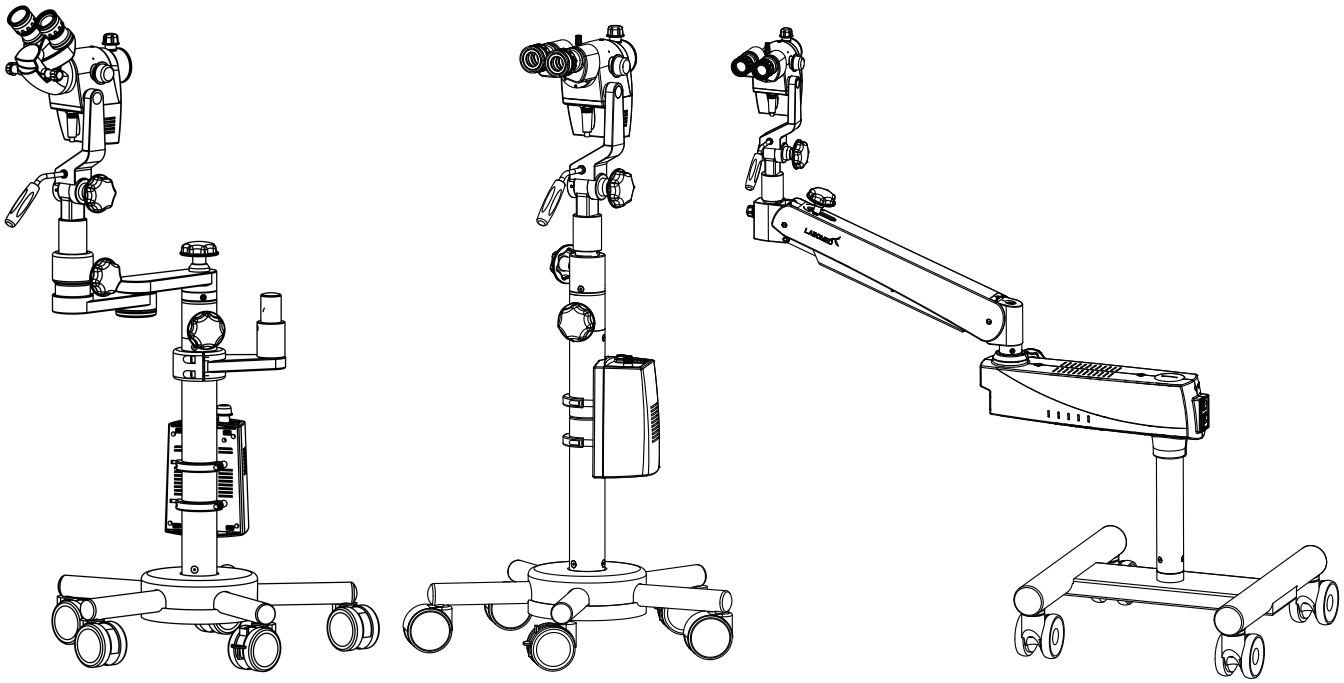
LABOMED
ideas for vision

Prima C/ Prima CS/ Prima C Plus
MICROSCOPE

User Manual



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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1. INTRODUCTION

Congratulation on the purchase of your new Prima C/ Prima CS / Prima C Plus Microscope.

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/ CS/ C Plus Microscope 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 Microscope 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, Immune suppression such as HIV, abnormal appearance of the Cervix and forensic examination of sexual assault.

INTRODUCTION (continued)

IMPORTANT GENERAL REFERENCES

Preliminary notes

LABOMED is renowned for providing innovative technologies and products in women's healthcare. PRIMA C / Prima CS/ Prima C Plus microscopes 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 microscopes in the world.

Determination-Appropriate Use

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

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 (German Medical Device l aw), microscopes may b e 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 Microscope.

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

☞ Any serious incident associated with this device should be reported to Labo America, Inc. USA and to your national health agency.

Indications for use

A Microscope 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 embryo genesis
9. Monitoring after treatment of dysplasia, regardless of treatment method
10. Evaluation of anogenital condylomatosis
11. Evaluation of vulva-perinea bowenoid papulosis
12. Preoperative evaluation before genital-tract surgery: hysterectomy, Treatment of genital prolapse,cervico vaginal plastic surgery, etc.
13. Lesion noted on routine gynecologic examination

INTRODUCTION (continued)

Contraindications for use

The Microscope 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 Microscope.

How to read these operating instructions

These instructions are structured around the operation of the Microscope, from assembly to the finished system. Basic troubleshooting information is also provided. Our goal is to make these Instructions easily understandable and technically feasible.

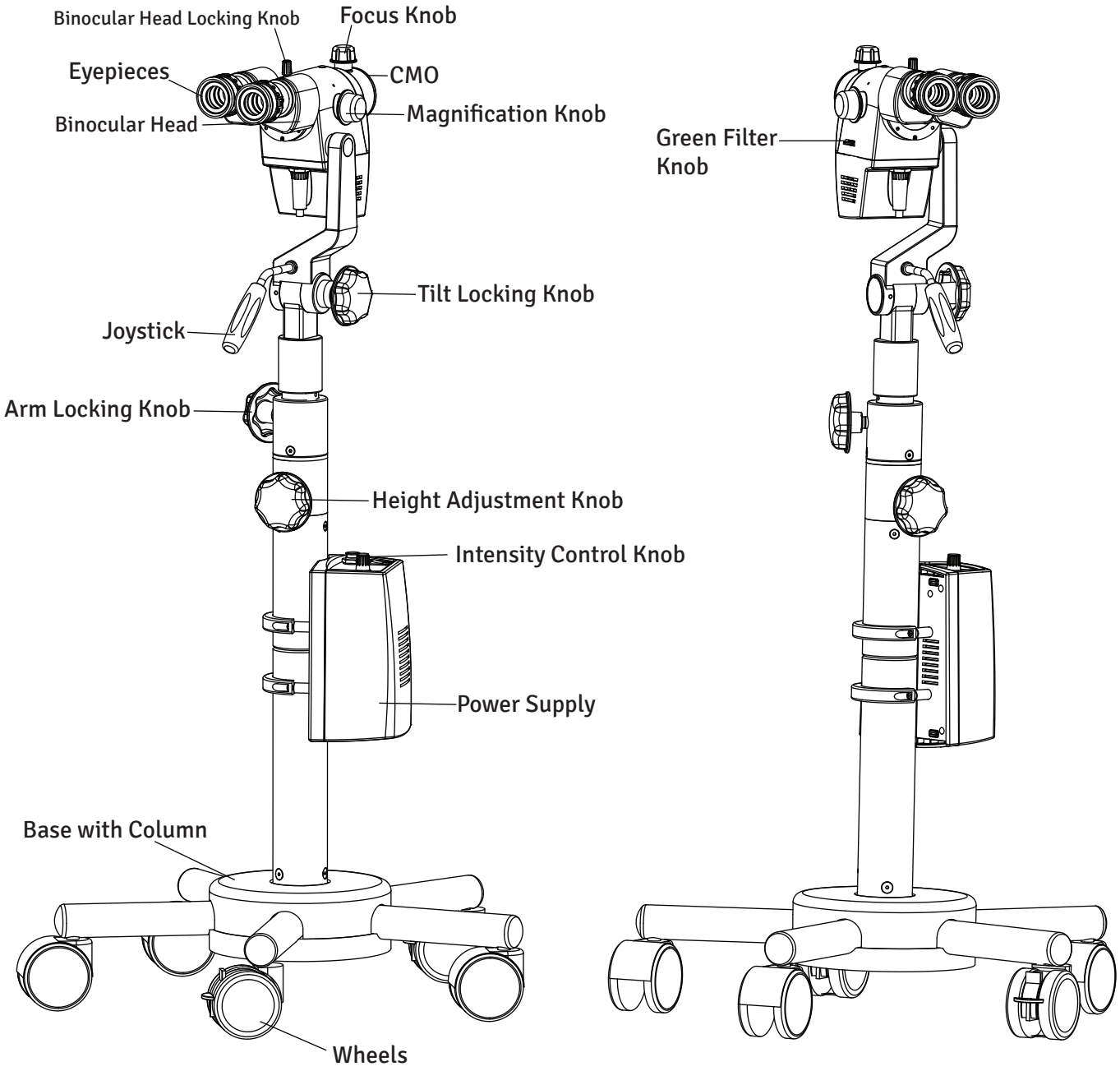
The instruments contents follow the structure of a Microscope: head, base, accessories, electrics, Maintenance and safety.

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

INTRODUCTION (continued)

Prima C:
Ergonomic stand for easy and accurate position. It has a vertical travel of 100mm.

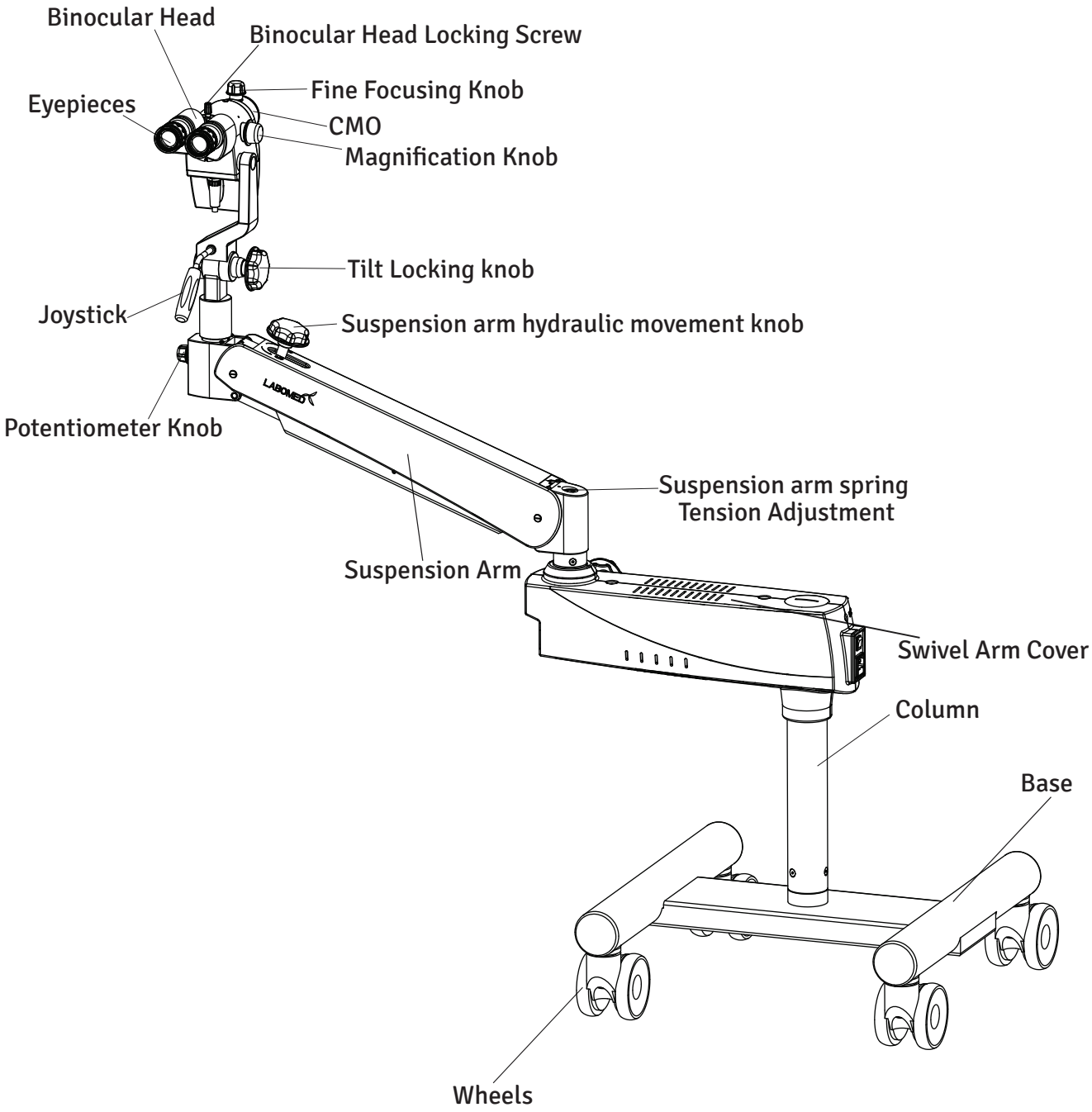
Control knob helps user in achieving the desired height by slightly loosening the swivel arm locking knob and then re-clamping after getting the required height.



INTRODUCTION (continued)

Prima CS:

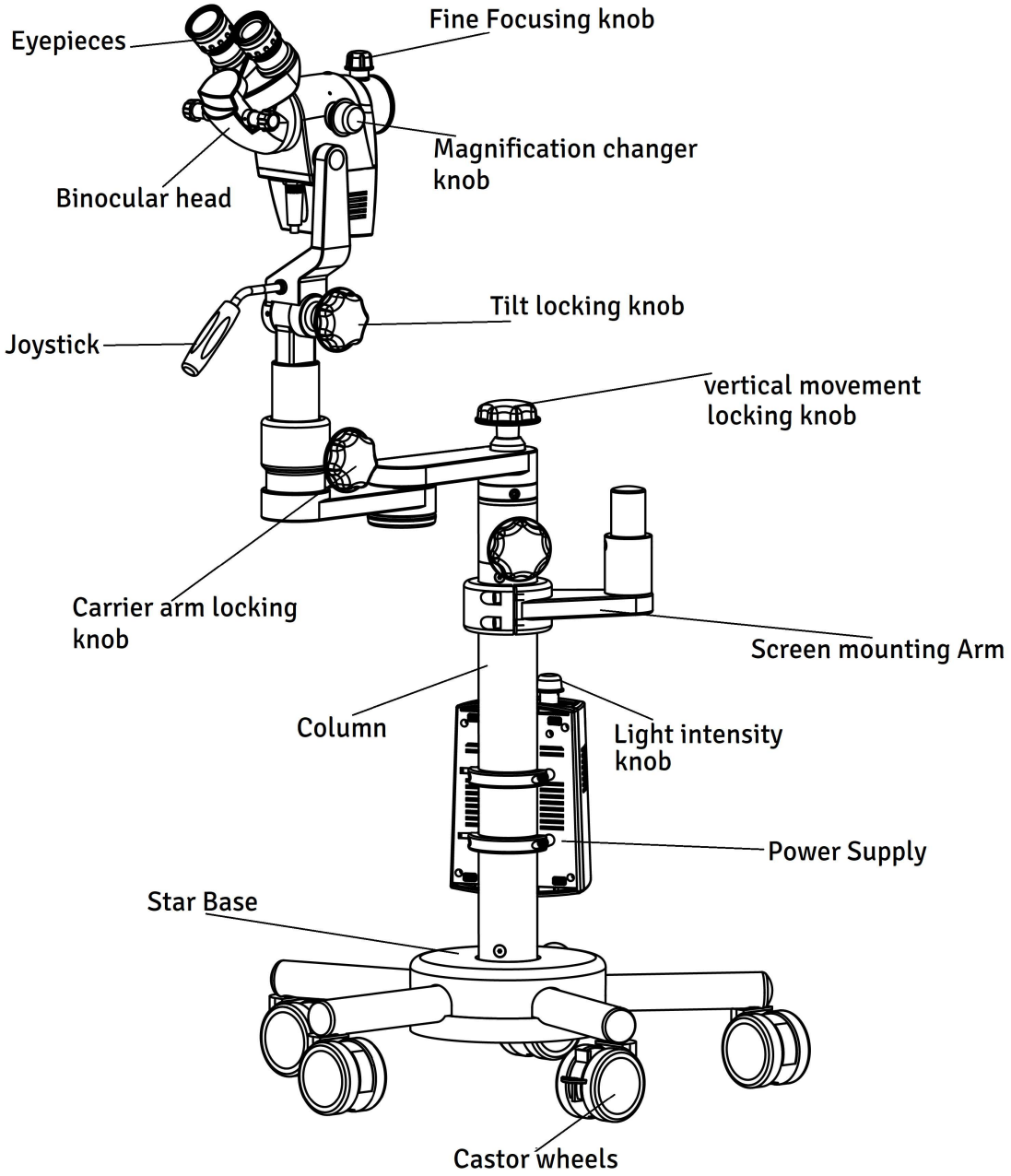
Microscope can be positioned easily with the help of a suspension arm within a vertical travel range of 500mm. It can be maneuvered easily with the help of a 980mm long pentographic arm as per user & patient comfort. When not in use, Microscope can be folded easily over the main body to store compactly.



INTRODUCTION (continued)

Prima C Plus:
Ergonomic stand for easy and accurate position. It has a vertical travel of 100mm and horizontal extender arm movement is 400mm.

Vertical movement locking knob helps user in achieving the desired height by slightly loosening the same and then re-tighten after getting the required height.



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.
- 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: 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 TECHNOLOGIES.

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 OR UPS 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: 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 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.

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.

WARNINGS & CAUTIONS (continued)

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: 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.

CAUTION: HEIGHT ADJUSTMENT KNOB HAS A SPRING LOADED MECHANISM TO ADJUST Microscope HEIGHT. CARE MUST BE TAKEN TO AVOID INJURY TO PATIENT AND USER WHO IS OPERATING THIS KNOB.

CAUTION: DEVICE SHOULD NOT BE OPERATED WITHOUT SILICONE COVERS FOR HANDLES AND ALL KNOBS.

WARNING LABELS AND NOTES


Caution


Warning


Brightness control


Accompanying documents must be consulted

REF Catalog number


Compliance to medical device Regulation (EU) MDR 2017/745


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- content 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.

SN Serial Number

EC REP Authorized European Representative


Waste of Electrical and Electronic Equipment


Accompanying Documents must be consulted.



Temperature Range

MD Medical Device


Max. Safe Load 9 Kg

IP 20 **Ingress Safety Protection**

WARNING LABELS AND NOTES

DIRECTIVES AND STANDARDS

CE Certification

The device is subjected to conformity assessment procedure complying with Article 52 (7) and technical documentation accordance to Annexure II and III of council regulation (EU) 2017/745. These Devices are Class 1 (without a measuring function, non-active and non-invasive) per Rule 1 annex VIII of the regulation MDR 2017/745. All the colposcopy provided with the CE mark indicates agreement with the legal Stipulations.

QUALITY MANAGEMENT

LABOMED has an established quality management system according to 13485:2016 and USFDA 21 CFR 820 CGMP requirements. 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 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 8600-5 First edition 2005-03-15 Optics and phonetics-Medical endoscopes and endotherapy devices Part 5: Determination of optical resolution of rigid endoscopes with optics.
- ISO 13485 quality management systems approved by UL(notified body).
- ISO 14971 Risk management to medical devices.

DIRECTIVE / REGULATIONS

- IEC 60601-1-3.1 edition (2012)
- IEC 60601-1-2 4th edition (2014)
- EN 55011:2016
- MDR 2017/745

CLASSIFICATIONS

- For Europe, per MDR 2017/745, the unit is a Class I instrument Per Annex VIII Rule 13
- For the United States, the FDA classification is Class II (510K Not Applicable).
- Please observe all applicable accident prevention regulations.
- IP Code - IP 20

INTENDED USE

LABOMED Microscope Prima C/CS/C Plus 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/CS/C Plus Microscope is purely for intended Operative and Diagnostic medical use. No contact is to be made between the patient and the device.

CONFIGURATIONS

Microscope	**Catalogue No.**
PRIMA C	6128000
PRIMA CS	6128600
PRIMA CPlus	6128900

3. CONDITION OF MATERIAL AT TIME OF SUPPLY

PRIMA C

The appliance is delivered in 6 assembled groups:

- Mobile supporting Base (Assembled) as shown in Fig. 1. Page 12
- Column (as shown in part 1. page 12)
- Illumination box with integrated electrical power supply (Refer Fig. 2.1 Page 13)
- Microscope Arm (Refer Fig. 2.2 Page 13)
- Microscope Head with Eyepieces (Inclined or Straight) Refer Fig. 2.13 Page 27

Fasteners are enclosed in the packing box.

PRIMA CS

The appliance is delivered in 5 C Boxes:

Three Boxes containing
- Wheel Support Base (Left)
- Wheel Support Base (Right)
- Centre Support Base

One Box containing
- Column
- Microscope Arm with integrated illumination box

One Box containing
- Carrier Assembly
- Microscope Head (Inclined or Straight)
- Eyepieces

Fasteners are enclosed in the packing box.

PRIMA C Plus

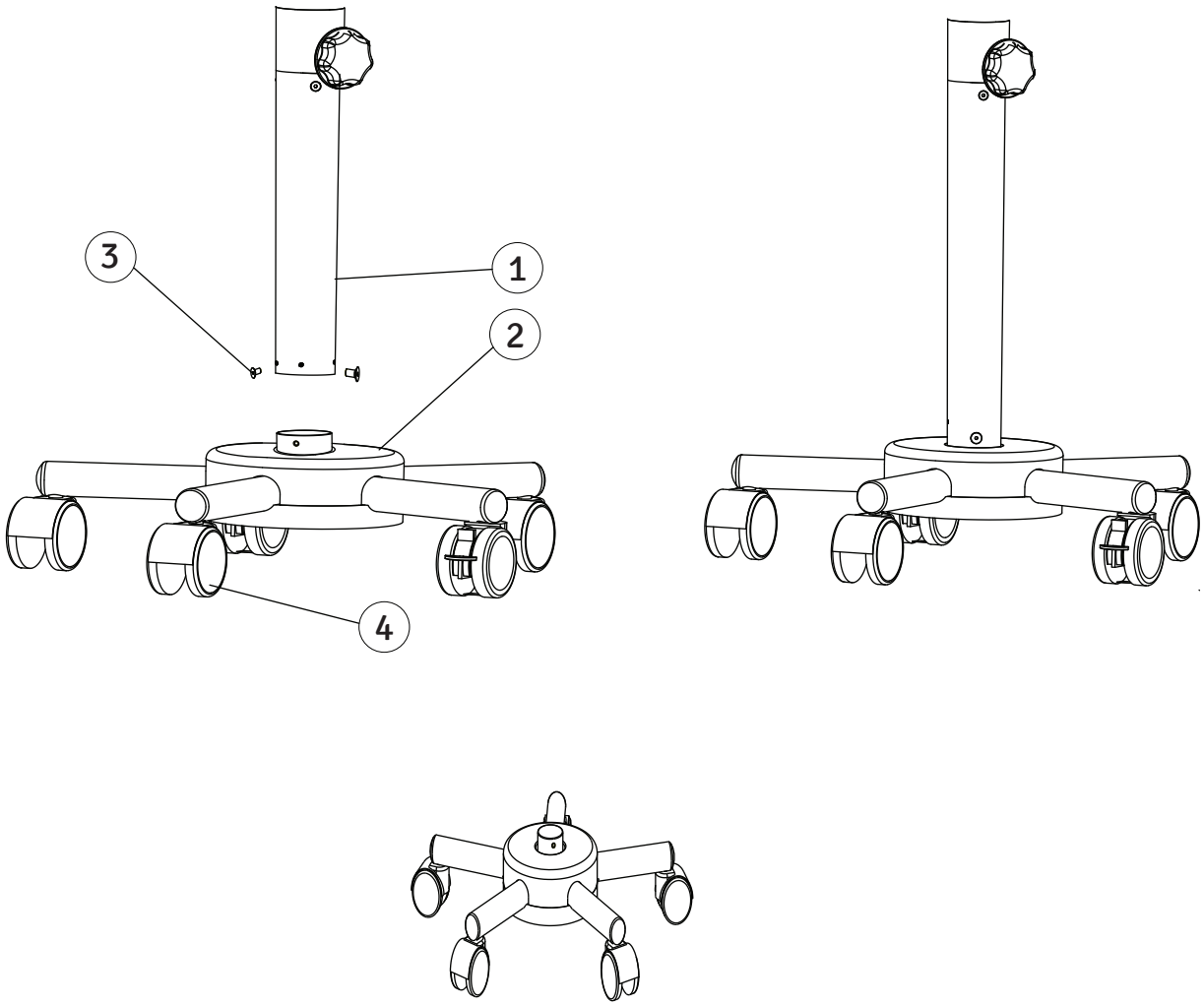
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- Illumination box with integrated electrical power supply (Refer Fig. 2.1 Page 13)
- Microscope Arm (Refer Fig. 2.2 Page 13)
- Microscope Head with Eyepieces (Inclined or Straight) Refer Fig. 2.13 Page 27

4. INSTALLATION INSTRUCTIONS OF PRIMA C

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).

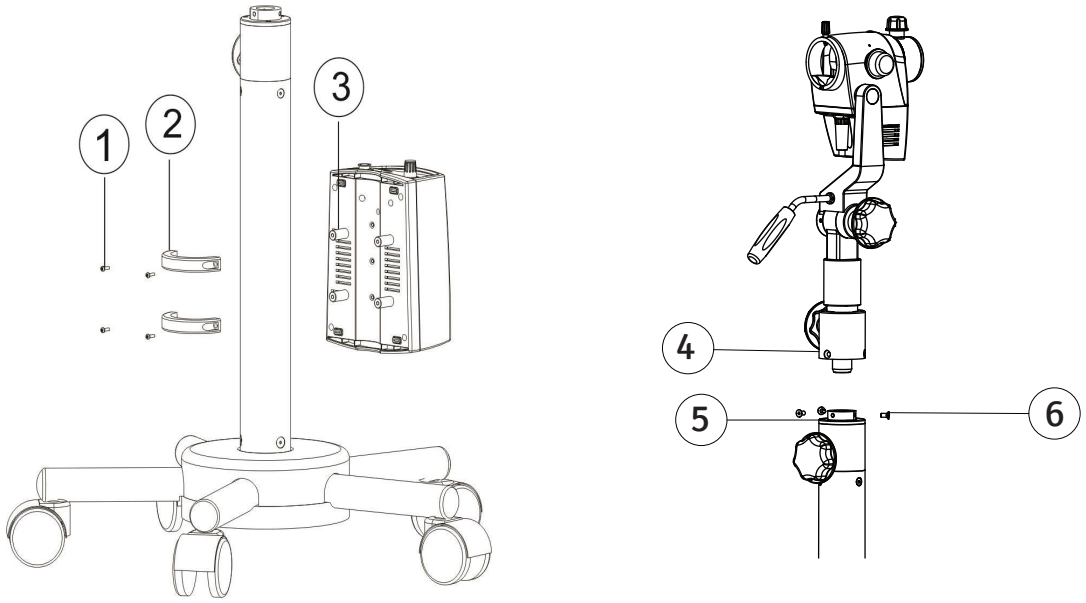


(Fig. 1)

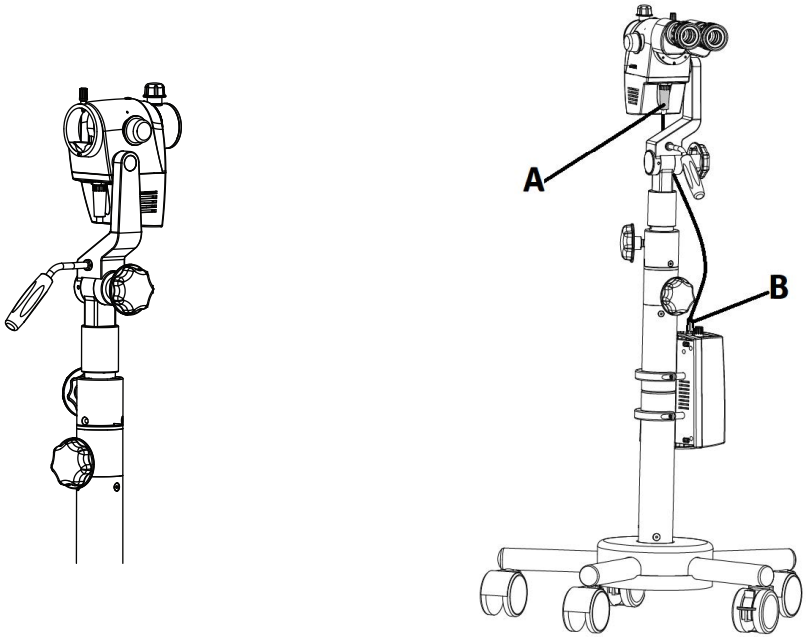
INSTALLATION INSTRUCTIONS OF PRIMA C (continued)

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).
- 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 arm (4).
- Connect the Power cable (A) to the inlet in magnichanger and (B) in the Power supply as shown (Fig-2.2).



(Fig 2.1)

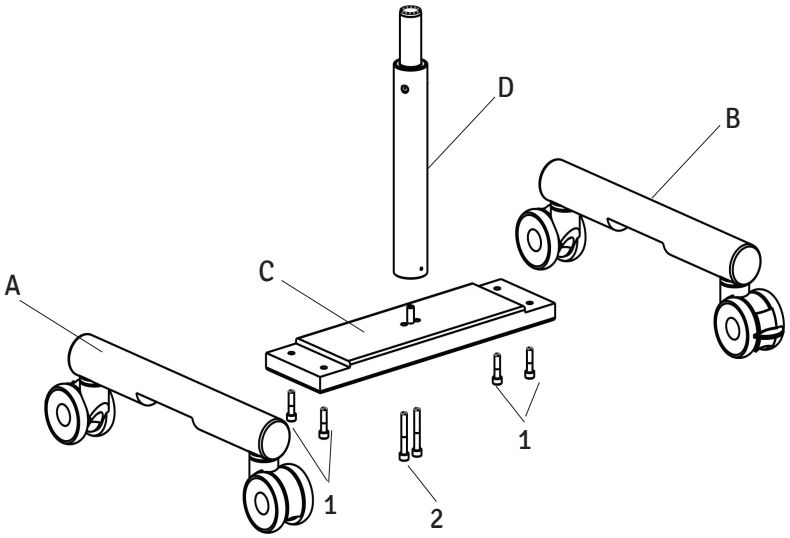


(Fig. 2.2)

5 . INSTALLATION INSTRUCTIONS OF PRIMA CS

- Install the left wheel support (A) and Right wheel support (B) on the Centre support base (C) by tighten the allen screws (1) provided from the bottom of metal plate. Refer Fig-2.3

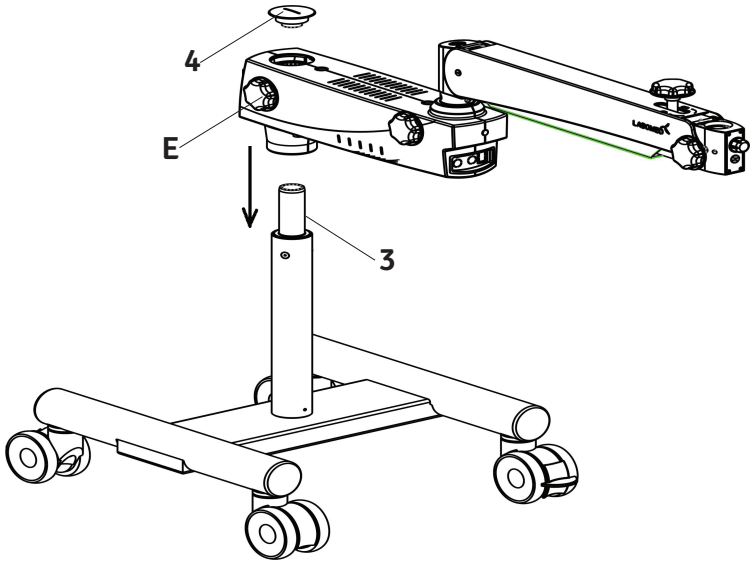
- Install the column (D) on the base. Engage the column to the indexing screw (E). Align the tapped hole of the Column in the screw seat, hold the column firmly and tighten the allen screw (2) from the bottom of the base. Refer Fig. 2.3



(Fig. 2.3)

- Ensure loosening of Swivel arm lock knob (E) and Install the Swivel arm & Suspension arm Assembly on the upright holding shaft (3). Refer Fig. 2.4

- Lock the Swivel arm with threaded screw (4) from the top. Refer Fig. 2.4



(Fig. 2.4)

INSTALLATION INSTRUCTIONS OF PRIMA CS (continued)

- Retrieve the carrier assembly from the packing and follow as below. refer Fig. 2.5

- Install the coupling to the suspension arm by sliding the guiding shaft (5) in to suspension arm.

- Lock the inclined coupling with the threaded plug (6).

- Secure the Flat Head Safety Screw (M5) using a flat head screw driver in the socket situated in Suspension arm front coupling as shown as (7) in fig. 2.5. The same is hanged with a tie to Potentiometer knob.

- Connect the power cable (A) to the inlet in the magnichanger as shown in Fig-2.5..

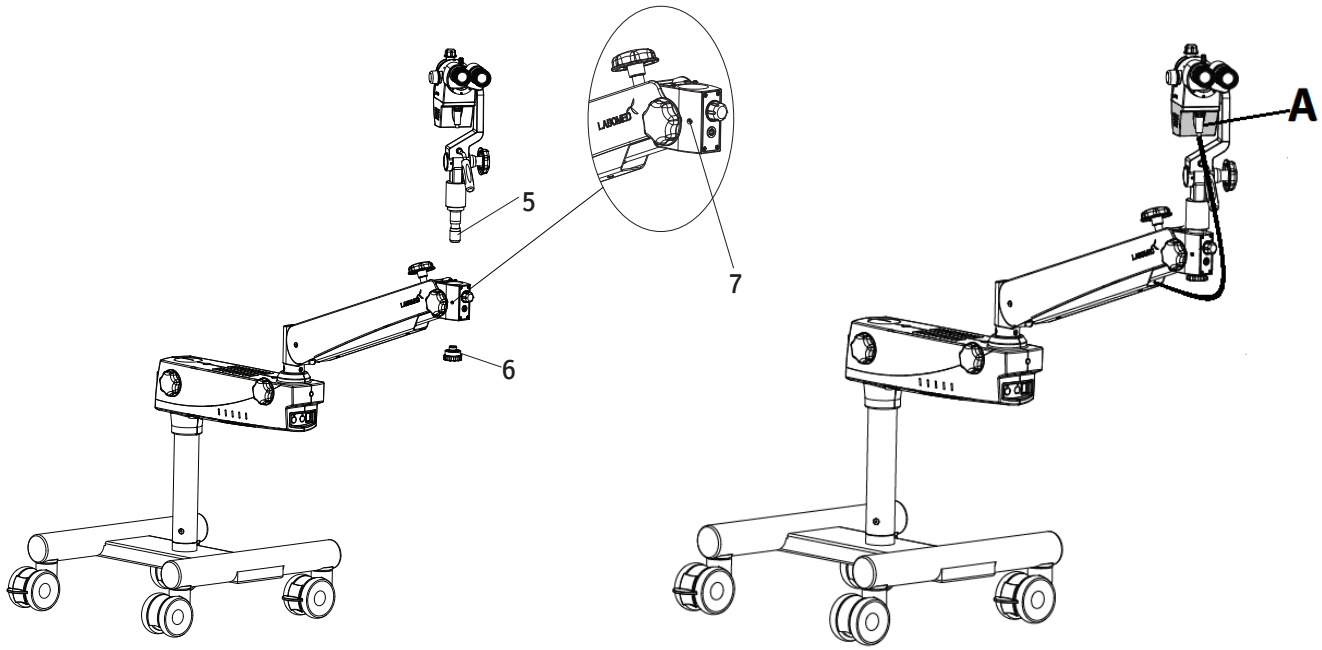


Fig. 2.5

5.1 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.

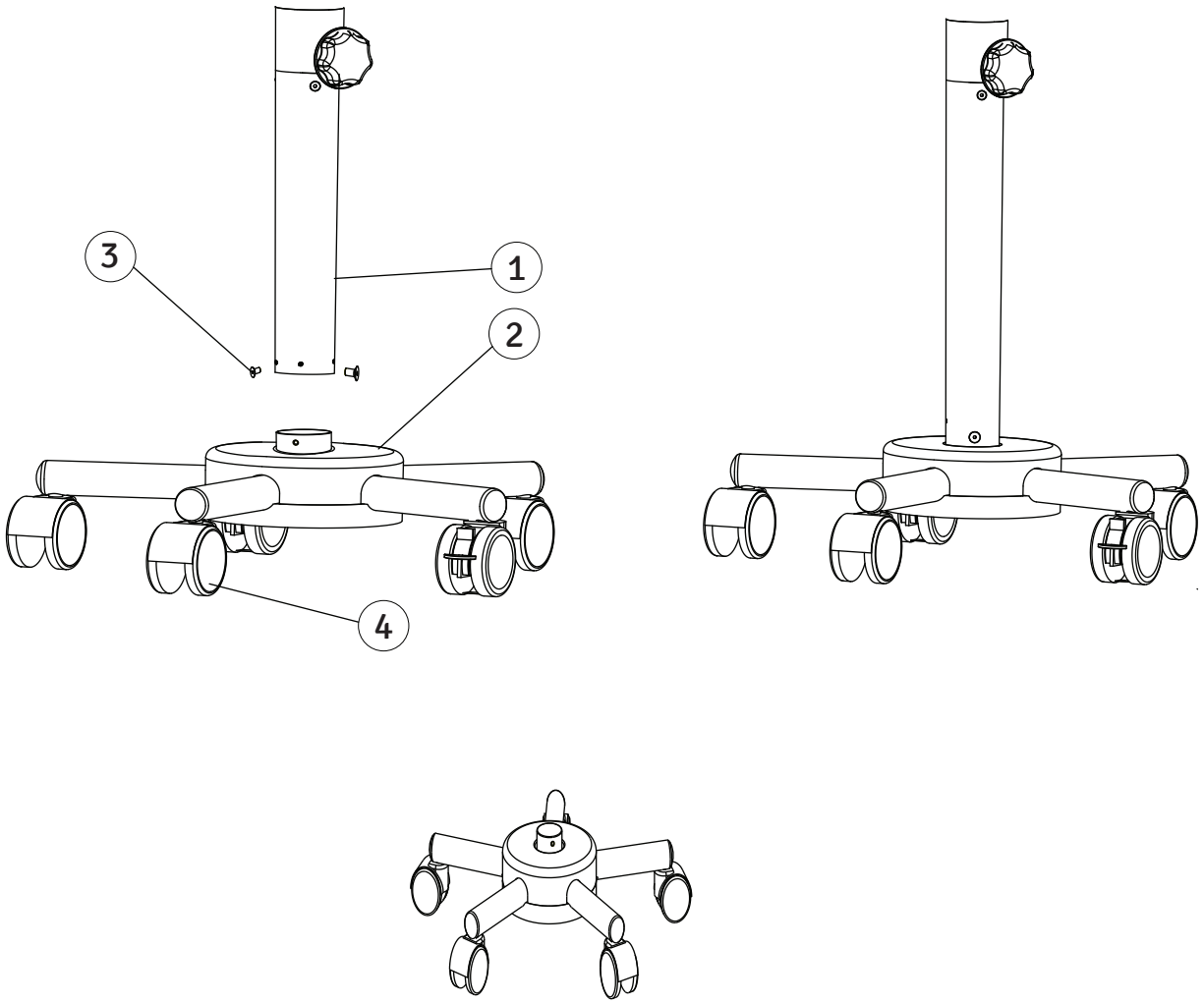
5.2 ADDITIONAL LOAD

- The load capacity and tilting stability is balanced with a Max. 9.0kg load with standard supplied parts and accessories.
- Please do not attach additional load.

6. INSTALLATION INSTRUCTIONS OF PRIMA C Plus

6.1 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).

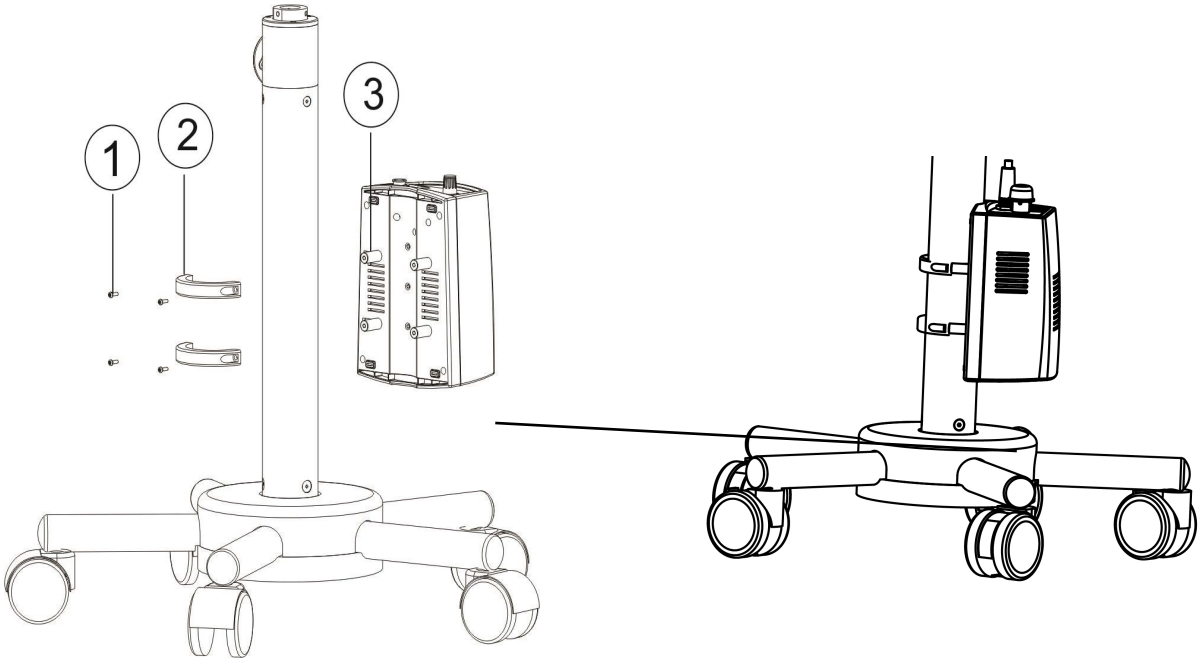


(Fig. 1)

INSTALLATION INSTRUCTIONS OF PRIMA C Plus (continued)

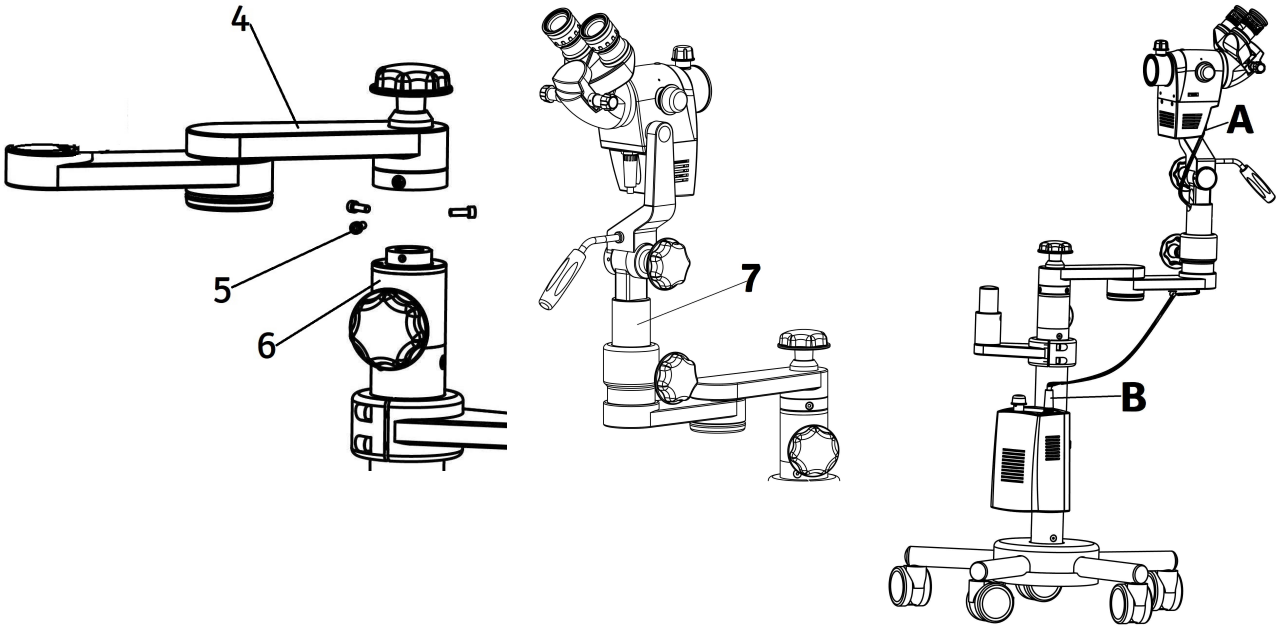
6.2 MOUNTING OF APPLIANCE

- 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 swivel arm (4) on the top of the column (6).
- Screws (5) to be tightened from both sides of the swivel arm (4).
- Insert the microscope carrier (7) in to the swivel arm (4) and tighten it.
- Connect the Power cable (A) to the inlet in the magnichanger and (B) to the inlet in the power supply as shown in Fig-2.2.

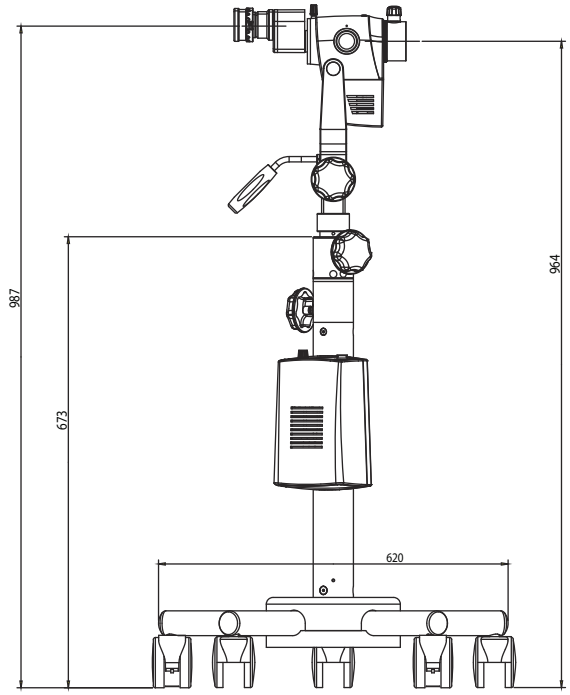


(Fig. 2.2)

7. DIMENSIONS & WEIGHT PRIMA C

DIMENSIONS & WEIGHT (Fig. 2.6) Prima C

Microscope with roller star base stand
Total weight: Approx. 45 kg.



(Fig. 2.6) Prima C

8. DIMENSIONS & WEIGHT PRIMA CS

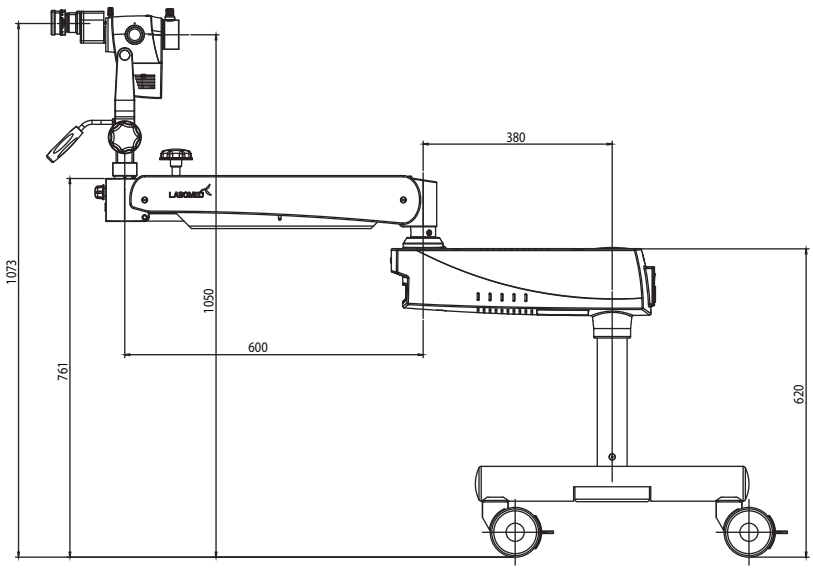
DIMENSIONS & WEIGHT (Fig. 2.7) Prima CS

Microscope with H Base Stand
Total weight Approx. 86.5kg.

Three Boxes containing:
Base left wheel support: 20 kg
Base right wheel support: 20 kg
Base center Support: 20Kg

One Box Containing:
Column: 8Kg
Microscope Arm: 15Kg

One Box Containing:
Carrier Assembly: 2.5Kg
Microscope Head: 600 Gms
Eyepieces and Accessories: 400 Gms



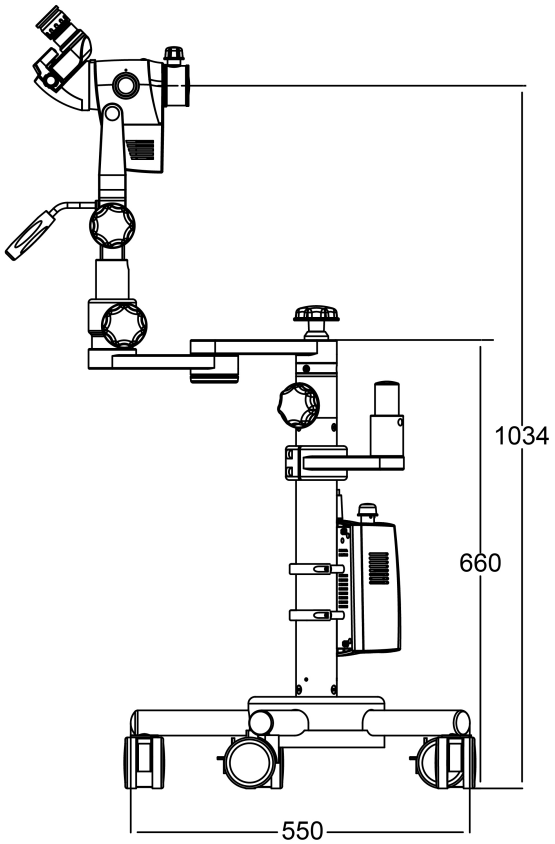
(Fig. 2.7) Prima CS

9. DIMENSIONS & WEIGHT PRIMA C Plus

DIMENSIONS & WEIGHT (Fig. 2.6) Prima C Plus

Microscope with roller star base stand
Total weight: Approx. 40.8 kg.

Microscope with carrier - 2.8 kg
Swivel arm - 8 kg
Base with pillar - 30 kg



9A. ELECTRICAL CONNECTIONS PRIMA CS

Connect the power cable to the AC inlet socket (2) provided on the back of the swivel arm as shown in the fig.-(i).

Switch on the power from on/off switch (1).

Note: Power supply is designed with universal input 100V - 240V AC, 50/60HZ. To plug in follow Instruction on electrical label provided at bottom of the arm as shown (3) here in Fig.-(i).

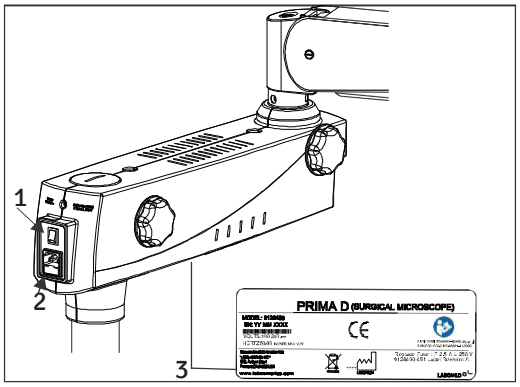


Fig. (i)

9.1 REPLACING THE ILLUMINATION SOURCE

Open the swivel arm cover's. Detach the fibre optic cable and replace the illumination assembly A with new assembly. Secure back the arm cover's.

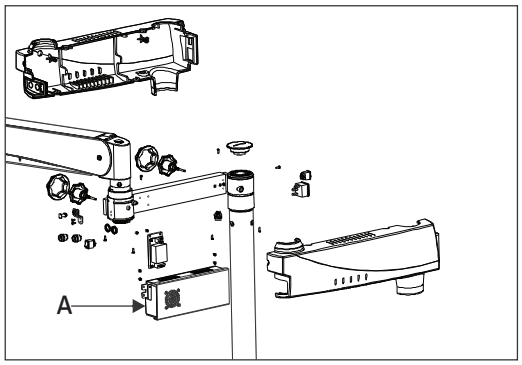


Fig. (ii)

9.2 FUSE REPLACEMENT

The fuse is located with the AC inlet, provided near the on/off switch. Use a flat head screw driver to open the fuse compartment. Two fuses are provided in this, i.e. one is live fuse and second as spare fuse. Replace the blown fuse with live fuse and secure back the fuse compartment. For fuse replacement refer label shown in fig.-(iii).

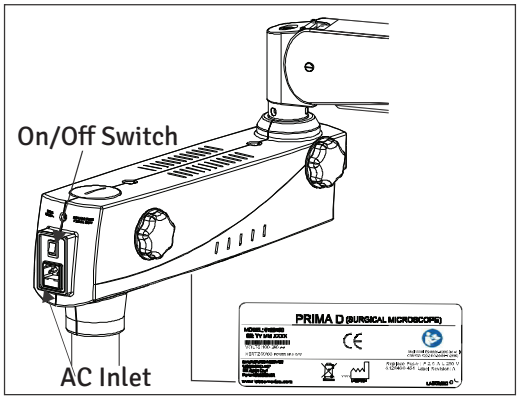
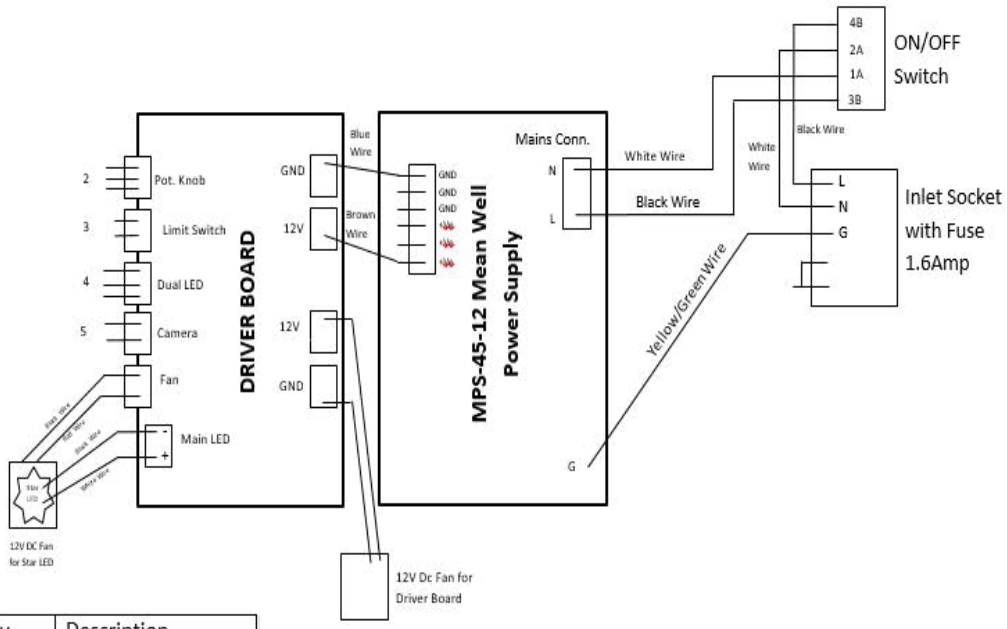


Fig. (iii)

9.3. WIRING CODING DIAGRAM



Wire Marking No.	Power Supply Marking	Description
2	KNOB	Potentiometer Wire
3	SW	Limit Switch Wire
4	DLED	Dual LED Wire
5	CAM	Camera Wire

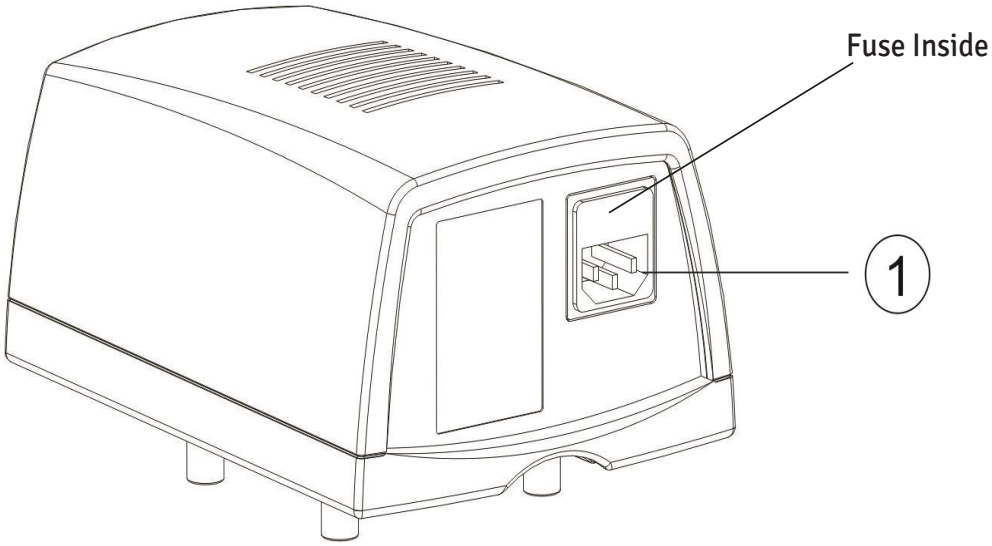
9B. ELECTRICAL CONNECTIONS PRIMA C/C Plus

Connect the power cable to the AC Inlet socket as 1 in figure number 2.8 below.
Switch on the power from on/off switch shown as 1 in figure number 2.9 on page no. 18.

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 2.8 below.

a. CHANGING OF FUSE

- **Note:** Fuses are in fuse holder:
  F 2.8(2 main 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: Fuses are allowed to change against the specified type only.



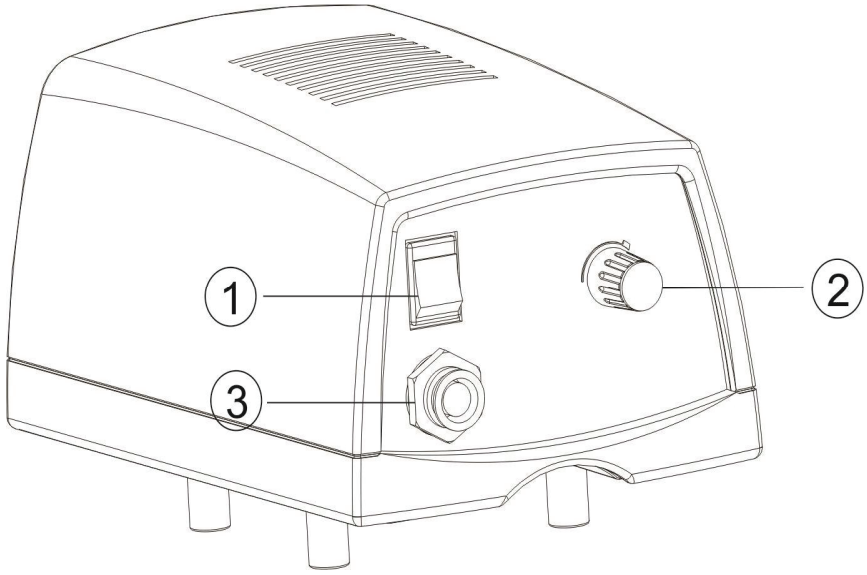
(Fig. 2.8)

10. OPERATING INSTRUCTIONS PRIMA C/C Plus

10.1 **ON/OFF SWITCH** shown as (1) in fig-2.9 is located on the upper side of the illumination box. After the appliance is swtiched on, the green illumination switch diode indicates that the microscope is ready for operation. The LED starts burning and the cooling fan starts working.

10.2 **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.

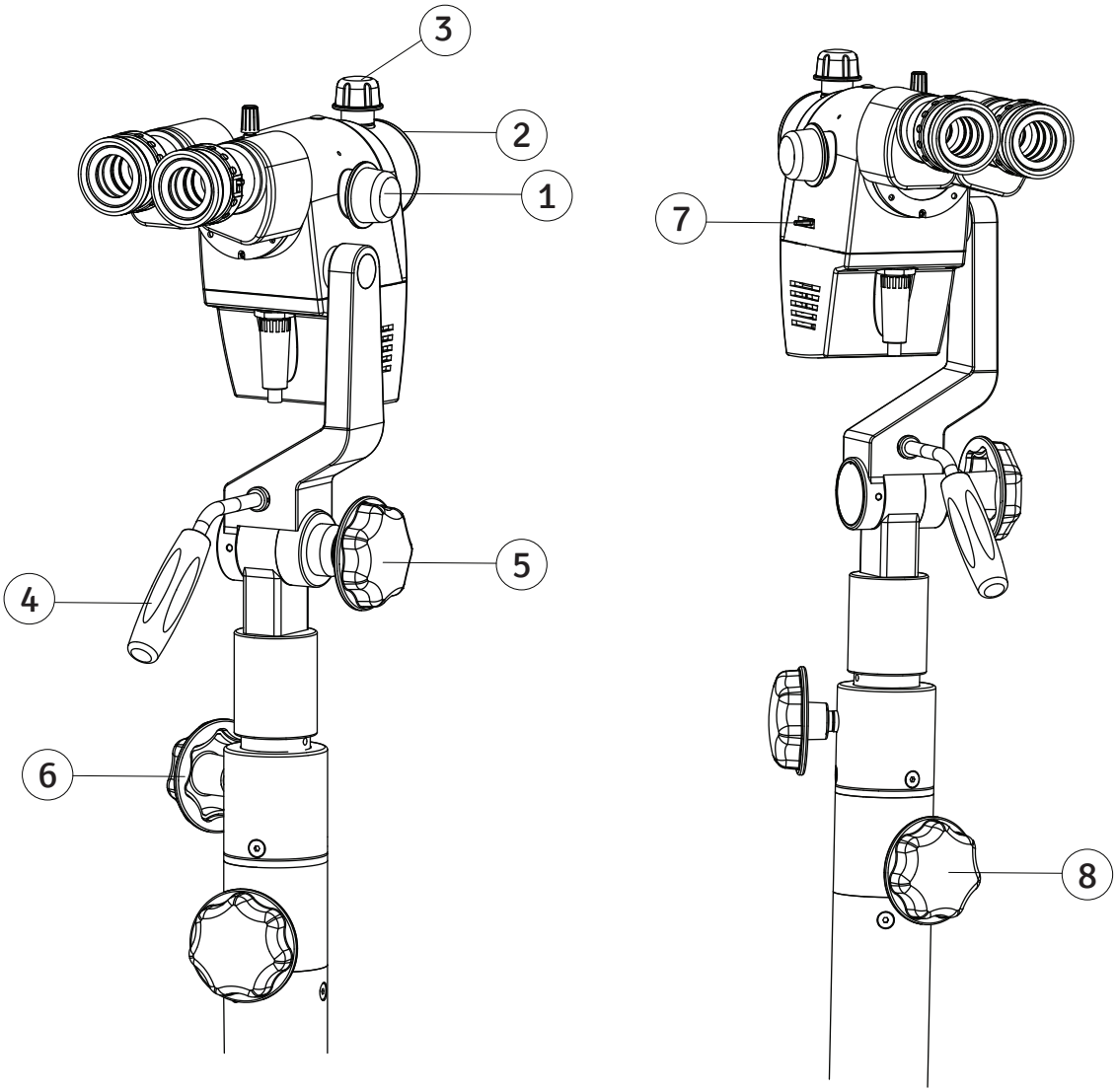


(Fig. 2.9)

11. CONTROL ELEMENTS PRIMA C

CONTROL ELEMENTS PRIMA C (FIG.2.10 & 2.11)

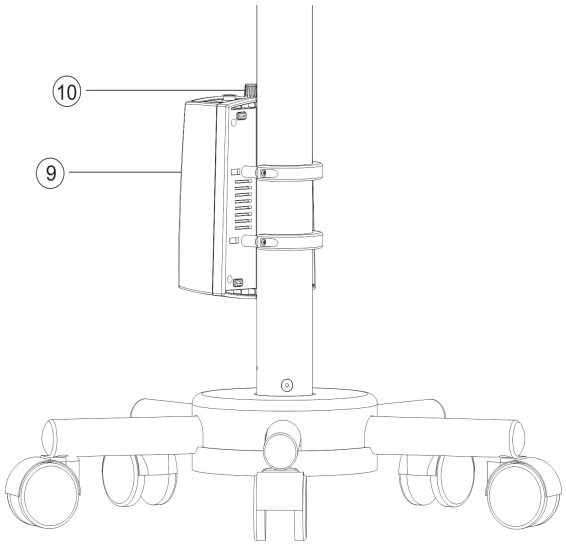
- Roller stand: 5 rollers to move the appliance and 2 brakes to lock the Appliance (see Fig. 1)
- Rotating knob to change the Magnification (1).
- Common Main Objective (CMO) (2).
- Fine focusing knob (3).
- Joystick to tilt the head arm forward and backward (4).
- Head arm locking knob (5).
- Knob to lock the arm (6).
- Knob to swing in green filter (7).
- Column height adjustment knob (8).



(Fig.2.10)

CONTROL ELEMENTS PRIMA C (continued)

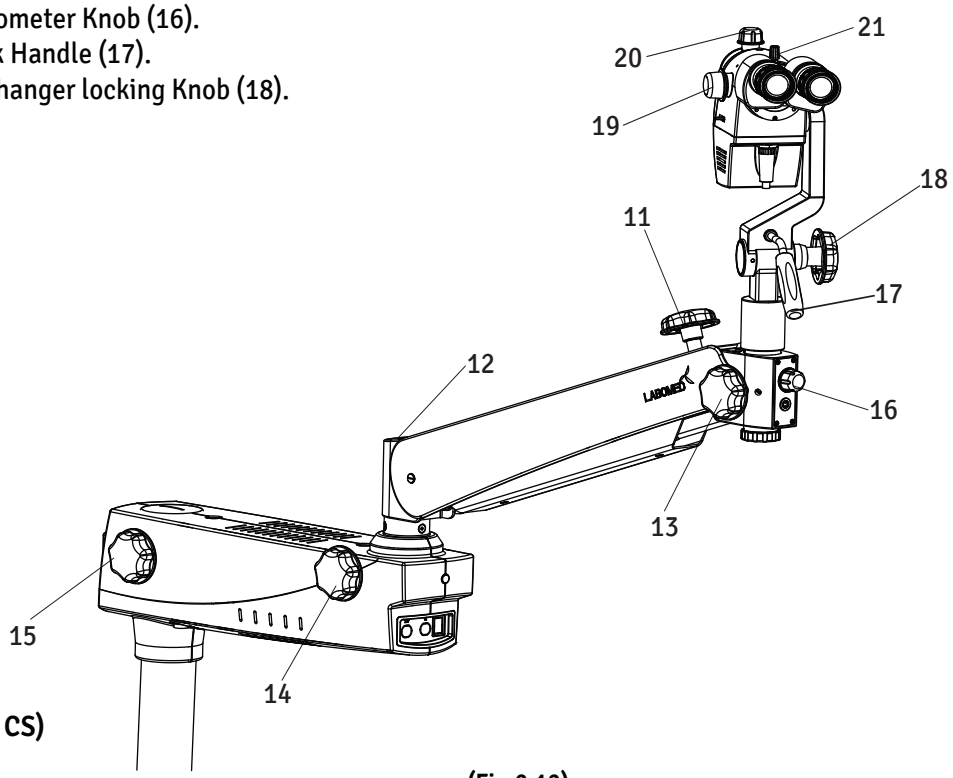
- Power Supply Box (9).
- Knob for brightness control (10).



(Fig. 2.11)

CONTROL ELEMENTS PRIMA CS

- Suspension arm hydraulic movement knob (11).
- Suspension arm spring Tension Adjustment (12).
- Microscope arm locking knob (13).
- Suspension arm locking knob (14).
- Swivel arm locking knob (15).
- Potentiometer Knob (16).
- Joystick Handle (17).
- Magnichanger locking Knob (18).
- Magnification Knob (19).
- Fine Focusing Knob (20).
- Head Locking Knob (21).



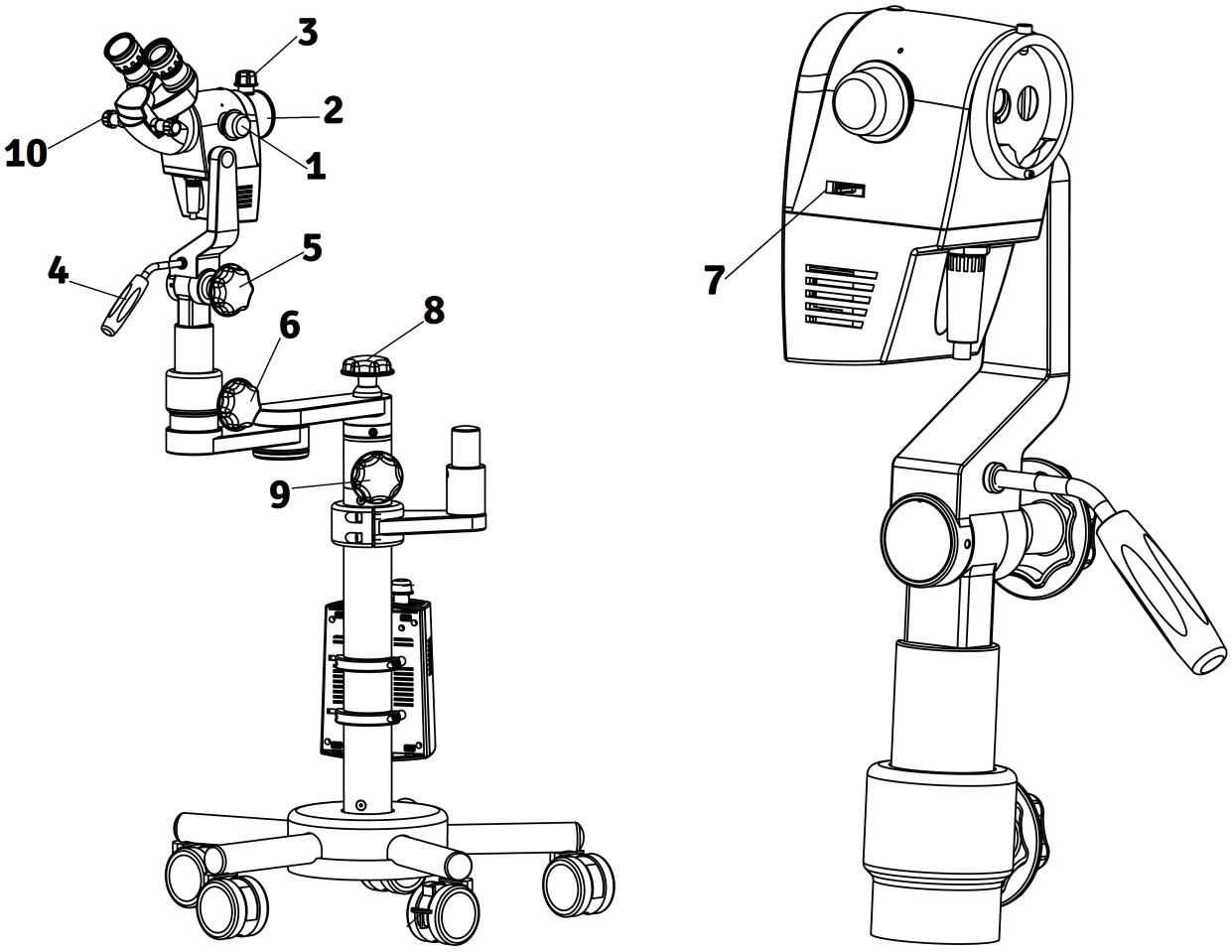
(Prima CS)

(Fig.2.12)

CONTROL ELEMENTS PRIMA C Plus

CONTROL ELEMENTS PRIMA C (FIG.2.10 & 2.11)

- 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).
- Horizontal Arm Lock Knob (9).
- IPD Knob (10).

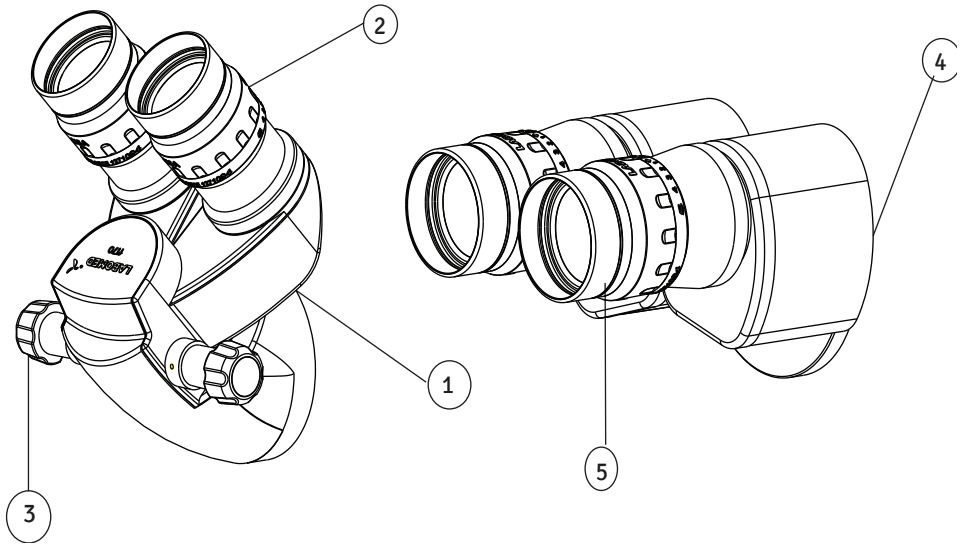


(Fig.2.10)

12. INSTRUCTIONS FOR USING THE MICROSCOPE

a. ADJUSTMENT OF INTERPUPILLARY DISTANCE (Fig. 2.13)

- 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.

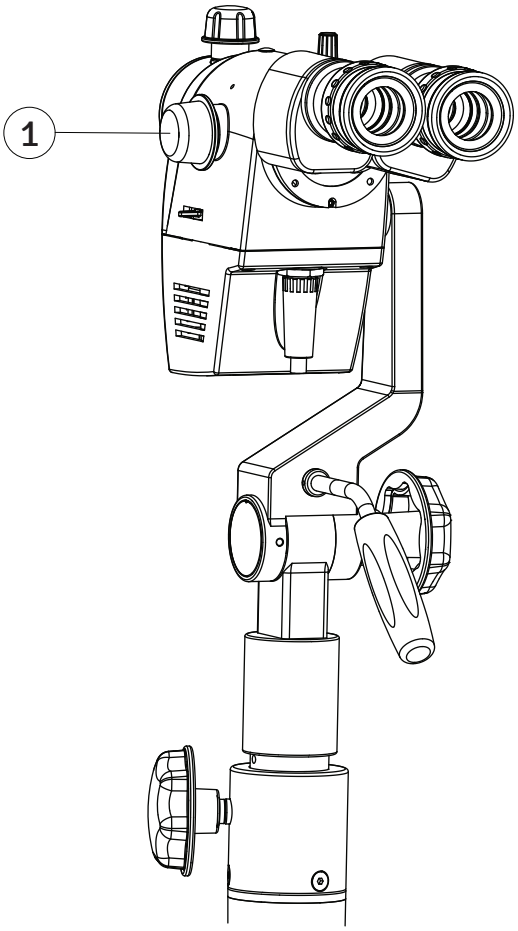


(Fig. 2.13)

INSTRUCTIONS FOR USING THE MICROSCOPE (continued)

b. CHANGING THE MAGNIFICATION (Fig.2.14)

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



(Fig. 2.14)

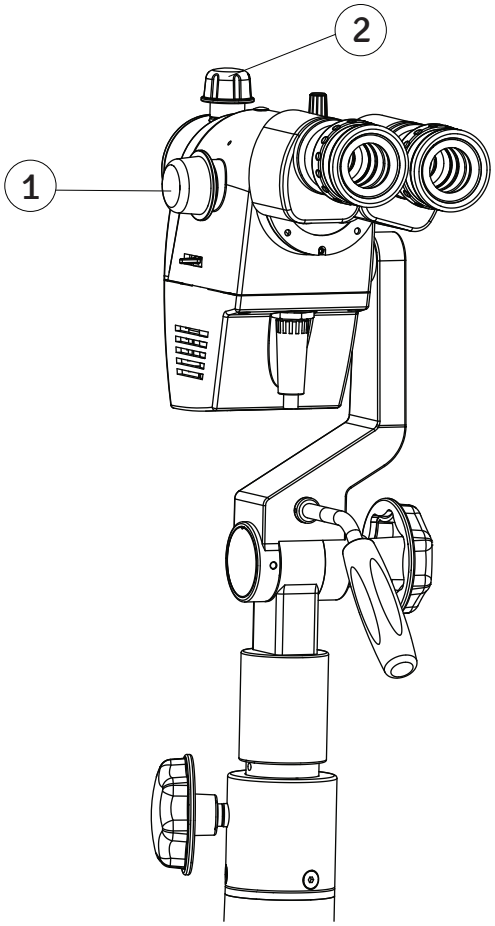
c. HOW TO FOCUS THE OBJECT (Fig. 2.15)

- Bring object into rough focus using arm movements.
- Rotate fine focusing knob 2 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- right and up- down.
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.

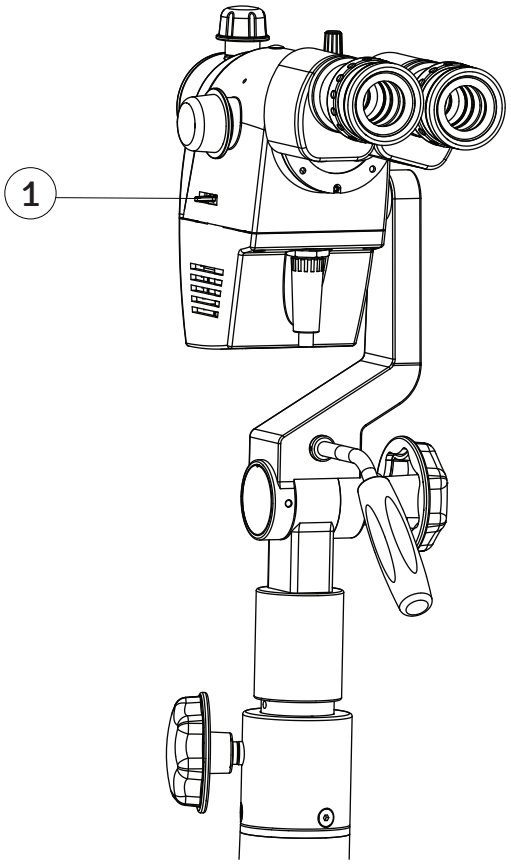
- On focusing the region of interest, change magnification through the magnification changing knob 1.



(Fig. 2.15)

d. RED FREE IMAGE OBSERVATION (FIG. 2.16)

- 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. 2.16)

e. EYEPIECES WITH DIOPTER (Fig. 2.17)

- You can adjust the diopter settings as per your vision correction.
- Diopter adjustment is 10x +/- 7D
- Diopter adjustment is 12.5x +/- 8D

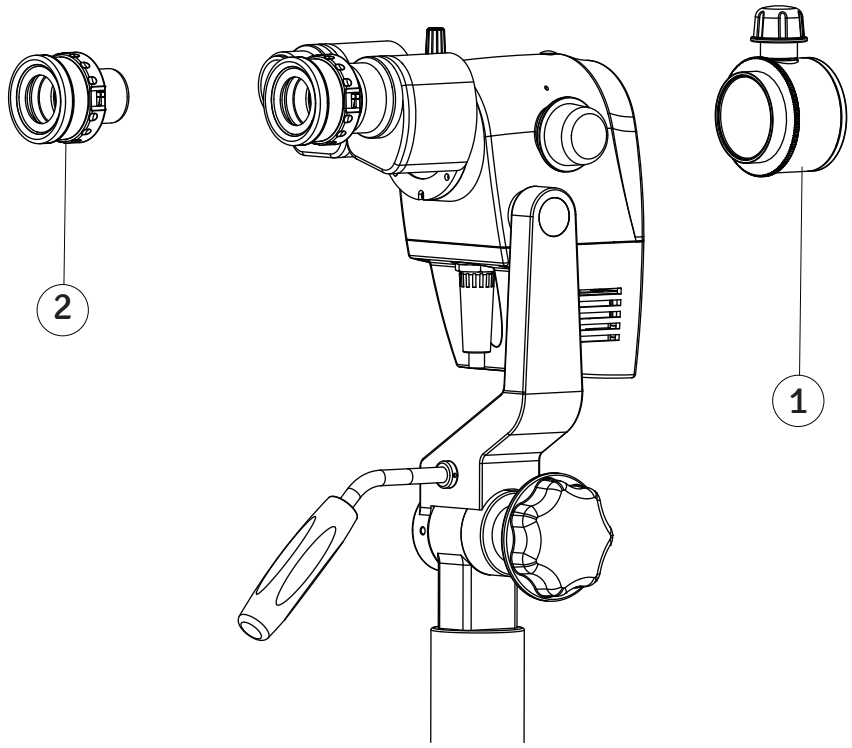


(Fig.2.17)

13. CHANGING THE OBJECTIVE / EYE PIECES

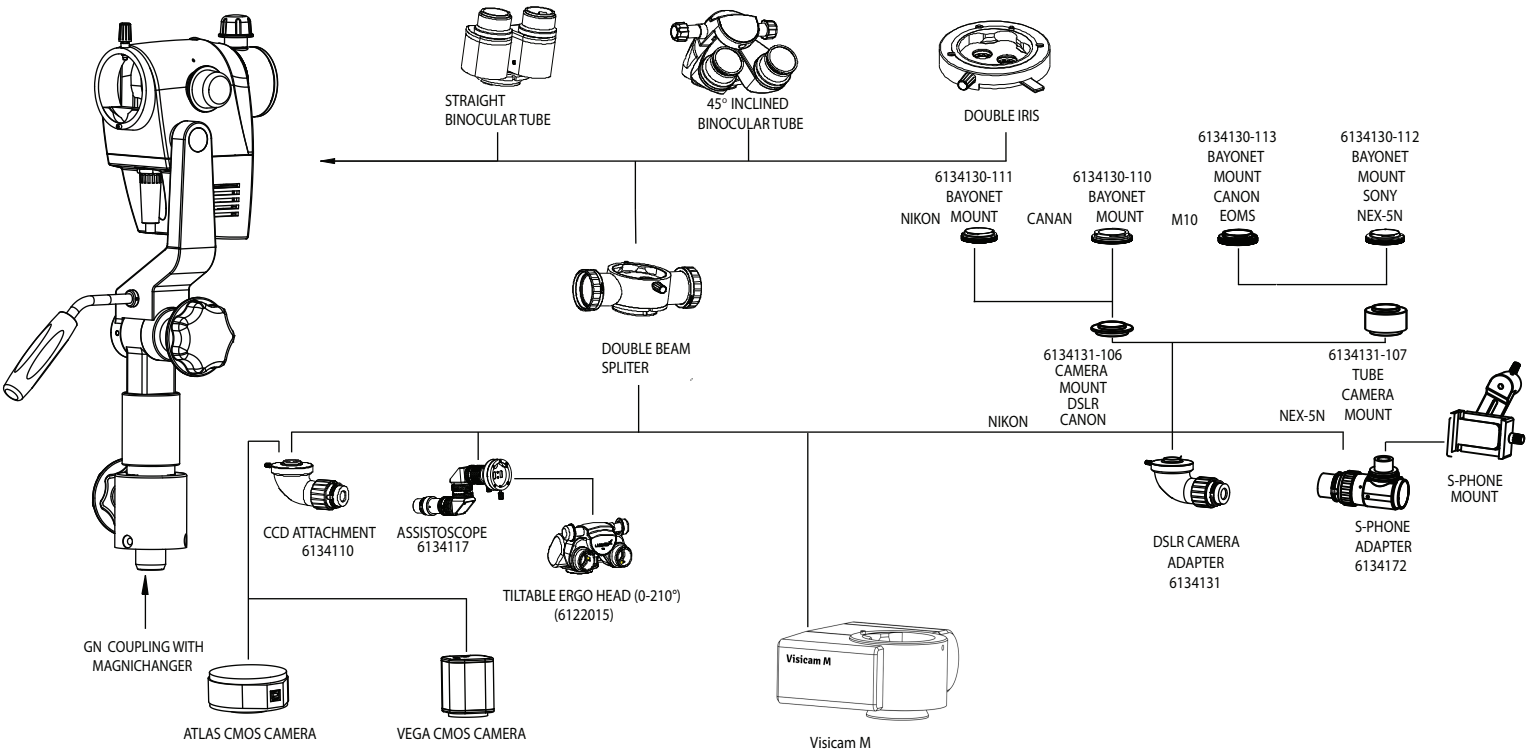
CHANGING THE OBJECTIVE / EYE PIECES (Fig. 2.18)

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



(Fig. 2.18)

14. USE OF ACCESSORIES



(Fig. 2.19)

1. Install double beam splitter by replacing the binocular tube (straight or 45° inclined).
2. Total four accessories are provided as follows
   2.1 DSLR camera adapter for Nikon, Canon and Sony
   2.2 CCD camera adapter for Vega.
   2.3 Adapter for Sony Handy-Cam.
   2.4 Assistoscope for assistant viewing
3. Install any one or two accessories on any side (Left or right) of the beam splitter
4. Reinstall binocular tube (straight or 45° inclined) on double beam splitter.

15. CARE & 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.

Surgical Microscope Maintenance/Servicing Check

Microscope: - **Owner: -** **Month: -** **Year:-**

Date of Purchase:

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
DAILY AFTER USE																															
Wipe of any oily marks/finger prints from eye piece & CMO other Optical parts with lens paper																															
Turn off Microscope																															
Replace Dust Cover																															
Each Month																															
Clean microscope body with water moistened tissue																															
Use lens cleaning fluid on lens tissue to wipe lenses																															
Remove Fibre Optical Cable and clean																															
6 monthly																															
Service Inspection																															
Smooth Function of Locking Knobs																															
Smooth Functioning of Torque Adjustment Mechanism on Suspension Arm																															
Rotary Motion of Carrier																															
INITIALS																															

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 Microscope 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.

CARE & MAINTENANCE (continued)

- 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: 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.
- LABOMED Maxi Lite coatings are fungal 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 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.

INSTRUCTIONS

WORKPLACE:

Remove surface contamination with a paper towel.

REPROCESSING:

Recommended reprocess a product immediately after use or as & when required as per below cleaning instructions.

CLEANING & SERVICING:

Needed: water, detergent, spirit, microfiber cloth

- Take a Linen or any soft cloth. Moist it Slightly with running tap water (<40°C), using a little detergent and clean the metallic and plastic parts.
- Clean all optical components with spirits or alcohol.
- Dry optical components using a microfiber cloth; dry the rest of the product using a paper towel.
- For servicing as and when required, inform LABOMED after- sales service department.

16. CLEANING AND DISINFECTION

FOLLOWING DISINFECTANTS ARE RECOMMENDED FOR CLEANING AND DISINFECTION

1. For cleaning and disinfecting the external painted, powder coated, anodized, plastic, Screen printed and bare metal parts:
Use Normal household bleach (Sodium hypochlorite 5%)- strength 5000 ppm(10 parts water 1 part bleach).

2. For cleaning of optical surfaces:
Use 70% Isopropyl alcohol.

PROCEDURE

- **Take a muskin cloth.**
- **Moist it to feel wet.**
- **Disinfect/clean the surface gently without much hand pressure by pulling the wipe from one end to other end. Do not rub the parts for cleaning.**

NOTE:

1. **Use mask and Gloves while performing cleaning and disinfection.**
2. **While cleaning, muslin cloth should not be dripped wet to prevent seepage and rusting to running/bare parts.**
3. **Alcohol is flammable, its use as a surface disinfectant should be in well-ventilated spaces only.**

AUTOCLAVING

The rubber caps, sleeves and grips supplied by labomed are recommend for the following program for autoclaving:

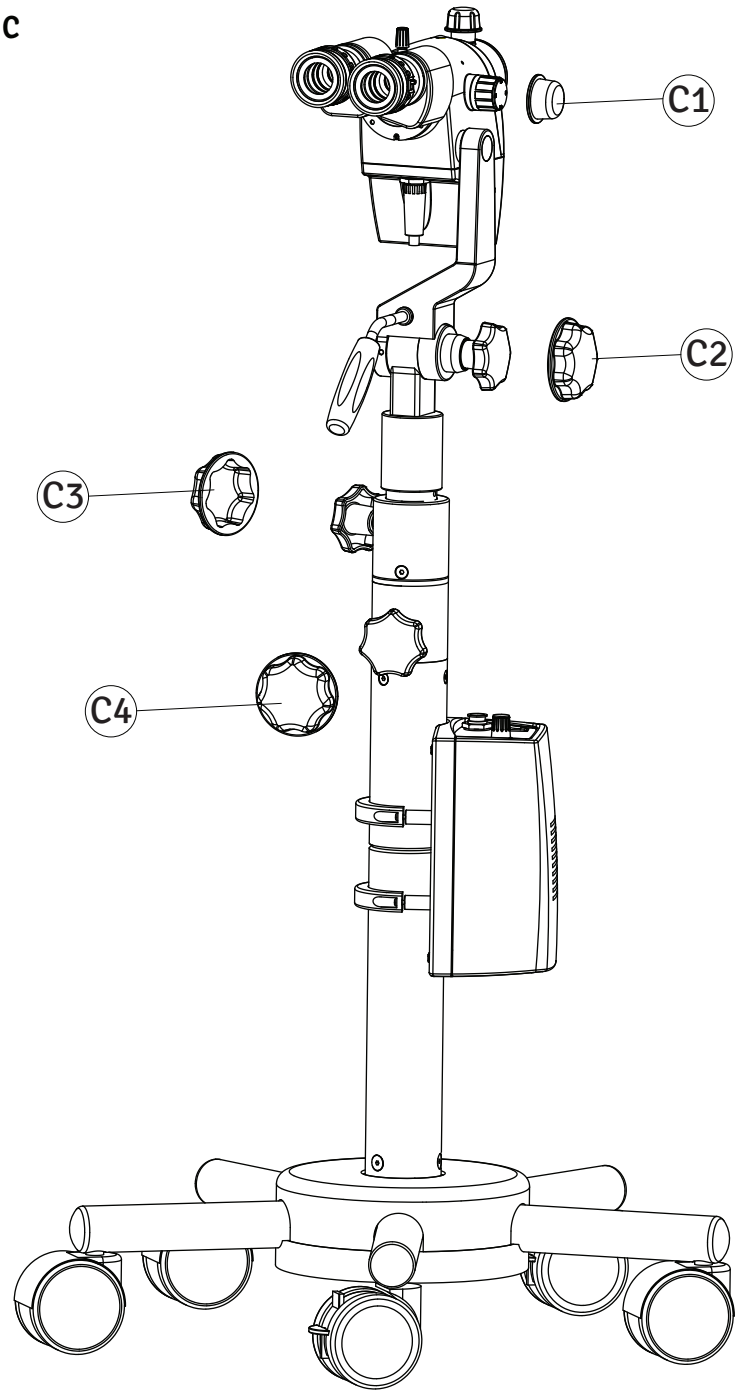
- Temperature: 134˚C
- Time: 10 minutes
- Instrument: Standard Autoclave

17. SCHEDULE OF AUTOCLAVABLE CAPS PRIMA C

Schedule of Autoclavable caps Prima C

Autoclavable caps:

(C1) Part no. 6122015-209
(C2) Part no. 6168000-219
(C3), (C4) Part no. 6168000-213

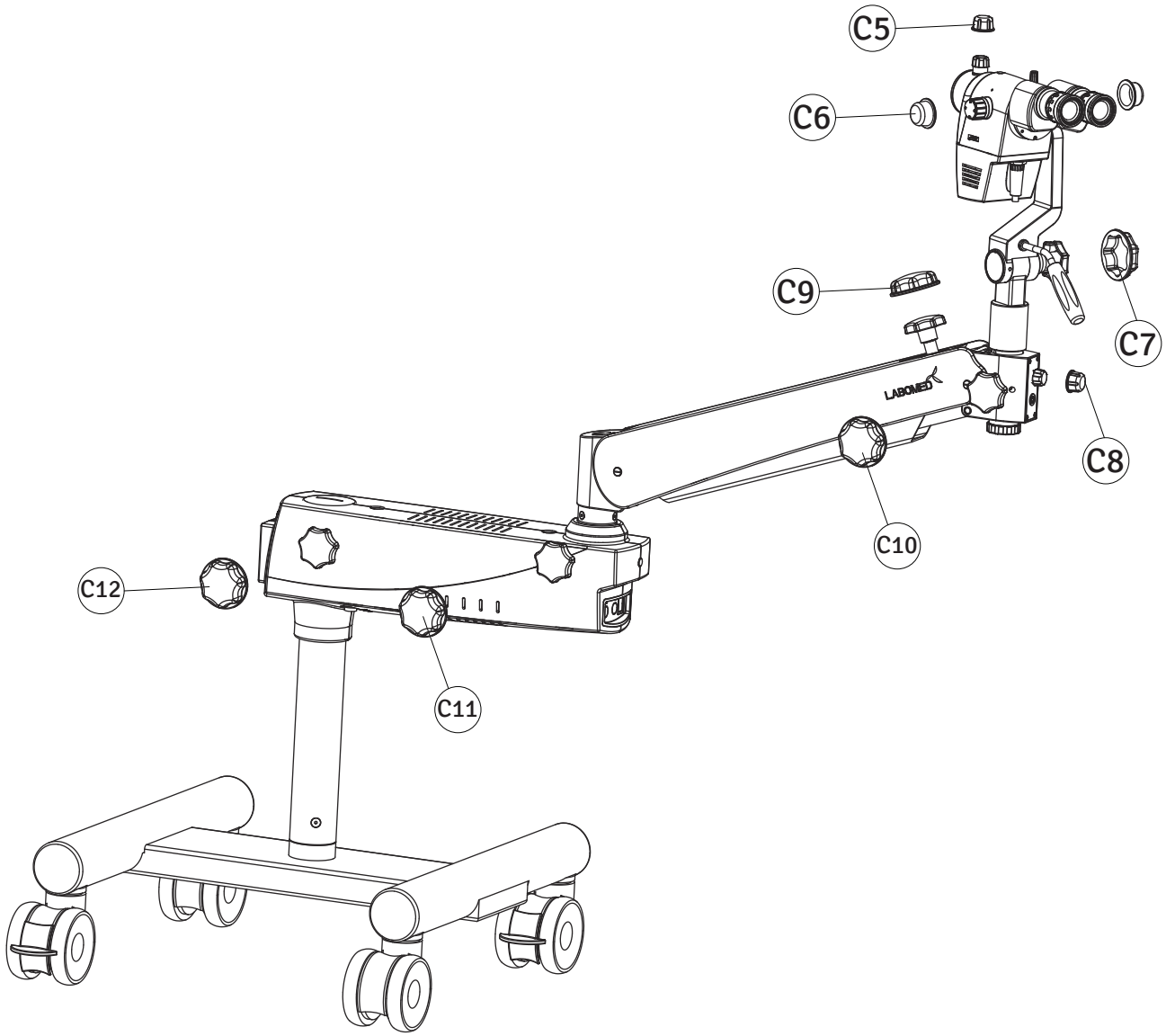


SCHEDULE OF AUTOCLAVABLE CAPS PRIMA CS

Schedule of Autoclavable caps Prima CS

Autoclavable caps:

(C5), (C6), (C8) Part no. 6122015-209
(C7) Part no. 6168000-219
(C9), (C10), (C11), (C12) Part no. 6168000-213

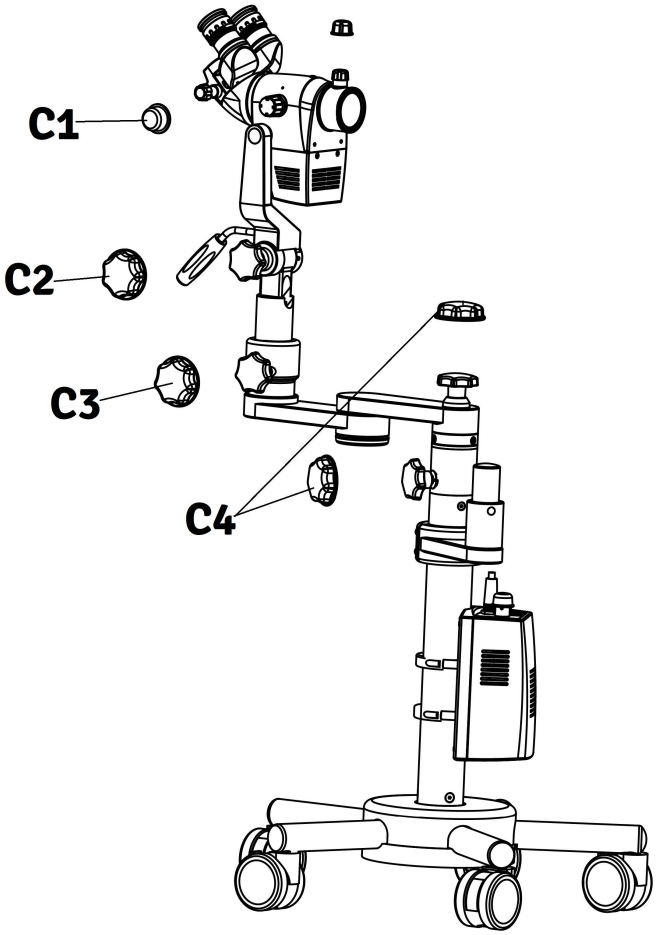


SCHEDULE OF AUTOCLAVABLE CAPS PRIMA C Plus

Schedule of Autoclavable caps Prima C Plus

Autoclavable caps:

(C1) Part no. 6122015-209
(C2) Part no. 6168000-219
(C3), (C4) Part no. 6168000-213



18. 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 device is subjected to conformity assessment procedure complying with Article 52 (7) and technical documentation accordance to Annexure II and III of council regulation (EU) 2017/745. These Devices are Class 1 (without a measuring function and non-invasive) per Rule 1 annex VIII of the regulation MDR 2017/745. All the colposcopy provided with the CE mark indicates agreement with the legal Stipulations.

19. DISPOSAL

Disposal must comply with locally applicable laws & regulations

20. TECHNICAL SPECIFICATION

PRIMA C

- Star Base Stand & Column, lockable wheels.
- Straight Observation tube, interpupillary distance **49-78mm. Optional:** 45° inclined.
- WF 10/18mm FOV, focusable eyepieces with retractable eye guards, diopter adjustment +/- 7mm **Optional:** WF 12.5x / 18mm,diopter adjustment +/- 8mm
- 5-step magnification: 0.4x, 0.6x, 1.0x, 1.6x, 2.5x.
- F-300mm objective. **Optional**: f-400mm.
- Built-in-green filter
- Inbuilt 27W LED (5700K)
- Vertical Height Adjustment: 100mm
- 60W max power consumption.
- 100V-240V; 50/60 hz, voltage input. Fuse F2.5 Amp.

NOTE: For Safety & Warranty Claims Eligibility

Use constant voltage stabilizer to avoid sudden input voltage variation and to enhance LED life.

PRIMA CS

- H 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 +/- 7mm Optional: WF 12.5 / 18mm,diopter adjustment +/- 8mm
- 5-step magnification: 0.4x, 0.6x, 1.0x, 1.6x, 2.5x.
- F-300mm objective. Optional: f-400mm.
- Built-in-green filter
- Inbuilt 27W LED (5700K)
- 60W max power consumption.
- 100V-240V; 50/60 hz, voltage input. Fuse F2.5 Amp.

NOTE: For Safety & Warranty Claims Eligibility

Use constant voltage stabilizer to avoid sudden input voltage variation and to enhance LED life.

PRIMA C Plus

- Star Base Stand & Column, lockable wheels.
- Straight Observation tube, interpupillary distance **49-78mm. Optional:** 45° inclined.
- WF 10/18mm FOV, focusable eyepieces with retractable eye guards, diopter adjustment +/- 7mm **Optional:** WF 12.5x / 18mm,diopter adjustment +/- 8mm
- 5-step magnification: 0.4x, 0.6x, 1.0x, 1.6x, 2.5x.
- F-300mm objective. **Optional**: f-400mm.
- Built-in-green filter
- Inbuilt 27W LED (5700K)
- Vertical Height Adjustment: 100mm
- Horizontal extender arm: 400mm
- 60W max power consumption.
- 100V-240V; 50/60 hz, voltage input. Fuse F2.5 Amp.

NOTE: For Safety & Warranty Claims Eligibility

Use constant voltage stabilizer to avoid sudden input voltage variation and to enhance LED life.

21. WARRANTY

This warranty applies to new products 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 LABOMED factory or authorized LABOMED Dealer.

All claims under this warranty must be in writing and directed to the LABOMED factory or its authorized dealer for this device making the original sale and 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. 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 reserves the right to make changes in design or to make additions to or improvements in its products without obligation to add such to products previously manufactured.

CLAIMS FOR CHANGES

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 materials 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.

WARRANTY (continued)

Liability release for wall and / or ceiling installations:

By signing below, purchaser confirms that the correct and secure installation of mounting plates and hardware for the LABOMED Prima microscope(s) purchased is the sole responsibility of the purchaser and appointed contractor, and will comply with applicable building codes and good practices. Labo America, Inc. and all of its affiliates will be held harmless and will not bear any liability for damage and/or injury caused by improperly installed and secured mounting plates and hardware.

Purchaser's name and address:

Project location (if different from above):

Licensed contractor/company name and details (address, lic#, phone number)

Client Signature:

Contractor Signature:

Date:

Date:

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Fremont CA 94538

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www.laboamerica.com

Revision History

Rev. No.	Date of Release	DCR #	Change	App. By
2.1	April 20,2019	DCR/12/19	Formatting to Improve Apperance of text and UPS requirement added.	S Bal
2.2	Nov 19,2020		Drawing changed.	S Bal
2.3	May 13,2020	DCR/09/23	Accessories Page Updated Specs Revised	S Bal
2.4	Aug, 2024	DCR/11/2024	Regulatory Information	S Bal
2.5	Sep ,2024	DCR/12/2024	**Symbols updated per EU MDR 2017/745 & ISO 15223**	S.bal
2.6	Jan ,2025	DCR/01/2025	**Max. Safe Load Symbol added**	S.bal
2.7	June ,2025	DCR/14/2025	Typo Error corrected (MDR Regulation (EU) 2017/745	S.bal
2.8	July,2025	DCR/**16**/2025	silicone cover instructions added	S.bal
2.9	Nov,2025	DCR/12/2025	new configuration added	S.bal
3.0	Feb,2026	DCR/02/2026	IP Code Added	S.bal

LABOMED
ideas for vision

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