ACCUTOME

A-Scan Plus

User's Guide

24-4016 Rev B

Federal law restricts this device to sale by or on the order of a physician.

FEDERAL COMMUNICATIONS COMMISSION (FCC) UNINTENTIONAL EMITTER PER FCC PART 15

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in an office installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions in the user manual, may cause harmful interference to radio or television reception. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio and television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment to an outlet on a different circuit from that to which the receiver is connected
- Consult Accutome Ultrasound, Inc or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation of this product is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION:
Changes or modifications not expressly approved by Accutome Ultrasound, Inc. could void the FCC compliance and negate your authority to operate the product.

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1 Introduction

Accutome A-Scan Plus Overview

The Accutome A-Scan Plus pictured below has all the features that make it easy to obtain extreme accuracy and improved patient outcomes.

Figure 1 Accutome A-Scan Plus

Features

The Accutome A-scan Plus is designed for easy access to all screens and functions.

The advanced User Input Knob provides unsurpassed ease of use and the straightforward Graphical User Interface guides you through every operation.

What you can't see on the surface is also important. Industry-leading signal acquisition and processing helps you assure accurate measurements. Reliable design and efficient manufacturing provide fiscal value. Upgradeable software protects your investment. The Accutome A-Scan Pluslets you accomplish even the complex simply.

The A-Scan provides the following general features:

- Large 7.5 inch high resolution LCD screen with intuitive User Interface
- Rotary User Input knob and dedicated tactile buttons
- External, universal input, worldwide power supply
- Desktop, slit lamp, or wall mountable
- Provides a variety of printouts
- 1.9" thick, portable

Measurements

The accuracy of the Accutome A-Scan Plus measurement is provided by the following:

- High-resolution, real-time waveform display with up to 8X zoom pinpoints tissue boundaries
- High-speed digitalization acquires over 4000 points per waveform
- Continuous display of Axial Length, ACD, Lens Thickness, and Vitreous dimensions
- Audible feedback of contact, signal quality, and capture
- Immersion mode yields improved accuracy - Contact mode also supported
- Automatically or Manually capture up to 5 waveforms for each eye

- Adjustable Gain, Time Gates, and Amplitude Thresholds
- Modify all waveform parameters using real-time or frozen waveforms
- On-the-Fly customization makes unique patients a breeze
- Predefined Eye Types and Velocities handle most situations such as phakic, dense cataract, pseudo-phakic, aphakic, and even silicone oil filled eyes. All velocities are fully adjustable.
- Custom Eye Types and Material Velocities can be created to handle individual preferences, special pathologies, or future trends
- Highly sensitive 10MHz composite Broadband^{TM}□□□□ probe features fixation light and multiple mounting options

IOL Calculations

The Accutome A-Scan Plus is also a leader in IOL Calculations and provides the following:

- Modern formulas including Hoffer Q, Holladay, SRK/T, and Haigis
- Compare results of all formulas simultaneously on a single screen for selected lenses
- Instantly calculates emmetropic and targeted ametropoic IOL powers for dozens of lenses, viewed three at a time, using the average of selected waveforms, a single waveform, or manually entered data
- Conveniently group lenses by favorite designation such as surgeon, user, type, manufacturer, etc.
- Personalization of IOL Constants is easy and straightforward, encouraging improved patient outcomes
- Maintains individual IOL Constants for each formula. Clearly identifies which IOL constant is used with the selected formula
- IOL Calculation for Post Refractive Surgery Patients

Components

The components that are standard with each Accutome instrument are:

- Ultrasonic probe
- Power Supply
- Keyboard
- Footswitch

Optional Components

There are also several optional components which further simplify the use of the Accutome A-Scan:

- External Printer
- Prager Shell
- Printer Cable
- Serial Cable
- Mounting Options

About This Manual

This manual is a guide for technicians and opthamologists who are experienced in ultrasonographic biometric techniques.

This manual is organized as follows:

Section 2	Safety	Summarizes safety precautions, warnings, symbols and terms.
Section 3	Getting Started	Provides assembly instructions, overview of Accutome A-Scan Plus basic operation.
Section 4	How to Use the Accutome Buttons and Screens	Describes the interface and how to use all the buttons and screens.
Section 5	Accutome A-Scan Preferences	Provides instructions on how to set up eye types and system operational functions.
Section 6	Performing Measurements	Provides detailed instructions on how to perform A-Scan measurements.
Section 7	Customizing Eye Types	Describes how to customize an eye type for an individual Patient.
Section 8	Performing Calculations	Describes the steps necessary to calculate IOL Power.
Section 9	Setting Up IOL Groups	Describes how to set up groups of IOLs for easy access.
Section 10	Personalizing Lens Constants	Provides instructions on why and how to personalize lens constants

Section 11	Storing and Recalling Patient Records	Provides instructions on how to save and recall patient records, and make adjustments to saved records.
Section 12	Printing Records	Provides detailed instructions on how to print patient records and the available printout formats
Section 13	Maintenance	Provides general maintenance instructions
Section 14	Specifications	Provides Accutome A-Scan physical and operational specifications
Section 15	Warranty and Repairs	Describes Accutome A-Scan warranty information and repair procedures.

Having read this manual you will be able to assemble the Accutome A-Scan, take measurements, calculate IOL power, customize IOL constants and eye types, and print and save Patient records.

Safety Information

The section lists:

- Safety Precautions associated with the Accutome A-Scan Plus
- Safety Precautions of a general nature

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Safety Issues to Consider When Using the Accutome A-Scan Plus

The Accutome A-Scan Plus is non-invasive. The ultrasonic biometry probe touches the surface of the anesthetized cornea during the scanning process. The probe must be cleaned before and after use.

Indications for use

This instrument is used for measuring the axial length, anterior chamber depth and lens thickness of the eye. It also is used for calculating the optical power of the IOL to be implanted during cataract surgery.

Symbol Definitions for the Accutome

Statements, graphics and symbols listed below are used on components of the Accutome A-Scan Plus. Descriptions and meanings are listed to the right of the symbols.

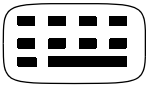
"Attention! Consult instruction manual."

Single phase alternating current

When pressed turns the power on and off.

Serial Link connector

Printer connector



Keyboard connector

Foot switch input connector

Power connector

Safety Precautions

There are several areas in the use of the Accutome A-Scan that require special attention, as they may pose a safety threat.

Sterilization

Sterilization issues are confined to the A-Scan probe that comes in contact with the patient's eye. In order to prevent the transmission of disease, OSHA and CDC guidelines are referenced for proper control of sterilization issues. These guidelines are frequently updated so be sure to contact OSHA, CDC, or your local disease control officer for the latest information and sterilization techniques.

Infection control techniques that are compatible with the Accutome A-Scan Plus probe include:

1. Immersion of the probe tip in an antibacterial solution, such as Sporicidin™ or Cidex™

***Note:** *Please follow the manufacturer's written protocol when using any antibacterial solution.*

This instrument has no user operated controls or settings that affect the acoustic output.

When using this instrument, the ALARA (As Low As Reasonably Achievable) principle should be followed. This principle is used to reduce unnecessary, potentially hazardous exposure to individuals, by keeping doses

and test repetition As Low As Reasonably Achievable to achieve the required diagnostic information.

Disinfection and Cleaning

The recommended disinfection technique is to clean the probe membrane and tip assemblies with isopropyl alcohol (and no other substance). It is imperative that the alcohol be given time to evaporate before applying a probe to the patient's eye.

WARNING! DO NOT AUTOCLAVE!

Disinfection issues are confined to the Accutome probe that comes in contact with the patient's eye. In order to prevent the transmission of disease, refer to the OSHA and CDC guidelines for proper control of disinfection. These guidelines are frequently updated so be sure to contact OSHA, CDC, or your local disease control for the latest information and disinfection technique.

WARNING! DO NOT IMMERSE THE PROBE'S CABLE OR METAL CONNECTOR. ALLOW TO DRY BEFORE USE.

CAUTION: General indications for use of the Accutome probe include on external structurally intact areas of the eye globe and orbit areas only.

Electrical Hazard and Safety

The instrument, foot switch and probe of the Accutome A-Scan Plus are electrical/electronic devices. Reasonable care should be taken when making electrical connection and handling electrically powered devices. Avoid use of damaged electrical equipment or frayed electrical cords. If repair or maintenance is being performed on the Accutome, the equipment must be turned off and the power cord disconnected.

Covers must not be removed except by qualified personnel. To avoid injury, do not operate the Accutome without protective covers.

The system is intended to operate from a power source of 100 - 240 VAC, 50/60 Hz. Protective earth grounding through the grounding connection in the power cords is essential for safe system operations.

Use only hospital-grade power cords and the connectors supplied with the Accutome A-Scan Plus. Also, be sure the power cords and connectors are in good condition.

To comply with IEC 601-1, the device should be connected to earth via the ground terminal located next to the DC input connector. Upon request, a ground cable can be provided; Accutome part number: 24-4045.

Avoiding Equipment Damage

Attach the Accutome A-Scan Plus only to medical grade *IEC-601-1 Medically Approved* equipment.

The Accutome A-Scan Plus provides no explosion protection from static discharge or arcing components. Do not operate the instrument in the presence of explosive gases such as flammable mixtures of anesthetic and air, or nitrous oxide.

To prevent overheating, keep ventilation holes, located on the back of the instrument, free from obstruction.

Assembling the Accutome A-Scan Plus

The Accutome A-Scan Plus is designed to be used in multiple environments and can be rested on a surface, mounted on a wall, or mounted on a pedestal, or camera mount. The instrument requires little assembly. All components, standard and optional, can be quickly and easily connected.

The instrument is built with connectors for each component that is part of the Accutome A-Scan Plus environment. There is also a serial port used to transfer data from the Accutome A-Scan Plus to a computer.

What you need

For a complete Accutome A-Scan environment you will need the following:

- Accutome A-Scan Plus instrument including display
- Ultrasonic Probe
- Power Supply
- Power Cord
- Keyboard - optional from Accutome
- Footswitch - optional from Accutome
- Printer - optional
- Printer Cable - optional from Accutome
- Serial Cable - optional from Accutome, for patient data download to computer

Figure 2 Accutome A-Scan Plus Components

Probe

The probe provided with the Accutome A-Scan is an essential component. No other probes should be used with the instrument.

Printer

The Accutome A-Scan can be configured with either a Laser Jet or Ink Jet printer. If using a Laser Jet printer, an HP Laser is recommended, specifically any printer that uses the HP PCL5 printer language. If using an Ink Jet printer, an HP Ink Jet is recommended, specifically any printer that uses the HP PCL3 printer language.

The Accutome A-Scan also provides generic text only printing that is compatible with most printers. When you print with the text only you will not be able to print graphic items such as Patient waveforms.

Serial Link Port

Another convenient feature of the Accutome A-Scan Plus is the serial port that can be easily linked to a PC (Personal Computer). The serial port makes it possible to export patient and waveform data (in a text format) to a Windows application that accepts generic text. You can configure the baud rate for the serial port.

Foot Switch

The foot switch can be used to capture, review and delete measurements.

Keyboard

The keyboard is not required for operation but provides convenience for entering alphanumeric data and performing shortcut operations.

Power Supply

The power supply provided with the Accutome A-Scan Plus is a small, compact external unit with worldwide power input capabilities.

Placing the Accutome A-Scan Plus

The instrument is designed to be placed almost anywhere; it is equipped with a quick-close kickstand and several options for mounting. It can be placed on a surface, such as a counter or a desk, using the quick-close kickstand provided with the instrument, or it can be mounted on a wall, a pedestal, a camera mount, or a cell phone mount.

Quick-Close Kickstand

The quick-close kickstand provided with the Accutome A-Scan Plus provides an easy, stable base for the instrument. To open the kickstand pull the kickstand away from the bottom of the instrument. When opening or closing the kickstand it is best to exert a small amount of outward pressure on the inner sides of the kickstand. Figure 3 below shows the kickstand in the closed position and Figure 4 on page 17 shows the kickstand opened.

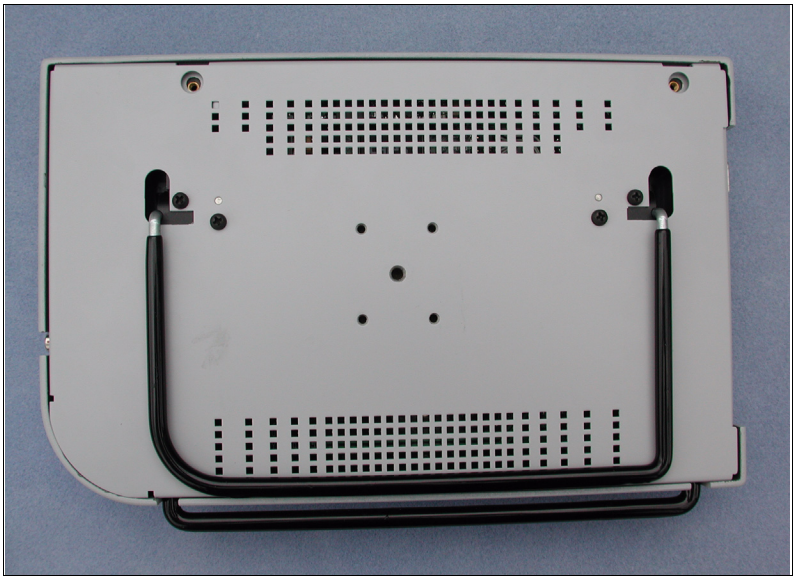


Figure 3 Closed Kickstand

Figure 4 Open Kickstand

Mounting

The Accutome A-Scan Plus is designed to be mounted with many types of hardware. The back of the Accutome has five threaded holes. Four of the holes are AMPS-NEC compatible and will accept any compatible mounting.

In the center of the four holes is one larger hole. The larger hole is designed to accept a camera tripod, pedestal, or wall mount.

***Note:** *For more information on mounting the Accutome A-Scan Plus and purchasing mounting hardware, contact the Accutome Support Group*

Figure 5 Accutome A-Scan Plus Mounted on a Pedestal

Connecting the Components

All of the connectors for the Accutome A-Scan Plus components, except for the probe, are located on the side, at the left of the instrument (facing the screen).

Connecting the Printer

To install the printer:

1. Locate the printer connector, on the side, at the left of the instrument (see Figure 6 on page 22).
2. Connect the printer cable from the printer to the printer connector.
3. Set the printer driver according to the printer connected (see "How to Set the Printer" on page 91 of this manual).

WARNING! THE PRINTER IS NOT HOT SWAPABLE AND THE INSTRUMENT AND THE PRINTER SHOULD BE TURNED OFF WHEN CONNECTING THE PRINTER.

Connecting the Footswitch

To connect the footswitch:

1. Locate the footswitch connector, on the side, at the left of the instrument (see Figure 6 on page 22).
2. Insert the connector of foot switch cable into the foot switch connector.

Connecting the Keyboard

To connect the keyboard:

1. Locate the keyboard connector, on the side, at the left of the instrument (see Figure 6 on page 22).
2. The keyboard cable is keyed with a side that is flat.
3. Insert the connector of the keyboard cable, with the flat side of the connector pointing to the back of the instrument, into the keyboard connector.

WARNING! CONNECT THE KEYBOARD ONLY WHEN THE Accutome A-Scan Plus IS TURNED OFF. DAMAGE TO THE INSTRUMENT MAY RESULT IF THE POWER IS ON.

Connecting the Serial Link

The settings required for the computer that will be connected to the serial link port are as follows:

- The baud rate can be set to 9600, 19200, 38400, 57600, or 115200.
- The communication parameters are 1 start bit, 8 data bits, 1 stop bit, no parity, hardware flow control

To utilize the serial link port, you must connect a serial cable from the serial link connector to an empty serial port on the PC. The cable required is required is a DB-9 Male to DB-9 Female Straight Through serial cable, Accutome part number 24-4012. You must also configure the serial link port in the Setup Screen. (Refer to "How to Set the Serial Link" on page 96 of this manual.)

1. Locate the serial port connector, on the side, at the left of the instrument (see Figure 6 on page 22).
2. Insert the serial cable connector of the into the serial link connector.

Connecting the Power

There are two components to connect power to the Accutome A-Scan Plus; there is a power supply which regulates the voltage going to the instrument, and there is a grounded power cable which connects from the power supply to an outlet.

To connect the power:

1. Locate the grounded power cable and insert it into the empty connector on the power supply.
2. Locate the power connector, on the side, at the left of the instrument (see Figure 6 below).
3. Insert the power supply connector into the power connector.

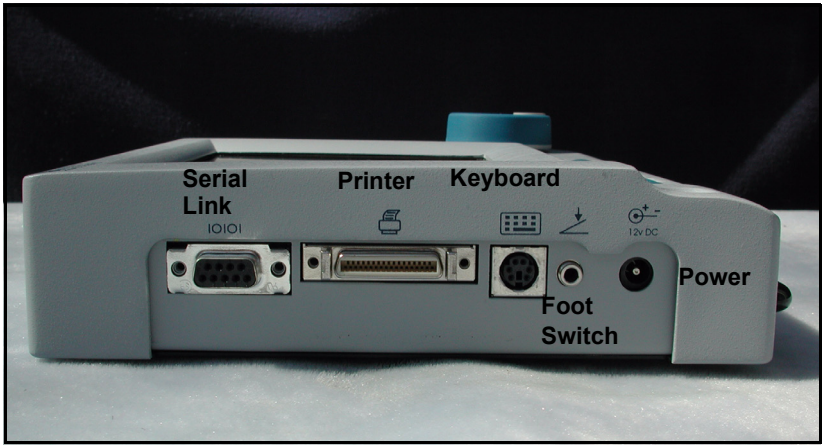


Figure 6 Component Connectors (Left Side of Instrument)

Connecting the Probe

The Accutome A-Scan Plus probe connector is located on the right side of the instrument (facing the instrument).

To connect the probe:

1. Locate the probe connector, on the side, at the right of the instrument, facing the screen (see Figure 7 below.)

Figure 7 Probe Connector (Right Side of Instrument)

2. The probe connector is keyed and has a red dot indicating the key.
3. Insert the probe with the red dot facing the back of the instrument. (Refer to Figure 8 below.)

Figure 8 Probe Connected

Probe Setup

The Accutome A-Scan Plus probe is an integral component. There are several options available for probe use. The Accutome A-Scan Plus probe can be used:

- With an immersion shell
- Mounted into a Goldman Tonometer
- With a probe handle extension

***Note:** *You cannot operate the Accutome A-Scan Plus without the Accutome probe.*

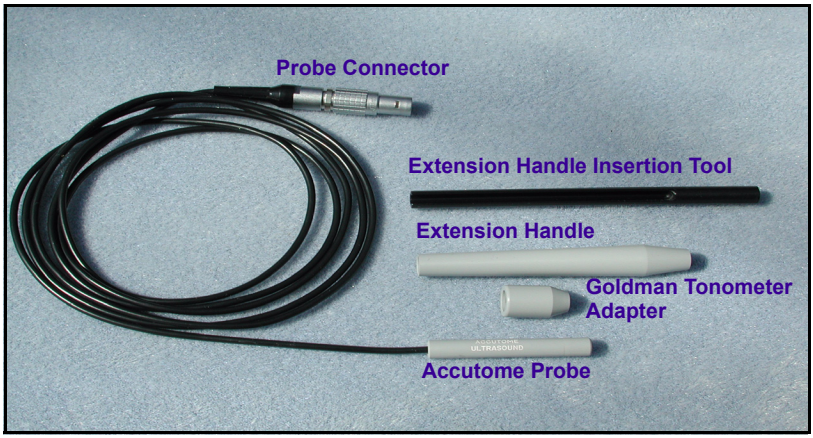


Figure 9 Accutome Ultrasonic Probe Kit (PN 24-4001)

Accutome Probe with an Immersion Shell

The Accutome probe is designed to be used with an Immersion Shell. When using an immersion shell ensure that there is a distance of 5 - 14.5 mm between the bottom of the probe and the bottom of the immersion shell, as shown in Figure 11 below

Figure 10 Accutome Probe

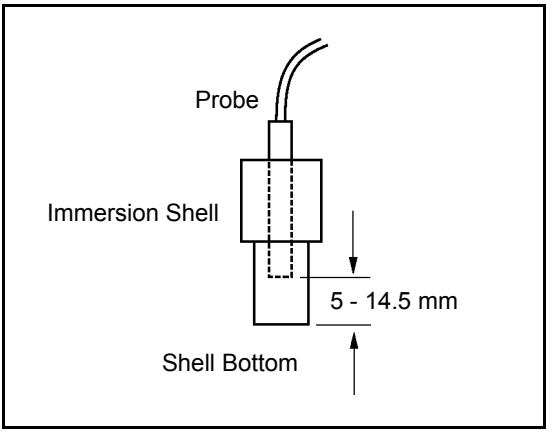


Figure 11 Probe Setup with Immersion Shell

Accutome Probe with Goldman Tonometer Adapter

The Accutome probe is designed to be used with an Goldman Tonometer Adapter. When using the Tonometer Adapter:

1. Slide the adapter over the end of the probe as shown in Figure 12 below.
2. Mount the probe by inserting the Adapter into the Goldman Tonometer.

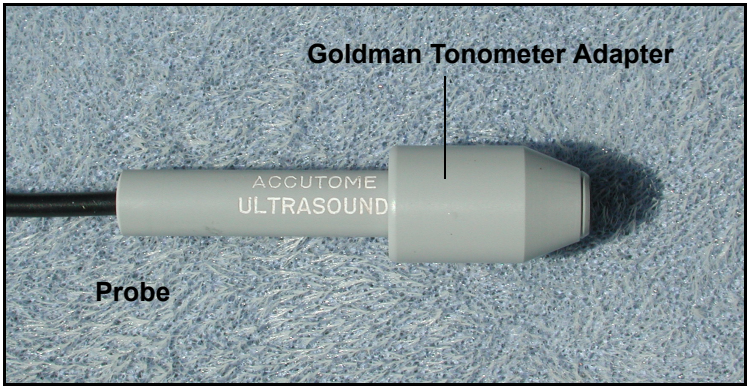


Figure 12 Probe with Goldman Tonometer Adapter

Accutome Probe with Handle Extension

The Accutome probe is designed to be used with an handle extension to increase the length of the probe. When using the probe handle extension:

1. Insert the probe into the handle extension as shown in Figure 13 below.
2. Slide the insertion tool into the handle extension making sure that the probe cable runs through the notched channel of the insertion tool.
3. Push the probe through the handle extension until the tip of the probe emerges from the extension.
4. Remove the insertion tool by sliding it back away from the handle extension.

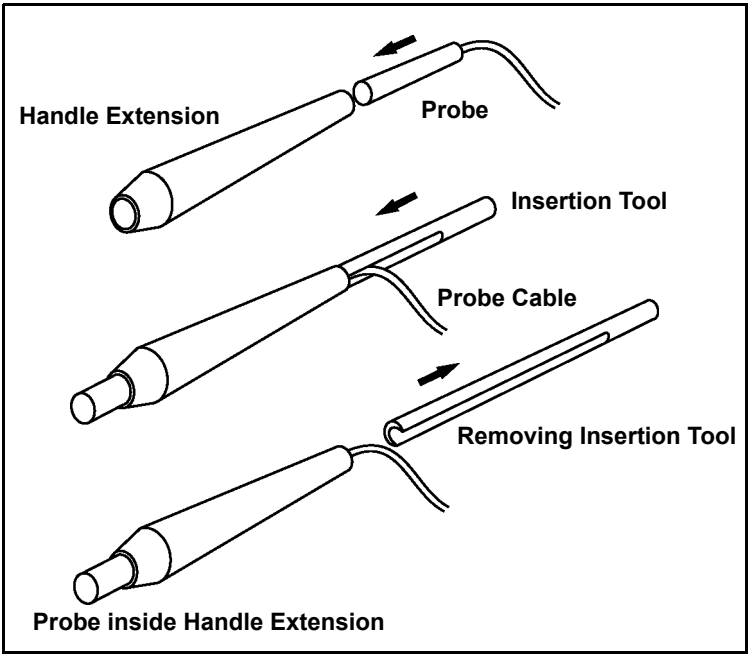


Figure 13 Inserting the Probe into the Handle Extension

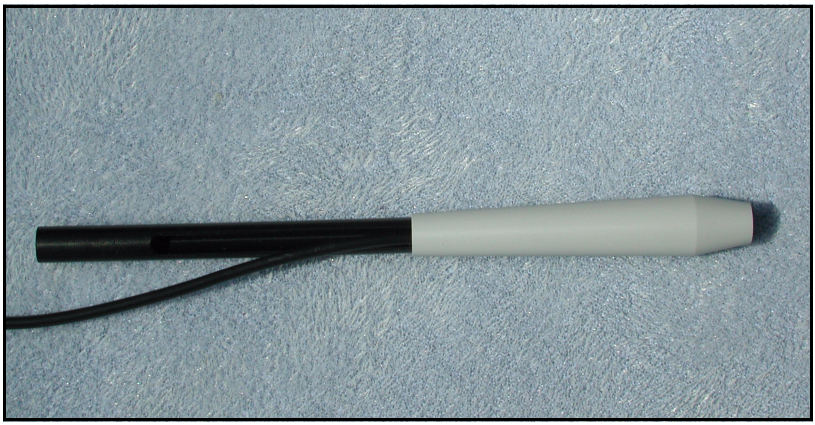


Figure 14 Probe with Handle Extension and Insertion Tool

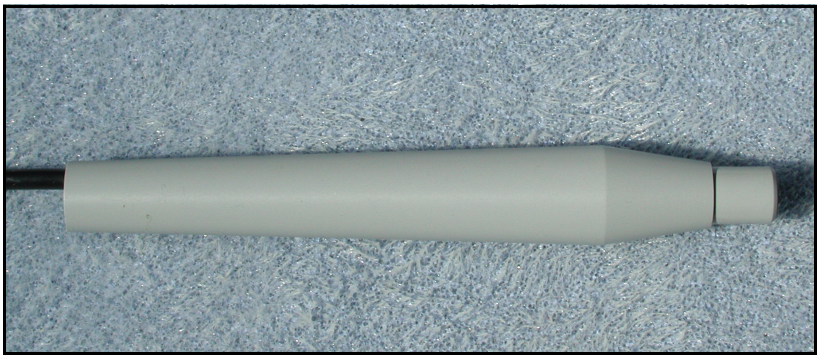


Figure 15 Probe with Handle Extension

Basic Operation

The basic operation of the Accutome A-Scan Plus consists of the following steps:

1. Power on the instrument.
2. Adjust the LCD display contrast.
3. Take five measurements per eye.
4. Calculate the IOL power for desired result.
5. Print or save the Patient Record.

How to Power On the Accutome A-Scan Plus

To power on the Accutome A-Scan Plus:

1. Push the power button located at the bottom left corner of the instrument (see Figure 16 below). When you power on the Accutome A-Scan Plus a splash screen will appear. The instrument will go through an initialization process and when completed will display the Measure Screen. The Accutome A-Scan Plus will also beep once indicating that the instrument is ready.

Figure 16 Turning on the Accutome A-Scan Plus

2. The first screen you see will be the Measure Screen. Scanning mode preferences are maintained while the instrument is powered off.

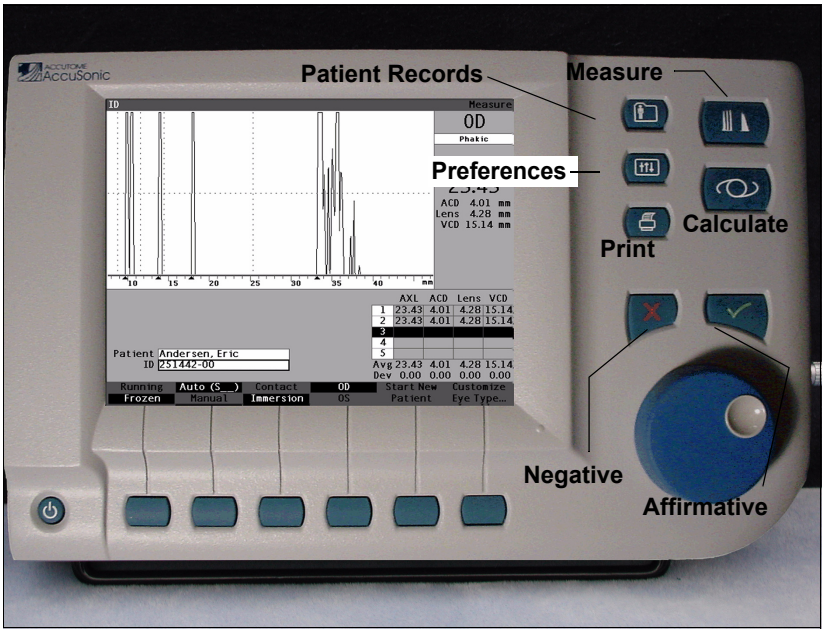


Figure 17 Measure Screen Displayed

How to Adjust the Contrast

When you turn on the Accutome A-Scan Plus you may have to adjust the contrast of the display. The display is an LCD (Liquid Crystal Display) and depending upon the angle from which you are viewing the screen, the images displayed may not be bright enough or may be too bright.

To adjust the Accutome A-Scan Plus screen contrast:

1. Press and hold the Preferences button (see Figure 17 on page 31).
2. Rotate the knob while observing the change in grey/white contrast on the screen.
3. When the contrast is properly adjusted release the Preferences button.

Using the Test Block

The Accutome A-Scan Plus is equipped with a test block, located at the top, right side (facing the display) of the instrument. Refer to Figure 18 below for location. The test block is provided as a way to test the basic operation of the instrument and the probe.

To test the Accutome A-Scan Plus and probe:

1. Apply some immersion fluid (water or BSS) to the test block.
2. Place the probe on the test block.
3. You should receive a waveform and AXL measurement in the Measure Screen.

***Note:** *If you cannot detect a waveform, call the Accutome Service Group at (610) 889-0200.*

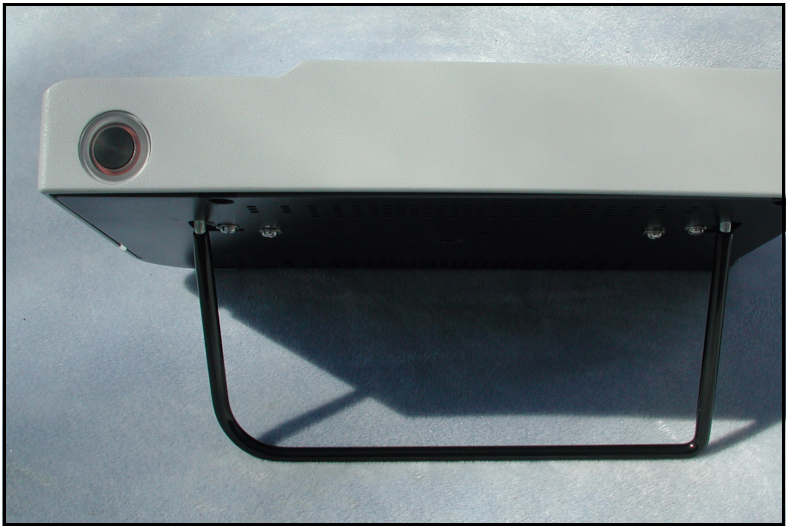


Figure 18 Accutome A- Scan Plus Test Block (Top of Instrument)

How to Start a New Patient

To start a new Patient:

1. Press the button under the "Start New Patient" selection on the Measure, Calculate IOL or Patient Records Screens. Refer to Figure 19 below.

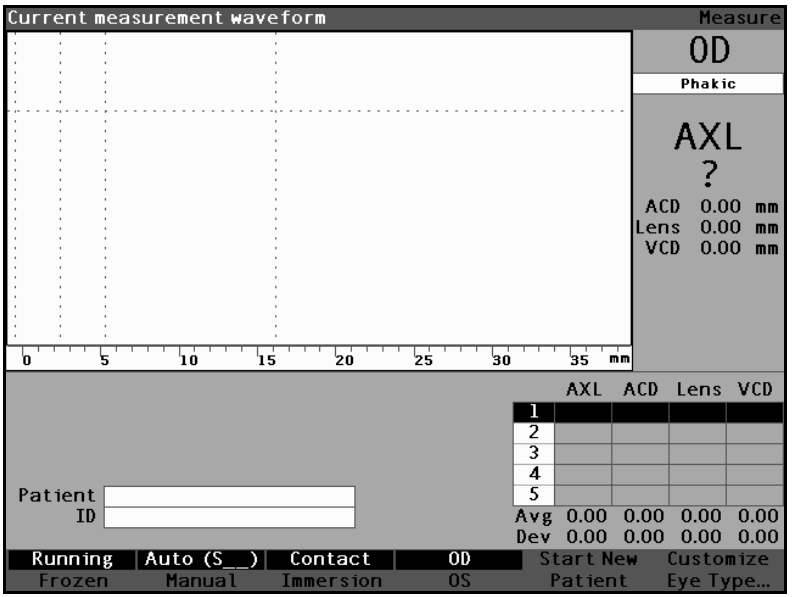


Figure 19 Measure Screen Starting New Patient

2. When you start a new patient the Accutome A-Scan Plus will clear all fields on the Measure Screen as follows:
   - ❖ Gain set to default
   - ❖ Gates/Threshold set to default
   - ❖ Waveforms deleted
   - ❖ K readings deleted
   - ❖ Entered AXL (if any) deleted.
   - ❖ Patient field deleted
   - ❖ ID field set to default (which may be blank)
3. If you wish to enter a Patient Name select the Patient field and press the knob or the √ button to activate the field as shown in Figure 20 below.

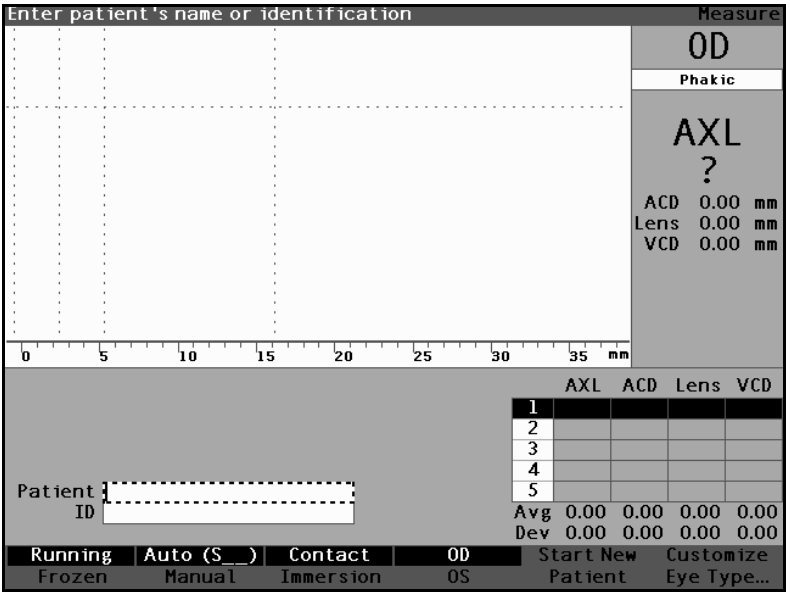


Figure 20 Patient Field Activated

4. Enter the Patient name. Press the knob or the √ button, to save the Patient name and deactivate the field.

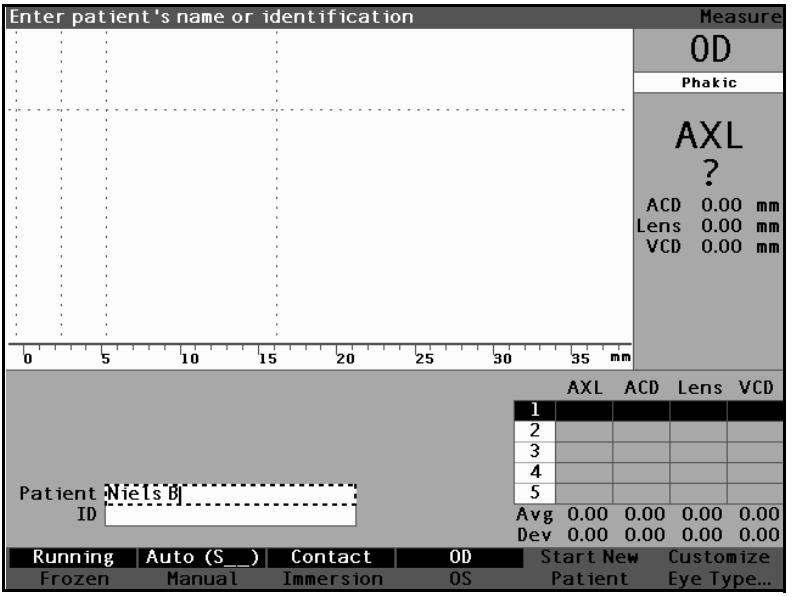


Figure 21 Entering New Patient Information

5. If you also need to enter an ID, select the ID field by turning the knob. Press the knob or the √ button, to activate the ID field.
6. Enter the ID and press the knob or the √ button, to save the ID and to deactivate the field.

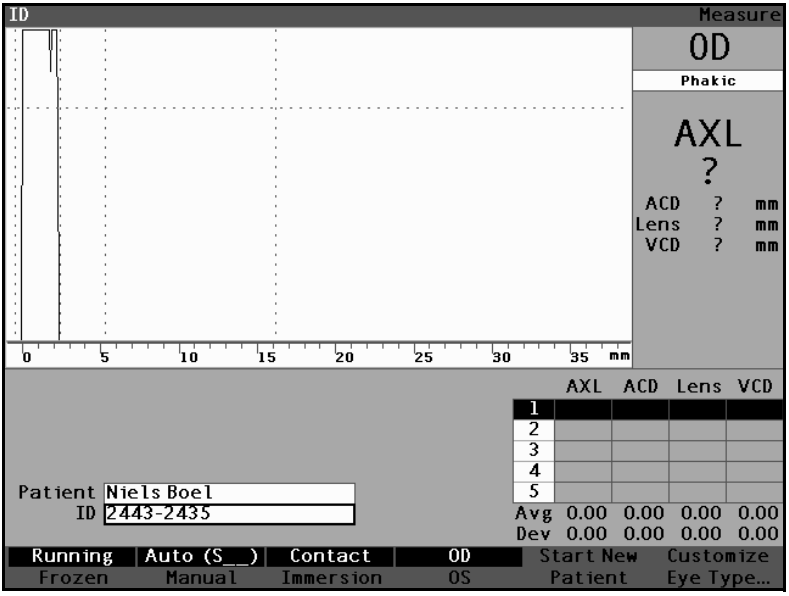


Figure 22 New Patient Information Entered

How to Enter Text without a Keyboard

The keyboard is optional with the Accutome A-Scan Plus. The keyboard makes entering text very easy. When a field is active requiring text, and you have a keyboard, you simply have to enter the text.

The Accutome A-Scan Plus also provides a method of entering text that does not require a keyboard. If a field is activated that requires text, and the keyboard has not been used, the instrument displays a screen keyboard in the soft menu area, shown in Figure 23 below, that contains all the alphanumeric characters.

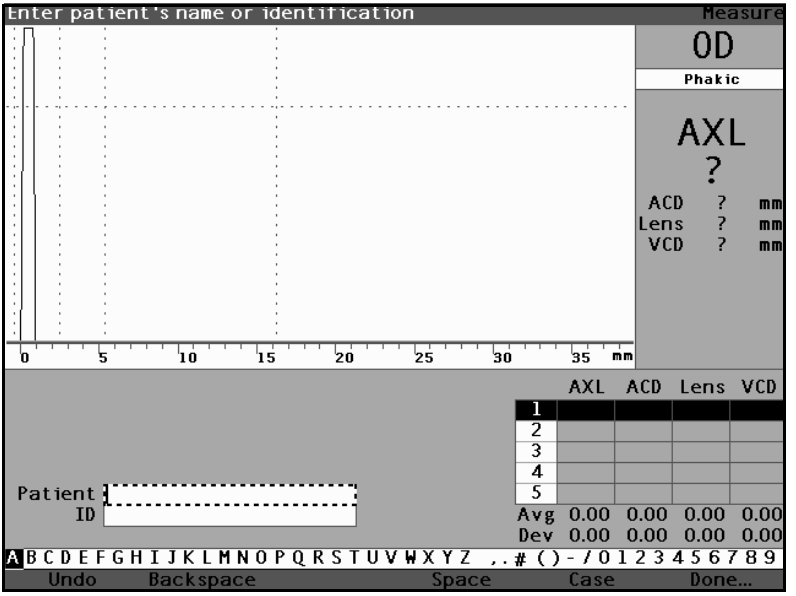


Figure 23 Screen Keyboard

Screen Keyboard Features

The screen keyboard is displayed at the bottom of the screen and is divided into a row of selectable alphanumeric characters and soft menu selections. The background of the selectable characters is white and has a border drawn around it to distinguish the characters from the active buttons.

The screen keyboard also has the following soft menu selections activated by buttons beneath the selection:

- Undo - clears the active field.
- Backspace - deletes the character immediately to the left of the cursor.
- Space - inserts a space after the last character.
- Case - toggles the selectable characters between upper and lower case.
- Done - exits the screen keyboard and returns you to the Measure screen. The selected field will display the edited text.

Special characters are located in between alpha and the numeric letters. You can enter a space in a field by selecting the space between the alpha and numeric characters or by pressing the button below the "Space" soft menu selection.

If you would like to switch to lower case press the button below "Case". The Accutome A-Scan Plus automatically selects upper case for a blank field, unless the field has been previously edited in lower case and will then revert to lower case.

The Accutome A-Scan Plus allows you to switch between using the optional keyboard and the screen keyboard. If you have the optional keyboard and would like to use the screen keyboard, press Ctrl-K . The screen keyboard will then be shown for current and future text edits until you press a key on the optional keyboard.

To quickly select characters on the screen keyboard turn the data knob quickly to accelerate the selection location.

Entering a Patient with the Screen Keyboard

To enter the Patient Name with the screen keyboard:

1. Select the Patient field by rotating the knob.
2. Press the knob or the √ button, to activate the field. The screen keyboard will appear at the bottom of the screen.
3. Rotate the knob to select the first letter, or number of the Patient field.
4. Press the knob or the √ button, to enter the character in the field.
5. Rotate the knob to select the next character.
6. Press the knob or the √ button, to enter the character in the field.
7. Continue entering all the text characters in this manner.
8. If you would like to insert a space, press the button beneath the "Space" selection.
9. If you would to change the case of the letters, press the button beneath the "Case" selection.
10. If you would like to remove a letter or more, press the button beneath the "Backspace" selection. iF you have made an error and would like to erase the entire field, press the button beneath the "Undo" selection.
11. When you have completed the Patient field, press the button beneath the "Done" selection.
12. The Accutome A-Scan Plus will close the screen keyboard and re-display the previous selections over the buttons.

How to Take a Measurement

After you have entered all the Patient information you should set the measurement selections to your liking.

The selections you can change are:

- Automatic/Manual - which method are you using to take the measurement automatic or manual? Automatic allows the Accutome to determine when the probe has acquired a measurement and manual allows the operator to determine when to capture the waveform.
- Contact/Immersion - which method of applying the probe are you using, contact or immersion?
- OD/OS which eye are you measuring, OD or OS?
- Eye type - which type of eye are you measuring; i.e. phakic, aphakic, dense cataract, etc.?

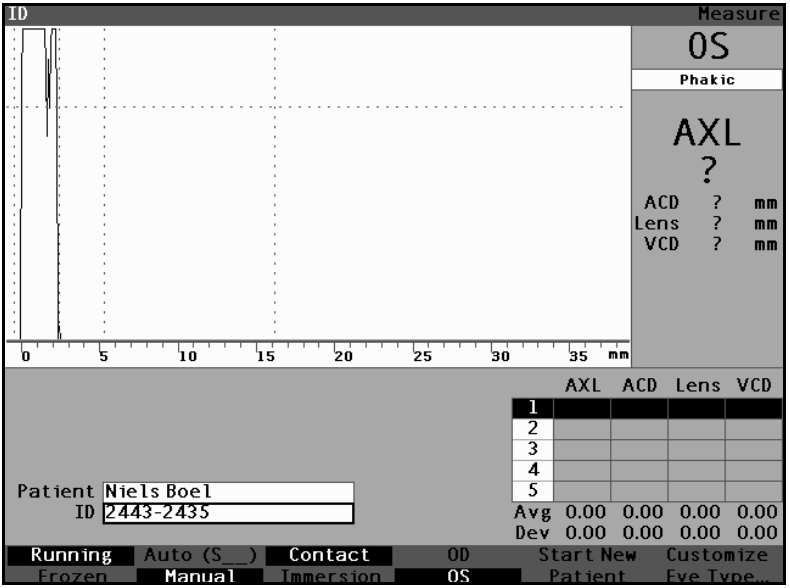


Figure 24 Measurement Fields Selected

To take a patient measurement:

1. Change the necessary measurement settings by pressing the buttons beneath the measurement selections. Each of the measurement selections toggle between one and the other.
2. Set the appropriate Eye Type (the field under OD or OS) for each eye, Phakic is the default and is fine for most cataractous eyes. If measuring an aphakic or pseudo phakic eye, the eye type must be set accordingly. To set the eye type, select the eye type field by rotating the knob, activate it and choose the appropriate type. The type is associated with each eye and is retained when the eye (OD or OS) selected. It is necessary to set the appropriate eye type for each eye if measuring each eye.
3. When all measurement settings for the current Patient are accurate apply the probe to the Patient's eye.
4. If you are not using the running mode, press the foot switch or the Running/Frozen selection. The Accutome A-Scan Plus will proceed to the next empty waveform (if available).
5. If you are using the Automatic mode, the Accutome A-Scan Plus will automatically freeze a measurement upon sclera detection, steep retina detection or upon capturing stable readings. (Auto Mode settings are defined in the Setup Screen.) The instrument will emit a high pitched chirp when you have automatically acquired a measurement.
6. If you are using the Manual mode, and you wish to capture the current waveform press the foot switch or the "Running/Frozen" selection.

***Note:** *The user must review auto measurements for quality. For more information on taking measurements refer to "Performing Measurements" on page 151 of this manual.*

How to Perform a Calculation

After you have completed a Patient's scans you can calculate the power of the IOL for the Patient. You can perform the calculation from the Calculate IOL Screen.

To calculate a lens:

1. Press the Calculate button, located at the right side of the front panel (see Figure 17 on page 31).
2. The Accutome will display the Calculate IOL Screen as shown in Figure 25 below.

***Note:** *For more information on Calculating IOLs refer to "Performing Calculations" on page 197 of this manual.*

3. Select the IOL Group, if necessary, by pressing the button beneath the selection "Select IOL Group" until the appropriate IOLs are displayed.

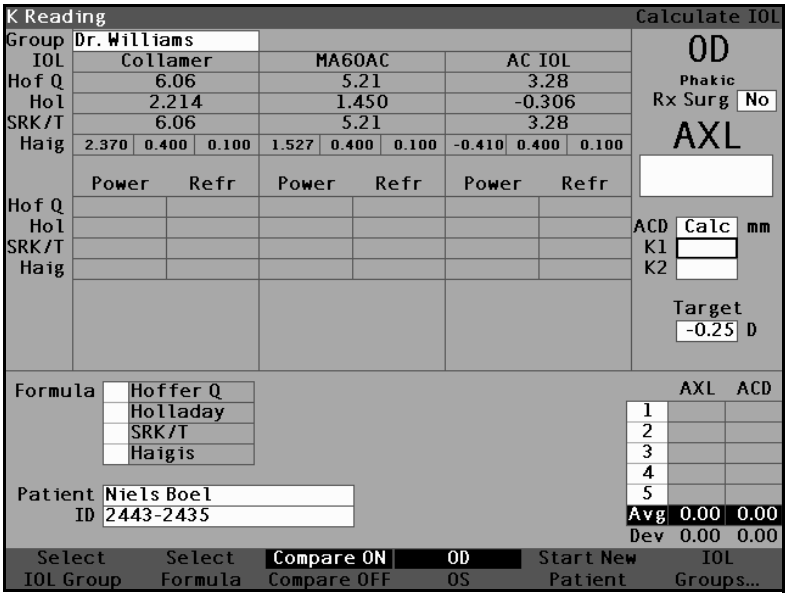


Figure 25 Calculate IOL Screen

4. Select the Formula, if necessary, by pressing the button beneath the selection "Select Formula" until the appropriate formula is displayed.
5. If using the Haigis formula, and the ACD value needs to be changed, rotate the knob to select the ACD field and press the knob or the √ button to activate the field. When the field is active either rotate the knob or manually enter the ACD value in millimeters (mm). If you would like the Accutome to calculate the phakic ACD press the "Delete" key or the X button to remove the entered value and replace it with "Calc" for a calculated value

***Note:** *The ACD field is only active if you are using the Haigis formula. If you have selected another calculation formula the field will not appear.*

Entered ACD should be a phakic ACD measurement. If this value is unknown, the ACD can be estimated by entering "0".

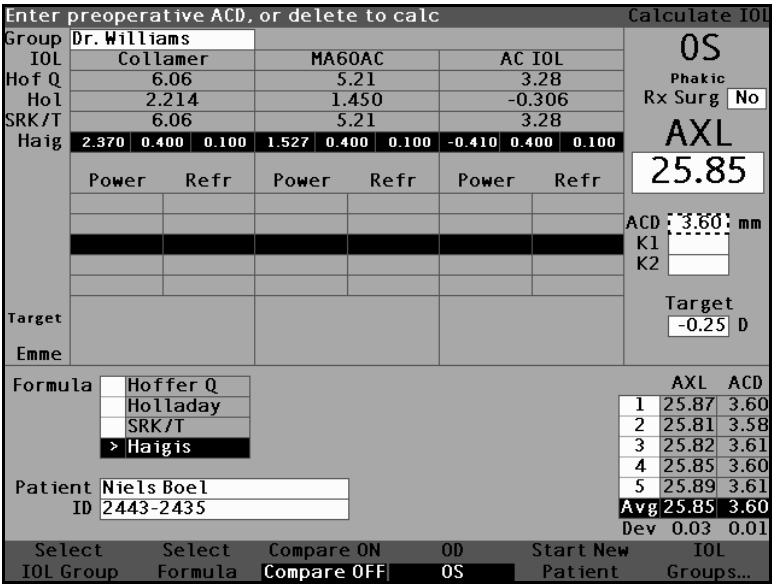


Figure 26 ACD Field Selected

6. Enter the K1 value in the designated area as shown in Figure 27 below. Rotate the knob to select the K1 field and press the knob or the √ button to activate the field. When the field is active enter the K1 values in Diopters or mm.
7. Enter K2 value in the same manner as K1.

***Note:** *When you first receive the Accutome A-Scan Plus the IOL Groups are empty. If there are no IOL Groups present on the Calculate IOL Screen you will not be able to perform a calculation. Refer to "Setting Up IOL Groups" on page 215 for further information.*

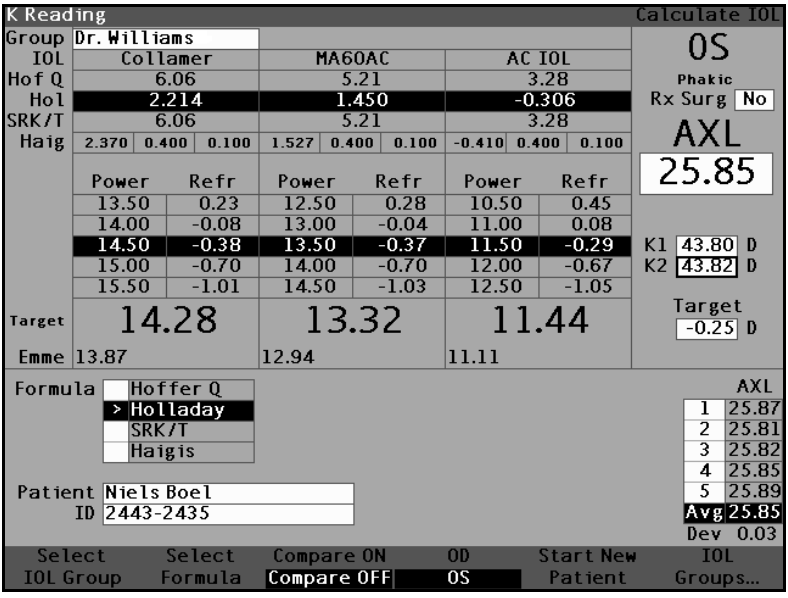


Figure 27 K1, K2 Values Entered

8. After entering the K1 and K2 values, the emmetropic power is calculated and displayed for each IOL.
9. Enter the Ametropoic Target value in the designated area as shown in Figure 28 below. Rotate the knob to select the Target field and press the knob or the √ button to activate the field. When the field is active enter the Target value in Diopters.
10. The Calculate IOL Screen will display the ametropoic power of the lens, for each lens, with the bold, large, black numbers. These values are the optimal lens, and do not necessarily exist in the real world. The Accutome A-Scan Plus also provides you with the power of the IOL that would achieve emmetropia. The emmetropic power is calculated and displayed under the ametropoic power in a smaller font.

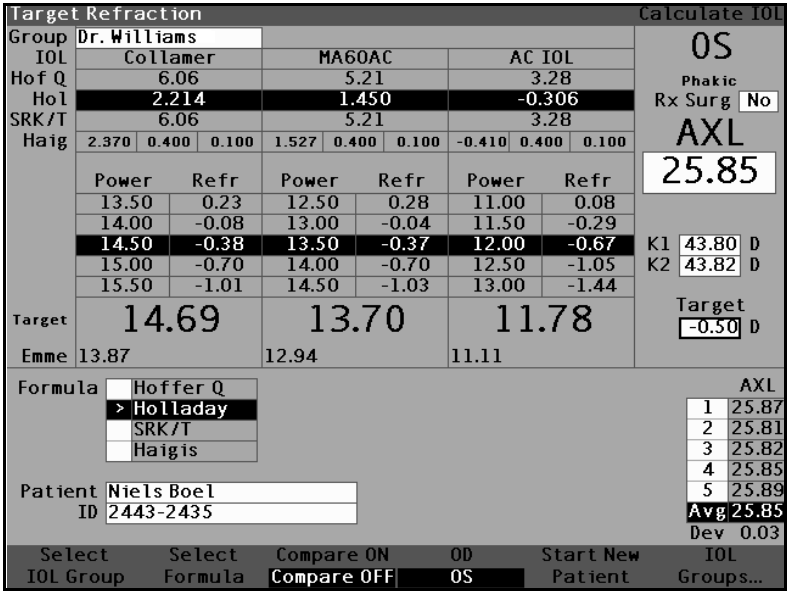


Figure 28 Calculation Completed

How to Print a Record

After you have calculated the lens you will want to print the Patient record. When you print from the Calculate IOL Screen the printout displays the waveform selected for the calculation, lens and formula information, and the calculations for both eyes (OD and OS).

To print a record:

1. With the appropriate Patient record active, press the "Print " button, located at the right side of the front panel.
2. The Accutome A-Scan Plus will print the calculation record.

How to Save Patient Records

The Accutome A-Scan Plus allows you to save patient records at any time. You can save the record after you have taken all the desired measurements or, after you have taken the measurements and performed the calculation.

You can recall a saved patient record and re-scan any of the patient waveforms. You can also adjust the gates/ threshold on any of the waveforms and recalculate the IOL power.

To save a Patient's record:

1. Press the "Patient Records" button located to the right of the instrument (see Figure 17 on page 31). The instrument will display the Patient Record Screen as shown in Figure 29 below.

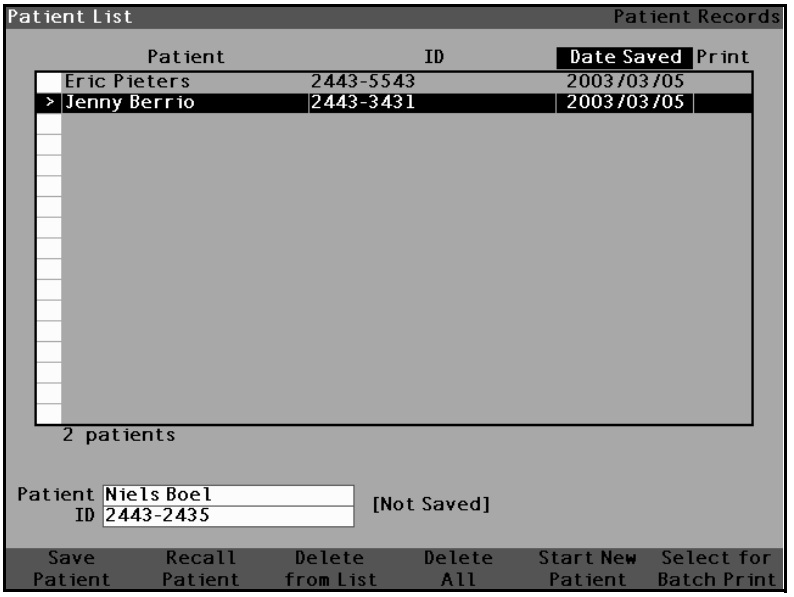


Figure 29 Patient Record Screen

2. Press the button below "Save Patient". The Accutome A-Scan Plus will store the Patient record. The "Not Stored" prompt Patient ID will be changed to "Stored" and a new entry will appear in the Patient List.

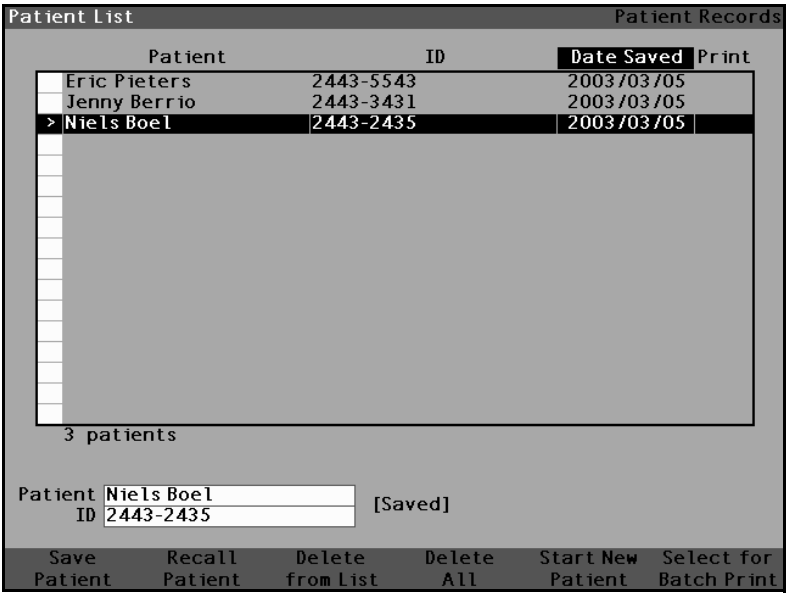


Figure 30 Patient Record Stored

4 How to Use the Buttons and Screens

Overview

The Accutome A-Scan Plus consists of a screen display with buttons located beneath the screen and buttons located to the right of the screen. The A-Scan allows you to control every feature for capturing waveforms and calculating IOL powers including waveform display, adding lens materials and eye types, adding IOLs, setting up IOL groups, and setting preferences. Any task performed with the Accutome A-Scan Plus is performed using the buttons and screens.

The buttons located to the right of the screen are dedicated to specific functions and display other screens or execute printing. The buttons located beneath the screen are soft menu buttons and provide functions that change within each screen (see Figure 31 on page 52.) The buttons have been designed to provide complete functionality with ease of use.

There is also a large knob with an indented push-button area located to the right of the screen, below the dedicated function buttons. The knob is the central component of the Accutome A-Scan Plus user interface. The knob allows you to select and change fields on every instrument screen.

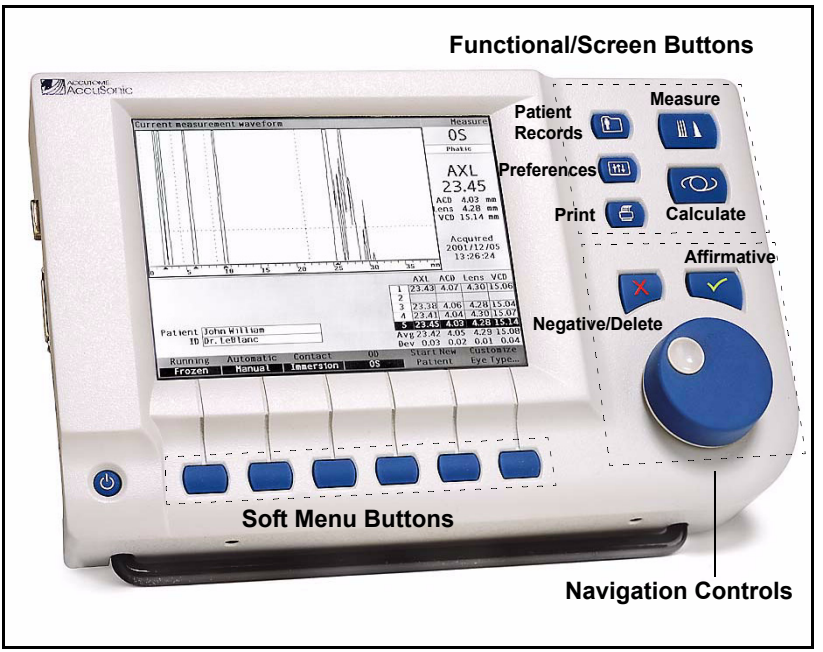


Figure 31 Accutome A-Scan Plus Buttons

Accutome A-Scan Plus Buttons

There are two types of buttons available on the Accutome A-Scan Plus front panel, dedicated buttons and soft menu buttons.

Dedicated Buttons

The dedicated buttons, located at the side of the front panel, in the same area as the knob, all perform a dedicated function. All of the dedicated buttons except the Print button, display other high level screens.

The buttons are as follows:

- Measure
- Calculate
- Patient Records
- Preferences
- Print

***Note:** *Two of the dedicated buttons, Calculate and Preferences, can be pressed multiple times to scroll through lower level linked screens.*

Measure Button

The Measure button displays the Measure Screen where the user can acquire patient waveforms and adjust waveform parameters. The Measure Screen can also display stored Patient waveforms, in the state in which the waveform was originally captured. From the Measure Screen you can also access the Customize Eye Type Screen.

The Measure button can also be used to replace the footswitch. Pressing the measure button is the same as pressing the footswitch.

Patient Record Button

The Patient Record button displays the Patient Record Screen where you save and recall patient measurements and calculations.

Calculate

The Calculate button displays the Calculate Screen where IOL calculations are performed. From the Calculate Screen you can also access the IOL Groups Screen.

If you press the Calculate button multiple times the Accutome will scroll and display the lower level logically linked screens; i.e. IOL Groups Screen and Personalize IOLs Screen.

Preferences

The Preferences button displays the Eye Types Screen where you can define eye types and velocities. From the Eye Types Screen you can access the Setup screen where you define default settings.

If you press the Preferences button a second time the instrument will display the lower level logically linked screen; i.e. Setup Screen.

Print

The Print button prints the information displayed on the current screen. When pressed from the Measurement Screen the print button will print up to five current eye waveforms (if five exist). When pressed from the Calculate IOL Screen the print button will print the calculations for both eyes including all measurements, lens and formula information.

Check or Affirmative (✓)

The Affirmative button acts like pressing the knob. Whenever you have selected a field and press the Affirmative button the field becomes active. If you press the Affirmative button a second time, on an active field the field is deactivated.

The Affirmative button also acts as "Yes" any time you are required to confirm an action; e.g. do you want to delete a record? Press the Affirmative button to continue with deleting the record.

Negative or Delete (X)

The Negative button will clear the contents of a selected field when pressed. For example, if the Patient field is active, when you press the Negative button the current Patient name will be wiped out.

The Negative button also acts as "No" any time you are required to confirm an action; e.g. do you want to delete a record? Press on the Negative button to cancel deleting the record.

Soft Menu Buttons

There is a series of buttons directly below the Accutome display. The buttons offer soft menu selections and change from screen to screen.

There are three types of soft menu selection:

- Buttons that perform a single action
- Buttons that toggle
- Buttons that display other screens or soft menus

Buttons that Toggle between Two Selections

Soft menu buttons that toggle cause the Accutome to switch between one state and another; e.g. on the Measure Screen the button under the Running/Frozen selection toggles the waveform between active and frozen. The active choice is highlighted in reverse video.

Buttons that Display Other Screens or Soft Menus

Soft menu buttons that have an ellipsis... to the right of the selection will display another screen or soft menu.

Accutome A-Scan Plus Knob

The large knob, located at the bottom of the right side of the Accutome A-Scan Plus is for selecting and activating fields and changing the parameters of the active field.

How the Knob Works

When a field on any screen requires data, you move around on the screen and select the field by rotating the knob until you have arrived at the appropriate field. When a field is selected there will be a solid black border around it. Also, when you move from one field to another, the field that is to become active flashes.

Once you have selected a field and you want to enter or change the data in the field, press on the knob. Pressing the knob causes an action. In this case it activates the field. After you have entered or changed data in a field, if

you press the knob again it will save the changes to the field and deactivate it.

If you are in a soft menu, requiring a user response, and you turn the data knob or press another ignored button the active soft menu will flash and beep.

Screens

The Accutome A-Scan Plus is set up as a series of high level screens with logically linked lower level screens. Each of the high level screens is accessed by pressing one of the dedicated function buttons. Two of the dedicated function buttons, Calculate and Preferences allow you to scroll through the lower level screens through the dedicated button. It is in the various screens that you perform all operations; measuring patients, calculating lens replacements, setting up the Accutome A-Scan Plus, setting up IOL groups, personalizing lens constants, etc. The name of each screen is displayed in the top right corner.

What the Screen Displays

Each screen displays tips for the active area, soft menus at the bottom of the screen and tables of information related to the screens function. For example, the Calculate Screen displays the Patient name and ID, the IOLs for the selected IOL Group, the calculation formulas and the K1, K2 and Target values.

Types of Information

The information displayed on each screen is determined by the screen's function. For example, the Patient Records Screen displays all saved patient records. Screen items that have a white background may be selected and modified using the knob.

Any item on a screen followed by an asterisk * indicates that the value has been changed and that it is non-standard, or, custom.

Any menu item followed by an ellipsis .... will take you to another screen when you push button beneath the menu item.

Soft Menus

Each screen has selections that will perform functions that change according to the screen.

Tips

One of the features that makes the Accutome A-Scan Plus so intuitive to use is the tips available on every screen. The tips are displayed at the top left of each screen. The message displayed describes the currently selected screen element.

Sounds

The Accutome A-Scan Plus will also provide you with audio cues.

There is a constant tone initiated when the probe contacts the eye. The frequency of the tone increases the closer the waveform is to being acceptable according to the criteria established in the Auto Mode.

A high continuous tone indicates valid measurements. No tone is emitted if the waveform cannot be measured. A quick double beep is emitted when the waveform is automatically captured. When you have completed capturing five waveforms the instrument will emit a high pitched chirp, indicating completion.

A confirmation beep sounds after a patient is saved and after a patient is recalled.

Error Messages

There are certain situations where the Accutome A-Scan Plus will provide an error message, as well as the tones indicating error. Error messages will be displayed when there is a problem with printing or any condition that requires user attention.

Moving between Screens

When moving from a high level to a lower level screen you only have to press the button beneath the menu item that indicates the lower level screen.

You can get to the IOL Groups Screen and subsequently the Personalize IOLs screen by pressing the dedicated Calculate button a second and third time. You can also access the Setup Screen by pressing the dedicated Preferences button a second time.

Screen Hierarchy

Figure 32 below illustrates the hierarchy of the Accutome A-Scan Plus screens. Notice how each high level screen is logically associated with the screens linked at a lower level.

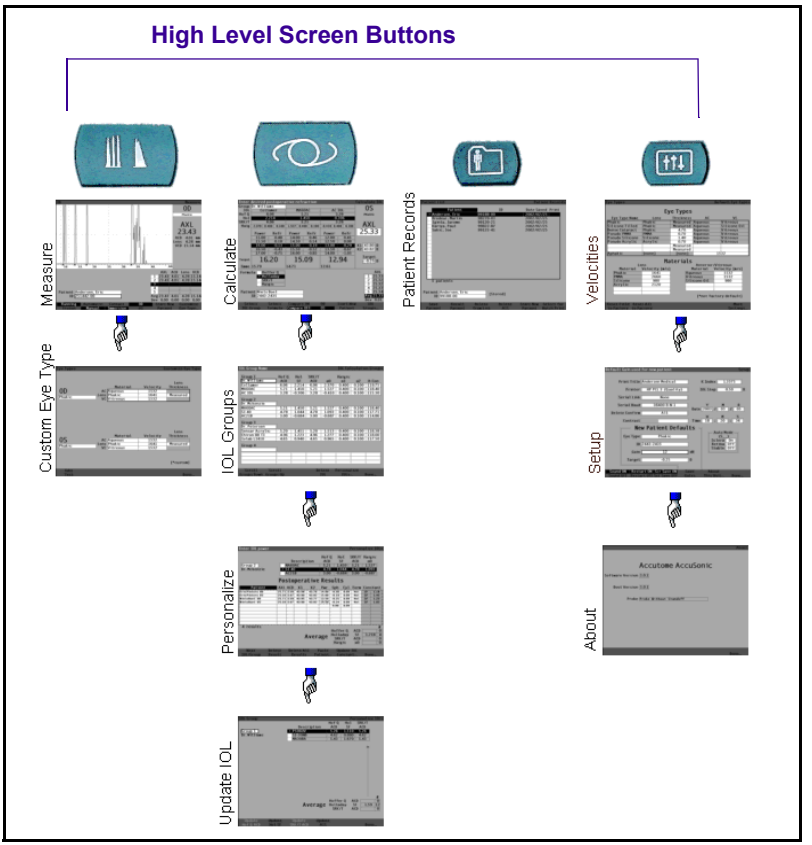


Figure 32 Accutome A-Scan Plus Screen Hierarchy

Top Level Screens

The top level screens are:

- Measure - for performing measurements
- Calculate - for calculating IOL power
- Patient Records - for saving and retrieving patient records
- Preferences - for defining eye types, velocities and Accutome settings

Associated Sub-Level Screens

Each of the high level screens has associated lower level screens that are accessed by pressing a soft menu button on the high level screen.

The associated high level and sub-level screens are as follows.

From the Measure Screen

From the Measure Screen you can access the on-the-fly Customize Eye Type Screen.

From the Calculate Screen

From the Calculate Screen you can access the IOL Groups Screen. From the IOL Groups Screen you can access the Personalize IOLs Screen. From the Personalize IOLs Screen you can access the Update IOL Constants Screen.

From the Patient Records Screen

There is no lower level screen available from the Patient Records Screen.

From the Preferences Screen

From the top level of the Preferences Screen, which is Eye Types, you can access the Setup Screen. From the Setup Screen you can access the About This Unit Screen.

How Buttons, Screens and Knob Work Together

The buttons, screens and knob work together in the following manner:

1. Select a high level screen by pressing one of the dedicated function buttons.
2. In the selected screen rotate the knob to select a field requiring change.
3. Press the knob, or the Affirmative button to activate the field.
4. Make the appropriate changes to the field either by selecting a pre-entered value or entering the required information.
5. Press the knob, or the Affirmative button to save the changes made to the field.
6. Rotate the knob to select the next field requiring change.

Changing Fields and Table Cells

When you are in any screen every field that is in a white box can be changed. Anything not in a white box can not be changed.

When you are moving around in tables, such as the IOL Group table, and you are making changes to a selected cell, press once and the cell becomes active. Pressing the same cell twice escapes the table.

Active Area

The active area on any screen is surrounded by a dashed border.

Text Entry

Certain screens require text entry. The Accutome A-Scan Plus has an optional keyboard, but if you don't have the keyboard the Accutome A-Scan Plus will automatically provide you with a new soft menu of alphanumeric characters. You select the various characters by rotating the knob and enter the characters into the text field by pressing on the knob or the Affirmative button. When you have completed the text entry you can return to the screens by pressing the button beneath the selection "Done".

Selecting a New Active Area

To select a new active area, you must first deactivate the current active area by pressing the knob, or the Affirmative button.

Changing Fields in the Active Area

There are two primary types of fields; pre-entered fields that have been set up at the factory and that can not be manually changed and fields that require information to be entered.

Pre-entered Fields

There are many fields that contain pre-entered information that cannot be changed. For example, in the Setup Screen there is a limited number of selections available for the Printer and three selections available for Delete Confirm.

To change the value of a pre-entered field:

1. Select the field by rotating the knob.
2. Activate the field by pressing the knob or the Affirmative button.
3. When the field is active, rotate the knob to select one of the pre-entered values.

Fields Requiring Information

There are several fields that require the input of information. For example, the Patient name field.

To enter information in a field:

1. Select the field by rotating the knob.
2. Activate the field by pressing the knob or the Affirmative button.
3. When the field is active, enter the appropriate information.

Numeric Fields

Fields that require a numeric value can be selected and adjusted with the knob. To enter a numeric value in a field:

1. Select the field by rotating the knob.
2. Activate the field by pressing the knob or the Affirmative button.
3. When the field is active, rotate the knob until you reach the appropriate value.

Keyboard Shortcuts

The Accutome A-Scan Plus allows you to perform operations from the keyboard. There is no need to push buttons to acquire patient measurements; all measurement functions can be executed using the keyboard shortcuts given in Table 1 below.

Table 1 Keyboard Shortcuts

	Action
CTRL+N	Start a **N**ew patient
CTRL+E	Next **E**ye type
CTRL+SHIFT+E	Previous **E**ye type
1, 2, 3, 4, 5	Select measurement
G or CTRL+G	**G**ain, increase 1 dB, hold for default
Z or CTRL+Z	**Z**oom, increase with wrap, hold for 1.6X
S or CTRL+S	**S**croll, increase 1 mm, hold for 0
V or CTRL+V	**V**iew
O or CTRL+O	**O**D/**O**S
C or CTRL+C	**C**ornea Gate, hold to select ALL
A or CTRL+A	**A**nterior Lens Gate, hold to select ALL
P or CTRL+P	**P**osterior Lens Gate, hold to select ALL
R or CTRL+R	**R**etina Gate, hold to select ALL
T or CTRL+T	**T**hreshold Gate, hold to select ALL
F1 to F6	Menu Keys **1** to **6**
F8	Footswitch
F9	Measure
F10	Calculate
F11	Patient Records
F12	Preferences
PRINT SCREEN	Print
ALT+P	**P**rint screen copy
ALT+S	Send **S**creen copy
TAB	Select next field
SHIFT+TAB	Select previous field
ENTER	Toggle select state of field
DELETE	Delete current selection
CTRL+HOME	First cell in table
CTRL+END	Last cell in table
HOME	First cell in current column
END	Last cell in current column
PAGE UP	Scroll table one page up
PAGE DOWN	Scroll table one page down

Using the Footswitch

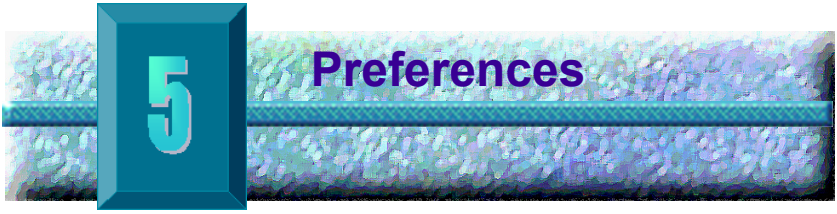
The footswitch performs four functions:

1. When you are acquiring measurements, the foot switch will capture a waveform.
2. Will select one of the five waveforms on the Measure Screen.
3. Will delete the current waveform on the Measure Screen.
4. Will access the Measure Screen from any other screen.

If you are in a screen, other than the Measure Screen, pressing the foot switch will bring you to the Measure Screen. In the Measure Screen the foot switch allows you to capture, select, or reject a waveform.

When on the eye and running, pressing the foot switch captures the data.

The foot switch can be used to select a waveform on the Measure Screen. If you want to scroll through the list of (up to) five waveforms, step on the foot switch. If you would like to recapture that waveform, step on the foot switch and keep pressing, for approximately one second, until the selected waveform clears from the measurements table.



Setting Up the Accutomre A-Scan Plus

The Accutome A-Scan Plus is equipped with personal preference options, and provides the flexibility necessary to customize your machine. You can not only add eye types and lens materials, you can also set many operational defaults. All preferences are set up at the Preferences screens.

Preference options include:

- Adding new anterior/vitreous chamber and lens materials and assigning velocities
- Adding new eye types
- Setting the Print Title
- Setting the Printer
- Setting the Serial Link
- Setting the Serial Baud
- Setting the Delete Confirmation
- Adjusting the contrast
- Setting the New Patient Defaults, including Eye Type, ID, Gain and Target
- Setting the K Index
- Setting the IOL Power Table Step
- Setting the Date and Time
- Turning the sound on and off
- Setting the Auto Restart option
- Turning the screen saver on and off
- Saving Default Gate/Threshold locations

How to Access Preferences

To access the Accutome A-Scan Plus Preferences press the Preferences button, located at the right side of the front panel (see Figure 33 below).

Figure 33 Preferences Button

***Note:** If you press the Preferences button a second time the Accutome A-Scan Plus will scroll to the Setup Screen, which is the next lower level linked screen.*

Top Level of Preferences

When you press the Preferences button the Accutome A-Scan Plus will display the Eye Types screen (see Figure 34 below). In the Eye Types screen you can add a new Eye Type, new lens material, new Anterior/ Vitreous material and assign velocities to each of these materials.

The Eye Types screen also has the following soft menu selections activated by buttons beneath the selection:

- Reset Field to Factory - resets the current field to the factory default.
- Reset All to Factory - resets all fields to the factory defaults. Fields labeled with * will be reset.
- More Settings... - displays the Setup screen.

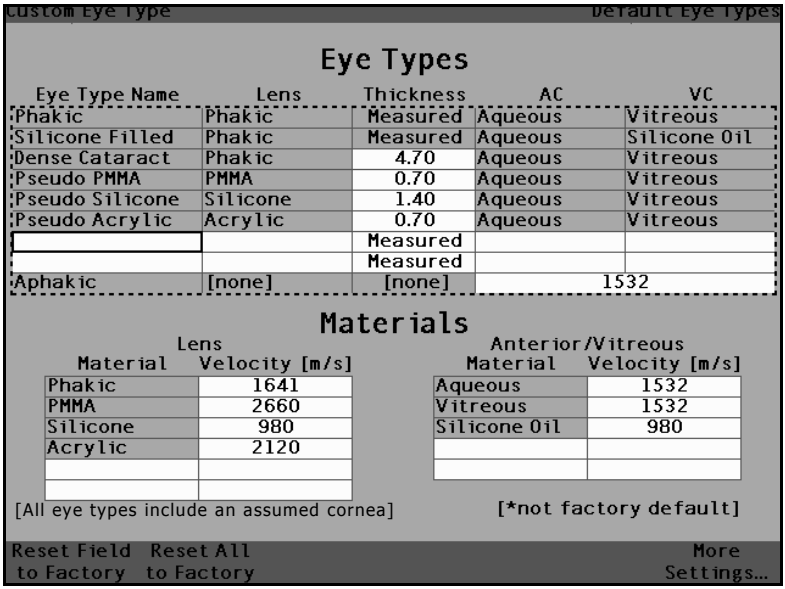


Figure 34 Eye Types Screen

How to Add a New Eye Type

The Accutome A-Scan Plus provides the ability to customize the current patient eye type for unique or rare eye types using the Customize Eye Type screen.

When you add a new eye type you will add the eye type to the Eye Types table shown in Figure 35 on page 69. Prior to adding the eye type to the table, you must define all materials that may constitute the new eye type. You must first, if necessary, add a new Lens Material and Velocity, and new Anterior/Vitreous Material and Velocity.

***Note:** *It is also possible to edit existing Eye Type information in the Accutome A-Scan Plus. To edit eye type information follow the same procedure as adding eye type information.*

CAUTION:

Changing eye type and velocity information does not effect the eye type information for current and saved patients.

The changes will be in effect the next time the changed eye type is selected or a new patient is started.

Current patient eye types that do not match the settings on the Eye Types Screen are indicated with * on the Measure and Calculate screens.

Adding a New Lens Material

Before using a material in the definition of an Eye Type, the lens material must exist in the lens material table.

To add a new lens material:

1. Rotate the knob and select the Lens Material table. The table is selected when it is surrounded by a solid black border.

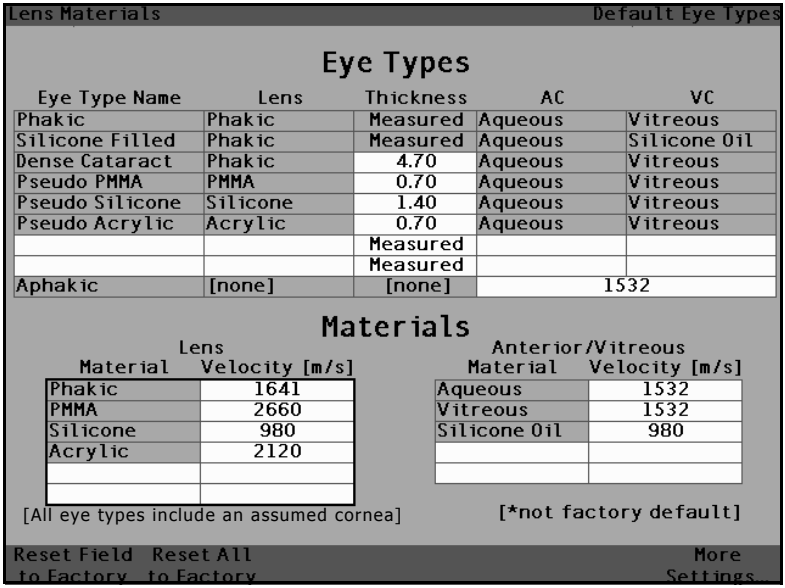


Figure 35 Selecting the Lens Materials Table

2. Press the knob to activate the Lens Material table. The table is activated when it is surrounded by a dashed border as shown in Figure 36 below.
3. When the table is activated rotate the knob until an empty cell in the Material column is selected. The cell will be selected when there it is surrounded by a solid black border.
4. Activate the cell by pressing the knob.

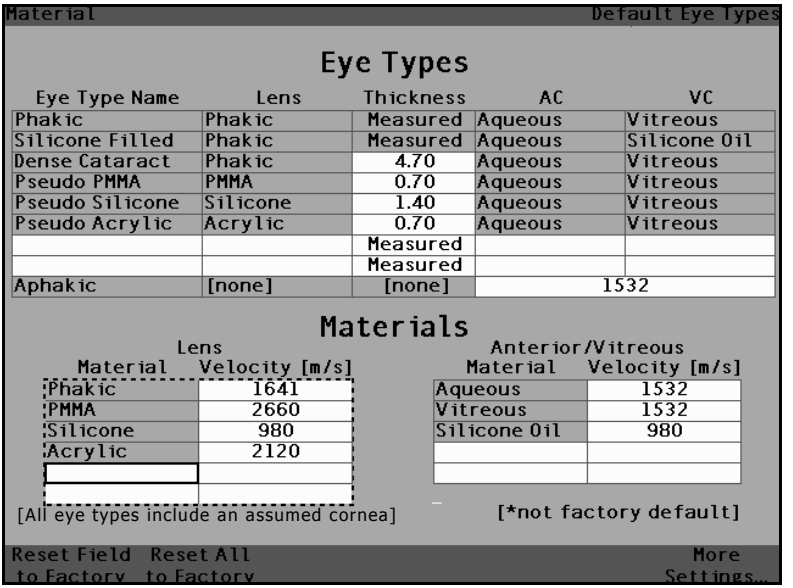


Figure 36 Selecting a Cell to Enter New Lens Material

5. Enter the name of the new Lens Material.
6. Press the knob or the √ button, to save the Material name and to deactivate the cell.

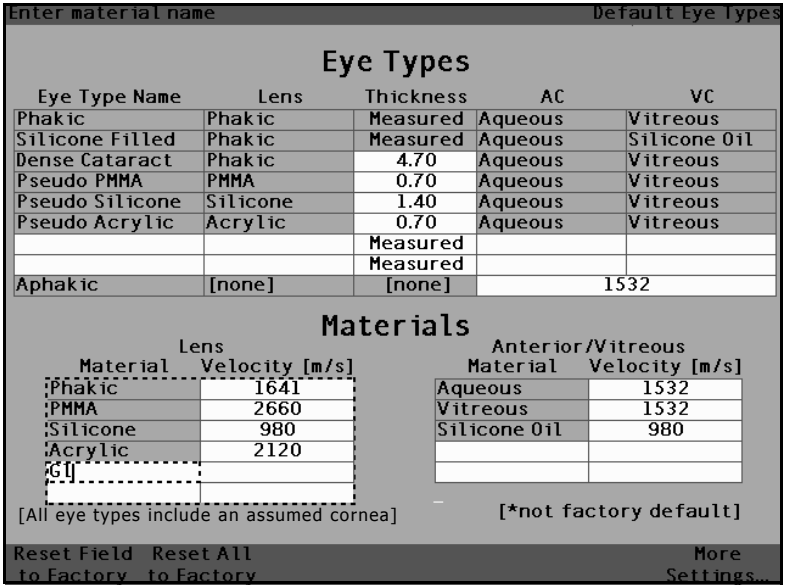


Figure 37 Entering the Name for New Lens Material

Assigning a Velocity to the New Lens Material

The Accutome A-Scan Plus is set up at the factory with default sonic velocities for the most common types of lens materials. For every eye type the Accutome A-Scan Plus knows which velocity to use. Whenever possible you should use one of the default lens materials and velocities.

If you need to modify the velocity of a new lens material:

1. Rotate the knob and select the Velocity cell for the newly added Lens Material, indicated by the solid black border.
2. Press the knob or the √ button, to activate the Velocity cell, indicated by the dashed border.
3. Enter the value of the new Velocity.
4. Press the knob or the √ button, to save the Velocity value and to deactivate the cell.
5. Press the knob or the √ button, a second time to deactivate the Lens Materials table.

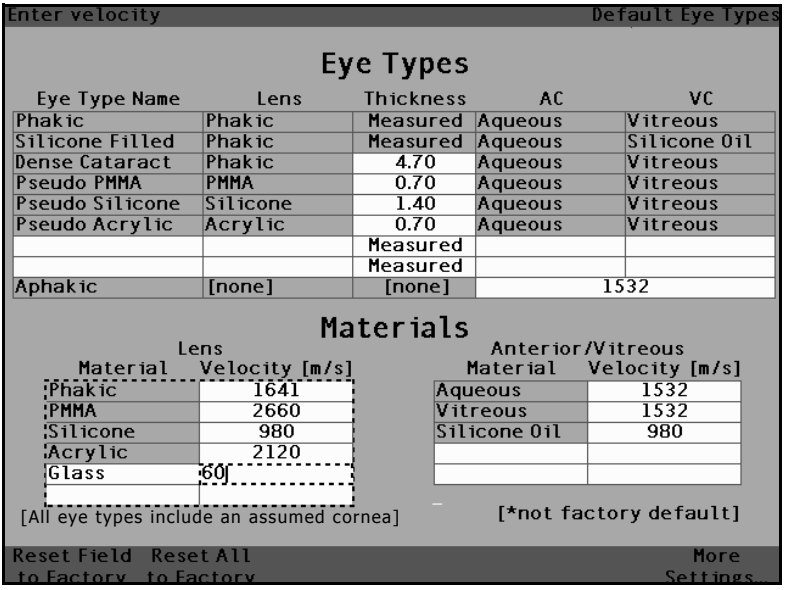


Figure 38 Adding New Material Velocity

Adding the New Eye Type Information

1. Rotate the knob and select the Eye Types table.
2. Press the knob or the √ button, to activate the Eye Types table.
3. Within the Eye Types table, rotate the knob to select an empty cell, indicated by a solid black border, for entering the new eye type name.

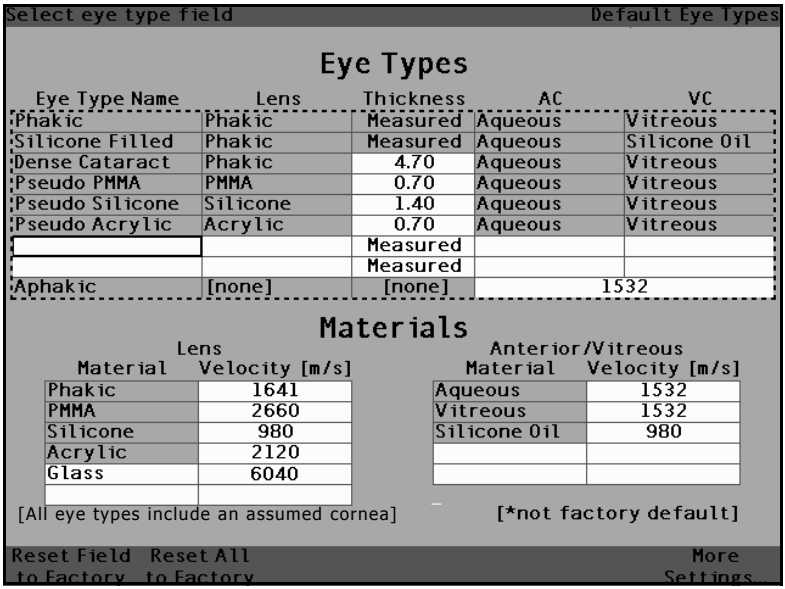


Figure 39 Selecting the Eye Type Name Cell

4. Enter the name of the new Eye Type.
5. Press the knob or the √ button, to save the Eye Type Name and to deactivate the cell.

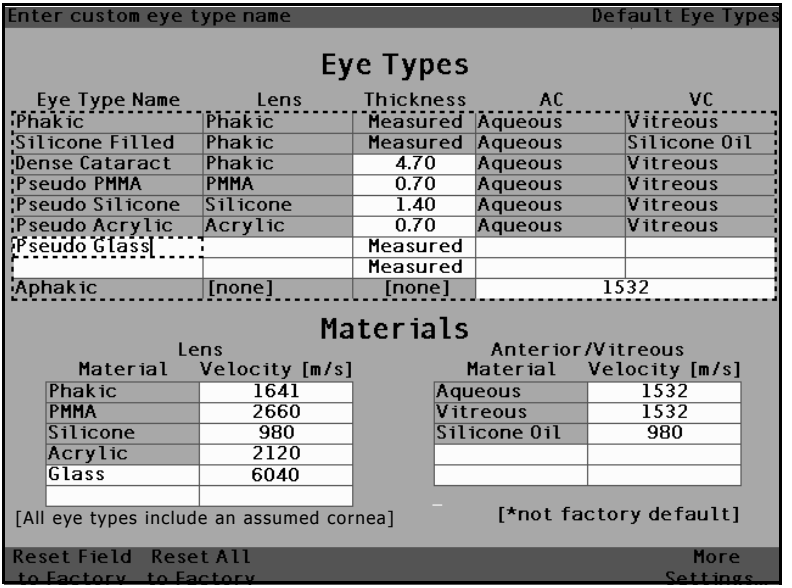


Figure 40 Adding the New Eye Type Name

6. Within the Eye Types table, rotate the knob to select the Lens cell associated with the Eye Type Name you just entered.
7. Press the knob or the √ button, to activate the cell, indicated by the dashed border.

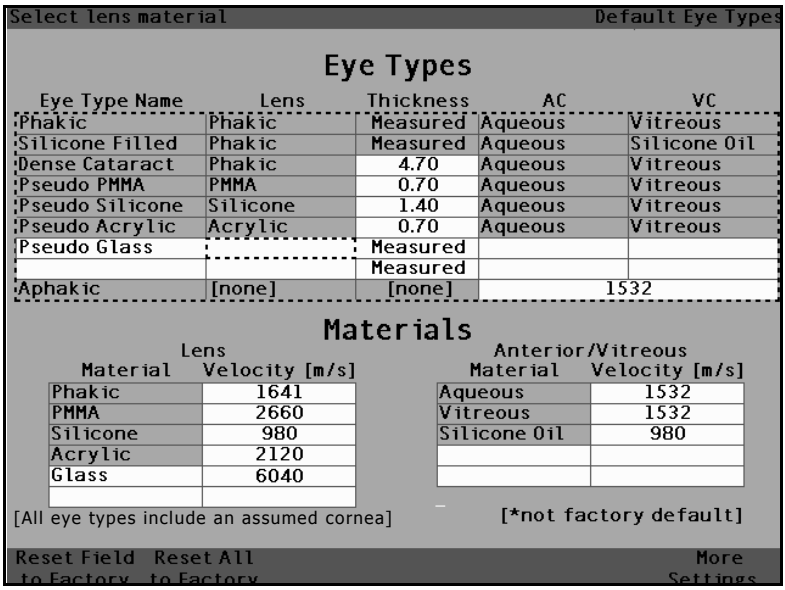


Figure 41 Activating the Area to Select New Lens Material

8. Within the Lens cell, rotate the knob to select one of the pre-entered Lens Materials. In the example below, Glass is the newly added and selected lens material. (If you previously added new lens materials, they should appear in this list.)
9. Press the knob or the √ button, to save the Lens Material and to deactivate the cell.

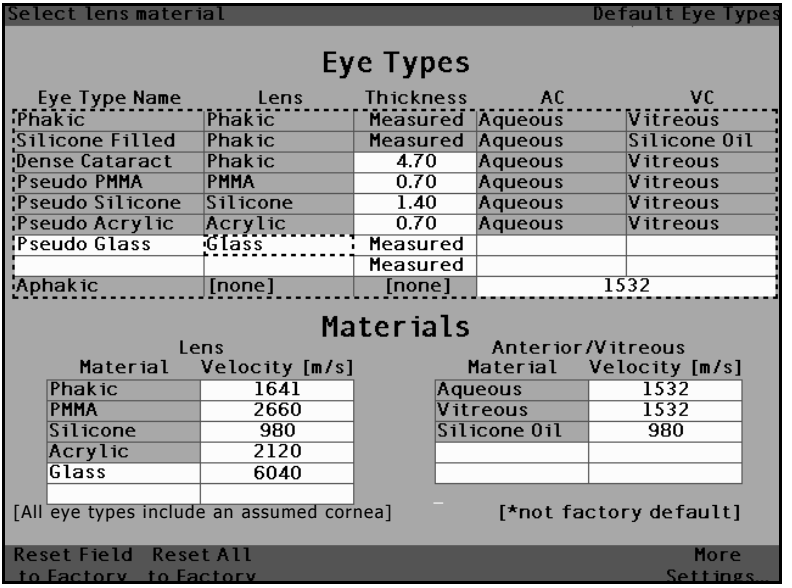


Figure 42 Lens Material Selected

10. Within the Eye Types table, rotate the knob to select the Lens Thickness Cell associated with the current Eye Type Name, and Lens.
11. Press the knob or the √ button, to activate the cell, indicated by the dashed border.
12. If the Lens thickness can be measured using ultrasound the entry should be "Measured". If the value for Lens Thickness is not "Measured" (and it's possible to measure the thickness), press the X button to remove the entered thickness and display "Measured".
13. If the Lens thickness can not be measured using ultrasound, enter an assumed lens thickness for this type of lens by turning the knob. In the example given, the thickness that has been entered is "3".

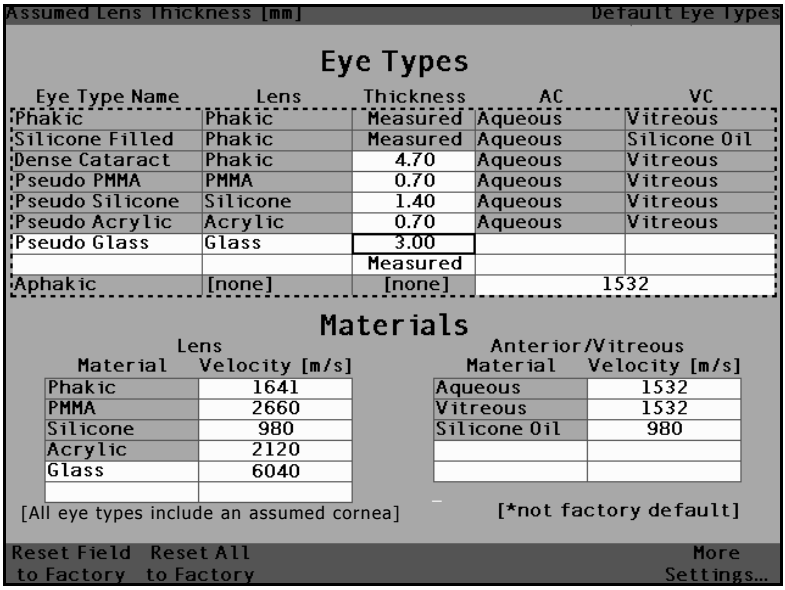


Figure 43 Lens Thickness Entered

14. Within the Eye Types table, rotate the knob to select the AC cell associated with the current Eye Type Name, and Lens.
15. Press the knob or the √ button, to activate the cell, indicated by the dashed border.
16. Within the AC cell, rotate the knob to select one of the pre-entered Anterior Materials. (If you previously added new anterior chamber materials, they should appear in this list.)
17. Press the knob or the √ button, to save the selected Anterior Material and to deactivate the cell.

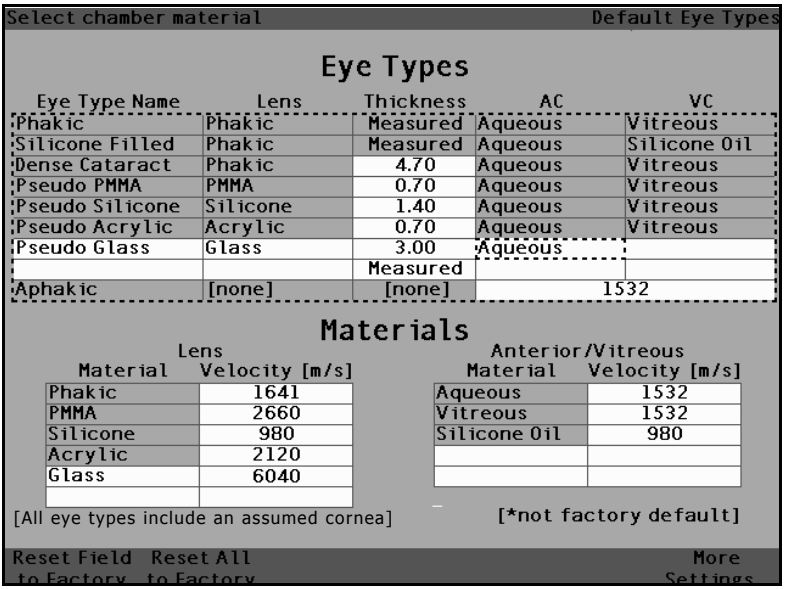


Figure 44 Anterior Chamber Material Selected

18. Within the Eye Types table, rotate the knob to select the VC cell associated with the current Eye Type Name, Lens, and Anterior Chamber.
19. Press the knob or the √ button, to activate the cell, indicated by the dashed border.
20. Within the VC cell, rotate the knob to select one of the pre-entered Vitreous Materials. (If you previously added new vitreous chamber materials, they should appear in this list.)
21. Press the knob or the √ button, to save the selected Vitreous Material and to deactivate the cell.
22. Press the knob or the √ button, a second time to deactivate the Lens Materials table.

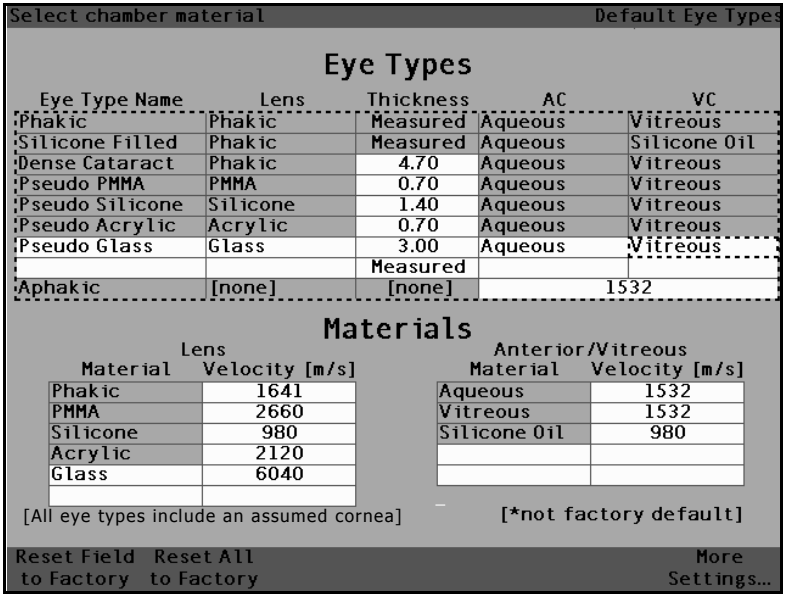


Figure 45 Vitreous Chamber Material Selected

Eye Type Screen Menu Selections

There are three menu selections available for execution at the bottom of the Eye Types Screen. Two of the selections, "Reset Field to Factory" and "Reset All to Factory" can be used to restore eye type information.

Any information that is displayed in a white field on the Eye Type screen can be changed. Most of these fields (excluding the empty fields for adding eye type information) contain default values for that have been pre-entered at the factory.

Reset Field to Factory

The Reset Field to Factory selection provides you with the ability to return any pre-entered field on the Eye Types Screen to its default factory value.

If you have already changed, or are editing a pre-entered field on the Eye Type screen, and you would like to reset it:

1. Rotate the knob until the field you would like to reset is selected with a solid black border as shown in Figure 46 below.

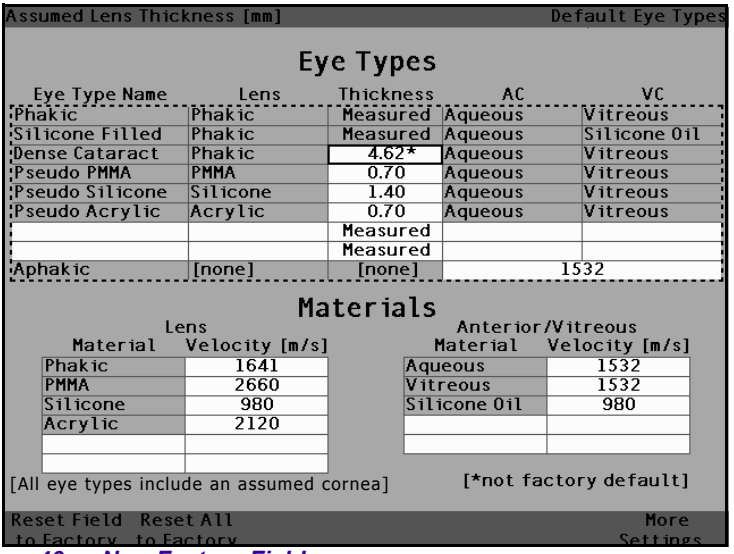


Figure 46 Non-Factory Field

2. Press the button beneath the "Reset Field to Factory" selection.
3. The Accutome A-Scan Plus will prompt you with the message "Are you sure?" as shown in Figure 47 below. You must select either "Cancel" or "Yes".
4. Press the button beneath the selection "Yes". (You can also press the Affirmative button located at the right side of the front panel.)

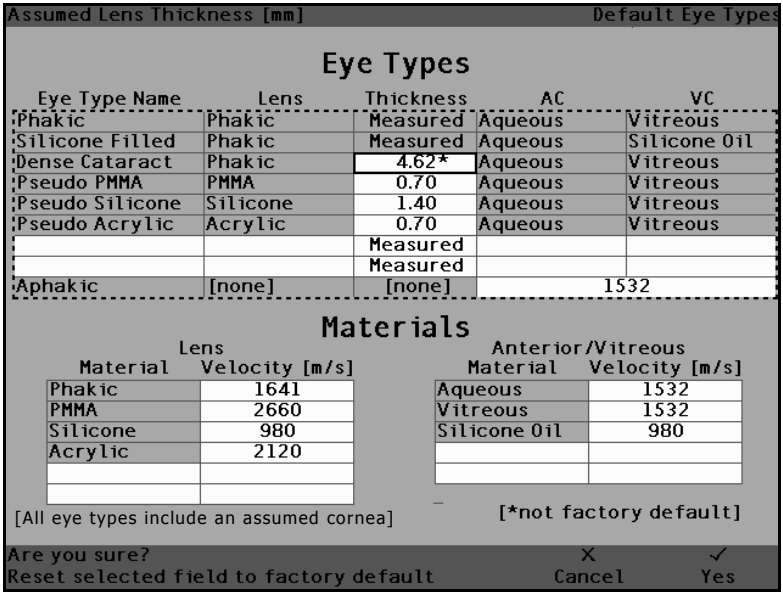


Figure 47 Restore Selected Field Prompt

5. The Accutome A-Scan Plus will reset the selected field to its factory default as shown in Figure 48 below.

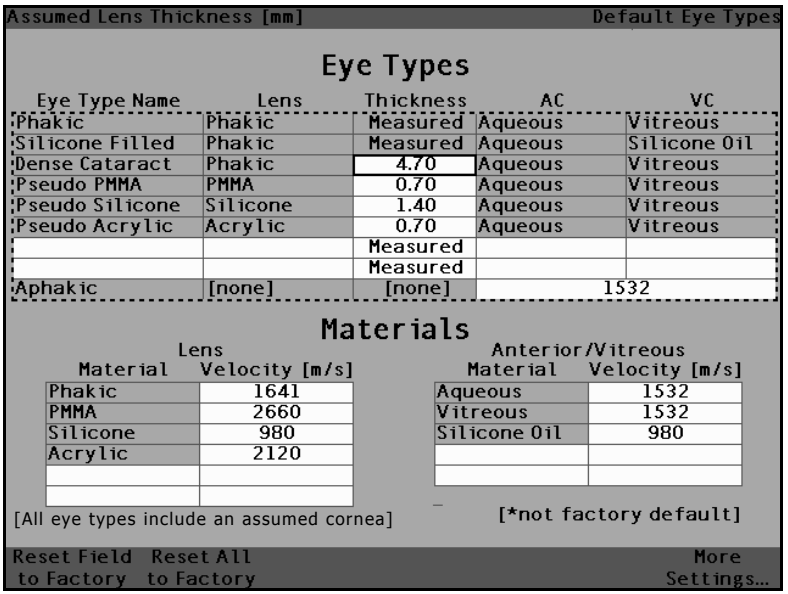


Figure 48 Selected Field Restored

Reset All to Factory

The Reset All to Factory selection provides you with the ability to return all pre-entered fields on the Eye Types Screen to their default factory values.

If you have already changed several pre-entered fields on the Eye Type screen and you would like to reset them:

1. Press the button beneath the selection "Reset All to Factory".

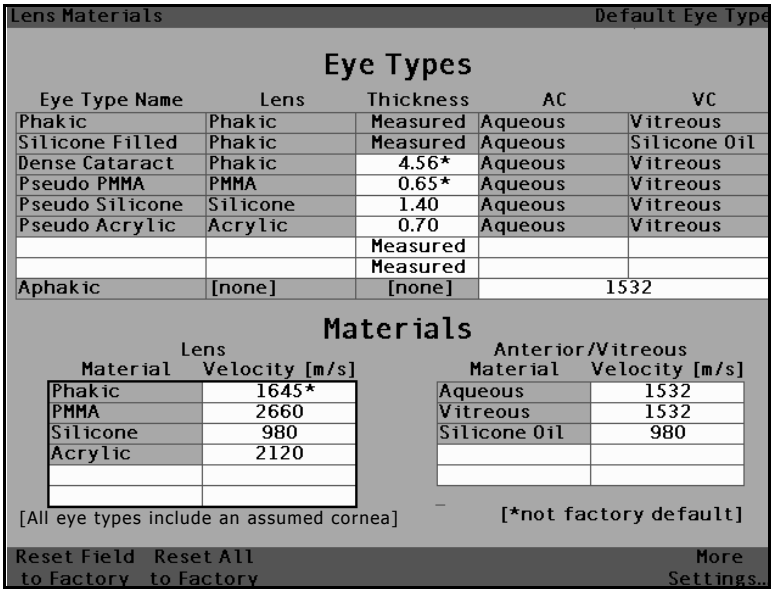


Figure 49 Non-Factory Fields Displayed

2. The Accutome A-Scan Plus will prompt you with the message "Are you sure?" as shown in Figure 50 below. You must either cancel or continue.
3. Press the button beneath the selection "Yes". (You can also press the Affirmative button located at the right side of the front panel.)
4. The Accutome A-Scan Plus will reset all fields to their factory default as shown in Figure 48 on page 82.

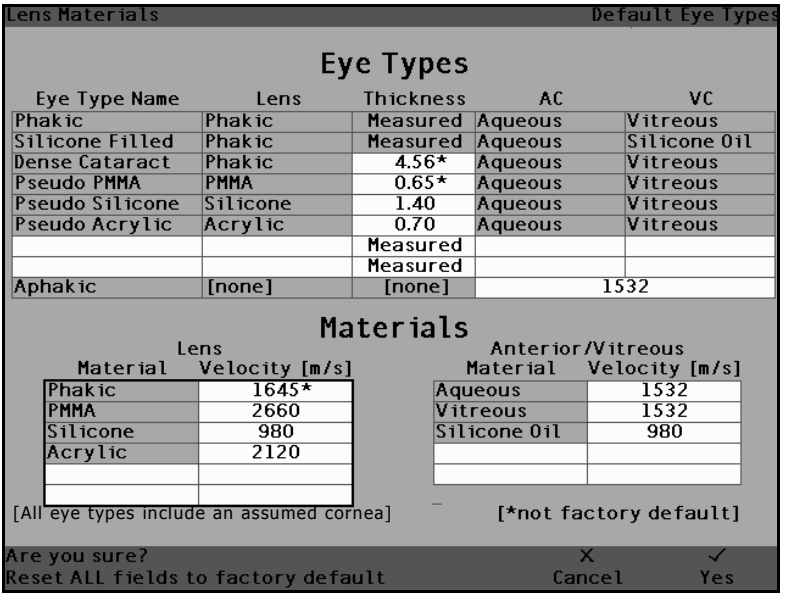


Figure 50 Restore All Fields Prompt

***Note:** At this point if you would like to continue with the setting preferences, press the button beneath the selection "More Settings..." or press the dedicated Preferences button a second time.*

More Settings

From the high level Eye Types Screen you can access the remainder of the preference options. When you press the button beneath the selection "More Settings" the Accutome A-Scan Plus will display the Setup Screen as shown in Figure 51 on page 86.

Setup Screen Fields

In the Setup screen you can change the following fields:

- Print Title
- Printer
- Serial Link
- Serial Baud
- Delete Confirm
- Contrast
- New Patient Defaults including; Eye Type, ID, Gain and Gates/Threshold
- Default K Index
- IOL Step for IOL Calculation Power Table
- Date
- Time
- Auto Mode

Setup Screen Soft Menu

The Setup screen has the following soft menu selections activated by the buttons beneath the selection:

- Sound On/Sound Off - toggles the measurement quality sound on and off
- Restart On/Restart Off - toggles automatic restart on and off
- Scr Save On/Scr Save Off - toggles the 30 minute inactivity screen saver on and off
- Save Gates - saves the location of the gates/ threshold as they as they are currently set, as the new patient default
- About This Unit - displays the "About Screen"
- Done... - exits the Setup Screen and returns you to the Eye Types Screen

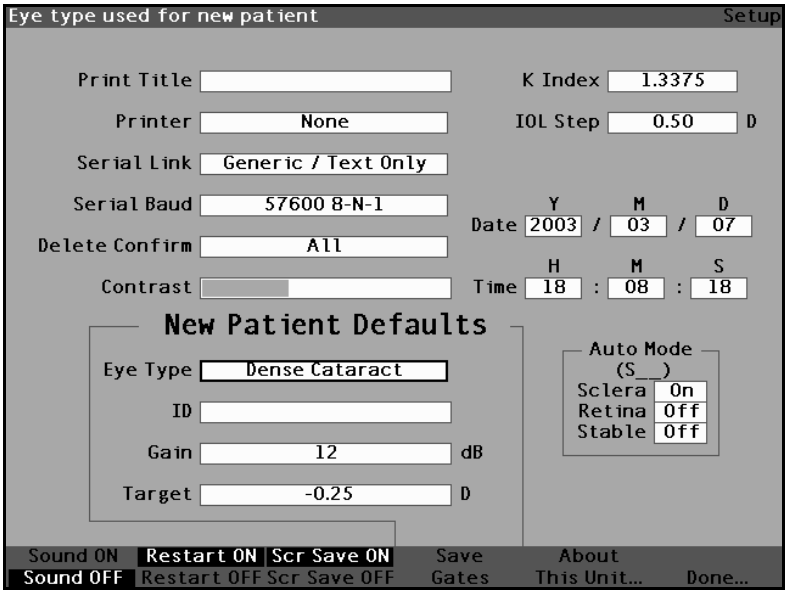


Figure 51 More Settings - Setup Screen

How to Set the Print Title

The Accutome A-Scan Plus provides you with the ability to have a title appear on every patient printout. For example, you may want to have a clinic name printed at the top of every page.

To set a Print Title:

1. Within the Setup Screen, rotate the knob to select the Print Title field, indicated by a solid black border.

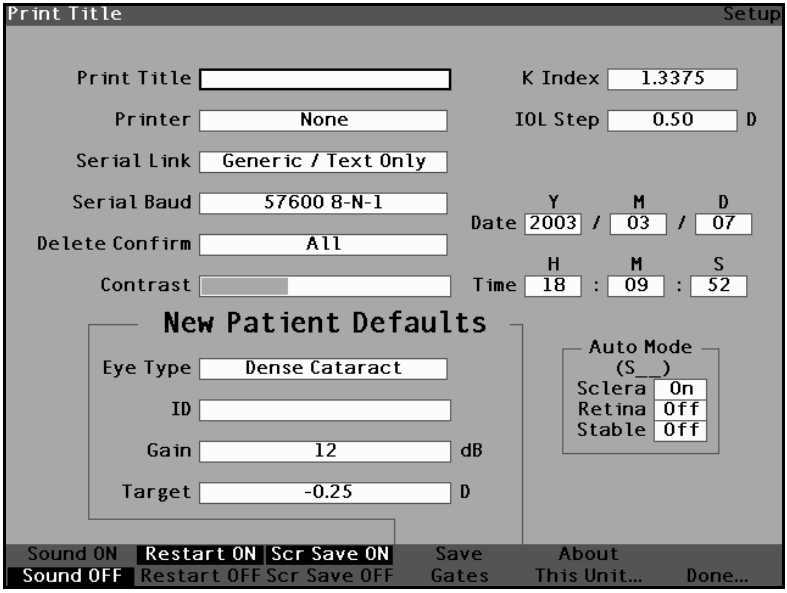


Figure 52 Print Title Field Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

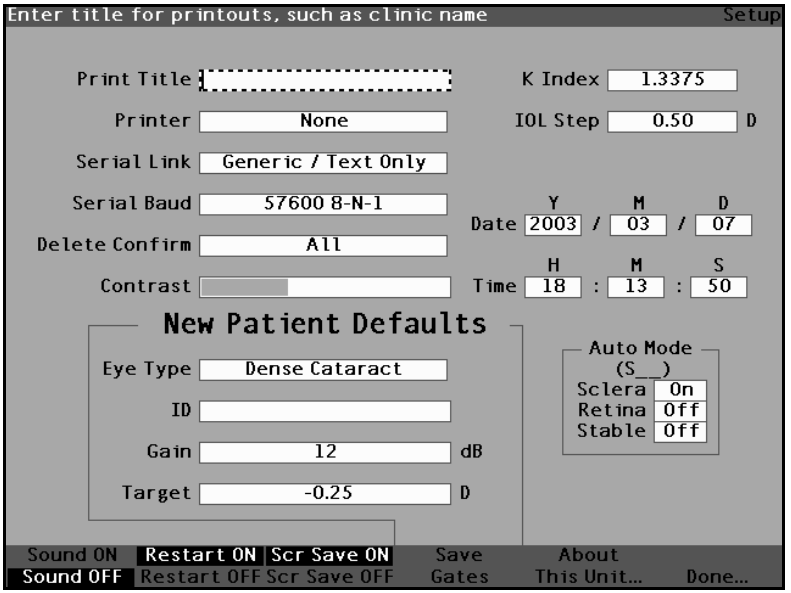


Figure 53 Print Title Field Activated

3. Within the Print Title field, enter the title you would like printed on every record.

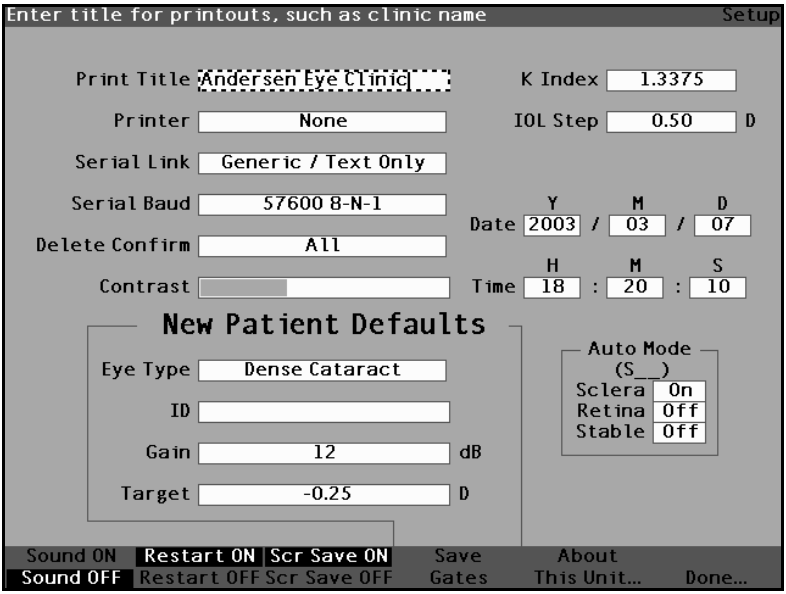


Figure 54 Entering the Print Title

4. Press the knob or the √ button, to save the entered Print Title and to deactivate the field.

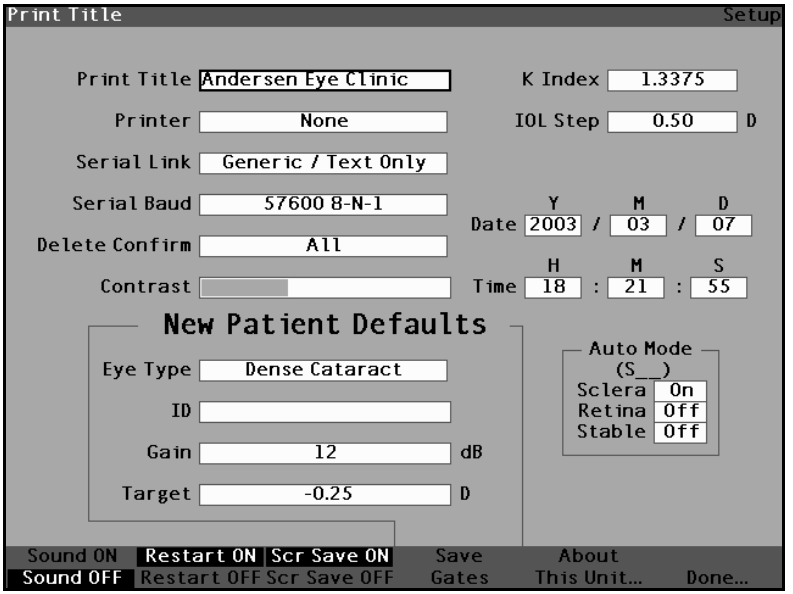


Figure 55 Print Title Added

How to Set the Printer

In order to obtain the best printouts from the Accutome A-Scan Plus, it is recommended that all records be printed on a laser printer that is compatible to an HP LaserJet. However, the Accutome A-Scan Plus provides many printer options to meet most printing needs. The printers available are as follows:

- HP LaserJet - the printer will operate with the HP PCL 5 print driver
- HP InkJet (Quality) - the printer will operate with the HP PCL 3 print driver and will print higher quality images
- HP InkJet (Speed) - the printer will operate with the HP PCL 3 print driver and will print records quicker
- None - no printer selected
- Generic / Text Only - for any printer not compatible with HP PCL 5 or HP PCL 3, the Accutome will print text only

The two InkJet graphics printer drivers HP InkJet (Quality) and 'HP InkJet (Speed)' will print all data the same as the HP LaserJet driver but on printers that are compatible to DeskJet printers. There are some differences in the graphics between HP LaserJet and HP InkJet.

The Quality version of the HP InkJet driver prints waveforms using 300 DPI and the Speed version of the driver prints waveforms at 150 DPI.

To set the Printer:

1. Within the Setup Screen, rotate the knob to select the Printer field, indicated by a solid black border.

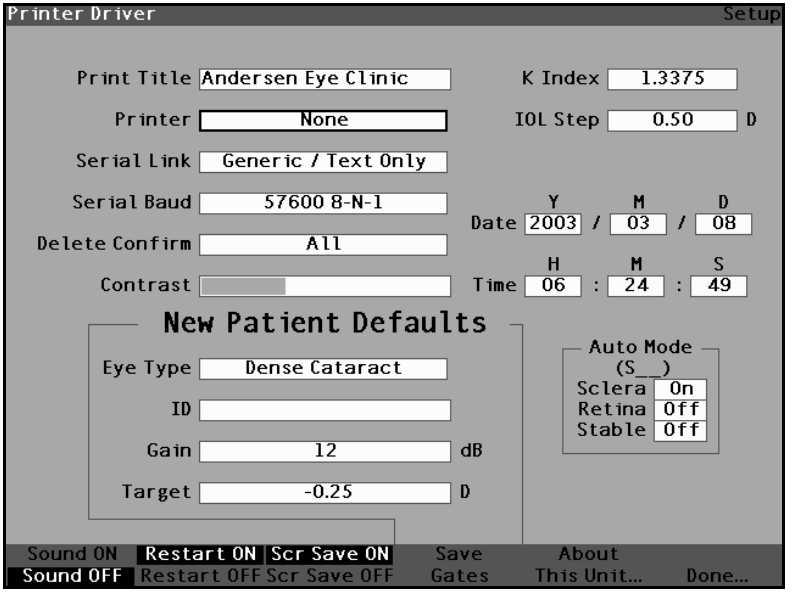


Figure 56 Printer Field Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

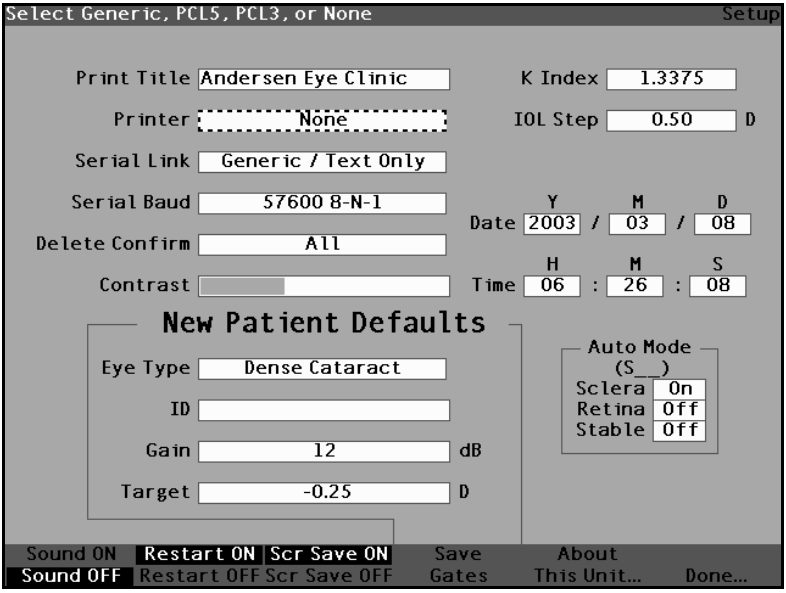


Figure 57 Printer Field Activated

3. Within the Printer field, rotate the knob to select one of the pre-entered options; HP LaserJet Compatible, HP InkJet (Speed), HP InkJet (Quality), Generic / Text Only, or None.

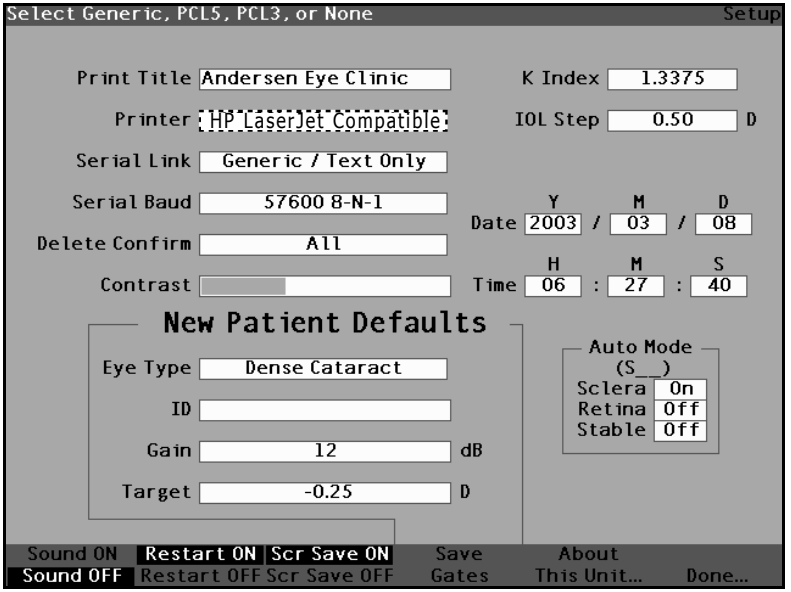


Figure 58 Selecting the Printer

4. Press the knob or the √ button, to save the selected Printer and to deactivate the field.

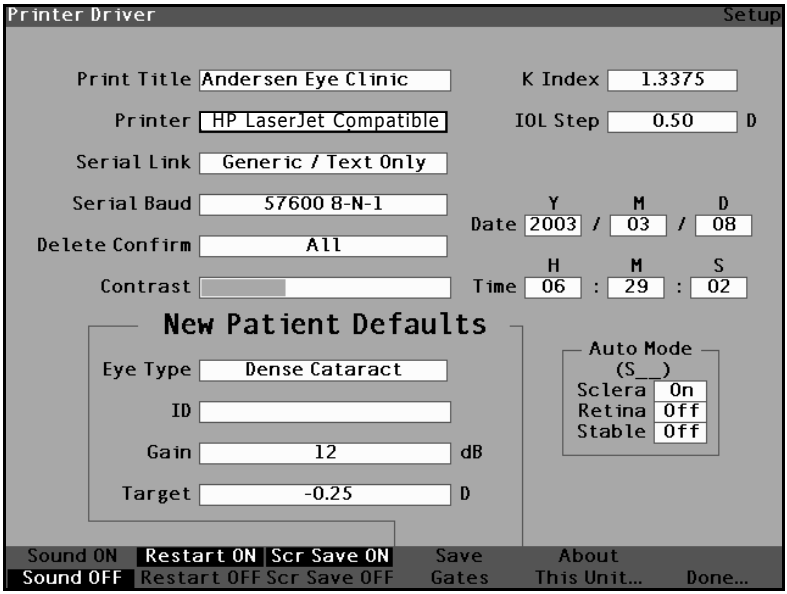


Figure 59 New Printer Selected

How to Set the Serial Link

The Accutome A-Scan Plus provides a serial port as a means of transferring information from the Accutome A-Scan Plus to a PC (Personal Computer). You can enable the port to link to a text application on the PC. Once you have the text data on the computer it can be used in many applications. The format of the data is the same as the Generic/ Text Only printer driver output

The three choices for setting the Serial Link are:

- Generic/Text Only
- Text with Data
- None

When the serial link is enabled, the current screen data is sent when the Print key is pressed. If both the Serial Link and the Printer are enabled, data will be both printed and sent out the serial port.

The receiving application on the PC and the serial baud must be set to the same rate. The user can select 9600, 19200, 38400, 57600, or 115200 as the serial link baud rate. The factory default is 38400.

The communication parameters for the serial link are: 1 start bit, 8 data bits, 1 stop bit (no parity), and hardware flow control. This is commonly shown as 8-N-1. 8-N-1 is the most common setting for serial devices.

Text with Data Driver

The "Text with Data" Serial Link driver sends waveform data after the standard patient Text Only printout. An example is given in Figure 60 on page 97. Waveform data is tab delimited for easy use in Microsoft Excel. Data sent for each waveform includes settings (gain, method, mode, date, and time), gate locations, tissue locations, and measurement data for both OD and OS.

Measurements

Eye	#	AXL	ACD	Lens	VCD	Date	Time	Gain	Method	Mode
OD	1	21.24	3.89	4.70	12.65	2003/03/07	11:27:17	20	Immersion	Auto (SR_)
OD	2	21.27	3.84	4.70	12.73	2003/03/07	11:27:37	20	Immersion	Auto (SR_)
OD	3	21.19	3.84	4.70	12.65	2003/03/07	11:27:37	20	Immersion	Auto (SR_)
OD	4	21.26	3.92	4.70	12.64	2003/03/07	11:27:38	20	Immersion	Auto (SR_)
OD	5	21.15	3.80	4.70	12.65	2003/03/07	11:27:54	20	Immersion	Auto (SR_)
OS	1	20.88				2003/03/07	11:31:13	20	Immersion	Auto (SR_)
OS	2	20.74				2003/03/07	11:31:18	20	Immersion	Auto (SR_)
OS	3	20.80				2003/03/07	11:31:21	20	Immersion	Auto (SR_)
OS	4	20.80				2003/03/07	11:31:22	20	Immersion	Auto (SR_)
OS	5	20.83				2003/03/07	11:31:23	20	Immersion	Auto (SR_)

Data Parameters

Points	4096
Levels	256
Rate	50000000

Gate Locations

Eye	#	Cornea	Ant Lens	Post Lens	Retina	Threshold
OD	1	0	182		1067	191
OD	2	0	182		1067	191
OD	3	0	182		1067	191
OD	4	0	182		1067	191
OD	5	0	182		1067	191
OS	1	0			1067	191
OS	2	23			1090	191
OS	3	26			1093	191
OS	4	26			1093	191
OS	5	5			1072	191

Tissue Locations

Eye	#	Cornea	Ant Lens	Post Lens	Retina
OD	1	27	278		1390
OD	2	42	290		1407
OD	3	38	286		1398
OD	4	36	289		1400
OD	5	36	281		1393
OS	1	63			1423
OS	2	76			1427
OS	3	75			1430
OS	4	72			1427
OS	5	64			1421

Measurement Data

OD 1	OD 2	OD 3	OD 4	OD 5	OS 1	OS 2	OS 3	OS 4	OS 5
0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0

.printed data removed here for brevity..

Figure 60 Serial Data Printout

To set the Serial Link:

1. Within the Setup Screen, rotate the knob to select the Serial Link field, indicated by a solid black border.

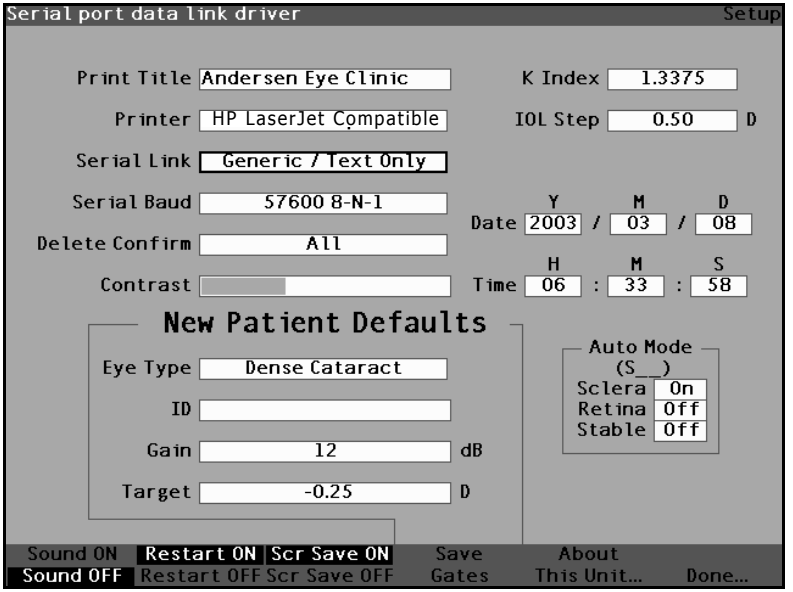


Figure 61 Serial Link Field Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

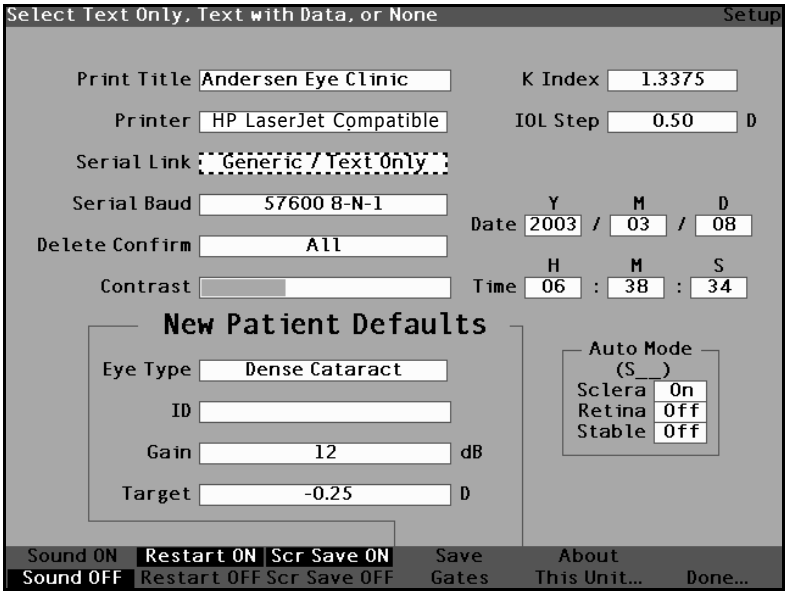


Figure 62 Serial Link Field Activated

3. Within the Serial Link field, rotate the knob to select one of the pre-entered options; Generic / Text Only, Text with Data, or None. The application to which you are connecting the serial port must be able to receive text. The Accutome A-Scan Plus will only transmit text.

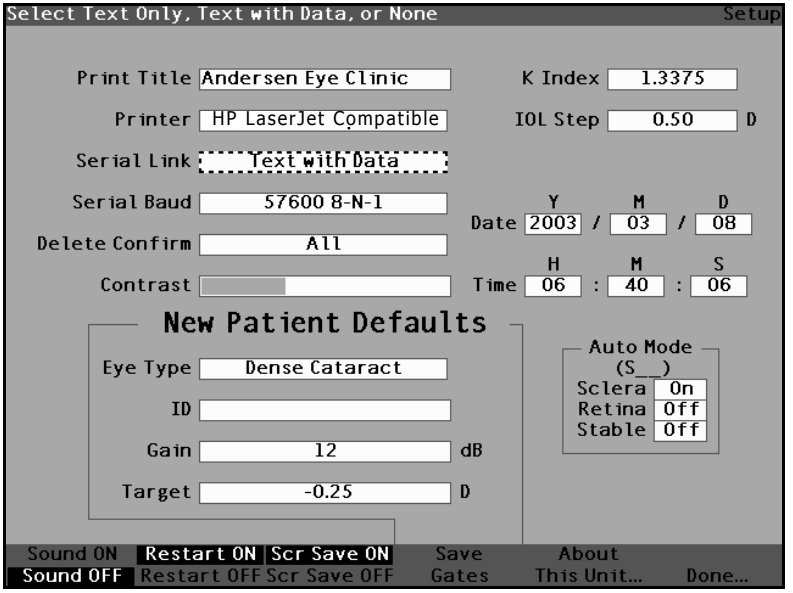


Figure 63 Selecting the Serial Link

4. Press the knob or the √ button, to save the selected Serial Link and to deactivate the field.

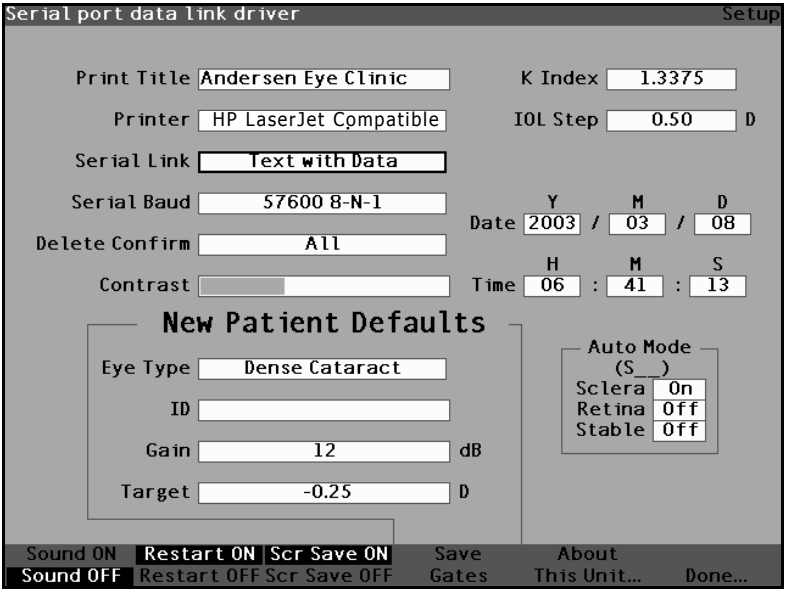


Figure 64 New Serial Link Selected

How to Set the Serial Baud

The Accutome A-Scan Plus allows you to set the baud rate at which data will be transmitted from the serial port to the computer. The factory default baud is 38400. The baud rates which you can select are:

- 9600 8-N-1
- 19200 8-N-1
- 38400 8-N-1
- 57600 8-N-1
- 115200 8-N-1

The "8-N-1" at the end of each baud rate indicates the communication parameters; 1 start bit, 8 data bits, 1 stop bit (no parity).

To set the Serial Baud:

1. Within the Setup Screen, rotate the knob to select the Serial Baud field, indicated by a solid black border.

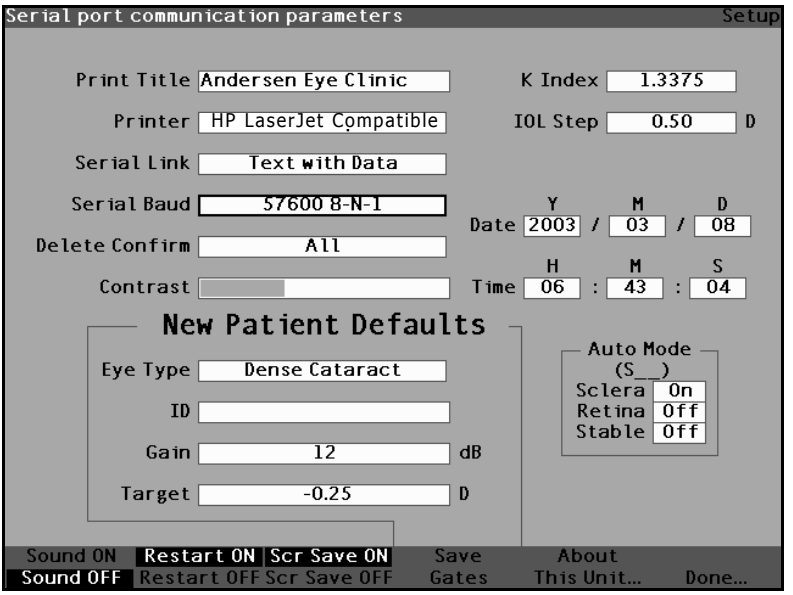


Figure 65 Serial Baud Field Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

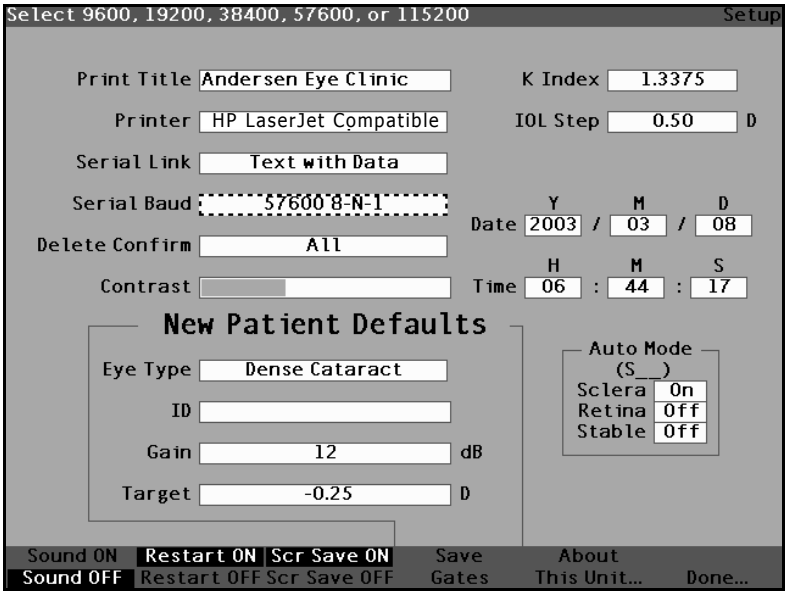


Figure 66 Serial Baud Field Activated

3. Within the Serial Baud field, rotate the knob to select one of the pre-entered options; 9600 8-N-1, 19200 8-N-1, 38400 8-N-1, 57600 8-N-1 or 115200 8-N-1

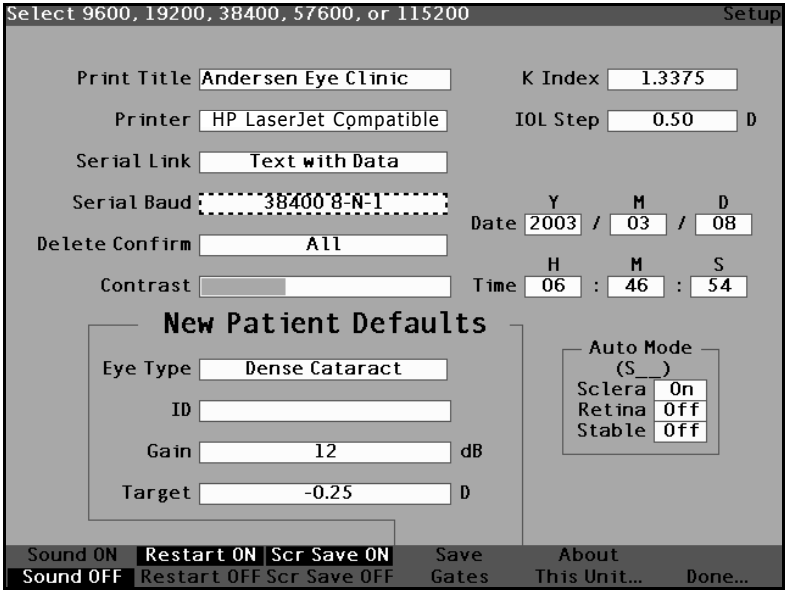


Figure 67 Selecting the Serial Baud

4. Press the knob or the √ button, to save the selected Serial Baud and to deactivate the field.

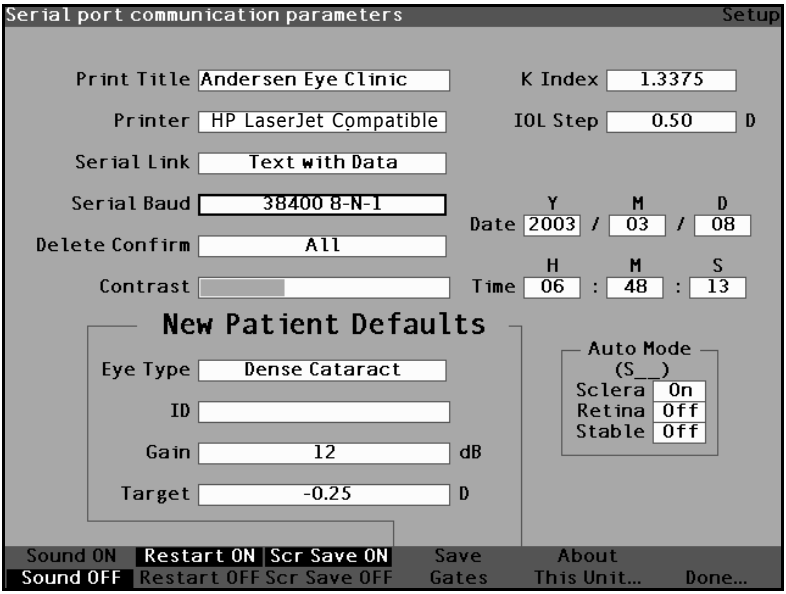


Figure 68 New Serial Baud Selected

How to Set Delete Confirm

The Delete Confirm field allows you to set the times that the Accutome A-Scan Plus will cue you when you are going to delete a Patient record, an IOL, or any other stored information. In other words, when you are going to delete something, the Accutome A-Scan Plus will require you, or not require you to confirm the deletion.

To set the Delete Confirm field:

1. Within the Setup Screen, rotate the knob to select the Delete Confirm field, indicated by a solid black border.

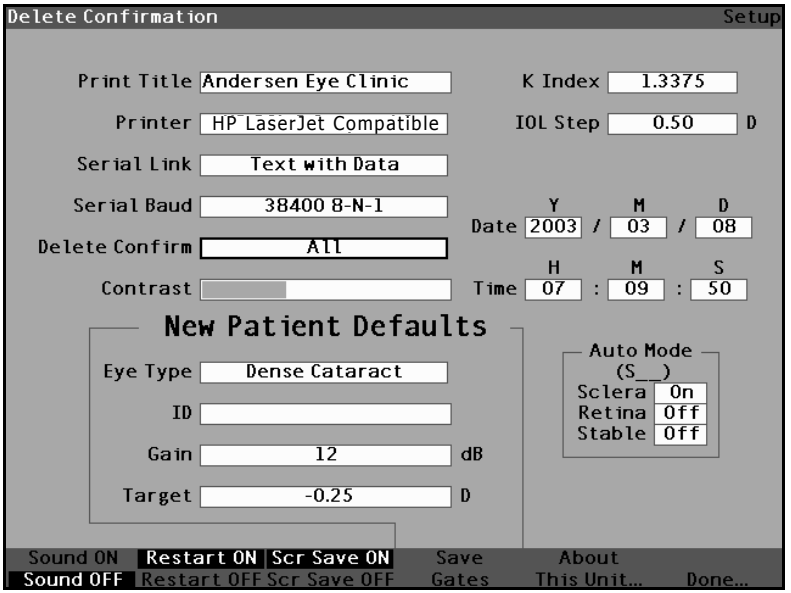


Figure 69 Delete Confirm Field Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

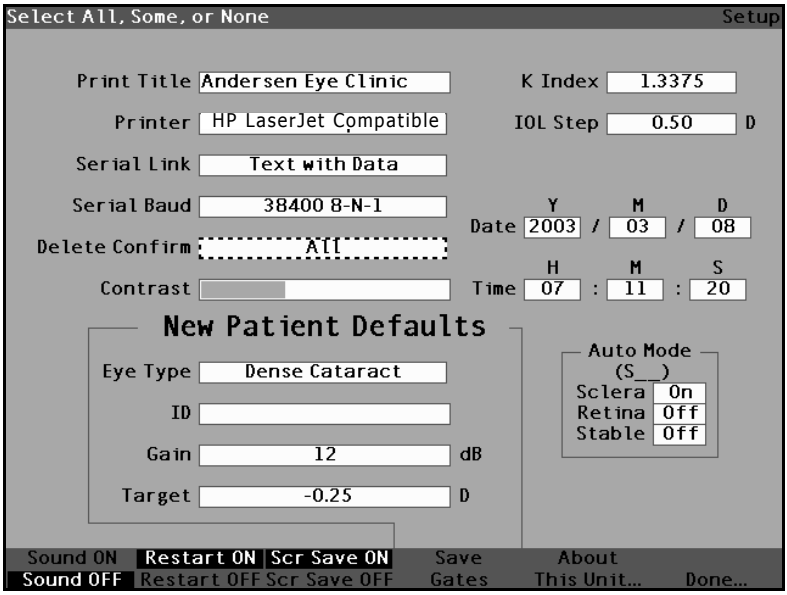


Figure 70 Delete Confirm Field Activated

3. Within the Delete Confirm field, rotate the knob to select one of the pre-entered options; All, Some, or None (all of the time, some of the time, or none of the time).

When Delete Confirm is set to All or Some (unless confirm set to None) the Accustome A-Scan Plus will ask for delete confirmation for the following situations:

- Start New Patient
- Reset All to Factory (Eye Types Screen)
- Delete All Results (IOL Personalization Screen)
- Reset Gates/Threshold to Factory (Setup Screen)

In addition, when Delete Confirm is set to All (unless confirm is set to None or Some) confirmation is required:

- Reset Field to Factory (Eye Types Screen)
- Delete IOL (IOL Groups Screen)
- Delete Result (IOL Personalization Screen)
- Delete Patient (Patient Records Screen)

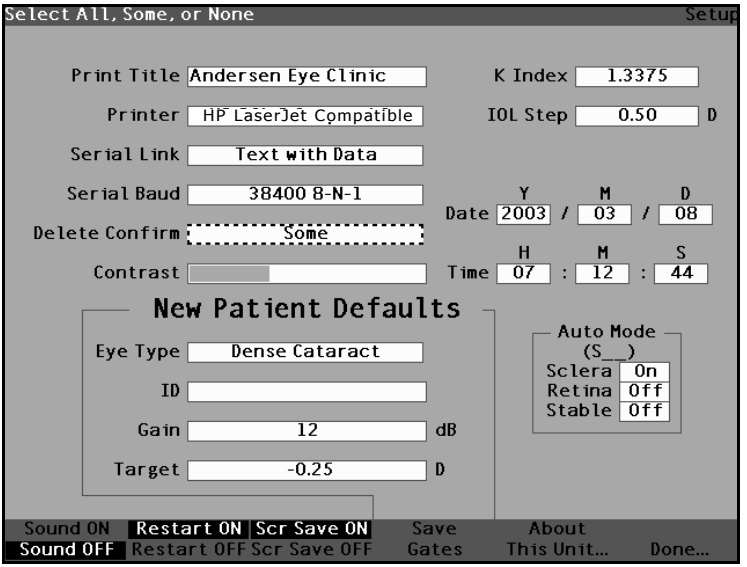


Figure 71 Selecting the Delete Confirm Value

4. Press the knob or the √ button, to save the selected Delete Confirm and to deactivate the field.

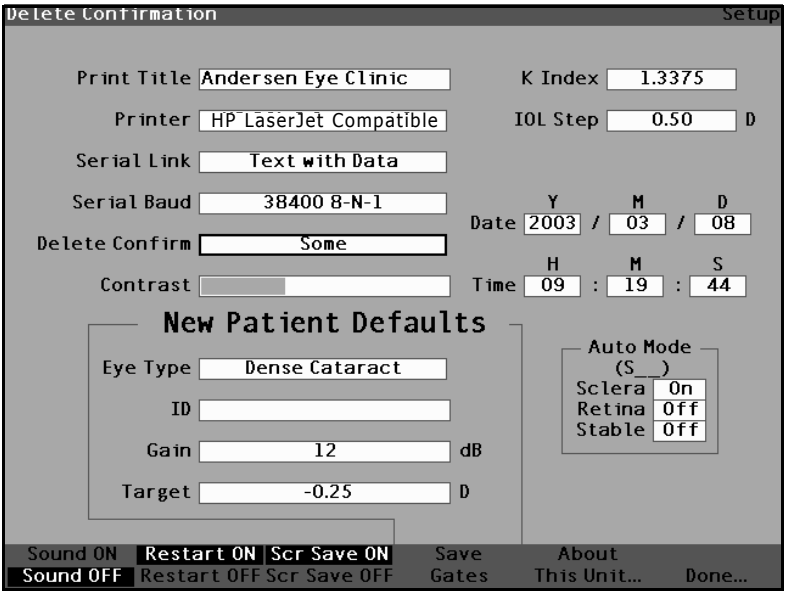


Figure 72 New Delete Confirm Entered

How to Adjust the Contrast

You may need to adjust the contrast because the optimal contrast setting varies with viewing angle and temperature. The Contrast feature in the Setup Screen allows you to adjust the contrast of the instrument's display screen.

***Note:** *The contrast can be adjusted at any time, on any screen, by pressing and holding the preferences button while turning the knob.*

To adjust the Accutome A-Scan Plus Contrast:

1. Within the Setup Screen, rotate the knob to select the Contrast field, indicated by a solid black border.

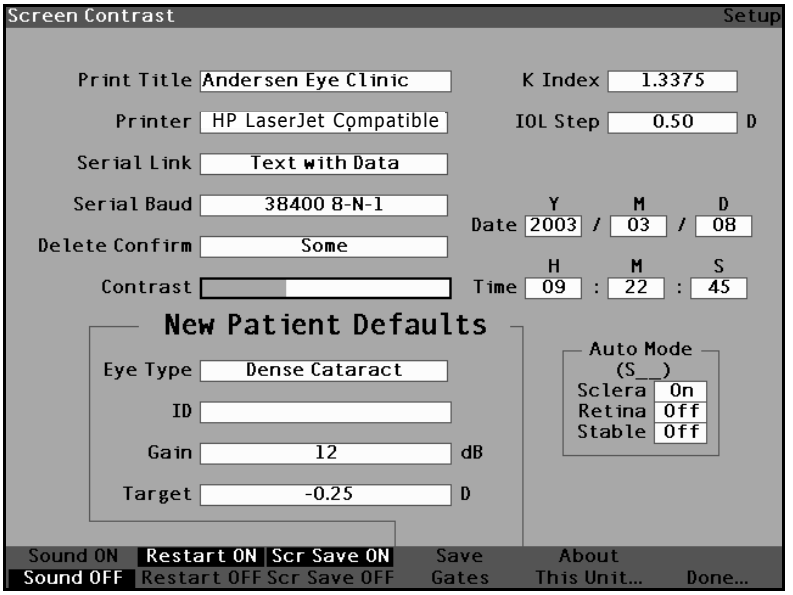


Figure 73 Contrast Field Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

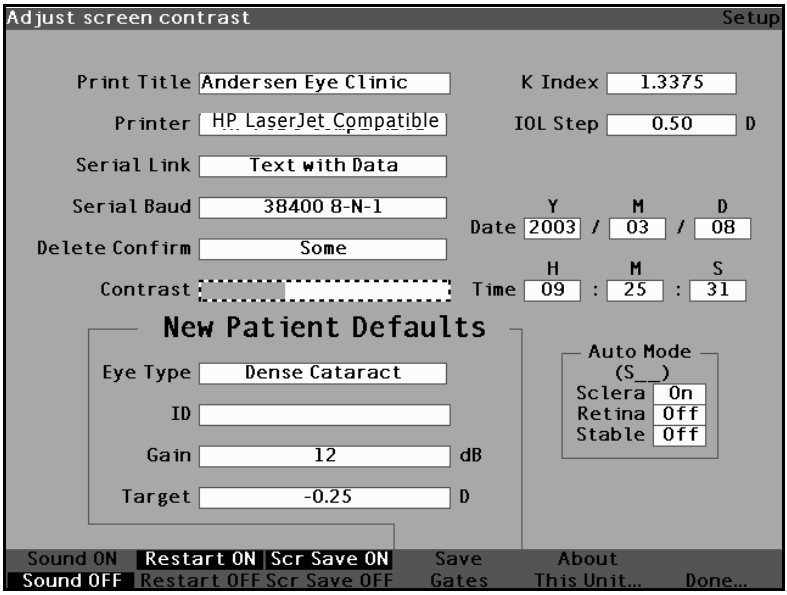


Figure 74 Contrast Field Activated

3. With the Contrast field active, rotate the knob to adjust the white/grey contrast of the screen. The amount of grey vs. white is indicated in the Contrast field by a solid grey bar, that increases or decreases as you adjust the contrast.

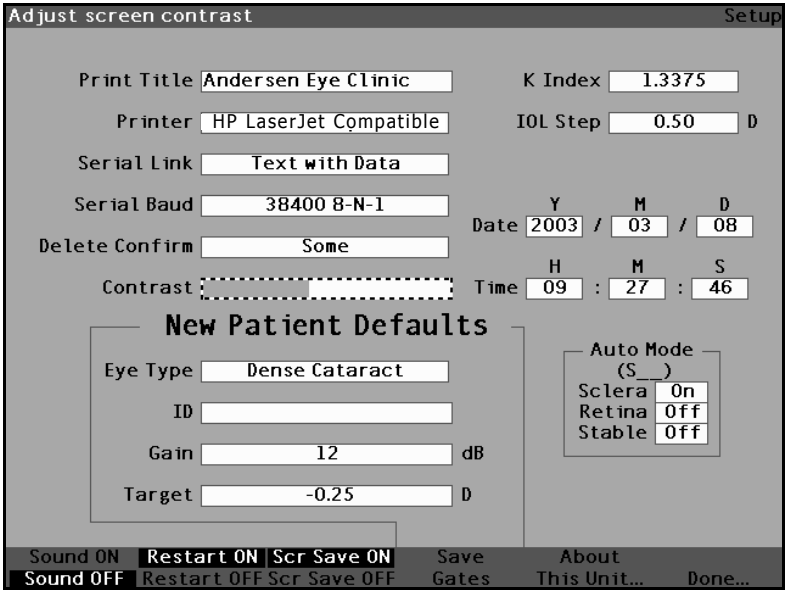


Figure 75 Adjusting the Contrast

4. Press the knob or the √ button, to save the altered Contrast and to deactivate the field.

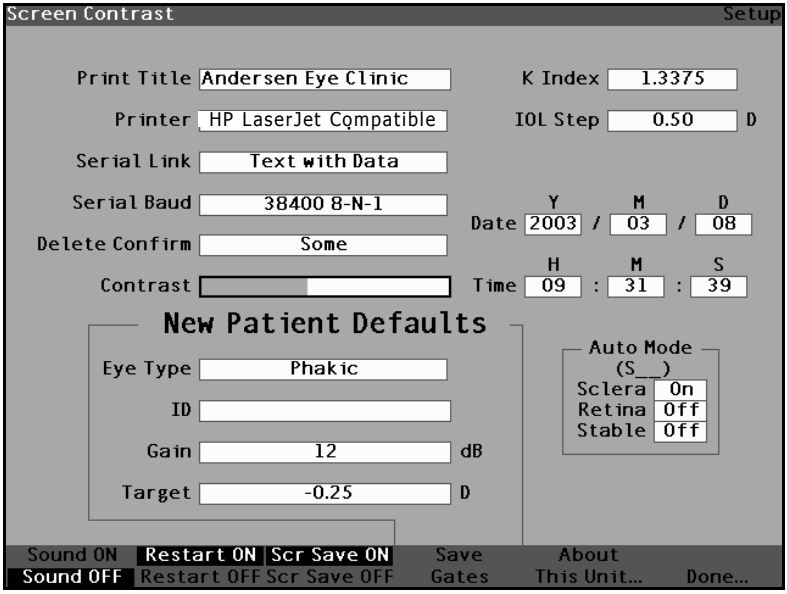


Figure 76 Contrast Adjusted

How to Set the Default Patient Eye Type

The Accutome A-Scan Plus has a default eye type setting so that every time you start a new patient you do not have to select an eye type. When you start a new patient the eye type displayed on the Measure Screen will be the default eye type selected in the Setup Screen.

To change the default eye type:

1. Within the Setup Screen, rotate the knob to select the Default Eye Type field, indicated by a solid black border.

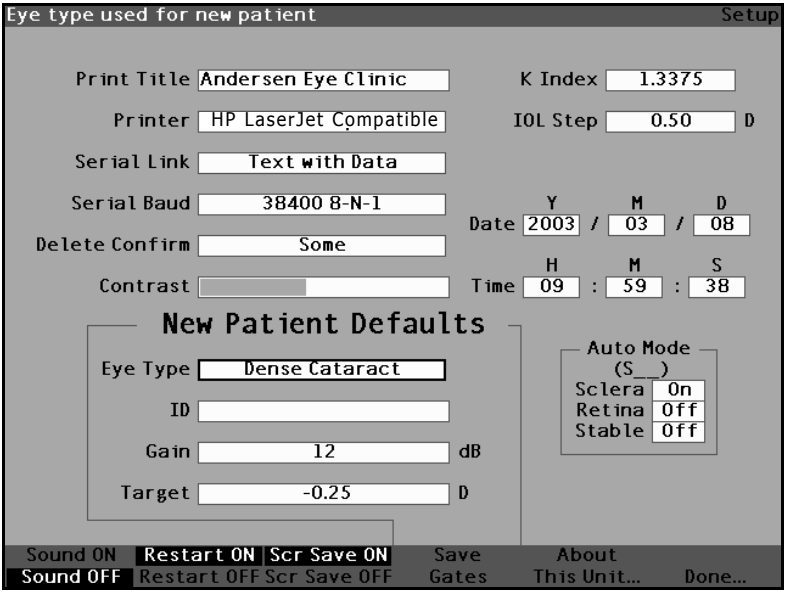


Figure 77 Default Eye Type Field Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

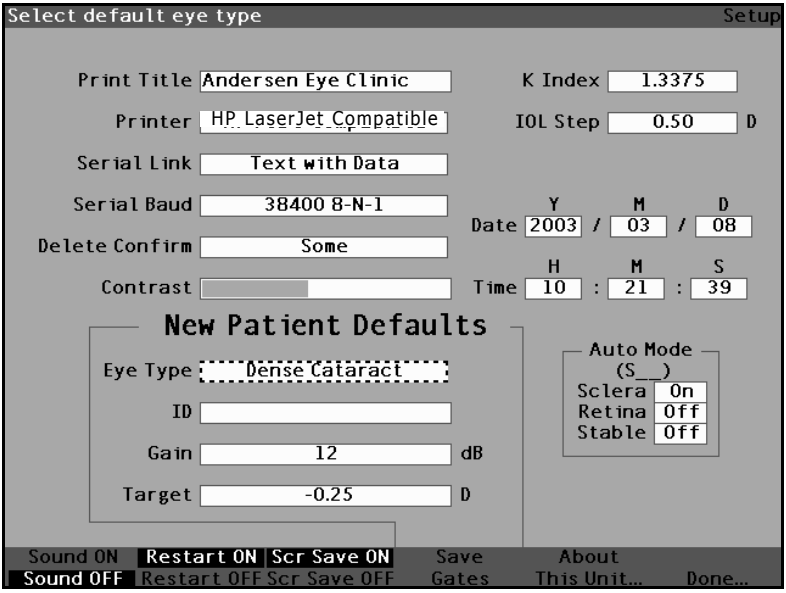


Figure 78 Default Eye Type Field Selected

3. Within the Default Eye Type field, rotate the knob to select one of the pre-entered Eye Types as shown in Figure 79 below

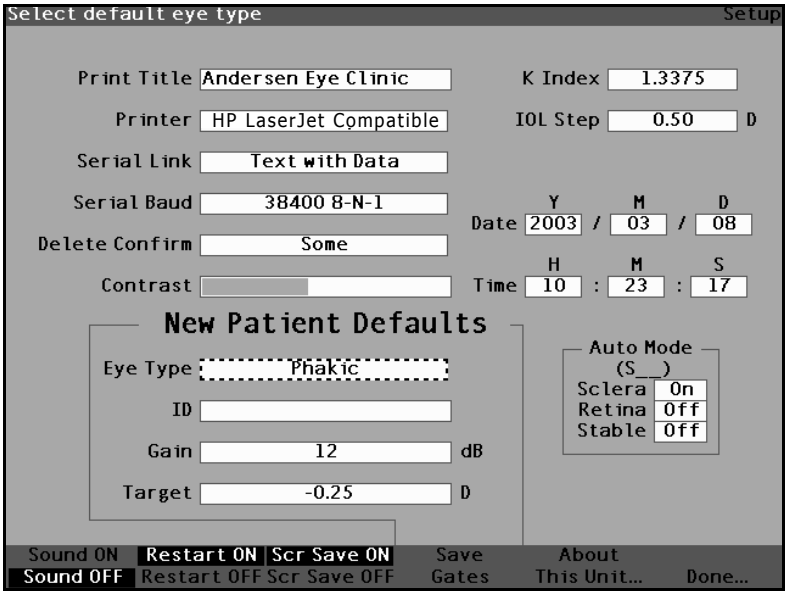


Figure 79 New Default Eye Type Selected

4. Press the knob or the √ button, to save the selected Default Eye Type and to deactivate the field.

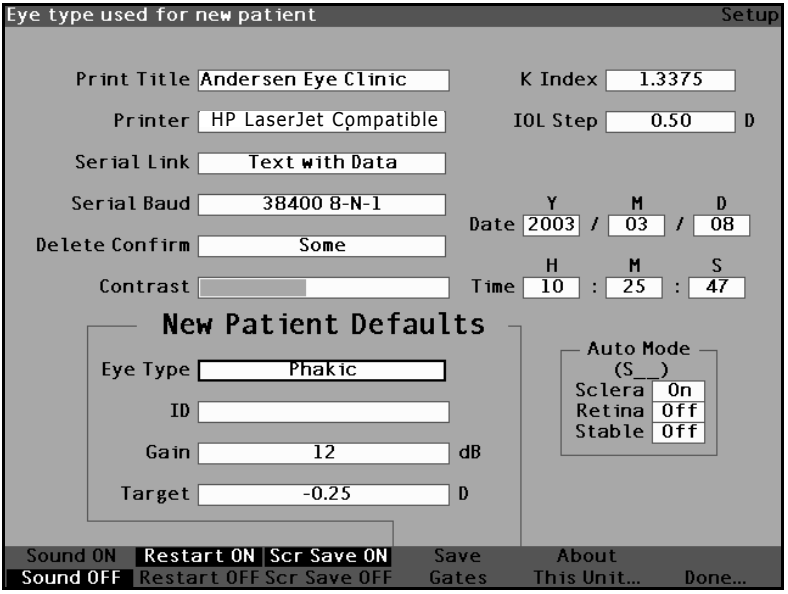


Figure 80 Default Eye Type Changed

How to Set the Default ID

The Accutome A-Scan Plus provides you with the ability to have a Default ID appear whenever you start a new patient. For example, you may want to have a doctor's name, or a clinic's name as a Default ID.

To set a Default ID:

1. Within the Setup Screen, rotate the knob to select the Default ID field, indicated by a solid black border.

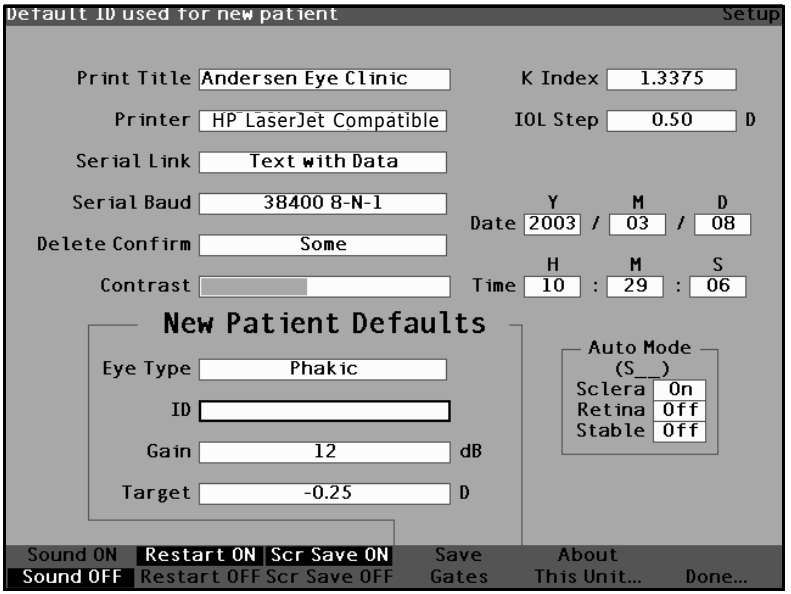


Figure 81 Default ID Field Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

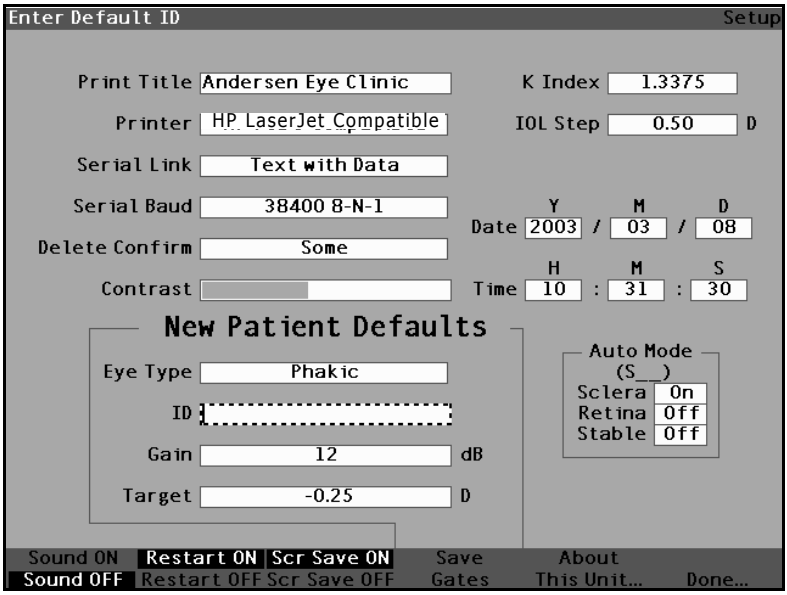


Figure 82 Default ID Field Activated

3. Within the Default ID field, enter the default ID.

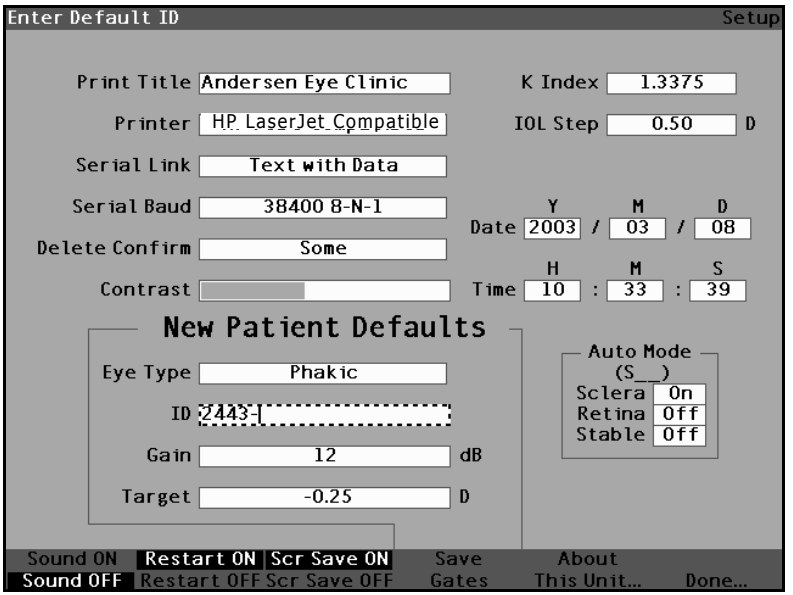


Figure 83 Entering the Default ID

4. Press the knob or the √ button, to save the entered Default ID and to deactivate the field.

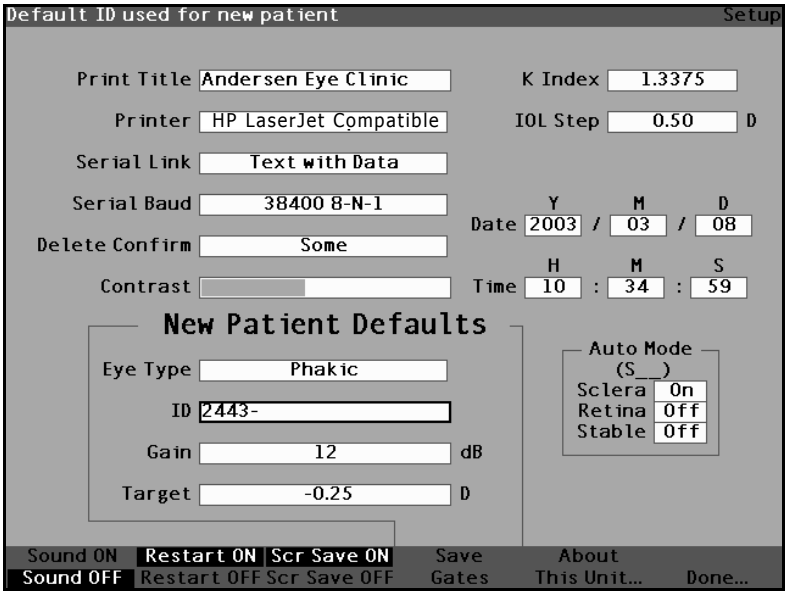


Figure 84 Default ID Added

How to Set the Default Gain

The Default Gain parameter allows you to adjust the new patient ultrasound gain. You can adjust the gain for any waveform from the Measure Screen, but when you adjust the gain value on the Setup Screen the adjusted gain becomes the default gain for all new patients. The gain can be adjusted throughout the range of 0dB to 20 dB in increments of 1dB.

To adjust the gain:

1. Within the Setup Screen, rotate the knob to select the Gain field, indicated by a solid black border.
2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

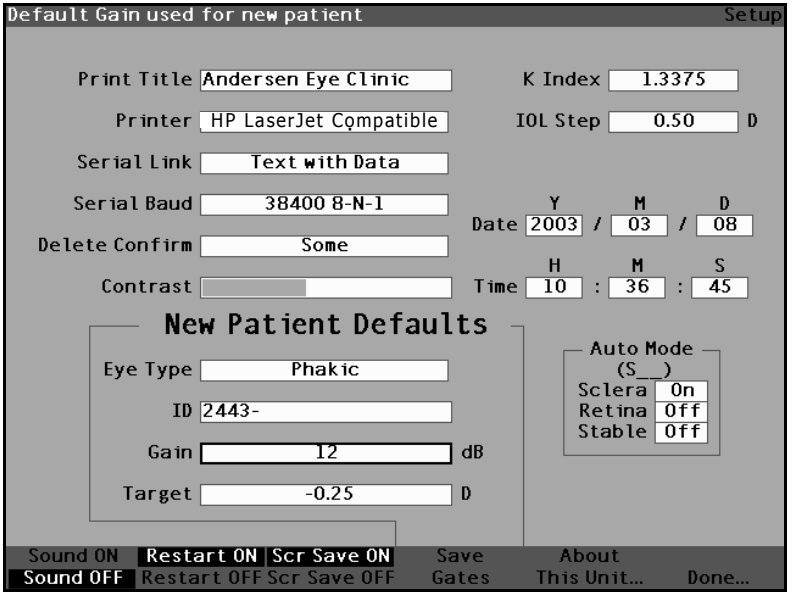


Figure 85 Default Gain Field Selected

3. Rotate the knob to select one of the pre-entered gain values, or manually enter the new value. The gain is adjustable in increments of 1 dB from 0 - 20 dB.
4. When the gain is at the appropriate level, press either the knob or the √ button, to save the adjusted value and to deactivate the field.

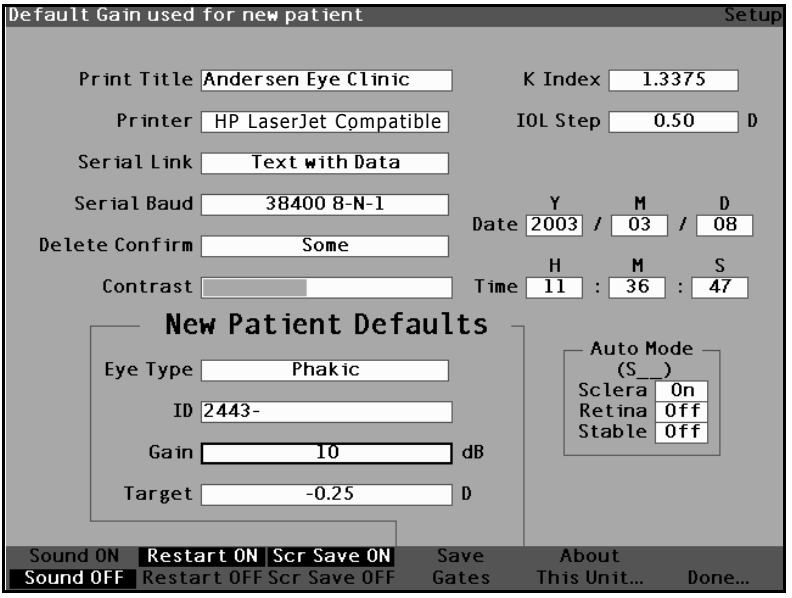


Figure 86 Default Gain Field Changed

How to Set the Target Refraction

When you are calculating IOLs one of the values you need to enter is the desired target refraction. The Accutome A-Scan Plus allows you to specify the default target refraction that is most common for patients. It is also possible to modify the target refraction on a per patient basis.

To set the Target Refraction:

1. Within the Setup Screen, rotate the knob to select the Target field of the New Patient Defaults, indicated by a solid black border.

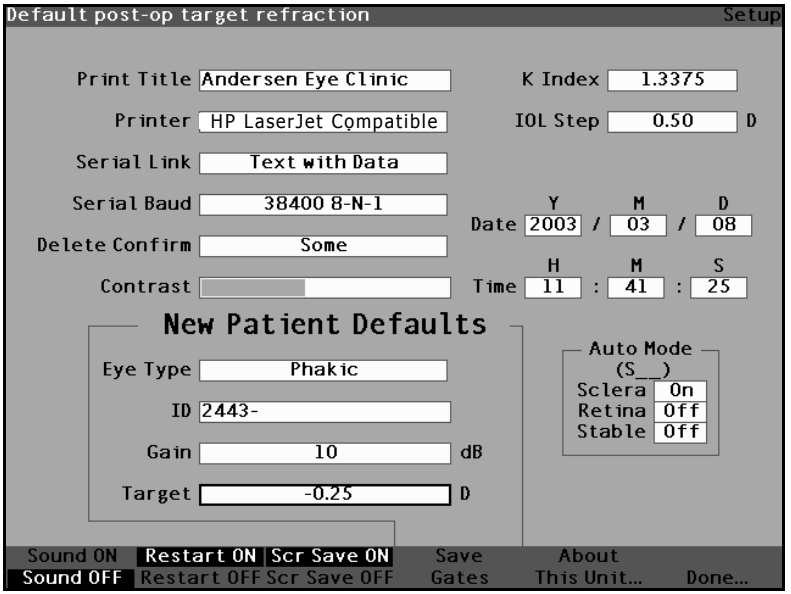


Figure 87 Target Field Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

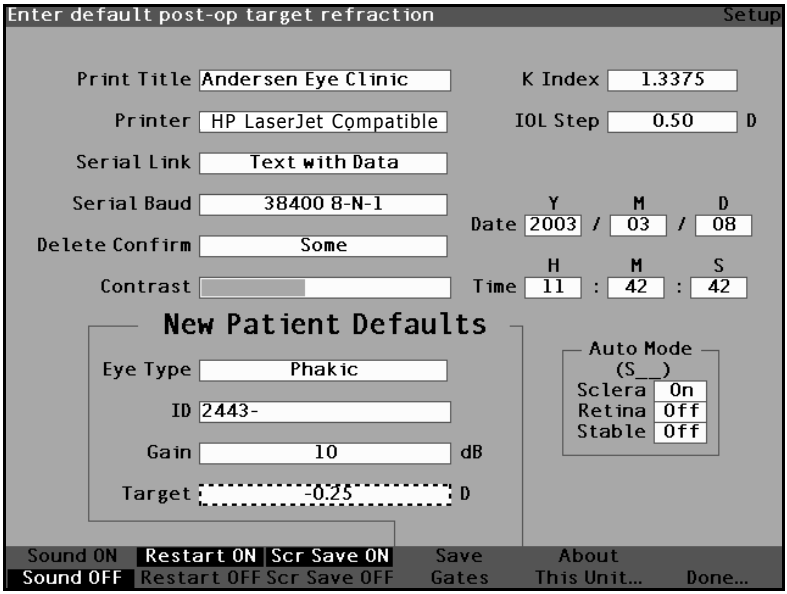


Figure 88 Target Field Activated

3. With the Target field active, rotate the knob until you reach the appropriate value or enter the target number on the keyboard.

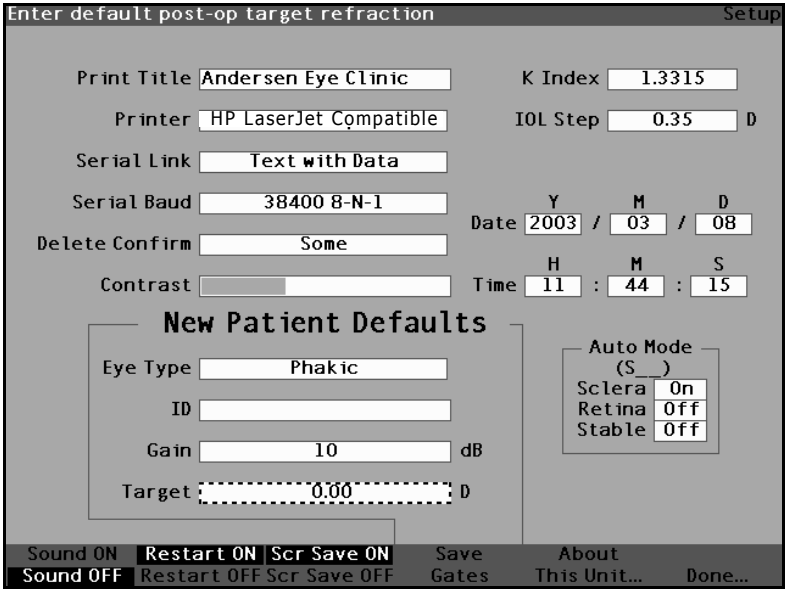


Figure 89 Adjusting the Target

4. Press the knob or the √ button, to save the adjusted Target and to deactivate the field.

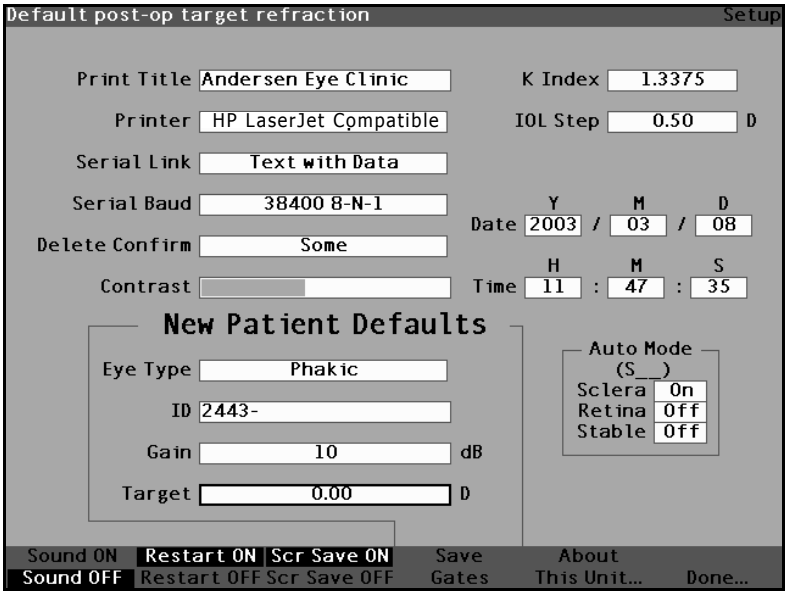


Figure 90 Target Adjusted

How to Set the K Index

The keratometer index of refraction, used to convert corneal radius to diopter power is not the same for all keratometers. In North America, most units have an index of refraction of 1.3375. European keratometers may have an index of refraction of 1.3315. The factory default is 1.3375.

The K Index value is only used when entering keratometer readings in diopters. K readings can be entered on the Calculate IOL screen as well as the Personalize IOL screen. The K index associated with diopter entries is not explicitly shown. When a keratometer reading is entered in diopters the default K index is copied from the setup screen. If the K. index of an entry is different than the Setup screen default K Index, a * appears beside the entry. To change or view the K index, change or reenter the diopter entry. The Accutome A-Scan Plus will prompt you with the default and current K indexes and ask which one you want associated with the entry.

To set the K index:

1. Within the Setup Screen, rotate the knob to select the K Index field, indicated by a solid black border.

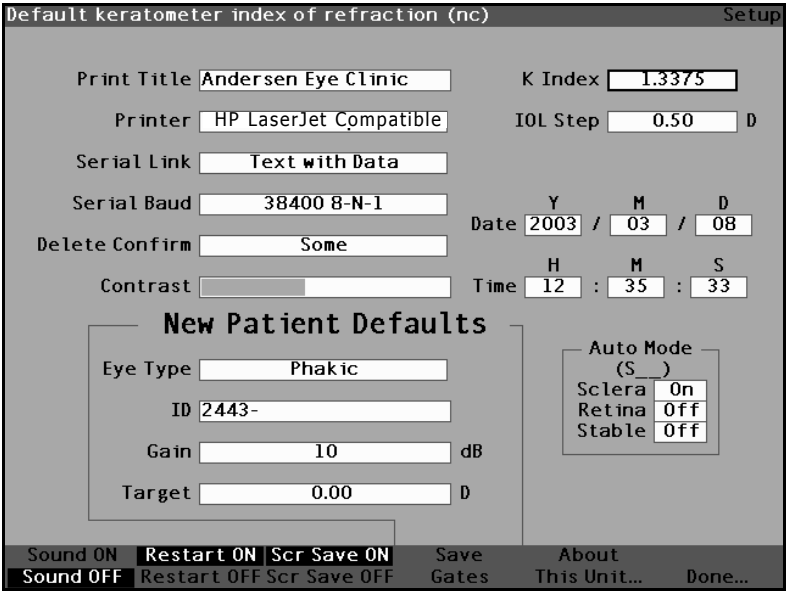


Figure 91 K Index Field Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

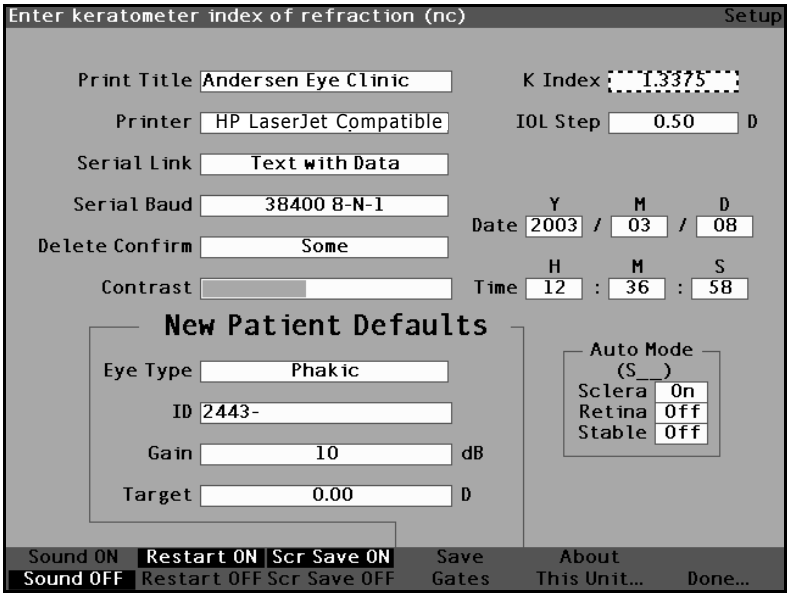


Figure 92 K Index Field Activated

3. Rotate the knob to adjust the K index , or manually enter the new value. The maximum value is 1.5000 and the minimum is 1.2500.

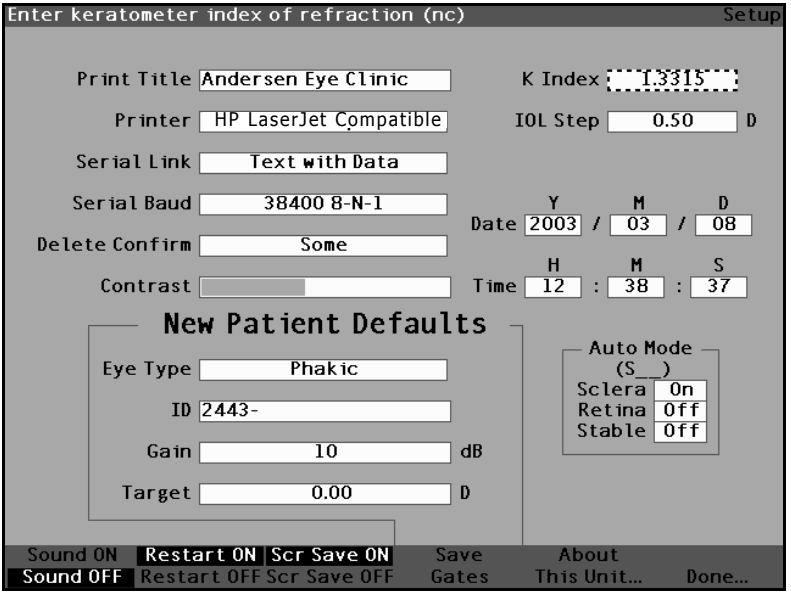


Figure 93 Adjusting the K Index

4. When the K index is correct, press either the knob or the √ button, to save the adjusted value and to deactivate the field.

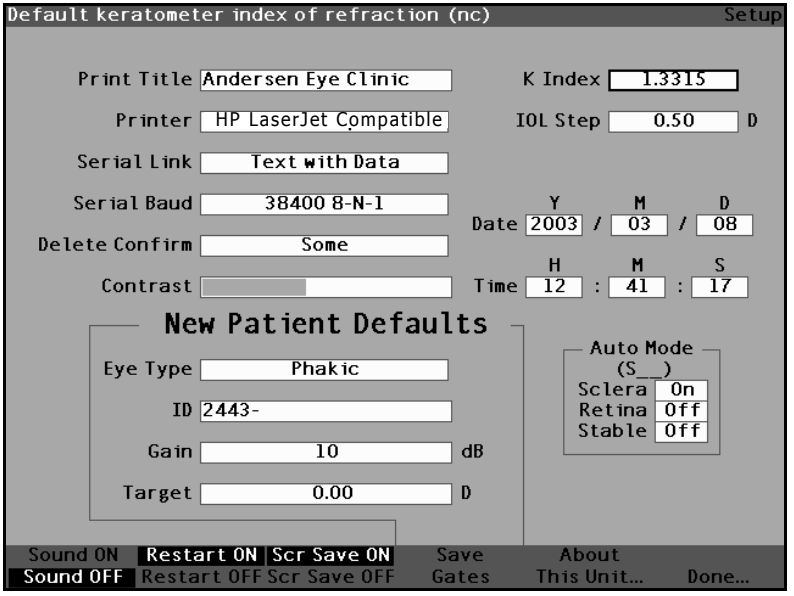


Figure 94 K Index Field Adjusted

How to Set the IOL Step

The Accutome A-Scan Plus allows you to modify the diopter step used when calculating IOL power lists.

To adjust the IOL Step:

1. Within the Setup Screen, rotate the knob to select the IOL Step field, indicated by a solid black border.

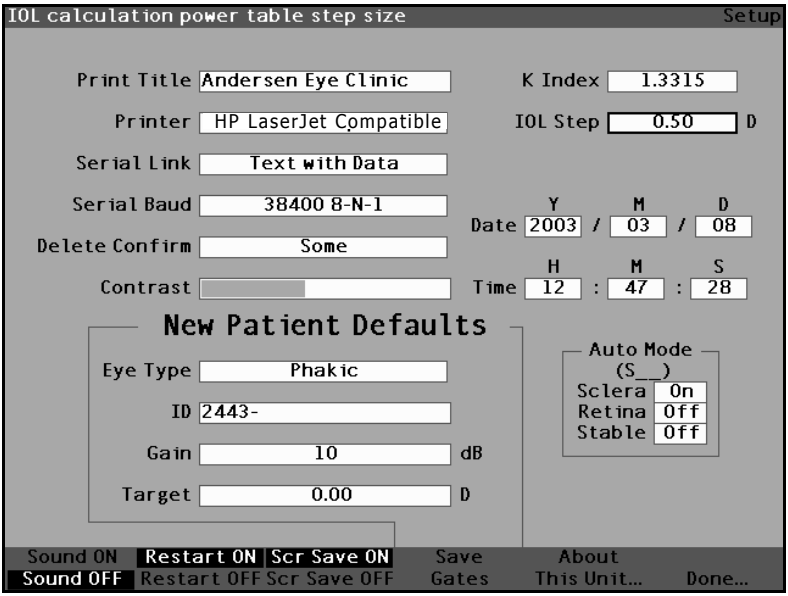


Figure 95 IOL Step Field Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

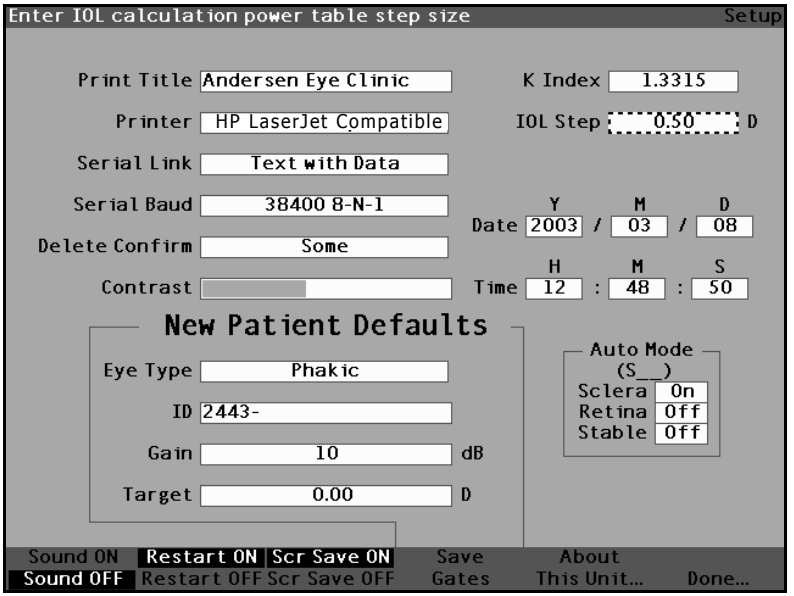


Figure 96 IOL Step Field Activated

3. Rotate the knob to select one of the pre-entered step values, or manually enter the new value. The IOL power step is adjustable in increments of 0.05 D from 0.05 - 5.00 D.

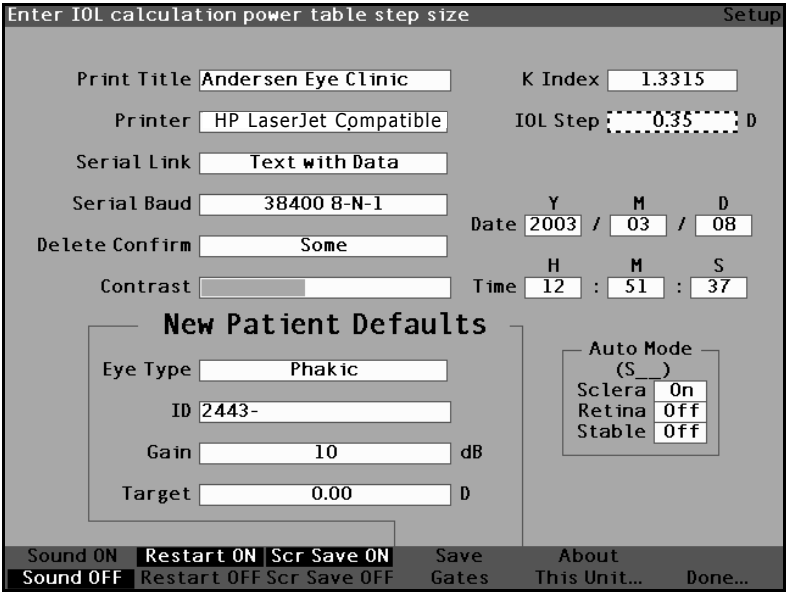


Figure 97 Adjusting the IOL Step

4. When the IOL Step is at the appropriate value, press either the knob or the √ button, to save the adjusted value and to deactivate the field.

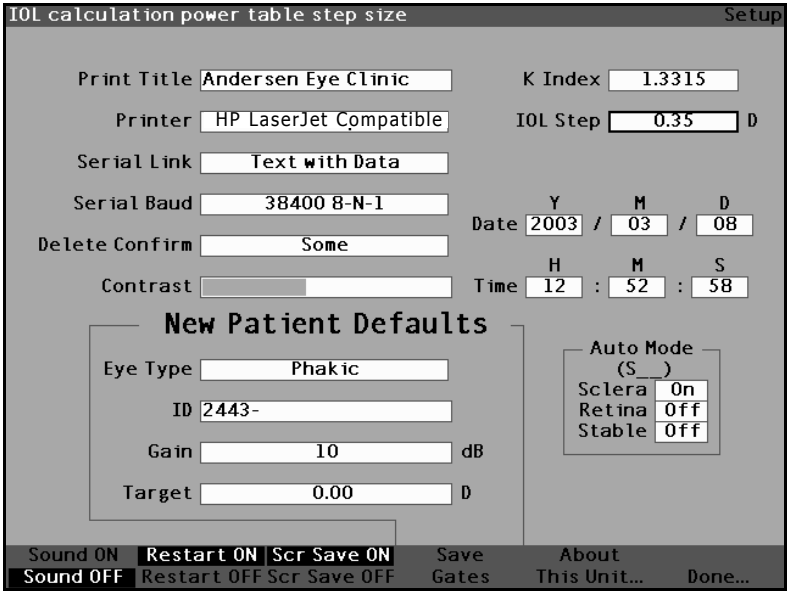


Figure 98 IOL Step Adjusted

How to Adjust the Date and Time

The Measure Screen displays the date and time that a waveform is captured. When you first set up the Accutome A-Scan Plus you can adjust the date and time as appropriate for your time zone. Both the date and time are divided into three separate fields. You adjust each field individually. The date is set up as: Year (Y), Month (M), and Day (D). The time is set up as: Hour (H), Minute (M), and Second (S). In the example given below the day of the date is adjusted.

To adjust the Date and Time:

1. Within the Setup Screen, rotate the knob to select the Day field of the date, indicated by a solid black border.

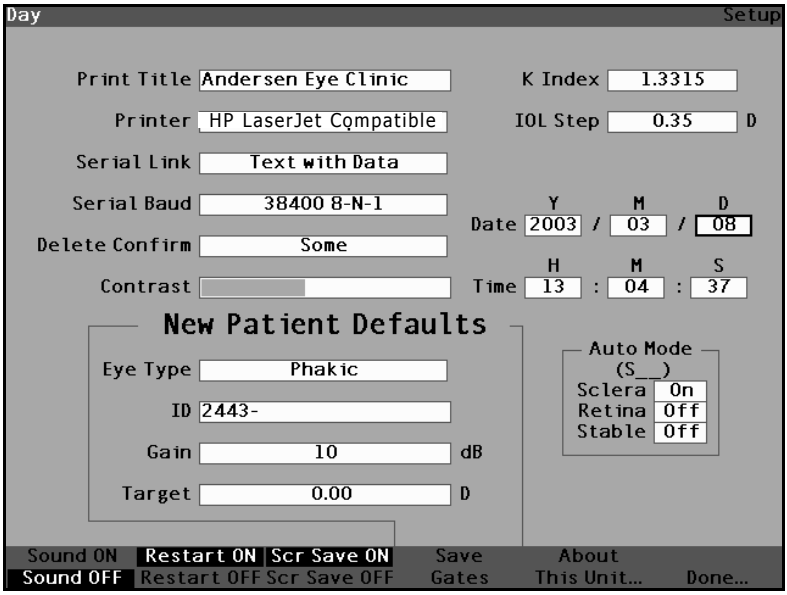


Figure 99 Day Field Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

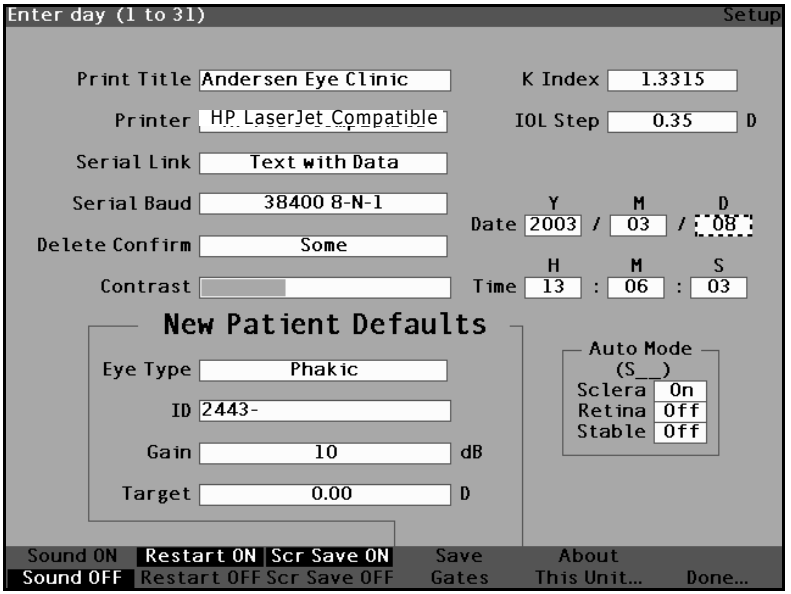


Figure 100 Day Field Activated

3. With the Day field active, rotate the knob until you reach the appropriate day number or enter the number with the keyboard.

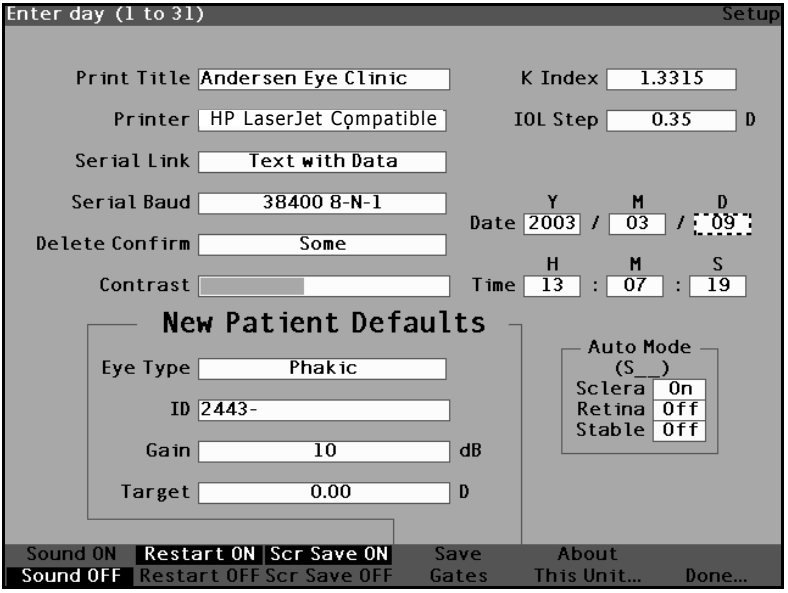


Figure 101 Adjusting the Day

4. Press the knob or the √ button, to save the adjusted Day and to deactivate the field.

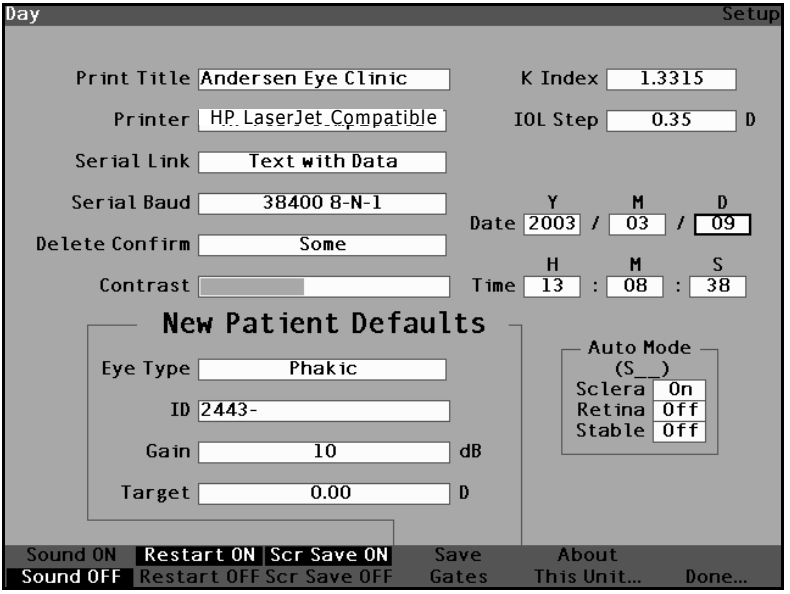


Figure 102 Day Adjusted

5. If necessary, adjust the Month (M) and Day (D) fields of the date in the same manner.
6. If necessary, adjust the Hour (H), Minute (M), and Seconds (S) fields of the time in the same manner.

How to Set the Auto Mode

The Accutome A-Scan Plus allows you to define the Automatic measurement mode by specifying how a measurement is automatically captured. There are a total of three criteria available and each can be turned off or on by the user on the Setup screen. The criteria are:

- Sclera - automatic capture determined by sclera detection
- Retina - automatic capture determined by retina detection
- Stable - automatic capture determined by measurement stability

The Auto Mode setting is displayed in the soft menu on the Measure Screen as 'Auto (SRS), where (SRS) means Sclera, Retina, Stable. If the feature is ON, the first letter appears in its place, otherwise a placeholder '_' is displayed.

The default is 'Sclera', displayed as 'Auto (S__)'. Sclera must have a distinct sclera echo after the retina, above the threshold. Between the Retina and Sclera the signal must go below the threshold.

'Retina', displayed as 'Auto (_R_)', must begin at the base line, have no data greater than 10% of the threshold in front it (for 1.5 mm), and be steeply rising.

"Stable', displayed as 'Auto (__S)', means the measurement needs to be within a tolerance for a certain amount of time.

***Note:** *The Stable Auto Mode setting is not recommended for contact method measurements. The measurement variance caused by hand or eye movements may make the stable auto lock requirement difficult to achieve.*

***Note:** *Sound, if enabled, reflects the quality of the measurement with respect to the current auto mode settings, even if you are using the Manual capture mode.*

To specify the Auto Mode:

1. Within the Setup Screen, rotate the knob to select the Sclera field of the Auto Mode, indicated by a solid black border.

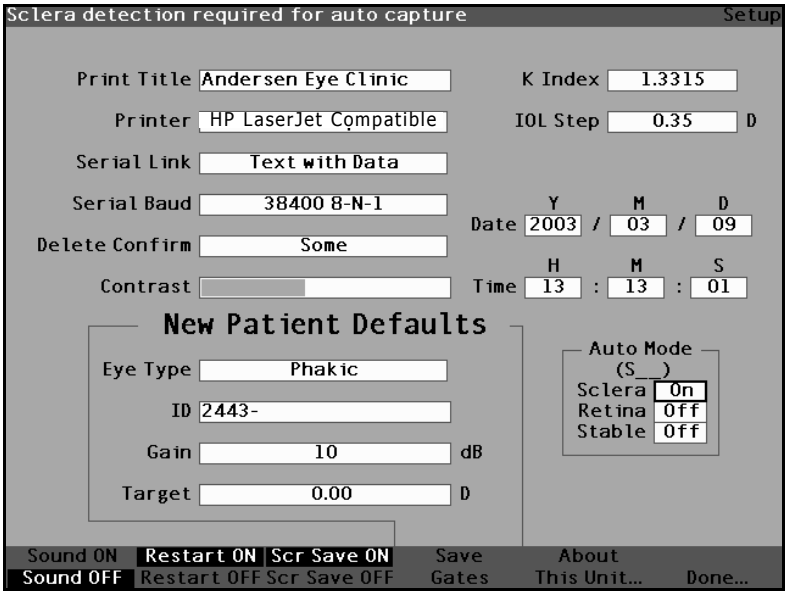


Figure 103 Auto Mode Sclera Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border.

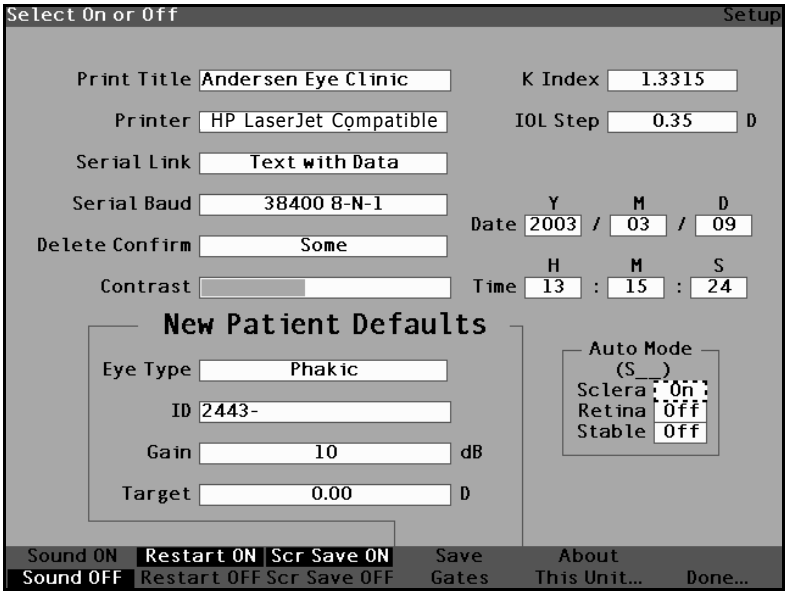


Figure 104 Auto Mode Sclera Field Activated

3. With the Sclera field active, rotate the knob until you the word "Off" is displayed. Automatic mode will no longer be triggered by sclera detection.

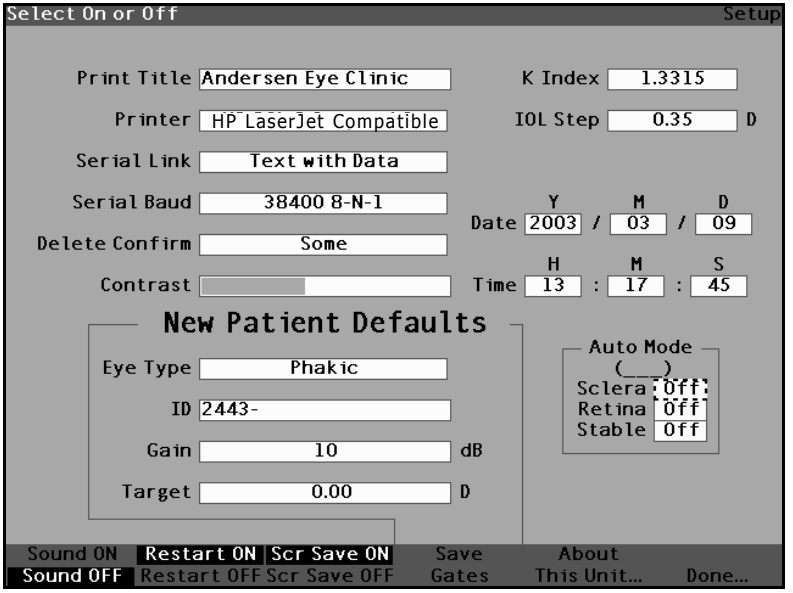


Figure 105 Changing the Auto Mode - Turning Off Sclera

4. Press the knob or the √ button, to save the adjusted Sclera and to deactivate the field.

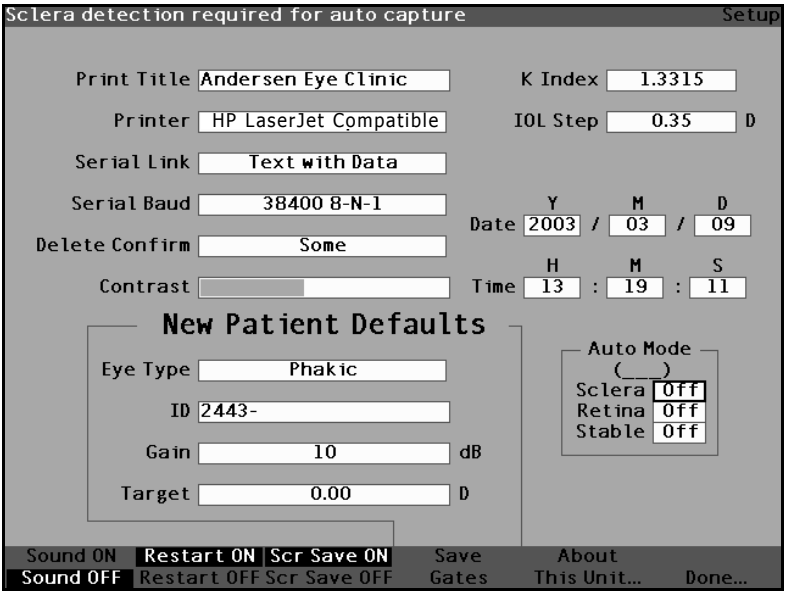


Figure 106 Auto Mode - "Sclera" Off

1. If you would like to define the Auto Mode by Retina signal quality, rotate the knob to select the "Retina" field.
2. Press the knob or the √ button, to activate the field, indicated by the dashed border.
3. Rotate the knob to switch from "Off" to "On"
4. Press the knob or the √ button, to save the adjusted Retina and to deactivate the field.
5. If you would like to define the Auto Mode by a stable measurement, rotate the knob to select the "Stable" field.
6. Press the knob or the √ button, to activate the field, indicated by the dashed border.
7. Rotate the knob to switch from "Off" to "On"
8. Press the knob or the √ button, to save the adjusted Stable and to deactivate the field.

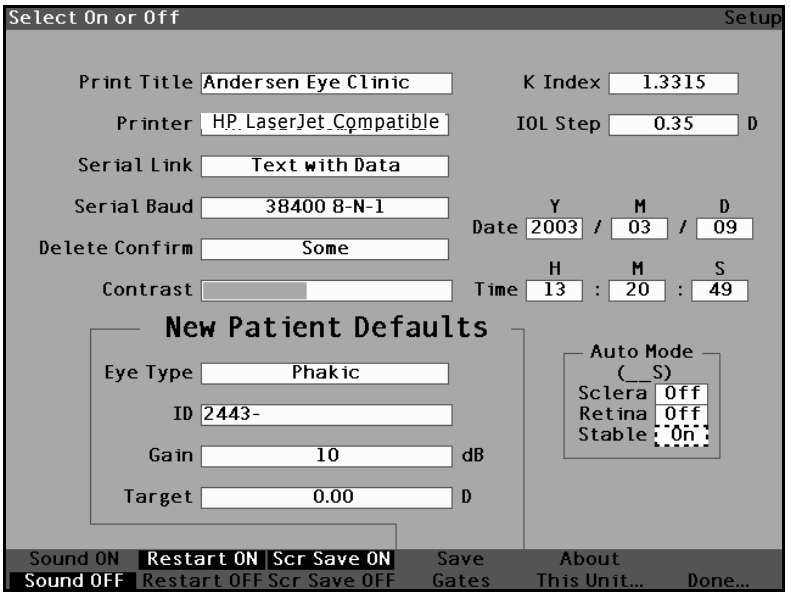


Figure 107 Auto Mode - "Stable" Selected

9. Press the knob or the √ button, to save Stable as On and to deactivate the field.

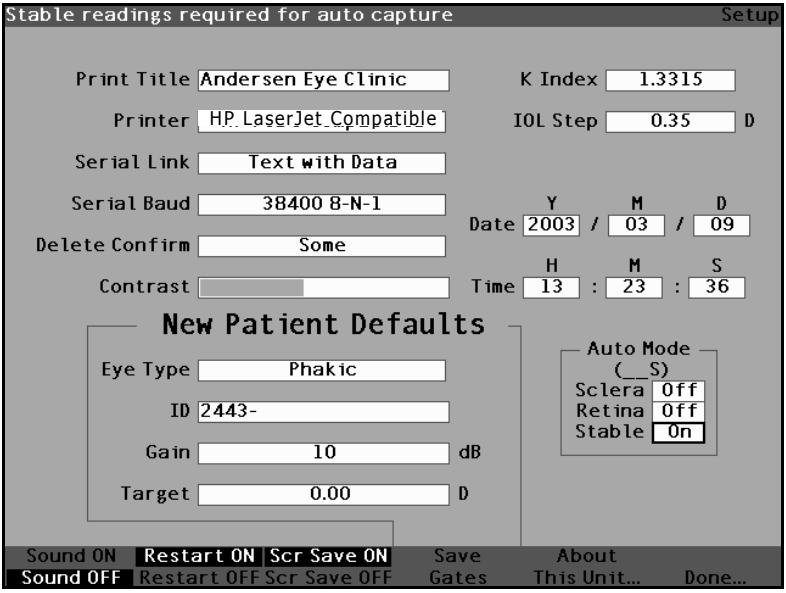


Figure 108 Auto Mode Defined by "Stable" Measurement

10. Select and turn on or off all the Auto Mode criteria until you have accurately defined how a measurement will be automatically captured.

Sound On/Sound Off

The Sound On/Sound Off selection toggles between the two. When "Sound On" is selected there will be sound during measurement. When "Sound Off" is selected there will be no sound during measurement.

The audible feedback is a constant tone initiated when the probe contacts the eye. The frequency of the tone increases as the waveform is closer to being acceptable according to the criteria associated with the Auto Mode (see "How to Set the Auto Mode" on page 141 of this manual).

Restart On/Restart Off

The Restart On/Restart Off selection toggles between the two and will prompt the Accutome, when operated in the "Automatic" mode, to automatically restart measuring after a successful reading or to stop after each successful reading.

When "Restart On" is selected the Accutome A-Scan Plus will automatically restart for up to five automatic readings. When "Restart Off" is selected the Accutome A-Scan Plus will stop after each reading.

Scr Save On/Scr Save Off

The Scr Save On/Scr Save Off selection toggles between the two and will display the screen saver or not.

The screen saver feature is provided to protect the LCD from unnecessary wear. If the screen saver is enabled and the Accutome A-Scan Plus is unused for 30 minutes, the instrument will display the screen saver and the display will go dark.

When " Scr Save On" is selected the screen saver will be displayed when the instrument is not in use. When "Scr Save Off" is selected the screen saver will not be displayed at all.

To restore the screen after the screen saver has blanked it, press any and the first key press will be ignored and the screen will be restored.

Save and Restore Factory Default Gates and Threshold

You may find after using the Accutome A-Scan Plus for a while, that you frequently have to adjust one or several gates and threshold. If you continually make the same adjustments to gates/threshold, you may want to save the adjusted settings as the default for gates/threshold. When you save gates/threshold the current locations of the gates and threshold become the new patient default locations.

To save gate/threshold settings as the default:

1. After you made gate adjustments to the current waveform in the Measure Screen, return to the Setup Screen (press the Preferences button, press more settings...). Refer to "How to Adjust Gates/ Threshold" on page 168 of this manual for more information.
2. Press the button beneath the selection "Save Gates". The Accutome A-Scan Plus will cue with a message displayed at the top of the screen indicating you have saved the current location of the gates and threshold as the default.

To restore the locations of the gate and threshold to the factory default:

1. Press and hold Save Gates button for approximately 1 sec. You will be prompted if you want to restore gates/threshold to the factory default.

About This Unit

When you press the button beneath the "About This Unit..." selection, the Accutome A-Scan Plus displays another screen, the "About this Unit" screen as shown in Figure 109 below. This screen is informational only and lists the software version, boot version, and the status of the probe. When you press the button beneath the "Done..." selection you will return to the More Settings screen.

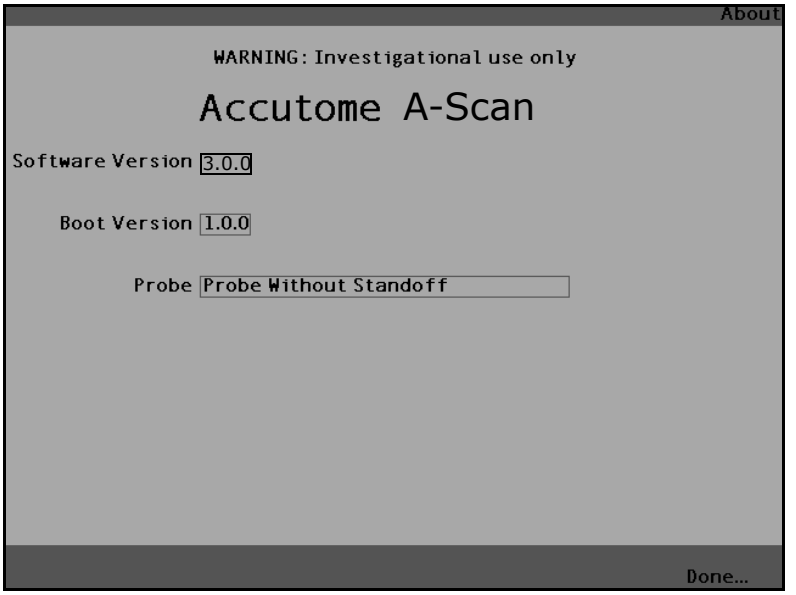


Figure 109 About This Unit Screen

***Note:** *If setup is complete, press the button beneath the selection "Done" and you will return to the Eye Types Screen.*

6 Performing Measurements

Overview

The Accutome A-Scan Plus is very simple to operate, and has advanced features to help you obtain the best possible measurements.

The Accutome A-Scan Plus takes measurements by sending a signal through the eye through the ultrasonic probe. The signal echoes off the various parts of the eye (cornea, lens, retina) and returns a signal through the probe. The returned signal is translated and displayed as the Patient waveform. The Accutome A-Scan Plus examines each of the echoes in the waveform and calculates the measurements from one echo to the next. All measurements are then displayed on the Measure Screen. The number of echoes detected is determined by a user selectable eye type, including Phakic, Aphakic, and Pseudophakic.

Five waveforms can be captured for each eye. Review and gate adjustment can be done after waveform capture to ensure proper measurement.

The Accutome A-Scan Plus provides many user controls to obtain accurate measurements. These include the support for contact or immersion method, individual velocities, automatic capture of readings, gain control, manual and automatic gate adjustment, and zoom.

During measurement, the instrument will provide audible feedback of contact, signal quality, and capture.

This chapter provides you with information to control, capture, and review waveforms.

Measure Screen

When you power on the Accutome A-Scan Plus the Measure Screen is displayed as shown in Figure 110 below. You can get to the Measure Screen at any time by pressing the Measure button located at the right side of the front panel or pressing the foot switch.

When you power on the instrument, or start a new Patient, all settings are set to predetermined values. The patient eye type, gain, gates/threshold, and ID are set as determined by the Setup Screen. The patient name field and all measurements are cleared.

Capture mode (automatic or manual), and probe coupling method (contact or immersion) remain as last set by the user and are retained while the Accutome A-Scan Plus is turned off.

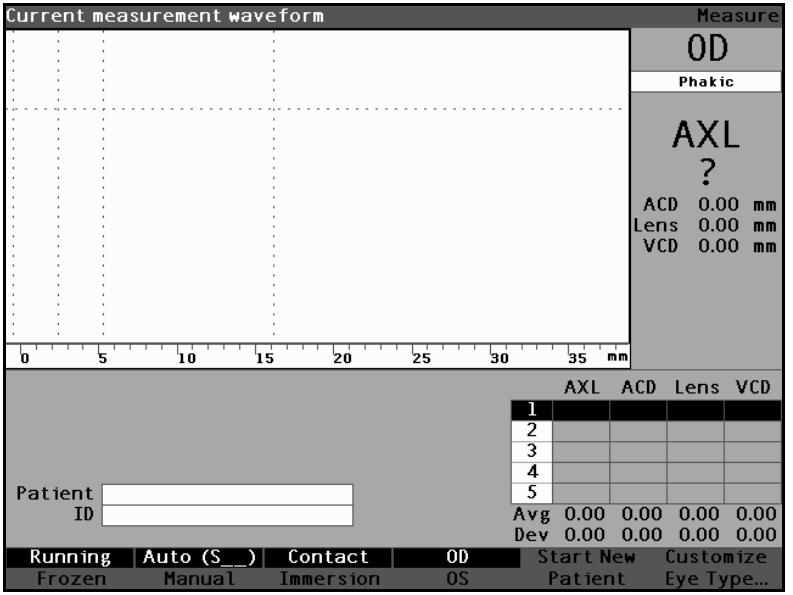


Figure 110 Measure Screen Displaying Current Settings

Information Displayed on the Measure Screen

The Measure Screen provides the continuous display of Axial Length, ACD, Lens Thickness, and Vitreous dimensions for the active patient.

The top, left side of the screen displays the active patient waveform. Within the waveform display are time gates and amplitude threshold to control the capture and measurement of the waveforms.

Below the waveform is a scale in millimeters (mm) that displays the location of detected echoes within the eye. Located to the immediate right of the current waveform is the current eye indicator, OD or OS, and its associated eye type. Below the eye type is the current waveform's live Axial Length, ACD, Lens Thickness, and Vitreous dimensions. These dimensions will change as you acquire data or change waveform parameters.

The bottom left corner displays the Patient name and ID. The bottom right corner displays the measurements for the currently selected eye of the patient.

Soft Menu Selections

The Measure Screen displays one of two soft menus at the bottom of the screen, the Main menu and the Waveform Control menu.

The Waveform Control menu is displayed when the waveform is actively selected, otherwise the main menu is displayed.

The Measure Screen Main Menu has the following soft menu selections located at the bottom of the screen:

- Running/Frozen - toggles between the live and frozen captured waveform
- Auto (_ _ _)/Manual - toggles between the automatic and manual mode of capturing patient waveforms
- Contact/Immersion - toggles between the contact and immersion methods of coupling the probe

- OD/OS - toggles between the OD and OS eye; selecting OD or OS displays the waveforms for that eye. OD/OS must be set accordingly before capturing waveforms.
- Start New Patient - clears the current patient information and measurements and resets gain, gate, and ID to default values.
- Customize Eye Type... - displays the Customize Eye Type screen where you can customize the eye type for the current patient or review the current eye type definition. Custom Eye Types are associated with the current patient only and are not available to other patients. Permanent changes to eye types can be made on the Eye Types Screen.

Starting a New Patient

You can start a new patient from either the Measure Screen, Calculate IOL Screen, or from the Patient Records Screen. Once you start a new patient, the Accutome A-Scan Plus will clear all previous patient information and set gain, gate and ID to the default values.

After starting a new patient, select the eye to be measured, OD or OS, and verify the eye type for that eye.

How to Set the Eye Type

When the Accutome A-Scan Plus is set up at the factory, it is equipped with predefined eye types and specific velocities for the predefined eye types. Descriptions of the factory installed eye types and their characteristics are given below, followed by instructions on modifying eye types on a per patient basis.

Eye Types

The following eye types are preset at the factory:

- Phakic - Setting for most patients.
- Silicone Filled - Phakic eye with Silicone Oil in the Vitreous.
- Dense Cataract - Use this setting when a dense cataract prevents measurement of lens thickness.
- Aphakic - Patient with no lens, lens is not measured or assumed.
- Pseudo PMMA - Patient with Pseudophakic PMMA IOL
- Pseudo Silicone - Patient with Pseudophakic Silicone IOL
- Pseudo Acrylic - Patient with Pseudophakic Acrylic IOL

***Note:** *All eye types, including Aphakic, have an assumed cornea of 0.55 mm at a velocity of 1641 m/sec. This assumption is included in the ACD measurment.*

Eye Type Materials and Velocities

The tables below list the preset eye types and define the materials and velocities for each eye type.

Table 2 Eye Types

Eye Type Name	Lens	Thickness	AC	VC
Phakic	Phakic	Measured	Aqueous	Vitreous
Silicone Filled	Phakic	Measured	Aqueous	Silicone Oil
Dense Cataract	Phakic	4.70	Aqueous	Vitreous
Pseudo PMMA	PMMA	0.70	Aqueous	Vitreous
Pseudo Silicone	Silicone	1.40	Aqueous	Vitreous
Pseudo Acrylic	Acrylic	0.70	Aqueous	Vitreous
Aphakic	[none]	[none]	1532	

Table 3 Lens Materials and Velocities

Material	Velocity [m/s]
Phakic	1641
PMMA	2660
Silicone	980
Acrylic	2120

Table 4 Anterior/Vitreous Materials and Velocities

Material	Velocity [m/s]
Aqueous	1532
Vitreous	1532
Silicone Oil	980

Setting the Eye Type

The patient's OD or OS eye type may not match the default provided by the Accutome A-Scan Plus default preferences.

To set the eye type:

1. Within the Measurement Screen, rotate the knob to select the eye type located at the top right side of the screen. Selection is indicated by a solid black border. (See Figure 111 below.)

Tip: You can use CTRL+E to select the next eye type directly from the keyboard. You can use CTRL+SHIFT+E to select the previous eye type directly from the keyboard.

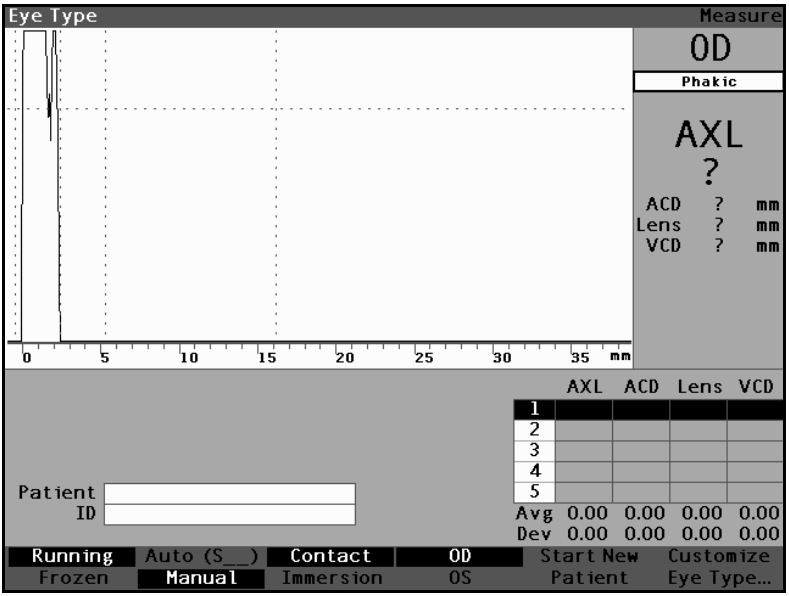


Figure 111 Eye Type Selected

2. Press the knob or the √ button, to activate the field, indicated by the dashed border. (See Figure 112 below.)

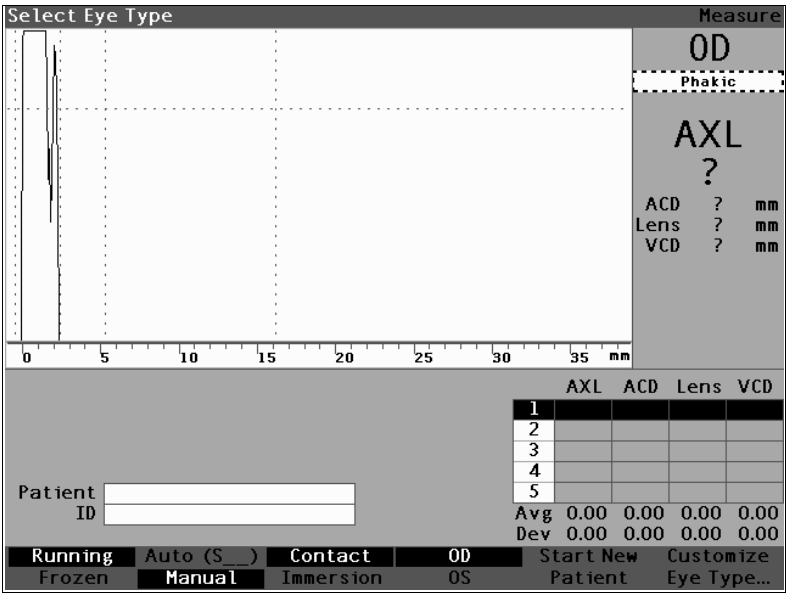


Figure 112 Eye Type Active

3. Within the eye type field, rotate the knob to scroll through the list of eye types. Select the appropriate eye type. Press the knob or the √ button to save the new eye type.

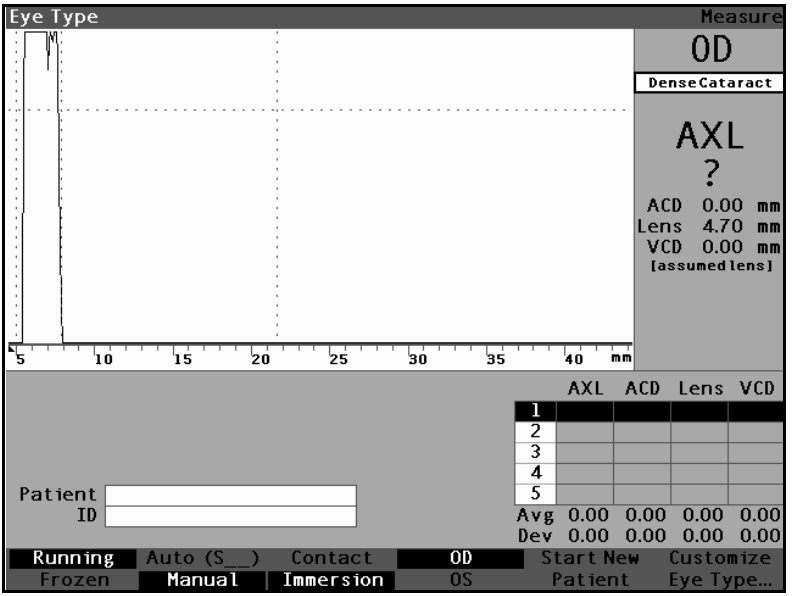


Figure 113 Eye Type Changed

Probe Application Methods

The Accutome A-Scan Plus supports two different methods of applying the probe to the cornea, contact and immersion.

Select the method you will be using by pressing the Contact/Immersion soft menu button.

Immersion

The Accutome A-Scan Plus makes it easy to use the Immersion method. The immersion method yields improved accuracy by allowing direct detection of the corneal echo and eliminating compression of the ACD associated with the contact method.

The immersion probe application method is used in conjunction with a Prager shell or Hansen shell with an immersion fluid. While using the immersion method the probe should be placed from 5 - 14.5 mm above the cornea.

Contact

The Contact method allows you to apply the probe directly to the anesthetized cornea.

CAUTION: When using the contact method, care should be taken to minimize corneal compression. Corneal compression will result in a shorter axial length measurement and will affect IOL calculations.

Capture Modes

The Accutome A-Scan Plus provides two methods of capturing measurements; Automatic, or 'Auto', and Manual. The Automatic mode allows the instrument to determine, based upon user established criteria, when a measurement is captured. The Manual mode allows the user to determine when a measurement is captured.

Auto Mode

When you are using the Auto mode the Accutome A-Scan Plus uses the definition of automatic measurement that has been set up in the unit's preferences.

The user is allowed define the Automatic measurement mode by specifying how a measurement is automatically captured. There are a total of three criteria available and each can be turned off or on by the user on the Setup screen. The criteria are:

- Sclera - automatic capture determined by sclera detection
- Retina - automatic capture determined by retina detection
- Stable - automatic capture determined by measurement stability

The Auto Mode setting is displayed in the soft menu on the Measure Screen as 'Auto (SRS)', where (SRS) means Sclera, Retina, Stable. If the feature is ON, the first letter appears in its place, otherwise a placeholder '_' is displayed.

The default is 'Sclera', displayed as 'Auto (S__)'. Sclera must have a distinct sclera echo after the retina, above the threshold. Between the Retina and Sclera the signal must go below the threshold.

'Retina', displayed as 'Auto (_R_)', must begin at the base line, have no data greater than 10% of the threshold in front it (for 1.5 mm), and be steeply rising.

"Stable', displayed as 'Auto (__S)', means the measurement needs to be within a tolerance for a certain amount of time.

***Note:** *For more information on setting the Auto mode refer to "How to Set the Auto Mode" on page 141 of this manual.*

Another aspect of the Auto Mode that is established in the Accutome A-Scan Plus setup is the Restart feature. If 'Restart' is set to 'ON' and less than five measurements have been taken, the Auto mode restarts measurement after automatic capture. The Restart setting is available on the Setup screen, by pressing the Preferences button and then the More Settings... soft menu selection, or by pressing the Preferences button twice.

***Note:** *For more information on setting the Auto mode refer to "Restart On/Restart Off" on page 148 of this manual.*

Manual Mode

Using the manual mode of capture you determine when a waveform is good and capture it manually.

How to Capture a Waveform

You can "freeze" or, capture, the waveform with the optional footswitch or by pressing the button beneath the Run/Frozen selection on the front panel, or by pressing the Measure button at the top right corner.

Using the Foot Switch

When you want to capture a waveform simply press on the footswitch. The Accutome A-Scan Plus will switch from "Running" to "Frozen".

Using the Running/Frozen Button

When you want to capture a waveform press the button beneath the Running/Frozen selection. The Accutome A-Scan Plus will switch from Running to Frozen.

Using the Measure Button

When you want to capture a waveform, press the Measure button at the top right corner. The Accutome A-Scan Plus will switch from Running to Frozen.

How to Select a Measurement

After you have taken measurements you may want to go back and review one of the captured waveforms. There are two ways to select a previous measurement; using the knob and button, or by using the foot switch.

Selecting a Measurement with the Knob

To select a measurement using the knob:

1. Within the Measurement Screen, rotate the knob to select the measurements table located at the bottom right corner of the screen. Selection is indicated by a solid black border.
2. Press the knob or the √ button, to activate the table, indicated by the dashed border. (See Figure 114.)
3. Within the measurements table, rotate the knob to scroll through the list of measurements. You can also just press the number (1 - 5) of the measurement on the keyboard. The measurement outlined with white text against a black background is the active measurement.

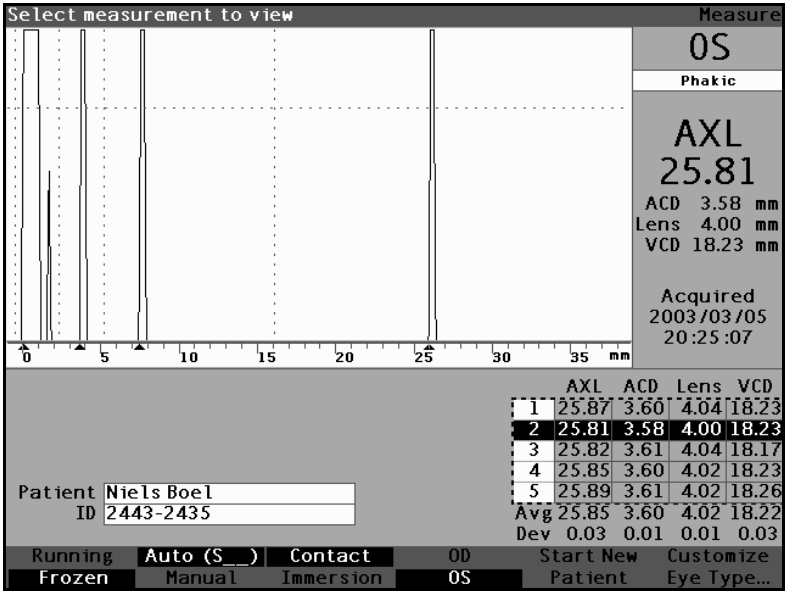


Figure 114 Measurement Selected

Selecting a Measurement Using Waveform Review Menu

The Waveform Review Menu will be displayed at the bottom of the Measure Screen when the waveform area is active.

To select a measurement using the Waveform Review Menu:

1. Within the Measurement Screen, rotate the knob to select the waveform area. Selection is indicated by a solid black border.
2. Press the knob or the √ button, to activate the waveform area, indicated by the dashed border. (See Figure 115 below.) The soft menu selections on the Measure Screen will change from the Main menu to the Waveform Review Menu.

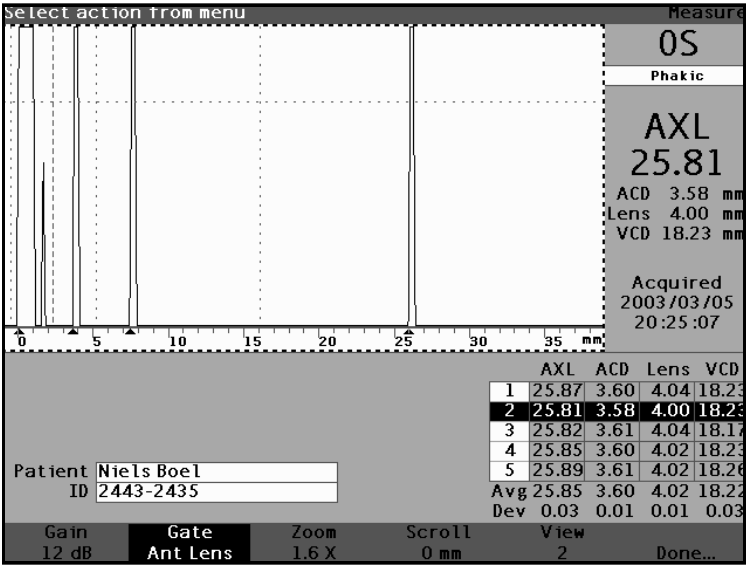


Figure 115 Measurement Activated with Waveform Review Menu

3. Press the button beneath the "View" selection. The measurement outlined with white text against a black background in the Measurement Table is the active measurement. The View button will scroll through all the measurements in the Measurement Table.

Tip: You can use CTRL+V to scroll through the measurements directly from the keyboard.

Selecting a Measurement with the Foot Switch

If you are in a screen, other than the Measure Screen, pressing the foot switch will bring you to the Measure Screen. In the Measure Screen the foot switch allows you to capture, select, or delete a waveform.

To select a measurement with the foot switch:

1. Within the Measure Screen, press and release the foot switch to select a measurement. The foot switch will scroll through the table of measurements each time you press it. Scrolling proceeds from top to bottom and then back to the top of the table again.

How to Delete a Measurement

You may want to delete one of the captured patient measurements. You can delete a measurement with the "X" button, the keyboard delete key or by using the foot switch

Deleting a Measurement with X Button or Keyboard

To delete a selected waveform press on the "X" button or the delete key on the keyboard when the waveform or measurement table is selected.

Deleting a Measurement with the Foot Switch

You can also press on the footswitch to delete the active measurement and start a new measurement. With the measurement you would like to delete selected, press on the footswitch and hold for approximately one second. The line in the measurement table will clear and you can recapture the waveform.

Tip: You can use DELETE on the keyboard to delete the active measurement.

How to Adjust Gates/ Threshold

The Accutome A-Scan Plus takes measurements by sending a signal through the eye via the ultrasonic probe. The various parts of the eye have different velocities. The signal passes through each part of the eye at different speeds depending upon the acoustic velocity of the eyes' components. (If there is already an IOL in the eye the signal will travel at a different speed than it would through a natural lens.)

Each time the signal encounters a change in velocity, due to the difference in material, the signal echoes off that part of the eye and is transmitted through the probe as a vertical spike in waveform. The vertical spikes in the waveforms are events, or the point in time when the signal encountered the different material. The Accutome A-Scan Plus measures the distances between these spikes and calculates the AXL value by summing all pieces of the waveform.

The events the Accutome A-Scan Plus seeks when scanning are:

- Cornea
- Anterior Lens (if eye is not Aphakic)
- Posterior Lens (if lens thickness is measurable)
- Retina

There is also unnecessary information captured in a waveform. There is a threshold for echoes to meet to be included as part of the measurement.

Accuracy depends upon the location of the gates and threshold along the waveform. The purpose of the gates/threshold is to delimit events. The gates/threshold tell the Accutome A-Scan Plus when to start looking for the different events in the waveform. Events will be detected to the right of the gate and above the threshold. The location of detected events are displayed in the scale below the waveform as indicated by solid black triangles.

If an event is not detected or is associated with an anomalous echo the user must reposition the gates/ threshold to properly measure the waveform.

The process of adjusting gates/threshold consists of:

- Selecting the gates/threshold
- Repositioning the gate location

Available Gates/Threshold

A gate delimits an event, such as the detection of the cornea. There are four vertical gates and one horizontal threshold along the horizontal and vertical axis of the waveform. The gates/threshold are as follows:

- Cornea Gate
- Anterior Lens Gate (visible if the eye type is not Aphakic)
- Posterior Lens Gate (visible if lens thickness is measurable)
- Retina Gate
- Threshold

The event being measured should be located to the right of the gate and above the threshold. You can reposition the gates/threshold if the events, gates and threshold do not align properly.

Selecting Gates/Threshold

All gates/threshold are visible in the current waveform. Each gate should be situated to the left of the event it is indicating.

To select a gate:

1. Within the Measure Screen, rotate the knob to select the current waveform area, indicated by a solid black border.

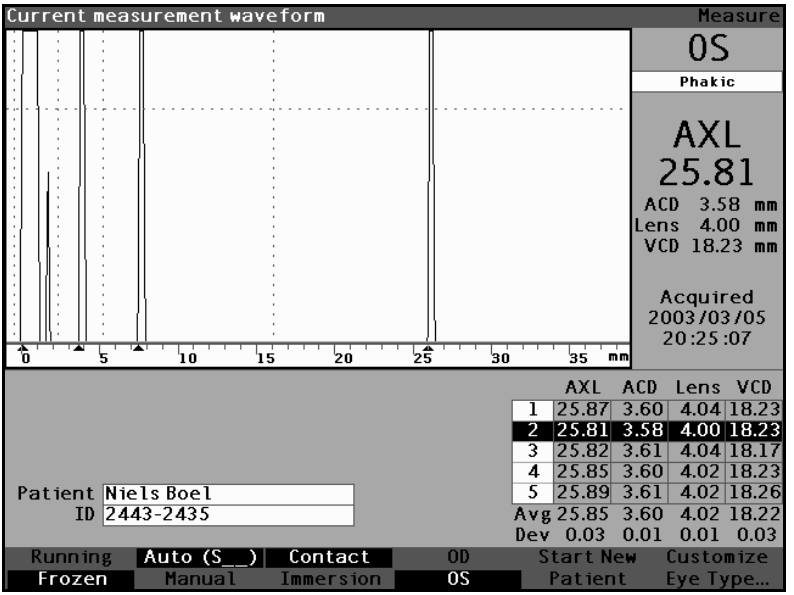


Figure 116 Current Measurement Waveform Selected

2. Press the knob or the √ button, to activate the current waveform area, indicated by the dashed border.
3. When the current waveform is active, the Accutome A-Scan Plus will display a new soft menu at the bottom of the Measure screen.

Waveform Review Menu

The Waveform Review menu has selections for adjusting gates/threshold, gain, zoom, scrolling, selecting a waveform and for exiting the menu.

To select an item from the menu for adjustment, press the button beneath the selection and then rotate the knob to make the adjustment.

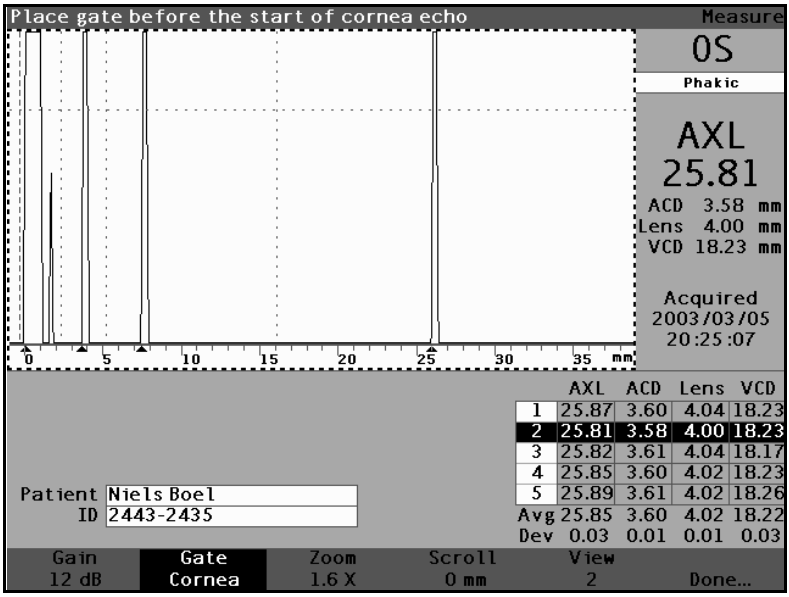


Figure 117 Waveform Review Menu Activated

How to Adjust the Cornea Gate

The cornea gate should be located **before** the start of the cornea echo. The active gate is displayed with dashed line while gates/threshold are indicated by dotted lines.

To adjust the cornea gate:

1. Press the button beneath the Gate selections until the "Gate Cornea" is displayed.

Tip: You can use CTRL+C to select the Cornea Gate directly from the keyboard, or hold to select cornea gates for all measurements.

2. Rotate the knob to move the cornea gate close to the cornea echo.
3. When the gate is in the proper position, either press the the button beneath the gate selections to select another gate for adjustment or press the button beneath "Done", the knob or the √ button to deactivate the menu.

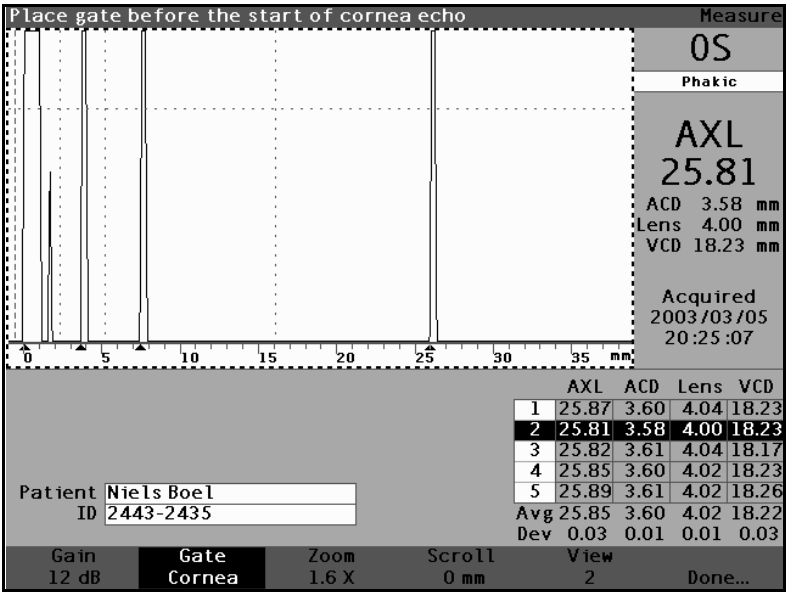


Figure 118 Cornea Gate Selected

How to Adjust the Anterior Lens Gate

The anterior lens gate should be located **before** the start of the first lens echo.

***Note:** *The anterior lens gate is only visible for non-Aphakic eye types*

To adjust the anterior lens gate:

1. Press the button beneath the Gate selections until the "Gate Ant Lens" is visible.

Tip: You can use CTRL+A to select the Anterior Lens Gate directly from the keyboard, or hold to select anterior lens gates for all measurements.

2. Rotate the knob to move the anterior gate close to the first lens echo.

3. When the gate is in the proper position, either press the the button beneath the gate selections to select another gate for adjustment or press the button beneath "Done", the knob or the √ button to deactivate the menu.

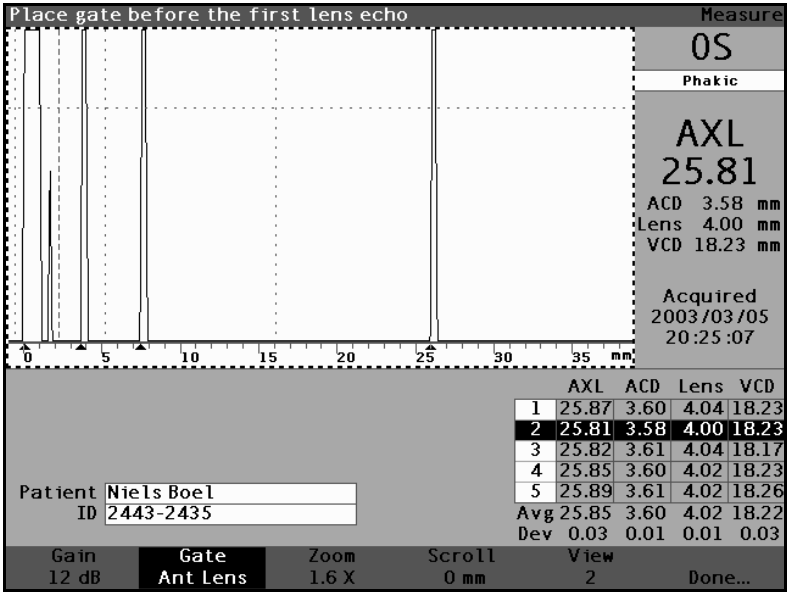


Figure 119 Anterior Lens Gate Selected

How to Adjust the Posterior Lens Gate

The posterior lens gate should be located **before** the start of the last lens echo.

***Note:** *The Posterior Lens Gate is visible only if the eye type requires the lens thickness to be Measured and not assumed.*

To adjust the posterior lens gate:

1. Press the button beneath the Gate selections until the "Gate Post Lens" is visible.

Tip: You can use CTRL+P to select the Posterior Lens Gate directly from the keyboard, or hold to select posterior lens gates for all measurements.

2. Rotate the knob to move the posterior lens gate before the last lens echo.

3. When the gate is in the proper position, either press the the button beneath the gate selections to select another gate for adjustment or press the button beneath "Done", the knob or the √ button to deactivate the menu.

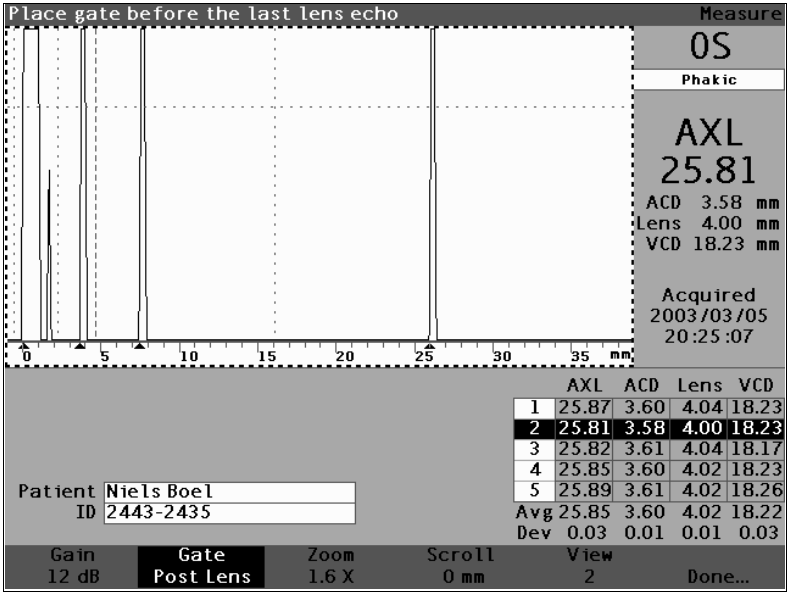


Figure 120 Posterior Lens Gate Selected

How to Adjust the Retina Gate

The retina gate should be located **before** the start of the retina echo.

To adjust the retina gate:

1. Press the button beneath the Gate selections until the "Gate Retina" is visible.

Tip: You can use CTRL+R to select the Retina Gate directly from the keyboard, or hold to select retina gates for all measurements.

2. Rotate the knob to move the retina gate before the start of the retina echo.
3. When the gate is in the proper position, either press the the button beneath the gate selections to select another gate for adjustment or press the button beneath "Done", the knob or the √ button to deactivate the menu.

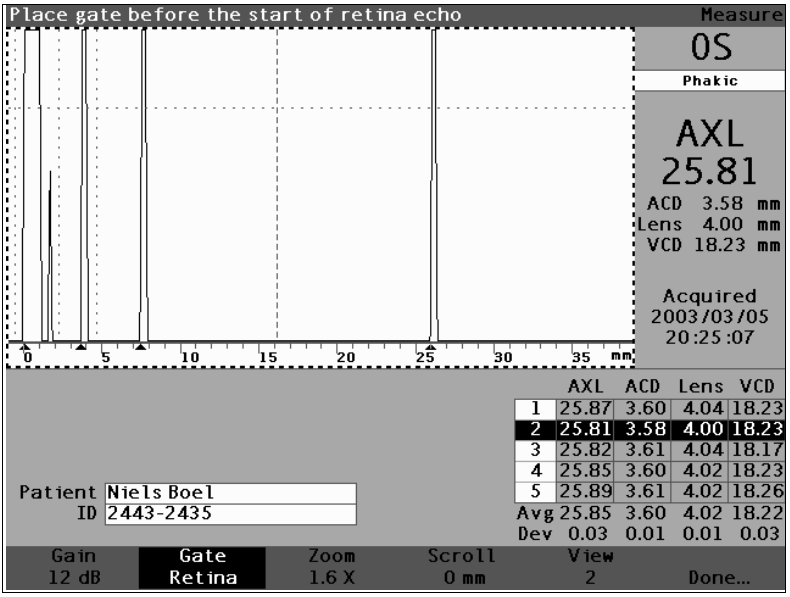


Figure 121 Retina Gate Selected

How to Adjust the Threshold

The threshold gate should be located at the minimum echo height or amplitude.

To adjust the threshold gate:

1. Press the button beneath the Gate selections until the "Gate Threshold" is visible.

Tip: You can use CTRL+T to select the Threshold Gate directly from the keyboard, or hold to select threshold gates for all measurements.

2. Rotate the knob to move the threshold below the minimum height of the echo.
3. When the gate is in the proper position, either press the the button beneath the gate selections to select another gate for adjustment or press the button beneath "Done", the knob or the √ button to deactivate the menu.

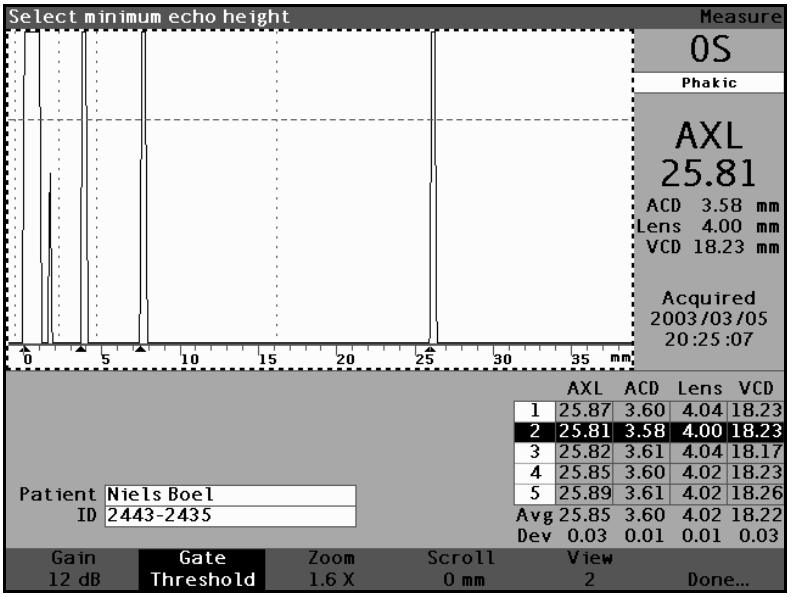


Figure 122 Threshold Gate Selected

How to Apply Gate Adjustments to All Waveforms

You may want to apply a gate adjustment to all current eye waveforms.

To apply a gate adjustment:

1. Press and hold the button beneath the Gate selections for approximately one second. The text on the Gate menu selection will then read "Gate (All)..." for whichever gate is selected. For example, you just completed selecting the anterior lens gate and you hold the Gate menu button; the selection will then read "Gate (All) Ant Lens Gate".
2. Move the gate to the desired location. The gate is moved in all waveforms for the current eye. For each movement, each waveform is re-evaluated and new measurements are updated in the measurement table.

How to Adjust the Gain

The Gain parameter on the Measure Screen allows you to adjust the gain of the signal received from the ultrasonic probe that is displayed as the waveform. The waveform must be selected and active to display the waveform Review menu. This feature can be useful if you are having difficulty getting a strong waveform image. The intensity of the signal ranges from a 20 dB to a minimum of 0 dB that can be adjusted in increments of 1.

To adjust the gain:

1. Press the button beneath the "Gain" selection.

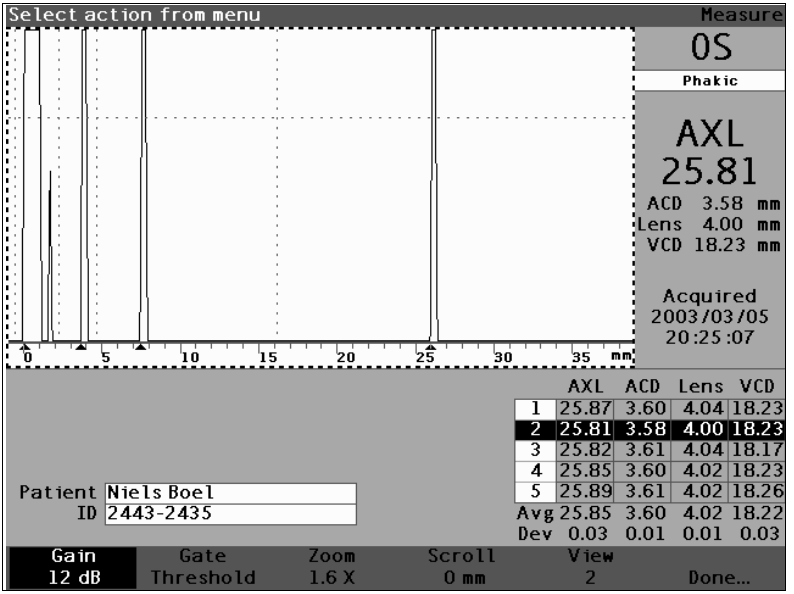


Figure 123 Gain Selected

2. Rotate the knob to select one of the pre-entered gain values.

***Note:** *To return the gain to the new patient default value, press and hold the gain button for approximately 1 second.*

Tip: You can use CTRL+G to increase the gain 1dB directly from the keyboard, or hold to set the gain to the default.

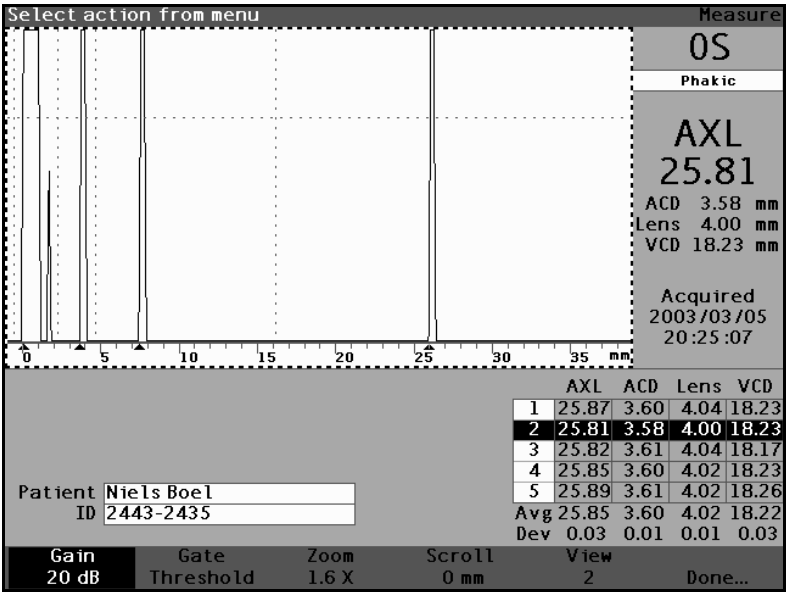


Figure 124 Gain Field Changed

How to Use Zoom

The zoom feature allows you to zoom in on a selected waveform. The height of the waveform remains the same, only the width changes. Zoom expands the distance scale. The waveform must be selected and active to display the waveform Review menu. Zoom can be useful if you are having difficulty detecting all the events in a reading, or if you are scanning an abnormal eye type. Zoom has eight preset values of multiplication; *8.0, 4.0, 2.7, 2.0, 1.6, 1.3, 1.1,* and *1.0*. Zoom value of 1.6 is typical setting.

To use the Zoom feature:

1. Press the button beneath the "Zoom" selection.

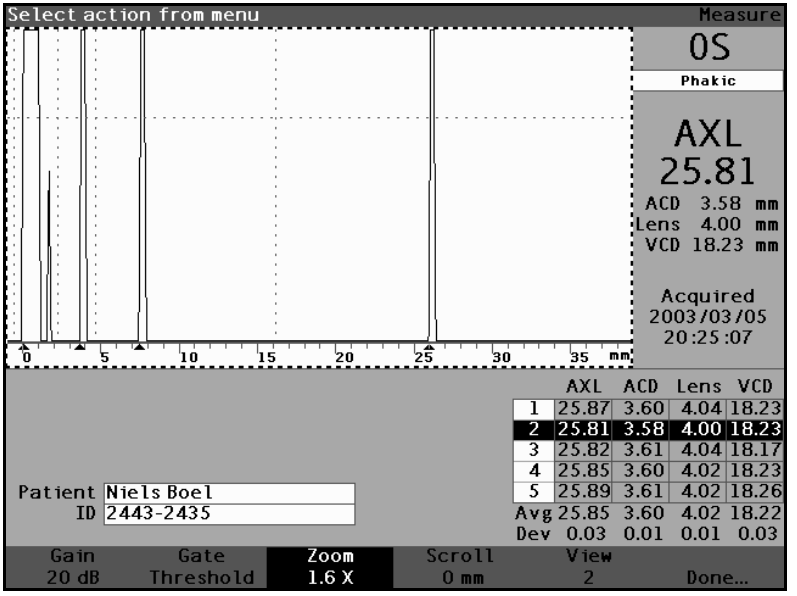


Figure 125 Zoom Selected

2. Rotate the knob to select one of the preset zoom values.

Tip: You can use CTRL+Z to increase the zoom with wrap directly from the keyboard, or hold to set the zoom to the default 1.6X.

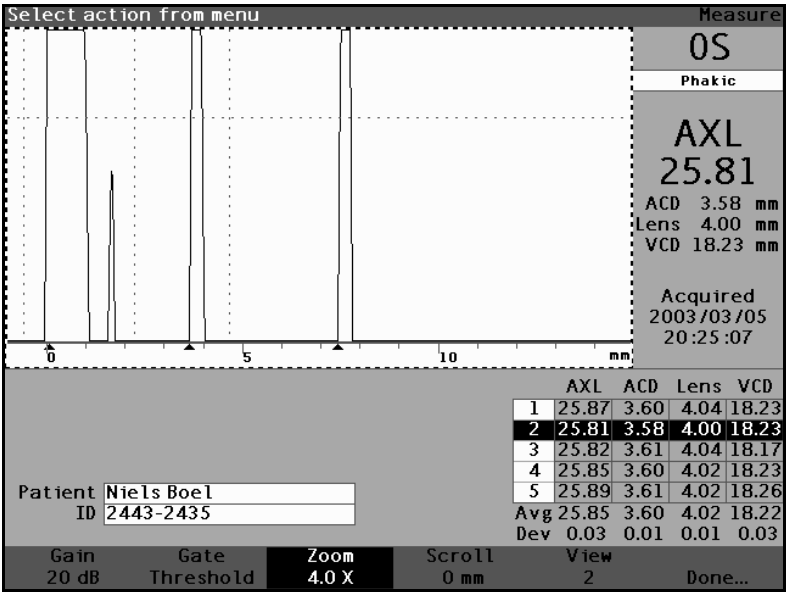


Figure 126 Zoom Changed

How to Scroll

The Scroll feature moves the active waveform from left to right and from right to left. Scroll allows you to view the horizontal dimension of a waveform. This feature can be useful if you are zooming in on a certain area of the measurement and you would like to look at another area of the waveform.

To scroll an image:

1. Press the button beneath the "Scroll" selection.

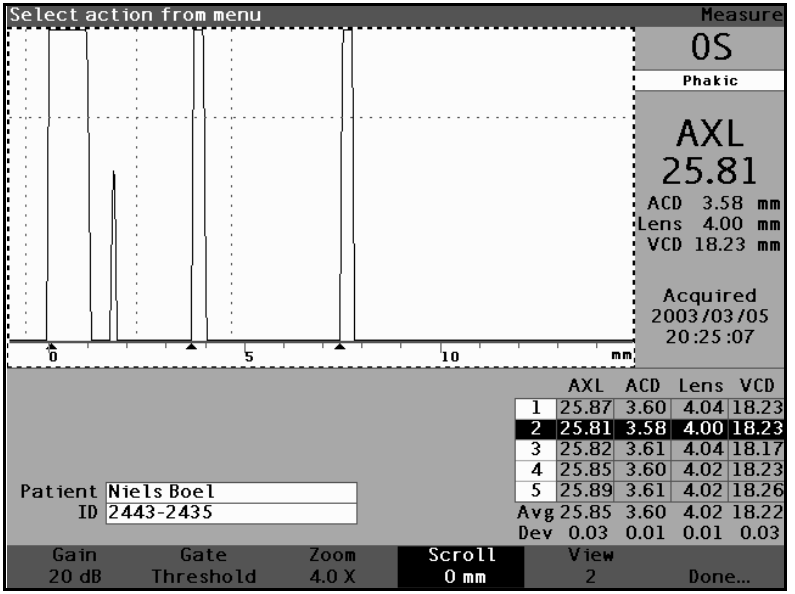


Figure 127 Scroll Selected

2. Rotate the knob to move the waveform.

Tip: You can use CTRL+ S to scroll the waveform increasing 1mm directly from the keyboard, or hold to set the scroll to 0.

3. When the waveform is in the correct position, either press another waveform menu selection or press the button beneath "Done", the knob or the √ button to deactivate the menu.

***Note:** *To scroll to the start of the waveform, press and hold the scroll button for approximately 1 second.*

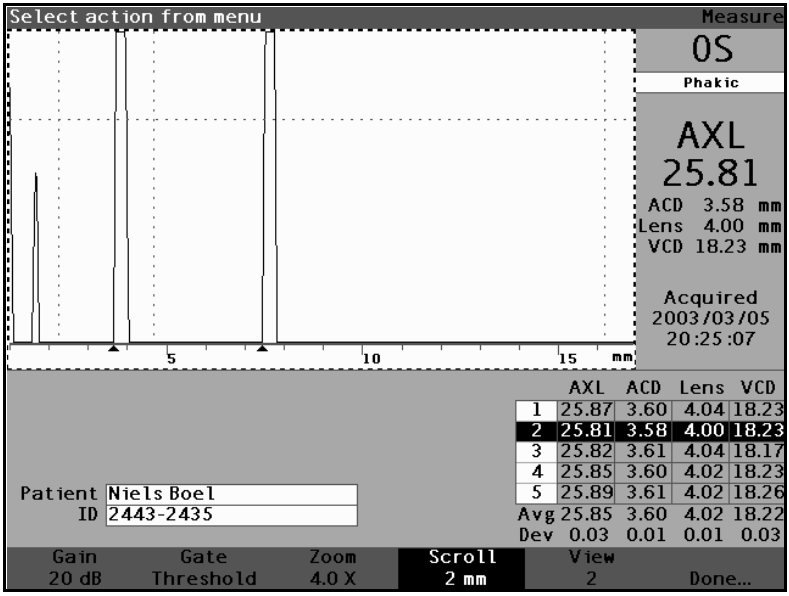


Figure 128 Measurement Scrolling Changed

Switching Eyes

It is very simple to switch between eyes using the Accutome A-Scan Plus. To switch from OD to OS, or from OS to OD press the button beneath the selection OD/OS. The waveforms and eye type for the selected eye will be displayed.

Tip: You can use O or CTRL+O to switch between OD and OS.

Customize Eye Type

You can also customize a Patient's eye type on the fly. The soft menu selection "Customize Eye Type..." launches the Customize Eye Type Screen where customizing on a per patient basis occurs.

Refer to "Customizing Eye Types" on page 187 of this manual for customizing eyes.

***Note:** *At this point you should either calculate the replacement lens or save the measurement record. Refer to either "Performing Calculations" on page 197 or "Storing and Recalling Records" on page 241 of this manual.*

7 Customizing Eye Types

Overview

The Accutome A-Scan Plus not only allows you to create and store custom eye types, you can also customize eye types on-the-fly for an individual patient.

Patient Customization

If you have a patient with a unique situation, you can specify the eye type, materials, and velocities for either the OD or OS while performing live measurements. A Custom Eye Type is linked to a patient eye, and is not a machine setting available for other patients.

All on-the-fly customization is performed at the Customize Eye Type Screen. Customization features include:

- Creating a new OD/OS eye type
- Changing/creating AC material and velocity for new eye type
- Changing/creating Lens material and velocity for new eye type
- Changing/creating Vitreous material and velocity for new eye type

***Note:** *An eye type is considered 'custom' if its definition, as displayed on the Customize Eye Type Screen, does not match an eye type definition displayed in the Eye Types Screen. This will occur if you customize the eye type directly. An eye type will be displayed as custom if its definition is permanently changed on the Eye Types screen and the current patient's eye type no longer matches. If you change the Eye Type definition on the Eye Type screen, and you wish to use that definition for the current patient, reselect the eye type from the Measure Screen.*

*An eye type that is considered custom will have a * beside its name on all patient data screens.*

Customize Eye Type Screen

The Accutome A-Scan Plus provides access to the Customize Eye Type screen through the Measure screen. When you power on the instrument it starts up at the Measure screen. When you press the button beneath the selection "Customize Eye Type" the Customize Eye Type screen will be displayed.

In the Customize Eye Type screen you can create and define new eye types or review the current eye type definition. You can select pre-entered selections in each field, or you can create your own.

Customize Fields and Menu Selections

The Customize Eye Type screen displays the following fields.

OD

The OD eye type name.

OS

The OS eye type name.

Eye Type Table

Located to the right of each eye type name is a table with fields defining the material and velocity for AC, Lens, and VC. You can change all the fields that are white. You cannot change any field that is filled grey.

AC

The AC (Anterior Chamber) material name and velocity

Lens

The Lens material name and velocity and thickness setting. Thickness can be measured or assumed. Press the Delete key to change the Lens Thickness field from assumed to measured.

VC

The VC (Vitreous Cavity) name material and velocity

The Customize Eye Type screen also has the following soft menu selections activated by the buttons beneath the selection:

- Edit Text - allows you to enter your own field names; you don't have to select pre-entered values.
- Done... - exits the Customize Eye Type Screen and returns you to the Measure Screen.

***Note:** *If there is an * (asterisk) to the right of any field in the Customize Eye Type Screen, it indicates that a value has been changed and that it is non-standard, or, custom.*

How to Customize an Eye Type

To customize an eye type for an active patient:

1. In the Measure Screen, press the button beneath the selection "Customize Eye Type...". The Customize Eye Type screen as shown in Figure 129 below will be displayed.

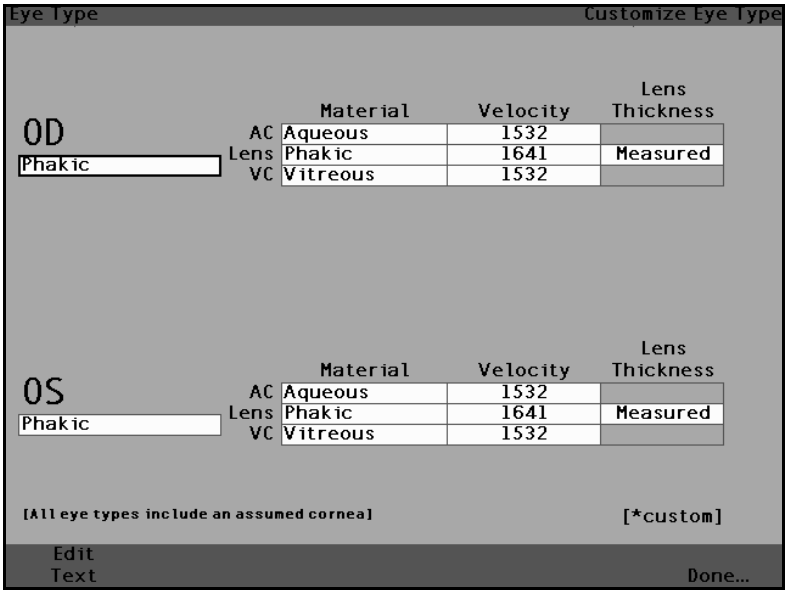


Figure 129 Customize Eye Type Screen

2. Within the Custom Eye Type Screen, rotate the knob to select the Material/Velocity table, indicated by a solid black border. There are two material/velocity tables on the screen. You should select the one to the right of the patient's eye that you are customizing.

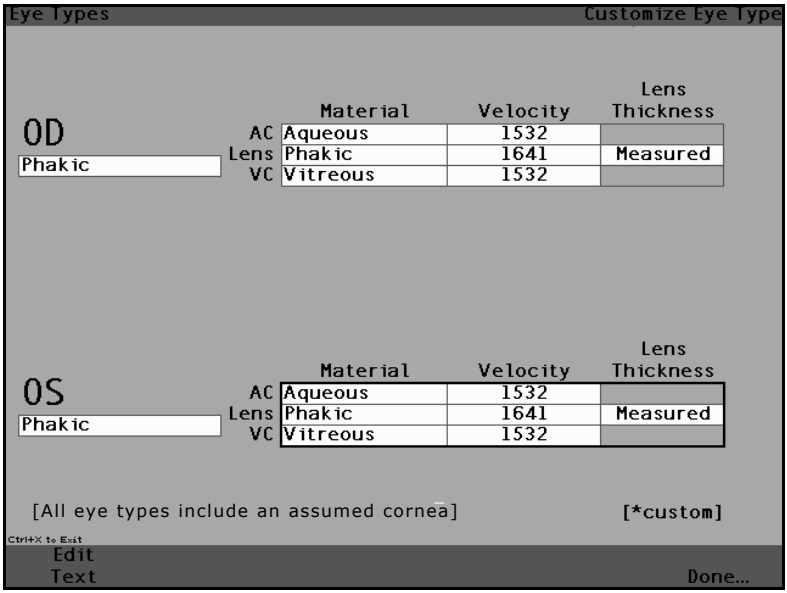


Figure 130 OS Materials Table Selected

3. Press the knob or the √ button, to activate the table, indicated by the dashed border.
4. Within the Material/Velocity table, rotate the knob to select the table cell you would like to change. In the example given in Figure 131 below the cell selected is the VC Material cell.

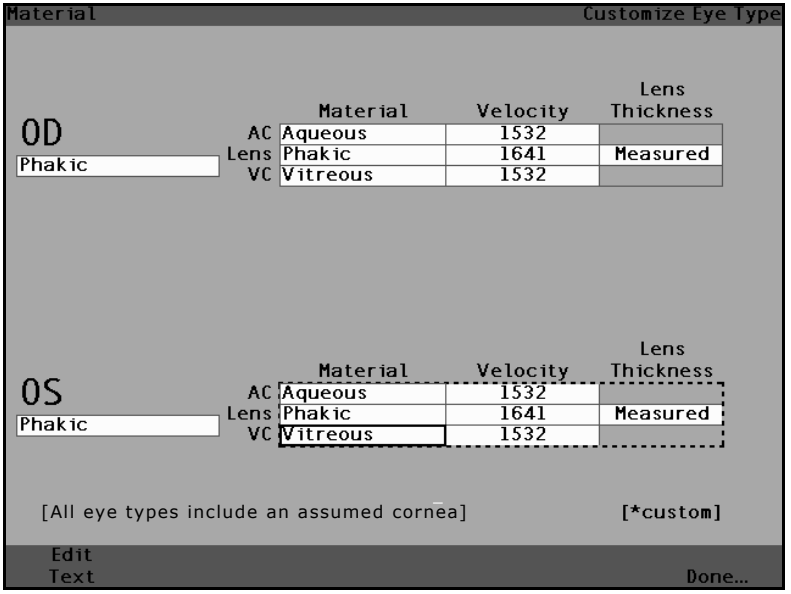


Figure 131 OS Materials Table Activated

5. Within the VC Material cell, rotate the knob to select one of the pre-entered materials as shown in Figure 132 below,
6. You can also press the button beneath the selection "Edit Text" and enter the material name; the material doesn't have to be pre-entered.

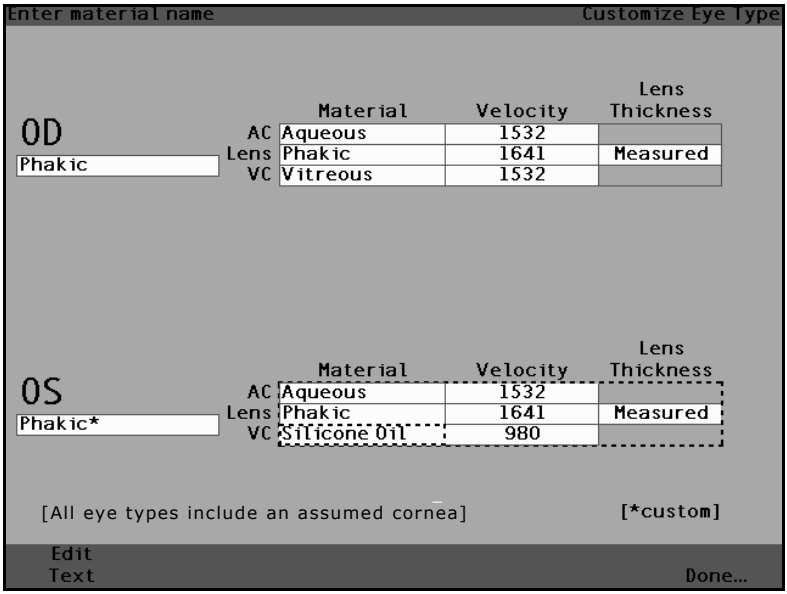


Figure 132 Changing VC Material

7. Press the knob or the √ button, to save the selected VC Material and to deactivate the field. Notice that they eye type name in Figure 133 below is now followed by an * indicating that is a custom eye type.

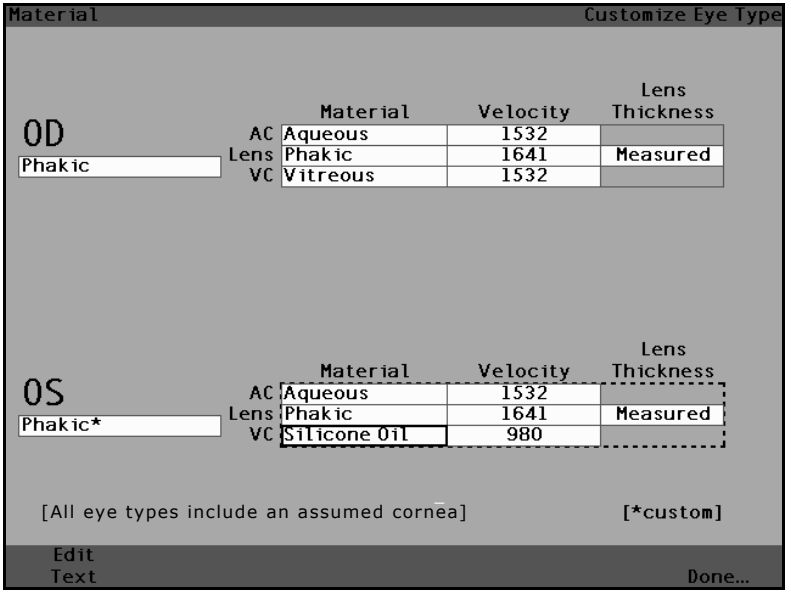


Figure 133 VC Material Cell Changed

8. Within the OS Material/Velocity table, rotate the knob to select the VC Velocity cell. The velocity may need to be changed to correlate to the change in material.
9. Within the VC Velocity cell, rotate the knob to adjust the velocity.
10. You can also press the button beneath the selection "Edit Text" and enter the material name; the material doesn't have to be pre-entered.

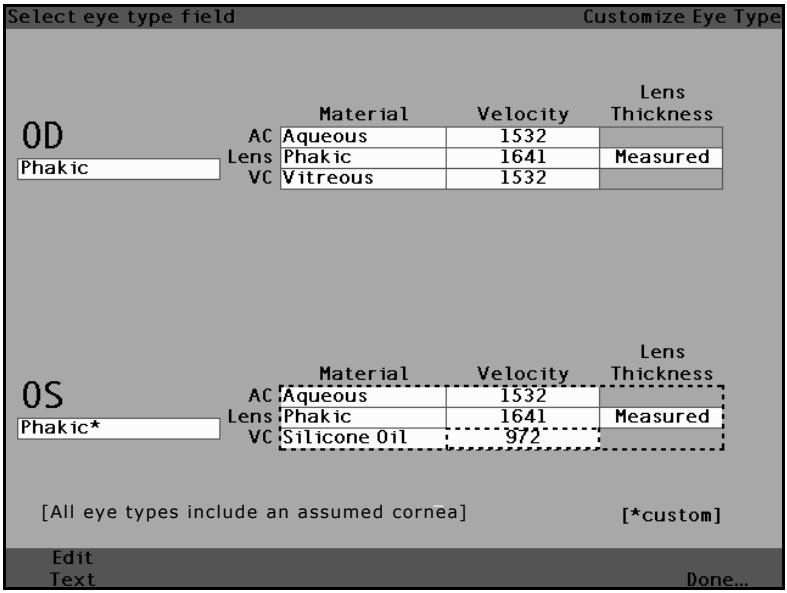


Figure 134 Changing Velocity Field

11. All the custom changes to the Patient Eye Type will be followed by an asterisk (*), as shown in Figure 135 below.
12. Adjust any other eye type fields following the same procedures.
13. When you have completed customizing the patient eye, press the button beneath the selection "Done..." to deactivate the Custom Eye Type Screen. You will return to the Measure Screen and the new eye type information will be displayed for the patient.

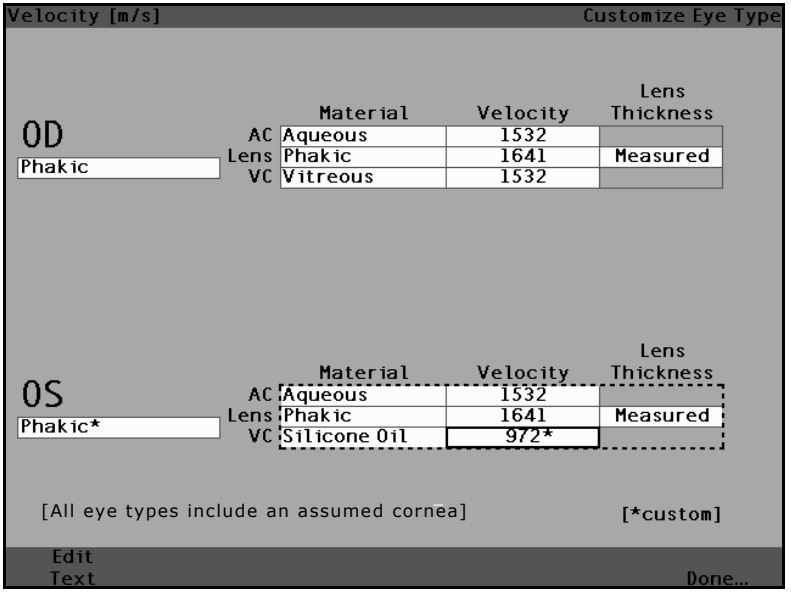


Figure 135 OS Eye Type Customized

8 Performing Calculations

Overview

Performing IOL calculations with the Accutome A-Scan Plus can be as simple as pressing the Calculate button. There are numerous features available to enhance the calculation process.

The Accutome A-Scan Plus instantly calculates emmetropic and targeted ametropoic IOL powers for dozens of lenses, viewed three at a time, using the axial length from the average of valid waveforms, a single waveform, or manually entered AXL.

Calculating the Lens

The IOL calculation provides the required power of IOLs using a measured or entered axial length, entered K1 and K2 values, and entered desired post operative refraction.

All calculations are made on the Calculate IOL Screen. To access the Calculate IOL Screen press the Calculate button, located at the right side of the instrument.

Calculation after Corneal Refractive Surgery

The A-Scan also has the advanced capability to calculate IOLs for patients that have had corneal refractive surgery.

For patients who have had corneal surgery, the characteristics and power of the cornea have been altered.

Calculations for post surgery patients are made using the Double K method, which uses both the pre and post corneal refractive surgery K values. For more information on the Double K method refer to page 207 of this manual.

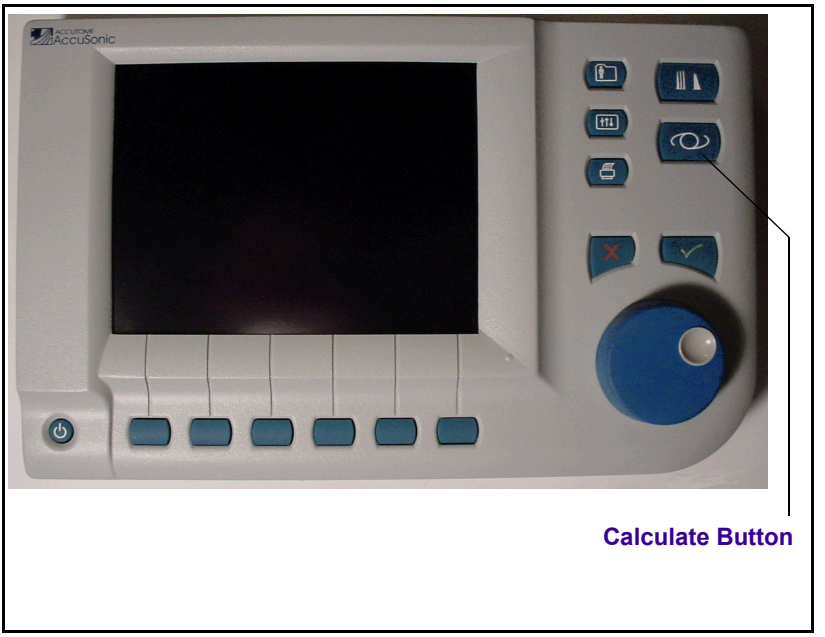


Figure 136 Calculate Button

Calculate IOL Screen

The Calculate IOL Screen shown in Figure 137 below displays the average of the five measurements for the selected eye (if there are five measurements available), the calculation for the currently selected formula and the three lenses of the current IOL Group.

The Accutome A-Scan Plus allows the user to fine tune the calculation by providing the ability to change the AXL value, the lens, formula and desired postoperative result refraction (the target).

The process for calculating the power of a lens is to select or enter an AXL value, select an IOL Group, select a formula, and enter the K1, K2 and Target values.

***Note:** *The Rx Surg (Post Refractive Corneal Surgery) field should be left at "No". Change the field to "Yes" to calculate IOLs for patients that have had corneal refractive surgery. Refer to "Calculating IOL Power After Corneal Refractive Surgery" on page 207 for instructions on changing the Rx Surg field.*

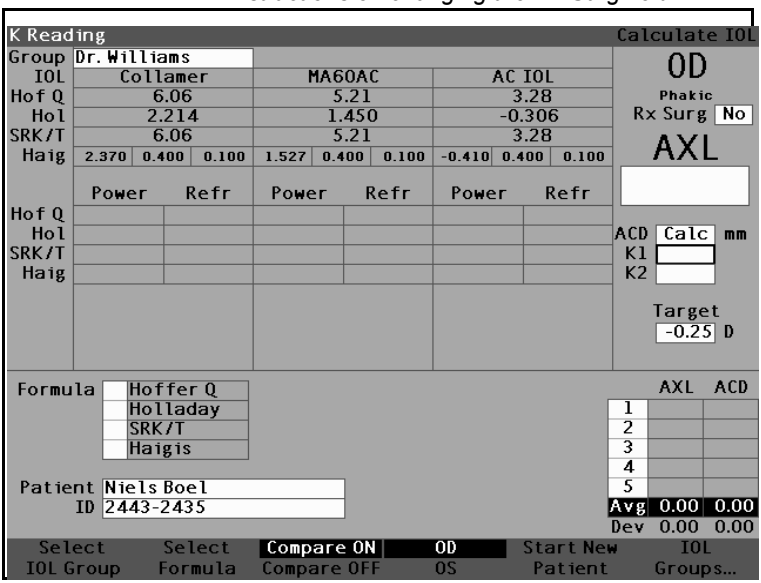


Figure 137 Calculation Fields

Selecting an IOL Group

You may want to select lenses from a different group. To access one of the available IOL groups press the button beneath the "Select IOL Group" selection. You can then scroll through the list of IOL Groups. Stop when you have reached the correct group. (Refer to "How to Set Up an IOL Group" on page 216 of this manual for further information.)

Selecting a Formula

You may want to change the formula used to calculate the IOL. To scroll through the list of available formulas press the button beneath "Select Formula" selection. The IOL constant used by the currently selected formula is highlighted as white text on black background for each IOL.

Entering an ACD Value with the Haigis Formula

The Haigis formula uses the measured ACD or calculated ACD value, as well as the axial length (AXL). The ACD is shown in the measurement history list, and an ACD field is added where the user can specify a calculated or manually entered ACD. ACD should be calculated for Aphakic and Pseudophakic eye types. The other formulas do not use the measured ACD field in any way and the field is only shown when Haigis is selected or the formula compare mode is on.

Specify the ACD value by allowing the Accutome A-Scan Plus to calculate (Calc) the value or manually enter the value.

To manually enter the ACD value:

1. Rotate the knob to select the ACD field and press the knob or the √ button to activate the field. When the field is active either rotate the knob, if necessary, to select "Calc" for a calculated value or manually enter the ACD value in millimeters (mm).
2. If you would like the A-Scan to calculate the ACD press the "Delete" key or the X button to remove

the entered value and replace it with "Calc" for a calculated value

***Note:** *The ACD field is only active if you are using the Haigis formula. If you have selected another calculation formula the field will not appear.*

Entered ACD should be a phakic ACD measurement. The ACD can be estimated by entering "0".

Changing the AXL Value

The Accutome A-Scan Plus allows the user to fine tune the calculation by providing the ability to change the AXL value. You can select the AXL from any of the five measurements, the average of the measurements, or you can enter your own axial length.

Selecting a Measurement

You may want to select a particular measurement with which to perform the calculation.

To select one of the available measurements:

1. Within the Calculate IOL Screen, rotate the knob to select the "AXL" list, located in the bottom right corner of the screen. Selection is indicated by a solid black border.
2. Press the knob or the √ button, to activate the list, indicated by the dashed border.
3. Within the AXL list, rotate the knob to select one of the AXL measurement values or the average.
4. Press the knob or the √ button, to save the selected AXL value and to deactivate the field.

Entering an AXL Value

You may not be satisfied with the average measurement of any of the five acquired measurements or you may want to enter the axial length from a previous measurement. The Accutome A-Scan Plus allows you to manually enter an AXL value.

To enter an AXL value:

1. Within the Calculate IOL Screen, rotate the knob to select the "AXL" field, located in the top right side of the screen. Selection is indicated by a solid black border.
2. Press the knob or the √ button, to activate the field, indicated by the dashed border.
3. Within the AXL field, enter the new AXL value.
4. Press the knob or the √ button, to save the entered AXL value and to deactivate the field.
5. The A-Scan will indicate that the AXL value is entered with the text "[entered]" below the AXL field.

Entering the K1, K2 Values

The keratometer index of refraction, used to convert corneal radius to diopter power is not the same for all keratometers. In North America, most units have an index of refraction of 1.3375. European keratometers may have an index of refraction of 1.3315. The factory default is 1.3375.

The K Index value is only used when entering keratometer readings in diopters. K readings can be entered on the Calculate IOL screen as well as the Personalize IOL screen. The K index associated with diopter entries is not explicitly shown. When a keratometer reading is entered in diopters the default K index is copied from the setup screen. If the K index of an entry is different than the Setup screen default K Index, a * appears beside the entry. To change or view the K index, change or reenter the diopter entry. The Accutome A-Scan Plus will prompt you with the default

and current K indexes and ask which one you want associated with the entry.

Keratometer data can be entered in mm as well as diopters. The ranges for these two units are mutually exclusive. Values less than 20 are assumed to be mm, values 20 or greater as assumed to be diopters. Units are displayed with all entries. Diopter entries have a keratometer index of refraction associated with them to allow for conversion to mm as needed by some of the formulas.

Enter the optical power of the cornea in diopters or mm, as measured on a keratometer or corneal topographer, as K1, K2.

To enter an K1, K2 values:

1. Within the Calculate IOL Screen, rotate the knob to select the "K1" field, located in the middle right side of the screen. Selection is indicated by a solid black border.
2. Press the knob or the √ button, to activate the field, indicated by the dashed border.
3. Within the K1 field, enter the K1 value or rotate the knob until you arrive at the value.
4. Press the knob or the √ button, to save the entered K1 value and to deactivate the field.
5. Enter the K2 value in the same manner.

Entering the Target Value

To enter the Target value:

1. Within the Calculate IOL Screen, rotate the knob to select the "Target" field, located in the middle right side of the screen. Selection is indicated by a solid black border.
2. Press the knob or the √ button, to activate the field, indicated by the dashed border.
3. Within the Target field, enter the target value or rotate the knob until you arrive at the value. The Target Value changes in 0.25 D steps. You can use the keyboard to enter a value within 0.01 D.
4. Press the knob or the √ button, to save the entered Target Value and to deactivate the field.

Calculation Results

After all fields have been entered, the Calculate IOL Screen will display the power of the IOL, for each lens with bold, large, black numbers. These values are the optimal powers for the specified target refraction, and do not necessarily exist in the real world.

A list of five IOL powers and their expected refraction, in 0.5 D increments and centered on the result closest to the target power, is displayed for each IOL.

The Accutome A-Scan Plus also provides you with a lens value for a zero target (Emmetropic). The zero target values are listed below the optimal IOL powers in small numbers.

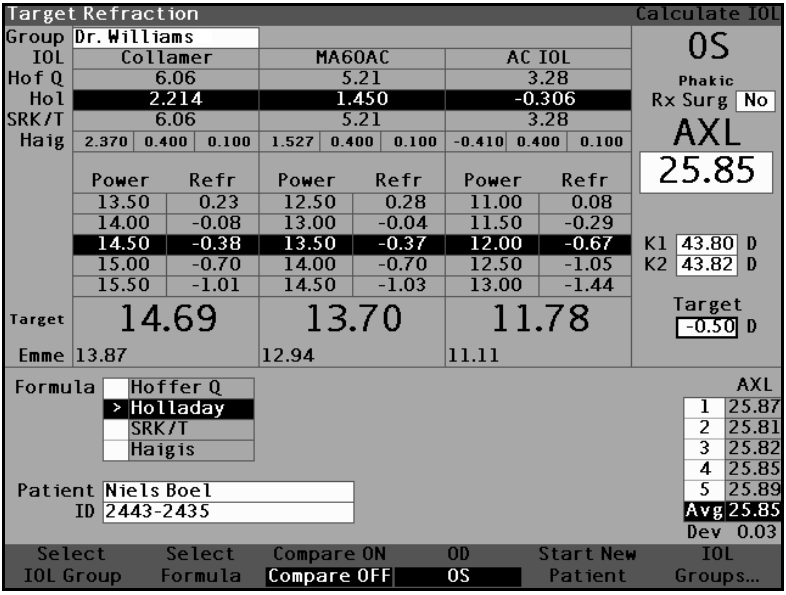


Figure 138 Calculate IOL Screen - All Fields Entered

Formula Compare Feature

The Formula Compare feature allows the comparison of all formulas for each calculation. When Compare is On it displays the closest matching IOL power that will achieve the target refraction with the expected postoperative refraction as calculated by each formula.

To compare calculations for all formulas, press on the button beneath "Compare On/Compare Off". This button toggles between the two and will display the calculations for one formula or all formulas as the button is toggled.

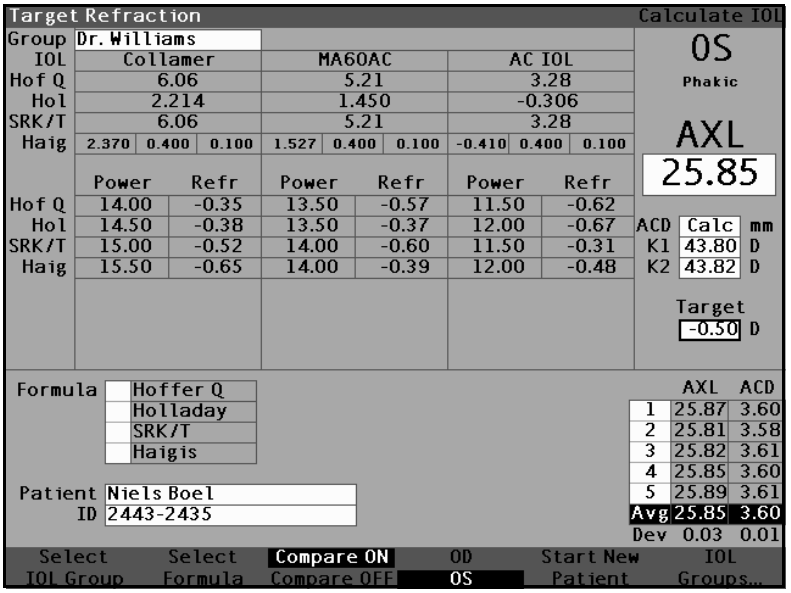


Figure 139 Compare On Selected

Switching Between OD/OS

To perform a calculation for the current Patient's other eye, press on the button beneath "OD/OS". This button toggles between the two eyes and will display the readings for either OD or OS as the button is switched.

Calculating IOL Power After Corneal Refractive Surgery

The Accutome A-Scan Plus also provides the ability to calculate IOLs for patients who have had corneal refratcitve surgery.

Corneal refractive surgery alters the characteristics and power of the cornea.

***Note:** *Calculating IOL powers for post refractive surgery patients is an evolving topic and requires research and careful planning on the part of the opthalmologist. The methods and formulas presented by the Accutome A-Scan Plus for this type of patient should only be used by a qualified individual who has done due diligience to determine the best method, and how to execute that method, for each patient. If a more appropriate formula or method for determining the current corneal power is available, the result of this formula can be used by selecting the 'Entered' Kpost formula and entering the power manually.*

Double K Method

All IOL formulas, except for the Haigis formula, use the K measurement in two ways: to know the power of the cornea, and to help estimate the position of the IOL.

The power of the cornea needs to be the current K of the patient (post refractive surgery). Estimating the position of the IOL should be based on the pre refractive surgery K of the patients. Using both the post and pre corneal refractive K is called the Double K Method.

When the **Rx Surg** field is set to Yes, indicating corneal refractive surgery, the Kpre and Kpost fields are displayed in the place of K1/K2. Both of these fields must have data for the formulas to calculate the IOL power.

When using the Haigis formula, the Kpre field is not shown. The Haigis formula does not use Kpre to determine the IOL position, the Haigis formula uses the measured ACD.

Determining Corneal Power after Refractive Surgery (Post Rx Surg)

The K value (corneal power or corneal curvature) for patients that have had corneal refractive surgery cannot be determined using common methods. Four K Post formulas, or methods, are available in the Accutome A-Scan Plus to determine the current corneal power for refractive patients (Kpost).

***Note:** *If you do not know the patients prerefractive surgery corneal power, you may want to consider using the Haigis formula which does not require this information.*

Post Rx Surg IOL Calculation Steps

The steps to complete a post refractive surgery IOL Calculation are almost the same as non refractive surgery eye calculations with the addition of selecting a Post K method.

To complete a post refractive surgery calculation:

1. Set the Rx Surg field to "Yes".
2. Select an IOL Group (see "Selecting an IOL Group" on page 200).
3. Select or enter an AXL value (see "Changing the AXL Value" on page 201 for instructions).
4. Enter the applicable averaged K1and K2 readings, Sphere, and Cyclinder values.
5. Enter the target value (see "Entering the Target Value" on page 204).

Selecting a K Post Calculation Method

The K Post calculation methods are:

1. Clinical History method - Calculates Kpost based on Kpre, refraction before and after refractive surgery.
2. Contact Lens method - Calculates Kpost based on refraction after refractive surgery with and without a hard contact lens of a known curve and power.

3. Shammas Clinical method - Calculates Kpost by adjusting on manual K reading after refractive surgery using simple formula Kpost = 1.14 * Kmeasured – 6.8
4. Entered - The user can enter the Kpost value presumably calculate using some external method.

The Kpost calculation methods are listed in order of preference, with the Clinical History method as the widely accepted as the most accurate. The Clinical History method is the default for new patients.

For the refractions entered, the vertex of the refraction is stored and becomes the default for the next patient.

Changing Rx Surg Field to Yes

***Note:** *The only time the Rx Surg field should be changed to yes is for a patient that has had corneal refraction surgery.*

In Figure 140 below the Rx Surg field is selected. To activate the Rx Surg field and change the field:

1. Rotate the knob to select the Rx Surg field and press the knob or the √ button to activate the field. When the field is active either rotate the knob to change "No" to "Yes".
2. Press the knob or the √ button to activate the Post Surgery function.

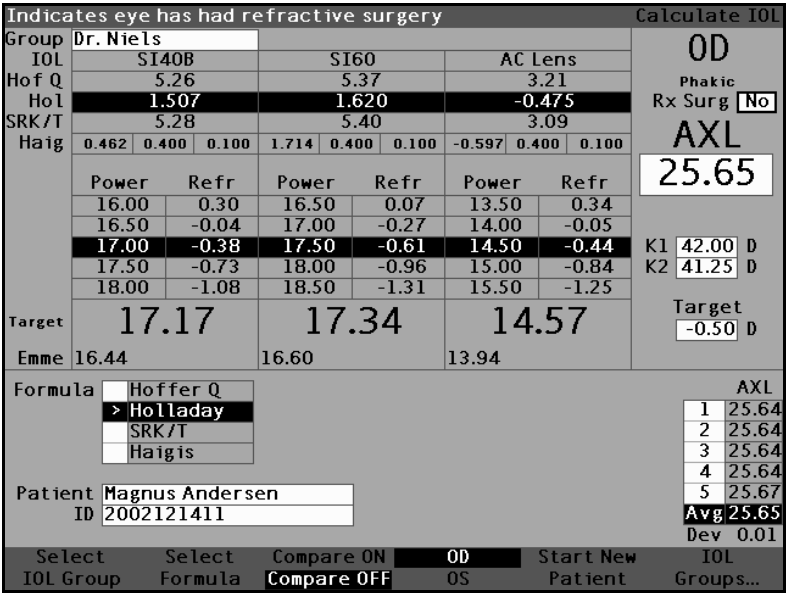


Figure 140 Post Rx Surgery Field (Rx Surg) Selected

When the Rx Surg field is set to Yes, the K1/K2 fields are replaced with Kpre and Kpost and the Kpost methods and associated fields appear in the middle, bottom of the screen. PLEASE NOTE: the Kpre field is an average of measured K1and K2 prior to corneal refractive surgery.

Clinical History Method

When using the Clinical History method, the default and preferred method, the Calculate IOL screen displays Kpre and Kpost fields and all fields associated with the Clinical History method.

Clinical History Fields

When using the Clinical History method for post refractive surgery IOL calculations you must enter the value in the following fields:

- Kpre - the average K value before refractive surgery
- Sphere and Cylinder before refractive surgery and the current refraction

1. Rotate the knob to select each field and press the knob or the √ button to activate the field. When the field is active either rotate the knob to change the value or manually enter the value with the key-board.

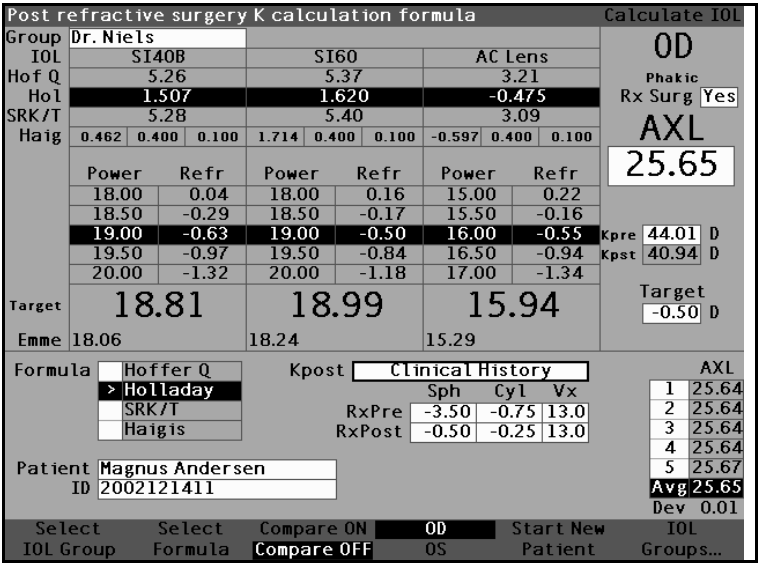


Figure 141 Post Rx Surgery Calculation Activated - Clinical History

Contact Lens Method

The Contact Lens method requires you to enter the following fields:

- Kpre-the average K value before refractive surgery
- Current refraction in sphere and cylinder.
- Refraction with contact lens on in sphere and cylinder.
- Base Curve (of the contact lens)
- Power (of the contact lens)

1. Rotate the knob to select each field and press the knob or the √ button to activate the field. When the field is active either rotate the knob to change the value or manually enter the value with the keyboard.

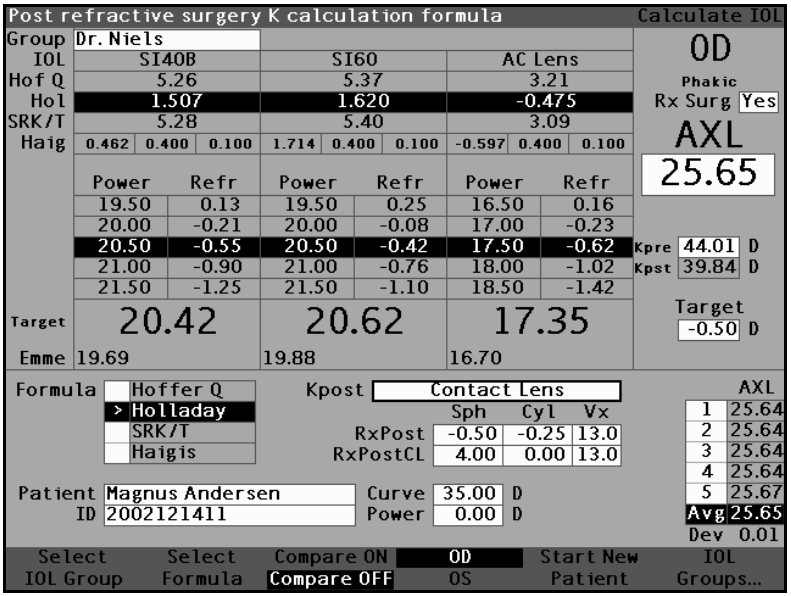


Figure 142 Post Rx Surgery Calculation with Contact Lens Method

Shammas Clinical Method

The Shammas Clinical method requires you to enter the following fields:

- Kpre-the average K value before refractive surgery
- K1 (measured)*
- K2 (measured)*

*Measured - using a manual keratometer on the post refractive surgery cornea.

1. Rotate the knob to select each field and press the knob or the √ button to activate the field. When the field is active either rotate the knob to change the value or manually enter the value with the keyboard.

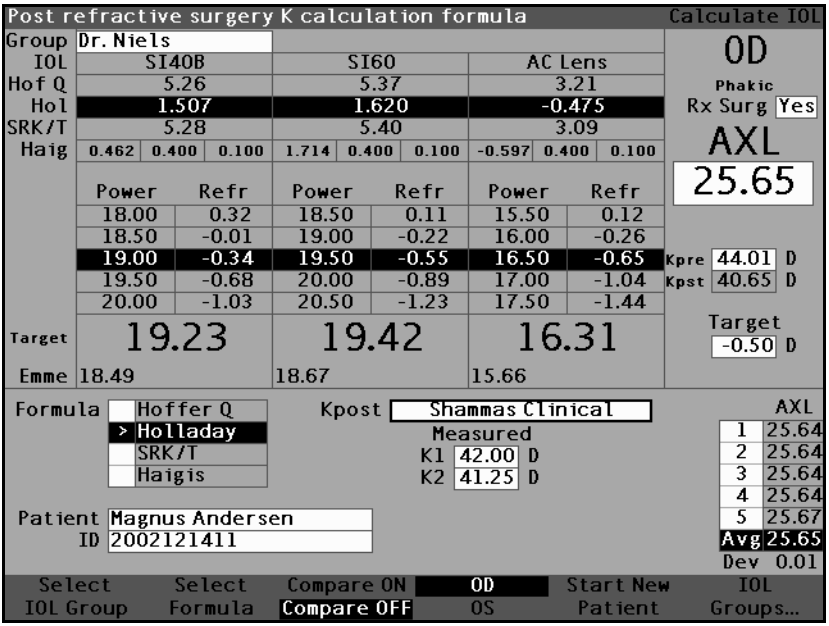


Figure 143 Post Rx Surgery Calculation with Shammas Clinical Method

Calculation Results

After all fields have been entered, the Calculate IOL Screen will display the power of the IOL, for each lens with bold, large, black numbers. These values are the optimal powers for the specified target refraction, and do not necessarily exist in the real world.

A list of five IOL powers and their expected refraction, in 0.5 D increments and centered on the result closest to the target power, is displayed for each IOL.

The Accutome A-Scan Plus also provides you with a lens value for a zero target (Emmetropic). The zero target values are listed below the optimal IOL powers in small numbers.

Switching Between OD/OS

To perform a calculation for the current Patient's other eye, press on the button beneath "OD/OS". This button toggles between the two eyes and will display the readings for either OD or OS as the button is switched.

How are IOL Groups Used

IOLs can be grouped by type, manufacturer, physician, location, patient pathology, or other criteria. IOLs are organized in groups of three. Each group can be given a custom name to distinguish its purpose. Any IOL group can be selected directly from the Calculate IOL Screen for quick selection of the desired IOLs for the current patient. You can setup 15 IOL Groups, each with up to 3 IOLs, for a system total of 45 IOLs.

When you set up IOL groups you set them up in the IOL Groups Screen. The IOL Groups Screen is the only location within the Accutome A-Scan Plus for entering IOL information.

How to Set Up an IOL Group

The process for setting up an IOL Group consists of:

- Entering an IOL Group Name
- Entering lens information associated with each group

All entry of IOL Groups takes place at the IOL Groups Screen. The IOL Groups screen is accessed from the Calculate IOL Screen.

To access the Calculate IOL Screen press the Calculate button, located at the right side of the instrument. The Calculate IOL Screen shown in Figure 144 below will then be displayed.

Accessing the IOL Groups Screen

In the Calculate IOL Screen:

1. Press the button beneath the selection "IOL Groups...". The IOL Calculation Groups Screen will then be displayed.

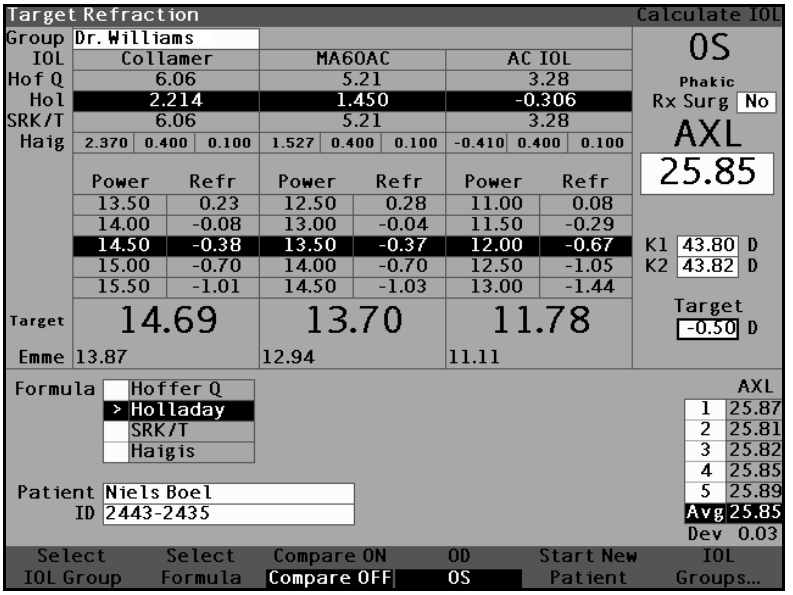


Figure 144 Select IOL Groups

IOL Calculation Groups Screen

The IOL Groups Screen as shown in Figure 145 below, displays a listing of all the IOL Groups and their associated lenses. The Accutome A-Scan Plus has a capacity to store 15 groups.

The left side of the screen displays a field for the group name. To the right of the group name field is the lens table for that group.

The screen can display four groups at a time. If you would like to view another of the possible 15 groups, press the button beneath the "Scroll Groups Down" or "Scroll Groups Up" selections.

The Delete IOL selection allows you to delete a selected IOL. The Personalize IOLs selection displays the Personalize IOL screen for personalizing the constants used with selected IOLs.

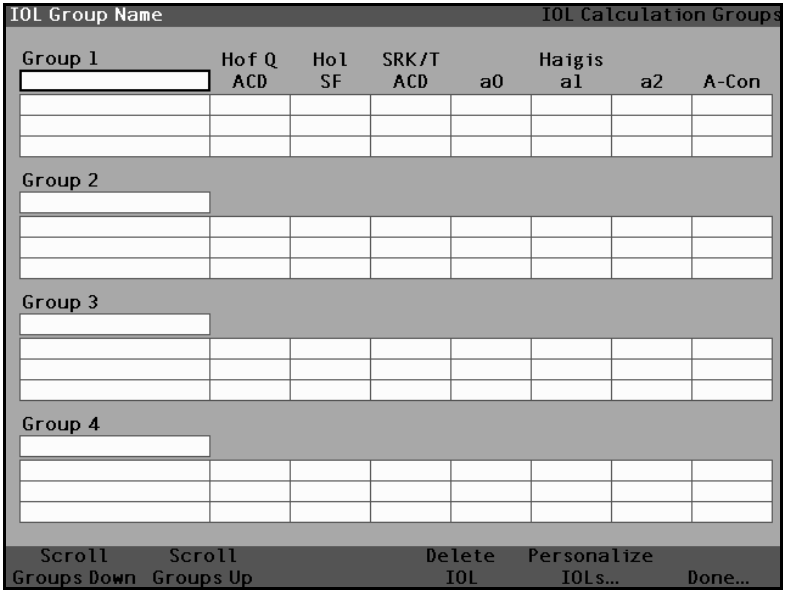


Figure 145 IOL Groups Screen

Entering IOL Group Names

To enter an IOL Group Name:

1. In the IOL Groups screen, rotate the knob to select an empty Group field. (Selection is indicated by a solid black border). You can also press the buttons beneath the "Scroll Groups Up" and Scroll Groups Down" selections to locate an empty space.
2. Press the knob or the √ button, to activate the field, indicated by the dashed border.
3. Within the Group field enter the name of the Group for which you are entering lenses.
4. Press the knob or the √ button, to save the selected Group name and to deactivate the field.

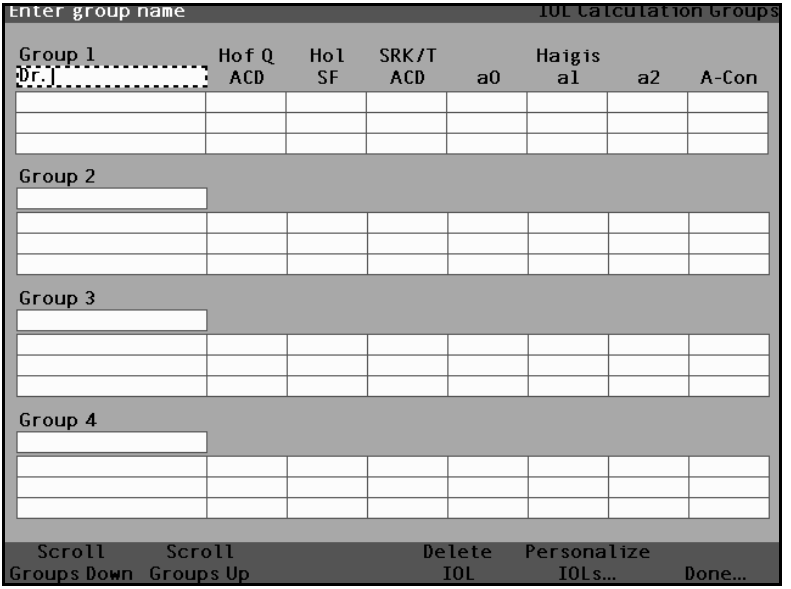


Figure 146 Entering the IOL Group Name

Entering the Group's Lenses

To enter an IOL Group's Lenses:

1. Select the lens table located to the right of the Group field. (Selection is indicated by a solid black border).
2. Press the knob to activate the table, indicated by the dashed border.
3. Within the lens table, rotate the knob and select the Description cell. (Selection is indicated by a solid black border).
4. Enter the description of the first lens you are entering.
5. Press the knob or the √ button, to save the description and to deactivate the field.

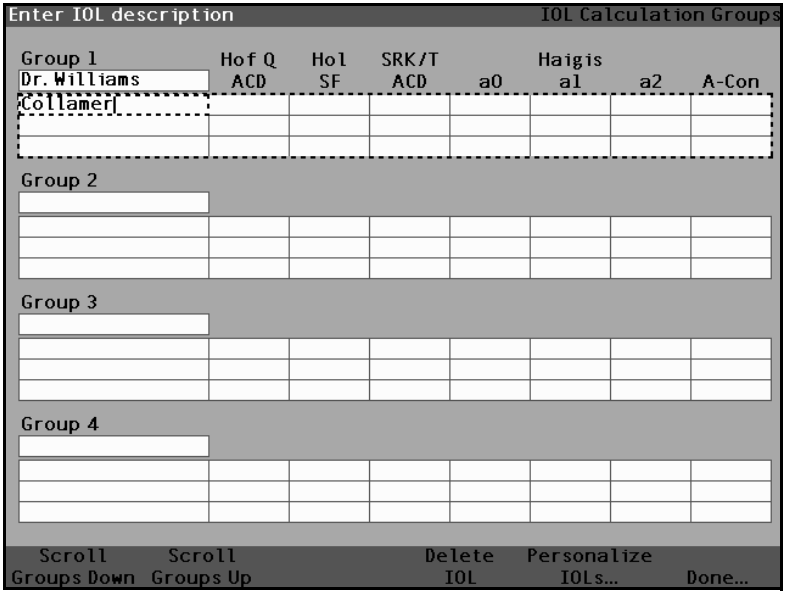


Figure 147 Entering the IOL Description

***Note:** *This procedure uses the A-Constant as the IOL constant. You can enter the ACD or SF as the first constant entered also. When entering a lens constant, the three constants for the Hoffer, Holladay and SRK/T are calculated if they are all empty. At the same time the Haigis constants a0, a1 and a2 are calculated. a1 is always 0.4, and a2 is always 0.1 unless specified by the user as a result of triple optimization. a0 is the IOL factor, a1 is the measured ACD factor, and a2 is the is the axial length factor for determining the post operative ACD of the IOL.*

If you have more than one constant for your lens, such as an A-Constant and a personalized SF, enter the non personalized A-Constant first, then overwrite the calculated SF with your personalized SF. Personalized constants should only be used with the formula they were derived from.

6. Within the lens table, rotate the knob and select the A-Con cell. (Selection is indicated by a solid black border).

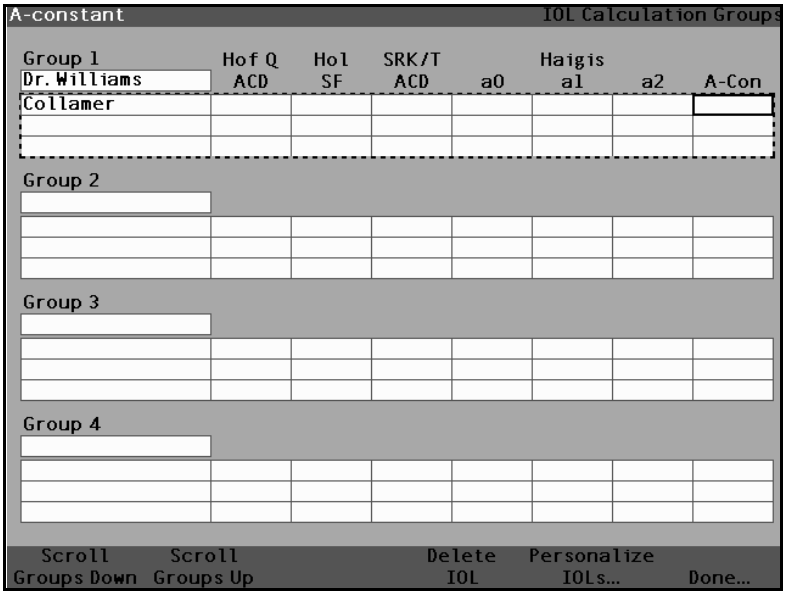


Figure 148 Selecting the A-Constant Field

7. Enter the A-Constant for the first lens you are entering.

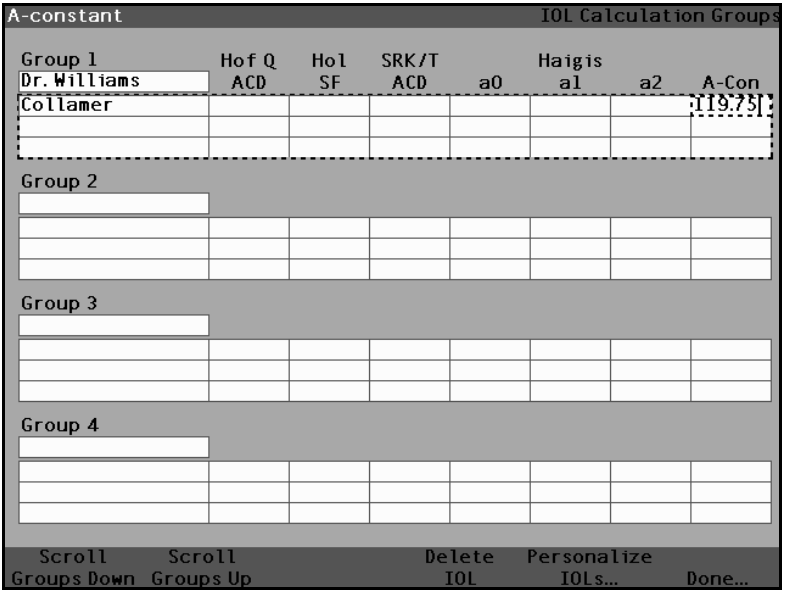


Figure 149 Entering the IOL Constant

8. Press the knob to save the value and to deactivate the field. The Accutome A-Scan Plus will then determine the corresponding IOL constant for each formula and automatically fill out the formula cells in the table.

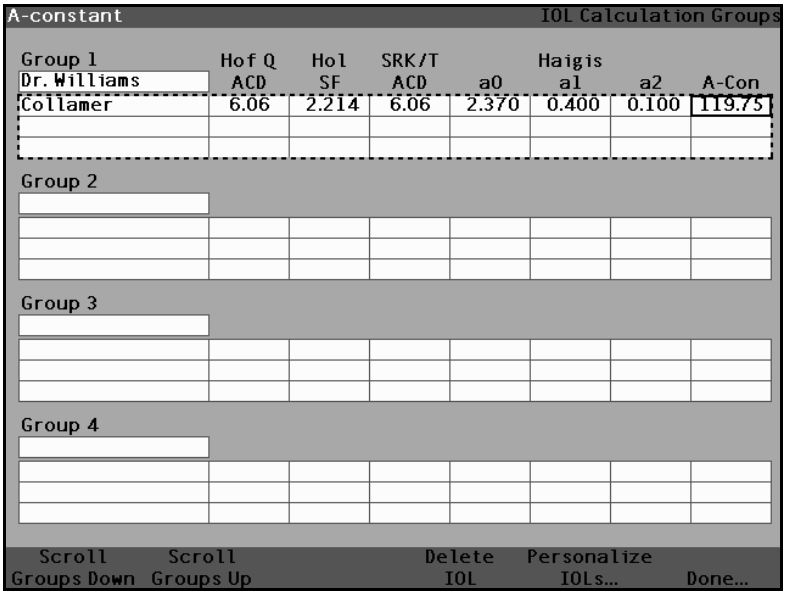


Figure 150 First Lens Entered for Group 1

9. Continue to enter all lens information for the IOL Group in the same manner. When you have completed the table press the knob or the √ button, once, to save the last cell entered and then again to deactivate the table.
10. If you have completed entering all IOL Group information press the button beneath the selection "Done..." to return to the Calculate IOL Screen.

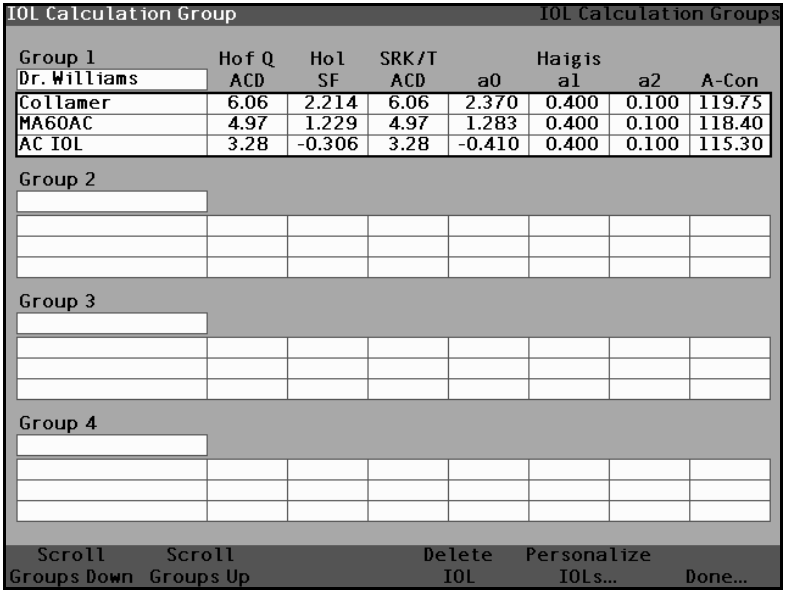


Figure 151 First IOL Group Complete

10 Personalizing Lens Constants

Overview

One of the great features of the Accutome A-Scan Plus is the ability to personalize the lens constants used in calculating lens power. This ability to fine tune lens constants results in even greater success for patient outcomes.

***Note:** *The Personalize IOLs screen does not allow the pasting of patient data for an eye that has Rx Surg set to Yes. If you attempt to personalize IOLS with post refractive surgery eyes the following message is shown: "Refractive surgery eyes cannot be used."*

Personalizing Lens Constants

IOL constant personalization is a method for removing consistent errors from the entire IOL implant procedure. It is important that as many variables as possible be consistent when personalizing constants for an IOL. These variables include:

- Diagnostic Technician
- Diagnostic Equipment (A-scan, Keratometer)
- Surgical Technique
- Surgical Equipment
- Patient Pathology
- IOL Manufacturer and Model
- IOL Calculation Formula

For this reason, the Accutome A-Scan Plus tracks personalized constants for each IOL and formula separately.

The process for personalizing lens constants involves entering postoperative results and allowing the Accutome A-Scan Plus to recalculate the constants used in the calculation formulas. The instrument tracks all the data entered in the postoperative results and optimizes all the data to determine the new formula constant.

How to Personalize Constants

The process of personalizing IOLs consists of:

- Selecting IOL Groups and Lenses
- Entering Postoperative Results
- Updating the IOL Constants

All personalization of IOL Constants takes place at the Personalize IOL Screen. The Personalize IOL Screen can be accessed from the Calculate IOL Screen via the IOL Groups Screen, or by pressing the Calculate button twice. To access the Calculate IOL Screen, and subsequently the IOL Groups screen, press the Calculate button, located at the right side of the front panel. The Calculate IOL Screen shown in Figure 152 below will be displayed.

Accessing the Personalize IOLs Screen

Starting at the Calculate IOL Screen:

1. In the Calculate IOL Screen, press the button beneath the selection "IOL Groups...". The IOL Groups screen will be displayed.

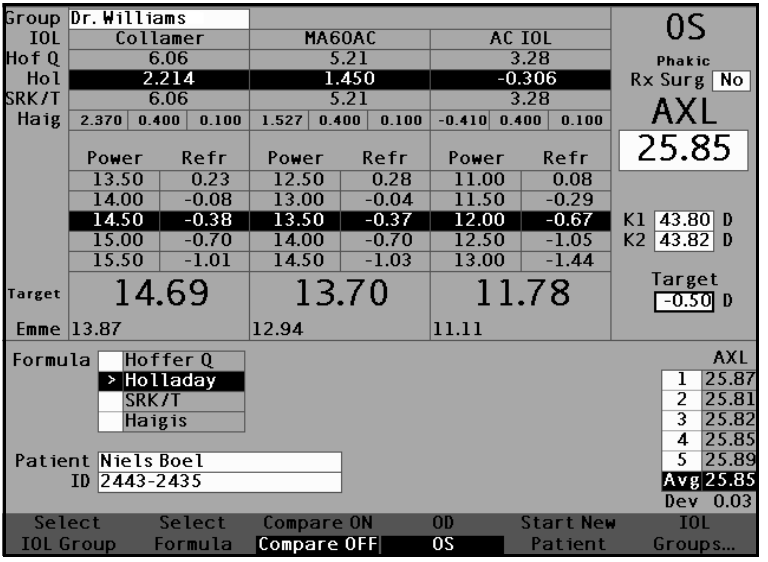


Figure 152 Calculate IOL Screen - IOL Groups Selection

2. In the IOL Groups screen press the button beneath the selection "Personalize IOLs...". The Personalize IOLs screen will be displayed.

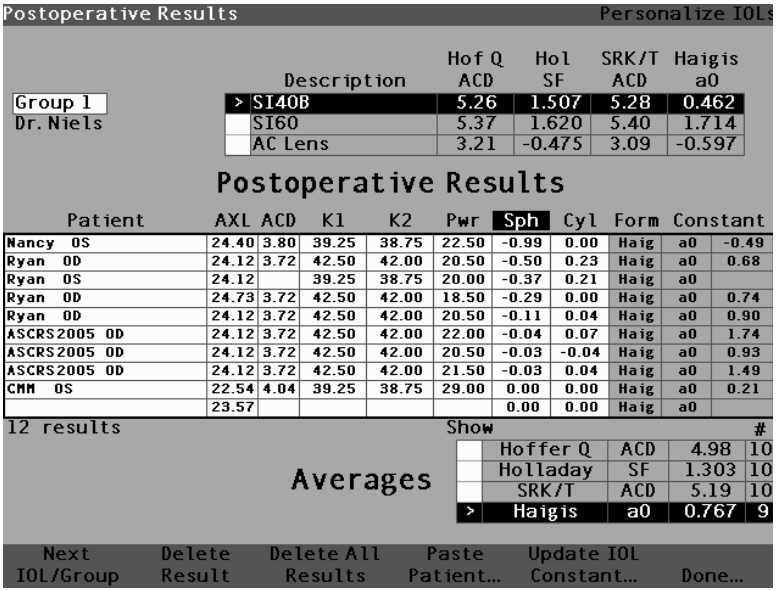


Figure 153 Personalize IOLs Screen

Personalize IOLs Screen

The Personalize IOLs screen displays a group field at the top left corner and to the right of the group field is an IOL table that displays the lenses for the currently selected group. Below the group field and IOL table is the Postoperative Results table.

To personalize an IOL's constants it is first necessary to enter postoperative results for a selected IOL group and lens.

Personalize IOLs Screen Soft Menus

At the bottom of the Personalize IOLs screen are the following soft menu selections:

- Next IOL/Group - selects the next IOL in the current group and then scrolls through IOL Group and associated lenses
- Delete Result - deletes the currently selected postoperative results, for the selected IOL within the selected IOL group
- Delete All Results - deletes all postoperative results for the selected IOL within the selected IOL Group
- Paste Patient - pastes current Patient records into the Postoperative Results table
- Update IOL Constant... - displays the Update IOL Constant screen for updating constants

Selecting an IOL Group and Lens

There are two ways to select an IOL Group and Lens: you can use the knob and first select and activate the IOL Group, and then select and activate the IOL Table, and then select and activate the IOL, **or** you can continuously press the button beneath the Next IOL/ Group soft menu selection.

Next IOL/Group

The Next IOL/Group selection scrolls through all entered IOL Groups and their associated lenses. Once you reach the last IOL in a group, the selection moves down to the next IOL group and scrolls through the next group's IOLs, and so on until the user reaches the end of the IOL Groups. If you then continue to press the button for the Next IOL/Group selection, the A-Scan will display the top of the list.

Selecting IOL Group with the Knob

To select an IOL Group and IOL:

1. In the Personalize IOLs screen, rotate the knob to select the IOL Group field, indicated by a solid black border. (You can also press the button beneath the selection 'Next IOL/Group' to select an IOL Group.)
2. Press the knob or the √ button, to activate the field, indicated by a dashed border.
3. Within the IOL Group field, rotate the knob to select one of the pre-entered IOL groups.
4. Press the knob or the √ button, to save the selected IOL Group and to deactivate the field.
5. Rotate the knob to select the IOL table which contains the lenses for the selected IOL group; selection indicated by a solid black border.
6. Press the knob or the √ button, to activate the IOL table, indicated by a dashed border.
7. Within the IOL table, rotate the knob to select the lens for which you will be entering postoperative results. (You can also press the button beneath the selection 'Next Group/IOL' to select the IOL.)
8. Press the knob to save the IOL selection and to deactivate the IOL table.

Entering Postoperative Results

Part of the process personalizing IOLs is to enter patient postoperative results so that the results can be used in calculating the new constant. It is important that as many variables of the postoperative results be kept constant; e.g. the results are all taken from the same machine using the same lens and formula. See "Overview" on page 225 for more information.

Part of each postoperative result is the Patient information that includes:

- Patient Name/ID
- AXL
- ACD
- K1
- K2

There are two ways to enter patient information: you can select and activate the Postoperative Results table, then select and activate each Patient field and manually enter the information **or** you can use the soft menu selection 'Paste Patient...'.

Pasting Patient Information

When you press the button beneath the soft menu selection 'Paste Patient...' the soft menu on the Personalize IOLs screen changes to Paste Patient selections. At any point on Personalize IOLs screen, no matter what field is active you can paste current patient info.

***Note:** *The Past Patient function is only available for the currently selected patient.*

1. Press the button beneath the 'Paste Patient' selection.
2. The soft menu selections will change as follows:
   - Paste Name, Paste ID - will toggle between pasting the patient name or ID
   - Paste OD - will paste all Patient OD information
   - Paste OS - will paste all Patient OS information
3. Press the button beneath the 'Paste OD' soft menu selection and all Patient OD information will be automatically entered into the Postoperative Results table.
4. Press the button beneath the 'Paste OS' soft menu selection and all Patient OS information will be automatically entered into the Postoperative Results table.
5. Enter the Postoperative Results described in "Entering Remaining Postoperative Results" on page 234 of this manual.

Manually Entering Patient Information

To enter patient information manually:

1. Rotate the knob to select the Postoperative Results table, indicated by a solid black border.
2. Press the knob or the √ button, to activate the postoperative results table.
3. Rotate the knob and select the Patient field of the first postoperative result that you are entering. The last row of the table is where you can enter post operative results. If the row is not there, you have reached the maximum number of results (50).
4. Enter the Patient ID.
5. Press the knob or the √ button, to save the entered ID.
6. Rotate the knob and select the AXL field of the first postoperative result that you are entering.
7. Enter the AXL value.
8. Enter the ACD value - required for Haigis formula.
9. Press the knob or the √ button, to save the entered value.
10. Rotate the knob and select the K1 field.
11. Enter the K1 value.
12. Press the knob or the √ button, to save the entered value.
13. Continue entering the field values until you have keyed in all the postoperative values for:
    - AXL- Axial Length in mm
    - K1, K2 - Keratometry measurements in Diopters or mm

***Note:** *The "0.00" values for the Sph and Cyl cells of the Postoperative Results table are present to indicate the last row of the table.*

Entering Remaining Postoperative Results

After all Patient Calculation information has been either pasted or manually entered, select, activate and enter the following fields.

- Power - Power of IOL implanted in Diopters
- Sphere - Spherical postoperative refraction in Diopters
- Cyl - Cylinder postoperative refraction in Diopters

Deleting Postoperative Results

Normal Postoperative results are essential in determining an effective personalized IOL constant. There may be times that you would like to delete some or all of the postoperative results; e.g. a value is very high or very low with respect to the average (outliers), entered data inaccurate, etc.

The Personalize IOLs Screen provides two methods of deleting postoperative results; you can delete the currently selected result or you can delete all postoperative results for the current IOL.

Deleting Current Postoperative Result

To delete the current postoperative result:

1. Ensure that the result you would like to delete is selected (there should be a cell with a solid black border).
2. Press the button beneath the selection "Delete Current Result".
3. The Accutome A-Scan Plus will then query you "Are you sure?". Press the button beneath the selection "Yes" to continue, or press the Check button (√) located at the right side of the front panel.
4. To discontinue deleting the current result press the button beneath the selection "Cancel", or press the Delete button (**X**) located at the right side of the front panel.

Deleting All Postoperative Results

To delete all postoperative results for the current IOL:

1. Press the button beneath the selection "Delete All Results".
2. The Accutome A-Scan Plus will then query you "Are you sure?". Press the button beneath the selection "Yes" to continue, or press the Check button (√) located at the right side of the front panel.
3. To discontinue deleting the all results press the button beneath the selection "Cancel", or press the Delete button (**X**) located at the right side of the front panel.

How to View Individual Results for a Formula

To view the individual results for a formula:

1. Select the Average Table.
2. Press the knob or the √ button.
3. Select the formula.

Individual results are shown for the selected formula for each patient. This is a view option only and does not affect the averages or results in any way.

How to Sort Postoperative Results

The Accutome A-Scan Plus provides the ability to sort Patient records by several fields:

- Patient
- AXL
- ACD
- K1
- K2
- Pwr
- Sph
- Cyl
- Formula & Constant

The sort fields are located above the Postoperative Results table.

To sort Postoperative results by a field:

1. Within the Personalize IOLs Screen, rotate the knob to select a sort field, indicated by a solid black border. The A-Scan will only select the current sort field. To select another sort field you must activate the current sort field first.
2. Press the knob or the √ button, to activate the field, indicated by the dashed border.
3. If you want to select another of the sort fields, rotate the knob until you have selected the appropriate field.
4. With the field selected by which you would like to sort, press the knob to change the sort order. If you activate the field more than once the A-Scan will toggle the sort order of the active field from ascending to descending and vice versa.
5. Press the knob or the √ button, to save the sort and to deactivate the field.

How to Update IOL Constants

While you enter postoperative results you will notice the data change in the Average table, located at the bottom right corner of the screen. The Average Table displays a count of postoperative results for each Calculation Formula (Hoffer Q, Holladay, and SRK/T and Haigis). The Average Table also displays the average IOL Constant extracted from the postoperative results.

The process for updating IOL constants consists of going to the Personalize IOLs Screen and selecting an IOL Group, associated lens and formula, and updating the constant for the selected formula. When you have determined you have enough postoperative results to update the IOL constants:

1. In the Personalize IOLs Screen, press the button below the selection "Update IOL Constant...". The Update IOL Constants Screen will be displayed. You can also press the dedicated Calculate button a second time to reach the screen.

Update IOL Constants Screen

The Update IOL Constants Screen (see Figure 154 below) displays an IOL Group field in the upper left corner. Located to the right of the Group field is a table displaying the selected IOL Group's lenses and the lenses' current formula constants. The lens name that is in white text against a black background is the currently selected lens.

The Average Table (from the Personalize IOLs Screen) is also displayed in the bottom right corner of the screen. The table displays the IOL constant information, optimized from postoperative results, for the currently selected lens. From this screen it is possible to select an IOL Group and update the IOL Constants for a selected lens and formula.

***Note:** *The Haigis formula does not do an average but rather a best fit regression. The other formulas calculate the 'average'.*

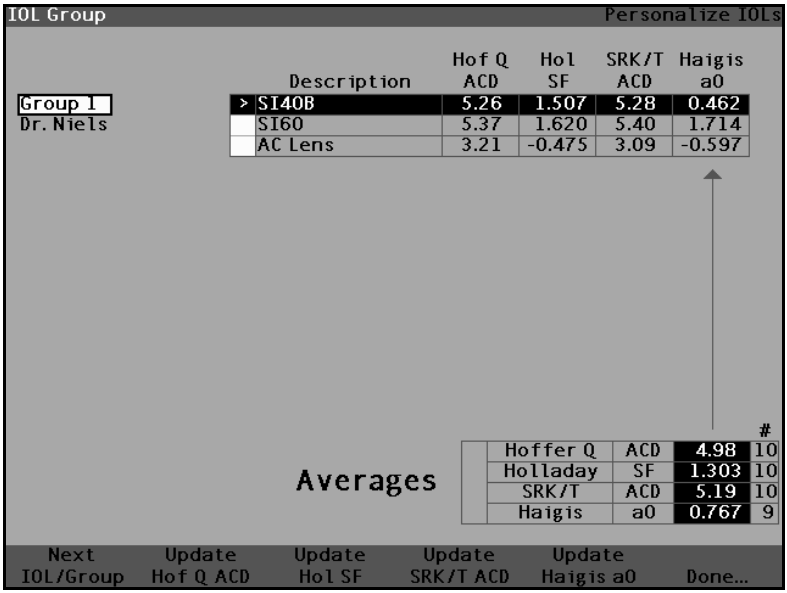


Figure 154 Update IOL Constants Screen

Selecting an IOL Group and Lens

Just like on the Personalize IOLs Screen, there are two ways to select an IOL Group and Lens in the Update IOL Constants Screen: you can use the knob and first select and activate the IOL Group, and then select and activate the IOL Table, and then select and activate the IOL, **or** you can continuously press the button beneath the Next IOL/Group soft menu selection. Refer to "Next IOL/ Group" on page 229 for more information.

If you are selecting and IOL Group IOL with the knob:

1. In the Update IOL Constants Screen, rotate the knob to select the IOL Group field, indicated by a solid black border. (You can also press the button beneath the selection 'Next IOL/Group' to select an IOL Group.)
2. Press the knob or the √ button, to activate the field, indicated by the dashed border.
3. Within the IOL Group field, rotate the knob to select one of the pre-entered IOL Groups.
4. Press the knob or the √ button, to save the selected IOL Group and to deactivate the field.
5. Rotate the knob to select the lens constant table for the selected IOL group. (Table selection is indicated by a solid black border.)
6. Press the knob or the √ button, to activate the table, indicated by the dashed border.
7. Within the IOL Constants Table, rotate the knob to scroll through the list of lenses.
8. After you have selected the lens, press the knob or the √ button, to activate the appropriate lens and to deactivate the table.
9. The Update IOLs screen will display the formulas requiring constants to be updated, as soft menu selections in black text against a gray background. "Update Hol SF" in black text indicates that the Surgeon Factor (SF) for the Holladay formula needs to be updated.
10. At the bottom of the screen, press the button beneath the appropriate formula to update:
    - ❖ Update Hoffer Q ACD

- Update Hol SF
- Update SRKT ACD
- Update Haigis a0

11. After pressing the button beneath the formula requiring its IOL constant to be updated, the new constant will replace the old one in the IOL table.

Overview

You can save a patient record at any time for later review or calculation. If you are away from your printer, you can save the current patient measurements and print the patient's record at a later date.

The Accutome A-Scan Plus makes storing patient records an easy process. Push the Patient Record button and the Patient Records Screen, where you can store and recall all measurement parameters and calculations, will be displayed. All waveform measurement and IOL calculation settings and data are stored with each patient record when it is saved. Recalling a patient record at a later date allows you to view the patient record exactly as it was saved. Changes to instrument settings including Eye Types and measurement controls made after the patient is stored and before the patient is recalled do not effect the recalled patient measurements or IOL calculations.

When you recall a patient record the instrument is set to same settings as when you stored the record. Asterisks will appear if settings have altered.

How to Store a Record

After you have taken all the desired measurements you can save a Patient's measurements to a record so that you can recall it at a later time.

To save a Patient's record:

1. Press the "Patient Records" button located at the right side of the instrument. The Patient Record Screen as shown in Figure 155 below will be displayed.

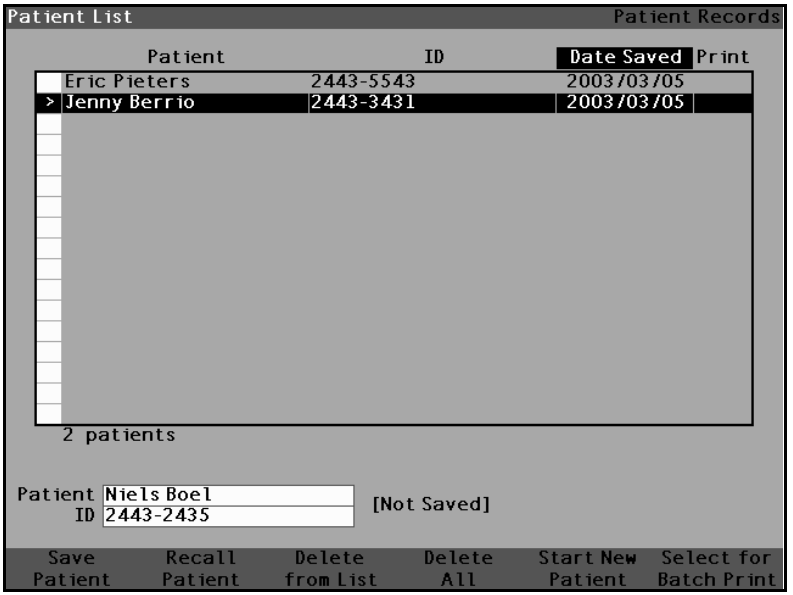


Figure 155 Patient Record Screen

2. Press the button below "Save Patient". The Accutome A-Scan Plus will store the Patient record and indicate record storage by changing the text beside the Patient ID that the record was stored. There will also be a line added to the Patient Records table.

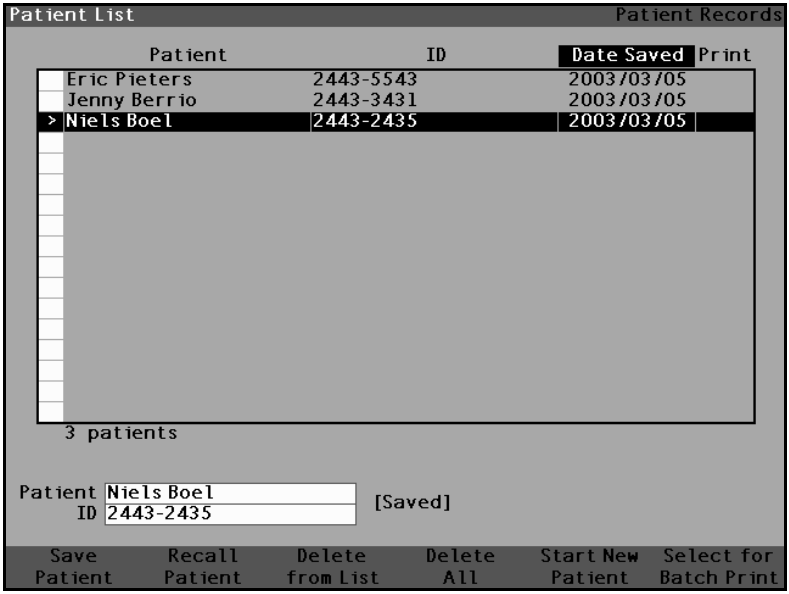


Figure 156 Patient Record Stored

How to Recall a Record

You may need to recall a patient record at a later date to review a measurement, or execute a calculation.

To recall a Patient's record:

1. Press the "Patient Records" button located at the right side of the instrument. The Patient Record Screen as shown in Figure 157 below will be displayed.
2. Within the Patient Records list, rotate the knob to select the correct patient record
3. Press the 'Recall Patient' soft menu button to recall the patient. If the current patient has not been saved the A-Scan will confirm that the current patient data will be lost when the stored patient is recalled.

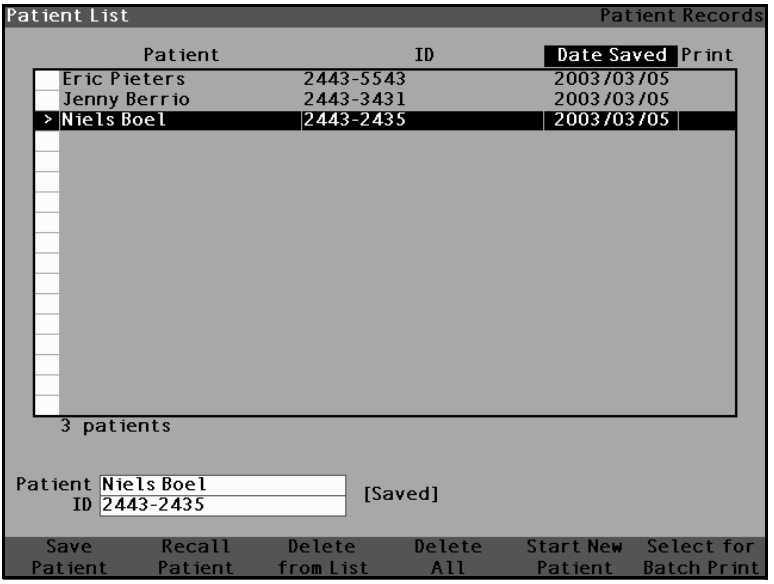


Figure 157 Recalling a Patient Record

4. Press the Measure or Calculate button, located at the right side of the front panel. The A-Scan will display the recalled patient record.

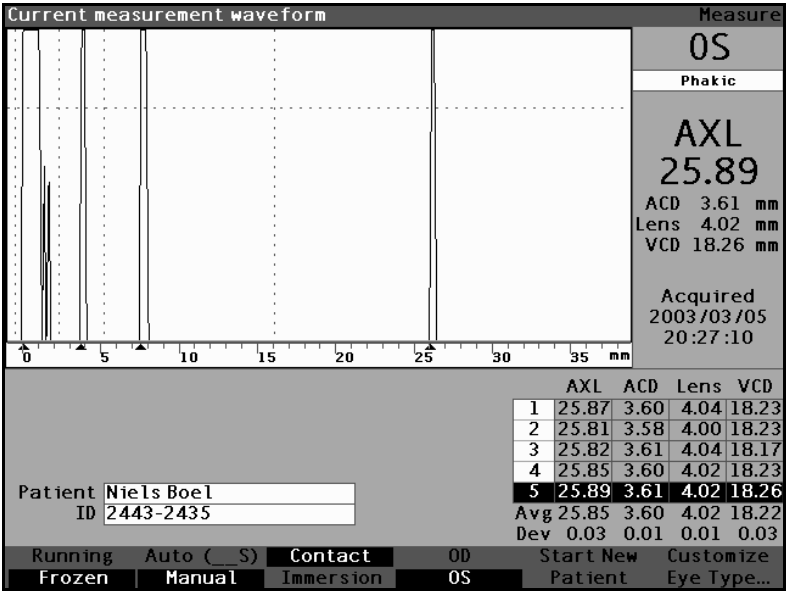


Figure 158 Recalled Patient Record

How to Adjust Parameters on Saved Records

You can adjust any of the waveform parameters on a saved record in exactly the same manner as you would on an active waveform.

To adjust parameters refer to the section "Performing Measurements" on page 151 of this manual.

How to Update Calculations

You can update calculations on a saved record in exactly the same manner as you would perform a calculation on an active measurement.

To update calculations refer to the section "Performing Calculations" on page 197 of this manual.

***Note:** *Changing a saved patient record does not change the saved record, and the patient record must be saved again. You may also want to delete the previously saved patient so that there is only one record of that patient.*

How to Sort Patient Records

The Accutome A-Scan Plus provides the ability to sort Patient records by several fields:

- Patient
- ID
- Date Saved

The sort fields are located above the Patient Records.

To sort Patient records by a field:

1. Within the Patient Records Screen, rotate the knob to selected sort field, indicated by a solid black border. The A-Scan will only select the current sort field. To select another sort field you must activate the current sort field first.
2. Press the knob or the √ button to activate the field, indicated by the dashed border.
3. If you want to select another of the sort fields, rotate the knob until you have selected the appropriate field.
4. With the field selected by which you would like to sort, press the knob to change the sort order. If you activate the field more than once the A-Scan will toggle the sort order of the active field from ascending to descending and vice versa.
5. Press the knob or the √ button to save the sort and to deactivate the field.

12 Printing Records

How to Print a Record

The Accutome A-Scan Plus makes printing accessible and easy. Whenever you want to print a patient record, or patient measurements you simply press the Print button. The Accutome A-Scan Plus will provide you with organized, accurate records of patient waveforms and calculations. You can also print any screen by keying "ALT+P" on the keyboard.

Printing also makes a permanent record of the entire state of the instrument including velocity, probe application method, capture mode, eye type, i.e. all recent settings, on an 81/2 X 11" piece of paper.

Screen Printout Formats

The type of page the Accutome A-Scan Plus prints is determined by the screen from which you execute the print command.

The screens and associated printout formats are:

- Measure Screen - will print up to five waveforms for either OD/OS and will display textual description of each waveform
- Calculate IOL Screen - will print out lens calculations, table of measurements and a selected waveform for both OD/OS
- Other Screens - print the data that is displayed on the screen

***Note:** *The Measure Screen print is available only for graphic printers. The Generic/Text Only printout is the same as the Calculation screen*

How to Select the Right Printout Format

You should choose the print format according to your needs. For example, if you need to view each of the waveforms for an irregularity, you should print the Measurement printout. If you need only the calculation information, you should print the Calculation printout.

Sample Printouts

Figure 159 below and Figure 160 through Figure 163 on page 255 are given to provide you samples of the printout formats.

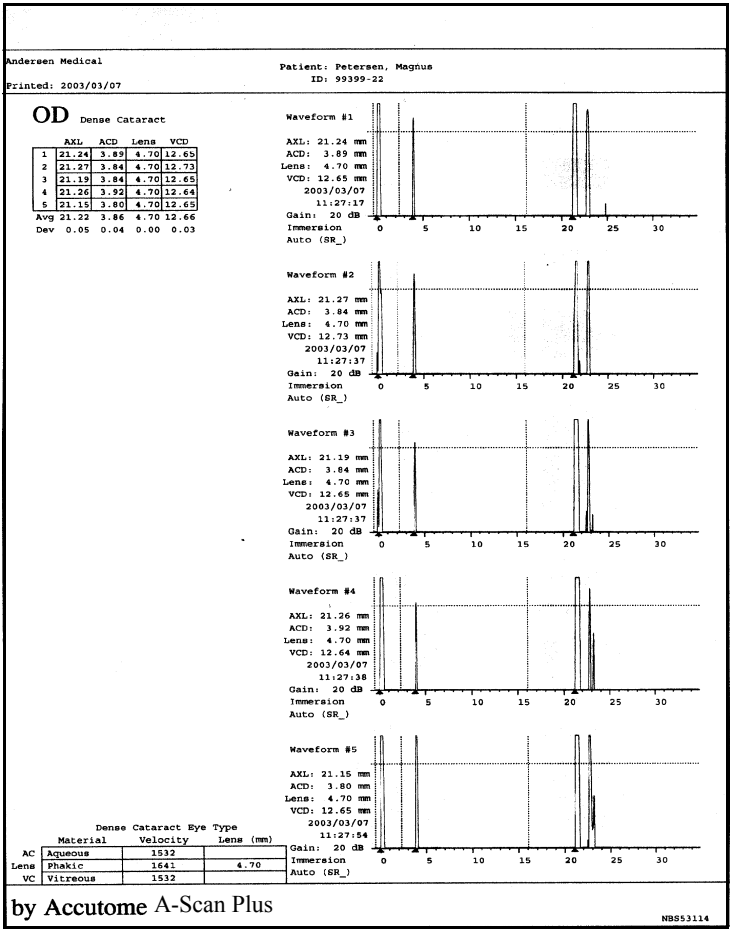


Figure 159 Measurement Printout

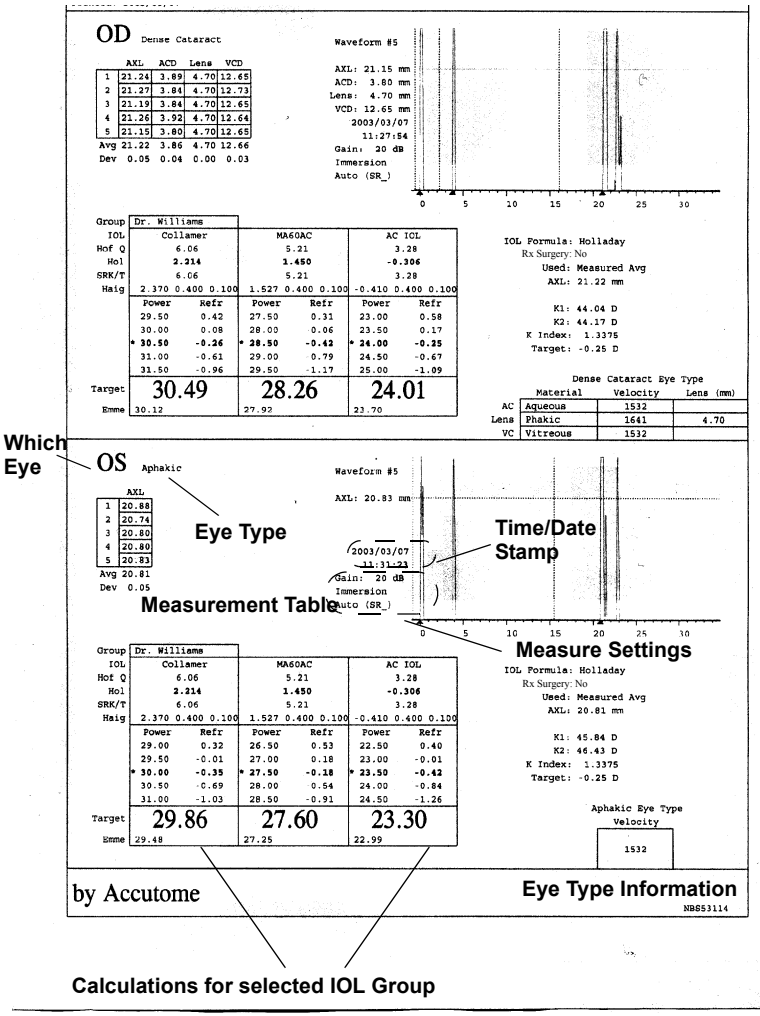
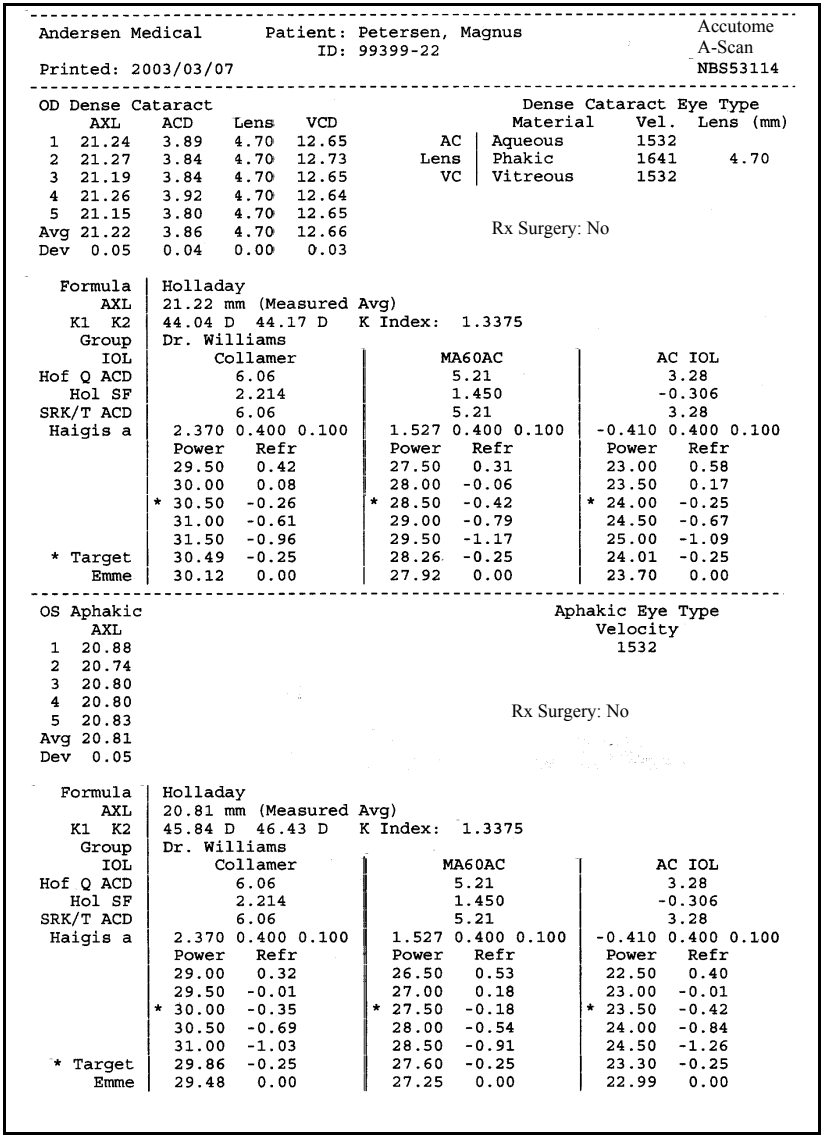


Figure 160 Calculation Printout



```
Andersen Medical          Patient: Petersen, Magnus                Accutome
                                ID: 99399-22                       A-Scan
Printed: 2003/03/07                                                NBS53114
```

OD Dense Cataract

	AXL	ACD	Lens	VCD
1	21.24	3.89	4.70	12.65
2	21.27	3.84	4.70	12.73
3	21.19	3.84	4.70	12.65
4	21.26	3.92	4.70	12.64
5	21.15	3.80	4.70	12.65
Avg	21.22	3.86	4.70	12.66
Dev	0.05	0.04	0.00	0.03

AC	Aqueous
Lens	Phakic
VC	Vitreous

Dense Cataract Eye Type

Material	Vel.	Lens (mm)
Aqueous	1532	
Phakic	1641	4.70
Vitreous	1532	

Rx Surgery: No

Formula	Holladay		
AXL	21.22 mm (Measured Avg)		
K1 K2	44.04 D 44.17 D	K Index: 1.3375	
Group	Dr. Williams		
IOL	Collamer	MA60AC	AC IOL
Hof Q ACD	6.06	5.21	3.28
Hol SF	2.214	1.450	-0.306
SRK/T ACD	6.06	5.21	3.28
Haigis a	2.370 0.400 0.100	1.527 0.400 0.100	-0.410 0.400 0.100
	Power Refr	Power Refr	Power Refr
	29.50 0.42	27.50 0.31	23.00 0.58
	30.00 0.08	28.00 -0.06	23.50 0.17
	* 30.50 -0.26	* 28.50 -0.42	* 24.00 -0.25
	31.00 -0.61	29.00 -0.79	24.50 -0.67
	31.50 -0.96	29.50 -1.17	25.00 -1.09
* Target	30.49 -0.25	28.26 -0.25	24.01 -0.25
Emme	30.12 0.00	27.92 0.00	23.70 0.00

OS Aphakic

	AXL
1	20.88
2	20.74
3	20.80
4	20.80
5	20.83
Avg	20.81
Dev	0.05

Aphakic Eye Type

Velocity
1532

Rx Surgery: No

Formula	Holladay		
AXL	20.81 mm (Measured Avg)		
K1 K2	45.84 D 46.43 D	K Index: 1.3375	
Group	Dr. Williams		
IOL	Collamer	MA60AC	AC IOL
Hof Q ACD	6.06	5.21	3.28
Hol SF	2.214	1.450	-0.306
SRK/T ACD	6.06	5.21	3.28
Haigis a	2.370 0.400 0.100	1.527 0.400 0.100	-0.410 0.400 0.100
	Power Refr	Power Refr	Power Refr
	29.00 0.32	26.50 0.53	22.50 0.40
	29.50 -0.01	27.00 0.18	23.00 -0.01
	* 30.00 -0.35	* 27.50 -0.18	* 23.50 -0.42
	30.50 -0.69	28.00 -0.54	24.00 -0.84
	31.00 -1.03	28.50 -0.91	24.50 -1.26
* Target	29.86 -0.25	27.60 -0.25	23.30 -0.25
Emme	29.48 0.00	27.25 0.00	22.99 0.00

Figure 161 Waveform Text Printout

How to Batch Print

The Accutome A-Scan Plus also provides a batch print capability. During a batch print you can print multiple, selected patient records using the IOL Calculation screen print format. As with direct printing, if the Serial Link is enabled on the Setup Screen, records that are batch printed will be sent out the serial link.

Holding down the 'Select for Batch Print' for approximately a second selects/deselects all patients in the patient list. If any patients are selected, all are unselected for batch print. If no patients are selected, all are selected for batch print.

To perform a batch print from the Patient Records screen:

1. Press the "Patient Records" button, located at the right side of the front panel. The Patient Records screen shown below will be displayed.

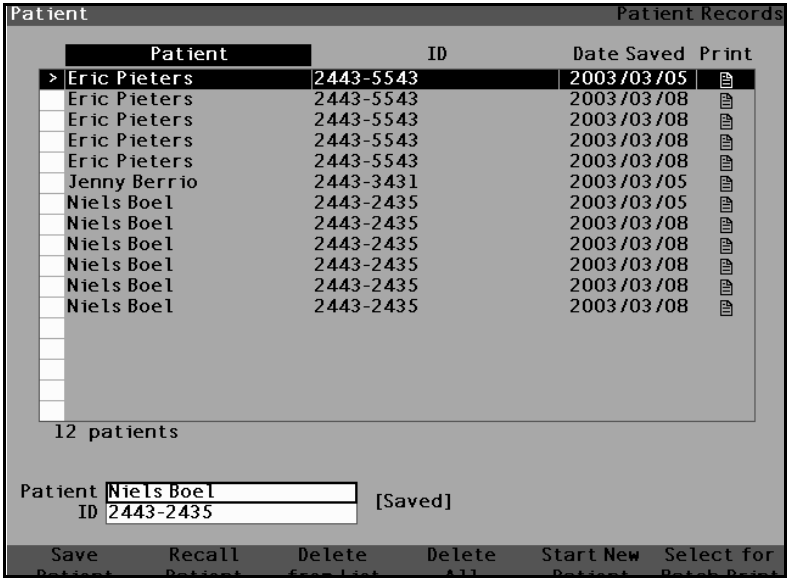


Figure 162 Saved Patient Record Screen

2. Rotate the knob until you have selected the Patient's record you would like to print.
3. Press the button below the "Select for Batch Print" selection.
4. If you would like to select all Patients, hold the "Select for Batch Print" button for one second. Conversely, if you would like deselect Patients already selected for batch print, hold the "Select for Batch Print" button for one second.
5. Continue to select all Patient records that you want to print.
6. Press the "Print" button located at the right side of the front panel.
7. The Accutome A-Scan Plus will print all records selected for batch print.

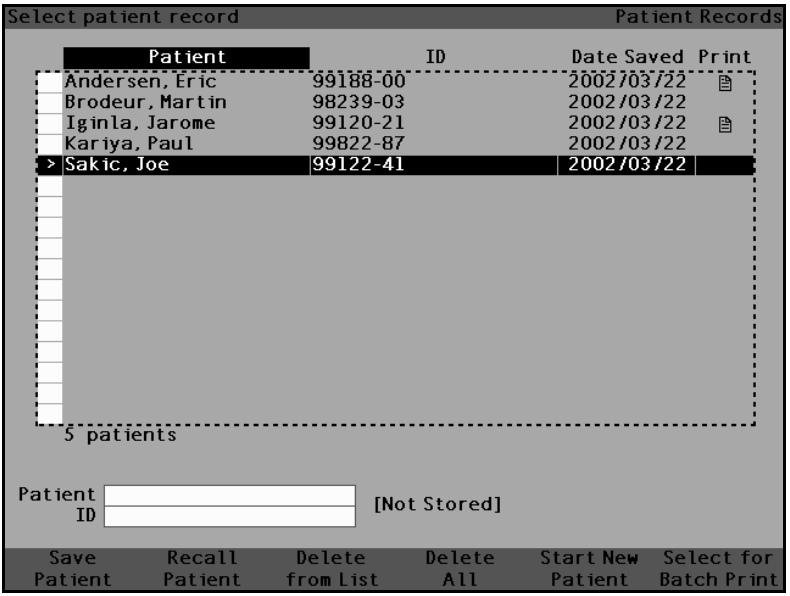


Figure 163 Saved Patient Record - Select for Batch Print

Required Printer

The Accutome A-Scan Plus will only print the waveforms when you have a printer that uses the HP LaserJet or the HP InkJet print driver. In order to obtain the best printouts from the instrument, it is recommended that all A-Scan records be printed on a laser printer that is HP LaserJet compatible. An HP Laser Jet printer is recommended, but any LaserJet or InkJet compatible printer will work.

If you do not have an HP LaserJet or HP InkJet printer, the Accutome A-Scan Plus also provides a generic printer driver that will print text only. You will not be able to print any of the waveforms when you use the generic printer driver.

General Maintenance

Maintenance that should be performed on the Accutome A-Scan Plus consists of activities such as keeping surfaces free of dust and dirt and storing in a dry and cool place so as to not adversely effect electronic parts.

Care must be taken to use only proper non-linting cloths and non-corrosive solvents when cleaning the screen.

CAUTION: No abrasives or harsh cleaning solutions should be used while cleaning the Accutome A-Scan Plus.

14 Specifications

Overview

This section provides the physical and operational specifications of the Accutome A-Scan Plus.

Physical Specifications

Table 5 below lists the physical specifications of the instrument and associated peripherals.

Table 5 Accutome A-Scan Plus Physical Specifications

Main Unit	
Dimensions	30.2 X 19.05 x 4.83 cm (11.9” x 7.5” x 1.9”)
Weight	1.98 Kg (4 lbs, 6 oz).
DC Input	12 V, 1.25 A
Display	
Type	Monochrome Liquid Crystal Display (LCD)
Size	18.29 cm (7.2”) diagonal viewable area
Resolution	640 x 480 pixels, 16-shades of gray
External I/O Connectors	
Printer	IEEE-1284 type C
Serial	RS-232C, DCE, 9-pin D-Sub, female
Keyboard	PS/2, 6-pin mini-DIN, female
Foot Switch	3.5 mm mono phone jack
DC Power	2.5 mm DC coaxial

Table 5 Accutome A-Scan Plus Physical Specifications

Probe (Use only Accutome PN 24-4001)	
Frequency	10 MHz
Dimensions	4.32 cm (1.7") long, 0.63 cm (0.25") diameter
Cable Length	1.5m (5 feet)
Accessories	Tonometer adapter, extension handle with installation tool
Keyboard (Use only Accutome PN 24-4003)	
Dimensions	28.19 X 13.21 X 2.29 cm (11.1" x 5.2" x 0.9")
Number of Keys	83
Footswitch (Use only Accutome PN 24-4004)	
Dimensions	8.89 X 6.60 X 2.54 cm (3.5" x 2.6" x 1")
Weight	198 g (7 oz.)
Environmental	IP20, IP68
External Power Supply (Use only Accutome PN 24-4008)	
Dimensions	12.95 X 7.87 X 4.06 cm (5.1" x 3.1" x 1.6")
Weight	425 g (15 oz.)
Input Voltage	100 to 240 VAC 50/60 Hz
Power (typical)	15 Watts
Output	12V, 1.25A
Safety	IEC601-1, UL2601, CSA601, CE

Table 5 Accutome A-Scan Plus Physical Specifications

Printer	
Connector	IEEE-1284 type C
Language	HP Laser Jet PCL5 printer or HP Ink Jet PCL3 language
Example Model	HP LaserJet Model 1200
Serial Link Port	
Connector	RS-232C, DCE, 9-pin D-Sub, female
Communication Parameters	9600, 19200, 38400, 57600, or 115200 baud 8 data bits, 1 stop bit, no parity, hardware flow control
Output Format	ASCII text format
Safety	
Meets IEC 601 Series electrical standards for medical equipment	

Environmental Specifications

Table 6 below lists the Accutome A-Scan Plus system operating and storage values for temperature and humidity.

Table 6 Environmental Specifications

Temperature	
Operating	+10° C to +40° C
Storage	-20° C to +60° C
Relative Humidity	
Operating	20% to 80% (non-condensing)
Storage	15% to 90% (non-condensing)
Atmospheric Pressure	
Operating	700 - 1060 hPa
Storage	500 - 1060 hPa

Measurement Accuracy

Table 7 below lists the accuracy for each type of measurement.

Clinical Accuracy (1 σ)	0.1 mm
Electronic Resolution (@1550 m/s)	0.016 mm

Table 7 Measurement Accuracy

Measurement	Clinical Accuracy (1 σ)	Range
Axial Length	0.1 mm	0.01 to 63.6 mm @1555 m/s
Anterior Chamber Depth	0.1 mm	0.01 to 62.7 mm @1532 m/s
Lens Thickness	0.1 mm	0.01 to 67.2 mm @1641 m/s
Vitreous	0.1 mm	0.01 to 62.7 mm @1532 m/s

Operating Modes

The following table summarizes the mode/application possibilities for each system/transducer combination:

Table 8 Operating Mode(s)

Clinical Application	A	B	M	PWD	CWD	CD	Com-bined (Specify)	Other† (Specify)
Ophthalmic	X							
Fetal Imaging & Other*								
Cardiac, Adult &								
Pediatric								
PeripheralVes-sel								

* Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-Skeletal (**conventional**), Musculo-Skeletal (**superficial**)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging.

Formula References

Table 9 below lists the references for the calculation formulas used in the Accutome A-Scan Plus.

Table 9 Formula References

Hoffer Q	Hoffer Q formulas are implemented as defined in “The Hoffer Q formula: A comparison of theoretic and regression formulas”, by HOFFER KJ: The Hoffer Q formula: A comparison of theoretic and regression formulas. J Cataract Refract Surg, 19:700-712, 1993; ERRATA 20:677, 1994. The article and its errata do not mention that restricting the calculated post operative ACD to 2.5 to 6.5 should no longer be done, as Dr. Hoffer now requires.
Holladay	Holladay formulas are implemented as defined in “A Three Part System For Refining Intraocular Lens Power Calculations”, by Jack T. Holladay, Journal of Cataract and Refractive Surgery, Vol 14, Jan 1988.
SRK/T	SRK/T formulas are implemented as defined in “Lens Implant Power Calculation, A Manual For Ophthalmologists & Biometrists”, by John A. Retzlaff, Donald R. Sanders, Manus Kraff, Third Edition.
Haigis	"Formulas for the IOL calculation according to Haigis", by Dr. W. Haigis, Wuerzburg July 8, 2002. The formula has been implemented as specified by Dr. Haigis and has received compliance certification from Dr. Haigis.

Storage/Range Specifications

Table 10 below lists the data storage and range specifications of the Accutome A-Scan Plus .

Table 10 Data Specifications

Stored Data Capacity	
Waveforms / Patient	10
Stored Patients	100
IOLs	45 total; 15 groups of 3
Post Operative Results	1000 total; 50 per IOL
Waveform Data	
Data Points Per Waveform	4096
Max Depth At 1555 m/sec	64 mm
Gain Adjustment Range	20 dB
Eye Type Storage	
Factory Eye Types	7
User Eye Types	2
Custom Eye Types	Unlimited
Factory Aqueous/Vitreous Materials	3
User Aqueous/Vitreous Materials	2
Factory Lens Materials	4
User Lens Materials	2
Material Velocity Range	500 to 9999 m/sec
Assumed Lens Thickness Range	0 to 9.99 mm
K Readings Range	20 to 60 D 5 to 19.99 mm

Table 10 Data Specifications

Calculation Field Ranges	
Target Refraction Range	-20 to 20 D
Entered AXL range	15 to 40 mm
Entered IOL A-constant range	110.5 to 122.5
Entered IOL ACD range	0.10 to 6.50 mm
Entered IOL SF range	-3.5 to 3.5 mm
Entered ACD range	0.01 mm to 9.99 mm
Entered IOL a0 constant range	-9.999 to 9.999
Entered IOL a1 constant range	-0.999 to 0.999
Entered IOL a2 constant range	-0.999 to 0.999
Accutome Clock	
Clock/calendar valid	Through year 2099

Acoustic Output

Table 11 below provides the acoustic output reporting for the following:

Transducer Model: Accutome A-Scan

Operating Mode: A-Scan

Application(s): Ophthalmic

Table 11 Acoustic Output Reporting Table for Track 1 Non-Autoscanning Mode

Acoustic Output			MI	$I_{SPTA.3}$ ($\mu W/cm^2$)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.14	2.62	4.11
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.41	-----	-----
	W_o (mW)		-----	0.198	0.198
	f_c (MHz)		9.34	9.34	9.34
	Z_{sp} (cm)		0.50	0.50	0.50
	Beam Dimensions	x_{-6} (cm)	-----	0.246	0.246
		y_{-6} (cm)	-----	0.332	0.332
	PD (μsec)		0.11	-----	0.11
	PRF (Hz)		5.8	-----	5.8
	EBD	Az. (cm)	-----	0.35	-----
		Ele. (cm)	-----	0.35	-----

Table 11 Acoustic Output Reporting Table for Track 1 Non-Autoscanning Mode

Operating Control Conditions	Control 1			
	Control 2			
	Control 3			
	Control 4			
	Control n			

These values are based on measurements of production units.

The “derated” intensity calculations are based on the measured center frequency of the acoustic signal (f_c, MHz) and the distance from the transducer under test to the hydrophone (z, cm) using the derating factor $e^{-0.069 f_c z}$.

Warranty

Accutome, Inc. warrants its new equipment to be free from defects in workmanship or materials. Any product that is proven to be defective will be repaired or replaced at our discretion, free of charge, up to one year from the date of purchase by the initial user of the equipment from Accutome, Inc. or any of its authorized distributors.

This warranty covers all repairs and servicing of parts that proved defective by manufacture and not by misuse or mishandling. This type of service will be handled by our trained sales force, or if necessary, in our home office. Shipping charges for returns or repair of non-warranted items will be the responsibility of the customer. Alteration, repair or modification of any product that is performed by persons not authorized by Accutome, Inc. will result in immediate loss of warranty.

Product Returns

Follow the instructions given below to return products to Accutome Inc.

Service and Repair

Before returning instruments for service or repair, contact the Accutome Technical Service Group for a Return Goods Authorization (RGA) number.

Toll Free (in USA):	1-800-979-2020
Tech Service:	1-610-889-0200
Fax:	1-610-889-3233

After receiving authorization, print the RGA number on the outside of the package and send the instrument to:

Technical Service Group

Accutome, Inc.

263 Great Valley Pkwy

Malvern, PA 19355

All Other Returns

Returns for non-service related reasons must be authorized by the Accutome Customer Service Department. Please contact Customer Service for an RGA number.

Merchandise returned within 60 days of date of invoice will be credited as follows:

- Full credit for all merchandise returned in resalable condition

Non-Returnable Merchandise

Accutome Inc. will not authorize a return for:

- Merchandise held longer than 60 days

Replacement Parts

Table 12 below lists items that are available from Accutome, Inc. or from your local sales representative. Please be sure to use the Accutome part number for the item when placing an order.

Table 12 Accutome Replacement Parts

Description	Accutome Part No.
Standard Parts	
Probe Kit	24-4001
Foot Switch	24-4004
Keyboard	24-4003
Power Supply	24-4008
Power Supply Cable	24-4012 (United States)
Ground Cable	24-4045
Optional Parts	
Immersion Shell	24-4100
Printer Cable	24-4010
Serial Link Cable	24-4012

Documentation

Accutome will make available on request circuit diagrams, component parts, lists, descriptions, calibration instructions or other information that will assist qualified technical personnel to repair the Accutome A-Scan Plus.