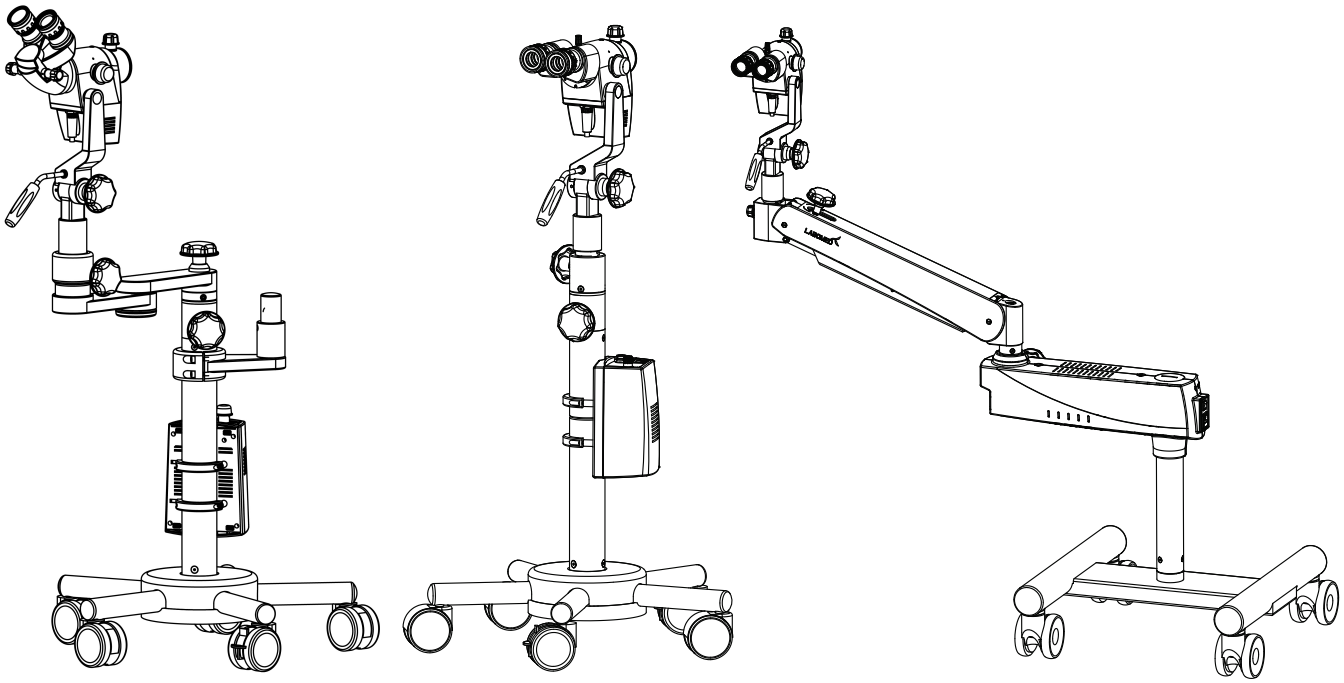
LABOMED
ideas for vision

Prima C/ Prima CS/ Prima C Plus

COLPOSCOPE

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 correct use of this instrument and to avoid injury during operation, read this manual completely before use.

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1. INTRODUCTION

Congratulations on the purchase of your new Prima C / Prima CS / Prima C Plus colposcope.

This manual is designed as a training and reference manual for the operation and maintenance of the instrument. We recommend that you read it carefully before use and follow the instructions 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 your authorized LABOMED dealer or from the LABOMED service department. Contact information is provided at the end of this guide.

The LABOMED Prima C / CS / C Plus colposcope is an optical instrument used in medical diagnostic procedures to examine cervical, vaginal and vulvar tissue with the aid of illumination and stereo-microscope optics.

The colposcope provides an enlarged view of the area of interest, allows normal and abnormal-appearing tissue to be distinguished visually, and serves as an aid in taking directed biopsies for further pathological examination.

It is also used for the visual examination of cytological abnormalities, the assessment of in-utero diethylstilbestrol exposure, immunosuppression such as HIV, and abnormal appearance of the cervix, and for forensic examination after sexual assault.

INTRODUCTION (continued)

IMPORTANT GENERAL REFERENCES

Preliminary notes

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

Appropriate Use

Only LABOMED accessories, bases and light sources may be used with LABOMED colposcopes.

The restrictions stated in the directions for use must be observed.

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

In accordance with the MPG (German Medical Devices Act), colposcopes may be operated only by persons who have been instructed in the expert handling of the device.

Correct installation and maintenance of the device are vital prerequisites for using the colposcope.

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

☞ Report any serious incident involving this device to Labotech Microscopes India Pvt. Ltd. or to your national health authority.

Indications for use

The colposcope may be helpful in the following situations:

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. Abnormal appearance of the cervix or vagina on 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 vulvoperineal bowenoid papulosis
12. Preoperative evaluation before genital tract surgery: hysterectomy, treatment of genital prolapse, cervicovaginal plastic surgery, etc.
13. Lesion noted on routine gynecological examination

INTRODUCTION (continued)

Contraindications for use

The colposcope is a device for viewing the body from a distance and is not intended for patient contact. For this reason, there are no contraindications for the use of the 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 easy to understand and technically sound.

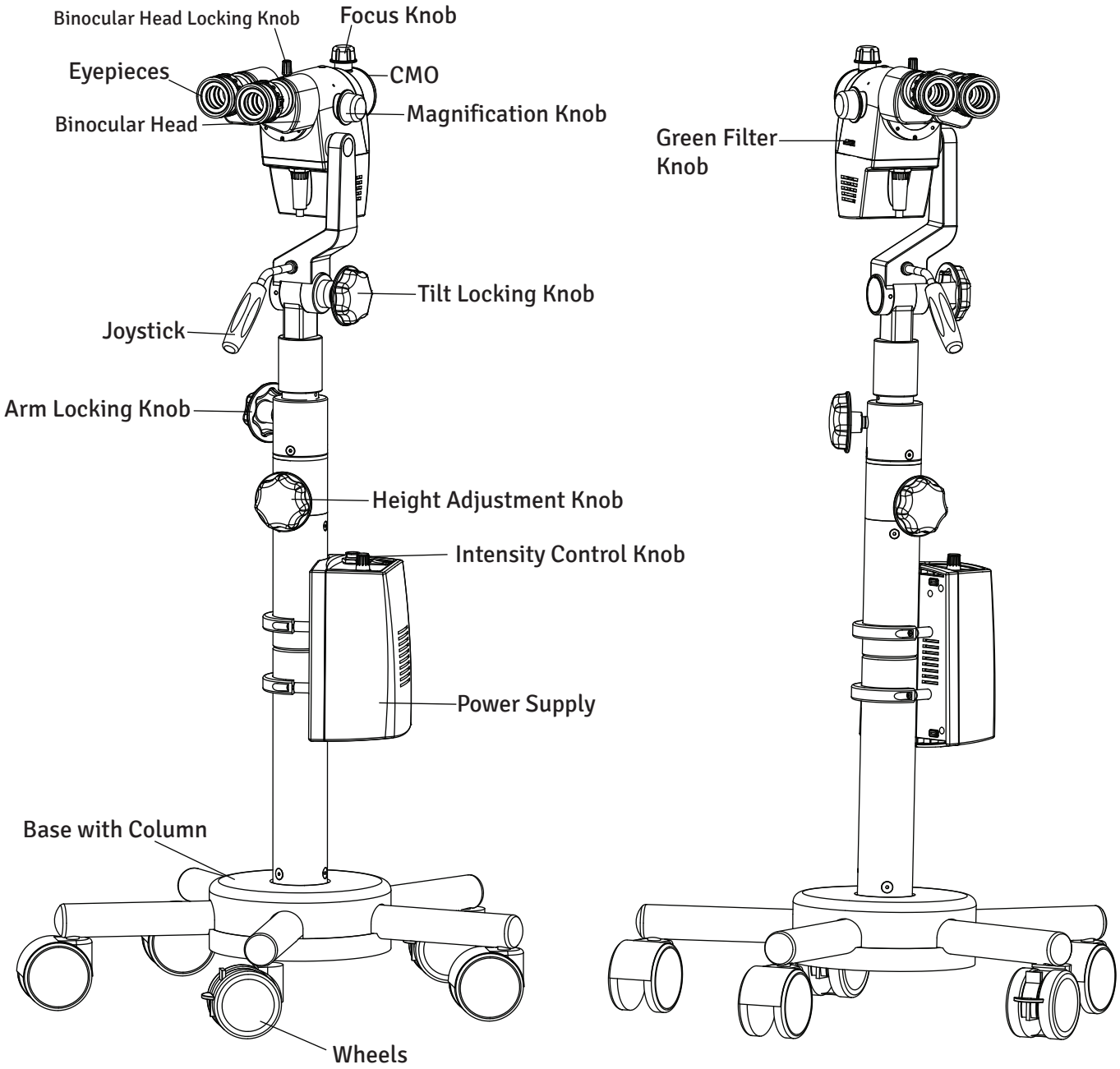
The contents follow the structure of the colposcope: head, base, accessories, electrics, maintenance and safety.

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

INTRODUCTION (continued)

Prima C:
Ergonomic stand for easy and accurate positioning, with a vertical travel of 100 mm.

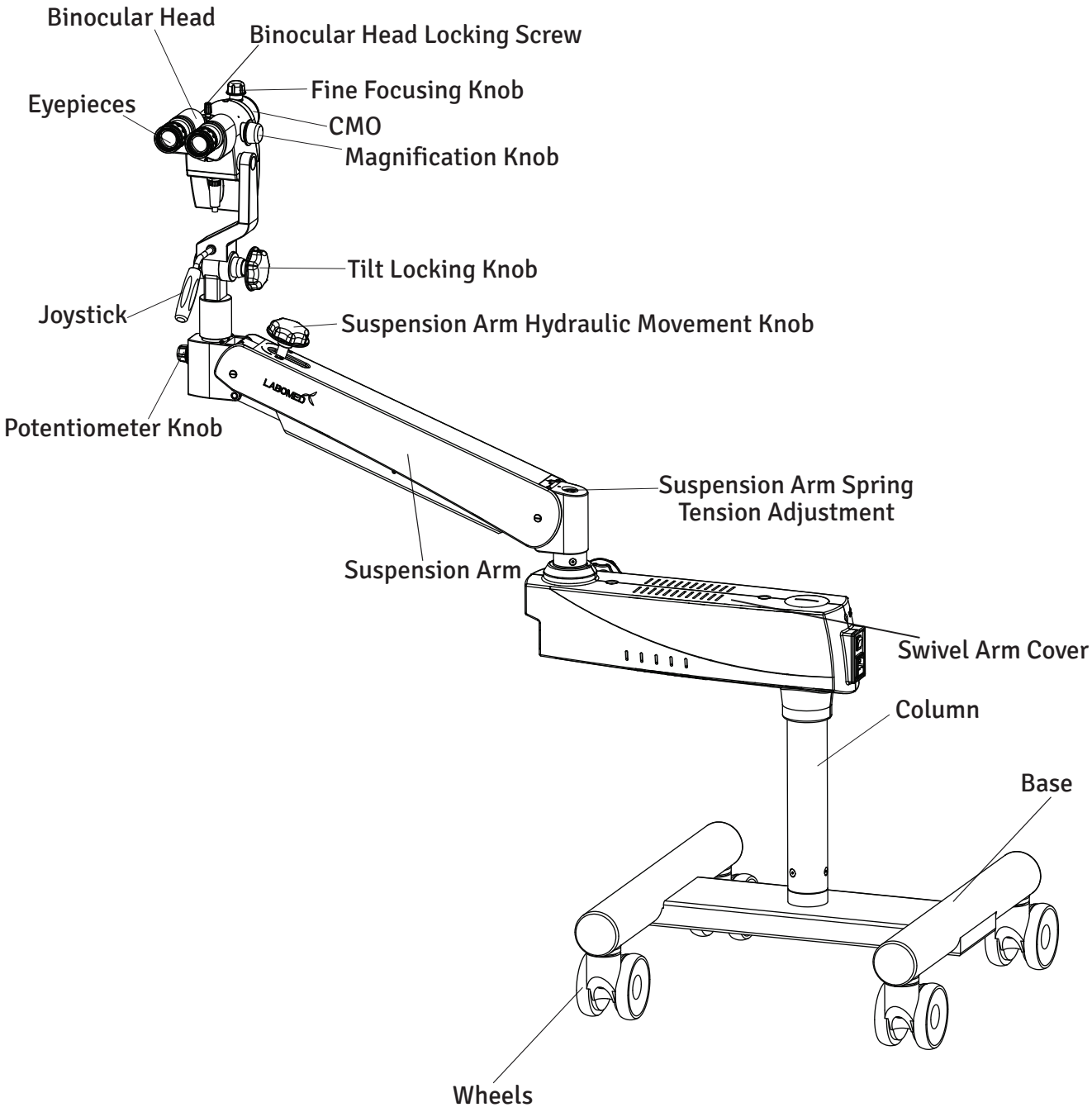
To set the desired height, slightly loosen the swivel arm locking knob, adjust the height and then clamp the knob again.



INTRODUCTION (continued)

Prima CS:

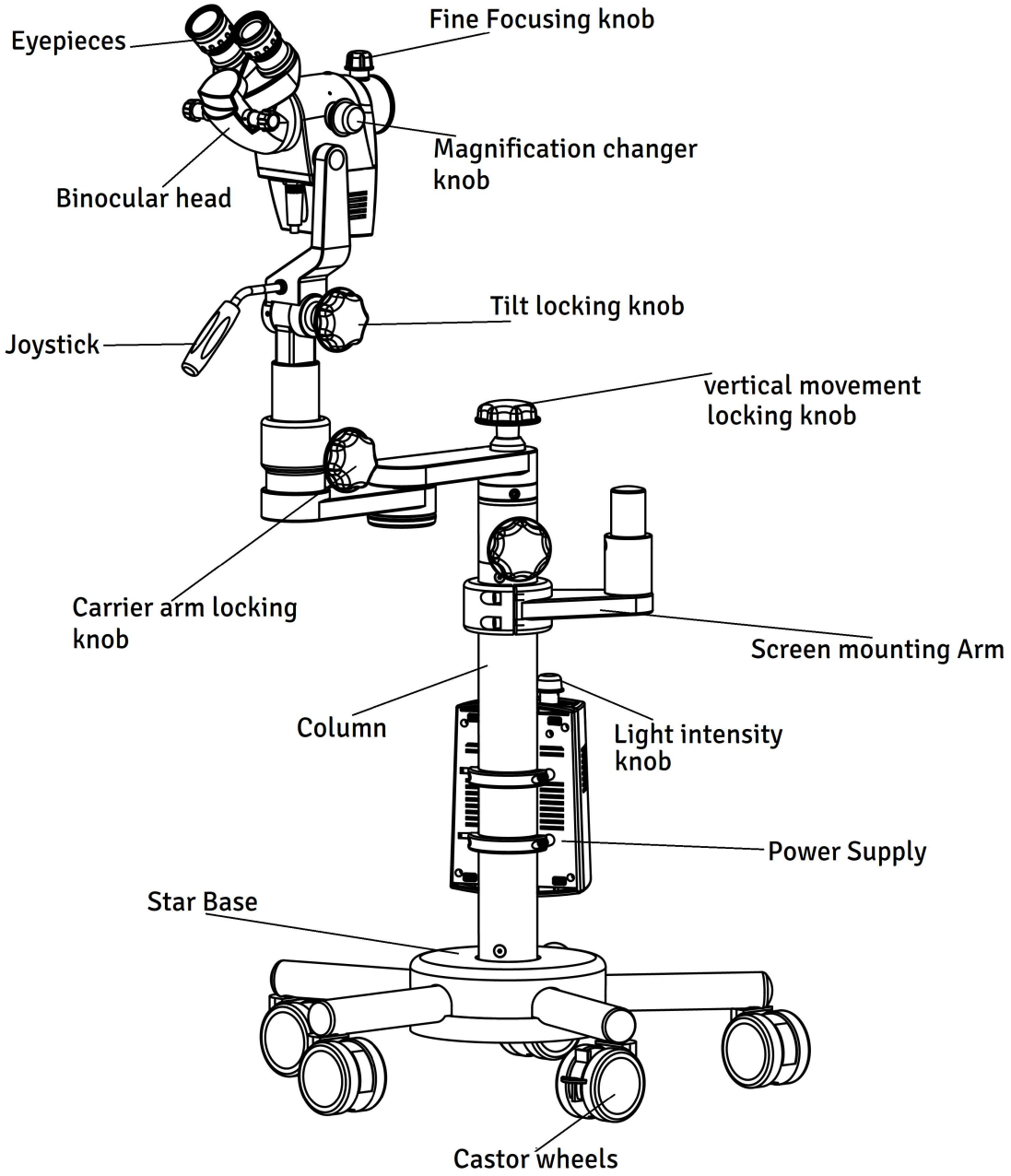
The colposcope can be positioned easily with the suspension arm within a vertical travel range of 500 mm. It can be maneuvered easily with the 980 mm long pantographic arm for user and patient comfort. When not in use, the colposcope can be folded easily over the main body for compact storage.



INTRODUCTION (continued)

Prima C Plus:
Ergonomic stand for easy and accurate positioning, with a vertical travel of 100 mm and a horizontal extender arm movement of 400 mm.

To set the desired height, slightly loosen the vertical movement locking knob, adjust the height and then retighten the knob.



2. WARNINGS & CAUTIONS

LABOMED is not responsible for the safety and reliability of this instrument when:
- Assembly, disassembly, repair or modification is carried out 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 OUTLINED IN THIS USER MANUAL. 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 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: 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. WHERE THE SUPPLY VOLTAGE FLUCTUATES, A CONSTANT-VOLTAGE STABILIZER OR UPS IS RECOMMENDED FOR SAFE AND EFFICIENT USE OF THE DEVICE.

WARNING: TO AVOID THE RISK OF ELECTRIC SHOCK AND FOR THE SAFETY OF THE INSTRUMENT, THIS INSTRUMENT MUST BE PLUGGED INTO AN OUTLET WITH AN EARTH GROUND. DO NOT REMOVE OR DEFEAT THE EARTH GROUND CONNECTION ON THE 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. 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 WITH OXYGEN OR NITROUS OXIDE.

WARNING: DO NOT PROLONG THE EXAMINATION UNNECESSARILY. SET THE BRIGHTNESS NO HIGHER THAN NEEDED FOR CLEAR VISUALIZATION OF THE EXAMINED TISSUE.

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 CONTAINS 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 ELECTRICAL EQUIPMENT NEEDS SPECIAL PRECAUTIONS WITH RESPECT TO ELECTROMAGNETIC COMPATIBILITY (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 UNLESS IT HAS BEEN TESTED TO THE APPLICABLE IEC OR ISO STANDARDS.

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

CAUTION: DO NOT OPERATE THE DEVICE WITHOUT THE SILICONE COVERS ON THE HANDLES AND ALL KNOBS.

WARNING LABELS AND NOTES


Caution


Warning


Brightness control


Accompanying documents must be consulted

REF Catalog number


Compliance with Regulation (EU) 2017/745 (MDR)


Protective earth


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


Keep dry: keep the transport package away from rain.

I O Power ON / OFF


Year of manufacture (on the product data plate)


Alternating current


Fragile: the contents of the transport package are fragile and 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 electrical and electronic equipment


Accompanying documents must be consulted.



Temperature Range

MD Medical Device


Max. safe load 9 kg

IP 20 Ingress protection

WARNING LABELS AND NOTES

DIRECTIVES AND STANDARDS

CE Certification

The device is subject to the conformity assessment procedure of Article 52 (7), with technical documentation in accordance with Annexes II and III of Regulation (EU) 2017/745. These devices are Class I (without a measuring function, non-active and non-invasive) per Rule 1 of Annex VIII of the regulation (MDR 2017/745). The CE mark on every colposcope indicates conformity with the legal requirements.

QUALITY MANAGEMENT

LABOMED has an established quality management system according to ISO 13485:2016 and the US FDA 21 CFR 820 cGMP requirements. Regular internal auditing is the key to continuous improvement. Monitoring by authorized external auditors ensures conformity 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 photonics. 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 Application of risk management to medical devices.

DIRECTIVES / 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 (510(k) not applicable).
- Please observe all applicable ac cident prevention regulations.
- IP code: IP 20

INTENDED USE

The LABOMED Prima C / CS / C Plus colposcope 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 to select areas for biopsy. It offers the user an excellent level of comfort and improves visual acuity during use.

Note: The Prima C / CS / C Plus colposcope is intended solely for operative and diagnostic medical use. No contact is to be made between the patient and the device.

CONFIGURATIONS

	Catalog No.
Colposcope PRIMA C	**6128000**
PRIMA CS	6128600
PRIMA C Plus	6128900

3. CONDITION OF MATERIAL AT TIME OF SUPPLY

PRIMA C

The appliance is delivered in 5 assembled groups:

- Mobile supporting base (assembled), as shown in Fig. 1, page 12
- Column (part 1, page 12)
- Illumination box with integrated electrical power supply (see Fig. 2.1, page 13)
- Colposcope arm (see Fig. 2.2, page 13)
- Colposcope head with eyepieces (inclined or straight), see Fig. 2.13, page 27

Fasteners are enclosed in the packing box.

PRIMA CS

The appliance is delivered in 5 boxes:

Three boxes containing
- Wheel support base (left)
- Wheel support base (right)
- Center support base

One box containing
- Column
- Colposcope arm with integrated illumination box

One box containing
- Carrier assembly
- Colposcope head (inclined or straight)
- Eyepieces

Fasteners are enclosed in the packing box.

PRIMA C Plus

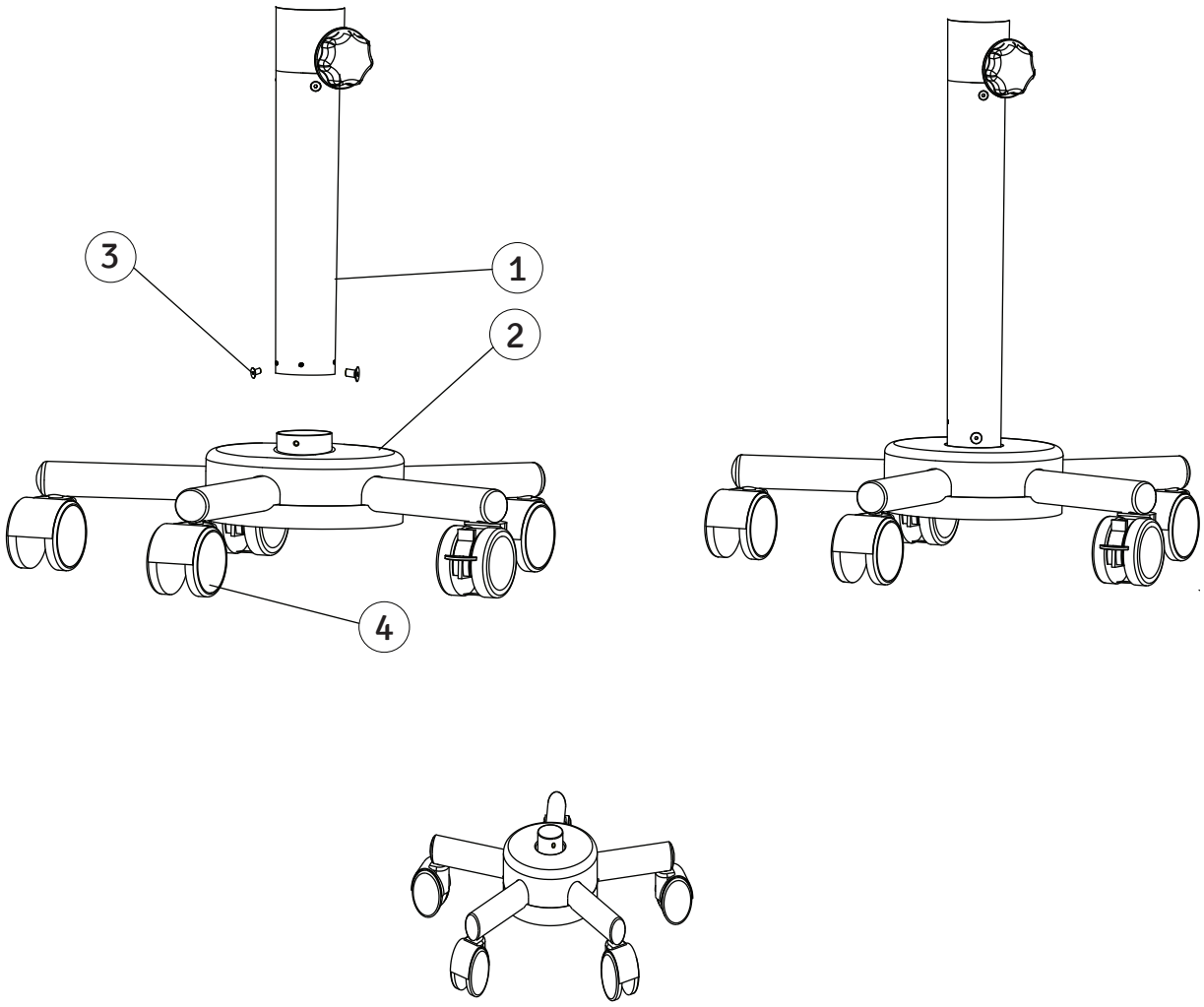
The appliance is delivered in 5 assembled groups:

- Mobile supporting base (assembled), as shown in Fig. 1, page 16
- Column (part 1, page 16)
- Illumination box with integrated electrical power supply (see Fig. 2.1, page 17)
- Colposcope arm (see Fig. 2.2, page 17)
- Colposcope head with eyepieces (inclined or straight), see Fig. 2.13, page 27

4. INSTALLATION INSTRUCTIONS OF PRIMA C

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

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

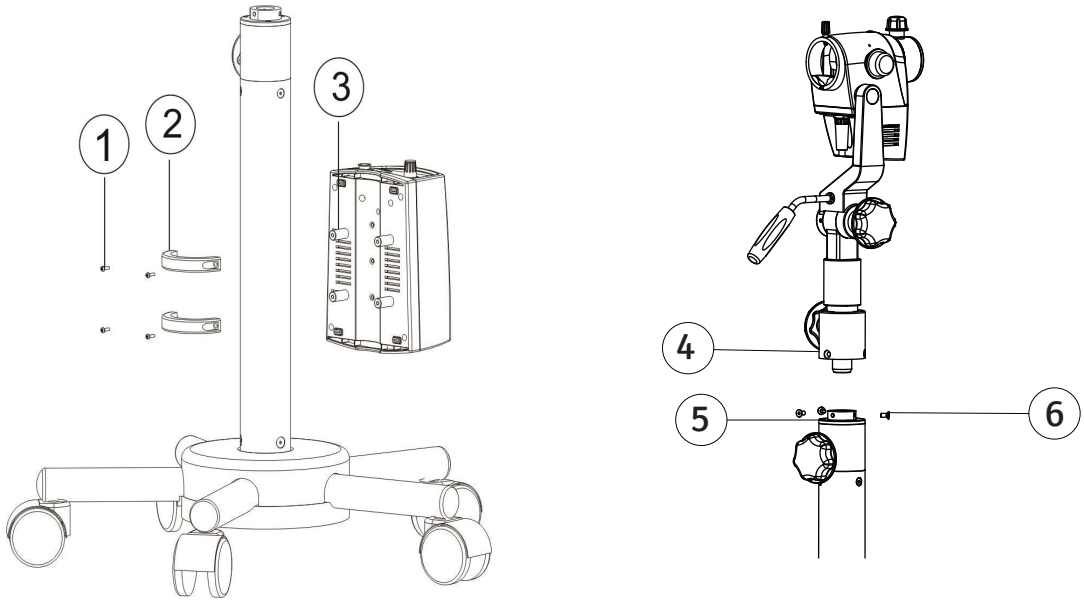


(Fig. 1)

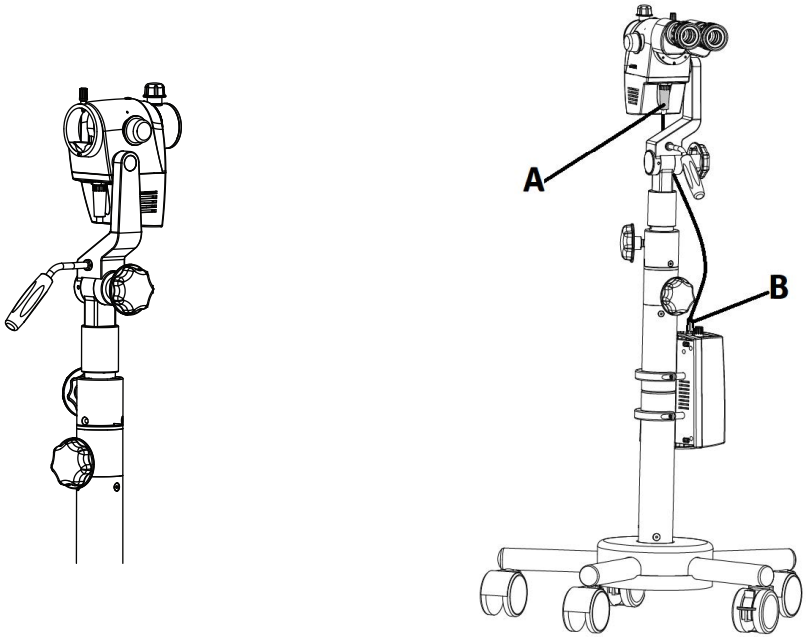
INSTALLATION INSTRUCTIONS OF PRIMA C (continued)

4.2 MOUNTING OF APPLIANCE

- Mount the illumination box (3) to the column against the vertical guide (2).
- Tighten the screws (1) to hold the box, as shown in Fig. 2.1.
- Insert the arm (4) of the colposcope head onto the top of the column (5).
- Tighten the screws (6) on both sides of the head arm (4).
- Connect the power cable (A) to the inlet on the magnification changer and (B) to the power supply, as shown in Fig. 2.2.



(Fig. 2.1)

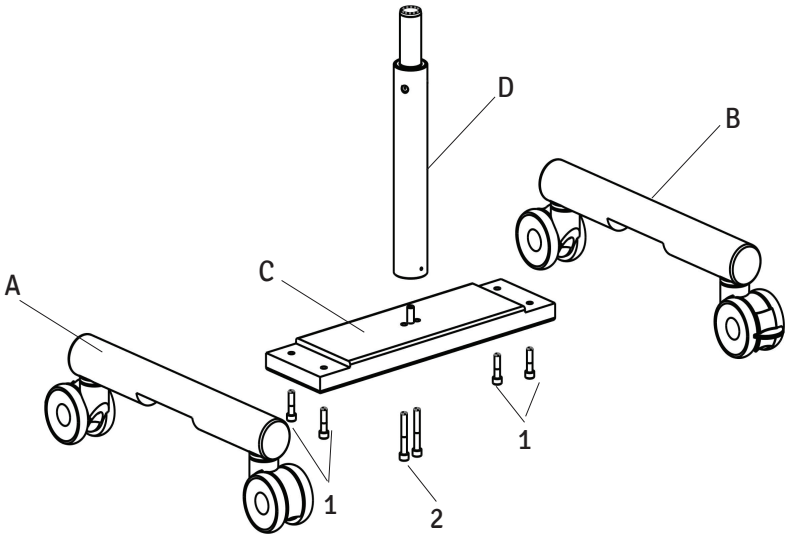


(Fig. 2.2)

5 . INSTALLATION INSTRUCTIONS OF PRIMA CS

- Install the left wheel support (A) and the right wheel support (B) on the center support base (C) by tightening the Allen screws (1) from the bottom of the metal plate. See Fig. 2.3.

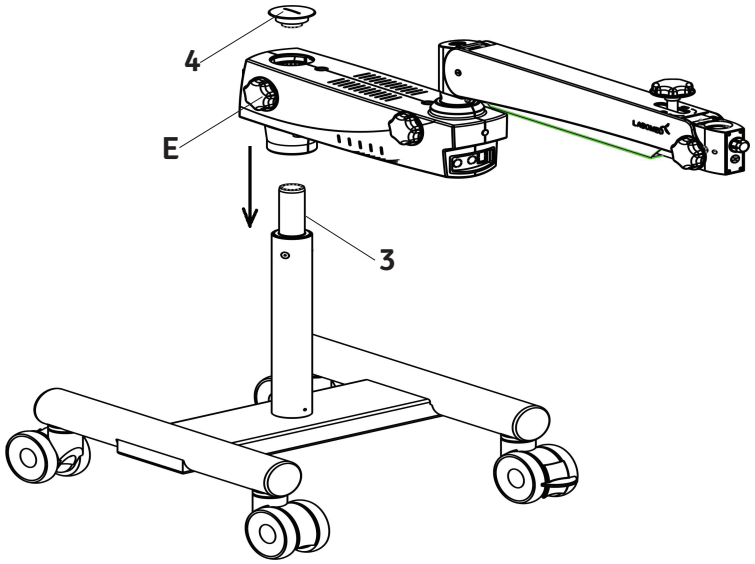
- Install the column (D) on the base. Engage the column with the indexing screw (E). Align the tapped hole of the column with the screw seat, hold the column firmly and tighten the Allen screw (2) from the bottom of the base. See Fig. 2.3.



(Fig. 2.3)

- Make sure the swivel arm lock knob (E) is loosened, then install the swivel arm and suspension arm assembly on the upright holding shaft (3). See Fig. 2.4.

- Lock the swivel arm with the threaded screw (4) from the top. See Fig. 2.4.



(Fig. 2.4)

INSTALLATION INSTRUCTIONS OF PRIMA CS (continued)

- Take the carrier assembly out of the packing and proceed as follows (see Fig. 2.5).

- Install the coupling on the suspension arm by sliding the guiding shaft (5) into the suspension arm.

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

- Secure the flat-head safety screw (M5) with a flat-head screwdriver in the socket of the suspension arm front coupling, shown as (7) in Fig. 2.5. The screw is attached with a tie to the potentiometer knob.

- Connect the power cable (A) to the inlet on the magnification changer, as shown in Fig. 2.5.

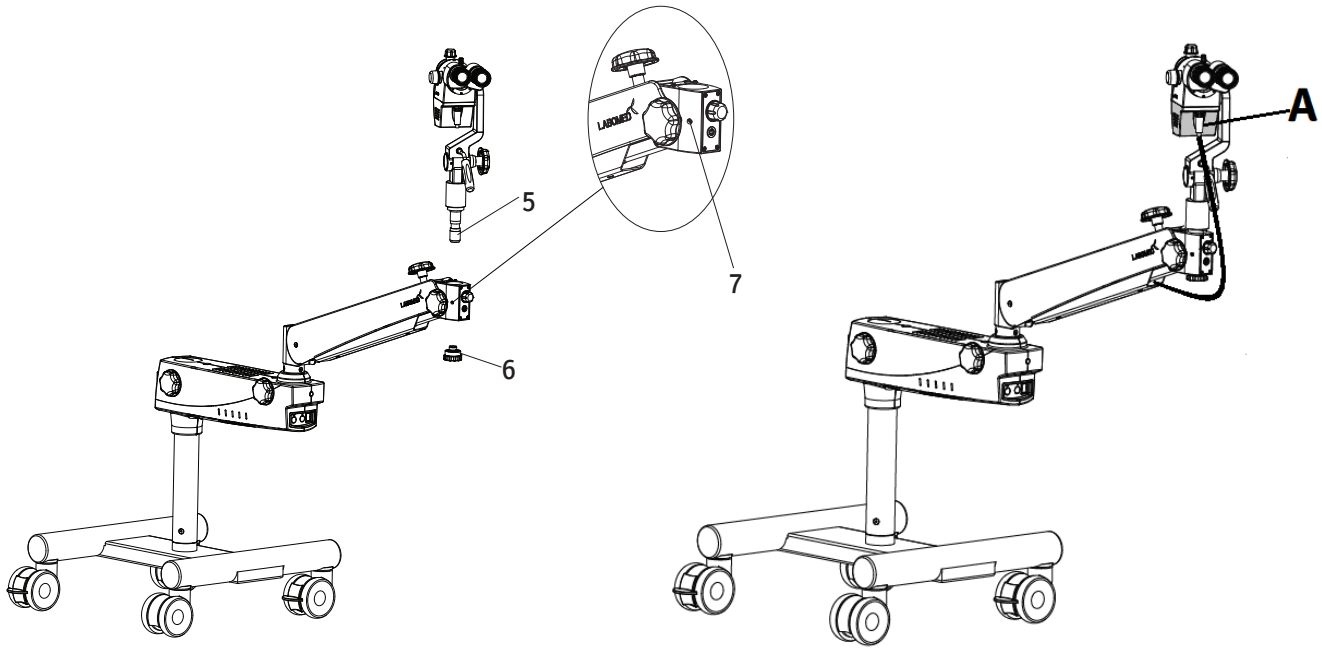


Fig. 2.5

5.1 SPECIAL INSTRUCTIONS:

- The joint that connects the swivel arm and the column is fitted with a stop to protect the internal cables.

- The total rotation of the swivel arm relative to the column is no more than 180°.
- On reaching the stop, do not rotate further, to prevent tearing or damage to the mechanism.

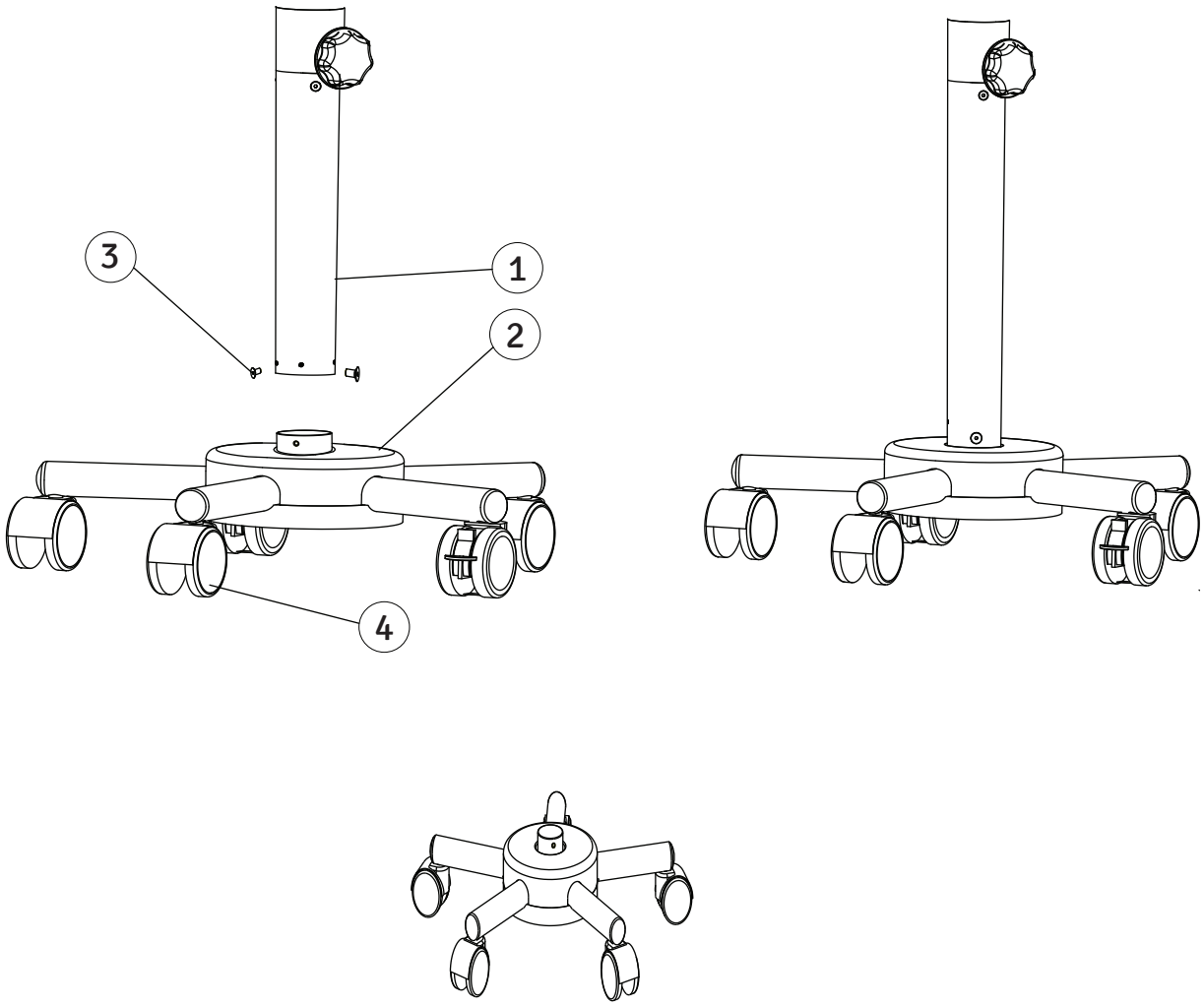
5.2 ADDITIONAL LOAD

- The load capacity and tilting stability are balanced for a maximum load of 9.0 kg with the standard supplied parts and accessories.
- Do not attach any additional load.

6. INSTALLATION INSTRUCTIONS OF PRIMA C Plus

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

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

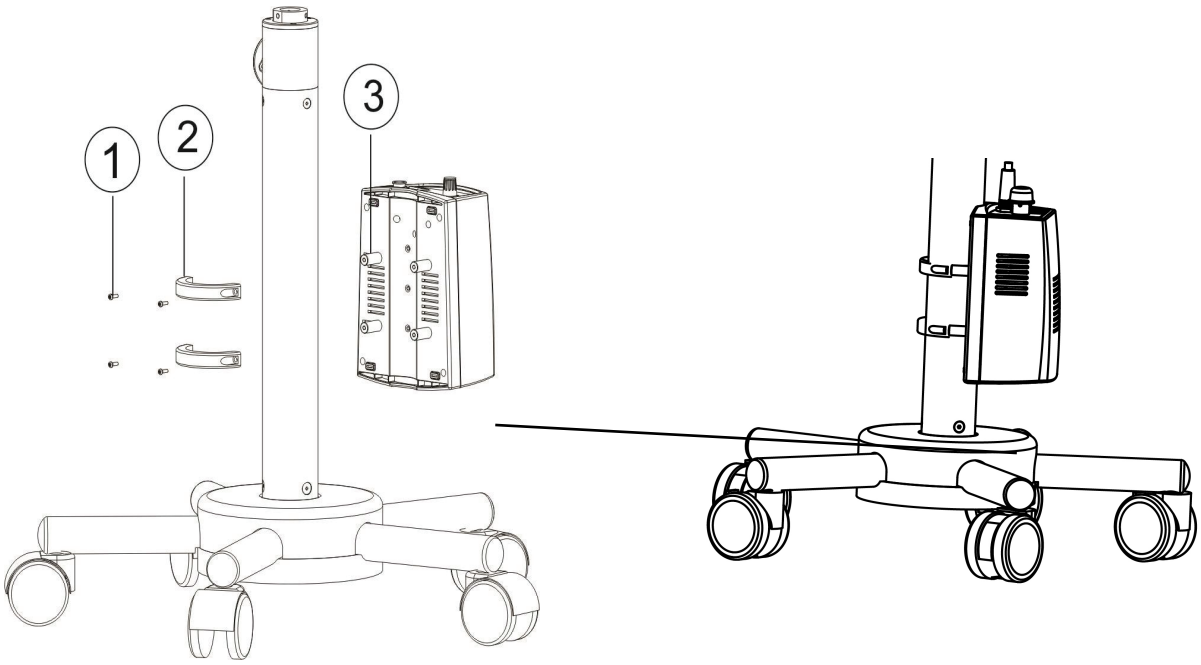


(Fig. 1)

INSTALLATION INSTRUCTIONS OF PRIMA C Plus (continued)

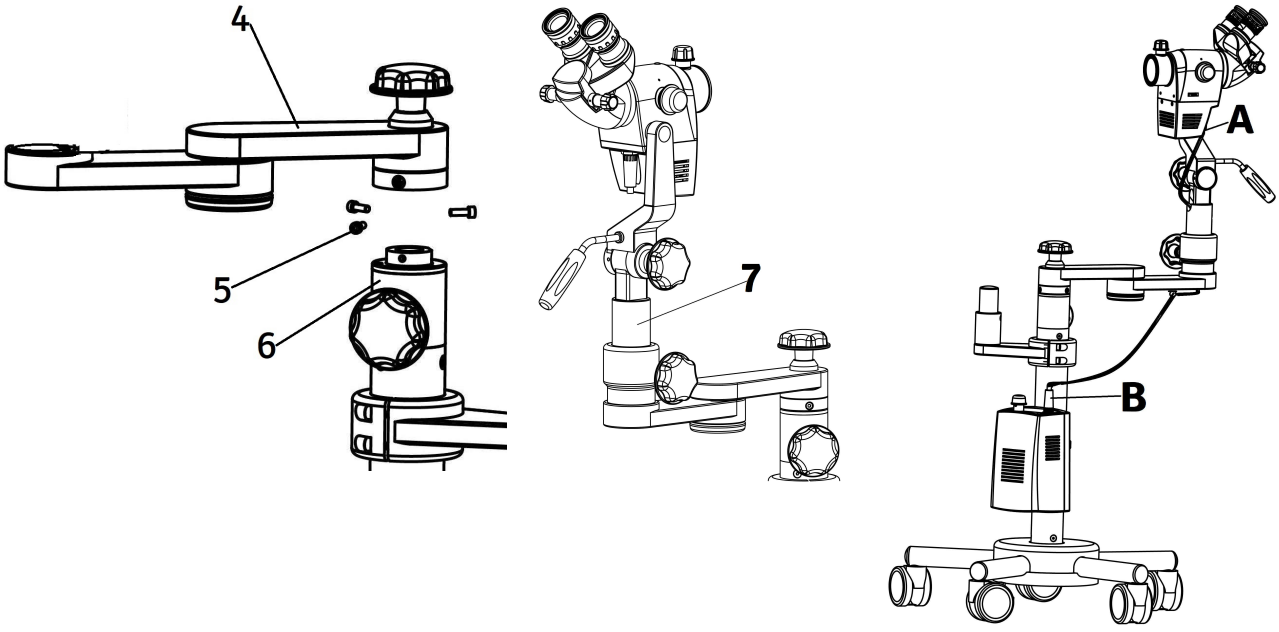
6.2 MOUNTING OF APPLIANCE

- Mount the illumination box (3) to the column against the vertical guide (2).
- Tighten the screws (1) to hold the box, as shown in Fig. 2.1.



(Fig. 2.1)

- Insert the swivel arm (4) onto the top of the column (6).
- Tighten the screws (5) on both sides of the swivel arm (4).
- Insert the colposcope carrier (7) into the swivel arm (4) and tighten it.
- Connect the power cable (A) to the inlet on the magnification changer and (B) to the inlet on the power supply, as shown in Fig. 2.2.

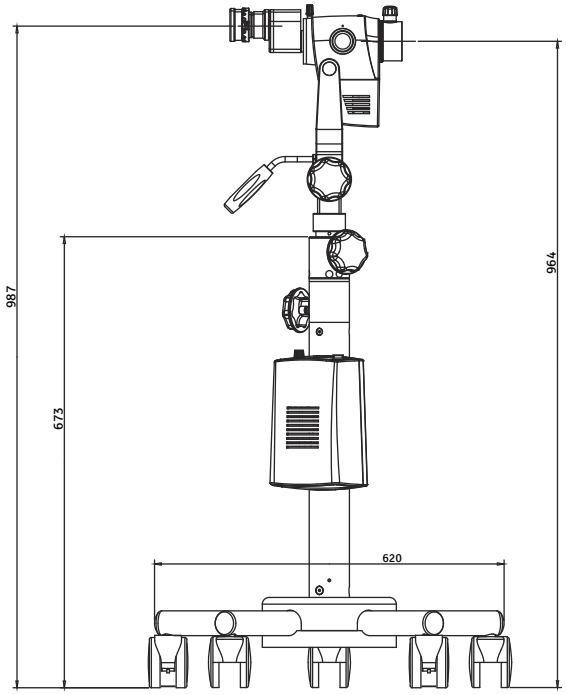


(Fig. 2.2)

7. DIMENSIONS & WEIGHT PRIMA C

DIMENSIONS & WEIGHT (Fig. 2.6) Prima C

Colposcope with roller star base stand
Total weight: approx. 45 kg.



(Fig. 2.6) Prima C

8. DIMENSIONS & WEIGHT PRIMA CS

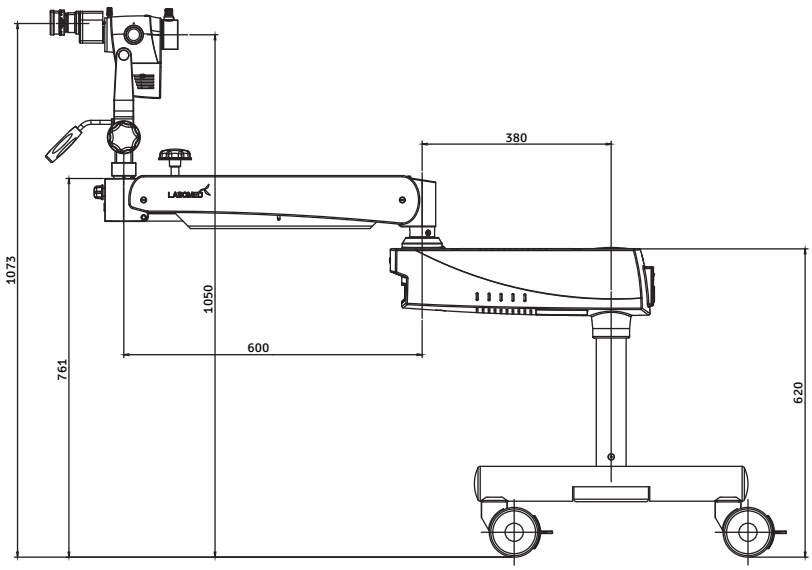
DIMENSIONS & WEIGHT (Fig. 2.7) Prima CS

Colposcope with H base stand
Total weight: approx. 86.5 kg.

Three boxes containing:
Base left wheel support: 20 kg
Base right wheel support: 20 kg
Base center support: 20 kg

One box containing:
Column: 8 kg
Colposcope arm: 15 kg

One box containing:
Carrier assembly: 2.5 kg
Colposcope head: 600 g
Eyepieces and accessories: 400 g



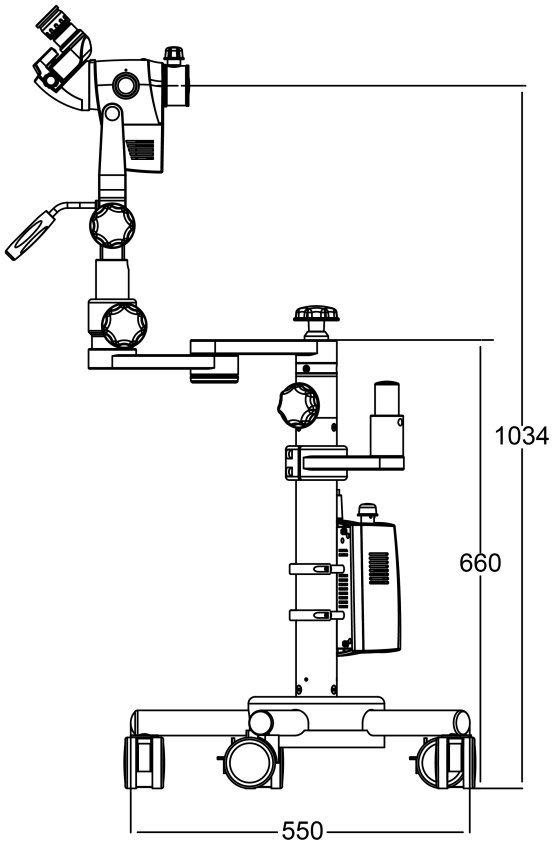
(Fig. 2.7) Prima CS

9. DIMENSIONS & WEIGHT PRIMA C Plus

DIMENSIONS & WEIGHT (Fig. 2.6a) Prima C Plus

Colposcope with roller star base stand
Total weight: approx. 40.8 kg.

Colposcope 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 Fig. (i).

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

Note: Power supply is designed with universal input of 100–240 V AC, 50/60 Hz. To connect it, follow the instructions on the electrical label at the bottom of the arm, shown as (3) in Fig. (i).

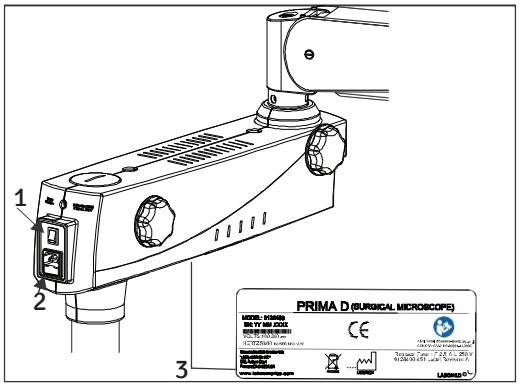


Fig. (i)

9.1 REPLACING THE ILLUMINATION SOURCE

Open the swivel arm covers. Detach the fiber optic cable and replace illumination assembly A with a new assembly. Refit the arm covers.

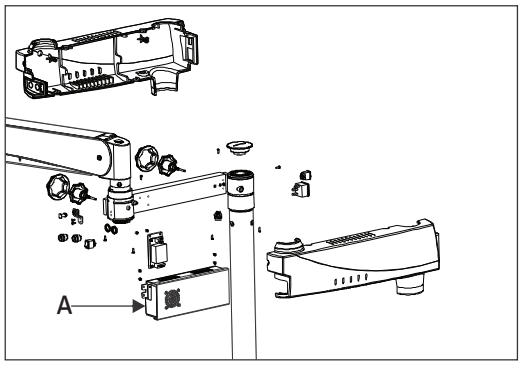


Fig. (ii)

9.2 FUSE REPLACEMENT

The fuse is located in the AC inlet, near the on/off switch. Use a flat-head screwdriver to open the fuse compartment. It holds two fuses: one in use and one spare. Replace the blown fuse with the spare fuse and close the fuse compartment. For fuse replacement, refer to the label shown in Fig. (iii).

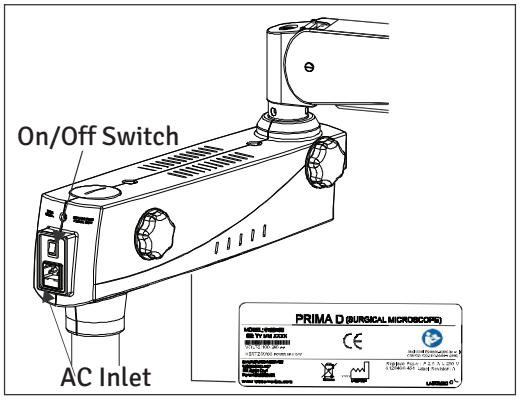
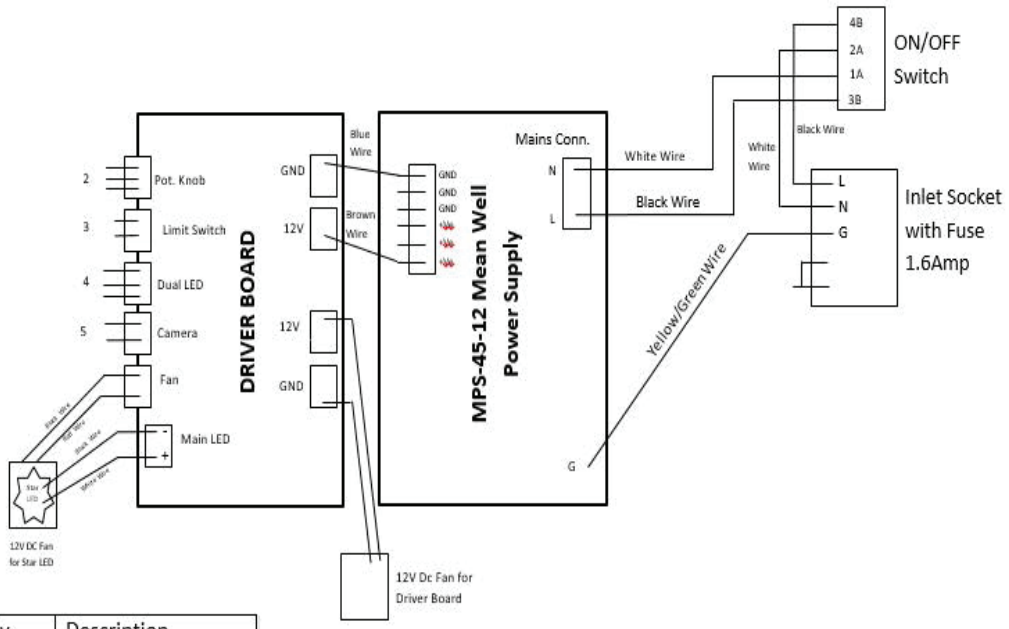


Fig. (iii)

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

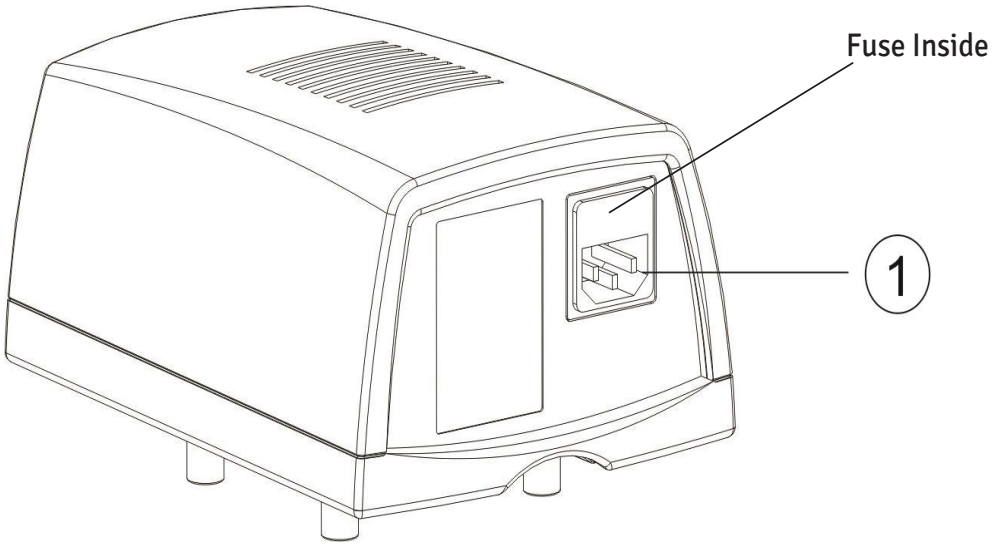
9B. ELECTRICAL CONNECTIONS PRIMA C/C Plus

Connect the power cable to the AC inlet socket, shown as 1 in Fig. 2.8 below.
Switch on the power with the on/off switch, shown as 1 in Fig. 2.9 on page 23.

Note: The power supply has a universal input of 100–240 V AC, 50/60 Hz. To connect it, follow the instructions on the electrical label at the back of the illumination box, shown in Fig. 2.8 below.

a. CHANGING THE FUSE

- **Note:** The fuses are in the fuse holder:
  F2.5 A (2 main input fuses for the lamp supply, mains voltage 100–240 V)
- Changing the fuse: Disconnect the power plug. Insert a screwdriver into the slot of the fuse holder and unscrew it to the left. Remove the cap and replace the fuse inside it. Refit the cap and screw it in to the right. Refer to the electrical label for the correct replacement fuse.
- Attention: Replace fuses only with the specified type.



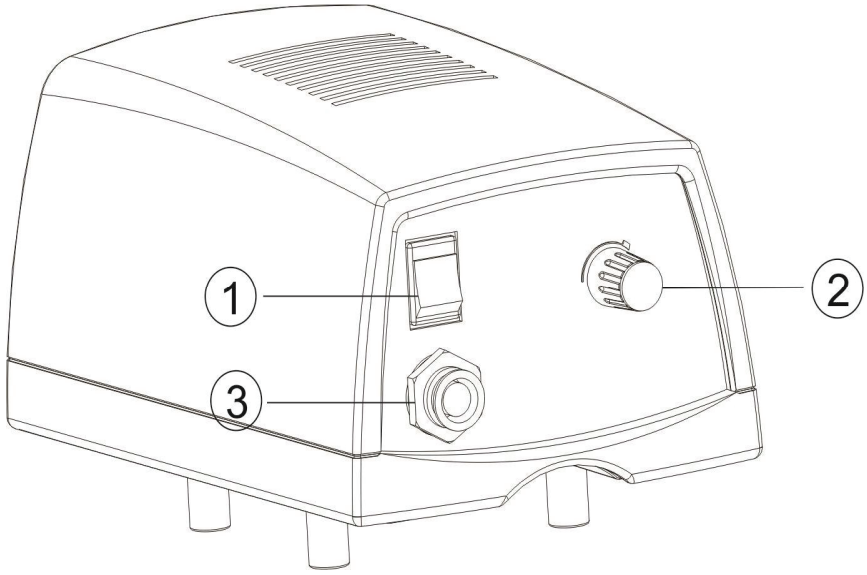
(Fig. 2.8)

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 switched on, the green diode in the illumination switch indicates that the colposcope is ready for operation. The LED lights up and the cooling fan starts.

10.2 **BRIGHTNESS CONTROL,** shown as (2), varies the light intensity when the knob is turned.

NOTE: To maximize LED life, switch off the colposcope when not in use.

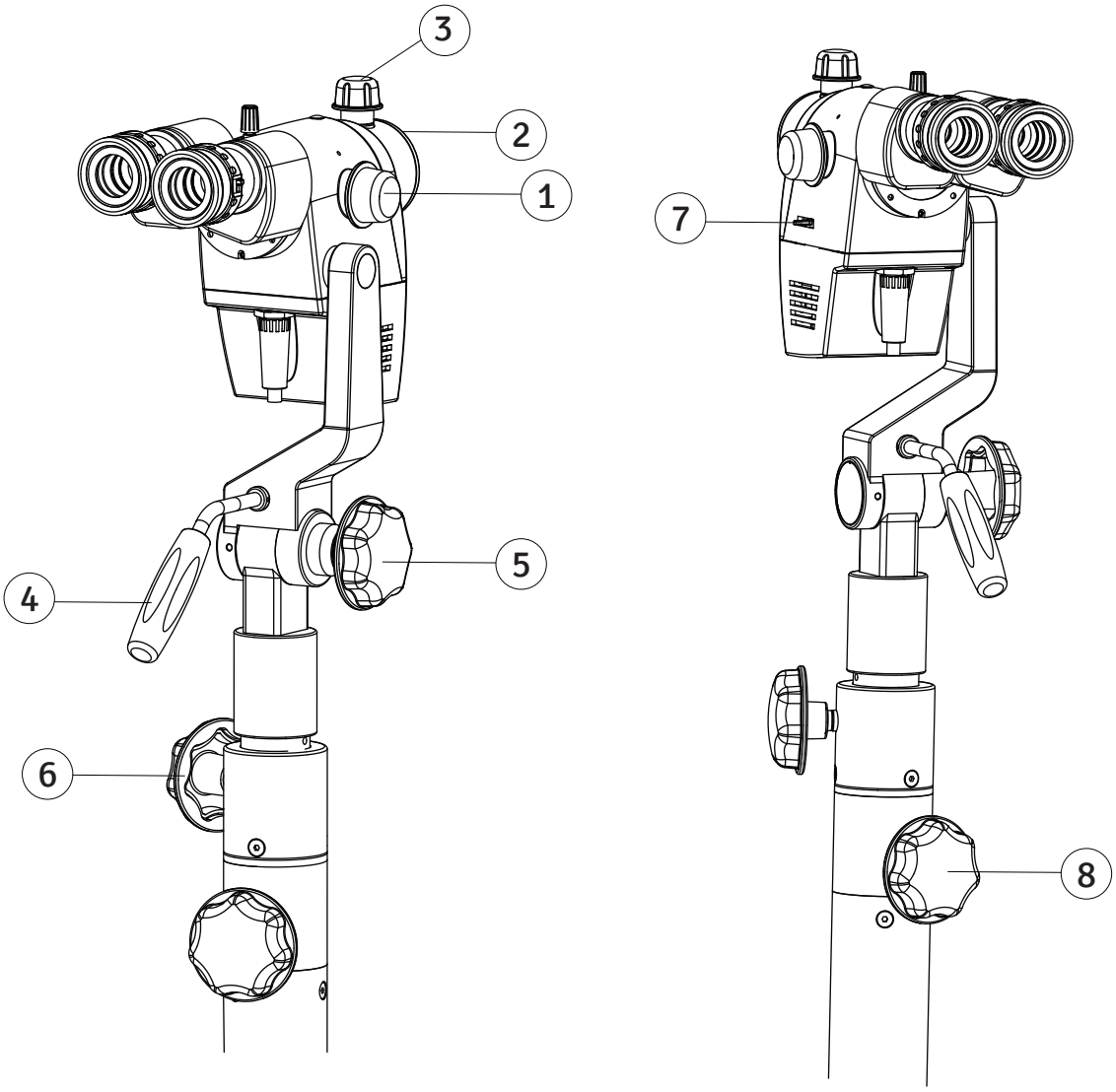


(Fig. 2.9)

11. CONTROL ELEMENTS PRIMA C

CONTROL ELEMENTS PRIMA C (Fig. 2.10 and 2.11)

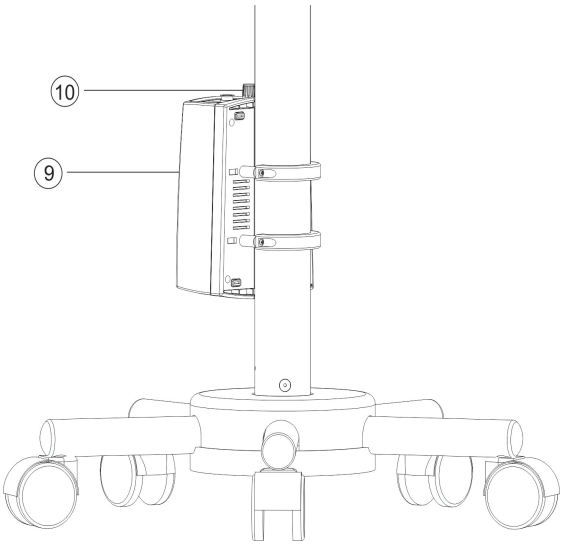
- Roller stand: 5 rollers to move the appliance and 2 brakes to lock it (see Fig. 1).
- Rotating knob to change the magnification (1).
- Common Main Objective (CMO) (2).
- Fine focusing knob (3).
- Joystick to tilt the head arm forward and backward (4).
- Head arm locking knob (5).
- Knob to lock the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



(Fig. 2.10)

CONTROL ELEMENTS PRIMA C (continued)

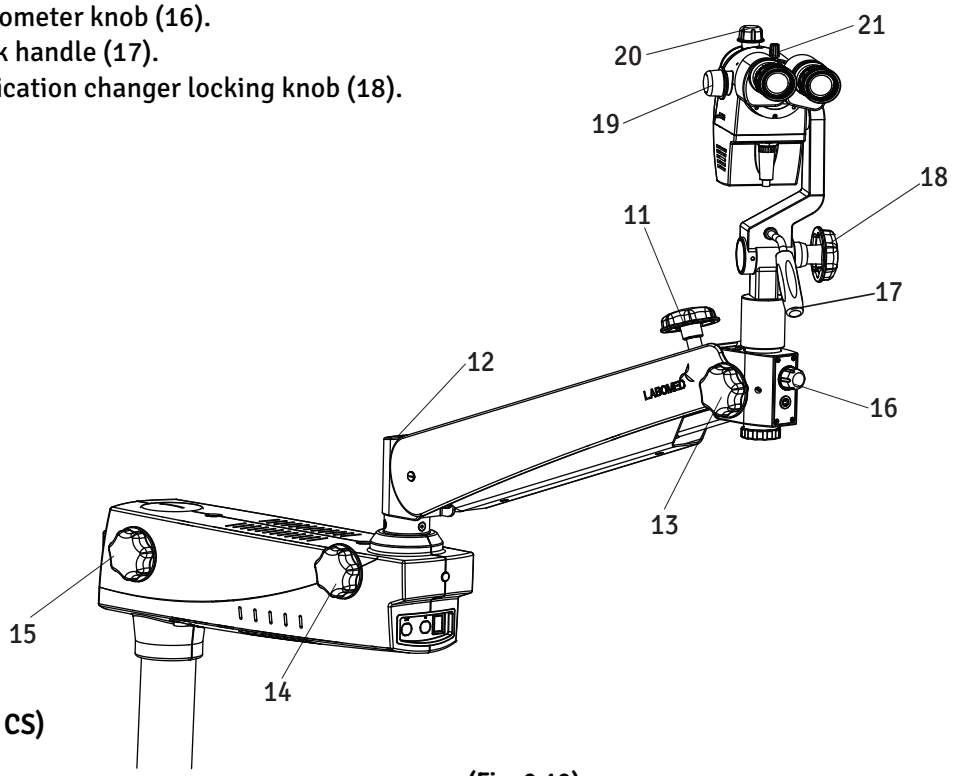
- Power supply box (9).
- Knob for brightness control (10).



(Fig. 2.11)

CONTROL ELEMENTS PRIMA CS

- Suspension arm hydraulic movement knob (11).
- Suspension arm spring tension adjustment (12).
- Colposcope arm locking knob (13).
- Suspension arm locking knob (14).
- Swivel arm locking knob (15).
- Potentiometer knob (16).
- Joystick handle (17).
- Magnification changer locking knob (18).
- Magnification knob (19).
- Fine focusing knob (20).
- Head locking knob (21).



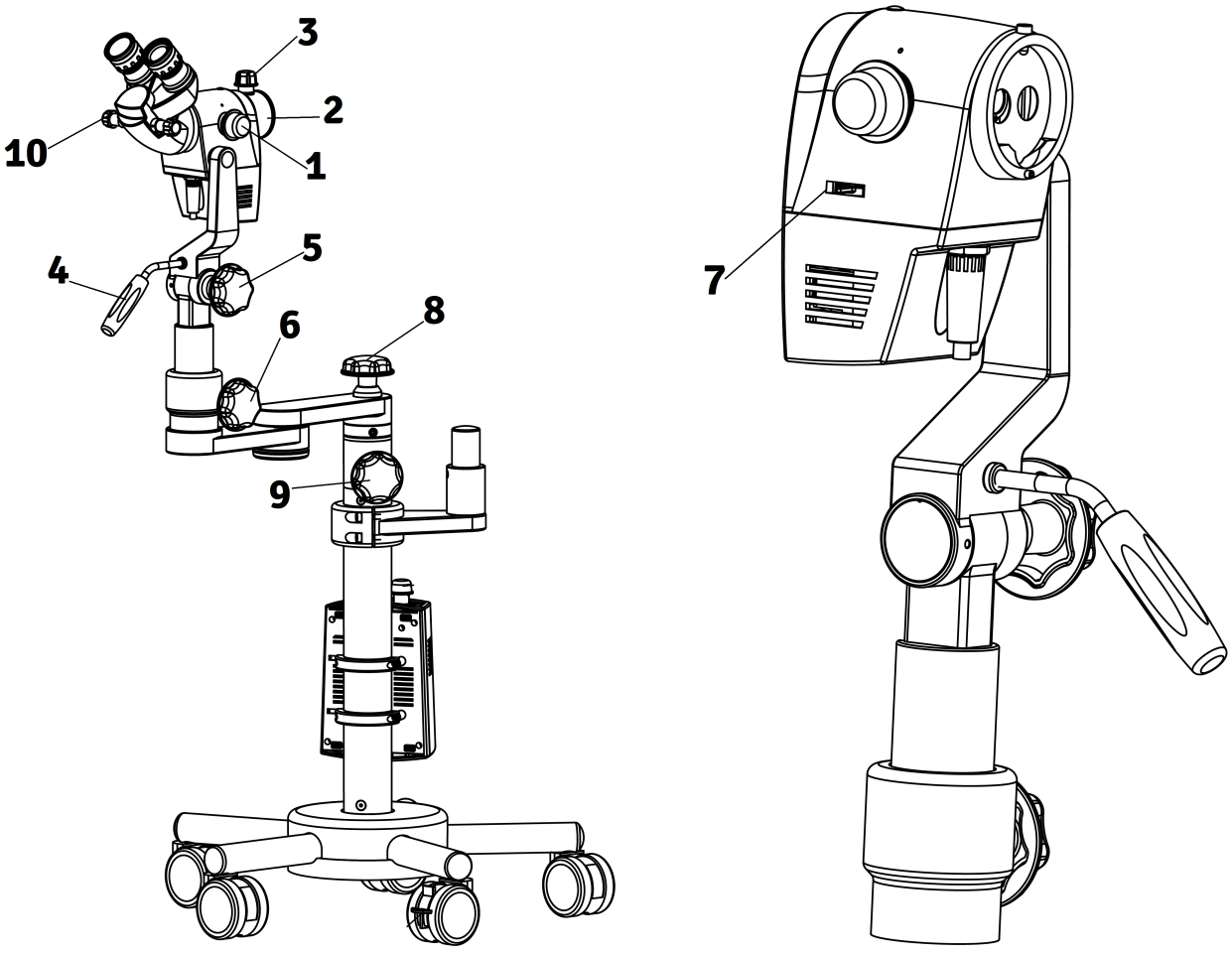
(Prima CS)

(Fig. 2.12)

CONTROL ELEMENTS PRIMA C Plus

CONTROL ELEMENTS PRIMA C Plus (Fig. 2.10a)

- Roller stand: 5 rollers to move the appliance and 2 brakes to lock it (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 the green filter (7).
- Column height adjustment knob (8).
- Horizontal arm lock knob (9).
- IPD knob (10).

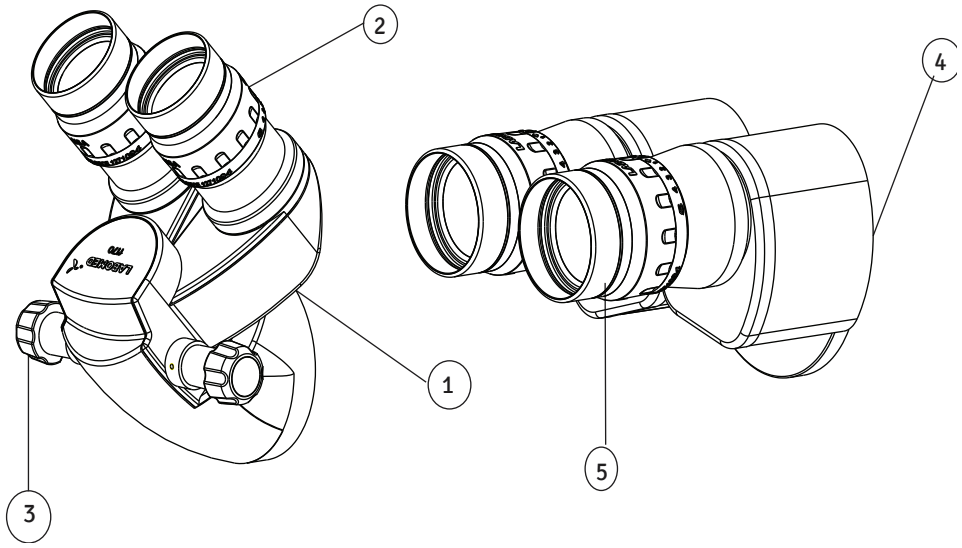


(Fig. 2.10a)

12. INSTRUCTIONS FOR USING THE COLPOSCOPE

a. ADJUSTMENT OF INTERPUPILLARY DISTANCE (Fig. 2.13)

- Turn the colposcope into the working position.
- Inclined tube 45° (1): Adjust the eyepieces (2) to the required IPD by turning the lateral knob (3).
- Straight tube (4): Adjust the eyepieces (5) by moving the binocular tube as required.

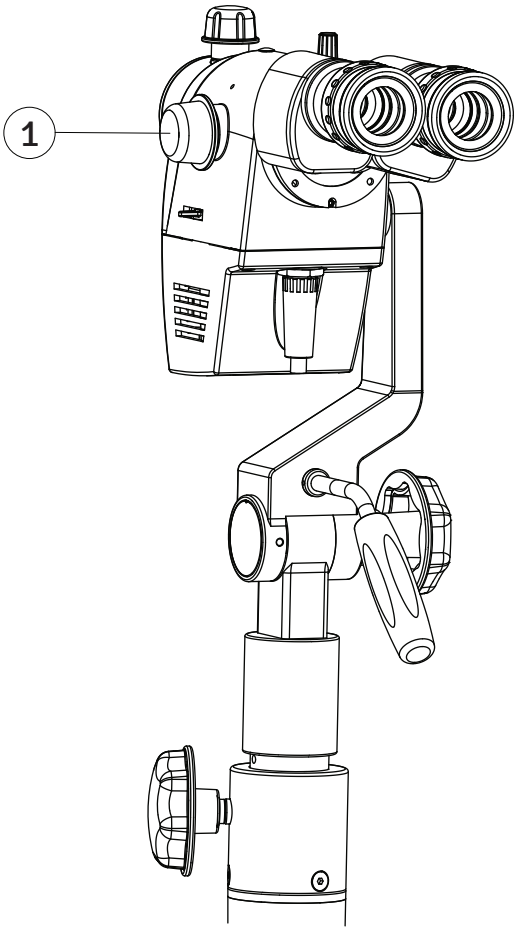


(Fig. 2.13)

INSTRUCTIONS FOR USING THE COLPOSCOPE (continued)

b. CHANGING THE MAGNIFICATION (Fig. 2.14)

- Adjust to the highest magnification with any of the rotating knobs (1) on the magnification changer.
- Make sure that the magnification step changer is engaged in the index position for the desired magnification.



(Fig. 2.14)

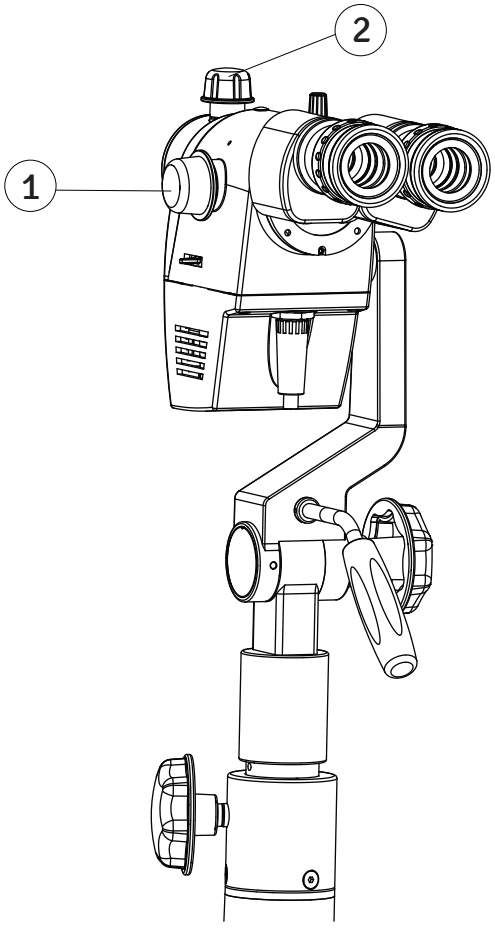
c. HOW TO FOCUS THE OBJECT (Fig. 2.15)

- Bring the object into rough focus using arm movements.
- Turn the fine focusing knob (2) clockwise or counterclockwise to bring the object into sharp focus.
- If the object is outside the range of the fine focusing knob, bring the complete colposcope into the focus range by any of the following means:

a. Roll the mobile stand forward and backward.
b. Adjust the arm left and right, and up and down.
c. Adjust the colposcope angle left and right. To do this, loosen the head arm knob and rotate the colposcope.

A combination of the above steps will give you the desired focus.

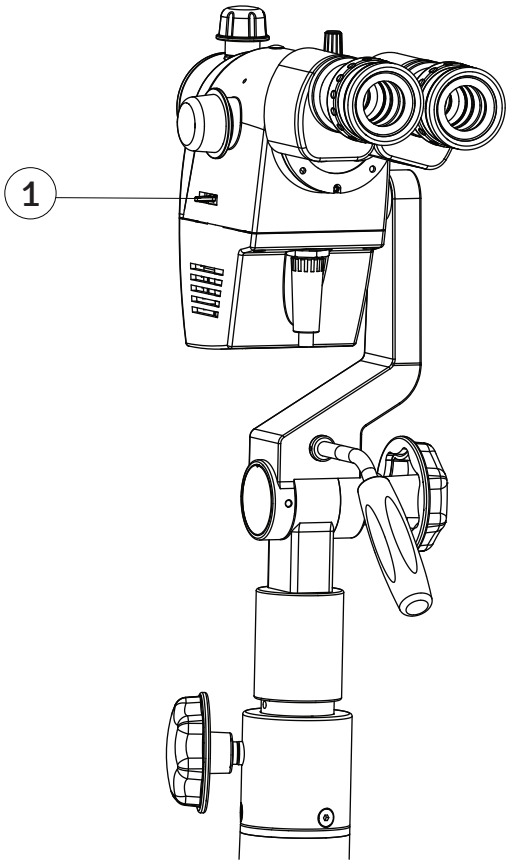
- Once the region of interest is in focus, change the magnification with the magnification changer knob (1).



(Fig. 2.15)

d. RED-FREE IMAGE OBSERVATION (Fig. 2.16)

- Turn the filter knob (1) to swing the red-free (green) filter in or out. The filter suppresses the red of the tissue in the observed image and enhances the image of the vessels and the vascular morphology.



(Fig. 2.16)

e. EYEPIECES WITH DIOPTER (Fig. 2.17)

- You can adjust the diopter setting to your vision correction.
- Diopter adjustment, 10x: ±5 D
- Diopter adjustment, 12.5x: ±5 D

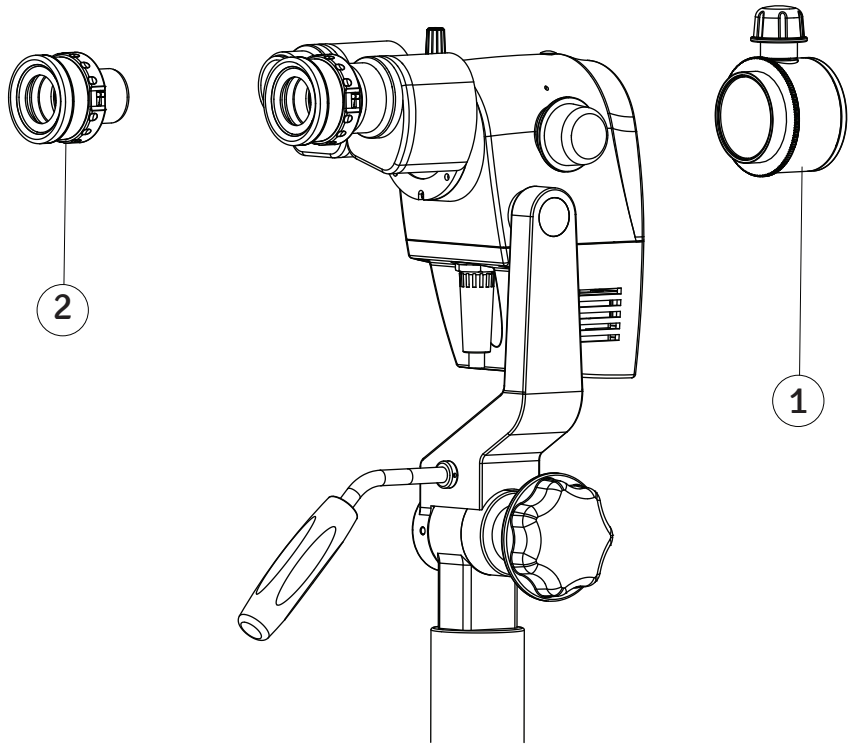


(Fig. 2.17)

13. CHANGING THE OBJECTIVE / EYEPIECES

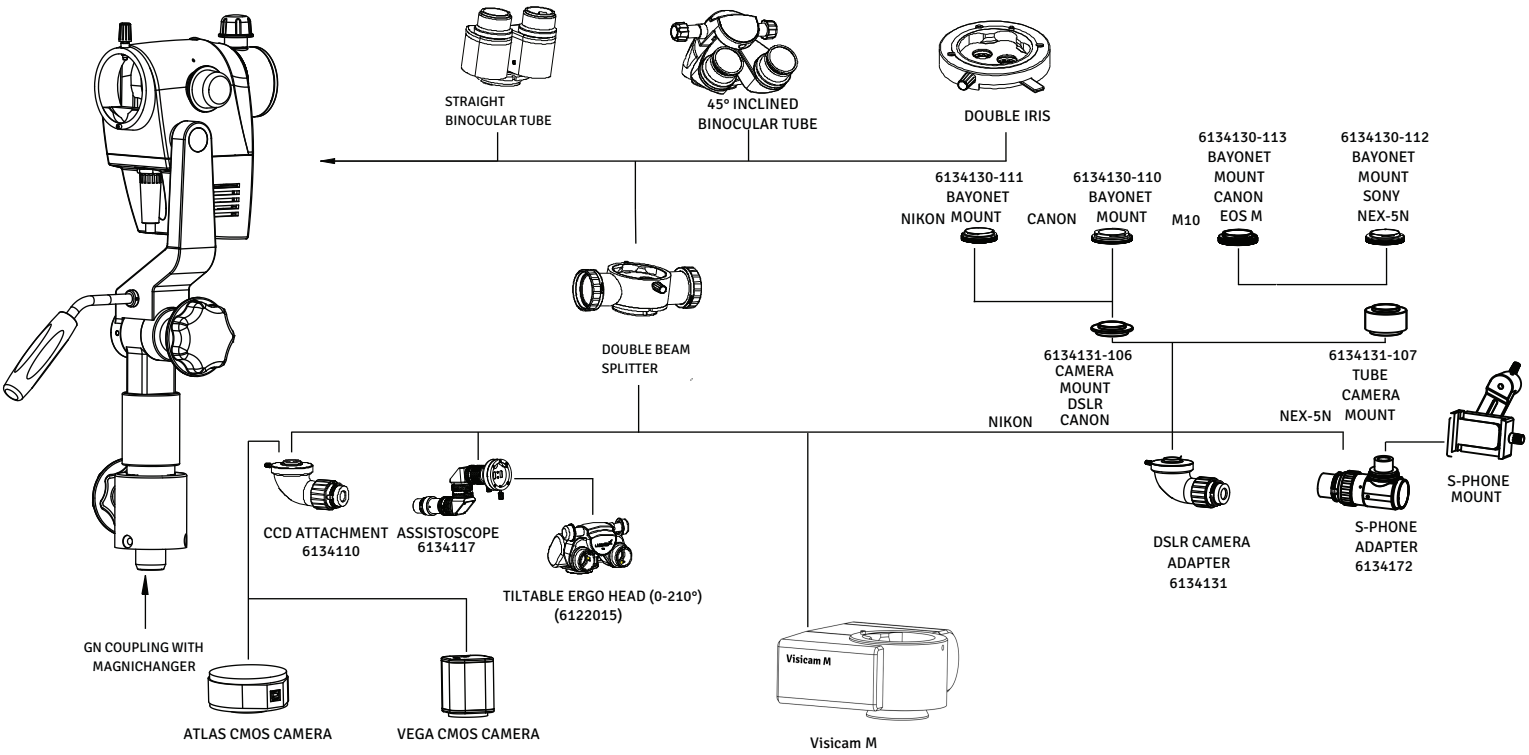
CHANGING THE OBJECTIVE / EYEPIECES (Fig. 2.18)

- The objective (1) has a screw mount. Unlock it by turning it counterclockwise and lock it by turning it clockwise.
- The eyepieces (2) are push-in type. Pull them out to change them.
- Other objectives and eyepieces can be selected as required.



(Fig. 2.18)

14. USE OF ACCESSORIES



(Fig. 2.19)

1. Install the double beam splitter in place of the binocular tube (straight or 45° inclined).
2. Four accessories are provided:
   2.1 DSLR camera adapter for Nikon, Canon and Sony
   2.2 CCD camera adapter for Vega.
   2.3 Adapter for Sony Handycam.
   2.4 Assistoscope for assistant viewing.
3. Install one or two accessories on either side (left or right) of the beam splitter.
4. Reinstall the binocular tube (straight or 45° inclined) on the double beam splitter.

15. CARE & MAINTENANCE

This instrument is a high-grade technological product and needs no special periodic maintenance if it is handled carefully. To ensure optimum performance and safe working order of the instrument, its safe functioning must be checked once every 12 months, as per the table below. We recommend having this check performed by our service representative as part of regular maintenance. If a failure occurs that you cannot correct with the troubleshooting table, attach an "out of order" sign to the instrument and contact our service representative for service parts, circuit diagrams, etc.

Colposcope Maintenance/Servicing Check

Colposcope: - **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 off any oily marks and fingerprints from the eyepieces, CMO and other optical parts with lens paper																															
Turn off the colposcope																															
Replace the dust cover																															
Each Month																															
Clean the colposcope body with a water-moistened tissue																															
Wipe the lenses with lens tissue and lens-cleaning fluid																															
Remove the fiber optic cable and clean it																															
Every 6 months																															
Service inspection																															
Smooth function of locking knobs																															
Smooth function of the torque adjustment mechanism on the suspension arm																															
Rotary motion of the carrier																															
INITIALS																															

CARE INSTRUCTIONS:

- Keep accessories away from dust when not in use, e.g. protect them with a dust cover.
- Remove dust with a rubber air blower and a soft brush.
- Use special optics cleaning cloths and pure alcohol for cleaning lenses and eyepieces.
- Protect the colposcope from moisture, fumes, acids and cosmetic materials. Do not store chemicals close to the instrument.
- Protect it from improper handling. Never install sockets for other devices or unscrew optical systems or mechanical parts unless explicitly instructed to do so in this manual.
- Protect the colposcope from oil and grease. Never oil or grease the guide surfaces or mechanical parts.

CARE & MAINTENANCE (continued)

- Protect the colposcope from oil and grease. Never oil or grease the guide surfaces or mechanical parts.

- Remove coarse contamination using a damp disposable cloth.
- Use disinfectants based on the following ingredients: aldehydes, alcohols, quaternary ammonium compounds.
- Camera: Clean optical components with a lint-free cloth moistened with a little methanol or glass cleaner. Do not use ethanol or spirit.
- Do not clean products and optical components in a cleaning/disinfecting device or an ultrasonic bath.
- LABOMED MaxLite coatings are fungus-resistant. If you clean as described above, the coatings will not be damaged.

TROPICAL ENVIRONMENT/FUNGUS:

LABOMED takes certain safety precautions 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 with silica gel and a plastic cover.

OCCUPATIONAL SAFETY AND HEALTH PROTECTION:

Observe the occupational safety and health protection of persons who process contaminated products.

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

INSTRUCTIONS

WORKPLACE:

Remove surface contamination with a paper towel.

REPROCESSING:

Reprocess the product immediately after use, or as required, following the cleaning instructions below.

CLEANING & SERVICING:

Needed: water, detergent, spirit, microfiber cloth.

- Take a linen or other soft cloth. Moisten it slightly with running tap water (<40 °C) and a little detergent, and clean the metal and plastic parts.
- Clean all optical components with spirits or alcohol.
- Dry optical components with a microfiber cloth; dry the rest of the product with a paper towel.
- For servicing as required, contact the LABOMED after-sales service department.

16. CLEANING AND DISINFECTION

THE 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 ordinary household bleach (sodium hypochlorite 5%) at a strength of 5000 ppm (10 parts water to 1 part bleach).

2. For cleaning optical surfaces:
Use 70% isopropyl alcohol.

PROCEDURE

- **Take a muslin cloth.**
- **Moisten it so that it feels wet.**
- **Disinfect/clean the surface gently, without much hand pressure, by drawing the wipe from one end to the other. Do not rub the parts.**

NOTE:

1. **Wear a mask and gloves while cleaning and disinfecting.**
2. **While cleaning, the muslin cloth must not be dripping wet, to prevent seepage into and rusting of moving or bare parts.**
3. **Alcohol is flammable; use it as a surface disinfectant in well-ventilated spaces only.**

AUTOCLAVING

The following autoclaving program is recommended for the rubber caps, sleeves and grips supplied by LABOMED:

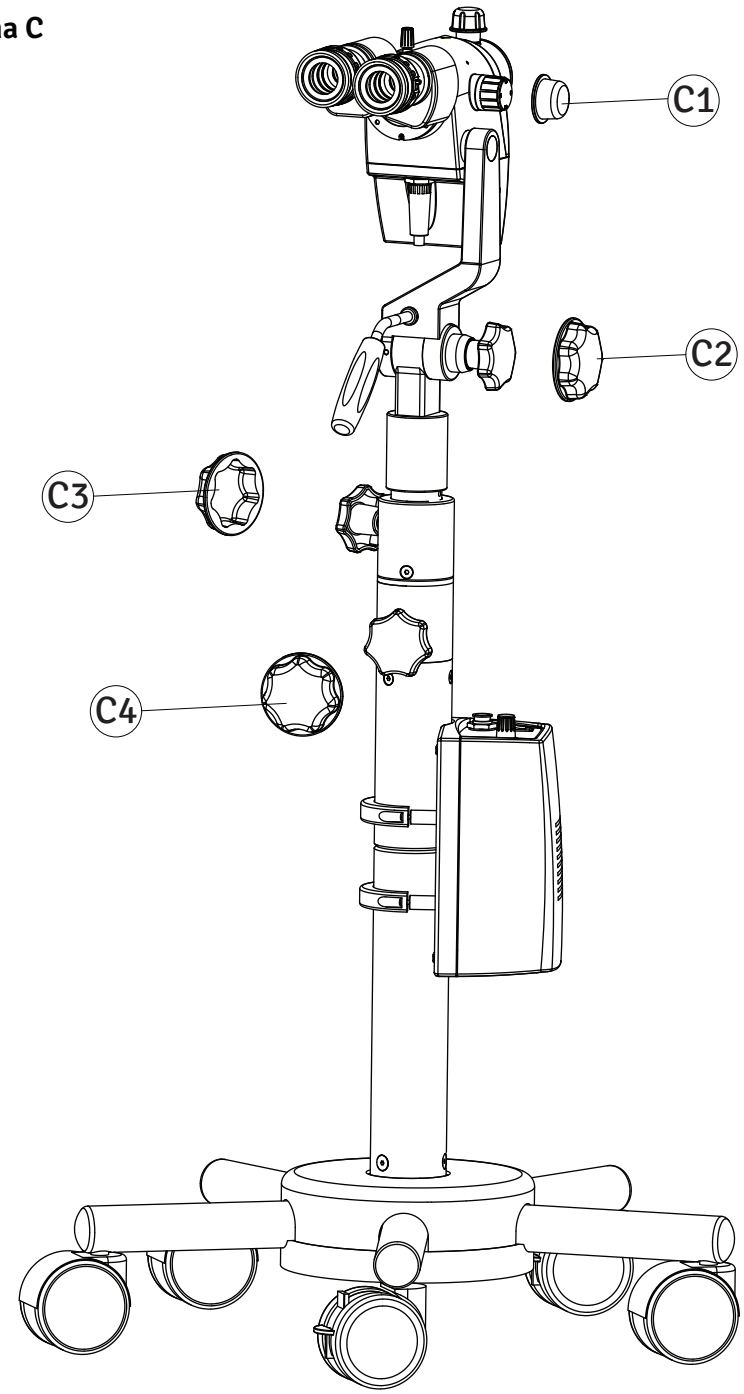
- Temperature: 134 °C
- Time: 10 minutes
- Instrument: Standard autoclave

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

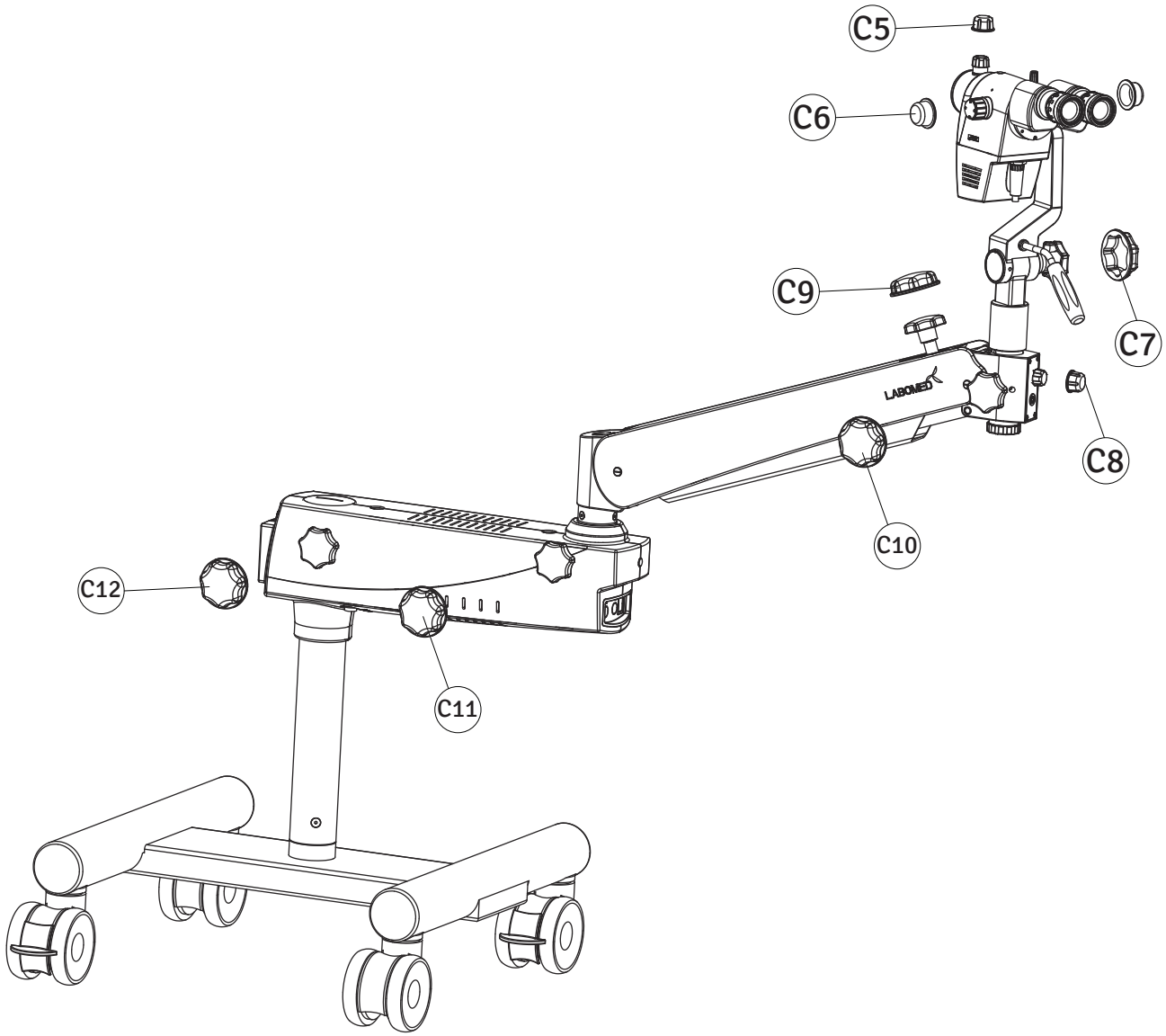


SCHEDULE OF AUTOCLAVABLE CAPS PRIMA CS

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

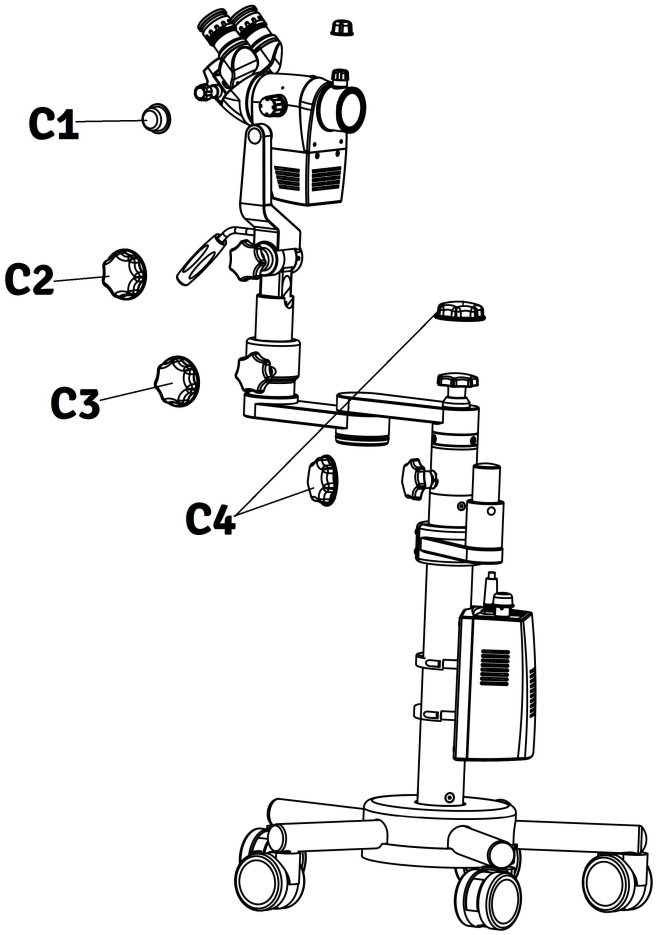


SCHEDULE OF AUTOCLAVABLE CAPS PRIMA C Plus

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 REQUIREMENTS

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 subject to the conformity assessment procedure of Article 52 (7), with technical documentation in accordance with Annexes II and III of Regulation (EU) 2017/745. These devices are Class I (without a measuring function and non-invasive) per Rule 1 of Annex VIII of the regulation (MDR 2017/745). The CE mark on every colposcope indicates conformity with the legal requirements.

19. DISPOSAL

Disposal must comply with local laws and regulations.

20. TECHNICAL SPECIFICATIONS

PRIMA C

- Star base stand and column, lockable wheels.
- Straight observation tube, interpupillary distance **49–78 mm. Optional:** 45° inclined.
- WF 10x/18 mm FOV, focusable eyepieces with retractable eyeguards, diopter adjustment ±5 D **Optional:** WF 12.5x/18 mm, diopter adjustment ±5 D
- 5-step magnification: 0.4x, 0.6x, 1.0x, 1.6x, 2.5x.
- f = 300 mm objective. **Optional:** f = 400 mm.
- Built-in green filter
- Built-in 27 W LED (5700 K)
- Vertical height adjustment: 100 mm
- 60 W maximum power consumption.
- Input voltage 100–240 V, 50/60 Hz. Fuse F2.5 A.

NOTE: For safety and warranty claim eligibility

Use a constant-voltage stabilizer to avoid sudden input voltage variations and to extend LED life.

PRIMA CS

- H base stand and column, lockable wheels.
- Straight observation tube, interpupillary distance 50–75 mm. **Optional:** 45° inclined.
- WF 10x/18 mm FOV, focusable eyepieces with retractable eyeguards, diopter adjustment ±5 D **Optional:** WF 12.5x/18 mm, diopter adjustment ±5 D
- 5-step magnification: 0.4x, 0.6x, 1.0x, 1.6x, 2.5x.
- f = 300 mm objective. **Optional:** f = 400 mm.
- Built-in green filter
- Built-in 27 W LED (5700 K)
- 60 W maximum power consumption.
- Input voltage 100–240 V, 50/60 Hz. Fuse F2.5 A.

NOTE: For safety and warranty claim eligibility

Use a constant-voltage stabilizer to avoid sudden input voltage variations and to extend LED life.

PRIMA C Plus

- Star base stand and column, lockable wheels.
- Straight observation tube, interpupillary distance **49–78 mm. Optional:** 45° inclined.
- WF 10x/18 mm FOV, focusable eyepieces with retractable eyeguards, diopter adjustment ±5 D **Optional:** WF 12.5x/18 mm, diopter adjustment ±5 D
- 5-step magnification: 0.4x, 0.6x, 1.0x, 1.6x, 2.5x.
- f = 300 mm objective. **Optional:** f = 400 mm.
- Built-in green filter
- Built-in 27 W LED (5700 K)
- Vertical height adjustment: 100 mm
- Horizontal extender arm: 400 mm
- 60 W maximum power consumption.
- Input voltage 100–240 V, 50/60 Hz. Fuse F2.5 A.

NOTE: For safety and warranty claim eligibility

Use a constant-voltage stabilizer to avoid sudden input voltage variations and to extend 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 that 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, directed to the LABOMED factory or to the authorized dealer who made the original sale of this device, and 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 consequential 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 SHORTAGES

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

1. **Carefully go through the packing material to be sure nothing was inadvertently overlooked when the unit was unpacked.**
2. **Call the dealer you purchased the product from and report the shortage. The 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.

Revision History

Rev. No.	Date of Release	DCR #	Change	App. By
2.1	April 20, 2019	DCR/12/19	Formatting to improve appearance 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

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ideas for vision

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