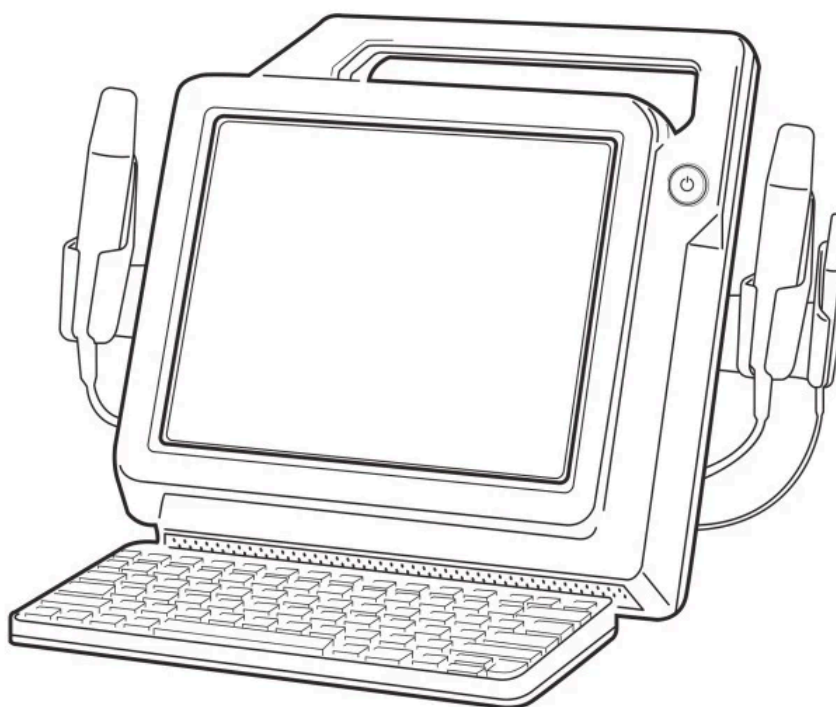

EUS-2600 Ultrasonic A/B Scanner

Operation Manual



ELI
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PRECAUTIONS

- This product should be operated by trained medical staff.
- It is prohibited to use this product on patients with eye trauma, inflammation or infection.
- Please read the User Manual carefully before installation and operation
- Please refer to Chapter 5. Cleaning, Disinfection and Sterilization to avoid cross-infection while using this product.
- Please unplug the power plug before cleaning this product!
- Please refer to Chapter 6. Maintenance, Precautions for Proper Use and Simple Ways to Troubleshooting for maintenance instructions.

WARNINGS

- The customer shall be fully responsible for managing and maintaining this product upon purchase of the product.
- Do not make any modification to the hardware or software of this product without prior authorization.
- The power adaptor provided with this product meets the safety standards of medical electrical devices. If it's damaged, contact the manufacturer for help. Use of other adaptors may cause safety risks.
- The manufacturer will not be responsible for any damage or injury caused by failure to follow instructions in the User Manual.
- The manufacturer reserves the right to modify device characteristics without prior notice under FDA Laws and MDD (93/42/EEC) Regulation.
- The quality assurance of this product will be invalid if it's opened (even partially opened), modified or repaired in any way by anyone who is not authorized by the manufacturer.
- This product is not intended for therapeutic use.
- This product is not made with natural rubber latex.
- Patients with eyelid trauma and severe eye infection are prohibited from using B-scan; and patients with keratitis and cornea trauma are prohibited from using A-Biometric scan.
- The A-Biometric scan should be used cautiously on patients without independent behavior abilities or those who are highly sensitive to contact-mode measurements, whose ineffective cooperation may result in inaccurate measurements.
- According to FDA laws, the EUS-2600 is a prescription device and is to be used by or under the supervision of a licensed physician.
- This product is not intended for use on babies under the age of two.
- When plugging the probe into the probe socket, make sure the red mark on the probe align with the red mark on the socket.

- When unplugging the probe from the probe socket, please be sure you are pulling the connector instead of the cable.
- Do not scratch the surface of the probe.
- Do not drop the probe.
- If the probe drops when it's used or moved, check the top and the housing of the probe carefully, and then check if it works well. Stop using it if there is any problem and contact the manufacturer or local distributor for service.
- Warnings of predicable potential hazards are contained in this User Manual. Please remain vigilant at any time to those unpredictable hazards. The manufacturer won't be responsible for damages and losses caused by negligence or ignorance of the preventive measures in this User Manual.
- Assembly, expansion, re-adjustment, improvement and repair of this product shall be performed by personnel authorized by the manufacturer. Users are not allowed to open the outer casing for unauthorized repair without prior permission by the manufacturer. The manufacturer is not responsible for any consequences of safety and effectiveness caused by unauthorized repair.
- Keep the original package properly. All detachable parts like probe should be put into the original packages for transportation when needed.
- Without prior written consent of the manufacturer, no individual or organization is allowed to copy, modify, or translate any part of this User Manual.

If you have any question, please contact the manufacturer or your local distributor.

CAUTIONS

HOW TO PREVENT CROSS-INFECTION

- It is prohibited to use this product on patients with eye trauma, inflammation or infection.
- Between uses on different patients, the probe and eye cup must be thoroughly cleaned and disinfected to prevent cross-infection.
- The manufacturer advocates a preventive measure and a cleaning procedure in Chapter 5. Cleaning, Disinfection and Sterilization.

CAUTION

- Federal (US) Law restricts this device to sale by or on the order of a physician.
- The EUS-2600 IOL calculator will calculate negative IOL values if such values are predicted by the data input. These are displayed with a minus sign "-". Do not ignore this sign.
- This product has no special protective action against discharging effect of cardiac defibrillator; and it's not suitable for use within the vicinity of high-frequency therapeutic equipment.

- Precautionary measures against electrostatic discharge shall be taken when connecting with USB ports with Electrostatic Discharge Warning symbol.
- All parts of this product shall not be serviced or maintained when it's used on a patient.
- This product includes wireless keyboard and mouse, the isolating distance with radio radiating sensitive equipment should be no less than 30cm, see Annex C for details.

TISSUE EXPOSURE TO ULTRASOUND ENERGY:

- This product is designed for use in ophthalmology only.
- While the manufacturer is not aware of any reports of adverse effects from using ophthalmic ultrasound scanner, even at FDA pre-enactment levels, no other use is intended or implied.
- The system controls limit of the output energy within the parameters specified for its intended purposes. Please refer to Annex A of this User Manual.
- No control of ultrasound energy is available to the users other than the duration of exposure, considering the current concern for possible unknown hazards, and despite the extremely low output intensities used in this ultrasound system.
- The manufacturer recommends that patients' exposure time during measurement be minimized.

Explanation of Labels and Symbols on the Product



Power Switch



"Type B" Applied Part



Caution ! Please Refer to accompanying documents



Please Refer to User Manual



(USB Ports) Electrostatic Discharge Warning



(Mouse and Keyboard) Non-ionizing Radiation

10MHz A-Probe

Socket for 10MHz A-Probe

10MHz B-Probe

Socket for 10MHz B-Probe

20MHz B-Probe

Socket for 20MHz B-Probe

USB

USB Ports

HDMI

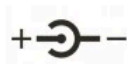
HDMI Interface

VIDEO OUT

Video Output Interface

FS

Footswitch Socket



DC-12V

Power Input Socket



Direct Current



Product Series Number



Manufacturer



0123

CE Conformity Marking



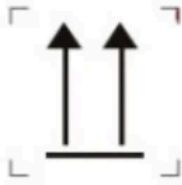
European Representative

Explanation of Labels and Symbols on the Adaptor



Disposal of the product after its life-cycle should comply with the relevant local environmental protection regulations.

Explanation of Labels and Symbols on the Packing Box



This Way Up



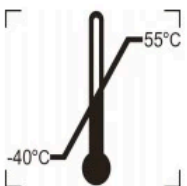
Fragile, Handle with Care



Keep Dry



Stacking Limit by 4



Temperature Limit



Humidity limitation

Chapter 1. General Introduction

1.1 Structure and Components

EUS-2600 Ultrasonic A/B Scanner for Ophthalmology is an ultrasonic imaging instrument specialized in ophthalmological diagnosis. It consists of a main unit, a power adaptor, a 10MHz B-Probe, a 20MHz B-Probe, a 10MHz A-Probe, a footswitch, a keyboard and a mouse.

The 10MHz B-Probe applies to normal ophthalmological ultrasonic diagnosis; and the 20MHz B-Probe applies to observation of details of intraocular and retina structure.

1.2 Intended Use

This product is intended for ophthalmological ultrasonic diagnosis and AL biometric measurement.

1.3 Intended Location of Use

This product is intended for use in hospitals and clinics with good environment. It should be operated by trained medical staff.

1.4 Contraindications

Patients with eyelid trauma and severe eye infection are prohibited from using B-Scan; and patients with keratitis and cornea trauma are prohibited from using A-Biometric scan.

The A-Biometric scan should be used cautiously on patients without independent behavior abilities or those highly sensitive to contact-mode measurements, whose ineffective cooperation may result in inaccurate measurements.

1.5 Expected Service Life

Based on the experience of products sold (and considering technology upgrade cycle), as well as the aging of major parts - transducer which will probably reduce the basic performance, the product's expected service life is determined as five years according to the normal usage of six hours each working day. (Service life may extend if the major parts, like probe, are returned to manufacturer for upgrade.)

1.6 Software Version

MD24S V1.0.

1.7 Basic Working Principle

a) B-Mode: Under the excitation of electric pulse, the 10MHz/20MHz ultrasound transducer emits ultrasonic pulse into eye and receives reflective echo from the surfaces of different tissue, thus forming real-time two-dimensional image of eye tissue.

b) A-Mode: Under the excitation of electric pulse, the 10MHz ultrasound transducer emits ultrasonic pulse into eye and receives reflective echo from the surfaces of three different tissues of anterior chamber, lens and vitreous body. The transmitting time of ultrasonic wave in different tissues are measured and the distance of each part will be calculated according to the acoustic velocity of different tissues and then the axial length (AL) will be calculated.

Chapter 2. Technical Specifications

2.1 Working Conditions

2.1.1 Adaptor

1. Working Temperature: 5℃-40℃;
2. Relative Humidity: lower than 80%;
3. Input Voltage of Power Adaptor: AC 100-240V, 50/60Hz;
4. Atmospheric Pressure: 70-106kPa.

2.1.2 Main Unit

1. Working Temperature: 5℃-40℃;
2. Relative Humidity: lower than 80%;
3. Input Voltage of Main Unit : DC 12V, 4A
4. Atmospheric Pressure: 70-106kPa.

2.2 Basic Parameters

1. Nominal Ultrasound Frequency: B-Probe: 10MHz/20MHz Available, A-Probe: 10MHz;
2. User Interface: monitor, keyboard, mouse, touch screen and footswitch;
3. Monitor: resolution≥1024×768, gray scale≥256;
4. Keyboard and Mouse: USB interface, wireless keyboard and mouse; see Annex D for the main specification;
5. Output Interface: 4×USB2.0 and HDMI interface;
6. Net Weight: 5.5kg;
7. Size: 34cm x 31cm x8cm.

2.3 Specifications

2.3.1 B-mode

1. Scanning Method: mechanical sector scan;
2. Display Mode: B, B+A;
3. Scanning Angle: 53°;
Display Depth Adjustable Range: 10MHz: 28mm~60mm; 20MHz: 19 mm~40mm;
4. Variable Delayed Depth: 10MHz: 0 mm~15 mm; 20MHz: 0 mm~10mm;
5. Gain Control Range: 1-105dB;
6. TGC: -20dB~20dB with dynamic range, manual sectional adjustment (6-section adjustable);
7. Grey Scale: 256 Levels;
8. Frame Rate: 10fps;
9. Image Saving: 100 images;
10. Dynamic Loop: 10s/100 images, loop or frame-by-frame playback;
11. Image Processing and Signal Post-processing: Frame-Averaging, Pseudo-Color Codes, and

Gamma Correction

12. Axial Resolution

- a) 10MHz Probe: No more than 0.1mm;
- b) 20MHz Probe: No more than 0.08mm;

13. Lateral Resolution

- a) 10MHz Probe: No more than 0.2mm;
- b) 20MHz Probe: No more than 0.15mm.

2.3.2 A-mode

1. AL Biometric Measuring Range: Axial Length (AL): 15mm-40mm;
2. AL Biometric Measuring Accuracy: No more than $\pm 0.05\text{mm}$;
3. Total Gain: 98dB, user's gain adjustability: 1~60dB;
4. Measuring Mode: 5 groups (Normal, Aphakic, Special, Cataract and Manual Measurement);
5. Measuring Method: Immersion/Contact;
6. IOL calculation: SRK-T, SRK-II, BINK-II, HOLLADAY, HOFFER-Q and HAIGIS;
7. Support IOL calculation after refractive surgery, two groups of formulas can be calculated contrastively and displayed simultaneously.
8. Automatic measurement and 10 groups averaging and display standard deviation.
9. Up to 8 groups of IOL constants can be stored.

2.4 Safety

1. The electrical safety of this product shall be in accordance with requirements of IEC60601-1, IEC60601-1-2 and IEC60601-2-37.
2. For information on Acoustic Output Parameters, please see Annex B.

2.5 Environmental Requirements for Storage and Transportation**1. Environmental Requirements for Storage**

This product shall be stored in a well-ventilated room without any corrosive gas.

Temperature: -20°C to 40°C ;

Relative Humidity: no more than 80%;

Atmospheric Pressure: 70-106kPa.

2. Environmental Requirements for Transportation

General modes of transportation are allowed for packaged product. However, the product shall be protected against severe impact, collision and exposure to rain and snow during transportation.

Temperature: -40°C to 55°C ;

Relative Humidity: no more than 80%;

Atmospheric Pressure: 70-106kPa.



Note: The operator shall pack detachable parts like probes into their original

packages for transportation when needed.

2.6 Classification

1. By type of protection against electric shock for Adaptor: Class I;
2. By degree of protection against electric shock: Type B Applied Part;
3. By degree of protection against ingress of liquids:
 - Main Unit: IPX0;
 - Footswitch: IPX1;
 - Probe: IPX7.
4. By disinfection and sterilization methods recommended by the manufacturer:
 - see Chapter 5. Cleaning, Disinfection and Sterilization of Probes;
5. By safety when being used together with flammable anesthetic gases mixed with air, oxygen or nitrous oxide: this product doesn't belong to AP/APG equipment;
6. By working mode: Continuous.

Chapter 3. Installation and Connection

3.1 Structure and Components

This product consists of a main unit, a power adaptor, a 10MHz A-Probe (Prb1000A/10-C), a 10MHz B-Scan probe (Prb2100B/10), a 20MHz B-Probe (Prb2100B/20), a footswitch, a mouse and a keyboard (shown in Figure 3-1).

The applied parts are 10MHz A-Probe, 10MHz B-Probe and 20MHz B-Probe.

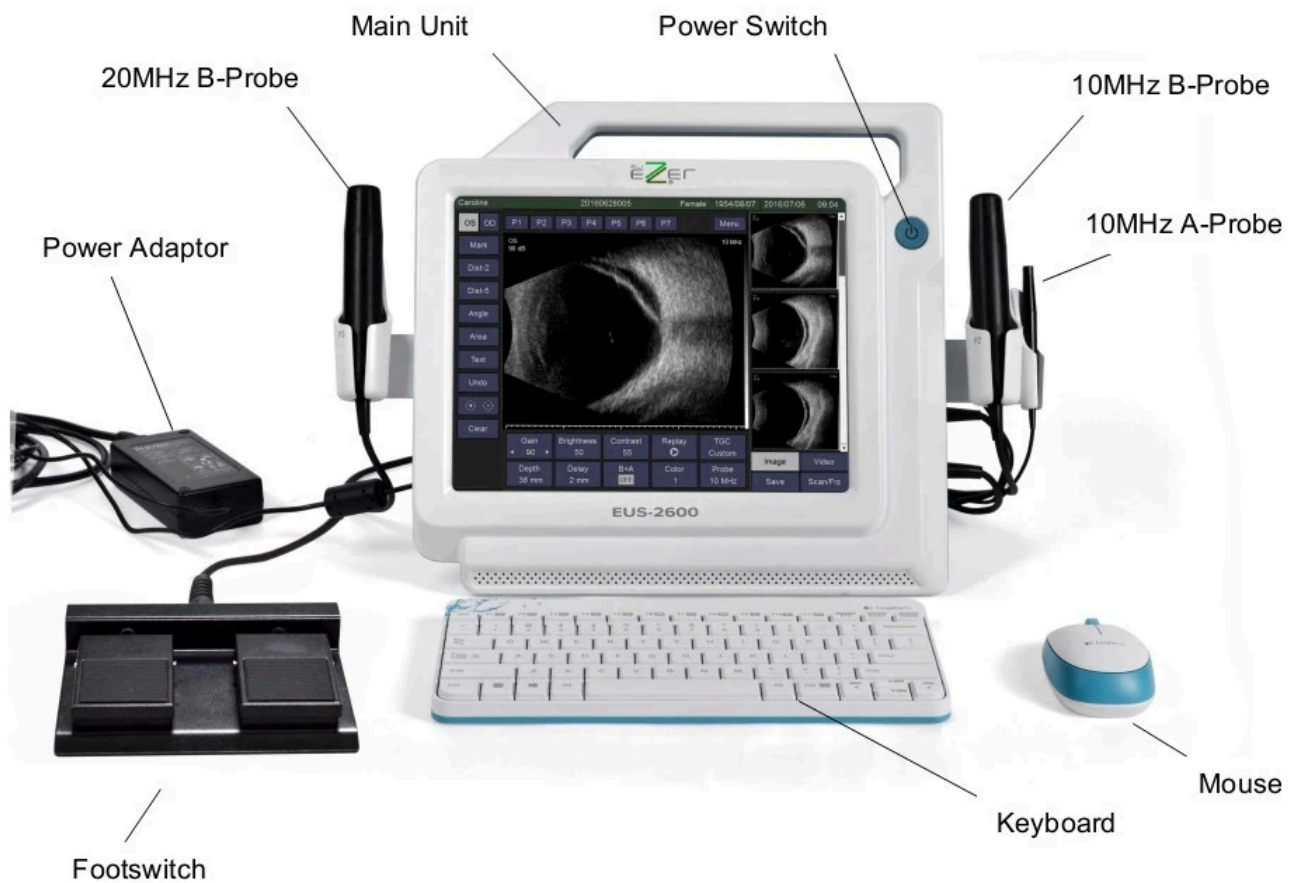


Figure 3-1 Configuration of EUS-2600

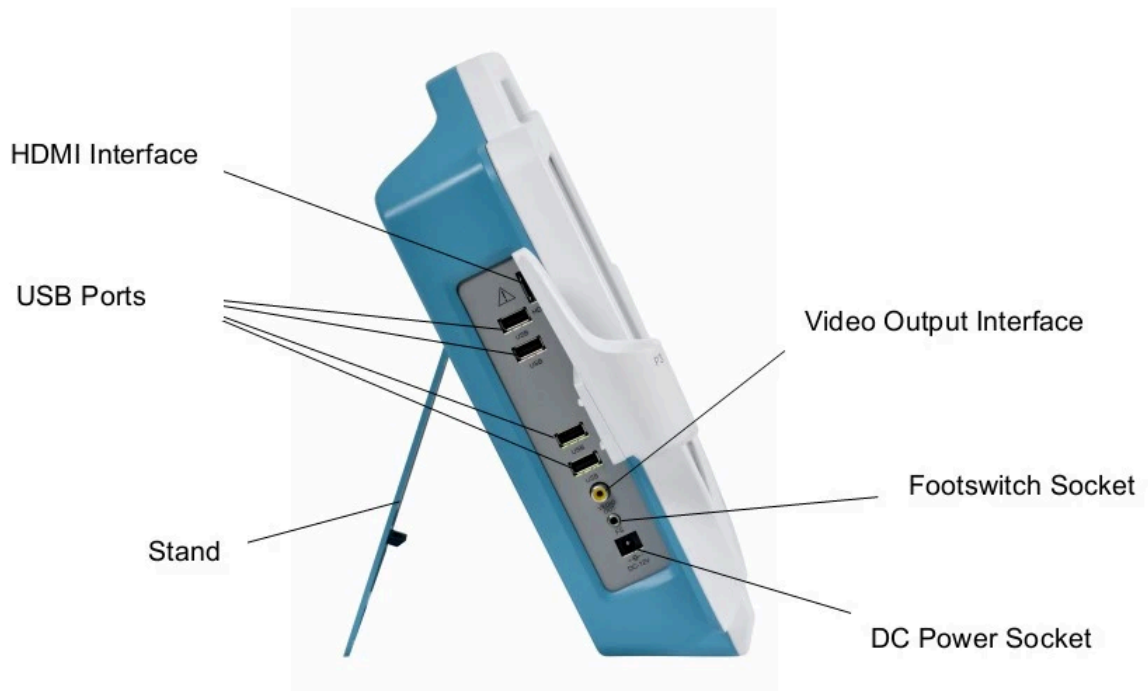


Figure 3-2 Left View of EUS-2600



Note:

The electrical equipment connected to EUS-2600 (through HDMI and Video Out interface) shall obtain IEC 60950 safety certification, to ensure that the safety performance of EUS-2600 shall not be affected by the risks arising from the failure of external equipment under normal use.

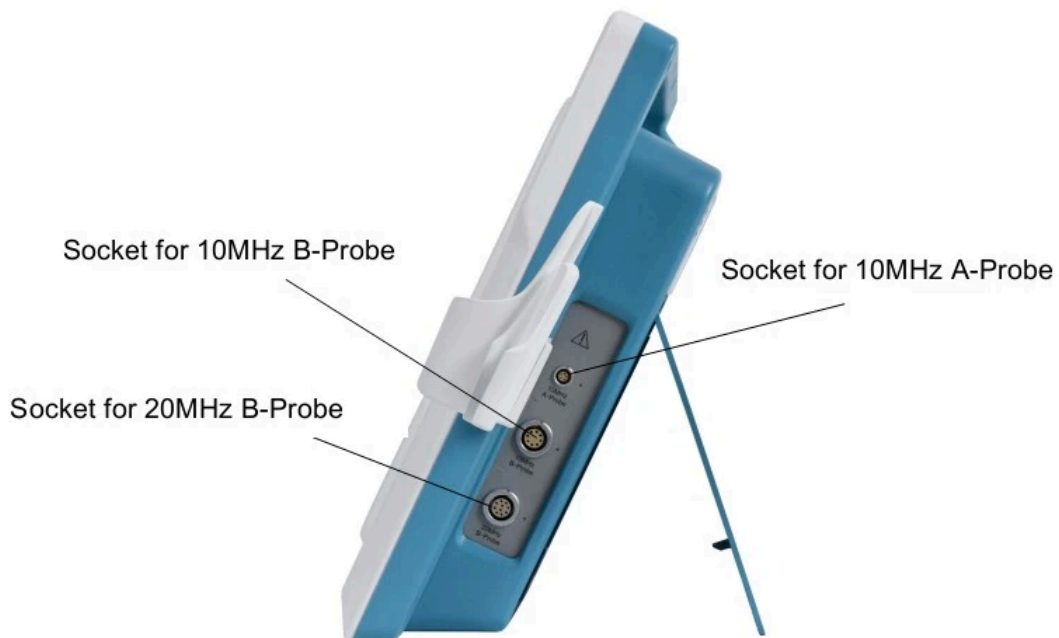


Figure 3-3 Right View of EUS-2600

3.2 Start-up and Shut-down

3.2.1 Checking before Start-up

1. Check if the site is appropriate for the product;
Check if there are devices that may interfere the product in its vicinity;
Check if the site is dry;
2. Check if the appearance of the entire unit is good;
Check if there are cracks on the outer casing and LCD of the product;
3. Check if the probe is securely connected:
Check if the plug of the probe is loose, and if there are cracks on the applied parts used on a patient;
Check if the cable of the probe is twined around other cables;
Check if there are cracks or damages on the surface of the probe and cables;
4. Check if the power connection is secured;
Check if the power adaptor and the DC power socket on the main unit are securely connected;
Check if the power adaptor is securely connected with mains power;
5. The operator shall run the above-mentioned checks, and turn on the unit for further check until everything is ok.

3.2.2 Start-up

Press power switch on the front panel of the main unit, and the power indicator light is on and turned blue, and the product starts up.

3.2.3 Routine Check before Use

Please run the routine check first after each start-up

1. Check if the power indicator light is on and turned blue;
2. Check if the mouse, keyboard or touch screen works;
3. Check the user setup (see §4.9 User Setup);
4. Check if the probe and eye cup are cleaned and disinfected according to §5 Cleaning, Disinfection and Sterilization.

3.2.4 Shut-down

Press the power switch on the front panel of the main unit, and the product shuts down.



Note: Pressing and holding the power switch for 3 seconds will lead to forced shut-down of the product. Forced shut-down of the product is not suggested, it may lead to the damage of the product.

3.3 Environmental Requirements

This product shall be placed on a flat surface, with an appropriate ambient temperature of 18□-30□ and an appropriate relative humidity of less than 80%. It's suggested the product be used in an air-conditioning environment.

This product shall be powered by a single-phase, three-pole power socket with good protective grounding, and its power supply voltage is AC100-240V, 50Hz/60Hz. This product shall be placed where interference of a strong electromagnetic field can be avoided, kept away from equipment with strong electromagnetic radiation (such as microwave, radio frequency (RF) treatment equipment), and stored away from direct exposure to sunlight.

The wireless keyboard and mouse of this product may emit some RF energy, which may cause RF interference to other medical equipment and wireless communication. To avoid such interference, this product meets the emission limitation for Group 1 Class A ME Equipment or ME System regulated in IEC60601-1-2.

The main unit and its supportive accessories of this product are applicable to patient environment.



Notes:

① The operator shall check if the protective grounding wire in the single-phase, three-pole power socket on the wall or voltage stabilizer works well, to guarantee the safety.

② This product is prohibited from being used together with a high-frequency surgical device.

3.4 Connection

1. Insert the 10MHz A-Probe, 10MHz B-Probe and 20MHz B-Probe into their corresponding sockets, respectively, shown in Figure 3-3;
2. Insert the wireless receiver of peripherals (wireless keyboard and mouse) into the USB port shown in Figure 3-2;
3. Insert the connector of the footswitch into the FS port shown in Figure 3-2;
4. Insert the power adaptor into the DC power socket shown in Figure 3-2.

3.5 Connection and Disconnection of Accessories and Replacement of Consumables

There's no dismountable part in the main unit, so users are not authorized or allowed to open the outer casing.

Move the main unit and other components with proper care when necessary.

The acoustic gel shall be purchased locally by users; and the bottle for acoustic gel shall be discarded in accordance with local regulations for environmental protection.

Chapter 4. Operation Instructions

4.1 Starting Application Program

Press the power switch to get direct access to the login interface of the program, as shown in Figure 4-1-1.

The login interface consists of a 'Login' box and a virtual keyboard. The 'Login' box has a 'UserName' dropdown menu showing 'User1' and a 'Password' text field. To the right of the 'Login' box are 'Exit' and 'OK' buttons. Below the 'Login' box is a virtual keyboard with the following layout:

`	1	2	3	4	5	6	7	8	9	0	-	=	<-Bspc
Tab->	q	w	e	r	t	y	u	i	o	p	[	]	\
Shift off	a	s	d	f	g	h	j	k	l	;	"	Enter	
Lang	z	x	c	v	b	n	m	,	.	/			
←	→	↑	↓	PgUp		PgDn		Del					

**Figure 4-1-1 Login Interface for EUS-2600 Ultrasonic A/B Scanner
for Ophthalmology**

Click **UserName** column, and select a user from its drop-down list; input its corresponding password in the **Password** column (the first four users are exempt from password and the last four customers' default initial password is "123"); support keyboard or virtual on-screen keyboard. **Lang** is for shifting English and Chinese; **Shift off**, **Shift on** and **Shift lock** represent locking lower case, capitalizing the initial letter, and locking capitalizing, respectively. Press **OK** to access the main interface of the program, as shown in Figure 4-1-2; or press **Exit** to exit. There are seven functions in the main menu on the left side of the main interface of the program. These functions include **New**, **Load**, **B scan**, **A scan**, **Report** and **Exit**.



Figure 4-1-2 Main Interface of EUS-2600 Application Program

4.2 Creating a New Patient

Click **New** (shortcut key F1) on the main interface to access “New Patient” interface as shown in Figure 4-2-1; fill in (select from their drop-down list) the columns of “Name”, “ID” (Case Number), “Sex” and “DOB” (Date of Birth), the column of “Name” shouldn’t be empty; and click **OK** to confirm the creation of the new patient.

 The image shows the 'New Patient' interface. It contains a form with the following fields:

- Name**: A text input field.
- ID**: A text input field.
- Sex**: A drop-down menu with 'Male' selected.
- DOB**: A date input field showing '2015/ 3/17'.

 Below the form are two buttons: 'OK' and 'Cancel'. At the bottom of the interface is a numeric keypad with the following layout:

`	1	2	3	4	5	6	7	8	9	0	-	=	<-Bspc	
Tab->	q	w	e	r	t	y	u	i	o	p	[	]	\	
Shift off	a	s	d	f	g	h	j	k	l	;	"	Enter		
Lang	z	x	c	v	b	n	m	,	.	/				
←	→	↑	↓	PgUp		PgDn		Del						

Figure 4-2-1 New Patient Interface

4.3 Loading a Patient Record from Database

Click **Load** on the main interface to access “Load Patients” interface (shown in Figure 4-3-1) if the

operator wants to load saved records for further operation. Select the corresponding patient record and click **Enter** to access the selected record and operate under the subsequent B-Mode and A-Mode. Click **Back** return to 4-1-2 Main Interface.

Select the current record, double-click or click **Preview** to review the details of current patient (shown in Figure 4-3-2). The scanning images, images, and case reports will be displayed, double-click the image area to open images, reports or play dynamic images. Click

Previous Record or **Next Record** to shift to the previous or the next patient. Click **BACK** to return to "Load Patients" interface.

Click **Find** to search for history records, and a dialog box pops up (shown in Figure 4-3-3) for the operator to search patient records by keywords, including "All Patients" (searching for all records), "Today" (searching for today's records), "Name" (searching for records of specific name), "ID" (searching for records of same IDs), "Sex" (searching for records according to sex), "DOB" (searching for records according to date of birth), "Doctor" (searching records according to operator), and "From and To" (searching for records according to time zone).

A quick search can be done by entering patient name (or some characters of the name) in the column of "Search by Name".

Click **Delete** to delete a selected patient record; and the operator's discretion is required.

No	Name	ID	Sex	DOB	D
1	Brandon	20170328001	Male	1998/03/28	U
2	Bruce	20170328002	Male	1987/03/12	U
3	Jackson	20170328003	Male	1980/01/28	U
4	Sunny	20170328004	Female	1978/04/05	U
5	Mary	20170328005	Female	1979/05/05	U
6	Michelle	20170328006	Female	2017/07/08	U

Search by Name

Preview Find Delete Back Enter

Figure 4-3-1 Load Patient Interface

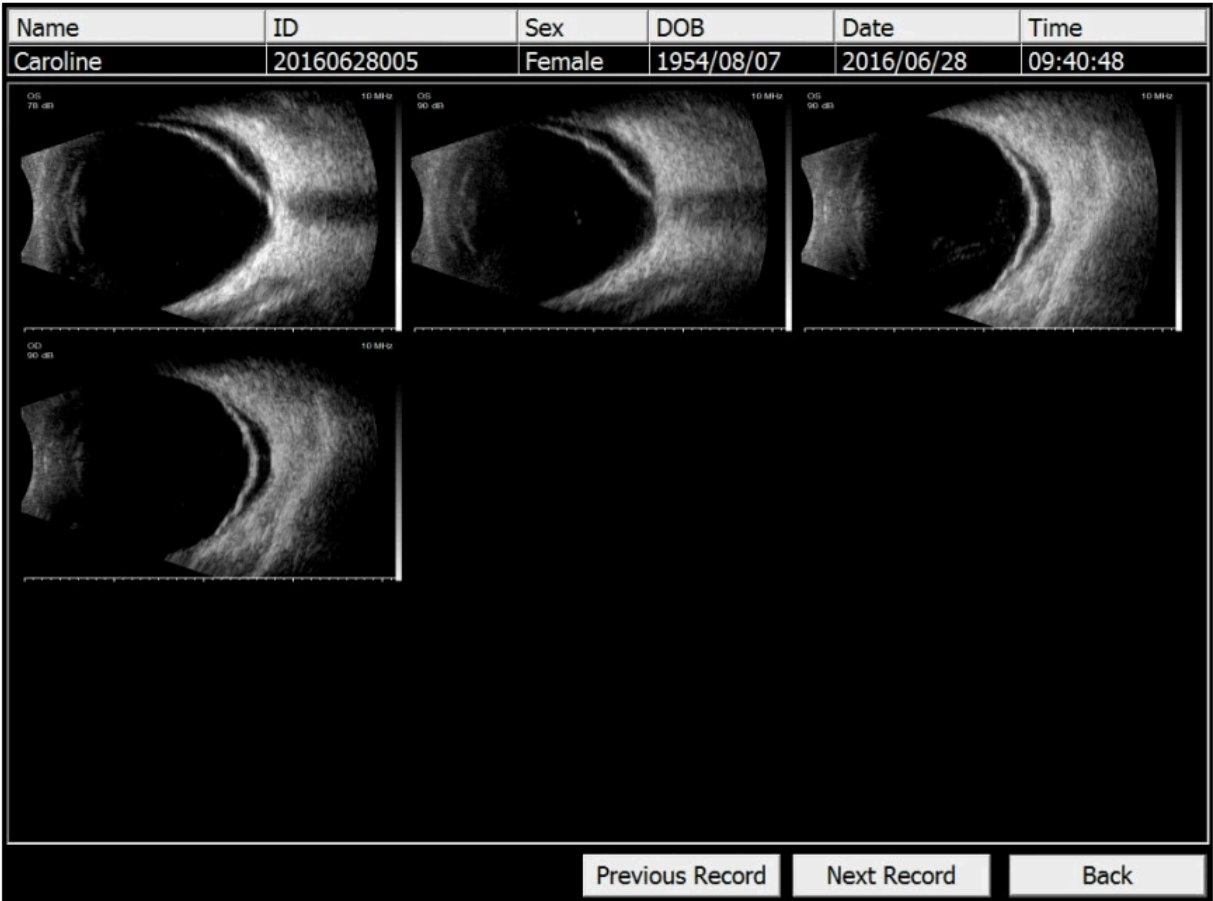


Figure 4-3-2 Patient Detail Interface

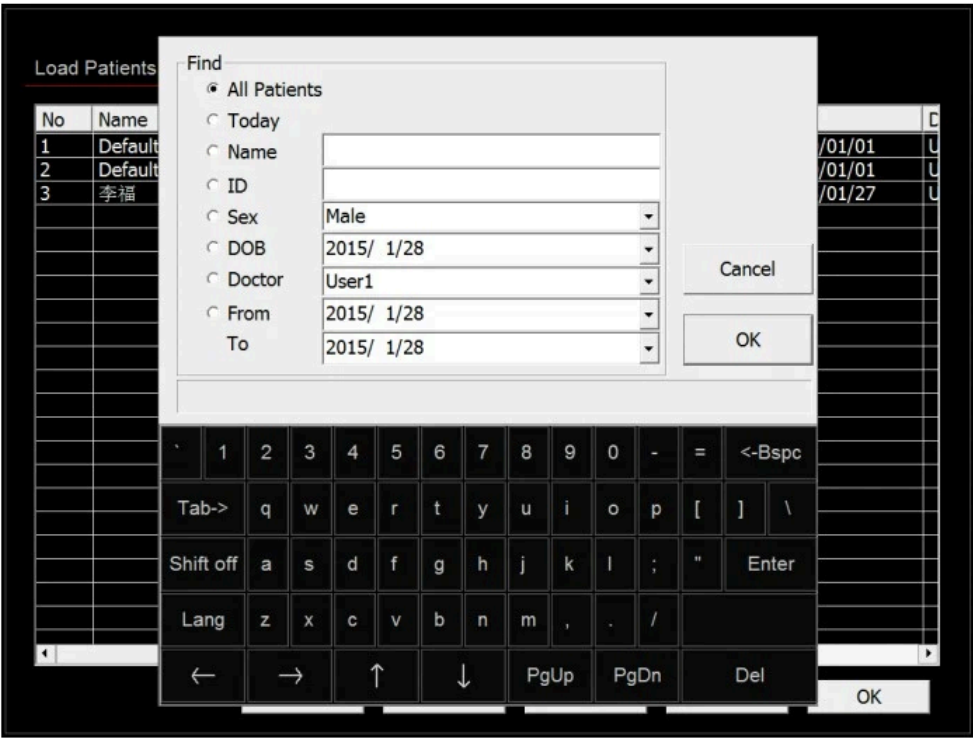


Figure 4-3-3 Dialog Box for Searching for History Records

4.4 B-Scan

Click **B scan** (shortcut key F2) on the main interface in Figure 4-1-2 to access "B scan" interface shown in Figure 4-4-1. The interface includes patient information area, scan mode selection area, scan control area, scan parameter adjustment area, image display area, image measurement annotation area.

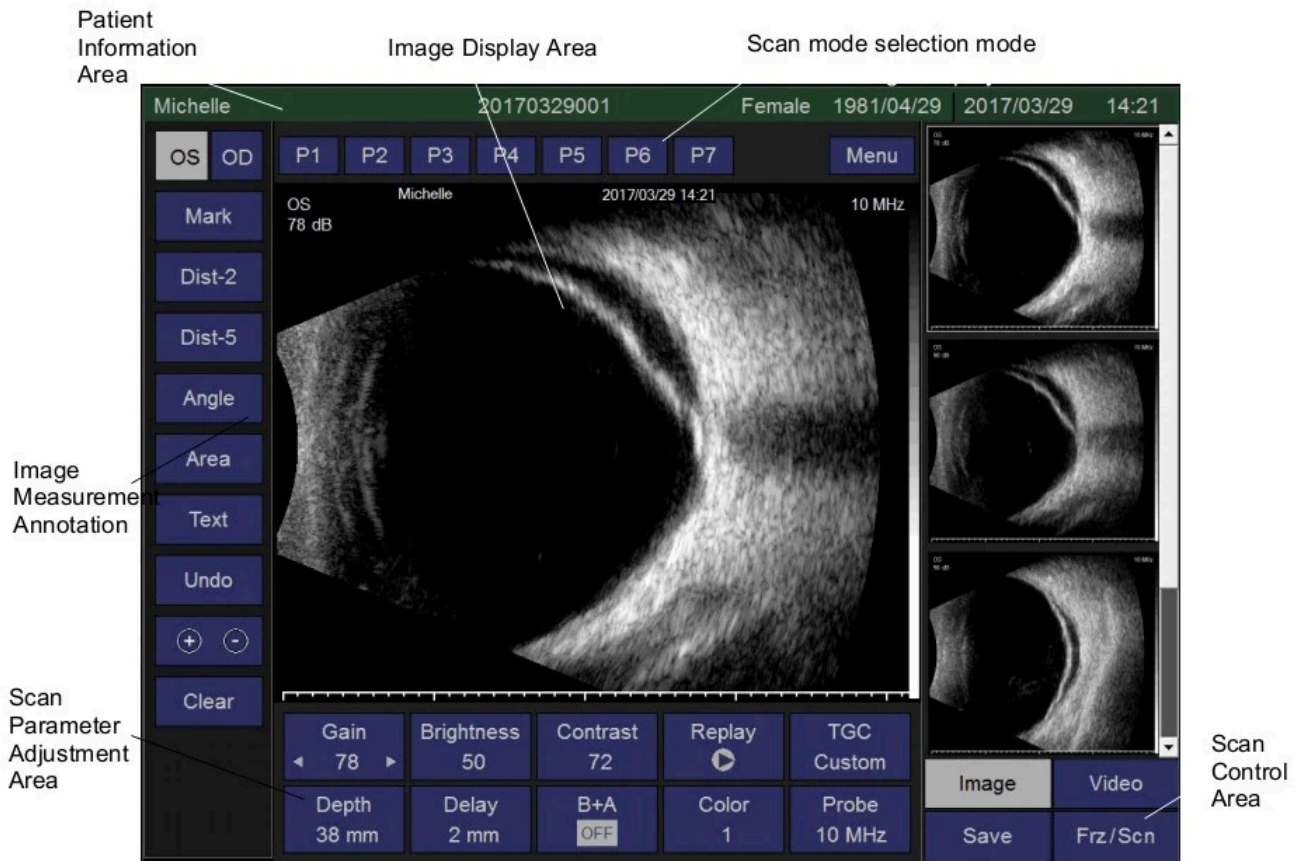


Figure 4-4-1 B scan Interface

1) Patient Information Area: is used to display the name, ID, sex, date of birth, and diagnosis time of the patient. Click the left side of the patient information area in Figure 4-4-1, and a dialog box for modifying the patient information or creating new patient information pops up, as shown in Figure 4-4-2. Click **Modify**, and a dialog box for modifying the patient information pops up, as shown in Figure 4-4-3; or click **New**, and a dialog box for creating new patient information pops up, as shown in Figure 4-2-1; or click **Cancel**, to give up the operation. Click the right side of the patient information area, to adjust the real-time clock.

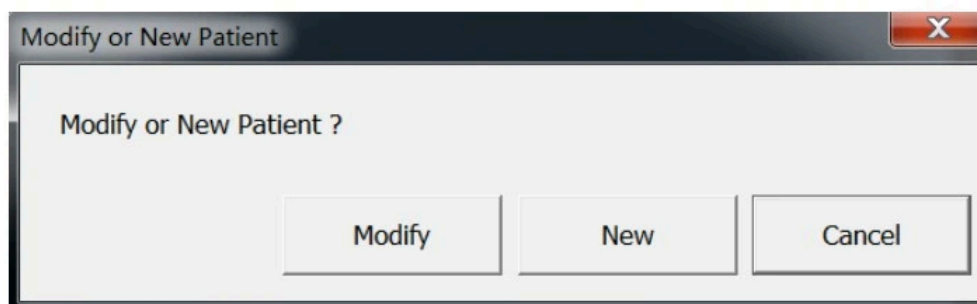


Figure 4-4-2 Dialog Box for Modifying Patient Information or Creating New Patient Information

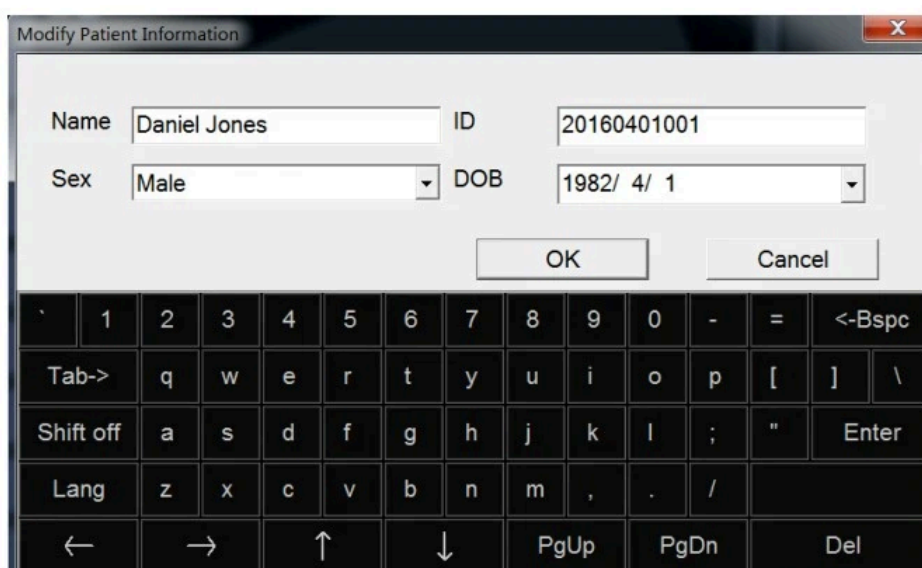


Figure 4-4-3 Dialog Box for Modifying Patient Information

2) Scan Mode Selection Area: **P1**, **P2**, **P3**, **P4**, **P5**, **P6** and **P7** representing 7 groups of scan parameters, respectively. Each group of scan parameters includes OD/OS, Mark, Gain, Bright, Contrast, TGC, Depth, Delay, B+A, Color and Probe, and saves the image of current frame. Click **P1** – **P7** by mouse, or press numeral keys (“1” – “7”) on the keyboard to switch among the 7 groups, the selected mode is highlighted. Click **Menu** (shortcut key Esc) on the right side of the scan mode selection area, to quit B Scan interface, and return to the main interface of the application program in Figure 4-1-2.

3) Scan Control Area: is used to control the probe scan, and save images and videos. Click **Frz/Scn** (shortcut key F5), press **FRZ/SCN** on the footswitch, or press “Space” key to enable the probe to scan (highlighted) or stop scanning. When **Image** key is highlighted, click **Save** (shortcut key F4) or press **SAVE** on the footswitch to save the current image to the image storage area on top of the scan control area. When **Video** key is highlighted, click **Save**, or press **SAVE** on the

footswitch to save images obtained in 10 seconds before freezing to the video storage area on top of the scan control area. When **Image** key is highlighted, left-click the image storage area on top of the scan control area, the selected image can be displayed in the image display area. When **Video** key is highlighted, left-click the video storage area on top of the scan control area, the corresponding video can be replayed. Right-click the image/video storage area, and delete the corresponding image when **Image** key is highlighted, or delete the corresponding video when **Video** key is highlighted, as shown in Figure 4-4-4.

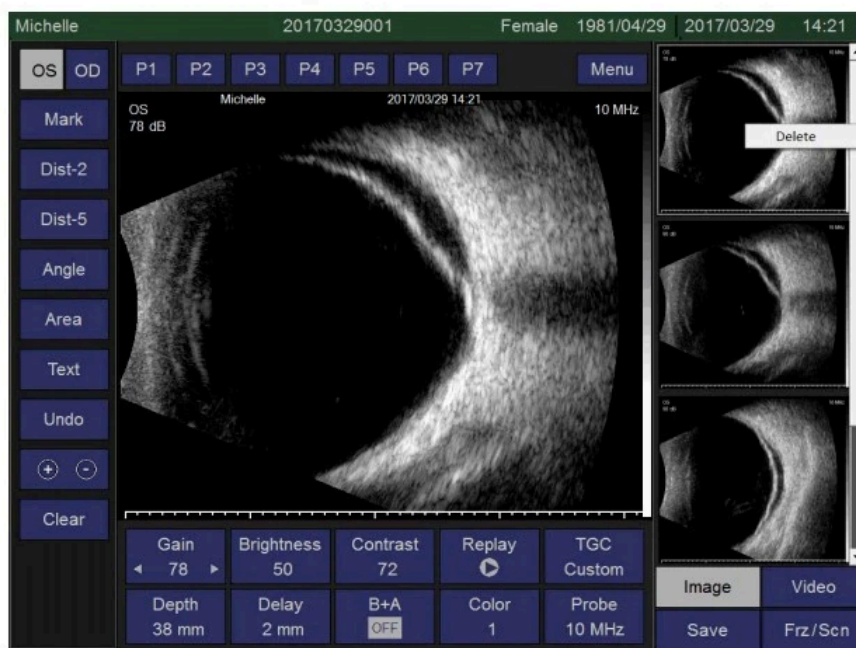


Figure 4-4-4 Image Deletion Function

4) Scan Parameter Adjustment Area: is used to adjust parameters in the real-time scan of B-scan images. The area includes functions like **Gain**, **Brightness**, **Contrast**, **Replay**, **TGC**, **Depth**,

Delay, **B+A**, **Color** and **Probe**. Click soft keys on the screen or press  or  key to switch among the functions. The dotted frame indicates that the function can be checked. The function key can be used to adjust parameters only when it is checked. When the function key is checked, scroll the scroll wheel, press  or , the left or right arrow key on the keyboard, or click  or , the soft key on the screen, to adjust the parameters.

Gain: to control gain, and display gain on the upper left corner of the image display area. Its adjustable range is 1-105dB.

Brightness: to adjust brightness of the image (Default: 58). Its adjustable range is 20-80.

Contrast: to adjust contrast of the image (Default: 40). Its adjustable range is 20-80.

Replay: to cineloop 100 images (in 10 seconds before freezing). Click  area by mouse, or

press “Enter” key on the keyboard to start to cineloop. Click  area by mouse, or press “Enter” key again, to stop the cineloop. When the cineloop is stopped, scroll the scroll wheel of the mouse, press  or , the left or right arrow key on the keyboard, or click  or , the soft key on the screen, to cineloop frame by frame.

TGC: to select TGC curves:

1-Default, the default mode

2-Vitr Enh, mode for enhanced TGC on vitreous body

3-Custom: mode for customization by users. Right-click , the soft key on the screen, and a TGC Setup dialog box pops up. The TGC curve can be set by clicking the vertical strings of the grid shown in Figure 4-4-5.

Depth: is used to set scan depth. The scan depth under 10MHz B-Scan mode is of 6 levels: 27mm, 38mm, 44mm, 49mm, 55mm and 60mm.

Delay: is used to adjust delayed depth, i.e., the distance from the front surface of the probe to the vertex of the image.

B+A: its default state is . Click  key on the function key by mouse, or press “Enter” key on the keyboard, to switch to the  state, to display B+A waveforms. Under the B+A mode, scroll the scroll wheel of the mouse, or press  or , the left or right arrow key on the keyboard, or click  or , the soft key on the screen, to select the position of the A-scan sampling line. Click  key on the function key by mouse, or press “Enter” key on the keyboard, to switch to the  state, to close B+A mode.

Color: to use pseudo-color codes, i.e., to switch among 8 groups of color codes. The default is the first group, the linear grey-scale code.

Probe: to access 10MHz B-Probe, mouse-click, scroll wheel,  or , the left or right arrow key on the keyboard, or “Enter” key to switch.

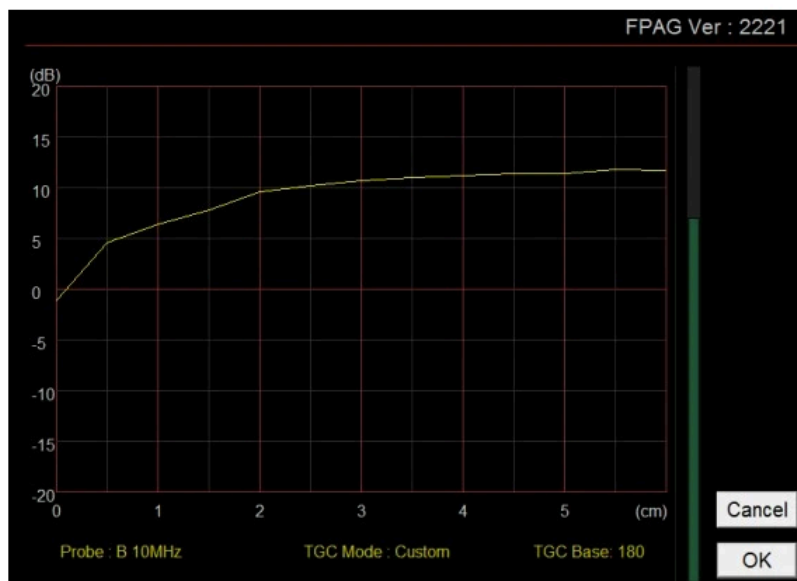


Figure 4-4-5 TGC Adjustment Interface

5) Image Display Area: is used to display images obtained through real-time scan, and saved images.

6) Image Measurement and Annotation Area: is used to perform functions of annotation and measurements on images.

OD (Oculus Dexter): Click , the soft key on the screen, to switch to the right eye.

OS (Oculus Sinister): Click , the soft key on the screen, to switch to the left eye.

Mark: is used to mark positions of eye. Left-click  to change  to mark the scan position of the probe.

Dist-2: is used to measure the distance between two points. Click  key, and it becomes highlighted. When the mouse comes into the image display area, its cursor becomes cross-shaped. Left-click desired starting and finishing points in the area, and the reading of the distance can be automatically displayed (shown in Figure 4-4-6). Click the cross-shaped cursor, or the area for measured results, the area turns to yellow. Use the arrow keys on the keyboard or drag the mouse to change its position.

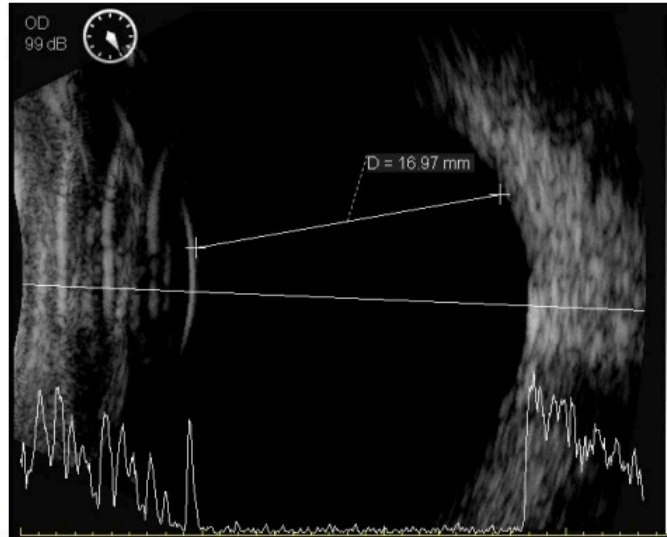


Figure 4-4-6 Dist-2 Two-Point Distance Measurement

Dist-5: is used to precisely measure AL under the B+A mode, see §4.6.1, 5-Point Marking Method under B+A Mode for Axial Length Measurement.

Angle: is used for angular measurement. Click **Angle**, and when the mouse comes into the image display area, its cursor becomes cross-shaped. Firstly, locate the cursor at a vertex of an angle to be measured; and then, locate two sides of the angle by placing cursors, and measured readings can be displayed on the screen (shown in Figure 4-4-7). Click the cross-shaped cursor, or the area for measured results, the area turns to yellow. Use the arrow keys on the keyboard or drag the mouse to change its position.

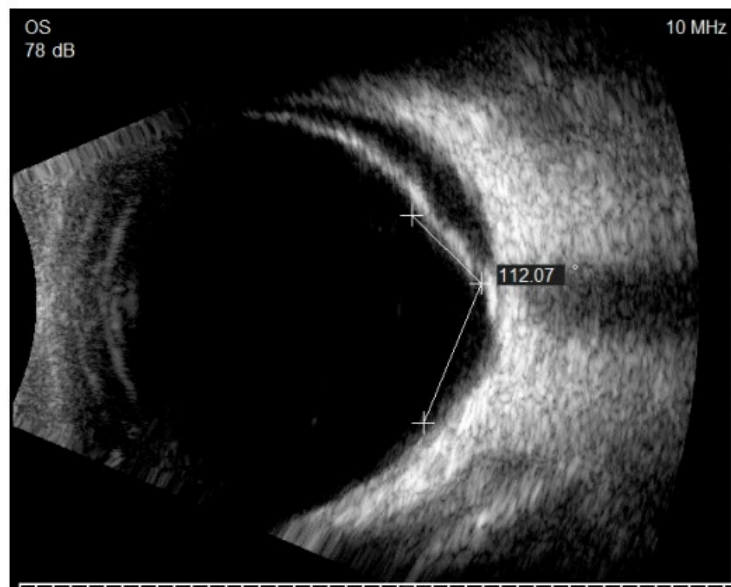


Figure 4-4-7 Angular Measurement

Area: is used for area measurement. Click **Area**; and drag your mouse along the boundary of an area to be measured while pressing the left button of the mouse down, and measured readings can be displayed on the screen by releasing the left button (shown in Figure 4-4-8).

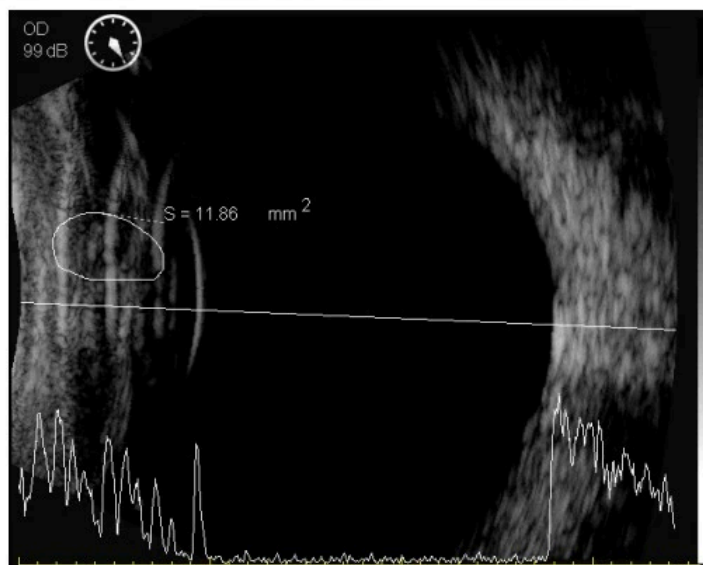


Figure 4-4-8 Area Measurement

Text: for annotation. Click **Text**; further left-click in the image-displaying area, and the “Text Input” dialog box pops up; input desired text to be annotated, and shift English and Chinese Input Method with “CTRL + Space Key”; click **OK**, and the annotated text can be displayed in the image-displaying area; and the text can be dragged by using the left button of the mouse (shown in Figure 4-4-9).



Figure 4-4-9 Annotation on Images

Undo: is used to undo the last action.

⊕ ⊖: is used for zoom-in & zoom-out. Click "⊕", to zoom in; and click "⊖", to zoom out. Press the left button of the mouse down for drag-and-display (shown in Figure 4-4-10), when the image zooms in.

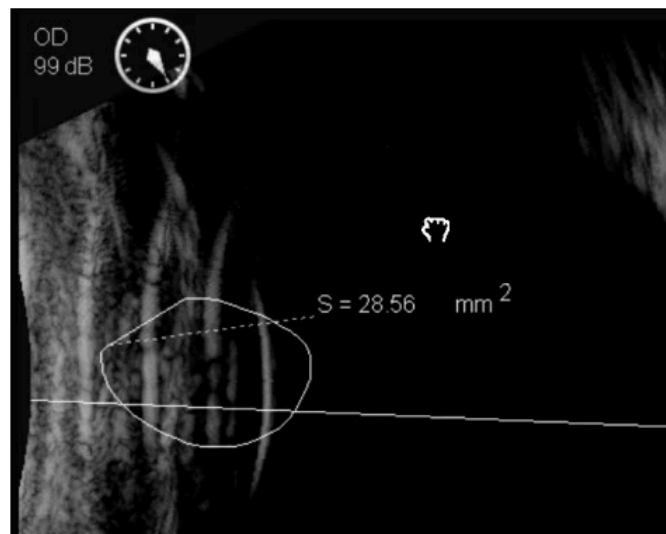
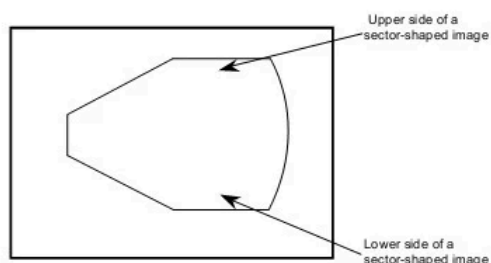


Figure 4-4-10 Zoom-in & Zoom-out of Images

Clear: is used to clear out marks for processing the image.

4.4.1 Analysis on Scan Direction and Position

Lower side of a sector-shaped image



A white marker is arranged on one side of the B-Probe. The image, to which the white marker corresponds, is always displayed on the upper side of the sector-shaped image. For instance, if the white marker of the probe is above the eye, an image of vertical section of the eye is displayed on the screen

(marked as ). The upper side of the "sector" corresponds to the upper side of the eye, and vice versa.

For another instance, if the white maker of the probe is on the nose side of the right eye, an image of horizontal section of the eye is displayed on the screen (marked as ). The upper side of the "sector" corresponds to the nose side of the eye, and the lower side of the "sector" corresponds to the tempora side of the eye.

4.4.2 Steps for B-Scan Examination

1. Create a new patient. If the patient to be examined has not been created through the **NEW**

operation, the operator shall create a new patient. Click **Menu**, in the B Scan interface in Figure 4-4-1, to return to the main interface in Figure 4-1-2. Click **NEW**, the function key to create a new patient; or click "Patient Information" area, and the dialog box for modifying the patient information or creating a new patient pops up, shown in Figure 4-4-2, click **NEW**, to create a new patient.

2. Tell the patient to lie face up and close his/her eyes.

3. Select scan mode. Select the scan mode from **P1** - **P7**.

4. Mark the eye to be scanned: click **OD**, the soft key, and mark the eye as the right one; click **OS**, the soft key, and mark the eye as the left one.

5. Mark the scan position of probe: click **Mark**, the soft key on the screen in the image processing area, to mark the current scan position of the probe.

6. Spread little acoustic gel on the eyelid, and place the B-Probe on the patient's eyelid with proper care.

7. Tread on the footswitch, or click **Frz/Scn** or Space key, to start the probe, and the ultrasound sectional image of the eye can be displayed on the screen in real time;

8. Adjust parameters, such as gain, brightness or contrast, to display clear scanned images, and to meet clinical demands. Tread on the footswitch or click **Frz/Scn** or space key to stop scanning, to finish the acquisition of a B-scan image. When necessary, switch to another scan mode for further scanning, to obtain B-scan images using different parameters.



Note: As one of key operations affecting the quality of a B-Scan image, gain adjustment may vary depending on patients and diagnosis conditions. However, it's not suggested that the gain remains unchanged nor that the higher the better.

9. When it's necessary to save images, Click **Save** or thread on **SAVE** of the footswitch to save the current image to the hard drive; or save the images (100 images) in 10 seconds before the

probe stops scanning, as a video file, and replay it when necessary.

4.5 A-Scan AL Biometric Measurement

In A-Scan biometric AL (Axial Length) measurement, an ultrasound-based distance measurement method is used to measure the anterior chamber depth, lens thickness and vitreous length of an eye, and AL can be calculated based on these readings. For increased accuracy, the operator shall enable ultrasound to enter the eye from the vertex of cornea and to superpose the axis.

Measurements can be performed automatically or manually. Automatic measurement is applicable to normal eyes, aphakic eyes, eyes with dense cataract, and other substances where ultrasound transmits at a known velocity.

Depending on whether the probe is in contact with cornea, Contact and Immersion methods are available for measurement.

For Contact method, the A-Probe is in direct contact with the vertex of cornea. It's simple and easy-to-use. However, the direct contact may lead to injury and slight distortion of the cornea, which affects the accuracy of measurement. Therefore, the operator shall perform the measurement with proper care without pressing the cornea. The contact method applies to both automatic and manual mode.

For Immersion method, the A-Probe acts on eyes through an acoustic coupling medium, it is not in direct contact with cornea. Fix an eye cup between upper and lower eyelids with proper care; fill the eye cup with physiological saline as a coupling medium; immerse the A-Probe in the physiological saline in the eye cup without contacting the cornea; and enable the probe to come closer to the cornea in a way that the probe is perpendicular to the cornea, and measurement automatically starts when the front end of the probe is 2mm-6mm away from the vertex of the cornea.

Click **A scan** (shortcut key F3) in the main interface in Figure 4-1-2, to access A-Scan interface (shown in Figure 4-5-1).

Click **Menu** (shortcut key Esc) to return to the Main Interface in Figure 4-1-2.

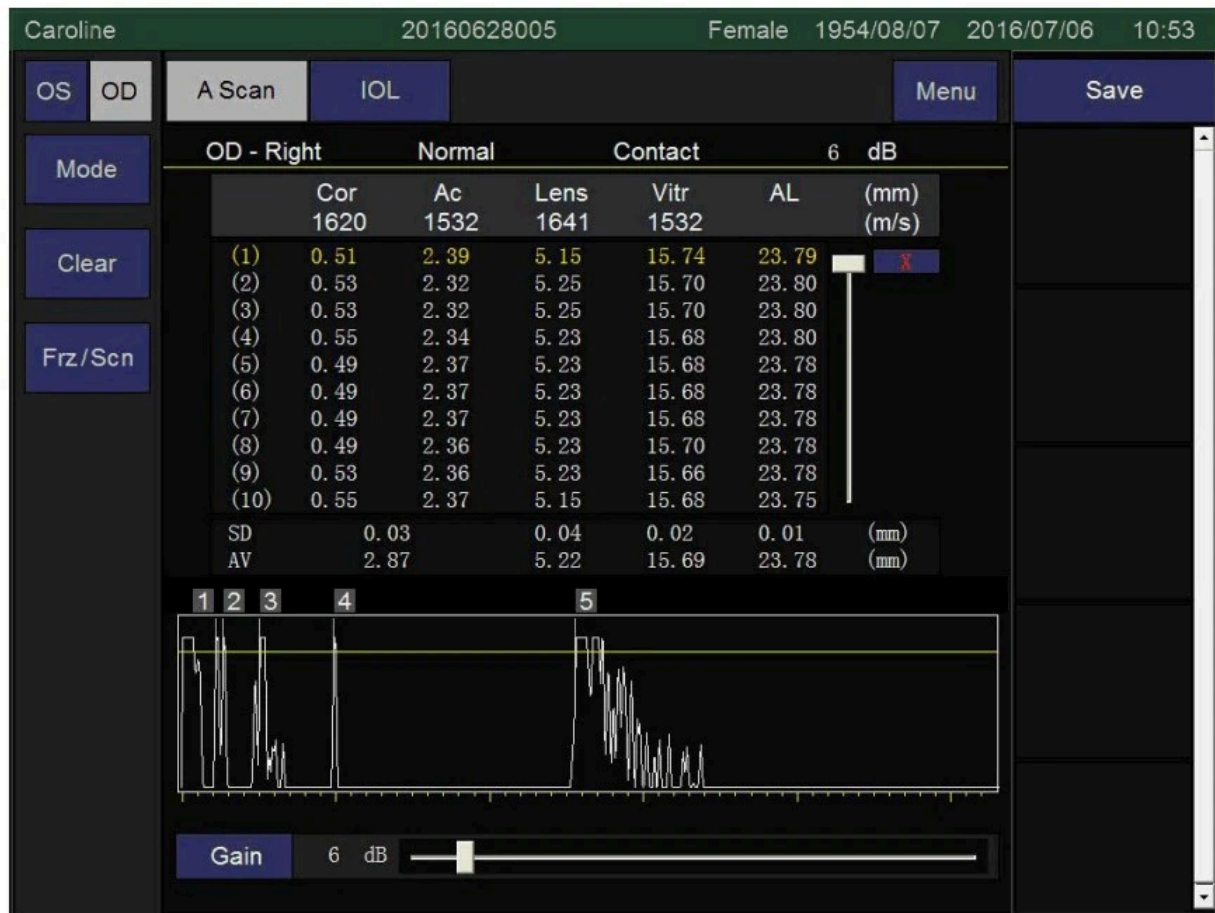


Figure 4-5-1 A-Scan Interface

Click the area of name and sex in Figure 4-5-1, the “Modify or New Patient Information” dialog box pops up (shown in Figure 4-4-3). Patient name and other information can be re-edited if required, click **Modify**, the “Modify Patient Information” dialog box pops up (shown in Figure 4-4-4); click New to create a new patient, the “New Patient” dialog box pops up (shown in Figure 4-2-1); click **Cancel** to give up the operation.

Click **Mode** to access “A-Scan Mode Setup” interface (shown in Figure 4-5-2).

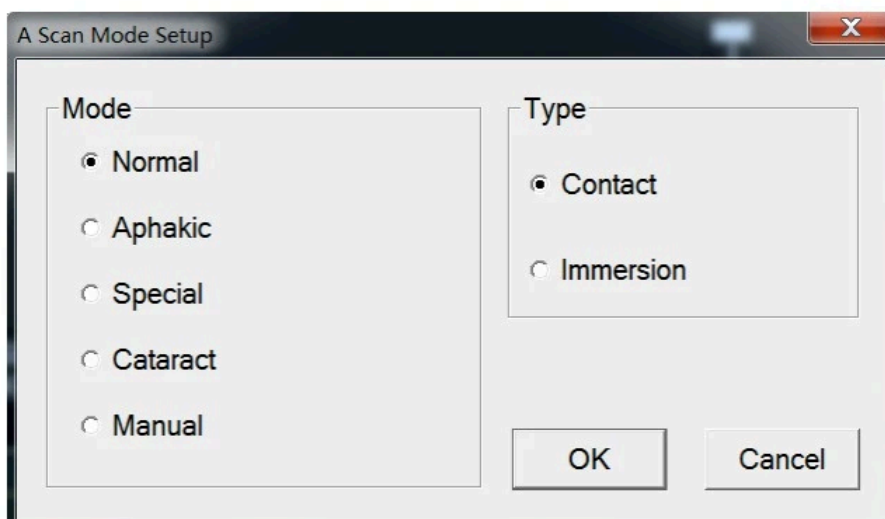


Figure 4-5-2 A-Scan Mode Setup Interface

Click “Normal”, “Aphakic”, “Special” or “Cataract” under the “Mode” column, to select eye type;

Click “Manual” under the “Mode” column, to select manual mode;

Click “Contact” or “Immersion” under the “Type” column, to select measurement type.

4.5.1 Steps for Automatic Measurement

1. Click **A scan** in the main interface to access A-Scan mode;
2. Mark the eye to be scanned; click **OS** (shortcut key F7) or **OD** (shortcut key F8) to identify left eye or right eye;
3. Click **Mode** to access “A-Scan Mode Setup” interface (shown in Figure 4-5-2);
4. Select the correct eye type from “Normal”, “Aphakic”, “Special” and “Cataract”;
5. Tell the patient to lie face up, keep his/her eye open, and perform topical anesthesia on the eye to be scanned;
6. Rinse the front end of the A-Probe with physiological saline;
7. Tread on the footswitch, or click **Frz/Scn** (shortcut key F5), to start the A-Probe;
 - If the contact method is selected, tell the patient to stare steadily at the probe, and place the probe with proper care on the vertex of the cornea of the eye to be scanned;
 - If the immersion method is selected, place the eye cup with proper care in the eyelid; fill the eye cup with physiological saline; immerse the probe in the eye cup in a way that the probe is perpendicular to the cornea; tell the patient to stare steadily at the probe; carefully move the probe towards the cornea; and measurement automatically starts when the front end of the probe is 2mm-6mm away from the cornea.
8. Adjust the gain to acquire better waveform;

9. If a string of beeps are heard, it is indicated that measurement results have been acquired and displayed on the screen; if not, move the probe slightly until the beeps are heard; measurements are automatically performed one after another and stop automatically after 10 groups of measurements.



Note: The operator (like a doctor) shall handle the probe with proper care and steadiness, because readings of a patient sampled need to be taken for several times and then averaged in each automatic measurement. The operator can take the probe away only when the device stops beeping and shows measured readings on the screen.

Drag the vertical slider in the measurement result area, the corresponding waveform displays accordingly. Check the readings for unreliable data: use the slider to move the ☐ mark to the row of unreliable data to be deleted, and click the mark to delete the selected row. The remaining readings will be re-averaged;

The unreliable readings to be deleted include:

- a) Position marker does not correspond to the rising edge of the waveform;
 - b) The peak of retina waveform is not steep;
 - c) The readings contrast sharply with the average.
10. Clear current readings for re-measurement: Click to clear current readings, and measure the patient again. Click or tread on the footswitch, there is a dialog box for indicating whether to clear the current readings (shown in Figure 4-5-3), and click to clear the readings and start scanning again, or click to give up current operation.
 11. Click (shortcut key F4) to save the measured readings in the linked area on the right side. Similar to the Image Deleting function under B scan (shown in Figure 4-4-2), right-clicking the linked area of saving to delete the corresponding measured readings.

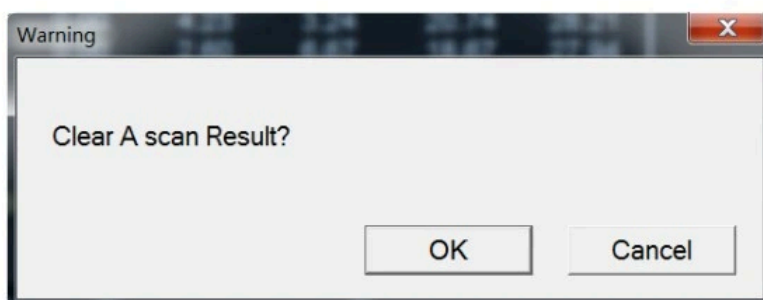


Figure 4-5-3 Prompt Dialog Box for Clearing Measured Readings

4.5.2 Steps for Manual Measurement

If it's difficult for the operator to take readings through automatic measurement, or for a patient to

follow the operator's instructions due to his/her physical conditions, the operator may take manual measurement; if it's not the case, the manual measurement is not suggested.

Click **Mode** in the A scan interface, to access the A scan Mode Setup interface shown in Figure 4-5-2; and select "Manual" mode.

The steps for manual measurement are similar to those for automatic measurement: Click **Frz/Scn** to activate the scan; adjust the gain for a better waveform; Click **Frz/Scn** again, so that the waveform can freeze up; put down markers on the waveform with the mouse (shown in Figure 4-6-4, for detailed steps, see §4.6.2 5-Point Marking Method under A-Scan Biometric Mode for Axial Length Measurement).

4.6 5-Point Marking Method

When passing through a human eye in the direction of optical axis, ultrasonic waves reflect at 5 interfaces (shown in Figure 4-6-1). These 5 interfaces are: □ front vertex of cornea, □ rear edge of cornea, □ front edge of lens, □ rear edge of lens, and □ retina.

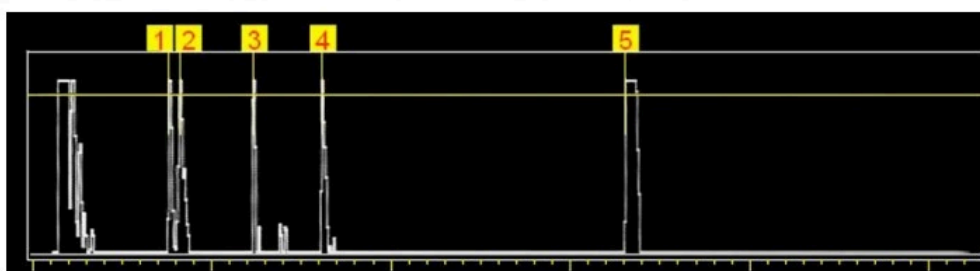


Figure 4-6-1 5-Point Marking Method

Due to the special structure of a human eye, ultrasonic waves travel through different eye components at different velocities:

Acoustic Velocity of Cornea: $V_{COR} = 1620 \text{ m/s}$ □ – □

Acoustic Velocity of Anterior Chamber: $V_{AC} = 1532 \text{ m/s}$ □ – □

Acoustic Velocity of Lens: $V_{LEN} = 1641 \text{ m/s}$ □ – □

Acoustic Velocity of Vitreous Body: $V_{VITR} = 1532 \text{ m/s}$ □ – □

Axial Length: $AL = V_{COR} * (t_2 - t_1) + V_{AC} * (t_3 - t_2) + V_{LEN} * (t_4 - t_3) + V_{VITR} * (t_5 - t_4)$ <Formula 1.1>

By precisely defining these five characteristic points, the operator can obtain the accurate results of axial length (AL) according to Formula 1.1. This is the so-called 5-Point Marking Method for AL measurement.

4.6.1 5-Point Marking Method under B+A Mode for Axial Length Measurement

1. Use the Immersion Method for scanning; don't stop scanning until satisfactory scanned images are acquired;

- Click **Dist-5** to use 5-Point Marking Method under B+A mode shown in Figure 4-6-2;
- Drag the 5 rectangular boxes (**1**, **2**, **3**, **4** and **5**), to their target positions; and the values of COR, AC, LENS, VITR and AL vary in real time; (if the operator is unable to distinguish the front and rear edges of cornea, both points (**1** and **2**) can be marked at Point **1**).
- Complete the adjustment by dragging those 5 boxes, and measured results of COR, AC, LENS, VITR and AL can be displayed on the screen.

⚠ Note: Click **Dist-5** to select the 5-Point Marking Method; right-click the area for setting acoustic velocities in the B-Scan interface (e.g. a rectangular area for displaying acoustic velocities at the upper part of the B-Scan interface), and a dialog box for setting acoustic velocities pops up (shown in Figure 4-6-3); amend the corresponding acoustic velocity in the edit boxes; and click **OK** for confirmation.

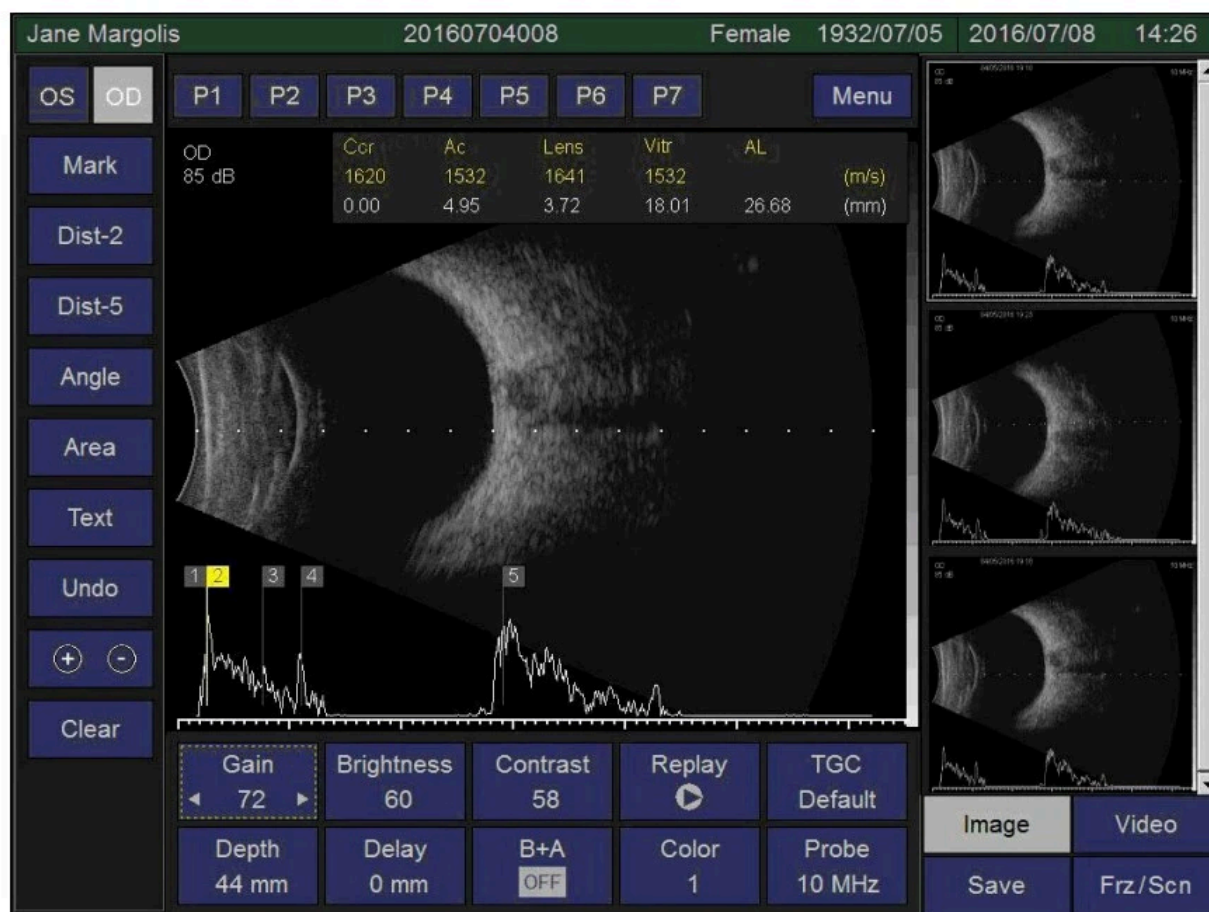


Figure 4-6-2 5-Point Marking Method under B+A mode

The screenshot shows a 'SPEED SETUP' dialog box with a table of acoustic velocities. The table has columns for 'V-cor', 'V-acd', 'V-lens', and 'V-vitr'. The rows represent different eye types: 'Normal', 'Aphakic', 'Cataract', 'Special', and 'Manual'. The 'Special' and 'Manual' rows have input boxes for 'V-acd', 'V-lens', and 'V-vitr'. Below the table are 'OK' and 'Cancel' buttons. At the bottom is a numeric keypad with digits 1-0, a decimal point, a minus sign, and a '<-Bspc' button. Below the keypad are buttons for 'Key Type', left arrow, right arrow, up arrow, down arrow, 'Lang', and 'Close'.

	V-cor	V-acd	V-lens	V-vitr
Normal	1620	1532	1641	1532
Aphakic	1620	1532	0	1532
Cataract	1620	1532	1629	1532
Special	1620	1532	1800	1532
Manual	1620	1537	1641	1532

OK Cancel

1 2 3 4 5 6 7 8 9 0 . - <-Bspc

Key Type ← → ↑ ↓ Lang Close

Figure 4-6-3 Setting Acoustic Velocities in 5-Point Marking Method under B-Scan Mode

4.6.2 5-Point Marking Method for Measuring Axial Length under A-Scan Biometric Mode

1. Click **A scan** to access A-Scan biometric mode;
2. Select the eye type from: "Normal", "Aphakic", "Special" and "Cataract";
3. Place the A-Probe on the cornea of a patient with proper care, and tread on the footswitch to conduct automatic measurement;
4. If the standard deviation (S.D.) of readings cannot meet clinical requirements, use 5-Point Marking Method for adjustment.
 - a) Drag the slider on the right side of measured readings; and check the A-Scan waveforms acquired; and correct inaccurate readings acquired from automatic measurement.
 - b) Drag the 5 rectangular boxes (**1**, **2**, **3**, **4** and **5**) in the A-Scan waveform area, to their target positions, and the values of COR, AC, LENS, VITR and AL vary in real time (if the operator is unable to distinguish the front and rear edges of cornea, both points (**1** and **2**) can be marked at Point **1**); and the average value and S.D. can be re-calculated (shown in Figure 4-6-4).

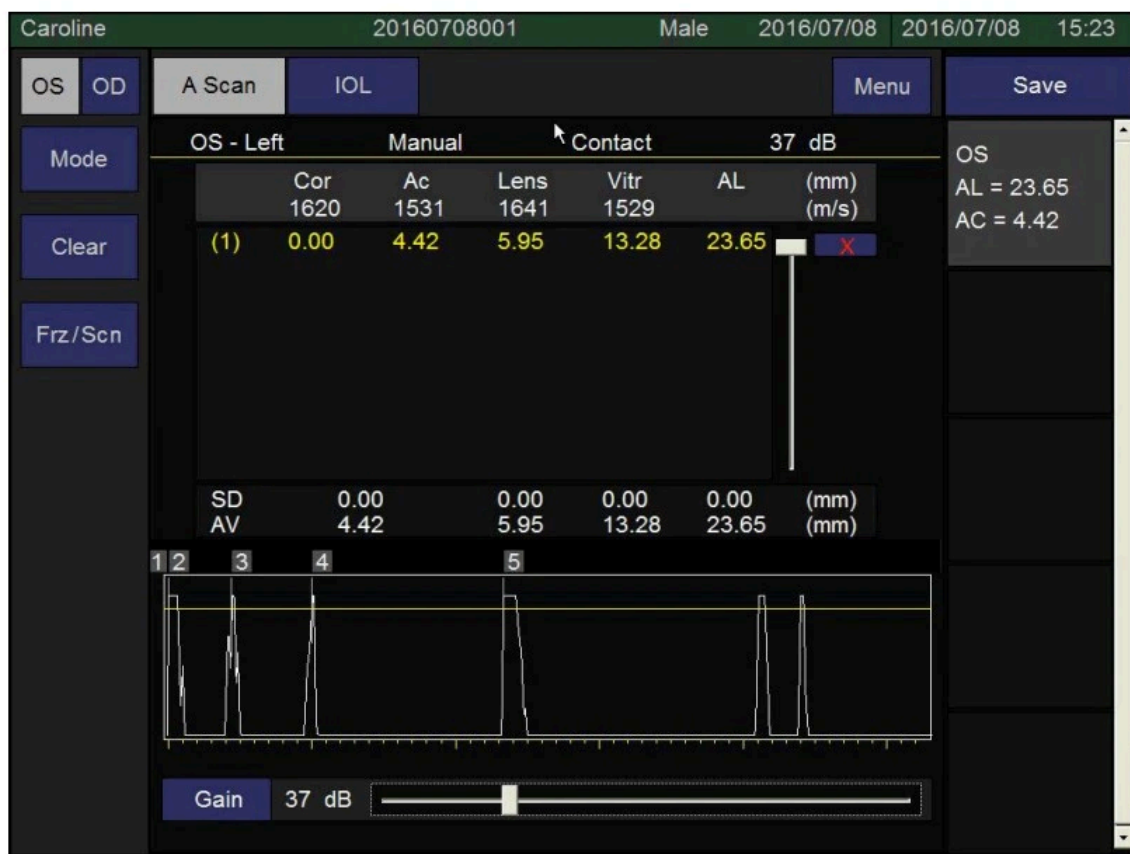


Figure 4-6-4 5-Point Marking Method under A-Scan Mode



Note: Acoustic velocities under different measuring modes:

Normal mode:

Acoustic Velocity of Cornea:	$V_{\text{COR}} = 1620 \text{ m/s}$	☐ - ☐
Acoustic Velocity of Anterior Chamber:	$V_{\text{AC}} = 1532 \text{ m/s}$	☐ - ☐
Acoustic Velocity of Lens:	$V_{\text{LEN}} = 1641 \text{ m/s}$	☐ - ☐
Acoustic Velocity of Vitreous Body:	$V_{\text{VITR}} = 1532 \text{ m/s}$	☐ - ☐

Aphakic mode:

Acoustic Velocity of Cornea:	$V_{\text{COR}} = 1620 \text{ m/s}$	☐ - ☐
Acoustic Velocity of Anterior Chamber:	$V_{\text{AC}} = 1532 \text{ m/s}$	☐ - ☐
Acoustic Velocity of Lens:	$V_{\text{LEN}} = 0 \text{ m/s}$	☐ - ☐
Acoustic Velocity of Vitreous Body:	$V_{\text{VITR}} = 1532 \text{ m/s}$	☐ - ☐

Cataract mode:

Acoustic Velocity of Cornea:	$V_{\text{COR}} = 1620 \text{ m/s}$	☐ - ☐
Acoustic Velocity of Anterior Chamber:	$V_{\text{AC}} = 1532 \text{ m/s}$	☐ - ☐
Acoustic Velocity of Lens:	$V_{\text{LEN}} = 1629 \text{ m/s}$	☐ - ☐
Acoustic Velocity of Vitreous Body:	$V_{\text{VITR}} = 1532 \text{ m/s}$	☐ - ☐

Acoustic velocities under “Special” and “Manual” modes, please refer to [<4.8 Setting Acoustic Velocity>](#).

4.7 IOL Calculation

This product provides different calculation methods for patients who have undergone refractive surgery and for those who haven't.

4.7.1 For patients who haven't undergone refractive surgery

1. Parameters for IOL Calculation

For patients who haven't undergone refractive surgery, the product provides 6 groups of IOL calculation formulas: SRK-II, SRK-T, BINK-II, HOLLADAY, HOFFER-Q and HAIGIS. Different formulas use different constants provided by IOL manufacturers. These constants include A, ACD and SF.

The BINK-II and HOFFER-Q formulas require ACD, i.e., the desired depth of anterior chamber; ACD can be calculated from A;

$$ACD = [(A \times 0.5663) - 65.60] + 3.595 / 0.9704$$

$$\text{or } ACD = (SF + 3.595) / 0.9704$$

The HOLLADAY formula requires SF, which can also be calculated from A;

$$SF = (A \times 0.5663) - 65.60$$

$$\text{or } SF = (ACD \times 0.9704) - 3.595$$

The constant A inputted into the product can be automatically transformed into SF.

The SRK-II and SRK-T formulas use A which can be calculated from the following formulas:

$$A = (SF + 65.60) / 0.5663$$

$$\text{or } A = 109.49 + (1.71358 \times ACD)$$

The HAIGIS formula uses three constants: a0, a1 and a2 which can be calculated from A:

$$a0 = (0.62467 \times A) - 72.434$$

$$a1 = 0.40$$

$$a2 = 0.10$$

2. Steps for IOL Calculation

- a) Click **IOL** in the A scan interface to access IOL interface (shown in Figure 4-7-1); and select “NO” under “Refractive Surgery” column;

Jane Margolis 20160704008 Female 1932/07/05 2016/07/06 16:17

OS OD A Scan IOL Menu Save

OS -- Left Refractive Surgery ? NO

AL = 24.65 mm

K1 = 43.00 D K2 = 43.50 D

Formula: SRK_II Formula: SRK_II

A = 115.80 DR = -1.0 D A = 118.50 DR = -0.5 D

D.em = 14.75 D D.am = 16.00 D D.em = 17.45 D D.am = 18.07 D

IOL	Refr	IOL	Refr
14.00	0.60	16.00	1.16
14.50	0.20	16.50	0.76
15.00	-0.20	17.00	0.36
15.50	-0.60	17.50	-0.04
* 16.00	-1.00	* 18.00	-0.44
16.50	-1.40	18.50	-0.84
17.00	-1.80	19.00	-1.24
17.50	-2.20	19.50	-1.64
18.00	-2.60	20.00	-2.04

Validity Checking :

Figure 4-7-1 IOL Interface (for Patient who haven't Undergone Refractive Surgery)

- b) Automatically acquire AL (Axial Length) through measurement;
- c) See Annex E <IOL Formulas> for detailed information on selecting IOL calculation formulas and parameters; the meaning of each parameter is as follows:

K1Pr: Keratometry before refractive surgery

K2Pr: Keratometry before refractive surgery

K1Po: Present Keratometry

K2Po: Present Keratometry

REFpr: Spectacles refraction before refractive surgery

REFpo: Spectacles refraction after refractive surgery

A/ACD: Constant of IOL

DR: Desired Refraction after implantation of IOL

ANTI/POST: Anterior Mode/Posterior Mode;

D.EM: Diopter of Emmetropia

D.AM: Diopter of Ametropia

- d) Click the combo box of Formula column to select 6 groups of constant formula; click the combo box on the right side of A/ACD, DR column to select appropriate parameters, in which, the parameter of A/ACD can be amended by clicking **A const**.
- e) Click **AL Select**, and a dialog box for selecting AL value pops up. "A Scan" row shows the AL value acquired from measurement under A-Scan mode; and "B Scan" row shows the AL value acquired from 5-Point Marking Method under B-Scan mode (shown in Figure 4-7-2).

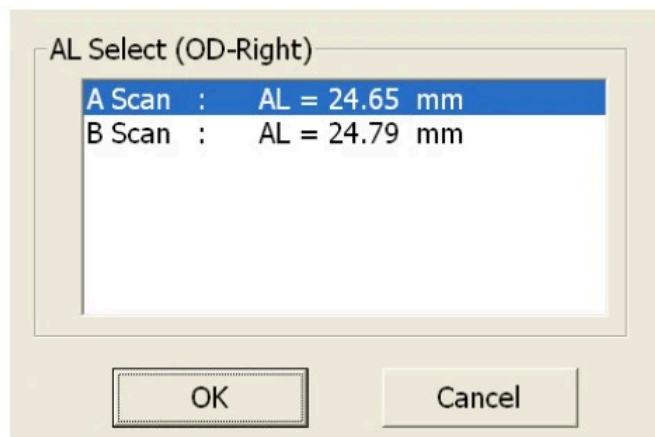


Figure 4-7-2 Dialog Box for Selecting AL Value

- f) Click **A const** to set Constant A or ACD, shown in Figure 4-7-3.

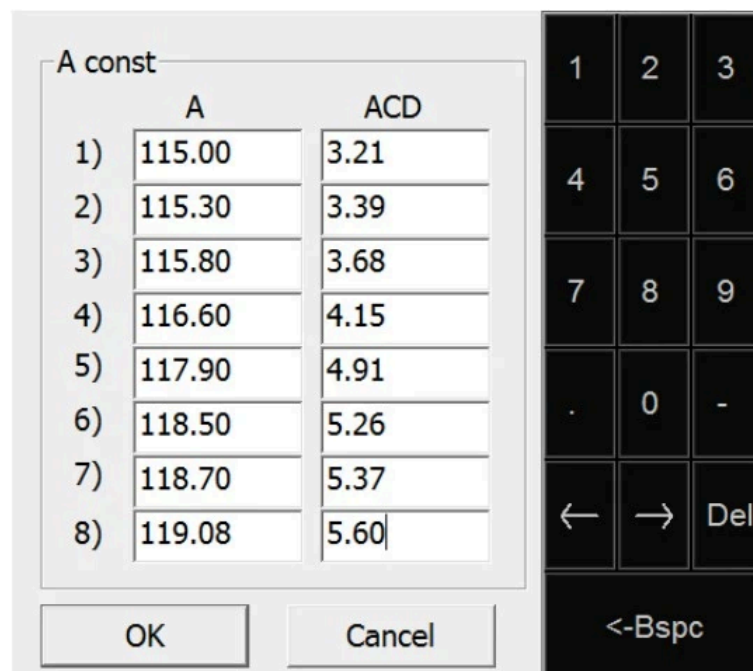


Figure 4-7-3 Dialog Box for Setting Constant A/ACD

- g) Click **Calculate** to perform IOL calculation and display IOL results; the diopter that

satisfies the DR input is marked as “*”.

- h) Click **Clear** to clear the current results.
- i) Click **Snap** to save the measured readings in the linked area on the right side. Similar to the Image Deleting function under B scan (shown in Figure 4-4-2), right-clicking the linked area of saving to delete the corresponding measured readings.

4.7.2 For patients who have undergone refractive surgery

1. Introduction to relevant parameters

For patients who have undergone refractive surgery, the product provides 5 groups of IOL calculation formulas: History derived method, Double K/SRK-T method, Refraction derived method, ROSA method, and SHAMMAS method. Different formulas use different constants provided by IOL manufacturers. These constants include A, ACD or SF (see §4.7.1 Parameters for IOL Calculation).

2. Steps for IOL Calculation

- a) Click **IOL** in the A scan interface to access IOL interface (shown in Figure 4-7-4); and select “YES” under “Refractive Surgery” column;

Jane Margolis 20160704008 Female 1932/07/05 2016/07/06 16:16

OS OD A Scan IOL Menu Save

AL Select

OS -- Left Refractive Surgery ? **YES**

AL = 24.65 mm Method DoubleK/SRK-T

K1Pr=43.00 D K2Pr=43.50 D REFPr = -6.00 D REFpo = -1.00 D

Formula: DoubleK Formula: DoubleK

A = 115.80 DR = -1.0 D A = 118.50 DR = -0.5 D

D.em = 20.83 D D.am = 22.08 D D.em = 23.95 D D.am = 24.65 D

IOL	Refr	IOL	Refr
20.00	0.66	22.50	1.01
20.50	0.26	23.00	0.67
21.00	-0.13	23.50	0.32
21.50	-0.53	24.00	-0.04
* 22.00	-0.94	* 24.50	-0.39
22.50	-1.35	25.00	-0.75
23.00	-1.76	25.50	-1.12
23.50	-2.19	26.00	-1.49
24.00	-2.61	26.50	-1.87

Validity Checking :

Clear

A Const

Calculate

Figure 4-7-4 IOL Interface (for Patients who Undergone Refractive Surgery)

- b) Automatically acquire AL (Axial Length) through measurement;
- c) Click combo box of Method column to select 5 kinds of calculation method.
- d) See Annex E <IOL Formulas> for detailed information on selecting IOL calculation formulas and parameters; the meaning of each parameter is as follows:

K1Pr: Keratometry before refractive surgery

K2Pr: Keratometry before refractive surgery

K1Po: Present Keratometry

K2Po: Present Keratometry

REFpr: Spectacles refraction before refractive surgery

REFpo: Spectacles refraction after refractive surgery

A/ACD: Constant of IOL

DR: Desired Refraction after implantation of IOL

ANTI/POST: Anterior Mode/Posterior Mode;

D.EM: Diopter of Emmetropia

D.AM: Diopter of Ametropia

- e) Click the combo box of Formula column to select 6 groups of constant formula; click the combo box on the right side of A/ACD, DR column to select appropriate parameters, in which, the parameter of A/ACD can be amended by clicking **A const**.
- f) Click **AL Select**, and a dialog box for selecting AL value pops up. "A Scan" row shows the AL value acquired from measurement under A-Scan mode; and "B Scan" row shows the AL value acquired from 5-Point Marking Method under B-Scan mode (shown in Figure 4-7-2).
- g) Click **A const** to set Constant A or ACD, shown in Figure 4-7-3a
- h) Click **Calculate** to perform IOL calculation and display IOL results; the diopter that satisfies the DR input is marked as "**".
- i) Click **Clear** to clear the current results.
- j) Click **Snap** to save the measured readings in the linked area on the right side. Similar to the Image Deleting function under B scan (shown in Figure 4-4-2), right-clicking the linked area of saving to delete the corresponding measured readings.

4.8 Setting Acoustic Velocity

Acoustic velocity refers to the velocity at which ultrasonic wave travels through each part of a human eye. Based on their respective acoustic velocities, this product defines 4 eye types: NORM (Normal Eye), APHA (Aphakic Eye), SPEC (Special Eye) and CATA (Dense Cataract). These acoustic velocities are shown in Table 4-8-1:

Table 4-1 Reference Table for Acoustic Velocity Settings

Unit: m/s

	NORM	APHA	SPEC	CATA
Anterior Chamber V (AC)	1532	—	1532	1532
Lens V (LEN)	1641	—	PMMA: 2718* Acrylic: 1946* Silicone: 1050*	1629
Vitreous Body V (VITR)	1532	1532		1532

* provided by IOL manufacturers

Click the area for setting acoustic velocities in the A-Scan interface (the rectangular area for displaying acoustic velocities (Cor, Ac, Lens, Vitr) at the upper part of the A-Scan interface), and a dialog box for setting acoustic velocities pops up (shown in Figure 4-8-1); amend the corresponding acoustic velocity in the edit box; and click **OK** for confirmation.

SPEED SETUP

	V-cor	V-acd	V-lens	V-vitr
Normal	1620	1532	1641	1532
Aphakic	1620	1532	0	1532
Cataract	1620	1532	1629	1532
Special	1620	1532	1946	1532
Manual	1620	1532	1641	1532

1 2 3 4 5 6 7 8 9 0

. - ← → Del <-Bspc

OK Cancel

Figure 4-8-1 Dialog Box for Setting Acoustic Velocities

4.9 User Setup

Click **Setup** in the main interface to access “User Setup” interface (shown in Figure 4-9-1).

No	Name	Password
1	User1	*****
2	User2	*****
3	User3	*****
4	User4	*****
5	User5	*****
6	User6	*****
7	User7	*****
8	Admin	*****

Hospital:

Work Path:

Buttons: Cancel, OK

Keypad: 1-0, -, =, <-Bspc, Tab->, q-w-e-r-t-y-u-i-o-p-[] \, Shift off, a-s-d-f-g-h-j-k-l-;- " Enter, Lang, z-x-c-v-b-n-m-, . /, ← → ↑ ↓ PgUp PgDn Del

Figure 4-9-1 User Setup Interface

Use the left part of the interface for setting usernames and their corresponding passwords. (No password authentication is required for No 1-4 logging in.)

Fill in the hospital name under the “Hospital Name”.

Set the storage path of the system under the “Work Path”. It is suggested to save the Data on Disc D which has larger storage space.

4.10 Case Report

Click **Report** (shortcut key F6) in the main interface to access the “Diagnosis Report” interface (shown in Figure 4-10-1).

Select Image Template Print Save Open Dictionary Back

Mania Hospital

The Ultrasound A/B Scanner Report

Name: Caroline ID: 20160708001 Sex: Male DOB: 2016/07/08

[Large dotted rectangular frame for report content]

Figure 4-10-1 Diagnosis Report Interface

Function keys, including “Select Image”, “Template”, “Print”, “Save”, “Open”, “Dictionary” and “Back”, are on the top of the diagnosis report interface.

Click “Select Image” key, or left-click the blank area in the dotted frame, a dialog box for selecting images pops up, shown in Figure 4-10-2. Click to select desired images, and click OK to display them in the report, or click Clear key, to remove the selected images.

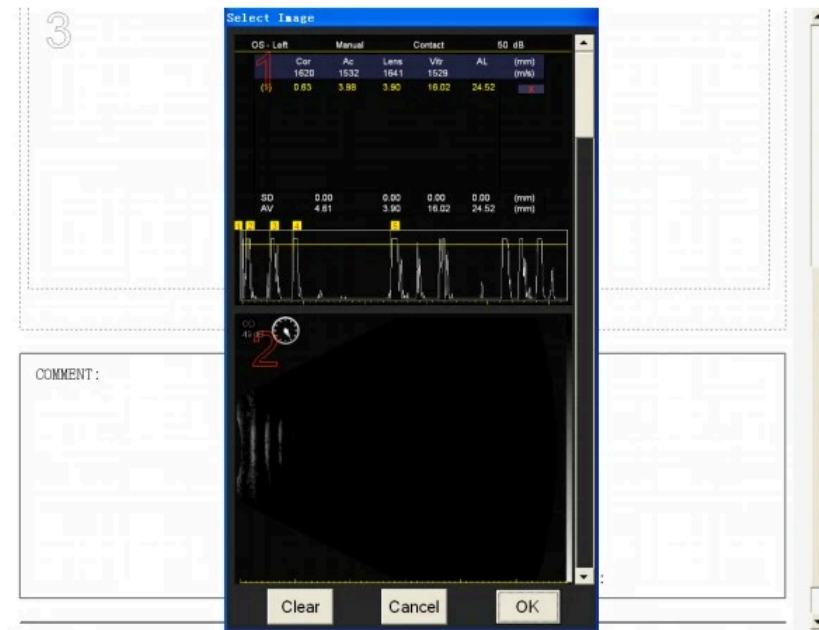


Figure 4-10-2 Interface for Selecting Images

Click **Template** key, and an editing and characterization interface pops up, shown in Figure 4-10-3.

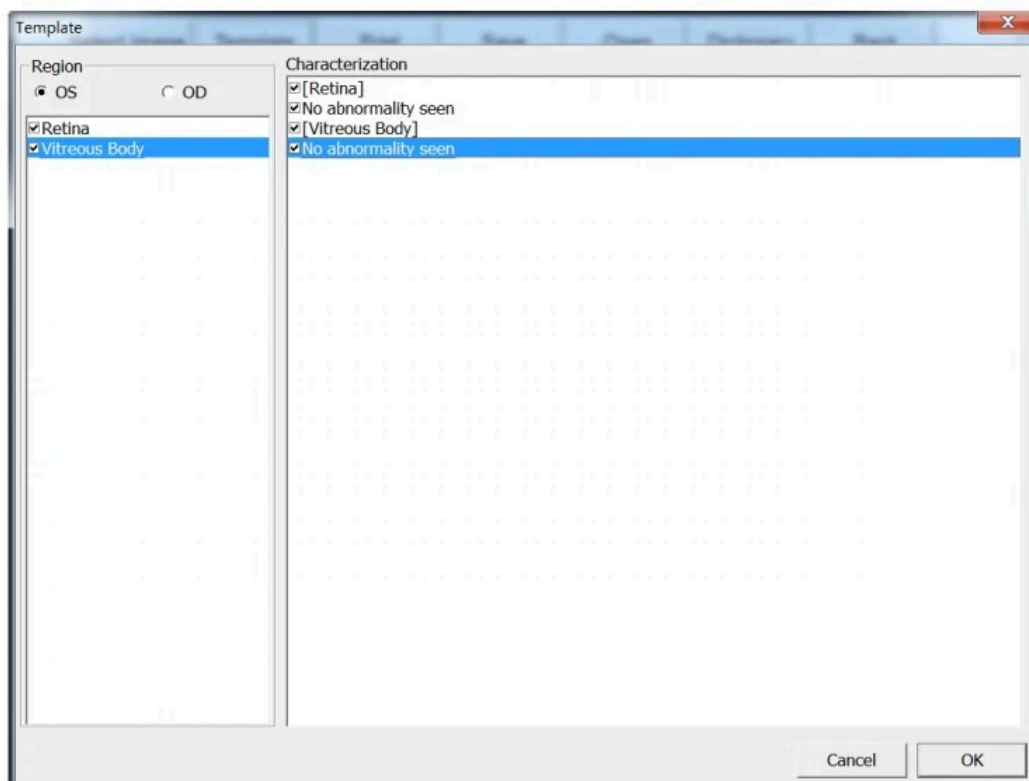


Figure 4-10-3 Editing and Characterization Interface

Click OS or OD key in the radio box in the “Region” area to select the current eye. Take the left eye as an example (the default current eye of the system is OS), click to check the square frames in front of eye parts like vitreous body or retina, under the Region area, to display the relevant

characterization corresponding to the selected eye part in the Characterization area on the right side. Uncheck the eye part on the left side, to clear the relevant characterization corresponding to the eye parts. Check the relevant entries in the Characterization area on the right side, to characterize the current eye. When characterizing the right eye (OD), click OD key, and perform the same operations as that with the left eye (OS). When the relevant characterization of the eye parts is finished, click OK, to close the dialog box for editing and characterization, and the selected characterization will be displayed in the COMMENT area in the diagnosis report interface. This indicates the completion of primary editing and typesetting. The user may further conduct relevant operations like adding or deleting. Right-click the area, and the user may also add characterization through the right-key menu, shown in Figure 4-10-4. Click the blank areas on the two sides, to quit the editing state. The eye parts and their corresponding characterization presented in the editing and characterization interface can be added in the diagnosis dictionary (Figure 4-10-5), for detailed operations, please refer to the introduction below on the diagnosis dictionary.

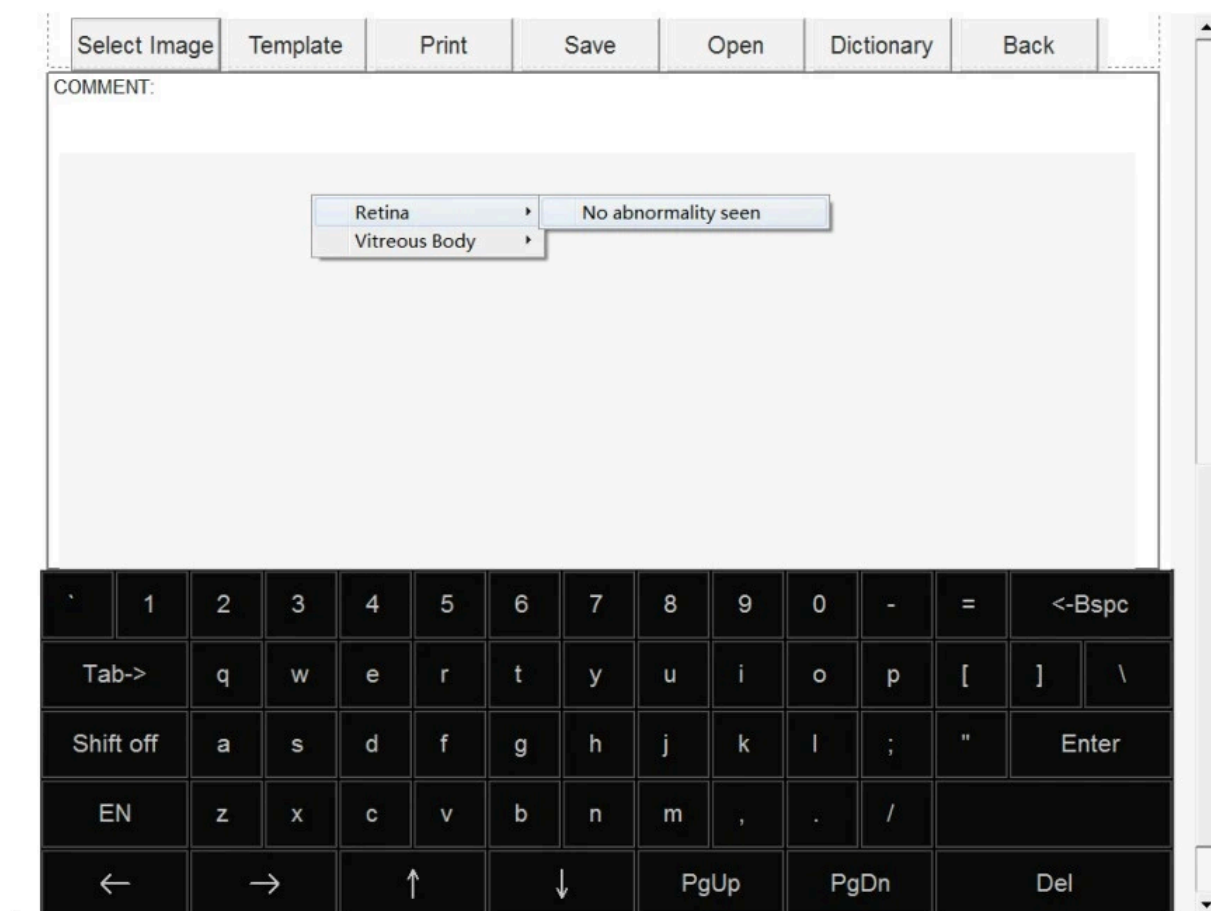


Figure 4-10-4 COMMENT area in Diagnosis Report Interface

Click **Print** key, to print the patient report.

Click **Save** key, to save the patient report in the PDF format.

Click **Open** key, to open the currently saved report in PDF format.

Click **Dictionary** key, and the dictionary interface pops up, shown in Figure 4-10-5.

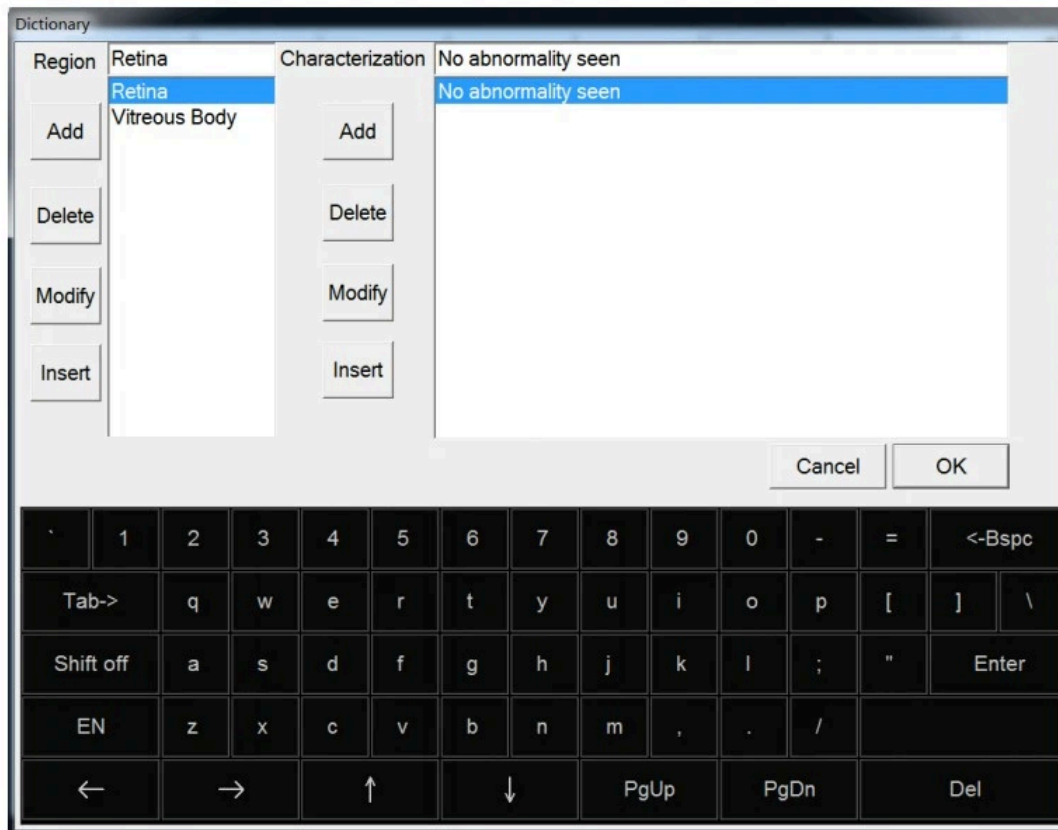


Figure 4-10-5 Dictionary Interface

Fill in eye parts, such as anteroposterior diameter, lens, vitreous body, retina, in the Region column on the left side, and fill in the relevant characterization in the Characterization column on the right side. Take the Region column on the left side for example, click **Add** key to add eye parts of the Region column, click **Delete** key to delete selected eye parts of the Region column, click **Modify** key to edit or modify selected eye parts of the Region column, or click **Insert** key to insert new content to selected eye parts of the Region column. The keys of **Add**, **Delete**, **Modify** and **Insert**, for the Characterization column on the right side perform the functions similar to those of the Region column on the left side. Press CTRL+SPACE, to switch between Chinese and English. The eye parts and their relevant characterization added from the diagnosis dictionary are added for the right-key menu in the editing and characterization interface (Figure 4-10-3) and COMMENT area (Figure 4-10-4).

Click **Back** key, to exit from the diagnosis report interface.

Click the COMMENT area of the diagnosis report interface (Figure 4-10-4), to re-edit the comment in the COMMENT area, and click the blank areas on the two sides, to quit the editing state.

Chapter 5. Cleaning, Disinfection and Sterilization

FOR EUROPE:

5.1 How to Prevent Cross-Infection

The probe must always be kept clean. It can be cleaned with soft tissue after each use.

Front part of the probe may be washed with distilled water, physiological saline water, alcohol, chloramphenicol eye drop or Cidex liquid disinfectant, which can usually be found in hospitals. Other FDA-cleared disinfectants may also be used.

- The probe can be immersed.
- Do not immerse the connector.
- Do not autoclave the probes.
- After cleaning, rinse the end of the probe thoroughly with clean water to remove all traces of the liquid used.
- Follow the instruction on the label of commercial disinfectants.
- The surface should then be dried with lint-free cloth.

5.2 Sterilization Procedure – Pre-sterilization and Sterilization of Probes

PREAMBLE

--- The operator should use standard method to ensure satisfactory sterilization of the probe after use.

--- The operator should use risky-patient protocol to ensure satisfactory sterilization of the probe every time after use on a patient where there is a risk of infection of Creutzfeld-Jacob disease.

OPERATOR'S CLOTHING

- One-off overall.
- Disposable gloves, sterile for sterilization.
- Glasses and anti-rejection masks.

EQUIPMENT

- Soft silk brush (surgical nail brush)
- 3×500 ml stainless steel (or plastic), autoclavable-soaking trays.
- One-off hand cloths.
- Distilled water.

PRODUCTS

- Cleaning-pre-disinfectant: Aniosyme[®] P.L.A. (Company: ANIOS),
or pre-disinfectant: Alkazyme[®] alcalin (Company: ALKAPHARM).

The products must be diluted at 0.5% with warm water (25 °-30 °) from the tap or distilled water.

The contents of the tray must be changed every day.

- Disinfectant type Alkacide[®] (Company: ALKAPHARM).

The product must be diluted at 5% with distilled water.

The solution must be changed every day.

- 6 Chlorometric degree solution of sodium hypo chloride at 20 °.

The contents of the tray must be changed after each use.

- Demineralized or distilled water.



Notes:

① Please disconnect the probes from the product. Please be sure the product is TURNED OFF before disconnecting probes.

② Avoid splashing liquids onto probe connectors (end of the cable, which is connected to the product).

5.3 Preparation of Sterilization Agent

STERILIZATION-PREDISINFECTION

- Proteolytic enzyme based agents (2 possibilities)

0.5% Alkazyme solution in water (20g sachet)

- 1) Pour in 1L warm clean water (25 ° -30 °)
- 2) Put in the unopened sachet.
- 3) Wait for 1 minute.
- 4) Pour in 4L water and stir it.

The Alkazyme solution can be used within 8 days if kept in sealed flasks. The solution can also be made up in a 4L recipient using demineralized or distilled water fill up the soaking tray from there.

OR:

0.5% Aniozyme solution in water (25g sachet):

- 1) Pour in 1L warm water (25-30°C).
- 2) Put into the unopened sachet.
- 3) Wait for 1 minute.
- 4) Pour in 4L warm water and stir.

Sterilization Agent

0.5% Alkacide solution in water.

- 1) Pour 5L distilled water in the flask.
- 2) Pour in the Alkacide.
- 3) Stir it.

The Alkacide solution can be used within 8 days if kept in the sealed flask.

Please pour in soaking tray (500ml) when sterilization is necessary.

Replacing contents of soaking trays

For frequent use, the contents of the trays should be replaced at the beginning of the morning and of the afternoon.

Wait 10 minutes after the last sterilization before emptying out the Alkazyme or Aniozyme solutions.

5.4 Standard Method



Notes:

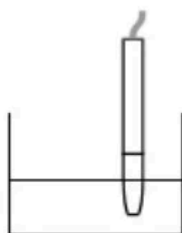
- ① Please disconnect the probes from the product. The product must be turned off first.
- ② Please avoid splashing any liquid onto the electrical connectors.

B-Probe

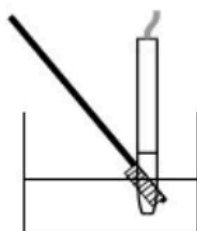
A-Probe

A) Decontamination-Pre-disinfection

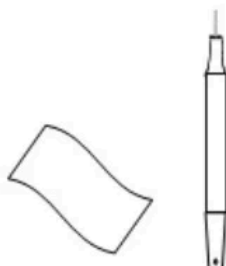
1. Immerse the first 5 cm maximum in a solution of either Alkazyme or Aniozyme for 5 to 15 minutes depending on the perceived level of risk.



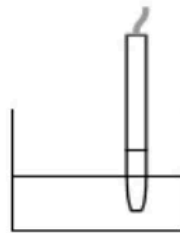
1. Clean the probe and the cable in the solution with the brush for 1 minute.



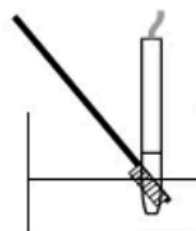
2. Clean the rest of the probe body and the cables using a swab lightly dampened with the same solution. Do not wet the connector.



1. Immerse the probe and the cable (except the connector) in the solution of Alkazyme or Aniozyme for 5 to 15 minutes depending on the perceived level of risk.



2. Clean the probe and the cable in the solution with the brush for 1 minute.



B) Rinsing

4. Rinse the end of the probe in demineralized or distilled water. Do not wet the connector.

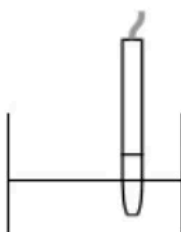
3. Rinse the probe and the cable in demineralized or distilled water. Do not wet the connector.



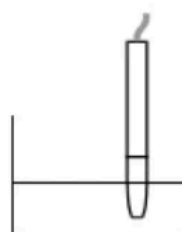
5. Dip the probe up to a maximum of 5cm in the Alkacide solution for 5 to 20 minutes depending on the estimated level of risk. Do not wet the connector.



4. Immerse the probe and the cable in the Alkacide solution for 5 to 20 minutes depending on the estimated level of risk. Please keep the connector dry.



6. Clean the probe body and the cable that were not soaked using a wipe lightly dampened with the Alkacide solution. Keep the connector dry.



C) Drying

7. Rinse the end of the probe with demineralized or distilled water. Keep the connector dry.

5. Rinse the end of the probe with demineralized or distilled water. Keep the connector dry.



8. Dry it with a sterile compress.

9. The B-Probe is ready for use.



6. Dry it with a sterile compress.

7. The A-Probe is ready for use.

5.5 Method for High-Risk Patients



Notes:

① **Please disconnect the probes from the product. The product must be turned off first.**

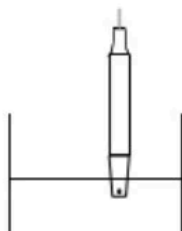
② **Please avoid splashing any liquid onto the electrical connectors.**

B-Probe

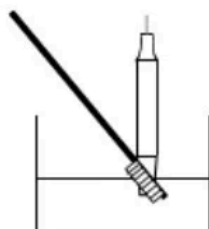
A-Probe

A) Decontamination – Pre-disinfection

1. Immerse the first 5cm maximum in a solution of either Alkazyme or Aniozyme for 5 to 15 minutes depending on the perceived level of risk.

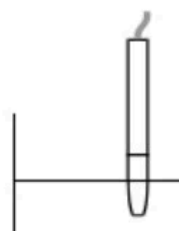


2. Clean the end of the probe in the chosen solution for 1 minute using the brush.

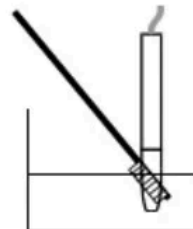


3. Clean the rest of the probe body and the cables using a swab lightly dampened with the same solution. Do not wet the connector.

1. Immerse the probe and the cable (except connector) in a solution of Alkazyme or Aniozyme for 5 to 15 minutes depending on the perceived level of risk.

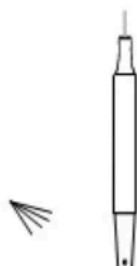


2. Clean the probe and the cable in the chosen solution for 1 minute using the brush.

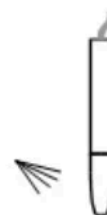


B) Rinsing

4. Rinse the end of the probe in demineralized or distilled water. Do not wet the connector.



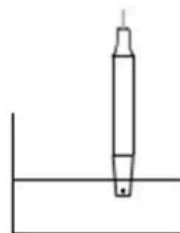
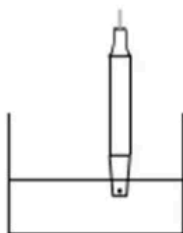
3. Rinse the probe and the cable with demineralized or distilled water. Please do not splash liquid onto the connector.



C) Inactivation

5. Immerse the first 5cm maximum in a 6 chlorometric degree solution of sodium hypochloride for 60 minutes at 20°C ensuring the connectors are kept dry.

4. Immerse the probe and the cable (except connector) in a 6 chlorometric degree solution of sodium hypochloride for 60 minutes at 20°C, keeping the connector dry.

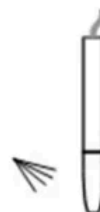


6. Clean the probe body and the cable that were not soaked using a wipe lightly dampened with the Alkacide solution.

D) Rinsing

7. Rinse the end of the probe with demineralized or distilled water.

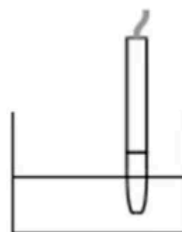
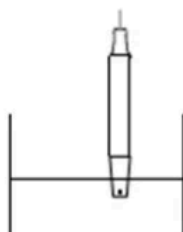
5. Rinse the probe and the cable with demineralized or distilled water.



E) Disinfection

8. Dip the probe up to a maximum of 5 cm in the Alkacide solution for 15 minutes.

6. Dry with a sterile compress if the rinsing water was sterile.



9. Clean the probe body and the cable that were not soaked using a wipe lightly dampened with the Alkacide solution. Keep the connector dry.

F) Rinsing

10. Rinse the end of the probe with demineralized or distilled water.

7. Rinse the probe end with demineralized or Distilled water keeping the connectors dry.

11. Dry with a sterile compress or a single use dry wipe if the rinsing water was sterile

8. Dry with a sterile compress if the rinsing water was sterile

12. The B-Probe is ready for use

9. The A-Probe is ready for use.

FOR U.S.A.

5.6 Cleaning of the Main Unit

Use soft cloth with water or neutral cleanser (e.g. diluted Bianex[®] Special Efficiency Multi-Enzymatic Cleanser) to clean the product surface. For further disinfection, please use soft cloth with disinfectant solution (e.g. Sporidicin Sterilizing and Disinfecting Solution) to wipe the product surface.

Remove the residual cleanser or disinfectant with clean soft cloth dampened in sterile water. Make sure the product is completely dry before using.



Notes:

- ☐ **Do not use any corrosive cleanser or disinfectant when cleaning the product surface; keep water and any other liquids away from the product.**
- ☐ **Do not immerse the product in disinfectant solution.**

5.7 How to Prevent Cross-Infection

The A-Probe and B-Probe used in immersion method and eye cup that are intended to come in contact with mucous membranes, belong to semi-critical devices.

The B-Probe used for normal measurement that are intended to come in contact with eyelid, belongs to non-critical device.

To prevent cross-infection, before initial use and in between patient uses, the probe and eye cup must be thoroughly cleaned and subjected to a germicidal process with a broad spectrum of activity.



Note:

It is prohibited to use the device on patients with eye trauma, inflammation or infection.

5.8 Method

Before initial use and after use on patients with no signs of infection, the probe and/or eye cup should be processed by high-level disinfection.

To prevent drying of soil on the surface prior to cleaning, the probe and eyecup should be cleaned by alcohol cotton immediately after use, and followed by thorough cleaning and disinfection. The recommended procedures are as below:

5.8.1 Preparation

a) OPERATOR'S CLOTHING

- Liquid-proof gowns.
- Disposable gloves.
- Eye protection and face masks.

b) EQUIPMENT

- Soft silk brush (surgical nail brush).
- A number of glass containers larger than 500ml and capable of immersing the probe and eye cup.
- One-off sterile cloth.
- Sterile water.

c) PRODUCTS

- Cleanser: Bianex[®] Special Efficiency Multi-Enzymatic Cleanser.
- Disinfectant: Sporidicin Sterilizing and Disinfecting Solution (K003087).

5.8.2 Thorough Cleaning

- a) Prepare the cleaning solution by adding 1-2ml Bianex[®] Special Efficiency Multi-Enzymatic Cleanser into 500ml of sterile water. Additional amounts may be required for hard-to-remove matter. The water temperature should be from 20°C to 64°C.
- b) Immerse the probe and/or eye cup to be disinfected into the container with 500ml cleaning solution for 5 minutes (Do not immerse the probe connector). Clean the probe and/or eye cup carefully in the cleaning solution with a soft silk brush and shake it to wash; and then take it out and wipe off the cleaning solution with sterile cloth.
- c) Rinse the cleaned probe and/or eye cup by immersing them in 500ml sterile water for 1 minute.
- d) Drain the probe and/or eye cup and wipe it with sterile cloth.



Notes:

- ☐ **Disposable gloves, eye protection and liquid-proof gowns should be worn when cleaning soiled probe and/or eye up.**
- ☐ **All detailed information for Bianex[®] Special Efficiency Multi-Enzymatic Cleanser,**

please refer to the manufacturer's instruction.

5.8.3 Disinfection

Use disinfectant solution immersion method:

- a) Activate and prepare the disinfectant solution (Sporicidin Sterilizing and Disinfecting Solution) according to the manufacturer's instructions.
- b) Sporicidin Indicators should be used before each use of this solution to determine whether glutaraldehyde is at or above its minimum concentration of 0.6% and phenol is at or above its minimum recommended concentration of 1.3%. Do not use beyond 14 days even if the respective concentration of active ingredients is above the minimum recommended concentration as indicated by the indicator strips.
- c) Disinfect the probe and/or eyecup by immersing them completely in about 500ml of disinfectant solution for a minimum of 20 minutes at 25°C for high-level disinfection. Please keep the probe connector dry during disinfection.
- d) Drain it and wipe off the disinfectant solution with sterile cloth.



Notes:

- ☐ **Disposable gloves, eye protection, face masks and liquid-proof gowns should be worn when disinfecting soiled probe and/or eye up.**
- ☐ **Containers filled with disinfectant solution should be kept closed and stored in a well ventilated, low traffic area at room temperature.**
- ☐ **All detail information for Sporicidin Sterilizing and Disinfecting Solution, please refer to the manufacturer's instruction.**

5.8.4 Rinsing after Disinfection

- a) Thoroughly rinse the disinfected probe and/or eye cup by immersing them in three separate copious volumes of 500ml sterile water. Each rinse should be a minimum of 1 minute in duration. Use fresh portions of water for each rinse.
- b) Take out the probe and/or eye cup, and let it dry naturally.
- c) After disinfection processing, put the probe and/or eye cup into a sterile box. Now the probe and/or eye cup are ready for use.



Notes:

- ☐ **Steam sterilization is prohibited.**
- ☐ **Disconnect the probe from the EUS-2600 before disinfection; the power of the**

EUS-2600 should be turned off before disconnecting the probe; hold the probe cable connector, and do not pull the probe cable; while connecting the probe, make sure the red mark on the probe align with the red mark on the socket.

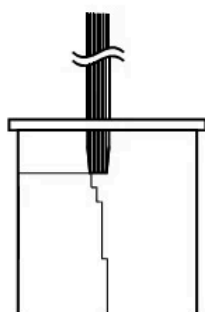
- ☐ **Do not immerse the probe cable connector into water or other liquid; keep the probe cable connector dry throughout the disinfection process of probe.**
- ☐ **After disinfection, check carefully whether the surface of the probe is deformed or damaged and whether the probe cable is damaged; check carefully whether the eye cup is deformed and whether the surface smoothness is reduced and so on.**
- ☐ **In case of any abnormality, stop using and contact the manufacturer or your local distributor for service.**

Chapter 6. Maintenance, Precautions for Proper Use and Simple Ways to Troubleshooting

6.1 Maintenance and Precautions for Proper Use of Product

1. The operator shall use a single-phase, three-pole power socket with good protective grounding.
2. It is generally appropriate for continuous use of this product within 4 hours, but it will become inappropriate when use for a longer time than that. When no examination on patients is performed, press **Scan** on the screen or tread on **FRZ/SCN** on the footswitch to stop probe scanning.
3. The operator shall handle the probe with proper care and protect it against collision and falling, so as to prevent ultrasonic transducers from cracking or their casing from being damaged; the operator shall also keep the probe clean.
4. The operator shall not use any corrosive cleanser to clean the surface of the product. The operator shall keep the product away from water or any other form of liquid. The operator may use a soft, wet rag with neutral cleanser or water for cleaning.
5. The product used in a humid climate or season shall be powered up for about 2 hours every month if being left unused for a long time, so as to expel moisture from the product.
6. The operator shall protect the product from falling and violent vibration when moving the product.
7. The operator shall not transport the product unless all the components, especially probes, are well packed in their original packages. Therefore, packages for the product shall be kept properly.

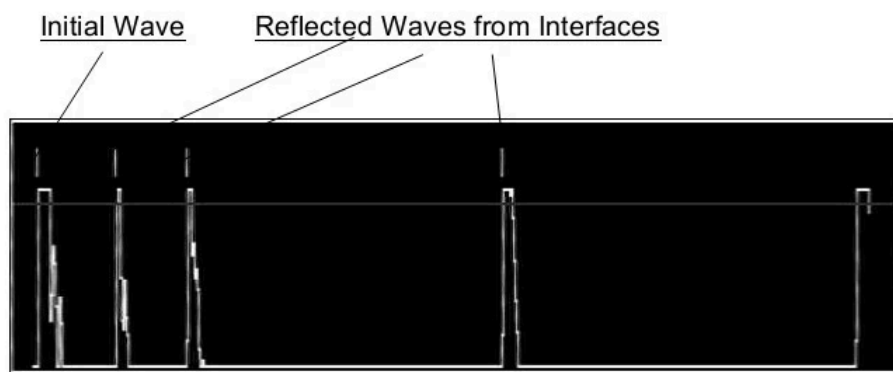
6.2 Biometric Test



This product comes equipped with a test object that simulates four acoustical reflection interfaces of a human eye. This test object is aimed to perform a qualitative test on biometric measuring functions of the product.

Fill the test object with degassed distilled water in which air bubbles must be eliminated; place with care the A-Probe onto the highest stage

in a way that the probe is perpendicular to the test object (see the left drawing); enter A-Scan mode by pressing **A scan**, enter the mode selection interface by pressing **Mode**, enter "manual" mode by selecting "Manual", and activate the scan by pressing **Frz/Scn**; and move the probe in a slight motion, and adjust "Gain" to a proper value, so that the initial wave and reflected waves from three interfaces can be clearly visible, and their waveforms tend to be steep on front edges and closely saturated (as shown below):



Enter the mode selection interface again by pressing "Mode", and select "Normal" to obtain the results of the staged target by automatic measurement.

Press "A scan" and "Scan" to repeat the measurement while keeping the probe still. It's indicated that the biometric function of the product works well, if measured results show good repeatability.

6.3 Simple Ways to Troubleshoot

6.3.1 The power indicator light on the main unit is not on, and the product fails to start up.

Check whether the plug of power adaptor is securely connected.

6.3.2 The mouse or keyboard doesn't work properly.

Check whether the receiver of wireless keyboard & mouse combo and the batteries of mouse and keyboard are installed correctly. If the mouse or keyboard fails to work properly, please check successively whether battery is installed correctly, whether wireless receiver is inserted in the main unit, whether the battery is used up, etc.

6.3.3 The footswitch doesn't work properly

Check whether the footswitch is well connected with the USB interface.

6.3.4 The main unit works, but the screen doesn't work or work properly.

Check whether the probe is securely connected.

If the product still fails to work properly through above-mentioned actions, the operator shall immediately contact the local distributor or the manufacturer rather than unauthorized tear-down and repair without the local distributor or the manufacturer's consent.

Please elaborate on faults when contacting the local distributor or the manufacturer, to facilitate the maintenance.

As a sophisticated high-tech device, this product can only be serviced by technicians trained and qualified by the manufacturer.

The manufacturer is not responsible for any kind of consequences of safety or effectiveness due to unauthorized repair by users without the manufacturer's consent.

When required by qualified service engineers or authorized service station, the manufacturer may provide service manuals including all necessary information for maintenance.

6.4 Disposal of Product after its Life-Cycle

Disposal of the product after its life-cycle should comply with the relevant local environment protection regulations. Same way can be taken with the electronic devices (computers, etc).

Chapter 7. Service and Support Information

7.1 Warranty

1. This product has a warranty of one year from the date of purchasing, on the premise of using in accordance with the User Manual.
2. If the product does not work properly, please contact your local distributor or the manufacturer immediately. The local distributor or the manufacturer has the right not to provide any warranty for products without warranty card or without receiving warranty registration card.
3. Following services will be charged within the warranty period due to the following reasons:
 - a) Problems caused by man-made damages;
 - b) Damage caused by unauthorized tear-down or repair;
 - c) Damage caused by inappropriate use and operation.
4. The manufacturer shall provide users with continuous maintenance service beyond warranty period with certain charges at the manufacturer's discretion.

7.2 Accessories and Materials

7.2.1 Detachable Parts

SN	Description	Model	Specification	Remark
1	Probe	Prb1000A/10-C	10MHz	/
2	Probe	Prb2100B/10	10MHz	/
3	Probe	Prb2100B/20	20MHz	/
4	Footswitch	/	/	/
5	Power Adaptor	HES49-12040	12V/4A	Optional
		FSP065-DHBM1	12V/5.42A (Max)	/
6	Logitech Wireless Combo	MK240	2.4GHz	/

7.2.2 Consumables

SN	Item	Manufacturer	Model	Specification
1	Acoustic Gel	—	—	The acoustic gel complies with local laws and regulations.



Notes:

- ☐ **The probes, power adaptor and footswitch used in the product must be provided by the Manufacturer.**

- **Consumables used in the product: Water-based polymer gel type coupling agent used for normal B-Scan and met with relevant industrial standards shall apply.**

7.3 Software Update and Services

The manufacturer will provide users with software update information and services.

In case of software update due to correction of defects, the manufacturer will provide users with free software update service.

For the expansion of software functions, the manufacturer will provide users with software update information, and according to users' demand, provide software update service with certain charges.

Annex A. Prudent Use Statement

A.1 Statement

Although there is no evidence so far the diagnostic ultrasound instrument will lead to biological effects in humans, it is possible to prove the existence of biological effects in future applications. The radiated acoustic power of the instrument itself is very low; still we must use ultrasound prudently in clinical applications. Do the best to complete patients' examinations within shortest time and with lowest power, on the premise of achieving necessary clinical information.

A.2 ALARA Principle (As Low As Reasonably Achievable)

The ALARA principle should be implemented to perform ultrasound procedure. Try to use lowest level of energy that will not result in biological effect. The ultrasonic energy depends on acoustic output intensity and exposure time. The ultrasonic intensity required may vary depending on different patients and clinical cases.

Not all examinations can be accomplished with lowest ultrasonic energy output. Lowest ultrasonic energy will produce low-quality image which will influence the reliability of diagnosis. However, the acoustic power higher than practical use will not be helpful to improve the quality of diagnostic information, but will increase the risk of biological effect.

The operator must be responsible for the safety of patients and use ultrasound on purpose, that is to apply ultrasonic output power according to ALARA principle.

Necessary measures have been taken in the design of this product to reduce the energy of Ultrasound. The operator is not allowed to adjust the acoustic output of this product (acoustic output parameters shown in Annex B). The operator is also suggested keeping each examination within shortest time and at reasonable frequency on the basis of ALARA Principle.

Annex B. Acoustic Output Reporting Table (IEC60601-2-37)

Test Mode: A

Transducer Type: A Probe 10MHz

Transducer No: G11072

Index Label				MI	TIS			TIB	TIC	
					Scan	Non-scan		Non-scan		
						$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$			
Maximum index value				0.19	-	-	-	-	-	
Associated acoustic parameter	p _{r,a}		(MPa)	0.60						
	P		(mW)		-	-		-	-	
	min of [P _a (z _s), I _{ta,a} (z _s)]		(mW)				-			
	z _s		(cm)				-			
	z _{bp}		(cm)				-			
	z _b		(cm)					-		
	z at max. I _{pi,a}		(cm)	2.12				-		
	d _{eq} (z _b)		(cm)					-		
	f _{awf}		(MHz)	9.91	-	-	-	-	-	
	Dim of A _{aprt}		X	(cm)		-	-	-	-	-
Y			(cm)		-	-	-	-	-	
Other Information	t _d		(μsec)	0.145						
	p _{rr}		(Hz)	62.5						
	p _r at max. I _{pi}		(MPa)	1.24						
	d _{eq} at max. I _{pi}		(cm)					-		
	I _{pa,3} at max. MI		(W/cm ²)	14.37						
	Focal Length		FLx	(cm)	-	-	-	-	-	-
			FLy	(cm)	-	-	-	-	-	-
Operating Control Conditions	Default Setting									

ANNEX B. ACOUSTIC OUTPUT REPORTING TABLE

Test Mode: B
B2M-131101

Transducer Type: B Probe 20MHz

Transducer

No:

Index Label				MI	TIS			TIB	TIC	
					Scan	Non-scan		Non-scan		
						$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$			
Maximum index value				0.10	-	-	-	-	-	
Associated acoustic parameter	p _{r,a}		(MPa)	0.38						
	P		(mW)		-	-		-	-	
	min of [P _a (z _s), I _{ta,a} (z _s)]		(mW)				-			
	z _s		(cm)				-			
	z _{bp}		(cm)				-			
	z _b		(cm)					-		
	z at max. I _{pi,a}		(cm)	2.04				-		
	d _{eq} (z _b)		(cm)					-		
	f _{awf}		(MHz)	14.79	-	-	-	-	-	
	Dim of A _{aprt}		X	(cm)		-	-	-	-	-
Y			(cm)		-	-	-	-	-	
Other Information	t _d		(μsec)	0.081						
	p _{rr}		(Hz)	10000						
	p _r at max. I _{pi}		(MPa)	1.10						
	d _{eq} at max. I _{pi}		(cm)					-		
	I _{pa,3} at max. MI		(W/cm ²)	11.64						
	Focal Length		FLx	(cm)	-	-	-	-	-	-
			FLy	(cm)	-	-	-	-	-	-
Operating Control Conditions	Default Setting									

ANNEX B. ACOUSTIC OUTPUT REPORTING TABLE

Test Mode: B

Transducer Type: B Probe 10MHz

Transducer No: B558-130526

Index Label				MI	TIS			TIB	TIC	
					Scan	Non-scan		Non-scan		
						A _{aprt} ≤1 cm ²	A _{aprt} >1 cm ²			
Maximum index value				0.46	-	-	-	-	-	
Associated acoustic parameter	p _{r,a}		(MPa)	1.39						
	P		(mW)		-	-		-	-	
	min of [P _a (Z _s), I _{ta,a} (Z _s)]		(mW)				-			
	Z _s		(cm)				-			
	Z _{bp}		(cm)				-			
	Z _b		(cm)					-		
	z at max. I _{pi,a}		(cm)	1.90				-		
	d _{eq} (Z _b)		(cm)					-		
	f _{awf}		(MHz)	9.21	-	-	-	-	-	
	Dim of A _{aprt}		X	(cm)		-	-	-	-	-
Y			(cm)		-	-	-	-	-	
Other Information	t _d		(μsec)	0.141						
	p _{rr}		(Hz)	10000						
	p _r at max. I _{pi}		(MPa)	2.56						
	d _{eq} at max. I _{pi}		(cm)					-		
	I _{pa,3} at max. MI		(W/cm ²)	116.10						
	Focal Length		FLx	(cm)	-	-	-	-	-	-
			FLy	(cm)	-	-	-	-	-	-
Operating Control Conditions	Default Setting									

Acoustic Output Reporting Table (UD2-2004 and FDA Guide for Track 1)

Mode	A Mode		
Probe	Prb1000A/10-C		
Acoustic Output	MI [unitless]	I_{SPAT.3} (mW/cm ²)	I_{SPPA.3} (W/cm ²)
Sample Size	3	3	3
K (P=0.90, gamma=0.9)	4.258	4 .258	4 .258
Mean (x)	0.113	0.047	4.986
StdDev (Sx)	0.021	0.015	1.762
Limit (X)	0.202	0.112	12.49

Mode	B Mode		
Probe	Prb2100B/10 Probe		
Acoustic Output	MI [unitless]	I_{SPAT.3} (mW/cm ²)	I_{SPPA.3} (W/cm ²)
Sample Size	3	3	3
K (P=0.90, gamma=0.9)	4.258	4 .258	4 .258
Mean (x)	0.13	8.92	6.323
StdDev (Sx)	0.01	1.60	0.897
Limit (X)	0.172	15.74	10.14

Mode	B Mode		
Probe	Prb2100B/20 Probe		
Acoustic Output	MI [unitless]	I_{SPAT.3} (mW/cm ²)	I_{SPPA.3} (W/cm ²)
Sample Size	3	3	3
K (P=0.90, gamma=0.9)	4.258	4 .258	4 .258
Mean (x)	0.12	6.13	6.39
StdDev (Sx)	0.01	1.436	1.381
Limit (X)	0.162	12.24	12.27

Annex C. Guidance and Manufacturer's Declaration

Table 1

Guidance and Manufacturer's Declaration - Electromagnetic Emission		
The EUS-2600 Ultrasonic A/B Scanner for Ophthalmology is intended for use in electromagnetic environment specified below. The customer or the user of EUS-2600 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment - Guidance
CISPR 11 RF emissions	Group 1	The EUS-2600 Ultrasonic A/B Scanner for Ophthalmology 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.
CISPR 11 RF emissions	Class A	The EUS-2600 Ultrasonic A/B Scanner for Ophthalmology is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2 Harmonic emissions	N/A	
IEC 61000-3-3 Voltage fluctuations/ flicker emissions	N/A	

Table 2

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The EUS-2600 Ultrasonic A/B Scanner for Ophthalmology is intended for use in the electromagnetic environment specified below. The customer or the user of EUS-2600 should assure that it is used in such an environment.			
Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	±1kV line(s) to line(s) ±2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T , (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T , (>95% dip in U_T) for 5s	Complies Complies Complies Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of EUS-2600 requires continued operation during power mains interruptions, it is recommended that EUS-2600 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic field should be that of a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Table 3

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The EUS-2600 Ultrasonic A/B Scanner for Ophthalmology is intended for use in the electromagnetic environment specified below. The customer of the user of EUS-2600 should assure that it is used in such an electromagnetic environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3Vrms 3V/m 80MHz to 2.5GHz	Portable and mobile RF communications equipment should be used no closer to any part of the EUS-2600, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = 2.3\sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$ 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).^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked within the following symbol: 
Note 1: At 80MHz and 800MHz, the higher frequency range applies. Note 2: These guidance may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM (Amplitude Modulation) and FM (Frequency Modulation) 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 EUS-2600 is used exceeds the applicable RF compliance level above, the EUS-2600 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EUS-2600.

Table 4

Recommended Separation Distance between Portable and Mobile RF Communications Equipment and EUS-2600			
The EUS-2600 Ultrasonic A/B Scanner for Ophthalmology is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EUS-2600 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EUS-2600 as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter W	Separation Distance according to Frequency of Transmitter (m)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 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 transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.			
Note 2: These guidance may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Note 3: EUS-2600 operates in compliance with its intended use in the presence of external electromagnetic disturbances.			

Annex D. Main Specification of Wireless Keyboard and Mouse

Keyboard:

Equipment Type	Y-R0036
Modulation Mode	GFSK
Frequency Range	2400-2483.5MHz
Frequency Tolerance	$\pm 75\text{kHz}$
Transmitting Power	$\leq 10\text{mW}$ (EIRP)
Occupied Bandwidth	$\leq 2\text{MHz}$
Spurious Emission Limits	$\leq -30\text{dBm}$ (effective value)

Mouse:

Equipment Type	M-R0041
Modulation Mode	GFSK
Frequency Range	2400-2483.5MHz
Frequency Tolerance	$\pm 75\text{kHz}$
Transmitting Power	$\leq 10\text{mW}$ (EIRP)
Occupied Bandwidth	$\leq 2\text{MHz}$
Spurious Emission Limits	$\leq -30\text{dBm}$ (effective value)

Annex E. IOL Formulas

Refractive Surgery?	Formula	Parameters									
		AC	K1	K2	A	ACD	ANTI/POST	K1pr	K2pr	REFpr	REFpo
NO	SRK_II	x	√	√	√	x	x	x	x	x	x
	SRK_T	x	√	√	√	x	x	x	x	x	x
	BINK_II	x	√	√	x	√	√	x	x	x	x
	HOFFER_Q	x	√	√	x	√	x	x	x	x	x
	HOLLADAY	x	√	√	√	x	x	x	x	x	x
	HAIGIS	√	√	√	√	x	x	x	x	x	x
YES	History Derived	SRK_II	x	√	√	√	x	x	√	√	√
		SRK_T	x	√	√	√	x	x	√	√	√
		BINK_II	x	√	√	x	√	√	√	√	√
		HOFFER_Q	x	√	√	x	√	√	√	√	√
		HOLLADAY	x	√	√	√	x	x	√	√	√
		HAIGIS	√	√	√	√	x	x	√	√	√
	DoubleK	DoubleK/SRK T	x	x	x	√	x	x	√	√	√
	Refraction Derived	SRK_II	x	√	√	√	x	x	x	√	√
		SRK_T	x	√	√	√	x	x	x	√	√
		BINK_II	x	√	√	x	√	x	x	√	√
		HOFFER_Q	x	√	√	x	√	x	x	√	√
		HOLLADAY	x	√	√	√	x	x	x	√	√
		HAIGIS	√	√	√	√	x	x	x	√	√
	ROSA	ROSA	x	√	√	√	x	x	x	x	x
	SHAMMAS	SHAMMAS	x	√	√	√	x	x	x	x	x
Remarks:											
1. "√" means the parameter is applicable to this formula and "x" means it is not applicable.											
2. The parameters of AL and DR are required for each formula; they are not listed in this table.											
3. The shaded area in the table is applicable to cases without refractive surgery.											

IOL FORMULA

IOL Formulae (For cases that patients have not undergone refractive surgery):

SRK-II
SRK-T
BINKHOST-II
HOLLADAY
HOFFER-Q
HAIGIS

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IOL Formulae (For cases that patients have undergone refractive surgery)

History Derived
DoubleK
Refraction Derived
ROSA
SHAMMAS

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Annex F. Instructions and Abbreviations

New — Create a new patient

Load — Load case library

B scan — Enter B mode scanning interface

A scan — Enter A mode scanning interface

Report — Case report

Setup — Set up the user name, hospital name and work path etc.

Exit — Quit the application

OS — Ocular sinister

OD — Oculus dexter

Clr Data — Clear calculated result

IOL — Intraocular lens

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