



PACSCAN™ SERIES
300A ♦ 300P ♦ 300AP
A-SCAN / PACHYMETER
INSTRUCTION MANUAL

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Section 1 INTRODUCTION

The PACSCAN™ series is the latest generation ophthalmic biometry instruments introduced by industry leading Sonomed. The series consists of three different models:

- **PACSCAN™ 300A.** This A-scan system allows for measuring the axial length (AXL), anterior chamber depth, and lens thickness of an eye and for calculating the associated IOL power for an implanted lens.
- **PACSCAN™ 300P.** This Pachymeter system allows for measuring and mapping corneal thickness.
- **PACSCAN™ 300AP.** This system seamlessly integrates the A-Scan and Pachymeter capabilities into a single system.

All 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 thereby making the system extremely portable, and the adjustable legs can be tilted to several angles for user comfort.

This manual is intended to provide a thorough overview of the PACSCAN™ series of instruments and their capabilities. Please also feel free to contact Sonomed customer service at 1-800-227-1285 at any time with questions or concerns regarding system use.

Thank you for your trust in Sonomed to provide for your ophthalmic biometry needs.

1.1

A-SCAN FEATURES

(For 300A and 300AP Models Only)

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

By placing the A-probe against a patient eye, a live A-Scan ultrasound pattern for an AXL measurement can be obtained. The image can 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 (depending on the specific program selected), 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 record to be printed may include the A-Scan image, table of IOL powers versus refraction, patient information, and user information.

Several features help to distinguish the Sonomed PACSCAN™ series including:

- Live A-Scan Display
- Gain Control
- Storage of 5 Scans for Later Review and IOL Calculation

- 5 Different Examination Modes
 - Cataract
 - Dense Cataract
 - Aphakic
 - Pseudophakic (with three IOL types: PMMA, Acrylic or Silicone)
 - Manual
- Velocity Compensation for Pseudophakic Lens Type (PMMA, Acrylic or Silicone)
- A-Scan Measurement Review Capability
 - Axial Length, Anterior Chamber Depth, and Lens Thickness Measures for Each Scan
 - Axial Length Average and Standard Deviation for Up to 5 Scans
- A-Scan Measurement Review Mode
- Six Available IOL Formulas
 - Binkhorst
 - Regression-II
 - Theoretic-T
 - Holladay
 - Hoffer-Q
 - Haigis (optional)
- Immersion Capabilities
- 5 Customizable User Profiles
- Clinical Accuracy ± 0.1 mm
- User-Performed Calibration Check
- Self-Test Routines at Start-Up
- Standard or Soft-Touch Probe Styles Available

1.2

PACHYMETER FEATURES

(For 300P and 300AP Models Only)

As mentioned, the Pachymeter mode of the PACSCAN™ series allows for measuring and

mapping corneal thickness.

By placing the pachymeter probe against a patient eye, an ultrasound image can be obtained and translated into a corneal thickness measurement. The measurement is displayed and can be stored within the system's memory at a corresponding location on the corneal map.

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

Several features help to distinguish the Sonomed PACSCAN™ series including:

- Average and Standard Deviation Computed for Each Reading – Reading is Result of 256 Individual Measurements
- Multiple Corneal Maps with Graphical Display
- Measurement Range 0.30 mm to 1.00 mm
- Measurement Review Mode
- Selectable Bias and Corneal Velocity
- 5 Customizable User Profiles
- Accuracy Better Than ± 5 Microns
- Precision ± 1 Micron
- Resolution of 1 Micron
- Acceptance Angle of 10°
- Automatic Calibration Check and Probe Sensitivity Test
- Straight or Angled Probe Styles Available

Section 2

GETTING STARTED

2.1

UNPACKING

The PACSCAN™ system is carefully packed to prevent damage during shipment. Before unpacking, please note any visible damage to the outside of the shipping containers.

Each item should be checked in order to ensure that all ordered items have been received. The following table lists the standard items which should be received with each particular system (note: additional optional items may also have been ordered).

Item	System		
	300A	300P	300AP
PACSCAN™ Unit	•	•	•
Stylus Touch Pen	•	•	•
Foot Pedal	•	•	•
AC Adapter	•	•	•
Instruction Manual	•	•	•
A-Scan Probe	•		•
Coupling Gel	•		•
Pachymeter Probe		•	•
Printer with Paper	•	Opt.	•
Carrying Case	Optional		

Each item should be examined for any noticeable defects or damage that may have occurred during shipment. If any defect or damage exists, please call your local representative or Sonomed immediately to report the problem.

2.2 SAFETY CONSIDERATIONS



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

BEFORE OPERATION, the instrument and this manual should be reviewed for safety markings and instructions. Specific warnings and cautions are found throughout the manual where they apply. These must be followed to ensure safe operation and to maintain the instrument in a safe condition.

REVIEW any other manuals and instruments supplied with the system in the same manner.

KEEP this manual for future reference.

TERMS AS MARKED ON THE EQUIPMENT

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 AS USED IN THIS MANUAL

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

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

GENERAL WARNINGS

Use only the AC Adapter that is supplied with the system.

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 remove 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.

The system should be placed on a level, stable surface during operation. A system and cart combination should be moved with care. Quick stops, excessive force, and uneven surfaces may cause the system and cart combination to overturn.

2.2 SOMMAIRE DES MESURES DE SÉCURITÉ



POUR VOTRE PROTECTION, S.V.P. lire ces instructions de sécurité complètement avant d'installer et de mettre sous tension ou d'opérer le system.

AVANT L'UTILISATION, l'instrument et ce manuel devraient être revue pour prendre connaissance des instructions et des points de sécurité. Des avertissements spécifiques et précautions se retrouvent à diverses endroits où elles s'appliquent elles doivent être suivies pour assurer une opération et le maintien sécuritaire de l'instrument.

ATTENTION dans certain cas d'autres manuels pourraient être fournis avec cet appareil et devraient être revus de la même manière.

GARDER ce manuel pour référence future.

TERMES TEL QU'INSCRIT SUR L'ÉQUIPEMENT

ATTENTION - Risque potentiel de blessure ou dommage à la propriété ou à l'équipement même.

AVERTISSEMENT- Risque de blessure ou de perte de vie.

DANGER - Indique un risque immédiat de blessure.

TERMES TEL QU'UTILISER DANS CE MANUEL

ATTENTION - Risque de dommage à l'équipement ou à d'autres propriétés.

AVERTISSEMENT - Risque de blessure ou de perte de vie.

AVERTISSEMENTS GÉNÉRAUX

Utilisez seulement l'adaptateur à C.A. qui est fourni avec le système.

Afin d'éviter tout risque d'explosion ne pas utiliser ce produit en présence de produits inflammable. L'opération d'un produit électrique dans de tel conditions constitue un risque d'explosion.

Pour éviter tout risque de blessure ne pas retirer le couvercle ou le panneau.

NE PAS utiliser le produit sans couvercle et panneau bien en place.

NE PAS tenter de réparer le system sauf tel que décrit dans le manuel autrement référez vous à du personnel compétant.

MISE EN GARDE

NE PAS obstruer les trous de ventilation situés à l'arrière et dessous l'instrument et ne jamais recouvrir l'instrument durant l'opération.

Protéger contre tous petits objets ou liquides pouvant pénétrer l'instrument.

Débrancher l'instrument si il ne sera pas utiliser pour une longue période.

Le system doit être placé de niveau sur une surface stable durant l'opération. Le system et chariot doivent être déplacés avec soins. Les arrêts rapides, forces excessives, et surfaces inégales peuvent endommager le system.

2.3 SYSTEM SET-UP

CONNECTING ACCESSORIES

1. Place the PACSCAN on a flat level surface.
2. Connect the foot pedal cable connector to the rear panel of the system into jack labeled "FOOT PEDAL". Place the foot pedal on the floor.
3. Verify that the Power Switch located on the rear panel of the system is in the "OFF" position.
4. Connect the jack plug of the AC Adapter cable to the DC input jack located on the rear panel of the system.
5. Connect the AC Adapter to a proper AC power source (i.e. wall outlet):
 - 100 VAC / 60 Hz
 - 120 VAC / 60 Hz
 - 220 VAC / 50 Hz
 - 220 VAC / 60 Hz



CAUTION

This instrument may be damaged if operated with an AC adapter other than that provided.

6. Connect the probe connector (A-Scan probe or pachymeter probe) to the jack on the right side of the system labeled "PROBE". Before inserting be sure to line up the red indicator marks on both the jack and cable connector.

OPTIONAL PRINTER SET-UP

1. Place the printer on a flat level surface.
2. Connect one end of the printer cable to the matching connector on the printer's rear panel and the other end to the matching connector on the right side of the system labeled "PRINTER".
3. See the included printer instruction manual for paper loading and power up instructions.

POWER UP CHECK

1. Slide the Power Switch of the PACSCAN located on the rear panel to the "ON" position.
2. Verify that the green LED on the face of the system illuminates and that the Main Screen appears on the display (see Figure 2-1).

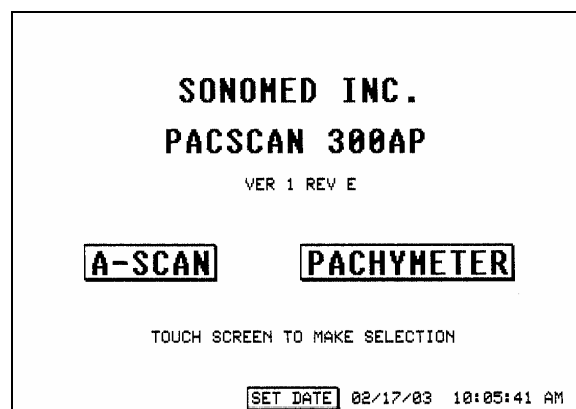


Figure 2-1. Main Screen Display



WARNING

In the event of loss of stored data including the system calibration values and user settings due to a discharged battery, a "STORED DATA LOST" warning message will be displayed. Please contact Sonomed service department for further assistance.

3. If either LED does not illuminate or Main Screen does not appear, immediately power OFF the system and contact your local representative or Sonomed for assistance.

USING THE TOUCH SCREEN

The touch screen provided with the PACSCAN 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 Stylus pen (do not use a pencil, pen, or other sharp object).

**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.

SCREEN CONTRAST ADJUSTMENT

1. From the Main Screen, select the **[SET DATE]** button at the bottom of the screen (see Figure 2-1). Verify that the Set Date and Time Screen appear on the display (see Figure 2-2).
2. To adjust the contrast, select the **[CONTRAST ↑]** or **[CONTRAST ↓]** button.

SETTING THE DATE AND TIME

1. From the Main Screen, select the **[SET DATE]** button at the bottom of the screen (see Figure 2-1). Verify that the Set Date and Time Screen appear on the display (see Figure 2-2).

Figure 2-2. Set Date and Time Screen Display

2. To edit the date, select the **[ENTER DATE]** button. Enter the appropriate two digits for the month (for example, “01” for January), and then select the **[ENTER]** button. Repeat for the day and year.

3. After entering the year, the display will return to the Main Screen. Verify that the correct date is displayed on the bottom right corner of the screen.
4. From the Main Screen, select the **[SET DATE]** button at the bottom of the screen (see Figure 2-1). Verify that the Set Date and Time Screen appears on the display (see Figure 2-2).
5. To edit the time, select the **[ENTER TIME]** button. Enter the appropriate two digits for the hour, and then select the **[ENTER]** button. Repeat for entering minutes. Hit the **[AM/PM]** button to select and then the **[ENTER]** button.
6. After entering the year, the display will return to the Main Screen. Verify that the correct time is displayed on the bottom right corner of the screen.

Section 3

A-SCAN OPERATION AND CLINICAL USE

(For 300A and 300AP Models Only)

The A-Scan mode of the PACSCAN™ 300AP allows for measuring the axial length (AXL) of an eye and calculating the associated IOL power for an implanted lens.

By placing the A-probe against a patient eye, a live A-Scan ultrasound pattern for an AXL measurement can be obtained. The image can 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 (depending on the specific program selected), 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 the A-Scan image, table of IOL powers versus refraction, patient information, and user information.

3.1 SELECTING A-SCAN MODE

1. Touch the [**A-SCAN**] button on the Main Screen (see Figure 3-1).
2. Ensure the Calibration Screen appears.

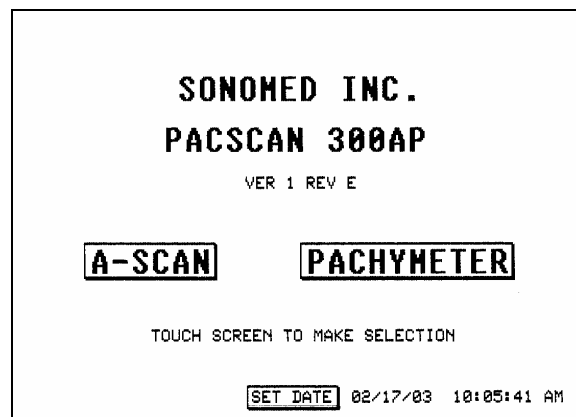


Figure 3-1. Main Screen Display

3.2 CALIBRATION

It is recommended that the functionality of the PACSCAN™ be verified by means of the calibration procedure prior to performing actual measurements.

The PACSCAN™ defaults into the Calibration Screen every time the A-Scan mode is selected.

To perform the calibration procedure, follow these steps:

1. Place a small amount of ultrasound coupling gel onto the tip of the A-scan probe.
2. Place the probe onto the calibration cylinder located on the right side of the system. The probe should be placed perpendicular to the cylinder.
3. Observe the measurement displayed on the touch screen. The measurement will freeze once it has stabilized and a calibration status message will be displayed.

4. Verify that the measurement obtained is 10.00 ± 0.1 mm. If it is not, repeat the calibration procedure until an acceptable measure is obtained.

If necessary, the gain control may be adjusted by touching the [**MIN**] and [**MAX**] buttons at the bottom center of the Calibration Screen. The resulting gain as a percentage of the maximum will be displayed. Alternatively, the [**AUTO GAIN**] button can be selected, which will instruct the PACSCAN™ to automatically adjust the gain setting.



IMPORTANT

If a measure within 10.00 ± 0.1 mm cannot be obtained, contact Sonomed service department for assistance.

It is recommended that calibration be performed prior to obtaining measurements; however, the calibration mode can be skipped if so desired by touching any of the other menu buttons on the right side of the screen when the Calibration Screen appears.

3.3

SYSTEM SET-UP

ENTERING USER INFORMATION

Up to five (5) different user profiles may be entered and permanently stored within the PACSCAN™ memory. User profiles allow for user identification and selection of a particular IOL formula and associated constants.

1. **Entering / Editing User Identification.** Touch the [**USER DATA**] button. Verify that the User Data Screen appears (see Figure 3-2).

USER1: DR. JONES
 FORMULA: THEORETIC-T
 A1=115.8D
 A2=115.8D

MAIN SCR
 PATIENT
 MEASURE
 IOL CALC
 CONSTANTS

02/17/03 10:29:39 AM

Figure 3-2. User Data Display

Touch the [**ADD USER**] button to add a new user profile, or the [**EDIT**] button to edit an existing user profile. Enter the name and/or ID of the user by touching the appropriate alphanumeric buttons. When finished, touch the [**ENTER**] button.

Touch the [**USER#**] button to advance to the next user selection.

Touch the [**DONE**] button when finished.

2. **IOL Formula Selection.** Within the User Data Screen, touch the [**FORMULA**] button to scroll through the different available IOL formulas. Note that default values for the associated constants are given with each formula. The constant default values are shown in Table 3-1.

IOL constants (main and alternate) are entered two per user for each of five users for a total of 10 constants.

Table 3-1
IOL Formula Constant Default Values

IOL Formula	Constants	Default Values
Hoffer-Q	ACD	3.68 mm
Theoretic-T	A-Constant	115.8 D
Regression	A-Constant	115.8 D
Holladay	S-Factor	-0.02 mm
Binkhorst	ACD	3.68 mm
Haigis (option)	A-Constant	115.8 D

In order to change the associated constants, touch the [**CONSTANTS**] button. Verify the Constants Screen appears (see Figure 3-3).

USER1: DR. JONES
FORMULA: THEORETIC-T
 A1: 115.8D LIMITS: 110D-130D
 A2: 115.8D

A-CONSTANT	S-FACTOR	ACD
1 115.8D	-0.02MM	3.68 MM
2 115.8D	-0.02MM	3.68 MM

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

02/17/03 10:31:48 AM

Figure 3-3. Constants Screen Display

As shown, all of the constants are displayed in the table of the Constants Screen. Select the [**1**] or [**2**] button to edit the appropriate constant. Touch the [**DONE**] button when finished.

ENTERING PATIENT INFORMATION

Patient information including name, identification number, K readings, and eye to be examined can be stored within PACSCAN™ memory. Only one patient may be stored at a time, but the information will remain until overwritten.

1. Touch the [**PATIENT**] button. Verify that the Patient Screen appears (see Figure 3-4).

PATIENT: JOHN DOE
 ID#: 123-45-6789
 EYE EXAMINED: RIGHT
 K-READINGS <D OR MM>: K1=44.00D
 K2=42.50D

A	B	C	D	E	F	G	H
I	J	K	L	M	N	O	P
Q	R	S	T	U	V	W	X
Y	Z	1	2	3	4	5	6
7	8	9	0	.	-	<	>

DELETE BSPACE

02/17/03 10:41:31 AM

Figure 3-4. Patient Screen Display

2. Within the Patient Screen, enter information for a new patient by touching the [**NEW PAT**] button or edit the existing patient information by touching the [**EDIT**] button.
3. Enter the patient name by touching the appropriate alphanumeric keys. When finished entering the name, touch the [**ENTER**] button.
4. Enter the patient ID number, and touch the [**ENTER**] button when finished.
5. Enter the eye to be examined by touching the [**OD / OS**] button to toggle between the left and right. When the correct eye has been selected, touch the [**ENTER**] button.
6. Enter the K1 and K2 readings touching [**ENTER**] after each reading. The K1 and K2 readings may be entered in either Diopters (range of 20.00D to 60.00D) or as radius of curvature (range 5.63mm to 16.87mm). Touch the [**DONE**] button when finished entering the patient information.

! WARNING

The PacScan assumes a keratometer index of refraction of 1.3375 for converting K readings. If entering K readings in millimeters which were obtained using a keratometer with a different index, the values must first be manually converted to Diopters and then entered.

3.4 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.

If an applanating device is to be used, bring the patient's forehead into contact with the cross bar and rest the chin on the chin support. Adjust the chin support so that the patient's eyes are approximately 1" to 2" below the cross bar.

NOTE: When using an applanating device for this procedure, it is not recommended that the head strap be utilized.

WATER IMMERSION TECHNIQUE

The patient should be seated with their head tilted slightly back. An ordinary chair is usually all that is needed, although in certain difficult cases, both patient and user will benefit from the use of a regular examination chair with headrest. Place a towel on the patient's shoulder. Consult

the instructions supplied with the immersion shell for further directions regarding use of the shell.

3.5 PATIENT EXAMINATION

Following entry of user and patient information, A-scan measurements may be obtained. Select the [**MEASURE**] button from any screen to display the Measure Screen (see Figure 3-5).

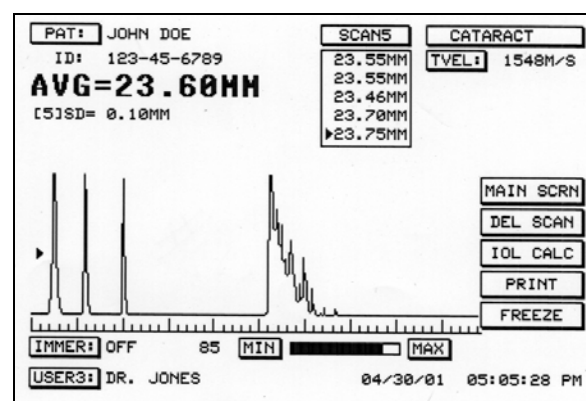


Figure 3-5. Measure Screen Display

DIRECT CONTACT SCANNING IN AUTOMATIC CAPTURE MODE

The PACSCAN™ is able to recognize an acceptable A-scan pattern and automatically capture the image, depending upon the type of measurement to be made.

1. **Examination Mode.** Ensure the correct examination mode is selected as indicated by the mode button in the upper right corner of the 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:

- Cataract
- Dense Cataract

- Aphakic
- Pseudophakic

When Pseudophakic mode is selected, one of three different pseudophakic lens types (PMMA, Acrylic or Silicone) may be selected using the [LENS] button. The tissue velocity will be automatically adjusted for the selected lens type.

2. **Tissue Velocity.** Ensure the appropriate tissue velocity is selected as indicated in the upper right corner of the Measure Screen (the system default tissue velocity is 1548 m/s). See Appendix A for standard values of tissue velocity used in the PACSCAN™.

The tissue velocity may be changed by first touching the [TVEL] button to display the Tissue Velocity Screen (see Figure 3-6).

PATIENT: JOHN DOE
ID#: 123-45-6789
EYE: RIGHT
CATARACT
TVEL: 1548M/S

1	2	3	4	5	BSPACE
6	7	8	9	0	ENTER

02/17/03 10:55:52 AM

Figure 3-6. Tissue Velocity Screen Display

Touch the [TVEL] button to edit the tissue velocity, enter the appropriate number, and touch the [ENTER] button. Verify that the tissue velocity has changed when returned to the Measure Screen.

3. **Immersion Option.** Ensure that the immersion option is OFF as indicated in the lower left corner of the Measure Screen. The immersion option may be toggled between ON and OFF by touching the [IMMER] button.

4. **Scan Eye.** Instruct the patient to look towards the red 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 pattern will be displayed and no further forward movement should be made.
5. **Automatic Scan Capture.** If the scan meets all the parameters of the selected examination mode, it will immediately be frozen, saved and a long audible tone will be emitted signifying that the instrument has accepted the measurement.

If necessary, the gain control may be adjusted by touching the [MIN] and [MAX] buttons at the bottom center of the Measure Screen. The resulting gain as a percentage of the maximum will be displayed. The default gain is 80%; however a gain of 84 to 86 has been shown to give satisfactory results for most eyes. The gain setting may not be changed for any scan which has already been frozen.

Once accepted, the scan pattern will be displayed on the screen; the axial length will be calculated and stored under "SCAN 1" in the upper center of the Measure Screen. The location of the key structures in the scan waveform will be indicated by flashing gate markers displayed above the waveform. The anterior chamber depth and lens thickness will also be displayed (except for Pseudophakic eye where a default lens thickness is used or for an Aphakic eye).



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.

6. **Repeat.** The protocol can be repeated to obtain up to five (5) scans. As the scans are captured, the axial length for each is displayed in the upper center 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 [SCAN#] button to scroll through the captured scans.
7. **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 system memory, and will exclude the associated axial length from the average and standard deviation calculations. If all scans are no longer desired, they may all be deleted by touching the [CLR SCANS] button.
3. **Immersion Option.** Ensure that the immersion option is OFF as indicated in the lower left corner of the Measure Screen. The immersion option may be toggled between ON and OFF by touching the [IMMER] button.
4. **Scan Eye.** Instruct the patient to look towards the red 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 pattern will be displayed and no further forward movement should be made.
5. **Image Capture.** Once an acceptable A-scan pattern is obtained, step on the footpedal or touch the [FREEZE] button to capture the image.

DIRECT CONTACT SCANNING IN MANUAL MODE

The PACSCAN™ also provides the ability to manually capture A-scan images.

1. **Examination Mode.** Ensure the manual examination mode is selected as indicated in the upper right corner of the Measure Screen. The examination mode may be changed by touching the mode button until the desired mode is shown.
2. **Tissue Velocity.** Ensure the appropriate tissue velocity is selected as indicated in the upper right corner of the Measure Screen (the system default tissue velocity is 1548 m/s).

The tissue velocity may be changed by first touching the [TVEL] button to display the Tissue Velocity Screen (see Figure 3-6).

Touch the [TVEL] button again to edit the tissue velocity, enter the appropriate number, and touch the [ENTER] button. Verify that the tissue velocity has changed when returned to the Measure Screen.

If necessary, the gain control may be adjusted by touching the [MIN] and [MAX] buttons at the bottom center of the Measure Screen. The resulting gain will be displayed in decibels.

6. **Measure Axial Length.** Once an A-scan pattern has been frozen, two (2) flashing vertical lines will appear on the display. These lines represent “gate 1” (left) and “gate 2” (right). In order to measure the axial length, place gate 1 just to the left of the corneal echo by using the **GATE 1:** [◀] [▶] controls and place gate 2 just to the left of the retinal echo by using the **GATE 2:** [◀] [▶] controls. The axial length displayed on the screen adjusts as the gates are moved.

The gates may be moved to measure other structures within the eye using the A-scan waveform and manually adjusting the tissue velocity accordingly.

Only one scan at a time may be saved when using the manual mode (averaging and standard deviation calculations are not available). Repeating the scanning procedure overwrites the existing scan information.

WATER IMMERSION TECHNIQUE

In addition to direct contact measurements, a water immersion technique may be used with the PACSCAN™ in order to completely eliminate concerns over corneal compression skewing results. The technique requires the use of a Prager scleral shell set and is described below using the automatic capture examination mode.

1. **Examination Mode.** Ensure the correct examination mode is selected as indicated in the upper right corner of the 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:

- Cataract
- Dense Cataract
- Aphakic
- Pseudophakic

2. **Tissue Velocity.** Ensure the appropriate tissue velocity is selected as indicated in the upper right corner of the Measure Screen (the system default tissue velocity is 1548 m/s).

The tissue velocity may be changed by first touching the [**TVEL**] button to display the Tissue Velocity Screen (see Figure 3-6).

Touch the [**TVEL**] button again to edit the tissue velocity, enter the appropriate number, and touch the [**ENTER**] button. Verify that the tissue velocity has changed when returned to the Measure Screen.

For Pseudophakic eye types use the [**LENS**] button to select the proper lens type and set the tissue velocity accordingly.

3. **Immersion Option.** Ensure that the immersion option is ON as indicated in the lower left corner of the Measure Screen. The

immersion option may be toggled between ON and OFF by touching the [**IMMER**] button.

4. **Prepare Prager Scleral Shell (see instructions provided with shell).** Unscrew the probe handle and pull it away from the probe tip. Insert the probe tip into the shell, advancing the probe until its tip is parallel with the line scored in the shell barrel. Once the correct position has been obtained, tighten the white nylon set screw to hold the probe in place.



IMPORTANT

Proper measurement data will only be obtained if the probe is properly placed in the Prager shell. Proper positioning must be confirmed by examining the captured scan waveform.

Once the probe has been positioned within the shell, attach a tubing set to the shell. Consult the instructions supplied with the Prager Shell for proper use.

Fill a 5cc or 10cc syringe with saline or BSS and connect to the catheter.

5. **Applanating the Prager Scleral Shell.** Rest the syringe on the towel which has been placed on the patient's shoulder, and hold onto the shell with probe in preparation for insertion. Direct the patient to look downward, toward the floor. Lift the patient's upper eyelid and insert the flared rim underneath the lid (the upper portion of the shell should make contact with the sclera while the lower part should be held away from the eye). Then direct the patient to look straight ahead toward the red fixation light in the probe tip. Pull the patient's lower eyelid down and *gently pivot* the lower portion of the shell into the lower fornix (i.e. *NOT* sitting atop a fold in the conjunctiva). This pivotal motion avoids contact with the cornea and ensures centering of the device around the limbus.

6. **Scan Eye.** Pick up the syringe from its place on the patient's shoulder and slowly inject the saline or BSS into the shell. As soon as the liquid fills the shell sufficiently to reach the tip of the probe (about 2cc), the characteristic waveforms of immersion biometry will be visible on the display. Gently tap the side of the probe tip to insure that no air bubbles have been trapped on the tip of the probe.
7. **Automatic Image Capture.** If the scan meets all the parameters of the selected examination mode, it will immediately be frozen, saved and a long audible tone will be emitted signifying that the instrument has accepted the measurement. The proper location of the corneal echo should be confirmed on the scan waveform (see Figure 3-7). The first spike seen on the waveform is the probe "main bang" followed by the corneal echo. The acceptable position for the corneal echo is indicated by the corneal echo window (horizontal bar) displayed below the waveform. The echo from the cornea must fall within this window for a proper immersion scan. If the corneal echo is outside of this window, the position of the probe within the Prager Shell should be adjusted accordingly.

If necessary, the gain control may be adjusted by touching the [MIN] and [MAX] buttons at the bottom center of the Measure Screen. The resulting gain as a percentage of the maximum will be displayed. Frequently a lower gain setting may be used in Immersion scanning than typically used in Direct Contact mode.

Once accepted, the scan pattern will be displayed on the screen; the axial length will be calculated and stored under "SCAN 1" in the upper center of the Measure Screen. The anterior chamber depth and lens thickness will also be displayed. Gate markers will be displayed above the waveform to indicate the detected positions of the cornea, lens anterior and posterior surfaces and the retina.

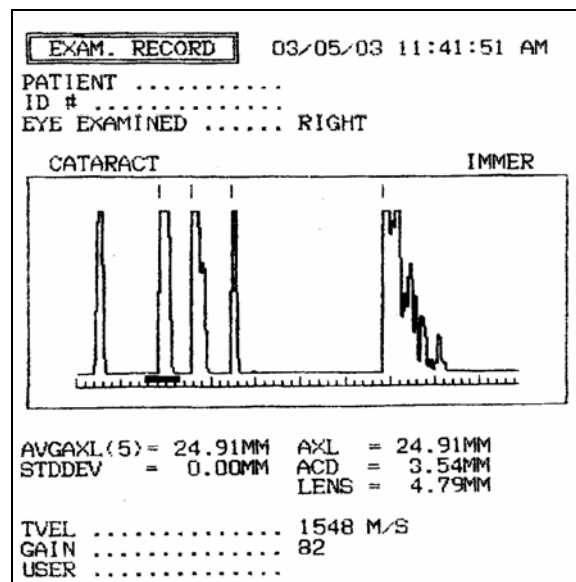


Figure 3-7. Immersion Mode Record Print



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.

8. **Repeat.** The protocol can be repeated to obtain up to five (5) scans. As the scans are captured, the axial length for each is displayed in the upper center 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 [SCAN#] button to scroll through the captured scans. The Prager scleral shell should be left in place until all desired scans are achieved.
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 system memory, and will exclude the associated axial length from the average and standard deviation calculations. If all scans are no longer

desired, they may all be deleted by touching the [CLR SCANS] button.

10. **Remove Prager 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, directing the patient to continue to look straight ahead. Pull the shell away from the eye without making contact with the cornea. Upon initial release, the remaining liquid contents of the shell will spill down the patient's cheek (which can be subsequently wiped with towel or tissue).

PERFORMING IOL CALCULATIONS

The PACSCAN™ uses the measurement data and selected IOL calculation formula to determine and display appropriate IOL powers.

1. **IOL Calculation.** After obtaining acceptable A-scans, the IOL powers can be determined by touching the [IOL CALC] button. The IOL Calculation Screen will be displayed (see Figure 3-8).

PATIENT: JOHN DOE
ID#: 123-45-6789
EYE: RIGHT

MEASURE
PRINT
CATARACT

THEORETIC-T K1: 44.00D K2: 42.50D
AXIAL: 23.60MM

A1: 115.8D		A2: 115.8D	
↑ IOL1 ↓	REFR	↑ IOL2 ↓	REFR
19.00	-0.98	20.00	-1.80
18.50	-0.57	19.50	-1.39
▶ 18.00	-0.17	▶ 19.00	-0.98
17.50	0.22	18.50	-0.57
17.00	0.61	18.00	-0.17

USER: DR. JONES 02/17/03 11:29:44 AM

Figure 3-8. IOL Calculation Screen Display

2. **IOL Power Table.** A table is presented which consists of commercially available IOL powers in ½ Diopter increments, and the expected refraction associated with each IOL power. Values are given for main lens and alternative lens. The table values are calculated using the specified IOL formula

(which can be changed by touching the formula button), the associated formula constants, the k readings previously entered, and the average axial length measured.

3. **Viewing Other IOL Powers.** The IOL power table is centered around those IOL powers which produce refraction which is as close as possible to emmetropia. Other powers and associated refractions can be viewed by scrolling using the [↑] and [↓] buttons, or by touching the [▶] button and entering a refraction value.

PRINTING

Printed records are available when using the optional thermal printer. Records are available for each scan performed and for the IOL powers calculation table.

1. **Print Record Format.**

- The examination record organizes data and information into formats as shown in Figures 3-8 and 3-9.

EXAM. RECORD 04/30/01 04:59:38 PM

PATIENT JOHN DOE
ID # 123-45-6789
EYE EXAMINED RIGHT

CATARACT

AVGAXL(5) = 23.60MM AXL = 23.75MM
STDDEV = 0.10MM ACD = 3.48MM
LENS = 4.20MM

USER DR. JONES

Figure 3-9. Measurement Exam Record

PATIENT: JOHN DOE		MEASURE	
ID#: 123-45-6789		PRINT	
EYE: RIGHT			
THEORETIC-T	K1: 44.00D	CATARACT	
AXIAL: 23.60MM	K2: 42.50D		
A1: 115.8D		A2: 115.8D	
↑ IOL1 ↓	REFR	↑ IOL2 ↓	REFR
19.00	-0.98	20.00	-1.80
18.50	-0.57	19.50	-1.39
▶ 18.00	-0.17	▶ 19.00	-0.98
17.50	0.22	18.50	-0.57
17.00	0.61	18.00	-0.17
USER1: DR. JONES		02/17/03 11:31:10 AM	

Figure 3-10. IOL Exam Record

2. **Printing.** Touch the **[PRINT]** button within either the Measure Screen or IOL Calculations Screen.

3.6**SOURCES OF ERRORS AND HOW TO AVOID THEM**

There are a few common errors which may occur when performing A-scans which deserve some mention. These errors are described below.

CORNEAL COMPRESSION

One of the most common mistakes made when performing axial length measurements is applying excessive pressure on the eye with the probe. When using a Direct Contact Probe (and to a lesser extent the Soft-Touch Probe) it is possible to indent the cornea to the extent that the measurements will be adversely affected.

In using the Direct Contact Probe extreme care should be taken to insure that only enough force necessary to maintain contact with the cornea is used. The problem is minimized to some degree in the case of the Soft-Touch probe since excessive pressure is evidenced by the fact that the probe will begin to recede into its housing.

Checking the measured ACD values listed in the Measure Scan screen for any inconsistencies will generally indicate whether or not there is sufficient corneal compression to require deleting that particular scan from the group.

A-SCAN PATTERN

Recognizing an optimal echo pattern is the basis for performing accurate A-scan measurements. Even when using one of the automatic modes the user should review each scan to determine whether or not the scan pattern is acceptable. It is important to remember that the automatic modes are meant to facilitate the examination procedure but not replace the examiner's clinical judgment. The examination results should not be blindly accepted and by reviewing the scans the user will reduce the possibility of any errors which may cause less than optimal results. In

reviewing, the user should compare the similarity of the characteristics of the particular scan under consideration with those of an optimal A-Scan pattern.

Characteristics of an Optimal A-Scan are as follows:

1. The cornea, lens and retinal echoes should all be approximately the same height.

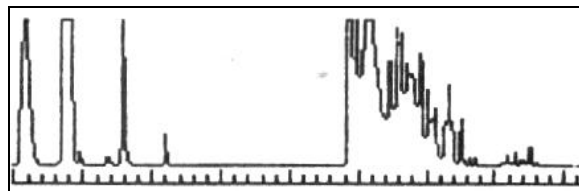


Figure 3-11. Correct A-Scan Pattern.

2. The retinal echo should rise sharply from the baseline forming a 90° angle.

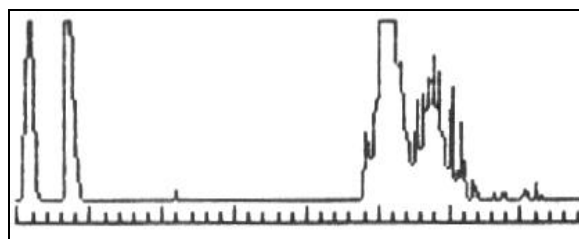


Figure 3-12. Poor Retinal Rise

3. The orbital pattern beyond the Retina should present a gradual decline. A sharp drop in this pattern may indicate that the probe is not aligned along the visual axis.

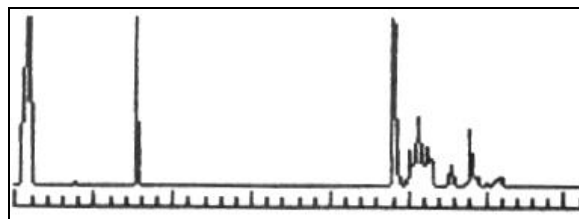


Figure 3-13. Poor Retinal Decline

The user should always strive to achieve these three basic criteria before accepting any measurements as accurate. Some anatomical variations may prevent all such criteria from being simultaneously achieved in any given

scan. In such a case, a scan may have to be accepted based on its meeting the remaining criteria.

EXAMINATION MODES

Before performing an axial length measurement the user should always verify the operating mode (cataract, dense cataract, aphakic, or pseudophakic). Since this mode governs the manner in which the instrument evaluates an A-Scan pattern and the parameters the instrument will utilize in its calculations, mistakes and/or large numerical errors will be avoided (even though the A-scan pattern appears satisfactory).

WATER IMMERSION TECHNIQUE

Although use of the water immersion technique completely eliminates corneal compression as a complicating factor, and can greatly assist with the alignment of the probe with the macula, it is still necessary to review and analyze waveforms to ensure an acceptable reading.

The probe must be properly positioned within the Prager shell in order for the PacScan™ to automatically capture the waveform. If a seemingly proper waveform is not automatically captured, check to see whether the leading edge of the corneal echo is either inside (as shown in Figure 3-14) or outside the limits of the corneal window. In either instance a warning message “POOR CORNEA” will be displayed.

Only scans with a steeply rising retinal spike should be accepted. A minor “stair-stepping” is inherent in a digital waveform, but a reading which is registered on a third or higher step should not be accepted. In other words, the horizontal threshold line (which is the “reading” line) should cross on the first or second vertical step of the retinal spike. Additionally, the retinal spike should be “stepped” only by the thickness

of a single line – scans with additional lines should be rejected.

There should also be a strong scleral spike, about 1.5 to 2.0 mm posterior to the retinal spike. The scleral spike amplitude should be close to that of the retinal spike, and can be slightly lower or higher.

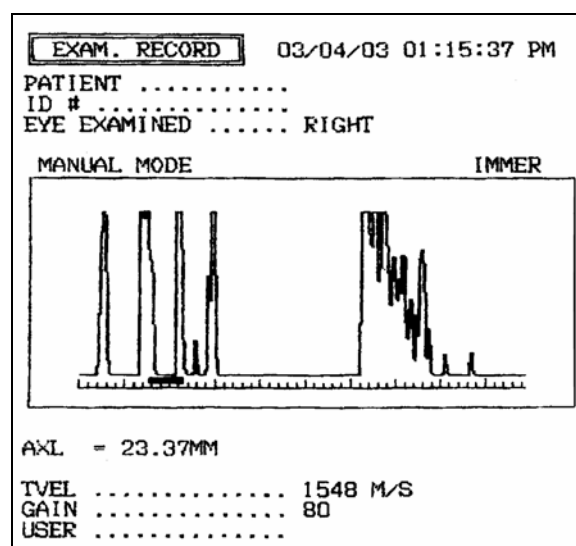


Figure 3-14. Poor Position in Immersion Mode

Section 4

PACHYMETER OPERATION AND CLINICAL USE

(For 300P and 300AP Models Only)

The Pachymeter mode of the PACSCAN™ series allows for measuring and mapping corneal thickness.

By placing the pachymeter probe against a patient eye, an ultrasound image can be obtained and translated into a corneal thickness measurement. The measurement is displayed and can be stored within the system's memory at a corresponding location on the corneal map.

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

4.1 SELECTING PACHYMETER MODE

1. Select the [**PACHYMETER**] button on the Main Screen (see Figure 4-1).

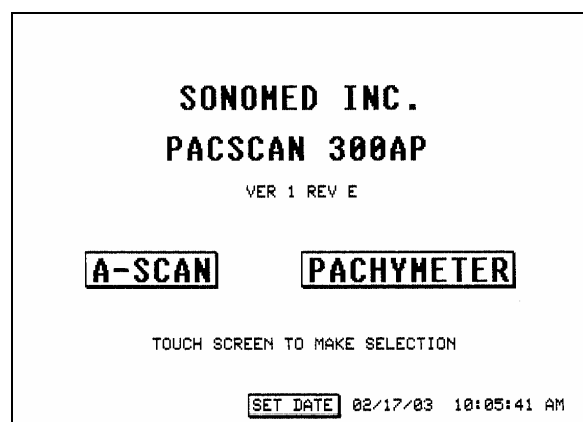


Figure 4-1. Main Screen Display

2. Ensure the Pachymeter Test Screen appears.

4.2 MEASUREMENT ACCURACY and PROBE SENSITIVITY TESTS

It is recommended that the functionality of the PACSCAN™ be verified by means of the measurement accuracy test and probe sensitivity test prior to performing actual measurements.

The PACSCAN™ defaults to the Pachymeter Test Screen every time the Pachymeter mode is selected.

To perform the measurement accuracy test procedure, follow these steps:

1. Make certain that the pachymeter probe is not connected to the PACSCAN™ system.
2. Touch the [**MEASUREMENT ACCURACY TEST**] button to begin the test, which consists of an internal calibration check which should generate a reading of $0.500 \text{ mm} \pm 0.001 \text{ mm}$.
3. Verify that the "System OK" message appears on the screen, thereby indicating system electronic measurement accuracy is acceptable.



IMPORTANT

If system measurement accuracy cannot be verified, contact Sonomed service department for further help.

It is recommended that the measurement accuracy test be performed prior to obtaining measurements; however, the test mode can be skipped if so desired by touching any of the other menu buttons on the right side of the screen when the Pachymeter Test Screen appears.

To perform the probe sensitivity test, follow these steps:

1. Connect the pachymeter probe to the PACSCAN™ system. Make sure that the probe tip is clean and dry and not in contact with any object before performing this test
2. Touch the **[PROBE SENSITIVITY TEST]** button to begin the test, which consists of analyzing the strength of the signal from the probe. A graph of the signal strength from 0 to 100% will be displayed.
3. Verify that the “PROBE OK” message appears on the screen, thereby indicating that the probe sensitivity is acceptable.



IMPORTANT

If acceptable probe sensitivity cannot be verified, contact Sonomed service department for further help.

It is recommended that the probe sensitivity test be performed prior to obtaining measurements; however, the test mode can be skipped if so desired by touching any of the other menu buttons on the right side of the screen when the Pachymeter Test Screen appears.

4.3

SYSTEM SET-UP

ENTERING USER INFORMATION

Up to five (5) different user profiles may be entered and permanently stored within the PACSCAN™ memory. User profiles allow for user identification.

1. **Entering / Editing User Identification.** Touch the **[USER DATA]** button. Verify that the User Data Screen appears (see Figure 4-2).

Figure 4-2. User Data Screen

Touch the **[ADD USER]** button to add a new user profile, or the **[EDIT]** button to edit an existing user profile. Enter the name and/or ID of the user by touching the appropriate alphanumeric buttons. When finished, touch the **[ENTER]** button.

Touch the **[DONE]** button when finished.

ENTERING PATIENT INFORMATION

Patient information including name, identification number, and eye to be examined can be stored within PACSCAN™ memory. Only one patient may be stored at a time, but the information will remain until overwritten.

1. Touch the **[PATIENT]** button. Verify that the Patient Screen appears (see Figure 4-3).

Figure 4-3. Patient Screen Display

2. Within the Patient Screen, enter information for a new patient by touching the **[NEW PAT]** button or edit the existing patient information by touching the **[EDIT]** button.
3. Enter the patient name by touching the appropriate alphanumeric keys. When finished entering the name, touch the **[ENTER]** button.
4. Enter the patient ID number, and touch the **[ENTER]** button when finished.
5. Enter the eye to be examined by touching the **[OD / OS]** button to toggle between the left and right. When the correct eye has been selected, touch the **[ENTER]** button.
6. Touch the **[DONE]** button when finished entering the patient information.

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 as follows:

1. Touch the **[MEASURE]** button if not already in the Measurement Screen.
2. In the Measurement Screen, touch the **[BIAS]** button.
3. Touch the **[BIAS]** button again to proceed to the Bias Edit Screen.
4. Touch the **[BIAS]** button and enter the desired bias by touching the appropriate alphanumeric keys. When finished entering the bias, touch the **[ENTER]** button.
5. Verify that the bias has been updated to the desired value.

CORNEAL VELOCITY

The corneal velocity is preset to 1636 m/s. The corneal velocity does not usually require changing, and is provided merely for the user's convenience (for example, changing the corneal velocity may allow for comparison of corneal thickness measures between the PACSCAN™ and other instruments). The value can be changed as follows:

1. In the Measurement Screen, touch the **[CVEL]** button.
2. Touch the **[CVEL]** button again to proceed to the Corneal Velocity Edit Screen.
3. Touch the **[CVEL]** button and enter the desired corneal velocity by touching the appropriate alphanumeric keys. When finished entering the corneal velocity, touch the **[ENTER]** button.
4. Verify that the corneal velocity has been updated to the desired value.

4.4 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.

4.5 PATIENT EXAMINATION

Following entry of user and patient information, corneal thickness measurements may be obtained. Select the **[MEASURE]** button from any screen to display the Measure Screen.

MEASUREMENT MODES

The user is provided with four (4) measurement modes:

- **Single Reading / One Point.** This mode allows the user to obtain a single reading at one point along the corneal surface. This mode is denoted as “**MAP1 SINGLE**”.
- **Multiple Readings / One Point.** This mode allows the user to obtain up to five (5) readings at one point along the corneal surface. This mode is denoted as “**MAP1 MULTI**”.
- **Single Reading / Multiple Points.** This mode allows for the user to obtain a single reading at five (5) different points along the corneal surface. This mode is denoted as “**MAP2 SINGLE**”.
- **Multiple Readings / Multiple Points.** This mode allows for the user to obtain up to five (5) readings at each of five (5) different points along the corneal surface. This mode is denoted as “**MAP2 MULTI**”.

It should be noted that each reading which is obtained actually consists of the average obtained from 256 individual measurements.

To select the desired mode, touch the mode button to scroll between the four (4) modes.

MEASUREMENTS – SINGLE READING SINGLE POINT

1. Make certain the probe tip is **clean & dry**.
2. 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.
3. Depress the foot pedal or touch the **[START]** button to activate the measurement function.
4. Upon completion of an acceptable measurement, the average reading will be displayed in the upper center of the screen along with the standard deviation for the reading (remember that each reading consists of 256 individual measurements). The reading is stored until another measurement is performed.

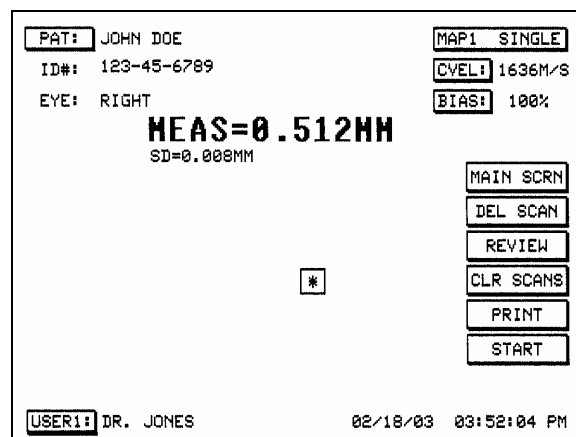


Figure 4-4. MAP1 SINGLE Screen Display

MEASUREMENTS – MULTIPLE READINGS SINGLE POINT

1. Make certain the probe tip is *clean & dry*.
2. 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.
3. Depress the foot pedal or touch the **[START]** button to activate the measurement function.
4. Upon completion of an acceptable measurement, the average reading will be displayed on the left of the screen along with the standard deviation for the reading (remember that each reading consists of 256 individual measures).
5. Repeat steps 1-4 to obtain another reading.
6. The second reading average and standard deviation will be displayed on the left of the screen underneath the first reading. Also displayed in the upper center of the screen will be the average and standard deviation for the group of readings.
7. Repeat for up to five (5) readings.
8. The readings are stored until another group of measurements is performed and/or a particular reading is deleted. Individual readings can be deleted by selecting the particular reading to delete and touching the **[DEL SCAN]** button. All readings may be deleted by touching the **[CLR SCANS]** button.

PAT: JOHN DOE		MAP1 MULTI
ID#: 123-45-6789		CVEL: 1636M/S
EYE: RIGHT		BIAS: 100%
AVG=0.514MM		
[5]SD=0.005MM		
SCANS	STD DEV	*
0.512MM	0.008MM	
0.518MM	0.000MM	
0.518MM	0.000MM	
0.504MM	0.006MM	
0.517MM	0.005MM	
MAIN SCRN DEL SCAN REVIEW CLR SCANS PRINT START		
USER1: DR. JONES		02/18/03 03:57:56 PM

Figure 4-5. MAP1 MULTI Screen Display

MEASUREMENTS – SINGLE READING MULTIPLE POINTS

1. Make certain the probe tip is *clean & dry*.
2. 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.
3. Depress the foot pedal or touch the [**START**] button to perform the measurement process.
4. Upon completion of an acceptable measurement, the average reading will be displayed in the upper center of the screen along with the standard deviation for the reading (remember that each reading consists of 256 individual measures).
5. To move to the next measurement location, touch the box corresponding to the new location. Repeat steps 1 – 4 to obtain the reading for the new location.
6. Repeat for up to five (5) locations.
7. To display the readings for all five locations at one time touch the [**REVIEW**] key. Touch the [**MEASURE**] key to return to the display of the location map.
8. The readings are stored until another group of measurements is performed and/or a particular reading is deleted. Individual readings can be deleted by selecting the particular reading to delete and touching the [**DEL SCAN**] button. To delete the readings for all locations, touch the [**CLR SCANS**] button.

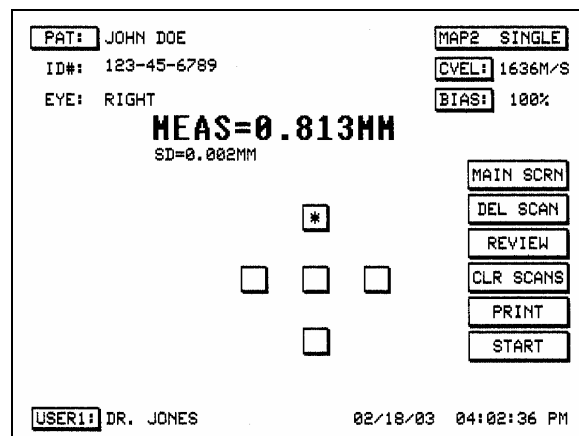


Figure 4-6. MAP2 SINGLE Screen Display

MEASUREMENTS – MULTIPLE READINGS MULTIPLE POINTS

1. Make certain the probe tip is *clean & dry*.
2. 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.
3. Depress the foot pedal or touch the [**START**] button to perform the measurement process.
4. Upon completion of an acceptable measurement, the average reading will be displayed on the left of the screen along with the standard deviation for the reading (remember that each reading consists of 256 individual measures). Also displayed in the upper center of the screen will be the average and standard deviation for the group of readings.
5. Repeat steps 1 – 4 to obtain another reading.
6. The second reading average and standard deviation will be displayed on the left of the screen underneath the first reading. Also displayed in the upper center of the screen will be the average and standard deviation for the two readings.
7. Repeat for up to five (5) readings.
8. To move to the next measurement location, touch the box corresponding to the new location. Repeat steps 1 – 4 to obtain the reading for the new location.
9. The readings are stored until another group of measurements is performed and/or a particular reading is deleted. Readings can be deleted by selecting the particular reading to delete and touching the [**DEL SCAN**] button. To delete all readings for all locations, touch the [**CLR SCANS**] button.

10. Readings for all locations can be displayed at one time by touching the [**REVIEW**] button.

The screenshot shows the MAP2 MULTI screen with the following layout:

- PAT:** JOHN DOE
- ID#:** 123-45-6789
- EYE:** RIGHT
- MAP2:** MULTI
- CVEL:** 1636M/S
- BIAS:** 100%
- AVG=0.834MM**
- [5]SD=0.017MM**
- SCANS** table:

SCANS	STD DEV
0.841MM	0.008MM
0.843MM	0.006MM
0.800MM	0.007MM
0.842MM	0.007MM
0.844MM	0.005MM
- MAIN SCRN**
- DEL SCAN**
- REVIEW**
- CLR SCANS**
- PRINT**
- START**
- USER1:** DR. JONES
- 02/18/03 04:09:22 PM**

Figure 4-7. MAP2 MULTI Screen Display

TROUBLESHOOTING THE MEASUREMENT PROCESS

If a reading is not obtained within approximately ten (10) seconds, the PACSCAN™ will emit a long audible tone and display a “Timeout” message on the screen. The procedure can be tried again.

1. It may be necessary to have the patient blink a few times in order to lubricate the cornea to better facilitate ultrasound transmission.
2. It is important to hold the probe very still while performing a measurement. The PACSCAN™ has a built-in mechanism for ensuring this occurs, as no reading will be accepted where the angle of the probe to the cornea fluctuates by more than $\pm 10^\circ$ (otherwise known as the “acceptance angle”).
3. The tip of the probe should be clean and dry between readings to insure proper readings.

If difficulties persist, contact your local representative or Sonomed for assistance.

PRINTING

Printed records are available when using the optional thermal printer.

1. *Print Record Format.*

- The examination record organizes data and information into a report format.

2. *Printing.* Touch the [**PRINT**] button.

4.6 TEST TARGET

A test target is included with the system which can be used to simulate the measurement process.

1. Remove the test target from its holder on the left side of the PACSCAN™ and place on a flat surface with the open end up.
2. Place a small amount of water inside of the test target and fully insert the pachymeter probe into the target.
3. Lift the probe and test target up to a vertical position with the test target on top of the probe, holding the two together.
4. Measurements may now be performed.

Section 5

MAINTENANCE AND SERVICE

5.1 ROUTINE MAINTENANCE

The maintenance described below should be performed routinely so that the PACSCAN™ is always operating in a safe and reliable manner. In some cases (calibration check, probe examination etc.) it is a good practice to carry out the procedure prior to using the system every time that it is powered-on. For example checking the instrument calibration is necessary if reliable measurements are to be made, while a physical examination of the probe will lessen the possibility of injury to the eye. In any event, a routine consideration of all the items is a good practice and may help to avoid major problems in the future.

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. For electrical-shock protection, the AC adapter should only be plugged into a properly wired AC receptacle.
5. 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.

6. Verify that the foot pedal functions properly, is placed in a convenient location, and that the cable is free from becoming entangled.

CLEANING

System: Periodic cleaning of the PACSCAN™ with a soft cloth is all that is usually required to keep the system looking new. Stubborn stains 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 cleansers as these may damage the system.



WARNING

To prevent electrical shock, it is recommended that the power cord be disconnected prior to cleaning the system.

Probes: 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 (5) 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.



CAUTION

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

STORAGE

When not in use, it is recommended that the power cord be disconnected and the PACSCAN™ be covered to keep dust and debris from entering the system. While stored the PACSCAN™

should be protected from temperature extremes and humidity which can cause condensation within the unit. The probes should be removed from the PACSCAN™ and stored where they will be protected from damage.

PROBE GENERAL INSPECTION

1. The probes should be checked daily for function as well as for any visible damage.
2. Always check the cable for frayed or broken wires which may interfere with the proper functioning of the probe.
3. When connecting the probe to the instrument be sure to align the red indicator dots on both the jack and cable connector.
4. Verify that the internal fixation light of the A-probe is operating.
5. Carefully examine the probe tip for any chipping or rough edges which may injure the cornea.
6. If applicable, examine the "Soft-Touch" mechanism of the A-probe to ensure that it slides freely and with minimal force.



CAUTION

DO NOT attempt to disassemble or lubricate the slide mechanism as this may cause permanent damage to the internal components.

5.2

A-SCAN FUNCTIONALITY CHECK

CALIBRATION CHECK

It is recommended that the functionality of the PACSCAN™ be verified by means of the calibration procedure prior to performing actual measurements.

The PACSCAN™ defaults into the Calibration Screen every time the A-Scan mode is selected. To perform the calibration procedure, follow these steps:

1. Place a small amount of ultrasound coupling gel onto the tip of the A-scan probe.
2. Place the probe onto the calibration cylinder located on the right side of the system. The probe should be placed perpendicular to the cylinder.
3. Observe the measurement displayed on the touch screen. The measurement will freeze once it has stabilized and a calibration status message will be displayed.
4. Verify that the measurement obtained is $10 \pm 0.1\text{mm}$. If it is not, repeat the calibration procedure until an acceptable measure is obtained.



IMPORTANT

If a measure within $10 \pm 0.1\text{mm}$ cannot be obtained, contact Sonomed service department for further help.

It is recommended that calibration be performed prior to obtaining measurements; however, the calibration mode can be skipped if so desired by touching any of the other menu buttons on the right side of the screen when the Calibration Screen appears.

A-SCAN SENSITIVITY TEST

Sonomed A-scan probes are constructed to be reliable products which may be used for several years. However, the nature of the transducers within the probes is such that degradation can occur over extended lengths of time. The sensitivity test can determine the sensitivity of an A-scan probe, and should be performed if the probe has begun exhibiting suspect performance.

1. Connect the probe connector to the side panel jack labeled "PROBE". Before inserting be sure to line up the red indicator dots on both the jack and cable connector.
2. Adjust the GAIN control to maximum.
3. Press [**MEASURE SCAN**] button to view A-Scan display.
4. Place a small amount of coupling gel onto the calibration cylinder.
5. Place probe against top surface of cylinder and apply a slight pressure to ensure good contact with the cylinder.
6. There should now be displayed three (3) echoes all equally spaced and of varying height.
7. A system operating at peak sensitivity should show a third echo at least $\frac{1}{2}$ the height of the second echo.

IMPORTANT

A system where the results of the sensitivity test are such that the third echo is not at least $\frac{1}{2}$ the height of the second echo (or which shows no third echo at all) may be not be sensitive enough to perform accurate scans.

In general this is due to a loss of sensitivity in the Probe. If this is the case the Probe should be replaced. However, in order to confirm that it is the probe which is the cause of the problem, it is necessary for evaluation by Sonomed.

For further assistance, please contact the Sonomed Service Department.

5.3 PACHYMETER FUNCTIONALITY CHECK

MEASUREMENT ACCURACY TEST

It is recommended that the functionality of the PACSCAN™ be verified by means of the measurement accuracy test procedure prior to performing actual measurements.

The PACSCAN™ defaults into the Pachymeter Test Screen every time the Pachymeter mode is selected. To perform the measurement accuracy test procedure, follow these steps:

1. Make certain that the pachymeter probe is not connected to the PACSCAN™ system.
2. Touch the [**MEASUREMENT ACCURACY TEST**] button to begin the test, which consists of an internal calibration check which should generate a reading of 0.500 mm $\pm$ 0.001 mm.
3. Verify that the "System OK" message appears on the screen, thereby indicating system electronic measurement accuracy is acceptable.

IMPORTANT

If system measurement accuracy cannot be verified, contact Sonomed service department for further help.

It is recommended that the measurement accuracy test be performed prior to obtaining measurements; however, the test mode can be skipped if so desired by touching any of the other menu buttons on the right side of the screen when the Pachymeter Test Screen appears.

PROBE SENSITIVITY TEST

Sonomed pachymeter probes are constructed to be reliable products which may be used for several years. However, the nature of the transducers within the probes is such that degradation can occur over extended lengths of time. The sensitivity test can determine the sensitivity of a pachymeter probe, and should be performed if the probe has begun exhibiting suspect performance.

The PACSCAN™ defaults into the Pachymeter Test Screen every time the Pachymeter mode is selected. To perform the measurement accuracy test procedure, follow these steps:

1. Connect the probe connector to the side panel jack labeled "PROBE". Before inserting be sure to line up the red indicator marks on both the jack and cable connector.
2. Make certain that the tip of the probe is clean and dry and not in contact with any object.
3. Press **[PROBE SENSITIVITY TEST]** button to begin test.
4. The test will commence and display the sensitivity of the probe on a scale from 0-100%.
5. If the test results are acceptable (>75%), the system will indicate the message "PROBE OK".



IMPORTANT

A probe which sensitivity test results are not acceptable ("PROBE WEAK") may not be sensitive enough for accurate measurements.

In general this would be due to a loss of sensitivity in the Probe. If this is the case the Probe should be replaced. However, in order to confirm that it is the probe which is the cause of the problem, it is necessary for evaluation by Sonomed.

For further assistance, please contact the Sonomed Service Department.

5.4 TROUBLESHOOTING



WARNING

To avoid personal injury, do not open system – there are no internal user-serviceable parts.

1. Check all cables and connections.
2. Check troubleshooting chart (Table 5-1) and take any suggested corrective action.

Table 5-1
Troubleshooting Chart

Symptom	Corrective Action
LCD screen does not illuminate when system powered on.	Ensure AC adapter connected to system and proper power source.
	Ensure power switch is in the ON position.
	Ensure the contrast control is properly adjusted.
Unable to freeze A-scans in the automatic capture modes (300A and 300AP only).	Verify that the appropriate capture mode has been selected (i.e. cataract, dense cataract, etc.).
No refractive data is shown in the IOL table (300A and 300AP only).	Verify that all necessary IOL data have been entered (i.e. k readings, formula constants).
Inconsistent axial length measures obtained (300A and 300AP only).	Check anterior chamber depth measures – if inconsistent, may reflect corneal compression occurring during measurements.
Orbital pattern beyond the retina does not gradually decline (300A and 300AP only).	Ensure the probe is aligned along the visual axis.

Symptom	Corrective Action
Pachymeter reading cannot be obtained (300P and 300AP only).	Have patient blink a few times in order to lubricate cornea to better facilitate ultrasound transmission.
	Ensure probe is held still during measurement (acceptance angle of $\pm 10^\circ$).
Paper does not advance in printer.	Reload paper in printer.

3. If problem cannot be solved, please contact Sonomed service department for further help. Prior to contacting Sonomed, please gather as much information as possible concerning the specific problem, and have the system and probes nearby. This will greatly aid the service representative in determining the cause of the problem.

If it is deemed necessary to return the system and/or probes to Sonomed for service, a return authorization will be issued. Please ensure that any materials returned to Sonomed are adequately packaged to avoid any damage during shipment.

ELECTROMAGNETIC INTERFERENCE

At times during normal use, the operator may experience periods of interruption caused by interference from outside sources such as electrostatic discharge, power generators or other office equipment.

Should any outside interference cause the system to “lock-up” or begin to operate in a manner inconsistent with the manufacturers instructions, simply turning the unit off for a few seconds will usually resolve the problem.

In some cases a “hard-reset” must be performed by the operator. This will cause all stored data to be replaced with the factory default settings, and should therefore only be used when absolutely necessary. For instructions on

performing a system reset, the operator should contact the Sonomed service department at 800-227-1285.

5.5 WARRANTY

Sonomed Inc. warrants each new instrument and its accompanying accessories and optional equipment (herein after called "Equipment") to be free from defects in material and workmanship for a period of twelve (12) months from the date of delivery to the original purchaser. This warranty is not applicable to any defect which is the result of an accident, misuse, mishandling, neglect, improper installation, improper repair or improper modification by persons other than qualified Sonomed personnel. This warranty also does not apply if the equipment has not been operated and maintained in accordance with the operating and maintenance manuals, instructions or bulletins issued in respect thereof by Sonomed. It is further understood that the cost of servicing replaceable and expendable items including parts and labor made in connection with the routine maintenance services as described in such Operators Manual is not covered under this warranty and is the responsibility of the purchaser.

This warranty is strictly limited to replacement or repair of the part which is found to be defective in material or workmanship. At the option of Sonomed said part shall be replaced or repaired free of charge F.O.B. our factory by Sonomed.

Sonomed reserves the right to make changes in the design and material of Equipment without incurring any obligations to incorporate such changes in equipment already completed on the effective date of any such change or changes.

This is the only warranty of this product and is expressly in lieu of all other warranties, express or implied by law or otherwise, including any implied warranties of merchantability and of fitness for a particular purpose. Without regard

to the alleged defect, Sonomed does not, under any circumstances, assume any responsibility for the loss of time, inconvenience or other consequential damages, including but not limited to, loss or damage to personal property, or loss of revenue. Sonomed has neither assumed nor authorized any other person (including any distributor authorized to sell its equipment) to assume for it any other liability in connection with the sale of equipment.

Section 6 SPECIFICATIONS

PHYSICAL			
Dimensions			
Width	239 mm	9.4"	
Depth	225 mm	8.9"	
Height	71 mm	2.8"	
Weight	2.7 kg	6.0 lbs	

ELECTRICAL			
Power Consumption	10.0 W (Typical)		
Incoming Line			
Voltage (±10%)	120 VAC	230 VAC	
Frequency	60 Hz	50 Hz	
Power Supply			
DC Output	13 VDC	13 VDC	
Current Output	750 mA	930 mA	

ENVIRONMENTAL			
Operating Temperature	5 - 40°C	(41 - 104°F)	
Operating Humidity	10 - 90%	Non-Condensing	
Storage Temperature	-40 - 70°C	(-40 - 158°F)	
Storage Humidity	10 - 90%	Non-Condensing	

INTERFACE	
DC Input	1-Pin Jack Connector
Foot Pedal	1-Pin Jack Connector
Probe Input	5-Pin Jack Connector with Insertion Key
Printer Output	36-Pin Parallel Centronics Connector

DISPLAY			
Type	LCD Backlit Display with Touch Screen Overlay		
Resolution	320 x 240 pixels (h x v)		
Dimensions			
Width	115 mm	4.5"	
Height	86 mm	3.4"	

PROBES	
A-Scan Probes	
Styles	Standard A-Probe Soft-Touch A-Probe
Frequency	10 MHz ± 10%
Focal Length	DC 22-27 mm / ST 22-27 mm
Fixation Light	Internal Red LED
Pachymeter Probes	
Styles	Straight Pachymeter Probe Angled Pachymeter Probe
Frequency	15 MHz ± 10%
Focal Length	0.5 mm
Probe Tip Diameter	1.75 mm

PRINTER (OPTIONAL)			
Model	Seiko DPU-414		
Type	Thermal Printer		
Paper Size			
Width	110 mm	4.3"	
Roll Diameter	50 mm	2.0"	

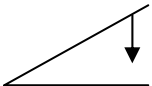
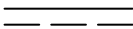
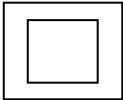
ACCESSORIES			
Item	System		
	300A	300P	300AP
PACSCAN™ Unit	•	•	•
Stylus Touch Pen	•	•	•
Foot Pedal	•	•	•
AC Adapter	•	•	•
Instruction Manual	•	•	•
A-Scan Probe	•		•
Coupling Gel	•		•
Pachymeter Probe		•	•
Printer with Paper	•	Opt.	•
Carrying Case	Optional		

A-SCAN SYSTEM PERFORMANCE	
Examination Modes	Automatic Capture Normal Cataract Dense Cataract Aphakic Pseudophakic Manual
Display Scale	Electronic Markers at 1.0 mm Intervals
Statistical Analysis	AXL Average AXL Standard Deviation Up to Five (5) Readings
IOL Programs	Binkhorst Regression-II Theoretic-T Holladay Hoffer-Q Haigis (optional)
IOL Calculations	Lens Power vs. Refraction Displayed in ½ Diopter Steps Selectable Refractions Customizable IOL Constants
Measurement Limits AXL Lens ACD	(in Automatic Mode @1550) 18 - 46 mm 2-6 mm 2-6 mm
Measurement Accuracy Electronic Clinical	0.0484 mm 0.1 mm
Amplifier	Low Noise Variable Gain Nominal Gain = 60 dB
Index of Refraction	1.3375 (see note 1)

PACHYMETER SYSTEM PERFORMANCE	
Measurement Modes	Single Reading / One Point Multiple Readings / One Point Single Reading / Multiple Points Multiple Readings / Multiple Points
Statistical Analysis	Average of 256 Individual Measures for Each Reading Standard Deviation for Each Reading Average of Up to 5 Readings for Each Point Standard Deviation of Up to 5 Readings for Each Point Average Across All Points Standard Deviation Across All Points
Customizable Parameters	Corneal Velocity Measurement Bias
Measurement Limits	(Tissue Velocity @ 1636) 0.30 – 1.00 mm
Measurement Accuracy	±5 microns
Measurement Precision	±1 micron
Amplifier	Low Noise Automatic Gain Control Maximum Gain = 60 dB

Notes:

1. The Index of Refraction used by the PACSCAN™ for conversion of keratometer readings is 1.3375. When using a keratometer with a different index of refraction, K readings specified in millimeters must be first manually converted to Diopters and then entered for the patient data. Consult the keratometer manufacturer for specific details.

SYMBOLS	
	Footswitch Port
	Direct Current Input
	Type BF Applied Part Output is isolated from live parts by double or reinforced insulation
	On-Charge (not currently used)-Off switch
	Attention, Consult Accompanying Documents
	Caution, Potential Hazard Exists If This Action or Function Is Not Performed Correctly
	Class II Equipment per EN60601
	CE Mark, Complies with all applicable New Approach Directives. The number beside the symbol is the identification number of the Notified Body that certified the quality system under the Medical Devices Directive 94/42/EEC
	Direct Current Input Polarity
	ETL Listing Mark

APPENDIX A

VELOCITY TABLES

VELOCITY OF SOUND USED IN VARIOUS MEASUREMENTS

AXIAL LENGTH MEASUREMENT

Classification of Eye	Average Velocity (m/s)
Cataract	1548
Dense Cataract	1548
Aphakic	1532
Normal (note 1)	1550
PMMA Pseudophakic (note 2)	1552
Acrylic Pseudophakic (note 2)	1549
Silicone Pseudophakic (note 2)	1507

SPECIFIC STRUCTURES

Structures	Velocity (m/s)
Cornea	1641
ACD	1532
Crystalline Lens	1640
Cataractous Lens	1629
Vitreous	1532
PMMA IOL	2718
Acrylic IOL	2120
Silicone IOL	1049
Silicone OIL	980

PMMA PSEUDOPHAKIC LENS

PMMA Lens Thickness	Average Velocity (m/s) (note 3)
0.5 mm	1549
0.6 mm	1551
0.7 mm (default)	1552
0.8 mm	1557
0.9 mm	1560
1.0 mm	1563

ACRYLIC PSEUDOPHAKIC LENS

Acrylic Lens Thickness (mm)	Average Velocity (m/s) (note 3)
0.7 mm	1547
0.8 mm (default)	1549
0.9 mm	1551
1.0 mm	1553
1.1 mm	1554
1.2 mm	1556

SILICONE PSEUDOPHAKIC LENS

Silicone Lens Thickness (mm)	Average Velocity (m/s) (note 3)
0.8 mm	1510
0.9 mm (default)	1507
1.0 mm	1505
1.1 mm	1502
1.2 mm	1499
1.3 mm	1496

Notes:

- The velocity for a normal eye is not preset in the instrument. To measure an eye requiring this velocity the user must enter it for the tissue velocity (TVEL).
- The velocities preset in the system for pseudophakic eye types are specified for the following thickness of the pseudophakic lens:

PMMA lens thickness = 0.7 mm

Silicone lens thickness = 0.9 mm

Acrylic lens thickness = 0.8 mm.

To measure an eye with a pseudophakic lens of a different thickness, see the appropriate table corresponding to the pseudophakic lens for the average tissue velocity to be used.

- The Average Velocity is calculated based on an axial length of 23.5 mm. These velocities are not preset in the instrument and to measure an eye requiring them the user must enter the value for the tissue velocity (TVEL).

APPENDIX B - TABLE OF IOL CONSTANTS

Information supplied by Jack T. Holladay, MD

<i>A-Constant</i>	<i>S-Factor</i>	<i>ACD</i>	<i>A-Constant</i>	<i>S-Factor</i>	<i>ACD</i>	<i>A-Constant</i>	<i>S-Factor</i>	<i>ACD</i>	<i>A-Constant</i>	<i>S-Factor</i>	<i>ACD</i>
110.0	-3.31	0.30	112.5	-1.89	1.76	115.0	-0.48	3.21	117.5	0.94	4.67
110.1	-3.25	0.36	112.6	-1.84	1.81	115.1	-0.42	3.27	117.6	1.00	4.73
110.2	-3.19	0.41	112.7	-1.78	1.87	115.2	-0.36	3.33	117.7	1.05	4.79
110.3	-3.14	0.47	112.8	-1.72	1.93	115.3	-0.31	3.39	117.8	1.11	4.85
110.4	-3.08	0.53	112.9	-1.66	1.99	115.4	-0.25	3.45	117.9	1.17	4.91
110.5	-3.02	0.59	113.0	-1.61	2.05	115.5	-0.19	3.51	118.0	1.22	4.96
110.6	-2.97	0.65	113.1	-1.55	2.11	115.6	-0.14	3.56	118.1	1.28	5.02
110.7	-2.91	0.70	113.2	-1.50	2.16	115.7	-0.08	3.62	118.2	1.34	5.08
110.8	-2.85	0.76	113.3	-1.44	2.22	115.8	-0.02	3.68	118.3	1.39	5.14
110.9	-2.80	0.82	113.4	-1.38	2.28	115.9	0.03	3.74	118.4	1.45	5.20
111.0	-2.74	0.88	113.5	-1.32	2.34	116.0	0.09	3.80	118.5	1.51	5.26
111.1	-2.68	0.94	113.6	-1.27	2.40	116.1	0.15	3.86	118.6	1.56	5.32
111.2	-2.63	1.00	113.7	-1.21	2.46	116.2	0.20	3.91	118.7	1.62	5.37
111.3	-2.57	1.06	113.8	-1.16	2.51	116.3	0.26	3.97	118.8	1.68	5.43
111.4	-2.51	1.11	113.9	-1.10	2.57	116.4	0.32	4.03	118.9	1.73	5.49
111.5	-2.46	1.17	114.0	-1.04	2.63	116.5	0.37	4.09	119.0	1.79	5.55
111.6	-2.40	1.23	114.1	-0.98	2.69	116.6	0.43	4.15	119.1	1.85	5.61
111.7	-2.34	1.29	114.2	-0.93	2.75	116.7	0.49	4.21	119.2	1.90	5.66
111.8	-2.29	1.35	114.3	-0.87	2.81	116.8	0.54	4.26	119.3	1.96	5.72
111.9	-2.23	1.40	114.4	-0.82	2.86	116.9	0.60	4.32	119.4	2.02	5.78
112.0	-2.17	1.46	114.5	-0.76	2.92	117.0	0.66	4.38	119.5	2.07	5.84
112.1	-2.12	1.52	114.6	-0.70	2.98	117.1	0.71	4.44	119.6	2.13	5.90
112.2	-2.06	1.58	114.7	-0.64	3.04	117.2	0.77	4.50	119.7	2.19	5.96
112.3	-2.00	1.64	114.8	-0.59	3.10	117.3	0.83	4.56	119.8	2.24	6.02
112.4	-1.95	1.70	114.9	-0.53	3.16	117.4	0.88	4.62	119.9	2.30	6.07
									120.0	2.36	6.13

APPENDIX C

HAIGIS IOL FORMULA

The Haigis IOL formula developed by Wolfgang Haigis, Ph.D. may be ordered as an option on the PACSCAN™ 300AP and PACSCAN™ 300A systems. For a clinical reference regarding the Haigis IOL formula consult “Comparison of immersion ultrasound biometry and partial coherence interferometry for IOL calculation according to Haigis”; Haigis, W, Lege, B, Miller, N and Schneider, B; Graefes Arch Clin Exp Ophthalmol (2000) 238:765-773. Another source for information regarding the Haigis IOL formula can be found on the Internet at <http://www.doctor-hill.com/haigis.htm>. This website was created by Warren E. Hill, M.D.

Two different types of IOL constants referred to as the “Standard” or “Optimized” constants (a_0 , a_1 and a_2) are used when employing the Haigis IOL formula. The Optimized constants are derived based upon an analysis of at least 50 sets of postoperative patient data. To obtain the Optimized constants contact:

Wolfgang Haigis, MS, Ph.D.
Head of the Biometry Department
University Eye Hospital
11, Josef-Schneider-Str.
D-97080 Wuerzburg / Germany

TEL: +49 (931) 201-20640 and +49 (931) 201-1
FAX: +49 (931) 201-20454
E-MAIL: w.haigis@augenklinik.uni-wuerzburg.de

At the present time there are two websites on the Internet which contain additional information and Microsoft Excel spreadsheets which can be used to record patient data for submission to derive the Optimized Haigis IOL Constants. These websites should be consulted for further information regarding the submission of clinical data.

For physicians primarily in Europe, Africa and Asia, consult the website:

<http://www.augenklinik.uni-wuerzburg.de/uslab/refbfrme.htm>

For physicians primarily in North and South America, consult the website:

<http://www.doctor-hill.com/download.htm>

