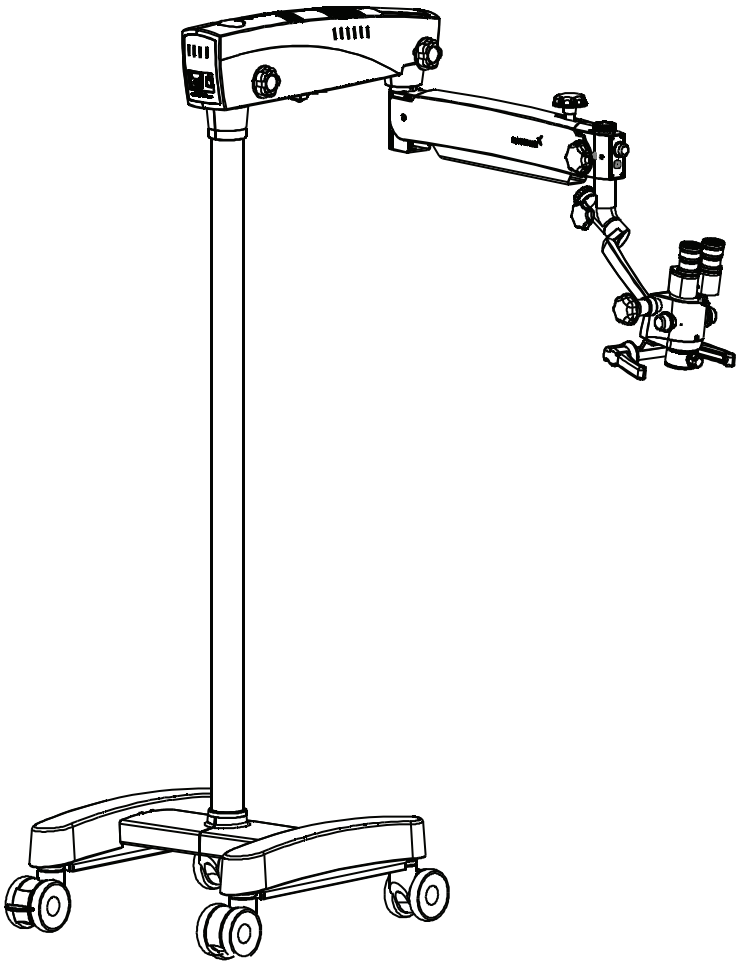
LABOMED
ideas for vision

PRIMA

Operating Surgical Microscopy

User Manual



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.

PRIMA is a Trade name of LABOMED Microscopes.

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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.

LABOMED products are designed and manufactured under quality processes that meet Quality management system requirements in compliance with ISO 13485.

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TABLE OF CONTENTS

1. INTRODUCTION AND INTENDED USE	1
2. PRODUCT DESCRIPTION	2-4
3. DIMENSIONS OF CASTOR MOUNTED	5
4. DIMENSIONS OF FLOOR MOUNTED	6
5. DIMENSIONS OF CEILING MOUNT	7-8
6. INSTALLATION REFERENCES (CEILING MOUNT)	9-15
7. CEILING MOUNT INSTALLATION	16-20
(A) DROP CEILING APPLICATIONS	
(B) LEVELING THE CEILING MOUNT SYSTEM	
(C) INSTALLING CEILING MOUNT ON CONCRETE CEILINGS	
8.DIMENSIONS OF WALL MOUNT ASSEMBLY	21-29
9.INSTALLATION REFERENCES (WALL MOUNT)	20-33
10. WALL MOUNT INSTALLATION PREPARATION	34-40
11.WALL MOUNT INSTALLATION PROCEDURE	41-42
12. WARNING AND CAUTIONS	43-44
13. EXPLANATION OF SYMBOLS	45
14. STANDARDS AND DIRECTIVES	46
15. CONDITION OF INSTRUMENT AT TIME OF UNPACKING/SUPPLY	47
16A. INSTALLATION OF BASE (MOBILE STAND)	48-49
16B. MICROSCOPE INSTALLATION	50-51
17. ELECTRICAL CONNECTIONS	52-53
18. CONTROL ELEMENTS	54-55
19. INSTRUCTIONS FOR USING THE MICROSCOPE	56-57
20. CHANGING THE OBJECTIVES & EYEPIECES	57
21. USE OF ACCESSORIES	58-59
22. THERMAL CUT-OFF	60
23. TENSION ADJUSTMENT	60
24. MOVING POSITION OF THE SYSTEM	61
25. CARE AND MAINTENANCE	62-63
26. CLEANING AND DISINFECTION	64
27. AMBIENT REQUIREMENT	65
28. DISPOSAL	65
29. TROUBLESHOOTING TABLE	66
30. TECHNICAL SPECIFICATIONS	67
31. GUIDANCE TABLES	68-71
32. GLOSSARY	72
33. WARRANTY	73-74

1. INTRODUCTION AND INTENDED USE

The LABOMED Prima 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 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 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 in magnichanger 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 microscope 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

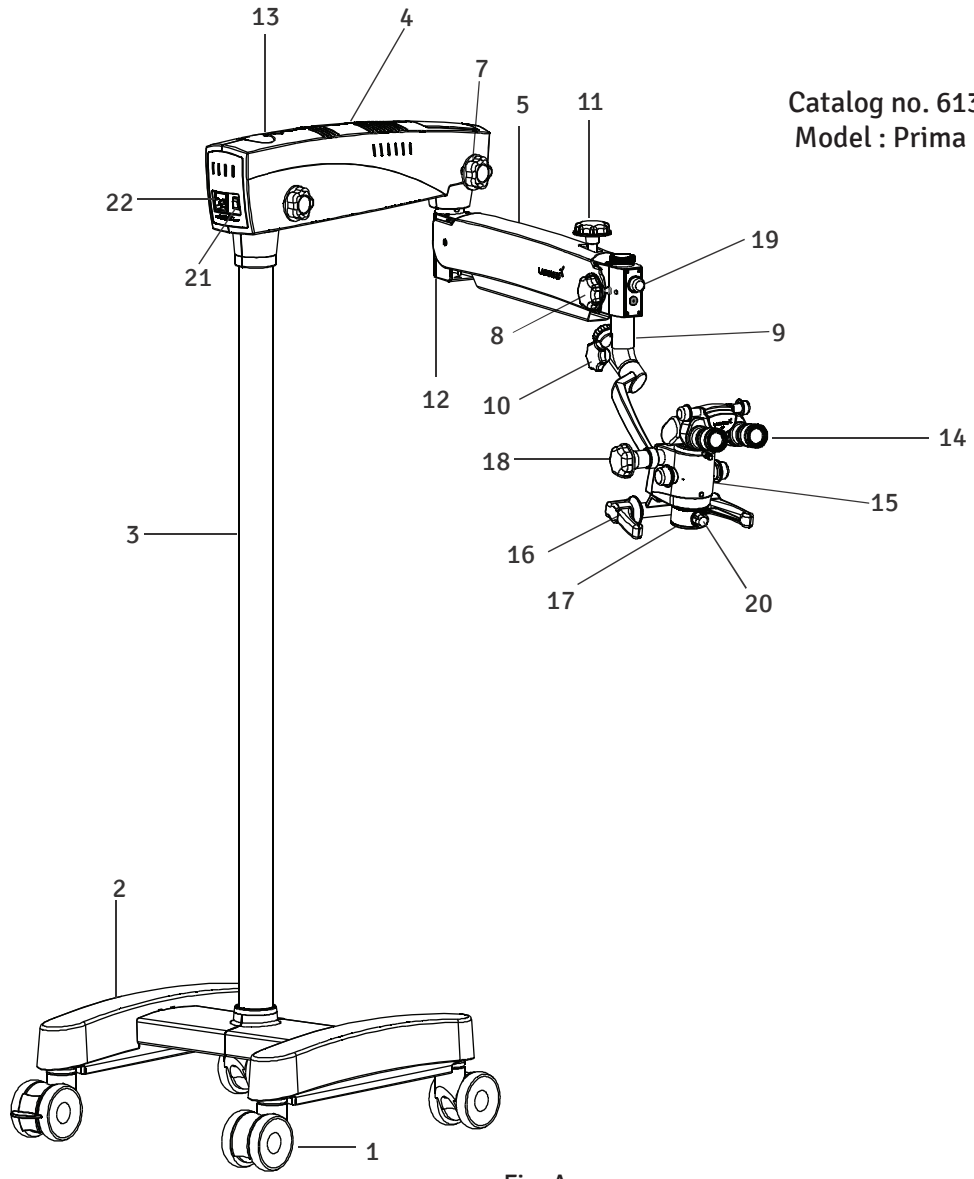
Prima Surgical Microscope is an AC powered device intended for use during diagnosis and Surgery to provide a magnified view of surgical field. .

Note: The use of Prima Microscope is purely for intended use.

CONFIGURATIONS

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

2. PRODUCT DESCRIPTION



Catalog no. 6138000-000
Model : Prima DNT

Fig. A

1. Wheel with Brakes
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. Inclined Coupling locking knob
9. Inclined coupling
10. Carrier Locking knob
11. Suspension arm hydraulic movement lock
12. Suspension arm spring tension adjustment
13. Swivel arm cover
14. Binocular head with eyepieces
15. Magnification changer
16. Handle
17. Common Main Objective
18. Magnichanger locking knob
19. Illumination Control Knob
20. Fine focusing knob
21. On/Off switch
22. Power inlet

PRODUCT DESCRIPTION(continued)

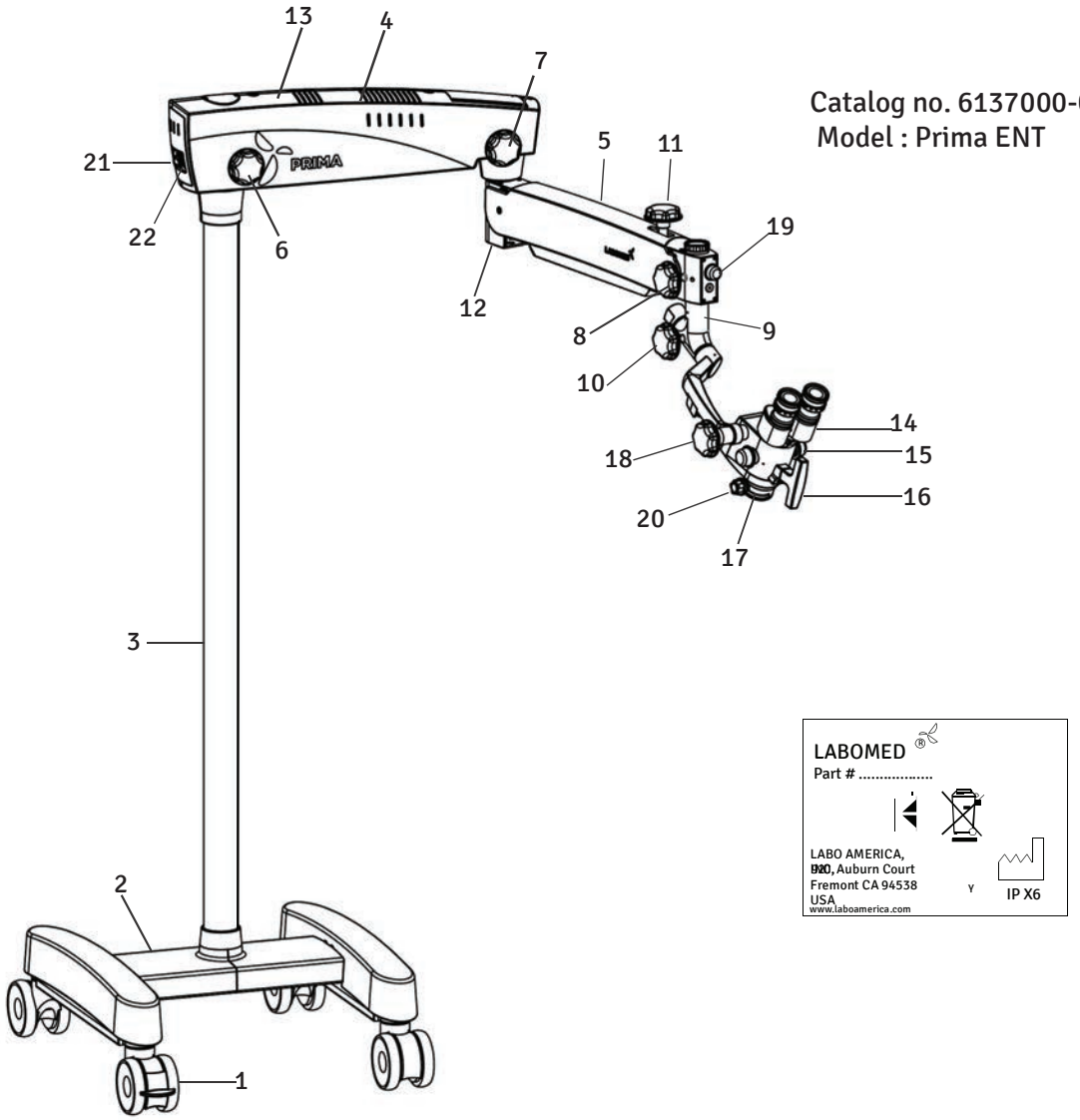


Fig. B

1. Wheel with Brakes
2. H shape metal Base
3. Column
4. Swivel arm
5. Suspension arm
6. Swivel Arm Locking Knob
7. Suspension arm locking knob
8. Inclined Coupling locking knob
9. Inclined coupling
10. Carrier Locking knob
11. Suspension arm hydraulic movement lock
12. Suspension arm spring tension adjustment
13. Swivel arm cover
14. Binocular head with eyepieces
15. Magnification changer
16. T - Handle
17. Common Main Objective
18. Magnichanger locking knob
19. Illumination Control knob
20. Fine focusing knob
21. On/Off switch
22. Power inlet

PRODUCT DESCRIPTION(continued)

Catalog no. 6137000-100
Model : Prima ENT, Z AXIS
Motorized

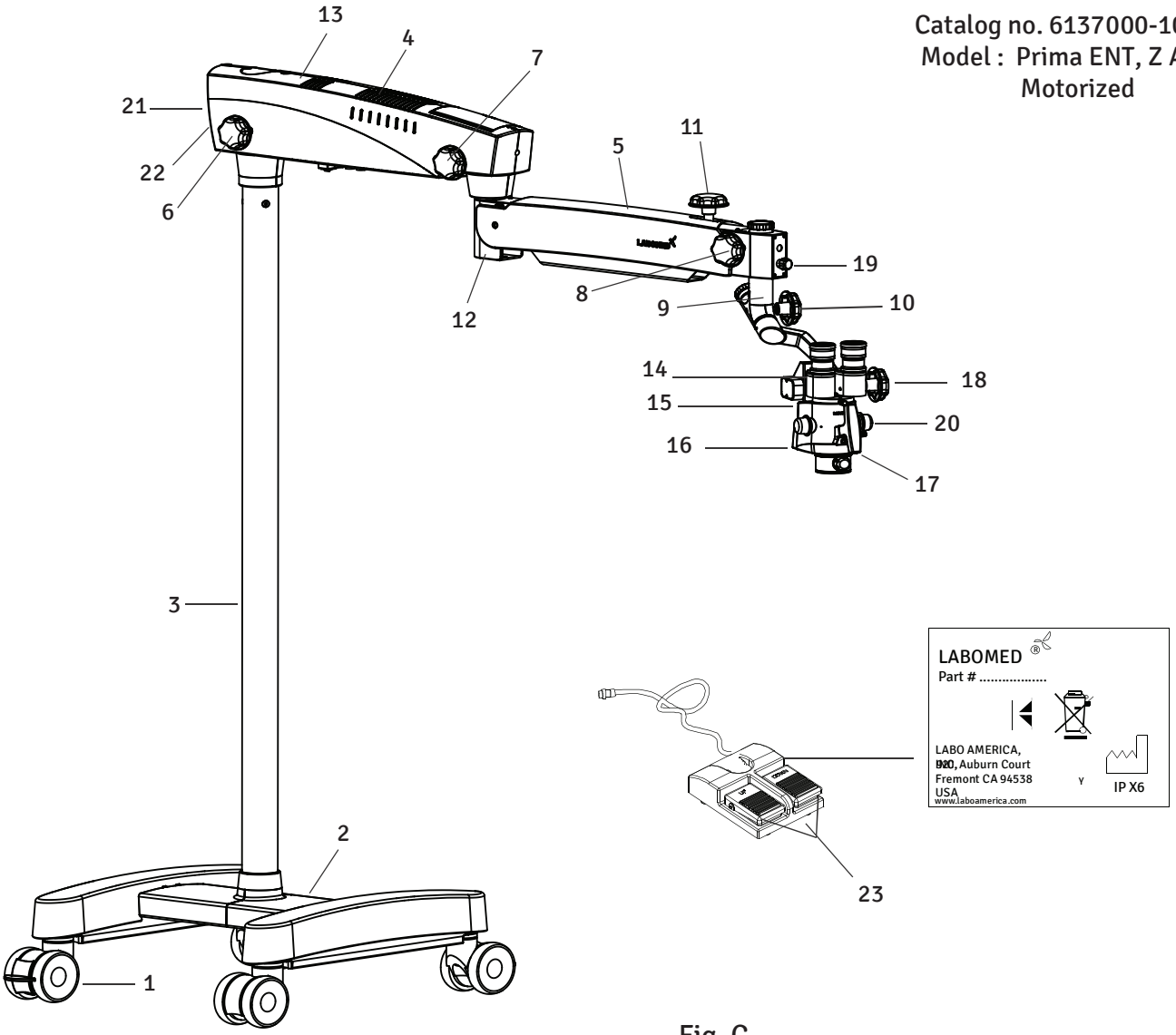


Fig. C

1. Wheel with Brakes
2. H shape metal Base
3. Column
4. Swivel arm
5. Suspension arm
6. Swivel Arm Locking Knob
7. Suspension arm locking knob
8. Inclined Coupling locking knob
9. Inclined coupling
10. Carrier Locking knob
11. Suspension arm hydraulic movement lock
12. Suspension arm spring tension adjustment
13. Swivel arm cover
14. Binocular head with eyepieces
15. Magnification changer
16. T - Handle
17. Common Main Objective
18. Magnichanger locking knob
19. Illumination Control knob
20. Fine focusing knob
21. On/Off switch
22. Power inlet
23. Foot Paddle for Z-axis

3. DIMENSIONS OF CASTOR MOUNTED

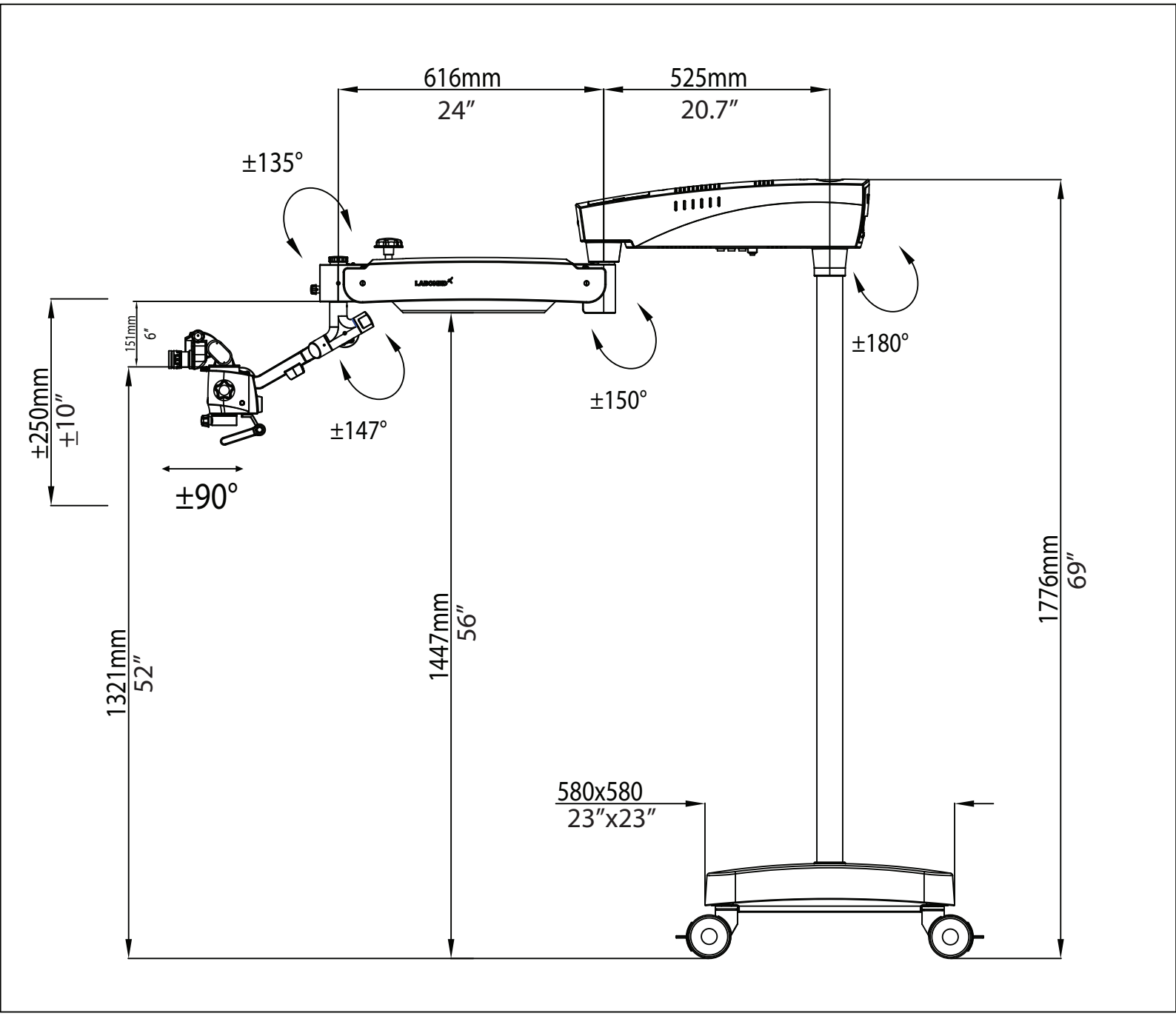


Fig. 1

4. DIMENSIONS OF FLOOR MOUNTED

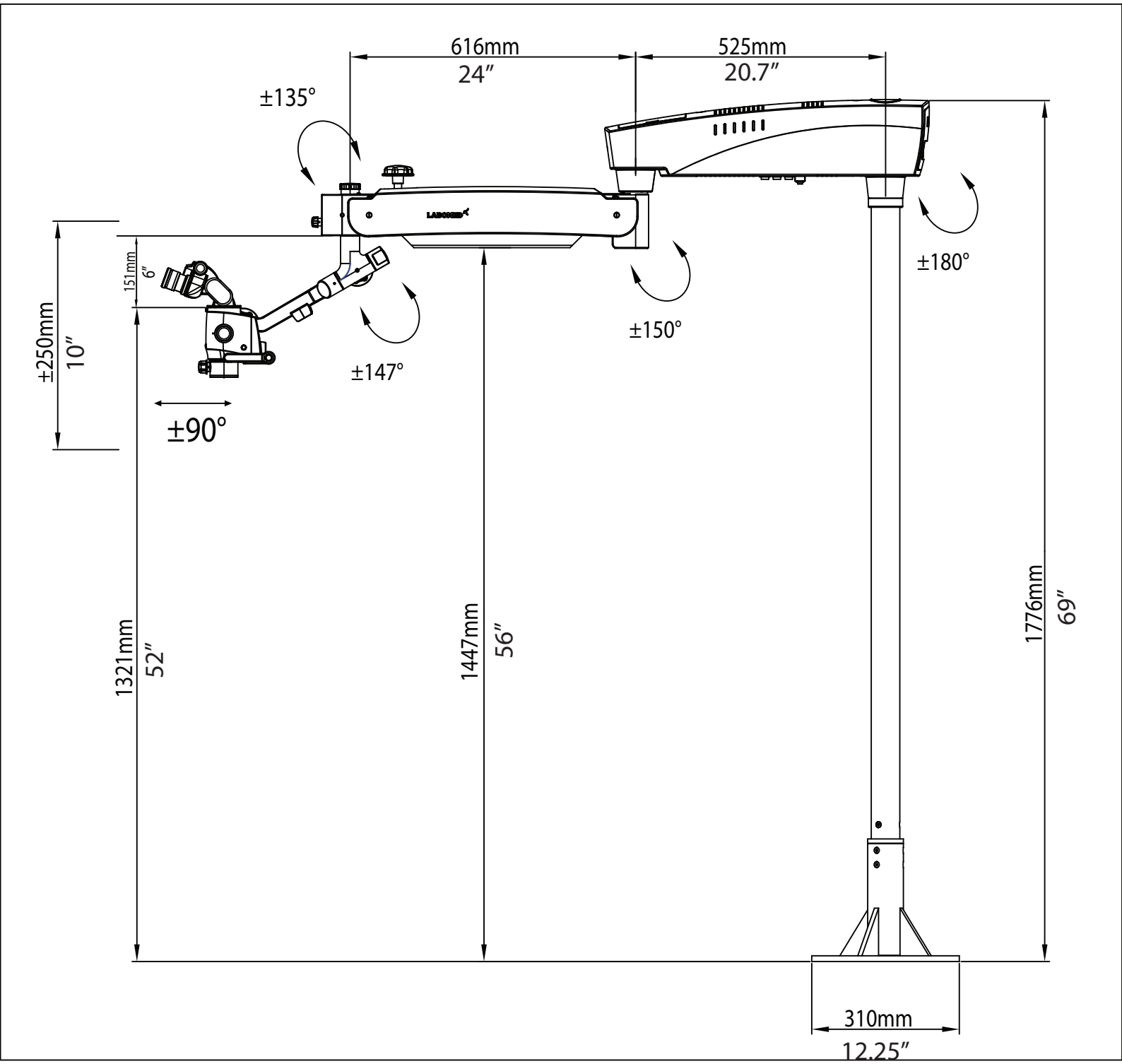


Fig. 2

5. DIMENSIONS OF CEILING MOUNT

CEILING MOUNT WITH STANDARD SUSPENSION ARM ON CONCRETE ROOF

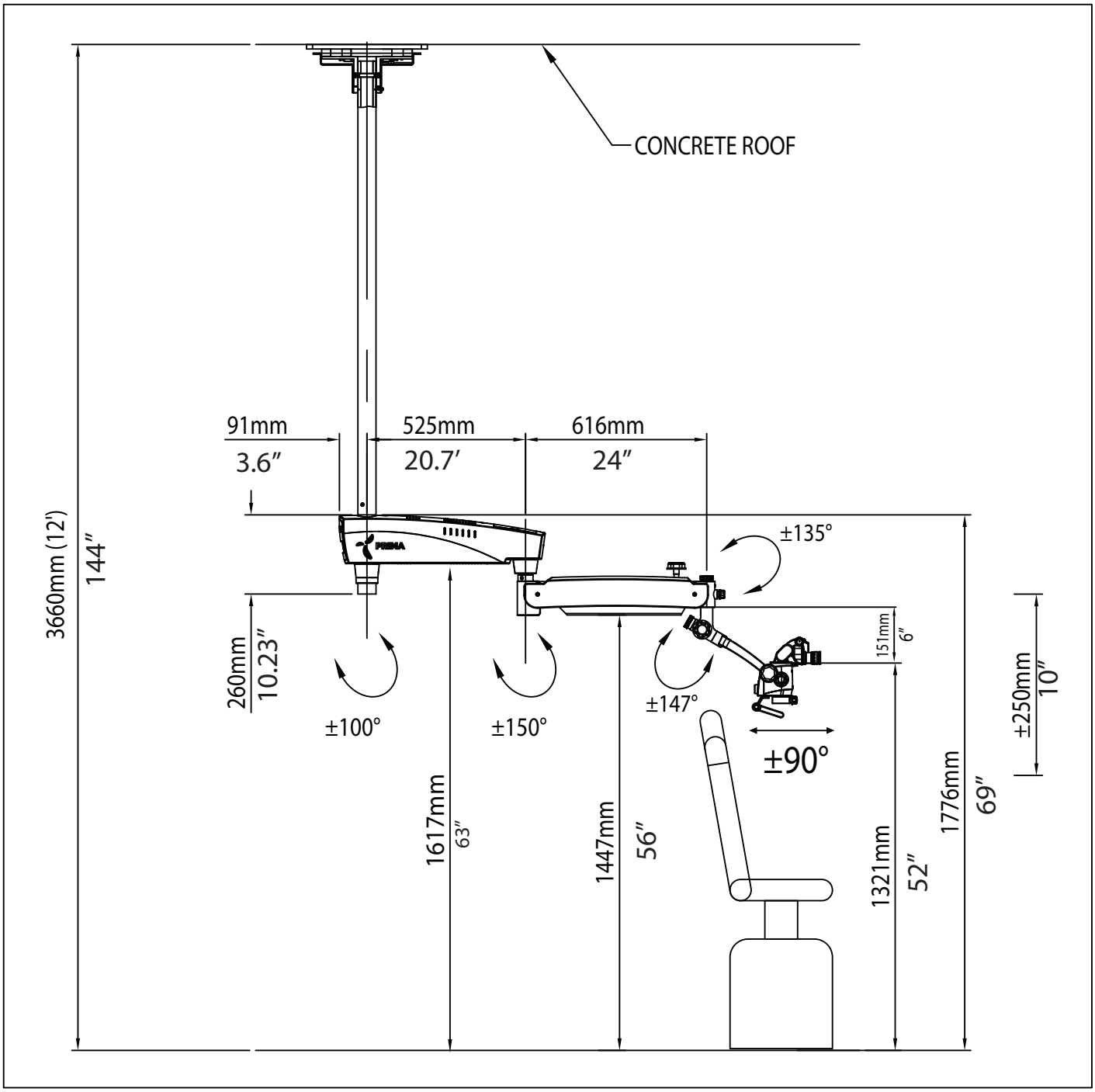


Fig.3

REQUIED COLUMN LENGTH FORMULA = (CEILING HEIGHT - 1875mm)
EXAMPLE :- COLUMN LENGTH = 3660mm - 1875mm = 1785mm(70.27)

DIMENSIONS OF CEILING MOUNT(continued)

CEILING MOUNT WITH LONG SUSPENSION ARM

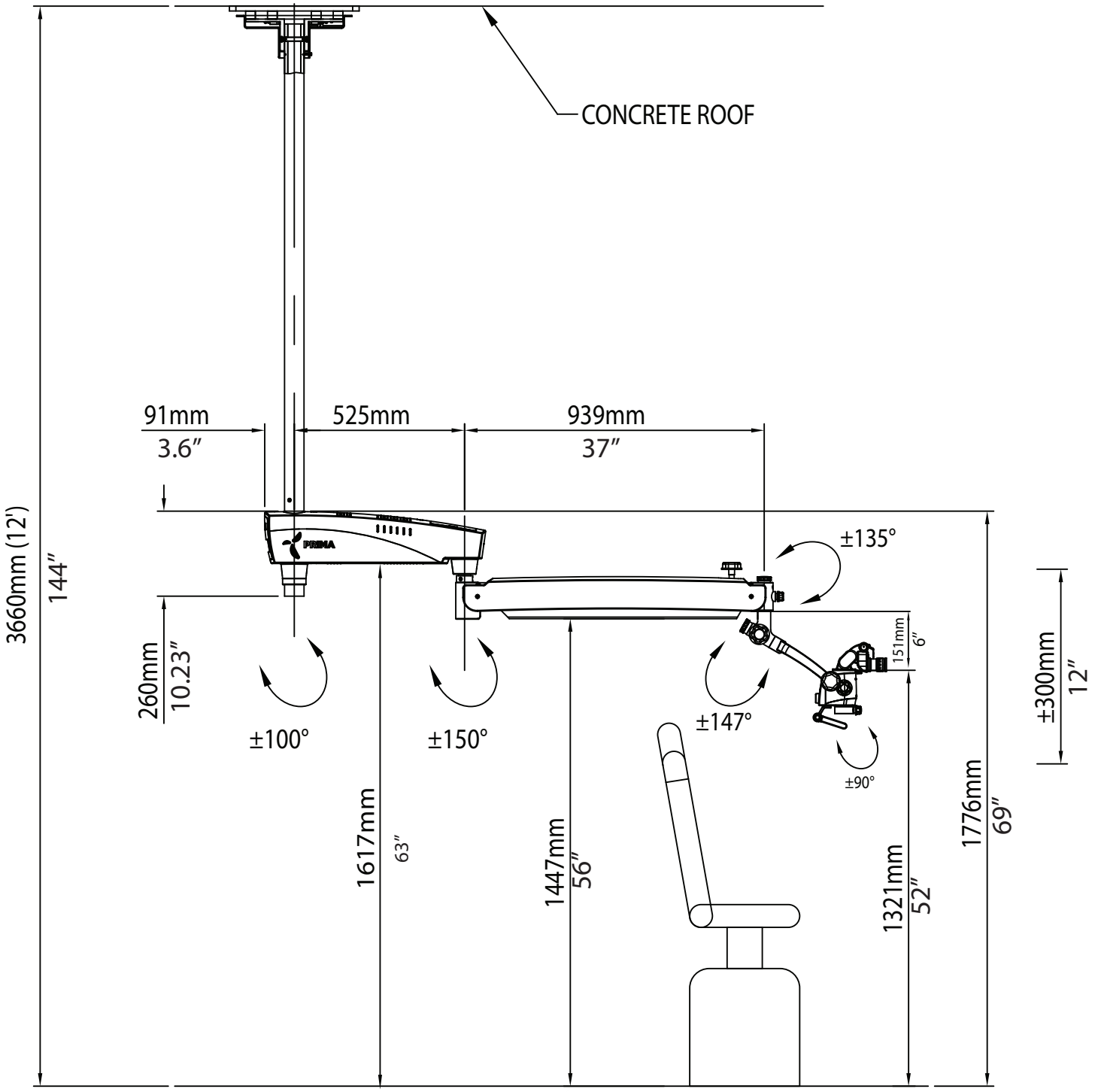
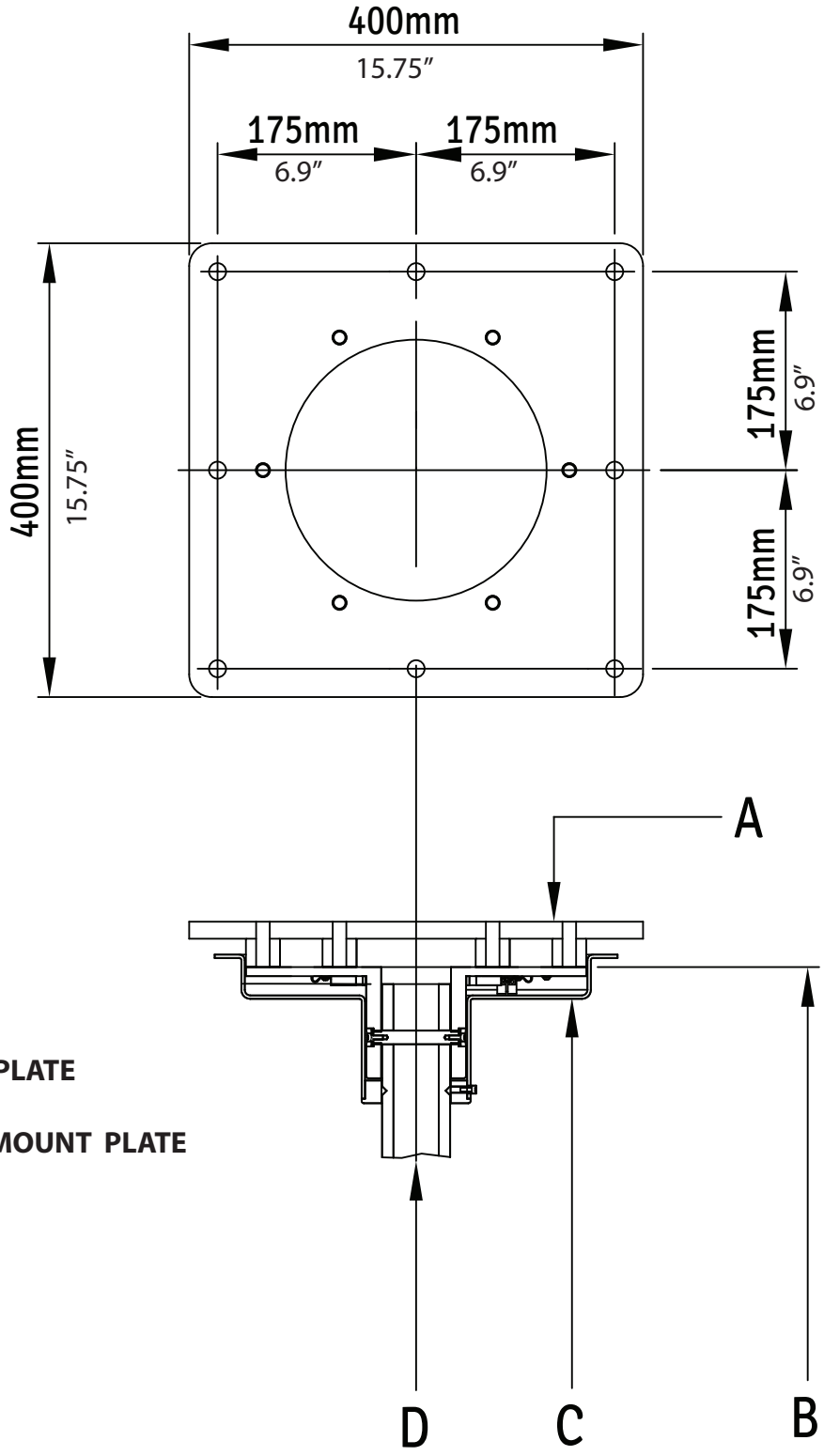


Fig.4

6. INSTALLATION REFERENCES CEILING MOUNT(For Concrete Ceiling)

MARKING REFERENCE



A - MASTER PLATE

B - CEILING MOUNT PLATE

C - COVER

D - COLUMN

Fig. 5

INSTALLATION REFERENCES (CONCRETE CEILING)

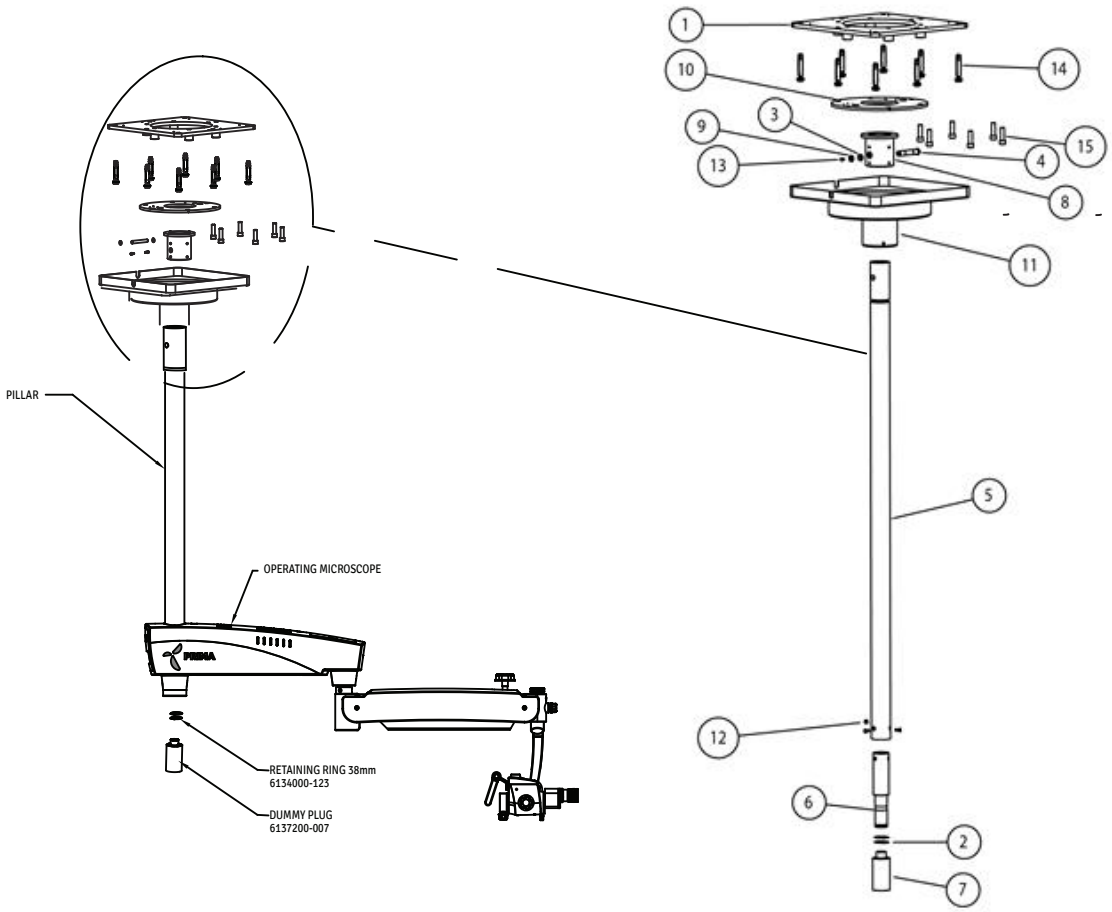


Fig.6

ITEM	QTY	PART NUMBER	DESCRIPTION
1	1	6129004-801	MASTER PLATE
2	2	6134000-123	RETAINING RING DIA 38
3	1	6136000-147	CHECK NUT
4	1	6137200-003	PIN
5	1	6137200-004	PILLAR
6	1	6137200-005	FRONT SHAFT
7	1	6137200-007	DUMMY PLUG
8	1	6137200-012	FLANGE BUSH
9	1	6137200-013	WASHER
10	1	6137200-804	ASSLY CEILING MOUNT PLATE
11	1	6137200-805	ASSLY CEILING COVER PRIMA
12	3	SS-800	SOCKET FLAT HEAD SCREW M6x16
13	1	SS-802	M5x10 CSK HEAD SCREW
14	8	SS-854	RAVAL PLUG M10
15	6	SS-921	M12x 40-SOCKET HEAD CAP SCREW

INSTALLATION REFERENCES (CONCRETE CEILING MOUNT)

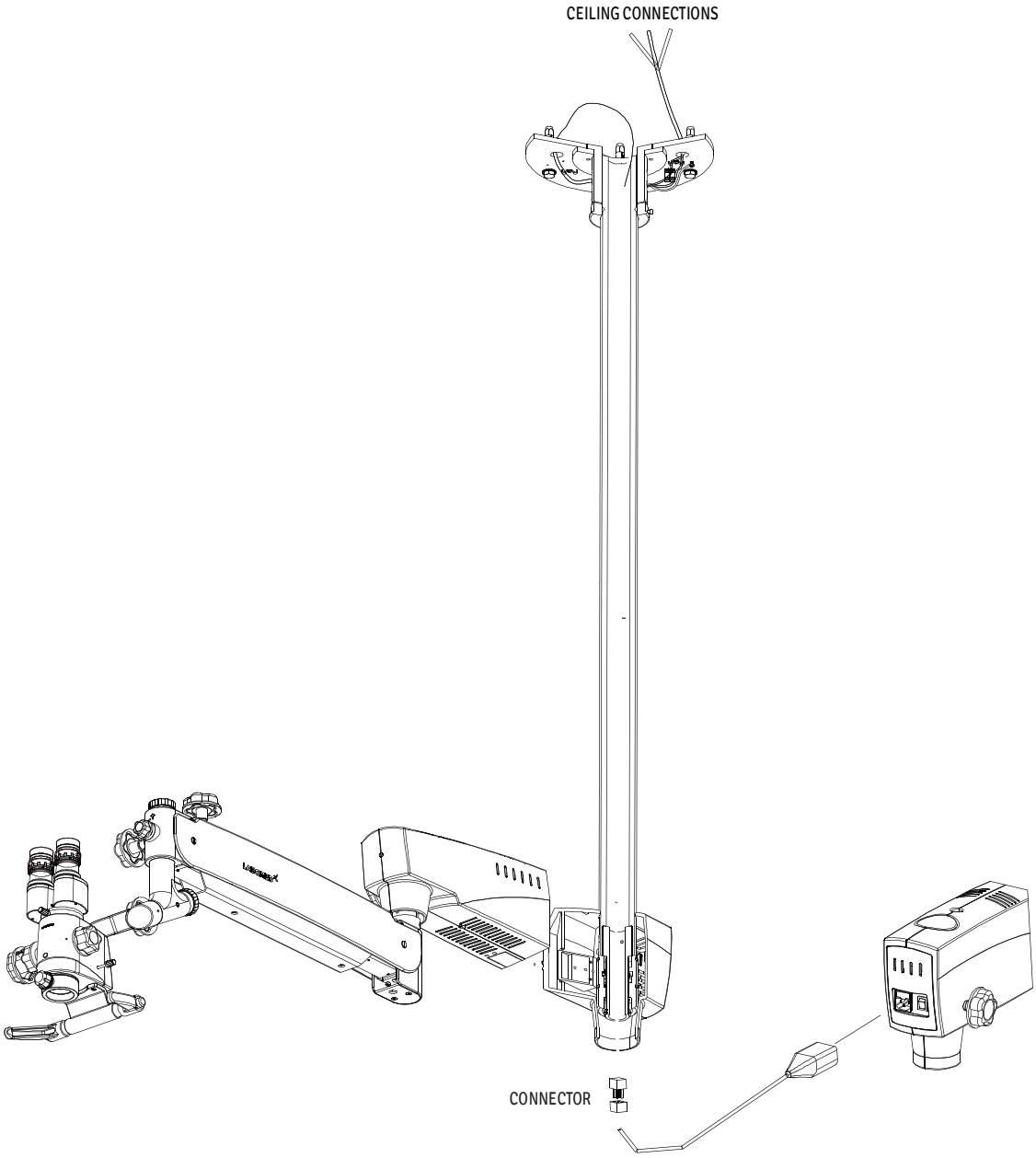


Fig. 7

INSTALLATION REFERENCES (CEILING MOUNT)

CEILING MOUNT: ALTERNATIVE INSTALLATION TO THE PATIENT'S SIDE WITH STANDARD ARM

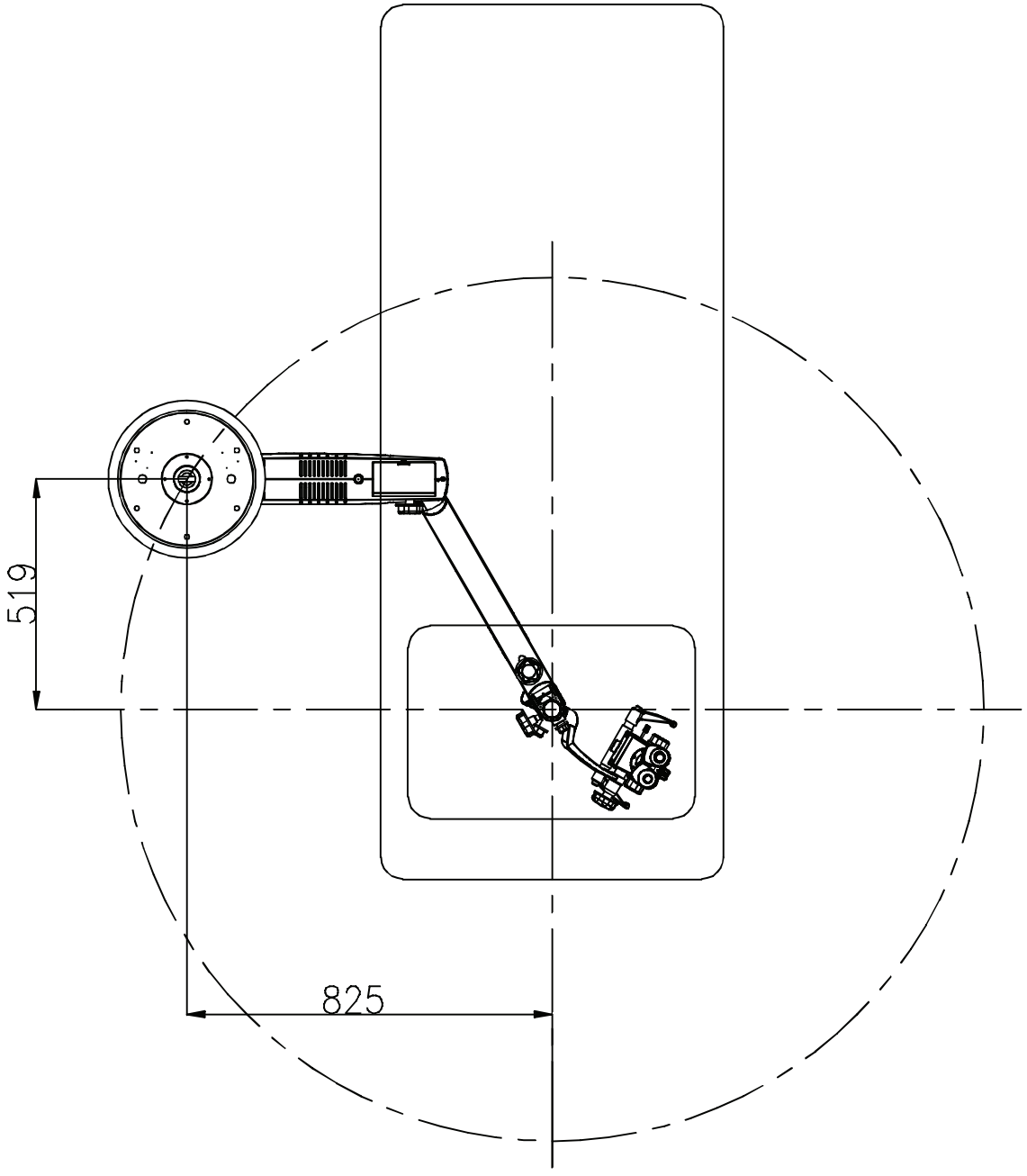


Fig. 8

INSTALLATION REFERENCES (CEILING MOUNT)(continued)

CEILING MOUNT: ALTERNATIVE INSTALLATION TO THE PATIENT'S SIDE WITH LONG ARM

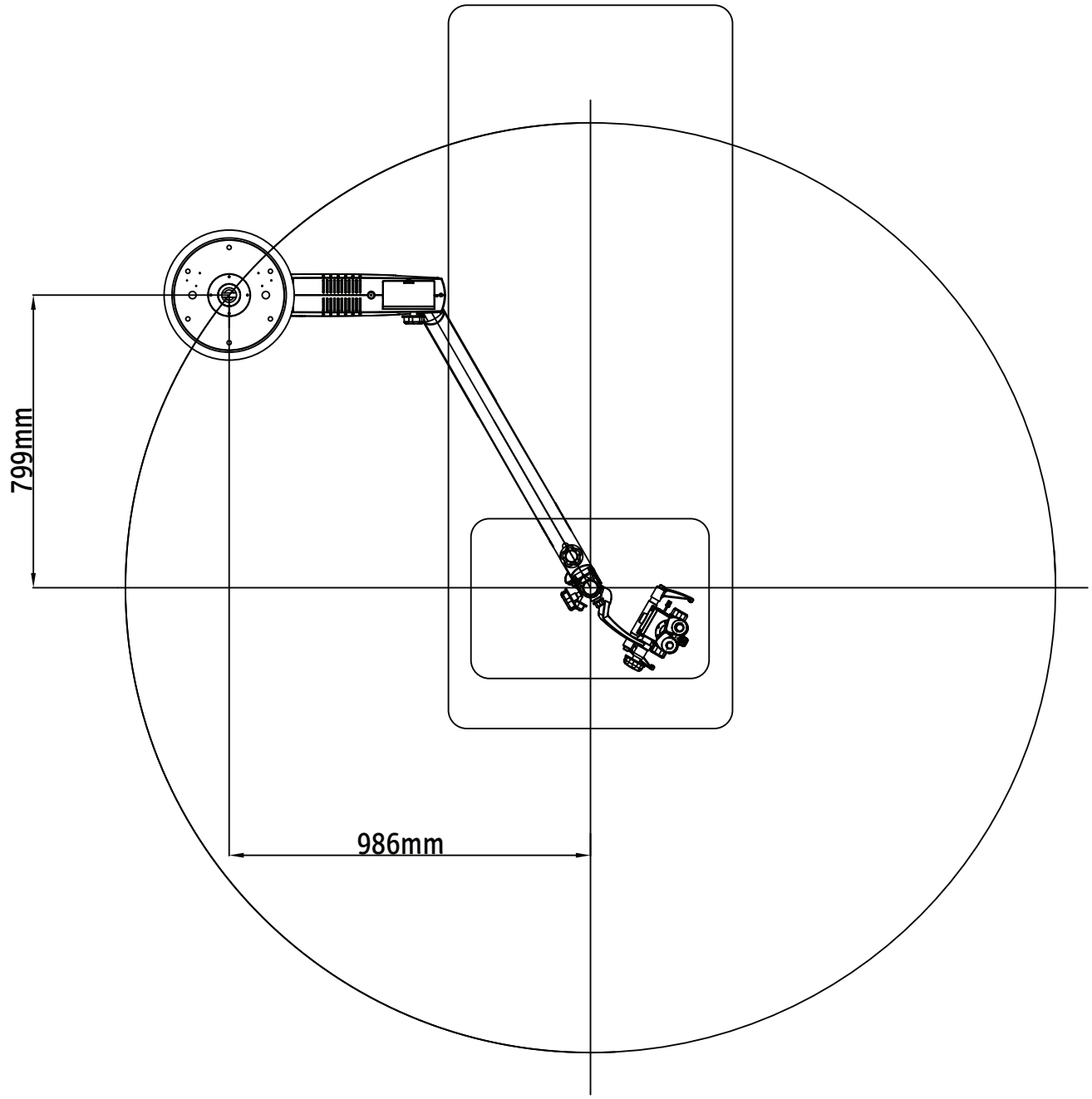


Fig. 9

INSTALLATION REFERENCES (CEILING MOUNT)(continued)

WORK RANGE RECOMMENDED FOR IDEAL INSTALLATION SITE
STANDARD ARM

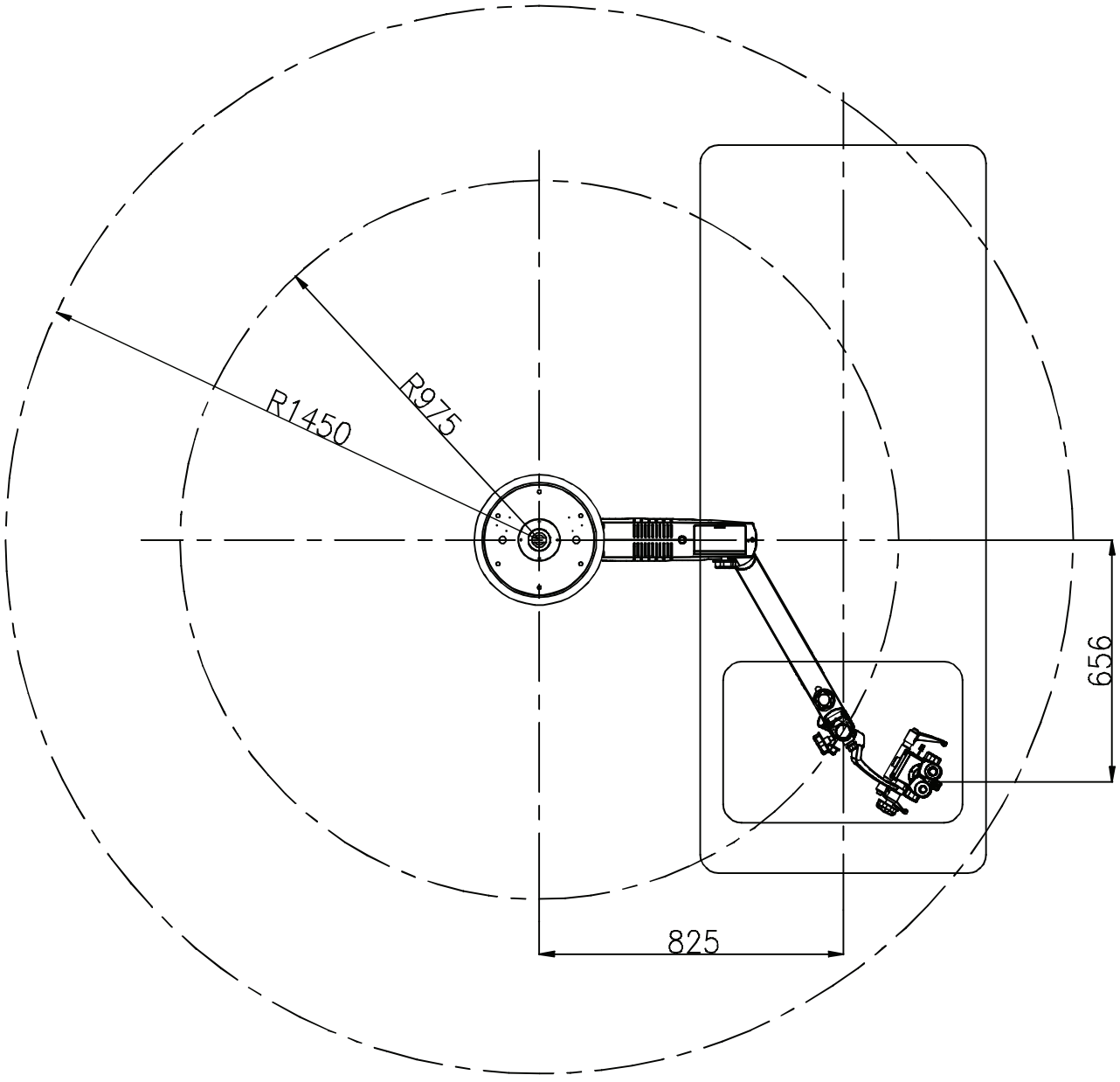


Fig. 10

INSTALLATION REFERENCES (CEILING MOUNT)(continued)

WORK RANGE RECOMMENDED FOR IDEAL INSTALLATION SITE
LONG ARM

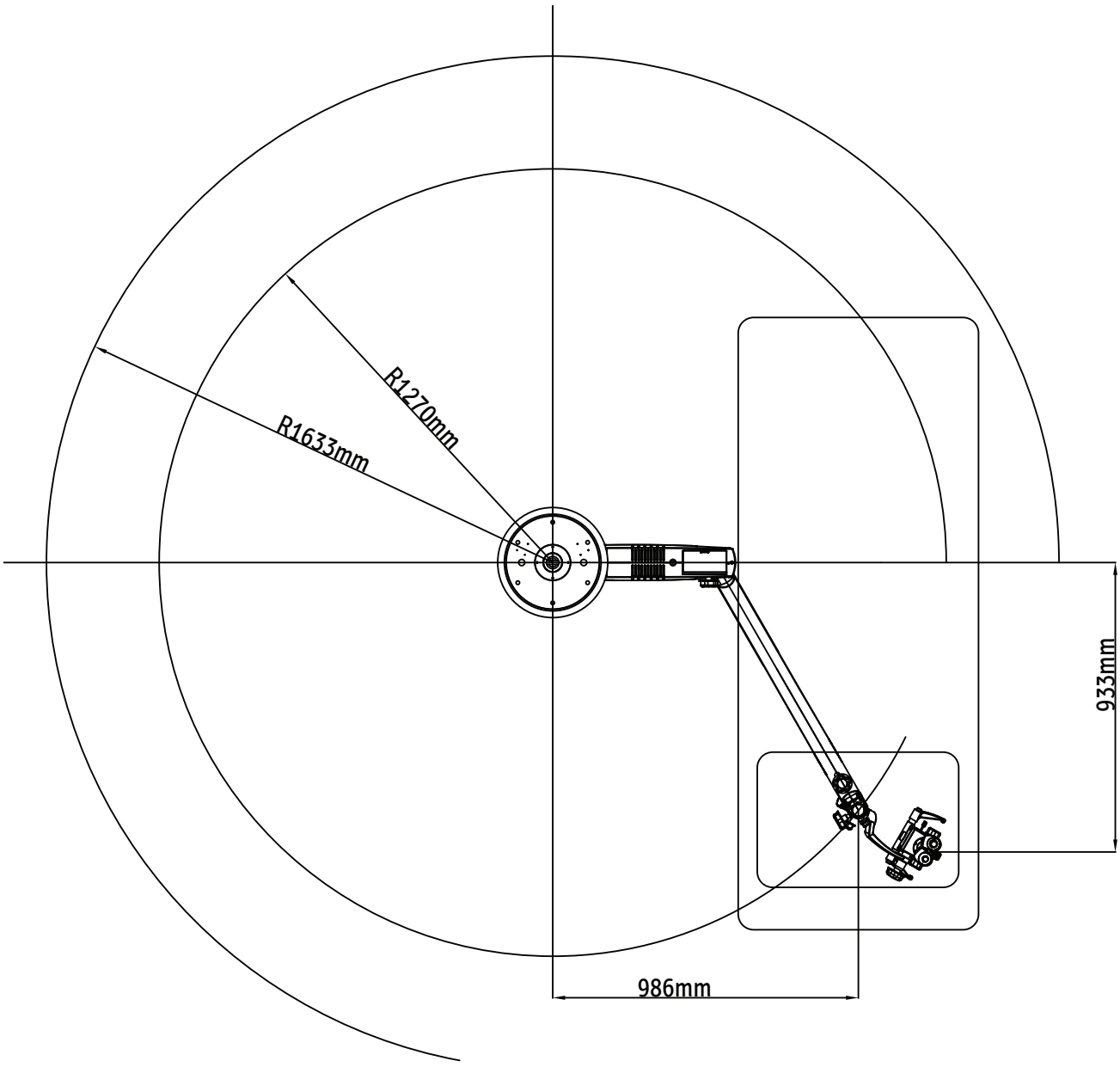


Fig. 11

7. CEILING MOUNT INSTALLATION

7A. DROP CEILING APPLICATIONS

Many newer constructions use drop ceilings. Whenever this type of application is used, all supporting structure and electrical service (115/230 VAC, 15A) is the customer's responsibility and must be completed before the installation.

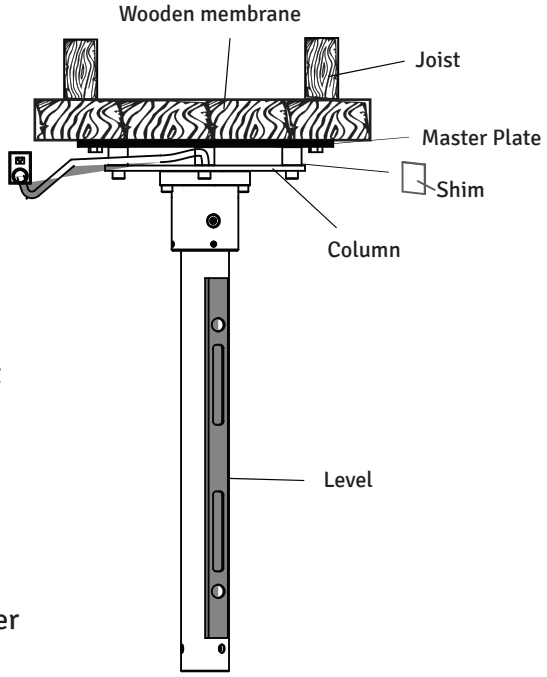
WARNING: THE SUPPORTING STRUCTURE FOR THE CEILING MOUNT AND WALL MOUNT INSTALLATION MUST BE CAPABLE OF SUPPORTING A MINIMUM WEIGHT OF 121 LBS (55 kg) AND BE STABLE LATERALLY AND VERTICALLY FREE FROM VIBRATION.

WARNING:

- **CEILING MOUNT AND COLUMN ASSEMBLY TOGETHER CAN WEIGHTS APPROXIMATELY UPTO 35 KG WITHOUT MICROSCOPE.**
- **TO AVOID PERSONAL INJURY TWO (2) PEOPLE ARE REQUIRED FOR PROPER INSTALLATION.**

PROCEDURE:

1. Ensure that there is a 350mm diameter hole in the drop ceiling to mount the master Ceiling plate.
2. Labomed Ceiling Mount system for wooden ceiling can be installed by fixing a flat wooden membrane at least 90mm thick to the joist and then mount the Master Ceiling Plate to the wooden membrane as shown in Fig.12 .
3. Using the Paper template provided, mark the positions of the Eight (8) mounting holes on wooden membrane refering figure.
4. Drill Eight (8) 1/4”(6mm) pilot holes either direct into Joist or the additional wooden membrane as per the roof available.
5. Place a 10mm flat washer over each of the Eight M10 X 100mm hex head lag screws.
6. Referring Flat side of Master Plate, line up the (6) holes with the pilot holes in the mounting surface Zand insert the hex head lag screws into the holes.
7. Tighten the master Plate with a 17mm Hex Socket Spanner.
8. Position and align the ceiling Mount against the master plate and insert 6 socket head bolts M12 X 40.
9. SlightlyTighten all the bolts using Allen key 10mm.
10. Use a level to ensure the column assembly is Levelled vertically. Refer Section “Leveling the ceiling Mount system” to correct any leveling concerns.
11. After levelling the column. Tighten all 6 bolts to the full torque.
12. Completing of all the procedure from 1 to 11 above is the responsibility of the customer. Labomed representative will complete rest of the microscope Installation after this.
13. Power up the system with the cable provided. Make sure AC outlet is hospital grade & grounded properly.
14. Put the drop ceiling tile back into place.



Normal Ceiling Mount
Fig.12

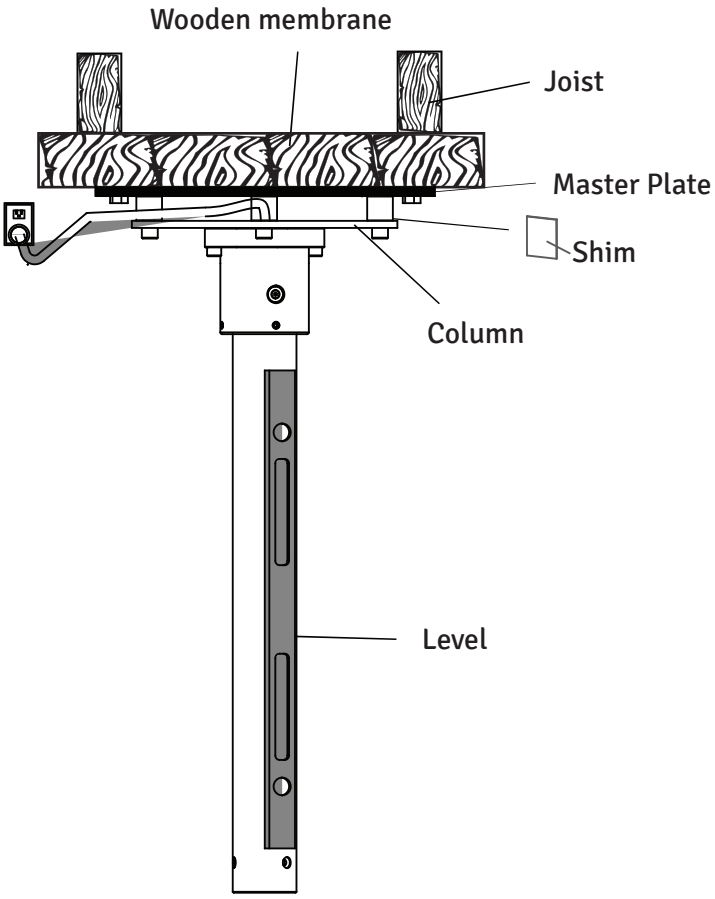
CEILING MOUNT INSTALLATION (continued)

7B. LEVELING THE CEILING MOUNT SYSTEM

It is important to ensure the column for the ceiling mount is Plumb after installation. The column must be perfectly vertical to prevent the microscope system from drifting from side to side.Use following procedure:

1. Use the 10mm Allen key to slightly loosen all of the (6)M10 bolts.
2. Place a level across the bottom of ceiling mount as shown in Figure and to check the Vertical leveling. Use Shims as required and adjust the RAWL Bolts/ Lag bolts until the column is Vertical.
3. Tighten all screws securely.

NOTICE:Shims and Shim materials are to be provided by the customer and are not furnished by Labomed. There are numerous shims and shim materials commercially available and no specific type or brand name is required.



Normal Ceiling Mount
Fig.13

CEILING MOUNT INSTALLATION (continued)

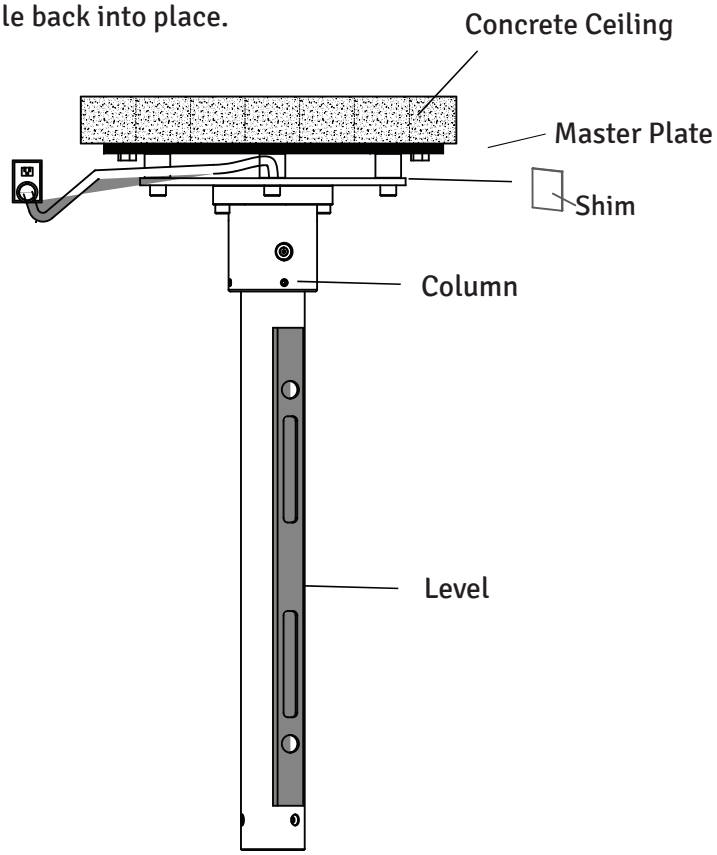
7C. INSTALLING CEILING MOUNT ON CONCRETE CEILINGS

Fixing of Master Plate:

1. Use the Paper template provided to mark the position for the anchors of Master Plate.
2. Drill the Eight (8) mounting holes 14mm diameter and 100mm deep.
3. Place a 10mm flat washer and a split washer over each of the Eight M10 X 75 hex head RAWL Plug.
4. Referring flat surface of Master Plate, align 8 holes with the pilot holes in the ceiling.
5. Insert the hex head RAWL screws into the holes and fully tighten the Master Plate with a 17mm hex socket spanner.

Installation of Ceiling Mount:

6. Position the ceiling Mount against the master plate and insert 6 socket head bolts M12 X 40 after aligning the 6 mounting holes.
7. Slightly tighten all the bolts using Allen key 10mm .
8. Use a level to ensure the column assembly is Leveled vertically. Refer Section “Leveling the ceiling Mount system” to correct any leveling concerns.
9. Fully tighten all the bolts with 10mm allen key.
10. All the procedure from Part 1 to 9 above is the responsibility of the customer to organise. Labomed representative will complete rest of the microscope Installation after this.
10. Power up the system with the cable provided. Make sure AC outlet is hospital grade & grounded properly.
11. Put the drop ceiling tile back into place.



Normal Ceiling Mount
Fig.14

CEILING MOUNT INSTALLATION (continued)

7d Constructional requirements for the ceiling mount installation on concrete ceiling

1. The ceiling mount must be installed as recommended in this manual.

2. The construction specialist responsible must confirm in writing that the applicable regional and local codes & regulations have been complyed and the points listed below are taken care. The customer must keep this confirmation with his records. A copy of this docu-ment must be provided to labomed representative dealer.

3. The roof on which ceiling mount is to be mounted must have the following load capacity:
Perpendicular force: minimum 1500 Nm
Torque: Perpendicular to the Ceiling 1500 Nm minimum.
Parallel to the Ceiling 1200 Nm minimum.
Also take into account any additional loads acting on the Ceiling and any other loads anchored in the Ceiling.

4. The Master Plate should be installed at the time of Construction.

5. Minimum edge distance required on all sides is 16".

6. The ceiling plate must be aligned in a parallel position (max. deviation ±1°).

NOTE:
If an existing ceiling mount is ever exchanged, never re-use the old anchors. New anchor holes must be drilled. When Calculating the effective strength of the new anchors, make sure to take into account the weakening effect of the old holes in the ceiling.

On the basis of the above aspects, the person responsible for the building must decide on and take responsibil-ity for the most suitable method of anchoring.

CEILING MOUNT INSTALLATION (continued)

7e Control and Power Supply of the ceiling mount system

Note:
The maximum weight of the surgical microscope including accessories must not exceed 55kg and The respective weight of all LABOMED accessory equipment is specified in the price list.

The weight of the mount including the surgical microscope is as follow:

Ceiling mount kit: Approx.....35 kg.

Surgical microscope: Approx....20kg.

Total: Approx.....55 kg.

Power line: 3 /1.5mm2
Fusing: 4.0Amp
Power consumption: max. 200W

Note:
A socket with properly installed protective earth connection must be provided at the installation site on Ceiling flange. The terminals for power connection are allocated on Ceiling Mount .

Potential equalization: Take the necessary actions in the building to include the instrument in the protective measure of “potential equalization.”

Note:
The series 6137200 suspension systems including the components mentioned here comply safety requirement with CE and IEC 60601-1-3rd.

Such activities as the installation of the flange and the installation of conduits and electrical lines are the customer’s responsibilities.

List of contents: Ceiling Kit

1. Raval Plugs- 6pcs
2. Washers- 6pcs
3. Ceiling Mount
4. Ceiling Mount cover
5. Column

8. WALL MOUNT ASSEMBLY(DIMENSIONS)

HORIZONTAL WALL MOUNT WITH STANDARD SUSPENSION ARM

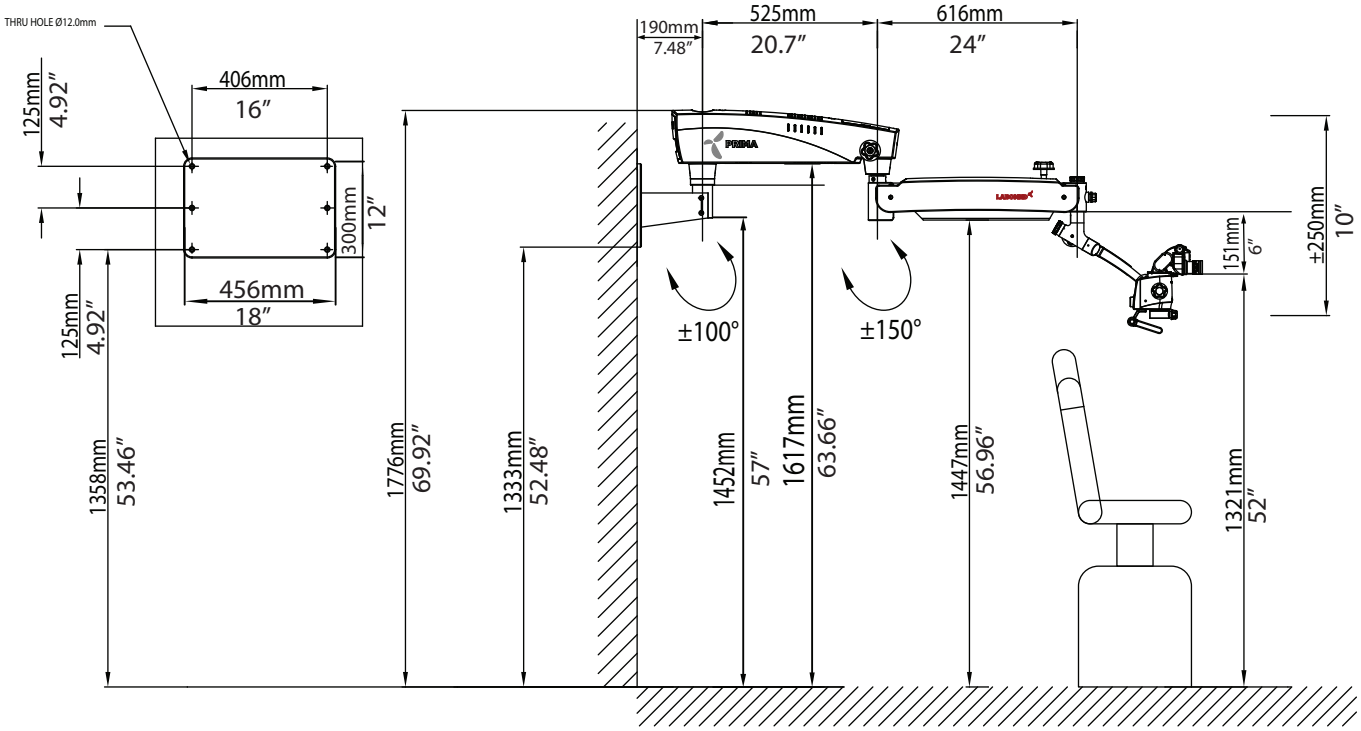


Fig .15

WALL MOUNT ASSEMBLY (Continued)

VERTICAL WALL MOUNT WITH STANDARD SUSPENSION ARM

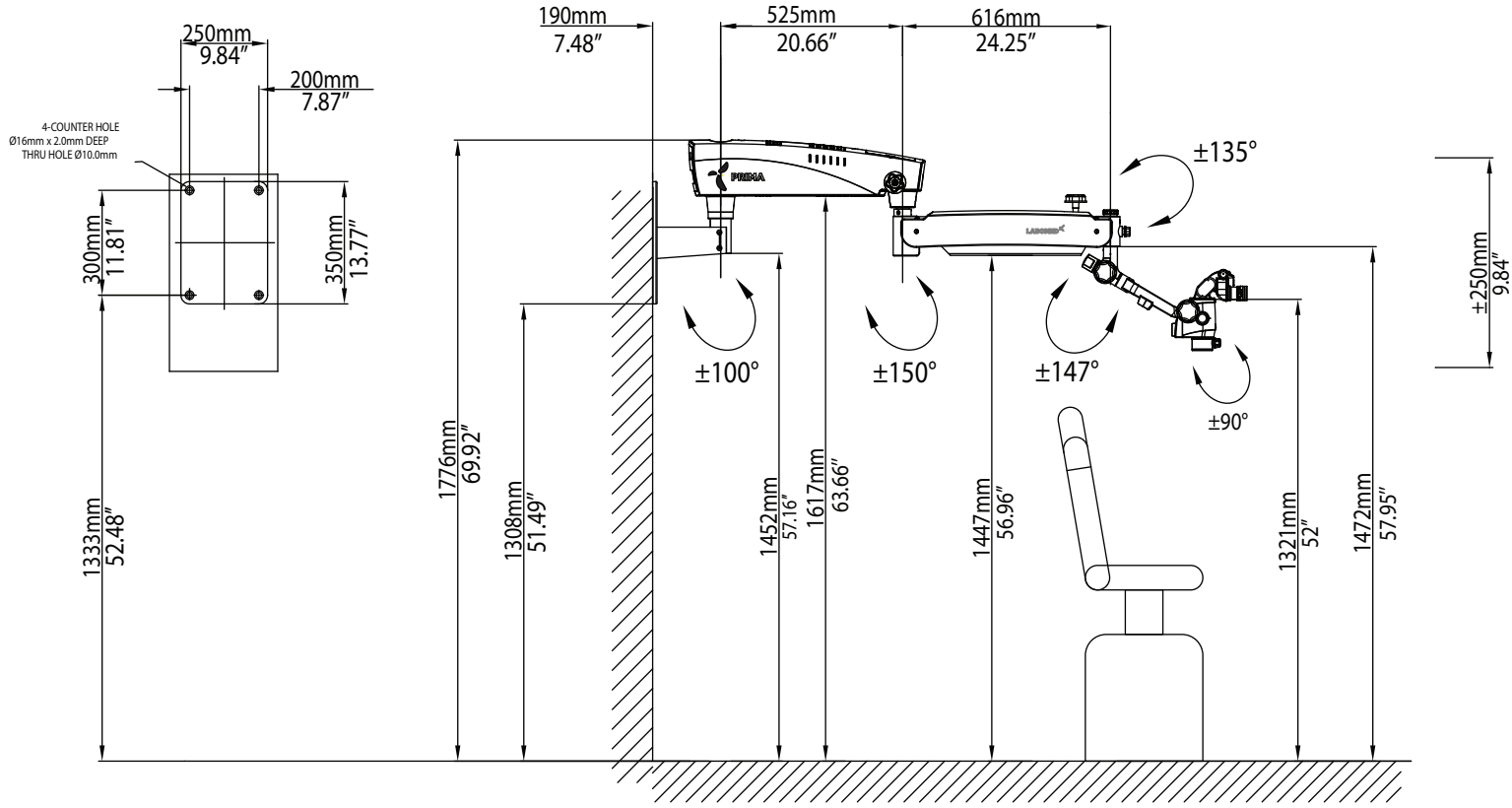


Fig. 15A

WALL MOUNT ASSEMBLY (continued)

LONG WALL BRACKET VERTICAL WITH STANDARD SUSPENSION ARM

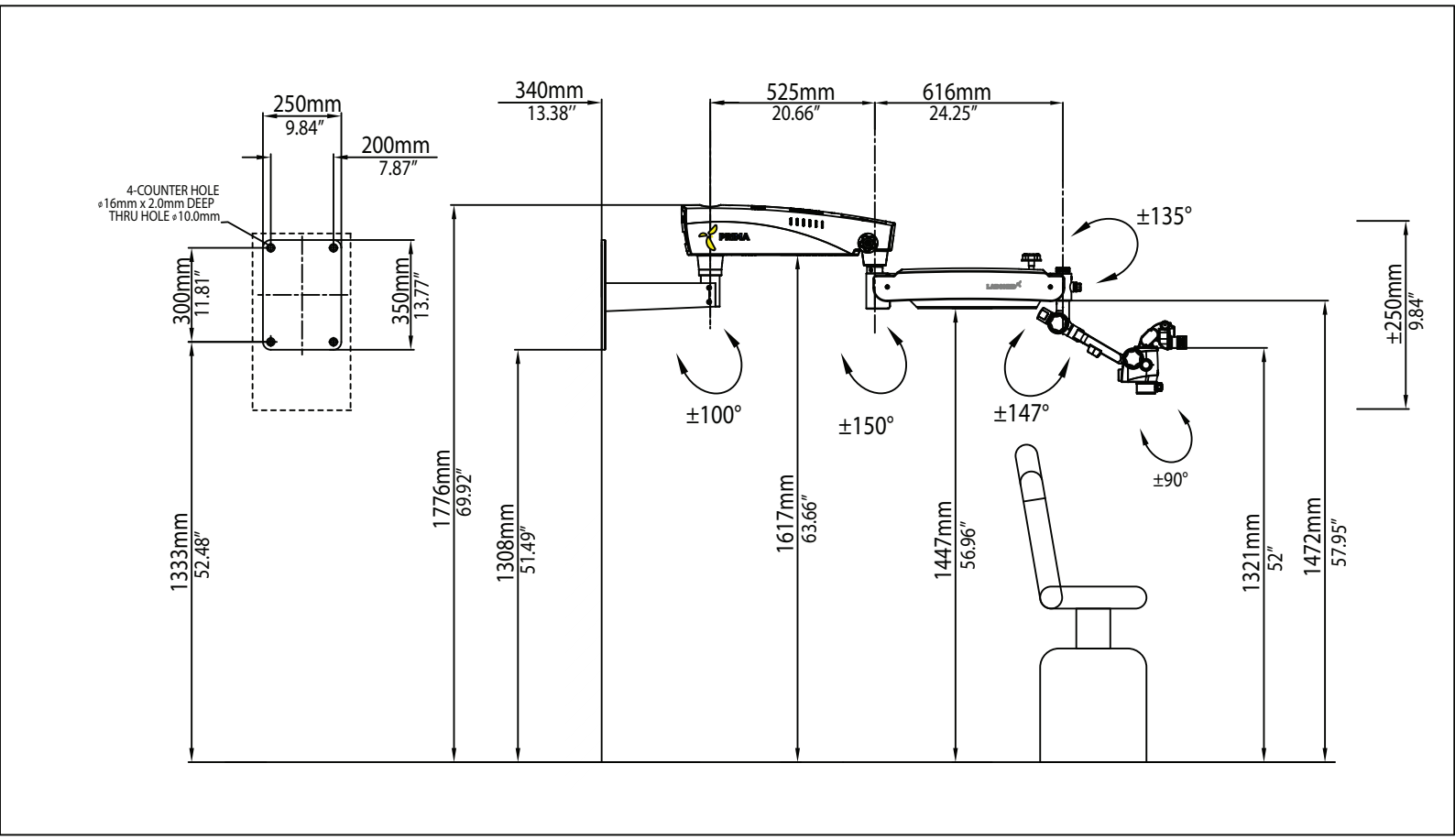


Fig. 16

WALL MOUNT ASSEMBLY(continued)

HORIZONTAL WALL MOUNT WITH LONG SUSPENSION ARM

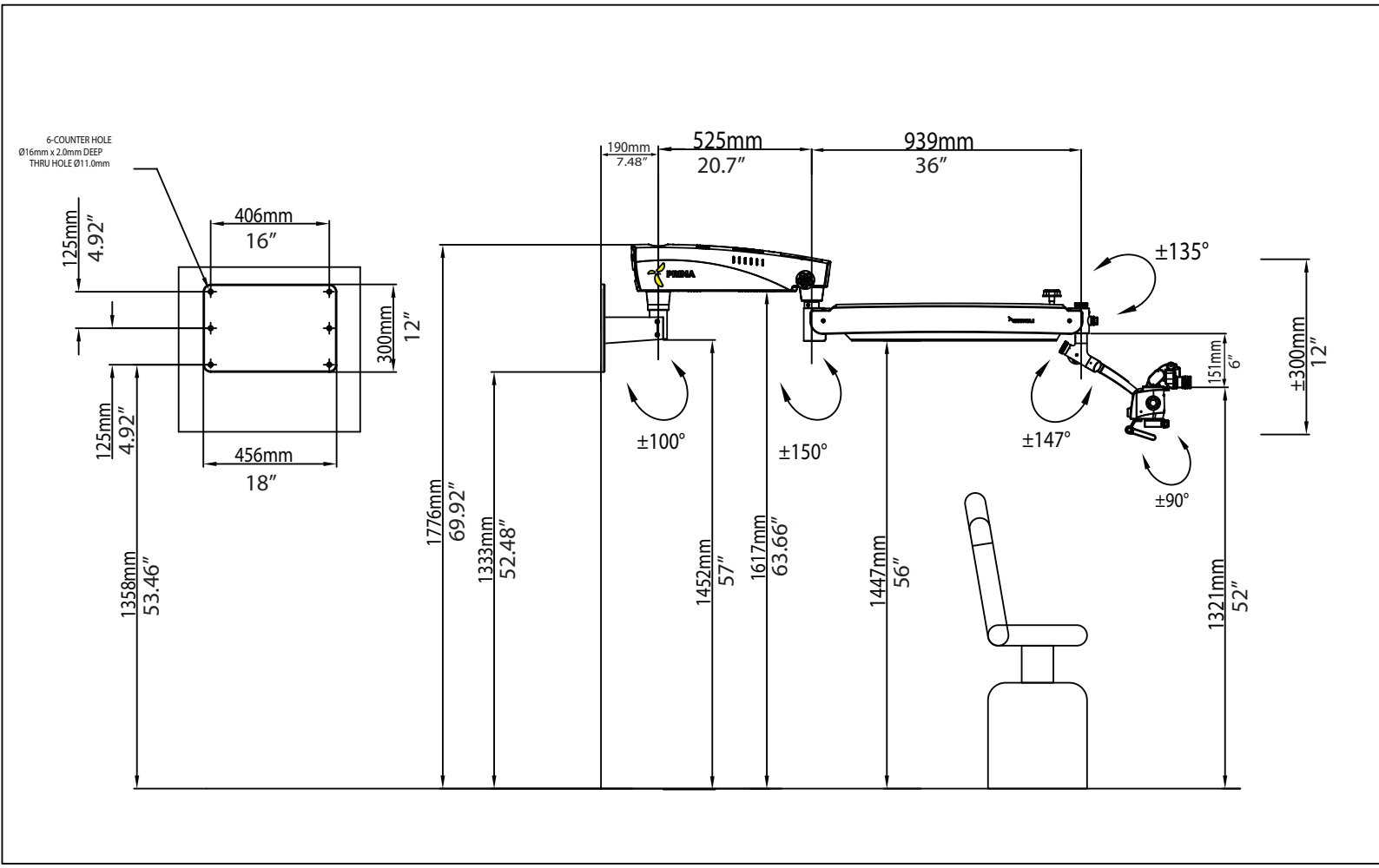


Fig. 17

WALL MOUNT ASSEMBLY (continued)

VERTICAL WALL MOUNT WITH LONG SUSPENSION ARM

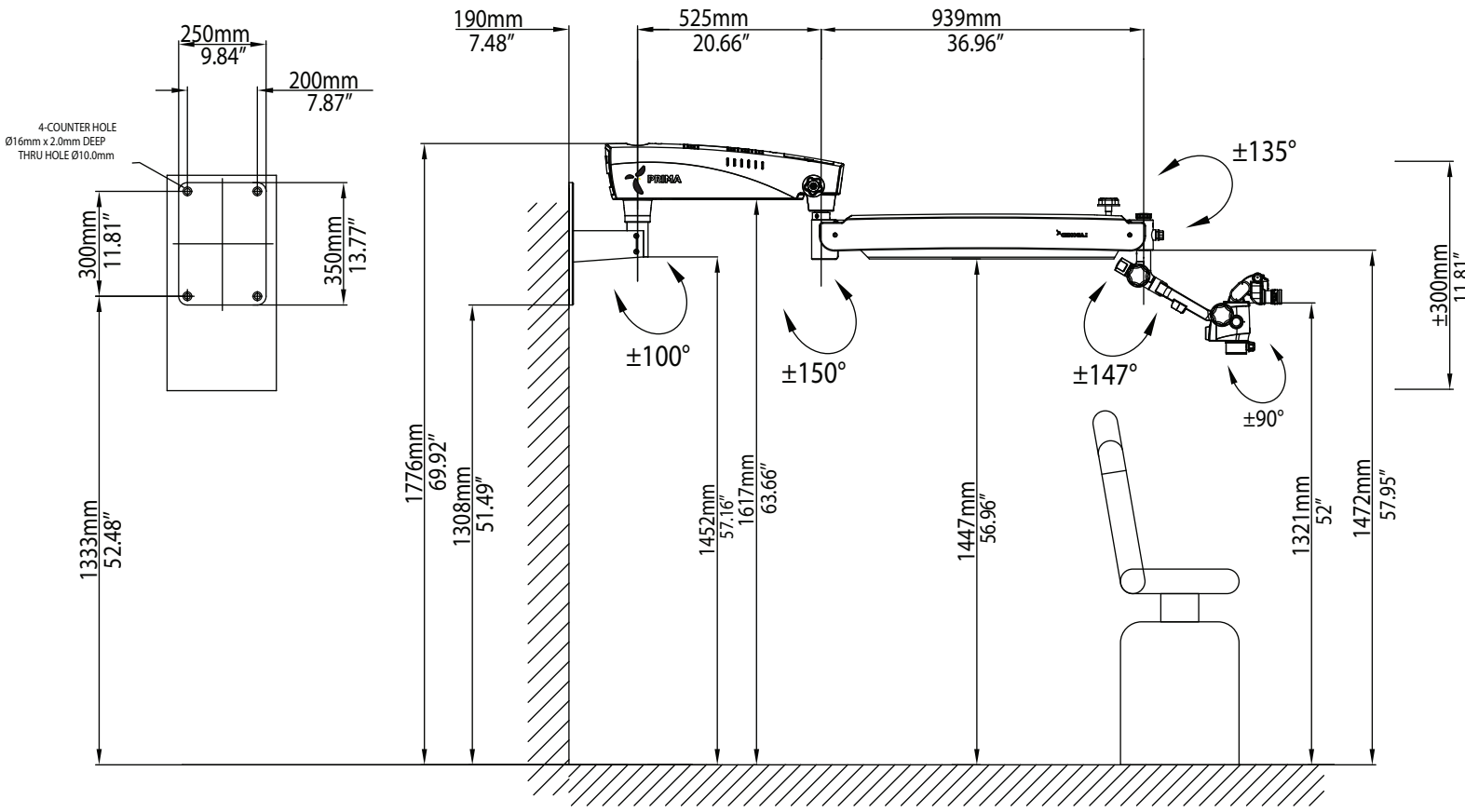


Fig.17A

WALL MOUNT ASSEMBLY (continued)

LONG SUSPENSION ARM WITH LONG WALL BRACKET VERTICAL

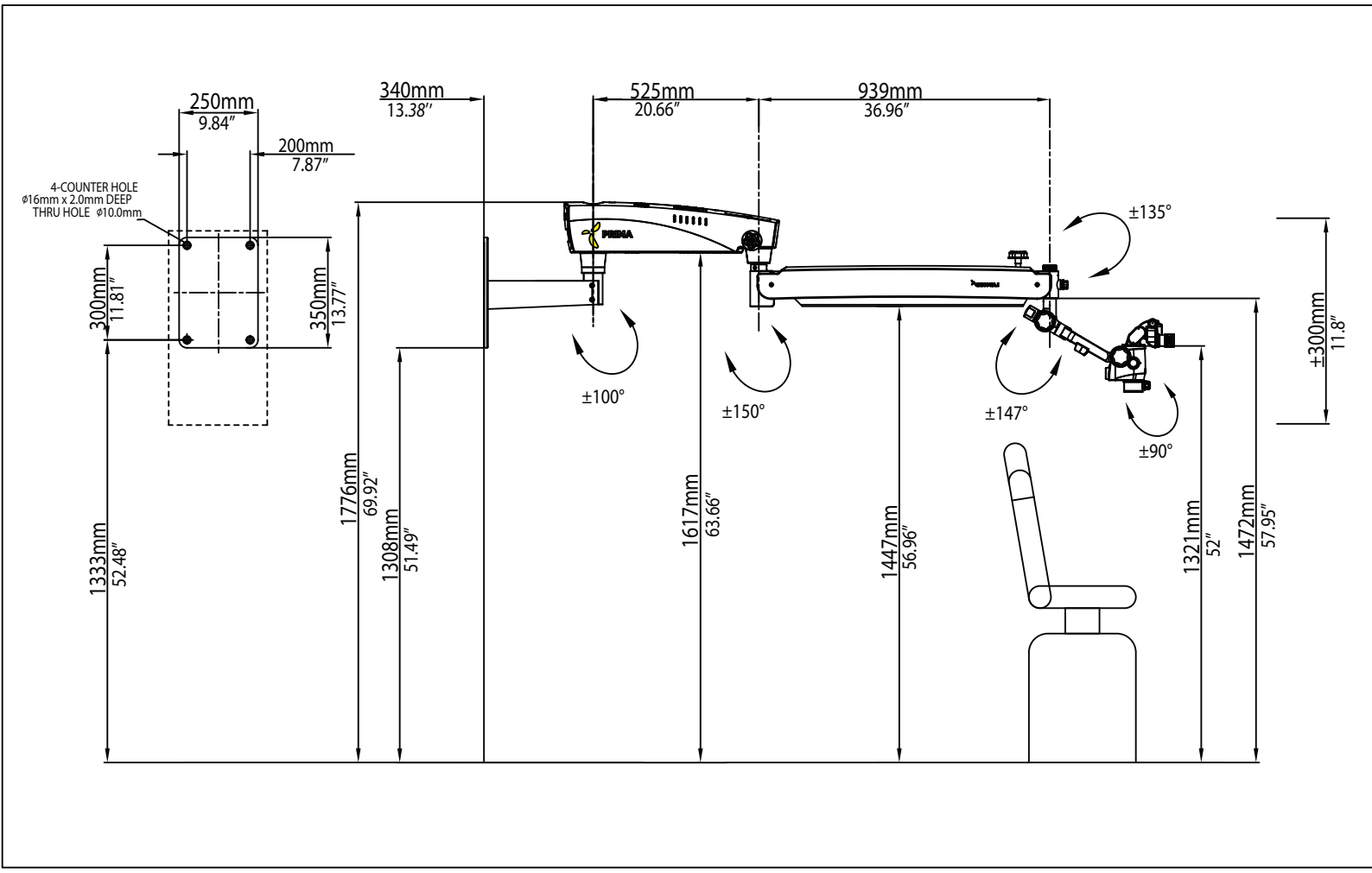


Fig. 17B

WALL MOUNT ASSEMBLY(continued)

HORIZONTAL WALL MOUNT WITH STANDARD SUSPENSION ARM AND EXTENSIONS

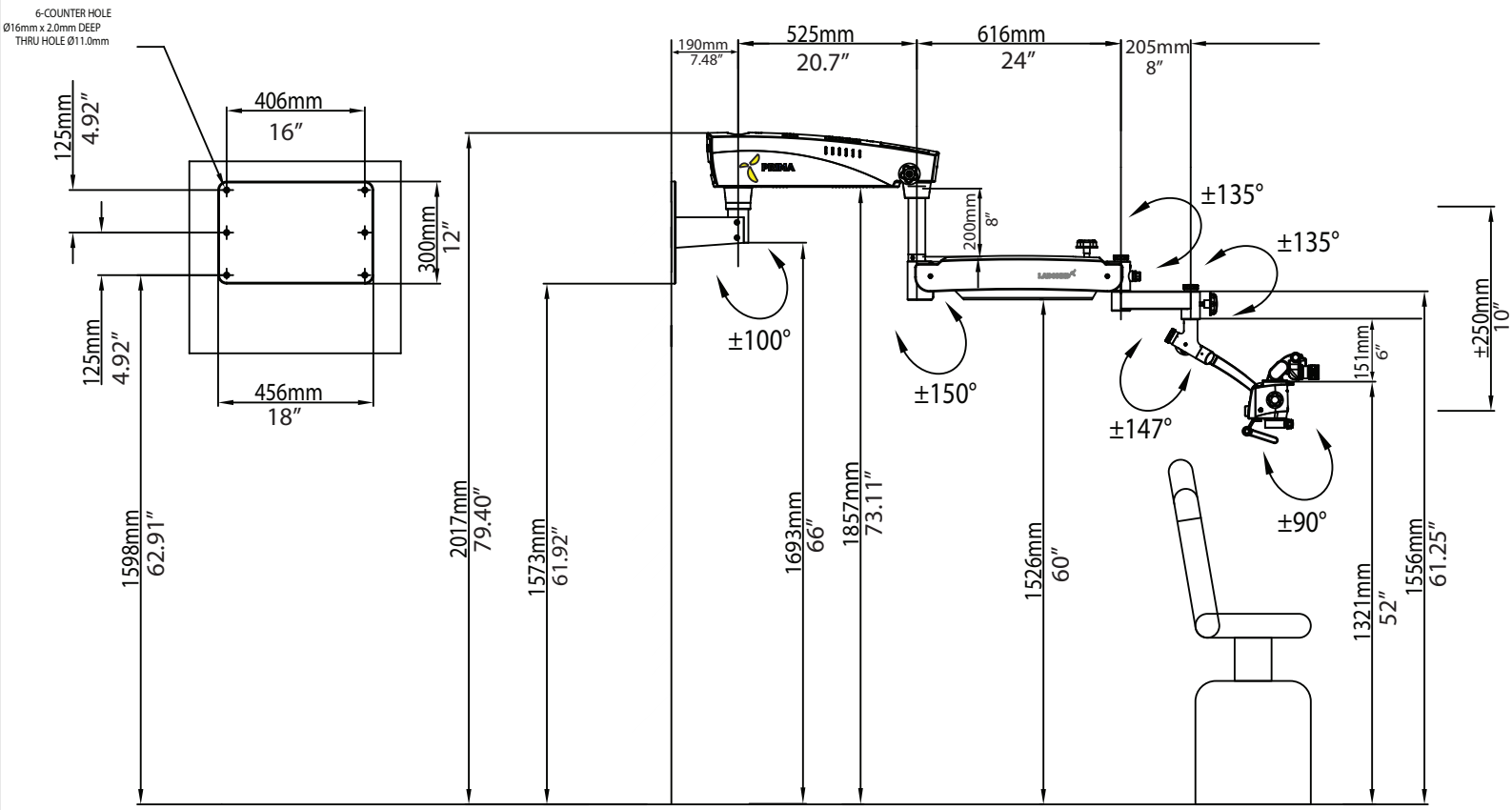


Fig.18

WALL MOUNT ASSEMBLY (continued)

VERTICAL WALL MOUNT WITH STANDARD SUSPENSION ARM AND EXTENSIONS

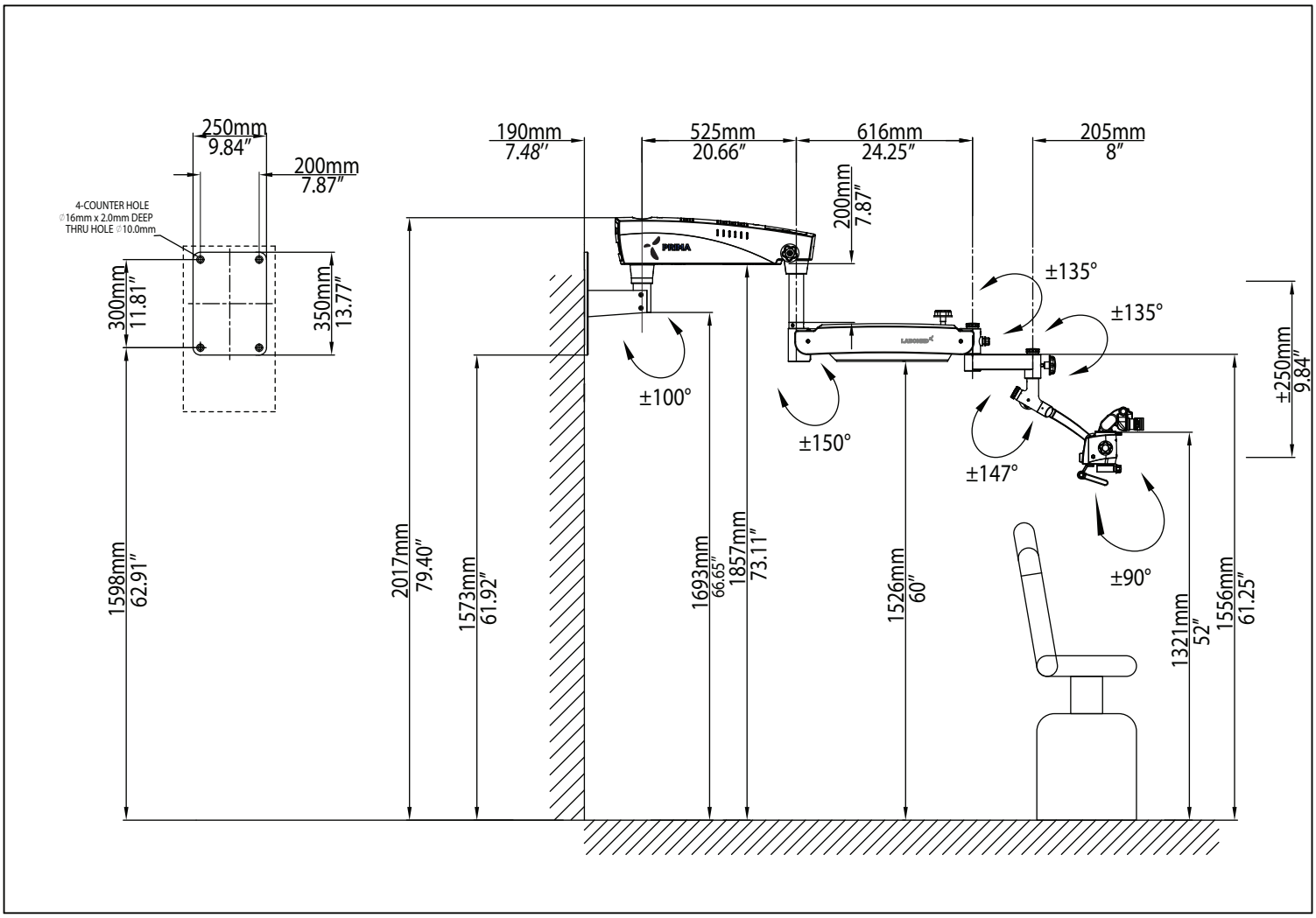


Fig.18A

WALL MOUNT ASSEMBLY (continued)

STANDARD SUSPENSION ARM WITH EXTENSIONS AND LONG WALL BRACKET VERTICAL

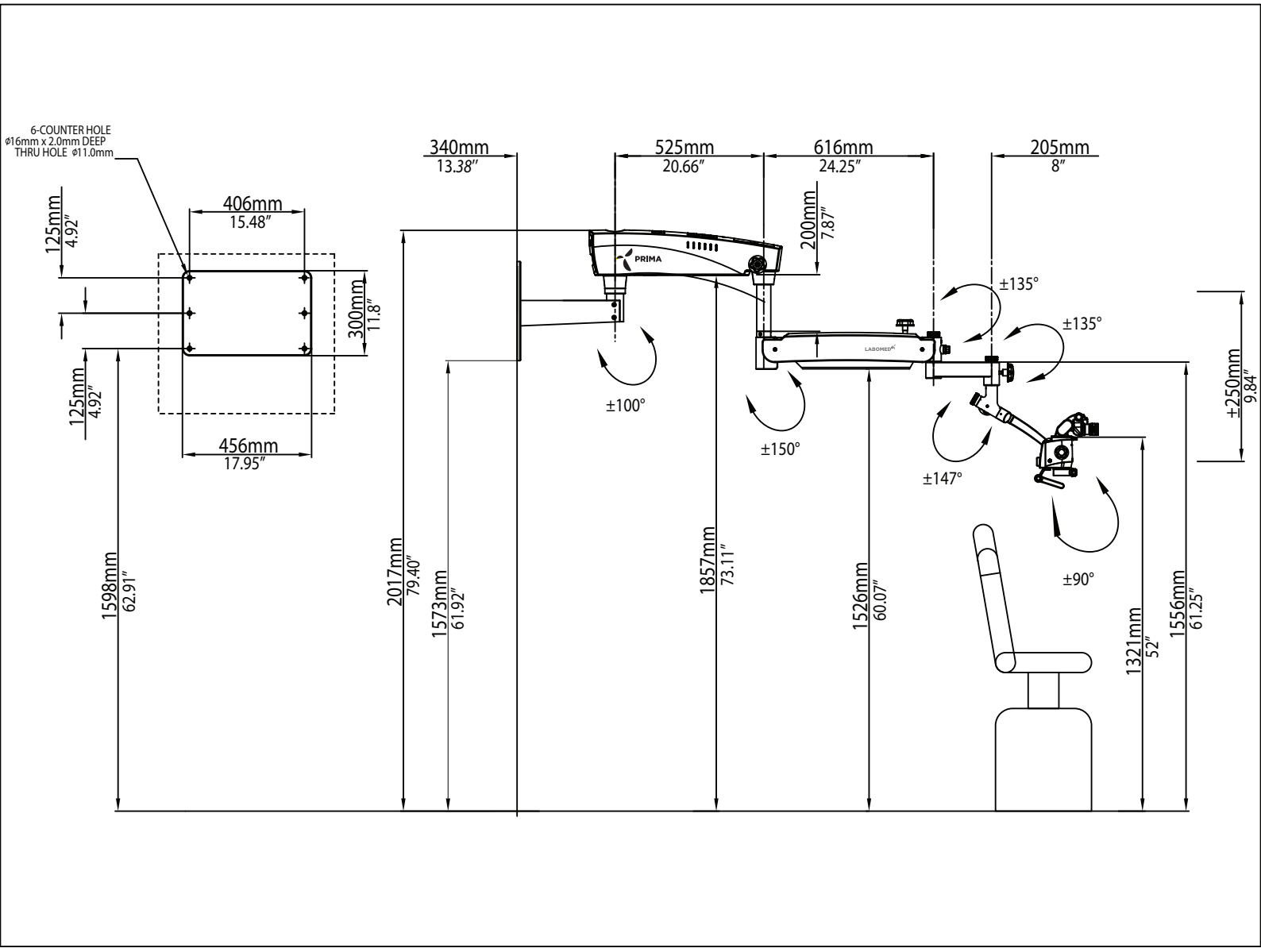


Fig. 18B

9. INSTALLATION REFERENCES (WALL MOUNT HORIZONTAL)

9a. Horizontal Wall mount: MARKING REFERENCE

Anchoring the Wall mount

Reference

A paper Template for marking

B Wall Mount Assembly

C Distance from floor - Refer suitable height as per ordered configuration from Figure. 15, 16, 17 and 18.

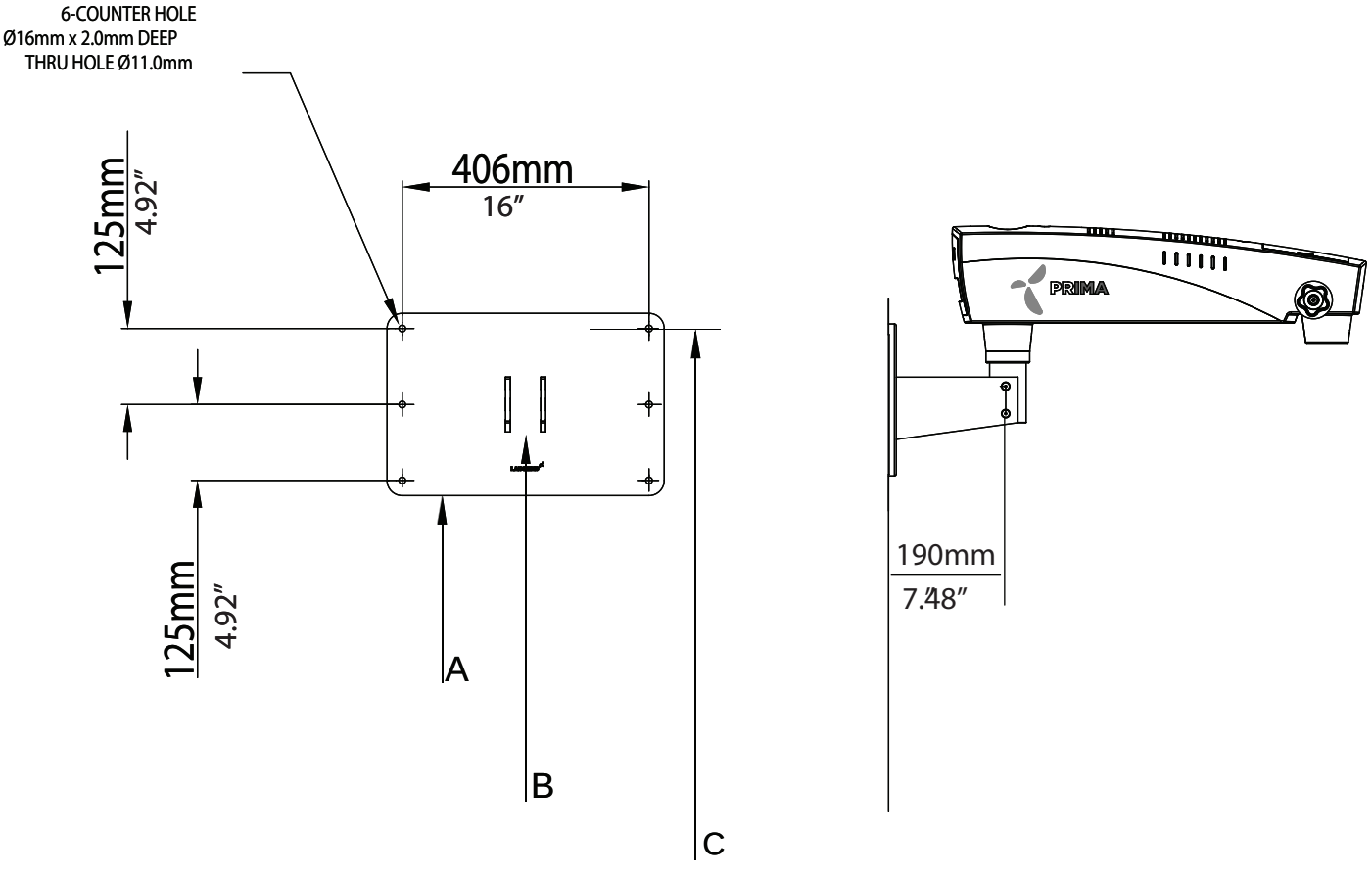


Fig .19

INSTALLATION REFERENCES (WALL MOUNT VERTICAL)

9b. Vertical Wall Mount: MARKING REFERENCE

According to the wall mount

Reference
A paper Template for marking
B Wall Mount Assembly
C Distance from floor - Refer suitable height as per ordered configuration from Figure. 15, 16, 17 and 18.

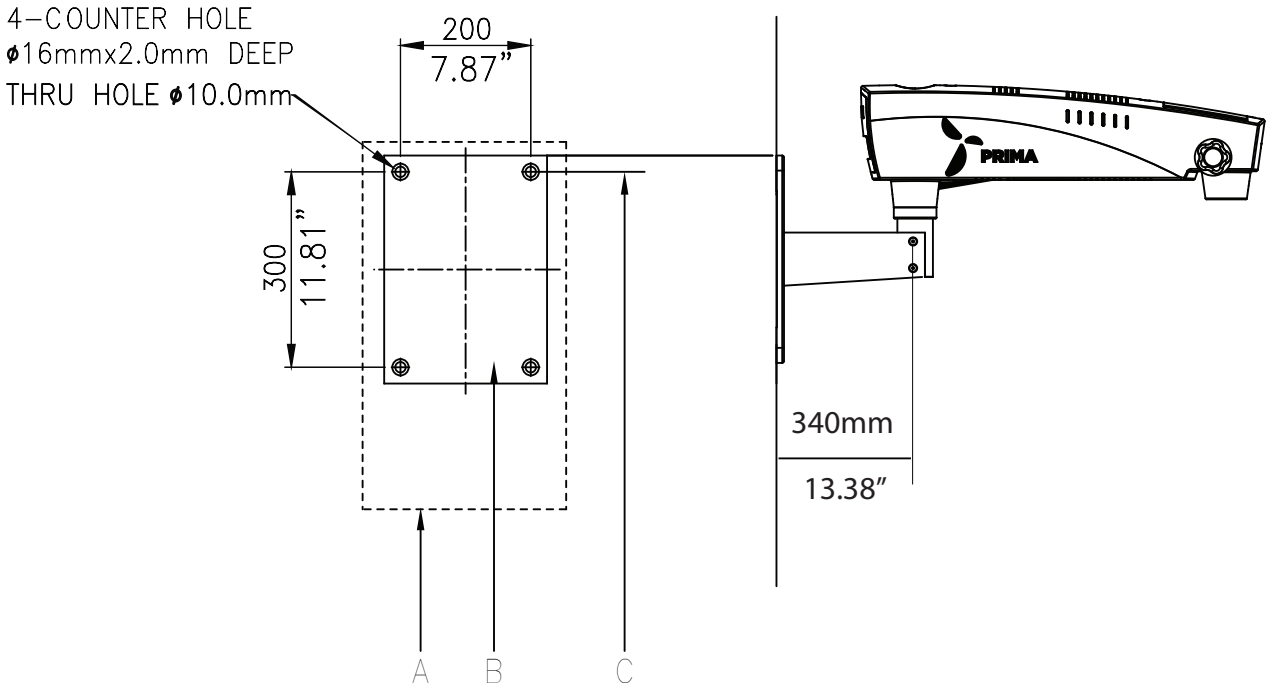


Fig .19A

INSTALLATION REFERENCES (WALL MOUNT)

Wall mount: Alternative installation to the patient's side
(With standard suspension arm)

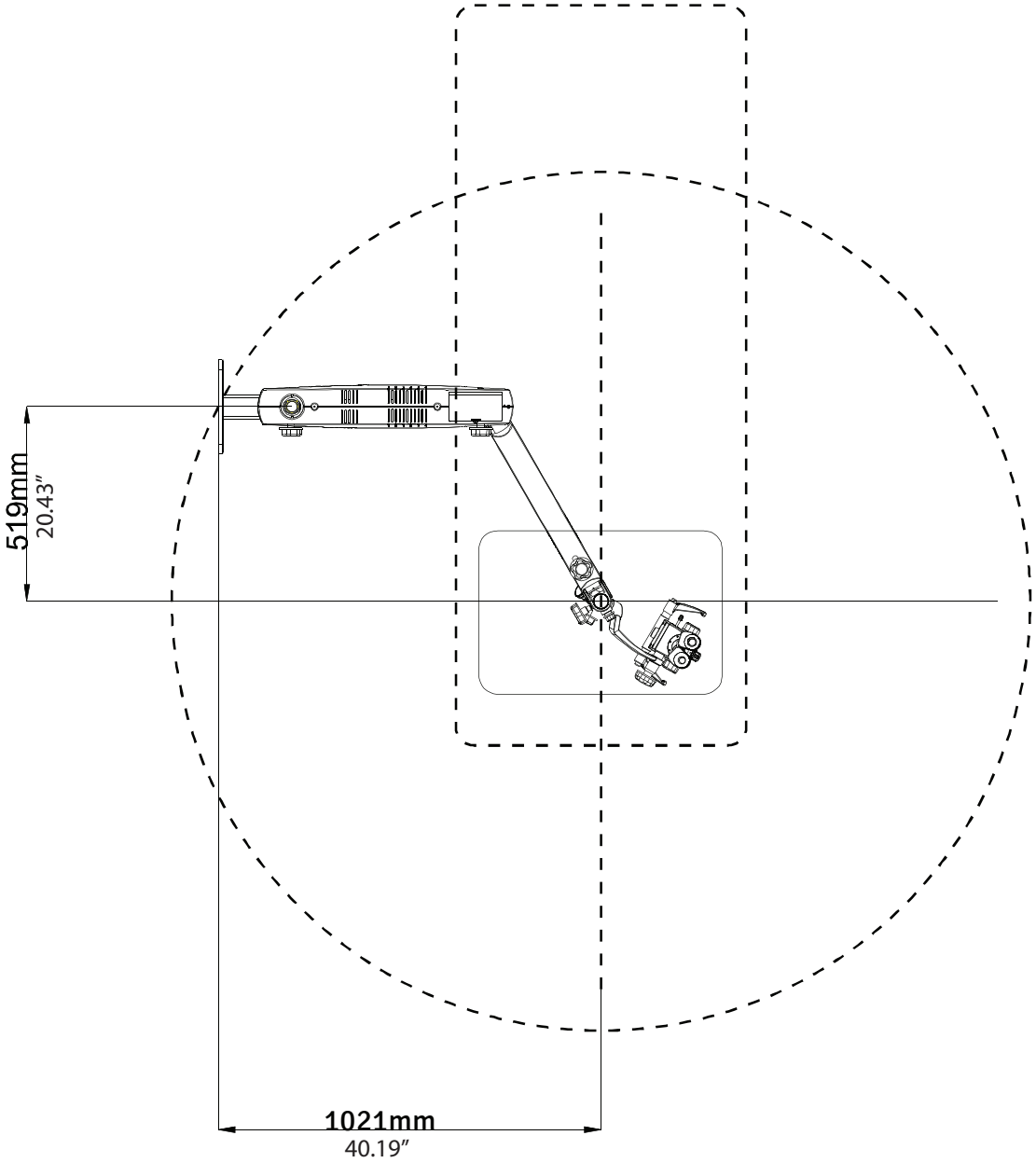


Fig. 20

INSTALLATION REFERENCES (WALL MOUNT CONTINUED)

Wall mount: Alternative installation to the patient's side (with long suspension arm)

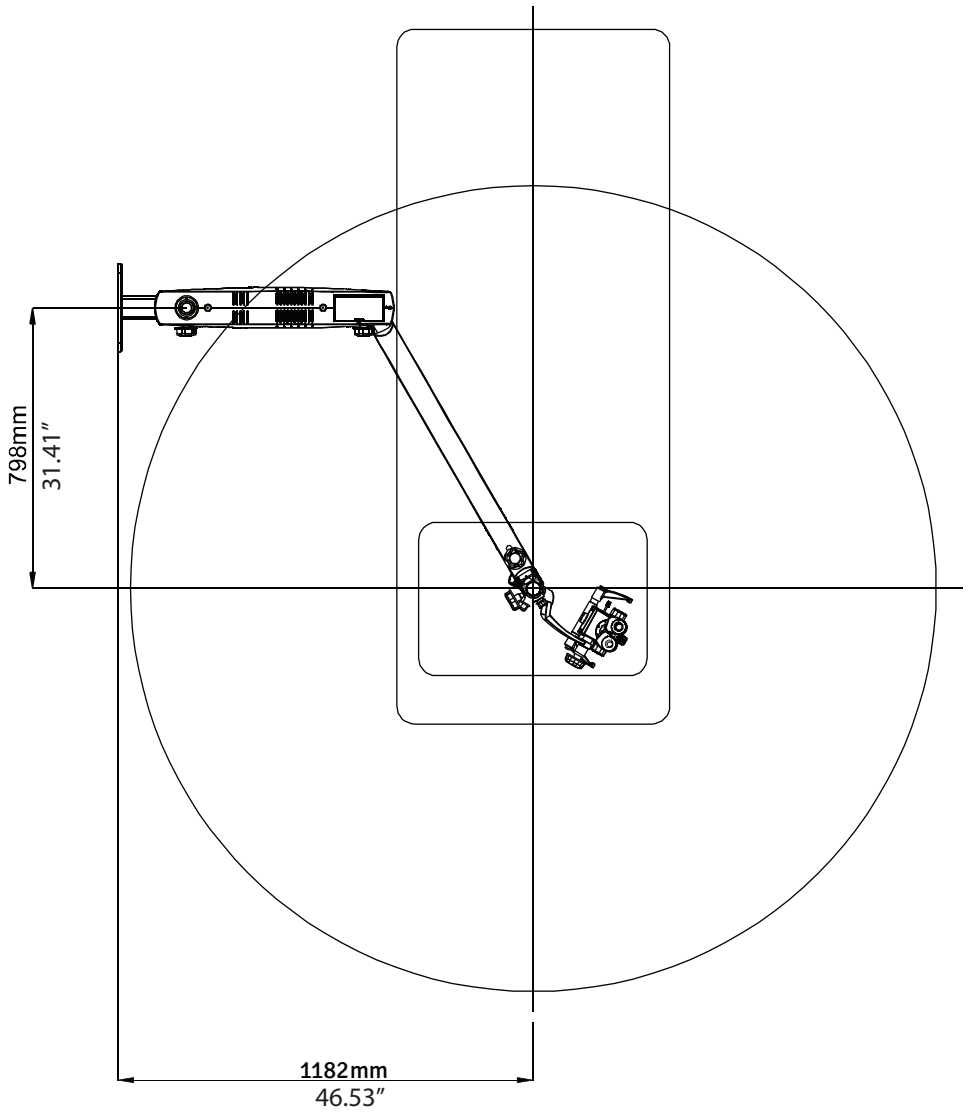


Fig .21

HORIZONTAL WALL MOUNT INSTALLATION

9c. Wooden Wall

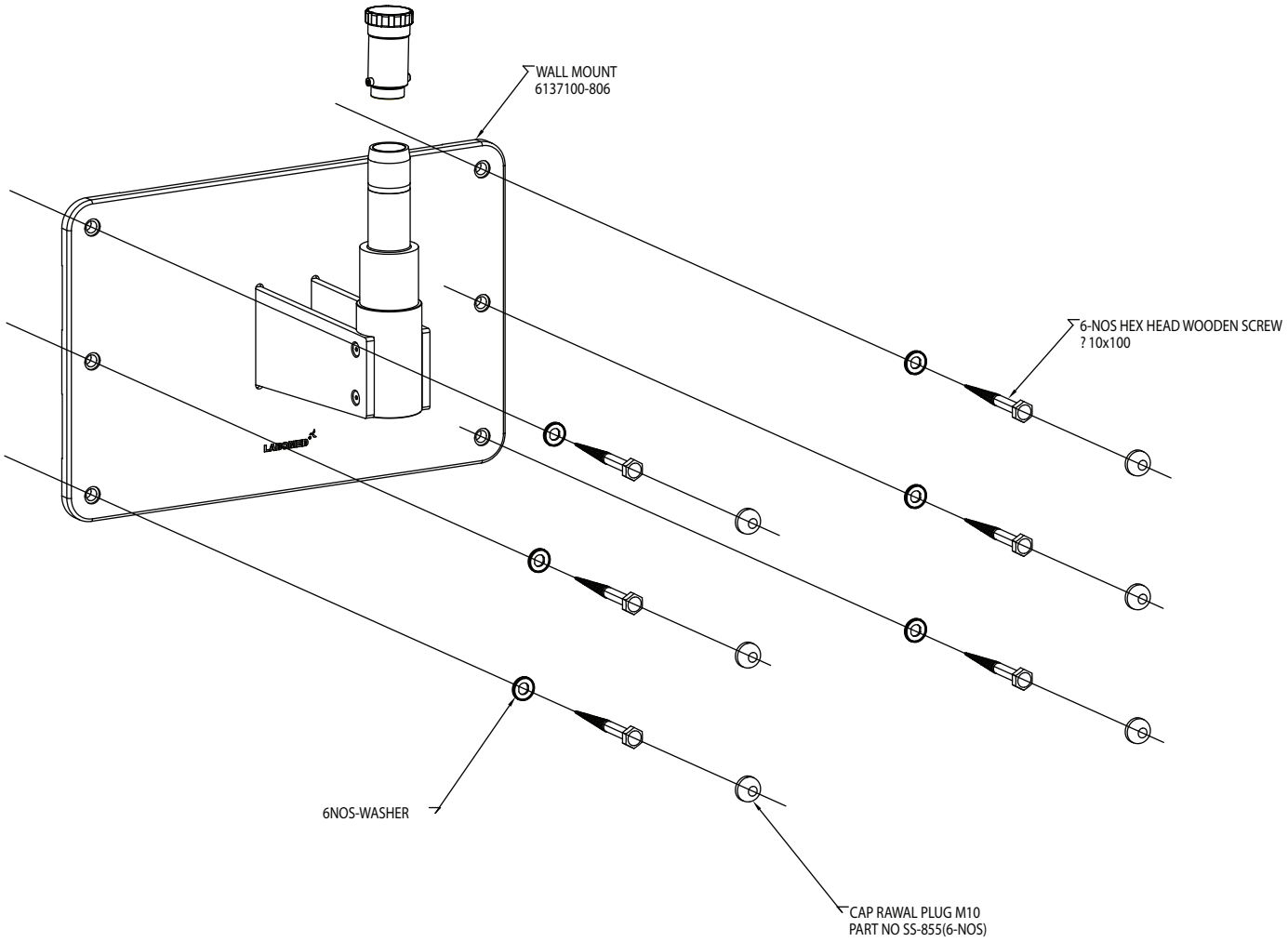
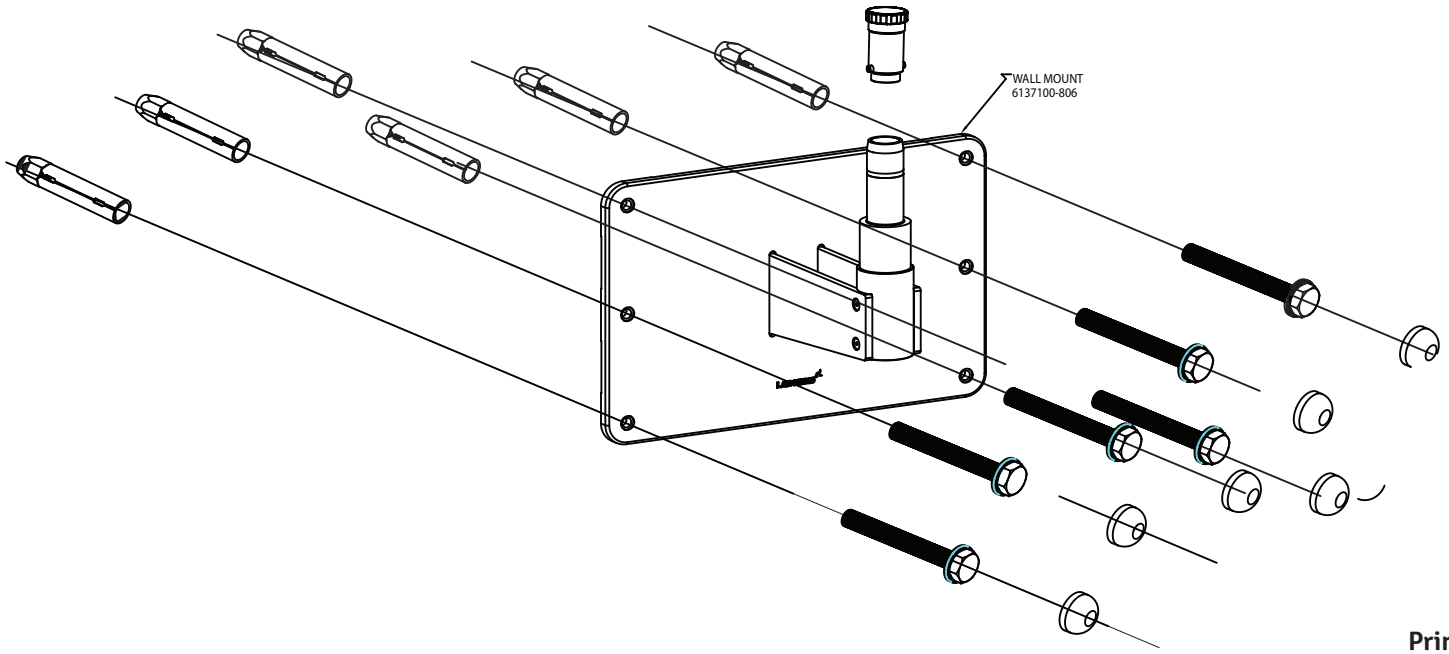


Fig .22

9d HORIZONTAL WALL MOUNT INSTALLATION (SOLID BRICK WALL)



Prima

9e VERTICAL WALL MOUNT INSTALLATION (SOLID BRICK WALL)

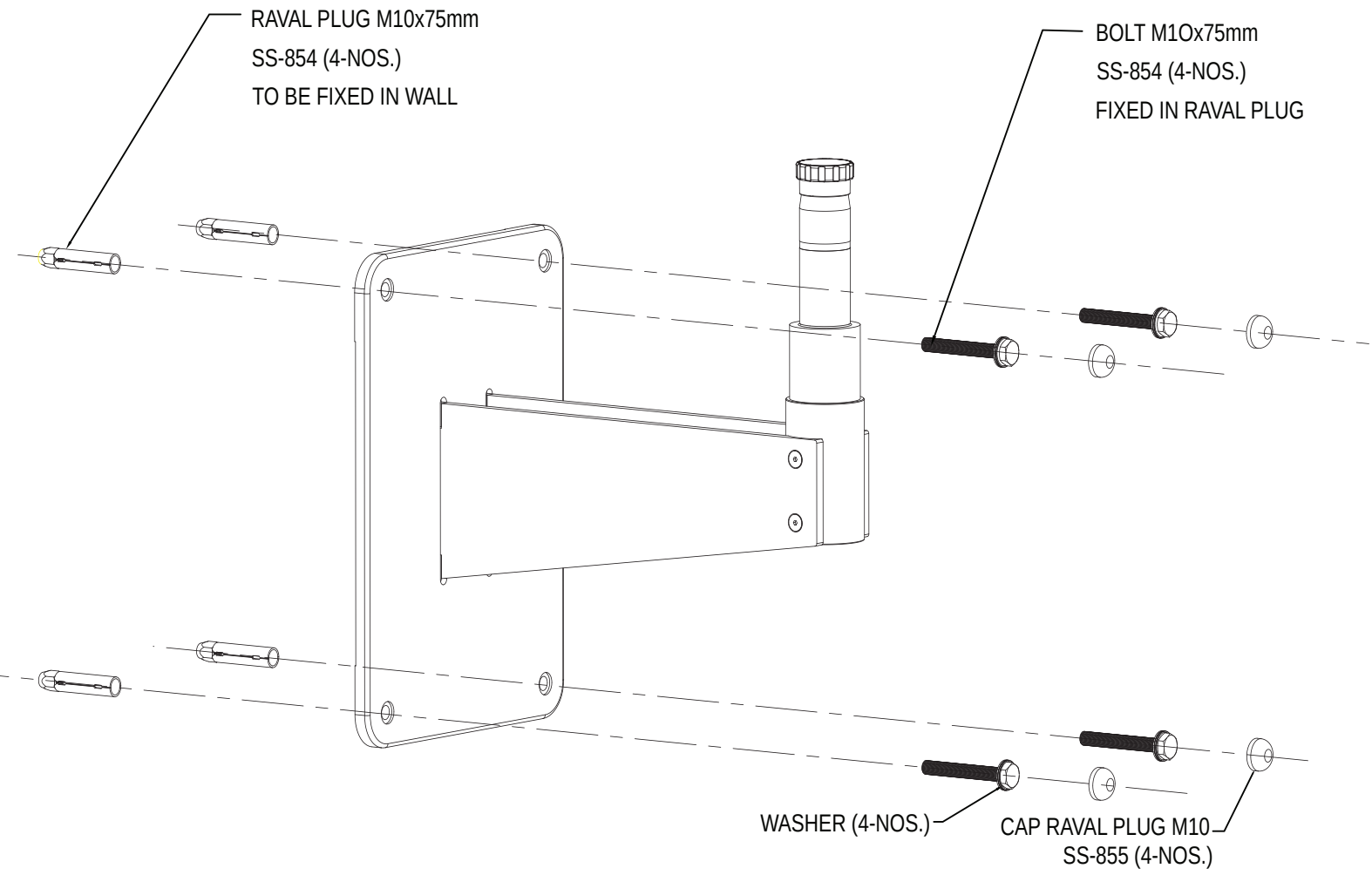


Fig.23

10. INSTALLATION PREPARATION (WALL MOUNT)

WALL MOUNT INSTALLATION

Before Initiating the installation of Labomed Wall Mount Microscopes, You must ensure that there is proper space available as per the configuration selected. Refer to Figure 20 and 21.

Measure the distance between the centers of the studs. The Labomed Wall Mount Model is designed to mount directly on a wall with wood studs spaced 406mm (16”) centers or on solid brick/concrete wall minimum 229mm (9”) thick wall.

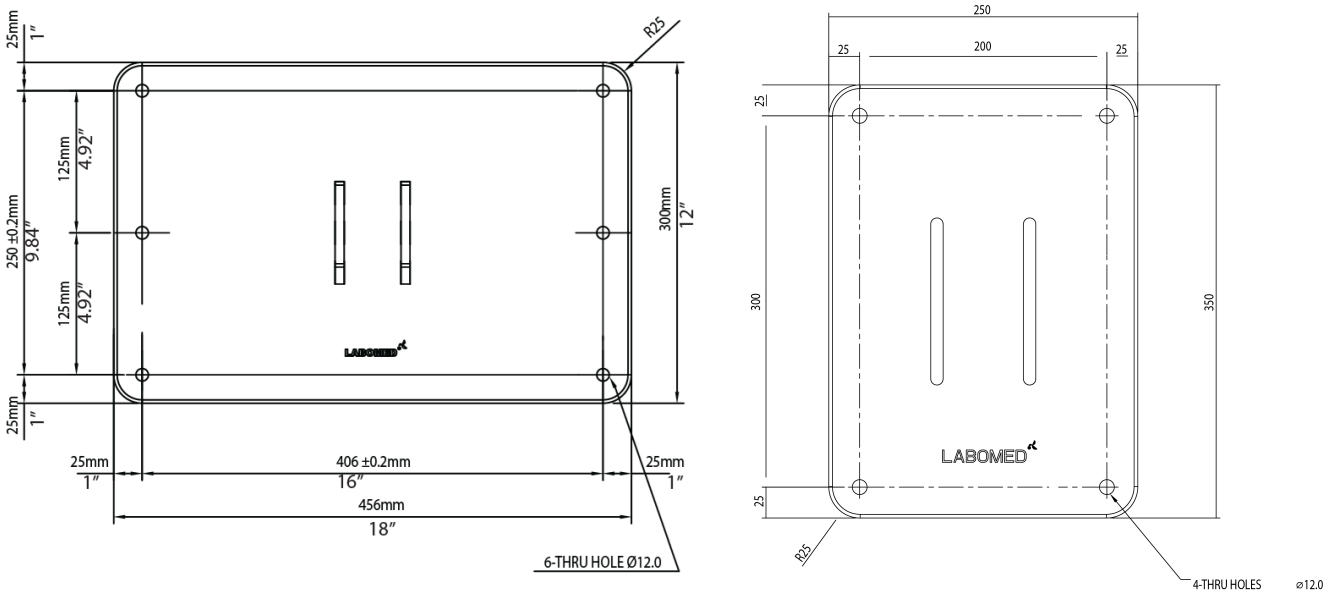


Fig .24

LIST OF CONTENTS

1. Paper template for marking - 1
2. Wall Mount Assembly -1
3. Hexagonal Lag bolts (for wooden walls) -6
4. Plain Washer -6
5. RAWL Anchor Bolts (for Masonry walls) -6
6. Cap set bolt -6

11. WALL MOUNT INSTALLATION PROCEDURE

WALL MOUNT INSTALLATION ON STANDARD SIXTEEN INCH(16"406 MM) WOODEN WALL STUD SPACING

For securing the Wall Mount System to construction using wooden wall studs spaced on 16 (406 mm) Inch centers, it is recommended that 3/8" x 4" hex head lag screws are used.

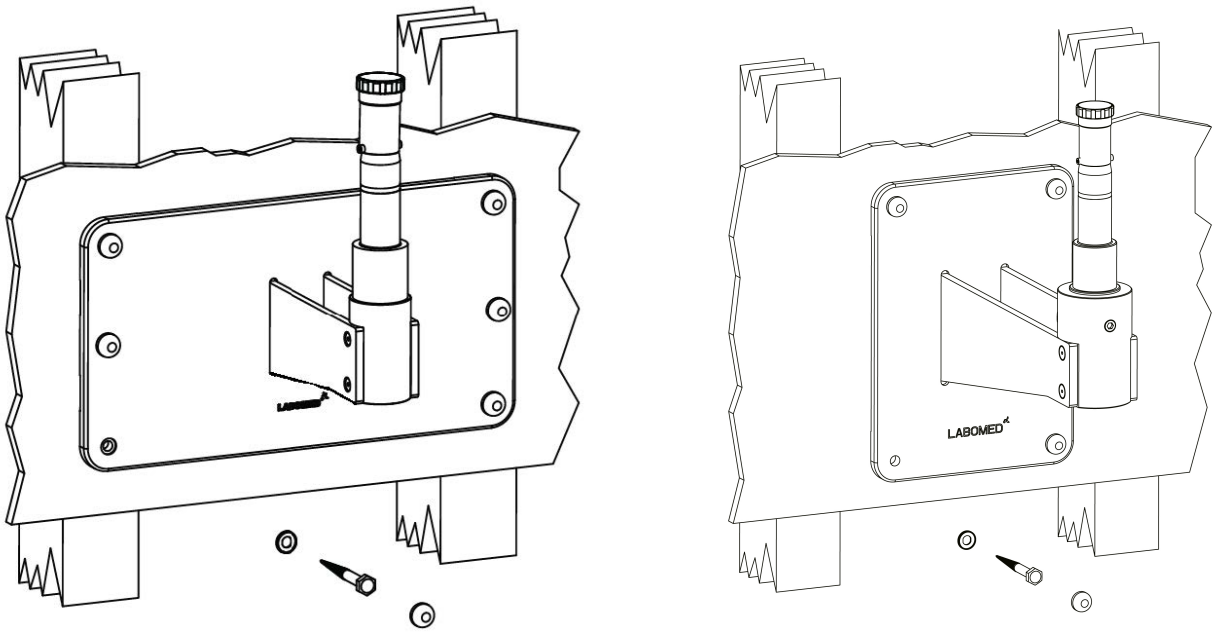


Fig.25

WARNING: THE MOUNTING HARDWARE SUPPLIED FOR WOODEN WALL IS NOT DESIGNED FOR INSTALLATION TO WALL WITH STEEL STUDS OR TO CINDER BLOCK/MASONRY WALLS.

WALL MOUNT INSTALLATION PROCEDURE(continued)

LEVELING THE WALL MOUNT PLATE ASSEMBLY

It is important to ensure that wall mount (6137100-806) is level both horizontally and vertically, after installation. Leveling of the wall mount assembly is necessary to prevent the microscope system from drifting from side to side when it is being used at full extension.

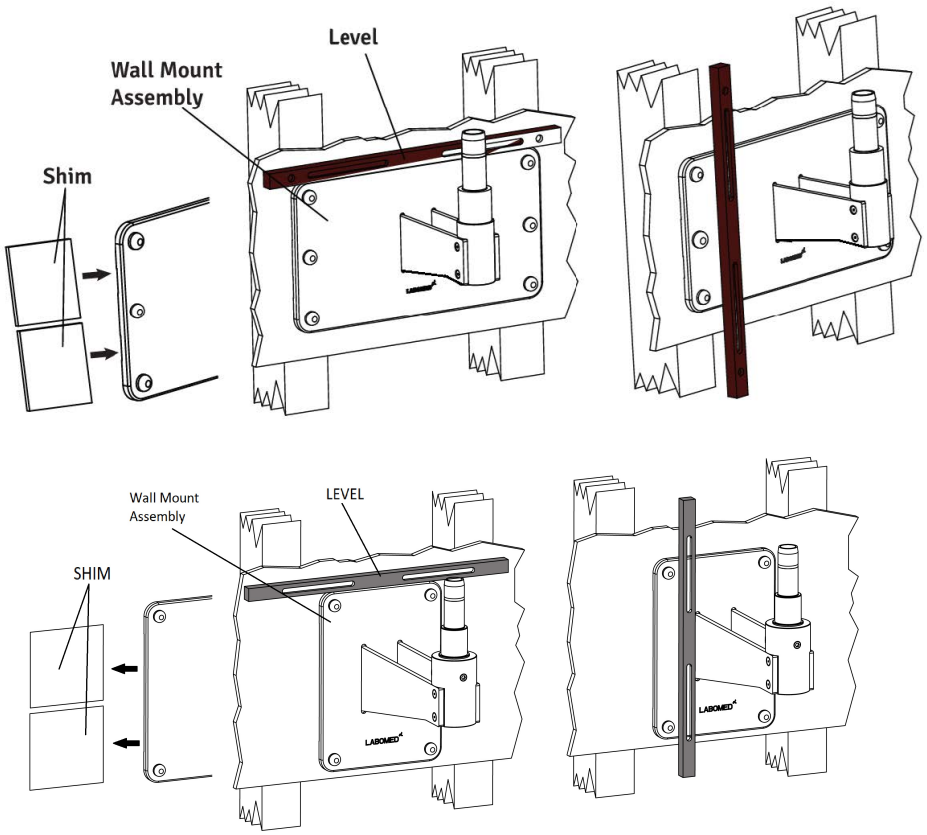


Fig .26

1. Slightly tighten the bolts on the top side- leaving the bottom bolts slightly loosened.
2. Place a level across the top of the back plate to check the horizontal leveling. See Figure 26 .
3. Use the 17mm socket and ratchet to slightly loosen the 3/8” x 4" hex head lag screws in the corners of the back plate.
4. Adjust the back plate until it is level and tighten the three lag screws on the bottom leaving the top lag screws loosened slightly.
5. Place a level vertically along the face of the wall Mount, on both sides, to ensure it is perpendicular to the floor. See Figure 26 .
6. If the wall mount is not perpendicular, insert shim material between the wall mount and the wall next to the lag screws Refer figure-26.
Check with the level and tighten the lag screws once the mount is level.
7. Check the other side and insert shims as needed and then tighten the lag screws.
8. When the Wall Mount is level, both horizontally and vertically, securely tighten all Six lag screws.

WALL MOUNT INSTALLATION PROCEDURE(continued)

WALL MOUNT INSTALLATION ON SOLID BRICK MASONRY WALL MINIMUM 9" THICK

For securing this Wall Mount Model to a Solid Brick wall, Use the Six(6) M10 X 75mm RAWL Anchor bolts provided. See Figure below.

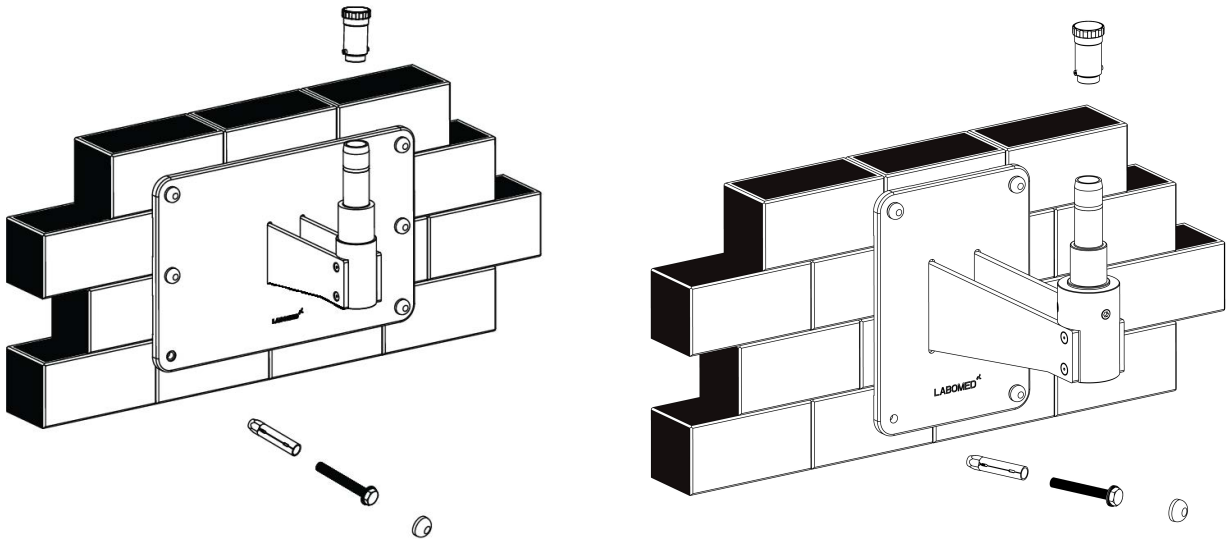


Fig .27

1. Determine the desired location on the wall where the microscope is to be mounted.
2. Place the Paper template against the wall and fix with tape. Mark Six (6) holes ensuring template is straight.
3. Using a 16mm" masonry drill bit, drill Six (6) 16mm holes min 65mm deep in the wall spaced as Outlined above.
4. Use 10mm X 75mm long RAWL Anchor bolts.
5. Place the RAWL bolts through the holes and carefully insert the bolts into the wall.
6. Take out the threaded bolt.
7. Position the wall mount against the wall .Place flat washer under head of coach bolt and thread in the Six (6) RAWL bolts in the wall.
8. Using a 17mm socket and ratchet arrangement, tighten the Six (6) RAWL bolts securing the wall mount into position. Ensuring the wall mount (top edge and front face) is level.

NOTICE: Shims and shim materials are to be provided by the customer and are not furnished by Labomed. There are numerous shims materials commercially available and no specific type or brand name is implied.

WALL MOUNT INSTALLATION PROCEDURE(continued)

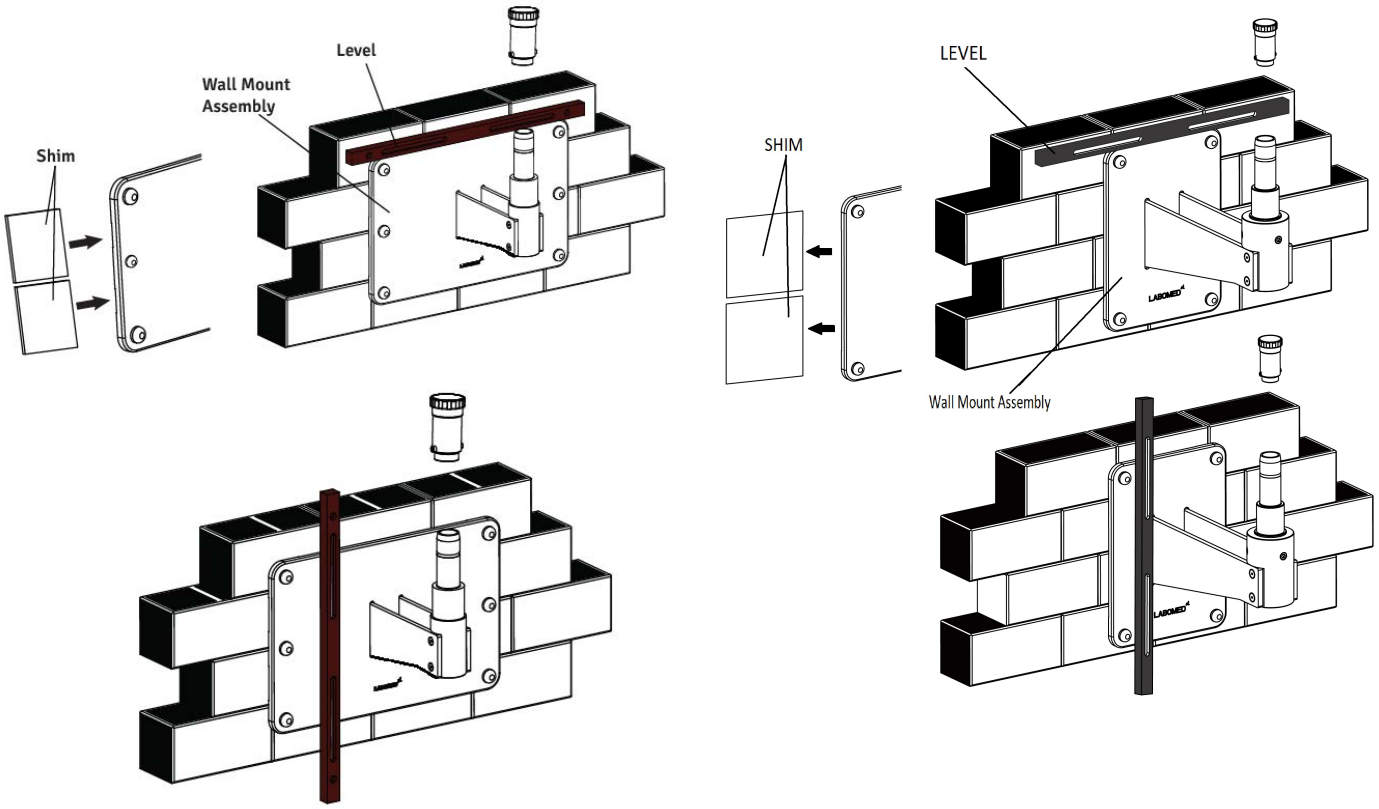


Fig.28

WALL MOUNT INSTALLATION PROCEDURE(continued)

LEVELING THE WALL MOUNT ON MASONRY WALL

1. Slightly tighten the bolts on the top side- leaving the bottom bolts slightly loosened.
2. Place a level across the top of the back plate to check the horizontal leveling. See figure-29.
3. Use a 17mm Socket & Ratchet arrangement to slightly loosen the Six (6) toggle bolts in the corners of the back plate.
4. Adjust the wall mount until it is level and tighten the three RAWL bolts on the bottom leaving the top toggle bolts loosened slightly.
5. Place a level vertically along the face of the back plate,on both sides, to ensure it is perpendicular to the floor. See figure-29
6. If the back plate is not perpendicular, insert shim material between the back plate and the wall next to the RAWL bolts. Check with the level and tighten the toggle bolts once the mount is level.
7. Check the other side and insert shims as needed and then tighten the toggle bolts. See figure-29.
8. When the back plate is level, both horizontally and vertically, securely tighten all Six toggle bolts.

INSTALLING THE MICROSCOPE ARM ASSEMBLY

1. Open the microscope arm box and take out the arm.
2. Unscrew the threaded plug from wall mount shaft as shown in fig-40.
3. Assemble the Arm on wall mount shaft referring fig.39 and Reinstall the threaded plug into place.
4. Complete the rest of Installation as per fig.1,2,3 or 4 as ordered.

WALL MOUNT INSTALLATION PROCEDURE(continued)

Constructional requirements for the wall mount

1. The 6137100 wall mount must only be installed as recommended in this manual.

2. The cinstruction specialist must confirm in writing the applicable regional and loacal bodies & regulations have been complied and the points listed below are taken care. The customer must keep this information with his records. A copy of this document must be provided to LABOMED representative dealer.

3. The Wall on which wall mount is to be mounted must have the following load capacity:
   Perpendicular force: minimum 1500 Nm
   Torque: Perpendicular 1500 Nm minimum.

Also take into account any additional loads acting on the wall.

4. The wall plate must be aligned in a parallel to wall position (max. deviation ±1˚).

NOTE:
If an existing wall mount is ever exchanged, never re-use the old anchors. New anchor holes must be drilled. When Calculating the effective strength of the new anchors, make sure to take into account the weakening effect of the old holes.

On the basis of the above aspects, the person responsible for the building must decide on and take responsibility for the most suitable method of anchoring.

12. WARNING 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 PERFORM ANY PROCEDURE. THEY SHOULD ALSO READ AND UNDERSTAND THE INSTRUCTIONS FOR ANY OTHER EQUIPMENT USED IN CONJUNCTION WITH THIS MICROSCOPE (i.e. ELECTRO SURGICAL GENERATORS). FAILURE TO DO SO MAY RESULT IN INJURY TO THE PATIENT AND/OR DAMAGE TO THE MICROSCOPE.

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. UNAUTHORIZED MODIFICATIONS MAY CAUSE SERIOUS INJURY TO THE OPERATOR OR PATIENT.

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.

WARNING: TO USE IN FLUCTUATION VOLTAGE ENVIRONMENT CONSTANT VOLTAGE STABILIZER OR UPS IS RECOMMENDED FOR SAFE & EFFICIENT USE OF DEVICE.

WARNING: 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 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 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 AND CAUTIONS(continued)

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

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.

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.

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

13. 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 **(EU) 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.

Manufacturer.

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.

Do not over balance more than 5 degree.

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.

Authorized European representative

Serial No (YY-Year, MM-Month, XXXX-Serial No)

Model No

Max. Safe load 9 Kg

IP 20 **Ingress Safety Protection**

14. 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 14971-2019 Risk management to medical devices.

DIRECTIVE USED/REGULATIONS:

- Regulations (EU) 2017/745
- 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 I.
- Please observe all applicable accident prevention regulations.
- IP Code - IP 20 (Foot Switch - IP 24)

15. 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. Inclined coupling with magni-changer assembly and objective (as ordered)
5. Observation Head, (inclined or ergo) as ordered.
6. Pair of eyepieces, as ordered.
7. Power cord.
8. Installation Kit
    a. Allen wrench 5 mm
    b. Allen wrench 8 mm
9. User manual

16A. INSTALLATION OF BASE (MOBILE STAND)

1. Open the center support assembly box as shown in fig.29.



Fig.29

2. Remove the tool kit and foam sheets as shown in fig.30.



Fig.30

3. Lift up the Centre Support assembly as shown in fig.31.



Fig.31

4. Place the Centre Support assembly on the floor as shown in fig.32.



Fig.32

5. Open the Wheel Support assembly boxes as shown in fig.33.



Fig.33

6. Remove the foam sheets as shown in fig.34.



Fig.34

INSTALLATION

7. Lift the wheel support assembly and cover as shown in fig.35. Place it (Wheels down) under one end of the center support as shown in Fig.36. Repeat procedure for the other wheel support assembly.



Fig.35

8. Align the holes of the centre support with the holes of both wheel supports and tighten the screws as shown in Fig.36. using the 8mm allen wrench.



Fig.36

9. Remove the ring, and open 3 screws from shaft as shown in Fig.37. Unscrew with 4mm allen wrench as shown in Fig.37.



Fig.37

10. Tighten all screws using the 8mm allen wrench. Place top cover on both wheel support assemblies as shown in fig.38.



Fig.38

16B. MICROSCOPE INSTALLATION

1 Open the Microscope Box. Remove Column from the box. Engage this column onto the shaft. Refer B in Fig.39.

1a. Align the holes of the column with the threaded holes of shaft Refer B Fig.39 and tighten three allen screws from the sides, as shown as C in Fig.40.

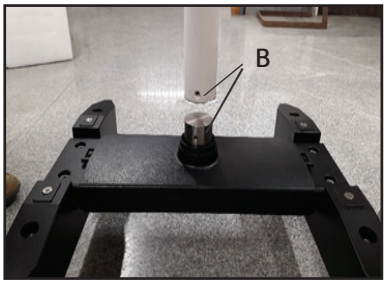


Fig.39

2 Make sure that during assembly of the column ring D is fixed in place, as shown in Fig.41.

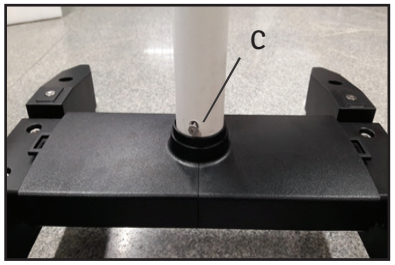


Fig.40

3 Remove the arm assembly from the box and follow the instructions below (see Fig.42).

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

⚠ Do not unscrew knob A completely (see fig.42). loosen only a few threads; otherwise the lock ring inside the column guide may disconnect and installation may not possible.

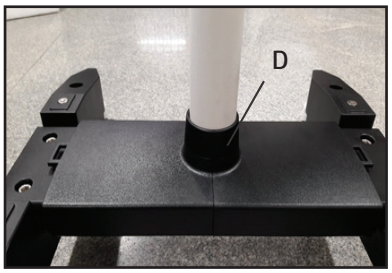


Fig.41

B. Place the arm assembly on the column shaft (1) shown in Fig.42.

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.

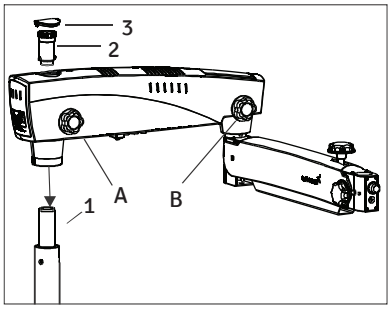


Fig.42

INSTALLATION

4 Retrieve the inclined coupling assembly(Z AXIS or Simple as ordered) from the packing and follow as below refering Fig.43.

- 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 (3).
- Ensure magnichanger handles (M) have silicone covers.

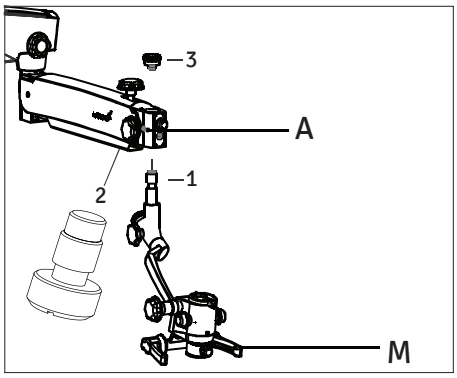


Fig.43

⚠ **Make sure that safety screw must tight in place at position (2) to avoid sudden falling of the coupling. Safety screw tagged within the arm.Safety screw alway tied with the suspension arm locking knob A as per fig.43.**

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 properly tighten into position as shown as A in Fig.44.
- 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.

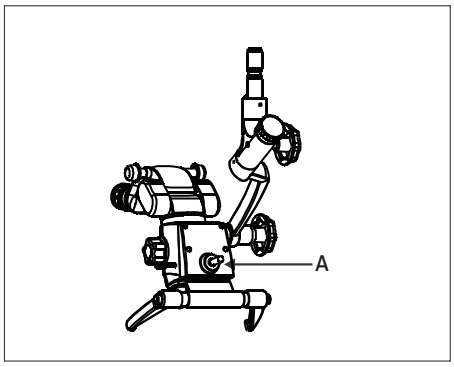


Fig. 44

6 Instally the Head & Eye Pieces .

- Take out the observation head (as ordered) and eye pieces from the box Refering fig 45, loosen the tighening screw 'A' using 2mm Allen wrench (provided) and fight the observation Head in position carefully in the eye pieces in both eye tubes and set both dioptre to zero .

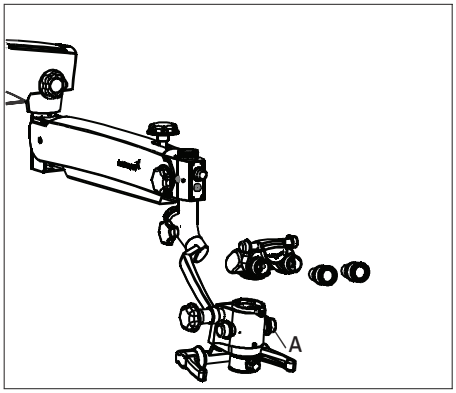


Fig. 45

7 Adjusting of Magnichanger counter Balancing Force

- Spring loaded counter Balancing mechanism is provided to adjust force on clockwise/anticlockwise rotation of carrier Arm to take care of extra loads of accessories. (if Provided) at the time of installation Refer Fig.45a.
- Referring Fig.-46a, unscrew the cap X and tighten nuts W1 and W2 with a hexagonal wrench to Adjust Counter Balancing forceas per requirement. Refix the nut X in position.

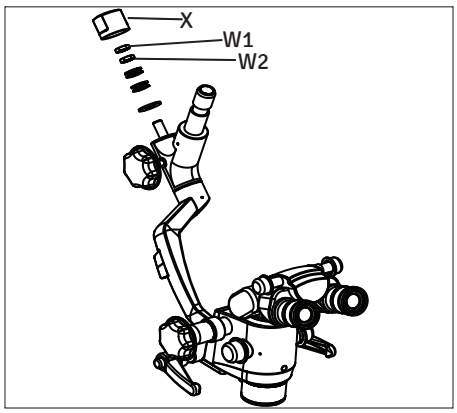


Fig. 45a

8 Foot Switch (IF ordered)

- Take out Foot Switch from locking connect to the Switch arm Refer C in fig 43 .

17. ELECTRICAL CONNECTIONS

1. Connect the power cable to the AC inlet (2) provided on the back of the swivel arm as shown in the fig.46.
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.46.

Note: If Voltage fluctuate more than +/-10% of the rated voltage at the place of installation use voltage stablizer to save the power supply .

2. If ordered Connect Foot Switch and Z-AXIS Cable to the relevant connectors Provided in the bottom of swivel Arm near Label Shown as 3 in Fig.46.

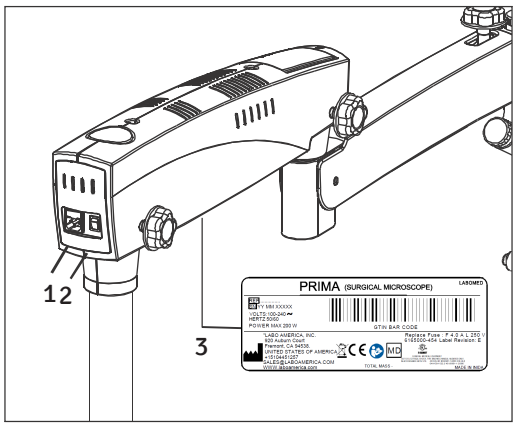


Fig. 46

1 REPLACING THE ILLUMINATION SOURCE

Open the swivel arm covers. Detach the fibre optic cable and replace the illumination assembly (A) with new assembly.. Ref. Fig. 47. Secure back the arm covers.

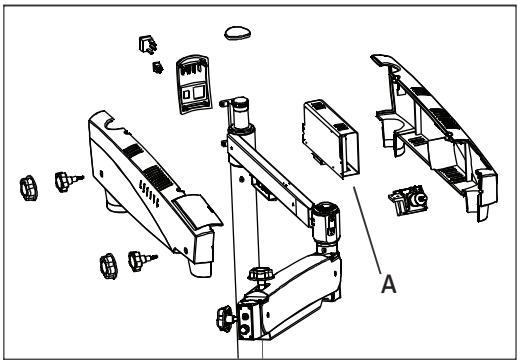


Fig. 47

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.48.

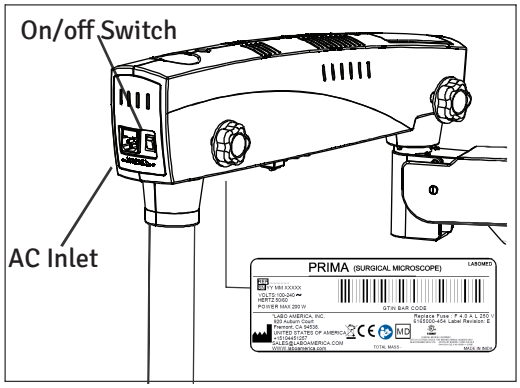
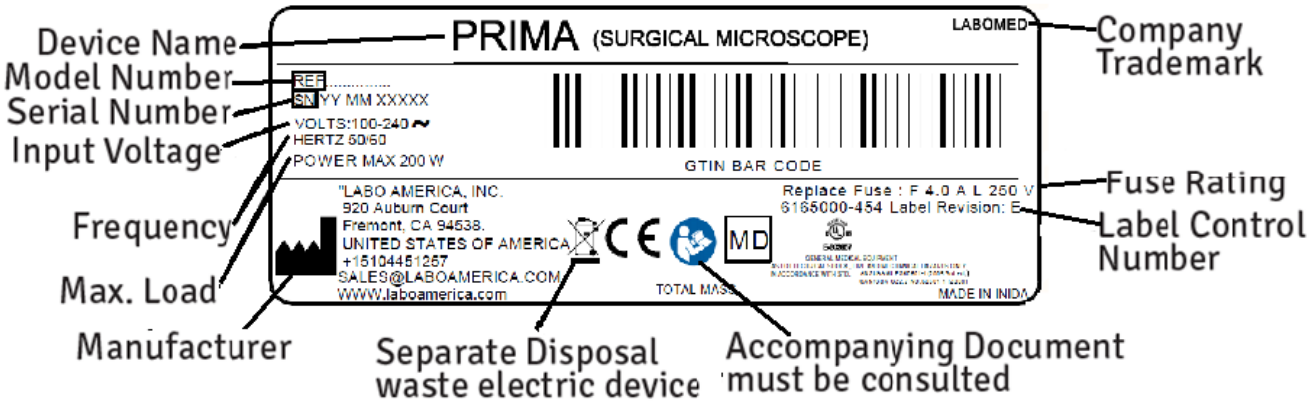


Fig. 48

3 DATA PLATE FOR PRIMA ENT/DNT MICROSCOPE

Foot Switch: Foot Switch Cannection Refer

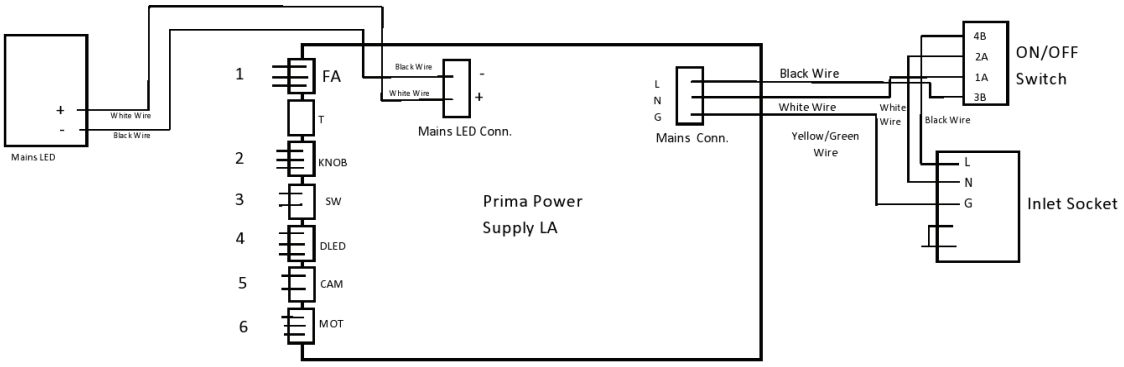
Section 8 of installation .



ELECTRICAL CONNECTIONS(continued)

4. PRIMA WIRING CODING DIAGRAM

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

18. CONTROL ELEMENTS

1 ON/OFF SWITCH

It is located on the back of the swivel arm Refer fig 48. 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.

2 INTENSITY CONTROL KNOB

It is located in front of the suspension arm shown as (A) in Fig.-49. Brightness of field of view can be adjusted as per user comfort using intensity control knob.

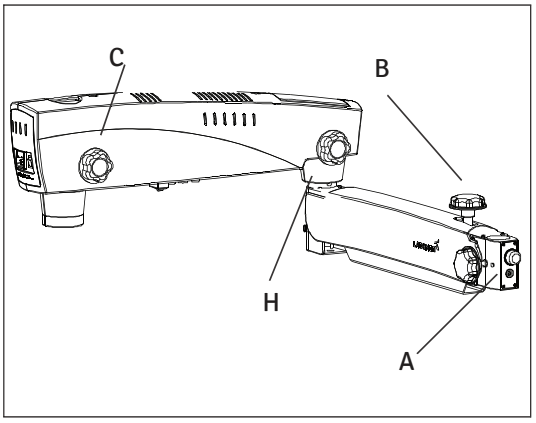


Fig.49

3 SWIVEL ARM LOCKING KNOB

This knob helps you to lock the movement of swivel arm at the desired position after initialfocusing of the attendance area by turning it clockwise, knob is shown as (C) in Fig.- 49.

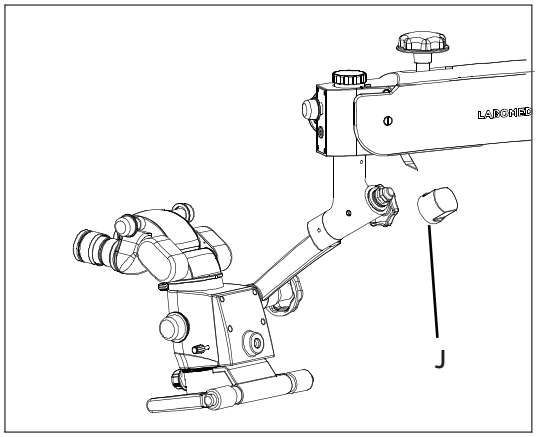


Fig. 50

4 SUSPENSION ARM LOCKING KNOB

This knob shown as (H) in fig 49 locks the Rotary movement of the Suspension Arm at the desired position by turning it clockwise.

5 SUSPENSION UP/DOWN MOVEMENT LOCKING KNOB

This knob shown as (B)in fig 49 locks the UP/Down movement of the suspension armat the desired height by turning it clockwise.

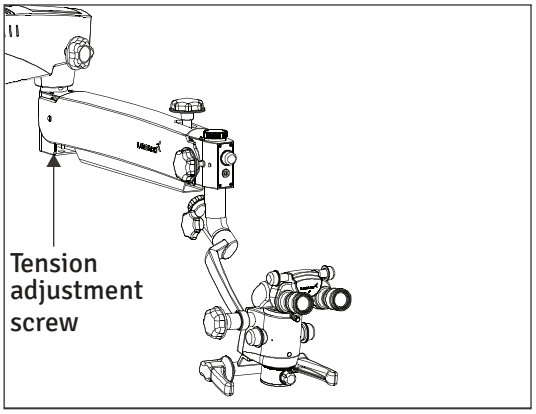


Fig. 51

6 ADJUSTING TENSION ON ROTATORY MOTION OF INCLINED CARRIER

Refer Fig. 50. Unscrew Knob (J). Adjust Tension by manipulating two Hex nuts and screw back the cap (J).as explaned in section 7 of installation Chapter.

6 FILTER CHANGE LEVER

Refer Fig. 52(K). Filter change Lever is located in right sideof the magnichanger housing. Use lever by pulling out to change the filter and push back to main light.

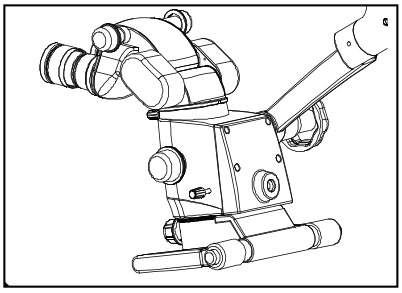


Fig. 52

7 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 (L) Fig.53.

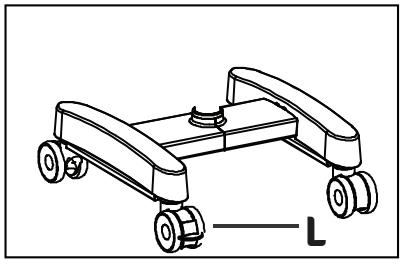


Fig.53

8 LED FEATURES

Single Chip White LED with over 2250 white lumen's. Large monolithic chip with uniform emitting area of 9mm. Lumen maintenance of greater than 70% after 60000 Hrs. Current driven LED with variable drive current less than 1Amp through 13.5 Amp. Environment friendly ROHS Compliant. Typical spectrum is 400 - 700 nm.

9 Z-AXIS Movement (only if ordered)

Refering fig 54a ,Z AXIS control allows motorized focusing of the area of interest within a travel range of 50 mm two Foot Padels are Provided on the Foot control to Facilitate up & down movement of Z AXIS .

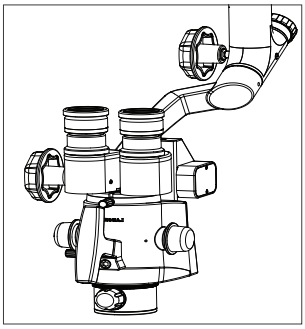


Fig.54a

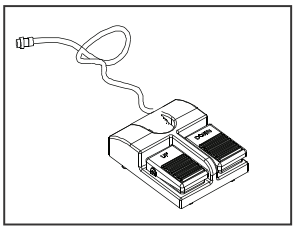


Fig.54b

10 Foot Switch (only if ordered)

Refering fig 54b Foot control (N) is used for motorized focusing Up & down with two Foot Padels.
Refer fig.54c user needs to connect the Foot switch wire to the inlet located as (M) beneath the swivel arm.

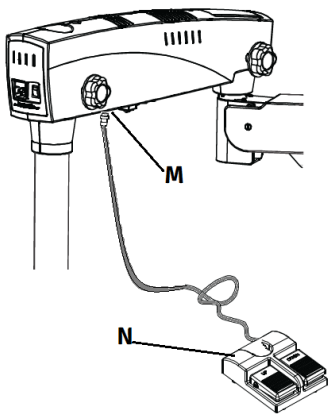


Fig.54c

19. INSTRUCTIONS FOR USING THE MICROSCOPE

WARNING: INSTRUMENT IS UNSAFE FOR MRI ENVIRONMENT.

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 pre-set 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 section 23 for more details. Refer Fig.-55 to see the exact location of tension adjusting screw.

3. Lock the up & Down movement of suspension arm using locking knob (B) in fig.55 after focusing of the area of interest.
4. Adjust Position of Ergo Head (if ordered) as user convenience .
5. In case of Motorized Z AXIS pre use Fine focusing Can done Using Foot Control .

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

7. Set Both Eye Pieces dioptre to Zero .

8. The illumination is controlled through the control knob (A), fig.55. Rotate it clockwise or anticlockwise to achieve desired illumination level.

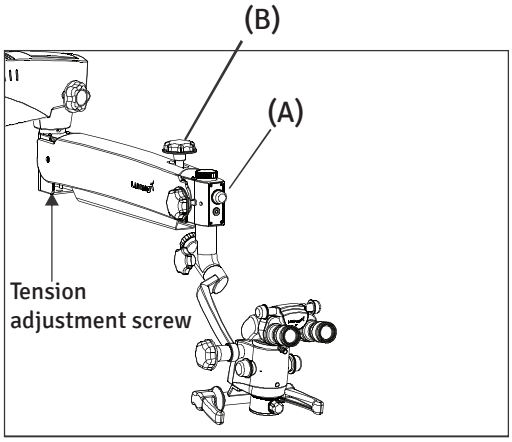


Fig. 55

SETTING UP OF MAGNIFICATION (Ref. Fig. 56)

1. Adjust to highest magnification with one of the rotating knobs (56a) 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 handles (56b).in Dental application and with front handles Fig 56(c).

4. Make sure that the magnification changer is engaged in the index point at the click stop position.
5. Focusing for highest magnification ,change all the magnification field of view must be in focus only fine focusing in reqmned for sharp focus .

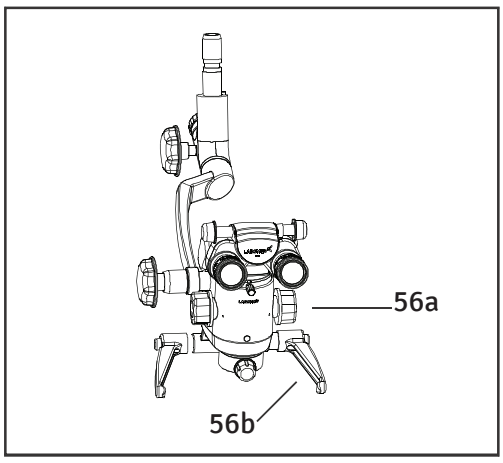


Fig. 56

MAIN MICROSCOPE

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

Also Variable working distance CMO like NuVar 7, NuVar 10 and NuVar 20 also available on demand. For more details of NuVar refer brochure.

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 10X (option:12.5X).

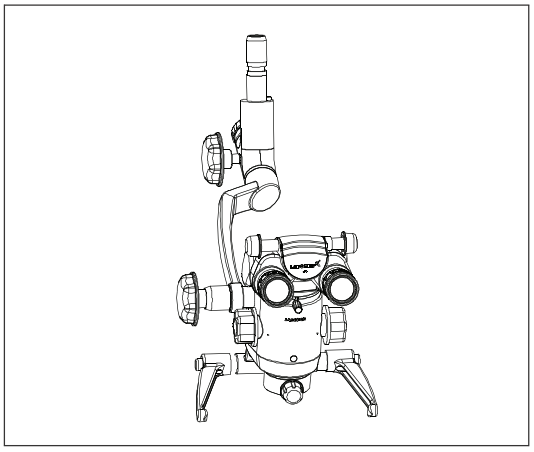


Fig. 57

20. CHANGING THE OBJECTIVES & EYEPIECES

1. The objectives can be taken out by rotating i in anti-clock wise direction. It can be thread 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.

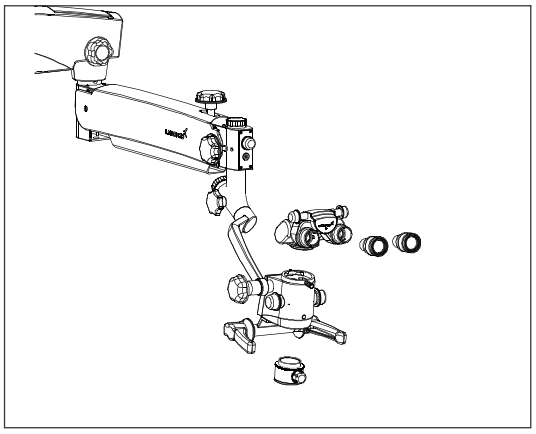


Fig. 58

21. USE OF ACCESSORIES

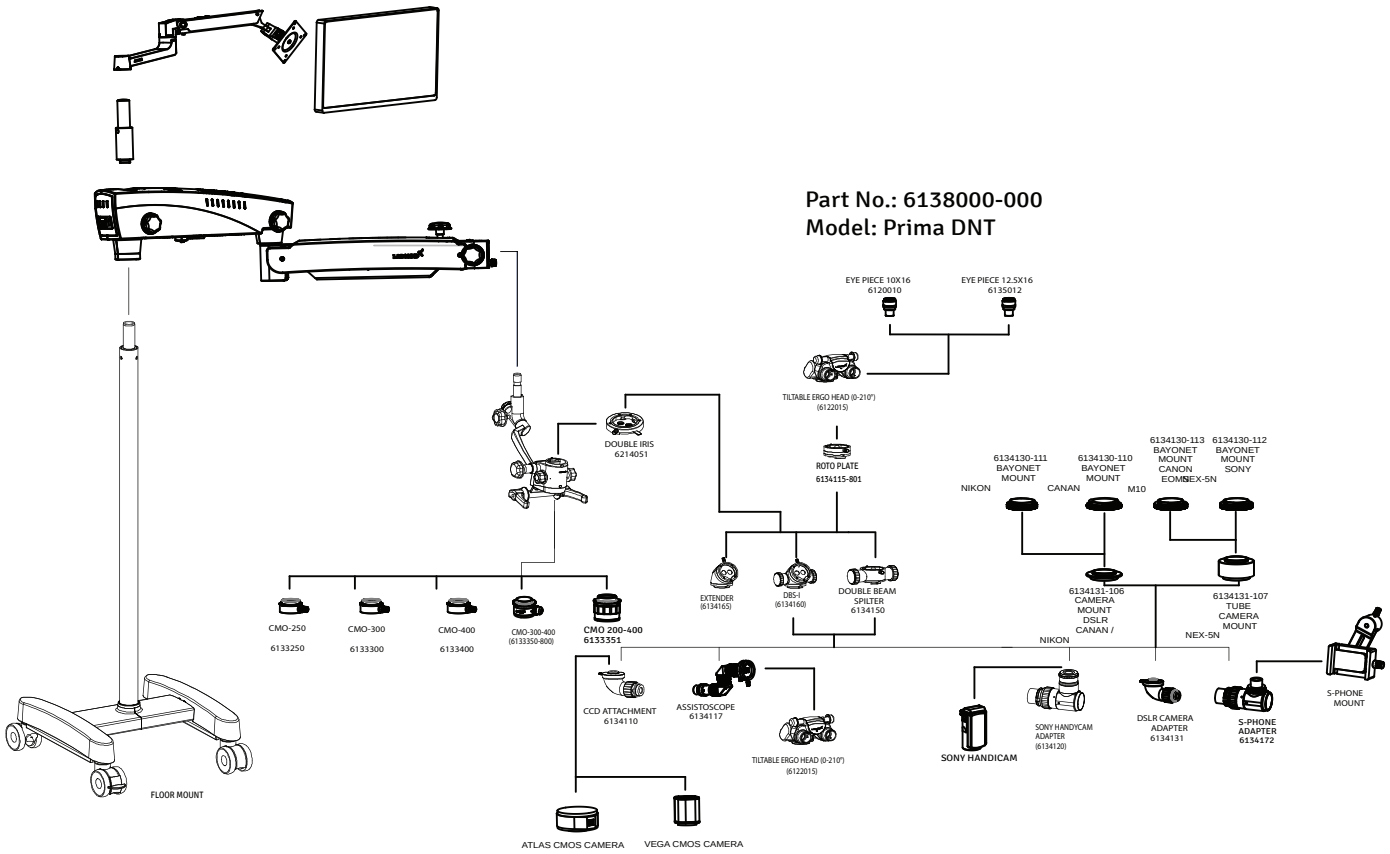


Fig. 59

1. Install double beam splitter by replacing the binocular tube (straight or ergo).
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 any side (Left or right) of the beam splitter
4. Reinstall binocular tube (straight or ergo) on double beam splitter.
5. ALL the accessories must be Carefully Mounted securly with the help of screw provided. falling down of accessery may damage it completely.

USE OF ACCESSORIES(continued)

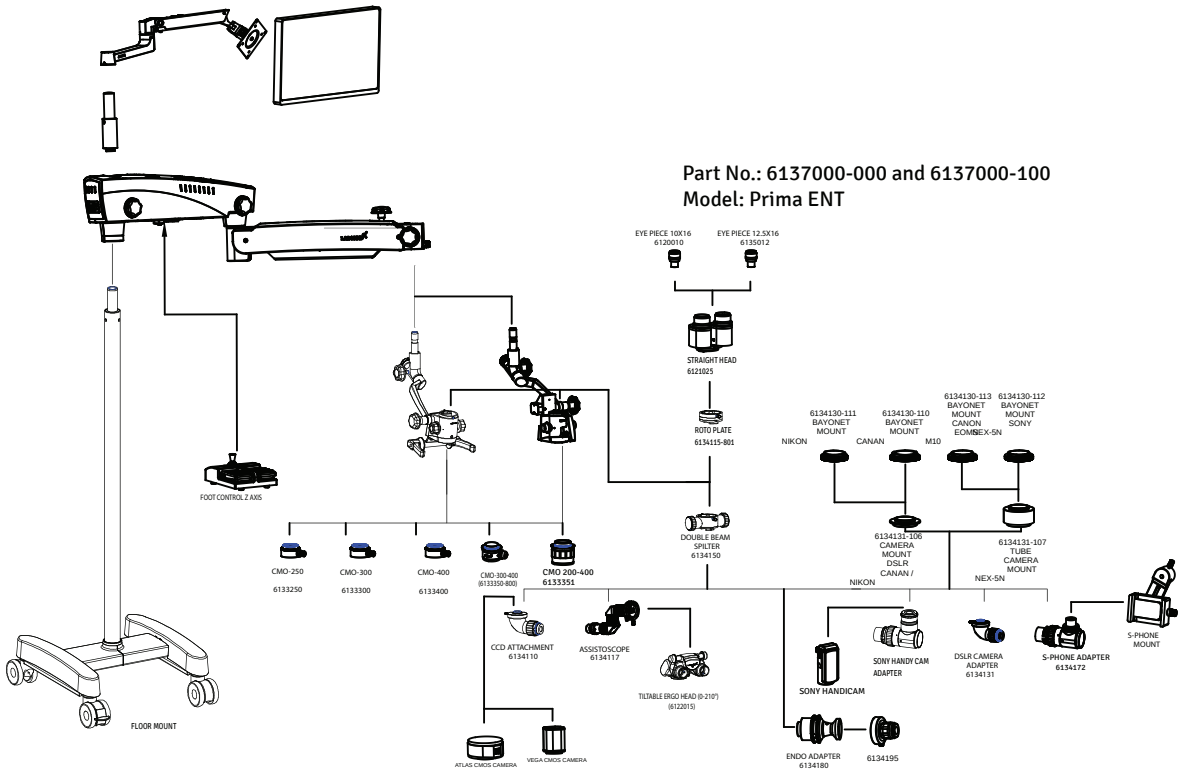


Fig. 60

1. Install double beam splitter by replacing the binocular tube (straight or ergo).
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 any side (Left or right) of the beam splitter
4. Reinstall binocular tube (straight or ergo) on double beam splitter.
5. ALL the accessories must be Carefully Mounted securly with the help of screw provided. falling down of accessery may damage it completely.

22. THERMAL CUT-OFF

The instrument is designed with safety provisions. fans in the electrical box provide free - and forced - air circulation to cool the electronic components. The instruments also includes a built-in-safety mechanism called "auto thermal cut-off". This mechanism is activated through Thermistors when the LED temperature rises above 80 degree C. This time Thermistor sensor activates and provide resistance
to circuit inflow. This causes LED light blinking as an indicator of high LED temperature. Allow the LED to cool down before switching it on again.

23. 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.-61

1. Remove plate by unscrewing two holes.

2. Loosen two allen bolts by using allen wrench of 4 mm as shown in fig.62.

3. Use hexagonal wrench of 8mm in bolt (A) shown in fig.63 rotate it clockwise to increase desired tension on Gas spring.

4. Re tighten the two screws.

5. Put back the plate.

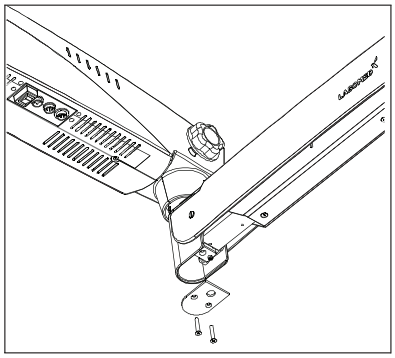


Fig. 61

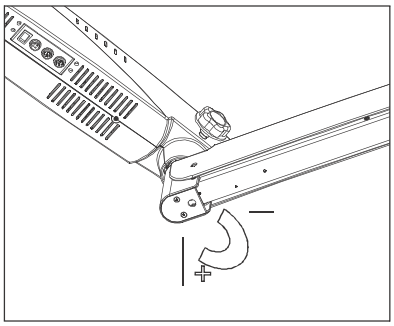


Fig. 62

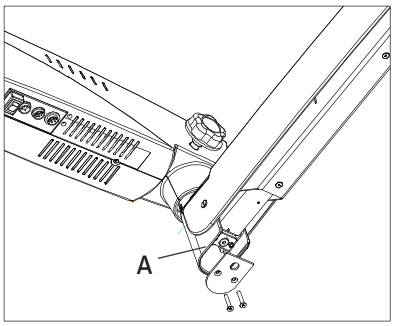
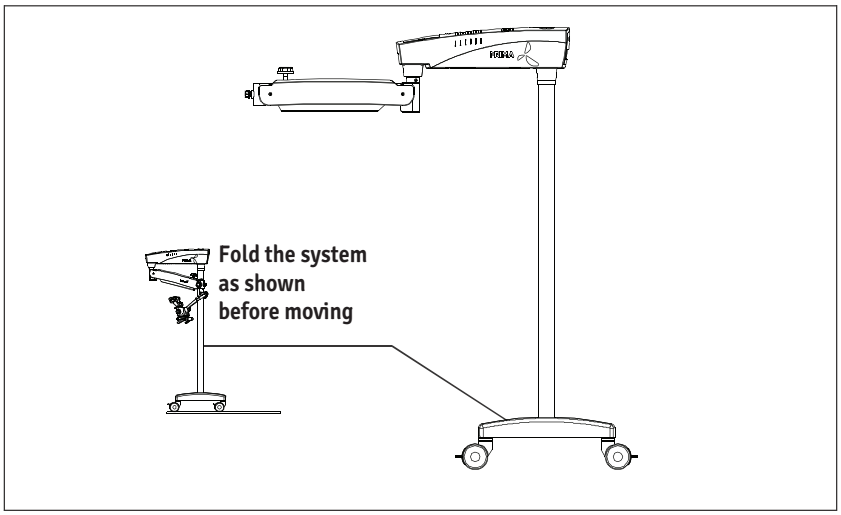


Fig. 63

24. MOVING POSITION OF THE SYSTEM



Position of the system for
safe transportation



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.

25. 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 AND MAINTENANCE(Continued)

CARE INSTRUCTIONS

1. Keep accessories away from dust when not in use, e.g. protect them from dust cover.
2. Remove dust with a pneumatic rubber blower and soft rush.
3. Protect your microscope from moisture, fumes, acids and cosmetic materials. Do not store chemicals close to the instrument.
4. Protect it from improper handling. Never install other deviced sockets or unscrew optical system and mechanical parts unless explicitly instructed to do so in this manual.
5. Protect the microscope from oil and grease. Never oil or grease the guide surfaces or mechanical parts.
6. Remove coarse contamination using a damp disposable cloth.
7. Use disinfectants based on the following ingredients: aldehyde's, alcohols, quaternary ammonium compounds.
8. Use special optics cleaning cloths and pure alcohol for cleaning lenses and eyepieces.
9. Clean optical components using a lint-free cloth.Soak the cloth using a little methanol or glass cleaner. Do not use ethanol and spirit.
10. Do not clean products and optical components in a cleaning/disinfecting devices or ultra sound bath.
11. LABOMED MaxiLite coatings are fungal resistant. If you clean as described above, the coatings will not be damaged.
12. If cleaning and disinfection is done as described above there is no impact of multiple cleaning/ Disinfection on mechanical and optical parts. Paints & Coating are rigid and life long.

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, cool and dry environment 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.

INSTRUCTION WORKPLACE

Remove surface contamination with a paper towel.

26. CLEANING AND DISINFECTION

FOLLOWING DISINFECTANTS ARE RECOMMENDED FOR CLEANING AND DISINFECTION

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

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

PROCEDURE

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

NOTE:

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

27. AMBIENT REQUIREMENT

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

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

28. DISPOSAL

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

29. 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
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

30. TECHNICAL SPECIFICATIONS

Binocular Tubes	Ergo viewing tube 0° - 210° (tiltable), IPD 49-78mm Optional: Straight viewing tube 90°, IPD 45-78mm
Eyepieces	WF 10x/18mm with retractable eye guards, diopter adjustment ± 7mm and diopter lock Optional: WF 12.5x/18mm diopter adjustment ± 8mm fixed eye guards.
Magnichanger	5 steps: 0.4x, 0.6X, 1.0X, 1.6X & 2.5x
FOV (Field of View)	2.7x – 17x
Magnification Range	80-13mm
Objective	f= 250mm, manual fine focus
Built-in filters	Yellow or Green
Vertical Movement of Arm	500 mm
Microscope Carrier	Inclined 120° Carrier
Accessories	Double Beam Splitter and Camera Adapters.
Light Source	50W LED; Maximum intensity 135000 LUX
Power Consumption	200W Maximum
Input Voltage	100V-240V; 50/60 Hz
Stand	Stable and sturdy H-base stand with 2 lockable wheels.
Elevation Stroke	570mm
Stand Height in Horizontal Position	1100mm
Base (Dimensions)	600mm width, 629mm length
Stand Height	1733mm
Net Weight	
Microscope arm with Magnichanger, Head & Eyepieces	16.5 Kg
H-Base	58 kg
Floor Column	9 Kg
Ceiling mount Column (for standard 3m ceiling mount)	8 kg
Wall Mount Bracket	12 Kg
Ceiling Mount Bracket	9 Kg

31. GUIDANCE TABLES

Guidance and Manufacturer's Deceleration

Electromagnetic Emissions

All Equipment and Systems

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Prima is intended for use in the electromagnetic environment specified below. The customer or user of the Prima 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 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 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 Deceleration

Electromagnetic Emissions

All Equipment and Systems

Guidance and Manufacturer's Deceleration - Electromagnetic Emissions

Prima is intended for use in the electromagnetic environment specified below. The customer or user of the Prima 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 requires continued operationduring power mains interruption, it is recommended that the Prima 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 Deceleration

Electromagnetic Immunity

Equipment and Systems that are NOT Life-Supporting

Guidance and manufacturer's Deceleration – Electromagnetic Immunity

The Prima 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 150kHz - 80MHz	(v1) = 3 vrms	Portable and mobile Rf communications equipment should be used no closer to any part of the Prima , including cables, than the recommended separationdistance 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 Prima 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.

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 for ME equipment and ME systems that are not Life-supporting.

Guidance and Manufacturer's Deceleration - Electromagnetic Immunity

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

The Prima is intended for use in electromagnetic environments in which radiated RF disturbances are controlled. The customer or user of the Prima can help prevent electromagnetic interference by Maintaining a minimum distance between portable and mobile RF communications equipment (Transmitters) and the Prima 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.

32. 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 (250mm).
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 250mm.
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 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 250mm 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.

33. WARRANTY

This product is warranted by LABOMED 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 the original purchaser). Under this warranty, LABOMED's obligation is to repair or replace the defective part or product at LABOMED's discretion.

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

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

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

PRODUCT CHANGES

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

CLAIMS FOR SHORTAGES

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

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

CLAIMS FOR DAMAGES IN TRANSIT

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

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

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
1.7	Feb 26,2019	DCR/6A/19	Added section 7.6 on page 13 & Net weight on page 30.	S.Bal
1.8	July,2021	DCR/08A/2021	Cleaning and disinfection	S.Bal
1.9	Sept 10,2021	DCR/15/2021	added wall mount and ceiling mount details	S.Bal
1.10	Nov ,2021	DCR/18/2021	Dimensional corrections in line diagrams of all models.	S.Bal
1.11	April 14,2022	DCR/11/22	ENT-Z AXIS details Added	S.Bal
1.12	May 13,2023	DCR/09/2023	Vertical wall mount details added	S.Bal
1.13	Feb 1, 2024		Ceiling and wall mount instructions added	S.Bal
1.14	Aug, 2024	DCR/11/2024	Regulatory Information	S.Bal
1.15	Sep ,2024	DCR/12/2024	**Symbols updated per EU MDR 2017/745 & ISO 15223**	S.bal
1.16	Jan ,2025	DCR/01/2025	**Max. Safe Load Symbol added**	S.bal
1.17	**Mar, 2025**	**DCR/07/2025**	**added wall mount diagrams for more clarification**	**S.Bal**
1.18	**June, 2025**	**DCR/14/2025**	**Typo Error corrected (MDR Regulation (EU) 2017/745**	**S.Bal**
1.19	July,2025	DCR/**16**/2025	silicone cover instructions added	S.bal
1.20	Nov,2025	DCR/**19**/2025	ENT-Z AXIS details Added	S.bal

Revision History

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1.21		ECR/22/2025	Celing Mount Details updated.	S.Bal
1.22	Feb,2026	DCR/04/2026	IP Code Added	S.Bal

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ideas for vision

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