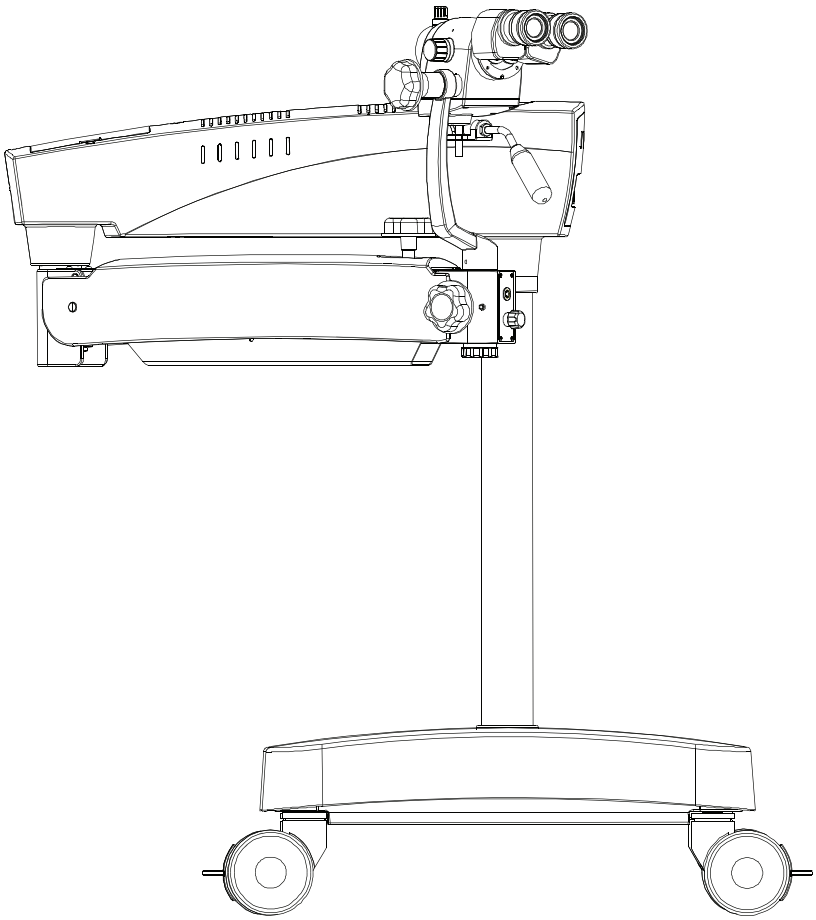
LABOMED
ideas for vision

PRIMA GN

User Manual

COLPOSCOPE



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

Part No.: 6165000-795
Issue 1.10
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All other trademarks are the property of their respective owners.

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

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

Caution: Federal law restricts this device to sale by or on the order of a licensed physician. Rx only.

LIST OF CONTENTS

1. INTRODUCTION AND INTENDED USE

The LABOMED Prima GN is a surgical and diagnostic instrument used for colposcopy in Gynecology, which is adaptable for different surgical needs without compromise to performance.

Salient features of this Colposcope are:

1. The observation head can easily be positioned with the help of a suspension arm.
2. An advanced 5-step magnification changer allows an optimal magnification for a particular surgery from five different magnifications.
3. Cold light illumination with a high intensity 50W LED lamp is provided using a fiber optic guide for proper illumination. The illumination is further adjustable up to its most suitable brightness using intensity control knob suitably located at the suspension arm, and is easily approachable to the surgeon.
4. When the colposcope is not in use, the suspension arm can be folded over the main body to store it compactly.
5. Dual iris Diaphragm allows greater depth of field particularly valuable for photography.
6. Rigid H-form base with castor wheels provides greater stability as well as mobility to the instrument.

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

INTENDED USE

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

Note: The use of Prima Gn Colposcope is purely for intended Operative and Diagnostic medical use.

CONFIGURATIONS

Colposcope	**Catalogue No.**
Prima GN	6165000-000

2. PRODUCT DESCRIPTION

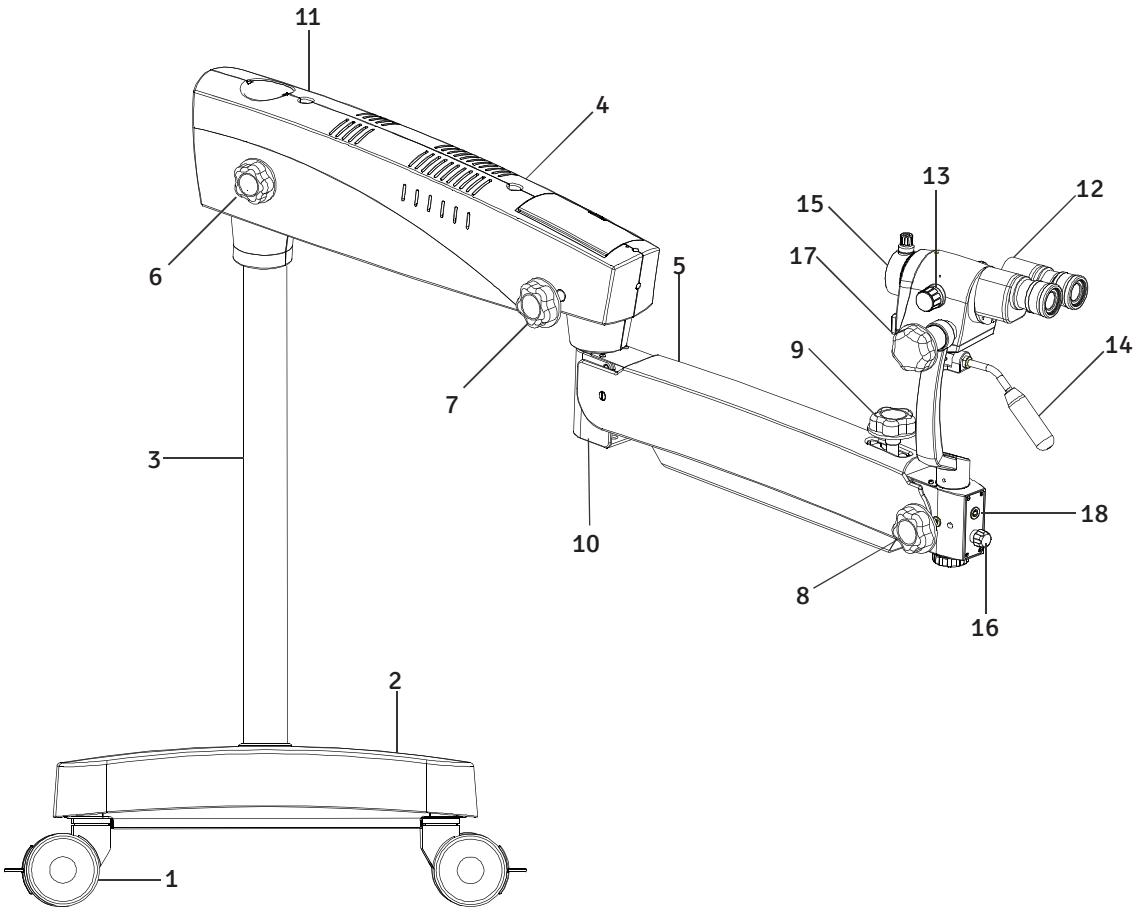


Fig. 1

1. Wheel with Brakes
2. Metal Base with plastic cover
3. Column
4. Swivel arm
5. Suspension arm
6. Swivel Arm Locking Knob
7. Suspension arm movement locking knob
8. Coupling movement locking knob
9. Suspension arm hydraulic movement lock
10. Suspension arm spring tension adjustment
11. Swivel arm cover
12. Binocular head with eyepieces
13. Magnichanger
14. Handle
15. Common Main Objective
16. Illumination Control Knob
17. Magnichanger tiltation control knob
18. Inlet for LABOMED camera

3. WARNINGS AND CAUTIONS

LABOMED is not responsible for the safety and reliability of this instrument when:
- Assembly, disassembly, repair, or modification is made by unauthorized dealers or persons.
- The instrument is not used in accordance with this user manual.

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

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

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

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

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

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

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

WARNING: ENSURE THAT THE VOLTAGE APPLIED TO THE UNIT IS THE SAME AS THE VOLTAGE THAT IS INDICATED ON THE DATA PLATE OR DAMAGE TO THE UNIT MAY OCCUR. TO USE IN FLUCTUATION VOLTAGE ENVIRONMENT CONSTANT VOLTAGE STABILIZER 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.

WARNINGS AND CAUTIONS

WARNING: LED RADIATION - DO NOT STARE DIRECTLY INTO THE BEAM WHEN THE MICROSCOPE IS IN THE ON POSITION.

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

WARNINGS AND CAUTIONS

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

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

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

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

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

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

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

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

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

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

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

4. EXPLANATION OF SYMBOLS

Caution:
Observe all warning labels and notes!
If any label in missing on your instrument or has become illegible, please contact us or one of our Authorized representatives. We will supply the missing labels.

Brightness Control: After the illumination has been switched on, the user can continuously Adjust brightness by turning the knob appropriately.

Accompanying documents must be consulted.

Compliance to medical device regulation MDR 2017/745

Protective earth.

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

Keep dry – the transport package shall be kept away from rain.

Year of manufacture used on product data plate.

Fragile- content of the transport package are fragile and should be handled with care.

Electromagnetic interference can occur in the vicinity of devices carrying this symbol.

Alternate current.

Recycling of packaging materials.

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

Separate disposal of waste electrical equipment.

Unsafe for use with MR (Magnetic Resonance).

Permissible humidity range during transport and storage.

Permissible pressure range during transport and storage.

The product complies with US and Canadian safety requirements.

Permissible temperature range during transport and storage.

Medical Device.

5. STANDARDS AND DIRECTIVES

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

- ISO 8600-3 First edition 1997-07-01 AMENDMENT 1 Optics and Optical instruments-Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics.
- ISO 8600-5 First edition 2005-03-15 Optics and phonetics-Medical endoscopes and endotherapy devices
  Part 5: 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.
- ISO 14971-2007 Risk management to medical devices.

DIRECTIVE USED

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

CLASSIFICATIONS

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

6. CONDITION OF INSTRUMENT AT TIME OF UNPACKING/SUPPLY

The appliance is delivered in sub-assembled modular groups along with one Installation Kit and one user manual.

Please check for the following when unpacking the device:

1. Mobile supporting base with brakes on castor wheels, or the type of mounting system.
2. Column, depending on the type of mount ordered.
3. Swivel arm and suspension arm assembly with fiber optic cable.
4. Cover for Swivel arm (pre-fitted to the microscope)
5. Inclined coupling with magni-changer assembly and objective (as ordered)
6. Observation Head, (inclined or ergo) as ordered.
7. Pair of eyepieces, as ordered.
8. Power cord.
9. Installation Kit
    a. Allen wrench 5 mm
    b. Allen wrench 8 mm
10. User manual

7A. INSTALLATION

7.1 Open the Microscope Box. Remove pillar (Column) from the box. Engage this column onto the shaft matching the guide holes on column has shaft, shown as B in fig.-13.

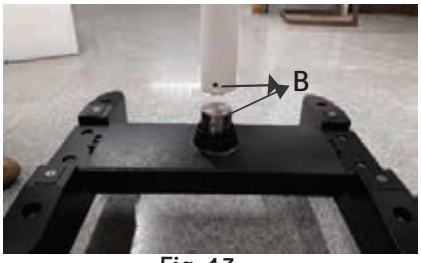


Fig. 13

7.1 a Tighten three allen screws from the sides, as shown as C in Fig.-14.

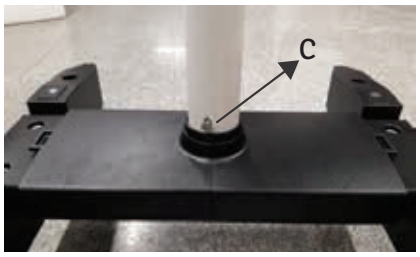


Fig. 14

7.2 Make sure that during assembly of the column ring D is fixed in place, as shown in Fig.-15.

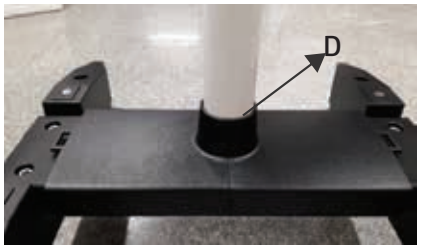


Fig. 15

7.3 Remove the arm assembly from the box and follow the instructions below (see Fig.-3).

A. Ensure loosening of swivel arm lock knob (A).

B. Place the arm assembly on the column shaft (1) shown in Fig.-3.

C. Screw in the threaded plug from the top (2).

D. Put the protective cap (3) in place, and loosen the suspension arm locking knob (B) so that it can be rotated.

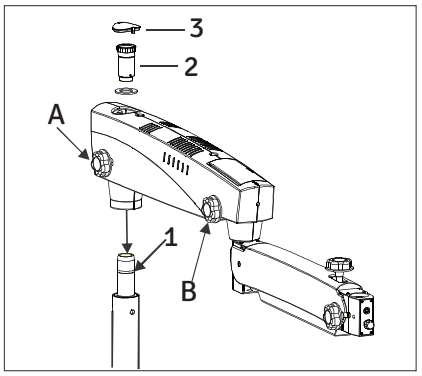


Fig. 3

INSTALLATION

7.4 Retrieve the inclined coupling assembly from the packing and follow as below refer Fig.-4.

- Install the coupling to the suspension arm by sliding the guiding shaft (1) into the suspension arm.
- Lock the inclined coupling with the threaded plug (2).

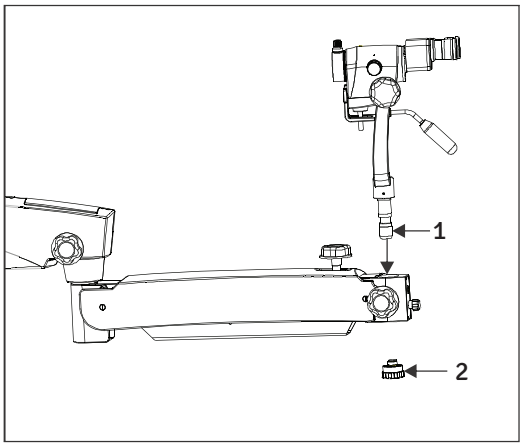


Fig. 4

7.5 Mounting the light guide

- Switch off the illumination system
- The light guide comes pre-routed through swivel arm (that houses the LED illumination system) and the suspension arm.
- Insert the light guide into the receptacle in the microscope till it properly tighten into position as shown as A in Fig.-5.
- Make sure that wire has been routed in such a way that the carrier system and the surgical microscope are not Obstructed, and that they can be moved in their entire range of movement without stretching, Extreme, kinking or twisting of the light guide.

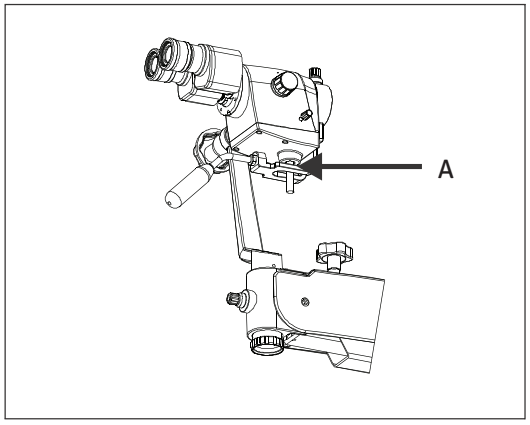


Fig. 5

7.6 Install the binocular head and eyepieces on the magni-changer. Secure the binocular head with head locking screw shown as (A) in Fig.-6.

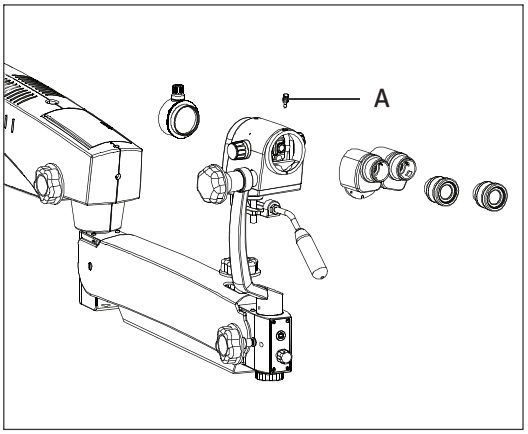


Fig. 6

8. ELECTRICAL CONNECTIONS

Connect the power cable to the AC inlet socket (2) provided on the back of the swivel arm as shown in the fig.-7.

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.-7.

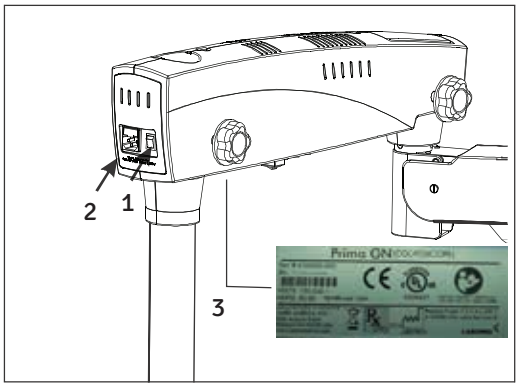


Fig. 7

8.1 REPLACING THE ILLUMINATION SOURCE

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

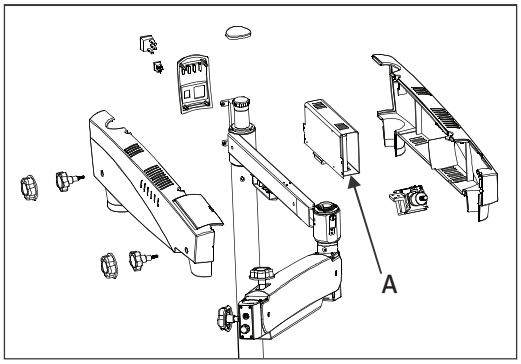


Fig. 8

8.2 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.-9.

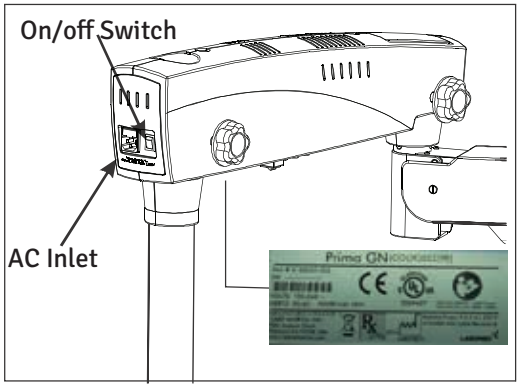
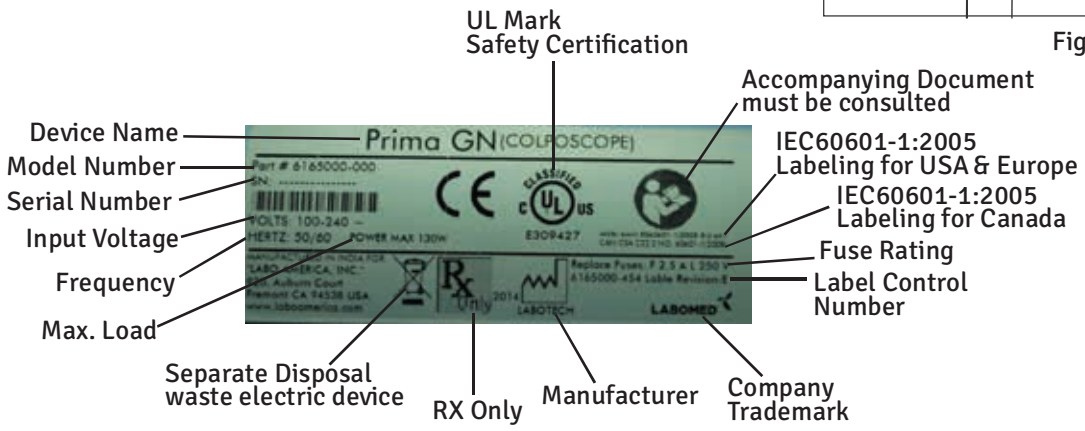


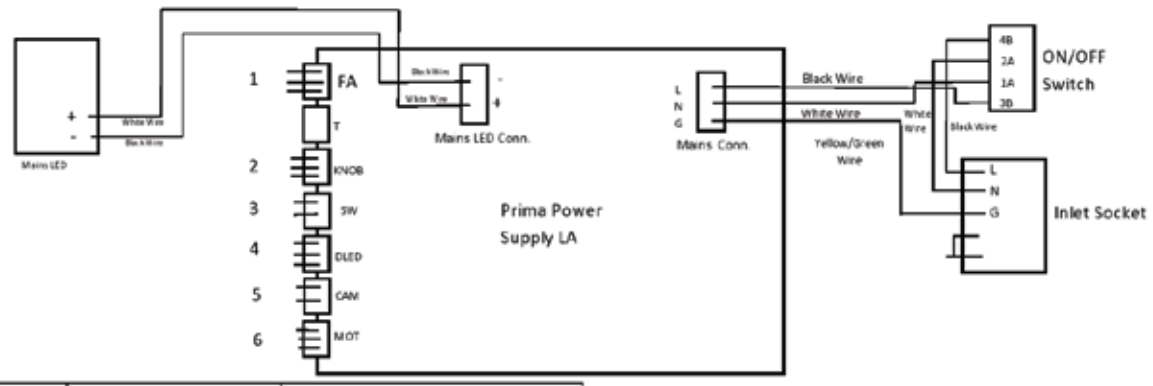
Fig. 9

8.3 DATA PLATE FOR PRIMA GN MICRO-SCOPE



ELECTRICAL CONNECTIONS

8.4. PRIMA WIRING CODING DIAGRAM



Wire Marking No.	Power Supply Marking	Description
1	FAN	Main LED Fan Wire
2	KNOB	Potentiometer Wire
3	SW	Limit Switch Wire
4	DLED	Dual LED Wire
5	CAM	Camera Wire
6	MOT	Motor Wire

9. CONTROL ELEMENTS

9.1 ON/OFF SWITCH (SHOWN AS 1 IN FIG. 7 ABOVE)

It is located on the back of the swivel arm. At 'ON' position, green LED glows and cooling fan starts running. Keep the intensity control knob at minimum level before switching on the system.

To save burning life of LED, switch OFF the Appliance if the microscope is not in use for longer time.

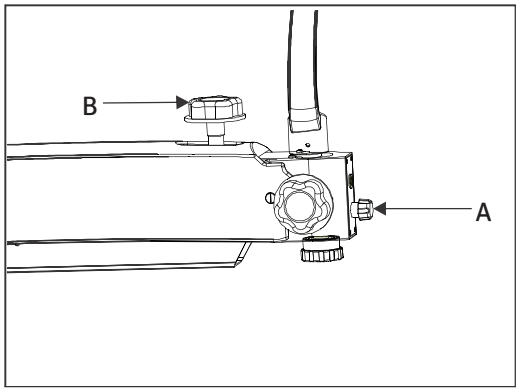


Fig. 10

9.2 INTENSITY CONTROL KNOB

It is located in front of the suspension arm shown as (A) in Fig.-10. Brightness of field of view can be adjusted as per user comfort using intensity control knob.

9.3 SWIVEL ARM LOCKING KNOB

This knob helps you to lock the movement of swivel arm at the desired position after initial focusing of the attendance area by turning it clockwise, knob is shown as (B) in Fig.- 10.

9.4 BRAKES

Locks the stand from unwanted movement by pressing down the two brakes provided on caster wheels. To unlock press upper portion of brake. See Figure-11.

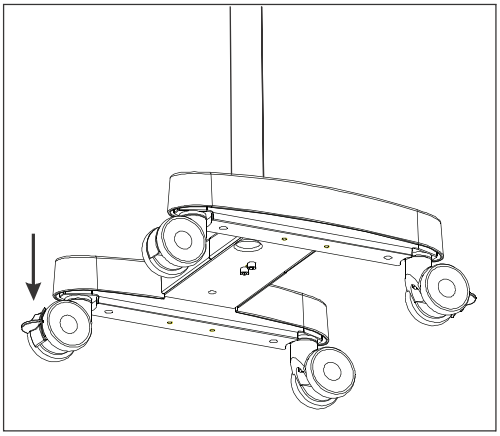


Fig. 11

10. INSTRUCTIONS FOR USING THE COLPOSCOPE

WARNING: INSTRUMENT IS UNSAFE FOR MRI ENVIRONMENT.

SETTING UP OF COLPOSCOPE:

1. Lock all the brakes on base wheels after setting up of microscope on the attendance area for stability.

2. Although tension on microscope is factory as per the ordered configuration. Still user can adjust up and down force by tuning the allen screw clockwise or anticlockwise with the help of a 8mm allen wrench. Refer Fig.-12 to see the exact location of tension adjusting screw.

3. Lock the up & Down movement of suspension arm using locking knob (B) in fig.-12 after focusing of the area of interest.

4. Adjust the eye distance as per IPD scale to your convenience.

5. The illumination is controlled through the control knob (A), fig.-12. Rotate it clockwise or anticlockwise to achieve desired illumination level functional setup keep it as minimum.

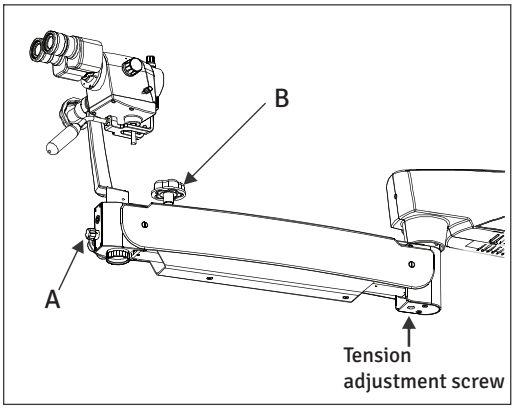


Fig. 12

SETTING UP OF MAGNIFICATION (Ref. Fig. 13)

1. Adjust to highest magnification with one of the rotating knobs (11a) provided at magnification changer.

2. Fine focusing is done by knob provided on CMO shown as (11d) in fig. 13.

3. Absolute centering of focused area in field of view can be done by manual handles (11c).

4. Make sure that the magnification changer is engaged in the index point at the click stop position.

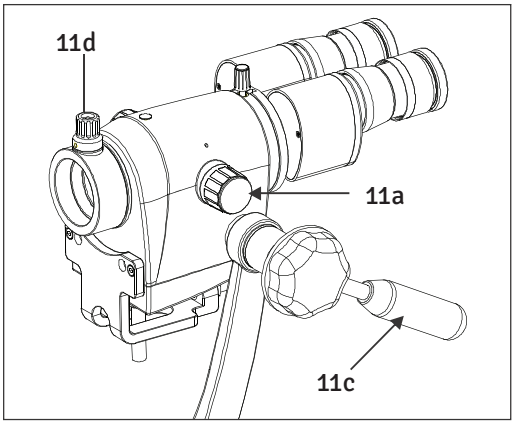


Fig. 13

MAIN COLPOSCOPE

The objective lenses with fine focusing knob and focal lengths of 300mm is available for different working distances.

The straight binocular tube is provided for the main surgery.

The standard equipment includes eyepieces with a magnification factor of 10X (option: 12.5X)

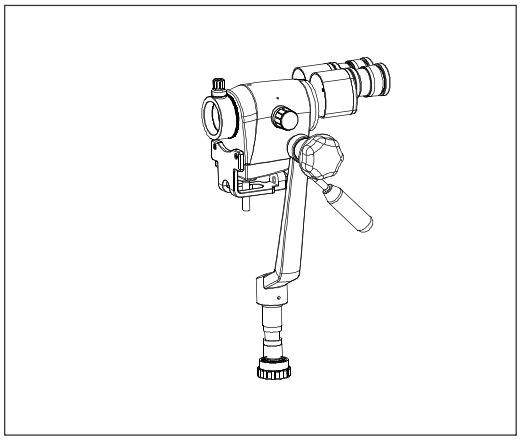


Fig. 14

11. CHANGING THE OBJECTIVES & EYEPIECES

1. The objectives can be taken out by rotating it in anti-clock wise direction. It can be threaded in by rotating in clockwise direction.

2. To install the eyepieces, insert in the eye tubes of observation head.

3. A range of objectives/eyepieces can be selected by choice.

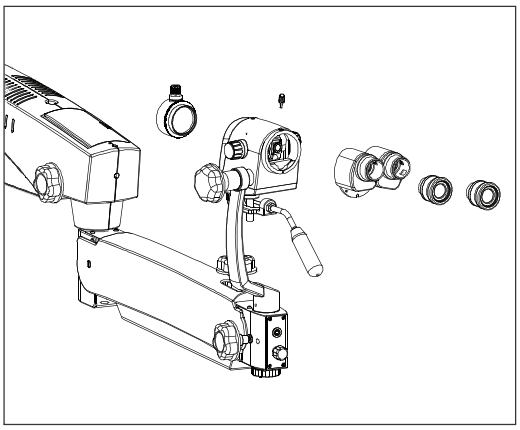


Fig. 15

12. USE OF ACCESSORIES

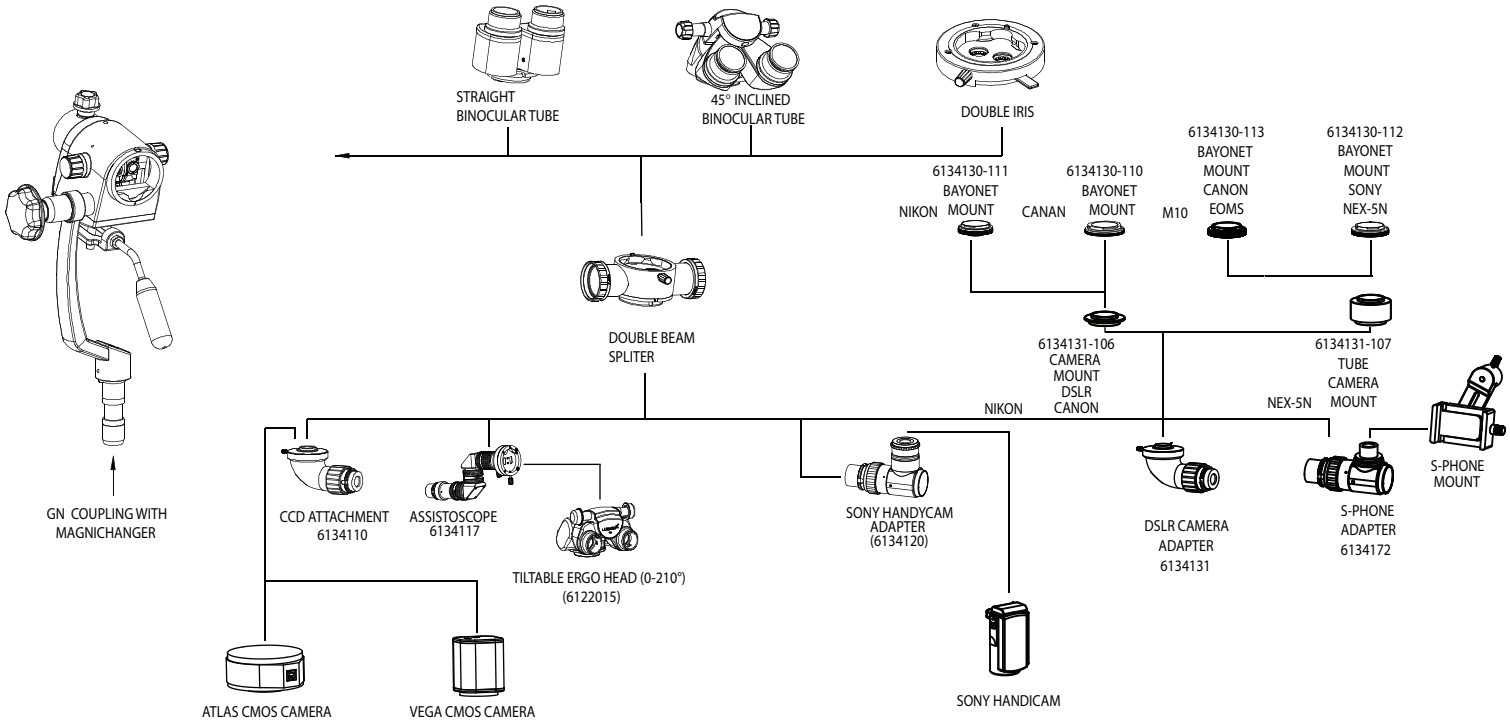


Fig. 16

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.

13. THERMAL CUT-OFF

Although instrument is designed for safe working condition thru sufficient cooling facility provided with proper free and forced air circulation by the fans provided in electrical box. Further instrument is designed with an inbuilt safety mechanism with “auto thermal cut-off” if the temperature of LED is above 70°C. In case if thermal cut-off fails no risk will happen to the instrument only LED may get fuse. Here user needs to replace the LED only and thermal cut-off will start working again. To replace the LED user may call LABOMED service personal or authorized dealer.

LED Specifications: 3.7 V, 18.5 Amp

14. TENSION ADJUSTMENT

After Supplementary accessories are mounted, the additional load of suspension arm must be compensated by adjusting tension on tension control screw provided on suspension arm by moving it clockwise or anticlockwise.

Refer fig.-18

1. Remove plate by unscrewing two holes.
2. Loosen two allen bolts by using allen wrench of 4 mm as shown in fig.-19.
3. Use hexagonal wrench of 8mm in bolt (A) shown in fig.-20 rotate it clockwise to increase desired tension on Gas spring.
4. Re tighten the two screws.
5. Put back the plate.

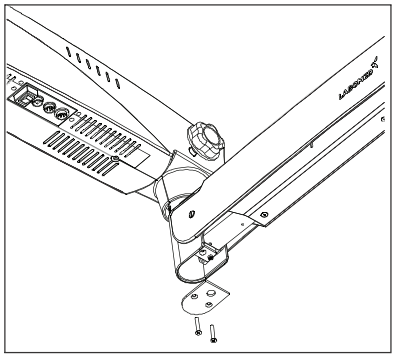


Fig. 18

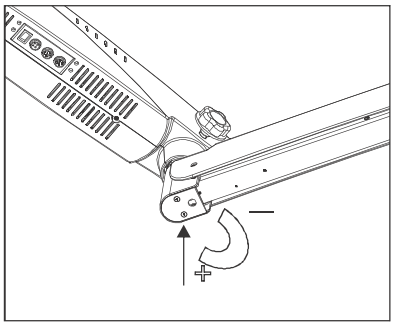


Fig. 19

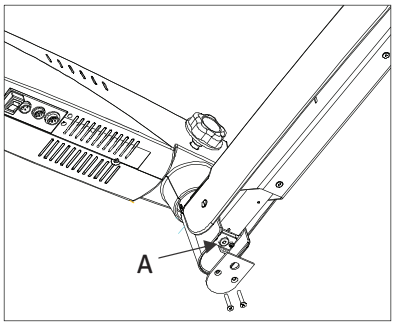
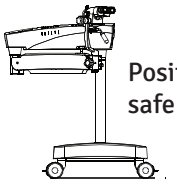


Fig. 20

15. MOVING POSITION OF THE SYSTEM



Position of the system for
safe transportation

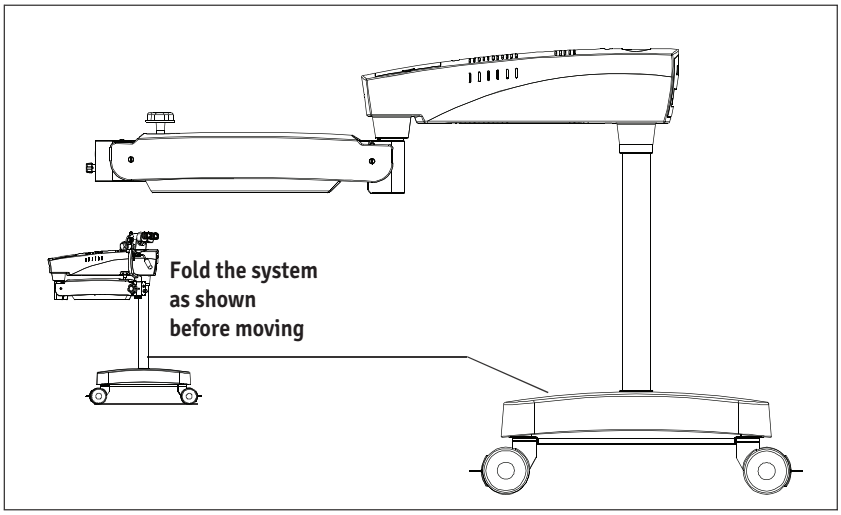


Fig. 21

RELOCATING THE STAND

1. Turn off the unit at the power switch.

2. Disconnect the power cable.

3. Remove the video cable from the video modules (e.g., video monitor, USB monitor) and the camera control unit.

4. Release locks by pressing the upper parts of the locks downwards.

5. Bring the unit into its moving position.

6. Be careful of heights when passing through doorways.

7. Avoid collision of any kind.

8. Do not go over steps and edges: the stand ,might topple!

9. Be extremely careful when moving over slopes.

10. Do not park the stand on slopes

11. Press lock downwards.

12. Check whether the stand is locked in position.

16. CARE AND MAINTENANCE

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

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 colposcope from moisture, fumes, acids and cosmetic materials. Do not store chemicals close to the instrument.
- Protect it from improper handling. Never install other devices sockets or unscrew optical system and Mechanical parts unless explicitly instructed to do so in this manual.
- Protect the microscope from oil and grease. Never oil or grease the guide surfaces or mechanical parts.

CARE AND MAINTENANCE

- 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 MaxiLite 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 an 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.

AUTOCLAVING:

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

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

17. AMBIENT REQUIREMENT

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

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

18. DISPOSAL

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

19. TROUBLESHOOTING TABLE

Problem	Possible Cause	Remedy
No illumination	Power cable not plugged in	Plug in power cable
	Power switch in OFF position	Press the power switch to ON position
	Defective instrument fuse	Change the fuse
	Defective power cable	Change the power cable
	Line power failure	Contact in-house technician
	Failure of suspension system electronics	Contact the service department
	Light guide not properly inserted in arm of microscope	Insert the light guide properly to get maximum illumination
Insufficient illumination	Brightness level set too low	Adjust brightness control knob
	Light guide not properly inserted in arm of microscope	Insert the light guide properly to get maximum illumination
	Defective light guide (illumination not uniform)	Change the light guide
Inoperative surgical field illumination	Inoperative surgical field illumination	Insert the light guide as far as it will go
	Failure of electronics	Illuminate the surgical field using an alternate illuminator,and contact the service department
	Switch off via limit-switch on suspension arm system	Move the suspension system into the working position
Insufficient illumination (continued)	The thermal cut-off in the lamp housing is contaminated	Clean the thermal cut-off with a dry brush or blow it clean, with compressed air
	Defective fan; failure of system electronics	Contact the service department
Up and down motion of the suspension system is stiff	The friction adjustment screw on the suspension system is tightened too firmly	Loosen the friction adjustment screw on the suspension system as needed

TROUBLESHOOTING TABLE

Problem	Possible Cause	Remedy
Stand is unstable	The brakes on the wheels are not in use	Engage the brakes
No image is visible in the field of view	Magnichanger is not indexed properly	Index magnichanger properly

20. TECHNICAL SPECIFICATIONS

Binocular Tubes	Straight viewing tube 90°, IPD 49-78mm Optional: 45° inclined head, IPD 55-75mm
Eyepieces	WF 10x/18mm with retractable eye guards, diopter adjustment ± 7mm and diopter lock Optional: WF 12.5x/18mm; fixed eye guards.
Magnichanger	5 step: 0.4x, 0.6X, 1.0X, 1.6X & 2.5x;
FOV (Field of View)	15° - 2.5° (80-13mm)
Objective	f= 300mm, manual fine focus
Built-in filters	Green
Vertical Movement of Arm	550mm
Microscope Carrier	Straight Carrier
Accessories	Double Beam Splitter and Camera Adapters.
Light Source	50W LED; Minimum Intensity upto 125,000 LUX @ 250
Power Consumption	200W Maximum
Input Voltage	100V-240V; 50/60 hz
Stand:	Stable and sturdy H-base stand with 2 lockable wheels.
Base (Dimensions):	600mm width 620mm length
Stand Height:	984mm
Weight: Microscope arm with all optical module H-base with pillar	 20 Kg. Approx. 60 Kg. Approx.
Elevation Stroke:	500mm
Stand Height in Horizontal Position:	775mm

21. GUIDANCE TABLES

Guidance and Manufacturer's Declaration

Electromagnetic Emissions

All Equipment and Systems

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Prima GN is intended for use in the electromagnetic environment specified below. The customer or user of the Prima GN should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1 Class A	The Prima GN uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonics IEC 61000-3-2	Class A	The Prima GN is suitable for use in all establishment, other than domestic, and those directly connected to the public low voltage power network that supplies buildings used for domestic purposes.
Flicker IED 61000-3-3	Complies	

GUIDANCE TABLES (continued)

Guidance and Manufacturer's Declaration

Electromagnetic Emissions

All Equipment and Systems

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Prima GN is intended for use in the electromagnetic environment specified below. The customer or user of the Prima GN should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± 6kv contact ± 8kv Air	± 6kv contact ± 8kv Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the R/H should be at least 30%.
EFT IEC 61000-4-4	± 2kv Mains ± 1kv I/Os	± 2kv Mains ± 1kv I/Os	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kv Differential ± 2kv Common	± 1kv Differential ± 2kv Common	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, dropouts, IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Main power quality should be that of a typical commercial or hospital Environment. If the user of the Prima GN requires continued operation during power mains interruption, it is Recommended that the Prima GN be Powered from an uninterruptable power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic field should be that of a typical commercial or hospital Environment.

GUIDANCE TABLES (continued)

Guidance and Manufacturer's Declaration

Electromagnetic Immunity

Equipment and Systems that are NOT Life-Supporting

Guidance and manufacturer's Declaration – Electromagnetic Immunity

The Prima GN is intended for use in the electromagnetic environment specified below. The customer or user of the Prima GN should ensure that it is used in such an environment.

Immunity Test	ICE 60601 Test Level	Compliance Level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 vrms 150kHz - 80MHz	(v1) = 3 vrms	Portable and mobile RF communications Equipment should be used no closer to any part of the Prima GN, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	80MHz to 2.5 GHz @ 3V/m	(E1) = 3 V/m	**Recommended Separation Distance:** **d=(3.5/v1)(Sqrt P)** **d=(3.5/E1)(Sqrt P)** **80 to 800 MHz** **d=(7/E1)(Sqrt P)** **800 MHz to 2.5 GHz** Where P is the max output power rating of the transmitter in watts (W) according to the transmitter manufacture and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 

Note 1: At 80 MHz to 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from Structures, objects and people.
*Field strengths from fixed transmitters, such as base stations for radio(cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic Environment due to fixed RF transmitters, an electromagnetic site survey should be considered. The measured field strength in the location in which the ME Equipment or ME system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment or ME System.
*Over the frequency range 150kHz to 80 MHz, field strengths should be less than [V1] V/m.

GUIDANCE TABLES (continued)

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Recommended separation distance for between Portable and Mobile RF Communications equipment and the Prima GN

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

Max Output Power of Transmitter (W)	Separation (m) 150kHz to 80 MHz d=(3.5/v1) (Sqrt P)	Separation (m) 80 to 800 MHz d= (3.5/E1) (Sqrt P)	Separation (m) 800 MHz to 2.5GHz d= (7/E1) (Sqrt P)
0.01	0.1166	0.1166	0.2333
0.1	0.3689	0.3689	0.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

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

Note 1: At 80MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

22. MEASURES AND WEIGHT

Prima GN- Colposcope with Mobile Stand
Total Weight: Approx. 80 kgs.

FLOOR MOUNT

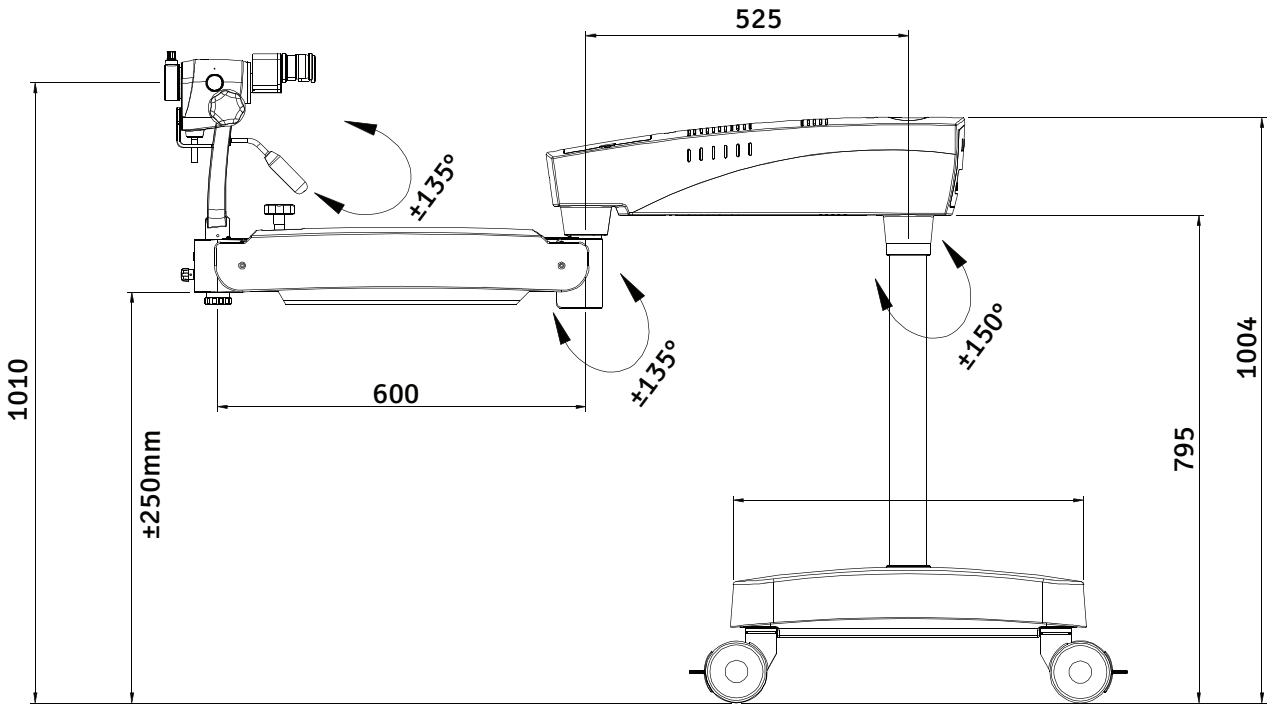


Fig. 22

23. GLOSSARY

Ametropia Compensation	Compensation of short-or-far-sightedness. This can be done for each eye using the two individual eyepieces (range: +5 to -5 diopters).
Working Distance	Distance front lens to object level (300mm).
Color Temperature	Refers to the color characteristic of a light source. Using color temperature, one can set the color of a light source to warm or cold light Relative to the color of natural light. The unit of measure for color temperature is Kelvin (K).
Light field diameter	The size of the field, which is illuminated at a distance of 300mm.
Field of View Diameter	The visible area of an object that can be seen through the colposcope. The greater the magnification level, the smaller the field of view and vice versa.
Green Filter	A color filter that darkens red and blue light and brightens green light. Thus, the contrast of the image is increased, blood vessels are shown more clearly.
Illumination Intensity	Specifies the luminous flux from a light source onto a certain area. The unit of measure for illumination intensity is Lux (Lx).
LED	Light Emitting Diode. Electronic semiconductor device that emits light when an electrical current passes through it.
Eyepiece	The optical portion facing towards the eyes, with which the enlarged image produced by the microscope can be viewed.
Convergent Beam Path	The two light beams for the right and left eye run together at a point that lies at a distance of 300mm in front of the front lens. This distance is in accordance with the working distance. This way, the eye does not has to focus on this point in its own, as it is the case with a parallel beam path.
White Balance	White balance is used to calibrate the camera to the color temperature of the light at the location.
DSLR Camera	(Digital Single Lens Reflex) camera with a digital imaging sensor.
CCD Camera	(Charged Coupled Device) camera with a technology to store a charge and move this charge out of the photo sensor in an organized way.
CMOS Camera	(Complementary Metal Oxide Semiconductor) camera in which images sensor is a silicon chip that captures and reads light.
DBS	(Double Beam Splitter) splits light beam into two directions (one to eye and one to side port) for simultaneous user viewing and photography, videography, or co-observation. Ratio of light distribution is 70% for eyes and 30% to side ports for photography, videography and co-observation.

24. WARRANTY

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

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

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

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

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

PRODUCT CHANGES

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

CLAIMS FOR SHORTAGES

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

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

CLAIMS FOR DAMAGES IN TRANSIT

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

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

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 the above):

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

Client Signature:

Contractor Signature:

Date:

Date:

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Revision History

Rev. No.	Date of Release	DCR #	Change	App. By
1.4	March 22,2016	DCR/13/16	Wiring Coding Diagram added	S Bal
1.5	July 05,2017	DCR/4A/17	UPS requirement added	S Bal
1.6	Oct 10,2018	DCR/19A/18	Information on weight	S Bal
1.7	April 20,2019	DCR/12/19	Formatting apperance of text	S Bal
1.8	April 14,2022	DCR/11/22	Reviewed	S Bal
1.9	May 13, 2023	DCR/09/23	Accessories Page Updated	S Bal
1.10	Aug, 2024	DCR/11/2024	Regulatory Information	S Bal

LABOMED
ideas for vision

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