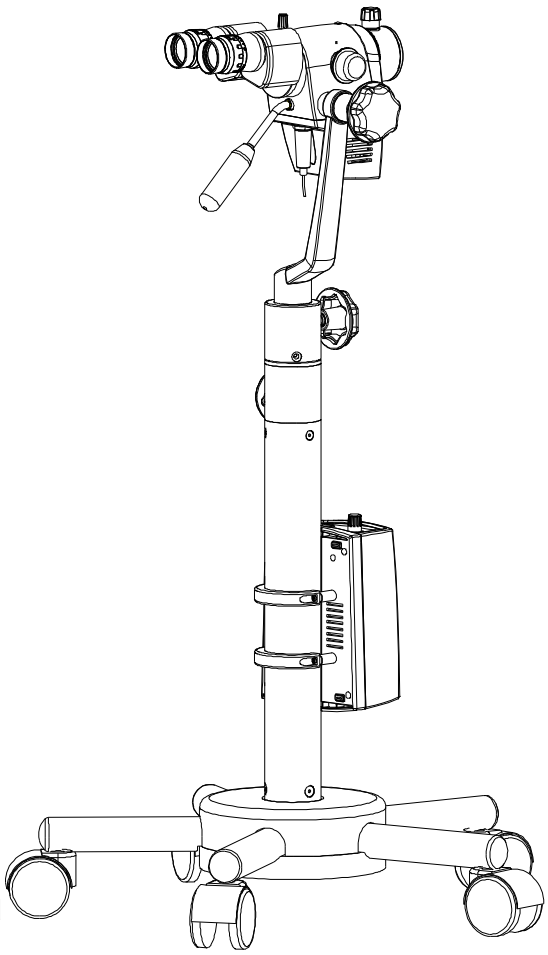
LABOMED®

Prima C/ Prima CS
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.

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List of Contents

1. INTRODUCTION

Congratulation on the purchase of your new Prima C/ Prima CS 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 Prima C / Prima CS 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, Immuno suppression such as HIV, abnormal appearance of the Cervix and forensic examination of a sexual assault.

Important general references

- **Preliminary notes**

LABOMED is renowned for providing innovative technologies and products in women's healthcare. PRIMA C / Prima CS colposcopes were developed in cooperation with practicing gynecologists. Experience, precision, and continuous manufacturing optimization has enabled LABOMED to became the leading manufacturer of colposcopic precision instruments, with the largest product range of colposcopes in the world.

- **Determination-Appropriate Use**

Only LABOMED accessories, bases, and source of light may be utilized with LABOMED colposcopes.

Restrictions, which are stipulated in the directions for use, are to be considered.

The device is designed for application in medical practices and/or clinics.

According to the stipulation of the MPG, colposcopes may be operated only by those persons who have been instructed in the expert handling of the device.

The proper installation and maintenance of the device are vital prerequisites before using the colposcope.

The user should check the functional stability and proper condition of the device before every procedure.

- **Indications for use**

A colposcope may be helpful in the following situation:

1. Major abnormality on pap smear
2. Persistent minimal abnormality on pap smear
3. Abnormalities of squamous or columnar cells
4. Persistence of an inflammatory appearance of the smear despite adequate treatment
5. Presence of keratinized cells suggestive of leukoplasia
6. Symptoms of metrorrhagia, in particular contact bleeding
7. Abnormalities appearance of cervix or vagina by naked eye examination
8. Evaluation after exposure to diethylstilbestrol(DES) or related drugs during embryogenesis
9. Monitoring after treatment of dysplasia, regardless of treatment method
10. Evaluation of anogenital condylomatosis
11. Evaluation of vulvo-perineal bowenoid papulosis
12. Preoperative evaluation before genital-tract surgery: hysterectomy, treatment of genital prolapse, cervicovaginal plastic surgery, etc.
13. Lesion noted on routine gynecologic examination

- **Contraindications for use**

The colposcope is a device for viewing the body from a distance and is not intended for patient contact. Because of this there are no contraindications for use of a colposcope.

- **How to read these operating instructions**
  These instructions are structured around the operation of the colposcope, from assembly to the finished system. Basic troubleshooting information is also provided. Our goal is to make these instructions easily understandable and technically feasible.

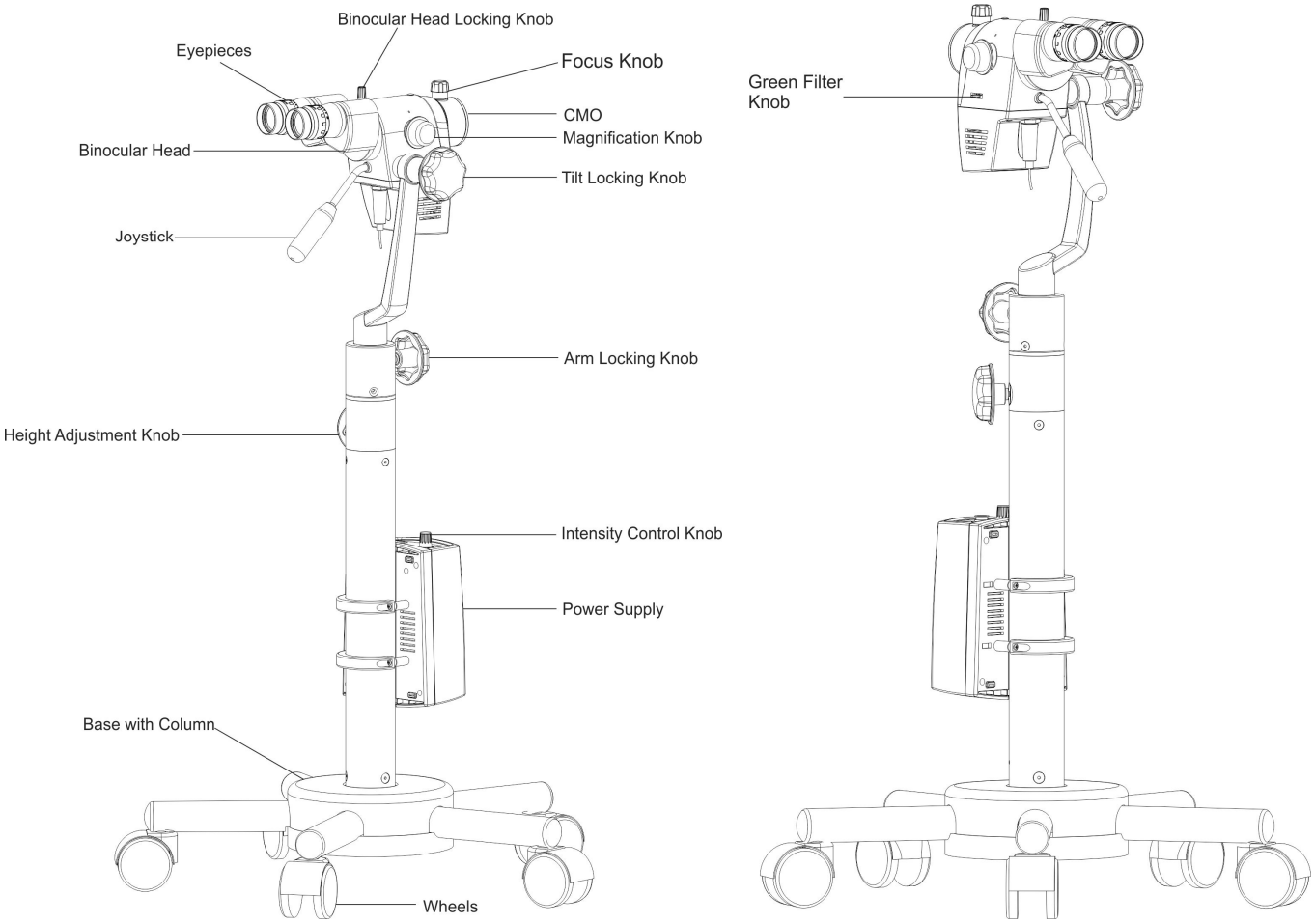
  The instruments contents follow the structure of a colposcope: head, base, accessories, electrics, maintenance and safety.

  The inside edge of each page is exclusively reserved for important key words, symbols and provides sufficient space for your personal notes.

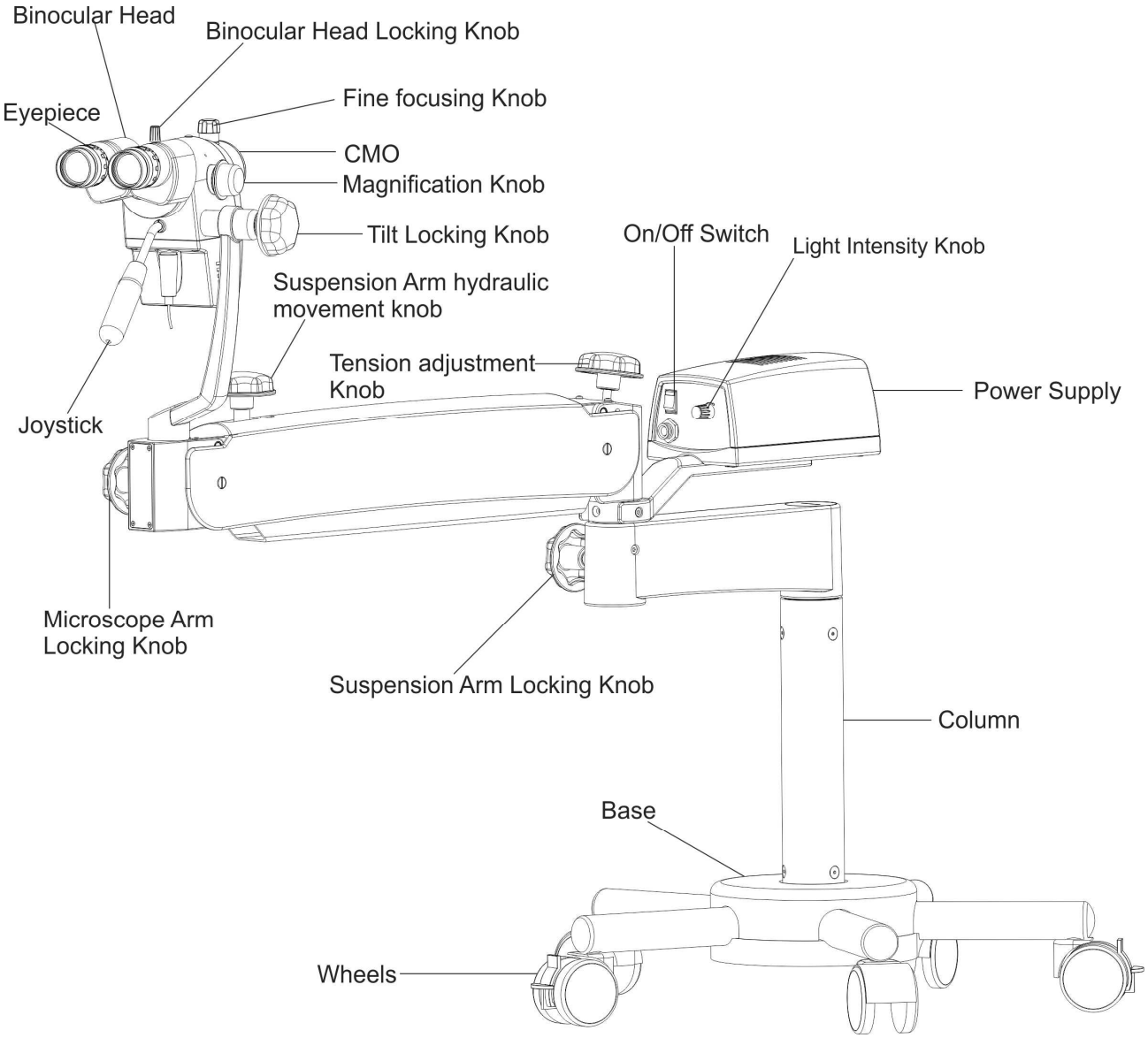
Prima C: Ergonomic stand for easy and accurate positioning. It has 9 vertical travels of 100 mm.

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

⚠ **Caution**: Height adjustment knob has a spring loaded mechanism to adjust colposcope height. Care must be taken to avoid injury to patient and user who is operating this knob.



Prima CS:


Binocular Head
Binocular Head Locking Knob
Eyepiece
Fine focusing Knob
CMO
Magnification Knob
Tilt Locking Knob
On/Off Switch
Light Intensity Knob
Suspension Arm hydraulic movement knob
Tension adjustment Knob
Power Supply
Joystick
Microscope Arm Locking Knob
Suspension Arm Locking Knob
Column
Base
Wheels

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 OTHERWISE 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 OTHERWISE 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 OTHERWISE DAMAGE TO THIS INSTRUMENT AND/OR INJURY TO THE OPERATOR OR PATIENT MAY OCCUR.

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

WARNING: THIS INSTRUMENT MUST BE PLUGGED IN TO AN OUTLET WITH AN EARTH GROUND. DO NOT REMOVE, DAMAGE OR DEFEAT THE EARTH GROUND CONNECTION NEITHER ON POWER INPUT CONNECTOR NOR ON THE POWER CORD SUPPLIED WITH THIS INSTRUMENT OTHERWISE 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 IF ADJACENT OR STACKED USE IS NECESSARY, THE EQUIPMENT OR SYSTEM SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION AND DESIRED OUTPUT.

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

WARNING: BECAUSE PROLONGED INTENSE LIGHT EXPOSURE CAN BE HARMFUL TO THE SENSITIVE TISSUES. THE USE OF THE DEVICE FOR EXAMINATION SHOULD NOT BE UNNECESSARILY PROLONGED, AND THE BRIGHTNESS SETTING SHOULD NOT EXCEED WHAT IS NEEDED TO PROVIDE CLEAR VISUALIZATION OF THE TARGET.

WARNING: THE USE OF ACCESSORIES OR CABLES OTHER THAN THOSE SPECIFIED, AND USE OF REPLACEMENT PARTS OTHER THAN SUGGESTED BY THE LABOMED, 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 THIS DOCUMENT.

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 OTHERWISE MUST BE TESTED TO APPLICABLE IEC OR ISO STANDARDS.

Warning Labels and Notes


Caution


Warning


Brightness control


Accompanying documents must be consulted

REF
Catalog number


Compliance to medical device directive 93/42/EEC


Protective earth


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


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

I O
Connection ON / OFF


Year of manufacture used on PRODUCT DATA PLATE


Alternating Current Power

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

Rx Only
Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

S/N
Serial Number

EC REP
Authorized European Representative


Waste of Electrical and Electronic Equipment


Accompanying Documents must be consulted.

Temperature Range

Directives and standards

CE Certification

The device is tested according to the specifications of the European Medical Device Directive [MDD] 93/42/EEC, dated 14th June 1993, and fulfills the necessary standards concerning the MPG Medical Product Law. All devices, which are manufactured by LABOMED, belong to Class I of non-invasive products, according to Appendix IX of EU Guideline 93/42/EEC. The Colposcopes are checked for compliance with the basic requirements according to Appendix I of Guideline 93/42/EEC and are provided with the CE mark which indicates agreement with the legal stipulations.

Quality Management

LABOMED has an established quality management system according to ISO 9001 since 13485 in January 2004. Regular internal auditing is the key for continuous improvements. Monitoring by authorized external auditors guarantees the agreement with the respective international standards.

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

- EN
- IEC

- For USA: FDA classification Class II
- ANSI/AAMI 60601-1:2005 (3rd edition) Compliance

- Please observe all applicable accidental prevention regulations.

- **Intended use**
  LABOMED colposcope Prima C and PRIMA CS 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 Prima C Colposcope is purely for intended Operative and Diagnostic medical use. No contact is to be made between the patient and the device.

- **Configuration:**

Microscope	Catalogue no.
PRIMA C	6128000
PRIMA CS	6128100

3. CONDITION OF MATERIAL AT TIME OF SUPPLY

The appliance is delivered in 6 assembled groups:

- Mobile supporting Base
- Column (S40 0r E40)
- Illumination box with integrated electrical power supply
- Microscope Arm
- Microscope Head (Inclined or Straight)

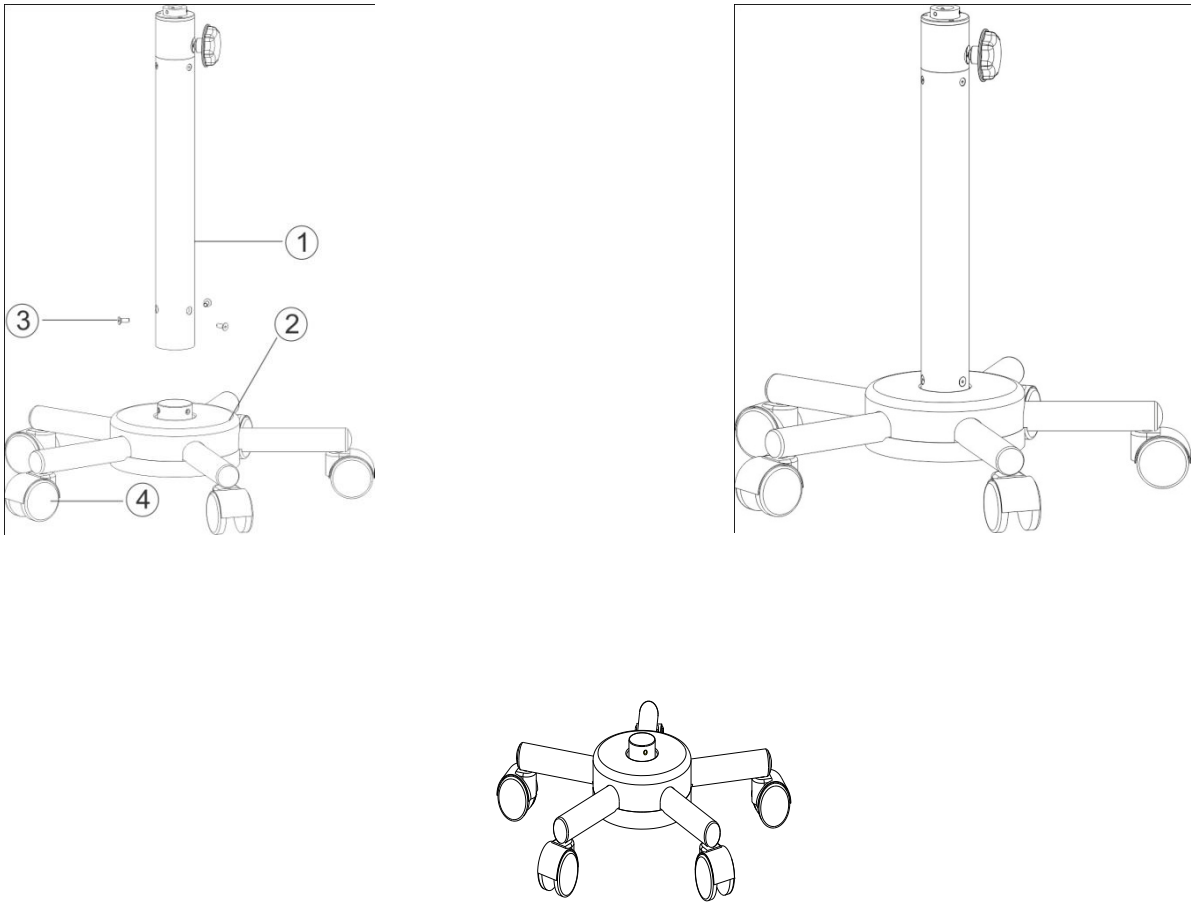
Fasteners are enclosed in the packing box.

4. INSTALLATION INSTRUCTIONS

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

- Insert column① into 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)

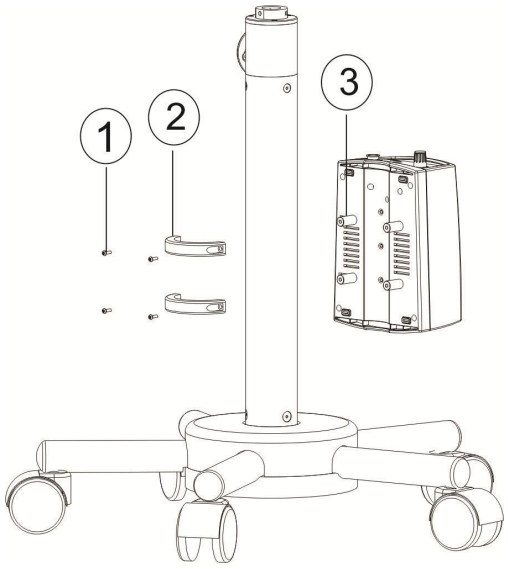
- **Indication:**
  The colposcope Prima C can be mounted on either of the two mobile stands (E40 & S40). The type is to be specified at the time of purchase.



(Fig. 1)

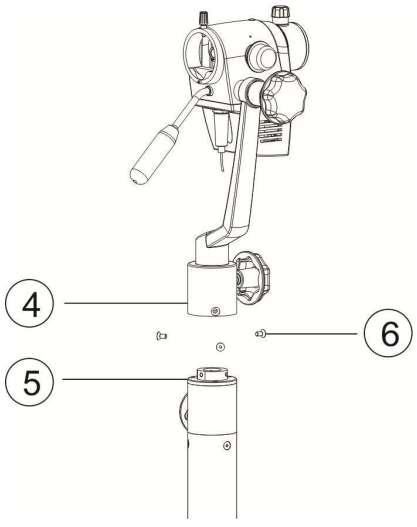
4.2 MOUNTING OF APPLIANCE

- 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).



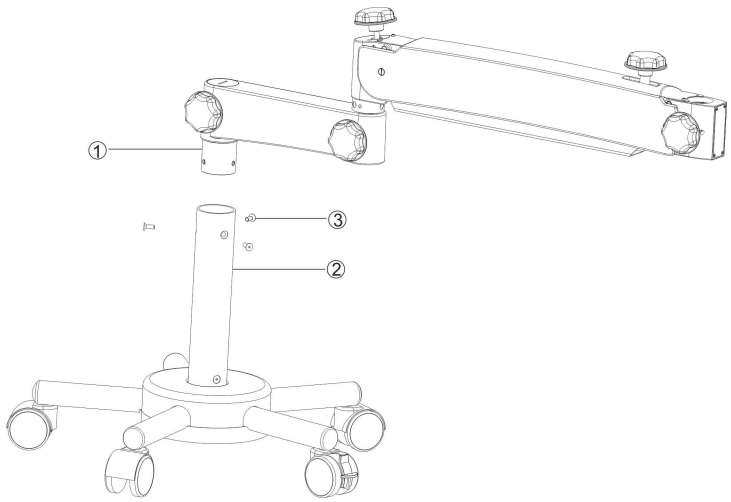
(Fig 2.1)

- Insert the arm ④ of the microscope head on the top of the column ⑤.
- Screws ⑥ to be tightened from both sides of the head arm④.



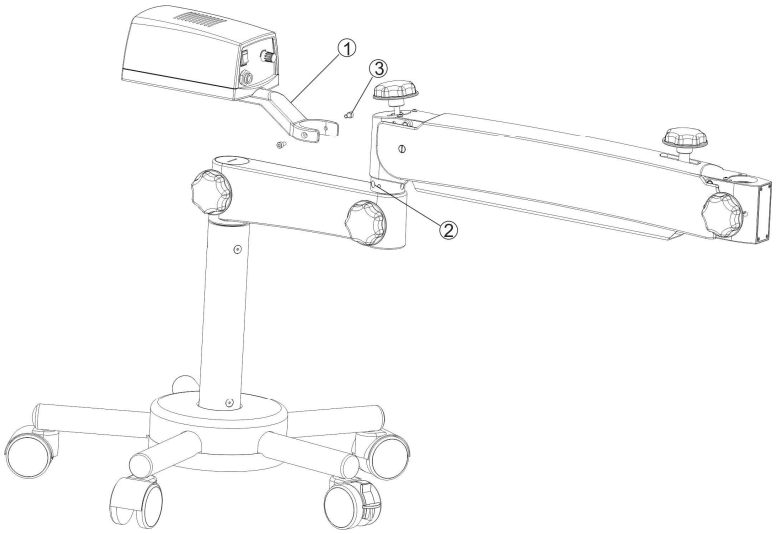
(Fig. 2.2)

- Mount swivel with suspension arm assembly ① on column ② by tighten the three screws ③ as shown in figure 2.3.



(Fig. 2.3)

- Mount illumination box ① with column on by tighten the screws ③ in between the swivel and suspension arm as shown as ②. (Refer figure 2.4).



(Fig. 2.4)

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.

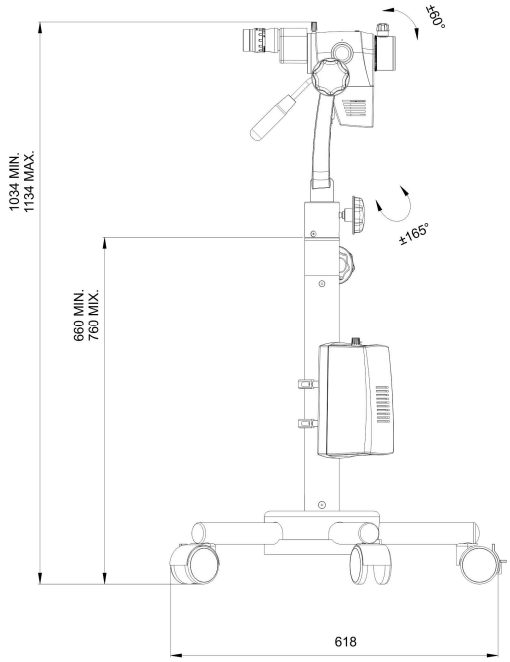
5. DIMENSIONS & WEIGHT (Fig. 3 & 3a)

E40 – **Colposcope** with roller stand

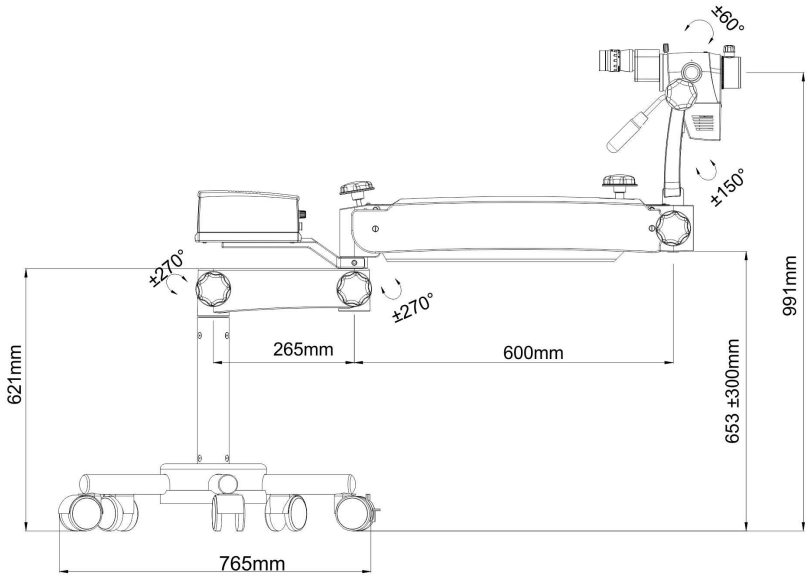
Total weight: Approx. 45 kg.

S 40 – Colposcope with roller stand

Total weight: Approx. 44 kg.



(Fig. 3) Prima C



(Fig. 3a) Prima CS

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 page no. 17 below.

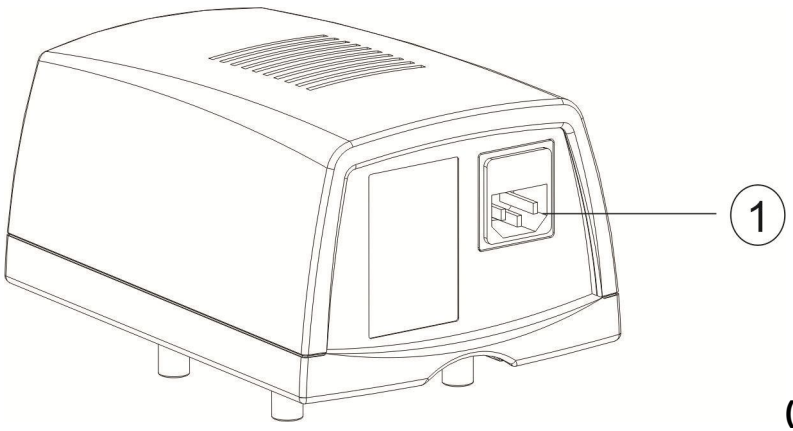
Note: Power supply is designed with universal input 100V-240V AC, 50/60Hz. To plug in follow instruction on electrical label provided at back of illumination box as shown in figure number 4 below.

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 electronical label for correct fuse replacement
- Attention: It is only allowed to change the fuses against fuses of the same type.



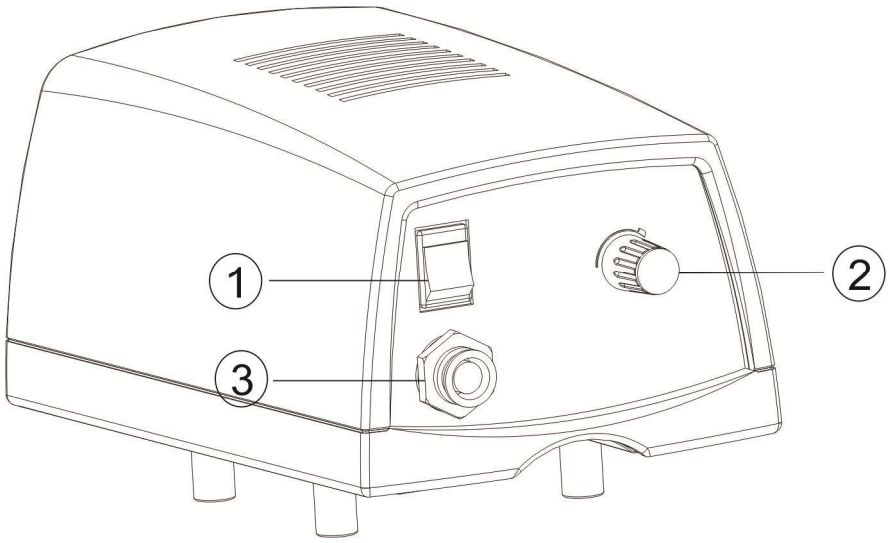
(Fig. 4)

7. OPERATING INSTRUCTIONS

7.1 **On / off switch** shown as ① in fig. 5 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 **BRIGHTNESS CONTROL** shown as ② facilitates variation in light intensity is made by rotating knob.

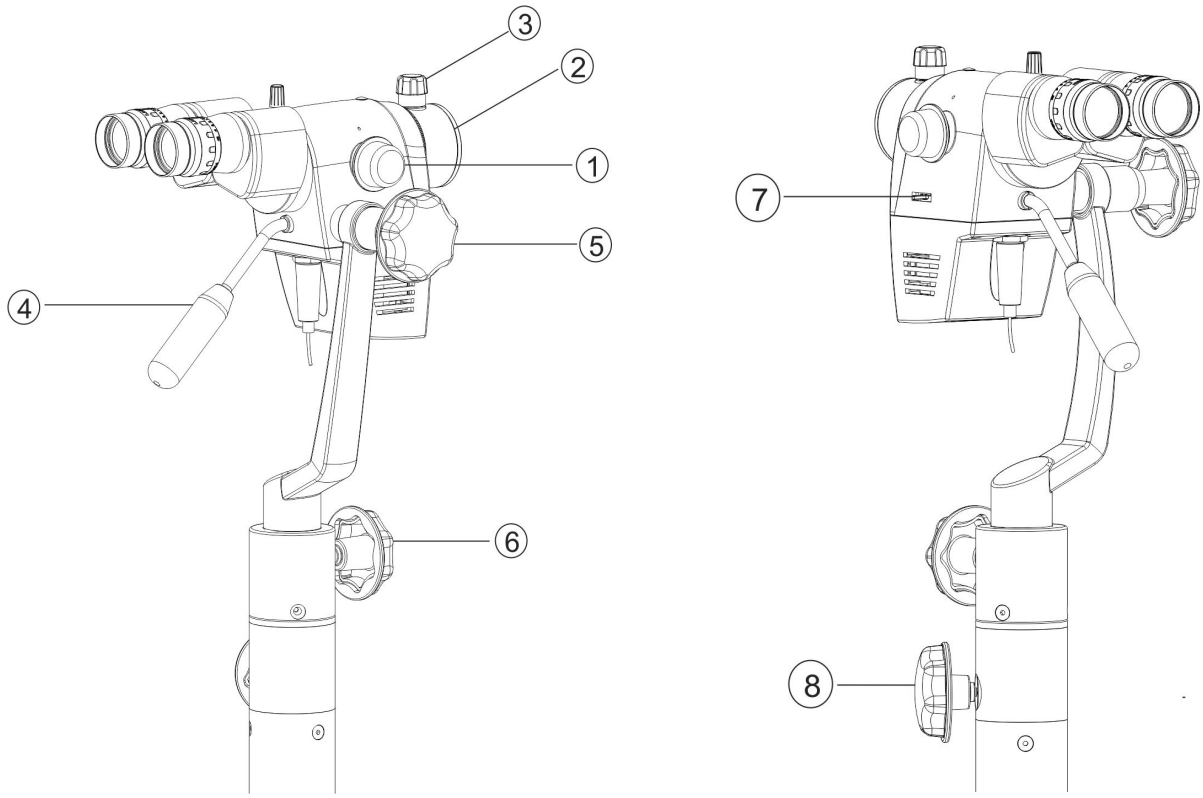
Note: To maximize LED life, switch off the microscope when not in use.



(Fig. 5)

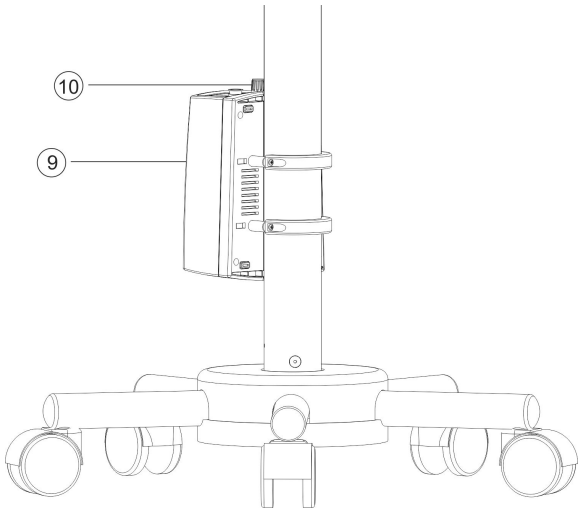
8. CONTROL ELEMENTS (Fig. 6.1 ,6.2 & 6.3)

- 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.
- Common Main Objective (CMO) ②.
- Fine focusing knob ③.
- Joystick to tilt the head arm forward and backward ④.
- Head arm locking knob ⑤.
- Knob to lock the arm ⑥.
- Knob to swing in green filter ⑦.
- Column height adjustment knob ⑧.



(Fig. 6.1)

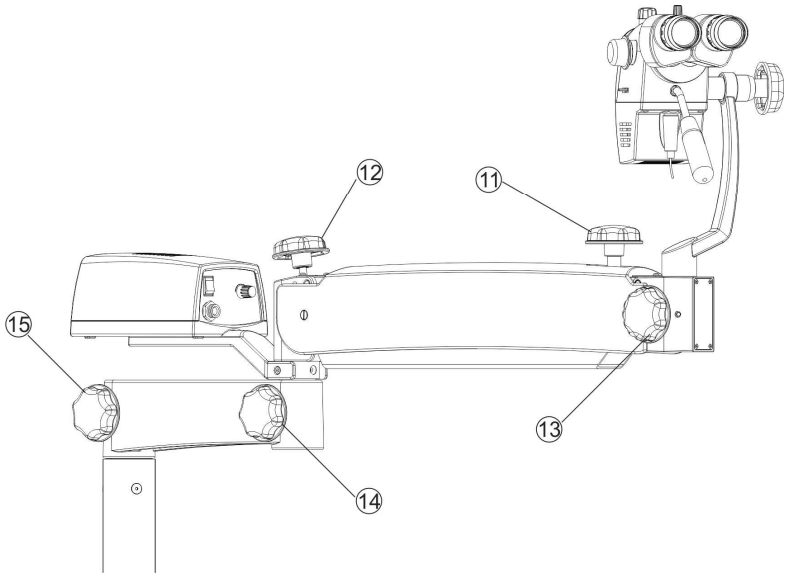
- Power Supply Box ⑨.
- Knob for brightness control ⑩.



(Prima C)

(Fig. 6.2)

- Suspension arm hydraulic movement knob ⑪.
- Tension adjustment knob ⑫.
- Microscope arm locking knob ⑬.
- Suspension arm locking knob ⑭.
- Swivel arm locking knob ⑮.



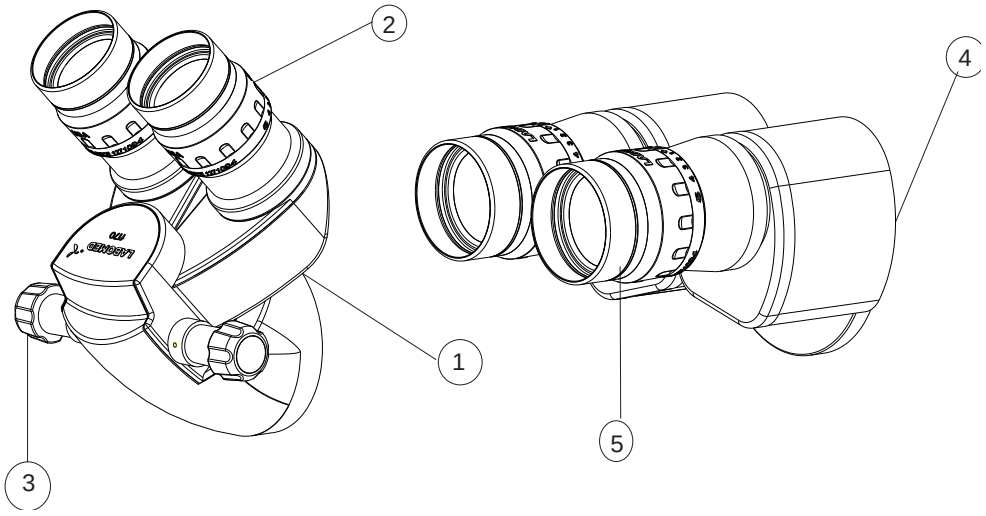
(Prima CS)

(Fig. 6.3)

9. INSTRUCTIONS FOR USING THE MICROSCOPE

a) ADJUSTMENT OF INTERPUPILLARY DISTANCE (Fig. 7)

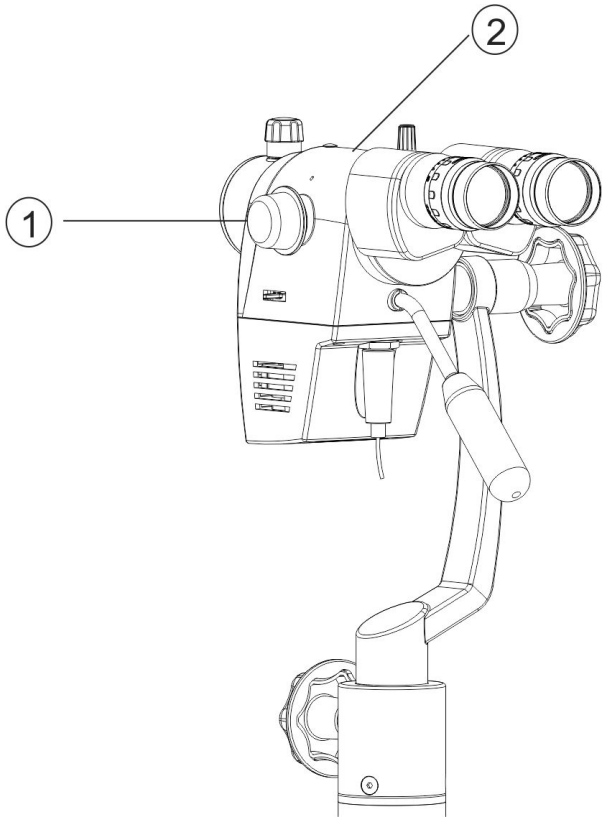
- Turn the microscope in working position.
- Inclined tube 45°①: Adjust eyepieces ②to the required IPD by turning the lateral knob③.
- Straight tube④: Adjust eyepieces ⑤ by moving the binocular tube as per your requirement.



(Fig. 7)

b) CHANGING THE MAGNIFICATION (Fig. 8)

- 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. 8)

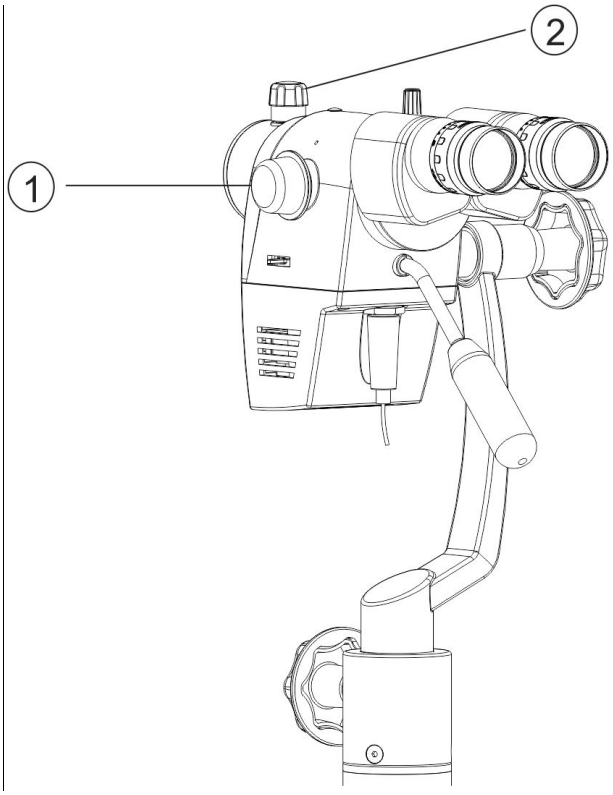
c) HOW TO FOCUSE THE OBJECT (Fig. 8.1)

- 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 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.

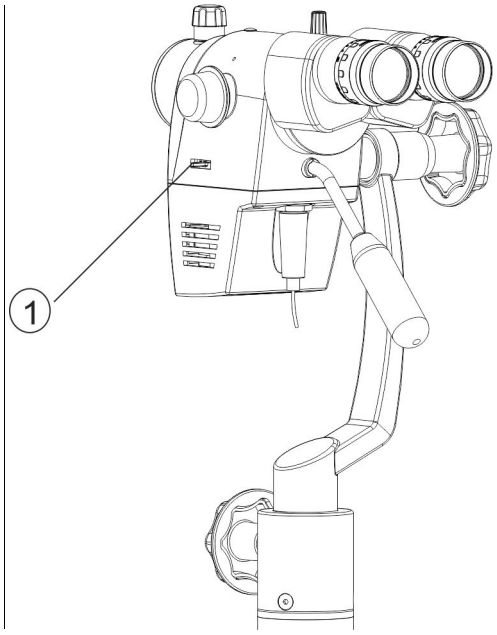
- On focusing the region of interest, change magnification through the magnification changing knob.



(Fig. 8.1)

d) Red free image observation (Fig. 8.2)

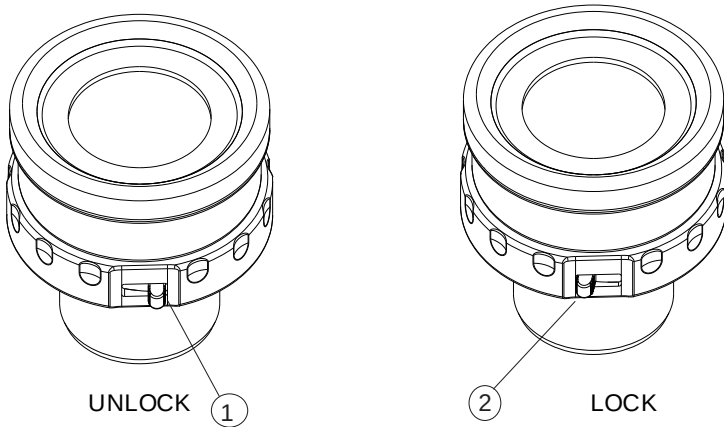
- Swing filter knob (1) to swing in or swing out the red free (Green) filter. This will help in filtering the red tissue in the image being observed and will highlight the enhance vessel image and the vascular morphology.



(Fig. 8.2)

e) EYEPIECES WITH DIOPTER LOCKING FACILITY (Fig. 8.3)

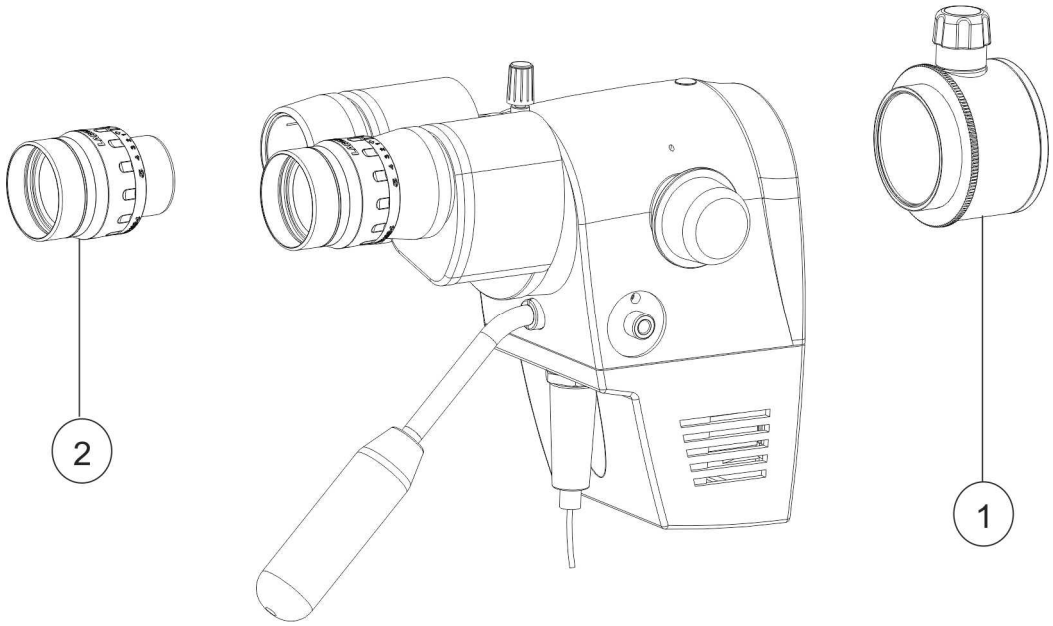
- LABOMED eyepieces have a unique locking facility.
- Diopter lock can be released by moving the slider on eyepiece ① toward right.
- You can adjust the diopter settings as per your vision correction.
- Once the diopter adjustment is done as per individual, the movement can be set and locked by moving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



(Fig. 8.3)

10. CHANGING THE OBJECTIVE / EYE PIECES(Fig. 9)

- 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. 9)

11. 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 12months. 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:**

o Keep accessories away from dust when not in use, e.g. protect them from dust cover.
o Remove dust with a pneumatic rubber bulb and soft brush.
o Use special optics cleaning cloths and pure alcohol for cleaning lenses and eyepieces.
o Protect your colposcope from moister, fumes, acids and cosmetic materials. Do not store chemicals close to the instrument.
o 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.
o Protect the microscope from oil and grease. Never oil or grease the guide surfaces or mechanical parts.
o Remove coarse contamination using a damp disposable cloth.
o Use disinfectants based on the following ingredients: aldehydes, alcohols, quaternary ammonium compounds.
o 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.
o Do not clean products with optical components in a cleaning/disinfecting device or ultra sound bath.
o **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:

o Keep optical part clean.
o Use and store them in a clean environment only.
o Store under UV light when not in use.
o Use in continuously climate-controlled rooms only.
o Keep moister 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
  - o Flush the surface with running water (<40° C), using a little detergent if necessary.
  - o Also use spirits to clean optical components.
  - o Dry optical components using a microfiber cloth; dry the rest of the product using a paper towel.
  - o 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 magnification①, tilt locking ②, arm locking ③, height adjustment knob ④.

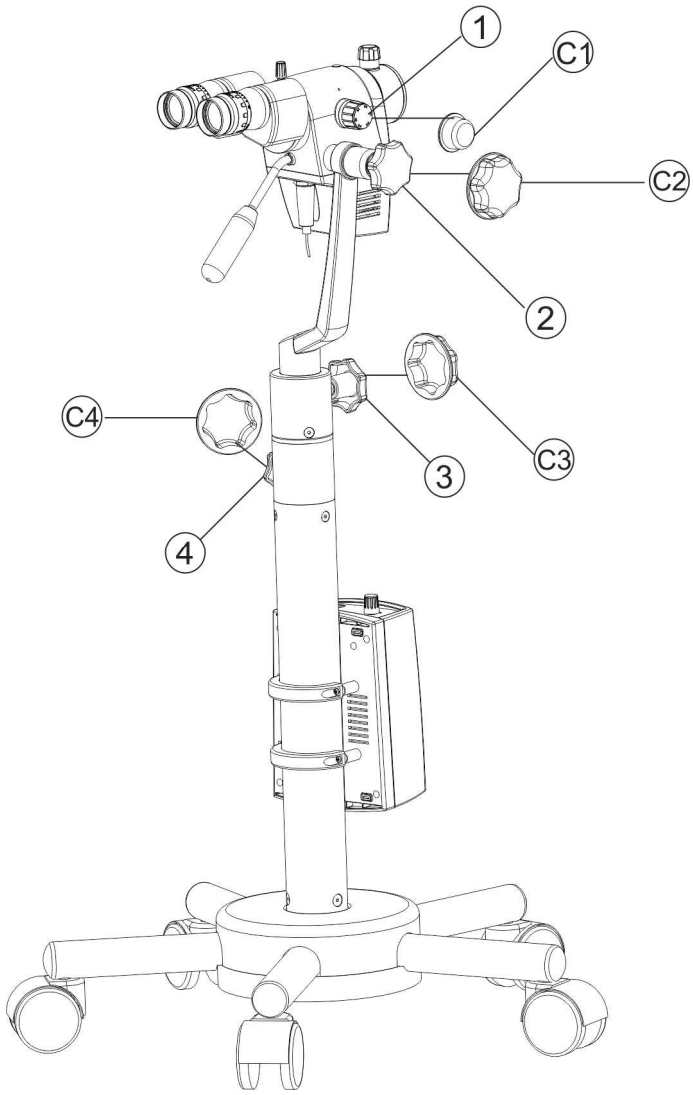
Autoclavable caps:

(C1) Part no. 6122015-209

(C2) Part no. 6168000-219

(C3), (C4) Part no. 6168000-213

Schedule of Autoclavable caps



(Fig. 10)

12. 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

13. DISPOSAL

Disposal must comply with locally applicable laws & regulations

14. TECHNICAL SPECIFICATION

Prima C

- Star Base Stand & Column, lockable wheels.
- Straight Observation tube, interpupillary distance 50-75mm. **Optional:** 45° inclined.
- WF 10/18mm FOV, focusable eyepieces with retractable eye guards, diopter adjustment +/- 5mm and diopter lock. **Optional:** WF 12.5x/18mm.
- 5-step magnification: 0.4x, 0.6x, 1.0x, 1.6x, 2.5x.
- F-300mm objective. **Optional:** f-400mm.
- Built-in-green filter
- Inbuilt 9W LED
- 15W max power consumption.
- 100V-240V; 50/60 hz voltage input.

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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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