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EC	REP
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Chapter 2 EMC Declaration

We Herewith Declare The SW-1000 Ophthalmic A Scan Conformity National Law ,The Provisions of Council Directive 93/42/EEC OF 14 June 1993 Concerning Medical Devices – AS Amended By Directive 98/79/EC On In Vitro Diagnostic Medical Devices .

ISO13485:2003 ; IEC 60601-1:1988+A1:1991+A2:1995 ; IEC60601-1-2:2001+A1:2004 ; IEC 60601-2-37:2001+A2:2005 ; IEC 60601-1-4:AMD1_1999 ; IEC 60601-1-6:2006 ; IEC 61157:1992 ; EN ISO 14971:2007 ; EN ISO 14155-1-2:2003 ; EN ISO 100993-1:2003 ; EN ISO 100993-5:1999 ; EN ISO 100993-10:2006 ; EN 980:2008 ; EN 1041:1998

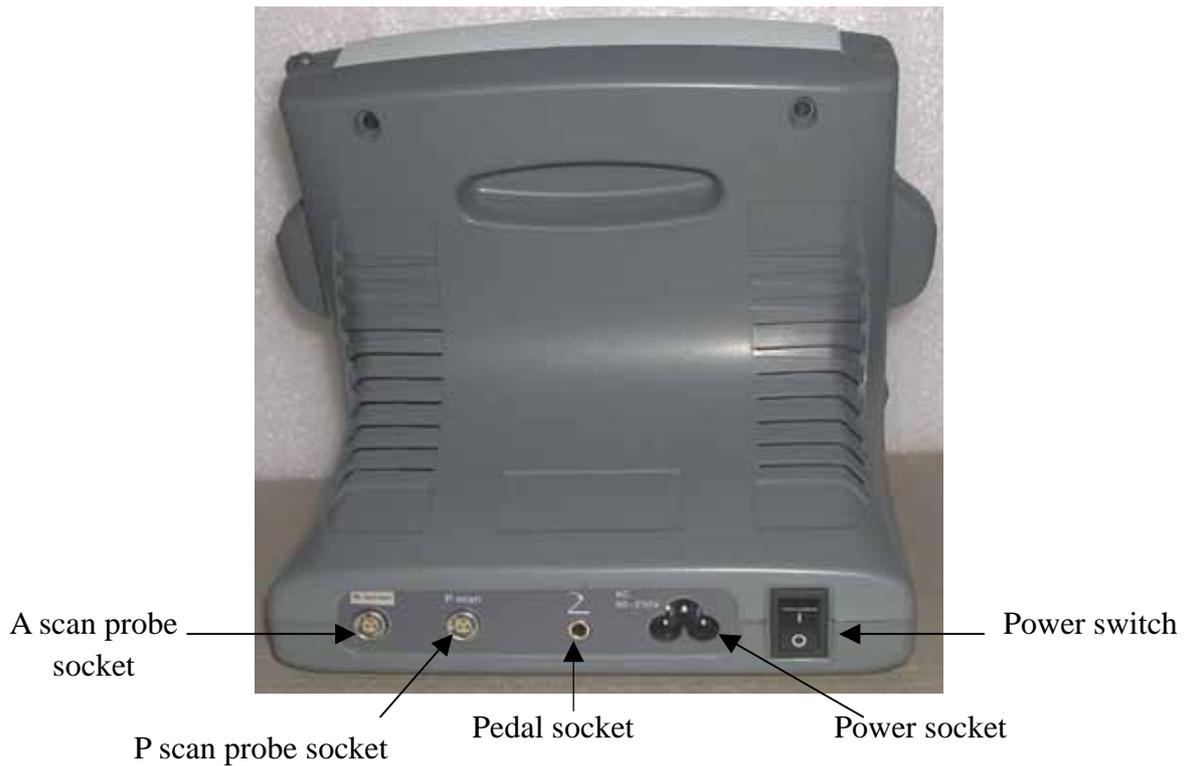
Chapter 3 Characteristics and Parameter

- A scan probe: 8MHz import solid probe, compact and built-in luminotron;
- A scan precision: $\pm 0.1\text{mm}$;
- Eye mode: Normal/ Aphakic/Dense/PMMA/Silicone/Acrylic;
- A scan IOL formula : SRK-II、SRK-T、BINKHORST- 、HOLLADAY、HOFFER-Q、HAIGIS-STD;
- Each ID can have the data of 5 scans, and 10 IDs can be saved;
- Measurement: Anterior chamber, lens, vitreous body and total length;
- Curve freezing: Manual/Auto mode, controlled by pedal.
- P scan probe: 20MHZ, angle of 45 degrees makes easier operation;
- P scan precision: $\pm 0.01\text{mm}$;
- Measuring range: 0.3mm~~1.2mm;
- Each ID can save 10 groups of data, and each group is the average of 20 measures;

- ID could be input and easy to check;
- Output: Thermal printer;
- Indication: Big size chromatic LCD;
- Input: Touch screen;
- Gain adjusting: 0-127db;Voltage
- Power Supply: AC100—240V 50/60Hz;
- Power: 60VA;
- Test results comply with **IEC 60601-1:1988 + A1: 1991 + A2: 1995 Class I Type B**;
- Size: 200 × 180 × 180 (mm) ;
- Weight: 3Kg.

Chapter 4 Instrument Components





<p>Pedal (Foot Switch)</p>	<p>A Scan Probe</p>
<p>P Scan Probe</p>	

💡 This type of unit contains two Fuses.

Specification of Fuses: **F1.5A250Vφ5×20mm.**

➡ Only the manufacturer or the professional electric engineer sent by manufacturer has an access to replace the Fuses..

➡ The replacement of Fuses operated by manufacturer must be under the superintendence of the professional electric engineer.

Chapter 5 Theory and Function

Ophthalmic A scan SW-1000 is composed of main unit, A scan probe, P scan probe, pedal and so on. The A scan probe contacts the cornea and sends out ultrasound of 8MHz. The echo wave from front surface, back surface of lens and retina is respectively detected. The signal is processed and then we get the depth of chamber, thick of lens and axial length. The data are transmitted to MP (Micro processor). The values of A constant and K1, K2 are input from keyboard. The MP automatically calculates the IOL according to the chosen formula (Default formula is SRK-II), data and values of A constant and K1, K2. The data of IOL are displayed on the color LCD screen through output interface, or stored in the machine, or printed out.

This A scan is designed for detecting axial length, depth of anterior chamber, thickness of lens and calculating the IOL. It has high resolution and is easy to operate, with the function of auto-calculating IOL and touch screen input. Six groups of formula could be chosen: SKR- 、SKR-T、BINKHORST- 、HOLLADAY、HOFFER-Q HAIGIS-STD. It has manual and auto measure mode. The build-in printer could print the data and IOL table.

The P scan probe contacts the cornea and sends out ultrasound of 20MHz. The echo waves from front and back surface of cornea are detected. The signal is processed and then we get the thickness of the cornea. The data are displayed on the color LCD screen through output interface, or stored in the machine, or printed out.

This P scan is designed for detecting thickness of cornea, which is easy to operate. It can continuously take measure in the same spot or different spots and calculate the average. The P scan is widely used in the examination before the refraction correcting operations, and the evaluation of the operation. It is featured with high precision, touch screen input, easy operation. The built-in thermal printer could print the report at any time.

Chapter 6 Field Of Application

This production is a precise ultrasonic biometer for ophthalmology. The A scan is designed for detecting axial length, depth of anterior chamber, thickness of lens and calculating the IOL. The P scan is designed for detecting thickness of cornea.

Chapter 7 Contraindications

1. Infective eye disease, such as Keratitis and so on.
2. Open eye damage, such as avulsion or perforation of cornea

3. Children under 5 years old that could not cooperate with the examination.

Chapter 8 Precaution

-  This instrument requires the power supply of **AC100—240V 50/60Hz**. The power socket indoors should have **ground line**. If the local power net could not fit the requirement, then we recommend you to use regulated power supply.
-  Improper power supply may cause instrument damage or person injury.
-  In order to determine whether the product to measure precisely, product shall run calibration test with belonging A scan and P scan calibration every week or after product through long-distance transportation.
-  All the **accessories** should be well kept. If anything is missing, the instrument could not be warranted.
-  The instrument should be installed indoors with good ventilation and avoid direct sun radiation.
-  Kept the instrument away from strong magnetic or electric field or other strong disturbance sources. The instrument does not allow operating with high frequency equipment.
-  The **probe** used for different type of unit is not available. Only the **accessories** manufactured by SUOWEI Company are approved and under warranty.
-  The **probe** is key, delicate and expensive. Do not stress it, knock it or fall it from high place. Don't dip it into alcohol to perform disinfections. Don't twist or pull the leading line violently.
-  The operational life of **A scan probe** and **P scan probe** supplied by SUOWEI Company is 8 years.
-  Align the salient on the **probe** connector to the gap on the probe socket, and plug it in. When you hear "click", the **probe** is ready. The **probe** must be treated gently following the steps above; otherwise it may be damaged by improper operation.
-  The instrument should be made security test when it has been used 5 years. E.g. leakage currents test under normal operational condition.
-  It is not permitted that user himself disassembles the **main unit** or **probe**. If there are any problems, please send it to the warranty station.
-  The warranty station near user's location executes the maintenance of **printer**. We

recommend you to send the **printer** to warranty station periodically. That will make the **printer** last longer.

 When the ambient temperature is under 10 °C, the instrument should warm up for 5 minutes before it begins to work.

 The treatments of discarding when a unit is over operational life:

1. Suoer company reclaim the discarded unit ;
2. The discarded unit should process discarding treatment in accordance with the local corresponding law.

 The surface temperature of transducer assembly can exceed 41 °C.

 **As to the safety and effective result caused by ignoring the declaration above, our company does not take the responsibility.**

Chapter 9 Safety Classification

 Test results comply with **IEC 60601-1:1988 + A1: 1991 + A2: 1995 Class I Type B.**

 Waterproof Classification of Probe: **IPX4**
 Waterproof Classification of Pedal (Foot Switch): **IPX1**

Chapter 10 Symbol

IPX1	Protected from drop
IPX4	Protected from splash
	Protective grounding
	TYPE B
	Warning, May cause hurt or damage
	Attention May do harm to machine and accessories
	Hint, how to use it better
	High voltage! Danger!
CE 0123	CE Approval

Chapter 11 Environment Requirement

1 Work Environment

- Ambient temperature : +10 ~ +40 ;
- Relative moisture : 80%;
- Power Supply : AC100—240V 50/60Hz;
- Power: 60VA;
- Atmosphere pressure : 700hPa~1060hPa;
- Keep away from strong magnetic or electronic field;
- Warm-up time : 3-5min.

2 Transport and Storage

- Ambient temperature : -40 ~ +55
- Relative moisture : 95% ;
- Atmosphere pressure : 500hPa~1060hPa

Chapter 12 Install and Connection

1. Check the package to see if anything missing.
2. Plug the probes, foot switch and power line in corresponding sockets.

 Align the salient on the probe connector to the gap on the probe socket, and plug it in. When you hear “click”, the probe is ready. The probe must be treated gently following the steps above; otherwise it may be damaged by improper operation. (See the Pic.3)



Pic.3 Plug and pull the probe

 The probe must be connected before power on. Don't plug or pull the probe when power is on.

 Pedal (Foot switch) is to freeze and unfreeze the images manually. Put the pedal (foot switch) at handy place. Gently step once and it will be ok. Don't use too much strength or not let it go.

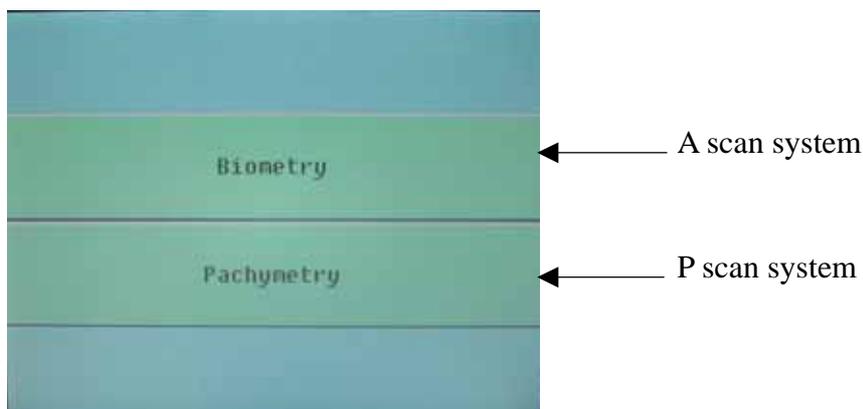
3. After all the parts have been connected, switch on the power. After a beep, the

machine automatically enters the measure mode.

- Do not turn on and turn off the power too swiftly. Otherwise random pictures will appear on the screen.

Chapter 13 Option of A scan and P scan

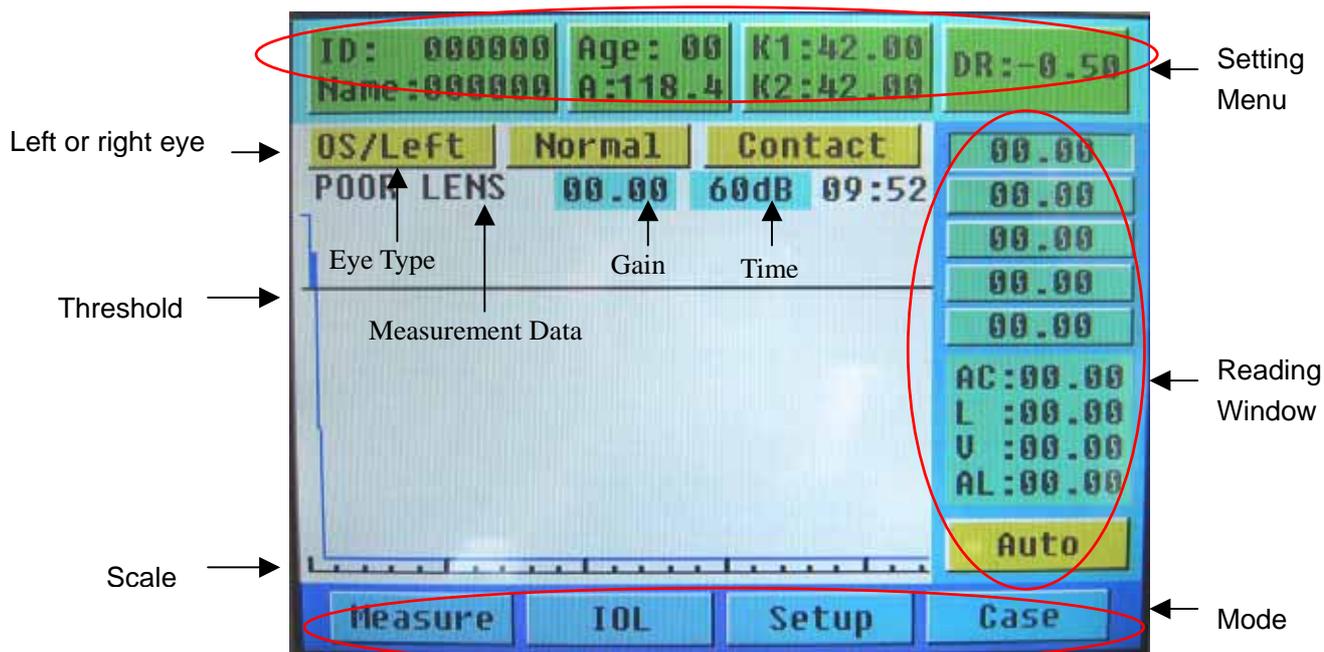
You will enter an option interface to choose systems after switch on the unit. You can press the icon of Biometry to operate A scan system; or you can press the icon of Pachymetry to operate P scan system. Two systems are working independently. To change other system, you need to switch off the unit and switch it on again. See the Pic.4 below:



Pic.4 Option interface

Chapter 14 The Interface and Setting Of A Scan

1 Interface Introduction



Pic.5 Measuring Interface

After switch on, the modes of **“Measure”** and **“Contact”** is default. See Pic.5. You can press the icon **“Contact”** to switch to **“Immersion”**.

1.1 On the upper part is the setting menu. Press the items to begin setting up data.

K1 : Horizontal diopter (auto stored after each input)	K2 : Vertical diopter (auto stored after each input)
DR* : The recover degree after the operation, set according to doctor's experience.	A : Constant A (auto stored after each input)

*: DR = 1.00 means the eyesight is expected to recover to 100 farsighted ; while DR = -1.00 means the recovery eyesight is expected to be 100 nearsighted, etc.

1.2 On the right is reading window displaying the result of measurement.

Readings : It shows each measuring data of eye axial length. 5 groups can be displayed.

AC : Depth of anterior chamber	L : Thickness of Lens
V : Thickness of vitreous body	AL : Eye axial length

1.3 On the lower part is the **Mode** menu. It shows the mode that is working with.

Measure : Perform A scan measure	IOL : IOL calculating displaying
Setup: Set up the time and velocity of ultrasound	Case : Show stored cases
Auto: Auto measuring mode; Press “Auto” to switch to “Manual”	

1.4 On the middle is the main window displays the A scan curve, scale, threshold, left/right eye setting, eye type setting and average of 5 scan

2 Setting

Input ID and Setting Parameters

Press **“ID”** in the setting menu. The interface will change into **“key in”** mode. (See pic.6) And the numbers begin to blink.

Press the number keys on the screen by touch pen to input ID. It is the same way to set AGE, A, K1,



Pic.6 Setting input

K2 and DR. If you want to set the name of patient, press **“Enter”** and the letter input interface will appear. Press the **Caps** and **Shift** can switch capital to lowercase.

➡ The touch screen is very sensitive. In order to prevent damage of touch screen, don't press it with much strength.

💡 If you want to re-enter the items, press other item or press **“Enter”**, then press the item you want to correct. Now you can reset the item. Use **Caps** and **Shift** to change between Capitalization and lowercase.

Eye mode

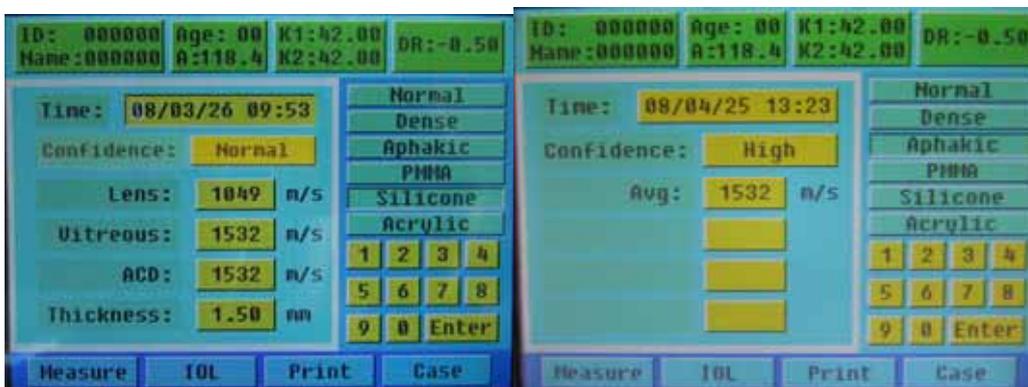
Press **“Normal”** in setting menu , and it will switch among different eye types.

Left/right eye setting

Press **“OD/right”** in main window , it will switch between **“OS/left”** and **“OD/right”**.

💡 The parameters could be input only in measure mode.

Press **“Setup”** in the main window.



Pic.7 Time& velocity setting

3 Time Setting

Press the icon of **“Time”** to re-set time via small keyboard at the right side of screen.

4 Precision Setting

Press the icon at the right side of **“Confidence”** to set confidence.

Normal & High: It's easier to take a reading under **“Normal”**, but with less precision, **“High”** can get more precise reading, but more difficult.

5 Velocity Setting

Use small keyboard to set up velocity. The data of each velocity is default. See the chart below:



AVG only can be used under eye mode APHAKIC.



Thickness only used under eye mode PMMA, SILICONE, and ACEYLIC.

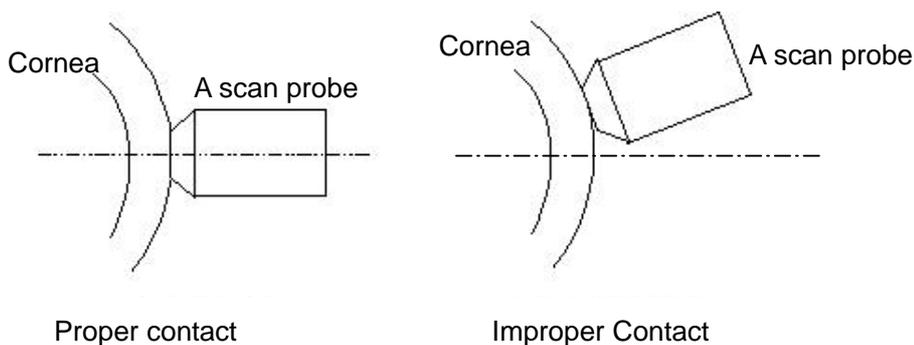
	LENS	VITREOUS	ACD	THICKNESS	AVG
NORMAL	1641	1532	1532		
DENSE	1629	1532	1532		
APHAKIC					1532
PMMA	2718	1532	1532	0.8	
SILICONE	1049	1532	1532	1.5	
ACRYLIC	2200	1532	1532	0.9	

6 Measure

- The surface of the A scan probe contacting the cornea should be sterilized by alcohol tampon before measurement. The probe can be used only after the alcohol has completely evaporated. Don't dip the A scan probe into the alcohol too long to perform disinfections.
- Let the patient lie in supine posture on the bed. Perform the anaesthesia of the cornea.

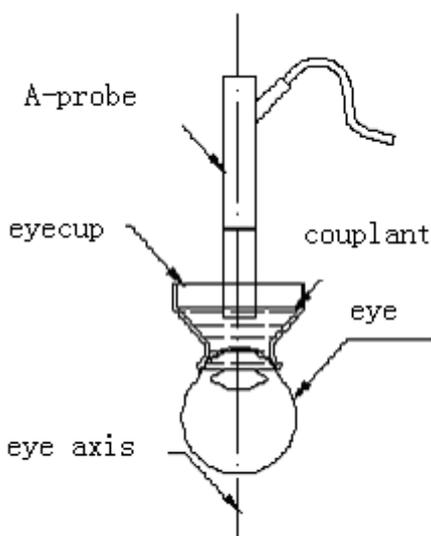
Contact

Make the transducer perpendicular to the center of the cornea and make them contact properly.



Immersion

1. In order to release the pain in the eye, the cornea needs anaesthesia.
2. Choose suitable size of eyecup.
3. Open patient's eyelid, first let patient move his/her sight down and put eyecup into upper eyelid; then let patient move his/her sight up and put eyecup into nether eyelid. Carefully and slowly adjust the position of eyecup until it is completely placed inside the eyelid.
4. Use suitable media for ultrasound transfer. Cause the eyecup contacts patient's eye directly, the media should be low acoustic impedance and can comfort patient (i.e. saline etc.). Some medias, which are used in B scan measurement, are not usable here.



Water bath method example

Auto Mode

- Click “**Measure**” below after setting the parameters to choose measure mode. When “**Auto**” is displayed on the lower-right corner of the screen, it shows that it is under “**Auto**” mode. (See pic.8)
- Make preparation as above-mentioned. The instrument will catch and freeze the waveform



Pic.8 Auto mode

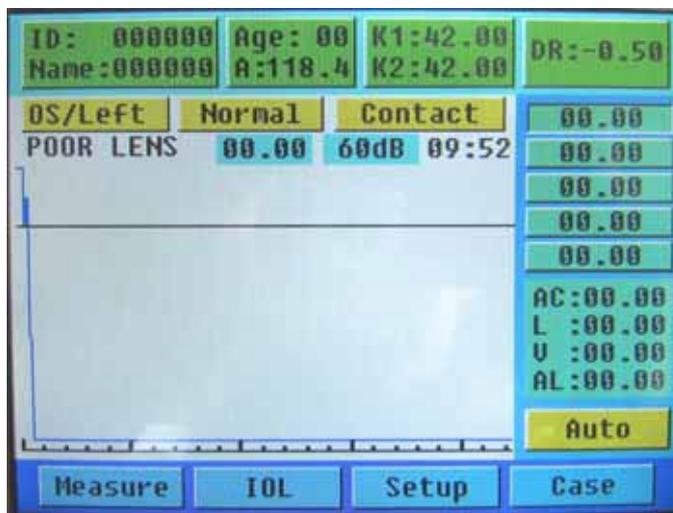
automatically, and beep to indicate the completion of a measure. 5 readings can be listed continuously. 5 AL (axial length) readings are listed on the right side of the screen. The average of these readings will be shown on the screen.

- After the auto measure is finished, you can click the **“AL”** readings by touch pen, and corresponding measure curves will appear on the main window. Choose the inaccurate reading by touch pen under freezing status, step pedal to unfreeze and enter the measure mode. Now you can measure again. In the main window will display the average after the re-measuring.

💡 If it was difficult to get the waveform or there were too many disturbing waves, you can adjust the gain by the gain tuner. The present gain value will appear in the main window. The gain value set in each measure will be saved automatically for the convenience of next measure.

Manual Mode

- In measure mode, press the **“Auto”** to switch to manual mode. And **“Manual”** will be shown on the screen. (See pic.9)

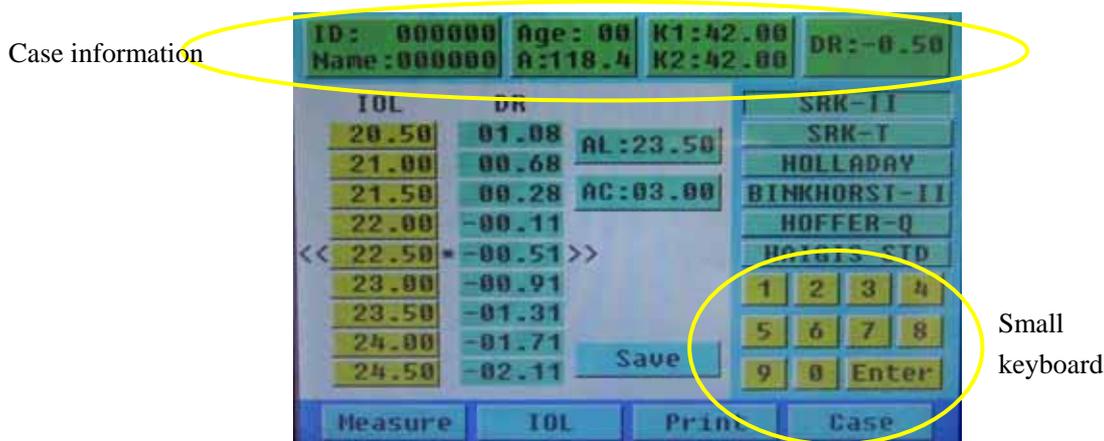


Pic.9 Manual Mode

- Preparations before measurement are the same as **“Auto”** mode. Put the probe perpendicular to the center of patient’s cornea. Observe the pulse waves and adjust the gain to make the waveform have four normal pulses. When the correct waveform appears, step pedal to freeze it.

💡 **AUTO** mode is the default mode

IOL Calculation



Pic.10 IOL calculation

After the measure is finished, press **IOL** to enter the IOL calculation mode. (see pic.10)

The calculation result is auto displayed on the main window. The value between the * is most close to the DR setting value.

Click **AC** on the left upper part, use small keyboard to revise the value. It can be used only in the formula **HAIGIS-STD**.

Click the formula by touch pen to apply it. And the value will change accordingly.

Press the IOL value, and you could use the small keyboard to adjust it. Press **Enter** to display the adjusting result. You can also amend the case information with the same method.

In the IOL adjusting mode, other operations could not be done. If you want to do other operations, please press **Enter** to exit first.

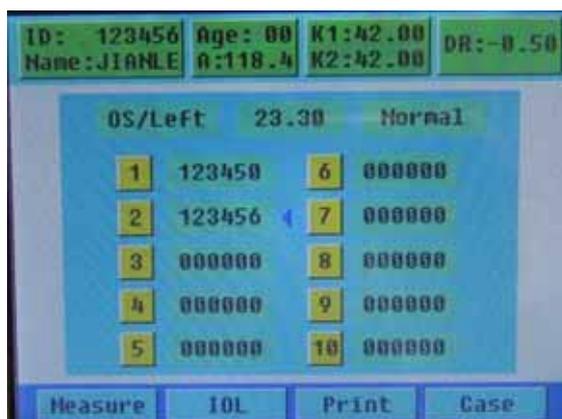
Press **Save** to save the present result.

Print

In IOL mode, after you select the data you need to print, press **Print** to print the data. It is including the basic information of patients, setting values, formula, A constant and IOL calculation table.

Case Review

Press **Case** and you could visit the 10 cases you have saved. Click the case number, and then click **IOL** to review the details of the selected case. (See pic.11)

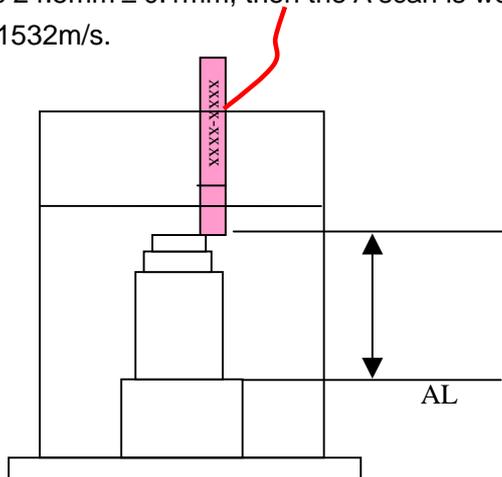


Pic.11 case review

7 System Criteria Testing

There is a test block as showed picture. It has 4 steps (acoustic reflecting surface). It is used to check if the A scan is working normally.

1. Temperature : 25
 Fill the test block with distilled water (No bubble in the water)
 Eye Type: Aphakic Eye
 Speed: 1520m/s
2. Gain: adjust the gain to a lower lever, around 50.
 Put the probe straight against first step, on the edge, move the probe slightly, make sure the ultrasound can get reflection from all the 4 steps. See the pic.12.
3. Choose Auto mode or Manual mode, observe the waves, when it has 4 waveforms, see the AL figure, if it is 24.5mm ± 0.1mm, then the A scan is working normally.
4. Set back the speed to 1532m/s.



Pic.12 how to calibrate

8 Change the Print Paper



Print paper specification: 30 × 65 mm, thermal sensitive print paper.



Pic.13 Open the printer



Pic.14 Take out the roller



Pic.15 Press S/L



Pic.16 Refill roller, see paper end



Pic.17 Press S/L to roller paper



Pic.18 Close the cover

Chapter 15 The Interface and Setting Of P Scan

1 Interface Introduction

Enter the **"Single"** mode after one chooses the Pachymetry. Pic.19 is the interface of P scan.



Pic.19 measure interface

1.1 On the upper part is the setting menu. Press the items to begin setting.

ID : Case number

Name : Patient's name

Phy: Operator's name

OD/Right: right eye; OS/Left: left eye

Start: Start to measure

Delete: Delete unsatisfied data

Corneal V : The velocity of sound thru the cornea. Default: 1640m/s. User could define it.

Actual/Bias: Actual is the actual measure data ; Bias is to add bias into the data. Bias could be expressed in μm or %

IOP: Value of eye pressure. Unite: mmHg

1.2 On the right is reading window displaying the result of measurement.

Avg : average of measure data ; Min : The minimum of measure data

SD : The standard deviation

300~1000um : Measure range.

There are 3 ranges: 150~350um, 300~1000um and 900~1500um. The default is 300~1000um.

1.3 On the lower part is the mode menu.

Single: measuring mode

Data: Displaying mode

Map: corneal topography measuring mode

Print : Press it in Data mode and it will print data automatically.

1.4 On the middle is the main window displays 10 groups of measured data. Each

group is the average of multiple measures up to 20.

2 Setting

Input ID, patient's name and operator's name



Pic.20 Setting Interface

Press the **ID** item in the setting menu. The interface will change into **Setting** mode. (See Pic.20) And the numbers begin to blink.

Press the number keys on the screen by touch pen to input ID. Then press "**Enter**" to confirm the input. Then the system automatically enters the **Name** setting mode. Click the letter icons to input the name of patient. Then click "**Enter**" to confirm. And the system automatically enters the "**Phy**" setting mode. The setting of "**Phy**" is the same with the Name. Press "**Enter**" alone could switch among **ID**, **Name** and "**Phy**" setting modes.

- ➡ Touch screen is very sensitive. Don't press it with much strength.
- ➡ After finished measurement, if one revises the ID, then the data of former ID will be deleted.



If you want to reenter the items, press "**Enter**" to switch to the item you want to correct. Then you can reset the item.

Left/right eye setting

Press the "**OD/right**" in up-right of main window , it will switch between "**OS/left**" and "**OD/right**".

Corneal V and Eye Pressure Setting

After power on, the corneal velocity is displayed in the upper center of the screen. Click it to enter the Corneal V setting mode. The default is 1640m/s. After setting, click "**Enter**" to confirm.

Click **IOP** to enter Eye Pressure setting mode. Click the corresponding numbers to input eye pressure which is measured with tonometer. Click eye setting to switch between “**OS/left**” and “**OD/right**”.

3 Bias Setting



Pic.21



Pic.22

If you want to set **Bias**, click the “**Actual**” key to switch to Bias input mode. “**Actual**” means the measure is the actual result without any bias. While “**Bias**” means that the result is adjusted by certain bias, which is set according to doctor’s experience.

In “**Bias**” mode, there are two ways to display: % and um. Click the “**um**” key under the “**Bias**” to switch to “%”. See Pic.21 and Pic.22. Click the number keys to set **Bias** and press “**Enter**” to confirm. After all the parameters have been set, click the icon “**Map**” or “**Single**” in the bottom of the screen to enter measure mode.

Time setting: Click icon “**Time**” to input time and then “**enter**” to confirm it.

Click “**Show Graph**” to observe the waveform when measuring. Click “**No Graph**” to conceal the waveform. After set all parameter you need, click the “**Single**” or “**Map**” and begin to measure.

➡ To avoid error, please finish all parameter setting before measuring.

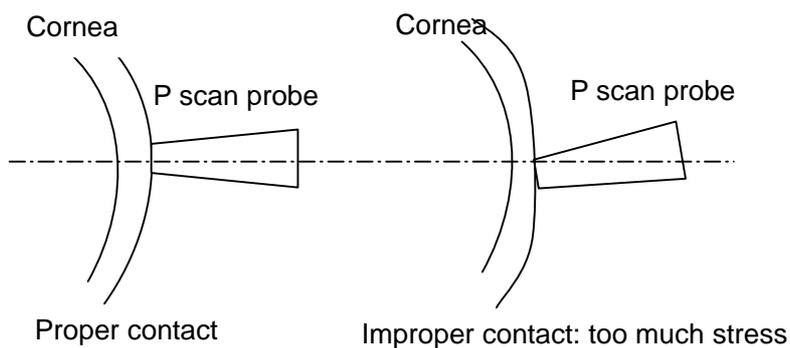
4 Measure

Preparation And Sterilization

➡ The surface of the P scan probe contacting the cornea should be sterilized by alcohol tampon before measurement. The probe can be used only after the alcohol has completely evaporated. Don’t dip the A scan probe into the alcohol to perform

disinfections.

- ➡ Let the patient lie in supine posture on the bed. Perform the anaesthesia of the cornea. Make the probe tip perpendicular to the center of the cornea and touch the surface of cornea tenderly. Don't apply too much stress lest of measure error caused by deforming of cornea.



Pic.23 tip of probe

Pic.24 Proper and improper contact

Single Mode



Pic.25 Show Graph



Pic.26 NO Graph

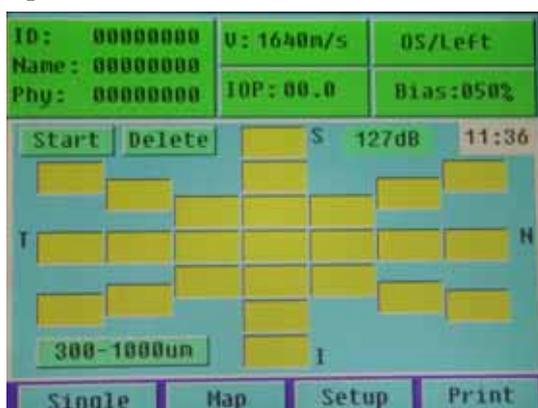
Click **“Single”** below after setting the parameters to enter measure mode. Press pedal to begin measuring.

- ➡ Select measure ranges: 150~350um , 300~1000um (default) or 900~1500um. Click the lower right key on the screen to set.
- ➡ Make preparation as above-mentioned. Perform disinfections and anesthesia. Contact

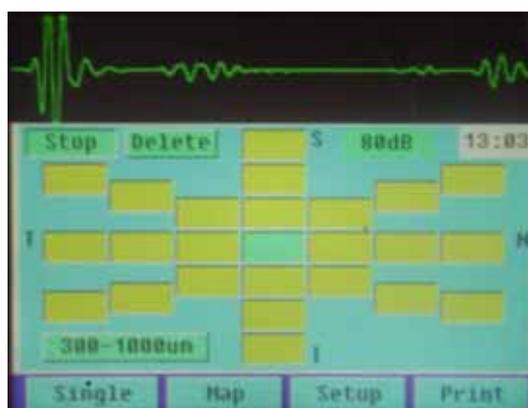
the probe to the cornea surface and the machine will automatically take measure. After each measure, the machine will give a beep to indicate. Each group could take 20 measures at most. The displayed value is the average of the measured data. When it reaches the maximum of measure times or when the probe leaves the surface of cornea, the machine will beep twice to indicate that a group is finished and enter the next group automatically. Ten groups of data could be taken and displayed. On the right of the screen displays the average, minimum and SD of the measured groups and real IOP value.

- ➡ After measure is finished, if there is unsatisfied result, you could click it to set it to zero, then measure again.
- ➡ If the data is beyond the setting range, the machine will not record this data and “**Out of range**” will appear on the lower part of the screen. Then the operator needs to adjust his posture or set a new range.

Map mode



Pic.27 NO Graph



Pic.28 Show Graph

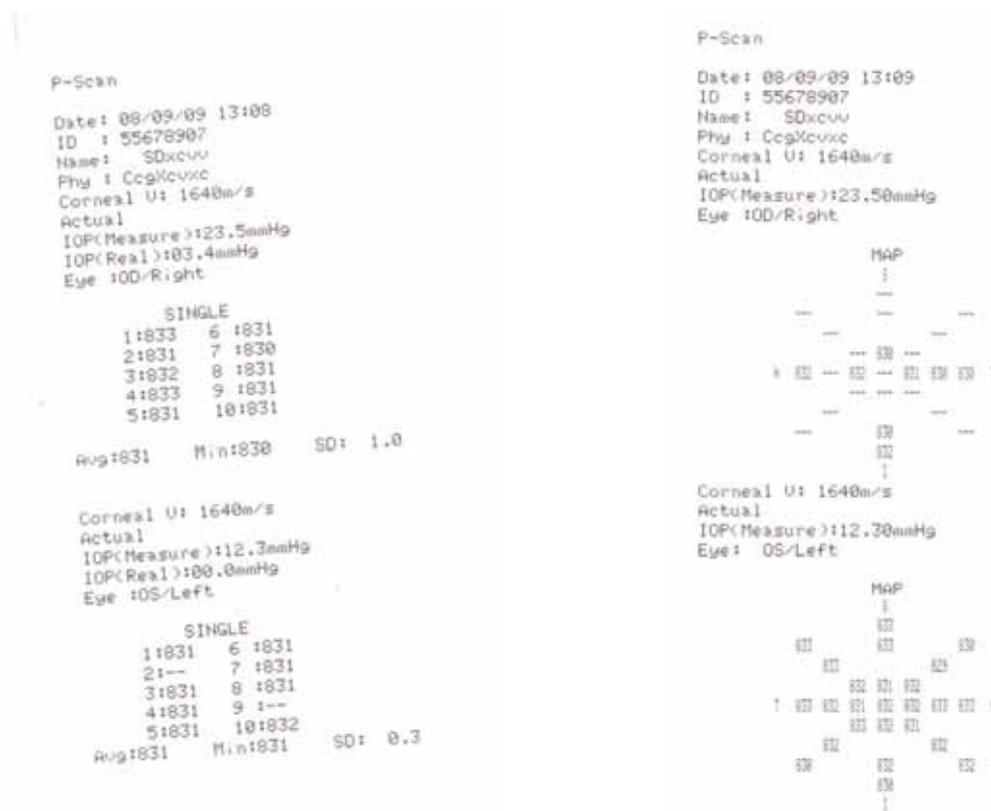
- Press “**Map**” in the lower part to enter into measure mode.
- It shows the map of cornea , press pedal to enter measure mode, it will measure the thickness of all the spots on the map. If you want to measure only some of the spots, choose the spot first, and then press pedal to measure.
- Choose measuring range : this instrument has three measuring ranges:150~350um ,

300~1000um (default) and 900~1500um. Press the button on the right lower part to switch them.

- If there are some measure data are unsatisfied, select it and press “delete” to delete it and re-measure.

Print

In “Single” or “Map” mode, press “Print” and it could print the case automatically after finish measurement. The printed report includes ID, patient’s name, operator’s name, left/right eye, value of eye pressure, ten groups of data and the average, minimum and SD and IOP. (See Pic.29)



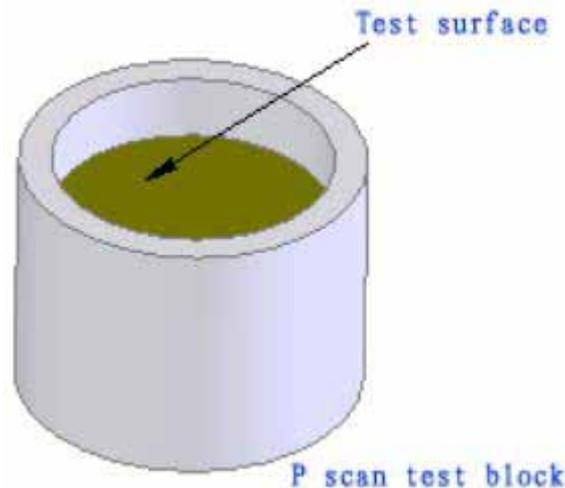
Pic.29 Printing Result

5 System Criteria Testing

There is a test block as showed picture. It stimulates reflecting surface of human eye. It is used to check if the P scan is working normally.

1. Test temperature : 25
Dip the probe tip with distilled water.
2. In “Single” mode (V=1640m/s), select “Show Graph”.
Gain: adjust the gain to 0.
3. Slightly place the probe perpendicularly against the surface of test block and begin

to measure. After finish measurement and get the average of thickness of test block, compare it to the standard data (850nm) marked at the test block. If precision is within $\pm 0.1\text{mm}$, then the P scan is working normally.



Pic.30 Test Block

Chapter 16 Package and Transportation

Transportation vehicles can transport the packed instrument. The instrument must not be transported together with goods that are easy to burn, explode, or corrode. Also it should be protected from shock and moisture.

The instrument should be stored in the environment with ambient temperature from -40 to 55 , with the relative humidity under 95%, where there is no corrosive gas, strong mechanical vibration, shock or magnetic effect. The room in which the instrument stored should be with good ventilation and avoid direct sun radiation.

Chapter 17 Daily Maintenance

1. In moist season, if the machine hasn't been put into use for a long time, it should be powered up for about one hour each month to drive the moisture away.
2. When the ambient temperature is under 10 , the machine should be warmed up for 5 minute before measuring.
3. Don't use any causticize cleanser when cleaning the device. Avoid water or any other liquid running into the keyboard or shell. You can clean with mild cleaner and soft tissue.
4. The lead and connector of the probe must be checked regularly. Any disjunction or

loose will influence the quality of the image and even cause the danger of electric leakage.

5. The maintenance of **probe**.

5.1 Keep the surface of probe clean. You can clean the tip by alcohol tampon, but don't dip the probe into alcohol or other disinfects liquid to perform disinfection.

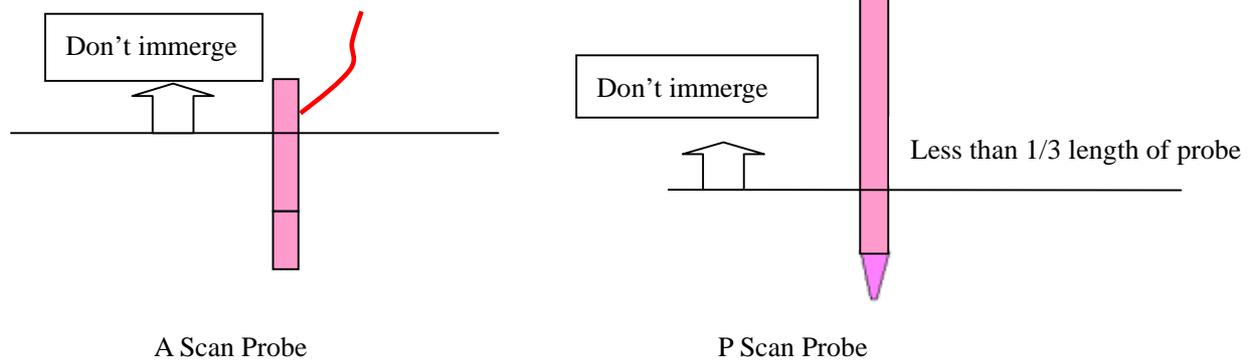
5.2 The surface of the P scan probe contacting the cornea should be sterilized by alcohol tampon before measurement. The probe can be used only after the alcohol has completely evaporated.

5.3 The surface of the P scan probe should be sterilized by alcohol tampon after measurement.

6. The instrument should be switch on and off at least once a week.

7. Print paper is expendable. Please refer to 2.3 Change the Print Paper and follow the steps to change print paper after it is consumed.

8. The part above the probe line could not touch the liquid. See the pictures below:



Chapter 18 Trouble Shooting

PHENOMENA	REASON	METHOD
Cannot freeze the image when measure.	The mode of unit is not right.	Choose the right mode.
	The value of gain is too low or too high.	Adjust the gain
	Disturbance problem	Keep away from strong magnetic or electronic field.
Cannot capture the image	Bad connection of pedal.	Turn off the unit and re-insert the pedal.
No normal echo wave	Bad connection of the probe	Turn off the unit and re-insert the probe.
No waveform appears when measure.	The probe does not contact the cornea.	Adjust the gesture.
	The surface of patient's cornea is dry.	Apply the saline to patient's eye.
Failure of measuring (irregular waveform appears)	Disturbance problem	Keep away from strong magnetic or electronic field.
	The unit is defective.	Note details and contact us.

Appendix I Probe Ultrasound Output Report

NO.	TEST ITEM	STANDARD REQUEST
1	P (MPa)	< 1
2	I_{spta} (mW/cm ²)	< 20
13	I_{ob} (mW/cm ²)	< 100

A Scan (8M) Probe Sound Output Parameter

P Scan (20M) Probe Sound Output Parameter

NO.	TEST ITEM	STANDARD REQUEST
1	P (MPa)	< 1
2	I_{spta} (mW/cm ²)	< 20
3	I_{ob} (mW/cm ²)	< 100

Notice : The ultrasound output parameter should not be republished.

Appendix II List

SW-1000

NO.	ITEM	QUANTITY
1	Main Unit	1
2	Touch Pen	1
3	8MHz A Scan Probe	1
4	20MHz P Scan Probe	1
5	Pedal/Footswitch	1
6	Power Line	1
7	Thermal Print Paper	4
8	A Scan Test Block	1
9	P Scan Test Block	1
10	USER'S GUIDE	1
11	Certification Of Qualification	1
12	Warranty Card	1