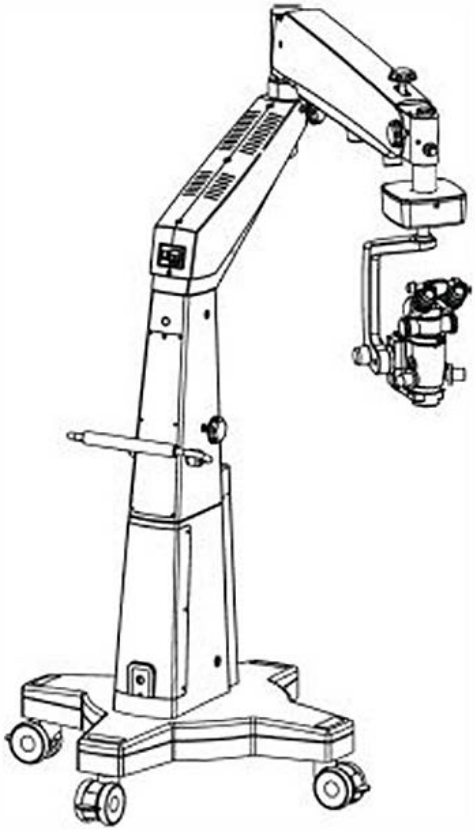
LABOMED
ideas for vision

# STELLA NEURO

## User Manual

## Surgical Microscope For Plastic, ReConstructive, Neuro & Spine Surgery



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

The LABOMED STELLA is a Surgical microscope for Plastic and Reconstructive Surgical 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:**

- Independent quick change over LED light surce without internpting the Surgery if LED Failed.
- IR & UV safe, high Intensity cold light (50 W LED )using fibre light guide system.
- An advanced foot operated motorized magnification changer allows hand free change in magnification.
- Dual Iris Diaphragm for depth management .
- Brilliant optics, excellent flexibility ,Superb illumination and good maneuverability .
- The 0-210° tiltable observation head can easily be positioned without disturbing the suspension arm position.
- Large Focusing range from 200 to 400 mm without the need of changing the objective .
- The illumination is adjustable to its most suitable brightness using intensity control knob suitably located at the suspension arm, and is easily approachable to the surgeon.
- Rigid Star type base rotatable with column together provides greater stability as well as mobility to the instrument.
- In Built tiltable Mechanism for more flexibility and for trans Sphenoidal and posterior fossa cases .
- . Integrated Spot illumination Provided to ensure Superb depth Percaption high Contrast and glare free Image.

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

# 2.TARGET GROUP

This user manual is intended for physicians, nurses and other medical staff who prepare, operate or maintain the system after the appropriate training and in accordance with the instructions given in this manual. It is the duty of the customer or institution operating the system to trainand instruct all staff using the system.

Installation and service work not described in this manual must only be performed by specialists from LABOMED.



# 3.FIELD OF USE

## INTENDED USE

STELLA is a surgical microscope intended for the illumination and magnification of the surgical area and for the support of visualization During surgical procedures in the field of Plastic & Reconstructive surgery .

## NORMAL USE

In line with the intended use, the system can be used for neuro and spine surgery .

The system-integrated illumination delivers a sharply defined, high-contrast image . The foot control panel ensure maximum operating comfort for the surgeon who can configure all settings required to meet his/her specific needs. The integrated tilting mechanism , and depth management system expand the surgeon's scope of work. After completion of the surgical procedure, the system should be cleaned and reset to original function to ensure an optimum starting position for the naxt surgery.

The system can be supplemented by various accessories and can be prepared for sterile use by attaching resterilizable caps, hand grips and drapes.

The system is intended for use in offices, hospitals or other human medicine institutions. For disposal, please observe the instructions in this manual as well as the applicable legal regulations in your country.

# 4. SAFETY COMPLIANCES AND STANDARDS

## SAFETY

The instrument described in this manual has been developed and tested in accordance with national and international regulations. A high degree on Instrument safety is thus ensured.

Additional safety notes are also contained in other parts of this user's manual; marked with a warning triangle containing an exclamation mark as shown here⚠. Please pay special attention to these safety notes.

Safety is only ensures when this instrument is operated properly. Please read this manual carefully before turning the instrument on. Also read thorough the user's manuals on the other equipment used with this instrument.

## DIRECTIVES AND STANDARDS

- Medical Device regulation (EU) 2017/745.
- IEC 60601-1-3.1 edition (2012)
- IEC 60601-1-2-4th edition (2014)
- EN 55011:2016
. ISO 14971-2019
. ISO 13485:2016
. ISO 10936-1
. ISO 10936-2
. ISO 15004-1
. ISO 15004-2
. ANSI Z80.36-2016

## CLASSIFICATIONS

- For Europe, per MDR 2017/745, the unit is a Class I instrument, per rule 13, Annex IX.
- 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)**

# 5. SAFETY AND LEGAL NOTES

## FOR SAFE WORKING ORDER

• Only trained personnel are allowed to use this instrument. Training to the operator is the responsibility of the customer or institution.

• Always keep this user manual at a place easily accessible at all times for the persons operating this device.

• The internal circuitry of the instrument contains electrostatic sensitive devices (ESD) that may be sensitive to static charges produced by the human body. Do not remove the covers without taking proper ESD precautions.

• Do not use solvents or strong cleaning solutions on any part of this instrument to avoid damage to the unit. see the care and maintenance section for detailed cleaning instructions.

• Portable and mobile RF communications equipment can affect medical electrical equipment.

• This instrument is not to be used near high-frequency emitting surgical equipment.

• Do not operate the equipment in:

- Areas having explosion or inflammability, risk the presence of inflammable anesthetics or Volatile solvents such as alcohol, benzene or similar chemicals.

- Do not install, store or use the instrument in damp rooms, It is important and cautionary To protect the instrument from being exposed to humidity, wet conditions, water splashes or water sprays.

- Do not use the instrument if you notice any electrical arcing, sparks, abnormal noises, smokes or fumes. Unplug it immediately and contact authorized LABOMED.

⚠ **Ensure that the power point is properly grounded**

⚠ **If Voltage Fluctuation are more than 10% of rated voltage. Always ensure to use a Constant Voltage stabilizer with this Instrument.**

• Do not force cable connections. If the male and female parts do not readily connect. Make sure that they are appropriate for one another. If any of the connectors are damaged, have our service representative to repair them.

• Should you wish to use other accessories with this equipment, make sure that labomed has certified its use.

• Do not pull at the light source cable, at the power cord or at other cable connections.

• Note the symbols and labels attached to the device!

# SAFETY AND LEGAL NOTES (continued)

**LEGAL REGULATIONS**

• Observe the legal regulations for accident prevention and occupational health and safety applicable in the country concerned.

• Modifications and repairs of this device or any equipment operated together with this device may only be performed by Labomed or other persons authorized by Labomed.

• This system must not be modified without Labomed approval. If modified, suitable inspections and testing must be completed to ensure that it can still be used safely.

• The manufacturer is not liable for damage caused by unauthorized persons tampering with the system. Furthermore, this will forfeit any rights to claim under warranty.

**TRANSPORT AND SERVICE**

• The device shall only be transported over long distances (e.g. move, re- turning for repair etc.) within its original packaging or in a special safe return packaging. For details, please contact your authorized dealer or the Labomed.

• To ensure optimum performance and safe working order, it is recommended having it checked as part of regular scheduled maintenance.

• In order to prevent any impairment of the device's safety due to age, wear, etc., the user must ensure that the device is subjected to the necessary safety checks per section "Care and Maintenance".

• Never attempt to forcefully connect any electrical connectors (plugs, sockets). If connection is not readily possible, check whether the plug fits the socket. If any of the connectors are damaged, approach Labomed or authorized service representative to repair them.

• If a failure occurs which you cannot correct with the aid of the chapter "troubleshooting ”, contact the Labomed.

• To cross over steps and edges, two persons are needed to jointly hold and lift the device: Risk of tripping.

• Avoid collisions of any kind.

• Be extremely careful when moving over slopes.

• Do not park the stand on slopes.

**OPTICS AND LIGHT**

• Never directly look with binocular tube, object lens or an eyepiece into the sun.

• Never directly look into the light source, e.g. a microscope object lens to avoid phototoxic damages to the eyes.

# SAFETY AND LEGAL NOTES (continued)

• Start with the lowest brightness and slowly increase it to the required but not more than the allowed brightness.

• With increasing age of the light source, the actual illumination intensity delivered at the respective setting decreases (this is a normal property of the system).

• The device is equipped with temperature monitoring for the LED light source. If the temperature is too high, the light source switches off automatically. When the LED has cooled down, the light source automatically switches on again. Therefore, constantly monitor the system when the light source is switched on in order to prevent any damage to the instrument.

## ACCESSORIES

• Any additional equipment connected to this medical electrical device must demonstrably comply with the applicable standards and directives .In addition; all configurations must meet the normative requirements per IEC 60601-1:2006.

• Please note that local legislation takes priority over the above-mentioned normative requirements. If you have any questions, please contact LABOMED.

• Never attempt to forcefully connect any electrical connectors (plugs, sockets). If connection is not readily possible, check whether the plug fits the socket. If any of the connectors are damaged, contact Labomed.

• When mounting accessory equipment, please make sure that the admissible total weight of the surgical microscope is not exceeded. (Refer label "Maximum load”)

• When mounting Non-Labomed equipment, make sure that sufficient free space is available for focus positioning.

## WARRANTY AND LIABILITY

• Warranty and liability depend on the applicable contractual stipulations .

## LOSS OF WARRANTY

• The manufacturer is not liable for damage caused by unauthorized persons tampering with the system. Furthermore, this will forfeit any rights to claim under warranty.

# 6. KEY NOTES FOR USER

**PRIOR TO THE VERY FIRST USE**

• Every operator is advised to be thoroughly familiarized with the content of this user manual before starting up the device to ensure correct use of this device.

• Labomed trained installation person or trained authorized representative of Labomed dealer will install the system. Please make sure that the following requirements continue to be met for further operation:
• The connecting components have been properly connected. The screw connections have been firmly tightened.

• The device is connected with the power cord supplied. The power cord being used is the one designed for use with this system.

• When using drapes for the surgical microscope, make sure to remove the protective cover from the drape window below the objective lens.

• The main plug shall only be connected to a socket with a faultless protective ground conductor.

**BEFORE EVERY USE**

• Always use the device within the scope of its intended use.

• When adding accessories and/or components please ensure the permissible total weight of the device is not exceeded (Refer label "Maximum load")

• Adjust gas cylinder torque to compensate for any added weight if any; this will enable the surgical microscope to maintain its balance in all positions of the working range.

• Before every use, limit the stroke of the suspension arm to prevent any contact with the patient if the surgical microscope is lowered accidentally.

• Position the instrument in such a way that you can move it away from the patient at any time.

• When connecting accessories, make sure that sufficient free space is provided and that the surgical microscope does not touch the patient.

• Before using a fundus viewing system, make sure that the room for movement is larger than the downward travel path of the microscope.

• To prevent accessories from falling down, check before every use that accessories are securely locked in position and securing screws are firmly tightened.

• Check that the movement of the surgical microscope is unobstructed to avoid any collisions and damage to cables.

• When mounting non-Labomed equipment, make sure that sufficient free space is available for focus positioning.

# KEY NOTES FOR USER (continued)

- Have an OR illuminator or Endo-illuminator ready during every procedure.

- Before every use, check the filter settings in order to prevent phototoxic injury to the patient's.

- Depending on the type of application, take appropriate precautions to ensure that the surgical procedure or treatment can still be completed even if the full functionality of this microscope (e.g. illumination) is not available.

- If you operate the device in a sterile area, make sure that you use the corresponding sterile accessories for the device.

- Make sure that the operating staff is briefed about sterile use of the system.

- Ensure that heat sink openings are free from dirt and are not covered.

- Make sure that all symbols and labels on the instrument are legible and understood by operators.

- Secure the system in position by pressing all of the locking tabs on the castors to prevent the stand from rolling away inadvertently.

- When mounting accessories (e.g. fundus viewing systems) on the system, make sure that sufficient free space is available for focus positioning and that the surgical microscope cannot touch the patient.

**DURING USE**

- Only use the system after it has been properly balanced.

- Never operate the system unattended.

- Never directly look into the light source, e.g. a microscope object lens or a light guide to avoid phototoxic damages to the eyes.

- Never leave a device unattended with the light source still switched on.

- In order to prevent phototoxic damages to the patient's , reduce the brightness and the light exposure of the surgical area to an amount that is absolutely necessary for the surgery.

- Adjust the illumination intensity by using the potentiometer.

# KEY NOTES FOR USER (continued)

• Defective or unidentified accessories may lead to increased leakage current on the system and injure the patient. Never connect any defective or unidentified accessories and never touch the power outlet or video interfaces while in contact with the patient.

• If you have mounted the fundus viewing system on the underside of the microscope and steeply tilt the microscope, the fundus viewing system may unintentionally move in and injure the patient. Remove the fundus viewing system before steeply tilting the microscope.

• Malfunctions in the motor's electronic system may cause the main functions to fail (XY movement, focus, zoom) and affect other functions. Use manual mode.

• In the event that the focusing function can no longer be controlled via the foot control panel, use the suspension arm to focus the surgical field. This may lead to patient injury or damaging attached equipment. Ensure to provide sufficient clearance between equipment and patient (min. 50 mm) when focusing manually. Ensure that any accessories installed do not come into contact with other objects.

• In the event that the X-Y movement of the surgical microscope can no longer be controlled via the foot control panel, position the device manually via the suspension arm. Again, you should ensure to provide sufficient clearance between equipment and patient (min. 50 mm).

• If a failure occurs which you cannot correct with the aid of the section “troubleshooting”, contact Labomed.

• Do not pull at the power cord or the foot control panel cable.

• Always switch off the system
  - Before disconnecting it from / connecting it to line power
  - If it will not be used for a prolonged period of time
  - Or for cleaning purposes.

**AFTER EVERY USE**

• Always use the master switch to turn off the device if it is not in use.

• Insufficient, incorrect or wrong cleaning or disinfection contrary to the directions in this user manual may expose the patient or medical staff to a considerable risk of infection. For more information, please refer section "Care and maintenance".

• lock all four castors to secure the floor stand in position. Make sure that the floor stand is stable and cannot roll away.

• Insufficient, incorrect or wrong cleaning or disinfection not complying with this user manual can expose the patient or medical staff to a considerable risk of infection.

# 7. WARNING AND LABELS

## Caution

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



## Instrument label plate

The instrument label plate indicates the following:

- Name of the unit
- Cat. No.
- Rated voltage and current consumption
- Rated frequency range
- Serial number
- Safety compliance
- Brand name

**XYZ Coupling cente ing position/button**

## Brightness Control

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



## Green LED

LED light shown here at front of swivel arm, always glow “GREEN” during working position of the instrument.




## Balance setting

Turn the screw to adjust the balance setting of the suspension arm.



## Maximum load

When the surgical microscope are mounted on the suspension systems the overall weight of the microscope including accessories and coupling must not exceed a maximum value of 12kg. Please consult the user manual for the suspension system about the admissible maximum load.

**Accompanying Documents must be consulted**

REF **Catalog Number**

**Compliance to Medical Device Regulation (EU) MDR 2017/745**

MD **Medical Device**

EC REP **Authorized European Representative**

# WARNING AND LABELS (continued)



**Protective Earth**



**This Way Up-Indicates correct upright position of the transport package.**



**Keep Dry- Transport package shall be kept away from rain.**



**The CE mark (an acronym for the French "Conformity Europeenne") Certifies that a product has met European Union Health, safety and Environment requirements which ensure consumer safety**



**Manufacturer**



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



**IPX label for foot control switch**



**Microscope Magnichanger Tilt**



**Arm Lock**



**Suspetion Arm Limit Stop knob**

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

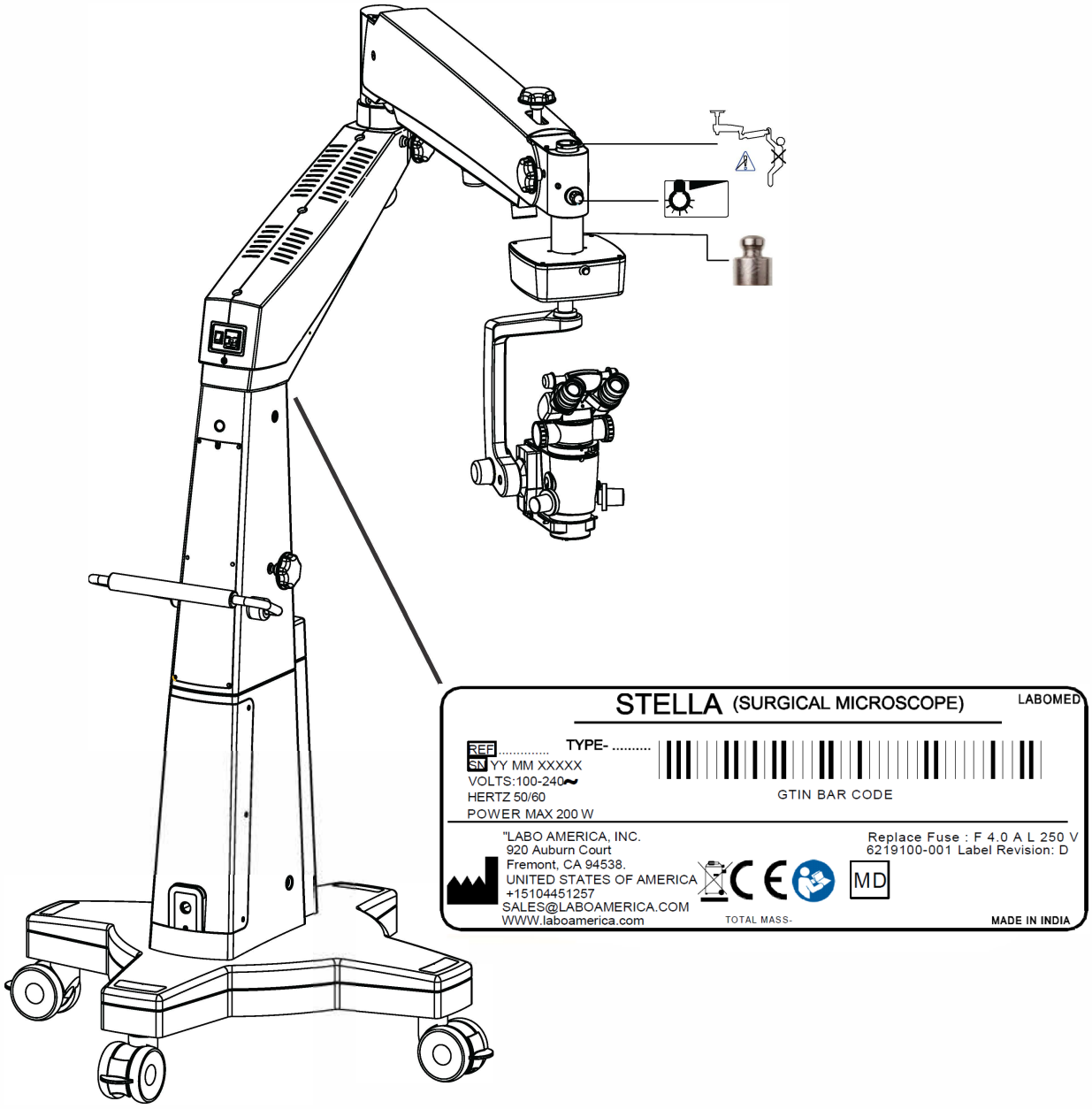
REF **Model No**



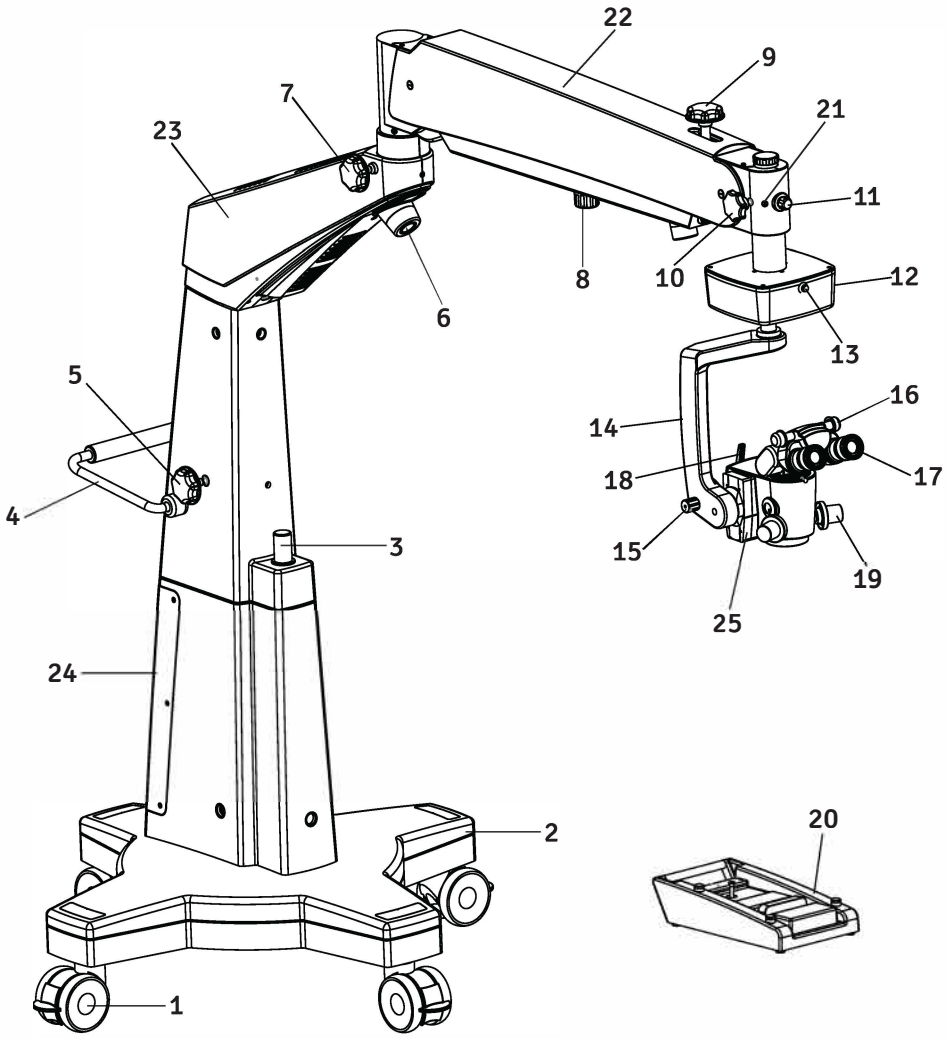
**Max. Safe load 12 Kg**

**IP 20 Ingress Safety Protection**

# WARNING AND LABELS (continued)

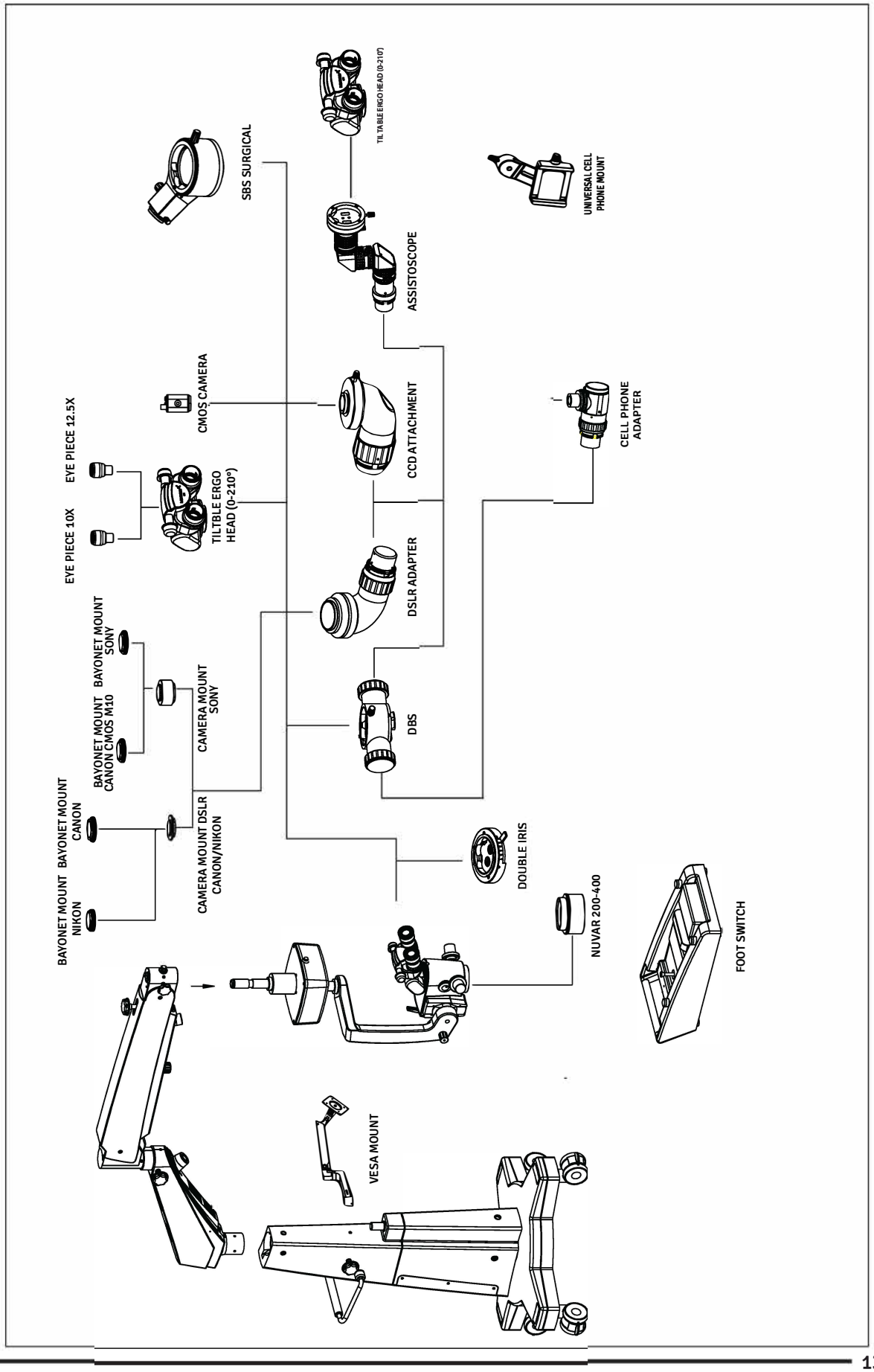


# 8. DESCRIPTION OF PARTS




1. Wheel with brake
2. Star Base
3. Monitor Mounting
4. Moving Handle
5. Locking Knob Column
6. Mesh Holder Fibre Cable
7. Locking Knob Suspension Arm
8. Lower limit stopper
9. Locking Knob Up and Down Arm
10. Locking Knob X-Y Coupling
11. Potentiometer
12. XYZ Assembly
13. Home Button XYZ
14. Microscope Carrier
15. Tilting Knob
16. Ergo Head
17. Eye Pieces
18. Lever Filter Change
19. Handle
20. Foot Switch
21. Safety Screw
22. Suspension Arm
23. Swivel Arm
24. Column Assembly
25. Z-Axis Assembly

# 9. SYSTEM DIAGRAM



# 10. 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 with spanner.

2. Column (Floor).

3. Suspension and Swivel Arm Assembly.

4. Observation Head, (inclined or ergo) as ordered.

5. DBS

6. Double Iris Attachment

7. Paired Eye Pieces, as ordered.

8. Foot Switch Assembly

9. Power Cord.

10. Set of sterilizable caps.

11. Installation Kit
    a) Allen Wrench 5.00mm.
    b) Allen Wrench 8.00mm.

12. Instruction cum Operating Manual.

13. Dust Cover.

# 11. INSTALLATION

1. Open Base assembly box shown in fig.-1.




Fig 1

2. Unbolt the two dead balts A & B as a shown in fig .-1 Remove sheets and open box as shown in fig .-2



Fig 2

3. Unscrew the safety nut tightened over wooden block in center of base using spanner 22mm provided with the micro-scope.



Fig 3

**CAUTION- BASE IS AROUND 130 KG WEIGHT. NEED 3-4 PERSONS TO LIFT SAFELY IT REQUIRED.**

4. Referring fig 2. Roll out the base fig 3. Clean and Keep as shown. Lock all the castors.



Fig 4

5. Open the column box as shown in fig.-4.

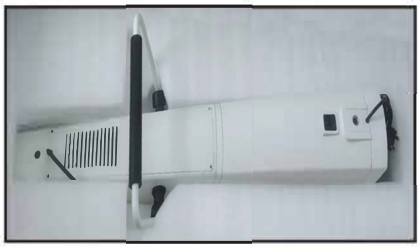


Fig 5

6. Unpack column safely as shown in Fig.-5

# INSTALLATION (continued)

7. Refering fig-6. Mount the column into base by aligning the Corresponding holes in Column (A) and Dowels (B) in base. Tighten 4 bolts under the base to secure column with base using 8mm allen key provided with instrument.

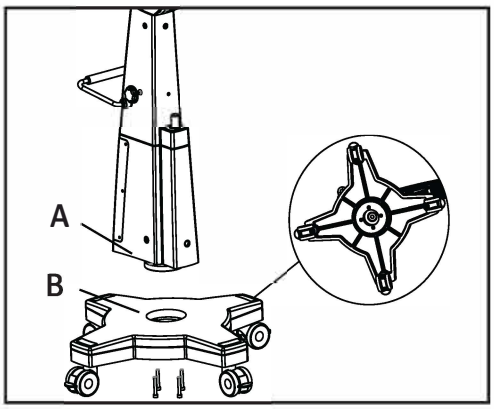



Fig 6

8. Unpack arm assembly box as shown in fig.-7.



Fig 7

9. Take out arm assembly safely and tools as shown in fig.-8.



Fig 8

# INSTALLATION (continued)

10. Align arm assembly over column and secure with 4 screws as shown in fig.-9.

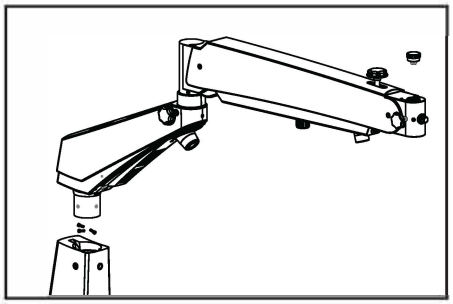


Fig 9

11. Open another box and take out the carrier assembly from its packaging following arm as shown in fig.-10.



Fig 10

12. Remove all the contents from package as shown in fig.-11.



Fig 11

13. Insert the carrier arm shaft 'X' into the suspension arm as shown in fig.-12.

• Lock the carrier arm with the threaded Knob (A) as shown in fig.- 12.

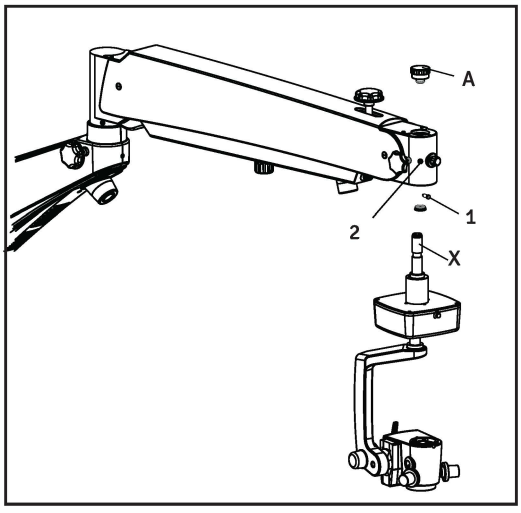



Fig 12

⚠ **Safety screw-** Make sure the safety screw (1) is installed and tightened at position (2) so the coupling does not detach if threaded knob (A) is accidentally unscrewed.

# INSTALLATION (continued)

Referring fig-13. Install Double Iris, DBS and Tiltable Binocular tube onto the magnichanger assembly.

Fix both eyepieces (D) on ergo head and set dioptreto 0.

Ensure magnichanger handles (F) have silicone covers.

CMO (E) is factory pre-installed.

Attach Fundus viewing system(F) if supplied .

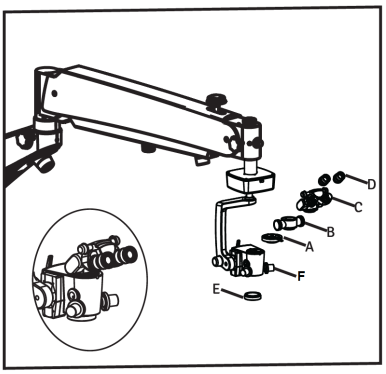



Fig. 13

## Mounting the light guide

- Switch off the illumination system.

- The light guide comes pre-routed through swivel arm (that houses the LED illumination system) and the suspension arm.

- Insert the light guide into the receptacle in the microscope from the back till it clicks into position (A) Refer fig.14 and Screw back the cover in place.

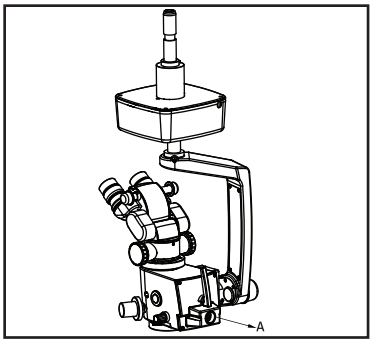



Fig. 14

- 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 can be moved in entire range of movement without stretching, extreme kinking or Twisting of the light guide.

## Electrical connections

Connect the power cable to the AC inlet socket (1) provided on the back of the swivel arm as shown in the fig-15.

Switch on the power from on/off switch (2).

Connect the foot switch cable in the connector (3). connect the XY coupling to theconnector (4) under suspension arm

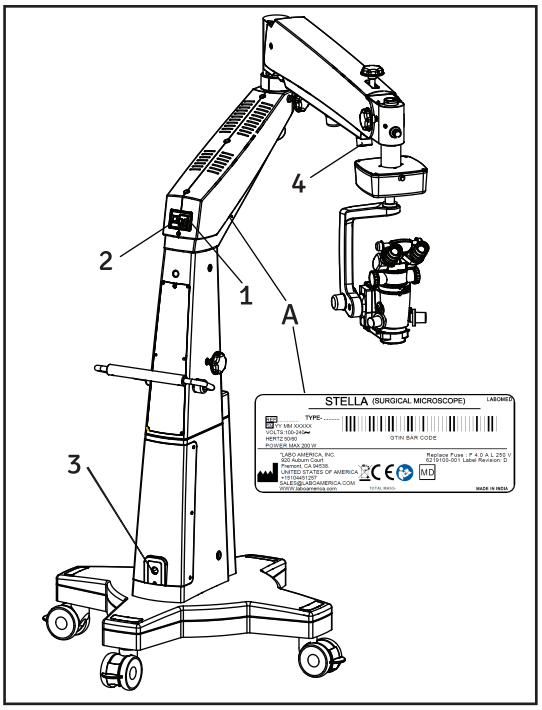
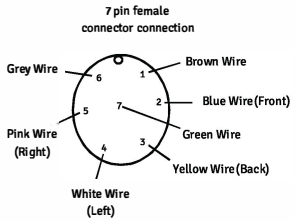



Fig. 15

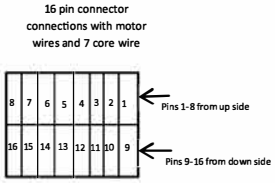
**Note: Power supply is designed with universal input 100V-240V AC, 50/60Hz. To plug in follow instruction on electrical label provided at bottom of the arm as shown (A) here in fig-15.**

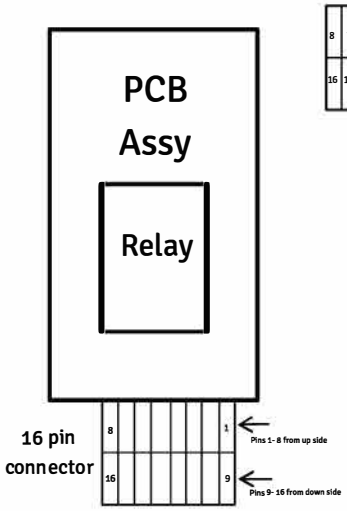
# 12.WIRING CODING DIAGRAM

## XY-Axis Motors Connection




Internal Wire- 1 Ft Each
7 core wire- 5Ft 5 Inch



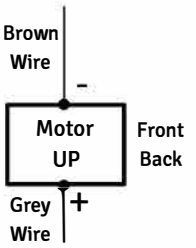

**7 core wire connection on 16 pin connector**

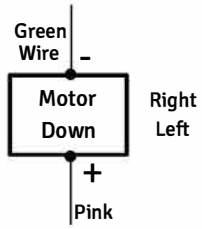
4. Yellow Wire
5. White Wire
8. Grey Wire
9. Brown wire
10. Blue wire
15. Pink Wire

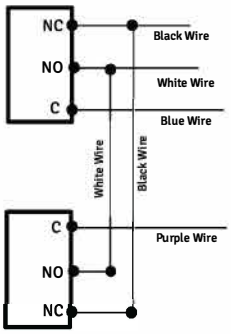
Green Wire is for Earthing Purpose

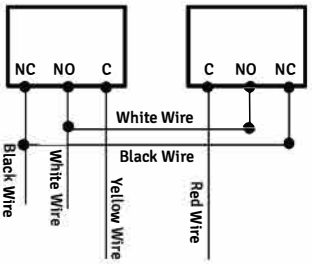
**Motor wire connection on 16 pin connector**

1. White Wire (NO+NO)
2. Brown Wire
3. Grey Wire
6. PinkWire
7. Green Wire
11. Blue Wire
12. Purple Wire
13. Yellow Wire
14. Red Wire
16. Black Wire (NC+NC)



# 13.CONTROLS AND FUNCTIONS

**1. ON/OFF SWITCH** (shown as 2 in fig-15 )

It is located on the back of the swivel arm. At 'I' position, microscope is on and cooling fan starts running.

**Caution** Keep the intensity control knob at Minimum level before switching on the system.

To save burning life of LED, when microscope is not in use. Either switch OFF the microscope or raises the suspension arm in uppermost position.

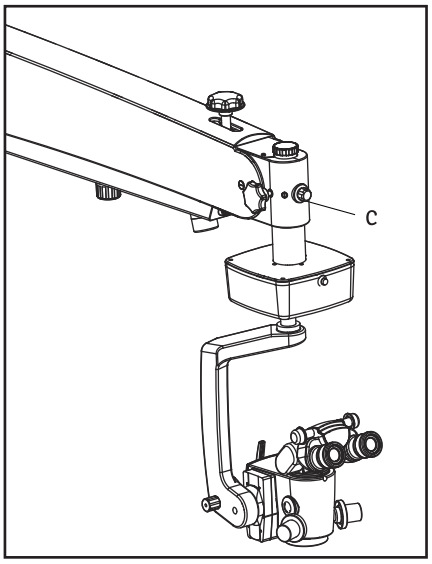



Fig. 16(A)

**2. INTENSITY CONTROL KNOB AND 70% MODE SWITCH**

It is located in front of the suspension arm shown Refer as (C) in fig-16(A). Brightness of field of view can be adjusted through a digital potentiometer in five equal steps, each of 20% incrementasfollows.

The potentiometer has one more control "sudden reduction of brightness". By pushing in the potentiometer from center will reduce fov brightness to 70% of setting and another push in will again increase the brightness to 100%.




Fig. 16(B)

**3. TRANSPORTING HANDLE**

Refer (X) fig 16(B). This handle is used to transport microscope from one place to another.

**4. FOOT SWITCH HANGER**

Referring (Y) fig 16(B) use this bracket to safely hang the foot switch when not in use or during transport.

**5. MONITOR ARM**

Referring (Z) fig 16(B) use this post for monitor arm as and when required.

# CONTROLS ON THE MICROSCOPE(continued)

### 6. SUSPENSION ARM UP DOWN LOCKING KNOB

This knob helps you to lock the up down m ovement of Swivel arm at the desired position after initial focusing of the area of interest. Clockwise turning is for locking and anticlockwise is for unlocking. Refer knob (B) in fig-17.

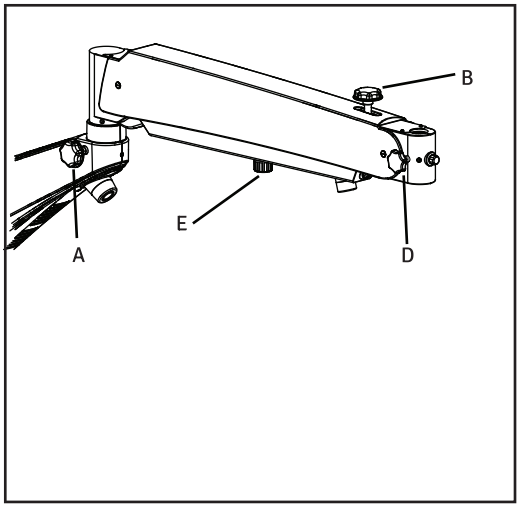



Fig. 17

### 7. FRICTION ADJUSTMENT KNOB FOR LIMITING DOWNWARD MOVEMENT

The knob is used to set the lower limit position of the suspension arm. This prevents the surgical microscope from getting into contact with the patient even if it is inadvertently lowered. Refer as (E) in fig-17.

### 8. FRICTION ADJUSTMENT KNOB FOR ROTATION OF XY COUPLING.

Referring as (D) in fig-17. This knob is used to lock or control the rotary movement of XY coupling and magnichanger.

### 9. FRICTION ADJUSTMENT KNOB TO CONTROL SUSPENSION ARM

Referring as (A) as in fig-17.Use this knob to adjust the friction on the swivel movement of the suspension arm. This prevents the drifting and accidental movement of surgical microscope from original focus point. User can adjust the friction as per his convenience, upon full tight in clockwise direction suspension arm movement will be locked.

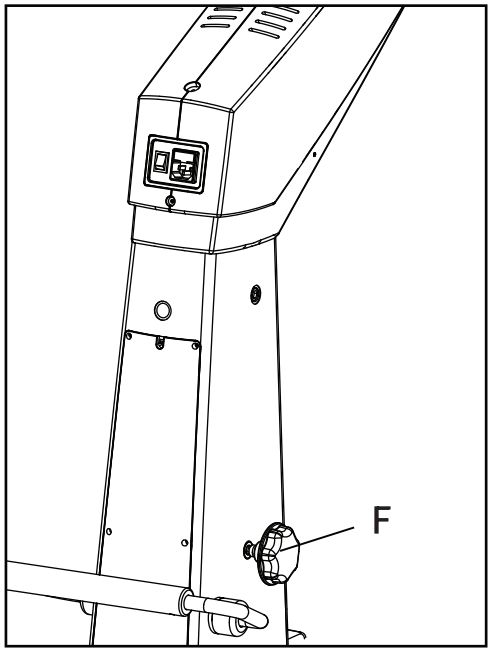



Fig. 18

### 10. FRICTION ADJUSTMENT KNOB TO CONTROL ROTARY MOTION OF COLUMN AND SWIVEL ARM

In Stella, truncated pyramid column and suspension arm rotates together for better center of gravity at any given position of arm. Referring as (F) as in fig-18, the knob is to adjust the friction on the movement of the column and swivel arm. User can adjust the friction as per his convenience, upon full tight in clockwise direction column and swivel arm will be locked for movement.

# CONTROLS ON THE MICROSCOPE(continued)

### 11. XY RESET BUTTON

The XY coupling allows motorized fine position of the magnichanger in a horizontal plane. The range of travel is 50 mm x 50 mm.
The XY coupling is provided with a recentering mechanism. Refer fig 19, Use the reset button (A) to move the XY coupling to the center position.

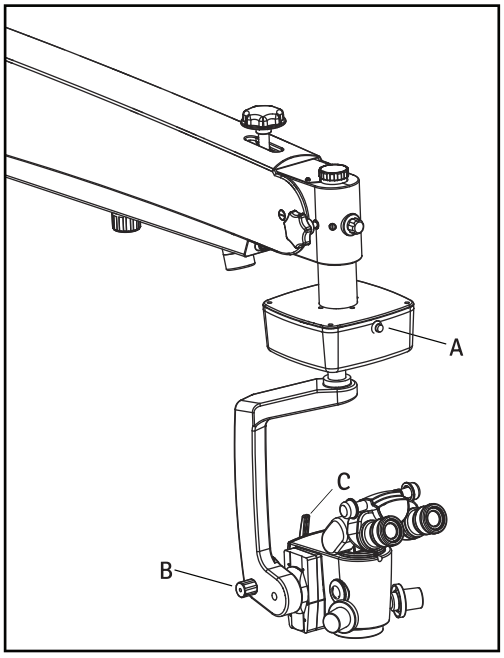


Fig. 19

### 12. SUPPORT ARM WITH TILT KNOB

Referring fig 19, Knob “B” is to tilt Angle of illumination.
By rotating knob clockwise and anticlockwise the optical axis is tilted to ± 90°to reduce the exposure of the macula to direct illumination. With this mechanism, Magnichanger is auto locked at any given position within the range of 0-180 degree tilt.

### 13. SWING IN FILTER LEVER

Referring 19 lever “C” is used to swing in –out the protection filter into the beam path
It has three positions in order:
1. No filter
2. Blue blocking (yellow) filter. Use this filter to protect the patient against unnecessary exposure to radiation (blue light).
3. Red free (green filter) for better recognition of blood vessels.

### 14. KNOB FOR ROTARY FILTER MECHANISM

Referring fig 20, the knob “A” is used to move in –out the following four positions into the beam path:

(i) No filter, free passage. The field of view is fully illuminated.

(ii) FAG (blue) filter. Fluorescent angiography (FAG), is a technique for examining the tumor using a fluorescent dye.

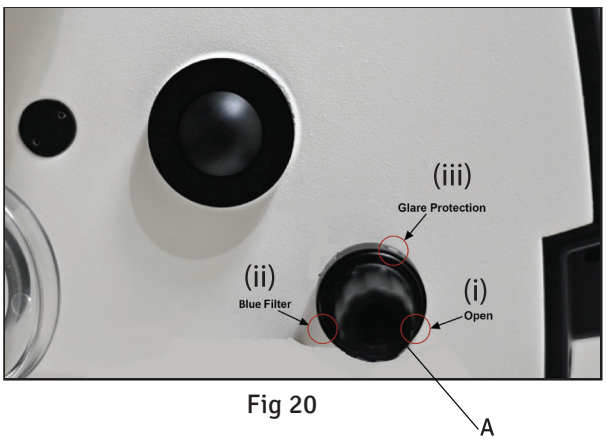


Fig 20

# CONTROLS ON THE MICROSCOPE(continued)

(iii) Retro-illumination contrast stop.
This stop reduces the stray reflected light Free passage diameter approx. 16 mm for spot illumination .

Diameter over approx. 16 mm is periphery with partially light transmission.

**15. KNOB FOR MAGNICHANGER MANUAL ADJUSTMENT (OPTIONAL)**

In the event of failure of motorized Magnichanger, you can use this Magnichanger adjustment knob on the microscope to manually set the required magnification.refer (C) fig 21

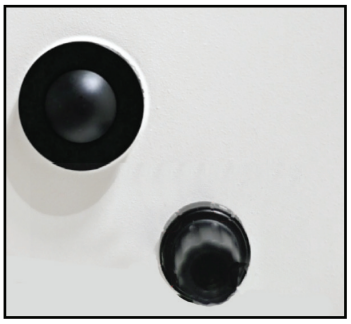


Fig. 21

**16. Handles**

provided in front of magnichanger to position the microscope.Refer (D) fig- 22

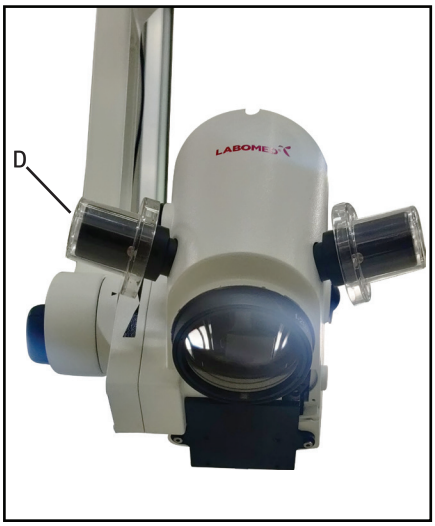



Fig. 22

**17. BRAKES**

Locks the stand from unwanted movement by pressing down the red crest provided on all four caster wheels. To unlock push the crest upward. refer (E) fig 23.

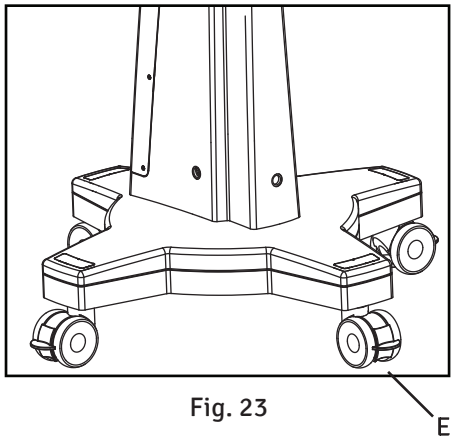



Fig. 23

# CONTROLS ON THE MICROSCOPE(continued)

### 17. Z-AXIS MOVEMENT

Z axis coupling allows fine moterized focusing of the area of interest within a travel range of 40mm. two foot paddles are provided on the foot control to facilitate up and down movement. refer (X) fig 22



Fig. 24

### 18. WIDEFIELD EYEPIECES (fig 24)

(i) Eyecup:
For adjusting the distance between the eyepiece and the eye.
(ii) Diopter setting ring:
With adjustable diopter scale from -7 D to +7 D.

### 19. BALANCE SETTING TENSION ADJUSTMENT SCREW

If any optional accessories are added to the microscope, suspension arm tension must be adjusted to compensate for the additional weight with the help of the screw provided to balance spring force on gas cylinder. Refer Fig.25 Use an 8mm Box Spanner (LK-008 BS) with long handle provided with microscope in bolt (B) . Rotate it clockwise to increase the tension as desired. Rotate it counter clockwise to decrease the tension as desired.

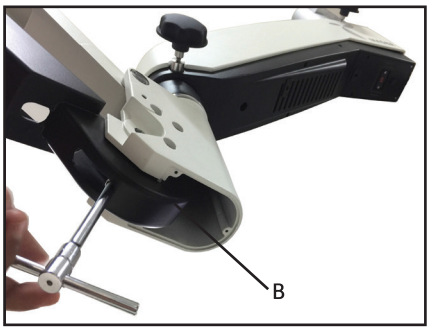


Fig. 25

### 20. COMPONENTS AND CONTROLS OF THE FOOT CONTROL

Referring fig 26, foot control with 10 functions and 3 meter cable is a wired foot control switch. It allows following functions of the microscope.

**1. Connector**
For the cable connecting the foot control with the microscope.
**2. Brackets**
For safe hanging of the foot control panel with the column.
**3. Joystick**
The joystick(3) is used for motorized fine adjustment of the X-Y coupling.
**4 Foot switch (focus)**
This switch is used to operate the "Focus" functions of microscope.
The horizontal settings are:
– Left press: focus up
– Right press: focus down
**5. foot switch for magnification changer**
– Left press: focus forward clockwise
– Right press: focus reverse anti-clockwise
**6. Illumination**
The functions of the illumination switches 6A and 6B are preconfigured as
6A: light intensity increase
6B: light intensity decrease
7 Stand by illumination if main led failed

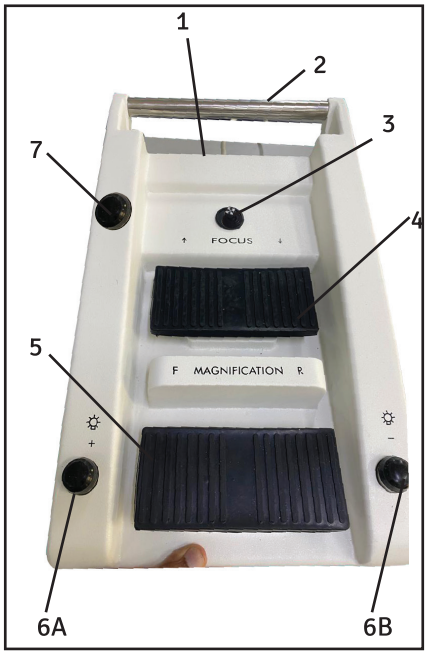


Fig. 26

# 14.USE OF MICROSCOPE (continued)

**1.SETTING UP OF MICROSCOPE:**

i.Switch on the microscope ,check the unit as per check list and move the microscope over the sergical field

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

iii. 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 8.0mm allen wrench. Refer fig.-27 to see the exact location of tension adjusting screw.

iv. position suspension arm parallel to ground. Bring magnichanger to the highest magnification factor and focus the attendance area using suspension arm updown range.Lock the Up & Down movement of suspension arm using locking knob (B) in fig.-27

v. Adjust the eye distance as per IPD scale according to your convenience.Refer (C) fig 28

vi. The illumination is controlled through the control knob (A), fig.-27. Rotate it clockwise or anti clockwise to achieve desired illumination level.During intial setup you can use press function of potentiometer to instant reduce the intasity to 70% ilulumination lavel. Again push will increase it to 100%.

viI Bring the blue blocking filter in to the light path.

**2.SETTING UP OF MAGNIFICATION, PARFOCALITY AND PARCENTERATION. (Ref. fig.-28)**

i. Adjust magnification changer to highest magnification factor using foot switch.

ii. Make sure that the magnification changer is engaged in the index point at the clock stop position.

iii. Set the both eyepieces to '0' dioptre setting.

iv. Fine focus the area of interest with left eye through foot switch.

v. Close the left eye and see the focus with right eye. Adjust eyepiece dioptre of the right eye if some error is noticed in left and right eye focussing.

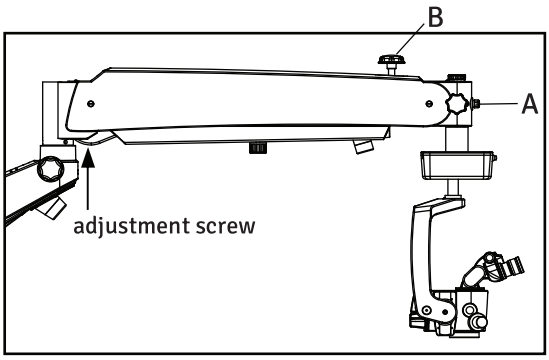



Fig. 27

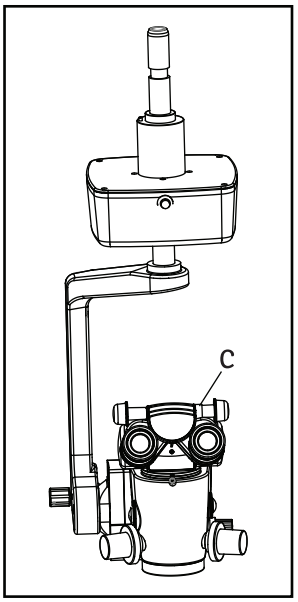



Fig. 28

# USE OF MICROSCOPE (continued)

vi.Visualize area of interest with both eyes.

vii. Bring area of interest in the center of field of view using xy joystick.

viii. change magnification from highest to lowest using foot switch. Area of interest should remain in focus and in the feild of view of eyepiece.

ix. Microscope is parfocal and parcentered.

**3. DEPTH OF FOCUS ADJUSTMENT**

To improve depth of focus, use iris controller. refer (B) fig 29

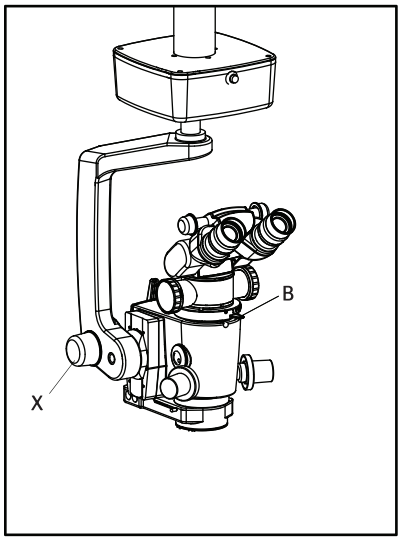


Fig. 29

4. USE OF Z-AXIS

To use Z-Axis attachment, Always Focus the microscope in such a way that index arrow (1) of the Z-Axis is in the middle of triangle (2) to use up & down movement range.Refer fig 30

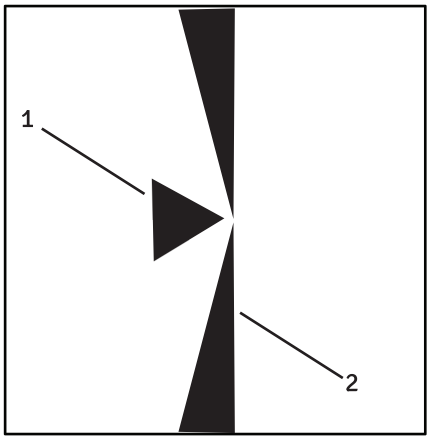


Fig. 30

**5. USE OF ACCESSORIES**

Use left and right port of DBS to mount accessories like assistoscope, mobile adaptor or camera adaptor. Use proline camera and mobile phone adapter for documentation needs. The light loss for the surgeon is only 20% and cannot be perceived subjectively.

# USE OF MICROSCOPE(continued)

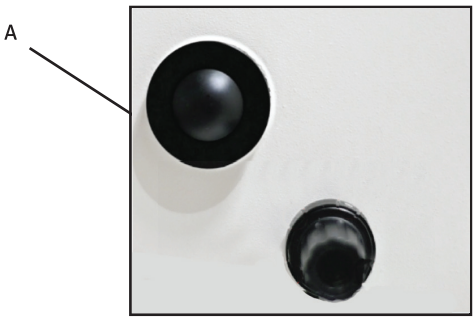



Fig. 31

**6.EMERGENCY USE OF MICROSCOPE**

I. Failure of zoom system

Manually adjust the magnification using zoom control (A) on the micro scope. Refer fig 31

II. Failure of X-Y coupling

• If the X-Y coupling fails, you can manually position the surgical micro scope utilizing the suspension arm

III. Failure of focusing system

• Focus the surgical microscope by moving the suspension arm or the lift arm of the suspension system you are using.

IV. Failure of Illumination

• Operate stand by illumination on foot switch,in case main LED failed for continues working Refer point 7 Fig.26

# 15. 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.fig 32

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

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

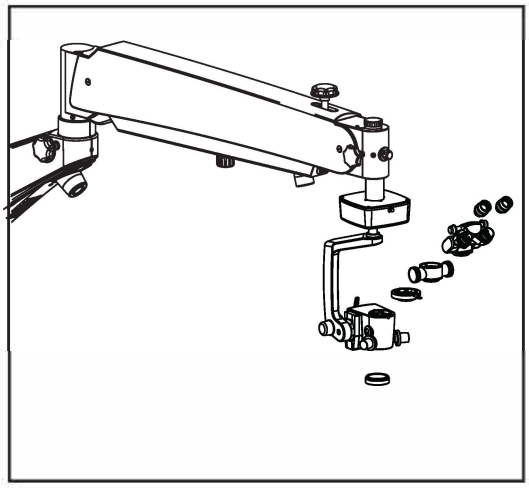


Fig. 32

# 16A.USE OF STAND BY LED ILLUMINATION IF MAIN LED FAILED

Operate stand by illumination on foot switch,in case main LED failed for continues working
Refer point 7 Fig.26

# 16B. REPLACING THE POWER SUPPLY

Replacing the LED Assembly, Open the swivel arm covers. Detach the fibre optic cable and replace the Power Supply 'A' with new assembly. Make connectors as in wire diagram and Secure back the arm covers. refer fig 33

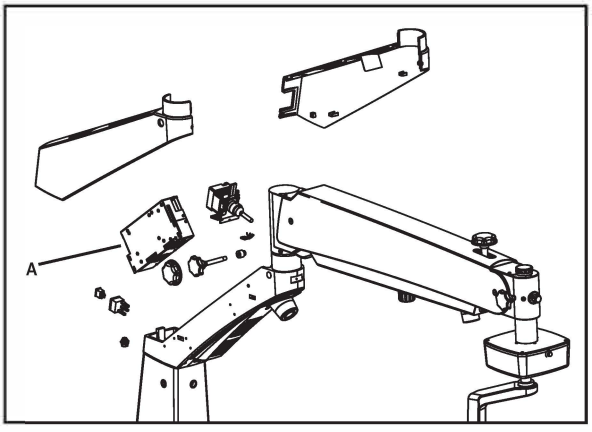



Fig. 33

# 17. FUSE REPLACEMENT

The fuse is located with 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.-34.

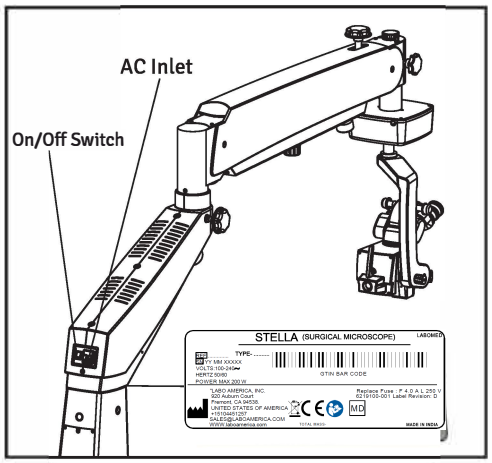



Fig. 34

# 18. THERMAL CUT-OFF

Although instrument is designed for safe working condition thru sufficient cooling facility provided with proper free and forced air circulation by the fans provided in electrical box.
Further instrument is designed with a 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 LED user may call LABOMED service personal or authorized dealer.

LED Specification: 3.7V 13.5 Amp

# 19. TENSION ADJUSTMENT

If any optional accessories are added to the microscope, suspension arm tension must be adjusted to compensate for the additional weight.

## Tension Adjustment for Ceiling / Wall Mount

Refer Fig.35 Use an 8mm Box Spanner (LK-008 BS) with long handle provided with microscope in bolt (B) . Rotate it clockwise to increase the tension as desired. Rotate it counter clockwise to decrease the tension as desired.

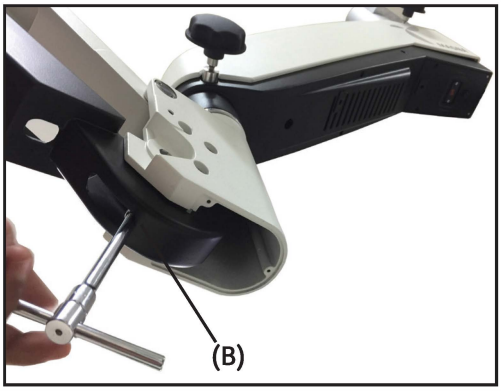
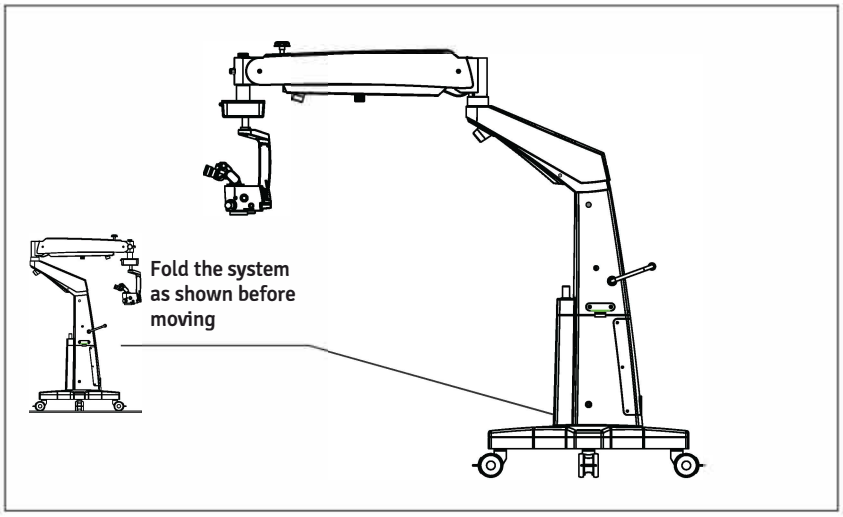



Fig. 35

# 20. MOVING POSITION



**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 downwards.
- 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.

# 21. 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.**

# 22. AMBIENT REQUIREMENT

| | | |
|---|---|---|
| For operation | Temperature Rel. humidity (without condensation) Air pressure | +10°C....+40° C<br>30%.....90%<br><br>700hPa.....1,060hPa |
| For transportation and storage | Temperature Rel. Humidity (without condensation) Air pressure | -40°C.....+70°C<br>10%.....100%<br><br>500hPa.....1,060hPa |

**The unit meets the essential requirements stipulated in Annex I of the MDR 2017/745 governing medical devices. The unit is marked with CE and is compliant to ANSI / AAMI EC 60601 - 1-1.**

# 23. CARE & MAINTENANCE

## CARE & MAINTENANCE

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

**Surgical Microscope Maintenance/Servicing Check**

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

Date of Purchase:

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

## CARE INSTRUCTIONS:

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

# CARE & MAINTENANCE (continued)

- Use disinfectants refered as in section (cleaning & disinfection) of this user guide.
- Use special optics cleaning cloths and pure alcohol for cleaning lenses and eyepieces.
- Clean optical components using a lint-free cloth. Soak the cloth using a little methanol or Glass cleaner. Do not use ethanol and spirit.
- **LABOMED Max Lite** coating are fungal resistant. If you clean as described above, the coatings will not be damaged.

## TROPICAL ENVIRONMENT/FUNGUS:

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

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

## OCCUPATIONAL SAFETY AND HEALTH PROTECTION:

Observe work safety and health protection of persons responsible for processing contaminated products.

Current regulation of hospital hygiene and prevention of infection must be observed in the Preparation, cleaning and disinfection of the products.

## INSTRUCTIONS

## WORKPLACE:

Remove surface contamination with a paper towel.

## REPROCESSING:

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

## AUTOCLAVING:

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

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

# 24. TROUBLESHOOTING TABLE

This instruments 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 safety must be checked once every 12 months. We recommended having this check performance by our service representatives 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..

| 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 |
| | LED Failed | Switch to stand by LED |
| 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) | Chance light guide. |
| Surgical field illumination inoperative or blinks | Light guide not properly inserted in microscope arm | Insert light guide as far as it will go |
| | Failure of electronics | Illumination surgical field using an or illuminator. Contact service dept. |
| | Switch off via micro switch on suspension system | Move suspension arm of suspension system into working position |

# TROUBLESHOOTING TABLE (continued)

| 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. | Contact service dept. Illumination surgical field using an or illuminator. Contact Service dept. |
| 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. |

# 25. DISPOSAL

Disposal must comply with locally applicable laws & regulations.

# 26. SPECIFICATIONS

## Technical Data (Specifications)

| | |
|---|---|
| Observation tubes: | 0-210° Binocular tilt able head F= 140mm |
| Stereo Base: | 24mm |
| Eyepieces: Standard: | WF 12.5X/18 mm with eye guards |
| Option: | WF 10X/18 mm with eye guards |
| Dioptre Adjustment: | ± 7 mm |
| Magnichanger: | MaxLite coated,Apochromatic, motorized stepper zoom system (Tilt able and auto locked at any position) |
| Motorized 5 steps: | 0.4X, 0.6X, 1.0X, 1.6X, 2.5X 5 |
| Objective: | NuVar 20 variable CMO,F=295-495mm, WD=200-400mm |
| FOV diameter: | 128.4mm-12.30mm |
| Magnification Range: | 1.4X-14.7X |
| Illumination field diameter: | 100-160mm |
| Fine focus: | Range 40 mm, motorized noise less |
| XY Travel: | 50 X 50 mm with auto reset |
| Light source: | UV & IR free 50W LED With stand by LED for emergency illumination |
| LUX: | 150K |
| Maximum Wattage: | 200 Watts |
| Color temperature: | 6500K |
| Built-in filters: | Flip in/out Blue, Yellow & Green |
| Optional accessories: | Double beam splitter (straight), Double Iris attachment for depth of filed management, Assistant binocular attachment, Proline range of camera adapters. |
| Swivel Arm: | 470mm |
| Suspension Arm: | 1000mm |
| Swivel Arm rotation: | ±180º |
| Suspension Arm rotational: | ±180º |
| X-Y rotation: | 270º |
| Vertical movement of suspension arm: | ±300mm |
| Foot Switch: | 10 function wired foot switch for XYZ, Magnichanger, intensity control and on- off functions. |
| Brakes: | Manual thru castors |
| Max. Suspension load: | 12 kg |
| Base diameter: | 850 mm |
| Base & column Weight: | 170 kg |
| Arm Weight: | 20 kg |
| X-Y suspension weight: | 8.7 kg |
| Total height: | 1880 mm |
| Maximum extension of arm | 1620 mm |

# 27. GUIDANCE TABLES

| | | |
|---|---|---|
| **Guidance and Manufacturer's Deceleration** | | |
| **Electromagnetic Emissions** | | |
| **All Equipment and Systems** | | |
| | | |
| **Guidance and Manufacturer's Declaration - Electromagnetic Emissions** | | |
| | | |
| The STELLA is intended for use in the electromagnetic environment specified below. The customer or user of the STELLA should ensure that it is used in such an environment. | | |
| | | |
| **Emissions Test** | **Compliance** | **Electromagnetic Environment Guidance** |
| RF Emissions<br>CISPR 11 | Group 1<br>Class A | The STELLA 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<br>IEC 61000-3-2 | Class A | The STELLA 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<br>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**

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

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|---|---|---|---|
| ESD<br>IEC 61000-4-2 | ± 6kv contact<br>± 8kv Air | ± 6kv contact<br>± 8kv Air | Floors should be wood, concrete or ceramic tile. If floors are synthetic, the R/H should be at least 30%. |
| EFT<br>IEC 61000-4-4 | ± 2kv Mains<br>± 1kv I/Os | ± 2kv Mains<br>± 1kv I/Os | Main power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ± 1kv Differential<br>± 2kv Common | ± 1kv Differential<br>± 2kv Common | Main power quality should be that of a typical commercial or hospital environment. |
| Voltage dips,<br>Dropouts,<br>IEC 61000-4-11 | >95% Dip<br>for 0.5 Cycle<br>60% Dip<br>for 5 Cycles<br>30% Dip<br>for 25 Cycles<br>>95% Dip<br>for 5 Seconds | >95% Dip<br>for 0.5 Cycle<br>60% Dip<br>for 5 Cycles<br>30% Dip<br>for 25 Cycles<br>>95% Dip<br>for 5 Seconds | Main power quality should be that of a typical commercial or hospital Environment. If the user of the STELLA requires continued operation during power mains interruption, it is recommended that the STELLA be powered from an uninterruptable power supply or battery. |
| Power Frequency<br>50/60Hz Magnetic<br>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 STELLA is intended for use in the electromagnetic environment specified below. The customer or user of the STELLA should ensure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic environment guidance |
|---|---|---|---|
| Conducted RF<br>IEC 61000-4-6 | 3 vrms<br>150kHz - 80MHz | (v1) = 3 vrms | Portable and mobile Rf communications equipment should be used no closer to any part of the Stella, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Radiated RF<br>IEC 61000-4-3 | 80MHz to 2.5 GHz<br>@ 3V/m | (E1) = 3 V/m | **Recommended Separation Distance:**<br>**d=(3.5/v1)(Sqrt P)**<br>**d=(3.5/E1)(Sqrt P)**<br>**80 to 800 MHz**<br>**d=(7/E1)(Sqrt P)**<br>**800 MHz to 2.5 GHz**<br>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).<br><br>Field strengths from fixed Rf transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels in each frequency range.<br><br>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 STELLA 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 Stella

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

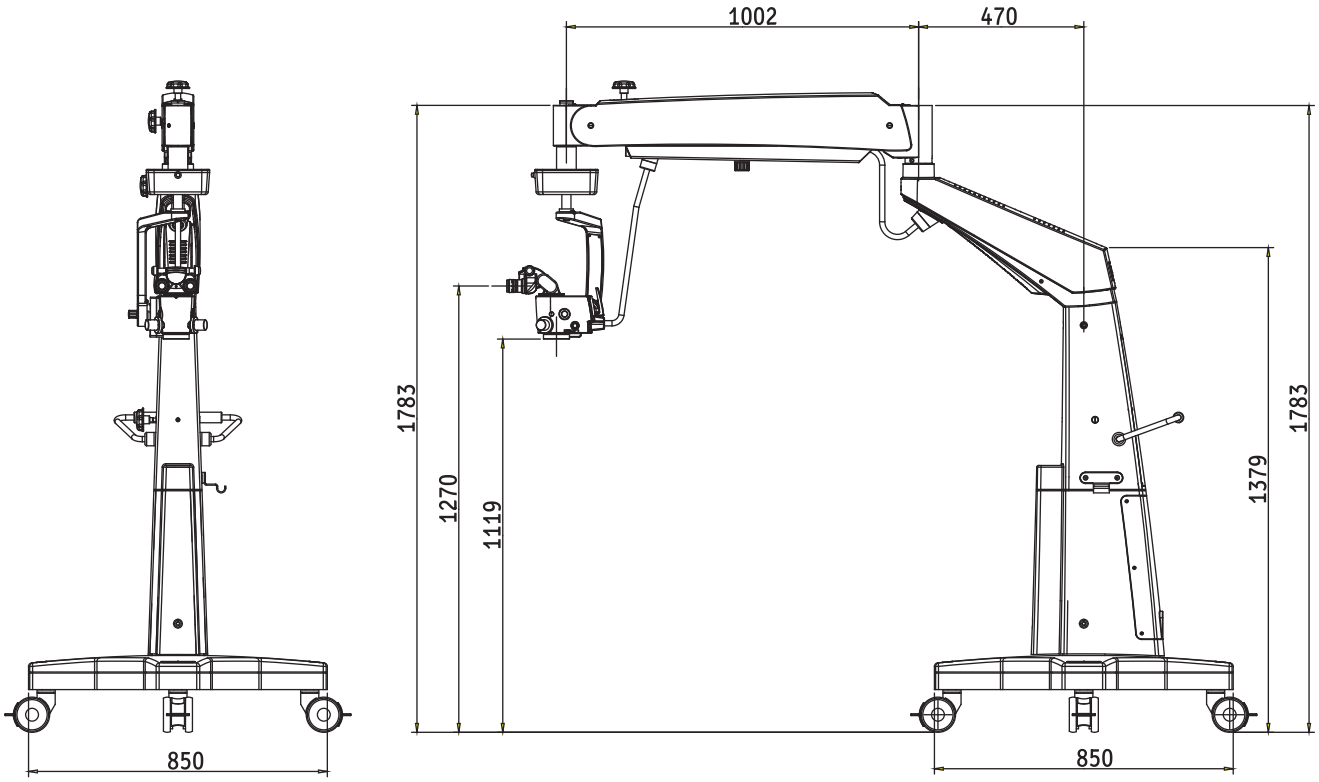
| Max Output Power of Transmitter (W) | Separation (m) 150kHz to 80 MHz d=(3.5/v1) (Sqrt P) | Separation (m) 80 to 800 MHz d= (3.5/E1) (Sqrt P) | Separation (m) 800 MHz to 2.5GHz d= (7/E1) (Sqrt P) |
|---|---|---|---|
| 0.01 | 0.1166 | 0.1166 | 0.2333 |
| 0.1 | 0.3689 | 0.3689 | 0.7378 |
| 1 | 1.1666 | 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.

# 28. DIMENSIONS



# 29. GLOSSARY

| | |
|---|---|
| Ametropia Compensation | Compensation of short-or-far-sightedness. This can be done for each eye using the two individual eyepieces (range: +7 to -7 diopters). |
| Working Distance | Distance front lens to object level (200mm). |
| 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 | Green Filters in the microscope make red tissue (blood vessels) and the pink tissue of the optic nerve appear gray. Green filter also known as red free filter. |
| Blue Filter | Blue Filter used in conjunction with fluorescein stain — Dye pods in area where the corneal epithelium is broken or absent. The dye absorbs blue light and emits green. |
| 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. |
| 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. |

# 30. 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.

**Revision History**

| Rev. No. | Date of Release | DCR # | Change | App. By |
|---|---|---|---|---|
| 1.0 | 1 April, 2022 | New Release | | S.BAL |
| 1.1 | Aug, 2024 | DCR/11/2024 | Regulatory Information | S.BAL |
| 1.2 | Jan, 2025 | DCR/12/2024 | Symbols updated per EU MDR 2017/745 & ISO 15223 | S Bal |
| 1.3 | Jan, 2025 | DCR/01/2025 | Max. Safe load symbol loaded | S Bal |
| 1.4 | June, 2025 | DCR/14/2025 | Typo Error corrected (MDR Regulation (EU) 2017/745 | S Bal |
| 1.5 | July,2025 | DCR/16/2025 | silicone cover instructions added | S.bal |
| 1.6 | Feb, 2026 | DCR/04/2026 | IP Code added | S.bal |

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ideas for vision

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