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Introduction

Dear User:

SW-1000 is a precise ultrasound measure instrument, designed for detecting axial length, depth of anterior chamber, thickness of lens and calculating the IOL.

This User's Guide is designed as a training and reference manual. We recommend you carefully read and follow the steps in this guide to ensure that the machine would have optimum performance.

Classification

SW-1000 is classified as Class I, Type B instrument.

This product has got ISO9001 and CE approval.

Symbol



Precaution

- This instrument requires the power supply of AC 90~230V, 50HZ±2%. 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.
- 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, and kept away from strong magnetic or electric field or other strong disturbance sources.

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 disinfection. Don't twist or pull the leading line violently.

It is not permitted that user himself dissembles the main unit or probe. If there are any problems, please send it to the warranty station.

The maintenance and warranty of the printer is executed by the warranty station near user's location. We recommend you to send the printer to warranty station periodically. That will make the printer last longer.

Contraindication of A scan:

- 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
- When the ambient temperature is under 10°C, the instrument should warm up for 5 minutes before it begins to work.
- As to the safety and effective result caused by ignoring the declaration above, our company does not take the responsibility.



Instrument Components

Pic.2 Back view of SW-1000

Theory and Function

Ophthalmic A scan SW-1000 is composed of main unit, probe, pedal and so on. The probe contacts the cornea and sends out ultrasound of 10MHz. The echo wave from front surface, back surface of lens and retina is 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. The data are displayed on the color LCD screen through output interface, or stored in the machine, or printed out.

This instrument 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 use, with the function of auto-calculating IOL and touch screen input. Six groups of formula could be chosen: SKR-II 、 SKR-T、BINKHORST-II、HOLLADAY、HOFFER-Q HAIGIS-STD. It has manual and auto measure mode. The build-in printer could print the data and IOL table.

Characteristics

- A Probe: 10MHz solid probe, compact and inner luminated;
- Resolution: ± 0.05 mm;
- Eye mode: Normal/Aphakic/Dense/PMMA/Silicone/Acrylic
- IOL formula: SRK-II、SRK-T、BINKHORST-II、HOLLADAY、 HOFFER-Q、 HAIGIS-STD;
- User could check the case according to the ID;
- Each ID can have the data of 5 scans, and 10 IDs can be saved;

- Output: IOL calculating table;
- Measure: Anterior chamber, lens, vitreous body and total length.
- Curve freezing: Manual/Auto mode, controlled by pedal;
- Output: Build-in fast thermal printer;
- Display: Color liquid-crystal screen;
- Input: touch screen.
- Power: 30W

Environment Requirement

1. Work Environment

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

2. Transport and Storage

- Ambient temperature: -40°C ~ +40°C
- Relative moisture: \leq 95%;
- Atmosphere pressure: 500hPa~1060hPa

3. Running

- Ambient temperature: +5°C~+40°C
- Relative moisture: \leq 80%
- Power Supply: AC 90~230V, 50x (1±2%) Hz
- Atmosphere pressure: 860hPa~1060hPa
- Warm-up time: 5min

Install and Connection

- Check the package to see if anything missing. (Reference to Appendix: package list)
- Insert probe, pedal and power plug to respective socket. (See Pic.3)

Align the salient on the probe

- And the second
- connector to the gap on the probe Pic.3 Pull and plug 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 probe must be connected before power on. Don't plug or pull the probe when power is on.
- Pedal is to freeze and unfreeze the image manually. Put the pedal at handy place. Gently step once and it will be ok. Don't use too much strength or not let it go.
- 3. After each part is properly connected, turn on the power. You could hear a "beep". The measure interface will appear in a second,.
- Do not turn on and turn off the power too swiftly. Otherwise on the screen will appear random pictures.



Foot switch



Introduction of the Interface and Setting



1. Interface Introduction

Pic.4 measure interface

After switch on, "Measure" mode and "Contact" is default. See Pic.4. Press "Contact" to switch to "Immersion".

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

setting up data.

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

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

| Readings: | the eye axial length of each measure. 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.

| Measure: Perform A scan measure | IOL: IOL calculating displaying | | | |
|---------------------------------------------------------------|---------------------------------|--|--|--|
| Setup: Set up the time and velocity | Case: Show stored cases | | | |
| of ultrasound | | | | |
| 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

2.1 Input ID and Setting Parameters

Press "ID" in the setting menu. The interface will change into "key in" mode. (See pic.5) 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, K2 and DR. If you want to set



the name of patient, press "Enter" and the letter input interface will appear.

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.

2.2 Eye mode

Press "Normal" in setting menu, and it will switch among different eye types.

2.3 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.

2.4 Time and velocity setting

Press "SETUP" in the main window.

| 10: 000000 Age: 00 K1:42.00 DR:-0.50 Name:000000 A:118.4 K2:42.00 | 1D: 808900 Age: 08 K1:42.00 Name:000000 A:118.4 K2:42.00 DR:-0.50 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| Normal Normal Confidence: Normal Dense Lens: 1049 n/s Uitreous: 1532 n/s ACD: 1532 n/s Thickness: 1.50 nn 9 0 Enter | Time: 08/04/25 13:23 Confidence: High Avg: 1532 n/5 Silicone Acrylic 1 2 3 4 5 6 7 8 9 0 Enter |
| Measure IOL Print Case | Heasure 10L Print Case |

Pic.6 Time& velocity setting Use small keyboard to set up time and velocity.

It has default data for the velocity, see the chart below:

| | 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 | |

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

AVG only can be used under eye mode APHAKIC

Thickness only used under eye mode PMMA, SILICONE, ACEYLIC

Measure

1. Preparation

- The surface of the 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 disinfection.
 - Let the patient lie in supine posture on the bed. Perform the anaesthesia of the cornea. Make the transducer perpendicular to the center of the cornea and make them contact properly.



Proper contact

Improper Contact

Immersion:

- 1. In order to release the pain in the eye, the cornea needs anaesthesia.
- 2. Choose suitable size eye cup and Put it in the eye lid.
- 3. Use suitable media (couplant) for ultrasound transfer. (which is low acoustic impedance, and can comfort patient)



Water bath method example

2. 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.7)



Pic.7 Auto mode

- Make preparation as above-mentioned. The instrument will catch and freeze the waveform 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.

3. Manual Mode

- In measure mode, press the "auto" to switch to manual mode. And "manual" will be shown on the screen.(See pic.8)
- Preparations before measurement are the same as AUTO mode. Put the probe perpendicular to the

| ID: 0860 Name:0000 | 88 Age: 6 88 A:118 | 00 K1:42.00 4 K2:42.00 | DR:-0.50 |
|-----------------------|-----------------------|---------------------------|--------------------------------------------------------------|
| <u>OSZLEFT</u> | Normal 00.00 | Contact 60dB 89:59 | 00.00 00.00 00.00 00.00 00.00 00.00 0.00.0 |
| Measure | IÖL | Setup | Case |

The probe perpendicular to the Pic.8 Manual Mode 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

4. IOL Calculation

| 1D: 000000 Age: 00 K1:42.00 DB:-0.50 Name:000000 A:118.4 K2:42.00 | | | |
|-----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|--|
| 10L 20.58 21.00 21.58 22.68 << 22.58 23.00 23.50 24.00 24.50 | DR 61.08 60.68 80.28 AL:23.50 90.11 -00.51>> -80.91 -01.31 -01.71 -82.11 Save | SRK-TI SRK-T HOLLADAY BINKHORST-TI HOFFER+Q HAIGIS-STD 1 2 3 4 5 6 7 8 9 8 Enter | |
| Measure | IOL Prin | t Case | |

Pic.9 IOL calculation

After the measure is finished, press IOL to enter the IOL calculation mode. (see pic.9)

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.

5. 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.

6. Case Review

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

| ID: 12345 Name:JIANL | 6 Age: 00 E A:118.4 | K1: K2: | 42.00 | DR:-0.50 |
|-------------------------|------------------------|------------|-------|----------|
| 0S/L | eft 23. | .30 | Nor | mal |
| | 123450 | 6 | 0000 | 30 |
| 2 | 123456 | 7 | 00001 | 30 |
| 3 | 000000 | 8 | 00000 | 10 |
| | 000000 | 9 | 00004 | 10 |
| 5 | 000000 | 10 | 00000 | 90 |
| Measure | IOL | Pr | int | Case |

7. System Criteria Testing

Pic.10 case review

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: 1520

- 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.11
- 3. Choose Auto mode or Manual mode, observe the waves, when it has 4 waveforms, see the AL figure, if it is 24.5mm ± 0.1 mm, then the A scan is working normally.
- 4. Set back the speed to 1532



Pic.11 how to calibrate

Change the Print Paper



Pic.12 Open the printer

Pic.13 Take out the roller



Pic.14 Press S/L

Pic.15 Refill roller, see paper end



Pic.16 Press S/L to roller paper



Pic.17 Close the cover

Package and Transportation

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

The instrument should be stored in the environment with ambient temperature from -10° C to 40° C, with the relative humidity under 80%, 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.

Daily Maintenance

- 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°C, the machine should be warmed up for 5 minute before measuring.
- 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.
- 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.
- Keep the surface of probe clean. You can wipe the tip by alcohol tampon, but don't dip the probe into alcohol or other disinfect liquid to perform disinfection.
- The part above the probe line could not touch the liquid. See the pictures below:



7. The warranty station nearby is responsible for the maintenance of printer. It is recommended that the printer be sent to the warranty station for maintenance periodically, for example, every 6 months. This can make the printer last longer.

Trouble Shooting

| PHENOMENA | REASONS | METHODS |
|--------------------------------------------------------------|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| Failure of lightening the power indicator | Bad connection of the power plug | Re-insert the plug to connect it well with the socket |
| Failure of freezing | The mode of the instrument is not correct. | Choose the mode again to make the instrument under measuring mode. |
| under the status of | The amplitude of the signals is not enough | Adjust the gain |
| measurement | The signals are too weak or there are too many disturbing waves | Adjust the gain |
| No normal echo wave under the status of measurement | Bad connection of the probe with its socket | Shutdown the instrument and re-insert the probe to connect it well with the socket |
| No waveform under the status of | The transducer does not contact the cornea | Adjust the hand with the probe to the correct position |
| measurement | The surface of the patient's cornea is dry | Apply the physiological saline to the patient's eye |
| No display on the screen or no echo wave | Disturbance or problems of the instrument | Take down the details of the problem and contact with us |
| The displayed image is disordered | Problems of the instrument | Take down the details of the problem and contact with us |