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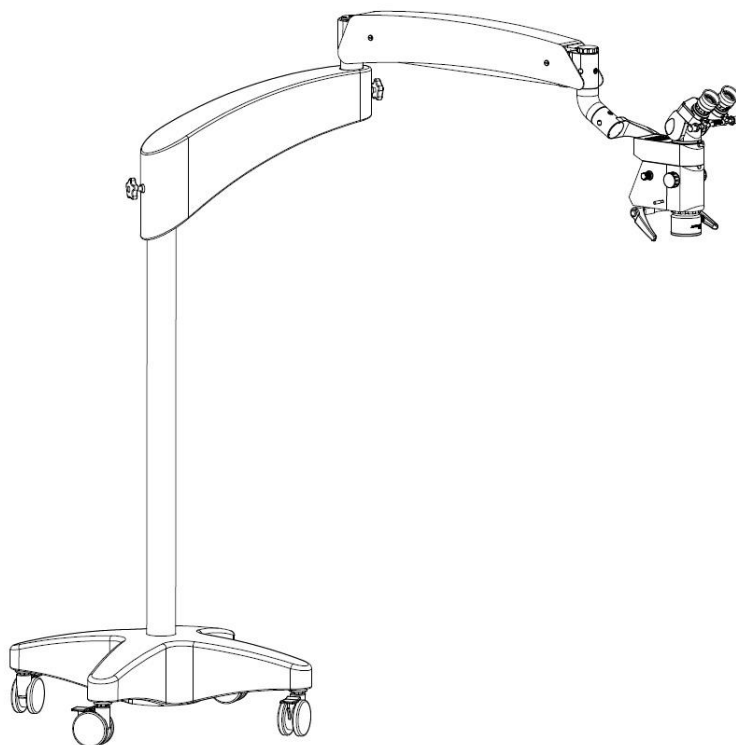


Instruction Manual

DOM3000D Operation Microscope

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Indications for Use Statement

510(k) Number: Exempted

Device Name: DOM 3000 Series Operation Microscope

Indications for Use:

The dental operation microscopes are AC-powered microscope intended for use in oral examination. They are used to aid in the diagnosis or surgeries of dental sectors as endodontic, implant, periodontics and prosthodontics esthetics, etc.

Prescription use _____ x _____
(Per 21 CFR 801 Subpart D)

and/or over-the counter use _____
(21 CFR 801 Subpart C)

Introduction

Thanks for purchasing DOM 3000D Microscope.

DOM 3000D Microscope has the following features:

- The newly-designed 4K Ultra HD (UHD) image recording system, based on Sony's high-end image sensor, supports high-speed (maximum frame rate 30fps) smooth display and recording of 4K resolution (non-software interpolation) surgical video, and the effective video pixels are four times that of the traditional image recording system of 1080P FHD;
- The maximum static image resolution is 12 million pixels, which is 6 times that of 1080P Full HD FHD system.
- The seamless control of the built-in camera can be realized by the mobile phone app, wireless remote controller, tablet computer, etc., including one-key video recording and setting of individualized parameters.
- The system applies a high-speed TF card as a storage medium and supports a TF card of maximum 128G.
- The image data recorded by the system can be downloaded wirelessly to the local machine for subsequent processing. It supports live streaming of video streams (requiring additional live broadcast modules), suitable for telemedicine, distance teaching and other areas.

This user manual covers an overview of the basic operation, troubleshooting, checking and maintenance of the DOM 3000 series Microscope system.

Keep this manual with the Microscope for future reference.

Specifications

Microscope System	
Eyepieces	12.5X/18B(Aperture:18mm)
Binoculars	0~210° inclinable
PD adjustable range	50mm~75mm
Diopter Range	±6D
Magnifications	DOM3000D: 3.6X~23X
Total magnification rate(*)	DOM3000D: ZOOM, built-in 4K UHD imaging system
Objective Lens	f=200mm-400mm
Diameter of FOV(*)	DOM3000D: 9.8mm~62.5mm
Illumination System	
Light source	LED module, variable brightness, over 6,0000h life span
Minimum illumination intensity (f=250)	> 80,000IX
Diameter of illumination spot	85mm
Filter	Orange, Green
Color temperature	6500k close to natural light, true color
Support System	
Standard base	Mobile base
Swing arm	Radius gyration: 460mm, 360° rotation
Microscope arm	Radius gyration:700mm, ±160° rotation, up & down ±315mm

Longest arm reach	1390mm
Dimension of base	516mm X 516mm
Net weight	115kg
Electric System	
Input Voltage	AC100-240V, 50/60Hz
Light source max consumption	20VA
Total consumption	70VA
Fuse	220V: T1.0AL 250V / 110V: T2.0AL 125V
Imaging System	
Video resolution	3840x2160 (4K, The effective number of pixels is 4 times that of 1080P)
Video frame rate	30fps@4K
Optional mode for video resolution	4K, 2.7K, 1440P, 1080P, 960P, 720P
Resolution of static image	4000x3000 (12 million, 6 times the effective number of pixels is 1080P)
Output Interface	Standard HDMI 2.0
Control Method	one-key video recording and camera parameter setting for wireless remote control, mobile phone, tablet computer, etc.
Settable parameters	White Balance, ISO, Sharpness, Metering Mode, Color Mode, Exposure Gain, etc.
Storage media	TF card (maximum supporting 128G)
Additional features (optional)	Live video broadcast function (additional purchase of live broadcast module)

Precautions

- In case any trouble happens, please refer to the trouble-shooting guide. If the failure cannot be fixed, please contact the authorized distributor or our Semorr support service.
- Do not use this Microscope in the location prone to fire, blast and dust or with high temperature. Use it indoor and be careful to keep its surface clean and dry.
- Check that all the wires are correctly and firmly connected before using. Ensure that the Microscope is well grounded.
- Please pay attention to all the ratings of the electrical connecting terminal.
- Turn off the main power first before replacing the main bulb, flash lamp and fuse.
- When replacing the power cable, please use the power cable in accordance with the notes in the instruction manual.
- Don't touch the surface of the Lens or prism with hand or hard objects.
- Read carefully the safety and other signals on this machine in order to use the product safely.

Displays and icons for safe use

In order to ensure the safe use of the product and to avoid any danger to users, or damage to property, important warning displays and icons are placed on the product and inserted in this manual. It's suggested for all users to learn the meaning of following displays and icons.

Displays/Icons	Meaning
	Manufacture Date
	Manufacture information
	European certificate of conformity
PN	Part number
SN	Serial number
	Warning
	Authorized representative in European community
	Ground fault protection
	Separate collection

Escape Clause

- Semorr shall not take any responsibility for damage due to fire, earthquakes, actions by a third party or other accidents, or the negligence and misuse of the user and use under unusual conditions.
- Semorr shall not take any responsibility for damage derived from the inability to use this Microscope, such as a loss of business profit and suspension of business.
- Semorr shall not take any responsibility for damage caused by operations other than those described in this Instruction Manual.
- Diagnoses shall be made on the responsibility of pertaining doctors and Semorr shall not take any responsibility for the results of such diagnoses.
- Semorr shall not take any responsibility for damage caused by the weakness of roof or floor of practices, which are not strong enough for supporting the Microscope.

Structural Components

- Surgical microscope is composed of optic system (objective lens, magnification system, optic observation system and eyepieces), illumination system, supporting stand and electrical installation. Corresponding accessories can be mounted basing on different needs.
- The details of surgical microscope are shown in Figure. 1

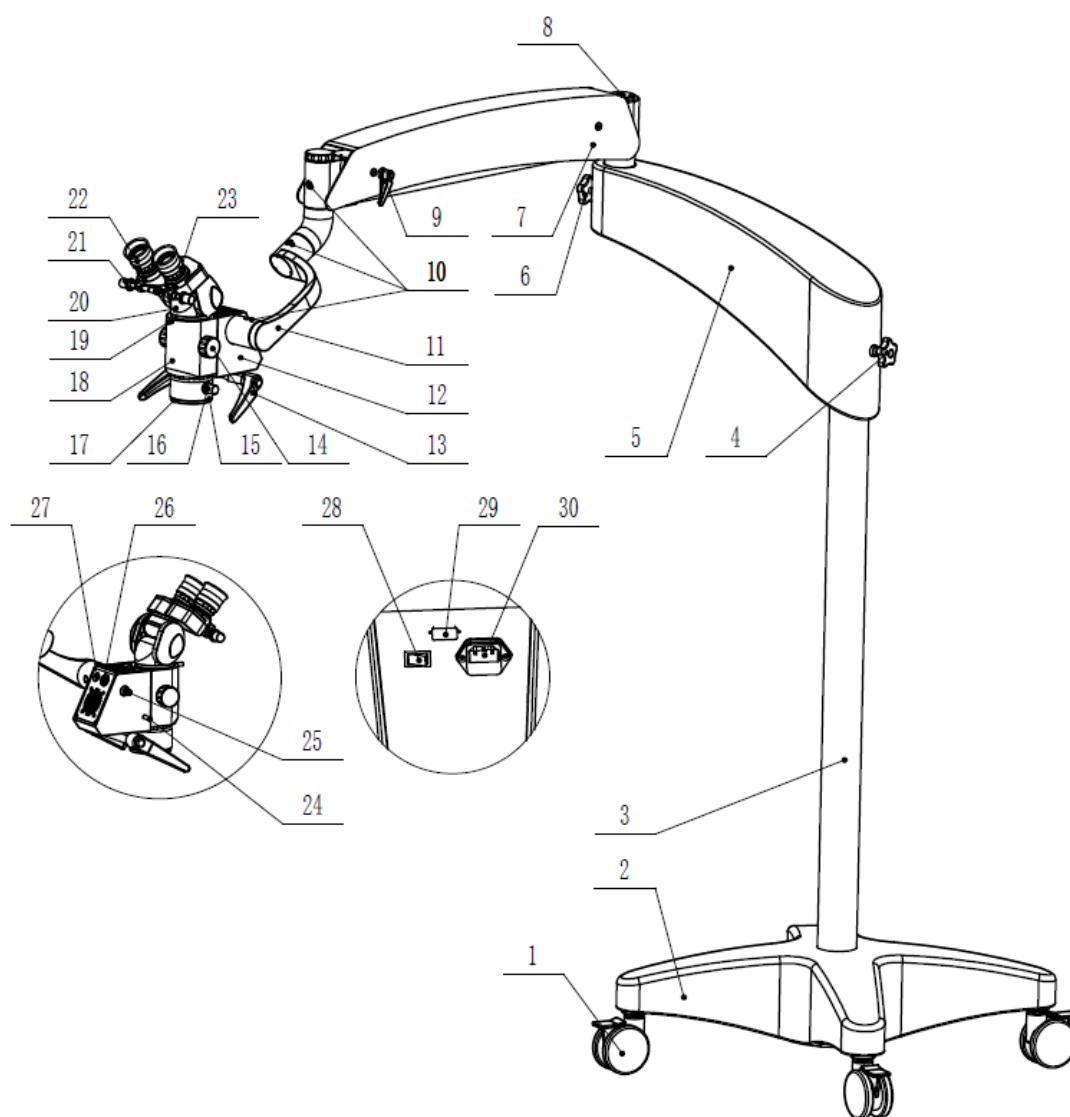
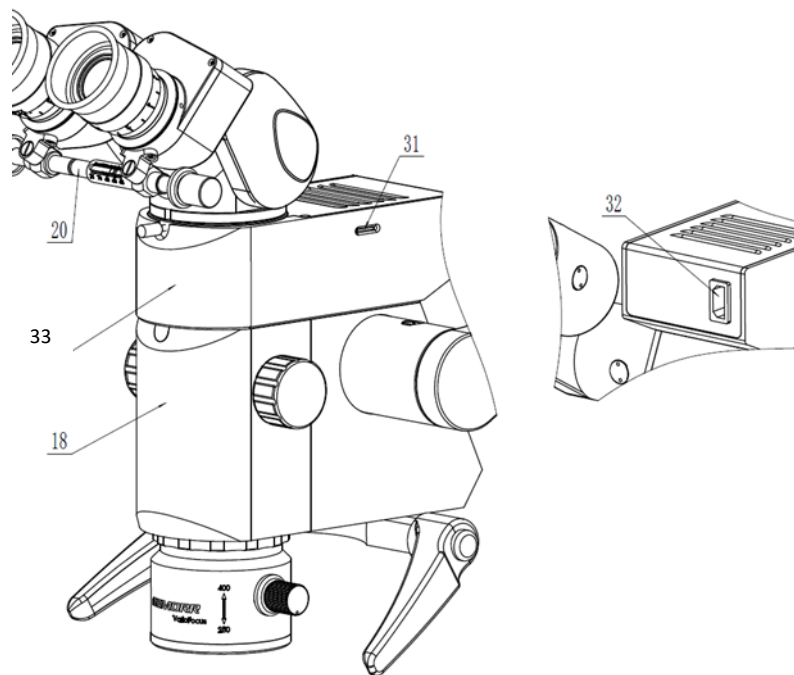


Fig.1 structure chart for microscope



- [1] Wheel: Move Microscope.
- [2] Mobile Base: Support Microscope.
- [3] Column
- [4] Lock knob of Cross Arm: Lock the cross arm from circumferential rotation.
- [5] Cross Arm: Power cable inside.
- [6] Lock knob of Swing Arm: Lock the Swing arm from circumferential rotation.
- [7] Swing Arm: Keep the balance of microscope and support up and down movement.
- [8] Balance knob: Maintain the balance of the microscope with accessories mounted.
- [9] Position lock knob: Lock swing arm from up and down movement.
- [10] Damping screw
- [11] Microscope Arm: Support microscope body
- [12] Illuminator: Provide lighting.
- [13] Handle
- [14] Magnification Knob: Adjust the microscope magnification.
- [15] Objective lens
- [16] Lens focusing knob: Fine focus
- [17] Splash cover
- [18] Microscope body
- [19] Lock screw: Fix Binoculars.
- [20] Binoculars
- [21] Pupil distance adjustment knob: Adjusting the pupil distance of binoculars
- [22] Eyepieces
- [23] Diopter adjustment ring: Adjust the Eyepieces visibility
- [24] Filter rod: Apply the filter or not.

- [25] Brightness Adjusting Knob: Adjust the brightness of the light.
- [26] Light socket: Supply power to illuminator
- [27] CCD socket: Supply power to CCD or other imaging system
- [28] Power Switch
- [29] HDMI Socket: Export HDMI images
- [30] Power Socket: Supply power for the whole microscope
- [31] TF card slot
- [32] HDMI socket
- [33] Built-in 4K UHD imaging module

Installation

The Microscope is easy to install with the help of this instruction manual. If there is any difficulty, please contact the authorized distributor or our Support service.

The microscope is packed in the carton with separated parts. Please follow the following steps to install the Microscope correctly.

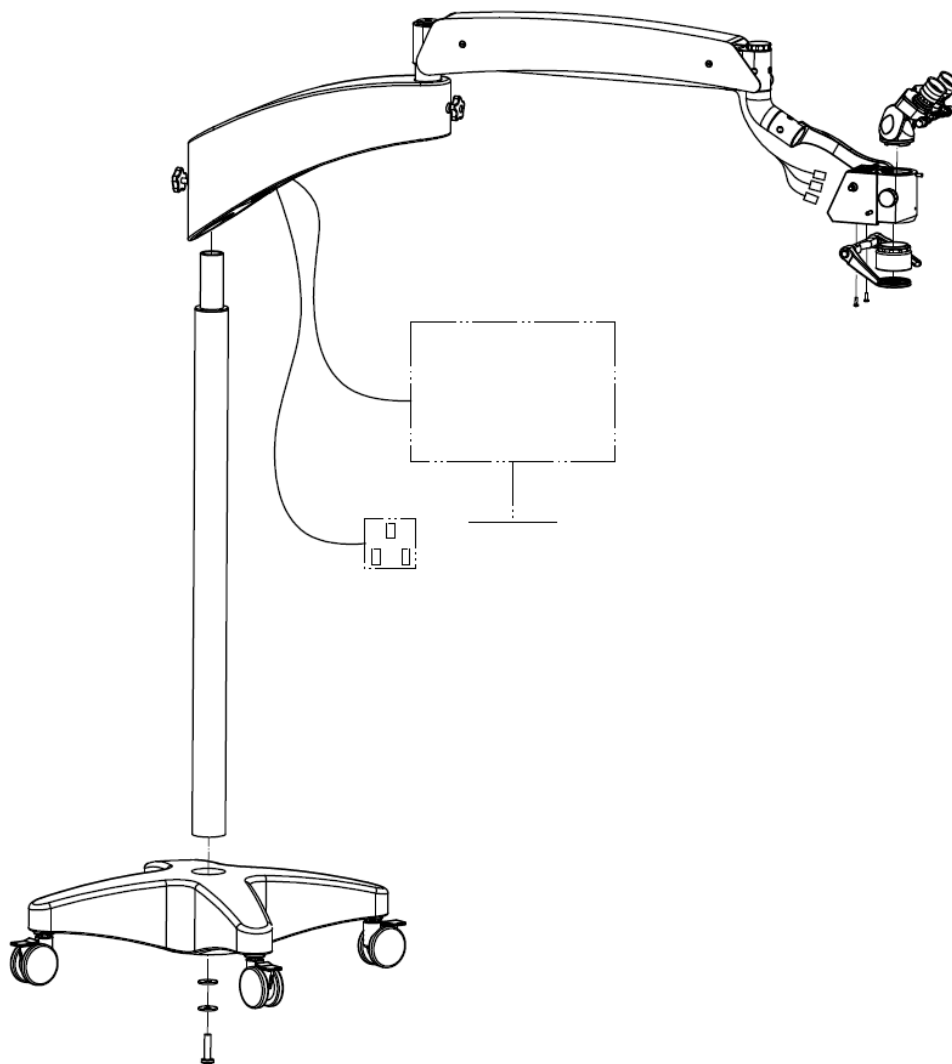


Fig.2 Microscope installation

Installation of Base

Unpack the box to take out the Base [2].

Take out the Column [3], wrung out screws and washer at the bottom. And then insert Column [3] into the hole of the base. Place the column into the hole of the base. Make sure to align the slot of the column with the cylindrical pin on the base.

Tighten the screw under base with a 10 mm Allen wrench (as pic below). Base installation is completed.

Installation of Cross Arm

Take out the Cross Arm part which includes the Cross arm [5], Swing Arm [7], Microscope Arm[11], Illuminator [12], Microscope Body [12], and install the assembly on the Column [3], tighten the Cross Arm lock knob [4] (Fig.2).

Installation of Handle

Take out the handle from box. Screw out the locking screws mounted on the bottom of Objective Lens. And then fix handle to microscope head. A 3 mm Allen wrench is needed, which can be found in the tool package.

Installation of binoculars

Take down the dust cap on top of microscope body[18], loosen the lock nut [19], take out the binoculars [20] and mount to the microscope body [18], tightening the lock nut [19]

Installation of Splash Cover

Take out splash cover [17] and mount it to objective lens [15].

Electrical connection of Cross Arm and Microscope

Plug the extended cable plug of swing arm [7] into the corresponding sockets. This product includes illumination plug (connecting illumination socket [26] to provide power for illuminator [12]), mini HDMI plug (connecting camera to transfer HD videos) and external power pack plug of camera (connecting cameras and offer continuous power). Take out power cable and connect power socket [30] and output power.

Note: If the microscope includes monitor and monitor frame, please fix it to the column [3], connect monitor power and then use HDMI cables to connect HDMI socket [29] and the HDMI input port of the monitor.

Check before use

- Confirm that the Voltage/Frequency is correct for the Microscope. Do not connect the microscope to the power besides indicated in this instruction manual.



Note: Use correct fuse according to local voltage:
220V: T1.0AL 250V / 110V: T2.0AL 125V

- The Microscope uses a 3 cores power cord. Please choose an appropriate Power Socket to match.



Note: In order to ensure good instrument grounding, please use the specified power cord or power cords meets articles IEC227 standard.



Note: Using unspecified cable may lead to poor performance of equipment.

- Power switch [28] on the Cross Arm. "ON" means power is on. "OFF" means power is off.
- Make sure the power switch is OFF before connecting the microscope to main power.

- Connect the microscope to main power and well grounded.
- Turn on the Switch to make sure the Bulb works well.
- After inspection, shut down the power supply.

Usage of Microscope

Adjustment of the Microscope before using

- Loosen slightly of all the lock knobs to test the flexibility of each mount.
- Hold the handle to move microscope to its focal plane (250mm from objective lens to operation surface). And then fasten to lock knob to get a stable observing position.



Note: The swing arm was well balance in factory. If an image kit is mounted to the microscope later, please rebalance the Swing arm [7] following the steps below:

- Fasten the position lock knob [9] of Swing Arm [7] from movement.
- Hold the Handle [13], swaying the Microscope [7] back and forth, tighten or untighten Microscope Damping Knob [10] according to the strength of damping force.
- Loosen the position lock knob [9], hold the handles [13], move the microscope up and down. Rotate balance knob [8] counterclockwise for mounting image kit to microscope, as shown in Fig. 4. Repeat the step until the up and down movement of swing arm is flexible.

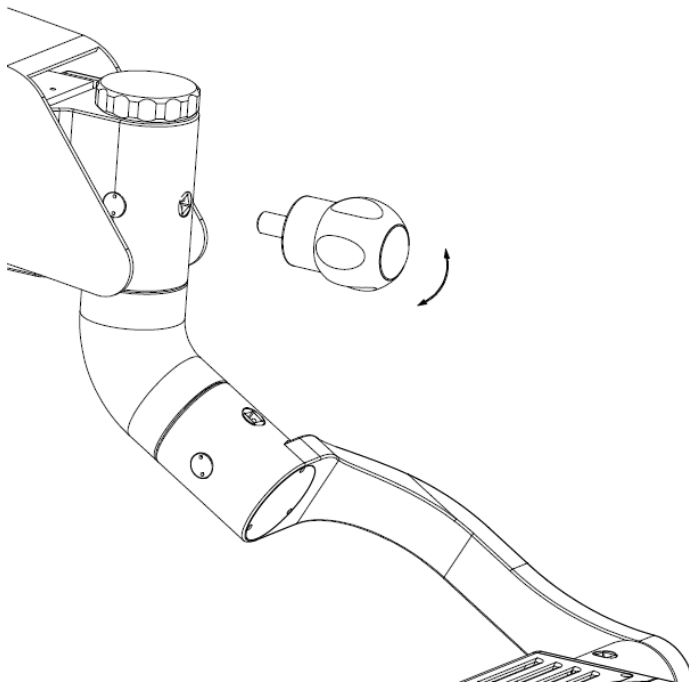


Fig. 3

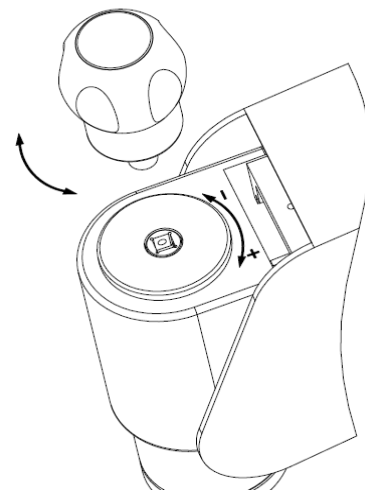
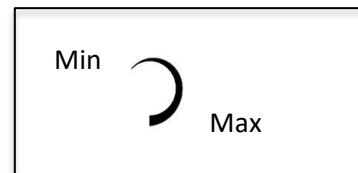


Fig.4

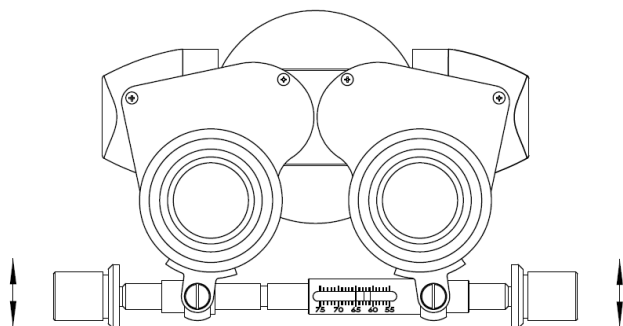
Regulation of Microscope in using

- Firstly move the Microscope to right place. Lock the brakes of the Wheel [1] to fix the Microscope.
- Connect the wire plug under the Cross Arm [5] into the Power Socket. Turn on Power Switch [28].

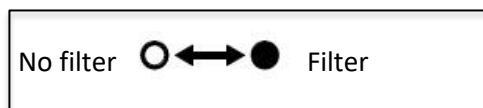
- Illumination Brightness control: rotating the Brightness Adjustment Knob [25] on the side of Illuminator [12] to regulate light intensity.
Min: clockwise rotating
Max: counterclockwise rotating.



- Changing Magnification: rotate Magnification Knob [14] to change magnification ratio.
- Focusing: rotate Magnification Knob [14] to minimum, loosen the Position Locking Knob [9], and hold the Handle [13] to move microscope to make sure the subject in the center of the spot, clear and sharp. Use fine focus knob to observe different positions.
- Diopter regulating: Adjusting range is $\pm 6D$, in step of 1D (100 degree).
- “+”: Myopia/ “-”: Hyperopia
- PD adjusting: turn the pupil distance adjusting knob under Eyepieces [21] until a clear and sharp stereo image appears in the microscope.



- Filter switch: pulling or pushing the Filter Rod-Yellow & Green [24] to apply the filter in or out of the optical path.



Move and storage after using

- Fold the Microscope arms to the side of Column [3]. Tighten the Lock Knob of each joint to fix the microscope.
- Shut down power supply.
- Loosen the brakes of the Wheel [1], hold the Cross Arm [5] and move Microscope carefully to avoid collision and dump.

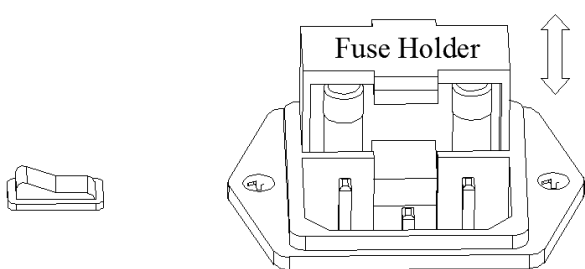


Note: when moving the equipment on slope ground, please move the Cross arm [5] and Swing arm [7] to the opposite direction of the slope, and move the wheels with brakes in the opposite direction of the moving direction.
For example, moving upward along the slope, Cross arm [5] and Swing arm [7] should be upward, two Wheels [1] with brake should be downward.

Routine Maintenance

Replacing the fuse

Remove the fuse in use from Power Socket [33] and insert a new one.



Note: Use correct fuse according to local Voltage. For safety, switch off the microscope and pull the plug out before replacing the fuse.

- The Microscope must be properly maintained. Please do not disassemble the Microscope without service technician's guide.
- Suggested cleaning and maintenance cycle is six months.
- Please do not put the Microscope in the environment with dust, moisture or containing corrosive gas.
- Please do not touch or remove the optical Lenses. If there is dust on the surface of lenses, blow away with blowing balloons or dust removal pen. Blood drop on lenses can be removed by cotton dipped in the mixture solvent of absolute alcohol and diethyl ether (proportion 1:1).
- Rub-up the external surface of the Microscope with wet cloth soaked in a mixture of 50% ethanol and 50% distilled water. Do not use corrosive cleaner.
- All the attachments not in use should be well preserved in box with desiccant inside.

Microscope cleaning and disinfecting

Trouble-shooting guide

In case any trouble happens, please refer to the trouble-shooting guide below. If the failure cannot be fixed, please contact the authorized distributor or Semorr support service.

Fault	Possible reasons	Solution
No illumination	Brightness adjusting knob in the minimum position	Adjust brightness adjusting knob
	Power cable not well connected	Plug again
	Fuse is broken	Replacing the fuse
Lighting is too dim	Brightness adjusting knob in the minimum position	Adjust brightness adjusting knob

Consumption Ordering

Item	Name	Specification	Recommended models
DOM3000 series Microscope	Fuse	220V: T1.0AL 250V 110V: T2.0AL 125V	51S-010H、51S-020L

Responsibility

A circuit diagram or an electrical components list will be provided to user for repair purpose. Please contact an authorized agent or Semorr support service.

Transportation and storage

The Microscope should be stored well placed in a moisture-proof warehouse. Violent vibration is prohibited during transportation.

The Microscope should be stored in the environment:

- ◆ Temperature: $-10^{\circ}\text{C} \sim +40^{\circ}\text{C}$
- ◆ Relative humidity: 30% ~ 80%
- ◆ Atmospheric pressure: 700 BPA and 1060 BPA
- ◆ No corrosive gas
- ◆ Good ventilation

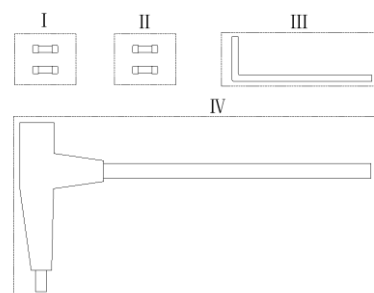
For short movement of the microscope, please fasten all lock knobs of the Microscope (see 5.3). If a there is slide is in the way of movement, the inclination angle should be less than 10 degree. The microscope must be packed in its original box for long distance delivery.

If the Microscope was stored in warehouse for more than 5 years, please contact an authorized dealers or Semorr support service to check the Microscope before using.

Please dispose the waste electrical and electronic equipment in accordance with relevant regulations and laws.

Spare parts and Tools

- i. 2 pieces of 220V T1.0 AL 250V fuses.
- ii. 2 pieces of 110V T2.0 AL 125V fuses.
- iii. 1 piece of 3 mm Allen wrench.
- iv. 1 piece of 10 mm Allen wrench.



Optional accessories and installation

Straight Binoculars tube (for ENT)

Loosen the Lock Screw [23] and demount the 210° Obliquity Binoculars [24]. Mount the Straight binoculars and fasten the Lock screw [23].

Inclined Binoculars tube (for surgery)

Demount the 210° Obliquity Binoculars [20]. Mount the Inclined binoculars.

Objective Lens (F200mm/F300mm/F350mm/F400mm)

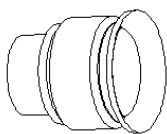
Remove the splash cover [17], demount the original objective lens [15] and replace with a specified one. Mount the splash cover [17] back.



Specifications	F200mm	F300mm	F350mm	F400mm
Magnification (Times against original spec)	1.25	0.83	0.71	0.63
Diameter of FOV (Times against original spec)	0.8	1.2	1.4	1.6
Diameter of illumination spot (Times against original spec)	0.8	1.2	1.4	1.6

10 X Eyepieces

Pull out 12.5X Eyepieces of Binoculars, and replace with 10X Eyepieces. The magnification ratio is 0.8 times against the original eyepieces. The observation field is the same.



16 X Eyepieces

Pull out 12.5X Eyepieces of Binoculars, and replace with 16X Eyepieces. The magnification ratio is 1.28 times against the original eyepieces. The observation field is the same.

Electromagnetic Compatibility

This equipment belongs to class A. It should be installed and used according to the Electromagnetic Compatibility requirements indicated in this instruction manual.

Portable devices as Wi-Fi router might cause disturbance to this equipment. Please use power cord that meets Electromagnetic Emission and anti-interference requirements:

Item	Length
Cable (10 A)	Less than 3m
Terminal wire	1.2m

Using unspecified accessories or cable might result in emission increasing or immunity reducing.

EMC precautions: Other medical instruments and equipment, which needs to be installed in the same location with this instrument, shall comply with the same electromagnetic compatibility principle. The equipment which is unable to comply with the electromagnetic compatibility or is known with poor electromagnetic compatibility shall be installed 3 meters at least away from this equipment and powered by different power supply.

Guide and Manufacturer's statement----Electromagnetic Emission		
This equipment is designed to be used in the following electromagnetic environment:		
Emission test	Compliance	Electromagnetic environment-- Guide
Frequency emission GB 4824(CISPR 11)	1 Group	The radio frequency energy emitted by this equipment is for its internal use only. Therefore, its radio emission is very low. It's not probable to cause interference to the other electronic equipment installed nearby.
Frequency emission GB 4824(CISPR 11)	Class A	None home use. No applicable to low-voltage supply network.
Harmonic radiation GB 17625.1	N/A	None home use. No applicable to low-voltage supply network.
Voltage fluctuation/ Scintillation emission GB 17625.2 IEC 61000-3-3)	N/A	None home use. No applicable to low-voltage supply network.

Guide and the manufacturer's statement - Electromagnetic Interference

This equipment is designed to be used in the following electromagnetic environment:

Perturbation resistance test	IEC60601 Experimental electric level	Actual electric level	Electromagnetic environment Guide
Electrostatic discharge(ESD) GB/T 17626.2 (IEC61000-4-2)	±6kV Contact discharge ±8kV Air discharge	±6kV Contact discharge ±8kV Air discharge	The ground should be wood, concrete or ceramic tile. If the ground covered with synthetic material, the relative humidity should be more than 30%.
Electrical fast transient burst GB/T 17626.4 (IEC61000-4-4)	±2kV power supply cord ±1kV Input & output cord	±2kV N/A	Power supply should be qualified for using in a typical commercial or hospital environment.
Surging GB/T 17626.5 (IEC61000-4-5)	±1kV cord to cord ±2kV cord to floor	±1kV ±2kV	Power supply should be qualified for using in a typical commercial or hospital environment.
Voltage sag , short supply interruption and the voltage change of power supply cord GB/T 17626.11 (IEC61000-4-11)	< 5% UT, lasts 0.5 cycles (above UT, > 95% temporary reduce) 40% UT, lasts 5cycles(above UT , 60% temporary reduce) 70% UT, lasts 25cycles(above UT ,30% temporary reduce) < 5% UT, lasts 5s (above UT ,> 95% temporary reduce)	< 5% UT, lasts 0.5cycle (above UT ,> 95% temporary reduce) 40% UT, lasts 5cycles(above UT , 60% temporary reduce) 70% UT, lasts 25cycles (above UT,30% temporary reduce) < 5% UT, lasts 5s (Above UT, > 95% temporary reduce)	Power supply should be qualified for using in a typical commercial or hospital environment.
Power frequency magnetic field (50/60Hz) GB/T 17262.8 (IEC 61000-4-8)	3 A/m	3 A/m	Power frequency magnetic field should have a typical power frequency magnetic field characteristic of commercial or hospital environment.

Note: UT means voltage of Ac power grid before applying test voltage.

Guide and the manufacturer's statement - Electromagnetic Immunity

This equipment is designed to be used in the following electromagnetic environment:

Perturbation resistance test	IEC60601 Experimental electric level	Actual electric level	Electromagnetic environment Guide
Radio frequency transmission GB/T 17262.6 (IEC61000-4-6)	3 V(Valid values) 150kHz - 80MHz	3 V(Valid values)	The equipment which is unable to comply with the electromagnetic compatibility or is known with poor electromagnetic compatibility shall be installed 3 meters at least away from this equipment and powered by different power supply. The distance is calculated with formula by the transmitter frequency. The recommended separation distance $d = 1.2 \sqrt{P}$ 150kHz-80MHz $d = 1.2 \sqrt{P}$ 80MHz-800MHz $d = 2.3 \sqrt{P}$ 800MHz-2.5GHz In the formula: P- based on maximum rated output power supplied by transmitter manufacturers. Unit is Watt. d- introduced separation distance. Unit is Meter. Stationary field strength of the Radio Frequency transmitter is measured based on electromagnetic site survey, in every frequency range. There will be interference near the mark 
Radiofrequency radiation GB/T 17262.3 (IEC61000-4-3)	3 V/m 80MHZ - 2.5GHZ	3 V/m	

symbol of the following Microscope.

Note 1: On the frequency of 80 MHZ and 800 MHZ, use the formula of high frequency.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic signal may be affected by buildings, objects or human body.

A Stationary transmitter such as: wireless cellular/cordless phones and grounded mobile radio base station, amateur radio, Am and FM radio and television broadcasting etc., the field intensity in theory can't be predicted.

For evaluating electromagnetic environment of fixed Radio Frequency transmitter, electromagnetic site survey should be taken into account. If measured Microscope field strength is higher than the mentioned Actual electric level, please make sure the Microscope runs well.

If there is abnormal performance, supplementary measures may be required, such as adjusting the direction or position of the Microscope.

B Throughout 150 KHZ - 80 MHZ frequency range, field strength should be lower than 3 v/M

Recommended separation distance between Portable or mobile radio communication equipment and other equipment

This Microscope is expected to be used in the environment with radiation harassment controlled.

Based on maximum power output, you can prevent electromagnetic interference by keeping minimum distance from Portable and mobile radio communication equipment with the Microscope.

Maximum rated output power of Transmitter W	Corresponded isolation distance (m) under different frequency transmitter		
	150kHz - 80MHz $d = 1.2\sqrt{(P)}$	80MHz - 800MHz $d = 1.2\sqrt{(P)}$	800MHz - 2.5GHz $d = 2.3\sqrt{(P)}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the above unmentioned maximum rated output power of the transmitter, recommended isolation distance (d) can be calculated by the formula in the Column of transmitter frequency. Unit is meters (m), P is maximum rated output power, supplied by the transmitter manufacturers, unit is watts (W).

Note 1: at 80 MHz and 800 MHz frequency, use high frequency formula.

Note 2: these guidelines may not be suitable for all situations, electromagnetic propagation will be effected by buildings, objects and human body.

Support Service

When calling for support service, please provide the following information about your unit:

Mode type

Product Serial number (SN) (Shown on the label stick on microscope body.)

Purchasing date

Detailed description of Problem

DOM 3000D OPERATION MICROSCOPE

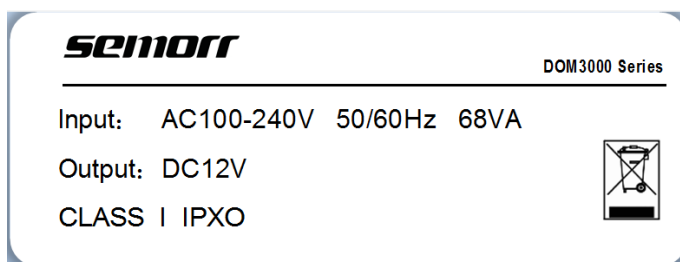
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