RetCam 3

Ophthalmic Imaging System

Service Manual

PN 21-100357 Rev. A

CE

Clarity medical systems

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1 Notices and Labels

The **RetCam3 Ophthalmic Imaging System** (system) is designed to allow the quick and easy capture of wide field, high resolution, fully digital images and videos of the eye.

Indications for Use

For general ophthalmic imaging, including retinal, corneal, and external.

Warnings and Cautions

CAUTION: Federal law (US) restricts this device to sale by or on the order of a physician or licensed medical practitioner.

WARNING: Prior to using the system, read all user safety information.

WARNING: Before using this equipment to acquire images from patient eyes, users must be trained in proper clinical technique by personnel authorized by Clarity.

WARNING: The RetCam system is designed and tested as a system. Omission or substitution of RetCam components may adversely affect system performance and is strongly not recommended.

WARNING: Unauthorized modifications or additions to the RetCam system (including hardware and software, etc.) could adversely affect system function and will void the warranty.

WARNING: Carefully inspect and clean the lens piece before each use. DO NOT USE if the lens piece has nicks, breaks, scratches, or rough surfaces that may damage the eye.

WARNING: To mitigate the potential for excess light exposure, always start at the lowest light intensity level and increase if necessary. Use only the shortest amount of exposure time necessary; no greater than 5 minutes.

WARNING: Use care when contacting the eye; i.e., use the least amount of pressure and/or movement necessary.

WARNING: A risk/benefit ratio must be assessed before confirming a patient for RetCam imaging if they are: photosensitive, concomitantly exposed to photosensitizing agents, or aphakic.

WARNING: To avoid the risk of electric shock, the equipment must be connected to a supply mains with protective earth**.**

WARNING: To mitigate the potential for excess light exposure, the user should avoid looking directly at the illuminated light source**.**

WARNING: There are high voltages within the FA module and the cover of the module is not to be removed by customers or distributors.

Electrical Safety Information

The system has been designed, inspected and tested to comply with the safety requirements of IEC60601-1 with respect to fire, shock and mechanical hazards only if used as intended.

Class I Type BF Electrical Equipment

Rated for Continuous Operation

Electromagnetic Emissions		
Compliance Level: Group 1, Class A		
Test Type	**Compliance Level**	**Notes**
Conducted Emissions CISPR 11/ EN 55011	Class A	The RetCam system uses RF energy for its internal function. Nearby electronic equipment may be affected.
Radiated Emissions CISPR 11/ EN 55011	Class A	
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	
FCC Part 15B	Complies	

Electromagnetic Immunity		
Test Type	**IEC 60601-1-2 test and compliance level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transients (AC Power) (I/O Lines) EN 61000-4-4	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment. AC Power electronic disturbances (transients) may cause the system's display to scroll continuously. If this occurs, imaging should not processed until the disturbance has ceased.
Surge Line to Line (AC Power) (I/O Lines) EN 61000-4-5	±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 and interruptions EN 61000-4-11	>95% dip in Ut 0.5 cycle 60% dip in Ut 5 cycles 30% dip in Ut 25 cycles >95% dip in Ut 5 seconds	If the user of the RetCam system requires continued operation during power mains interruptions, it is recommended that the RetCam system be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated Immunity EN 61000-4-3	80MHz-2.5GHz 3V/m 80%@1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the RetCam system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 3.5 / E_1 \sqrt{P}$ 80 MHz to 800 MHz $d = 7 / E_1 \sqrt{P}$ 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). E_1 is 3 V/m. Conducted Immunity: $d = (3.5 / V_1) \sqrt{P}$ where V_1 is 3 Vrms. Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 
Conducted Immunity EN 61000-4-6	0.15-80MHz 3 Vrms 80%@1kHz AC Mains	

WARNING: Interference may occur in the vicinity of equipment marked with the following symbol.

This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as:

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

An error message may be displayed, which then may require a system reset. To perform a system reset, press the system power switch on the control panel for ~6 seconds until the system powers down, wait 6 seconds, then press the switch again to power the system back on.

WARNING: This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the system or shielding the location.

WARNING: To avoid the risk of electric shock, this equipment must be connected to a supply mains with protective earth.

WARNING: For continued protection against risk of fire, replace only with same type and rating fuse.

Important User Safety Notices

1. Never contact the front of the lens piece with hard or sharp objects. This could damage the precision optics and sealing.
2. DO NOT AUTOCLAVE any part of the device.
3. Appropriately power down and unplug the unit and allow the illumination lamp to cool before replacing it.
4. Always return the handpiece to the holster when not imaging. You can drape the handpiece cable over the cord wrap post on the side, but do not wrap it tightly or damage to the fiber optic may result.
5. Do not block access to the holster.
6. The system is not intended to be transported outdoors.
7. Newly acquired data may be lost if power is interrupted during live imaging.

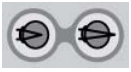
Note: backup battery power is available for at least 15 minutes after interrupt.

8. The system comes protected from viruses, worms, and spyware with Microsoft's anti-malware. Please refer to your warranty prior to adding any additional software or contact Clarity Service.

Labels and Symbols

System Power Switch

Focus



Focus Controls

Lamp Illumination

Intensity Controls

SNAP (capture) switch

Read instructions

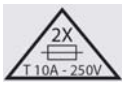
Caution:
Do not look directly into light source

Caution: Electrical hazard
High voltage in the FA unit

Chassis ground

Protective earth (ground)

Alternating current (AC)



System contains 2 fuses of indicated type.
Do not use any other type.

Backup battery

Computer network

Non-ionizing electromagnetic radiation

FA = Fluorescein Angiography

FA Intensity, increase clockwise

FA light OFF

FA light ON

Light source (fiber optic) connector

Handpiece connector

USB connector

Read accompanying user documentation

Fragile contents

This side of carton up

Temperature limits

Authorized representative in the EU

Type BF equipment (applied part is handpiece)

To prevent damage to lens piece, carefully store handpiece in holster when not in use.

Clean lens piece after use

Separate collection of waste at end-of-life as required by European directives. Contact Clarity for equipment disposal instructions.

European conformity

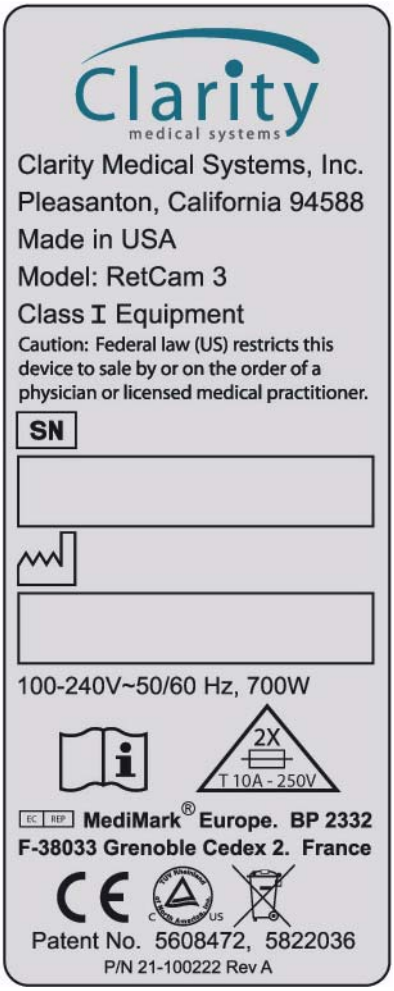
North American compliance certification

Serial number

Date of Manufacture

Keep away from rain

Product Label



2 Introduction

The RetCam 3 Wide Field Imaging System (system) is designed using state-of-the-art digital technology to allow the quick and easy capture of wide field, high resolution, fully digital images and videos of the eye.

The system is designed for easy use and operation by either a physician or trained staff members. High resolution digital images and videos can be quickly captured, stored, displayed for review, transferred and/or printed by simply using the mouse to point and click.

The system as delivered is intended for use indoors, at normal room temperatures (50º F to 95º F or 10º C to 35º C), non-condensing humidity range 30% to 90%, upright, on a level surface, with the front casters locked.

This manual contains maintenance instructions, specifications and service instructions.

Only those modules identified within this service manual are “authorized” for replacement by the customer. Any service outside the scope of this manual shall void the warranty and may compromise the safety/efficacy of the system.

This manual is meant to be used in conjunction with the RetCam 3 User’s Manual.

The supplier will make available on request, component part lists, descriptions, or other information which will assist the user's appropriately qualified technical personnel to replace those parts of the equipment which are designated by the manufacturer as replaceable.

CAUTION: Use of this manual is intended for qualified technical personnel only. If in doubt, please contact the manufacturer before proceeding.

Storage and Transport

Note: Always return the handpiece to the holster on the top surface when not imaging. The handpiece cable can be draped over the side cord wrap post, but do not wrap it tightly or damage to the fiber optic may result.

For storage of the system when not in use, disconnect the power cord and store it in one of the drawers. Remove all loose objects from the top surface. Wipe down the surfaces with a soft cloth. Lock the casters.

The system can be easily moved between operations or between beds in the NICU while it is running. To relocate the system while it is running, disconnect the power cord at both ends, release the front caster locks and gently roll the system to the new location. The internal batteries will keep the computer and monitor running for several minutes. Once in the new position, lock the casters, reconnect the power

cord at both ends and continue with imaging. If the floor is uneven, move the system carefully to avoid damage from excessive vibration.

The system is not intended to be transported outdoors from building to building. For information on how to safely transport the system out of doors or in anything but an upright position, please contact Customer Service. The RetCam 3 has been designed, inspected and tested to comply with the safety requirements of IEC60601-1 with respect to fire, shock and mechanical hazards only if used as intended. Inspection and testing of the system by a factory-trained technician after transport outdoors or in a non-upright configuration is necessary to insure continued compliance with all safety standards.

System Description

The RetCam 3 system consists of several modules mounted in a stable, high quality integrated mobile cart for easy, safe transportation from one location to another. The front pair of lockable casters allow for easy maneuverability and positioning. (See Figure 1 on page 18).

- **Display**: A high resolution LCD flat panel display is standard with the system.
- **Control Panel**: A control panel turns the system on with one button, and has controls for illumination intensity, camera focus and snap (capture an image or start/stop video recording).
- **Handpiece**: The handpiece contains a 3-chip CCD. It is light weight and easy to use. The front lens pieces are removable, and allow quick and easy exchange.
- **Interconnect Cable**: The interconnect harness contains three separate cables, the fiber optic cable for transmission of illumination light, the camera cable, and the focus motor control cable.
- **Power Supply Box**: The power supply box contains the input power converter, power to charge the battery backup, power for the computer, camera controller and the electro/optic circuits.
- **CEO Box**: (Computer Electro/Optical Box) The computer is a Pentium based system, running a specialized Embedded Windows XP, with an external DVD drive and proprietary software. The system has an integrated network adapter, and USB hub. The Electro/Optical box contains a CCD camera control unit, a halogen illumination lamp, and the control circuitry for light intensity, focus, image capture and system logic.

- **Battery Backup**: The battery backup helps to protect against accidental loss of images due to sudden power loss. The battery backup can store enough energy to power the computer and display for several minutes allowing the system to be unplugged from the electrical outlet and moved from room to room or bed to bed without having to reboot the system.
- **Footswitch**: The footswitch is a rocker style unit with a function switch on each side, and a push button in the middle.

  The pedal on the left side controls focusing. Rock this pedal to the left to focus closer, and to the right to focus more distant.

  The pedal on the right controls illumination light intensity. Rock this pedal to the left to decrease intensity and to the right to increase intensity.

  The push button in the middle is called the snap switch. An image is captured and stored each time the snap switch is depressed. In video mode, this switch can be used to alternately start and stop video recording.
- **Storage Drawers**: Two storage drawers are supplied on the system for lenspieces and accessories. The upper drawer contains a mounted external DVD drive.
- **Image and Report Printer**: A high resolution inkjet printer can print images using 5” x 7” photo paper or reports on 8.5” x 11” paper.
- **Fluorescein Angiography Source (optional)**: A blue exciter light source is available complete with green barrier filter for the handpiece for doing Fluorescein Angiography (F.A.) digital photography with the RetCam 3.

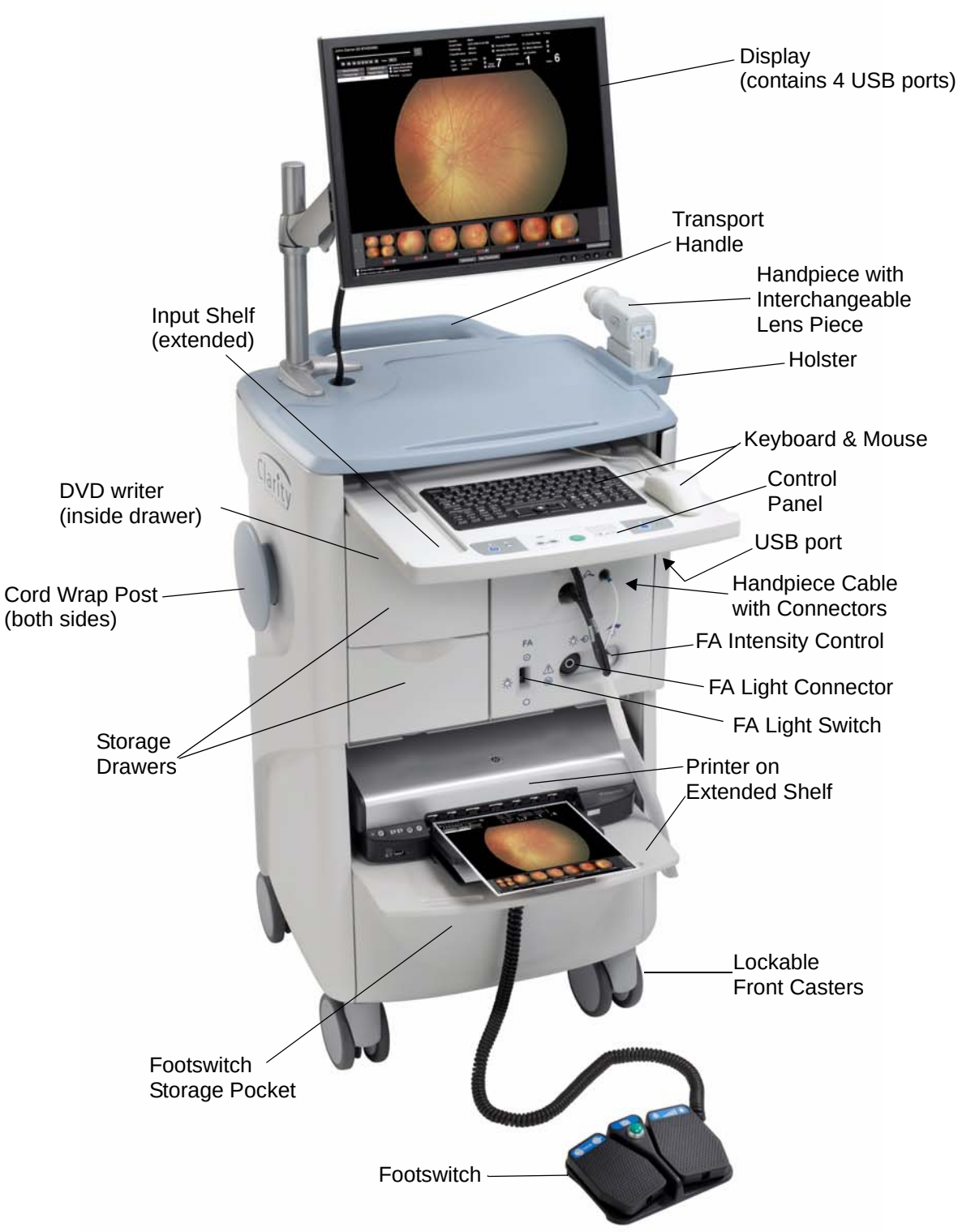


Figure 1 RetCam 3 Ophthalmic Imaging System Front View*

*Shown with optional FA (Fluorescein Angiography) feature

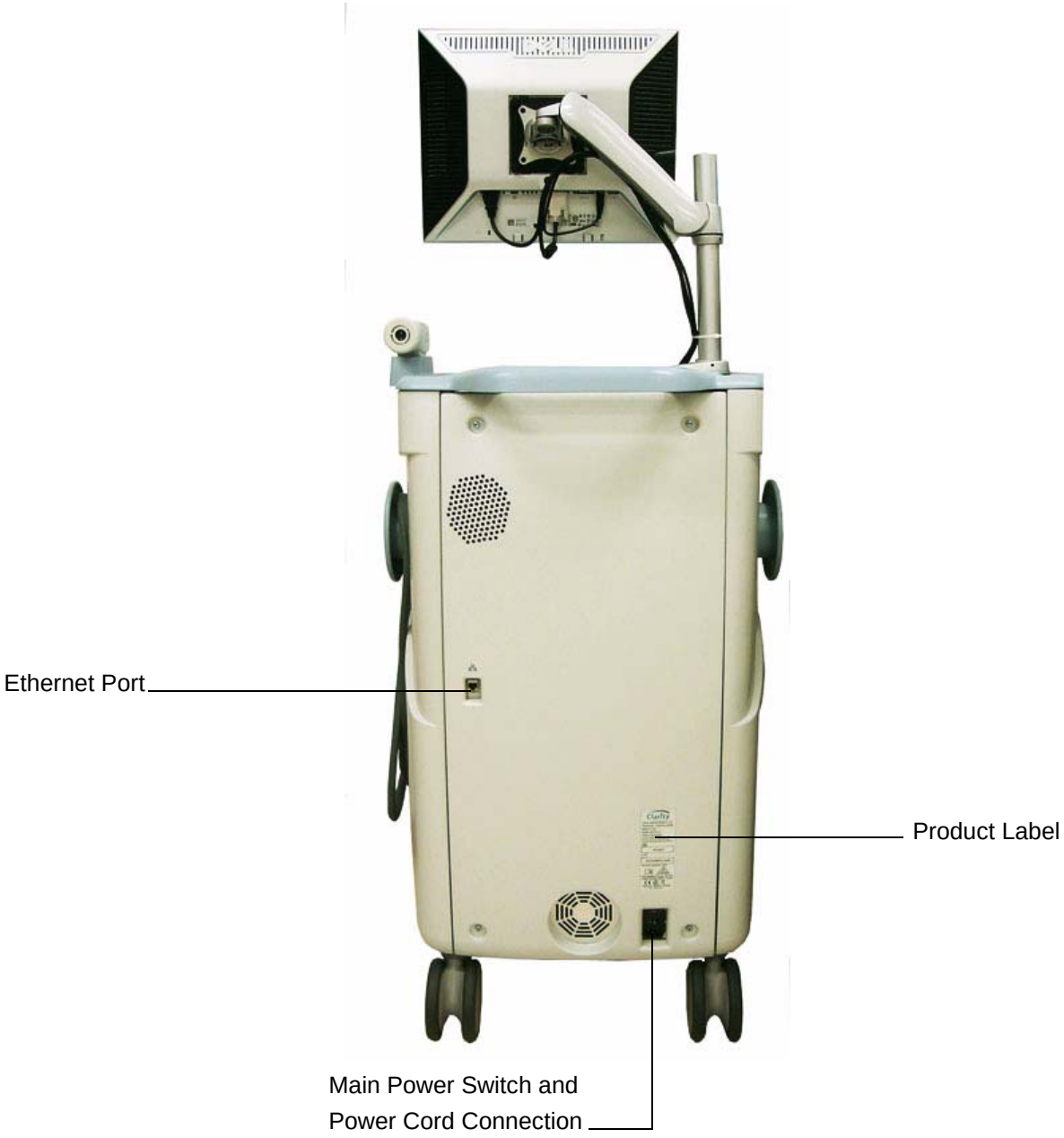


Figure 2 RetCam 3 Ophthalmic Imaging System Rear View

Figure 3 Handpiece and Lens Piece

Figure 4 Lens Piece Selection

Lens Model	Application	Common Field of View
D1300	Premature Infant	130 Degrees
B1200	Standard Baby	120 Degrees
E800	High Contrast Children's & Adults	80 Degrees
C300	High Magnification	30 Degrees
PL200	Portrait Lens	N/A

Control Panel

The control panel is located at the front edge of the keyboard tray. It provides controls and indicators of system status.

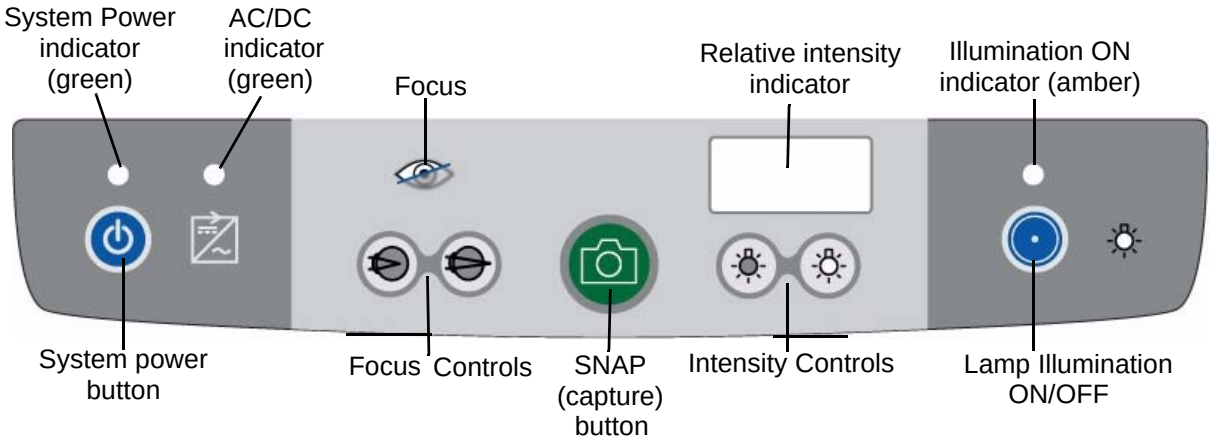


Figure 5 Control Panel

3 Maintenance

This section addresses maintenance and support under the following topics:

- Recommended Maintenance Schedule, below
- Installing Lens Pieces, page 24
- Cleaning Procedures, page 25
- Camera Color Balance Adjustment, page 36
- Lamp Replacement, page 40
- Fuse Replacement, page 43
- Key Validation, page 45
- Servicing the Interior of the Cart, page 47

Recommended Maintenance Schedule

Between patients: Clean and inspect lens piece.

Weekly: Wipe down the system.

Monthly: Inspect cables and connections for wear.

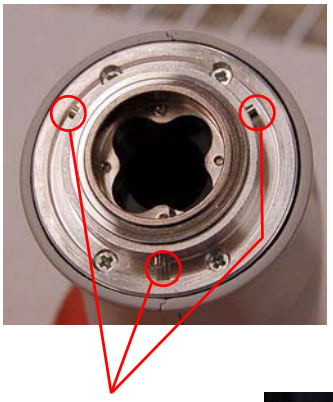
System powered for at least 8 hours (AC powered - AC/DC indicator ON light solid) to assure backup battery is fully charged.

Burned out bulb: Replace illumination bulb.

Blown fuse: Replace system fuses.

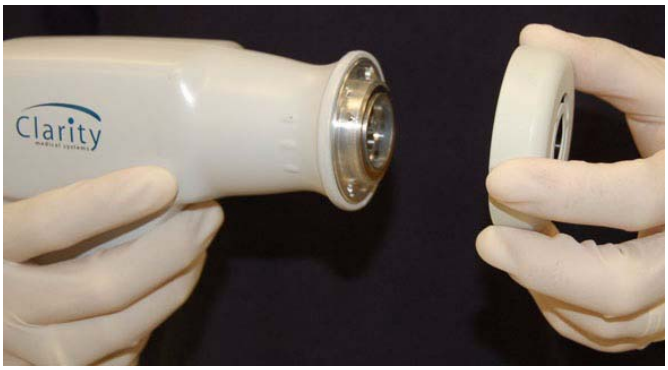
Installing Lens Pieces

1. Fit the lens piece on the handpiece, aligning the 3 radial pins on the front of the handpiece with the spaces between the tabs of the spring ring on the lens piece.
2. Twist the lens piece clockwise (as shown in Figure 6) until you hear a click, indicating that the lens piece is locked in place.



alignment pins on handpiece

Align lens piece to fit over pins



Carefully tighten clockwise until it clicks in place. Do not overtorque.

Figure 6 Installing a lens piece on the handpiece

3. Verify that the handpiece is connected to the system as shown in Figure 7.

Figure 7 Handpiece connections

Cleaning Procedures

For cleaning purposes, the RetCam3 is divided into two categories:

- The Lens Piece that contacts the patient
- The rest of the system

Cleaning the Lens Piece

The patient contact area lens should be cleaned immediately after use to prevent the coupling gel from hardening.

1. Wipe away debris from the front lens piece surface with a soft dry tissue, sterile water soaked tissue, or combination.
2. Then, using a clean soft cloth (such as sterile gauze) saturated in a fresh solution of 70% IPA (isopropyl alcohol), gently wipe the front of the lens piece, being sure to pay special attention to the concave contact lens area, to remove any remaining debris; at least 11 wipes with a clean saturated cloth. Pre-packaged 70% IPA swabs (such as ReliOn Alcohol swabs or BD Alcohol Swabs) may be used.
3. Rinse surface thoroughly using sterile water.
4. Air dry.
5. Verify that the lens surface is free of debris and coupling gel. Repeat above steps if necessary.
6. Inspect the lens for damage and clarity. Do not use the lens if there are chips, cracks, or rough edges on the lens which may injure the patient's eye.

CAUTION: Do not autoclave any part of the system. Autoclaving causes irreparable damage and voids the warranty.

CAUTION: Never immerse the entire lens piece or handpiece in any liquid or solution. If necessary, only the distal 4 mm can be immersed. See Figure 8. It is important not to immerse the joint where the polished metal tip meets the painted housing, since it is susceptible to corrosion.

WARNING: If you clean or disinfect, rinse the lens with sterile water to avoid corneal de-epithelialization that may be caused by residual solution.

Note: For disinfection, see attached Information Statement from the American Academy of Ophthalmology.

CAUTION: As disinfection solutions may cause corrosion of the lens piece, soak times that exceed the recommendation should be avoided.

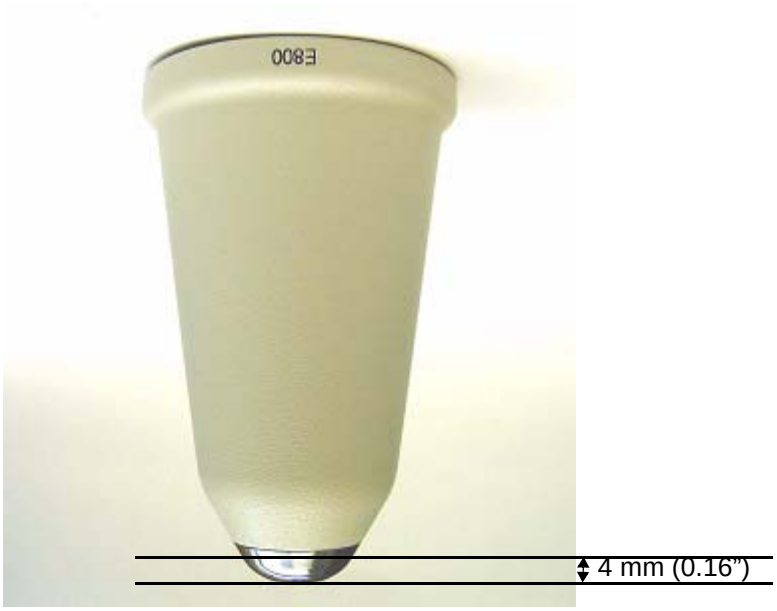


Figure 8 Inverted lens piece showing permissible depth of immersion

Cleaning the Rest of the System

As with any medical device, use good public health practices when handling the equipment, based on CDC guidelines. In addition, as with typical office equipment, a gentle wiping with a cloth moistened with mild soap and/or water is recommended. Do not spray cleaning solutions on any part of the system.

Disposal of Materials

Dispose of waste materials according to local and national requirements. Contact Clarity Service if additional assistance is required.

Information Statement

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

Minimizing Transmission of Bloodborne Pathogens and Surface Infectious Agents in Ophthalmic Offices and Operating Rooms

Introduction

This document is intended to provide guidance to ophthalmologists and their staff about minimizing transmission of infection in their offices and operating rooms. This document addresses prevention of bloodborne pathogens such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), and other viruses, such as adenovirus and herpes simplex virus. These recommendations are mainly based on broad guidelines issued by the U.S. Department of Health and Human Services (DHHS) and the U.S. Department of Labor for health care workers.

Bloodborne pathogens may be present in blood, blood-contaminated products or other bodily fluids especially if contaminated with or mixed with blood. Percutaneous injuries (e.g., a needlestick or cut with a sharp object) represent the greatest risk of transmission of bloodborne pathogens to health care workers. Universal precautions apply to blood and other body fluids containing visible blood, but not to tears unless they contain visible blood.[1] The use of universal precautions, including handwashing and barriers, reduces contact with blood and bodily fluids, thus reducing exposure of health care workers to bloodborne pathogens. The use of safety devices and techniques to reduce handling of sharp instruments also reduces the number of percutaneous injuries.

Exposure to HIV in health care settings has been of major concern. As of June, 2000, the Centers for Disease Control and Prevention (CDC) received reports of 56 U.S. health care personnel with HIV transmission associated with occupational exposure, and another 138 reports of possible transmission to date.[2] For health care personnel exposed through percutaneous means to HIV-infected blood, the estimated risk for HIV infection is 0.3%.[2] Risks associated with a mucous membrane exposure are estimated to be 0.09%.[2] Risks for HIV seroconversion after a percutaneous exposure have been found higher for those exposed to a larger quantity of blood, (i.e., a device visibly contaminated with blood, a needle being placed directly in a vein or artery, or a deep injury) or when the source patient was terminally ill with AIDS.[2]

Transmission of HBV poses a risk to health care workers. In 1994, approximately 1,000 health care workers were infected with HBV from occupational exposure.[2] Since implementation of routine preexposure vaccination of health care personnel and precautions to prevent exposure to blood, there has been a significant decrease in HBV infection among health care personnel.[2] HBV is transmitted by mucosal or percutaneous exposure to blood and serum-derived body fluids from persons with acute or chronic infection. The risk of developing clinical hepatitis from exposure to the blood that was both hepatitis B surface antigen (HbsAg) and hepatitis E antigen (HbeAg) positive was 22 to 31%.[2] Any person who is seropositive for hepatitis B surface antigen can be infectious. The CDC recommends that health care personnel who have routine contact with blood and bodily fluids be vaccinated.[3] For applicable settings, the OSHA standard requires that hepatitis B vaccine be made available to personnel with occupational exposure to blood, at the employer's expense.[4]

American Academy of Ophthalmology®
P.O. Box 7424
San Francisco, CA 94120-7424
415.561.8500
http://aao.org

HCV is the cause of most parenterally transmitted cases of non-A, non-B hepatitis in the U.S. There is no vaccine currently available and postexposure prophylaxis has not appeared effective in preventing infection. HCV is thought to be transmitted relatively rarely through occupational exposure to blood.[2] The incidence of seroconversion after percutaneous exposure to an HCV-positive source is estimated to be 1.8%.[2] Hepatitis C virus (HCV) has been isolated in tears and aqueous humor.

Adenovirus has been the main cause of nosocomial outbreaks of conjunctivitis. These outbreaks have mostly occurred in eye clinics or offices. Adenovirus can survive for long periods on environmental surfaces and ophthalmic instruments can become contaminated and transmit infection. Handwashing, glove use and disinfection of instruments can all help to prevent or limit the transmission of adenovirus. Infected personnel should not provide patient care for the duration of symptoms after onset of adenoviral conjunctivitis

Background

The National Society to Prevent Blindness, in cooperation with the American Academy of Ophthalmology assembled a Task Force to examine the risk of acquiring HIV infection in the course of eye examinations and treatments. The Task Force helped develop precautions to reduce spread of pathogens that might be present in tears.[5]

In August 1987, the Centers for Disease Control and Prevention (CDC) issued revised recommendations for the prevention of HIV transmission in a health-care setting.[6] This was followed two months later by a joint advisory notice from the U.S. Department of Labor and the U.S. Department of Health and Human Services regarding the protection against occupational exposure to HBV and HIV.[7] These documents addressed the risk that health care workers may face in the course of their duties and made broad recommendations labelled universal precautions that all health care workers should follow. Neither document distinguished the risks and needs of healthcare workers in ophthalmology from any other health care occupation.

In June 1988, the CDC further clarified their recommendations, particularly as they relate to the protection of health care workers, by stressing the far greater risk of bloodborne viral infections (e.g., HIV and HBV) posed by blood and blood-contaminated bodily fluids than by such bodily secretions as tears.[8] In that document, they noted that "Universal precautions do not apply to ... nasal secretions, sputum, sweat, tears... unless they contain visible blood." Thus, normal tear exposure does not require bloodborne pathogen precautions. In June, 2001, the U.S. Public Health Services updated recommendations for the management of occupational exposures to HBV, HCV and HIV.[2]

In March 1992, the Occupational Safety and Health Administration (OSHA), issued a set of regulations entitled, "Occupational Exposure to Bloodborne Pathogens, "which requires that employers establish safeguards which protect workers against hazards related to bloodborne pathogens.[4] These regulations require identification of who is at risk of occupational exposure, the communication of hazards to employees at risk for exposure, exposure prevention control measures, and what to do if an exposure occurs. In April 2001, the Needlestick Safety and Prevention Act became effective, revising the bloodborne pathogens standard to require employers identify and make use of safer medical devices which can be used to reduce worker exposure.[9]

In 1992, the American Academy of Ophthalmology Public Health Committee developed updated recommendations for ophthalmic practice in relation to HIV.[10] The Committee noted that there were two distinct areas of concern to ophthalmic medical personnel and patients:

1. Transmission of ocular surface infectious agents such as adenovirus or herpes virus. Prevention of transmission of these pathogens requires good hygienic techniques, such as routine hand washing, tonometry cleaning and trial contact lens disinfection.

2. Transmission of bloodborne pathogens such as HIV or HBV. Prevention of transmission of these agents requires the use of bloodborne pathogen precautions, which include the proper use of gloves, needle disposal and other precautions such as administering hepatitis B vaccine in workers exposed to bloodborne pathogens.

Recommendations

The Committee recommended specific measures that would provide adequate protection for the patient, for health care workers in the ophthalmic care setting, and for the ophthalmologist. This document updates four areas:

- Procedures for protection of the patient
- Procedures for protection of the staff
- Procedures for protection of the ophthalmologist
- Responsibilities toward patients with known or suspected HIV infection

I. Procedures for Protection of the Patient

Protection of patients from exposure to the HIV during examination and treatment of eye disorders incorporates

the application of good public health principles and specialized precautions. Since the infection was first recognized in 1981, there has been no evidence to indicate that the HIV has been transmitted through any of the diagnostic or surgical procedures performed by ophthalmologists. According to the CDC, the likelihood of transmission through contact with tears is extremely remote.[8] However, because the virus is potentially lethal, is present in surface epithelia in the eye and in low titers in tears and ocular fluids of infected individuals, and can (in theory at least) be transmitted through mucous membranes, public health officials have recommended that reasonable precautions be taken. Furthermore, because many HIV carriers may be unaware of their infection and show no sign of the disease, the following recommendations should be routinely used for **all** patients. Recommendations for the safe usage of ophthalmic instruments and contact lenses are provided. These guidelines represent good, general ophthalmic technique, because they reduce the risk of transmitting both bloodborne pathogens (HIV, HBV and HCV) and surface infectious agents (e.g., herpes simplex virus, adenovirus, etc.) likely to be encountered in patients presenting for eye examinations.

Recommendations

A. Handwashing.

Handwashing represents the single most effective means of avoiding the risk of transmitting or acquiring infections in the course of examination.[11] The CDC recommends that ophthalmic medical personnel performing eye examinations or other procedures involving contact with tears should wash their hands immediately after a procedure and between patients.[5] Handwashing should be encouraged when there is any doubt about the necessity for doing so. For routine handwashing, a vigorous rubbing together of all surfaces of the lathered hands is recommended for at least 10 seconds, followed by a thorough rinsing under a stream of water.[11] Plain soap can be used for handwashing for most routine activities. Gloves may be used as an extra margin of safety. When gloves are worn, handwashing is still recommended because gloves can become perforated and bacteria can grow rapidly on gloved hands. If there are cuts, scratches, or dermatological lesions (e.g., weeping lesions) on the hands, then use of gloves is advisable.

B. Eyedrops.

The bottle tip should not come into direct contact with the patient's tears or conjunctiva. If the tip does touch the patient, the bottle should be discarded.

C. Gowns, masks and protective eye wear.

Gowns, masks and protective eyewear are unnecessary for the usual ophthalmic examination.

D. Disinfection procedures.

Disinfection is a process to eliminate most or all pathogenic microorganisms from inanimate objects, such as medical devices or equipment.[12] This is usually performed using chemicals known as germicides or disinfectants. High-level disinfection kills all organisms and is performed suing a germicide which is regulated by the Food and Drug Administration. The CDC recommends that if there are questions about high-level disinfectants or how to disinfect a particular medical device, the office should contact the manufacturer of the product.[13]

The CDC has recommended the following, which are proven to inactivate infectious HIV, herpes simplex virus, and adenovirus.[5]

- Wiping clean and then disinfecting with bleach is recommended by the CDC as an effective way to inactivate HIV. Remove the entire prism from the tonometer and place it in a suitable receptacle that allows the applanating surface and adjacent 2–3 mm of the tonometer to be immersed in a 1:10 dilution of household bleach (sodium hypochlorite). One method uses a Petri dish with small holes drilled in the lid, which allows just the tonometer tip to be partially immersed in the solution.[14] After a five-minute period of soaking, the tip should be washed under running water and dried before use. Two tonometer prisms should be available so that one can be used while the other is being disinfected. Soaking the entire tip may eventually remove the coloring of the etched calibration marks. These disinfecting solutions should be changed at least once daily.

- As an alternative, the CDC recommends that a similar approach with a 5 to 10 minute exposure to a fresh solution of either 3% hydrogen peroxide, 70% ethanol, or 70% isopropanol can be followed. These solutions need to be changed at least twice daily.

Goldmann-type Tonometers

A recent study compared several methods of disinfecting Goldmann tonometer tips, which were inoculated with hepatitis C virus.[15] The methods that resulted in the greatest decrease in concentration of HCV RNA were a 5-minute soak in 3% hydrogen peroxide or 70% isopropyl

alcohol following by washing in cold water. A 5-second 70% isopropyl alcohol wipe was not as effective, and a 5-second wipe with povidone iodine was more effective than the isopropyl alcohol wipe in reducing HCV RNA.

The washes are important to avoid corneal de-epithelialization that might be caused by residual disinfectant solution.

Schiotz Tonometer

The tonometer should be dissembled between each use, cleaning the barrel with two pipe cleaners (the first soaked in alcohol, the second dry) and the footplate with an alcohol swab. All surfaces must be dried before reassembly. Disposable covers are also available.

Non-contact Tonometers

The non-contact tonometer may not make contact with the cornea or tears, but may cause micro-aerosol formation. The front surface may be wiped with an alcohol-soaked sponge since it may occasionally touch the eye.

Digital Pneumotonometer

Tips of pneumotonometers should be cleaned with an alcohol sponge, taking care that the surface is dry before using it again. It is important to allow the alcohol to evaporate completely to avoid damage to the corneal epithelium.

Diagnostic Contact Lenses (Goldmann, etc.)

The lens is inverted so that the contact lens surface is uppermost. The outer casing and inner surface of the lens are then vigorously wiped with an alcohol sponge
As an alternative, the inner cup may be filled to the rim or partly immersed within a fresh 1:10 dilution of household bleach. After five minutes, the bleach is removed and the device is briskly irrigated with running water and dried. This method allows cleansing of the outer surface of the lens as well as the contact portion without exposing the anti-reflective coating on the operator surface of the contact lens to the bleach. It is important to rinse to avoid corneal de-epithelialization that might be caused by residual disinfectant solution.

Other Instruments That May Come Into Contact With Patients

The HIV is a fragile virus and there is no evidence of casual spread from surfaces of ophthalmic instruments. However, it is known that other viruses, such as adenovirus, may persist for many hours on a dry surface and, thus, could conceivably be transmitted to other patients.[16] Therefore, if an instrument, such as a slit lamp biomicroscope, has been used for a patient who is suspected of having an ocular infectious disease, it is strongly recommended that the surfaces on the instrument be cleaned with alcohol or bleach.

Trial Fitting Contact Lenses

Contact lenses need to be disinfected between patients. Rigid gas permeable and hard contact lenses can be disinfected using a hydrogen peroxide or a chlorhexidene-containing disinfectant system. Soft contact lenses can be disinfected with either hydrogen peroxide or a heat disinfection system.[5]

E. Tissue Transplantation.

The Eye Bank Association of America has strict criteria in place to screen corneal and scleral tissue for transplantation, to prevent transmission of diseases. There have been no confirmed cases of occupational transmission of transmissible spongiform encephalopathies, such as Creutzfeld-Jakob disease. The CDC recommends use of stringent chemical and autoclave sterilization methods for heat-resistant instruments that come into contact with high infectivity tissues in patients with suspected or confirmed CJD.[17] For infection control of transmissible spongiform encephalopathies, the World Health Organization recommends the following in situations where there is contact with high infectivity tissues in patients with suspected or confirmed CJD:[18]

1. Use single-use surgical instruments
2. Avoid mixing instruments used on tissues of high infectivity vs. no infectivity
3. Destroy re-usable instruments, where possible
4. If destruction is not possible, decontaminate instruments.

The Risk of Acquiring HIV Infection from Ophthalmic Medical Personnel

The risk of patients being infected by an ophthalmologist or ophthalmic medical personnel who has been infected with the HIV is considered extremely remote. Standard office practices, as discussed above, will minimize even the unlikely risk of contamination of patients. Surgical patients are protected by the routine use of barriers (e.g., gloves). Certainly, an instrument that punctures the skin of an ophthalmologist or the surgical assistant must be removed from the operating field and sterilized. The surgeon or assistant must reglove after all bleeding has stopped and any residual blood has been removed.

The CDC Guideline for Infection Control in Healthcare Personnel also provides advice about management of patient contact and other situations when health care personnel have HIV and other illnesses which could be transmitted to patients.[19]

II. Procedures for Protection for the Staff

Protection of the ophthalmic medical personnel involves preventive measures to avoid infection with ocular surface contaminants (such as adenovirus or herpes simplex virus), as well as bloodborne pathogens (such as HIV, HBV and HCV).

Bloodborne pathogen precautions further reduce the unlikely risk of contamination of the ophthalmic medical personnel and patient, alike. Employers under OSHA's rule with health care workers who are exposed to bloodborne pathogens are required to establish a program that informs employees and employers of the risks of occupational exposure to bloodborne pathogens and how to reduce those risks.[3]

Human tears are not considered to contain significant amounts of bloodborne pathogens, and thus do not require OSHA's bloodborne pathogen precautions; but exposure to human tears does require good office hygiene practices such as handwashing. However, contact with tears contaminated with blood, such as in minor surgery, requires the use of bloodborne pathogen precautions.

As the prevalence of HIV infection continues to increase throughout the United States, it is inevitable that patients carrying HIV will be more commonly encountered in eye examining rooms and in surgery. Some of these patients will be known to be infected with the HIV, but in many, it will be unrecognized. All health care personnel engaged in delivering ophthalmic care to such patients might, in the course of their normal duties, be exposed to the blood of individuals who may be shedding the virus. Although the risk of infection in these circumstances appears to be extremely remote, precautions by health care employers and employees are justified as recommended by the OSHA and the CDC.

The following recommendations for hygienic procedures to be used in the delivery of eye care to patients are effective ways to minimize this risk as well as the risks of contracting or transmitting other much more common infectious diseases encountered in patients. Because it is impractical to identify all patients who may be carrying these infectious agents, these recommendations should be the routine for all patient encounters.

General Precautions Against Infection – Office

A. Handwashing.

The hands should be washed with soap and water and thoroughly dried on a fresh or disposable towel between each eye examination. Fingernails should be kept short and clean. The hands and fingers should be inspected frequently for cuts, abrasions, and breaks in the skin or paronychia.

B. Gloves.

The CDC suggests in its recommendations for the prevention of HIV transmission in health care setting, released in 1987[7], and updated in 1988[8], that:

> "All health care workers should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with the blood or blood-contaminated fluids of any patient is anticipated. Gloves should be worn for touching blood and blood-contaminated fluids, for handling items or surfaces soiled with such fluids and for performing venipuncture and other vascular access procedures. Gloves should be changed after contact with each patient. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other bodily fluids. Hands should be washed immediately after gloves are removed.
>
> Health care workers who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment until the condition resolves.
>
> Pregnant health care workers are not known to be a greater risk of contracting HIV infection than health care workers who are not pregnant; however, if a health care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health care workers should be especially familiar with and strictly adhere to precautions to minimize the risk of HIV transmission."

In accordance with these recommendations, disposable gloves should be readily available for all ophthalmic medical personnel and they should be instructed regarding the rationale for wearing gloves and their appropriate usage. It should be noted particularly that gloves:

- Are not a substitute for handwashing, and
- Are for single use only, and should be discarded after each patient encounter.

C. Gowns and Masks.

Gowns and masks are unnecessary in the normal ophthalmic office setting.

D. Protective eye wear.

In situations when splashing with blood or blood-contaminated fluids may be anticipated, protective eyewear is indicated.

E. Handling of tissue.

In the course of assisting in the examination of eye patients, ophthalmic medical personnel may be required to handle the eyelids and surrounding facial skin and thus, may come in contact with tears and the conjunctival membrane. To minimize direct contact with these tissues, particularly if the patient has a known or suspected eye infection, ophthalmic medical personnel should be instructed in the use of gloves or in "no-touch" techniques involving the use of cotton-tipped applicators to stabilize the tissues whenever possible.

F. Hepatitis B vaccination.

Ophthalmic medical personnel who frequently come in contact with needles, blood or blood products are advised to receive hepatitis B vaccine to avoid infection with the virus.[3] OSHA regulations require that the employer make hepatitis B vaccine available to all employees who have occupational exposure.[4]

Procedures

A. Handling of sharp instruments.

The CDC has recommended that all health care workers adopt precautions to prevent injuries caused by needles, scalpels and other sharp instruments or devices[8]:

- During procedures
- When cleaning used instruments
- When disposing of used needles, and
- When handling sharp instruments after procedures

To prevent needlestick injuries, ophthalmic medical personnel should be instructed in the proper handling of needles, i.e., needles should not be recapped, or purposely bent or broken by hand, removed from disposable syringes or otherwise manipulated by hand. Health care workers should be instructed to place disposable syringes and needles, scalpel blades and other sharp items in puncture resistant containers following their use. Puncture resistant containers should be provided and should be located as close as practical to the area where needles and syringes are in use. Newer devices have engineering controls such as injury protections and needleless systems to minimize injuries.

OSHA's revised Occupational Exposure to Bloodborne Pathogens Standard now requires that the employers governed by this rule review annually and update to reflect changes in technology that could reduce exposure to bloodborne pathogens, and maintain a sharps injury log.[20] OSHA's Bloodborne Pathogens Standards applies to all employers with employees who have occupational exposure to blood or other potentially infectious materials. However, workplaces with 10 or fewer employers are exempt from OSHA recordkeeping requirements, including a Sharps Injury Log.[21]

B. Fluorescein and Indocyanine green (ICG) angiography.

It is recommended that photographers and other health care workers who may come in contact with blood while performing fluorescein and ICG angiography wear gloves and adhere to the procedures as outlined in this section.

C. Contact lens fitting.

Ophthalmic medical personnel involved in the fitting of contact lenses should be instructed in the precautions outlined by the CDC for disinfection of lenses.[4]

D. Minor office surgical and diagnostic procedures.

During the performance of minor surgical and diagnostic procedures, particularly where contact with blood or blood-contaminated fluids may occur, gowns, disposable gloves and masks, and protective eyewear should be worn.

Surgery

Ophthalmic medical personnel assisting at eye surgery should be instructed to avoid the direct handling of needles and those parts of instruments that have come into contact with body tissues and fluids. Thus, needles should be manipulated with forceps or needle holders rather than by the gloved fingers, instruments should be held by the handle rather than by the tips, and the cleaning of instruments should be performed in such a way that accidental perforation of the gloves is avoided. If an instrument punctures a glove or the skin, it must be removed from the operating field and sterilized. These practices should be incorporated into standard operating room infection control procedures and should be monitored for compliance, as are other infection control procedures.

If an ophthalmic medical personnel does accidentally sustain a skin puncture, the following actions should be taken. The individual should temporarily discontinue participation in surgery (if possible) and cleanse the wound for five minutes with an antiseptic solution.

The wound should then be dressed with a bandage after rescrubbing. If there is no oozing or weeping of the wound, the person may reglove, and complete the surgery.

Under experimental conditions, it has been reported that oral polio vaccine virus was cultured from the laser plume after excimer laser ablation.[22] Another experimental study postulated that infectious virus particles could be aerosolized during excimer laser photoablation.[23] Another study using a model system did not find any transmission of virus by the excimer laser plume.[24] It seems prudcnt then to maintain the same procedures in excimer laser surgery procedures as practiced as in other surgical procedures, e.g., masks, gloves, sterilization of instruments, etc.

Management of Exposures

These recommendations are based on the U.S. Public Health Service Guidelines, published in 2001.[2] Occupational exposures are considered urgent medical concerns so that timely management can be administered.[2] Studies show that postexposure prophylaxis should be initiated as soon as possible, because it is most effective within 24 to 36 hours after exposure. However, even after 24 to 36 hours, it can be considered, because it might still be effective.

If a person has been exposed to a source person already known to be seropositive for HIV or there is a strong likelihood that the source person is HIV infected, then postexposure prophylaxis (PEP) can be initiated as soon as possible, in consultation with physicians with expertise in antiretroviral therapy and HIV transmission. If the source person's HIV status is not known, the use of PEP can be decided on a case-by-case basis. All persons with occupational exposure to HIV should receive follow-up counseling, testing and medical evaluation. For HIV PEP, recommendations include a basic 4-week regimen of drugs, if tolerated, and an expanded regimen for exposures that pose an increased risk for transmission.[2,25]

If the source person is seronegative for HIV, then baseline testing or further follow-up of the exposed health care personnel is not necessary. Otherwise, health care personnel should be tested for HIV within hours of exposure. Serologic testing should be made available to all health care personnel who are concerned that they might have been infected.

For personnel exposed to HBV, it is recommended to initiate the hepatitis B vaccine series to an unvaccinated person, and provide PEP with hepatitis B immune globulin or hepatitis B vaccine in appropriate cases, preferably within 24 hours.[1]

For personnel exposed to HCV, the Public Health Service does not recommend immune globulin or antiviral agents as PEP.[2] However, there have been studies outside the United States that have utilized interferon early in the course of acute hepatitis C to prevent the establishment of chronic hepatitis C.[2,26] In case of percutaneous or mucosal exposure to blood, the CDC recommends that health care institutions have policies to follow-up for HCV infection, which could include testing of the source person for anti-HCV antibodies, and follow-up testing for anti-HCV antibodies of the affected personnel, if the source person is found positive for HCV.[2]

If there is exposure to blood, fluid containing visible blood, or other potentially infectious fluid (not including tears), then the status of the source person should be evaluated for HIV, HBV, and HCV infection as soon as possible.

It is recommended that health care organizations have systems in place for prompt reporting, evaluation, counseling, treatment and follow-up of occupational exposures to bloodborne pathogens.[2] Health care personnel should be educated to report occupational exposures immediately after they occur, because treatment can be most effective if administered as soon as possible after the exposure. Employers subject to OSHA regulations are required to establish exposure control plans that include post-exposure follow-up and to comply with incident reporting requirements.[4]

III. Procedures for protection of the ophthalmologist

Ophthalmologists might be at risk of acquiring HIV, HBV or HCV infection in their professional activities from two major sources: 1) the patient examination, and 2) the setting of surgical intervention.

General Precautions Against Infection – Office

The ophthalmologist personally should follow the same procedures designed to protect office staff and described in Section II. These include handwashing, wearing of gloves where appropriate and taking precautions to prevent injuries caused by needles, scalpels and other sharp instruments. Avoid touching one's own eyelids or contact lenses with the fingers without thorough hand washing.

In the normal ophthalmic office setting, gowns, masks and protective eyewear are usually unnecessary except in situations when splashing with blood or blood-contaminated fluids may be anticipated.

Minor Office Surgical and Diagnostic Procedures

The universal precautions should be observed when performing minor procedures and intravenous fluorescein angiography. In addition to gloves and masks, protective

eyewear should be used if there is a possibility of blood or body fluid splashing.

Surgery

Ophthalmologists are probably most at risk of exposure to HIV and other bloodborne pathogens while performing or assisting in surgery. The following procedures are recommended during surgical procedures:

- Adopt universal precautions for all patients
- Wear gloves when performing all injections
- Handle suture needles with needle holders only
- Develop techniques for safe handling and transfer of sharp instruments
- Follow guidelines given in Section II regarding surgery

IV. Responsibilities Towards Patients with Known or Suspected HIV Infection

Like all physicians, ophthalmologists have a moral and ethical responsibility for providing care to all patients, regardless of whether they are known to be infected with HIV, are known to be seropositive or fall within a "high-risk" group.

Ophthalmologists and ophthalmic medical personnel are at little risk of contracting HIV infection in the course of routine clinical practice. Risks may be further minimized when dealing with those known to be seropositive or suffering from clinical AIDS, but one should remain cognizant of the fact that many seropositive individuals have not been tested. Given the above scenario, bloodborne precautions are warranted for all appropriate patients.

Conclusion

The risk of contracting HIV infection in the ophthalmic healthcare setting is estimated to be extremely remote. Although HIV has been isolated from tears and other ocular fluids, the titer is extremely low and is considered by many authorities to be below an inoculating dose. To date, there is no evidence that the infection has been acquired from contact with tears. However, it must be remembered that these precautions will be effective against other more infectious agents than may be encountered in patients with HIV infection. These OSHA and CDC guidelines are intended to help protect the public and ophthalmic medical personnel, and minimize transmission of bloodborne pathogens and surface infectious agents.

Additional Resources:

Further information on the CDC guidelines can be obtained by viewing the CDC website for Division of Healthcare Promotion http://www.cdc.gov/ncidod/hip/.

Further details on the OSHA regulations including regulations governing HIV and HBV research laboratories and production facilities can be obtained by viewing the OSHA website (http://www.osha.gov/) or ordering publications online (http://www.osha-slc.gov/OshDoc/Additional.html)

Occupational Safety and Health Bloodborne Infectious Disease
www.cdc.gov/niosh/bbppg.html

State needle safety legistation: www.cdc.gov/niosh/ndl-law.html

Exposure management resources:

National Clinicians' Postexposure Prophylaxis Hotline (PEPline)
1-888-448-4911

Needlestick! www.needlestick.mednet.ucla.edu

Hepatitis hotline 1-888-443-7232

Reporting to CDC: Occupationally acquired HIV infections and failures of PEP
1-800-893-0485

HIV/AIDS treatment information service
www.hivatis.org

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Fluorescein Angiography Frequently Asked Questions

WARNING: There are high voltages within the FA module and the cover of the module is not to be removed by customers or distributors.

Q: Can the FA Light Source generate other colors and wavelengths of light?

A: No, it is designed for 471 nanometer blue excitation exclusively.

Q: How long does the Xenon bulb last?

A: The bulb is a special order and extensive testing data does not exist. However, a guideline is that the intensity may reduce to one half the original value after 50 hours of use, and then continue to reduce slowly after that. Some users have been performing successful FA imaging up to 200 hours of lamp time.

Q: Can the bulb be replaced in the field?

A: It is not designed for field replacement. Return the unit to the factory if the output is reduced or the lamp will not illuminate. Call Customer Service for assistance.

Q: How much does a replacement bulb cost?

A: It depends on the circumstances and what else is out of specification at the time of service. You will be quoted the costs for repair of your FA Light Box before any work is begun.

Q: Can I get a replacement barrier filter if mine is lost or broken?

A: Yes, contact Customer Service for a quotation.

Q: Can the FA Light Source be returned for service without returning the whole RetCam 3?

A: Yes, the FA Light Source is a module that is removable by a person with the skill level of a nominal biomedical technician. Be sure to package it as a sensitive medical instrument with at least 3” of padding on all sides in a sturdy box, sealed well, shipped insured for USD $20,000. NOTE: Clarity can send appropriate packaging material to you if needed.

Camera Color Balance Adjustment

You must remove the front panel as illustrated below to access the color balance buttons.

Pull from bottom outward and remove

Figure 9 Removing the front panel

When to Adjust Color Balance: Clarity Medical performs these procedures at the factory before shipment. You should have to adjust the camera color balance only rarely, and then only when the colors of the live image are very different from the real object. If this occurs, we recommend you perform first a black balance and then a white balance, in that order.

If you find that you must adjust the color balance frequently, please contact Clarity Customer Service.

Automatic Black Balance (ABB)

The automatic black balance adjustment corrects the camera controller to display black accurately. To adjust the automatic black balance, follow these steps:

1. With the system running, initiate a new imaging session and check on screen to see that the camera is working (receiving an image).

Note: To start a new imaging session, you must select or create a patient record.

2. Disconnect the fiber optic (lamp) cable. The handpiece should now not be projecting any light.
3. Hold the front of the handpiece, with or without a front lens, against a towel or soft cloth to block all light from entering the camera.
4. Press the **ABB** button on the front panel for about 1 second until characters “ABB” appear and release button.

Figure 10 Automatic black balance test button

The characters **“ABB”** will stop blinking and the characters **“ABB OK”** will appear for approximately 1 second. Black balance adjustment is successful.

If the characters **“ABB NG”** appear, it means that the automatic black balance cannot be performed (NG = no good). Usually this is due to light leaking into the black image. Try blocking ambient light more completely and press **ABB** again. If the problem persists, please contact Clarity customer service.

Automatic White Balance (AWB)

The automatic white balance adjustment corrects the camera controller to display colors accurately.

Note: This procedure should be done under room lighting that simulates conditions during actual use.

To adjust the automatic white balance, follow these steps:

1. Perform automatic black balance as described above.
2. Reconnect the fiber optic (lamp) cable. The handpiece should now be projecting light. Adjust the handpiece light level to that of normal usage.
3. Attach any front lens, if not already present. See Installing Lens Pieces on page 24.
4. Place a blank, white piece of paper on a flat surface. Hold the handpiece perpendicular to the paper. Hold the tip of the lens approximately 2” (50 mm) from the paper, so that the center of the image on the screen appears uniformly bright. Adjust the light intensity on the control panel to read ~ 20 on the indicator as a starting point. The outer area or ring of the image may be slightly gray or yellow in color.
5. Press the **AWB** button on the front panel until the characters “AWB” appear on the screen.

Figure 11 Automatic white balance test button

The characters **“AWB”** will stop blinking and the characters **“AWB OK”** will appear for approximately 1 second. White balance adjustment is successful.

If the characters **“AWB NG, LEVEL NG”** appear, automatic white balance adjustment cannot be performed because the light level is too high or too low. Adjust the light level up or down as indicated and repeat steps 4. and 5. again. If **“AWB OK”** still does not appear, try adjusting the ambient (room) lighting up or down, or vary the distance from the front lens tip to the paper. If the problem persists, please call customer service.

Lamp Replacement

WARNING: Appropriately power down and unplug the unit and allow the illumination lamp to cool before replacing it.

Replacement illumination lamps are available from Clarity.

Follow these steps to replace the illumination lamp:

1. If it is not already turned OFF, turn OFF the instrument.
2. Disconnect the main power cord from the wall.
3. Unplug the fiber optic cable from the front panel.
4. Remove the light box cover.

Figure 12 Light box cover removed

5. Remove the two screws from the lamp assembly drawer, the smaller panel with the black handle on the front.

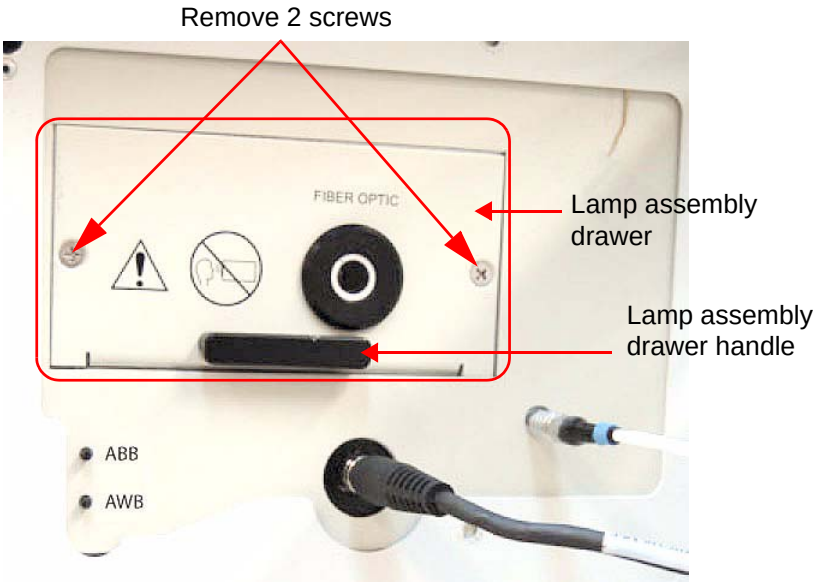


Figure 13 Front panel showing the lamp assembly drawer

6. Grip the handle on the lamp assembly drawer. Pull the drawer out slowly. Stop when the light bulb is fully exposed.
7. Just behind the socket and extending from the rear of the illumination lamp is a thick gray wire, the “lamp ejector” indicated in the picture below. Be prepared to grab or catch the illumination lamp unit as you gently rotate this wire toward you (rotate it up, or counterclockwise), which ejects the lamp. Remove the old illumination lamp.

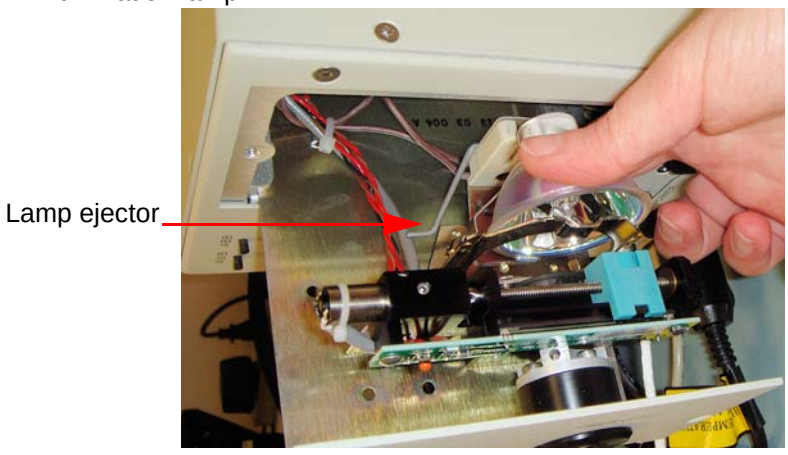


Figure 14 Removing the illumination lamp

CAUTION: Only touch the exterior surface of the illumination lamp. Do not touch the bulb, which is located in the center of the reflector, nor the inner (concave) surface of the reflector. Skin oils will adhere to the bulb and reflector, which reduces the cooling efficiency of the bulb and thereby creates a hot-spot leading to premature burnout. Handle by the outside of the lamp only, as shown.

8. **Holding the new lamp only on the outside,** as shown, replace it in the assembly, aligning the two pins in the rear with the corresponding tracks in the socket and pushing it gently and evenly into place.
9. Check the position of the new bulb to make sure that the reflector of the bulb is located in the center of the lamp socket's opening.
10. Push the lamp assembly drawer back in carefully. Use caution to avoid pinching wires in the area.
11. Replace the two screws on the small front panel.

Fuse Replacement

Locate the power entry module on the lower right side of the rear of the cart. Make sure to remove the power cord before proceeding any further. (See Figure 15.)

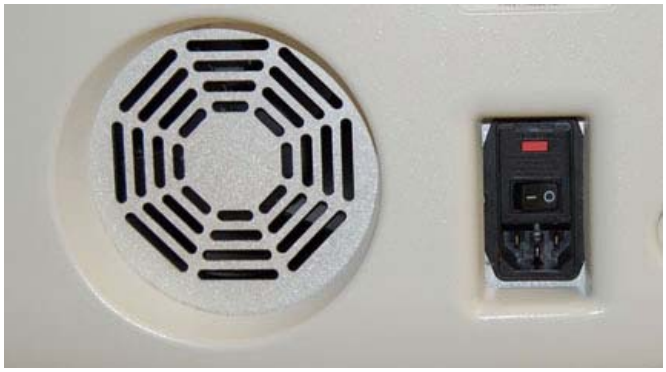


Figure 15 Power Entry Module

Using a flat blade screwdriver, gently pry open the cover of the fuse holder at the top of the power entry module. (See Figure 16.)

Figure 16 Opening the fuse holder cover

Remove the fuse holder. (See Figure 17.)

Figure 17 Removing the fuse holder

Remove the blown fuse or fuses from the fuse holder and replace it with a new fuse of same type and rating. (See Figure 18.) Re-insert the fuse holder.

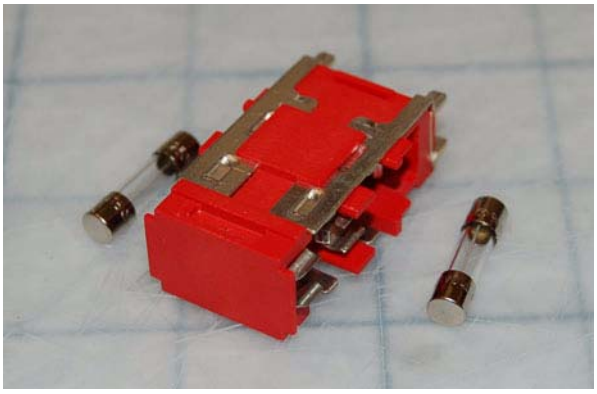


Figure 18 Fuses removed

CAUTION: For continued protection against risk of fire, replace only with same type and rating fuse.

Replacement fuses are available from Clarity Customer Service.

.

Figure 19 Fuse holder re-inserted

Key Validation

Note: New RetCam3 systems ship with their license key already registered and validated. However, significant changes to the system hardware or a re-load of the system software for any reason (including software upgrade) may require you to perform the key validation process as described below. Key validation requires that you get a license key from Clarity to use the revamped system, and you cannot request this key until after installation is complete. Since it may take up to two (2) business days to obtain a license key after submitting a request, we recommend that you effect system or software upgrades when you can manage two business days without use of the system.

Note: To ensure the preservation of your patient data and images, we strongly recommend that you perform a complete backup of the system's images before you begin any software installation.

When key validation is necessary, the Key Validation dialog appears when you start the system (and each time thereafter until you complete this step), before the Site Awareness dialog.

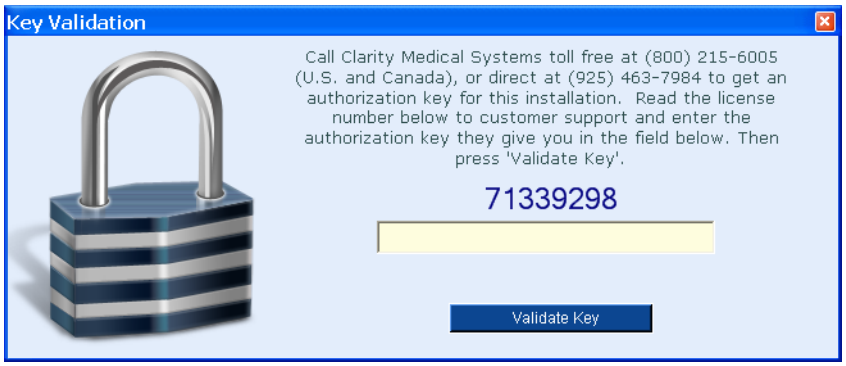


Figure 20 Key Validation dialog

Follow the instructions on screen: Call Clarity and provide to the customer support representative the large license number in the dialog (71339298 in the example above), which is unique for your system. You will be provided in turn a unique authorization key.

0 Tip: You may also send the license number via email to **service@retcam.com** and receive the authorization key by return email.

You must enter the authorization key in the field and click **Validate Key** to access the system software. If you call, to make sure you enter the number correctly, we recommend you do not hang up until the number is accepted.

Servicing the Interior of the Cart

WARNING: Removing the back panel should be done by qualified technical personnel only. Maintenance personnel should be familiar with the usual precautions regarding the service of electronic and electrical equipment.

Contact Technical Service for help troubleshooting problems to the module level.

If it is determined that a module needs to be replaced, guidance from Technical Service will be given in the form of a written procedure or verbal instruction. No repairs are to be performed by the customer within the modules with the exception of the lamp within the CEO box, as stated in the contents.

The modules comprising this system are:

- Display
- Handpiece
- Lens piece
- CEO box
- FA (option)
- Power Supply box
- Footswitch
- Batteries

WARNING: When doing this level of service, Electrical Safety Retesting of the system is required to maintain compliance with IEC requirements. Contact Customer Service before beginning.

Only those modules identified within this service manual are “authorized” for replacement by the customer. Any service outside the scope of this manual shall void the warranty and may compromise the safety/efficacy of the system.

4 Technical Specifications

Hardware

Physical

- 26”(660 mm) wide x 24”(610 mm) deep x 54”(1372 mm) minimum height
- Approximately 200 lbs. (91 Kg) fully loaded

Electrical

- Ratings: 100-240 V~, 50/60 Hz, 700 VA
- Fuses: 3AG 10A 250V slo-blo 5 x 20 mm
- Power consumption: 700W with all options
- Detachable hospital grade power cord

Cart Features

The RetCam 3 cart includes the following features:

- System has been designed, inspected and tested to comply with the safety requirements of IEC60601-1
- Internal Battery Backup
- Multi function Control Panel
- Tri-function footswitch
- Waterproof Keyboard
- Mouse
- LCD flat panel display
- Display arm for angle and height adjustment
- Handpiece cable hanger
- Integrated cooling ducts
- Dual Front locking castors
- Upper Storage drawer within which is mounted external DVD drive
- Lower Storage drawer with lenspiece holders
- Color report and image printer on slide out tray.
- USB ports
- Ethernet port

Handheld Imager

- 3-chip RGB CCD
- Built in fiber optics
- Quick-change lenspieces

Computer and Electro-optics

- Adjustable intensity iris
- Automatic black and white balance functions
- Lemo focus motor connector
- Custom fiber optic interlock
- Easy-access bulb replacement
- Embedded Computer
- 2.16 GHz Intel Processor
- 2 GB memory
- Hard drive storage

Fluorescein Angiography Light Source (Optional)

- Continuous arc xenon lamp
- Narrow-line blue excitation filter (~ 471 nm)
- Iris intensity control
- Fiber optic safety interlock
- Green emission (blocking) filter for handheld imager (~ 510 nm)

Color Printer

Software

- The software allows for networkability.
- MS Windows® XP Embedded operating system with service pack 2
- Proprietary image acquisition, storage and processing
- Live color image display
- Integrated patient database
- Still and video capture modes
- Review functions
- Compare functions
- Transfer functions
- Backup functions
- Image export as MLX, DICOM, or open standard, i.e. jpeg, bmp or png

- Image annotation
- Data export as XML, CSV or TXT
- Image import of RetCam supported files; .hdr, .mli, .mlv, .mlx, .mrl
- Fluorescein Angiography mode

Environmental Conditions

The system as delivered is intended for use indoors, at normal room temperatures and humidity, upright, on a level surface, with the brakes applied to the front casters.

Condition	Operating	Storage and Transport
Temperature	50º to 95º F (10º to 35º C)	-20º to 122º F (-29º to 50º C)
Relative Humidity	30% to 90% non-condensing	10% to 85% non-condensing
Atmospheric Pressure	20.7 to 31.3 inches Hg (70 to 106 kPa)	14.7 to 31.3 inches Hg (50 to 106 kPa)
Altitude	-1255 to 9882 feet (-382 to 3012 meters)	-1255 to 18288 feet (-382 to 5574 meters)

Note: Specifications subject to change without notice.

5 Troubleshooting Guide

This section lists common issues for the **RetCam3 Ophthalmic Imaging System** and provides suggested corrective actions for each issue. If corrective actions do not resolve the issue, contact Clarity Technical Support at (800) 215-6005 or email service@retcam.com.

RetCam 3 Troubleshooting Guide	
Issue	Troubleshooting Recommendations
No power to RetCam 3 system	Verify power cord is connected. Verify power source is correct voltage for system and is functioning correctly. Verify the main power switch in the back of the RetCam system turned on. If the system has not been plugged into the wall for at least 4 hours before the intended use, plug the system in to let the battery charge, then press the power button on the control panel.
No display	The display will be dark initially while the program is loading. If the display is still dark after five minutes, verify that the monitor is turned on. Verify monitor power indicator light is on. Verify monitor cable and power cord are connected properly. Verify monitor functionality; • Connect monitor to alternate system. • Connect alternate monitor to system.
No RetCam 3 program	Restart the system. Verify RetCam splash screen displays. Verify error messages displayed. Obtain details. If system is connected to network, disconnect from network and restart the system.

RetCam 3 Troubleshooting Guide	
Issue	Troubleshooting Recommendations
No camera image	Verify connections are secure. Verify the hand-piece camera cable is connected to the CEO box. Verify the camera cable is connected securely. If there is still no image, contact the Clarity service department at (800) 215-6005.
Unable to save image	Verify destination location of file to be saved (local, USB, network, etc.) Verify there is sufficient available space at the destination location. Observe any error messages displayed while saving. Obtain details.
Unable to transfer an image	Check the file transfer destination location. If networking the system, verify settings and permissions. Verify that the destination device or network location is resident in RetCam program. Verify that the device is recognized in File Explorer. If network location is available and the file transfer fails: • Verify you have successful connectivity to network Share directory. • Verify you are successfully logged on to your network. • Verify network share file parameters.
Unable to print report or image file	Verify printer power indicator lights are on. Verify printer cable connections are properly connected. Observe any printer error codes displayed. Verify printer media is properly installed.

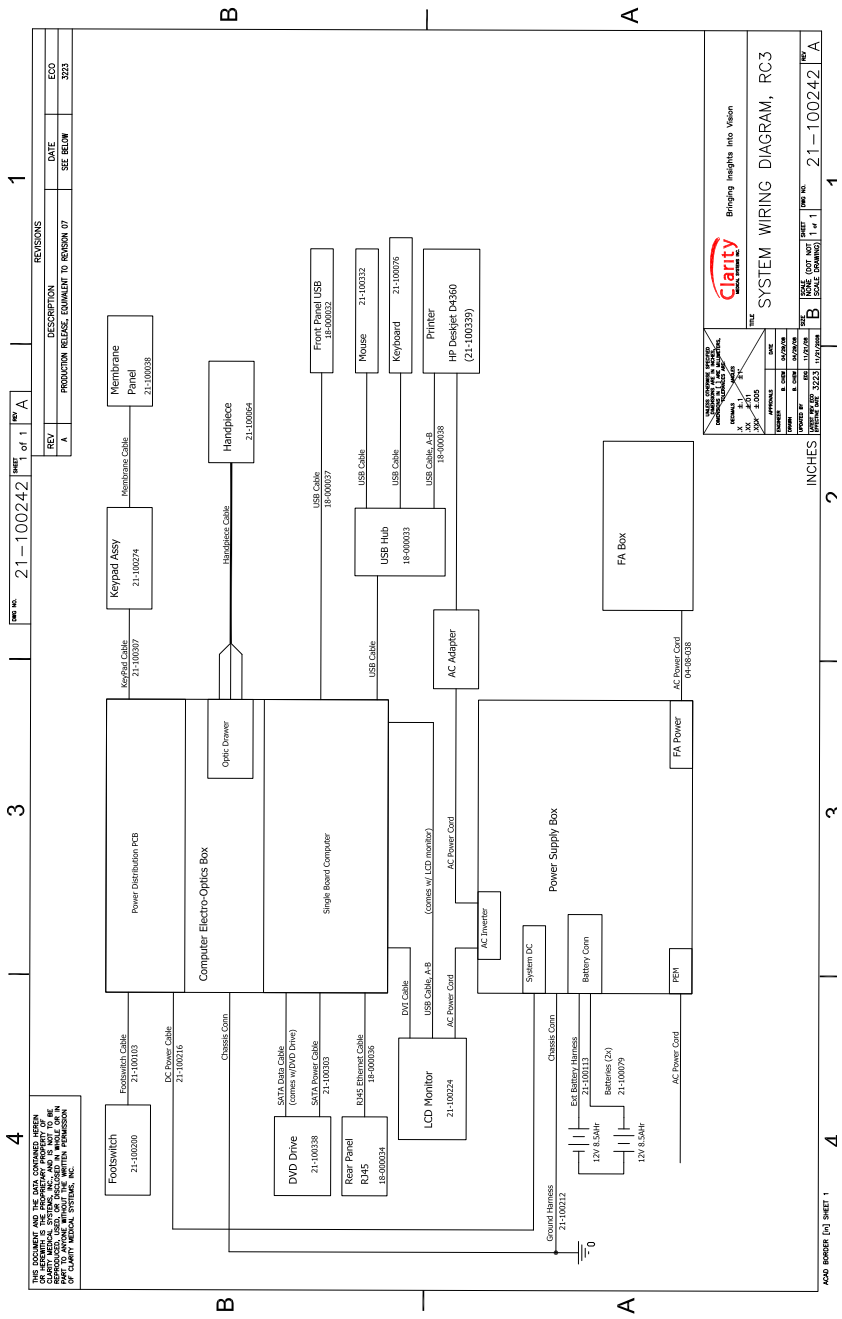
RetCam 3 Troubleshooting Guide	
Issue	Troubleshooting Recommendations
No light from hand-piece	Verify the fiber optic cable from the handpiece is inserted in the fiber optic port of the CEO box and the lamp button on the control panel is turned on. Leave the lamp off for 10 minutes to allow the lamp to cool down and then turn it back on. If after these measures are taken the lamp does not turn on, then replace the illumination bulb. See Lamp Replacement on page 40.
Light intensity does not increase or decrease	Press the light intensity button on the control panel first, and then press the light intensity pedal on the footswitch. Observe the intensity of light coming out of the handpiece. If the intensity does not change with either action, contact customer service.
Live image problem	If the color of the live image is not balanced, perform the Automatic White Balance procedure in the User or Service manuals. If there are color “streaks” in the live image, the handpiece must be sent in for service. If live image freezes, start and stop video.
Image does not focus	Check the lenspiece for cleanliness. If there is dried gel on the lenspiece, clean off with sterile water. Verify that the handpiece focus cable is connected to the CEO box correctly. When the focus button is pressed, listen for the sound of the motor turning within the handpiece. Verify footswitch pedals are not jammed. If you cannot hear the motor, contact Clarity Medical Systems. For further assistance please contact Clarity Technical Support at (800) 215-6005 or email service@retcam.com.

RetCam 3 Troubleshooting Guide	
Issue	Troubleshooting Recommendations
Image capture is not working	If you can capture a live image using the software, verify that an image can also be captured using the control panel button. If you can capture an image using the control panel button, then take an image using the snap button on the footswitch. If you can capture an image using the snap button on the footswitch, but not using the control panel, the control panel must be replaced. Contact Clarity Technical Support at (800) 215-6005 or email service@retcam.com
No numbers displayed on control panel for light intensity	If the system is turned on and the RetCam program is displayed on the monitor but no numbers appear on the control panel for light intensity, then press the intensity button to turn the lamp on.
USB stick is not recognized	Because the operating system of the RetCam 3 is embedded, not all USB sticks will be recognized. If the USB stick is not recognized in the Utilities screen, then use the USB stick provided by Clarity.
Keyboard does not work	If repairs to the computer have been performed recently, then verify the keyboard cable is inserted into the keyboard connection at the CEO box.
The system turns off when it is unplugged and moved	This can happen when the battery is in a low charge condition. The normal time a system can be unplugged from the power source with the program running can be from 10 to 20 minutes on a fully charged battery. It is best to leave the RetCam 3 plugged in when not in use so the battery can charge.

RetCam 3 Troubleshooting Guide	
Issue	Troubleshooting Recommendations
No light from the FA	Verify that the fiber optic cable from the handpiece is fully inserted in the fiber port of the FA. If no blue light can be seen while the light switch on the front of the FA is turned on, the module must be returned to the factory for service. Contact Clarity Technical Support at (800) 215-6005 or email service@retcam.com.
No network connection	Contact your Information Technology (IT) department.
The machine does not move freely.	Check the locks on the front wheels.

6 Block Diagrams

RetCam 3 Internal Wiring



7 Replacement Parts

Spare parts and supplies can be ordered by calling or faxing the part description and part number to Customer Service.

Customer Service Contact Information

Phone: (925) 463-7984

Fax: (925) 474-2093

Toll free:(800) 215-6005

Consumables

Part Description	Part Number
Illumination Bulb (halogen)	02-04-501
USB STICK	03-12-025
Fuses - 3AG 10A/250V, slo blo, 5 x 20 mm	15-000053
Printer paper, HP Premium, 5 x 7 inches	03-12-012

Components

Part Description	Part Number
Flat Panel Display	21-100224
Footswitch	21-100200
Handpiece	21-100064
CEO box	21-100194
Portrait Lens (PL200)	18-000024
Premature Infant lens (130°)	01-00-015
Standard Baby lens (120°)	01-00-001-1
High Contrast lens (80°)	01-00-016
High Magnification lens (30°)	01-00-014-1
FA Barrier Filter	09-00-015
FA install Kit (order with a new FA)	21-100362
FA Lightbox	21-100225
Printer	21-100339
Mouse	21-100332
DVD writer drive	21-100338

8 Technical Support

How to Get Support

The User Manual and Service Manual have been written to answer the majority of questions that arise with the product. Please consult these manuals before calling for service.

Clarity Medical Systems, Inc.'s (CMS) in-house technical staff is dedicated to helping our users with any specific problems and questions you may have with the RetCam 3. Please have your serial number ready and include the serial number on all correspondence. The serial number is located on a sticker affixed to the base of the cart at the back just above the power cord connection.

Please be as specific and give as much information as possible. If you encounter a system malfunction of any kind, please record the exact steps taken leading to the failure, so that our staff can replicate the problem.

Customers in the rest of the world outside the US, please contact your distributor.

Support Within the US

Telephone Support

Direct dial: (925) 463-7984

Toll Free: (800) 215-6005

FAX Support

(925) 474-2093

Telephone support is typically available between the hours of 9am and 5pm Pacific Time.

Write to Clarity

You can send written requests to Clarity at the address below:

Clarity Medical Systems, Inc.
5775 West Las Positas Blvd.
Pleasanton, CA 94588
USA

E-mail Support

Send e-mail messages to customer support at the address below:

service@retcam.com

Our technical support staff responds to your questions as soon as a staff member is available. In most cases, you will receive an answer within 48 hours. Complex questions that require testing or special research may take longer.

Note: Questions about products no longer under warranty and questions other than to explain ordinary use of the product may incur engineering charges. Please ask for an hourly quotation before incurring charges.

Returning Parts for Repair

If a part or component is defective or damaged and is to be returned to Clarity Medical Systems for repair or replacement, a Service Ticket number must be issued by CMS. The Service Ticket number must be noted on the return shipping documents so that the disposition of the part is known when it is received at CMS offices.

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Any attempt to decompile, reverse engineer or otherwise copy this software shall be considered a breach of this agreement.

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issued by U.S. and other governments. For additional information see http://www.microsoft.com/exporting/.

10 Appendix Guide

Appendix Table

Appendix Number	Procedure Number	Revision	Document Title
1	30-000071	A	RetCam 3 Handpiece Replacement

Appendix 1

Field Replacement Procedure 30-000071 Rev. A

RetCam 3 Handpiece Replacement

Rev	ECO	Revision History	Author
A	3267	Release	Calvin Meister

1.0 Purpose

1.1 To provide instructions on how to replace a Handpiece in a RetCam 3 System.

2.0 Scope

2.1 This procedure provides the step by step process to replace the Handpiece.

3.0 References

3.1 Plastic Housing Handpiece 21-100064

3.2 RetCam 3 Service Manual 21-100357

4.0 Equipment and Tooling

4.1 NA

5.0 Material and Supplies

5.1 NA

6.0 Handpiece Replacement Procedure

6.1 Remove the handpiece from the RetCam 3.

6.1.1 Power down the system according to the RetCam 3 User Manual.

6.1.2. Disconnect the system power cord from the base of the system.

6.1.3. Lock the front casters.

6.1.4. Pull out the fiber optic cable.

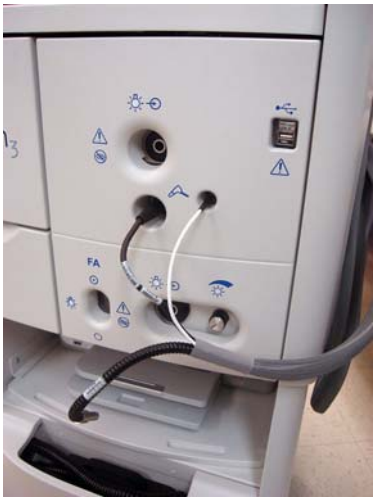

Figure 21 Pull out the fiber optic cable

6.1.5 Pull out the front cover.

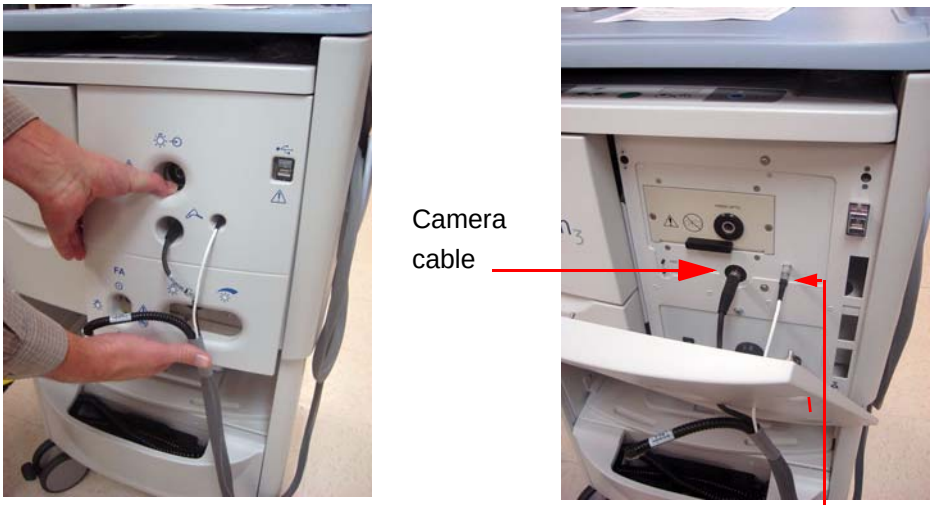

Figure 22 Pull out the front cover

6.1.6 For focus connection insertion and removal be aware of the red alignment dots on the connections. To remove the focus connector, pull back on the metal connector sleeve.

6.1.7. To remove the camera cable from the CEO box, turn the metal sleeve counterclockwise at least 5 turns and slowly pull out on the connector.

6.1.8. Remove the cabling from the front cover.

Figure 23 Removing the cabling

6.1.9. Carefully set aside the handpiece.

6.2 Install the replacement handpiece.

6.2.1. Remove the replacement handpiece from the box.

Figure 24 Remove handpiece from box

6.2.2. Thread the handpiece focus and camera cables through the front cover.

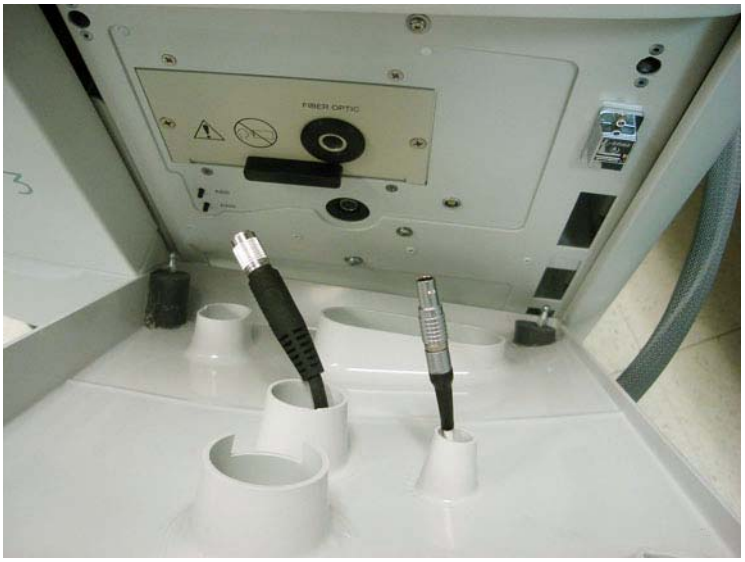

Figure 25 Threading cables through the front cover

6.2.3. To install the focus cable, align the red dots on the connectors and insert the metal sleeve.

6.2.4. To install the camera cable, align the slot on the cable connector with the pin (at the 6 o'clock position) in the port and insert. Then thread on the sleeve of the connector clockwise until tight.

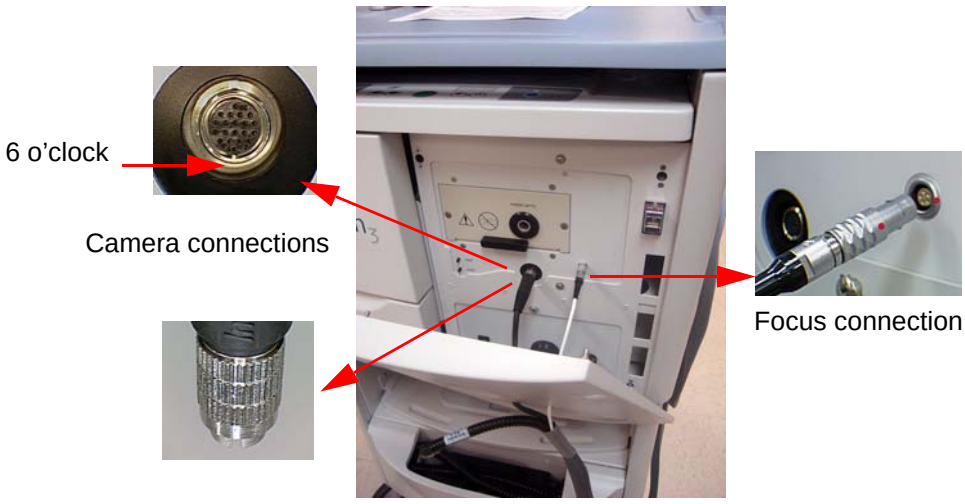

Figure 26 Cable connections

6.2.5. Install the front cover

6.2.6. Install the fiber optic cable

Figure 27 Install front cover and fiber optic cable

6.3. Verifying the handpiece works

6.3.1. Plug the RetCam 3 system in and turn it on.

6.3.2. Install a lenspiece on the handpiece.

6.3.3. Select a test patient and go to new exam.

6.3.4. View image for color balance.

6.3.5. If the colors of the live image are very different from the real object, follow the Camera Color Balance Adjustment method in the Maintenance section of the Service Manual. If the color balance is similar to the real object then proceed to the next step.

6.4. Restore the System to original condition.

6.4.1. When testing is complete and the system is not being used then press the power button to turn off.

7.0 For the Handpiece to be returned to Clarity

7.1. Place the handpiece to be returned to Clarity in the box as shown.

Figure 28 Place handpiece in shipping box

7.2. Ship the handpiece to Clarity

5775 W. Las Positas Blvd.
Pleasanton, CA 94588
USA
Phone: (925) 463-7984
Fax: (925) 251-0078
Toll free: 1-800-215-6005
www.claritymsi.com