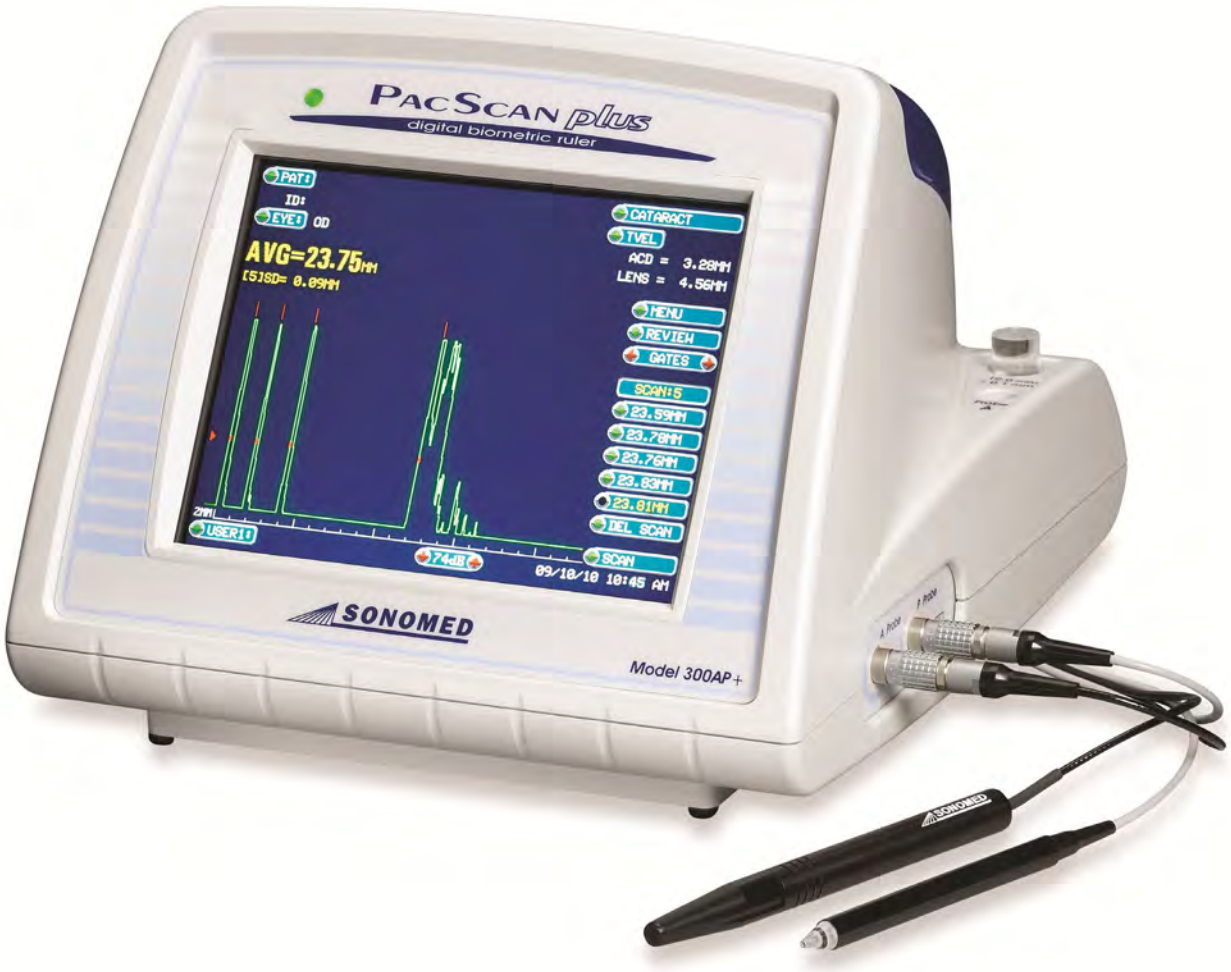
PacScan Plus

A-Scan / Pachymeter



USER MANUAL

SonomedEscalon™

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United States Federal law and European regulations restrict this medical device to use by, or on the order of, a physician. This device should only be used under the supervision of an experienced ophthalmic medical practitioner in a clinical setting. Before examining a patient, the user should become acquainted with the operating procedures, warnings and precautions set forth in the operator's manual. The user should consult additional resources as necessary for further information regarding the proper application of ultrasound technology. If difficulty is experienced when operating the unit after carefully reviewing this operator's manual, contact your local Sonomed Escalon distributor for assistance.
This instrument should be used in strict accordance with the instructions outlined in this operator's manual. The safety of the operator and the performance of the instrument cannot be guaranteed if used in a manner not specified by Sonomed Escalon.
Do not use the device together with HF surgical equipment. HF surgical equipment may be damaged, which may result in fire.

There are no user-serviceable parts within the PacScan Plus system.

To receive a translated copy of this manual, contact your in-country distributor, or call Sonomed directly at 516-354-0900 or 800-227-1285. For technical service and support please contact Sonomed Escalon or your local distributor.

TABLE OF CONTENTS

Section 1
INTRODUCTION

The PACSCAN™ Plus is an ophthalmic biometry instrument intended to be used to visualize and measure the eye using A-scan and pachymeter ultrasound. The series consists of two 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™ 300AP+***. This system integrates the A-Scan and Pachymeter capabilities into a single system.

> ⚠ **IMPORTANT**
> *Remove the black protective probe cover before attempting to use the Pachymeter probe to obtain a measurement*

All systems utilize a high-resolution, color backlit touch screen liquid crystal display (LCD) by which the user can enter information and view data and calculations. Each system also includes a built-in thermal printer. The system is compact and lightweight thereby making the system extremely portable.

This manual is intended to provide a thorough overview of the PACSCAN™ Plus 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.

Contraindications
The PacScan Plus is not intended for fetal use.

1.1 A-SCAN FEATURES (For 300A+ and 300AP+ Models)

The A-Scan mode of the PACSCAN™ Plus 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's 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 built-in 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™ Plus A-Scan 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 5 IOL types: PMMA, Acrylic, Silicone-I & II, or Custom)
  - Manual

- Velocity Compensation for Pseudophakic Lens Type (PMMA, Acrylic or Silicone-I & II)

- A-Scan Measurement Review Capability
  - Axial Length, Anterior Chamber Depth, Lens Thickness & Vitreous Length 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

- Three Post Refractive IOL Formulas
  - Latkany Myopic
  - Latkany Hyperopic
  - Aramberri Double K

- Immersion Capabilities

- 5 Customizable User Profiles

- 8 IOL A-Constants per User

- IOL Lens Review Screen

- Clinical Accuracy ±0.1 mm

- User-Performed Calibration Check

- Self-Test Routines at Start-Up

1.2 PACHYMETER FEATURES (For 300AP+ Model)

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 built-in thermal printer.

Several features help to distinguish the Sonomed PACSCAN™ Plus Pachymeter including:

- Average and Standard Deviation Computed for Each Reading – Reading is Result of 128 Individual Measurements
- Multiple Corneal Maps with Graphical Display
- Measurement Range 0.130 mm to 1.00 mm
- Measurement Review Mode
- Selectable Bias and Corneal Velocity
- 5 Customizable User Profiles
- Accuracy Better Than ±5 Microns
- Precision of 1 Micron
- Acceptance Angle of 10º
- Automatic Calibration Check and Probe Sensitivity Test

1.3 SYSTEM COMPONENTS

Calibration Cylinder

10 MHz A Probe

20 MHz Pachymeter Probe

Foot Pedal (Footswitch)

AC Power Adapter

Section 2
GETTING STARTED

2.1 UNPACKING

The PACSCAN™ Plus 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	300A+	300AP+
PACSCAN™ Unit	•	•
Stylus Touch Pen	•	•
Foot Pedal	•	•
AC Adapter	•	•
Instruction Manual	•	•
A-Scan Probe	•	•
Calibration Cylinder	•	•
Pachymeter Probe		•
Test Target		•
Printer with Paper	•	•

Examine the unit and components for any noticeable defects or damage that may have occurred during shipment. Visually examine the probes to ensure no cracks, scratches or damage exists. Please call your local representative or Sonomed immediately to report any problems.

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.

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 and/or indicate areas needing special attention to ensure proper use of the equipment.

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.

Do not place the unit near heat sources such as a heater or operate in the presence of flammable anesthetics, 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.

Switching on a cold instrument near 0° Celsius may cause permanent damage. Allow the instrument to reach a normal room temperature for half a day in order to allow the internal elements to warm up and to avoid any thermal shock hazards when switched on. The cover will quickly reach room temperature, but not the internal circuitry.

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Isolation from the supply mains may be achieved by disconnecting the main power cord from the supply outlet.

DO NOT disassemble, modify, or remodel the unit or accessories. This may cause unit damage, malfunction, electrical shock, fire, or personal injury.

DO NOT attempt to repair or service this instrument. Any repair or service to this instrument must be performed by experienced personnel who are trained by Sonomed Escalon. Attempts to repair or service the instrument may result in serious injury to the operator or patient.

Measurements should not be attempted when ocular integrity is questionable. The user needs to exhibit care in manipulating the measurement tip. Force should not be exerted against the eye.

Disconnect the AC POWER before cleaning the system.
The transducers are fragile. Dropping or striking any probe can cause malfunctions; handle all probes with care. If a probe should be dropped, inspect it carefully for chips and cracks, and make a “test” scan on a known object. Damage to the front of the transducer will reduce efficiency, and may cause premature failure of the electronics or may cause damage to the cornea.

DO NOT USE PROBES IF TIP IS DAMAGED. ALWAYS EXAMINE PRIOR TO USE.

This device is not intended for fetal use.

Never autoclave a transducer or expose it to high heat.

Do not attempt to connect the device to any accessories or supplemental equipment other than that provided by Sonomed Escalon. This could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation. Equipment connected to the system must be IEC 60601-1 or IEC 60950 compliant.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on or off. Try to correct the interference using one or more of the following: Reorient or relocate the receiving device, increase the separation between the equipment, connect the equipment to an outlet on a different circuit from that to which the other devices(s) are connected and or/ consult the factory field service technician for help.

Modifications to this instrument are not allowed. This may cause unit damage, malfunction, electrical shock, fire, or personal and/or patient injury.

Do not use the device together with HF surgical equipment. HF surgical equipment may be damaged, which may result in fire.

GENERAL CAUTIONS

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.

Care should be taken by user to minimize exposure of patient to ultrasound energy by keeping examinations as short as possible.

Position such that console is well ventilated with easy access to disconnect power cords, and do not block the power adapter in the event that disconnecting should be necessary.

Probes must be connected or disconnected only when the unit is switched OFF.

The unit should not be connected to a Multiple Power Switch Outlet (MPSO) which is also used to provide power to devices not intended to be used in the patient environment. Doing so may compromise electrical safety of the device.

In order to prevent patient-to-patient transfer of infection, after each use disinfect the measurement tip following accepted clinical procedures. Refer to the Maintenance, and Service in section 5 regarding the use of disinfectants and for probe cleaning instructions.

Dispose of all products in accordance with local and national regulations and codes.

The PacScan Plus conforms to the emissions and immunity requirements IEC 60601-1-2:2014, Conducted Emissions, Group 1, Class B.

Essential performance of the PacScan Plus may be lost if the unit is adversely exposed to external electromagnetic disturbances resulting in loss of patient data. When tested for electromagnetic disturbances, the device did not exhibit malfunction or degradation of performance when subjected to power frequency magnetic fields of 50 Hz and 60 Hz, but it is recommended that use in close proximity to or stacking of other electronic devices should be avoided because it could result in improper operation. If such use is necessary, the PacScan Plus and other equipment should be observed to verify normal operations.

In the event adverse external electromagnetic disturbances causes the device to lockup, the unit may require a system reboot by restarting.

Third Party Equipment: The use of third-party equipment, cables or accessories, not made or authorized by Sonomed Escalon, invalidates the warranty of the unit, and adversely affect the unit's safe operation.

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 – 240VAC
   50 - 60 Hz

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

6. Connect the probe connectors (A-Scan probe and Pachymeter probe) to the jacks on the right side of the system labeled "A-PROBE" and “PACH PROBE”. Before inserting, be sure to line up the red indicator marks on both the jack and cable connector.

PRINTER SET-UP

1. Place the instrument on a flat level surface.

2. Open the printer door by pressing the White button labeled “Press to release cover” located to the left of the paper exit slot.

3. Place the roll of thermal paper into the holder with the paper coming off the roll from the bottom and toward the front of the unit.

4. Thread the paper through the inside of the exit slot and close the door by pressing on the two areas marked “Press to secure cover”.

POWER UP CHECK

1. Slide the Power Switch of the PACSCAN PLUS 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).

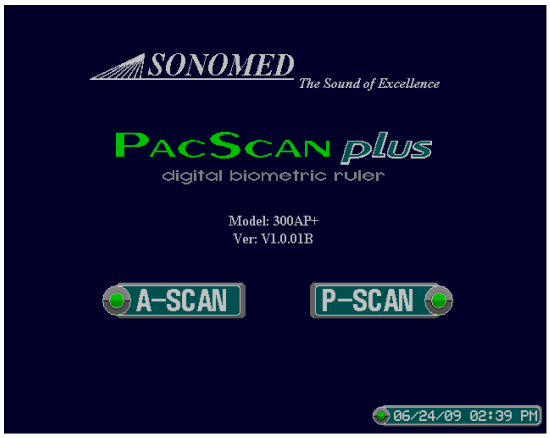


Figure 2-1 Main Screen Display

> ⚠ **IMPORTANT**
> *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 PLUS 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 is may become permanently damaged.*

SCREEN CONTRAST ADJUSTMENT

1. From the Main Screen, select the **[A-SCAN]** button at the bottom of the screen (see Figure 2-1). Verify that the CALIBRATION screen appears on the display (*see Figure 2-2*).
2. Press the **[USER1]** button on the lower left corner of the display.
3. To adjust the contrast, select the **[CONTRAST ↑]** or **[CONTRAST ↓]** button located at the bottom center of the display.
4. Press [MENU] then [MAIN] to return to Main screen.

SETTING THE DATE AND TIME

1. From the Main Screen, select the [DATE and TIME] button at the bottom right of the screen. Verify that the Date/Time screen appears. (*See Figure 2-3*).
2. To edit the date, select the [MONTH] button and enter the appropriate two digits for the current month (for example, “01” for January, etc.), and then select the [ENTER] button. Repeat for the day and year.
3. Select the [HOUR] button to the right and enter the two digit hour of the day (01-12). Press [ENTER].
4. Press [MINUTE] and enter the appropriate two digits for the minute setting (00-59) and press [ENTER]. Press the [AM/PM] button to toggle between AM and PM.
5. After entering the Date and Time, press [DONE] to return to the Main Screen. Verify that the correct time is displayed on the bottom right corner of the screen.

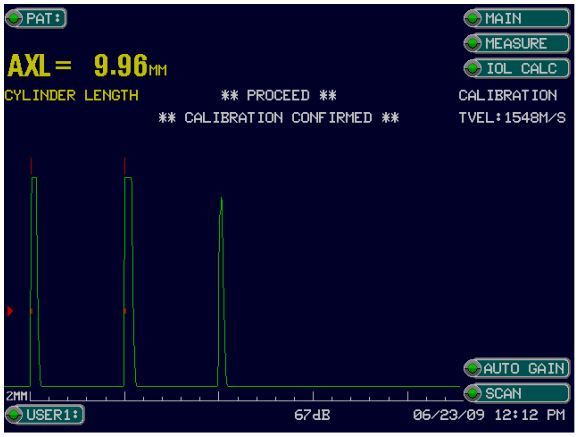


Figure 2-2

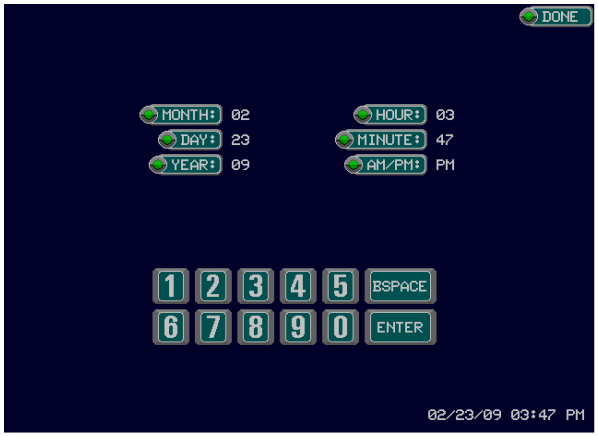


Figure 2-3

Section 3
A-SCAN OPERATION AND CLINICAL USE
(For 300A+ and 300AP+ models)

The A-Scan mode of the PACSCAN™ Plus 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's 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 built-in 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. (See Fig. 3-2).

Figure 3-1 Main Screen Display

3.2 CALIBRATION

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

The PACSCAN™ Plus 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 calibration cylinder located on the right, rear side of the system.

2. Adjust the Gain to 100db (Max.)

3. Place the probe onto the calibration cylinder.The probe should be placed perpendicular to the cylinder. Press the footswitch or the [SCAN] button on the bottom right of the display.

4. Observe the measurement displayed on the upper left of the display (Yellow Text). The measurement will freeze once it has stabilized and a calibration status message will be displayed.

5. 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 (See Figure 3-2)

   The gain defaults to 94db when the Calibration Screen is selected. The gain control may be adjusted by touching the **[↑]** and **[↓]** buttons at the bottom center of the Calibration Screen. The resulting gain (60-100db) will be displayed. Alternatively, the **[MAN GAIN]** *(Manual Gain)* button can be selected, which will toggle to **[AUTO GAIN]** and instruct the PACSCAN™ Plus 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 upper right side of the screen when the Calibration Screen appears.

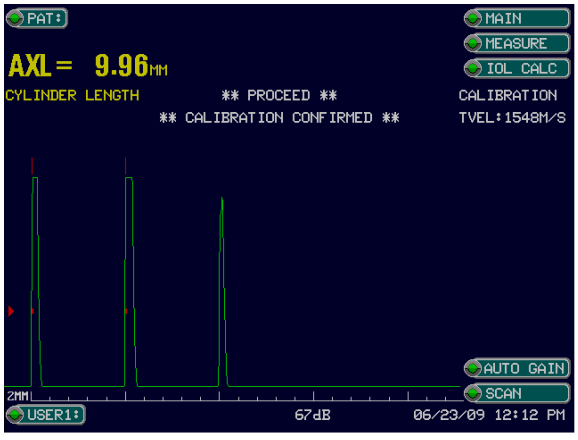


Figure 3-2 Calibration Screen Display

3.3 SYSTEM SET-UP

ENTERING USER INFORMATION

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

1. ***Entering / Editing User Identification***.
   ♦ Touch the **[USER1]** button. Verify that the User Data Screen appears (see Figure 3-3).

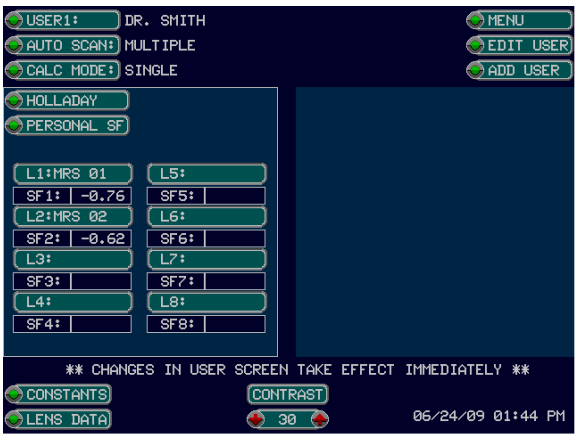


Figure 3-3 User Data Display

   ♦ Touch the **[USER1]** button (again). To add a new user profile, press the **[ADD USER]** button. Enter the name of the user by touching the appropriate alphanumeric buttons. When finished, touch the **[ENTER]** button.
   ♦ Touch the **[USERS]** button to verify that the name was entered.
   ♦ Touch the **[DONE]** button when finished.

2. [**AUTO SCAN]**: Touch [AUTO SCAN] to toggle between "Multiple" and "Single. "Multiple" will allow consecutive scans to be made without having to press the footswitch between scans; "Single" will perform one scan at a time, using the footswitch to activate a new scan.

3. [**CALC MODE]**: Press [CALC MODE] to toggle between "Single" and "Comparative" Modes. "Single" will allow the user to calculate up to 8 different IOL's using one IOL Formula. "Comparative" will allow the user to calculate up to 8 different IOL's comparing two different IOL formulas.

4. ***IOL Formula Selection***. Within the User Data Screen, touch the "*Formula"* button. (This key will have one of the available IOL formulas already displayed). Touching this key will cause a "drop-down" menu to appear listing all available IOL formulas. Touch the name of the desired IOL formula to select it. If in "Comparative" mode, a second formula can be selected by repeating the above steps using the "*Formula"* button located in the right side formula box. Note that default values for the associated constants are given with each formula. The constant default values are shown in Table 3-1.

5. ***IOL Constants.*** Up to eight (8) IOL constants may be selected from the Lens database, for each of the five user profile, for a total of thirty (30) IOL constants (See Entering Lens Information for details).

ENTERING LENS INFORMATION

Up to ten (10) different IOL constants with their corresponding name, optic diameter (mm), and overall length (mm), can be entered and permanently stored within the PACSCAN™ Plus lens database. The user can then select up to eight (8) lenses from the lens database at any given time.

1 Entering/Editing Lens Data Information.

Touch the **[USER DATA]** button. Verify that the User Data Screen appears (see Figure 3-3).

Touch the **[LENS DATA]** button Verify that the Lens Data Screen appears see Figure 3-4.

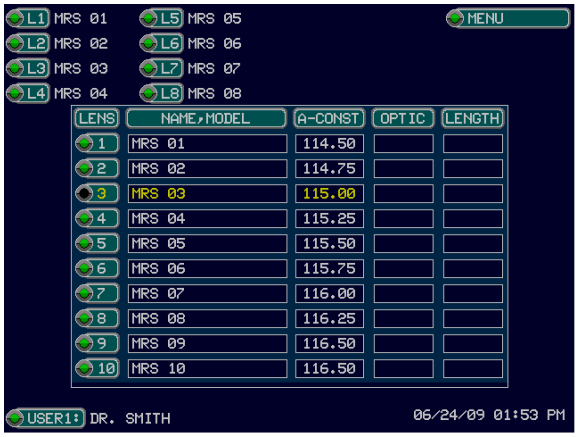


Figure 3-4 Lens Data Display

There are a total of 10 possible lenses that can be added into the database (listed #1-#10) within the table.

a) Press [#1] under the word "LENS" in the table.
b) Press [MENU] and select [EDIT LENS].
c) Press [LENS 1:] and using the keypad, enter a name for this lens followed by [ENTER]. (Use the "Delete" key to erase previous information).
d) Enter the *A-constant, Optic Size* (optional), and *Length* (optional) for the selected lens style and press [ENTER] after each entry. Press [DONE]

To add a new lens to the database, press **[ADD LENS]**. The Lens # will automatically show the next available space. Enter the New Lens information following the above procedure. Enter the Name, IOL Constant, Optic (Optional), Length (Optional) and **[ENTER]** buttons. When finished, touch the **[DONE]** button.

2 Selecting a LENS from the Lens Database.

a. Select the LENS # in the database (#1-#10).
b. Select the desired Lens (L1-L8) located in the upper left corner of the display.

The lens info for the selected lens from the database will appear at the corresponding selection. Repeat for the remaining "7" lenses.

Once finished, touch the **[USER#]** button to return to the User Data Screen, or the **[IOL CALC]** button to return to the IOL Calculation Screen, or the **[LENS REVIEW]** to review your lens selections. Press [MENU] to select an alternative mode (Measure, IOL Calc, Patient info, or the Main Screen.

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

3 *Changing A-constants from the Constant Screen.*

To change the associated constants, touch the **[USER #]** button (bottom left). Verify that the desired Formula appears. (See Figure 3-5).

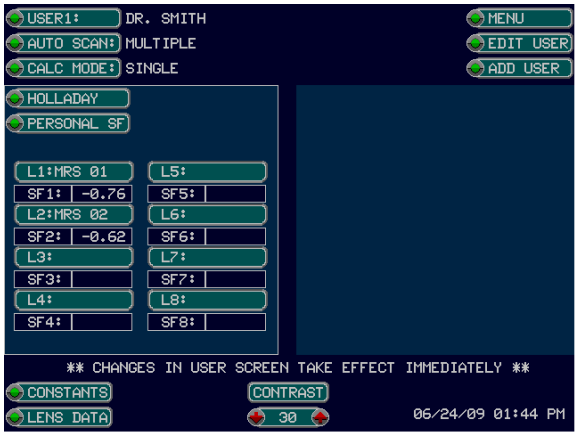


Figure 3-5 Constants Screen Display

As shown, eight (8) constants are displayed in the table of the Constants Screen.

Select the desired button **[L1-L8]** to edit the appropriate constant. Continue until all lenses have been updated. 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™ Plus memory. Only one patient may be stored at a time, but the information will remain until overwritten.

1. From the MEASURE Screen touch the **[PATIENT]** button. Verify that the Patient Screen appears (see Figure 3-6).

Figure 3-6 Patient Screen Display

2. Within the Patient Screen, enter information for a new patient by touching the **[NEW PAT]** 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 information by touching the **[OD and OS]** buttons respectively and follow the instructions below.

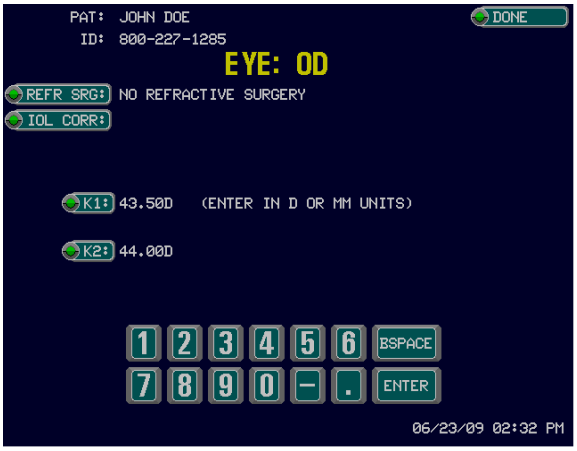


Figure 3-7 Refractive Screen Display

6. If the current Patient has not had refractive surgery on the selected eye, Press **[ENTER]** and follow the prompts for entering the K-readings. 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]. (*See Fig. 3-7*).

7. If the selected eye has had previous refractive surgery, press **[REFR SRG]** and verify that "Post Refractive Surgery" appears as shown in Figure 3-8. Press **[IOL CORR]** to select:

   a) "**Latkany Myopic Regression Formula"**

   b) "Latkany Hyperopic Regression Formula"

   c) "Aramberri Double K IOL Correction formula".

   Touch the **[DONE]** button when finished entering the patient information. Continue with information for the fellow eye as above. Press **[MEASURE]** to return to the Measure Screen.

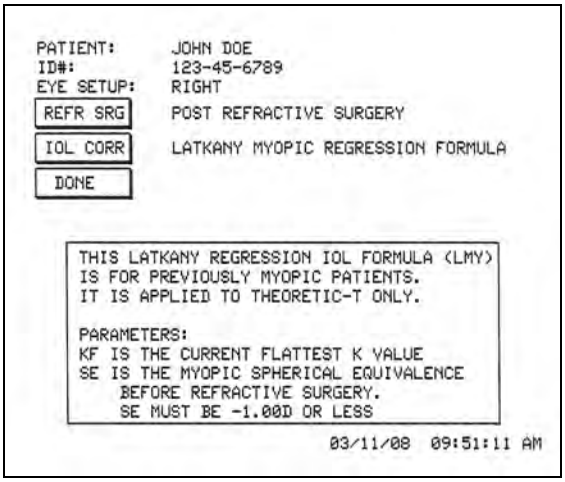


Figure 3-8 Post Refractive Screen Display

⚠ CAUTION

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. 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 3-9).

Figure 3-9 Measure Screen Display

DIRECT CONTACT SCANNING IN AUTOMATIC CAPTURE MODE

The PACSCAN™ Plus 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 four different Pseudophakic lens types (PMMA, Acrylic, Silicone-1, or Silicone-2) 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 velocities are selected by pressing the **[TVEL]** button located in the upper right corner of the Measure Screen (the system default velocities are **1532m/s** for the 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 PACSCAN™ Plus.

   Any tissue velocity may be changed by first touching the **[TVEL]** button to display the Tissue Velocity Screen (see Figure 3-10).

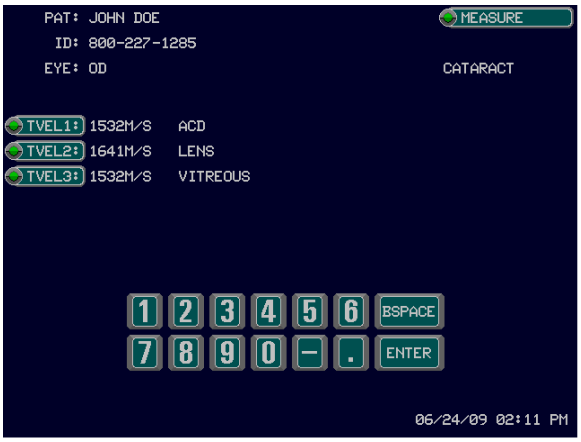


Figure 3-10 Tissue Velocity Screen Display

   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 before returning to the Measure Screen.

3. ***Immersion Option***. Ensure that the immersion option is OFF by first pressing the **[MENU]** key. A drop-down menu will appear. The immersion option may be toggled ON and OFF by touching the **[IMMER ON/OFF:]** key.

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.

   NOTE: Depending on whether "Single" or "Multiple" scan mode was selected earlier (see pg. 3-2) will determine whether or not the footswitch will be required to advance to the next scan.

   The gain control may be adjusted by touching the **[🡅]** or **[🡇]** buttons at the bottom center of the Measure Screen. The resulting gain will be displayed (60-100db). The maximum gain is 100db; however a gain of 75 to 80 has been shown to give satisfactory results for average length 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 lower right 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).

   *Note: If the pattern recognition software identifies a particular echo in error (as is possible in the case of a dense cataract), the user may reposition the "GATE" in the question by pressing the **[🡄 GATES 🡆]** buttons until the desired Gate marker is flashing and reposition the gate by using the **[🡄], [🡆]** buttons.*

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 lower right of the Measure Screen. Additionally, the axial length average and standard deviation for the group of scans will be displayed (in Yellow). 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 after selecting the scan as described above. 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, they may all be permanently deleted by touching the **[CLR ALL]** button located on the Review Screen.

DIRECT CONTACT SCANNING IN MANUAL MODE

The PACSCAN™ Plus 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 and selecting the desired mode from the menu.

2. ***Tissue Velocity***. Ensure the appropriate tissue velocities are selected by pressing the **[TVEL]** button located in the upper right corner of the Measure screen.

   Any tissue velocity may be changed by first touching the **[TVEL]** button to display the Tissue Velocity Screen (*see Figure 3-10*).

   Touch the **[TVEL#]** button corresponding to the specific tissue velocity, enter the appropriate number, and touch the **[ENTER]** button. Verify that the tissue velocity has changed. When required changes have been completed, touch **[MEASURE]** to return to the Measure Screen.

3. **Gates.** Depending on the Eye Type, the user may also wish to change the number of gates being used (Aphakia, etc.). This can be accomplished by pressing the **[#GATES]** button located to the right of the **[TVEL]** button. This button will allow the user to select *4-Gates* (Normal), *3-Gates* (Pseudophakic), or *2-Gates* (Aphakic). The number of Gates must be selected prior to measuring. *Changing the number of Gates after a measurement has been taken, will cause the scan to be erased permanently*

4. ***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 [MENU] key and selecting the **[IMMER ON/OFF]** key from the drop-down menu.

5. ***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.

6. ***Image Capture***. Once an acceptable A-scan pattern is obtained, step on the footswitch or touch the **[FREEZE]** button to capture the image.
   If necessary, the gain control may be adjusted by touching the **[🡅]** and **[🡇]** buttons at the bottom center of the Measure Screen. The resulting gain will be displayed in decibels.
7. ***Measure*** Once an A-scan pattern has been frozen, flashing vertical lines will appear on the display. These lines represent the echoes selected by the gate for measurement. The number of flashing lines is dependent on the number of gates selected above. The user may reposition any "GATE" in question by pressing the [GATE] button until the desired Gate marker is flashing and reposition the gate by using the red **[🡄],[🡆]** buttons. The selected gate marker will continue flashing for approximately 15 seconds after adjustment unless another gate is selected.

   Only one scan at a time may be saved when using the manual mode. Repeating the scanning procedure overwrites the existing scan information. *In order to proceed scanning while saving the previous scan ,it is necessary to press the **[SCAN#]** button and manually advance to the next open line.*

WATER IMMERSION TECHNIQUE

In addition to direct contact measurements, a water immersion technique may be used with the PACSCAN™ Plus in order to completely eliminate concerns of possible corneal compression skewing results. The technique requires the use of a "Scleral Shell" and is described below using the automatic capture mode.

> ⚠ **IMPORTANT**
>
> *If using a Prager immersion shell proper measurement data can only be obtained if the probe is properly placed in the shell. Proper positioning must be confirmed by examining the captured scan waveform.*

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 and selecting the desired mode from the drop-down menu. The following automatic capture examination modes are available:

   - Cataract
   - Dense Cataract
   - Aphakic
   - Pseudophakic

2. ***Tissue Velocity***. Ensure the appropriate tissue velocities are selected by pressing the **[TVEL]** button located in the upper right corner of the Measure Screen.

   Any tissue velocity may be changed by first touching the **[TVEL]** button to display the Tissue Velocity Screen (see Figure 3-10). Touch the **[TVEL#]** button corresponding to the specific tissue velocity, enter the appropriate number, and touch the **[ENTER]** button. Verify that the tissue velocity has changed. When required changes have been completed, touch **[MEASURE]** to return to the Measure Screen.

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

3. ***Immersion Option***. Ensure the immersion option is ON by pressing the [MENU] key and pressing [IMMER OFF] from the drop-down menu. The immersion option may be toggled between ON and OFF by touching the [**IMMER ON/OFF**] key.

Prepare 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 (Prager Shell®/.

NOTE: Some scleral shells have an automatic "stop" built in to align the probe properly in the shell.

Once the probe has been positioned correctly within the shell, attach a tubing set to the shell. Consult the instructions supplied with the Shell for proper use. (The Prager Shell will be used for purpose of instruction).

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

4. ***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 conjuctiva). This pivotal motion avoids contact with the cornea and ensures centering of the device around the limbus.

5. ***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.

   NOTE: If "Single" mode has been selected through the User screen, the footswitch will need to be pressed before each new scan.

6. ***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 3-11). 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 white 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 **[↑]** and **[↓]** buttons at the bottom center of the Measure Screen. The resulting gain 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 lower right 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.

Note: *The immersion procedure in Manual Mode is identical with the exception of the automatic scan capture feature. The operator must identify the correct pattern and depress the footswitch (or press the Freeze button) to select the scan for measurement and manually advance to the next scan.*

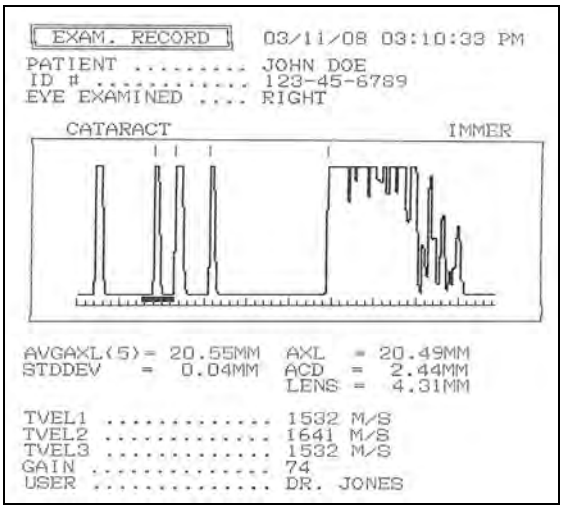


Figure 3-11 Immersion Mode Record Print

7. ***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 lower right of the Measure Screen. Additionally, the axial length average and standard deviation for the group of scans will be displayed (in yellow). Each scan pattern may be reviewed by touching the **[SCAN#]** button to view each of the captured scans. The Prager scleral shell should be left in place until all desired scans are achieved.

8. ***Deleting Scans***. If a scan is captured which is no longer desired, it may be deleted by touching the **[DEL SCAN]** key. 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 permanently deleted by touching the **[CLR ALL]** button located on the review screen.

9. ***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).

MEASURE REVIEW SCREEN

> ⚠ ***IMPORTANT***
>
> *It is important to remember that the auto modes are meant to facilitate the examination procedure but not to 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.*

The Measure Review Screen allows the user to review all scan data prior to printing. (See Figure 3-12)

All measurement data including ACD, Lens Thickness, Vitreous and Axial length for each of the measurements performed will be displayed on this screen along with the Averages, Range of Measurement, and Standard Deviation for each item.

Also included is a column labeled "DIFF" which represents the difference from the average measurement .One data line will have an asterisk (*) after the "difference". This is meant to bring attention to this scan as the one which shows the greatest distance from the average. It is not meant to indicate neither the best nor poorest scan, but is only meant to bring the users attention to it as the largest deviation from the average reading.

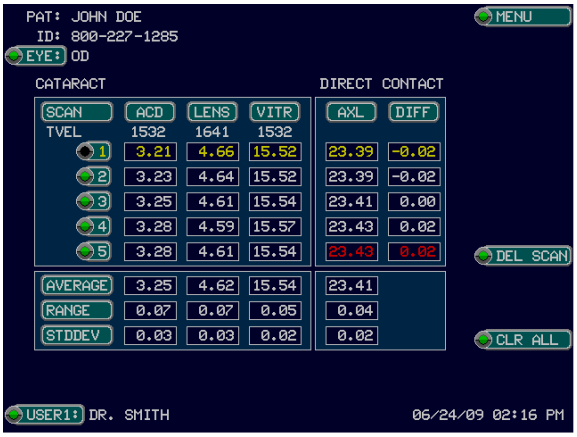


Figure 3-12 Measure Review Screen

PERFORMING IOL CALCULATIONS

The PACSCAN™ Plus 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 3-13).

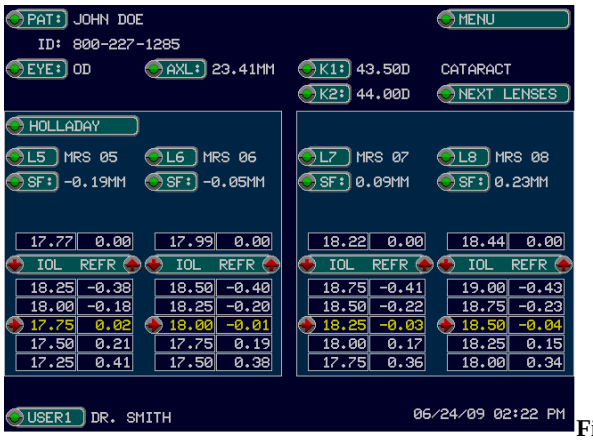


Figure 3-13 IOL Calculation Screen Display

2. ***IOL Power Table***. A table is presented which consists of commercially available IOL powers in ¼ (.25) Diopter increments, and the expected refraction associated with each IOL power. Values are given for up to 8 lenses. 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 a 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 desired refraction value.

   If the corresponding constants have been entered (As per "Entering Lens Information" in page 3-3), touching **[NEXT LENSES]** will permit the next set of IOL calculations/results to be displayed.

   Touching **[USER#]**, will cause the User Data Screen to be displayed. Pressing **[LENS DATA]** will allow the Lens Review Screen to be displayed. This screen allows the user to view and edit the six (8) lens names or models with the corresponding I.O.L. powers and refractions associated with it (See Figure 3-14).

Figure 3-14 Lens Review Screen Display

4. ***Post Refractive Formulas.*** If the patient has had previous refractive surgery, and this was entered under the Patient Information screen, the IOL formula selected would be the Theoretic/T. The IOL screen would therefore display:

[THEORET-T-ADK] for "Aramberri Double-K",

[THEORET-T-LMY] for the "Latkany Myopic Regression"

[THEORET-T-LHY] for the "Latkany Hyperopic Regression" Formulas.

Note: *The exact "Target Refraction" and corresponding IOL power is displayed in the space located below the Constants Field.*

PRINTING

5. Printed records are available by using the built-in thermal printer. Records are available for each scan performed and for the IOL powers calculation table.

1. ***Print Measurement Record***.

   - The examination record organizes data and information into formats as shown in Figures 3-15 and 3-16.

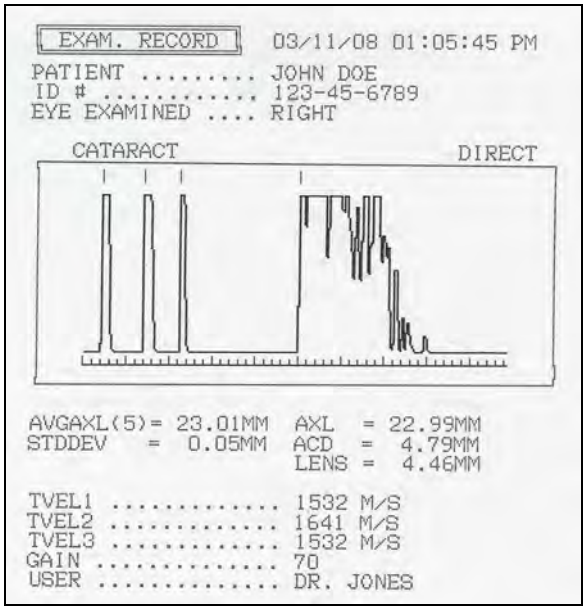


Figure 3-15 Measurement Exam Record

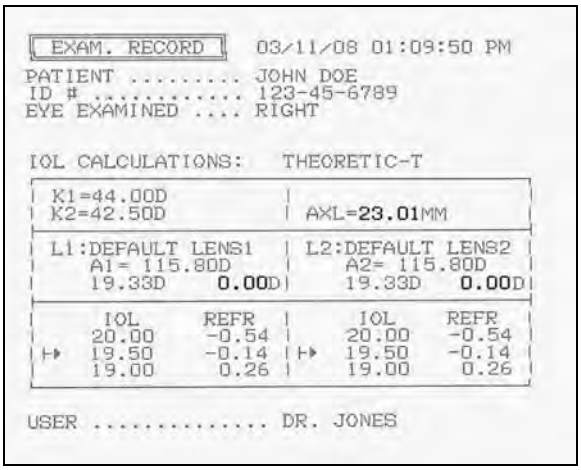


Figure 3-16 IOL Exam Record

Printing. Touch the **[PRINT]** button within either the Measure Screen or IOL Calculations Screen to produce a hard copy record of the desired data.

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 direct contact it is possible to indent the cornea to the extent that the measurements will be adversely affected. Extreme care should be taken to ensure that only enough force necessary to maintain contact with the cornea is used.

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.

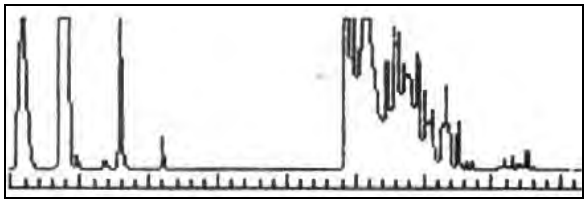


Figure 3-16 Correct A-Scan Pattern.

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

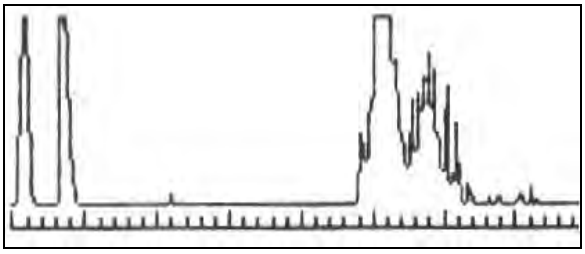


Figure 3-18 Poor Retinal Rise

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.

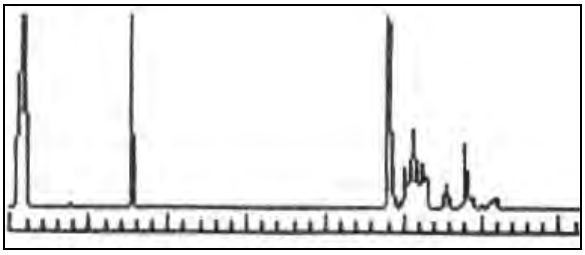


Figure 3-19 Poor Retinal Decline

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 3-20) 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 1.0mm posterior to the retinal spike. The scleral spike amplitude should be close to that of the retinal spike, but can be slightly lower.

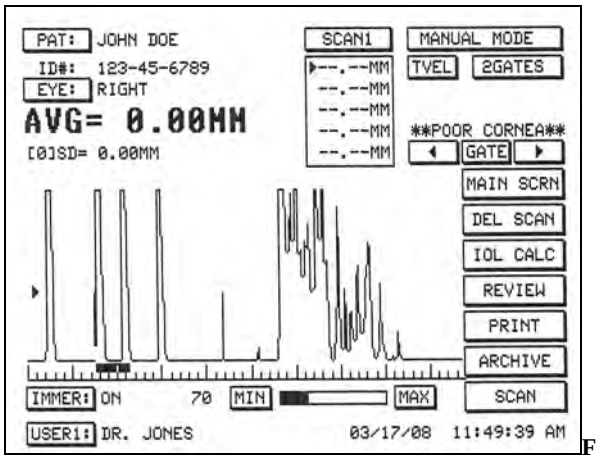


Figure 3-20 Poor Position in Immersion Mode (Corneal Echo Outside of "Window")

Section 4
PACHYMETER OPERATION AND CLINICAL USE
(For 300AP+ models)

IMPORTANT
Remove the black protective probe cover before attempting to use the probe to obtain a measurement

The Pachymeter mode of the PacScan™ Plus series allows for measuring and mapping corneal thickness.
By applanating the Pachymeter probe to a patient eye, an ultrasound signal 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 or the results may be obtained by using the built-in thermal printer.

4.1 SELECTING PACHYMETER MODE

1. Select the [PACHYMETER] button on the Main Screen (See Figure 4-1).
2. Ensure that the Pachymeter Calibration Screen appears.

Figure 4-1 Main Screen Display

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

4.2 MEASUREMENT ACCURACY and PROBE SENSITIVITY TESTS

The PACSCAN™ Plus 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™ Plus system.
2. Touch the **[MEASUREMENT ACCURACY TEST]** button to begin, followed by the **[START]** button. The test consists of an internal calibration check which should generate a reading of 0.500 mm ±0.001 mm. (0.499 – 0.501mm).
3. Verify that the "System OK" message appears just above the measurement on the display, thereby indicating system electronic measurement accuracy is acceptable.

⚠ IMPORTANT
If system measurement accuracy cannot be verified, contact the 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, followed by the **[START]** button. The test, analyzes 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 just above the measurement on the display, 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™ Plus memory. User profiles allow for user identification.

1. ***Entering / Editing User Identification***. Touch the **[USER]** button located on the upper right of the display. Verify that the User Data Screen appears (see Figure 4-2).

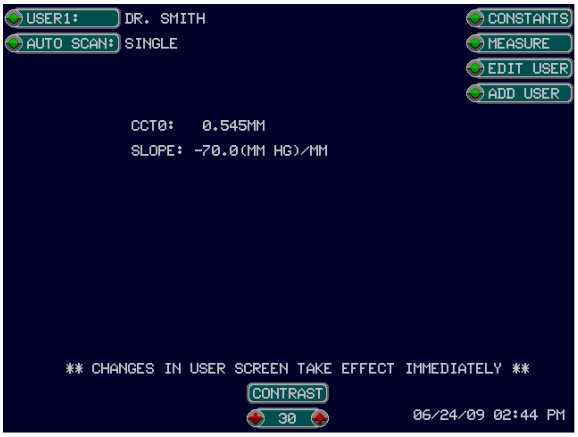


Figure 4-2 User Data Screen

Touch the **[USER #]** button. To add a new user profile touch the **[ADD USER]** button, Enter the name and/or ID of the user by touching the appropriate alphanumeric buttons. Press the [USERS] button to verify that the information has been entered. Touch the **[DONE]** button when finished.

IOP CORRECTION

Included under the User Data Information is an IOP correction formula based on published data (Ehlers and others -1975).If desired, the user can input another formula by touching the **[CONSTANTS]** button and entering the desired changes.
Default settings are:

CCTØ = 0.545mm (Avg.CCT)
Slope = -70mm Hg/mm.

AUTO SCAN

Pressing this button will toggle between "Single" (Footswitch required between each scan) and "Multiple" (instrument will auto-advance between scans) scan settings.

ENTERING PATIENT INFORMATION

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

1. Touch the **[PAT:]** button on the MEASURE SCREEN. 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.

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. Press the **[OD:]** button and enter the "Measured" IOP reading for the RIGHT eye. Press **[ENTER]** when completed.

6. Press the **[OS:]** button and enter the "Measured" IOP reading for the LEFT Eye. Press **[ENTER]** when completed.

7. Touch the **[MEASURE]** 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 to proceed to the Bias Edit Screen.

3. Touch the **[BIAS]** button and enter the desired bias by touching the appropriate alphanumeric keys. When finished entering the bias, touch the **[ENTER]** button to return to the Measure Screen.

4. 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™ Plus and other instruments). The value can be changed as follows:

1. In the Measurement Screen, touch the **[CVEL]** button to proceed to the Corneal Velocity Edit Screen.

2. 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 to return to the Measure Screen.

3. 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:

- "**MAP1 - SINGLE**".
  Single Reading / One Point. This mode allows the user to obtain a single reading at one point along the corneal surface.

- **"MAP1 – MULTI".**
  Multiple Readings / One Point. This mode allows the user to obtain up to five (5) readings at one point along the corneal surface.

- **"MAP2 – SINGLE".**
  Single Reading / Multiple Points. This mode allows for the user to obtain a single reading at five (5) different points along the corneal surface.

- **"MAP2 – MULTI"**
  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.

It should be noted that each reading which is obtained actually consists of the average obtained from 128 individual measurements.
To select the desired mode, touch the mode button and select one of 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 left (Yellow) of the screen along with the standard deviation for the reading (remember that each reading consists of 128 individual measurements). The reading is stored until another measurement is performed. (See Fig. 4-4)

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. The individual reading and standard deviation for that point will be displayed on line 1 in the box just below the average.

5. Since "Multiple" was selected, the measurements will continue without pressing the footswitch between measurements.

6. The second reading and standard deviation will be displayed in the box on the left of the screen beneath the first reading. Also displayed in the upper left (Yellow) of the screen will be the average and standard deviation for the group of readings.

7. Repeat for up to five (5) readings. (See Fig. 4-5)

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 scan # (1-5) to delete and touching the [CLR SCAN] button**. All readings may be deleted by touching the [REVIEW] button followed by the [CLR ALL] button.**

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 left of the screen along with the standard deviation for the reading (In yellow). Remember that each reading consists of 128 individual measurements.

5. To move to the next measurement location, touch one of the empty boxes [ ] 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. (See Fig. 4-6)

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 scan # (1-5) to delete and touching the [CLR SCAN] button. **All readings may be deleted by touching the [REVIEW] button followed by the [CLR ALL] button.**

Figure 4-6 MAP2 SINGLE Screen Display

MEASUREMENTS – MULTIPLE 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 on the left of the screen along with the standard deviation (In yellow). Remember that each reading consists of 128 individual measurements..

5. Repeat steps 1 – 4 to obtain another reading.

6. The second reading and standard deviation will be displayed in the box on the left of the screen beneath the first reading. Also displayed in the upper left of the screen (in yellow) will be the average and standard deviation for the two readings.

7. Repeat for up to five (5) readings. (See Fig. 4-7)

8. To move to the next measurement location, touch one of the empty boxes [ ] 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. Individual readings can be deleted by selecting the particular scan # (1-5) to delete and touching the [CLR SCAN] button.

10. Readings for all locations can be displayed at one time by touching the **[REVIEW]** button. **All readings may be deleted by touching the [REVIEW] button followed by the [CLR ALL] button.**.

Figure 4-7 MAP2 MULTI Screen Display

TROUBLESHOOTING THE MEASUREMENT PROCESS

If a reading is not obtained within approximately ten (10) seconds, the PACSCAN™ Plus 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™ Plus 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 ±10º (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 built-in thermal printer.

1. Press the [MENU] button on either the Measure or Review screen.

2. Touch the **[PRINT]** button to begin printing the measurement data and all associated patient information.

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™ Plus 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 MAINTENANCE/CLEANING AND DISINFECTION

The maintenance described below should be performed routinely so that the PACSCAN™ Plus 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. Always ensure probes are not scratched, cracked or damaged.
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™ Plus 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: Probes must be cleaned and disinfected between patients to prevent patient-to-patient transmission of infection. Prior to any cleaning or disinfecting, unplug the probe from its cable. Cleaning is intended to remove dirt and debris form the probe, and to reduce the presence of microorganisms. Disinfection is performed after cleaning.

Cleaning: A few drops of common concentrated dishwashing detergent diluted in a liter of warm tap water may be used. Scrub the probe in a soapy solution that facilitates the suspension and washing away of the unwanted contaminants. The probes may be vigorously scrubbed, as needed, to remove contaminants. A soft bristle brush may be used to scrub the narrow gap where the probe window joins the probe cover. Rinse the probe thoroughly with water and allow to air dry or blot dry with a soft, lint-free cloth or gauze.

Disinfection:
For low-to-moderate disinfection: After cleaning, immerse the probe in 70% isopropyl alcohol (70% IPA) for 5-10 minutes. Rinse the probe thoroughly with distilled or deionized water and allow to air dry or wipe dry with a soft, lint-free cloth or gauze. If not used immediately, the probe may be placed in a clean bag for storage.

For a higher level of disinfection: After cleaning, immerse the probe in 2-3% W/W hydrogen peroxide for 8-10 minutes. Rinse the probe thoroughly with distilled or deionized water and allow to air dry or blot with a soft, lint-free cloth or gauze. If not used immediately, the probe may be placed in a clean bag for storage. Other FDA-approved high-level disinfectants may be used for up to 10 minutes.

Probes are hermetically sealed and, if necessary, the entire probe (up to the connector) may be immersed in disinfecting solution. However, this should be reserved for rare cases where it is judged by the clinician that the entire probe has been contaminated. When this is not the case, then it is only necessary to immerse the portion of the probe that has been in contact with the patient, plus approximately 2 cm. of the probe cover.

**** CAUTION: NEVER IMMERSE THE CONNECTOR AT THE END OF THE PROBE! ****

Probe Cleaning and Disinfecting Tips:

- Do not allow probes to come in contact with any solutions for longer than 10 minutes at a time
- Thorough rinsing with distilled or deionized water is recommended after contact with any cleaning or disinfectant solution to remove traces of the solution
- Air drying is acceptable following rinse
- If a cloth is used, blot dry with clean, soft, lint-free material that does not leave visible debris or lint on the probe
- Diluted sodium hypochlorite solution (1:10 bleach solution) may be used as a high-level disinfectant, rinse very thoroughly
- FDA-cleared disinfectants may be used on the probes according to the facility and/or manufacturer's instructions, but not longer than 10 minutes
- Thorough and continuous rinsing with copious amounts of the disinfectant solution for several minutes may be performed in between patients.

STORAGE

When not in use, it is recommended that the power cord be disconnected and the **PACSCAN™ Plus** be covered to keep dust and debris from entering the system. While stored the **PACSCAN™ Plus** should be protected from temperature extremes and humidity which can cause condensation within the unit. The probes should be removed from the **PACSCAN™ Plus** and stored in the compartment beneath the printer access door 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.

5.2 A-SCAN FUNCTIONALITY CHECK

CALIBRATION CHECK

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

The **PACSCAN™ Plus** 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. Adjust GAIN to maximum (100dB).
3. Press [SCAN] and Observe the measurement displayed on the touch screen. The measurement will freeze once it has stabilized and a calibration status message will be displayed in the center of the display.
4. Verify that the measurement obtained is 10 ±0.1mm.

⚠ IMPORTANT

If a measurement of 10 ±0.1mm cannot be obtained, contact the Sonomed service department for further help.

NOTE: *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 is 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 ½ 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 ½ 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 the probe is the cause of the problem, it must be evaluated 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, then touch **[START]** to begin the test, which consists of an internal calibration check which should generate a reading of 0.500 mm ±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.

NOTE: *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™ Plus 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]** then **[START]** 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 for 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 the probe is the cause of the problem, it must be evaluated 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 is 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+).	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+).	Verify that all necessary IOL data have been entered (i.e. K-readings, formula constants).
Inconsistent Axial Length measures obtained (300A+ and 300AP+).	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+).	Ensure the probe is aligned along the visual axis.
Pachymeter reading cannot be obtained (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 ±10°).
Paper does not advance in printer.	Reload paper in printer.

3. If problem cannot be resolved, 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 manufacturer’s 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 only be used when absolutely necessary. For instructions, contact Sonomed Service dept at 800-227-1285.

5.5 WARRANTY

Sonomed Escalon warrants its products are free of defects of labor and material for two (2) years for consoles, one (1) year for probes and cables, and one (1) year for associated computer components.

The following items are not covered:

- Physical damage to the console or probes due to misuse or shock is not covered.
- Damage or data loss due to power failures or fluctuations. The use of a line-interactive UPS is recommended to avoid this type of failure.
- Loss or corruption of data or software due to user error or the installation or use of any third-party hardware or software.
- Damage to transducers caused by autoclaving or exposure to excessive heat.

Repairs not covered by warranty will be invoiced on the basis of parts and labor. At Sonomed Escalon's discretion, the damaged component may be exchanged at a flat rate.

Servicing of the unit may only be performed by Technicians certified by Sonomed Escalon. For additional information regarding system repair, maintenance, or exchange please contact US:

Sonomed Escalon
1979 Marcus Avenue, C105
Lake Success, NY 11042 USA
Tel: 800-227-1285
Fax: 516-354-5902
www.sonomedescalon.com

5.6 DISPOSAL

When disposal is required, the equipment and associated cleaning and disinfecting chemicals should be disposed of in accordance with local, state and federal laws.

In the European Union, follow Waste Electrical & Electronic Equipment (WEEE) Directive 2012/19/EU Annex I, 4.07.2018

5.7 TECHNICAL SERVICE &SUPPORT

There are no user-serviceable parts within the system. Please contact Sonomed Escalon or your local distributor to request technical service and support. Technical support 800-227-1285 or 516-354-0900.

Email: ultrasound-support@escalonmed.com

Any serious injury or incident occurring as a result of ophthalmic ultrasound use should be reported to Sonomed Escalon immediately. Patients and users should report serious incidents to the appropriate regulatory authorities.

Section 6
SYSTEM SPECIFICATIONS

PHYSICAL		
Dimensions		
Width	216 mm	8.5 ”
Depth	254 mm	10 ”
Height	178 mm	7.0”
Weight	2.7 kg	6.0 lbs

ELECTRICAL	
Power Consumption	36 W (Typical)
Incoming Line	
Voltage (±10%)	100 - 240 VAC
Frequency	50 - 60 Hz
Power Supply	
DC Output	15 VDC
Current Output	4 A

ENVIRNOMENTAL	
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
A-Scan Probe	5-Pin Jack with Insertion Key
Pachymeter Probe	2-Pin Jack with Insertion Key

DISPLAY		
Type	LCD Backlit Display with Touch Screen Overlay	
Resolution	640 x 480 pixels (h x v)	
Dimensions		
Width	132 mm	5.2 ”
Height	99 mm	3.9”

PROBES	
A-Scan Probes	
Style	Standard A-Probe (DC)
Frequency	10 MHz ± 10%
Focal Length	22-27 mm
Fixation Light	Internal Red LED
Pachymeter Probes	
Style	Straight Pachymeter Probe
Frequency	20 MHz ± 10%
Focal Length	0.5 mm
Probe Tip Diameter	1.75 mm

PRINTER (Internal)		
Model	Seiko	
Type	Thermal Printer	
Paper Size		
Width	76.2 mm	3.0”
Roll Diameter	45.7 mm	1.8”

Item	300A+	300AP+
PACSCAN 300+™ Unit	•	•
Printer with Paper	•	•
A-Scan Probe	•	•
Calibration Cylinder	•	•
Pachymeter Probe		•
Test Target		•
AC Adapter	•	•
Stylus Touch Pen	•	•
Foot Pedal	•	•
Instruction Manual	•	•

A-SCAN SYSTEM PERFORMANCE	
Examination Modes	Automatic Capture Normal Cataract Dense Cataract Aphakic Pseudophakic Manual
Display Scale	Major Markers 10.0 mm Intervals Minor Markers 2.0 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)
Post Refractive Surgery Formulas	Latkany: Myopic Regression Formula Hyperopic Regression Formula Aramberri: Double_K IOL Correction
IOL Calculations	Lens Power vs. Refraction Displayed in 1/4 Diopter Steps Selectable Refractions Customizable IOL Constants
Measurement Limits AXL Lens ACD	(in Automatic Mode @1550) 18 - 45 mm 2-6 mm 2-6 mm
Measurement Accuracy Electronic Clinical	 .02 mm 0.1 mm
Amplifier	Low Noise Variable Gain Nominal Gain = 60 dB
Index of Refraction	1.3375 (see note)

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 128 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
Customizable Parameters	Corneal Velocity: 1620-1650 m/s Measurement Bias: 80–120 %
	Intra-Ocular Pressure Correction (IOP) formula (Parameters adjustable)
Measurement Limits Tissue Vel = 1636 m/s	 0.130 – 1.00 mm
Measurement Accuracy	5 microns
Measurement Precision	±1 micron
Amplifier	Low Noise Automatic Gain Control Maximum Gain = 46 dB

Note:

The Index of Refraction used by the PACSCAN 300+™ 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.

ALARA SECTION AND EMISSIONS

ALARA SECTION
(As Low As Reasonably Achievable)

Statistical Analysis of Measured Data:

A statistical analysis was performed on the data to examine the upper output limits based on a one-sided tolerance limit approach. The mean and standard deviation of the Spatial-Peak, Time-Average Intensity and Mechanical Index were found, and the upper output limits were calculated from the following formula:

$$X = \underline{x} + K * S_x$$

Where **X** is the upper output parameter limit, $\underline{x}$ is the average of the measured output parameter, and S_x is the standard deviation of the measured output parameter. A value of **K** was chosen which corresponds to a 90% probability that 90% of all probes would fall below the calculated limits of **X**. Since there were three samples, the K value used is 4.258.

Results:

Statistical analysis showed that the probes tested produced MI and $I_{spta.3}$ values below FDA limit values.

Accuracy

The accuracy of the emissions figures is approximately 24.5% for all intensity values reported, 12.3% for all pressure values reported and 12.3% for the Mechanical Index.

Caution

To minimize exposure, examinations should be kept as short as possible.

10 MHZ (A-SCAN) TRANSDUCERS

Material: Lead Metaniobate
Nominal Center Frequency: 10 MHz
Pulse Repetition Frequency: 19.1 Hz.
Type: A-Scan, Energy emitted while pedal or button is activated.

Ultrasonic Intensities in Tissue at the measured transducer focus.

Mode	*A-Mode*	
Probe:	***10 MHz** Transducer*	
	MI [unit less]	**$I_{SPTA.3}$** [mW/cm^2]
Sample Size	3.0	3.0
K	4.258	4.258
Mean	0.189	0.025
Std. Dev.	0.006	0.001
Limit	**0.215**	**0.029**

20 MHZ (PACHYMETER) TRANSDUCERS

Material: Ceramic
Nominal Center Frequency: 20 MHz
Pulse Repetition Frequency: 17 kHz.
Type: A-Scan, Energy emitted while pedal or button is activated.

Ultrasonic Intensities in Tissue at the measured transducer focus.

Mode	*A-Mode*	
Probe:	***20 MHz** Transducer*	
	MI [unit less]	**$I_{SPTA.3}$** [mW/cm^2]
Sample Size	3.0	3.0
K	4.258	4.258
Mean	0.0683	4.02
Std. Dev.	0.00681	0.809
Limit	**0.0973**	**7.47**

The energy will always be attenuated by the tissue between the transducer and the focus when used as recommended. The values presented here are the values at the focal point, the point of maximum intensity.

10 MHZ (A-SCAN) TRANSDUCER

Acoustic Output Reporting Table for Track 1, Non-Auto Scanning Mode
Transducer Model: Sonomed (S/N D09A657)
Operating Mode: A-Mode **Application(s):** Ophthalmic

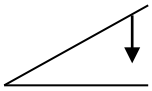
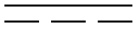
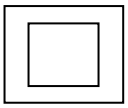
Acoustic Output			MI	Ispta.3 (mW/cm^2)	Isppa.3 (W/cm^2)
Global Maximum Value			0.194	0.0257	15.1
Associated Acoustic Parameters	Pr.3 (MPa)		0.591		
	W_0 (mW)			2.46E-3	2.46E-3
	f_c (MHz)		9.28	9.28	9.28
	z_{sp} (cm)		2.10	2.10	2.10
	Beam Dimensions	x_{-6} (cm)		0.174	0.174
		y_{-6} (cm)		0.183	0.183
	PD (μS)		0.0890		0.0890
	PRF (Hz)		19.1		19.1
	EBD	Az (cm)		0.47	
		Ele. (cm)		0.47	
Operating Control Conditions					

20 MHZ (PACHYMETER) TRANSDUCER

Acoustic Output Reporting Table for Track 1, Non-Auto Scanning Mode
Transducer Model: Sonomed (S/N PD20.0-0108-0341)
Operating Mode: A-Mode **Application(s):** Ophthalmic

Acoustic Output			MI	Ispta.3 (mW/cm^2)	Isppa.3 (W/cm^2)
Global Maximum Value			0.0760	4.91	3.69
Associated Acoustic Parameters	Pr.3 (MPa)		0.323		
	W_0 (mW)			0.236	0.236
	f_c (MHz)		17.9	17.9	17.9
	z_{sp} (cm)		1.00	1.00	1.00
	Beam Dimensions	x_{-6} (cm)		0.153	0.153
		y_{-6} (cm)		0.142	0.142
	PD (μS)		0.0780		0.0780
	PRF (Hz)		1.70E+4		1.70E+4
	EBD	Az (cm)		0.2	
		Ele. (cm)		0.2	
Operating Control Conditions					

Track 1 Reporting Tables show the worst-case indices for each probe type and operating conditions that must be reported

SYMBOLS	
	Footswitch Port
	No serviceable parts in the device
	Direct Current Input
	Type BF Applied Part Output is isolated from live parts by double or reinforced insulation
	Attention, Consult Accompanying Documents
	Caution, Potential Hazard Exists If This Action or Function Is Not Performed Correctly
	Class II Equipment per EN60601
	Direct Current Input Polarity
	CE Mark, Device complies with 93/42/EEC Medical Device Directive The number beside the symbol is the identification number of the Notified Body that certified the quality system under the Medical Devices Directive 93/42/EEC
	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
Vitreous	1532
PMMA IOL	2718
Acrylic IOL	2120
Silicone IOL	1049
Silicone OIL	980

Average Velocities are given for reference only. The actual measurements and distance calculations made using the PacScan are done using individual velocities for the ACD, Lens and Vitreous. The above table shows the default values for these structures but the user may change these values if desired by touching the [TVEL] button while in the [MEASURE] screen.

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:

1. 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).

2. 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
   Acrylic lens thickness = 0.8 mm.
   Silicone lens thickness = 0.9 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.

3. 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)

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APPENDIX B - TABLE OF IOL CONSTANTS

Information supplied by Jack T. Holladay, MD

A-Constant	*S-Factor*	*ACD*	*A-Constant*	*S-Factor*	*ACD*	*A-Constant*	*S-Factor*	*ACD*	*A-Constant*	*S-Factor*	*ACD*
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™ Plus 300A+ and 300AP+ 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 (a0, a1 and a2) 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:

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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