

COLPOSCOPE 955

USER'S MANUAL

Including installation instructions for all mounting options



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This device is restricted to the sale and the use by authorized and trained personnel.



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INTRODUCTION

To Our Valued Professionals,

On behalf of the Seiler Medical Division, I would like to thank you for your recent purchase. We stand by our products and are thrilled that when choosing one of the most important aspects of your practice, you chose us.

We are proud to say that, as a company, we have over 70 years' experience in the optical field. We have the expertise to provide you with modern, reliable devices that incorporate some of the most advanced optical design tools on the market. This product's intent is to amplify an image while providing the user with an exceptional level of comfort, improved visual acuity, and provide flawless maneuverability for any office or hospital.

All of our products are manufactured according to strict medical and ISO standards. We also ensure all optical components have undergone an anti-reflective, multi-layer treatment; guaranteeing the efficiency of the system and enhancing the longevity of all of our products. Along with strict manufacturing standards and rigorous testing, we also stand behind all of our products by offering a lifetime warranty on all optics and mechanics for microscopes purchased in the United States, as well as a 3-year warranty on all international purchases.

Every Seiler Medical Division team member is here to provide you with outstanding service, quality, and knowledge. Our number one priority is, and always will be, providing 100% customer satisfaction to every one of our customers. If you need any further information about the equipment or just have a question, please contact us using the information below.

Thank you again for your purchase and we look forward to serving all of your optical needs for years to come.

Sincerely,

Dane Carlson

Medical Division Manager

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THE DIVISIONS OF SEILER INSTRUMENT



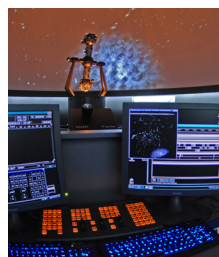
Manufacturing



Geospatial



Medical



Planetarium



Design Solutions

INTENDED USE

The Seiler Colposcope is intended to provide magnified visualization of the tissues of the vulva, vagina, cervix, and anogenital area. It is used to evaluate these tissues, select areas for biopsy, as necessary, and to facilitate related procedures, e.g., LEEP, conization, etc.

Caution: Federal law restricts this device to sale by or on the order of a physician or practitioner trained in its use.

This manual is intended to give assistance in the assembly and operation of the Colposcope Model 955.

This handbook includes a chapter to acquaint the user with the assembly process.

Read this handbook carefully prior to operating the colposcope.

Do not allow persons unfamiliar with the equipment to operate the colposcope.



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TECHNICAL DATA

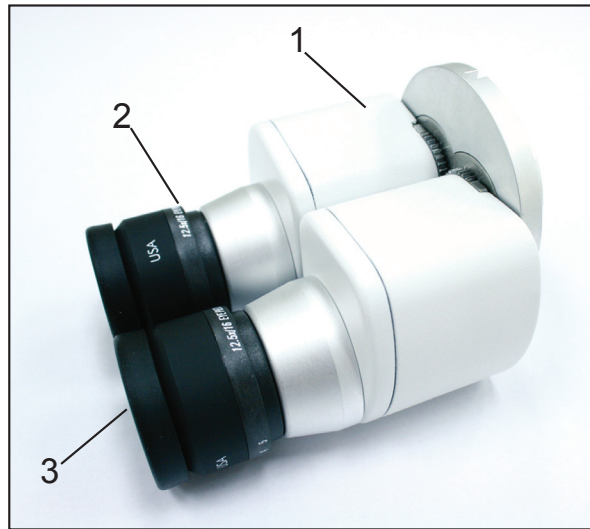
A - Colposcope Head

Microscope	Galilean System
Binoculars	F= 170 MM (optional: Inclined, F=135 mm)
Objective (focus)	300 mm (optional: 200 – 400 mm)
Eyepieces	Wide angle type 12,5x, adjustable (-6 to +6 dioptries)
Magnification	See table
Observation field	See table
Illumination field	See table
Interpupillary distance	Adjustable between 42 mm and 75 mm
Illumination System:	
Source	LED Illumination System
Filter	Green filter
Focusing:	
Macro	Moving the pantographic arm
Micro	Fine Focus: 11mm
Total weight of the head	3.0 Kg

B- Colposcope stand

Horizontal reach	725 mm. - first arm 600 mm, second arm 110 mm.
Angular rotation (arms)	340°
Distance between the floor and the objective	635 mm to 1295 mm
Load adjustment	4 to 7 kg
Base	Base with five casters, two with brakes
Total floor stand set weight	34 kg

BINOCULARS



1. Binoculars body
2. Eyepieces with diopter adjustment
3. Eye Protectors

OBJECTIVE

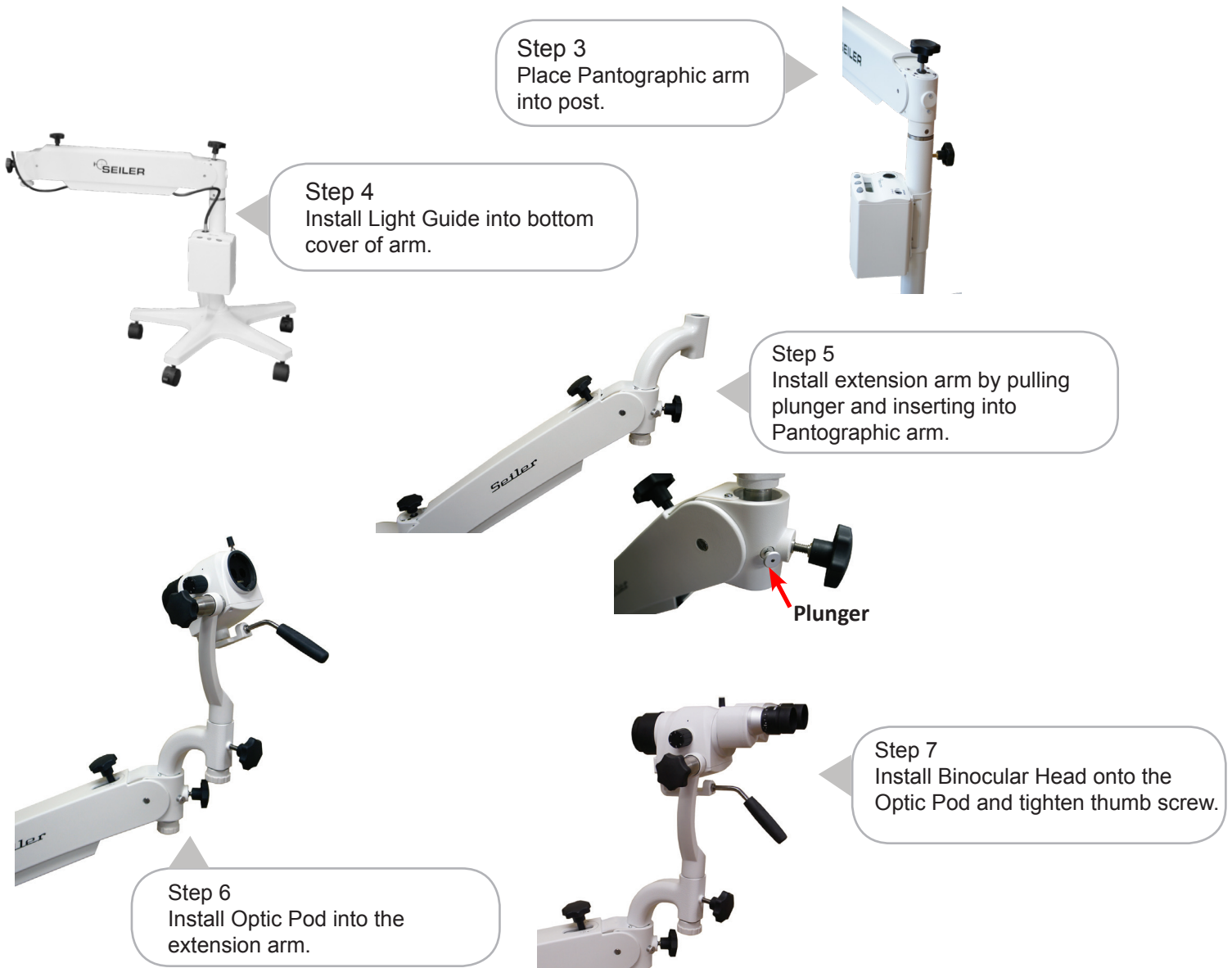
The Colposcopes are factory shipped with the following objective:
F = 300 mm

The following optional objectives are available:

- F = 200 mm
- F = 250 mm
- F = 300 MM
- F = 400 mm

COLPOSCOPE ASSEMBLY





Remove these parts from the packing case, with maximum care:
a) Optical Head Support b) Binoculars

Installing the Extension Arm (Step 5)

Loosen the tension knob and pull the plunger on the pantographic arm while inserting the spindle. Release the plunger (safety retainer) then tighten the tension knob just enough to prevent drifting. Install the safety knob to secure to the extension arm spindle.

Installing the Optic Pod (Step 6)

Loosen the tension knob on the extension arm while inserting the spindle. Fully insert the spindle then tighten the tension knob just enough to prevent drifting. Install the safety knob to secure to the optic pod spindle.

Installing the Binoculars to the Colposcope (Step 7)

Align the guide-pin to the groove, adjust the base of the Binoculars to point the flange, and tighten the set screw. Finally check if the Binoculars are well secured and do not move.

The Binoculars Eyepieces

The eyepieces are mounted to the binocular housings. Make sure that they are well seated.

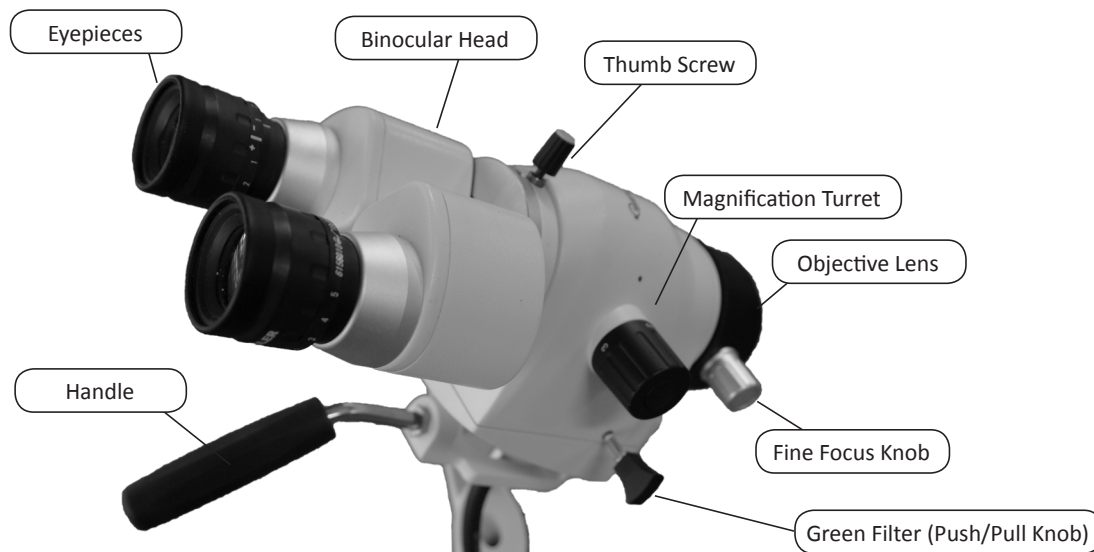
The Eye Protectors

The Eye Protectors are threaded to the Binoculars. The Eye Protectors protect the eyes, prevent the intake of lateral lights and create a suitable darkroom to the observer.

Precautions

The Binoculars contain optical parts internally that cannot be cleaned without disassembly.

It is therefore advisable to keep the eyepieces inserted in the eye tubes at all times in order to keep impurities from getting inside the housing. It is recommended that if the eyepieces are removed, a clean cloth be placed over the openings.



PREPARATION FOR USE

INSPECT AND CLEAN

Before each use, inspect the colposcope including power cable, base, casters, lightsource and light guide. Do not use the colposcope if any of the components are damaged, missing, or are not secure. Verify that the light guide is properly installed in both the lightsource and the optic pod. Clean and disinfect the colposcope before and after each use.

EYECUPS

The binocular eyecups are adjustable to allow use either with or without eyeglasses. For optimal viewing while wearing eyeglasses, fold the eyecups down to a low profile position. While using the colposcope without eyeglasses, ensure the eyecups are unfolded in the extended position.

INTERPUPILLARY DISTANCE ADJUSTMENT

The binocular interpupillary distance (IPD) is adjustable to match the distance between the pupils of the user's eyes and provides a stereoscopic view thru the colposcope. A stereoscopic view is necessary for depth perception.

Look through the two eyepieces with both eyes open and grasp each tube of the binoculars. Using a soft and semi-rotation movement, adjust IPD until the image of each eye superimposes and appears as only one image.

PARAFOCALIZING PROCEDURE:

The binocular eyepieces offer a diopter adjustment to allow use of the colposcope either with or without corrective lenses. However, the diopter adjustment can only accommodate nearsightedness (myopia) and/

or farsightedness (hyperopia). Other eye defects, such as astigmatism, cannot be corrected using the diopter setting and require the use of corrective lenses (i.e. contacts or glasses.) The eyepiece diopters should only be adjusted during this parfocalizing procedure. During normal colposcope use, do not adjust the eyepiece diopters.

- 1) Set each eyepiece diopter setting to the zero (0) position and keep this zero position until instructed to adjust the diopter in step 3.
- 2) Turn the magnification selector to the highest setting (5) and focus sharply on a target, such as a piece of paper with an "X" drawn on it. Coarse focus by moving the entire colposcope then sharp focus by using the objective fine focus knob.
- 3) Without disrupting the colposcope position or the objective fine focus, turn the magnification drum to the lowest setting (1) then focus each eyepiece diopter by turning clockwise or counter clockwise until sharp focus is achieved.
- 4) Once the image is clear in both eyes, Parfocalizing is complete. To verify, repeat steps 2 and 3 until no diopter adjustment is needed to achieve sharp focus.

COLPOSCOPE USE

Prepare the colposcope for use following the PREPARATION FOR USE instructions.

Turn the light source on and set the desired brightness following the instructions in the LED LIGHT SOURCE section. Turn the lightsource off while the colposcope is not being used.

POSITION THE COLPOSCOPE



CAUTION: Horizontal and vertical forces create instability and may result in an overbalance condition which could cause injury to personnel or damage to equipment. Do not push on the support pole surfaces. Transport and use on flat surfaces only to prevent colposcope tipping and causing injury to personnel or damage to equipment.

Position the colposcope for use at a distance approximately equal to the objective lens focal length which is engraved on the external face of the objective. Example: With a 300mm objective, keep a distance of about 300mm between the objective and the specimen.

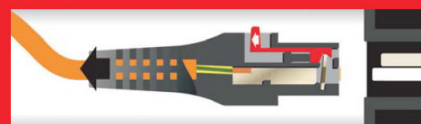
If the arms or colposcope head drift in a rotating direction, apply slight tension to the appropriate tension adjustment knob. The tension knobs should be just tight enough to prevent drift but not too tight that maneuverability becomes difficult.

If the arms drift in an up or down direction, see PANTOGRAPHIC ARM BALANCING

How it works!

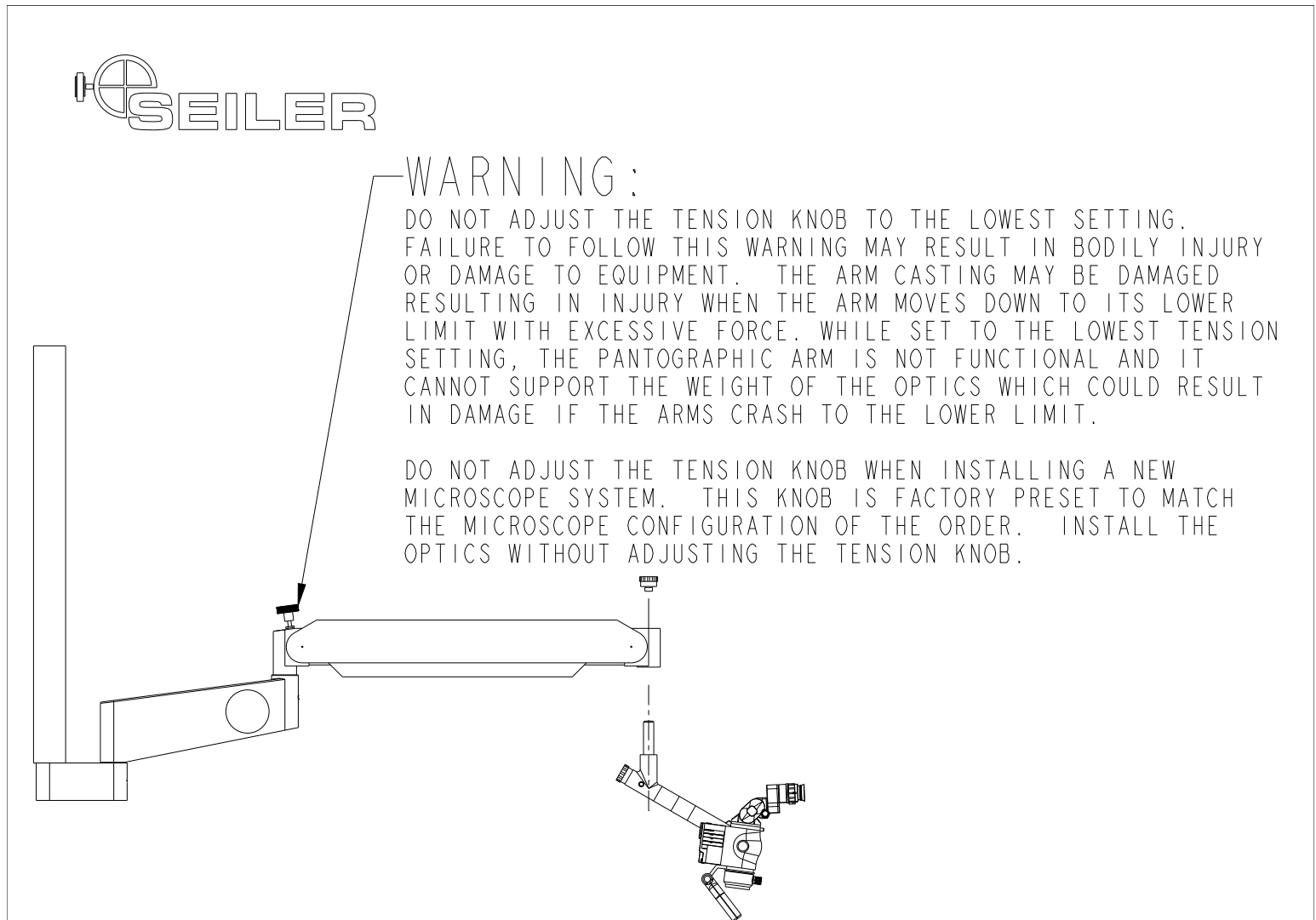
IEC
LOCK

- Push the connector into the standard IEC inlet and it is locked in position
- Connector **CANNOT** be accidentally pulled or vibrated out of the inlet
- Slide back the 'red' tab to release and remove connector from inlet



PANTOGRAPHIC ARM BALANCING

The pantographic arm is factory adjusted for balancing and allows relatively effortless positioning of the colposcope head to the desired viewing position. The colposcope should not drift after the releasing in the desired position. If the Pantographic Arm drifts up or down then tension adjustment is required. Turn counter-clockwise to add tension, clockwise to release tension on pantographic arm. This may need to be performed if camera/video are added to the scope. This will increase or decrease the tension to desired function for user. The Pantographic Arm may have to be in the horizontal position to make adjustments.



FOCUSING THE COLPOSCOPE

Coarse focus is achieved by slowly moving the entire colposcope. While looking through the eyepieces, move the colposcope in a direction farther away then closer to the area of interest. Note the direction that improves focus then continue moving the colposcope in that direction until focus is relatively sharp.

Fine focus is achieved by rotating the Fine Focus Knob on the objective lens. Rotate the Fine Focus Knob until the image is sharp. Perform coarse focus when sharp focus cannot be achieved as the focal point may be beyond the fine focus range.

MAGNIFICATION SETTINGS

The 955 and 985 colposcopes offer 5 magnification settings. To set the magnification, simply rotate the magnification selector to the desired position. Setting 1 offers the lowest magnification and widest field of view. As the selector number increases, magnification also increases but field of view decreases. When the colposcope is configured with a 300mm objective lens and straight binocular the magnifications are 2.8x, 4.25x, 7x, 11.3x and 17.7x. The fields of view are 70.6 mm, 47 mm, 28.2 mm, 17.7 mm, and 11.3 mm respectively. See MAGNIFICATION TABLE for other configurations.

COLOR FILTER

A green color filter is available to help highlight vascular patterns and offers tissue contrast viewing options. Use the Push/Pull Knob to select either white or green light

OPTICAL AND FIELD MAGNIFICATION TABLE

The optical magnifications achieved with the Colposcope are determined by 3 variables: the objective focal distance, the position of the Magnification Selector and the eyepiece used.

The table shows the optical magnification and the observed field diameters, in millimeters, depending on those variables. At the bottom line of the table the illuminated field is shown, corresponding to the light disk incident on the field, with a diameter that depends only on the focus of the work objective.

The magnification selector has 6 positions: 1, 2, 3, 4, and 5. The 3 position is repeated in the selector. The working position is the one aligned to the red dot mark.

Magnification Table for 955

Binocular Head Focal Length: F=170mm

Eyepiece	Position of Button	Objective Lenses								
		175		200		250		300		400
		Magnification	Field	Magnification	Field	Magnification	Field	Magnification	Field	Magnification
10X/18	1(0.4)	3.89	46.32	3.40	52.94	2.72	66.18	2.27	79.41	1.70
	2(0.6)	5.83	30.88	5.10	35.29	4.08	44.12	3.4	52.94	2.55
	3(1.0)	9.71	18.53	8.50	21.18	6.80	26.47	5.67	31.76	4.25
	4(1.6)	15.54	11.58	13.60	13.24	10.88	16.54	9.07	19.85	6.80
	5(2.5)	24.29	7.41	21.25	8.47	17.00	10.59	14.17	12.71	10.63
12.5X/16	1(0.4)	4.86	41.18	4.25	47.06	3.40	58.82	2.83	70.59	2.13
	2(0.6)	7.29	27.45	6.38	31.37	5.10	39.22	4.25	47.06	3.19
	3(1.0)	12.14	16.47	10.63	18.82	8.50	23.53	7.08	28.24	5.31
	4(1.6)	19.43	10.29	17.00	11.76	13.60	14.71	11.33	17.65	8.50
	5(2.5)	30.36	6.59	26.56	7.53	21.25	9.41	17.71	11.29	13.28
16X/16	1(0.4)	6.22	41.18	5.44	47.06	4.35	58.82	3.63	70.59	2.72
	2(0.6)	9.33	27.45	8.16	31.37	6.53	39.22	5.44	47.06	4.08
	3(1.0)	15.54	16.47	13.60	18.82	10.88	23.53	9.07	28.24	6.80
	4(1.6)	24.87	10.29	21.76	11.76	17.41	14.71	14.51	17.65	10.88
	5(2.5)	38.86	6.59	34.00	7.53	27.20	9.41	22.67	11.29	17.00
Illuminated Field		65		72		90		108		144

CLEANING

The Objective, pointed to the field under clinical or surgical treatment, is exposed to blood and other bodily fluids. Spots on the objective dim the passage of the light. Stains blur the light, reducing the luminosity of the optical observation.

Cotton padding wetted in alcohol rubbed softly, in CIRCULAR MOVEMENTS over the optical surface, is enough to clean the stains, except those of clotted blood. Clotted blood shall be cleaned with cotton and hydrogen peroxide.

If the eyepieces are too dirty, change the cotton at each circular friction motion to avoid spreading out the dirt.

On the other hand, there is an effective protector for the objective, fitted under pressure at the outer edge of the lens which protects the objective against “splatter” and contamination.

To have the eyepieces and objective well cleaned for clinical use, it is sufficient to use cotton.

TROUBLESHOOTING

ELECTRIC CONNECTIONS

Ensure that none of the following are present:

Broken wires inside the cable.

Loose wires at the connector.

Broken wires at the fixation, inside the connector.

Oxidized connectors terminals.

LED LIGHT SOURCE

1.0 INTENDED USE

Seiler’s LED Heliolux is a source of continuous high intensity illumination for surgical microscopy applications.

It is intended for use providing illumination to Class I or Class II surgical microscope systems which, as larger systems are subject to FDA regulations. It is intended to be used as a sub-component of a larger surgical imaging system and is not intended to be used as a stand-alone medical device.

Seiler’s LED Heliolux is intended to deliver illumination only through non-electrical light cables made with optical fibers or optical cavities (liquid light guides).

Seiler’s LED Heliolux is intended for use in a professional healthcare facility environment.

Seiler’s LED Heliolux is only to be used with light cables having the exact mating profile necessary to ensure proper coupling of the light source to the light cable.

Illumination from this device is to be used for observation of body cavities, body surfaces, teeth, and other surgical sites.

Portable and mobile RF communications equipment can affect medical electrical equipment.

1.1 PRECAUTIONS FOR USE - CONTRADICTIONS

- Do not operate Seiler’s LED Heliolux in an explosive atmosphere.
- Do not operate Seiler’s LED Heliolux in an MRI environment.
- Do not operate Seiler’s LED Heliolux for home health care.
- Do not modify Seiler’s LED Heliolux.
- Do not use Seiler’s LED Heliolux to illuminate eyes.
- Do not use near (12 inches or closer) equipment sensitive to electro-magnetic interference. This device complies with International Standards (as set forth in manufacturer’s declaration following) for electromagnetic compatibility for medical electrical equipment and/or systems. These standards are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.

1.2 ACCESSORIES

Precautions to take regarding accessories:

- Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical

equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Any equipment connected to the signal input part or signal output part configures a medical system. Therefore this equipment, and new configuration, must comply with the requirements of the system standard IEC 60601-1-1.

Approved Accessories

Mains Cable	Hospital Grade Only - Consult Factory
Light Guide Cable (For Light Port)	Non-Electrical, Liquid or Fiber Based, Having Appropriate Ferrules for Insertion - Consult Factory
Camera (For Camera Port)	Use only cameras that operate from 12 VDC at 500 ma or lower consumption and having certifications suitable for the particular medical application – for use of HelioLux with a surgical microscope this requires that the camera be certified to IEC 60601-1 and IEC 60601-1-2 and any additional standards relevant for the application. Consult Factory with any questions.
Programming Port	FOR FACTORY USE ONLY!

1.3 FEDERAL LAW MAY GOVERN THE USE OF THIS DEVICE

Federal law restricts the use of certain medical devices. Seiler's LED HelioLux is intended to be a sub-component of a medical device (system). Such device (system) may be regulated by Federal Law. It is the user's responsibility to ensure that the device is being used in a manner appropriate with Federal Law.

1.4 QUALIFICATION OF PERSONNEL

At a minimum, personnel working with the device should have the following qualifications:

1.5 MANUFACTURER'S DECLARATION

	Version	Type		Guidance
EN55011	2009	Emissions		Pass
A1	2010	Emissions		Pass
CISPR 11	2009	Emissions	Group 1, Class B	Pass
A1	2010	Emissions		Pass
EN 61000-3-2	2014	Harmonic Current		Pass
IEC 61000-3-2	2014	Harmonic Current	Class A Pass	
EN 61000-3-3	2013	Flicker		Pass
IEC 61000-3-3	2013	Flicker		Pass
EN 61000-4-2	2009	ESD		Pass
IEC 61000-4-2	2008	ESD	Contact 8KV, Air Discharge 2KV, 4KV, 8KV, 15KV	Pass
EN 61000-4-3	2006	Radiated Immunity		Pass
A1	2008	Radiated Immunity		Pass
A2	2010	Radiated Immunity		Pass
IEC 61000-4-3	2006	Radiated Immunity	3 V/M, 80 Mhz to 2.7 Ghz in 1% increments (professional use), 80% Sinusoidal AM at 1000 Hz	Pass

A1	2007	Radiated Immunity		Pass
A2	2010	Radiated Immunity		Pass
EN 61000-4-4	2012	EFT		Pass
IEC 61000-4-4	2012	EFT	2KV Open Circuit for AC Mains – 1KV for I/O Ports	Pass
EN 61000-4-5	2014	Surge		Pass
IEC 61000-4-5	2014	Surge	0.5 / 1.0 KV – Diff. and Common Mode – 2KV Common Mode	Pass
EN 61000-4-6	2014	Conducted Immunity		Pass
IEC 61000-4-6	2013	Conducted Immunity	3VRMS, 150Khz to 80 MHz – 1% Increments, 1s Dwell, 80% Sinusoidal AM at 1000 Hz	Pass
EN 61000-4-8	2010	Magnetic		Pass
IEC 61000-4-8	2009	Magnetic	30 A/m RMS at 50 and 60 Hz Frequency	Pass
EN 61000-4-11	2004	Voltage Dips and Interrupts		Pass
IEC 61000-4-11	Version 2004	Type Voltage Dips and Interrupts	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT ; 1 cycle 70 % UT ;25/30 cycles Single phase: at 0° 0% UT; 250/300 cycle	Guidance Pass
IEC 62471	2006	Photobiological Safety of Lamps		Risk Group 2 (Moderate Risk)

2.0 SYMBOLS USED IN THIS MANUAL OR ON THE DEVICE

The following symbols are used in these Instructions for Use and/or on the Device itself.

NOTE! This term contains important information regarding set-up and operation to facilitate ease of use and obtain effective results.

WARNING! This term contains critical information by identifying conditions or practices that may result in injury or loss of life if these instructions are not followed.



This term contains critical information regarding safe handling and use of this system. Device malfunction or property damage could result if these instructions are not followed.



This symbol cautions that surfaces may be hot and could be a burn hazard.

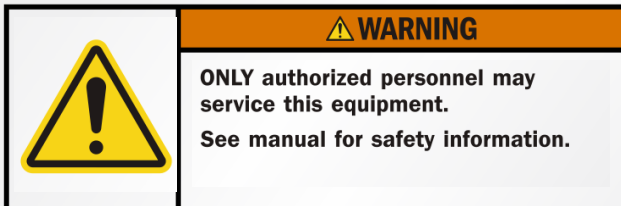


This symbol cautions of extremely intense light hazards.



This symbol cautions of electrical shock hazard.

3.0 HAZARDS ASSOCIATED WITH IMPROPER INSTALLATION



Failure to read and understand these Instructions for Use is hazardous.	Personnel tasked with installation of the device should fully familiarize themselves with the contents of these Instructions for Use and only attempt installation or maintenance of the device once they have a complete understanding of these Instructions.
Failure to select an appropriate installation location is hazardous	Employ only authorized and properly trained personnel to perform the installation. Care must be exercised during the mounting of the unit. Fasteners of incorrect length can damage internal circuitry and circuit boards.



This device is capable of causing a fire, burns, or ignition of flammable materials.

Do not locate or operate the unit near any flammable materials including flammable gases and liquids.

Maintain at least 6" around the fan intakes and exhausts for adequate ventilation to prevent overheating.

Do not operate the device unless an approved light cable is connected between the device and the relevant system. Energy exiting the light cable is concentrated and can cause burns or fires – always ensure that the light cable is properly installed before powering the device.



This device emits some level of electromagnetic energy.

Select an appropriate location and power source for the unit as described below.

Ensure there is adequate separation distance between the unit and any device which may be affected by the electromagnetic energy coming from the unit.

Power the unit from a circuit different from any circuit that contains a device that could be affected by the electromagnetic energy from the illuminator.

- Installation – hospital engineer or similar training plus specific training by the supplier of the larger medical system (surgical microscope for instance).
- Operation – medical or dental training in surgical procedures / dental health procedures plus specific training by the supplier of the larger medical system (surgical microscope for instance).

3.1 INSTALLATION INSTRUCTIONS/PREPARING AND SITING

READ FULLY BEFORE ATTEMPTING INSTALLATION

- Familiarize with all the instructions on all the device placards, including on the rear of the device. If unable to read, move closer and increase illumination.
- If, at any point during or after the installation, an event of dropping, fluid ingress, or other such event that could reasonably create damage or a hazard STOP and arrange for qualified maintenance personnel to inspect.
- If, at any point, you suspect something is wrong then terminate installation / operation of the Seiler's LED Heliolux by pressing the MAINS ON/OFF (blue switch with international 0/1 designation). The blue light should be off. Then remain the MAINS cable. Consult the factory with information as to why the installation was halted.
- If, at any point, you determine that the ESSENTIAL PERFORMANCE of the device has been impaired (due to electro-magnetic interference or other causes), then terminate installation / operation and consult the factory before continuing.

- Do not use sharp instruments during installation as doing so could damage internal components and create a hazard.
- Ensure no residual packaging materials (foam peanuts, etc.) are inside the unit.
- Use of a disposable material over the device to prevent fluids from splashing on the unit, is discouraged. Should it be used it is the installer's responsibility to ensure it does not block airflow AND is not a flammable material. Failure to follow this instruction could result in a fire.
- Do not operate the device without an approved light guide installed.
- Never look directly into light port.
- Never connect any device to the factory programming port on the rear panel.
- Read the rear label at angle under 10 degrees from distance less than 0.25 meter with minimum lighting of 1500 lux.

Site (position) the device:

- To avoid risk of electric shock this equipment must be connected to a supply mains with protective earth. Confirm such mains power is available within range of the hospital grade power cord.
- Site the device in such a way as the MAINS ON/OFF switch and the MAINS supply cable are not obstructed (difficult to access).
- Site the device a minimum of 24 inches from any other electrical / electronic devices to mitigate electro-magnetic efforts between devices.
- Ensure no flammability issues with the siting.
- Ensure no electromagnetic compatibility issues with the siting.
- Ensure no ventilation issues with the siting.
- Seiler's LED Heliolux should be positioned as far from the patient as is possible within the constraints of the larger system and the light cable.
- Seiler's LED Heliolux is not designed for use in STACKED Configuration. Do not stack multiple units together.
- Do not site the device near any materials that could be impacted by high intensity light (such as light curing adhesives, photo-sensitive materials, etc.)

3.2 INSTALLATION INSTRUCTIONS

- Inspect shipping containers for damage. In event damage is discovered STOP and arrange for qualified maintenance personnel to inspect.
 - Mount the illuminator per the system level documentation and in accordance with the hazard mitigation instructions.
 - Install the appropriate electrical and non-electrical cables
 - Install an appropriate light cable per the system level documentation and in accordance with the hazard mitigation instructions.
 - Install the MAINS power cable.
 - Plug an approved camera input power jack into the illumination (optional for pole mount only) per the system level documentation and in accordance with the hazard mitigation instructions.
- Perform Functional Test for ESSENTIAL PERFORMANCE
 - Turn on MAINS ON/OFF switch (blue switch with international 0/1 designation).
 - Confirm LCD screen provides indication (active) and is in STANDBY mode.
 - Shift to RUN mode by pushing the RUN / STANDBY mode button, "Lamp button".
 - Select dimming level by pressing UP or DOWN buttons.
 - Confirm ESSENTIAL PERFORMANCE:
 - Free flow of air.
 - Illumination.
 - Consistent noise (no scraping, clicking, etc.).
 - No interference with nearby critical equipment.
 - No interference from operation of nearby equipment (large unshielded motors, etc.)
 - Power down – installation is complete. 17-

4.0 HAZARDS ASSOCIATED WITH IMPROPER USE

WARNING!

Failure to read and understand these Instructions for Use is hazardous.	Personnel tasked with installation of the device should fully familiarize themselves with the contents of these Instructions for Use and only attempt installation or maintenance of the device once they have a complete understanding of these Instructions. Users should refrain from operating the equipment in any manner other than is set forth in these Instructions for Use.
---	--



This device is capable of causing a fire, burns, or ignition of flammable materials.	Do not locate or operate the unit near any flammable materials including flammable gases and liquids. Maintain at least 6" around the fan intakes and exhausts for adequate ventilation to prevent overheating. Do not operate the device unless an approved light cable is connected between the device and the relevant system. Energy exiting the light cable is concentrated and can cause burns or fires – always ensure that the light cable is properly installed before powering the device.
--	--



This device emits intense illumination that can be harmful.	Never look directly at the LED ports or reflected from the LED or the fiber optic light guides. Limit exposure of tissue or organs other than is required for the relevant surgical procedures. Do not illuminate patient until ready and turn illumination off when the procedure has been completed. Do not direct the illumination beam at the patient's eyes / shield the patient's eyes if necessary. Do not operate the illuminator with the light guides disconnected.
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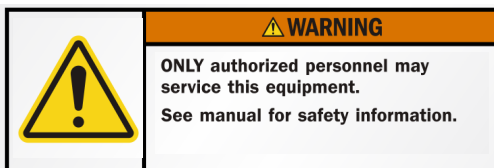
4.1 USE INSTRUCTIONS

READ FULLY BEFORE ATTEMPTING OPERATION

- Familiarize with all the instructions on all the device placards, including on the rear of the device. If unable to read, move closer and increase illumination.
- If, at any time after the installation, an event of dropping, fluid ingress, or other such event that could reasonably create damage or a hazard STOP and arrange for qualified maintenance personnel to inspect.
- If, at any point, you suspect something is wrong then terminate operation of the Seiler's LED Heliolux by pressing the MAINS ON/OFF (blue switch with international 0/1 designation). The blue light should be off. Then remain the MAINS cable. Consult the factory with information as to why the installation was halted.
- Do not use sharp instruments during use as doing so could damage internal components and create a hazard.

- Do not operate the device without an approved light guide installed.
- Turn MAINS power OFF before removing power.
- Never look directly into light port.
- Read the rear label at angle under 10 degrees from distance less than 0.25 meter with minimum lighting of 1500 lux.
- Confirm device has been properly installed.
 - Appropriate light cable is installed at both ends (Seiler's LED Heliolux and device requiring illumination).
 - Hospital grade power cable is properly installed.
 - Device is not located near critical device that could be influenced by electro-magnetic energy levels.
 - Venting on device is not blocked.
 - No damage is present on device.
 - Not in presence of flammable gases or fluids.
- Turn on MAINS ON/OFF switch (blue switch with international 0/1 designation).
- Confirm LCD screen provides indication (active) and is in STANDBY mode.
- Select dimming level by pressing UP or DOWN buttons.
- Ensure output of illumination does not violate any of the hazard mitigation instructions (i.e is not directed into someone's eyes).
- Shift to RUN mode by pushing the RUN / STANDBY mode button.
- Adjust dimming as required.
- To remove illumination for short periods of time (less than 60 minutes) press STANDBY to extinguish the illumination.
- To power down (when illumination is not required in the following 60 minutes) press the MAINS ON/OFF button.
 - Confirm blue back light on the MAINS ON/OFF is OFF.

5.0 HAZARDS ASSOCIATED WITH IMPROPER USE



<p>Failure to read and understand these Instructions for Use is hazardous.</p>	<p>Personnel tasked with maintenance of the device should fully familiarize themselves with the contents of these Instructions for Use and only attempt maintenance of the device once they have a complete understanding of these Instructions.</p> <p>Only qualified personnel shall inspect the unit for internal damage.</p> <p>Employ only authorized and properly trained personnel to perform maintenance functions.</p>
--	---



<p>This device contains high voltages.</p> <p>Maintenance of this device poses additional hazards.</p>	<p>Do not operate with the cover removed.</p>
--	---

5.1 FIELD MAINTENANCE INSTRUCTIONS

READ FULLY BEFORE ATTEMPTING FIELD MAINTENANCE

- Familiarize with all the instructions on all the device placards, including on the rear of the device. If unable to read, move closer and increase illumination.
- If, at any time after the installation, an event of dropping, fluid ingress, or other such event that could reasonably create damage or a hazard STOP and arrange for qualified maintenance personnel to inspect.
- If, at any point, you suspect something is wrong then terminate operation of the Seiler's LED Heliolux by pressing the MAINS ON/OFF (blue switch with international 0/1 designation). The blue light should be off.
- Then remain the MAINS cable. Consult the factory with information as to why the installation was halted.
- Do not use sharp instruments during field maintenance as doing so could damage internal components and create a hazard.
- Always wait a minimum of 10 minutes after removing AC power from the unit before attempting maintenance as this will provide adequate time for any energy storage devices to dissipate their energy. Failure to follow this procedure could result in a hazard.
- Read the rear label at angle under 10 degrees from distance less than 0.25 meter with minimum lighting of 1500 lux.
- Confirm device has been properly installed.
 - Appropriate light cable is installed at both ends (Seiler's LED Heliolux and device requiring illumination).
 - Hospital grade power cable is properly installed.
 - Device is not located near critical device that could be influenced by electro-magnetic energy levels.
 - Venting on device is not blocked.
 - No damage is present on device.
- Perform Functional Test
 - Turn on MAINS ON/OFF switch (blue switch with international 0/1 designation).
 - Confirm LCD screen provides indication (active) and is in STANDBY mode.
 - Select dimming level by pressing UP or DOWN buttons.
 - Shift to RUN mode by pushing the RUN / STANDBY mode button.
 - Confirm functionality:
 - Free flow of air.
 - Illumination.
 - Consistent noise (no scraping, clicking, etc.).
 - No interference with nearby critical equipment.
 - No interference from operation of nearby equipment (large unshielded motors, etc.)
- Simple Troubleshooting
 - Should the device appear to not power up
 - Check MAINS CABLE – is it installed correctly? Is it connected to MAINS power?
 - Remove MAINS Cable then remove the fuses – check for fuse integrity.
 - Should no illumination be present
 - Confirm unit is in RUN mode (not standby)
 - Select higher dimming level.
 - Confirm light cable is properly installed
 - Confirm there is no fault detected / displayed on the LCD display
 - System indicates TEMPERATURE FAULT
 - Ensure vents are not blocked
 - Ensure fans are rotating
- Should the above troubleshooting guide fail to correct a condition or any other such failure condition such

as visible damage, irregular noise, excessive heat, no illumination, fault code, etc. be present during the above evaluation make note of the condition and contact the factory for instructions.

6.0 CLEANING INSTRUCTIONS

Seiler's LED Heliolux is not designed to resist spillage from any direction. Keep the device dry and free from spillage at all times.

To clean:

- Do not use any of the following for cleaning:
 - Full strength bleach.
 - Steam sterilization.
 - Dishwasher.
 - Acetone, lacquer thinner or other solvents.
- Do not use spray cleaners as the spray could enter through vents and damage the device.
- Ensure device is turned off.
- Use a cloth dampened with any of the following solutions.
 - Water with liquid detergent.
 - Isopropyl alcohol.
 - Household bleach and water mixed 9 parts water to 1 part bleach.
 - Commercial disinfectant.
- Dry with a soft cloth.
- Allow to fully dry before next use.

7.0 DISPOSAL INSTRUCTIONS

Disposal of the device once it has been determined to be at its end of life should be done in accordance with the following:

- Ensure it is not connected to MAINS power.
- Clean thoroughly with anti-bacterial solution to mitigate any residual bacterial contamination.
- Disassemble (consult factory for instructions):
- Recycle (as appropriate for local regulations):
 - Metals
 - Electronics
- The device is in compliance with Rohs.

8.0 SPECIFICATIONS

8.1 SYSTEM DESCRIPTION

Seiler's LED Heliolux generates illumination from a proprietary light engine which relies up a light emitting diode and coupling reflectors designed to transfer the light from the LED into light cables at ideal beam angles and beam diameters.

Seiler's LED Heliolux uses a proprietary driver to power the LED. Other than power the LED this driver performs the following functions:

- Monitors the health of the device (temperature, current, voltage, wires, etc.)
- Sends relevant data to a digital display.

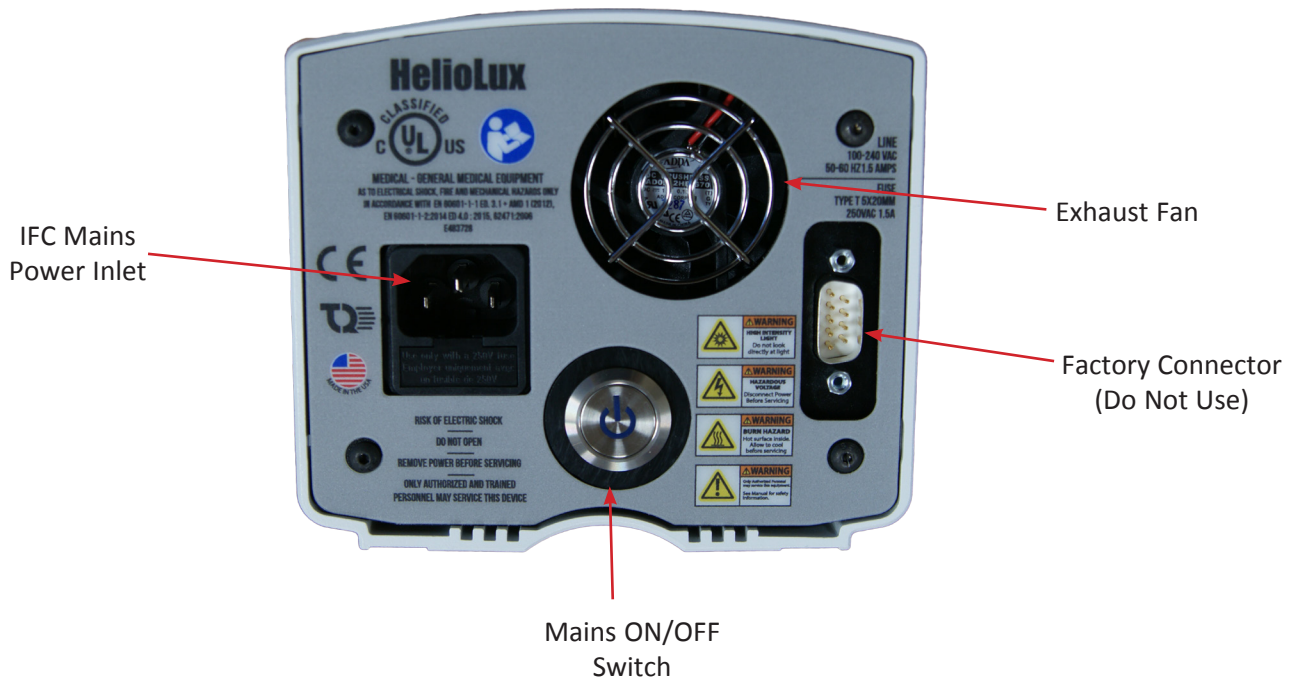
8.2 FRONT PANEL



CAMERA POWER Jack -
12 VDC at 500 ma max

For installation
of LIGHT CABLE

8.3 REAR PANEL



IFC Mains
Power Inlet

Exhaust Fan

Factory Connector
(Do Not Use)


Mains ON/OFF
Switch


8.4 CONTROLS


CONTROL PAD



There are (3) basic controls.

An UP button for increasing intensity. 

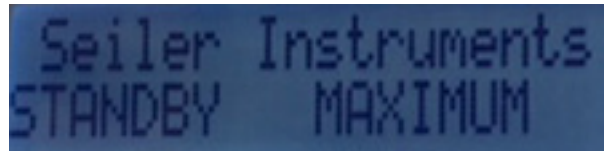
A DOWN button for decreasing intensity. 

A LAMP button for toggling the device between STANDBY mode and RUN mode. Standby mode will remove power to the LED / Extinguish the illumination but will leave other circuits active and is intended to provide a faster response time than the MAINS ON/OFF switch (between procedures). 

The UP and DOWN buttons can be operated in two modes:

- a) Press and Release – this “jumps” intensity.
- b) Press and Hold – this will cause the device to slowly scroll through all available dimming levels.

LCD DISPLAY



The top line of the display identifies the company or brand.

The bottom line displays status as well as dimming level.

The bottom line will indicate STANDBY or RUN. Each SQUARE represents 10% of the range (ie 3 SQUARES ~ 30% of maximum illumination).

Should the device detect a fault it will indicate FAULT followed by the type of fault.

8.5 POLE MOUNTING

POLE CLAMP



There are (4) threaded holes located underneath the illuminator. Caution must be exercised to use screws that project into the chassis NO MORE THAN $\frac{1}{8}$ ". Exceeding this can cause damage to the internal circuitry.

8.6 OTHER SPECIFICATIONS

Specification Area	Units (or Method)	Specification Value
Light Source		Light Emitting Diode
Lifespan	Hours	Light Emitting Diode should operate minimum 30,000 hours before maintenance is required.
Flux, CRI, CCT, Numerical Aperture		Depends on customer configuration - consult factory
Line Input Power Voltage Range	Voltage	100 - 240
Line Input Power Frequency Range	Frequency	50 - 60 Hz
Line Input Power Current Range	Amperes	1.5
Total Power Consumption	Watts	100
Temperature: Operating	Degrees Celsius	0 - 40
Temperature: Storage	Degrees Celsius	0 - 50
Relative Humidity: Operation		50% - 75% Non-Condensing
Relative Humidity: Storage		30% - 75% Non-Condensing
Atmospheric Pressure: Operating	Hpa	700 - 1060
Thread Pitch (For Pole Mounting)	UNC	10 - 32
Dimming Levels		1024
Modes		RUN, STANDBY
Fuses		250VAC 1.5A, GMA 5mm x 20mm










9.0 LIMITED WARRANTY







Your LED light source carries a 3-year warranty from the date of shipment on workmanship and all defects of material, excluding replaceable sweatbands, headband, fiberoptic cable and lamps. Should your product prove to have such defects within three years of the shipment. Seiler Instrument will repair or replace the product or component part without charge. Should your LED Light Source product(s) need servicing under this warranty, please contact, Seiler Instrument return authorization documentation. You should carefully pack unit in a sturdy carton and ship it to the factory. Please include a note describing the defects, your name, telephone number and a return address. Warranty does not cover equipment subject to misuse, accidental damage, normal wear and tear or if transferred to a new owner without authorization from Seiler Instrument. This warranty gives you specific legal rights and you may also have other rights that vary from state to state.

POST WARRANTY REPAIRS: You may return your product(s) for repair, shipping prepaid to the factory. Your product will be inspected and an estimate of repair charges will be submitted to you for approval. Payment must be received before repairs are completed.

- In the US: 800-489-2282 (toll free)
- FAX number: 314-968-3601







SYMBOLS USED IN THIS MANUAL OR DEVICE

MARKING/SYMBOL	MEANING
	Symbol for “Consult instructions for use” or “Consult operating instructions.”
	Symbol for “Caution, consult accompanying documents” or “Attention, see instructions for use.”
	Symbol for “Caution Hot Surface”. This symbol cautions that surface should not be touched as it may be hot and could be a burn hazard.
	Symbol cautions of shock hazard.
	Symbol cautions of intense light. Do not look directly at light source.
	Alternating Current
	Direct Current
	Direct Current Polarity
	Catalog Number

	<p>Symbol for “Serial Number.” This symbol shall be followed by, or above, the manufacturer’s serial number.</p>
	<p>Symbol for “Authorized Representative in the European Community.” This symbol shall be adjacent to the name and address of the authorized representative in the European Community. The address is not required on an immediate container unless the immediate container is the outer container.</p>
	<p>Symbol indicating “Not for general waste.” For European Union (EU) States, this symbol should be used to mark devices that are reusable and not contaminated at the end of the device life.</p>
	<p>This symbol is a mandatory marking for devices entering the European market to indicate conformity with the essential health and safety requirements set out in European Directives.</p>
	<p>Symbol for “Manufacturer.” This symbol shall be adjacent to the name and address of the manufacturer.</p>
	<p>Symbol indicating the “date of manufacture.” The symbol shall be adjacent to the date that the product was manufactured, expressed as four digits for the year and two digits for the month and where appropriate, two digits for the day.</p>

WARNINGS

This manual contains critical information regarding safe handling, use and care of this system. Harm to personnel or property damage could result if all instructions are not followed.

	HAZARD DESCRIPTION	HAZARD MITIGATION
	<p>Failure to read and understand these Instructions for Use is hazardous and may result in injury to personnel.</p>	<p>Personnel tasked with use and maintenance of the device should fully familiarize themselves with the contents of these Instructions for Use and only attempt use of the device once they have a complete understanding of these Instructions. Users should refrain from operating or servicing the equipment in any manner other than is set forth in these Instructions for Use.</p>
	<p>Transporting on surfaces which are not flat may result in the colposcope tipping and causing injury to personnel or damage to equipment.</p>	<p>Transport on only flat surfaces.</p>
	<p>Tilting the colposcope will create an overbalance condition which could cause Injury to personnel or damage to equipment.</p>	<p>Do not tilt the colposcope. Use the colposcope on flat surfaces only.</p>
	<p>Horizontal and vertical forces create instability and may result in an overbalance condition which could cause injury to personnel or damage to equipment.</p>	<p>Do not push on the support pole surfaces.</p>
	<p>Shock hazard. This device contains high voltages. Maintenance of this device poses additional hazards.</p>	<p>Do not operate with the cover removed. Employ only authorized and properly trained personnel to perform maintenance functions</p>
	<p>This device emits intense illumination that can be harmful. Eye damage or fire hazards exist if used improperly.</p>	<p>Never look directly at the LED ports or reflected from the LED or the fiber optic light guides. Limit exposure of tissue or organs other than is required for the relevant surgical procedures. Do not illuminate patient until ready and turn illumination off when the procedure has been completed. Do not direct the illumination beam at the patient's eyes/ shield the patient's eyes if necessary. Do not operate the illuminator with the light guides disconnected.</p>

Dear Purchaser,

Congratulations on the purchase of your microscope. Your instrument has been carefully assembled and shipped to you. Please complete the Warranty Registration online at the link below and answer the questions to activate and guarantee your warranty. Retain this warranty document for your records.

Thank you for purchasing a Seiler microscope.

INTERNATIONAL WARRANTY

Except as set forth in this Three (3) Year International Warranty, Seiler Instrument Company ("SIC") hereby warrants that each Seiler microscope product manufactured and/or sold by SIC shall be free from defects in materials and workmanship under normal use and service for three years. International Warranty includes mechanics, optics, and hardware (such as casters, knobs, tension band). This warranty is non-transferable and is valid only with respect to the original purchaser of the product. SIC obligation under this warranty shall be limited to repairing or replacing, at SIC facility and at SIC expense, any parts or components which are demonstrated to be defective. The purchaser shall be responsible for shipment of the product to SIC facility at 3433 Tree Court Industrial Blvd., St. Louis MO 63122, Attention: Micro Product Department, or such other facility as SIC may otherwise designate. Under certain circumstances which are pre-approved by SIC, necessary repairs may be made at the purchaser's facility. A return authorization is required before returning any product for warranty service by calling 1-800-489-2282 x347.

This warranty shall not apply to electronic and electrical components of the microscope or accessories such as video equipment, monitors and laptop which carry a three (3) year warranty OR any components which are consumable or are required to be replaced or disposed of in normal use of the product, such as lamps, fiber-optic cables and rubber eye cups OR any product which was purchased prior to April 29, 2016.

This warranty shall be void and of no effect: (1) if the product is damaged due to misuse, use in a manner other than pursuant to the instruction for the use of the product, abuse, physical mishandling or natural causes such as flood, fire, earthquake or other perils, as determined by SIC, or (2) if any repairs are made by persons unauthorized by SIC to perform such services.

The warranties set forth here are in lieu of any and all other warranties expressed or implied, including, without limitation, warranties of merchantability and fitness for a particular purpose. Purchaser's rights thereunder are granted in lieu of any other rights purchaser may have and purchaser hereby waives all other rights, warranties, remedies or guarantees whatsoever with respect to the product.

SIC shall not be liable for any reason to any third parties in respect of the product or its performance. Further, SIC shall not be liable for, and purchaser hereby releases SIC from any direct, indirect, consequential, special, incidental or punitive damages in respect to the product. In no event shall SIC be liable for any breach of warranty or other claim in an amount exceeding the purchase price of the product.

The customer is responsible for the shipping costs to Seiler Instrument Company. Seiler Instrument Company will pay the most economical method of shipping back to the customer. Any special shipping method will be paid by the customer.

Warranty must be registered online at:

<http://www.seilermicro.com/products/warranty-registration/>



Toll-Free: 800.489.2282 | Local: 314.968.2282 | Fax: 314.968.3601 | E-mail: micro@seilerinst.com | www.seilerinst.com

Dear Purchaser,

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Thank you for purchasing a Seiler microscope.

LIFETIME WARRANTY

Except as set forth in this Limited Lifetime Warranty, Seiler Instrument Company ("SIC") hereby warrants that each Seiler microscope product manufactured and/or sold by SIC shall be free from defects in materials and workmanship under normal use and service for the life of the product. Lifetime Warranty includes mechanics, optics, hardware (such as casters, knobs, tension band). This warranty is non-transferable and is valid only with respect to the original purchaser of the product. SIC obligation under this warranty shall be limited to repairing or replacing, at SIC facility and at SIC expense, any parts or components which are demonstrated to be defective. The purchaser shall be responsible for shipment of the product to SIC facility at 3433 Tree Court Industrial Blvd., St. Louis MO 63122, Attention: Micro Product Department, or such other facility as SIC may otherwise designate. Under certain circumstances which are pre-approved by SIC, necessary repairs may be made at the purchaser's facility. A return authorization is required before returning any product for warranty service by calling 1-800-489-2282 x347.

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The warranties set forth here are in lieu of any and all other warranties expressed or implied, including, without limitation, warranties of merchantability and fitness for a particular purpose. Purchaser's rights thereunder are granted in lieu of any other rights purchaser may have and purchaser hereby waives all other rights, warranties, remedies or guarantees whatsoever with respect to the product.

SIC shall not be liable for any reason to any third parties in respect of the product or its performance. Further, SIC shall not be liable for, and purchaser hereby releases SIC from any direct, indirect, consequential, special, incidental or punitive damages in respect to the product. In no event shall SIC be liable for any breach of warranty or other claim in an amount exceeding the purchase price of the product.

The customer is responsible for the shipping costs to Seiler Instrument Company. Seiler Instrument Company will pay the most economical method of shipping back to the customer. Any special shipping method will be paid by the customer.

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<http://www.seilermicro.com/products/warranty-registration/>



Toll-Free: 800.489.2282 | Local: 314.968.2282 | Fax: 314.968.3601 | E-mail: micro@seilerinst.com | www.seilerinst.com



Certificate of Compliance

Application of Council Directive: 2004/108/EC - EMC Directive &
Application of Council Directive: 93/42/EEC - Medical Device Directive

Standards to which Conformity is Declared:

EN 60601-1: 2007 including:
CISPR 11:2015/A1, EN 61000-3-2:2014/A2:2009, EN 61000-3-3:2013,
EN 60601-1-2:2014 including:
EN 61000-4-2:2008, EN 61000-4-3:2006/A1:2007/A2:2010, EN 61000-4-4:2012,
EN 61000-4-5:2014, EN 61000-4-6:2013, EN 61000-4-8:2009, EN 61000-4-11: 2004
EN 62471:2008, EN 60601-1:2007

Applicant: Seiler Instrument
Address: 3433 Tree Court Industrial Blvd
 St. Louis, MO 63122
 Tel: (314) 218-6365

Product Tested: Colposcope
 935 LED 955 LED 985 LED
 30935-3LED 30955-5LED 30985-OTS-LED

Equipment Type: Class 1

Tested By: ITC Engineering Services, Inc.
 9959 Calaveras Road, PO Box 543
 Sunol, California 94586-0543
 Tel: 925.862.2944 Fax: 925.862.9013
 Email: info@itcenc.com
 http://www.itcenc.com

Date of Issue: April 5, 2016

Report Numbers: 20161212-01 (EMC) 20161212-01 (62471)
 20161212-01 (MD)

I, the undersigned hereby declare that the model(s) listed above was tested and conforms to the Directives and Standards listed above.

Certified By:

Date September 05, 2017

Mr. Michael Gbadebo, PE
(California License # 11503)
Chief Engineer/Principal Consultant



L2470

ISO/IEC17025:2005 Accredited Laboratory

Declaration of Conformity

Application of Council Directive: 2004/108/EC - EMC Directive &
Application of Council Directive: 93/42/EEC - Medical Device Directive

Standards to which Conformity is declared:

EN 60601-1:2007 including:
CISPR 11:2015/A1, EN 61000-3-2:2014, EN 61000-3-3:2013,
EN 60601-1-2:2014 including:
EN 61000-4-2:2008, EN 61000-4-3:2006/A1:2007/A2:2010, EN 61000-4-4:2012,
EN 61000-4-5:2014, EN 61000-4-6:2013, EN 61000-4-8:2009, EN 61000-4-11:2004
EN 62471:2008, EN 60601-1:2007

Manufacturer: *Seiler Instrument*
Address: *3433 Tree Court Industrial Blvd
St. Louis, MO 63122 USA
Tel: +1(314) 218-6365*
Contact: *Mr. Dane Carlson*
Email: *dcarlson@seilerinst.com*

Equipment Tested: *Colposcope*
935 LED 955 LED 985 LED
30935-3LED 30955-5LED 30985-OTS-LED
Equipment Type: *Class 1*

Tested By: *ITC Engineering Services, Inc.*
9959 Calaveras Road, PO Box 543
Sunol, California 94586-0543
Tel: *+1(925) 862-2944* Fax: *+1(925) 862-9013*
Email: *info@itcemo.com* <http://www.itcemo.com>

Test Report Number(s): *20161212-01 (EMC), 20161212-01 (62471)*
20161212-01 (MD)

Test Date(s): *July 01-30, 2017*

*We, the undersigned hereby declare that the model number(s) above
was tested and conforms to the Directives and Standards listed above.*

[Signature]
Signature
Dane Carlson
Name

9/1/2017
Date
Division Manager
Title

Signature
Name

Date
Title

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EC REP

Atlantico Systems Ltd.

34 Oldfield

Kingston, Galway

Ireland

www.atlanticosystems.com

Phone: +35391443609