Phoenix ICON Instructions for Use

IFU ROW English (Finnish)
OPL-0016_E

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

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User Responsibility

The Phoenix ICON 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

IMPORTANT	Notice for European Union only: Any serious incident that has occurred in relation to the device should be reported to PTG and the competent authority of the Member State in which the user and/or patient is established.

Käyttäjän vastuu

Phoenix ICON -laite toimii käyttöohjeissa, huolto-oppaassa ja mukana toimitettavissa etiketeissä ja/tai käyttöoppaissa olevan kuvauksen mukaisesti, kun se kootaan ja kun sitä käytetään, huolletaan ja korjataan annettujen ohjeiden mukaisesti. Tämä tuote on tarkistettava säännöllisesti. Viallista tuotetta ei saa käyttää. Rikkoutuneet, puuttuvat, selvästi kuluneet, vääristyneet tai saastuneet osat on vaihdettava välittömästi. Jos tällainen korjaus tai vaihto on tarpeen, Phoenix Technology Group suosittelee tekemään huoltopyynnön ottamalla yhteyttä asiakaspalveluun. Tätä tuotetta tai sen osia ei saa korjata muuten kuin Phoenix Technology Groupin antamien kirjallisten ohjeiden mukaisesti ja Phoenix Technology Groupin kouluttaman henkilöstön toimesta. Tuotetta ei saa muuttaa ilman Phoenix Technology Groupin etukäteen antamaa kirjallista lupaa. Phoenix Technology Group ei ole vastuussa

vahingoista tai seurauksista, jotka johtuvat luvattomista yrityksistä avata, muokata tai korjata laitetta. Tämä tuotteen luvaton huolto mitätöi myös takuun.

Tämän tuotteen käyttäjä on yksin vastuussa kaikista toimintahäiriöistä, jotka johtuvat virheellisestä käytöstä, virheellisestä kunnossapidosta, virheellisestä korjauksesta, vahingoittumisesta tai jonkun muun kuin Phoenix Technology Groupin tekemistä muutoksista. Käyttäjä vastaa myös siitä, että hänen tarkastelemansa käyttöoppaan versio on ajan tasalla ja että ohjeita ja vaatimuksia noudatetaan.

℞	**HUOMIO:** Yhdysvaltojen lakien rajoitusten mukaan tämän laitteen myynti on sallittua vain lisensoidun lääkärin toimesta tai määräyksestä.

TÄRKEÄÄ!	Vain Euroopan unionia koskeva huomautus: Mahdollisista laitteeseen liittyvistä vakavista vaaratilanteista on ilmoitettava PTG:lle ja käyttäjän ja/tai potilaan oman jäsenvaltion toimivaltaiselle viranomaiselle.

Chapter 1: About Phoenix ICON

1.1 Indications for Use

The Phoenix ICON 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.

Luku 1: Tietoa Phoenix ICON -järjestelmästä

1.1 Käyttöaiheet

Phoenix Technology Group LLC:n valmistama Phoenix ICON -kärryjärjestelmä on tarkoitettu silmän, erityisesti verkkokalvon, sarveiskalvon ja silmän ulkoisten rakenteiden, yleiseen kuvantamiseen. Laite on hyväksytty käytettäväksi eri ikäryhmiä edustaville lapsille ja aikuisille:

- Aikuiset
- Lapset:
    - Vastasyntyneet: syntynyt enintään 28 päivää sitten
    - Pikkulapset: 29 päivän – 2 vuoden ikäiset
    - Lapset: 2–12-vuotiaat
    - Nuoret: 12–18-vuotiaat
    - Siirtymävaiheen nuoret A: 18–21-vuotiaat
    - Siirtymävaiheen nuoret B: 18–21-vuotiaat.

1.2 Intended Users

The Phoenix ICON System should only be operated by health care providers or others designated by health care providers who are trained in its operation and familiar with the risks of this type of device.

1.2 Tarkoitetut käyttäjät

Phoenix ICON -järjestelmää saavat käyttää vain terveydenhuoltopalveluiden tarjoajat tai muut terveydenhuoltopalveluiden tarjoajien nimeämät henkilöt, jotka on koulutettu kärryn käyttöön ja jotka tuntevat tämäntyyppisen laitteen riskit.

1.3 Product Description

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

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

The system runs on Windows 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.

1.3 Tuotekuvaus

Phoenix ICON -järjestelmässä on optiikkaa, joka on suunniteltu ottamaan kuvia ja videoita verkkokalvosta, sarveiskalvosta ja silmän ulkoisesta rakenteesta kosketusmenetelmien avulla. Tallennetut mediat voidaan tallentaa ja viedä.

Phoenix ICON -järjestelmä koostuu käsikappaleessa olevasta kamerasta, joka käyttää pienitehoista valodiodivalonlähdettä (LED) valaisemaan verkkokalvoa. Kamera hyödyntää uusinta herkkää CMOS-anturiteknologiaa, joka mahdollistaa heikot valotasot, mikä vähentää herkkiin potilaisiin kohdistuvaa stressiä.

Käsikappaleessa on kaksi irrotettavaa valomoduulia. Toinen on valkoisen valon moduuli yleiseen värikuvantamiseen, toinen on sinisen valon moduuli fluoreseiiniangiografiaan. Estosuodatin siirretään paikalleen käsikappaleen vivulla käytettävän valomoduulin mukaan.

Kevyessä, helposti siirrettävässä kärryssä on moottoroidut Ylös-/Alas-ohjaimet ja neljä lukittavaa rullapyörää. Kärryssä on tietokone, näppäimistö, tarkennus-/valaistusnäppäimistö, ohjauspallohiiri, kosketusnäyttö, valaistuksen ohjauslaatikko ja akun varmuuskopiointi järjestelmän siirrettävyyden ylläpitämiseksi. Ohjauslaatikossa on jalkakytkin, jota käytetään valaistuksen muokkaamiseen ja kuvan tarkentamiseen.

Järjestelmä toimii Windows 10 IoT Enterprise -käyttöjärjestelmällä. Vahvemmat kiristys- ja haittaohjelmien torjuntatyökalut sekä kyberturvallisuustyökalut ovat osa Windows IoT Enterprisea mahdollisten tulevien uhkien torjumiseksi. Lisäksi käyttäjät ja järjestelmänvalvojat voivat saada salasanalla suojatut salatut kirjautumistiedot ja tietokannan, mukaan lukien kaikki potilas- ja käyttäjätiedot sekä kaikki kuvien liittämiset tiettyyn potilaaseen.

1.4 Essential Performance

The Phoenix ICON 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 Phoenix ICON system is 5 years

1.4 Olennainen suorituskyky

Phoenix ICON tarjoaa mahdollisuuden visualisoida ja ottaa kuvia sekä viedä/poimia kuvia verkkokalvosta, sarveiskalvosta ja silmän ulkoisista rakenteista kosketusmenetelmien avulla.

HUOMAA	Phoenix ICON -järjestelmän käyttöikä on viisi vuotta.

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
	TUV Rheinland (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.
	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 Phoenix ICON System
NOTE	Background information provided to clarify a particular step or procedure. Information in this category is not considered precautionary

Luku 2: Turvallisuustiedot

2.1 Symbolit

Seuraavia symboleja käytetään näissä käyttöohjeissa, laitteen pakkauksessa, laitteessa ja lisävarusteiden merkinnöissä.

Symboli	Kuvaus
#	Viitenumero; osanumero
REF	Luettelotunniste
LOT	Eränumero

	Sarjanumero
	Valmistuspäivämäärä
	Laillisen valmistajan nimi
	Valmistusmaa
	Noudata käyttöohjeita.
	Vain lääkemääräyksellä (Yhdysvallat)
	Tämä tuote on luokiteltu lääkinnälliseksi laitteeksi Euroopan yhteisössä / Euroopan unionissa.
	Vaihtovirta
	Valtuutettu edustaja Euroopassa
	TÜV Rheinland (kolmannen osapuolen sähköturvallisuutta ja EMC-vaatimustenmukaisuutta testaava yritys)
	Särkyvä
	Tämä käyttöopas on käännetty englannista.
	Tuote sisältää sähkölaitteita. Siksi käyttäjät eivät saa hävittää tätä tuotetta muun kotitalousjätteen mukana.
	Tyypin B käytetyt osat
	**HUOMIO**-lausekkeen ohessa käytettävä symboli, joka varoittaa käyttäjää tärkeistä tiedoista

	**VAROITUS**-merkinnän ohessa käytettävä symboli, joka varoittaa käyttäjää tärkeistä tiedoista
IPX6	Älä altista pölylle. Mistä tahansa suunnasta jalkakytkimen koteloon voimakkaasti suihkutetulla vedellä ei ole haitallisia vaikutuksia.
	Pidä laite poissa auringonvalosta.
	Pidä laite kuivana.
	Vakavan sähköiskun tai palovamman vaara
	Epästeriili
	Katso käyttöopas/esite.
UDI	Unique Device Identifier
M.E.E	Medical Electrical Equipment (lääketieteellinen sähkölaite)
VAROITUS	**VAROITUS**-lauseketta käytetään, kun loukkaantumisen mahdollisuus on olemassa.
HUOMIO	**HUOMIO**-lauseketta käytetään, kun laitteen vaurioitumisen mahdollisuus on olemassa.
TÄRKEÄÄ!	Ohjeet, jotka auttavat varmistamaan oikeat kliiniset tulokset ja takaamaan Phoenix ICON -järjestelmän käytön laadun.
HUOMAA	Tietyn vaiheen tai menettelyn selventämiseksi toimitetut taustatiedot. Tämän luokan tietoja ei pidetä varotoimenpiteinä.

2.2 Warnings and Cautions

Before using the Phoenix ICON 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 Phoenix ICON 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 Phoenix ICON is disconnected and turned off prior to making any repairs or performing any maintenance procedures.

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 10 *min* 19 *sec*.** This product is designed with an internal timer which stops light emissions after 10 minutes. After the system shuts off the light, repeat use of the device on the same eye may increase the risk of retinal injury to some patients and is not recommended.

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 62 *min* 3 *sec*.** This product is designed with an internal timer which stops light emissions after 10 minutes. After the system shuts off the light, repeat use of the device on the same eye may increase the risk of retinal injury to some patients and is not recommended.

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. 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 Phoenix ICON is designed, tested, validated and verified as a medical device. Modifications and substitutions to the device are prohibited.

CAUTION:
The Phoenix ICON 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 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 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 Phoenix ICON other than those specified by Phoenix Technology Group LLC may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT

CAUTION:
None of the Phoenix ICON 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 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:
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 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.

2.2 Varoitukset ja varotoimet

Lue koko tämä käyttöopas ennen kuin käytät Phoenix ICON -järjestelmää. Kuten kaikkien kliinisten laitteiden kohdalla, jos tätä laitetta yritetään käyttää tuntematta perusteellisesti sen toimintaa ja tarkoitusta, se voi tehdä laitteesta tehottoman tai vahingoittaa potilasta. Tätä laitetta saa käyttää vain henkilöstö, joka on perehtynyt tämäntyyppisen laitteen riskeihin ja hyötyihin. Lisävarotoimet on lueteltu tämän käyttöoppaan tekstissä. Jos Phoenix ICON -järjestelmä tai jokin sen lisävarusteista vioittuu tai vahingoittuu, valmistajan tai sen valtuutetun huoltoedustajan on korjattava tai vaihdettava ne. Kaikki luvattomat korjaukset tai peukaloinnit mitätöivät sovellettavat takuut. Älä käytä lisävarusteita, joita valmistaja ei ole toimittanut. Varmista aina, että Phoenix ICON irrotetaan ja kytketään pois päältä ennen korjausten tai kunnossapitotoimenpiteiden suorittamista.

HUOMIO:
Tämän laitteen lähettämä valkoinen valo voi olla vaarallista. Mitä pidempi altistuksen kesto on, sitä suurempi on silmävaurion riski. **Valkoiselle valolle altistuminen tästä laitteesta, kun sitä käytetään enimmäisvoimakkuudella, ylittää suositellun enimmäisaltistuksen 2,2 J/cm2 62 minuutin ja 3 sekunnin kuluttua, ellei käyttäjä ryhdy lisätoimiin altistumisen minimoimiseksi**. Verkkokalvon vaurion riski 2,2 J/cm2:n altistustasolla ei ole suuri, mutta koska jotkin potilaat voivat olla muita alttiimpia vammoille, tämän säteilyaltistusarvon ylittämisessä on noudatettava varovaisuutta. Yli 10 J/cm2:n altistustasolla vamman riski on kuitenkin merkittävä, joten yli **282 minuuttia ja 3 sekuntia** kestävää altistusta tulee välttää.

HUOMIO:
Tämän laitteen lähettämä sininen valo voi olla vaarallista. Mitä pidempi altistuksen kesto on, sitä suurempi on silmävaurion riski. **Siniselle valolle altistuminen tästä laitteesta, kun sitä käytetään enimmäisvoimakkuudella, ylittää suositellun enimmäisaltistuksen 2,2 J/cm² 10 minuutin ja 19 sekunnin kuluttua, ellei käyttäjä ryhdy lisätoimiin altistumisen minimoimiseksi**. Verkkokalvon vaurion riski 2,2 J/cm2:n altistustasolla ei ole suuri, mutta koska jotkin potilaat voivat olla muita alttiimpia vammoille, tämän säteilyaltistusarvon ylittämisessä on noudatettava varovaisuutta. Yli 10 J/cm2:n altistustasolla vamman riski on kuitenkin merkittävä, joten yli **46 minuuttia ja 54 sekuntia** kestävää altistusta tulee välttää.

VAROITUS:
Kuvantamismenettelyn alussa ja lopussa kameran käsikappaleen kärki on puhdistettava ja desinfioitava kunnossapitomenettelyn mukaisesti. Varmista alkoholin ja muiden desinfiointiaineiden käytön takia, että linssin kärki on HUUHDELTU steriilillä tai tislatulla vedellä sarveiskalvon vaurioiden välttämiseksi.

VAROITUS:
sähköiskun vaaran välttämiseksi akkulaturin ja kannettavan tietokoneen saa kytkeä vain suojamaadoituksella varustettuun vaihtovirtajohtoon.

HUOMIO:
Phoenix Technology Group LLC ei suosittele minkään muun kolmannen osapuolen ohjelmiston lataamista toimitetulle tietokoneelle eikä ole vastuussa ohjelmiston suorituskyvystä, jos kolmannen osapuolen ohjelmisto on ladattu. Luvattoman ohjelmiston asentaminen mitätöi takuun.

HUOMIO:
Phoenix ICON on suunniteltu, testattu, validoitu ja vahvistettu lääkinnälliseksi laitteeksi. Laitteen muutokset ja korvaamiset ovat kiellettyjä.

HUOMIO:
Phoenix ICON -järjestelmää ei saa altistaa sähkömagneettisille tai muille häiriöille, jotka ovat suurempia kuin standardissa IEC 60601-1-2 määritellyt tasot.

HUOMIO
Kannettava ja mobiili radiotaajuusviestintä voi vaikuttaa ICON-kärryjärjestelmään.

HUOMIO
Kun tätä laitetta käytetään muiden laitteiden ympärillä, on oltava varovainen, jotta vältetään keskinäiset häiriöt. Mahdollisia sähkömagneettisia tai muita häiriöitä voi esiintyä tälle tai muille laitteille. Yritä minimoida nämä häiriöt olemalla käyttämättä muita laitteita tämän laitteen kanssa.

HUOMIO:
perusturvallisuuden ja olennaisen suorituskyvyn varmistamiseksi käytä ICON-kärryjärjestelmää alueella, jossa sähkömagneettisia häiriöitä on vähän tai ei ollenkaan.

VAROITUS:
Tämä lääkinnällinen laite on suunniteltu täyttämään sähkömagneettista turvallisuutta koskevan standardin IEC 60601-1-2 4. painoksen vaatimukset. Tämä laite tuottaa, käyttää ja voi säteillä radiotaajuusenergiaa. Jos laitetta ei asenneta ja käytetä ohjeiden mukaisesti, se voi aiheuttaa haitallisia häiriöitä muille lähellä oleville laitteille. Ei ole kuitenkaan takeita sille, etteikö häiriötä voisi esiintyä yksittäisessä asennuksessa. Muille laitteille aiheutuvat haitalliset häiriöt voidaan määrittää kytkemällä tämä laite päälle ja pois päältä. Yritä korjata häiriö toteuttamalla yksi tai useampi seuraavista toimenpiteistä:

- Suuntaa tai sijoita vastaanottava laite uudelleen.
- Sijoita laitteet kauemmaksi toisistaan.
- Kytke laite pistorasiaan, joka on eri piirissä kuin se, johon muut laitteet on kytketty, ja pyydä apua tehtaan kenttähuoltoteknikolta.
- Pyydä apua valtuutetulta jälleenmyyjältä.

HUOMIO:
jos Phoenix ICON -järjestelmän kanssa käytetään muita kuin Phoenix Technology Group LLC:n määrittelemiä lisävarusteita, muuntimia ja kaapeleita, se voi johtaa lisääntyneisiin PÄÄSTÖIHIN tai LAITTEEN heikentyneeseen HÄIRIÖNSIETOON.

HUOMIO:
mitään Phoenix ICON -järjestelmän komponentteja ei saa vaihtaa ilman Phoenix Technology Group LLC:n konsultointia ja lupaa.

HUOMIO:
Tätä LAITETTA ei saa käyttää muiden laitteiden vieressä tai pinottuna niiden kanssa. Jos käyttö vierekkäin tai pinottuna muiden laitteiden kanssa on tarpeen, LAITETTA on tarkkailtava normaalin toiminnan varmistamiseksi kokoonpanossa, jossa sitä käytetään.

HUOMIO:
ICON-kärryjärjestelmä on hyväksyttävän päästörajan alapuolella tavallisen lääkinnällisen laitteen sähköturvallisuustestauksen mukaan, ja järjestelmä saa olla vain sellaisten laitteiden lähellä, joiden on osoitettu toimivan normaalisti näissä olosuhteissa.

HUOMIO:
Tarkista ennen kuvantamista linssin kärki mahdollisten naarmujen tai lohjenneiden reunojen varalta potilaan sarveiskalvon terveyden ja turvallisuuden suojelemiseksi. ÄLÄ KÄYTÄ kameraa, jos linssin kärki on vaurioitunut.

HUOMIO:
älä upota kameran käsikappaleen kärkeä mihinkään nesteeseen siten, että nesteen taso ulottuu ruostumattomasta teräksestä valmistetun kärjen ohi.

HUOMIO:
älä autoklaavaa kameran käsikappaletta.

HUOMIO:
älä pudota kameran käsikappaletta.

HUOMIO:
Tarkkaile koko kuvantamisjakson ajan silmämääräisesti verkkokalvon valtimo- ja laskimohaaroja sykkimisen varalta. Jos sykkimistä ilmenee, se viittaa liialliseen silmään kohdistuvaan paineeseen. Jos sykkimistä ilmenee, vie kamera hieman pois silmästä, kunnes sykkiminen pysähtyy, tai poista kamera kokonaan silmästä ja aseta se uudelleen kuvantamisen jatkamiseksi.

VAROITUS:
käsikappaleen liittimien virheellinen asettaminen voi johtaa siihen, että käsikappale ei toimi oikein tietokoneeseen yhdistämisen ja kuvan ottamisen aikana. Se voi vaikuttaa tarkennuksen ja/tai valaistuksen ohjaukseen.

HUOMIO:
järjestelmän mihinkään osaan ei saa suorittaa huoltoa tai kunnossapitoa LAITTEEN käytön aikana.

HUOMIO:
ICON-diffuusori on tarkoitettu vain kosketuksettomaan kuvantamiseen. Diffuusorin kärki ei saa koskaan joutua kosketuksiin potilaan silmän kanssa.

HUOMIO:
ICON-käsikappaleen käytön vasta-aiheet kosketustilassa ovat seuraavat:

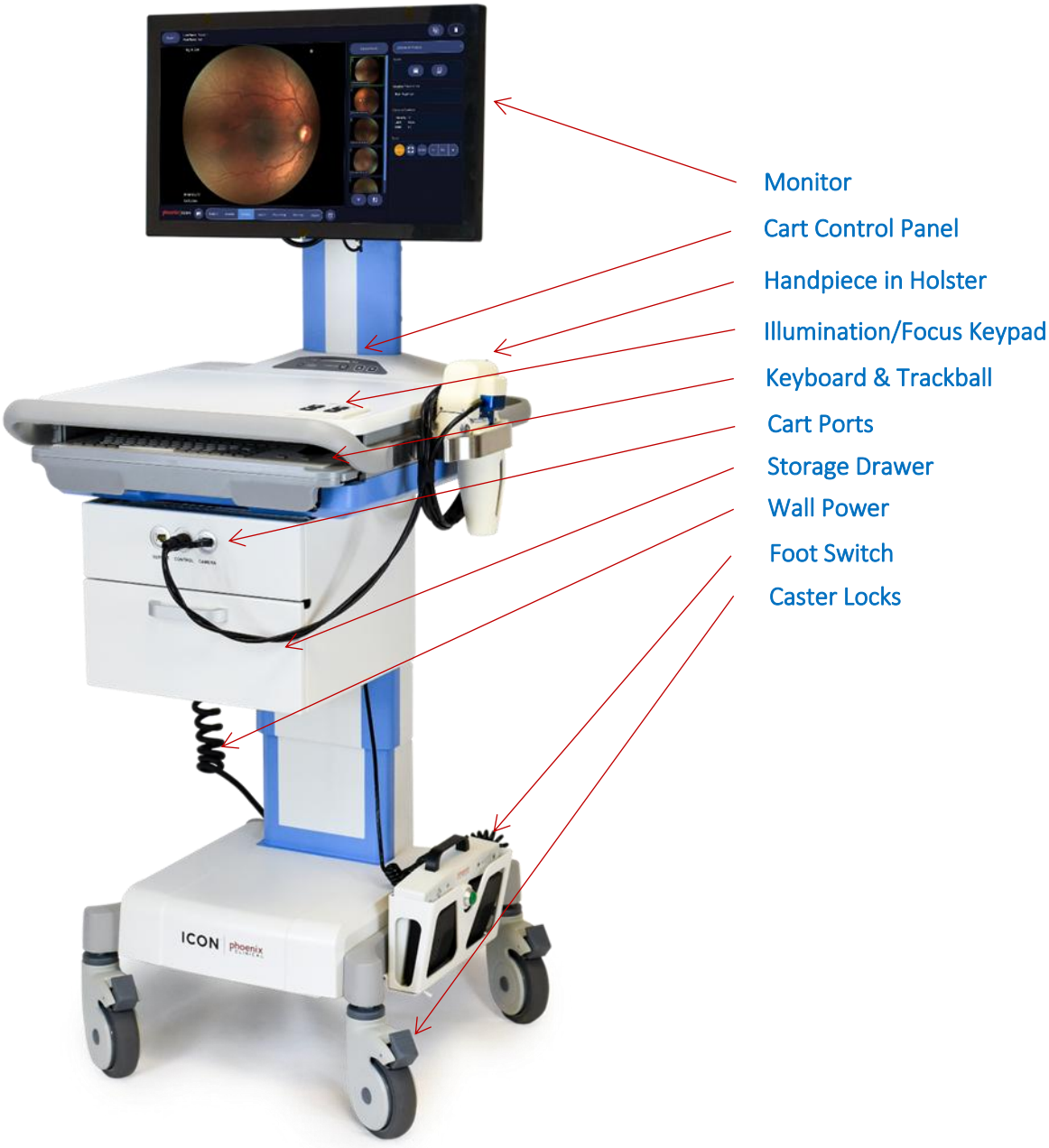
5. Jos linssin kärki on murtunut tai vahingoittunut jollain tavalla, kameraa ei saa käyttää silmään.
6. Jos potilaalla on avoin silmävamma, kameraa ei saa käyttää silmään ennen kuin haava on korjattu ja parantunut.
7. Potilasta, jolle on äskettäin tehty leikkaus, ei saa kuvata niin, että kamera koskettaa silmää.
8. Jos potilaalla on tiedossa oleva silmätulehdus, kamera ei saa koskettaa silmää ennen kuin sen katsotaan olevan turvallista.

HUOMIO:
Kosketuksellisen kuvauksen ajoituksen uudelleenarviointia koskevat ohjeet ovat seuraavat:

4. Jos pupilli ei ole laajentunut, silmä voi vaatia lisälaajentumista.
5. Jos potilas on stressaantunut ja tarvitsee tauon, kuvantamisen ajoitus on arvioitava uudelleen.
6. Jos lääkäri ilmoittaa, että hänen hoidossaan oleva potilas on fyysisesti epävakaa kuvantamista varten, toimenpidettä on lykättävä.

Chapter 3: Components and Controls

3.1 User Accessible Parts:



3.2 Phoenix ICON Components in Detail

3.2.1 Cart Control Panel

Cart Power Button	Press and hold this button for 5 seconds to turn cart power on/off
Battery Indicator	The lights indicate the charge status of the cart batteries. As the cart is charging, the lights will blink from Low to Full status
Computer Power Button	A single press of this button turns the computer on or off
Cart Up	The cart lift motor will raise the operating height of the cart
Cart Down	The cart lift motor will lower the operating height of the cart

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

3.2.2 Cart Ports

There are four ports on the front of the Phoenix ICON assembly:

USB	Port for data transfer to USB media
Camera	Main USB port for the handpiece which sends data to the system
Control	The round connector provides power to the hand piece.
Service	The Service Ethernet port is for system maintenance use only, including maintaining data integrity by exporting data to a server. The Ethernet

port must not be used during an active imaging session and may NOT be used in an operating theater after an imaging session

3.2.3 Keyboard

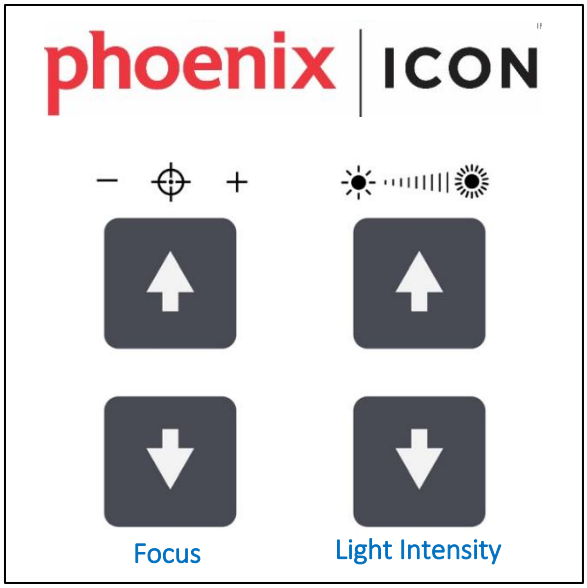
The keyboard is mounted within a drawer assembly for convenient access and storage when not in use. Being medical grade, with a spill resistant covering, it may be wiped or cleaned using disinfectant wipes. There is a small keyboard light that can be turned on and off located in the center, just under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

3.2.4 System Battery

The cart comes with a battery which allows system usage for imaging and system backup. The system can be utilized on battery for imaging sessions for up to 6 hours. If utilizing wall power supply when performing imaging exams, the battery will mitigate data loss by keeping the computer powered on.

3.2.5 Cart Keypad

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



WARNING:
Do not place objects on keypad

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

- ***Up arrow*** focuses towards the back of the eye
- ***Down arrow*** focuses to the front of the eye

Light Intensity When the handpiece light module is on, these controls increase or decrease the projected brightness

- ***Up arrow*** increases illumination
- ***Down arrow*** decreases illumination

3.2.6 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

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

3.2.7 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 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 with the patient's eye. Note that the patient-contacting lens must be cleaned according to appropriate infection control procedures after use and between patients.

An interchangeable 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 module 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 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 Startup Procedure

1. Plug in the Phoenix ICON using the main power cable.
2. Remove the camera handpiece from the drawer and place it in the side holster on the cart.
3. Deploy the foot pedal and place it nearby on the floor.
4. Turn on the cart power by pressing the power button for 5 seconds.
5. Depress the button for the computer power. The computer software will start up at the “Login” screen.

4.2 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. To shut down the system, press and hold the Cart Power button on the Cart Controls for 5 seconds until the battery light indicator turns off.
5. Disconnect the handpiece from the cart and store safely in the provided cart drawer.
6. Disconnect the cart from the wall if connected

NOTE The cart may also be plugged into the wall while off to charge

4.3 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.

4.3.1 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

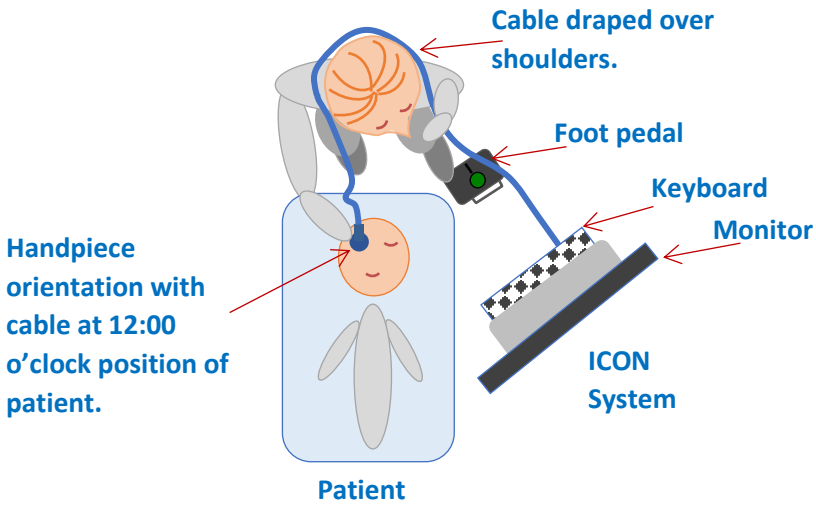
3. The viewing angle of the screen will make a difference to the operator's perception of illumination brightness of the retinal image. For imaging consistency, the operator should position the system so that they are looking straight at zero degrees to the center of the monitor.

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

4.3 ICON-käsikappaleen käyttö

HUOMAA Käsikappaletta saa käyttää enintään 3 minuuttia kerrallaan. Tämän käyttöjakson jälkeen on pidettävä 3 minuutin tauko ennen seuraavaa käyttöjaksoa.

4.3.1 Käyttäjän ja kameran sijoittuminen kuvantamisen aikana

7. Järjestelmän normaalin käytön aikana käyttäjän on oltava riittävän lähellä potilasta sellaisessa asennossa, että hän voi pitää käsikappaletta mukavassa asennossa, voi käyttää jalkapolkimen tarkennus-/kuvanotto-ohjaimia ja nähdä näytön helposti.

8. Käyttäjän on oltava selinmakuulla olevan potilaan pään yläpuolella siten, että potilaan jalat ovat poispäin käyttäjästä.

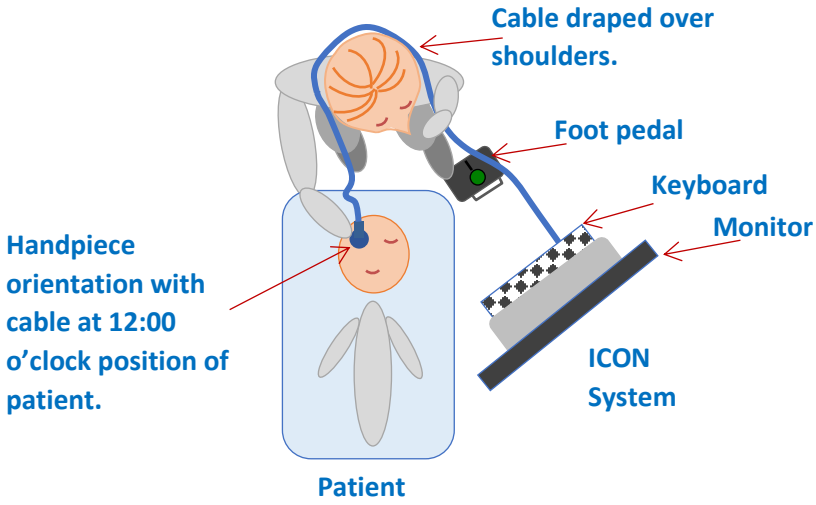
9. Näytön katselukulma vaikuttaa käyttäjän käsitykseen verkkokalvon kuvan valaistuksen kirkkaudesta. Kuvantamisen johdonmukaisuuden vuoksi käyttäjän on sijoitettava järjestelmä niin, että hän katsoo suoraan nollan asteen kulmassa näytön keskelle.

10. Ennen kuin kameran käsikappale tuodaan kosketuksiin potilaan silmän kanssa, käyttäjän on käytettävä lattialla olevaa jalkapoljinta ja asetettava jalkansa tarkennus-/kuvanotto-ohjaimien käyttämiseksi.

11. Käyttäjän on kohdistettava kameran käsikappale siten, että kaapeli on potilaan otsalla kello 12.00:n kohdalla siten, että kaapeli tulee käyttäjää kohti. Tämä varmistaa, että kuva on oikein suunnattu näytöllä.

    HUOMAA: nopea tapa tarkistaa ICON-kameran suunta on osoittaa kamera näppäimistölle, jolloin kirjainten pitäisi näkyä ylösalaisin.

12. Irrota kärry seinästä, jos se on kytketty pistorasiaan.



Peruskaavio potilaan, käsikappaleen ja ICON-kameran suunnasta

4.3.2 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).

4.3.2 Valomoduulin vaihtaminen

Jos käyttäjä haluaa vaihtaa värikuvantamisen ja fluoreseiiniangiografian välillä, hänen on vaihdettava valomoduuli. Valkoisen valon moduulia käytetään värikuvantamiseen. Sinisen valon moduulia käytetään fluoreseiiniangiografiaan.

1. Löysää valomoduulin takana olevat kaksi peukaloruuvia kokonaan, vedä moduuli takaisin ja irrota.

2. Kohdista uusi moduuli ja aseta se käsikappaleen pohjaan. Kiristä kaksi peukaloruuvia varovasti yksi kerrallaan varmistaaksesi moduulin oikean istuvuuden.

3. Varmista, että sinisen valon moduuli on asetettu ICON™-kameran käsikappaleeseen ja että käsikappaleen suodatinvipu on estosuodattimen sijainnissa (sininen piste).

4.3.3 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

4.3.3 ICON-diffuusorin käyttö

ICON-diffuusori on ICON-käsikappaleen lisävaruste, joka on tarkoitettu käytettäväksi otettaessa kuvia silmän ulkoisista rakenteista. ICON-käsikappaleessa käytetty muokkaamaton valaistusjärjestelmä on suunniteltu verkkokalvon suuren kontrastin ja korkean resoluution kuviin. Kun käsikappaletta käytetään ilman diffuusoria, kuvan keskelle voi ilmestyä artefakteja. Diffuusori poistaa nämä artefaktit, jolloin käyttäjä voi ottaa korkealaatuisia ulkoisia kuvia.

ICON-diffuusorin käyttö

1. Valmistele ICON-kamerajärjestelmä kuvantamista varten tässä käyttöoppaassa edellä olevien ohjeiden mukaisesti:
    c. Kytke virta ICON- tai ICON GO -järjestelmään.
    d. Kirjaudu ICON-ohjelmistoon.

2. Puhdista ja valmistele ICON-käsikappale oikein tämän käyttöoppaan kappaleen 5 mukaisesti.

3. Varmista, että ICON-käsikappaleen valo on pois päältä kohdistamalla käsikappaleen kärki pintaan, joka on suunnattu poispäin käyttäjästä ja tarkkailemalla, että käsikappaleesta ei tule valoa.

4. Liu'uta ICON-diffuusori ICON-käsikappaleen nokkaan.

5. Valmistele potilas silmän ulkoisten rakenteiden kuvantamiseen.

6. Ota yksi tai useampi kuva silmän ulkoisista rakenteista.
    a. Valitse ICON-ohjelmiston Potilas-näytöltä olemassa oleva potilas tai syötä uusi potilas.
    b. Napsauta "Hanki" siirtyäksesi kuvanhankintanäytölle.
    c. Valitse olemassa oleva tutkimus tai valitse Luo uusi tutkimus.

d. Valitse, kumpaa silmää kuvataan.
e. Sytytä valo napsauttamalla ohjelmiston valon virtapainiketta.
f. Määritä alkuperäinen voimakkuus ja vahvistus tai valitse edellisen segmentin esiasetus.
g. Aseta ICON-käsikappale siten, että potilaan silmän halutut ulkoiset rakenteet näkyvät kameran näkökentässä ICON-näytöllä näkyvällä tavalla.
h. Keskitä niin, että rakenteet ovat selvästi näkyvissä.
i. Ota kuvia ja/tai video silmän ulkoisista rakenteista.
j. Sammuta käsikappaleen valo.

7. Kun kuvantaminen on valmis, liu'uta ICON-diffuusori pois ICON-käsikappaleen nokasta ja säilytä se ICON-diffuusorin mukana toimitetussa laatikossa.

4.4 Transporting the System

For short transport of just a few yards:

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

For long transport:

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

4.4 Järjestelmän kuljettaminen

Lyhyt, vain muutaman metrin kuljetus:

- Järjestelmässä on vara-akku, joka pitää järjestelmän toiminnassa kuljetuksen aikana.
- Laske kärry ALIMPAAN asentoon kärryn ohjaimilla.
- Tarkista, että akku on ladattu täyteen ennen järjestelmän irrottamista.
- Irrota järjestelmä pistorasiasta, jotta järjestelmä palautuu akkuvirtaan.
- Avaa rullapyörien lukitus.
- Työnnä järjestelmä uuteen paikkaan.

- Aseta järjestelmä ja lukitse rullapyörät.
- Kytke järjestelmä takaisin pistorasiaan.
- Nosta kärry haluttuun käyttökorkeuteen.

Pitkä kuljetus:

- Laske kärry ALIMPAAN asentoon kärryn ohjaimilla.
- Irrota käsikappale ja pakkaa se varovasti kärryn laatikkoon.
- Irrota kärryn virtajohto ja ripusta se kärryn pieneen virtajohdon ripustimeen.
- Varmista, että koko kärryjärjestelmä on kytketty pois päältä.
- Laita järjestelmä hyväksyttyyn kuljetuspakkaukseen ennen kuljetusta.

4.5 Environmental Protection

1. The Phoenix ICON 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 Phoenix ICON system, do not throw cart and handpiece into the waste bin. Contact Customer Support for disposal options

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

4.5 Ympäristönsuojelu

4. Phoenix ICON -järjestelmässä ei käytetä kertakäyttötarvikkeita.
5. Noudata organisaatiosi hävittämismenettelyjä hävittääksesi tehokkaasti kaikki järjestelmän kanssa käytetyt puhdistustarvikkeet.
6. Hävittäessäsi Phoenix ICON -järjestelmää älä heitä ohjauslaatikkoa ja käsikappaletta jätesäiliöön. Ota yhteyttä asiakastukeen saadaksesi tietää hävitysvaihtoehdoista.

HUOMAA	Kaikessa hävittämisessä on noudatettava paikallisia määräyksiä.

	Sähkö- ja elektroniikkalaiteromua ei saa hävittää lajittelemattomana yhdyskuntajätteenä, ja se on kerättävä erikseen laitteiden odotetun käyttöiän päätyttyä. Ota yhteyttä valmistajan valtuutettuun edustajaan saadaksesi tietoja laitteesi käytöstä poistamisesta.

Chapter 5: Routine Maintenance Procedures

This chapter includes procedures for routine maintenance of the Phoenix 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 Phoenix ICON at the institution.
- Phoenix ICON has been visually damaged or subjected to mechanical shock (i.e., dropped).
- Phoenix ICON has been submitted for maintenance or scheduled performance verification.

Luku 5: Rutiinikunnossapitotoimenpiteet

Tämä luku sisältää Phoenix ICON -järjestelmän rutiinikunnossapitotoimenpiteet. Nämä toimenpiteet voidaan suorittaa minkä tahansa seuraavan tapahtuman jälkeen ja/tai laitoksen kunnossapitoaikataulun mukaisesti:

- Phoenix ICON -järjestelmän ensimmäinen vastaanotto laitoksessa.
- Phoenix ICON -järjestelmä on vaurioitunut visuaalisesti tai altistunut mekaaniselle iskulle (eli pudonnut).
- Phoenix ICON -järjestelmä on lähetetty kunnossapitoa tai ajoitettua suorituskyvyn todentamista varten.

5.1 Servicing the Phoenix ICON System

There are no serviceable parts in the ICON system. If it is suspected that something is not operating correctly, contact **Customer Support at +1.877.839.0080 or service@theneolight.com**. Please have the following information available:

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

5.1 Phoenix ICON -järjestelmän huolto

ICON-järjestelmässä ei ole huollettavia osia. Jos epäilet, että jokin ei toimi oikein, ota yhteyttä **asiakastukeen numeroon +1 877 839 0080 tai osoitteeseen service@theneolight.com**. Pidä seuraavat tiedot saatavilla:

- toimipaikan sijainti (esim. sairaalan nimi, osasto jne.)
- järjestelmäaseman tunnus (sijaitsee kirjautumisnäytöllä)
- järjestelmän sarjanumero (kärryn takana ylhäällä oleva etiketti).

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.

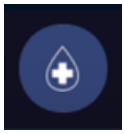
SETUP THE SOAK TIMER.

1. Log in as an Administrator.

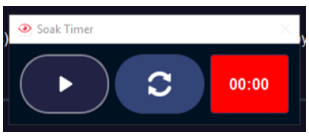
2. Go to Settings / Camera and set the soak timer to match the required soak time for the chemistry chosen.
3. Log out and log back in as user prior to performing disinfection.

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.



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

5.2 Liotusajastimen käyttö

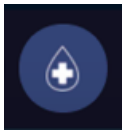
ICON-ohjelmisto sisältää myös liotusajastinominaisuuden, joka tarjoaa visuaalisen laskennan ja tarkastuslokin desinfioinnin liotusprosessista. Ohjelmiston tarkastuslokimerkintä kirjoitetaan joka kerta, kun liotusajastin käynnistetään ja pysäytetään. Jokainen lokimerkintä sisältää nykyisen käyttäjän käyttäjätunnuksen sekä päivämäärän ja kellonajan.

MÄÄRITÄ LIOTUSAJASTIN.

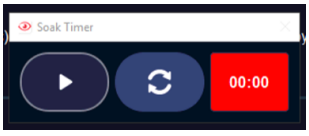
4. Kirjaudu sisään järjestelmänvalvojana.
5. Siirry kohtaan Asetukset/Kamera ja aseta liotusajastin vastaamaan valitun kemikaalin edellyttämää liotusaikaa.
6. Kirjaudu ulos ja kirjaudu takaisin sisään käyttäjänä ennen desinfioinnin suorittamista.

LIUOTUSAJASTIMEN KÄYTTÖ

3. Kun ICON-käsikappale on upotettu liotusnesteeseen, napsauta näytön alareunassa olevaa liuotusajastinkuvaketta.



4. Liotusajan laskuri tulee näkyviin alkaen järjestelmänvalvojan asettamasta liotusajasta.



5. Järjestelmässä näkyy 00:00 punaisessa ruudussa, kun aika on kulunut.

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, 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 4 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
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.

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

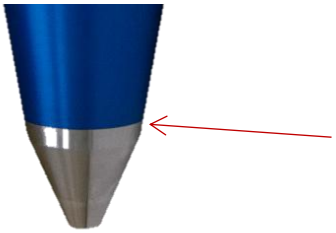
NOTE The remaining steps do not apply if HLD is performed without a soaking cup.

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	1. Prepare per manufacturer's instructions at 25°C.

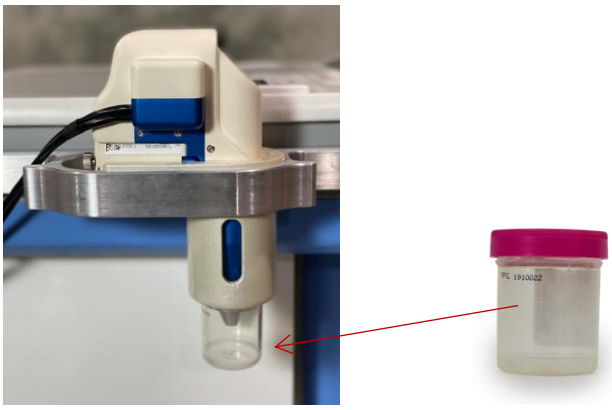
			2. After soaking for 90 mins rinse with sterile water for a minimum of 1 minute. 3. Repeat rinse for a total of 3 full rinse cycles.
Ortho-phthalaldehyde (OPA)	Cidex	12 mins	1. Prepare per manufacturer's instructions at 20℃ 2. After soaking for 12 mins rinse with sterile water for a minimum of 1 minute. 3. Repeat rinse for a total of 3 full rinse cycles.
Hydrogen Peroxide (7.5%)	Generic	30 mins	1. Rinse with sterile water for 1 minute after soaking for 30 mins and wipe with soft cloth to dry. 2. 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



Do not submerge past edge of the silver cone.

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 as noted

5.3 Puhdistus- ja desinfiointimenettely (noudatettava vain Yhdysvalloissa):

5.3.1 ICON-käsikappaleen linssin puhdistus ja desinfiointi

TÄRKEÄÄ!	Puolikriittiset limakalvoja koskettavat laitteet on uudelleenkäsiteltävä käyttämällä korkean tason desinfiointia. Mikäli korkean tason desinfiointiaineita ei käytetä, sterilointi voi olla riittämätön. Tämän seurauksena voi olla infektio tai muita haittavaikutuksia.

PUHDISTUS JA KESKIKORKEAN TASON DESINFIOINTI:

Tarvittavat tarvikkeet:

steriili sideharso tai steriilejä pyyhkeitä
steriiliä tai tislattua vettä
steriili Starplex Scientific -kuppi (B902L)
suositeltu puhdistusaine (valitse alla olevasta luettelosta).

Suositellut puhdistusaineet:

Liuos	Yleinen tuotenimi
Steriili tai tislattu vesi	Sairaalan standardi
Isopropyylialkoholipyyhkeet tai -liuos (> 70 %)	Sairaalan standardi
Isopropanoli (17,2 %) ja ammoniumkloridi	CaviWipes-pyyhe/-pyyhkeet
Kvaternaarinen ammonium ja isopropyylialkoholi (IPA)	Bakteereja tappavat Super Sani-Cloth -pyyhkeet
Viruksia, bakteereja, mykobakteereja ja sieniä tappava desinfiointiaine	Oxivir Tb
Natriumhypokloriitti (≥ 6 %)	Valkaisuliuos
Vetyperoksidi (≥ 6 %)	Sairaalan standardi

1. Pyyhi linssin kärki välittömästi jokaisen potilaan jälkeen steriilillä tai tislatulla vedellä kyllästetyllä pehmeällä pyyhkeellä tai sideharsolla varmistaaksesi, että kytkentäainegeeli, orgaaninen aine ja mahdolliset hiukkaset on poistettu kokonaan ennen desinfiointiaineiden käyttöä.

   HUOMAA: Pelkkä liottaminen alla olevissa desinfiointiliuoksissa ei hajota eikä poista kuivanutta geeliä.

2. Jos käytät muuta puhdistuskemikaalia kuin steriiliä tai tislattua vettä, pyyhi linssin kärki steriiliin veteen kyllästetyllä pehmeällä liinalla mahdollisesti jäljellä olevien kemikaalien poistamiseksi.

3. Kun geeli tai neste on poistettu, suorita linssin desinfiointimenettely alla kuvatulla tavalla.

HUOMAA	Jos kuvassa on jäljellä keltaista sameutta linssin kehällä, toista menettely ja varmista, että linssin kärjen ulkoreuna on täysin kuiva. Voi olla hyödyllistä käyttää kyllästettyä vanupuikkoa linssin kärjen ulkoreunan ympärillä.

Suositeltavat desinfiointiaineet keskikorkean tason desinfiointiin (ILD):

Kemikaali	Tuote-esimerkit	Liotusaika	Erityisohjeet
Isopropanoli (17,2 %) ja ammoniumkloridi	CaviWipes-desinfiointipyyhkeet	3 min	1. Pyyhi ruostumattomasta teräksestä valmistettu kärki ja linssi CaviWipes-pyyhkeillä niin, että pyyhittävät alueet pysyvät märkinä 3 minuutin ajan. 2. Tarvittaessa voit käyttää useampia pyyhkeitä, jotta kärki ja linssi pysyvät varmasti märkinä 3 minuutin ajan. 3. Poista kemikaalijäämät ruostumattomasta teräskärjestä ja linssistä pyyhkimällä ne puhdistettuun veteen kastetuilla nukkaamattomilla liinoilla. 4. Toista vaihe 3 kahdesti eli suorita se yhteensä 3 kertaa. 5. Kuivaa osat steriileillä nukkaamattomilla liinoilla. Anna niiden kuivua.
Isopropanoli (55 %)	Super-Sani® Cloth -desinfiointipyyhkeet	4 min	6. Pyyhi ruostumattomasta teräksestä valmistettu kärki ja linssi Super-Sani® Cloth -pyyhkeillä

			niin, että pyyhittävät alueet pysyvät märkinä 4 minuutin ajan. 7. Tarvittaessa voit käyttää useampia pyyhkeitä, jotta kärki ja linssi pysyvät varmasti märkinä 4 minuutin ajan. 8. Poista kemikaalijäämät ruostumattomasta teräskärjestä ja linssistä pyyhkimällä ne puhdistettuun veteen kastetuilla nukkaamattomilla liinoilla. 9. Toista vaihe 3 kahdesti eli suorita se yhteensä 3 kertaa. 10. Kuivaa osat steriileillä nukkaamattomilla liinoilla. Anna niiden kuivua.

PUHDISTUS JA KORKEAN TASON DESINFIOINTI:

Tarvittavat tarvikkeet:

steriili sideharso tai steriilejä pyyhkeitä
steriiliä tai tislattua vettä
steriili Starplex Scientific -kuppi (B902L)
suositeltu puhdistusaine (valitse alla olevasta luettelosta).

Suositellut puhdistusaineet:

Liuos	Yleinen tuotenimi
Steriili tai tislattu vesi	Sairaalan standardi
Isopropyylialkoholipyyhkeet tai -liuos (> 70 %)	Sairaalan standardi
Isopropanoli (17,2 %) ja ammoniumkloridi	CaviWipes-pyyhe/-pyyhkeet
Kvaternaarinen ammonium ja isopropyylialkoholi (IPA)	Bakteereja tappavat Super Sani-Cloth -pyyhkeet
Viruksia, bakteereja, mykobakteereja ja sieniä tappava desinfiointiaine	Oxivir Tb
Natriumhypokloriitti (≥ 6 %)	Valkaisuliuos
Vetyperoksidi (≥ 6 %)	Sairaalan standardi

1. Pyyhi linssin kärki välittömästi jokaisen potilaan jälkeen steriilillä tai tislatulla vedellä kyllästetyllä pehmeällä pyyhkeellä tai sideharsolla varmistaaksesi, että kytkentäainegeeli, orgaaninen aine ja mahdolliset hiukkaset on poistettu kokonaan ennen desinfiointiaineiden käyttöä.

   HUOMAA: Pelkkä liottaminen alla olevissa desinfiointiliuoksissa ei hajota eikä poista kuivanutta geeliä.

2. Jos käytät muuta puhdistuskemikaalia kuin steriiliä tai tislattua vettä, pyyhi linssin kärki steriiliin veteen kyllästetyllä pehmeällä liinalla mahdollisesti jäljellä olevien kemikaalien poistamiseksi.

3. Kun geeli tai neste on poistettu, suorita linssin desinfiointimenettely alla kuvatulla tavalla.

HUOMAA	Jos kuvassa on jäljellä keltaista sameutta linssin kehällä, toista menettely ja varmista, että linssin kärjen ulkoreuna on täysin kuiva. Voi olla hyödyllistä käyttää kyllästettyä vanupuikkoa linssin kärjen ulkoreunan ympärillä.

4. Varmista ennen linssin desinfiointia, että kaikki työntekijät ovat lukeneet ja ymmärtävät asianmukaisen desinfiointiaineen käyttöturvallisuustiedotteet (KTT).

5. Aseta ICON-käsikappaleen pidike valmiiksi ja varaa tarvittaessa liotuskuppi saataville. Liotuskuppia ei tarvita korkean tason desinfiointiin (HLD) Tristel Duo OPH -pyyhkeillä.

6. Valitse yksi desinfiointikemikaali alla olevasta osiosta. Noudata käytettyyn suositeltuun desinfiointiaineeseen liittyviä ohjeita. Vaiheet löytyvät alla olevasta Erityisohjeet-sarakkeesta.

   HUOMAA: Voit käyttää ICON-järjestelmän sisäänrakennettua liotusajastinta seurataksesi ICON-käsikappaleen desinfiointiaineessa liotuksen kestoa. Liuotusajastimen käyttöohjeet ovat yllä.

Suositeltavat desinfiointiaineet korkean tason desinfiointiin (HLD) ilman liotuskuppia:

Kemikaali	Tuotemerkit	Liotusaika	Erityisohjeet
Klooridioksidi (ClO_2)	Tristel OPH ja Tristel Duo OPH	2 min	1. Valmistele valmistajan ohjeiden mukaisesti. 2. Levitä Tristel OPH -pyyhe kämmenellesi ja annostele siihen kaksi (2) annosta Tristel OPH -vaahtoa. 3. Sulje pyyhe varovasti käteesi ja odota 10 sekuntia. Älä purista.

			4. Levitä vaahto hierovalla liikkeellä ICON-käsikappaleen linssin kärkeen ja ruostumattomasta teräksestä valmistettuun hopeanväriseen kartioon. Pyyhi desinfioitavat alueet 4 kertaa. Huolehdi, että kaikki pinnat on pyyhitty ja laite näyttää märältä. Kiinnitä erityistä huomiota mahdollisiin rakoihin, kohoumiin ja painaumiin. **HUOMIO**: Älä kastele laitetta ruostumattomasta teräksestä valmistetun hopeanvärisen kartion yläpuolelta, jotta nestettä ei pääse laitteen sisään. 5. Älä koske laitteeseen pyyhkimisen jälkeen. Aseta laite puhtaalle pinnalle, jotta se ei kontaminoidu uudelleen. Korkean tason desinfioinnin edellyttämä kontaktiaika on kaksi (2) minuuttia. 6. Poista Tristel OPH -vaahdon jäämät huolellisesti puhtaalla Tristel OPH -pyyhkeellä.

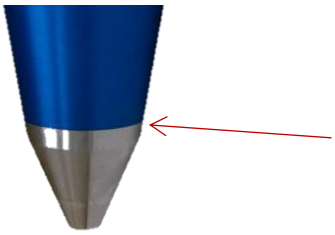
HUOMAA Seuraavia vaiheita ei sovelleta, jos korkean tason desinfiointi tehdään ilman liotuskuppia.

Suositeltavat desinfiointiaineet korkean tason desinfiointiin (HLD) käyttämällä liotuskuppia:

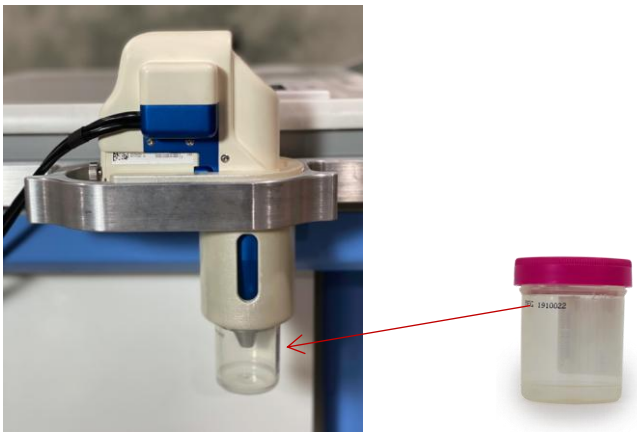
Kemikaali	Tuote-esimerkit	Liotusaika	Erityisohjeet
Glutaarialdehydi (> 2 %)	MetriCide Plus 30, ProCide D	90 min	4. Valmista valmistajan ohjeiden mukaisesti 25 °C:ssa. 5. 90 minuutin liotuksen jälkeen huuhtele steriilillä vedellä vähintään 1 minuutin ajan. 6. Toista huuhtelu yhteensä 3 täydellä huuhtelukierroksella.
Orto-ftaalialdehydi (OPA)	Cidex	12 min	4. Valmista valmistajan ohjeiden mukaisesti 20 ° C:ssa.

			5. 12 minuutin liotuksen jälkeen huuhtele steriilillä vedellä vähintään 1 minuutin ajan. 6. Toista huuhtelu yhteensä 3 täydellä huuhtelukierroksella.
Vetyperoksidi (7,5 %)	Yleiset	30 min	3. 30 minuutin liotuksen jälkeen huuhtele steriilillä vedellä 1 minuutin ajan ja pyyhi kuivaksi pehmeällä liinalla. 4. Toista huuhtelu yhteensä 3 täydellä huuhtelukierroksella.

7. Täytä liotuskuppi 50 ml:n viivaan asti niin, että liuos peittää linssin ja ruostumattomasta teräksestä valmistetun kärjen riittävästi.



8. Ruuvaa liotuskuppi ICON-käsikappaleen pidikkeeseen kuvan osoittamalla tavalla.



9. Aseta käsikappale liuokseen ja käynnistä liotusajastin (tarvittaessa).

10. Kun desinfiointi on valmis, valmistele steriiliä vettä sisältävä kylpy. Pyyhi ruostumattomasta teräksestä valmistettu kärki ja linssi steriiliin veteen kastetulla nukkaamattomalla liinalla. Huuhtele ruostumattomasta teräksestä valmistettu kärki huolellisesti upottamalla se steriiliin veteen 1 minuutin ajaksi. Pyyhi ja huuhtele ruostumattomasta teräksestä valmistettu kärki ja

linssi vielä 2 kertaa käyttämällä uutta nukkaamatonta liinaa ja steriiliä vettä sisältävää kylpyä. Upota ne steriiliin veteen 1 minuutiksi. Pyyhi ja huuhtele yhteensä 3 kertaa.

11. Kun kameran kärki on desinfioitu käytön jälkeen, puhdistusliuos voidaan hävittää ja kuiva kuppi voidaan kiinnittää liotuskoteloon.

HUOMIO:
Jotkin korkean tason desinfiointiaineet edellyttävät useita huuhtelukertoja. Tarkista huuhteluvaatimukset valitun menetelmän ohjeista.

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

5.3.2 Muut järjestelmän komponentit

Pyyhi näppäimistö, tietokoneen ohjauspallo, kärryn työtaso, diffuuseri, käsikappaleen kotelo ja käsikappaleen kaapeli desinfiointipyyhkeillä potilaiden välillä ja päivän kaikkien kuvantamisistuntojen päättymisen jälkeen. Varmista, että kaikki geelit tai hiukkaset on poistettu. Kun desinfiointi on valmis, huuhtele komponentit steriiliin tai tislattuun veteen kyllästetyllä pehmeällä liinalla.

Liuos	Liotusaika	Tuote-esimerkit
Isopropanoli (17,2 %) ja ammoniumkloridi	3 min	CaviWipes-pyyhe/-pyyhkeet
Kvaternaarinen ammonium ja isopropyylialkoholi (IPA)	2 min	Bakteereja tappavat Super Sani-Cloth -pyyhkeet
Viruksia, bakteereja, mykobakteereja ja sieniä tappava desinfiointiaine	1–5 min	Oxivir® Tb

5.4 Cleaning and Disinfection Procedure (To be followed Outside the United States):

5.4.1 ICON Handpiece Lens Cleaning and Disinfection Procedure

CAUTION:
The ICON camera hand piece lens should be cleaned and disinfected after each patient

NOTE	Prior to disinfecting the ICON camera handpiece lens surface, perform the following basic cleaning procedure

CLEANING:

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

1. After each patient, 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.

DISINFECTION:

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 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 is 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.

NOTE	Phoenix Technology Group has not performed any specific cleaning studies to further verify effectiveness of cleaning and disinfection of the following solutions. Please

consult individual manufacturer websites and product package inserts for instructions for use.

Manufacturer	Solution
Antiseptica	1. Descogen 3% 2. Descogen liquid rfu (for soaking 30 minutes / 60 minutes in case of tuberculosis contamination)
Schülke	1. Mikrozid AF 2. Mikrozid AF Wipes 3. Antifect N liquid 4. Pursept AF 0.5% Note: For precautionary reasons, wipe with water after exposure time to remove surfactant residues from disinfected surfaces

5.4 Puhdistus- ja desinfiointimenettely (noudatettava Yhdysvaltojen ulkopuolella):

5.4.1 ICON-käsikappaleen linssin puhdistus ja desinfiointi

HUOMIO:
ICON-kameran käsikappaleen linssi on puhdistettava ja desinfioitava jokaisen potilaan jälkeen.

HUOMAA	Ennen ICON-kameran käsikappaleen linssin pinnan desinfiointia suorita seuraava peruspuhdistusmenettely.

PUHDISTUS:

Tarvittavat tarvikkeet:

steriili sideharso tai steriilejä pyyhkeitä
steriiliä tai tislattua vettä
steriili Starplex Scientific -kuppi (B902L)
suositeltu puhdistusaine (valitse alla olevasta luettelosta).

Suositellut puhdistusaineet:

Liuos	Yleinen tuotenimi
Steriili tai tislattu vesi	Sairaalan standardi

7. Pyyhi linssin kärki välittömästi jokaisen potilaan jälkeen steriilillä tai tislatulla vedellä kyllästetyllä pehmeällä pyyhkeellä tai sideharsolla varmistaaksesi, että kytkentäainegeeli, orgaaninen aine ja mahdolliset hiukkaset on poistettu kokonaan ennen desinfiointiaineiden käyttöä.

   HUOMAA: Pelkkä liottaminen alla olevissa desinfiointiliuoksissa ei hajota eikä poista kuivanutta geeliä.

8. Jos käytät muuta puhdistuskemikaalia kuin steriiliä tai tislattua vettä, pyyhi linssin kärki steriiliin veteen kyllästetyllä pehmeällä liinalla mahdollisesti jäljellä olevien kemikaalien poistamiseksi.

9. Kun geeli tai neste on poistettu, suorita linssin desinfiointimenettely alla kuvatulla tavalla.

HUOMAA	Jos kuvassa on jäljellä keltaista sameutta linssin kehällä, toista menettely ja varmista, että linssin kärjen ulkoreuna on täysin kuiva. Voi olla hyödyllistä käyttää kyllästettyä vanupuikkoa linssin kärjen ulkoreunan ympärillä.

DESINFIONTI:

10. Varmista ennen linssin desinfiointia, että kaikki työntekijät ovat lukeneet ja ymmärtävät asianmukaisen desinfiointiaineen käyttöturvallisuustiedotteet (KTT).

11. ICON-käsikappaleen pidikkeen asetus

12. Valitse yksi desinfiointikemikaali alla olevasta osiosta. Noudata käytettyyn suositeltuun desinfiointiaineeseen liittyviä ohjeita. Vaiheet löytyvät alla olevasta Erityisohjeet-sarakkeesta.

    HUOMAA: Voit käyttää ICON-järjestelmän sisäänrakennettua liotusajastinta seurataksesi ICON-käsikappaleen desinfiointiaineessa liotuksen kestoa. Liuotusajastimen käyttöohjeet ovat yllä.

Suositeltavat desinfiointiaineet korkeatasoisen desinfioinnin saavuttamiseksi:

Kemikaali	Tuotemerkit	Liotusaika	Erityisohjeet
Klooridioksidi (ClO_2)	Tristel OPH ja Tristel Duo OPH	2 min	1. Valmistele valmistajan ohjeiden mukaisesti. 2. Levitä Tristel OPH -pyyhe kämmenellesi ja annostele siihen kaksi (2) annosta Tristel OPH -vaahtoa. 3. Sulje pyyhe varovasti käteesi ja odota 10 sekuntia. Älä purista. 4. Levitä vaahto hierovalla liikkeellä ICON-käsikappaleen linssin kärkeen ja ruostumattomasta teräksestä valmistettuun hopeanväriseen kartioon. Pyyhi desinfioitavat alueet 4 kertaa. Huolehdi, että kaikki pinnat on pyyhitty ja laite näyttää märältä. Kiinnitä erityistä huomiota mahdollisiin rakoihin, kohoumiin ja painaumiin. **HUOMIO**: Älä kastele laitetta ruostumattomasta

			teräksestä valmistetun hopeanvärisen kartion yläpuolelta, jotta nestettä ei pääse laitteen sisään. 5. Älä koske laitteeseen pyyhkimisen jälkeen. Aseta laite puhtaalle pinnalle, jotta se ei kontaminoidu uudelleen. Korkean tason desinfioinnin edellyttämä kontaktiaika on kaksi (2) minuuttia. 6. Poista Tristel OPH -vaahdon jäämät huolellisesti puhtaalla Tristel OPH -pyyhkeellä.

HUOMAA

Phoenix Technology Group ei ole suorittanut erityisiä puhdistustutkimuksia seuraavilla liuoksilla suoritettavien puhdistuksen ja desinfioinnin tehokkuuden varmistamiseksi. Katso käyttöohjeet yksittäisen valmistajan verkkosivuilta ja tuotteen pakkausselosteista.

Valmistaja	Liuos
Antiseptica	3. Descogen 3% 4. Descogen Liquid r.f.u. (30 minuutin / 60 minuutin liottamiseen tuberkuloosikontaminaation yhteydessä)
Schülke	5. mikrozid AF 6. mikrozid AF -pyyhkeet 7. antifect N -neste 8. Pursept AF (0,5 %) Huomaa: varotoimenpiteenä pyyhi vedellä altistusajan jälkeen pinta-aktiivisten aineiden jäämien poistamiseksi desinfioiduilta pinnoilta.

5.5 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

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.
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	- This is the intended functionality of the Archive function to free up hard disk space.

Issue	Potential Solutions
videos and delete the local copies	

5.5 Vianmääritysopas

Ongelma	Mahdolliset ratkaisut
Unohtunut salasana	- Jos käyttäjän salasanaa ei ole, voit käyttää järjestelmänvalvojan salasanaa saadaksesi toiminnallisen pääsyn järjestelmään. - Jos kirjautumiseen ei ole käytettävissä järjestelmänvalvojaa, ota yhteyttä asiakastukeen salasanan palautusta ja järjestelmän käyttöä varten.
Ei kuvaa	- Varmista, että kamera on kytketty verkkovirtaan ja että järjestelmä on kytketty päälle oikein. - Tarkista kaikki kaapelit vaurioiden varalta. Vaurioita voivat olla liialliset kiertymät tai kaapelia ympäröivän eristeen näkyvät vauriot. - Jos kaikki liittimet on kytketty oikein, järjestelmässä on virtaa, eikä näkyviä vaurioita ole, ota yhteyttä asiakastukeen.
Järjestelmä sammuu.	- Mahdollinen akun vikaantuminen. Ota yhteyttä asiakastukeen.
Vaihteleva tai välkkyvä kuva, tai kuva muuttuu harmaasävyiseksi.	- Irrota ja kytke käsikappaleen USB-kaapeli uudelleen.

Ohjelmiston ponnahdusikkunat ja varoitukset sekä mahdolliset ratkaisut	
Kameran yhteys katkaistu.	- Järjestelmä ei näe yhdistettyä kameraa. Varmista, että käsikappaleen USB-pistoke on asennettu ohjainlaatikon USB-porttiin. Jos järjestelmä on oikein kytketty verkkovirtaan, mutta kameraa ei näy, ota yhteyttä asiakastukeen.
VAROITUS: ohjaintauluun yhdistäminen epäonnistui.	- Järjestelmä ei löydä pääohjaustaulua käsikappaleen toimintojen ohjaamiseksi. Peru ohjelmiston käynnistys valitsemalla Keskeytä. Tai valitse "Ohita" jatkaaksesi ohjelmiston käynnistystä, vaikka jotkin järjestelmän toiminnot eivät ole käytettävissä. - Palauttaaksesi yhteyden ohjaustauluun käynnistä järjestelmä uudelleen. Jos virheviesti tulee uudelleen näkyviin, ota yhteyttä asiakastukeen.
Seuraavat tiedostot ovat jo olemassa.	- Yrität viedä tai arkistoida tiedostoja, jotka on jo viety kyseiseen sijaintiin. Jatka valitsemalla annetuista vaihtoehdoista.
RetinalImagingSystem.exe on lakannut toimimasta.	- Ohjelmisto on kaatunut. Käynnistä järjestelmä uudelleen, ja jos ongelma jatkuu, ota yhteyttä asiakastukeen.
Kuvien arkistointi/vienti epäonnistui.	- Järjestelmä ilmaisee, mitä kuvia ei voitu viedä. Voit yrittää viedä/arkistoida ne uudelleen. Kokeile myös viennin/arkistoinnin sijainnin vaihtamista. Jos ongelma jatkuu, ota yhteyttä asiakastukeen.
Väärä salasana	- Käytä oikeaa salasanaa. Tarkista, oletko kirjoittanut salasanan vahingossa Caps Lock -näppäimen ollessa päällä, tai ota yhteyttä järjestelmänvalvojaan saadaksesi pääsyn järjestelmään.

Ongelma	Mahdolliset ratkaisut
Turvallinen irrottaa laitteistosta	- Tämä osoittaa, että irrotettava asema on turvallisesti irrotettu järjestelmästä ja voidaan poistaa fyysisesti.
Arkistointi luo kopion kuvista ja videoista ja poistaa paikalliset kopiot.	- Tämä on arkistointitoiminnon tarkoitus tilan vapauttamiseksi kiintolevyltä.

Chapter 6: Product Specification

Electrical (AC Power)	
Electrical ratings	100 – 240 VAC, 50 – 60 Hz, Max 4.5A
Battery Type	Lithium-Iron Phosphate (LFP)
Battery Charge Time	< 3 hr. DOD 100%
Battery Capacity	420 Wh
Battery Runtime	
(Depends on system configuration and use)	~ 6 hours

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 (FOV)	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

Luku 6: Tuotetiedot

Sähkö (vaihtovirta)	
Sähköiset luokitukset	100–240 VAC, 50–60 Hz, enintään 4,5 A
Akkutyyppi	Litium-rautafosfaattiakku
Akun latausaika	< 3 h DoD 100 %
Akkukapasiteetti	420 Wh
Akun käyttöaika	
(riippuu järjestelmän kokoonpanosta ja käytöstä)	N. 6 tuntia

Valonlähde	**Valkoisen valon moduuli**	**Sinisen valon moduuli**
Valonlähteen tyyppi, aallonpituus	10 W:n valkoinen LED-valo, suodatettu 450–675 nm	10 W:n sininen LED-valo, 450–460 nm, suodatettu 450–500 nm
Valonlähteen suurin lähtöteho	4 mW/cm²	25 mW/cm²
Valon voimakkuuden säätö	Nollasta maksimiin	Nollasta maksimiin

Kamera	**Valkoisen valon moduuli**	**Sinisen valon moduuli**
Kuva-ala (FOV)	100 astetta	100 astetta
Resoluutio	2 048 x 1 536 (3,15 MP)	2 048 x 1 536 (3,15 MP)
Kuvataajuus	30 kuvaa sekunnissa	30 kuvaa sekunnissa

Muut lisävarusteet	**Valkoisen valon moduuli**	**Sinisen valon moduuli**
Aseta suodatin	Suodattimen asetusta ei tarvita.	Käytetään sinisen valon moduulin kanssa. Aseta suodatin paikalleen käsikappaleen kytkimellä. Suodatin estää kaistat 500 nm:ssä, reuna 515 nm
Kuvantamislinssi	Litteän kentän ulkoinen kamera	–
Silmien kanssa kosketuksiin joutuvat materiaalit	Goniosol- tai GenTeal-geeli	Goniosol- tai GenTeal-geeli

Suorituskyky	**Valkoisen valon moduuli**	**Sinisen valon moduuli**
Kuvien tiedostomuoto	.TIF / .JPEG / .AVI	.TIF / .JPEG / .AVI

Kuvantamisresoluutio	1 240 x 1 240 pikseliä	1 240 x 1 240 pikseliä

Käyttö-, kuljetus- ja varastointiympäristö	
Ympäristö	Leikkaussali, lääkärin tutkimushuone
Käytön ympäristöolosuhteet	Lämpötila: +10 °C – +30 °C Suhteellinen kosteus: 30–90 % Ilmanpaine: 800–1 060 hPA
Kuljetuksen ympäristöolosuhteet	Lämpötila: –40 °C – +70 °C Suhteellinen kosteus: 10–95 % Ilmanpaine: 500–1 060 hPA
Varastoinnin ympäristöolosuhteet	Lämpötila: –10 °C – +55 °C Suhteellinen kosteus: 10–95 % Ilmanpaine: 700–1 060 hPA

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 B device.

Warnings

- 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 B	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 B	
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 ±2, 4, 8, 15 kV air discharge	±8 kV contact discharge ±2, 4, 8, 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 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 over 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

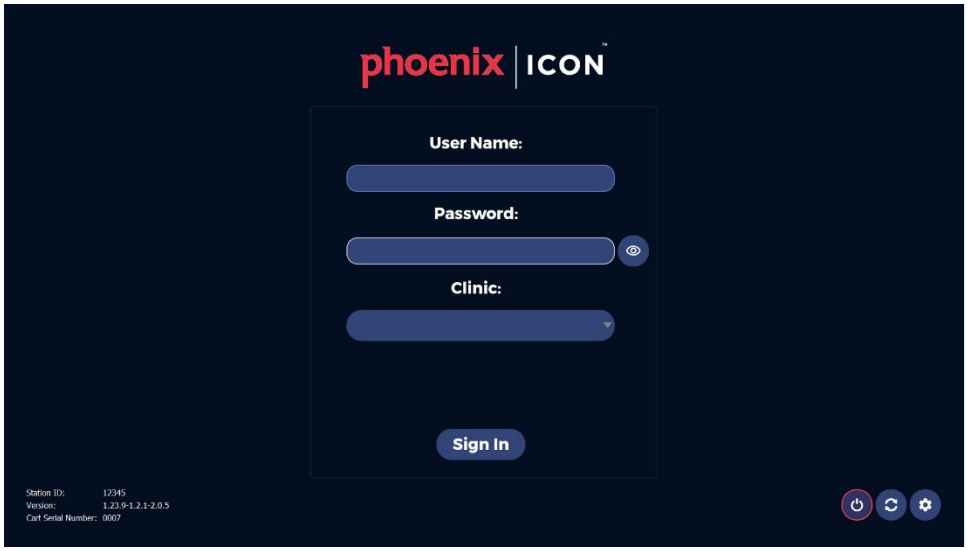
Users gain access to the ICON software and system using unique user logins, passwords, and assigned clinics. Users may utilize the User Login screen as a HIPPA compliant screen for short system transport.

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.
Show Password		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

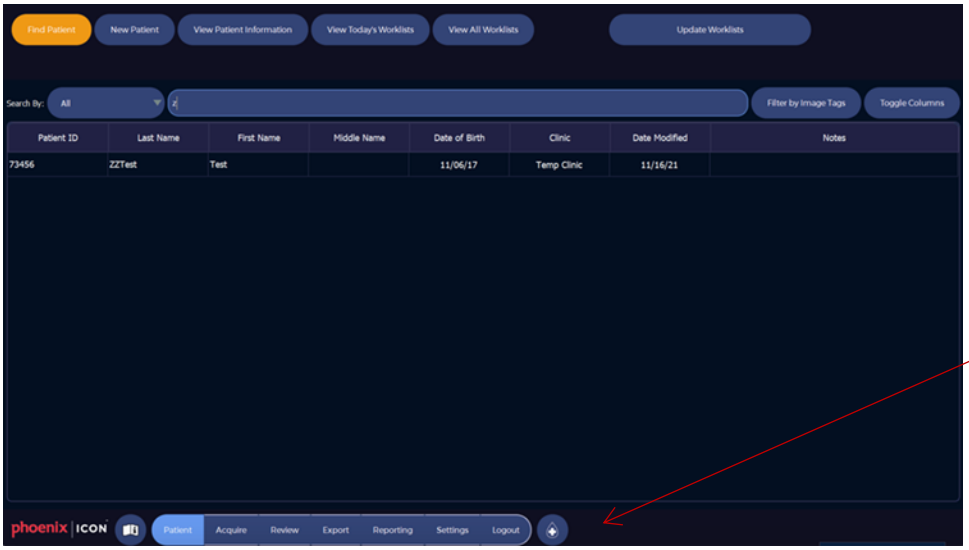
8.2.3 Logging in to the ICON Software

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:

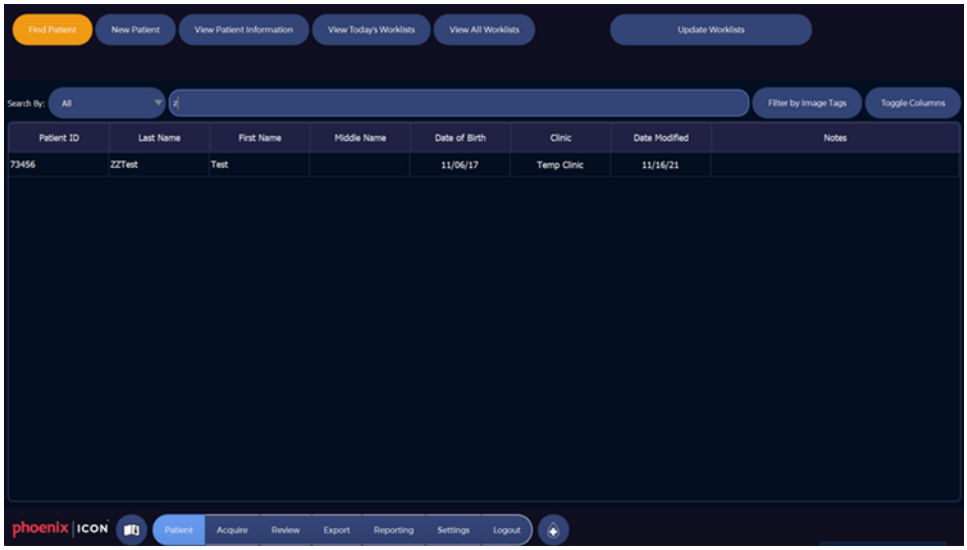
Patient	Find existing patients, enter new patient information, view and edit patient information, view worklists, and update worklists. This screen also provides the ability to move a Patient from one Clinic to another
Acquire	Capture photos and videos utilizing specialized camera controls
Review	Review 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**



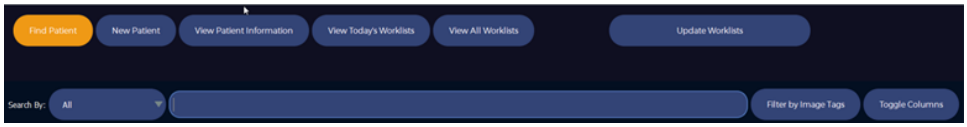
These operations are described in the following sections

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 (*).

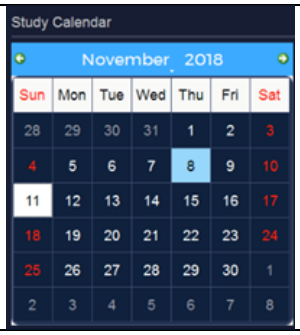
- Select the Month, Day and Year of birth using the dropdown menus. The date can also be set by using the calendar selector, available by clicking the "…" button as shown below.
- Enter any of the remaining patient data that should be tracked for the Patient, including any notes.
- Click ***Save***
- ***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 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 the ***Save*** at the bottom of the screen.
-

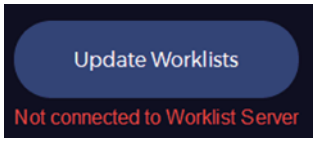
WORKING WITH MODALITY WORKLISTS

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 setup, 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.

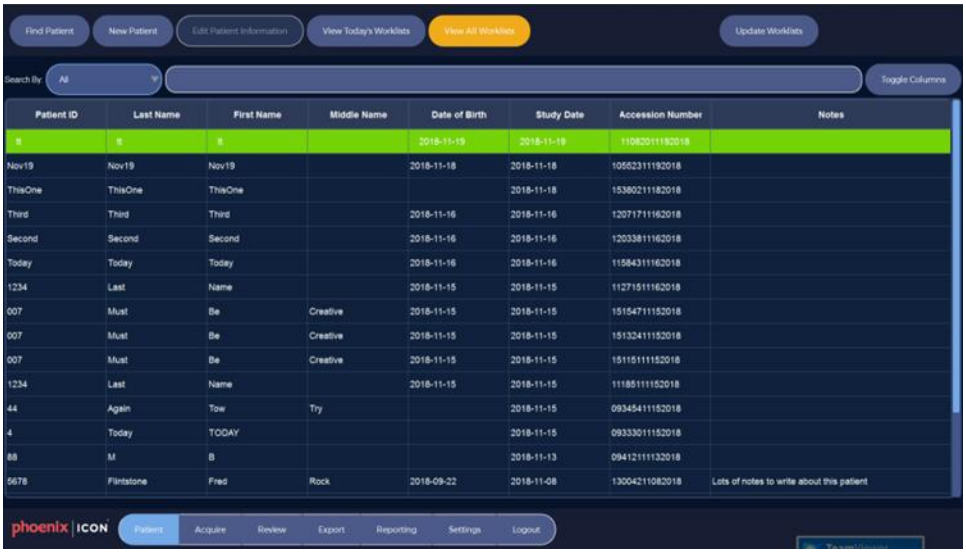
2. ***Viewing Today's Worklist:*** Click ***View Today's Worklist*** to list the imaging procedures to be performed today. Each procedure is associated with one and only one patient. Each worklist procedure is clickable. When you click on a procedure, the following actions are taken:
    a. If the associated 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 all the operator to capture images and videos of the corresponding Patient.

    After one or more images have been captured in the study, the worklist entry will be marked as 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.

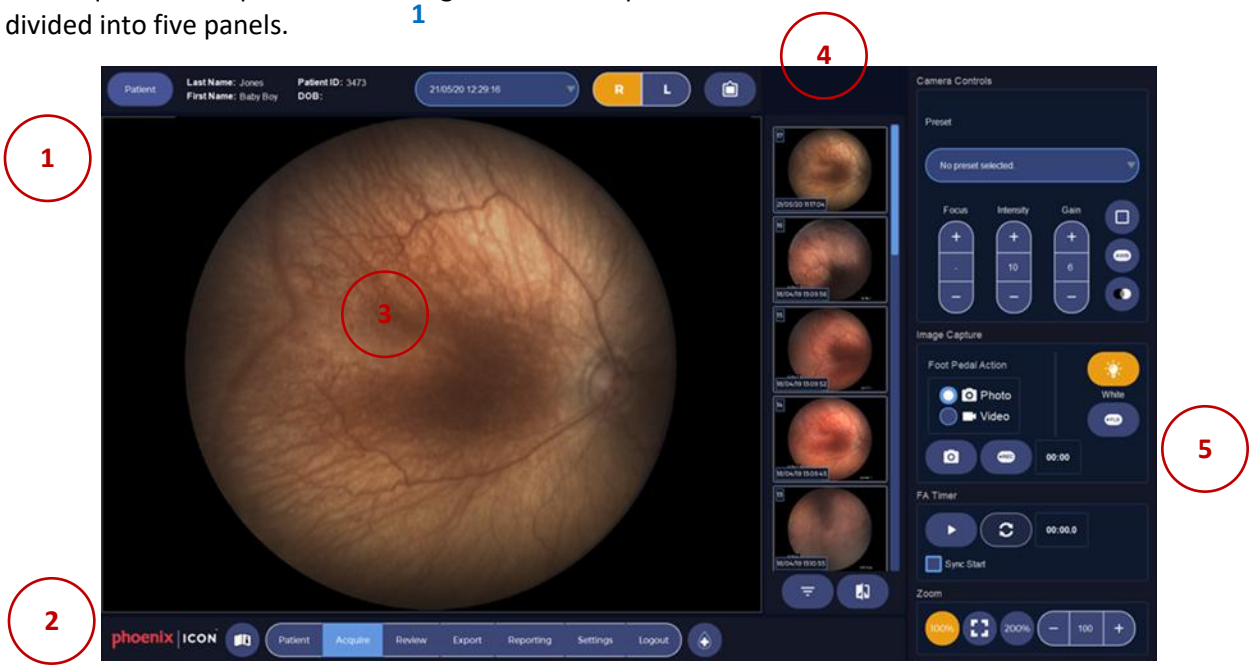


By initiating the image acquisition process from the View Worklist screen, you are associating the study with the recording of the provided accession number. When these images are later in DICOM format, or sent to a PACS using the ICONnect PACS connector, the accession number will be present, and this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

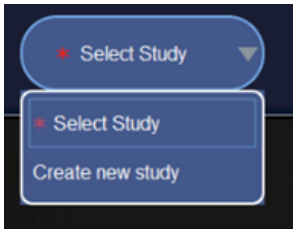
The Acquire screen presents the image and video capture interface for the ICON camera. The screen is divided into five panels.



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

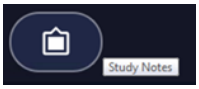
b. Select Eye

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**

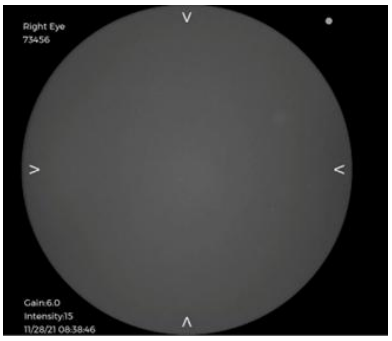
Panel 3 **Image Display Window**

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.

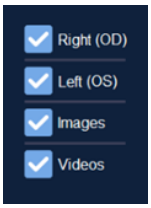
Panel 4 **Thumbnail Tray**

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

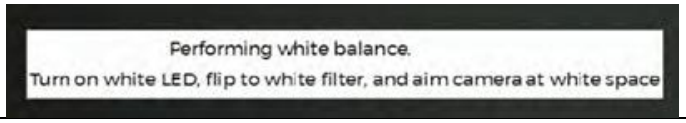
The ICON Software supports a full-screen mode in which only the live view of the camera image is displayed. In this view, all of the controls need to be accessed via keyboard shortcuts (set up on the Settings > Shortcuts screen) or the hardware controls (foot pedal, cart keypad).

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.

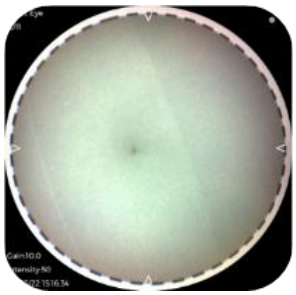
AWB (Adjust White Balance)

The ICON Cart 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.

HUOMIO: Valkotasapaino ei toimi oikein, jos intensiteetti- tai vahvistusasetuksia ei ole määritetty oikein. Automaattinen valkotasapaino ei myöskään toimi oikein, jos estosuodatin on paikallaan käsikappaleessa. Jos kuvat näyttävät epänormaalin punaisilta tai keltaisilta, varmista, että kameran ohjausasetukset on määritetty oikein ja että keltainen estosuodatin ei ole käytössä, ja suorita automaattinen valkotasapaino manuaalisesti.

HUOMAA: Käyttäjät voivat kytkeä automaattisen valkotasapainon manuaalisesti, jos järjestelmä on sammutettu tai siirretään eri valaistusympäristöihin kuvantamispäivän aikana. Kun käyttäjä on suorittanut automaattisen valkotasapainon onnistuneesti, ilmestyneeltä näytöltä voidaan poistua ja potilaan kuvantamisen valmistelut voidaan aloittaa. Muista säätää voimakkuus ja vahvistus potilaan kuvantamiseen tarvittaviin asetuksiin.

HUOMIO: Valkotasapaino ei toimi, jos estosuodatin on paikallaan käsikappaleessa. Jos kuva näyttää epänormaalin keltaiselta ja valkotasapaino ei toimi, varmista, että keltainen estosuodatin ei ole käytössä.

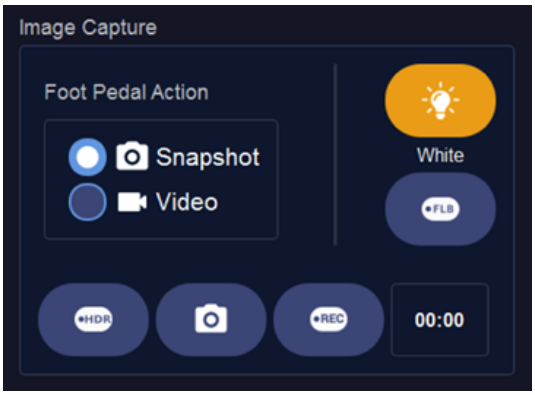
Greyscale

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.

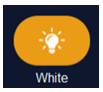
NOTE: A Greyscale by default option is available in the Settings screen should you want all fluorescein imaging to be captured in this mode.

3. Image Capture

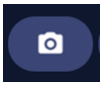
The Image Capture section of the System Controls is used to turn on the camera light, control the capture mode (video, photo, Flashback), determine which action is taken when the foot pedal capture button is pressed, and provide an on-screen means of capturing images. Each of the operations is described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



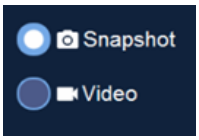
Turn the light illumination on, by clicking the light bulb button. The color of the light module inserted in the hand piece (white or blue) is labeled underneath. The illumination button also powers camera focusing. If it is off, there may be a live view on the screen, however the camera won't focus.



Click the *Camera* button to capture a photo.

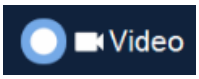


Control Foot Pedal Action. The selections on this panel indicate whether the Foot Pedal will capture a Snapshot or Video when the Foot pedal snap button is depressed.

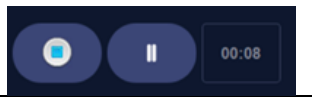


4. Video Capture

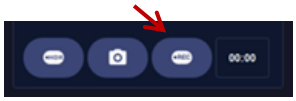
When the Video mode is selected, each time the Snap button on the foot pedal is depressed it will toggle between capture mode and pause mode. This enables you to pause the video capture if the view is not ideal, or you are no longer on the eye but have more areas to image. (Note that it is recommended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



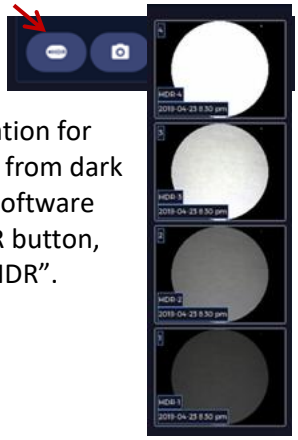
When you are finished capturing, click the Stop button on the software. This will prompt you to save your video. Still



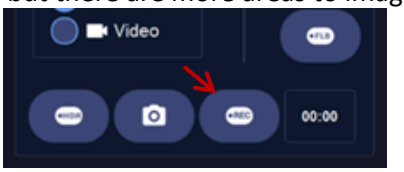
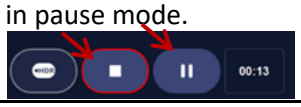
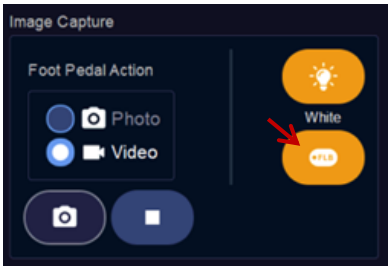
images (photos) may be captured from the video at a later time and the video may be deleted to save hard disc space.

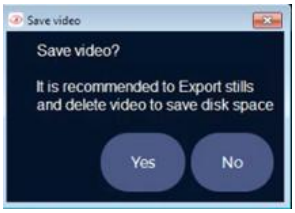


Record video using the software by clicking the Rec button. The duration of the video as it captures is displayed. Videos will be recorded using the Foot pedal if the Video capture mode is enabled. The maximum video length is two minutes which can be reduced in the Settings screen.



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”.

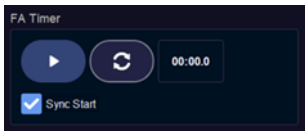
VIDEO CAPTURE MODES	
Normal Video Recording Mode (REC)	Flashback Mode (FLB)
When the REC video recording mode is selected, each time the Snap button on the foot pedal is depressed it will toggle between capture mode and pause mode. This enables video capture to be paused if the view is not ideal, the 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. 	 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

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.	automatically save after the defined number of seconds of video recording are complete.

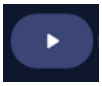
5. Fluorescein Angiography

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.

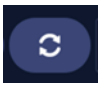
Because fluorescein angiography is a time sensitive series of images you can add a timer to the bottom right of the image using FA Timer controls. Timing of the test is also visible on the FA Timer controls.



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



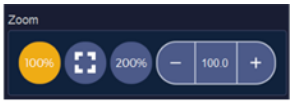
Reset FA Timer: Each stop of the Start Video button provides the option to save a video. During the next video capture, the timer will continue from the last stopped time unless the Reset button is clicked to return the timer to 00.00.0



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.

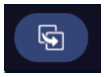


Quickly zoom to 100% or 200% zoom using the shortcut buttons. A 100% zoom will fill the frame vertically.

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.

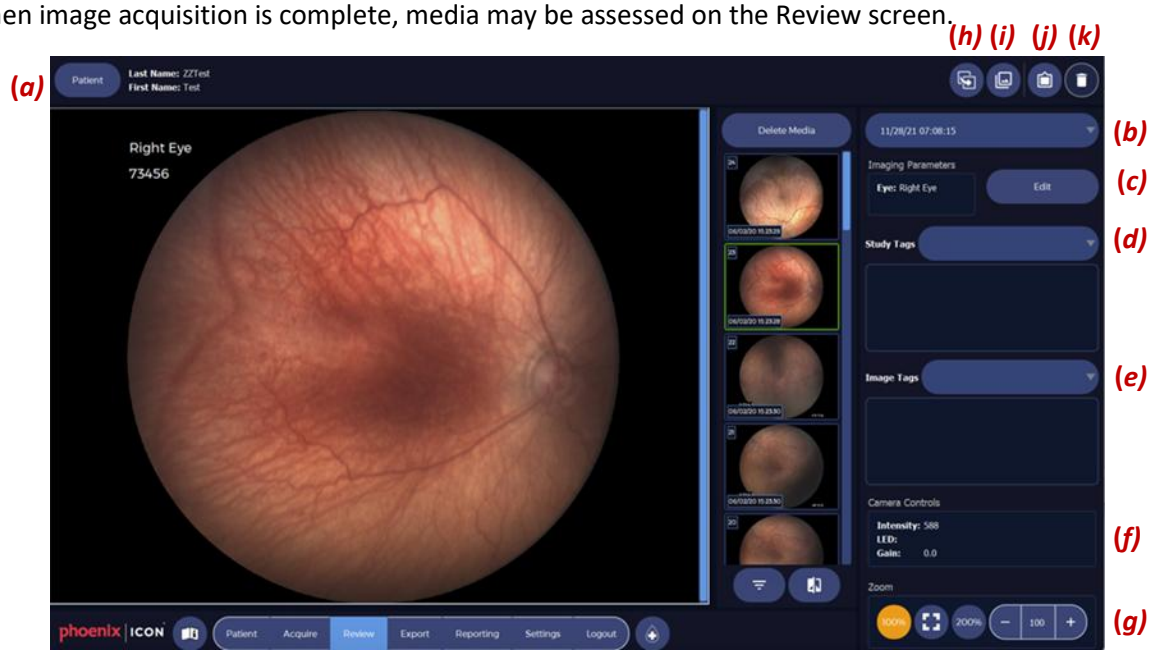
Quick Tip: It is possible to zoom captured images in Review mode. These zoomed areas may be saved as separate images by clicking Save Image as Copy.



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.

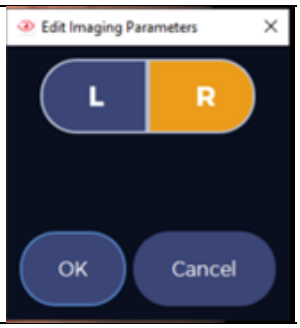


The following operations can be performed on the review screen:

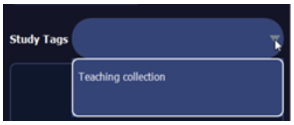
1. **Patient Name**: The name of the Patient is visible at the top left of the Review screen **(a)**. Click the Patient button to return to the Patient Screen to select a different patient to review.

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

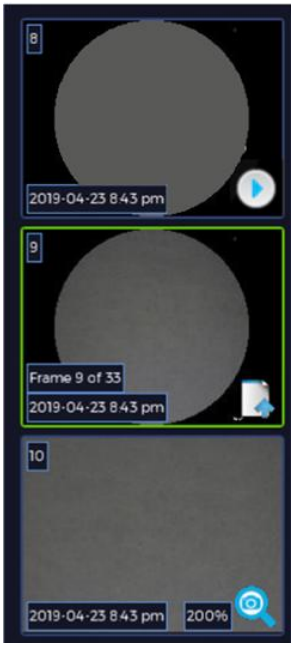
 Study Notes

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.

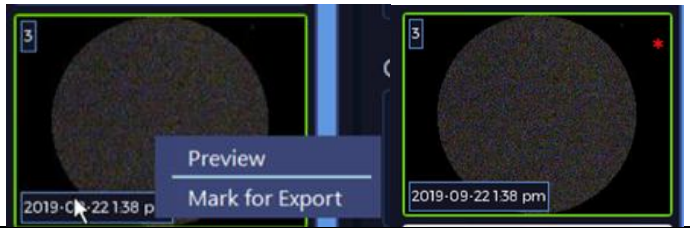


Videos: A thumbnail displaying a forward-facing blue arrow or “play” icon indicates a video has been captured.

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.

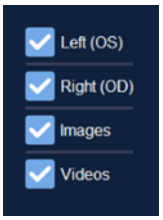
Copy of Zoomed Image: A blue magnifying glass icon on the bottom right of a thumbnail indicates that a zoomed version of the image has been saved. The degree of magnification is also displayed. This feature can be performed in the Review screen.

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.

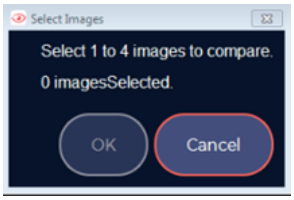
Quick Tip: When viewing the Thumbnail Tray, if some captured images appear to be missing, check the Filter to ensure all images are being shown**.**

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.

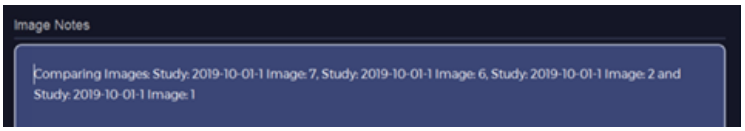
d. Each image is presented with Zoom Controls, allowing the operator to zoom in to areas of interest. Once zoomed in, the image may be panned to move to other areas of the frame. The size of the windows in the compare mode can be adjusted so that all images don’t have to be the same zoomed magnification. 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

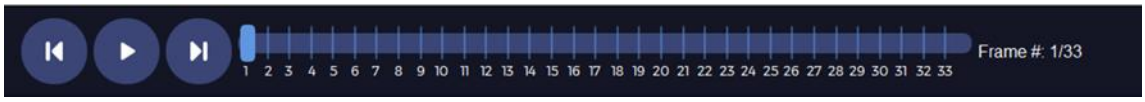
NOTE: It is not possible to compare videos or still photos of compared frames.



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.

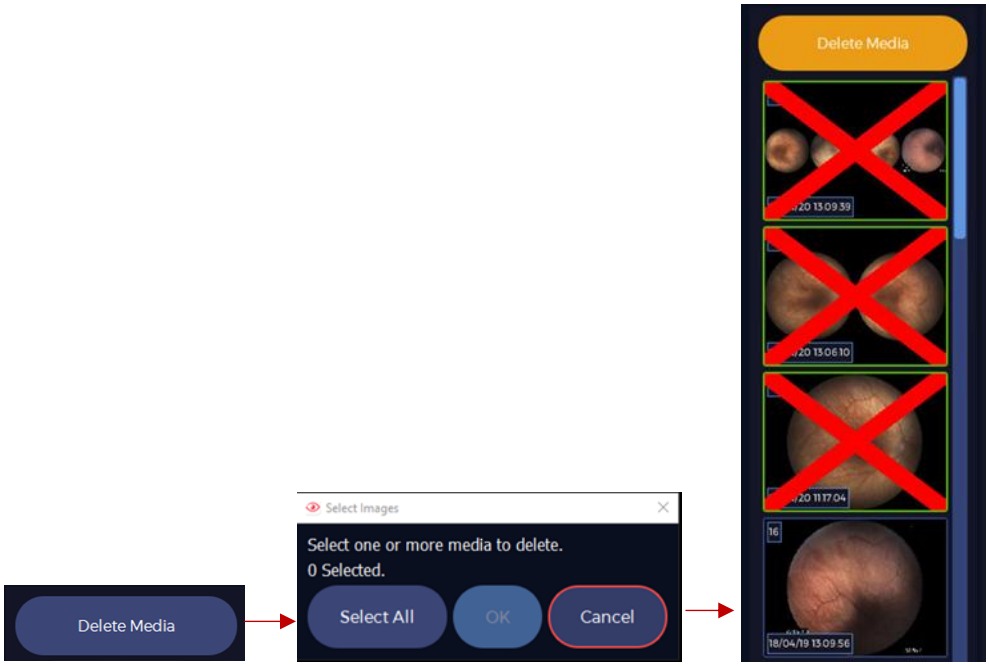
Save a Frame: To capture a still photo, advance the video to the desired frame and click the Save a Frame button. The new image will appear in the Thumbnail Tray.

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

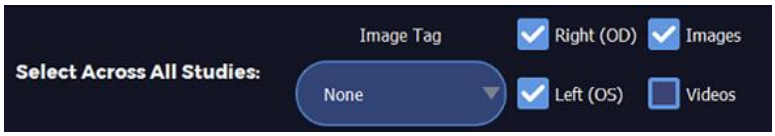
Two buttons at the top of the screen allow the operator to *Search by Patient* or *Search by Study Date*:

- 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.

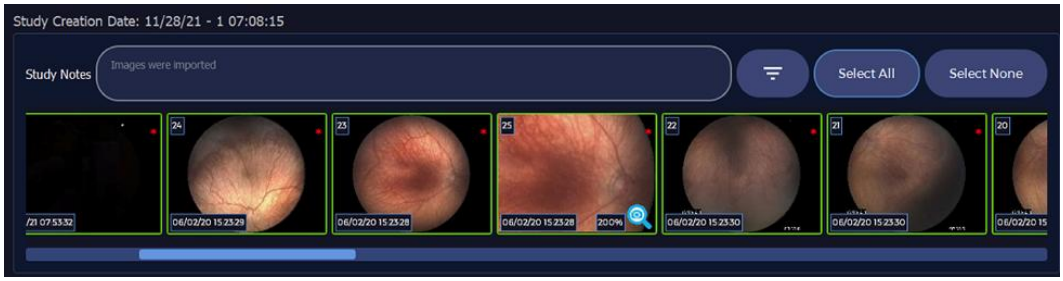
Export Video: There are several ways to select the images or videos to export:

a. Select Across All Studies.



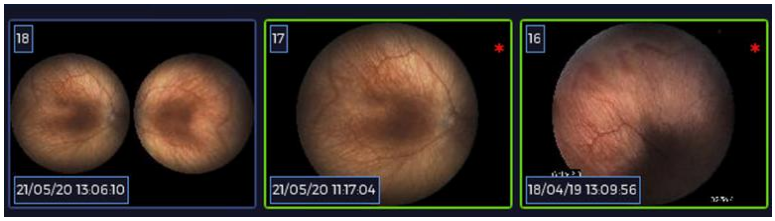
   i. Once a search result by Patient of Study Date populates the Export screen, additional filtering may be done.
   ii. Mark the check boxes for Images/Videos as well as for the eye you want to export. You may further filter the selection by making a selection available in the Image Tag dropdown.

b. Select images in an individual study



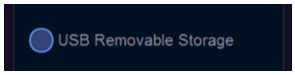
Use the filter button, Select All or Select None to choose images or videos across a single study date.

   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.

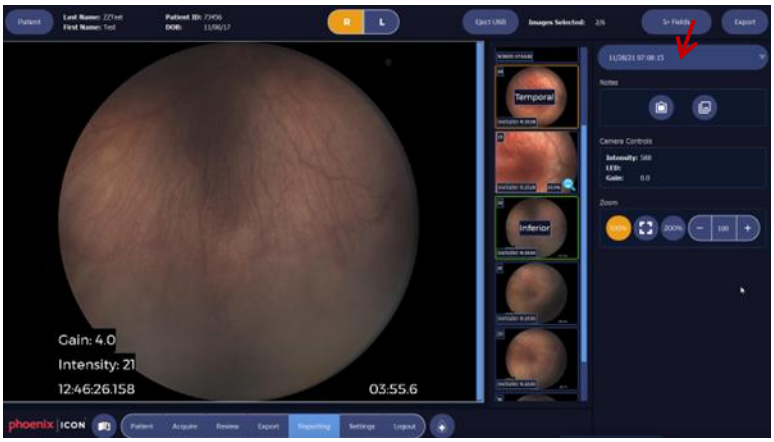


e. Finally, click the Export button to initiate the export or archive operation. A progress dialog box will be displayed while the images are copied.
f. Exported selections will remain selected after export so that a 2nd file type may be exported without having to re-select images. To deselect images 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.

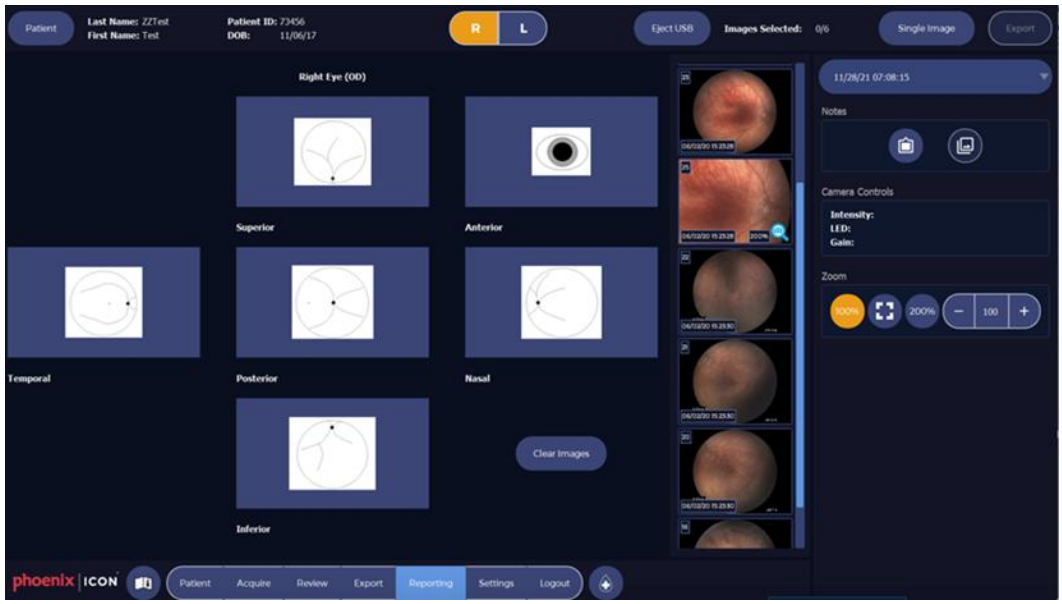
8.8 Reporting

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 seven 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 ,

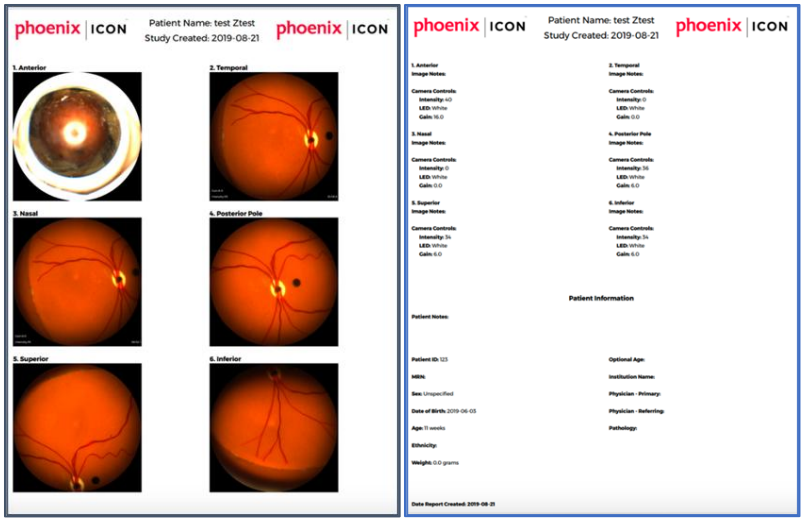
and montage. Drag and drop the appropriate image to the image placeholder to complete the set of 5 fundus.



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

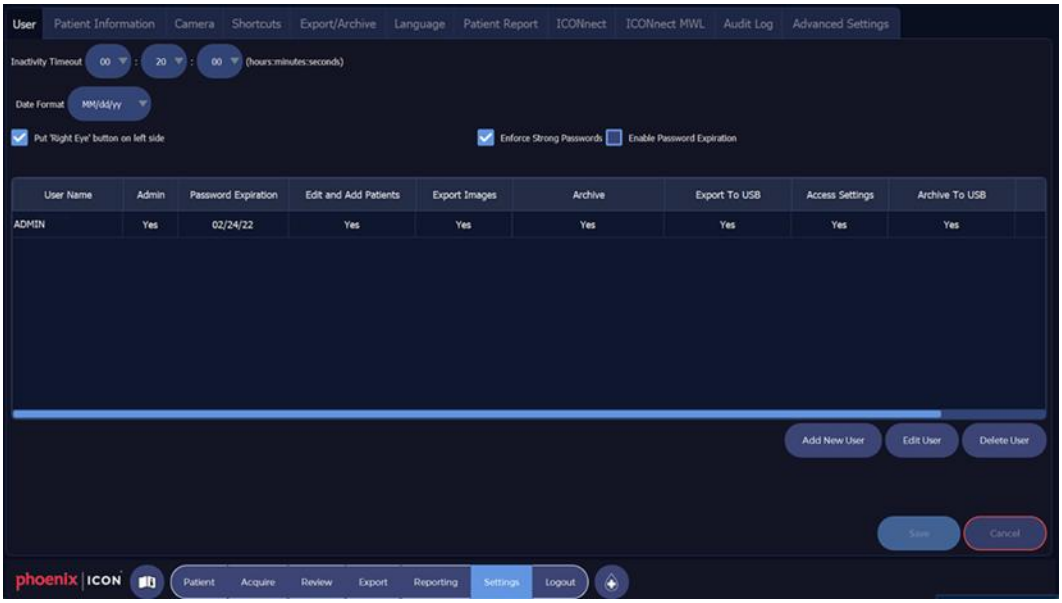
Create Password:

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



Inactivity Timeout

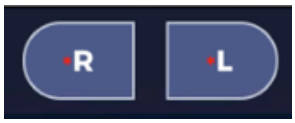
This setting controls the timeout period for all User sessions. The software will timeout and return to the Login screen after the specified duration indicated in hours / minutes / seconds.

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.

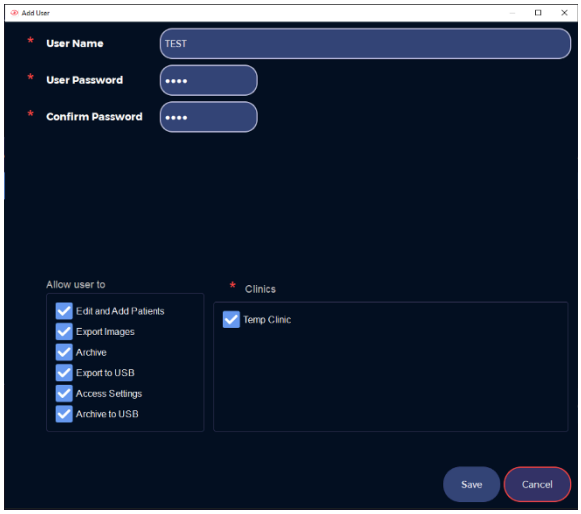
When this option is **checked**, strong password rules apply to **all** passwords. Strong passwords must meet the following conditions:

- 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.

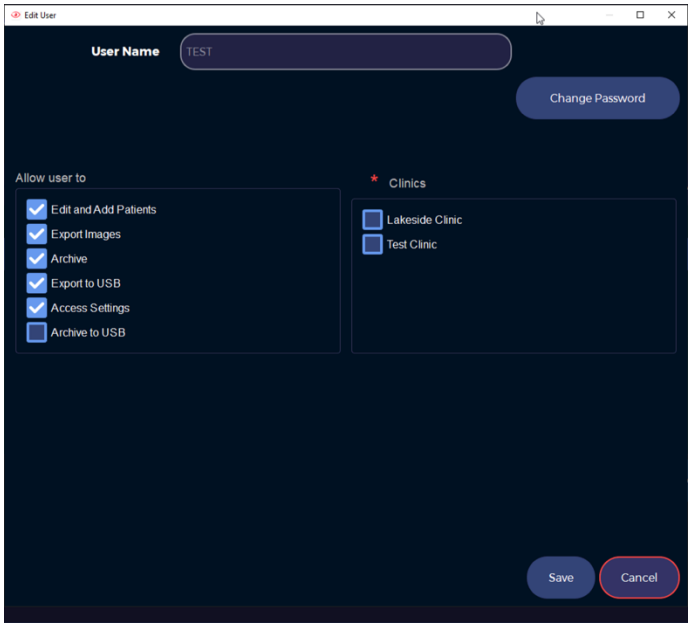
- Edit and Add Patients
- Export Images
- Archive Images
- Export to USB
- Access Settings
- Wipe Database

- 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

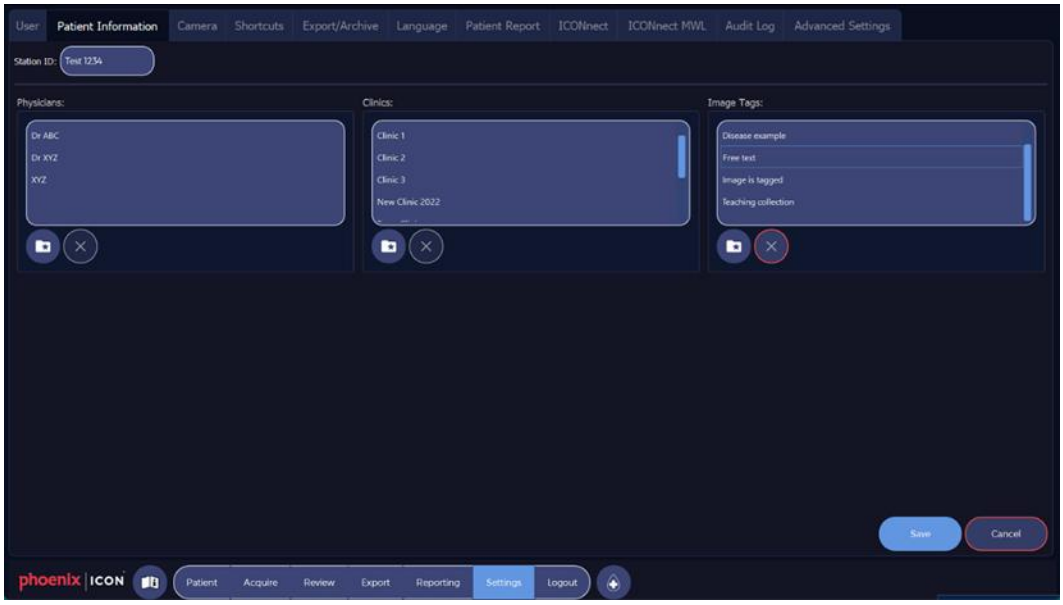
The ***Patient Information*** tab is used to confirm that Station ID for this ICON system, set the list of physicians that can be associated with a given Patient, and set the list of Clinics that can be associated with a Patient or a User.

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 special user ADMIN can see all Patients, regardless of the Clinic chosen at login.

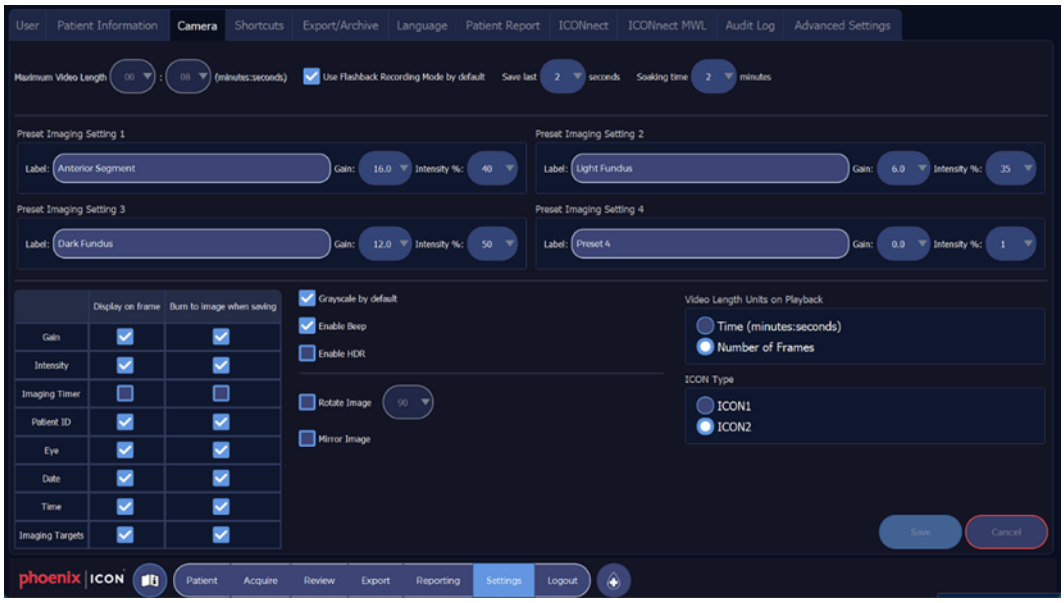
To add a clinic, click the ***Folder*** button under the Clinics field. A new line will appear in which you will type the name of the new Clinic. Press the return on the keyboard to save the entry. Clinics are assigned to Users on the Users tab.

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 in the Patient screen as well as in 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.

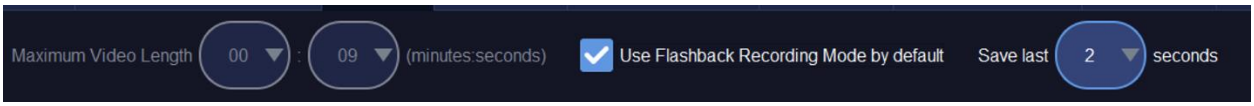


Maximum Video Length

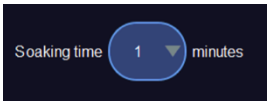
Select the maximum length, in minutes and seconds, of a captured video. Note that each minute of video consumes 4.2 GB of data.

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

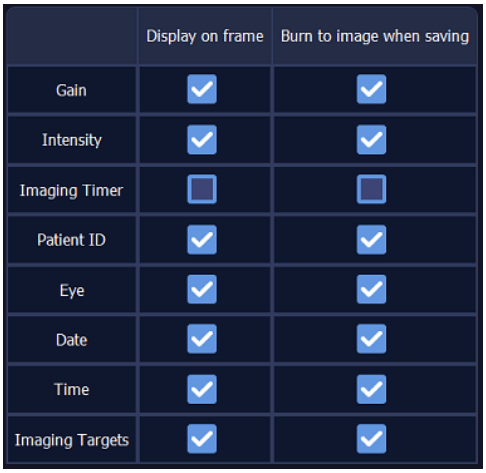
Four ***Presets*** for camera exposure can be set. These appear on the Acquire Screen and speed setting the camera for different imaging scenarios. For each present, assign the name that will appear in the dropdown, and select the Gain and Intensity associated with the preset label.

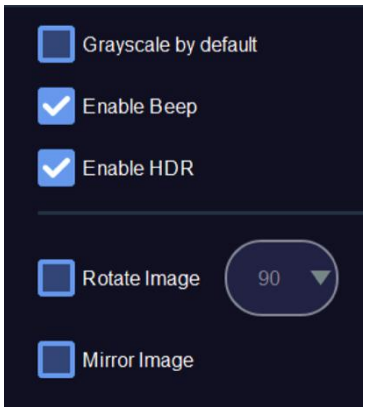
Frame Information Display

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.

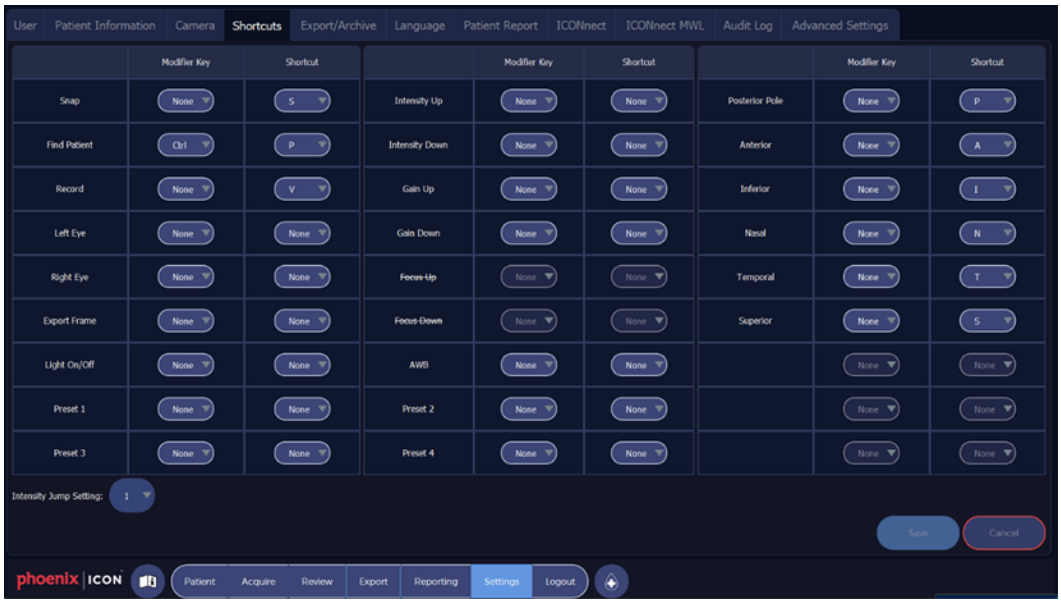
Rotate Image: When using the ICON camera, the expectation is that the operator approaches a supine patient from the top of the head. Thus, the standard orientation of the camera should be so that the hand piece cable comes towards the user at the midline of the patient's forehead. The **Rotate Image**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

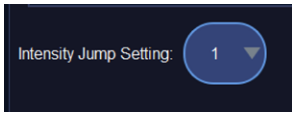
ICON Type sets the version of ICON camera hand piece installed on your system.

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.)

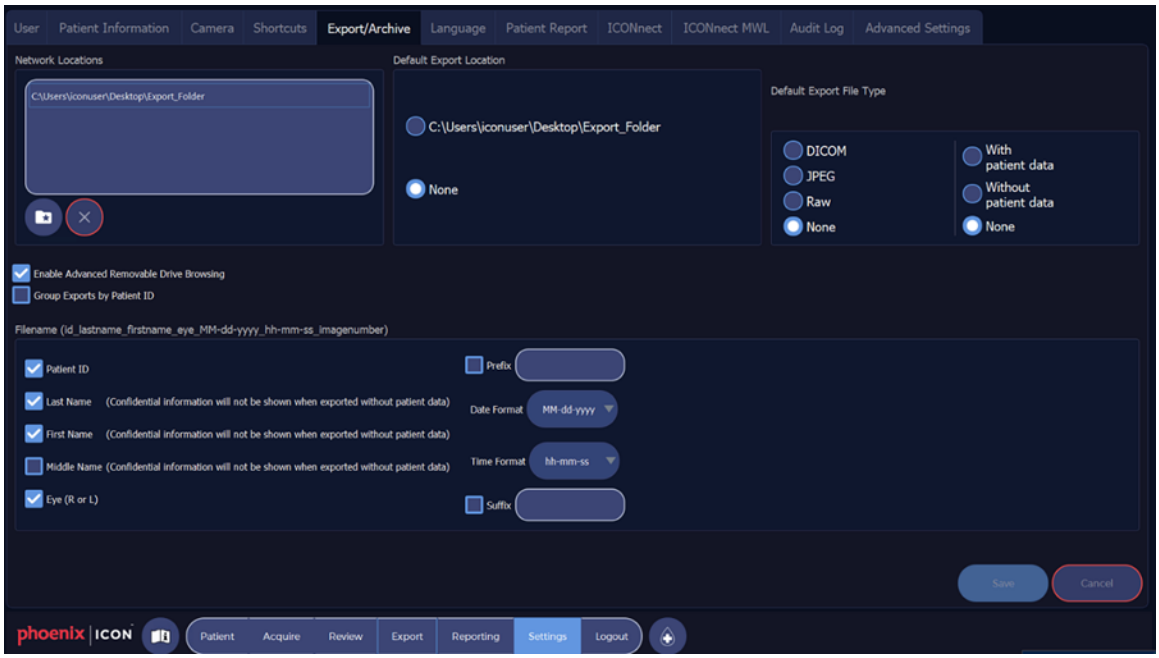
To remove a location from the list of Network Locations, select a location on the list and click the ***X.***

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:

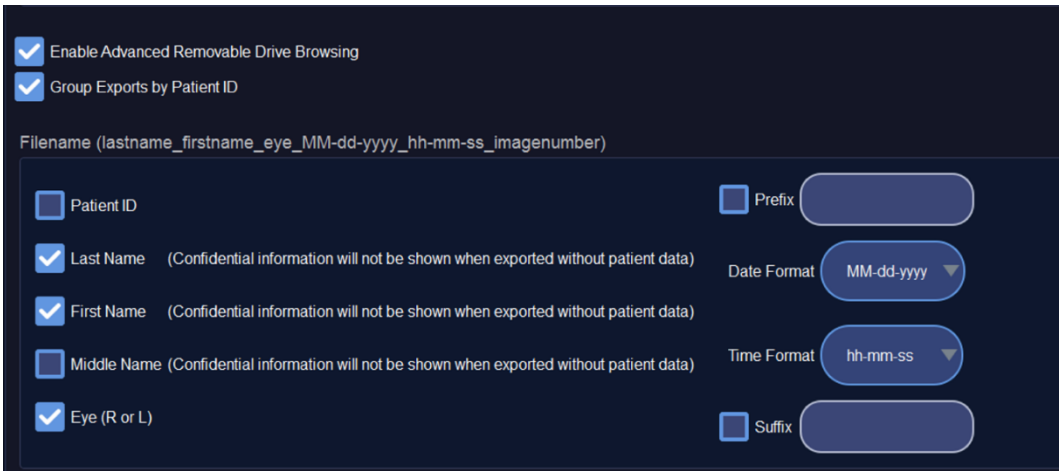
Select from the available options to make a File Type pre-selected when an Export action is being performed. Choosing None means the user must select a file type with every export.



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.

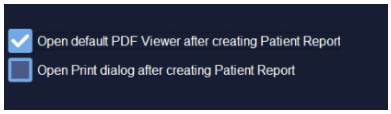


8.9.6 Settings: Language

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.

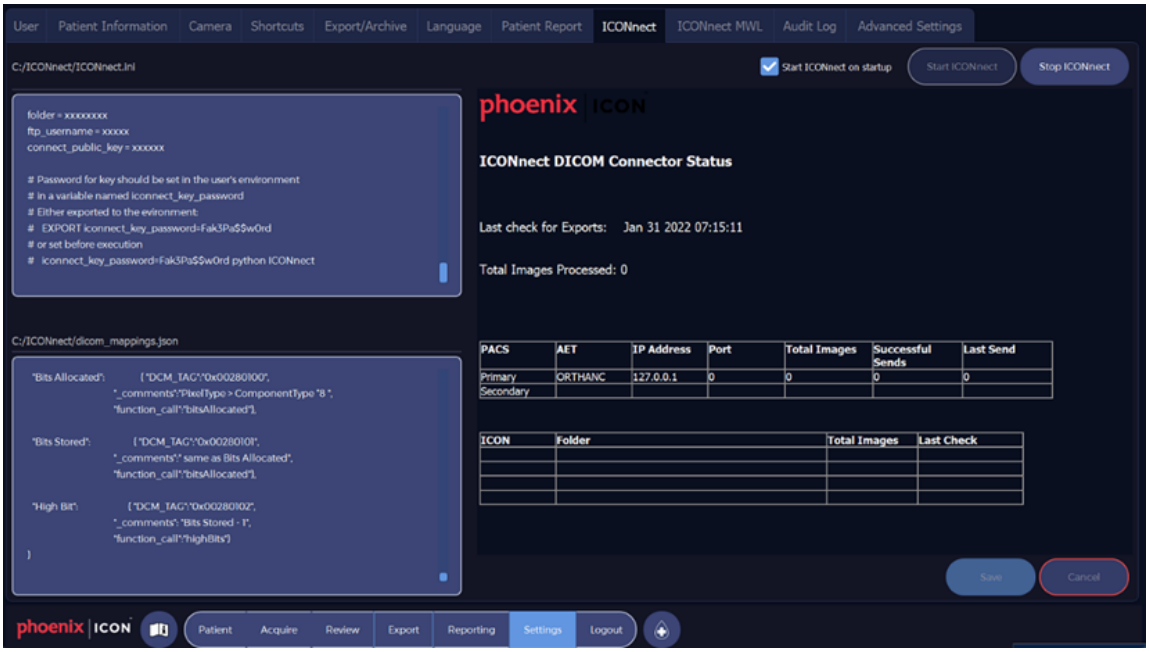
8.9.7 Settings: Patient Report

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 Neolight (parent company of Phoenix Technology Group)
- Study Instance UID:
    - OID, plus
    - Numeric digits of the ICON Cart Serial Number, plus
    - Study ID generated by the ICON Software

- Series Instance UID:
  - Study Instance UID, plus
  - '.1'
- SOP Instance UID:
  - Series Instance UID, plus
  - Image ID generated by the ICON Software
- Instance ID:
  - Station ID from the ICON Software, plus
  - Study ID generated by the ICON Software

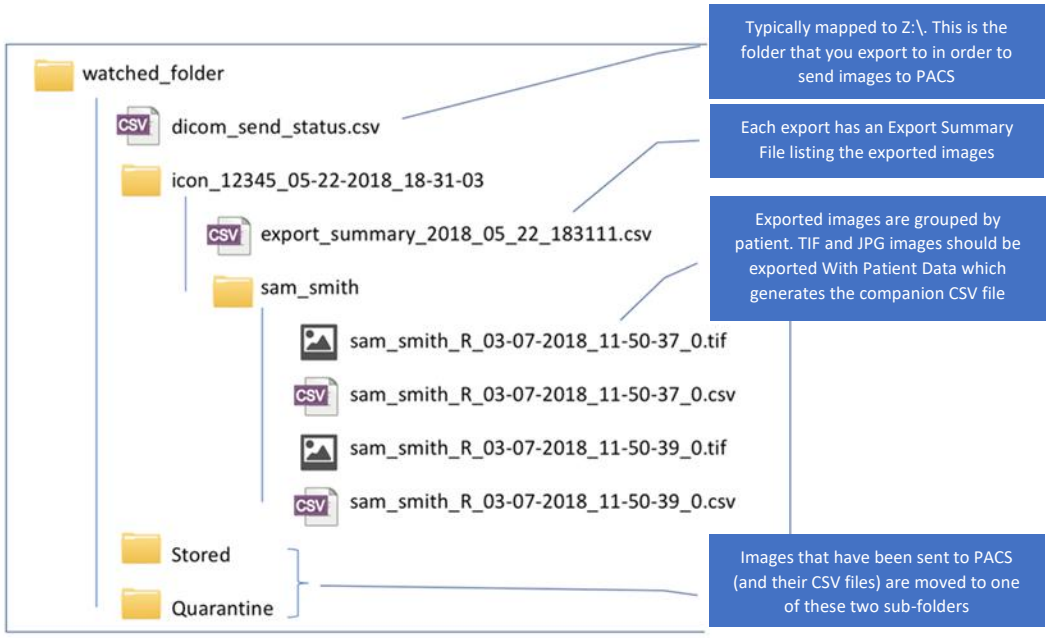
ICONnect Folder Structure

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 **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.

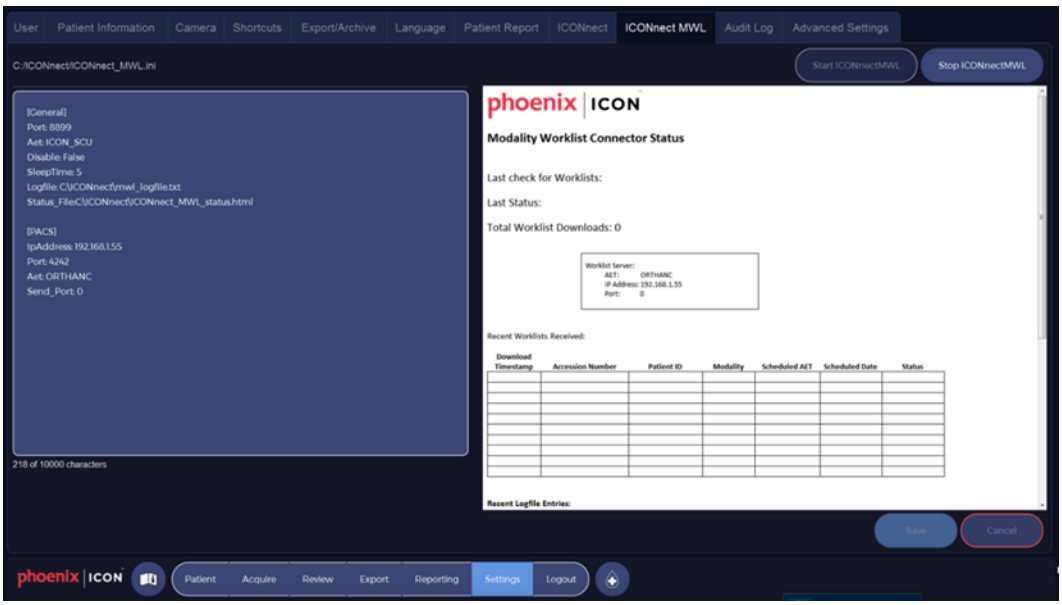
IpAddress:	Values: valid IP address This is the IP address of the PACS
Port:	Values: integer port number Connections to the PACS will be made on this TCP port
Aet:	Values: text string This is the Application Entity Title of the PACS
Send_Port:	Values: integer port number This is an optional parameter. 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

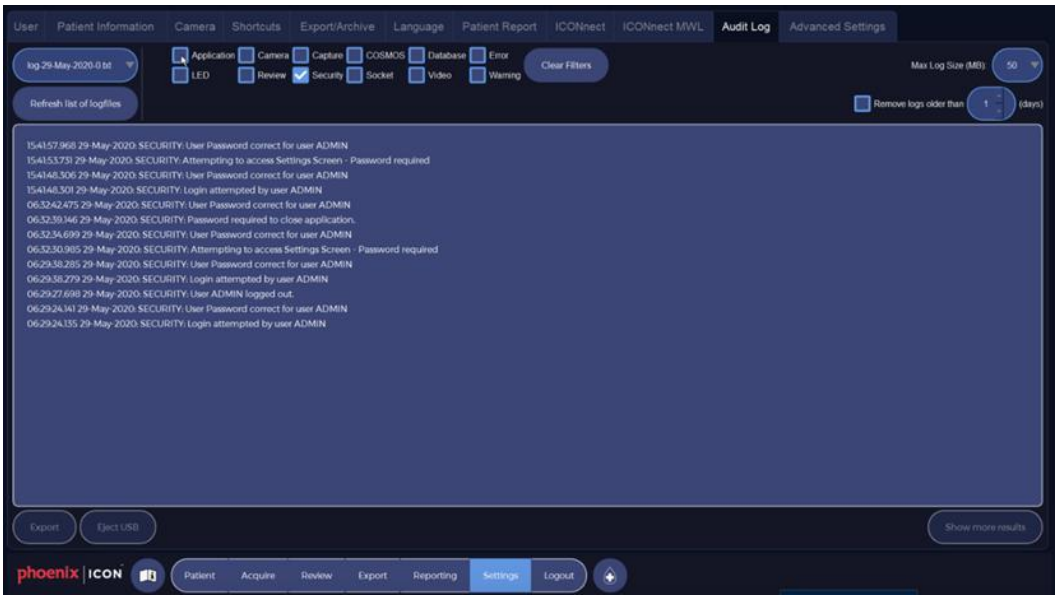
The status screen found in the righthand pane of the settings page for ICONnect MWL provides a frequently updated status view of the ICONnect MWL connector companion application. When displayed, it is updated every 5 seconds and shows:

- **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).

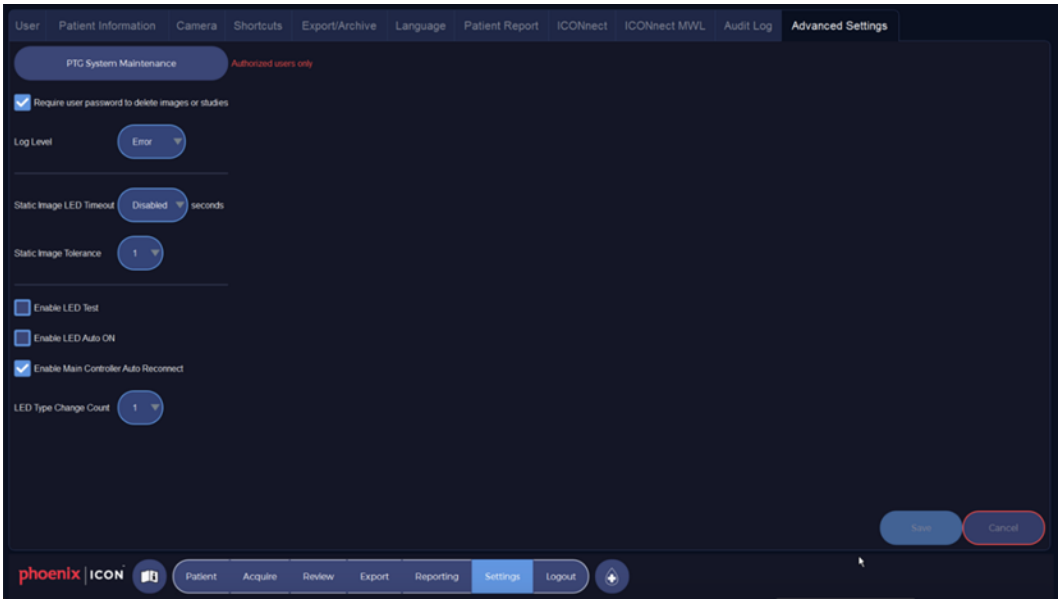
Export Log: Click the ***Export*** button to export the currently displayed log file. Logs are exported to a removable thumb drive for use in analysis by external systems. The operator will be promoted to select a folder for the export. Exported log files are named with the date of export.

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.

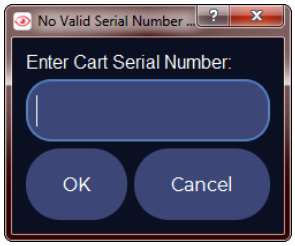
Operating System Updates

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

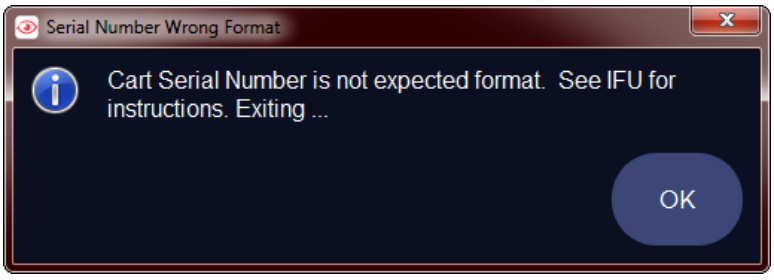
This setting is not within the Settings screen and is used for troubleshooting.

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:

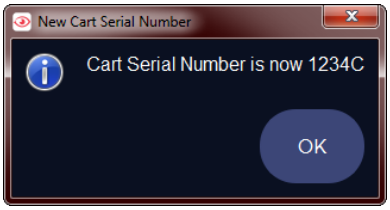


The system does a pattern match for 4 valid numbers in a row followed by either a “C”, “P”, “c”, “p”, or “ “ (a space).

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.

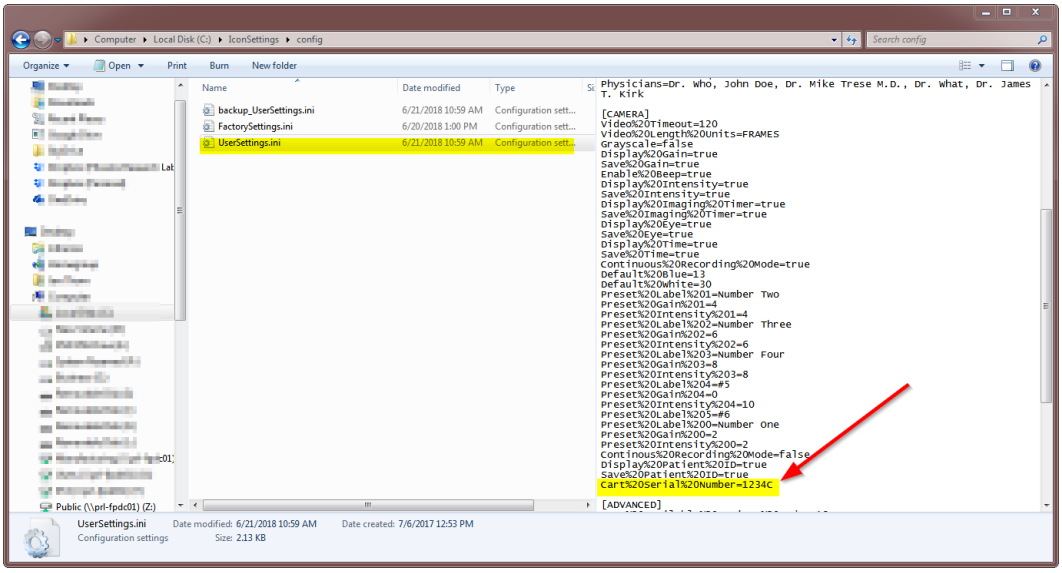


8.9.14 UserSettings.ini

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”):



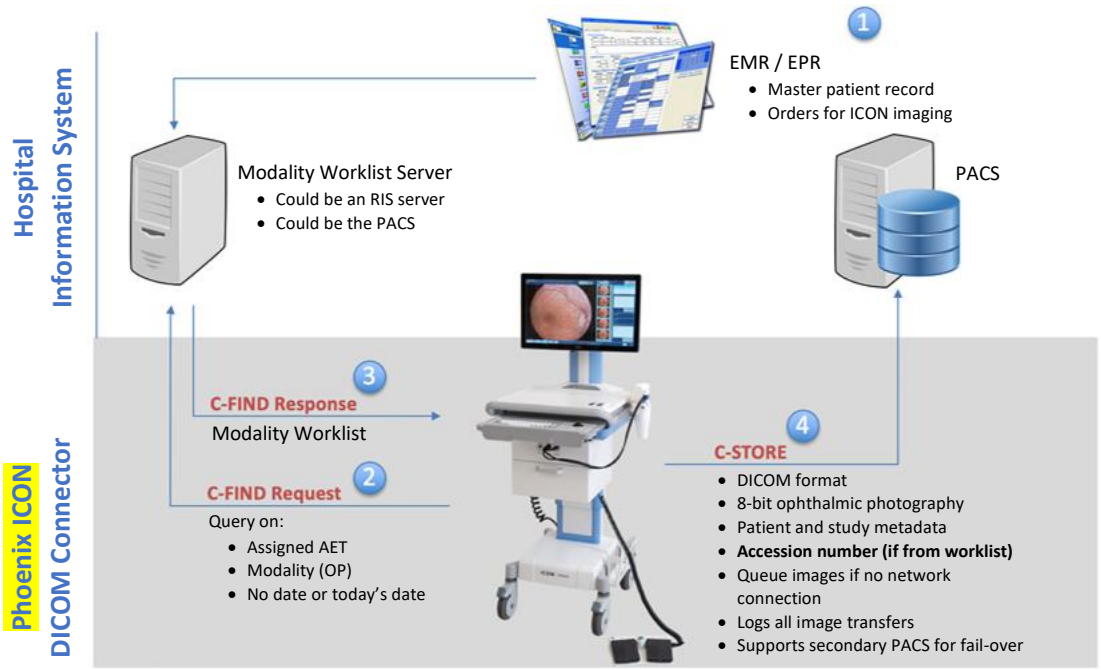
The field can be manually modified from here if needed.

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 setup these features. Note that downloading a modality worklist and exporting to a PACS can be configured and used separately or together.



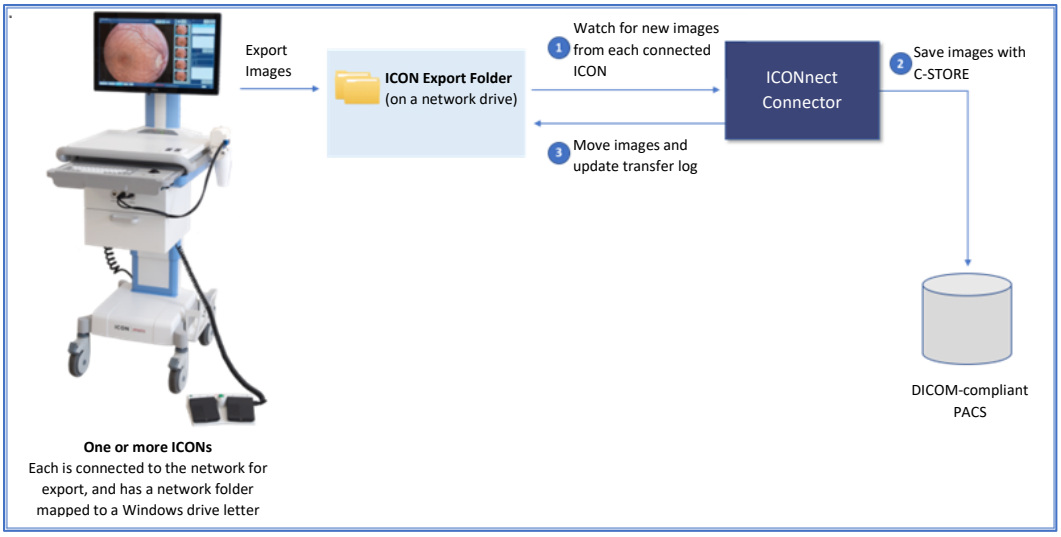
The diagram above describes a typical DICOM integration. In this workflow:

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

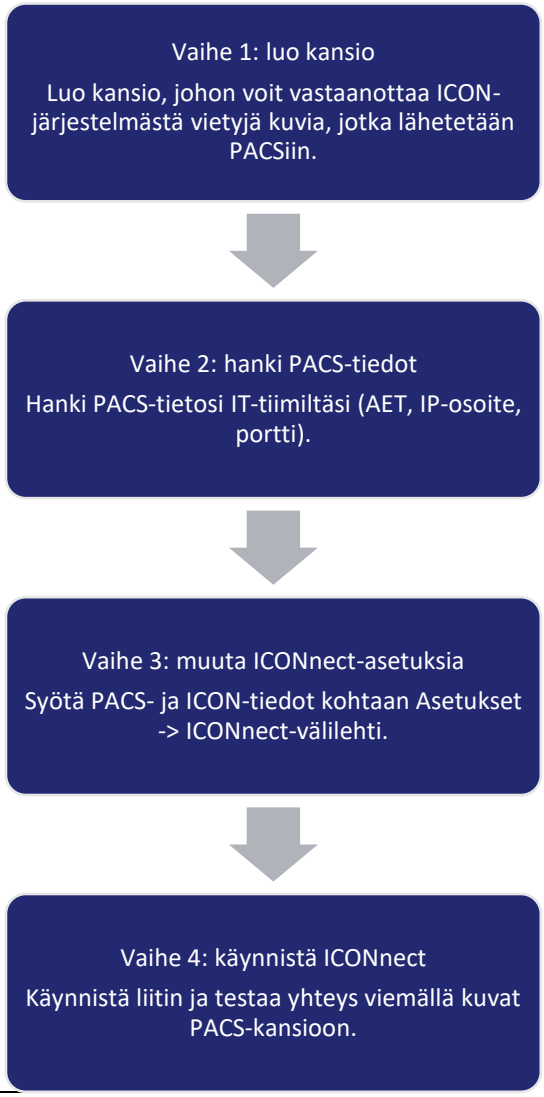
The ICON camera software has the ability to export images to a folder. In addition, the software comes with a built-in DICOM connector that can watch a file folder, and when it sees an export from the ICON software, it retrieves the exported images, packages them, and sends them to a connected PACS.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



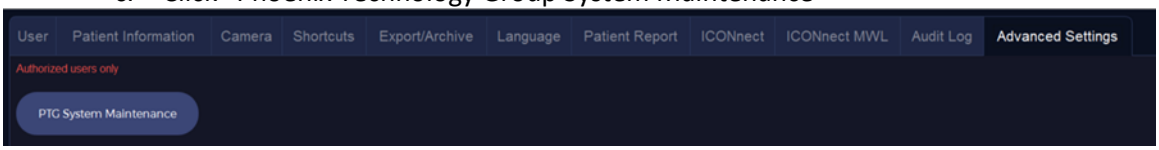
The connector to send images to a PACS is called ICONnect. Settings and the status log for ICONnect can be found on the Settings tab of the ICON software.

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

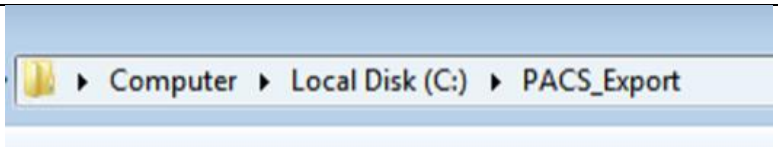
Note that there are a number of more advanced settings and parameters that can be used to adjust ICONnect to fit the configuration of your PACS, and those are described later in this manual.



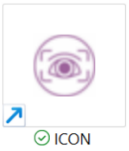
1. To get to the desktop, on the ICON camera
    a. Go to Settings -> Advanced tab
    b. Enter your password (note this requires the Settings permission for your username)
    c. Click "Phoenix Technology Group System Maintenance"



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.



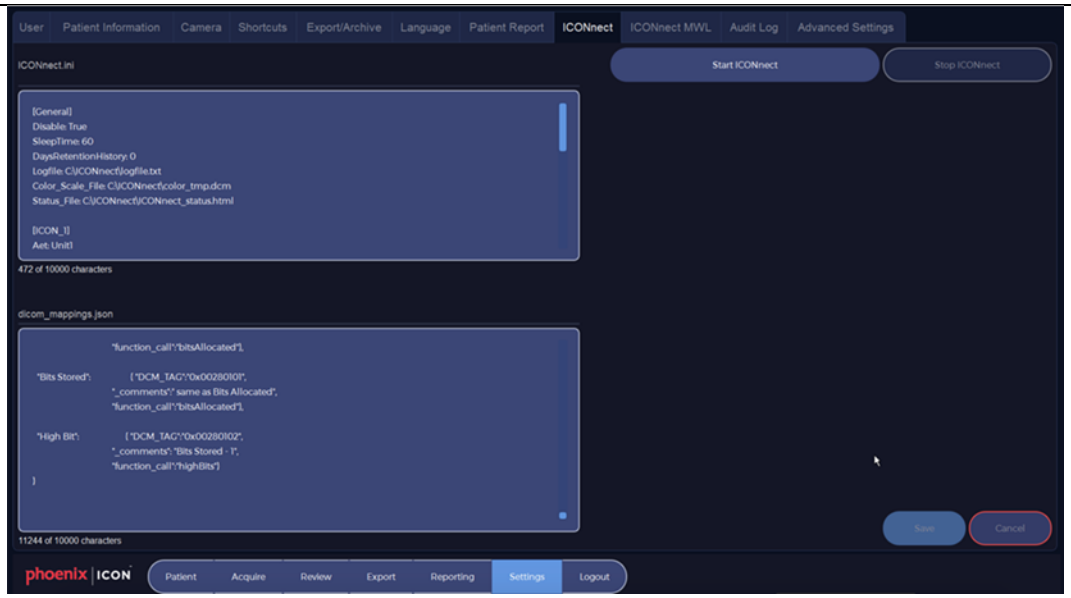
3. You'll need to get this information from your PACS administrator:
    a. The AET name that you should use for the ICON camera
    b. The AET name of your PACS
    c. The IP address of your PACS
    d. The port number of your PACS
4. Restart the ICON software if it's not already running by double-clicking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

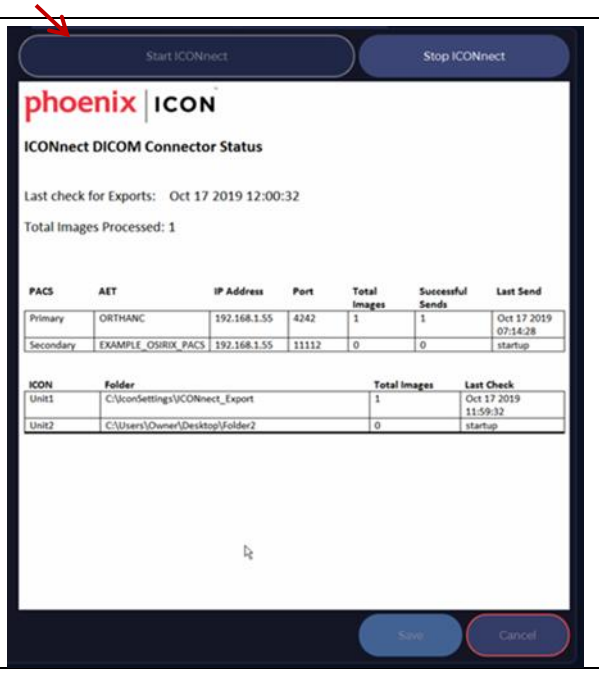
[PACS_2]
Server
pacs_aet =
ip_address =
pacs_port =
# Client
sending_aet = ICON_SCU
folder = C:\Users\iconuser\Desktop\Export_Folder

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

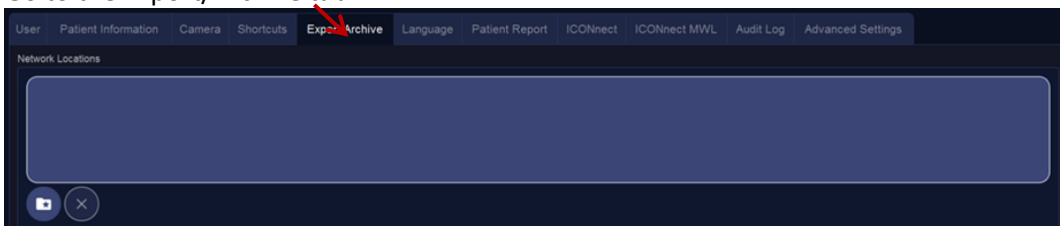
```
transfer_syntax = ExplicitVRLittleEndian

# 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

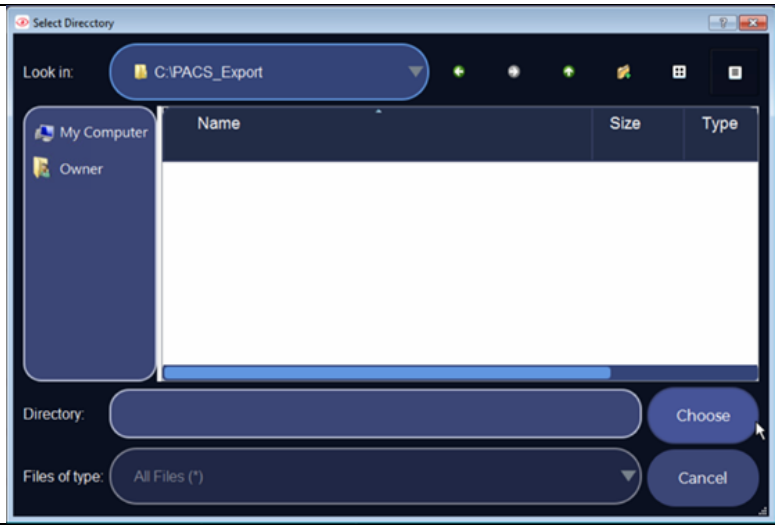
9. Click Start ICONnect



10. Go to the Export/Archive tab

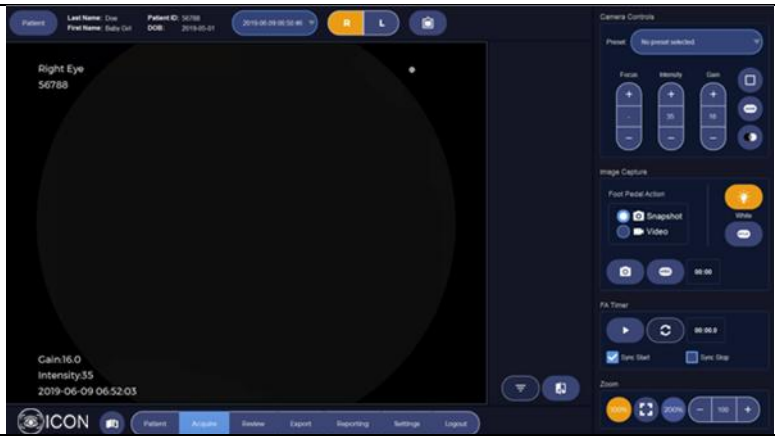


11. Add the PACS export folder to the list of valid export destinations

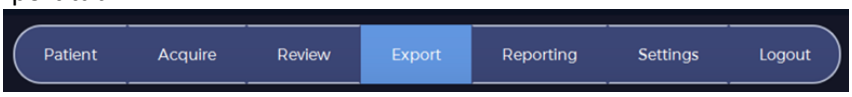


12. Click Save

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

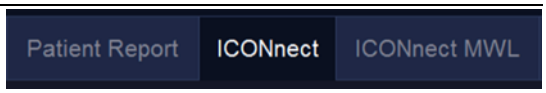


15. Select one or more images to send to the PACS:

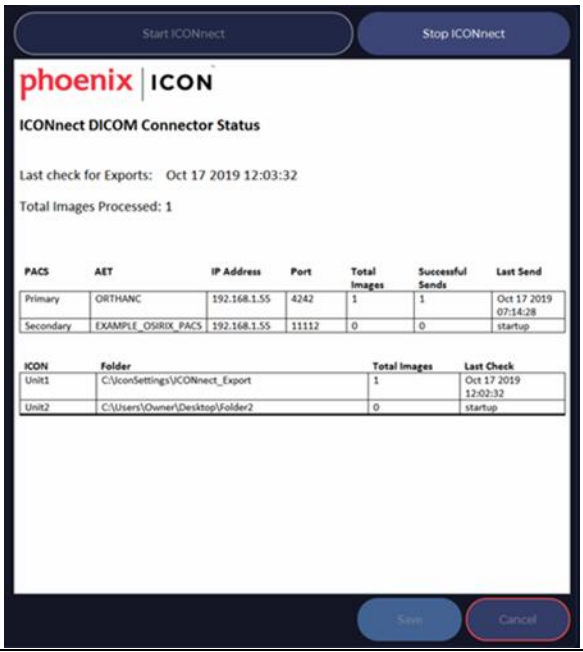
    a. Select the image(s)
    b. Select DICOM as the image format
    c. Select the PACS export folder
    d. Click Export
    e. Click OK

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

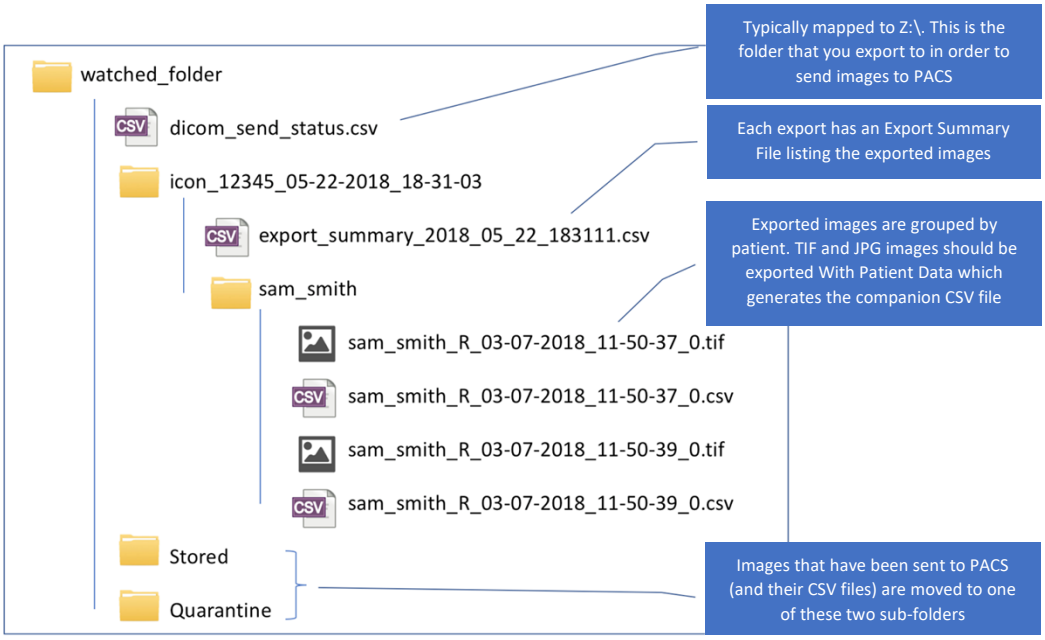
PACS Export Folder Structure

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

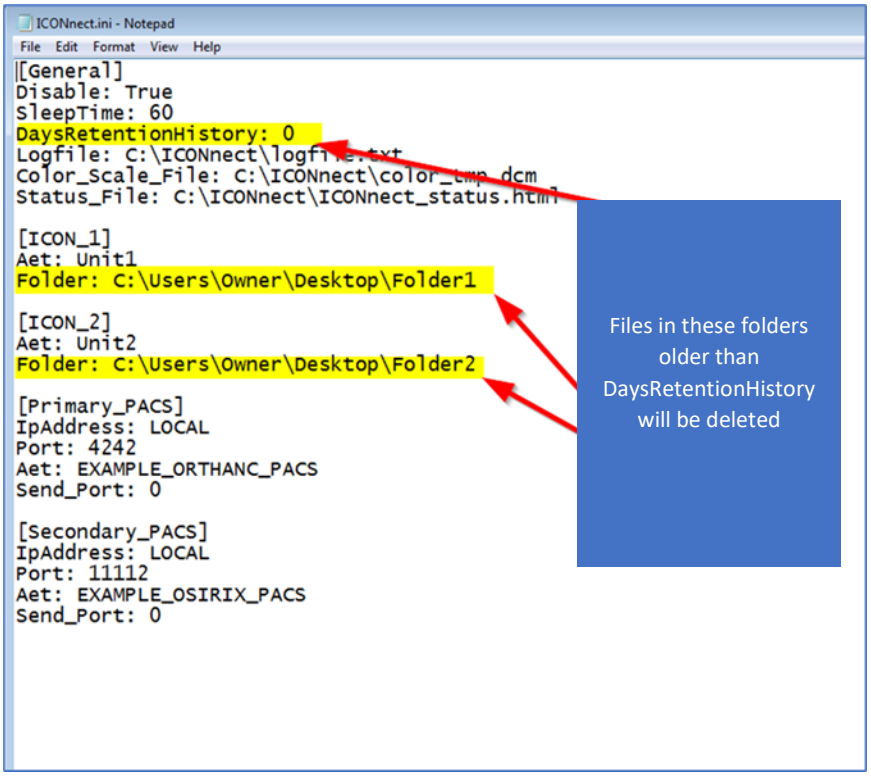
In the *iconnect.ini* file, you setup the pathname to the folder that will receive image exports. We call this the watched folder. This folder is mapped to a drive letter on the ICON system to make it easy to access. In the ICON software, you setup this folder as one of the targets for exports.

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.

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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

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

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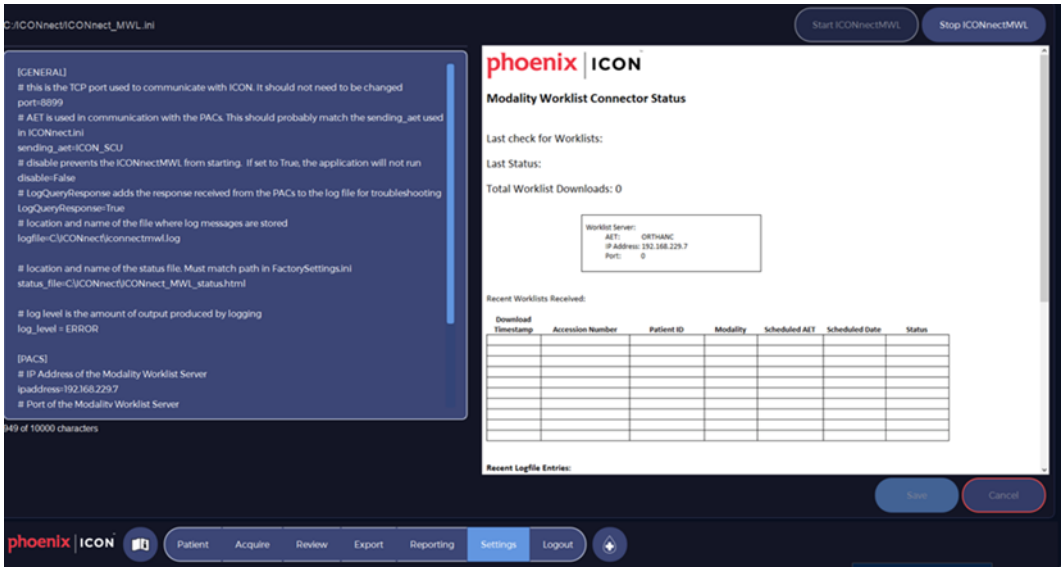
3. Go to Settings -> ICONnect MWL. (You will be required to reenter your password.)

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 (Model Number: PCI 40-1000) comprises 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 Cart Control Box	PCI 40-1003	
ICON Cart and ICON Control Box	PCI 40-1001	
ICON Camera Holster Assembly Kit	PCI 40-1046	
Cart AC Cable	NA	
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 Phoenix ICON may reduce treatment efficacy. Phoenix Technology Group LLC declines all responsibility for any damage or consequences resulting in using unauthorized parts with our Phoenix ICON

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 Phoenix ICON System to be free from defects in materials and workmanship for two years. Phoenix Technology Group, LLC. will repair or replace such product or part thereof which, upon inspection by Phoenix Technology Group, LLC. is found to be defective in materials or workmanship. As a condition 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 Phoenix ICON 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 Phoenix ICON 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.

Phoenix Technology Group, LLC

Chapter 11: Customer Service:

Don't hesitate to get in touch with Customer Service if you need assistance setting up, using, or maintaining your ICON 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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