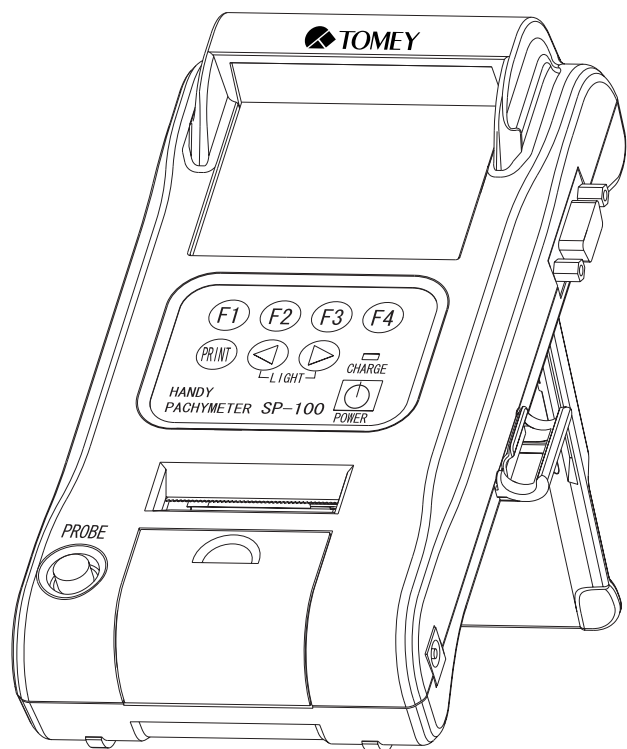


OPERATION MANUAL

HANDY PACHYMETER SP-100



Read this Operation Manual carefully before using the SP-100 for proper and safe operation. If you come up any questions about this instrument or the Manual, ask your Tomey representative or local distributor.

Notes

- Do not use this instrument by any procedures other than those specified in this Manual.
- Only well-trained or skilled personnel is allowed to operate this instrument.
- Keep the Operation Manual in a place where you can easily access while operating the instrument.



WARNINGS



- ***DO NOT USE THE INSTRUMENT WITH THE OUTER COVER AS LEFT OPEN OR REMOVED, otherwise you may be exposed to direct high voltage.***



- ***Always use the sterilized or disinfected Pachymeter Probes for measurement.***
- ***NEVER USE the Probe if it may be subjected to any visible damage on its tip. Such use may not only cause an incorrect measurement, but also damage the cornea.***



- ***This instrument is designed exclusively for ophthalmic use. DO NOT USE the instrument for any purpose other than ophthalmic use.***
 - ***DO NOT connect the terminals of the instrument with any cable other than those specified in the Manual, otherwise the instrument may be damaged.***
-

HOW TO USE THIS OPERATION MANUAL

THE COMPOSITION OF THE OPERATION MANUAL

The following items are provided for your efficient and effective use of this instrument.

The Operation Manual is composed of the following parts.

1. PRIOR TO USE

Precaution and confirmation items related to the installation and usage of the instrument.

2. NAMES AND FUNCTIONS OF THE COMONENTS

Names and functions of the components of the instrument

3. OPERATING PROCEDURES

Vital information, required for installing and using the instrument

4. TECHNICAL INFORMATION

Useful technical information, which may be convenient for your use

5. MAINTENANCE AND INSPECTION

Routine replacement, maintenance, and inspection, including replacing spare parts

6. TROUBLESHOOTING

Countermeasures for troubles

7. SPARE PARTS AND OPTIONAL PARTS

Accessories and optional parts

8. SPECIFICATIONS

Specifications for the instrument

9. INDEX

Refer to the index as a guide, if necessary.

SYMBOLS USED IN THE MANUAL

The symbols, such as "DANGER", "WARNING", "CAUTION" and "NOTE" used in this Operation Manual, represent the following messages.



- *Precaution for an operation state that, if unheeded, will cause a hazardous situation where there is an imminent danger of serious injury or death.*



- *Precaution for an operation state that, if unheeded, may cause a hazardous situation where there is the possibility of serious injuries or death.*



- *An operational precaution that, if unheeded, may cause or lead to minor or moderate injuries or property damages.*



- *Special precaution that is related either directly or indirectly to personal safety or to property protection.*

Contents

1.	PRIOR TO USE	1-1
1.1	Precautions	1-1
1.2	Unpacking	1-3
1.3	Symbols, used in this manual	1-4
1.4	Outline of Measurement Principle	1-5
2.	NAMES AND FUNCTIONS OF THE COMPONENTS	2-1
2.1	Front and Right side of Main Unit	2-1
2.2	Rear and left side of Main Unit	2-1
2.3	Operation Keys	2-2
3.	OPERATING PROCEDURES	3-1
3.1	Safety precautions	3-1
3.2	Preparation before operation	3-2
3.2.1	Connection of accessories	3-2
3.2.2	Disinfection of the probe	3-2
3.2.3	Optional components	3-3
3.3	Adjustment and Setting	3-4
3.3.1	Main power on and screen adjustment	3-4
3.3.2	Startup Display	3-5
3.3.3	Screen Contents	3-7
3.3.4	Measuring conditions	3-9
3.4	Preparation for measurement	3-12
3.4.1	Calibration of the Probe	3-12
3.4.2	Operation Check	3-13
3.4.3	Measurement Preparation for Patient	3-13
3.5	Measurement	3-14
3.5.1	Single measurement	3-15
3.5.2	Delete Each Data Reading	3-16
3.5.3	Delete Data (Eye by eye or patient by patient)	3-17
3.6	Printout	3-19
3.6.1	How to Printout the data	3-19
3.6.2	Description of Printout	3-20
3.6.3	IOP Calculation Printout	3-21
3.7	Menu	3-22
3.7.1	Description of the Screen display	3-22
3.7.2	Operation for the MENU Screen	3-23
3.7.3	Operating procedures of the Menu Screen	3-24

3.7.4	IOP Calculation	3-29
3.8	Sending and receiving data	3-32
3.8.1	How to connect the serial communication cable	3-32
3.8.2	Setting of communication conditions	3-33
3.8.3	Data Export	3-35
3.8.4	Data Receiving	3-37
3.9	Data Management with TOMEY Link (Electronic Medical Record Support System)	3-39
3.9.1	Patient Data Receiving	3-39
3.9.2	Data Sending	3-41
3.10	Battery	3-43
3.10.1	Battery charge balance	3-43
3.10.2	Low Battery Warning	3-44
3.10.3	Charge indicator	3-45
3.10.4	How to Install / Uninstall Battery	3-45
3.10.5	Lifetime of rechargeable battery	3-46
3.10.6	Expected operating time of hours	3-46
4.	REFERENCE TECHNICAL INFORMATION	4-1
4.1	How to calculate corneal thickness	4-1
4.2	Acoustic Output	4-1
4.2.1	MI (Mechanical Index)	4-1
4.2.2	TIS (Soft Tissue Thermal Index)	4-1
5.	MAINTENANCE AND INSPECTION	5-1
5.1	Warranty	5-1
5.2	Routine maintenance	5-2
5.2.1	Measurement Probe	5-2
5.2.2	Maintenance of the Main Unit	5-4
5.3	Replacing of the printer paper	5-5
5.4	Storage	5-6
5.5	Precautions for disposal of packing materials	5-6
6.	TROUBLESHOOTING	6-1
7.	SPARE PARTS AND OPTIONAL PARTS	7-1
7.1	Spare parts	7-1
7.2	Optional parts	7-1
8.	SPECIFICATIONS	8-1
8.1	Specifications	8-1
8.1.1	Measuring function	8-1
8.1.2	Measuring Probe	8-1

8.1.3	Main unit	8-1
8.1.4	AC Adapter	8-1
8.1.5	Enclosed battery	8-1
8.2	Ultrasound energy and other information	8-2
8.2.1	Influences of ultrasound energy on the human body	8-2
8.2.2	Ultrasound energy	8-2
8.3	Noise generation	8-4
8.4	Operating Environment	8-4
8.5	Conformed Standard	8-4
9.	INDEX	A-1

1. PRIOR TO USE



- ◆ *Make sure that the instrument is free from any equipment that may cause an intensive magnetic field, which otherwise causes the instrument with noises or may make it unable to allow correct diagnosis or measurement.*
- ◆ *Care must be taken not to place any object on the instrument.*
- ◆ *Be sure to read this Manual before using the instrument for your safe and correct operation.*
- ◆ *Do not use the instrument in any procedures other than specified in this Manual.*

1.1 Precautions



- *Though measuring accuracy is $\pm 5 \mu\text{m}$, accuracy with actual measurement may be out of the measuring accuracy, depending on condition of cornea. Please review and retake the measurement or try other inspections, when the result seems to be suspicious with past corneal medical history of the patient.*
- *Only skilled operators are allowed to use this instrument.*
- *When installing the instrument, observe the following items.*
 - *Install the instrument in a place where it is free from water and/or chemicals.*
 - *Install the instrument in a place where it is free from such adverse influences as direct sunbeams, high temperature and moisture, dust, and salts or sulfur-contained air.*
 - *Install the instrument in a stable place where it is free from inclination, vibration, and/or shocks.*
 - *Do not install the instrument in or near the store area of chemical substances or a place where any gas is generated.*
 - *Use specified frequency, voltage and allowable current (or allowable power consumption).*
 - *Make sure that the conditions of power source (discharge, polarity, etc) are proper.*



■ ***Observe the following items before using the instrument.***

- *Check on the settings of switch connections, polarity, and volumes and make sure that the instrument operates accurately.*
- *Make sure that all the cord connections are made properly.*
- *Recheck the components or parts that directly touch the Patient.*

■ ***Observe the following items when you use the instrument.***

- *Avoid using an excessive period of measurement for each Patient.*
- *Closely and continuously watch to check to see if the instrument works in normal condition and the Patient is secured in safe condition.*
- *If any abnormal condition is found with the instrument or the Patient, take appropriate actions or remedy, first to secure Patient's safety and next to stop the operation of the instrument.*
- *Sufficient care should be given not to cause the Patient to touch the instrument while the instrument is in operation.*

■ ***Observe the following items after using the instrument.***

- *Before turning the power off, return the instrument to its original condition in specified procedure.*
- *Do not apply undue force to the power cable when disconnecting, such as by pulling the cord itself.*
- *As for storing the instrument and related components, see "5.4 Storage" in this Manual.*
- *Store the Pachymeter Probe, accessories, and cords in order after cleaning them properly.*
- *Be sure to properly clean the instrument to be ready for your next use.*

■ ***It is advised that in case the instrument is disorderd, stop using the instrument and contact your TOMEY representative for corrective inspection and/or repair.***

■ ***Do not uncover except battery cover or remodel the main instrument in any ways.***

■ ***Do not remodel or redesign the instrument, or the Warranty will be invalid.***

■ ***Periodical inspection should be given to the instrument and related components.***

■ ***When using the instrument after recess for a while, make sure that it operates properly and safely.***

■ ***Please USE AC power adapter provided from TOMEY as SP-100 standard accessory. When using other AC power adapters, the warranty will be invalid and the unit may not work properly.***

1.2 Unpacking

Make sure, when unpacking the shipment, the instrument, including probe and supplies all arrived at your place in their proper conditions. Check these commodities on any damages and malfunctions.

Note ♦ *Be sure to keep all the shipping and packing materials, which may be used when the instrument is moved to the other place.*

- Main unit, HANDY PACHYMETER SP-100
 (Lithium-Ion Battery Included) 1
- Pachymeter Probe
 (with the protective cap and the case) 1
- Pachymeter test piece 1
- AC adapter 1
- Printer paper roll (1 roll in the instrument) 3
- Serial communication terminal protective cap 1
- Operation Manual (this manual) 1
- Carrying Bag 1
- Inner Case 1
- Quick Guide 1

1.3 Symbols, used in this manual

The terms and symbols, used for the instrument, shall imply the following means.

PROBE

Pachymeter probe terminal

Connects the Probe to this terminal.



Power Switch

Turns main power ON and OFF.



Contrast adjusting volume

Adjusts the contrast of the monitor



Serial communication terminal

Various data is sent and received through the external by using the serial communication cable.



Maintenance switch

This switch should be used for maintenance purpose only
Do not touch this switch for changing.



AC adapter terminal

Connects the AC adapter, included in the box.

1.4 Outline of Measurement Principle

- Note** ♦ *After taking measurement, the oscillator is not emitting ultrasound waves.*

The SP-100 is designed for pachymeter or corneal thickness measurement by using ultrasound transducer, built in Pachymeter probe.

- SP-100 emits the ultrasound from the Pachymeter probe and the probe also receives the ultrasound reflected by surface between corneal posterior face and anterior chamber.
- SP-100 measures the period of time from emitting ultrasound to receiving the same ultrasound, reflected by corneal posterior part. Applying a calculation formula shown below, corneal thickness can be calculated.

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

Where, L: Corneal Thickness

V: Converted sound velocity
(Ultrasound Velocity through cornea)

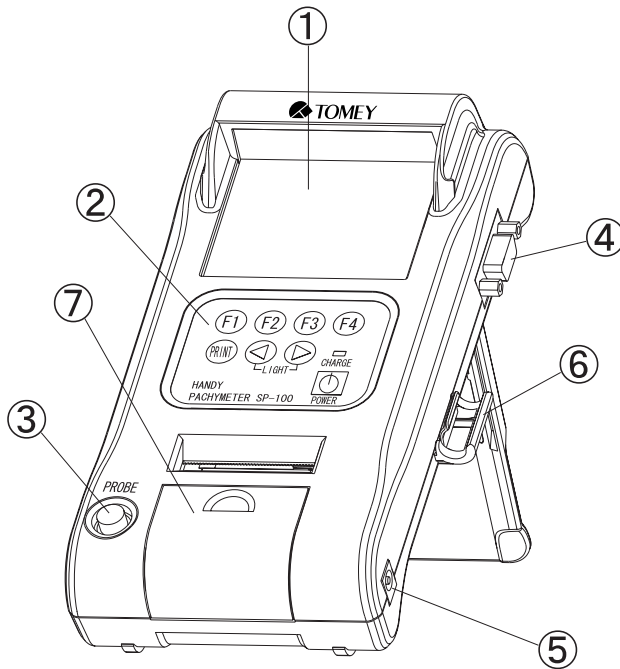
T: Measured time (Ultrasound transmission
time between emitting and receiving)

- This instrument is powered by rechargeable battery or AC power adapter. Even when the battery power is running short, SP-100 can perform measurements, while charging the battery, by plugging to AC power adapter.
- This instrument is designed to take corneal thickness measurement automatically, when the probe is applied to cornea properly.
- This instrument is capable of sending and receiving patient information and measurement data between the external equipment through the serial communication port. (Additional cable must be used, when using this function)

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2. NAMES AND FUNCTIONS OF THE COMPONENTS

2.1 Front and Right side of Main Unit



① SCREEN

Measurement data and other information can be displayed.

② OPERATING PANEL

The keys are located on the panel with various functions.

③ PACHYETER PROBE TERMINAL

Pachymeter Probe should be connected to this terminal.

④ SERIAL COMMUNICATION TERMINAL

Serial Communication Cable can be connected for data communication.

⑤ AC ADAPTER TERMINAL

AC Adapter can be connected for supplying power for operation and charging battery.

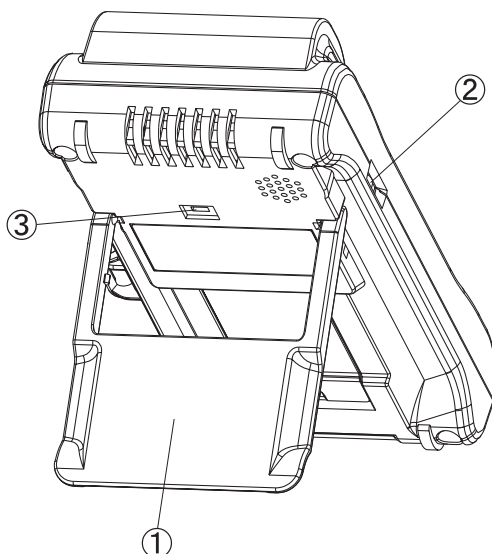
⑥ PROBE HOLDER

Pachymeter Probe can be hold and kept as stable position. Use the holder, while the probe is not in use.

⑦ BUILT-IN THERMAL PRINTER

Patient and Measurement information can be printed by selected Standard or Simple mode.

2.2 Rear and left side of Main Unit



① INSTRUMENT STAND

The main unit stands on desk tilted for easy operation and monitoring.

② CONTRAST VOLUME DIAL

LCD contrast can be adjusted.


③ MAINTENANCE SWITCH

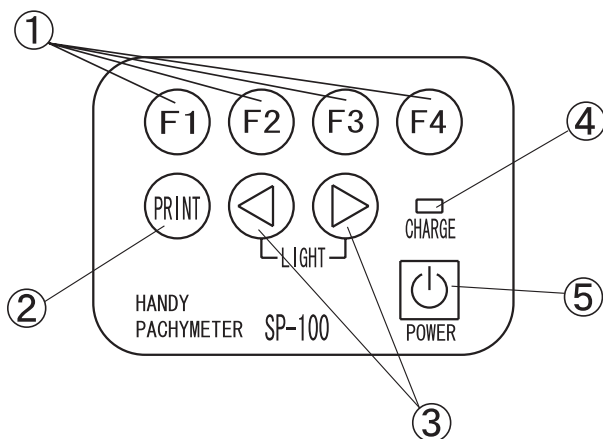
This Switch is for maintenance use only. DO NOT change any setting this switch, or the unit is damaged.

2.3 Operation Keys

General key assignments are explained in this part. However, other functions are assigned on the same key, depending on the screen. Read each part of the manual carefully in order to understand the key operation completely.

(Example)

RIGHT	1: 548	5: 583
LAST	2: 572	6: 6
	3: 553	7:
	4: 548	8:
AVG. :	561 μ m	SD: 28.3
R/L	INDEX	EDIT
		NEW



① FUNCTION KEYS

Each key works as assigned function shown on the bottom of the screen. Four boxes from left to right on screen indicate each function of F1, F2, F3 and F4 keys.

② PRINT KEY

Patient and Measurement Data can be printed by built-in thermal paper. Please refer to [3.6 Printout] for details.

③ ◀, ▶ KEYS

Data selection, Patient ID & Name can be typed in by using the keys. Press both keys simultaneously to turn LED ON and OFF. (When the unit is only powered by battery and no operation for one minute, it automatically turns LED off)

④ CHARGE INDICATOR

The light keeps turning ON, while charging the internal battery. When it turns OFF, charging battery is completed.

⑤ POWERKEY

The main power turns ON and OFF. When the unit is only powered by battery and no operation for three minutes, it automatically turns OFF to save battery power. (Auto Power OFF)

(F-keys Example) Each key, on this page, is assigned its function as follows:

- F1 R/L
- F2 INDEX
- F3 EDIT
- F4. NEW

3. OPERATING PROCEDURES

3.1 Safety precautions



- *The Probe must always be disinfected before its use.*
 - *Never use the Probe, if there is any visible damage on its tip, which may otherwise cause an incorrect measurement or damage the cornea.*
-

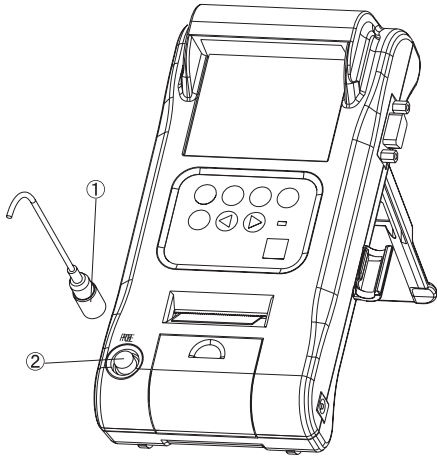


- *This instrument is Ophthalmic Medical Device, designed for only skilled operators.*
 - *Do not use this instrument other than Ophthalmic applies.*
 - *Do not use any terminal other than specified in this Operation Manual, which may otherwise cause to damage the instrument.*
 - *Do not leave the instrument plugged with the AC Adapter when the battery is fully charged, otherwise, this may enshorten the lifetime of built-in rechargeable battery.*
 - *When the probe is not in use, please place the probe cap and place the probe to the holder to protect from getting damaged.*
-

3.2 Preparation before operation

3.2.1 Connection of accessories

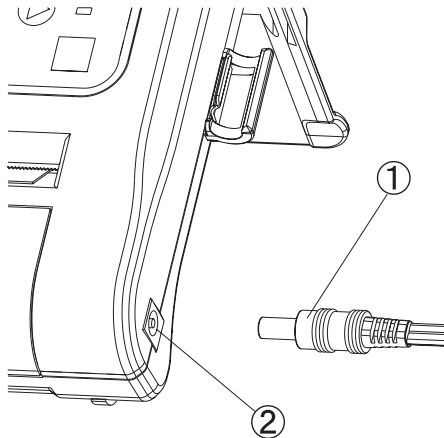
a) Connection of Pachymeter Probe

**Note**

Connector of the Probe should be inserted in specified direction. Insert the connector as deep as it sounds "click".

Insert the connector ① into the connecting terminal ② marked "PROBE" on the front side of Main Unit.

b) Connection of AC Adapter

**Note**

Insert the connector to the terminal completely

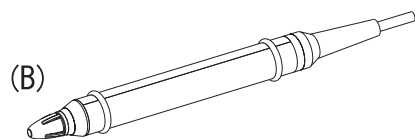
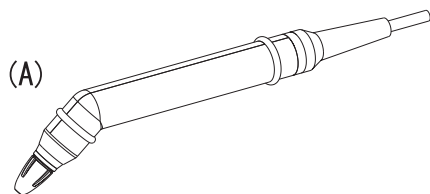
Insert AC adapter connector ① into the connecting terminal ② provided on the right side of the Unit.

3.2.2 Disinfection of the probe

Disinfect the probe with proper procedure, before its use. Please refer to [5.2.2 Disinfecting Pachymeter Probe] for details.

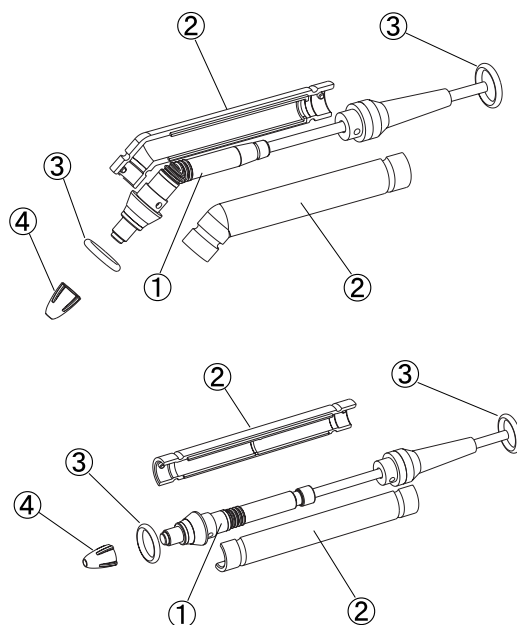
3.2.3 Optional components

Assembling of the Disposal Tip Pachymeter Probe and alternative Probe shapes



The Disposal Type Pachymeter Probe (supplied as an optional component) consists of the inner probe, case, fixed ring, and disposal tip.

The Probe can be changed in two alternative shapes: (A) with 45° shape and (B) in straight shape, depending on the application convenience.



<How to assemble>

- 1) Cover the inner probe ① with a pair of cases ② to make the inner probe clipped in between and fix it with the rubber rings ③.
- 2) Apply a small amount of methylcellulose (such as Dry Eye Gel) on the tip of the inner probe ①.
- 3) Then securely insert the disposal tip ④ not to cause air bubbles inside of the tip.

<How to assemble the Probe in alternative shape>

- 1) Disassemble the disposal tip ④, fixed ring ③, and the case ② in order.
- 2) Assemble the case ② to be changed and next fix it with the rings ③.
- 3) Next apply a small amount of methylcellulose to the tip of the inner probe.
- 4) Then securely insert the disposal tip ④ not to cause air bubbles inside of the tip.

3.3 Adjustment and Setting

3.3.1 Main power on and screen adjustment

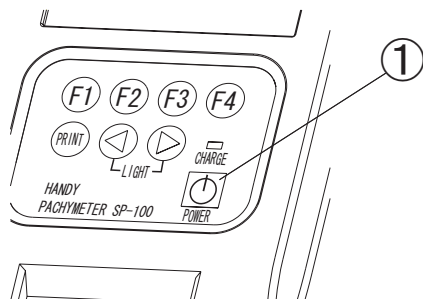
Note

Confirm the following items before turning the power on.

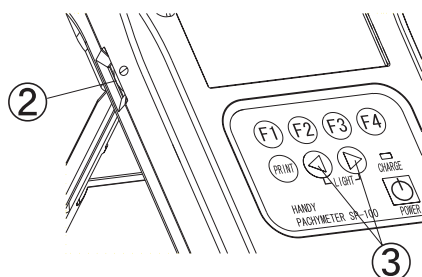
- Make sure the battery is sufficiently charged. If not, connect the AC adapter for power supply. (With battery operation and 3 minutes of non operating time, the unit goes into Auto Power off mode and measured data will be lost)
- Make sure the Probe has been connected.
- Make sure the tip of the Probe is dry.

Note

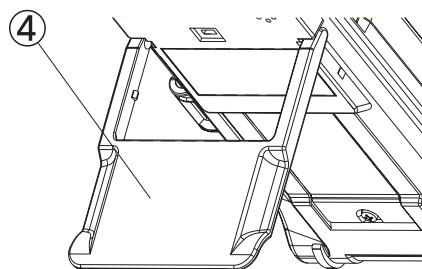
Tilt the LCD screen on the proper position in order to get better view from the front



(Fig. 1)



(Fig. 2)



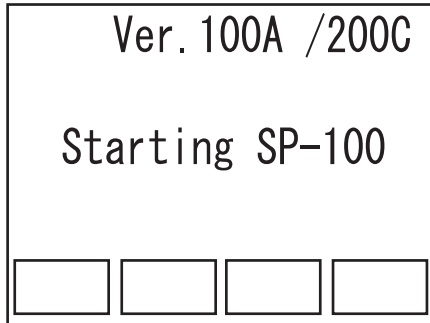
(Fig. 3)

- 1) Press the power key ① to start operation. The instrument will automatically calibrate the connected Probe. If "PROBE ERROR!" is displayed on the screen, check if the tip of the Probe is dry. (Refer to [3.3.2 Startup Display] for details)

- 2) Adjust the LCD contrast, according to the brightness of the clinical room by using contrast adjusting dial ② on the left side of the unit.
When the room is dark, press the "◀" and "▶" keys ③ simultaneously to turn the lighting LED on.

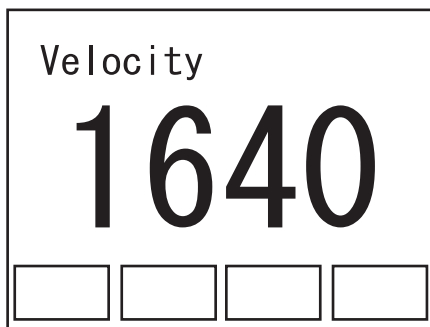
- 3) Adjust Instrument Stand ④ on back of the unit to tilt it to get better screen view.

3.3.2 Startup Display



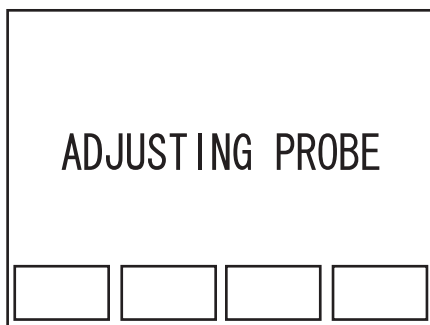
(Fig. 1)

- 1) The startup screen is displayed immediately after the power is on. The software version is seen on the screen.
(Fig. 1)



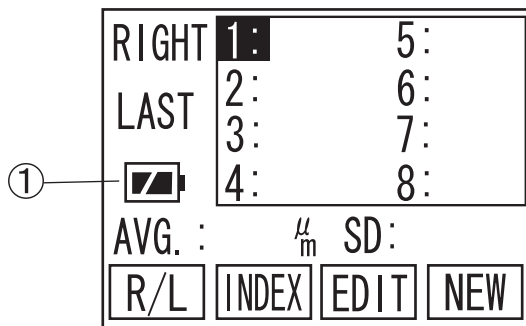
(Fig. 2)

- 2) The ultrasound velocity, set for measurement, is displayed.
(Fig. 2)



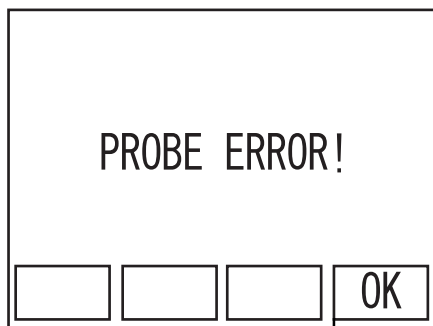
(Fig. 3)

- 3) The unit calibrates the probe automatically.
(Fig. 3)



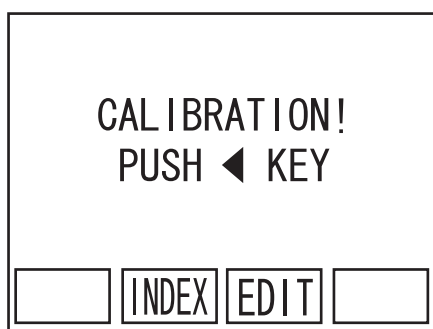
(Fig. 4)

- 4) When the calibration has been completed properly, measurement Pachy screen (initial screen) is displayed.
(Fig. 4)



(Fig. 5)

- 5) When the Probe is not calibrated properly, "PROBE ERROR!" will be displayed. Press F4 key ① "OK" (Fig. 5) to show CALIBRATION screen (Fig. 6).



(Fig. 6)

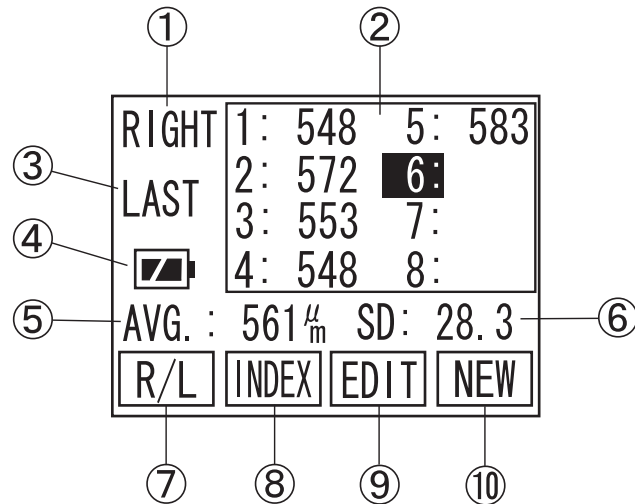
- 6) Check the connection of the Probe and the Probe tip, then press the "◀" to recalibrate the Probe.

When error appears in the screen, go to "6. TROUBLE-SHOOTING" for the solution.

When "ERROR" repeatedly appears, contact TOMEY representative.

3.3.3 Screen Contents

a) Pachy screen



- ① The eye to be measured

Either left or right eye, to be measured, is selected on this part of the screen.

- ② Measurement data

The data, taken by the unit will be listed.

- ③ Average

Average value of the listed data will be displayed.

- ④ Battery Life Indicator

Remaining power in the built-in battery appears. (Two Steps)



- ⑤ Type of listed data

Average, Minimum or Latest options can be selected as a type of listed data

- ⑥ R/L (F1 key)

Left or right eye for measurement is switched over.

- ⑦ INDEX (F2 key)

Switch screen to INDEX, to input Patient ID and name.

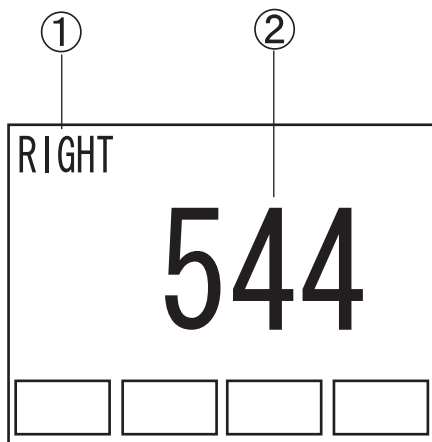
- ⑧ EDIT (F3 key)

Switch screen to EDIT, to edit measured data

- ⑨ NEW (F4 key)

To measure new patient, use this key to clear Patient data and measured readings.

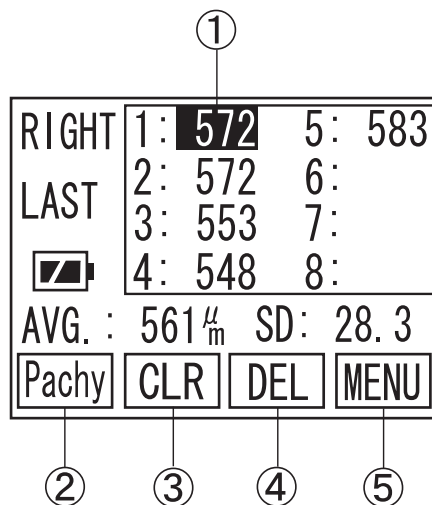
b) Measurement screen



- ① The eye to be measured
Either left or right eye, to be measured, is selected on this part of the screen.
- ② Measurement data
The data, taken by the unit will be listed.

While taking measurement, the screen automatically changes and shows large size measuring data.

c) Edit screen



- ① Cursor
Selected data is highlighted on the list. Other data is selected by using "◀" or "▶" keys.
- ② Pachy (F1 key)
Press this key to change screen to Pachy mode.
- ③ CLR (F2 key)
Press this key and keep holding it to clear all measurement data.
- ④ DEL (F3 key)
Press this key and keep holding it to clear only highlighted measurement data
- ⑤ MENU (F4 key)
Press this key to change into MENU screen.

3.3.4 Measuring conditions

The following measuring conditions have been set, when turning the power on.

- Eye to be measured: Right eye (OD)
- Corneal ultrasound velocity: Last value, when it is turned off.

a) Input Patient ID and name

Note Please refer to "3.9 Data Management with TOMEYLink (Electronic Medical Record Support System)" to send Data to TOMEYLink.

Note In case of using Data Communication, Patient ID must be typed in. Otherwise the data cannot be sent.

The Patient ID and name are input in the "INDEX" screen. 14 letters can be typed in either the Patient ID or Patient name.

RIGHT 1: 5:
LAST 2: 6:
3: 7:
4: 8:
AVG. : μ_m SD:
R/L INDEX EDIT NEW

(Fig. 1)

①

- 1) Press F2 key ① to change into INDEX Screen. (Fig. 2)

Sep/24/2004 16:30
ID :
NAME :
Pachy ID NAME COM

(Fig. 2)

②

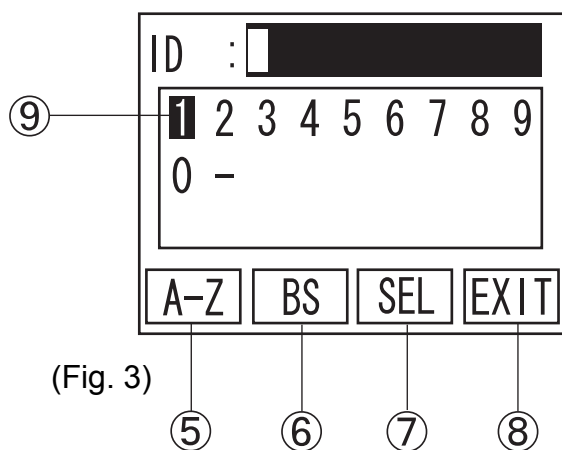
③

④

- 2) Press F2 key ③ to change into ID input screen to type in Patient ID. (Fig. 3)

Press F3 key ④ to change into Patient NAME input screen to type in Patient Name. (Fig. 4)

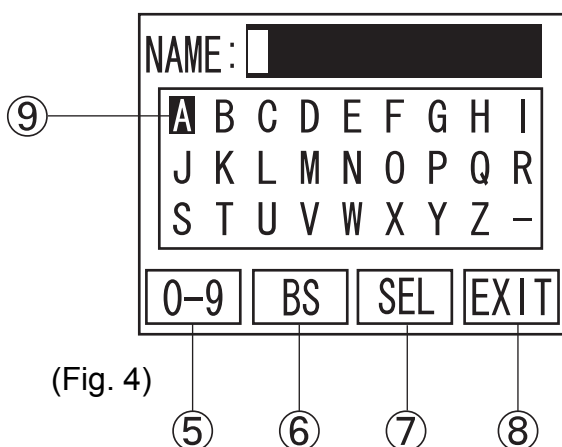
F1 key ② to go back to Pachy Screen (Fig. 1).



- 3) Press "◀" or "▶" keys to move Cursor ⑨ to the figures or letters, you wish to input. (Fig. 3) Then, press SEL ⑦ to enter selected character.

- 4) Press F1 key ⑤ to switch over input mode between figures and letters.

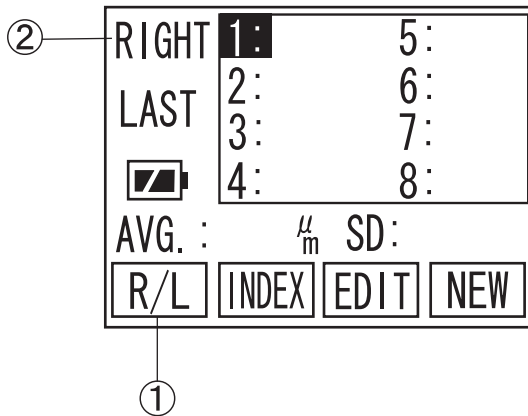
- 5) Press F2 key ⑥ to enter Back Space.



- 6) When Patient ID type in completed, press F4 key ⑧ to go back to INDEX Screen (Fig. 1).

- 7) Repeat the above procedure again to type in Patient name. (Fig.4)

b) The eye to be measured



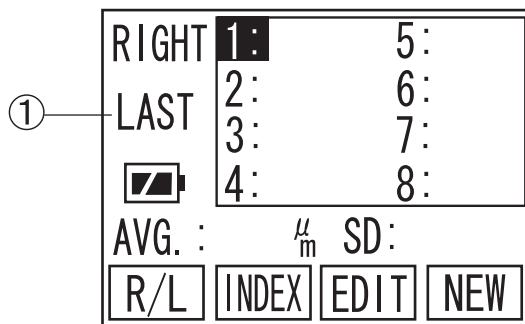
Select Right eye or Left eye, to be measured.

Press F1 key ① to switch over Right and Left display.

c) Corneal ultrasound velocity

Ultrasound Velocity can be changed by going into setting Menu. Please refer to "3.7.3 c) corneal Ultrasound Velocity (VELOCITY)" for details.

d) Listed data on screen



One, out of three, data type ① can be selected as listed data type. The three options are as follows.

■ **AVERAGE**

The mean value of each data box is listed.

■ **LATEST**

The last measurement for each data box is listed.

■ **MINIMUM**

The minimum value of all measurements for each data box is displayed.

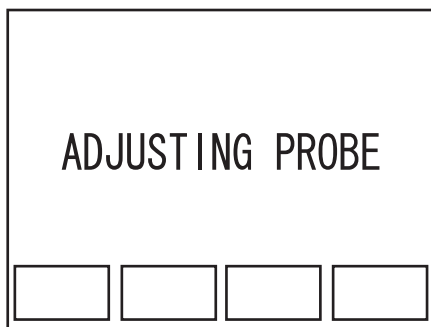
Please refer to "3.7.3 d) Setting of the type of display data (DATA SELECTION)" for details.

3.4 Preparation for measurement

3.4.1 Calibration of the Probe

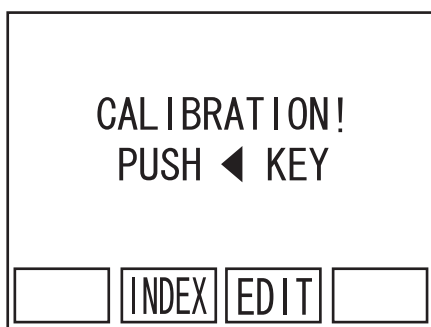
Notes

- *In case of using the disposal tip probe, be sure to calibrate it with the disposal tip attached.*
- *Be sure the tip of the Probe is dry and free from any water, before calibrating probe.*
- *In case of using the disposal tip Probe, the disposal tip is automatically detected by SP-100. Therefore, no measurement can be made without calibrating the Probe.*



(Fig. 1)

- 1) This instrument automatically calibrates the Probe, when the power is turned on and the probe is plugged. (Fig. 1)



(Fig. 2)

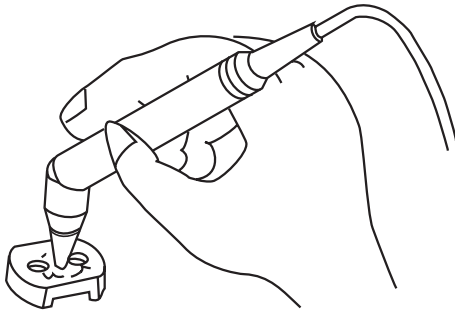
- 2) When the probe is removed or the tip of the probe is removed with disposable tip probe, the instrument automatically detect the abnormal situation and shows CALIBRATION screen (Fig.2).

Check the connection of the probe and tip, then press "◀" for re-calibration.

3.4.2 Operation Check

Note

The test piece included in the accessory box is supplied for checking the operation of the instrument. The measurement result varies, depending on room temperature and other factors. The instrument cannot test its accuracy by measuring this test piece.



- 1) Go to Pachy screen
- 2) Place the test piece into water until it covers over the piece. Apply the Probe into either of the dents on the piece perpendicularly, so the instrument will start measurement automatically.

3.4.3 Measurement Preparation for Patient

Note

Patients' cooperation is necessary for smooth operation.

Prior to measurement, explain about the purpose of examination and measuring procedures to the Patient so as not to give fears, but to relax in a good mood.

- 1) Review the settings and calibrate the Probe or check the instrument, if necessary.
- 2) Give eye-drops anesthesia to the eye to be measured. The patient should be seated with the Back Rest or should lie on a bed.
- 3) If the eye seems to be dry or has little tears, apply balanced salt solution to avoid dry surface of cornea.

3.5 Measurement



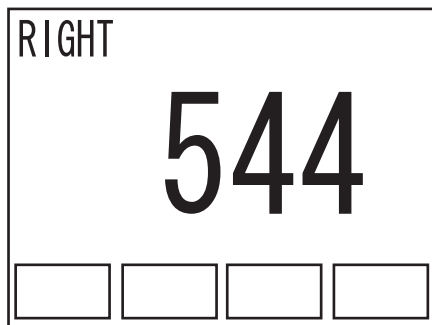
- *The Probe should always be disinfected before its use.*
 - *The disposal tip should be disinfected before its use.*
 - *Do not use the Probe with its tip damaged. This causes inaccurate measurement as well as the corneal damage for patients.*
-

Notes

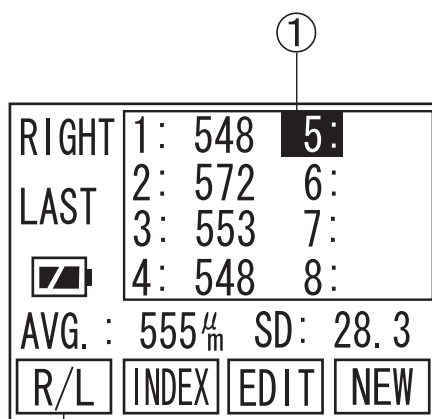
- *The corneal ultrasound velocity has direct influence on measurement results. Before taking measurement, make sure that the appropriate velocity is set for measurement. Please refer to "3.7 Menu" for details.*
- *In case the corneal surface is dry, apply balanced salt solution for moisture.*
- *Auto Measurement Function is an assistant function to make measurement easy, but does not clinically determine actual diagnosis. In case of applying results, the examiner should always evaluate them for use.*

3.5.1 Single measurement

a) Measuring procedures



(Fig. 1)



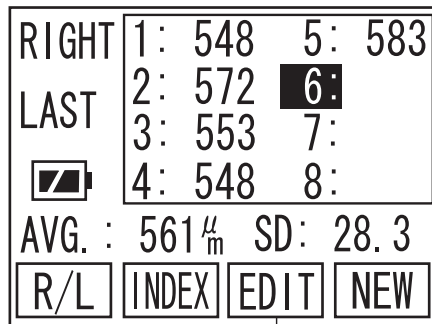
(Fig. 2)

- 1) Place the probe perpendicularly to the corneal surface, where the thickness needs to be taken.
- 2) When the measuring conditions meets a certain level, the instrument automatically starts taking measurement (Fig.1).
The instrument makes beep, when measurement has been taken into the unit.
- 3) When twenty measurements have been taken, the instrument sounds two "beeps" to announce the measurements are completed.
- 4) Move the Probe away from cornea, so the cursor ① will move to next memory in order to be ready for another measurement (Fig.2). 20 measurements will not be necessary to complete it in one place. The instrument completes the measurement in the position, when the probe is taken away and it beeps twice.
- 5) Repeat the measurement process to fill 8 memories with data. When Retake measurement on certain memories with overwriting, go to EDIT screen to move highlighted memory, then back to Pachy screen to take the measurement.
- 6) For the measurement of the other eye, press F1 key ② to switch between Right and Left.

3.5.2 Delete Each Data Reading

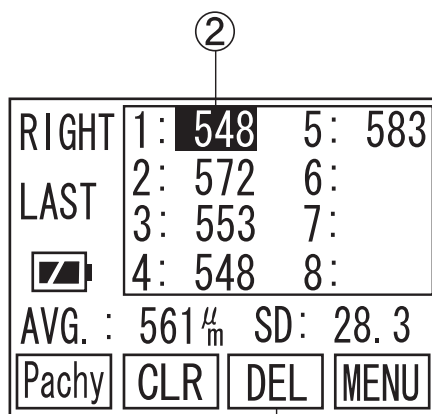
Note

When the data is once deleted, it can never be recalled and the deleted data will be lost. Please pay special attention, not to delete necessary measurements.



(Fig. 1)

- 1) Press F3 key ① on Pachy screen (Fig. 1) to change screen into EDIT (Fig. 2).



(Fig. 2)

- 2) Press "◀" or "▶" to move Cursor ② to highlight the measurement that should be deleted.
- 3) Press F3 key ③ and keep holding it for a while, until the instrument sounds "beep" to complete deleting.

3.5.3 Delete Data (Eye by eye or patient by patient)

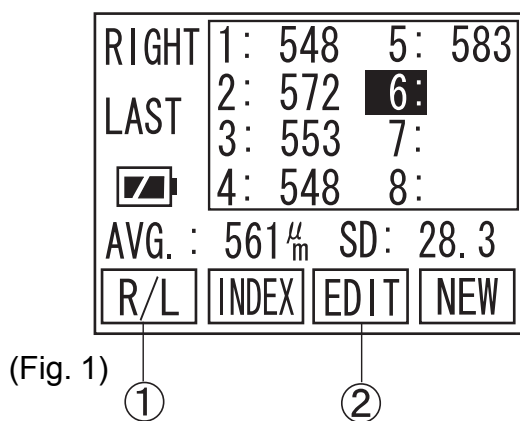
Note

When the data is once deleted, it can never be recalled and the deleted data will be lost. Please pay special attention, not to delete necessary measurements.

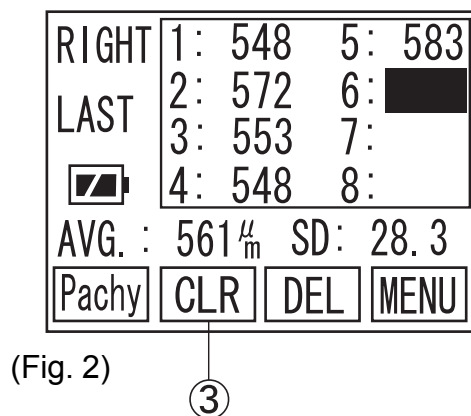
a) Delete Data of one eye (Retaking measurements of the same eye)

Delete all data on screen.

- 1) Press F1 key ① in Pachy Screen (Fig. 1) to select which eye data should be deleted.




- 2) Press F3 key ② to change screen to EDIT (Fig. 2).



- 3) Press F2 key ③ and keep holding it for a while, until the instrument sounds "beep" to confirm all the data on screen has been deleted.

-
- b) Delete Data of both Right and Left Eye including patient information (Ready for new patient measurement)

RIGHT	1: 548	5: 583
LAST	2: 572	6:
	3: 553	7:
	4: 548	8:
AVG. : 561 μ m SD: 28.3		
R/L	INDEX	EDIT NEW

①

Delete all the data on both eyes, as well as Patient ID and name.

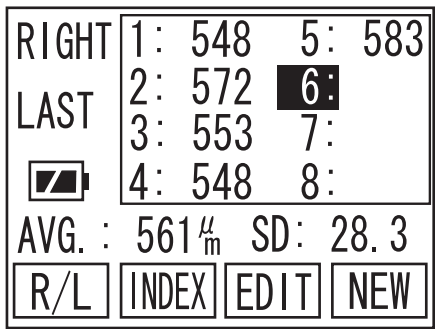
Press F4 key ① on pachy screen and keep holding it for a while, until the instrument sounds "beep" to confirm all the data has been deleted.

3.6 Printout

3.6.1 How to Printout the data

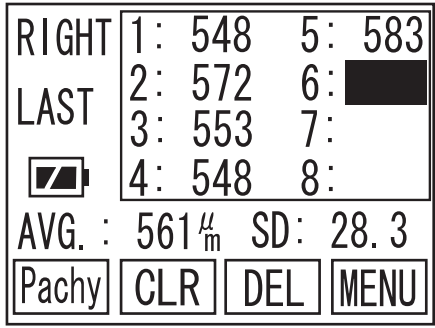
Notes

- *Prior to Printout, make sure the proper paper is set correctly and the paper remains sufficiently.*
- *Please be careful not to cut yourself, when cutting the paper by hand.*

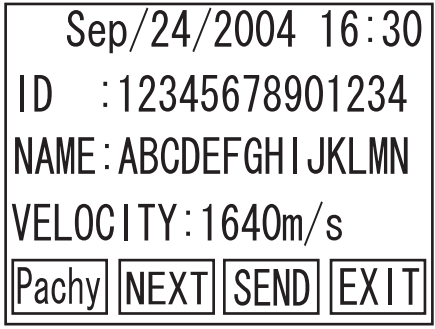


(Fig. 1)

Press the PRINT Key for operation in the Measurement Standby Screen (Fig. 1), the EDIT Screen (Fig. 2), or the DATA COMMUNICATION, SEND Screen (Fig. 3) for Printout of measured data.



(Fig. 2)



(Fig. 3)

3.6.2 Description of Printout

a) Standard mode

①	2004/ 9/24 16:30	①	Time/Data
	ID:12345678901234	②	ID number
	NAME	③	Patient's name
	ABCDEFGHI JKLMN	④	Corneal Ultrasound Velocity
④	Vel:1640 Average	⑤	Type of display data
⑥	RIGHT	⑥	Eye to be measured
	1: 548 2: 572	⑦	Measured data
	3: 553 4: 548	⑧	Average of measured data
	5: 583	⑨	SD(Standard Deviation) of measured data
⑧	Avg: 561 SD:28.3		
	LEFT		
	1: 823 2: 830		
	3: 826		
	Avg: 826 SD: 2.9		

b) Simple mode

```
2004/ 9/24 16:30
ID:12345678901234
Vel:1640 Average
RIGHT
1: 548 2: 572
3: 553 4: 548
5: 583
Avg: 561 SD:28.3
LEFT
1: 823 2: 830
3: 826
Avg: 826 SD: 2.9
```

Patient Name and Breaking Line are out of printout paper on Simple Mode.

3.6.3 IOP Calculation Printout

a) Standard mode

①— 2004/ 9/24 16:30
ID: 12345678901234 —②
NAME
ABCDEF GHI JKLMN —③

④— Vel: 1640 Average —⑤
⑥— RIGHT -----
1: 548 2: 572
3: 553 4: 548 } —⑦
5: 583
⑧— Avg: 561 SD: 28.3 —⑨

IOP CALCULATION
⑩— PARAM: 554, 0.045 —⑪
CCT : 561 —⑫
TONOMETRY : 25.0 —⑬
Adjust. IOP: 26.5 —⑭
LEFT -----
1: 823 2: 830
3: 826
Avg: 826 SD: 2.9

IOP CALCULATION
PARAM: 554, 0.045
CCT : 826
TONOMETRY : 24.8
Adjust. IOP: 26.3

- ① Time/Data
- ② Patient ID
- ③ Patient's Name
- ④ Corneal Ultrasound Velocity
- ⑤ Right/Left
- ⑥ Eye to be measured
- ⑦ Measured data
- ⑧ Measured data average
- ⑨ Measured data SD (standard deviation)
- ⑩ Parameter 1
- ⑪ Parameter 2
- ⑫ CCT (Central Corneal Thickness)
- ⑬ IOP (Inter Ocular Pressure)
- ⑭ Adjusted IOP

④ ~ ⑨ will not be printout, when there is no measured data.

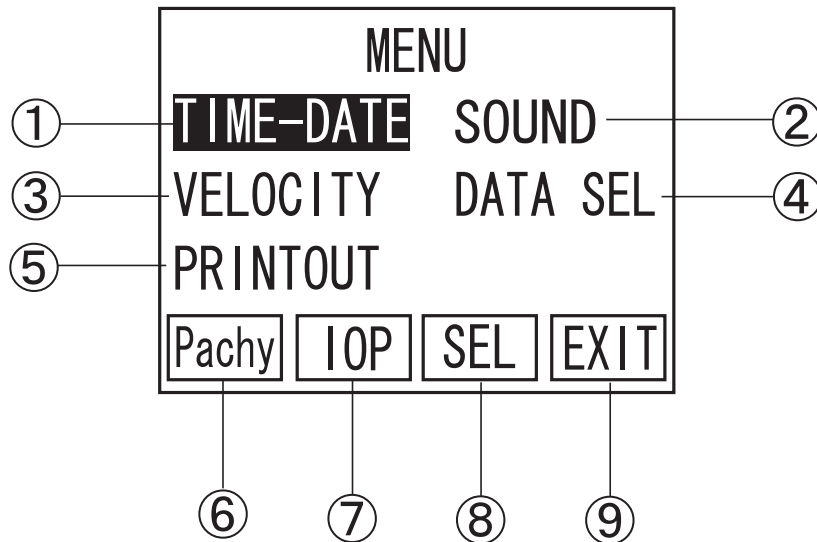
b) Simple mode

2004/ 9/24 16:30
ID: 12345678901234
RIGHT -----
IOP CALCULATION
PARAM: 554, 0.045
CCT : 561
TONOMETRY : 25.0
Adjust. IOP: 26.5
LEFT -----
IOP CALCULATION
PARAM: 554, 0.045
CCT : 826
TONOMETRY : 24.8
Adjust. IOP: 26.3

Only Time/Date, Patient ID, Adjusted IOP related data will be printout by Simple mode.

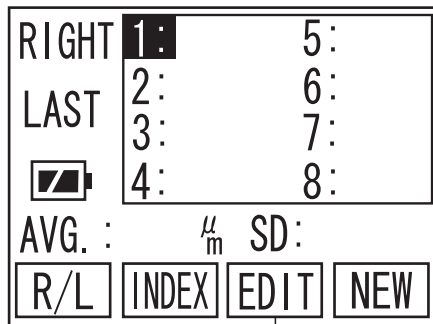
3.7 Menu

3.7.1 Description of the Screen display



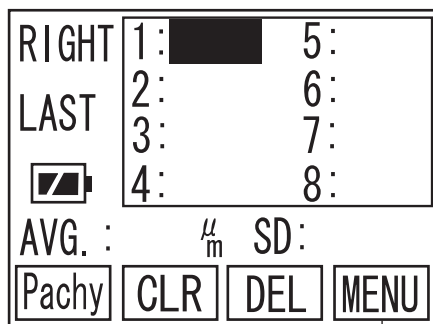
- ① TIME-DATE
Date and time are set.
- ② SOUND
The sound volume is set.
- ③ VELOCITY
The corneal ultrasound velocity is set.
- ④ DATA SEL
The mode of display data is set.
- ⑤ PRINTOUT
The print mode is set.
- ⑥ Pachy (F 1)
The screen is changed to the Measurement Standby Screen.
- ⑦ IOP (F 2)
Move to IOP Calculation Main Screen.
- ⑧ SEL (F 3)
The Highlighted function is selected.
- ⑨ EXIT (F 4)
The screen is returned to the EDIT Screen.

3.7.2 Operation for the MENU Screen



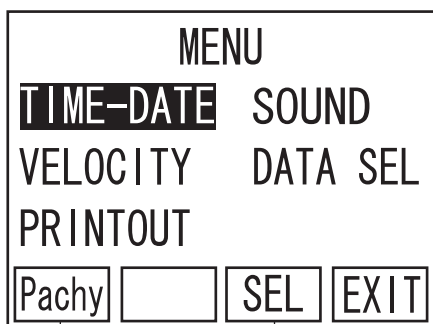
(Fig. 1)

- 1) Press F3 Key ① in the Measurement Standby Screen, to change the screen to the EDIT Screen (Fig. 2).



(Fig. 2)

- 2) Press F4 Key ② in the EDIT Screen, to change the screen to the MENU Screen (Fig. 3).



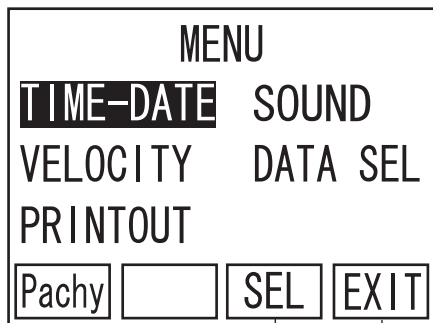
(Fig. 3)

- 3) Press "◀" or "▶" of the Operating Panel and next press F3 Key ③ by aligning the Select Cursor to the item to be set, to change the screen for each item.

Press F1 Key ④ to return the screen to the Measurement Standby Screen (Fig. 1).

3.7.3 Operating procedures of the Menu Screen

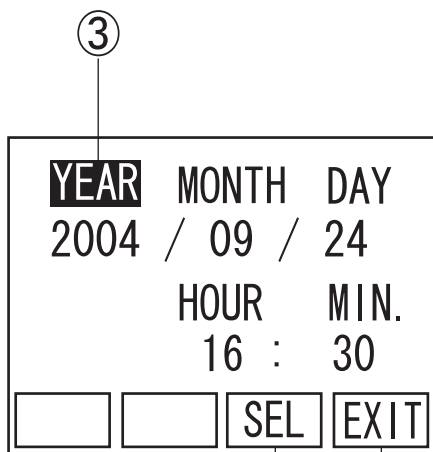
a) Setting of date and time (TIME/DATE)



(Fig. 1)

①

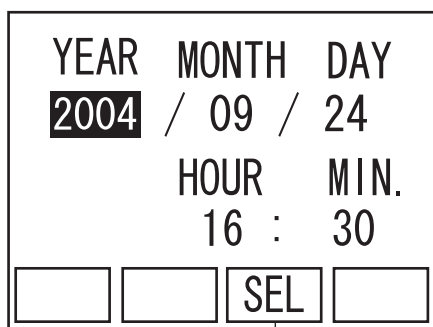
②



(Fig. 2)

④

⑤



(Fig. 3)

⑥

- 1) Press "◀" or "▶" of the Operation Panel, to align the Cursor to "TIME/DATE". Next press F3 Key ① to change the screen to the Time/Date Screen (Fig. 2).

Press F4 Key ② to return the screen to the EDIT Screen.

- 2) Press "◀" or "▶" of the Operation Panel, to align the cursor ③ to YEAR. Next, press F3 key ④ to change the screen to the Setting Screen (Fig. 3).

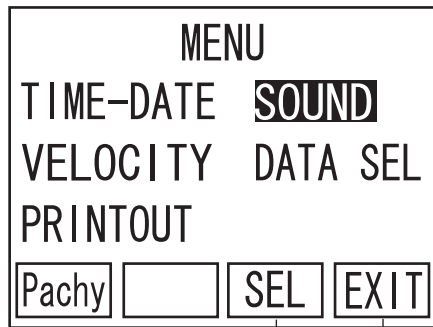
Pressing of the EXIT key ⑤ returns the screen to the MENU Screen (Fig. 1).

- 3) Press "◀" or "▶" of the Operation Panel, to increase or decrease the dominical year at the cursor position. Pressing F3 key ⑥ after the dominical year has been set returns the screen to the Setting Screen (Fig. 2).

Set the other items in a similar manner.

Pressing F4 Key ⑤ returns the screen to the Date and Time Setting Screen (Fig. 2).

b) Sound volume (SOUND)



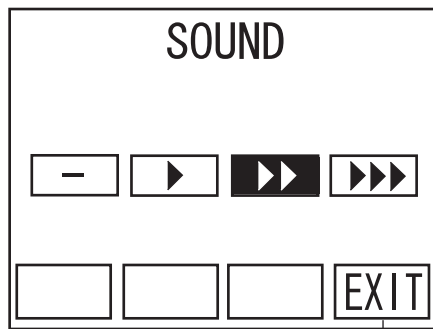
(Fig. 1)

①

②

- 1) Press "◀" or "▶" of the Operation Panel, to align the cursor to "SOUND". Next, press the SEL key ① to change the screen to the Sound Volume Setting Screen (Fig. 2).

Pressing F4 key ② returns the screen to the EDIT Screen.



(Fig. 2)

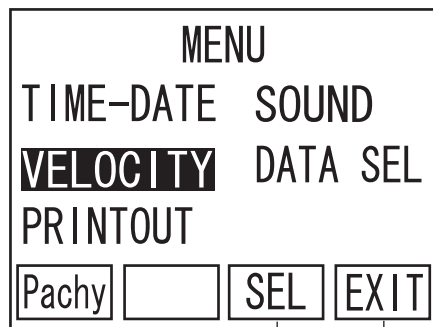
③

- 2) Press "◀" or "▶" of the Operating Panel, to increase or decrease the sound volume.

Pressing F4 Key ③ returns the screen to the MENU Screen (Fig.1).

- "-": No SOUND
- ">": Small SOUND
- ">>": Medium SOUND
- ">>>": Large SOUND

c) Corneal Ultrasound Velocity (VELOCITY)



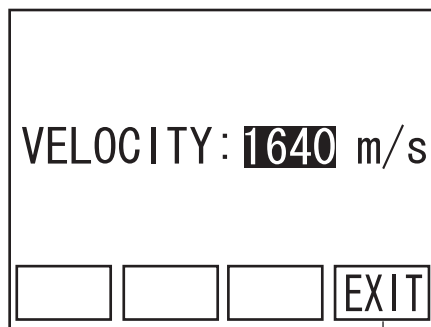
(Fig. 1)

① ②

- 1) Press "◀" or "▶" of the Operating Panel to align the cursor to "VELOCITY".

Next press F3 Key ① to change the screen to the Corneal Ultrasound Velocity Screen (Fig. 2).

Pressing F4 Key ② returns the screen to the EDIT Screen.



(Fig. 2)

③

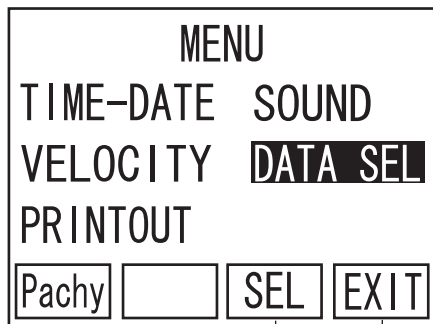
- 2) Pressing "◀" or "▶" of the Operating Panel increases or decreases the sound velocity.

[Input range]

Corneal ultrasound velocity: 1,400 to 2,000 m/s

Pressing F4 Key ③ returns the screen to the MENU Screen (Fig. 1).

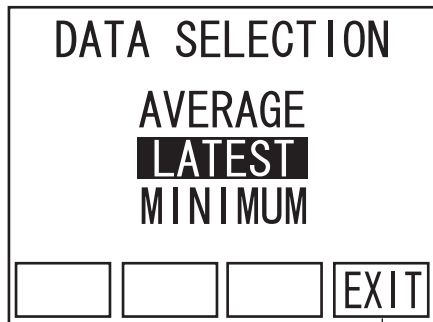
d) Setting of the type of display data (DATA SELECTION)



(Fig. 1)

- 1) Press "◀" or "▶" of the Operating Panel to align the cursor to "DATA SEL".
Next press F3 ① and change the screen to the Setting Screen (Fig. 2) for the type of data to be displayed.

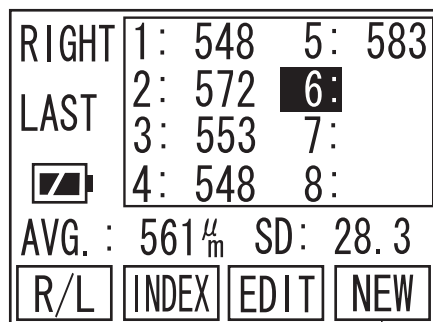
Pressing F4 Key ② returns the screen to the EDIT Screen.



(Fig. 2)

- 2) Press "◀" or "▶" of the Operating Panel to align the cursor to the type of data desired to be displayed.

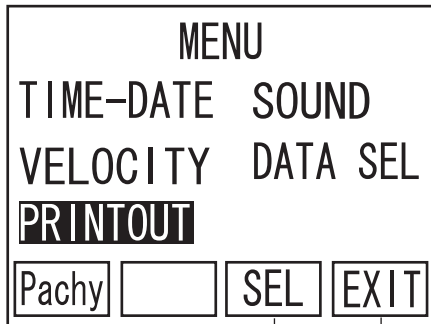
Pressing F4 Key ③ returns the screen to the MENU Screen (Fig. 1).



(Fig. 3)

If measured data are left remaining in the screen, the type of display data cannot be changed. Resetting of the type of display data shall be made after deleting the data by returning the screen to the Measurement Standby Screen (Fig. 3) and long pressing F4 Key ④.

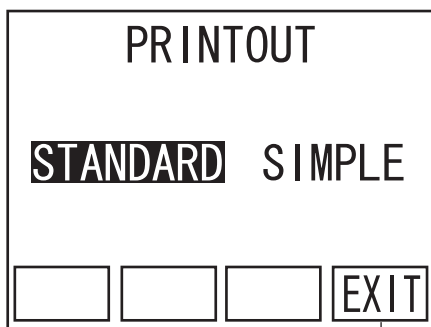
e) Print mode



(Fig. 1)

- 1) Press "◀" or "▶" of the Operation Panel, to align the cursor to "PRINTOUT". Next, press F3 key ① to change the screen to the Printout Setting Screen (Fig. 2).

Pressing F4 key ② returns the screen to the EDIT Screen.

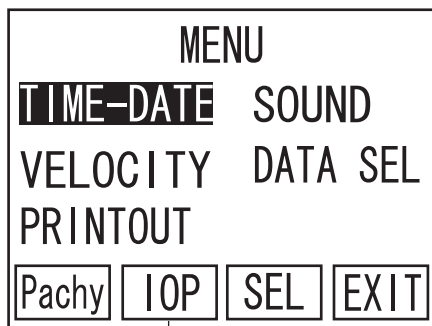


(Fig. 2)

- 2) Press "◀" or "▶" of the Operation Panel, to align the cursor to "STANDARD" or "SIMPLE". (See 3.6.2 for the description.)

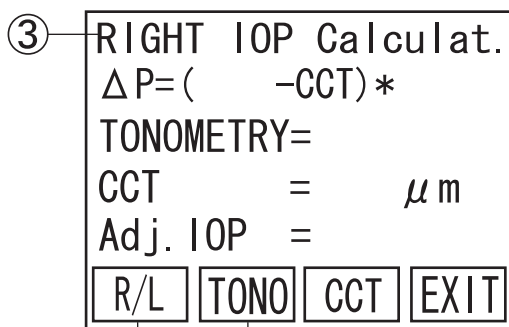
Pressing F4 key ③ returns the screen to the MENU Screen (Fig. 1).

3.7.4 IOP Calculation



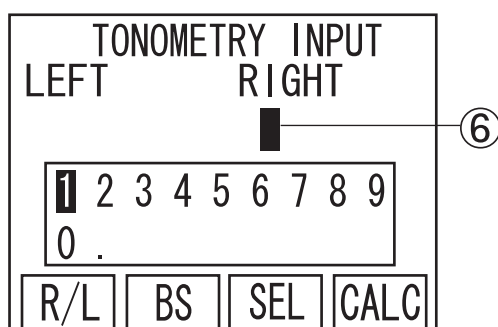
(Fig. 1)

- 1) Press F2 ① to change the screen to IOP calculation (Fig.2).



(Fig. 2)

- 2) Press F1 ② to select either RIGHT/LEFT eye data should be calculated ③.



(Fig. 3)

- 3) Press F2 ④ to change the screen to Tonometry Input (Fig.3).

Press F1 ⑤ to move cursor ⑥ between RIGHT and LEFT.

Input the Tonometry for IOP Calculation formula. Press "◀" or "▶" to select the figures and press F3 ⑦ to enter.

**[Tonometry Input Range] : 1 ~ 60 mm
Hg : 133~7998Pa**

RIGHT IOP Calculat.
 $\Delta P = (\quad -CCT) * \quad$
 TONOMETRY=26.0mmHg
 CCT = μm
 Adj. IOP =
 [R/L] [TONO] [CCT] [EXIT]

⑨

(Fig. 4)

Press F4 ⑧ to select the screen to IOP Calculation (Fig.4)

CCT INPUT
 LEFT RIGHT
 μm **553** μm
 [1] [2] [3] [4] [5] [6] [7] [8] [9]
 [0]
 [R/L] [BS] [SEL] [PARAM]

⑩ ⑪ ⑫ ⑬

(Fig. 5)

- 3) Press F3 ⑨ to change the screen to CCT Input (Fig.5) Average of total measurement data will be automatically input, when there is any data for calculation.

Press F1 ⑩ to move cursor ⑪ between RIGHT and LEFT.

Press "◀" or "▶" to select the figures and press F3 ⑫ to enter.

[CCT Input Range] : 0 ~ 1,500 μm

PARAMETERS INPUT
 $\Delta P = ([16] -CCT) * [17]$
 [1] [2] [3] [4] [5] [6] [7] [8] [9]
 [0]
 [1/2] [BS] [SEL] [CALC]

⑭ ⑮ ⑯ ⑰ ⑱

(Fig. 6)

- 4) Press F4 ⑬ to change the screen to PARAMETERS INPUT (Fig.6)

Press F1 ⑭ to move highlighted cursor between Parameter 1 ⑯ and 2 ⑰.

Press "◀" or "▶" to select the figures and press F3 ⑫ to enter Parameter 1 ⑯ and 2 ⑰.

[Parameter Range]

Parameter 1 : 0 ~ 1,500 μm

Parameter 2 : 0 ~ 1.000 μm

RIGHT IOP CALCULAT.
 $\Delta P = (545 - CCT) * 0.045$
TONOMETRY=26.0mmHg
CCT = 553 μ m
Adj. IOP =25.6mmHg

R/L

TONO

CCT

EXIT

19

20

(Fig. 7)

- 5) Press F4 18 to change the screen to IOP Calculation (Fig.7) to show calculation result 19.
- 6) Press F4 20 to go back to Main MENU (Fig.1).

3.8 Sending and receiving data



Connect the instrument to the equipment which complies with the IEC06-1 or the IEC950 and of which power source is isolated with the dielectric transformer, by using the serial communication cable.

This instrument can send and receive data to and from the external equipment, by using the serial communication cable.

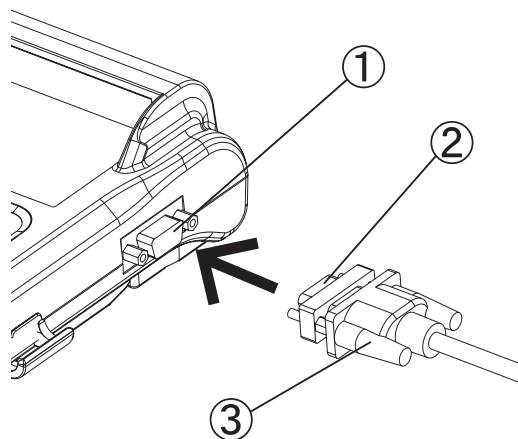
3.8.1 How to connect the serial communication cable



The insertion direction of the connector is specified. Securely insert the connector in specified direction without looseness.

The serial communication cable used for this instrument is of a female type. In case of connecting this connector with the personal computer, connect the male/female adapter to the male/female cable or the female/female cable in accordance with the following procedure.

- 1) Connect the serial communication cable connector ② to the serial communication cable terminal ① and secure these parts with the fixed screw ③.



[Positions of D-sub 9 pins]

Pin No.	Signal name
1	-
2	RxD
3	TxD
4	DTR
5	SG
6	DSR
7	RTS
8	CTS
9	-

It is noted that No. 4 and No.6 pins and No.7 and No. 8 pins are shorted inside of the instrument.

3.8.2 Setting of communication conditions

RIGHT	1: 548	5: 583
LAST	2: 572	6:
	3: 553	7:
	4: 548	8:
AVG. : 561 μ m SD: 28.3		
R/L	INDEX	EDIT NEW

(Fig. 1)

①

- 1) Press F2 Key ① to change the screen to the INDEX Screen. (Fig. 2)

Sep/24/2004 16:30			
ID : 12345678901234			
NAME: ABCDEFGHI JKLMN			
VELOCITY: 1640m/s			
Pachy	ID	NAME	COM

(Fig. 2)

②

- 2) Press F4 Key ② to change the screen to the DATA COMMUNICATION Screen. (Fig. 3)

COMMUNICATION			
SEND		RECEIVE	
SETUP			
Pachy		SEL	EXIT

(Fig. 3)

③

④

- 3) Use "◀" or "▶" keys to select "SETUP" to go to the COM Set-up screen (Fig. 4).

Press F4 key ④ to go back to INDEX screen (Fig. 2).

COM Set-up

BAUD RATE 38400

DATA BIT 8 BIT

PARITY NONE

DEF NEXT EXIT

(Fig. 4)

⑤ ⑥ ⑨

- 4) Press "◀" or "▶" of the Operating Panel to set the BAUD RATE. The baud rate is selective from three stages of 9600, 19200, and 38400. Press F1 key ⑤ to set as 38400 (default).

When F2 Key ⑥ is pressed, the screen will be changed as shown in Fig. 5. The Machine number can also be set by pressing "◀" or "▶" of the Operating Panel.

COM Set-up

STOP BIT 1 BIT

FLOW NONE

MACHINE 0

DEF NEXT EXIT

(Fig. 5)

⑦ ⑧ ⑨

When F2 Key is pressed again, the screen will be returned to the screen shown in Fig. 4.

[Communication Setup]

BAUD RATE: 9600, 19200, 38400

DATA BIT: 8BIT (Fixed)

PARITY: NONE (Fixed)

STOP BIT: 1BIT (Fixed)

FLOW: NONE (Fixed)

MACHINE: 0 to 99

Press F4 key ⑨ to go back to DATA COMMUNICATION screen (Fig.3).

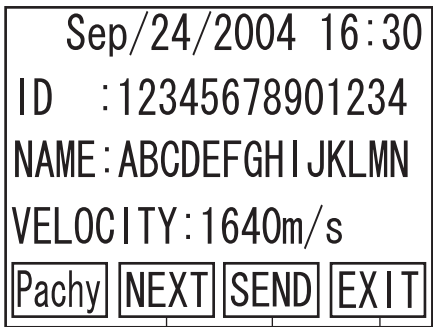
3.8.3 Data Export

Please refer to "3.9 Data Management with TOMEYLink (Electronic Medical Record Support System)" to send Data to TOMEYLink.



(Fig. 1)

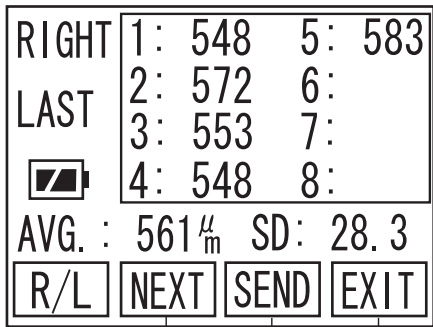
- 1) Press "◀" or "▶" of the Operating Panel in the DATA COMMUNICATION Screen and align the cursor to "SEND".
Press F3 Key ① to change the screen to the Data Communication Screen (Fig. 2).



(Fig. 2)

- 2) Press F2 Key ② to change the screen to the Data Confirmation Screen (Fig.3)

Make sure in this screen that the serial communication cable is connected to the external equipment and press F3 Key ④, so the data will be sent to the external equipment. (It should be noted that no data can be sent unless related ID has been entered.)



(Fig. 3)

Sep/24/2004 16:30			
ID :12345678901234			
NAME:ABCDEFGHIJKLMN			
NOW COMMUNICATING			
			EXIT

(Fig. 4)

⑤

- 3) "NOW COMMUNICATING" is displayed while data is being sent. (Fig. 4) When F4 Key ⑤ is pressed, while data is being sent, the process of sending data is cancelled.

Sep/24/2004 16:30			
ID :12345678901234			
NAME:ABCDEFGHIJKLMN			
SENT COMPLETE!			
			OK

(Fig. 5)

⑥

- 4) When data is properly sent, "SENT COMPLETE!" is displayed. (Fig. 5) Then, press F4 ⑥ to return the screen to the Data Communication Screen (Fig. 2).

3.8.4 Data Receiving

Please refer to "3.9 Data Management with TOMEYLink (Electronic Medical Record Support System)" to send Data to TOMEYLink.

RIGHT	1:	5:
LAST	2:	6:
	3:	7:
	4:	8:

AVG. : μ_m SD:

R/L INDEX EDIT NEW

①

(Fig. 1)

- 1) Make sure before receiving data that there is no data left in the Data Standby Screen. Then, change the screen to the Data Communication Screen (Fig. 2). If any data is left remaining in the screen, delete such data by long pressing F4 Key ①.

COMMUNICATION

SEND RECEIVE

SETUP

Pachy [] SEL EXIT

②

(Fig. 2)

- 2) Next press "◀" or "▶" of the Operating Panel and align the cursor to "RECEIVE". Then press F3 Key ② to change the screen to the Data Receiving Screen (Fig. 3).

ID :

NAME:

DATA RECEIVE

Pachy [] OK EXIT

③ ④

(Fig. 3)

- 3) When F3 Key ③ is pressed, the screen will be ready for receiving data. Then, operate the data sending side to send data.

ID :
NAME:
NOW COMMUNICATING
Pachy OK EXIT

(Fig. 4)

- 4) The screen displays "NOW COMMUNICATING" while in the process of receiving data. (Fig. 4) When F4 Key ⑤ is pressed, receiving data is cancelled.

ID :12345678901234
NAME:ABCDEFGHIJKLMN
RECEIVED COMPLETE!
 OK

(Fig. 5)

- 5) When data is properly received, "RECEIVED COMPLETE!" is displayed.(Fig. 5) Then press F4 ⑥ to return the screen to the Data Communication Screen (Fig. 2).

3.9 Data Management with TOMEYLink (Electronic Medical Record Support System)

Note

SP-100 must be connected with external devices, complied with IEC601-1 Standard or the devices complied with IEC950 Standard and electrically insulated by insulation transformer.

Please refer to Operation Manual of TOMEYLink (Electronic Medical Record Support System) to setup TOMEYLink software and LAN adapter (LA-100).

Patient ID is necessary in order to send the data outside the unit by TOMEYLink. Optional Key-Pad is used in this manual to explain how to input Patient ID.

3.9.1 Patient Data Receiving

RIGHT	1:	5:
LAST	2:	6:
	3:	7:
	4:	8:
AVG. : μ_m SD:		
R/L	INDEX	EDIT NEW

(Fig. 1)

①

Sep/24/2004 16:30			
ID :			
NAME :			
Pachy	ID	NAME	COM

(Fig. 2)

②

- 1) On Main Screen (Fig.1), press F2 key ① to go to INDEX screen (Fig.2).

- 2) Press F4 key ② to go to DATA COMMUNICATION (Fig.3).



COMMUNICATION

SEND **RECEIVE**

SETUP

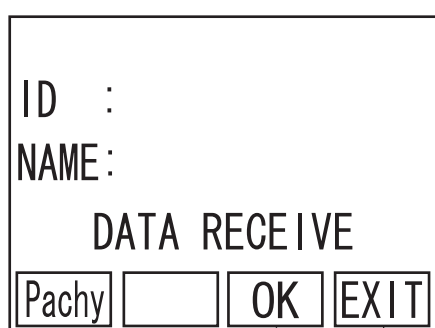
Pachy SEL EXIT

(Fig. 3)

③

- 3) Press "◀" or "▶" key to move the cursor to RECEIVE.

Press F3 key ③ to go to Data Receiving (Fig.4).



ID :

NAME:

DATA RECEIVE

Pachy OK EXIT

(Fig. 4)

④

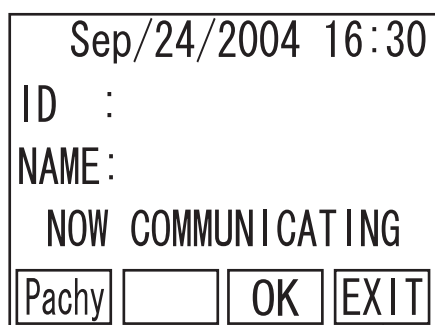
⑤

- 4) When F3 key ④ is pressed, data receiving will be ready. Input Patient ID through Key pad, connecting with LAN adapter (LA-100).

Press F4 key ⑤ to go back to DATA COMMUNICATION (Fig.3).

Note

Patient ID, typed in SP-100 has nothing to do with TOMEYLink Patient ID. TOMEYLink Patient ID will always have priority to register data on TOMEYLink. Please note that the ID on SP-100 will be ignored.



Sep/24/2004 16:30

ID :

NAME:

NOW COMMUNICATING

Pachy OK EXIT

(Fig.5)

⑥

- 5) "NOW COMMUNICATING" will be displayed, while SP-100 is receiving data (Fig.5). Press F4 key ⑥ to cancel receiving data.

(Fig. 6)

- 6) When data is properly received, RECEIVED COMPLETE! is displayed (Fig.6). When there is no registered patient on TOMEYLink, according to input ID, only the ID will be received. Press F4 key ⑦ to go back to DATA COMMUNICATION (Fig.3).

(Fig. 7)

- 7) Press F1 key ⑧ to return to the Measurement Screen (Fig.1) and start taking measurement.

Patient Data can also be received, after taking measurement. Please follow the instruction 2), after taking measurement.

3.9.2 Data Sending

(Fig. 1)

- 1) Press "◀" or "▶" button to move cursor to SEND on DATA COMMUNICATION (Fig.1). Press F3 key ① to go to DATA SENDING screen (Fig.2).


Sep/24/2004 16:30			
ID :12345678901234			
NAME:ABCDEFGHIJKLMN			
VELOCITY:1640m/s			
Pachy	NEXT	SEND	EXIT

(Fig. 2)

②

③

④

RIGHT	1: 548	5: 583
LAST	2: 572	6:
	3: 553	7:
	4: 548	8:
AVG. : 561 _m SD: 28.3		
R/L	NEXT	SEND
		EXIT

(Fig. 3)

②

③

④

Sep/24/2004 16:30			
ID :12345678901234			
NAME:ABCDEFGHIJKLMN			
NOW COMMUNICATING			
			EXIT

(Fig. 4)

⑤

Sep/24/2004 16:30			
ID :12345678901234			
NAME:ABCDEFGHIJKLMN			
SENT COMPLETE!			
			OK

(Fig. 5)

⑥

- 2) Press F2 key ② to switch screen from DATA SENDING (Fig.2) to DATA CONFIRMATION (Fig.3).

Make sure Serial Communication Cable is properly connected to external device. Press F3 key ③ to send data to TOMEYLink. When ID is missing, whole data will not be sent.

Press F4 key ④ to go back to DATA COMMUNICATION (Fig.1).

- 3) "NOW COMMUNICATING" is displayed, while data is sent (Fig.4). Press F4 key ⑤ to cancel sending data.

- 4) When data is properly sent, SENTCOMPLETE! is displayed (Fig.5). Press F3 key ⑥ to go back to DATA SENDING screen (Fig.2).

3.10 Battery



- *Please use the battery only specified for SP-100. The use of wrong type may cause Heating/Fire/Explosion of the battery and main unit.*

Notes

- *After the battery has been charged, pull off the AC Adapter from the instrument. If the battery is left as being connected to the instrument for long time, the service life of the battery may be affected.*
- *This instrument is enclosed with its exclusive battery; therefore, it can be used without the AC Adapter as connected.*

3.10.1 Battery charge balance

The remaining amount of battery charge is displayed in the Monitor Screen, which is displayed in the following two steps.



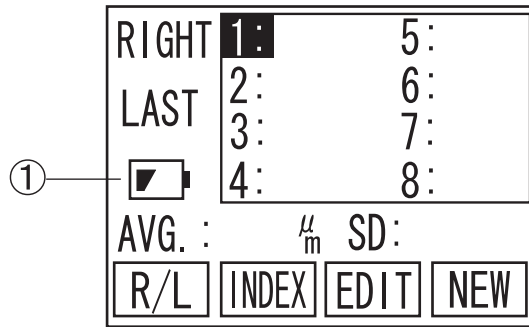
: Sufficient charge left in the battery



: Less charge left in the batter
(Battery Recharging is necessary)

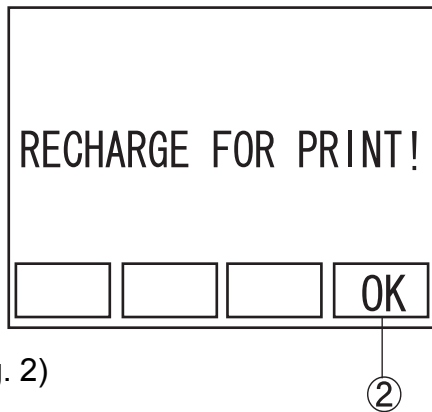
Recharge the battery if the charge level becomes low.

3.10.2 Low Battery Warning





(Fig. 1)

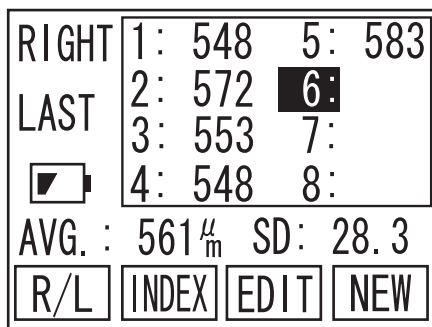
1) When capacity of the battery becomes low ①, SP-100 screen starts blinking and beeping (Fig.1). Under this condition, the unit shuts down after 10 minutes of non-operating time, automatically. Within 10 minutes, the battery needs to be charged or measured data will be lost. Auto Power Off waiting time is 3 minutes, but it will be extended to 10 minutes, when the battery is low, in order to keep a certain time to start recharging the unit. When the unit is powered by AC adapter, it starts charging battery, then blinking and beeping stop automatically.



(Fig. 2)

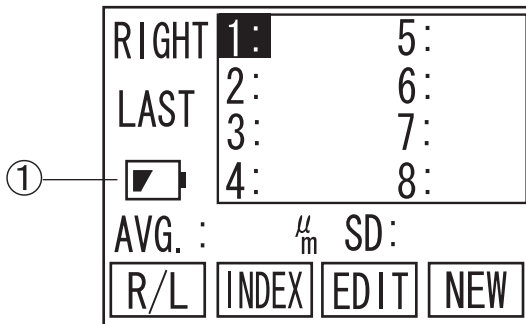
2) When the battery is low ①, built-in printer becomes out of service. When PRINT is pressed, a warning (Fig.2) comes up on screen. Press F4 key (②) to go back to main screen.

If the measured data is on screen (Fig.3), when battery icon becomes  to , printout is available only once within 9 minutes. After 9 minutes, since the battery becomes low or print-out is provided once, the printer becomes out of service and a warning (Fig.2) comes up, when PRINT is pressed.



(Fig. 3)

3.10.3 Charge indicator



The charge indicator ① on the Operating Panel lights up, while the battery is being recharged. When the charge indicator light goes off (Full Charged), disconnect the AC Adapter from the instrument.

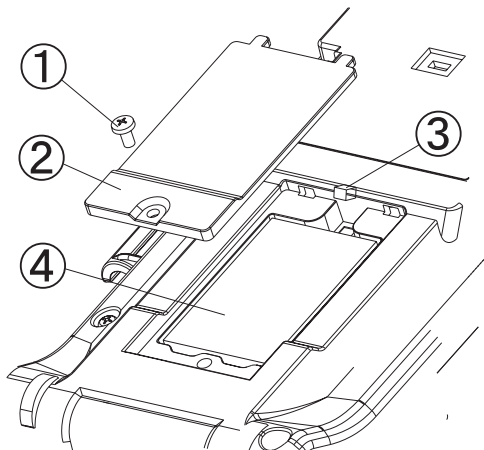
3.10.4 How to Install/Uninstall Battery

Note

Please pay special attention not to disconnect the battery cable.

Note

Please be careful not to cut the battery cables by putting them between main unit and its cover, pulling them hard or carrying the battery by holding only these cables.



1) Remove the Screw on backside of the unit ①, then remove the battery cover ②.

2) Unplug the Battery Connector ③ carefully with tweezers. Then, remove the battery ④ slowly from the unit.

3) Connect the new battery ④ and plug the connector carefully.

4) Place the battery cover back and tighten the screw ①.

5) Please refer to “5.5 Precautions for disposal of packing materials” on this book, for battery disposal.

3.10.5 Lifetime of rechargeable battery

The battery, built-in the instrument, keeps 85% of its capacity even after 500 times recharge and discharge under 25 degree Celsius room temperature.

Since any battery has its lifetime, replace with new battery, when its discharging time is getting shorter than it used to be.

3.10.6 Expected operating time of hours

The battery enclosed in the instrument is serviceable for the following operating time with its fully charged condition provided in its initial stage.

- 3 minutes measurement for one Patient, without printout:
Approx. 6 hours.
- 3 minutes measurement for one Patient with printouts for both eyes: Approximately 4 hours.

The above operating time is only an assumed measure, which varies upon the using environments and conditions.

4. REFERENCE TECHNICAL INFORMATION

4.1 How to calculate corneal thickness

The corneal thickness is calculated in the following calculation by using the converted sound velocity in the cornea.

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

where,

T_c: Corneal thickness

V: Converted sound velocity in the cornea

t: Measuring time

4.2 Acoustic Output

4.2.1 MI (Mechanical Index)

MI is a parameter to show mechanical bio-effects of ultrasound. Examples of mechanical effects are motion (or streaming) around compressible gas bubbles as ultrasound pressure waves pass through tissues, and energy released in the collapse, via cavitation, of transient gas bubbles.

4.2.2 TIS (Soft Tissue Thermal Index)

TIS is a parameter to show thermal bio-effects of ultrasound. Thermal effect is temperature rise of tissue by ultrasonic exposure.

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5. MAINTENANCE AND INSPECTION

5.1 Warranty

Tomey 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 (or the term regulated by local government) 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. Lamps, paper and consumable items shall not be covered by this warranty. This warranty also shall NOT apply if the product has not been installed, operated or maintained in accordance with the OPERATION 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.

5.2 Routine maintenance

5.2.1 MeasurementProbe

Notes

- *Be sure to hold the connector of the Probe cable to disengage the Probe from the instrument. Do not pull the cord itself, which may cause to damage the cord or to ruin its power connection.*
- *Do not touch the connector, or the Probe may be damaged.*
- *Before applying the probe to patient, please make sure there is no damage, such as crack or split, on the probe tip.*
- *Please make sure there is no loose connector nor disconnecting cable.*

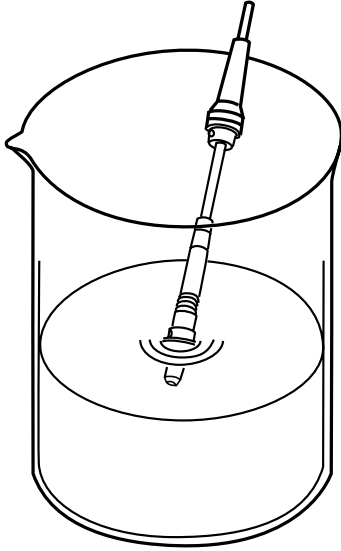
a) Cleaning

Notes

- *Use sanitary cotton for cleaning of the eye contacting part of the Probe not to damage.*
 - *Do not pull the cord of the Probe while cleaning.*
 - *Do not wet the connector contacting part of the Probe when cleaning.*
-
- For cleaning of the Probe, wipe stains with sanitary cotton absorbed with ethanol for disinfection and then clean it with water soaked cloth.
 - Completely remove water from the Probe after cleaning.

b) Disinfection

- For disinfecting of the Probe, immerse the part of the Probe within 15mm from the eye contacting part it in disinfection ethanol or 0.5% sodium hydrochloride water solution for 10 to 20 minutes and then wash it with distilled water and then dry sufficiently.



c) Sterilization



The use of the autoclave for sterilization of the Probe is prohibited, or the Probe is severely damaged otherwise.

<Sterilization conditions>

EtO: Ethylene oxide 20%, and carbon dioxide 80%.

Sterilization temperature: $50 \pm 5^{\circ}\text{C}$

Sterilization pressure: $(9.8 \pm 0.98) \times 10000\text{Pa}$

Sterilization time: 5 ± 1 hr.

Aeration time: Pachymeter Probe....More than 10 hours

Disposable Tip.....20 sets of 30 minutes aeration

5.2.2 Maintenance of the Main Unit

Notes

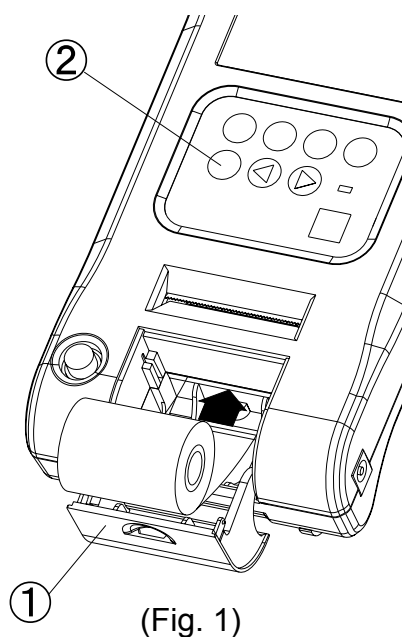
- *Do not use such organic solvents as thinners for cleaning the Main Unit of the instrument. Such organic solvents may cause to damage the surface of the Main Unit.*
 - *Do not pull the power cord with an undue force.*
 - *Care is to be taken not to touch the Probe connecting terminals.*
-
- Remove stains from the instrument body by lightly rubbing the surface with a piece of cloth which has been wetted with water and then squeezed to remove water, and then by finishing with a piece of dry cloth. In case of an excessive amount of stains, wet the stained surface with a piece of cloth which has been wetted with a diluted neutral agent. Furthermore, carefully wipe the surface with wet and dry cloths.
 - Cleaning of stained monitor display is to be given by dry cloth. In case of an excessive amount of stains, remove the stains with a piece of cloth which has been wetted with a neutral cleanser and tightly squeezed and furthermore by wiping wet and dry cloth.
 - If the instrument is suspended for a while, disconnect the power plug from the receptacle and place the dust cover over the instrument.

5.3 Replacing of the printer paper

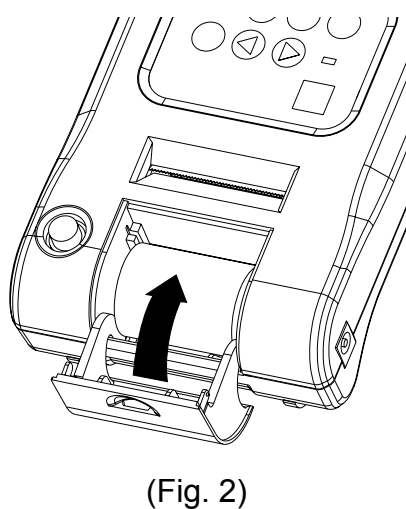
Replace the printing paper when the red lines appear on the both sides of the roll paper, according to the following procedure.



Care is to be taken not to damage your hand with the paper cutter, when opening and closing the Printer Cover.



- 1) Open the Printer Cover ① to your side.
- 2) Remove the roll shaft for printing paper to be replaced.
- 3) The printer paper is set by inserting and pushing the paper end is inserted into the Printer and, at the same time, pressing the PRINT Key ②. Make sure that the paper has been placed with its face side turned on the printing side. (Fig. 1)



- 4) Close the Printer Cover. Be sure to securely close the Cover until it snicks. (Fig. 2)
- 5) Trim an extra length of paper.

5.4 Storage



- *Store the instrument in a place where it is free of water, moisture and chemicals.*
- *Do not store the instrument in a place where it is subjected to high temperature and high humidity and to any adverse influences that the instrument may be exposed to dust, salts, and/or sulfur.*
- *Minute care must be given not to cause the instrument with inclination, vibration, or shock in routine operation and also when moving it from one place to the other.*
- *Do not store the instrument in or close to a place where chemicals or any gases are stored or used.*

-
- After using the Probe, clean and dry it. The protective cap should be used for the Probe tip and stored in the Probe case.
 - If the instrument is used after a long period of recession, make sure that it functions properly and safely before use.
 - Store the instrument under following Storing conditions to avoid enshortening lifetime of built-in battery.

<Storing conditions>

Ambient temperature range: -20 to +45°C

Relative humidity range: lower than 95%

5.5 Precautions for disposal of packing materials



- *Keep the containers and packing materials for future use. The packing container and cushion materials will be necessary when moving or transporting the instrument.*
- *Be sure to store the cushion materials when storing the container.*
- *Disposing of the instrument and packing materials shall be done in accordance with the national and local environmental rules and regulations.*
- *This instrument is provided with the printed board using the lithium cells. It is specially noted the disposal of lithium cells differ in local rules, so please follow your local rules and regulations.*

6. TROUBLESHOOTING

Before presuming the instrument is disordered, check the following items. If the following items do not correct the malfunction, consult with your local representative for countermeasures.



- *Do not remove the outer cover of this instrument while in operation, which will otherwise expose you to the direct high voltage.*

Notes

- *Do not attempt to use the instrument for any purposes other than those specified in this Manual.*
- *If the following items do not correct the malfunction, ask your local representative for inspection and repair.*

- When the power is turned on, the Monitor Screen is not displayed.

?Cause 1 Improper connection of the AC Adapter.

Remedy ➞ Check to see if the AC Adapter is securely connected to the instrument and the power receptacle.

?Cause 2 No power is supplied.

Remedy ➞ Check to see if the power is supplied to the power receptacle.

-
- No information is displayed in the Monitor Screen.

?Cause 1 The Auto Power-off Function is in actuation, which automatically turns the power of the instrument off if it does not continue operation for longer than 3 minutes.

Remedy ➡ Turn the power for the instrument on.

?Cause 2 The switch for maintenance which is located at the rear side of the instrument, is in its middle position (A).

Remedy ➡ Turn the power off, next return the switch to its middle position (A), and then turn the power on.

- The Monitor Screen is too dark to see.

?Cause 1 The brightness of the Monitor is low.

Remedy ➡ Adjust the contrast of the Monitor Screen by turning the Contrast Adjusting Volume. Turn the backlight LED ON, if necessary. (2.3 Operation Keys)

- No printout can be made.

?Cause 1

The Printer paper has run out.

Remedy ➡

Check to see if the Printer paper is left sufficient for printout.

Also check to see if the Printer paper is provided properly in such a manner that is specified in "5.4 How to replace the Printer paper".

-
- The Clock in the screen is in cease.

?Cause 1 The INDEX Screen displayed after data measurement has been made is shown.

Remedy ➡ In case the INDEX Screen displayed after data measurement has been made is shown, the date and time when data measurement was made are displayed in the screen.

The then time will be displayed by first deleting the data and then displaying the INDEX Screen.

- The LED does not light.

?Cause 1 The Auto LED Off Function is in actuation, which automatically turns the LED off if the instrument ceases operation longer than one minute.

Remedy ➡ Pressing "◀" and "▶" keys in the Operation Panel concurrently lights up the LED.

- Ultrasound Velocity and Display Settings cannot be changed.

?Cause 1 The measured data is stored in main memory.

Remedy ➡ Press New, CLR or DEL button to delete the stored data to change current settings.

<Measuring Function>

- "PROBE ERROR!" is displayed in the calibration of the Pachymeter Probe given when the power is turned on.

?Cause 1 The connection of the Pachymeter Probe is not proper.

Remedy ➡ Properly connect the Probe, in accordance with the procedure specified in "3.2.1 a Connecting of the Pachymeter Probe".
After the above, calibrate the Probe in the procedure specified in "3.4.1 Calibration of the Pachymeter Probe" or after once turning the power off and then rebooting the the instrument.

- Measurement data is not stable or proper.

?Cause 1 The connection of the Pachymeter Probe is not proper.

Remedy ➡ Properly connect the Probe in accordance with the procedure specified in "3.2.1 a Connecting of the Pachymeter Probe".

?Cause 2 Using of the Probe is not proper.

Remedy ➡ Apply the Probe at a right angle to the corneal part to be measured.

?Cause 3 Setting of the conversion sound velocity has not been properly set.

Remedy ➡ Make sure that the converted sound velocity has been set properly.

?Cause 4 The eye contact part of the Pachymeter Probe is damaged.

If such damage is found, stop measurement immediately
Remedy ➡ and consult with your local representative.

? Cause 5 The Pachymeter Probe has not been properly calibrated.

Remedy ➡ Clean the tip of the Probe and re-calibrate the Probe in the procedure specified in "3.4.1 Calibrating of the Pachymeter Probe" or once turn the power off, next reboot the instrument, and the calibrate the Probe.

- No automatic measurement can be given.

? Cause 1 The Pachymeter Probe has not been properly calibrated.

Remedy ➡ Clean the end of the Probe and re-calibrate the Probe in the procedure specified in "3.4.1 Calibrating of the Pachymeter Probe" or once turn the power off, next reboot the instrument, and the calibrate the Probe.

? Cause 2 Surrounding noises have been interfered.

Remedy ➡ Such noise sources as motor and laser surgery equipment, if provided close to the instrument, must be moved away from the instrument.

? Cause 3 The eye contact part of the Pachymeter Probe is damaged.

Remedy ➡ If so damaged, promptly discontinue measurement and consult with your local representative.

-
- Monitor sounds do not stop. Measurement data is taken when measurement is not in process.

?Cause 1 The tip of the Pachymeter Probe is wet with water.

Remedy ➡ Remove the water from the tip of the Probe.

- Monitor sound is not made.

?Cause 1 The sound volume is set as OFF.

Remedy ➡ Turn the Sound Volume to a position other than OFF, in accordance with "3.10.2 Sound Setting".

7. SPARE PARTS AND OPTIONAL PARTS

The following spare parts and optional parts are available upon ordering to your Tomey local distributor or representative.

7.1 Spare parts

- Printer paper
Specify your order article as "Printer paper for SP-100 " when you order.

7.2 Optional parts

- Pachymeter Probe (Standard Probe)
Specify your order part as "Standard Pachymeter Probe for SP-100" when you order.
- Disposal tip type Pachymeter Probe
Specify your order part as "Disposal tip type Pachymeter Probe for SP-100" when you order.
- Disposal tip
Specify your order part as "Disposal tip for SP-100" when you order.

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8. SPECIFICATIONS

8.1 Specifications

8.1.1 Measuring function

- Default Converted Ultrasound Velocity and Setting Range
 - Corneal Ultrasound Velocity : 1,640 m/s
(1,400 to 2,000 m/s)
- Measuring range
 - Corneal thickness
 - Standard Probe : 150 to 1,200μm
 - Disposal tip type Probe : 150 to 1,200μm
- Instrument accuracy
 - Measuring accuracy : ± 5μm
- Minimum Display Unit : 1μm

8.1.2 Measuring Probe

- Probe type
 - Standard Probe : Solid type/45° with angle
 - Disposal tip type Probe : Solid type/45° with angle, straight
- Transducer frequency : 20MHz ± 20%

8.1.3 Main unit

- Printer : Enclosed thermal printer
- Monitor screen : STN liquid crystalline display panel, 2.7 inch black and white
- Dimensions/Weight : 118(W) × 207(D) × 59(H)mm/530g
- Power Consumption : 23VA + less than 15%

8.1.4 AC Adapter

- Power Voltage & Frequency : AC 120V 60Hz 30W
AC 230V 50Hz 125mA
- Manufacturer : Globtek, Inc.
- Product Name : WD24C2000LCP-N-MED
WD24C2000L1P-N-MED

8.1.5 Enclosed battery

- Battery : Lithium ion battery
Rated capacity 1,000mAh
Nominal voltage 3.7V

* The above specifications and exterior appearance may be revised for improved performances of the instrument.

8.2 Ultrasound energy and other information

8.2.1 Influences of ultrasound energy on the human body



- ***SP-100 Pachymeter is exclusively designed and built for ophthalmic use. Do not use the instrument for any purposes other than ophthalmic use.***

SP-100 Pachymeter, exclusively designed and built for ophthalmic pachymeter purpose, is set at very weak ultrasound energy appropriate for ophthalmic application. Minutes care should be taken not to cause the Patient to be excessively exposed with ultrasound energy while measurement.

8.2.2 Ultrasound energy

Acoustic Output Reporting Table(FDA)

Acoustic Output		MI	Ispta.3 (mW/cm ²)	Isppa.3 (W/cm ²)
Pre-enactmet Maximum Acoustic Output		0.23	17	28
Global M aximum Value		0.15	12.71	26.21
Associated Acoustic Parameter	pr.3(Mpa)	0.44		
	W0(mW)		0.021	0.021
	fc(MHz)	19.98	19.92	19.89
	Zsp(cm)	0.05	0.05	0.05
	Beam dimensions	x-6(cm)	0.065	0.065
		y-6(cm)	0.065	0.065
	PD(usec)	0.075		0.075
	PRF(PRF)	8000		8000
	EBD	Az.(cm)	0.19	
		Ele.(cm)	0.18	

- MI : the Mechanical index
- Ispta3 : the derated spatial-peak temporal-average intensity.
- Isppa3 : the derated spatial-peak pulse-average intensity.
- pr : the peak rarefactional pressure.
- pr.3 : the deratad peak rarefactional pressure.
- Wo : the ultrasonic power
- fc : the center frequency
- Zsp : the axial distance at which the reported parameter is measured.
- x-6, y-6 : are respectively the in-plane(azimuthal)and out of plane(elevational)
-6dB dimensions in the x-y plane where Zsp is found

PD : the pulse duration
 PRF : the puls repetition frequency
 EBD: the entrance beam dimensions for the azimuthal and elevational planes

Acoustic Output Report (IEC60601-2-37)

Index label		MI	TIS Non-scan(Aaprt \leq 1cm ²)
Maximum index value		0.15	2.005×10^{-3}
Associated acoustic parameters	pr, α [Mpa]	0.44	NA
	P [mW]	NA	0.0211
	Min.of [P α (zs), lta, α (zs)]	NA	NA
	Zs	NA	NA
	zbp	NA	NA
	Zb	NA	NA
	Z at max.lpi, α [cm]	0.05	NA
	deq (zb)	NA	NA
	fawf [MHz]	19.9	19.9
	Dim of Aaprt [cm]	X	0.19
		Y	0.18
Other information	Td [us]	0.075	NA
	Prr [Hz]	8000	NA
	Pr at max.lpi [MPa]	0.45	NA
	deq at max.lpi	NA	NA
	lpa, α at max.MI [W / cm ²]	26.21	NA
Operating control conditions	Control	NA	NA

NA : Not Applicable

a : ACOUSTIC ATTENUATION COEFFICIENT
 Aaprt : -12dB OUTPUT BEAM AREA
 Deq : EQUIVALENT APERTURE DIAMETER
 deq : EQUIVALENT BEAM DIAMETER
 fawf: ACOUSTIC WORKING FREQUENCY
 lpa : PULSE-AVERAGE INTENSITY
 lpa, a : ATTENUATED PULSE-AVERAGE INTENSITY
 lpi : PULSE-INTENSITY INTEGRAL
 lpi, a : ATTENUATED PULSE-INTENSITY INTEGRAL
 MI : MECHANICAL INDEX
 P : OUTPUT POWER
 Pa : ATTENUATED OUTPUT POWER
 Pr : PEAK-RAREFACTIONAL ACOUSTIC PRESSURE
 Prr : PULSE REPETITION RATE
 TIS : SOFT-TISSUE THERMAL INDEX
 td : PULSE DURATION
 X,Y : -12dB OUTPUT BEAM DIMENSIONS

z:	DISTANCE FROM THE SOURCE TO A SPECIFIED POINT
zb:	DEPTH FOR TIB
zbp:	BREAK-POINT DEPTH
zs:	DEPTH FOR TIS

8.3 Noise generation

This instrument makes monitoring sounds at the following occasions.

- When turning the power on.
- When Printout
- When operating various keys and buttons
- When taking measurement (such as taking data)

8.4 Operating Environment

This instrument must be used under following environment.

<Working Environment>

- Ambient temperature range: +10 to 40°C
- Relative humidity range: 30 to 75% non-condensing

Store the instrument under following Storing conditions to avoid enshortening lifetime of built-in battery.

<Storage Condition>

- Ambient temperature range: -20 to +70°C
- Relative humidity range: Less than 95%

8.5 Conformed Standard

IEC 60601-1 : 1988
 Amendment 1 : 1991
 Amendment 1 : 1995
 IEC 60601-1-2 : 2001
 IEC 60601-2-37 : 2001

9. Index

INDEX

A

AC Adapter 2-1, 3-2, 3-39, 6-1
AC adapter terminal 1-4
AC power adapter 1-5
Acoustic Output 4-1
Auto Measurement Function 3-14
Auto Power Off 3-4, 6-2
Average 3-7, 3-11, 3-20

B

Battery 3-7, 3-35, 3-39, 8-1
BAUD RATE 3-30
Biometry probe 1-3

C

calculation formula 1-5
CALIBRATION 3-6, 3-12
Charge indicator 2-2, 3-41
Cleaning 5-2
CLR (F2 key) 3-8
COM 3-29
Communication Setup 3-30
Contrast 1-4, 2-1, 6-2
converted sound velocity 6-4
Corneal thickness 4-1, 8-1
Corneal Ultrasound Velocity 3-9, 3-14, 3-20, 3-21, 3-25, 8-1
Cursor 3-8, 3-16

D

D-sub 9 pins 3-28
DATA BIT 3-30
DATA COMMUNICATION 3-19, 3-29, 3-30, 3-31
DATA SEL 3-21, 3-26
DEL (F3 key) 3-8
Delete 3-17, 3-18

Disinfection 3-2, 5-3
disposal 5-6
Disposal Tip 3-3
Disposal tip 3-14, 7-1

E

EDIT 3-7, 3-15, 3-16, 3-17, 3-26
EOG 5-3
ERROR 3-6
EXIT 3-21
Explosion 3-39
Eye to be measured 3-20

F

Fire 3-39
FLOW 3-30
Frequency 8-1
FUNCTIONKEYS 2-2

H

Heating 3-39

I

ID number 3-20
INDEX 3-7, 3-9, 3-10, 6-3
Instrument Stand 2-1, 3-4

L

LATEST 3-11
LED 6-3
Low Battery 3-40

M

MACHINE 3-30
Maintenance switch 1-4, 2-1
Measured data 3-20
Measurement data 3-7, 3-8
Measurement Standby Screen 3-22
Measuring time 4-1
Memory card 1-3
MENU 3-22, 3-26
MENU (F4 key) 3-8
MI (Mechanical Index) 4-1
MINIMUM 3-11

N

NEW 3-7
NOW COMMUNICATING 3-32, 3-34, 3-36, 3-38

O

OPERATING PANEL 2-1
Optional parts 7-1

P

Pachy 3-8, 3-21
Pachy screen 3-7
Pachymeter Probe 3-2
Pachymeter probe terminal 1-4, 2-1
packing materials 5-6
PARITY 3-30
Patient ID 3-9, 3-10
Patient name 3-9, 3-10, 3-20
Power cable 1-3
power cable 1-2
Power consumption 8-1
POWERKEY 2-2
Power Switch 1-4
Power voltage 8-1
PRINT 2-2, 3-19, 5-5
PRINTER 2-1
Printer Cover 5-5
Printer paper 1-3, 5-5, 7-1
Printout 3-19, 3-20, 3-21, 3-27
PROBE ERROR! 3-4, 3-6, 6-4
PROBE HOLDER 2-1

R

R/L (F1 key) 3-7
RECEIVE 3-33
Resolution 8-1
Retake 3-15
Routine maintenance 5-2

S

SCREEN 2-1
SD 3-20
SEL 3-10, 3-21
SEND 3-19, 3-31
Serial communication 1-3, 1-4, 2-1, 3-28
SETUP 3-29
Simple mode 3-20
software version 3-5

SOUND 3-21, 3-24
sound volume 6-6
Spare parts 7-1
Specifications 8-1
Standard Probe 7-1
Sterilization 5-3
STOP BIT 3-30
Storage 5-6, 8-4
Symbols 1-4

T

test piece 1-3, 3-13
The eye to be measured 3-7, 3-8
TIME/DATE 3-20, 3-21, 3-23
TIS (Soft Tissue Thermal Index) 4-1
TROUBLESHOOTING 6-1
Type of display data 3-20
Type of listed data 3-7

U

Ultrasound energy 8-2
ultrasound velocity 3-5

V

VELOCITY 3-21

W

Warranty 5-1
Working Environment 8-4

Y

YEAR 3-23

Manufacturer

Tomey Corporation
2-11-33Noritakeshinmachi
Nishi-ku, Nagoya 451-0051 JAPAN
Tel: +81 52-581-5327
Fax: +81 52-561-4735

EC-representative

Tomey GmbH
Am Weichselgarten 19a
91058 Erlangen GERMANY
Tel: +49 9131-77710
Fax: +49 9131-777120

AUTHORIZED TOMHEY SERVICE CENTERS

Headquarters, Pacific rim

Tomey Corporation
2-11-33Noritakeshinmachi
Nishi-ku, Nagoya 451-0051 JAPAN
Tel: +81 52-581-5327
Fax: +81 52-561-4735

Europe

Tomey GmbH
Am Weichselgarten 19a
91058 Erlangen GERMANY
Tel: +49 9131-77710
Fax: +49 9131-777120

