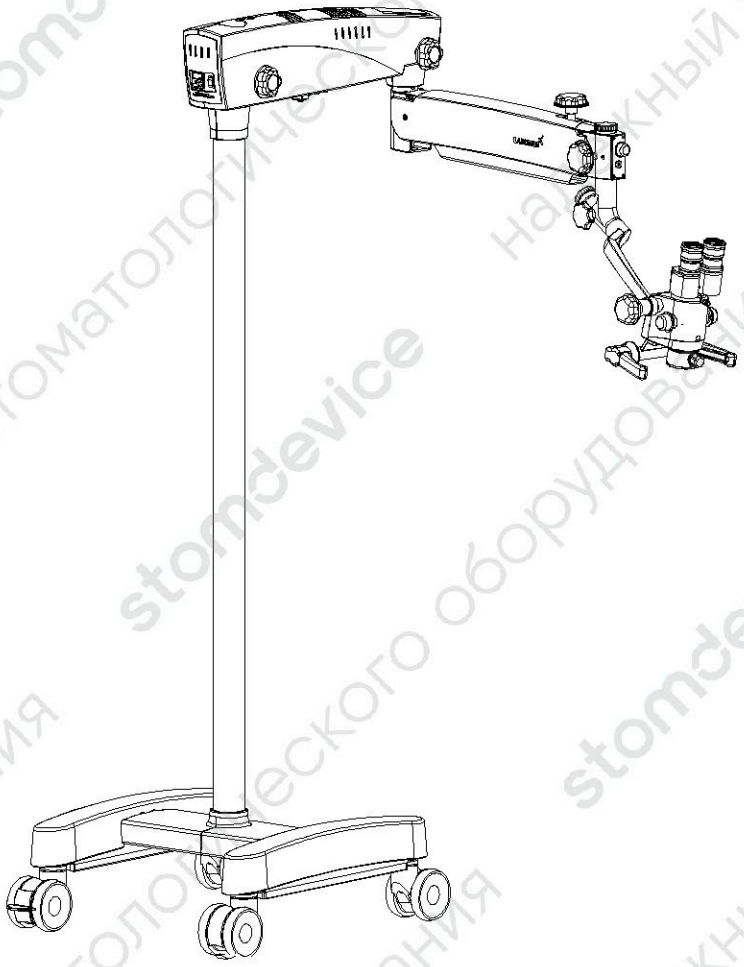
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LABOMED

PRIMA ENT/DNT

User Manual

Operating Surgical Microscopy



To ensure proper use of this instrument as well as to avoid injury while operating instrument, understanding this manual completely before use is highly recommended.

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1 INTRODUCTION AND INTENDED USE

LABOMED Prima DNT& ENT is a surgical and diagnostic microscope, which is adaptable for different surgical needs for consistent visualization during all intra operative phases of ENT & dentistry surgeries by providing a magnified view of the surgical field without compromise to performance.

The microscope provides extremely high optical image quality, good depth of focus and wide field of view for precise surgery. Illumination control, inbuilt tilt, adjustment of the observation head help to reduce the surgeon's work fatigue and allow comfortable use over long period.

Salient features of this Microscope are:

1. The observation head can easily be positioned with the help of 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. Rigid H-form base with castor wheels provides greater stability as well as mobility to the instrument.
6. Dual Iris Diaphgram allows greater depth of field particularly valuable for photography.

Intended use

Priam ENT/DNT surgical microscopes is an AC powered device intended for use during diagnosis and surgery to provide a magnified view of surgical field

NOTE: The use of Prima ENT/DNT Microscopes is purely for intended use.

Configuration:

Microscope	**Catalogue no.**
Prima ENT	6137000-000
Prima DNT	6138000-000

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2 PRODUCT DESCRIPTION

Catalog no. 6138000-000
Model: Prima DNT

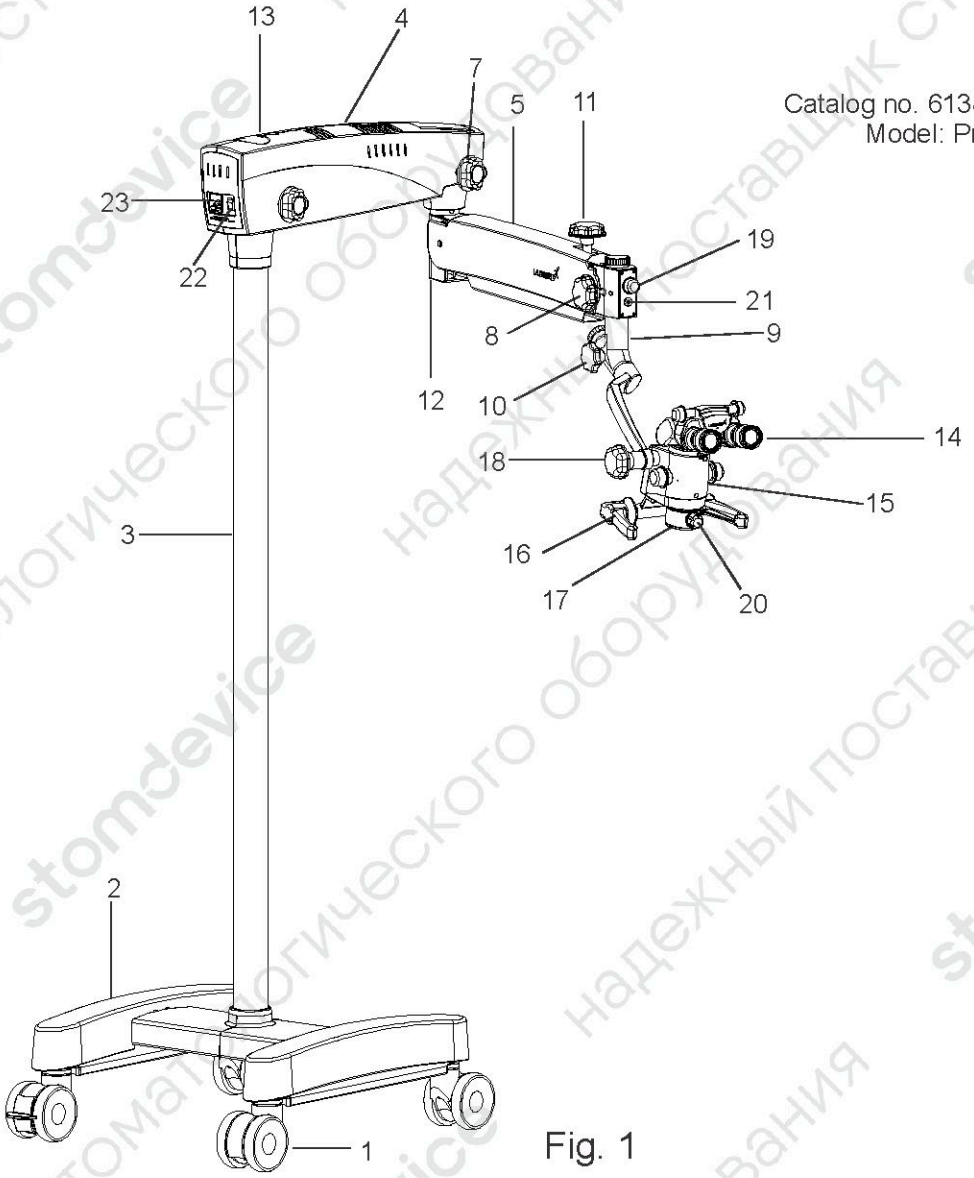


Fig. 1

1. Wheel with brake
2. H shape metal base
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. Inclined coupling
10. Inclined coupling movement knob
11. Suspension arm hydraulic movement lock
12. Suspension arm spring tension adjustment
13. Swivel arm covers
14. Binocular head with eyepieces
15. Magnification changer
16. Handles
17. Common main objective
18. Magnichanger inclination movement lock
19. Illumination control knob
20. Fine focusing knob
21. iVu Camera inlet
22. On/Off switch
23. Power inlet

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Catalog no. 6137000-000
Model: Prima ENT

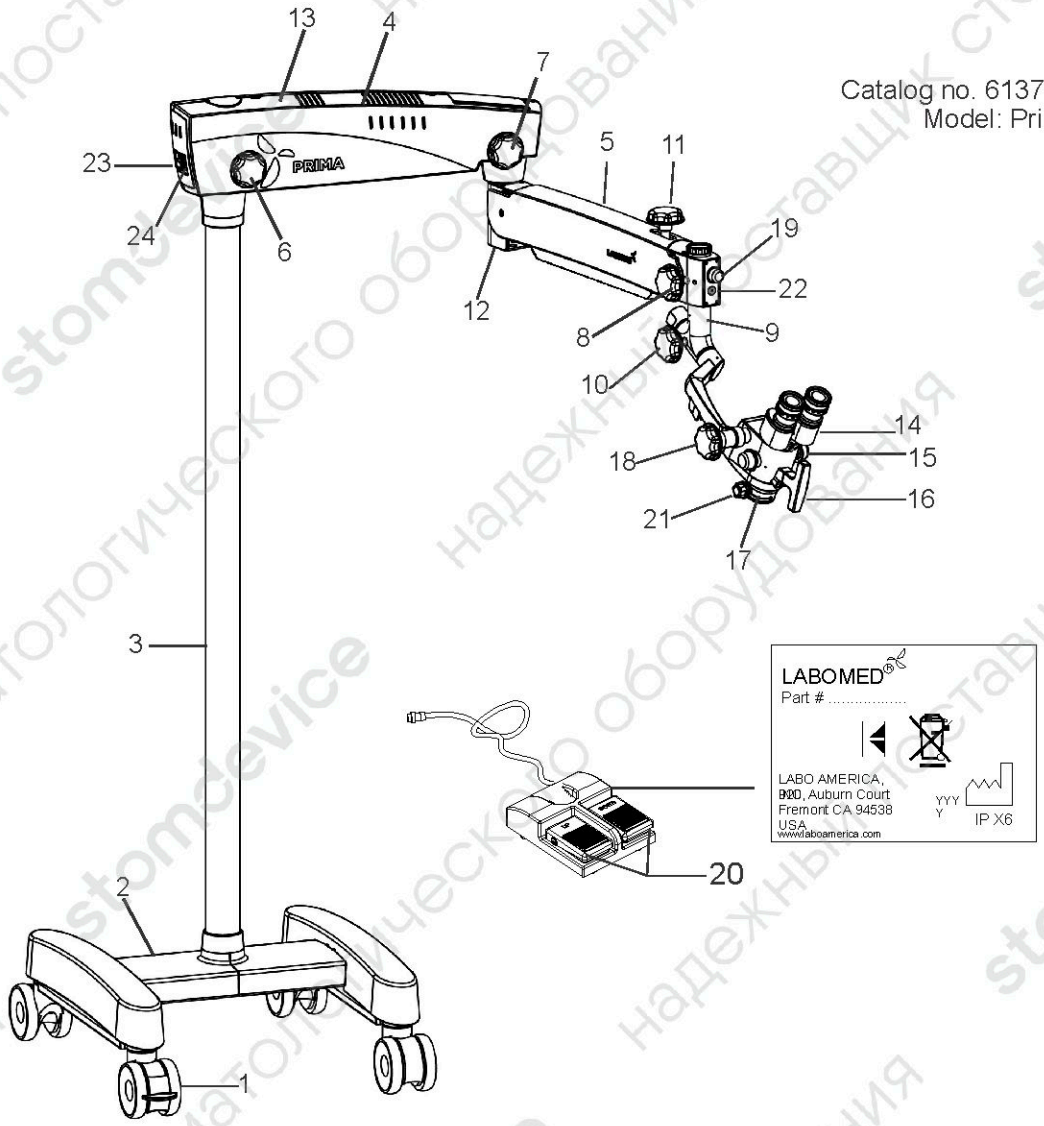


Fig. 1.1

1.	Wheel with brake	2.	H shape metal base
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.	Inclined coupling	10.	Inclined coupling movement knob
11.	Suspension arm hydraulic movement lock	12.	Suspension arm spring tension adjustment
13.	Swivel arm covers	14.	Binocular head with eyepieces
15.	Magnification changer	16.	T - Handle
17.	Common main objective	18.	Magnichanger inclination movement lock
19.	Illumination control knob	20.	Foot Paddle for Z-axis
21.	Fine focusing knob	22.	iVu Camera inlet
23.	On/Off switch	24.	Power inlet

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3 WARNING & CAUTIONS

LABOMED is not responsible for the safety and reliability of this instrument when:
- Assembly, disassembly, repair, or modification is made by unauthorized dealers or persons.
- Instrument is not used in accordance with this User's Guide.

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



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

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

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

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

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

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

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

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

WARNING: THE EQUIPMENT OR SYSTEM SHOULD NOT BE USED ADJACENT OR STACKED WITH OTHER EQUIPMENT LIKE MRI, RFID, SECURITY SYSTEM LIKE METAL DETECTORS OR SIMILAR DEVICES. 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.

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

WARNING: LED RADIATION DO NOT STARE DIRECTLY INTO BEAM WHEN MICROSCOPE IS IN 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.

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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 DISCHARGE SENSITIVE DEVICES (ESDS) THAT MAY BE SENSITIVE TO STATIC CHARGES PRODUCED BY THE HUMAN BODY. DO NOT REMOVE THE COVERS WITHOUT TAKING PROPER ESDS PRECAUTIONS.

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

CAUTION: MEDICAL ELECTRONIC EQUIPMENT NEEDS SPECIAL PRECAUTIONS REGARDING EMC AND NEEDS TO BE INSTALLED AND PUT IN TO SERVICE ACCORDING TO THE EMC INFORMATION PROVIDED IN THE ACCOMPANYING DOCUMENTS.

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

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

CAUTION: DO NOT CONNECT ANY UNITS TO THE DEVICE OTHER THAN THE INTENDED.

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 THE ELECTRIC SHOK MIGHT RESULT.

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

CAUTION: DO NOT ROLL THE MICROSCOPE OVER CABLES OR HOSES ON THE FLOOR.

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

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4 EXPLANATION OF SYMBOLS



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



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



Accompanying documents must be consulted



Compliance to medical device directive 93/42/EEC



Protective earth



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



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



Year of manufacture used on PRODUCT DATA



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



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



Alternating Current



Permissible humidity range during transport and storage



Permissible pressure range during transport and storage



Recycling of packaging materials



The product complies with US and Canadian safety requirements



Permissible temperature range during transport and storage



Separate disposal of waste electrical equipment



MR (Magnetic Resonance) unsafe symbol.



Do not over balance more than 5 degree.

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5 STANDARDS AND DIRECTIVES

The instrument described in this 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 8600-3 First edition 1997-07-01 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 9001/13485 quality management systems approved by UL (notified body).
- ISO 14971-2007 Risk management to medical devices.

Directives used

- Directives 93/42/EEC, Article II, Section 5, Annex VIII.
- IEC 60601-1-3rd edition (2005).
- IEC 60601-1-2
- EN 55011:2007

Classification

- For Europe, per Directive 93/42/EEC, the unit is a Class I instrument, per rule 12, Annex IX.
- For the United States, FDA classification Class I
- Please observe all applicable accidental prevention regulations.

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6 UNPACKING

The appliance is delivered in sub-assembled groups along with one set of Installation Kit and one instruction / service manual.

Please check following at the time of unpacking:

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 fibre optic cable.
4. Inclined coupling with magni-changer assembly and common main objective (focal length as ordered)
5. Observation Head, (inclined or ergo) as ordered
6. Paired Eye Pieces, as ordered
7. Power Cord
8. Installation Kit
   a) Allen Wrench 5.00mm
   b) Allen Wrench 8.00mm
9. User Manual

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7A INSTALLATION OF BASE (MOBILE STAND)

1 Open the center support assembly box as shown in fig. 1



Fig 1

2 Remove the tool kit and foam sheets as shown in fig. 2



Fig 2

3 Lift up the Centre Support assembly as shown in fig. 3 .



Fig 3

4 Place the Centre Support assembly on the floor as shown in fig. 4.



Fig 4

5. Open the wheel Support assembly boxes as shown in Fig. 5.



Fig 5

6. Remove the foam sheets as shown in Fig. 6.



Fig 6

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7 Lift the wheel support assembly and cover as shown in fig. 7. Place it (Wheels down) under one end of the center support as shown in Fig. 8. Repeat procedure for the other wheel support assembly.



Fig 7

8 Align the holes of the center support with the holes of both wheel supports and tighten the screws as shown in Fig. 8. using the 8mm allen wrench.

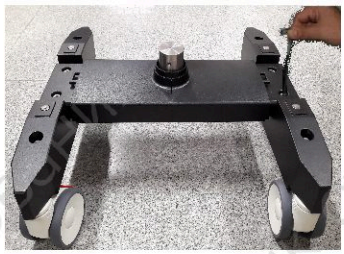


Fig 8

9 Remove the ring, and open 3 screws from shaft as shown in Fig. 9. Unscrew with 4mm allen wrench as shown in Fig. 9.



Fig 9

10 Tighten all screws using the 8 mm allen wrench. Place top cover on both wheel support assemblies as shown in fig. 10.



Fig 10

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7B MICROSCOPE 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 and shaft, as shown as B in Fig. 11.

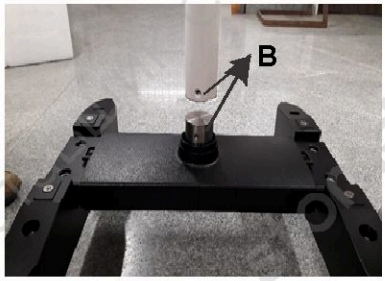


Fig. 11

7.1 a Align the tapped holes of the column with the shaft and tighten three allen screws from the sides, as shown as C in Fig. 12.

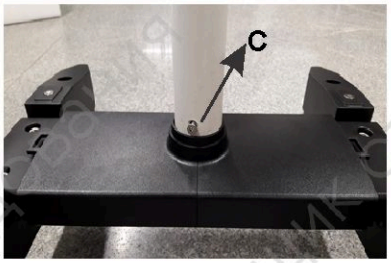


Fig. 12

7.2 Make sure that during assembly of the column ring D is fixed in place, as shown in Fig. 13.

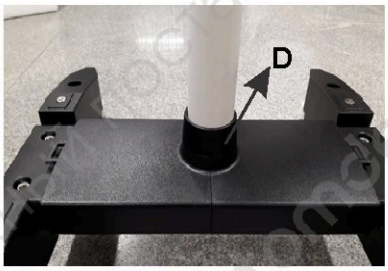


Fig. 13

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

⚠ A. Ensure that the swivel arm lock knob (A) is loosened.

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.

⚠ Do not unscrew knob A completely (See Fig. 14). Loosen only a few threads; otherwise the lock ring inside the column guide may disconnect and installation may not possible.

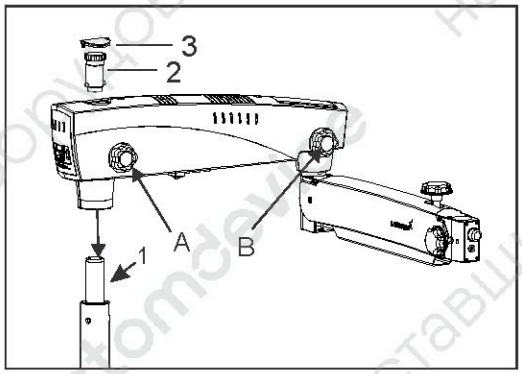


Fig. 14

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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) to the suspension arm.
- Lock the inclined coupling with the threaded plug (3).

  Make sure that safety screw must tight in place at position (2) to avoid sudden falling of the coupling. Safely screw tagged within the arm.

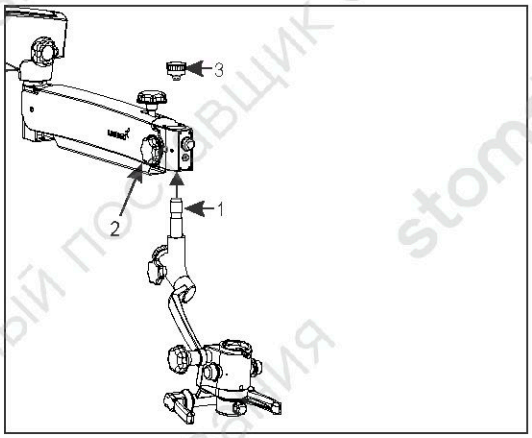


Fig. 4

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.
- Remove the dust cap from the receptacle.
- Insert the light guide into the receptacle in the microscope till it clicks into position as shown as A in Fig. 5
- Make sure that the light guide 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.

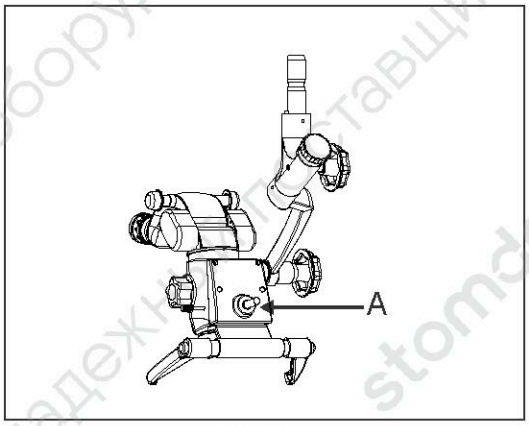


Fig. 5

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

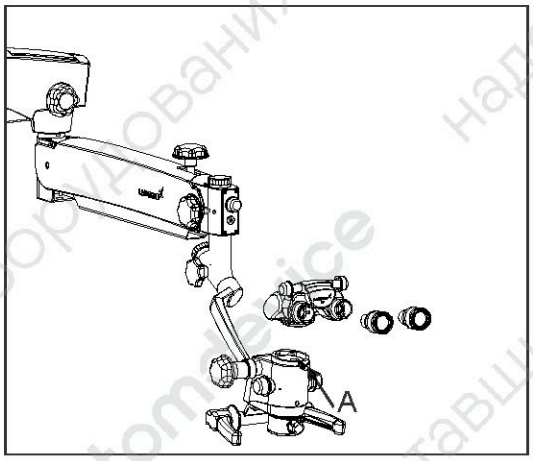


Fig. 6

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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 (2).

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. 8.

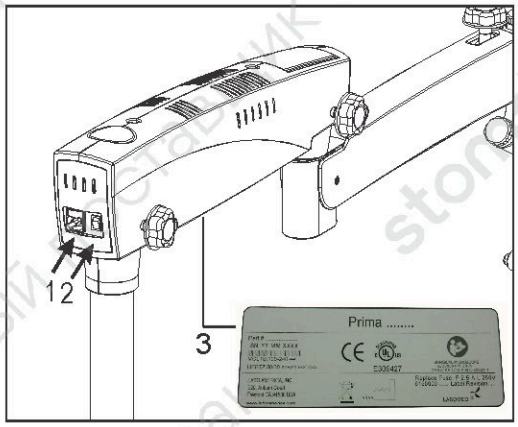


Fig. 7

8.1 Replacing the illumination source

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

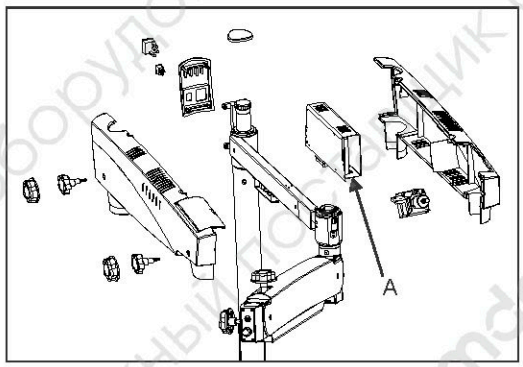


Fig. 8

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

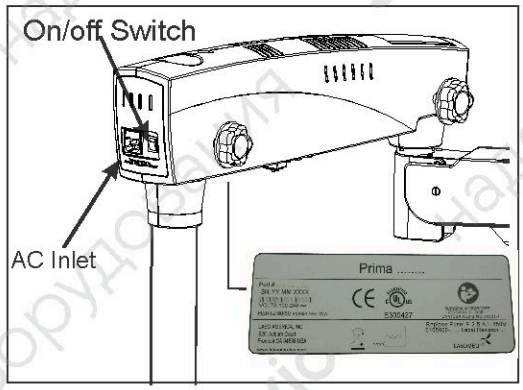
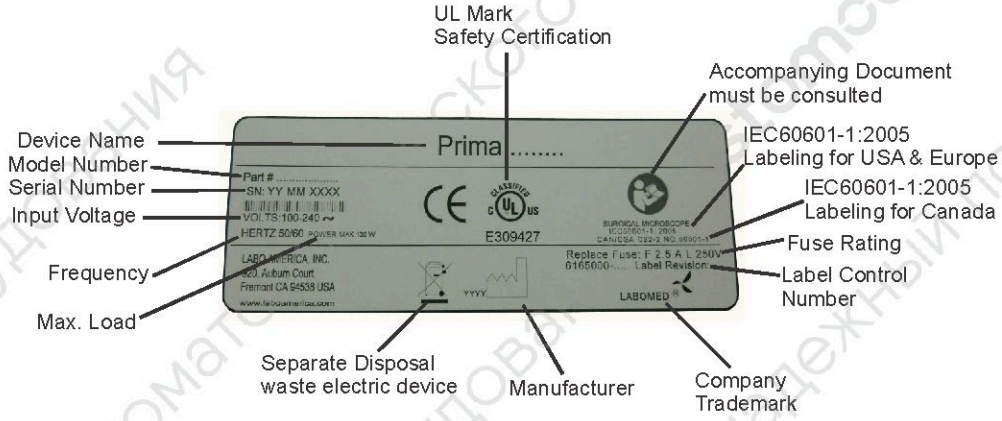


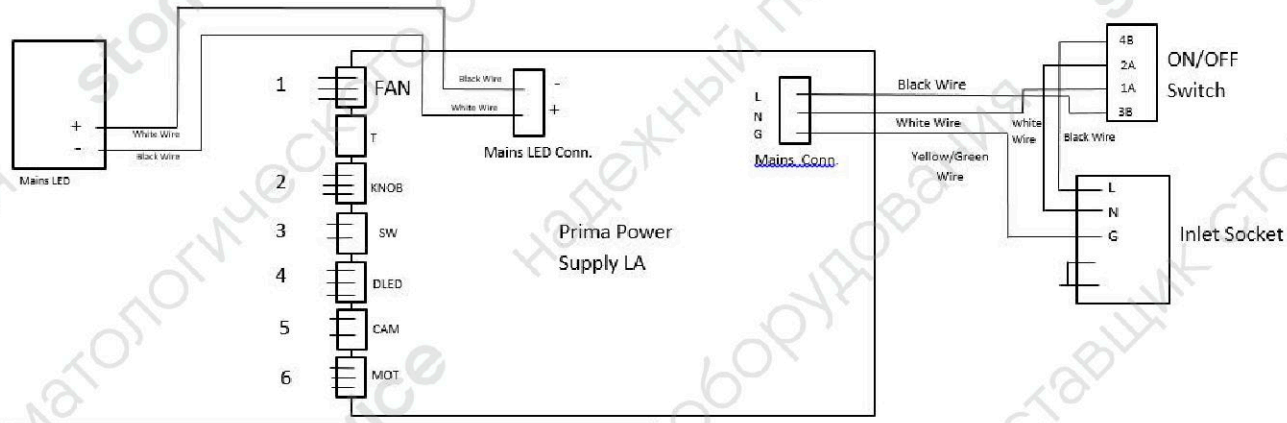
Fig. 9

8.3 Data Plate for Prima ENT/DNT Microscope



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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

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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.

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.

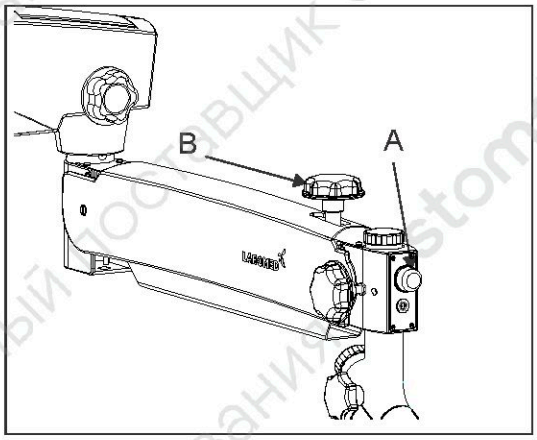
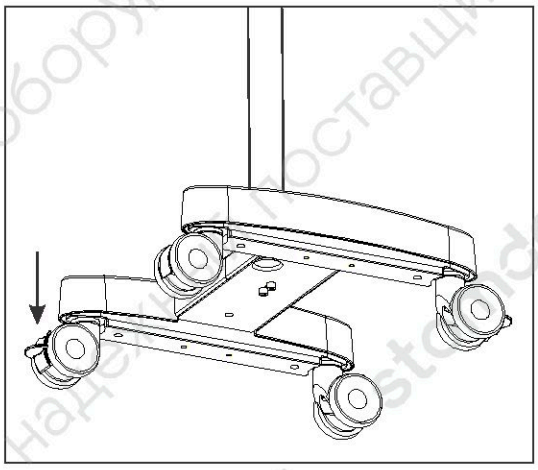


Fig. 10

9.3 Swivel arm locking knob

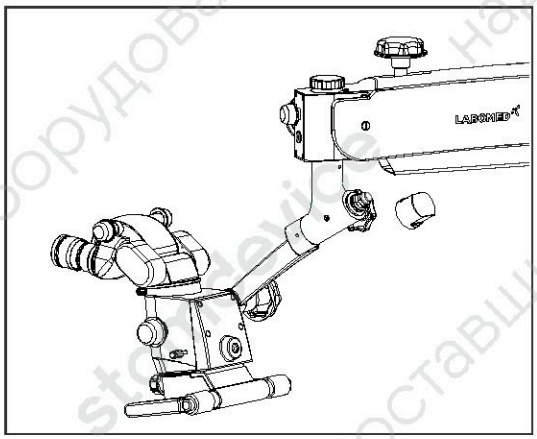
This knob helps you to lock the movement of swivel arm at the desired position after initial focusing of the attendance area by turning it clockwise, knob is shown as (B) in Fig. 10 .


Fig. 11

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.

9.5 Adjusting tension on rotatory motion of inclined carrier


Fig. 12

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10 INSTRUCTIONS FOR USING THE MICROSCOPE

WARNING: INSTRUMENT IS UNSAFE FOR MRI ENVIRONMENTS

Setting up of Microscope:

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 preset 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 8.0 mm allen wrench. Refer section 14 for more details.
Refer Fig. 13 to see the exact location of tension adjusting screw.

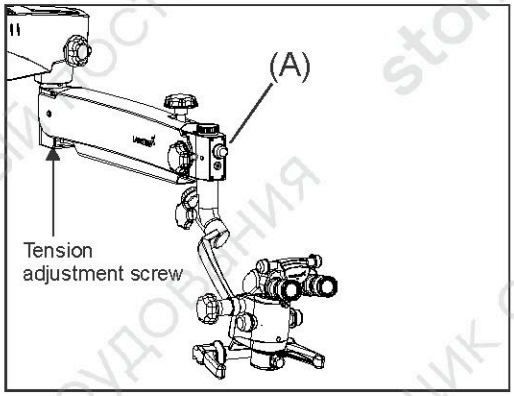


Fig. 13

3 Lock the Up & Down movement of suspension arm using locking knob (B) shown in fig. 10 after coarse focusing of area of interest.

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

5 The illumination is controlled through the control knob (A), fig. 13. Rotate it clockwise or anti clock wise to achieve desired illumination level Functional setup keep it as minimum.

Setting up of magnification (Ref. Fig. 14)

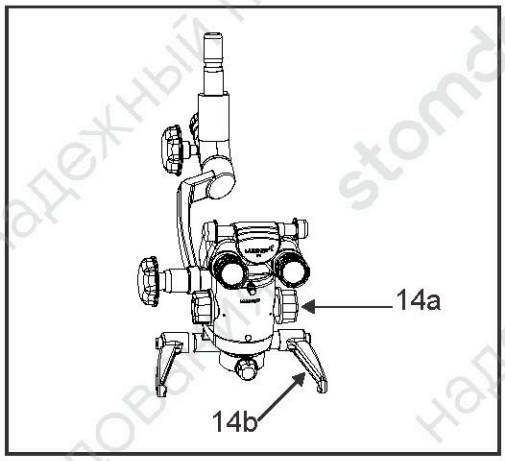


Fig. 14

1 Adjust to highest magnification with one of the rotating knobs (14a) provided at magnification changer.

2 Fine focusing is done through fine focus knob or foot paddle

3 Absolute centering of focused area in field of view can be done by manual handle(14b).

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

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Main microscope

The objective lenses with the focal lengths of 250 mm,300 mm and 400mm are available for different working distances.

The ergonomic straight or 210 degree binocular tube is provided for the main surgeon. The large tilt range allows work with minimum fatigue.

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

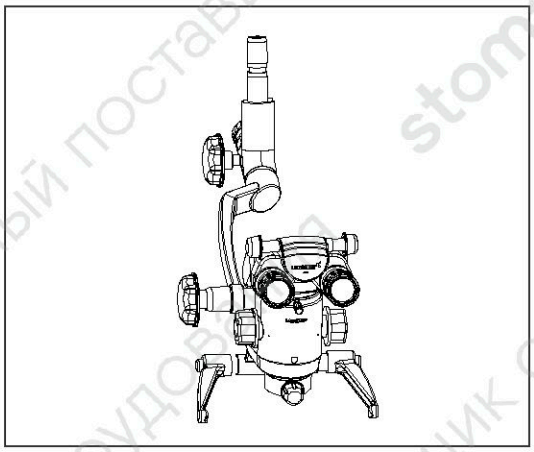


Fig. 15

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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 clock wise 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.

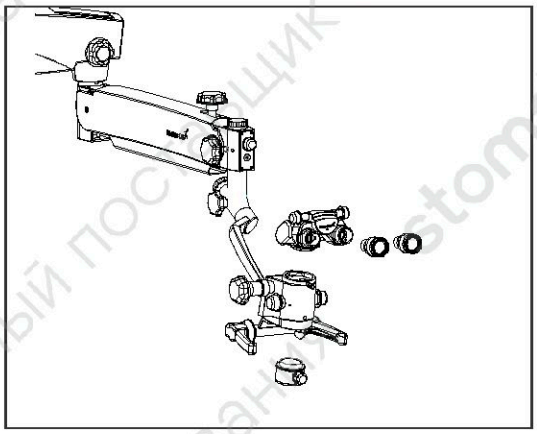


Fig. 16

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12 USE OF ACCESSORIES

Part No.: 6138000-000
Model: Prima DNT

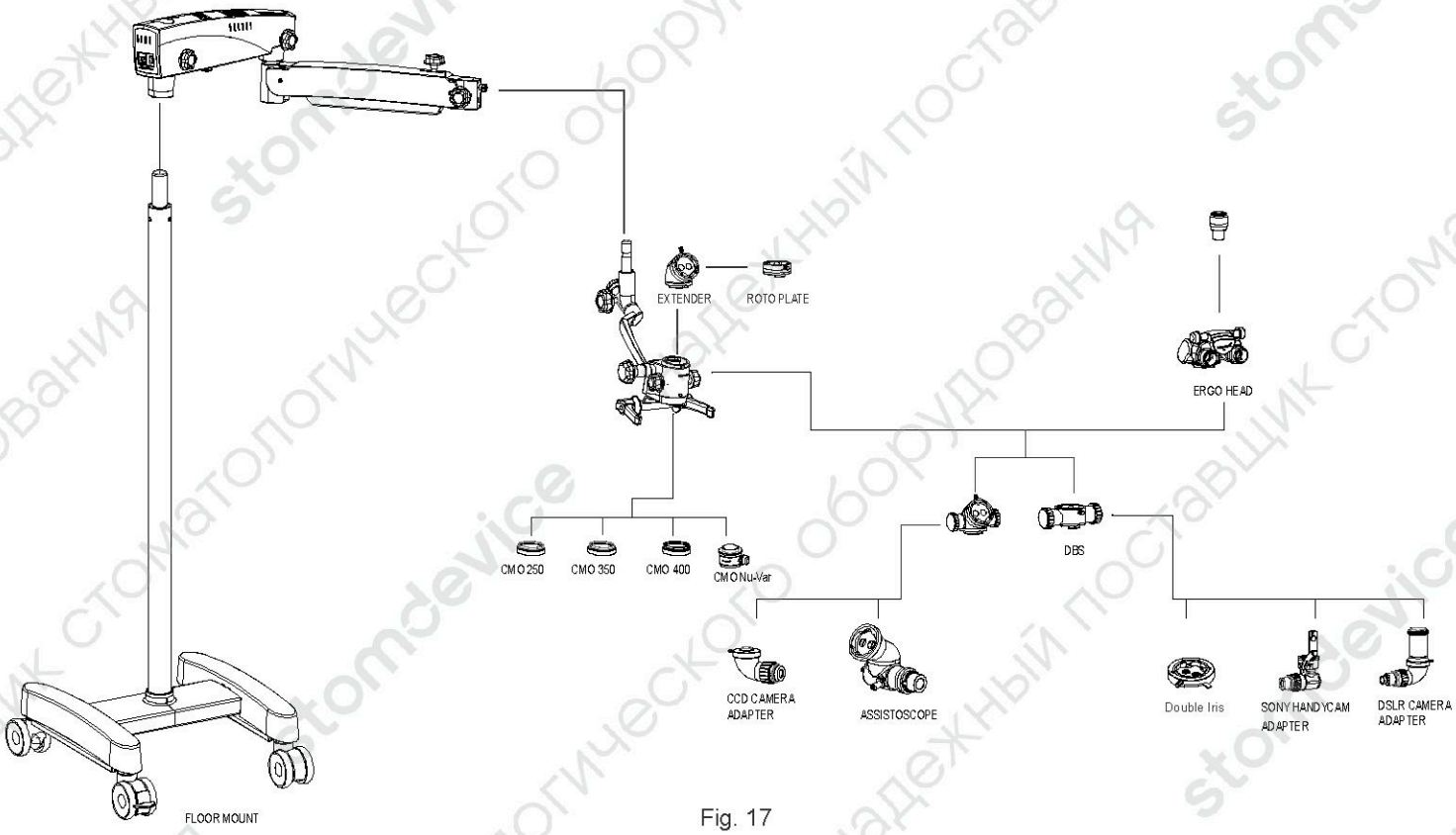


Fig. 17

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

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Part No.: 6137000-000
Model: Prima ENT

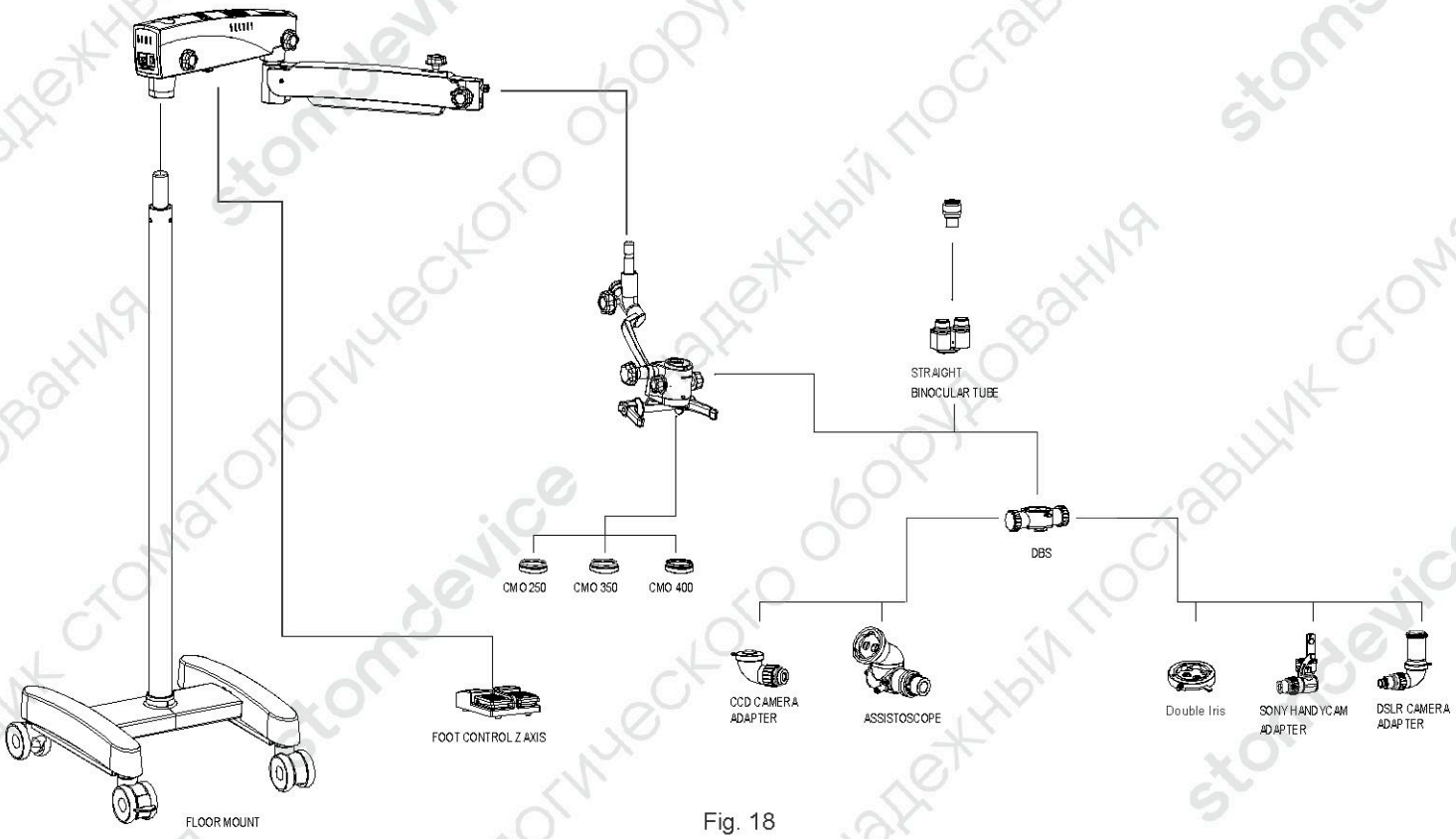


Fig. 18

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

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13 THERMAL CUTT-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, 13.5 Amp

14 TENSION ADJUSTMENT

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

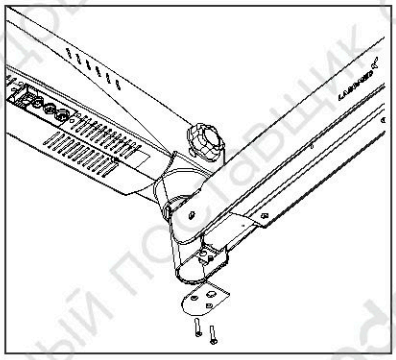


Fig. 19

Refer fig. 19

1. Remove plate by unscrewing two holes.
2. Loosen two allen bolts by using allen wrench of 4 mm as shown in fig 20
3. Use hexagonal wrench of 8mm in bolt (A) shown in fig. 21 rotate it clockwise to increase desired tension on Gas spring
4. Re tighten the two screws
5. Put back the plate

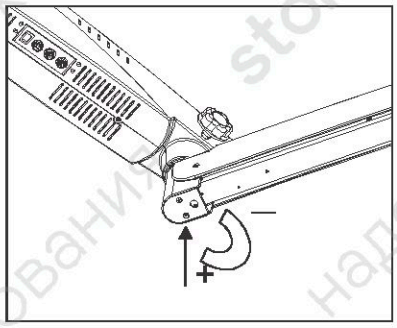


Fig. 20

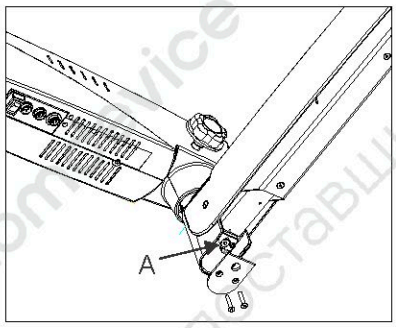


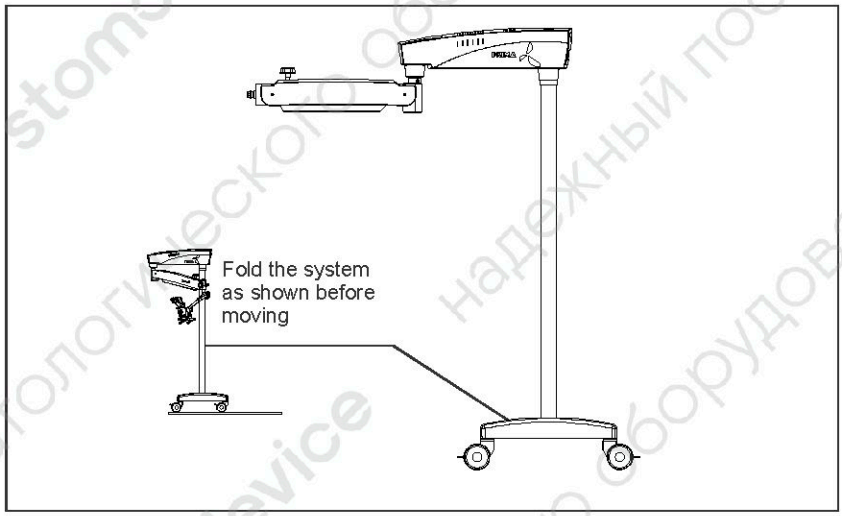
Fig. 21

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15 MOVING POSITION OF THE SYSTEM



Position of the system for safe transportation.



Relocating the stand

Turn off the unit at the power switch

Disconnect the power cable from line power.

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

Release locks by pressing the upper parts of the locks downward.

Bring the unit into its moving position.

Be careful of heights when passing through doorways.

Avoid collision of any kind.

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

Be extremely careful when moving over slopes.

Do not park the stand on slopes

Press lock downward.

Check whether the stand is locked in position.

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16 CARE & MAINTENANCE

This instrument is a high grade technological product and not required any special periodical maintenance if handed carefully. To ensure optimum performance and safe working order of the instruments, its safe functioning must be checked once every 12months 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 with dust cover.
  - Remove dust with a pneumatic rubber bulb and soft brush.
  - Use microfiber cloth and pure 99% isopropyl alcohol for cleaning lenses and eyepieces.
  - Protect your microscope from moisture, fumes, acids and cosmetic materials. Do not store chemicals close to the instrument.
  - Protect it from improper handling. Never install other devices sockets or unscrew optical system and mechanical parts unless explicitly instructed to do so in this manual.
  - Protect the microscope from oil and grease. Never oil or grease the guide surfaces or mechanical parts.

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- Remove coarse contamination using a damp disposable cloth.
- Use disinfectants based on the following ingredients: aldehydes, alcohols, quaternary ammonium compounds.
- Camera: Keep optical components clean using the microfiber cloth. Soak the cloth using a little methanol or glass cleaner. Do not use ethanol 99% isopropyl alcohol.
- Do not clean products with optical components in a cleaning/disinfecting device or ultra sound bath.

- **Tropical environment/fungus:**

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

- Keep optical part clean.
- Use and store them in a clean environment only.
- Store under UV light when not in use.
- Use in continuously climate-controlled rooms only.
- Keep moisture away and cover using a plastic cover filled with silica gel.

- **Occupational safety and health protection:**

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

- **Workplace:**

Remove surface contamination with a paper towel.

- **Reprocessing:**

Recommended: reprocess a product immediately after use.

- **Cleaning& Servicing:**

- Wipe the instrument and stand (non-optics) with a damp (not dripped wet) cloth regularly. Standard mild household detergents should be used at suitable dilution. Afterward wipe with a dry, non-fuzzing cloth.
- Do not use harsh or corrosive cleaning agents, they can cause damage to painted printed and plastic parts.
- Avoid splashing water, may cause device-as safety clause in IPXO.
- Use 99% isopropyl alcohol to clean optical components.
- Dry optical components using a microfiber cloth; dry the rest of the product using a paper towel.
- Service as and when required should be informed to LABOMED after – sales service department.

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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 to the 93/42/EEC directive governing medical devices. The unit is marked with: CE and is compliance to **ANSI / AAMI EC 60601-1:2005**.

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18 DISPOSAL

Disposal must comply with locally applicable laws & regulations.

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19 TROUBLESHOOTING TABLE

Problem	Possible Cause	Remedy
No Illumination at all	Power cable not plugged	Plug in power cable.
	Power switch not pressed	Press power switch
	Defective instruments fuse	Change instrument fuse
	Defective power cable	Change power cable
	Line power failure	Contact in-house Technician
	Failure of suspension system electronics	Contact service dept.
	Light guide not properly inserted in arm or microscope.	Insert light guide properly to get maximum illumination.
Insufficient Illumination	Brightness level set too low	Adjust brightness using the brightness control knob.
	Light guide not properly inserted in arm or microscope.	Insert light guide properly to get maximum illumination
	Defective light guide (illumination not uniform)	Change light guide.
Inoperative surgical field illumination	Light guide not properly inserted in microscope arm	Insert light guide as far as it will go
	Failure of electronics	Illumination surgical field using alternate illuminator and contact service dept.
	Switch off via microswitch on suspension system	Move suspension arm of suspension system into working position

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Problem	Possible Cause	Remedy
	Thermal cut-off in lamp housing is contaminated.	Clean thermal cut-off with a dry brush; blow it clean, if necessary
	Defective fan. Failure of system electronics.	Illuminate surgical field using alternate illuminator and contact service deartment
Up & Down motion of screw on suspension system too stiff	Friction adjustment screw on suspension system tightened too firmly.	Loosen friction adjustment screw on suspension system as require
Microscope Unstable	Brakes on wheels not used.	Use Brakes.
No image visible in field of view.	Magnichanger is not indexed properly.	Index magnichanger properly.

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20 TECHNICAL SPECIFICATIONS

Technical Data (Specifications)

Binocular tubes	Ergo viewing tube 0°-210°(tiltable), IPD 55-75mm **Optional:** Straight viewing tube 90°, IPD 50-75mm
Eyepieces	WF 10x/18mm with retractable eye guards, diopter adjustment + 5mm 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° (80-13 mm)
Objective	f=250mm, manual fine focus
Light source	50W LED; Maximum intensity 80,000 LUX
Built-in filters	Green & Yellow
Vertical movement of arm	550 mm
Microscope carriers	120° Carrier
Accessories	Double Beam Splitter and Camera Adapters
Power Consumption	130 W max.
Input Voltage	100V-240V; 50/60 hz
Stand:	Stable and sturdy H-base stand with 2 lockable wheels.
Base (Dimensions):	600 mm width 620mm length
Stand Height:	1733 mm
Weight:	
Microscope arm with all optical module	20 Kg. Approx.
H-base with pillar	68 Kg. Approx
Elevation Stroke:	570 mm
Stand Height in Horizontal Position:	1100 mm

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Guidance Tables

Guidance and Manufacturer's Declaration **Electromagnetic Emissions** All Equipment and Systems		
Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Prima ENT/DNT is intended for use in the electromagnetic environment specified below.The customer or user of the Prima ENT/DNT 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 ENT/DNT 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 ENT/DNT is suitable for use in all establishments, other than domestic, and those directly connected to the public low-voltage power network that supplies buildings used for domestic purposes.
Flicker IEC 61000-3-3	Complies	

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GuidanceTables (continued)

Guidance and Manufacturer's Declaration

Electromagnetic Immunity

All Equipment and Systems

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Prima ENT/DNT is intended for use in electromagnetic environment specified below The customer or user of the Prima ENT/DNT 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	Mains 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	Mains power quality should be that of a typical commercial or hospital environment.
voltage Dips/Dropout 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Prima ENT/DNT requires continued operation during power mains interruptions, it is recomended that the Prima ENT/DNT be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 vrms 150 kHz to 80 MHz	(v1) = 3 vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Prima ENT/DNT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. 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 manufacturer 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 
Radiated RF IEC 61000-4-3	80 MHz to 2.5 GHz @ 3V/m	(E1) = 3 v/m	

Note 1: At 80 MHz and 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 assess 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 150 kHz to 80 MHz, field strengths should be less then [V1] V/m.

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Guidance Tables (continued)

Recommended Separation Distances between
Portable and Mobile RF Communications Equipment and the Prima ENT/DNT for ME Equipment and ME Systems that are NOT Life-supporting.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Recommended Separation Distances for between
Portable and Mobile RF Communications Equipment and the Prima ENT/DNT

The Prima ENT/DNT is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Prima ENT/DNT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment (transmitters) and the Prima ENT/DNT as recommended below, according to the maximum output power of the communications 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) 800MHz 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 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

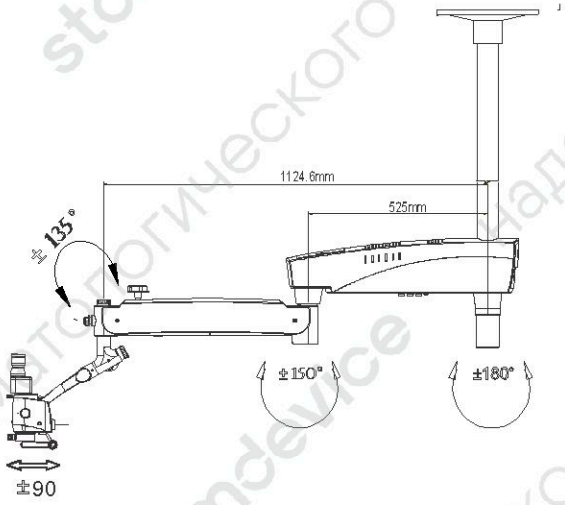
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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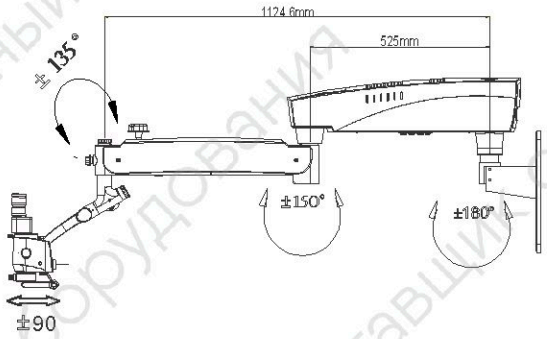
22 MEASURES & WEIGHT

Prima ENT/DNT- Microscope with Mobile Stand
Total Weight: Approx. 88 kgs.

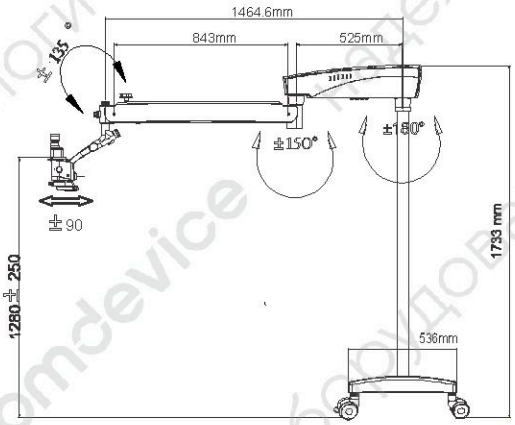
Ceiling Mount



Wall Mount



Floor Mount



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23 GLOSSARY

Ametropia compensation	Compensation of short- or far-sightedness. This can be done for each eye individually by means of the two eye-pieces (range: +5 to -5 diopters).
Working distance	Distance front lens to object level (= 250 mm).
Colour temperature	Specifies the colour impression of a light source. Using colour temperature, one can set the colour of a light source in relation ('hot' or 'cold' light) with the colour of natural light (sunlight). The unit of measurement for colour temperature is Kelvin (K).
Light field diameter	The size of the field, which is illuminated at a distance of 250 mm.
Field of view diameter	The visible area of an object that can be seen through the microscope. The greater the magnification level, the smaller the field of view and vice versa.
Green filter	A colour 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.
Intensity of Illumination	Specifies the luminous flux from a light source onto a certain area. The unit of measurement for illumination intensity is lux (Abbrev.: lx).
LED	Light Emitting Diode. Electronic semiconductor device that emits light when an electrical current passes through.
Eyepiece	The optical portion facing towards the eyes, with which the enlarged image produced by the colposcope can be viewed.
Beam path, convergent	The two light beams for the eyes run together in a point that lies at a distance of 250 mm 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 on its own, as it is the case with a parallel beam path.
White Balance	White balance is used to calibrate the camera to the colour temperature of the light at the location.
DSLR Camera	(Digital single-lens reflex camera) with a digital imaging sensor.
CCD Camera	(Charge-coupled device) a camera with a technology to store electro charge and move this charge out of photo sensor in organized way.
CMOS Camera	(Complementary Metal Oxide Semiconductor) cameras in which image sensors are silicon chips that capture and read light.
DBS	(Double beam splitter) Splits each light beam into two directions (eye and to side port) for simultaneous user view & photography, videography or co-observations. Ratio of light distribution is 70% for eyes & 30% to side ports for photography, videography or co-observations, installed between observation head and main microscope.

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24 WARRANTY

This product is warranted by Labotech Microscopes India Pvt. Ltd. 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, Labotech Microscopes India Pvt. Ltd. sole obligation is to repair or replace the defective part or product at Labotech/Labomed discretion.

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