

User's Guide
for
Portable Ultrasound
Bio-microscope
(UBM)

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Introduction

Dear User:

Welcome to use Portable Ophthalmic UBM & image workstation made by us.

This unit is a precise ultrasound instrument, designed for detecting the anterior part of eye structure and disease, including cornea, chamber angle, ciliary body, iris, anterior chamber and so on.

This User's Guide is designed as a training and reference manual. We recommend you carefully read and follow the steps in this guide to ensure optimum performance from your new instrument.









If you need more information, please contact with after-sales of our Company:

Classification













This unit is classified as Class I, Type B instrument.

This product has got ISO9001 approval.

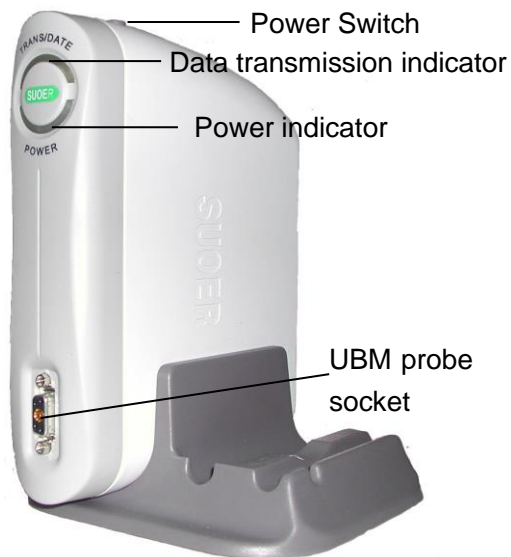
Symbol

- | | | | |
|---|--|---|--------------------------------------|
|  | Protective grounding |  | Type B |
|  | Power |  | Warning, it may cause hurt or damage |
|  | Attention May do harm to machine and accessories. How to prevent such problems | | |
|  | Hint, how to use it better | | |
|  | Danger, high |  | Refer to the instruction |

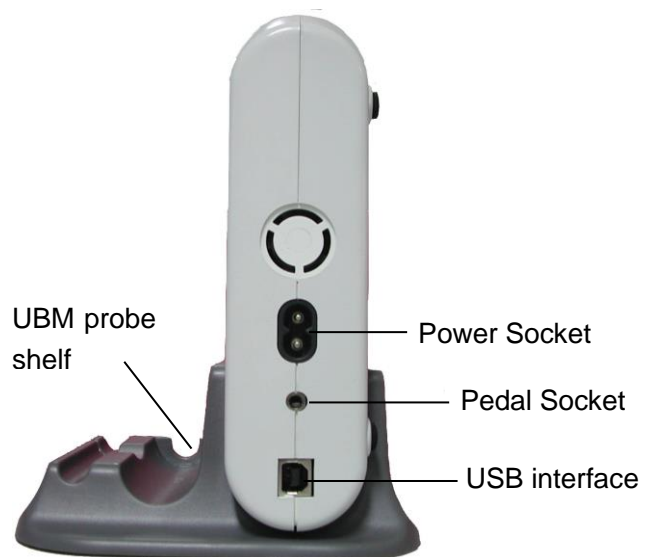
Precautions

-  This instrument requires the power supply of 90~230V, 50HZ±2%. If the local power net could not fit the requirement, then the regulated power supply is recommended. To ensure that the workstation could work steadily, a UPS is recommended. All parts of the system should be connected to ground for protection.
-  Improper power supply may cause instrument damage or person injury.
-  All the accessories as well as CD should be well kept. If any thing is missing, the instrument could not be warranted.
-  The probe is key, delicate and expensive. Do not stress it, knock it or fall it from high place. Do not twist or pull the leading line violently.
-  The main unit and probe should not be disassembled by user. If there are any problems, please send it to the warranty station.
-  It is forbidden that users install other software by themselves. Installing other software may cause unexpectable system problems, such as collision of different devices, speed slow-down, virus attack and so on.
-  Don't change the system setting and parameters arbitrarily.
-  The instrument should be kept away from strong magnetic or electric field or other strong disturbance source.
-  The instrument should be placed at drafty place without directly irradiated by the sun.
-  Don't store or use this instrument in moist environment.
-  When the ambient temperature is under 10°C, the instrument should warm up for 5 minutes before it begins to work.
-  As to the safety and effective result caused by ignoring the declaration above, our company does not take the responsibility.

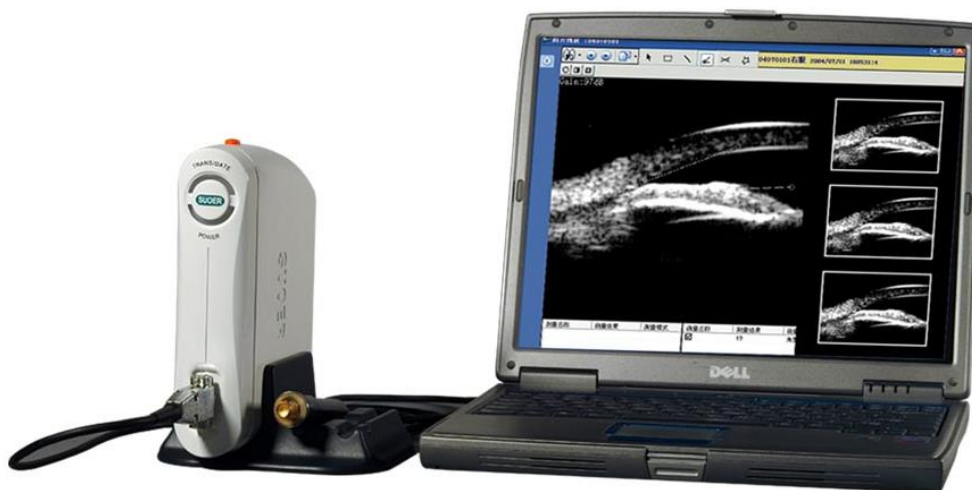
Instrument Components



Pic.1 Front view



Pic.2 Back view of



Pic.3 Portable computer image workstation

Introduction and Clinic application

1. Introduction

This Ophthalmic UBM is a professional ophthalmic ultrasound image device. It is composed of main unit, 50MHz fan scan probe, image workstation and so on.

This device is for ultrasound diagnose in hospital or clinic. Its main application is detecting the anterior part of eye structure and disease, including cornea, chamber angle, ciliary body, iris, anterior chamber and so on.

This device should be operated by trained doctor.

2. Clinic application of UBM

- Anterior chamber angle detecting and form observing
- Measure the depth of anterior and posterior chamber.
- Detecting the thickness of iris, the form of tissue around iris and attach position.
- Get to know the form, position of lens and its relation with tissues around
- Detecting the form and location of ciliary body
- Diagnose whether the ciliary body or choroidea is off its place, and know the degree of dropsy.
- After the artificial lens is planted, its location can be observed by UBM.
- For the eye injury, UBM could show the precise location of the injury on the cornea and sclera, whether the chamber angle is set back , whether iris is broken from the root or the lens is out of place. Also the UBM helps to show the size and position of the eyewinker in the anterior eye.
- UBM is helpful to the diagnosing and instruction therapy of coloring glaucoma.
- In case of angle closure glaucoma, it helps to know the theory of anterior angle closure after the darkroom experiment.
- For cornea opacity patients, UBM could detect the structure of cornea,

pupil and lens, which normal optical instrument could not detect. So the UBM could perform normal examination before cornea plant operation.

- Valuate the form and function after the Glaucoma Filtration Surgery.
- The diagnoses and identification of anterior segment cyst and solid tumor.

3. Contraindication of UBM Examination

The following cases are forbidden to UBM examination:

- Infective eye disease, such as Keratitis and so on.
- Open eye damage, such as avulsion or perforation of cornea
- Children under 5 years old that could not cooperate with the examination.

Environment Requirement

1. Work Environment

- Ambient temperature: $+5^{\circ}\text{C} \sim +40^{\circ}\text{C}$
- Relative moisture: $\leq 80\%$
- Power Supply: AC 90~230V, $50 \times (1 \pm 2\%)$ Hz
- Keep away from strong magnetic or electronic field.

2. Transport and Storage

- Ambient temperature: $-40^{\circ}\text{C} \sim +55^{\circ}\text{C}$
- Relative moisture: $\leq 95\%$;
- Atmosphere pressure: 500hPa~1060hPa。

3. Running

- Ambient temperature: $+5^{\circ}\text{C} \sim +40^{\circ}\text{C}$
- Relative moisture: $\leq 80\%$
- Power Supply: AC 90~230V, $50 \times (1 \pm 2\%)$ Hz
- Atmosphere pressure: 860hPa~1060hPa
- Warm-up time: 5min

Characteristics

1. Basic Parameters

- Probe: 50MHz fan scanning UBM probe;
- Vertical precision: 50 μ m;
- Lateral precision: 50 μ m;
- Scanning mode: fan scan, cornea protection, safety alarm;
- Gain: 20-105dB;
- SNR: 100dB;
- Gray scale: 256 shades;
- Display resolution: 0.01mm;
- Micro mode 5mm \times 5mm and Full scale 12mm \times 10mm;
- Geometry location precision: Vertical \leq 5%, Lateral \leq 10%;
- Power supply: AC 90~230V, 50 \times (1 \pm 2%) Hz;
- Power : 10W;
- Workstation OS: Windows XP , with USB2.0 interface , EMS memory 512 MB;
- Image store ability: 80G for image store in hard disk, and the store ability could be expanded by CD burning.

2. Software Function


- Long-time protection for probe: When the probe has been continuously working for 10 minutes, it will auto freeze and stop scanning.
- High Gain, High SNR, Wide dynamic range;
- When the probe is blocked or too close to cornea, it will give out alarm sound ,freeze automatically and stop scanning.
- The functions are designed according to the procedure of ophthalmic examination. The operation is simply and practical, fit for doctor's habits.

- Image display: Black&White, all kinds of false color.
- Abundance of measure and after process software, recording 4 groups of distance, 2 groups of angles, perimeter and area.
- Image output: all kinds of format including avi,zip and so on;insert Windows browser whenever you like.
- Real time image acquisition, auto record 100 frames in 10 seconds before freezing. Images could be reviewed one-by-one or continuously, convenient for doctors to have dynamic review.
- Case output: provide PDF format case report with law validity, while auto backup at the same time for future check up. The case reports can be archived, searched or counted.
- More than 20 kinds of eye location signals help to precisely locate the focus.
- Detailed professional dictionary makes the operation easier.


3. Safety

- Accord with the requirement for GB9706.1-1995 Class I Type B devices and GB9706.9.

Install and Connection

1. Check the package to see if anything missing.(reference to Appendix Package list)
2. This system should be install on steady and level ground, with ambient temperature at 18 °C ~ 30 °C and relative humidity under 80%. It is recommended that the device is used in the room with air condition.
 This device should use three-pole power socket with good connection to ground, with power supply of AC 90~230V, 50/60Hz. The install place should avoid strong EM field disturbing, strong impact instrument (such as dental drill) and sun shine.
3. Connect the power cable, display screen, printer, pedal and so on according

to the instruction. Plug the probe into the probe socket on the back and screw it .

 **Notice: Please check the ground line in the socket on the wall or adapter, to see if it is connected well to the ground to ensure the safety use.**

4. Start the computer.
5. Install the workstation software SUSBMATE in the computer which fits the requirement. As to the requirement and steps to install the software, please refer to the software instruction. If the computer has installed the software, you can skip this step and go on the next one.
6. Connect the computer and main unit with USB2.0 data line. When connecting, the yellow data transmission indicator will turn on for a second, then turn off. Now the computer will automatically install the driver for it.
7. When the driver has been installed, press the power switch on the top of the main unit. The blue power indicator till turn on.
8. Run SUSBmate software. When running the software, the yellow light will turn on flashing.

Operations of Main Parts

1. UBM probe


The UBM probe of unit is portable UBM probe, which features in high frequency of 50MHz. (see pic.4).

The probe is designed as sealed, and there is no liquid surface limit when operating.



Pic.4 UBM probe

2. Pedal

 The left pedal is to freeze and unfreeze the image, while the right pedal is to acquire images. Place the pedal at handy place. When need to freeze or acquire a picture, step the pedal once and it will freeze the image.



Pic5 Pedal/Footswitch

- ➡ Don't step with too much strength or not let it go.
- ➡ You can also use the manual freezing key (F4 on the computer keyboard) and acquisition key (F6 on the keyboard).



This pedal could also be used in high voltage application. But in this system, the voltage on the pedal is low enough to sure the personal safety.

Examine Steps

Examine of UBM and other B scan examines have many in common. When examining, the probe must be placed at the examine part. The 2-D transverse image is obtained through the mechanical scanning of the probe. The biggest difference lies in that the scanning part of UBM probe is not covered by film. So the water bath is the best examine way to obtain ideal images.

1. Preparation of Patient

UBM is a high frequency, no-invade ultrasound examine method. Before examination, doctors should explain it clear to patients so as to sweep away their fear. Sometimes doctors could demonstrate it to patients to obtain their cooperation. Usually, fitting the eyecup will cause discomfort. So before examine, examinee's eye should be surface anesthetized to reduce the sensitivity of cornea and conjunctiva. Besides, during examination the liquid in eyecup may flow out by eye rolling. So prepare some tissue to clean the out-flow liquid before examine.

When examining, Patient should be lying down in a supine position and look up at the ceiling. Examiner should be at the head side. Both examinee and examiner should keep comfortable during examination, and the probe could freely move around in examine area.

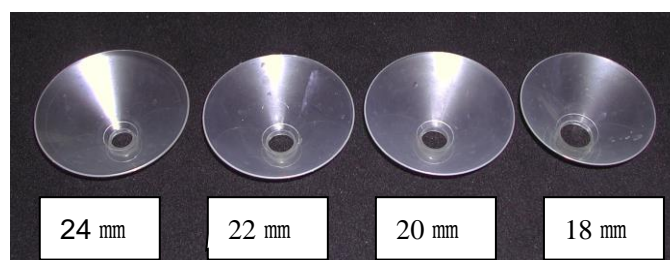
2. Preparation of Instrument

2.1 Eye cup

For better cooperation to examine, eyecup could be inserted into the eyelids to keep eye open. The inner and outer edge of eyecup is smooth and

the upper diameter is much larger than lower part. Large upper edge allows observing the position of probe and the relative location of probe and focus during examine , and moving the probe to obtain better image.

The standard eyecup of UBM is from 18mm to 24mm. Generally the 22mm and 24mm ones fit the adult eyeball, and 18mm is for children. Here is the eyecup series (Pic.6) :



Pic.6 eyecups

The way to set eyecup: To relieve the suffering of patient and better cooperation to examine, surface anaesthesia is needed before setting the eyecup. Choose appropriate eyecup according to the size of palpebral fissure. Examiner open the eyelid by hand, tell patient to look downward. Gently lift the upper eyelid, insert one side of eyecup under the upper eyelid, then tell patient to look upward. Pull the lower eyelid downward to expose the lower part of the eye. Insert the entire eyecup into the conjunctival sac.



Pic.7 Eyecup setting

The eyecup could apply to the examination of not only eye structure but also the eyelid. Place the eyecup on the focus surface when examining the

eyelid. If the focus is too large or irregular to be contained by the eyecup, you can apply other methods such as the water bath made by a latex glove.

2.2 Choose Couplant

It is necessary to fill the couplant between the probe and eyeball when performing UBM examination. The couplant will directly contact with eye tissues such as the cornea and conjunctiva, so the selected couplant should have good acoustical transmission efficiency and not make the eye uncomfortable in a short period. Also, it should have some viscosity to prevent the outflowing of liquid during the examination. Normal couplant for B scan is not fit for UBM examination, because its main component is methyl cellulose, which is irritating to eye tissues and will cause much discomfort to the patient.

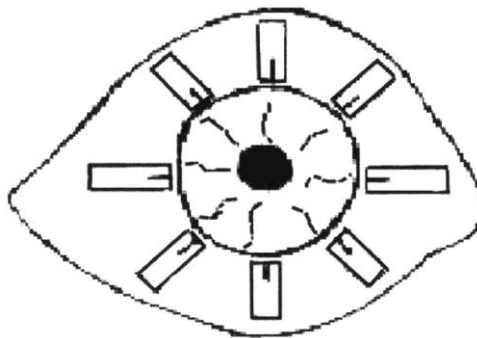
There may be some bubbles on the surface of the probe or in the couplant during the examination. This will be an obstacle to the transmission of the acoustic wave. So when filling the couplant, avoid much bubbles flowing into it. The big bubbles could be swept away by a cotton stick.

3. Examine Method

It is important to keep the patient and examiner comfortable during examination. The preparation is like above: keep the patient lying on their back and staring at the ceiling. Insert the eyecup into the eyelids, fill the couplant and sweep away the bubbles. The examiner usually sits at the patient's head side, with one hand fixing the eyecup and the other holding the probe.

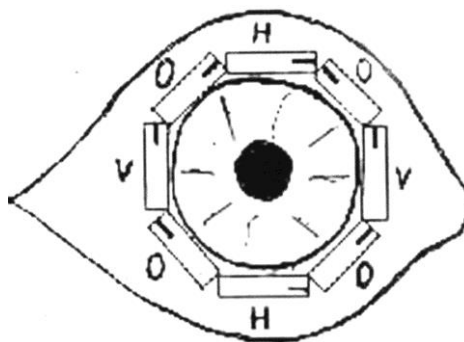
The only way to obtain the best image is to keep the probe perpendicular to the examining part. In operation, the doctor could draw back the probe and tell the patient to roll their eyes so as to expose the focus.

1) . Radiate examine: rotate the probe clockwise from 12 o'clock, and keep the probe perpendicular to the cornea all along. This way of examination is very helpful to the anterior eye disease observation, especially to the anterior chamber disease. (see pic.8)



Pic.8 Radiate Examine Method

2) . Horizontal examine: In some cases, the horizontal examine method could help to observe the cilia body disease in more details, such as the quantity of ciliary process and the connection between the ciliary body and sclera. The probe is parallel to the cornea surface. But doctors should pay more attention to distinguishing the image.



Pic.9 Horizontal Examine Method

Run the Software

Please refer to the UBM software instruction.

Disassembly and Replacing

There is no component that could be disparted in the main unit. User should not open the main unit by himself.

When transporting, the probe should be pull off from the main unit and put into the probe box. Display screen, printers and so on should also be disconnected and put into package.

Cleaning, Disinfection and Maintenance of the Probe

1. Cleaning and disinfection

You can use cotton ball with distilled water, saline solution or alcohol to wipe the front of the probe gently. This is to disinfect and make the signal clearer. Be careful not to scratch the surface of audio film.

The probe could not be disinfected by high temperature, nor it could be dip in alcohol or other disinfect liquid.



WARNING!

Testing has shown the following to be harmful to the probe and transducer.

1. Sodium Hypochlorite (i.e., bleach)

Diluted and undiluted bleach solutions attack the gold plated surfaces of the probe and, once a breach has been made, the underlying metals are rapidly corroded. Therefore, cleaning/ disinfection methods employing Sodium Hypochlorite are specifically contraindicated.

2. Saline Solutions

Saline solution has been found to be mildly corrosive to the gold plated surfaces of the probe and transducer. To prolong the life of the probe, always rinse any surface of the probe that has been in contact with saline solution with sterile water or ethyl alcohol, followed by a thorough drying. Never allow the probe to be immersed in saline for prolonged periods, nor allow saline residues to dry on the probe surfaces. Although saline is not contraindicated (i.e., it is indicated as a scanning "bath"), it is recommended that exposure to saline be limited as much as feasible.

3. Tap Water

Contaminants in common tap water have been found to attack and corrode the metal surfaces of the probe and transducer. The use of tap water, rather than sterile deionized or distilled water is, therefore, contraindicated. Should the probe surfaces be soaked in or rinsed with tap water (e.g., accidentally), rinse

with distilled or deionized water and lightly wipe the surfaces clean of any residues.

4. Abrasives

The gold plating on the transducer surface is very thin and cannot be thickened without negatively affecting transducer frequency and performance. Therefore, extreme care must be taken to avoid scratching or otherwise damaging the gold surface of the film. Never use any kind of abrasive cloth or tissue when wiping the transducer surface. Camera lens cleaning papers or soft gauze may be used. Apply no more force than is needed when wiping the transducer surfaces. Minor scratches to the gold surface will not damage performance.

2. Using and Transporting

The probe should be hung on the probe shelf when it is not used. Avoid falling or scratching the probe.

When transporting, the probe must be pull off from the main unit and put into the probe box.

If the probe falls in use or transport, check the top surface and shell of the probe to see if there is injury. Isolation injury may cause electric shock. If such things happen, please stop using and contact with the warranty station.

Maintenance

- The power supply socket must be the three-pole socket with good connection to the ground.
- After turn off the device, put POWER on OFF.
- The probe is easy to wear when it is performing high speed mechanical scanning. Sway the probe only when diagnosing, so as to extend the life of probe.
- Pick up and put down the probe gently, avoid bumping or falling. Keep the audio film clean.
- Don't use any causticize cleanser when cleaning the device. Avoid

water or any other liquid running into the keyboard or shell. You can clean with mild cleaner and soft tissue.

Package and Transportation

The packed instrument can be transported by transportation vehicles. It must not be transported together with goods that are easy to burn, explode, corrode. It should be protected from shock and moisture.

The instrument should be stored in the environment with ambient temperature from -10°C to 40°C , with the relative humidity under 80%, and without the corrosive gas, strong mechanical vibration, shock and magnetic effect. The room in which the instrument stored should be with good ventilation.

Trouble Shooting

Phenomena	Analyze	Solution
The main unit could not start up normally.	If the connection of power line is correct and reliable?	Insert the power line into the corresponding interface and power supply socket and ensure that the connection is right and reliable.
	If the main unit is started at the temperature above 5°C ?	Ensure that the main unit start up at the ambient temperature above 5°C , and has been placed under normal temperature for more than 10 minutes.
	Whether the fuse is broken?	Replace new fuse
Display could not work properly.	If the connection between the main unit and power line is correct and reliable?	Insert the power line into the corresponding interface and power supply socket and ensure that the connection is right and reliable.
	If the brightness and contrast is correct?	Adjust the brightness and contrast with adjusting buttons on the display.

The keyboard or mouse doesn't work	If the keyboard cable is connected right and reliable?	Shut down the main unit and re-insert the keyboard cable.
	If the inside of mouse is too dirty?	Clean the bottom of mouse and the ball by dry tissue.
	The movement of mouse cursor is slow and with deviation.	Ensure that the plane under the mouse is clean and level.
No signal from the probe	Is the probe connected to the main unit?	Insert the probe cable into its socket, and ensure that it is connected reliably.
	If the gain of software is right?	Adjust the gain through toolbar on the software.
No image	The probe is freezing.	Press Freeze key to unfreeze the probe.
	Instrument failure	Record detail phenomenon and contact with manufacturer.

If the method above doesn't work, please take the warranty card with you and contact the warranty station, tell the details of the problem so that manufacturer could repair it as soon as possible. Please don't open the device without permission.

This device is delicate designed high-tech product. Only the trained certificated technical engineers can do the repair work.

As to the safety and effective result caused by user's repairing, our company does not take the responsibility.

Appendix Warranty and Support

1. Warranty Announcement

- This device is warranted for 1 year free of charge from the purchase date if users always follow the instruction of this User's Guide.
- If the device gets some problem when all the operation instructions are followed, please take the warranty card and contact with the warranty station. The repair is free of charge in the warranty period with the warranty card. If there is no warranty card or warranty station hasn't received it, then the warranty station can refuse to repair it.
- During the Warranty period, the items below are charged:
 - Accident caused by man-made damage;
 - Accident caused by user's own repair on the machine, which is without permission.
 - The damage caused by wrong operation.
 - After the warranty is expired, it will continue to carry on with some reasonable repair charge.

2. Attachment supply and technical support

For purchasing the probe and the print paper of video printer, you can contact with the supply company.