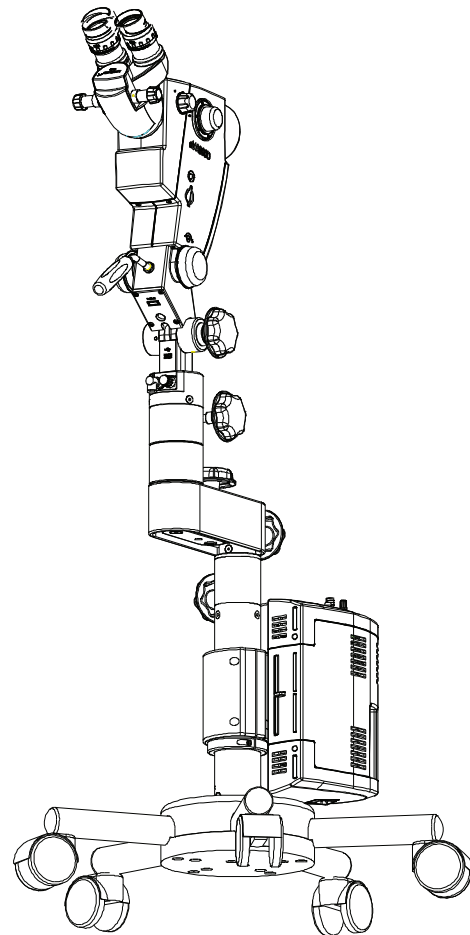


# eVA 500

## User Manual

### COLPOSCOPE



**Caution:**

U.S. Federal Law restricts this device to sale by or on the order of a licensed Physician. Rx only  
To ensure proper use of this instrument as well as to avoid injury while operating instrument,  
Understanding this manual completely before use is highly recommended.

Part No.: 6169000-795  
Issue 1.3  
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LABOMED is a registered trademark of Labo America, Inc.

Ez-Lift™ is a trademark of Labotech Microscopes India Pvt Ltd. for fine motion lifting mechanism.

All other trademarks are the property of their respective owners.

The information contained in this document was accurate at the time of publication. Specifications are subject to change without prior notice. LABOMED reserve the right to make changes to the product described in this user manual without notice and without incorporating those changes in any products already sold.

ISO 9001/13485 Certified - LABOMED products are designed and manufactured under quality processes that meet ISO 9001/13485 requirements.

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# 1. INTRODUCTION AND INTENDED USE

Congratulation on the purchase of your new eVA 500 COLPOSCOPE.

This instruction manual is designed as a training and reference manual for the operation and maintenance of the instrument. We recommend that you read it carefully prior to use and follow the instruction to ensure optimum performance of your new instrument.

Please retain this manual for future reference and to share with other users. Additional copies can be obtained from our authorized LABOMED dealer or from the LABOMED service department. Contact information is provided at the end of this guide.

LABOMED eVA 500 COLPOSCOPE is an optical instrument used in a medical diagnostic procedure to examine Cervix, Vaginal and Vulva tissue with the aid of illumination techniques and optical stereo Colposcope.

A Colposcope provides an enlarged view of area of interest and allows visual distinguishing of normal and abnormal appearing tissues and also as an aid of taking direct biopsies for further pathological examination.

## INTENDED USE

LABOMED Colposcope eVA 500 is a device designed to permit direct viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. it is used to diagnose abnormalities and select areas for biopsy.

**Note:** The use of eVA 500 Colposcope is purely for intended Operative and Diagnostic medical use.

## CONFIGURATIONS

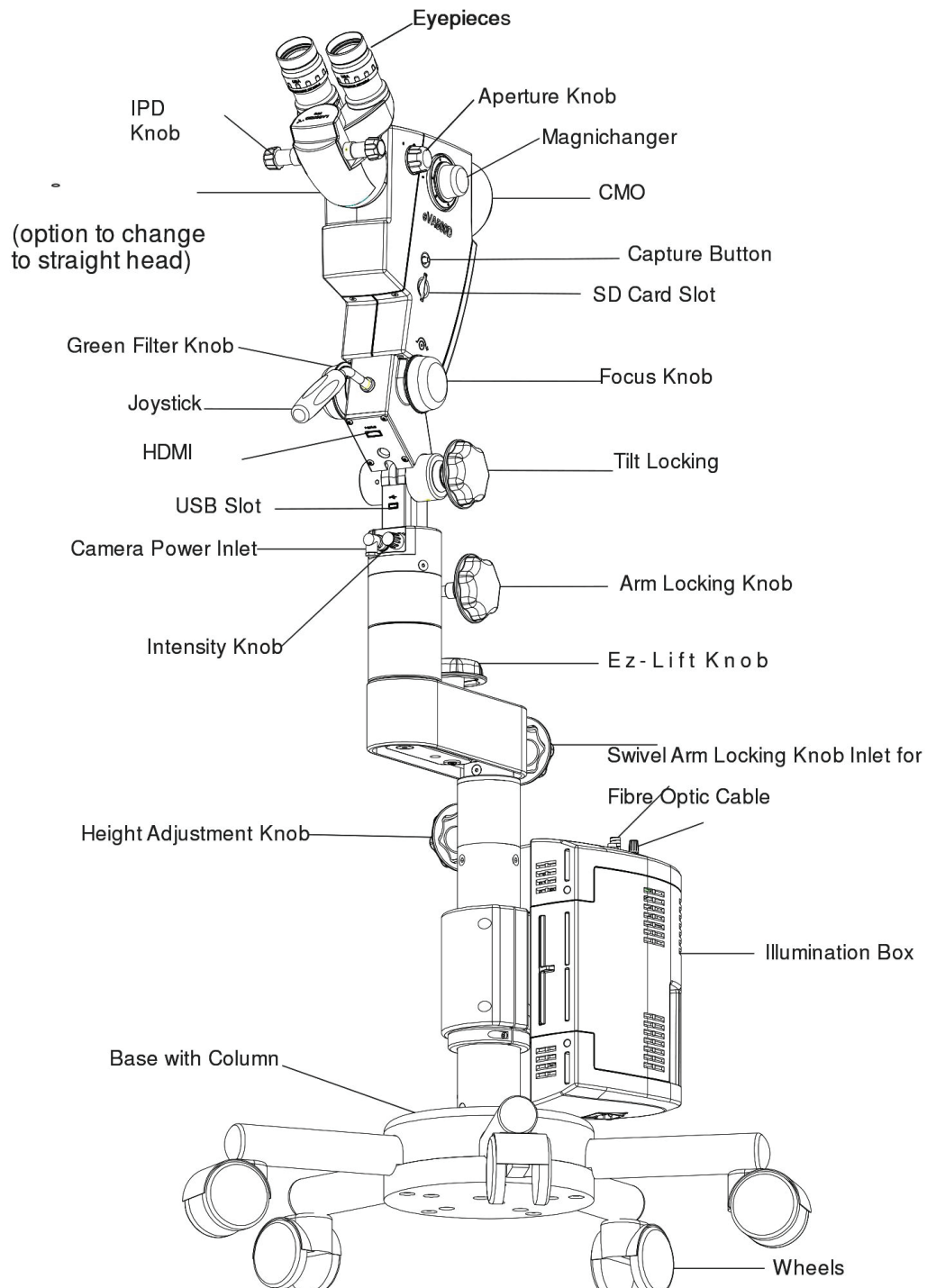
Colposcope  
eVA 500

Catalogue No.  
6169000-000

## 2. PRODUCT DESCRIPTION

**With E50 Stand:** Once patient is set for examining the Ez-Lift™ lift mechanism helps user for easy and accurate positioning without disturbing the patient. It has total vertical travel of 125 mm (100 mm coarse positional travel and 25 mm fine positional travel).

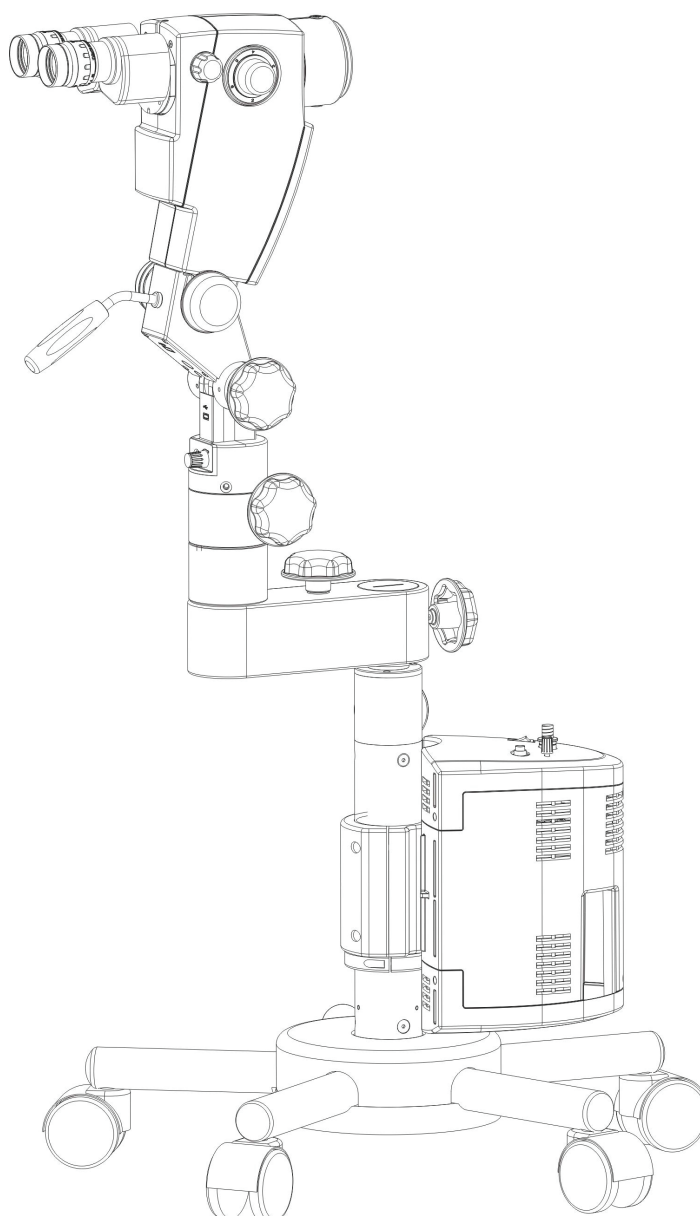
Control knob helps user in achieving the desired height by slight loosening the swivel arm locking knob and then re-clamp after getting the required height.



## 2. PRODUCT DESCRIPTION

**With Straight Head:** Once patient is set for examining the Ez-Lift lift TM mechanism helps user for easy and accurate positioning without disturbing the patient. It has total vertical travel of 125 mm (100 mm coarse positional travel and 25 mm fine positional travel).

Control knob helps user in achieving the desired height by slight loosening the swivel arm locking knob and then re-clamp after getting the required height.



### 3. WARNINGS AND CAUTIONS

LABOMED is not responsible for the safety and reliability of this instrument when:

- Assembly, disassembly, repair, or modification is made by unauthorized dealers or persons.
- The instrument is not used in accordance with this user manual.



A **WARNING** is an instruction that draws attention to the risk of injury or death.

**WARNING:** USERS OF THIS EQUIPMENT SHOULD BE THOROUGHLY TRAINED IN THE APPROPRIATE MEDICAL PROCEDURES. FURTHERMORE, THEY SHOULD TAKE THE TIME TO READ AND UNDERSTAND THESE INSTRUCTIONS BEFORE PERFORMANCE ANY PROCEDURE. THEY SHOULD ALSO READ AND UNDERSTAND THE INSTRUCTIONS FOR ANY OTHER EQUIPMENT USED IN CONJUNCTION WITH THIS COLPOSCOPE (i.e. ELECTRO SURGICAL GENERATORS). FAILURE TO DO SO MAY RESULT IN INJURY TO THE PATIENT AND/OR DAMAGE TO THE COLPOSCOPE.

**WARNING:** UNITED STATES FEDERAL LAW AND EUROPEAN REGULATIONS REQUIRE THAT THIS DEVICE BE PURCHASED ONLY BY A PHYSICIAN OR A PERSON ACTING ON BEHALF OF A PHYSICIAN.

**WARNING:** THIS INSTRUMENT SHOULD BE USED IN STRICT ACCORDANCE WITH THE INSTRUCTIONS OUTLINES IN THIS USER'S GUIDE. THE SAFETY OF THE OPERATOR AND THE PERFORMANCE OF THE INSTRUMENT CANNOT BE GUARANTEED IF USED IN A MANNER NOT SPECIFIED BY LABOMED.

**WARNING:** DO NOT REPAIR OR SERVICE THIS INSTRUMENT WITHOUT AUTHORIZATION FROM THE MANUFACTURER. ANY REPAIR OR SERVICE TO THIS INSTRUMENT MUST BE PERFORMED BY EXPERIENCED PERSONAL OR DEALERS WHO ARE TRAINED BY LABOMED OR SERIOUS INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

**WARNING:** MODIFICATIONS TO THIS INSTRUMENT ARE NOT ALLOWED. ANY MODIFICATION TO THIS UNIT BE AUTHORIZED BY LABOMED OR SERIOUS INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

**WARNING:** IF THIS INSTRUMENT IS MODIFIED, APPROPRIATE INSPECTION AND TESTING MUST BE CONDUCTED TO ENSURE CONTINUED SAFE USE OF THIS INSTRUMENT.

**WARNING:** ENSURE THAT THE VOLTAGE APPLIED TO THE UNIT IS THE SAME AS THE VOLTAGE THAT IS INDICATED ON THE DATA PLATE OR DAMAGE TO THE UNIT MAY OCCUR. TO USE IN FLUCTUATION VOLTAGE ENVIRONMENT CONSTANT VOLTAGE STABILIZER IS RECOMMENDED FOR SAFE & EFFICIENT USE OF DEVICE.

**WARNING:** TO AVOID RISK OF ELECTRIC SHOCK AND FOR SAFETY OF INSTRUMENT THIS INSTRUMENT MUST BE PLUGGED INTO AN OUTLET WITH AN EARTH GROUND. DO NOT REMOVE OR DEFEAT THE EARTH GROUND CONNECTION ON POWER INPUT CONNECTOR OF THE UNIT'S POWER CORD.

**WARNING:** THE EQUIPMENT OR SYSTEM SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT AND THAT IF ADJACENT OR STACKED USE IS NECESSARY, THE EQUIPMENT OR SYSTEM SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

**WARNING:** ALL SIGNAL INPUT AND OUTPUT (I/O) CONNECTORS ARE INTENDED FOR CONNECTION TO PERIPHERAL DEVICES LIKE LAPTOP, TV AND PC ONLY THROUGH USB OR HDMI PORT AND THESE PERIPHERAL DEVICES MUST BE IN COMPLIANCE WITH IEC 60601-1 (GENERAL REQUIREMENTS FOR IEC SAFETY, MEDICAL ELECTRICAL EQUIPMENT) OR OTHER IEC STANDARDS (FOR EXAMPLE IEC 60950, INFORMATION TECHNOLOGY EQUIPME-T-SAFETY) AS APPROPRIATE TO THE NATURE OF THE

# WARNINGS AND CAUTIONS

PERIPHERAL DEVICE. CONNECTING ADDITIONAL PERIPHERAL TO THIS COLPOSCOPE MAY INCREASE THE RISK ASSOCIATED WITH CHASSIS OR PATIENT LEAKAGE CURRENTS. TO MAINTAIN OPERATOR OR PATIENT SAFETY, THE USERS SHOULD CONSIDER THE SYSTEM LEAKAGE CURRENT REQUIREMENTS OF IEC 60601-1-1 (MEDICAL ELECTRICAL EQUIPMENT, SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEM).

**WARNING:** IF PERIPHERAL DEVICES LIKE: LAPTOP, TC AND PC DO NOT COMPLY WITH IEC 60601-1 (MEDICAL ELECTRICAL EQUIPMENT; SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS) THEY MUST BE KEPT OUT OF THE PATIENT AREA (6 FEET MINIMUM FROM PATIENT).

**WARNING:** THIS INSTRUMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE AN ESTHETIC MIXTURES, SUCH AS OXYGEN OR NITROUS OXIDE.


**WARNING:** LED RADIATION DOES NOT STARE DIRECTLY INTO BEAM WHEN COLPOSCOPE IS IN ON POSITION.

**WARNING:** THE USE OF ACCESSORIES OR CABLES OTHER THAN THOSE SPECIFIED, WITH THE EXCEPTION OF THOSE SOLD BY THE MANUFACTURER AS REPLACEMENT PARTS FOR THE INTERNAL COMPONENTS, MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE EQUIPMENT OR SYSTEM.

A **CAUTION** is an instruction that draws attention to the risk of damage to the product.

**CAUTION:** THE INTERNAL CIRCUITRY OF THE INSTRUMENT CONTAIN ELECTROSTATIC SENSITIVE DEVICES (ESD) THAT MAY BE SENSITIVE TO STATIC CHARGES PRODUCED BY THE HUMAN BODY. DO NOT REMOVE THE COVERS WITHOUT TAKING PROPER ESD PRECAUTIONS.

**CAUTION:** DO NOT USE SOLVENTS OR STRONG CLEANING SOLUTIONS ON ANY PART OF THIS INSTRUMENT, AS DAMAGE TO THE UNIT MAY OCCUR SEE THE CARE AND MAINTENANCE SECTION FOR DETAILED CLEANING INSTRUCTIONS.

 **CAUTION:** MEDICAL ELECTRONIC EQUIPMENT NEEDS SPECIAL PRECAUTIONS WITH RESPECT TO ELECTROMAGNETIC CHARGE (EMC) AND NEEDS TO BE INSTALLED AND SERVICED ACCORDING TO THE EMC INFORMATION PROVIDED IN THE ACCOMPANYING DOCUMENTS.

**CAUTION:** PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT CAN AFFECT MEDICAL ELECTRICAL EQUIPMENT.

**CAUTION:** THIS INSTRUMENT IS NOT TO BE USED NEAR HIGH-FREQUENCY EMITTING SURGICAL EQUIPMENT.

**CAUTION:** DO NOT CONNECT ANY EQUIPMENT TO THE DEVICE OTHER THAN THOSE INTENDED FOR USE WITH THE DEVICE.

**CAUTION:** DO NOT USE A CONVERTER ADAPTER THAT WILL CONVERT THE THREE-PRONG AC PLUG TO A TWO-PRONG LINE PLUG, THE POWER SUPPLY IN THIS MICROSCOPE WILL NOT BE PROPERLY GROUNDED, AND ELECTRIC SHOCK MAY RESULT.




















**CAUTION:** REMOVE THE AC POWER PLUG FROM THE WALL SOCKET WHILE CHECKING FOR A BLOWN FUSE.

**CAUTION:** DO NOT ROLL THE COLPOSCOPE OVER CABLES OR HOLES.

**CAUTION:** DO NOT REMOVE FERRITE BEADS IF APPLIED TO CABLES.



## 4. EXPLANATION OF SYMBOLS

-  **Caution:**  
Observe all warning labels and notes!  
If any label is missing on your instrument or has become illegible, please contact us or one of our Authorized representatives. We will supply the missing labels.
-  **Brightness Control:** After the illumination has been switched on, the user can continuously Adjust brightness by turning the knob appropriately.
-  Accompanying documents must be consulted.
-  Compliance to medical device regulation MDR 2017/745  
Protective earth.
-  This way up – indicates the correct upright position of the transport package.
-  Keep dry – the transport package shall be kept away from rain.
-  Year of manufacture used on product data plate.
-  Fragile- content of the transport package are fragile and should be handled with care.
-  Electromagnetic interference can occur in the vicinity of devices carrying this symbol.
-  Alternate current.
-  Recycling of packaging materials.
-  U.S. Federal law restricts this device to sale by or on the order of a physician.
-  Separate disposal of waste electrical equipment.
-  Unsafe for use with MR (Magnetic Resonance).
-  Permissible humidity range during transport and storage.
-  Permissible pressure range during transport and storage.
-  The product complies with US and Canadian safety requirements.
-  Permissible temperature range during transport and storage.
-  Serial number of the product
- SN

## 5. STANDARDS AND DIRECTIVES

The instrument described in this user manual has been designed in compliance with the following standards:

- ISO 8600-3 First edition 1997-07-01 AMENDMENT 1 Optics and Optical instruments-Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics.
- ISO 8600-3 First edition 1997-07-01 Optics and Optical instruments-Medical endoscopes and endoscopic Accessories Part 3: Determination of field of view and direction of view of endoscopes with optics.
- ISO 8600-5 First edition 2005-03-15 Optics and photonics-Medical endoscopes and endotherapy devices Part 5: Determination of optical resolution of rigid endoscopes with optics.
- ISO 9001/13485 quality management systems approved by UL(notified body).
- ISO 14971 Risk management to medical devices.

### DIRECTIVE USED

- MDR 2017/745 Annex VIII And Rule 13
- IEC 60601-1-3rd edition (2005)
- IEC 60601-1-2
- EN 55011:2007

### CLASSIFICATIONS

- For Europe, per MDR 2017/745, the unit is a Class I instrument AnnexVIII Rule 13.
- For the United States, the FDA classification is Class II 510K Exempted
- Please observe all applicable accident prevention regulations.

## 6. CONDITION OF INSTRUMENT AT TIME OF UNPACKING/SUPPLY

The appliance is delivered in 6 assembled groups:

- Mobile supporting Base
- Column (E50)
- Illumination box with integrated electrical power supply
- Swivel Arm (E50)
- Colposcope Arm (eVA 500 )
- Colposcope Head (Inclined or Straight)

Fasteners are enclosed in the packing box.

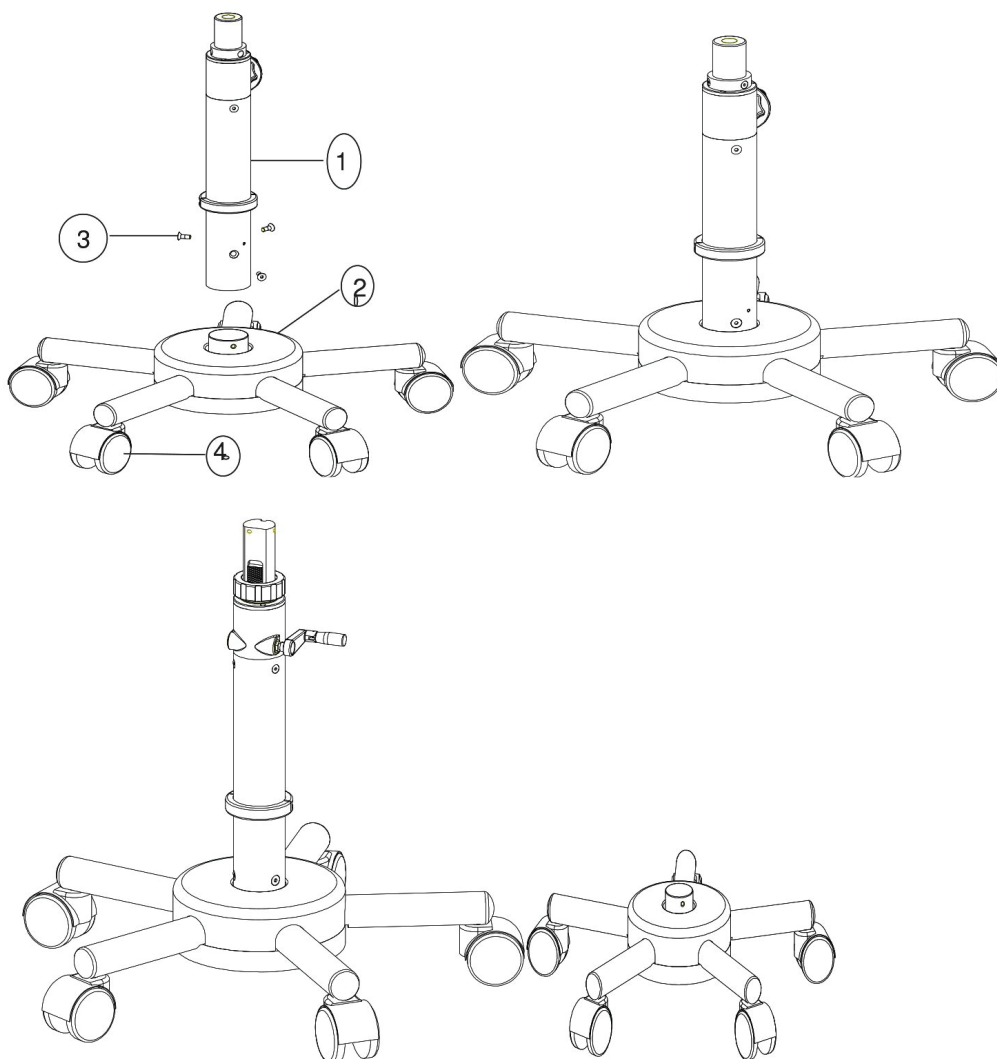
## 7. INSTALLATION

### a. MOUNTING OF ROLLER STAND AND COLUMN (Fig. 1.1)

- Insert column into ① the mobile base②.
- Fasten screw ③ with enclosed hexagon socket wrench to column ①.
- The mobile bases have 5 rollers④ out of two have locking breaks(red)

#### Indication:

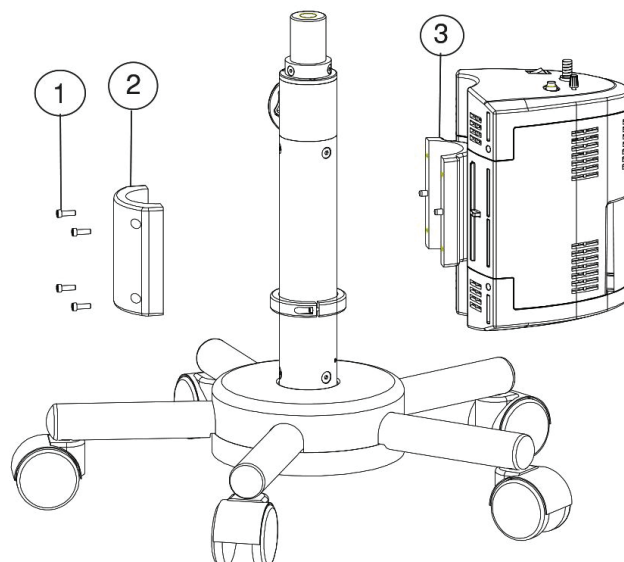
The colposcope eVA 500 / 500D can be mounted on either of the two mobile stands (E50). The type is to be specified at the time of purchase.



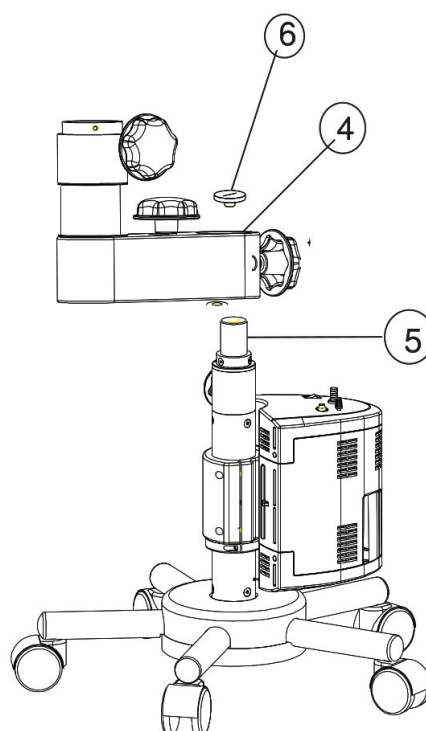
(Fig.1)

**a. MOUNTING OF APPLIANCE**

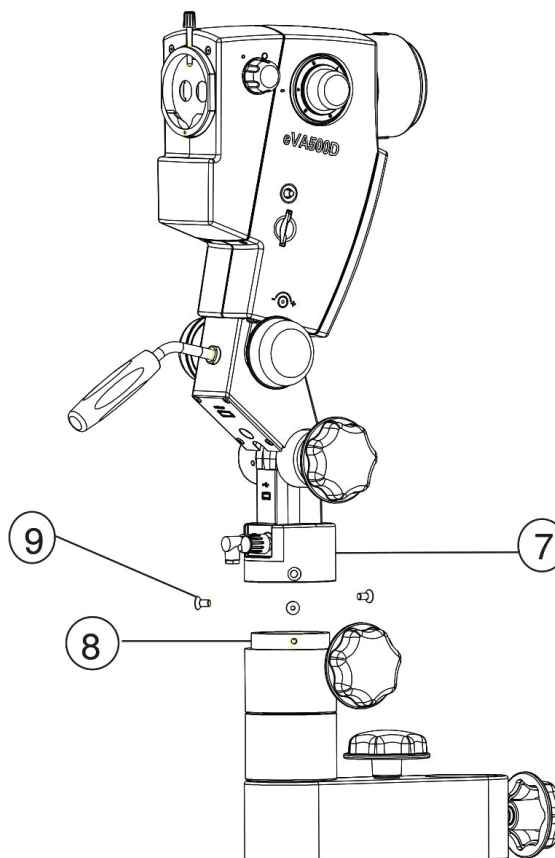
- Mount the illumination box to the column against ③ the vertical guide ②.
- Screws ① to be tighten to hold the box as shown (Fig. 2.1).

**(Fig 2.1)**

Insert swivel arm ④ on top of the column head ⑤ and screw ⑥ it on the top as shown (Fig. 2.2)

**(Fig. 2.2)**

- Insert the arm of the Colposcope head on the top ⑦ of the swivel arm ⑧.
- Screws ⑨ to be tightened from both sides of the head arm ⑦.



**(Fig. 2.3)**

**a. Special Instruction:**

- The joint which connects swivel arm and the column is fitted with a stop to prevent the inner assembled cables.
- The total rotation of the swivel arm is not more than 180° to the column.
- On reaching the stop, do not rotate further, to prevent any tear off or damage to the mechanism.

**b. ADDITIONAL LOAD**

- The load capacity and tilting stability is balanced with standard suggested parts and accessories.
- Please do not attach additional load.

## 1. Electrical Connections

Connect the power cable to the AC Inlet socket as 1.

Switch on the power from on/off switch.

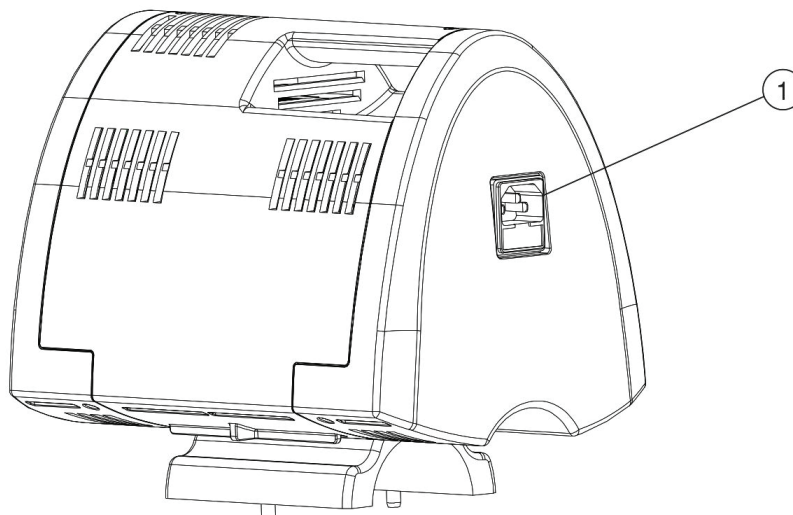
Note: Power supply is designed with universal input 100V-240V AC, 50/60Hz. To plug in follow instruction on electrical label provided at back of illumination box as shown in figure number 4 below.

### a) CHANGING OF FUSE

· Fuses Note: are in fuse holder:

F 2.5 A (2 mains input fuses for lamp supply for mains voltage 100-240 V)

· Changing of Fuse: Draw out the plug. Insert a screw driver into the slit of fuse holder and screw out to the left. Remove cap and replace the fuse placed in it. Once the fuse is replaced cap it again and screw in to the right. Refer electrical label for correct fuse replacement

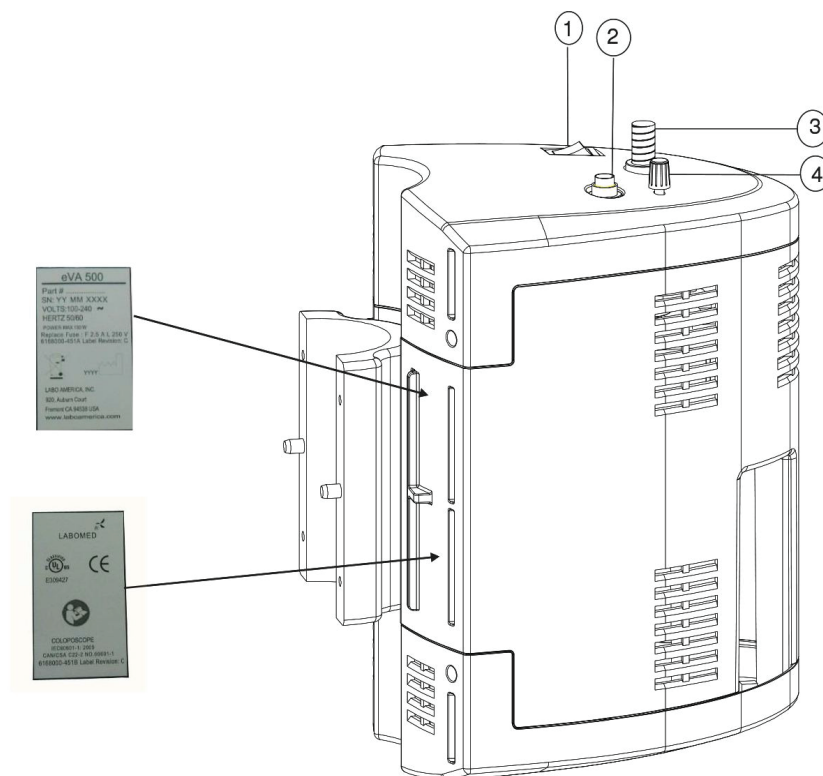


(Fig. 4)

## 1. OPERATING INSTRUCTIONS AND CONTROL ELEMENTS

- a. On / off switch shown as is located on the upper side of the illumination ① box. After the appliance is switched on, the green illumination switch diode indicates that the Colposcope is ready for operation. The LED starts burning and the cooling fan working.
- b. Inlet for cable to camera power and light intensity regulation shown as ② .
- c. Inlet for fiber optic cable shown as ③ .Insert fiber optic cable in the inlet and run it through the swivel arm, to direct the light from illumination box to the Colposcope.
- d. Filter knob shown as ④ facilitates to change the filter if required to adjust contrast.  
Note: To maximize LED life, switch off the Colposcope when not in use.

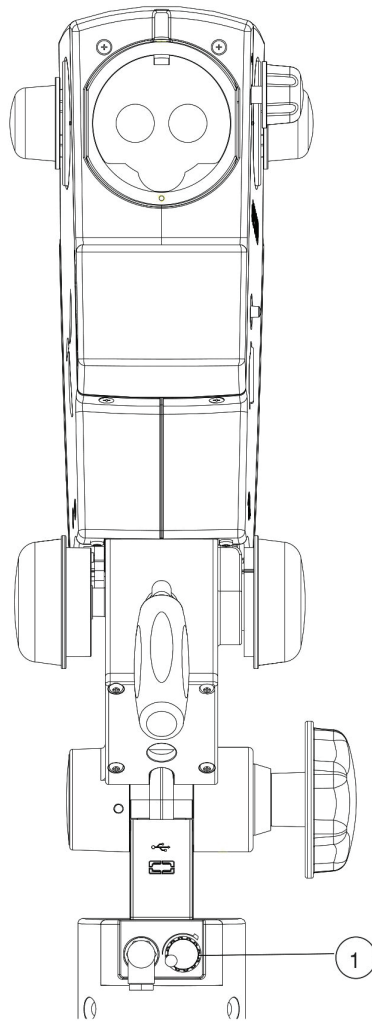
 **WARNING:**  **INSTRUMENT IS UNSAFE FOR MRI ENVIRONMENTS**



**(Fig. 5)**

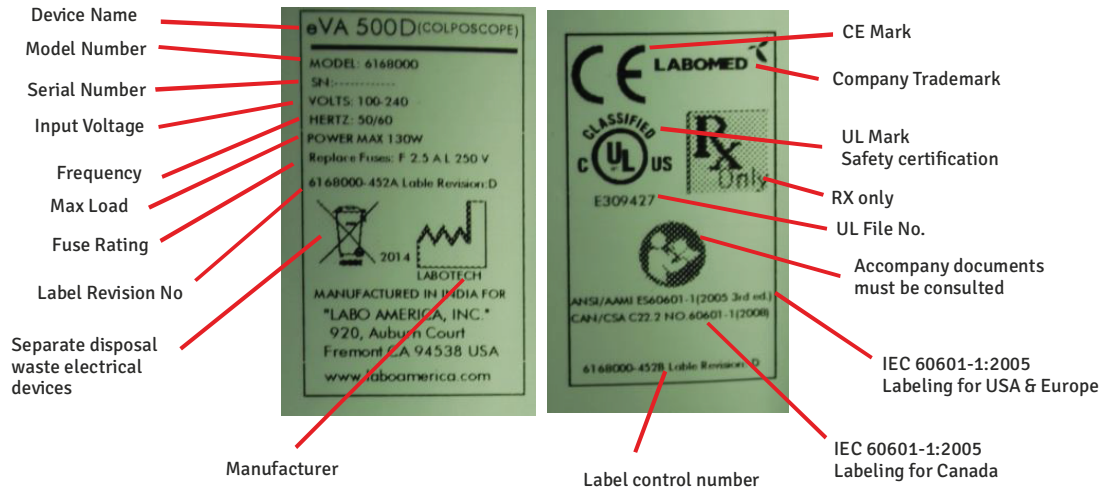


e) BRIGHTNESS CONTROL (Fig. 6): A variation in light intensity is made by rotating knob ①.



(Fig 6)

### 10. Data Plate for Colposcope



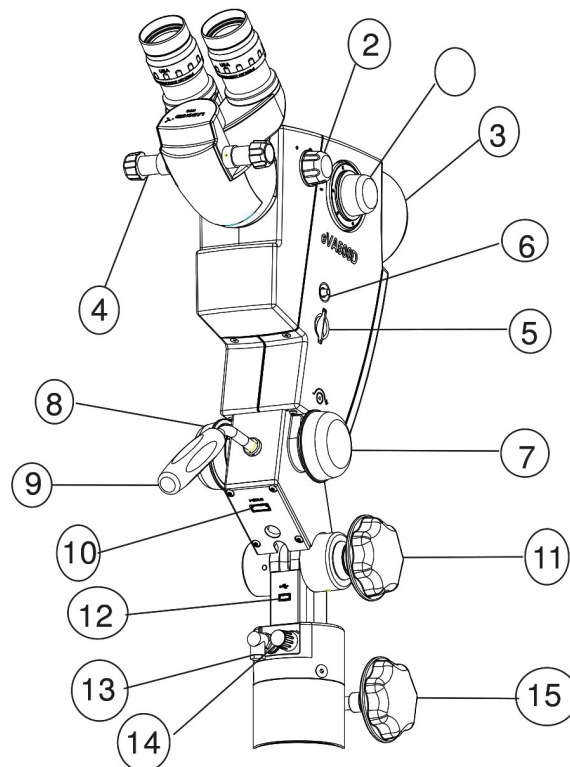
(Fig 7)

## 11. CONTROL ELEMENTS (Fig. 7.1 & 7.2)

### Roller stand:

5 rollers to move the appliance and 2 brakes to lock the Appliance

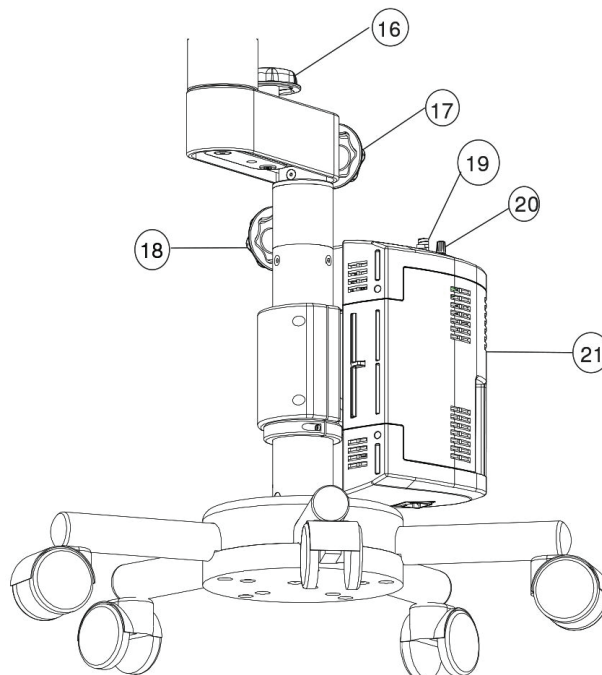
- Rotating knob to change the Magnification ①.
- Aperture knob to change the aperture size ②. (If required)
- Common Main Objective (CMO) ③.
- IPD knob to change interpupillary distance by turning it laterally ④.
- Fine focusing knob ⑦
- Knob to swing in green filter ⑧.
- Joystick to tilt the head arm forward and backward ⑨.
- Head arm locking knob ⑩
- Inlet for power ⑬.
- Knob for brightness control ⑭.
- Knob to lock the arm ⑮.



(Fig. 7.1)

Ez-Lift™ control knob . ( with E50 ⑯ column configuration)

- Swivel arm locking knob⑰.
- Column height adjustment knob (E50 stand) ⑱and Column height adjustment handle⑲
- Inlet for fiber optic cable⑳.
- Knob to swing in the Filter ㉑.
- Illumination Box 21



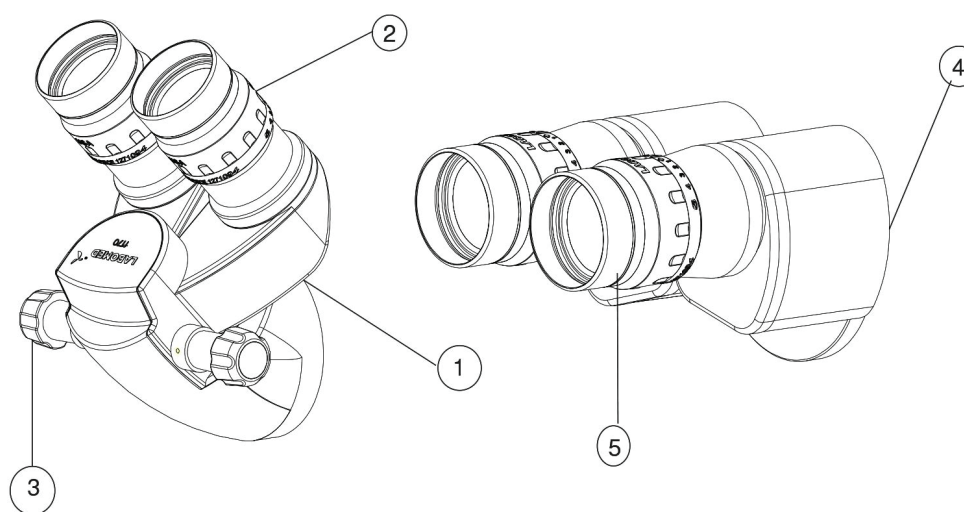
**(E50Stand)**

**(Fig 7.2)**

## 11. INSTRUCTIONS FOR USING THE COLPOSCOPE

### a) ADJUSTMENT OF INTERPUPILLARY DISTANCE (Fig. 8)

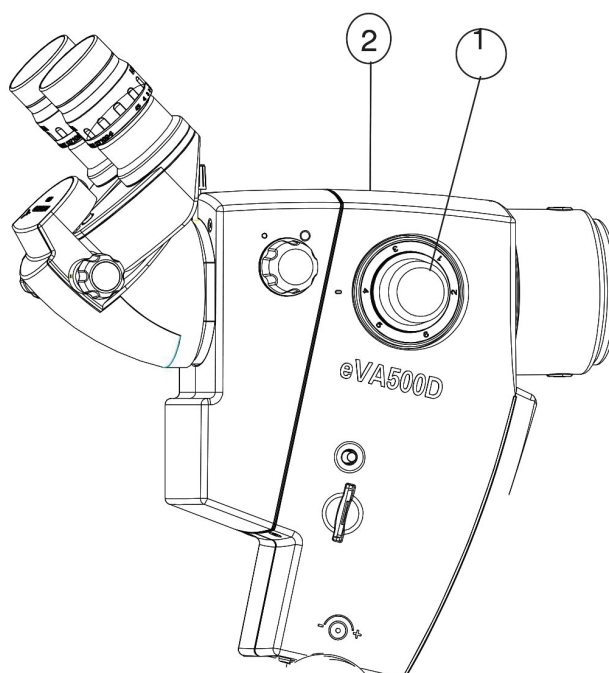
- Turn the Colposcope in working position.
- Inclined tube 45° : Adjust eyepieces to the required IPD by turning ① ② the lateral knob③.
- Straight tube④: Adjust eyepieces ⑤ by moving the binocular tube as per your requirement.



(Fig. 8)

**b) CHANGING THE MAGNIFICATION (Fig. 9)**

- Adjust to the highest magnification with any of the rotating knobs on ① the magnification changer ②.
- See to it that the magnification changer step is engaged into its index position, related to the desired magnification.

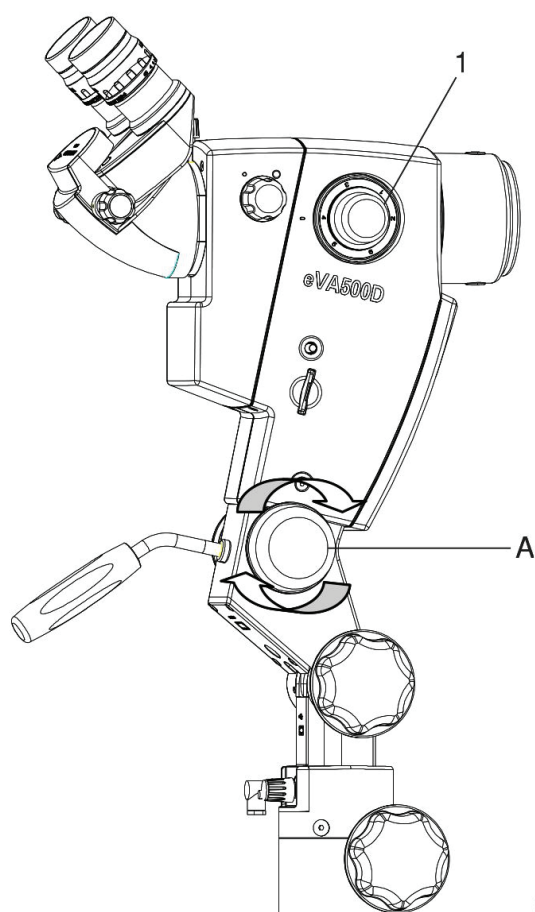
**(Fig. 9)**

## HOW TO FOCUS THE OBJECT (Fig. 9.1)

- Bring object into rough focus.
- Rotate fine focusing knob clockwise or anticlockwise to bring object into sharp focus.
- If the object is outside the range of the fine focusing knob, bring the complete Colposcope in the focus range by any of the following means:
  - i) Roll the mobile stand forward and backward.
  - ii) Adjust the swivel arm towards left and right.
  - iii) Adjust the Colposcope angle left and right. For this loosen the head arm knob and rotate the Colposcope.

A combination of the above steps will give you the true desired focusing median.

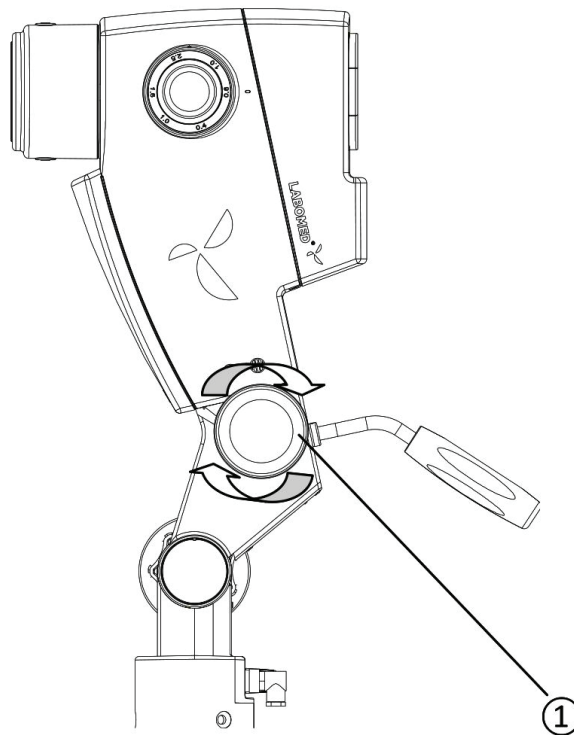
- On focusing the region of interest, change magnification through the magnification changing knob.



**(Fig. 9.1)**

#### d) Red free image observation (Fig. 9.2)

- Rotate filter knob (1) to swing in or swing out the red free (Green) filter. This will help in filtering the red tissue in the image being observed and will highlight the enhance vessel image and the vascular morphology.

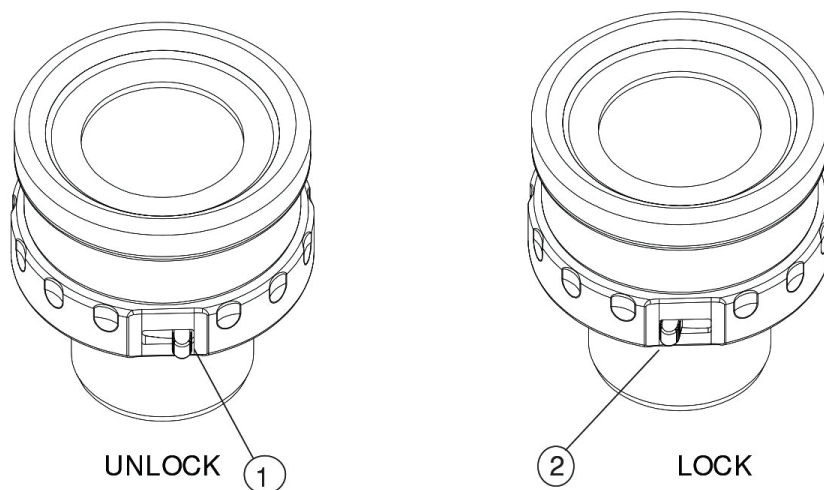


(Fig. 9.2)



### e) EYEPIECES WITH DIOPTR LOCKING FACILITY (Fig. 9.3)

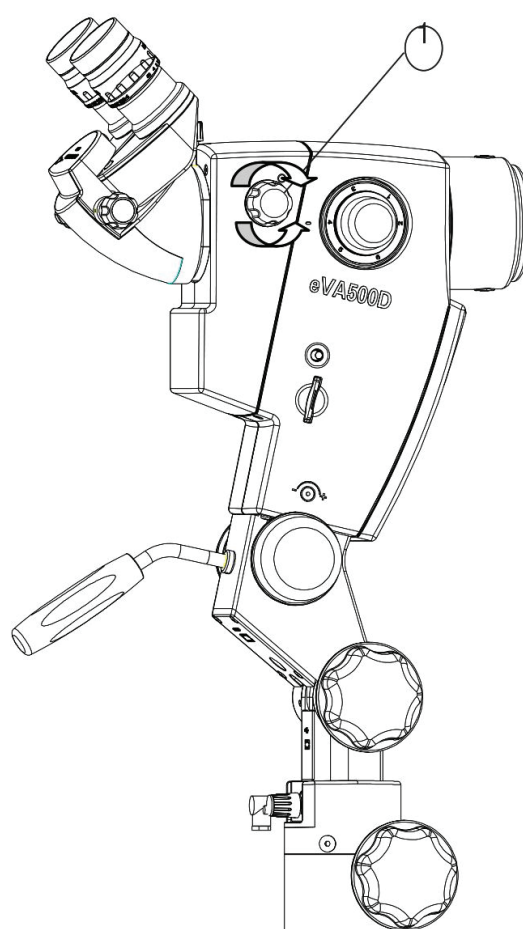
- LABOMED eyepieces have a unique locking facility.
- Diopter lock can be released by moving the slider on eyepiece ① toward right.
- You can adjust the diopter settings as per your vision correction.
- Once the diopter adjustment is done as per individual, the movement can be set and locked by moving the slider ② to the left.



(Fig. 9.3)

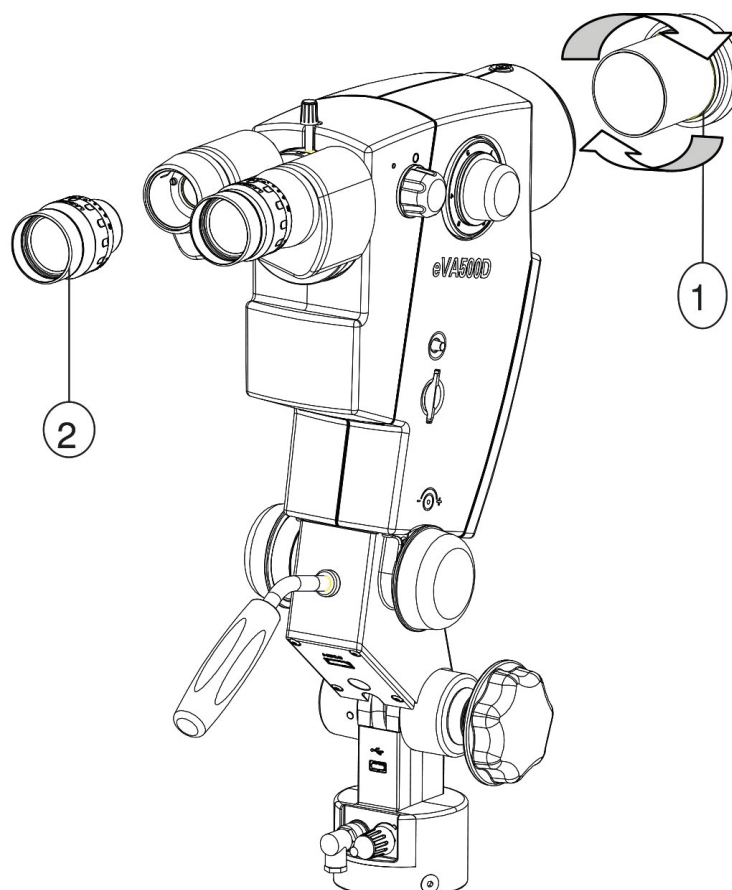
**f) APERTURE SETTINGS FOR THE COLPOSCOPE (Fig. 9.4)**

- To increase the contrast and depth of focus while working at higher magnification the aperture knob can be put in place by ① rotating it clockwise.

**(Fig. 9.4)**

## CHANGING THE BINOCULAR TUBE (Fig. 10.1)

- Loosen the knob from the top of the head arm to remove the inclined ① ④ tube 45° ② or the straight tube ③.
- When setting up the binocular tube, two plugs should lock into the nuts ⑤ of the magnification unit. Take care that the tube gets engaged properly. Lock the knob ①.



(Fig. 10.1)

## 15. CARE AND MAINTENANCE

This instrument is a high grade technological product and not required any special periodical Maintenance if handed carefully. To ensure optimum performance and safe working order of the Instrument, its safe functioning must be checked once every 12 months as per table below. We Recommended having this check performance by our service representative as part of regular Maintenance work. If a failure occurs which you cannot correct using the trouble-shooting table, Attach a sign to the instrument stating out of order and contact our service representative for servicing part or circuit diagram etc.

### CARE INSTRUCTIONS:

- Keep accessories away from dust when not in use, e.g. protect them from dust cover.
- Remove dust with a pneumatic rubber bulb and soft rush.
- Use special optics cleaning cloths and pure alcohol for cleaning lenses and eyepieces.
- Protect your colposcope from moisture, fumes, acids and cosmetic materials. Do not store chemicals close to the instrument.
- Protect it from improper handling. Never install other devices sockets or unscrew optical system and Mechanical parts unless explicitly instructed to do so in this manual.
- Protect the Colposcope from oil and grease. Never oil or grease the guide surfaces or mechanical parts.
- Remove coarse contamination using a damp disposable cloth.
- Use disinfectants based on the following ingredients: aldehyde, alcohols, quaternary ammonium compounds.
- Camera: Clean optical components using a lint-free cloth. Soak the cloth using a little methanol or glass cleaner. Do not use ethanol and spirit.
- Do not clean products and optical components in a cleaning/disinfecting device or ultra sound bath.

### TROPICAL ENVIRONMENT/FUNGUS:

LABOMED employs certain safety precaution in its manufacturing techniques and materials. other preventive measures include:

- Keep optical parts clean.
- Use and store them in a clean environment only.
- Store under UV light when not in use.
- Use in continuously climate-controlled rooms only.
- Keep moisture away using silica gel and cover with a plastic cover.

### OCCUPATIONAL SAFETY AND HEALTH PROTECTION:

Observe work safety and health protection of persons responsible for processing contaminated products.

Current regulation of hospital hygiene and prevention of infection must be observed in the preparation, cleaning and disinfection of the products.

# CARE AND MAINTENANCE

## INSTRUCTIONS

### WORKPLACE:

Remove surface contamination with a paper towel.

### CLEANING & SERVICING:

- Clean the surface using running water with a mild detergent if necessary.
- Use 99% isopropyl alcohol to clean optical components.
- Dry optical components using a microfiber cloth; dry the rest of the product using a paper towel.
- Service as and when required should be informed to LABOMED after – sales service department.

## 16. AMBIENT REQUIREMENT

For Operation	Temperature Rel. Humidity (without condensation) Air Pressure	+10°C.....+40°C 30%.....90% 700hPa.....1,060hPa
For Transportation and Storage	Temperature Rel. Humidity (without condensation) Air Pressure	-40°C.....+70°C 10%.....100% 500hPa.....1,060hPa

The unit meets the essential requirements stipulated in Annex I of the 93/42/EEC directive Governing medical devices. The unit is marked with CE and is compliant to ANSI / AAMI EC 60601 - 1:2005.

## 17. DISPOSAL

Disposal of the instrument must comply with locally applicable laws and regulations.

## 18. TROUBLESHOOTING TABLE

Problem	Possible Cause	Remedy
No illumination at all	Power cable not plugged in	Plug in power cable
	Power switch not pressed	Press the power switch to ON position
	Defective fuse	Change the fuse
	Defective power cable	Change the power cable
	Line power failure	Contact in-house technician
	Failure of suspension system electronics	Contact the service department
	Light guide not properly inserted in arm of microscope	Insert the light guide properly to get maximum illumination
Insufficient illumination	Brightness level set too low	Adjust brightness control knob
	Light guide not properly inserted in colposcope	Insert the light guide properly to get maximum illumination
	Defective light guide (illumination not uniform)	Change the light guide
Inoperative surgical field illumination	Light guide not properly inserted in colposcope	Insert the light guide as far as it will go
	Failure of electronics	Illuminate the surgical field using an alternate illuminator, and contact the service department
	Defective fan. Failure of system electronics	Illuminate the surgical field using an alternate illuminator, and contact the service department
Colposcope Unstable	Breaks on wheels not used.	Use breaks
No image visible in field of view	Magnichanger is not indexed properly	Index magnichanger properly

## 19. TECHNICAL SPECIFICATIONS

Stand	Star Base Stands with E50 column, lockable wheels
Observation tubes	Straight, Interpupillary distance 49-78 mm Optional: 45° inclined
Eyepieces	WF 10X/18mm, focusable with retractable eye guards, diopter adjustment $\pm 7$ mm and diopterlock Optional: WF 12.5X/18mm
Magnichanger	5 Step: 0.4x, 0.6x, 1.0x, 1.6x, 2.5x
Objective	f-300mm, high contrast aperture stop
Built-in filters	Green
Light Source	LED 50W, Maximum intensity 80,000 LUX ,lamp life up to 60,000 hours . 50W LED; Maximum intensity 80,000 LUX
Power Consumption	130 W max.
Input Voltage	100V-240V; 50/60 hz.
Digital Imaging	N.A




## 20. GUIDANCE TABLES

<b>Guidance and Manufacturer's Declaration</b> <b>Electromagnetic Emissions</b> <b>All Equipment and Systems</b>		
<b>Guidance and Manufacturer's Declaration - Electromagnetic Emissions</b>		
<p>The eVA 500 is intended for use in the electromagnetic environment specified below. The customer or user of the eVA 500 should ensure that it is used in such an environment.</p>		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment Guidance</b>
RF Emissions CISPR 11	Group 1 Class A	The eVA 500 uses 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.
Harmonics IEC 61000-3-2	Class A	The eVA 500 is suitable for use in all establishment, other than domestic, and those directly connected to the public low voltage power network that supplies buildings used for domestic purposes.
Flicker IED 61000-3-3	Complies	

# GUIDANCE TABLES (continued)

Guidance and Manufacturer's Declaration			
<h2>Electromagnetic Emissions</h2> <h3>All Equipment and Systems</h3>			
Guidance and Manufacturer's Declaration - Electromagnetic Emissions			
eVA 500 is intended for use in the electromagnetic environment specified below. The customer or user of the eVA 500 should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± 6kv contact ± 8kv Air	± 6kv contact ± 8kv Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the R/H should be at least 30%.
EFT IEC 61000-4-4	± 2kv Mains ± 1kv I/Os	± 2kv Mains ± 1kv I/Os	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kv Differential ± 2kv Common	± 1kv Differential ± 2kv Common	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, dropouts, IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Main power quality should be that of a typical commercial or hospital Environment. If the user of the eVA 500 requires continued operation during power mains interruption, it is Recommended that the eVA 500 be Powered from an uninterruptable power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic field should be that of a typical commercial or hospital Environment.

# GUIDANCE TABLES (continued)

Guidance and Manufacturer's Declaration			
<h2 style="text-align: center;">Electromagnetic Immunity</h2> <h3 style="text-align: center;">Equipment and Systems that are NOT Life-Supporting</h3>			
Guidance and manufacturer's Declaration – Electromagnetic Immunity			
The eVA 500 is intended for use in the electromagnetic environment specified below. The customer or user of the eVA 500 should ensure that it is used in such an environment.			
Immunity Test	ICE 60601 Test Level	Compliance Level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 vrms 150kHz - 80MHz	(v1) = 3 vrms	Portable and mobile RF communications Equipment should be used no closer to any part of the eVA 500, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			<p><b>Recommended Separation Distance:</b></p> <p style="text-align: center;"><math>d = (3.5/v1)(\text{Sqrt } P)</math></p> <p style="text-align: center;"><math>d = (3.5/E1)(\text{Sqrt } P)</math></p> <p style="text-align: center;">80 to 800 MHz</p> <p style="text-align: center;"><math>d = (7/E1)(\text{Sqrt } P)</math></p> <p style="text-align: center;">800 MHz to 2.5 GHz</p> <p>Where P is the max output power rating of the transmitter in watts (W) according to the transmitter manufacture and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> <div style="text-align: right;">  </div>
Radiated RF IEC 61000-4-3	80MHz to 2.5 GHz @ 3V/m	(E1) = 3 V/m	
<p>Note 1: At 80 MHz to 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> <p>*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 access the electromagnetic Environment due to fixed RF transmitters, an electromagnetic site survey should be considered. The measured field strength in the location in which the ME Equipment or ME system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment or ME System.</p> <p>*Over the frequency range 150kHz to 80 MHz, field strengths should be less than [V1] V/m.</p>			

## GUIDANCE TABLES (continued)

Recommended separation distance between Portable and Mobile RF Communications equipment and the eVA 500 for ME equipment and ME systems that are not Life-supporting.

### Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Recommended separation distance for between Portable and Mobile RF Communications equipment and the eVA 500

The eVA 500 is intended for use in electromagnetic environments in which radiated RF disturbances are controlled. The customer or user of the eVA 500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the eVA 500 as recommended below, according to the maximum output power of the Communication equipment.

Max Output Power of Transmitter (W)	Separation (m) 150kHz to 80 MHz $d=(3.5/\sqrt{P})$ (Sqrt P)	Separation (m) 80 to 800 MHz $d= (3.5/E1)$ (Sqrt P)	Separation (m) 800 MHz to 2.5GHz $d= (7/E1)$ (Sqrt P)
0.01	0.1166	0.1166	0.2333
0.1	0.3689	0.3689	0.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

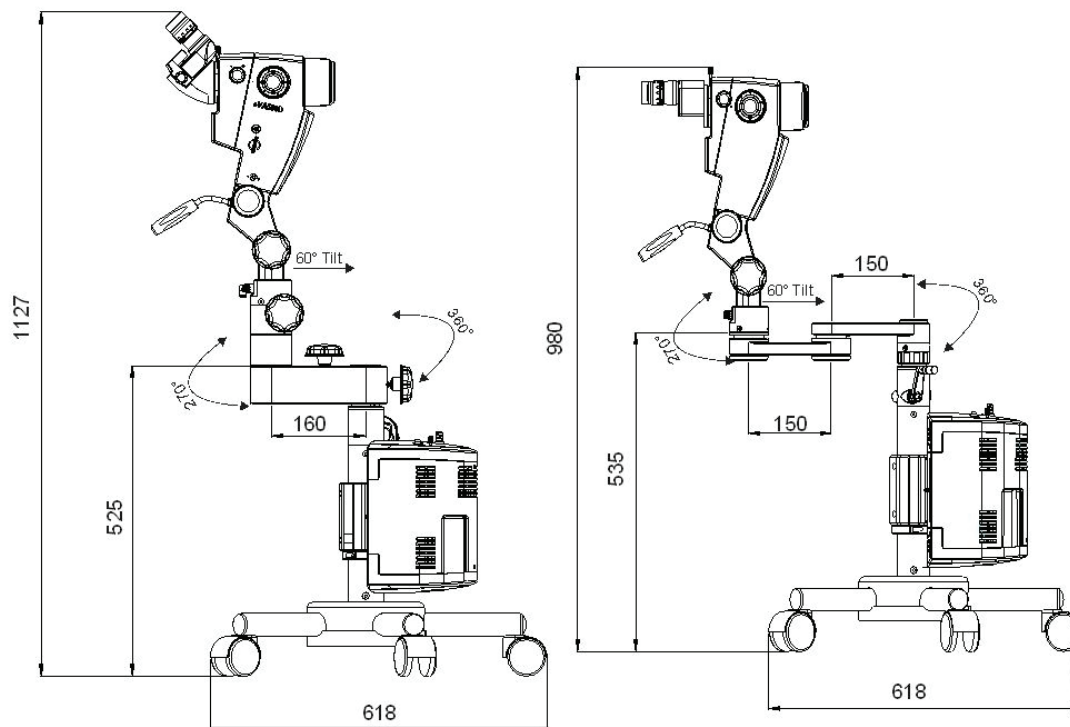
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter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

Note 1: At 80MHz 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.

## 21. MEASURES AND WEIGHT

eVA500 – Colposcope with roller stand  
Total weight: Approx. 44 kg.



(Fig 11)

## 22. GLOSSARY

Ametropia Compensation	Compensation of short-or-far-sightedness. This can be done for each eye using the two individual eyepieces (range: +5 to -5 diopters).
Working Distance	Distance front lens to object level (= 300mm).
Color Temperature	Refers to the color characteristic of a light source. Using color temperature, one can set the color of a light source to warm or cold light Relative to the color of natural light. The unit of measure for color temperature is Kelvin (K).
Light field diameter	The size of the field, which is illuminated at a distance of 300mm.
Field of View Diameter	The visible area of an object that can be seen through the colposcope. The greater the magnification level, the smaller the field of view and vice versa.
Green Filter	A color filter that darkens red and blue light and brightens green light. Thus, the contrast of the image is increased, blood vessels are shown more clearly.
Illumination Intensity	Specifies the luminous flux from a light source onto a certain area. The unit of measure for illumination intensity is Lux (Lx).
LED	Light Emitting Diode. Electronic semiconductor device that emits light when an electrical current passes through it.
Eyepiece	The optical portion facing towards the eyes, with which the enlarged image produced by the microscope can be viewed.
Convergent Beam Path	The two light beams for the right and left eye run together at a point that lies at a distance of 300mm in front of the front lens. This distance is in accordance with the working distance. This way, the eye does not has to focus on this point in its own, as it is the case with a parallel beam path.
Ez-Lift™	Once patient is set for examining the Ez-Lift™ lift mechanism helps user for easy and accurate positioning without disturbing the patient. It has total vertical travel of 125 mm (100 mm coarse positional travel and 25 mm fine positional travel).

## 23. WARRANTY

This product is warranted by Labo America Inc. against defective material and workmanship under normal use for a period of one year from the date of invoice to the original purchaser. (An authorized dealer shall not be considered an original purchaser). Under this warranty, Labo America Inc. sole obligation is to repair or replace the defective part or product at Labotech/Labomed descretion.

This warranty applies to new product and does not apply to a product that has been tampered with, altered in any way, misused, damaged by accident or negligence, or which has had the serial number removed, altered or effaced. Nor shall this warranty be extended to a product installed or operated in a manner not in accordance with the applicable LABOMED instruction manual, nor to a product which has been sold, serviced, installed or repaired other than by a Labo America Inc. factory or authorized LABOMED Dealer.

Lamps, bulbs, charts, cards and other expendable items are not covered by this warranty.

All claims under this warranty must be in writing and directed to the LABOMED factory, or authorized instrument dealer making the original sale ands must be accompanied by a copy of the purchaser's invoice.

This warranty is in lieu of all other warranties implied or expressed. All implied warranties of merchantability or fitness for a particular use are hereby disclaimed. No representative or other person is authorized to make any other obligations for a LABOMED product. Labotech/Labomed shall not be liable for any special, incidental, or consequent damages for any negligence, breach of warranty, strict liability or any other damages resulting from or relating to design, manufacture, sale, use or handling of the product.

### PRODUCT CHANGES

LABOMED reserve the right to make changes in design or to make additions to or improvements in its products without obligation to add such to product previously manufactured.

### CLAIMS FOR SHORTAGES

We use extreme care in selection, checking, rechecking and packing to eliminate the possibility of error. If any shipping errors are discovered:

1. Carefully go through the packing material to be sure nothing was inadvertently overlooked when the unit was unpacked.
2. Call the dealer you purchased the product from and report the shortage. The material are packed at the factory and none should be missing if the box has never been opened.
3. Claims must be filed within 30 days of purchase.

### CLAIMS FOR DAMAGES IN TRANSIT

Our shipping responsibility ceases with the safe delivery in good condition to the transportation company. Claims for loss or damage in transit should be made promptly and directly to the transportation company.

If, upon delivery, the outside of the packing case shows evidence of rough handling or damage, the transportation company's agent should be requested to make a "Received in Bad Order" notation on the delivery receipt. If within 48 hours of delivery, concealed damage is noted upon unpacking the shipment and no exterior evidence of rough handling is apparent, the transportation company should be requested to make out a "Bad Order" report. This procedure is necessary in order for the dealer to maintain the right of recovery from the carrier.



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