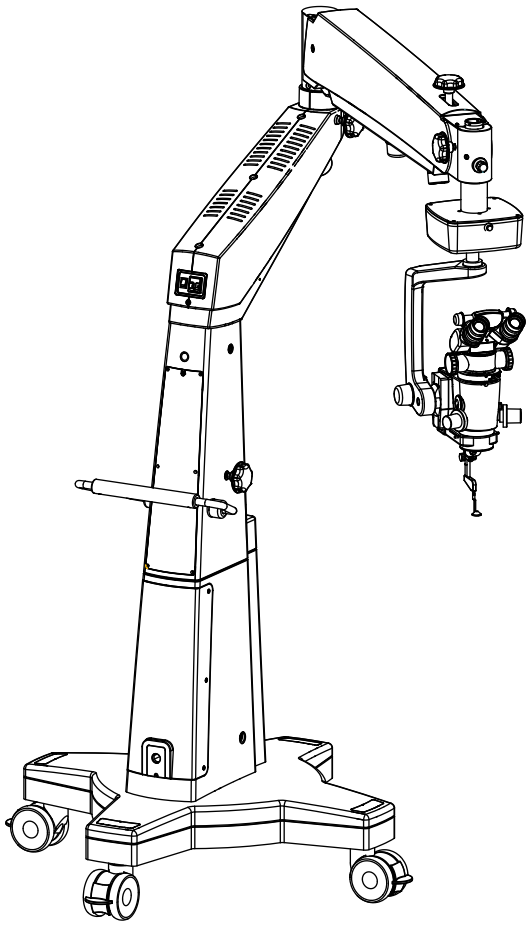
LABOMED®
ideas for vision

STELLA

User Manual

Ophthalmic Microscope



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

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1. INTRODUCTION

The LABOMED STELLA is an ophthalmic surgical and diagnostic microscope that adapts to different surgical needs. It provides consistent visualization during all intraoperative phases of ophthalmic surgery by giving a magnified view of the surgical field, without compromising performance.

The microscope provides very high optical image quality, good depth of focus and a wide field of view for precise surgery. Illumination control, the built-in tilt and the adjustable observation head help reduce surgeon fatigue and allow comfortable use over long periods.

Key features of this microscope:

- IR- and UV-safe, high-intensity cold light (50 W LED) with a fiber-optic light guide system.
- An advanced motorized magnification changer allows hands-free changes of magnification.
- Double iris diaphragm for depth management, valuable for photography and retina surgery.
- Integrated swing-in retina protection device and blue-blocking filter for retinal safety during surgery.
- The 0–210° tiltable observation head is easily positioned with the suspension arm.
- Excellent red reflex.
- The illumination can be set to the most suitable brightness with the intensity control knob, which is located on the suspension arm within easy reach of the surgeon.
- When the microscope is not in use, the suspension arm can be folded over the main body for compact storage.
- The rigid star-type base, which rotates together with the column, gives the instrument greater stability and mobility.
- Built-in tilting mechanism for indirect illumination.

2. TARGET GROUP

This user manual is intended for physicians, nurses and other medical staff who prepare, operate or maintain the system after appropriate training and in accordance with the instructions in this manual. The customer or institution operating the system is responsible for training and instructing all staff who use the system.

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

3. FIELD OF USE

INTENDED USE

STELLA is a surgical microscope intended to illuminate and magnify the surgical area and to support visualization during surgical procedures in ophthalmology.

NORMAL USE

In line with its intended use, the system can be used for surgical procedures on both the anterior segment of the eye (e.g. cataract, cornea, glaucoma) and the posterior segment of the eye (retina, vitreous).

The system-integrated illumination provides an optimum red reflex and a sharply defined, high-contrast image of the patient's eye. The foot control panel ensures maximum operating comfort for the surgeon, who can configure all the settings needed to meet individual requirements. The integrated tilting mechanism, retina protection device and depth management system extend the surgeon's scope of work. After the surgical procedure, clean the system and reset it to its original settings so that it is ready for the next surgery.

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

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

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

4. SAFETY COMPLIANCE AND STANDARDS

SAFETY

The instrument described in this manual has been developed and tested in accordance with national and international regulations. This ensures a high degree of instrument safety.

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

Safety is ensured only when this instrument is operated correctly. Read this manual carefully before switching the instrument on. Also read the user manuals of the other equipment used with this instrument.

DIRECTIVES / REGULATIONS:

- Medical Device Regulation (EU) 2017/745
- IEC 60601-1, edition 3.1 (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

CLASSIFICATION

- 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.
- 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 may use this instrument. The customer or institution is responsible for training the operators.
- Keep this user manual where it is easily accessible at all times to 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.
- Do not use this instrument near high-frequency emitting surgical equipment.
- Do not operate the equipment in:

- Areas with a risk of explosion or fire, or where flammable anesthetics or volatile solvents such as alcohol, benzene or similar chemicals are present.

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

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

⚠ **Make sure that the power outlet is properly grounded.**

⚠ **If voltage fluctuations exceed 10% of the rated voltage, always use a constant-voltage stabilizer with this instrument.**

- Do not force cable connections. If the male and female parts do not connect easily, make sure that they match. If any connector is damaged, have it repaired by our service representative.
- If you wish to use other accessories with this equipment, make sure that LABOMED has certified them for use.
- Do not pull on the light source cable, the power cord or any other cable connection.
- Note the symbols and labels attached to the device!

SAFETY AND LEGAL NOTES (continued)

LEGAL REGULATIONS

- Observe the legal regulations on accident prevention and occupational health and safety that apply in the country concerned.
- Modifications and repairs to this device, or to any equipment operated together with it, may be performed only by LABOMED or by other persons authorized by LABOMED.
- This system must not be modified without LABOMED approval. If it is modified, suitable inspections and tests must be carried out to ensure that it can still be used safely.
- The manufacturer is not liable for damage caused by unauthorized persons tampering with the system. Such tampering also forfeits any rights to claim under warranty.

TRANSPORT AND SERVICE

- Over long distances (e.g. when moving, or when returning it for repair), transport the device only in its original packaging or in special protective return packaging. For details, contact your authorized dealer or LABOMED.
- To ensure optimum performance and safe working order, have the device checked as part of regular scheduled maintenance.
- To prevent any impairment of the device's safety due to age, wear, etc., the user must make sure that the device undergoes the necessary safety checks described in the section "Care and Maintenance".
- Never attempt to force any electrical connectors (plugs, sockets). If a connection cannot be made easily, check whether the plug fits the socket. If any connector is damaged, have it repaired by LABOMED or an authorized service representative.
- If a failure occurs that you cannot correct with the help of the "Troubleshooting" chapter, contact LABOMED.
- Two persons are needed to hold and lift the device together over steps and edges. 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 look directly at the sun through the binocular tube, an objective lens or an eyepiece.
- Never look directly into the light source, e.g. into a microscope objective lens, to avoid phototoxic damage to the eyes.

SAFETY AND LEGAL NOTES (continued)

- Start with the lowest brightness and increase it slowly to the level required, but never above the permitted brightness.

- As the light source ages, the illumination intensity delivered at a given setting decreases (this is a normal property of the system).

- The device has 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 switches on again automatically. Therefore, monitor the system constantly while the light source is switched on, to prevent any phototoxic injury to the patient's eye.

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 of IEC 60601-1:2006.

- Local legislation takes priority over the normative requirements mentioned above. If you have any questions, contact LABOMED.

- Never attempt to force any electrical connectors (plugs, sockets). If a connection cannot be made easily, check whether the plug fits the socket. If any connector is damaged, contact LABOMED.

- When mounting accessory equipment, make sure that the permissible total weight of the surgical microscope is not exceeded (see the "Maximum load" label).

- 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. Such tampering also forfeits any rights to claim under warranty.

6. KEY NOTES FOR THE USER

PRIOR TO THE VERY FIRST USE

- Every operator should become thoroughly familiar with the content of this user manual before starting up the device, to ensure its correct use.

- The system will be installed by a LABOMED-trained installer or by a trained, authorized representative of a LABOMED dealer. 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 in use is the one designed for this system.

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

- Connect the mains plug only to a socket with a fault-free protective ground conductor.

BEFORE EVERY USE

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

- When adding accessories and/or components, make sure that the permissible total weight of the device is not exceeded (see the “Maximum load” label).

- Adjust the gas cylinder torque to compensate for any added weight; this allows the surgical microscope to stay balanced in all positions of its 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 so 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 of the microscope.

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

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

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

KEY NOTES FOR THE USER (continued)

- Have an OR illuminator or endo-illuminator ready during every procedure.
- Before every use, check the filter settings to prevent phototoxic injury to the patient's eye.
- 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 has been briefed on sterile use of the system.
- Make sure that the 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 the operators.
- Secure the system in position by pressing all the locking tabs on the casters, so that the stand cannot roll 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

- Use the system only after it has been properly balanced.
- Never operate the system unattended.
- Excessive radiation exposure times may lead to retinal injury in the patient's eye. Never leave a system unattended while the light source is switched on.
- Never look directly into the light source, e.g. into a microscope objective lens or a light guide, to avoid phototoxic damage to the eyes.
- Never leave a device unattended with the light source switched on.
- To prevent phototoxic damage to the patient's eye, reduce the brightness and the light exposure of the surgical area to the minimum that is absolutely necessary for the surgery.
- Phototoxic effect of light beams: when operating on the eye, always use the retina protection filter (blue barrier filter) in the light source to ensure that the patient's eye is not exposed to unnecessary (blue) radiation.
- Adjust the illumination intensity with the potentiometer.

KEY NOTES FOR THE USER (continued)

- Defective or unidentified accessories may lead to increased leakage current in 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 the fundus viewing system is mounted on the underside of the microscope and you tilt the microscope steeply, the fundus viewing system may move in unintentionally and injure the patient. Remove the fundus viewing system before tilting the microscope steeply.

- Malfunctions in the motor electronics may cause the main functions (XY movement, focus, zoom) to fail and may affect other functions. Use manual mode.

- If the focusing function can no longer be controlled with the foot control panel, use the suspension arm to focus on the surgical field. This may lead to patient injury or damage to attached equipment. Make sure to provide sufficient clearance between equipment and patient (min. 50 mm) when focusing manually. Make sure that no installed accessories come into contact with other objects.

- If the X-Y movement of the surgical microscope can no longer be controlled with the foot control panel, position the device manually with the suspension arm. Again, make sure to provide sufficient clearance between equipment and patient (min. 50 mm).

- If a failure occurs that you cannot correct with the help of the “Troubleshooting” section, contact LABOMED.

- Do not pull on the power cord or the foot control panel cable.

- Always switch off the system:
  - before disconnecting it from or connecting it to line power,
  - if it will not be used for a prolonged period,
  - for cleaning.

AFTER EVERY USE

- Always use the master switch to turn off the device when it is not in use.

- Insufficient, incorrect or improper 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, see the section “Care and Maintenance”.

- Lock all four casters to secure the floor stand in position. Make sure that the floor stand is stable and cannot roll away.

- Insufficient, incorrect or improper cleaning or disinfection that does not comply with this user manual can expose the patient or medical staff to a considerable risk of infection.

7. SAFE USE OF THE FUNDUS IMAGING SYSTEM (E.G. MERLIN)

When using a fundus imaging system (e.g. Merlin from Volk), which is usually installed between the surgical microscope and the patient, make sure that the patient is neither put at risk nor injured by the motorized focusing system or by movement of the stand arm.
Use only accessories expressly certified by LABOMED for combination with the surgical microscope described in this manual.

Caution!

- With the fundus imaging system swung out of position, always position the microscope body so that the index arrow (A) on the microscope arm is in the middle of the two triangles marked (B) (see Fig. 1).
- Select a medium magnification (e.g. 1.0).
- Lower the surgical microscope toward the surgical field until you see the patient's cornea sharply defined.
- Turn the screw that limits the downward movement clockwise as far as it will go.
- It is vital that you read the user manual of the fundus imaging system (e.g. Merlin from Volk).

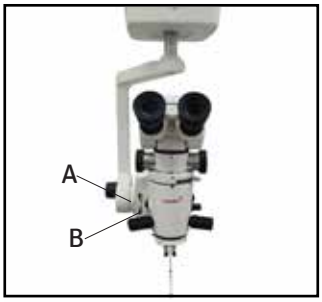
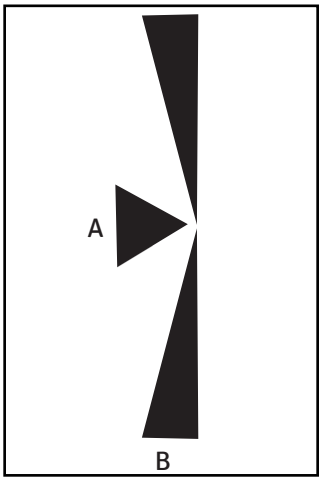


Fig. 1

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8. NOTES ON PHOTOTOXICITY & RADIATION SAFETY

General

Several papers have been published on the problems of phototoxicity during eye surgery. A comprehensive review of these publications identifies the following five aspects of particular concern:
– Illumination characteristics (spectral composition)
– Intensity of illumination
– Angle of illumination
– Focus of the light source
– Exposure time to light

These aspects are explained below, with a brief description of how LABOMED, as the manufacturer, addresses each of them in the STELLA microscope:

ILLUMINATION CHARACTERISTICS (SPECTRAL COMPOSITION)

- Studies on the exposure of the eye to light of varying spectral composition date back to the early 1950s. These studies suggest that the potential hazard of phototoxic injury to the patient's retina can be reduced by blocking out blue and ultraviolet light below a wavelength of 475 nm.

- To protect the retina, LABOMED uses UV- and IR-safe LEDs to illuminate the eye in the STELLA ophthalmic microscope and provides the swing-in blue-blocking filter as a standard feature of this surgical microscope. This reduces the exposure to light not only of the patient's eye but also of the surgeon's eyes.



- An important point to note, however, is that the use of filters inevitably changes the perceived color of the light. The surgeon may therefore initially have to get used to the changed appearance of the anatomical structures.

INTENSITY OF ILLUMINATION

Most researchers suggest that the surgeon should use the lowest light intensity necessary to guarantee good viewing during surgery.

LABOMED addresses this concern with a device that continuously varies the brightness of the light source. This allows the surgeon to adapt the light intensity at the patient's eye optimally to the conditions in each case.

ANGLE OF ILLUMINATION

A number of publications suggest that the microscope should be tilted to reduce the exposure of the macula to direct illumination.
The LABOMED STELLA surgical microscope is therefore equipped with a tilting mechanism for the main microscope to allow indirect illumination.

FOCUS OF THE LIGHT SOURCE

Studies show that injuries are likely if the filament of the light source is imaged on the patient's retina. The peak intensity of a direct filament is considerably higher than that of an even, extended light guide such as a fiber guide. This is why LABOMED uses fiber-optic illumination in the STELLA surgical microscope.

NOTES ON PHOTOTOXICITY & RADIATION SAFETY (continued)

EXPOSURE TIME TO LIGHT

According to some publications, the phakic or aphakic eye should not be exposed to the light source for longer than a few minutes. In every operation, the exposure of the retina to light depends on the type and duration of surgery and on any complications that occur. In ophthalmic surgery, it is therefore recommended to keep the light intensity as low as possible, or to use a device that prevents light from entering through the patient's pupil. The surrounding light sources should also not cause additional strain on the patient's eye.
LABOMED has addressed this problem with a swing-in retinal protection device that is inserted into the beam path of the surgical microscope. This device completely eclipses the pupil and prevents light from entering the patient's eye. It can be swung out when a red reflex is required.

IN CONCLUSION

LABOMED recommends:
- Use of the blue-blocking eye protection filter.
- Reduction of the illumination of the surgical area to the level required for the patient's safety and for microscopic visualization.
- Tilting of the microscope body as required.
- Insertion of the retinal protection device.
- Maximum reduction of the exposure of the patient's eye to light from surrounding light sources. These measures should help the surgeon reduce the likelihood of phototoxic retinal injury.

⚠ RADIATION EXPOSURE SAFETY

Looking into a light source through a tube, an objective lens or an eyepiece may cause eye injury. Never look into a light source or the sun through a tube, an objective lens or an eyepiece.

When selecting the brightness level for the patient's eye, always keep the strain on the patient's eye to a minimum.

If the red reflex is not needed, move the retinal protection device into the beam path. Use the retro-illumination contrast stop only if the surgical procedure requires a red reflex.

When operating on the eye, always use a retina protection filter to ensure that the patient's eye is not exposed to unnecessary (blue) radiation (retinal injury).

9. WARNING LABELS

Caution

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



Instrument label plate

The instrument label plate shows the following:

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

XYZ coupling centering position/button

Brightness control

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



Red and green LED

The LED indicator at the front of the swivel arm, shown here, glows GREEN while the instrument is in its working position. It glows RED when the suspension arm is parked in its uppermost position, i.e. when the instrument is not in its working position. To use the instrument again, bring the arm down until the LED turns green. In the parking position, the illumination LED switches off to extend its life, while the fans keep running to keep the unit cool and safe.



Balance setting

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



Maximum load

When the surgical microscope is mounted on a suspension system, the total weight of the microscope including accessories and coupling must not exceed 12 kg. See the user manual of the suspension system for the permissible maximum load.



Consult accompanying documents

REF **Catalog number**

CE **Compliance with Medical Device Regulation (EU) 2017/745**

MD **Medical device**

WARNING LABELS (continued)



Protective earth



This Way Up: indicates the correct upright position of the transport package.



Keep Dry: keep the transport package away from rain.



The CE mark (from the French “Conformité Européenne”) certifies that a product meets the European Union health, safety and environmental requirements that ensure consumer safety.



Manufacturer



Fragile: the contents of the transport package are fragile and must be handled with care.



IPX label for the foot control switch



Microscope magnichanger tilt



Arm lock



Suspension arm limit stop knob

Authorized European representative

Serial No. (YY-year, MM-month, XXXX-serial no.)

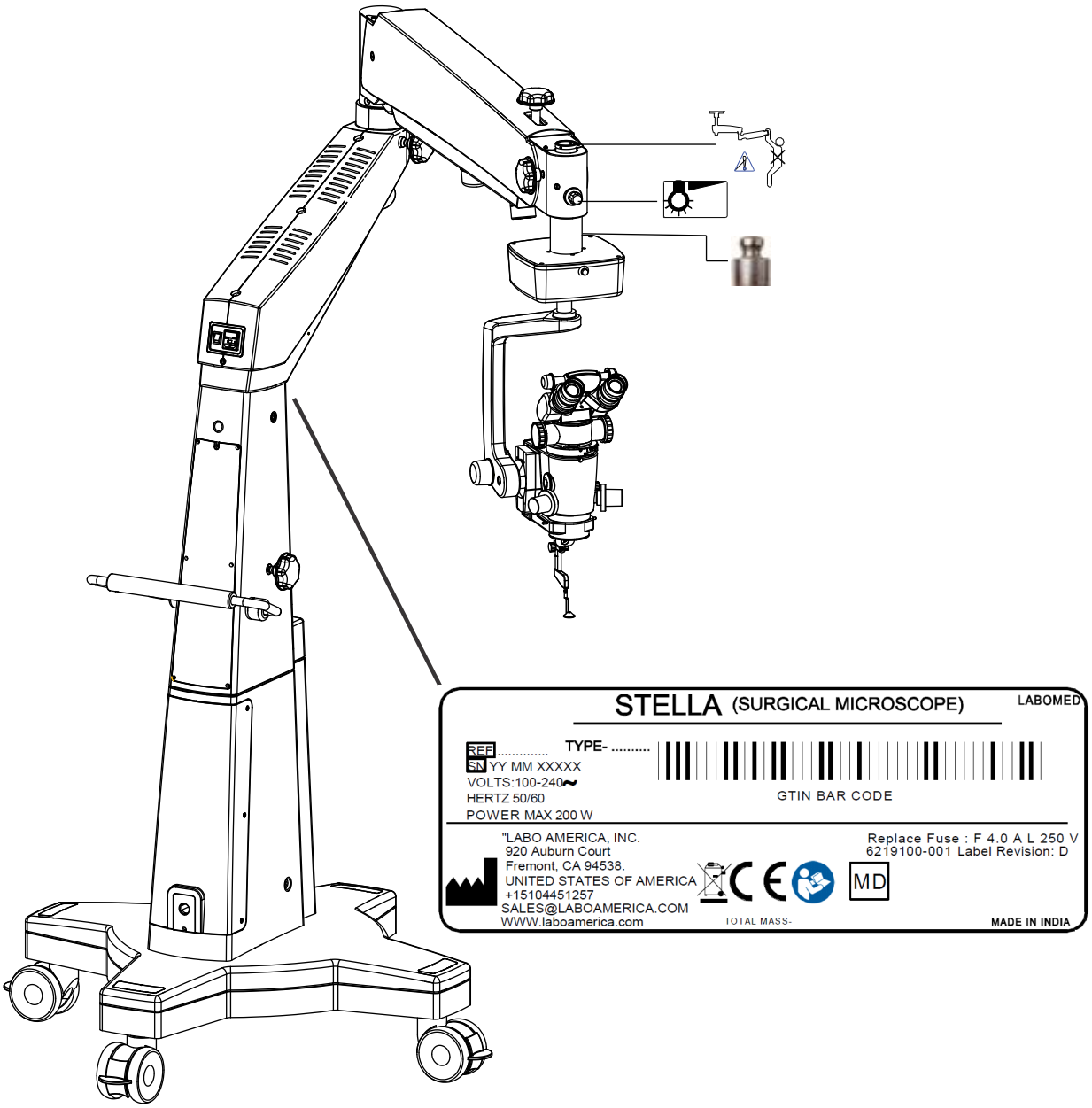
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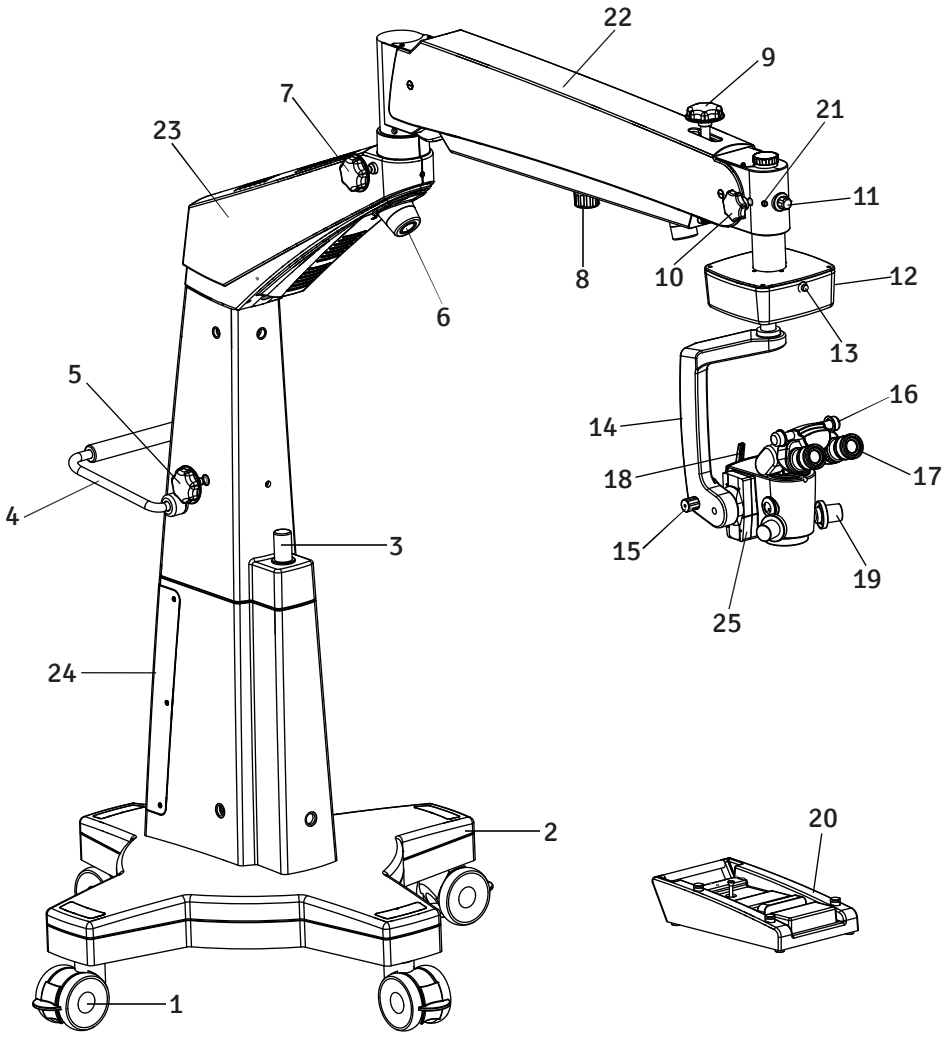
Max. safe load 12 kg

IP 20 ingress protection

WARNING LABELS (continued)

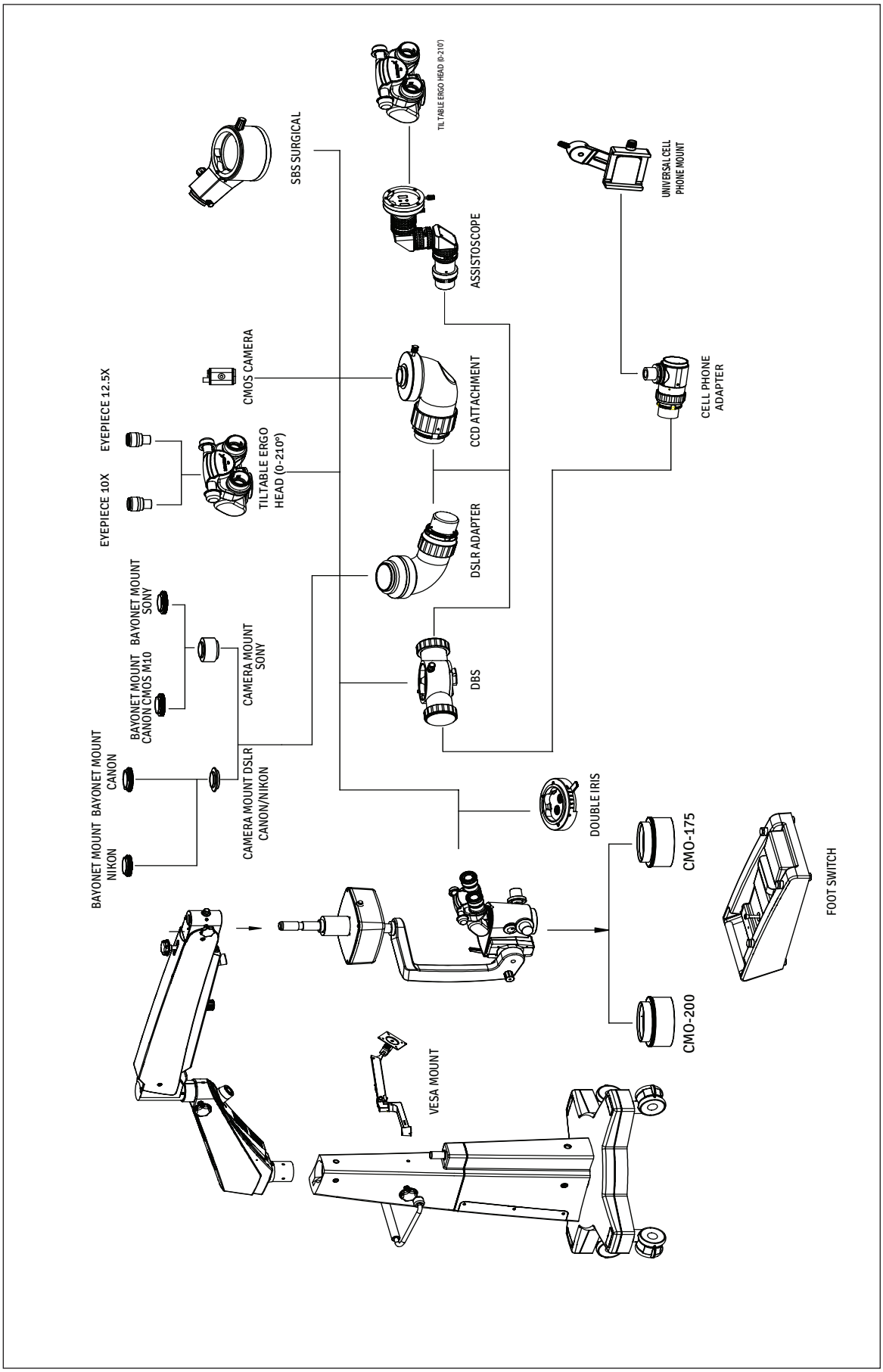


10. DESCRIPTION OF PARTS



1. Wheel with brake
2. Star base
3. Monitor mounting
4. Moving handle
5. Column locking knob
6. Fiber cable mesh holder
7. Suspension arm locking knob
8. Lower limit stopper
9. Up and down arm locking knob
10. X-Y coupling locking knob
11. Potentiometer
12. XYZ assembly
13. XYZ home button
14. Microscope carrier
15. Tilting knob
16. Ergo head
17. Eyepieces
18. Filter change lever
19. Handle
20. Foot switch
21. Safety screw
22. Suspension arm
23. Swivel arm
24. Column assembly
25. Z-axis assembly

11. SYSTEM DIAGRAM



12. UNPACKING

The instrument is delivered in subassemblies, together with one installation kit and one instruction and service manual.

On unpacking, check for the following:

1. Mobile base with brakes on caster 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. Pair of eyepieces, as ordered.

8. Foot switch assembly.

9. Power cord.

10. Set of sterilizable caps.

11. Installation kit:
    a) Allen wrench 5.00 mm
    b) Allen wrench 8.00 mm

12. Instruction and operating manual.

13. Dust cover.

13. INSTALLATION

1. Open the base assembly box as shown in Fig. 1.



Fig. 1

2. Remove the two dead bolts A and B as shown in Fig. 1. Remove the sheets and open the box as shown in Fig. 2.


Fig. 2

3. Unscrew the safety nut on the wooden block in the center of the base with the 22 mm spanner supplied with the microscope.

4. Referring to Fig. 2, roll out the base (Fig. 3). Clean it and keep it as shown. Lock all the casters.


Fig. 3

⚠ **CAUTION: THE BASE WEIGHS ABOUT 130 KG. 3 TO 4 PERSONS ARE NEEDED TO LIFT IT SAFELY IF REQUIRED.**


Fig. 4

5. Open the column box as shown in Fig. 4.

6. Unpack the column carefully as shown in Fig. 5.


Fig. 5

INSTALLATION (continued)

7. Referring to Fig. 6, mount the column in the base by aligning the corresponding holes in the column (A) and the dowels (B) in the base. Secure the column to the base with the 4 bolts under the base, using the 8 mm Allen key supplied with the instrument.

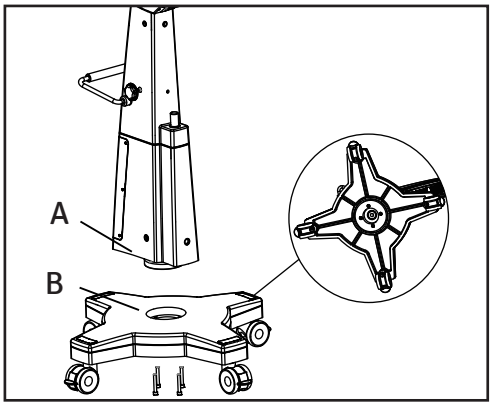


Fig. 6

8. Unpack the arm assembly box as shown in Fig. 7.



Fig. 7

9. Carefully take out the arm assembly and the tools as shown in Fig. 8.



Fig. 8

INSTALLATION (continued)

10. Align the arm assembly over the column and secure it with 4 screws as shown in Fig. 9.

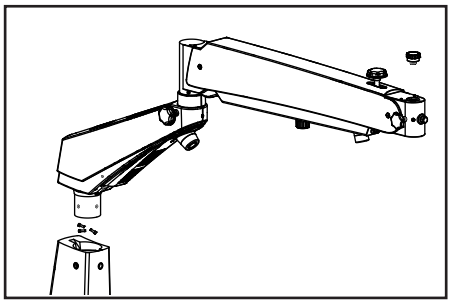


Fig. 9

11. Open another box and take the carrier assembly out from its packaging, as shown in Fig. 10.



Fig. 10

12. Remove all the contents from the 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.

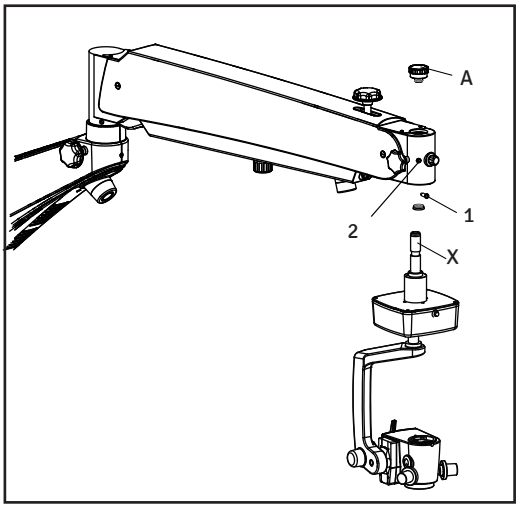


Fig. 12

⚠ **Safety screw:** make sure the safety screw (1) is installed and tightened at position (2), so that the coupling cannot detach if the threaded knob (A) is unscrewed accidentally.

INSTALLATION (continued)

Referring to Fig. 13, install the double iris, DBS and tiltable binocular tube on the magnichanger assembly.

Fit both eyepieces (D) on the ergo head and set the diopter to 0.

Make sure handles (F) have silicone covers.

The CMO (E) is factory-installed.

Attach the fundus viewing system (F), if supplied.

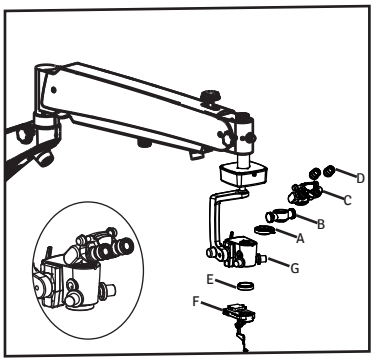


Fig. 13

Mounting the light guide

- Switch off the illumination system.
- The light guide comes pre-routed through the swivel arm (which houses the LED illumination system) and the suspension arm.
- Insert the light guide into the receptacle in the microscope from the back until it clicks into position (A) (see Fig. 14), and screw the cover back in place.

⚠ The fiber cable must index in position while being inserted into the fiber-optic mount.

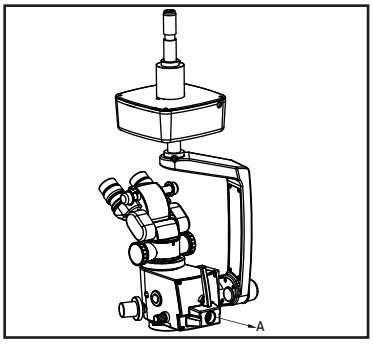


Fig. 14

⚠
- Make sure that the light guide is routed so that the carrier system and the surgical microscope are not obstructed and can move through their entire range without stretching, kinking or twisting the light guide.

Electrical connections

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

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

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

⚠ **Note: The power supply has a universal input of 100–240 V AC, 50/60 Hz. Before plugging in, follow the instructions on the electrical label at the bottom of the arm, shown as (A) in Fig. 15.**

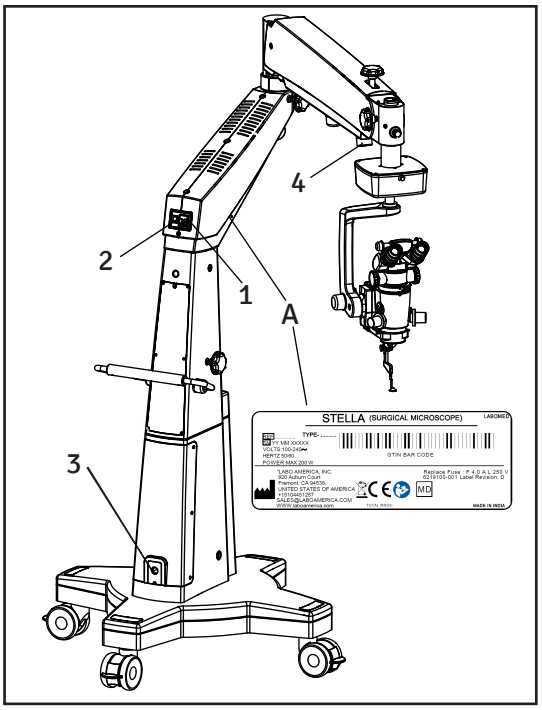
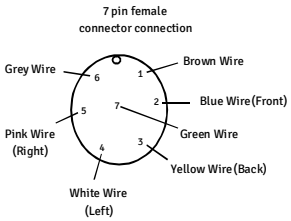


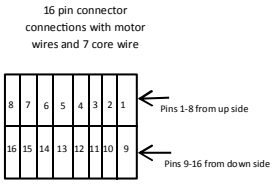
Fig. 15

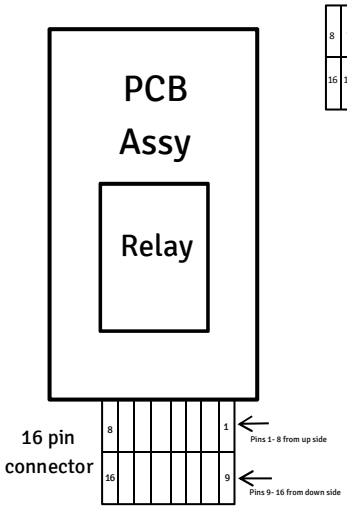
14. WIRING DIAGRAM

XY-Axis Motor Connection



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





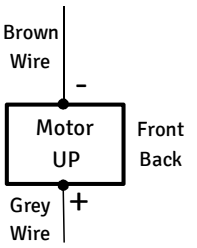
7 core wire connection on 16 pin connector

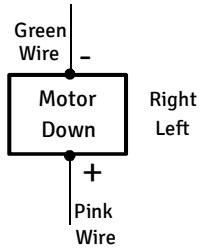
4. Yellow Wire
5. White Wire
8. Grey Wire
9. Brown wire
10. Blue wire
15. Pink Wire

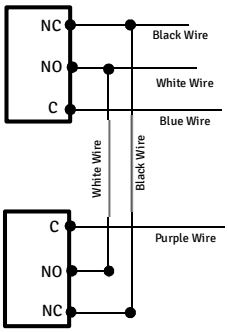
Green Wire is for Earthing Purpose

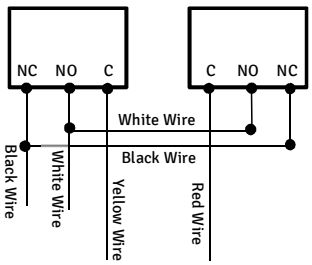
Motor wire connection on 16 pin connector

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)









15. CONTROLS AND FUNCTIONS

1. ON/OFF SWITCH (shown as 2 in Fig. 15)

It is on the back of the swivel arm. In the 'I' position, the microscope is on and the cooling fan runs.

⚠ **Caution:** Set the intensity control knob to minimum before switching the system on.

To extend LED life, switch the microscope off or raise the suspension arm to its top position when not in use.

2. INTENSITY CONTROL KNOB AND 70% MODE SWITCH

The knob is at the front of the suspension arm, shown as (C) in Fig. 16(A). The brightness of the field of view is set with a digital potentiometer in five equal steps of 20% each.

The potentiometer has one more function, "sudden reduction of brightness". Pushing the potentiometer in at the center reduces the field brightness to 70% of the setting; pushing it again restores 100% brightness.

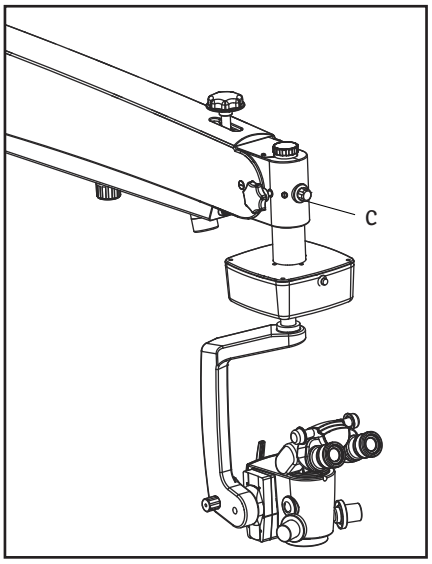


Fig. 16(A)

3. TRANSPORT HANDLE

See (X), Fig. 16(B). Use this handle to move the microscope from one place to another.

4. FOOT SWITCH HANGER

See (Y), Fig. 16(B). Use this bracket to hang the foot switch safely when it is not in use or during transport.



Fig. 16(B)

5. MONITOR ARM

See (Z), Fig. 16(B). Use this post for a monitor arm when required.

CONTROLS AND FUNCTIONS (continued)

6. SUSPENSION ARM UP/DOWN LOCKING KNOB

This knob locks the up and down movement of the arm in the desired position after initial focusing on the area of interest. Turn it clockwise to lock and counterclockwise to unlock. See knob (B) in Fig. 17.

7. FRICTION ADJUSTMENT KNOB FOR LIMITING DOWNWARD MOVEMENT

This knob sets the lower limit position of the suspension arm. It prevents the surgical microscope from coming into contact with the patient even if it is lowered inadvertently. See (E) in Fig. 17.

8. FRICTION ADJUSTMENT KNOB FOR ROTATION OF THE XY COUPLING

See (D) in Fig. 17. This knob locks or controls the rotary movement of the XY coupling and magnichanger.

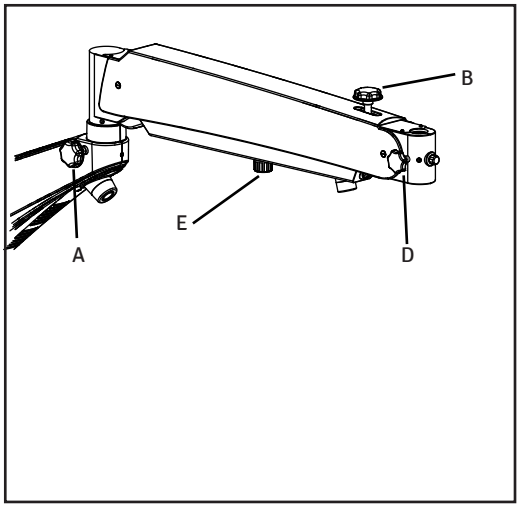


Fig. 17

9. FRICTION ADJUSTMENT KNOB FOR THE SUSPENSION ARM

See (A) in Fig. 17. Use this knob to adjust the friction on the swivel movement of the suspension arm. This prevents the surgical microscope from drifting or moving accidentally away from its original focus point. Adjust the friction as required; when the knob is fully tightened clockwise, the suspension arm movement is locked.

10. FRICTION ADJUSTMENT KNOB FOR ROTARY MOTION OF THE COLUMN AND SWIVEL ARM

In the STELLA, the truncated-pyramid column and the suspension arm rotate together for a better center of gravity in any arm position. The knob, shown as (F) in Fig. 18, adjusts the friction on the movement of the column and swivel arm. Adjust the friction as required; when the knob is fully tightened clockwise, the column and swivel arm are locked.

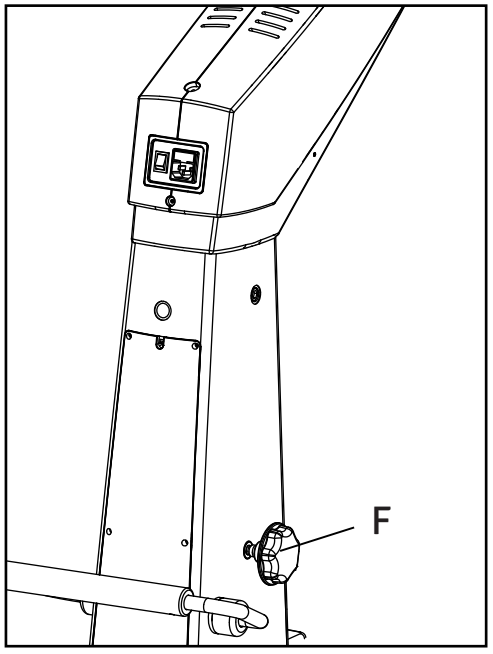


Fig. 18

CONTROLS AND FUNCTIONS (continued)

11. XY RESET BUTTON

The XY coupling allows fine, motorized positioning of the magnichanger in the horizontal plane. The range of travel is 50 mm × 50 mm.
The XY coupling has a re-centering mechanism. See Fig. 19: use the reset button (A) to move the XY coupling to the center position.

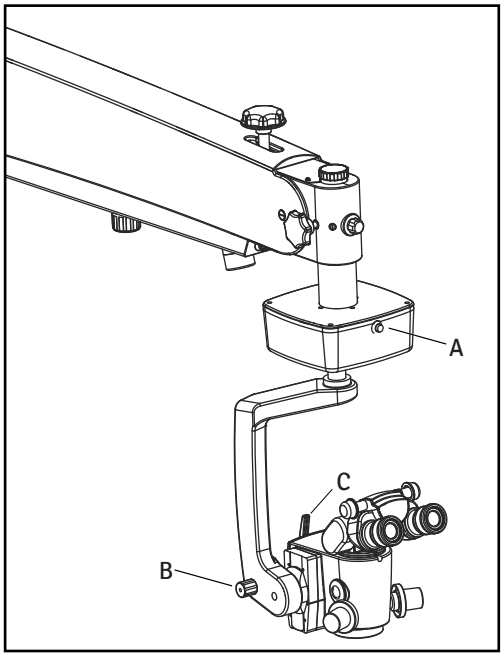


Fig. 19

12. SUPPORT ARM WITH TILT KNOB

See Fig. 19. Knob "B" tilts the angle of illumination. Turning the knob clockwise or counterclockwise tilts the optical axis by up to ± 90° to reduce the exposure of the macula to direct illumination. The magnichanger locks automatically in any position within the 0–180° tilt range.

13. SWING-IN FILTER LEVER

See Fig. 19. Lever "C" swings the protection filter into and out of the beam path. It has three positions:
1. No filter
2. Blue-blocking (yellow) retina protection filter. Use this filter when operating on the eye to protect the patient's eye against unnecessary exposure to radiation (blue light).
3. Red-free (green) filter for better recognition of blood vessels.

14. KNOB FOR THE ROTARY FILTER MECHANISM

See Fig. 20. Knob "A" moves the following four positions into and out of the beam path:

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

(ii) FAG (blue) filter. Fluorescein angiography (FAG) is a technique for examining the circulation of the retina and choroid (parts of the fundus) with a fluorescent dye. Sodium fluorescein is added to the systemic circulation and the retina is illuminated with blue light at a wavelength of 490 nanometers.

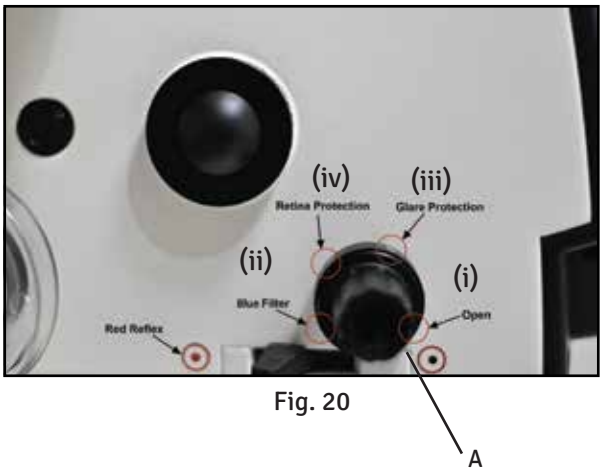


Fig. 20

CONTROLS AND FUNCTIONS (continued)

(iii) Retro-illumination contrast stop.
This stop reduces the stray light reflected from the sclera. Free passage diameter approx. 16 mm (with objective lens f = 200 mm).
Beyond a diameter of approx. 16 mm, the periphery has partial light transmission.

(iv) Retinal protection device.
Injuries are likely if the light intensity is high. This is why LABOMED provides a retina protection device that can be moved continuously in the light path.

15. SLIDING KNOB FOR RED REFLEX

See Fig. 21. Knob "B" switches the red reflex on and off. When the knob is at the red dot, the red reflex is ON; when it is at the black dot, the red reflex is OFF.
NOTE that this also affects the homogeneity of the illuminated area, which is normal behavior.

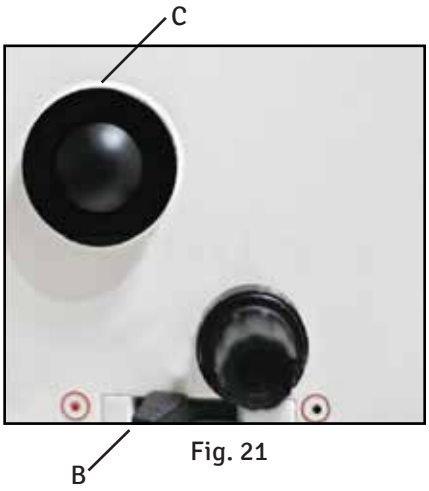


Fig. 21

16. CONNECTOR FOR MERLIN (VOLK) FUNDUS VIEWING SYSTEM

- A standard feature of the LABOMED STELLA.
- A black plate mounted at the bottom of the magnichanger (see (B), Fig. 22).
- This black plate has mounting holes for the Merlin (Volk) system.



Fig. 22

17. KNOB FOR MANUAL MAGNICHANGER ADJUSTMENT (OPTIONAL)

If the motorized magnichanger fails, use this adjustment knob on the microscope to set the required magnification manually. See (C), Fig. 21.

18. HANDLES

Provided at the front of the magnichanger to position the microscope. See (D), Fig. 22.

19. BRAKES

Press down the red crest on all four caster wheels to stop the stand from moving. To release, push the crest upward. See (E), Fig. 23.

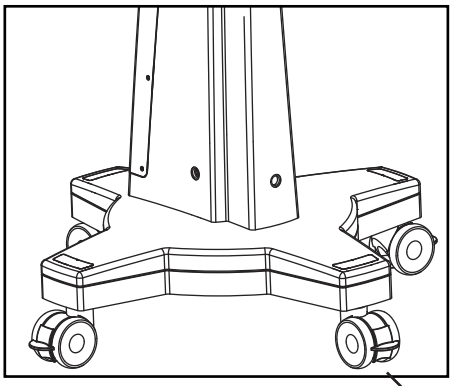


Fig. 23

CONTROLS AND FUNCTIONS (continued)

20. Z-AXIS MOVEMENT

The Z-axis coupling allows fine, motorized focusing on the area of interest within a travel range of 40 mm. Two foot pedals on the foot control move it up and down. See (X), Fig. 22.



Fig. 24

21. WIDE-FIELD EYEPIECES (Fig. 24)

(i) Eyecup:
For adjusting the distance between the eyepiece and the eye.

(ii) Diopter setting ring:
With adjustable diopter scale from -5 D to +5 D.

22. BALANCE SETTING TENSION ADJUSTMENT SCREW

If optional accessories are added to the microscope, the suspension arm tension must be adjusted to compensate for the additional weight, using the screw that balances the gas cylinder spring force. See Fig. 25: insert the 8 mm box spanner (LK-008 BS) with long handle, supplied with the microscope, in bolt (B). Turn it clockwise to increase the tension or counterclockwise to decrease it.

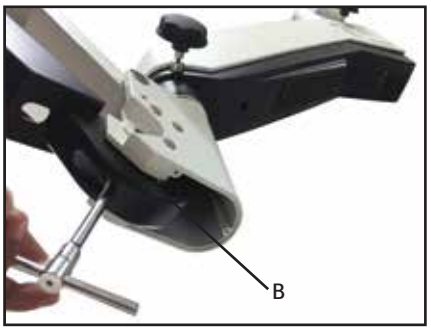


Fig. 25

23. COMPONENTS AND CONTROLS OF THE FOOT CONTROL

See Fig. 26. The wired foot control has 10 functions and a 3 m cable. It controls the following microscope functions:

1. **Connector** For the cable connecting the foot control to the microscope.
2. **Brackets** For hanging the foot control panel safely on the column.
3. **Joystick** The joystick (3) is used for motorized fine adjustment of the X-Y coupling.
4. **Foot switch (focus)** This switch operates the microscope “Focus” functions. The horizontal settings are:
– Left press: focus up
– Right press: focus down
5. **Foot switch for the magnification changer**
– Left press: forward (clockwise)
– Right press: reverse (counterclockwise)
6. **Illumination** The illumination switches 6A and 6B are preconfigured as follows: 6A: light intensity increase; 6B: light intensity decrease

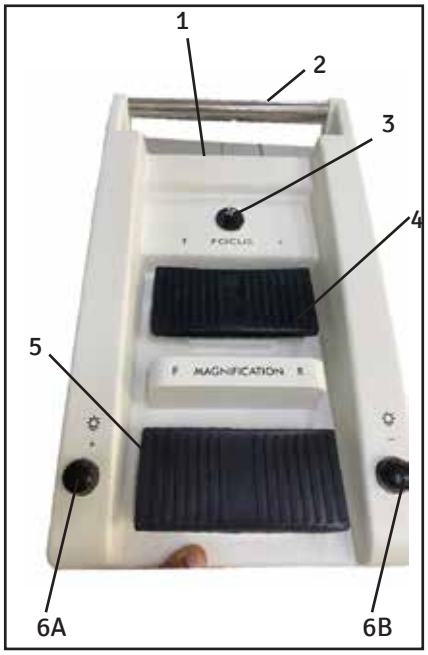


Fig. 26

16. USE OF THE MICROSCOPE

1. SETTING UP THE MICROSCOPE:

i. Switch on the microscope, check the unit against the checklist and move the microscope over the surgical field.

ii. Lock all the brakes on the base wheels after positioning the microscope at the area of interest, for stability.

iii. The tension on the microscope is factory-preset for the configuration ordered. You can still adjust the up and down force by turning the Allen screw clockwise or counterclockwise with an 8.0 mm Allen wrench. See Fig. 27 for the location of the tension adjusting screw.

iv. Position the suspension arm parallel to the ground. Set the magnichanger to the highest magnification and focus on the area of interest with the up/down range of the suspension arm. Lock the up and down movement of the suspension arm with the locking knob (B) in Fig. 27.

v. Set the interpupillary distance on the IPD scale for comfortable viewing. See (C), Fig. 28.

vi. The illumination is controlled with the control knob (A), Fig. 27. Turn it clockwise or counterclockwise to set the illumination level. During initial setup, you can press the potentiometer to reduce the intensity instantly to 70%; pressing it again restores 100%.

vii. Bring the blue-blocking filter into the light path.

2. SETTING UP MAGNIFICATION, PARFOCALITY AND PARCENTRATION (see Fig. 28)

i. Set the magnification changer to the highest magnification with the foot switch.

ii. Make sure that the magnification changer is engaged at an index (click-stop) position.

iii. Set both eyepieces to '0' diopter.

iv. Fine-focus on the area of interest with the left eye, using the foot switch.

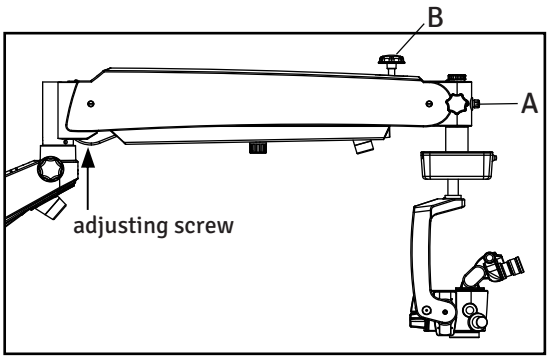


Fig. 27

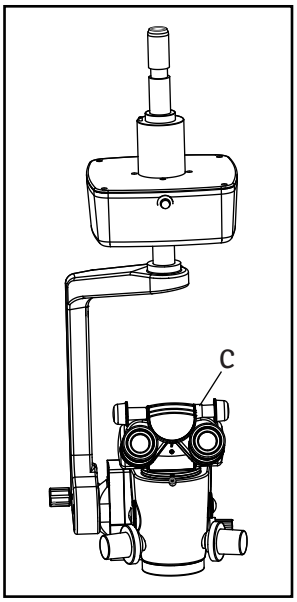


Fig. 28

USE OF THE MICROSCOPE (continued)

v. View the area of interest with both eyes.

vi. Center the area of interest in the field of view with the XY joystick.

vii. Change the magnification from highest to lowest with the foot switch. The area of interest should stay in focus and in the field of view.

viii. The microscope is parfocal and parcentered.

3. DEPTH OF FOCUS ADJUSTMENT

To increase the depth of focus, use the iris control. See (B), Fig. 29.

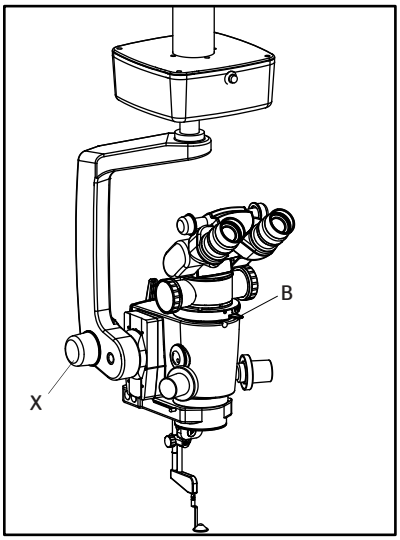


Fig. 29

4. USE OF THE RED REFLEX

See Fig. 30. Slide knob “B” to the red dot to illuminate the red reflex, or to the black dot if the red reflex is not required.



Fig. 30

5. USE OF ACCESSORIES

Use the left and right ports of the DBS to mount accessories such as an assistoscope, mobile phone adapter or camera adapter. Use Proline camera and mobile phone adapters for documentation. The light loss for the surgeon is only 20% and is not perceptible.

6. USE OF THE FUNDUS IMAGING SYSTEM

A fundus imaging system, e.g. Merlin (Volk), is usually installed between the surgical microscope and the patient. Make sure that the patient is not put at risk or injured by the motorized focusing system or by movement of the suspension arm.

⚠ With the fundus imaging system swung out of position, always position the microscope body so that the index arrow (1) of the microscope focus is in the middle of triangle (2) of the marking. See Fig. 31.

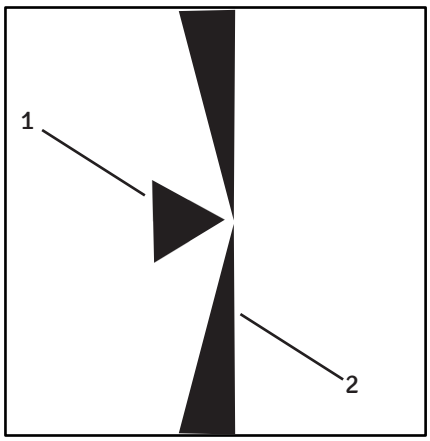


Fig. 31

USE OF THE MICROSCOPE (continued)

7. RECOMMENDATIONS FOR SAFE USE OF THE MICROSCOPE

Avoid looking directly into the light source, e.g. into the microscope objective lens or into a fiber light guide.

When selecting the brightness level for the patient's eye, always keep the strain on the patient's eye to a minimum.

When operating on the eye, always use a blue-blocking filter (provided with the microscope) to ensure that the patient's eye is not exposed to unnecessary (blue) radiation (retinal injury).

To protect the patient's eye against photoretinitis, a retinal protection device is provided. This device can be swung into the illumination beam path if no red reflex is required.

Use the tilting feature of the microscope to tilt the angle of illumination and reduce the exposure of the macula to direct light.

8. EMERGENCY USE OF THE MICROSCOPE

i. Failure of the zoom system

Adjust the magnification manually with the zoom control (1) on the microscope.

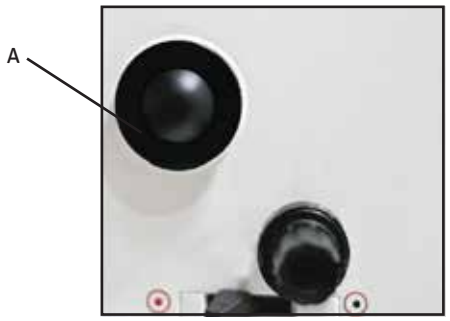


Fig. 32

ii. Failure of the X-Y coupling

- If the X-Y coupling fails, you can position the surgical microscope manually with the suspension arm.

iii. Failure of the focusing system

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

17. CHANGING THE OBJECTIVES & EYEPIECES

1. To remove an objective, turn it counterclockwise. To fit it, thread it in clockwise (Fig. 33).

2. To install the eyepieces, insert them into the eyepiece tubes of the observation head.

3. A range of objectives and eyepieces is available.

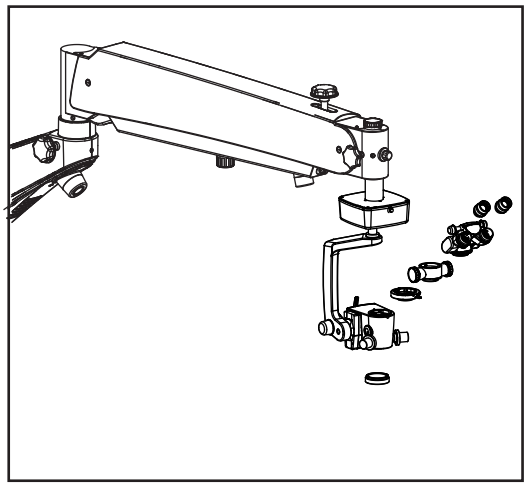


Fig. 33

18. REPLACING THE POWER SUPPLY

To replace the LED assembly, open the swivel arm covers. Detach the fiber-optic cable and replace power supply 'A' with a new assembly. Make the connections as shown in the wiring diagram and refit the arm covers. See Fig. 34.

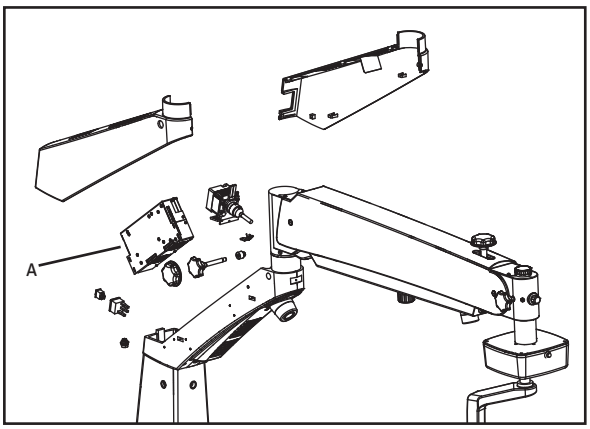


Fig. 34

19. FUSE REPLACEMENT

The fuse holder is part of the AC inlet, next to the on/off switch. Open the fuse compartment with a flat-head screwdriver. It holds two fuses: one in use and one spare. Replace the blown fuse with a new fuse and close the fuse compartment.

For fuse replacement, see the label shown in Fig. 35.

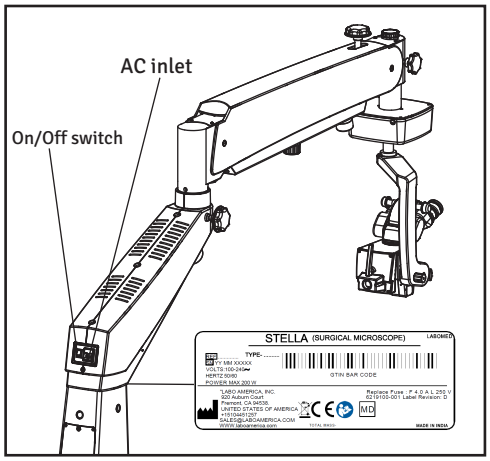


Fig. 35

20. THERMAL CUT-OFF

The instrument is designed for safe operation, with sufficient cooling provided by free and forced air circulation from the fans in the electrical box.
In addition, the instrument has a built-in “auto thermal cut-off” safety mechanism that operates if the LED temperature exceeds 70 °C. If the thermal cut-off fails, there is no risk to the instrument; only the LED may fail. In that case, only the LED needs to be replaced, and the thermal cut-off then works again. To replace the LED, call LABOMED service personnel or an authorized dealer.

LED specification: 3.7 V, 13.5 A

21. TENSION ADJUSTMENT

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

Tension adjustment for ceiling / wall mount

See Fig. 36. Insert the 8 mm box spanner (LK-008 BS) with long handle, supplied with the microscope, in bolt (B). Turn it clockwise to increase the tension or counterclockwise to decrease it.

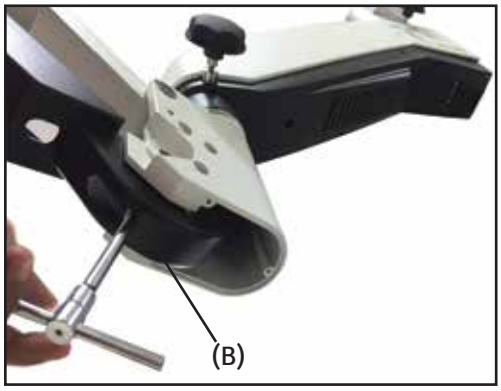
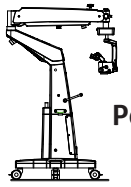
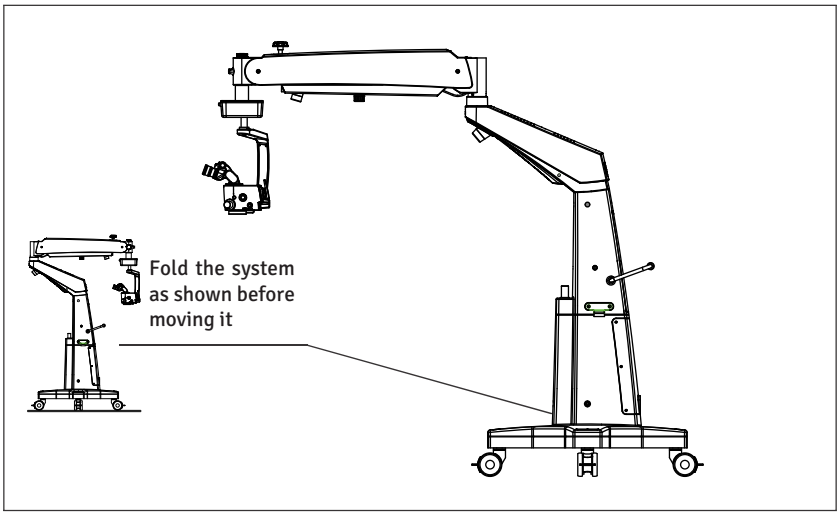


Fig. 36

22. MOVING POSITION



Position of the system for safe transportation.



RELOCATING THE STAND

- Switch off the unit at the power switch.
- Disconnect the power cable from the line supply.
- Disconnect the video cable from the video modules (e.g. video monitor, USB monitor) and the camera control unit.
- Release the locks by pressing their upper parts downward.
- Bring the unit into its moving position.
- Watch the height when passing through doorways.
- Avoid collisions of any kind.
- Do not move the stand over steps or edges: it may tip over!
- Be extremely careful when moving over slopes.
- Do not park the stand on slopes.
- Press the locks downward.
- Check that the stand is locked in position.

23. CLEANING AND DISINFECTION

THE FOLLOWING DISINFECTANTS ARE RECOMMENDED FOR CLEANING AND DISINFECTION

1. For cleaning and disinfecting the painted, powder-coated, anodized, plastic, screen-printed and bare metal external parts:
Use ordinary household bleach (sodium hypochlorite 5%), diluted to 5000 ppm (10 parts water to 1 part bleach).

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

PROCEDURE

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

NOTE:

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

24. AMBIENT REQUIREMENTS

For operation	Temperature Rel. humidity (non-condensing) Air pressure	+10 °C ... +40 °C 30% ... 90% 700 hPa ... 1,060 hPa
For transportation and storage	Temperature Rel. humidity (non-condensing) Air pressure	-40 °C ... +70 °C 10% ... 100% 500 hPa ... 1,060 hPa

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

25. CARE & MAINTENANCE

CARE & MAINTENANCE

This instrument is a high-quality technical product that requires no special periodic maintenance if handled carefully. To ensure optimum performance and safe working order, check its safe functioning once every 12 months as shown in the table below. We recommend having this check performed by our service representative as part of regular maintenance. If a failure occurs that you cannot correct using the troubleshooting table, attach an “out of order” sign to the instrument and contact our service representative for service parts, circuit diagrams and other assistance.

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:

- When accessories are not in use, protect them from dust, e.g. with a dust cover.
- Remove dust with a rubber blower bulb and a soft brush.
- Clean lenses and eyepieces with special optical cleaning cloths and pure alcohol.
- Protect the microscope from moisture, fumes, acids and cosmetic materials. Do not store chemicals close to the instrument.
- Protect it from improper handling. Never install other device sockets or unscrew the optical system or 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 with a damp disposable cloth.

CARE & MAINTENANCE (continued)

- Use the disinfectants given in the section “Cleaning and Disinfection” of this user manual.
- Clean lenses and eyepieces with special optical cleaning cloths and pure alcohol.
- Clean optical components with a lint-free cloth moistened with a little methanol or glass cleaner. Do not use ethanol or spirit.
- **LABOMED Max Lite** coatings are fungus-resistant. If you clean as described above, the coatings will not be damaged.

TROPICAL ENVIRONMENTS / FUNGUS:

LABOMED uses specific safety precautions in its manufacturing techniques and materials. Other preventive measures include:

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

OCCUPATIONAL SAFETY AND HEALTH PROTECTION:

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

Follow current regulations on hospital hygiene and infection prevention when preparing, cleaning and disinfecting the products.

INSTRUCTIONS

WORKPLACE:

Remove surface contamination with a paper towel.

REPROCESSING:

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

AUTOCLAVING:

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

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

26. TROUBLESHOOTING TABLE

This instrument is a high-quality technical product that requires no special periodic maintenance if handled carefully. To ensure optimum performance and safe working order, have its safety checked once every 12 months. We recommend having this check performed by our service representatives as part of regular maintenance. If a failure occurs that you cannot correct using the troubleshooting table, attach an “out of order” sign to the instrument and contact our service representative for service parts, circuit diagrams and other assistance.

PROBLEM	POSSIBLE CAUSE	REMEDY
No illumination at all	Power cable not plugged in	Plug in power cable.
	Power switch not pressed	Press the power switch.
	Defective instrument fuse	Replace the instrument fuse.
	Defective power cable	Replace the power cable.
	Line power failure	Contact the in-house technician.
	Failure of suspension system electronics	Contact the service department.
	Light guide not properly inserted in the arm or microscope	Insert the light guide properly to get maximum illumination.
Insufficient illumination	Brightness level set too low	Adjust the brightness with the brightness control knob.
	Light guide not properly inserted in the arm or microscope	Insert the light guide properly to get maximum illumination.
	Defective light guide (non-uniform illumination)	Replace the light guide.
Surgical field illumination inoperative or blinks	Light guide not properly inserted in the microscope arm	Insert the light guide as far as it will go.
	Failure of electronics	Use an OR illuminator for the surgical field. Contact the service department.
	Switched off by the micro switch on the suspension system	Move the suspension arm into the working position.

TROUBLESHOOTING TABLE (continued)

PROBLEM	POSSIBLE CAUSE	REMEDY
	Thermal cut-off in the lamp housing is contaminated.	Clean the thermal cut-off with a dry brush; blow it clean if necessary.
	Defective fan. Failure of system electronics.	Contact the service department. Illuminate the surgical field with an OR illuminator.
Up and down movement of the suspension system too stiff	Friction adjustment screw on the suspension system tightened too firmly	Loosen the friction adjustment screw on the suspension system as required.
Microscope unstable	Wheel brakes not applied	Apply the brakes.
No image visible in the field of view	Magnification changer not properly indexed	Index the magnification changer properly.

27. DISPOSAL

Dispose of the device in accordance with locally applicable laws and regulations.

28. SPECIFICATIONS

Technical Data (Specifications)

Observation tubes:	0–210° tiltable binocular head, f = 140 mm
Stereo base:	24 mm
Eyepieces: Standard:	WF 12.5x/18 mm with eye guards
Option:	WF 10x/18 mm with eye guards
Diopter adjustment:	± 5 D
Magnichanger:	MaxLite-coated, apochromatic, motorized stepper zoom system (tiltable and auto-locking in any position)
Motorized, 5 steps:	0.4X, 0.6X, 1.0X, 1.6X, 2.5X 5
Objective: Standard:	f = 200 mm; optional: f = 175 mm
FOV diameter:	64.30–10.30 mm
Magnification range:	2.80 – 17.50
Illumination field diameter:	55 mm
Fine focus:	Range 40 mm, motorized, low-noise
XY travel:	50 × 50 mm with auto reset
Light source:	UV- and IR-free 50 W LED
LUX:	60K
Maximum wattage:	200 W
Color temperature:	5700 K
Built-in filters:	Flip in/out: blue, yellow and green
Optional accessories:	Double beam splitter (straight), double iris attachment for depth of field management, assistant binocular attachment, Proline range of camera adapters.
Swivel arm:	470 mm
Suspension arm:	1000 mm
Swivel arm rotation:	±180°
Suspension arm rotation:	±180°
X-Y rotation:	270°
Vertical movement of suspension arm:	±300 mm
Foot switch:	10-function wired foot switch for XYZ, magnichanger, intensity control and on/off functions.
Brakes:	Manual, via casters
Max. suspension load:	12 kg
Base diameter:	850 mm
Base & column weight:	170 kg
Arm weight:	24.5 kg
X-Y suspension weight:	8.5 kg
Total height:	1880 mm
Maximum arm extension:	1620 mm

29. GUIDANCE TABLES

Guidance and Manufacturer's Declaration

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 CISPR 11	Group 1 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 IEC 61000-3-2	Class A	The STELLA is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power network that supplies buildings used for domestic purposes.
Flicker IEC 61000-3-3	Complies	

GUIDANCE TABLES (continued)

Guidance and Manufacturer's Declaration

Electromagnetic Immunity

All Equipment and Systems

Guidance and Manufacturer's Declaration - 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**
ESD IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	± 2 kV mains ± 1 kV I/Os	± 2 kV mains ± 1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential ± 2 kV common	± 1 kV differential ± 2 kV common	Mains 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the STELLA requires continued operation during power mains interruptions, it is recommended that the STELLA be powered from an uninterruptible power supply or battery.
Power frequency 50/60 Hz magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be those of a typical commercial or hospital environment.

GUIDANCE TABLES (continued)

Guidance and Manufacturer's Declaration

Electromagnetic Immunity

Equipment and Systems that are NOT Life-Supporting

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The 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 IEC 61000-4-6	3 Vrms 150 kHz – 80 MHz	(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 IEC 61000-4-3	80 MHz to 2.5 GHz @ 3 V/m	(E1) = 3 V/m	**Recommended Separation Distance:** **d=(3.5/v1)(Sqrt P)** **d=(3.5/E1)(Sqrt P)** **80 to 800 MHz** **d=(7/E1)(Sqrt P)** **800 MHz to 2.5 GHz** Where P is the maximum 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 level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. *Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME equipment or ME system is used exceeds the applicable compliance level, 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 reorienting or relocating the ME equipment or ME system. *Over the frequency range 150 kHz 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 Declaration - Electromagnetic Immunity

Recommended separation distance between portable and mobile RF communications equipment and the STELLA

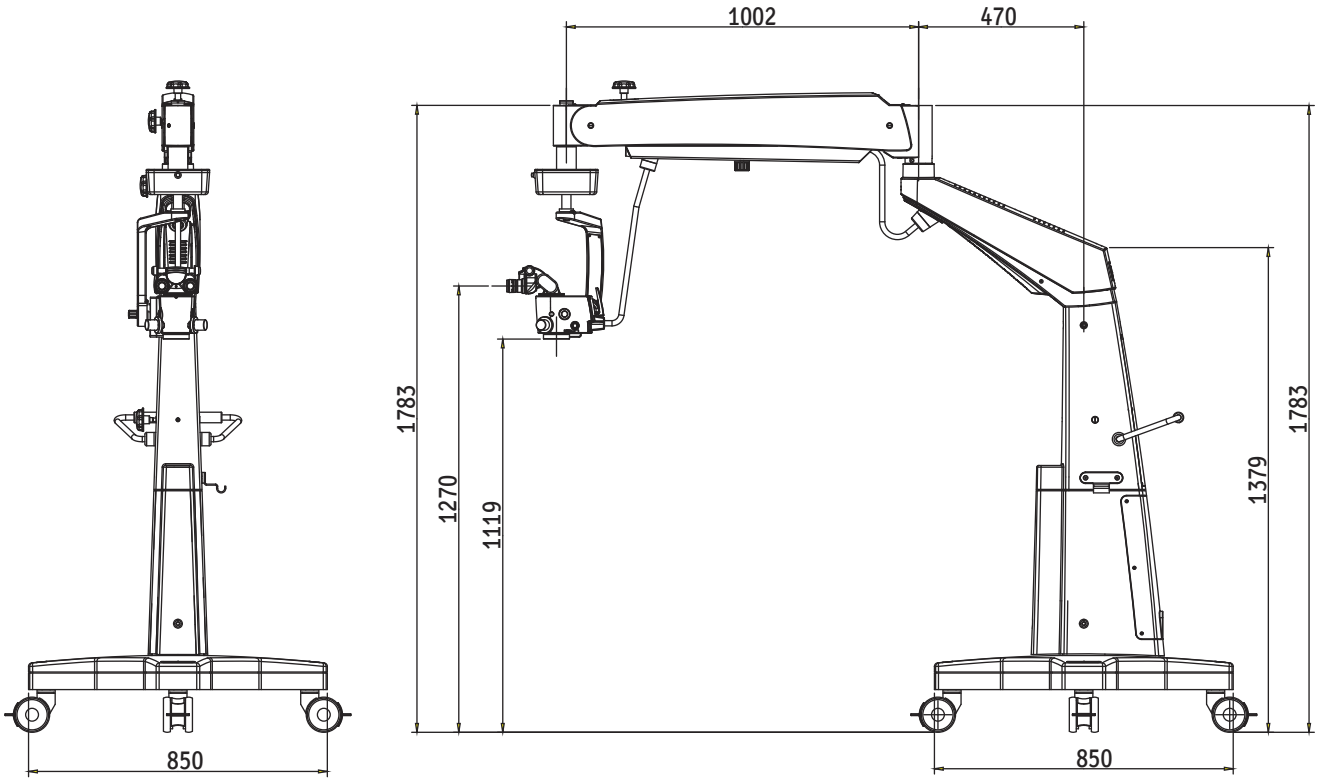
The STELLA is intended for use in electromagnetic environments in which radiated RF disturbances are controlled. The customer or user of the STELLA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and 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 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

30. DIMENSIONS



31. GLOSSARY

Ametropia Compensation	Compensation of nearsightedness or farsightedness for each eye with the two individual eyepieces (range: +5 to -5 diopters).
Working distance	Distance from the front lens to the object plane (200 mm).
Color temperature	The color characteristic of a light source. Color temperature describes a light source as warm or cold relative to natural light. Its unit of measure is the kelvin (K).
Light field diameter	The size of the field illuminated at a distance of 250 mm.
Field of view diameter	The visible area of an object that can be seen through the microscope. The greater the magnification, the smaller the field of view, and vice versa.
Green filter	Green filters in the ophthalmic microscope make red tissue (blood vessels) and the pink tissue of the optic nerve appear gray. The green filter is also known as a red-free filter.
Blue filter	The blue filter is used with fluorescein stain. The dye pools in areas where the corneal epithelium is broken or absent; it absorbs blue light and emits green.
Illumination intensity	The luminous flux from a light source onto a given area. Its unit of measure is the lux (lx).
LED	Light-emitting diode. An electronic semiconductor device that emits light when an electric current passes through it.
Eyepiece	The optical part facing the eyes, through which the enlarged image produced by the microscope is viewed.
Convergent beam path	The light beams for the right and left eye converge at a point 250 mm in front of the front lens. This distance corresponds to the working distance. The eye therefore does not have to focus on this point by itself, as it does with a parallel beam path.
DSLR Camera	(Digital single-lens reflex) camera with a digital imaging sensor.
CCD Camera	(Charge-coupled device) camera with a technology that stores a charge and moves it out of the photo sensor in an organized way.
CMOS Camera	(Complementary metal-oxide semiconductor) camera in which the image sensor is a silicon chip that captures and reads light.
DBS	(Double beam splitter) splits the light beam in two directions (to the eyes and to the side port) for simultaneous viewing and photography, videography or co-observation. The light is distributed 70% to the eyes and 30% to the side ports for photography, videography and co-observation.

32. WARRANTY

This product is warranted by LABOMED against defects in 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 that has had the serial number removed, altered or effaced. Nor shall this warranty be extended to a product installed or operated in a manner not in accordance with the applicable LABOMED instruction manual, nor to a product that has been sold, serviced, installed or repaired other than by a LABOMED factory or an authorized LABOMED dealer.

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

This warranty is in lieu of all other warranties, express or implied. All implied warranties of merchantability or fitness for a particular use are hereby disclaimed. No representative or other person is authorized to assume any other obligations for a LABOMED product. LABOMED shall not be liable for any special, incidental or consequential damages for any negligence, breach of warranty, strict liability, or any other damages resulting from or relating to the 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 selecting, checking, rechecking and packing to eliminate the possibility of error. If any shipping errors are discovered:

1. Carefully go through the packing material to make sure nothing was inadvertently overlooked when the unit was unpacked.
2. Call the dealer from whom you purchased the product and report the shortage. The materials are packed at the factory, and nothing 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 ends with 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, on delivery, the outside of the packing case shows evidence of rough handling or damage, ask the transportation company's agent to note "Received in Bad Order" on the delivery receipt. If, within 48 hours of delivery, concealed damage is found when unpacking the shipment and there is no exterior evidence of rough handling, ask the transportation company to make out a "Bad Order" report. This procedure is necessary for the dealer to maintain the right of recovery from the carrier.

Revision History

Rev. No.	Date of Release	DCR #	Change	App. By
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 added	S Bal
1.4	July, 2025	DCR/14/2025	Typo Error corrected (MDR Regulation (EU) 2017/745and caution for fibre optic cable indexing added	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

LABOMED
ideas for vision

Manufacturer: Labotech Microscopes India Pvt. Ltd.
Sales and Distribution:
Labo America Inc.
920 Auburn Court
Fremont, CA
94538
U.S.A.

Phone: 510-445-1257
Email:
sales@laboamerica.com
www.laboamerica.com

EC REP

Labomed Europe b.v
Essebaan 50
2908 LK Capelle aan den IJssel
The Netherlands
Tel: +31 (0)10 4584222
E-mail: info@labomedeurope.com
www.labomedeurope.com

CE

DQS Inc.
Labo America Inc.
Registered to ISO 9001:2015
BR Number 10005565

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