

# **SPA-100 Series**

Ophthalmic Ultrasound A-Scan/Pachymetry

**Operators Manual** 

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# **Section 1 INTRODUCTION**

The SPA-100 series is the latest generation ophthalmic ultrasound biometry instruments introduced by us. The series consist of three different models:

**SPA-100A** This A-Scan system allows for measuring the axial length, anterior chamber depth, lens thickness and vitreous depth of eyes and calculating the associated IOL power for an implanted lens.

**SPA-100P** This Pachymeter system allows for measuring and mapping corneal thickness.

**SPA-100AP** This system integrates the A-Scan and Pachymeter capabilities into a single system seamlessly.

These three systems utilize a high-resolution backlit touch screen liquid crystal display (LCD) by which the user can enter information and view data and calculations. The system is compact and lightweight with a thermal printer build-in thereby making the system extremely portable.

All three systems can be connected to PC running Windows XP, Windows Vista or Windows 7 through USB connection. The application APScanSync running on Windows is provided to retrieve and manipulate data from SPA-100 series. The SPA-100 series provide full capabilities for biometry or pachymetry, which can work WITH or WITHOUT PCs.

This manual is intended to provide a thorough overview of the SPA-100 series of instruments and their capabilities. The operation guide of APScanSync is *NOT* included in this manual.

Thank you for your trust in us to provide for your ophthalmic

ultrasound biometry needs.

# 1.1 A-SCAN FEATURES (For SPA-100A and SPA-100AP Only)

As mentioned, the A-Scan mode of the SPA-100 series allows for measuring the axial length (AXL) for eyes and calculating the IOL power for an implanted lens.

By placing the A-probe against the patient eye, a live A-Scan ultrasound echogram for an AXL measurement can be obtained. The echogram can then be frozen automatically (by build-in algorithm) or manually (by foot pedal) and the measured value for the AXL (also ACD, Lens and Vitreous) will be display along with other related information. Using the AXL measurements, the karatometer readings, and an IOL program parameter, the system calculates the required IOL power.

After the completion of the measurements and calculations, a hardcopy can be obtained of the results by using the build-in thermal printer. The records to be printed may include the A-Scan echogram, statistics of results, table of IOL powers versus desired refraction with patient information and operator information.

Several features help to distinguish the SPA-100 series including:

- -Live Echogram Display
- -Gain Control
- -Storage of 5 Scans for Later Review and IOL Calculation for Both Eyes
- -6 Different Examination Modes
  - -Normal Phakic
  - -Normal Cataract
  - -Dense Cataract
  - -Aphakic

- -Pseudophakic
- -Custom Defined
- -Velocity Compensation Pseudophakic Lens Type (PMMA, Acrylic or Silicone)
- -Echogram Measurement Review and Adjust Capability
- -Axial Length, Anterior Chamber Depth, Lens Thickness & Vitreous Length for Each Scan
- -Average and Standard Deviation for Echo Segment Up to 5 Scans
- -Six Available IOL Formulas
  - -SRK-II
  - -SRK-T
  - -Binkhorst-II
  - -Holladay
  - -Hoffer-O
  - -Haigis (standard)
- -Immersion Capabilities
- -Clinical Accuracy  $\pm$  0.1mm
- -Data Output Through USB Connection

# 1.2 PACHYMETER FEATURES (For SPA-100P and SPA-100AP Only)

By placing the pachymetry probe against the patient eye, a live Pachymetry ultrasound echogram for cornea thickness measurement can be obtained. The echogram can then be frozen automatically (by build-in algorithm) and the measured value for the corneal thickness will be displayed along with other related information. Using the central cornea thickness and the means Intra-Ocular Pressure (IOP), the true IOP can be calculated automatically.

After the completion of the measurements and calculations, a hardcopy can be obtained of the results by using the build-in thermal printer. The records to be printed include the statistics of results with patient information and operator information.

Several features help to distinguish the SPA-100 series including:

- -Average and Standard Deviation Computed for Each Readings
  - -Corneal Map with Graphical Display.
  - -Measurement Range: 125 to 1000 microns.
  - -Adjustable Bias and Corneal Velocity.
  - -Accuracy Better than  $\pm$  10 Microns
  - -Precision  $\pm 1$  Microns

# **Section 2 GETTING STARTED**

**FOR YOUR PROTECTION,** please read these safety instructions completely before installing, applying power to, or operating the system.

# 2.1 UNPACKING

The SPA-100 series is carefully packed to prevent damage during shipment. Before unpacking, please note any visible damage to the outside of the shipping containers.

Items should be checked in order to ensure that all ordered items have been received. The following table lists the items which should be received with each particular system.

Table 2-1 Items List for SPA-100 Series

SPA-100A	SPA-100P	SPA-100AP
√	√	√
√		√
√		<b>√</b>
	√	$\checkmark$
	√	√
<b>√</b>	√	<b>√</b>
√	√	<b>√</b>
√	√	√
√	√	√
	√ √ √ √ √	

Power Cable	√	√	✓
SPA-100 Series Operators'	✓	√	✓
Manual			
APScanSync Users' Guide	√	√	√
Compact Disc for APScanSync	√	√	√
Software			

Each item should be examined for any noticeable defects or damage that may have occurred during shipment although it is packed carefully. If any defect or damage exists, please contact to your local representative immediately to report the problem.

# 2.2 SAFETY CONSIDERATIONS

Before operation, the instrument and this manual should be reviewed for safety markings and instructions. Specific warning and cautions are found throughout the manual. These must be followed to ensure safety operation and to maintain the instrument in a safe condition.

Review any other manuals and instruments supplied with the system in the same manner. And keep this manual for future reference.

# TERMS MARKED ON THE INSTRUMENT

CAUTION indicates a personal injury hazard not immediately accessible as one reads the markings, or a hazard to property, including the equipment itself.

WARNING indicates conditions or practices that could result in personal injury or loss of life.

DANGER indicates a personal injury hazard immediately

accessible as one reads the marking.

#### TERMS USED IN THIS MANUAL

CAUTION statements identify conditions or practices that could result in damage to the equipment, patient data or other property.

WARNING statements identify conditions or practices that could result in personal injury or loss of life.

#### **GENERAL WARNINGS**

To avoid explosion, DO NOT operate this product in the presence of flammable gases or fumes. Operation of any electrical instrument in such an environment constitutes a definite safety hazard.

To avoid personal injury, DO NOT removes the product covers or panels.

NO user serviceable parts inside. DO NOT attempt to service the system except as described in the operating instructions. For all other servicing refer to qualified service personnel.

#### **GENERAL CAUTIONS**

In particular DO NOT cover instrument with dust cover when power is being applied to the instrument.

Guard against any small objects or liquid from entering the instrument.

Unplug the AC Adapter from the outlet when the instrument will not be used for an extended period of time.

Guard against any conflict of hard objects to the screen.

DO NOT use hard or sharp tools as touch pen to operate the equipment, use the touch pen provided or fingers.

The system should be placed on a level, stable surface during

operation.

# 2.3 SYSTEM SETUP

# **CONNECTING ACCESSORIES**

- 1. Place the SPA-100 series on a flat level surface.
- 2. Connect the foot pedal cables connector to the back panel of the system into jacks labeled "Foot Pedal" (Figure 2-1). Place the foot pedal on the floor.

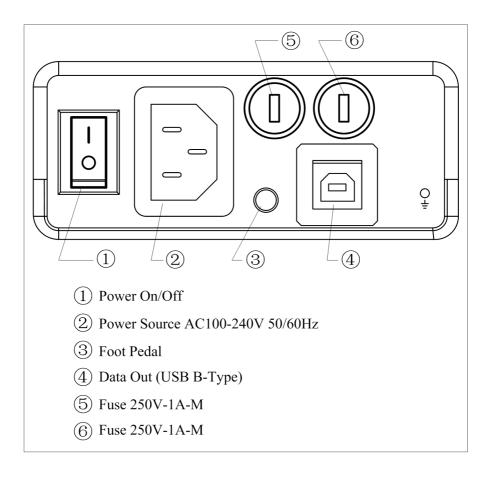


Figure 2-1 Back Panel

 Connect the probe connector (A-Scan probe or Pachymetry probe) to the jacks on the right side of the system labeled "A" (for A-Scan) or "P"(for Pachymetry). Before inserting be sure to line up the red indicator marks on both jacks and cables connector. (Figure 2-2)

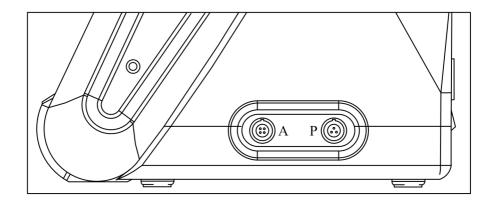


Figure 2-2 Probe Connection Panel

- (Optional) Connect the B Type connector of USB cables to the back panel of the system into jacks labeled "DATA OUT".
   Connect the A Type connector of USB cables to PC running Windows.
- 5. Verify that the Power Switch located on the back panel of the



This instrument may be damaged if operated with improper source power.

system is in the "OFF" position.

6. Connect the power cables to a proper AC power source (100-240VAC, 50/60Hz).

# CAUTION

Care should be taken when using or storing the system so that excessive force is not applied to the touch screen, as it may become permanently damaged.

## THERMAL PRINTER PAPER ASSEMBLING

- 1. Open the door of paper repository.
- 2. Fill scrolled thermal printer paper, make outside of paper up (For paper other than provided together with the system may be opposite).
- 3. Close the door of paper repository firmly.

## **USING THE TOUCH SCREEN**

The touch screen provided with the SPA-100 series system is a highly sensitive device which enables selections to be made and recorded on screen. On-screen selections should only be made by gently using a finger or the provided touch pen (do not use a pencil, pen, or other sharp object).

## **POWER UP**

- 1. Slide the Power Switch of the SPA-100 system located on the back panel to the "ON" position.
- Verify that the green LED on the face of the system illuminates and that the Main Screen appears on the display (Figure 2-3) after a splash screen of Logo. (Main Screen is equivalent within SPA-100 series with a little difference of absence of some buttons and labels).
- If either LED does not illuminate or Main Screen does not appear, turn OFF the system immediately and contact your local representative for assistance.

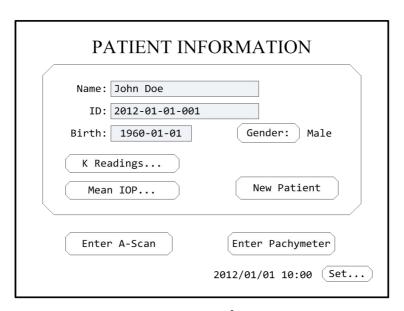


Figure 2-3 Main Screen for SPA-100AP

## SETTING THE DATE AND TIME

1. From the Main Screen, select the [SET...] button on the bottom-right of the screen (Figure 2-3). Verify that the Set Date and Time Dialog Box appear on the display (Figure 2-4).

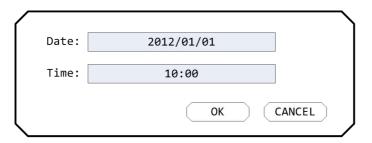


Figure 2-4 Date and Time Setup Dialog Box

2. To edit date, select the Date edit box (labeled "Date:" on the left side) and use the Number Key Board shown accordingly to input numbers (Figure 2-5). The date format is "YYYY / MM / DD". Here 'Y' stands for year, 'M' stands for month and 'D' stands for Day. The acceptable range of date from "2000 / 01 / 01" to "2099 / 12 / 31". Improper date is not acceptable, for example "2012 / 06 / 31" or "2013 / 02 / 29".

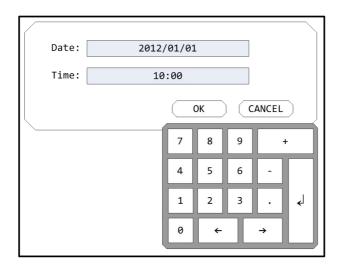


Figure 2-5 Date Edit Screen with Number Key Board Showing

- 3. To edit time, select the Time edit box (labeled "Time:" on the left side) and use the Number Key Board shown accordingly to input numbers. The time format is "HH: mm". Here 'H' stands for hour, 'm' stands for minute. SPA-100 series using 24 hours format with acceptable range from "00: 00" to "23: 59".
- 4. After entering the year and the time, select [OK] button to confirm date and time, and the dialog box will be closed accordingly. Or select [CANCEL] button to close the dialog box WITHOUT date and time confirm.

It is better to check if the date and time setup is correctly every time when system powered up before taking measurements.

# **Section 3 MAIN SCREEN**

The Main Screen is used for patient information input, system time setup and a place to enter A-Scan or Pachymetry. The Main Screen is equivalent within SPA-100 series with a little difference of absence of some buttons and labels.

PATIENT INFORMATION				
Name: John Doe  ID: 2012-01-01-001  Birth: 1960-01-01  K Readings  Mean IOP	Gender: Male  New Patient			
Enter A-Scan	Enter Pachymeter  2012/01/01 10:00 Set			

Figure 3-1 Main Screen

# 3.1 PATIENT INFORMATION

#### NAME INPUT

Select the patient name edit box (labeled "Name:" on the left side), using the Full Key Board shown accordingly to enter characters (Figure 3-2). Press [Enter] button on the key board to confirm the patient name when finished.

#### **ID INPUT**

Select the patient ID edit box (labeled "ID:" on the left side), using the Full Key Board shown accordingly to enter characters. Press [Enter] button on the key board to confirm the patient ID when finished.

## **BIRTH DATE INPUT**

Select the patient birth date edit box (labeled "Birth:" on the left side), using the Number Key Board shown accordingly to enter numbers. The acceptable birth date is in the range of "1900-01-01" to "2099-12-31". Incorrect date for example "1960-06-31" or "1970-02-29" is not acceptable by the system. Press [Enter] button on the key board to confirm the patient birth date when finished.

## **GENDER SELECT**

Touch the [Gender:] button to select patient gender for "Male" or "Female", the selected gender for the patient will be shown on the right side of the button.

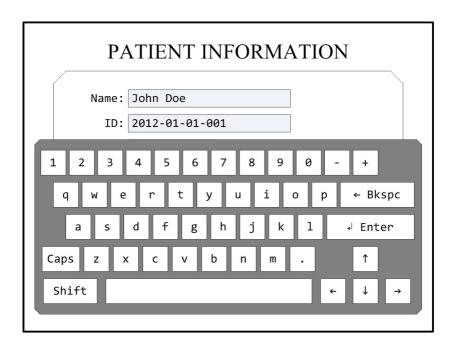


Figure 3-2 Edit Name and ID

# K READINGS INPUT (For SPA-100A and SPA-100AP Only)

The keratometer readings are needed for IOL power calculations. One is optional to input K readings from main screen following these steps:

1. Select [K Readings...] button, the K Readings Setup Dialog Box (Figure 3-3) is shown accordingly.

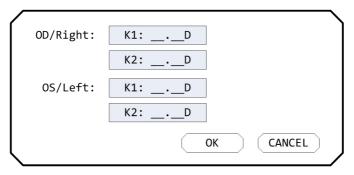


Figure 3-3 K Readings Dialog Box

- 2. Enter Keratometer readings of left and right eyes with the unit of Diopter.
- 3. Select [OK] button of the dialog box to confirm the K readings or select [CANCEL] button to close the dialog box WITHOUT K readings' confirmation.

# MEAN IOP INPUT (For SPA-100P and SPA-100AP Only)

Mean Intra-Ocular Pressure (IOP) reads from tonometer can be corrected by build-in IOP Correction program. Mean IOP can be input in main screen following these steps:

- 1. Select [Mean IOP...] button; the Mean IOP Setup Dialog Box (Figure 3-4) will be shown accordingly.
- 2. Entering Mean IOPs with the unit of "mmHg".
- Select [OK] button of the dialog box to confirm the mean IOP readings or select [CANCEL] button to close the dialog box WITHOUT mean IOP readings' confirmation.

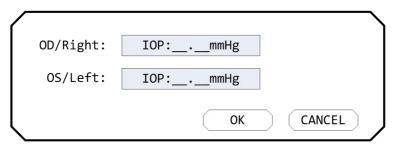


Figure 3-4 Mean IOP Setup Dialog Box

# 3.2 CREATE NEW PATIENT OPERATION

[New Patient] button is used to create a new patient and clear all previous patients' data including patient information, A-Scan data and pachymetry data. Notice dialog box will display for one to confirm the clearance of data.

The New Patient Operation can be response by the software APScanSync running in PC when connected. The information about the APScanSync software is included in the APScanSync Software Operation Manual.

# 3.3 ENTER A-SCAN OR PACHYMETRY

When patient information is ready, select [Enter A-Scan] to start A-Scan measuring, or Select [Enter PACHYMETER] to start pachymetry measuring. A-Scan measurement information is in section 4; pachymetry information is in section 5.

# Section 4 A-SCAN OPERATION (For SPA-100A and

# SPA-100AP)

The A-Scan mode of SPA-100 series allows for measuring the axial length (AxI) of an eye and calculating the associated IOL power for an implanted lens.

By placing the A-porbe against a patient eye, a live A-Scan echogram for an Axl measurement can be obtained. The echogram then be "frozen" and the measured value for the Axl will be displayed along with other pertinent information. Using the Axl measurement, the keratometer readings and an IOL program parameter, the system calculates the required IOL power.

After completion of measurements and calculations, a hardcopy may be obtained of the results using the optional thermal printer. The hardcopy may include A-Scan echogram, table of IOL powers versus refraction, patient information, and user information.

# 4.1 ENTERING A-SCAN MODE AND BACK TO MAIN SCREEN

Touch the [Enter A-Scan] button on the Main Scree (Figure 3-1) to Enter A-Scan Mode. Touch the [Patient] button on the top-left corner of the A-Scan Screen (Figure 4-1) return back to Main Screen.

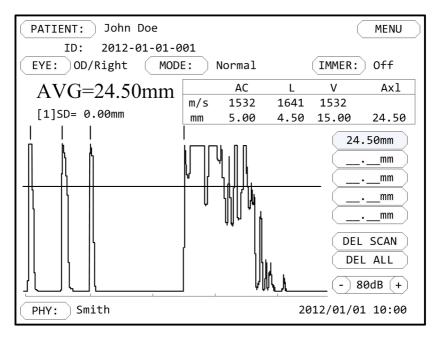


Figure 4-1 A-Scan Screen

# 4.2 SYSTEM SETUP

## **ENTERING PHYSICIAN NAME**

Three different physicians' name may be entered and permanently stored within SPA-100 memory.

By touching the [PHY:] button on the bottom-left corner of the screen, a Physicians Menu will be displayed on the screen (Figure 4-2). Select the [Edit...] Item to edit three physicians' names within the pop up Physicians Setup Dialog Box (Figure 4-3).

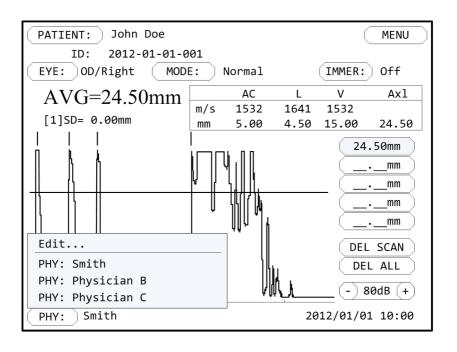


Figure 4-2 Physicians Menu

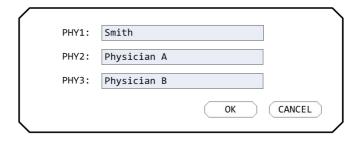


Figure 4-3 Physicians Setup Dialog Box

After physician name setup properly, one can select physician's

name from the menu for convenience. (A-Scan and Pachymetry shares the same physicians list and selection.)

# **VELOCITY SETUP**

Velocity for every segments of different kind of eyes should be setup correctly before taking measurements. Following these steps:

- 1. Select the [MENU] button on the top-right corner.
- 2. Select the [Velocity Setup...] from the menu (Figure 4-4). The Velocity Setup Dialog Box (Figure 4-5) will be shown accordingly.

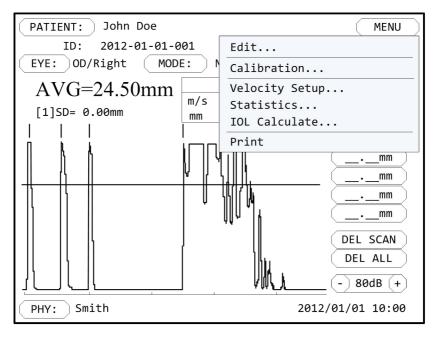


Figure 4-4 Menu of A-Scan

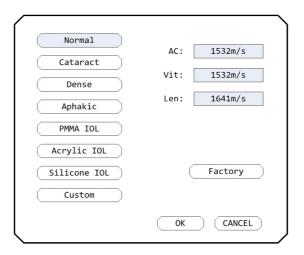


Figure 4-5 Velocity Setup Dialog Box

- 3. Select scan eye type from the left using check buttons and then edit the velocities in the edit box on the right. Or select [Factory] button to restore the velocities for selected scan eye type to factory setup.
- 4. Velocity Compensation for Pseudophakic Lens Type (PMMA, Acrylic or Silicone) needs both lens' velocity and Thickness as parameters.
- Select [OK] button to confirm the modification of velocities and close the dialog box. Or select [CANCEL] button to close the dialog box only.

# 4.3 CALIBRATION

It is recommended that the functionality of SPA-100 Series be verified by means of the calibration procedure prior to performing actual measurements. The SPA-100 series A-Scan system provide a

stainless steel Calibration Cylinder (Figure 4-6) for calibration.

To perform the calibration procedure, follow these steps:

1. Enter A-Scan Calibration Screen (Figure 4-6) by select the [Calibration...] item in the Menu of A-Scan (Figure 4-4).

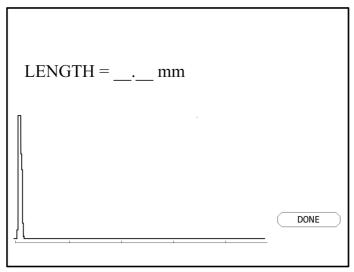


Figure 4-6 A-Scan Calibration Screen

- 2. Place a small amount of ultrasound coupling gel onto the Calibration Cylinder (Figure 4-7).
- 3. Place the probe onto the Calibration Cylinder. The probe should be placed perpendicular to the cylinder.



Figure 4-7 A-Scan Calibration Cylinder

- 4. Observe the measurement displayed on the touch screen. The measurement will freeze automatically.
- 5. Read the calibration LENGTH of the Calibration Cylinder, labeled on the Calibration Cylinder storage box.
- 6. Verify that the measurement obtained is LENGTH  $\pm$  0.1mm. If it is not, repeat the calibration procedure by press the foot pedal until an acceptable measure is obtained
- 7. If a measure within LENGTH  $\pm$  0.1mm cannot be obtained, contact to your local representative for assistance.
- 8. Return to A-Scan Screen press [DONE] button.

# 4.4 PATIENT PREPARATION

Apply a drop of topical anesthetic to the eye that is to be measured prior to performing the A-Scan.

## **DIRECT CONTACT MEASUREMENTS**

The patient should be seated in a comfortable, upright position preferably in an examination chair with a headrest. If the scan is to be performed using the "hand-held" method, the headrest should be positioned comfortably behind the patient's head in order to minimize movement away from the probe.

# WATER IMMERSION TECHNIQUE

The patient is placed in a supine position on a flat examination table or in a reclining examination chair. Consult the instructions supplied with the immersion shell for further directions regarding use of the shell.

# 4.5 PATIENT EXAMINATION

Following entry of physician and patient information A-Scan measurement may be obtained. Press the Foot Pedal if echogram is frozen in the A-Scan Measure Screen (Figure 4-8).

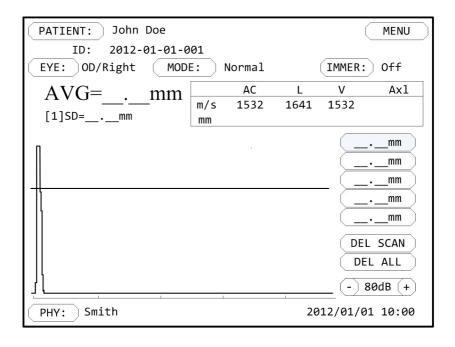


Figure 4-8 A-Scan Measure Screen

## DIRECT CONTACT SCANNING IN AUTOMATIC CAPTURE MODE

The SPA-100 series is able to recognize an acceptable A-Scan echogram and automatically freeze the echogram, depending upon the mode of measurement to be made:

 Examination Mode. Ensure the correct examination mode is selected as indicated by the [MODE:] button in up-side of the A-Scan Measure Screen. The examination mode could be changed by touching the [MODE:] button until the desired mode is shown. The following automatic capture examination modes are available: Normal (Phakic)

Cataract

Dense (Cataract)

Aphakic

PMMA (Pseudophakic)

Acrylic (Pseudophakic)

Silicone (Pseudophakic)

Custom (Phakic)

The tissue velocity will be automatically adjusted for selected mode.

- Tissue Velocity. Ensure the appropriate tissue velocities are selected by selecting the [Velocity Setup...] item in the menu. The system default velocities are 1532m/s for ACD, 1641m/s for the crystalline lens and 1532m/s for the vitreous. See Appendix A for standard values of tissue velocity used in the SPA-100 series.
- 3. **Immersion Option**. Ensure that the immersion options if OFF as indicated in the top-right corner of the A-Scan Measure Screen. The immersion option may be toggled between ON and OFF by touching the [IMMER:] button.
- 4. **Eye Select**. Touching the [EYE:] button to select "OD/Right" or "OS/Left" for measuring eye. The eye selection may be toggled between "OD/Right" or "OS/Left" by touching the [EYE:] button.
- 5. Make sure the probe tip is *clean* and *dry*.

Instruct the patient to look towards the red 6. Scan Eye. fixation light in the probe tip and visually align the probe along the patient's visual axis. Move the probe forward until contact with the cornea is achieved. Once contact is made, a live A-Scan echogram will be displayed and no further forward movement should be made.



# IMPORTANT

It is important to setup the velocity and examination mode properly before taking measurement for the change of velocities and examination modes will lead to automatic delete of obtained measurements.

7. **Automatic Scan Capture**. If echogram meets the criteria of the selected examination mode, it will immediately be frozen, save and a long audible tone will be emitted signifying that the instrument has accepted the measurement.

The gain control may be adjusted by touching the minus side of the gain button or plus side of the gain button located at the bottom right corner of the Measure Screen. The default gain is 80dB shown on the button. The gain setting is not able changed for any scan which has already been frozen.

The reference line may be adjusted by touching under the line or up the line on the touch screen. The reference line can be placed at two levels. The high level indicates high confidential level of the pattern recognition algorithm; lower level indicates lower confidential level of the pattern recognition algorithm.

Once accepted, the scan echogram will be displayed on the screen; the axial length will be calculated and shown on the result buttons on the right side of the Measurement Screen. The anterior chamber depth and lens thickness and vitreous will be displayed in the table versus tissue velocity on the top-right side. The location of the key structures in the scan echogram will be indicated by the gate markers display above the peaks of echogram.

Note: If the pattern recognition software identifies a particular echo in error (as in the case of a dense cataract), the user may reposition the "Gate" in the question by touching the markers. Gate marker is flashing. Reposition the gate by using the  $[\leftarrow]$ ,  $[\rightarrow]$  buttons (Figure 4-9). Cornea gate is not adjustable when using contact technique. Press the foot pedal is able to confirm the adjustment. Touching elsewhere on screen other than the markers could also confirm the adjustment.

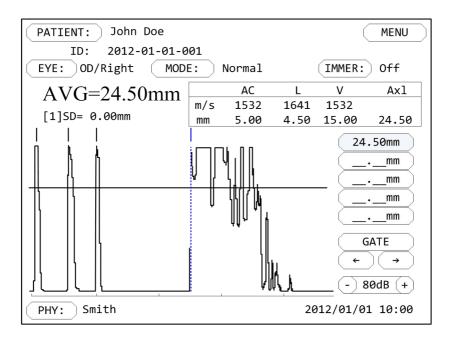


Figure 4-9 Adjust Gate Position

- 8. **Repeat**. The protocol can be repeated to obtain up to five scans. As the scans are captured, the axial length for each is displayed in the upper left of the Measure Screen. Additionally, the axial length average and standard deviation for the group of scans will be displayed. Each scan pattern may be reviewed by touching the result check buttons.
- 9. Deleting Scans. If a scan is captured which is no longer desired, it may be deleted by touching the [DEL SCAN] button. Deleting a scan will remove the scan pattern and all associated data from the system memory, and will exclude the associated axial length from the average and standard deviation calculations. If ALL scans are no longer desired for

current eye, they may all be permanently deleted by touching the [DEL ALL] button.



# ! IMPORTANT

It is important to remember that the auto modes are meant to facilitate the examination procedure but not replace the examiner's clinical judgment. All scans should be thoroughly evaluated by the user prior to being accepted and used for calculating lens powers.

## DIRECT CONTACT SCANNING IN AUTOMATIC MANUAL MODE

The SPA-100 series also provide the ability to manually capture A-Scan echogram by foot pedal. Manual mode is act as compliment for automatic capture mode. When measuring for automatic scan capture, one can press the foot pedal to freeze the echogram manually and adjust the gates of key structures.

## **BEEP**

When measuring, the frequency of short beep indicates the approximations to the auto-capture rules. When one scan is captured automatically a long beep will generate. If all five scans are captured, a longer beep will generate indicates the completion of measurement.

# WATER IMMERSION TECHNIQUE

In addition to direct contact measurements, a water immersion technique may be used with the SPA-100 series in order to completely eliminate concerns over corneal compression skewing results. The technique requires the use of a scleral shell. The immersion technique following these steps:

 Examination Mode. Ensure the correct examination mode is selected as indicated by the [MODE:] button in up-side of the A-Scan Measure Screen. The examination mode may be changed by touching the [MODE:] button until the desired mode is shown. The following automatic capture examination modes are available:

Normal (Phakic)

Cataract

Dense (Cataract)

**Aphakic** 

PMMA (Pseudophakic)

Acrylic (Pseudophakic)

Silicone (Pseudophakic)

Custom (Phakic)

The tissue velocity will be automatically adjusted for selected mode.

- Tissue Velocity. Ensure the appropriate tissue velocities are selected by selecting the [Velocity Setup...] item in the menu. The system default velocities are 1532m/s for ACD, 1641m/s for the crystalline lens and 1532m/s for the vitreous. See Appendix A for standard values of tissue velocity used in the SPA-100 series.
- 3. Immersion Option. Ensure that the immersion options if ON

- as indicated in the top-right corner of the A-Scan Measure Screen. The immersion option may be toggled between ON and OFF by touching the [IMMER:] button.
- 4. Prepare Scleral Shell. For the difference between scleral shells, see instructions provided with shells.
- 5. Applanating the Scieral Shell. Instruct the patient to look downward, Lift the patient's upper eyelid and insert the flared rim underneath the lid (the upper portion of the shell should be make contact with the sclera while the lower part should be held away from the eye). Then instruct the patient to look straight ahead. Pull the patient's lower eyelid down and gently pivot the lower portion of the shell into the lower fornix. This pivotal motion avoids contact with the cornea and ensures centering the device around the limbus.

## IMPORTANT

It is important to setup the velocity and examination mode properly before takina measurement for the change of velocities and examination mode will lead to automatic delete of

- 6. Make sure the probe tip is *clean*.
- 7. **Eye Select**. Touch the [EYE:] button to select "OD/Right" or "OS/Left" for measuring eye. The eye selection may be toggled between "OD/Right" or "OS/Left" by touching the

[EYE:] button.

- 8. **Scan Eye.** Slowly inject the saline or BSS into shell. As soon as the liquid fills the shell sufficiently to reach the tip of the probe, the characteristic echogram of immersion biometry will be visible on the display. Gently tap the side of the probe tip to insure that no bubbles have been trapped on the tip of the probe.
- 9. Automatic Scan Capture. If the scan meets the criteria of the selected examination mode, it will immediately be frozen, save and a long audible tone will be emitted signifying that the instrument has accepted the measurement.

The gain control may be adjusted by touching the minus side of the gain button or plus side of the gain button located at the bottom right corner of the Measure Screen. The default gain is 80dB shown on the button. The gain setting may not be changed for any scan which has already been frozen.

The reference line may be adjusted by touching under the line or up the line on the touch screen. The reference line can position at two levels. The high level indicates high confidential level of the pattern recognition algorithm; lower level indicates lower confidential level of the pattern recognition algorithm.

Once accepted, the scan echogram will be displayed on the screen; the axial length will be calculated and shown on the check buttons on the right side of the Measurement Screen. The anterior chamber depth and lens thickness and vitreous will be displayed in the table versus tissue velocity on the top-right side. The location of the key structures in the scan echogram will be indicated by the gate markers display

above the peaks of echogram.

Note: If the pattern recognition software identifies a particular echo in error (as in the case of a dense cataract), the user may reposition the "Gate" in the question by touching the markers. Gate marker is flashing. Reposition the gate by using the  $[\leftarrow]$ , [→] buttons. Press the foot pedal is able to confirm the adjustment. Touching elsewhere on screen other than the markers could also confirm the adjustment.

- 10. **Repeat**. The protocol can be repeated to obtain up to five scans. As the scans are captured, the axial length for each is displayed in the upper left of the Measure Screen. Additionally, the axial length average and standard deviation for the group of scans will be displayed. Each scan pattern may be review by touching the result check buttons.
- 11. Deleting Scans. If a scan is captured which is no longer desired, it may be deleted by touching the [DEL SCAN] button.



## ! IMPORTANT

It is important to remember that the auto modes are meant to facilitate the examination procedure but not replace the examiner's clinical judgment. All scans should be thoroughly evaluated by the user prior to being accepted and used for

Deleting a scan will remove the scan pattern and all associated data from the system memory, and will exclude the associated axial length from the average and standard deviation calculations. If *ALL* scans are no longer desired for current eye, they may all be permanently deleted by touching the [DEL ALL] button

- 12. Remove Scleral Shell. Once all desired scans have been captured, raise the upper eyelid to release the top portion of the shell from under the eyelid. Pivot the shell downward, instructs the patient to continue to look straight ahead. Pull the shell away from the eye without making contact with the cornea.
- 13. **Echogram Print**. When measuring finished, the selected echogram with correspond data can be printed by selecting the [Print] item in the Menu.

#### **MEASURE REVIEW AND STATISTICS**

The Statistics Dialog Box (Figure 4-10) allows the user to review all scan data and statistics. The dialog box is opened by selecting the [Statistics...] item in menu.

One can select [Print] button to print the reviews. The printed data include data review with correspond patient data.

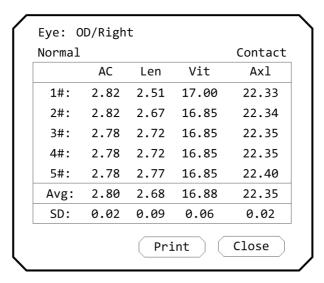


Figure 4-10 Statistics Dialog Box

#### PERFORMING IOL CALCULATIONS

The SPA-100 series uses the measurement data and selected IOL calculation formula to determine and display appropriate IOL powers. The IOL Calculation Dialog Box (Figure 4-11) opened by selecting the [IOL Calculate...] item in the menu.

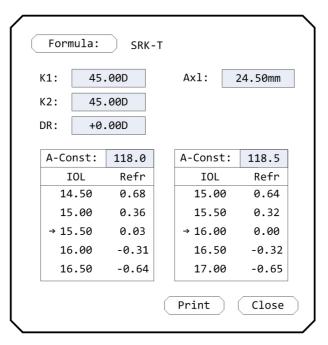


Figure 4-11 IOL Calculation Dialog Box

To perform IOL Calculation, follow these steps:

- Select Formula. Six formulas can be selected by touching the [Formula:] button. These formulas include: SRK-II, SRK-T, Holladay, Binkhorst-II, Hoffer-Q and Haigis (standard).
- Input K Readings. K readings can be input in Main Screen instructed in Section 3. They can also be input in IOL Calculation Dialog Box.
- 3. **Input Desired Refraction**. Input Desired Refraction in the edit box labeled "DR:" . The Desired Refraction use diopter as its unit.
- 4. **Check Axial Length**. Check the using of proper Axial Length. The Axl is filled automatically if measurement finished. One can modify the Axl value.

- 5. Check Anterior Chamber Depth. While using Haigis (standard) formula, ACD is needed as a parameter.
- Two IOL Calculation Tables are available 6. **Input A-Const**. with IOL power versus refraction. Two A-Constant is needed for these calculations.
- 7. Calculation. When all parameters above are input, the calculation will perform automatically. Any change of these parameters will cause the calculations performed accordingly.



## IMPORTANT

It is important to make sure proper Axl and ACD values are used for IOL Calculations for they are

8. Print. Select [Print] button to print the IOL Calculation Tables with corresponding patient information.

## Section 5 PACHYMETRY OPERATION (For

### SPA-100P and SPA-100AP)

The Pachymetry mode of the SPA-100 series allows for measuring and mapping corneal thickness.

By applanating the Pachymeter probe to a patient eye, an ultrasound echogram can be obtained, shown on the screen and translated into corneal thickness measurement. The measurement is displayed and can be stored within the system's memory at a corresponding location of the corneal map.

After completion of measurements, a hardcopy may be obtained of the results by using the optional thermal printer.

# 5.1 ENTERING PACHYMETRY AND BACK TO MAIN SCREEN

Touch the [Enter PACHYMETER] button on the Main Scree (Figure 3-1) to Enter Pachymeter Mode. Touch the [Patient] button on the top-left corner of the Pachymetry Screen (Figure 5-1) return back to Main Screen.

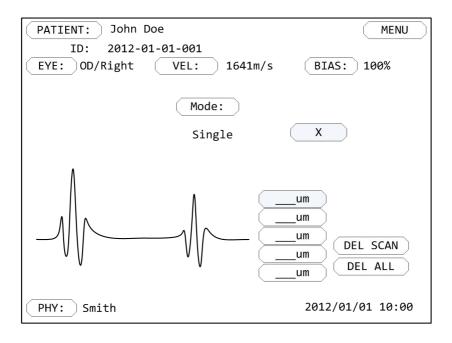


Figure 5-1 Pachymetry Screen

### **5.2 SYSTEM SETUP**

#### **ENTERING PHYSICIAN NAME**

Three different physicians' name may be entered and permanently stored within the SPA-100 memory. Refer to Section 4.2 for more information.

#### **VELOCITY SETUP**

Velocity of ultrasound in cornea is adjustable. Touch the [VEL: ] button on the upper center of the Pachymetry Screen, the Corneal

Velocity Setup Dialog Box (Figure 5-2) is shown.

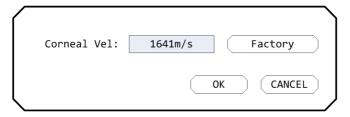


Figure 5-2 Corneal Velocity Setup Dialog Box

Edit the velocity in the edit box, or one can restore the velocity to Factory Setup. The default velocity is 1641m/s. Press the [OK] button to confirm the velocity.

#### **MEASUREMENT BIAS**

The measurement bias is preset to 100%. The user should select the appropriate value for measurement bias based on the surgical technique and/or surgical apparatus to be used for the particular procedure. The value can be changed in Bias Setup Dialog Box (Figure 5-3) by shown by touching the [BIAS:] button.

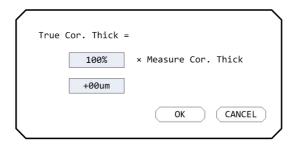


Figure 5-3 Bias Setup Dialog Box

The biased value is affected by both percentage and offset. For

example, if the percentage bias is set to 50%, and offset bias is set to -10um, the pre-biased cornea thickness is 600um, then the biased value is  $600 \times 50\% + (-10) = 290$ um.

The bias parameters are shown on the right of the [BIAS:] button.



## ! IMPORTANT

It is important to setup the velocity and bias properly before taking measurement for the change of velocities and examination mode will lead to automatic delete of obtained measurements.

#### **IOP CORRECTION**

The IOP correction formula is based on published data (Ehlers and others -1975). If desired, the user can adjust the parameters in the IOP Correction Dialog Box (Figure 5-4).

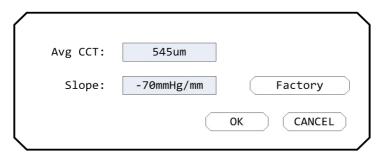


Figure 5-4 IOP Correction Dialog Box

One can edit average CCT and Slope in edit boxes. Press [Factory] button will restore the parameters to default values. The default settings are:

Avg. CCT = 0.545mm Slope = -70 mmHg/mm

Remember that [OK] button needed to be pressed to confirm the adjustment.

#### 5.3 CALIBRATION

It is recommended that the functionality of verified by means of the calibration procedure prior to performing actual measurements. The SPA-100 series provide a stainless steel Calibration Slice for Pachymetry calibration.

To perform the calibration procedure, follow these steps:

1. Enter Pachymetry Calibration Screen (Figure 5-5) by select the [Calibration...] item of the Menu of Pachymetry Screen.

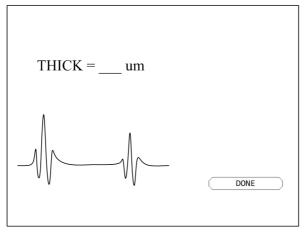


Figure 5-5 Pachymetry Calibration Screen

- 2. Place a small amount of ultrasound coupling gel (water is acceptable) onto the Calibration Slice (Figure 5-6).
- 3. Place the probe onto the center of Calibration Slice. The probe should be placed perpendicular to the slice.



Figure 5-6 Pachymetry Calibration Slice

- 4. Observe the measurement displayed on the touch screen. The measurement will be retrieved automatically.
- 5. Read the calibration THICK of the Calibration Slice labeled on the Calibration Slice storage box.
- 6. Verify that the measurement retrieved is THICK  $\pm\,10$  micron. If it is not, repeat the calibration procedure until an acceptable measure is obtained
- 7. If a measure within THICK  $\pm$  10 micron cannot be obtained, contact to your local representative for assistance.
- 8. Return to Pachymetry Screen by press the [DONE] button.

#### 5.4 PATIENT PREPARATION

Apply a drop of topical anesthetic to the eye that is to be measured prior to performing the corneal measurements.

The patient should be either seated or placed in a supine position. Providing a fixed target for the patient to view may assist in alignment of the probe.

#### 5.5 PATIENT EXAMINATION

Following entry of physician and patient information, corneal thickness measurements may be obtained.

#### **MEASUREMENT MODES**

The user is provided with two measurement modes:

1. **Single Mode**. This mode allows for the user to obtain five readings at one point along the corneal surface. (Figure 5-7)

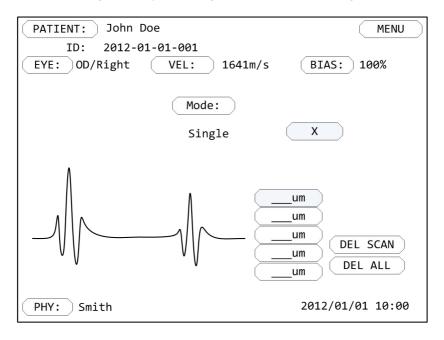


Figure 5-7 Single Mode of Pachymetry

2. **Map Mode**. This mode allows for the user to obtain five readings at five different points along the corneal surface. (Figure 5-8)

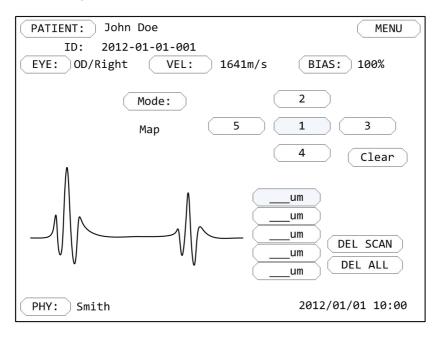


Figure 5-8 Map Mode of Pachymetry

It should be noted that each reading which is obtained actually consists of the average obtained from 10 individual measurements.

To select the desired mode, touch the [MODE:] button to switch between the two modes.

#### MAP ORDERING SETUP

The measurement point can be changed automatically according to the map ordering. Set the map ordering in the Map Ordering Setup

Dialog Box (Figure 5-9) shown by selecting the [Map ordering...] item in the menu.

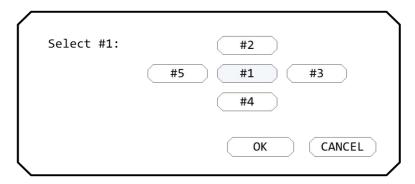


Figure 5-9 Map Ordering Setup Dialog Box

The "Select #X" label indicates the ordering number of the current press of the check button. Press [OK] button to confirm the ordering.

#### **MEASUREMENTS – SINGLE MODE**

- 1. Make sure the cornea velocity properly setup. The default velocity is 1641m/s.
- 2. Make sure the bias is properly setup.
- 3. Select measurement eye within "OD/Right" and "OS/Left" by touching [EYE:] button.
- 4. Make sure the probe tip is *clean* and *dry*.
- 5. Place the probe tip onto the cornea starting at the optical center. Making certain that the probe tip is *perpendicular* to the surface of the cornea.
- 6. The echogram will show on the screen. If not, one needs to press the foot pedal to activate the measurement function.
- 7. Upon completion of an acceptable measurement, the average reading will be displayed on right of the screen in the check

button. When cornea thickness is obtained, the echogram will be hidden, the average and standard deviation of obtained readings and IOP correction will displayed on the left of the screen.

- 8. Raise the probe away from the cornea, next reading will start automatically.
- 9. Repeat steps 2-5 to obtain other readings. Repeat for five readings.
- 10. Individual readings can be deleted by selecting the particular reading to delete and touching the [DEL SCAN] button or press the foot pedal. All readings may be deleted by touching the [DEL ALL] button.
- 11. Select [Print] item in the menu (shown by touching the [MENU] button on the top-right corner) to print the obtained data along with patient information.

#### **MEASUREMENTS – MAP MODE**

- 1. Make sure the cornea velocity properly setup. The default velocity is 1641m/s.
- 2. Make sure the bias is properly setup.
- 3. Select measurement eye within "OD/Right" and "OS/Left" by touching [EYE:] button.
- 4. Make sure the probe tip is *clean* and *dry*.
- 5. Place the probe tip onto the cornea starting at the optical center. Making certain that the probe tip is *perpendicular* to the surface of the cornea.
- 6. The echogram will show on the screen. If not, one needs to press the foot pedal to activate the measurement function.
- 7. Upon completion of an acceptable measurement, the average reading will be displayed on right of the screen in the check

- button. When cornea thickness is obtained, the echogram will be hidden, the average and standard deviation of obtained readings and IOP correction will displayed on the left of the screen.
- 8. Raise the probe away from the cornea, next reading will start automatically.
- 9. Repeat steps 5-8 to obtain other readings. Repeat for five readings.
- 10. Individual readings can be deleted by selecting the particular reading to delete and touching the [DEL SCAN] button or press the foot pedal. All readings may be deleted by touching the [DEL ALL] button.
- 11. When all five readings are obtained for a certain point, raise the probe, a tick sound will generate direct the user to take measurement for another point. Just applanating the point on the other point will make the measurement of another point started automatically.
- 12. Repeat 5-11 for all five points' measurements.
- 13. The measurements can be deleted for all five points by touching the [Clear] button on the bottom-right corner of the map check buttons.
- 14. Select [Print] item in the menu (shown by touching the [MENU] button on the top-right corner) to print the obtained data along with patient information.

## **Section 6 MAINTENANCE**

The maintenance described below should be performed routinely so that the SPA-100 series are always operating in a safe and reliable manner.

#### 6.1 SYSTEM GENERAL INSPECTION

- 1. Be sure the instrument is located on a flat, level and stable surface and in a comfortable viewing position.
- 2. Examine each item for any defects or damage.
- 3. Visually examine the instrument, prior to use, for loose or disconnected cables or cables which appear frayed or broken.
- 4. Verify that operational conditions are such as to prevent either small objects or liquids from entering the unit in order to prevent component damage or a fire hazard.
- Verify that the foot pedal functions properly, is placed in a convenient location, and that the cable is free from becoming entangled.

#### 6.2 CLEANING

Periodic cleaning of the SPA-100 series with a soft cloth is all that

is usually required to keep the system looking new. Stubborn stains



## CAUTION

DO NOT soak probes in alcohol for extended periods of time, as damage can occur.

may be removed using a soft cloth dampened with a mild detergent solution.



## CAUTION

Never use strong solvents such as benzene, acetone, thinner or abrasive cleaners as these may damage the

Place the probe into a suitable receptacle that allows the applanating surface and adjacent 2-3 mm of the probe to be immersed into 70% isopropyl alcohol. After a five minute soaking period, wash the probe tip under running water and then dry. The remainder of the probe and cord may be wiped down with alcohol.

#### 6.3 STORAGE

When not in use, it is recommended that the power cord be disconnected and the SPA-100 series be covered to keep dust and debris from entering the system. While stored the SPA-100 equipment should be protected from temperature extremes and humidity which can cause condensation within the unit. The probes should be removed from the main unit and stored within the package.

## Appendix A SPECIFIC STRUCTURES VELOCITY

## **TABLE**

Table A-1 specific structures velocity

Structures	Velocity (m/s)
Cornea	1641
ACD	1532
Crystalline Lens	1641
Vitreous	1532
PMMA IOL	2718
Acrylic IOL	2120
Silicone IOL	1049

## **Appendix B TABLE OF IOL CONSTANTS**

Table B-1 IOL Constants

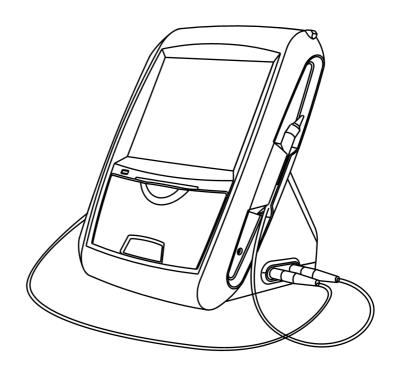
A-Constant	S-Factor	ACD	A-Constant	S-Factor	ACD
110.0	-3.31	0.30	113.0	-1.61	2.05
110.1	-3.25	0.36	113.1	-1.55	2.11
110.2	-3.19	0.41	113.2	-1.50	2.16
110.3	-3.14	0.47	113.3	-1.44	2.22
110.4	-3.08	0.53	113.4	-1.38	2.28
110.5	-3.02	0.59	113.5	-1.32	2.34
110.6	-2.97	0.65	113.6	-1.27	2.40
110.7	-2.91	0.70	113.7	-1.21	2.46
110.8	-2.85	0.76	113.8	-1.16	2.51
110.9	-2.80	0.82	113.9	-1.10	2.57
111.0	-2.74	0.88	114.0	-1.04	2.63
111.1	-2.68	0.94	114.1	-0.98	2.69
111.2	-2.63	1.00	114.2	-0.93	2.75
111.3	-2.57	1.06	114.3	-0.87	2.81
111.4	-2.51	1.11	114.4	-0.82	2.86
111.5	-2.46	1.17	114.5	-0.76	2.92
111.6	-2.40	1.23	114.6	-0.70	2.98
111.7	-2.34	1.29	114.7	-0.64	3.04
111.8	-2.29	1.35	114.8	-0.59	3.10
111.9	-2.23	1.40	114.9	-0.53	3.16
112.0	-2.17	1.46	115.0	-0.48	3.21
112.1	-2.12	1.52	115.1	-0.42	3.27

112.2	-2.06	1.58	115.2	-0.36	3.33
112.3	-2.00	1.64	115.3	-0.31	3.39
112.4	-1.95	1.70	115.4	-0.25	3.45
112.5	-1.89	1.76	115.5	-0.19	3.51
112.6	-1.84	1.81	115.6	-0.14	3.56
112.7	-1.78	1.87	115.7	-0.08	3.62
112.8	-1.72	1.93	115.8	-0.02	3.68
112.9	-1.66	1.99	115.9	0.03	3.74

(to be continued)

A-Constant	S-Factor	ACD	A-Constant	S-Factor	ACD
116.0	0.09	3.80	118.0	1.22	4.96
116.1	0.15	3.86	118.1	1.28	5.02
116.2	0.20	3.91	118.2	1.34	5.08
116.3	0.26	3.97	118.3	1.39	5.14
116.4	0.32	4.03	118.4	1.45	5.20
116.5	0.37	4.09	118.5	1.51	5.26
116.6	0.43	4.15	118.6	1.56	5.32
116.7	0.49	4.21	118.7	1.62	5.37
116.8	0.54	4.26	118.8	1.68	5.43
116.9	0.60	4.32	118.9	1.73	5.49
117.0	0.66	4.38	119.0	1.79	5.55
117.1	0.71	4.44	119.1	1.85	5.61
117.2	0.77	4.50	119.2	1.90	5.66
117.3	0.83	4.56	119.3	1.96	5.72
117.4	0.88	4.62	119.4	2.02	5.78
117.5	0.94	4.67	119.5	2.07	5.84
117.6	1.00	4.73	119.6	2.13	5.90

117.7	1.05	4.79	119.7	2.19	5.96
117.8	1.11	4.85	119.8	2.24	6.02
117.9	1.17	4.91	119.9	2.30	6.07
			120.0	2.36	6.13



## **APScan Sync**

PC Workstation for SPA-100

**Operators Manual** 

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## 1 INTRODUCTION

The APScanSync software running in Windows system is used to retrieve captured data in SPA-100 Series. Connecting the SPA-100 can be connected to PC with USB cable. APScanSync can retrieve Biometry Data, Pachymetry Data and Patient Data from SPA-100 instruments through USB connection. Users can than store the information for further manipulations.

#### 1.1 Main Screen

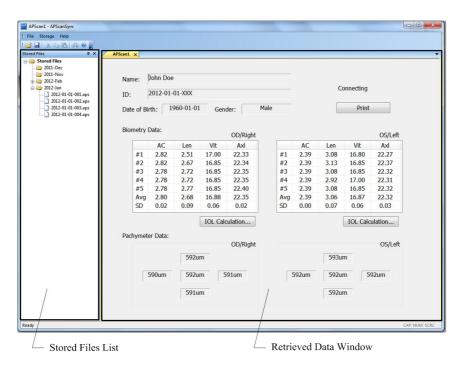


Figure 1-1 Main Screen

The stored files are listed on the left side of the Main Screen. These folders and files are included in the Storage Folder.

The retrieved data are located on the right side of the screen, including Patient Information, Biometry data and Pachymetry data for Left and Right eyes.

### 2 INSTALLATION

The APScanSync software running in Windows system is used to retrieve captured data in SPA-100 Series. Connecting the SPA-100 can be connected to PC with USB cable. APScanSync can retrieve Biometry Data, Pachymetry Data and Patient Data from SPA-100 instruments through USB connection. Users can than store the information for further manipulations.

#### 2.1 Installation of USB Driver for Windows XP

To connect the SPA-100 Series to a personal computer with a USB cable, it is necessary that you install a dedicated USB driver, exclusively for the instrument. Install the USB driver according to the following instructions:

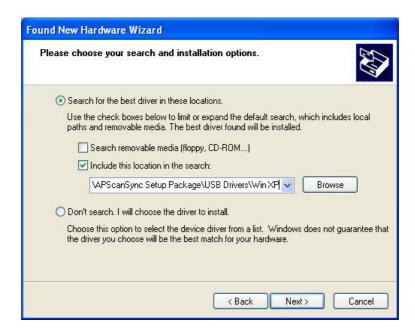
1. When the "Found New Hardware Wizard" dialog box is displayed. Select "No, not this time" then click the [Next] button.



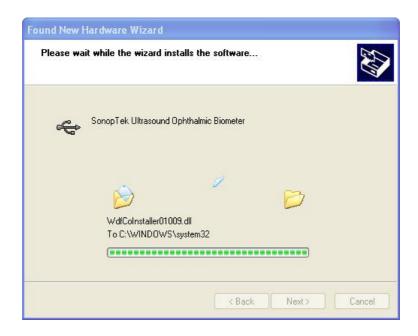
2. Select "Install from a list or specific location (Advanced)" in the displayed dialog box and click the [Next] button.



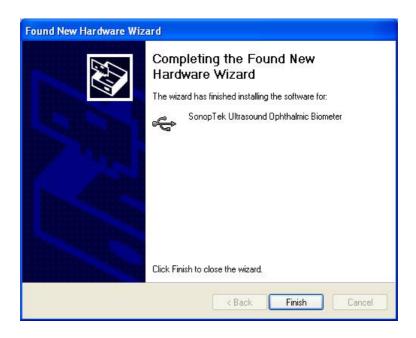
 Select "Search for the best driver in these locations" in the displayed dialog box and check "Include this location in the search".
 Specify the folder where Biometer.inf is saved and click the [Next] button.



4. The following dialog box will be displayed when the installation is processing.



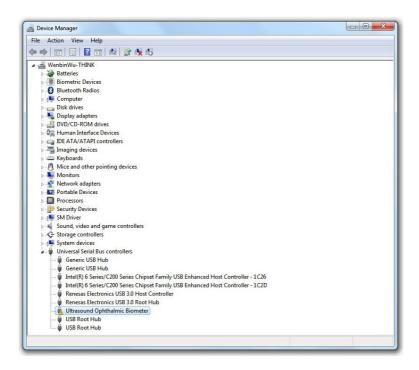
5. The following dialog box will be displayed when installation finished. Click the [Finish] button.



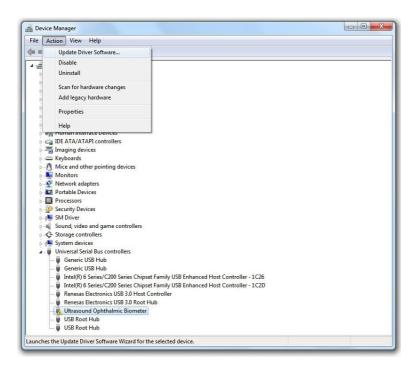
#### 2.2 Installation of USB Driver for Windows 7

To connect the SPA-100 Series to a personal computer with a USB cable, it is necessary that you install a dedicated USB driver, exclusively for the instrument. Install the USB driver according to the following instructions:

1. Open Device Manager and select the "Ultrasound Ophthalmic Biometer" device as below.



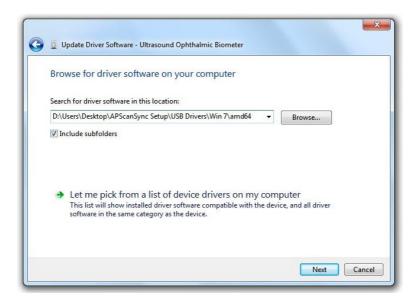
2. Select Action->Update Driver Software...



3. Select "Browse my computer for driver software".



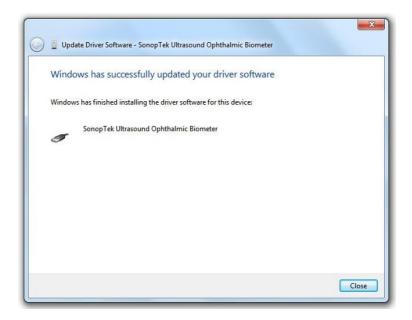
4. Specify the folder where Biometer.inf is saved. For 64bit Windows7, it is located in the subfolder "amd64"; for 32bit Windows7, it is located in the subfolder "x86".



5. If a Windows Security dialog box is displayed, select "Install this driver software anyway".



6. When driver installation finished, the following dialog box is displayed. Click [Close] button.



## 2.3 Installation of APScanSync Software

- 1. Execute the SETUP.EXE by double click the file.
- 2. The following display appears (Figure 2-1). Click [Next].



Figure 2-1 Step 1

3. The dialog box to specify a folder as the installation destination of the software is displayed (Figure 2-2). Change the folder if necessary. Then, click [Next].

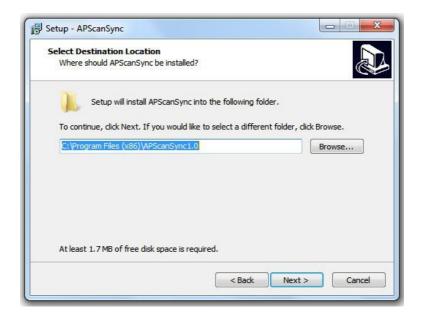


Figure 2-2 Step 2

4. The dialog box to specify a Start Menu Folder is displayed (Figure 2-3). Change the Start Menu Folder is necessary. Then click [Next].

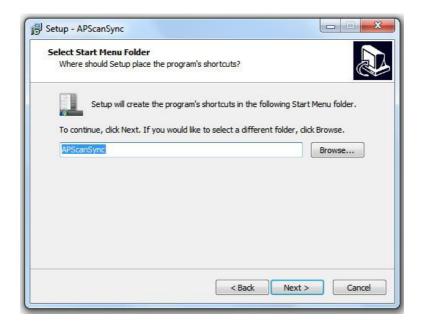


Figure 2-3

5. The dialog box to specify the creation of a desktop icon is displayed (Figure 2-4). Select to create a desktop icon or not. Then click [Next].

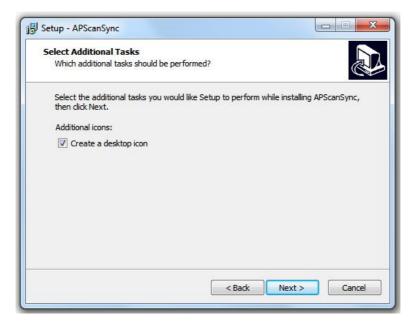


Figure 2-4

6. The dialog box to review the installation parameters is displayed (Figure 2-5). Select [Install] to start the installation.

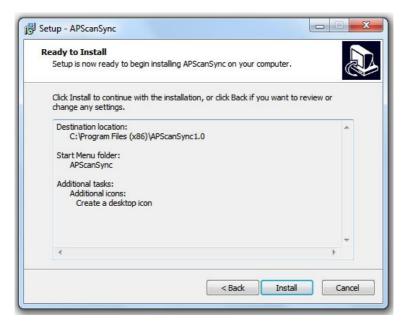


Figure 2-5

7. When the following dialog box is displayed, the installation is completed. Click [Finish] to exit the setup program.



Figure 2-6

## **3 OPERATION**

## 3.1 Storage List

The Storage List will list the files and sub-folders of a selected folder automatically.

The Storage Folder can be select through menu: Storage->Select Storage Folder, within the dialog box (Figure 3-1). Users need to restart the software to make the modification available.

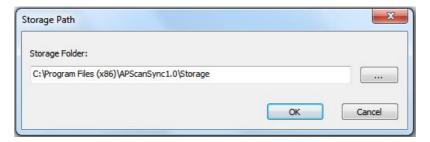


Figure 3-1 Select Storage Folder

#### 3.2 Data Retrieve

When patient information is changed all new data is captured, APScanSync will retrieve the changed data automatically when the instrument is connected and the driver is installed properly.

When the instrument is connected to APScanSync at the first time, a message box will pop up to notice the connection. Users can select YES to confirm the connection or NO to reject the connection. Users can connect to instrument after rejection by select menu: File ->

Connect to Device.

When connection established, APScanSync will response to data changes automatically and retrieve new data accordingly.

The most important is when the [New Patient] button is pressed on the instruments, APScanSync will generate a new file automatically to receive data for a new patient.

These newly retrieve data are NOT saved automatically, users have to save these files as their responsibility for further use.

The connecting state of a file is marked on the top-right corner of the Retrieved Data Window.

Users can print the retrieved data by press the [Print] button.

#### 3.3 IOL Calculation

IOL Calculation can be made by selecting the [IOL Calculation...] button under the Biometry Data List Box. The IOL calculation dialog is shown as figure 3-2.

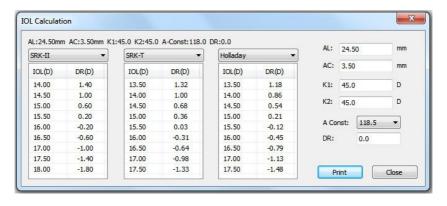


Figure 3-2 IOL Calculation Dialog Box

Edit the parameters in the boxes, and print the IOL calculation

results by selecting the [Print] button. Users can select formula from 6 formulas for each table in the drop down list box.

## 3.4 File Format

The default file format called APS files with the extension name of ".aps". Users can select menu: File -> Save to save the file as an APS file. Users can also select menu: File -> Save As to save the file as APS file or Text file will the extension name of ".txt".

# 4 SPECIFICATION REQUIRED

## 4.1 Computer requirements

Platform	IBM/PC-AT compatible machine
CPU	Pentium III 1GHz or more
Memory	256MB or more
Hard Disk	The empty capacity should be 1GB or more
Display	VGA 1024*768 or larger.
os	Tested for Windows XP, Windows 7 (32/64bit)
Other	USB2.0 available