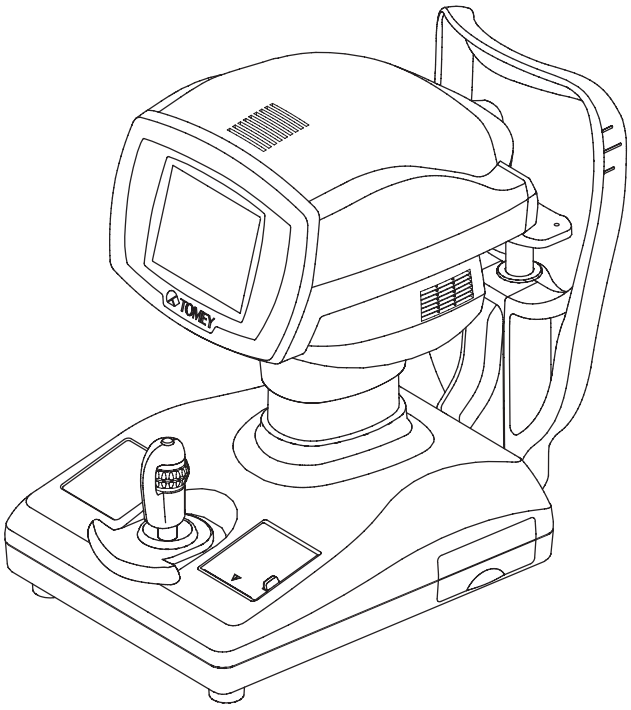
INSTRUCTION MANUAL

NON-CONTACT TONOMETER

FT-1000



Carefully read this instruction manual before using this instrument to ensure correct and safe operation.
If you have questions about operations, please contact Tomey Corporation or our local distributor.

Note **Always follow the operation procedures described in this manual.**

Keep this manual in a readily available location while operating the instrument.

Contact our local distributor if you lose this instruction manual.

VIEWLIGHT
POWERED BY INNOVATION

TOMEY

401A9090-3C

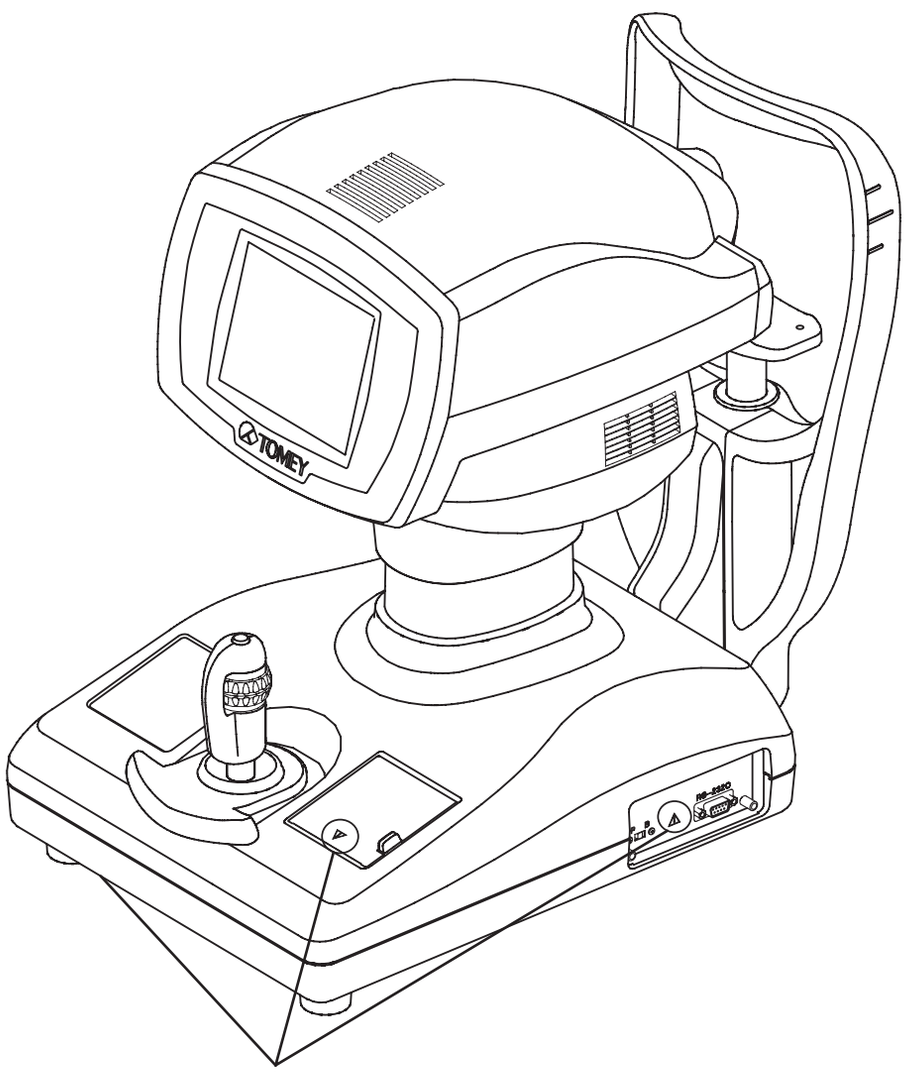
- ***Do not install this instrument in a location where explosives or inflammable substances are used or stored. Otherwise, fire or explosion may occur.***
- ***Do not remove the cover of the instrument. You may be directly exposed to high voltage sections.***
- ***Do not disassemble or modify the instrument. You may be directly exposed to high voltage sections.***

- ***Disconnect the power cord from the instrument before servicing the instrument. Otherwise, you may get an electric shock.***
- ***Do not commence service or maintenance work while the instrument is being used for a patient.***

- ***Do not place water or chemicals on the instrument. Any water or chemicals entering the instrument may cause an electric shock or failure.***
- ***Only use the specified terminal for connection of the instrument. Using another type of terminal may result in failure of the instrument.***
- ***This instrument is a measuring device specially designed for ophthalmology. Never use the instrument for other purposes.***
- ***The external output terminal is not isolated from the internal circuit. Inappropriate wiring may damage the internal circuit. Contact us before using the external output terminal.***

■ *Never damage or cause caution marks provided for the instrument to become illegible. Caution labels are provided on the sides, bottom, and physician's side of the instrument.*

■ *If a label is damaged or becomes illegible, please contact Tomey Corporation or our local distributor.*



Caution label

Outline

This manual is structured as follows.

1. PRIOR TO USE

   Describes safety precautions and important information to be understood before installing and using the instrument.

2. NAMES AND FUNCTIONS OF PARTS AND COMPONENTS

   Describes names and functions of each section of the instrument.

3. OPERATION PROCEDURES

   Describes information required for installing and using the instrument.

4. TECHNICAL INFORMATION

   Describes useful technical information about the instrument.

5. INSPECTION AND MAINTENANCE

   Describes procedures for replacing consumable parts, etc. that the user of the instrument should normally conduct.

6. TROUBLESHOOTING

   Describes how to solve problems.

7. CONSUMABLES AND OPTIONAL EQUIPMENT

   Describes consumable parts and optional equipment.

8. SPECIFICATIONS

   Describes the specifications of the instrument.

9. INDEX

   Refer to the index when needed.

SYMBOLS USED IN THIS MANUAL

The symbols below indicate 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, could result in a hazardous situation where there is a possibility of serious injury or death.*

■ *This is a precaution that, if unheeded, may result in a situation where there is a possibility of minor or moderate injury or damage to property.*

■ *This is an additional instruction which may contain a special precaution on company policy related, either directly or indirectly, to the safety of personnel or to the protection of property.*

1. PRIOR TO USE

Note

- ***Read this manual thoroughly before using the instrument to ensure proper and safe operation.***
- ***Always follow the operation procedures described in this manual.***
- ***Check that there is no device that generates strong magnetic field near the instrument. The strong magnetic field may cause noise and affect measurement.***

1.1 Precautions for operation

- ***Only allow adequately skilled operators to use the instrument.***

- ***Precautions for installing the instrument***

– *Install the instrument in a location free of water or chemicals. Any water or chemicals entering the instrument may cause an electric shock or failure.*

– *Do not install the instrument in a place where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the instrument and ignite.*

– *Check the frequency, voltage, and allowable current (or power consumption) of the power source. Operating the instrument connected to an inappropriate power source may cause fire or an electric shock.*

– *Connect the power plug to a grounded 3P-outlet. Otherwise, a short circuit due to failure of the instrument may result in an electric shock.*

– *Do not place any heavy object on the power cord or squash the power cord. This may cause fire or an electric shock.*

– *Completely insert the power plug into the outlet. Faulty contact, allowing any metal to contact exposed plug terminals, or dust accumulated on exposed plug terminals may result in fire or an electric shock.*

– *Do not connect any device with data transmission specifications that are not compatible with the instrument. Connecting such a device may cause fire or an*

electric shock. When connecting a device to the instrument using the RS-232C connector, contact Tomey Corporation or our local distributor.

– *Ground the instrument appropriately. Otherwise you may get an electric shock.*

– *Do not hold the measuring head, chin rest, forehead pad, or joystick when lifting the instrument. These components are detachable and the instrument may drop, resulting in injuries.*

– *Install the instrument in a location not subject to direct sunlight, high temperature and humidity, or air with significant dust, salt, and/or sulfur content. These may cause failure or malfunction of the instrument.*

– *Install the instrument in a level and stable location free of vibration or mechanical impact to ensure correct measurement, and prevent the instrument from falling or being dropped, resulting in fire or fatal accidents.*

– *Install the instrument between the patient and physician so that they can face with each other.*

– *Install the instrument in a location that it is sufficiently clear of any other equipment that may interfere with the examination when using the instrument.*

■ *Precautions before using the instrument*

– *Check that all cables are connected correctly and completely.*

– *Check the sections that the patient will directly touch.*

– *Peel off the top sheet of chin rest paper and clean the forehead pad with a cloth dampened with alcohol before measurement.*

– *Check that the instrument is correctly grounded.*

– *Check that the date set in the instrument conforms to the actual operation date and time.*

■ *Precautions during operation*

– *Do not place any container with liquid in it on the instrument. Any liquid entering the instrument may cause an electric shock or failure.*

– *If any smoke, offensive odor, or abnormal sound occurs, turn off the instrument immediately, disconnect the power plug from the outlet, and contact our local distributor or Tomey Corporation.*

– *When moving the measuring head and/or chin rest of the instrument, pay attention to the position of the patient's face, hands, and fingers. The patient may be injured by the moving section of the instrument.*

– *When supporting the patient's face with a hand, pay the utmost attention to the position of the hand or fingers and carefully operate the instrument. The hand or fingers may be caught between the head and forehead pad, resulting in injuries.*

– *Do not allow any person to place their hands or fingers in the clearance under the measuring head or the section under the chin rest. Their hands or fingers may be crushed and injured.*

– *Do not lean on the instrument or press on the instrument from the top. The instrument may fall, resulting in mechanical failure or injuries.*

– *Complete the measurement within the prescribed time and repetitions.*

– *Observe both the instrument and patient to ensure there are no problems.*

– *If a problem with the instrument or the patient occurs, take appropriate action such as stopping the machine to ensure the safety of the patient.*

– *Do not allow the patient to touch the instrument.*

– *Never touch the cutter in the printer, or you may be injured.*

– *Peel off the top sheet of chin paper and clean the forehead pad with a clean cloth before measuring the next patient. Clean the forehead pad and chin rest with a cloth dampened with alcohol as needed.*

■ *Precautions after operation*

– *Do not place any container with liquid in it on the instrument. any liquid entering the instrument may cause an electric shock or failure.*

– *Do not use organic solvents such as thinner, benzene, or acetone to clean the instrument. These solvents may cause fire or an electric shock, and may also corrode the resin or coating of the cover of the instrument.*

– *Hold the plug when disconnecting the power cord from the outlet to avoid applying excessive force on the cord. Pulling the cord may damage inner core wires, resulting in electric shock or fire.*

– *Disconnect the power cord when the instrument is not operated for a long period of time.*

– *Refer to "5.6 Storing" for instructions on storing the instrument.*

– *Clean the instrument appropriately at the end of operation to get ready for the next operation.*

– *Clean and neatly arrange the accessories and cables.*

– *If any smoke, offensive odor, or abnormal sound occurs, turn off the instrument immediately, disconnect the power plug from the outlet, and contact our local distributor or Tomey Corporation.*

■ ***If any instrument failure occurs, stop operation immediately, indicate the failure, and contact our local distributor to request repair.***

– *Never modify the instrument. Doing so may cause electric shock or failure of the instrument. The instrument contains high-voltage sections. Touching these sections will result in death or serious injuries.*

– *Disconnect the power cord from the outlet when replacing fuses. Otherwise you may get an electric shock, resulting in death or serious injuries.*

– *Use the power cord and fuses provided with the instrument or specified by Tomey to ensure safety. Also, do not use the accessories provided with the instrument for other equipment.*

– *When any instrument failure occurs, indicate the failure, and contact our local distributor to request inspection and repair. Do not attempt to repair the instrument yourself.*

– *Conduct regular inspections of the instrument and components.*

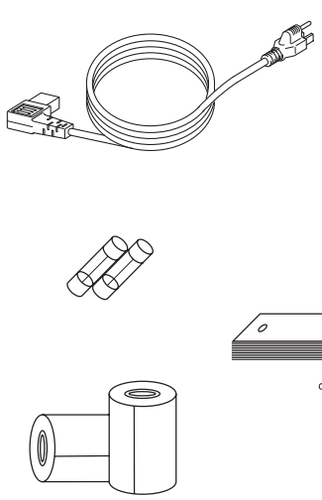
– *When the instrument is not used for 1 month or longer, refer to "5.3 Inspection" in this manual and check that the instrument is operating correctly and safely before starting operation.*

1.2 Checking contents of package

Open the package and check that the specified amount of the following items are included in the package and are not damaged. If any item is missing or damaged, contact our local distributor as soon as possible.

Note

- ***Keep the box and packing materials for use when moving or transporting the instrument.***
- ***When taking the instrument out of the box, pull the outer box upward and then remove the packing materials. Be careful not to lift the instrument up by directly holding the measuring head, chin rest, forehead pad, or joystick. The instrument may be damaged.***



- Main unit of NON-CONTACT TONOMETER FT-1000 1
- Power cord 1
- Fuses (2 fuses are installed in the main unit) .. 4
- Chin rest paper 1
- Pins for Chin rest paper 2
- Printer paper (One is already installed.) 3
- Dust cover 1
- INSTRUCTION MANUAL (this book) 1
- DATA Transfer Installation CD 1
- DATA Transfer startup guide 1

1.3 Glossary

[aIOP]:	Intraocular pressure adjusted according to the cornea thickness (CCT)
[mIOP]:	Measured intraocular pressure
[AVG]:	Average of measured intraocular pressure
[CCT]:	Central cornea thickness
[IOP]:	Intraocular pressure
[Temporary]:	Function to temporarily change the measuring condition(s)
[TOMEY Link]:	Digital medical record system to control the data measured with Tomey products
[DATA Transfer]:	System to output the measurement data from Tomey products to digital files
[Auto Measurement mode]:	Mode to automatically conduct alignment and measurement
[Auto Shot]:	Function to automatically conduct measurement when the sight in up/down/right/left/focus directions becomes optimal
[Auto Alignment]:	Function to automatically align the sight in up/down/right/left/ focus directions
[Auto Power Off]:	Function to automatically turn the LCD off, with only the power lamp flashing, when the instrument is not operated for the specified time (Auto Power Off mode). Touch any button to return to Normal mode.
[Quick mode]:	The measuring head retracts from the patient's eye after measurement is completed in Normal mode; however, in Quick mode, the next measurement can be conducted continuously without retracting the measuring head. This is effective when the sight of the patient is unstable and difficult to be aligned.
[Touch Alignment]:	Function to move the measuring head by touching the screen; used for rough alignment
[Touch panel]:	Allows you to make various settings and execute the touch alignment function by directly touching the screen.
[Manual Measurement mode]:	Mode to manually conduct alignment and measurement by operating the joystick.

1.4 Outline of operation

Note ■ *This instrument is designed to calculate the intraocular pressure. For more details regarding accuracy, precision, and clinical comparison of the IOP measurements to the Goldmann applanation tonometer please refer to Section 4.3 of the Instruction Manual.*

FT-1000 is an instrument used to measure the intraocular pressure of a patient's eye.
The patient this instrument is indicated for the measurement of intraocular pressure without contacting the eye to aid in the screening and diagnosis of glaucoma places their chin on the chin rest and looks into the sight-fixing lamp in the measurement window to fix their sight.
After the physician observes the patient's eye on the monitor screen and roughly aligns the measuring position, fine alignment and measurement is automatically conducted.
When the intraocular pressure cannot be measured automatically, align the measuring position with the joystick and press the measurement button to start measurement.
When measurement has started, air blows from the nozzle of the measurement window. When the cornea becomes flat due to blown air, corneal reflex light from the light source is received by the light receiving element. The instrument calculates the intraocular pressure according to the air pressure at this moment and shows the result on the monitor screen.
Touch the "PRINT" button to print out the measurement data.

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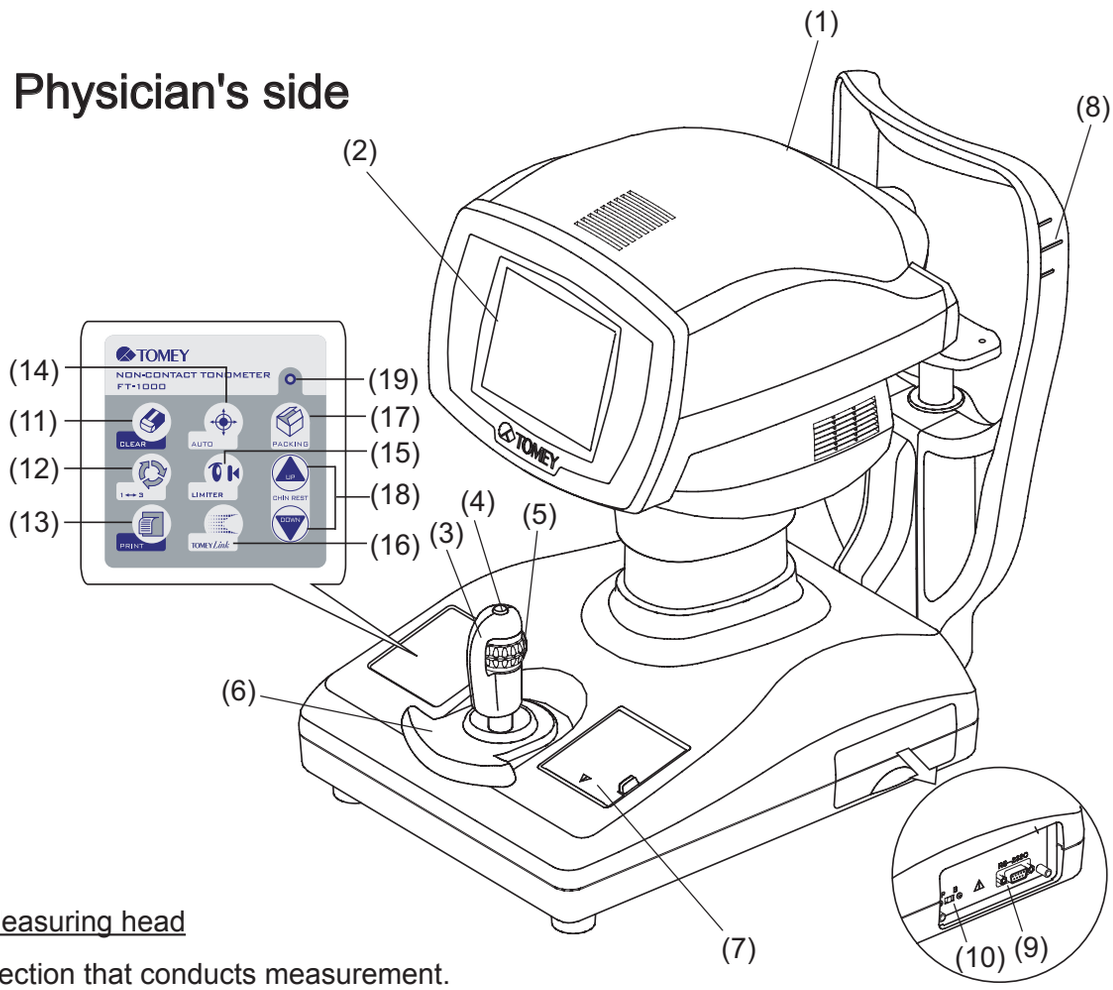
2. NAMES AND FUNCTIONS OF PARTS AND COMPONENTS

2.1 Physician's side



(1) Measuring head

Section that conducts measurement.

(2) Monitor / touch panel

Displays the measurement screen and various setting screens. Touch the touch panel buttons shown on the LCD to make various settings and operate the instrument.

(3) Joystick

Tilting the joystick to the right, left, back, and forth moves the measuring head to the right, left, forward, and backward for fine positioning.

(4) Measuring switch

Starts measurement.

(5) Up/down ring

Moves the measuring head up and down. Moving the ring up and down moves the measuring head for rough positioning. Turning the ring moves the head for fine positioning.

(6) Hand rest

Place your hand on the rest to operate the joystick. Sliding the rest forward, backward, to the right, and left moves the measuring head in the corresponding direction for rough positioning.

(7) Printer

Prints the measurement data.

(8) Eye level mark

Reference mark when aligning the height of the patient's eye

(9) RS-232C connector

Connection terminal to connect external equipment

(10) Service mode switch

This switch is reserved for use by serviceman performing maintenance work. Do not operate this switch.

(11) "CLEAR" button

Deletes the examination data.

(12) 1 <=> 3 button (select number of measurements)

Sets the number of times measurement is performed ("1" or "3") when Auto Shot is ON.

(13) "PRINT" button

Manually prints the measurement results.

(14) "AUTO" button

Manually switches the operation mode (AUTO or MANUAL).

(15) "LIMITER" button

Determines the stop position of the measuring head to prevent the nozzle from contacting the patient's eye.

(16) "TOMEY Link" button

Sends the measurement data to TOMEY Link or DATA Transfer.

(17) "PACKING" button

Pressing this button for 3 seconds moves the measuring head to the lowest position for packing (lower dead center).

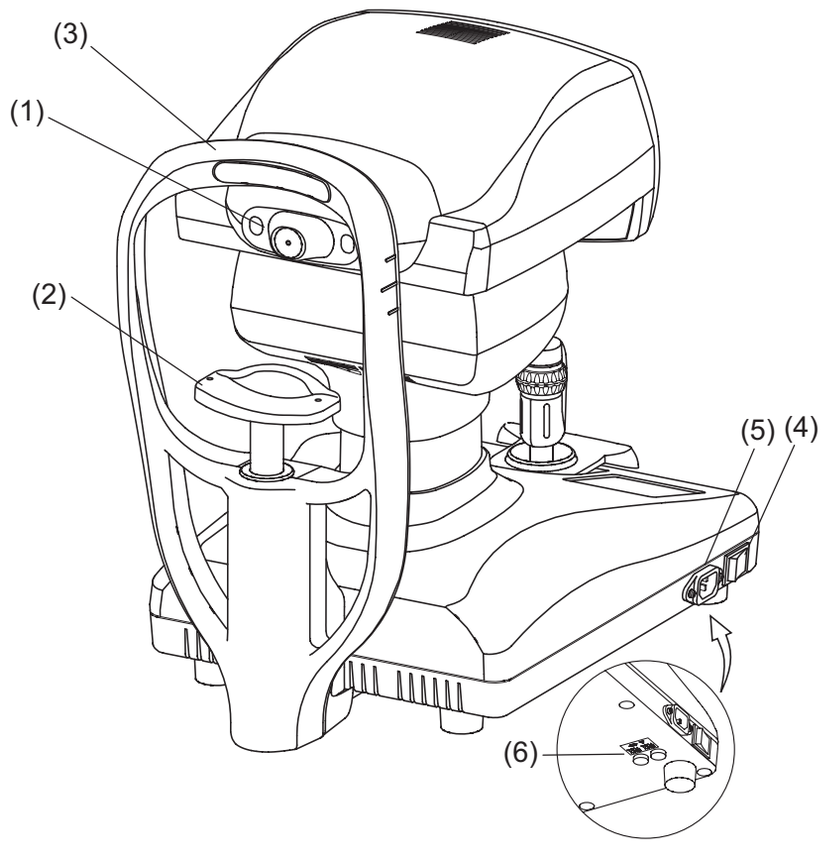
(18) "CHIN REST" button

Touching the UP and DOWN buttons moves the chin rest up and down respectively.

(19) Power lamp

Stays lit while the instrument is turned on.

2.2 Patient's side



(1) Measurement window

Blows air onto the patient's eye from the center nozzle.

(2) Chin rest

The patient places their chin on this rest.

(3) Forehead pad

The patient presses their forehead against this pad.

(4) Power switch

Press the [I] or [O] side to turn the instrument on or off respectively.

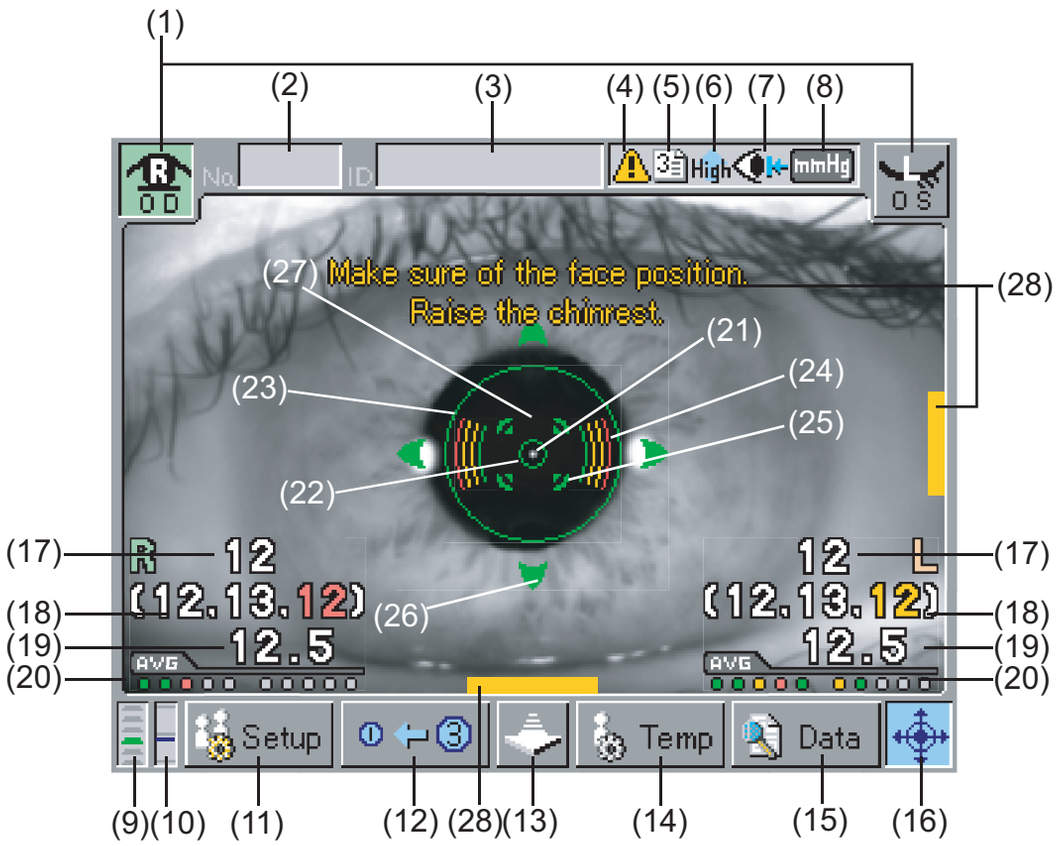
(5) Power connector

Connect the power cord here.

(6) Fuse holder

Insert the fuses here.

2.3 Measurement screen



(1) Eye display button [R]/[L]

Displays the right or left eye on which the measuring head is positioned, using the corresponding color. Touch this icon to move the measuring head when changing the eye to be examined.

(2) Examination number [No.]

Indicates the examination number. The number increases in increments of 1 whenever a new measurement is started.

(3) ID number [ID]

Displays an ID number when external communication is activated.

(4) Safety function cancellation

This mark appears when any safety function is disabled in the setting. Check the details of the setting and operate the instrument with the utmost cares.

(5) 3 data output

This marks appears when “3” is selected for the data output setting. Only the most reliable three data will be displayed on the screen, printed out, and output.

(6) High intraocular pressure measurement mode [High]

This mark appears when the instrument is in High Intraocular Pressure Measurement mode. The pressure can be measured up to 30 mmHg in Normal mode and from 25 - 60 mmHg in this mode.

(7) Limiter

This mark is shown in light blue when the limiter is activated; flashes red when not activated.

(8) Intraocular pressure unit [mmHg]/[hPa]

Displays the measurement unit of intraocular pressure.

(9) Chin rest height

Displays the current chin rest height according to the preset 6 levels.

(10) Measuring head height

Displays the current measuring head height according to the preset 11 levels.

(11) "Setup" button

Sets operation conditions for each function

(12) 1<=> 3 (number of measurements) button

Sets the number of times measurement is performed ("1" or "3") when Auto Shot is ON.

(13) Measuring head retract button

Retracts the measuring head while the button is pressed.

(14) "Temp" (temporary setting) button

Sets temporary measurement conditions for a specific examination.

(15) "Data" button

Recalls the data saved in the memory.

(16) "AUTO" button

Switches automatic measurement and manual measurement.

(17) Latest intraocular pressure

Displays the latest measurement data of intraocular pressure.

(18) Measured intraocular pressure

Displays the latest measurement data, with the most recent on the left.

(19) Average intraocular pressure

Displays the average of the measured values.

(20) Stored data

The dot corresponding to the number of the stored data turns green, yellow, or red according to reliability. "Green" is regarded as the most reliable and "red" as the least reliable.

(21) Target center-point

Indicates the position of the cornea vertex.

(22) Target ring

Index reference used when aligning the patient's eye position for measurement. When Touch Alignment is ON, the measuring head moves toward the eye while this icon is pressed.

(23) Alignment ring

Indicates the effective range of Auto Alignment. This also shows the area on the cornea to which air is blown. Be sure that no part of the eyelid or eyelashes are within this range to ensure precise measurement.

(24) Focus indicator

Displays the distance between the measuring head and the patient's eye. When bars appear horizontally, the measuring head is too far from the eye. When bars appear vertically, the measuring head is too close to the eye.

(25) Auto Shot mark

Displayed when Auto Shot is ON.

(26) Auto Alignment mark

Displayed when Auto Alignment is ON.

(27) Alignment OK mark

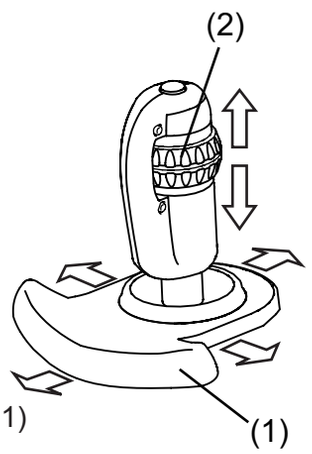
Displayed when alignment conditions are optimal.

(28) Measuring head position limit

Displayed when the measuring head is near the limit of the operation range. The bar appears on the top, bottom, right, or left on the screen according to the head position, as well as the countermeasures are specified.

2.4 Operation of the joystick

There are two types of operations - rough operation for moving the measuring head into rough position and fine operation for finely adjusting the position of the measuring head. The measurement button is located on the top of the joystick.



(Fig. 1)

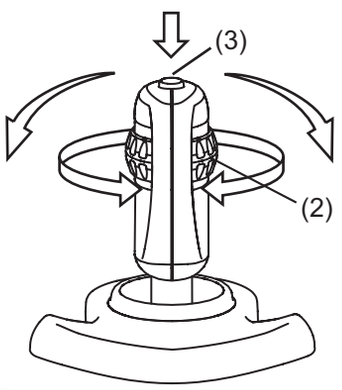
<Rough operation>

Forward, backward, right, and left

Slide the hand rest (1) in the direction the measuring head is to be moved. The further you slide the rest, the faster the head moves.

Up and down

Slide the up/down ring (2) in the direction the measuring head is to be moved.



(Fig. 2)

<Fine operation>

Forward, backward, right, and left

Tilt the joystick in the direction the measuring head is to be moved.

Up and down

Turn the up/down ring (2).

Clockwise … Raises the measuring head.

Counterclockwise … Lowers the measuring head.

<Measurement start>

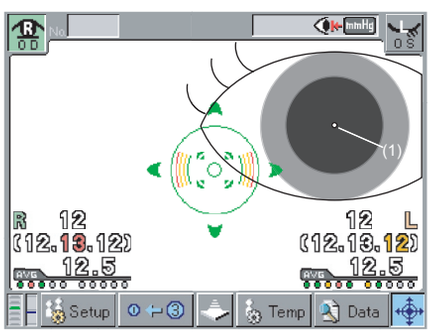
Press the measurement button (3) to start the measurement.

2.5 Touch Alignment

Touch Alignment is a function for alignment using the touch panel. Touch Alignment needs to be enabled before it can be used (refer to "3.7.1 Initial setup"). This is available in all measurement modes.

Note

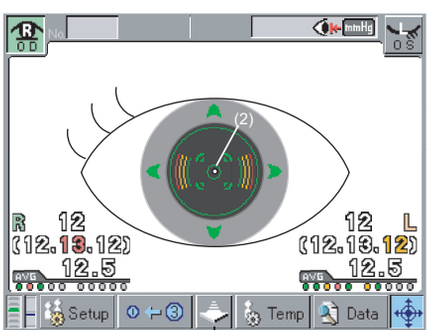
- ***Touch Alignment is used for rough positioning. Use the joystick for fine positioning.***
- ***Do not press hard against the touch panel or with a sharp edged object. Otherwise the panel may be damaged.***
- ***When moving an element using Touch Alignment, touch the panel and release your finger immediately. Do not press the panel continuously.***



(Fig. 1)

Up/down/right/left

When directly touching the panel, the measurement head moves so the touched point moves to the center. Touch the point where the center of the pupil (1) is shown. The pupil center (1) moves to the center of the screen.



(Fig. 2)

Forward/backward (focus)

Keep touching the target ring (2) in the center of the screen move the measuring head forward to the patient's eye and focus the image. The measuring head stops when you release your finger from the screen.

Press the measuring head retract button (3) to retract the measuring head.

2.6 RS-232C connector

WARNING

- *When operating this instrument connected to other devices, only use devices that comply with IEC60601-1 or that comply with IEC60950-1 and whose power source is isolated with an isolation transformer. Furthermore, all devices should be configured to comply with the standard IEC60601-1 ME system. Anyone who connects any additional device to the RS-232C connector will be considered a person configuring a medical system, and is therefore responsible for complying with the requirements of an IEC60601-1 ME system. Contact our local distributor or Tomey Corporation if you have any questions.*

Note

- *Turn the instrument off before changing the connection, which may otherwise cause failure or malfunction of the instrument.*
- *Only use the specified cable, which may otherwise cause failure or malfunction of the instrument.*
- *The network system "TOMEY Link" (available separately) or examination data retrieval software "DATA Transfer" (provided with the instrument) is required for data communication with the instrument.*
- *Refer to the corresponding instruction manual for installation, settings, and operation of TOMEY Link and DATA Transfer.*
- *Special settings are required to communicate with TOMEY Link and DATA Transfer. Refer to "3.7.1 d) Output Setup" and make appropriate settings.*

The RS-232C connector is a terminal used to export measurement data to an external device. When connecting a computer running TOMEY Link or DATA Transfer, use the following cable and adapter.

Connection cable:	RS-232C cable
	(D-Sub 9 pin: Interlink or cross)
Adapter:	D-Sub 9 pin (male) - D-Sub 9 pin (male)

TOMEY Link LAN adapter: When connecting LA-100 (available separately), refer to the LA-100 Instruction Manual.
Contact our local distributor or Tomey Corporation for detailed information.

2.7 Symbols used for marking

Refer to instruction manual.

Caution

“ON” (power)

“OFF” (power)

Type B applied part

Grounding (earth)

Dangerous voltage

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3. OPERATION PROCEDURES

3.1 Safety precautions

3.1.1 Precautions for installing the instrument

- *Install the instrument in a location free of water or chemicals. Any water or chemicals entering the instrument may cause an electric shock or failure.*
- *Do not install the instrument in a place where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the instrument and ignite.*

- *Do not hold the measuring head, chin rest, forehead pad, or joystick when lifting the instrument. These components are detachable and the instrument may drop, resulting in injuries.*
- *Install the instrument in a location not subject to direct sunlight, high temperature and humidity, or air with significant dust, salt, and/or sulfur content. These may cause failure or malfunction of the instrument.*
- *Install the instrument in a level and stable location free of vibration or mechanical impact to ensure correct measurement, and prevent the instrument from falling or being dropped, resulting in fire or fatal accidents.*

3.1.2 Precautions for connecting the power cord

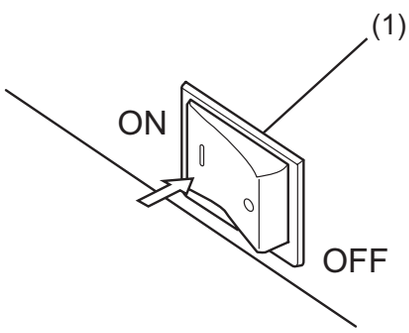
- *Connect the power plug to a grounded 3P-outlet. Otherwise, a short circuit due to failure of the instrument may result in an electric shock.*
- *Do not place any heavy object on the power cord or squash the power cord. This may cause fire or an electric shock.*
- *Completely insert the power plug into the outlet. Faulty contact, allowing any metal to contact exposed plug terminals, or dust accumulated on exposed plug terminals may result in fire or an electric shock.*

- *Check the frequency, voltage, and allowable current (or power consumption) of the power source. Operating the instrument connected to an inappropriate power source may cause fire or an electric shock.*

3.2 Preparation for measurement

3.2.1 Starting

■ ***Immediately after starting the instrument, the measuring head moves and an air blow test is performed. Do not allow the patient to place their face on the chin rest until the air blow test is complete. Otherwise the patient may be injured.***



Turn on the power switch (1).

- The power lamp lights and the title screen appears. The measuring head also moves to its initial position.
- The air blow test then automatically starts (refer to "5.3 Inspection").
- If no problem is found during the test, the measurement screen appears.

3.2.2 Setting

Refer to "3.7 Settings" and set measurement conditions.

3.2.3 Checking the printer paper

■ ***Never touch the cutter in the printer, or you may be injured.***

Remove the printer cover and check that the paper is installed correctly.

- Refer to "5.5.1 Printer paper" for details on how to remove the cover, etc.

3.3 Measurement

Note

■ *This instrument is designed to calculate the intraocular pressure. For more details regarding accuracy, precision, and clinical comparison of the IOP measurements to the Goldmann applanation tonometer please refer to Section 4.3 of the Instruction Manual.*

■ *When the measured value is doubtful as described below, review the examination result by re-measurement with this instrument or using the Goldmann applanation tonometer.*

- *The error code (e or E) is added to the measured value.(The value turns yellow or red on the screen.)*

Displayed colors

Green : Measurement data is within the accepted range, and does not affect intraocular pressure data.

Yellow : Measurement data is more or less within the accepted range, and may have some effect on intraocular pressure data.

Red : Measurement data is outside the acceptable range, and may have some effect on intraocular pressure data.

(If the color indicator light is yellow or red, the measurement should be retaken.)

- *The difference between the value measured on the right eye and that on the left eye is too large.*
- *The displayed intraocular pressure largely deviates from the standard value.*

■ *For the reason of its measurement principle, a non-contact tonometer tends to be influenced by pulse waves, breathing, eyelashes, and others. Therefore, be sure to obtain an average value from 3 or more times of measurements under the condition that the patient's eyes are fully opened.*

3.3.1 Precautions

■ *Do not use this instrument for eyes with weak corneas due to disease or surgery. Doing so may result in complications or damage to the cornea.*

■ *What is the weak corneas?*

Example : Corneal ablation eye, corneal transplantation eye, Refraction correction eyes such as LASIK, Corneal transplantation eye, Vitreous body eye, Diffuse punctuate keratopathy, Bullous keratopathy, Aphakic eye, etc.

■ *Explain the measurement procedure to the patient to avoid surprise when air is suddenly blown onto their eye.*

Tell the patient to remove their eyeglasses or contact lens and explain the measurement procedure before starting the measurement.

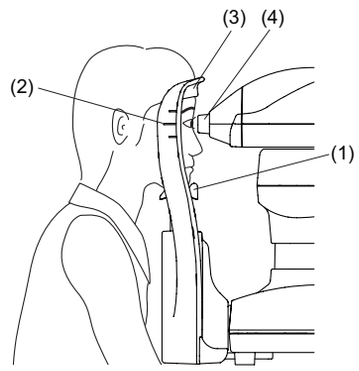
3.3.2 Patient's eye height adjustment

■ *When moving the measuring head and/or chin rest of the instrument, pay attention to the position of the patient's face, hands, and fingers. The patient may be injured by the moving section of the instrument.*

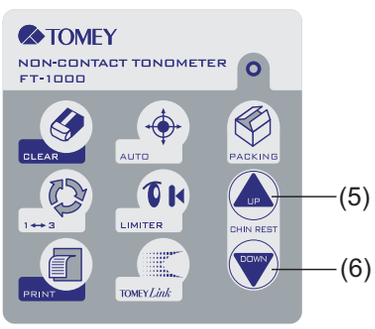
■ *The chin rest paper is provided to keep the chin rest clean. Use this paper for the chin rest as well as the patient to use this instrument comfortably.*

■ *Peel off the top sheet of chin rest paper and clean the forehead pad and measurement window with a cloth dampened with alcohol before measuring the next patient.*

■ *If the measurement window is contaminated with tears, etc., clean the window referring to "5.4 Routine maintenance." Contamination on the window may affect measurements.*



(Fig. 1)

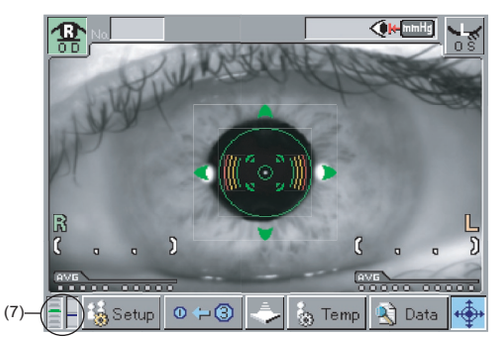


(Fig. 2)

1) Have the patient place their face on the chin rest (1). Adjust the chin rest height so that the height of the corner of the eye is aligned with eye level mark (2).

   – Touch the "CHIN REST UP" button (5) to raise the chin rest; "CHIN REST DOWN" button (6) to lower the chin rest.

   – The positions of the chin rest and measuring head can be checked by the height mark (7) in the lower left corner of the measurement window. The right and left indicators indicate the head height and chin rest height respectively. When the head height indicator is positioned in the center of the mark, the measurement window (4) and the eye level mark (2) are aligned at the same height.

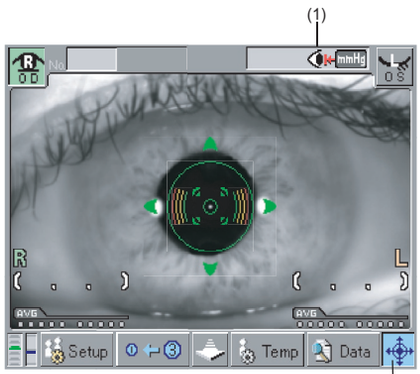


(Fig. 3)

2) When the patient's eye height is determined, lightly push the patient's face against the forehead pad (3) to secure the patient's position.

3.3.3 Nozzle limiter setting

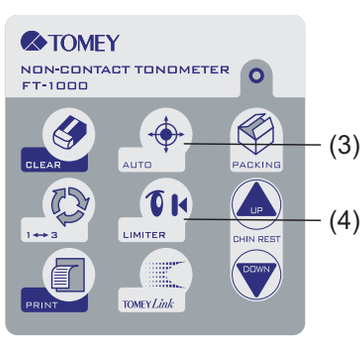
- ***Set the nozzle limiter before each examination to ensure the safety of the patient. The nozzle may directly contact the patient, resulting in injuries.***
- ***Check the distance between the patient's eyes and the nozzle from the side so that the nozzle does not contact the patient while setting the nozzle limiter.***
- ***Disable Auto Measurement when setting the nozzle limiter. Setting the nozzle limiter with Auto Measurement enabled may start measurement unintentionally during this setting.***



(Fig. 1)

Auto Measurement ON Auto Measurement OFF

(Fig. 2)



(Fig. 3)

1) Check that the limiter mark (1) in the upper right of the screen indicates that the nozzle limiter is OFF. If ON, touch the "LIMITER" button to turn it OFF.

   ON: Light blue

   OFF: Flashing red

2) Touch the "AUTO" button (2) in the lower right of the screen or press the "AUTO" button (3) on the main unit to disable Auto Measurement.

3) Use Touch Alignment or the joystick to slowly move the nozzle toward the cornea, checking the distance between the eye and the nozzle from the side.

4) When the nozzle reaches a point 7 - 8 mm from the cornea, touch the "LIMITER" button (4). (Measurement is conducted at a point where the distance between the nozzle and the cornea is 11 mm.)

5) Check that the limiter mark (1) in the upper right of the screen indicates that the nozzle limiter is ON. Move the measuring head back and forth to check that the head stops at the set limiter position.

6) Touch the "AUTO" button (2) in the lower right of the screen or press (3) on the main unit to enable Auto Measurement, and start measurement.

3.3.4 Alignment

Caution

- *When supporting the patient's face with a hand, pay the utmost attention to the position of the hand or fingers and carefully operate the instrument. The hand or fingers may be caught between the head and forehead pad, resulting in injuries.*
- *Do not allow any person to place their hands or fingers in the clearance under the measuring head or the section under the chin rest. Their hands or fingers may be crushed and injured.*

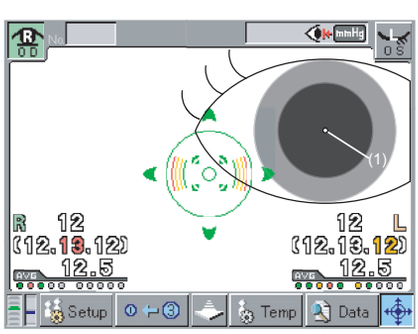
Note

- *The eyelid and/or eyelash covering the automatic alignment ring during measurement may affect measurement results. Ask the patient to open their eyes wide or have the physician lightly hold the patient's upper eyelid with their fingers.*
- *Auto Alignment may not be effective when the patient blinks frequently during measurement. Ask the patient to stop blinking during measurement.*
- *Ask the patient to look into the fixation lamp in the measurement window. If the patient looks in a different direction or moves, the measurement may not be correctly conducted.*

<Positioning by Touch Alignment>

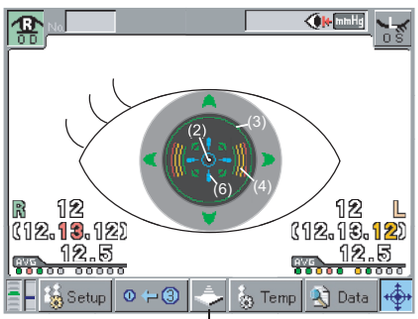
Note

- *When moving an element using the touch panel, touch the panel and release your finger immediately without pressing the panel continuously.*



(Fig. 1)

1) Use Touch Alignment or the joystick to position the patient's eye on the screen.



(Fig. 2)

2) Lightly touch the cornea center (1) on the screen.

   – The measuring head moves so the patient's eye is positioned in the center of the screen. When the target center-point (2) in the center of the cornea enters the alignment ring (3), focusing in the horizantial vertical directions automatically starts.

3) When the measuring head is on the physician's side and the focus indicator (4) does not appear, press the center of the screen.

   – Pressing the screen moves the measuring head toward the patient and the focus indicator (4) appears.

   – Press the measuring head retract button (5) to retract the measuring head.

4) When the focus indicator (4) appears on the screen, focusing in the cross direction automatically starts.

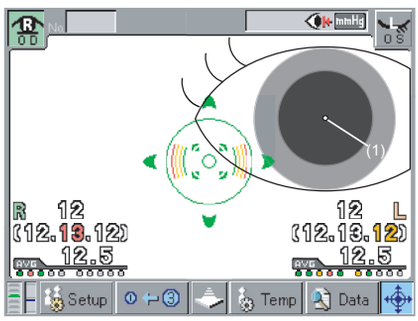
   – When alignment conditions are optimal, the alignment OK mark (6) is displayed.

<Positioning by the joystick>

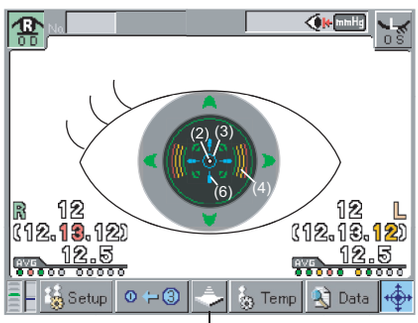
Note

■ *This instrument is designed to perform measurement in Auto mode to ensure higher accuracy through standard operation. However, Auto Alignment may not be particularly effective when insufficient light is reflected due to deformation or inflammation of the cornea. In this case, conduct measurement manually.*

■ *The reflection in the center of the cornea may not be clearly viewed when the deformation and/or inflammation of the cornea is severe. In this case, an error may occur even in Manual mode.*



(Fig. 1)



(Fig. 2)

1) Operate the joystick so the center of the cornea (1) enters the target ring (3). The target center-point (2) is displayed.

2) Move the joystick back and forth to move the measuring head so the focus indicator (4) on the screen becomes small.

   – When the focus indicator (4) is shown horizontally, the measuring head is too far from the eye; when the focus indicator is shown vertically, the measuring head is too close to the eye.

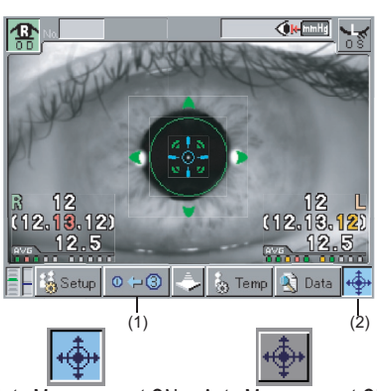
   – When alignment conditions are optimal, the alignment OK mark (6) is displayed.

3) When the focus indicator (4) does not appear, align the focus with the target center-point (2) or the iris.

3.3.5 Measuring intraocular pressure

Note ■ ***Conduct measurement manually only when unavoidable, even when the sight of the patient is unstable. It is difficult to ensure accurate alignment in manual measurement, resulting in frequent measurement errors.***

<When Auto Measurement is ON>

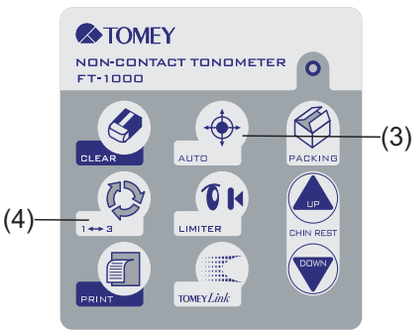


(Fig. 1)

When alignment is complete, air blows from the nozzle and measurement starts.

Auto Measurement will turn OFF when one eye has been measured three times if the number of measurements (1) shown is "3"; once if "1" is shown on the screen.

The setting of the measurement times can be changed by the measurement times switch button at the bottom of the screen (1) or on the main unit (4).



(Fig. 2)

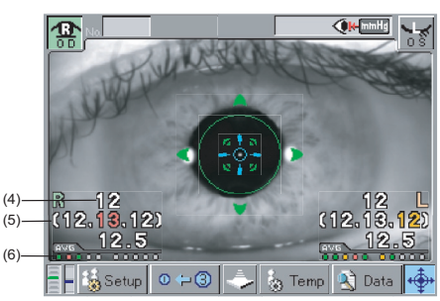
After measurement is complete, the number of measurements is incremented by one every time Auto Measurement is enabled by touching the "AUTO" button (2) on the screen or pressing (3) on the main unit.

Auto Measurement will turn OFF when any additional measurements are completed.

<When Auto Measurement is OFF>

After alignment is complete, press the measurement switch on the joystick. Air blows from the nozzle and measurement starts.

<Intraocular pressure measurement screen>



The latest measurements (4) appear in the lower left of the screen. Three new measurements (5) appear under the latest data.

The values are shown in white, yellow, or red in order of higher reliability.

Dots (6) under the value represent the stored data. The dot color changes from the left as the number of measurements increase. Green, yellow, and red show the reliability of the measurement, with green regarded as the most reliable result. These colors are equivalent to "A, B, C," "e," and "E" on the reliability shown on the printout.

Displayed colors

Green : Measurement data is within the accepted range, and does not affect intraocular pressure data.

Yellow : Measurement data is more or less within the accepted range, and may have some effect on intraocular pressure data.

Red : Measurement data is outside the acceptable range, and may have some effect on intraocular pressure data.

(If the color indicator light is yellow or red, the measurement should be retaken.)

The intraocular pressure data for 10 measurements per eye can be saved. When the number of measurements exceeds this limit, the oldest data will be deleted accordingly.

<When measurement is difficult>

When measurement cannot be conducted or an error occurs in the measurement result, check the following and take appropriate action.

Blinking or nystagmus

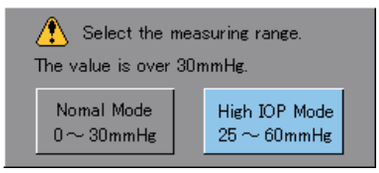
Ask the patient to look into the lamp to steady their eye and start measurement again. If the eye of the patient frequently moves due to nystagmus, etc. and Auto Shot is disabled, press the switch when the target center-point is visible (manual measurement).

Eyelid or eyelash is on the alignment ring

Ask the patient to open their eyes wide or have the physician lightly hold the patient's upper eyelid with their fingers, and conduct measurement again.

3.3.6 Popup window for selecting the measurement range

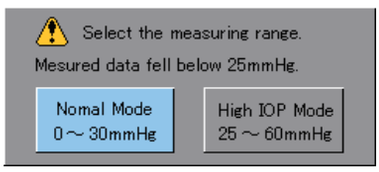
<Measurement in Normal mode>



(Fig. 1)

When “OVER” is measured twice consecutively, the popup window for selecting the measurement range (Fig.1) appears. Select the measurement range.

<Measurement in High IOP mode>

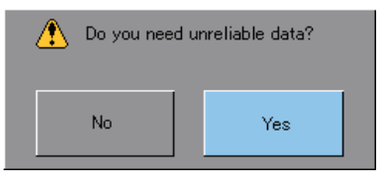


(Fig. 2)

When “UNDER” is measured twice consecutively, the popup window for selecting the measurement range (Fig.2) appears. Select the measurement range.

3.3.7 Popup window for loading low reliable data

<When loading of low reliable data is disabled>



(Fig. 1)

When the check-eye error is detected twice consecutively, the popup window for loading low reliable data (Fig.1) appears. Select whether to load low reliable data.

<When loading of low reliable data is enabled>

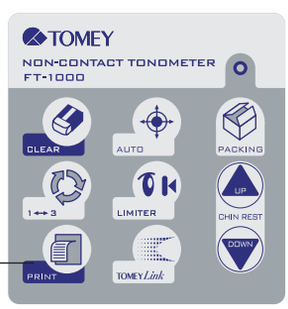
The popup window for loading low reliable data does not appear.

3.4 Printout

3.4.1 Printing procedure

Note

- ***Check that the paper roll is set in the built-in printer (refer to "5.5.1 Printer paper").***
- ***When the next measurement is conducted after printing, the measured data is automatically deleted and the examination number increases by one.***
- ***The printer in this instrument is thermosensitive. This means the descriptions printed on the paper will fade over time. Make a copy when storing the measurement data for a long time.***



(1)

After the measurement, touch the "PRINT" button to print the data.

If Auto Print is ON, the measurement data is automatically printed when both eyes have been correctly measured the specified number of times in Auto Shot mode. However, the data is not automatically printed if any additional measurements are required, or the instrument considers an additional measurement to be attempted when:

- The measurement switch of the joystick is used for measurement.
- Valid data is not obtained within the specified number of measurements due to errors.

Refer to "3.7.1 Initial setup" for Auto Print settings.

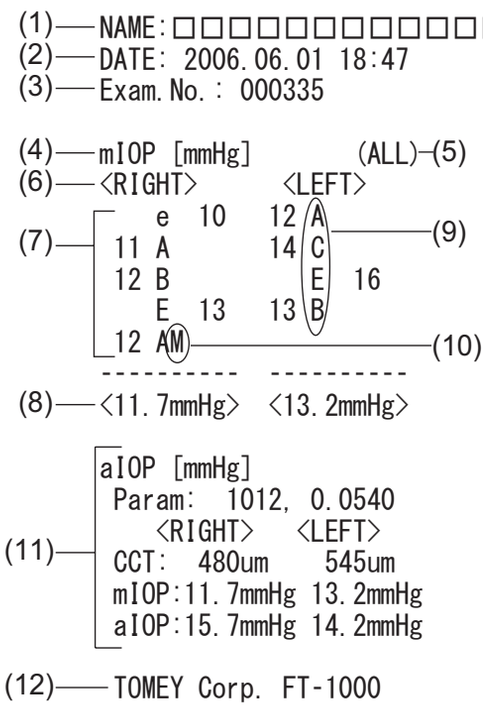
3.4.2 Printing format

The contents to be printed can be selected. Set the Print Form settings on the Output Setup screen. Refer to "3.7.1 Initial setup" for details.

Printing item (* indicates initial settings upon delivery.)

Item	Descriptions	
Date/Time	Enable *	Prints the date and time.
	Disable	Does not print the date and time.
Date Form	Y, M, D *	Shows the year, month, and date in this order.
	M, D, Y	Shows the month, date, and year in this order.
	D, M, Y	Shows the date, month, and year in this order.
Patient ID	Enable *	Prints the examination number (Patient ID).
	Disable	Does not print the examination number.
Name	Enable *	Prints the patient's name field.
	Disable	Does not print the patient's name.
IOP Data	All *	Prints all the data in the memory.
	3	Prints the most reliable three data.
	AVG	Prints only the average value.
IOP Reliability	Enable *	Prints the reliability "A," "B," or "C."
	Disable	Does not print the reliability.
Product Name	Enable *	Prints the instrument name (FT-1000).
	Disable	Does not print the instrument name.
Line Space	Normal *	Prints with normal line spacing.
	Narrow	Prints with narrower line spacing.
e, E data	Enable *	Prints all data.
	Disable	Does not print the data of which reliability is “e” and “E.” (If only “e” and “E” data exist, all data will be printed out.)

<Example printout>



(1) Patient's name field

(2) Measurement date and time

(3) Examination number

When COM (external communication) is ON, the patient ID is shown.

(4) Unit of intraocular pressure

(5) Printing format (ALL, 3, or AVG)

(6) Measured eye

(7) Measured intraocular pressure

(8) Average value

(9) Reliability

The reliability of the measurement is indicated using three ranks: A, B, or C. "e" or "E" indicates unreliable data. In this case, the measured value is printed to the right of the reliability code.

(10) Manual measurement

Provided only when the central cornea thickness and intraocular pressure correction expression is entered (refer to “3.5.2 Adjusting the measurement data”).

(11) Correction of intraocular pressure

(12) Product name

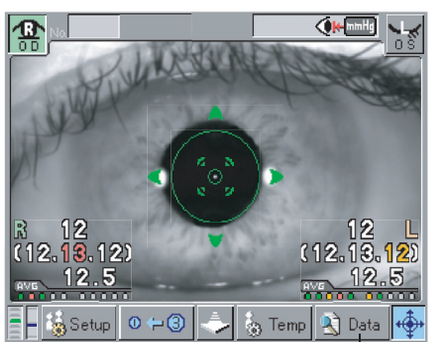
3.5 Displaying data in the memory

3.5.1 Viewing the measurement data

Recall the measurement data stored in the memory on the monitor.

Note

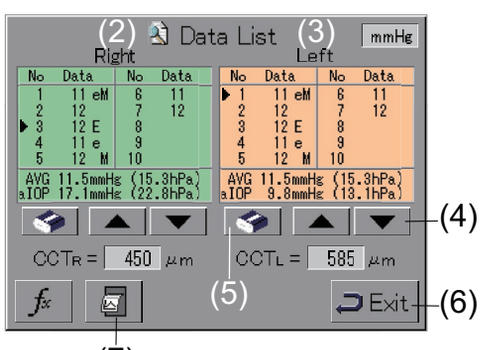
- ***Touch the "CLEAR" button to delete all data stored in the memory.***
- ***When the next measurement is conducted after printing the measurement data, the printed data is deleted from the memory.***



(Fig. 1)

1) Touch the "Data" button (1) on the touch panel. The Data List screen (Fig. 2) opens.

2) The measurement data of the right eye (2) and left eye (3) is displayed. When no corresponding data is saved in the memory, "NO VALUE" is displayed.



(Fig. 2)

3) When selecting only the necessary data, use the "UP" and "DOWN" buttons (4) to select the unnecessary data to be deleted and touch the eraser button (5).

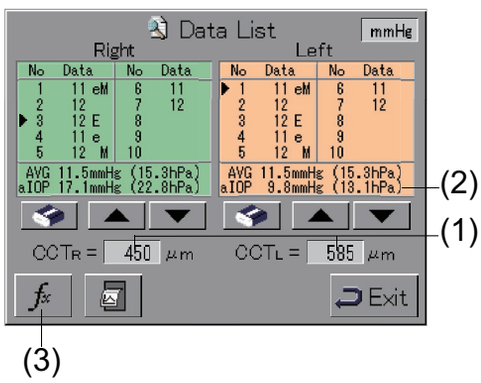
   – The average value will be recalculated after the data is deleted.

4) Touch the "Exit" button (6) to return to the previous screen (Fig. 1).

5) Touch the internal data printout button (7) to print the internal data useful for locating the cause of defective data. Report the details of the problem during measurement to our local distributor or Tomey Corporation using the printout of the internal data.

3.5.2 Adjusting the measurement data

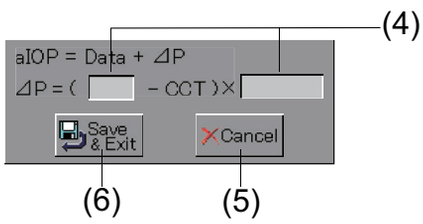
Adjust the measurement data stored in the memory according to the central corneal thickness (CCT).



(Fig. 1)

1) Touch the central corneal thickness field (CCTR or CCTL) of the data to be adjusted (1). The keypad appears. Enter the measured central corneal thickness.

2) The intraocular pressure adjusted according to the central corneal thickness is shown in the "aIOP" field (2).



(Fig. 2)

3) Touch the "fx" button (3). The correction coefficient entry screen (Fig. 2) appears.

4) Enter the coefficient for the intraocular pressure correction expression in the same manner as step (1). Refer to "4. TECHNICAL INFORMATION" for the correction expression.

5) Touch the "Cancel" button (5) to cancel the entered coefficient and return to the previous screen (Fig. 1).

6) Touch the "Save & Exit" button (6) to save the entered coefficient and return to the previous screen (Fig. 1). The adjusted intraocular pressure is displayed.

Caution

■ *This instrument provides capability to adjust intraocular pressure (IOP) based on central corneal thickness (CCT) and regression parameters from equation describing the relationship of CCT to IOP. Please note, however, no particular set of adjustment parameters have been studied or validated in the development of the device.*

3.6 Data communication

Note

- *The network system "TOMEY Link" (available separately) or examination data retrieval software "DATA Transfer" (provided with the instrument) is required for data communication with the instrument.*
- *Refer to the corresponding instruction manual for settings for TOMEY Link and DATA Transfer.*
- *Special settings are required to communicate with TOMEY Link and DATA Transfer. Refer to "3.7.1 d) Output Setup" and make appropriate settings.*

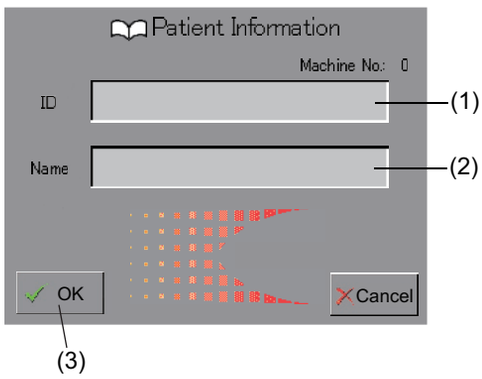
3.6.1 Entering the ID and patient's name

Note

- *It is recommended to enter the ID for data communication.*

  The data can be sent without the ID entered. However, it may not be possible to locate a patient's data according to the examination data output from DATA Transfer. If the data is sent without the ID entered, check the examination data immediately after it is sent, and move and save the data file in the appropriate location.

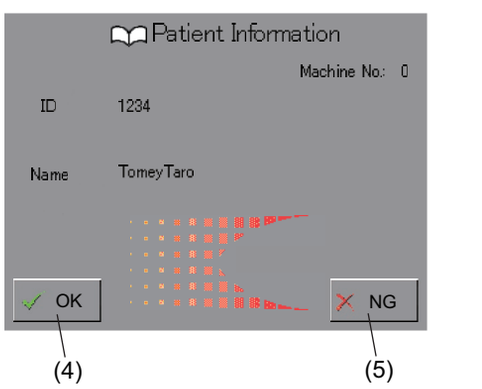
  In addition, all data sent to TOMEY Link without the ID is regarded as the information of one patient. Be extremely careful not to misidentify the data.
- *The ID or patient's name cannot be entered after examination. Be sure to enter these before examination.*



(Fig. 1)

1) When COM (external communication) on the Output Setup screen is ON, the Patient Information screen (Fig. 1) appears after the operations listed below. Enter the ID and/or patient's name as needed.

- Immediately after starting the instrument
- Immediately after touching the "CLEAR" button
- Immediately after sending the measurement data
- Immediately after enabling the COM (external communication) setting



(Fig. 2)

2) Touch the ID field (1) or name field (2). The character keypad appears. Enter the ID and/or patient's name as needed. Touching the "OK" button (3) goes to the Patient Information screen (Fig. 2). When you do not need to enter the ID or patient's name, simply touch the "OK" button (3).

3) Check the ID and/or patient's name displayed on the screen and touch the "OK" button (4). The measurement screen appears and the entered ID is displayed in the ID field.

   If you touch the "NG" button (5), the received patient data is discarded and the screen returns to the Patient Information screen (Fig. 1).

3.6.2 Retrieving patient data

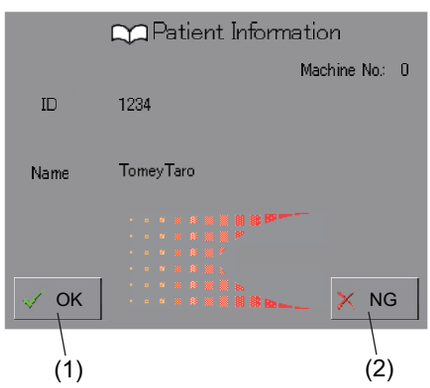
Note

- ***The network system "TOMEY Link" (available separately) is required to use the patient data inquiry function. You cannot make patient data queries using the "DATA Transfer" supplied with the instrument.***
- ***Only the last 14 digits of the ID are shown in the ID field on the measurement screen. Be sure to check that the ID is correct on the Patient Information screen.***

1) The Patient Information screen allows you to load the ID entered by DATA Transfer (examination data retrieval software) to the instrument. When you wish to enter the ID via a barcode or electromagnetic card, connect the appropriate reading device to the computer with DATA Transfer installed.

   The patient data query function of TOMEY Link also allows you to display the entered ID and corresponding patient's name registered in TOMEY Link on the instrument.

   Refer to the TOMEY Link and DATA Transfer instruction manuals for details.



2) When retrieving patient data from TOMEY Link or DATA Transfer, the Patient Information screen appears, displaying the ID and patient's name (the data can also be retrieved in Auto Power Off mode).

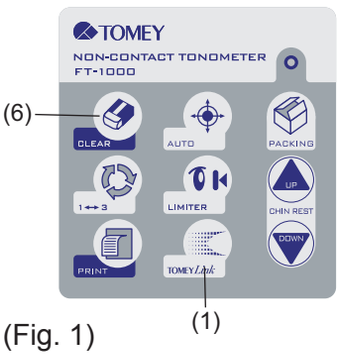
   Check the ID and patient's name displayed on the screen and touch the "OK" button (1). The measurement screen appears and the entered ID is displayed in the examination number field.

   Touch the "NG" button (2) to discard the retrieved patient data and return to the Patient Information screen.

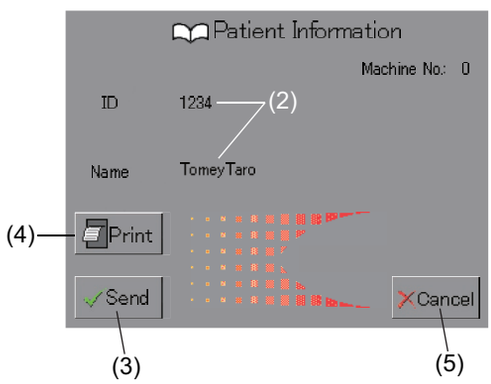
3.6.3 Sending examination data

Note

- *The network system "TOMEY Link" (available separately) or examination data retrieval software "DATA Transfer" (provided with the instrument) is required for data communication with the instrument.*
- *Refer to the corresponding instruction manual for settings for TOMEY Link and DATA Transfer.*
- *Special settings are required to communicate with TOMEY Link and DATA Transfer. Refer to "3.7.1 d) Output Setup" and make appropriate settings.*
- *Check that the ID is correct before sending the data. If the ID is incorrect, the data may be processed as the data of another patient.*
- *It is recommended to enter the ID for data communication. The data can be sent without the ID entered. However, it may not be possible to locate a patient's data according to the examination data output from DATA Transfer. If the data is sent without the ID entered, check the examination data immediately after it is sent, and move and save the data file in the appropriate location. In addition, all data sent to TOMEY Link without the ID is regarded as the information of one patient. Be extremely careful not to misidentify the data.*



(Fig. 1)



(Fig. 2)

1) Touch the TOMEY Link button (1) after measurement to recall the Patient Information screen (Fig. 2). When Auto Print is ON, this screen appears automatically after printing is complete.

   Touching the "CLEAR" button (6) deletes the patient data and measurement data, and returns you to the Patient Information screen.

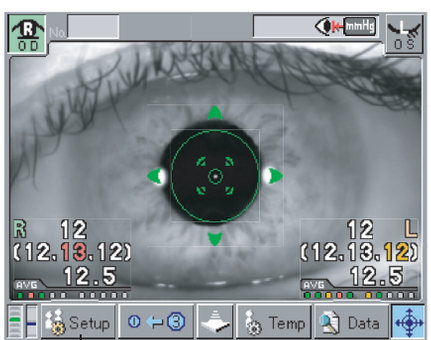
2) Touch the "Print" button (4) to print the measurement data. When sending the measurement data, check the patient data (2) and touch the "Send" button (3). Touching the "Cancel" button (5) returns you to the measurement screen, retaining the ID and measurement data.

3.7 Settings

3.7.1 Initial setup (Setup)

The operation conditions can be set here. Any settings made here are effective unless directly changed.

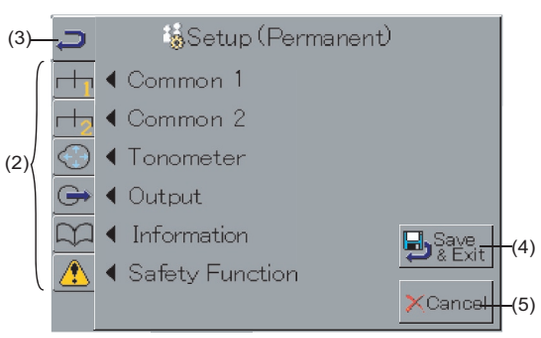
Note ■ ***After changing the settings, be sure to touch the "Save & Exit" button to exit the screen. If the "Cancel" button is touched, no changes are made to the settings and the conditions previously set are still effective.***



(Fig. 1)

Touch the "Setup" button (1) on the touch panel to display the Setup (Permanent) screen (Fig. 2). Touch one of the icons (2) listed on the left of the screen to select the setting item and set conditions as needed on the corresponding screen.

Touch the return icon (3) after setting is complete to return to the previous screen. Touch the "Save & Exit" button (4) to save the new settings and return to the measurement screen (Fig. 1). Touching the "Cancel" button returns you to the measurement screen without changing any settings.

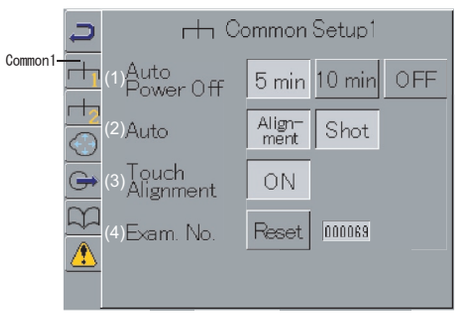


(Fig. 2)

- Common 1: Related to operation conditions
- Common 2: Time setting
- Tonometer: Related to intraocular pressure measuring conditions
- Output: Related to data output
- Information: Product information
- Safety function: Related to the safety functions

a) Common 1

Set items related to operation conditions.



(1) Auto Power Off

5 min: Enters Auto Power Off mode when the instrument is not operated for 5 minutes.

10 min: Enters Auto Power Off mode when the instrument is not operated for 10 minutes.

OFF: Does not enter Auto Power Off mode.

(2) Auto

Alignment: Disables the Auto Measurement function.

Shot: Enables the Auto Measurement function.

(3) Touch Alignment

ON: Enables the Touch Alignment function.

OFF: Disables the Touch Alignment function.

(4) Exam No.

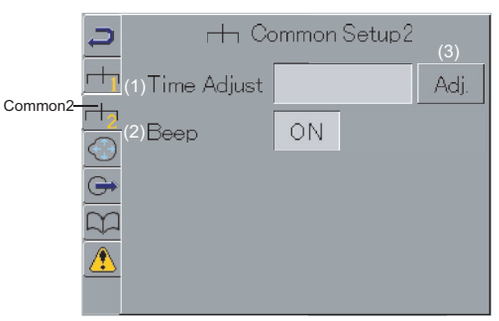
Reset: Resets the examination number to "000001."

b) Common 2

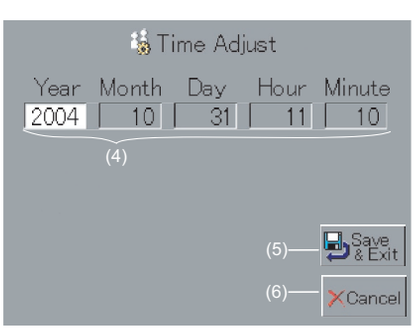
Set the time.

Note

- ***This instrument is equipped with an internal battery for the clock and backup. When the error message "Internal battery low" appears, contact your local distributor or Tomey Corporation. Do not attempt to replace the internal battery.***
- ***If you need the correct time displayed but the battery has expired, set the time after turning on the instrument. The clock works correctly while the instrument is turned on, but the time setting will be lost when the instrument is turned off.***



(Fig. 1)



(Fig. 2)

(1) Time Adjust

Adj: Sets the date and time.

Touch the "Adj" button (3). The Time Adjust screen (Fig. 2) appears. Touching any of the date/time fields (4) displays the keypad for you to change the setting. After adjusting the date and time, touch the "Save & Exit" button (5) to save the setting and return to the previous screen (Fig. 1).

Touch the "Cancel" button (5) to cancel changes to the setting and return to the previous screen (Fig. 1).

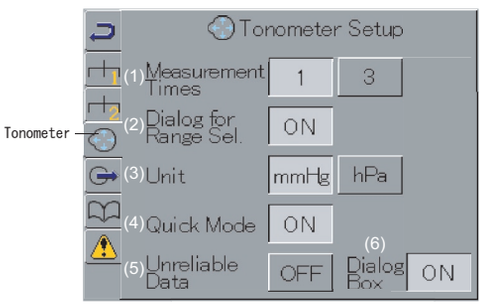
(2) Operation sound

ON: Sounds a beep when buttons on the touch panel or main unit are operated.

OFF: Does not sound a beep, except for the alarm when the measurement window is too close to or in contact with the patient.

c) Tonometer Setup

Set the measurement conditions.



(1) Measurement Times

1: Conducts measurement once when Auto Shot is ON.

3: Conducts measurement three times continuously when Auto Shot is ON.

(2) Popup window for selecting the measurement range

ON: Enables the popup window for selecting the measurement range.

OFF: Disables the popup window for selecting the measurement range.

(3) Unit

Set the units for displaying the pressure. mmHg or hPa

(4) Quick Mode

ON: When Auto Shot is ON, the instrument conducts the next measurement continuously without retracting the measuring head.

OFF: When Auto Shot is ON, the instrument retracts the measuring head once, adjusts alignment, and conducts the next measurement.

(5) Loading low reliable data

ON: Enables to load the low reliable data.

OFF: Disables to load the low reliable data.

(6) Popup

ON: Enables the popup window for loading the low reliable data.

OFF: Disables the popup window for loading the low reliable data.

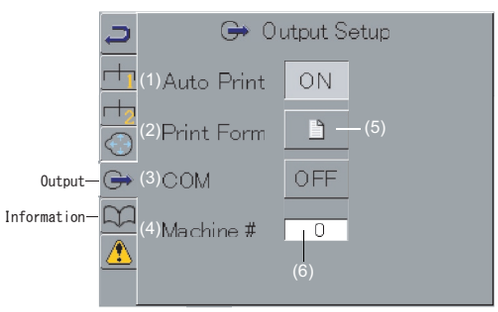
d) Output Setup

Set conditions for the output of measurement data.

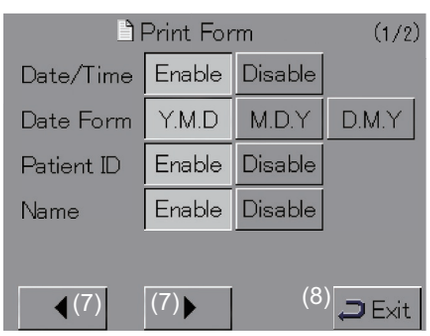
Note

■ *When COM is ON, the instrument allows you to enter the patient data and the Patient Information screen appears after the Output Setup is completed. Refer to "3.6.1 Entering the ID and patient's name" for details.*

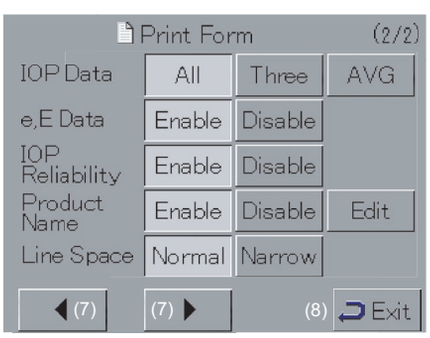
■ *When several of these instruments are installed in the same facility, set a unique number for "Machine #."*



(Fig. 1)



(Fig. 2)



(Fig. 3)

(1) Auto Print

ON: Enables the Auto Print function.

OFF: Disables the Auto Print function.

(2) Print Form

Sets the printing format for the built-in printer.

Touch the print form button (5). The Print Form screen (Fig. 2) appears. There are 9 setting items on 2 screens. Use the arrow buttons (7) to switch the screens. Refer to "3.4.2 Printing format" for details of each setting item.

Touch the "Exit" button (8) to return to the previous screen (Fig. 1).

(3) COM

ON: Enables communication with TOMEY Link or DATA Transfer to send or retrieve data.

OFF: Disables communication with any external device.

(4) Machine #

Touch the entry field (6). The keypad appears. Enter the instrument number.

If there are multiple instruments of the same model, the instrument is identified by the number set in "Machine #" during external communication.

e) Information

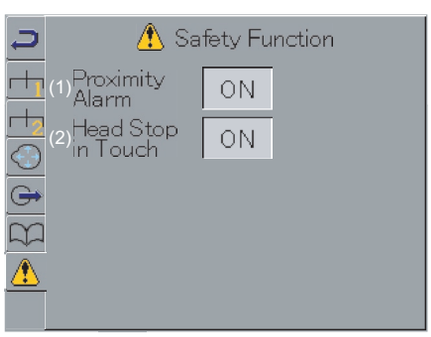
Displays the product information.

f) Safety function

Makes the settings for the safety functions.

Note

- ***When the alarm for nearness is set to OFF, the physician may not notice that the nozzle moves too close to the patient and the nozzle makes contact with the patient, resulting in injuries. Carefully operate the instrument, checking the distance between the patient and nozzle.***
- ***When the function to automatically stop the measurement window upon contact with the patient, the patient may get injured when they make contact with the measurement window. Carefully operate the instrument, checking the distance between the patient and measurement window.***



(Fig. 1)

(1) Alarm for nearness

ON: Sounds an alarm when the measurement window moves too close to the patient.

OFF: Does not sound an alarm when the measurement window moves to close to the patient.

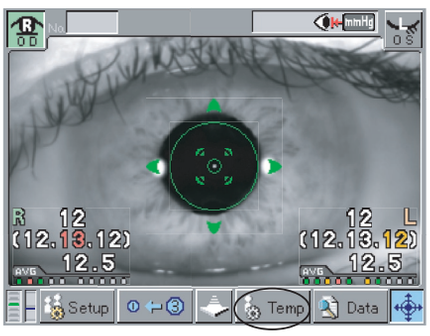
(2) Forward stop upon contact

ON: Stops forwarding the measurement window when it makes contact with the patient.

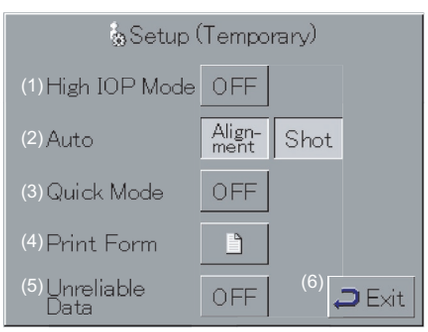
OFF: Allows the measurement window to continue to move forward when it makes contact with the patient.

3.7.2 Temporary setup (Temporary)

Set conditions for a specific measurement only. The setting is canceled when the corresponding measurement is completed. Refer to "3.7.1 Initial setup" for settings for continuous operation conditions.



(Fig. 1)



(Fig. 2)

Touch the "Temp" button.

Set the following items and touch the "Exit" button (6). The changes are reflected in the settings and the screen returns to the measurement screen (Fig. 1).

(1) High IOP Mode

ON: Temporarily enables High IOP mode.

OFF: Temporarily disables High IOP mode.

(2) Auto

Alignment: Temporarily enables the Auto Alignment function.

Shot: Temporarily enables the Auto Shot function.

(3) Quick Mode

ON Temporarily enables Quick mode.

OFF: Temporarily disables Quick mode.

(4) Print Form

Temporarily changes the format for the built-in printer.

(5) Loading low reliable data

ON: Enables to load the low reliable data.

OFF: Disables to load the low reliable data.

4. TECHNICAL INFORMATION

4.1 Adjusting intraocular pressure according to cornea thickness

It is generally said that measurement of the intraocular pressure, typically by the Goldmann applanation tonometer, is largely affected by the cornea. The influence of the cornea can be adjusted to some extent by the measured central corneal thickness (CCT). The correction expressions referred to previously are as follows.

1) *adjusted IOP = measured IOP - (CCT - 554) x 0.045*
Burvenich H, et al. Bull Soc belge Ophthalmol, 276, 15-18, 2000

2) *adjusted IOP = measured IOP - (CCT - 550) x 0.05*
Michelson G, Online J Ophthalmol, 1-2, 2001

All the above expressions are obtained by the primary regression of the corneal thickness and intraocular pressure. However, in practical cases, other factors such as difference due to ethnic groups, refractive index, and radius of corneal curvature are related, and no expression can be specified as the correct one. This instrument is designed to calculate the adjusted intraocular pressure by coefficients of these expressions and the central corneal thickness (CCT) measured by the pachymeter. Refer to "3.5.2 Adjusting the measurement data" for the correction method.

■ ***This instrument provides capability to adjust intraocular pressure (IOP) based on central corneal thickness (CCT) and regression parameters from equation describing the relationship of CCT to IOP. Please note, however, no particular set of adjustment parameters have been studied or validated in the development of the device.***

4.2 Performance test result for the device

4.2.1 Method

The test was performed with three pressure-controlled model. The pressure was set every 10mmHg from the lower limit value to the upper limit in each model. (0,10,20,30, 40,50,60mmHg)

The measurement was performed using the auto alignment function and the above-mentioned procedure was repeated 10 times in each model.

4.2.2 Result

It is shown the performance test results through use of pressure-controlled model below.

No.1 for pressure-controlled model

	0mmHg	10mmHg	20mmHg	30mmHg	40mmHg	50mmHg	60mmHg
avg	0.3	10.2	20.0	30.2	40.1	49.6	59.8
s.d.	0.48	0.42	0.47	0.42	0.57	0.52	0.42
CV	1.61	0.04	0.02	0.01	0.01	0.01	0.01

No.2 for pressure-controlled model

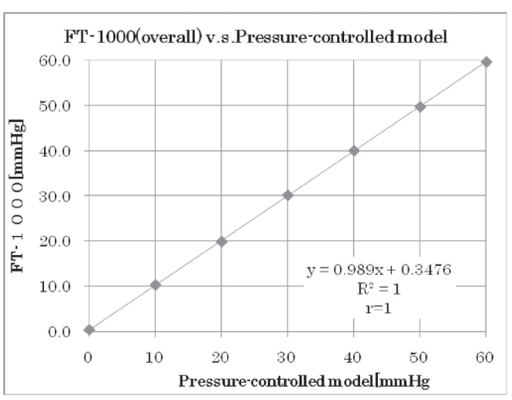
	0mmHg	10mmHg	20mmHg	30mmHg	40mmHg	50mmHg	60mmHg
avg	0.4	10.4	19.7	30.1	39.8	49.8	59.6
s.d.	0.52	0.52	0.48	0.32	0.42	0.42	0.52
CV	1.29	0.05	0.02	0.01	0.01	0.01	0.01

No.3 for pressure-controlled model

	0mmHg	10mmHg	20mmHg	30mmHg	40mmHg	50mmHg	60mmHg
avg	0.4	10.3	19.9	30.2	40.0	49.7	59.7
s.d.	0.49	0.47	0.43	0.38	0.49	0.45	0.55
CV	1.29	0.05	0.02	0.01	0.01	0.01	0.01

Overall

	0mmHg	10mmHg	20mmHg	30mmHg	40mmHg	50mmHg	60mmHg
avg	0.4	10.3	19.9	30.2	40.0	49.7	59.7
s.d.	0.49	0.47	0.43	0.38	0.49	0.45	0.55
CV	1.34	0.05	0.02	0.01	0.01	0.01	0.01



4.3 NON-CONTACT TONOMETER FT-1000 Clinical data (ISO8612:2001)

The range from 0 - 60 mmHg was evaluated on the bench.

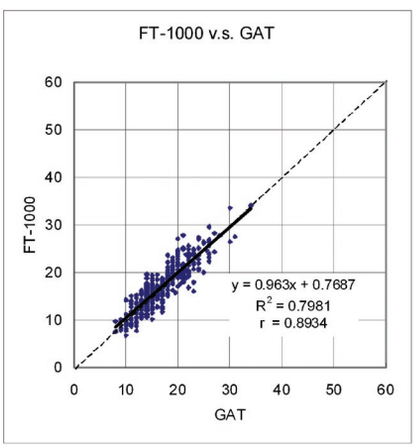
Additionally, the range 7 mmHg - 34 mmHg was clinically evaluated against the Goldmann applanation tonometer

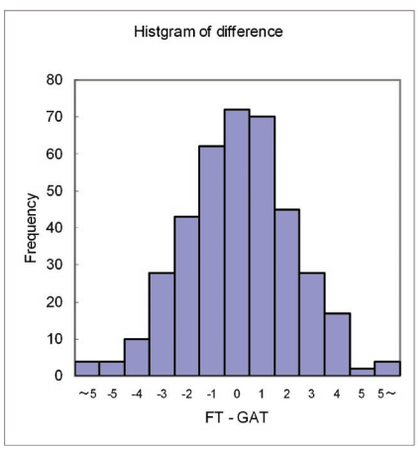
Test method : Performed as described in ISO8612:2001 Annex A,B.

Test period : 11 Mar. 2006 – 29 Jun. 2006

Test site : Mikawa ophthalmological clinic (Tokushima, JAPAN)
Ueda ophthalmological clinic (Kagawa, JAPAN)
Hata ophthalmological clinic (Hata Hospital) (Tokushima, JAPAN)

Result :





n = 389

GAT : 17.0±4.5 (mean±s.d.)
0.26(CV)
8 - 34(min - max)

FT-1000 : 17.2±4.8 (mean±s.d.)
0.27(CV)
7.4 - 34.1(min - max)

FT1000 – GAT: 0.1±2.2 (mean±s.d.)

IOP range [mmHg]	Tolerance [mmHg]	Min. num. of eyes	Num. of eyes	Num. of >5mmHg	%
7 to 16	+/-5.0	40	193	1	0.5
>16 to <23	+/-5.0	40	152	5	3.3
>=23	+/-5.0	40	44	2	4.5
Total		150	389	8	2.1

*The subjects having Corneal transplantation, diffuse punctate keratopathy, vitrious body, bullous keratophy, or aphakia were withdrawn from the clinical trial.

Caution

■ *The above clinical results conform to ISO8612:2001.*

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5. INSPECTION AND MAINTENANCE

5.1 Warranty

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 (1) year or other term complying with local regulations from the date of invoice issued by Seller to the original purchaser.
Lamps, paper and other 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 INSPECTION MANUAL of Tomey Corporation (here in after called "Tomey"). Neither seller not Tomey shall be liable for any damages caused by purchaser's failure to follow instruction for proper installation, use and maintenance of 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 modification of this product, by persons other than personnel duty authorized by Tomey, not 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 SELLER AND TOMEY. NEITHER 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 Durable years

This instrument is designed to be durable for 8 years when operated under the appropriate environment and adequately inspected and serviced.

5.3 Inspection

Caution

- ***Immediately after starting the instrument, the measuring head moves and an air blow test is performed. Do not allow the patient to place their face on the chin rest until the air blow test is complete. Otherwise the patient may be injured.***

Note

- ***If any problem occurs in the instrument, correct measurement may not be assured. Contact our local distributor or Tomey Corporation for necessary repairs as soon as possible.***

The instrument automatically performs an air blow test when started. After the instrument has started, the title screen appears and the measuring head moves to the initial position. Air is then blown onto the eye and the pressure is automatically measured. If there is a problem, an error is displayed on the screen.

5.4 Routine maintenance

Caution

- *Hold the plug when disconnecting the power cord from the outlet to avoid applying excessive force on the cord. Pulling the cord may damage inner core wires, resulting in electric shock or fire.*

Note

- *Do not use organic solvents such as thinner, benzene, or acetone to clean the instrument. These solvents may damage the surface coating of the instrument.*
- *Disconnect the power cord and place the dust cover over the main unit when the instrument is not operated.*

5.4.1 Measurement window

Note

- *Be extremely careful not to allow trash or dust to enter the nozzle while cleaning.*
- *Do not wipe or rub the window hard if contaminated with trash or dust. The surface of the glass may be damaged.*

The measurement window stands out from the main unit and is positioned the closest to the patient's eye of any section of the instrument. This means the measurement window may easily be contaminated with dust or tears. When the window is contaminated, clean it as follows.

1) Blow off any dust from the measurement window using a commercial blower brush, etc.
2) Gently clean the window glass with an applicator or soft cloth dampened with ethanol.

5.4.2 Forehead pad

Gently wipe the sections that patients directly touch, such as the forehead pad, with a soft cloth dampened with alcohol before starting measurement for a new patient.

5.4.3 Outer surface

When the outer surface of the instrument becomes dirty, clean it with a dry, soft cloth. When very dirty, clean the surface using a cloth dampened with diluted neutral detergent and thoroughly wrung out, and then wipe the surface with a dry cloth.

Note ■ *Clean the monitor of the main unit using a soft cloth with glass cleaner applied.*

5.5 Replacing consumables

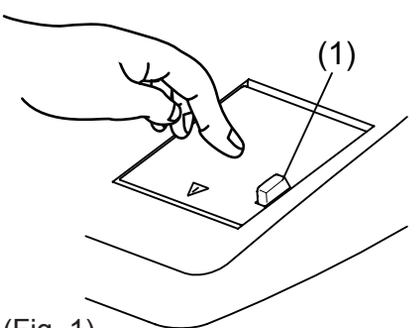
5.5.1 Printer paper

Caution

- ■ *Do not touch, or allow patients to touch, the printer cutter. Touching the cutter may result in injuries.*

Note

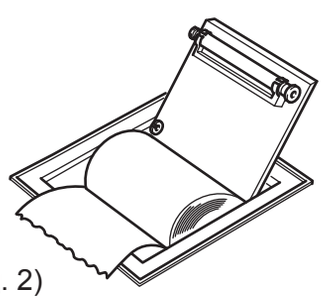
- ■ *Use the specified paper for the printer. Using other types of paper may cause printer failure.*
- ■ *Do not start printing without paper set in the printer. The printer head may be damaged.*
- ■ *Do not pull paper forcibly. Trying to pull the paper out may cause printer failure. If the "PRINT" button is touched when there is no data saved, paper is simply fed.*



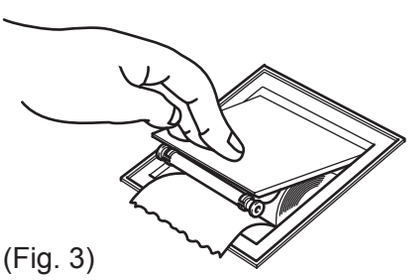
(Fig. 1)

Replace a paper roll when red lines appear on the sides of the printer paper.

1) Press the button (1) to lift the printer cover.
2) Take out the old printer paper roll.
3) Install a new paper roll. If the paper roll is installed in the wrong direction, nothing will be printed (Fig. 2).
4) Firmly close the printer cover until you hear a click, with the end of the paper protruding from the outlet.
5) Cut off any unnecessary paper.



(Fig. 2)



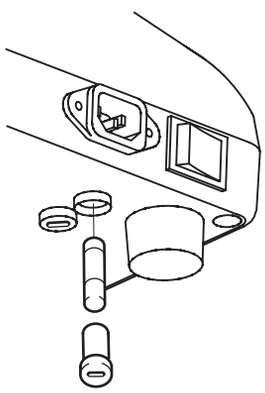
(Fig. 3)

5.5.2 Fuses

■ *Disconnect the power cord from the outlet when replacing fuses. Otherwise you may get an electric shock, resulting in death or serious injuries.*

■ *Use fuses specifically designed for the FT-1000.*

■ *When the instrument does not work correctly after fuses are replaced, there may be other causes of the problem. Turn off the instrument immediately and contact our local distributor.*



1) Turn power off.

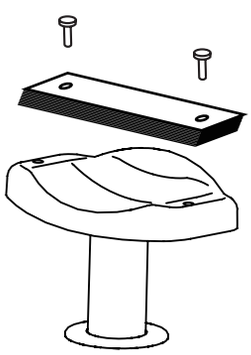
2) Disconnect the power cord from the outlet.

3) Insert a coin or similar in the slot on the fuse case located at the bottom of the main unit. Turn the screw counterclockwise to remove it.

4) Replace the blown fuse with a new one.

5) Reverse the procedure above to install the fuse holder.

5.5.3 Chin rest paper



1) Remove the two chin rest paper pins.

2) Place new chin rest paper on the chin rest and secure the paper with the paper pins again.

5.6 Storing

WARNING

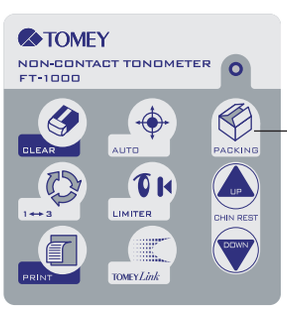
- ■ *Store the instrument in a location free of water or chemicals. Any water or chemicals entering the instrument may cause an electric shock or failure.*

Caution

- ■ *Do not store the instrument in a place where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the instrument and ignite.*
- ■ *Do not hold the measuring head, chin rest, forehead pad, or joystick when lifting the instrument. These components are detachable and the instrument may drop, resulting in injuries.*
- ■ *Disconnect the power cord from the outlet to ensure safety when the instrument is not operated for 1 month or longer.*
- ■ *Store the instrument in a location not subject to direct sunlight, high temperature and humidity, or air with significant dust, salt, and/or sulfur content. These may cause failure or malfunction of the instrument.*
- ■ *Store the instrument in a level and stable location free of vibration or mechanical impact to ensure correct measurement, and prevent the instrument from falling or being dropped, resulting in fire or fatal accidents.*

Note

- ■ *Place the dust cover over the main unit when not being used. The measurement accuracy will be deteriorate if the optical section in the instrument becomes dirty.*



(1)

Completely lower the measuring head to the lower dead center when storing the instrument.

Touch the "PACKING" button (1) for 3 seconds to return the measuring head to the lower dead center. Turn power off.

5.7 Disposal

Note

- *Keep the box and packing materials for use when moving or transporting the instrument.*
- *Keep the packing materials and the box together.*
- *When disposing of the packing materials, sort them by type and disposed of them as directed by relevant laws and local rules and regulations.*
- *A lithium battery is used in the instrument. Handling of the lithium battery varies depending on governing bodies. Follow relevant laws and local rules and regulations, or contact our local distributor or Tomey Corporation.*

6. Troubleshooting

Check the following first when you find problems with the instrument. If the problem is not solved even after checking the applicable item listed below, contact our local distributor.

■ *Do not remove the cover of the instrument. Otherwise, you may be directly exposed to high voltage sections.*

Note

■ *Do not take any actions other than those specified below.*

■ *If the problem is not solved even after checking the applicable item listed below, contact our local distributor.*

- The power lamp or monitor does not turn on when the power switch is turned on.

Cause 1 Faulty power plug

Solution Check that the power plug is firmly connected to the instrument and power outlet.

Check that the power cord is not cracked, torn, etc.

Cause 2 Power not supplied

Solution Check that power is supplied to the power outlet to which the power cord is connected.

Cause 3 Blown fuse

Solution Check that fuses are not blown and replace the fuse as needed (Refer to "5.5.2 Fuses"). If the replaced fuse blows again, there may be other problems. Contact our local distributor for repair.

- The monitor is dark when the power switch is turned on.

Cause 1 Auto Power Off, which automatically turns off the display when the instrument is not operated for a specific time, is ON.

Solution ➡ Touch the LCD

- The data cannot be printed by the built-in printer.

Cause 1 The printer has run out of paper. The error message "Printer Paper End" is displayed.

Solution ➡ Check the amount of printer paper remaining (refer to "5.5.1 Printer paper").

Cause 2 The printer cover is open. The error message "Printer Cover Open" is displayed.

Solution ➡ Check that the printer cover is completely closed.

Cause 3 The printer paper is not set in the correct direction.

Solution ➡ Check that the printer paper is set correctly (refer to "5.5.1 Printer paper").

- The error message "Printer Error" is displayed.

Cause 1 There is a problem with the printer.

Solution ➡ Contact our local distributor.

- Stable measurement results are not obtained. The measured value is inappropriate or greatly deviates from the previous value.

Cause 1 The measurement window is dirty.

Solution ➡ Check that the measurement window is clean.

- The error message "Internal Error" is displayed.

Cause 1 There are problems with the internal functions of the instrument.

Solution Stop using the instrument and contact our local distributor.

- The error message "Internal Battery Empty" is displayed.

Cause 1 The internal battery has expired.

Solution Contact our local distributor and have the internal battery replaced.

- The error message "Calender / Clock Error" is displayed.

Cause 1 There are problems with the date/clock function.

Solution Contact our local distributor.

- The error message "Air Paff Error" is displayed.

Cause 1 There are problems with the air blowing function.

Solution Contact our local distributor.

- The error message "Chin Rest Error" is displayed.

Cause 1 There are problems with the chin rest elevator.

Solution Contact our local distributor.

- The error message "Joy Stick Error" is displayed.

Cause 1 There are problems with the joystick.

Solution Contact our local distributor.

- The error message "Alignment Motor Error" is displayed.

Cause 1 There are problems with the alignment function.

Solution Contact our local distributor.

- The error message "Unknown Error" is displayed.

Cause 1 An error of unknown origin has occurred.

Solution Stop using the instrument and contact our local distributor.

- The error message "External Communication Error" is displayed.
- Nothing is retrieved even when the ID is entered for TOMEY Link and/or DATA Transfer.

Cause 1 Faulty cable connection

Solution Check the connection between the instrument's RS-232C connector and the adapter or RS-232C cable, or the connection of the RS-232C connector on the connected equipment.

Cause 2 TOMEY Link or DATA Transfer is not running.

Solution Check that TOMEY Link and/or DATA Transfer (including the relay software) is running correctly. Refer to the instruction manual of TOMEY Link and/or DATA Transfer for details.

Cause 3 There may be an error in TOMEY Link and/or DATA Transfer.

Solution Check that there is no error in TOMEY Link or DATA Transfer (including the relay software). Refer to the instruction manual of TOMEY Link and/or DATA Transfer for details.

7. Consumables

Contact our local distributor to order any of the following consumables.

- Built-in printer paper

  Specify the paper type as "Built-in printer paper for FT-1000."

- Chin rest paper (100 sheets/set)

- Fuse

  Specify the fuse type as "Fuse for FT-1000."

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8. Specifications

8.1 Specifications

8.1.1 Measuring IOP

- Measurement range : 0 - 60 mmHg (0 - 30 mmHg / 25 - 60 mmHg)
- Measurement : 1 mmHg (1 hPa) increments within the measurement range

8.1.2 Main unit

- Built-in printer : Thermal Printer
- Stroke of moving section
  - Right-Left : 88mm
  - Forward-Backward : 40mm
  - Up-Down : 45mm
- Stroke of chin-rest : 70mm
- Data output type : RS-232C
- Display : 5.7 inch color LCD
- Dimensions and weight
  - Dimensions : 306 (W) x 493 (D) x 463 (H) mm
  - Weight : Approx. 18 kg

8.1.3 Power source

- Voltage : 100VAC - 240VAC
- Frequency : 50/60Hz
- Power consumption : 85VA - 110VA

8.2 Energy and other consumption

Energy of visible light and infrared light

Light for measuring intraocular pressure

Light source	Light emitting diode	
Wavelength	880 nm	
Output	Alignment	< 50 µW (Limit[1] : 210 µW)
	Measurement	< 100 µW (Limit[1] : 3200 µW, t = 0.05 s)

Fixation lamp

Light source	Light emitting diode (3-color chip)	
Wavelength	Red	630 nm
	Green	520 nm
	Blue	470 nm
Output	Red	< 0.1 µW (Limit[1] : 3.7 µW)
	Green	< 0.1 µW (Limit[1] : 3.7 µW)
	Blue	< 0.1 µW (Limit[1] : 3.7 µW)

Light for anterior eye segment

Light source	Light emitting diode
Wavelength	780 nm
Output	< 100 µW (Limit[1] : 450 µW)

[1]AEL class 1 conforming to IEC 60825-1:2001

8.3 Noise

The instrument generates machine noise when:

- Turning power on
- Printing out data
- Moving the measuring section
- Moving the chin rest
- Measuring the data (loading the measurement data, etc.)
- Operating the main unit buttons and touch panel
- Moving the measurement window too close to the patient or to be in contact with the patient

8.4 Operating environment

Operate the instrument under the following environmental conditions.

- Installation..... Indoors, not in direct sunlight
- Operating temperature range ... +10°C - +40°C
- Humidity..... 30 - 75% RH
- Atmospheric pressure... 800 - 1060 hPa
- Power fluctuation..... Less than ±10% of nominal voltage

Store and/or transport the instrument in the instrument's box under the following environmental conditions.

- Temperature .....-20°C - +60°C
- Humidity.....10 - 95% RH

8.5 Classification

Protection against electrical shock: Class I ME equipment
Applied parts: B applied parts (Forehead pad, Chin rest)
IP Code: IP20

Mode of Operation: Continuous operation

8.6 Declaration of Conformity to EMC

- ***When using specified accessories or cables excluding internal parts sold as repair parts of Tomey Corporation, electromagnetic emission of the FT-1000 may increase or electromagnetic immunity may decrease.***
- ***When using handheld or portable communication equipment, locate it more than 30cm(12inches) away from the FT-1000. It may degrade the performance of the FT-1000 if the equipment is located closer.***
- ***Do not use the FT-1000 adjacent to or stacked on other equipment. If it needs to be adjacent to or placed on other equipment, it must be confirmed that FT-1000 operates correctly in such location.***

- ***The FT-1000 falls under Group 1, Class B according to EN 55011(CISPR 11). This means that the FT-1000 does not generate RF energy intentionally in the form of electromagnetic irradiation, inductive coupling and/or capacitive coupling for processing of materials or inspection/analysis, and that it is suitable for use in facilities directly connected to a low-voltage power network that supplies power to general household facilities and buildings used for home use.***
- ***The FT-1000 can be used in a specialized health care facility such as hospitals and clinics (except anywhere near the source of a strong EMI) and a general commercial facility such as eye glasses stores.***
- ***The FT-1000 requires special attention for EMC and needs to be installed, serviced and used based on the following information.***
- ***Do not use cables other than those provided or specified by Tomey Corporation.***
- ***The person who connects additional equipment to the signal I/O section as part of the medical system, shall take responsibility for ensuring the system conforms to IEC/EN 60601-1-2 requirements.***

Cable list

Name	Specification	Length	Note
AC Power Cord	Unshielded	2.5m	Accessories
RS-232C cable	Unshielded	1.8m	Not accessories

Essential performance：Measure intraocular pressure and display measured value.

<EMISSIONS>

Test	Standard	Compliance
		HOME HEALTHCARE ENVIRONMENT
Conducted Emissions	CISPR 11	Group 1 Class B
Radiated Emissions	CISPR 11	Group 1 Class B
Harmonic distortion	IEC 61000-3-2	Harmonic Class A
Voltage fluctuations and flicker	IEC 61000-3-3	Complies

<IMMUNITY>

Table 1【ENCLOSURE PORT】

Test	Standard	IMMUNITY TEST LEVELS
		HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80MHz – 2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table 2
RATED power frequency magnetic fields	IEC 61000-4-8	30 A / m 50Hz or 60Hz

Table 2【Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment】

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V / m)
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ±5kHz deviation 1kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800 / 900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1 720	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1 845						
1 970						
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b / g / n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5 240	5 100 - 5 800	WLAN 802.11 a / n	Pulse modulation 217Hz	0.2	0.3	9
5 500						
5 785						

Table 3【Input a.c. power PORT】

Test	Standard	IMMUNITY TEST LEVELS
		HOME HEALTHCARE ENVIRONMENT
Electrical fast transients / bursts	IEC 61000-4-4	± 2kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1kV, ±2kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V 0.15MHz - 80MHz 6V in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0°,45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U_T; 1 cycle and 70% U_T; 25 / 30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T; 250 / 300 cycle

Table 4【Signal input / output parts PORT】

Test	Standard	IMMUNITY TEST LEVELS
		HOME HEALTHCARE ENVIRONMENT
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz

9. INDEX

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Original instructions

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