

PROMISEVISION 3D™

DENTAL 3D OPERATING MICROSCOPE 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 Precision Microscopes, 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 three-year warranty on all 3D microscopes.

Every Seiler Precision Microscopes team member is here to provide you with outstanding service, quality, and knowledge. Our number one priority is, and always will be, providing 100 percent 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,

Tony Tomevski

Owner & Director of MINT Devices

Seiler Precision Microscopes

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INTENDED USE

This is a 3D instrument intended for use in a dental operator by a dental professional performing various dental procedures.

Seiler's PromiseVision 3D™ unit is an optical instrument that provides the surgeon with a 3D, stereoscopic, high quality, magnified and illuminated image of the small structures in the surgical area. It will be used in the same manner as a dental microscope, except the operator will look straight forward at the 3D monitor instead of looking down through the binocular eyepieces, which are no longer present.

Circularly polarized glasses are used to view the image in 3D on a 3D-equipped monitor. Two cameras replace the eyepieces of a standard dental microscope. See the detailed system presentation in the system overview below.



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EC REP

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PRECAUTIONS FOR USE – CONTRAINDICATIONS

Do not operate Seiler **PromiseVision 3D™ Instrument** in an explosive atmosphere.

Do not operate Seiler **PromiseVision 3D™ Instrument** in an MRI environment.

Do not operate Seiler **PromiseVision 3D™ Instrument** for home health care.

Do not modify Seiler **PromiseVision 3D™ Instrument**.

Do not use Seiler **PromiseVision 3D™ Instrument** to illuminate eyes.

This device complies with international standards (as set forth in manufacturer's declaration) 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 health care 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.








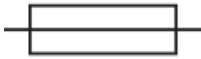


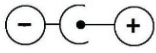


WARNING: *Portable and mobile RF communications equipment can affect medical electrical equipment.*









SYSTEM OVERVIEW

The 3D head-up vision system consists of a variable magnification stereo microscope system capable of being mounted on an articulated arm of a commercial microscope stand. The standard microscope eyepieces are replaced with custom optics and two digital cameras. They are connected to a video processing unit in the electronics module that converts the camera outputs to a realtime stereo image. This image is presented on a 21.5-inch flat-panel commercial 3D monitor that can be adjusted up or down to an individual's eye level. The working distance is about 32 inches from the eyes. In this implementation, the image is viewed through passive polarized 3D glasses, using the same technology employed in most 3D vision systems found in medical environments and also in RealD 3D movie theaters.

This image is a realtime presentation of the microscope's field of view; there is no perceptible delay. The operator can manipulate objects and perform work in a head-up position while viewing the image on the monitor, which is to be positioned directly in front on a horizontal line with the dentist. The configuration provides sound ergonomics, permitting excellent posture during long periods of use.

SYMBOLS USED IN THIS MANUAL OR DEVICE

| MARKING/SYMBOL | MEANING |
|---|--|
|  | Consult instructions |
|  | Surface may be hot and could be a burn hazard; do not touch. |
|  | Shock hazard |
|  | Intense light; do not look directly at lightsource. |
|  | Shock protection “Type B.” Adequate protection against electric shock with regards to leakage current and reliability. |
|  | Fuse |
|  | Alternating Current (AC) |
|  | Direct Current (DC) |
|  | Direct Current Polarity |
|  | Catalog Number |
|  | Care must be taken to avoid a tipping hazard. Move only using handles on post. The 3D instrument must be folded toward the post. |

| MARKING/SYMBOL | MEANING |
|---|--|
|  | Manufacturer's serial number |
|  | Authorized Representative in the European Community |
|  | Not for general waste; device is reusable and not contaminated at the end of the device life. |
|  | Indicates conformity with the essential health and safety requirements set out in European directives |
|  | Manufacturer |
|  | Date of manufacture, located 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 |
| WARNING! | Identifies conditions or practices that may result in injury or loss of life if instructions are not followed. Vents must be kept free for air flow Non-continuous operation of linear motor |
|  | Caution, consult accompanying documents or see instructions for use Qualified personnel only This equipment has passed testing for EMI/RFI radiation and susceptibility; however if not installed and used in accordance with the instructions, interference to other devices in the near vicinity may occur. Electromagnetic energy can travel through the power cord or through radio transmission. Ensure there is adequate separation distance between the unit and any device that may be affected by the electromagnetic energy coming from the unit. Power the illuminator from a separate AC main circuit that does not have a device connected that could be affected by the electromagnetic energy coming from the illuminator. |
|  | Important information |

TECHNICAL DESCRIPTION

AC POWER CONTROL

AC power control is provided by the illuminator's main on/off switch.

The illuminator has two front panel connectors that can source a total of 8.3A. This DC power is supplied by the illuminator's internal switching power supply.

One output connector is assigned to the monitor. The second output connector is assigned to the rear electronics.

USER CONTROLS

All system setup parameters are stored in nonvolatile memory, so basic operation of the 3D head-up vision system consists of turning on power and placing the microscope over the area of interest.

The user can adjust the LED lamp brightness using the remote switch for the illuminator.

Motor control for up/down vertical movement of the monitor is provided on the rear of the camera module. At this same location is a partial shutdown switch that enables the operator to place the cameras and monitor into a sleep mode.

Handles on the microscope can be used to adjust the location of the camera module and microscope.

MICROSCOPE

The microscope configuration uses common main objective (CMO) optics with six selectable magnifications via a rotating internal optical turret. Output goes through an optical block to two high definition video cameras (1080p60) mounted at right angles to the microscope optics.

Working distance is typically 250mm. It can be changed by the variofocus main objective lens.

Internal lens turret has slots for three Galilean telescope elements with six detent positions that allow the Galilean telescope elements to be used in either the forward or reverse directions.

LIGHTSOURCE

The LED lightsource is shipped mounted underneath the rear arm.

CAMERA MODULE

The camera module contains the optical block, two cameras and an interface circuit board. It attaches to the dovetail mount on the top of the microscope head.

VIDEO CAMERAS

The optics are designed for a c-mount digital color camera with a typical resolution of 1920X1080 pixels at 60 frames per second.

INPUTS

The inputs to the video processing unit (VPU) are DVI signals from two HD video cameras located inside the camera module. A custom optical block transfers the images from the stereo microscope to the right and left cameras. The camera output signals are connected to the rear electronics enclosure via two HDMI cables. These are the system inputs to the VPU electronics.

CAMERA SETUP

The video cameras setup and 3D video processing hardware are preprogrammed at the factory for optimum performance.

OUTPUTS

The 3D vision system provides three video outputs and a two-line diagnostic display output from the VPU electronics in the rear electronics module.

VIDEO OUTPUT

3D MONITOR

The operator's monitor type is a row-interlaced XPOL 3D monitor, 1920 x 1080 pixels. Typical size is 21.5 inches diagonally.

2D VIDEO OUTPUT

This can be used for an assistant's monitor, a frame grabber or video recorder. This output provides a 2D video output in either DVI or HDMI format (the output mode of this port is selected when the system is configured).

HDMI 1.4A 3D VIDEO OUTPUT

This output can drive any standard HDMI-based 3D display device (flat panel display, television or projector) to provide a second 3D display. This capability would typically be used to provide a large-screen 3D image in an instructional setting.

DIAGNOSTIC MESSAGE DISPLAY

The 3D vision system provides a two-line alphanumeric display for status and diagnostic messages. It is located on the electronics module on the cover's vertical surface.

See Appendix B for error codes and definitions.

PANTOGRAPHIC ARM

The pantographic arm is part of the microscope stand. It is attached to the 3D instrument on site. The vertical dual tube assembly connects to the pantographic arm and supports the monitor and the electronics module. A horizontal arm segment is attached to the vertical tube assembly. This segment positions the camera module and microscope assembly about 20 inches from the monitor and permits the dentist to sit with the display approximately 30 inches from the eyes of the operator.

The force required to move the microscope vertically is controlled by the user-adjustable friction controls on the pantographic arm assembly.

Further flexibility is provided by mounting the monitor on the vertical arm so it can be moved when the microscope arm is raised or lowered. When the microscope is rotated, the monitor remains in a level position.

SPECIFICATIONS

| General Details | | |
|--------------------------------------|--------------|-------|
| Working Distance Minimum Possible | 175 mm | 8 in |
| Working Distance Maximum Possible | 400 mm | 16 in |
| Microfocus Vertical Adjustment Range | 150 mm | |
| *3D instrument Weight (Floor Model) | 120kg | |
| Packaging | Custom boxes | |

| Optical Details | | |
|----------------------|----------------------------------|------------------------------------|
| | Standard Setup | Optional Setup |
| Objective Lens | 200-350 mm | 175-400mm |
| Min Focus | 150 mm Fine Focus | |
| Field of Vision | 5 - 110 mm | *5 - 133 mm |
| Magnification Levels | 2.8x, 4.1x, 5.3x, 8.7x, 11x, 17x | **Max Low: 1.3x Max High: 48.5x |

| Electrical Details | |
|----------------------|--|
| Power Supply | Mains Power 96-264 VAC 47-63 Hz |
| Auxillary Power Jack | 12 VDC 8.3A maximum |
| Fuses | (2) 1.5A 250VAC, Type GMA 5mm X 20mm Fast Blow 5x20mm |
| Power Cable | IEC 320/C13 Hospital Grade |

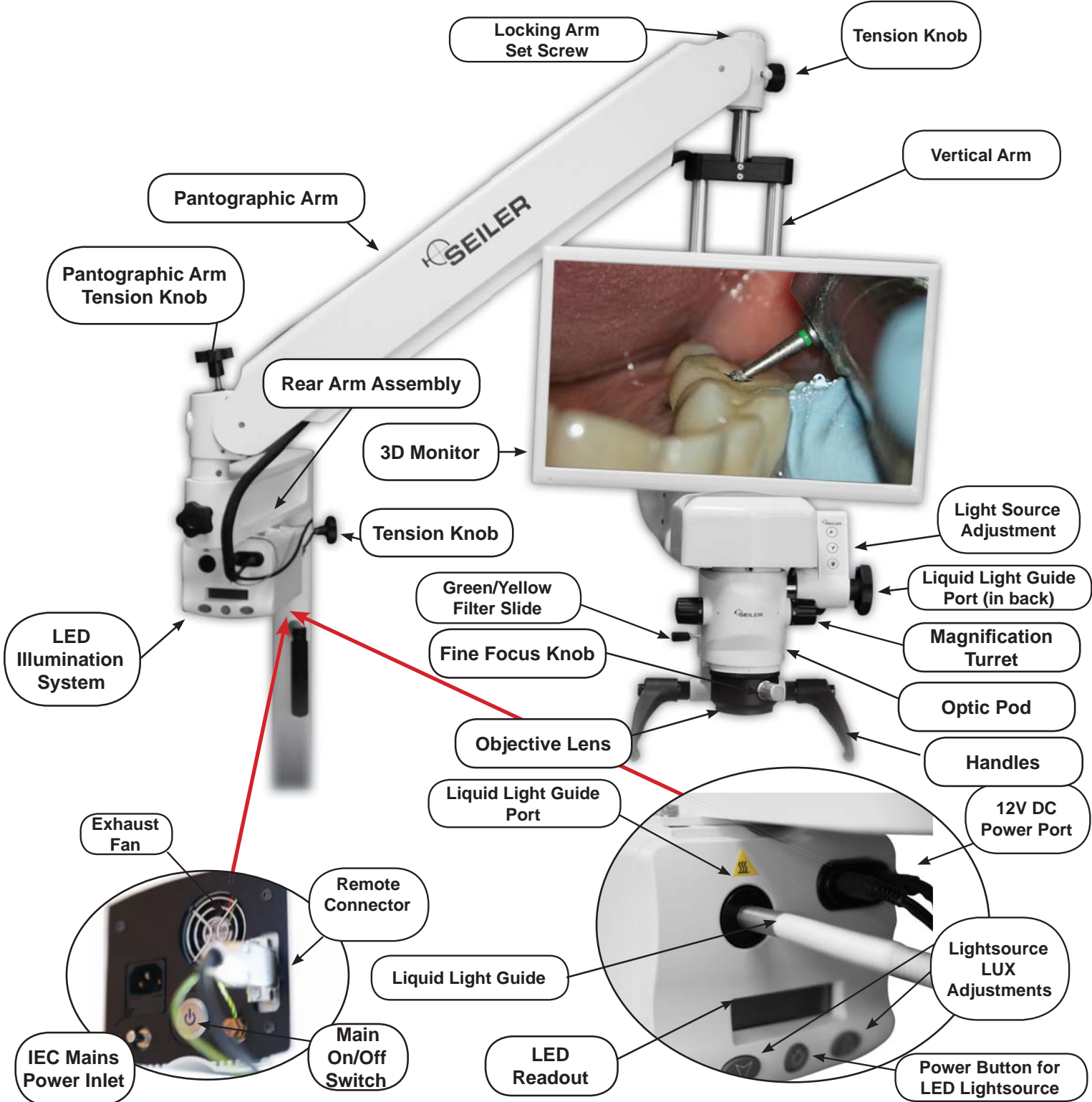
| LED Illumination Details | |
|--|--|
| Photometric Specifications and Performance | |
| Light Source Type | LED (Light Emitting Diode) |
| Color Temperature | Depends on customer configuration |
| LED Life | >30,000 Hours |
| Typical Illuminance | 5k-40k |
| Controls | |
| Brightness Control | Digital - 1024 Resolution |
| Mode of Operation | Run/Standby |
| Input Voltage | 100-240 |
| Regulatory Approvals | |
| Equipment Class | Class I, Type B |
| EMC | CISPR 11, Group 1 Class B |
| EMC | IEC 61000-4-3 |
| Product Safety | IEC 60601-1:2005 |
| Photobiological Safety | IEC 62471 2006 |
| Operating Environment | |
| Water Resistance | IPXO |
| Temperature | 50°- 104°F (0°- 40°C) |
| Relative Humidity | 30 - 75% non-condensing |
| Air Pressure | 700 HPA to 1060 HPA |
| Flammability | Equipment not suitable for use in presence of flammable mixtures |
| Storage Environment | |
| Temperature | 32°- 122°F (0°- 50°C) |
| Relative Humidity | 30 - 75% non-condensing |
| Air Pressure | 700 HPA to 1060 HPA |

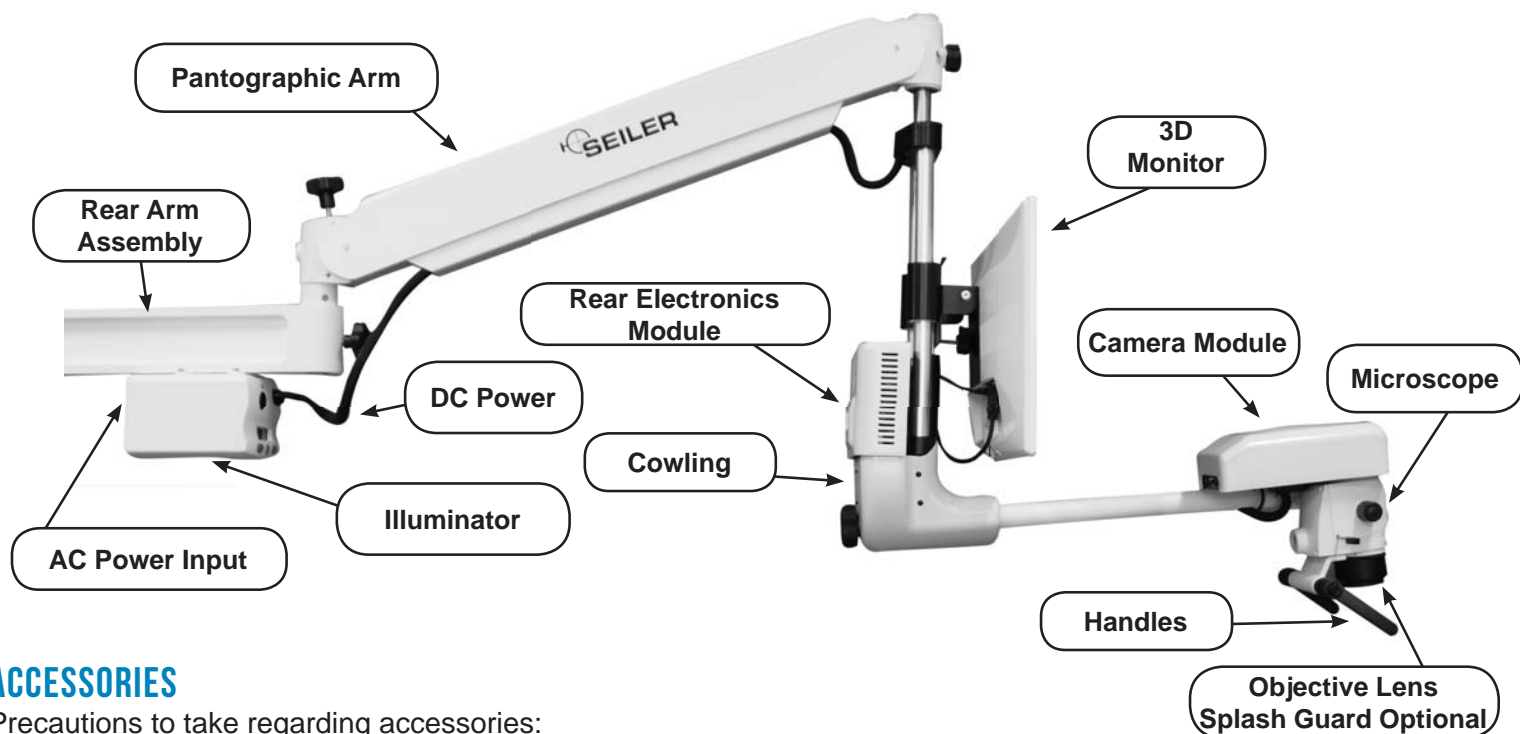
MANUFACTURER'S DECLARATION

| | Version | Type | | Guidance |
|---------------|---------|-----------------------------|--|----------|
| EN55011 | 2009 | Emissions | | Pass |
| A1 | 2010 | Emissions | | Pass |
| CISPR 11 | 2009 | Emissions | | Pass |
| A1 | 2010 | Emissions | | Pass |
| EN 61000-3-2 | 2014 | Harmonic Current | | Pass |
| IEC 61000-3-2 | 2014 | Harmonic Current | | 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 | | 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 | | Pass |
| A1 | 2007 | Radiated Immunity | | Pass |
| A2 | 2010 | Radiated Immunity | | Pass |
| EN 61000-4-4 | 2012 | EFT | | Pass |
| IEC 61000-4-4 | 2012 | EFT | | Pass |
| EN 61000-4-5 | 2014 | Surge | | Pass |
| IEC 61000-4-5 | 2014 | Surge | | Pass |
| EN 61000-4-6 | 2014 | Conducted Immunity | | Pass |
| IEC 61000-4-6 | 2013 | Conducted Immunity | | Pass |
| EN 61000-4-8 | 2010 | Magnetic | | Pass |
| IEC 61000-4-8 | 2009 | Magnetic | | Pass |
| EN 61000-4-11 | 2004 | Voltage Dips and Interrupts | | Pass |

PARTS AND COMPONENTS

INSTRUMENT COMPONENTS





ACCESSORIES

Precautions to take regarding accessories:



Use only approved hospital-grade mains supply cables 23-gage or better.



Use only 3D glasses approved by Seiler.

OPTIONAL ACCESSORIES (NOT PROVIDED WITH THE DEVICE)

Assistant 3D Monitor

Assistant 2D Monitor

Video Recorder

Frame Grabber



Use only 2D devices that are compatible with the 2D output signal from the electronics module.



Use only a HDMI 1.4b 3D TV monitor compatible with the 3D TV output signal from the electronics module.

FEDERAL LAW MAY GOVERN THE USE OF THIS DEVICE

Federal law restricts the use of certain medical device systems. It is the user's responsibility to ensure the device is being used in a manner appropriate with federal law.

QUALIFICATION OF PERSONNEL

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

Installation: Hospital engineer or similar training plus specific training by Seiler or approved contractor.

Operation: Dental training in surgical procedures and in dental health procedures plus specific training by Seiler or approved contractor.

INSTALLATION



Installation of the device may be done only by an authorized agent.

BEFORE INSTALLATION

Familiarize yourself 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 occurs that could reasonably create damage or a hazard, stop and arrange for qualified maintenance personnel to inspect.

Emergency use only: If at any point you suspect something is wrong, terminate installation/operation by pressing the MAINS on/off (blue switch with international 0/1 designation) on the illuminator. The blue light should be off. Then remove the MAINS cable. Consult technical support with information as to why the installation was halted.

If at any point you determine the essential performance of the device has been impaired (due to electromagnetic interference or other causes), terminate installation/operation and consult technical support before continuing.

Do not use sharp instruments during installation; doing so could damage internal components and create a hazard.

Ensure no residual packaging materials (foam peanuts, etc.) are left inside the unit.

Use of a disposable material over the device to prevent fluids from splashing on the unit is permitted only when the power has been removed. 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.

Read the rear label at angle under 10 degrees from distance less than 0.25 meter with minimum lighting of 1,500 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).

Ensure there are no flammability issues with the siting.

Ensure there are no electromagnetic compatibility issues with the siting.

Ensure there are no ventilation issues with the siting.

INSTALLATION SETUP INSTRUCTIONS

INSPECT SHIPPING CONTAINERS FOR DAMAGE.

Carefully examine all the boxes for damage before opening the boxes or removing contents.

If shipping damage is suspected, notify Seiler or your authorized dealer immediately.

UNPACKING

The complete Seiler PromiseVision 3D™ system is packaged in several boxes.

Carefully unpack all components.

INSPECTION

If necessary, the unit can be cleaned with isopropyl alcohol and a soft cloth. Inspect all components for any signs of damage that may have occurred during shipping.

Please verify that you have received these items:

This User Guide

Mounting Option (Floor, ceiling, wall or high wall)

Rear Arm Assembly (including preassembled lightsource)

Hospital-Grade Cord with Lock

Rubber Handle Covers
Mobile Base F/EVO/IQ
Pantographic Arm F/3D
EVO/IS Pole for Mobile Floor Stand
Zoom Base Stabilize
Leg Ext / Weight Set
EVO/IQ Caster w/o Brake
EVO/IQ Caster w/Brake 4"
3D Instrument Heads-Up Display
Variofocus 200-350 mm Lens
DC Power Cable, Extension, 4'
3D Monitor
92-LLG 92" Liquid Light Guide
CP3DFRAMES Admiral Frame Style
CP3D Terminator Terminator Frame Style
D400-5101 Large Nylon Cove

Additional accessories purchased with the 3D instrument. See the packing list included in the shipment.



The control box, the illumination box and the pantographic arm must be handled carefully, because the external surfaces of these modules can be easily damaged. A sharp impact on these surfaces may result in scratches or other damages. The 3D instrument is the most delicate part. Take care during use, transportation or handling.



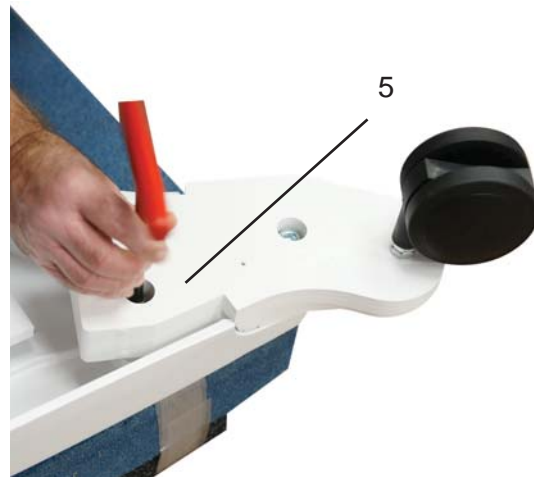
The optical module is assembled at the factory in a sealed block. Disassembly will void the warranty.

ASSEMBLING THE EQUIPMENT

ASSEMBLING THE BASE

When assembling the base:

1. Place two boxes about 5" thick under the base to support it when it is sitting on the neck.
2. Remove the two countersunk screws with a 7/32" hex wrench.
3. Place the two spacers between the plate and the stabilizer bar with the white pads facing you and bolt it on with the two bolts supplied with the spacers.
4. Add outer bolt to leg without the spacer. Start a few threads.
5. Add spacer to the inner bolt hole, insert bolt. Tighten both.



6. Make sure leg attachments protrude outward as shown in photo 6.

PANTOGRAPHIC ARM AND 3D INSTALLATION

INSERT THE PANTOGRAPHIC ARM INTO THE LIGHT SOURCE ARM.

It is not necessary to adjust the tension of the pantographic arm. It is set at the factory as required to hold the 3D arm assembly in a stable position. It will move up and down subject only to operator control.



INSERT THE VERTICAL ARM OF THE 3D SYSTEM INTO THE PANTOGRAPHIC ARM.

Be sure to unscrew and loosen the black knob and pull the silver plunger out in order to insert the spindle of the 3D unit. After seating the spindle, release the plunger and screw down the white locking nut.

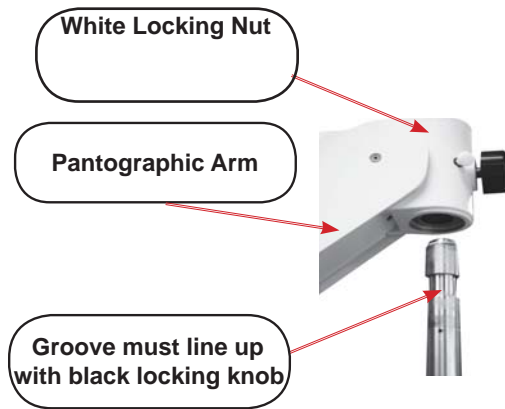


Figure 2



WARNING :

DO NOT ADJUST THE TENSION KNOB TO THE LOWEST SETTING. FAILURE TO FOLLOW THIS WARNING MAY RESULT IN BODILY INJURY OR DAMAGE TO EQUIPMENT. THE ARM CASTING MAY BE DAMAGED RESULTING IN INJURY WHEN THE ARM MOVES DOWN TO ITS LOWER LIMIT WITH EXCESSIVE FORCE. WHILE SET TO THE LOWEST TENSION SETTING, THE PANTOGRAPHIC ARM IS NOT FUNCTIONAL AND IT CANNOT SUPPORT THE WEIGHT OF THE OPTICS WHICH COULD RESULT IN DAMAGE IF THE ARMS CRASH TO THE LOWER LIMIT.

DO NOT ADJUST THE TENSION KNOB WHEN INSTALLING A NEW MICROSCOPE SYSTEM. THIS KNOB IS FACTORY PRESET TO MATCH THE MICROSCOPE CONFIGURATION OF THE ORDER. INSTALL THE OPTICS WITHOUT ADJUSTING THE TENSION KNOB.

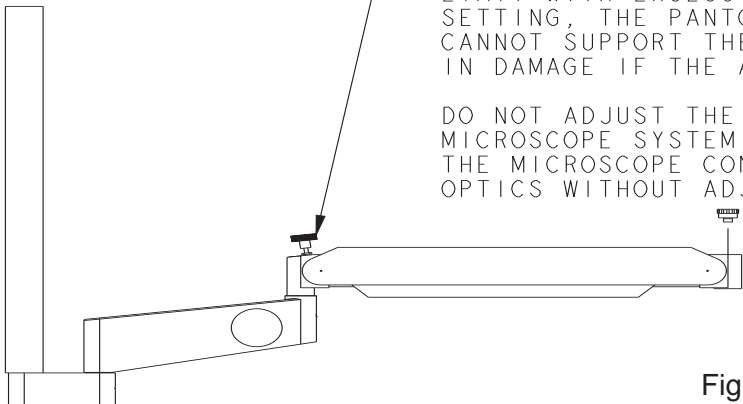


Figure 3



WARNING: Improper installation of pantographic arm is hazardous.

INSTALL THE LIQUID LIGHT GUIDE

Plug the white liquid light guide into the port on the scope body.

Thread the light guide through the pantographic arm channel and plug it into the port on the lightsource. Leave service loops as required.

ASSEMBLE MONITOR TO VERTICAL TUBE ASSEMBLY

Remove the 3D monitor from its box and inspect for damage.

A mounting bracket is attached to the VESA mount on the rear of the monitor.

Remove the two shoulder screws, which are threaded into the bracket on the vertical arm assembly. Be careful to retain the washers supplied with each shoulder screw.

With an assistant, place the monitor's bracket ears on the outside of the vertical arm bracket ears. Place a washer between the ears of the two brackets and tighten the shoulder screw. Repeat on the opposite side.

The monitor must tilt up and down freely. A tilt adjustment knob is included with the vertical arm bracket. Set so the monitor is approximately vertical to the floor. This will be adjusted later per the operator's instructions.



CONNECT THE CABLES FROM THE 3D SYSTEM

Uncoil the cables extending from the 3D vertical assembly and pass these cables through the pantographic arm channel. There are two 12-volt power cables enclosed in a braided metal sleeve. They protrude from a hole in the metal braid about 12 inches before the end of the braid.

There is one signal cable. It is from the membrane switch at the end of the horizontal arm, next to the scope body. Plug the signal cable into the DB15 connector located at the rear of the LED lightsource. This cable allows remote control of the lightsource from the small touch pad to the right of the microscope body.



Remote switch and
signal cable

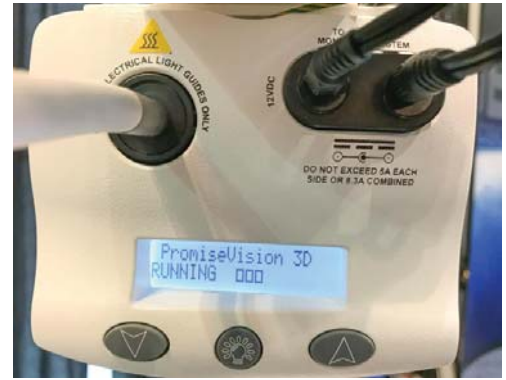


Remote cable
connection to
illuminator

Extend the braided grounding cable (associated with the 12 power cables) to the rear of the lightsource and connect it securely to the grounding pin on the rear panel. Use the threaded nut already on the grounding pin for this connection. Use threadlocker supplied in a small packet to securely fasten the nut.

Connect the six-inch pigtail from the grounding pin to an 8-32 tapped hole on the bottom of the rear arm using the provided 8-32 x.5-inch screw.

Insert the two 12-volt power cables into the two ports on the upper right of the illuminator front panel per the system level documentation and in accordance with the hazard mitigation instructions.



Front Panel of Illuminator:
Two DC Power cables and Liquid
Light Guide

LED LIGHTSOURCE



WARNING: Read fully before attempting operation.

LED ILLUMINATOR OPERATION

READ ALL WARNINGS

Illuminator LCD Display



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

The bottom line displays status and dimming level.

The bottom line will indicate “STANDBY” or “RUN.”

Each square represents 10 percent of the range (three squares means 30 percent of maximum illumination).

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

Familiarize yourself 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.

Do not operate the device without an approved light guide installed.

Never look directly into light port.

If at any time after the installation an event of dropping, fluid ingress or other such event occurs 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, first shut down the VPU system operation by depressing the rear enclosure button and wait until green LED is off. Then terminate operation of the lightsource by pressing the MAINS on/off (blue switch with international 0/1 designation). The blue light should be off. Consult technical support with information as to why the installation was halted.

Confirm MAINS power is off, then remove the MAINS cable.

The rear label can be read at an angle less than 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: the LED lightsource and the microscope body

Hospital-grade power cable is properly installed

All electronic cables are present and properly connected

Device is not located near any critical device that could be influenced by electromagnetic energy levels

Venting on device is not blocked

No damage is present on device

Not in presence of flammable gases or fluids

LED OPERATION

Turn on MAINS on/off switch on the LED lightsource (blue switch with international 0/1 designation).

Confirm LCD screen on the illuminator provides indication (active) and is in STANDBY mode.

Ensure output of illumination will not violate any of the hazard mitigation instructions (is not directed into someone's eyes).

Enable the LED lamp by pushing the LED-ON/STANDBY mode button on the illuminator.

Select dimming level by pressing up or down buttons on the illuminator or the remote.

The remote switch is a small remote control for controlling the operation of the LED lightsource. It is located at the end of the horizontal arm that holds the optical pod and the camera module. The buttons on this remote control operate exactly as the three momentary buttons on the front of the illuminator.

To remove illumination for short periods of time (under 60 minutes), press LED lamp off button on either the illuminator or the remote switch.

To change intensity, press and release either the up or down button (do not press both at once) and the light level will increase or decrease approximately 10 percent, depending on which button was depressed. If you require fine tuning of the light level, press and hold either button and it will slowly scroll through 10 different illumination settings (this can be much slower than press-and-release). Do not press more than one of the three buttons at a time. It is important that you use the correct procedure to power down the system correctly when the unit will be idle for long periods of time (such as nights and weekends). This is to avoid unnecessary wear on the electronics.

CONTROLS

Monitor vertical position adjustment using the up/down switch on the camera module.



WARNING: Do not excessively operate the monitor position control. The motor will overheat. Maximum number of cycles before a five-minute cooling period is three over full range of movement.

System power on/off on rear electronics module

- Partial shutdown button on the camera module
- Monitor on/off switch
- Remote switches for the illuminator on the microscope
- Illuminator mains on/off switch on rear of Illuminator

- Up and down buttons on the front of illuminator to increase and decrease light intensity
- Lamp button on the front of Illuminator to toggle between standby and run modes

OTHER SPECIFICATIONS

RANGE OF MOTION OF THE 3D INSTRUMENT

Supports translation in all three spatial directions, X, Y and Z.

Supports tilt of 90 degrees toward the user, i.e. for direct vision applications, and 45 degrees away from the user.

Supports rotation to the left and right by 90 degrees, 180 degrees total.

SEILER PROMISEVISION 3D™ INSTRUMENT OPERATION

TURNING ON THE 3D SYSTEM

Confirm the illuminator has been properly installed and the MAINS on/off switch is turned off.

Confirm the two 12VDC power cables (in the metal sleeve) are connected to the illuminator. They are shipped preattached to the rear enclosure and covered by the cowling.

Apply system AC power by turning on the illuminator MAINS on/off switch. This will apply power to the 3D system components and the 3D system will automatically begin to power up.



NOTE: The 3D imaging elements have components similar to an office PC and therefore the systems will take 45 seconds to 60 seconds to “boot up” and be ready for use.

The green LEDs on the camera module and the rear electronics module will turn on when the 3D system is ready for use.

The LCD display on the electronics module will become illuminated and show the status of the system and the display(s) connected to it.

The display top line will display the three available video outputs, either “3D-Mon 2D-TV 3D-TV” or “3D-Mon 2D-Mon 3D-TV,” depending on the basic configuration of the Seiler PromiseVision 3D™ instrument.

The second line will display the status of each video output as either “NC,” “OFF,” “INIT” or “ON.”

The LCD two-line display will show error codes in the event of any failure of the 3D unit (See Figure Three).

See Troubleshooting for error codes and definitions.

Verify the monitor power is on. If not, press the button at the lower right corner of the 3D monitor to turn on the monitor.

Turn on the LED lightsource with the button located at the front of the lightsource, or use the remote touch pad to the right of the microscope head. A bright circle of light should become illuminated below the microscope objective lens. The light may be turned up or down from the remote touch pad. When the 3D system is not in use, use the remote touch pad to shut off the LED lightsource.

45 seconds to 60 seconds after the illuminator/power supply is turned on, the boot up operation will be complete and a 3D image should appear on the monitor. Place your hand or some object about 250 mm from the objective lens to confirm the 3D image is present.

Put on a pair of 3D polarized glasses to view the image in 3D.

When not wearing the 3D glasses supplied with the system, the image you see will appear as a double image. This double image consists of the separate images the left and right eye would see as one image when using the 3D polarizing glasses.

TURNING OFF THE 3D IMAGING SYSTEM

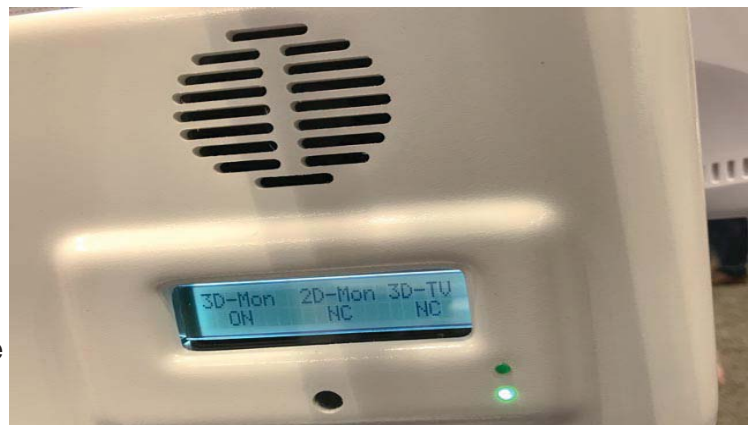


Figure Three

The 3D system is turned off by pressing the small button on the rear electronics module cover.

The two-line display will then show “shutting down” and within a few seconds, the display will turn off and the green LEDs will also extinguish. The amber LED will remain lit until system power is removed at the illuminator.

After the system has shut down (the two-line display turns off and the green LEDs extinguish), the power button at the back of the illuminator/power supply can be depressed to shut down the entire system.



WARNING: Do not shut off the power supply or pull the AC plug before the 3D electronics have fully shut down. Disconnecting power before the 3D electronics have fully shut down may temporarily disrupt the operating system of the 3D electronics and cause a two to three-minute delay at the next startup as the operating system recovers from the previous loss of power during shutdown.

EMERGENCY STOPPING DEVICES

Push the on/off button on the illuminator.

Pull the power cord.

USING THE INSTRUMENT

ADDITIONAL INFORMATION FOR USE OF THE SEILER PROMISEVISION 3D™ INSTRUMENT

THE IMPORTANCE OF A HEALTHY, ERGONOMICALLY-BALANCED POSTURE

Seiler's PromiseVision 3D™ system was designed to give a head-up image to improve the posture and ergonomics of dentists as they work. Dentists oftentimes develop neck and back injuries due to an unhealthy, unbalanced posture associated with operative dentistry. Sixty percent of dentists surveyed by the ADA reported they were practicing in pain with neck and back injuries. Ultimately the injuries associated with poor work posture can lead to short-term or even long-term, career-ending disability.

POSITIONING YOURSELF FOR A HEALTHY BALANCED WORK POSTURE

For a balanced posture, seat yourself at a comfortable height with your thighs angled downward at a 10 to 15-degree angle. When working, as much as possible, keep your elbows below your shoulders and position yourself near the patient's head so it is not necessary to reach forward to work in the mouth.

As you position yourself to work on a patient, pay careful attention not to lean forward. Try to keep your head positioned on a vertical line extending upward from the shoulders. Ergonomic experts look for ears positioned directly above the shoulders. Hold your head so your line of sight will be horizontal when looking at the 3D monitor. Having a horizontal line of sight is critical to a healthy, balanced working posture and fundamental to the benefit provided by a head-up 3D image.

POSITIONING THE 3D MONITOR FOR A HEAD-UP HORIZONTAL LINE OF SIGHT

A small toggle switch on the back of the camera module should be used to raise or lower the 3D monitor. Use this toggle switch to move the monitor to a vertical position where your horizontal line of sight is approximately in the middle of the monitor image. If necessary, further adjust the angle of the monitor so your line of sight is perpendicular to the monitor surface. A rotary knob behind the monitor causes the monitor to be angled upward or downward from the initial vertical display surface.

For very tall individuals or for those shorter than 5'2," it may be necessary to further adjust the angle of the monitor to accommodate the dentist's height.

POSITIONING THE 3D INSTRUMENT FOR AN IMAGE OF THE MOUTH OR SELECTED DENTITION

When first beginning to use the Seiler PromiseVision 3D™ instrument, the operator must stop and think about where they would be positioned for the best view. They must also analyze where they would position their head and their eyes to get the necessary field of view. The Seiler PromiseVision 3D™ system can obtain the desired view without putting the dentist in an unhealthy posture.

Move the optical head of the 3D instrument into the position previously taken by your head and eyes and angle the optical head to achieve the preferred field of view. Position the optical head in a comfortable position where the objective lens is 250mm to 350mm from the patient's mouth. This distance gives a wide field of view and provides adequate room to use typical dental instruments.

PRACTICE BY STAGING TYPICAL VIEWS OF THE MOUTH WITH AN ASSISTANT

To learn how to obtain the necessary view of the patients, it is recommended that the dentist and an assistant practice staging several typical dental procedures to assist in analyzing the position needed for the 3D instrument. For example:

A CROWN PREP ON #31 IN THE LOWER RIGHT MANDIBLE

- Where would the dentist be positioned?
- Where would the dentist's head be?
- How would the patient's head be turned to get the right field of view?
- Would a mirror be used?

A CLASS II PREP ON A UPPER LEFT MAXILLARY MOLAR OR BICUSPID

- Where would the dentist be positioned?
- Where would the dentist's head be?
- How would the patient's head be turned to get the right field of view?
- Would a mirror be used?

A RESTORATION ON A LINGUAL SURFACE OF A MAXILLARY INCISOR

- Where would the dentist be positioned?
- Where would the dentist's head be?
- How would the patient's head be turned to get the right field of view?
- Would a mirror be used?

OTHER COMMON PROCEDURES IN THIS PRACTICE

For each of these staged procedures, position the 3D instrument to get the image on the monitor that you would have seen with your eyes or loupes. Practice with these staged procedures should help to establish the process by which a familiar image is achieved for all the procedures in your dental practice.

USE OF MAGNIFICATION

Seiler's PromiseVision 3D™ permits much greater magnification than would typically be used in general dental practices. The Seiler PromiseVision 3D™ instrument can offer magnification in excess of 20X, but initially higher magnifications should not be used until the dentist feels comfortable and familiar with the system's use. Therefore, for the first week or two of use, use only the lowest magnification (the number one on the magnification changer should be facing the operator), which represents 5X magnification.

When using the initial magnification setting of one at 5X, you will notice a very wide field of view, which allows a full arch to be seen, and an extraordinary depth of field in excess of 40mm. This depth of field allows most procedures to be done without any focus adjustments.

After one to two weeks, the operator should increase magnification to the second setting. This gives 8X magnification to subjects seen on the monitor. Practice at this higher magnification for an additional week before increasing the magnification. Over time, use of magnification levels of 15X to 18X may be helpful for root canal procedures or detailed cosmetic procedures. Higher magnification levels, however, have much shorter depth of field levels and are inherently less familiar/intuitive from an eye-hand coordination standpoint and therefore take longer periods of time for their use to become efficient and comfortable.

CORRECTLY POSITIONING THE FOCAL PLANE

You must exercise care in focusing on subjects to avoid discomfort and, in some cases, headaches. It is important when focusing on a tooth or teeth, for operative purposes, to pull focus on the nearest part, or on top of the subject. To practice this focusing process, mark a small dot on the occlusal surface of a tooth and bring it into focus with the 3D glasses off. As focus is achieved, the two dot positions (representing the image for the left and right eyes) will merge into a single dot. At this convergence point, the dot on the top of the occlusal surface is perfectly in focus and the focal plane of the 3D instrument is set on the plane of the dot.

When the marked dot converges to a single dot (with the 3D glasses off), the remainder of the tooth structure will appear in focus, but will be a double image. When the 3D glasses are put on, the entire tooth or tooth structure and gum structure will be in focus and normal depth perception will be present. The depth of field with the 3D instrument at a low magnification can cause all the surrounding tissue to be in focus, but the focal plane has been established at the top of the tooth (where the two dots converged to one dot). This means the depth of the 3D image, for all the remaining tissue, will appear to be behind the surface of the 3D image. This is the correct situation for a 3D image.

Conversely, it is possible to establish the focal plane of the instrument at the bottom of the subject when focusing so the tooth appears to extend forward from the monitor surface. While this 3D effect may be impressive, with any extended use, it becomes uncomfortable and is not well-tolerated. This discomfort results from a disparity between the accommodation of the lens in the eye, and the convergence of eyes on near subjects. Accommodation and convergence are both controlled by the brain, and negative disparity occurs when the brain attempts to converge the eyes in front of the monitor surface (as when a tooth would appear to be in front of the monitor). Negative disparity with a 3D image causes fatigue and discomfort and is not well-tolerated.

Therefore special care must be taken to place the focal plane of the 3D image on the top of the subjects being viewed and avoid the phenomenon of negative disparity.

MOUNTING

ANCHOR TYPES

WEDGE ANCHORS

Wedge anchors are for attaching fixtures to concrete. The installed end of the anchor features a conical segment with a metal clip around it. Upon setting the anchor, the cone pulls up through the clip and pushes the clip against the sides of the hole. This gives the anchor its holding power within the hole. Anchor diameter will be equal to the hole size.

Expansion of the wedge anchor creates large point bearing stresses within the hole, therefore requiring a solid base material to develop its full capacity. For this reason, brick and partially-filled mortar joints in brick walls or paving may be unsuitable for wedge anchor usage.

SLEEVE ANCHORS

Sleeve anchors also are used to attach fixtures to solid materials. A bolt is surrounded by a cylindrical metal sleeve. They operate by the expansion of the sleeve into the base material when the bolt is tightened. Expanding the sleeve along the length of the anchor enables a larger bearing surface than that offered by the wedge anchor, and can better adhere to irregular surfaces within the base material than the wedge anchor can. Therefore, sleeve anchors can be better suited for brick masonry than wedge anchors. Sleeve anchor diameter will be equal to the hole size.

Sleeve anchors come in models with round-headed bolts, flat-headed bolts, bolts with a hex nut/washer assembly and bolts with an acorn nut/washer assembly.

DROP-IN ANCHORS

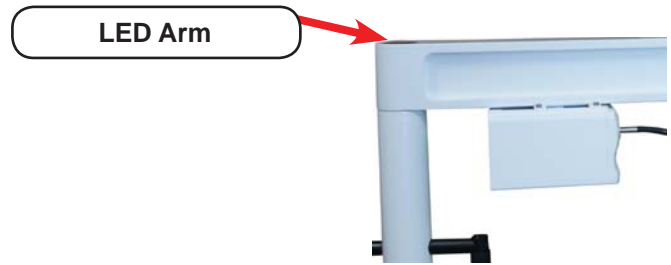
Drop-in anchors are designed for solid concrete base material, and are not recommended for masonry or brick. Drop-in anchors are a female mating part anchor with coarse threads. The drop-in anchor requires a setting tool for expanding the anchor.

EXPANSION SHIELD

Expansion shields may be single or double-piece design. Both are inserted for shear loads or where the bolt may be under side pressure or vibration. Expansion shields consist of a nut, a cone and a tubular shield that are put together as a single unit. The two-piece tubular shield in either version contains a wedge-shaped nut at one end, a wedge shaped hollow cone at the other end and is held in place by two spring bands. The expansion at both ends of the shield spreads the anchored load throughout its length.

HIGH WALL MOUNTING

1. Determine suitable location: Wall next to doctor, wall behind doctor, etc. at a distance no greater than 60" and no less than 30" from the wall to the patient's mouth.
2. Position the wall bracket with the threaded opening facing down and with the lower mounting holes approximately 81" above the floor. Fasten the wall bracket to the wall, making sure the wall construction is wood stud (16" on center) or cinder block. All other constructions require wall bracing; Contact your building maintenance department or an outside contractor in this case.
3. Remove the rear arm assembly from the shipping carton and connect this assembly to the bottom of the wall bracket by carefully threading the shaft into the wall bracket using the gray cap on the arm assembly to thread in the shaft.
4. Two holes are used to insert a tool for loading the internal bearings. One hole contains a setscrew you can adjust to lock the desired tension.
5. After the entire 3D instrument is assembled to the high wall bracket, check for satisfactory rotational movement.
6. After you have set the tension and checked the rotational movement, tighten the setscrew in the front of the wall bracket.
7. A thru-hole is provided to wire the 3D instrument into the wall/ceiling. Check your local electrical code for proper wiring.
8. You are now ready to install the pantographic arm and 3D instrument.



Seiler does not supply screws for mounting all brackets. The type of screws and/or anchors used should be determined by a qualified contractor. If mounting to a metal-studded wall, there needs to be backing such as plywood mounted to each side of the wall and screws to attach the wall bracket through both pieces of plywood so it is structurally sound. For mounting to a wood-studded wall, large lag screws should be sufficient. A professional contractor should determine size and length.

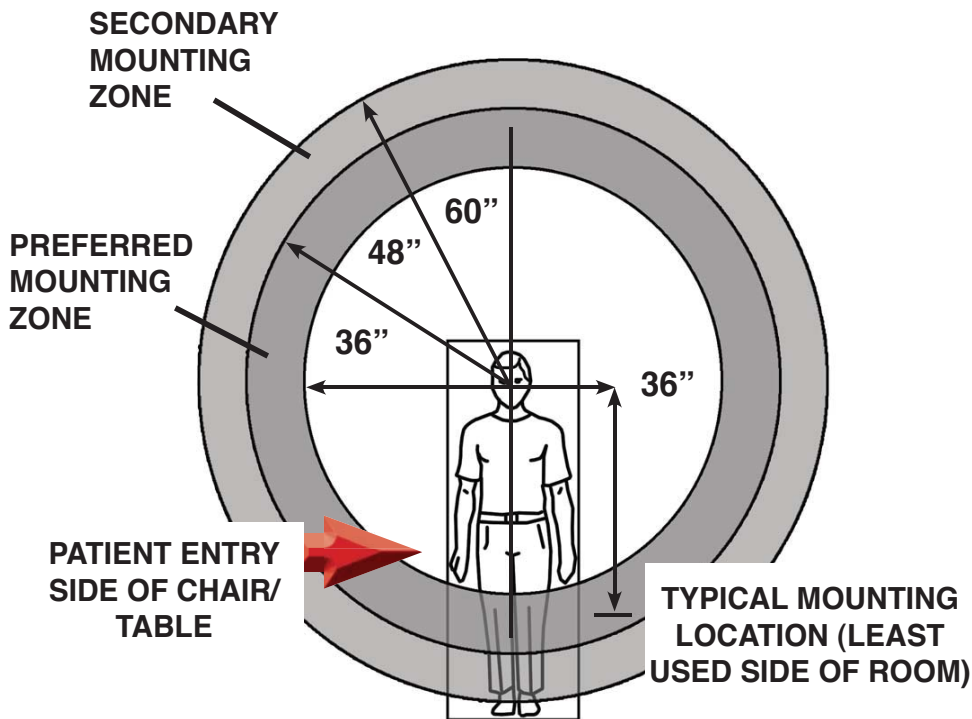
WALL MOUNTING

1. Determine suitable location: Wall next to doctor, wall behind doctor, etc. at a distance no greater than 60" and no less than 30" from the wall to the patient's mouth.
2. Position the wall bracket with the threaded opening facing down and with the lower mounting holes between 55" and 70" above the floor. Fasten the wall bracket to the wall making sure the wall construction is wood stud (16" on center) or cinder block. All other constructions require wall bracing. Contact your building maintenance department or an outside contractor in this case.
3. After the wall bracket is securely attached to the wall, carefully thread the bearing and holder assembly into the bottom opening of the bracket until it is hand tight. Tighten set screw on front of wall bracket.



Seiler does not supply screws for mounting all brackets. The type of screws and/or anchors used should be determined by a qualified contractor. If mounting to a metal studded wall, there need to be backing such as plywood ounted to each side of the wall and screws to attach the wall bracket through both pieces of plywood so it is structurally sound. For mounting to a wood studded wall, large Lag screws should be sufficient. A professional contractor should determine size and length.

HIGH WALL AND CEILING RECOMMENDED MOUNTING LOCATION



NOTE:

If the typical position is not available, locating the microscope within the Preferred Mounting Zone (vertically shaded) will ensure that there is maximum maneuverability of the microscope in all directions. Locating the microscope within the Secondary Mounting Zone (diagonally shaded) is possible, depending upon the specific layout of a room, but may reduce maneuverability.

CEILING MOUNTING

To be sure the unit is properly secured to the structural members of the building, ensure mounting integrity and stability. Such members will usually be located above a dropped ceiling. If it is necessary to span between members to mount the unit, the installer must ensure that whatever material they use (lumber, angles, channels, etc.) possesses the strength and rigidity required to provide stability.

Unpack all boxes and verify all parts are present, noting that some are in a sub-assembly state. Any loose pieces will be labeled with their corresponding part number.

Using the template provided, transfer the hole locations onto the structural members to which the unit will be mounted. It is recommended that the unit be thru-bolted into the member using 1/2" bolts and nuts. In some applications, when thru-bolting is not possible, it may be necessary to use lag bolts or some other type of anchoring.

The unit can be installed at a nominal height with plus/minus adjustment of four inches available in two-inch increments. The center hole of the five pin-locating holes in the mounting post is the nominal height. If the unit must be mounted closer to the ceiling than the nominal height, it will be necessary for the installer to provide either a four-inch diameter opening above the mounting plate assembly for the mounting post to protrude into, or cut off any of the mounting post material that comes within 3/8 inch of the back of the mounting plate assembly. This provides the clearance necessary to allow for any tilt adjustment.

If unit needs to be mounted closer to ceiling and no provision is made in which the mounting tube can protrude into, it will be necessary to cut the tube so it is at least 3/8" from the back of the mounting plate assembly.



CEILING MOUNT INFORMATION

DATE _____

OFFICE

Doctor's Name

Practice Name

Street Address

City, State, ZIP

MEASUREMENTS

| | | |
|--|-------|---------|
| "True" ceiling mounting structure to floor | _____ | inches |
| Bottom of ceiling tile to floor | _____ | inches |
| Placement of pole in relation to chair | _____ | o'clock |
| Reach needed from center of pole to patient's mouth | _____ | inches |
| Bottom of objective to floor when in optimal working position with patient | _____ | inches |

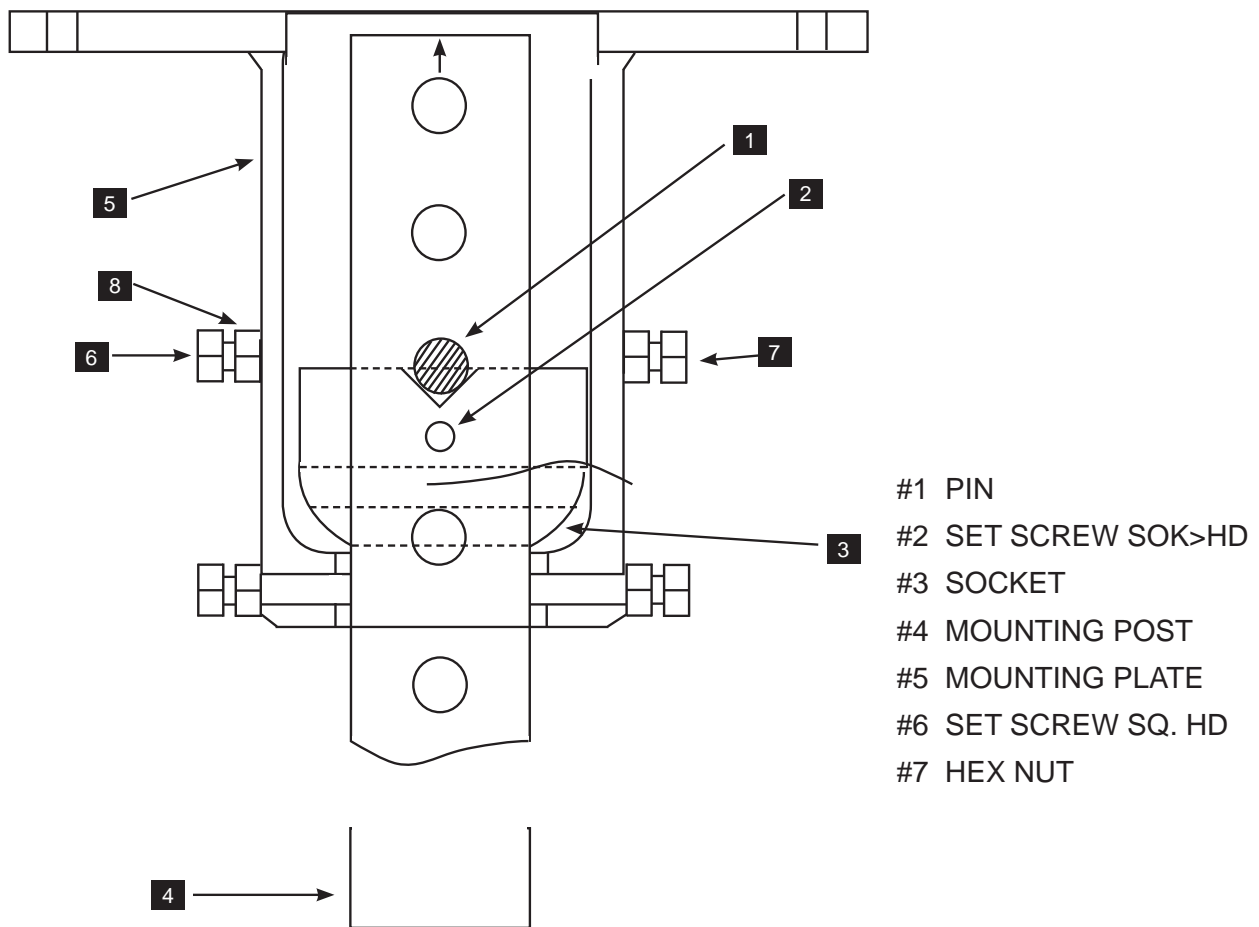
HOLES

| | | |
|------------------------------|---------|------------|
| Entry hole* needed for power | Top Y/N | Bottom Y/N |
| Entry hole* needed for HDMI | Top Y/N | Bottom Y/N |

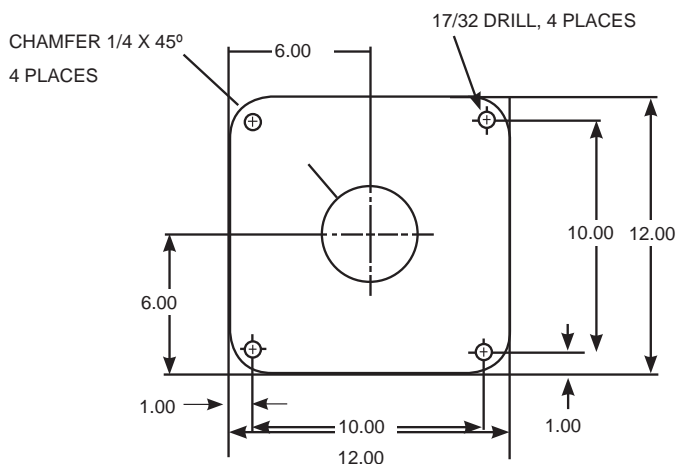
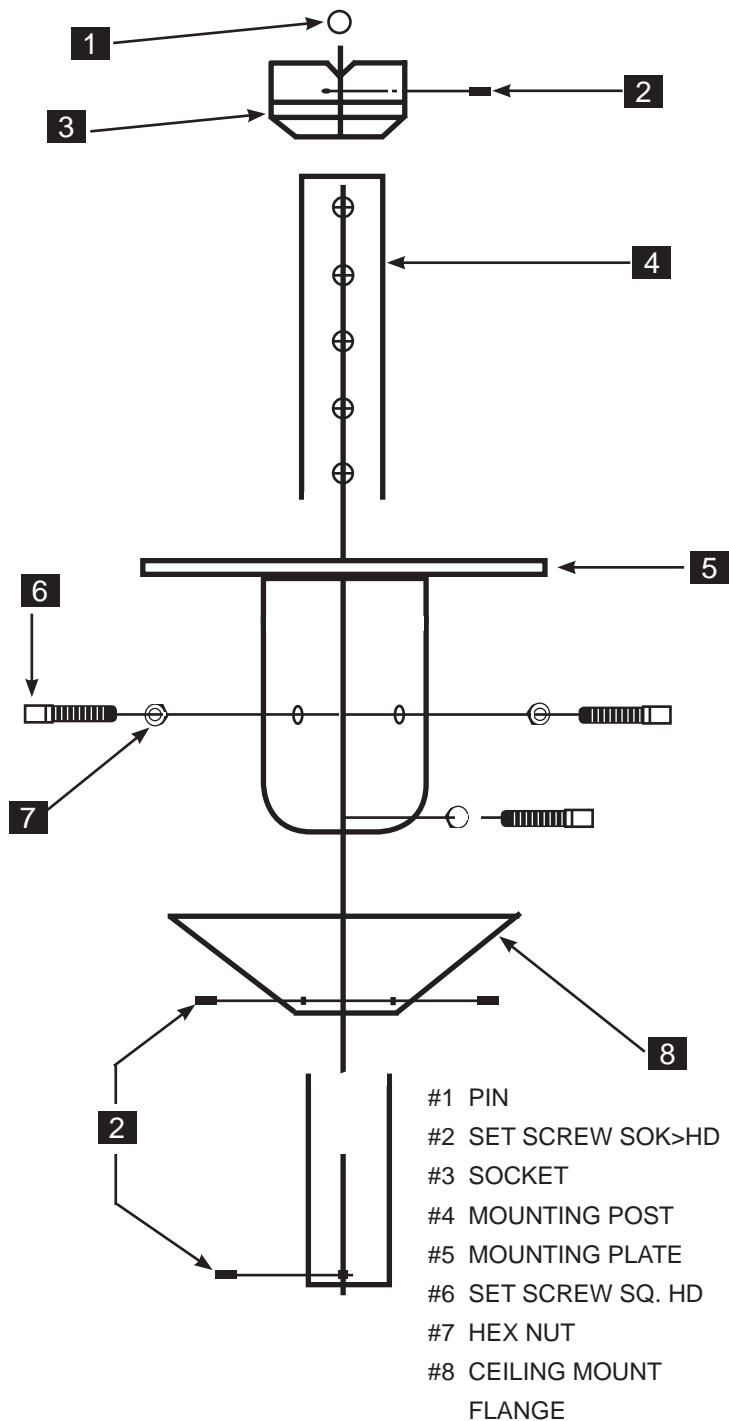
*Custom charges apply

NOTES

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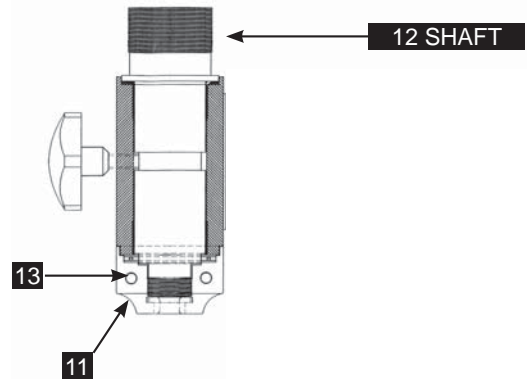


Place the mounting plate assembly **5** on its side to allow parts to be placed into it from both the top and bottom. Back out all square head set screw **6** in order to insert column **4**. Feed in mounting post **4** through the opening of mounting plate with the end of the mounting post that has the five pin mounting holes entering first. Push the mounting post through far enough to allow the socket **3** to be installed onto the mounting post in such a position that the pin **1** can be installed in the proper holes above the socket. Then slide the socket back up so the pin engages in the V-groove in the socket and ensure the pin protrudes the same amount from each side of the post. While holding the socket firmly against the pin, tighten the set screw **2** (1/8" hex key) in the socket to lock it to the post. Then pull the mounting post back through the mounting plate assembly and hand tighten the six set screws **6** to hold the post/socket assembly in place while attaching the complete unit to the ceiling structure (Note: loosen the hex nuts **7** to allow movement of the set screws **6**). Have an assistant lift the post assembly into position and fasten the assembly into the structural member. If there is any rocking motion due to a non-flat mounting surface, it will be necessary to shim between the surface and the assembly to ensure that there is a solid coupling between the two.



POSITIONING

The next step is to level and secure the mounting post **4**. To do this, loosen the six set screws **6** to allow the mounting post to tilt (it has a five-degree tilt angle in all directions). Using a carpenter's level against the mounting post and the mounting post is plumb position, continue to tighten the set screws, ensuring the column remains plumb. The six nuts **7** may then be tightened against the mounting plate assembly tube. In this next step, install the ceiling flange assembly **8** over the mounting post **4** with the flat side towards the ceiling. Slide it up the post approximately two feet and lightly tighten the three set screws **2** to hold the flange assembly in this temporary position. Thread the shaft **12** into the mounting post until it stops against the shoulder of the shaft and then insert the set screw **2** into the mounting post and tighten it (1/8" hex key) to lock the shaft into place.



Note: Turning the cap **11** clockwise or counter-clockwise will adjust Rotation Tension. Only one hole contains a Set Screw which locks the desired tension. Tighten Set Screw **13** to secure.

Prior to shipping, the set screw was tightened arbitrarily in order to allow previously mentioned assembly procedure.

After the entire 3D instrument is assembled to the Ceiling Mount, check for satisfactory rotational movement.

Optional: Cut off male plug from cord and feed up through cap **11** until into ceiling space and install connector

A thru hole is provided to wire the Assembly into the ceiling. Check with the electrical code on how to wire for the ceiling outlet.

The caps must be tightened to prevent the arm from drifting.

TROUBLESHOOTING

DEVICE NOT POWERING UP

- Check MAINS cable. Is it installed correctly? Is it connected to MAINS power?
- Remove MAINS cable.
- Remove the fuses from the fuse holder on the mains jack.
- Check for fuse integrity by measuring resistance.
- Replace fuses as necessary.
- Close fuse holder drawer.
- Reattach mains power cable.
- If this does not restore mains power, call technical support.

NO ILLUMINATION

- Confirm unit is in RUN mode (not standby).
- Select higher light level (reduce dimming).
- Confirm light cable is properly installed.
- Confirm there is no fault detected/displayed on the Illuminator LCD display.

ILLUMINATOR SYSTEM INDICATES TEMPERATURE FAULT

- Ensure vents are not blocked.
- Ensure fans are rotating.

TWO-LINE DISPLAY SHOWS ERROR CODE

- Look up definition in list of error codes and call technical support.

CAMERAS AND MONITOR ARE OFF

- Verify the camera module switch is in Run mode by depressing the camera module button twice.

Should the above troubleshooting guide fail to correct a condition or any other such failure condition occurs such as visible damage, irregular noise or excessive heat, make note of the condition and call technical support for instructions.

TWO-LINE DISPLAY ERROR CODES

CONFIGURATION ERROR (BACKLIGHT: WHITE)

| ERR value | Description |
|-----------|---|
| 0001 | Configuration file read error |
| 0002 | Configuration file format does not match required format |
| 0003 | Debounce limit value out of range (>10) |
| 0004 | Status backlight PWM values out of range (<0 or > 100) |
| 0005 | Illumination DAC value out of range (>4095) |
| 0006 | 1.1V monitor parameters out of limits |
| 0007 | 1.5V monitor parameters out of limits |
| 0008 | 3.0V monitor parameters out of limits |
| 0009 | 3.3V monitor parameters out of limits |
| 000A | 5.0V monitor parameters out of limits |
| 000B | 12V monitor parameters out of limits |
| 000C | Temperature limits out of range (<0 or >127 degrees C) |
| 000D | Temperature limit hysteresis out of range (<0 or >min temp limit) |
| 000E | Fan PWM values out of range (<0 or > 100) |
| 000F | 3D monitor input clipper settings out of range |
| 0010 | 3D monitor scaler settings out of range |

| | |
|------|--|
| 0011 | 3D monitor output clipper settings out of range |
| 0012 | 3D monitor alpha generator settings out of range |
| 0013 | 3D monitor mixer settings out of range |
| 0014 | 3D TV input clipper settings out of range |
| 0015 | 3D TV scaler settings out of range |
| 0016 | 3D TV output clipper settings out of range |
| 0017 | 3D monitor mixer settings out of range |
| 0018 | 2D Monitor settings out of range |

FPGA LOAD FAILURE (BACKLIGHT RED)

| ERR value | Description |
|-----------|---|
| 0019 | Error reading FPGA configuration data file |
| 001A | Timeout waiting for nSTATUS ==1 before pulsing nCONFIG |
| 001B | Timeout waiting for nSTATUS == 1 after pulsing nCONFIG |
| 001C | FPGA load error: CONF_DONE == 0 after sending config data |
| 001D | Timeout waiting for INIT_DONE |

FPGA COMMUNICATION FAILURE (BACKLIGHT: RED)

| ERR value | Description |
|-----------|--|
| 001E | Communication error between FPGA and system controller |
| 001F | Illegal FPGA command |

OVER TEMPERATURE FAULT (BACKLIGHT: RED)

First line: Over temperature

Second line: Temp= XX.X C

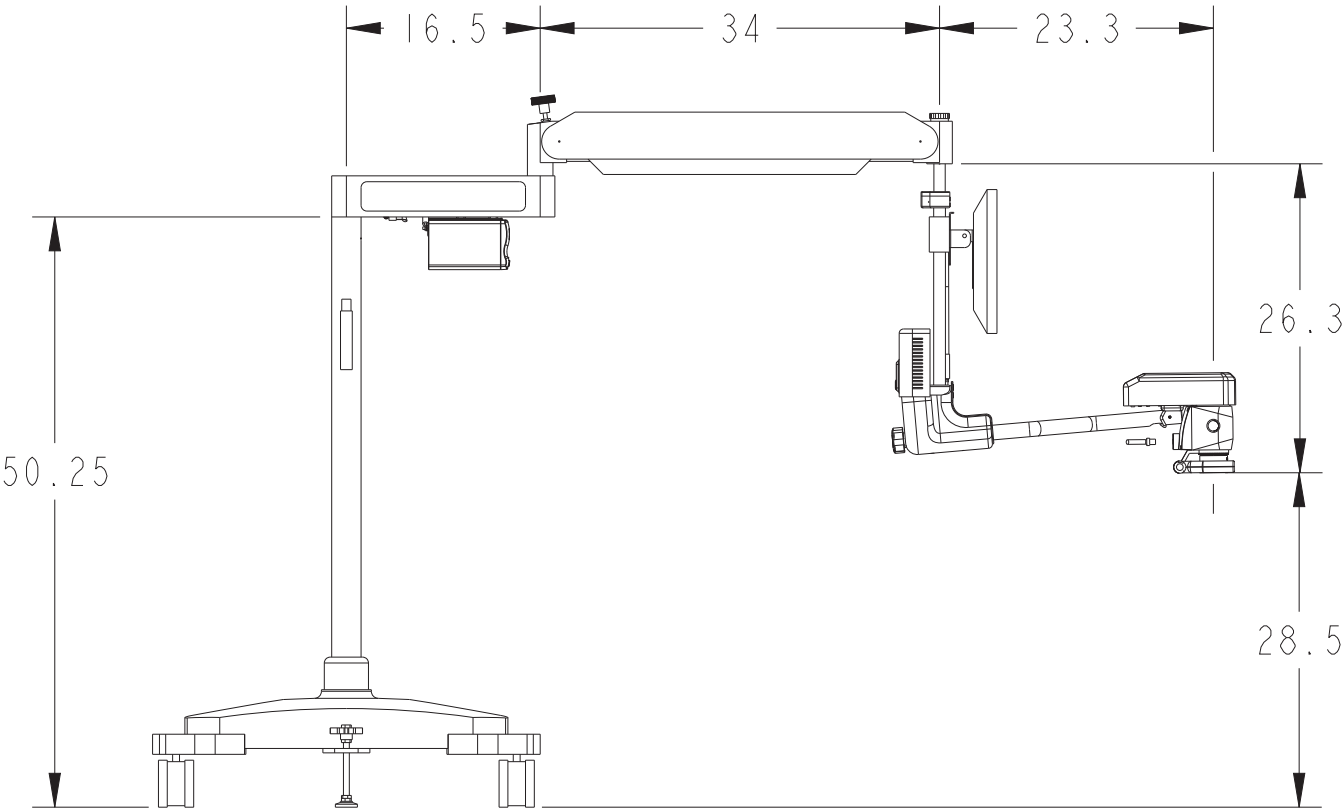
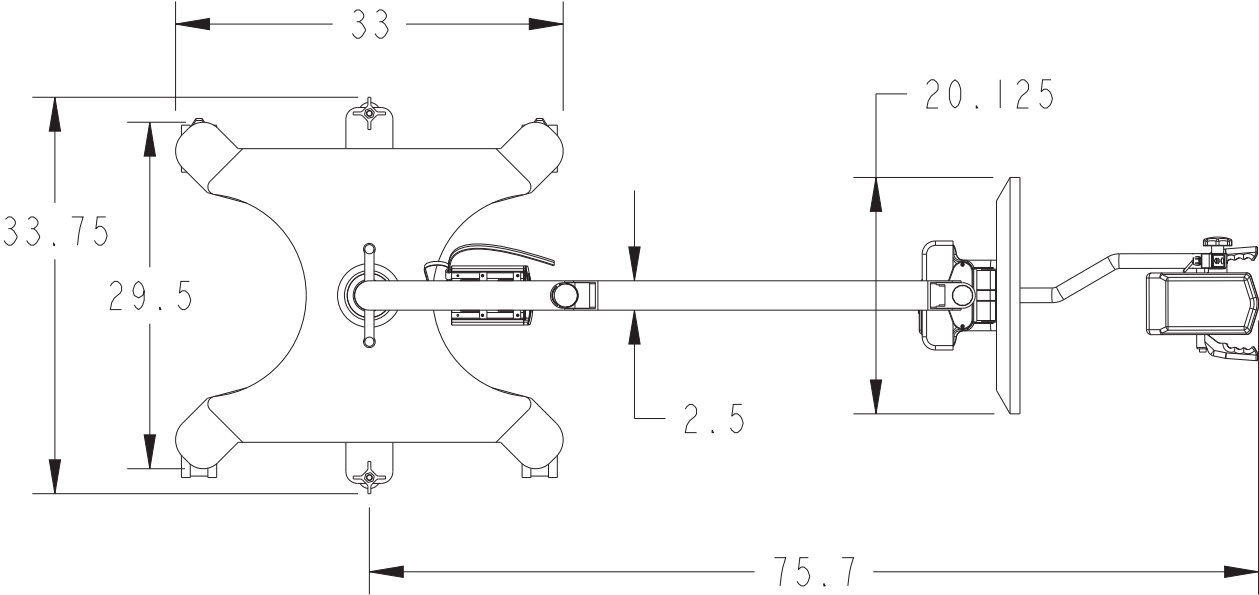
POWER SUPPLY FAULT (BACKLIGHT: RED)

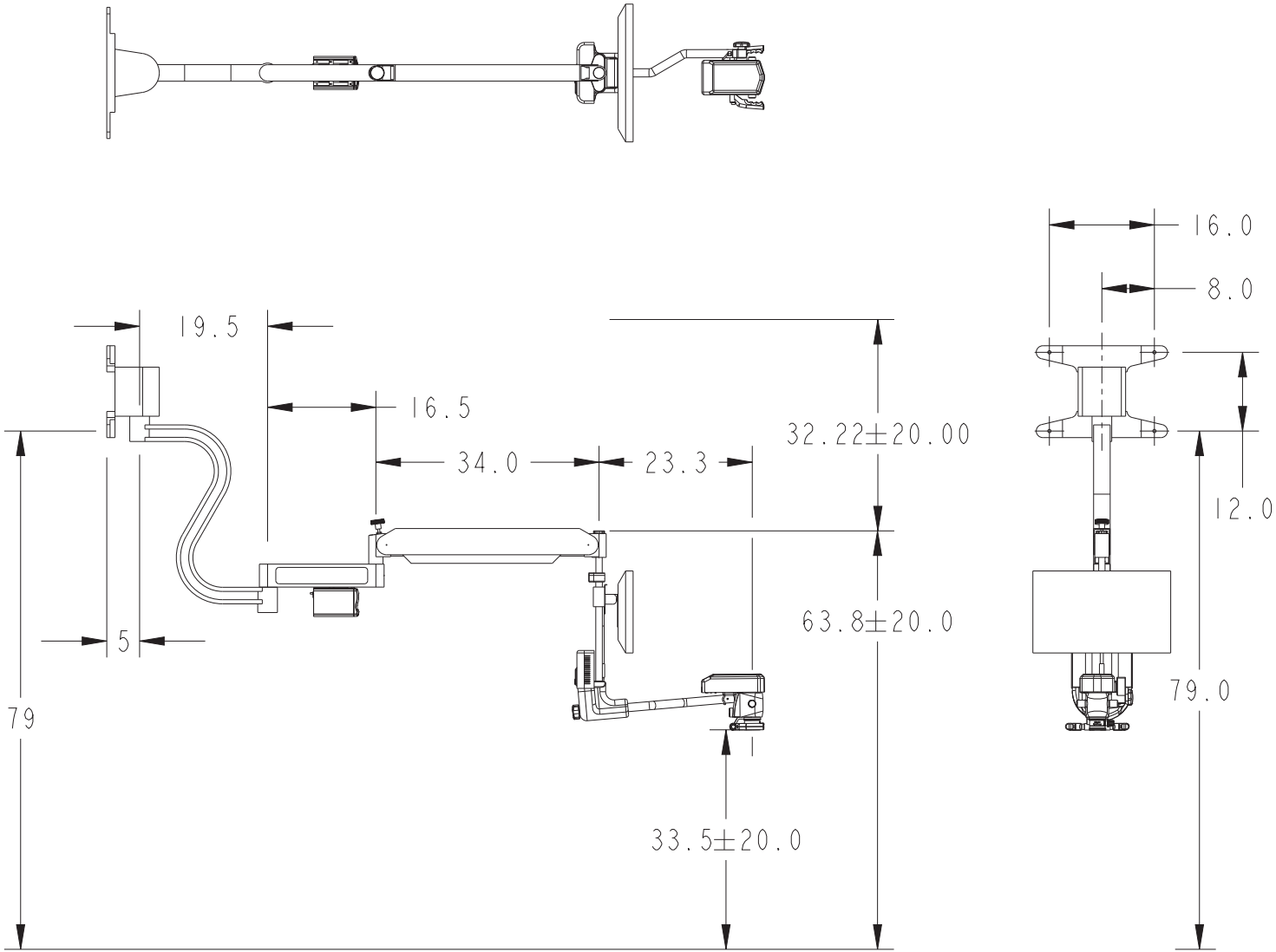
First line: Power fault

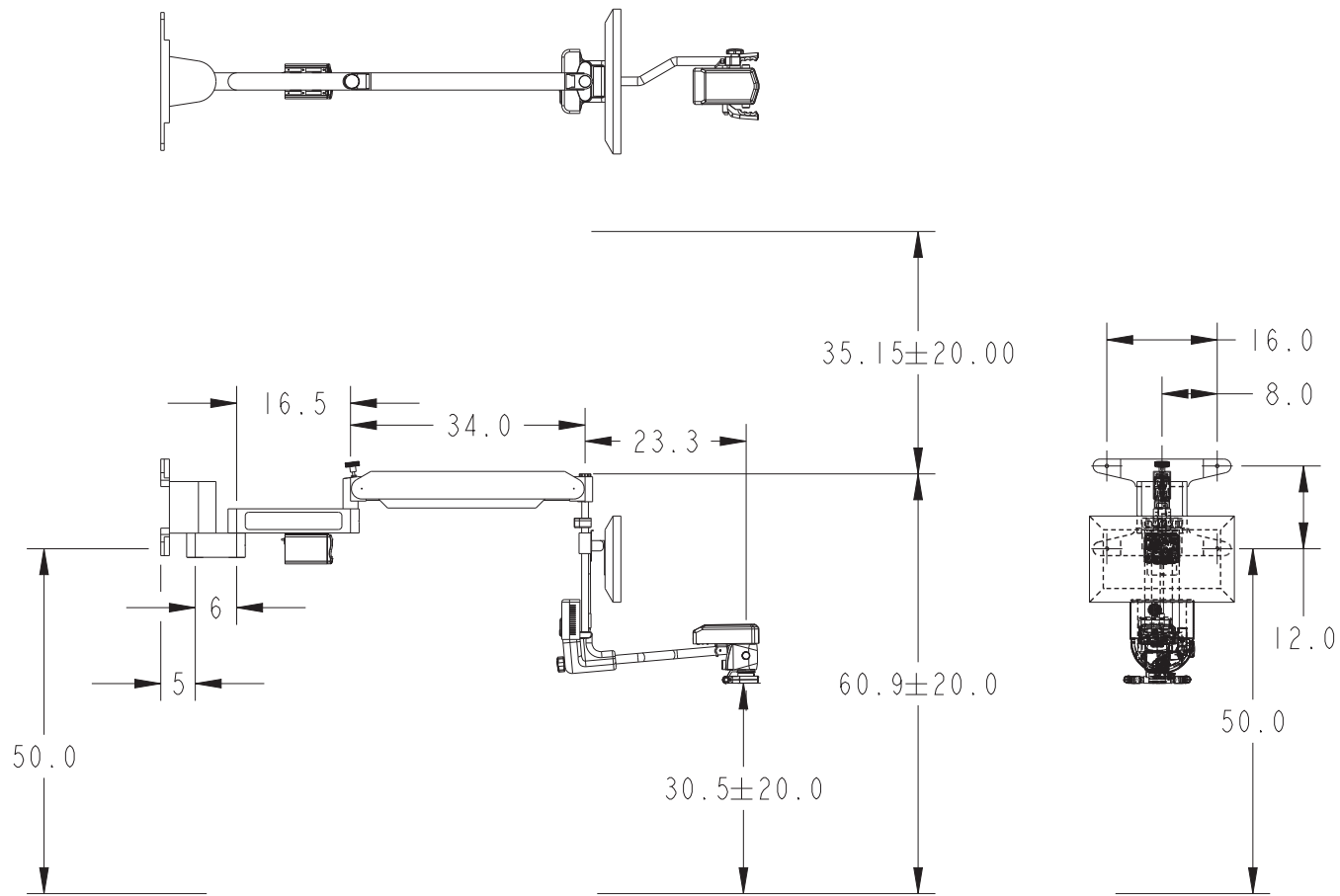
Second line: "XX.X V Supply=XX.X V"

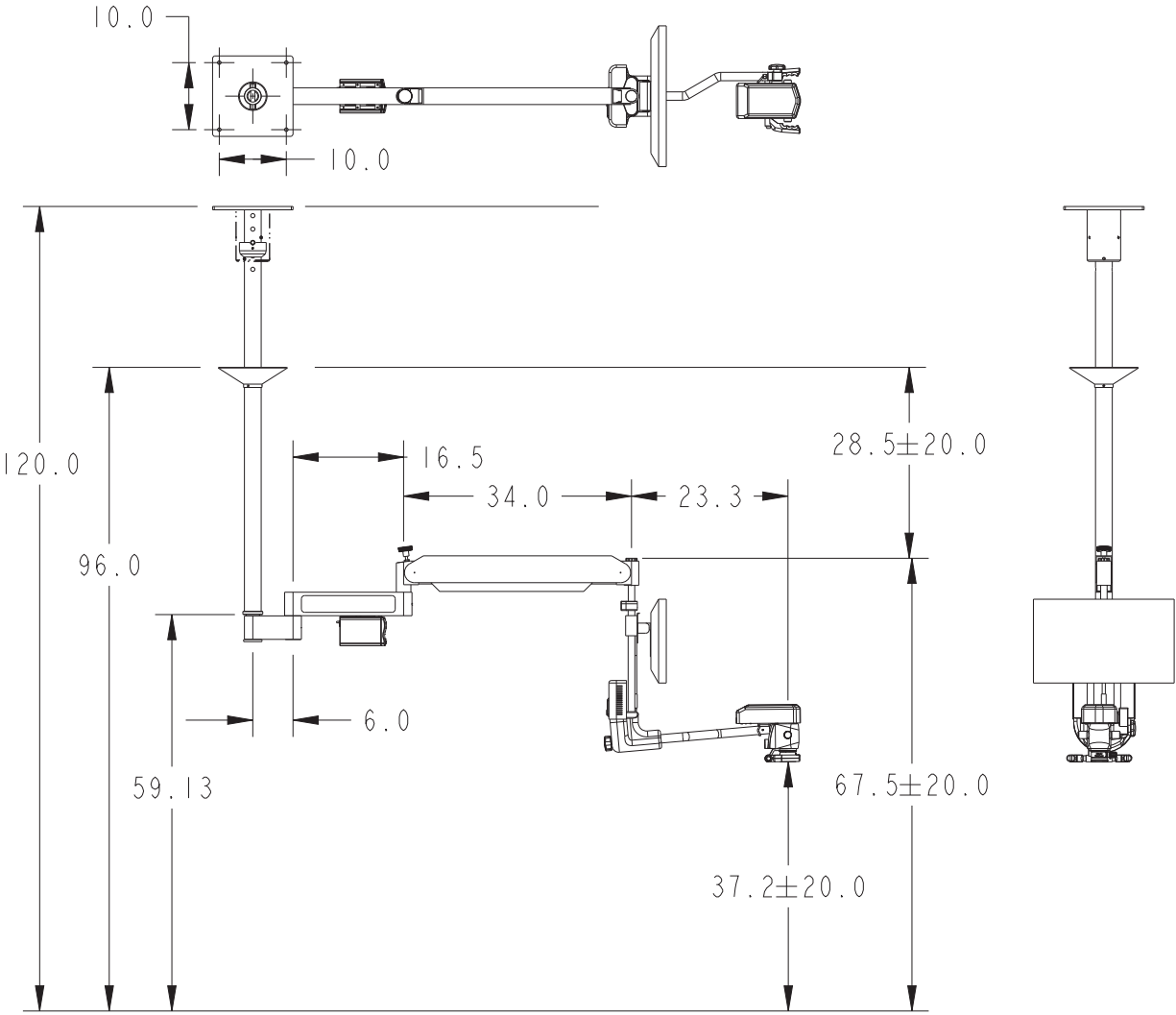
DIMENSIONS

FLOOR









CLEANING AND MAINTENANCE

HAZARDS ASSOCIATED WITH IMPROPER MAINTENANCE



WARNING: Failure to read and understand these instructions is hazardous.

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.



Only qualified personnel shall inspect the unit for internal damage or perform maintenance functions beyond cleaning and troubleshooting.

ROUTINE MAINTENANCE INSTRUCTIONS

Perform maintenance annually or as required.



WARNING: Read carefully before beginning any maintenance.

- 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 less than 10 degrees from distance less than 0.25 meter with minimum lighting of 1500 lux.
- Confirm device has been properly installed.
- Appropriate cables are installed.
- Check to ensure hospital-grade power cable is properly installed.
- Device is not located near critical device that could be influenced by electromagnetic energy levels.
- Venting on device is not blocked.
- Ensure device is not damaged.
- Inspect microscope optics. Make sure they are clear of debris and smudges.
- Perform functional test:
 - Turn on MAINS on/off switch (blue switch with international 0/1 designation) located on the illuminator.
 - After boot up is complete, confirm illuminator LCD screen provides indication (active) and is in STANDBY mode. Confirm green power indicator LEDs are on.
 - Confirm two-line display indicates which monitor(s) are connected and there are no error messages.
 - Set light level by pressing up or down buttons to control illumination level.
 - Shift to RUN mode by pushing the RUN/STANDBY mode button.
 - Confirm essential performance:
 - Confirm free flow of air for the camera module, the rear enclosure and the illuminator.
 - Confirm illumination and 3D image are displayed on the dentist's monitor.
 - Confirm consistent noise (no scraping, clicking, etc.).
 - Confirm no interference with nearby critical equipment.
 - Confirm no interference from operation of nearby equipment (large unshielded motors, etc.).

PREPARING TO CLEAN

Ensure power to the system is turned off. Follow your laboratory's prescribed procedures for removing blood stains or other contaminants from the equipment.

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.

The metallic parts (chrome-plated or painted) may be cleaned with a cloth dampened with any of the following solutions:

- Water with liquid detergent
- Isopropyl alcohol
- Household bleach and water (one part bleach to nine parts water)
- Commercial disinfectant

CLEANING THE MICROSCOPE

The objective lens is exposed to blood and topical medicines. The spots dim the passage of the light, with loss of brightness in the optical observation.

Keep dust from accumulating on the vent on the head by blowing the vent with compressed air.

Alcohol or ether applied with a clean cotton swab can be used to remove all smudges. Use a soft circular movement. Change swabs as necessary.

Follow manufacturer instructions for use, strength and dilution amounts.

Dry with a soft cloth.

Allow to fully dry before next use.

Use standard screen-cleaning procedures.

The objective lens can be protected by the use of an objective protector. It is screwed onto the external margin of the lens and protects from contamination and blows from surgical instruments.

CLEANING THE 3D INSTRUMENT

Do not attempt to clean any internal components. Keep dust from accumulating on the vents for the rear enclosure and the openings on the bottom of the camera module. Blow it clean with compressed air or carefully remove dust with cotton swabs. Do not go too far inside the units.

SERVICE AND REPAIR

WARRANTY REGISTRATION

Register your product warranty online:

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

END OF PRODUCT LIFE

We encourage our customers to recycle this product whenever possible. Disposal of this unit must be performed in accordance with the applicable local environmental regulations.

Please contact customer service to issue a return authorization to return product to manufacturer at the end of product life.

RETURN POLICY

Buyer must obtain a Return Material Authorization (RMA) number from seller prior to shipping any product back to seller. All returns to be sent prepaid by buyer. At the discretion of the seller, unused and undamaged standard products may, under certain circumstances, be accepted back for credit or exchange. A restocking charge may apply. Please consult the factory. Custom made products which are returned as defective, but are found to meet the specifications

agreed upon, will be subject to a retesting charge.

FIELD SERVICE

Defective items of equipment are to be serviced and repaired exclusively by persons authorized by the manufacturer. All repair work shall employ original manufacturer's parts only.

System repair is accomplished by swapping out modules in the field. Contact technical support before starting.

All device rework to be performed at the manufacturer's site.

There are no user-serviceable parts. Return modules to manufacturer for service and repair.

SERVICEABILITY

Perform regular preventive maintenance checks and look for any parts that could be subject to mechanical wear or mechanical misalignment.

FUSE REPLACEMENT



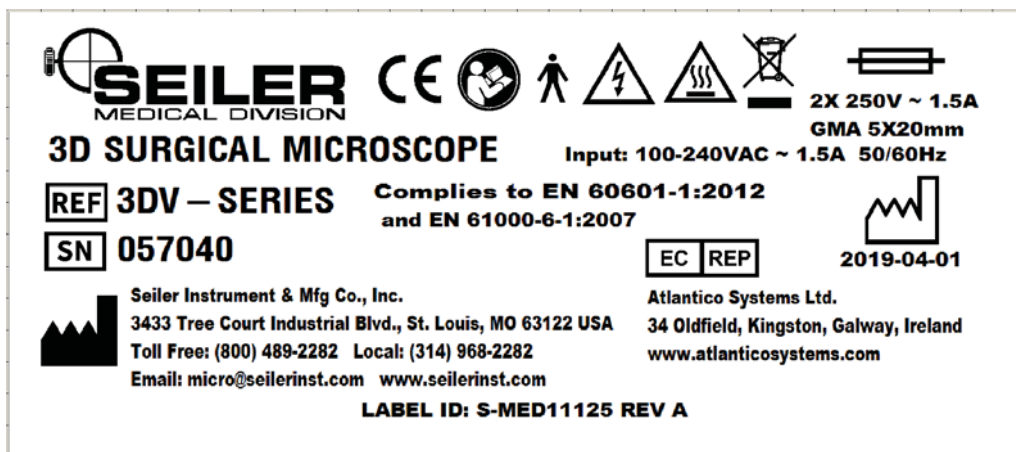
WARNING: Always disconnect power cord and turn main switch off before fuse replacement.

Turn lightsource off and unplug power cord. Remove fuse underneath unit by prying fuse cover and pulling out fuse.

Replace fuse with 250VAC 1.5A-rated fuse, type GMA 5mm X 20mm long. Insert back into fuse housing.

Reconnect the power cord and turn on the LED lightsource.

SYSTEM LABEL



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 antibacterial solution to mitigate any residual bacterial contamination.

- Disassemble (consult the service representative for instructions).
- Return any defective or obsolete parts to the representative.
- Recycle (as appropriate for local regulations):
 - Metals
 - Electronics
- The device is in compliance with RoHS.

WARRANTY



WARNING: Opening the system chassis housing by unapproved personnel will void the warranty.

LIMITED WARRANTY

Seiler Instrument & Mfg Co., Inc warrants the Seiler PromiseVision 3D™ instrument to be free from defects in material and workmanship. Your Seiler PromiseVision 3D™ carries a three-year warranty. The warranty starts from the date of shipment. Should your product prove to have such manufacturing defects within three years of the shipment, Seiler Instrument will repair or replace the product and/or component part without charge. Should your LED lightsource product(s) need servicing under this warranty, please contact Seiler Instrument for return authorization documentation. Carefully pack the 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, neglect, accidental damage, normal wear and tear, alteration or use in any manner inconsistent with the instructions in this manual or if transferred to a new owner without authorization from Seiler Instrument. Obligations under this warranty are limited to the repair, replacement or reimbursement of the product only, and in no event is Seiler Instrument & Mfg Co., Inc liable for any consequential or special damages or costs related to the transportation, installation or any other costs related to a warranted product. 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.

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 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 accessories such as video equipment, monitors and laptop, which carry a one-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/>



CERTIFICATE OF COMPLIANCE



Certificate of Compliance

Application of Council Directive: 2014/30/EU - EMC Directive &
Application of Council Directive: 93/42/EEC - Medical Device Directive

Standards to which Conformity is Declared:

EN 60601-1: 2012 including:
CISPR 11:2015/A1:2016, EN 61000-3-2:2018, 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 60601-1:2012

Applicant: Seiler Instrument
Address: 3433 Tree Court Industrial Blvd
St. Louis, MO 63122
Tel: (314) 218-6365
Product Tested: Promise Vision 3D Surgical Microscope
3DV-100: 3D SURGICAL MICROSCOPE FLOOR MODEL
3DV-200: 3D SURGICAL MICROSCOPE WALL MOUNT
3DV-300: 3D SURGICAL MICROSCOPE HIGH WALL MOUNT
3DV-400: 3D SURGICAL MICROSCOPE CEILING MOUNT
3DV-500: 3D SURGICAL MICROSCOPE BOLTED FLOOR MOUNT
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@itcemc.com
http://www.itcemc.com
Date of Issue: April 3, 2019
Report Numbers: 20180508-01-EMC

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 April 3, 2019

Mr. Michael Gbadebo, PE
(California License # 11303)
Chief Engineer/Principal Consultant



ISO/IEC17025:2017 Accredited Laboratory

CERTIFICATE OF CONFORMITY

Declaration of Conformity

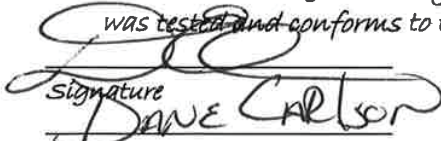
Application of Council Directive: 2014/30/EU - EMC Directive &
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EN 60601-1-2:2014 including:
EN 61000-4-2:2008, EN 61000-4-3:2006/A1:2007/A2:2010, EN 61000-4-4:2012,
EN 61000-4-5:2014, EN 61000-4-6:2013, EN 61000-4-8:2009, EN 61000-4-11: 2004
EN 62471:2008, EN 60601-1:2012

Manufacturer: Seiler Instrument
Address: 3433 Tree Court Industrial Blvd
St. Louis, MO 63122
Tel: (314) 218-6365
Contact: Mr. Dane Carlson
Email: dcarlson@seilerinst.com
Equipment Tested: Promise Vision 3D Surgical Microscope
3DV-100: 3D SURGICAL MICROSCOPE FLOOR MODEL
3DV-200: 3D SURGICAL MICROSCOPE WALL MOUNT
3DV-300: 3D SURGICAL MICROSCOPE HIGH WALL MOUNT
3DV-400: 3D SURGICAL MICROSCOPE CEILING MOUNT
3DV-500: 3D SURGICAL MICROSCOPE BOLTED FLOOR MOUNT
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@itcemc.com
<http://www.itcemc.com>
Test Report Numbers: 20180508-01-EMC
Test Date(s): 12/21/2018 - 12/26/2018

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


Signature
Name

4/20/19
Date
Division Manager
Title

Signature

Name

Date

Title



Mint Devices (Australia) Pty Ltd
PO Box 290 Potts Point NSW 2011
info@mintdevices.com.au
www.mintdevices.com.au
+61 2 8090 0994



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