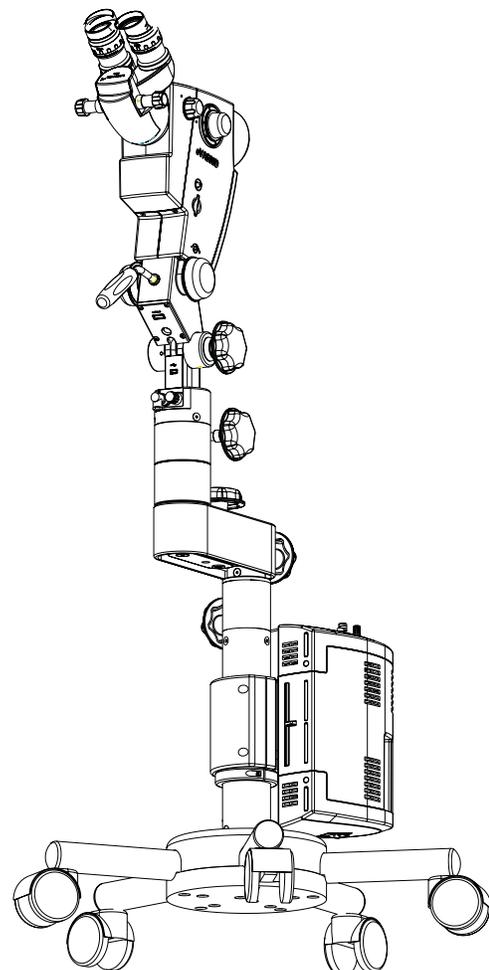


eVA 500 / 500D User Manual

COLPOSCOPE



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.

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1. INTRODUCTION

Congratulation on the purchase of your new eVA 500 / 500D 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 / 500D 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 microscope.

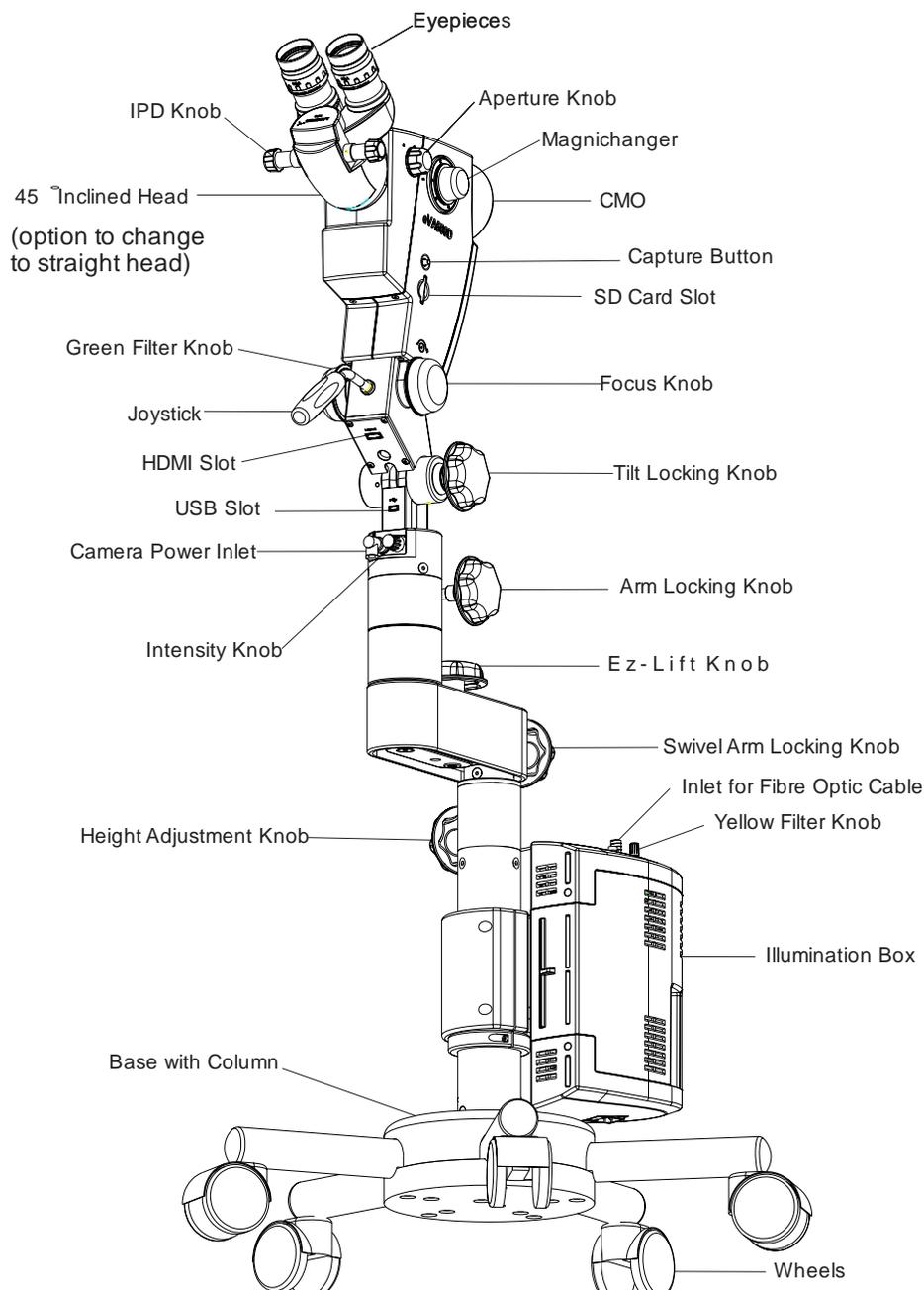
A Colposcope provides an enlarged view of area of interest and allows visual distinguishing of normal and abnormal appearing tissues and also as an aid of taking direct biopsies for further pathological examination.

It is also used for visual examination of Cytological abnormality as well as assessment of Diethylstilbestrol exposure in-utero, Immunosuppression such as HIV, abnormal appearance of the Cervix and forensic examination of a sexual assault wherein, a Colposcope fitted with a camera is of great benefit for the purpose of image capturing.

With E50 Stand: Provided with Ez™-lift mechanism for easy and accurate positioning. It has total vertical travel of 125 mm (100 mm coarse positional travel and 25 mm fine positional travel).

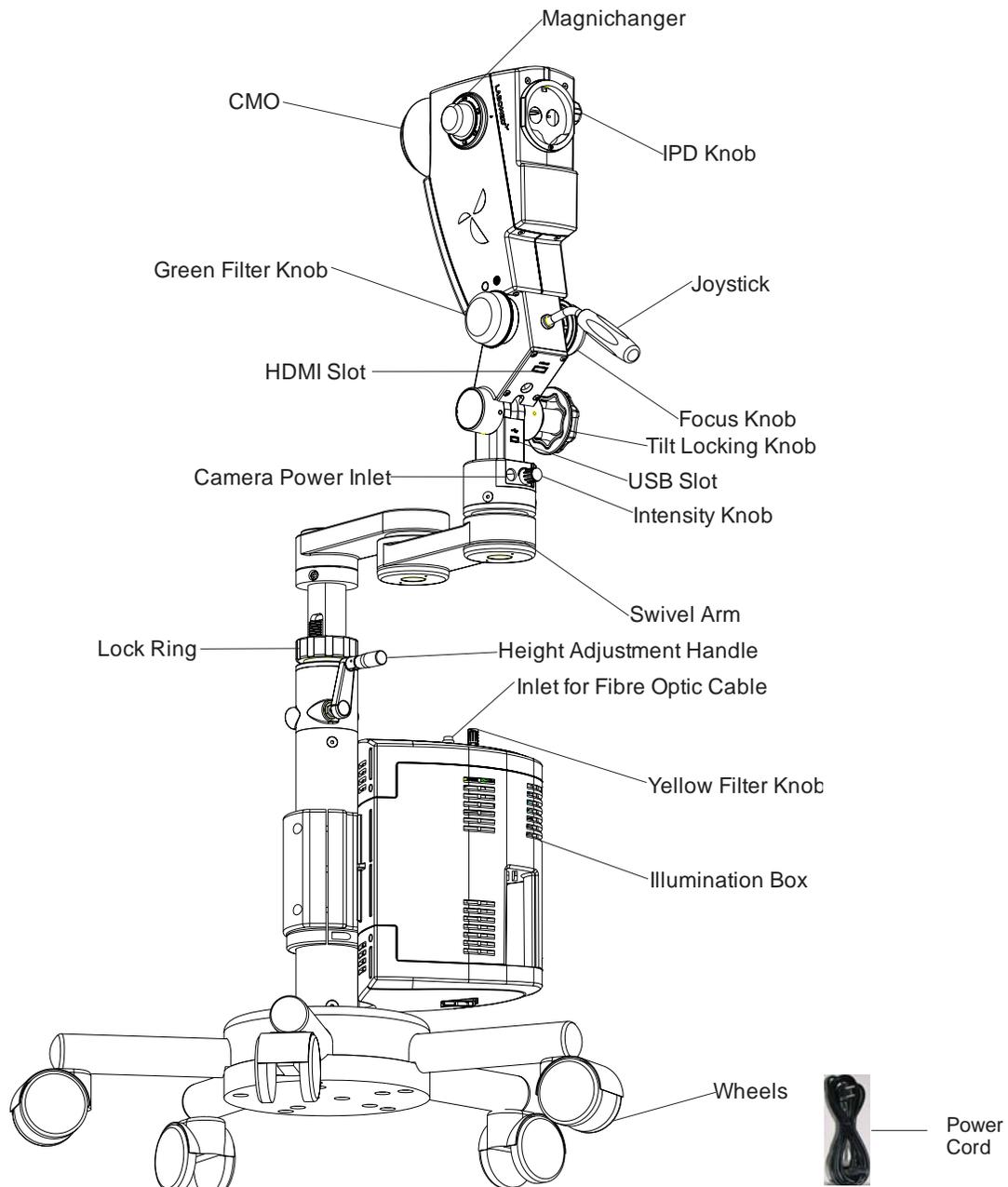
Control knob helps user in achieving the desired height by slight loosening the swivel arm locking knob and then re-clamp after getting the required height.

Ez lift knob is used for fine & perfect position of colposcope to view the desired field with comfort & ease of both user and patient. It has a total fine adjustment travel of 25 mm.



With S50 Stand: S50 stand is provided with a vertical range of height up to 125 mm with the help of the rack and pinion arrangement. User can adjust colposcope as per convenience for exact view of interest.

S50 stand also has a foldable provision when not in use to park in a compact position.



2. Warnings & 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.
- Instrument is not used in accordance with this User's Guide.

WARNING: AN INSTRUCTION THAT DRAWS ATTENTION TO RISK OF INJURY OR DEATH.



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 OUT LINED 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 PERSONNEL 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 MUST 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: TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAIN WITH PROTECTIVE EARTH OR DAMAGE TO THIS INSTRUMENT AND/OR INJURY TO THE OPERATOR OR OTHERWISE PATIENT MAY OCCUR.

WARNING: ENSURE THAT THE VOLTAGE APPLIED TO THE UNIT IS THE SAME AS THE VOLTAGE IS INDICATED ON THE DATA PLATE OR DAMAGE TO THE UNIT MAY OCCUR.

WARNING: THIS INSTRUMENT MUST BE PLUGGED IN TO AN OUTLET WITH AN EARTH GROUND. DO NOT REMOVE OR DEFEAT THE EARTH GROUND CONNECTION ON POWER INPUT CONNECTOR OR THE UNIT'S POWER CORD OF THIS INSTRUMENT OR DAMAGE TO IT AND/OR INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

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: THIS INSTRUMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE AN ESTHETIC MIXTURES, SUCH AS OXYGEN ON IT ROUSOXIDE.

WARNING: BECAUSE PROLONGED INTENSE LIGHT EXPOSURE CAN DAMAGE THE RETINA, THE USE OF THE DEVICE FOR OCULAR EXAMINATION SHOULD NOT BE UNNECESSARILY PROLONGED, AND THE BRIGHTNESS SETTING SHOULD NOT EXCEED WHAT IS NEEDED TO PROVIDE CLEAR VISUALIZATION OF THE TARGET STRUCTURES. THIS DEVICE SHOULD BE USED

WITH FILTERS THAT ELIMINATE UVRADIATION(<400NM) AND, WHENEVER POSSIBLE, FILTERS THAT ELIMINATE SHORT- WAVELENGTH BLUE LIGHT(<420NM).

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.

CAUTION: AN INSTRUCTION THAT DRAWS ATTENTION TO THE RISK OF DAMAGE TO THE PRODUCT.



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

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

CAUTION: MEDICAL ELECTRONIC EQUIPMENT NEEDS SPECIAL PRECAUTIONS REGARDING EMC AND NEEDS TO BE INSTALLED AND PUT IN TO SERVICE 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: THIS INSTRUMENT IS NOT INTENDED TO BE CONNECTED TO EQUIPMENT OUTSIDE THE CONTROL OF LABOMED OR MUST BE TESTED TO AN APPLICABLE IEC OR ISO STANDARDS.

Warning Labels and Notes



Caution:

Observe all warning labels and notes!

If any label is missing on your instrument or has become illegal, please contact us or one of our authorized representatives. We will supply the missing labels.



Instrument label plate:

The instrument label plate indicates the following:

- Name of the unit
- Cat. number
- Rated voltage and current consumption
- Rated frequency range
- Serial number
- Safety compliance
- Brand name



Brightness control:

After the illumination has been switched on, you can continuously adjust the brightness of the fiber illumination by turning the appropriate knob.



Accompanying documents must be consulted



Catalog number

REF

Compliance to medical device directive 93/42/EEC



Protective earth



Yellow filter knob on illumination box.



Aperture knob



Green filter knob.



CMO fine focusing knob.



This way up- indicates correct upright position of the transport package.



Keep dry- transport package shall be kept away from rain.



The CE mark (an acronym for the French "Conformit e Europ eenne") certifies that a product has met European Union health, safety and environment requirements, which ensure consumer safety.



Year of manufacture used on PRODUCT DATA



Fragile- contents of the transport package are fragile and therefore shall be handled with care



Directives and standards

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

- EN
- IEC
- UL
- CSA

In accordance with Directives 93/42/EEC, Annex II, Article 3, the quality management system of LABOMED has been approved by UL which is notified body.

- As per Directive 93/42/EEC, the unit is a Class I instrument
- For USA: FDA classification Class II
- IEC 60601-1:2005 (3rd edition) Compliance
- Please observe all applicable accidental prevention regulations.

- **Intended use**

LABOMED colposcope eVA 500 and eVA 500D 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. It helps the user an excellent level of comfort and improves visual acuity during use.

- **NOTE:** The use of eVA500/500D Colposcope is purely for intended Operative and Diagnostic medical use. No contact is to be made between the patient and the device.

3. **CONDITION OF MATERIAL AT TIME OF SUPPLY**

The appliance is delivered in 6 assembled groups:

- Mobile supporting Base
- Column (S50 Or E50)
- Illumination box with integrated electrical power supply
- Swivel Arm (S50 Or E50)
- Microscope Arm (eVA 500 or eVA 500D)
- Microscope Head (Inclined or Straight)

Fasteners are enclosed in the packing box.

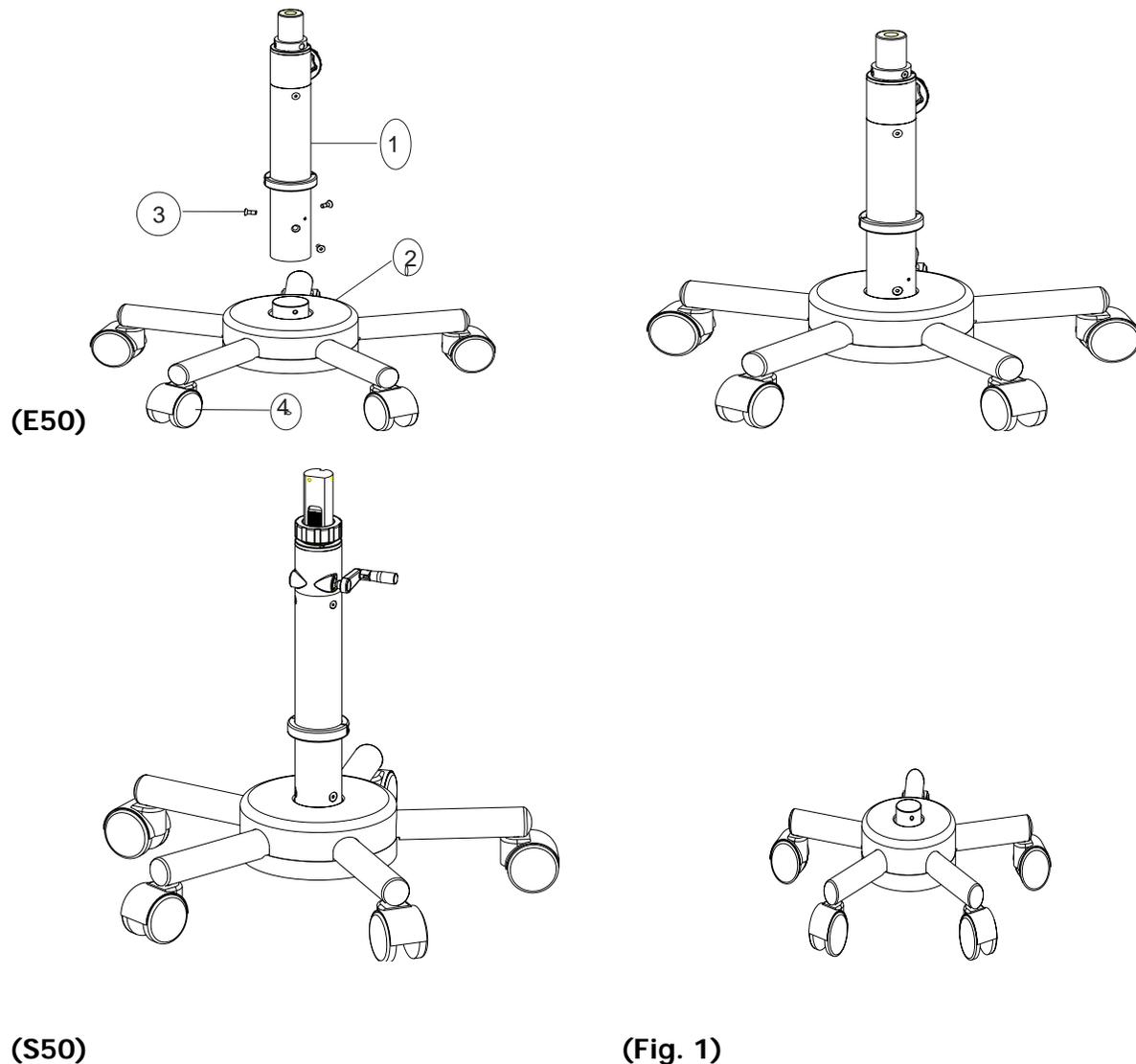
4. INSTALLATION INSTRUCTIONS

4.1 MOUNTING OF ROLLER STAND AND COLUMN (Fig. 1)

- Insert column ① into the mobile base ②.
- Fasten screw ③ with enclosed hexagon socket wrench to column ①.
- The mobile bases have 5 rollers ④ out of two have locking breaks (red)

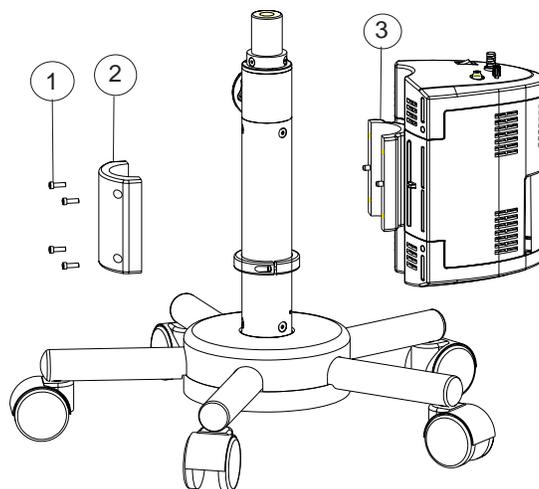
• **Indication:**

The colposcope eVA 500 / 500D can be mounted on either of the two mobile stands (E50 & S50). The type is to be specified at the time of purchase.



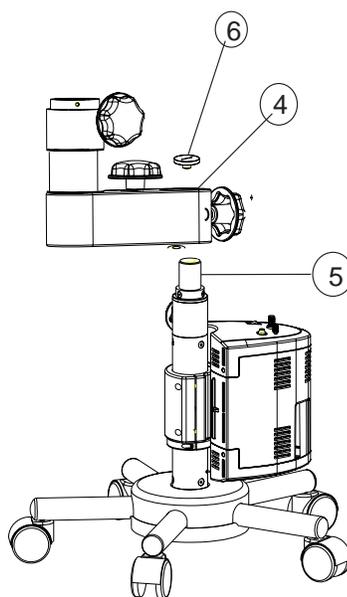
4.2 MOUNTING OF APPLIANCE

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



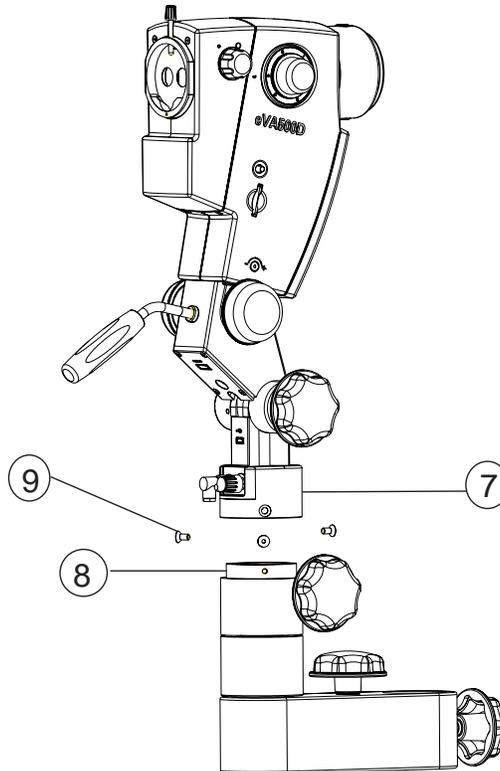
(Fig 2.1)

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



(Fig. 2.3)

4.3 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.

4.4 ADDITIONAL LOAD

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

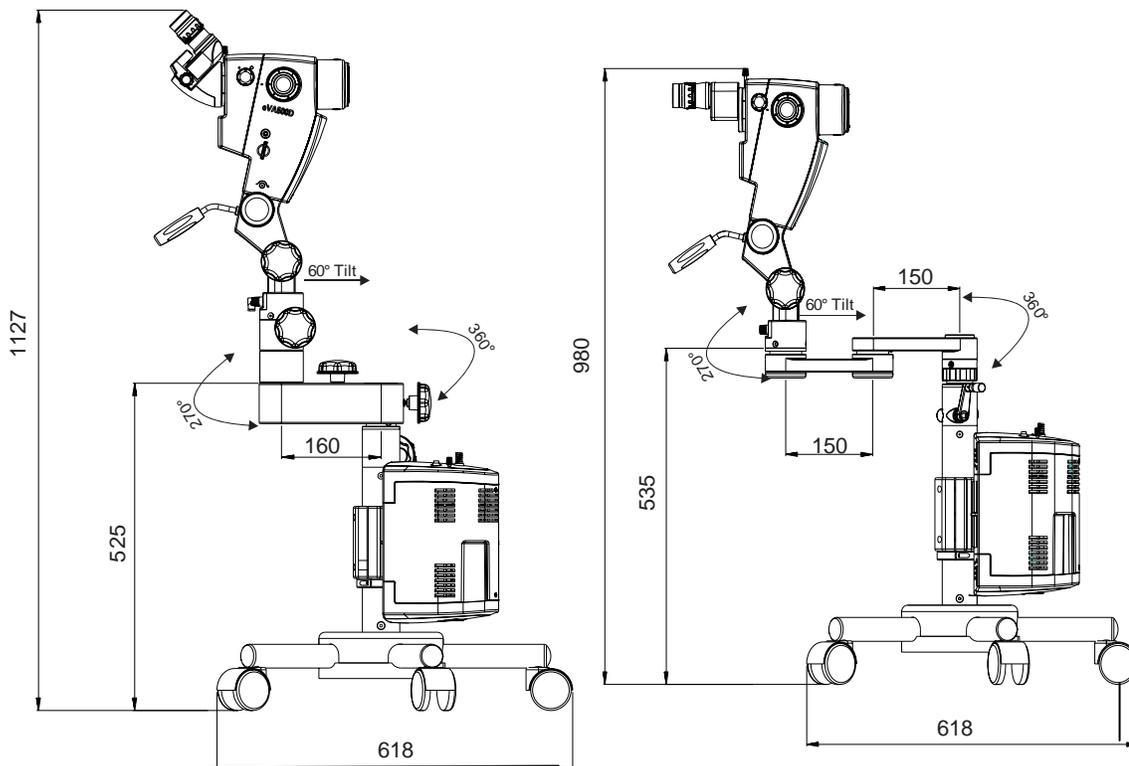
5. DIMENSIONS & WEIGHT (Fig. 3)

eVA 500D– Digital Colposcope with roller stand

Total weight: Approx. 45 kg.

eVA 500– Colposcope with roller stand

Total weight: Approx. 44 kg.



(Fig. 3)

6. Electrical Connections

Connect the power cable to the AC Inlet socket as 1 in figure number 4 below.

Switch on the power from on/off switch shown as 1 in figure number 5 on 16 below.

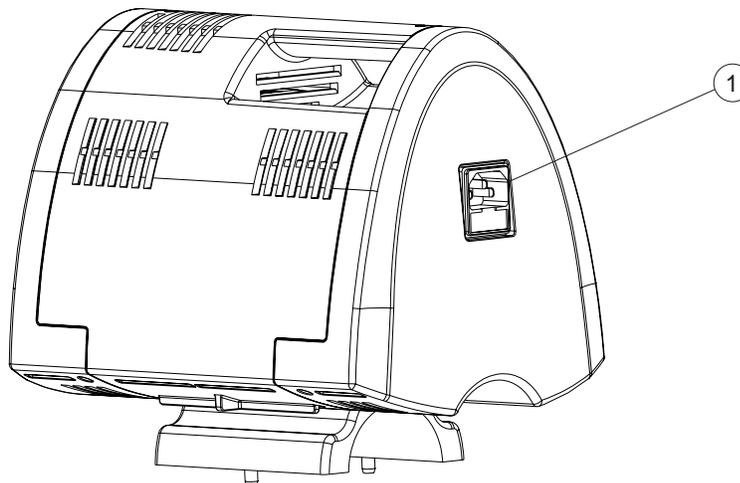
Note: Power supply is designed with universal input 100V-240V AC, 50/60Hz. To plug in follow instruction on electrical label provided at back of illumination box as shown in figure number 4 below.

a) CHANGING OF FUSE

- **Note:** Fuses 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
- Attention: It is only allowed to change the fuses against fuses of the same type.

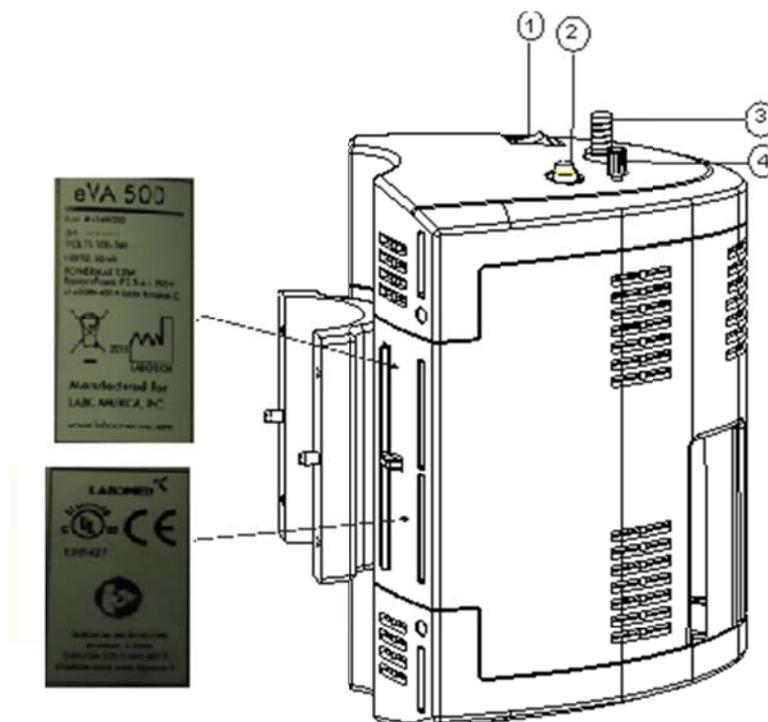


(Fig. 4)

7. OPERATING INSTRUCTIONS

- 7.1 **On / off switch** shown as ① in fig. 6 is located on the upper side of the illumination box. After the appliance is switched on, the green illumination switch diode indicates that the microscope is ready for operation. The LED starts burning and the cooling fan working.
- 7.2 **Inlet for cable to camera** power and light intensity regulation shown as ② in fig 6.
- 7.3 **Inlet for fiber optic cable** shown as ③ in fig. 6. Insert fiber optic cable in the inlet and run it through the swivel arm, to direct the light from illumination box to the microscope.
- 7.4 **Yellow filter knob** shown as ④ facilitates to change the filter if required to improve contrast.

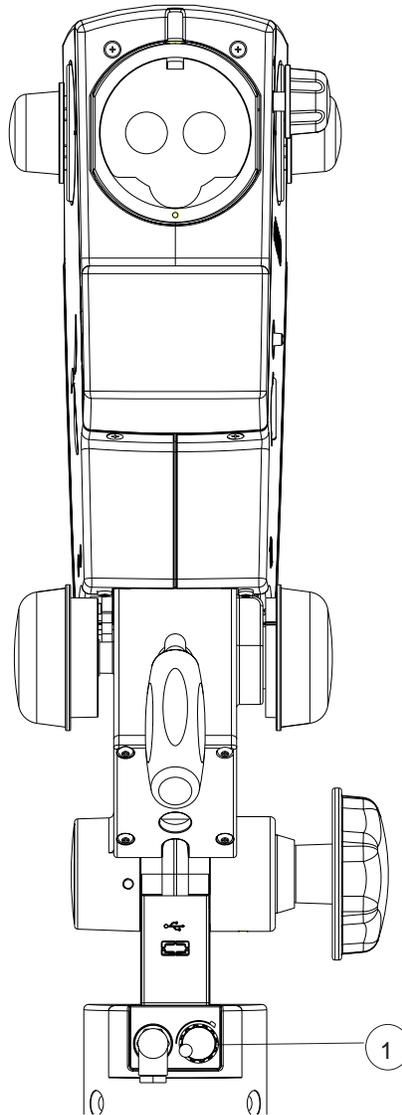
Note: To maximize LED life, switch off the microscope when not in use.



(Fig. 5)

7.5 BRIGHTNESS CONTROL (Fig. 6)

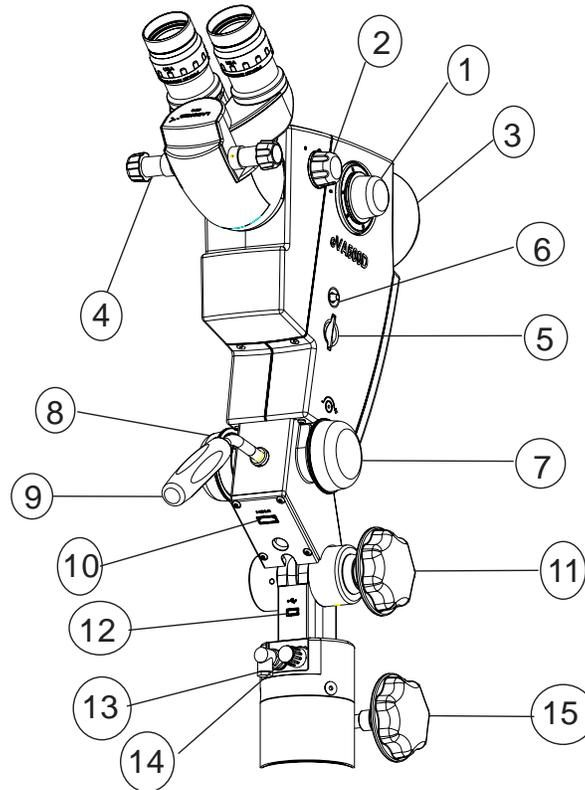
- A variation in light intensity is made by rotating knob ①.



(Fig 6)

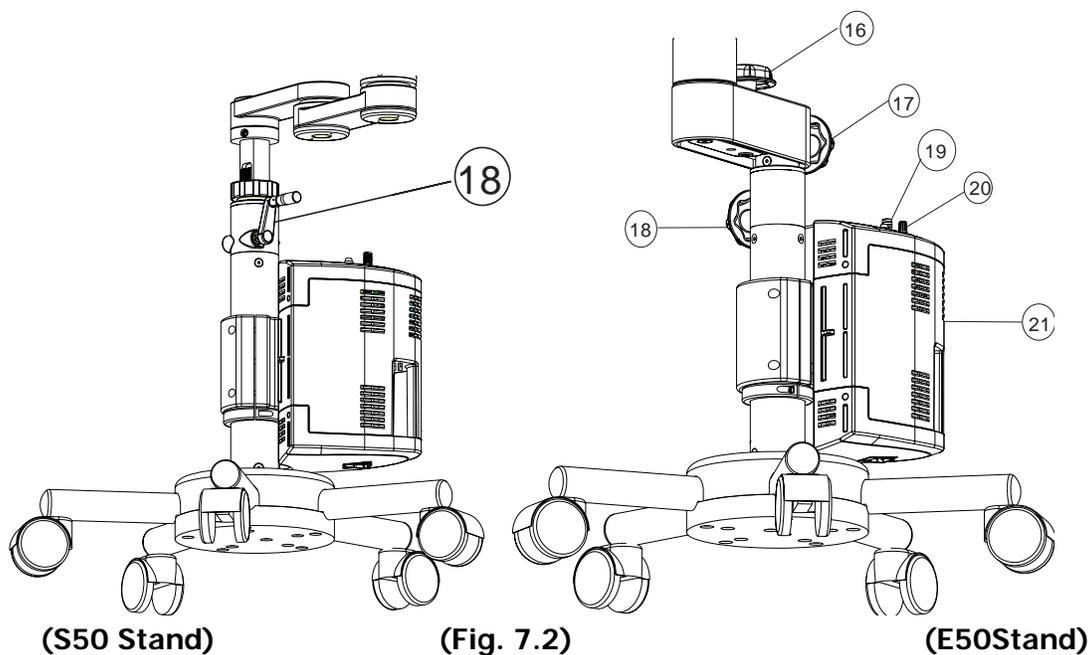
8. CONTROL ELEMENTS (Fig. 7.1 & 7.2)

- Roller stand:
- 5 rollers to move the appliance and 2 brakes to lock the Appliance (see Fig. 1)
- 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.
- SD card slot ⑤. (Only in eVA 500D)
- Button to capture the image ⑥. (Only in eVA 500D)
- Fine focusing knob ⑦
- Knob to swing in green filter ⑧.
- Joystick to tilt the head arm forward and backward ⑨.
- HDMI slot for suitable attachment ⑩.(Only in eVA 500D)
- Head arm locking knob ⑪
- USB attachment ⑫. (Only in eVA 500D)
- Inlet for power ⑬.
- Knob for brightness control ⑭.
- Knob to lock the arm ⑮.



(Fig. 7.1)

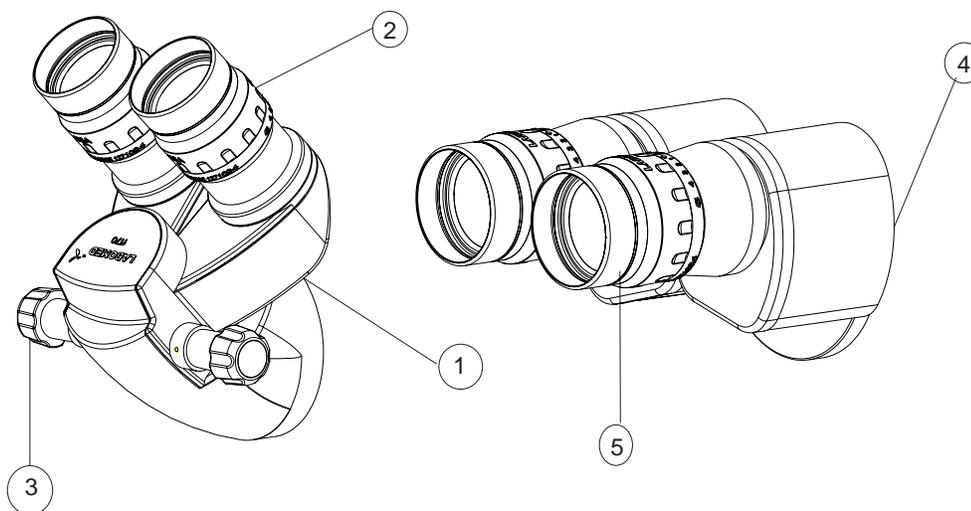
- Ez-lift control knob (16). (with E50 column configuration)
- Swivel arm locking knob(17).
- Column height adjustment knob (E50 stand) (18)and Column height adjustment handle(18) (S50 stand).
- Inlet for fiber optic cable(19).
- Knob to swing in the Yellow Filter (20).
- Illumination Box (21)



9. INSTRUCTIONS FOR USING THE MICROSCOPE

a) ADJUSTMENT OF INTERPUPILLARY DISTANCE (Fig. 8)

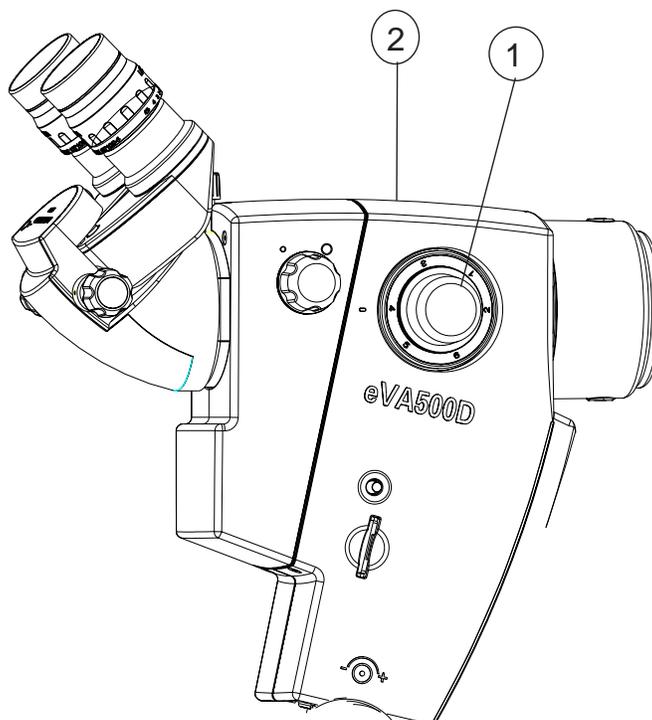
- Turn the microscope in working position.
- Inclined tube 45° ①: Adjust eyepieces ② to the required IPD by turning the lateral knob ③.
- Straight tube ④: Adjust eyepieces ⑤ by moving the binocular tube as per your requirement.



(Fig. 8)

b) CHANGING THE MAGNIFICATION (Fig. 9)

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



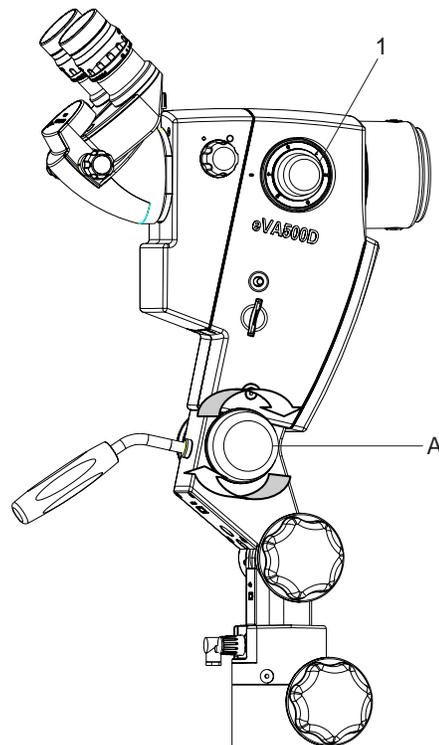
(Fig. 9)

c) **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 microscope in the focus range by any of the following means:
 - a) Roll the mobile stand forward and backward.
 - b) Adjust the swivel arm towards left and right.
 - c) Adjust the microscope angle left and right. For this loosen the head arm knob and rotate the microscope.

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

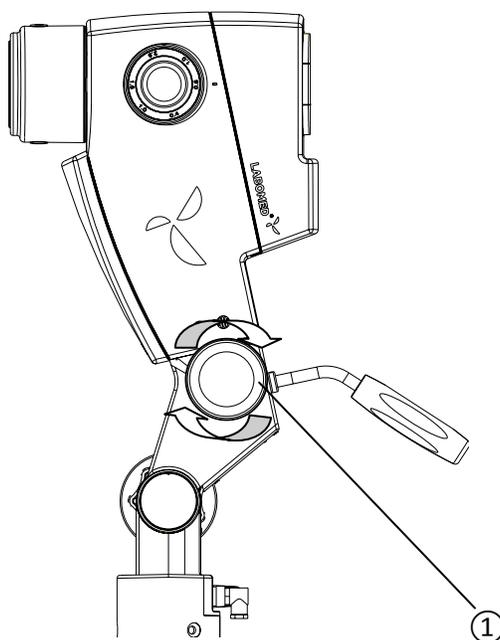
- On focusing the region of interest, change magnification through the magnification changing knob.



(Fig. 9.1)

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

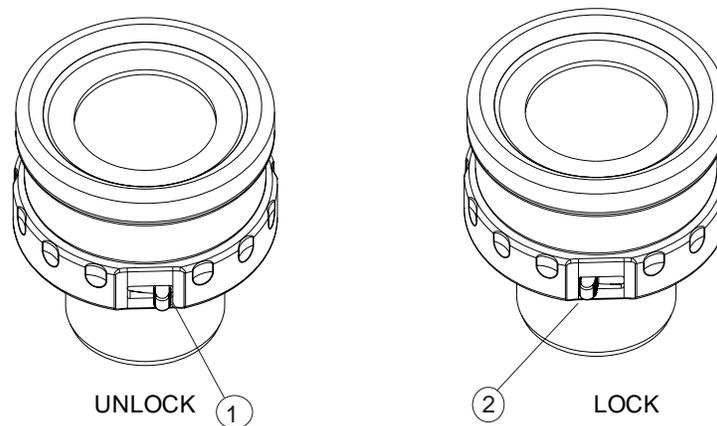
- Rotate filter knob (1) to swing in or swing out the red free (Green) filter. This will help in filtering the red tissue in the image being observed and will highlight the enhance vessel image and the vascular morphology.



(Fig. 9.2)

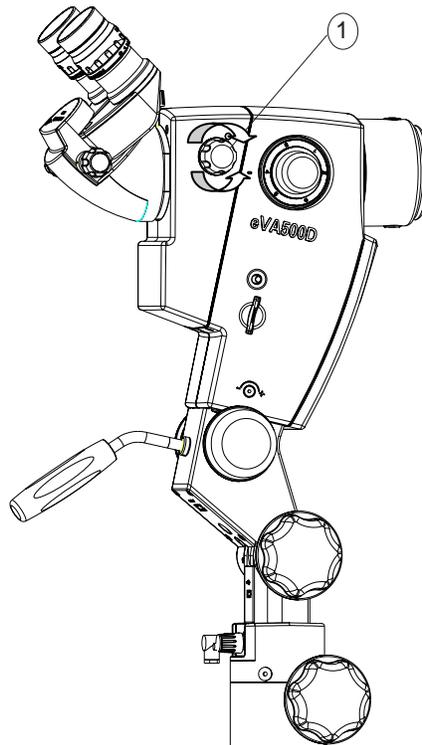
e) EYEPIECES WITH DIOPTER LOCKING FACILITY (Fig. 9.3)

- 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)**

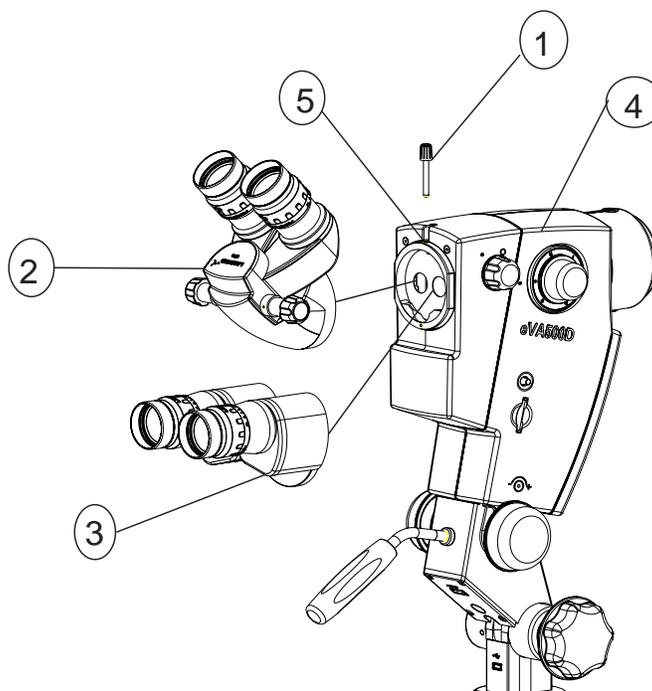
- To increase the contrast and depth of focus while working at higher magnification the aperture knob ① can be put in place by rotating it clockwise.



(Fig. 9.4)

10. CHANGING THE BINOCULAR TUBE (Fig. 10)

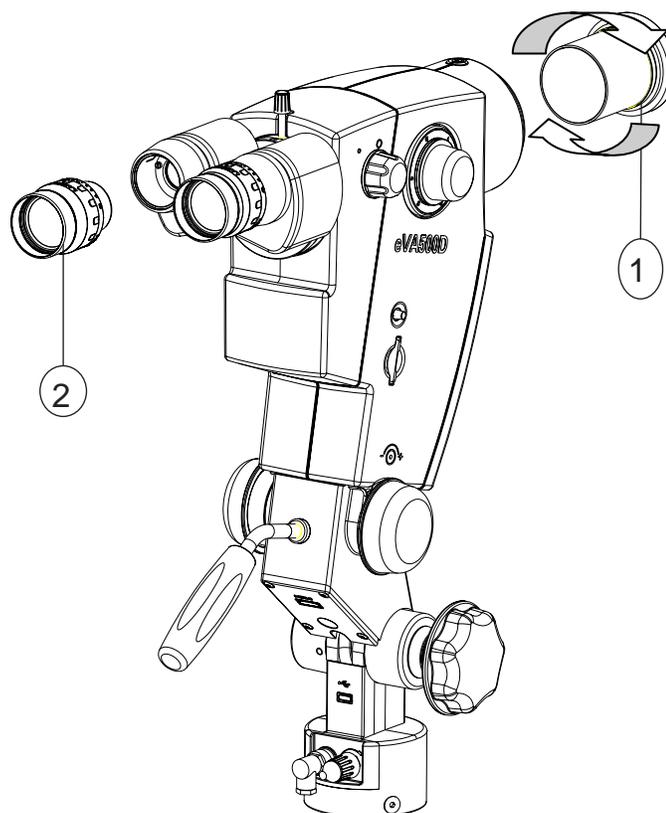
- Loosen the knob ① from the top of the head arm ④ to remove the inclined tube 45° ② or the straight tube ③.
- When setting up the binocular tube, two plugs should lock into the nuts ⑤ of the magnification unit. Take care that the tube gets engaged properly. Lock the knob ①.



(Fig. 10)

11. CHANGING THE OBJECTIVE / EYEPIECES (Fig. 10.1)

- The objective (1) has screw type mounting. Unlock it by turning anti-clock wise and lock them by turning clock wise.
- Eyepieces (2) are inserted / draw out for changing.
- Other objectives / eyepieces can be selected by choice.



(Fig. 10.1)

12. CARE & MAINTENANCE (Fig. 11)

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 instruments, its safety must be checked once every 12 months. 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 troubleshooting 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 brush.
- 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 microscope 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: aldehydes, alcohols, quaternary ammonium compounds.
- Camera: Keep optical components clean 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 with optical components in a cleaning/disinfecting device or ultra sound bath.
- **LABOMED MaxLite** coatings are very resistant. If you clean as described above, the coatings will not be damaged.

- **Tropical environment/fungus:**

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

- Keep optical part 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 and cover using a plastic cover filled with silica gel.

- **Occupational safety and health protection:**
Observe work safety and health protection of persons responsible for processing contaminated products.
Current regulations of hospital hygiene and prevention of infection must be observed in the preparation, cleaning and disinfection of the products.

Instructions

- **Workplace:**
Remove surface contamination with a paper towel.
- **Reprocessing:**
Recommended: reprocess a product immediately after use.
- **Cleaning& Servicing:**
Needed: water, detergent, spirits, microfiber cloth
 - Flush the surface with running water (<40° C), using a little detergent if necessary.
 - Also use spirits 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.
- **Autoclaving:**
The asepsis sets available from LABOMED contain rubber caps, sleeves and grips recommend for the following program for autoclaving:

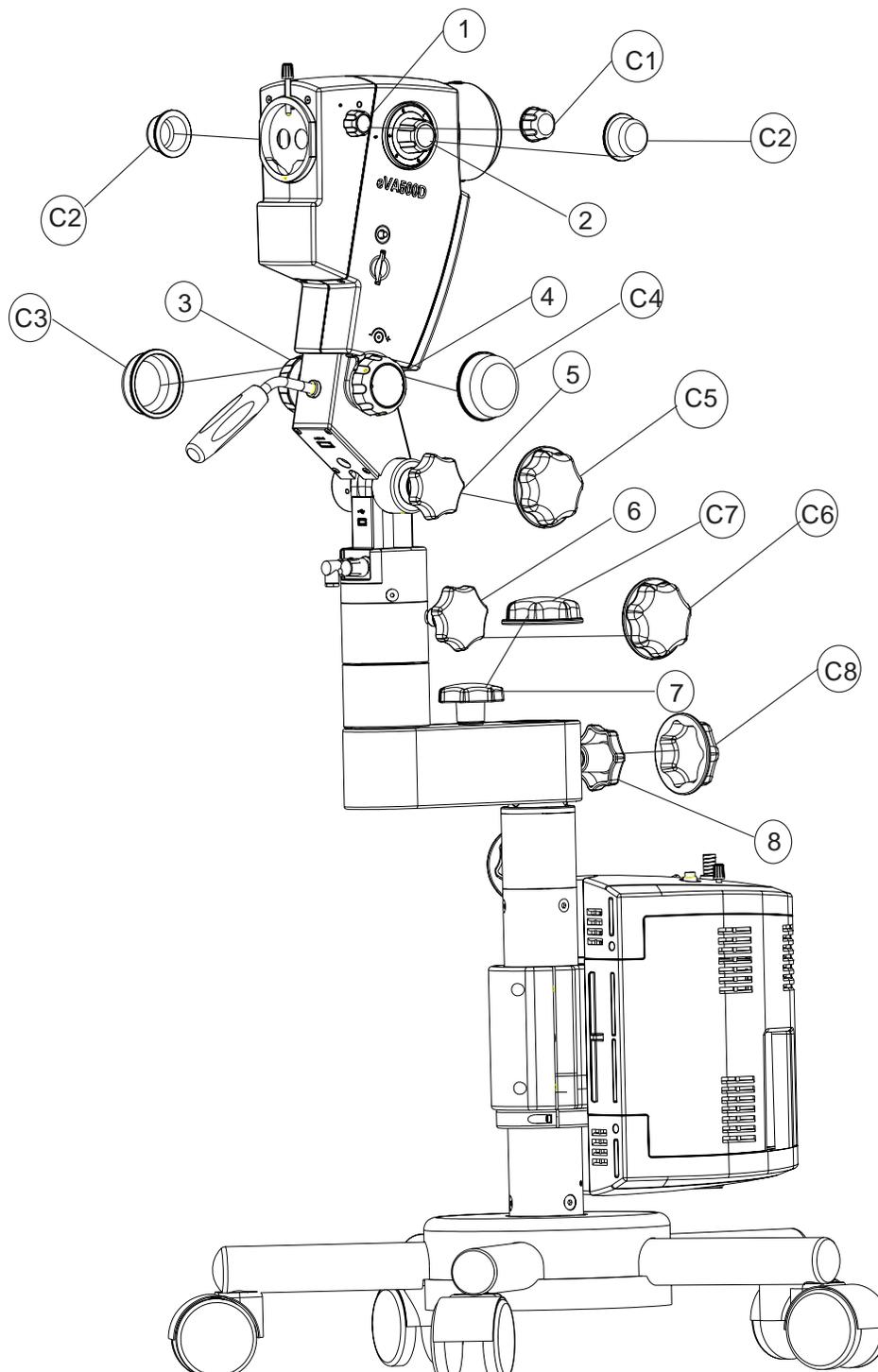
Temperature:	134° C
Time:	10 minute
Instrument:	Standard, Autoclave

There are also rubber autoclavable caps for the rotating knobs for aperture ①, magnification②, green filter ③, fine focusing ④, tilt locking ⑤, arm locking ⑥, Ez-lift ⑦, and swivel arm locking ⑧.

Autoclavable caps:

- (C1) Part no. 6122015-209
- (C2) Part no. 6168000-219
- (C3), (C4) Part no. 6168000-213
- (C5), (C6), (C7), (C8) Part no. 6168000-216

Schedule of Autoclavable caps



(Fig. 11)

13. 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

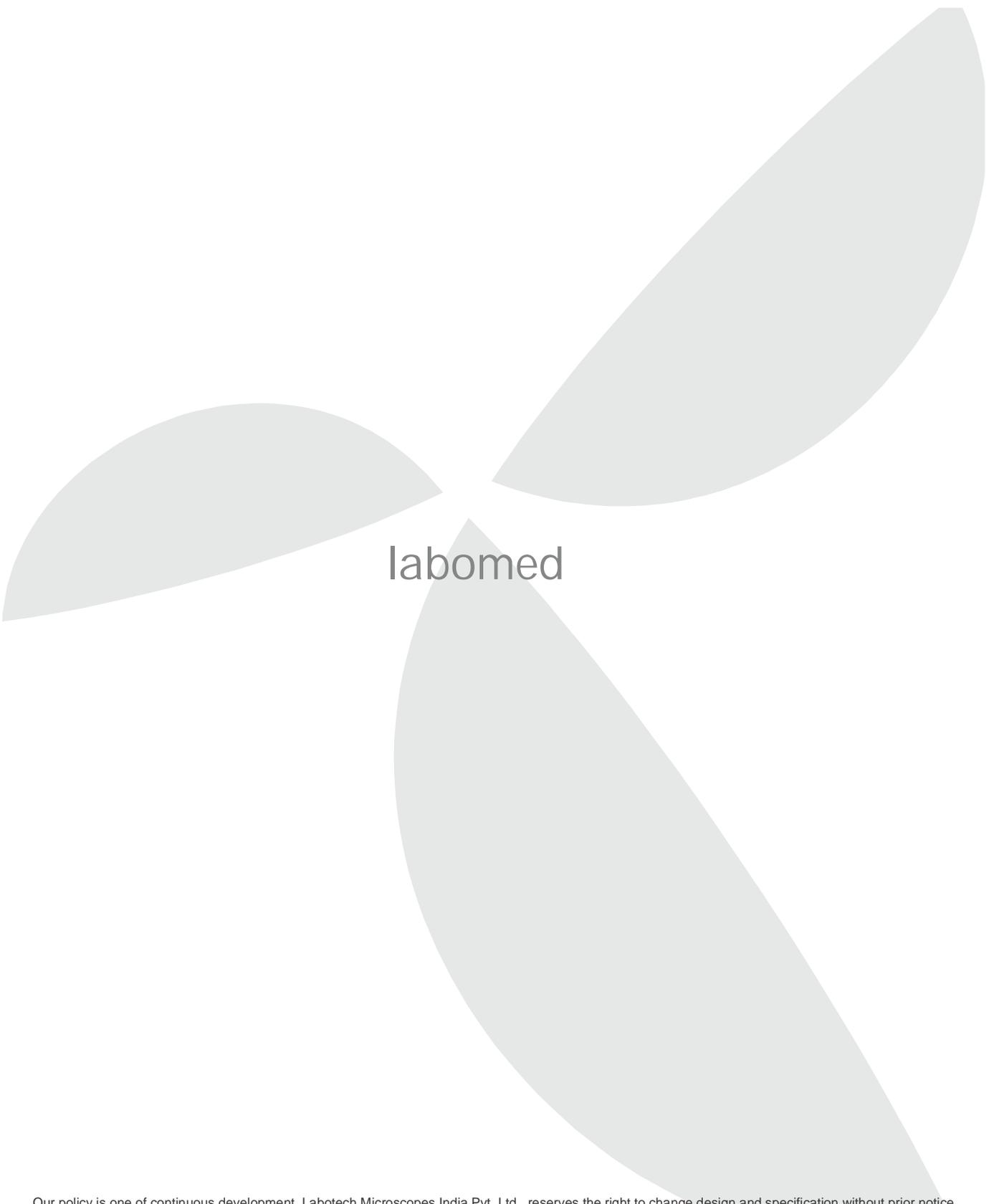
The Unit meets the essential requirements stipulated in Annex I to the **93/42/EEC** directive governing medical devices. The unit is marked with: **CE** and is compliance to **IEC 60601-1:2005 (3rd edition)**.

14.DISPOSAL

Disposal must comply with locally applicable laws & regulations

15. TECHNICAL SPECIFICATION

Item	Specification	
	eVA 500	eVA 500D
• Stand	Star Base Stands with S50 & E50 column, lockable wheels	Star Base Stands with S50 & E50 column, lockable wheels
• Observation tubes	Straight/Inclined 45°. Interpupillary distance 47-75 mm inclined tubes is provided with control knob for IPD adjustment.	Straight/Inclined 45°. Interpupillary distance 47-75 mm inclined tubes is provided with control knob for IPD adjustment.
• Eyepieces	Wide field 10x, 18mm FOV, focusable with retractable eye guards, diopter lock, anti-fungal	Wide field 10x, 18mm FOV, focusable with retractable eye guards, diopter lock, anti-fungal
• Achromatic Magnichanger	5 Step: 0.4x, 0.6x, 1.0x, 1.6x, 2.5x	5 Step: 0.4x, 0.6x, 1.0x, 1.6x, 2.5x
• Objective	f-300mm, high contrast aperture stop	f-300mm, high contrast aperture stop
• Built-in filters	Green positioned at mag-changer	Green positioned at mag-changer
• Light Source	LED 50W, lamp life up to 60,000 hours with built in Yellow filter	LED 50W, lamp life up to 60,000 hours with built in Yellow filter
• Power consumption	130 W max.	130 W max.
• Input voltage	100V-240V; 50/60 hz.	100V-240V; 50/60 hz.
• Digital Imaging	N.A	Integrated 5 MP Imaging Camera 1080p HDMI output USB v2.0 output for PC connectivity Integrated Capture Button Online capturing on integrated SD Card PixelPro* Camera Control Software



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Our policy is one of continuous development. Labotech Microscopes India Pvt. Ltd., reserves the right to change design and specification without prior notice.

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