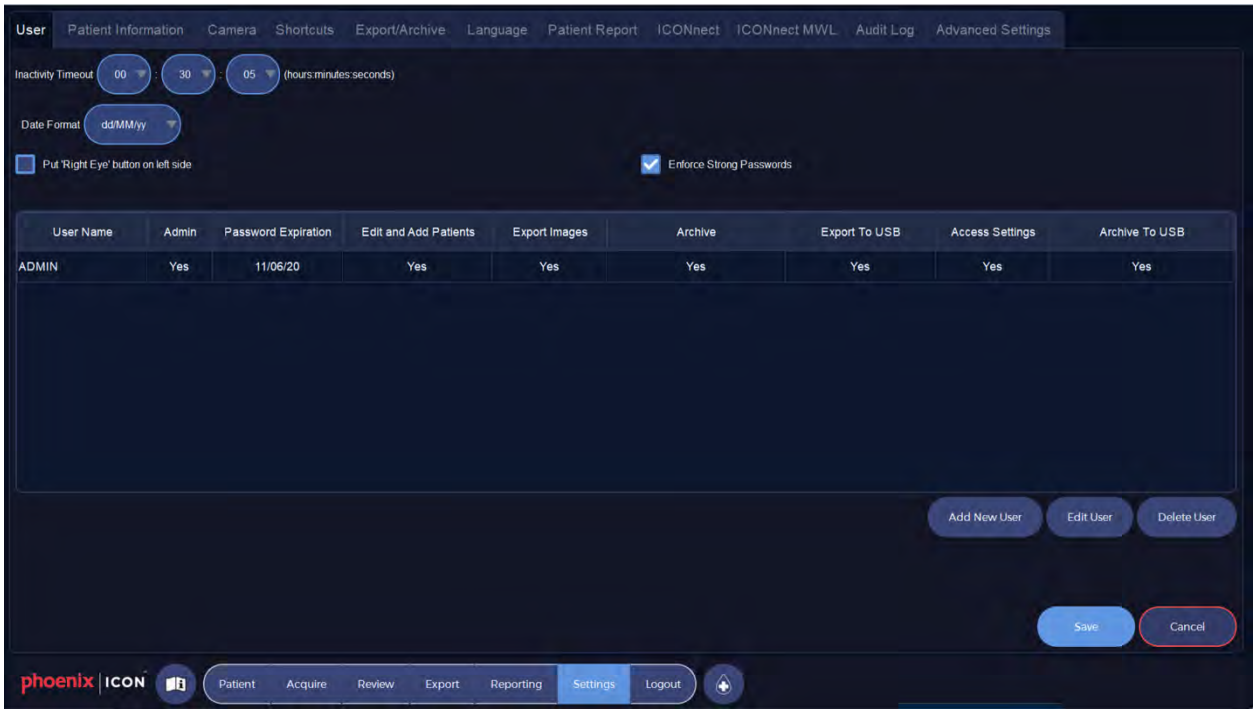
The Settings screen requires that a User reenter their password each time the Settings screen is opened.

Within the Settings screen, there are several tabs to access the various groups of configurable parameters and administer the system, as shown below.

Each Settings tab is described in the following sections.

## 15.1. Settings: User Tab

The ***User*** tab includes settings that control passwords, inactivity timeouts, and provides the interface to create and manage users of the ICON software.




The default User Name and password after installation is “ADMIN” and “5678” which is set to expire after 30 days. When you enter the next password, you will be forced to follow the password rules that are in place at that time.

Lost Password
If there is no user password, you can use the Admin password to gain functional access to the system. If there is no Admin available to login, please contact Customer Support (iconhelp@phoenixtech.com) for password recovery and system access.

### 15.1.1. Inactivity Timeout

This setting controls the timeout period for all User sessions. The software will timeout and return to the Login screen after the specified duration indicated given in hours / minutes / seconds. Note: On the Phoenix ICON GO laptop, be sure to log out of the software before the laptop is put in sleep mode so that patient information is protected.

### 15.1.2. Date Format

This setting controls the appearance of dates throughout the ICON Software. Select the format from the drop-down menu.

### 15.1.3. Put Right Eye button on left side

The option controls swapping the labels of the Right/Left eye buttons on the capture screen to left/right.


*Swap laterality button*

### 15.1.4. Enforce Strong Passwords

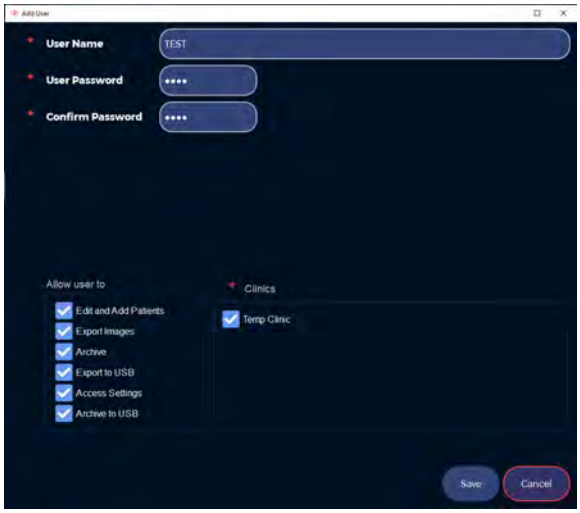
When this option is **unchecked**, passwords may be any length or combination of letters or numbers.

When this option is **checked**, strong password rules apply to **all** passwords. Strong passwords must meet the following conditions:

- At least 8 characters
- Both upper and lower case letters
- At least one number
- At least one special character (!@#$%^&*_+-=[]\{}|<>? )
- When a User changes their password, they may not reuse the prior 5 passwords.

### 15.1.5. Add New User

To add a new User, click Add User



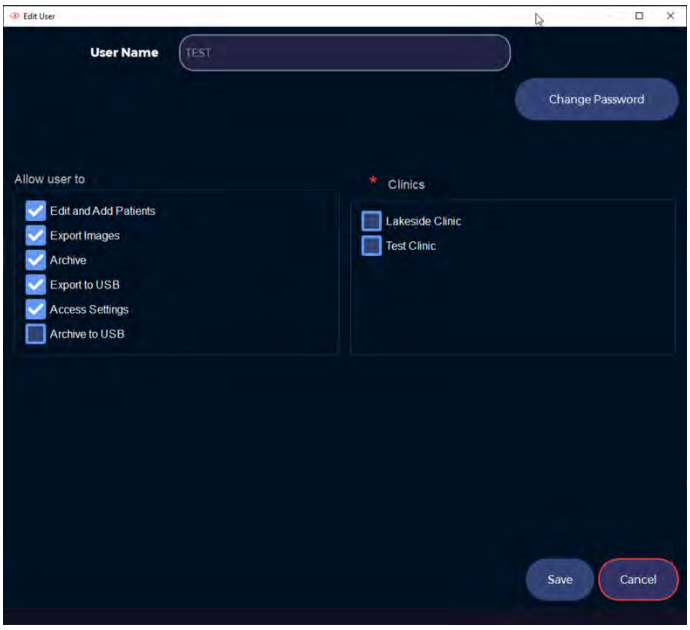

- Enter the User Name. The User Name must be unique across users.
- Select a Clinic for the User (configuring Clinics is described below)
- Enter an initial User Password. If "strong passwords" are enabled, the password must meet the strong password requirements.
- Repeat the User Password to confirm

> **Quick Tip**: If a password is incorrectly entered 5 times the user account gets locked and the password needs to be changed. This is done by the Administrator who unlocks the account in the Settings page. The Administrator account is never locked even if you exceed 5 times. The Administrator password will expire after 30 days. The User password will expire after 90 days.

- Select the permissions to grant to the newly created user.
    - Edit and Add Patients
    - Export Images
    - Archive Images
    - Export to USB
    - Access Settings
    - Wipe Database
- Click **Save** at the bottom right of the screen, to apply any changes.

### 15.1.6. Edit User

- To edit a user, click in the User Name in the list of users and select the Edit User button.
- Click the Change Password button to initiate a password change.
- Check or uncheck the boxes to allow or disallow users to perform software functions listed above.




- Check or uncheck boxes to allow the user access to the Clinics that have been created on the system. If a user has seen patients under one clinic, and they are no longer given permission to view that clinic, the patients are still available to view by the Administrator.
- Click Save at the bottom of the screen to apply any changes,

### 15.1.7. Delete User

To delete a user, click on the User Name in the list of users and click the ***Delete User*** button.

## 15.2. Settings: Patient Information

The ***Patient Information*** tab is used to confirm that Station ID for this Phoenix ICON system, set the list of physicians that can be associated with a given Patient, and set the list of Clinics that can be associated with a Patient or a User.


**Station ID**:
Indicates the Station Name of the Phoenix ICON system.

**Physicians**:
Names entered in this field will enter as dropdown selections in the ***New Patient*** and ***Edit Patient*** screens for Primary Physician and Referring Physician

Click the File Folder icon to add a name to the list.

- Edit the list by selecting a name and double clicking.
- After data has been entered or changed, click outside the field or press the Return key on your keyboard.
- Delete an entry by clicking the X button. Should a physician not be on the drop-down list, their name may be entered manually in the **Patient Information** screen.

- Click **Save** or **Cancel** any changes made to the **Patient Information** tab.

**Clinics**

The Phoenix ICON Software supports creating Clinics, which are logical groupings of Patients. When a User logs in, the User selects a Clinic to use for the duration of their login session. When a new Patient it created, it is assigned to the Clinic associated with the User's current session. Only Patients associated with the current Clinic will be visible during the login session. This has the effect of controlling access to patient data for an ICON system that is moved from one location to another.

> **Quick Tip**: The special user ADMIN can see all Patients, regardless of the Clinic chosen at login.

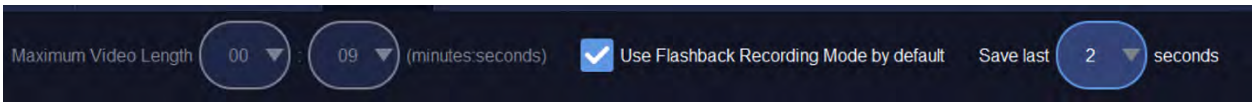
To add a clinic, click the ***Folder*** button under the Clinics field. A new line will appear in which you will type the name of the new Clinic. Press the return on the keyboard to save the entry. Clinics are assigned to Users on the Users tab.

## 15.3. Settings: Camera

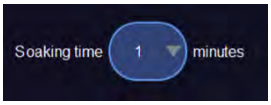
Settings in this tab control camera features and functions, including exposure presets, information that is watermarked on to an image at time of capture, and other imaging options.

**Maximum Video Length**
Select the maximum length, in minutes and seconds, of a captured video. Note that each minute of video consumes 4.2 GB of data.

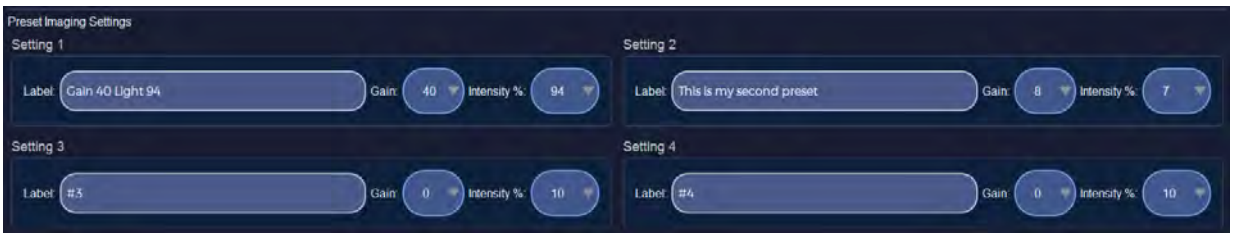
**Use Flashback Recording Mode by default**
Flashback Recording Mode is a feature that allows you to look back in time. In this mode, the system is always buffering video. When it is enabled, an image capture event causes the most recently captured video to be saved (like looking back in time). Set the number of seconds to be saved in the Flashback buffer using the dropdown menu. One to two seconds is optimal. Click the **Use Flashback Recording Mode by default** checkbox to make the button (FLB) active in the Acquire screen without having to select it.




**Soaking Time**
The Phoenix ICON™ Software enables easy adherence to infection control policies by providing a ***Soak Timer***. The Soak Timer can be used to time soaking of the ICON camera hand piece in appropriate disinfection solution. An audit log record is written each time the Soak Time is started and stopped that includes the current User Name, date and time, and this forms a disinfection log. Select the soaking time, in minutes, that corresponds to the institution's designated disinfection procedure.

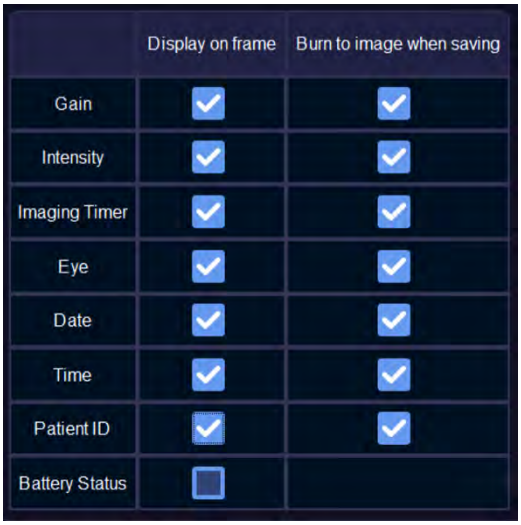



**Preset Imaging Settings**
Four ***Presets*** for camera exposure can be set. These appear on the Acquire Screen and speed setting the camera for different imaging scenarios. For each present, assign the name that will appear in the dropdown, and select the Gain and Intensity associated with the preset label.



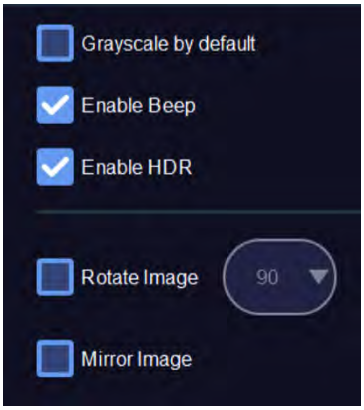
**Frame Information Display**

The following information may be displayed on the black mask of the image: Gain, Intensity, Imaging Timer, Eye, Date, Time, and Patient ID. On the portable Phoenix ICON GO™, the Battery Status indicator of the laptop can also be displayed.




For each data item, the item can be displayed on the black mask of the image, and/or the data item can be added as a watermark on the black mask when an image is saved ("Burn to image when saving"). (Note that the Battery Status can only be displayed, not saved)

For each data item, check the boxes to configure the desired display and watermarking behavior.




**Grayscale by default:** Check this box to default imaging to grayscale when the Blue light module is inserted.

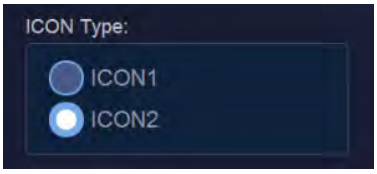
**Enable Beep:** When selected an audio beep will sound when images are captured in still imaging mode.

**Enable HDR**: Check this box to enable the HDR button on the Acquire Screen.

**Rotate Image:** When using the Phoenix ICON™ camera, the expectation is that the operator approaches a supine patient from the top of the head. Thus, the standard orientation of the camera should be so that the hand piece cable comes towards the user at the midline of the patient's forehead. The **Rotate Image** and **Mirror Image** buttons allow the standard orientation of the view to be changed.

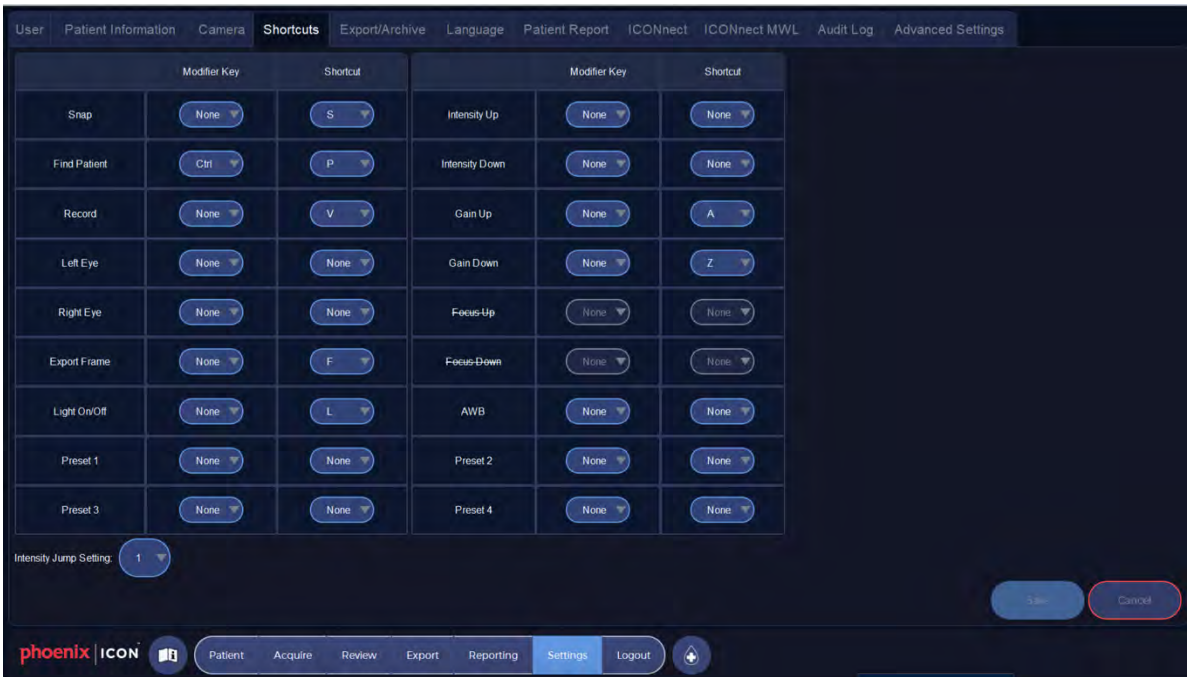
**Video Length Units on Playback**: Select whether the length of videos on the Review screen is shown in minutes/seconds or frames.

**ICON Type** sets the version of Phoenix ICON™ camera hand piece installed on your system.

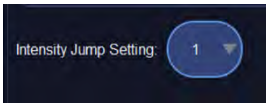



## 15.4. Settings: Shortcuts

Keyboard shortcuts can be configured to provide quick access to imaging functions when acquiring images on the Acquire screen. To enable a shortcut, set the modifier key (none, shift, control, alt) and the key.

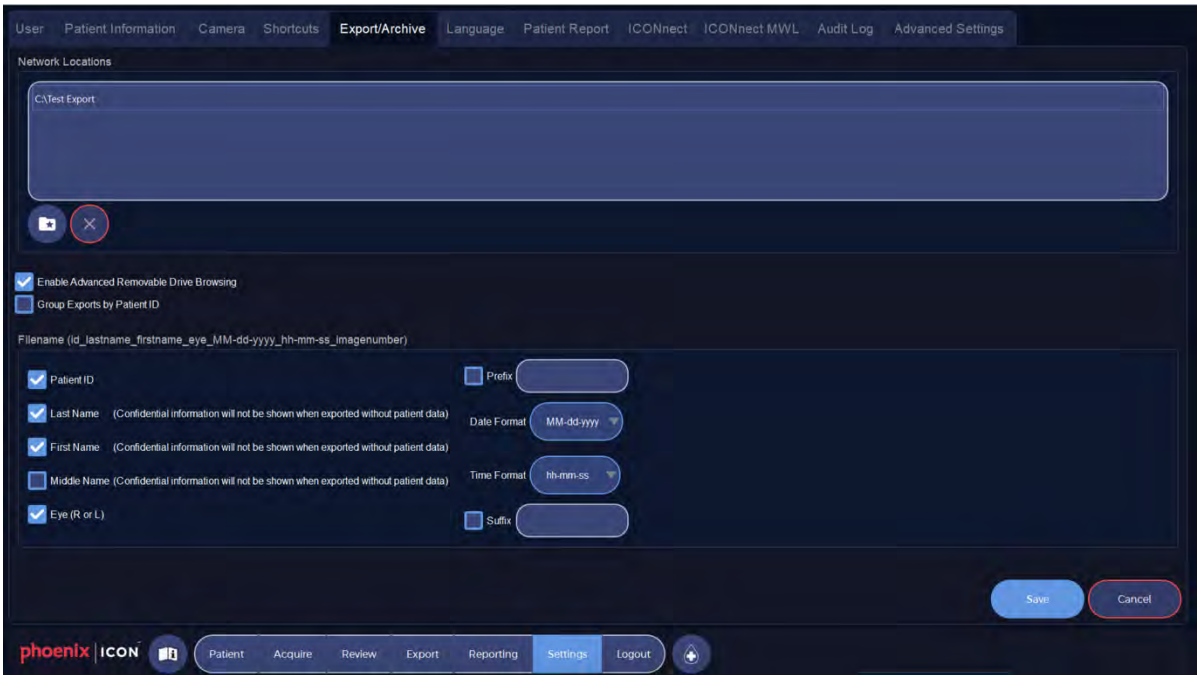



**Intensity Jump setting**: Use the dropdown to adjust the number values the light intensity will change when using the intensity controls on the Software, foot pedal and keypad (on cart-based systems).



## 15.5. Settings: Export/Archive

Configure the export locations, export filename format, and other options for the export and archive functions. (Note that Reports can only be saved to one of the configured export/archive locations.)



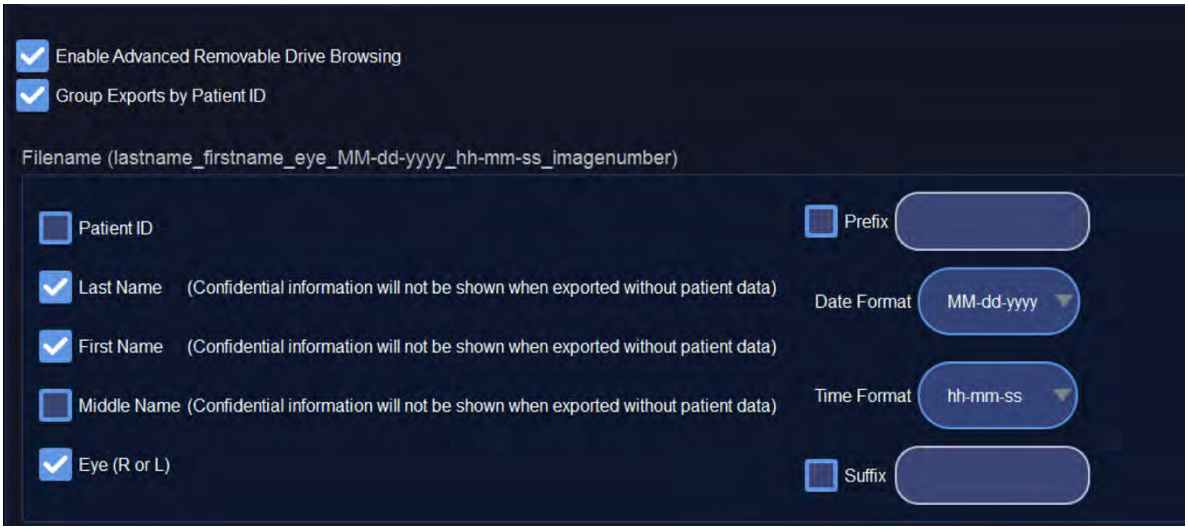

**Network Locations:** Click the ***Folder*** icon to add a folder to the list to list of available locations that will appear on the Export and Reporting screens. (Note that in order to export to a shared folder location, the network destination must be mapped to a Windows Drive Letter.)

To remove a location from the list of Network Locations, select a location on the list and click the ***X.***

**Enable Advanced Removable Drive Browsing:** Clicking this checkbox enables browsing of a currently inserted USB Removable Storage device so that a sub-folder can be chosen as an export location. When this box is unchecked, exporting to a removable storage device places the export in the root folder of that device.

**Group Exports by Patient ID**: This option controls the naming of the export folder. When this option is checked, exports are grouped by Patient ID. When unchecked, exports are grouped by Patient Name.

**Filename**: The names of exported image files are constructed from the data fields on this list. Select the items to include in the list. An arbitrary text string may be added to the filename. An arbitrary text string may be added a suffix. The date and time format can be selected from the two dropdowns. After each change to the format, the filename format is previewed above the list of selections.

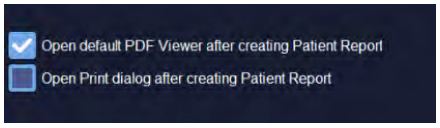



## 15.6. Settings: Language

Select a language from the dropdown menu. Options are English, Spanish, German, Italian, Turkish and French.

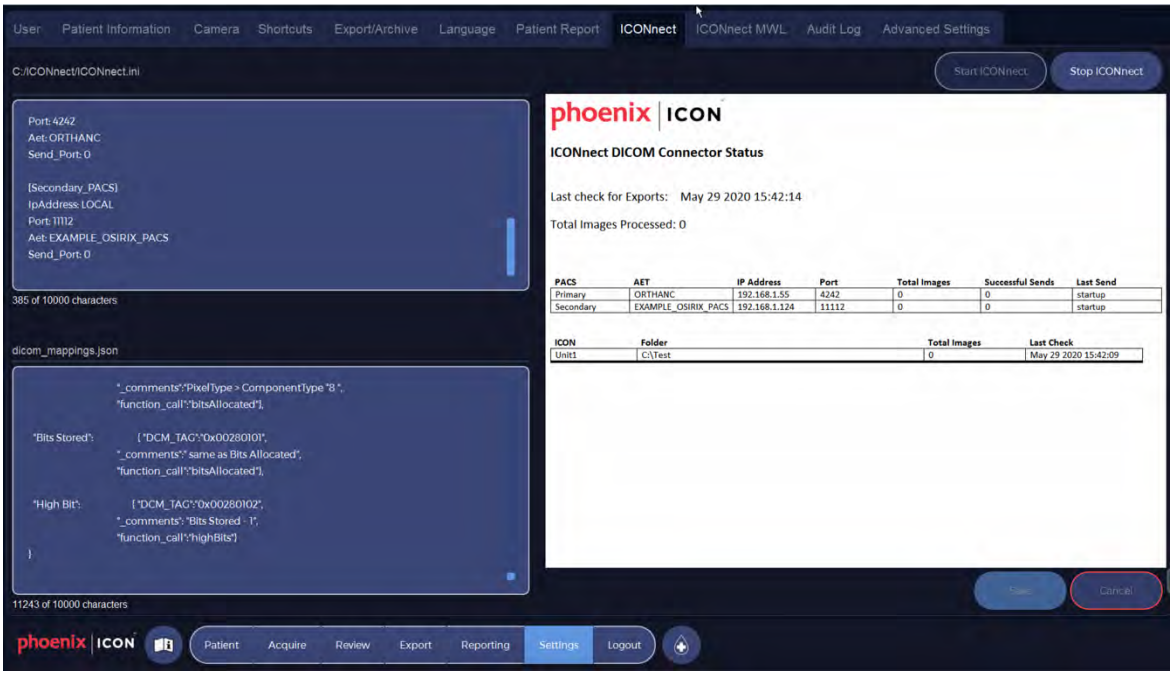

## 15.7. Settings: Patient Report

Select the desired options to optionally open a PDF view when a Patient Report is generated, and optionally open a print dialog after the Patient Report is generated.



## 15.8. Settings: ICONnect

ICONnect is the PACS connector that is built into the Phoenix ICON Software. This tab controls the configuration and operation of the connector.




The left-hand side of the tab presents the settable parameters that control the operation of the PACS connector. This is an editor for a Windows .ini file. Parameters are grouped into named sections, and each parameter is in the form for a name, a colon, a space, and a value.

Press save after the parameters are edited to save changes.

Press the ***Stop ICONnect*** button to stop the connector.

Press the ***Start ICONnect*** button to start the connector.

When the connector is running, the righthand panel of the ICONnect tab will show the current status of the connector. This is useful to confirm the configuration of the connector, and see an indication of when exports were last processed.

In advance of setting up the system for used with a PACS, it is useful to gather all the network settings by filling out the DICOM Setup Questionnaire found at the back of the ICON Integration and Networking section.

### 15.8.1. Forming UIDs

The following scheme is used when creating UIDs for DICOM images sent to PACS:

- The default SOP Class UID is **1.2.840.10008.5.1.4.1.1.77.1.5.1** (Ophthalmic Photography 8-bit Image Storage). This can be overridden in iconnect.ini configuration file.
- The OID is set in the configuration file and defaults to the OID for Phoenix Technology Group
- Study Instance UID:
  OID, plus

  Numeric digits of the ICON Cart Serial Number, plus

  Study ID generated by the ICON Software
- Series Instance UID:

  Study Instance UID, plus

  '.1'
- SOP Instance UID:

  Series Instance UID, plus

  Image ID generated by the ICON Software
- Instance ID:

  Station ID from the ICON Software, plus

  Study ID generated by the ICON Software

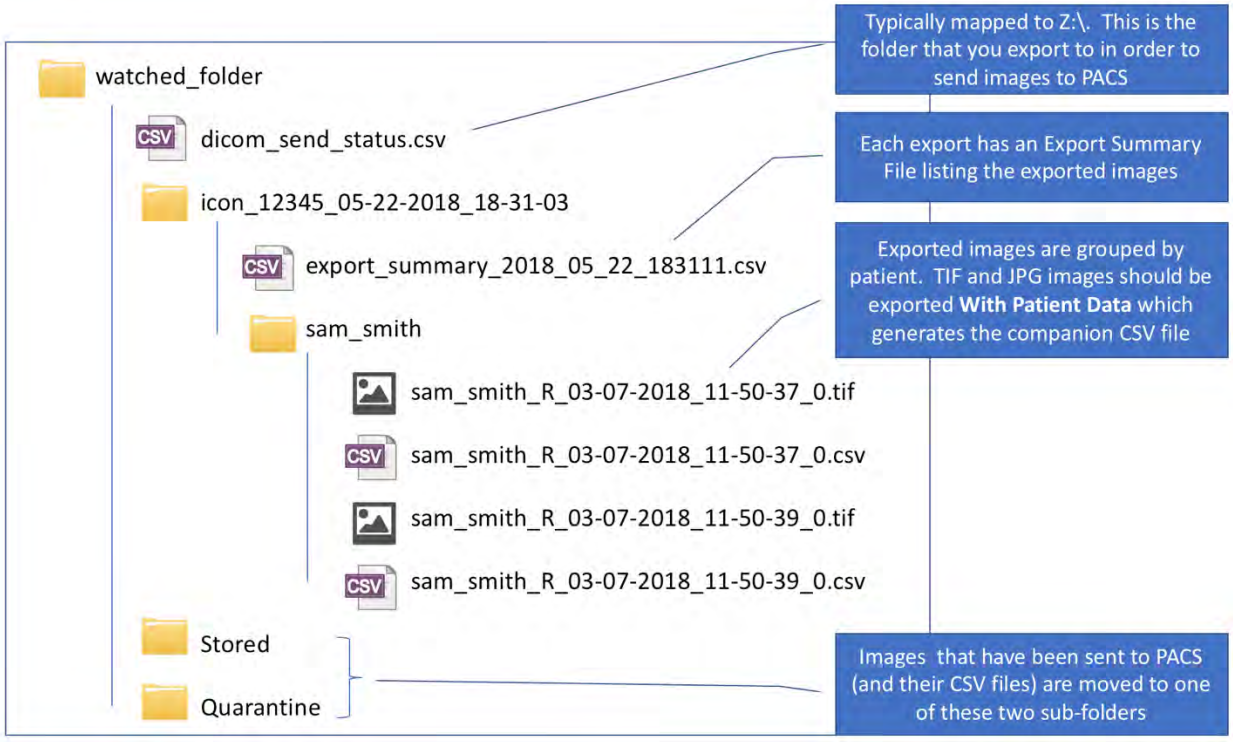
### 15.8.2. ICONnect Folder Structure

It is useful to understand the structure of the folders that are used by the Phoenix ICON software and the ICONnect connector.

The ***watched folder*** is set as one of the configuration parameters for the ICONnect connector. This folder is also set as one of the export destinations in the ICON software. This folder typically lives on the hard drive of the ICON camera system. The PACS connector periodically checks this folder for imaging studies that have been exported and are waiting to be sent to a PACS.

> **NOTE:** ICONnect does not delete images after they are sent to a PACS. You will need to periodically purge the Stored and Quarantine sub-folders found under the Watched Folder. This is by design, allowing you a fallback in the event there's an error processing images on the PACS.

Below is an example of the structure of the ***watched folder***.




*Watched folder structure*

There is a field in ICONnect settings called DaysRetentionHistory. By default, this field is '0' which means it never deletes anything. If the user sets this to an integer value, X, then any file located in the watched folder that is older than X days is will be deleted. This will purge all of the files that have been exported successfully, quarantined, AND files that are queued up for export but have not been exported and sat there for longer than the allowed retention history.

### 15.8.3. ICONnect Settings

**[General]**

This section starts with the section title "[General]" and contains parameters that control the general operation of the ICONnect PACS connector.

**Disable**: Values: True or False

Set this parameter to **True** to enable the PACS connector. When this setting is **False**, the connector will not be runnig and any files exported to **watched folder** will not be processed.

**SleepTime**: Values: integer seconds

This parameter determines how frequently the PACS connector checks the **watched folder** for new or pending exports that are waiting to be processed. The PACS connector wakes up periodically, checks the **watched folder** for exported images that are waiting to be processed, attempts to connect to the configured PACS, sends those images and the sleeps for SleepTime seconds.

**DaysRetentionHistory**: Values: integer days

After an export of images has been sent to one of the configured PACS, the exports is moved to a "processed" folder. This allows a system administrator to recover images that were not properly processed by the PACS. This setting determines when those images are deleted by the system. A setting of zero (0) means that the processed images are never deleted and must be manually purged by a system administrator. A setting of greater than zero directs the system to delete all processed exports that are older than the indicated number of days. Note that the ICON Software must be running and the PACS connector must be enabled for the processed images to be purged.

**Logfile**: Values: valid file pathname

Sets the file used to log processing, warning, and error messages. In general, this should be left at the factory default.

**Color_Scale_File**: Values: valid file pathname

Sets the base DICOM file that is used as a template for all DICOM images sent to the PACS. In general, this should be left at the factory default.

**Status_File**: Values: valid file pathname

This is a pathname to the HTML file that is displayed on the righthand side of the ICONnect settings tab presenting the status of the PACS connector. The PACS connector updates this file by writing status information to tagged fields in the

HTML file. The HTML page is set to refresh every 5 seconds. In general, this should be left at the factory default.

**SOP_Class**: Values: valid UID

This is an optional parameter. When not present, the SOP Class UID is **1.2.840.10008.5.1.4.1.1.77.1.5.1** (Ophthalmic Photography 8-bit Image Storage). This can be overridden with any valid SOP Class UID.

**Modality**: Values: text string

This is an optional parameter. The default modality for images sent to PACS is "OP". This can be overridden with any valid modality by setting this parameter.

**OID**: Values: valid UID

This is an optional parameter. When not present, the standard Phoenix OID is used (**1.2.826.0.1.3680043.9.7518**). This can be overridden by specifying any valid OID.

**OID_Name**: Values: text string

This is an optional parameter. When not present, the standard Phoenix OID Name is used (**Phoenix Technology Group ICON**). This can be overridden with any valid OID name.

**[ICON_1]**

Parameters in this section define the name of this ICON system used in DICOM associations, and the folder that is watched for exports. This section starts with the section title "[ICON_1]". (It is possible to configure the ICONnect connector to process exports from more than one ICON camera system. In this configuration, the connector would run on a single ICON system, and all of the ICON systems would export their images that are destined for a PACS to some shared folder. This is an advanced configuration and should be used with care)

**Aet**: Values: text string

This parameter sets the Application Entity Title of the ICON Software. This will be used in all associations established to send images.

**Folder**: Values: valid folder pathname

This folder must be one of the valid export folders set on the export/archive tab of the **Settings** screen. The PACS connector will look in this folder for images to send to the PACS. This parameter can be set before the folder exists and before the folder is configured as an export destination. However, the connector should not be started until this folder has been created.

### 15.8.4. Primary_PACS Section

The ICONnect PACS connector must be configured with at least one PACS called the primary PACS. This section starts with the section title "[Primary_PACS]".

The ICONnect PACS connector will first attempt to send exported images that are destined for the PACS to this primary PACS. If the primary PACS is unresponsive, and a secondary PACS is configured (Secondary_PACS section), then it will attempt to send the images to the secondary PACS. For large organizations with multiple PACS systems, this provides redundancy to ensure images find their way to long-term storage even when there is an outage with one of the PACS.

**IpAddress**: Values: valid IP address

This is the IP address of the PACS

**Port**: Values: integer port number

Connections to the PACS will be made on this TCP port

**Aet**: Values: text string

This is the Application Entity Title of the PACS

**Send_Port**: Values: integer port number

This is an optional parameter. When present, this parameter sets the **outgoing** port number used on the ICON system. This is useful when network routes and firewall rules are controlled to a specific outgoing port number. When this parameter is absent, the outgoing port will be one of the dynamically assigned ports and may vary from association to association.

**DimseTimeout**: Values: integer seconds

This is an optional parameter that sets the DIMSE timeout value. When this parameter is absent, the default value is 30.

**AcseTimeout**: Values: integer seconds

This is an optional parameter that sets the ACSE timeout value. When this parameter is absent, the default value is 60.

**NetworkTimeout**: Values: integer seconds

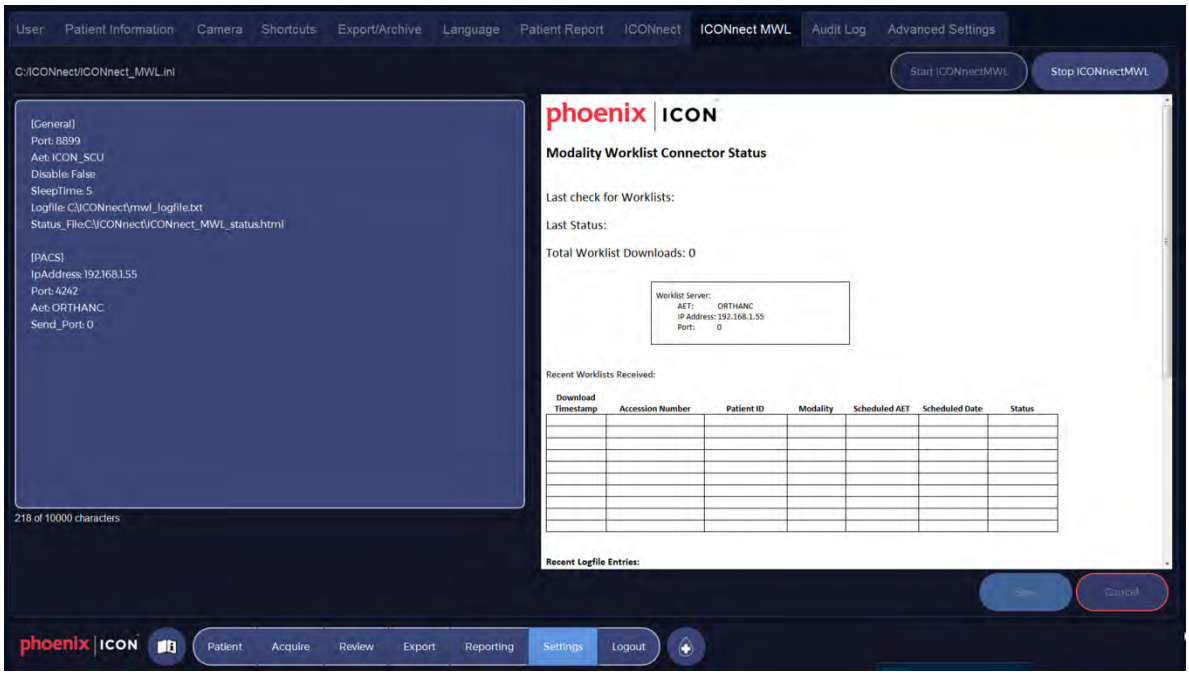
This is an optional parameter that sets the network timeout value. When this parameter is absent, the default value is 60.

**[Secondary_PACS]**

The parameters in this section are identical to the Primary_PACS section. These parameters define a connection to a backup PACS that is contacted when the primary PACS is unreachable (see the Primary PACS section).

## 15.9. Settings: ICONnect MWL

The Phoenix Software includes a DICOM connector called ICONnect MWL. This connector retrieves a modality worklist from a DICOM-compliant server (typically a radiology information system (RIS) or a PACS). Modality worklists are retrieved with the query/response protocol (C-FIND with the "W" (Modality Worklist Information) model).




The left-hand side of the tab presents the settable parameters that control the operation of the modality worklist connector. This is an editor for a Windows .ini file. Parameters are grouped

into named sections, and each parameter is in the form for a name, a colon, a space, and a value.

Press save after the parameters are edited to save changes.

Press the ***Stop ICONnect MWL*** button to stop the connector.

Press the ***Start ICONnect MWL*** button to start the connector.

When the connector is running, the righthand panel of the ICONnect MWL tab will show the current status of the connector. This is useful to confirm the configuration of the connector and see an indication of when modality worklists were last processed.

In advance of setting up the system, it is useful to gather all the network settings by filling out the DICOM Setup Questionnaire found at the back of the ICON Integration and Networking section.

### 15.9.1. Worklist Fields

The ICONnect MWL connector processes the following DICOM fields of a worklist entry:

AccessionNumber
PatientName
PatientID
PatientSex
PatientWeight
PatientBirthDate
StudyInstanceUID
SeriesInstanceUID
Laterality
ReferringPhysicianName
ScheduledProcedureStepStartDate
ScheduledPerformingPhysicianName
ScheduledProcedureStepDescription
Modality
OtherPatientIDs
EthnicGroup
InstitutionName
AdmittingDiagnosesDescription
PatientComments

### 15.9.2. ICONnect MWL Settings

**[General]**

This section starts with the section title "[General]" and contains parameters that control the general operation of the ICONnect MWL connector.

**Disable**: Values: True or False

Set this parameter to **True** to enable the modality worklist connector. When this setting is **False**, the connector will not be initialized.

**Aet**: Values: text string

This is the application entity title of this ICON system. This will be provided in the C-FIND request as the ScheduledStationAeTitle

**SleepTime**: Values: not currently implemented

**Logfile**: Values: valid file pathname

This should be set to the pathname of a destination logfile. ICONnect MWL logs query / retrieve transactions and indicates the number of retrieved worklists as well as whether patient data was inserted or updated into the ICON database. Note that the utility automatically rotates between two logfiles that are limited to 5MB each. In general, this setting should be left at the factory default.

**Status_File:** Values: valid file pathname

This is a pathname to the HTML file that is displayed on the righthand side of the ICONnect MWL settings tab presenting the status of the worklist connector. The worklist connector updates this file by writing status information to tagged fields in the HTML file. The HTML page is set to refresh every 5 seconds. In general, this should be left at the factory default.

**[PACS]**

**IpAddress**: Values: valid IP address

This is the IP address of the modality worklist server

**Port**: Values: integer port number

Connections to the to the modality worklist server will be made on this TCP port

**Aet**: Values: text string

This is the Application Entity Title of the modality worklist server

**Study_Start_Date_Format**: Values: YYYYMMDD
This optional is an optional parameter. Set it to YYYYMMDD to override the default format the connector expects for incoming dates (which is YYYY-MM-DD)

**[Query]**
**Match_ Modality**: Values: text string (must be valid 2 or 3 letter DICOM modality)
This optional parameter provides a modality (e.g. "OP" or "CT") to be including in the query packet sent with the C-FIND command, in effect asking the modality worklist server to only return the worklist for the indicated modality. The default is "OP". To query for all modalities, configure a blank value by including the line "Match_Modality: "

**Match_Aet**:
This optional parameter provides an AET to include in the C-FIND packet as the ScheduledStationAETitle, effectively asking the worklist server to only return worklist items that are scheduled for a named device. When blank, the query asks for worklist items for all devices (that match the other criteria).

**Match_Date**: Values: today
This optional parameter will cause the ICON software to only keep scheduled procedure steps that are scheduled for the current day.

### 15.9.3. ICONnect MWL Status

The status screen found in the righthand pane of the settings page for ICONnect MWL provides a frequently updated status view of the ICONnect MWL connector companion application. When displayed, it is updated every 5 seconds and shows:

**Last Check for Worklists** which indicates the date and time of the last time the connector queried the worklist server

**Last Status** indicates if there was an error, and if not, the number of worklists that were returned by the server

**Total Worklists Downloaded** indicates the number of worklists that have been downloaded from the server since the last time the connector was started.

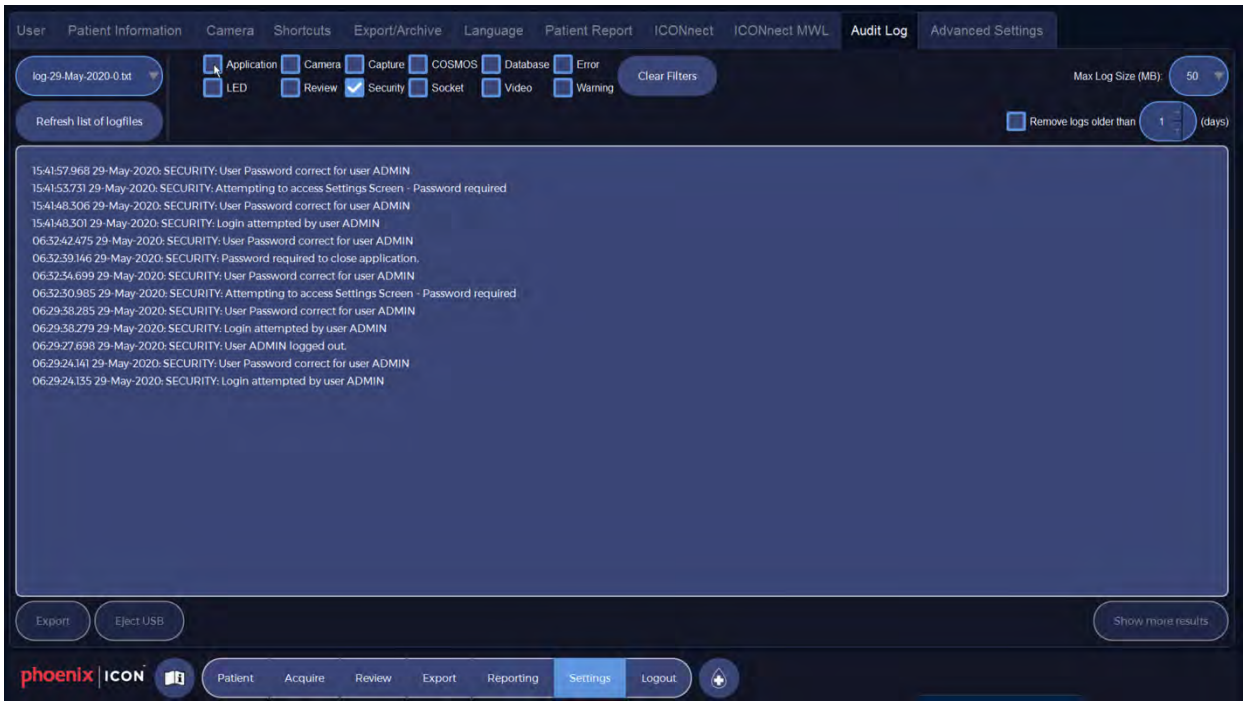
**AET, IP Address, and Port** are shown in the box in the center of the pane and these reflect the settings used to connect to the modality worklist server.

**Transaction History** is shown in the table below, which indicates the timestamp the worklist was retrieved, the accession number and patient ID, and other details in the query response. This information is similar to the data provided in the logfile and provides the administrator with a convenient view of the interaction between the connector and the worklist server.

To start the ICONnect MWL server, click **Start ICONnectMWL**. If this button is greyed-out then the worklist connector companion application is running in the background. Click **Stop ICONnectMWL** to stop the companion application.

## 15.10. Settings: Audit Log

The Phoenix ICON™ Software includes a system auditing function that captures critical events in a log that can be viewed and exported by an administrator. The log captures security events, disinfection (soaking) events, and events that can be useful in diagnosing system issues.



Some of the security events logged include:

- edits to patient information
- export of images
- archive of information
- deletion of image/study if password is required
- reset of password
- password expiration
- login attempt
- successful login
- incorrect password entered

Other events logged include:

- software and device errors
- software and device warnings
- inter-process communication events related to the DICOM connector.

The log file viewing and management options are described below.
**Select Log File**: To view a log file, click a date available in the dropdown in the upper right.

- Application
- Camera
- Capture
- Cosmos
- Database
- Error
- Led
- Review
- Security
- Socket
- Video
- Warning

**Max Log File Size (MB)**: Set the maximum size of a single logfile. When the maximum size is reached, the file is closed, and a new log file is created.

**Enable Old Log Removal**: To automatically delete old log files, select the check box and specify a number of days to automatically remove files (other than the current log file).

**Export Log**: Click the ***Export*** button to export the currently displayed log file. Logs are exported to a removable thumb drive for use in analysis by external systems. The operator will be

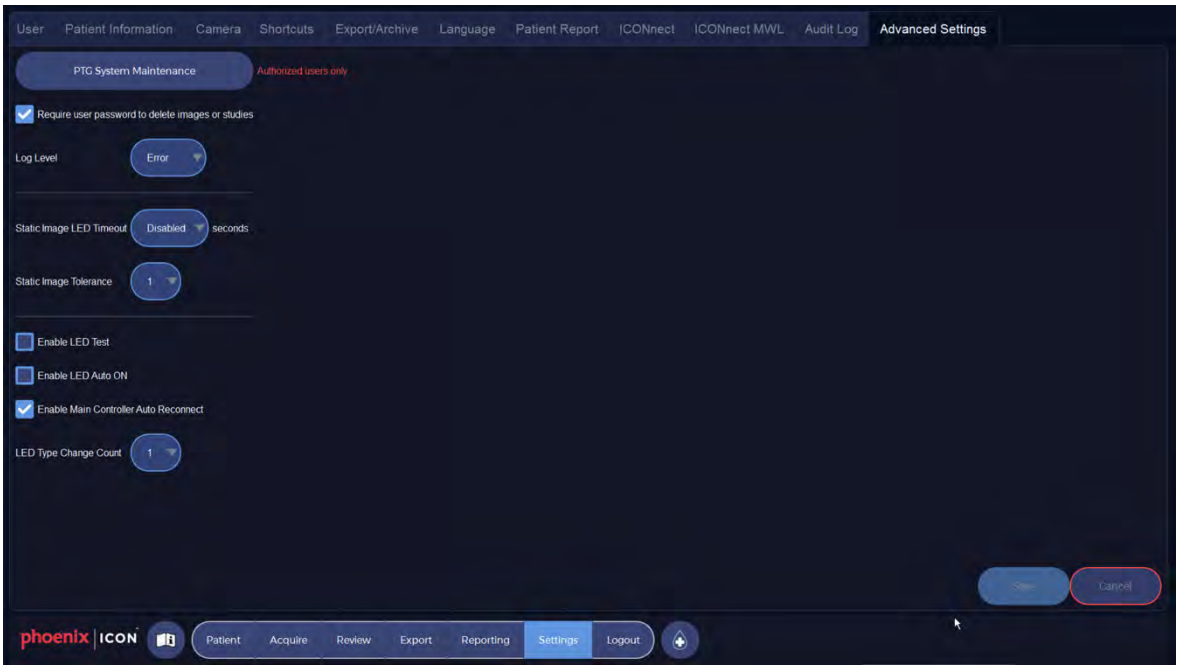
promoted to select a folder for the export. Exported log files are named with the date of export.

## 15.11. Settings: Advanced Settings

**Only trained and authorized, users should access these settings.**

This settings tab includes advanced settings that may change the behavior of the Phoenix ICON hardware and software. These settings should only be adjusted by a Phoenix Technology Group technician or an authorized representative of Phoenix.

The settings available on this tab are described below.




**PTG System Maintenance**
Click PTG System Maintenance and enter the Administrator password to quit out of the ICON software and access the Windows desktop.

**Require admin password to delete images or studies:** Select the checkbox to require an admin password to delete images from on the Review screen.

**Log Level:** Choose Error, Debug or Verbose from the dropdown to set the level of detail provided by the Audit Log

**Static Image LED Timeout:** Use this dropdown to set the Phoenix ICON hand piece to turn off the light module in Acquire mode if no movement is seen on the sensor for a user defined amount of time.

**Static Image Tolerance:** This setting modifies the "Static Image LED Timeout". Should the system see any pixel fluctuations from static noise, it may not consider the image still enough, and may not automatically turn off the light module when the camera is not being used during the Acquire mode. Use the values in the dropdown to set the tolerance to enable the light module to turn off based on what the software sees as a static frame during a set duration.

**Enable LED test:** Activating this check box is to be used by Phoenix Technology Group maintenance personnel only. If enabled, the software will look for external diagnostic hardware.

**Enable LED Auto ON:** Activating this check box will turn the light module on if it has unintentionally turned off.

**Enable Main Controller Auto Reconnect**
Activating this button will make the main control board auto reconnect to the camera if the signal is interrupted.

**LED Type Change Count:** The Light Module Type indication is located under the lamp on/off button on the Acquire screen. The description, or type, is usually White, No LED, Blue and it changes based on the LED connected. The LED Type Change Count indicates the amount of half seconds that will lapse before the software will report the light module type in the Acquire screen. If there are 5 counts in a row of No LED, the light module will turn off.

## 15.12. Accessing Windows for Network and Folder Setup

Phoenix ICON camera systems run the Microsoft Windows operating system. Depending on the time of purchase, an ICON camera system may be running one of three versions of the operating system:

- Initially, the ICON camera shipped with Windows 7 (non-hardened)
- When Windows 7 became "end of life", Phoenix began shipping with Windows 10 IoT Enterprise 2019 (non-hardened)
- Beginning with the release of v1.23 of the Phoenix ICON Software, cart-based Phoenix ICON cameras ship with a hardened version of Microsoft Windows 10 IoT Enterprise

2019, and the Phoenix ICON GO camera ships with a hardened version of Windows 10 Pro.

All version of Windows 10 IoT Enterprise make use of the "long term servicing channel" or LTSC. All versions of Windows 10 Pro make use of the "semi-annual channel" or SAC. These approaches reduce the number of operating system updates that need to be applied to the systems while still maintaining security.

### 15.12.1. Accessing Windows in Non-hardened Versions

**PTG System Maintenance**
Click PTG System Maintenance and enter the Administrator password to quit out of the ICON software and access the Windows desktop.

### 15.12.2. Hardened Windows: Overview

Upon startup of the ICON camera, the system will boot up under the one Windows application user account ("iconuser"). This account has been configured to only allow execution of the applications associated with the ICON software. This hardened configuration includes:

- Auto-start of the ICON software on login without a username / password prompt
- All Windows shortcut keys for switching users and closing the application have been disabled
- The Windows key and Windows command line have been disabled
- Access to File Manager has been disabled, however access to the file system is permitted for the ICON executables
- Access to non-ICON related executables is disabled, including access to a web browser
- All incoming network connections are blocked using the software firewall
- Outbound network connections are permitted, as are responses to network transactions initiated by the ICON software (such as C-FIND and C-STORE for DICOM communications)
- Access to a network shared folder (over SMB) is permitted for the ICON software. Note that the network share needs to be mapped to a drive letter, and this mapping is done under the administrative Windows user (see below)

- Access to removable media (thumb drive) is permitted only for the ICON software. The administrator of the ICON software can enable the permission to export to a thumb drive on an ICON user-by-user basis

- The "shutdown" button on the ICON software login screen is the only way to exit the ICON software and exiting the ICON software shuts down the system

This single-user, hardened approach has the side effect of preventing an implementation in which a user first authenticates on the ICON camera using their Active Directory domain account before launching the ICON software.

### 15.12.3. Hardened Windows: Admin Account

A second user account has been configured for administering the device ("***phoenixpaints***". Side note, "paints" stands for posterior, anterior, inferior, nasal, temporal, superior).

Accessing the administration account is done by holding down the Shift key on startup, which will present the user with a username / password prompt. The administrator logs in as ***phoenixpaints*** using a password supplied by Phoenix (that can be changed by the customer) and is then given administrative access to the device. The password to this account will be provided by Phoenix with the system.

This user has full and unrestricted access to Windows to perform system and software updates, configure network settings, map a network drive for access to a shared network folder, and perform other administrative tasks.

### 15.12.4. Endpoint Security

The ICON camera is preconfigured with Windows Defender for anti-virus and anti-malware protection. Updates to the Windows Defender definition files are scripted so that when the ICON camera is connected to the Internet, the device will automatically check for, download, and install virus and malware definition updates. This script also ensures that the virus definition updates are not performed when there is no connection to the Internet. We do not recommend changing this configuration or switching to an alternative endpoint security solution as the customer would need to also disable and de-configure the Windows Defender setup.

### 15.12.5. Operating System Updates

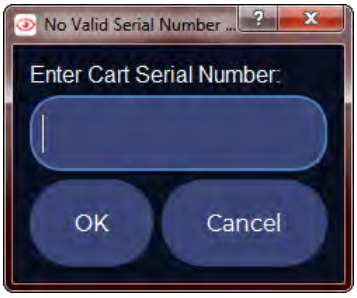
Phoenix will monitor Microsoft updates on a regular basis for important and critical security or functional updates to the operating system. When such releases become available, Phoenix

will build and validate a new hardened release of the operating system and this will be provided as an update that the customer can apply to the camera system. Updates will be applied under the administrative user, as described above. Note that Phoenix plans to develop and deploy an update server to simplify the distribution of operating system (and ICON software) updates.

## 15.13. Phoenix Serial Number

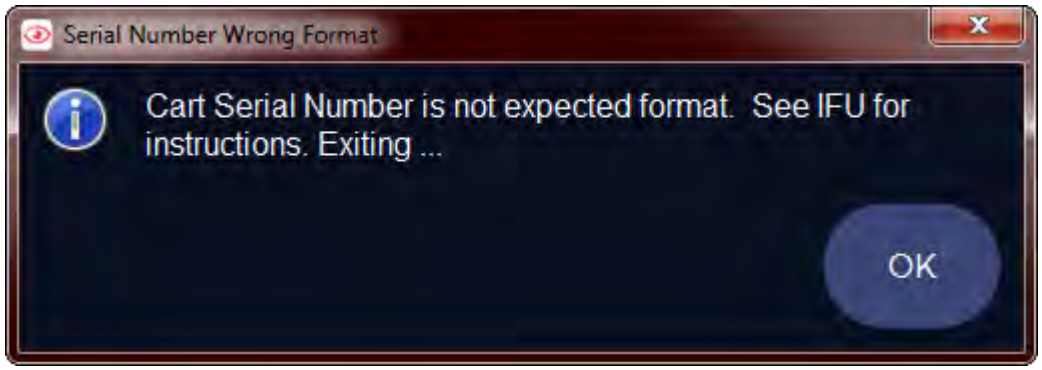
This setting is not within the Settings screen and is used for troubleshooting.

If the Phoenix ICON Software does not detect a valid serial number saved in the UserSettings.ini file it will prompt the operator to enter one:

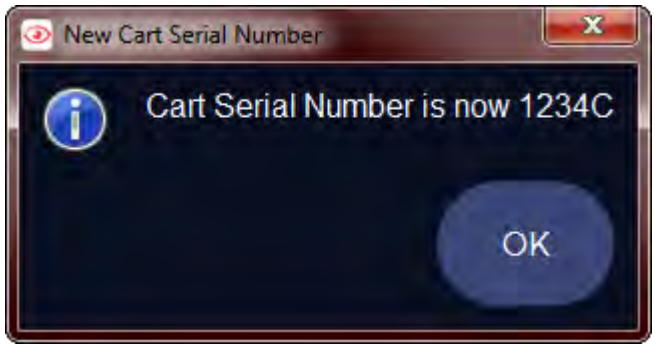



The system does a pattern match for 4 valid numbers in a row followed by either a “C”, “P”, “c”, “p”, or “ “ (a space).

An invalid password will prompt the following message and close the software. To get another chance to enter a valid password, restart the Phoenix ICON Software again and the “Enter Cart Serial Number” prompt will reappear as no serial number was saved to the .ini file.




Entering a valid serial number will cause the system to give an affirming prompt (see below) and save the newly entered Serial Number to the UserSettings.ini file where it will be used when exporting images.

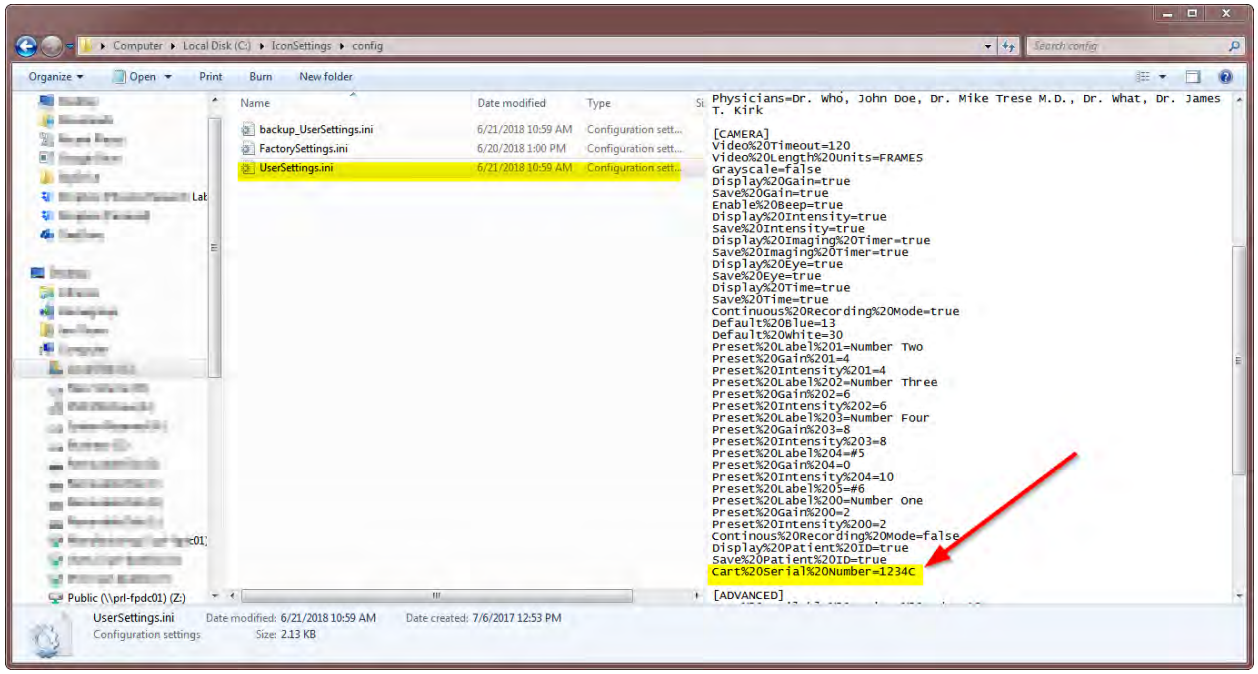



## 15.14. UserSettings.ini

The UserSettings.ini file is located in:

C:\IconSettings\config\UserSettings.ini

The field “Cart Serial Number” is located under the [CAMERA] heading (the system interprets spaces as %20 so the field will actually read “Cart%20Serial%20Number”):




The field can be manually modified from here if needed.

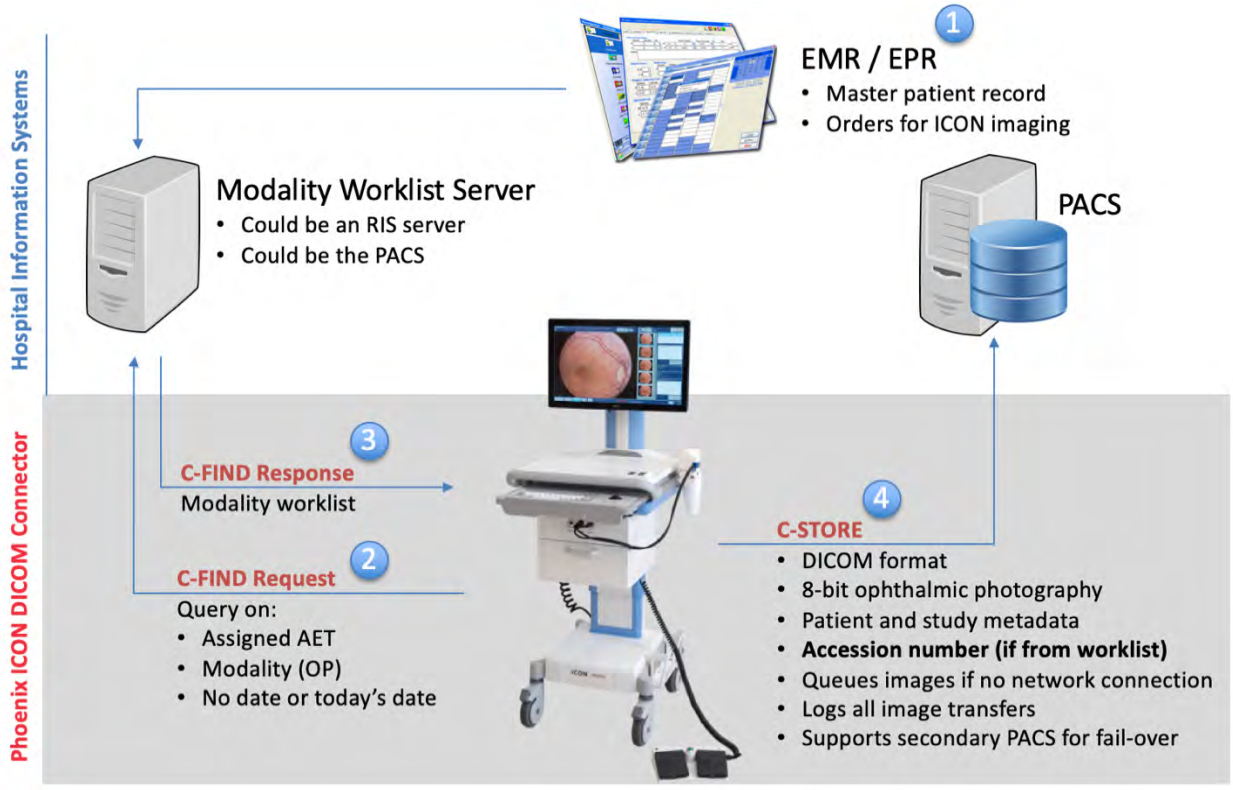
If a valid serial number is in the UserSettings.ini file the system will not prompt you to enter one.

# 16. DICOM Workflow

The Phoenix ICON Software includes two built-in DICOM integration features:

- A connector (ICONnect MWL) to retrieve a modality worklist from a DICOM-compliant radiology information server (RIS) or photo archive and communication system (PACS).
- A connector (ICONnect) to export images directly to a DICOM-compliant PACS.

The diagram below presents an overview of a typical information flow with both connectors enabled:




In this workflow:

1. An order for imaging is entered an electronic medical record (EMR) system, which in turn causes a modality worklist entry to be made in a PACS or RIS.
2. The operator on the ICON camera clicks a button to download today's worklist, which causes the ICON camera to issue a C-FIND request to the modality worklist server.

3. The response includes the patient and study data for the imaging studies to be captured on the ICON camera. These are presented to the operator in a worklist. When the operator selects one of the studies, the ICON software automatically creates a new patient and study in its local database using the data provided by the PACS/RIS. If the patient already exists in the ICON database, the database is updated to match the data provided by the PACS/RIS.

4. After the operator captures the required images using the ICON camera, the images can be exported to a PACS. If the imaging session was started from a modality worklist, the accession number provided in the worklist will be included in the DICOM file sent to the PACS.

Setup of these features is described in the Software Administration (Settings Screen) section, above.

# Section 3:

# Phoenix ICON™ System

# Cleaning Procedures

(Applies to both the cart-based Phoenix ICON™ and the portable Phoenix ICON GO™ systems)

# Table of Contents

# 1. Cleaning Procedure

## 1.1. Phoenix ICON™ Camera: Hand Piece Lens

The Phoenix ICON camera hand piece lens should be cleaned after imaging each patient, as follows:

### 1.1.1. Basic Cleaning

Prior to disinfecting the patient-contacting surface of the ICON camera hand piece, perform the following basic cleaning procedure:

- Inspect the lens tip for any nicks or chips to avoid injury to the patient's cornea. Should the tip of the lens appear, or is, damaged or rough in any way, ***do not use!***
- ***After*** each patient, wipe the tip of the lens with a tissue or gauze to ensure that the coupling gel and any particulates are completely removed before using any disinfecting agents.
- If there is dried gel, remove it using a tissue or gauze that has been wet with sterile or distilled water. Pay particular attention to the edge of the lens. Soaking in the disinfectant solutions below will not break down and remove dried gel. It can be helpful to run a dry cotton bud along the rim of the lens to remove any moisture.
- Once gel or fluid has been removed, the lens will be clean, **but not disinfected**.

### 1.1.2. Disinfection

One basic cleaning is complete, perform the following disinfection procedure. (For additional instructions on soaking the hand piece tip, see below.)

**For Customers within the United States:**

- ***Before*** each imaging session per patient, clean and disinfect the hand piece tip gently using a 5-minute soak in 70% isopropyl alcohol. *Since alcohol is used, rinse with sterile or distilled water to avoid any corneal damage.*
- Allow the lens to air dry, or dry it using a soft, clean or sterile tissue or gauze.

**For Customers Outside of the United States:**

***Before*** each imaging session with a patient, use **one** of the following cleaning and disinfection methods:

- Wipe with four 70% isopropyl alcohol pre-moist wipes using each one separately; **or**,
- 5-minute soak in a 70% isopropyl alcohol. Since alcohol is used, rinse with sterile or distilled water to avoid any corneal damage; **or**,
- 5-minute soak in a 10% bleach solution. Example preparation: 10ml of 6% hypochlorite solution to 90ml of distilled/sterile water, therefore 1:10 dilution of 6% bleach; **or,**
- 30-minute soak in a 6% H2O2 solution; **and then**
- ***Rinse with sterile or distilled water to avoid any corneal damage***
- Allow the lens to air dry, or dry it using a soft, clean or sterile tissue or gauze.

### 1.1.3. Inspecting for Dried Gel

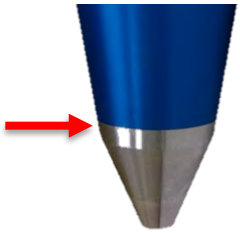
Note: If there is a yellow haze remaining at the periphery of the lens in the image, repeat the procedure and ensure the outer edge of the lens tip is completely dry. It may be helpful to run a cotton bud around the outer edge of the lens tip.

### 1.1.4. Soaking the ICON Camera Hand Piece Tip

The patient contacting surfaces of the Phoenix ICON camera hand piece can be soaked in cleaning solution, as described above.

When soaking the hand piece tip, it is important that the tip **not be submerged above the stainless-steel tip**.

The hand piece **should not be autoclaved**.



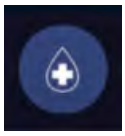
### 1.1.5. Use of the Soaking Cup and Soak Timer

Recent versions of Phoenix ICON camera systems include a threaded soaking cup that attaches to the base of the hand piece holster. This can be used to safely secure the hand piece while also immersing the tip of the hand piece in cleaning solution.

The ICON software also includes a soaking timer feature which provides a visual count-down timer to time the soak process. An audit log entry is written each time the soaking timer is started and stopped. Each log entry includes the current user's User Name and the date and time, which creates an infection control record.

To use the soaking cup and soaking timer, follow these instructions:

- As an administrator, set the soaking timer duration once on the Settings -> Camera tab
- Follow the basic cleaning procedures listed above
- Fill the soaking cup with the selected cleaning solution
- Attach the soaking cup to the holster
- Insert the Phoenix ICON™ camera hand piece in the holster




- Click the soak timer icon on the Pheonix ICON™Software, which is found at the bottom of every screen, and wait for the timer to expire. It will count down from the soaking time that has been selected in the Settings->Camera.
- Remove the Pheonix ICON™ camera hand piece from the holster and **rinse the tip with sterile or distilled water**.

The soaking cup is a 60 ml disposable specimen cup (Starplex Scientific B902L) and are available from Phoenix Technology Group, LLC.

If the tip of the camera has been soaking in sterile or distilled water as a rinse after the first disinfection soak, it may be dried with a soft gauze.

> **NOTE:** To avoid any corneal damage, ensure that there is no confusion between the solution that is used for soaking or used as a rinse.

## 1.2. Additional High-Level Disinfection Cleaning Solutions

**For Use Outside of the United States Only**

The cleaning solutions below have been recommended for use in cleaning the Phoenix ICON™ hand piece patient contacting surfaces by the respective manufacturers for High Level disinfection. This recommendation is based on a review by the manufacturers that included:

1) a thorough review of the materials used in the manufacture of the Phoenix ICON™
2) the effectiveness of those solutions on the material
3) review of the use modality and indications for use of the Phoenix ICON™
4) effective use of the recommended cleaning solutions on similar devices in the ophthalmic imaging industry.

Phoenix Technology Group has not performed any specific cleaning studies to further verify effectiveness of these solutions.

Please consult individual manufacturer websites and product package inserts for instructions for use:

Antiseptica
Descogen 3%
Descogen liquid rfu (for soaking 30 minutes / 60 minutes in case of tuberculosis contamination)

Schülke
Mikrozid AF
Mikrozid AF Wipes
Antifect N liquid
Pursept AF 0.5%

Note: For precautionary reasons, wipe with water after exposure time to remove surfactant residues from disinfected surfaces.

Tristel

Duo Wipes

# 2. Cleaning the Non-Hand-Piece System Components

### 2.1.1. Phoenix ICON Cart-based System

Between patients and at the end of all imaging sessions for the day:

- Wipe down the keyboard, computer trackball, cart work surface, hand piece holster, and hand piece cable in between patients with disinfectant wipes. Ensure that any gel or particulates are removed.

- Wipe down the touch screen monitor with 70% isopropryl alcohol.

### 2.1.2. Phoenix ICON GO System

Between patients and at the end of all imaging sessions for the day:

- Wipe down the keyboard and track pad with disinfectant wipes between patients.

- Wipe down the touch screen monitor with 70% isopropyl alcohol.

When moving the system from one facility to another:

- Clean the system as instructed above

- Pack the Phoenix ICON GO™system in the system carrying cases following the instructions in Section 1 of this manual

- Wipe down the exterior of the rolling hard-case with 70% isopropryl alcohol.

- Wipe down the exterior of the laptop backpack with 70% isopropryl alcohol.

# 3. Materials and Environment

### 3.1.1. Patient Contacting Materials

In expected operation of the Phoenix ICON system, the lens tip comes in contact with the patient. This exposes the patient to the following materials intended for limited (<24 hours continuous) contact/usage:

- Plano-Concave Lens: BK7 fused silica glass
- Tip: Machined 316 Stainless Steel
- Adhesive: Medical grade epoxy (ISO 10993 tested)

### 3.1.2. Environmental Protection

- Please use your organization's disposal procedures for effective discarding of all cleaning supplies used with the system

- NOTE: All disposals must comply with local regulations

- For disposal of the Phoenix ICON™ system, do not throw cart and hand piece into the waste bin. Contact Customer Support for disposal options

# Section 4:

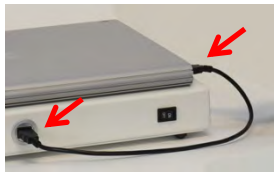
# Phoenix ICON™

# Quick Start Guides

(Applies to both the cart-based Phoenix ICON and the portable Phoenix ICON GO systems)

# Table of Contents

# Phoenix ICON™ GO - Assembly Guide


**1. Set up control box and laptop**

- Place control box on flat, stable surface
- Place fully charged laptop on top of control box
- Plug USB cable into laptop and into the back of the control box

**2. Insert batteries**

- Pull back latches on left side of the control box to open battery compartments
- Insert fully charged batteries into the compartment, tag side facing up and outwards

**3. Raise holster arm**

- Pull back latch on the right side of the control box and raise the holster arm until locked into a vertical position

| | |
|---|---|
|  | **4. Attach Holster**<br>• Pull back the latch on the upper-inside of the arm and slide the holster attachment into the channel |
|  | **5. Install handpiece**<br>• Place the handpiece into the holster<br>• When time to clean the tip, screw a soaking cup filled with 50 mL of sterilization solution into the bottom of the holster |
|  a  b | **6. Connect handpiece**<br>• Plug handpiece USB cable into the laptop (a)<br>• Plug twelve-pronged cord into the back of the control box (b)<br>• Ensure the handpiece cables are free to move for imaging |
|  | **7. Connect footswitch**<br>• Place footswitch in convenient floor location near the control box<br>• Plug nine-pin cord into the back of the control box |
|  Power switch Control box back  Battery toggle Control box front | **8. Power on**<br>• Turn on power switch on back of control box<br>• Toggle battery switch to preferred battery<br>• Turn on laptop and wait for Windows software to launch followed by ICON software |
| **Customer Support**<br>+1.877.839.0080 - Technical Support<br>iconhelp@phoenixtech.com - Email | **Customer Support Portal: https://support.phoenixtech.com**<br>Select "**New Support Ticket**", and your issue will be routed to our staff. |

# Quick Reference Guide: First Login and Basic User Setup Software v1.23

The Phoenix ICON Software controls the operation of the Phoenix ICON system. Each operator should have a unique User Name. This allows permissions to be assigned to individuals and ensures that security and infection control data that is logged is associated with the correct operator.

Perform the following steps the first time the ICON system is started:

## Power Up the System and Login

1) Power on the Phoenix ICON according to the instructions for your system.
   a) The ICON Software will launch to display the Login screen.

2) Enter the following:
   a) User Name: ADMIN
   b) Password: 5678
   c) Select "Temp Clinic" from the Clinic Dropdown list.
   d) If no clinic is listed, click the ***Sign In*** button

3) The software will open to the Patient screen.

## Add or Update a Clinic

4) Click **Settings** button from the Navigation Panel at the bottom of the screen
   a) Enter the Password 5678

5) Select the ***Patient Information*** tab
   a) "Temp Clinic" will be shown in the list of Clinics. This is the default clinic.
   b) Double click "Temp Clinic" to change the name. Enter the new name and press Enter.
   c) Click the ***Folder*** button at the bottom of the Clinic list to add a new Clinic. Type in the name of the Clinic in the empty field and press Enter.

## Add Users

6) Select the ***User*** tab (still on the Settings screen)
   a) To enable strong passwords, click the "Enable Strong Passwords" checkbox. This means that new user Passwords will require at least 8 characters, both upper- and lower-case letters, at least one number, at least one special character.

   b) Click the ***Add New User*** button to add a user to the system

   a) Enter a User Name and a Password. Re-enter the password to confirm the password. (Note the expiration date of the password.)

   c) Select the permissions for the User
      i) Select the check boxes next to the functions that the user will be allowed to perform.

      ii) Select the Clinic(s) to which the user will have access.


## Set the Date Format

7) Select the desired date format form the ***Date Format*** dropdown (still on the Settings->User screen)
   a) Click the ***Save*** button to save the new user and the date format settings.

8) Click ***Patients*** in the Navigation Panel to leave the Settings screen.

## Set the Windows Time Zone

9) Click the Logout button on the Navigation Panel

10) Click the shutdown icon on the ICON Software login screen

11) Wait for the system to shut down, and then hold down the Shift key and restart the system. A Windows login screen will be presented.

12) Login as the Windows user ***phoenixpaints***, with the password <<XXX>>.

13) Go to **Start** > **Settings** > **Time & Language** > **Date & time** and set the time zone

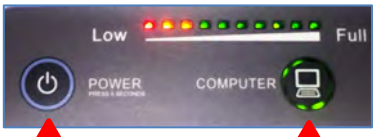
While logged in a ***phoenixpaints*** it may be convenient to also configure the network settings to connect the ICON camera system to the network, and to map a Windows drive letter to a shared folder. This drive letter can be used as a destination to export images.

The ICON system is now ready to use.

# Phoenix ICON™ Quick Reference Guide – Software v1.23

*This document does not replace reading the Phoenix ICON Instructions for Use (IFU)*
*The IFU is accessible through the Phoenix ICON software*
*A printed copy may be requested through the Phoenix Technology Customer Support Portal*

*Phoenix ICON IFU button*



CART power
Hold for 5 seconds

COMPUTER
power ON
Press once

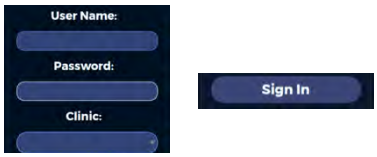
**1. Turn on the System**

**For the Phoenix ICON Cart-based system,**

- Hold down the **CART Power** button for **5 seconds** until the battery status lights appear
- Press the **COMPUTER power** button
  It will illuminate green when 'ON'

**For the portable Phoenix ICON GO,**

- Insert batteries in control box, connect laptop, camera and foot pedal. Power on control box and laptop

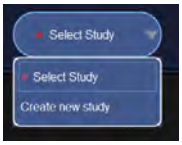



**2. Login**

- Enter your User Name, Password and Clinic
- Click **Sign In**
- The patient screen will be displayed


**3.** Click **Find Patient** or **New Patient**

- **Find Patient**: Start typing the name or ID in the blank search field. Click on the name or;
- **New Patient**: Enter data in all fields marked with a red asterisk
- Click **Save** (bottom left)



**4. Acquire**

Click **Acquire** in task bar at bottom of the screen
Follow the prompts in the white boxes on the screen

- Turn on the Phoenix ICON™ light by clicking the light bulb icon on the screen
- **Perform White Balance**: Aim the camera at a white space. Ensure the lever on the handpiece is set to the white dot
- **Select Study** – touch the dropdown and select – **Create new study**
- Select (**R or L**) eye and switch as needed

Photo Video Record time


Video Stop/Pause

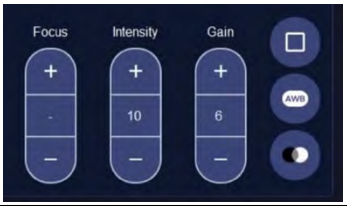
Flashback

**5. Capture Images**

- Ensure the monitor is at eye level and directly in view so that you are looking straight at zero degrees to the center
- To capture an image or video, use the buttons on the touch screen or press the green button on the foot pedal

**Image capture controls:**

- **Photo**: Capture one image at a time
- **Video**: Record/Pause/Save up to two minutes of video
- **FLB:** If selected, will save the last few seconds of video (can be set for 1-10 seconds)

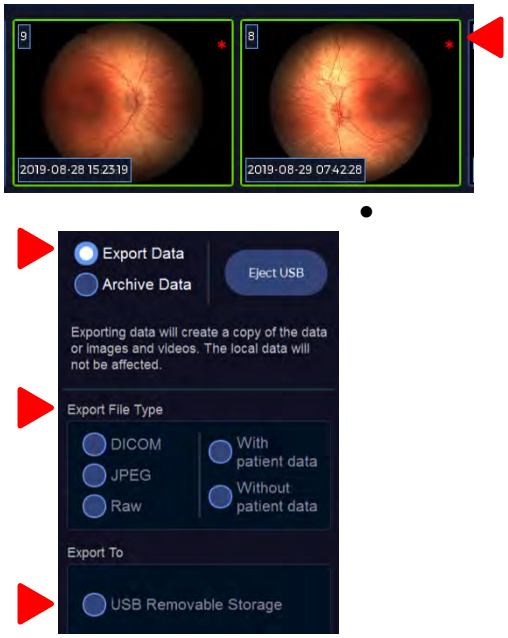



**6. Image Optimization**

- **Focus**, **Intensity** and **Gain** are located in the 'Camera Controls' section. Optimize the image using these tools prior to capture
- The foot pedal can also change focus and intensity. Use the left rocker for focus and right rocker for light intensity


**7. Review Images**

- Click the **Review** tab in the task bar at bottom of the window
- Scroll through thumbnails on the touchscreen, with the computer mouse or keyboard up/down arrow keys
- Select a video to review (shown with a small blue forward arrow)
  Drag the playhead using the mouse, through the video to any frame, or use the < and > keyboard arrows to go frame-by-frame to find the best image
  Click **the Save Frame** button or use a keyboard shortcut



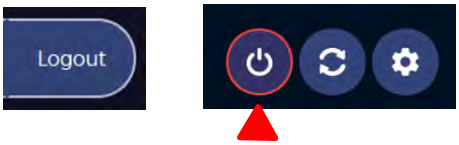

**8. Export images**

- Click the **Export** tab oin the taskbar at bottom of window
- '**Select All'** or choose specific images or data sets to export by clicking the thumbnails. A red asterisk (*) will appear on selected images.
- Choose File type and export location
- Choose **DICOM**, **JPEG** or **Raw**
- Select **With Patient Data** or **Without Patient Data** (JPEG or Raw)
- Select ibe if the export locations from the list (these are setup on the Settings screen)
- Click the **Export** button

- **To Export to a USB drive**
- Unplug the front USB camera cable
- Insert the USB drive
- Wait for it to appear on the **Export To** list as USB Removable Storage
- Click **Export**
- Create a New Folder for the files
- Click **OK** and wait for '**Export successful'** notification
- Use button at top right of screen to safely **Eject USB**
- Reconnect camera USB Cable

**9. Clean the lens tip**

- Use the Soak Timer and Cleaning Instructions to adhere to infection control policies for disinfecting the lens tip




- **Shutdown**
- Click the **Logout** tab on the task bar
- Click the Power button on the software

***ICON Cart based system***
When the computer has turned off, hold down the cart power button to turn off the cart battery

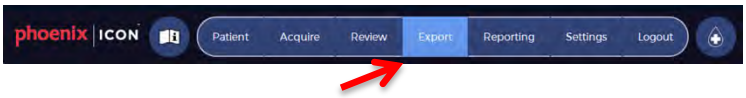
***ICON GO portable system***
Turn off control box. Remove batteries if putting away in the transit case.

**Customer Support**
+1.877.839.0080 - Technical Support
iconhelp@phoenixtech.com – E-mail

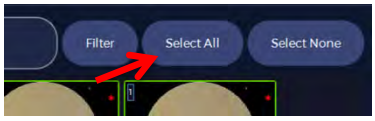
**Customer Support Portal: https://support.phoenixtech.com**
Select "**New Support Ticket**", and your issue will be routed to our staff.

# Phoenix ICON™ Quick Reference Guide – Export v1.23

1) **Click Export**



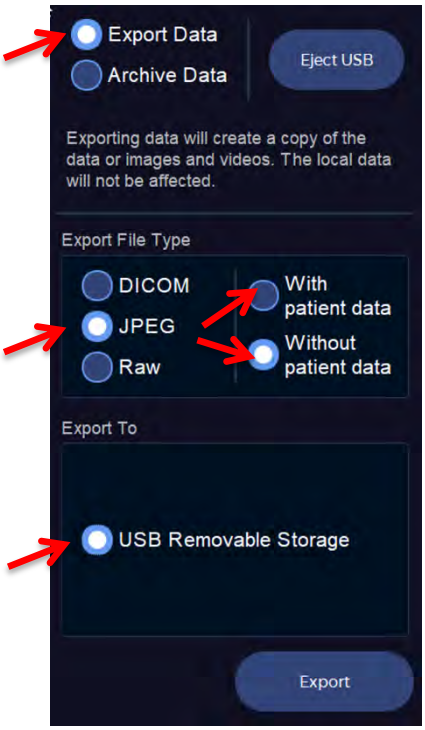

2) **Select Images**
**Select All** for each patient or select individual files by clicking each thumbnail. A red asterisk will appear on selected images.




3) Select **Export Data button**

4) Select **Export File Type**
   - Chose DICOM, JPEG or Raw
   - Select
     **With** patient data or
     **Without** patient data

5) Select **Export To** location
   - Select the Drive or Path location from the options listed




**TIPS**

- To remove the patient ID from the filename, go to Settings > Export/Archive and uncheck the Patient ID box.

- Thumbnails may be pre-selected for export in the **Review** screen by right clicking the image and selecting “Mark for Export”. A red asterisk will appear.