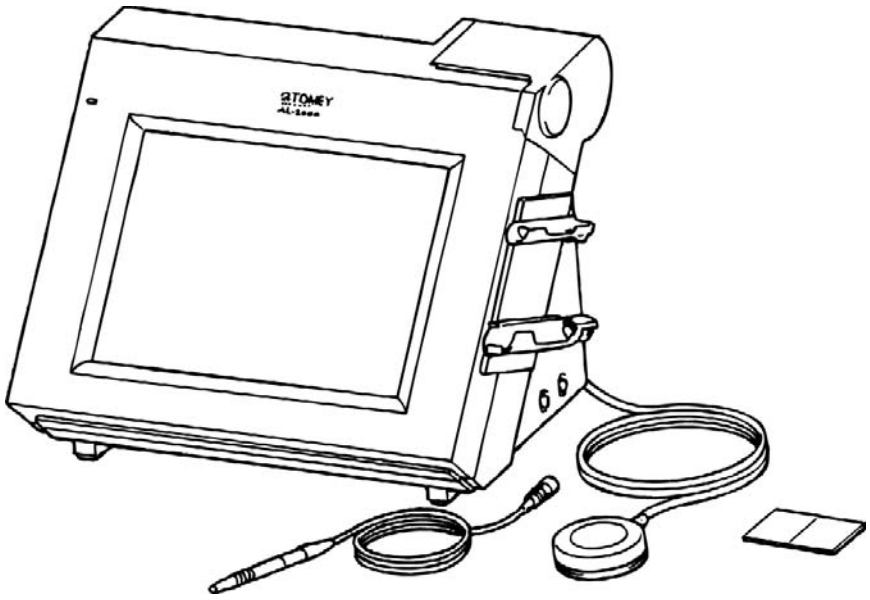
TOMEY

OPERATOR MANUAL

AL-2000 Biometer & Pachymeter



WARNINGS

- Read this Operator Manual carefully before using this instrument for proper and safe operation.
- Do not use procedures other than those specified in this manual.
- Only well-trained personnel should operate the instrument.
- Keep the Operator Manual in a place where you can easily access it when operating the instrument.
- For any questions about the instrument or the manual, contact your Tomey representative or local distributor.

- DO NOT REMOVE THE OUTER COVER of the instrument. If you do, you may be subjected to direct high voltage.

- ALWAYS use a clean probe for eye measurements (see section 10.2.1).
- NEVER use the probe if there is any visible damage to its tip. Such use may cause an incorrect measurement and/or damage to the cornea.

- This instrument is designed exclusively for ophthalmic use. DO NOT use the instrument for any other purpose.
- The controlling voltage, pulse repetition frequency and pulse duration of the ultrasound output are fixed; they CANNOT be changed.
- DO NOT use cables or memory cards other than those specified in the manual. Such connection may result in damage to the instrument.

SYMBOLS USED IN THIS MANUAL

The symbols used in this manual represent the following:

- This is a precaution that, if unheeded, will result in a hazardous situation where there is an imminent danger of serious injury or death.

- This is a precaution that, if unheeded, may cause a hazardous situation where there is the possibility of serious injury or death.

- This is a precaution that, if unheeded, may cause minor or moderate injury or property damage.

- This is a special precaution that is related, either directly or indirectly, to personal safety or to protection of property.

CONTENTS

1. PRIOR TO USE

Notes

- **Read this Operator Manual carefully before using the instrument in order to operate it properly and safely.**
- **Do not use any procedures that are not specified in the manual.**

1.1 Cautionary Notes

CAUTION

- **Only well-trained personnel should operate this instrument.**
- **When installing this instrument, observe the following:**
  - Do not install the instrument in a place where it might be exposed to moisture or chemicals.
  - Do not install the instrument in a place where it is subject to adverse conditions, such as direct sunlight, high temperature, excessive humidity, dust, sulfur or salt.
  - Ascertain that any adverse factors such as excessive slope, vibration and impact will not endanger the instrument (including during transportation).
  - Do not install the instrument in or near the storage area of chemical substances or where any gas may be generated.
  - Follow frequency, voltage and allowable current (or allowable power consumption) specifications.
  - Be cautious of electrical power conditions such as discharge, polarity, etc.
  - Ascertain that the power source is properly grounded.
- **Before using this instrument, observe the following:**
  - Ascertain that all cables and cords are properly connected.
  - Carefully inspect the probe tip before using.
- **While using this instrument, observe the following:**
  - Always make sure that the patient is comfortable.
  - If any complication or abnormality is encountered, either with the patient or the instrument, ensure the safety of the patient by discontinuing testing.
  - Make sure the patient has no contact with the instrument (other than the probe) during testing.
- **After using this instrument, observe the following:**
  - Be sure to clean the probes after each use (see section 10.2.1).

- When disconnecting the power cord, hold the plug, not the cord, and do not use excessive force.
- If you do not plan to use the instrument for a considerable period of time, refer to Section 10.4 for storage instructions.

- **In case of a malfunction, do not attempt to repair the instrument yourself. Place a sign on the instrument indicating that it is malfunctioning and contact your Tomey representative.**

1.2 Unpacking

When unpacking the instrument, make sure that all of the components are present and that none of them are visibly damaged. If any items are missing or damaged, contact your Tomey representative.

Note

- **Be sure to keep the box and the packing material for use if the instrument is moved to another location.**

List of Components:

- Main unit
- Biometry probe
- Probe holder
- Foot switch
- Power cord
- Memory card
- Biometry test piece
- Printer paper
- Dust cover
- Fuses (2)
- Operator manual

Pachymetry Components:

- Pachymetry probe
- Pachymetry test piece

1.3 Outline of Operation

The AL-2000 is an ultrasound instrument designed for measuring the axial length of the eye and the thickness of the cornea for medical ophthalmic use.

- Ultrasound energy is emitted from the probe tip. The probe acts as both the transmitter and receiver of ultrasound energy.
- Some of the energy is reflected back toward the probe in the form of echoes. Measurement data can be calculated based on the time it takes the echoes to travel back to the probe from the eye and the preset converted velocity.
- The time from the echo for the corneal epithelium to the echo for a measuring object is measured. The length of a biological object is calculated using a set conversion value for the speed of sound.

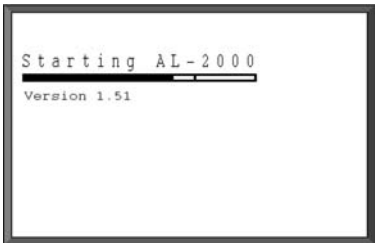
$$L = V \times t/2$$

where L = length of the biological object
V = converted sound speed
t = measuring time

- The axial length and corneal thickness measurement are acquired automatically and do not depend on the operator's experience and capability.
- IOL power calculation can be performed immediately after measuring the axial length. Six standard IOL formulae are provided.
- The instrument can store axial length, corneal curvature and implanted IOL data, on the basis of which personal lens constants may be determined.

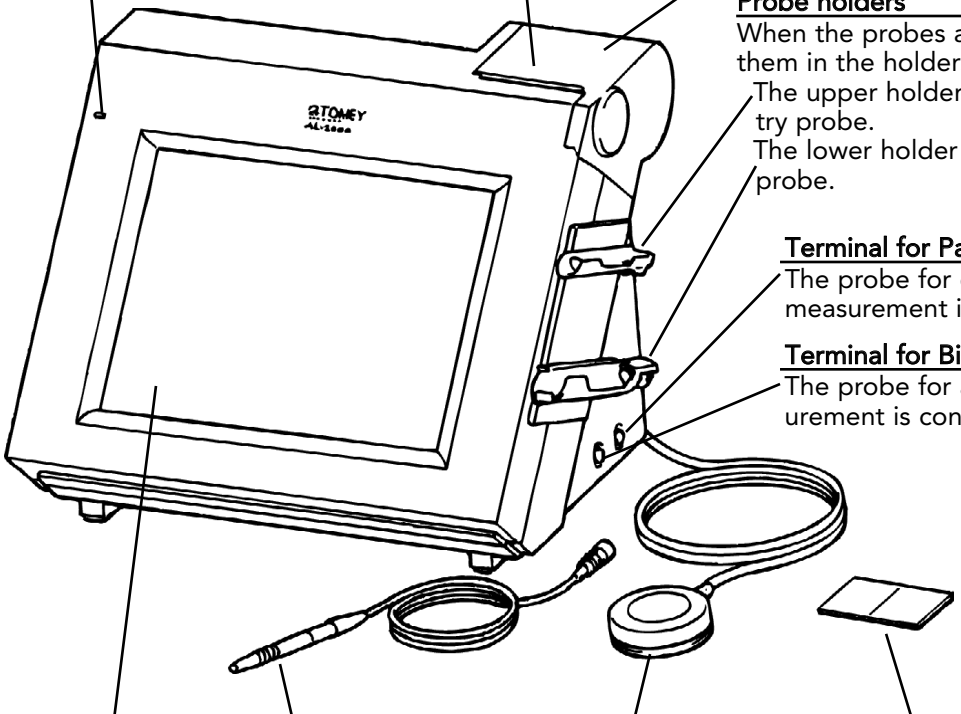
1.4 Software Version

The version of the installed software appears on the monitor when the instrument is turned on.



2. COMPONENTS

2.1 Front and right side of AL-2000



Printer
Prints measured data and calculated results

Power indicator
Lit when power is on.

Printer Cover
Remove the cover in order to replace the printer paper.

Probe holders
When the probes are not in use, place them in the holders.
The upper holder is for the pachymetry probe.
The lower holder is for the biometry probe.

Terminal for Pachymetry Probe
The probe for corneal thickness measurement is connected here.

Terminal for Biometry Probe
The probe for axial length measurement is connected here.

Biometry probe
Use for axial length measurement.

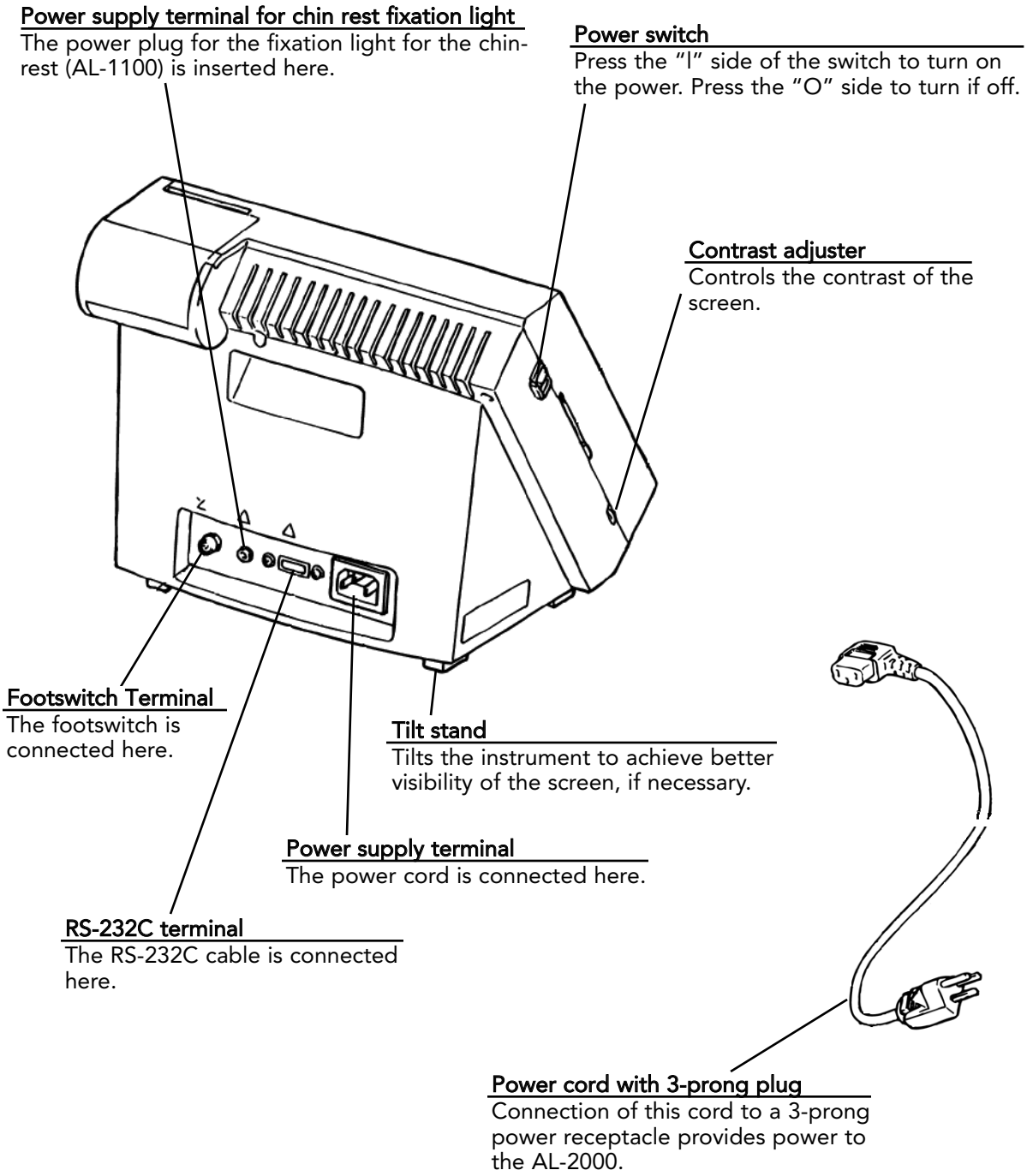
Memory card
Stores acquired data.

Footswitch
Depress to acquire data in the manual measurment mode

Screen (touch panel)
Measurement data and other information are displayed on the screen. The instrument is operated by touching the keys.

2.1 Front and right side of AL-2000

2.2 Back and left side of AL-2000



3. SETUP

3.1 Safety precautions

- ALWAYS clean the probe tip before taking a measurement on a human eye (see section 10.2.1).
- NEVER use the probe if there is any visible damage to its tip. Such use may cause an incorrect measurement and/or damage to the cornea.

- This instrument is designed exclusively for ophthalmic use. DO NOT use the instrument for any purpose other than ophthalmic use.
- DO NOT use any cables or memory cards other than those specified in this manual. Such use may result in damage to the instrument.

3.2 Preparing the instrument for use

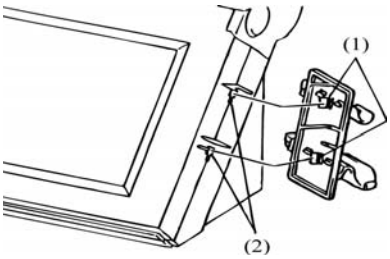
3.2.1 Installation Site

- Ascertain that the power receptacle is electrically grounded and be sure to use the 3-prong power cord provided.
- Do not install the instrument in a location where it might be exposed to moisture or chemicals.
- Do not install the instrument in a place where it is subject to adverse conditions, such as direct sunlight, high temperature, excessive humidity, dust, sulfur or salt.
- Ascertain that any adverse factors such as excessive slope, vibration and impact will not endanger the instrument (including during transportation).
- Do not put anything on top of the instrument.
- Make sure that there is no equipment that generates a strong magnetic field near the instrument.

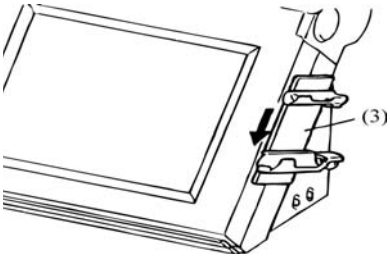
Note Strong magnetism may cause interference and may result in incorrect measurement.

3.2.2 Connection of accessories

a) Inserting the probe holder

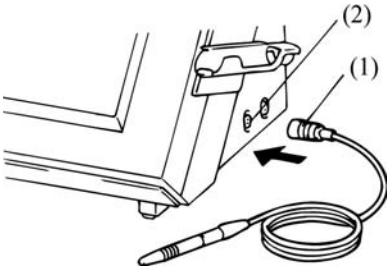


1. Insert the protruding rectangular tabs (1) on the probe holder into the holes (2) on the right side of the instrument.



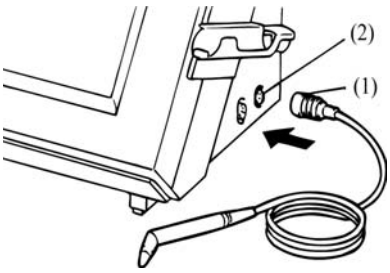
2. Push inward on the center of the probe holder (3) and pull it downward to lock it in place.

b) Connecting the biometry probe



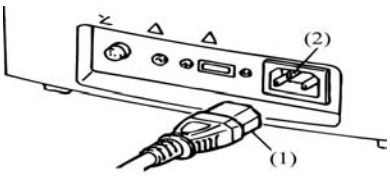
Plug the biometry probe connector (1) into the terminal (2) labeled BIO on the right side of the instrument. When it is properly inserted, you will hear it click.

c) Connecting the pachymetry probe



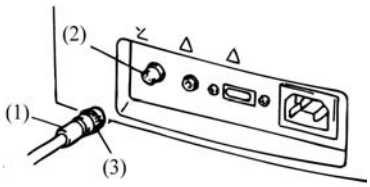
Plug the pachymetry probe connector (1) into the terminal (2) labeled PACHY on the right side of the instrument. When it is properly inserted, you will hear it click.

d) Connecting the power cord



Plug the power cord connector (1) into the terminal (2) on the back of the AL-2000

e) Connecting the foot switch

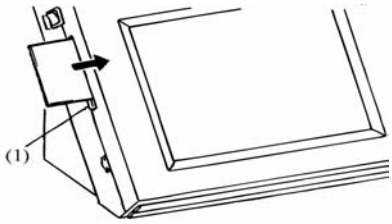


1. Plug the connector (1) for the foot switch to the terminal (2) labeled FOOT SW on the back of the AL-2000. Line up the slot of the connector with the tab on the terminal.
2. To secure the connector, turn the locking ring (3) until you hear it click into place.

f) Inserting and removing the memory card

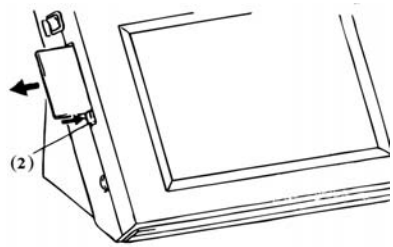
Notes

- **Before using the memory card for the first time, set the battery in accordance with the Instruction Manual for Memory Card (located in the box that contains the card). Follow the instructions for BN-HSR series.**
- **Since the memory card pops quickly out of the slot when removed, hold the edge of the card when pressing the button for card removal.**



Inserting the card:

Hold the front of the memory card toward you and insert it into the slot until the card is aligned with the removal button (1).



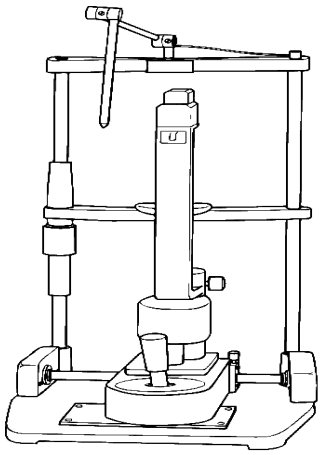
Removing the card:

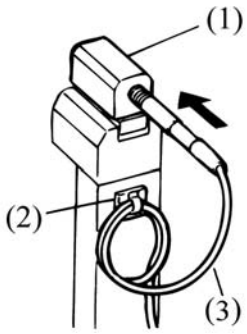
Remove the memory card by pressing the button (2).

3.2.3 Chin rest installation (AL-1100)

An optional chin rest with a fixation light is available for use when measuring axial length.

a) Installing the chin rest



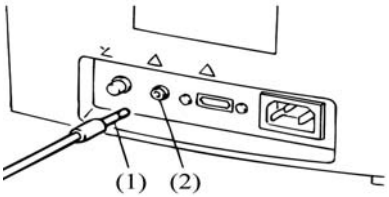


The entire chin rest apparatus is shown in the upper figure. The lower figure shows a larger view of the top portion.

1. Grasp the slider (1) on both sides to immobilize it.
2. From the operator's side, carefully insert the biometry probe into the slider until it locks into place. (Be careful not to damage the eye contact area of the probe.)
3. Coil the probe cord twice (as shown) and secure it with the cord hook (2). The cord length (3) from the probe to the hook should be approximately 20 cm to prevent tension on the cord when the slider is moved forward during measurement.

Note Make sure that the slider moves smoothly.

b) Connecting the fixation lamp power plug



Insert the power plug (1) for the chinrest fixation lamp into the terminal (2) labeled "FIX LIGHT" on the back of the AL-2000.

The fixation lamp lights up when the AL-2000 power is turned on.

4. BIOMETRY (AXIAL LENGTH MEASUREMENT)

WARNING

- ALWAYS clean the probe tip before taking a measurement on a human eye (see section 10.2.1).
- NEVER use the probe if there is any visible damage to its tip. Such use may cause an incorrect measurement and/or damage to the cornea.

CAUTION

- As with any ultrasound instrument, it is recommended that the exposure be kept as low as reasonably achievable (ALARA).

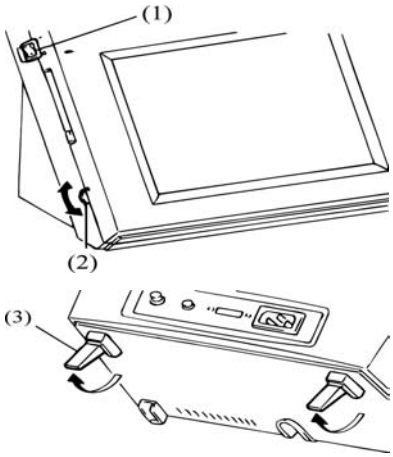
Notes

Before turning on the power:

- Make sure that the power plug is properly connected to the receptacle.
- Make sure the biometry probe is properly connected.

4.1 Biometry Mode Setup

4.1.1 Turning on power and initial adjustments



1. Turning on the power switch (1) at the upper left side of the instrument initiates self-checking of the probe. If the biometry probe is not detected (i.e., no probe or pachymetry probe connected), the message "*Probe Check ... NG*" (no good) will be presented.

2. Adjust the contrast of the screen with the contrast adjuster (2).

3. Tilt the screen forward by pulling out the "legs" (3) on the bottom of the instrument, if desired.

Note

If the instrument starts up in Pachymetry mode, to change to Biometry mode:

a. Press the UTILITY button at the bottom of the screen.
b. Press the AL button near the bottom of the screen.
c. Press the OK button to the right of the AL button.

Note

If the screen is not touched for approximately 3 minutes, the automatic power saving function is activated and the screen will become dark. To re-illuminate the screen, touch it.

4.1.2 Description of Windows

a) Measurement window

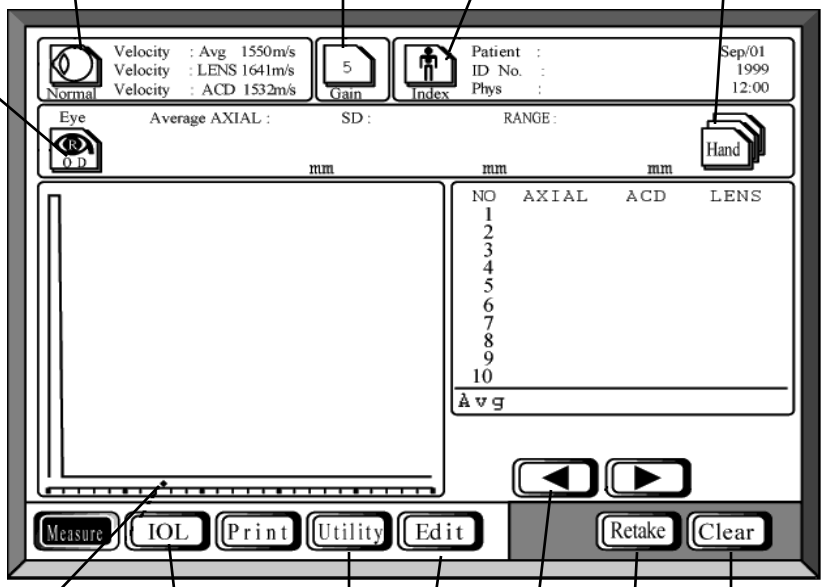
Eye type/converted velocity
Displays the eye type to be measured and the converted velocity.

Patient, Physician, Date & Time
Displays the patient's name and ID number, the physician's name and the date and time.

Eye (R/L)
Displays the eye to be measured (right or left).

Gain
Displays the gain. Press to change (8 levels).

Measurement mode
Automatic (Hand/Chin) and manual measurement modes are available.



Retinal waveform cursor selection
The waveform to the right of this cursor is taken as the retinal waveform.

Clear key
Deletes the measurement data of both eyes.

Retake key
Deletes the measurement data of right (R) or left (L) eye.

IOL key
Press to enter the IOL calculation mode.

Utility key
Press to display to Utility window.

Retinal waveform cursor shift key
Press to shift the position of the retinal waveform cursor.

Edit key
Press to display the measurement review window.

b) Measurement review window (1)

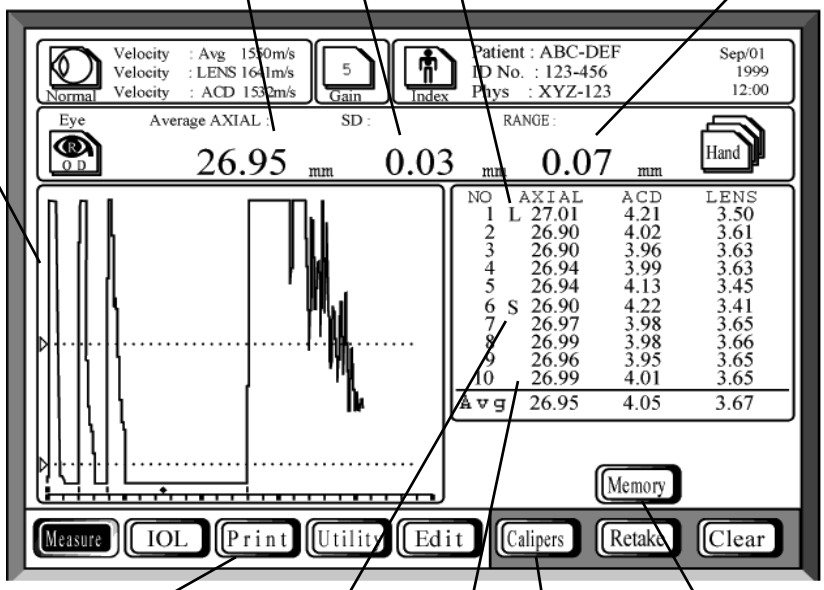
Standard deviation
Standard deviation of axial length measurements.

Mean axial length
Mean of the axial length measurements.

Range
Difference between minimum and maximum axial length measurement.

A-mode waveform
A-mode waveform is displayed in real time during measurement.

L
Maximum axial length.



Print key
Press to obtain a printout of the data.

S
Minimum axial length.

Memory key
Press to store data on the memory card.

Caliper key
Press to switch to caliper window.

Measured data
Each row displays memory number, axial length, anterior chamber depth and lens thickness for each individual measurement. The last row displays the mean of all measurements.

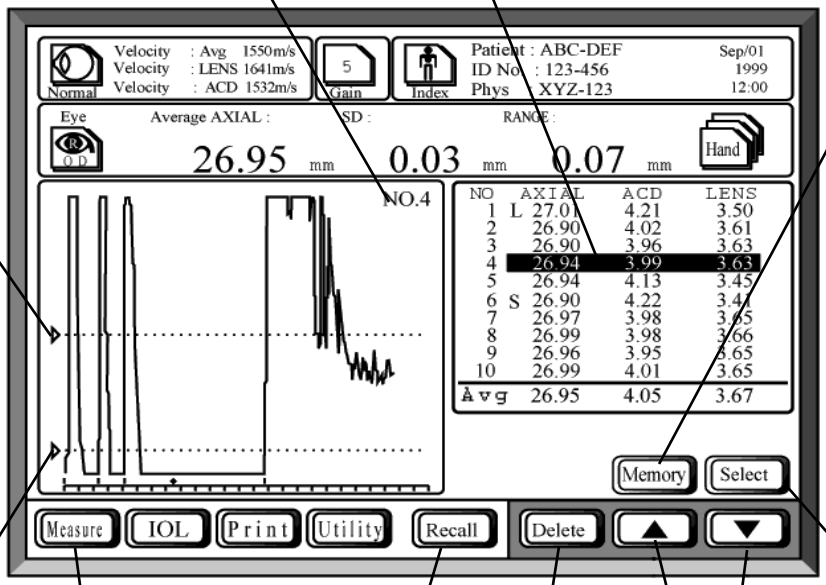
c) Measurement review window (2)

Selected measurement
Displays the waveform for the selected measurement and indicates the memory number.

Level cursor/level line
In the automatic measurement mode, the measurement data are acquired only when there are crests rising above the cursor level.

Display selection
The selected measurement is highlighted.

Memory Key
Press to store data on the memory card.



Measure key
Press to change to the measurement window.

Delete key
Deletes data.

Select key
Select Axial length measurement to be used for IOL calculation.

Measurement cursor/measurement line
Distances are measured from the level of this cursor.

Recall key
Press to retrieve data that were deleted using the Delete key.

Selection keys
Used to select the measurement data to be displayed.

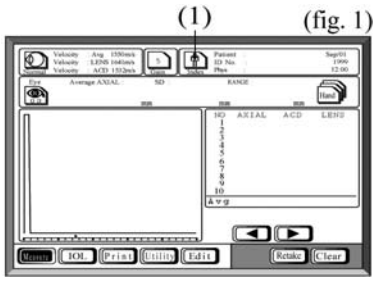
4.1.3 Setting the measurement conditions

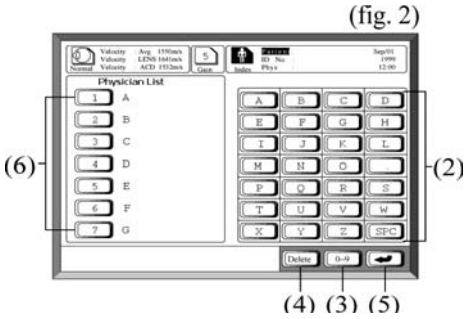
Before measuring axial length, the following measurement conditions should be set:

- Patient name, patient ID and physician name
- Eye (right/left)
- Eye type
- Gain
- Measurement mode
- Retinal waveform

a) Patient name, patient ID number and physician name

Note **Stored data are controlled by ID numbers. If you plan to store data on the memory card, you must enter a patient ID number.**



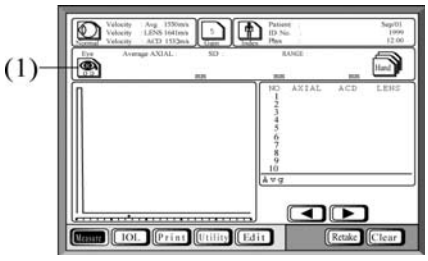


Up to 10 letters can be entered for each item.

1. Touch the **Index** key (1) on the measurement window (fig. 1) to display the Name/ID entry window (fig. 2).
2. Touch the number keys and the alphabetic character keys (2) to enter the patient's name, ID number and physician's name. If the physician's name is already registered in the Physician List, it can be selected by pressing the corresponding number (6).

   To switch between letters and numbers, use the switch-over key (3). In the event of an erroneous entry, touch the **Delete** key (4).
3. To set the entered value and advance to the next entry, touch the **Return** key (5). The cursor location indicates the category of the next entry.
4. Touch the **Index** key (1) again to return to the measurement window (fig. 1).

b) Setting the eye to be measured



Touch the **Eye** key (1) to select the eye you wish to measure (right or left).

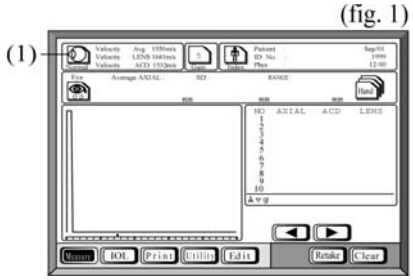
The right eye (OD) or the left eye (OS) is selected alternately each time the **Eye** key is touched.

c) Setting the eye type and converted velocity

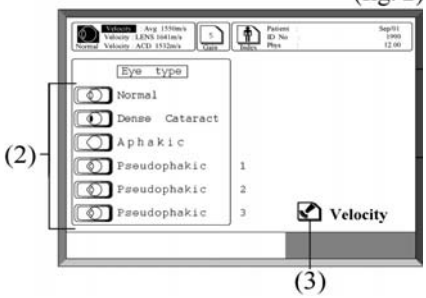
The AL-2000 can be set to measure the following types of eyes:

- Normal: Select when the lens nucleus of the patient's eye is rather soft, e.g., incipient cataract.
- Dense cataract: Select when the lens nucleus of the patient's eye is rather hard, e.g., hypermature cataract.
- Aphakic: Select when the patient's eye is aphakic.
- Pseudophakic: Select when the patient's eye is pseudophakic.

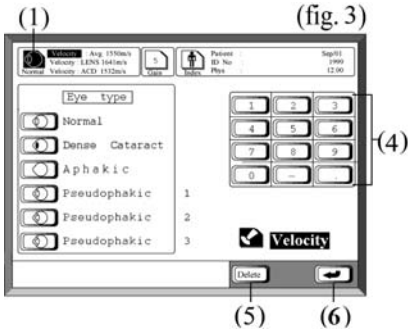
(fig. 1)



(fig. 2)



(fig. 3)



1. Touch the **Eye type** key (1) on the measurement window (fig. 1) to display the window shown in fig. 2.
2. Select the eye type (2) by touching the desired option.
3. Touch the **Velocity** key (3) to change the converted velocity for the selected eye type (fig. 3).
4. Enter the converted velocity using the number keys (4). See range of converted velocities below.

   In the event of an erroneous entry, touch the **Delete** key (5).
5. Press the **Return** key (6) to set the entered value and advance to the next entry. The cursor location indicates the category of the next entry.
6. Press the **Velocity** key to return to the screen shown in fig. 2.
7. Press the **Eye type** key (1) to return to the measurement window (fig. 1).

For aphakic eyes, ACD and LENS cannot be measured. With a dense cataract, the instrument sometimes does not identify a wave shape behind the cataract due to multiple echoes, and nothing is shown in the LENS column.

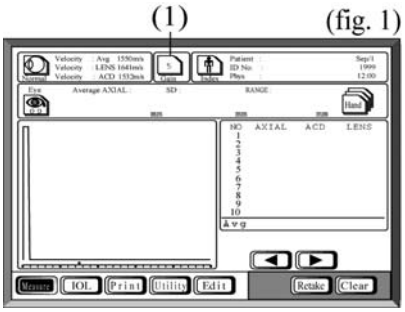
Range of Converted Velocity

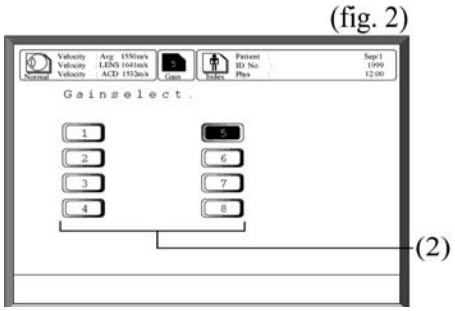
- Normal
  Average axial length velocity: 1,500 m/s - 1,600 m/s
  Lens velocity: 1,540 m/s - 1,740 m/s
  Anterior chamber velocity: 1,430 m/s - 1,630 m/s
- Dense cataract
  Average axial length velocity: 1,500 m/s - 1,600 m/s
  Lens velocity: 1,540 m/s - 1,740 m/s
  Anterior chamber velocity: 1,430 m/s - 1,630 m/s

Range of Converted Velocity (continued)

- Aphakic
  Average axial length velocity: 1,430 m/s - 1,630 m/s
- Pseudophakic
  IOL velocity: 800 m/s - 3,000 m/s
  Average velocity (BIO): 1,000 m/s - 2,000 m/s
  Anterior chamber velocity: 1,430 m/s - 1,630 m/s
  IOL thickness: 0.10 mm - 4.00 mm

d) Setting the gain

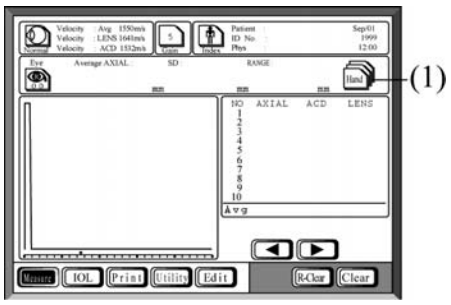




Set the gain level based on the waveform amplitude. The higher you set the gain, the larger the amplitude will be.

1. Touch the **Gain** key (1) on the measurement window (fig. 1) to display the window shown in fig. 2.
2. Touch one of the Gain level keys (2) to set the gain level. The screen will return to the measurement window (fig. 1).

e) Setting the measurment mode



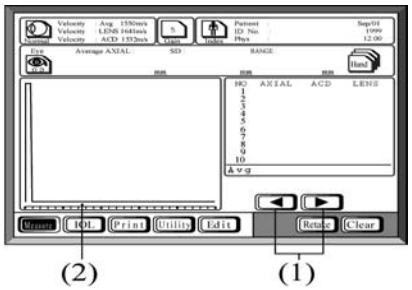
Set the measuring mode by touching the **Mode** button (1). Successive presses of the button scroll through the options. There are two automatic modes and one manual mode.

Automatic modes: Measurements are acquired automatically when the probe tip is applied to the cornea.

1. Hand-held measurement: Select if you wish to hold the probe by hand.
2. Chin rest measurement: Select if you wish to use the chin rest.

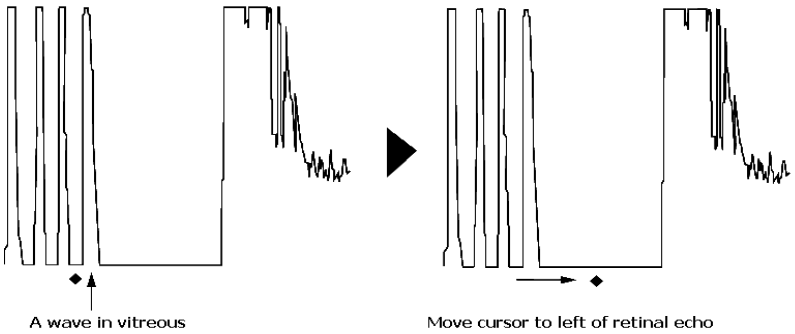
Manual mode: Measurements are acquired by pressing the footswitch. Select when performing biometry on patients from whom it may be difficult to obtain measurements.

f) Selecting the location of the retinal waveform



In the event that a spike occurs between the back of the lens and the retina (e.g., due to a vitreous hemorrhage), manually reposition the retinal cursor (2) by pressing the retinal cursor shift keys (1).

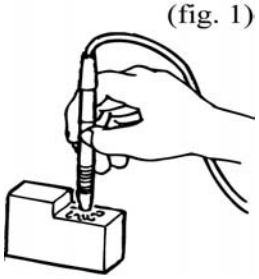
The waveform to the right of this cursor location is taken as the retinal waveform.



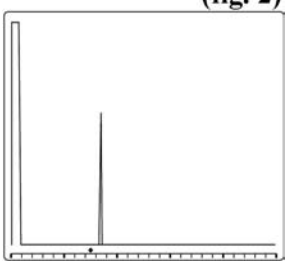
4.1.4 Checking the performance

Check the performance of the AL-2000 by using the biometry test piece (found in the box containing the biometry probe). (See fig. 1.)

(fig. 1)



(fig. 2)



1. Select the following settings:
   Eye type/converted veolcity: Aphakic/1,532 m/s
   Gain: 8
   Measurement mode: Hand-held
2. Apply a drop of water to the upper and to the lower test piece surfaces.
3. Apply the biometer perpendicular to the upper surface. Up to 15 measurements will be automatically taken, each indicated by a beep. When measurement is complete, a higher-pitched beep will sound.
4. Repeat steps 2 and 3 for the lower test piece surface.

Expected results:

Waveform:
A representative waveform is shown in fig. 2.

Average AXIAL value (shown above the waveform):
Upper surface: 22.0 mm ± 2 mm
Lower surface: 16.0 mm ± 2 mm

Note **The biometry test piece is used only for checking the operating performance of the instrument. It cannot be used for determining the precision of the instrument or for calibration of the instrument.**

4.2 Performing Biometry (Axial Length Measurement)

4.2.1 Preparation for measurement

1. Confirm that the measurement conditions have been set.
2. Anesthetize the eye with an appropriate topical anesthetic.
3. When taking measurements using the chin rest, instruct the patient to sit in front of the chin rest. Adjust the height of the chair, the lift table and/or the chin rest to maximize patient comfort.

   When taking measurements holding the probe by hand, instruct the patient to be seated or to lie supine.
4. If the fixation light is used to guide the direction of gaze (when using the chin rest), set it at an appropriate height for the patient to fixate.

Note

- If the patient is relaxed and cooperative, the measurement will be easier and more successful. Prior to taking measurements, explain the purpose and method of measurement to the patient to reduce his/her anxiety.

4.2.2 Measurement methods

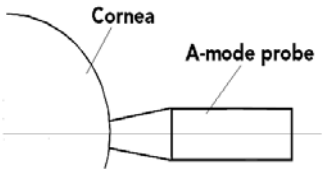
- ALWAYS clean the probe tip before taking a measurement on a human eye (see section 10.2.1).
- NEVER use the probe if there is any visible to its tip. Such use may cause an incorrect measurement and/or damage to the cornea.
- ALWAYS anesthetize the eye with an appropriate topical anesthetic before performing measurements.
- Avoid applying excessive force to the cornea during measurement. Be careful not to push the probe beyond the allowable sliding range when using the chin rest.

Notes

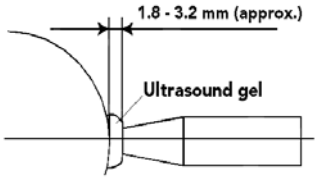
- The converted velocity directly affects the measurement. Ascertain that you have set the desired converted velocity.
- In immersion mode, the ultrasound gel must intervene between the eye contact area of the biometer probe and the cornea so that the distance between the probe and the cornea is approximately 1.8 to 3.2 mm.
- Excessive ultrasound gel may affect the accuracy of the measurement.
- When performing IOL calculation (see Section 4.3), be sure to use quality readings for accuracy.

a) Probe mode

(fig. 1)



(fig. 2)



There are two probe modes:

1. Contact mode

   In Contact mode (fig. 1), the tip of the biometry probe is applied directly to the surface of the cornea.

2. Immersion mode

   In Immersion mode (fig. 2), ultrasound gel is used between the probe and the cornea.

Using both probe modes, the probe should be applied perpendicular to the corneal apex such that the visual axis and the axis of the probe are aligned.

See instructions in section 7.3.6 for selecting the probe mode.

b) Methods of performing measurements

There are two automatic modes, hand-held and chin rest, and one manual mode. Set the measuring mode by touching the **Mode** button (1) as described in section 4.1.3e.

(1) Automatic measurement modes (hand-held and chin rest)

a. If the chin rest is used in contact probe mode, use a slider movement of 2 to 4 mm.

b. When the probe tip is applied to the cornea, the instrument automatically starts taking measurments. When a satisfactory measurement is taken, the instrument makes a "beep" sound.

c. Using the hand-held method, up to 15 measurements in the range of +/- 0.2 mm from the average value are taken. If measurement data are largely scattered, "ERROR" is displayed.

d. Using the chin rest method, measurements are taken until 10 measurements within +/- 0.1 mm of the average value are obtained.

e. When data acquisition is complete, a higher-pitched beep sounds and the waveform for the measurement closest to the average value is displayed.

(2) Manual measurement mode

a. If the chin rest is used in contact probe mode, use a slider movement of 2 to 4 mm.

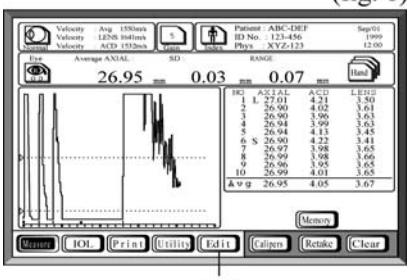
b. Apply the probe tip to the cornea and press the footswitch to acquire a measurement.

c. When a satisfactory measurement is taken, the instrument makes a beep sound. When 10 measurements have been acquired, the instrument makes a higher pitched beep and the waveform for the measurement closest to the average value is displayed.

4.2.3 Data review and selection for IOL calculation

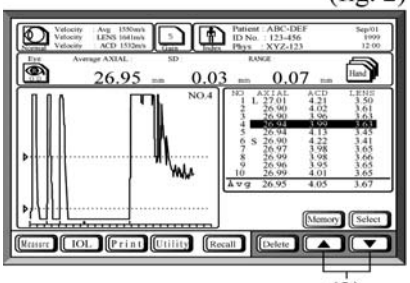
a) Displaying a waveform

(fig. 1)



(1)

(fig. 2)



(2)

The waveforms for each eye of the current patient measurements can be retrieved and reviewed at any time during the measuring process.

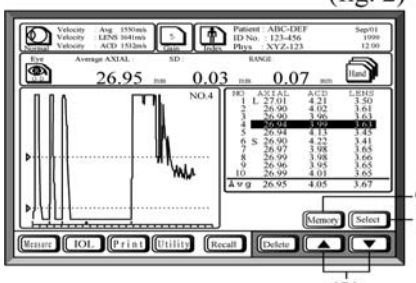
1. Touch the **Edit** key (1) on the measurement window (fig. 1) to display the measurement review window (fig 2). The waveform for the measurement closest to the average is displayed.
2. If you wish to review the waveform for a particular measurement, select the measurement by pressing the up and down arrow keys (2). The selected data will be highlighted and the corresponding waveform will be displayed.
3. Touch the **Measure** key to return to the measurement window and display the average waveform.

b) Selecting data for IOL power calculation

(fig. 1)

(1)

(fig. 2)



(4)
(3)
(2)

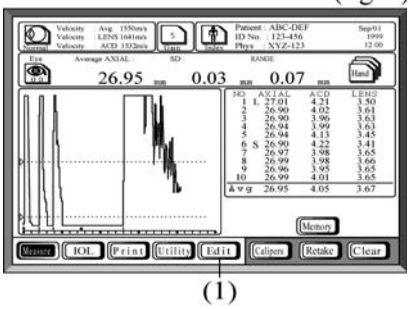
1. If you wish to use the values for an individual measurement for the IOL power calculation rather than the average values, touch the **Edit** key (1) on the measurement window (fig. 1) to display the measurement review window (fig 2). (If a particular waveform is not selected, the mean values are used for IOL power calculation.)
2. Touch the up and down arrow keys (2) to select the measurement data you wish to use.
3. Touch the **Select** key (3) to choose the selected data for IOL power calculation.
4. Touch the **Memory** key (4) to store the data on the memory card.
5. Touch the **Measure** key to return to the measurement window.

If you wish to revert to using the mean values for IOL calculation, after returning to the measurement window, touch the **Memory** key.

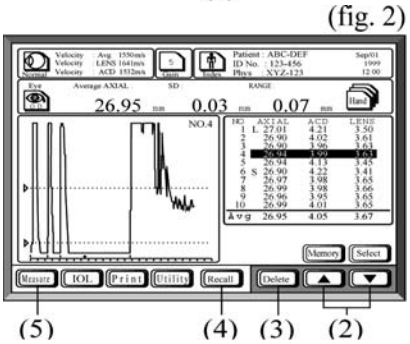
See Section 4.3 for detailed instructions on IOL calculation.

c) Deleting individual measurements

(fig. 1)



(fig. 2)



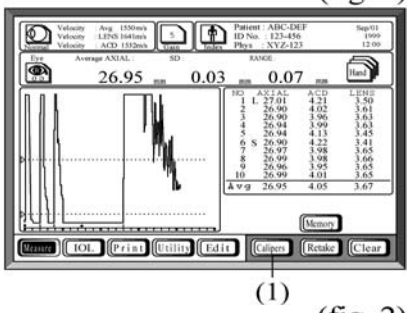
1. Touch the **Edit** key (1) on the measurement window (fig. 1) to display the measurement review window (fig 2).
2. Touch the up and down arrow keys (2) to select the measurement you wish to delete.
3. Delete the data by touching the **Delete** key (3).

   In the event that measurements are accidentally deleted, touch the **Recall** key (4) to recover the data. Once you have exited the measurement review window, however, the data cannot be recovered.
4. Touch the **Measure** key to return to the measurement window.

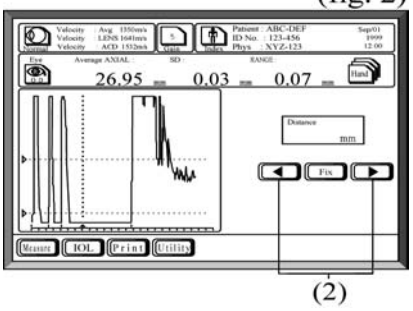
4.2.4 Caliper Function

Note A reading displayed in the caliper mode is an approximation and may be different from the actual reading.

(fig. 1)



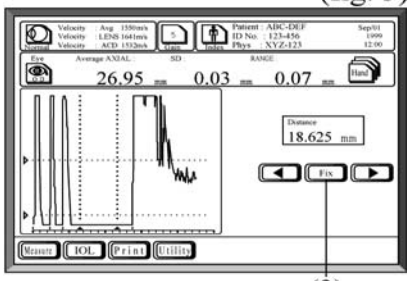
(fig. 2)



After completing measurement, the distance between two points can be measured on the waveform that is closest to the average waveform. In this function, a velocity of 1550 m/s is used.

1. After measurement, touch the **Caliper** key (1) on the measurement window (fig. 1) to enter Caliper mode (fig. 2).
2. Press the right or left arrow key (2) to set the point from which to start measuring, which will be indicated by a vertical dashed line.
3. Touch the **Fix** key (3) to set the location (fig. 3, next page).
4. Touch the right or left arrow key again to set the second measurement location, which will be indicated by a second vertical dashed line. The distance between the two points will be displayed in real time.

(fig. 3)

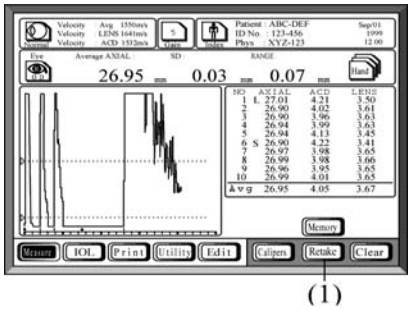


4. By pressing the **Fix** key, the caliper can be switched alternativey between the two measurement locations, and the location can be changed using the arrow keys.
5. Touch the **Measure** key to return to the measurement window.

4.2.5 Deleting data

Note Once data have been deleted, they cannot be restored. Any deletion must, therefore, be done carefully.

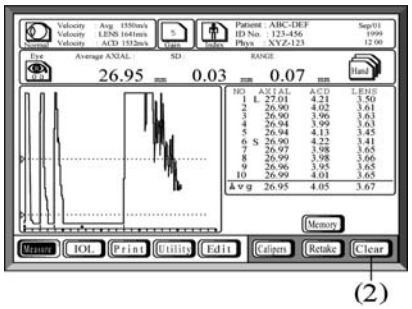
a) Deleting all data for one eye



To delete all data currently displayed for either the right or the left eye, press the **Retake** key (1) until you hear a beep.

NOTE: This deletes currently acquired data from the screen; it does not delete stored data from the memory card. (To delete data from the memory card, see section 7.3.4d).

b) Deleting all data for both eyes



To delete all data for both eyes of the current patient, press the **Clear** key (2) until you hear a beep sound. The patient's name and ID number will be deleted from the screen. The eye type will default to Normal and the selected eye will default to the right eye (OD).

NOTE: This deletes currently acquired data from the screen; it does not delete stored data from the memory card. (To delete data from the memory card, see section 7.3.4d).

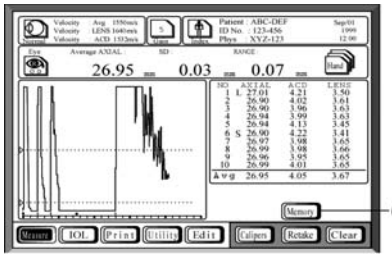
4.2.6 Storing data

Notes

- Before storing data, make sure that a memory card is inserted in the slot.
- All data are managed using patient ID numbers. Therefore, if you plan to store data, you must enter a patient ID number.
- The PC memory card used with the AL-2000 is an SRAM type card. Therefore, an SRAM type card reader, not a Flash Memory reader, must be used. If a Flash Memory reader is used, data stored on the memory card may be corrupted.

The memory card that came with the AL-2000 can store data from both eyes of 237 patients. The following binocular data will be stored:

- Average axial length (Average AXIAL)
- Average anterior chamber depth (Average ACD)
- Average lens thickness (Average LENS)
- Waveform that is closest to the average waveform



After measurements have been acquired, press the **Memory** key (1) to store the data.

Be sure to enter a patient ID number when storing data on the memory card. (See Section 4.1.3a for details.)

To display stored axial length data, compile IOL data and display personal lens constants, see Section 7.3.4. To display graphs of biometry and IOL data, see Section 7.3.5.

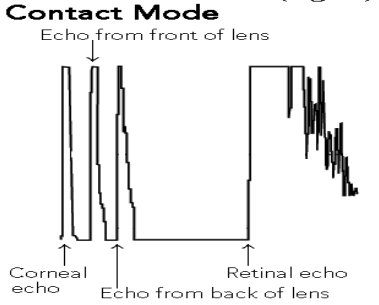
4.2.7 Acceptable waveforms

In the automatic measurement modes, waveforms are evaluated and acquired only if the following criteria are met:

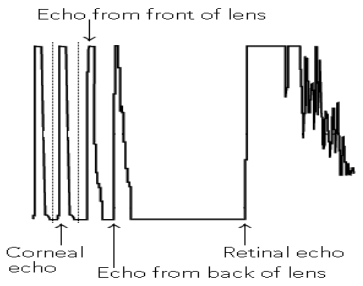
1. The following crests rise above the level cursor:
   - Normal: The crests of the back and front of the lens and of the retina.
   - Dense cataract: The crest of the front of the lens and of the retina.
   - Aphakic: The crest of the retina.
   - Pseudophakic: The crests of the front of the IOL and of the retina.
2. The retinal waveform stands upright.
3. The variability among measurements is low.

In immersion mode, the echo from the front of the lens is located between 1.8 mm and 3.2 mm from the initial echo (leftmost dotted line in fig. 2).

(fig. 1)



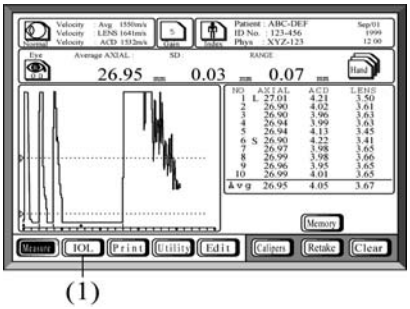
(fig. 2)



4.3 IOL Power Calculation

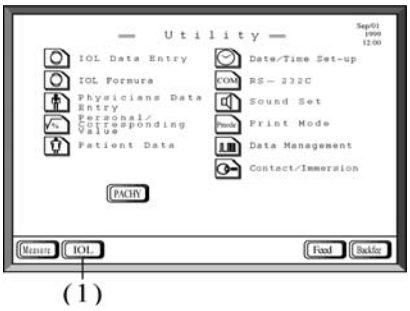
4.3.1 Changing to IOL power calculation mode

a) From the Biometry mode



If you wish to calculate IOL power after axial length measurement, touch the IOL key (1) to enter the IOL power calculation mode.

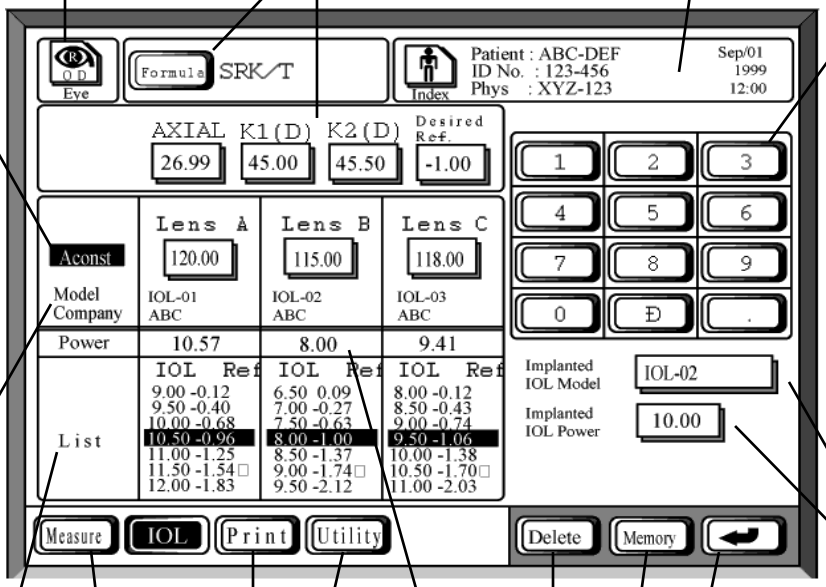
b) From the Utility mode



If you are in the Utility mode and wish to calculate IOL power, touch the IOL key (1) to enter the IOL power calculation mode.

4.3.2 Description of IOL power calculation window

a) Entry of data and display of calculation results



IOL constants
- A-const: SRK II, SRK/T, Haigis standard
- a0, a1, a2: Haigis optimized
- Surgeon factor (SF): Holladay
- Postoperative anterior chamber depth (ACD): Hoffer-Q

Patient, Physician, Date & Time
Displays the patient's name and ID number, the physician's name and the date and time.

Calculation data
- Axial: Axial length
- K1, K2: Keratometry readings
- Desired Ref: Desired postoperative refraction.

Eye (R/L)
Displays the eye for which IOL power is to be calculated (right or left).

IOL Formulae
Displays the selected IOL calculation formula.

Number keys
Enter numerical values using these keys.

IOL Model/ Manufacturer
Enter and display IOL model name and manufacturer.

Print key
Initiates printout.

Delete key
Deletes incorrect data.

Implanted IOL
Displays model name and refractive power of selected IOL.

Calculation results
Displays results of IOL power calculation

IOL & predicted postop refraction
Calculated IOL power and predicted postoperative refraction.

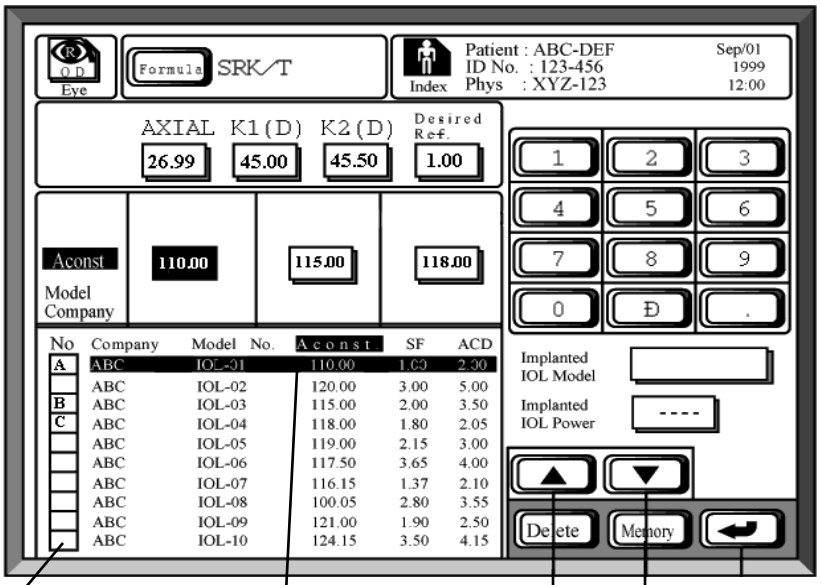
Return key
Registers entered data.

Utility key
Changes to Utility window.

Measure
Changes to axial length measurement mode.

Memory key
Stores calculation results on the memory card.

a) Display of IOL data list



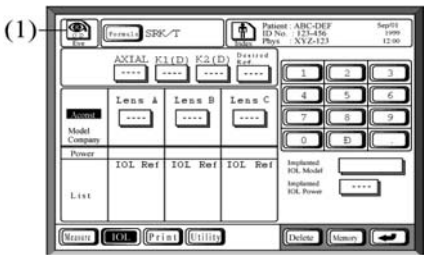
A, B, C
Indicate display location of selected lenses.

IOL data selection key
Selects the desired IOL data.

IOL data
Lists entered IOL models and displays lens constants for each model.

4.3.3 Setting the calculation conditions

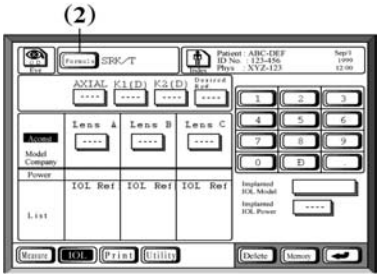
a) Setting the eye to be calculated



Touch the **Eye** key (1) to select the eye for which you wish to calculate IOL power (right or left).

The right eye (OD) or the left eye (OS) is selected alternately each time the **Eye** key is touched.

b) Selecting the IOL formula

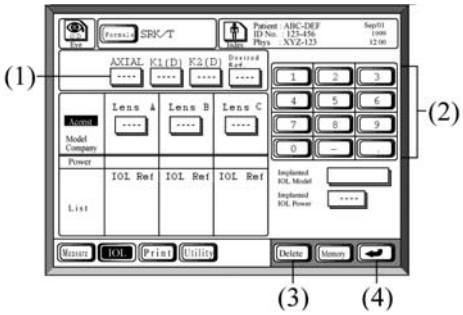


To select the desired IOL formula, consecutively touch the Formula key (2) to scroll through the formulas that have been selected using the IOL Formula utility (see section 7.3.2). Up to five formulae may be selected.

Six pre-set formulae are available: SRK II, SRK/T, Holladay, Hoffer-Q, Haigis standard and Haigis optimized (see section 7.3.2.)

4.3.4 Data entry for IOL calculation

a) Axial length (Axial)

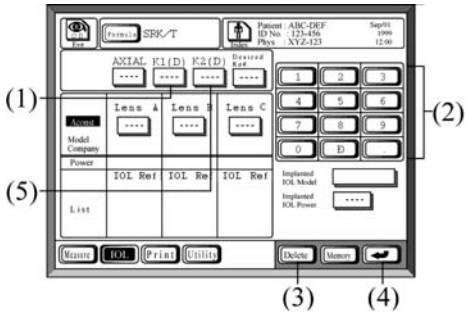


Following axial length measurement, the data will be automatically entered. Therefore, no data entry is required.

If axial length measurement has not been performed using the AL-2000, follow these steps to enter axial length:

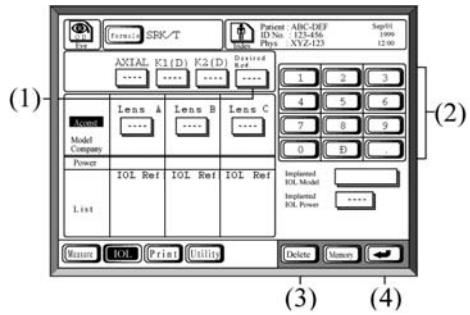
1. Prepare to enter axial length by touching the **Axial** key (1). The databox will be reverse highlighted.
2. Touch the number keys (2) to enter the axial length value. The acceptable range is 15 - 40 mm.
   In the event of an erroneous entry, touch the **Delete** key (3).
3. Complete the data entry by touching either the **Return** (4) or the **Axial** (1) key.

b) Keratometry readings (K1/K2)



1. Prepare to enter the K values by touching **K1** (1). The databox will be reverse highlighted.
2. Touch the number keys (2) to enter the first K value. The acceptable range is 30.00 - 60.00 D or 5.00 - 11.00 mm.
   In the event of an erroneous entry, touch the **Delete** key (3).
3. Complete the data entry by touching the **Return** key (4) or the **K1** key (1).
4. Touch the **K2** key (5) to enter the second K value and proceed with the same procedure as for K1.
   Note: Either the flat K or the steep K may be entered in either diopters or millimeters.

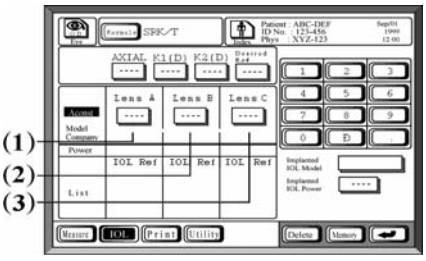
c) Desired postoperative refraction (Desired Ref.)

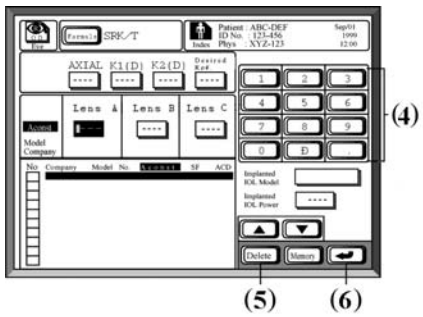


1. Prepare to enter the desired postoperative refraction by touching the **Desired Ref.** key (1). The databox will be reverse highlighted.
2. Touch the number keys (2) to enter the data. The acceptable range is -10.00 - +10.00 D.
   In the event of an erroneous entry, touch the **Delete** key (3).
3. Complete the data entry by touching either the **Return** key (4) or the **Desired Ref.** key (1).

d) Constants (Aconst., SF, ACD)

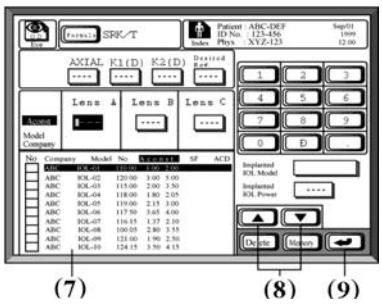
Values for A constant, Surgeon's Factor and Anterior Chamber Depth constant may be entered on the IOL calculation window, or stored IOL models with pre-entered constant values may be selected from the IOL data list (see Section 7.3.1). IOL power may be calculated for up to three different lens models.





To enter values on the IOL calculation window:

1. Prepare to enter values by touching the **Lens A** key (1), the **Lens B** key (2) or the **Lens C** key (3). The databox will be reverse highlighted.
2. Touch the number keys (4) to enter values. The acceptable ranges are:
   Aconst: 100.00 - 130.00
   SF: -5.00 - +10.00
   ACD: 0.00 - 10.00
   (For the Haigis optimized formula, a0, a1 and a2 must be entered using the IOL Data Entry utility; see section 7.3.1.)
   In the event of an erroneous entry, touch the **Delete** key (5).
3. Complete the data entry by touching the **Return** key (6).

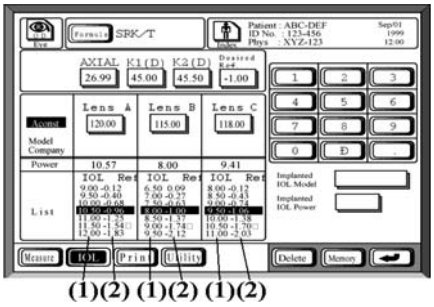


To select pre-entered lens models from the IOL data list:

1. Prepare to enter a lens model by touching the **Lens A** key (1), the **Lens B** key (2) or the **Lens C** key (3).
2. Select the IOL with the desired parameters from the IOL list (7) using the up/down arrow keys (8).
3. Touch the **Return** key (9) to enter the selection. The constant value and the name of the IOL model and manufacturer will be displayed for the selected IOL.

4.3.5 IOL power calculation

a) Automatic power calculation



When all necessary values have been entered, IOL power calculations will be performed automatically and results will be displayed.

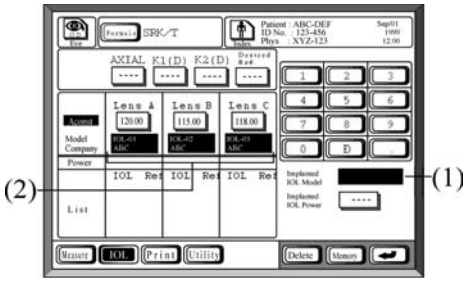
Seven IOL power options (1) and the resulting refraction for each (2) will be displayed for each lens. The IOL power that produces the refractive result closest to the specified desired refraction (Desired Ref.) will be highlighted.

Notes

In the calculation process, small errors may occur due to the number of significant figures.

In some IOL formulas, an imaginary number may be generated due to square root calculations and the result may be displayed as an ERROR.

b) Registration of the IOL model name

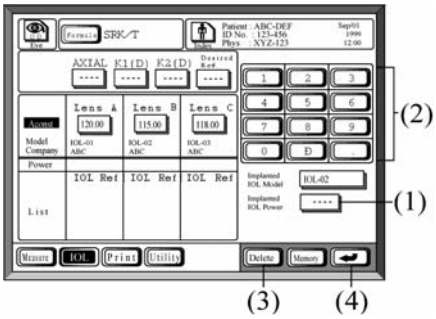


If you wish to store the IOL model that you have selected for the patient:

1. Touch the **Implanted IOL Model** key (1).
2. Touch the highlighted area where IOL model and manufacturer name are displayed (2) to store the IOL model name.

The IOL model name will be stored on the memory card and may be used for statistical data analysis (provided that IOL power is also stored, as described below).

c) Entering IOL power



If you wish to store the IOL power of the lens that you have selected for the patient:

1. Touch the **IOL Power** key (1).
2. Enter the IOL power using the number keys (2). The acceptable range is 0.01 - 50.00 D.

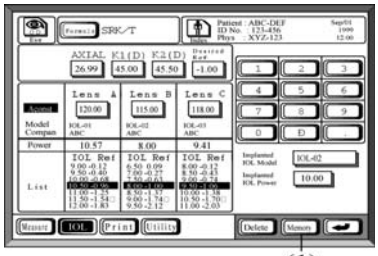
   In the event of an erroneous entry, touch the **Delete** key (3).
3. Touch the **Return** key (4) or the IOL key (1) to register the IOL power.

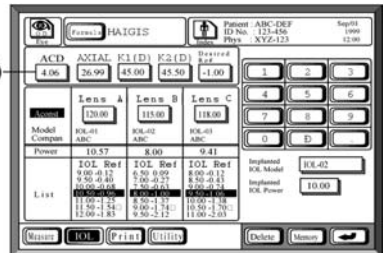
The IOL power will be stored on the memory card and may be used for statistical data analysis (provided that IOL Model is also stored, as described above).

4.3.6 Storing patient data

Notes

- Before storing data, make sure that a memory card is inserted in the slot (see section 3.2.2f).
- All data are managed using patient ID numbers. Therefore, you must enter a patient ID number before storing data (see section 4.1.3).
- The PC memory card used with the AL-2000 is an SRAM type card. Therefore, an SRAM type card reader, not a Flash Memory reader, must be used. If a Flash Memory reader is used, data stored on the memory card may be corrupted.





The memory card that came with the AL-2000 can store data from both eyes of 237 patients.

Touch the **Memory** key (1) to store the following data:

- Axial length (AXIAL)
- Keratometry values (K1/K2)
- Desired postoperative refraction (Desired Ref.)
- Lens constants (Aconst, SF, ACD*)
- Model name of IOL (IOL Model)
- Refractive power of IOL (IOL Power)

*The anterior chamber depth value (2) is used only for the Haigis standard and Haigis optimized formulas.

NOTE: In the Data Management utility (see section 7.3.5), patient data are compiled according to IOL Model name. Therefore, if you plan to perform statistical analysis of surgical outcomes, be sure to enter the Implanted IOL model (and power) before storing patient data.

5. PACHYMETRY (CORNEAL THICKNESS MEASUREMENT)

WARNING

- ALWAYS clean the probe tip before taking a measurement on a human eye (see section 10.2.1).
- NEVER use the probe if there is any visible damage to its tip. Such use may cause an incorrect measurement and/or damage to the cornea.

CAUTION

- As with any ultrasound instrument, it is recommended that the exposure be kept as low as reasonably achievable (ALARA).

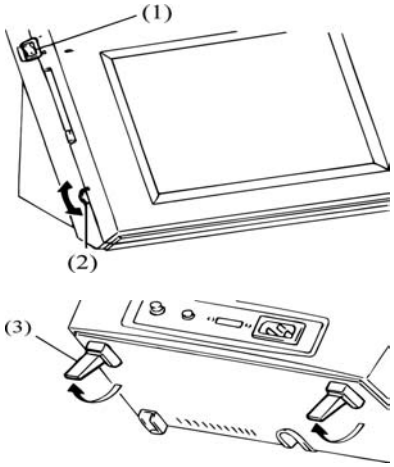
Notes

Before turning on the power:

- Make sure that the power plug is properly connected to the receptacle.
- Make sure the pachymetry probe is properly connected.

5.1 Pachymetry Mode Setup

5.1.1 Turning on power and initial adjustments



1. Turning on the power switch (1) at the upper left side of the instrument initiates self-checking of the probe. If the pachymetry probe is not detected (i.e., no probe or biometry probe connected), the message "*Probe Check ... NG*" (no good) will be presented.
2. Adjust the contrast of the screen with the contrast adjuster (2).
3. Tilt the screen forward by pulling out the "legs" (3) on the bottom of the instrument,

Note

If the instrument starts up in Biometry mode, to change to Pachymetry mode:

a. Press the UTILITY button at the bottom of the screen.
b. Press the PACHY button near the bottom of the screen.
c. Press the OK button to the right of the AL button.

Note

If the screen is not touched for approximately 3 minutes, the automatic power saving function is activated and the screen will become dark. To re-illuminate the screen, touch it.

5.1.2 Description of Windows

a) Map mode window

Patient, Physician, Date & Time
Displays the patient's name and ID number, the physician's name and the date and time.

Converted velocity/Bias value
Displays the converted velocity and the bias rate or compensated bias value.

Measuring range
Displays the measurement range.

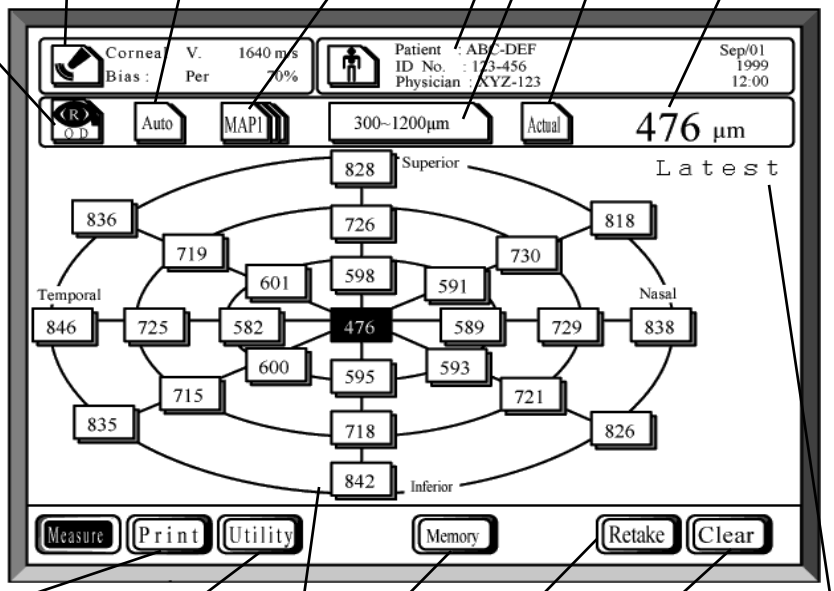
Eye (R/L)
Displays the eye to be measured (right or left).

Measurement mode
Displays the measurement mode.

Method of data presentation
Indicates whether the value is an actual value or a biased value.

Measurement method
Displays the method of measurement.

Selected value
Displays the measurement that is currently selected.



Print key
Press to initiate printing.

Clear key
Deletes the measurement data of both eyes.

Utility key
Press to display the Utility window.

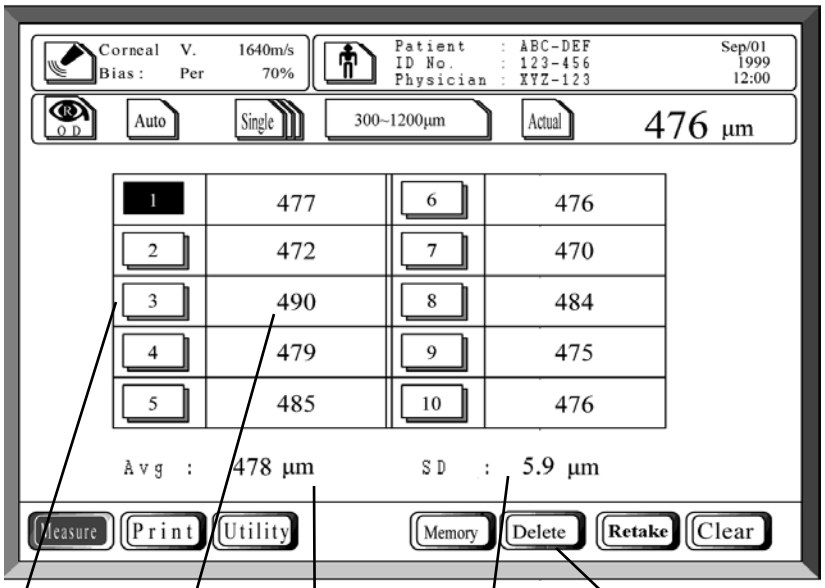
Retake
Deletes the measurement data of right (R) or left (L) eye.

Memory key
Stores the data on the memory card.

Display of data
Indicates whether the average values, minimum values or latest (most recent) values are displayed.

Map display
Displays the measurement data in order of selected elements.

b) Single mode window



Memory number
Displays the measurement number.

Measurement data
Displays the measurement data.

Mean
Displays the mean of the pachymetry measurements.

Standard deviation
Displays the standard devation of the pachymetry measurements.

Delete key
Deletes the selected measurement.

5.1.3 Setting the Measurement Conditions

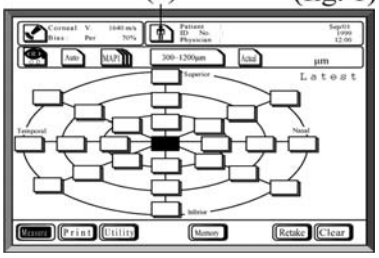
Before measuring corneal thickness, the following measurement conditions should be set:

- Patient name, patient ID and physcian name
- Eye (right/left)
- Converted velocity and bias mode
- Acquisition mode
- Measurement mode
- Measurement range
- Measurement display
- Data presentation mode

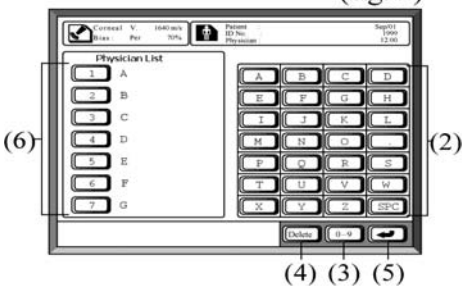
a) Patient name, patient ID number and physician name

Note **Stored data are controlled by ID numbers. If you plan to store data on the memory card, you must enter a patient ID number.**

(1) (fig. 1)



(fig. 2)

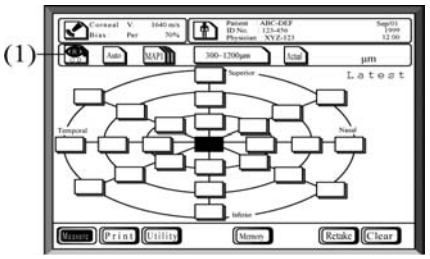


Up to 10 letters can be entered for each item.

1. Touch the **Index** key (1) on the measurement window (fig. 1) to display the Name/ID entry window (fig. 2).
2. Touch the number keys and the alphabetic character keys (2) to enter the patient's name, ID number and physician's name. If the physician's name is already registered in the Physician List, it can be selected by pressing the corresponding number (6).

   To switch between letters and numbers, use the switch-over key (3). In the event of an erroneous entry, touch the **Delete** key (4).
3. To set the entered value and advance to the next entry, touch the **Return** key (5). The cursor location indicates the category of the next entry.
4. Touch the **Index** key (1) again to return to the measurement window (fig. 1).

b) Setting the eye to be measured



Touch the **Eye** key (1) to select the eye you wish to measure (right or left).

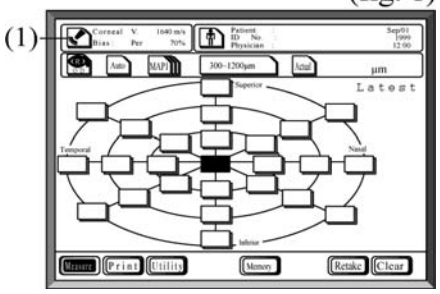
The right eye (OD) or the left eye (OS) is selected alternately each time the **Eye** key is touched.

c) Setting converted velocity and bias mode

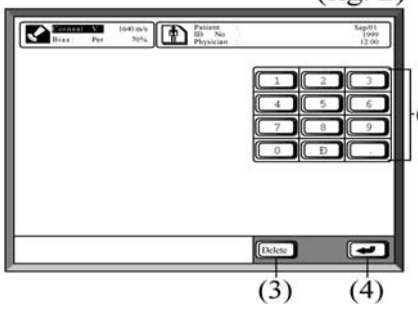
Bias may be applied in the following two ways:

- Percentage:
  A percentage of the actual value is calculated.
- Plus/minus:
  A compensating value is added to or subtracted from the actual value.

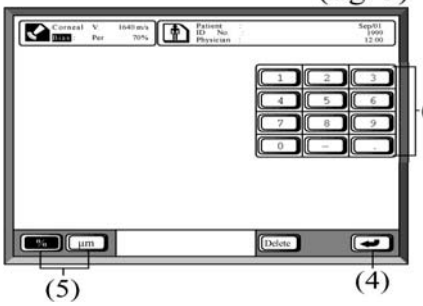
(fig. 1)



(fig. 2)



(fig. 3)



1. Touch the converted velocity key (1) on the measurement window (fig. 1) to access the setting window (fig. 2).
2. Enter the converted velocity by touching the number keys (2). The acceptable range is 1,200 - 2,000 m/s.

   In the event of an erroneous entry, touch the **Delete** key (3).
3. Touch the **Return** key (4) to set the entered value.
4. Select either percent bias (%) or plus/minus bias (μm) at the bottom of the window (5).
5. When setting percent bias, enter the bias rate by touching the number keys (2). When setting the plus/minus bias, enter the compensating value by touching the number keys (2). The acceptable ranges are:

   Bias rate (%): 60 - 130%
   Compensating value: -600 - +450 μm

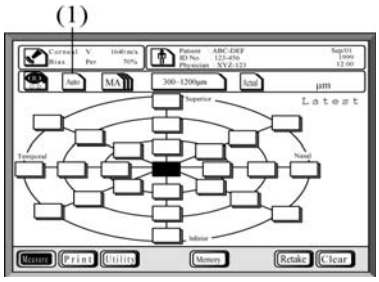
   In the event of an erroneous entry, touch the **Delete** key (3).
6. Touch the **Return** key (4) to set the entered values.
7. Touch the converted velocity key (1) to return to the measurement window (fig. 1).

Note **The bias value (% or μm) can be changed after the measurement has been performed.**

d) Setting automatic vs. manual acquisition

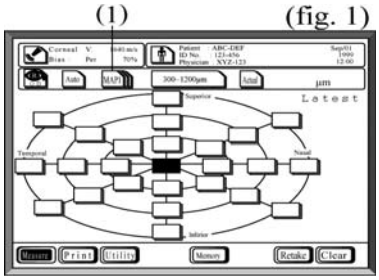
There are two data acquisition modes:

- Auto:
  The data are automatically acquired when all criteria are met.
- Manual:
  If data acquisition is difficult or erratic, data may be acquired manually using the footswitch.



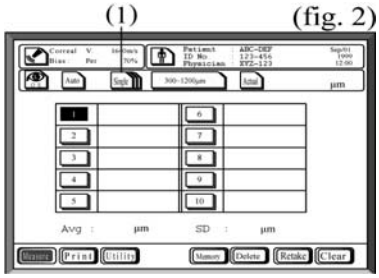
Touch the **Auto/Manual** key (1) to select the desired measurement mode. Automatic mode and manual mode are alternately set each time the key is touched.

e) Setting the measurement mode and the map



There are two measurement modes:

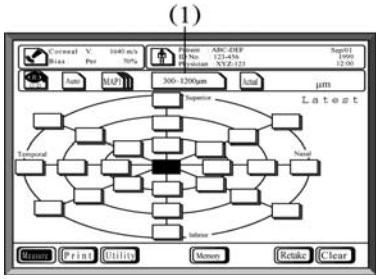
- Map mode (fig. 1):
  Measurements are acquired from an array of locations which are set in the Utility mode (see Section 7.4.1). Two map arrays (MAP 1 and MAP 2) can be registered.



- Single mode (fig. 2):
  Single mode is used to acquire multiple thickness measurements from a single point on the cornea.

Consecutively press the **Mode** key (1) to select MAP 1, MAP 2 or Single mode.

f) Setting the measurement range

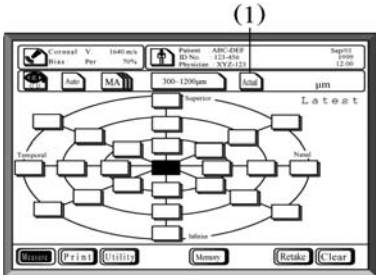


Press the **Range** key (1) to set the measuring range. Consecutively press the key to scroll through the following range settings:

150 - 350 µm
300 - 1,200 µm
1,000 - 1,500 µm

The message "Out of range" is presented when an echo is acquired that is out of the currently set range. Touch the **Range** key to change the range and resume measurement.

g) Setting the data display method

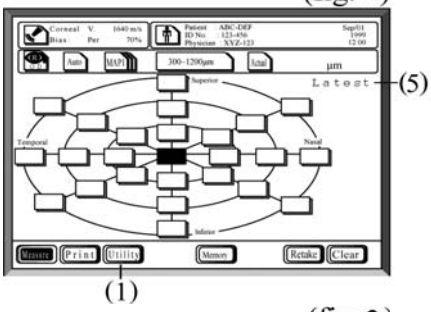


There are two ways that the measurement data may be displayed: actual value or biased value.

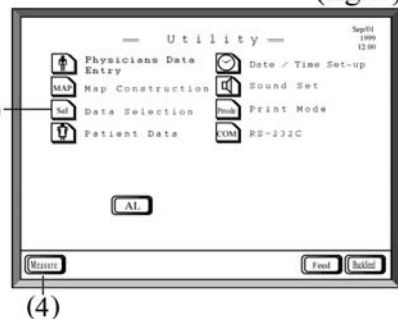
Set the display method by pressing the data display key (1). Consecutively press the key to alternate between actual value display and bias value display.

h) Setting the data presentation mode

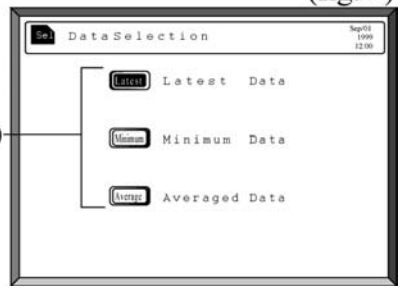
(fig. 1)



(fig. 2)



(fig. 3)



You may select which measurement data you would like to display from the following three options:

- Latest:
  The most recently acquired measurement at each point.
- Minimum:
  The minimum of all measurements taken at each point.
- Average:
  The mean of all measurements taken at each point.

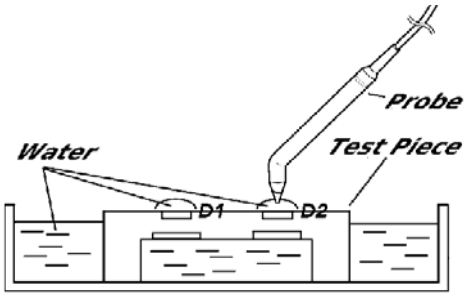
Set the value to be displayed as follows:

1. Press the **Utility** Key at the bottom of the Pachymetry measurement window (fig. 1) to display the Utility window (fig. 2).
2. Press the **Data Selection** key (2) to display the Data Selection window (fig. 3).
3. Press the desired data display option (**Latest**, **Minimum** or **Average**) by touching the adjacent key (3). The screen will return to the pachymetry Utility window (fig. 2).
4. Press the **Measure** key (4) on the Utility window to return to the Pachymetry measurement window.

The data presentation mode (5) is displayed at the upper right of the measurement window (fig. 1).

5.1.4 Checking the performance

Check the performance of the AL-2000 by using the pachymetry test piece (found in the box containing the pachymetry probe).



1. Select the following settings:
   Converted veolcity: 1,640 m/s
   Acquisition mode: Automatic
   Measurement mode: Single
   Measurement range: 300-1,200 μm
   Data display method: Actual value
   Data presentation mode: Average
2. Immerse the test piece under water.
3. Apply the pachymetry probe perpendicularly in one of the holes in the test piece.
4. Take 10 series of measurements, as described in section 5.2.2b, and select the 5 smallest values. The range of these values should be less than 10 μm.
5. Take the average of these 5 values.
6. Repeat steps 3, 4 and 5 for the other test piece hole.

Expected results (see NOTE below):
Shallower hole (D1): 465 μm ± 50 μm
Deeper hole (D2): 850 μm ± 50 μm

NOTE: The expected results are for an ambient room temperature of 24 degrees C (75 degrees F). Compensate for higher (lower) temperature by adding (subtracting), as follows:

D1: 1 μm per degree
D2: 2 μm per degree

Note **The biometry test piece is used only for checking the operating performance of the instrument. It cannot be used for determining the precision of the instrument or for calibrating the instrument.**

5.2 Performing Pachymetry

5.2.1 Preparation for measurement

1. Confirm that the measurement conditions have been set.
2. Anesthetize the eye with an appropriate topical anesthetic.
3. Instruct the patient to sit back or to lie supine to maximize patient comfort.

Note **If the patient is relaxed and cooperative, the measurement will be easier and more successful. Prior to taking measurements, explain the purpose and method of measurement to the patient to reduce his/her anxiety.**

5.2.2 Measurement methods

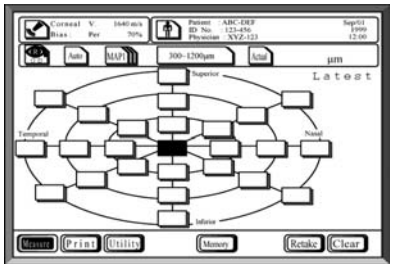
WARNING

- ALWAYS clean the probe tip before taking a measurement on a human eye (see section 10.2.1).
- NEVER use the probe if there is any visible damage to its tip. Such use may cause an incorrect measurement and/or damage to the cornea.
- ALWAYS anesthetize the eye with an appropriate topical anesthetic before performing measurements.
- Avoid applying excessive force to the cornea during measurement.
- If the cornea is dry, wet it to avoid corneal injury.

Notes

- The converted velocity directly affects the measurement. Ascertain that you have set the desired converted velocity.
- The instrument can be set to display actual or baised values. Ascertain that the desired data display method is set.

a) Automatic acquisition in map measurement mode (MAP 1, MAP 2)

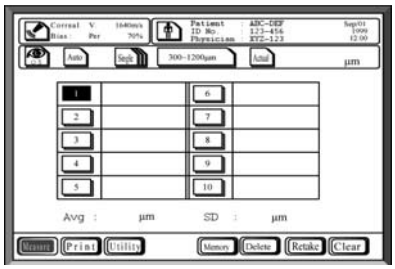


When using either of the two map arrays, pachymetry is performed as follows:

1. Apply the pachymetry probe perpendicular to the cornea at the location corresponding to the reverse-highlighted location on the map array.
2. When the measurement conditions are satisfactorily set, a beep will indicate that the instrument is ready to acquire data, following which measurements will be automatically acquired.
3. When 20 measurements have been acquired, a prolonged beep will indicate that measurement at this location has been completed.

   Data acquisition can be concluded before 20 values have been obtained by lifting the probe off the cornea.
4. Remove the probe from the cornea, place the probe at the next location, which is highlighted in reverse on the map array, and repeat steps 2 and 3.
5. Measure each corneal location as described above.
6. If you would like to re-test any locations, touch the location on the screen to reverse-highlight it and re-acquire measurements.

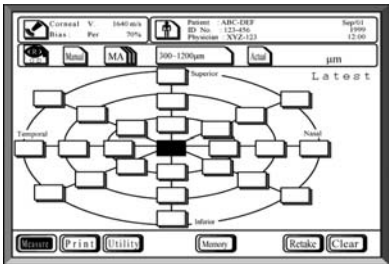
b) Automatic acquisition in single measurement mode



1. Apply the pachymetry probe perpendicular to the cornea at the desired location.
2. When the measurement conditions are satisfactorily set, a beep will indicate that the instrument is ready to acquire data, following which measurements will be automatically acquired.
3. When 20 measurements have been acquired, a high-pitched beep will indicate that measurement at this location has been completed.

   Data acquisition can be concluded before 20 values have been obtained by lifting the probe off the cornea.
4. Measurement may be repeated up to 10 times. The average for each series of values will be displayed in each data slot.
5. If you would like to replace any of the measurements, touch the data slot on the screen to reverse-highlight it and re-acquire measurements.

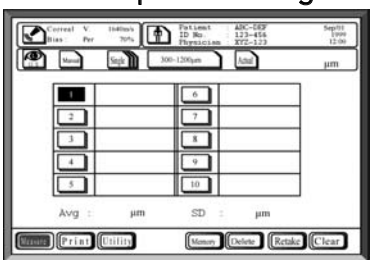
c) Manual acquisition in map measurement mode



1. Apply the pachymetry probe perpendicular to the cornea at the location corresponding to the reverse-highlighted location on the map array.
2. When the measurement conditions are satisfactorily set, a beep will indicate that the instrument is ready to acquire data.
3. Press the footswitch to take measurements. The instrument will beep each time a measurement is taken.
4. When 10 measurements have been acquired, a higher-pitched beep will indicate that measurement at this location has been completed.

   Data acquisition can be concluded before 10 values have been obtained by lifting the probe off the cornea.
5. Remove the probe from the cornea, place it at the next location, which is high-lighted in reverse on the map array, and repeat the above steps.
6. Measure each corneal location as described above.
7. If you would like to re-test any location, touch the location on the screen to reverse-highlight it and re-acquire measurements.

d) Manual acquisition in single measurement mode

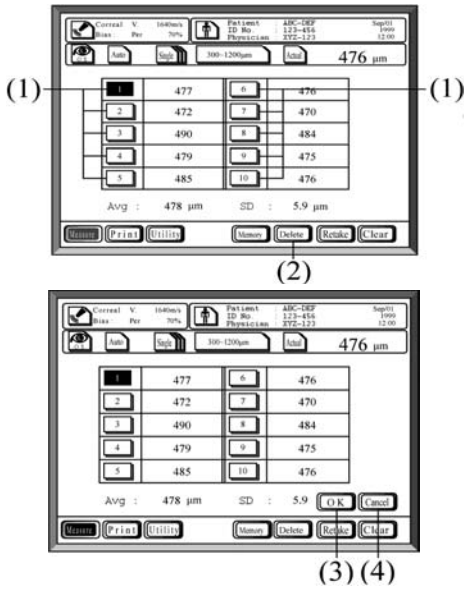


1. Apply the pachymetry probe perpendicular to the cornea at the desired location.
2. When the measurement conditions are satisfactorily set, a beep will indicate that the instrument is ready to acquire data.
3. Press the footswitch to take measurements. The instrument will beep each time a measurement is taken.
4. Remove the probe from the cornea, move to the next location and repeat the above steps.
5. Repeat the above procedure up to 10 times.
6. If you would like to re-test any location, touch the data slot on the screen to reverse-highlight it and re-acquire measurements.

5.2.3 Deleting data

a) Partial deletion of data in single measurement mode

Note Once data have been deleted, they cannot be restored. Any deletion must, therefore, be done carefully.

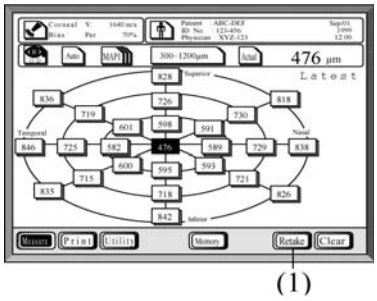


Data for a particular location can be deleted as follows:

1. Touch the memory number (1) to select the data to be deleted.
2. Press the **Delete** key (2).
3. Next, press the **OK** key (3) to proceed with the deletion.

   To discontinue deletion, press the **Cancel** key (4).

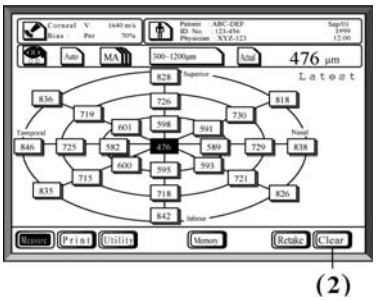
b) Deleting all data for one eye



To delete all data currently displayed for either the right or the left eye, press the **Retake** key (1) until you hear a beep.

NOTE: This deletes currently acquired data from the screen; it does not delete stored data from the memory card. (To delete data from the memory card, see section 7.3.4d).

c) Deleting all data for both eyes



(2)

To delete all data for both eyes of the current patient, press the **Clear** key (2) until you hear a beep sound. The patient's name and ID number will be deleted from the screen.

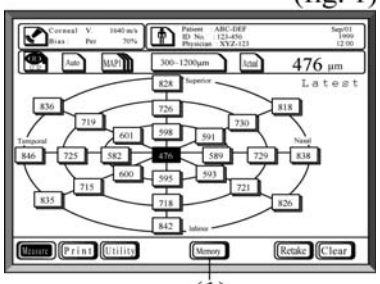
NOTE: This deletes currently acquired data from the screen; it does not delete stored data from the memory card. (To delete data from the memory card, see section 7.3.4d).

5.2.4 Storing data

Notes

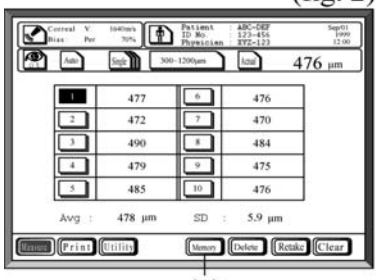
- **Before storing data, make sure that a memory card is inserted in the slot (see section 3.2.2f).**
- **All data are managed using patient ID numbers. Therefore, you must enter a patient ID number before storing data (see section 5.1.3a).**
- **The PC memory card used with the AL-2000 is an SRAM type card. Therefore, an SRAM type card reader, not a Flash Memory reader, must be used. If a Flash Memory reader is used, data stored on the memory card may be corrupted.**

(fig. 1)



(1)

(fig. 2)



(1)

The memory card that came with the AL-2000 can store data from both eyes of 237 patients.

In map measurement mode, data from up to 25 points is stored (fig. 1).

In single measurement mode, up to 10 measurements are stored (fig. 2).

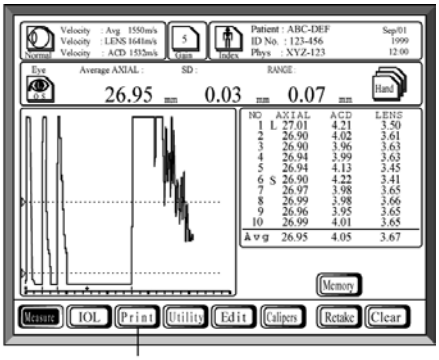
In both measurement modes, after measurements have been acquired, press the **Memory** key (1) to store the data.

A patient ID number must be entered in order to store data on the memory card. (See section 5.1.3a for details.)

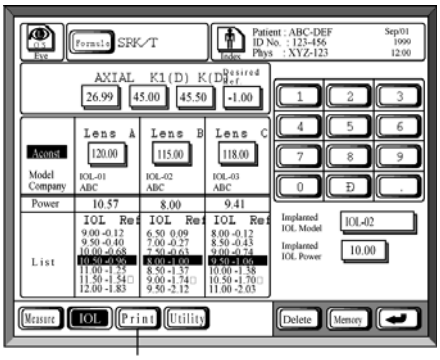
To display stored pachymetry data and to view cross-sectional diagrams of the cornea, see Section 7.4.3.

6. PRINTING

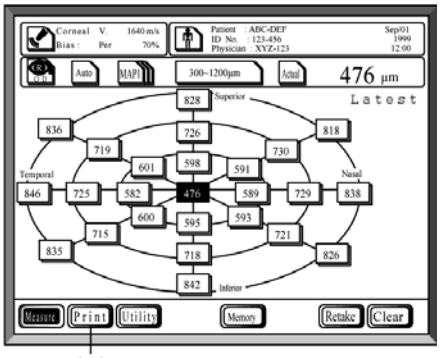
6.1 Initiating Printing



(1)



(1)



(1)

After biometry measurement, IOL calculation or pachymetry measurement, touch the **Print** key (1) to initiate printing.

6.2 Printout Modes

There are two printout modes, standard and simple. Sample printouts are shown in Section 6.3. (See Section 7.5.5 to select the desired mode.)

Standard: Includes date, patient name and ID number, physician name and all data.

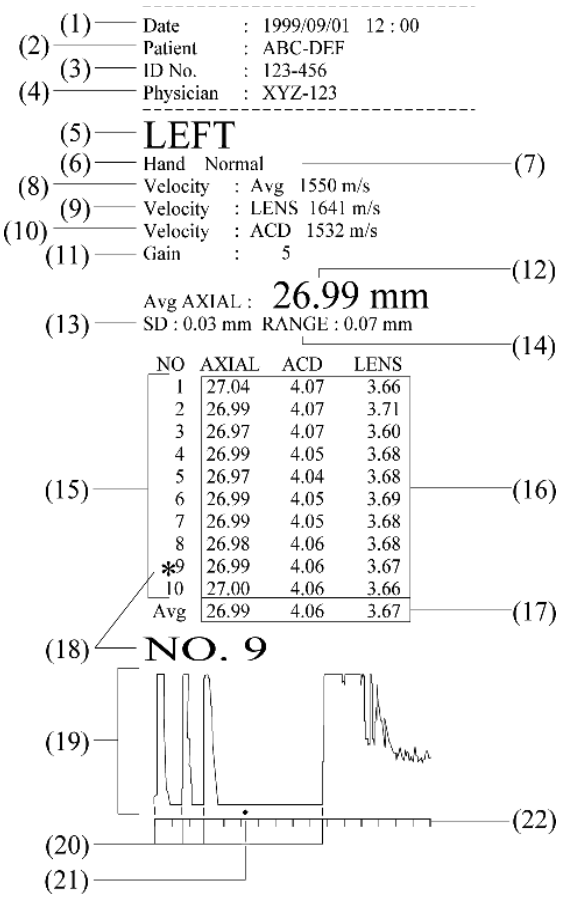
Simple: Includes no identifying information and, for some printouts, provides an abbreviated version of the data. The simple printout mode uses less paper.

6.3 Sample Printouts

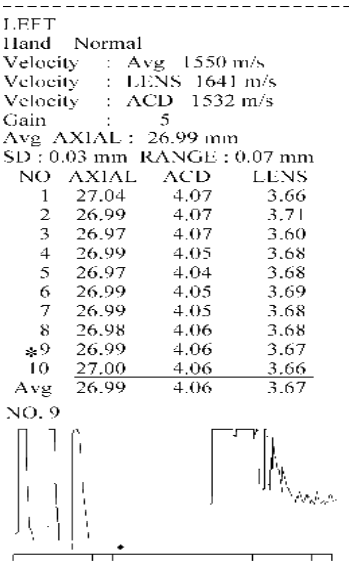
6.3.1 Sample biometry printout

a) Standard mode

(1) Time/Date
(2) Patient name
(3) Patient ID number
(4) Physician name
(5) Eye (Right/Left)
(6) Measurement mode
(7) Eye type
(8) Average axial length velocity
(9) Lens velocity
(10) ACD velocity
(11) Gain
(12) Average axial length
(13) Standard deviation of axial length data
(14) Difference between minimum and maximum axial length
(15) Memory number
(16) Measurement data (axial length/ACD/lens thickness)
(17) Mean measurement data values
(18) Memory number of the displayed waveform
(19) Waveform
(20) Selection cursor for retinal waveform
(21) Selection cursor for retinal echo
(22) Scale (2 mm/div)



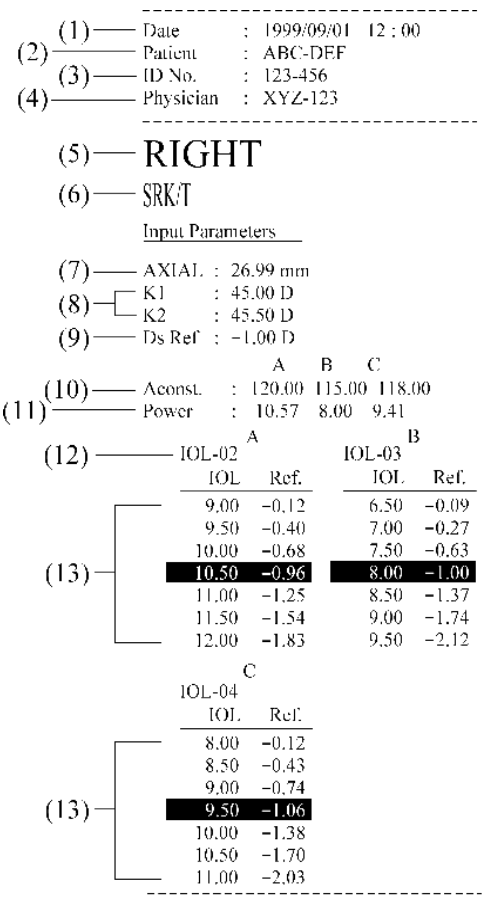
b) Simple mode



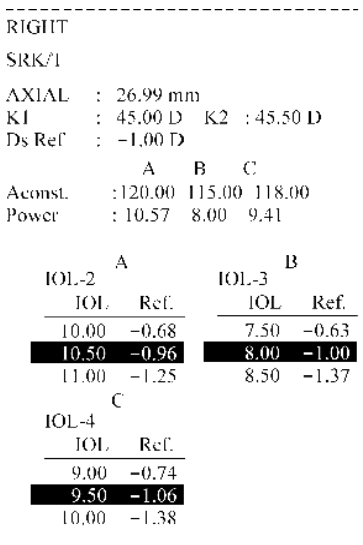
6.3.2 Sample IOL power calculation printout

a) Standard mode

(1) Time/Date
(2) Patient name
(3) Patient ID number
(4) Physician name
(5) Eye (Right/Left)
(6) IOL calculation formula
(7) Axial length
(8) Keratometry values
(9) Desired postoperative refraction
(10) Lens constants
(11) Power calculation results
(12) IOL model name
(13) Seven IOL power levels and the predicted postoperative refraction for each lens model



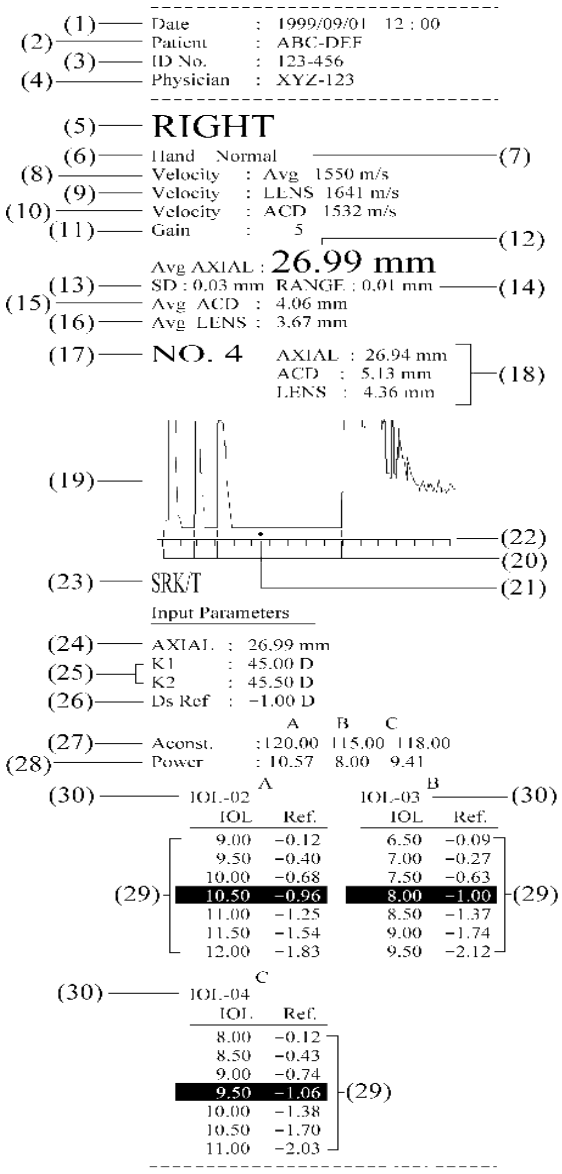
b) Simple mode



6.3.3 Sample IOL power calculation printout following biometry (SRK/T)

a) Standard mode

(1) Time/Date
(2) Patient name
(3) Patient ID number
(4) Physician name
(5) Eye (Right/Left)
(6) Measurement mode
(7) Eye type
(8) Average axial length velocity
(9) Lens velocity
(10) ACD velocity
(11) Gain
(12) Average axial length
(13) Standard deviation of axial length data
(14) Difference between minimum and maximum axial length
(15) Average ACD
(16) Average lens thickness
(17) Memory number of displayed waveform
(18) Axial length/ACD/lens thickness of the displayed waveform
(19) Waveform
(20) Selection cursor for retinal waveform
(21) Selection cursor for retinal echo
(22) Scale (2 mm/div)
(23) IOL calculation formula
(24) Mean axial length
(25) Keratometry values
(26) Desired postoperative refraction
(27) Lens constants
(28) Power calculation results
(29) Seven IOL power levels and the predicted postoperative refraction for each lens model
(30) IOL model name



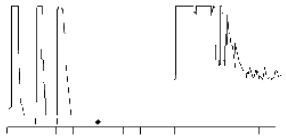
b) Simple mode

RIGHT

Hand Normal
Velocity : Avg 1550 m/s
Velocity : LENS 1641 m/s
Velocity : ACD 1532 m/s
Gain : 5

Avg AXIAL: 26.99 mm

NO. 4 AXIAL :26.99 mm
ACD : 5.13 mm
LENS : 4.36 mm



SRK/T

AXIAL : 26.99 mm
K1 : 45.00 D K2 : 45.50 D
Ds Ref : −1.00 D

	A	B	C
Aconst.	120.00	115.00	118.00
Power	10.57	8.00	9.41

A

IOL-2 IOL.	Ref.
10.00	−0.68
10.50	−0.96
11.00	−1.25

B

IOL-3 IOL.	Ref.
7.50	−0.63
8.00	−1.00
8.50	−1.37

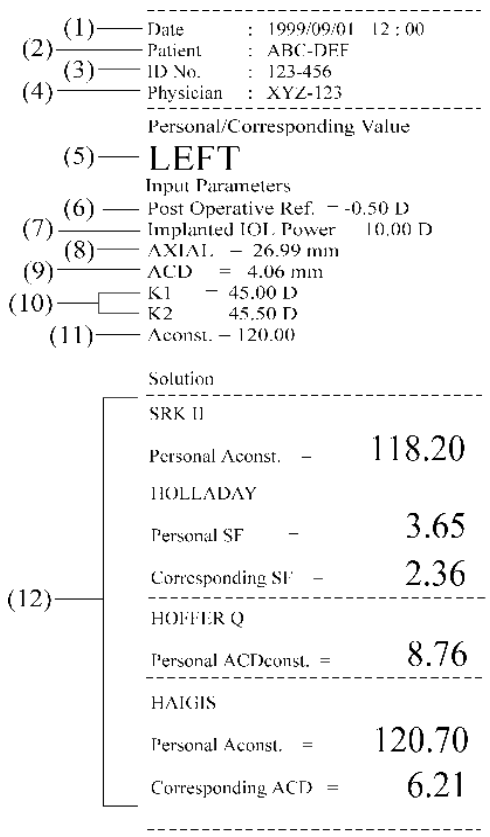
C

IOL-4 IOL.	Ref.
9.00	−0.74
9.50	−1.06
10.00	−1.38

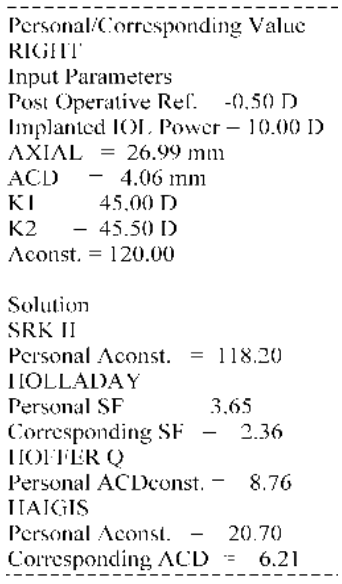
6.3.4 Sample printout using personal/corresponding surgeon factor values

a) Standard mode

(1) Time/Date
(2) Patient name
(3) Patient ID number
(4) Physician name
(5) Eye (Right/Left)
(6) Desired postoperative refraction
(7) Implanted IOL power
(8) Axial length
(9) Anterior chamber depth (ACD)
(10) Keratometry values
(11) Lens constant
(12) Results of calculations



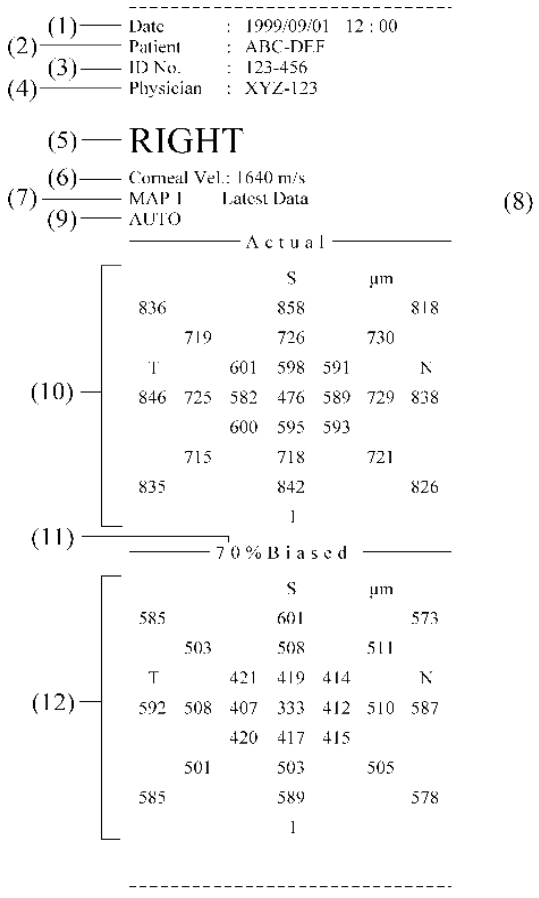
a) Simple mode



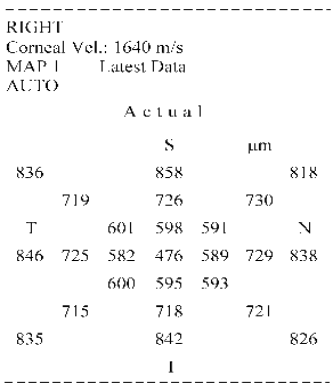
6.3.5 Sample pachymetry printout - map mode

a) Standard mode

(1) Time/Date
(2) Patient name
(3) Patient ID number
(4) Physician name
(5) Eye (Right/Left)
(6) Converted ultrasound velocity
(7) Measurement mode
(8) Data presentation mode
(9) Data acquisition method
(10) Actual corneal thickness at each location
(11) Bias rate
(12) Biased corneal thickness at each location



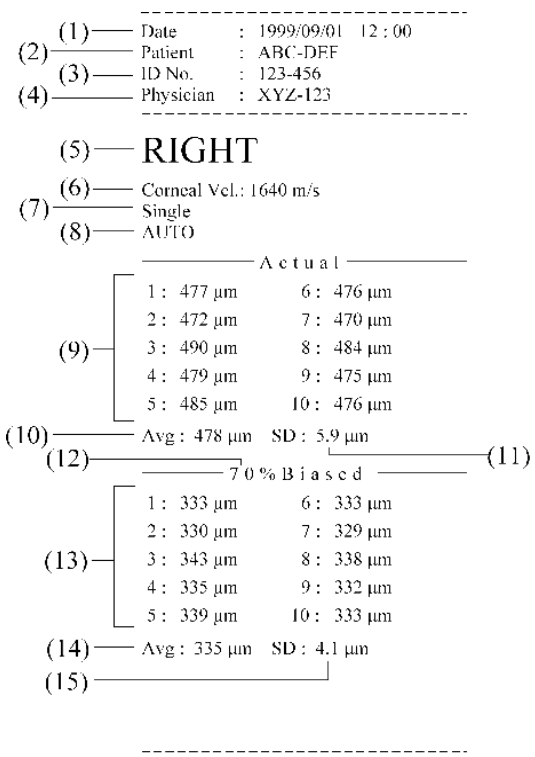
b) Simple mode



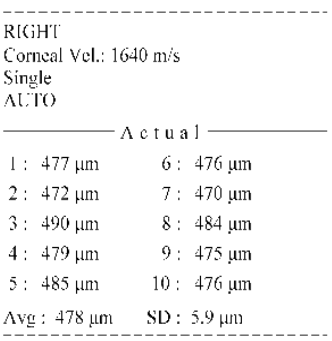
6.3.6 Sample pachymetry printout - single mode

a) Standard mode

(1) Time/Date
(2) Patient name
(3) Patient ID number
(4) Physician name
(5) Eye (Right/Left)
(6) Converted ultrasound velocity
(7) Measurement mode
(8) Data acquisition method
(9) Actual corneal thickness at each location
(10) Average actual value
(11) Standard deviation of actual values
(12) Bias rate
(13) Biased corneal thickness at each location
(14) Average biased value
(15) Standard deviation of biased values



b) Simple mode

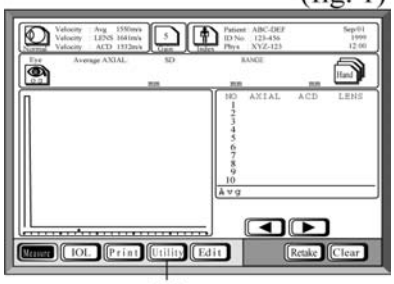


7. UTILITIES

7.1 Accessing the Utility Window

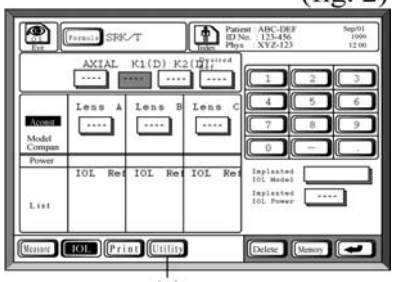
7.1.1 Accessing the Utility window from biometry mode

(fig. 1)



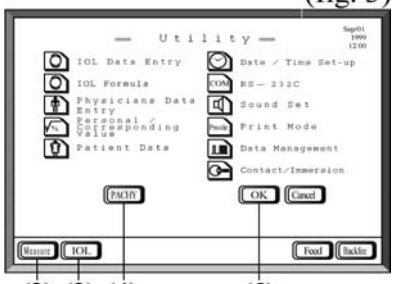
(1)

(fig. 2)



(1)

(fig. 3)

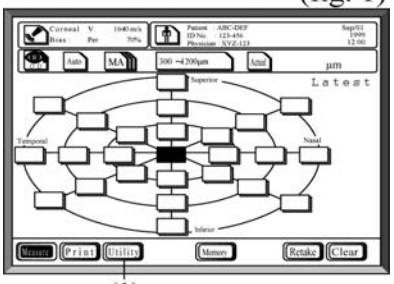


(2) (3) (4) (5)

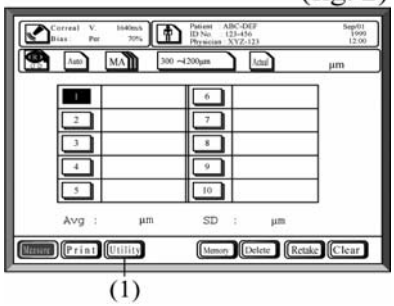
1. Touch the **Utility** key (1) on the Biometry measurement window (fig. 1) or on the IOL calculation window (fig. 2) to display the Utility window (fig. 3).
2. If you wish to access the Biometry measurement window, touch the **Measure** key (2).
3. If you wish to access the IOL calculation window, touch the **IOL** key (3).
4. If you wish to enter Pachymetry mode, touch the **PACHY** key (4) and then touch the **OK** key (5).

7.1.2 Accessing the Utility window from pachymetry mode

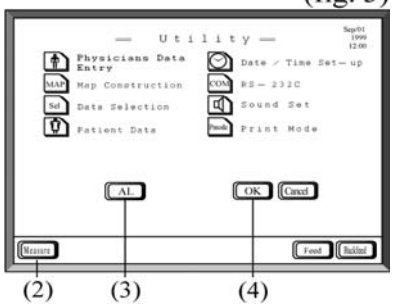
(fig. 1)



(fig. 2)



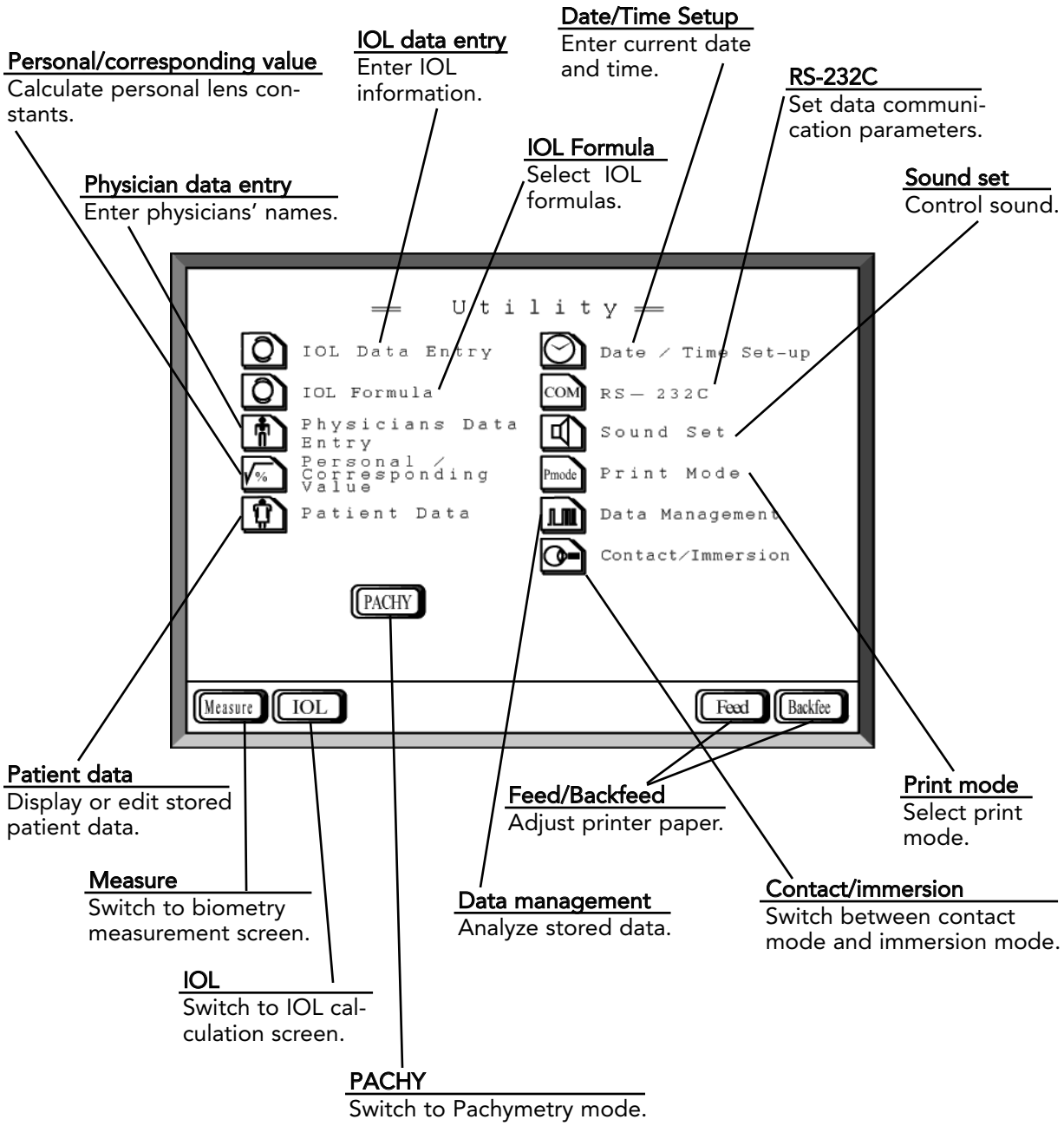
(fig. 3)



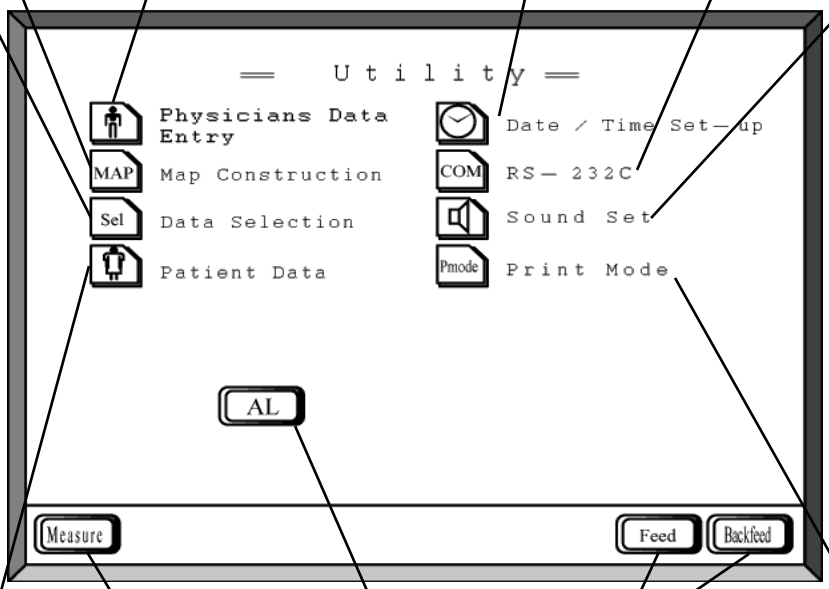
1. Touch the **Utility** key (1) on the Pachymetry map mode measurement window (fig. 1) or on the Pachymetry single mode measurement window (fig. 2) to display the Utility window (fig. 3).
2. If you wish to return to Pachymetry measurement, touch the **Measure** key (2).
3. If you wish to enter Biometry mode, touch the **AL** key (3) and then touch the **OK** key (4).

7.2 Description of Utility Windows

7.2.1 Utility window for biometry mode



7.2.2 Utility window for pachymetry mode



Data selection
Select the data presentation mode.

Map construction
Select the pachymetry map locations.

Physician data entry
Enter physicians' names.

Date/Time Setup
Enter current date and time.

RS-232C
Set data communication parameters.

Sound set
Control sound.

Measure
Switch to pachymetry measurement screen.

Feed/Backfeed
Adjust printer paper.

Print mode
Select print mode.

Patient data
Display stored patient data and cross-sectional view of cornea.

AL
Switch to Biometry/IOL calculation mode.

7.3 Utility Setup for Biometry and IOL Calculation

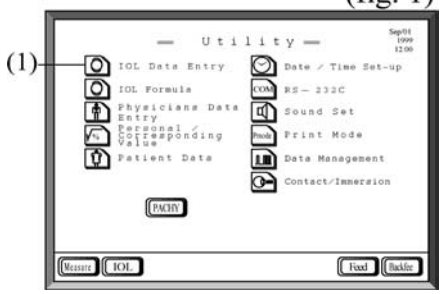
7.3.1 IOL data entry

Up to 10 lens models with associated constant values may be entered in the IOL data list. These lens models may be selected and their pre-set values used for IOL power calculation.

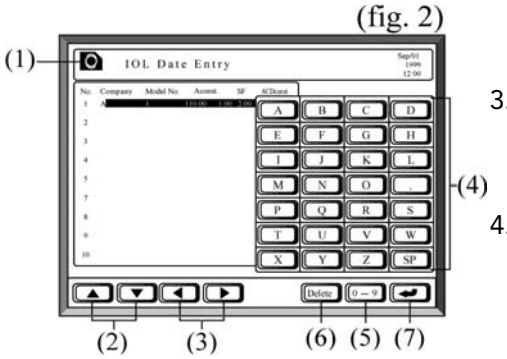
The appropriate lens constant for each IOL calculation formula is listed below:

- SRK II formula: A constant
- SRK/T formula: A constant
- Holladay formula: Surgeon's factor (SF)
- Hoffer-Q formula: ACD constant
- Haigis standard formula: A constant
- Haigis optimized formula: a0, a1, a2

(fig. 1)



(fig. 2)



The procedure for entering IOLs is as follows:

1. Touch the **IOL Data Entry** key (1) on the biometry Utility screen (fig. 1) to access the IOL data entry window (fig. 2).
2. Select the memory number to be entered using the up and down arrow keys (2) and the item to be entered using the right and left arrow keys (3). The location of the flashing cursor indicates the category for the next data entry. If you do not want to enter data in this category, move to the desired category using the right and left arrow keys. Continue pressing the arrow keys to enter a0, a1 and a2.
3. Enter the IOL data using the alphabetic character and number keys (4). Switch between the alphabetic character keys and the number keys by touching the **Switchover** key (5).
4. The following information may be entered:
   - Company: Up to 10 letters or numbers
   - Model No.: Up to 10 letters or numbers
   - A-const.: Acceptable range 100.00 - 130.00
   - SF: Acceptable range -5.00 - +10.00
   - ACDconst:: Acceptable range 0.00 - +10.00
   - a0: Acceptable range: -9.99 - +9.99
   - a1, a2: Acceptable range: -0.99 - +0.99

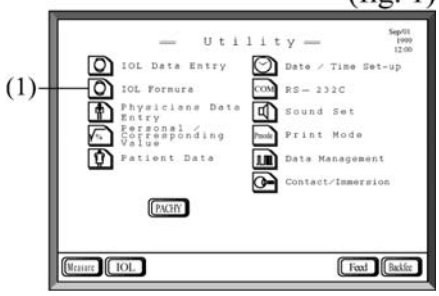
   The constants a0, a1 and a2 are used under the following conditions:

   $2 < a0 + a1 \times 3.37 + a2 \times 23.39 < 7$
   $2 < a0 + a1 \times 2.53 + a2 \times 20.00 < 7$
   $2 < a0 + a1 \times 3.50 + a2 \times 27.00 < 7$

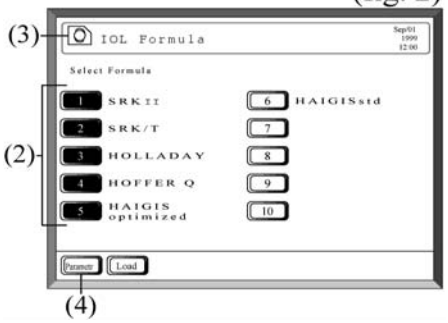
   In the event of an erroneous entry, press the **Delete** key (6).
5. Set entered data by touching the **Return** key (7).
6. When data entry is complete, touch the **IOL Data Entry** key (1) to return to the biometry Utility screen.

7.3.2 IOL formula setup

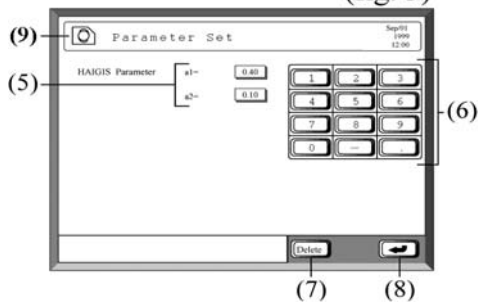
(fig. 1)



(fig. 2)



(fig. 3)



Six pre-set IOL calculation formulae are available. To select the formulae that you plan to use, do the following:

1. Touch the **IOL Formula** key (1) on the Biometry Utility screen (fig. 1) to display the formula selection screen (fig. 2).
2. The six available formulas are: SRK II, SRK/T, Holladay, Hoffer Q, Haigis standard and Haigis optimized.
3. To select a formula, touch the adjacent number key so that it is reverse-highlighted (black).

   You may select up to five of the six formlas. Those chosen will be available for selection from the IOL power calculation window (see section 4.3).
4. After making your selections, touch the **IOL Formula** key (3) to return to the Biometry Utility screen (fig. 1).

To set a1 and a2 for the Haigis standard formula:

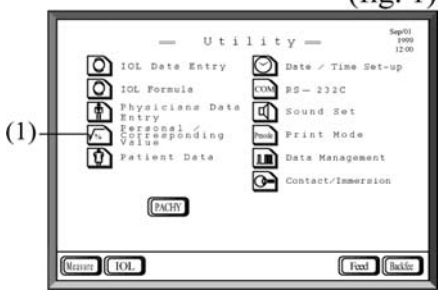
1. Press the **Parametr** key (4) on the formula selection screen to activate the parameter setting screen (fig. 3).
2. Touch the item keys (5) to select a1 and a2 and enter the desired value for each using the number keys (6).

   In the event of an erroneous entry, press the **Delete** key (7).
3. After the values have been entered, touch the **Return** key (8) to register the entries.
4. After both a1 and a2 have been set, touch the **Parameter Set** key (9) to return to the formula selection screen (fig. 2) and touch the **IOL Formula** key (3) to return to the biometry Utility screen (fig. 1).

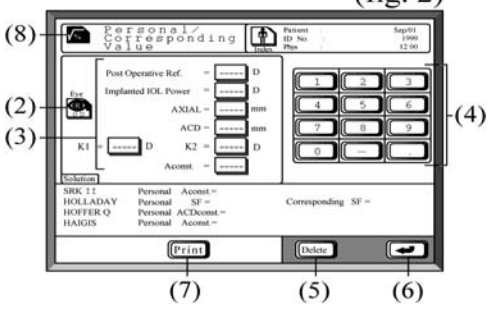
Please contact your Tomey representative to inquire about loading additional IOL formulae.

7.3.3 Personal lens constant calculation (personal/corresponding value)

(fig. 1)



(fig. 2)



After the IOL has been implanted and the post-operative refraction has been determined, the optimal lens constants (personal A-constant, personal SF, corresponding SF and personal ACD) can be calculated as follows:

1. Touch the **Personal/Corresponding Value** key (1) on the biometry Utility screen to display the calculation screen (fig. 2).
2. Touch the **Eye** key (2) to select the eye (right or left) for which you wish to calculate constants.
3. Touch the databox (3) for each item and enter the value using the number keys (4). The selected databox will be reverse highlighted (black).

   In the event of an erroneous entry, press the **Delete** key (5).
4. Touch either the **Return** key (6) or touch the databox (3) again to register the value.
5. Repeat steps 3, 4 and 5 for each item: post-operative refraction, implanted IOL power, axial length, anterior chamber depth, keratometry values* and A constant.

   *Either the flat K or the steep K may be entered first. Values may be entered in either diopters or millimeters.
6. After all values have been entered, the instrument will automatically display the calculation results.
7. Touch the **Eye** key (2) if you wish to calculate constants for the other eye and repeat steps 3-7.
8. Touch the **Print** key (7) to obain a printout of the calculation results.
9. When you are finished, touch the **Personal/Corresponding Value** key (1) to return to the biometry Utility screen (fig. 1).

Based on the outcome of multiple surgeries, the optimal personal lens constant values for a particular surgeon may be determined using the Data Management utility (see section 7.3.5).

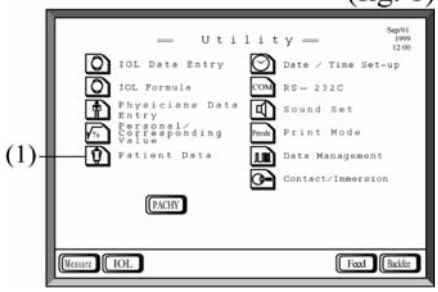
7.3.4 Display and compilation of patient data

Notes

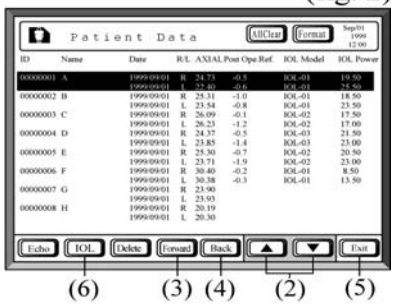
- The memory card must be inserted securely, as instructed in section 3.2.2f, in order to display and compile stored patient data.
- The memory card must be formatted before using, as described in section 8.4.

a) Displaying axial length data

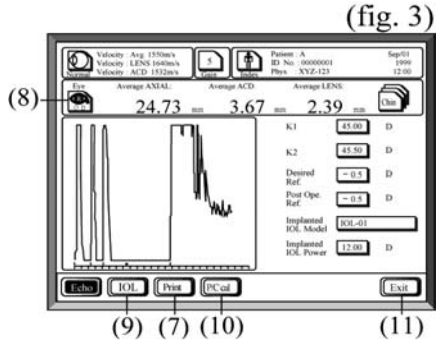
(fig. 1)



(fig. 2)



(fig. 3)



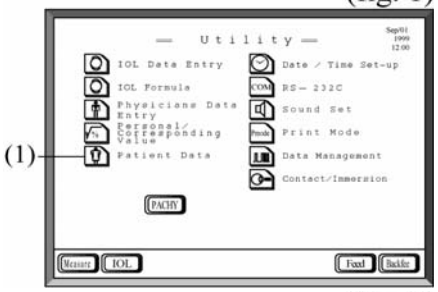
To display stored axial length data:

1. Touch the **Patient data** key (1) on the biometry Utility screen to display the Patient Data list (fig. 2).
2. Touch the **arrow** keys (2) to select the patient whose axial length data you want to display. If necessary, change the page using the **Forward** key (3) or **Back** key (4).

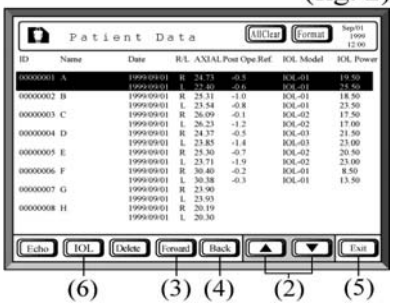
   If you wish to return to the biometry Utility screen at any time, touch the **Exit** key (5).
4. Touch the **Echo** key (6) to display the selected patient's axial length data (fig. 3).
5. To obtain a printout of the data, touch the **Print** key (7).
6. To display the axial length data for the patient's other eye, touch the **Eye** key (8).
7. If you wish to display the patient's IOL data, touch the **IOL** key (9) and follow the instructions in section 7.3.4b.
8. If you wish to view personal lens constants, touch the **P/C cal** key (10). (If you wish to calculate personal lens constants, see section 7.3.3.)
9. To return to the Patient Data list (fig. 2), touch the **Exit** key (11).

b) Compiling IOL data

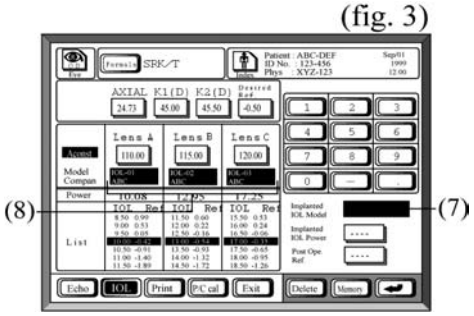
(fig. 1)



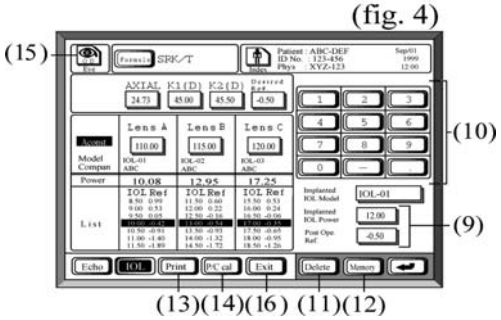
(fig. 2)



(fig. 3)



(fig. 4)



To compile a patient's IOL data:

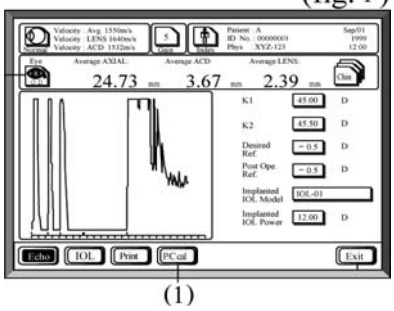
1. Touch the **Patient data** key (1) on the biometry Utility screen to display the Patient Data list (fig. 2).
2. Touch the **arrow** keys (2) to select the patient whose data you want to display. If necessary, change the page using the **Forward** key (3) or **Back** key (4).

   If you wish to return to the biometry Utility screen at any time, touch the **Exit** key (5).
3. Touch the **IOL** key (6) to display the screen for compilation of the selected patient's IOL data.
4. To prepare to enter the the IOL model and manufacturer, touch the **Implanted IOL Model** key (7). The lens **Model** and **Company** names (8) will be reverse highlighted.
5. Touch the model/manufacturer of the selected IOL to enter it in the **Implanted IOL Model** databox.
6. To enter the implanted IOL power and post-operative refraction, touch the **Implanted IOL Power** and **Post Op. Ref.** keys (9) and enter the value for each using the number keys (10). The acceptable ranges are:
   Implanted IOL Power: 0.01 - 50.00 D
   Post Op Refraction: -10.00 - +10.00 D

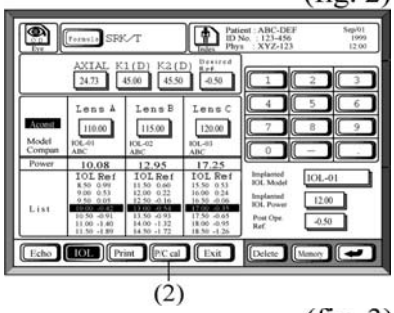
   In the event of an erroneous entry, press the **Delete** key (11).
7. To store the implanted IOL model and power and the postoperative refraction, touch the **Memory** key (12).
8. To obtain a printout, touch the **Print** key (13).
9. If you wish to view personal lens constants, touch the **P/C cal** key (14). (If you wish to calculate personal lens constants, see section 7.3.3.)
10. To display IOL data for the patient's other eye, touch the **Eye** key (15).
11. To return to the Patient Data list (fig. 2), touch the **Exit** key (16).

c) Displaying personal lens constants

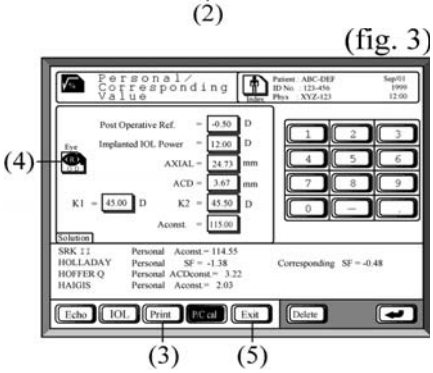
(fig. 1)



(fig. 2)



(fig. 3)

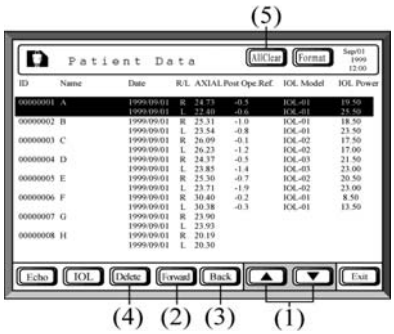


To display personal lens constant data:

1. Touch the **P/C cal** key (1) on the axial length data screen (fig. 1) or the **P/C cal** key (2) on the IOL data screen (fig. 2) to display the personal lens constant screen (fig. 3).
2. If all of the required values have been entered, the results of the personal lens constant calculations will be displayed.

   Note: Values cannot be entered on this screen. To enter values, see sections 4.3.4, 4.3.5 and 7.3.3.
3. To obtain a printout, touch the **Print** key (3).
4. To display personal lens constant data for the patient's other eye, touch the **Eye** key (4).
5. To return to the Patient Data list, touch the **Exit** key (5).

d) Deleting patient data



To delete patient data from the memory card:

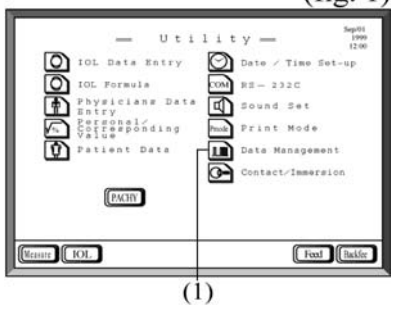
1. Touch the **Patient Data** key on the biometry Utility screen to display the Patient Data list.
2. Touch the **arrow** keys (1) to select the patient whose data you want to delete. If necessary, change the page using the **Forward** key (2) or **Back** key (3).
3. To delete the selected patient's data, touch the **Delete** key (4) for approximately one second until you hear a beep. Data for both eyes will be deleted.
4. To delete all patient data, touch the **All Clear** key (5) for approximately one second until you hear a beep.

7.3.5 Biometry/IOL Data Management

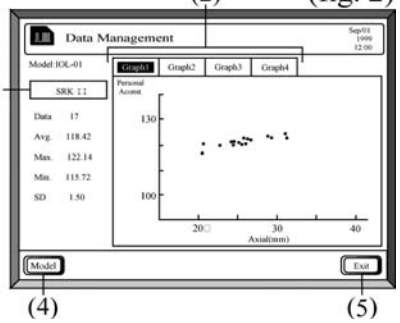
Notes

- Ascertain that the memory card is securely inserted as instructed in section 3.2.2f.
- The memory card must be formatted before using, as described in section 8.4.

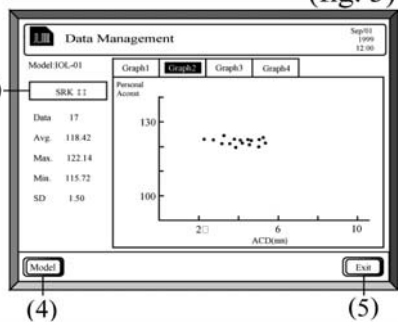
(fig. 1)



(fig. 2)



(fig. 3)



IOL data stored on the memory card (as described in section 7.3.4b) may be analyzed to display four types of graphs, illustrated in figs. 2-5. The patient data are compiled according to IOL Model name. If two or more IOLs bear the same name, they will be treated as the same lens even if they have different lens constants.

1. Insert the memory card as instructed in section 3.2.2f.
2. Touch the **Data Management** key (1) on the biometry Utility screen (fig. 1) to display the Graph screen (figs. 2-5).
3. The following four graphs may be displayed by touching the corresponding **Graph** key (2):

   Graph 1: Relationship between axial length and personal lens constant (fig. 2).

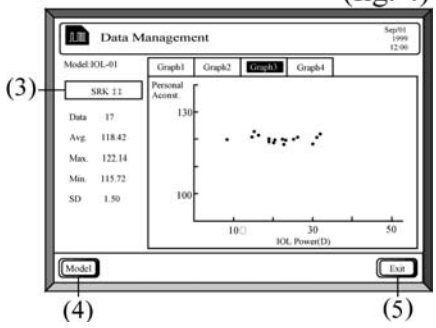
   Graph 2: Relationship between anterior chamber depth and personal lens constant (fig. 3).

   Graph 3: Relationship between IOL power and personal lens constant (fig. 4, next page).

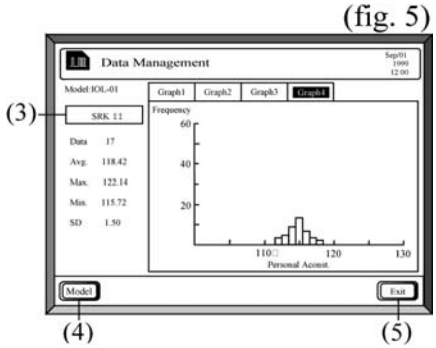
   Graph 4: Histogram showing personal lens constant values (fig. 5, next page).

   The following values for the lens constant associated with the selected formula and lens model are displayed at the left of the screen: mean value, maximum value, minimum value and standard deviation. The number of data points is also displayed.
4. Touch the **Formula** key (3) to change the calculation formula for which data are displayed.
5. Touch the **Model** key (4) to change the IOL model for which data are displayed.
6. Touch the **Exit** key (5) to return to the biometry Utility screen.

(fig. 4)

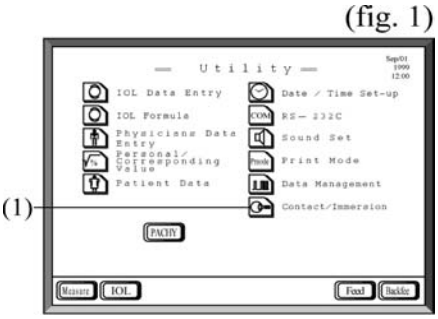


(fig. 5)

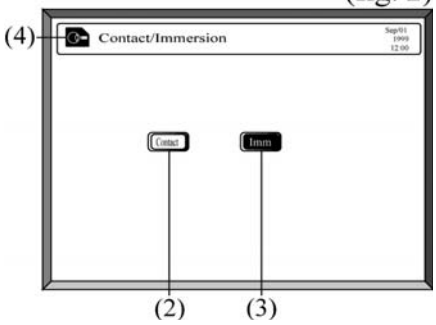


7.3.6 Contact/Immersion

(fig. 1)



(fig. 2)



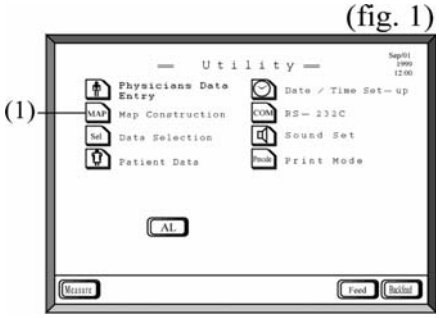
To select the biometry probe mode:

1. Touch the **Contact/Immersion** key (1) on the biometry Utility screen (fig. 1) to display the Contact/Immersion screen (fig. 2).
2. Touch the **Contact** key (2) or the **Immersion** key (3). The selected option is reverse highlighted.
3. Touch the **Contact/Immersion** key (4) to return to the biometry Utility screen.

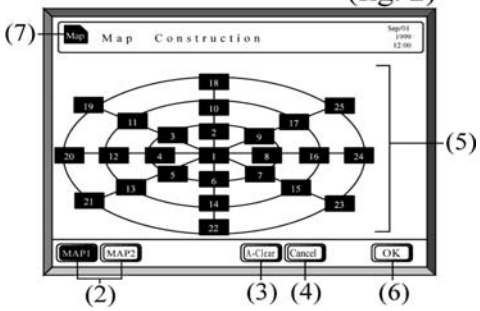
7.4 Utility Setup for Pachymetry

7.4.1 Map construction

(fig. 1)



(fig. 2)



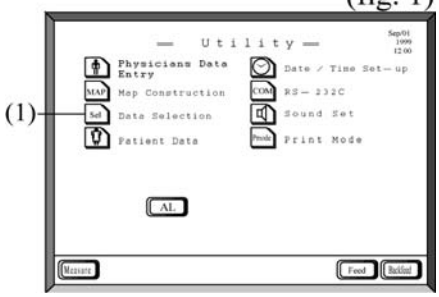
For the map measurement mode, the measuring locations and the order in which the measurements are taken should be pre-set. Two maps, MAP 1 and MAP 2, may be constructed.

To construct MAP 1 and MAP 2:

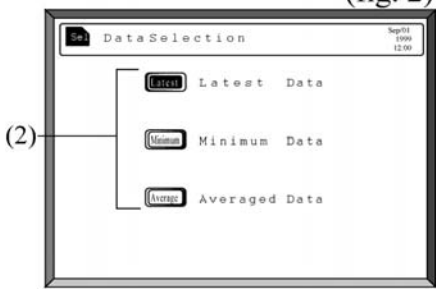
1. Touch the **Map Construction** key (1) on the pachymetry Utility screen (fig. 1) to display the map construction screen (fig. 2).
2. Touch the **MAP 1** key (2) to select MAP 1. The key for the selected map is reverse highlighted.
3. To delete the pre-set map, touch the **A-Clear** key (3). In the event that you have accidently deleted or wish to stop deleting, touch the **Cancel** key (4) to restore the previous map.
4. Consecutively touch as many elements (5) as you want to measure in the order that you want to measure them. The selected elements will be reverse highlighted. The numbers in the boxes indicate the measuring order. Non-selected elements are blank.
5. If you wish to remove an element, touch it again. In the event of an erroneous removal, touch the **Cancel** key (4) to restore the previous selection.
6. After the elements have been selected, touch the **OK** key (6) to register the map.
7. Touch the **MAP 2** key (2) and repeat steps 3-6 to construct Map 2.
8. When map construction is complete, touch the **Map Construction** key (7) to return to the pachymetry Utility screen (fig. 1).

7.4.2 Data display selection

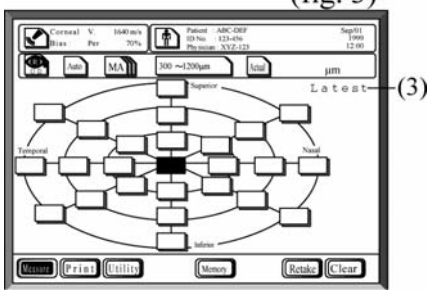
(fig. 1)



(fig. 2)



(fig. 3)



The following data display options are available:

Latest: Most recently acquired measurement.

Minimum: Minimum measurement value.

Average: Mean of all measurement values.

The data display option can be changed after the measurements have been taken.

To select the desired data display option:

1. Touch the **Data Selection** key (1) on the pachymetry Utility window (fig. 1) to activate the Data Selection window (fig. 2).
2. Select the desired data display option by touching the appropriate key (2). The screen will return to the pachymetry Utility window (fig. 1).

When measurement results are displayed (fig. 3), the selected data display option will be indicated to the upper right of the map.

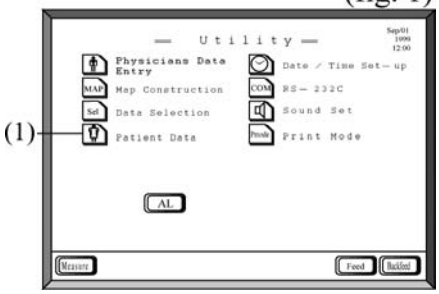
7.4.3 Patient data and corneal cross-section display

Notes

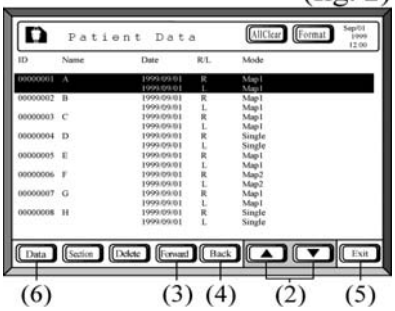
- In order to display patient data, the memory card must be inserted securely, as instructed in section 3.2.2f.
- The memory card must be formatted before using as described in section 8.4.

a) Displaying stored pachymetry data

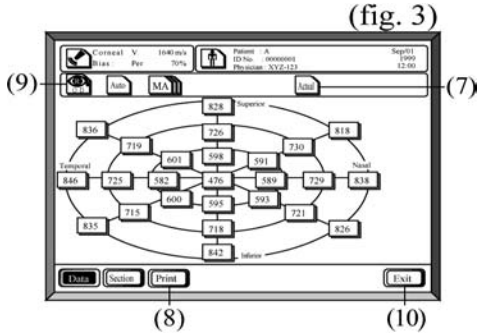
(fig. 1)



(fig. 2)



(fig. 3)



To display stored pachymetry data:

1. Touch the **Patient data** key (1) on the pachymetry Utility screen to display the Patient Data list (fig. 2).
2. Touch the **arrow** keys (2) to select the patient whose pachymetry data you want to display. If necessary, change the page using the **Forward** key (3) or **Back** key (4).

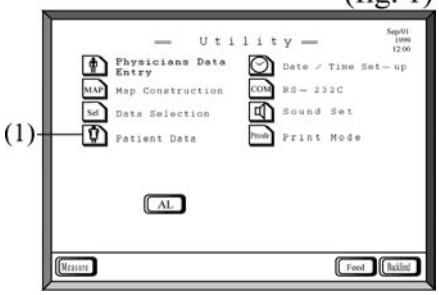
   If you wish to return to the pachymetry Utility screen at any time, touch the **Exit** key (5).
3. After selecting the patient, touch the **Data** key (6) to display the selected patient's pachymetry data (fig. 3).
4. If you wish to change from actual value display to biased value display, touch the data display key (7).
5. To obtain a printout of the data, touch the **Print** key (8).
6. To display the pachymetry data for the patient's other eye, touch the **Eye** key (9).
7. To return to the Patient Data list (fig. 2), touch the **Exit** key (10).

b) Displaying cross-sectional view of cornea

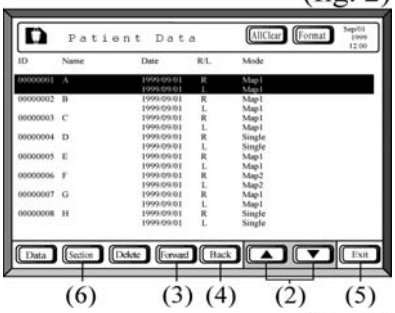
Notes

- At least the central corneal thickness and the 8 data points surrounding (adjacent to) the center are necessary in order to display a cross-sectional view of the cornea.
- The cross-sectional view is not scaled. The average K value is used [(K1 + K2)/2], not the individual K1 and K2 values.

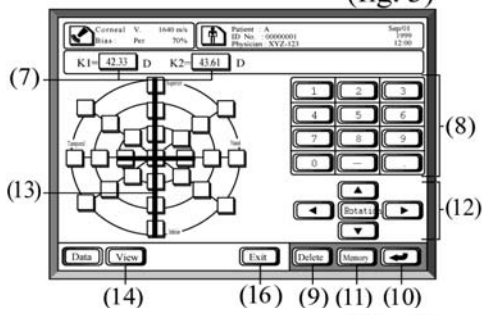
(fig. 1)



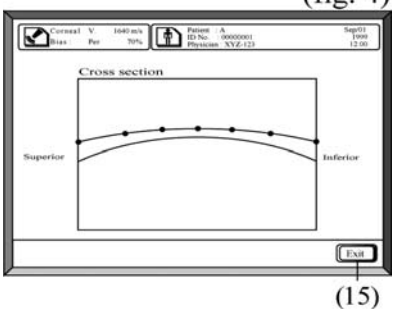
(fig. 2)



(fig. 3)



(fig. 4)



To display a cross-sectional corneal view for stored pachymetry data:

1. Touch the **Patient data** key (1) on the pachymetry Utility screen to display the Patient Data list (fig. 2).
2. Touch the **arrow** keys (2) to select the patient whose pachymetry data you want to display. If necessary, change the page using the **Forward** key (3) or **Back** key (4).

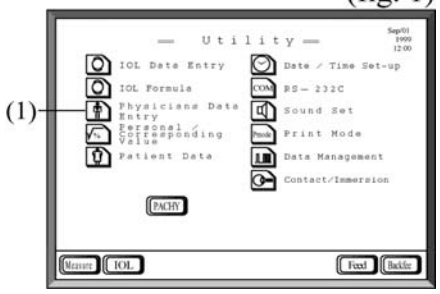
   If you wish to return to the pachymetry Utility screen at any time, touch the **Exit** key (5).
3. Touch the **Section** key (6) to display the cross-section selection screen for the selected cornea (fig. 3).
4. Select the **K1** key (7) and enter the K1 value using the number keys (8). Then select the **K2** key (7) and enter the K2 values. (Either the flat K or the steep K may be entered first. K values may be entered in either diopters or millimeters.)

   In the event of an erroneous entry, press the **Delete** key (9).
5. Register the entered values by touching the **Return** key (10).
6. Touch the **Memory** key (11) to store the K1 and K2 values on the memory card.
7. Touch the arrow keys (12) to determine the location of the cross-sectional view.
8. Touch the **Rotation** key (12, center) to rotate the meridian (13) of the cross-section viewed by 45 degrees counterclockwise.
9. Touch the **View** key (14) to display the cross-sectional diagram of the cornea.
10. To return to the cross-section selection screen (fig. 3), touch the **Exit** key (15).
11. To return to the Patient Data list (fig. 2), touch the **Exit** key (16) on the cross-section selection window (fig. 3).

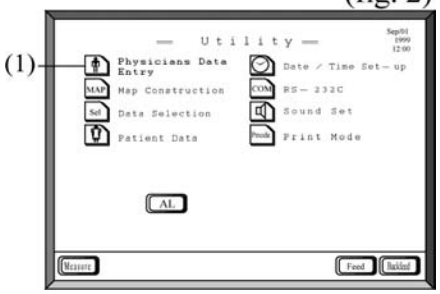
7.5 Utility Setup for General Items

7.5.1 Physicians data entry

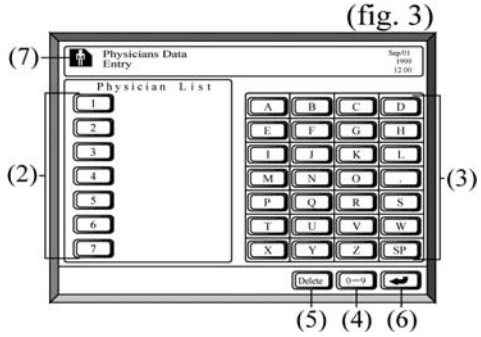
(fig. 1)



(fig. 2)



(fig. 3)



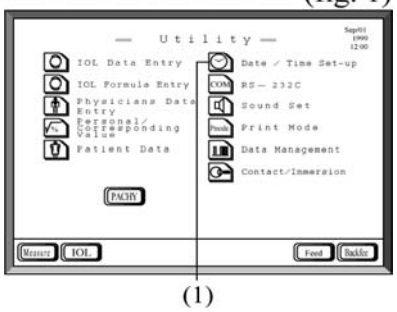
Up to seven names can be entered in the Physician List.

1. Touch the **Physicians Data Entry** key (1) on the biometry Utility screen (fig. 1) or the pachymetry Utility screen (fig. 2) to display the Physician List (fig. 3).
2. Touch a number (2) to activate that slot in the list. The selected number will be reverse highlighted.
3. Enter the physician's name using the letter keys (3). To switch from letters and numbers, touch the **0-9** key (4). To switch back to letters, touch the **A-Z** key.

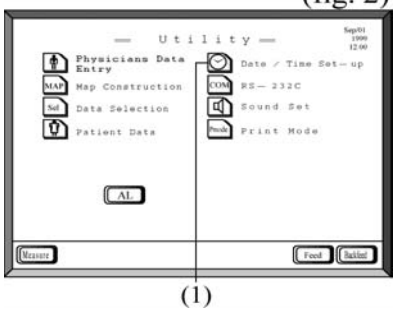
   In the event of an erroneous entry, touch the **Delete** key (5).
4. If you wish to enter another physician to the list, touch the next number key (2) to select the next slot.
5. Touch the **Return** key (6) to set the entered data.
6. Touch the **Physicians Data Entry** key (7) to return to the biometry or pachymetry Utility screen (fig. 1 or fig. 2).

7.5.2 Date/time setup

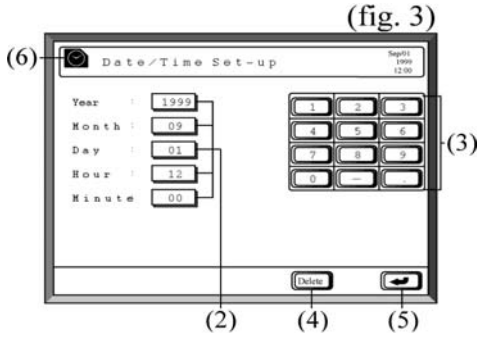
(fig. 1)



(fig. 2)



(fig. 3)

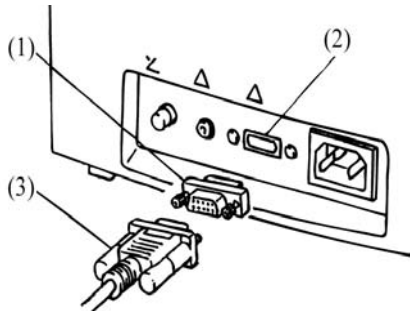


To set the data and time:

1. Touch the **Date/Time Setup** key (1) on the biometry Utility screen (fig. 1) or the pachymetry Utility screen (fig. 2) to display the Date/Time Setup screen (fig. 3).
2. Touch each item key (2) to prepare to enter information for that item. The selected item will be reverse highlighted.
3. Enter the information using the number keys (3).

   In the event of an erroneous entry, touch the **Delete** key (4).
4. Touch the **Return** key (5) to register each value.
5. When settings are completed, touch the Date/Time Setup key (6) to return to the biometry or pachymetry Utility window (fig. 1 or 2).

7.5.3 Data Communication Port (RS-232C)



Measured data may be transferred to a computer via a data communication port (RS-232C).

Follow these steps to attach an RS-232C communication cable:

1. Insert the connector adapter (1) to the RS-232C connection terminal (2) on the back of the instrument and secure the connection by tightening the screws.
2. Connect the RS-232C communication cable (3) to the adapter and secure the connection by tightening the screws.

Accessory equipment connected to the RS-232C interface must be certified according to the appropriate IEC 60601-1 standard for medical equipment. Furthermore, all configurations must comply with the IEC 60601-1 system standard. Anyone who connects additional equipment to the signal input port or signal output port is configuring a medical system and is, therefore, responsible for assuring that the system complies with the requirements of the IEC 60601-1 system standard. If in doubt, contact the Tomey technical service department or your local Tomey representative.

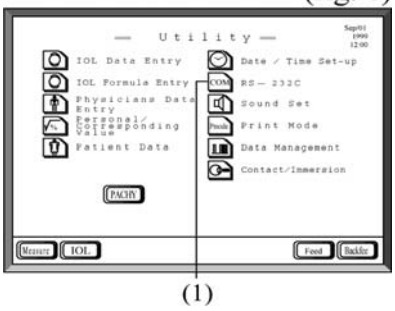
a. Pin positions of the RS-232C connection terminals

Pin #	1	2	3	4	5	6	7	8	9
Signal	--	RxD	TxD	DTR	SG	DSR	RTS	CTS	--

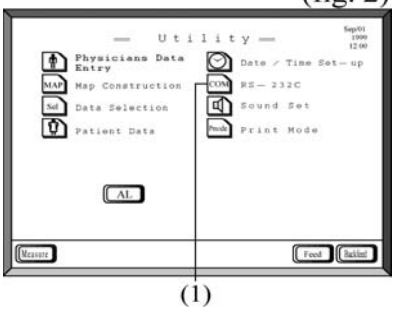
RxD: Receive data
TxD: Transmit data
DTR: Data terminal ready
SG: Signal ground
DSR: Data set ready
RTS: Request to send
CTS: Clear to send

b. Setting the communication conditions

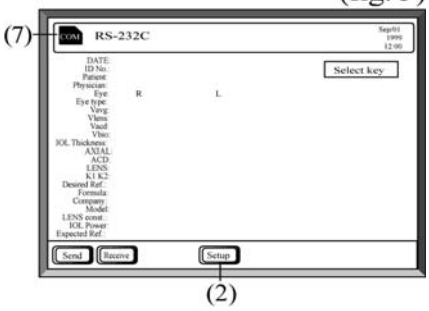
(fig. 1)



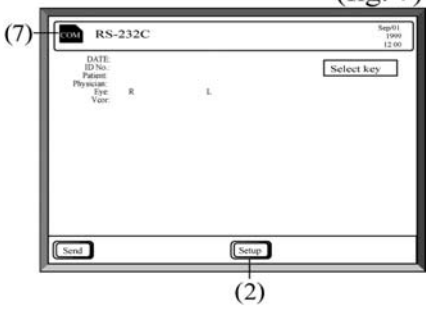
(fig. 2)



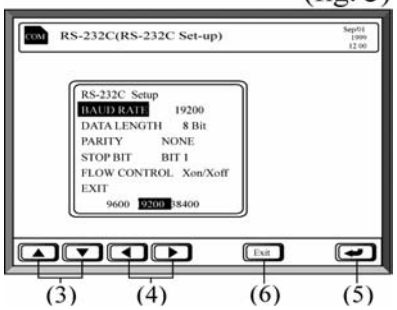
(fig. 3)



(fig. 4)



(fig. 5)

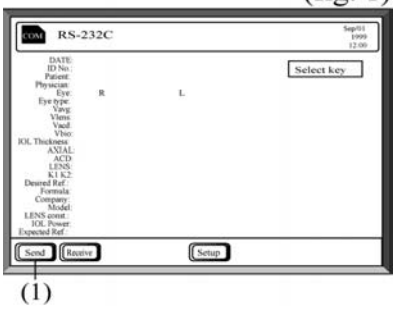


To set the communication conditions:

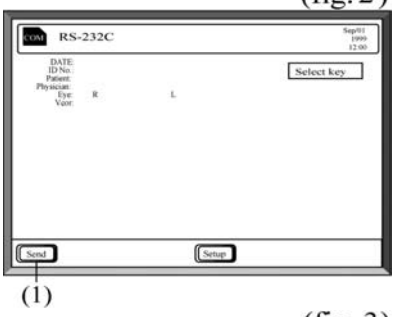
1. Touch the **COM** (RS-232C) key (1) on the biometry Utility screen (fig. 1) or the pachymetry Utility screen (fig. 2) to display the biometry or pachymetry RS-232C Data Communication screen (fig. 3 and fig. 4, respectively).
2. Touch the **Setup** key (2) to display the RS-232C Setup screen (fig. 5).
3. Select the parameter to be set using the up/down arrow keys (3). The options for the selected parameter are shown at the bottom of the screen.
4. Select the desired option for each parameter using the left/right arrow keys (4).
5. Touch the **Return** key (5) to register each selection.
6. Touch the **Exit** key (6) to return to the RS-232C Data Communication screen for biometry (fig. 3) or pachymetry (fig. 4).
7. To return to the biometry or pachymetry Utility screen, touch the **COM** (RS-232C) key (7) on the RS-232C screen (fig. 3 or fig. 4).

c. Transmitting data

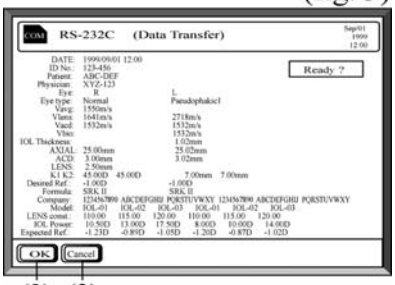
(fig. 1)



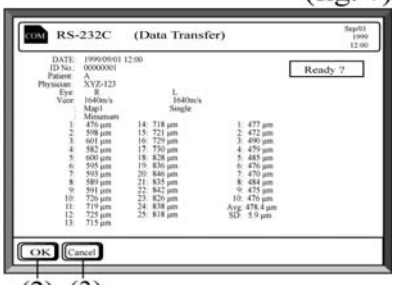
(fig. 2)



(fig. 3)



(fig. 4)

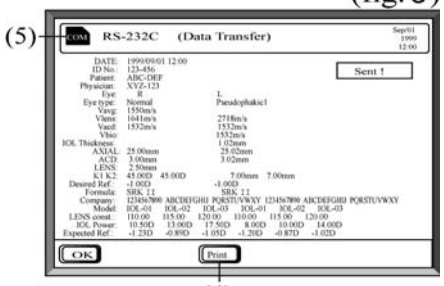


After biometry or pachymetry measurements have been acquired from one or both eyes, the biometry and IOL data or pachymetry data can be transmitted to another AL-2000 or to a computer (PC) as follows:

1. Touch the **COM** (RS-232C) key on the biometry Utility screen or the pachymetry Utility screen (see section 7.3.5b, figs. 1 & 2) to display the appropriate RS-232C Data Communication screen.
2. After the communication conditions have been set (as described in section 7.3.5b), touch the **Send** key (1) on the biometry RS-232C screen (fig. 1) or the pachymetry RS-232C screen (fig. 2) to display the data (fig. 3 and fig. 4, respectively).
3. Touch the **OK** key (2) to initiate data transmission.

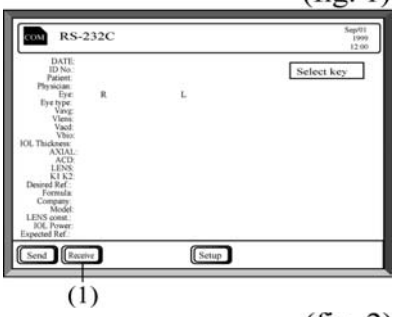
   To abort the transmission, touch the **Cancel** key (3).
4. After the data transmission is complete (indicated by *"Sent!"* at the upper right of the screen), you may obtain a printout of the transferred data by touching the **Print** key (4). (Shown for biometry in fig. 5.)
5. To return to the Utility screen, touch the **COM** (RS-232C) key (5).

(fig. 5)

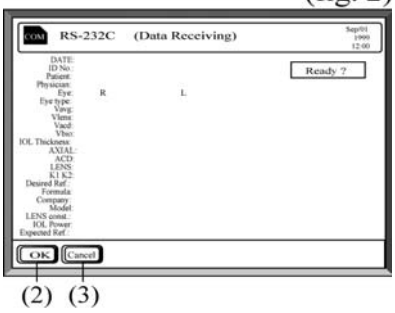


d. Receiving data

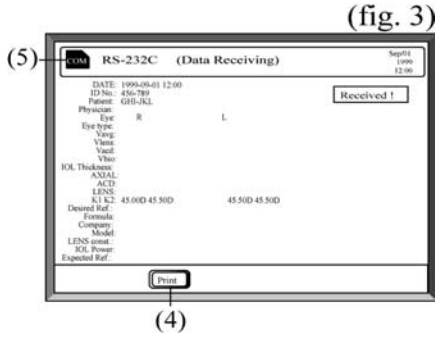
(fig. 1)



(fig. 2)



(fig. 3)



Biometry data may be received from another AL-2000 or from a computer (PC). (Pachymetry data cannot be received.)

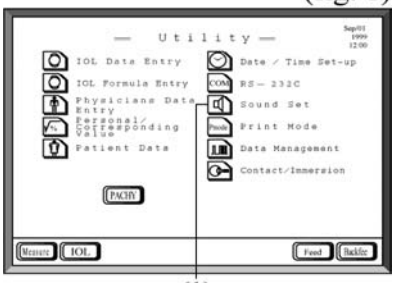
To receive data:

1. Touch the **COM** (RS-232C) key on the biometry Utility screen to display the RS-232C Data Communication screen (fig. 1).
2. After the communication conditions have been set (as described in section 7.5.3b), touch the **Receive** key (1) on the biometry Data Communication screen (fig. 1). The instrument is ready for receiving data (fig. 2).
3. Click the **OK** key (2) to initiate data reception.

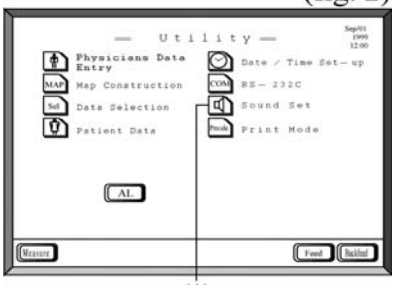
   To abort the reception, touch the **Cancel** key (3).
4. After the data reception is complete (indicated by *"Received!"* at the upper right of the screen), you may obtain a printout of the received data by touching the **Print** key (4).
5. To return to the Utility screen, touch the **COM** (RS-232C) key (5).

7.5.4 Sound Setup

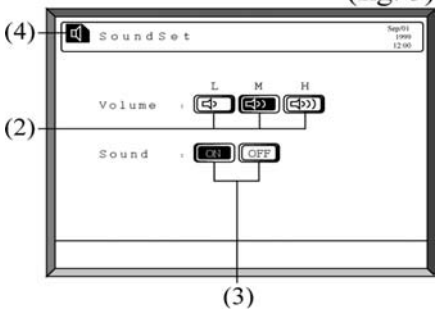
(fig. 1)



(fig. 2)



(fig. 3)

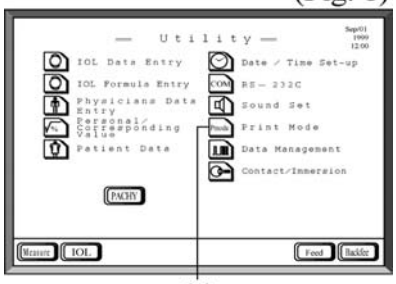


To adjust the sound:

1. Touch the **Sound Set** key (1) on the biometry Utility screen (fig. 1) or the pachymetry Utility screen (fig. 2) to display the Sound Adjustment window (fig. 3).
2. Touch the **Volume** keys (2) to adjust the sound level. The options are:
   - L: Low
   - M: Medium
   - H: High
3. To turn the sound on or off, touch the **On** or **Off** key (3).
4. Touch the **Sound Set** key (4) to return to the biometry or pachymetry Utility screen (fig. 1 or fig. 2).

7.5.5 Print Mode Setup

(Fig. 1)

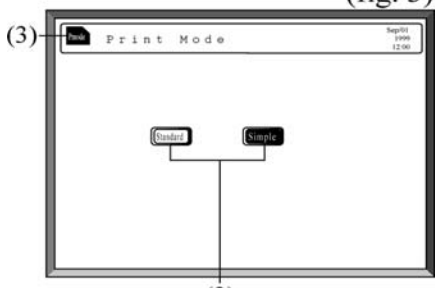


(1)

(Fig. 2)

(1)

(fig. 3)



The printout options are:

- Standard: Includes date, patient name and ID number, physician name and all data.
- Simple: Includes no identifying information and, for some printouts, provides an abbreviated version of the data.

1. Touch the **Print Mode** key (1) on the biometry Utility screen (fig. 1) or the pachymetry Utility screen (fig. 2) to display the Print Mode window (fig. 3).
2. Touch the **Standard** or **Simple** key to select the desired printout mode.
3. Touch the **Print Mode** key (3) to the biometry or pachymetry Utility screen (fig. 1 or fig. 2).

8. MEMORY CARD

Notes

- **Biometry measurements, IOL data and pachymetry measurements can be stored on the memory card. If a memory card other than the one provided is used, there is no guarantee that the data will be properly stored.**
- **The PC memory card used with the AL-2000 is an SRAM type card. Therefore, an SRAM type card reader, not a Flash Memory reader, must be used. If a Flash Memory reader is used, data stored on the memory card may be corrupted.**
- **If data on the memory card are edited using a computer, the card no longer can be used with the AL-2000. It will be necessary to reformat the card before it can be used with the AL-2000.**

8.1 Memory Card Specifications

The memory card is 68 pin SRAM card that complies with the PC Card Standard.

- Configuration: Type 1
- Bytes of memory: 512 Kb
- Power voltage: 5 ± 0.5 V
- Access time: 200 ns

Cards with 1 Mb and 2 Mb are also available.

8.2 Memory Card Capacity and Maximum Number of Entries

Capacity of Memory Card	Biometry or Pachymetry Data (both eyes)
512 Kb	237 patients
1 Mb	484 patients
2 Mb	980 patients

Either biometry measurements and IOL data or pachymetry measurements can be stored for both eyes of the specified number of patients. In other words, there are 237 "bins" on the 512 Kb memory card. Either biometry/IOL data or pachymetry data for one or both eyes can be stored in each bin.

8.3 Memory Card Battery

8.3.1 Replacing the battery

If the message "*Memory card is low battery!*" is displayed, replace the battery by following the directions in the memory card Instruction Manual.

IMPORTANT: If the battery is not replaced within 10 minutes of receiving the "low battery" message, data stored on the memory card might be lost.

8.3.2 Battery life

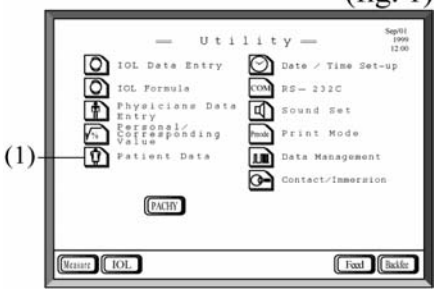
The life of the battery varies as a function of the memory capacity, as indicated below.

Capacity of Memory Card	Battery Life (at 25° C)
512 Kb	Approximately 5 years
1 Mb	Approximately 5 years
2 Mb	Approximately 3 years

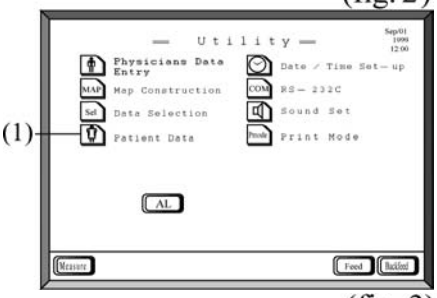
8.4 Formatting the Memory Card

Note The memory card must be formatted before its initial use.

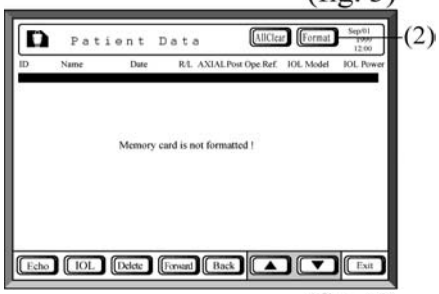
(fig. 1)



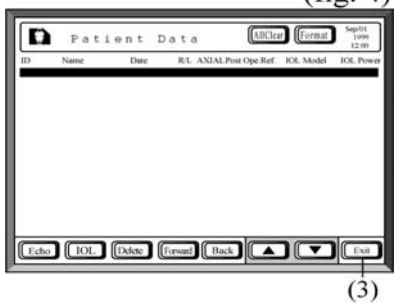
(fig. 2)



(fig. 3)



(fig. 4)



See instructions in Section 3.2.2f) for inserting the memory card.

Before using the memory card for the first time, format it as follows:

1. Touch the **Patient Data** key (1) on the biometry Utility screen (fig. 1) or the pachymetry Utility screen (fig. 2) to display the Patient Data screen.
2. If the memory card has not been formatted, the message "*Memory card is is not formatted!*" will be displayed (fig. 3).
3. Touch the **Format** key (2) for approximately one second until you hear a beep. The memory card will be formatted (fig. 4) and ready for data storage.
4. Touch the **Exit** key (3) to return to the biometry or pachymetry Utility screen (fig. 1 or fig. 2).

8.5 Reading the Memory Card on a Windows Computer

8.5.1 Rewriting the Windows PC system configuration file

1. Open the CONFIG.SYS file in the root directory of the C drive using Notepad.
2. Add the following information to the last line of the Config.sys file:

```
DEVICE=C:\WINDOWS\CSMAPPER.SYS
DEVICE=C:\WINDOWS\SYSTEM\CARDDRV.EXE /SLOT=2
```

   The directory shown in the box may differ for different computers. Specify the directory that contains the Windows system file.
3. Save the CONFIG.SYS file, overwriting the previous version.
4. Re-start Windows.

8.5.2 PC data: location, filename and format

1. Insert the Memory Card into the PC card slot. You will hear a beep when Windows identifies the Memory Card.
2. Open Windows Explorer and view the contents of the Memory Card removable drive. You will find two directories:
   - Axialdt: Stores biometry and IOL data.
   - Pachydt: Stores pachymetry data.
3. Each of the data files may be opened using Notepad.

   The files are identified by patient ID.
   Axial length and corneal thickness data are stored in text mode.
   Axial length waveform data are stored in binary mode.

8.5.3 Removing the Memory Card from the computer

1. Click on the Windows **Start** button.
2. Select **Settings**.
3. Select **Control Panel**.
4. Double-click on the **PC Card [PCMCIA]** icon.
5. On the Socket Status window, select the socket that contains the Memory Card.
6. Click the **Stop** button
7. When the message "*You may safely remove this device*" is displayed, click **OK** and remove the Memory Card by pressing the button (see section 3.2.2f).

8.5.4 Handling the Memory Card files

Files from the AL-2000 Memory Card are read-only files. If you wish to modify the contents of the file, you must make a copy of it and release the read-only attributes of the copy.

9. TECHNICAL INFORMATION

9.1 IOL Calculation Formulae

9.1.1 SRK/II

a. Emmetropic IOL power (D)

$$P_{emme} = A1 - 0.9K - 2.5L$$

b. Ametropic IOL power (D)

$$P_{ame} = P_{emme} - REF \times CR$$

c. Desired postoperative refraction

$$REF_{iol} = (P_{emme} - P)/CR$$

Where:

if L < 20.0 mm, then A1 = A + 3
if 20.0 ≤ L < 21.0 mm, then A1 = A + 2
if 21.0 ≤ L < 22.0 mm, then A1 = A + 1
if 22.0 ≤ L < 24.5 mm, then A1 = A
if L ≥ 24.5 mm, then A1 = A - 0.5

if $P_{emme} \leq 14$, then CR = 1.00
if $P_{emme} > 14$, then CR = 1.25

A: A-constant
K: Corneal refraction (D) [(K1 + K2)/2]
L: Axial length (mm)
P: Power of IOL implant (D)
REF: Postoperative refractive power

9.1.2 SRK/T

a. Emmetropic IOL power (D)

$$P_{emme} = \frac{1000na \cdot X}{(L1 - C1)Y}$$

b. Ametropic IOL power (D)

$$P_{ame} = \frac{1000na \{X - 0.001\ REF\ (V \cdot X + L1 \cdot r)\}}{(L1 - C1)\ \{(Y - 0.001\ REF)\ (V \cdot Y + C1 \cdot r)\}}$$

c. Desired postoperative refraction

$$REF_{iol} = \frac{1000na \cdot X - P(L1 - C1)\ Y}{na\ (V \cdot X + L1 \cdot r) - 0.001P\ (L1 - C1)(V \cdot Y + C1 \cdot r)}$$

Where:

$X = na \cdot r - (nc - 1)\ L1$
$Y = na \cdot r - (nc - 1)\ C1$

r: Average corneal radius of curvature (mm) = 337.5/K
LC: Modified axial length (mm)
if $L \geq 24.2$, then LC = L
if $L < 24.2$, then LC = -3.446 + 1.716L - 0.0237L*L
W: Corneal thickness by calculation (mm) = -5.41 + 0.58412LC + 0.098K
H: Height of the corneal dome (mm) = r - SQRT(r*r - W*W/4)
Ofst: Calculated distance between the iris surface and IOL optical surface (including the corneal thickness) (mm)
= ACD const = -3.336
= (0.62467A - 68.747) - 3.336
C1: Estimated postoperative anterior chamber depth (mm)
= H + Ofst
V: Vertex distance (mm) = 12
na: Refractive index of aqueous and vitreous = 1.336
nc: Refractive index of cornea = 1.333
L1: Optical axial length (mm) = L + (0.65696 - 0.02029L)
L: Measured axial length (mm)
A: A-constant
K: Average corneal refractive power: (K1 + K2)/2 (D)
REF: Desired postoperative refraction (D)
P: Power of IOL implant (D)

d. Personal A-constant

$$A = P + AREF \cdot F + 2.5L + 0.9K - COR$$

Where:

P: Power of IOL implant (D)
S: Spherical index (D)
C: Cylindrical index (D)
AREF: Postoperative refraction <equivalent to the spherical index (D)>
= S + C/2
RF: Refractive factor
if P > 16, then RF = 1.25
if P ≤ 16, then RF = 1
L: Axial length
K: Average corneal refraction (K1 + K2)/2 (D)
COR: Correcting value
if L < 20.0, then COR = 3
if 20.0 ≤ L < 21.0, then COR = 2
if 21.0 ≤ L < 22.0, then COR = 1
if 22.0 ≤ L < 24.5, then COR = 0
if L ≥ 24.5, then COR = -0.5

9.1.3 Holladay

a. IOL power (D)

$$P = \frac{1000na\,\{X - 0.001REF\,(V \cdot X + L2 \cdot r)\}}{(L2 - C2 - SF)\,[Y - 0.001REF\,\{V \cdot Y + r(C2 + SF)\}]}$$

b. Desired postoperative refraction (D)

$$P_{emme} = \frac{1000na \cdot X - P \cdot Q \cdot Y}{na(V \cdot X + L2 \cdot r) - 0.001P \cdot Q\,\{V \cdot Y + r(C2 + SF)\}}$$

Where:

$X = na \cdot r - (nc - 1)\,L2$
$Y = na \cdot r - (nc - 1)\,(C2 + SF)$
$Q = L2 - C2 - SF$

na: Refractive index of aqueous and vitreous = 1.336
nc: Refractive index of cornea = 4.0/3.0
L: Measured axial length (mm)
r: Average corneal radius of curvature (mm) = 337.5/K
K: Average corneal refractive power = (K1 + K2)/2 (D)
SF: Surgeon factor
(Distance between iris surface and optical center of IOL) (mm)
REF: Desired postoperative refraction
V: Vertex distance (mm) = 12
P: Power of IOL implant (D)
L2: Modified axial length (mm) = L + 0.2
C2: Anatomical anterior chamber depth (mm) (distance between corneal apex and iris surface) (mm)

$$= 0.56 + Rag - \sqrt{Rag^2 - AG^2/4}$$

if r < 7 mm, then Rag = 7 mm
if r ≥ 7 mm, then Rag = r
AG = 12.5L/23.45 (if AG > 13.5 mm, then AG = 13.5 mm)

c. Personal SF

$$SF = \{-BQ - \sqrt{BQ^2 - 4AQ \cdot CQ}\}/(2AQ - C2)$$

Where:

$$AQ = (nc - 1) - 0.001AREF[V(nc-1) - r]$$
$$BQ = 0.001AREF\{L2 \cdot V(nc-1) - r(L2 - v \cdot na)\} - \{(nc-1)L2 + na \cdot r\}$$
$$CQ1 = 0.001AREF[V\{na \cdot r - (nc - 1)L2\} + L2 \cdot r]$$
$$CQ2 = 1000na\{na \cdot r - (nc - 1)L2 - CQ1\}/P$$
$$CQ3 = L2 \cdot na \cdot r - 0.001AREF \cdot L2 \cdot V \cdot r \cdot na$$
$$CQ = CQ3 - CQ2$$

na: Refractive index of aqueous and vitreous = 1.336
nc: Refractive index of cornea = 4.0/3.0
L: Measured axial length (mm)
r: Average corneal radius of curvature (mm) = 337.5/K
K: Average corneal refractive power = (K1 + K2)/2 (D)
V: Vertex distance (mm) = 12
P: Power of IOL implant (D)
L2: Modified axial length (mm) = L + 0.2 (mm)
S: Spherical index (D)
C: Cylindrical index (D)
AREF: Postoperative refraction <equivalent to the spherical index (D)>
= S + C/2
C2: Anatomical anterior chamber depth (mm) (distance between corneal apex and iris surface) (mm)

$$= 0.56 + Rag - \sqrt{Rag^2 - AG^2/4}$$

if r < 7 mm, then Rag = 7 mm
if r ≥ 7 mm, then Rag = r
AG = 12.5L/23.45 (if AG > 13.5 mm, then AG = 13.5 mm)

d. Corresponding SF

$$SF = 0.5663A - 65.60$$

Where:

A: A-constant

9.1.4 Hoffer Q

a. Emmetropic IOL power (D)

$$P = \frac{1336}{L - C - 0.05} - \frac{1.336}{\frac{1.336}{K + R} - \frac{C + 0.05}{1000}}$$

Where:

$$R = \frac{Rx}{1 - 0.012Rx}$$

b. Desired postoperative refraction by spectacle (D)

$$R_{xi} = \frac{R_i}{1 + 0.012R_i}$$

Where:

$$R_i = \frac{1.336}{\frac{1.336}{\frac{1336}{L - C - 0.05} - P} + \frac{C + 0.05}{1000}} - K$$

$C = X + Y$
$X = C1 + 0.3(L - 23.5) + (\tan K)^2$
$Y = 0.1M(23.5 - L)\ 2 \tan \{0.1(G - L)^2\} - 0.99166$
if $L \leq 23.0$, then $M = +1$, $G = 28.0$
if $L > 23.0$, then $M = -1$, $G = 23.5$
if $L > 31.0$, then $L = 31.0$
if $L < 18.5$, then $L = 18.5$

P: Power of IOL implant (D)
L: Measured axial length (mm)
C1: Personalized anterior chamber depth (mm)
K: Average refractive power = (K1 + K2)/2 (D)
Rx: Desired postoperative refraction by spectacle (D)

c. Personal ACD

$$ACD = \frac{L + N - \sqrt{(L - N)^2 + \frac{4 \cdot 1336(N - L)}{P}}}{2} - 0.05$$

Where:

$$N = \frac{1336}{K + AR}$$

$$AR = \frac{ARx}{1 - 0.012ARx}$$

d. Predicted postoperative anterior chamber depth (ACD)

$$ACD = X + Y$$

Where:

$X = C1 = 0.3(L - 23.5) + (\tan K)^2$

$Y = 0.1\ M(23.5 - L)^2 \tan\{0.1(G - L)^2\} - 0.99166$

if $L \leq 23.0$, then $M = +1$, $G = 28.0$
if $L > 23.0$, then $M = -1$, $G = 23.5$
if $L > 31.0$, then $L = 31.0$
if $L < 18.5$, then $L = 18.5$

P: Power of IOL implant (D)
L: Measured axial length (mm)
C1: Personalized anterior chamber depth (mm)
K: Average refractive power = (K1 +K2)/2 (D)
ARx: postoperative refraction by spectacle (D)

9.1.5 Haigis standard

a. IOL power (D)

$$P = \frac{1000na}{L-d} - \frac{na}{\frac{na}{z} - \frac{d}{1000}}$$

Where:

$$z = K + \frac{REF}{1 - \frac{REF \cdot V}{1000}}$$

$d = a0 + a1 \cdot ACD + a2 \cdot L$ $(ACD \neq 0)$
$d = (a0 - 0.241 \cdot a1) + (a2 + 0.139 \cdot a1)L$ $(ACD = 0)$
$a0 = 0.62467A - 72.434$
ACDconst - A 0.62467-68.747
[If a1 = 0.4 and a2 = 0.1, a0 = 0.62467A-72.434]

$$K = \frac{1000(nc - 1)}{r}$$

b. Predicted postoperative refractive power (D)

$$REF_{iol} = \frac{1000\,(1000Y - K \cdot X)}{V\,(1000Y - K \cdot X) + 1000X}$$

Where:

$X = d^2 \cdot P + 1000L \cdot na - d \cdot L \cdot P$
$Y = na(1000 \cdot na - L \cdot P + d \cdot P)$

na: Refractive index of aqueous and vitreous = 1.336
nc: Refractive index of cornea = 1.3315
r: Average corneal radius of curvature (mm)
K: Average corneal refractive power (D)
L: Axial length (mm)
ACD: Anterior chamber depth (mm)
REF: Desired postoperative refractive power (D)
V: Vertex distance (mm) = 12
P: Power of IOL implant (D)
a1: 0.4 (default value)
a2: 0.1 (default value)
VKpr: 3.37
ELpr: 23.39

c. Personal A-constant

$$A = \frac{d - a1 \cdot ACD - a2 \cdot L + 73.434}{0.62467} \qquad (ACD \neq 0)$$

$$A = \frac{d - L(a2 + 0.139 \cdot a1) + 0.241 \cdot a1 + 72.434}{0.62467} \qquad (ACD = 0)$$

Where:

$$d = \frac{P(L \cdot z + 1000na) - \sqrt{4P \cdot z(1000L \cdot na \cdot z + 1000L \cdot na \cdot P - 1000^2 \cdot na^2}}{2P \cdot z}$$

$$z = K + \frac{AREF}{1 - \frac{AREF \cdot V}{1000}}$$

$$K = \frac{1000(nc - 1)}{r}$$

na: Refractive index of aqueous and vitreous = 1.336
K: Average corneal refractive power (D)
L: Axial length (mm)
ACD: Anterior chamber depth (mm)
AREF: Postoperative refractive power (D)
V: Vertex distance (mm) = 12
P: Power of IOL implant (D)
a1: 0.4
a2: 0.1

9.1.6 Haigis optimized

a. IOL power (D)

$$P = \frac{1000na}{L-d} - \frac{na}{\frac{na}{z} - \frac{d}{1000}}$$

Where:

$$z = DC + \frac{REF}{1 - \frac{REF \cdot V}{1000}}$$

$$d = a0 + a1 \cdot ACD + a2 \cdot L \qquad (ACD \neq 0)$$
$$d = (a0 - 0.241 \cdot a1) + (a2 + 0.139 \cdot a1)L \qquad (ACD = 0)$$

$$DC = \frac{1000(nc - 1)}{RC}$$

b. Predicted postoperative refractive power (D)

$$REF_{iol} = \frac{1000\,(1000Y - DC \cdot X)}{V\,(1000Y - DC \cdot X) + 1000X}$$

Where:

$$X = d^2 \cdot P + 1000L \cdot na - d \cdot L \cdot P$$
$$Y = na(1000 \cdot na - L \cdot P + d \cdot P)$$

na: Refractive index of aqueous and vitreous = 1.336
nc: Refractive index of cornea = 1.3315
RC: Average corneal radius of curvature (mm)
DC: Average corneal refractive power (D)
L: Axial length (mm)
ACD: Anterior chamber depth (mm)
REF: Desired postoperative refractive power (D)
V: Vertex distance (mm) = 12
P: Power of IOL implant (D)

$-10 < a0 < +10$
$-1 < a1 < +1$
$-1 < a2 < +1$
$2 < a0 + a1 \times 3.37 + a2 \times 23.39 < 7$
$2 < a0 + a1 \times 2.53 + a2 \times 20.00 < 7$
$2 < a0 + a1 \times 3.50 + a2 \times 27.00 < 7$

9.2 Ultrasound Velocity used in Axial Length Measurement

9.2.1 Normal

- Average ultrasound velocity: 1,550 m/s
- Average ultrasound velocity in the lens: 1,641 m/s
- Average ultrasound velocity in the anterior chamber: 1,532 m/s

Axial length is calculated using the following formula:

$$L = \frac{V \cdot t}{2}$$

Where:

L: Axial length
V: Average ultrasound velocity
t: Time

9.2.2 Dense Cataract

- Average ultrasound velocity: 1,548 m/s
- Average ultrasound velocity in the lens: 1,629 m/s
- Average ultrasound velocity in the anterior chamber: 1,532 m/s

Axial length is calculated using the same formula as for the normal lens.

9.2.3 Aphakic

- Average ultrasound velocity: 1,532 m/s

Axial length is calculated using the same formula as for the normal lens.

9.2.4 Pseudophakic

- Ultrasound velocity in IOL*:
  - Pseudophakic 1 - PMMA 2,718 m/s
  - Pseudophakic 2 - Silicon 1,049 m/s
  - Pseudophakic 3 - Acrylic 2,200 m/s

*Ultrasound velocity may vary between materials and manufacturers and depending on temperature.

- Biometric ultrasound velocity: 1,532 m/s
- Average ultrasound velocity in the anterior chamber: 1,532 m/s

Axial length is calculated using the following formula:

$$Lp = L + Th\left(1 - \frac{V_{BIO}}{V_{IOL}}\right)$$

Where:

Lp: Axial length
L: Axial length calculated with the biometric ultrasound velocity
Th: Central thickness of IOL (must be entered)
V_{BIO}: Biometric ultrasound velocity
V_{IOL}: Ultrasound velocity in the IOL (must be entered)

9.3 Axial Length Calculation in Eyes with Silicone Oil

9.3.1 Normal eyes in which vitreous is replaced by silicone oil

After performing axial length measurement with the eye type set for Normal (default setting), use the following formula to calculate axial length:

$$AL(S) = \left[\left(\frac{AL}{V(a)} - \frac{LENS}{V(lens)} - \frac{ACD}{V(ac)}\right) \times V(sil)\right] + LENS + ACD$$

Where:

AL(S)	=	Axial length for eye with silicone oil
AL	=	Axial length (measured)
LENS	=	Lens thickness (measured)
ACD	=	Anterior chamber depth (measured)
V(a)	=	Average ultrasound velocity (default = 1,550 m/s)
V(lens)	=	Velocity in lens (default = 1,641 m/s)
V(ac)	=	Velocity in anterior chamber (default = 1,532 m/s)
V(sil)	=	Velocity in silicone oil (provided by silicone oil manufacturer)

9.3.2 Pseudophakic eyes in which vitreous is replaced by silicone oil

After performing axial length measurement with the eye type set for the appropriate Pseudophakic setting, use the following formula to calculate axial length:

$$AL(S) = \left[\left(\frac{AL(P) - Th}{V(bio)} - \frac{ACD(P)}{V(ac)}\right) \times V(sil)\right] + ACD(P) + Th$$

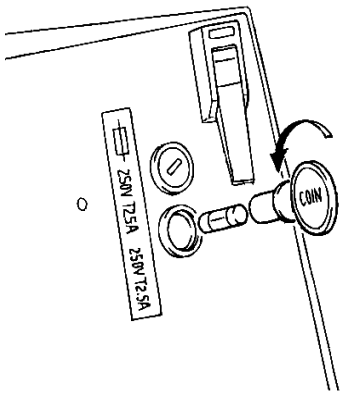
Where:

AL(S)	=	Axial length for eye with silicone oil
AL(P)	=	Axial length (measured in pseudophakic eye)
ACD(P)	=	Anterior chamber depth (measured in pseudophakic eye)
Th	=	IOL thickness (provided by IOL manufacturer)
V(bio)	=	Average ultrasound velocity (default = 1,532 m/s)
V(ac)	=	Velocity in anterior chamber (default = 1,532 m/s)
V(sil)	=	Velocity in silicone oil (provided by silicone oil manufacturer)

10. MAINTENANCE

10.1 Replacing fuses

CAUTION Unplug the power cord when replacing fuses.



If the AL-2000 does not operate when the power switch is turned ON (and you have ascertained that the power outlet is functioning properly), it is possible that a fuse is defective.

To replace the fuses:

1. Turn the AL-2000 off and unplug the power cord from the power outlet.
2. Rotate the fuse holders counter clockwise approximately 90 degrees using a coin or a screwdriver, and the holder will pop out.
3. Check both fuses and replace them if necesssary.

   A good fuse will have a thin strip of metal from one end to the other without any noticeable breaks. A blown fuse will have all or a portion of the metal melted away inside.
4. Reinsert the fuse holders and turn clockwise to lock them in place.

10.2 Routine maintenance

10.2.1 Maintenance of the probes

CAUTION When disconnecting the probes, be sure to hold the plug, not the cable.

Notes

- Do not use an autoclave to sterilize the probes since this may severely damage them.
- Do not pull on the probe cords when cleaning the probes.

a. Disinfecting the probes

Disinfect the biometry probe and the pachymetry probe by immersing the tip in a 0.5% solution (1 to 10 dilution) of sodium hypochlorite for 10 to 20 minutes. Then rinse with distilled water and allow to dry before use.

b. Cleaning the probe handle and cord

The procedure for cleaning the probe handle and cord is as follows:

1. Wipe the probe handle with a soapy or alcohol-soaked cloth and then rinse it with water.
2. Clean the cord using a wet cloth.
3. After cleaning, remove excess water from the probe and the cord.

10.2.2 Maintenance of the main unit

Notes

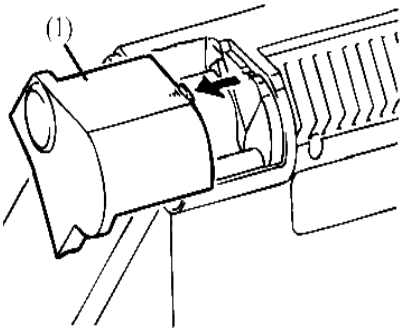
- **Do not use organic solvents for cleaning the AL-2000 as they may cause damage to the surface.**
- **When removing the power cord, grasp the plug, not the cord and do not apply undue force.**

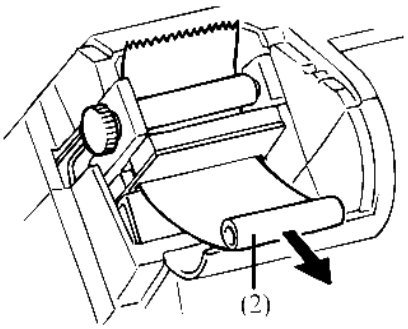
Wipe off dirt gently with a wet cloth and then remove excess water with a dry cloth. If dirt is difficult to remove, use a diluted, mild detergent.

Clean the surface of the monitor with a dry cloth. If dirt is difficult to remove, use diluted, mild detergent on a soft cloth. Then rinse and remove excess moisture with a dry cloth.

10.3 Replacing Printer Paper

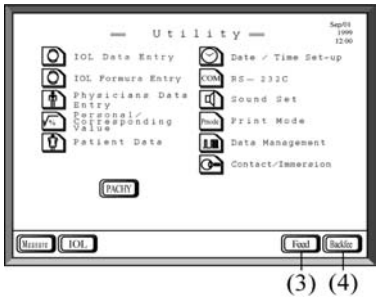
Replace the paper when red lines appear on both sides of the paper.

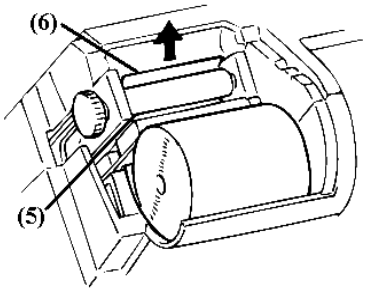




1. Display either the biometry Utility screen or the pachymetry Utility screen (see section 7.1).
2. With the power on, remove the printer cover (1) by sliding it in the direction of the arrow.
3. Remove the used roll of paper. If necessary, touch the **Feed** key (3) or the **Backfeed** key (4) on the Utility screen (shown for biometry Utility screen).
4. Insert the leading end of the new roll of paper into the paper insertion slot (5). The paper will be detected and automatically fed into the printer. (See figure on next page.)

   Care should be taken to place the paper with the correct side up, as indicated in the diagram.
5. When the leading end of the paper emerges from the outlet slot (6), touch the **Feed** key (3) or the **Backfeed** key (4) to adjust it. (See figures on next page.)
6. Place the printer cover in position and cut off the excess paper.





10.4 Storage

When storing the AL-2000, the protective cap should be placed on the clean biometry probe tip and both probes should be placed in the cases provided.

If the instrument is not to be used for a prolonged period, disconnect the power cord and place the dust cover over the instrument.

CAUTION

- **Do not store this instrument in a location where it might be exposed to water.**
- **Avoid excessive atmospheric pressure, high temperature, excessive humidity, poor ventilation, direct sunlight, dust, salt or sulfur in the air.**
- **Do not store this instrument near chemical substances or in a location where gas may be generated.**
- **Ascertain that factors such as excessive slope, vibration and impact will not endanger the instrument (including during transportation).**

10.5 Packing materials

Notes

- **Keep the carton and packing materials for future use.**
- **If you discard the packing materials, be sure to comply with local ordinances and regulations for disposal.**

10.6 Tomey One-Year Limited Warranty

The Seller warrants this product to be free from defects in material and workmanship under the normal use of this product for one year from the date of invoice issued by the Seller to the original purchaser.

This warranty shall apply only to the original purchaser and shall NOT, in any way, be transferable or assignable to any other party than the original purchaser.

This warranty also shall NOT apply if the product has not been installed, operated or maintained in accordance with the OPERATOR MANUAL of Tomey Corporation (hereinafter called "Tomey"). Neither the Seller nor Tomey shall be liable for any damages caused by the purchaser's failure to follow instructions for proper installation, use and maintenance of the product.

This warranty is only applicable to the new product and does NOT cover any damage resulting from or caused by accident or negligence, abuse, misuse, mishandling, improper installation, improper repair or improper modification of this product, by persons other than personnel duly authorized by Tomey, nor to a product whose serial number or batch number is removed, altered or effaced.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED (INCLUDING SPECIFICALLY, WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE), AND ALL OTHER OBLIGATION AND LIABILITY ON THE PART OF THE SELLER AND TOMEY. NEITHER THE SELLER NOR TOMEY SHALL BE LIABLE FOR INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES UNDER ANY CIRCUMSTANCES OR FOR MORE THAN REPAIR, REPLACEMENT OR REFUND OF THE PURCHASE PRICE OF DEFECTIVE GOODS.

11. TROUBLESHOOTING

DO NOT REMOVE THE OUTER COVER OF THIS INSTRUMENT. If you do, you may be exposed to the danger of direct high voltage.

Note **Do not attempt to use this instrument for any purposes other than those specified in the manual**

Before presuming that the instrument is malfunctioning, check the following troubleshooting suggestions. If you are still unable to correct the problem, contact your local Tomey representative.

11.1 General problems

> No power when the instrument is turned on. (Power indicator light not lit.)
- Is the power plug securely connected to the power receptacle?
- Is the power properly supplied?
- Is the power cord securely inserted into the power source receptacle on the back of the AL-2000? (See section 3.2.2d)
- Are the fuses intact? (See section 10.1)

> The monitor screen is too dark.
- Is the power on (see above)?
- Is the contrast adjusted properly? (See section 4.1.1)
- Is the auto power-off function activated? (See section 4.1.1)

> Cannot obtain printout.
- Is the printer paper loaded properly? (See section 10.3)
- Is there any paper left?
- Is Is the correct type of printer paper used?

11.2 Biometry function

> Biometry probe check is negative.
- Is the biometry probe securely connected to the terminal labeled BIO? (See section 3.2.2b)

> Biometry measurement cannot be obtained.
- Is the biometry probe securely connected to the terminal labeled BIO? (See section 3.2.2b)
- Have the biometry settings been entered? (See sections 4.1.3 and 7.3)

> Automatic measurement cannot be performed.
- Is the instrument set for manual measurement. (See section 4.1.3e)
- Is there any contamination due to the proximity of electromagnetic radiation (e.g., from a motor or high voltage power line)?
- Is the patient fixating properly?
- Is the tip of the biometry probe damaged?

> Manual measurement cannot be performed.
- Is the footswitch properly connected? (See section 3.2.2e)
- Is the instrument set for automatic measurement? (See section 4.1.3e)

> The measurement data are not accurate.
- Is the biometry probe securely connected? (See section 3.2.2b)
- Is the pachymetry probe connected to the terminal labeled BIO?
- Is the probe cord pulling on the chin rest slider? (See section 3.2.3a)
- Is the tip of the biometry probe damaged?
- Is the converted velocity set properly? (See section 4.1.3c)
- Is an excessive amount of corneal protective agent being used?
- Is too much pressure being applied to the cornea?
- Is the biometry probe applied to the cornea at a right angle?
- Does the waveshape appear to be correct? (See section 4.2.7)
- Is there any waveshape between the actual retinal wave and the retinal wave cursor? (See section 4.2.7)

> The beep sounds when measurements are not being taken.
- Is the biometry probe immersed in water?

> A beep does not occur when a measurement is taken.
- Is the Utility Sound setting set to OFF? (See section 7.5.4)

> The waveshape is contaminated with noise.
- Is the biometry probe securely connected? (See section 3.2.2b)
- Is the power receptacle properly grounded?
- Is a source of electromagnetic radiation (such as a motor or high voltage power line) located close to the instrument?

11.3 Pachymetry function

> Pachymetry probe check is negative.
- Is the pachymetry probe securely connected to the terminal labeled PACHY? (See section 3.2.2c)

> Pachymetry measurement cannot be obtained.
- Is the pachymetry probe securely connected to the terminal labeled PACHY? (See section 3.2.2c)

- Have the pachymetry settings been entered? (See sections 5.1.3 and 7.4)
- Is "Out of range" indicated? (See section 5.1.3f)

> Automatic measurement cannot be performed.
- Is the instrument set for manual measurement. (See section 5.1.3d)
- Is "Out of range" indicated? (See section 5.1.3f)
- Is the tip of the pachymetry probe damaged?
- Is the probe applied to the cornea at a right angle?
- Is the corneal surface too dry?

> Manual measurement cannot be performed.
- Is the footswitch properly connected? (See section 3.2.2e)
- Is the instrument set for automatic measurement? (See section 5.1.3d)
- Is "Out of range" indicated? (See section 5.1.3f)
- Is the tip of the pachymetry probe damaged?
- Is the probe applied to the cornea at a right angle?
- Is the corneal surface too dry?

> The measurement data are not accurate.
- Is the pachymetry probe securely connected? (See section 3.2.2c)
- Is the biometry probe connected to the terminal labeled PACHY?
- Is the tip of the pachymetry probe damaged?
- Is the converted velocity set properly? (See section 5.1.3c)
- Is too much pressure being applied to the cornea?
- Is the probe applied to the cornea at a right angle?

> The beep sounds when measurements are not being taken.
- Is the pachymetry probe immersed in water?

> A beep does not occur when a measurement is taken.
- Is the Utility Sound setting set to OFF? (See section 7.5.4)

11.4 Memory card

> Data cannot be stored on the memory card.
- Is an ID number entered for the patient? (See sections 4.1.3a and 5.1.3a)
- Is the memory card properly inserted? (See section 3.2.2f)
- Is the memory card write protected? (See back of card)
- Is the memory card full? (Message *"Memory card is full"* will appear.)

> Data stored on the memory card is lost.
- Is the memory card battery dead? (See Sectin 8.3)
- Is the battery properly installed? (See Memory Card Instruction Manual)

> Data stored on the memory card cannot be read on a computer.

- Was the memory card properly inserted? (See Section 3.2.2f)
- Is the memory card write protected? (See back of card)
- Was the Config.sys file rewritten? (See Section 8.5.1)
- Does the computer have the capacity to use a memory card?

12. SPARE PARTS AND OPTIONAL PARTS

To order spare parts and/or optional parts, contact your local Tomey representative or distributor. When ordering, be sure to specify that your order is for the AL-2000.

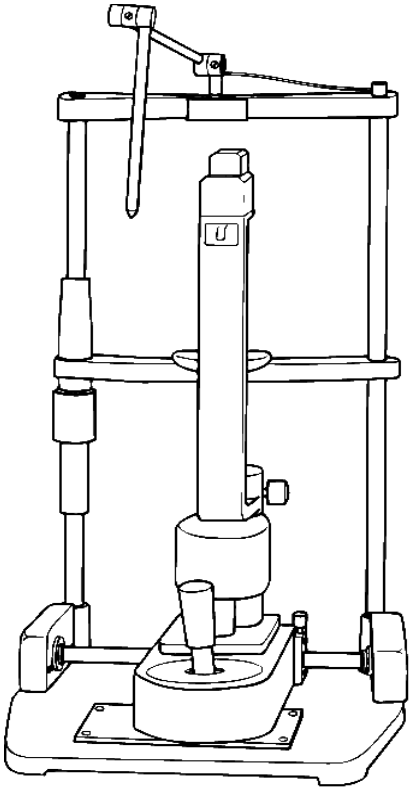
12.1 Spare parts

Printer paper

Memory card
(512 Kb, 1 Mb or 2 Mb)

12.2 Optional part

Chin rest
(AL-1100)



13. SPECIFICATIONS AND MISCELLANEOUS INFORMATION

13.1 Specifications

13.1.1 Biometry/IOL power calculation

> Measurement range
- Axial length: 15.00 - 40.00 mm
- Anterior chamber depth: 2.00 - 7.00 mm
- Lens thickness: 2.00 - 6.00 mm

> Measurement accuracy and resolution
- Accuracy: ±0.1 mm
- Resolution: 0.01 mm

> Converted velocity - factory setting and setting range
- Mean velocity of axial length

Normal:	1,550 m/s	1,500 - 1,600 m/s
Dense cataract:	1,548 m/s	1,500 - 1,600 m/s
Aphakic:	1,532 m/s	1,430 - 1,630 m/s

- Lens velocity

Normal:	1,641 m/s	1,540 - 1,740 m/s
Dense cataract:	1,629 m/s	1,540 - 1,740 m/s

- Anterior chamber velocity

Normal:	1,532 m/s	1,430 - 1,630 m/s
Dense cataract:	1,532 m/s	1,430 - 1,630 m/s
Aphakic:	1,532 m/s	1,430 - 1,630 m/s

- Velocity of vitreous body and anterior chamber

Pseudophakic:	1,532 m/s	1,000 - 2,000 m/s

- IOL velocity

Pseudophakic 1:	2,718 m/s	800 - 3,000 m/s
Pseudophakic 2:	1,049 m/s	800 - 3,000 m/s
Pseudophakic 3:	2,200 m/s	800 - 3,000 m/s

- IOL thickness

Pseudophakic:	1.00 mm	0.10 - 4.00 mm

> IOL formulae
- SRK II
- SRK/T
- Holladay
- Hoffer-Q
- Haigis standard
- Haigis optimized

> Biometry probe
- Type: solid state
- Fixation light: built-in red LED
- Transducer frequency: 10 MHz ±10%
- Tip radius: 5.0 mm (concave)
- Dimensions/weight: 8 mm x 100 mm/30 g

13.1.2 Pachymetry

- > Measurement range: 150 - 1,500 μm
- > Measurement accuracy and resolution
  - Accuracy: ±5 μm
  - Resolution: 1.00 μm
- > Bias setting range
  - Percent bias: 60 - 130 %
  - Plus/minus bias: -600 - +450 μm
- > Converted velocity - factory setting and setting range
  - Factory setting: 1,640 m/s
  - Range: 1,400 - 2,000 m/s
- > Pachymetry probe
  - Type: solid state
  - Transducer frequency: 20 MHz ±10%
  - Tip radius: 1.5 mm with an angle of 45° (flat)
  - Dimensions/weight: 8.8 mm x 90 mm/40 g

13.1.3 Main Unit

- > Display: 9.4" monochrome LCD; 640 x 480
- > Dimensions: 300 (w) x 209 (d) x 235 (h) mm
  11.8 (w) x 8.2 (d) x 9.3 (h) in
- > Weight: 5.4 Kg/11.9 lb

13.1.4 Power Requirements

- > Voltage: AC100V/230V
- > Frequency: 50/60 Hz
- > Power consumption: Less than 50VA ±15%

*All specifications are subject to change without notice.

13.2 Ultrasound energy

13.2.1 Acoustic Output Reporting Table

Biometry Probe

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Pre-enactment Maximum Acoustic Output			0.23	17	28
Global Maximum Value			0.175	0.618	8.584
Associated Acoustic Parameter	$P_{r.3}$ (Mpa)		0.50		
	W_o (mW)			10.12	10.12
	f_c (MHz)		10	10	10
	z_{sp} (cm)		26.3	26.3	26.3
	Beam dimensions	x_{-6} (cm)		0.12	0.12
		y_{-6} (cm)		0.12	0.12
	PD (µsec)		0.24		0.24
	PRF (PRF)		360		360
	EBD	Az. (cm)		0.4	
		Ele. (cm)		0.4	

Pachymetry Probe

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Pre-enactment Maximum Acoustic Output			0.222	15.62	25.72
Global Maximum Value			0.128	13.55	19.63
Associated Acoustic Parameter	$P_{r.3}$ (Mpa)		0.48		
	W_o (mW)			1.7	1.7
	f_c (MHz)		20	20	20
	z_{sp} (cm)		0.08	0.08	0.08
	Beam dimensions	x_{-6} (cm)		0.1	0.1
		y_{-6} (cm)		0.1	0.1
	PD (µsec)		0.081		0.081
	PRF (PRF)		8000		8000
	EBD	Az. (cm)		0.19	
		Ele. (cm)		0.18	

Symbols used in the table are described below:

- $I_{SPTA.3}$ Derated spatial-peak temporal-average intensity (milliwatts per square centimeter)
- $I_{SPPA.3}$ Derated spatial-peak pulse-average intensity (watts per square centimeter)
- MI Mechanical index
- $p_{r.3}$ Derated peak rarefactional pressure (megapascals) associated with the transmit pattern giving rise to the value reported under MI
- W_o Ultrasonic power (milliwatts)
- f_c Center frequency (MHz)

z_{sp} Axial distance at which the reported parameter is measured (centimeters)

x_{-6}, y_{-6} In plane (azimuthal) and out of plane -6 dB dimensions, respectively, in the x-y plane where z_{sp} is found (centimeters)

PD Pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of the respective parameter

PRF Pulse repetition frequency (Hz) associated with the transmit pattern giving rise to the reported value of the respective parameter

EBD Entrance beam dimensions for the azimuthal and elevational planes (centimeters).

13.2.2 Acoustic Output Evaluation - Biometer

a) **Test**: One-sided T test

Formula: $L \geq X + Ks$

Where:

L: Limit

X: Mean of measured values

s: Standard deviation of measured values

K: Factor described in **Table A. 12d**, p. 315, ***Statistical Intervals***, Hahn et al.,

Where:

γ: Confidence level = 1 - α

p: Proportion of distribution < X = Ks

n: Sample size

b) **Measured data**

unit: W/m^2

n	MI	ISPTA.3	ISPPA.3
1	0.156	0.600	7.624
2	0.148	0.532	6.568
3	0.177	0.511	8.692
4	0.168	0.620	7.256
5	0.145	0.511	5.404
6	0.150	0.536	6.109
X	0.157	0.552	6.942
s	0.013	0.047	1.168

c) **Statistical calculation**

	γ	p	n	K	X	S	X + Ks	L
MI	0.90	0.95	6	3.092	0.157	0.013	0.20	0.23
	0.95	0.95	6	3.708	0.157	0.013	0.20	0.23
	0.99	0.95	6	5.406	0.157	0.013	0.23	0.23
ISPTA.3	0.90	0.95	6	3.092	0.552	0.047	0.70	17.00
	0.95	0.95	6	3.708	0.552	0.047	0.73	17.00
	0.99	0.95	6	5.406	0.552	0.047	0.80	17.00
ISPPA.3	0.90	0.95	6	3.092	6.942	1.168	10.55	28.00
	0.95	0.95	6	3.708	6.942	1.168	11.27	28.00
	0.99	0.95	6	5.406	6.942	1.168	13.26	28.00

d) Conclusion:

No values exceed the upper limit of the 99% confidence level. From this we conclude that the ultrasound output is safe for human patients.

13.2.3 Acoustic Output Evaluation - Pachymeter

a) **Test**: One-sided T test

Formula: $L \geq X + Ks$

Where:

L: Limit

X: Mean of measured values

s: Standard deviation of measured values

K: Factor described in **Table A. 12d**, p. 315, ***Statistical Intervals***, Hahn et al.,

Where:

γ: Confidence level = 1 - α

p: Proportion of distribution < X = Ks

n: Sample size

b) Measured data

unit: W/m^2

n	MI	ISPTA.3	ISPPA.3
1	0.093	11.430	18.290
2	0.109	12.830	19.730
3	0.098	13.100	18.890
4	0.098	11.500	19.170
5	0.125	13.100	18.720
6	0.125	12.760	18.230
X	0.108	12.453	18.838
s	0.014	0.778	0.564

c) Statistical calculation

	γ	p	n	K	X	S	X + Ks	L
MI	0.90	0.95	6	3.092	0.108	0.014	0.15	0.23
	0.95	0.95	6	3.708	0.108	0.014	0.16	0.23
	0.99	0.95	6	5.406	0.108	0.014	0.19	0.23
ISPTA.3	0.90	0.95	6	3.092	12.453	0.778	14.86	17.00
	0.95	0.95	6	3.708	12.453	0.778	15.34	17.00
	0.99	0.95	6	5.406	12.453	0.778	16.66	17.00
ISPPA.3	0.90	0.95	6	3.092	18.838	0.564	20.58	28.00
	0.95	0.95	6	3.708	18.838	0.564	20.93	28.00
	0.99	0.95	6	5.406	18.838	0.564	21.89	28.00

d) Conclusion

No values exceed the upper limit of the 99% confidence level. From this we conclude that the ultrasound output is safe for human patients.

13.3 Sounds generated by the AL-2000

The instrument emits monitoring sounds on the following occasions:

- When the power is turned on.
- When giving self-diagnosis.
- When initiating printing.
- When various keys are operated.
- When measurements are acquired.

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