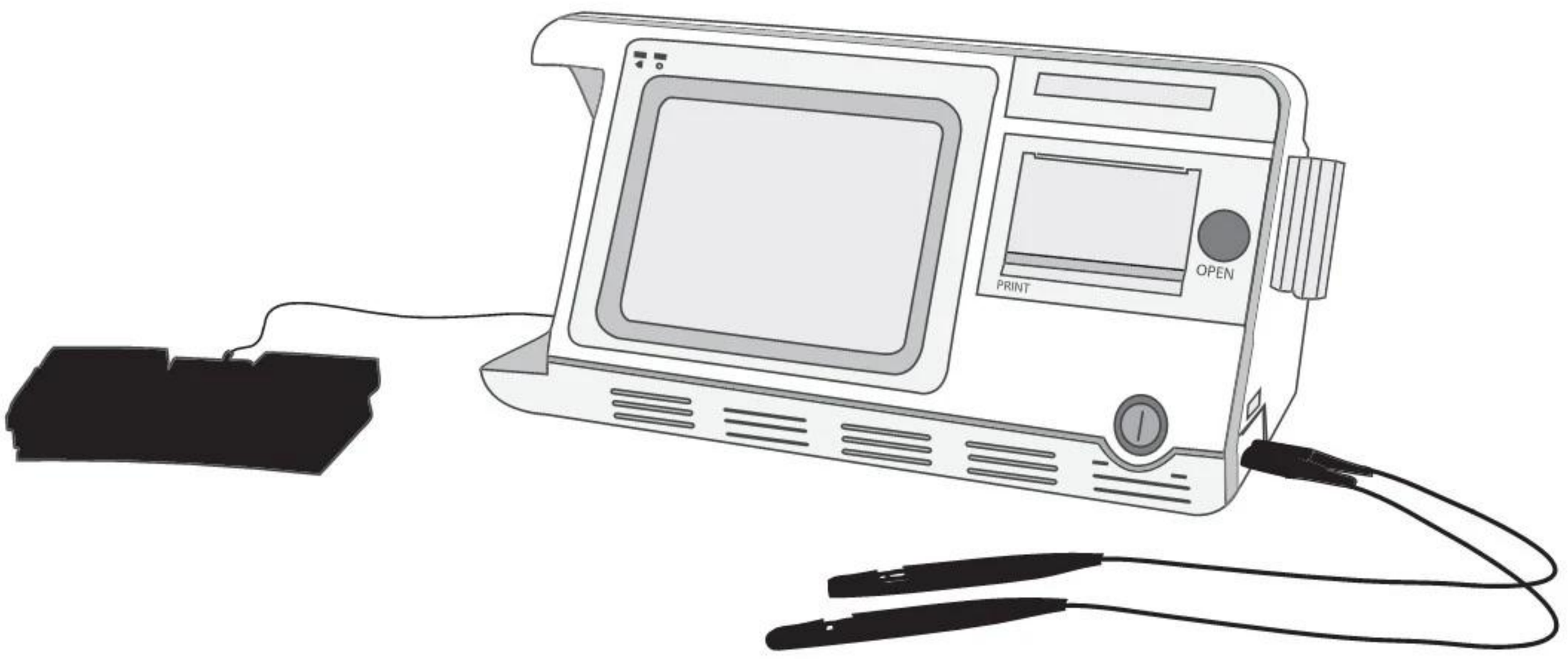
Operation Manual

EUS-1800 A/P BIOMETER + PACHYMETER



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PRECAUTIONS

- The device should be operated by trained doctors.
- Please read the manual carefully before installation and operation
- Please refer to Chapter 5. Cleaning, Disinfection and Sterilization to avoid cross-infection while using.
- Disconnect AC power before cleaning the housing case.
- Please refer to Chapter 7. Maintenance, Attentions and Simple Defects Treatment for maintenance attentions.

WARNINGS

- The customer is fully responsible for maintenance and management of the instrument after purchasing.
- Do not make any modification to the software and hardware of the device without authorization.
- The power adaptor provided with the device meets the safety standard of medical electrical devices. If damaged, contact the Manufacturer to purchase. Use of other adaptors may cause safety risk.
- The manufacturer won't be responsible for any damage or injury caused by any failure to follow the instructions in the **Operation Manual**.
- The manufacturer reserves the right to modify equipment characteristics without previous notice under FDA Laws and MDD (93/42/EEC) Regulation.
- The quality guarantee of the device will be invalid if it is opened (even partially), modified or repaired in any way by anyone who is not authorized by the manufacturer.

- This device is not intended for therapeutic use.
- The device should be used cautiously to babies or patients without independent behavior abilities, whose ineffective cooperation may results in inaccurate measurements.
- According to FDA laws, EUS-1800 A/P is a prescription Device and is to be used by or under the supervision of a licensed physician.
- While plugging in the probe, make sure the red mark on the probe align with the red mark on the socket.

- While plugging off the probe, please be sure you are pulling the connector instead of the cable.
- Do not scratch the surface of the probe.
- Do not drop the probes.
- If the probe drops during using or moving, check the top and the housing of probe carefully, and then check if it works well. Stop using if there is any problem and contact the manufacturer or local distributor for service
- Warnings of predicable potential hazards are contained in the **Operation Manual**. Please maintain vigilance 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 the **Operation Manual**.
- The assembly, expanding, readjustment, improvement and repair should be operated by personnel authorized by the manufacturer. Do not open the housing for repair without permission. The manufacturer won't be responsible for the consequences of safety and effectiveness caused by unauthorized repair.
- Keep the original package properly. All detachable accessories should be put into the original package before moving.
- Without written consent of the manufacturer, no individual or organization is allowed to copy, modify, or translate any part of the **Operation Manual**.

For any question, please contact the Manufacturer or your Local Distributor

Address: 9990 NW 14 ST Suite 105
Doral, FL 33172
Phone: +1-888-334-4640
Fax:+1-786-621-1842
Email: info@usophthalmic..com

CAUTION

HOW TO PREVENT CROSS-INFECTION

- Between uses on different patients the probe must be cleaned to prevent cross-infection.
- Manufacturer advocates a preventive action and a cleaning procedure in Chapter 5. Cleaning, Disinfection and Sterilization.

CAUTION

- The EUS-1800 A/P IOL calculator will calculate negative IOL values if such is predicted by the data input.
- These are displayed with a minus sign "-". Do not ignore this sign.

TISSUE EXPOSURE TO ULTRASOUND ENERGY:

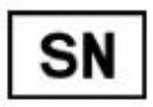
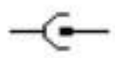
- The EUS-1800 A/P is designed for use in ophthalmology only.
- While the manufacturer is not aware of any reports of adverse effects from using ophthalmic ultrasound scanner, even at FDA pre-enactment levels, no other use is intended or implied.
- The system controls limit of the output energy within the parameters specified for its intended purpose. Please refer to Annex A of **Operation 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 SYMBOLS

Front Panel

	Power On or Power Off
OPEN	Paper Housing Switch
PRINT	Thermal Printer

Rear Panel

	Symbol of "Type B"
	Refer to Operation Manual
	Serial Number
 0123	CE Mark
	Manufacturer
FOOT SWITCH	Foot Switch Socket
	Power Input Socket

Right Panel

A-Probe	A Biometric Probe Socket
P-Probe	Pachymetric Probe socket

Operation Manual

	NOTE! Important information that operator must read carefully.
IPX1/IPX7	The degree of protection against ingress of liquids

Chapter 1 Introduction

1.1 General Description

EUS-1800 A/P Ultrasonic Biometer for Ophthalmology is an ultrasonic measuring instrument based on pulse reflection. It contains two units: A Mode Eye Axis Biometric Parameter Measuring Unit (A Biometer) and Corneal Thickness Measuring Unit (Pachymeter).

The A Biometer:

The A Biometer consists of a 10MHz A-Scan probe (probe model: Prb1000A/10-C) and an axis biometric parameter measuring unit. The axis is usually divided into three segments: anterior chamber, lens and vitreous body. Since the tissue within the eye is different in different areas, the speed through these areas is also different. The summation of these three segments (ACD + LENS + VITR) provides the axial length (AL). The ultrasonic A-biometry is on the basis of the interface reflection of these three different tissues to measure the transmitting time of ultrasonic wave through different tissues and to calculate the distances of each segment and obtaining the axial length.

The Pachymeter：

The Pachymeter consists of a 15-20MHz pachymetric probe (probe model: Prb1000P) and the measuring unit. It is on the basis of the measurement of time interval between the anterior and post interface reflection wave to get the thickness of the cornea.

EUS-1800 A/P has a build-in Thermal Printer, used to print out patient information, A-Scan measuring waveform, IOL calculating parameter and result; as well as corneal thickness measuring result and corneal thickness distribution map.

The built-in memory of EUS-1800 A/P can store 180 patients' records. After examinations, it can be connected with computer to upload the stored measuring data and information to the computer, thus realize mass storage.

1.2 Intended Use

EUS-1800 A/P is intended for axial biometric parameter measurement and corneal thickness measurement in ophthalmologic clinic.

1.3 Intended Location of Use

EUS-1800 A/P is suitable to be applied in ophthalmic clinics.

As the foot switch's protective degree against ingress of liquids is IPX1, it is not suitable to be used in operating room and other locations where it is easy to splash liquid.

The device is not suitable to be connected with computers in patient's environment. If the measuring data need to be uploaded to computer, it should be done in non-medical room after examinations.

1.4 Contraindications

Cornea trauma or inflammation patients are prohibited to use the device.

1.5 Expected Service Life

Based on the experience of products sold (and considering technology update 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 update.)

1.6 Software Version

MDAP 10X V1.0

Chapter 2 Specifications

2.1 Working Conditions

Environmental Temperature: 10℃－40℃

Relative Humidity: ≤80%

Atmospheric Pressure: 70kPa－106kPa

The separate Power Supply: Input: AC100~240V, 50/60Hz, 50 VA

Output: DC12V, 4A

2.2 Main Specifications

2.2.1 A Biometer

Ultrasonic frequency: 10MHz;

Display resolution: 0.01mm;

Total gain of receiver: ≥100dB;

Adjustable gain scope: 0～50dB;

Measuring scope (AL): 15 mm～40mm;

Measuring accuracy: ≤±0.05mm;

Measuring Parameter: ACD, LENS, VITR and AL;

Measuring mode: automatic mode or manual mode can be selectable. Automatic mode for Normal, Cataract and Aphakic mode;

Measuring method: contact and immersion, can be selectable;

IOL calculation: SRK/T, SRK-II, BINK-II, HOLLADAY, HOFFER-Q, HAIGIS.

2.2.2 Pachymeter

Ultrasonic frequency: 15-20MHz;

Display resolution: 1μm;

Measuring scope: 0.23mm～1.2mm;

Measuring accuracy: ≤±5μm

2.3 Safety

Satisfy the requirements of IEC 60601-1:2005 and IEC 60601-2-37:2007.

The acoustic output parameters: see Annex D.

2.4 Storage and Transportation Conditions

2.4.1 Storage Conditions

The device should be stored in non-corrosive gas and well-ventilated room with environmental temperature -20℃—40℃ and relative Humidity≤80%.

2.4.2 Transportation Conditions

The accessories such as Probe should be packed into original package before transportation. Severe impact and crash, rain and snow shall be avoided.

2.5 Classification

As per the type of protection against electric shock: Class I

As per the degree of protection against electric shock: Type B

As per the degree of protection against ingress of liquids:

— Main unit: IPX0;

— Part of Probe that can be immersed: IPX7;

— Foot switch: IPX1

As per disinfection and sterilization recommended by the manufacture:

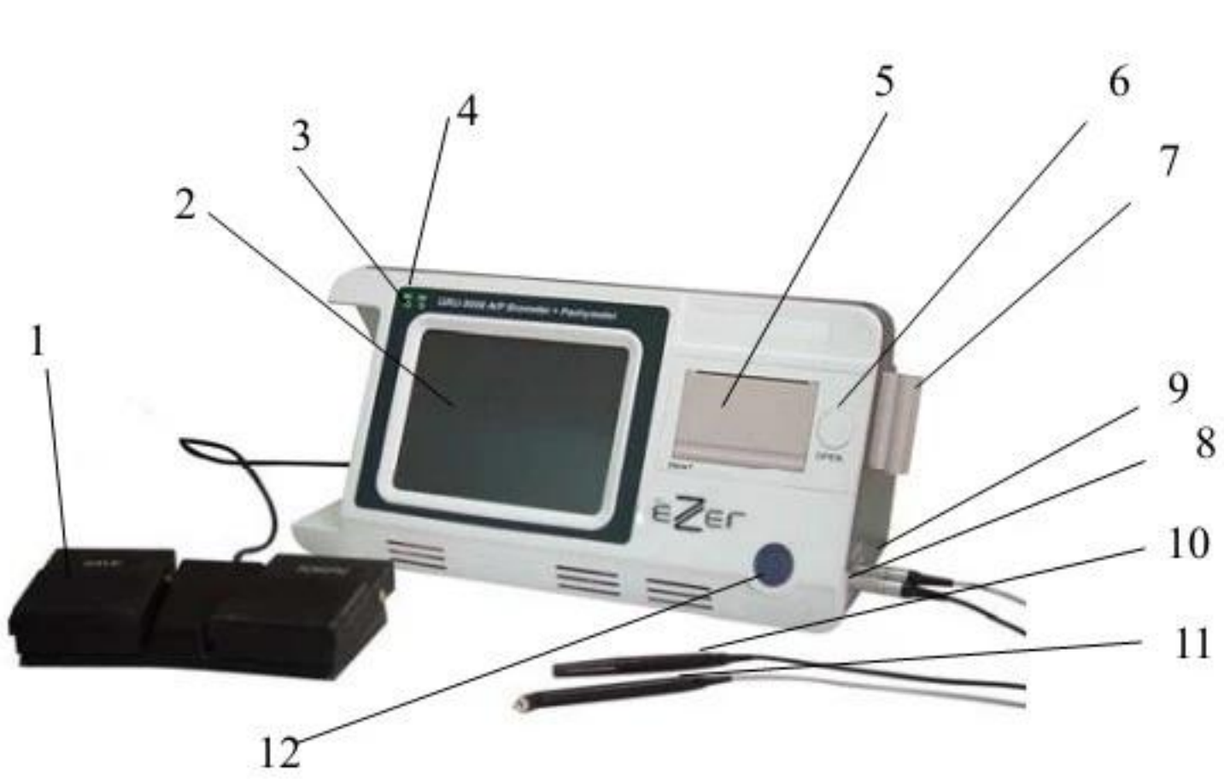
— see §5 Cleaning, Disinfection and Sterilization.

As per the safety degree when used under flammable anesthetic gas mixed with air or under flammable anesthetic gas mixed with oxygen or Nitrous oxide: not allowed.

Chapter 3 Installation

3.1 Structure

The structure of the instrument: See Figure 3.1.



1. Foot Switch
2. Color LCD Touch Screen
3. Power Indicator
4. Working Indicator
5. Paper Housing Cover
6. Paper Housing Switch
7. Probe Holder
8. A-Biometer Probe Socket
9. Pachymeter Probe Socket
10. A-Biometer Probe
11. Pachymeter Probe
12. Power Switch

Figure 3.1 Structure of the Instrument

The Rear Panel: See Figure3.2

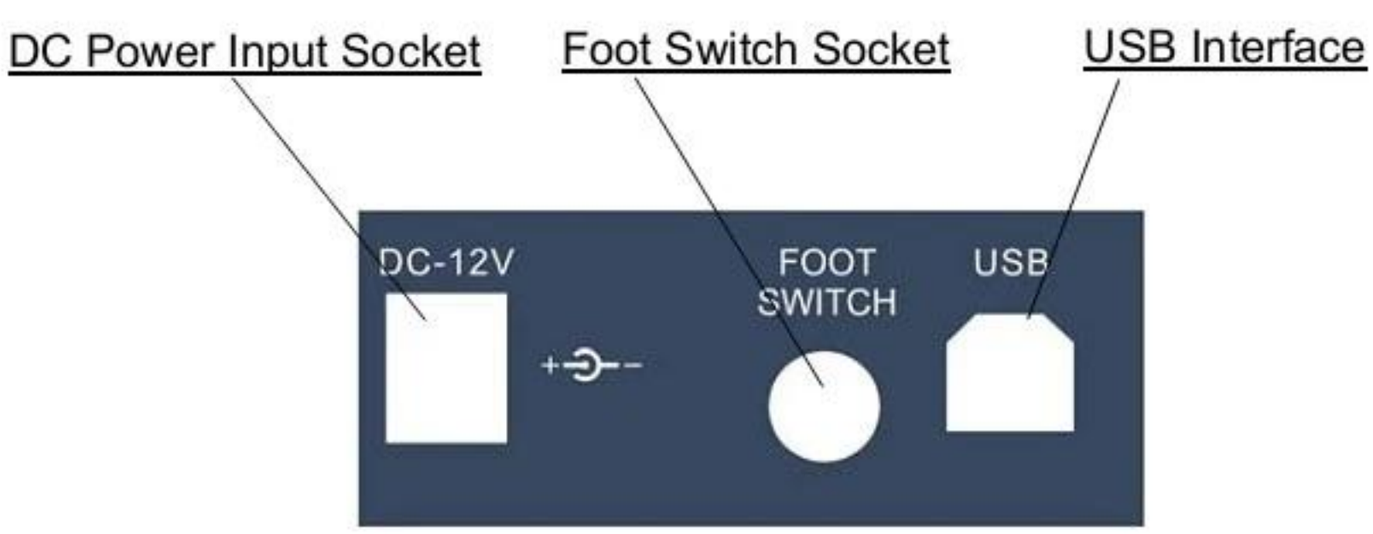


Figure 3.2 Rear Panel of the Instrument

The power adaptor of the product, with input voltage of AC100-240V and output voltage of DC12V/4A, meets the safety requirements of medical electric device. As shown in Figure 3.3:

Figure 3.3 Power Adaptor and Power Cable of the Adaptor

3.2 Environmental Requirements

1) The instrument should be operated in a clean environment. Air-conditioned environment is recommended.

2) The instrument should be placed on a stable worktable or platform. Avoid direct sunlight.

3) Please use the supplied Power Adaptor which is in accordance with the safety standard of Medical Electric equipment; do not use any other adaptors.

4) The power outlet should be with good grounding. Improper connection of protective earth may cause not only interference, but also the risk of increasing leakage current.

5) Do not block the ventilation window of the instrument. When the temperature of the instrument is not normal, please contact the manufacturer for service.

6) Although anti-interference measures have been adopted, the instrument should be placed to avoid strong electromagnetic radiation equipment (such as microwave, radio frequency therapy equipment, etc.).

7) Please do not put the instrument in a place where it is difficult to disconnect the power supply.

8) The instrument should be placed in a position where the operator can face the instrument and view the screen easily. The distance between the instrument and the patient should enable the probe to contact the patient's eye conveniently.

9) The instrument should always be placed in a secure location to prevent falling injuries.

10) The instrument has no special protective measures for discharge effect of cardiac defibrillators; it is not suitable for use with high-frequency surgical equipment.

3.3 Connection

⚠ **Note: It is prohibited to plug in or plug off any accessories while the instrument is running.**

3.3.1. Connection of Probe

Plug the A-Biometer probe into the A-Probe socket on the right panel;

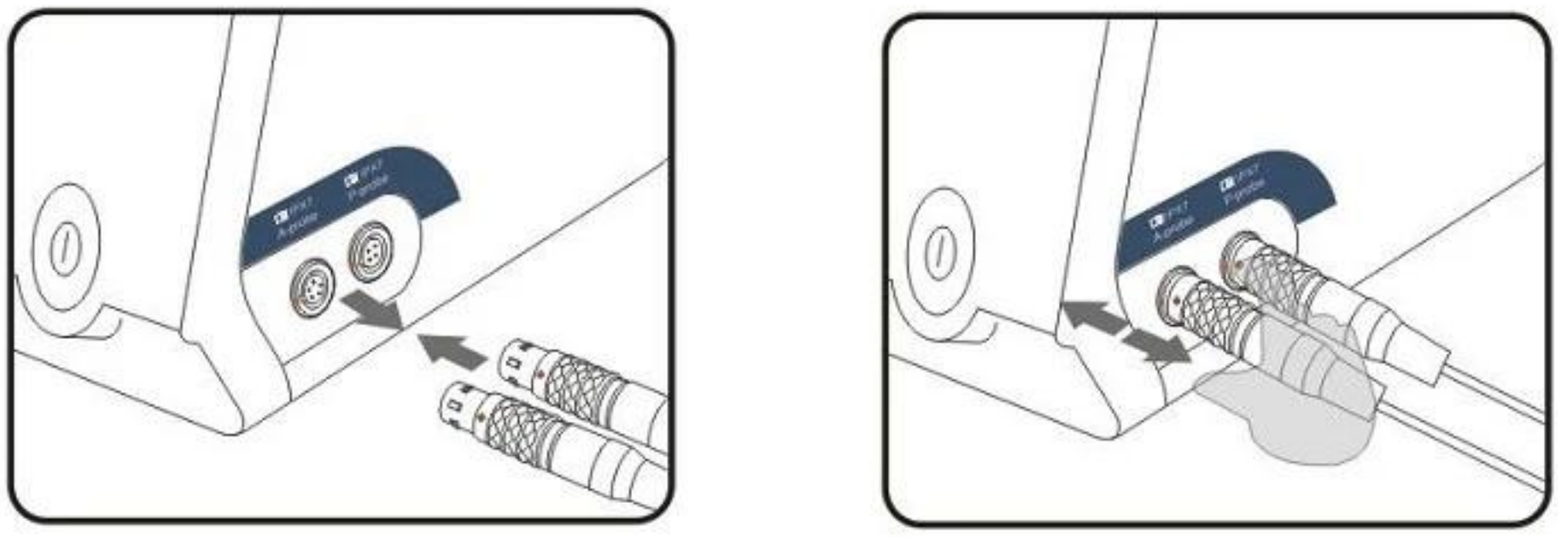
Plug the Pachymeter probe into the P-Probe socket on the right panel.

⚠ **Note: While plugging in the probe, make sure the red mark on the probe align with the red mark on the socket, as shown in Figure 3.4 (a).**

3.3.2. Disconnection of Probe

To disconnect the probe, please hold the ring of the connector and pull it off along the horizontal direction, as shown in Figure 3.4 (b).

⚠ **Note: Don't plug probe cable while plugging off the probe.**



(a) Plugging In of Probe (b) Plugging Off of Probe

Figure 3.4 Plugging In/Off of Probe

3.3.3. Connection of Power Supply

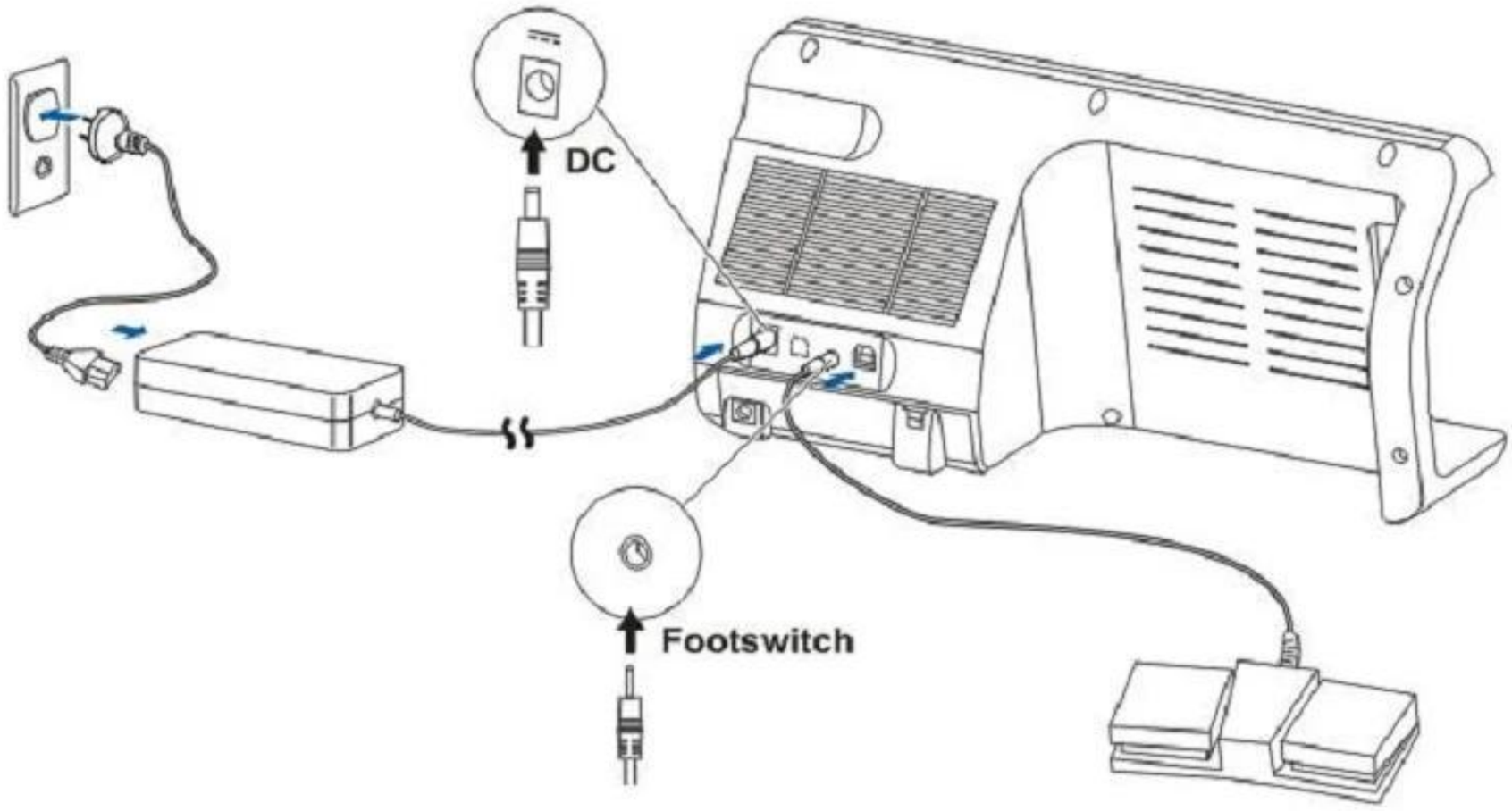


Figure 3.5 Connection of External Interface

1) Plug the DC Power Output Plug of the Power Adaptor in the Power Input Socket on the rear panel of the instrument;

2) Connect one end of the Power Cable with the Power Adaptor, and the other end to the wall outlet, as shown in Figure 3.5.

3.3.4. Disconnection of Power Supply

1）Turn off the Power Switch on the front panel;

2）Disconnect the main power plug of the Power Adaptor and the wall outlet.

3.3.5. Connection of Foot Switch

Plug the Foot Switch plug into the Foot Switch Socket on the rear panel of the instrument, as show in Figure 3.5.

3.3.6. Replacement of Printing Paper

The built-in printer is a thermal printer that uses thermal printing paper. Please purchase and replace the printing paper according to specific model provided by our company, see §8.2.1 Consumables.

Replacement of printing paper:

1) Press "OPEN" button to open the cover of the paper housing;

2) Take out the reel of the paper from the paper holder and add new paper, see Figure 3.6;

Figure 3.6 Replacement of Printing Paper

3) Pull out the printing paper from the paper slot for about 1cm, and push lightly to close the cover of the paper housing. Pay attention not to let the paper stuck in the slot. Close the paper housing finally.

⚠ **Note: 1) If the paper doesn't run properly, please check installing method and reinstall.**

2) The thermal paper has thermal side, when the paper runs normally but no word printed out, please open the paper housing and reinstall the printing paper with the other side.

Chapter 4 Operation

4.1 Startup and Shutdown

4.1.1. Check before startup

Please make following checks before the instrument is started up:

1）Whether the instrument is put in a proper place and whether the equipment around may cause interference;

2）Whether the appearance of the instrument is fine and whether there is crack on the housing and LCD screen;

3）Whether the probe is connected properly, and whether there is crack or damage on the surface of probe and cable; whether the probe cables are intertwined or intertwined with other cables;

4）Whether the foot switch is connected properly and has mechanical response when press, and whether the foot switch cable is intertwined with other cables.

5）Whether there is printing paper.

6）Whether the connection of power supply is completed and the Power Indicator lights up; whether the Power Cable is intertwined with other cables.

4.1.2. Startup Procedure

1）Make sure there is no problem and the Power Indicator lights up before the instrument is started up.

2）Start up the instrument

Press the Power Switch button on the Front Panel for over 2 seconds, the instrument starts working. Now the Working Indicator lights up and the main interface appear on the screen.

4.1.3. Check before Use

Please make following checks after the instrument is started up:

1) Whether the Working Indicator lights up;

2) Whether the touch screen is effective;

3) Whether waveform displayed when clicking SCAN/FREEZE key under the ASCAN Interface, and whether the red indicator in the front end of the probe lights up when measurement.

4) Check the parameter setting, following §4.3.6 Amendment and Storage of Parameters, and Amendment of Time for operation in detail.

5) Whether disinfection and sterilization of probe has been carried out as required.

4.1.4. Shutdown Procedure

While the instrument is switched on, press the Power Switch on the front panel for 2 seconds, the instrument will switch off.

Place the instrument and its accessories properly after shutdown:

1) Put the probe into the probe holder and make sure the probe cable can't be dragged by accident, or disconnect the probe and put it properly;

2) Put the foot switch properly and make sure the foot switch cable be placed properly to prevent others from stumbling by the cable and drop of instrument;

3) Plug out the Main Power Plug of the Power Adaptor cable and put it properly.

4.2 Interface Introduction

4.2.1. ASCAN Interface

Switching on EUS-1800 A/P will enter ASCAN Interface directly. The default setting of the system is automatic measurement (AUTO), contact method (CONT) and normal eye (NORM), the interface is shown in Figure 4.1.

Figure 4.1 ASCAN Interface

The function of each part under ASCAN Interface:

Data Display Area: The result of measurement display area.

Waveform Display Area: A Scan ultrasonic echo waveform display area.

Threshold: A value associated with voltage. The echo pulse with amplitude more than the value is determined to be the reflective wave of acoustic interface for different tissues. The cross point of the reflected pulse front and the threshold will be the basic point to calculate transmission time of ultrasound in different tissues.

Threshold line: The graphic display of relationship between threshold and ultrasound transmission distance.

Date and clock display area: display current date and time.

GAIN: Gain control key. Range of variation: 0-50dB; the default value is 30dB. Click to select and the key turned to green, and the value of gain is adjusted by ▲ ▼ key;

OS: OS/OD (left/right eye) selection key. Click to switch between left eye and right eye;

AUTO: Automatic measuring key. Click to switch between AUTO (automatic measurement) and MANL (manual measurement);

CONT: Measuring method selection key. Click to switch the measuring methods between CONT (contact measurement) and IMME (immersion measurement);

NORM: Eye model setting key. Click to open MODE SETTING dialogue box and set eye model. MODE SETTING dialogue box includes settings of: Measuring Modes, Measuring Methods and Eye Models, see §4.3.2.2.c for specific operation;

SCAN/FREEZE: Scan/Freeze control key. Click to start or freeze scanning. The key is blue indicates the state of scanning stopped; while green indicates scanning;

▲ ▼: Up and Down key, used to adjust position and value. The keys are used to adjust the position of Threshold Line when the Threshold Line displayed. The keys are used to adjust the gain when the GAIN function is activated. In other cases, the keys are used to change the position of cursor indicator (blue point) and cursor bar. The position of cursor and cursor bar indicates the position of current operating data group;

MARK: Mark key, used to mark unreliable data group. The marked group stores data and waveform, but doesn't participate in calculation. The cursor stays in the marked group, click again to cancel the mark;

DEL: Delete key, used to delete unreliable data and waveform. Click to call out dialogue box. Choose YES to delete selected data and waveform. The deleted data will not be restored. Choose NO to give up deletion and quit the dialogue box;

CLEAR: Clear key, used to clear data and waveform. Click to call out dialogue box. Choose YES to clear all data and waveform displayed. The cleared data will not be restored. Choose NO to give up clear and quit the dialogue box, see §4.3.2.6 Save and Clear under Measuring Interface;

IOL: IOL (Intraocular Lens) Calculation key. Click to enter IOL interface;

MENU: Menu key. Click to enter menu interface, from where it is able to enter other interfaces;

MEM: Memory key. Click to save data, which includes patient information, measuring data, all kinds of parameters and waveforms. If it's necessary to save complete information, please enter IOL interface and complete parameter input and calculation; then click MEM key to save.

To enter PATIENT interface directly from this interface, it's able to click directly the patient information display area at the bottom of the screen.

4.2.2. Patient Information Interface

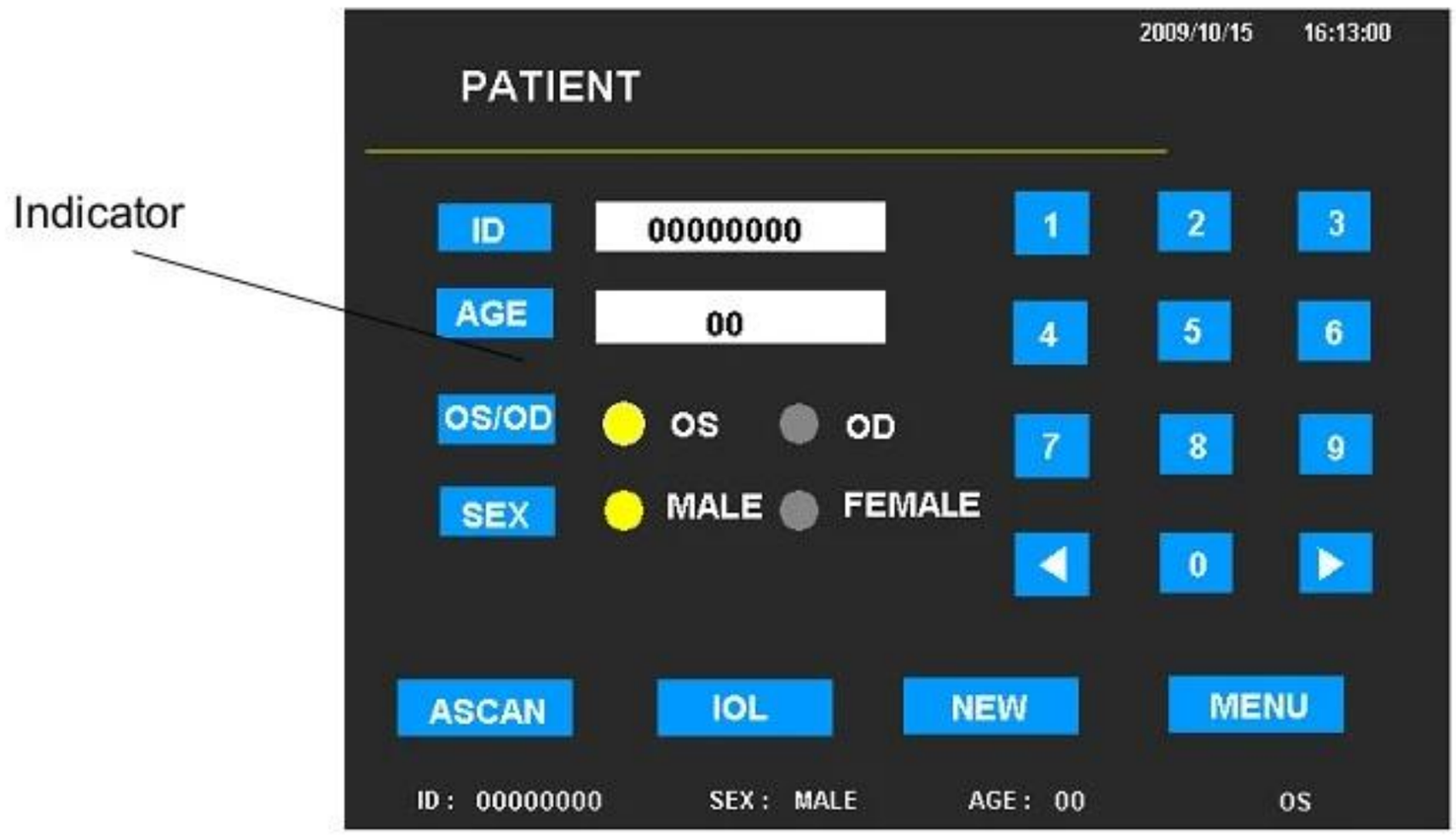


Figure 4.2 PATIENT Interface

In normal measuring interface, for example ASCAN interface, click patient information display area at the bottom of the screen to enter the patient information interface. Patient Information Interface is used to input the patient information, include the patient ID, age, OS/OD and sex accordingly.

Click the position of corresponding key to move the cursor to that position, and then input the information. ID is made up of 8 digits with the input range from 00000000 to 99999999, click the numerical key at the right side to input numbers when the cursor is located in the text box. Input age with the same method and the range for age is 00-99.

There are two ways to select OS/OD: one is clicking OS/OD key, the OS and OD lights up alternatively (the indicator lights up means selected); the other is clicking the area of OS or OD directly for selection.

Patient's sex can be set with the same method.

ASCAN: Click it to choose returning to ASCAN interface;

IOL: Click it to choose returning to IOL interface;

NEW: New Patient key. Click it, Patient ID will be restored to default value, when new patient information can be input, meanwhile all data measured in other interfaces will be cleared;

MENU: MENU key. Click it to return to MENU interface.

Numerical keys are used to input number 0-9, the ◄ ► key are used to control the left and right movement of cursor respectively.

In PATIENT interface, in case of changing into other interfaces, the patient information will be displayed at the bottom of the screen. The displayed information contains: ID, age, sex and OS/OD for reference. If the information is not input, the default ID is: ------ and the age is: --.

4.2.3. MENU Interface

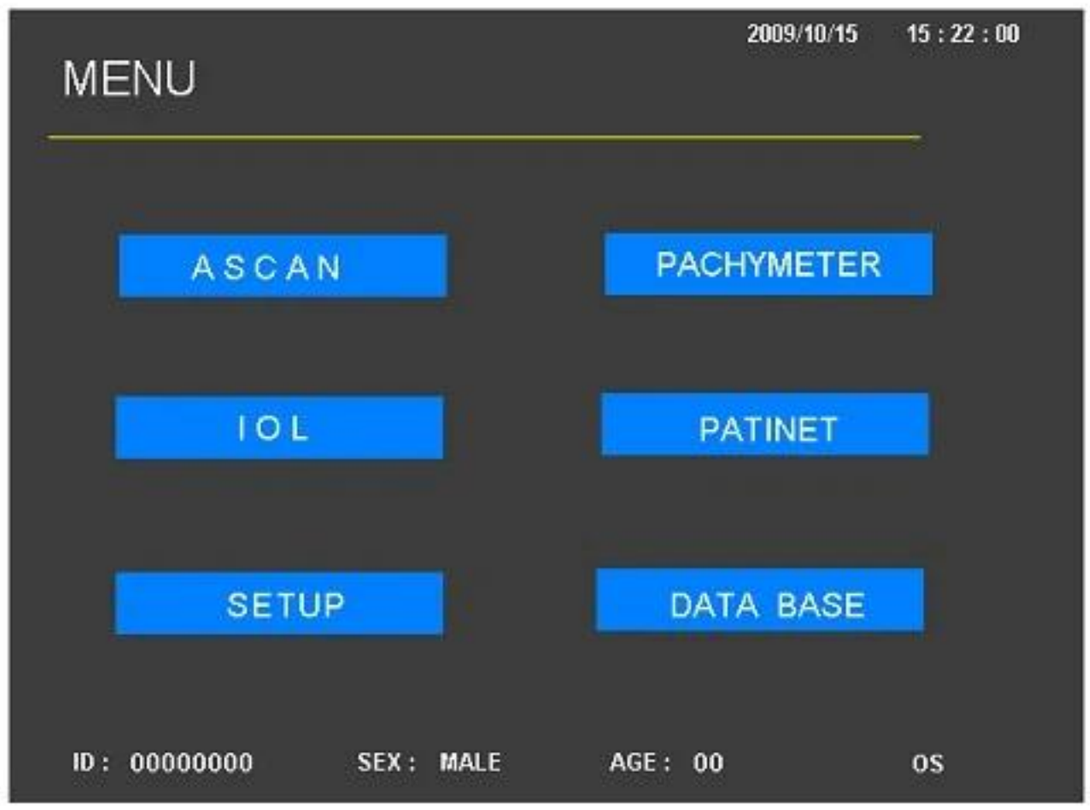


Figure 4.3 MENU Interface

Click MENU key to enter MENU interface, as shown in Figure 4.3. Click the six keys in the interface to enter the corresponding interface, which are: ASCAN interface, PACHYMETER interface, IOL interface, PATIENT interface, SETUP interface and DATA BASE interface.

4.2.4. IOL Interface

IOL calculation interface, as shown in Figure 4.4. The keypad at the bottom of the interface is used to input numbers.

AL: Axial Length AL, which can be achieved by the measuring result of A Biometer, or input by the keypad;

AC: Anterior Chamber depth AC, which can be achieved by the measuring result of A Biometer, or input by the keypad;

⚠ **Note: AC can only be used in HAGIS formula; it is inactive in other formulas.**

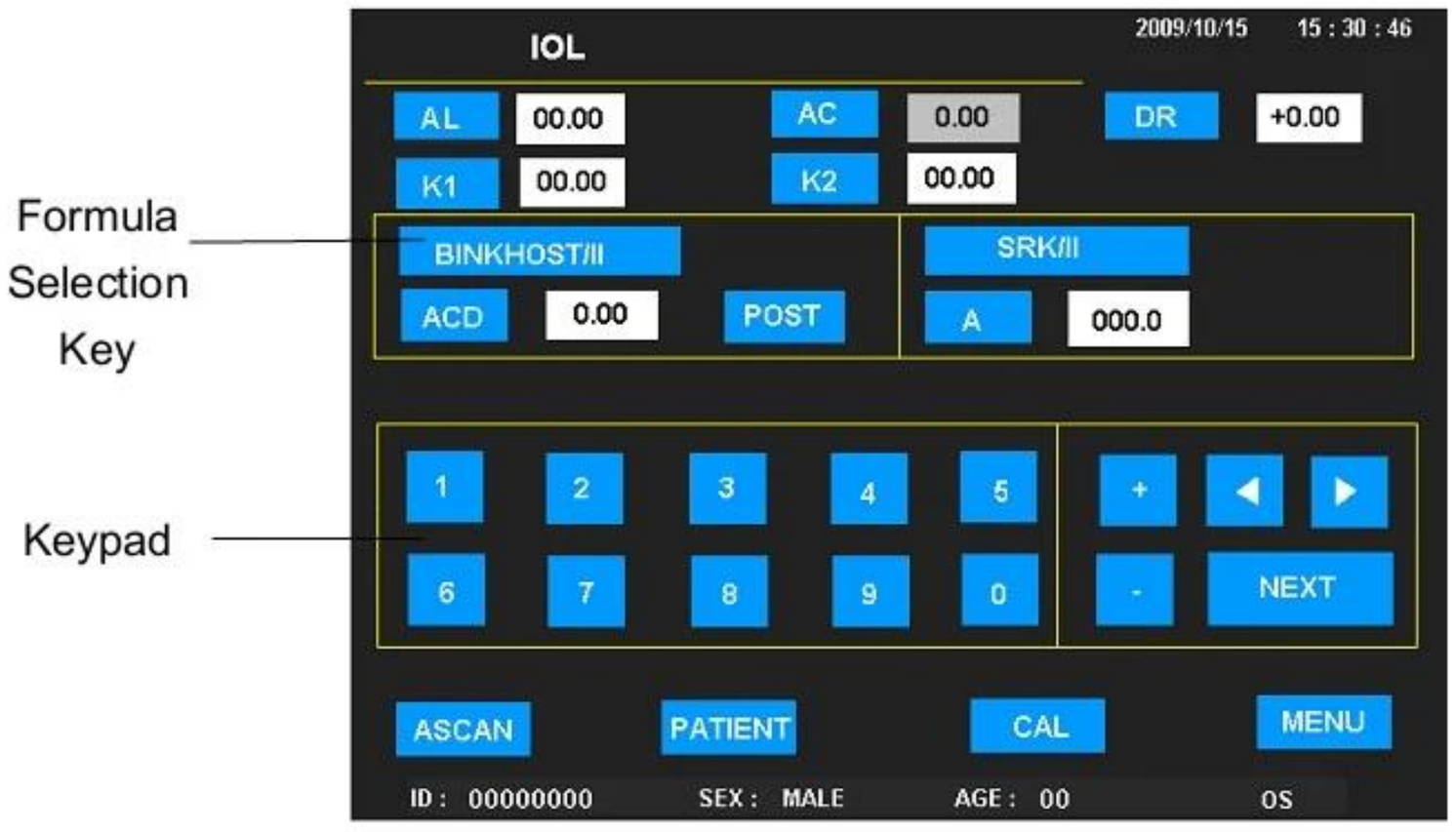


Figure 4.4 IOL Interface

There are two formula selections areas for user's choice of an applicable IOL calculation formula. Click Formula Selection key to make selection.

The formulas provided are: SRK-II, SRK/T, HOLLADAY, HOFFER-Q, HAIGIS and BINK-II.

The parameters of each formula can be input according to specific circumstances; click the number and [+] [−] as well as the left and right keys ([◀] [▶]) on the keypad to input the parameters.

The meaning of parameters is as follows:

DR: Refraction Desired,

K1: Keratometry,

K2: Keratometry,

A: Constant of IOL;

ANTI/POST: Anterior Mode/Posterior Mode;

D.EM: Diopter of Emmetropia;

D.AM: Diopter of Ametropia.

ASCAN: Click it to return to ASCAN interface;

PATIENT: Click it to return to PATIENT interface;

MENU: Click it to return to MENU interface;

CAL: Calculation key, click it to make calculation and enter calculating result display interface.

When clicking CAL key, if the input parameter is out of range, the system will prompt to make amendment and then recalculate.

When the calculation completed, the keypad will disappear and calculating result will appear on the screen. Meanwhile, the keys will change, as it is shown in Figure 4.5.

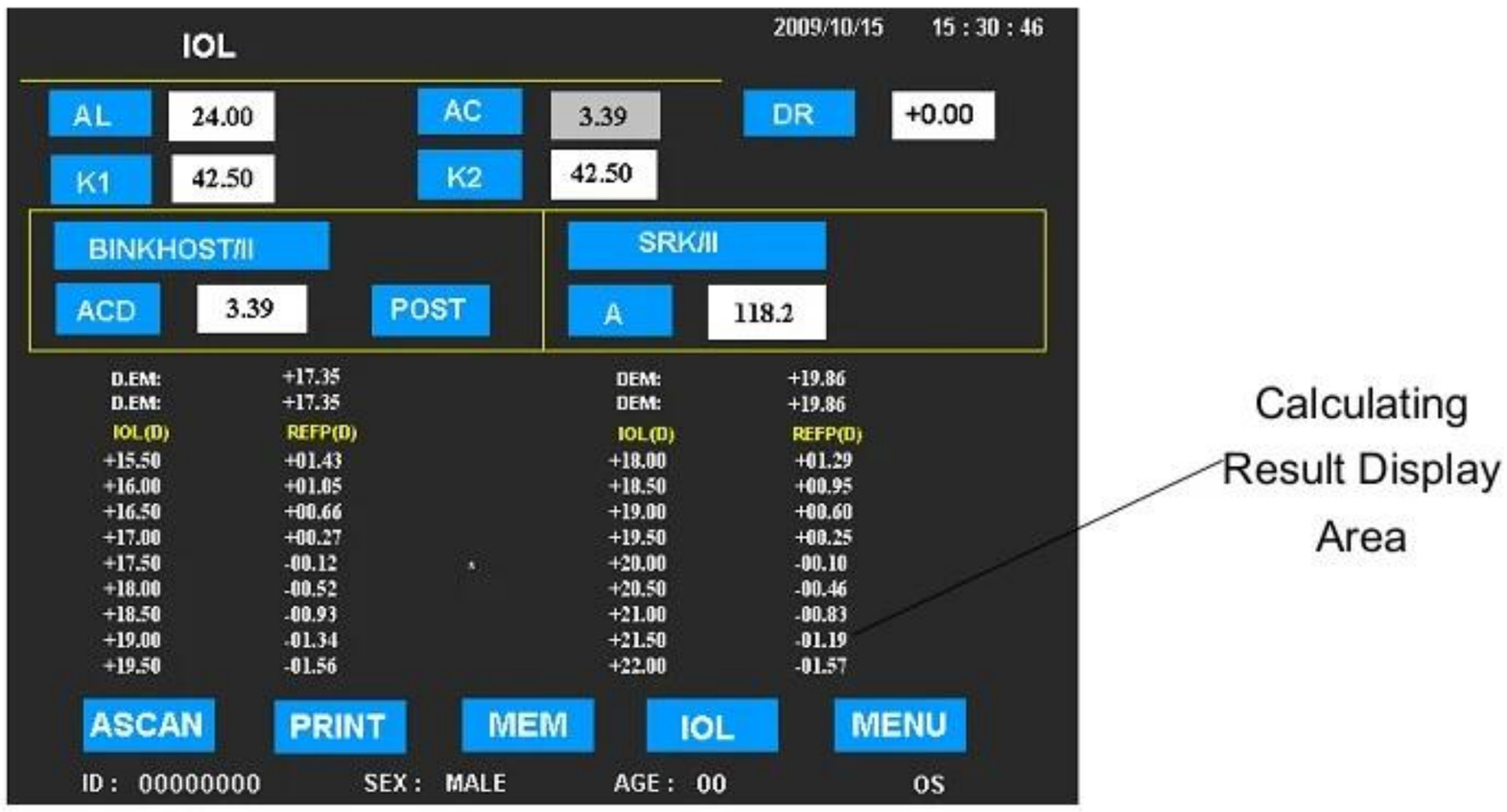


Figure 4.5 IOL calculating interface

MEM: Memory key, click it to save all the relative information, including patient information, measuring data, waveform and IOL calculating parameters.

PRINT: PRINT key, click it to print the saved result.

IOL: Click it to return to IOL interface, calling out keypad, changing parameters and recalculating.

4.2.5. PACHYMETER

Corneal thickness measuring interface, as shown in Figure 4.6.

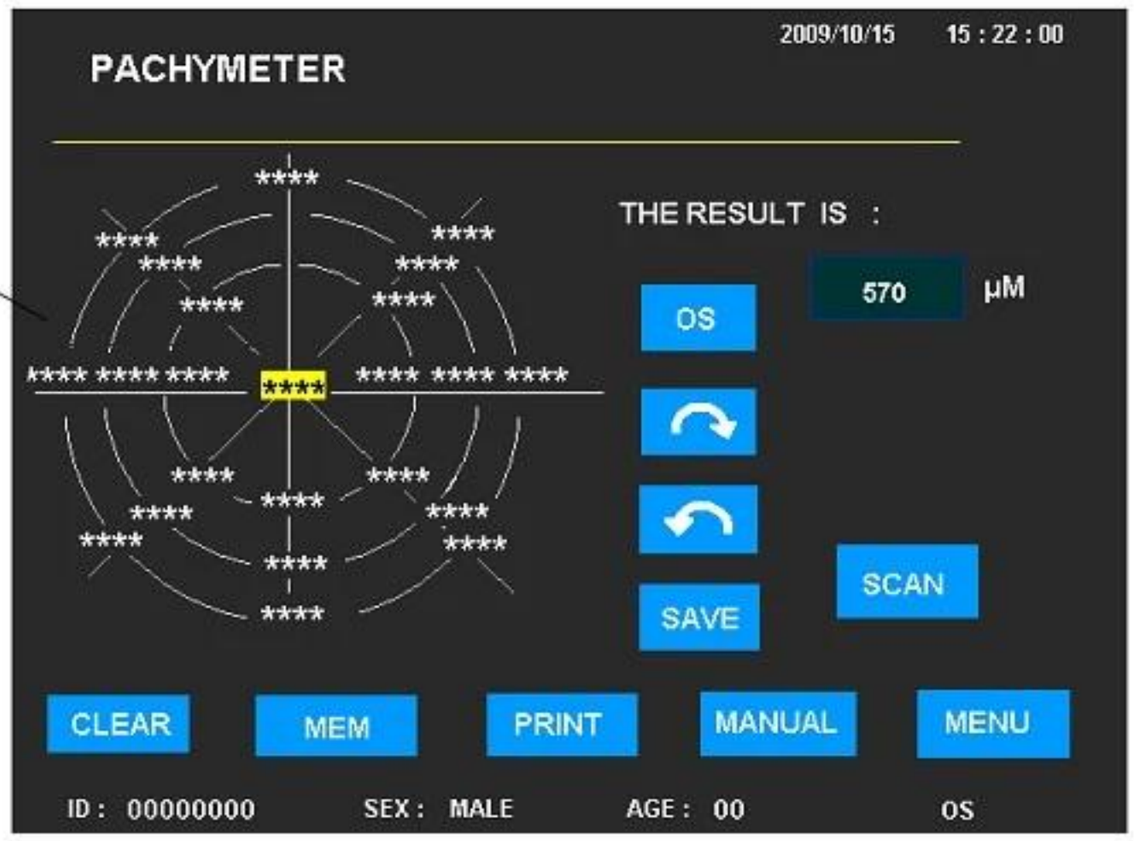


Figure 4.6 PACHYMETER

↷ ↶ : Direction key. Use clockwise and counterclockwise arrows to control the cursor's forward and reverse circular motion. Thus determine the input position of measuring data;

SAVE: Input key. Click it to save the current measuring value to the cursor's position; meanwhile the cursor will move to the next position;

OS: OS/OD selection key. Click it to change left/right eye selection;

SCAN: Start-to-measure key. Click it to start measuring; the color of key will be changed from blue to green;

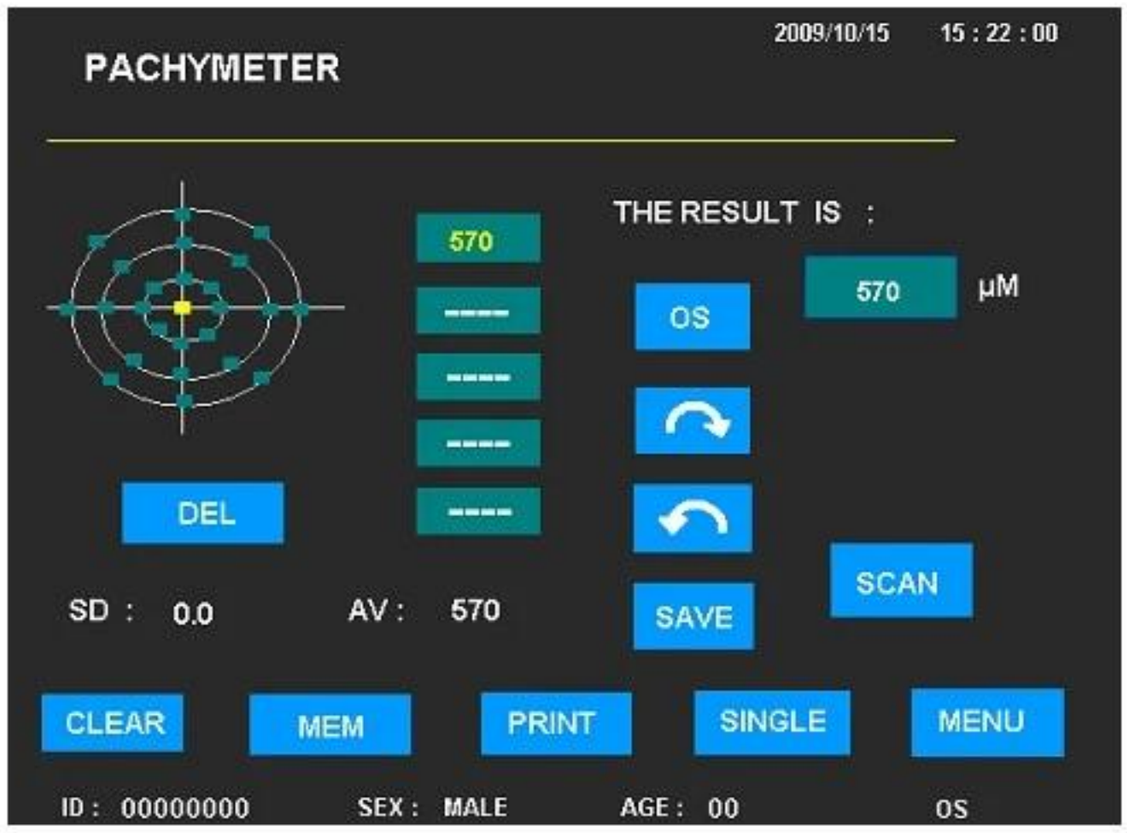
CLEAR: Clear key. Click it to clear all measuring results;

MENU: Menu key. Click it to enter MENU interface;

MEM: Memory key. Click it to save measuring results;

PRINT: Print key. Click it to print results;

MANUAL: Manual or automatic selection key. Click it to select manual or automatic measurement, where there are five display statuses respectively Manual, Group 1, Group 2, Group 3 and Singe-point Multiple Measurement (SINGLE). The corresponding corneal thickness distribution map will be changed also.



Figue 4.7 Single-point Multiple Measurement (SINGLE) Interface

DEL: Delete key under singe-point multiple measurement interface. Click it to delete the selected measuring result. The average value of each group and standard deviation displayed will be updated accordingly.

Click the patient information display area at the bottom of the screen will enter the PATIENT interface as well.

4.2.6. SETUP

Parameter setup interface, as shown in Figure 4.8.

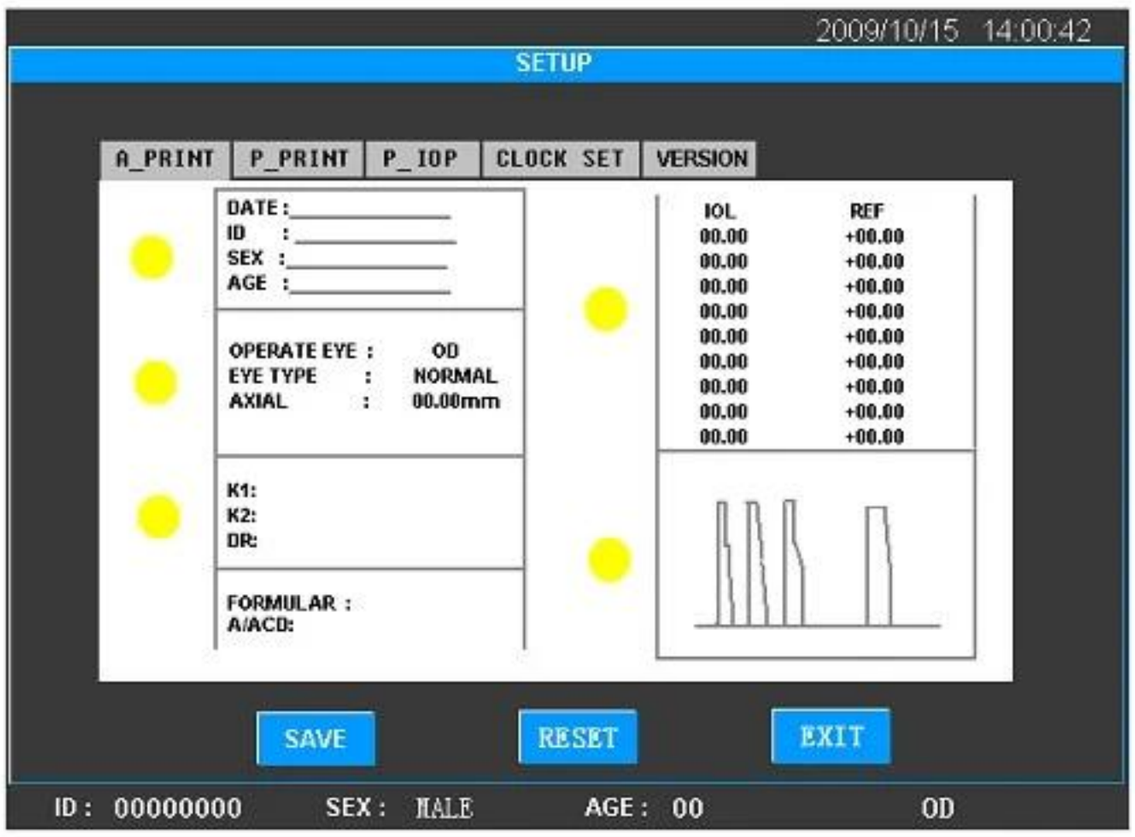


Figure 4.8 SETUP Interface

The parameter setup interface contains four setup interfaces. Click relative key to enter.

A-PRINT: Click it to enter the print parameter setup interface for A Biometer;

P-PRINT: Click it to enter the print parameter setup interface for Pachymeter;

P-IOP: Click it to enter the IOP parameter setup interface for Pachymeter;

CLOCK SET: Click it to enter clock setup interface;

The functions of other keys under SETUP interface are as follows:

VERSION: Click it to enter version information interface;

SAVE: Click it to save selected result;

RESET: Reset key. Click it to restore default value;

EXIT: Click it to exit from the interface.

⚠ **Note：1) Under other interfaces except that of clock setting, click SAVE key will save all parameters in A-PRINT, P-RINT and P-IOP interfaces; and click PRESET key will restore all parameters to default settings. Please confirm before operation.**

2) Click SAVE or PRESET key will save the state of all parameters automatically, so please make the relative change cautiously.

4.2.7. DATA BASE

Patient data management interface, as shown in Figure 4.9.

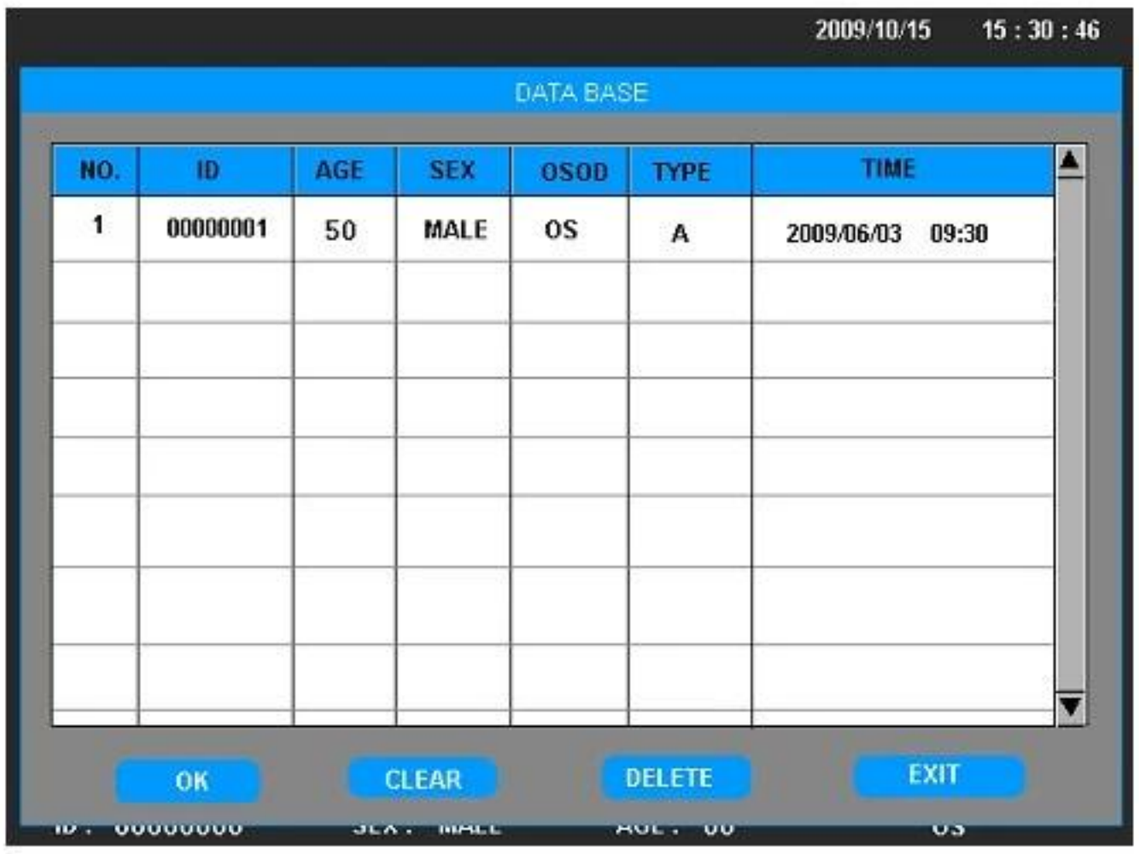


Figure 4.9 DATA BASE Interface

This interface will list all the saved patient information in tabular format. The content displayed includes patient ID, age, sex, OS/OD, scanning type (A Biometer or Pachymeter) and storage time. Patient information can be checked. Click the position of corresponding patient information, the blue bar appears, then click OK to enter the interface of restoring and observe the measuring result. (Please refer to §4.3.4 DATA BASE and §4.3.5 Display of Saved Information)

CLEAR key is used to clear all the patient information, clicking this key will call out dialog box to confirm the request of clear or not. Choose YES to clear all information which can not be restored; choose NO to exit directly. Click DELETE key to delete the selected information only. All deletions are not recoverable, please operate cautiously. Click EXIT key to exit.

⚠ **Note: The maximum storage capacity of EUS-1800 A/P is 180 items of patient information. Please process the data in time to prevent storage error.**

4.3 Operation

4.3.1 Positioning

Place positioning the instrument beside the patient. The distance between should enable the probe to contact the patient's eye easily. The instrument should face the operator and the foot switch should be placed appropriately for operation. Please ensure the instrument is located safely and will not cause falling and hurting people by accidental operation. Switch on the instrument after completing the above steps.

4.3.2 A Biometer Unit

4.3.2.1 Input Patient Information

In ASCAN interface, click the patient information display area at the bottom of the screen to enter PATIENT interface, (or click MENU key to enter menu interface, then click PATIENT key to enter patient information interface) and input the patient's information accordingly. The default patient ID

is: ----, age: ------, and sex: MALE. Please update the patient information in time to prevent any error.

4.3.2.2 Mode Selection

a) Selection of measuring mode

There are two kinds of measuring modes: automatic measuring mode (AUTO) and manual measuring mode (MANUAL). The default mode is automatic measuring mode.

Manual measuring mode is usually used in some special cases, when the system can not identify the waveform or can't mark automatically due to the limited conditions.

Five-Point Marking Method is used to measure A-Biometer data, as shown in Figure 4.10.

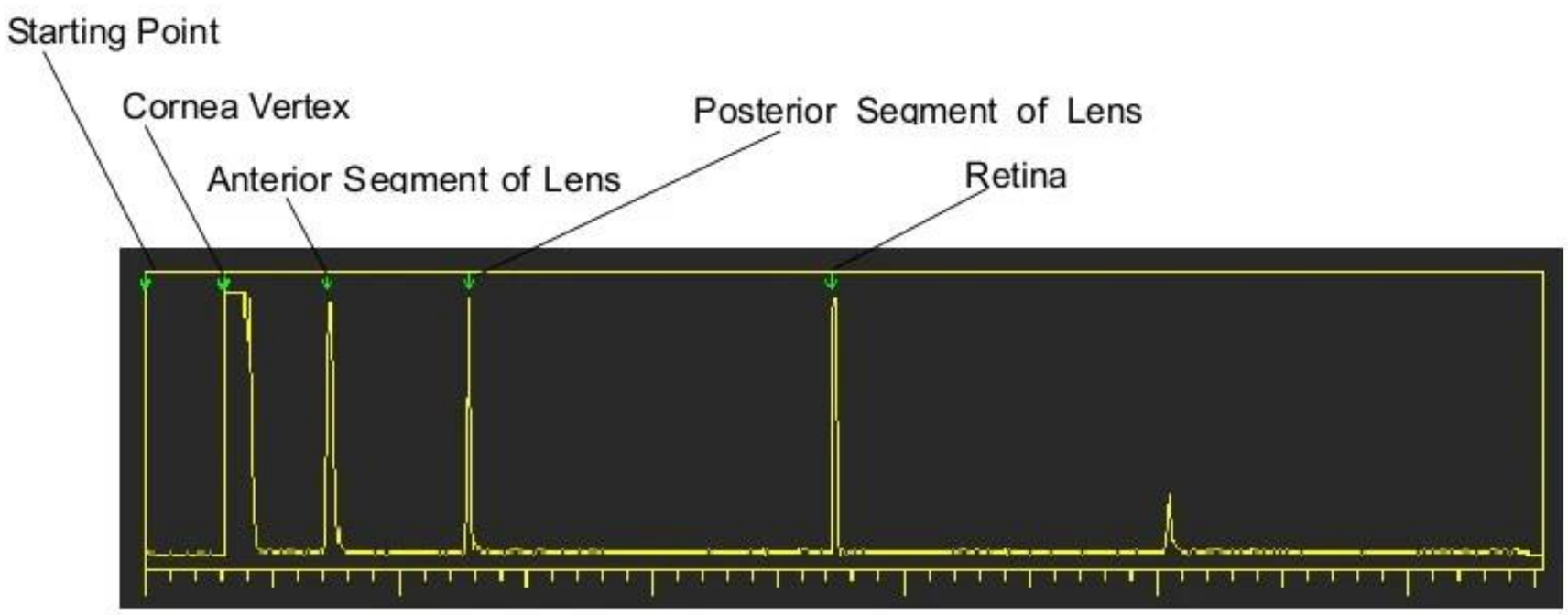


Figure 4.10 Five-Point Marking Method

The five points are respectively: cornea vertex, cornea posterior segment (sometimes in the superposition with cornea vertex), anterior segment of lens, posterior segment of lens and retina.

For AUTO mode, the instrument will automatically determine the five points and then calculate; and for MANUAL mode, the operator is required to determine the positions of the five points, mark them separately to acquire measuring data. With contact method, the starting point is in superposition with cornea vertex and cornea thickness is ignored, that is to say the cornea vertex is in the superposition with the cornea posterior segment. With immersion method, the starting point is not in superposition with cornea vertex, and cornea thickness can be measured in some cases, at that time the cornea vertex is not in superposition with the cornea posterior segment.

In MANUAL mode, the operator is required to move the position of arrow manually and the system calculates according to the marked position and displays data. The MANUAL mode is applied in some special cases, which are due to limited conditions, the system can not automatically recognize the waveform and can not mark the arrow correctly.

Under AUTO mode, the system's default setting is NOMAL eye, Contact method and Automatic measurement mode.

In MANUAL mode, the system's default setting of display is: NORMAL eye, Immersion method, which cannot be modified, but the operator can select to use contact or immersion measuring

method to make measurement. Special attention should be given to mark the starting point of the Five-Point Marking Method. It should be at the starting point of the graph for Contact method, and at cornea vertex for Immersion method.

The specific selection method for measuring mode is: click AUTO or MANL key to switch between AUTO and MANUAL, the content displayed will change accordingly. Select a suitable mode, or click NORM key to open MODE SETTING dialogue text. Please refer to item d).

b) Selection of measuring method

According to whether A-Biometer probe will contact cornea, the measuring method is divided into CONTACT method and IMMERSION method.

CONTACT method indicates the A-Biometer probe will contact cornea vertex directly. The operator is required to handle the probe gently while measuring. It is applicable for both automatic and manual measurement.

IMMERSION method indicates the A-Biometer probe will not contact cornea directly, but through acoustic coupling medium.

The specific selection method is: click CONT or IMME key to choose measuring method, the content of key will change accordingly (display CONT or IMME). Select a suitable method, or click NORM key to open MODE SETTING dialogue text. Please refer to item d).

c) Selection of eye model

According to the different conditions of patients, four EYE models can be selected, that is: NOMAL, APHAKIC, SPECIAL and CATATACT. Open MODE SETTING dialogue box to select. Please refer to item d).

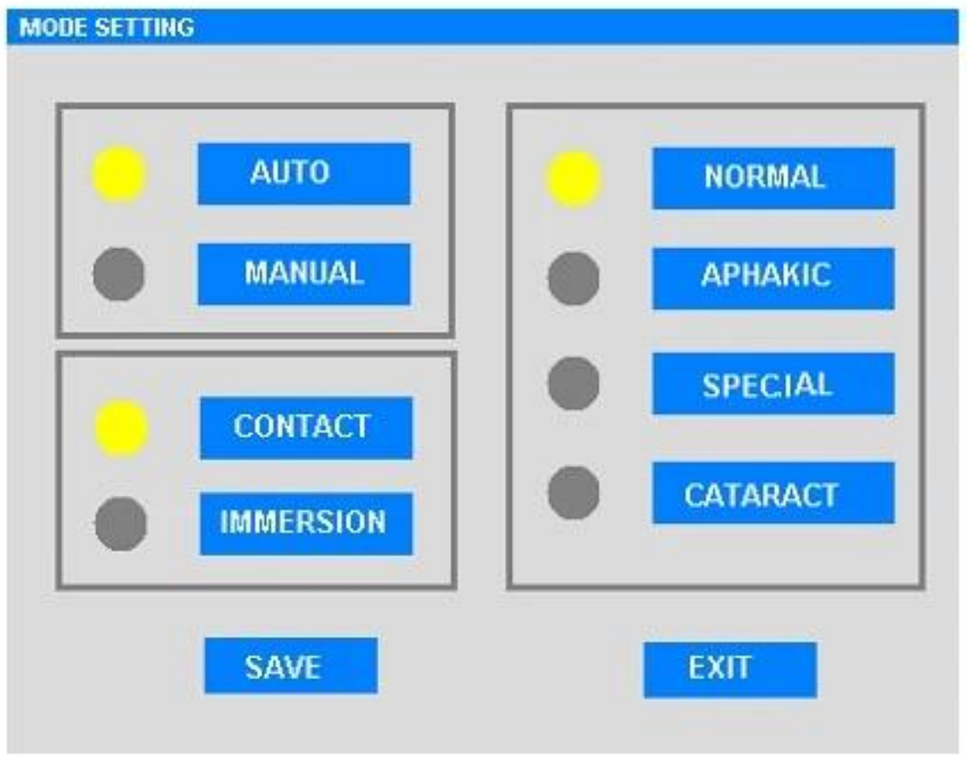


Figure 4.11 Eye Model Selection Interface

d) MODE SETTING dialogue box

Click NORM key to call out the dialogue box, as shown in Figure 4.11.

The dialogue box consists of three parts, namely: measuring mode setting, measuring method setting and eye model setting.

Click the keys respectively to select AUTO or MANUAL, CONTACT or IMMERSION; NORMAL, APHAKIC, SPECIAL, CATARACT.

The acoustic velocity is the system's default setting. If CATARACT or APHAKIC is selected, the system will change the acoustic velocity automatically.

If special eye is selected, the dialogue box is

Figure 4.12 IOL Acoustic Velocity Setting

popped up (as show in Figure 4.12) for selection of the velocity of several common IOL. The types of IOL to be selected are: PMMA/ACRYLIC/SILICONE or USERSET, among which, USERSET is the type provided to users to input required acoustic velocity according to patient's condition.

Click specific position to select the corresponding IOL acoustic velocity (indicator lights up), which is displayed in the dialogue box. The value can be modified but can't be saved as the instrument's parameter. It is only used under the current condition when SPECIAL eye is selected, quit the selection, then the input or selected acoustic velocity will disappear. Click SAVE key to save the acoustic velocity set; or clicks EXIT key to exit (no parameters saved under this mode).

The Default Acoustic Velocity set is shown below:

Unit: m/s

IOL	PMMA	ACRYLIC	SILICONE	CATARACT
Acoustic Velocity (m/s)	2718	1946	1050	1629

4.3.2.3 Measurement under the AUTO Mode

1) CONTACT Method

Switching on the instrument will enter AUTO mode automatically, or select AUTO mode according to the description of **Mode Selection** in section §4.3.2.2a, the default measuring method is CONTACT, and the operation procedure is as follows：

a) Let the patient lie down, open his/her eye to perform surface anesthesia.

b) Use Chloromycetin eyedrop to wash the probe front.

c) Step onto the foot switch or click SCAN/FREEZE key to start measuring.

d) Place the probe gently onto the patient's cornea vertex, and tell the patient to look at the probe straightly.

e) Generally, it is not necessary to adjust gain and threshold. For some special cases (e.g. severe cataract patients), low retina reflective amplitude or poor waveform maybe appear, adjust the gain or threshold then to get the clear reflective waveform of the tissue interface, sharp front edge is preferred.

f) When the probe is properly aligned you will hear a series of beep sounds, the wave is automatically frozen and data will be displayed on the screen. The EUS-1800 A/P supports up to eight groups of data, and there will be a long beep sound after all eight groups of data are acquired. The instrument will stop measuring automatically after data displays on the screen, and the probe can be removed then. The average value of each group and standard deviation display on the upper side of the waveform display area.

g) If the data are not acquired, please move the probe slightly until getting the measurement. Keep the probe stably in the position found, eight groups of data will be acquired.

h) If the standard deviation is big, it may caused by the moving of probe during measurement. Move the cursor with ▲ ▼ key and observe each group of data and its corresponding waveform. Click MARK key to mark unreliable data, click again to cancel the mark. The marked data will not be calculated. Or click DEL key to delete the inaccurate data.

⚠ **Note: 1) The deleted data will not join in calculation; they are unrecoverable, so please operate cautiously.**

2) Since the results of each automatic measurement will subject to multiple sampling averages, the operator is required to perform the scanning gently and smoothly. The probe can only be removed after the measurement completed, the image is automatically frozen and the data is displayed on the screen.

3) The probe should be placed align with the axial to guarantee the accuracy of measurement.

4) Don't move the probe directly on the patient's cornea to avoid injury of cornea.

2) IMMERSION Method

Under automatic measurement, if IMMERSION method is selected according to §4.3.2.2b, the operator should gently put the eyecup onto patient's eyelid, fix the eyecup with eyelid and inject physiological saline into eyecup as coupling medium. Place A-Biometer probe into the coupling medium, and make sure the probe will not contact cornea. The probe should be placed perpendicular to the cornea and moved towards the cornea. When the distance between the probe front and cornea vertex is 2-8mm, start automatic measurement. The rest operations are same with that of CONTACT method.

4.3.2.4 Threshold modification under the AUTO mode

The threshold can be set according to the actual demand. The adjustment range of threshold is 50-120 and the default state is that the threshold line is hidden and threshold value is 100. Double click the upper part of waveform quickly to display the threshold line and the current threshold value, as shown in Figure 4.13. Adjust the position of threshold line by clicking the up and down arrow. Click the threshold line to hide the threshold line and the threshold value.

Figure 4.13 Diagram of Threshold Line

⚠ **Note: 1) Normally, the threshold value is not necessary to be modified and the default setting is recommended.**

2) The threshold value will return to default setting after the system is switched off.

4.3.2.5 Measurement under the MANUAL mode

Figure 4.14 Arrow Move Dialogue Box

Select manual measuring mode according to §4.3.2.2a), the arrow move dialogue box and ARROW MOVE key will pop up automatically. The arrow move dialogue box is used to move the arrow for marking peak of wave and amend data displayed. ARROW MOVE key is used to call out arrow move dialogue box for remark the arrow. See Figure 4.14:

The arrow move dialogue box contains ◄ ► key, ENTER key, Zoom In and Zoom Out, as well as AMEND key and EXIT key. The ◄ ► key are used to move the arrow; ENTER key is used to confirm the arrow position; Zoom In is used to magnify the part indicated by the arrow and Zoom Out is used to cancel magnification and return to normal state. Click ENTER key after all arrow positions are selected, the measuring result will be displayed in the position of the first group and then switch to the next group's measurement. Click EXIT key will exit this interface directly. If amendment is required, click AMEND key to clear all arrow positions and re-select.

The default setting under MANUAL mode is immersion method; however, either contact method or immersion method can be selected during using. The difference is that the starting point of the five-point positions is not same. (See §4.3.2.2a)

For CONTACT method, the procedure is as follows:

a) Select manual measuring mode, click SCAN/FREEZE key or step on the foot switch to start scanning.

b) Operate according to procedure a) to e) for automatic measuring mode.

c) Move the probe slightly to observe the reflected waveform. When the reflected waveform is clear, click SCAN/FREEZE key again or step the foot switch to freeze the waveform. The first group of waveform displays as ——.——.

d) Since contact method is used, the starting point is the cornea vertex and is in superposition with posterior segment of cornea. Click ENTER key twice and confirm the position of cornea vertex and posterior segment. Then click ◄ ► again to move the cursor, and the moving distance of cursor displays in the dialogue box; when the cursor is moved to the reflected pulse's rising edge for anterior segment of lens, click ENTER key and the value displayed in the dialogue box will input in

column of ACD. Keep on moving the cursor to acquire VITR value with the same method. After the above measurement, click ENTER key again, the measuring value of AL displays on the screen, and at the moment the first measuring waveform disappears, the blue dot cursor skips to the second group for the measurement.

e) There are Zoom In and Zoom Out keys in the arrow move dialogue box. The Zoom In key is used to magnify five points within left and right range with cursor as the center. If accurate positioning is required during measurement, click Zoom In to move the cursor accurately inside the magnified area. Click Zoom Out to cancel magnification and return to normal state.

f) If the arrow positions need to be amended during the process of determination, click AMEND key and the arrow disappeared to remark the arrow position.

Figure 4.15 Arrow Move Dialogue Box

g) Click EXIT key after measurement and exit from the dialogue box. And click up and down key to load the waveforms of each group of measuring data.

Under MANUAL mode, up to 5 groups of data can be acquired and the average value and standard deviation display at the upper side of the waveform display area. For uncertain measuring data group, the operator can click MARK key to mark. When necessary, click DEL key to delete the data or click ARROW MOVE key to call out arrow move dialogue box and make amendment by clicking AMEND key and remarking the position of arrow. The marked or deleted data will influence the final calculation of average value and standard deviation. The final results will come into the IOL calculation.

If IMMERSION method is used under manual measurement, attentions should be given for marking the measuring waveform: for the case the starting point of the waveform is not in superposition with cornea vertex, clicking ◄ ► first to move the arrow to the reflected pulse's rising edge of cornea vertex, click ENTER key to confirm; if the reflected waveform can't distinguish the posterior segment of cornea, click ENTER key again to ignore cornea; if the reflected waveform can distinguish the posterior segment of cornea, then move the arrow to the reflected waveform's rising edge of posterior segment of cornea, click ENTER key then, the cornea thickness input in the COR column of the screen. The measurement for other segments is same with that of the contact method.

4.3.2.6 Save and Clear under Measuring Interface

In ASCAN interface, metrical information and data can be saved. Click MEM key to save the current results, system will pop out dialogue box to confirm the operation. Choose YES to save and choose NO to exit.

Please refer to §4.3.4 and §4.3.5 for load and display of saved information.

⚠ **Note: Save in ASAN interface can store patient information, waveform and measuring data, the calculated parameter and result can not be saved. If save is required, please enter IOL interface to calculate and save.**

In ASCAN interface, if the measured data and waveform are not satisfactory and need to be re-measured, please click CLEAR key to clear all the data and waveforms. Click CLEAR key,

System will pop out dialog box to confirm the operation. Choose YES to clear, and the cleared data will not be recovered. Choose NO key to exit without clearing.

4.3.2.7 Manual Amendment of Measuring Result under AUTO Mode

For experienced doctors, if the standard deviation of the eight groups of data, which are acquired by automatic measurement, is big, it is able to move the cursor with up and down arrow and observe the measured waveform corresponding to each group of data; and for the uncertain data that the arrow does not align with the rising edge of the waveform, it's possible to remark manually. The detailed operation is as follows:

a) Double click data display area quickly to call out the arrow move dialogue box as shown in Figure 4.15, and amend the data indicated by cursors.

b) Click ENTER key after the dialogue box is called out. The color of arrow will change to red successively. Select the position of arrow that need to be amended and click AMEND key to confirm the amendment at the arrow position.

c) The ◄ ► key will change from un-selectable grey to selectable yellow. Click ◄ ► key to move the arrow to the rising edge of waveform, if required, select ZOOM IN and ZOOM OUT to observe the waveform. The operation procedure is same with the ZOOM IN and ZOOM OUT function of above Manual Measuring Mode.

d) Move the arrow to the required position and click ENTER key again to input the new result, the arrow's selectable status will move to the position of next arrow. Repeat the above process to make amendment.

e) Click EXIT key to exit.

4.3.2.8 IOL Calculation

The measuring result will display in the IOL interface automatically after measurement. Click IOL key in ASCAN interface or click IOL key in MENU interface can enter IOL calculation interface (see §4.2.4).

In IOL interface, the measuring result of AL can be acquired by the calculation interface directly, or be input manually.

Select the required formula by click the formula selection keys (see Figure4.4). Different formula will appear by each click. The formulas appear repeatedly until the required formula appears. EUS-1800 A/P provides following IOL formulas: SRK-II, SRK/T, HOLLADAY, HOFFER-Q, HAIGIS, BINK-II. Input the parameter of each formula with keypad according to the practical situation. The system will save the parameter automatically until the next amendment.

Click CAL key to make calculation after all parameters are input. The calculating result will display on the screen. The operator can select print or save the result according to the practical situation.

4.3.3 Pachymetry

Click PACHYMETER key in MENU interface to enter PACHYMETER interface.

4.3.3.1 Click patient information field at the bottom of the screen to enter Patient Information interface. Input patient's information as per the same method of §4.2.2 and then return to PACHYMETER interface. If patient information is not input, the system's default selection is OS, MALE, which appears in the patient information field at the bottom of the screen.

4.3.3.2 Click MANUAL key to choose manual mode: MANUAL, automatic mode: AUTO(1), AUTO(2), AUTO(3), or enter SINGLE interface. To switch to automatic mode, the key turned from light blue to green.

4.3.3.3 Give surface anesthesia to the cornea to be tested, sterilize the front top of the P probe and make it dry. Or click SCAN key and move the probe within 5 seconds onto the corresponding position of cornea indicated by the corneal thickness distribution map cursor. Touch the cornea gently and make measurement. The measuring result appears in the dialogue box on the right top of the screen. The SCAN key is green during measurement, and returns to light blue after measurement. If no suitable data acquired, the instrument will stop measurement after 5 seconds and return to the status ready for measurement.

4.3.3.4 Under automatic measuring mode, if suitable data are acquired, the instrument will input the value in the position of the cursor by itself, and then the cursor will skip to the next measuring position.

Under manual measuring mode, it's required to click SAVE key or press the left switch (SAVE) of the foot switch to input data which appears in the position of the cursor, and then the cursor will skip to the next position. If required, use up and down keys to adjust the cursor and determine the next measuring position.

Under single-point multiple measuring mode (as shown in Figure 4.7), click SAVE key or press the left switch (SAVE) of the foot switch to input data which appears in the text box of the left cursor. Maximum five measuring data will be displayed; and the average value and standard deviation will be calculated according to the input data. The final average value will be input into the position of cursor. Click SAVE key will not change the measuring position. If the measuring position needs to be changed, use direction keys to move the indicated position.

If the selected position of the cursor is in the position of cornea center, △IOP (Intraocular Pressure adjusting value) will appear on the right center of the screen.

⚠ **Note: The calculation result of △IOP is only the reference value of intraocular pressure, see §4.3.6.3 for details.**

4.3.3.5 Click MEM key to save or PRINT key to print the data after measurement.

4.3.3.6 To measure new patient, please enter patient information interface. Click NEW key to re-input patient information and enter PACHYMETER interface again.

4.3.3.7 Click CLEAR key to clear the measuring data.

⚠ **Note: Please make sure the front top of P probe is dry and the corneal surface is moist each time when you start measurement.**

4.3.4 DATA BASE

Click DATA BASE key in MENU interface to enter data base to check patient information.

In each measuring interfaces, if data are saved after measurement, the patient's information will be saved in the data base.

The data base will display the saved patient information in tabular format, as shown in Figure 4.17. The displayed information include: patient ID, age, sex, OS/OD and type of measurement (A Biometer or Pachymeter).

The operator can select the patient information (by clicking the position of the patient information, blue bar means selected). Click OK to call out measuring data display interface and observe the measured result. At the moment, some of the functions are invalid in the measuring data display interface. The invalid functional keys turn to grey and there is no response after clicking. Please refer to §4.3.5 for details.

CLEAR key is used to clear all patients' information. Click this key and the dialogue box will be called out to confirm the operation. Select "YES" to confirm clearance of all data. The data cleared are recoverable. Select "NO" to exit without clearing. Click DELETE key to delete one patient's information. The use of DELETE key is similar with that of CLEAR key. Click EXIT key to exit.

⚠Note : **1) All deletions are unrecoverable, so please operate cautiously.**

2) The maximum storage capacity of EUS-1800 A/P is 180 items of patient information. Please process the data in time to prevent storage error.

4.3.5 Display of Saved Information

EUS-1800 A/P has the function of saving and displaying the measuring data. The saved measuring interface and data at the time of measuring can be loaded according to the operator's selection, which is convenient for the observation and analysis. See Figure 4.16.

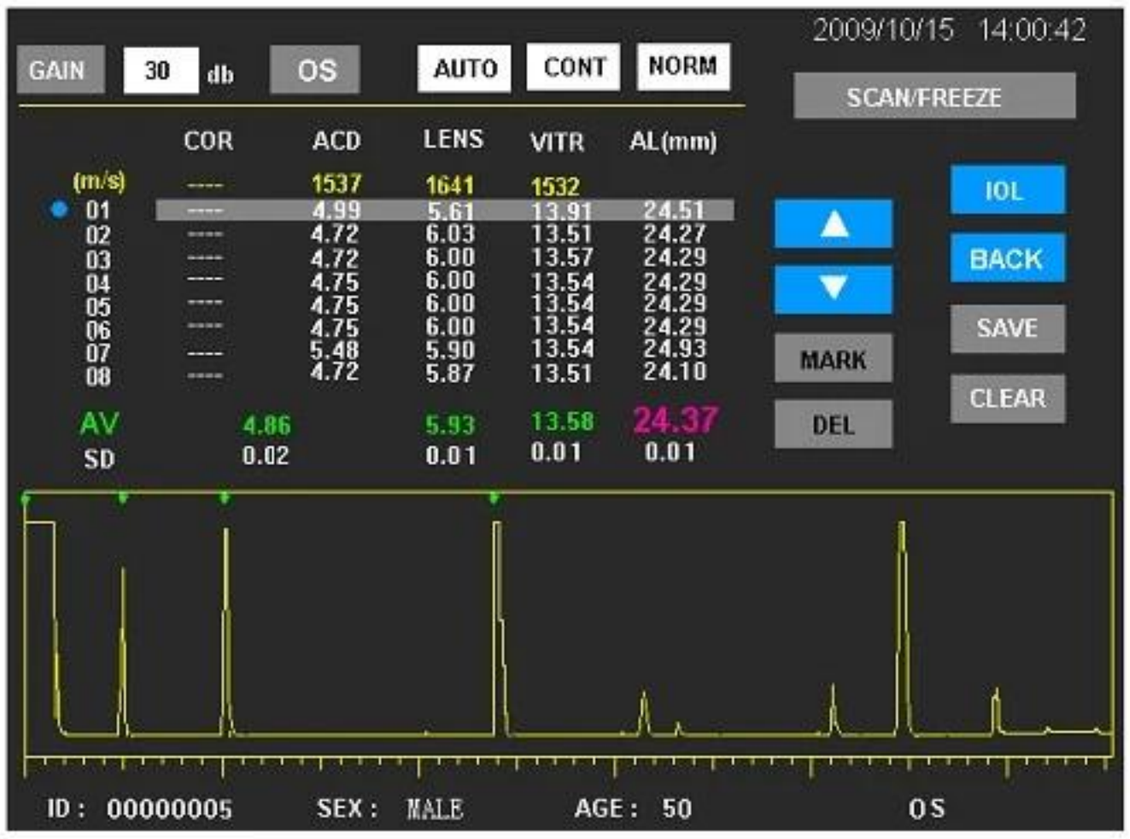


Figure 4.16 Measuring Data Display Interface

The operating method is as follows:

1) Enter into the DATA BASE to check patient information. Click the needed patient information and a blue bar displays indicates that the current item is selected. (See Figure 4.17 in which item 2 is selected.)

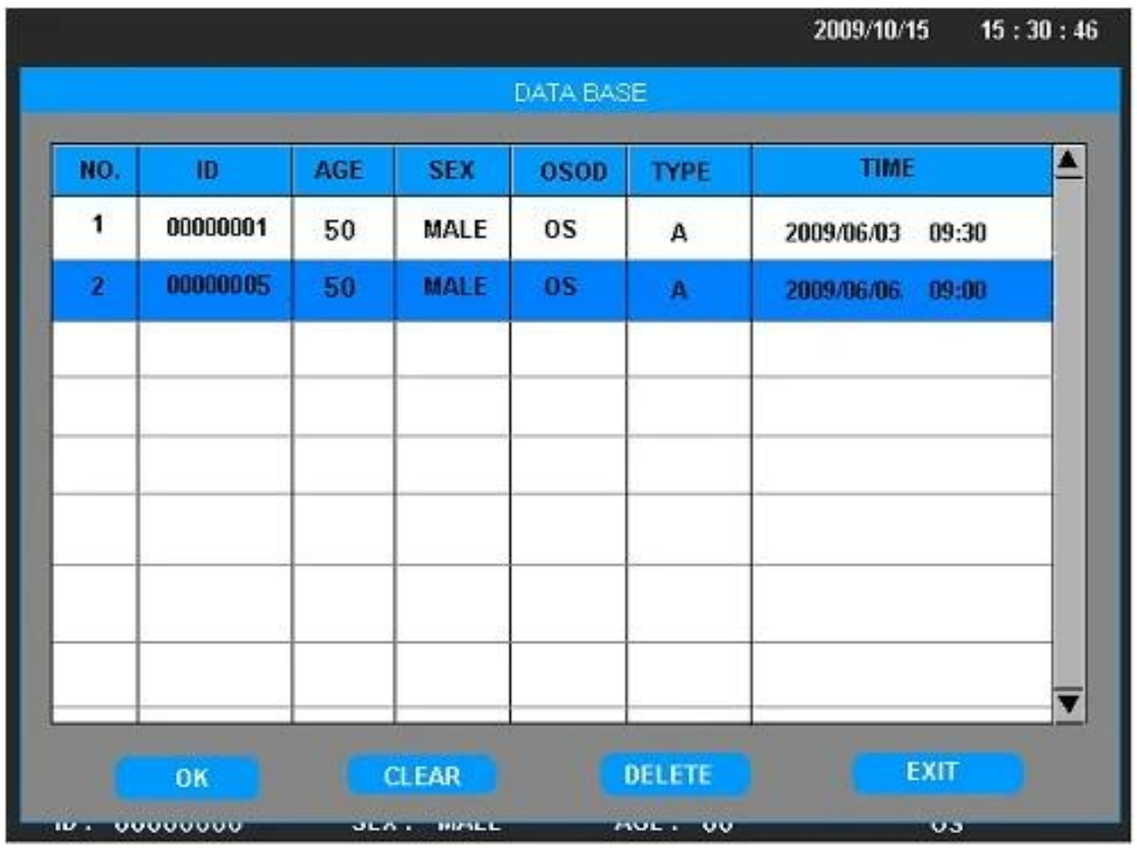


Figure 4.17 DATA BASE-Patient Information Management Interface

2) Click OK to enter Measuring Data Display Interface. If no item is selected, the dialogue box will indicate Nothing Selected. In Measuring Data Display Interface, some function keys under the interface are invalid. The keys turn to grey and there is no response when clicking.

3） Under Measuring Data Display Interface of ASCAN (see Figure 4.16), the data group can be selected and the measuring waveform be displayed by controlling the up and down key. The Measuring Data Display Interface displays the measuring result saved initially but can not make amendment for the saved data and waveforms, and without measuring functions. The threshold value can be observed but not be amended. Under Measuring Data Display Interface, it is able to enter IOL interface from ASCAN interface to check saved data or input

the parameters for recalculation. The new input parameters and calculated result can't be saved. If measurement or storage of new data is required, please return to normal working interface.

To exit from IOL interface, it's required to click ASCAN key to enter the ASCAN interface and click BACK key to return to Patient Information Management Interface; click EXIT key to exit from Measuring Data Display Interface.

Under Measuring Data Display Interface for Pachymetry, Print can be selected to print out the saved data. Other functions are unavailable. The "****" under this interface means there is no data input during measurement. Click BACK key to exit from Measuring Data Display Interface and return to DATA BASE interface.

Under Measuring Data Display Interface, the data can not be processed. If clearance or deletion is required, please exit from this mode and return to DATA BASE interface to clear or delete the selected information.

4.3.6 Amendment and Storage of Parameters, and Clock Setting

In EUS-1800 A/P system, click SETUPkey in the MENU interface to enter parameter setup interface, in which there are five interfaces.

4.3.6.1 Printing Parameter Setup for A-Biometer

Click A_PRINT key to enter A_PRINT interface, as shown in Figure 4.18, which is the interface for ASCAN to set up printing parameters. The operator can choose the information need to be printed out. The default setting is to print out all information, including: patient information, measuring information, calculating parameters, calculating results and output waveforms.

The indicator light indicates the corresponding printing information on the right. Yellow indicates the selected status, while grey indicates the unselected status.

Click the position of indicator light with finger belly to select, the yellow light lights up means that this part is selected to be printed out. Click again to turn off the indicator light, which turned to grey and means the selected part will not be printed out.

About the printing parameter setup of A-Biometer, except for patient information and measuring information, the printing status for other parts can be changed. (The calculating result synchronizes with printing status of calculating parameter, that is to say, both items can be selected to print out or cancel printing synchronously.

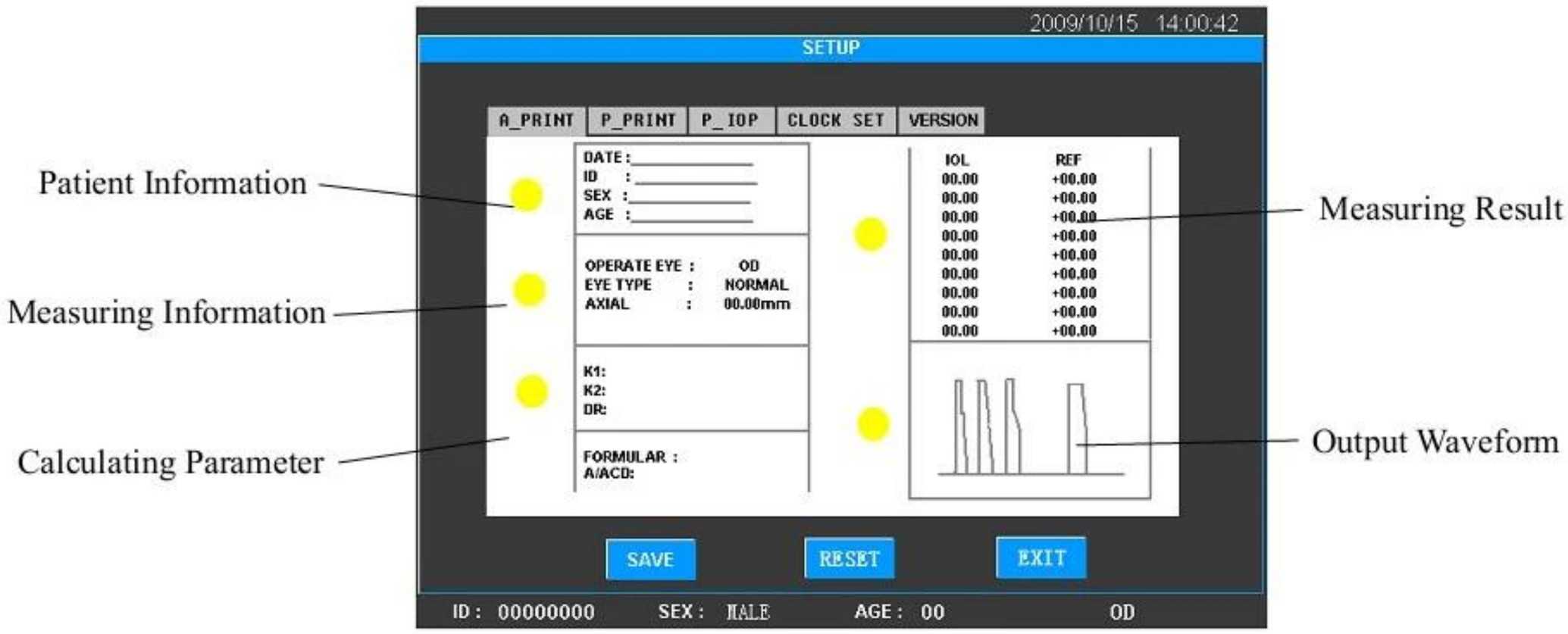


Figure 4.18 A_PRINT Interface

4.3.6.2 Printing Parameter Setup for Pachymeter

Click P_PRINT key to enter P_PRINT interface, which is the interface to set up printing parameters of pachymetry. The default printing information includes: patient information, corneal thickness distribution map and measuring results. The amendment of printing parameter is same with that of A-Biometer. (Patient information is the necessary part for printing; while measuring result and corneal thickness distribution map can be selected to print out one item, or to print out all of them.)

4.3.6.3 IOP Parameter Setup

Click P_IOP key to enter IOP Parameter Setup interface, as shown in Figure 4.19. IOP (Intraocular Pressure) consists of Standard Central Corneal Thickness (Standard CCT) and IOP Coefficient. The deviation of corneal thickness measuring value to the standard CCT can be substituted (added) into the empirical formula and works out the IOP adjusting value (△IOP). The △IOP is only for reference to measure the IOP.

The system's IOP parameter setting is: Standard CCT: 550 μm, and IOP Coefficient: 0.50mmHg/10 μm.

The empirical formula is: △IOP = (Standard CCT – Measuring CCT) × IOP Coefficient

⚠ **Note: Please refer to Annex E, References B**

Experienced doctors may amend the set value of IOP parameter based on the relative research results. Click IOP parameter dialogue box to make amendment, using keypad to input data which can be used only after saving by clicking the SAVE key.

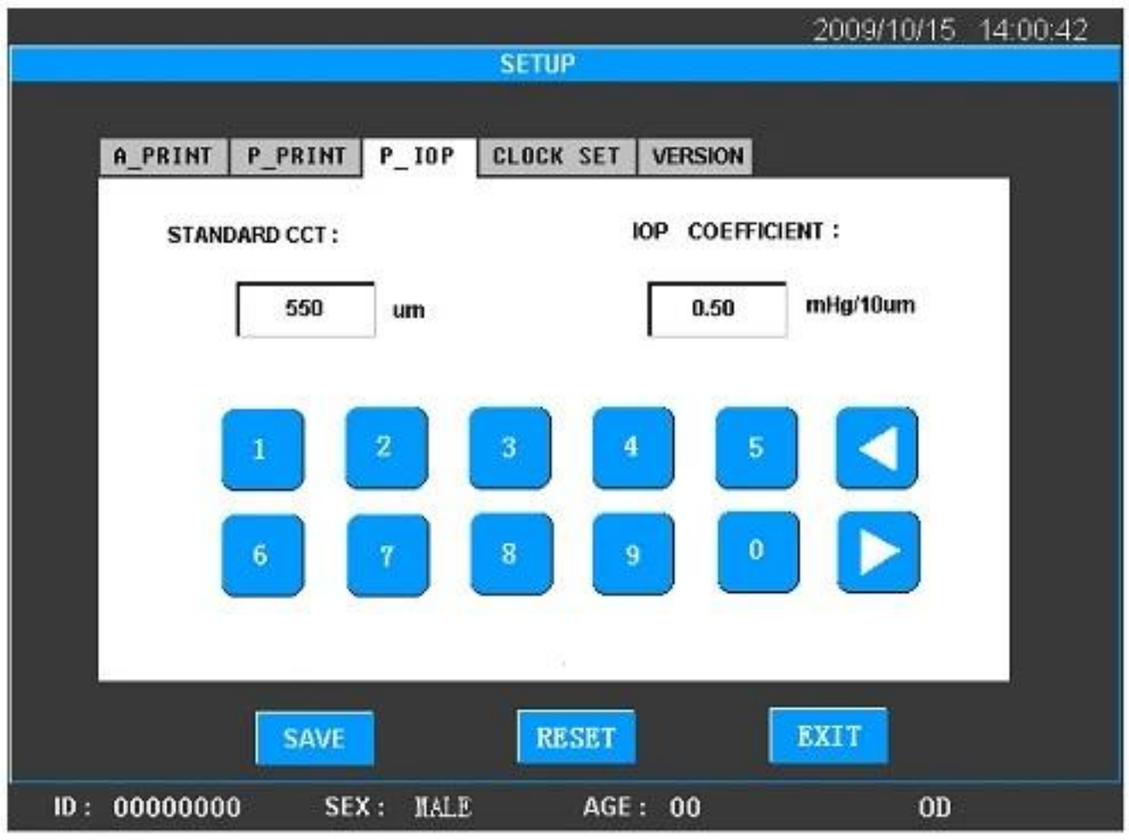


Figure 4.19 IOP Parameter Setup Interface

Complete all amendments mentioned in 4.3.6.1～4.3.6.3 and select SAVE key to save the selected result. Click RESET key to recover the initial values. Click EXIT key to exit from the interface.

⚠ **Note: The functions of SAVE and RESET will save all parameters in A_PRINT, P_PRINT or P_IOP interface, or reset all settings to initial values. Please confirm before the operation.**

4.3.6.4 Clock Setting

If it is required to reset date and time, please click CLOCK SET key in this interface to enter clock set interface, as shown in Figure 4.20, where time is displayed in real-time. Click CLOCK SET key to change the clock setting. At that time, the clock stops, click NEXT key to move the cursor in the text box to the next position successively and circularly until reaching the right position. Input the correct time with the keypad and click SAVE key to store. The amended value appears on the top right corner to display time. Click RESET key to restore to zero. Click EXIT key once to exit from clock editing status; double click EXIT key to exit from the dialogue box.

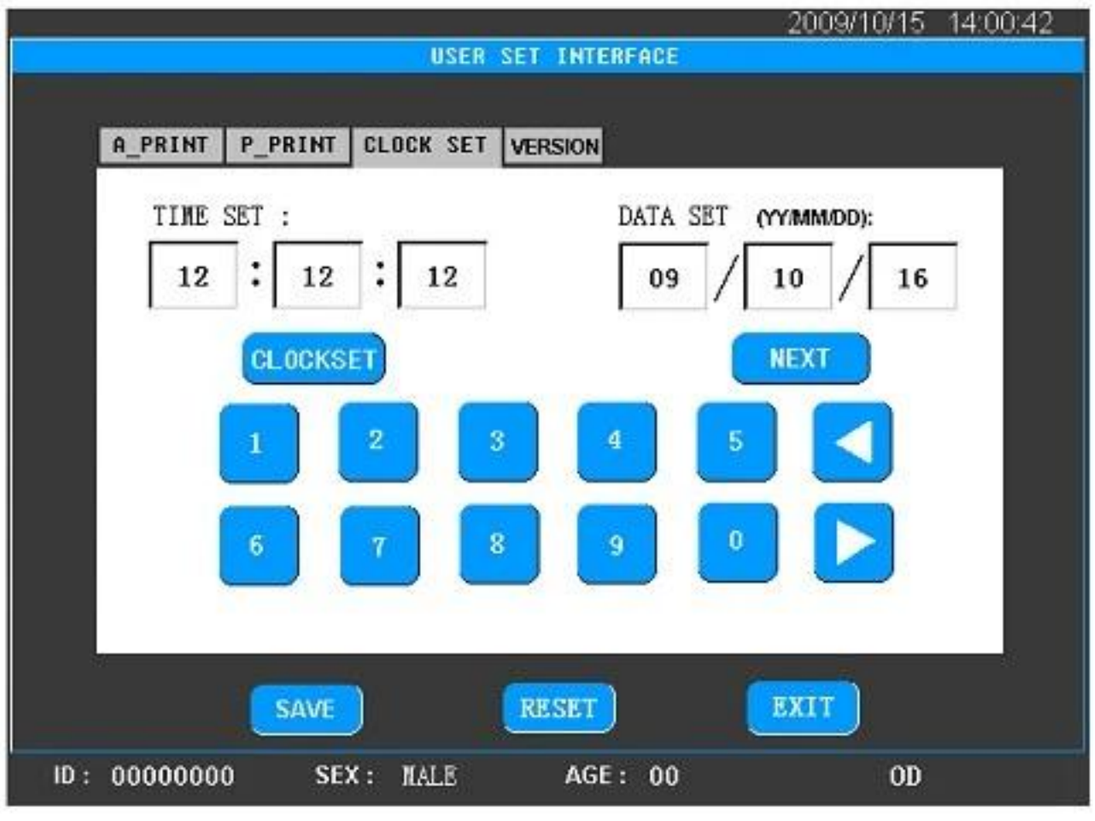


Figure 4.20 CLOCK SET

4.3.6.5 Click VERSION key to display the stated interface, which includes the software version and contact information of the company.

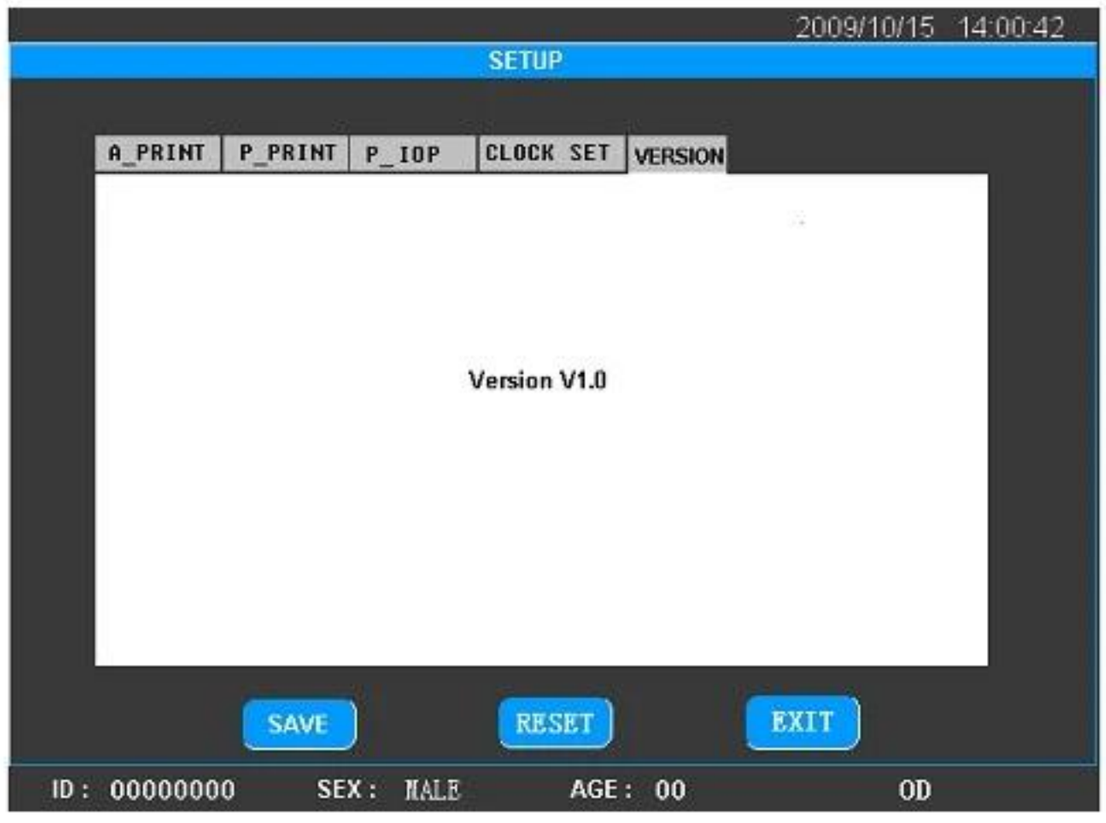


Figure 4.21 VERSION

4.3.7 Data Uploading and Saving

If data uploading software is purchased, please install and operate according to the instruction book of the software.

Chapter 5 Cleaning, Disinfection and Sterilization

5.1 How to prevent Cross-Infection

The surface of the probe must be always clean, which 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 is usually 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 Cleaning, Disinfection of Eye Cup.

The following procedure of disinfection is suggested for the eye cups we provided:

1) Immerse eye cups in the solution of Cidex for about 20 minutes.

2) Take out the eye cups and remove the remains of Cidex with alcohol, and let it dry naturally.

3) Put the disinfected eye cups in a sterilizing tray (or box) for next uses.

5.3 Sterilization Procedure – Pre-sterilization and Sterilization of the Probes

Forward:

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

---- 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-predisinfectant: Aniosyme ® P.L.A. (Company: ANIOS),

  or predisinfectant: 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 changed 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:

★ Please disconnect the probes from the instrument. Please be sure the instrument is TURNED OFF before disconnecting probes.

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

5.4 Preparation of Sterilization Agent

STERILIZATION-PREDISINFECTION

1) Proteolytic enzyme based agents (2 possibilities)

   1-0.5% Alkazyme solution in water (20g sachet)

2) Pour in 1L warm clean water (25-30℃)
3) Put in the unopened sachet.
4) Wait for 1 minute.
5) Pour in 4 L 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:

---- 1-0.5% Aniozyme solution in water (25g sachet):

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

Sterilization Agent

1) ---- 1-0.5% Alkacide solution in water:
2) Pour 5L distilled in flask
3) Pour in the Alkacide
4) Stir it

The Alkacide solution can be used within 8 days if kept in 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 beginning of the afternoon.

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

5.5 Standard Method

NOTES:

★ Please disconnect the probes from the machines. Machines must be turned off first.

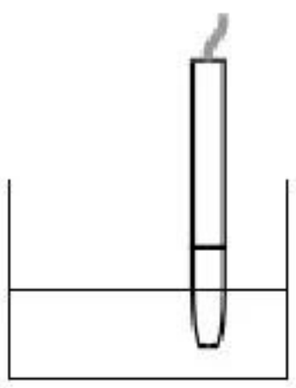
★ Please avoid splashing any liquid onto the electrical connectors.

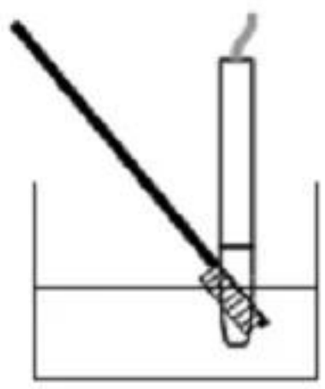
A-Probe

Sterilization

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

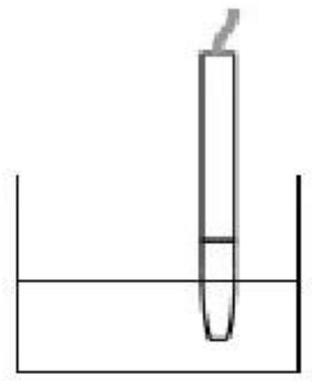
2. Clean the probe and the cable in the solution with the brush for 1 minute.





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

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 connectors dry.



5. Rinsing

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

6. Drying

Dry it with a sterile compress.

7. Now the probe is ready for use.

METHOD FOR HIGH RISK PATIENTS

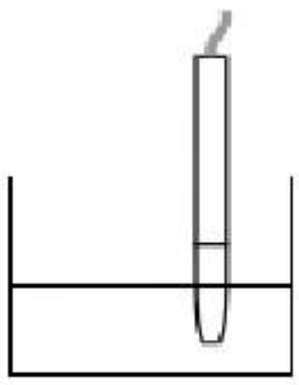
NOTES:

★ Please disconnect the probes from the machines. Machines must be turned off first.

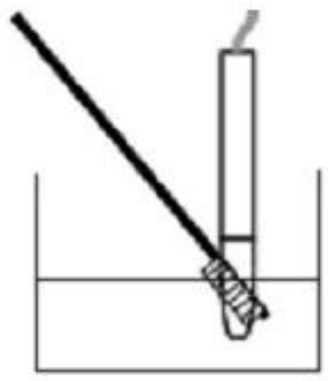
★ Please avoid splashing any liquid onto the electrical connectors.

A) Sterilization & Pre-sterilization

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.

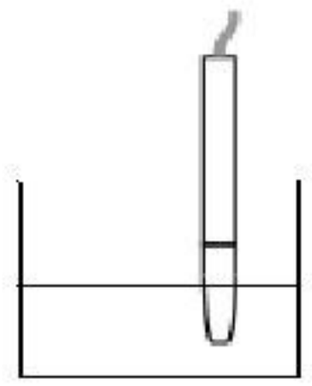


B) Rinsing

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

C) Sterilization

4. Immerse the probe and the cable (except connector) in a 6 chlorometric degree solution hypochloride for 60 min. at 20 ℃ keeping the connectors dry.



D) Rinsing

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

E) Disinfection

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

F) Rinsing

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

G) Drying.

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

9. The probe is ready for use.

Reminder:

- **For P-Probe, please reference the method for A-Probe.**

Chapter 6 Labeling

6.1 External Label

1） Printing Paper Packaging Label

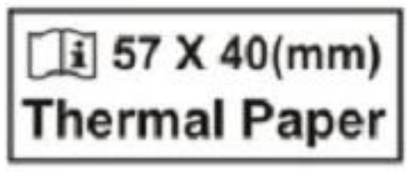


Figure 6.1 Printing Paper Packaging Label

2） Probe Socket Label

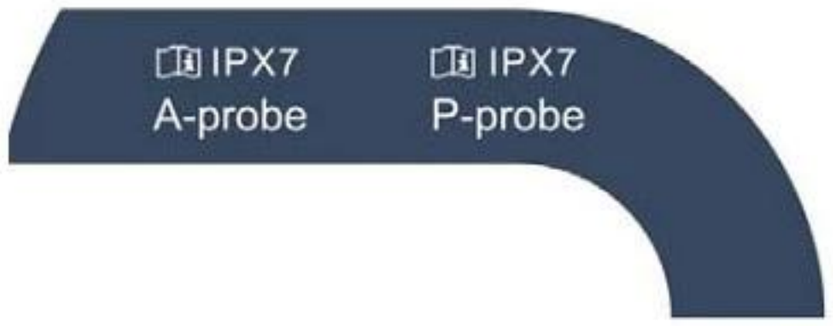


Figure 6.2 Probe Socket Label

6.2 Internal ID

1） Button cell: CR2032/3V, lithium cell

Figure 6.3 ID of Button Cell inside the Main Unit

Chapter 7 Maintenance, Attentions and Simple Defects Treatment

7.1 Maintenance and Attentions to Instrument

1) The instrument should be operated in a clean environment. Air-conditioned environment is recommended.

2) The instrument should be placed on a stable worktable or platform. Avoid direct sunlight.

3) Please use the supplied Power Adaptor which is in accordance with the safety standard of medical electric equipment; do not use other adaptors or adaptors of other equipment with the instrument

4) Although anti-interference measures which are in accordance with IEC 60601-1-2 have been adopted, the instrument should be placed to avoid strong electromagnetic radiation equipment (such as microwave, radio frequency therapy equipment, etc.)

5) Routine inspection and maintenance should be carried out only if the mains power is switched off. None corrosive detergent is allowed to clean the housing. Avoid water and liquid flowing into the housing. Only a mild detergent may be used with soft tissue cloth.

6) In humid area and/or season, if the instrument is not used for a long time, it should be power-on for one hour per month to get the damp out.

7) Avoid drop or severe shock when moving the instrument. Give particular attention to protect the probe.

8) Do not block the ventilation window of the instrument. When the temperature of the instrument is not normal, please contact the manufacturer for service.

9) The instrument should always be placed in a secure location to prevent probe falling damages.

10) The instrument has no special protective measures for discharge effect of cardiac defibrillators; it is not suitable for use with high-frequency surgical equipment

11) Please follow the relative provisions of the local environment protection when the instrument is abandoned. Same way can be taken with the electronic devices (computers, etc).

7.2 Maintenance and Attentions to Probe

1) Do not autoclave the probes.

2) Don't wind the probe cable in coil less than 9 cm (3.5 inches); Check the probe cable regularly and stop using immediately if it is damaged or broken, contacting the manufacturer or the

local distributor for service.

3) Probe should be handled gently to avoid collision and drop, in order to prevent break and damage.

4) Avoid drop or scratch of the surface of probe when the probe is used or moved; make sure the probe is removed from the main unit and put into the packing bag during transportation.

5) If the probe drops during using or moving, check the top and the housing of probe carefully, and then check if it works well. Stop using if there is any problem and contact the manufacturer or local distributor for service.

6) The whole probe cable including the cable plug is prohibited to be immersed into water or other liquid.

7) The connection and/or disconnection of probe should be done only if the system is powered off. While plugging in the probe, make sure the red mark on the probe align with that on the socket. Hold the probe plug and don't plug probe cable while plugging off the probe.

8) If the dialogue box on the screen prompts “PLEASE CHECK THE PROBE!”. It indicates the probe connection is abnormal, click "OK" to close the dialogue box and check if the probe is well connected.

9) The probes provided with the instrument should be used in the instrument only and not be used for other purposes.

7.3 Maintenance of LCD Screen

1) Clean the LCD screen with glasses cloth, lens tissue or other soft material.

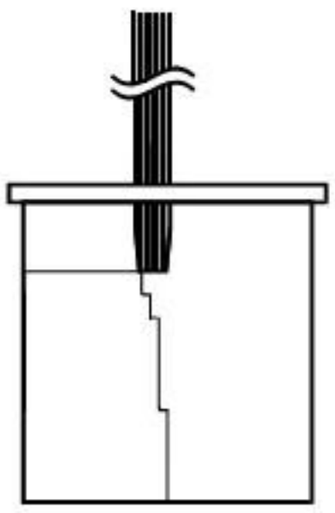
2) Don't touch the LCD screen with hard object, which will cause irreparable damage to the screen.

3) Avoid strong shock and vibration during transportation.

4) Complete the touch-screen operation with finger belly.

7.4 Check before Use

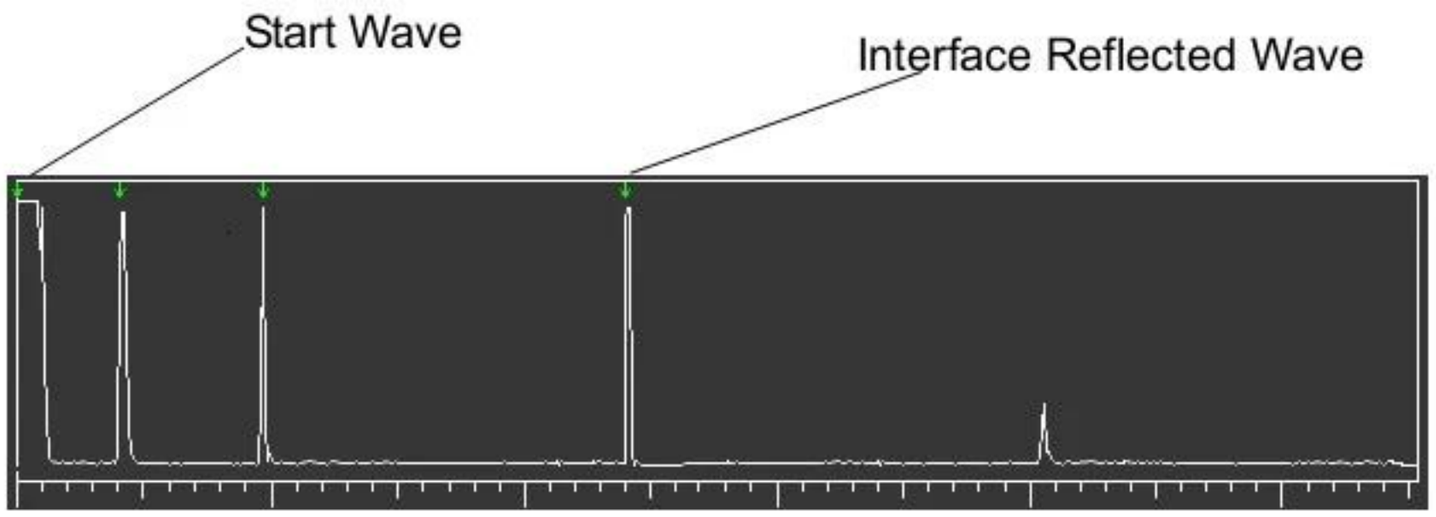
Biometric Measuring function



There is a test tank with each EUS-1800 A/P which imitates four acoustical reflect interfaces of human eyes and used to test the biometric measuring.

Fill the tank with distilled water. Be sure that there is no air bubbles in the water. Operate according to automatic biometry. Gently put the A probe onto the highest stage perpendicularly into the tank (see left drawing).

Click SCAN/FREEZE key under ASCAN interface, the automatic measuring result to ladder target will be achieved, as shown below:



Keep the probe unmovable; click SCAN/FREEZE key to repeat measuring. If the results show good repeatability, it indicates the biometry mode of the equipment works well.

7.5 Trouble Shooting

1) In case of the connection failure, please check first if the power supply and probe are well connected.

2) In case of printing failure, please check first if it is out of printing paper or paper jam.

3) In case of clock failure which can not be restored by restarting, possibly, the clock battery is used up. The battery can't be replaced by operator, please contact your distributor for repair.

4) In case of display or operation failure, please switch off the power and restart, check if it is back to normal.

5) In case of overheat or other abnormalities, please switch off the mains power immediately to prevent danger.

6) The over-current protection fuse is sealed inside the power adaptor and can't be replaced by user. If the power adaptor has no DC output, please pull out the main power plug and contact the manufacturer for repair.

If above operation is not effective, please don't open the housing without authorization. Contact your local distributor immediately. Explain the problems in detail for proper and in time support.

If required, we can provide the complete maintenance and repair manual to the authorized qualified engineers of service stations.

The Biometer is a high-tech product designed and built with high level of precision. Only qualified trained engineers are authorized to repair the instrument.

We are not responsible for problems caused by any kind of unauthorized repair.

Chapter 8 Service and Support Information

8.1 Warranty

1) The product has a warranty of one year from the date of purchasing, on the premise of using in accordance with the Operation Manual.

2) If the device does not work properly, please contact your local distributor or the manufacturer immediately.

3) Following repairs will be charged within warranty period:

- Problems caused by man-made damages;
- Damages caused by unauthorized repair;
- Damages caused by inappropriate operation.

4) We provide continuous maintenance and repair after warranty period with certain charges.

8.2 Accessories and Materials

8.2.1 Consumables

SN	Description	Manufacturer	Model	Specification
1	Printing Paper	Beijing Xun Pu Electronic Technology Company	——	57mm×40mm Thermal Printing Paper

8.2.2 Detachable Parts

SN	Description	Model	Specification
1	A Probe	Prb1000A/10-C	10MHz
2	P Probe	Prb1000P	15MHz~20MHz
3	Power Adaptor	HES49-12040	12V/4A
4	Foot Switch	MD-65	——

8.2.3 Materials

Material of Housing	Model
Flame Retardant ABS Engineering Plastic（not less than FV-2）	MCN-6000

⚠ **Note: 1) The probes, power adaptor and foot switch used in the system must be provided by our company.**

2) The consumables used in the system must be product (with specification) designated by our company.

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 Principle of ALARA（As Low As Reasonably Achievable）

The principle of ALARA 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 or weak Doppler signal 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 the principle of ALARA.

Annex B Guidance and Manufacturer's Declaration

Annex C Prompt Message

1. **System start up prompt:** Switch on the system, it will read parameter and self-check, displaying "THE SYSTEM IS CHECKING …PLEASE WAIT…". After checking, it will enter normal interface.

2. **Probe checking prompt:** If probe is not connected, the system will prompt automatically when scanning. The dialogue box will display "PLEASE CHECK THE PROBE!" reminding you to check the probe connection.

3. **Nothing Selected prompt:** If the operation is wrong and unable to select the correct item, the dialogue box will prompt "PLEASE SELECT AN ITEM!", or "NO DATA!", indicating that no correct item is selected.

4. **Confirming prompt for deleting or saving:** When deleting some item or saving the result of a patient's case, the dialogue box will pop up. "ARE YOU SURE TO DELETE? ' prompts to confirm deletion or not. "ARE YOU SURE TO CLEAR ALL THE DATA PERMANENTLY?" "ARE YOU SURE TO DELETE THE ITEM PERMANENTLY?"prompts the deleted data are not recoverable and whether to continue the deletion. "ARE YOU SURE TO SAVE?" prompts to confirm saving or not.

5. **Whistle prompt:**

   a) Three short beeps of buzzer "beep - beep - beep" prompt measurement failed.

   For A Biometer, please check if measurement is performed for eight groups of data.

   For Pachymeter, three short beeps prompt that proper measuring data are not found.

   b) A long beep of buzzer "beep-" prompts measurement completed.

   Under automatic measuring status for A Biometer, it prompts the measurement for eight groups of data have been completed.

   For Pachymeter, it prompts proper data have been found within measuring time.

   c) A short beep of buzzer "beep" prompts single measurement completed.

   Under automatic measuring status for A Biometer, there will be a short beep each time when proper data have been acquired, then the data will display in the corresponding group of cursor.

Annex D The Acoustic Output Parameters

Probe Model：Prb1000A/10-C　　Operating Mode：A Mode

Index Label			MI	TIS			TIB	TIS
				scan	Non-scan		Non-scan	
					A_{aprt}≤1cm^2	A_{aprt}≥1cm^2		
Global Maximum Index Value			0.08	-	-	-	-	-
Associated Acoustic Parameter	P_{ra}	MPa	0.24					
	P	mW		-	-		-	-
	Min. of P_α(ZS), $I_{ta,\alpha}$(ZS)	mW				-		
	Zs	cm				-		
	Z_{bp}	cm				-		
	Z_b	cm					-	
	Z at max. $I_{pi,\alpha}$	cm	3.15					
	d_{eq}	cm					-	
	f_{awf}	MHz	9.21	-	-	-	-	-
	Dim of A_{aprt} X	cm		-	-	-	-	-
	Dim of A_{aprt} Y	cm		-	-	-	-	-
Other Information	t_d	μsec	0.141					
	p_{rt}	Hz	9.54					
	p_r at max. I_{pi}	MPa	0.67					
	d_{eq} at max. I_{pi}	cm					-	
	$I_{pa,\alpha}$@MI_{max}	W/cm^2	2.73					
Operating Control Conditions	Frequency Setting（MHz）			-	-	-	-	-

Annex E IOL Formula

Six formulae are used in **EUS-1800 A/P** they are:

SRK-II

SRK-T

BINKHOST-II

HOLLADAY

HOFFER-Q

HAIGIS

Please refer to **REFERENCES A** for further information.

REFERENCES A:

HAIGIS W: Biometrie, in: Augenärztliche Untersuchungsmethoden, Straub W, Kroll P, Küchle HJ (Hrsg), F.Enke Verlag Stuttgart, 255-304, 1995

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RETZLAFF J, SANDERS DR, KRAFF MC: Development of the SRK/T intraocular lens implant power calculation formula. J Cataract Refract Surg 16 (3):333-340, 1990

SANDERS DR, KRAFF MC: Improvement of intraocular lens power calculation using empirical data, Am Intra-Ocular Implant Soc J 6: 263-267, 1980

SANDERS DR, RETZLAFF J, KRAFF MC: Comparison of the SRK II formula and other second generation formulas. J Cataract Refract Surg 14: 136-141, 1988

HOFFER KJ: The effect of axial length on posterior chamber lens and posterior capsule position. Current Concepts Ophthalmic Surg, 1:20-22, 1984

HOLLADAY JT, PRAGER TC, CHANDLER TY, MUSGROVE KH, LEWIS JW, RUIZ RS: A three-part system for refining intraocular lens power calculations. J Cataract Refract Surg, 14:17-24, 1988

REFERENCES B:

Sunil Shah, FRCS(ED) , FRCOphth. Accurate intraocular pressure mea-sure-ment-the myth of modern ophthalmology? Ophthalmology, 2000，107:1805-1807.

EUS-1800 A/P BIOMETER

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