Phoenix ICON GO Instructions for Use

phoenix TECHNOLOGY GROUP

IFU GO US English
June 2025
OPL-0147_E

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This device is classified as a medical device in the European Community / European Union

Contents

User Responsibility 5
Chapter 1: About ICON GO 6
1.1 Indications for Use 6
1.2 Intended Users 6
1.3 Product Description 6
1.4 Essential Performance 6
Chapter 2: Safety Information 7
2.1 Symbols 7
2.2 Warnings and Cautions 10
Chapter 3: Components and Controls 15
3.1 User Accessible Parts: 15
3.2 ICON GO Components in Detail 17
3.3 ICON Camera Handpiece 19
Chapter 4: Operation 21
4.1 Setting Up the ICON GO System 21
4.2 Startup Procedure 24
4.3 Shutdown Procedure 24
4.4 Using the ICON Handpiece 24
4.5 Packing the ICON GO 28
4.6 Charging the Control Box Battery 29
4.7 Transporting the System 30
4.8 Environmental Protection 30
Chapter 5: Routine Maintenance Procedures 31
5.1 Servicing the ICON Go System 31
5.2 Using the Soak Timer 31
5.3 Cleaning and Disinfection Procedure (To be followed inside the United States Only): 33
5.4 Troubleshooting Guide 39
Chapter 6: Product Specification 41
Chapter 7: Compliance Declaration 43
Chapter 8: ICON Software for both Phoenix ICON and ICON GO 46
8.1 Feature Summary 46
8.2 Login Screen 47

8.3 Navigation Panel 48
8.4 Patient Screen 50
8.5 Acquire Screen 54
8.6 Review Screen 62
8.7 Export Screen 67
8.8 Reporting 69
8.9 Software Administration (Settings Screen) 71
8.10 ICONnect and DICOM Setup 94
Chapter 9: Accessories and Replacement Parts 108
Chapter 10: Warranty 109
Chapter 11: Customer Service: 110
Chapter 12: Patent and Trademark Information 110

User Responsibility

The ICON GO device will perform in conformity with the description contained in the instructions for use (IFU), service manual, and accompanying labels and/or guides, when assembled, operated, maintained, and repaired in accordance with the instructions provided. This product must be checked periodically. A defective product should not be used. Parts that are broken, missing, plainly worn, distorted, or contaminated should be replaced immediately. Should such repair or replacement become necessary, Phoenix Technology Group recommends making a service request by contacting Customer Service. This product or any of its parts should not be repaired other than in accordance with written instructions provided by Phoenix Technology Group and by Phoenix Technology Group trained personnel. The product must not be altered without Phoenix Technology Group 's prior written approval. Phoenix Technology Group is not responsible for any damages or consequences resulting from unauthorized attempts to open, modify, or repair the device. This unauthorized service of the product also voids the warranty.

The user of this product shall have the sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Phoenix Technology Group. The user is also responsible for ensuring the manual version they reference is the most up-to-date and that the instructions and requirements are followed.

CAUTION:
U.S. Federal law restricts this device to sale by or on the order of a licensed medical practitioner

Chapter 1: About ICON GO

1.1 Indications for Use

The ICON GO System, manufactured by Phoenix Technology Group LLC, is intended for general ophthalmic imaging applications, specifically for retinal, corneal, and external structures of the eye. The device is approved for use in both pediatric and adult populations across various age groups:

- Adults
- Pediatrics:
    - Neonate/Newborn: Birth through 28 days
    - Infant: From 29 days to 2 years of age
    - Child: From 2 years to 12 years of age
    - Adolescent: From 12 years to 18 years of age
    - Transitional Adolescent A: 18 through 21 years of age
    - Transitional Adolescent B: 18 through 21 years of age.

1.2 Intended Users

Typical clinical users of the ICON GO include, but are not limited to, trained medical professionals such as ophthalmologists, neonatologists, nurses, ophthalmic photographers and ophthalmic technicians.

1.3 Product Description

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

The ICON GO system is designed to be used with a Windows laptop that meets a set of minimum system requirements. The ICON software is installed on the laptop. The laptop connects to the ICON GO control box and the ICON handpiece. A laptop is supplied with the ICON GO System. The brand and model of the laptop may change over time.

The system runs on 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, and all association of images to a specific patient.

1.4 Essential Performance

The ICON GO provides the ability to visualize, capture and export/extract images of the retina, cornea and external eye through contact methods.

NOTE The service life of the ICON GO System is 5 years

Chapter 2: Safety Information

2.1 Symbols

The following symbols are used in this IFU, on the device packaging, on the device, and accessory labeling.

Symbol	Description
	Reference Number; Part Number
	Catalog Identification
	Lot Number
	Serial Number
	Manufacturing Date
	Legal Manufacturer Name
	Country of Manufacture
	Follow Instructions for Use
	Prescription-only (USA)
	This item is classified as a medical device in the European Community / European Union
	Alternating Current
	European Authorized Representative
	Intertek (3rd party electrical safety and EMC compliance testing mark)

	Fragile
	This manual has been translated from English
	The product contains electrical equipment. Therefore, users should not discard this product along with other household waste
	Type B Applied parts
	Symbol placed next to **CAUTION** to alert the users to important statements
	Symbol placed next to **WARNING** to alert the users to important statements
IPX6	Do not expose to dust. Water projected in powerful jets against the foot switch enclosure from any direction shall have no harmful effects.
	DC Current
	Keep the device away from sunlight
	Keep the device dry
	Hazard of severe electric shock or burn
	Non-Sterile
	Refer to the instruction manual/leaflet
UDI	Unique Device Identifier
M.E.E	Medical Electrical Equipment

WARNING	A **WARNING** statement is used when the possibility of injury exists
CAUTION	A **CAUTION** statement is used when the possibility of damage to the equipment exists
IMPORTANT!	Instruction provided to help ensure correct clinical results and provide quality assurance to the use of the ICON System
NOTE	Background information provided to clarify a particular step or procedure. Information in this category is not considered precautionary

2.2 Warnings and Cautions

Before using the ICON GO read through this entire manual. As with all clinical equipment, attempting to use this device without a thorough understanding of its operation and intent may render it ineffective or injurious to the patient. This device should only be operated by personnel familiar with the risks and benefits of this type of device. Additional precautions are listed in the text of this manual. If the ICON GO or any of its accessories fail or are damaged, they should be repaired or replaced by the manufacturer or its authorized service representative. Any unauthorized repair or tampering will void applicable warranties. Do not use any accessories not supplied by the manufacturer. Always make sure the ICON GO is disconnected and turned off prior to making any repairs or performing any maintenance procedures.

CAUTION:
The white light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater is the risk of ocular damage. Exposure to white light from this instrument when operated at maximum intensity will exceed the recommended maximum exposure (RME) of 2.2 J/cm2, unless additional action is taken by the user to minimize exposure, after $\mathbf{62\ min\ 3\ sec}$. The risk of retinal injury at an exposure of 2.2 J/cm2 is not high, but because some patients may be more susceptible than others, caution is advised if this radiant exposure value is exceeded. However, because of a significant risk of injury at exposures exceeding 10 J/cm2, the user should avoid exposures longer than $\mathbf{282\ min\ 3\ sec}$.

CAUTION:
The blue light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater is the risk of ocular damage. Exposure to blue light from this instrument when operated at maximum intensity will exceed the recommended maximum exposure (RME) of 2.2 J/cm2, unless additional action is taken by the user to minimize exposure, after $\mathbf{10\ min\ 19\ sec}$ Min. The risk of retinal injury at an exposure of 2.2 J/cm2 is not high, but because some patients may be more susceptible than others, caution is advised if this radiant exposure value is exceeded. However, because of a significant risk of injury at exposures exceeding 10 J/cm2, the user should avoid exposures longer than $\mathbf{46\ min\ 54\ sec.}$

WARNING:
At the beginning and end of the imaging procedure, the tip of the camera hand piece must be cleaned and disinfected following maintenance procedure. Since alcohol and other disinfectants are used, ensure that the tip of the lens has been RINSED with sterile or distilled water to avoid any corneal damage.

WARNING:
To avoid the risk of electric shock, the battery charger and laptop must only be connected to an AC supply main with protective earth ground.

CAUTION:
Phoenix Technology Group LLC does not recommend loading any other third-party software onto the provided computer and is not liable for the performance of the

software if third-party software is loaded. Installing unauthorized software will void the warranty.

CAUTION:
The ICON GO is designed, tested, validated and verified as a medical device. Modifications and substitutions to the device are prohibited.

CAUTION:
The ICON GO system should not be exposed to or be in the presence of electromagnetic or other interferences greater than the levels specified by the IEC 60601-1-2 standard.

CAUTION
Portable and mobile RF communications can affect the ICON GO system

CAUTION
Care must be taken when operating this equipment around other equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with this device.

CAUTION:
To ensure basic safety and essential performance, please operate the ICON GO in an area with minimal or free of electromagnetic disturbance.

WARNING:
This Medical Equipment has been designed to comply with electromagnetic safety standards IEC 60601-1-2, 4th edition. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:

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

CAUTION:
The use of accessories, transducers, and cables with the ICON GO other than those specified by Phoenix Technology Group LLC may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT

CAUTION:
None of the ICON GO components should be replaced without consultation and authorization by Phoenix Technology Group LLC

CAUTION:
This EQUIPMENT should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the EQUIPMENT should be observed to verify normal operation in the configuration in which it will be used

CAUTION:
The ICON GO system is below the acceptable limit of emissions conducted in standard medical device electrical safety testing and should only be around equipment which has been proven to operate normally under these conditions

CAUTION:
Prior to imaging, inspect the tip of the lens for any nicks, or chipped edges to protect the health and safety of the patient's cornea. DO NOT USE the camera if the lens tip is damaged

CAUTION:
Do not immerse the tip of the camera hand piece in any liquid in such a way that the level of the liquid extends past the stainless-steel tip

CAUTION:
Prior to using the control box, look for any signs of visible damage to the batteries. If any damage is present, DO NOT USE due to the risk of causing potential physical harm. If any questions, please contact Phoenix Technology Group

CAUTION:
Only use the charger provided with the ICON GO System to recharge the batteries

CAUTION:
Do not autoclave the camera hand piece

CAUTION:
Do not drop the camera hand piece

CAUTION:
Throughout an 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

WARNING:
Incorrect insertion of the hand piece connectors may result in the hand piece not functioning correctly in terms of connection to the computer, image capture, and may impact the ability for focus control and/or illumination control

CAUTION:
No service or maintenance should occur on any part of the system while the EQUIPMENT is in use.

CAUTION:
The handpiece and cables should be stored in the designated hard-sided rolling case. The handpiece holster is only for use during the imaging session.

WARNING:
Insertion of the incorrect fuse in the control box may disable the system so that it will not turn on or function or render it unprotected from an overcurrent situation

CAUTION:
Users should be careful to keep their hands clear of the foldable holster arm when deploying or collapsing it to avoid potential pinch points.

CAUTION:
Users must not fold down the holster arm when the ICON handpiece is seated in the holster.

CAUTION:
Users must not fold down the holster arm when the soaking cup is attached and filled with liquid.

CAUTION:
Users should be careful when closing the battery doors on the control box to avoid potential pinch points.

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

CAUTION:
Contraindications to using the ICON handpiece in the contact mode are:

1. If the tip of the lens is cracked or damaged in any way, the camera must not be used on the eye.
2. Should a patient have an open globe injury, the camera should not be used on the eye until the wound has been repaired and healed.
3. A patient who has had recent surgery should not be imaged with the camera on the eye.
4. Should a patient have a known eye infection, the camera should not come into contact with the eye until it is deemed safe to do so

CAUTION:
Indications to reassess the timing of contact imaging are the following:

1. If the pupil is not dilated, the eye may require further dilation.
2. If a patient is in distress and requires a break, timing for imaging should be re-evaluated.

3. If a physician indicates a patient under their care is physically unstable for imaging, the procedure should be postponed

Chapter 3: Components and Controls

3.1 User Accessible Parts:

NOTE The Blue Light Module is sold separately and not available in all geographies

Part	Description/Function
ICON Handpiece	Used for ocular imaging per the indications for use. It can be detached from the control box
Diffuser	Slips over the nose of the ICON camera for non-contact external . structure imaging
Holster	Is attached/removed from the holster arm to secure the ICON Handpiece
White Light Module	The primary light source for the camera
Control Box	The main power component for the camera
Control Box Battery charger	Used to charge control box batteries independently of the control box
Control Box Batteries	One rechargeable Li-ion battery to power the control box
Foot pedal	Hardware used for focus, intensity control, and image capture
Laptop	Required for software, image capture, and data management
Laptop power charging cord	Required to charge the laptop prior to use.
USB cable 1.5 ft	Data connection between the laptop and the control box
Power strip	Provides convenient charging of batteries and laptop when system not in use
Slim Laptop Backpack	Provides safe storage, easy access convenience for the laptop
Blue Light Module	An exciter light accessory for fluorescein angiography (only available in select markets)
Soaking cup	A disposable, sterile polypropylene container for cleaning the tip of the lens on the ICON handpiece
Rolling Hard-Sided Transit Case	Provides safe storage and transportation of ICON GO components

NOTE ICON software will not provide imaging capability if the laptop is on ac power. It functions on battery power only

3.2 ICON GO Components in Detail

3.2.1 Laptop

The following laptops are currently compatible with ICON GO

Microsoft Surface

Lenovo ThinkPad E15/L15

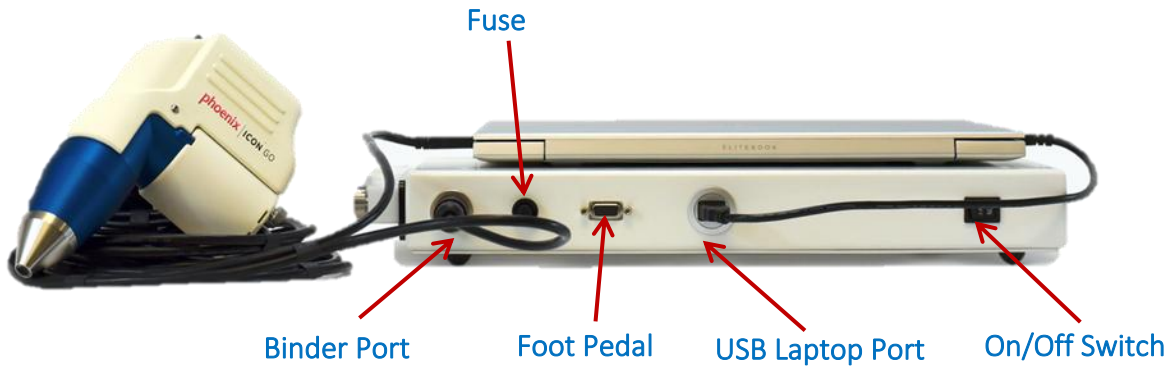
Dell Precision 5680/5690 (needs USBC Dongle)

Dell Precision 3581/3591

3.2.2 USB-C to Ethernet and USB Hub Dongle

In select models that don't have a USB-C to Ethernet Adapter with 3-Port USB Hub is used to connect the USBA terminals from Control Box and Handpiece. Refer the laptop section for details about the models that need this Dongle

3.2.3 ICON GO Ports



3.2.4 Foot Pedal

Effortlessly operate the ICON solo with foot pedal controls for focus and illumination within easy reach.

LED light intensity (Right Side Switch)

- Right side increases illumination
- Left side decreases illumination

Camera Focus (Left Side Switch)

- Right side focuses towards the back of the eye
- Left side focuses to the front of the eye

Capture Image/Video:

- Press green button to capture image or video
- Press green

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 ICON camera. This will allow the 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

3.2.5 Ethernet Port

The Ethernet port is available for maintenance only. Maintenance is defined as:

1. Retrieving a modality worklist (MWL)
2. Storing images to a PACS
3. Exporting or backing up patient and image information
4. Downloading system security patches

CAUTION:
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.

CAUTION:
Only use the AC Cable supplied with the ICON GO system

3.3 ICON Camera Handpiece

ICON imaging systems capture videos and images using the ICON camera handpiece. The camera handpiece consists of optics, a digital sensor, and an interchangeable

light module. The contact lens on the tip of the camera handpiece has a smooth concave surface, which will come in contact with coupling gel and gently contact 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 light module generates and emits the light for the camera. The handpiece has two detachable light modules: one is white light for general color imaging; the other is a blue light for fluorescein angiography.

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

In expected operation of the ICON GO 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
- Handpiece Tip: Machined 316 Stainless Steel
- Adhesive: Medical grade epoxy (ISO 10993 tested)

Chapter 4: Operation

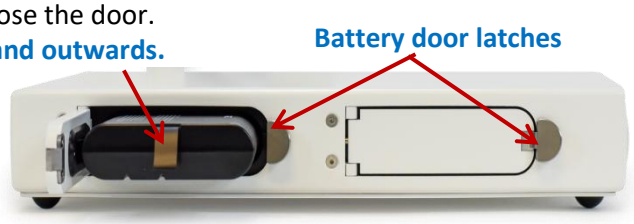
4.1 Setting Up the ICON GO System

4.1.1 Unpack and Assemble

1. Place the rolling case down on a flat surface so the lid can be safely unlatched and opened.
2. Remove the ICON GO Control box from the rolling case and place it on a stable surface.
3. Remove the charged laptop from the backpack and place it on top of the Control box.
4. Plug the USB cable into the the laptop and into the port in the back of the Control box

4.1.2 Insert the Control Box Batteries

1. The ICON GO Control box holds two rechargeable batteries which you will insert into the system. When one battery gets low, you can easily switch power over to the second one.
2. To insert the batteries, open the battery door by pulling back the latches on the left side of the control box.
3. Insert both of the fully charged batteries into the compartments with the label side facing up and outwards and close the door.



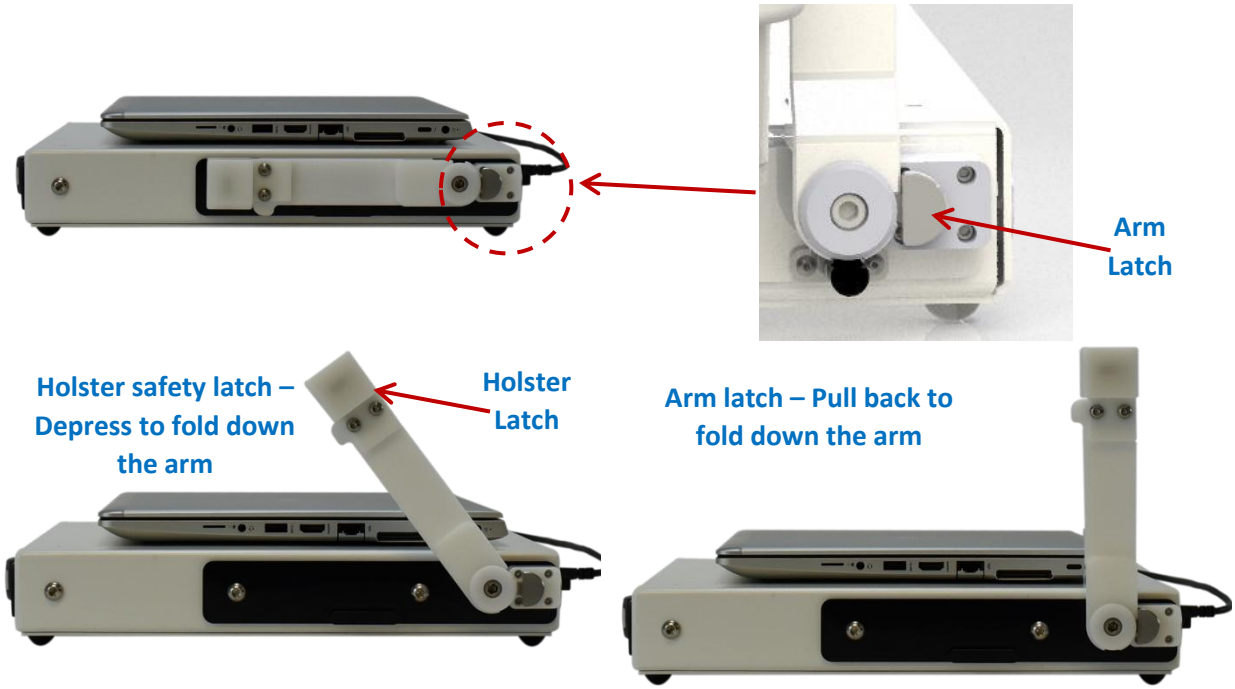
NOTE	The ICON GO is a completely battery-operated device. As standard practice before any imaging session, ensure the laptop has been charged using the accompanying laptop power cable. The laptop is not connected to wall power during imaging. Additionally, the control box batteries should be fully charged in advance using the battery charger provided.

4.1.3 Deploy Holster Arm

A holster is used to secure the ICON handpiece when the camera is not in use. The holster is attached to an arm which folds down when the system is stored.

1. To deploy the holster arm, pull back the metal latch on the right side of the control box
2. Raise the arm until it is locked into a vertical position.

3. Ensure the safety latch is engaged so that the holster is not able to fold down unless the safety is depressed as well as the arm latch.



4.1.4 Attach Holster to Holster Arm

Pull back the latch on the upper-inside of the holster arm and slide the black holster attachment tab into the channel on the holster arm.

4.1.5 Attach Soaking Cup to Holster

The ICON GO comes equipped with a disposable, clear, threaded specimen container to be used as a soaking cup to disinfect the contact surface of the ICON camera handpiece. If the cleaning procedure of the facility does not include soaking the tip of the camera handpiece, the soaking cup may still be attached to the holster as a protective cover.

1. Remove the soaking cup from rolling hard case, unscrew the pink top.

2. Pour enough cleaning solution into the cup so that the tip of the lens will be within the liquid as described in the Cleaning Instructions.

3. Screw the 60 mL cup on to the bottom of the holster. 90ml B902L sterile polypropylene containers are longer but will also thread onto the holster.

CAUTION:
Do not collapse the holster arm when the ICON GO hand is placed in the holster or when there is cleaning solution in an attached soaking cup

4.1.6 Connect Camera Handpiece to Control Box and Laptop

1. Once the Holster Arm is securely deployed, remove the handpiece from the rolling hard case and insert it into the holster.

2. There are two connections on the handpiece; a USB and a round binder connection. The binder connector provides power to the handpiece. The USB sends data from the handpiece to the system.

3. Plug the handpiece USB cable into the laptop.

Laptop	USB Type	USB Location
Microsoft Surface Book	USB-A	Left Side
Lenovo ThinkPad E15	USB-A	Left and Right Side
Dell Precision 5680	USB-C	Right Side
Dell Precision 3581	USB-A	Right Side

4. Connect the round binder connection into the back of the control box as shown. When connecting, align the notch on the cable with the cutout notch on the connection port. When removing the binder cable from the port, gently pull back on the external spring-loaded sleeve to release.

4.1.7 Connect Foot Pedal

1. Remove foot pedal from rolling hard case and place in convenient location on the floor.

2. Plug the foot pedal cable into the back of the control box.

3. Turn the screws on each side of the connector to secure the connector and prevent unintended disconnection.

4.2 Startup Procedure

1. Turn on the power switch on the back of the control box.

2. Toggle the battery switch to preferred battery on the front of the box.

3. Turn on the laptop.

4. Wait for the Windows software to launch followed by the ICON software.

4.3 Shutdown Procedure

1. Clean the handpiece tip as recommended in **Section 5**

2. Log out the software by clicking the Log Out button on any of the screens. This will take you to the Welcome/Login page.

3. Click the Cart Power Button.

4. Turn off the Control Box using the power switch on the back of the control box.

4.4 Using the ICON Handpiece

NOTE The handpiece should be used for a maximum of 3 minutes at a time, followed by a 3-minute rest period before it can be used again in the same manner.

4.4.1 Operator and Camera Positioning During Imaging

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

2. 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

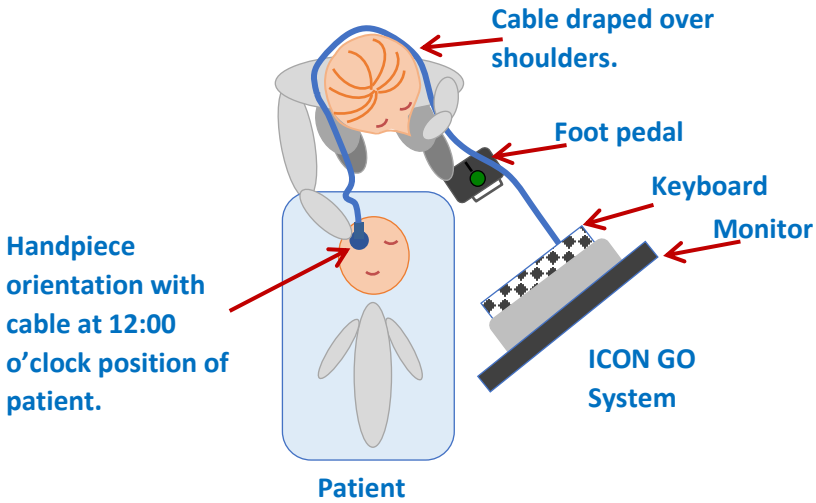
3. The viewing angle of the screen will make a difference to the operator's perception of illumination brightness of the retinal image. For imaging consistency, the operator should position the system so that they are looking straight at zero degrees to the center of the monitor.

4. Before bringing the camera handpiece 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.

5. The operator should align the camera handpiece 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.

   NOTE: A quick way to verify ICON camera orientation is to point the camera at the keyboard, where the letters should appear upside down

6. Disconnect the cart from the wall if connected



Basic schematic of orientation of patient, Handpiece and ICON

4.4.2 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.

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

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

3. Ensure that the blue light module is inserted in the ICON™ camera handpiece and that the filter lever on the handpiece is on the barrier filter position (blue dot).

4.4.3 Using the ICON Diffuser

The ICON Diffuser is an accessory for the ICON handpiece that is intended for use when capturing images of the external structures of the eye. The unmodified illumination scheme used in the ICON handpiece 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 ICON Diffuser

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

2. Properly clean and prepare the ICON handpiece, as noted in Section 5 of this manual

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

4. Slide the ICON Diffuser on to the nose of the ICON handpiece

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 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 ICON handpiece so that the desired external structures of the patient’s eye are visible in the camera’s field of view as seen on the 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 handpiece

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

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

4.5 Packing the ICON GO

1. To keep the packaging clean, ensure the system has been wiped down with disinfection wipes according to the procedure in Section 5.
2. It is best practice to charge the laptop and batteries before putting them away. Given that there may be multiple people using the system, also check that they are charged prior to use.
3. Turn off the control box using the On/Off switch at the back of the unit.
4. Unplug both ends of the USB cord that connects the laptop and the control box.
5. Unplug the handpiece USB from laptop.
6. Fully charge the laptop and pack the laptop, charger, and USB cord in the backpack.
7. Pack the diffuser and USB sticks, if used, into the bottom layer of rolling hard case.
8. Unplug the two handpiece connections from the control box. Gently Pull back on the spring-loaded release of the round binder cable to detach the cable. Unplug the handpiece USB connection.
9. Remove the handpiece from the holster and ensure the tip is clean and dry. Pack it into the rolling hard case foam and coil the cords into the slot in the foam.
10. Dispose of the soaking cup and place a new, clean soaking cup in the foam cutout in the hard case.
11. Pull back latch and slide holster off the holster arm. Pack the holster into the rolling hard case in the appropriate foam cutout.
12. Pull back on the bottom latch of the holster arm and return the holster arm to the flat (down) position.
13. Pull back the latches on the left side of the control box to open both battery doors.
14. Remove the batteries from the control box, use the external battery charger to fully charge them, and pack them into the rolling hard case foam.
15. Place the foam layer on top of the bottom layer of the rolling hard case.
16. Unplug the footswitch from the control box and slide into right slot in the hard case.
17. Ensure all cords are unplugged from the control box and that it is turned off.
18. Ensure that the holster arm is folded down and place the control box on top of the foam layer.
19. Close the lid and lock the case latches

4.6 Charging the Control Box Battery

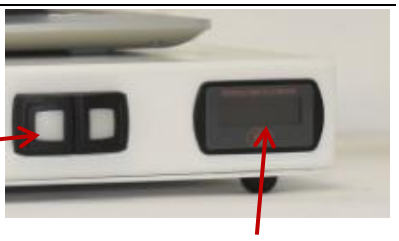
1. Charge each of the control box batteries with the benchtop charger. The battery charger has a red light that will change to yellow and green depending on the state of charge. When the light is green, the battery is fully charged.

NOTE: The ICON GO is only compatible with the supplied standard Li-ion battery pack type RRC2054-2. It may be purchased from Phoenix Technology Group, LLC or from Mouser, RRC, or other vendor

2. To check the charge on the battery, press the button on the battery to show the state of charge. Each light indicates 25% of charge; one light would indicate 0-25%, two lights, 26%-50%, three lights 51%-75%, and four lights 75%-100%.

3. When the batteries are inserted into the control box, the battery meter on the front of the control box will show the percentage charged. Once the battery gets low, toggle the battery switch to activate the second charged battery.

4. A low battery may be removed for charging while the control box is in operation, as long as it is not the battery being used for power. Note: The control box meter display may vary +0/- 25%.



NOTE

The ICON GO is a mobile system intended to perform imaging functions on battery power only. When fully charged will typically last for over 6 hours. Batteries are charged outside of the control box in an external battery charger described above. The amount of charge for each battery is visible on the battery, as well as on the front of the control box when the battery is inserted.

The duration may vary depending on system configuration and use. The laptop is charged using the accompanying charge AC cable. The laptop should not be plugged in during imaging with the ICON GO control box and handpiece. If the laptop is plugged into AC power during imaging, the light module will not turn on. Other administrative functions and image review or export can be done while the laptop is connected to mains power.

4.7 Transporting the System

For short transport and brief storage:

- Batteries can stay in the control box. When transporting, ensure the On/Off switch at the back of the control box is Off

For long transport and storage:

- Batteries should be fully charged and stored in the rolling hard case foam

4.8 Environmental Protection

1. The ICON GO system does not utilize any disposables
2. Please use your organization's disposal procedures for effective discarding of all cleaning supplies used with the system
3. For disposal of the ICON GO system, do not throw Control Box and handpiece into the waste bin. Contact Customer Support for disposal options

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NOTE All disposals must comply with local regulations

Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately at the end of their expected service life. Contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment

Chapter 5: Routine Maintenance Procedures

This chapter includes procedures for routine maintenance of the ICON. These procedures may be performed after any of the following events and/or as prescribed by the institution's maintenance schedule:

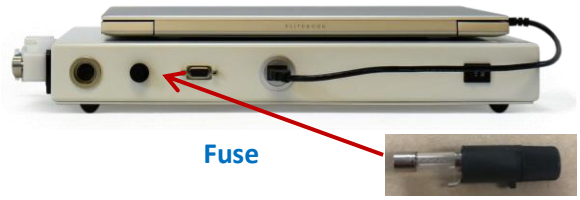
- Initial receipt of the ICON GO at the institution.
- ICON GO has been visually damaged or subjected to mechanical shock (i.e., dropped).
- ICON GO has been submitted for maintenance or scheduled performance verification.

5.1 Servicing the ICON Go System

5.1.1 Change the control box fuse

The fuse may be blown if the light on the ICON camera handpiece will not turn on. If it is suspected that something other than a fuse is not operating correctly, please contact Customer Support

1. Locate the fuse assembly which is found at the back of the control box
2. If checking or replacing the fuse, turn off the control box power.
3. Push and rotate the cap of the fuse assembly counter-clockwise one-quarter turn.
4. The fuse assembly will eject.
5. Remove the blown fuse from the cap.
6. Insert the new fuse into the cap. Insert the fuse assembly into the control box and turn clockwise one-quarter turn.



5.1.2 Standard and Preventative Maintenance

1. Check before each use to ensure the tip of the handpiece is not chipped, cracked, rough or damaged in any way.
2. Disinfect the handpiece lens tip before and after use on a patient according to the cleaning recommendations included in the instructions for use document.
3. Ensure cables are not overly crimped or bent when storing in the transit case.
4. Periodically allow the control box batteries to run down and then fully charge them to maintain battery health.
5. Ensure the pins on the binder connection are not bent before inserting into the port.
6. Check the handpiece cable at the binder and USB connectors as well as at the insertion to the handpiece ensure there are no exposed wires.
7. The ICON GO is a modular system, therefore any components (control box, foot switch, handpiece, laptop) requiring service should be returned to the factory and are not serviceable onsite at the customer facility.

5.2 Using the Soak Timer

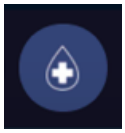
The ICON software also includes a soak timer feature which provides a visual count-down and audit log of the disinfection soak process. A software audit log entry is written each time the soaking timer is started and stopped. Each log entry includes the current user's User Name and the date and time.

SETUP THE SOAK TIMER.

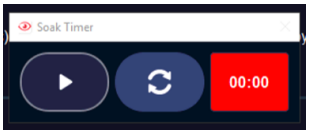
1. Log in as an Administrator.
2. Go to Settings / Camera and set the soak timer to match the required soak time for the chemistry chosen.
3. Log out and log back in as user prior to performing disinfection.

USING THE SOAK TIMER

1. Once the ICON Handpiece is submersed in the soaking liquid, click the soak timer ICON located at the bottom of the screen.



2. The soak time countdown will appear starting with the soak time set by the administrator.



3. The system will indicate 00:00 in the red box once the time has elapsed.

5.3 Cleaning and Disinfection Procedure (To be followed inside the United States Only):

5.3.1 ICON Handpiece Lens Cleaning and Disinfection

IMPORTANT	Semi-critical devices that contact mucosal membranes must be reprocessed using high-level disinfection. Failure to use high-level disinfectants may result in inadequate sterilization, potentially leading to infection or other adverse effects.

CLEANING AND INTERMEDIATE LEVEL DISINFECTION:

Supplies Needed:

Sterile Gauze or Tissues
Sterile or Distilled Water
Starplex Scientific Sterile Cup (B902L)
Desired Cleaning (Choose from list below)

Desired Cleaning Agents:

Solution	Common Brand Name
Sterile or Distilled water	Hospital standard
Isopropyl Alcohol (¬>70%) wipes or solution	Hospital standard
Isopropanol (17.2%) and Ammonium Chloride	CaviWipes towelette(s)
Quaternary ammonium and Isopropyl alcohol (IPA)	Super Sani-Cloth germicidal wipes
Virucide, Bactericide, Tuberculocide, Fungicide, Sanitizer	Oxivir Tb
Sodium Hypochlorite (≥ 6%)	Bleach solution
Hydrogen Peroxide (≥ 6%)	Hospital Standard

1. After each patient (or prior to the first imaging session of the day), immediately wipe the tip of the lens with a soft tissue or gauze saturated in sterile or distilled water to ensure that the coupling gel, organic matter, and any particulates are completely removed before using disinfecting agents.

   NOTE: Just soaking in disinfectant solutions below will not break down and remove dried gel

2. If using a cleaning chemical other than sterile or distilled water, wipe the tip of the lens with a soft tissue saturated in sterile water to remove any residual chemicals.

3. Once gel or fluid has been removed, perform lens disinfection procedure methods as described below.

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 saturated cotton bud around the outer edge of the lens tip.

Desired Disinfection Agents to achieve Intermediate-Level Disinfection (ILD):

Chemistry	Product Examples	Soak Time	Special Instructions
Isopropanol (17.2%) and Ammonium Chloride	CaviWipes - Disinfecting Towelettes	3 mins	1. Using CaviWipe (s), wipe the stainless-steel tip and lens so that these areas remain wet for 3 minutes. 2. Additional wipes may be used as needed to ensure the stainless-steel tip and lens remains wet for 3 minutes. 3. Using lint-free cloth(s) dampened with purified water (PURW) wipe the stainless-steel tip and lens to remove any chemical residue. 4. Repeat step 3 two more times for a total of 3 times 5. Dry the articles using sterile lint-free cloth(s). Then allow to air dry.
55% Isopropyl Alcohol	Super-Sani® Cloth wipes - Disinfecting	4 mins	1. Using Super-Sani® Cloth, wipe the stainless-steel tip and lens so that these areas remain wet for 4 minutes. 2. Additional wipes may be used as needed to ensure the stainless-steel tip and lens remains wet for 3 minutes. 3. Using lint-free cloth(s) dampened with purified water (PURW) wipe the stainless-steel tip and lens to remove any chemical residue. 4. Repeat step 3 two more times for a total of 3 times 5. Dry the articles using sterile lint-free cloth(s). Then allow to air dry.

CLEANING AND HIGH-LEVEL DISINFECTION:

Supplies Needed:

Sterile Gauze or Tissues	Starplex Scientific Sterile Cup (B902L)
Sterile or Distilled Water	Desired Cleaning (Choose from list below)

Desired Cleaning Agents:

Solution	Common Brand Name
Sterile or Distilled water	Hospital standard
Isopropyl Alcohol (¬>70%) wipes or solution	Hospital standard
Isopropanol (17.2%) and Ammonium Chloride	CaviWipes towelette(s)
Quaternary ammonium and Isopropyl alcohol (IPA)	Super Sani-Cloth germicidal wipes
Virucide, Bactericide, Tuberculocide, Fungicide, Sanitizer	Oxivir Tb
Sodium Hypochlorite (≥ 6%)	Bleach solution
Hydrogen Peroxide (≥ 6%)	Hospital Standard

1. After each patient (or prior to the first imaging session of the day), immediately wipe the tip of the lens with a soft tissue or gauze saturated in sterile or distilled water to ensure that the coupling gel, organic matter, and any particulates are completely removed before using disinfecting agents.

   NOTE: Just soaking in disinfectant solutions below will not break down and remove dried gel

2. If using a cleaning chemical other than sterile or distilled water, wipe the tip of the lens with a soft tissue saturated in sterile water to remove any residual chemicals.

3. Once gel or fluid has been removed, perform lens disinfection procedure methods as described below.

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 saturated cotton bud around the outer edge of the lens tip.

4. Prior to lens disinfection ensure all personnel have read and understand the appropriate disinfectant solution Safety Data Sheets (SDS).

5. Setup the ICON Handpiece holder and obtain a soaking cup, if required. A soaking cup is not required for High-Level Disinfection (HLD) using Tristel Duo OPH.

6. Select one disinfection chemistry from the section below. Follow the steps specific to the recommended disinfectant used. The steps can be found below under the column “Special Instructions.”

NOTE: You may use ICON inbuilt soak timer to help track the duration ICON handpiece soak inside the disinfectant. The instructions on how to use the soak timer are listed above.

Desired Disinfection Agents to achieve High-Level Disinfection (HLD) without a soaking cup:

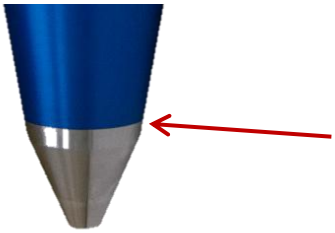
Chemistry	Brand(s)	Soak Time	Special Instructions
Chlorine dioxide (ClO_2)	Tristel OPH and Tristel Duo OPH	2 mins	1. Prepare per manufacturer instructions. 2. Lay the Tristel OPH Wipe in the palm of your hand and apply two (2) doses of Tristel OPH Foam. 3. Gently close hand around the wipe and wait for 10 seconds. Do not squeeze. 4. Wipe the ICON handpiece lens tip and the silver-colored stainless-steel cone to spread the foam using a massaging motion covering disinfection areas 4 times. Ensure all surfaces are covered and the device is visibly wet. Pay particular attention to any crevices, ridges, or indentations. **CAUTION**: Do not wet past the silver stainless steel cone to avoid fluid ingress. 5. After wiping, leave the device undisturbed. Place the device on a clean surface to avoid recontamination. Contact time for high-level disinfection is two (2) minutes. 6. Use a clean Tristel OPH Wipe to thoroughly remove residue of the Tristel OPH Foam

NOTE The remaining steps do not apply if HLD is performed without a soaking cup.

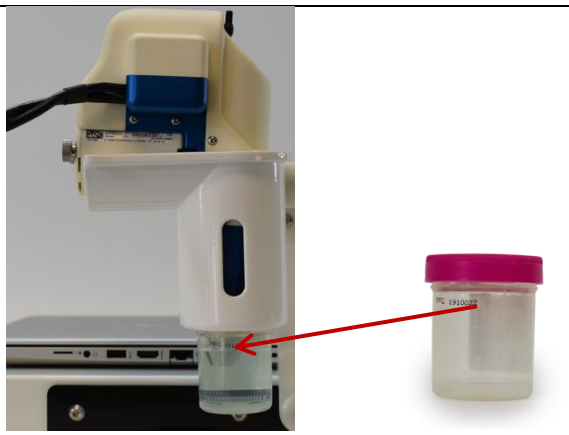
Desired Disinfection Agents to achieve High-Level Disinfection (HLD) with a soaking cup:

Chemistry	Product Examples	Soak Time	Special Instructions
Glutaraldehyde (>2%)	Metricide Plus 30, ProCide D	90 mins	• Prepare per manufacturer's instructions at 25°C. • After soaking for 90 mins rinse with sterile water for a minimum of 1 minute. • Repeat rinse for a total of 3 full rinse cycles.
Ortho-phthalaldehyde (OPA)	Cidex	12 mins	• Prepare per manufacturer's instructions at 20°C • After soaking for 12 mins rinse with sterile water for a minimum of 1 minute. • Repeat rinse for a total of 3 full rinse cycles.
Hydrogen Peroxide (7.5%)	Generic	30 mins	• Rinse with sterile water for 1 minute after soaking for 30 mins and wipe with soft cloth to dry. • Repeat rinse for a total of 3 full rinse cycles

7. Fill the soaking cup, to the 50 mL line so that the solution adequately covers the lens and stainless-steel tip



8. Screw the soaking cup into the ICON holder as shown



9. Place the Handpiece into the solution and start the soak timer (if required)

10. Once the disinfection soak is complete, prepare a bath of sterile water. Using a non-linting cloth soaked with sterile water, wipe the stainless-steel tip and lens. Thoroughly rinse the stainless-steel tip by immersing it in sterile water for one minute. Using a new non-linting cloth and bath of sterile water for each rinse, wipe and rinse the stainless steel tip and lens two more times by immersing in sterile water for one minute for a total of three wipes and rinses.

11. Once the camera tip has been disinfected after use, the cleaning solution may be discarded, and a dry cup may be attached to the soaking holster.

CAUTION:
Some high-level disinfectants require a multi-rinse process, verify rinse requirements per method chosen

5.3.2 Other System Components

Between patients and at the end of all imaging sessions for the day, wipe down the keyboard, computer trackball, cart work surface, diffuser, hand piece holster, and hand piece cable in between patients with disinfectant wipes. Ensure that any gel or particulates are removed. Once the disinfection is complete, rinse the components using a soft cloth saturated in sterile or distilled water.

Solution	Wet Time	Product Examples
Isopropanol (17.2%) and Ammonium Chloride	3 mins	CaviWipes towelette(s)
Quaternary ammonium and Isopropyl alcohol (IPA)	2 mins	Super Sani-Cloth germicidal wipes
Virucide, Bactericide, Tuberculocide, Fungicide, Sanitizer	1 to 5 mins	Oxivir® Tb

5.4 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. - 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. - Inspect all cables for damage. Damage can include excessive kinks or visible damage to the insulation surrounding the cable. - 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.
Choppy or flickering image or image changes to gray scale	- Disconnect and reconnect handpiece USB cable
LED light ICON is on and there is a live image but no light from the camera (ICON GO only)	- Check that batteries are inserted in the control box - Verify the batteries in the control box are charged
LED doesn't turn on (ICON GO only)	- The ICON GO is battery powered only. The light module will not turn on if the laptop is on AC power. Disconnect the laptop from AC power

Software pop ups and warnings and possible 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. - 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.

Issue	Potential Solutions
Safe to Remove Hardware	- This indicates that the 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.

Chapter 6: Product Specification

Electrical (AC Power)	
Electrical ratings	Nominal Voltage: 14.4 Vdc , Maximum Current Draw: 2.5A
Control Box Battery Type	Li-ion battery pack type RRC2054-2
Control Box Battery Charge Time	< 3 hr. DOD 100%
Control Box Battery Capacity	14.4V/6900mAh/99.4Wh
Battery Runtime (Depends on system configuration and use)	~ 6 hours
Control Box Fuse replacement	233 Series 2.5A Size: 5mm X 20mm Diameter: 5.2mm Voltage rating: 125VAC
Environment	Operating Room, Medical Exam Room
Weight of Components	ICON GO control box (including batteries, holster and soaking cup): 9 lbs. ICON 2 Handpiece: 1.9 lbs. Footswitch: 2.8 lbs. Laptop (Surface Book 2): 4.2 lbs. 1.5m USB cable: 1oz. ICON GO transit case 18 lbs.
Laptop Minimum Specifications	15-inch display 16 GB Memory Intel Core i7 8th Gen 1TB hard drive Resolution: 3240 x 2160, 3:2 aspect ratio 2 USB (full size) ports
ICON Handpiece	Applied part

Light Source	White Light Module	Blue Light 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

Camera	White Light Module	Blue Light Module
Field of View	100 degrees	100 degrees
Resolution	2048 x 1536 (3.15 MP)	2048 x 1536 (3.15 MP)
Frame Rate	30 frames per second	30 frames per second

Other Accessories	White Light Module	Blue Light Module
Insert filter	No insert filter needed.	Used with the blue light module. Use switch on the handpiece to

		put filter into place. Filter blocks band at 500nm, edge 515nm
Imaging lens	Flat field external camera	N/A
Eye Contact Materials	Goniosol or GenTeal Gel	Goniosol or GenTeal Gel

Performance	**White Light Module**	**Blue Light Module**
Imaging Format	.TIF / .JPEG / .AVI	.TIF / .JPEG / .AVI
Imaging Resolution	1240 x 1240 pixels	1240 x 1240 pixels

Use, Transportation and Storage Environment	
Environment	Operating Room, Medical Exam Room
Environmental condition of use	Temperature: +10°C to +30°C Relative Humidity: 30% to 90% Atmospheric Pressure: 800 hPA to 1060 hPA
Environmental transport conditions	Temperature: -40°C to +70°C Relative Humidity: 10% to 95% Atmospheric Pressure: 500 hPA to 1060 hPA
Environmental storage conditions	Temperature: -10°C to +55°C Relative Humidity: 10% to 95% Atmospheric Pressure: 700 hPA to 1060 hPA

Classifications
Internally powered MD Equipment
Control Box IP20, Footswitch is IPX6
Type BF Applied Parts
Mode of operation: Continuous Use
Not intended to be sterilized
Not intended for use in an Oxygen Rich Environment

Chapter 7: Compliance Declaration

EN/IEC 60601-1:2005+A1:2012 (Ed 3.1)	Medical Electrical Equipment- Part 1: General Requirements for basic safety and essential performance
EN/IEC 60601-1-2:2014 + A1:2020 (Ed 4.1)	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
EN/IEC 60601-1-6:2010 + A1:2013 (Ed 3.1)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ANSI Z80.36: 2021	Ophthalmics - Light Hazard Protection For Ophthalmic Instruments

Electromagnetic Compatibility (EMC)

This equipment has been tested and found to comply with the limits for a Class A device.

WARNING:

- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity of the equipment. Medical equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the medical equipment should be observed to verify normal operation in the configuration in which it will be used.
- This equipment uses and can generate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference. If interference is suspected, move equipment away from sensitive devices or contact the manufacturer. Modifications or use of accessories not expressly approved by the manufacturer are prohibited and may void the user's authority to operate the equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.		
Emission Tests	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions 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.
R.F. emissions CISPR 11	Class A	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 IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliant	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Class B is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±2, 15 kV 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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5% U_T (95 % dip in U_T) for 5 s	< 5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5% U_T (95 % dip in U_T) for 5 s	The Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME Equipments or ME systems] requires continued operations during power mains interruptions, it is recommended that the [ME Equipments or ME systems] be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field 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 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. The user should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	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 **Recommended separation distance**

			d=1.2sqrt(P), 80 MHz to 800 MHz **d=2.3sqrt(P), 800 MHz to 2.5 GHz** where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). 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. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
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 Model 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. 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 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	Separation distance according to frequency of transmitter m		
	d=1.2sqrt(P)	d=1.2sqrt(P)	d=2.3sqrt(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 determined 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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

Chapter 8: ICON Software for both Phoenix ICON and ICON GO

This section is applicable to ICON software v1.23 or newer.

8.1 Feature Summary

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

1. **Software Interface**
    a. Patient and study data Input
    b. User-specific Usernames and Passwords
    c. User-specific permissions for access to key features
    d. Encryption of database including
        i. All patient information
        ii. All user information
        iii. All association of images to a specific patient
    e. Multiple clinic or department locations
    f. Built-in soak timer and audit log for disinfection
    g. Security event logging in an audit log that is available to device administrators.

2. **Live Capture**
    a. Snap single images stored in .TIFF format.
    b. Record videos up to 2 minutes in length in Standard mode or 10 seconds in Flashback.
    c. Capture still or video recording with the keyboard, foot pedal or touch screen software controls.
    d. Control focus and illumination using on-screen controls, the foot pedal (and on a control pad on the ICON system)
    e. Adjust Automatic White Balance and Gain using integrated camera control functions.
    f. Use Gain as a tool to brighten an image instead of increasing light intensity.
    g. Create 4 presets for Exposure/Gain preferences.
    h. Enter/edit study notes on a visit or individual image frame.
    i. Apply a timer to images for time-based studies such as fluorescein angiography.
    j. Capture images in color or gray scale monochrome.
    k. Capture 4 simultaneous images of varying gain settings for later HDR blending.
    l. Show screen guides to assist placement of the optic nerve in the image.

3. **Image and Video Review**
    a. Review images captured during an imaging study.
    b. Review a single image.
    c. Compare up to 4 images from one or multiple visits.
    d. Save compared images to the most recent study.
    e. Playback video
    f. Extract a single frame from a video file.
    g. Save magnified image.
    h. Enter, edit and review study and image notes.
    i. Edit eye designation.

4. **Image Export**
    a. Export images with patient data to a DICOM image file.
    b. Export images as .TIFF or .JPEG, with patient data in a companion .CSV file or without patient data.
    c. Still images and images captured from video are both 1240 x 1240 pixels and approximately 6 MB .TIFF files.
    d. DICOM files are approximately 4 MB.
    e. 1 second video is approximately 69 MB.
    f. JPEG files are approximately 600 kb.
    g. Archive data (DICOM or TIFF)

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

6. **Reporting**
    a. Drag and drop images over the 5+ fields placeholders
    b. Use shortcuts to mark the correct fields
    c. Creation of a patient report, including camera control information, images notes, patient notes, patient demographic data, and selected images
    d. Export of the report to a PDF file

8.2 Login Screen

Users gain access to the ICON software and system using unique user logins, passwords, and assigned clinics. Users may utilize the User Login screen as a HIPPA compliant screen for short system transport.

8.2.1 Login Screen Overview

System specific information is located in the bottom left-hand corner:

The Station Id	Customer sets station # in settings. See section 8.9.2
Software And Firmware Version	ICON Software - Control Box Firmware - Handpiece Firmware
Cart Serial Number	Alphanumeric digits
Username	Individually assigned credentials that are not case sensitive. Text will automatically show in all caps
Password	Individually assigned credentials that are case sensitive. To view text users may utilize the "Review Password" Button
Clinic	Individually assigned credentials that populate in the form of a list based on access.

		Confirm the password entered by clicking the Reveal Password button
Shutdown Computer		shutdown the ICON software
Reset Connection		reset connections within the ICON software
Change Password		reset user password (see section 8.9.1 Settings: User Tab regarding password changes)

8.2.2 Logging in the First Time

Logging in to the ICON software for the first time - The system ships initially configured with one user account.

- Username: ADMIN
- Password: 5678
- Clinic: Temp Clinic

After initial login the administration account may be edited, and multiple user accounts can be created following the steps in Section 8.9.1

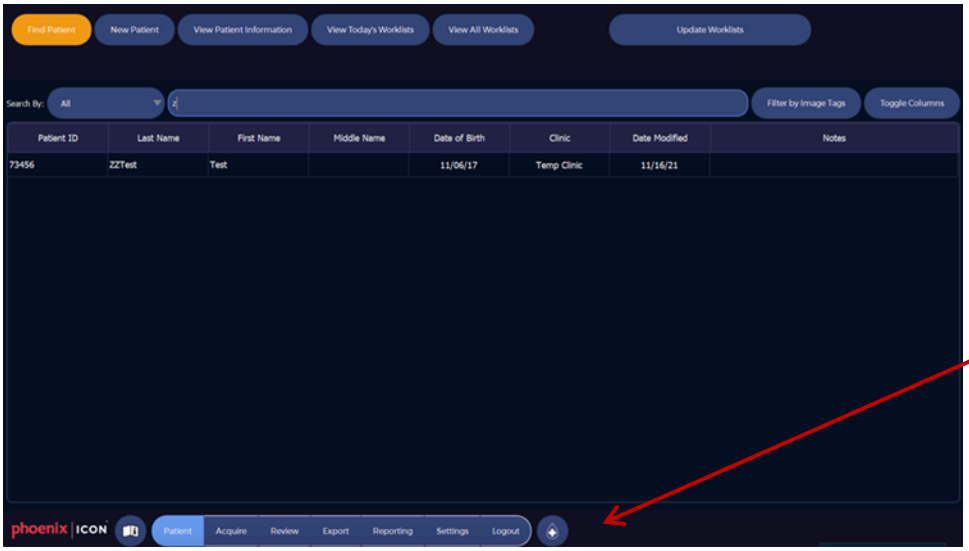
8.2.3 Logging in to the ICON Software

Logging in to the ICON software with user credentials

1. Enter Username
2. Enter Password
3. Select Clinic
4. Click Sign In

8.3 Navigation Panel

Users navigate between the main functions of the ICON software via the Navigation Panel found at the bottom of the screen.



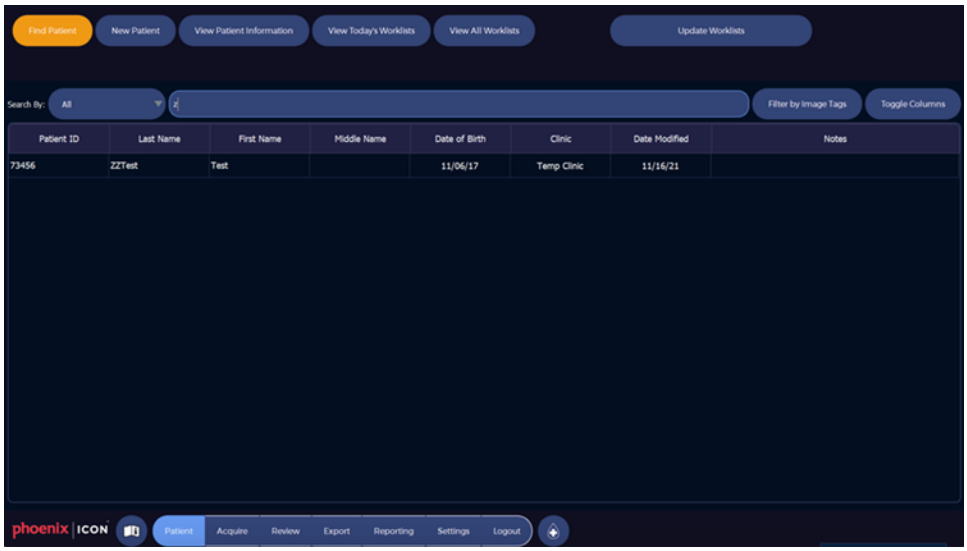
Use the Navigation Panel to access eight sets of functions:

Patient	Find existing patients, enter new patient information, view and edit patient information, view worklists, and update worklists. This screen also provides the ability to move a Patient from one Clinic to another
Acquire	Capture photos and videos utilizing specialized camera controls
Review	Review photos and videos for all imaging studies for the patient
Export	Export images associated with a single patient study or a range of study dates
Reporting	Label or drag and drop image fields (Posterior, Anterior, Inferior, Nasal, Superior) over placeholders. Generate and export a patient report that includes patient demographic information, imaging study information, and the selected images
Settings	Adjust the settings of the ICON software. This screen is only available to administrators of the ICON Software or users given access. 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 ICON camera hand piece. Using the timer creates an audit log of all disinfection actions.

8.4 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.

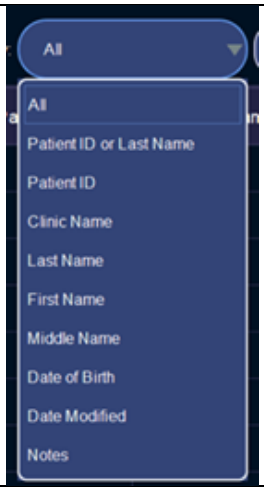
There are three primary buttons at the top of the screen: **Find Patient**, **New Patient**, and **View Patient Information.** In addition, there are three buttons related to working with modality worklists: **View Today's Worklists, View All Worklists,** and **Update Worklists**



These operations are described in the following sections.

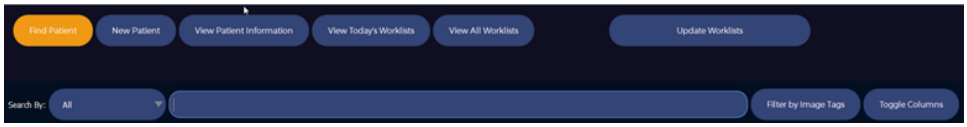
FIND PATIENT

- 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.
- ***Quick Tip***: 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 sort the column (ascending). Click on the column again to change to descending sort.



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.



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.

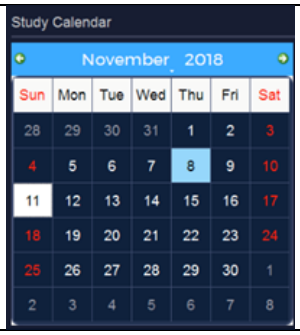
- Two fields are always required: **Last Name**, and **First Name**. A **Patient ID** may also be required if the corresponding setting is enabled on the Settings screen. The Patient ID must be unique across all patients. Mandatory fields are marked with a red asterisk (*).
- Select the Month, Day and 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.
- Enter any of the remaining patient data that should be tracked for the Patient, including any notes.
- Click ***Save***
- ***Quick Tip***: 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.
- ***Quick Tip***: 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.

VIEW PATIENT INFORMATION

Click on a name in the Patient list and select the ***View Patient Information*** button at the top of the Patient screen. Information for the selected Patient will be displayed.

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 the 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.



VIEW/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 ***View 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 Save at the bottom of the screen.
-

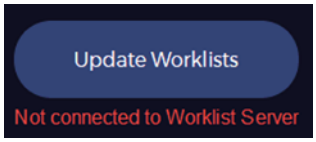
WORKING WITH MODALITY WORKLISTS

The 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 ICON camera and improve the integration with hospital and clinic information systems.

The modality worklist feature is configured on the Settings screen. See Section 8.9.9: Setting – ICONnect MWL

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

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

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

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:
   a. If the associated patient is new to the ICON Software, the patient record is automatically created in the ICON Software database.
   b. If the associated patient is already known to the 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 ICON Software)
   c. 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.

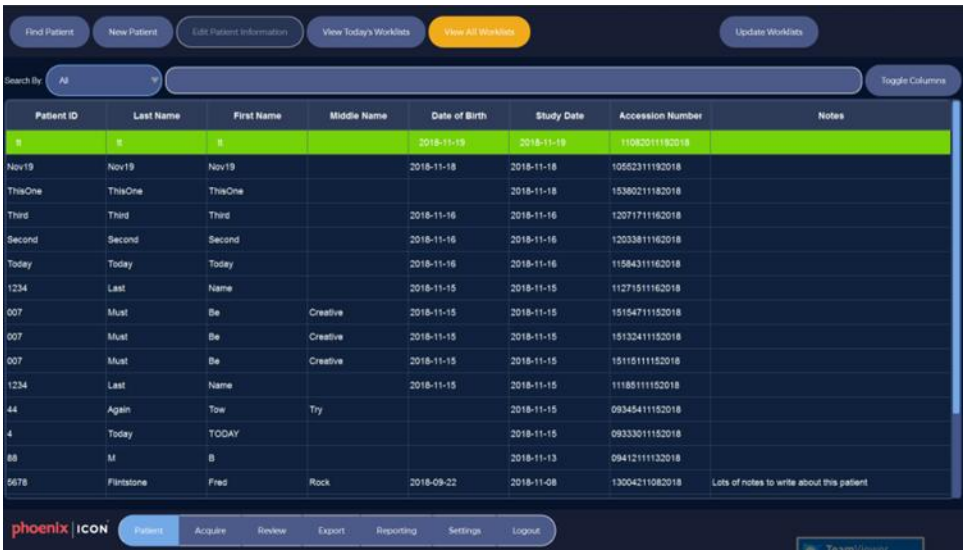
d. The Acquire screen is opened to begin capturing images for the patient.

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

- When a new worklist is received, the 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 ICON database are overwritten with the data provided by the modality worklist server. This includes overwriting the patient name, as the 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.
- Today, the ICON software only processes the first scheduled procedure step in a returned modality worklist. Additional scheduled procedure steps are ignored in the current release.

3. **Initiating Imaging from the Worklist:** Double clicking on a worklist entry launches the Acquire screen to allow the operators 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 blue on the next visit to the ***Patient -> View Worklist*** screen. All worklist procedures that have associated images (associated studies) will be highlighted in blue. 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.



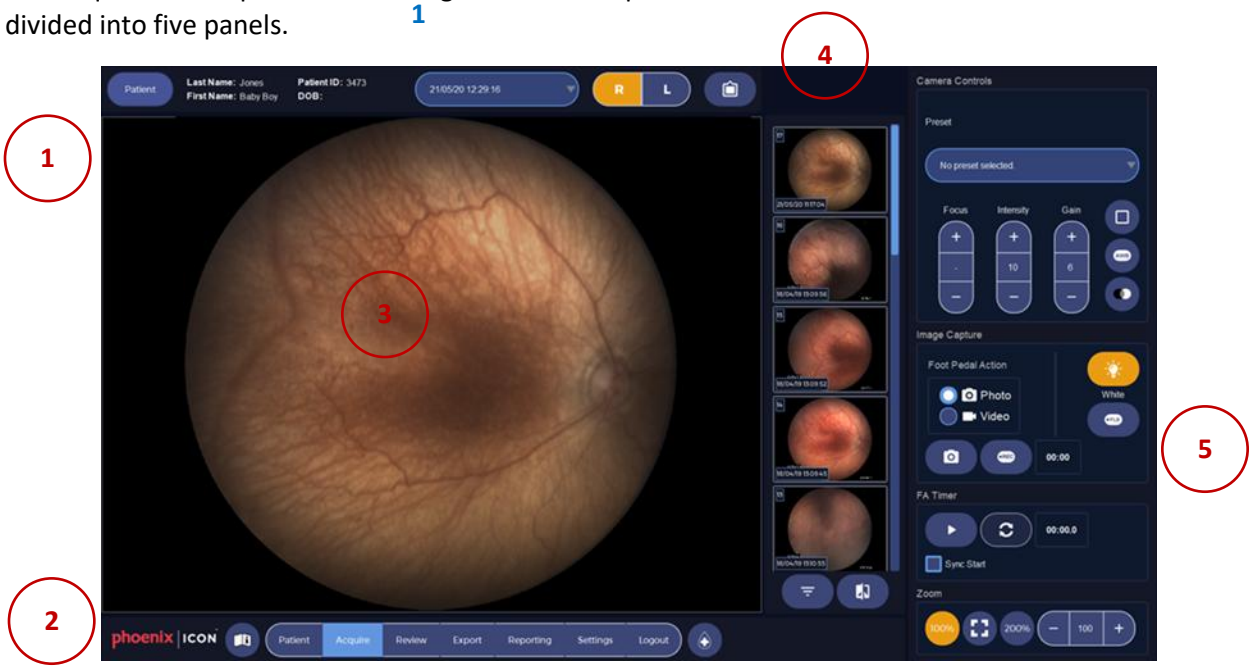
   By initiating the image acquisition process from the View Worklist screen, you are associating the study with the recording of the provided accession number. When these images are later in DICOM format, or sent to a PACS using the ICONnect PACS connector, the accession

number will be present, and this can be used by the IT systems to connect the images to the patient record.

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.

8.5 Acquire Screen

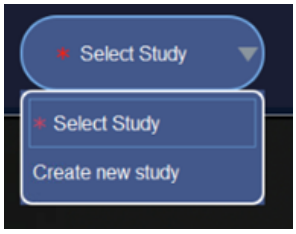
The Acquire screen presents the image and video capture interface for the ICON camera. The screen is divided into five panels.



Panel 1 Patient/Study Information

a. Select Study

To begin 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***

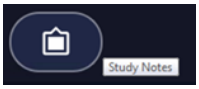
To add images to a study that you started today, select today's date and continue imaging. The new images will be added to the previous images in the thumbnail panel.

b. Select Eye

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

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

c. 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.

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

Panel 2 **Navigation Panel**

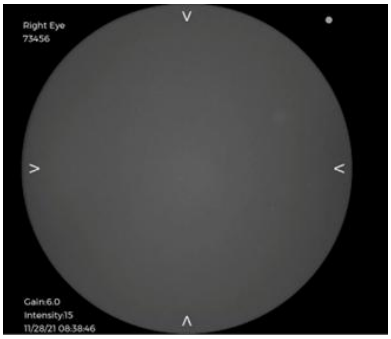
Panel 3 **Image Display Window**

The large area in the center of the Acquire screen presents a live view of the 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. The Acquire view has additional tools to assist the user.



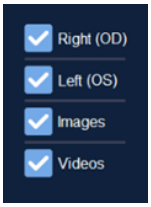
Imaging Targets are white arrows positioned at 12:00, 3:00, 6:00 and 9:00 of the image display window. They may be turned on or off in the Settings/Camera tab. They enable a user to place a structure such as the optic disk, as close as possible to the target to facilitate reproducible field placement over time.

Panel 4 **Thumbnail Tray**

Thumbnails of photos 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 are 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.

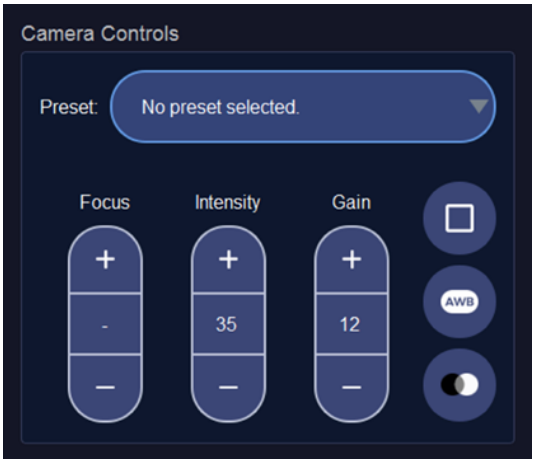
Click the Compare Images button to open the Review screen to compare images from the same or different studies of the same patient.

Panel 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.

1. Camera Controls

The ICON camera provides two controls to adjust image exposure: intensity and gain. Intensity controls the brightness of the camera illumination. 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.

NOTE: The controls are greyed out until the White light module 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 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 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 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 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 ICON systems, the intensity can be adjusted using the foot pedal (see the hardware section of the manual).

Gain

Gain adjusts the 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 by 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

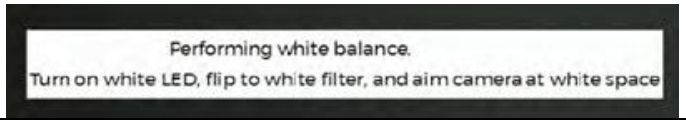
The ICON Software supports a full-screen mode in which only the live view of the camera image is displayed. In this view, all of the controls need to be accessed via keyboard shortcuts (set up on the Settings > Shortcuts screen) or the hardware controls (foot pedal, cart keypad).

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)

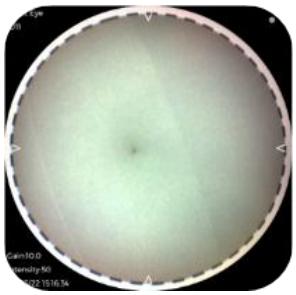
The ICON systems are equipped with integrated camera controls to allow users to Adjust Automatic White Balance (AWB). When powering on and utilizing the imaging system for the first time each imaging day, the AWB function will automatically engage, and a dialogue box will appear in the image display area. Below are important steps to ensure proper AWB before starting patient imaging sessions.

a. With the system powered on and the user logged in, navigate to the acquire screen.
   NOTE: a patient does not need to be selected for AWB.
b. Remove the camera from the holster and ensure it is pointed at an open, non-reflective surface.



NOTE: if the system carries out AWB before the user is prepared, continue to carry out the following steps and manually engage AWB after step 5.

c. Adjust the light Intensity setting to 50 using the camera controls screen function, cart top functions, or foot pedal functions.
d. Adjust the Gain setting to 10 using the camera controls screen functions.
e. Point the camera handpiece toward the target (located on the bottom of this reference) so that the target outline is just visible. This ensures the correct distance for the set intensity and gain for proper AWB.
f. When the system has completed AWB the dialogue box will disappear from the image display area.



CAUTION: The white balance will not work properly if intensity or gain settings are not set correctly. AWB will also not work properly if the barrier filter is in position on the hand piece. If images look abnormally red or yellow, ensure the camera control settings are set correctly, and that the yellow barrier filter is not engaged, and manually perform AWB.

NOTE: Users may manually engage AWB if the system has been powered down or moved to different lighting environments throughout the imaging day. Once the user has successfully completed AWB the acquired screen can be exited and preparations for patient imaging can begin. Please remember to adjust intensity and gain to necessary settings for patient imaging.

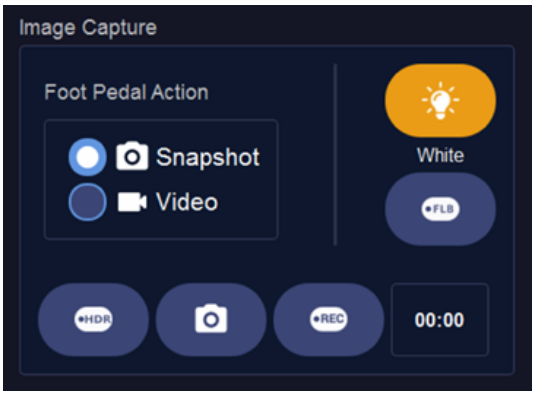
CAUTION: The white balance will not work if the barrier filter is in position on the hand piece. If the image looks abnormally yellow, and the white balance does not function, ensure the yellow barrier filter is not engaged.

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.

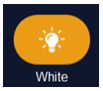
NOTE: A Greyscale by default option is available in the Settings screen should you want all fluorescein imaging to be captured in this mode.

3. Image Capture

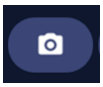


The Image Capture section of the System Controls is used to turn on the camera light, control the capture mode (video, photo, Flashback), determine which action is taken when the foot pedal capture button is pressed, and provide an on-screen means of capturing images. Each of the operations is described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

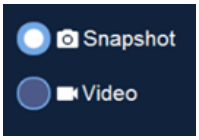
Turn the light illumination on, by clicking the light bulb button. The color of the light module inserted in the hand piece (white or blue) is labeled underneath. The illumination button also powers camera focusing. If it is off, there may be a live view on the screen, however the camera won't focus.



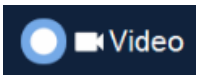
Click the *Camera* button to capture a photo.



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.

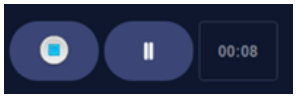


4. Video Capture

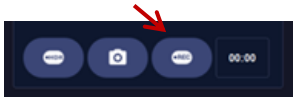


When the Video mode is selected, each time the Snap button on the foot pedal is depressed it will toggle between capture mode and pause mode. This enables you to pause the video capture if the view is not ideal, or you are no longer on the eye but have more areas to image. (Note that it is recommended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

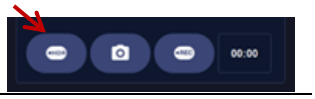
When you are finished capturing, click the Stop button on the software. This will prompt you to save your video. Still images (photos) may be captured from the video at a later time and the video may be deleted to save hard disc space.



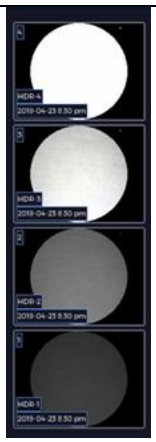
Record video using the software by clicking the Rec button. The duration of the video as it captures is displayed. Videos will be recorded using the Foot pedal if the Video capture mode is enabled. The maximum video length is two minutes which can be reduced in the Settings screen.

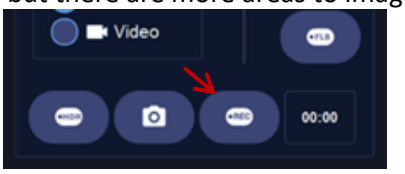
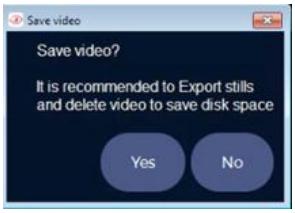
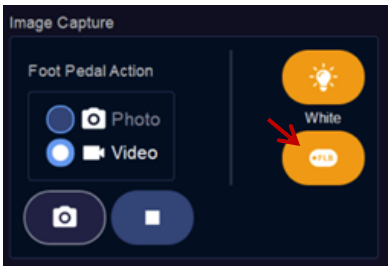


Capture HDR by clicking the HDR button to set a mode that will simultaneously capture four images of the same region



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 third-party software to create an image of high dynamic range. To enable the HDR button, go to Settings/Camera and select the check box for “Enable HDR”.

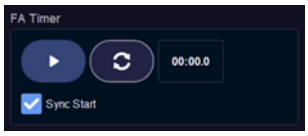


VIDEO CAPTURE MODES	
Normal Video Recording Mode (REC)	Flashback Mode (FLB)
When the REC video recording mode is selected, each time the Snap button on the foot pedal is depressed it will toggle between capture mode and pause mode. This enables video capture to be paused if the view is not ideal, the 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. Four red dots will display on the image display window during recording. They will be visible but not pulsing 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. A *No* will present an “are you sure” dialog.	 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.

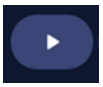
5. Fluorescein Angiography

To perform fluorescein angiography, an accessory blue light module is required for the ICON hand piece. Fluorescein angiography blue light module is sold separately and is available only in certain markets.

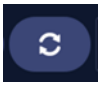
Because fluorescein angiography is a time sensitive series of images you can add a timer to the bottom right of the image using FA Timer controls. Timing of the test is also visible on the FA Timer controls.



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



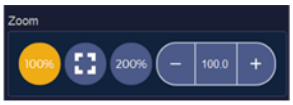
Reset FA Timer: Each stop of the Start Video button provides the option to save a video. During the next video capture, the timer will continue from the last stopped time unless the Reset button is clicked to return the timer to 00.00.0



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.

6. Zoom

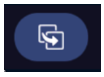
Use the software controls to zoom into the image during live imaging or when reviewing images. The percentage of the zoom is indicated for reference.



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.

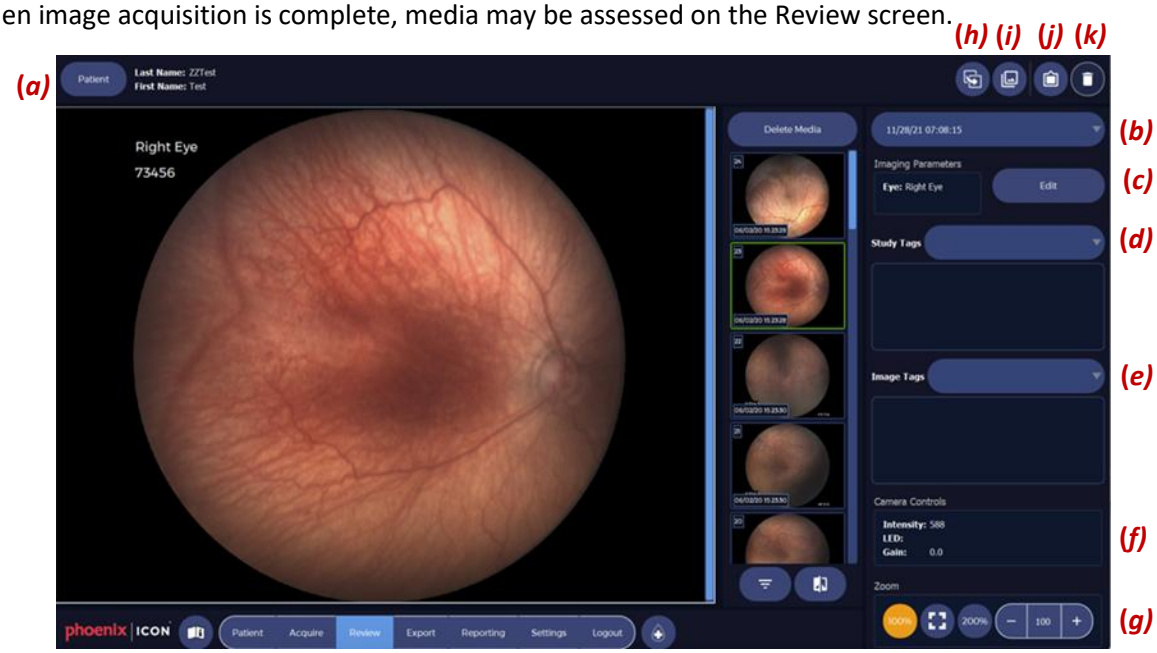
Quick Tip: It is possible to zoom captured images in Review mode. These zoomed areas may be saved as separate images by clicking Save Image as Copy.



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.

8.6 Review Screen

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

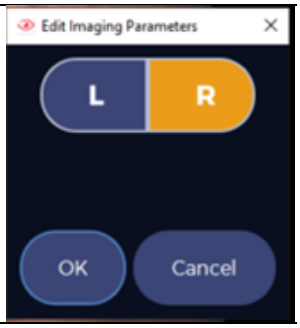


The following operations can be performed on the review screen:

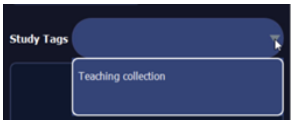
1. **Patient Name**: The name of the Patient is visible at the top left of the Review screen **(a)**. Click the Patient button to return to the Patient Screen to select a different patient to review.

2. **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.

3. **Edit Imaging Parameters**: Click the Edit button **(c)** to change the eye laterality from one eye to another (for example from a right eye to a left eye). Parameters can only be changed one eye at a time.



4. **Study Tags (d)**: Tags are applied to studies to make studies and associated images easier to find.
   a. Click the down arrow to reveal any Study Tags that have already been entered.



   b. Place the curser inside the Study Tags field to type a new tag. Click the Return key to enter it. It will now populate the Study Tag dropdown list.

c. Study Tags may also be pre-populated in the Settings/Patient Information under Image Tags (See Settings section).

5. **Image Tags (e):** Image tags work the same way as the Study Tags above, and use the same list of entries. Image tags are applied on the image level to mark specific frames of interest. They may also be used as a search criterion in the Patient tab under "Filter by Image Tags".

6. **Camera Controls**: Details about the currently selected image are shown on the right of the Review screen, and the exposure settings (intensity, gain, and whether the white or blue light module was used **(f)**.

7. **Zoom**: Zoom controls **(g)** 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 11.4.6.

8. **Save a Copy**: Click the "Save a Copy" button in the upper right of the Review screen **(h)** to save the current view of the selected image as a copy. This is useful as it 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.

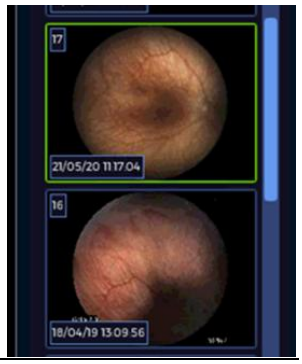
9. **Viewing and Editing Notes**: Information relevant to the selected study or the currently viewed image may be added to the Study Notes **(j)** and Image Notes **(c)**.

 Image Notes

 Study Notes

10. **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)**.

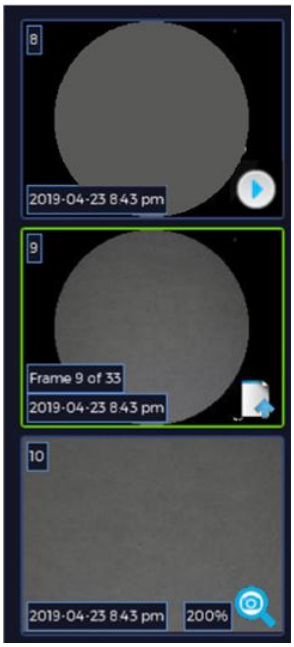
11. **Interacting with Thumbnails on the Review Screen**
Similar to the Acquire screen, thumbnails of still photos and videos are displayed in the Thumbnail Tray of the Review screen with the most recent images appearing at the top of the column.



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

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

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

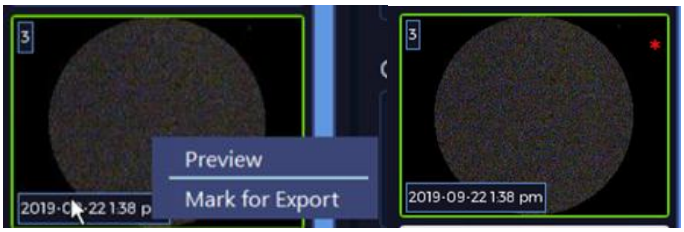


Videos: A thumbnail displaying a forward-facing blue arrow or "play" icon indicates a video has been captured.

Frame from Video: A frame saved from a video is marked with an arrowed document in the lower right corner, and 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.

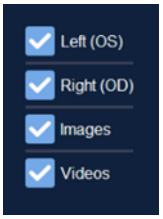
Mark for Export: Thumbnails may be preselected for export on the Review screen by right clicking the image and choosing "Mark for Export". This will place a red asterisk on the image. The image will be pre-selected on the Export screen.



The "Mark for Export" tags will persist after exporting for that patient or when navigating to a screen other than the Export screen to enable a 2nd export in a different file format if needed.

12. 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.



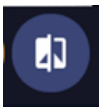
Click the Filter button found at the bottom of the thumbnail tray, and then select the items to be shown. The Thumbnail Tray will refresh to show thumbnails of only matching images.

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**.**

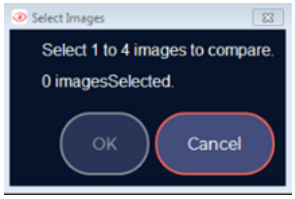
13. Comparing Images

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.

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



b. 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.



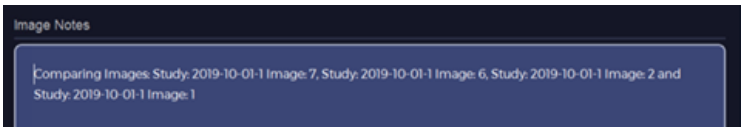
c. The Compare screen will be displayed.

d. Each image is presented with Zoom Controls, allowing the operator to zoom in to areas of interest. 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.

e. 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).

f. The dates of the comparisons may be viewed under Image Notes

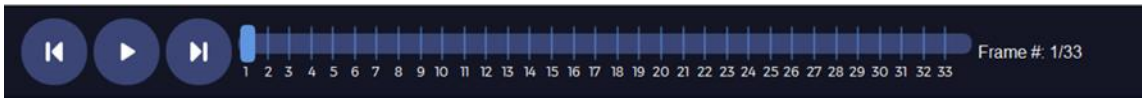
NOTE: It is not possible to compare videos or still photos of compared frames.



14. 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 photo. 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 photo (at the same resolution and size as would have been used if the image was captured in still photo 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.

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

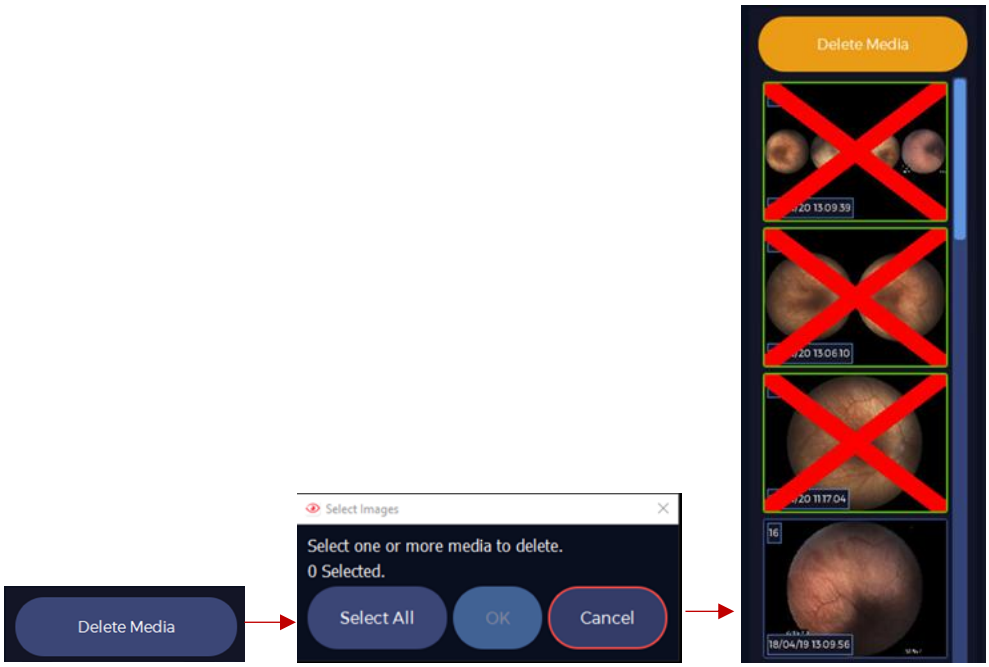
15. Deleting Images and Videos

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

To delete individual images or video:

a. Click the Delete Media button **(I)** found on the upper right corner of the Review screen.
b. 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.
c. A dialogue box will appear asking the operator to select 1 or more images to delete.
d. 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)
e. Click the OK button in the select images dialog and the videos or still photos 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.



8.7 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.

8.7.1 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.

If using removable media, note that it is important to click the Eject USB button on the software for safe removal of the device.

8.7.2 Selecting Data to Export/Archive

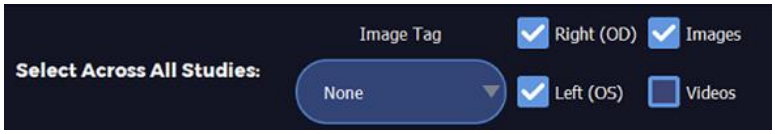
Two buttons at the top of the screen allow the operator to *Search by Patient* or *Search by Study Date*:

- 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.

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.

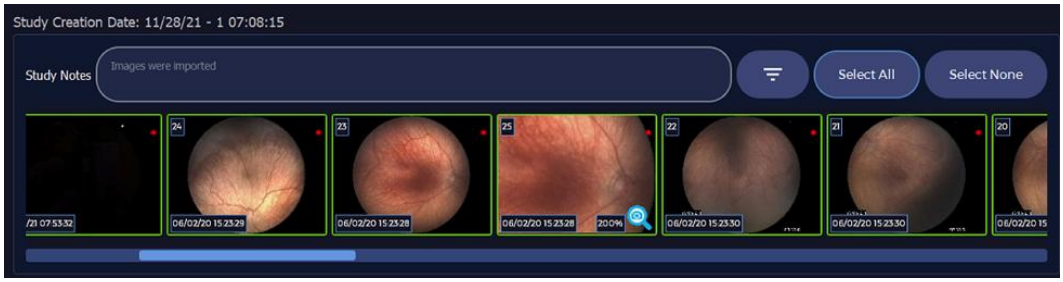
Export Video: There are several ways to select the images or videos to export:

a. Select Across All Studies.



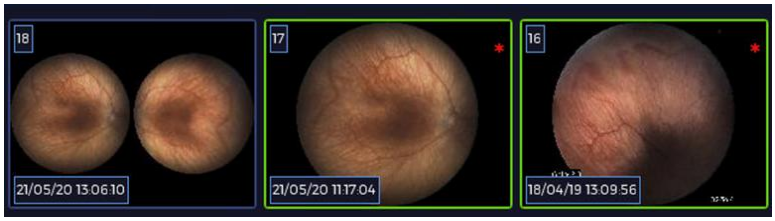
   i. Once a search result by Patient of Study Date populates the Export screen, additional filtering may be done.
   ii. Mark the check boxes for Images/Videos as well as for the eye you want to export. You may further filter the selection by making a selection available in the Image Tag dropdown.

b. Select images in an individual study



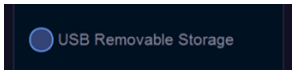
Use the filter button, Select All or Select None to choose images or videos across a single study date.

   i. Click an image/video 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
   ii. To unselect an image, click the image a second time.



c. Next, select the Export File Type from the list.
   i. DICOM, JPEG or Raw images (Raw images are .TIFF file format)
   ii. When exporting to Raw or JPEG, select with or without patient data
   iii. NOTE: images may only be archived in DICOM or Raw (TIFF) format.

d. 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.

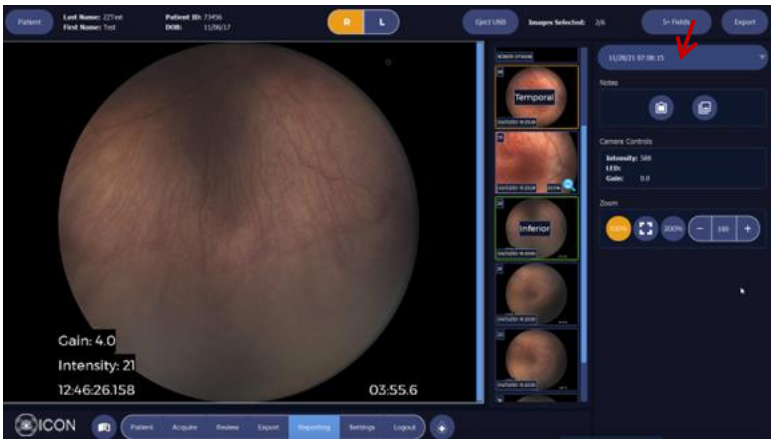


e. Finally, click the Export button to initiate the export or archive operation. A progress dialog box will be displayed while the images are copied.
f. Exported selections will remain selected after export so that a 2nd file type may be exported without having to re-select images. To deselect images after export, click the “Select None” button.

CAUTION:
Archiving images copies the images to the selected external storage location and DELETES them from the ICON database. This helps free up space on the computer hard drive. The patient’s name will remain in the patient list for reference. Archiving creates DICOM or Raw (Tiff) formats. It is not possible to re-import archived images to auto populate patient studies and imaging dates.

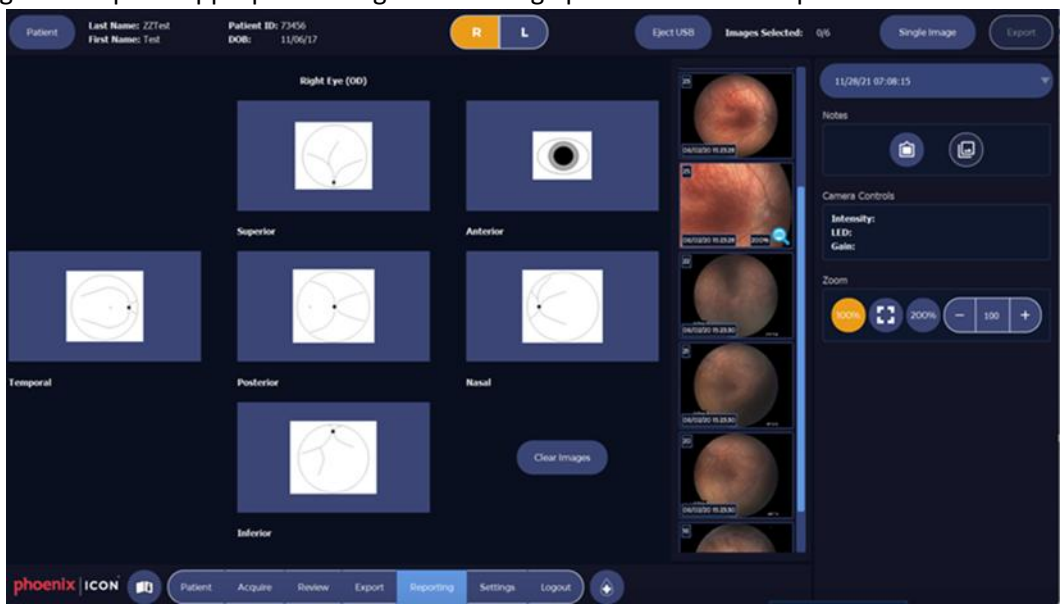
8.8 Reporting

The 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 7 images from one eye of an imaging study. Reports are generated as a PDF file and can be exported to one of the configured Export locations.



1. Click the ***Patient*** button, found on the upper left-hand corner of the Reporting screen, to select a different patient for the report.
2. Click the ***Study Dropdown***, found on the upper right-hand corner of the Reporting screen, to select an imaging study for the report.
3. Select the Eye to be displayed on the report. The associated thumbnails will display.
4. Select the images to be included on the Report by right-clicking on an image in the Thumbnail Tray and selecting the retina quadrant. Alternatively, use keyboard shortcuts to mark the quadrants. (Posterior (P), Anterior (A), Inferior (I), Nasal (N), Temporal (T), Superior (S). These shortcuts may be customized in Settings/Shortcuts.

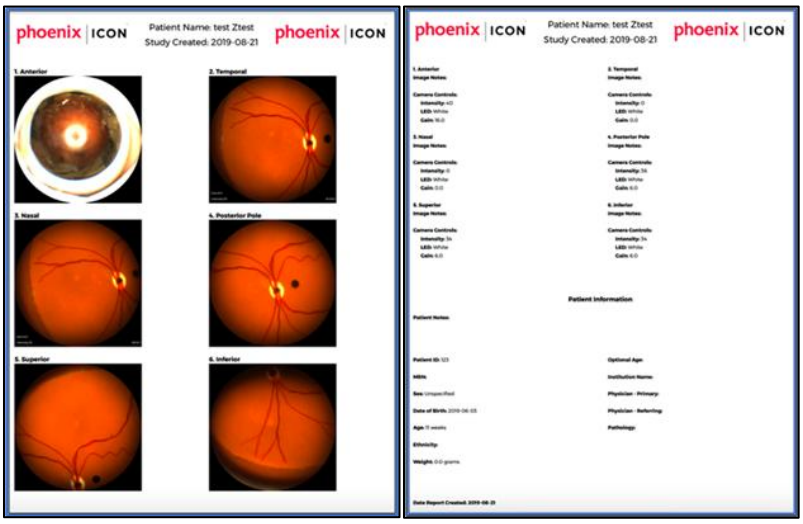
5. A selection counter at the top of the screen indicates how many of the six images have been selected.
6. The **Filter** button at the bottom of the thumbnails allows you to limit the images shown in the Thumbnail Tray to images from only the right eye or the left eye individually.
7. Alternatively click the "5+ Fields" button at the top right of the screen. This will display placeholders for the 5 fundus fields plus one for the anterior segment to show pupil dilation. Drag and drop the appropriate image to the image placeholder to complete the set of 5 fundus.



8. fields for a given eye report. Click the "Single image" button at the top right of the screen to return to the previous view.
9. Once at least one image has been selected, the Export button becomes enabled. If more than seven images are selected, the Export button will become disabled until the number of selected images is seven 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.

10. 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 ICON software.
11. A sample report is shown below:



12. Be sure to click the “Eject USB” button on the Reporting screen to safely remove the device.

8.9 Software Administration (Settings Screen)

The 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.

8.9.1 Settings: User Tab

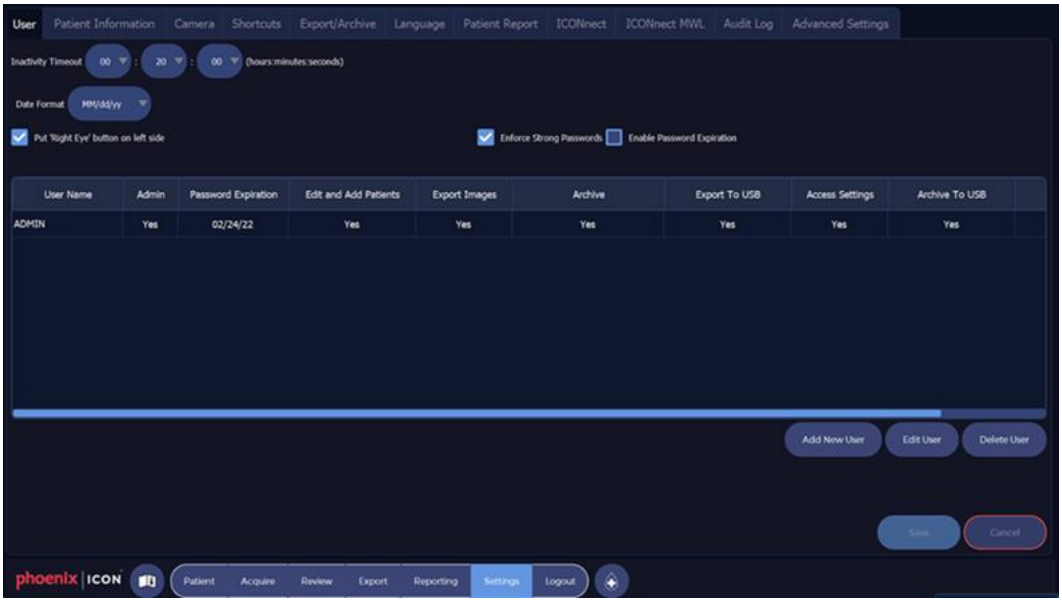
Create Password:

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 Username 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 and Gain Control

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 (support@theneolight.com) for password recovery and system access.



Inactivity Timeout

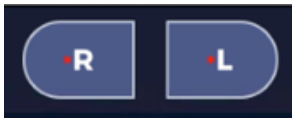
This setting controls the timeout period for all User sessions. The software will timeout and return to the Login screen after the specified duration indicated: given in hours / minutes / seconds. Note: On the ICON GO laptop, be sure to log out of the software before the laptop is put in sleep mode so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

Date Format

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

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.



Enforce Strong Passwords

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

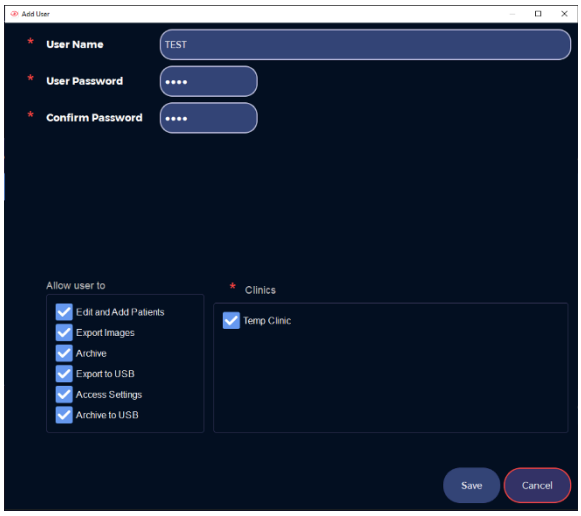
When this option is **checked**, strong password rules apply to **all** passwords. Strong passwords must meet the following conditions:

- 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.

Enable Password Expiration

When this option is checked, ADMIN password will expire after 30 days, and User passwords will expire after 90 days.

Add New User



- To add a new User, click Add User
- Enter the Username. The Username 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 unless Enable Password Expiration is unchecked.

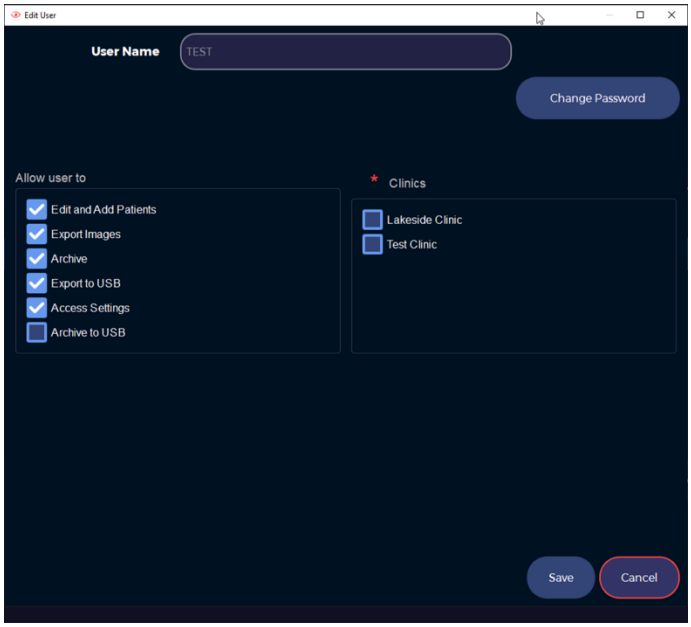
Select the permissions to grant to the newly created user.

- 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.

Edit User

- To edit a user, click on the Username 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,

Delete User

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

8.9.2 Settings: Patient Information

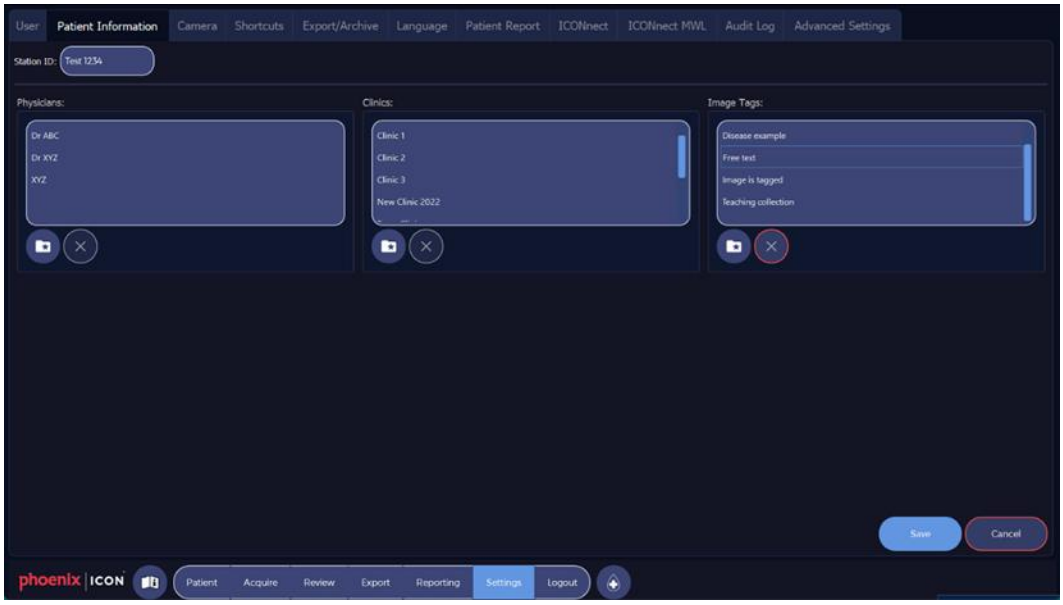
The ***Patient Information*** tab is used to confirm that Station ID for this ICON system, set the list of physicians that can be associated with a given Patient, and set the list of Clinics that can be associated with a Patient or a User.

Station ID: Indicates the Station Name of the 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 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 ADMIN user can see all Patients, regardless of the Clinic chosen at login.

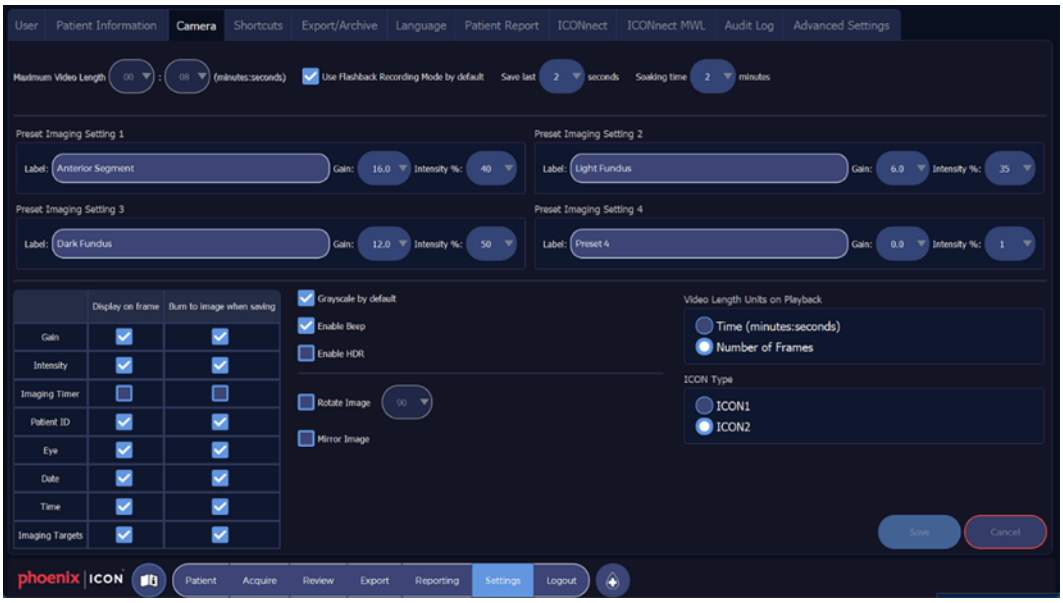
To add a clinic, click the ***Folder*** button under the Clinics field. A new line will appear in which you will type the name of the new Clinic. Press the return on the keyboard to save the entry. Clinics are assigned to Users on the Users tab.

Image Tags:

Image tags make it possible to mark images or studies based on user-defined descriptions. Image tags may be entered in the Settings/Patient Information screen, or dynamically in the Review screen. The list in the Image Tags also populates the selection for the Study Tags. Tags are searchable on the Patient screen as well as on the Export screen.

8.9.3 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.

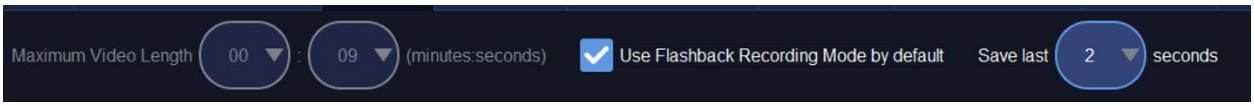


Maximum Video Length

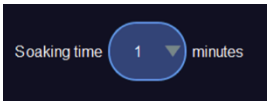
Select the maximum length, in minutes and seconds, of a captured video. Note that each minute of video consumes 4.2 GB of data.

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



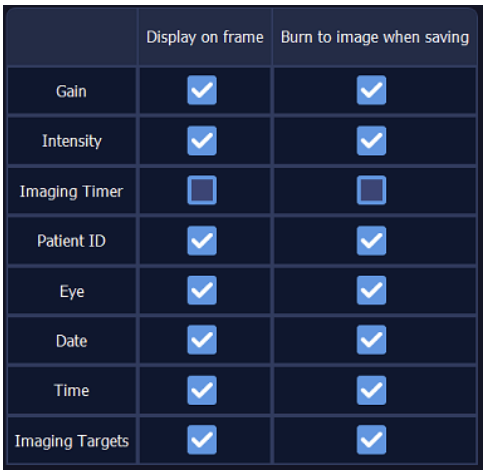
The ICON Software enables easy adherence to infection control policies by providing a ***Soak Timer***. The Soak Timer can be used to time soaking of the ICON camera hand piece in appropriate disinfection solution. An audit log record is written each time the Soak Time is started and stopped that includes the current Username, 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.

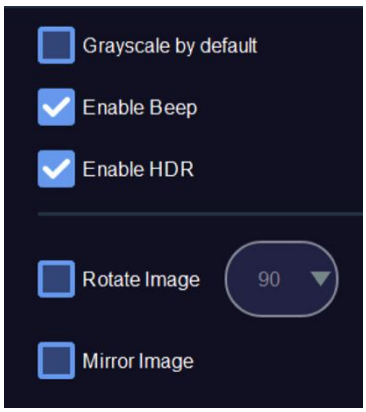
Frame Information Display

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 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 Photo imaging mode.

Enable HDR: Check this box to enable the HDR button on the Acquire Screen. This feature will auto capture 4 images with Gain values of 0, 6, 12 and 24.

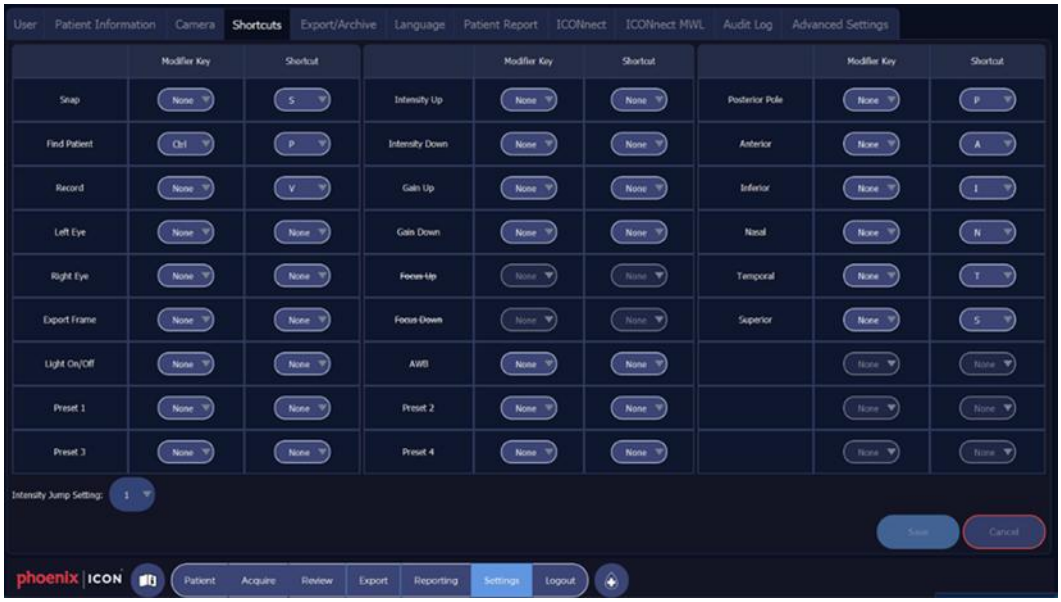
Rotate Image: When using the ICON camera, the expectation is that the operator approaches a supine patient from the top of the head. Thus, the standard orientation of the camera should be so that the hand piece cable comes towards the user at the midline of the patient's forehead. The **Rotate Image**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

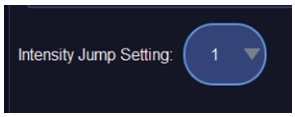
ICON Type sets the version of ICON camera hand piece installed on your system.

8.9.4 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).



8.9.5 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 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.)

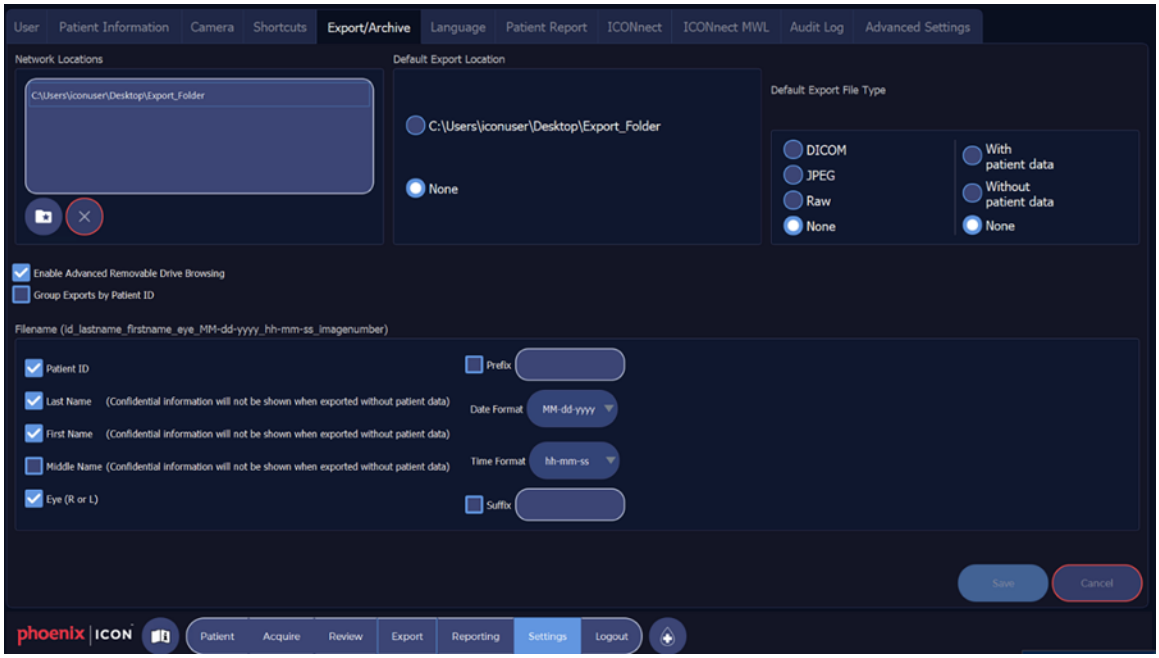
To remove a location from the list of Network Locations, select a location on the list and click the ***X.***

Default Export Locations:

Select from the available options to make a location pre-selected when an Export action is being performed. Choosing None means the user must select a location with every export.

Default File Type:

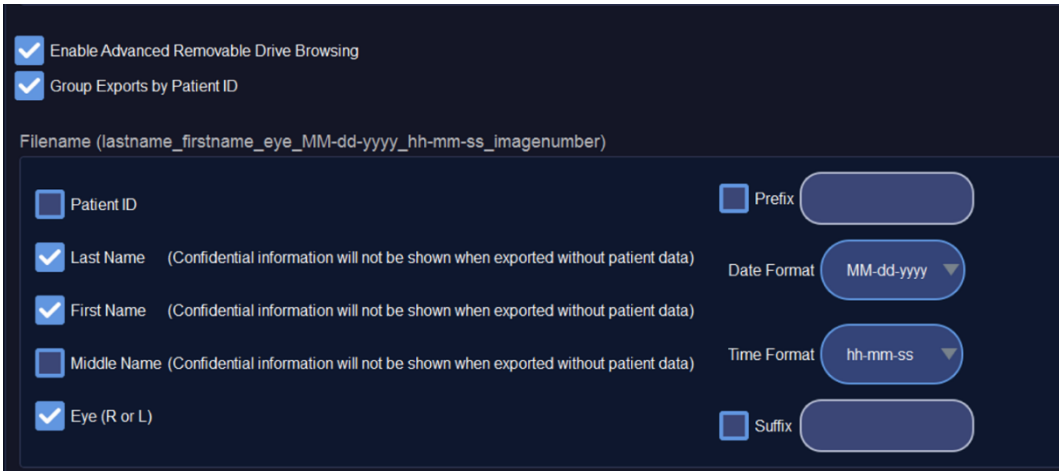
Select from the available options to make a File Type pre-selected when an Export action is being performed. Choosing None means the user must select a file type with every export.



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.

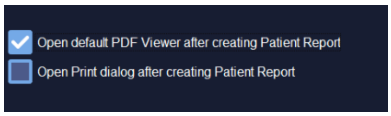


8.9.6 Settings: Language

Users can select a default language for the Graphic User Interface (GUI) from the available options, followed by the default language for the Instructions for Use (IFU) from the Settings screen. The IFU can be reviewed at any time by clicking the IFU button.

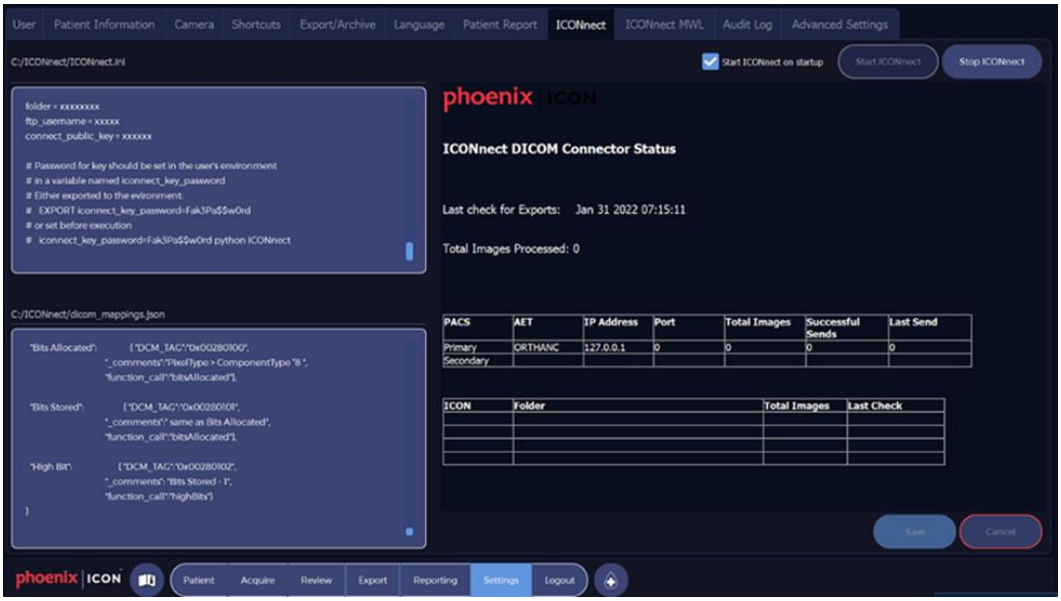
8.9.7 Settings: Patient Report

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.



8.9.8 Settings: ICONnect

ICONnect is the PACS connector that is built into the 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.
- Select the checkbox for “Start ICONnect on startup” to enable this as a default action.
- 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.

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 LLC
- 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

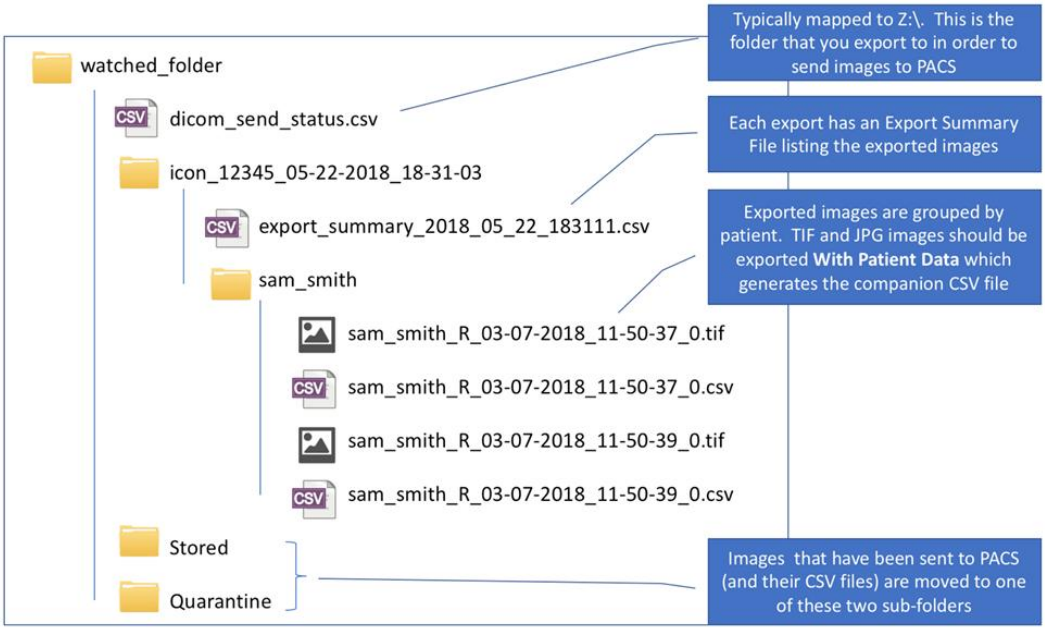
ICONnect Folder Structure

It is useful to understand the structure of the folders that are used by the 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***.



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 will be deleted. This will purge all 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.

ICONnect Settings [General]

This sub-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 running and any files exported to the **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 are 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 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 to 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 to 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 to 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 Technology Group 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 Technology Group OID Name is used (**Phoenix ICON**). This can be overridden with any valid OID name.

ICONnect Settings [ICON_1]

Parameters in this sub-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 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.

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.

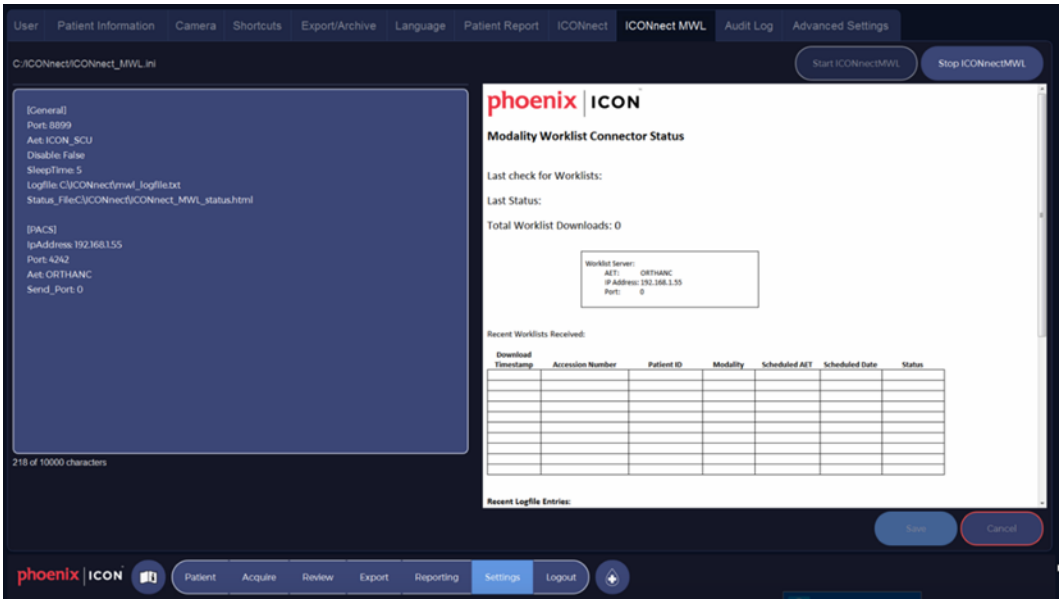
DimseTimeout:	Values: integer seconds This is an optional parameter that sets the DIMSE timeout value. When this parameter is absent, the default value is 30.
AcseTimeout:	Values: integer seconds This is an optional parameter that sets the ACSE timeout value. When this parameter is absent, the default 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 Section

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).

8.9.9 Settings: ICONnect MWL

The 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.

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

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 to the factory default.

ICONnect MWL Settings [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).

ICONnect MWL Settings [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 included 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.

ICONnect MWL Status

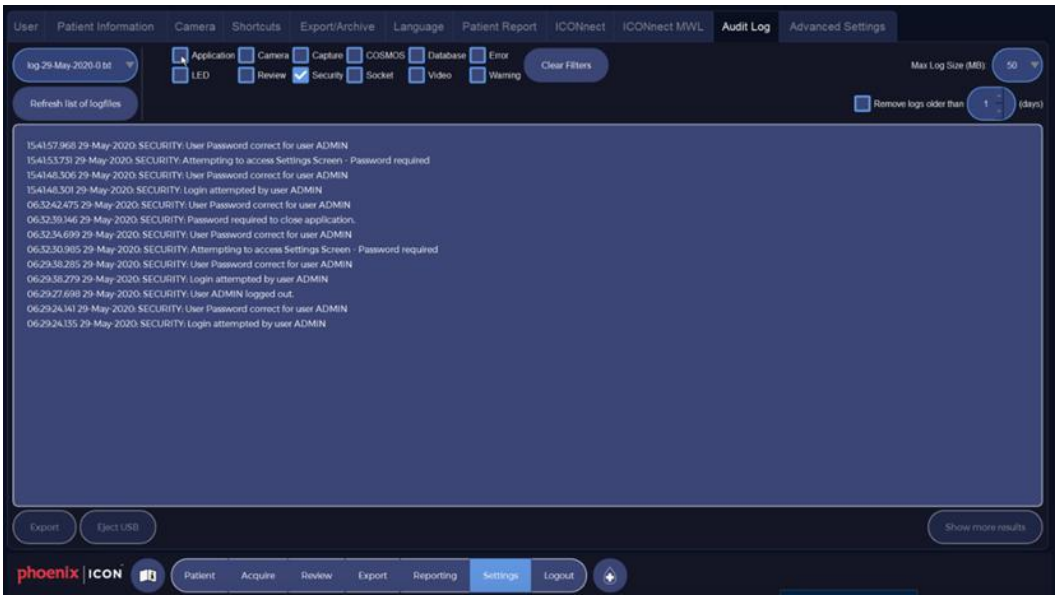
The status screen found in the righthand pane of the settings page for ICONnect MWL provides a frequently updated status view of the ICONnect MWL connector companion application. When displayed, it is updated every 5 seconds and shows:

- **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.

8.9.10 Settings: Audit Log

The 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).

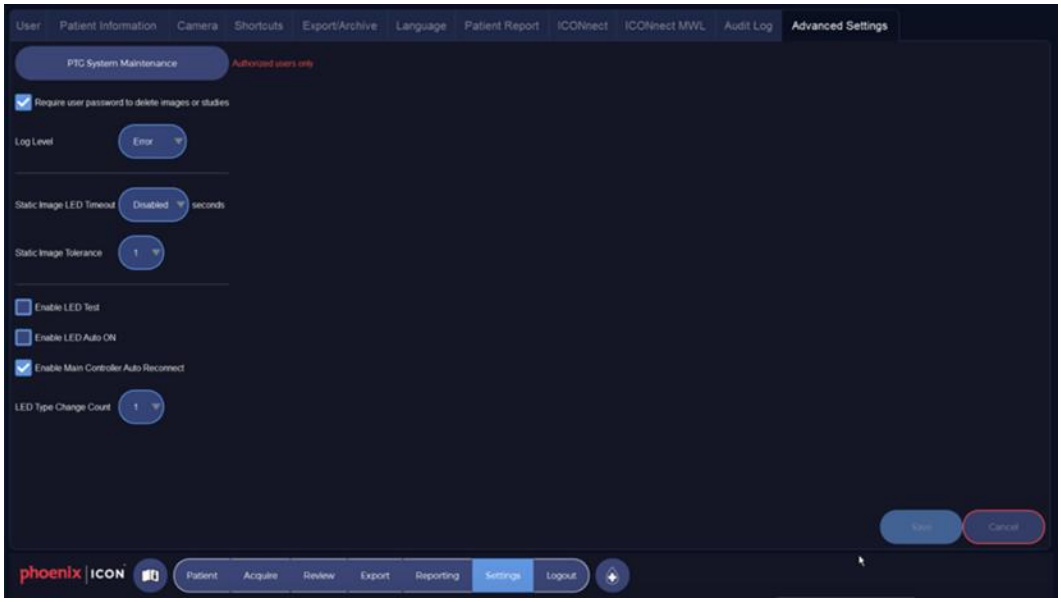
Export Log: Click the ***Export*** button to export the currently displayed log file. Logs are exported to a removable thumb drive for use in analysis by external systems. The operator will be promoted to select a folder for the export. Exported log files are named with the date of export.

Export USB: Click this button to safely eject removable media.

8.9.11 Settings: Advanced Settings

CAUTION:
Only trained and authorized, users should access these settings.

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



The settings available on this tab are described below.

- **Phoenix Technology Group System Maintenance**
  Click Phoenix Technology Group 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
- **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 reports 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.

8.9.12 Accessing Windows for Network and Folder Setup

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 Technology Group began shipping with Windows 10 IoT Enterprise 2019 (non-hardened)
- Beginning with the release of v1.23 of the ICON Software, cart-based ICON cameras ship with a hardened version of Microsoft Windows 10 IoT Enterprise 2019, and the ICON GO camera ships with a hardened version of Windows 10 Pro.

All versions 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.

Accessing Windows in Non-hardened Versions: Phoenix Technology Group System Maintenance

Click Phoenix Technology Group System Maintenance and enter the Administrator password to quit out of the ICON software and access the Windows desktop.

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.

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 Technology Group (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 Technology Group 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.

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.

Operating System Updates

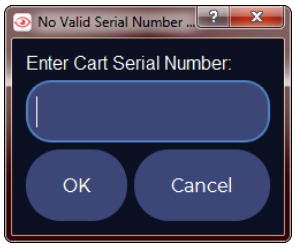
Phoenix Technology Group will monitor Microsoft updates on a regular basis for important and critical security or functional updates to the operating system. When such releases become available, Phoenix

Technology Group 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 Technology Group plans to develop and deploy an update server to simplify the distribution of operating system (and ICON software) updates.

8.9.13 Serial Number

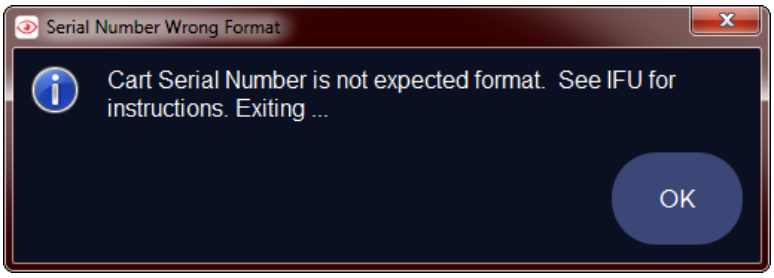
This setting is not within the Settings screen and is used for troubleshooting.

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

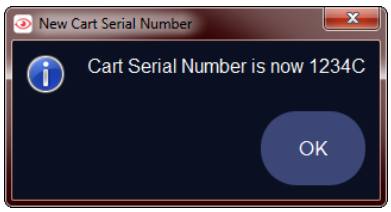


The system does a pattern match for 4 valid numbers in a row followed by either a “C”, “P”, “c”, “p”, or “ “ (a space).

An invalid password will prompt the following message and close the software. To get another chance to enter a valid password, restart the 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.

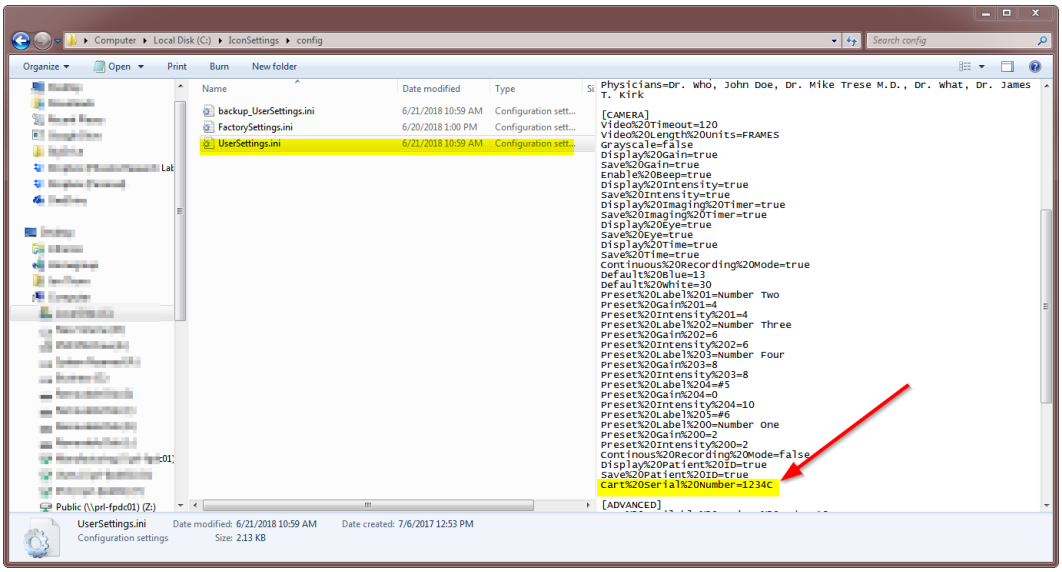


8.9.14 UserSettings.ini

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”):



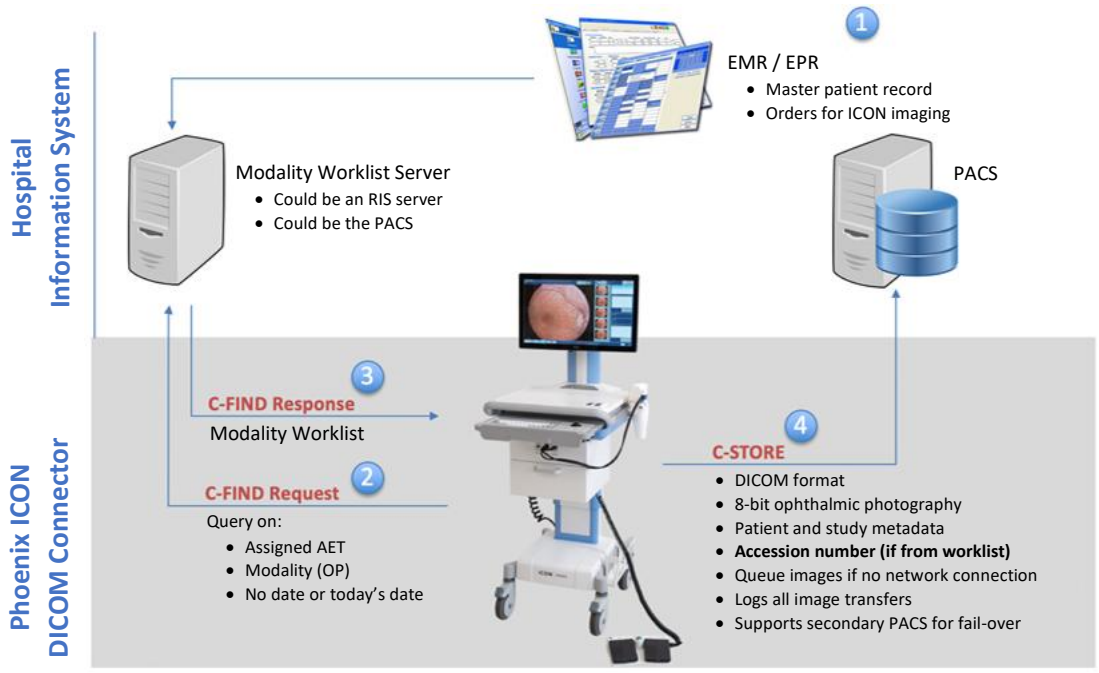
The field can be manually modified from here if needed.

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

8.10 ICONnect and DICOM Setup

8.10.1 Overview and Getting Started

The ICON camera includes built-in features to retrieve a modality worklist from a DICOM-compliant radiology information server (RIS) or photo archive and communication system (PACS). The ICON camera also includes features to export images directly to a DICOM-compliant PACS. In this section we present an overview of the typical modality worklist and PACS workflow and provide details on how to set up these features. Note that downloading a modality worklist and exporting to a PACS can be configured and used separately or together.



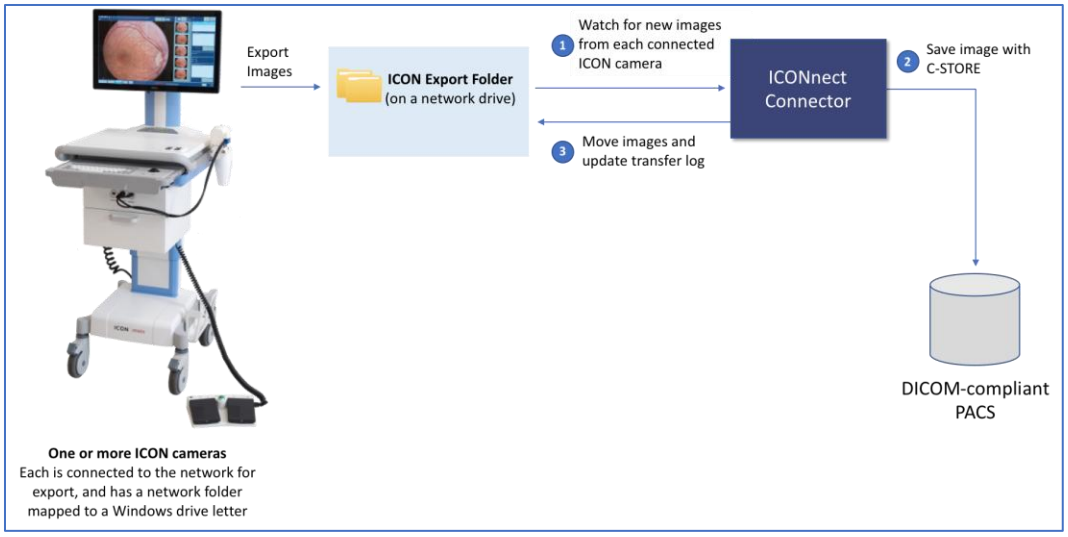
The diagram above describes a typical DICOM integration. In this workflow:

1. An order for imaging is entered into 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.

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.

8.10.2 Setting Up PACS Export

The ICON camera software has the ability to export images to a folder. In addition, the software comes with a built-in DICOM connector that can watch a file folder, and when it sees an export from the ICON software, it retrieves the exported images, packages them, and sends them to a connected PACS. The diagram below shows the basic process:

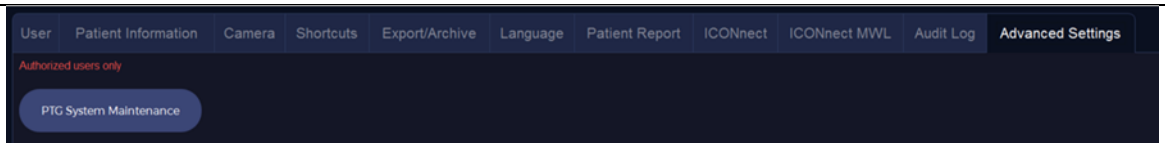


The connector to send images to a PACS is called ICONnect. Settings and the status log for ICONnect can be found on the Settings tab of the ICON software.

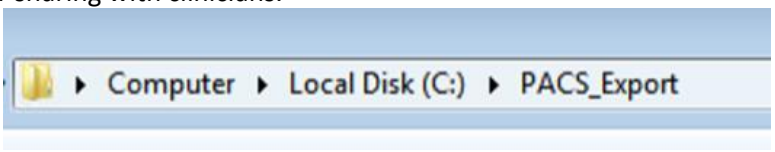
The four setup steps you'll go through are shown at right and presented in more detail in the table below.

Note that there are a number of more advanced settings and parameters that can be used to adjust ICONnect to fit the configuration of your PACS, and those are described later in this manual.

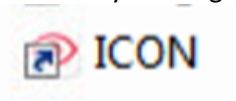
1. To get to the desktop, on the ICON camera
    a. Go to Settings -> Advanced tab
    b. Enter your password (note this requires the Settings permission for your username)
    c. Click "Phoenix Technology Group System Maintenance"



2. Create a folder somewhere on your network that will hold exported images that are being sent to a PACS. We call this the watched folder. This folder will be dedicated to exports that are being sent to a PACS and may be in addition to other folders that you have setup, such as a folder for sharing with clinicians.



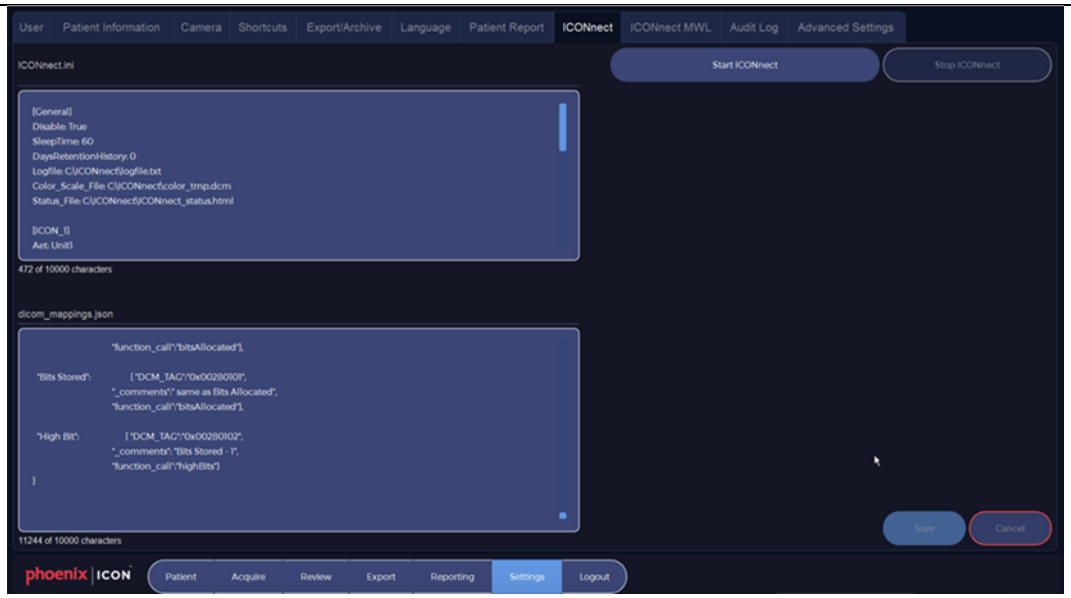
3. You'll need to get this information from your PACS administrator:
    a. The AET name that you should use for the ICON camera
    b. The AET name of your PACS
    c. The IP address of your PACS
    d. The port number of your PACS
4. Restart the ICON software if it's not already running by double-clicking the ICON desktop icon



5. Login to your user account

6. Go to Settings->ICONnect. (You will need to enter your password to access the Settings tabs.)

7. On the left of the screen you will set the settings for ICONnect. On the right-hand side, you will see the status display which refreshes every five seconds and provides information about images sent to the configured PACS



The window provides access to the C:/ICONnect/ICONnect.ini file shown below. Actions required are explained as headers in the body of the file.

[GENERAL]
# Default values for DICOM files which override what is writen in *.dcm file
# if oid_name is not set, the value in the *.dcm file will not be overridden
oid_name = Phoenix ICON
# if valid, the sop_class is used as sop_class_uid
# expected to start with 1.2.840.10008.5.1.4.1.1
sop_class = 1.2.840.10008.5.1.4.1.1.77.1.5.1
modality = OP

location and name of the status file. Must match path in FactorySettings.ini
status_file = C:/ICONnect/ICONnect_status.html

Logging
logfile = C:\ICONnect\iconnect.log
log level is the amount of output produced by logging
log_level = ERROR

Interval time for ICONnect to check defined folders for files to send
sleep_time = 5

files older than days_retention number of days will be deleted. If 0, files will never be deleted
WARNING: Do not use shared folders as ALL files in the target folder will be checked and deleted
days_retention = 0

Other required settings for FTP transfer

7zip_location =
connect_public_key =

----
at the defined sleep_time interval, ICONect will check for files in the location defined by 'folder'
and send them to the defined Server or CONNECT FTP site
For each [PACS<NAME>] entry, the following settings are required:
pacs_aet, ip_address, pacs_port, sending_aet, folder

[PACS_1]
Server
pacs_aet =
ip_address =
pacs_port = 4242
Client
sending_aet = ICON_SCU
folder = C:\Users\iconuser\Desktop\Export_Folder

Defines a port from which ICONnect sends to the PACs system.
send_port = 0
Note: in this release, only *.dcm is supported
extensions_to_send = *.dcm
# Note: transfer_syntax must be one of the following:
# ExplicitVRLittleEndian, ImplicitVRLittleEndian, DeflatedExplicitVRLittleEndian, ExplicitVRBigEndian
transfer_syntax = ExplicitVRLittleEndian

[PACS_2]
Server
pacs_aet =
ip_address =
pacs_port =
# Client
sending_aet = ICON_SCU
folder = C:\Users\iconuser\Desktop\Export_Folder

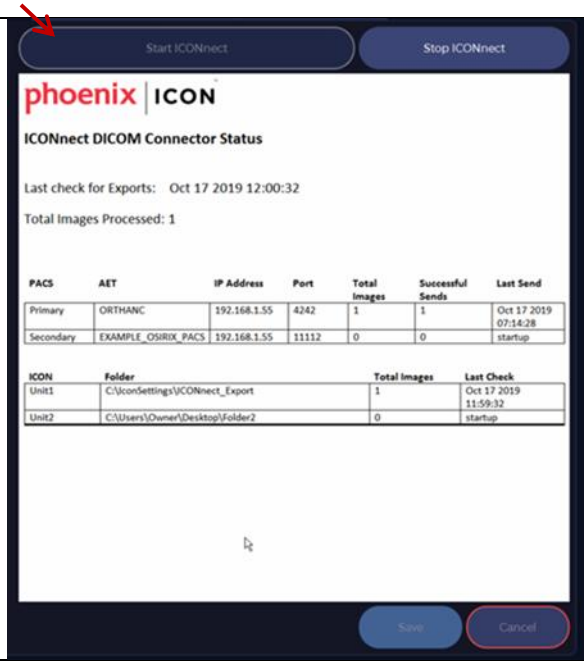
Defines a port from which ICONnect sends to the PACs system
send_port = 0
Note: in this release, only *.dcm is supported
extensions_to_send = *.dcm
# Note: transfer_syntax must be one of the following:
# ExplicitVRLittleEndian, ImplicitVRLittleEndian, DeflatedExplicitVRLittleEndian, ExplicitVRBigEndian
transfer_syntax = ExplicitVRLittleEndian

For each [CONNECT_CLINIC<NAME>] entry, the following settings are required:

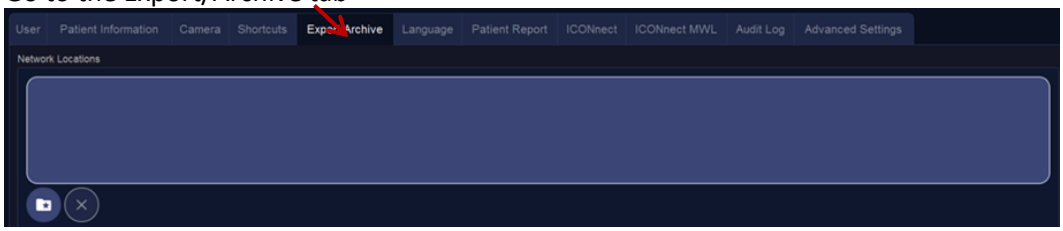
```
# ftp_url, connect_public_key, ftp_username, folder
[CONNECT_CLINIC_1]
# ftp_url shouldn't have the protocol on the string
# Original              Value
# ftp://client.example.org -> client.example.org
ftp_url = xxxxx.xxxxx.xxx
folder = xxxxxxxx
ftp_username = xxxxx
connect_public_key = xxxxxx

# Password for key should be set in the user's environment
# in a variable named iconnect_key_password
# Either exported to the evironment:
#   EXPORT iconnect_key_password=Fak3Pa$$w0rd
# or set before execution
#   iconnect_key_password=Fak3Pa$$w0rd python ICONnect
```

8. Once entries have been added for your configuration, Click Save

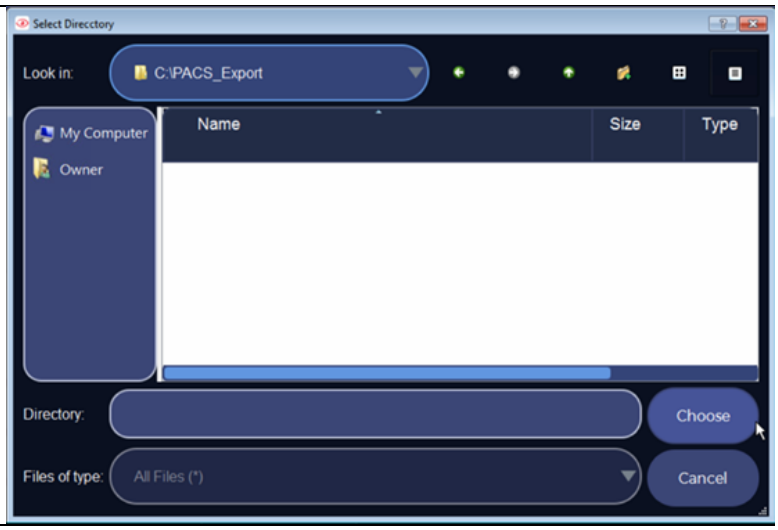
9. Click Start ICONnect



10. Go to the Export/Archive tab

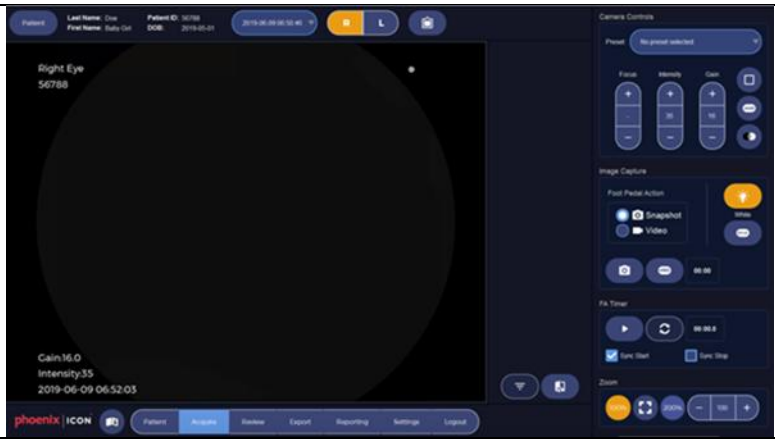


11. Add the PACS export folder to the list of valid export destinations

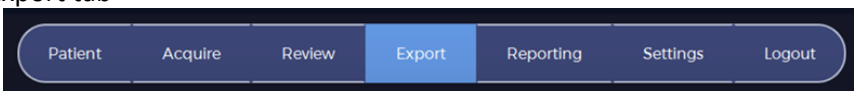


12. Click Save

13. Now select a test patient, or create a test patient and capture some test images into a test study.



14. Go to the Export tab

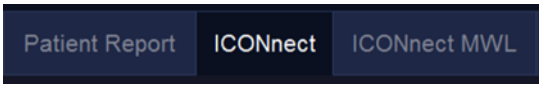


15. Select one or more images to send to the PACS:

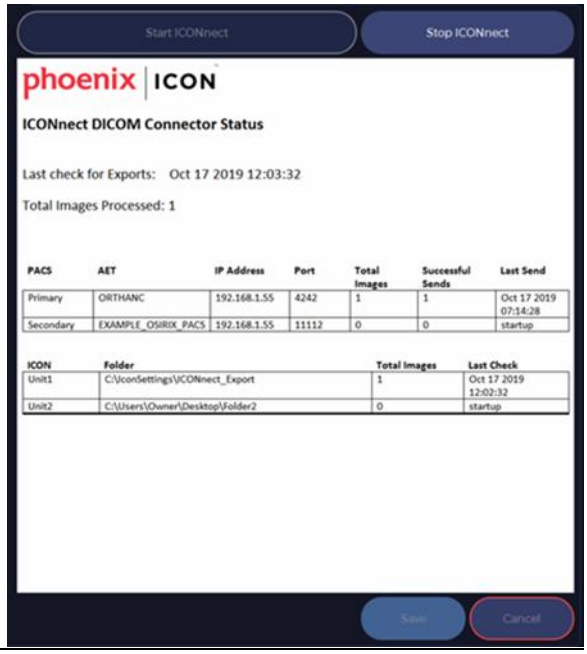
    a. Select the image(s)
    b. Select DICOM as the image format
    c. Select the PACS export folder
    d. Click Export
    e. Click OK

This will stage the images in a folder, and if things are setup correctly, the ICONnect DICOM connector will see the images and send them to the PACS.

16. Go to Settings -> ICONnect



17. Observe the status page to confirm that the images were sent to PACS



18. Ask your PACS administrator to confirm that the images were properly received by the PACS

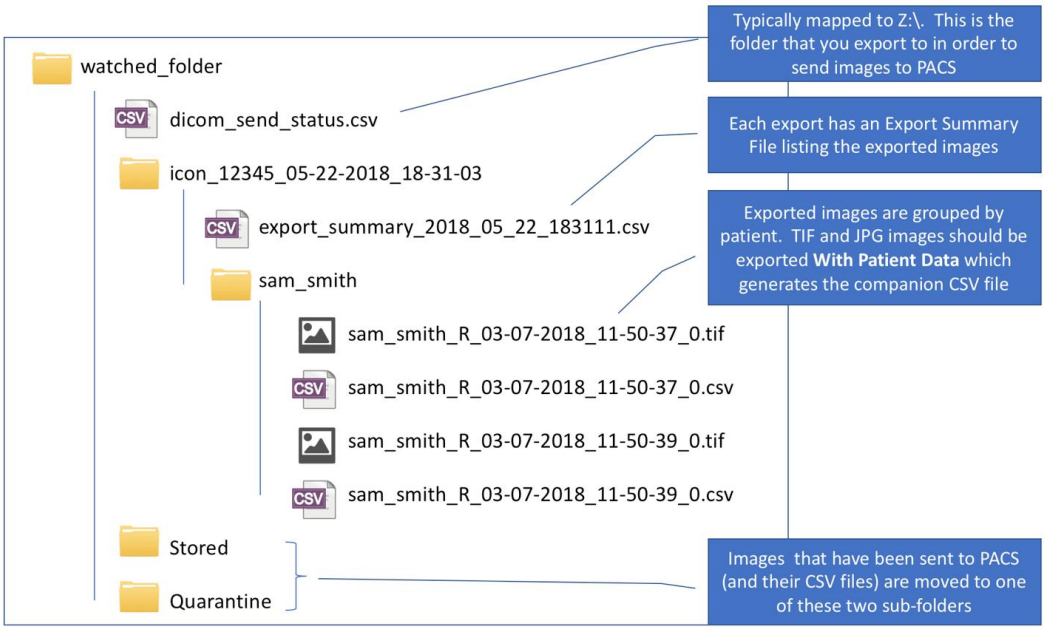
PACS Export Folder Structure

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

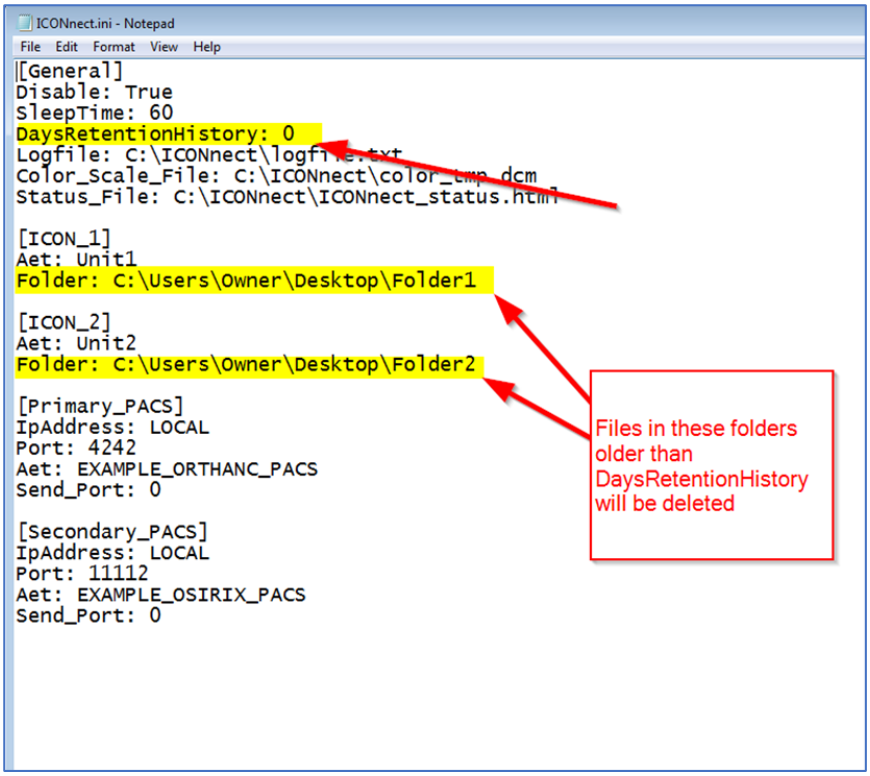
In the *iconnect.ini* file, you setup the pathname to the folder that will receive image exports. We call this the watched folder. This folder is mapped to a drive letter on the ICON system to make it easy to access. In the ICON software, you setup this folder as one of the targets for exports.

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.

When you export images to the watched folder, you'll see a folder structure like this (note the structure may be different if you have turned off "group by patient ID" in settings):



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.



PACS Export: Forming UIDs

The ICON camera software exports images in three formats: DICOM (.dcm), JPEG (.jpg) and Raw (.tif). When images are exported in DICOM format the UIDs for study, series, and image are built by the ICON camera software. When images are exported in JPEG or Raw, ICONnect uses the data in the CSV file to form the UIDs. Both software applications use the following scheme when creating UIDs:

- 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 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 Cart Serial Number from the ICON camera software, plus
    - Study ID generated by the ICON camera software
- Series Instance UID:
    - Study Instance UID, plus
    - '.1'
- SOP Instance UID:
    - Series Instance UID, plus
    - Image ID generated by the ICON camera software
- Instance ID:
    - Station ID from the ICON camera software, plus
    - Study ID generated by the ICON camera software

PACS Export: Additional Configuration File Details

Several behaviors of the ICONnect connector are controlled by the configuration file, named ***iconnect.ini***. The configuration file is monitored for changes and reloaded whenever the modified date on the file is more recent than the last time it was read. Details of each configuration setting are presented in the following table.

General Settings that control the overall behavior of the ICONnect connector

SleepTime	The number of seconds to sleep after checking and/or processing available exports
Logfile	Pathname to the logfile. If not present, logging will only be to the Console (stdout)
Color_Scale_File	Pathname to the "color scale file". This file is used as the base file to form DICOM files that are sent to the PACS. This file comes with the ICONnect installation and should always be present.
SOP_Class	Override the SOP class of the images that are sent. 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
OID	The organization UID that is used as the base for all UIDs generated for studies, series, and instances. The default, provided in the standard .ini file, is Phoenix's OID.
OID_Name	This is the OID Name used for all submitted images. The default provided in the standard .ini file is Phoenix's OID Name.

ICON_n Setup for one ICON that is being monitored for exports to be sent to a PACS. "n" is an integer, as in PACS_1, PACS_2, etc.

Aet	The entity name of the ICON
Folder	The folder that ICON is exporting to

Primary_PACS Settings associated with connecting to a PACS. There are two related sections: Primary_PACS and Secondary_PACS. Primary_PACS is the first PACS that is pinged when there are images to send.

IpAddress	IP address of the PACS. When the address set to LOCAL the connector will look for the PACS on the same computer as the connector. This is useful for testing.
Port	Port of the PACS
Aet	AET for the PACS (the SCP in the association)
DimseTimeout	The DICOM Message Service Element timeout. The default is 30
AcseTimeout	The Association Control Service Entity timeout. The default is 60
NetworkTimeout	The network communications timeout. The default is 60.

Secondary_PACS Settings for an optional secondary PACS. Same format as Primary_PACS.

DICOM_Map

For JPEG and Raw (TIFF) images, the patient and study metadata is present in a companion CSV file. Those metadata fields are mapped to DICOM fields. This section in the configuration file allows you to change the default mapping. The configuration fields and default mappings are listed below.

ID	0x00100020
MRN	0x00101000
Date of Birth	0x00100030 # 'PatientBirthDate'
Ethnicity	0x00102160 # 'EthnicGroup'
Weight (grams)	0x00101030 # 'PatientWeight'
Optional Age	0x00101010 # 'PatientAge'
Institution Name	0x00080080 # 'InstitutionName'
Primary Physician	0x00081048 # 'PhysiciansOfRecord'
Referring Physician	0x00080090 # 'ReferringPhysicianName'
Pathology Notes	0x00081080 # 'AdmittingDiagnosesDescription'
Patient Notes	0x00104000 # 'PatientComments'
Station ID	0x00081010 # 'StationName'
Cart Serial Number	0x00181000 # 'DeviceSerialNumber'
Study Date	0x00080020 # 'StudyDate'
Study Time	0x00080030 # 'StudyTime'
Study Notes	0x00324000 # 'StudyComments'
Image Date	0x00080022 # 'AcquisitionDate'
Image Time	0x00080032 # 'AcquisitionTime'
Image Notes	0x00204000 # 'ImageComments'
Eye	0x00200062 # 'ImageLaterality'
Sex	0x00100040 # 'PatientSex'

Configuring Modality Worklists

The ICON® camera software includes a DICOM connector to retrieve a modality worklist from a DICOM-compliant PACS or RIS.

The modality worklist connector is referred to as ICONnect MWL. The steps below will guide you through the setup of a connection to retrieve modality worklists over a DICOM connection.

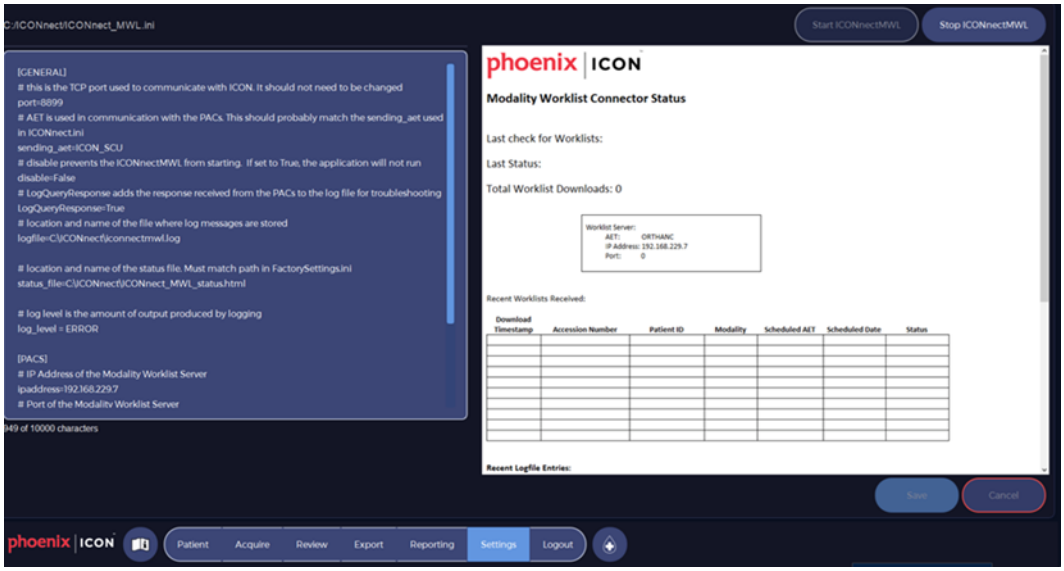
1. Collect the following information from your RIS / PACS administrator:
    a. AET of the RIS/PACS server that will be providing modality worklists
    b. IP address of the RIS/PACS
    c. Port number of the RIS/PACS
    d. AET assigned to this ICON
    e. The modality (such as OP) that will identify the worklist entries that will be retrieved
    f. Whether the worklist will be assigned to a specific AET

2. Login to the ICON software using a username with permission to adjust the software settings

3. Go to Settings -> ICONnect MWL. (You will be required to reenter your password.)

On the left of the screen you will see the settings for the ICONnect MWL connector. This is a portal to the .ini file.

On the right you will see the status page for the ICONnect MWL connector. This is updated every 5 seconds and includes a list of the last 10 worklist steps retrieved from the worklist server, a summary of the configuration parameters, and the most recent entries from the connector's logfile.



Chapter 9: Accessories and Replacement Parts

Please contact Phoenix Technology Group LLC Customer Service for any replacements and parts needed. The following parts are critical components to the efficacy and safety of our products and must be replaced as directed.

The Phoenix ICON GO (Model Number: PCI 40-2001) comprise of the following replaceable components:

Part Name	Catalog Number	Recommended Replacement Time
White Light Module	PCI 40-1005	Replace when damaged and unusable
Blue Light Module	PCI 40-1004	
ICON Handpiece	PCI 40-1002	
ICON Diffuser	PCI 40-1017	
Foot Switch	PCI 30-1000	
ICON GO Control Box	PCI 40-1030	
FUSE, 2.5A/125v (233 series)	PCI 30-1186	
External USB-C Hub	PCI 30-2018	
Li-ion Battery Pack	PCI 30-1162	
Microsoft Surface Book	PCI 30-1161	
Lenovo ThinkPad L15	PCI 30-2015	
Lenovo ThinkPad E15	PCI 30-2016	
Dell Precision 5680	PCI 30-2017	
Dell Precision 3581	PCI 30-2019	
Camera Holster Assembly Kit	PCI 40-1046	
ICON GO Wheeled Hard Case	PCI 50-1125	
ICON GO Slim Laptop Backpack	PCI 50-1143	
Battery charger is the model RRC-SMB-MBC	NA	Replace when damaged and unusable. Buy directly from the vendor [Link]
60 ml replacement soaking cups	NA	Replace when damaged and unusable. Buy directly from the vendor Starplex Scientific Model#: B602L [Link]
90 ml replacement soaking cups	NA	Replace when damaged and unusable. Buy directly from the vendor Starplex Scientific Model#: B902L [Link]

The use of non- Phoenix Technology Group LLC accessories with the ICON GO may reduce treatment efficacy. Phoenix Technology Group LLC declines all responsibility for any damage or consequences resulting in using unauthorized parts with our ICON GO.

WARNING!
The use of accessories, replacement parts, or power cords other than those specified by the manufacturer may affect the unit's performance. It could damage the unit or unsafe conditions for the patient and the operator

Chapter 10: Warranty

Phoenix Technology Group, LLC. warrants your ICON GO 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 of 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 ICON GO System 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 ICON GO System.

If warranty problems arise, or if you need assistance in using your 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.

Chapter 11: Customer Service:

Don't hesitate to get in touch with Customer Service if you need assistance setting up, using, or maintaining your PHOENIX ICON GO or to report any unexpected operation or events. Phoenix Technology Group LLC Customer Service can be reached at:

support@theNeoLight.com

Customer Support: + 1-866-934-8945 x 1
Technical Support: + 1-866-934-8945 x 3

When returning any products, please include your name, address, phone number, and Return Material Authorization (RMA) number provided by Customer Service. All product returns should be mailed to:

Phoenix Technology Group LLC
6630 Owens Dr,
Pleasanton, CA 94588

Chapter 12: Patent and Trademark Information

This product is covered by one or more of the following patents:

- U.S. Patent No. 9,622,657 | 9,872,618 | 10,244,943 | 10,893,803
- Canada Patent No. 2960501
- European Patent No. 3127475
- Japanese Patent No. JP7075178

Additional patents may be pending in the U.S. and elsewhere. For more information about these patents, please contact the Phoenix Technology Group LLC.

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