

WALLACH®

MODEL: STAR COLPOSCOPE USER'S MANUAL

**ZOOMSTAR™ with TRULIGHT™ COLPOSCOPE
TRISTAR™ with TRULIGHT™ COLPOSCOPE**

REF: 906057T, 906057-40TU, 906140T



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Read all safety information and instructions before using this product!

CAUTIONS:

- **DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.**
- **OBSERVE PRECAUTIONS FOR ELECTROSTATIC DISCHARGE (ESD) AND ELECTROMAGNETIC INTERFERENCE (EMI) TO AND FROM OTHER EQUIPMENT.**
- **LED RADIATION; DO NOT STARE DIRECTLY INTO BEAM.**
- **DO NOT OPERATE PRODUCT IF IT APPEARS TO HAVE BEEN DROPPED OR DAMAGED.**
- **REMOVE AC POWER FROM ZOOMSTAR BEFORE CHECKING FOR A BLOWN FUSE.**
- **FOR TRANSPORTATION OF THE COLPOSCOPES, PLACE COLPOSCOPE HEAD IN LOWEST POSITION TO ASSURE STABILITY DURING TRANSPORTATION.**

The Wallach family of Star colposcopes feature zoom and multi-step magnification models mounted on a center post with an easily maneuverable 5-legged base. The upright rolling unit is sturdy and stable.



ZoomStar™

The Wallach® ZoomStar™ colposcope features Nikon continuous zoom optics for a sharp, 3D image for a correct magnification and field of view at all times. High power white light emitting diodes allow the user to view images in pure white light. A green LED is used to pick up blood vessels. The ZoomStar is mounted on a 5 point base for stability and maneuverability.

ASSEMBLY INSTRUCTIONS

The ZoomStar™ with Trulight™ colposcope has three parts.

- **The Optics with eyepieces**
- Center Pole with the power control box
- The Floor stand

1. Place the floor stand on the floor.
2. Insert the tapered end of the shaft on the bottom of the center pole into the center hole of the floor stand. Attach the center pole to the floor stand using the tools and hardware supplied with the floor stand.
3. Place the microscope head into the retaining ring with ocular tubes pointed upwards. Hand-tighten the thumbscrew. Remove protective caps from the diopter rings. Gently push the eyepieces into the binocular tubes.



OPERATING INSTRUCTIONS

To operate the ZoomStar with Trulight colposcope:

1. Set it to the height that best suits your position via the two height adjusting controls. The control that sets the coarse height adjustment is the large knurled hand screw on the Stand System.
2. Raise the Optics to the desired height and then tighten the hand screw on the stand. The fine height adjustment is the handle that protrudes at a right angle from the column. Turning this handle will raise or lower the Optical head, but since this is a fine height adjustment, the degree of adjustment is limited.
3. Plug the power cord into a standard 115/240 volt receptacle.
4. The master power switch (lighted green rocker switch) is located on the side panel of the electronics box located on the pole. This switch turns the main power source ON ("I") or OFF ("O").
5. The black switch on the side panel turns on the white light or the green light. The black illumination knob on the front panel adjusts the viewing light intensity.
6. Adjust the tilt position of the head using the tilt handle which protrudes from the side of the fine focus rack.

7. To lock the head tilt angle, tighten the head pitch knob snugly, but do not over tighten. Loosen the knob to release angle position.
8. For transportation of the colposcope, place the colposcope head in the lowest position to assure stability during transportation.

ILLUMINATION

- a. LED Light Frequency
- b. Dominant Wave Length for Green Light Emitting Diode

Minimum value 530 nm (nanometers)
Maximum value 535 nm (nanometers)

FOCUSING INSTRUCTIONS

1. Place microscope optics into the mounting ring on scope; hand tighten the set screws.
2. Remove protective "Nikon" caps from diopter rings.
3. Slide in eyepieces.
4. Turn on the white light.
5. Turn both diopter rings on the binocular tubes until the end surface of each ring coincides with the black engraved lines.
6. Looking into the eyepieces, adjust the interpupillary distance by moving the binocular tubes so that both circular view fields are brought into coincidence.
7. Set the zoom knob to 3x. (If power zoom is available, the footswitch should be used.)
8. Position microscope head at a starting point approximately 12" from the target. Rotate the fine focus knobs to bring the target into focus. The fine focus knobs can be tightened or loosened to adjust travel ease by rotating them in opposite directions. Do not re-adjust fine focus after a clear image is viewed at the 3x zoom magnification.
9. Rotate the zoom knob to 0.7x.
10. Close your right eye; adjust the left diopter ring to bring the target into fine focus. Close your left eye; adjust the right diopter to bring the target into fine focus.
11. At this point, focusing has been completed. Steps 6 - 9 can be repeated to check for exact focusing if desired. As long as the scope is not moved out of position, or the fine adjustment is not moved, the target will keep its sharpness all the time regardless of the zoom magnification level.

MAGNIFICATION

Final magnification is determined by multiplying the eyepiece power times the microscope body power times the objective lens power. The Wallach ZoomStar with Trulight is normally shipped with 20x eyepieces and a 1/3 objective lens. Therefore, at the lowest setting of the magnification power knob on the microscope body (0.7), the final magnification would be:

$$20 \times 0.7 \times 1/3 = 4.6x \text{ power}$$

At the highest setting of the magnification power knob (3.0) the final magnification would be:

$$20 \times 3.0 \times 1/3 = 20.0x \text{ power}$$

ZOOMSTAR WITH TRULIGHT, USB VIDEO

Sentech USB Camera Setup

1. Install Sentech Image Viewing Software (StCamSWare) onto laptop desktop. (see Quick Start Guide IMSC031)
2. Attach Video ZoomStar microscope head to laptop via USB cable provided.
3. Turn on Colposcope.
4. Double click on the “STCamSWare” icon on the desktop.
5. Using the cursor, choose “Options,” then “Settings”. A window will open at the bottom right of screen.
6. Check the “Auto” boxes next to the Gain and Shutter features.
7. Click on the “Save” button, and then choose “Yes”.
8. Focus to get the desired image on the screen.
9. To capture the image on the screen, choose “Capture” and then “Snap Shot”.
10. A window will open to the right of the main image.
11. To save the image, click to “select” the image with your left mouse button. This will cause a “blue” border to appear around the image of interest.
12. With the mouse over the image, click using the right mouse button and a menu will appear. Select “Save”.
13. The image may be saved in one of four formats: Bitmap, TIFF, JPEG or PNG.
14. Complete the information as you would for any software program and save to a location of your choice.

TriStar™

The TriStar™ with Trulight™ Colposcope is a highly versatile triple magnification stereoscopic colposcope. A magnification of 8x, 13x and 21x is obtained with the 3-step magnification changer. The field of view diameters are 24mm, 15mm and 9mm. A vessel delineation filter is incorporated to provide clear visualization of vascular patterns. The optical beamsplitter permits the attachment of a co-observation teaching tube and photographic accessories for documentation purposes, thereby extending the capability of this instrument from routine gynecologic examination to gynecologic research. The image obtained through the accessory ports is identical to that viewed through the binocular tubes via the optical beamsplitter. Photographic documentation capabilities include video and digital photography.

High power white light emitting diodes allow the user to view images in pure white light. A green LED is used to pick up blood vessels. The TriStar mounts on a 5 point base for stability and maneuverability.

ASSEMBLY INSTRUCTIONS

The TriStar has two parts. The following are easy assembly instructions for the new colposcope:

1. Identify the two parts
 - a. The optical head with eyepieces on the center pole with control box
 - b. The Floorstand
2. Place the Floorstand on the floor.
3. Insert the tapered end of the shaft on the bottom of the center pole into the center hole of the Floorstand. Attach the center pole to the Floorstand by inserting the large screw into the bottom of the stand. Tools and hardware are supplied with the Floorstand.

OPERATING INSTRUCTIONS

1. Set the colposcope to the height that best suits your situation via the two height adjusting controls. The control that sets the *coarse height adjustment* is the large knurled hand ring on the Stand System. Raise the Optical System to the desired height and then tighten the hand screw on the Stand. The *fine height adjustment* is the handle that protrudes at a right angle from the column. Turning this handle will raise and lower the Optical System, but since this is the fine height adjustment, it will only raise the height a limited distance.
2. Plug the cord into a standard wall outlet.
3. The master power switch is located on the side panel of the control box assembly. This switch turns the main power source “ON” or “OFF”.
4. The light switch on the side panel turns the light to “white” or “green”. The light intensity is adjusted by the knob on the front of the control box.

ILLUMINATION

- c. LED Light Frequency
- d. Dominant Wave Length for Green Light Emitting Diode
 - Minimum value 530 nm (nanometers)
 - Maximum value 535 nm (nanometers)

FOCUSING THE TRISTAR

1. Set the binocular eyepieces to "0" and adjust them to the proper interpupillary distance.
2. Peering through the eyepieces, move the entire TriStar backwards or forwards to get a "rough" focus on the target. (12" or 300mm from objective lens to target.)
3. Set the fine focus by rotating the fine focus adjust lever (the same lever as the tilt adjust) until the rack is at the midpoint.
4. Focus at the highest magnification. Focusing at this magnification is extremely critical and leads to perfect focusing for all other magnification levels. Thereafter, the physician only has to switch to another magnification without the need to refocus the instrument. If the instrument is repositioned, however, the procedure must be repeated.
5. To set the image of the target in each eye, turn the eyepieces themselves. (Notice that the eyepieces are calibrated to help refocus the eyepiece setting next time.)
6. Focusing is complete.

ACCESSORIES

Your TriStar split beam colposcope is designed to provide the ultimate ease in colposcopic digital photography. The complete system of photographic equipment for digital pictures has been created to allow even the novice photographer to clearly document visual observations for patient files.

No special techniques are required and there is no need to remove the camera when photography is not intended. Camera focusing is achieved through the TriStar oculars.

Digital Camera Attachment

1. Remove camera lens cover. Attach the adaptor mounting ring to the camera by aligning the red mark on the ring with the red dot on the camera lens mount. Then turn the ring until a click is heard when the attachment is secured.
2. Remove the black cap on the digital camera photo adaptor by loosening the stainless steel set screw. Place the end of the adaptor mounting ring into the photo adaptor and retighten the set screw.
3. Attach the digital camera photo adaptor to the colposcope accessory port. The camera may be mounted on either the right or the left accessory port.
4. Remove the protective accessory port cap. Guide slots on the photo adaptor permit the positioning of the camera. Align the slots in the photo adaptor with the guides on the adaptor ring. Slide the adaptor ring over the photo adaptor and tighten gently in a counterclockwise direction. DO NOT OVER TIGHTEN
5. The camera is now ready for use.

Digital Photography

Refer to instruction manual for digital camera.

Looking through the oculars, adjust the instrument for focus and composition. When the desired image is obtained, press the shutter release button on the camera to make the exposure.

Teaching Tube

For teaching or co-observation the teaching tube provides a second party viewing head as an optional accessory.

The teaching tube may be mounted on either the right or the left accessory port provided on the beamsplitter. Remove the protective accessory port cap. Guide slots on the teaching tube allow for positioning of the unit. Align the slots on the teaching tube with the guides on the adaptor ring. Slide the adaptor ring over the teaching tube and tighten gently in a counterclockwise direction. DO NOT OVER TIGHTEN.

USB Video Attachment



There is a video camera C-Mount Adaptor available to attach any analog or USB camera. (Please note that only one side of the C-Mount Adaptor can attach to the TriStar.)

The instructions are as follows:

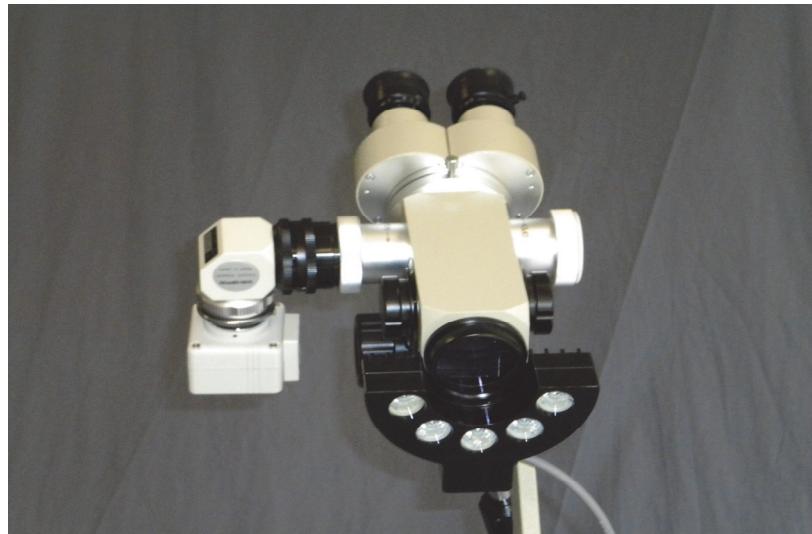
1. Attach the mounting ring to the camera.



2. Attach the entire camera to the C-mount Adaptor.



3. Then attach the C-Mount Adaptor to the TriStar.



4. Plug in the S video cable if you have an analog camera. Next, plug in the power supply. Then plug the power supply into the wall. For a USB camera, plug the USB cable into the camera and the other end into the US port on the laptop or PC.
5. After the C Mount has been attached to the colposcope, the camera needs to be oriented so that the image on the monitor is the same as that viewed through the optical head. On the C mount, loosen the large silver knurled ring. Rotate the camera head until the image on the monitor is the same as what is viewed through the optical head. Once it is aligned properly, rotate the knurled ring clockwise until it is locked in a snug position.

Electrical

The Wallach Colposcope with Trulight requires a 100-240V ~50-60 Hz power source to operate. It is supplied through a 2.5 meter medical grade detachable cord. For your safety, assure that your electrical outlets meet code regulations.

Replacing the Fuses

1. Shut OFF (labeled "O") the master switch and unplug the power cord.
2. The electronics box contains two fuses beneath the power socket.



3. To remove, pull out the drawer beneath the power socket.
4. Remove the blown fuse from the holder and replace with a 2 amp, 5mm x 20mm Fast Blow Fuse (Part Number 109645).
5. Push the fuse holder back into the electronics box.

Maintenance

PRECAUTION: DO NOT IMMERSE EQUIPMENT COMPONENTS IN LIQUID; UNPLUG BEFORE CLEANING; DRY BEFORE USE.

Clean the lenses and protective light covers with silicone-treated lens tissue paper ONLY. The colposcope finish is a high-gloss enamel and may be wiped down with disinfectant. Keep the instrument clean and dust-free. When the colposcope is not in use, replace protective covers.

Warranty Information

The Wallach Star series of colposcopes is supported by a seven-year warranty from date of purchase covering any failure of the device due to defective workmanship or components, when used in compliance with the product's intended use.

Service and Repair

Only Wallach Surgical Devices is authorized to service or repair this unit. If repair is attempted outside the factory, the warranty will be considered void. Wallach Surgical Devices is not responsible for any injury resulting from repairs made by other individuals or organizations not certified by Wallach Surgical Devices.

In the event your Colposcope with Trulight becomes inoperative, please make the following checks before calling the factory.

1. Check that the unit is plugged into a working wall receptacle.
2. Check for a blown fuse (if fuse needs to be replaced see directions)

If your Colposcope with Trulight is still inoperative, remove the unit from use and contact our qualified factory service personnel at (866) 928-3211.

If a repair is needed, equipment must be sanitized and carefully packaged in a protective carton for return to the factory. All shipments must be made via pre-paid parcel post or U.S. Mail. COD packages will not be accepted. It is not necessary to ship the base unless there is a problem with it. Return carton to:



Attention: Repair Department
95 Corporate Drive
Trumbull, CT 06611 USA
Phone: (203) 799-2000
Fax: (203) 799-2002

Explanation of Symbols

REF	Reorder number
SN	Serial number
	Consult instructions for use
	Caution
R_x Only	U.S. Federal law restricts this device to sale by or on the order of a physician.
	For professional use only
	Product conforms to the Medical Device Directive 93/42/EEC
EC REP	Authorized Representative in the European Community.
	Manufacturer
	AC Main Power OFF
	AC Main Power ON
	Shock Hazard
	Pinch Point
	In order to preserve, protect and improve the quality of the environment, protect human health and utilize natural resources prudently and rationally—do not dispose of waste electrical or electronic equipment (WEEE) as unsorted municipal waste. Contact local WEEE disposal sites.

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Zoomstar™, Tristar™ and TrueLight™ are trademarks of CooperSurgical, Inc.

Nikon® is a registered trademark of Nikon Corporation in the United States and certain other countries.

STCamSWare is a product of Sentech America, Inc.

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Specifications

ZOOMSTAR™ SPECIFICATIONS

- Nikon Continuous Zoom Optics 4.5x to 20x
- Maximum height 51"; minimum height 40"
- Overall weight 23 ½ lbs.
- Center of column to end of leg 12"
- Height of microscope to floor 36" to 46"
- 8 ½ foot grounded power cord
- Fused power input lamp 2.0 amp, two fuses, 2 amp 5mm x 20mm Fast Blow Fuses
- 100-120V/200-240V AC, 50/60 Hz, 100VA

TRISTAR™ SPECIFICATIONS

Type	3-Step Magnification with beamsplitter
Warranty	7 Years
Power Requirements	100-120V/200-240V AC, 50/60Hz, 100VA
Mounting System	5-Leg Rolling Base

Standard Optical Configurations

Objective Lens (working Distance)	300mm
Total Magnification	8x, 13x, & 21x
Field of View	8.5x=23.4mm, 13.6x=14.6mm, 21.3x=9.4mm
Depth of Field	8x=3.1mm, 13.6x=1.2mm, 21.3x=0.9mm
Ocular (Eyepieces)	16x Highpoint, with locking diopters
Diopter Adjustment	Independent adjustment with position locking -6/+4
Interpupillary Range	54mm to 80mm
Tilt of Viewing Head	59 degrees
Binocular Tube Design	Straight
Binocular Tube Length	160mm
Magnification Changer Factor	1.0x, 1.6x, 2.5x
Vessel Delineation Filter	Yes

Illumination System

Illumination	Light Emitting Diodes (LED) (5000/7000 degrees Kelvin) Green LED for blood vessel delineation.
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Photographic Capabilities

Digital, Video	Yes
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Options

Teaching Tube	Yes
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For All Star Colposcope Models

CLASSIFICATION

Model	Safety Class
Star with Trulight Colposcopes	I

- ALL models of Colposcopes have no Applied Parts.
- Do not get fluid into the Colposcope. Should any liquid or solid object fall into the unit, unplug the unit and call Technical Support (866) 928-3211.
- The LED Model Colposcopes are suitable for continuous operation.
- The LED Model Colposcopes are classified as normal equipment (IPX0) according to protection against ingress of water.

ENVIRONMENT CONDITIONS

Use	
Environmental Temperature:	between +10 °C and +40 °C
Relative Humidity:	between 10% and 90%
Air Pressure:	between 700 hPa and 1060 hPa

Shipping and Storage:	
Environmental Temperature:	between +10 °C and +40 °C
Relative Humidity:	between 10% and 90%
Air Pressure:	between 700 hPa and 1060 hPa

LED LIGHT SPECIFICATION

White LED:

Correlated Color Temperature	3000-3200K
Rendering Index	90 min
Radiometric Power	80 mW
Total Irradiance	Less than 1 W/m ² at max intensity
Lifetime [max. drive I=1000mA]	Min. 25,000 hours

Green LED:

Average Wavelength	520-535 nM
Radiometric Power	80 mW
Total Irradiance	Less than 1 W/m ² at max intensity

Wallach Colposcopes EMC Compliance Information

- MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.
- Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Wallach Colposcope is intended for use in the electromagnet environment specified below. The customer or the end user of the Wallach Colposcope should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment- Guidance
RF emissions CISPR 11	Group 1	Wallach Colposcopes use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Wallach Colposcopes are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Wallach Colposcopes are intended for use in the electromagnet environment specified below. The customer or the end user of the Wallach Colposcopes should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environmental – Guidance
Electromagnetic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Wallach Colposcope requires continued operation during power mains interruptions, it is recommended that the Wallach Colposcope be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level. In this case 230 V.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environmental - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Wallach Colposcope, including cables , than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$

<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>	
^a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Wallach Colposcopes are used exceeds the applicable RF compliance level above, the Wallach Colposcope should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Wallach Colposcope.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distance

This section discusses the Recommended Separation Distance between portable and mobile RF communications equipment and the Wallach Colposcopes.

The Wallach Colposcopes are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Wallach Colposcopes can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Wallach Colposcopes as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter <u>Watts</u>	Separation distance according to frequency of transmitter Meters		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{v_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.1167	0.1167	0.2333
0.1	0.3689	0.3689	0.7379
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3789
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer.

For the Wallach Colposcopes

$v_1 = 3$ Vrms

$E_1 = 3$ V/m

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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