C.A.R.E.S.

by neolight

ICON™ Ophthalmic Imaging System

NeoLight is a modern medical device company that engineers, designs, and manufactures technologies that treat infants with life threatening medical conditions. Our mission is to reinvent newborn health care through empathy-driven solutions.

Table of Contents

C.A.R.E.S.
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General Product Information

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The ICON™ Ophthalmic Imaging System allows your hospital system to offer each patient access to high-level ophthalmic imaging while remaining in the care of the Neonatal Intensive Care Unit (NICU) and other vital pediatric care units. Having the ICON within your hospital based neonatal and pediatric eye imaging program allows you to offer best-in-class patient care while collaborating across specialties.

The objective of the NeoLight **C.A.R.E.S.** (**C**ontinuing **A**dvancements and **R**esources in **E**ducation **S**upport) toolkits are to offer helpful reference tools and clinical guidance to physicians and staff who utilize NeoLight products. It is not intended to offer medical advice and does not preclude the necessary assessments, judgements, and medical determinations that are the exclusive responsibility of the physician. The information provided in this document is based on clinical and peer recommendations in all medical fields as it pertains to neonatal and pediatric eye imaging.

Our mission for this NeoLight C.A.R.E.S. kit is to provide a fundamental outline of neonatal and pediatric eye imaging to support facilities in successful integration and use of the ICON for screening infant and child eye diseases.

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NeoLight is a medical device company that markets empathy driven, best in class solutions for treating correctable and preventable conditions in the newborn care market. The ICON™ Ophthalmic Imaging System is the next generation in general ophthalmic imaging for retinal, corneal, and external structures of the eye. The ICON uses direct illumination and a patented optical design to produce amazing high-resolution and high-contrast retinal images – especially on darkly pigmented fundi.

ICON Innovative Design Features:

A wide-angle, hand-held retinal imaging system that delivers stunning, high-resolution, high-contrast images – on both light and dark retinas.

Advanced Illumination & Optics

- Capture clinically useful information even in less-than-ideal scenarios.
- High contrast & high-resolution images.
- Reduces haze in dark retinas.
- Eliminates central dark spots in "poor dilation" cases.

Patented Optics Innovation

- Directly introduces light through the optical system.
- Delivers even illumination utilizing less light.
- Allows for less scatter & reflection reducing haze & glare.
- Preview the posterior pole without touching the patient

Advanced Software Innovation

- Multi-mode adjustable focus & intensity.
- Patented 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.
- Constantly buffering Flashback video Function. When the operator sees the perfect frame, they can initiate a capture which will save the current frame and the prior few seconds to help ensure that the best frame is available upon review.

Improved Image Capture with Advanced Hardware

- Cart & portable options utilize the same software and handpiece.
- HD touchscreen monitor on both the cart and portable options. detachable screen with the go.
- Image on battery for 6-hours with both the cart and portable options.
- Built-in infection control log.
- Motorized height adjustment with the cart.

Fluorescein Angiography

- Superior resolution over legacy systems while using 1/3 less light.
- Quick change white/blue led modules.
- Barrier filter built into the handpiece.

Clinical/Operational Benefits:

Today, it's not just about capturing stunning images. It's HOW you capture them in a safe and hygienic way.

Patient Safety

- A hand piece holster with a built-in soaking cup makes patient-to-patient disinfection easy. The hand piece soak timer built into the software creates an infection control audit log for all camera cleaning events.

Wide-field Digital Eye Imaging vs. Binocular Indirect Ophthalmoscopy

- Objective wide field image vs narrow hand drawing.
- Effectively monitors disease progression over time.
- Provides a superior platform to obtain second opinions.
- Empowers NICU to control the screening process.
- Improves education for parents to increase compliance.
- Objective documentation mitigates risk of medico-legal action.

ICON Cart

- Available in a cart-format for the operating room and high volume imaging.

ICON GO

- Available in an easily portable system for remote screening and portability on a large campus.

100 degrees Field-of-View is the best choice

- The designers found 100 degrees to be the perfect choice. This maintains the intense concentration on image quality without sacrificing convenience for retinal surveys.
- The 100 degree lens supports thorough retinal surveys with the addition of only one image, resulting in an ideal montage within ICON CONNECT™

Financial Benefits:

The ICON products provide advanced ocular imaging through lens and light innovation, providing stunning ocular images that give clinicians the needed speed, confidence, and connectivity for patient exams.

- Reduce revenue loss from needless transfer.
- By connecting nursing, ophthalmology, and neonatology teams, ICON Products help facilitate timely expert screening of patients in any NICU, enabling delivery of the best care.
- ICON Products have a proven screening workflow that generates critical photo documentation to enhance treatment determination and reduce risk.

Parent/Guardian Education and Support

Learning about Retinopathy of Prematurity (ROP)

What is the Retina?

The retina is a light-sensitive layer in the back part of the eye. When light hits the retina it sends information to the brain to allow us to see.

What is Retinopathy of Prematurity?

Retinopathy of Prematurity is an eye disease that can affect babies born prematurely. The retinal vessels that help to feed nutrients and supply healthy oxygen to the eye, stop developing as they normally should. This unwanted vessel growth in the retina can cause scaring and potentially cause the retina to pull away, which may cause long term visual problems.

What causes Retinopathy of Prematurity?

Studies have shown that the smaller a baby is at birth and the more premature a baby is at birth, the more likely they may be to have ROP.

During pregnancy there is a lot of growth happening. When a baby is born prematurely normal vessel growth in the retina may stop. This means the edges of the eye will not get the oxygen and nutrients they need.

The baby's body may respond by making weak unwanted vessels. Weak and fragile blood vessels can be unstable, leaking blood into the light-sensitive layers of the retina causing scaring or potential detachment.

Who should be screened for Retinopathy of Prematurity?

According to the American Academy of Pediatrics guidelines, all babies with a birth weight of less than or equal to 1500 grams or babies with a gestational age of 30 weeks or less should be screened for this disease. Some babies with a birth weight between 1500 grams and 2000 grams or a gestational age of greater than 30 weeks may also be screened for this disease if the doctor makes that decision.

Retina

Retinal Vessels

Optic Nerve
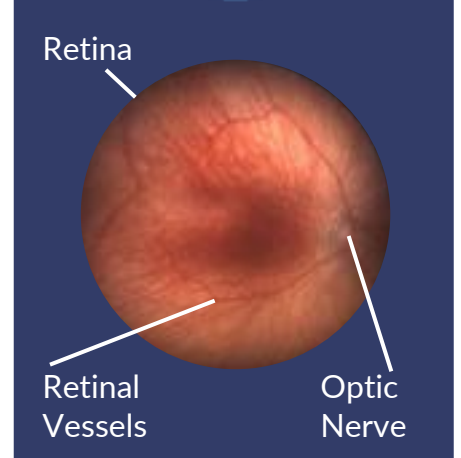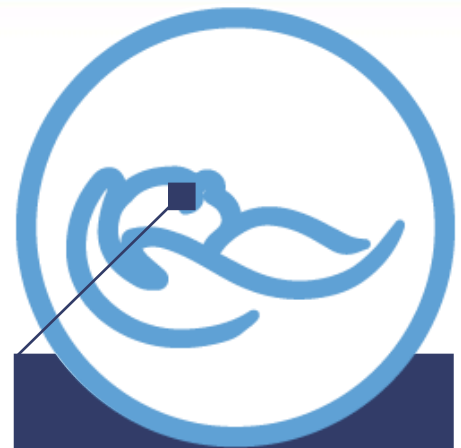
EYE FUNCTION

The eyes develop rapidly during the last 12 weeks of pregnancy. As a result, premature babies have eyes that are not fully developed.

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How can my care team look for Retinopathy of Prematurity?

To decide if your baby has ROP a doctor will look inside the eye to see the retinal vessels. For an eye exam, your baby's eyes will be dilated to allow light into the eye. A lid speculum is often used to hold the eyelids open to allow the retina to be viewed without blinks. Two types of exams can be performed to see the retina and look for signs of unwanted retinal vessel growth.

A digital image with the ICON™ Ophthalmic Imaging System may be taken by your care team for remote viewing. With a special camera, your care team will point light to different parts of the retina to image and document findings, either normal or abnormal. These images can be used as a baseline to watch over time, or to determine if immediate treatment is recommended. Once the images have been reviewed, the ophthalmologist will write down their findings to share with you and the care team.

An ophthalmologist may examine your baby's eyes at the bed side. A tool which helps move the eye into different positions so the entire retina can be checked may or may not be used. A special lens that focuses light into the eye will allow the doctor to see the retina. Once the eye exam is complete, the ophthalmologist will write down their findings to share with you and the care team.
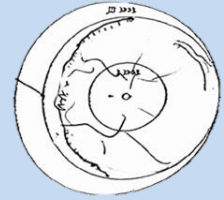
How do doctors describe Retinopathy of Prematurity?

Retinopathy of Prematurity is typically described in a Zone (location and extent), a Stage (severity of peripheral disease), and Plus (condition of central vessels). Plus disease may be defined as Plus or Pre-Plus disease and is typically the main indicator for determining treatment.

How is Retinopathy of Prematurity treated?

Early stages of ROP do not require any treatment but must be monitored closely. If ROP advances, laser treatment or injections into the eye can be used to slow or reverse the abnormal blood vessels.

The Zones in ROP help doctors to explain the location of the disease. ROP findings within Zone 1 may affect vital visual structures, thus, are often watched more closely.

Why are exams after my baby leaves the hospital so important?

When your baby leaves the NICU, he/she may still need thorough eye exams to ensure that the eyes continue to develop completely.
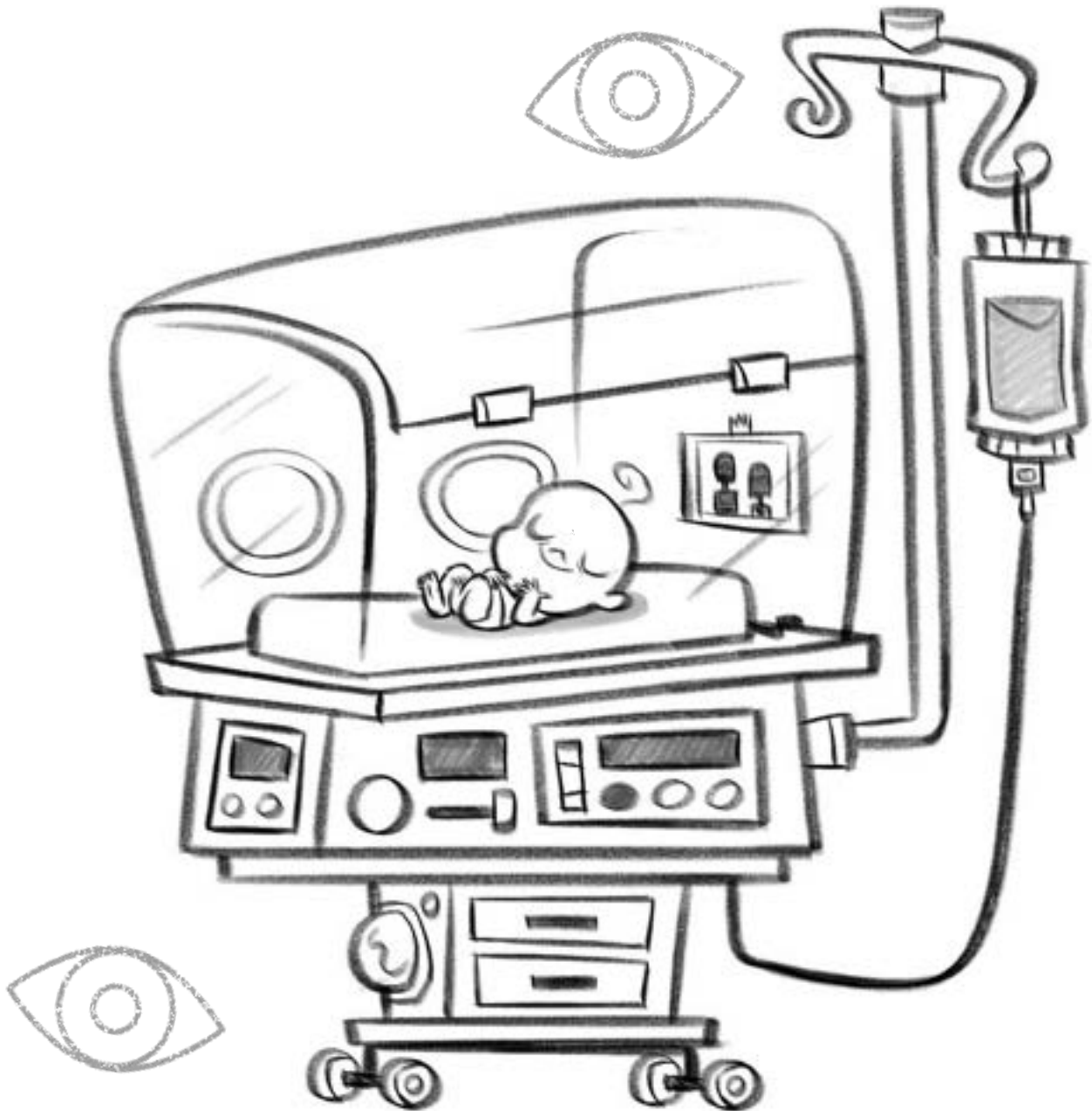
Your understanding of ROP is essential for keeping important follow-up appointments so that any continued treatment needed in order to save your baby's vision can be done in a timely and prompt manner.

Notes:

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Proper Product Use and Workflow Support

Clinical Practice Guideline Snapshot (AAP): Screening Examination of Premature Infants for Retinopathy of Prematurity

Clinical Snapshots are general information provided as a reference that only represents NeoLight's understanding of current guideline recommendations that relate to the listed subject matter. NeoLight does not create company detailed recommendation of proper methods of care for any disease. The ultimate judgment regarding any specific care must be made by the physician and the patient. This Clinical Snapshot reflects the best available data at the time the guideline was prepared. The results of future studies may require revisions to the recommendations in this guideline to reflect new data.

Recommendations

1. All infants with a birth weight of ≤1500 g or a gestational age of 30 weeks or less (as defined by the attending neonatologist) and selected infants with a birth weight between 1500 and 2000 g or a gestational age of >30 weeks who are believed by their attending pediatrician or neonatologist to be at risk for ROP (such as infants with hypotension requiring inotropic support, infants who received oxygen supplementation for more than a few days, or infants who received oxygen without saturation monitoring) should be screened for ROP. Retinal screening examinations should be performed after pupillary dilation by using binocular indirect ophthalmoscopy with a lid speculum and scleral depression (as needed) to detect ROP. Dilating drops should be sufficient to allow adequate examination of the fundi, but care should be taken in using multiple drops if the pupil fails to dilate because poor pupillary dilation can occur in advanced ROP and administering multiple doses of dilating drops can adversely affect the cardiorespiratory and gastrointestinal status of the infant. Separate sterile instruments or instruments cleaned in accord with the anti-infective protocol for metal instruments for each NICU should be used to examine each infant to avoid possible cross-contamination by infectious agents. One examination is sufficient only if it unequivocally reveals the retina to be fully vascularized in both eyes. Effort should be made to minimize the discomfort and systemic effect of this examination. In recent literature, authors suggest that a carefully organized program of remotely interpreted wide-angle fundus camera ROP screening may initially be used in place of binocular indirect ophthalmoscope examinations up to the point at which treatment of ROP is believed to be indicated; at this point, indirect ophthalmoscopy is required.

Timing of First Eye Examination Based on Gestational Age at Birth

TABLE 1 Timing of First Eye Examination Based on Gestational Age at Birth

Gestational Age at Birth, wk	Age at Initial Examination, wk	
	Postmenstrual	Chronologic
22[a]	31	9
23[a]	31	8
24	31	7
25	31	6
26	31	5
27	31	4
28	32	4
29	33	4
30	34	4
Older gestational age, high-risk factors[b]	—	4

Shown is a schedule for detecting prethreshold ROP with 99% confidence, usually before any required treatment. —, not applicable.
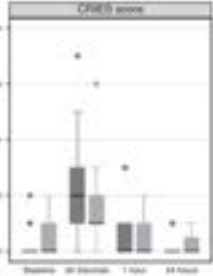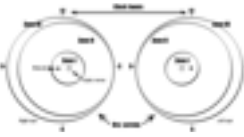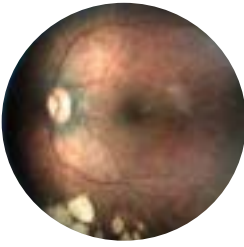
[a] This guideline should be considered tentative rather than evidence based for infants with a gestational age of 22 to 23 wk because of the small number of survivors in these postmenstrual age categories.

[b] Consider timing on the basis of the severity of comorbidities.

1. Walter M. Fierson, AMERICAN ACADEMY OF PEDIATRICS Section on Ophthalmology, AMERICAN ACADEMY OF OPHTHALMOLOGY, AMERICAN ASSOCIATION FOR PEDIATRIC OPHTHALMOLOGY AND STRABISMUS, AMERICAN ASSOCIATION OF CERTIFIED ORTHOPTISTS, Michael F. Chiang, William Good, Dale Phelps, James Reynolds, Shira L. Robbins, Daniel J. Karr, Geoffrey E. Bradford, Kanwal Nischal, John Roarty, Steven E. Rubin, Donny Won Suh, Sharon S. Lehman, George S. Ellis; Screening Examination of Premature Infants for Retinopathy of Prematurity. Pediatrics December 2018; 142 (6): e20183061. 10.1542/peds.2018-3061

Authors:	**Title:**	**Publication:**	**Year:**
Malshi Karunatilake, MD, Sibasis Daspal, MD, Veronica Mugarab Samedi, MD, Shehla Rubab, MD, Vasudha Erraguntla, MD	Screening for Retinopathy of Prematurity Through Utilization a Pediatric Retinal Camera at Jim Pattison Children's Hospital: A Vision for Improved Care	Sage Journals	2021

The diagnostic value of a wide-field digital retinal imaging system along with its role in efficiency, safety, and patient comfort has made it a valuable asset to the NICU at JPCH. The Phoenix ICON has been particularly ideal during the pandemic since it requires minimal contact with the patient. Its role in rural ROP screening should be further explored when developing a teleophthalmology program that strive for improved level of patient care.

Authors:	**Title:**	**Publication:**	**Year:**
Kenneth Teow Kheng Leong, Siti Nur Amira Abu Kassim, Jasvinjeet Kaur Sidhu, Zayani Zohari, Thivakar Sivalingam, Sunder Ramasamy, Safinaz Mohd Khialdin, Noraihan Mohd Nordin & Jamalia Rahmat	Neonatal eye screening for 203 healthy term new-borns using a wide-field digital retinal imaging system	BMC Ophthalmology	2021

Universal eye screening for all new-borns using a wide-field digital imaging system is possible, safe, and useful in detecting posterior segment disorders. The most common abnormality detected is retinal hemorrhage.

Authors:	**Title:**	**Publication:**	**Year:**
Ji Wang,Cui Liu,Huan Wu,Tsz Kin Ng &Mingzhi Zhang	Diagnostic Accuracy of Wide-Field Digital Retinal Images in Retinopathy of Prematurity Detection: Systematic Review and Meta-Analysis	Current Eye Research	2022

The diagnostic accuracy based on WFDRI is substantial and comparable to BIO, supporting its application in the ROP screening programs.

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	Authors: M Teresa Moral-Pumarega, Sonia Caserío-Carbonero, Javier De-La-Cruz-Bértolo, Pilar Tejada-Palacios, David Lora-Pablos and Carmen R Pallás-Alonso	**Title:** Pain and stress assessment after retinopathy of prematurity screening examination: Indirect ophthalmoscopy versus digital retinal imaging	**Publication:** BMC Pediatrics	**Year:** 2012
	A transient short-term pain and stress response occurs with both BIO and WFDRI. Infants examined for screening of ROP with digital retinal imaging present less pain and stress at 30 seconds following completion of the exam when compared with binocular indirect ophthalmoscopy.			

	Authors: Alejandra Barrero-Castillero, MD, MPHa,b,Brian K. Corwin, MDc, Deborah K. VanderVeen, MD, Jason C. Wang, MD, PhDe	**Title:** Telehealth for Pediatricians, An Issue of Pediatric Clinics of North America	**Publication:** Elsevier	**Year:** 2020
	In the United States, the Stanford University Network for Diagnosis of Retinopathy of Prematurity followed premature infants eligible for ROP for 6 years, using remote retinal photographs by an ROP provider in 6 NICUs in California. During the duration of the program, telemedicine was found a safe, reliable, and cost-effective complement of ROP providers.			

	Authors: Michael F. Chiang, MD; William Good, MD; Dale Phelps, MD; James Reynolds, MD; Shira L. Robbins, MD; Daniel J. Karr, MD; Geoffrey E. Bradford, MD; Kanwal Nischal, MD; John Roarty, MD; Steven E. Rubin, MD; Donny Won Suh, MD; Sharon S. Lehman, MD; George S. Ellis, Jr, MD	**Title:** Screening Examination of Premature Infants for Retinopathy of Prematurity	**Publication:** American Academy of Pediatrics	**Year:** 2018
	Digital retinal imaging may also be a useful tool for objective documentation of retinal findings and for teaching NICU staff and parents about examination results, even if it is not the primary method used for ROP screening in the NICU.			

	Authors: SPONSORED BY Phoenix Technology Group	**Title:** Innovations in Wide-Angle Retinal Imaging	**Publication:** The Ophthalmologist	**Year:** 2018
	The Phoenix team takes pride in being an innovator yet recognizes that without adoption, all the innovation in the world is meaningless. After over 20 years of innovating in the wide-angle, contact retinal imaging arena, Phoenix has earned the endorsements and accolades from a host of trailblazing ophthalmologists, including Dr. Mike Trese and Dr. Carol Shields, who use Phoenix ICON cameras to image their patients.			

ICON Indications for Use:

ICON™ Ophthalmic Imaging System is indicated for general ophthalmic imaging including retinal, corneal, and external structures of the eye.

ICON Intended Use:

This device 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. The ICON imaging system is equipped with optics designed to capture images and videos of the retinal, corneal, and external structures of the eye through both contact and non-contact methods. Dilation of the pupils for retinal imaging is generally required. The essential performance of the ICON is to capture, store, review and export images and video.

Policy:

The ICON 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.

ICON Parent Education material will be given to parents at the beginning of retinopathy of prematurity care plans.

Supportive Data:

The ICON consists of a camera within a handpiece that uses a low power light emitting diode (LED) light source to illuminate the retina. The camera utilizes the very latest in sensitive sensor technology, allowing for low light levels, which reduces stress on sensitive patients. Training on the use of the ICON camera system must be performed by an authorized representative.

The ICON Software and the ICON hardware have built-in timeouts that automatically turn off the LED light module. The expected duty cycle is maximum continuous patient illumination of 3 minutes with a 50% duty cycle. The maximum patient exposure to blue light is 5 minutes. The maximum patient exposure to white light is 25 minutes.

Responsible Department/Person(s)	Procedure
Nursing/Patient Care Provider (RN, LPN, PCS, ARNP, NNP): Personnel trained in the use of the ICON™ Ophthalmic Imaging System	**Equipment**
	1. ICON™ Ophthalmic Imaging System 2. Topical anesthetic and dilating drops 3. Clear base ophthalmic coupling gel 4. Appropriate size sterile lid speculum (recommend 2 on hand) 5. Gauze or Lint-Free Cloth 6. Gloves 7. Prepared wipes, detergent solution, or disinfectant to clean lens 8. Purified water to rinse lens tip 9. Blanket to wrap or bundle infant 10. Comfort measures for infant
	Example Nursing Procedure
	1. RN/NNP will verify medical order 2. RN/NNP will provide and document parent/guardian with education on ROP and ROP exam(s) 3. On the day of the scheduled exam, the nurse will verify that topical anesthetic and dilating drops are readily available and initiate administration __ min prior to the start time of the exam. 4. Patient will be properly identified 5. Standard universal precautions will be followed throughout the procedure 6. RN/NNP will administer comfort measures prior to the start of the procedure and PRN as needed throughout the procedure 7. Assisting nurses will support positioning the infant using developmental supportive principles (ie. swaddling and pacifier) to provide containment throughout the procedure 8. Document vital signs and pain score prior to, during, and after the procedure per unit policy. Provide a rest period as needed during the exam based on patient tolerance during procedure.
	Recommended Patient Preparation
	1. Prior to imaging, prepare the patient for ophthalmic imaging according to individual hospital or clinic procedures and protocols for ophthalmic procedures.
	Required Device Preparation
	1. Check the ICON system for any damage, especially for damage to the patient contacting surface of the camera hand piece tip. 2. Clean and disinfect the hand piece tip according to the maintenance procedure of this document. 3. Turn on the ICON system, login as a user, select a clinic, and either a) enter patient data, b) select a patient from the ICON patient directory, or c) select a procedure from the modality worklist. 4. Position the handset cables so they are away from the patient and do not interfere when acquiring images. 5. Enter the Acquire Screen and test the light module on/off, focus, intensity, gain and capture mechanisms to ensure the ICON system is functioning as expected prior to beginning an imaging session.

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Responsible Department / Person(s)	Procedure
Nursing/Patient Care Provider (RN, LPN, PCS, ARNP, NNP): Personnel trained in the use of the ICON™ Ophthalmic Imaging System	**Recommended Procedure Setup-Fundus Imaging** 1. Ensure that the white LED light module is inserted in the ICON camera hand piece. 2. Position the ICON system and foot pedal close to the examination table at a comfortable viewing distance for the examiner, ideally, while standing at the head of the bed of the patient. 3. Position the monitor at eye level. Deploy the foot pedal on the floor close to the examiner's foot. 4. Reduce the ambient light of the room and minimize glare and reflections on the monitor. 5. Before retinal imaging, pre-focus the camera at infinity by pointing the tip of the camera hand piece at an object across the room, or by turning the hand piece sideways and focusing on the ICON monitor. Sharpen the image you see by adjusting the focus using the foot pedal. This will set the focusing plane near the correct range for retinal imaging. 6. Either select a preset from dropdown for the type of imaging session or adjust the illumination to low by adjusting the intensity with the foot pedal. 7. Select the R/L eye designation using the touch screen. Change the R/L eye designation when moving to the contralateral eye during the image series. 8. Administer topical anesthetic to the eyes. 9. Select appropriately sized lid speculum for age and size of patient. Insert the lid speculum into the eye being imaged. 10. Apply coupling gel as needed throughout the procedure, taking care to minimize bubbles. 11. Hold the camera hand piece close to the tip of the lens with the light module positioned over the hand between the index finger and thumb. 12. Gently place the tip of the camera in the gel on the eye while supporting the camera. 13. The hand piece cable should be placed at the patient's 12:00 o'clock position of the forehead to maintain the correct image orientation. 14. Adjust the intensity and focus as necessary with the foot pedal or have an assistant use the software controls. Pivot the camera to visualize the peripheral areas of the retina. ○ Note: Throughout the imaging session, visually monitor the central retinal arterial and venous branches for pulsation, indicative of excessive pressure to the eye. If pulsations occur, bring the camera away from the eye slightly until they cease, or remove the camera from the eye entirely and reposition it to continue imaging.
	Recommended Procedure Setup-Fluorescein Angiography 1. Ensure that the blue LED light module is inserted in the ICON camera hand piece. 2. Position the ICON system and foot pedal close to the examination table at a comfortable viewing distance for the examiner. 3. Perform the procedure seated, if possible. Position the monitor at eye level. Deploy the foot pedal on the floor close to the examiner's foot. 4. Decide if you will do the angiogram in Video or Photo mode as the procedures differ slightly. 5. Click Greyscale to capture the photos in black and white if this is not selected by default in Settings.

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Responsible Department / Person(s)	Procedure

Nursing/Patient Care Provider (RN, LPN, PCS, ARNP, NNP): Personnel trained in the use of the ICON™ Ophthalmic Imaging System	6. Select Video or Photo mode for the foot pedal operation.
	    o If video is chosen for the foot pedal, select the Sync Start check box. This will start the timer when the foot pedal is depressed. You must be in Video mode for the timer to sync with the foot pedal.
	7. Instill topical anesthetic in both eyes. If the patient is under anesthesia, insert a lid speculum in both eyes after and apply coupling gel to keep the corneas hydrated. (Placing a lid speculum in both eyes allows the efficient capture of the early phase for both eyes without losing time.)
	8. Hold the camera hand piece close to the tip of the lens with the light module positioned over the hand between the index finger and thumb.
	9. Gently place the tip of the camera in the gel on the eye while supporting the camera.
	10. The hand piece cable should be placed at the patient's 12:00 o'clock position of the head to maintain the correct image orientation.
	11. Place the camera on the eye and increase the Gain setting so that the fundus vessels are visible.
	12. Alternatively, select a Preset for Fluorescein with the Gain at 20 and the Intensity at 100. Be prepared to reduce the Gain during mid phase.
	13. Select the R/L eye designation using the touch screen. Change the R/L eye designation when moving to the contralateral eye during the image series.
	14. Administer topical anesthetic to the eyes.
	15. Modify focus so the vessels are sharp.
	    o Important: Position the handpiece filter lever to the blue dot to move the barrier filter in place without moving the camera on the eye. The filter will permit only light emitted from the fluorescein to pass through to the camera, therefore the image will be dark until dye fills the vessels.
	16. Have an assistant inject fluorescein intravenously while the camera is held steadily on the eye. Instruct assistant to wait for the clinical team to be ready with the camera on the eye before administering the fluorescein injection.
	17. It can be useful to perform a countdown of 3-2-1 Start at which time the injection is started, the timer on the system and the first photograph/video is taken.
	18. Depress the green capture foot pedal button at the start of the injection. This will begin the video capture and record as dye enters the eye vessels. Stop the video using the controls on the software at the end of the early phase and save the video. Continue with another video as time passes into the mid phase.
	19. During video capture, you may also click the green foot pedal button to toggle pause and record.
	20. The video must be saved before changing the eye designation.
	    o Note: Throughout the imaging session, visually monitor the central retinal arterial and venous branches for pulsation, indicative of excessive pressure to the eye. If pulsations occur, bring the camera away from the eye slightly until they cease, or remove the camera from the eye entirely and reposition it to continue imaging.
	21. If Photo mode is chosen for the foot pedal operation, have the assistant press the timer arrow at the start of the injection. The timer will be running on the lower right of the screen.
	22. Photo mode may be used to capture snapshots in a rapid progression 1 – 2 seconds apart as the dye enters the eye and fills the vessels.

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Responsible Department / Person(s)	Procedure
Nursing/Patient Care Provider (RN, LPN, PCS, ARNP, NNP): Personnel trained in the use of the ICON™ Ophthalmic Imaging System	23. Apply coupling gel as needed throughout the procedure, taking care to minimize bubbles. 24. Change the R/L eye designation using the touch screen when moving to the contralateral eye during the image series. 25. Adjust the illumination and focus as necessary with the foot pedal or have an assistant use the software controls.
	Required Final Steps
	1. Clean and disinfect the hand piece tip according to maintenance procedure section of this document at the end of each patient imaging session. 2. When all imaging sessions are complete properly stow the ICON system according to the instructions in this document. 3. Document procedure per facility policy

1. When imaging the user must position themselves, the ICON Imaging System, and patient in the appropriate orientation. Check all that apply
   a) The operator should be positioned at the top of the head of a supine patient
   b) Position the system so that there is an unobstructed view of the center of the monitor
   c) Place the imaging system near a window or open door
   d) Align the camera hand piece so that the cable is at the 12:00 o'clock position of the forehead of the patient

2. According to documentation regarding telemedicine for Retinopathy of Prematurity, a standard image set would likely include:
   - An anterior segment/iris photo
   - A posterior pole photo
   - A temporal retinal field photo
   - _____
   - A superior retinal field photo
   - An inferior retinal field photo

   a) A cheek area field photo
   b) A nasal retinal field photo
   c) An Optic Nerve only photo
   d) A lower retinal field photo

3. For darkly pigmented retinas, a feature called ___ is available within the software. This tool will brighten an image without having to increase light intensity.
   a) Image Adjust
   b) Illumination Intensity
   c) Gamma Control Adjustment
   d) Gain

4. What supply is needed to assist with fluid movement of the lens and help refract light so that the best possible image can be taken?
   a) Eye Drops
   b) Dilating Gel
   c) Coupling Gel
   d) Camera Handpiece

5. ICON camera systems have the ability to capture in what three imaging modes?
   a) Still Mode, Voice Capture, and Flash Forward
   b) Video Record, Save Stills, and Flashback
   c) Filter Captured, Video Mode, and Auto Still
   d) Record Still, Movie Mode, and Still Flash

6. To correctly orient the camera handpiece for retinal imaging the user must:
   a) Hold the camera with both hands
   b) Keep the cable towards the user at the midline of the patient's
   c) forehead.
   d) Place the camera on the bedside table
   e) Hold the lens separately from the handpiece

7. To pre-focus the camera for retinal imaging the user can focus on the ___ before applying the camera handpiece to the eye. This will bring the focal plane close to the range of the retina.
   a) Light source
   b) Keyboard
   c) Object across the room
   d) Patients head

8. With the ICON Imaging System, still imaging can be engaged with the:
   a) Footswitch; Keyboard; Screen
   b) Footswitch; Voice Command; Power Button
   c) Membrane Control Panel; Blue Switch; Monitor
   d) Voice Command; Membrane Keyboard; Footswitch

9. When removing a USB after image export, it is important for the user to press the ___ ___ before remove the USB from the system.
   a) End Export
   b) Log Out
   c) Eject USB
   d) Push Command

10. At the beginning of an imaging day, it is recommended to perform __ to ensure the camera colors are set prior to exams.
    a) AWB – Adjust White Balance
    b) ACB – Adjust Color Balance
    c) USB – Understand Balancing
    d) FLB – Flash Light Balance

Fluorescein Angiography

11. When starting a Fluorescein Angiography imaging session at what point should the user start the timer?
    a) After the device is turned ON
    b) After carefully inspecting the lens piece
    c) During the dye injection
    d) At the time of dye injection

12. For Fluorescein Angiography, carefully engage the ____ filter on the camera handpiece.
    a) Injection
    b) Barrier
    c) Angio
    d) Plastic

1. When imaging the user must position themselves, the ICON Imaging System, and patient in the appropriate orientation. Check all that apply
   a) **The operator should be positioned at the top of the head of a supine patient**
   b) **Position the system so that there is an unobstructed view of the center of the monitor**
   c) Place the imaging system near a window or open door
   d) **Align the camera hand piece so that the cable is at the 12:00 o'clock position of the forehead of the patient**

*Answer: **a, b, d.** During normal use the system the operator should be situated with adequate access to the patient, in a position comfortably holding the hand piece, able to operate the foot pedal focus/capture controls, and able to easily see the monitor.[1]*

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.[1]

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.[1]

Before bringing the camera hand piece into contact with the patient's eye, the operator should deploy the foot pedal on the floor and have their foot positioned to operate the focus/capture controls.[1]

The operator should align the camera hand piece so that the cable is at the 12:00 o'clock position of the forehead of the patient with the cable coming towards the operator. This will ensure the image is correctly oriented on the screen.[1]

2. According to documentation regarding telemedicine for Retinopathy of Prematurity, a standard image set would likely include:
   - An anterior segment/iris photo
   - A posterior pole photo
   - A temporal retinal field photo
   - _____
   - A superior retinal field photo
   - An inferior retinal field photo

   a) A cheek area field photo
   b) **A nasal retinal field photo**
   c) An Optic Nerve only photo
   d) A lower retinal field photo

*Answer: **b. A nasal retinal field photo.** Image protocol recommendations are taken from the guidance of multiple documents, such as the 2018 AAP Screening Examination of Premature Infants for Retinopathy of Prematurity policy statement[2], The 2021 International Classification of Retinopathy of Prematurity 3rd Edition[3], and the 2015 AAP Telemedicine for Evaluation of Retinopathy of Prematurity Joint statement.[4]*

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3. For darkly pigmented retinas, a feature called ___ is available within the software. This tool will brighten an image without having to increase light intensity.
   a) Image Adjust
   b) Illumination Intensity
   c) Gamma Control Adjustment
   d) Gain

   *Answer: **d. Gain.** 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.[1]*

4. What supply is needed to assist with fluid movement of the lens and help refract light so that the best possible image can be taken?
   a) Eye Drops
   b) Dilating Gel
   c) Coupling Gel
   d) Camera Handpiece

   *Answer: **c. Coupling Gel.** Coupling gel not only assists with fluid movement of the lens, it also helps to refract light so that the best possible image can be taken. The appropriate amount of gel in the appropriate place will help yield the best image quality possible. Gel should be readily available and applied frequently throughout the imaging exam.[1,4]*

5. ICON camera systems have the ability to capture in what three imaging modes?
   a) Still Mode, Voice Capture, and Flash Forward
   b) Video Record, Save Stills, and Flashback
   c) Filter Captured, Video Mode, and Auto Still
   d) Record Still, Movie Mode, and Still Flash

   *Answer: **b. Video Record, Save Stills, and Flashback.** Still image capture: In this mode, the operator is capturing single images with each capture operation. Video: In this mode, the operator is recording a video from the camera. The operator can toggle between record and pause to save up to two minutes of video per file. Flashback Video: In this mode, the ICON system is constantly buffering the prior few seconds of video. When the operator sees the perfect frame, they can initiate a capture which will save the current frame and the prior few seconds to help ensure that the best frame is available upon review.[1]*

6. To correctly orient the camera handpiece for retinal imaging the user must:
   a) Hold the camera with both hands
   b) Keep the cable towards the user at the midline of the patient's forehead
   c) Place the camera on the bedside table
   d) Hold the lens separately from the handpiece

   *Answer: **b. Keep the cable towards the user at the midline of the patient's forehead.**[1]*

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7. To pre-focus the camera for retinal imaging the user can focus on the ___before applying the camera handpiece to the eye. This will bring the focal plane close to the range of the retina.
   a) Light source
   b) Keyboard
   c) Object across the room
   d) Patients head

   Answer: **c. Room.** *Before retinal imaging, pre-focus the camera at infinity by pointing the tip of the camera hand piece at an object across the room, or by turning the hand piece sideways and focusing on the ICON monitor. Sharpen the image you see by adjusting the focus using the foot pedal. This will set the focusing plane near the correct range for retinal imaging.[1]*

8. With the ICON Imaging System, still imaging can be engaged with the:
   a) Footswitch; Keyboard; Screen
   b) Footswitch; Voice Command; Power Button
   c) Membrane Control Panel; Blue Switch; Monitor
   d) Voice Command; Membrane Keyboard; Footswitch

   Answer: **a. Footswitch; Keyboard; Screen**[1]

9. When removing a USB after image export, it is important for the user to press the ___ ___ before remove the USB from the system.
   a) End Export
   b) Log Out
   c) Eject USB
   d) Push Command

   Answer: **c. Eject USB**[1]

10. At the beginning of an imaging day, it is recommended to perform __ to ensure the camera colors are set prior to exams.
   a) AWB – Adjust White Balance
   b) ACB – Adjust Color Balance
   c) USB – Understand Balancing
   d) FLB – Flash Light Balance

   Answer: **a. AWB – Adjust White Balance.** *The white balance of the ICON camera can be adjusted using the Adjust White Balance button. Turn on the camera light, point the lens towards a white surface or white piece of paper so that it completely fills the live image on the screen, and press the AWB button. The dialogue box below will appear in the image display area during AWB.[1]*

Fluorescein Angiography

11. When starting a Fluorescein Angiography imaging session at what point should the user start the timer?
    a) After the device is turned ON
    b) After carefully inspecting the lens piece
    c) During the dye injection
    d) At the time of dye injection

    *Answer: **d. At the time of dye injection.** Fluorescein dye is injected into a vein and a rapid series of images is captured as the fluorescein flows through the retinal arteries and veins. Administration of dye must happen simultaneously with imaging.[5]*

12. For Fluorescein Angiography, carefully engage the ____ filter on the camera handpiece.
    a) Injection
    b) Barrier
    c) Angio
    d) Plastic

    *Answer: **b. Barrier.** Carefully engage the barrier filter into the camera handpiece prior to starting the FA.[1]*

Resources:

1. Phoenix ICON Instructions for Use - OPL-0016-19 Release: July 2020
2. Walter M. Fierson, AMERICAN ACADEMY OF PEDIATRICS Section on Ophthalmology, AMERICAN ACADEMY OF OPHTHALMOLOGY, AMERICAN ASSOCIATION FOR PEDIATRIC OPHTHALMOLOGY AND STRABISMUS, AMERICAN ASSOCIATION OF CERTIFIED ORTHOPTISTS, Michael F. Chiang, William Good, Dale Phelps, James Reynolds, Shira L. Robbins, Daniel J. Karr, Geoffrey E. Bradford, Kanwal Nischal, John Roarty, Steven E. Rubin, Donny Won Suh, Sharon S. Lehman, George S. Ellis; Screening Examination of Premature Infants for Retinopathy of Prematurity. Pediatrics December 2018; 142 (6): e20183061. 10.1542/peds.2018-3061
3. Chiang MF, Quinn GE, Fielder AR, Ostmo SR, Paul Chan RV, Berrocal A, Binenbaum G, Blair M, Peter Campbell J, Capone A Jr, Chen Y, Dai S, Ells A, Fleck BW, Good WV, Elizabeth Hartnett M, Holmstrom G, Kusaka S, Kychenthal A, Lepore D, Lorenz B, Martinez-Castellanos MA, Özdek Ş, Ademola-Popoola D, Reynolds JD, Shah PK, Shapiro M, Stahl A, Toth C, Vinekar A, Visser L, Wallace DK, Wu WC, Zhao P, Zin A. International Classification of Retinopathy of Prematurity, Third Edition. Ophthalmology. 2021 Oct;128(10):e51-e68. doi: 10.1016/j.ophtha.2021.05.031. Epub 2021 Jul 8. PMID: 34247850.
4. Walter M. Fierson, Antonio Capone, the AMERICAN ACADEMY OF PEDIATRICS SECTION ON OPHTHALMOLOGY, AMERICAN ACADEMY OF OPHTHALMOLOGY, and AMERICAN ASSOCIATION OF CERTIFIED ORTHOPTISTS, David B. Granet, Richard J. Blocker, Geoffrey E. Bradford, FAAP. Sharon S. Lehman, Steven E. Rubin, R. Michael Siatkowski, James B. Ruben; Telemedicine for Evaluation of Retinopathy of Prematurity. Pediatrics January 2015; 135 (1): e238–e254. 10.1542/peds.2014-0978
5. THE OPHTHALMIC PHOTOGRAPHERS' SOCIETY INC. 2022. Fluorescein Fundamentals. [online] Available at: <https://www.opsweb.org/page/FA> [Accessed 11 August 2022].

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ICON Ophthalmic Imaging System Skills Checklist

Name/Title	
Department	

This task validation chart and the task exercises have been designed as a basic practice tool for clinical personnel.

Task Description	Date	Initials	Method of Evaluation D - Demonstrated V - Verbalized O - Observed		
			D	V	O
Properly identify cart controls and buttons.					
Demonstrates setting up the ICON system.					
Demonstrates start-up procedure.					
Demonstrates transporting the system.					
Demonstrates proper user of the camera hand piece including care and maintenance, changing the light module, and using the diffuser.					
Demonstrates understanding of main ICON software concepts and general software workflow.					
Demonstrates standard operating procedures such as patient preparation, device preparation, and procedure setup.					
Demonstrates understanding of the login screen.					
Demonstrates navigating the patient screen to find patients, enter new patients, edit patient information, and work with modality worklist.					
Demonstrates proper adjust white balance procedure.					
Demonstrates understanding of the acquire screen to enter patient/study information and system controls.					
Demonstrates understanding of the review screen to interact with thumbnails, compare images, review videos, and delete images and videos.					
Demonstrates understanding reporting screen to select images and export.					
Demonstrates understanding export screen and export options.					
Demonstrates understanding of DICOM Workflow (if applicable).					

Task Description	Date	Initials	Method of Evaluation D - Demonstrated V - Verbalized O - Observed		
			D	V	O
Demonstrates understanding of hand piece cleaning procedure.					
Demonstrates understanding cleaning the non-hand piece system components.					
Demonstrates shutdown procedure.					
MY SIGNATURE VERIFIES THAT I HAVE COMPLETED AND UNDERSTAND THE TASKS DESCRIBED ABOVE					

Date:		Notes:
Employee Signature:		
Monitor Signature:		
Monitor Title:		

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ICON Quick Reference Guide

This document does not replace reading the ICON Instructions for Use (IFU). The IFU is accessible through the ICON software

1. Turn on the System

For the Phoenix ICON Cart-based system,

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

For the portable Phoenix ICON GO,

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

2. Login

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

3. Click Find Patient or New Patient

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

4. Acquire

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

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

5. Capture Images

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

Image capture controls:

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

6. Image Optimization

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

Save Frame

7. Review Images
- Click the **Review** tab in the task bar at bottom of the window
- Scroll through thumbnails on the touchscreen, with the computer mouse or keyboard up/down arrow keys
- Select a video to review (shown with a small blue forward arrow)
  Drag the playhead using the mouse, through the video to any frame, or use the < and > keyboard arrows to go frame-by-frame to find the best image
    - Click **the Save Frame** button or use a keyboard shortcut
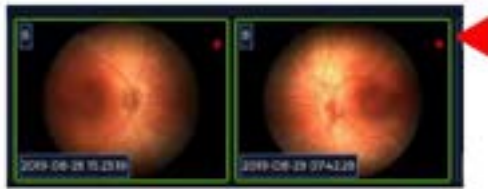
8. Export images
- Click the **Export** tab oin the taskbar at bottom of window
- **'Select All'** or choose specific images or data sets to export by clicking the thumbnails. A red asterisk (*) will appear on selected images.
- Choose File type and export location
- Choose **DICOM, JPEG or Raw**
- Select **With Patient Data** or **Without Patient Data** (JPEG or Raw)
- Select ibe if the export locations from the list (these are setup on the Settings screen)
- Click the **Export** button

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

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

COMPUTER power
Turn OFF with Software

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

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

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

5+ Field Imaging Guide

Capture the 5 fields of the retina by placing the landmark of the optic nerve at the center, left, right, top and bottom of each frame. This will result in images of the posterior pole, temporal, nasal, superior, and inferior retinal fields.
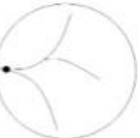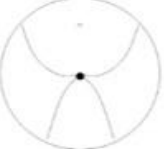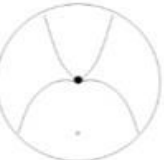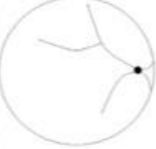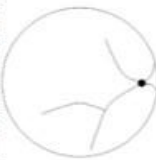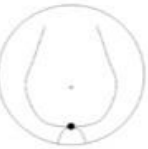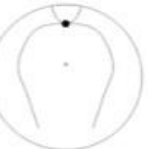
Capture the anterior segment image by holding the camera away from the eye so the nasal and temporal canthi (corners of the eye) are in view and the iris is in focus.

Left Eye
(OS)

Superior

Temporal

Posterior Pole

Nasal

Inferior

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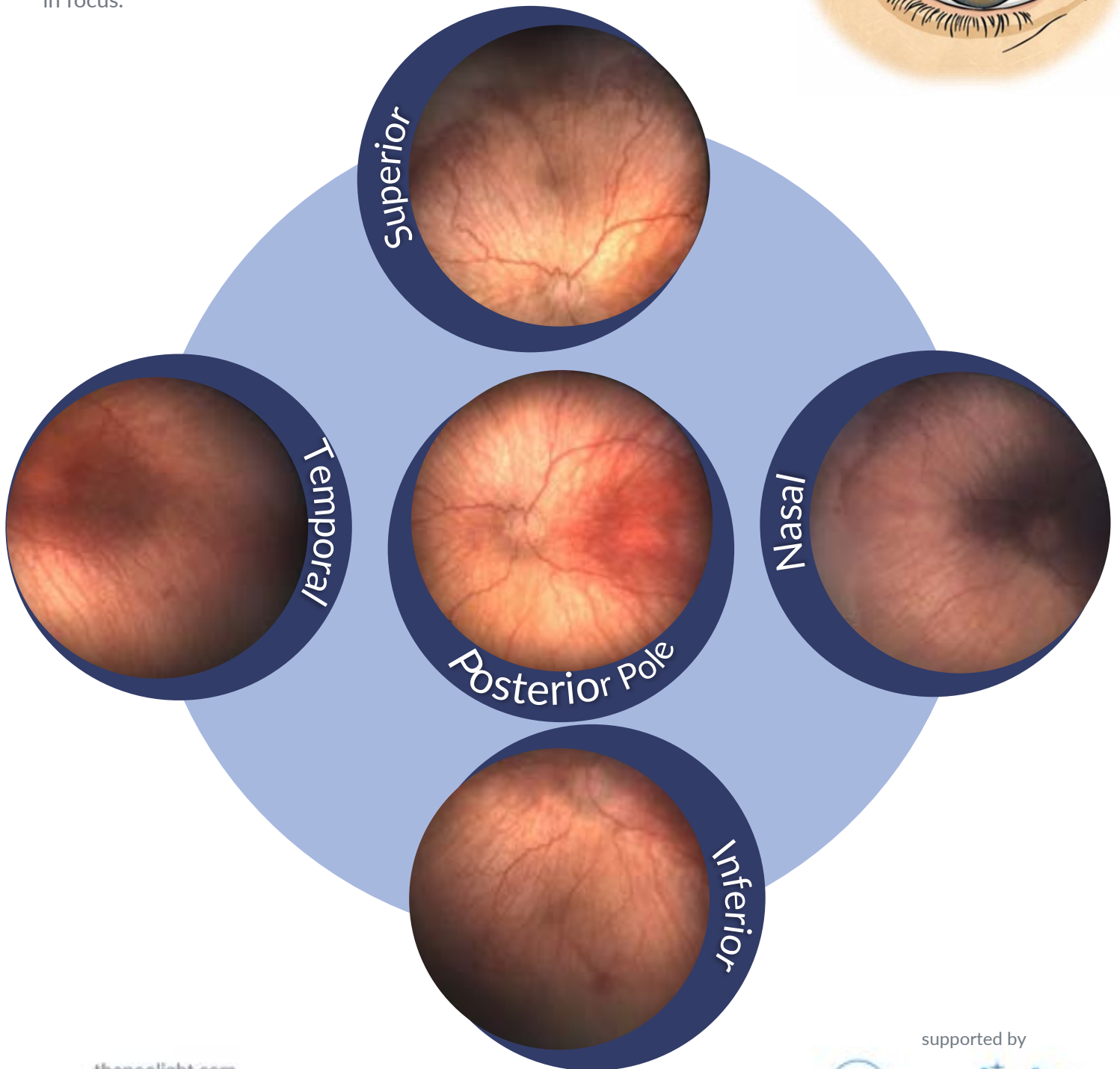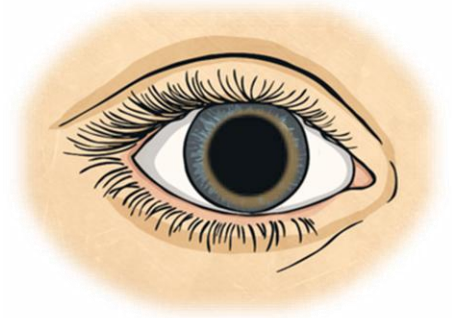
5+ Imaging Field Check List Tool

This is a work sheet tool to help you keep track of the fields you are selecting to export.

Right Eye (OD)

RIGHT TEMP

RIGHT SUP

RIGHT POST

RIGHT INF

RIGHT NAS

RIGHT EXT

Left Eye (OS)

LEFT EXT

LEFT NAS

LEFT SUP

LEFT POST

LEFT INF

LEFT TEMP

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Adjust White Balance (AWB) Quick Reference Sheet

The ICON systems are equipped with integrated camera controls to allows 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.

1.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.*
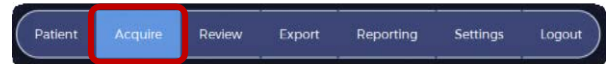
2.Remove the camera from the holster and ensure it is pointed at an open, non-reflective surface.
Note: if the system carries out AWB before the user is prepared, continue to carry out the following steps and manually engage AWB after step 5.
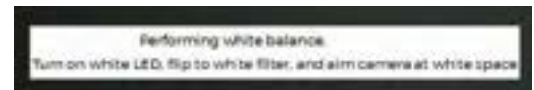

3.Adjust the light Intensity setting to 50 using the camera controls screen function, cart top functions, or foot pedal functions.
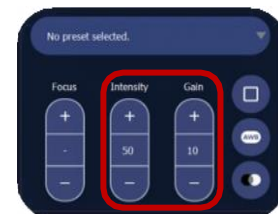

4.Adjust the Gain setting to 10 using the camera controls screen functions.

5.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.
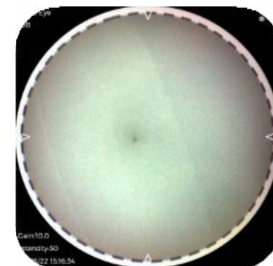
6.When the system has completed AWB the dialogue box will disappear from the image display area.
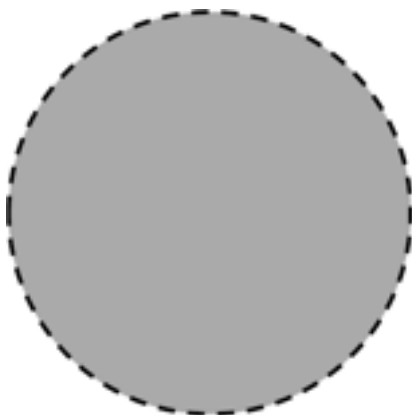
Quick Tip: The white balance will not work properly if intensity or gain settings are not set correctly. AWB will also not work properly if the barrier filter is in position on the hand piece. If images look abnormally red or yellow, ensure the camera control settings are set correctly, and that the yellow barrier filter is not engaged, and manually perform AWB.

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 acquire screen can be exited and preparations for patient imaging can begin. Please remember to adjust intensity and gain to necessary settings for patient imaging.

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TBN-0027 Rev B

Progress Review and Goals for Expanded Use

Goal Champion Contact Information	
Name	
Email	
Goal Assessment for Use and Implementation	

Progress Review and Goals for Expanded Use	
Date	
Education Material Review Goals	
Practice Use Goals	
Live Use Goals Data Collection and Study Opportunities	