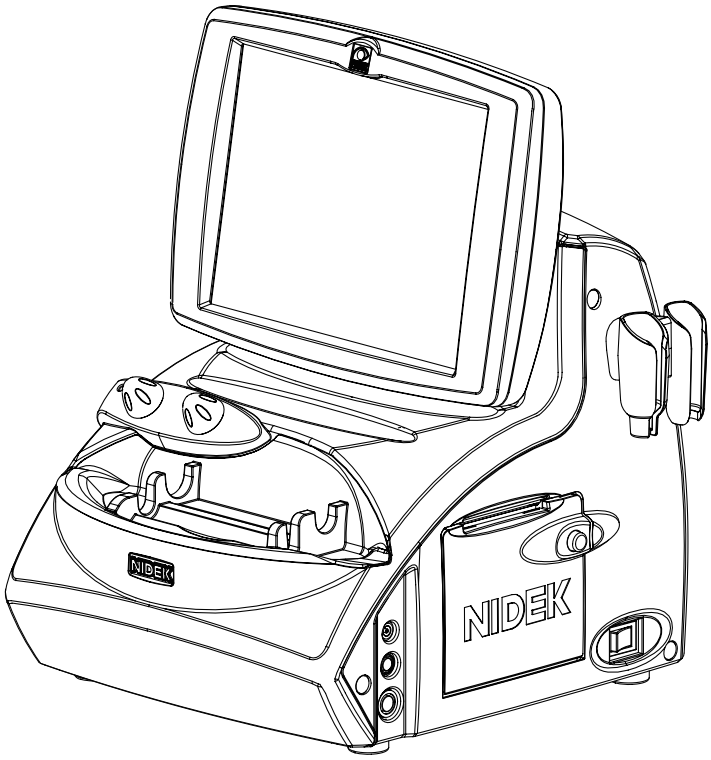
NIDEK

US-4000
ECHOSCAN

OPERATOR'S MANUAL



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Use this device properly and safely.

⚠ BEFORE USE, READ THIS MANUAL.

This Operator's Manual contains information necessary for the operation of the NIDEK US-4000 ECHOSCAN. This manual includes the operating procedures, safety precautions, and specifications.

IEC standards are applied in this manual.

The safety precautions and operating procedures must be thoroughly understood prior to operation of the device. Keep this manual handy for reference.

Use of the device is limited to ophthalmologists or personnel involved in medical practice under the ophthalmologists' instructions in accordance with the instructions in the operator's manual. The ophthalmologists are responsible for other applications of this device.

Use of the device outside the scope of this maual may cause unexpected troubles and adverse events.

If you encounter any problems or have questions about the device, please contact NIDEK or your authorized distributor.

Safety precautions

In this manual, signal words are used to designate the degree or level of safety alerting. The definitions are as follows.

⚠ **CAUTION** • Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or property damage accident.

Even situations indicated by "⚠CAUTION" may result in serious injury under certain conditions. Safety precautions must be strictly followed at all times.

Use precautions

Before Use

⚠ **CAUTION**

- **Never use the device for other than its intended purpose.**
  NIDEK will assume no responsibility for accident or malfunction caused by improper use.
- **The safety precautions and operating procedures must be thoroughly understood prior to operation of the device.**
  Use of the device outside the scope of this maual may cause unexpected troubles and adverse events.
- **Do not use the deviec if any abnormality is found in the visual check or operation check before use.**
  If there is any abnormality in power output, communication, or operation, the device may become unusable.
  Intended effect cannot be obtained with a failured device and unexpected health hazard may result from unexpected troubles and misdiagnosis.
- **Never modify nor touch the internal structure of the device.**
  Electric shock or malfunction may result.
- **Install the device in an environment that meets the following conditions. The following conditions must be maintained during use.**
  Use conditions
  Ambient temperature: +10ºC to +35ºC
  Humidity: 30 to 75% (Non-condensing)
  Atmospheric pressure: 800 hPa to 1060 hPa
  Minimal dust in the air
  Little influence of disturbance light
  Level and stable surface free from vibration and bumping
  If the device is not installed and used under the above conditions, the reliability of measurement results is lowered, and malfunction may result. In addition, injury may result if the device is bumped or falls down.
- **Install the device in an environment where no contaminants such as corrosive gas, acid, and salt are contained in the air.**
  Corrosion or malfunction of the device may result.
- **Avoid installing the device where it is exposed to direct air flow from an air conditioner.**
  Changes in temperature may result in condensation inside the device or adversely affect measurement results.
- **Be sure to use a power outlet which meets power requirements.**
  If the supplied voltage is too high or low, the device may not deliver full performance, and malfunction or fire may result.
- **The power outlet must be equipped with a grounding terminal. If not, connect the device to the protective earth ground using a ground conductor.**
  Electric shock or fire may result from current leakage caused by malfunction.
- **Insert the mains plug into an outlet as far as the prongs of the plug will go.**
  Imperfect connection may result in fire.

⚠ **CAUTION**

- **For supplying the device with the power, never use a table tap or an extension cable.**
  There is a fear of reduction in electrical safety.
- **Never use any power cord other than the speficied one or use the accessory power cord for other instruments.**
  Malfunction or fire may result.
- **Never crush or pinch the power cord with heavy objects.**
  Damage may result in electric shock or fire.
- **Before connecting cables to the device, turn the device off and disconnect the power cord from an outlet.**
  Malfunction may result.
- **Before transporting the device, pack the device in the specified packing materials to avoid impact from falling or other causes.**
  Excessive vibration and impact to the device may result in device failure.

Installation precautions

⚠ **CAUTION**

- **In installation, be sure that the following conditions are satisfied:**
  - Protected form direct sunlight or ultraviolet rays
  - Not exposed to rain or water
  - Dust free environment with air containing no sulfur or salt
  - Level and stable surface free form vibration and bumping
  - The specified environmental conditions during use are satisfied
- **Install the US-4000 in a place where there is no other devices such as laser devices that radiate strong electromagnetic waves.**
  Strong electromagnetic waves may interfere with proper measurement.
  If the US-4000 must be installed in the same place as any other device that radiates strong electromagnetic waves, perform the measurement using the US-4000 after stopping operation of the other device.
- **Install the device so that the air vent on the cover of the main body is not blocked.**
- **Do not use this device in an operating room.**

During Use

⚠ **CAUTION**

- **Do not use the deviec if any abnormality is found in the visual check or operation check before use.**
  Intended effect cannot be obtained with a failured device and unexpected health hazard may result from unexpected troubles and misdiagnosis.

⚠ **CAUTION**

- **In the event that a strange odor or smoke is noticed coming from the device, turn it off and unplug the power cord immediately. After confirming that the smoke is no longer being produced, contact NIDEK or your authorized distributor.**
  Continued use may result in electric shock or fire. In case of fire, use a dry chemical (ABC) extinguisher.
- **If the internal wires of the power cord are exposed, power to the device is interrupted by moving the cord, or the plug or cord becomes extremely hot, this indicates that the cord is damaged. Immediately replace the power cord.**
  Immediately remove the plug from the outlet and contact NIDEK or your authorized distributor for replacement; otherwise, electric shock or fire may result.
- **Never press the LCD screen with a hard object such as a ball-point pen. Keep magnetic objects away from the LCD screen.**
  Malfunction may result.
- **Do not operate the LCD screen with wet hands.**
  Water intrusion may result in malfunction of the device.
- **There may be a few "constantly-lit", "missing" or "dead" pixels in your LCD screen which are a characteristic of the LCD screens, This does not represent a failure of the LCD screen; continuously use the monitor.**
- **Do not use cables and accessories that are not specified for the device.**
  The electromagnetic compatibility (EMC) may be decreased and the device operation may be affacted.
- **Do not use the device near portable and mobile radio frequency communication systems.**
  They may have an adverse effect on operation of the device.
- **Do not use the device in the same room with other equipment such as life-support equipment, other equipment that has major affects on the life of the patient and results of treatment, or other measurement or treatment equipment that involves small electric current.**
- **If the instrument is connected to a PC that does not comply with IEC60601-1 (except one that uses an AC adapter that meets the Class II requirements of IEC60950-1), supply power to the instrument and PC through isolation transformers.**
  Contact NIDEK or your authorized distributor for installing isolation transformers.
- **Perform the measurements using appropriate sonic velocity values.**
  Accurate axial length and pachymetry cannot be obtained with inappropriate sonic velocity values.
- **This device uses a heat-sensitive printer paper. To keep the printed data for a long period of time, make copies of the printouts.**
  The paper degrades over time and the printed data may become illegible.

Probe

⚠ **CAUTION**

- **Always hold the plug, not the cable, when connecting or disconnecting the probe.**
  If the cable breaks near the probe side, it is necessary to replace the whole probe.
- **Disinfect the probe tip for every patient.**
  Failure to do so may cause infection of patient's cornea.
- **Before measurement, confirm that there are no scratches, chips, or cracks on the surface of the probe tip.**
  If there are, proper measurement may not be possible.
- **Before measurement, confirm that there are no scratches or chips on the surface of the probe tip which contacts the cornea.**
  If there are, the cornea may be damaged.
- **Pay attention not to bump the probe tip.**
  The probe tip may be deformed or chipped.
- **Do not press the probe against the patient's cornea with excessive force.**
  The measurement result becomes unstable and the patient's eye may be damaged.
- **After using the probe, put the protective cover on the probe and keep it in the case.**
- **Do not move the probe while it is in contact with the patient's cornea.**
  The corneal epithelium may become damaged.
- **Never perform autoclaving, EOG sterilization, or ultrasonic cleaning of the A-scan, B-scan, or Pachymetry probe.**
  The probes may become damaged.

After use

⚠ CAUTION

- **When the device is not in use, turn off power to it and place the dust cover over it.**
  Dust may affect the accuracy of measurements.
- **Always hold the power plug, not the cord, to remove it from an outlet.**
  The metal core of the cord may be damaged and electric shock, malfunction, or fire may result.
- **Wipe between the prongs of the power plug periodically.**
  Dust that may settle between the prongs attracts moisture and could result in short circuit, electric shock, or fire.
- **If the device will not be used for a long period of time, disconnect the power cord from the power outlet .**
  Fire may result.
- **Maintain the surrounding temperature and humidity at the following ranges during transportation and storage of the device.**
  Environmental conditions:
  Ambient temperature: –10ºC to +55ºC
  Humidity: 10 to 95% (non-condensing)
  Minimal dust in the air
  Protected from direct sunlight
- **To transport the device, use the packing materials in which the device was delivered to protect it from excessive vibration and bumping.**
  Excessive vibration or bumping may result in device failure.

Maintenance and checks

⚠ **CAUTION**

- **Only service personnel properly trained by Nidek are allowed to service the device.**
  Nidek assumes no responsibility for accidents resulting from improper servicing.
- **When performing maintenance work, secure a sufficient maintenance space.**
  Maintenance work in an insufficient space may result in injury.
- **When the device is sent back to NIDEK for repair or maintenance, wipe the surfaces (especially, the parts that come into contact with the patients) of the device with a clean cloth soaked with ethyl alcohol for disinfection.**
- **Each time the system starts, be sure to make a check of the device.**
  If not, accurate measurement values cannot be obtained.
- **When replacing the printer paper, use the specified type.**
  Failure to do so may cause a malfunction of the printer.
- **When replacing fuses, use the specified ones.**
  Failure to do so may cause a malfunction or a fire.
- **When cleaning the cover of the device and touch screen, never use organic solvents such as thinners or abrasive detergents.**
  The cover of the device and touch screen may be damaged.
- **If the LCD screen becomes dirty, wipe it with a soft cloth or gauze soaked in with ethanol.**
  Other cleaning methods may damage the touch screen.
  After the cleaning, when the accessories are dry, be sure to visually check their exterior.
- **Only service personnel properly trained by NIDEK are allowed to disassemble and repair the device.**
  NIDEK assumes no responsibility for accidents caused by improper repair.

Disposal

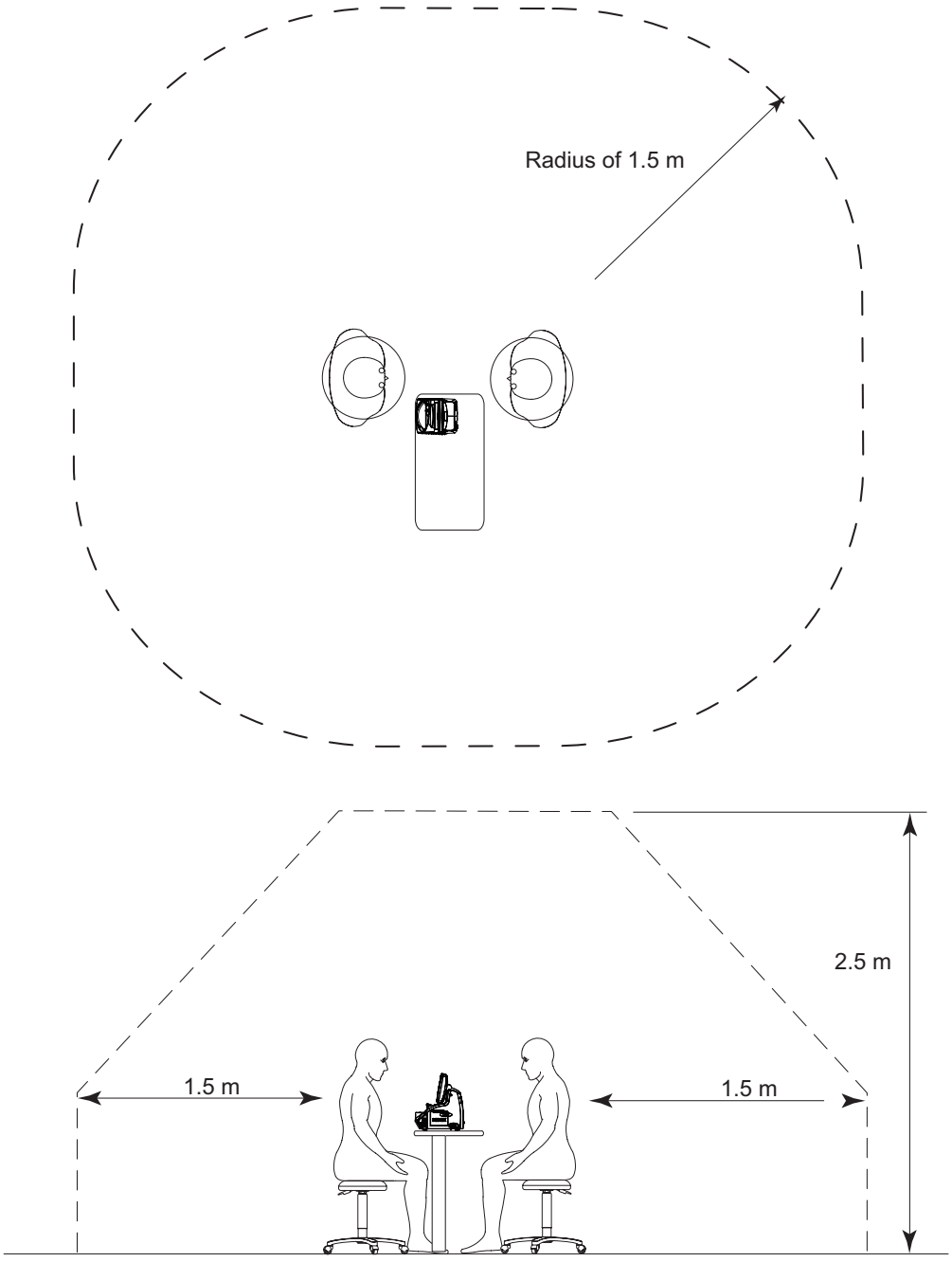
⚠ **CAUTION**

- **Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.**
  It is recommended to commission the disposal to a designated industrial waste disposal contractor.
- **When disposing of packing materials, sort them by material and follow local governing ordinances and recycling plans.**

Patient environment

The patient environment is the volume of space in which contact can occur between the patient and any part of the device or between the patient and any other person(s) touching the device.

Use devices that comply with IEC6060-1 in the patient environment. If any device that does not comply with IEC 60601-1 is to be used, use an isolating transformer or common protective grounding.



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1. BEFORE USE

1.1 Outline of Device

The NIDEK US-4000 Echoscan is an ultrasonic device to visualize the shape and properties of the eye interior and provide the image information to be used for diagnosis. It also measures the axial length and corneal thickness and provides the information to be used for diagnosis.

Axial length is one of the parameters used to determine the refractive power of an IOL prior to cataract surgery. By inputting the measured axial length with other parameters, the refractive power of an IOL can be calculated.

Corneal thickness is a necessary parameter when considering the clinical influence of surgery, drugs and contact lenses upon endothelium tissue. Pachymetry is now commonly performed prior to and after corneal refractive surgery using devices such as the excimer laser.

The US-4000 is comprised of a touch screen, main body with a built-in printer, an A-scan probe, a B-scan probe, a Pachymetry probe, and a foot switch. Items such as a video printer are also available as optional accessories.

1.2 Indications for Use

The NIDEK US-4000 Echoscan is a medical device used for measuring the axial length, anterior chamber depth, corneal thickness, lens thickness, and vitreous body thickess, for calculating IOL power, and for observing the interior of the eye in B-scan imaging.

1.3 Principles

Ultrasonic waves are the sound waves pitched above the range of human hearing whose frequency is 20,000 Hz or more. In the medical field, ultrasonic waves of frequencies between 1 and 15 MHz are applied, and these types of high sound waves have the following characteristics similar to light:

They have a high tendency to travel in a straight direction.

They have characteristics such as reflection and refraction at the boundaries of media which have different acoustic impedances.

(Acoustic impedance = Density of medium × Sonic velocity in the medium)

Special material is adopted to transmit and receive the ultrasonic pulses. Electrodes are placed on both sides of a thin piece of material, and the thickness of the material is changed by the fluctuation of voltage when a voltage is applied between them. The material vibrates with its inherent frequency when voltage is applied, and transmits the ultrasonic pulses. Conversely, when this material vibrates by the impact of the ultrasonic pulses, voltage of the same frequency is generated on both electrodes and it becomes possible to register the ultrasonic pulses as electrical signals. This phenomena is called the “Piezo effect”, and the converter, which electrically generates the ultrasound waves and changes them into voltage, is called a transducer.

In A-scan biometry, the ultrasonic pulse travels inside the eye when the probe is put on the eyeball. A portion of the pulses is reflected from the boundary of the cornea, anterior chamber, lens, vitreous body and retina, and their echoes are received at the same probe. The received echoes are converted to the electronic acoustic signals and indicated on the LCD as an amplitude. In addition, the time difference of each echo is measured and the size of each area of tissue (anterior chamber depth, lens thickness, vitreous body length and axial length) is calculated according to the time difference and known inherent sonic velocity through each kind of tissue.

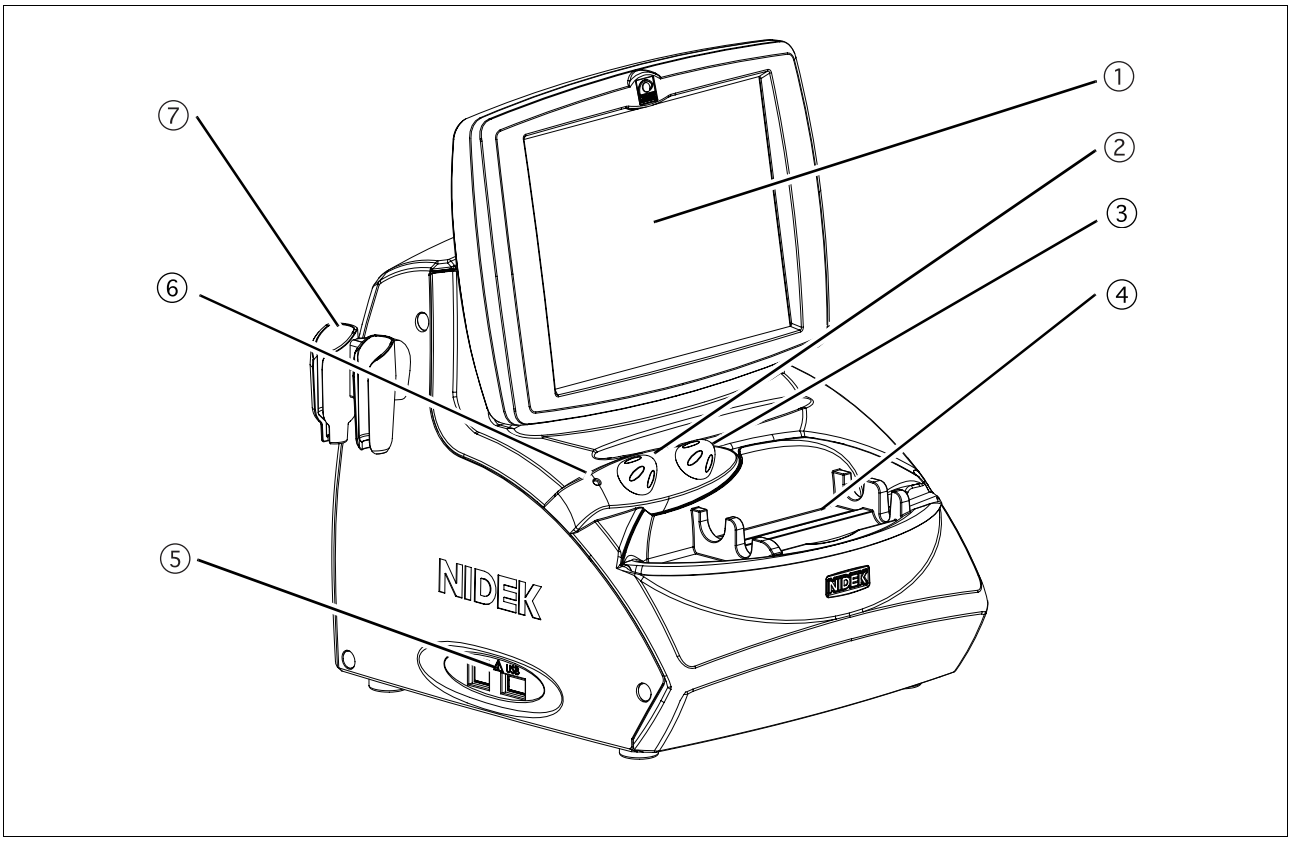
In B-scan imaging, touching the mechanical sector scan probe with a built-in transducer to the eye emits the ultrasonic pulses that travel inside the eye. These pulses are reflected at boundaries of the cornea, anterior chamber, anterior chamber, crystalline lens, vitreous body, and retina. The reflected pulses (echoes) are received by the same mechanical sector scan probe to be converted to electrical signals. Then the amplitude of the electrical signals is converted to brightness to display the two-dimensional static and dynamic images of the eye interior on the screen.

In pachymetry, the ultrasonic pulses are transmitted when the probe is put on the cornea. A part of the pulses is reflected at the front and rear surface of the cornea. When the probe receives the reflected echoes, the time difference of each echo is measured and the corneal thickness is calculated according to the time difference and known inherent sonic velocity through the cornea.

If the directions of the ultrasonic waves are not perpendicular to each boundary surface in both axial length and pachymetry, the echoes become weak and may not return to the probe. Therefore, it is very important to coincide the direction of the ultrasonic wave with the visual axis in order to achieve accurate measurement.

1.4 Device Description

○ Front view



① LCD touch screen

A 8.4-inch color LCD that is used as a touch screen for data input.

The LCD touch screen can be tilted for the operator's convenience.

② Knob 1

Used to change the TGC (Time Gain Control) or area of magnification.

③ Knob 2

Used to change the gain or area of magnificaiton.

④ Probe rest

Used to keep the probes when not in use.

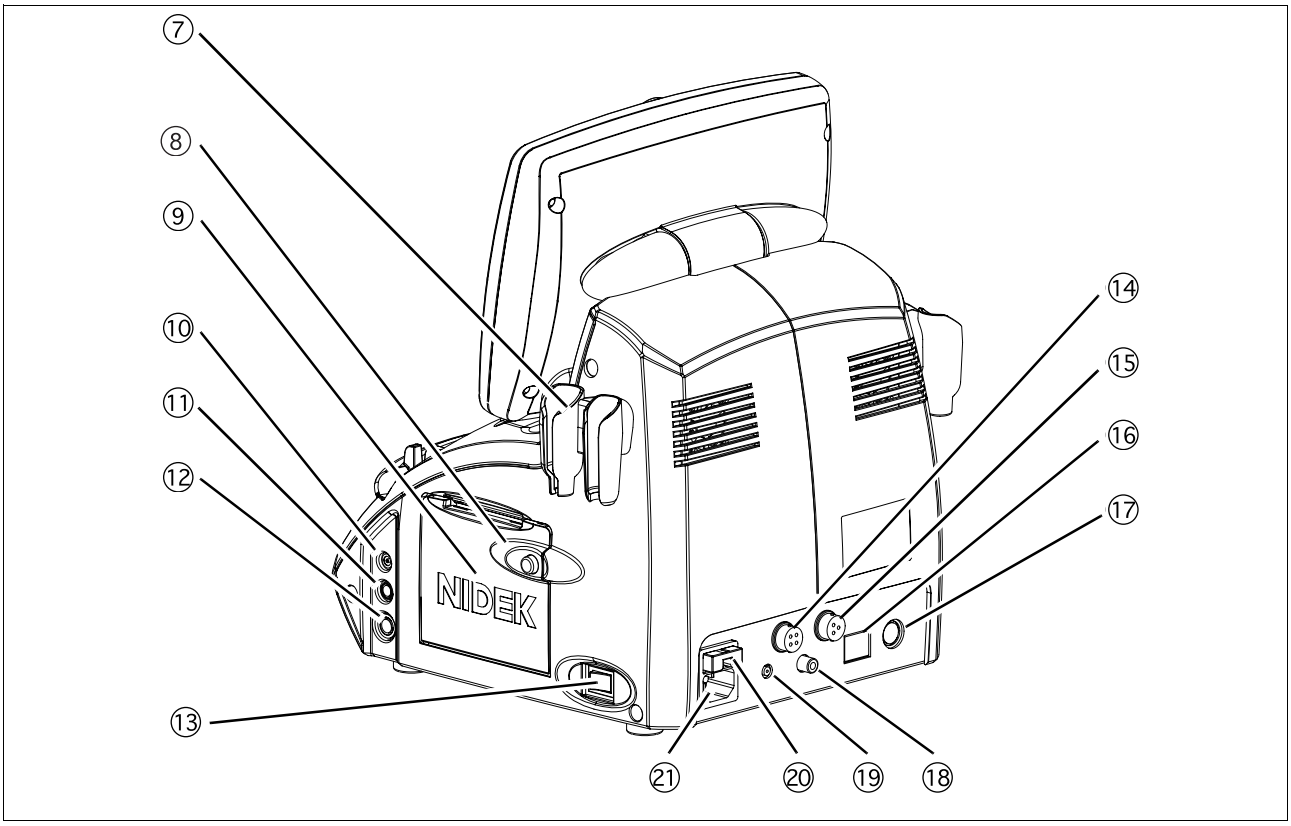
⑤ USB port

Used to connect the USB flash drive to save images, measurement data, and device parameters.

⑥ Pilot lamp

Illuminates when power is supplied to the device.

○ Rear view



⑦ **Probe holder**

Place for keeping the probe.

⑧ **Cover open button**

Pressed to open the printer cover.

⑨ **Printer cover**

Used cover the internal printer with an automatic paper cutter. The printer cover is opened by pressing the Cover open button when replacing the printer paper.

⑩ **Probe connector (P)**

Used to connect a Pachymetry probe (45° angled probe, 45° angled probe with detachable tip, or straight probe).

⑪ **Probe connector (BIO)**

Used to connect the A-scan probe.

⑫ **Probe connector (B)**

Used to connect the B-scan probe.

⑬ **Power switch**

Pressed to turn ON and OFF power to the device.

⑭ **External fixation lamp connector**

When using the probe stand, power for its fixation lamp is supplied from this connector.

⑮ **Foot switch connector**

The cable plug of the foot switch is connected here.

⑯ **LAN port**

Used to connect the US-4000 with an external device (PC) using a LAN cable for data transmission.

⑰ **External communication connector**

An RS-232C interface connector used to connect the US-4000 with an external device such as a PC for data transmission. When the US-4000 is connected to a NIDEK Keratometer, data obtained by the Keratometer can be imported to the US-4000.

⑱ **Video output terminal**

Used to connect the video printer (optional) to print images.

⑲ **Remote connector**

Used to connect the remote cable for the video printer (optional).

⑳ **Fuse holder**

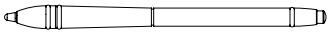
Contains fuses. The fuses are blown when overcurrent flows to the device.

㉑ **Inlet**

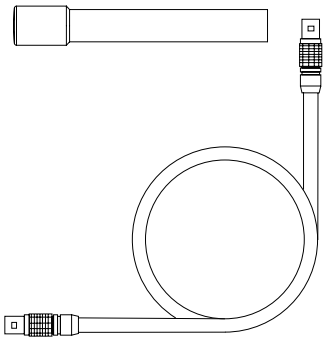
Used to connect the power cord.

㉒**Stylus**

Used to manipulate the screen.

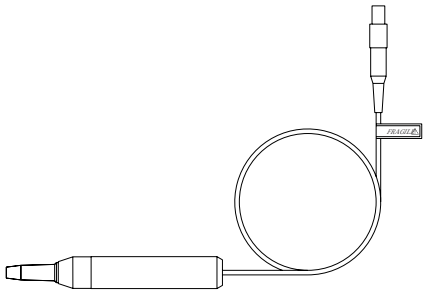


㉓**B-scan probe**



㉔**A-scan probe**

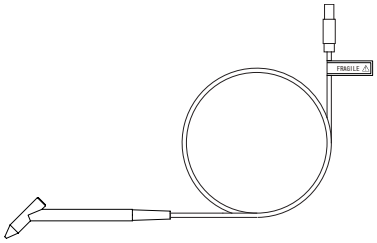
A solid probe with a built-in fixation lamp



㉕**Pachymetry probe**

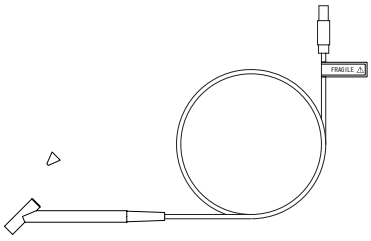
45° Probe

A solid probe for pachymetry



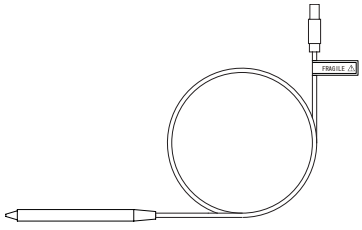
45° probe (with detachable tip)

A solid probe for pachymetry with a detachable tip



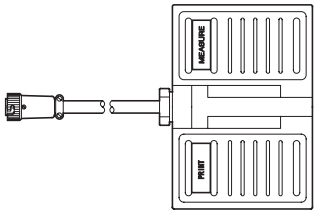
Straight probe

A straight-type solid probe for pachymetry



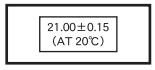
㉖**Foot switch**

Used for A-scan biometry, pachymetry, and B-scan imaging.

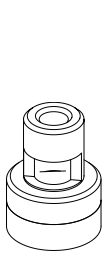


㉗**Test piece**

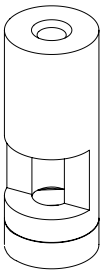
(for A-scan biometry)



(for pachymetry)

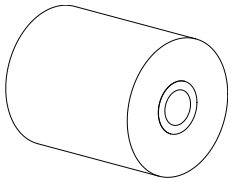


For 45° probe



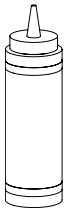
For straight probe

㉘**Printer paper (3 rolls)**



㉙**Ultrasound gel**

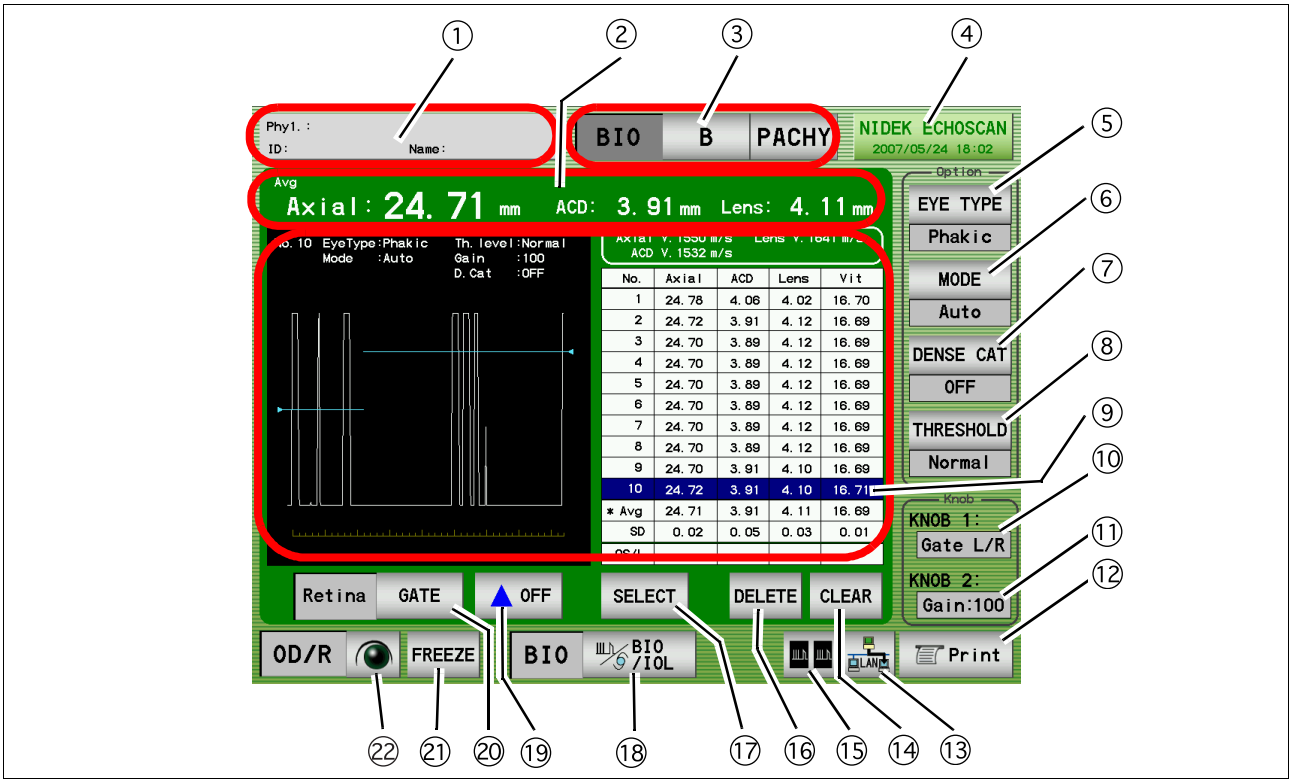
Applied to the eyelid for B-scan imaging.



㉚**Dust cover**

1.5 Screen Description

1.5.1 A-scan biometry screen



① Patient switch

Pressed to register patient information and display the physician's name and the patient ID.

② Measurement value

Displays axial length, anterior chamber depth, and lens thickness.

③ Mode switch

Pressed to display the desired screen among the A-scan biometry, B-scan imaging, and Pachymetry screens.

④ Date and time switch

Displays the current date and time. Pressed to display the A-scan biometry utility screen.

⑤ EYE TYPE switch

Pressed to select the type of the eye to be measured.

•Phakic: Phakic Eye

The axial length is converted from the average sonic velocity. Then the anterior chamber depth and the lens thickness are converted from their respective sonic velocities.

•Phakic2: Phakic Eye

The axial length is calculated by adding the anterior chamber depth, lens thickness, and vitreous body length that are converted from their respective sonic velocities.

•APhakic: APhakic Eye

•IOL: Pseudophakic Eye

⑥ MODE switch

Pressed to change the measurement method.

Auto: The measurement is completed when acceptable measurement conditions continue for a determined duration.

Speedy: The measurement is completed automatically and the acceptability of the waveform is determined by the device.

Manual: The measurement is performed by depressing the foot switch.

⑦ DENSE CAT switch

OFF: A normal eyes are measured.

ON: An eye with a dense cataract are measured.

(The parameters are changed as follows: THRESHOLD to "Flat Low," gain to 100%, Axial Velocity to 1548 m/s and Lens Velocity to 1629 m/s. These parameters can be changed in the Utility screen.)

* This switch is not displayed when the Eye Type is Aphakic or IOL.

⑧ THRESHOLD switch

Pressed to change the programmed threshold which automatically determines the measurement value of each intraocular part. Each time this switch is pressed, the threshold indication below the switch changes among “Normal,” “Low,” and “Flat Low.”

* Generally set to “Normal”. If the measurement cannot be performed with an eye with mature cataract even by increasing the gain, the measuerment may become possible by changing the threshold to “Low” or “Flat Low.”

⑨ Measurement data list indication area

Up to 10 measurement values (three times of three measurement values (nine times in total) in Speedy mode) for axial length and each intraocular part are indicated. Whenever the measurement data is obtained, the average (Avg) and standard deviation (SD) in the list are calculated and indicated.

* The measurement value of each intraocular part varies according to the selected Eye Type as shown in the table below.

Eye type	Axial length	Anterior chamber depth	Lens thickness	Vitreous body length
Phakic	O	O	O	O
Phakic2	O	O	O	O
APhakic	O	-	-	-
IOL	O	O	-	O

⑩ Gate display

The specified gate can be moved using Knob 1.

⑪ Gain display

Displays the gain during the A-scan biometry.

The gain is adjusted with Knob 2.

⑫ PRINT switch

Pressed to print the data being displayed.

⑬ Data save switch

Pressed to save data.

⑭ CLEAR switch

Pressed to delete the measurement data in the measurement data list. Once the data is deleted, it cannot be restored.

⑮ DUAL switch

Pressed to display the DUAL window where data (waveform and measurement data) is read from the internal memory, USB flash drive, or the PC.

⑯ DELETE switch

Pressed to delete the measurement data in the list.

To delete data, highlight the data to delete by pressing it with the finger or stylus, then press the DELETE switch. When the DELETE switch is pressed, it changes to the RECALL switch which restores the deleted data.

⑰ SELECT switch

Pressed to decide the measurement data to be used for IOL power calculation.

When this switch is pressed, the "*" mark is attached to the selected data which is to be used for IOL power calculation.

If this function is not used, the average data is used for IOL power calculation.

* The A-scan biometry data to be used for IOL power calculation can also be input in the IOL power calculation screen.

⑱ BIO/IOL Select switch

Pressed to switch the A-scan biometry screen and IOL power calculation screen.

⑲ Gate display switch

Pressed to toggle display of each gate between ON and OFF.

⑳ Gate switch

Pressed to select the desired gate and enable or disable the manual gate function for each gate. Four gate types are available: Cornea, Lens-F (anterior), Lens-B (posterior), and Retina.

㉑ FREEZE/LIVE switch

Pressed to start or stop the A-scan biometry.

㉒ OD/OS switch

Pressed to change the eye to be measured.

1.5.2 IOL power calculation screen

① **A-scan biometry data**

A-scan biometry data is automatically input. The data also can be input manually.

② **Keratometer reading**

Corneal curvature radius (mm) and/or corneal refractive power (D) are input.

③ **Target**

Target postoperative refractive power is input.

④ **Formula switch**

Pressed to select the desired IOL formula.

⑤ **IOL Select switch**

Pressed to select IOLs to be used.

⑥ **IOL power calculation result table**

Displays the IOL power calculation results when the values required for the calculation are input. For each IOLs, IOL powers that are closest to the calculation result and the expected postoperative refractive power with those IOL powers are displayed. The highlighted row shows the values closest to the target postoperative refractive power.

⑦ **IOL Select switch**

Pressed to select the IOL to be used for surgery from IOL1 to IOL3.

The selected IOL is highlighted (white characters on a dark background) on the calculation result printout.

⑧Print switch

Pressed to print the calculation results.

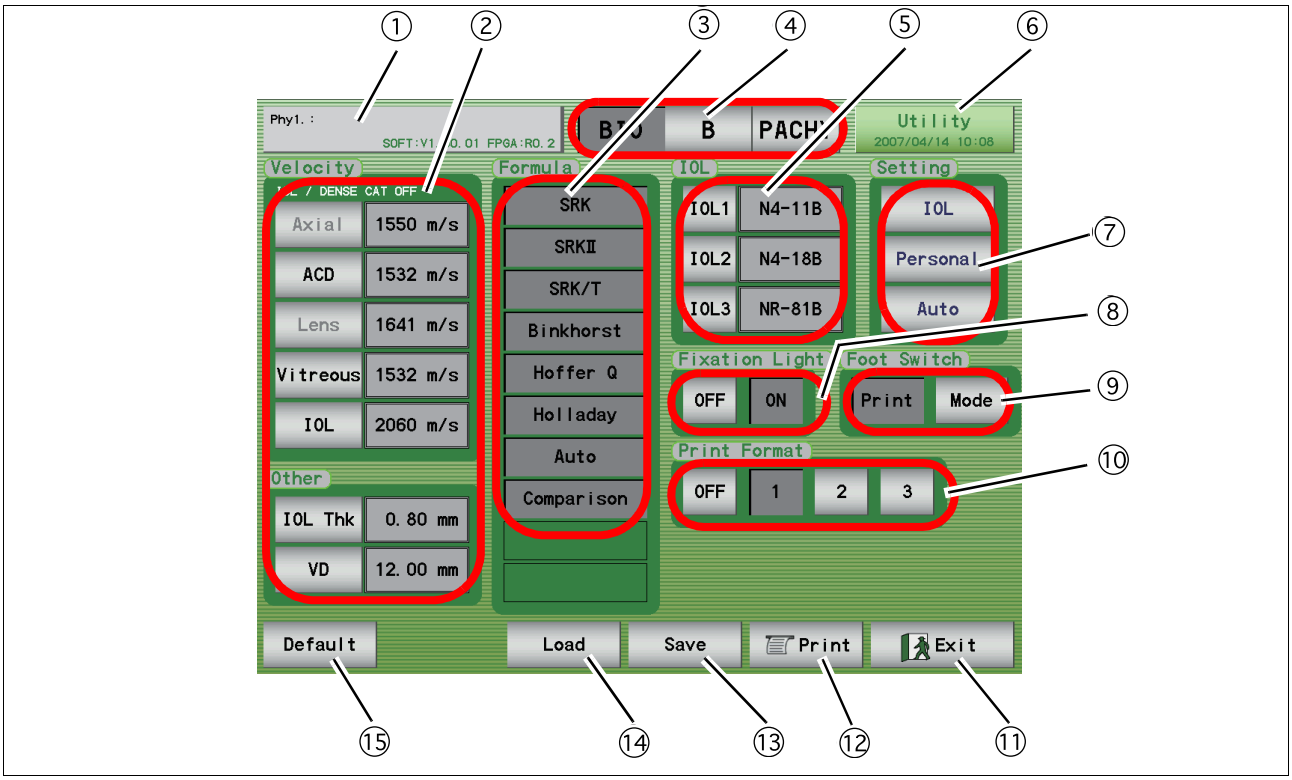
⑨BIO/IOL Select switch

Pressed to switch the A-scan biometry and IOL power calculation screens.

⑩OD/OS switch

Pressed to switch the eye to be measured.

1.5.3 A-scan biometry utility screen



① Physician switch

Pressed to select the physician (1 to 5) and register the Physician data.

Conditions set in ②, ③, ⑤ and ⑧ to ⑩ can be set for each physician.

② Velocity input area

Pressing each switch displays the ten-key window and the sonic velocity to calculate distance can be input.

Pressing the Default switch resets all the values to the default values.

③ Formula area

The IOL formula to be used in the IOL power calculation is selected. (Multiple formulas can be selected.)

④ Mode switches

Pressed to display the desired screen among the A-scan biometry, B-scan imaging, and Pachymetry utility screens.

⑤ IOL area

The IOLs used for IOL1, 2, and 3 are selected.

⑥ Utility switch

Pressed to display the Utility screen.

⑦ Setting switches

IOL switch: Pressed to register IOLs.

Personal switch: Pressed to calculate the Personal value.

Auto switch: Pressed to perform calculation for the selected IOL within the specified axial length.

⑧ Fixation Light switches

Pressed to toggle the fixation light in the A-scan probe between ON and OFF.

⑨Foot Switch switches

Pressed to toggle the function of the PRINT switch between printing and changing of the measurement mode.

⑩Print Format switches

Pressed to select the desired print format.

⑪Exit switch

Pressed to return to the A-scan biometry screen.

⑫PRINT switch

Pressed to print the A-scan biometry utility settings.

⑬Save switch

Pressed to save the A-scan biometry utility settings.

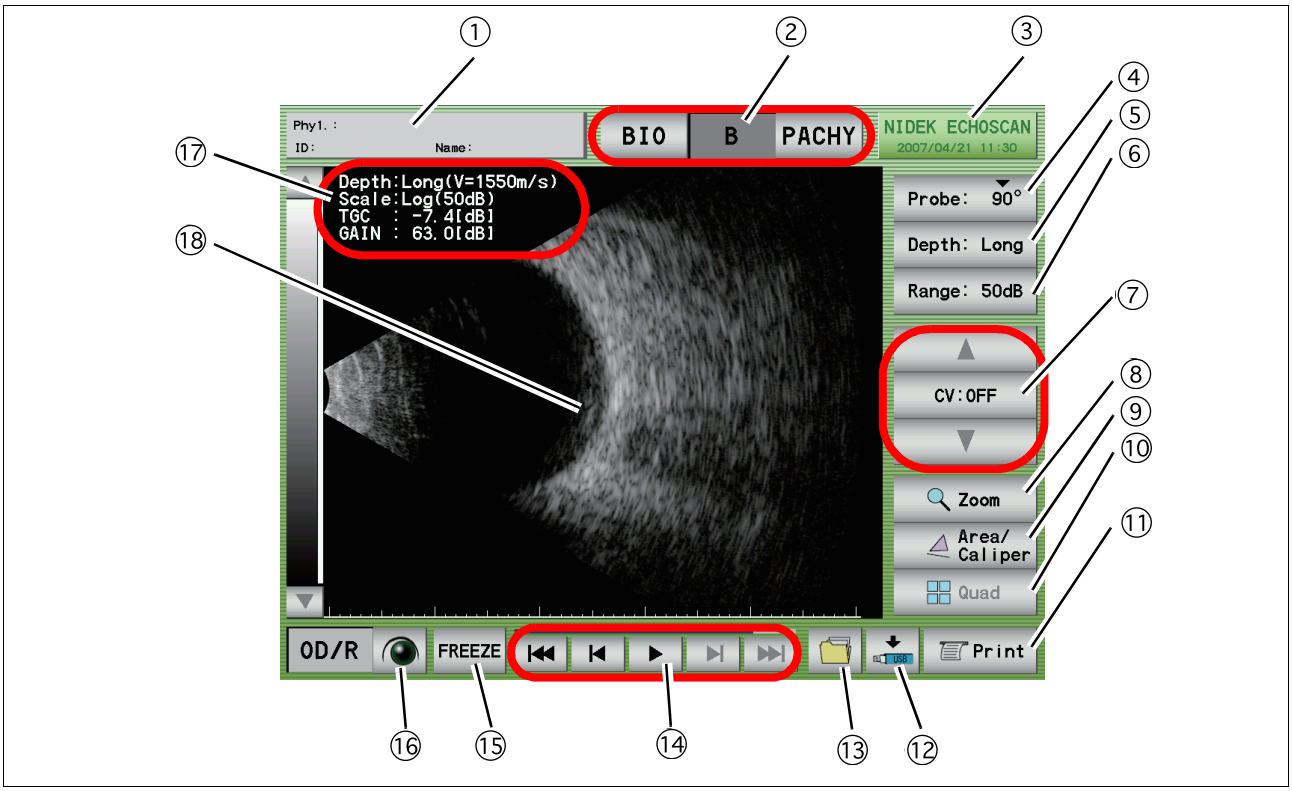
⑭Load switch

Pressed to return the A-scan biometry utility settings to the saved ones.

⑮Default switch

Pressed to return the A-scan biometry utility settings to the default.

1.5.4 B-scan imaging screen



① Patient switch

Pressed to register patient information and display the physician's name and the patient ID and name.

② Mode switches

Pressed to display the desired screen among the A-scan biometry, B-scan imaging, and Pachymetry screens.

③ Date and time switch

Displays the current date and time. Pressed to display the B-scan imaging utility screen.

④ Probe angle switch

Displays the angle of the probe on the eye to be measured. The default value is "90°" and each pressing of the switch increases the angle by 45°.

⑤ Observation depth switch

Pressed to switch the observation depth (from the tip of the probe).

Norm (35 mm) ⇔ Long (50 mm)

⑥ Display range switch

Pressed to change the display range.

Enabled when the gain curve pattern is set to "Log." The display range can be selected among 10, 20, 30, 40, and 50 dB.

⑦ CV (Cross Vector) mode switches

The triangle switches are pressed to move the cross ventor line. The CV switch in the center is pressed to toggle the CV mode between ON and OFF.

⑧ Zoom switch

Pressed to magnify the image on the screen to "×2.5" or "×5."

In the magificination screen, the image navigator "Zoom Navi" is displayed.

⑨ Area/Caliper screen switch

Pressed to display the Area/Caliper screen.

⑩ Four-image display switch

Pressed to display the Four-image display screen.

The Four-image display screen cannot be displayed if no data is saved in the internal memory.

⑪ Print switch

Pressed to print the data being displayed.

⑫ Data save switch

Pressed to save the measurement data to an external (USB flash drive or PC) or the internal memory.

⑬ Data read switch

Pressed to display the FILE window and read the data from the stored location.

⑭ Moving image operation switches

Pressed to play the moving image of about 20 seconds (200 frames) just before the FREEZE switch is pressed.

The saved moving image is deleted in the following cases:

When the LIVE condition is resumed
When power to the device is turned off
When a New Patient is added

⑮ LIVE/FREEZE switch

Pressed to start (LIVE) or stop (FREEZE) the measurement. The same operation can be performed with the foot switch.

⑯ OD/OS switch

Pressed to switch the eye to be measured.

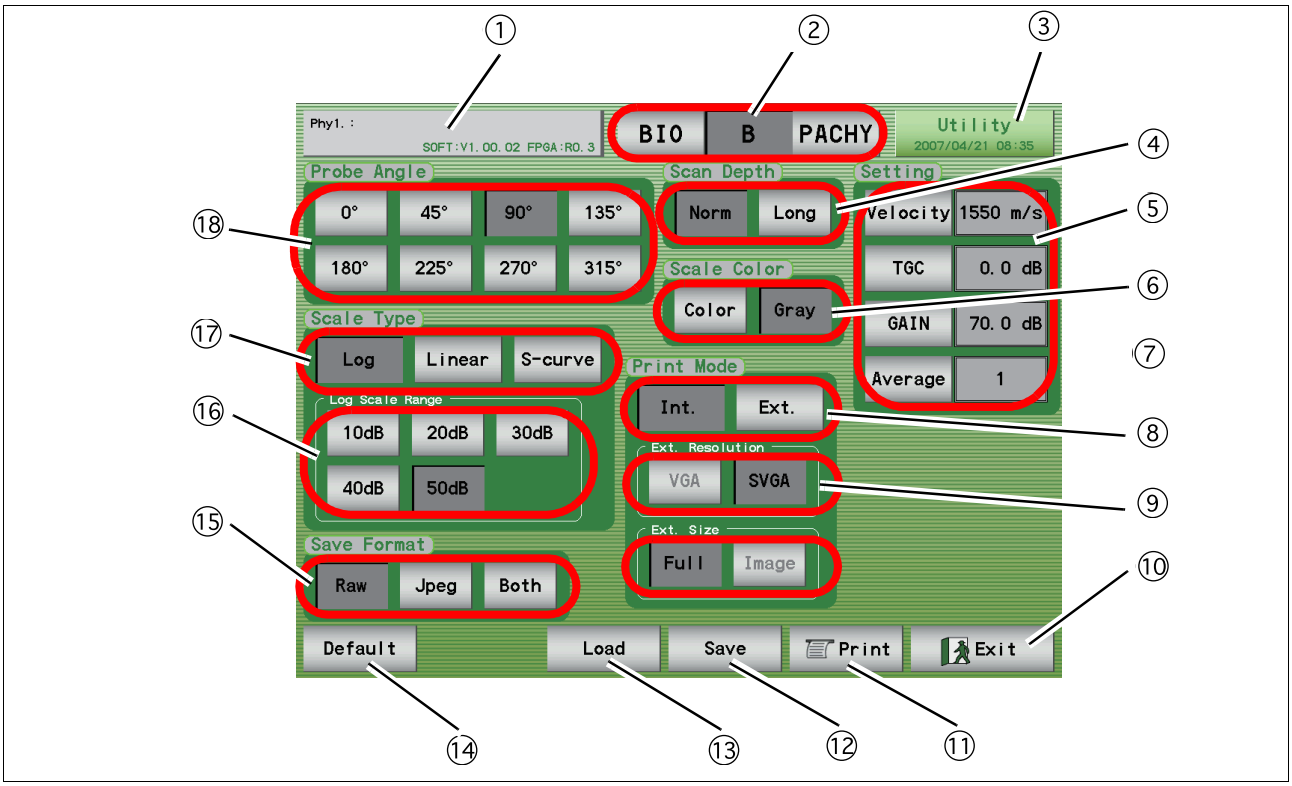
⑰ Measurement condition display

Displays the B-scan imaging conditions.

⑱ B-scan image display

Displays the B-scan image and cross-vector line.

1.5.5 B-scan imaging utility screen



① Physician switch

Pressed to select the desired physician (1 to 5) or register Physician data.

Conditions set in ④ to ⑨, and ⑮ to ⑱ can be set for each physician.

② Mode switches

Pressed to display the desired screen among the A-scan biometry, B-scan imaging, and Pachymetry utility screens.

③ Utility switch

Pressed to display the Utility screen.

④Scan Depth switches

Pressed to select the scan depth at the time of device power-up. (This setting can be changed in the B-scan imaging screen.)

⑤ Setting switches

Pressed to set the sonic velocity to calculate distance in B-scan imaging, TGC and GAIN at the time of device power-up, and the times of averaging (1 to 5) of the B-scan images.

⑥ Scale Color switches

Pressed to toggle the scale color between multiple colors and gray scale.

⑦ Print Mode switches

Pressed to toggle the printer for B-scan images between the built-in printer and an external printer.

⑧ **Ext. Resolution switches**

Pressed to toggle the resolution of an external printer between VGA (640 × 400) and SVGA (800 × 600).

⑨ **Ext. Size switches**

Pressed to toggle the area to be printed between Full (Entire screen) and Image (only waveform).

⑩ **Exit switch**

Pressed to return to the B-scan imaging screen.

⑪ **PRINT switch**

Pressed to print the B-scan imaging utility settings.

⑫ **Save switch**

Pressed to save the B-scan imaging utility settings.

⑬ **Load switch**

Pressed to return the B-scan imaging utility settings to the saved ones.

⑭ **Default switch**

Pressed to return the B-scan imaging utility settings to the default.

⑮ **Save Format switches**

Pressed to select the format of the data to be saved between "Raw (raw data)" and "Jpeg (Joint Photographic Experts Group)", or both.

⑯ **Log Scale Range switches**

Pressed to select the range level for when the scale type (gain curve) at the time of device power-up is "Log." (This setting can be changed in the B-scan imaging screen.)

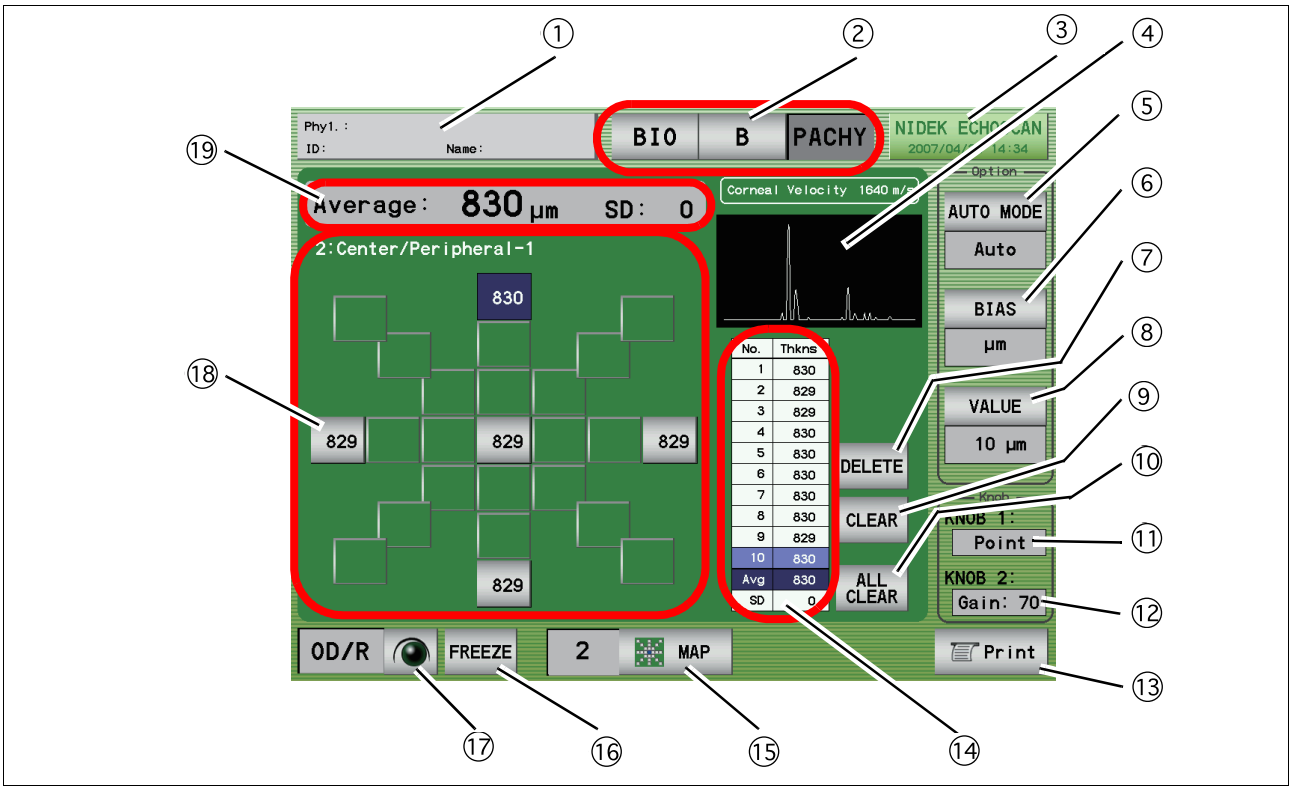
⑰ **Scale Type switches**

Pressed to select the gain curve to be used among “Log,” “Linear,” and “S-curve.”

⑱ **Probe Angle switches**

Pressed to set the probe angle at the time of device power-up. (This setting can be changed in the B-scan imaging screen.)

1.5.6 Pachymetry screen



① **Patient switch**

Pressed to register patient information and display the physician's name and the patient ID and name.

② **Mode switches**

Pressed to display the desired screen among the A-scan biometry, B-scan imaging, and Pachymetry screens.

③ **Date and time switch**

Displays the current date and time. Pressed to display the Pachymetry Utility screen.

④ **Waveform display area**

Displays the waveform during pachymetry.

⑤ **AUTO MODE switch**

Pressed to toggle the measurement mode between "Auto" and "Speedy."

⑥ **BIAS switch**

Pressed to change the displays of the pachymetry value.

Non: The measurement value is displayed as it is.
µm: The measurement value is displayed with a bias amount (-999 to 999 µm) added.
%: The measurement value is displayed multiplied by a bias rate (10 to 200%).

⑦DELETE switch

Pressed to delete the selected data in the list.

To delete data, highlight the data to delete by pressing it with the finger or stylus, then press the DELETE switch.

When the DELETE switch is pressed, it changes to the RECALL switch that restores the deleted data.

⑧ VALUE switch

Pressed to input the bias value. The bias values are not displayed when the BIAS switch is "Non."

⑨ CLEAR switch

Pressed to delete the measurement data at each measurement point.

⑩ ALL CLEAR switch

Pressed to delete all the measurement data of the measurement map.

⑪ Point display

The specified measurement point can be moved using Knob 1.

⑫ Gain display

Displays the gain during pachymetry measurement.

The Knob 2 is used to adjust the gain.

⑬ Print switch

Pressed to print the data being displayed.

⑭ Measurement value list

Displays the corneal thickness at the specified measurement point.

Displays the Measurement values and their average (Avg) and standard deviation (SD).

⑮ MAP switch

Pressed to change the measurement map.

Pressing this switch changes the Map number from 1 to 6.

* Six types of measurement maps are available.

⑯ LIVE/FREEZE switch

Pressed to start (LIVE) or stop (FREEZE) the measurement. The same operation can be performed with the foot switch.

⑰ OD/OS switch

Pressed to switch the eye to be measured.

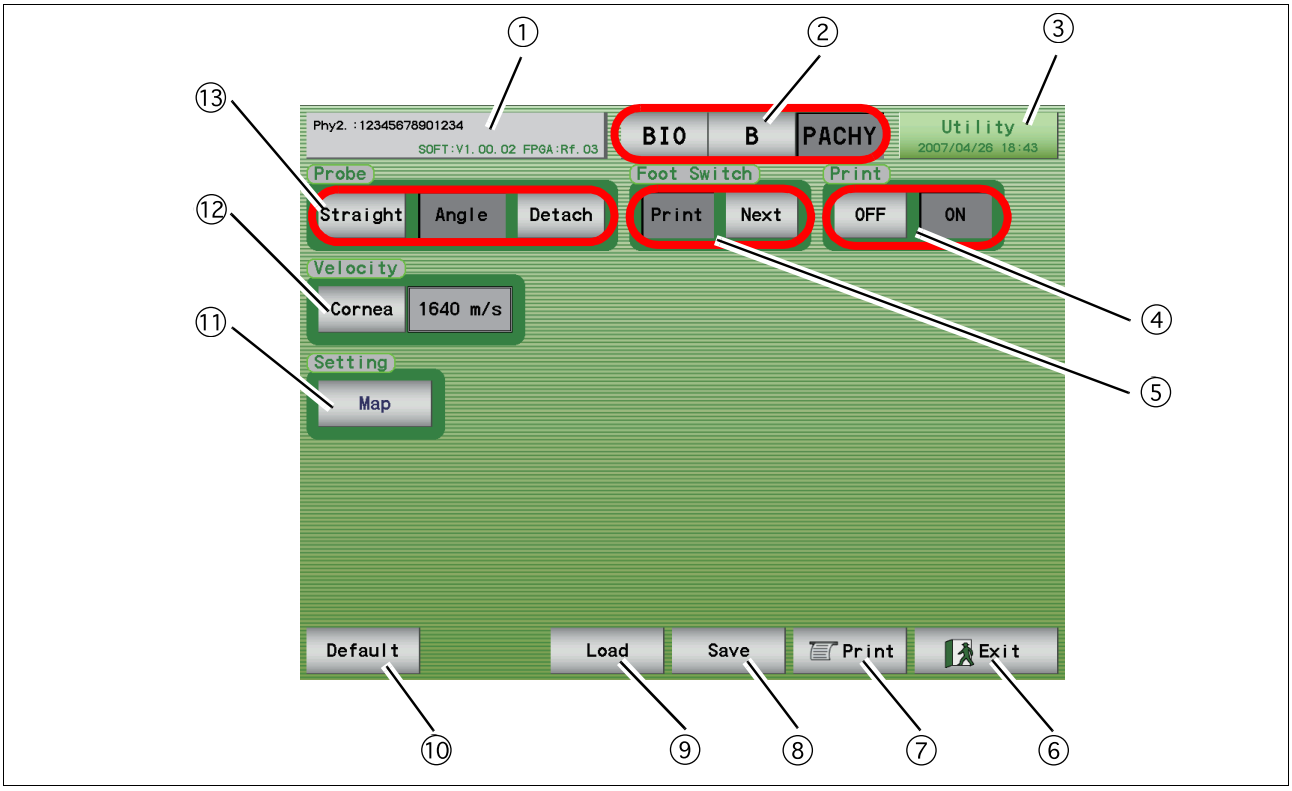
⑱ Measurement point display

Displays the measurement points. The measurement point can be moved by pressing the desired point on the screen.

⑲ Corneal thickness display

Displays the average and standard deviation of the measurement value list.

1.5.7 Pachymetry utility screen



① **Physician switch**

Pressed to select the desired physician (1 to 5) or register Physician data.

Conditions set in ④, ⑤, ⑫, and ⑬ and the Map No. selected in ⑪ can be set for each physician.

② **Mode switch**

Pressed to display the desired screen among the A-scan biometry, B-scan imaging, and Pachymetry utility screens.

③ **Utility switch**

Pressed to display the Utility screen.

④ **Print ON and OFF switches**

Pressed to enable or disable printing of the pachymetry results.

⑤ **Foot switch switches**

Pressed to toggle the function of the PRINT switch of the foot switch between “Print (printing)” and “Next (moving to the next measurement point)."

⑥ **Exit switch**

Pressed to return to the Pachymetry screen.

⑦**PRINT switch**

Pressed to print the Pachymetry utility settings.

⑧ Save switch

Pressed to save the Pachymetry utility settings.

⑨ Load switch

Pressed to return the Pachymetry utility settings to the saved ones.

⑩ Default switch

Pressed to return the Pachymetry utility settings to the default.

⑪Map switch

Pressed to set the map number for at the time of device power-up. (This setting can be changed in the Pachymetry screen.)

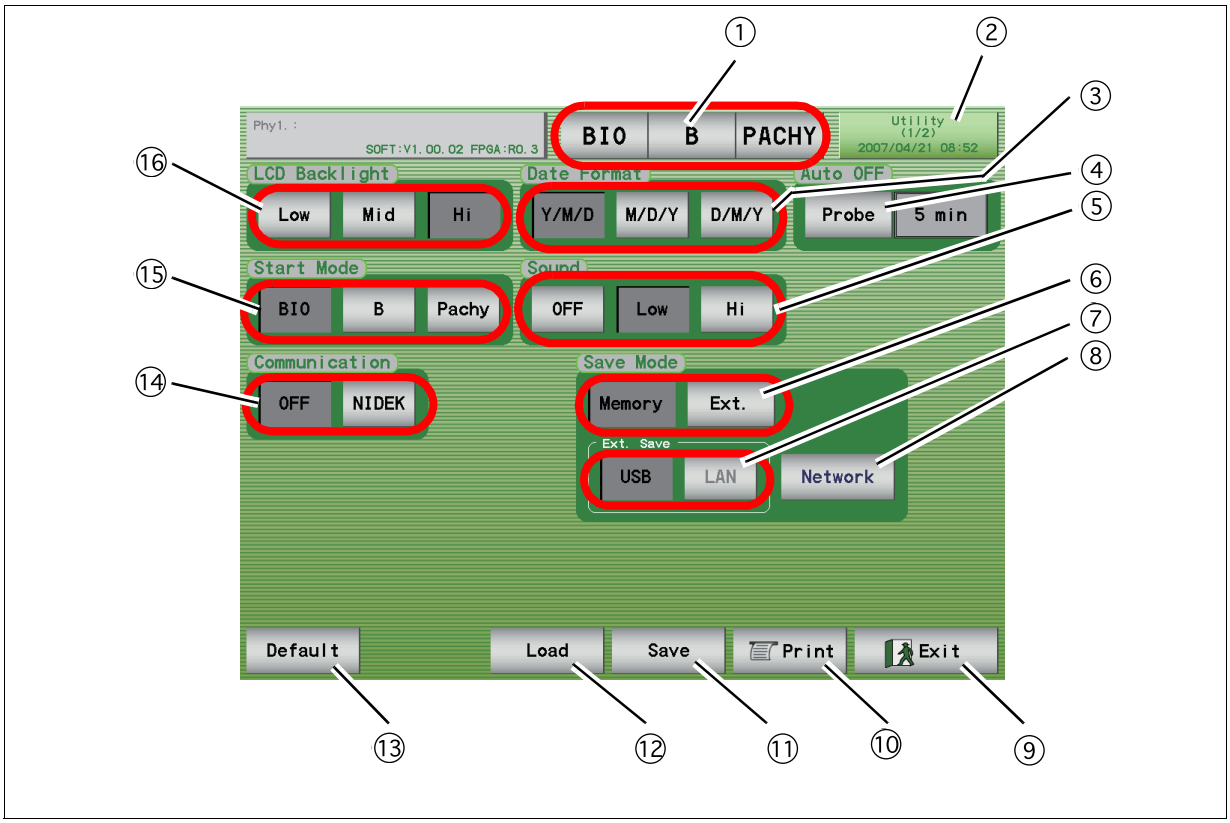
⑫Velocity switch

Pressed to set the sonic velocity to calculate distance.

⑬Probe switch

Pressed to select the type of the Pachymetry probe.

1.5.8 Utility screen (1/2)



① **Mode switch**

Pressed to display the desired screen among the A-scan biometry, B-scan imaging, and Pachymetry utility screens.

② **Utility switch**

Pressed to display the Utility (2/2) screen.

③ **Date Format switches**

Pressed to select the desired date display format.

④ **Auto OFF switches**

Pressed to set the maximum time of the LIVE condition.

⑤ **Sound switches**

Pressed to change the sound pitch. The sound can be turned off as well.

⑥ **Save Mode switches**

Pressed to toggle the location to save data between the internal or external memories.

⑦ **Ext. Save switches**

Pressed to toggle the external location to save data between "USB (USB flash drive)" and LAN (PC)."

⑧**Network switch**

Pressed to set the network.

⑨ **Exit switch**

Pressed to return to the measurement screen.

⑩ **Print switch**

Pressed to print the utility setting.

⑪ **Save switch**

Pressed to save the utility setting.

⑫**Load switch**

Pressed to return the settings to the ones saved in the Utility screen.

⑬**Default switch**

Pressed to return the utility setting to the default.

⑭**Communication switches**

Pressed to select communicaiton with the device (PC) that is connected using the external communication connector.

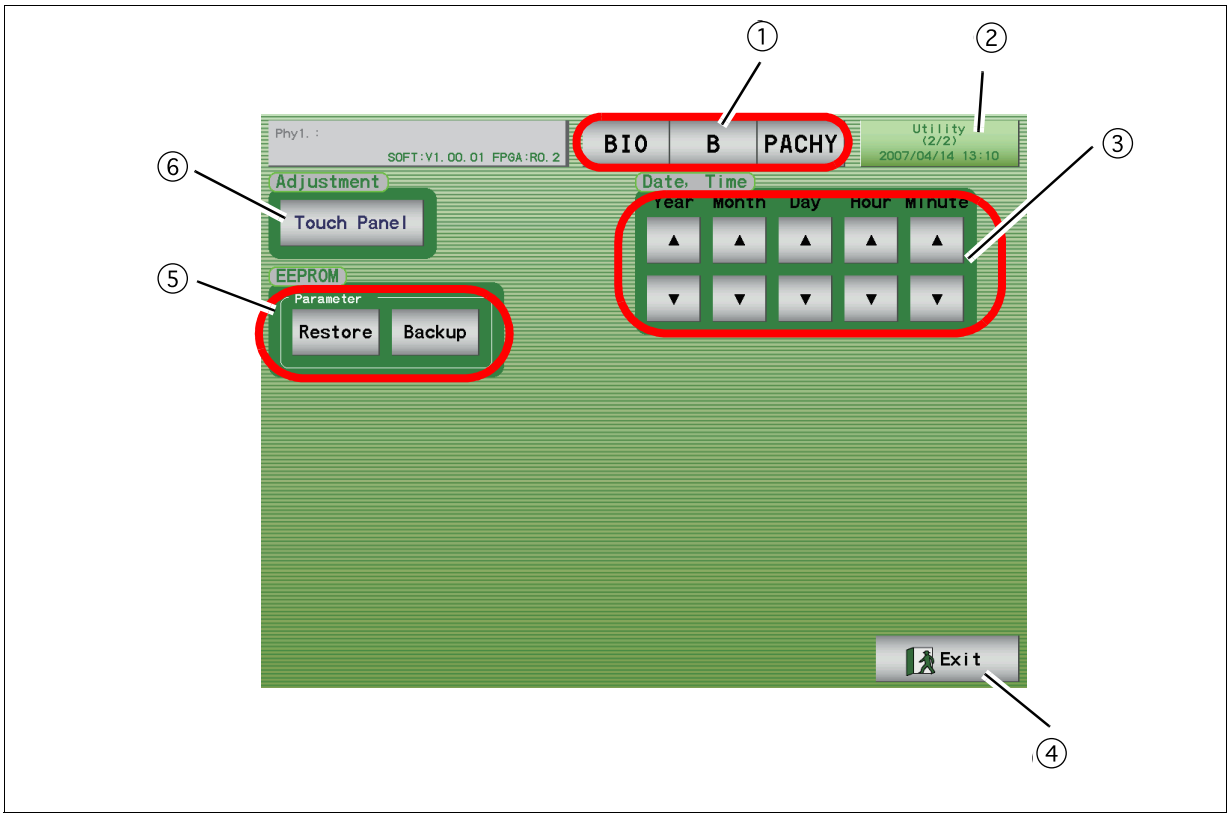
⑮**Start Mode switches**

Pressed to set the screen (A-scan biometry, B-scan imaging, and Pachymetry) for at the time of device power-up.

⑯**LCD backlight switches**

Pressed to select the brightness of the backlight.

1.5.9 Utility screen (2/2)



① **Mode switch**

Pressed to display the desired screen among the A-scan biometry, B-scan imaging, and Pachymetry utility screens.

② **Utility switch**

Pressed to display the utility (1/2) screen.

③ **Date and time switches**

Used to set the data and time by pressing the arrow switches.

④ **Exit switch**

Pressed to return to the measurement screen.

⑤ **Parameter switches**

Pressed to restore or backup the specified settings.

⑥ **Touch Panel switch**

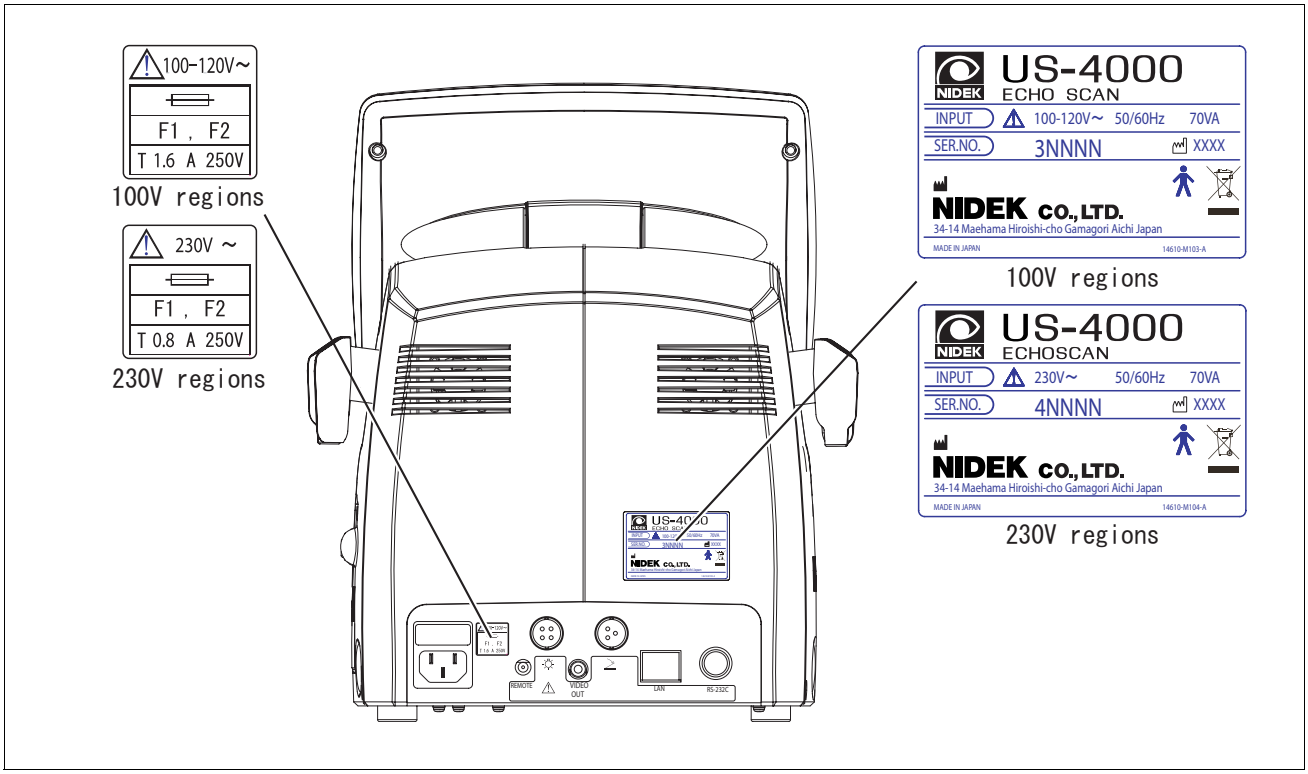
Pressed to adjust the displayed screen and the coordinates of the touch screen.

1.6 Labels and Indications on the Device

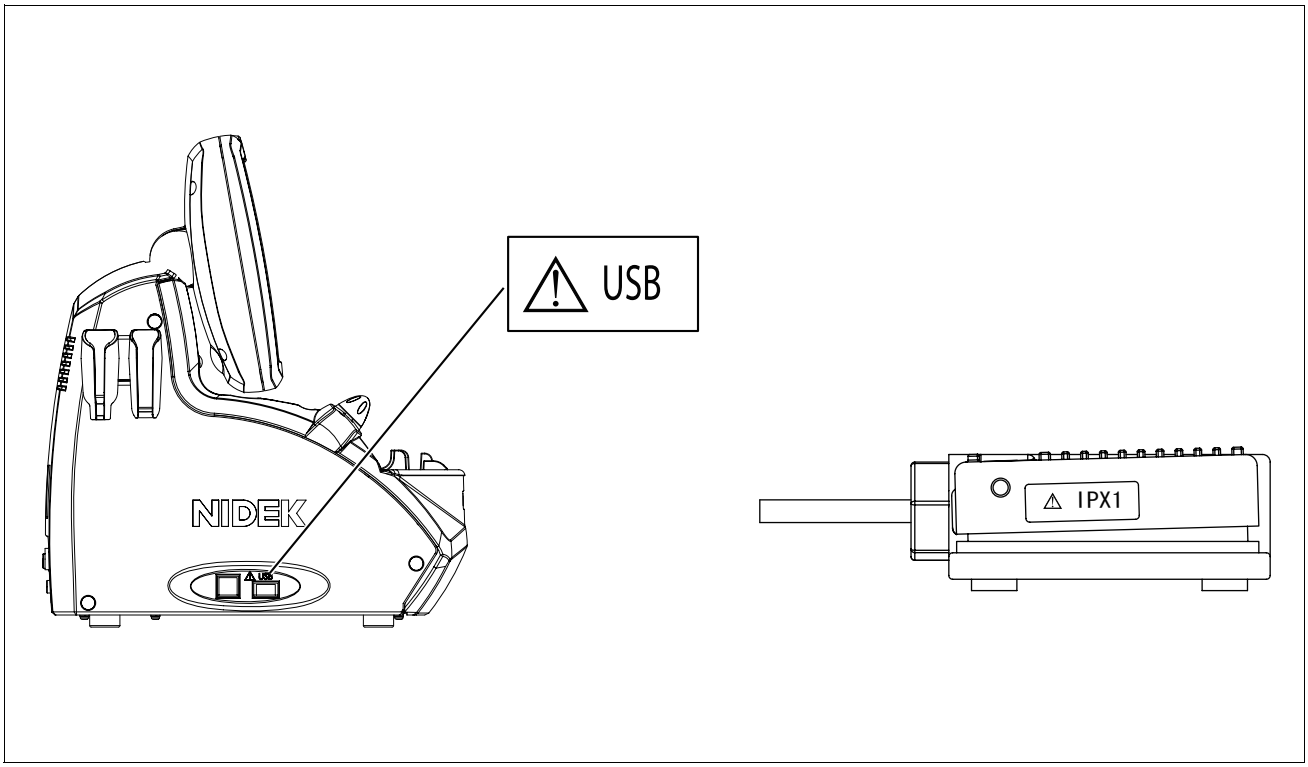
To call the operator’s attention, the device is provided with labels and indications.
If labels are curling up or characters are faded and become barely legible, contact NIDEK or your authorized distributor.

	Indicates that important descriptions are contained in the operator’s manual and that the operator must refer to the operator's manual prior to operation.
	Indicates that the degree of protection against electric shock is of a Type B Applied Part.
	Indicates that when the switch is pressed to this symbol side, power is not supplied to the device.
	Indicates that when the switch is pressed to this symbol side, power is supplied to the device.
	Indicates that the device must be supplied only with alternating current.
	Indicates the fuse rating.
	Indicates that the u pedal is to be connected to this port.
	Indicates the connector for the fixation lamp cable of the probe stand.
	Indicates the manufacturer.
	Indicates the date of manufacture.
	Indicates that this product shall be disposed of in a separate collection of electrical and electronic equipment in EU.

Rear view



Left side view



1.7 Checking Contents

Unpack the contents from the shipping carton and check if all the necessities are included.

The following is included into the standard configuration:

- Main body
- B-scan probe
- A-scan probe
- Pachymetry 45° probe
- Foot switch
- Test piece (for A-scan biometry)
- Test piece (for pachymetry)
- Printer paper
- Power cord
- Stylus
- Ultrasonic gel
- Dust cover
- Spare fuses
- Probe rest
- Operator's manaul

2. OPERATING PROCEDURES

2.1 Operation flow

Connecting accessories

"2.2 Device Setup (Page 32)"
"2.2.1 Connecting power cord (Page 32)"
"2.2.2 Connecting foot switch (Page 33)"
"2.2.3 Attaching probe rest (Page 33)"
"○ A-scan probe (Page 34)"
"○ Connecting B-scan probe (Page 35)"
"○ Connecting Pachymetry probe (Page 35)"
"2.2.5 Connecting Probe stand (optional) (Page 36)"

Preparing for measurement

"2.3 Preparation (Page 37)"
"2.3.1 Adding new patient data (Page 39)"
"2.3.2 Setting physician data (Page 41)"

Starting measurement

A-scan biometry

"2.4 A-scan Biometry (Page 44)"
"2.4.1 Basic operation of A-scan biometry (Page 44)"
"2.4.2 Cautions in A-scan biometry (Page 50)"
"2.4.3 Manual gate (Page 51)"
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"2.4.5 Comparison in DUAL screen (Page 56)"
"2.4.6 Setting A-scan biometry utility (Page 58)"
"○ Changing sonic velocity to calculate distance (Page 58)"
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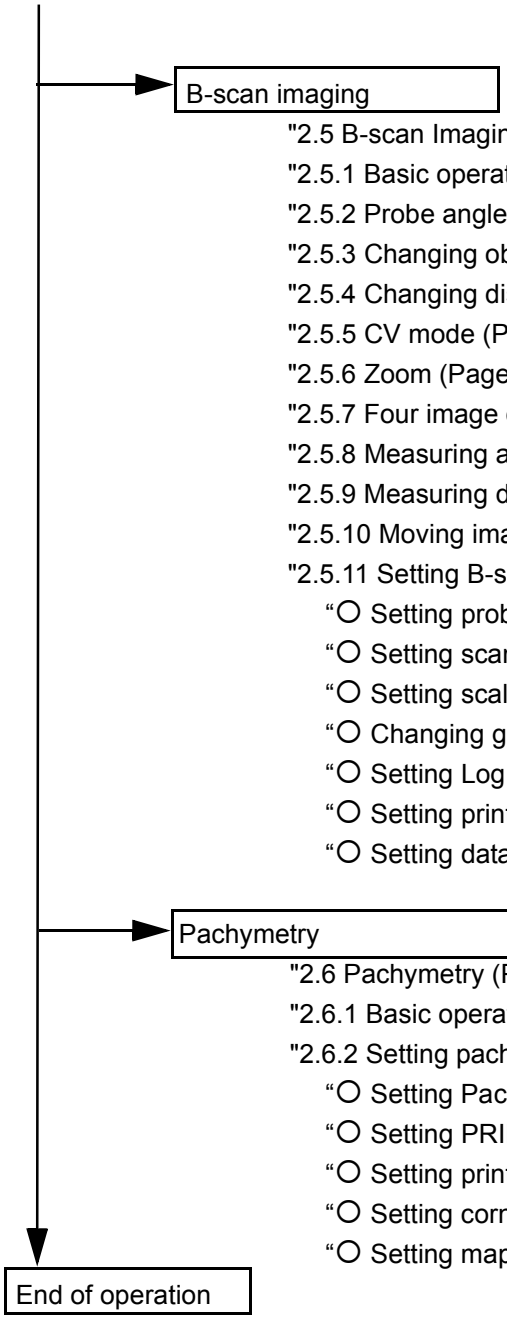
"○ Setting fixation light ON/OFF (Page 62)"
"○ Setting print format (Page 63)"
"○ Setting printer mode (Page 89)"
"○ Inputting IOL data (Page 64)"
"○ Calculating personal value (Page 66)"
"○ Setting IOL power calculation formula in specified axial length range (Page 69)"



"2.5 B-scan Imaging (Page 71)"
"2.5.1 Basic operation of B-scan imaging (Page 71)"
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"2.5.7 Four image display (Page 79)"
"2.5.8 Measuring area on B-scan imaging screen (Area screen) (Page 81)"
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- “O Setting probe angle (Page 86)”
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"2.6 Pachymetry (Page 91)"
"2.6.1 Basic operation of pachymetry (Page 91)"
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- “O Setting map selected at device power-up (Page 97)”

"2.8 Completion of Operation (Page 109)"

Initial setting

2.2 Device Setup

2.2.1 Connecting power cord

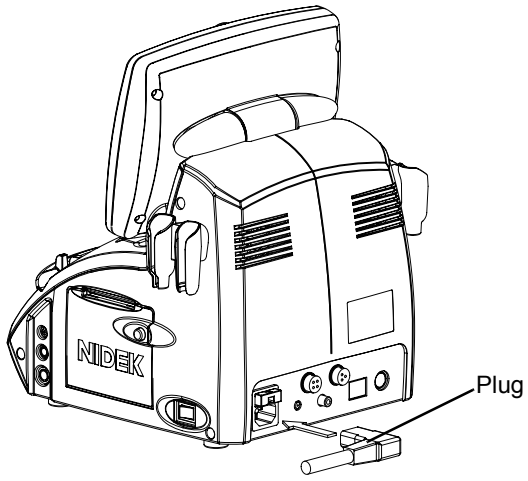
1 Turn off the power switch.

2 Securely connect the power cord to the inlet on the rear side of the device while adjusting the direction of the plug to the inlet.

3 Position the power cord so that it does not interfere with operation.

4 Securely connect the plug of the power cord to a wall outlet with a protective ground.

* Be sure to connect the power cord to the power outlet with a protective ground.

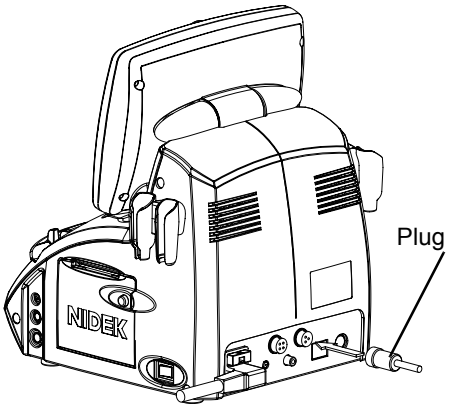


2.2.2 Connecting foot switch

1 Set the foot switch in a convenient position, and position the cable so that it does not interfere with operation.

2 Align the notch of the foot switch cable plug, and connect it to the connector on the rear side of the device.

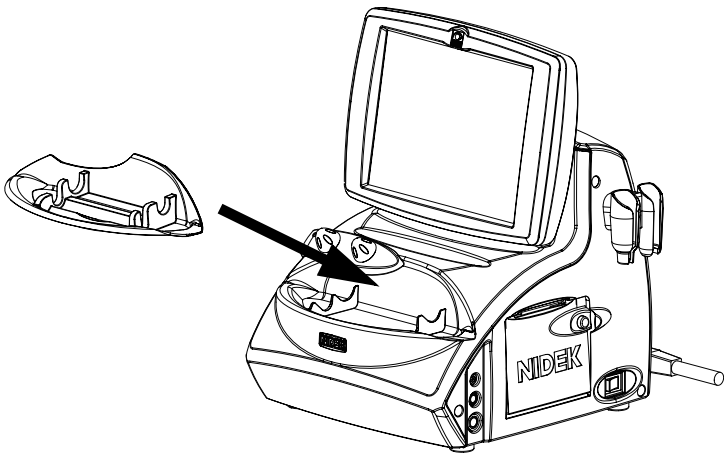
3 Rotate the knurled ring of the plug clockwise to secure.



2.2.3 Attaching probe rest

1 Attach the probe rest to the main body of the device.

Attach the probe rest so that it fits the shape of the main body.

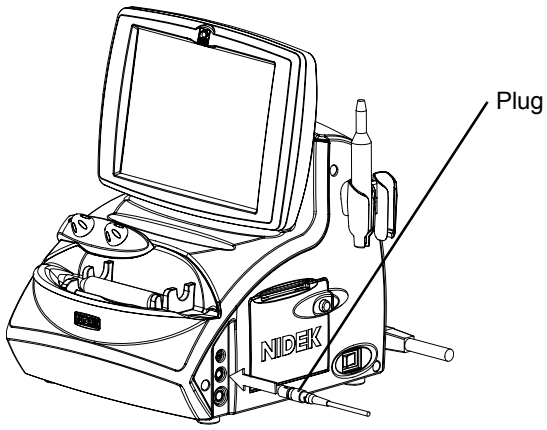


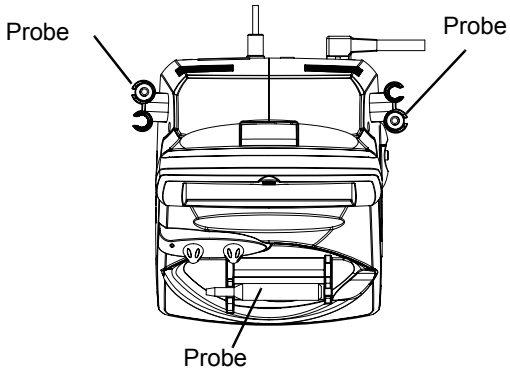
2.2.4 Connecting probe

○ A-scan probe

1 Align the red mark of the cable plug of the probe with that of the probe connector (BIO) on the front side of the device, and insert the plug as far as it goes.

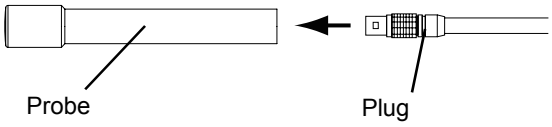
2 Place the probe on the probe rest of the device.





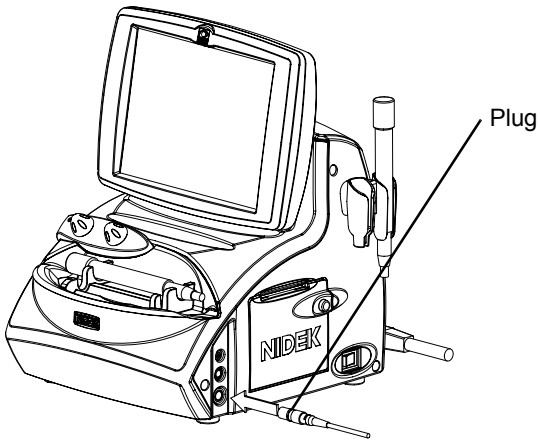
○ Connecting B-scan probe

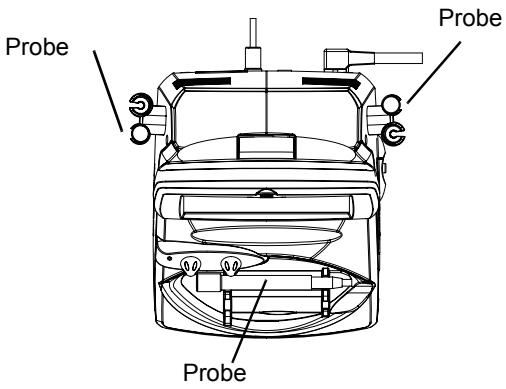
1 Connect the probe and the plug of the probe cable.



2 Align the red mark of the cable plug of the probe with that of the probe connector (B) on the front side of the device, and insert the plug as far as it goes.

3 Place the probe on the probe rest of the device.

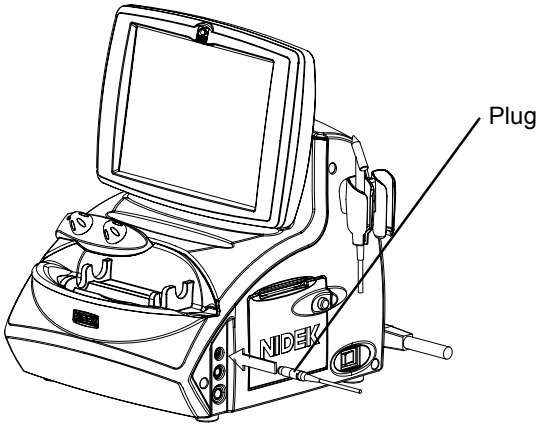


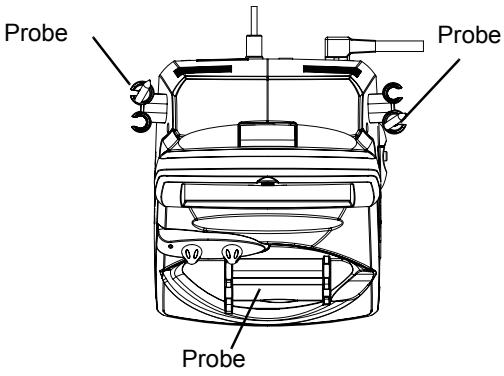


○ Connecting Pachymetry probe

1 Align the red mark of the cable plug of the probe with that of the probe connector (P) on the front side of the device, and insert the plug as far as it goes.

2 Place the probe on the probe rest of the device.



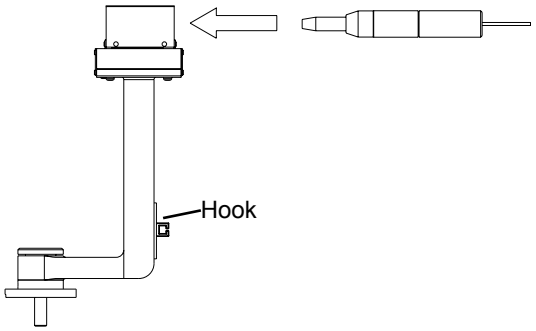


2.2.5 Connecting Probe stand (optional)

○ Attaching A-scan probe

1 Hold the probe holder of the probe stand with one hand so that it does not move.

2 Insert the probe held by the other hand from the physician's side of the probe holder. At this time, pay attention not to contact the probe tip with the probe holder**.**



3 Fasten the probe cable on the hook with the probe holder moved to the patient's side. At this time, loop the probe cable twice on the hook while leaving enough slack.

4 Connect the probe to the device referring to "○ Attaching A-scan probe (Page 36)."

○ Attaching cable for fixation lamp

1 Position the illumination cable so that it does not interfere with the operation.

2 Align the notch of the other side of the plug to the connector for the external fixation lamp connector on the rear side of the device.

3 Insert the plug directly, and turn the knurled ring of the plug clockwise to secure.

2.3 Preparation

1 Turn ON (|) the power switch on the right side of the device.

The pilot lamp on the front side of the device lights up with a beep sound, and the opening screen appears.

After a few seconds, the screen becomes the A-scan biometry screen automatically.

If it is hard to see the indications on the screen, rotate the legs to adjust the inclination of the device.

⚠ **CAUTION** • Remove the USB flash drive when turning ON power to the US-4000.
Data may become corrupted.

2 Check the system.

Check the device referring to "4.1 Checks Before Use (Page 117)".

After checks, record each result in the list "4.3 Check List (Page 121)".

3 Disinfect the probe.

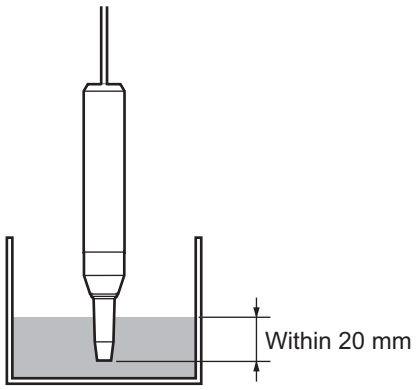
Disinfect the probe with the power switch of the device OFF.

Before measurement, be sure to disinfect the probe for every patient.

When using the probe stand, disinfect the forehead rest and chinrest with gauze dampened with ethanol.

1) If the tip of the probe is contaminated, clean it as necessary.

2) Soak the probe tip (max. 20mm) in the following or for 10 minutes.



0.1% Chlorhexdine Gluconate Solution

Ethanol for disinfection

3) Wipe the probe tip, which was soaked in the disinfection solution, with the disinfected absorbent gauze dampened with ethanol.
4) Dry the probe.

4 Prepare the patient.

For A-scan biometry or pachymetry

1) Apply the surface anesthesia to the patient's eye to be measured.
2) Ask the patient to take a posture suitable for the measurement.
3) Apply the corneal protection agent to the probe tip if necessary.

   Be sure not to apply too much corneal protection agent to avoid interference with measurement.

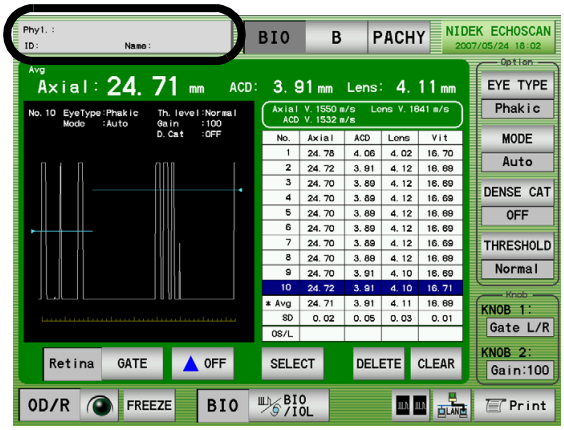
For B-scan imaging

1) Apply the ultrasound gel to the patient's eyelid.

2.3.1 Adding new patient data

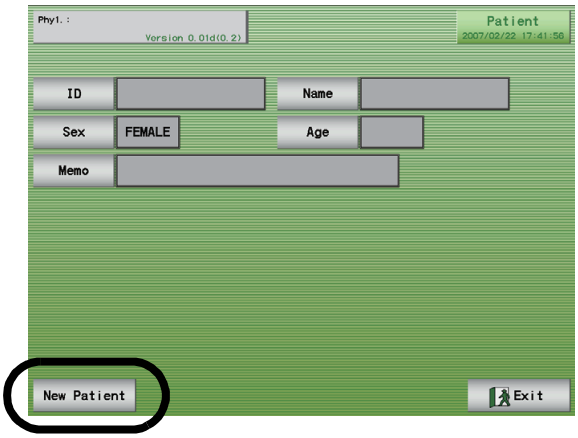
New patients can be added in the A-scan biometry, B-scan imaging, IOL power calculation, and Pachymetry screens.

1 Pressing the Patient switch displays the screen shown in Step 2.



2 To add a new patient to the Patient list, press the New Patient switch.

Pressing this switch deletes the saved patient information and measurement results and blanks the fields beside the switches.



3 Press the ID switch to input or change the patient's ID. Then press the Enter switch.

Pressing the ID switch enables input of characters using the keyboard window.

* A maximum of 14 characters can be input.

4 Press the Name switch to input or change the patient's name. Then press the Enter switch.

Pressing the Name switch enables input of characters using the keyboard window.

* A maximum of 14 characters can be input.

5 Press the Sex switch select the sex of the patient.

Pressing the Sex switch displays "MALE" and "FEMALE" alternately in the field beside the switch.

6 Press the Age switch to input or change the patient's age. Then press the Enter switch.

Pressing the Age switch enables input of characters using the ten-key window.

* Numerical characters can be input in the range from 0 to 200.

7 Press the Memo switch to input or change the comments on the patient. Then press the Enter switch.

Pressing the Memo switch enables input of characters using the keyboard window.

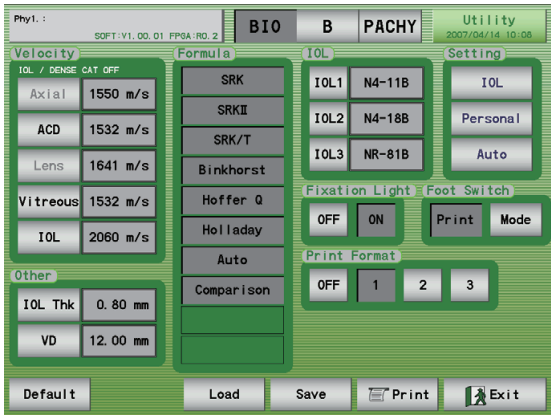
* A maximum of 34 characters can be input.

8 Press the Exit switch to return to the measurement screen.

2.3.2 Setting physician data

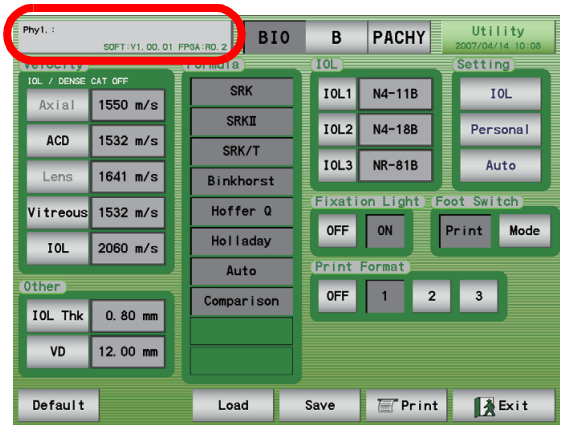
A maximum of five physicians can be saved with individual settings.

1 Press the switch that displays the date and time in the A-scan biometry, IOL power calculation, B-scan imaging, or Pachymetry screen.



2 Press the Physician switch to display the setting of the physician to check or change.

Each time the Physician switch is pressed, the next physician number and the settings are displayed.



3 Holding down the Physician switch displays the keyboard window. If necessary, input or change the physician's name and press the Enter switch.

* A maximum of 14 characters can be input.

4 If necessary, change the sonic velocity to calculate distance.

Pressing the switches listed below displays the ten-key window that can be used to input and change the sonic velocity to calculate distance required for the calculation in the A-scan biometry, pachymetry, and IOL power calculation.

Pressing the Default switch returns all the settings to the default.

The switches and their default input value and input range are as shown in the table below.

Switch	Input value	Default value	Input range
Axial (Aphakic)	Axial length average sonic velocity to calculate distance	1550 m/s (1532 m/s)	1000 to 2000 m/s
ACD	Anterior chamber sonic velocity to calculate distance	1532 m/s	1000 to 2000 m/s
Lens (DENSE CAT ON)	Lens sonic velocity to calculate distance	1641 m/s (1629 m/s)	1000 to 2000 m/s
Vitreous	Vitreous body conversion sonic velocity	1532 m/s	500 to 2000 m/s
IOL	IOL sonic velocity to calculate distance (acrylic)	2060 m/s	500 to 3000 m/s
Cornea	Cornea sonic velocity to calculate distance	1640 m/s	1000 to 2000 m/s
IOL Thk	IOL thickness	0.80 mm	0.02 to 5.00 mm
VD	Vertex distance	12.00 mm	0.00 to 20.00 mm

* If the Eye Type is "Aphakic" (aphakic eye), the measurement is performed with the sonic velocity to calculate distancesonic velocity to calculate distance as specified with the switches above.
* If the DENSE CAT is "ON", the measurement is performed with the sonic velocity to calculate distance as specified with the switches above.

5 If necessary, change the IOL formula used for IOL power calculation.

Select the desired IOL formula under "Formula."

6 If necessary, input or change the IOL data used for IOL power calculation.

Pressing the IOL switch displays the screen for presetting the IOL data to be used for IOL power calculation.

When the IOL settings are present in this screen, the IOL power can be calculated soon after A-scan biometry.

* For details, see "○ Inputting IOL data (Page 64)."

7 If necessary, calculate the Personal value.

Pressing the Personal switch displays the Personal value calculation screen where the physician inputs various data for the preoperative and postoperative measurement to be calculated.

8 If necessary, change the print format.

Change the print format by pressing any of the switches next to “Print Format”: OFF, 1, 2, or 3.

For details of the print format, see "○ Setting print format (Page 63)."

9 Press the Save switch to save the settings.

To reset to the previous data, press the Load switch.

* If the Save switch is not pressed, the settings in this screen are not saved in the device.

10 If necessary, press the Print switch to print the various data in the screen.

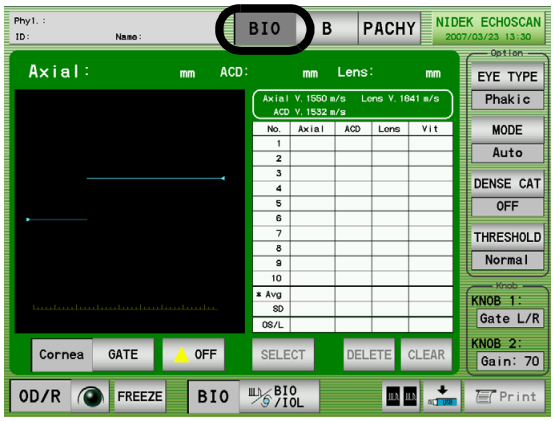
11 To confirm or change the data setting for other physicians, return to Step 2.

12 Press the Exit switch to return to the measurement screen.

2.4 A-scan Biometry

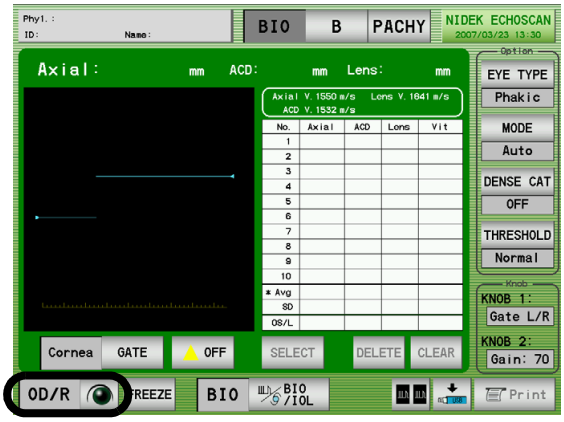
2.4.1 Basic operation of A-scan biometry

1 Press the BIO switch to display the A-scan biometry screen.



2 Press the OD/OS switch to select the right or left eye to be measured.

Each time the switch is pressed, the eye to be measured indicated above the switch is toggled between “OD/R” (right eye) and “OS/L” (left eye).



3 Press the EYE TYPE switch to specify the patient’s eye type.

Each time the switch is pressed, the patient’s eye type indicated above the switch is changed in the order of “Phakic”, “Phakic2”, “Aphakic”, “IOL” and “Phakic”.

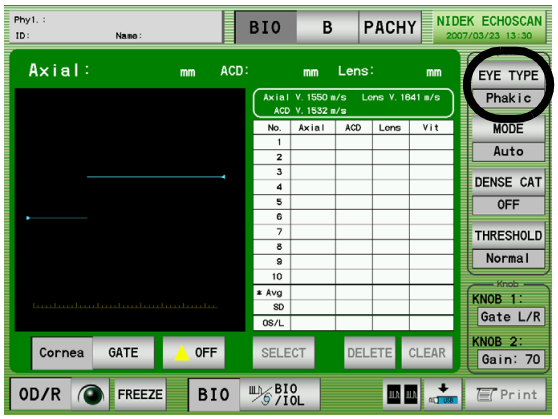
* When the patient’s eye type is changed, contents of the sonic velocity to calculate distance indicated on the left side of the switch are also changed. The patient’s eye type and sonic velocity to calculate distance are as follows:

Phakic: sonic velocity to calculate distance of average (Axial V.), anterior chamber depth (ACD V.) and lens thickness (Lens V.)

Phakic2: sonic velocity to calculate distance of anterior chamber depth (ACD V.), lens thickness (Lens V.) and vitreous length (Vit V.)

Aphakic: sonic velocity to calculate distance of aphakic eye (Axial V.)

IOL: sonic velocity to calculate distance of anterior chamber depth (ACD V.), IOL (IOL V.) and vitreous length (Vit V.) and IOL thickness (IOL Thk.)



4 Press the MODE switch to specify the measurement mode.

Each time the switch is pressed, the measurement mode indicated above the switch is changed among “Auto,” “Speedy,” and “Manual.”

Auto: The measurement conditions are evaluated when the measurement is started.

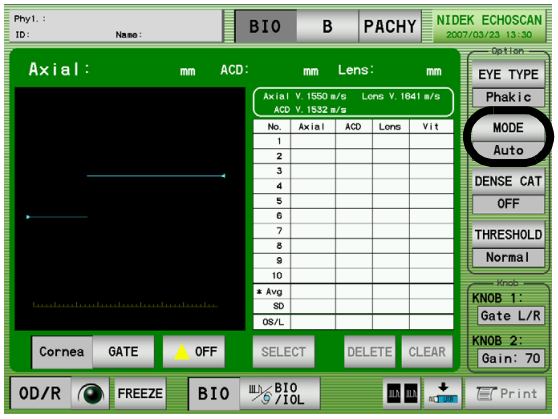
When the measurement conditions are acceptable, a beep sounds and data sampling is performed. The stability of the measurement data is continuously evaluated during the data sampling. When ten sets of data with the stability of ±0.1 mm are obtained, a beeping sounds and the measurement is automatically stopped.

Speedy: Data sampling begins when the measurement is started. The measurement automatically stops when three sets of data is obtained.

The measurement data of the past three times are listed. If the measurement is performed more than three times, the oldest three sets of data is deleted.

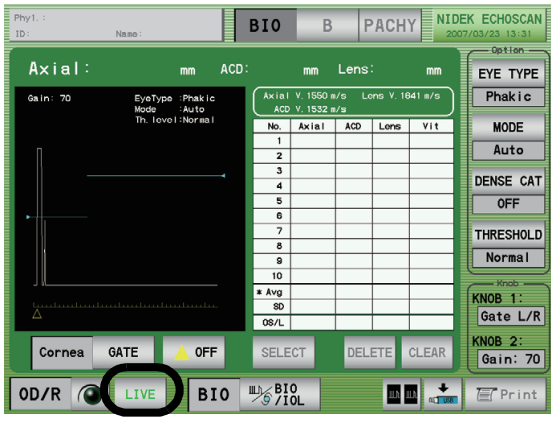
Manual: The physician performs data sampling when the measurement is started.

The measurement automatically stops when 10 sets of data are obtained.



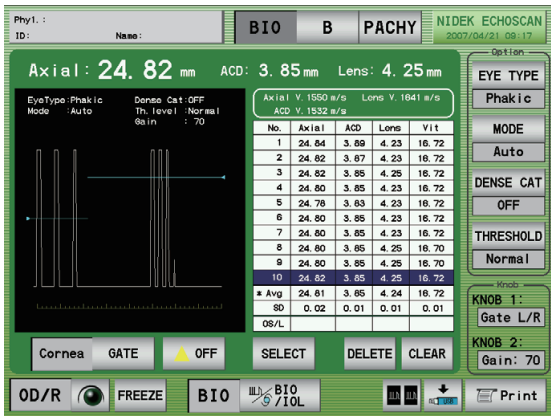
5 Press the FREEZE switch or the MEASURE switch of the foot switch to start A-scan biometry.

The indication of the switch becomes “LIVE”, and A-scan biometry starts.



6 Put the A-scan probe on the center of the cornea.

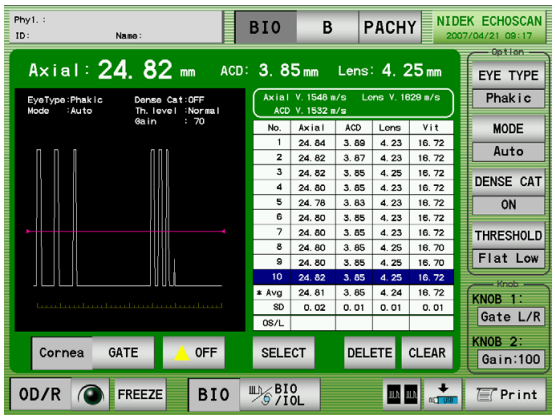
1) A-scan waveform appears, and A-scan biometry is performed according to the selected measurement mode.



2) Adjust the gain by rotating Knob 2 so that a proper A-scan waveform can be obtained. The gain can be changed in the range between 0 and 100 in 10 dB increments.

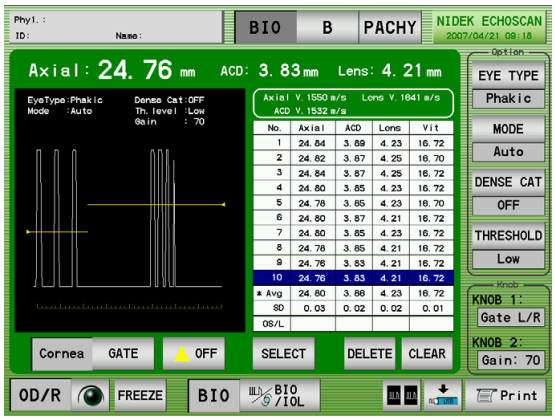
* The most recently selected gain is indicated in this screen after the device power is turned ON again.

3) To measure eyes with hypermature cataract, press the DENSE CAT switch.



4) If necessary, press the THRESHOLD switch to change the programmed threshold among "Normal," "Low," and "Flat Low" with which the program determines the acceptability of the measurement value of each intraocular part.

* If there is an additional echo near the threshold preceding any of the valid echoes, redo the measurement referring to "2.4.3 Manual gate (Page 51)".



Note

- When the patient's eye type is Aphakic, the anterior chamber depth (ACD), lens thickness (Lens) and vitreous length (Vitreous) are not measured. For IOL implanted eyes, the lens thickness (Lens) is not measured and the value between the cornea and the front surface of the IOL is indicated as the anterior chamber depth (ACD).
- The Auto mode is an auxiliary function to facilitate the A-scan biometry operation. It is not intended for clinical judgement. When using the values obtained in Auto mode for IOL power calculation, physicians have to examine the obtained values.

7 Repeat Step 5.

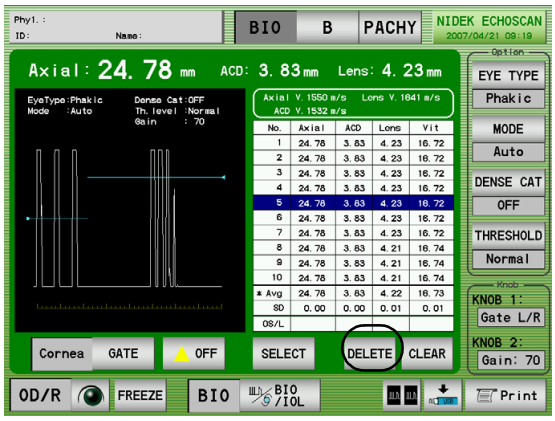
Repeat Step 5 several times to ensure validity of the obtained data.

Up to 10 sets of data of the axial length and each intraocular part can be indicated on the list.

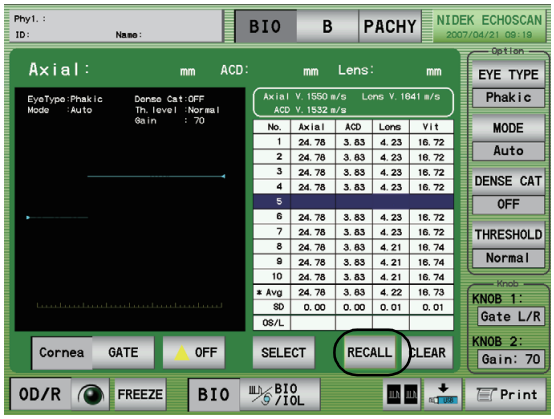
8 Arrange the data if necessary.

To delete data due to fluctuations compared to other data, arrange the data according to the procedure below.

To delete one set of data, highlight the data with the stylus or finger and press the DELETE switch.

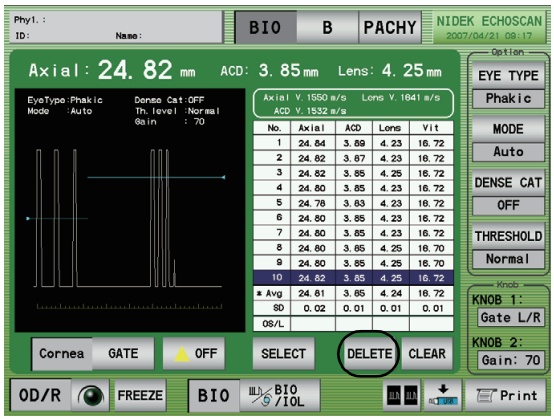


To undo deletion of a set of data, highlight the No. of the deleted data with the stylus or finger and press the RECALL switch.



To delete all the measured data on the list, press the CLEAR switch. (However, this deletion cannot be undone. Care should be taken when data is deleted in this manner.)

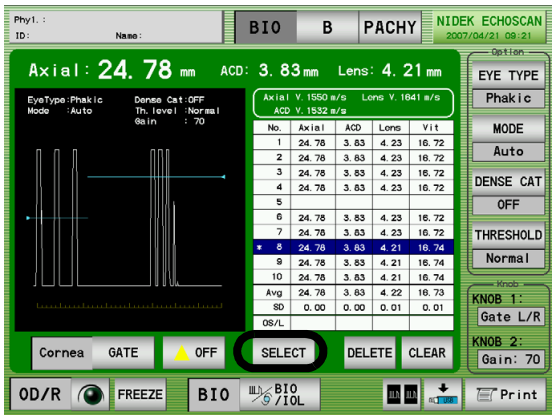
* Each time the data is deleted and the deletion is undone, the average (Avg) and standard deviation (SD) are recalculated.



9 If necessary, select the measured data used for IOL power calculation.

To use the measurement data in the data list, highlight the data with the stylus or finger, and press the SELECT switch to enter. (The "*" mark is indicated next to the No. of the selected data.)

* If this setting is not performed, the average value is used for IOL power calculation.



10 Press the Data save switch to save the data obtained in the A-scan biometry screen.

In this window, a maximum of 12 sets of measurement data displayed in the A-scan biometry screen can be saved (to the internal memory) with the date and patient's name. A maximum of 1000 sets of measurement data can be saved in an external memory.

2.4.2 Cautions in A-scan biometry

To carry out A-scan biometry smoothly and accurately, pay attention to the following:

(1) Instruct the patient not to move their eyes.

If the patient is nervous, instruct them to relax.

(2) Confirm that the probe is in contact with the center of the cornea.

Contact between the probe and the cornea is an important factor in obtaining accurate A-scan biometry values. Change the probe contact angle so that a proper A-scan waveform is obtained.

A proper A-scan waveform means that it has echoes from the following three parts: the cornea, and the anterior and posterior surfaces of the lens. An proper A-scan waveform has also a large retinal echo which rises sharply accompanying a small scleral echo.

When the echoes of the retina and sclera are not separated, rotate Knob 2 to decrease the gain.

(3) Check the following points before freezing the obtained A-scan biometry value:

a) Has a proper A-scan waveform been obtained?

b) Is the probe in contact with the cornea properly?

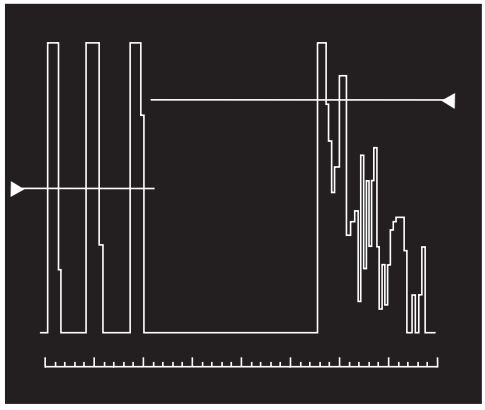
c) Is the patient's eye fixed?

d) Are the obtained values stable? (Is the variations in the obtained values within ±0.05 mm?)

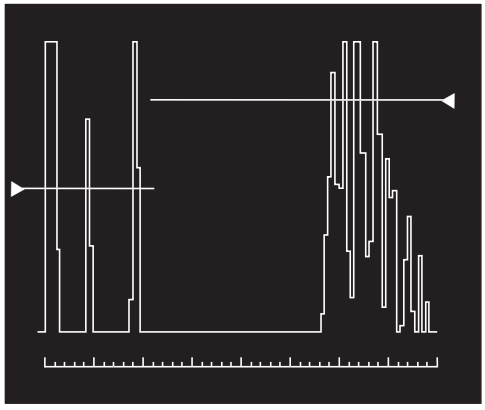
* If the A-scan biometry is performed hurriedly, accurate values cannot be obtained. Take enough time for the A-scan biometry.

(4) In Auto mode, if the display does not stop (FREEZE) even when the obtained values are indicated, the retinal echo may have not risen properly or there is no lens echo or it is too weak.

Change the contact and angle of the probe so that a proper waveform as shown below is obtained.



Proper

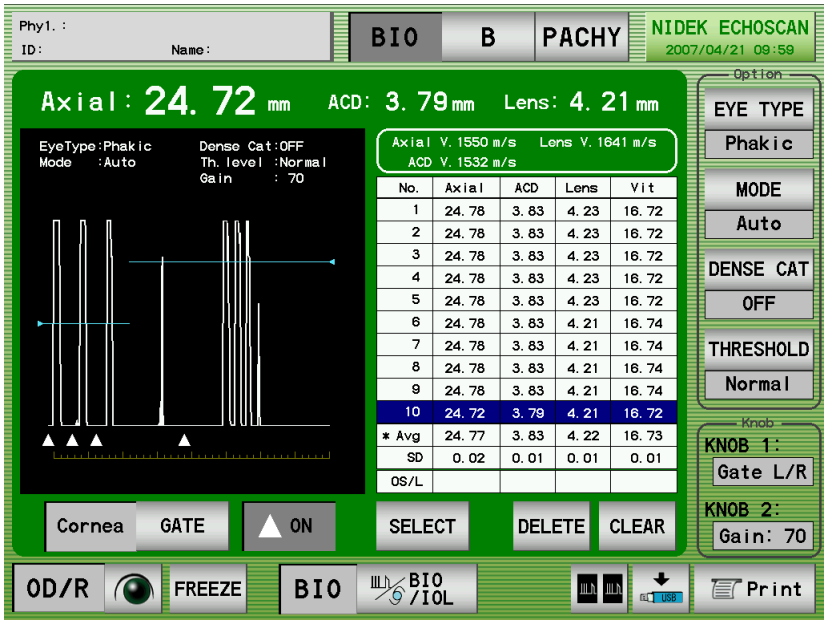


Improper

2.4.3 Manual gate

If there is an additional echo near the threshold value preceding any of the valid echoes, this additional echo is mistakenly considered a valid echo. This Manual Gate function is used to eliminate the influence of extraneous echoes. This function is also used if there are many multiple echoes in the measurement of an eye with an IOL implanted.

The Manual Gate can be displayed by selecting a gate type (Cornea, Lens-F (anterior), Lens-B (posterior), or Retina) and pressing the ON/OFF switches. Then the displayed gate position can be adjusted.



1 In the FREEZE screen, confirm that no improper A-scan waveform or intraocular biometry values are found.

1) Press the MEASURE switch of the foot switch or the LIVE switch to stop the A-scan biometry operation.
2) In the FREEZE screen, observe the A-scan waveform and intraocular biometry values.

   If the A-scan biometry values are improper due to extraneous echoes, go to Step 2.

2 Adjust the Manual Gate position.

1) Select the gate type by pressing the GATE switch and press the ON/OFF switch to display the Manual Gate.

   * There are gates for Cornea, Lens-F (anterior), Lens-B (posterior), and Retina. Move each gate to the respective echo.

2) Turn Knob 1 and move each gate just to the left side of the respective echoes.

   * The gate can also be moved using the stylus or finger.

3 Restart the A-scan biometry operation and confirm the change of the values of each intraocular part by the Manual Gate.

1) Press the MEASURE switch on the foot switch or the FREEZE switch to restart the measurement.

2) Check whether the values of each intraocular part are changed.

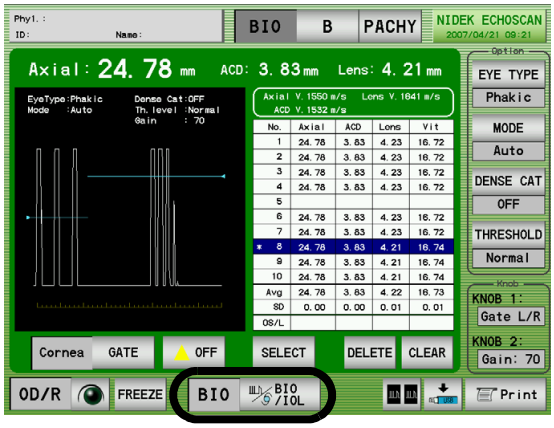
   Echoes on the left side of the set manual gate are no longer considered valid echoes, and all intraocular values are changed by the Manual Gate function.

* Since an extraneous echo in the A-scan biometry may indicate an intraocular lesion, it is recommended to check for such a possible lesion using other methods (such as B-scan imaging).

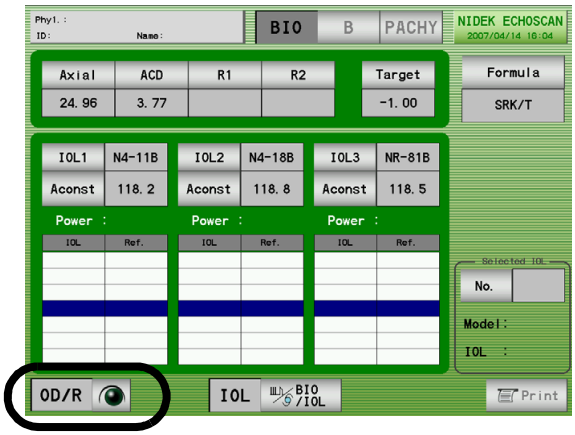
2.4.4 Calculation of IOL refractive power

Pressing the IOL switch after the A-scan biometry displays the IOL power calculation screen in which the IOL power is calculated. The calculation is performed when the necessary data is input, and the calculated results of the selected IOL type are listed. The IOL data must be input in advance referring to "○Inputting IOL data (Page 64)."

1 After the A-scan biometry, press the BIO/IOL switch to display the IOL power calculation screen.



2 Press the OD/OS switch to select the eye in which to implant an IOL.



3 Press the R1 and R2 switches to input the corneal curvature radius (mm) and/or corneal refractive power (D).

Pressing any of the R1 and R2 switches displays the ten-key window. After inputting the values using the ten-key, press the Enter switch.

4 Press the Formula switch to select the IOL formula used to calculate the IOL power.

Each time the switch is pressed, the IOL formula registered in the physician setting screen is indicated in order.

The selected IOL formula is indicated on the switch.

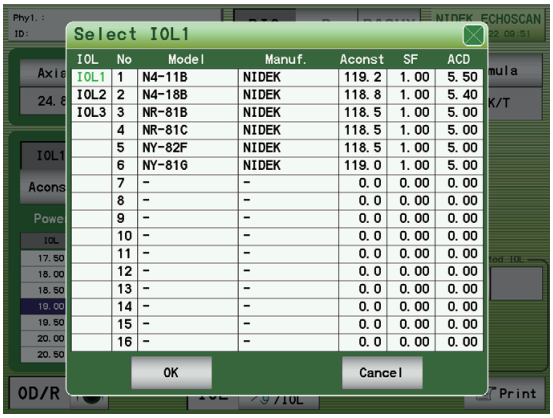
Auto: An IOL formula is automatically selected based on the axial length.

Comparison: The IOL power is calculated with all the IOL formula.

* The most recently selected IOL formula is indicated in this screen after the device power is turned OFF and then ON again.

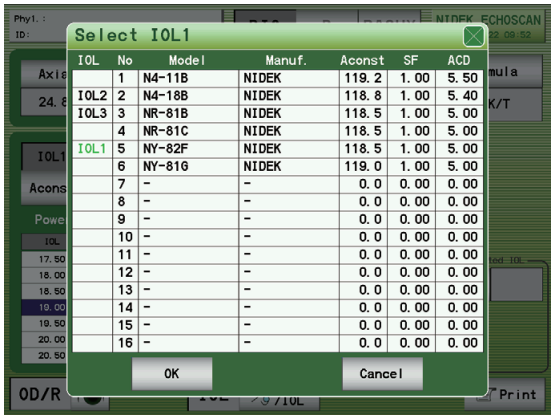
5 Press any of the IOL 1, IOL 2, and IOL 3 switches to display the IOL list window. Select up to three IOL types to be used for the IOL power calculation.*2

1) Press the IOL number to be changed to display the IOL list window.



2) Select the IOL in the list with the stylus or finger.

* If there is no desired IOL, register a new one.



3) Press the OK switch to determine the IOL used for the calculation and close the window.

* To close the IOL list window without any changes, press the Cancel switch.

4) To change the IOL selected with other switches, repeat Steps 1) to 3).

* The same IOL cannot be selected with multiple switches.

6 If necessary, temporarily change the IOL constant selected in Step 5.*3

1) Press the Aconst switch (such as ACD and SF) just below the IOL whose IOL constant is the item to be changed to display the numeric key window.

* The indicated switch is one of “Aconst,” “SF,” and “ACD” according to the IOL formula to be used.

*2 If three types of IOLs are not necessary for the IOL refractive power calculation, leaving the IOL model name blank deletes the registered IOL data, and the deleted IOLs are not used for the calculation. (For the inputting method, see “○ Inputting IOL data (Page 64).” Unless this setting is saved in the IOL data input screen, the blank IOL model name is returned to the original once power to the device is turned off.

*3 Changes made in this step are temporary, and the values return to the original once power to the device is turned off.

2) Input a new IOL constant using the ten-key window, and press the Enter switch.

* The following lists the switches and ranges of each constant. Values cannot be input outside the ranges:

Aconst (A constant) (Aconst switch) .....100 to 130

ACD (Predicted postoperative anterior chamber depth) (ACD switch)..... 1.6 to 9.99

SF (Surgeon factor) (SF switch)... 0 to 9.99

* Each time the BS switch is pressed, the input numerical values are deleted from the right end.

* To close the ten-key window without any changes, press the Cancel switch.

3) To change the IOL constant of the other two IOLs, repeat Steps 1) to 2).

7 Input the obtained data of each intraocular part to carry out the IOL power calculation.

1) Select either the right (OD/R) or left (OS/L) eye to enter data first.

2) Press the Axial switch to display the ten-key window, and input the axial length.

* When the A-scan biometry is completed, the average or measured data with a "✱" mark has already been input.

3) Press the R1/R2 switch to display the ten-key window, and input the corneal curvature or refractive power.

* The following are the ranges of corneal curvature and corneal refractive power, and the values cannot be input outside the ranges:

Corneal curvature: 5.00 to 19.99 mm

Corneal refractive power: 20.00 to 60.00 D

* When the NIDEK Keratometer is connected, the corneal curvature or refractive power that was obtained with the Keratometer has been already input.

4) Press the Target switch to display the ten-key window, and input the desired postoperative refractive power.

* The range of the desired postoperative refractive power is between -10.00 D and +10.00 D, and the value cannot be input outside the range.

5) The IOL powers for each set of input data are calculated.

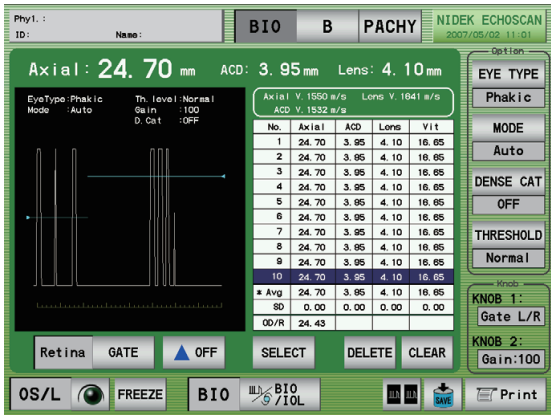
The IOL power which is the closest to the desired postoperative refractive power is highlighted in the middle row on the calculation list.

6) Input the data for the other eye in the same manner as Steps 2) to 4) to calculate the IOL power for it.

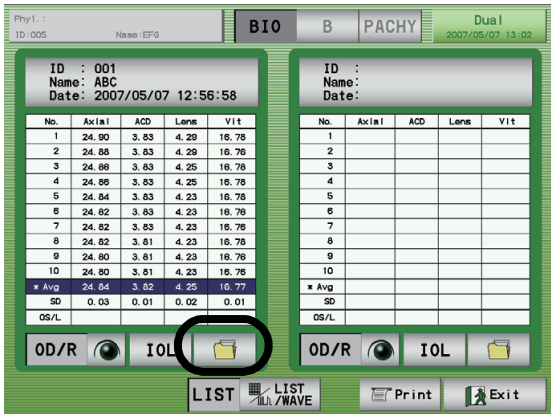
8 Press the Print switch to print the calculation results.

2.4.5 Comparison in DUAL screen

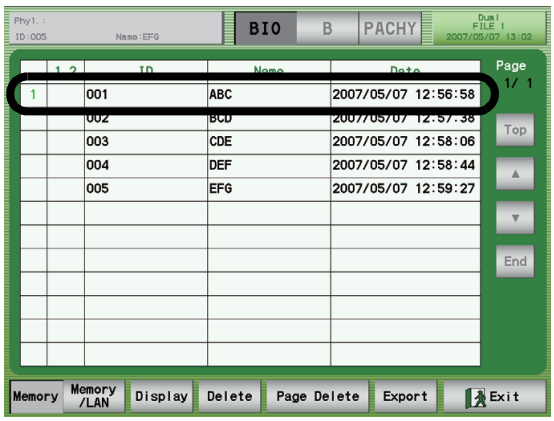
1 Press the DUAL switch in the A-scan biometry screen to display the DUAL screen.



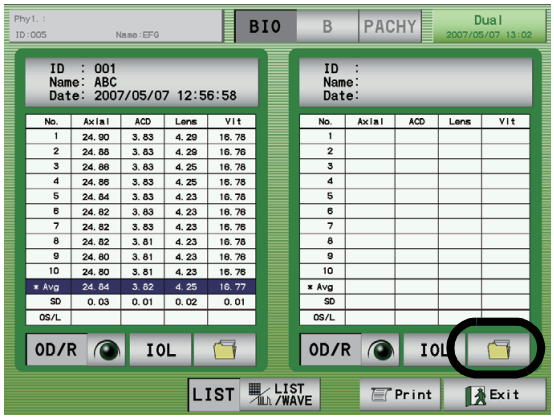
2 Press the Data Read switch below the table on the left side of the screen to display the file list.



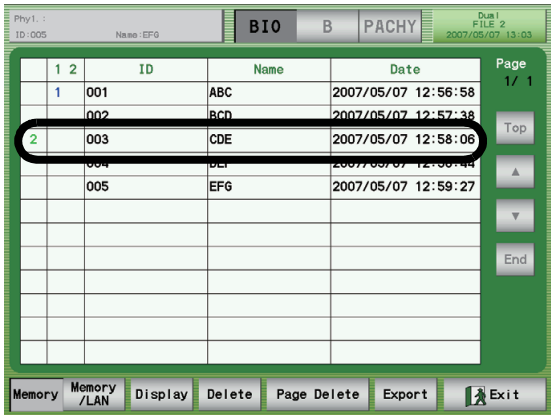
3 Select the desired file from the list to be displayed on the left side (1) of the screen by the stylus or finger, and press the Display switch.



4 Press the Data Read switch below the table on the right side of the screen to display the file list.

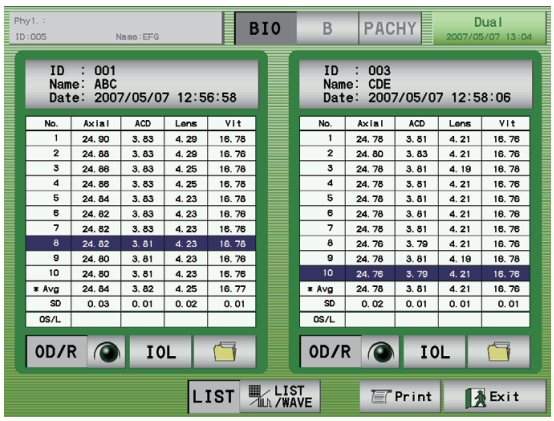


5 Select the desired file from the list to be displayed on the right side (2) of the screen by the stylus or finger, and press the Display switch.



6 Press the LIST/WAVE switch to display the lists.

7 Select appropriate data from the list by the stylus or finger.

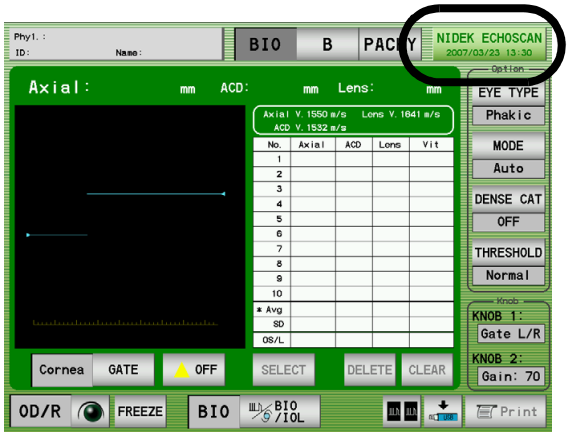


8 Press the LIST/WAVE switch to display the waveform and confirm that it is appropriate.

9 Press the IOL switch to calculate the IOL power.

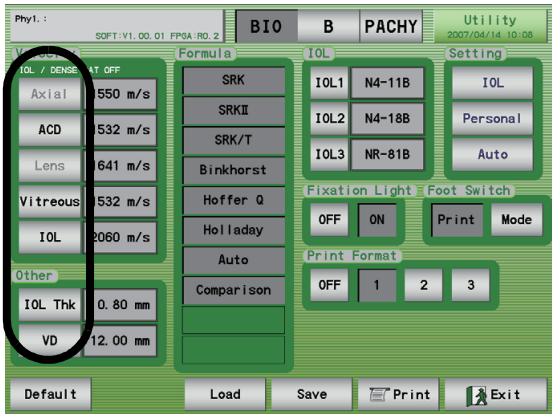
2.4.6 Setting A-scan biometry utility

1 Press the switch that indicates the date and time in the A-scan biometry screen to display the A-scan biometry utility screen.

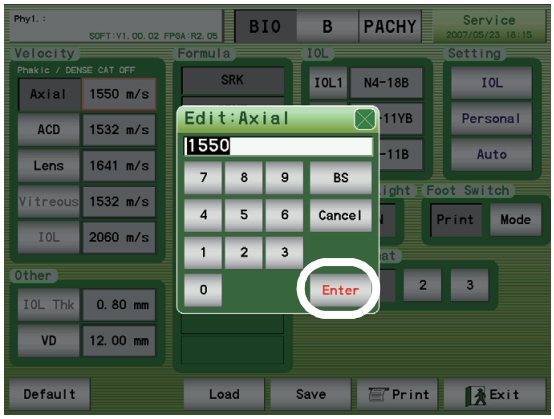


○ Changing sonic velocity to calculate distance

1 Press any of the Axial, ACD, Lens, Vitreous, and IOL switches to change the sonic velocity to calculate distance. To change other values, press the IOL Thk or VD switch.



2 Input the sonic velocity to calculate distance and other values and press the Enter switch.



Switch	Input value	Default value	Input range
Axial (Aphakic)	Axial length average sonic velocity to calculate distance	1550 m/s (1532 m/s)	1000 to 2000 m/s
ACD	Anterior chamber sonic velocity to calculate distance	1532 m/s	1000 to 2000 m/s
Lens (DENSE CAT ON)	Lens sonic velocity to calculate distance	1641 m/s (1629 m/s)	1000 to 2000 m/s
Vitreous	Vitreous body sonic velocity to calculate distance	1532 m/s	500 to 2000 m/s
IOL	IOL sonic velocity to calculate distance (PMMA)	2060 m/s	500 to 3000 m/s
IOL Thk	IOL thickness	0.80 mm	0.02 to 5.00 mm
V.D.	Vertex distance	12.00 mm	0.00 to 20.00 mm

* If the Eye Type is "Aphakic" (aphakic eye), the measurement is performed with the sonic velocity to calculate distance as specified with the switches above.
* If the DENSE CAT is "ON", the measurement is performed with the sonic velocity to calculate distance as specified with the switches above.

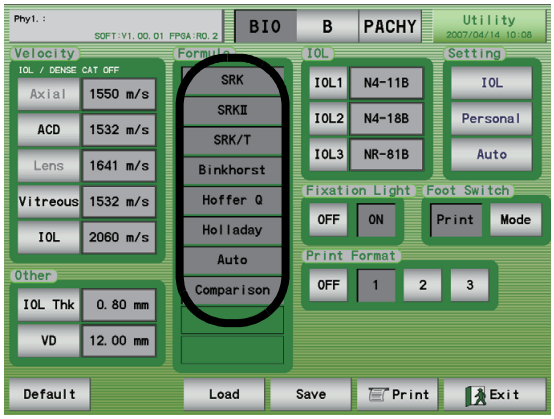
Pressing the Default switch resets all the settings to the default values.

3 Press the Save switch to save the data.

○ Setting IOL formula

1 Select the IOL formula(s) to be used for the IOL power calculation.

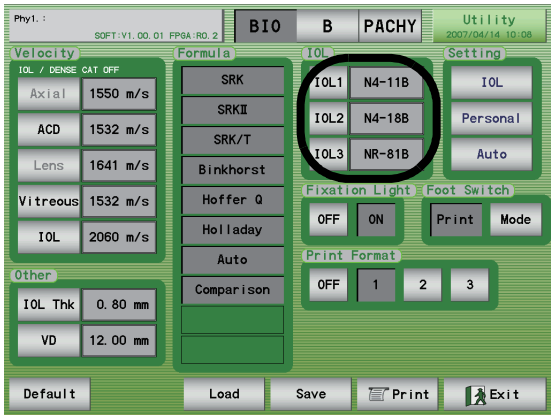
Auto: An IOL formula is automatically selected based on the axial length.



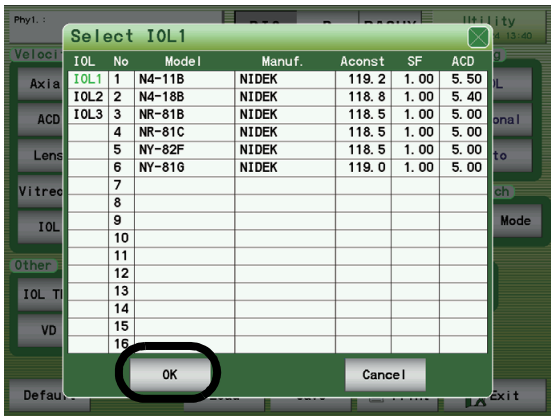
2 Press the Save switch to save the setting.

○ Setting normally used IOL

1 Press any of the IOL1, 2, or 3 switches to display the IOL list.



2 Select the desired IOL from the IOL list, and press the OK switch.

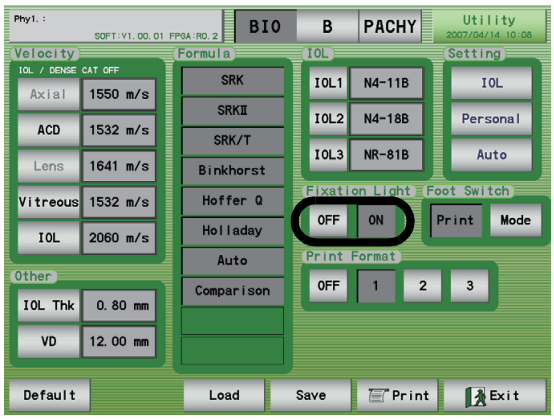


3 Press the Save switch to save the setting.

○ Setting fixation light ON/OFF

Toggle the fixation light inside the A-scan probe between lit and unlit.

1 Select "ON" or "OFF."



2 Press the Save switch to save the setting.

○ Setting print format

Set the print format in the A-scan biometry.

1 Select the print format from "Off," "1," "2," and "3."

	Printed item	Off	1	2	3
A-scan biometry	Patient data	-	O	O	O
	Physician's name	-	O	O	O
	Operation conditions	-	O	O	O
	Eye (left or right)	-	O	O	O
	Measurement data list, the average value (Avg) and the standard deviation (SD)	-	O	-	-
	A-scan biometry value used for IOL power calculation Value with "*" in the IOL list on the screen	-	O	O	O
	Selected A-scan waveform	-	O	O	-
	Print date and time	-	O	O	O

	Printed item	Off	1	2	3
IOL power calculation	Patient data	-	O	O	O
	Physician's name	-	O	O	O
	Operation conditions	-	-	-	O
	IOL formula	-	O	O	O
	Eye (left or right)	-	O	O	O
	A-scan biometry value used for IOL power calculation Value with "*" in the IOL list on the screen	-	-	-	O
	Selected A-scan waveform	-	-	-	O
	Input axial length	-	O	O	O
	Corneal curvature radius (mm)/ Refractive power (D)	-	O	O	O
	Target postoperative refractive power	-	O	O	O
	IOL data, optimal IOL value, and selectable IOL and refractive power (Selectable range of IOL: ± 1.0D or ± 1.5D)	-	O (± 1.5D)	O (± 1.0D)	O (± 1.0D)
	Print date and time	-	O	O	O

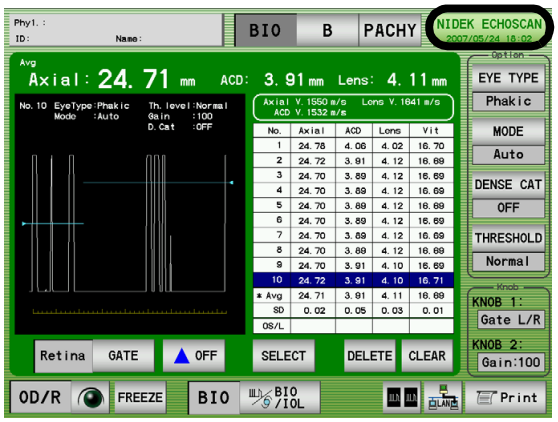
2 Press the Save switch to save the setting.

* If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

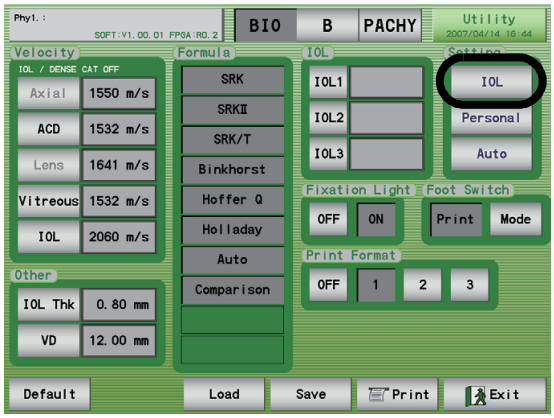
○ Inputting IOL data

When the IOL data is preset in this screen, it becomes possible to calculate the IOL power to be used for the surgery soon after the A-scan biometry. (A maximum of 16 sets of IOL data can be input.)

1 Press the switch with the date and time indications in the A-scan biometry screen.

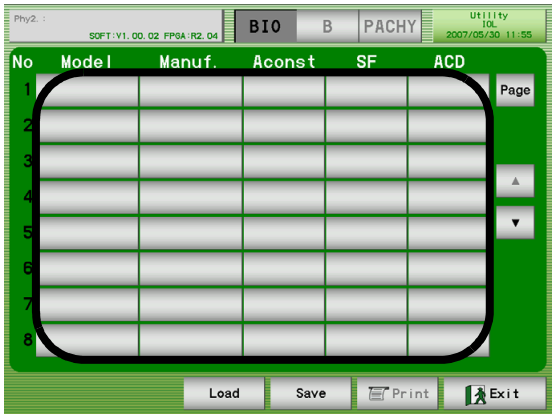


2 Press the IOL switch.



3 Press the box to input (or change) with the stylus or finger.

If any box in the Model and Manuf column is pressed, the keyboard window is displayed. If any box in the Aconst, SF, and ACD columns is pressed, the ten-key window is displayed.



4 Input (or change) the IOL data.

The switches and changeable contents are as follows:

Model: Model of the IOL

Manuf.: Manufacturer

Aconst: A constant

SF: Surgeon factor

ACD: Predicted postoperative anterior chamber depth

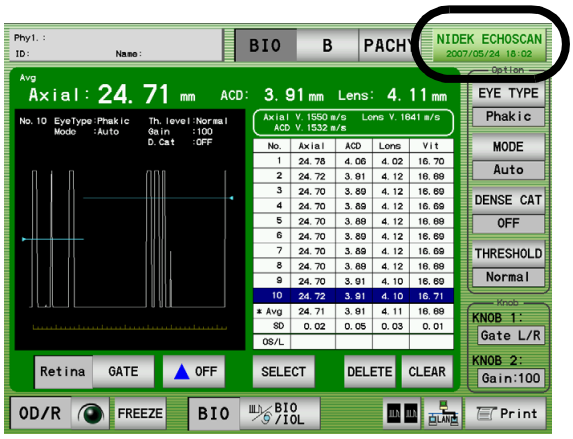
* If three types of IOLs are not necessary for the IOL refractive power calculation, leaving the IOL model name blank deletes the registered IOL data, and the deleted IOLs are not used for the calculation.

5 Press the Save switch to save the data.

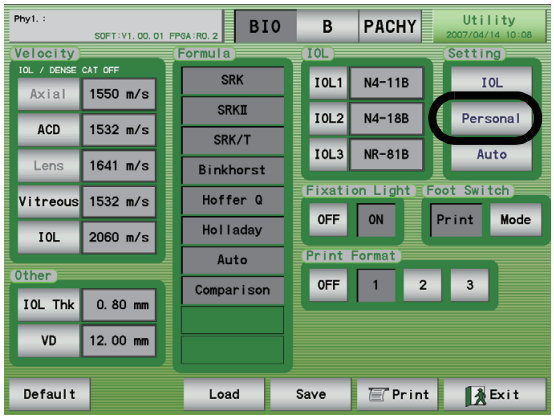
○ Calculating personal value

The values such as the IOL constant can be calculated by inputting the corneal curvature radius/ refractive power, axial length, IOL power and postoperative refractive power.

1 Press the switch that indicates the date and time to display the A-scan biometry utility screen.



2 Press the Personal switch.



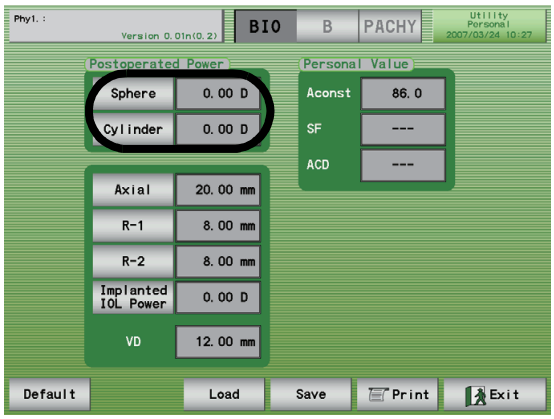
3 Input the postoperative refractive power.

Pressing any of the postoperative power switches displays the ten-key window which enables inputting the refractive power required to calculate the IOL constant.

The following lists the switches (setting items) and ranges of the refractive power. Values cannot be input outside the ranges:

Sphere switch (postoperative spherical power) - 20.00 to + 20.00 D

Cylinder switch (postoperative cylindrical power) - 20.00 to +20.00 D



4 Press the Axial switch to input the axial length of the eye to be treated.

Pressing this switch displays the ten-key window which enables inputting of the axial length.

The input range of axial length is between 12.00 and 40.00 mm, and the axial length cannot be input outside the range.

5 Press the R1/R2 switches to input the corneal curvature radius or corneal refractive power of the eye to be treated.

Pressing this switch displays the ten-key window which enables inputting of the corneal curvature radius or corneal refractive power.

The input ranges of corneal curvature radius and corneal refractive power are described below, and the values cannot be input outside the ranges. In addition, the units (mm or D) are automatically changed according to the input value.

Corneal curvature 5.00 to 19.99 mm

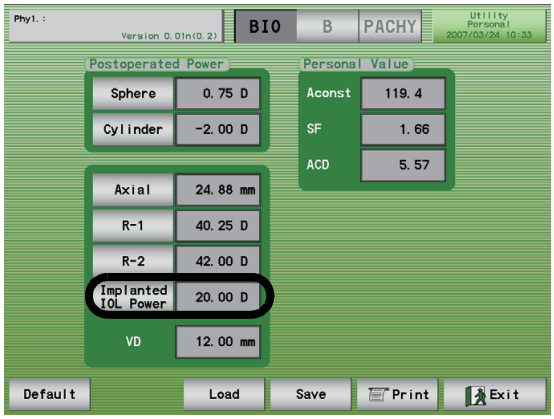
Refractive power 20.00 to 60.00 D

6 Press the Implanted IOL Power switch to input the implanted IOL power.

Pressing this switch displays the ten-key window which enables inputting the implanted IOL power.

The input range of the implanted IOL power is between -40.00 and +40.00 D, and the value cannot be input outside the range.

When the necessary data is input, the IOL constant is automatically calculated, and Aconst (A constant), SF (surgeon factor) and ACD (predictable postoperative anterior chamber depth) are indicated in the boxes under “Personal Value”.

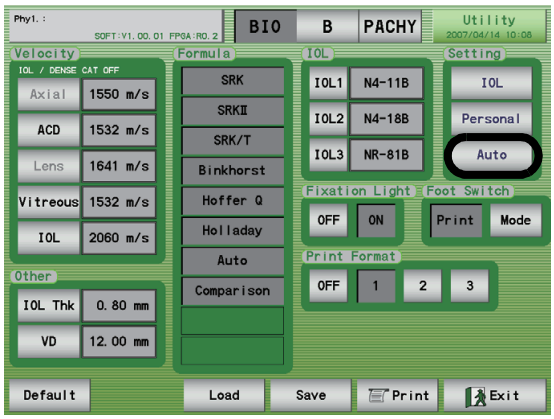


7 If necessary, press the Print switch to print the data on this screen.

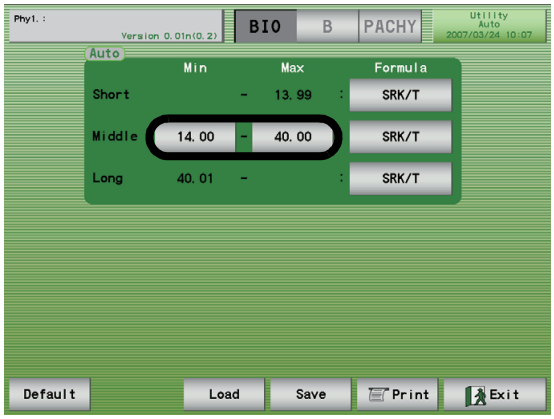
8 Press the Exit switch twice to return to the A-scan biometry screen.

○ Setting IOL power calculation formula in specified axial length range

1 In the A-scan biometry utility screen, press the Auto switch to display the Auto screen.



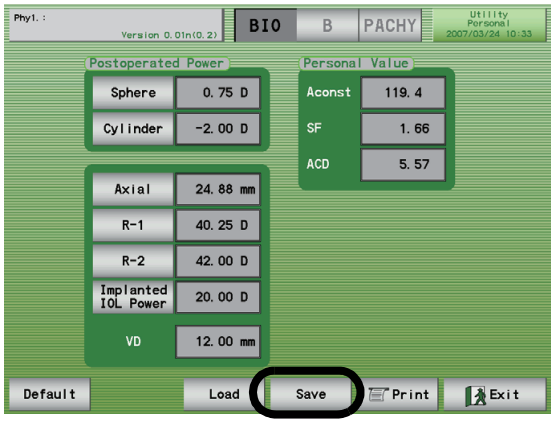
2 Press the Min Max switch to display the ten-key window. Input the axial length range (values) using the ten-key. (Unit: mm)



3 Pressing any of the Formula switches displays the Formula select screen. Select the desired IOL formula for each axial length range.

4 Press the Save switch to save the setting.

Press the Load switch to reset the settings to the saved ones. Pressing the Default switch resets the settings to the default.



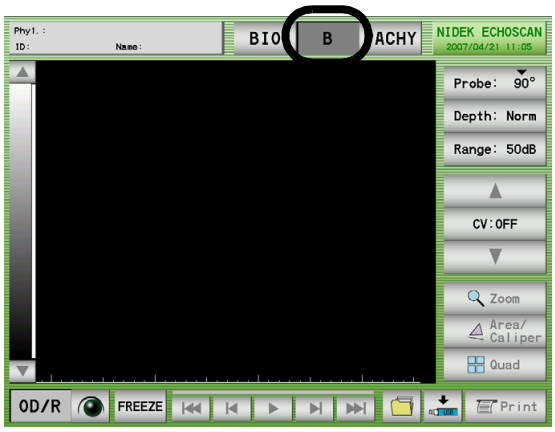
5 If necessary, press the Print switch to print the setting.

6 Press the Exit switch twice to return to the A-scan biometry screen.

2.5 B-scan Imaging

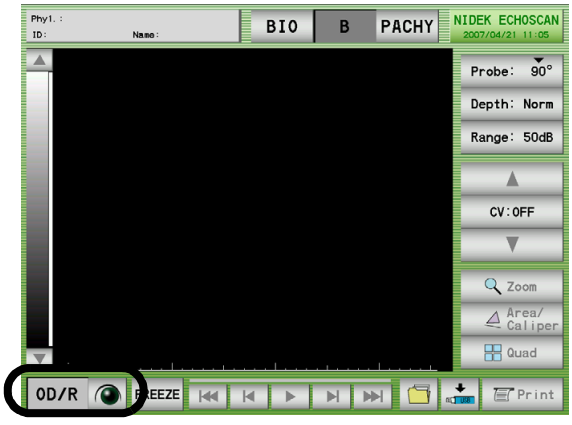
2.5.1 Basic operation of B-scan imaging

1 Press the B switch to display the B-scan imaging screen.

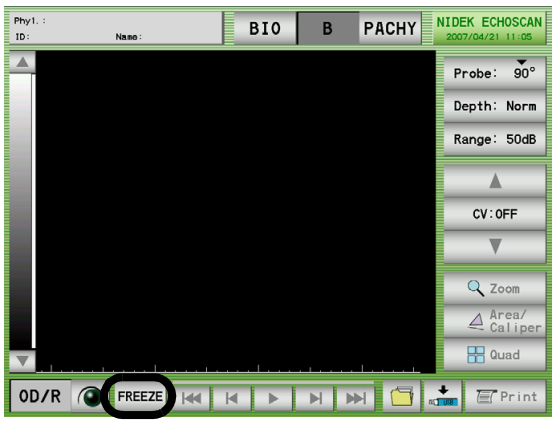


2 Press the OD/OS switch to select the right or left eye for which the B-scan imaging is to be performed.

Each time the switch is pressed, the eye indication above the switch changes between "OD/R" (right eye) and "OS/L" (left eye).



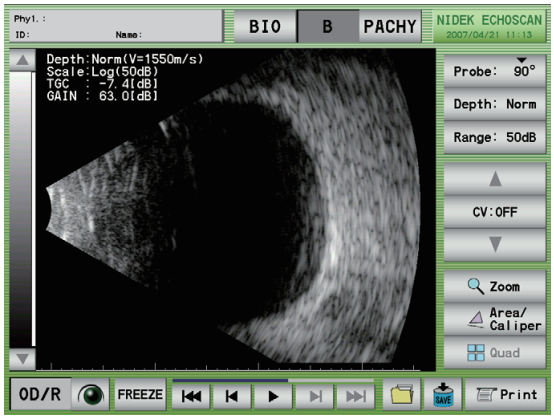
3 Press the FREEZE switch or the MEASURE switch of the foot switch to start the image observation.



4 Apply the B-scan probe on the eyelid of the patient.

5 As necessary, change the settings such as TGC (-20 to 0 dB), GAIN (0 to 90 dB), probe angle, observation depth, display range, and display color. Then start the image observation.

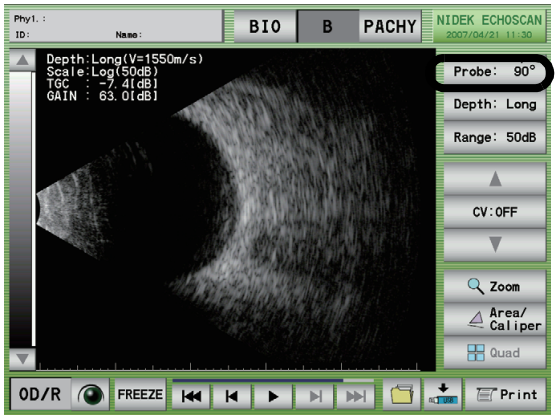
6 When the desired image is captured, press the LIVE switch or press the MEASURE switch of the foot switch to FREEZE the image.



7 If necessary, press the PRINT or Data Save switch to save the necessary data.

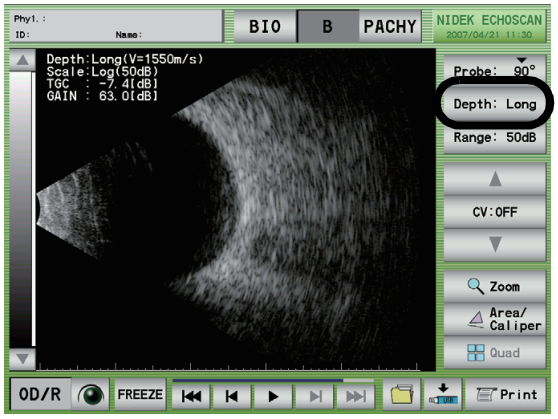
2.5.2 Probe angle

The angle of the probe touching the eyelid is displayed. Each pressing of the switch rotates the angle by 45° clockwise.
(ex.: 0° → 45° → 90° → 135° → 180° → 225° → 270° → 315° → 0° → 45° → ...)



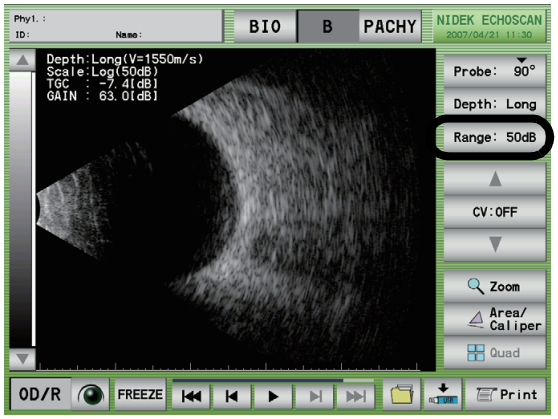
2.5.3 Changing observation depth

Press the Depth switch to change the observation depth.



2.5.4 Changing display range

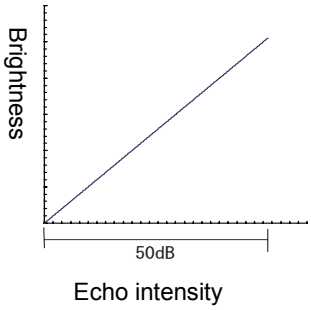
The Range switch is available when the gain curve is set to "Log." Each pressing of the Range switch changes the value as "50 → 40 → 30 → 20 → 10 → 50dB..."

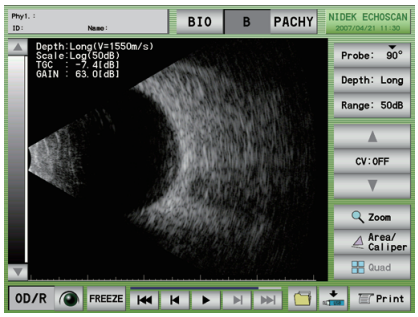


The B-scan image is displayed in 256 gray scales within the range of the echo intensity (50 dB).

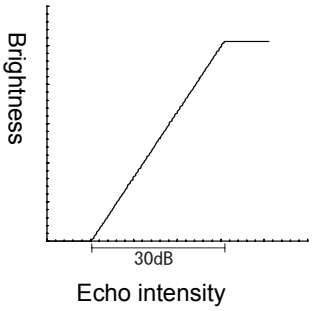
The range of the echo intensity can be changed as necessary. For example, when the range is changed to 30 dB, the echo intensity is displayed in 256 gray scales within the range of 30 dB. By adjusting the range of 30 dB to the desired echo intensity, the image of the selected echo intensity can be displayed in clear and emphatic contrast.

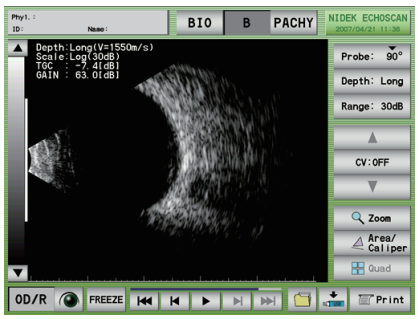
・Range: 50 dB



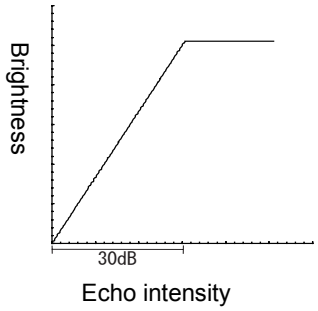


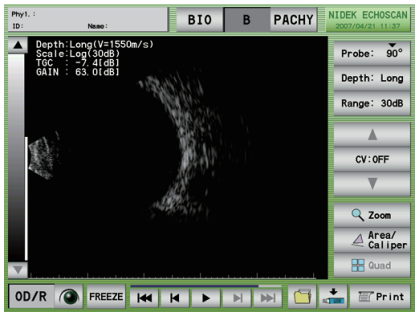
・Range: 30 dB　Middle intensity echoes are displayed clearly



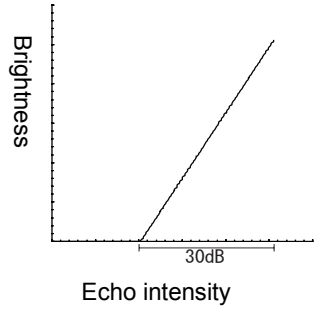


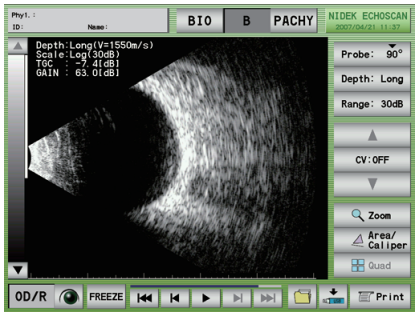
・Range: 30 dB　Low intensity echoes are displayed clearly





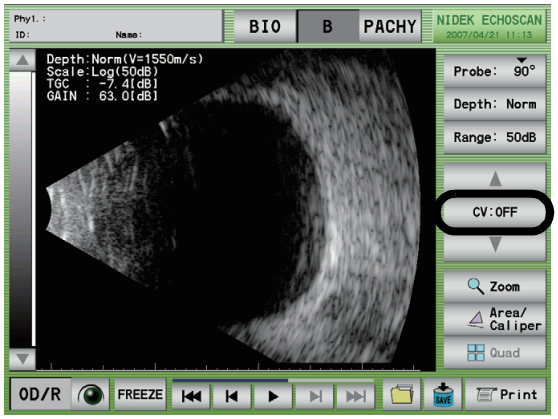
・Range: 30 dB　High intensity echoes are displayed clearly



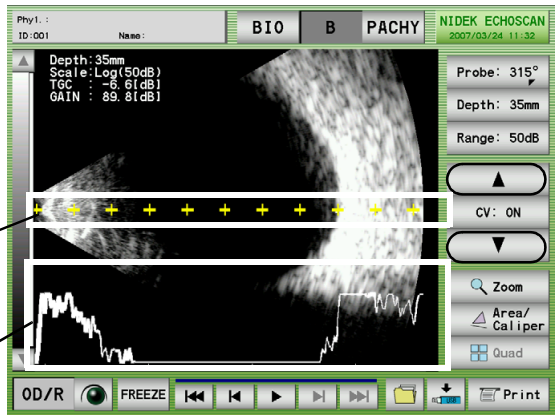


2.5.5 CV mode

1 Press the "CV:OFF" switch.

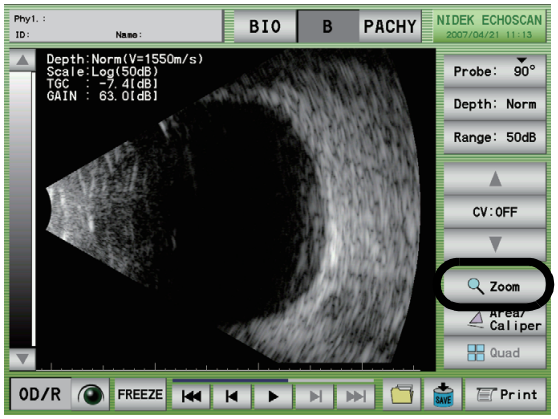


2 Pressing the triangle switches moves the cross-vector line. The A-scan waveform for the cross-vector line and the entire B-scan image are displayed together. The cross-vector line also can be moved with the stylus or finger.

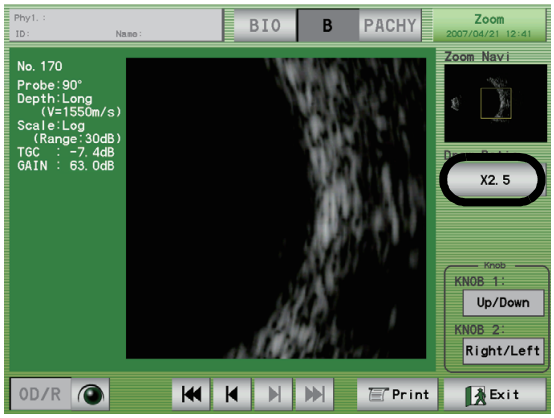


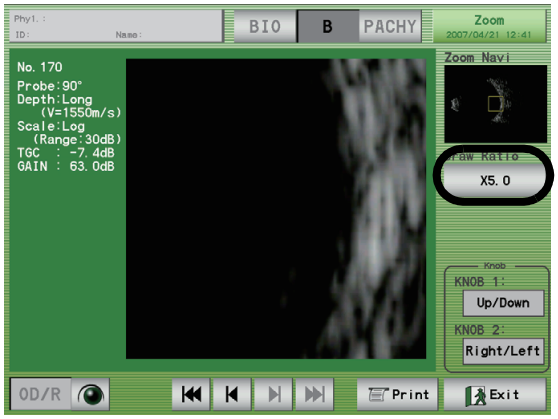
2.5.6 Zoom

1 Press the Zoom switch in the B-scan imaging screen to display the Zoom screen.



2 Press the Draw Ratio switch to toggle the magnification between x2.5 and x5.





3 Rotate Knob 1 and 2 to move the area of magnification in the up, down, left, and right directions.

A square appears in the Zoom Navi display to indicate the area of magnification. The area of magnification can be moved by touching the desired part in the Zoom Navi display with the stylus or finger.

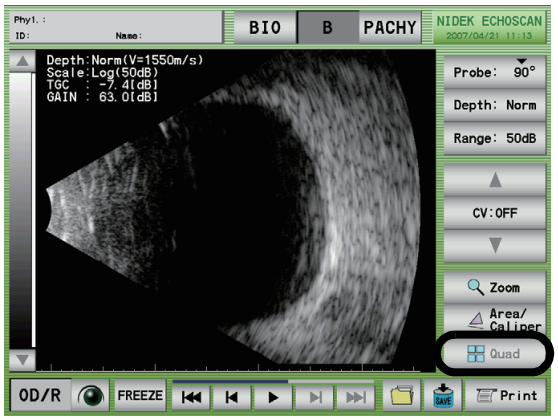
4 Press the Print switch to print the image on the screen.

5 Press the Exit switch to return to the B-scan imaging screen.

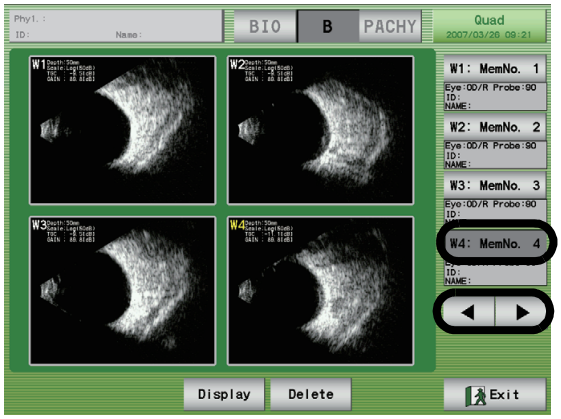
2.5.7 Four image display

1 Press the Quad switch in the B-scan imaging screen to display the four image display screen.

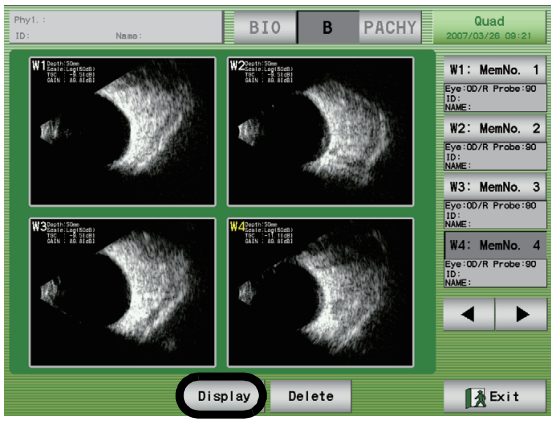
If the desired data is stored in an external storage device, import the data by pressing the Data Read switch.



2 Press the image or the MemNo. switch to select an image. Pressing the ◀ and ▶ switches displays 12 saved images consecutively (three consecutive sets of four images).



3 Press the Display switch to display only one image.

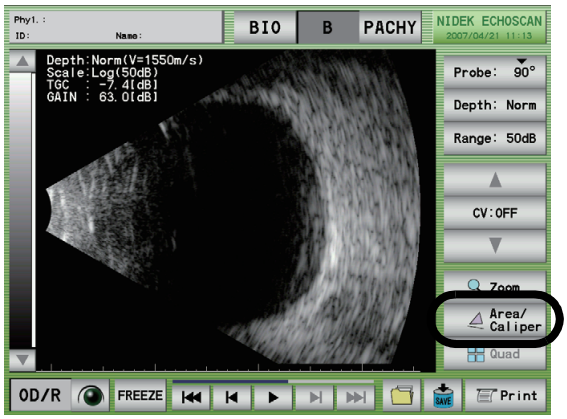


4 Press the Delete switch to delete the selected image.

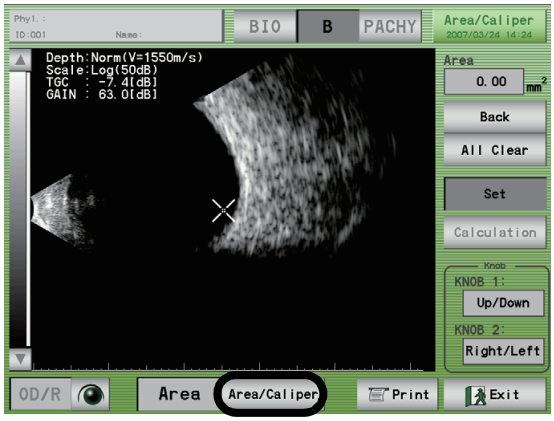
5 Press the Exit switch to return to the B-scan imaging screen.

2.5.8 Measuring area on B-scan imaging screen (Area screen)

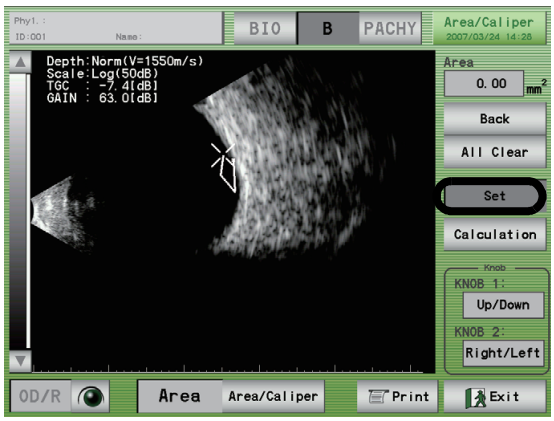
1 Press the Area/Caliper switch in the B-scan imaging screen to display the Area/Caliper screen.



2 Press the Area/Caliper switch in the Area/Caliper screen to display the Area screen.



3 Move the "×" mark on the image to the desired start point by turning Knob 1 and 2, or specify the start point with the stylus and confirm it by pressing the Set switch.

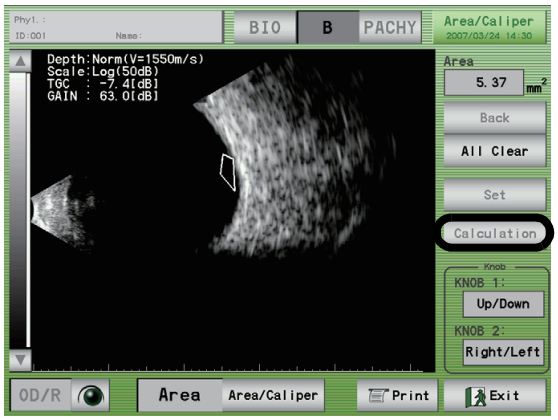


4 Repeat Step 3 to specify the desired range.

To change the position of the previous point, press the Back switch.

To clear all the points, press the All Clear switch.

5 Specify the end point to the same position as the start point, and press the Calculation switch to calculate the area.

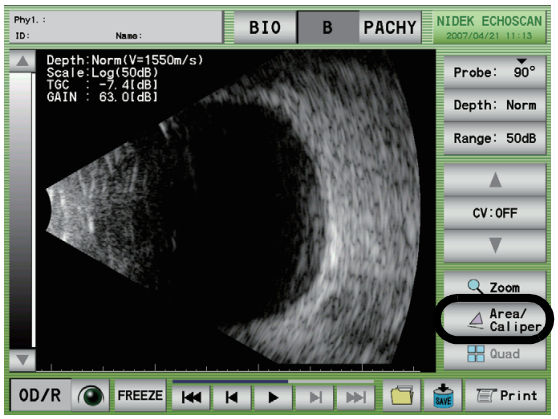


6 Press the Print switch to print the image in the screen.

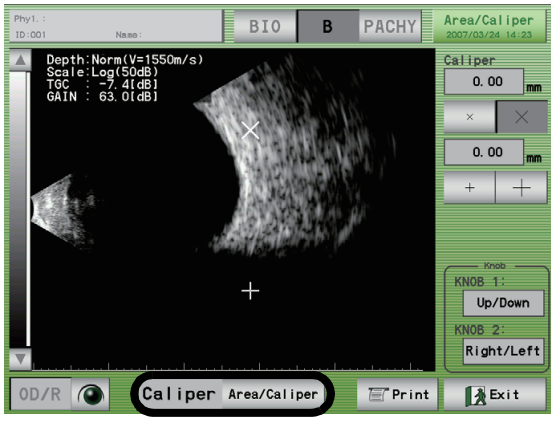
7 Press the Exit switch to return to the B-scan imaging screen.

2.5.9 Measuring distance on B-scan image (Caliper screen)

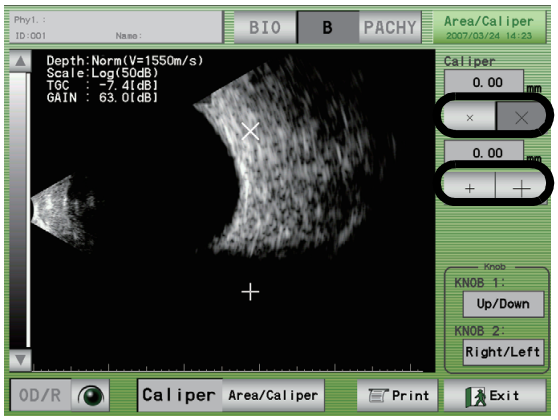
1 Press the Area/Caliper switch in the B-scan imaging screen to display the Area/Caliper screen.



2 Press the Area/Caliper switch in the Area/Caliper screen to display the Caliper screen.



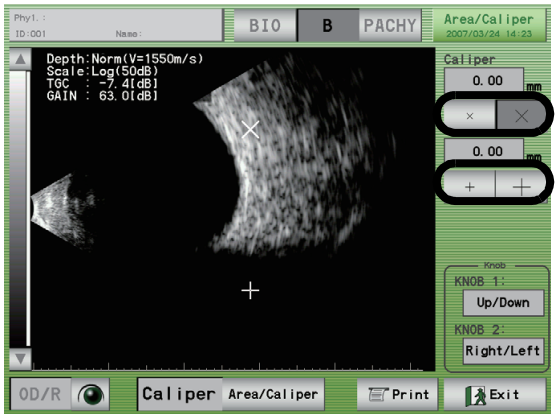
3 Select the desired marker (+, +, X, or x).



4 Move the selected marker using Knob 1 and 2 or specify the desired point using the stylus.

5 Select the marker paired with the selected one (**+** and + / **X** and x) and specify its position as in Step 4.

The distance is displayed when the marker positions are specified.

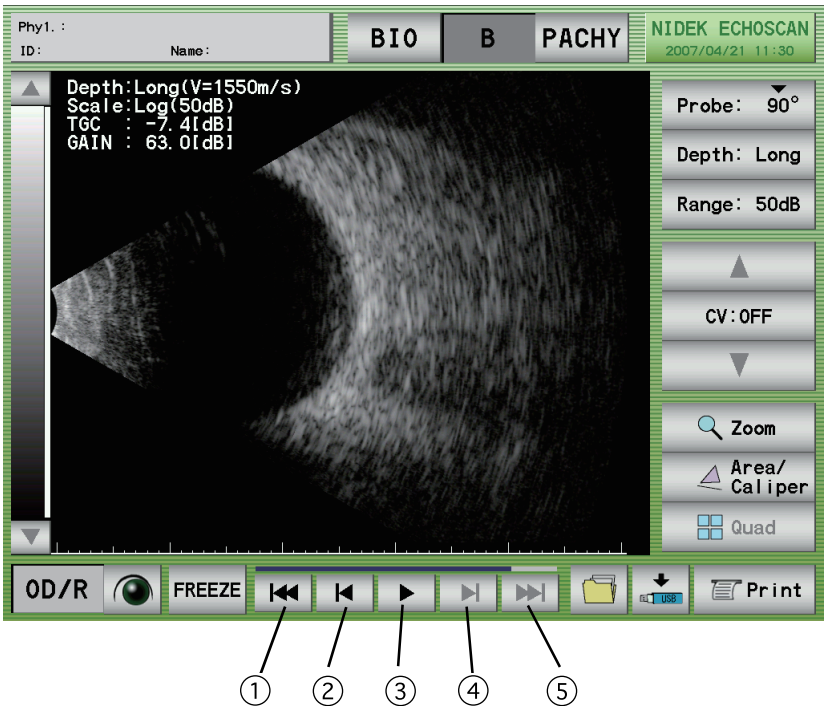


6 Press the Print switch to print the image in the screen.

7 Press the Exit switch to return to the B-scan imaging screen.

2.5.10 Moving image operation

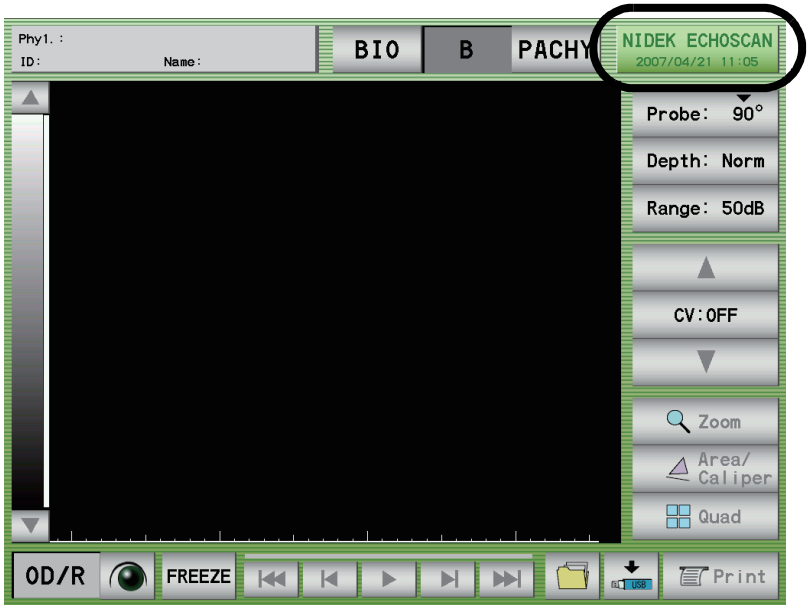
Play a moving image of 20 seconds' LIVE condition just before the FREEZE switch was pressed.



③ Play switch: Plays a moving image of about 20 seconds' LIVE condition just before the FREEZE switch was pressed.
③ Stop switch: The Play switch becomes the Stop switch while the moving image is played.
② ④ Scroll backward and forward switches: 1 image
① ⑤ Skip backward and forward switches: 5-image jumps

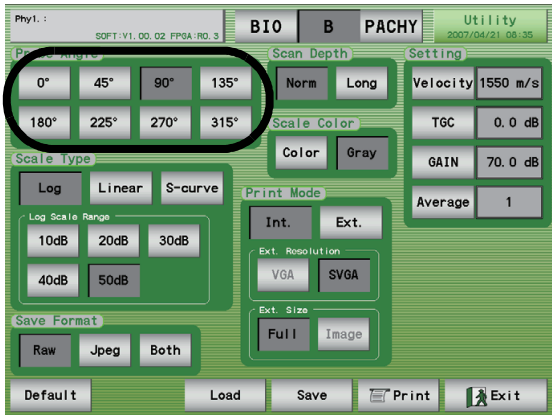
2.5.11 Setting B-scan imaging utility

1 Press the switch that indicates the date and time in the B-scan imaging screen to display the B-scan imaging utility screen.



○ Setting probe angle

1 Select the desired probe angle for at the time of device power-up.

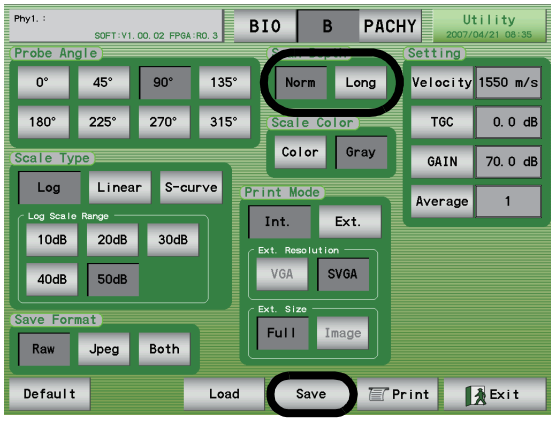


2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting scan depth

1 Select the desired scan depth for at the time of device power-up.

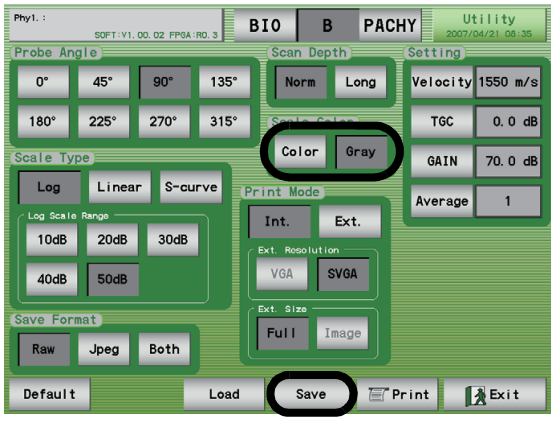


2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original.

○ Setting scale color

1 Select the desired scale color.



2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Changing gain curve pattern

1 Set the gain curve to be used.

Types and characteristics of the gain curves are as described below.

1.LOG:

The brightness of the image is in proportion with the logarithm of the echo intensity.

In the range width of 50 dB, the whole image can be observed from the parts of weak to strong echoes. The desired part can be magnified by changing the display range.

2.Linear:

The brightness of the image is in proportion with the echo intensity.

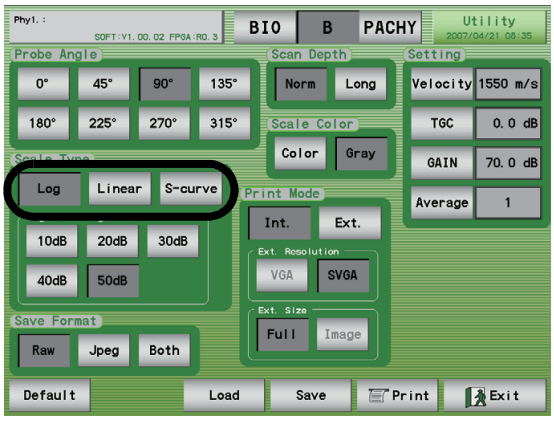
Areas of echo intensity a little higher than the middle intensity are displayed in high contrast.

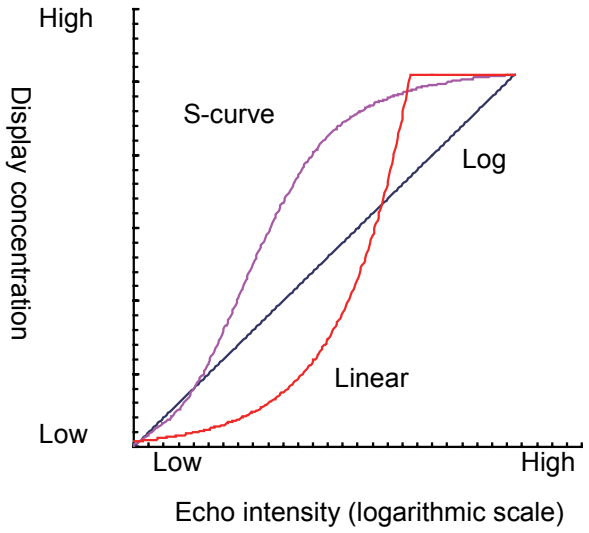
Areas of high echo intensity are displayed in white.

3.S-curve:

Areas of the echo intensity a little lower than the middle intensity are displayed in high contrast.

The other areas are displayed in low contrast.



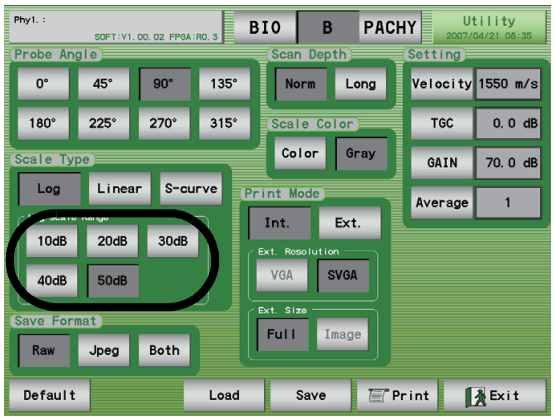


2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting Log scale range

1 Set the range level at the time of device power-up when the scale type (gain curve) is "LOG."

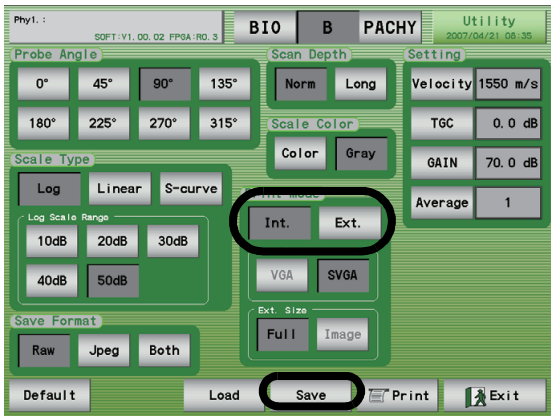


2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting printer mode

1 Select the printer for B-scan imaging between the built-in printer (Int.) and an external printer (Ext.).



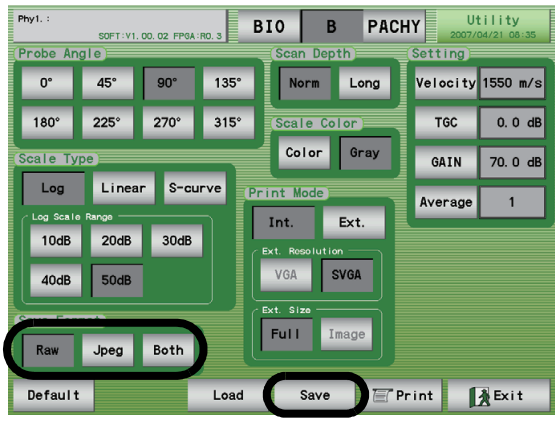
2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting data format

1 Select the data format in which the data is to be saved from "Raw (raw data)", "Jpeg (Joint Photographic Experts Group)", or both.

If “Jpeg” is selected, the saved data cannot be read by the US-4000 again.

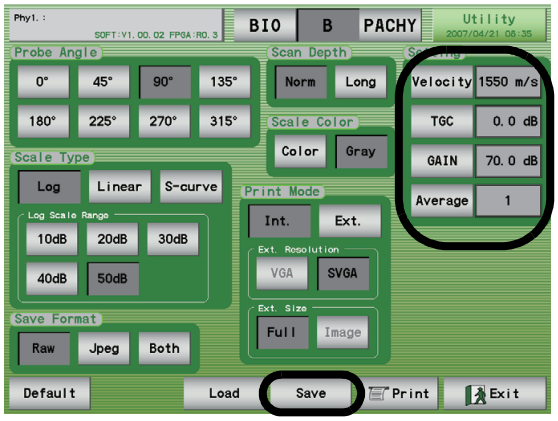


2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○Other settings

1 Press the Velocity, TGC, and GAIN switches to set those values at the time of device power-up.



2 Press the Average switch to set the times (1 to 5) of averaging of the B-scan waveform.

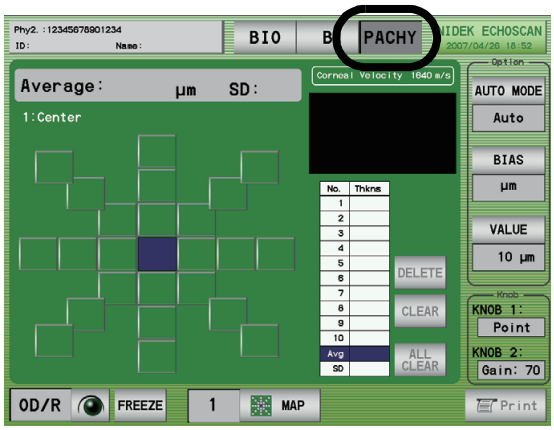
3 Press the Save switch.

Unless the Save switch is pressed, the settings above at the time of device power-up return to the original once power to the device is turned off.

2.6 Pachymetry

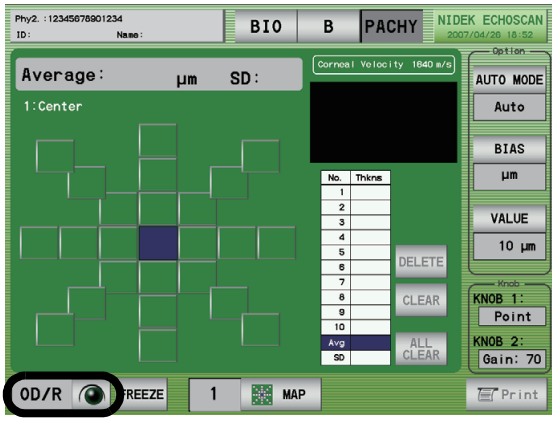
2.6.1 Basic operation of pachymetry

1 Press the PACHY switch to display the Pachymetry screen. (If the Pachymetry probe is not connected, a warning message appears and the Pachymetry screen cannot be displayed.)



2 Press the OD/OS switch to specify the eye to be measured between the right or left.

Each time the OD/OS switch is pressed, the eye being selected is changed between “OD/R” (right eye) and “OS/L” (left eye).

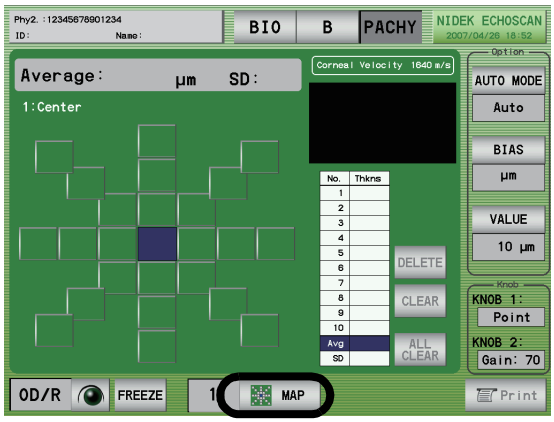


3 Press the Map No. switch to select the desired map.

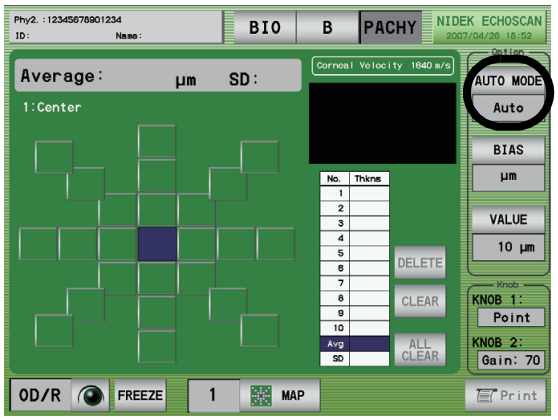
Six types of maps are available. Each map is indicated with a number from “1” to “6” on the left side of the switch.

Each time the Map No. switch is pressed, the map number and corresponding map are changed in order.

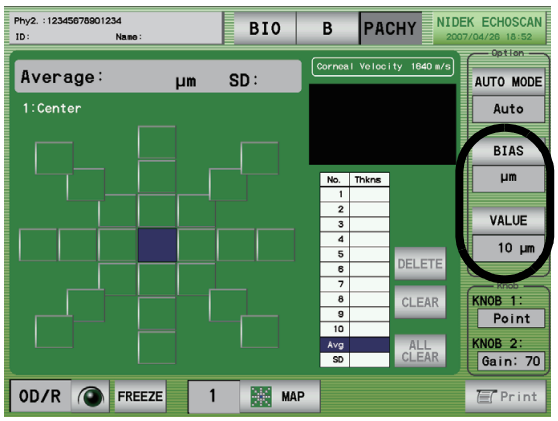
* The point with the color different from the background is the measurement point of this map.



4 Press the AUTO MODE switch to toggle between "Auto" and "Speedy."



5 Press the BIAS switch to set the bias indication and bias amount.



(A) To indicate an unbiased value

Press the BIAS switch until “Non” is indicated below the switch.

* Non: The measurement value is displayed as it is.

(B) To indicate a biased value

Press the BIAS switch until “µm” or “%” is indicated below the switch.

When “µm” or “%” is indicated, the VALUE switch appears below the indication.

When the bias setting is anabled, the biased average value shown on each measurement point in the map is the result of averaging after adding the bias value to each measurement value of the measurement point. Therefore, the shown biased average value may differ from one that is obtained by simply adding the bias value to the average vale.

* µm : The biased value (measurement value + bias value) is indicated in as the measurement value.

% : The biased value (measurement value × bias value) is indicated as the measurement value.

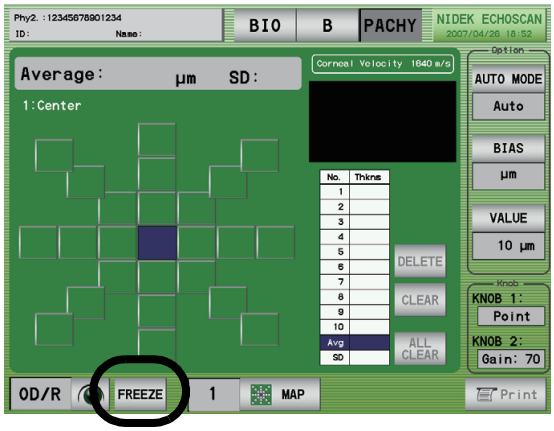
[Bias setting]

Both in the case of “µm” and “%”, press the VALUE switch to display the ten-key window to input the bias amount. The following is the ranges of bias amount, and the value cannot be input outside the ranges:

µm : - 999 to 999 µm % : 10 to 200 %

6 Press the MEASURE switch of the foot switch or the FREEZE switch to start the measurement.

The indication of the FREEZE switch changes to “LIVE,” and pachymetry is started..



7 Put the probe tip on the point of the cornea corresponding to the highlighted measurement point on the map.

Each time the measurement starts, a short beep sounds, and the average measurement value is indicated on the highlighted measurement point. In the list, the measurement values, average value, and standard deviation of each measurement are indicated. In the waveform display above the list, the current waveform is indicated.

Highlighted row in the list indicates the currently-measured data, and the highlighted row moves down a row as each measurement is finished.

When the Auto-measurements for the set times are finished, a beeping sounds, and the indication on the LIVE switch changes to “FREEZE.”

8 Release the probe tip from the cornea.

9 If necessary, manipulate the measured data on the list.

If the dispersions in the measurement data is great compared to other data, manipulate the data with the procedures below.

To delete a set of data in the list, highlight the data with the stylus or finger, and press the DELETE switch.

To restore the deleted data, highlight the deleted data with the stylus or finger, and press the RECALL switch.

To delete all the measurement data in the list, press the ALL CLEAR switch, then the OK switch. (If the measurement data is deleted in this method, the deleted data cannot be restored even by pressing the RECALL switch. Care should be taken when deleting the measurement data.)

* Each time a set of measurement data is deleted or restored, the average value (Avg) and standard deviation (SD) are recalculated.

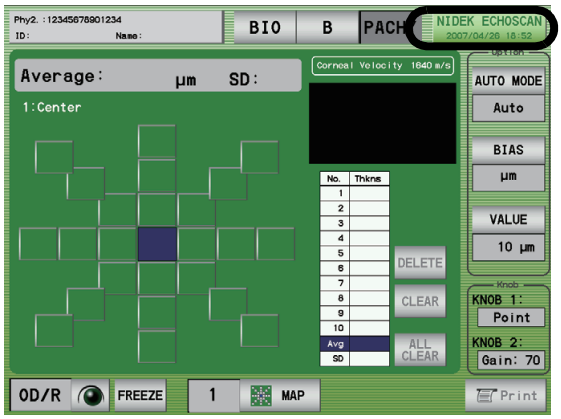
10 Press the PRINT (NEXT) switch of the foot switch or press the next measurement point with the finger to change the highlighted measurement point.

11 Press the MEASURE switch of the foot switch or the FREEZE switch to start measurement at the new measurement point.

12 Repeat Steps 7) to 11) until the measurement of all the measurement points on the map are completed.

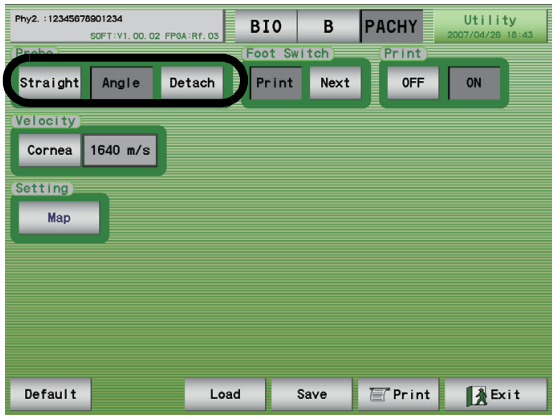
2.6.2 Setting pachymetry utility

1 Press the switch that indicates the date and time in the Pachymetry screen to indicate the Pachymetry utility screen.



○ Setting Pachymetry probe

1 Select the type of the Pachymetry probe to be used.

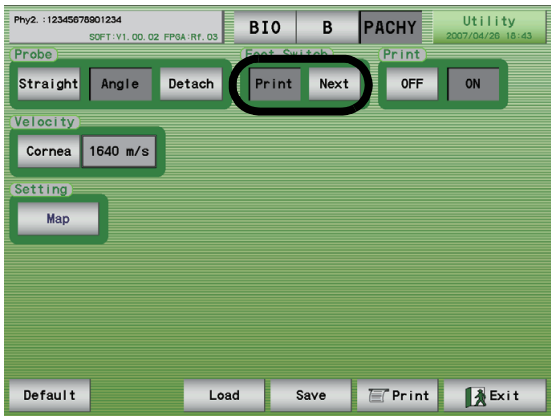


2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting PRINT switch of foot switch

1 Toggle the function of the PRINT switch of the foot pedal between "PRINT (printing)" and "Next (moving to the next measurement point)."

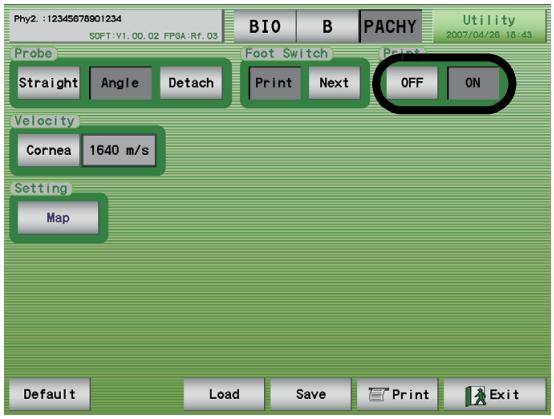


2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting printing of pachymetry results

1 Toggle printing of the pachymetry results between "ON" and "OFF."

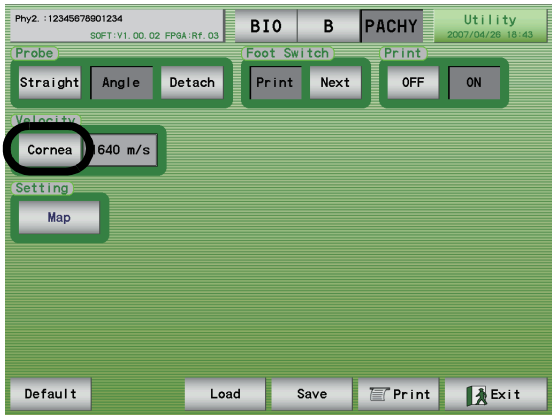


2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting corneal thickness sonic velocity to calculate distance

1 Press the Cornea switch.



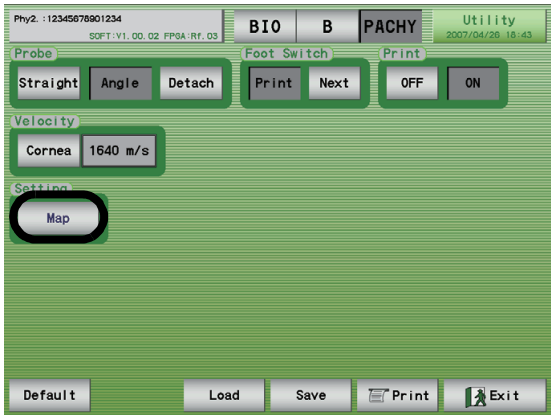
2 Input the sonic velocity to calculate distance.

3 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting map selected at device power-up

1 Press the Map switch.



2 Select the desired map.

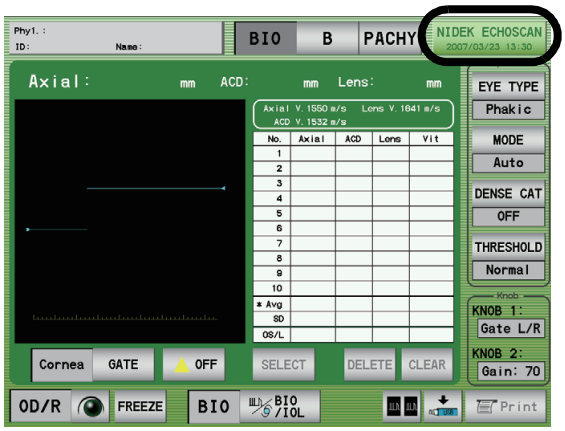
3 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

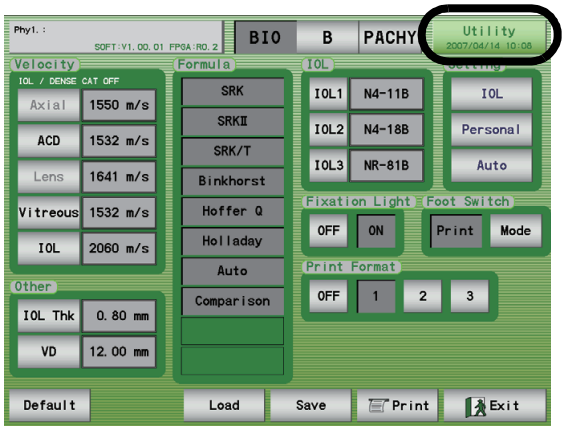
2.7 UTILITY

2.7.1 Displaying Utility screen

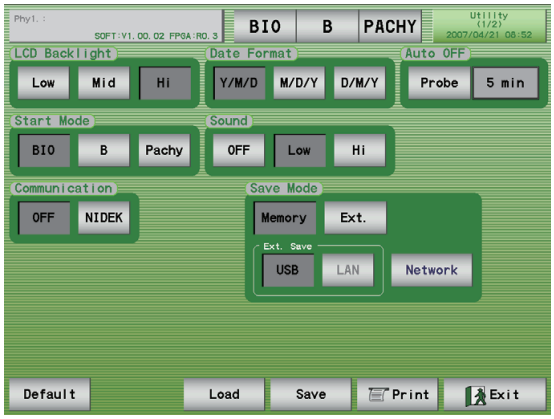
1 Press the switch that indicates the date and time in each measurement screen.



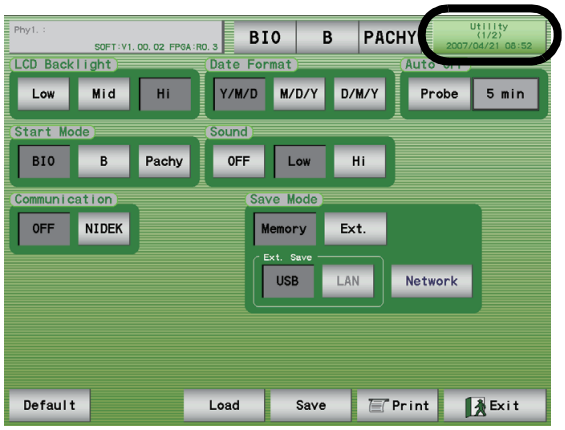
2 Press the Utility switch.



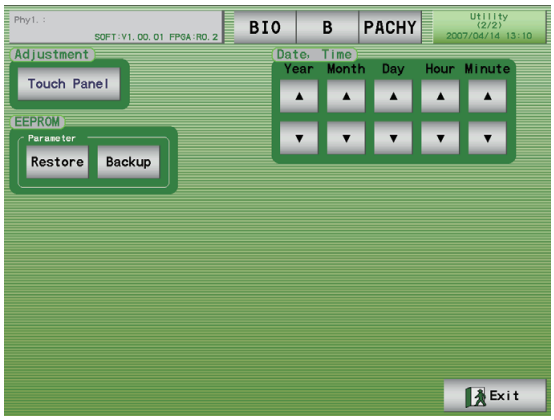
3 Change the settings in the Utility (1/2) screen.



4 Press the Utility switch.



5 Change the settings in the Utility (2/2) screen.

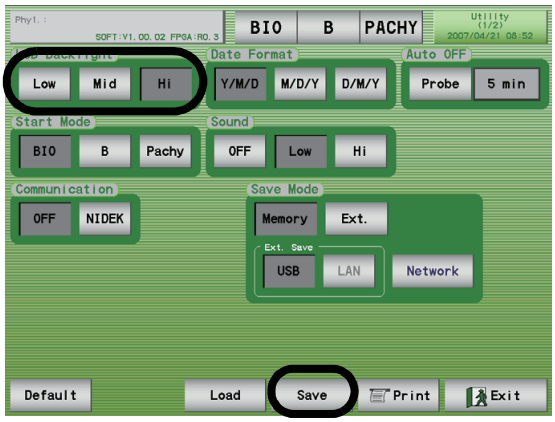


6 Press the Exit switch to return to the measurement screen.

2.7.2 Setting Utility (1/2)

○ Setting backlight

1 Press the desired LCD backlight switch (Low, Mid, or Hi) to set the brightness of the LCD backlight. The default setting is ”Hi."

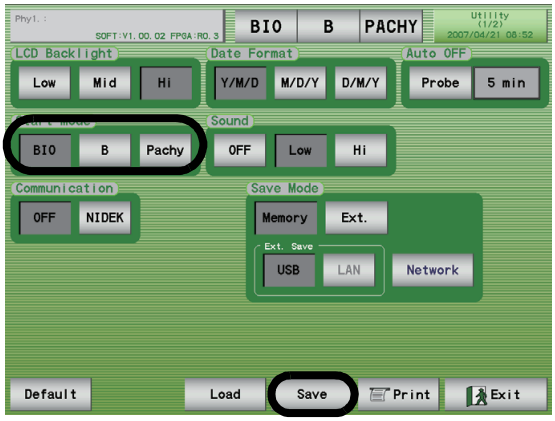


2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting Start Mode

1 Select the initial screen after device power-up among "BIO," "B," and "Pachy."



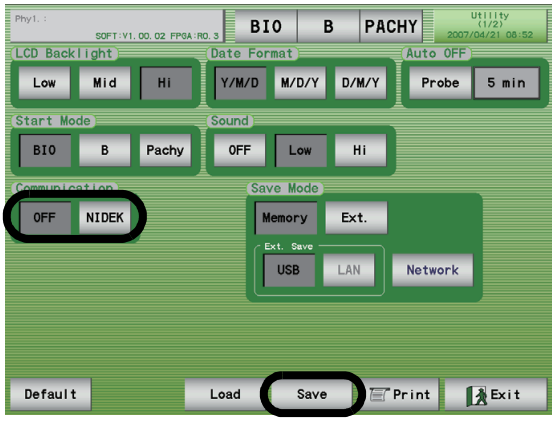
2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting Communication

1 Select the method of data transmission to other connected devices.

Toggle bewteen "OFF" and "NIDEK." The default setting is "OFF."

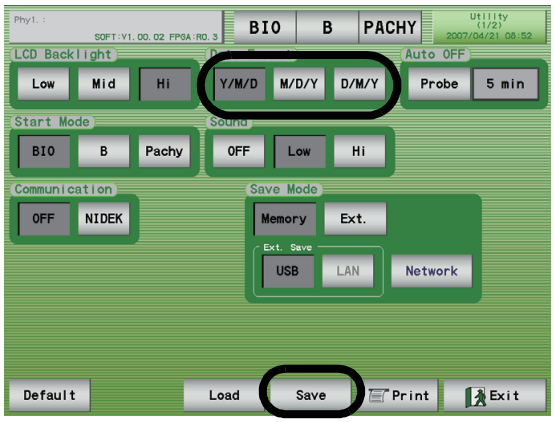


2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting date and time indication format

1 Select the format of the date and time indication. The default setting is "Y/M/D."

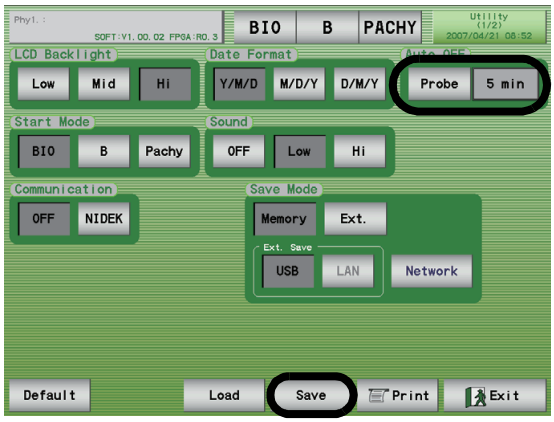


2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting Auto OFF

1 Press the Probe switch to input the maximum time of the LIVE (measurement) condition.



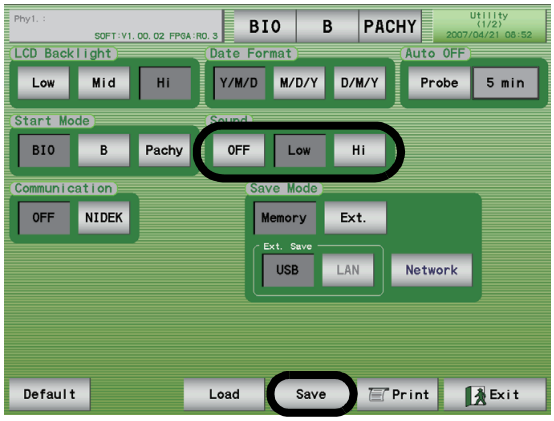
2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting sound volume

1 Select the desired sound pitch.

In a noisy environment, setting “Hi” increases the audibility of the sound.

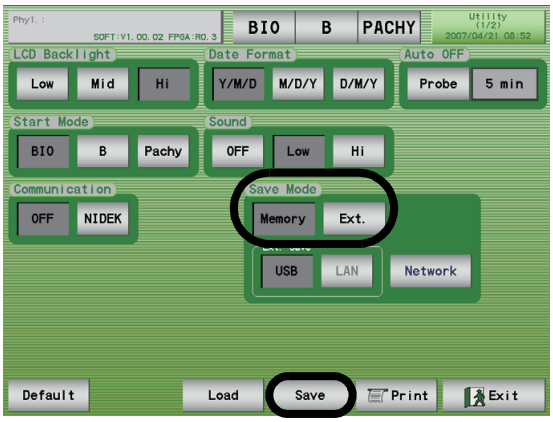


2 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

○ Setting save mode

1 Toggle the location to save the data between the internal memory (Memory) and an external storage device (Ext.).



2 If the internal memory (Memory) is selected, press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

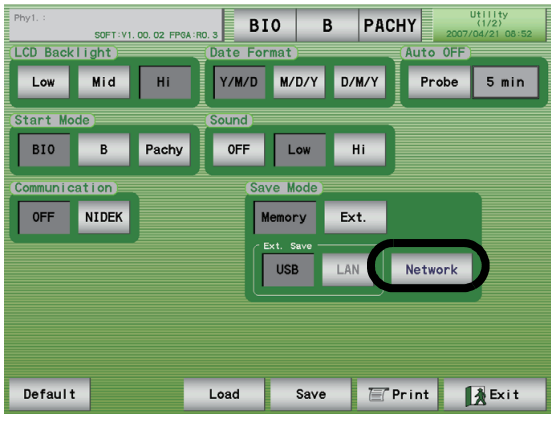
If the internal memory is selected, the saved data is deleted once power to the device is turned off.

3 To use an external storage device, select "USB" or "LAN."

4 If "USB" is selected, press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.

5 If "LAN" is selected, press the Network switch.



6 Obtain the following information from the network administrator. (IP Address of the US-4000)

TCP/IP

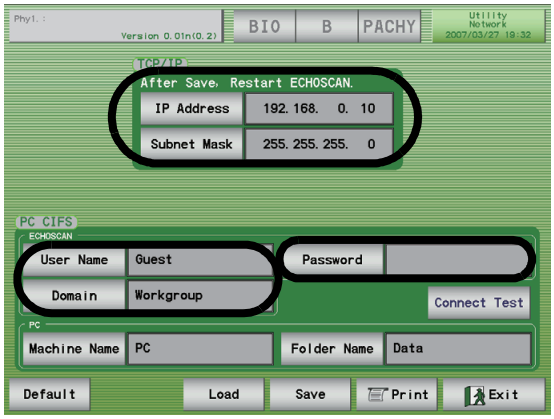
IP Address, Subnet Mask

PC CIFS

User Name, Pass word, Domain

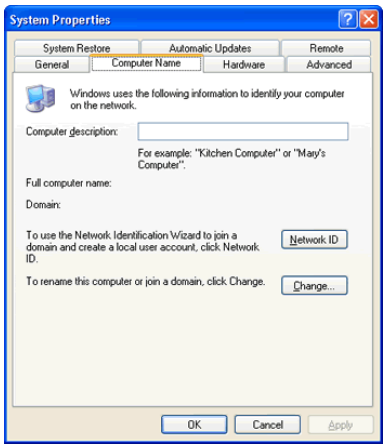
7 Input the information obtained from the network administrator.

Input a fixed IP address in the IP Address box. DHCP is not supported.



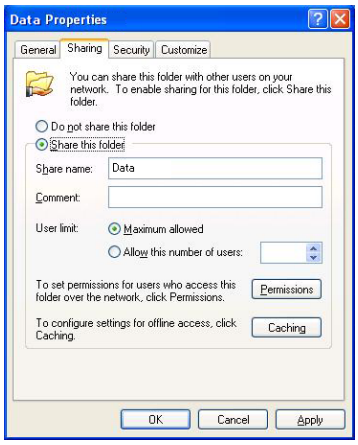
8 Confirm the computer name and domain in the Syetem Properties window on the PC.

(Ask the network administrator for detailed procedures.)

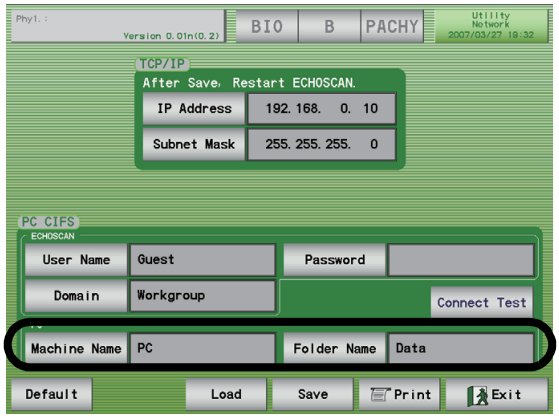


9 Create a folder for saving data on the PC.

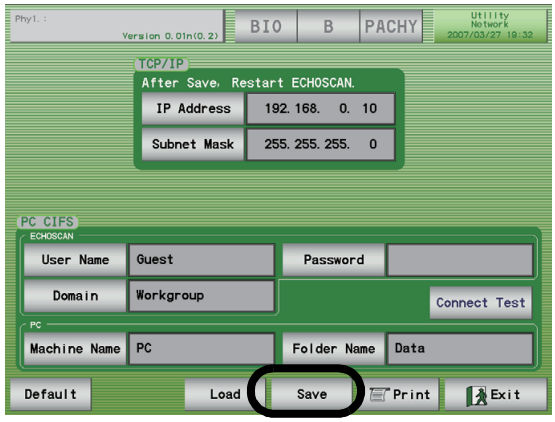
10 Select "Share this folder" under the Sharing tab in the Properties window of the created folder. Press the Permissions switch and set the access permission. Then press the OK switch.



11 Input the names of the PC and the folder for saving data.



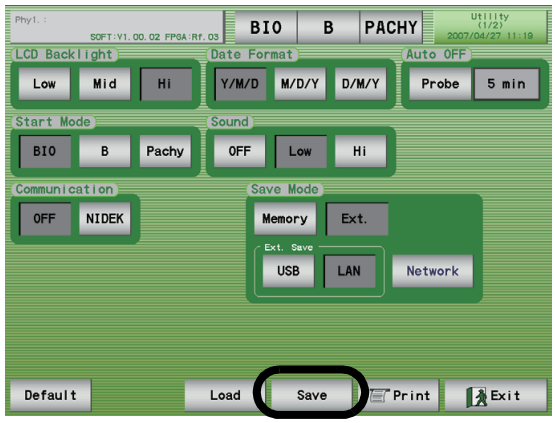
12 Press the Save switch.



13 Press the Exit switch to return to the Utility (1/2) screen.

14 Press the Save switch.

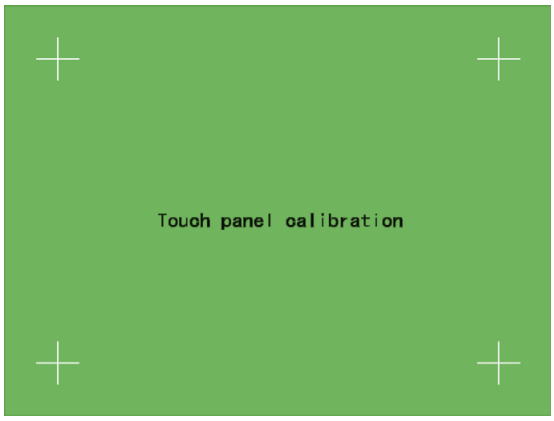
If the Save switch is not pressed, the setting is reset to the original once power to the device is turned off.



2.7.3 Setting Utility(2/2)

○ Adjusting touch screen

1 Press the Touch Panel switch in the Utility screen to display the screen shown below. Press the centers of the four red crosses with the stylus.



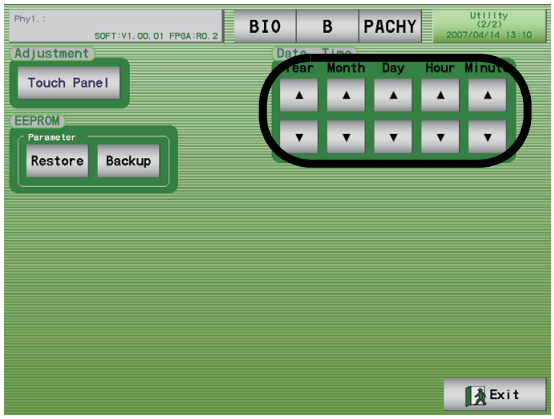
Note

- If any place other than the center of the red cross is touched with the stylus and the position of the screen is adjusted improperly, turn ON power to the device while pressing Knob 2.
  The touch screen can be adjusted again.

○ Setting date and time

1 Set the date and time with the arrow mark switches. The setting is reflected in the Utility switch.

The date and time is set without pressing the Save switch.



○ Handling EEPROM parameters

Loading backup of various settings (from USB flash drive)

1) Connect the USB flash drive that contains the backup data to the USB port of the device.
2) Press the Restore switch.

Saving various settings to USB flash drive

1) Connect the backup USB flash drive to the USB port of the device.
2) Press the Backup switch.

2.8 Completion of Operation

When the A-scan biometry, IOL power calculation, B-scan imaging, and pachymetry are finished, complete the operation following the procedure below.

1 Measure any additional patients.

To measure an additional patient, go back to"2.3 Preparation (Page 37)".

2 After the last patient is measured, turn OFF the power switch on the right side of the device.

3 Clean the used probes.

Remove any contamination by wiping the probe lightly with a soft cloth soaked with water or rubbing alcohol and wrung out. (See "5.6.1 Cleaning ultrasound probe (Page 133)".)

4 Disinfect the used probe and store it in the special case.

Perform the sterilization if necessary. (See "5.6.2 Disinfecting ultrasound probe (Page 134)".)

1) Soak the probe tip (max. 20mm) in the following disinfentant solutions:

   0.1% Chlorhexdine Gluconate Solution

   Ethanol for disinfection

2) Wipe the probe tip with the disinfected absorbent gauze dampened with ethanol.
3) Leave the probe sit until the tip is dry.
4) Put the cap on the probe tip, disconnect the probe from the device, and store it in the special case.

5 Clean the exterior of the device and touch screen if necessary.

Clean them referring to "5.5 Cleaning (Page 131)".

6 Put the dust cover on the device to keep dust out.

The operation of the device is completed.

3. OPERATION WHEN PERIPHERAL DEVICES ARE CONNECTED

The US-4000 can export the measurement data to a connected external device such as a PC. When the US-4000 is connected to a NIDEK Keratometer, data (R1 and R2) obtained by the Keratometer can be imported to the US-4000.

⚠ **CAUTION** • **Before connecting cables to devices, turn the devices off and disconnect all power cords from outlets.**
Malfunction may result.

3.1 Connecting to Keratometer

3.1.1 Outline

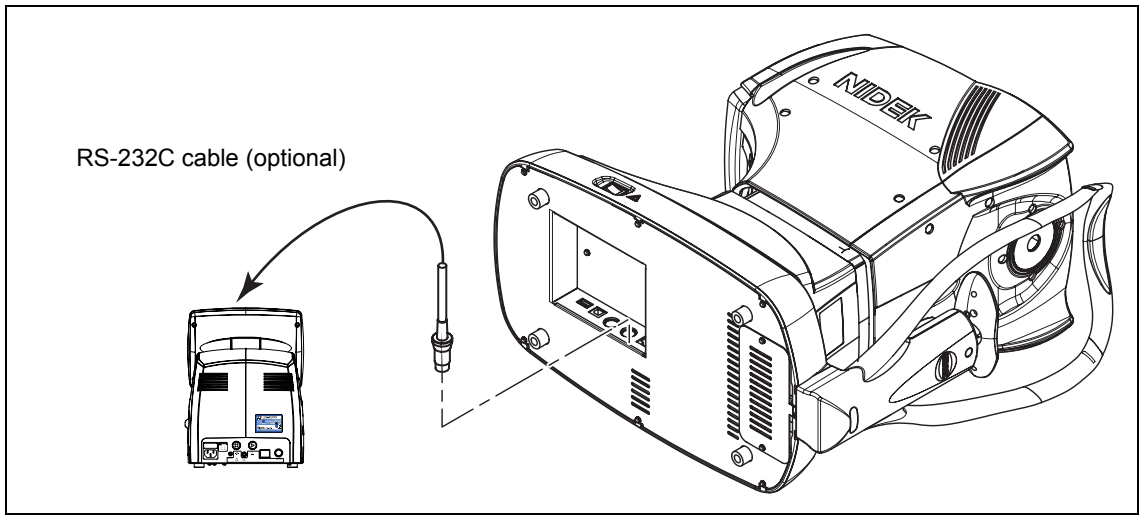
The US-4000 can be connected to devices such as the Auto Ref/Keratometer (ARK-530 series and ARK-700 series), Keratometer (KM-500, etc.), Handy Auto Ref/Keratoemter (ARK-30, etc.), OPD-SCAN (ARK-9000, etc.), and Auto Ref/Kerato/Tonometer (RKT-7700, etc.).

Note • The measurement data obtained by the KM is transmitted through the RS-232C interface.

3.1.2 Method of connection (example)

1 The US-4000 and the data output connector of the Keratometer is connected with a communication cable (optional).

Connect the RS-232C connectors at the back of the US-4000 and the Keratometer.



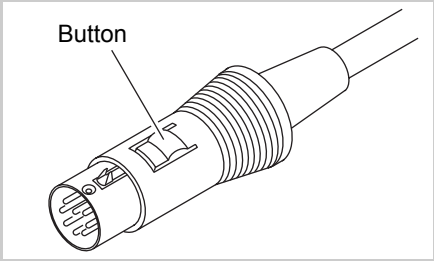
3.1.3 Operating procedure

1 After measurement with a keratometer, displaying the IOL power calculation screen with the US-4000 automatically transfers the measurement data from the keratometer to the US-4000.

Note

- To disconnect the interface cable, press the button on the connector.

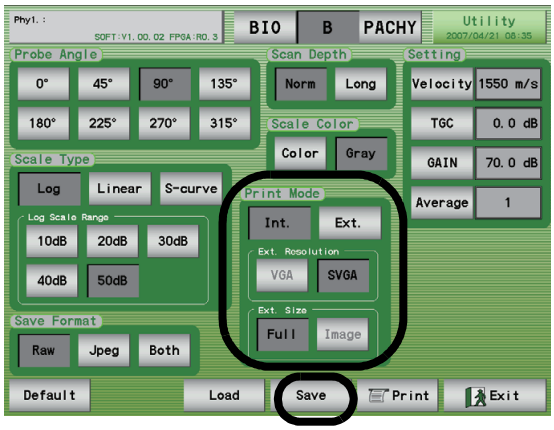
  When the cable is connected, the button is located on the underside of the connector.



3.2 Connecting to Video Printer

The US-4000 can be connected to a video printer for printing B-scan images.
Use a video printer that complies with IEC60601-1.

1 In the B-scan imaging utility screen, set "Print Mode" to "Ext."



2 Select the resolution (VGA/SVGA) of the video printer.

3 Select the information to be printed (Full (all the information in the screen) / Image (only the waveform)).

4 Press the Save switch to save the setting.

5 Connect the remote terminal of the US-4000 and the remote control terminal of the video printer.

6 Connect the video output terminal of the US-4000 and the VIDEO IN connector of the video printer.

7 Press the Print switch in the B-scan imaging screen to print the B-scan image.

* For use of the video printer, refer to its operator's manual.

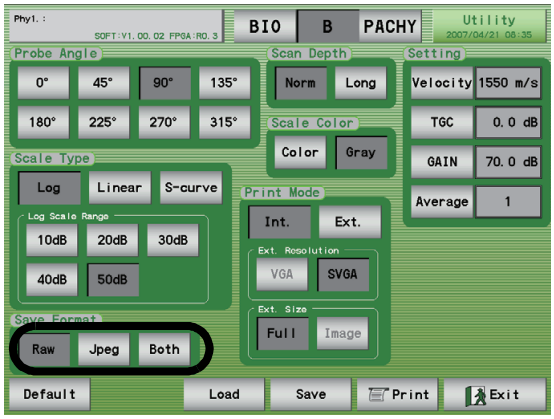
3.3 Connecting to USB Port

A USB memory key is connected to the US-4000 to save measurement images and values by selecting "USB" in the file setting in the B-scan imaging or A-scan biometry screen.
Use one of the recommended USB flash drives listed below. Other USB flash drives may not be used.

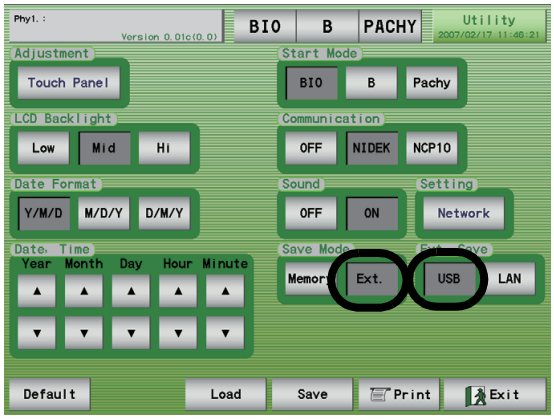
Recommended USB flash drives:

IO-DATA TB-B512, TB-B1G, TB-B2G, TB-BH4G/G
BUFFALO. RUF-C512ML/U2, RUF-C1GL-B/U2, RUF-Q16/4P,
SanDisk SDCZ6-1024-J65
TRANSEND . . . TS1GJFV10

1 In the B-scan imaging utility screen, select "Save Format" to "Raw," "Jpeg," or "Both," and press the Save switch.



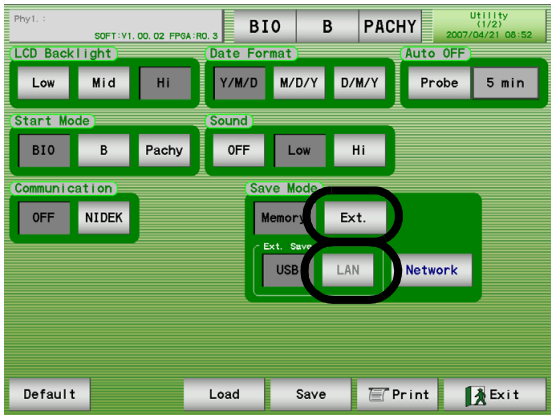
2 In the Utility (1/2) screen, set "Save Mode" to "Ext.," and "Ext.Save" to "USB," and press the Save switch.



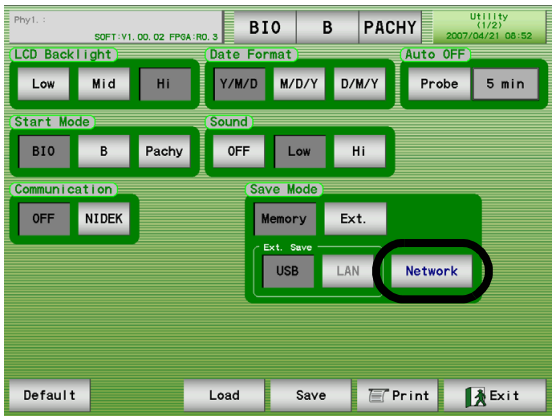
⚠ **CAUTION**
- Do not remove the USB flash drive from the US-4000 during data transfer.
- Remove the USB flash drive prior to turning ON power to the US-4000.

3.4 Connecting to LAN Port

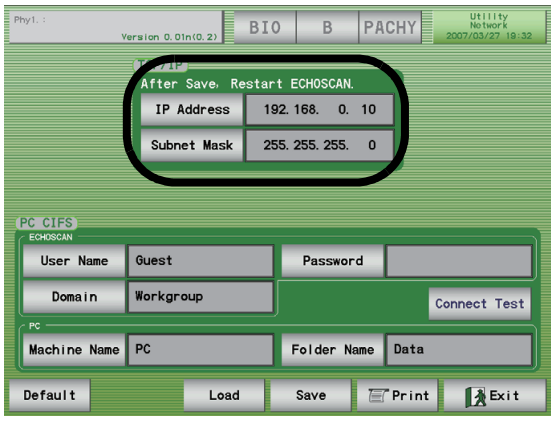
1 In the Utility (1/2) screen, set "Save Mode" to "Ext." and "Ext. Save" to "LAN", and press the Save switch.



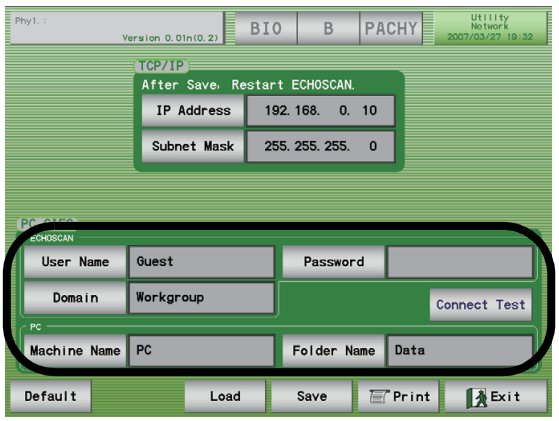
2 Press the Network switch to display the Network Utilty screen.



3 Press the IP Address and Subnet Mask switches and input the IP address and subnet mask.



4 Press the User Name, Password, Domain, Machine Name, and Folder Name switches and input the respective information.



5 Press the Save switch to save the settings.

6 Turn OFF power to the US-4000.

7 Connect a LAN cable to the US-4000.

8 Turn ON power to the US-4000.

4. CHECKS

4.1 Checks Before Use

Before using the device, be sure to check the following items. Record each result in the list on "Check List (Page 121)".

(1)Appearance

Check the appearance of the device for damage and/or stains which hinder the operation of the device. Stains produced by chemical agents may lead to a malfunction of the device.

(2)Power cord

Check whether the power cord is properly connected to a wall outlet with a protective ground whose type is single-phase of the specified voltage.

(3)Start-up

When the power switch is turned ON (|), the pilot lamp lights up and a beep sounds, as the opening screen appears. Confirm that the initial screen (set in the Utility screen) displayed after the device power-up appears a few seconds later.

(4)Probe

Check the surface of the A-scan, B-scan, and Pachymetry probes for scratches, chips, and/or cracks. Also check if the probe connectors are loose.

(5)Operation of A-scan biometry and the measured value

Measure the axial length using the test piece, and verify that the operation is normal and that the measured value is within the range indicated on the test piece.

(Refer to “4.2.1 Usage of test piece for A-scan biometry” (Page 118).)

(6)B-scan imaging operation

Start the measurement in the B-scan imaging screen.

Confirm that the transducer at the tip of the B-scan probe is vibrating and that the B-scan waveforms are displayed.

(7)Pachymetry operation/value

Press the Pachy switch to display the Pachymetry screen. Measure the pachymetry using the test piece to check whether the operation is normal and the measured value is within the range indicated on the test piece.

(See “4.2.2 Usage of test piece for pachymetry” (Page 119).)

(8)Printer operation

Print the result of items (5) or (6) by pressing the Print switch. Confirm that there are no mis-aligned and blurred areas on the printout.

4.2 Usage of the Test Piece

Before using the device be sure to check the operation using the test piece, and record the results on “4.3 Check List” (Page 121).

Note

- When the test piece is at a high temperature, the measured value cannot be indicated due to the attenuation of ultrasonic waves.

  In such a case, cool down the test piece.

4.2.1 Usage of test piece for A-scan biometry

1 Turn ON(|) the power switch tand display the A-scan biometry screen.

2 Confirm that the patient’s eye type is “Aphakic” and the sonic velocity to calculate distance is 1532 m/s.

a) If the patient’s eye type is not “Aphakic”, press the Eye Type switch to set it to “Aphakic”.

b) If the sonic velocity to calculate distance is not 1532 m/s, refer to “2.3.2 Setting physician data” (Page 41) to set it to 1532 m/s.

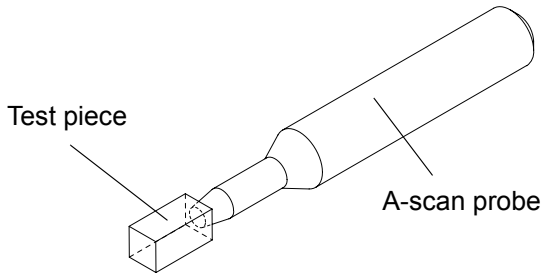
3 Wet the probe tip with water, and put it vertically on the test piece as shown in the figure below.

Be sure not to let in bubbles between the probe tip and test piece.

4 Press the FREEZE switch on the screen or the MEASURE switch of the foot switch to start the measurement.

The measurement value and A-scan waveform are indicated. (They are not frozen automatically.)

5 Confirm that the measured value is within the range indicated on the test piece.



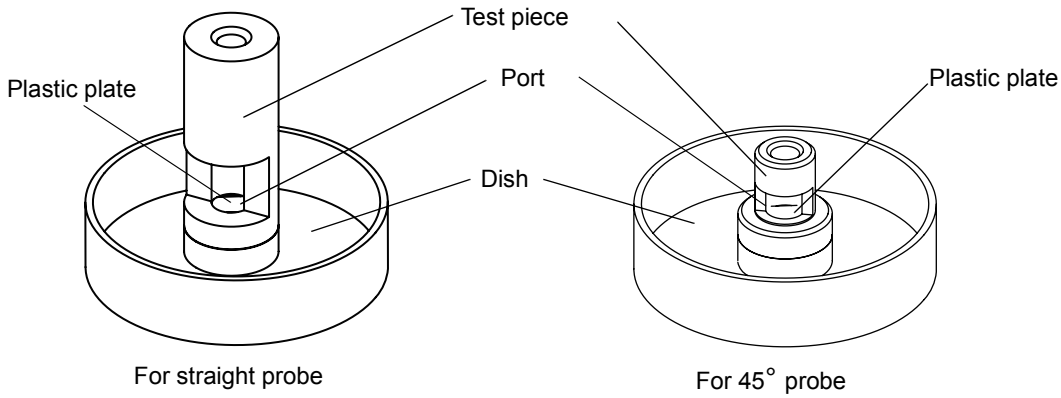
4.2.2 Usage of test piece for pachymetry

1 Prepare the test piece.

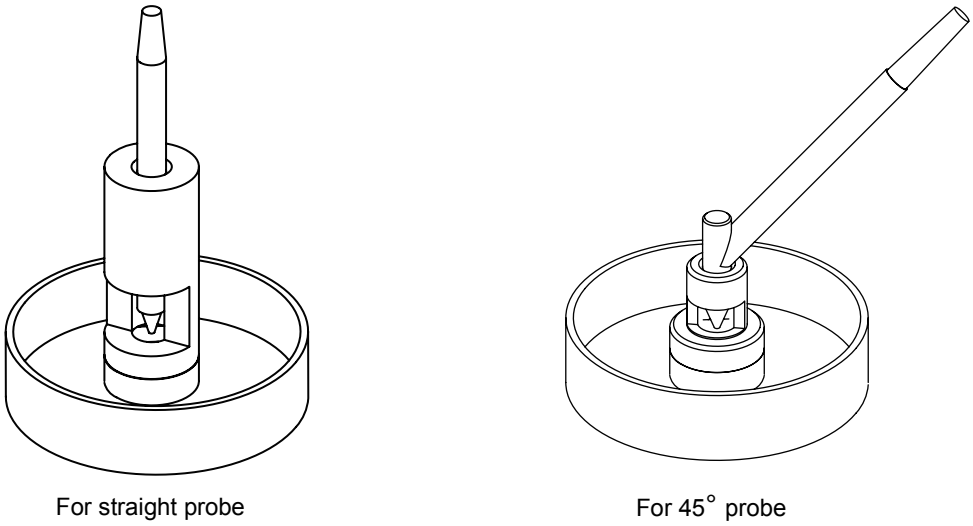
1) Place the test piece on a dish (such as petri dish) as illustrated.

2) Pour water into the port and fill the dish of the lower part of the test piece with water by using an injector or the equivalent.

Take care not to let in bubbles under the transparent plastic plate.



2 Wet the probe tip with water, and insert the probe into the test piece so that the tip vertically comes into contact with the plastic plate inside the test piece.



3 Turn ON (|) the power switch to show the A-scan biometry display.

4 Press the Pachy switch to display the Pachymetry screen.

5 Confirm that the sonic velocity to calculate distance is 1640 m/s.

If the sonic velocity to calculate distance is not 1640 m/s, refer to “2.6.2 Setting pachymetry utility” (Page 95) to set to 1640 m/s.

6 Press the FREEZE switch in the screen or the MEASURE switch of the foot switch to start the measurement.

When the measurement value cannot be obtained, check the following points:

- Is the probe tip wet?
- Are there no bubbles under the plastic plate of the test piece?

7 Confirm that the measurement value is within the range indicated on the test piece.

4.3 Check List

Record the result of items in “4.1 Checks Before Use” (Page 117) on the list below.

Date	Check items							
	Appearnce	Power cord	Start up	Probe appearance	A-scan biometry	B-scan imaging	Pachymetry	Printer
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5. MAINTENANCE

5.1 Troubleshooting

If any problem occurs with the device, refer to the following table before requesting repair.

Problem	Suggested action
The LCD does not turn on.	• The power cord may not be connected properly. Reconnect it securely. • The power switch may not have been turn on. Check the power switch.
The device cannot print out data.	• Check the printer paper. If the printer is short of paper, set a new printer paper roll. • The Print Format or Print setting in the A-mode utility or Pachymetry utility screen may be set to “Off.” Reset the parameter.
The printer does operate, however, the printout does not come out.	• The printer paper roll may be set with the wrong side up. Set it with the correct side up.
The indication "Printer Error" is displayed by pressing the Print switch, even when the printer paper is set.	• Check if the printer cover is closed securely. Open the printer cover and close it securely. • The Print switch may have been pressed too soon after the printer cover was closed. After the printer cover is closed, it takes several seconds until the printer becomes ready for use.
The printer paper is stuck and cannot be ejected properly.	• The printer paper roll may be set at an angle or shifted to one side. Open the printer cover and check whether the printer paper roll is set properly.

Contact NIDEK or your authorized distributor if the above suggestions do not eliminate the corresponding problem.

5.2 Various error codes and Suggested Actions

If any of the following error codes is displayed in the screen or printed, follow the suggestions in the “Cause and suggested action” column.
When contacting NIDEK or your authorized distributor for servicing, report the device serial number, the Message number, and the symptom for proper servicing.

Message number	Cause and suggested action
No.001 EEPROM Error	• EEPROM writing error. The device is shut off while data is being written to EEPROM, or a malfunction of electric circuit board or EEPROM on the electric circuit board is probable. • If the same error code is displayed even after the device is turned on again, shut off the device and contact NIDEK or your authorized distributor.
No.002 Time may have shifted.	Shortage of clock IC hold voltage Correct the time in the Utility screen. If the same error code is displayed even after the device is turned on again, shut off the device and contact NIDEK or your authorized distributor.
No.003 EEPROM File Checksum Error.	Error in reading EEPROM file The EEPROM file is corrupted or has been rewritten. If the same error code is displayed even after the device is turned on again, shut off the device and contact NIDEK or your authorized distributor.
No.010 BIO no signal detection.	BIO signal detection timeout If the same error code is displayed even after the device is turned on again, shut off the device and contact NIDEK or your authorized distributor.
No.020 B no signal detection.	B-scan probe is not connected. Connect the B-scan probe. If the same error code is displayed again, shut off the device and contact NIDEK or your authorized distributor.
No.030 Pachy no signal detection.	Pachymetry signal detection timeout If the same error code is displayed even after the device is turned on again, shut off the device and contact NIDEK or your authorized distributor.
No.031 Pachy Probe No Connection	The Pachymetry probe is not connected. Connect the Pachymetry probe. If the same error code is displayed, shut off the device and contact NIDEK or your authorized distributor.
No.064 RS232C No Connection	The communication cable is not connected, or the other end of communication is not ready for communication. Confirm that the communication cable is connected to the external communication connector securely. If the same error code is displayed, shut off the device and contact NIDEK or your authorized distributor.
No.065 Com Time Up Error	No response is received during the communicaiton. The communication cable is not connected properly. Confirm that the communication cable is connected to the external communication connector securely. If the same error code is displayed, shut off the device and contact NIDEK or your authorized distributor.
No.100 Printer Error.	Printer error (Failure of the printer) If the same error code is displayed, shut off the device and contact NIDEK or your authorized distributor.

Message number	Cause and suggested action
No.101 Initialize Error.	Printer initialization error (Failure of the printer) If the same error code is displayed, shut off the device and contact NIDEK or your authorized distributor.
No.102 Send Data Error.	Printer data transmission error (Failure of the printer) If the same error code is displayed, shut off the device and contact NIDEK or your authorized distributor.
No.103 Head Voltage Error.	Printer head voltage error (Failure of the printer) If the same error code is displayed, shut off the device and contact NIDEK or your authorized distributor.
No.140 Reset Error.	Printer reset error (Failure of the printer) If the same error code is displayed, shut off the device and contact NIDEK or your authorized distributor.
No.141 Hardware Error.	Printer connection error (Printer connection error or failure) If the same error code is displayed, shut off the device and contact NIDEK or your authorized distributor.
No.144 No Paper.	There is no printer paper. (The printer cover is open.) Supply a new roll of printer paper. (Close the printer cover.)
No.145 Head Up.	The printer cover is open. Close the printer cover.
No.146 Head Temperature Error.	The printer head temperature is excessively high (in continuous image printing). Start printing again after a while.
No.201 Invalid Information Data.	USB flash drive read data format error (Data has been edited outside the USB flash drive. Data is corrupted.) If the same error code is displayed, shut off the device and contact NIDEK or your authorized distributor.
No.202 Invalid RAW Data.	USB flash drive read waveform data format error Data has been edited outside the USB flash drive. Data is corrupted.
No.203 USB Memory Error.	USB flash drive error An error regarding the USB flash drive occurred. (ex.: File deletion error that occurs when any file is deleted while it is being transferred.)
No.250 Can't Access USB memory.	The USB flash drive is not connected. Connect the USB flash drive.
No.251 Can't Write USB memory.	USB flash drive writing error The USB flash drive is write-protedted or full. Disable the write protection or check the free space of the USB flash drive.
No.252 There is no Raw Data File.	There is no raw data file. Only Jpge files are saved or Raw data files are deleted. In the B-scan imaging utility screen, select "Raw" in "Save Format."
No.253 Can't Display All USB Data.	All the data in the USB flash drive cannot be displayed in the list. Only a maximum of 1000 sets of data in the USB flash drive can be displayed. More than 1000 data sets cannot be displayed.

Message number	Cause and suggested action
No.254 Can't Delete USB Memory.	Data cannot be deleted. The USB flash drive is write-protected. Disable the write protection.
No.255 Can't Read USB Memory.	Data cannot be read. Data is corrupted or does not exist.
No.300 CIFS Error.	Windows file sharing error
No.301 Invalid Information Data.	Network read data format error Data has been edited outside, or corrupted.
No.302 Invalid RAW Data.	Network read waveform image data format error Waveform image data has been edited outside, or corrupted.
No.303 Hardware Error.	IC error IC was damaged by any cause such as electrostatic discharge. If the same error code is displayed even after the device is turned on again, shut off the device and contact NIDEK or your authorized distributor.
No.350 Can't Access Network.	Network cannot be accessed. Enabling access to the network may take a while after the device start-up. Check the LAN cable connection and the IP address and subnet mask in the Network setting in the Utility screen.
No.351 Can't Write Network.	Network writing error (Write-protection is enabled or no free space is left.) Check if the Write permission is granted to the destination folder in the PC and sufficient free space is left.
No.352 There is no Raw Data File.	There is no Raw data file. (Only the Jpeg file has been saved or the Raw data file has been deleted.) In the B-scan imaging utility screen, select "Raw" for "Save Format."
No.353 Can't Display All PC Data.	All the data sets in the PC cannot be displayed in the list. (Only a maximum of 1000 data sets can be displayed.) More than 1000 data sets cannot be displayed.
No.354 There is no Machine Name in this Network.	The PC of the specified name does not exist. The PC name specified in "Machine Name" in "Ext. Save" in the Utility screen, or the LAN connection is not established.
No.355 Read Only Folder.	Read-only attribute (Writing of data was tried to a folder with the read-only attribute.) Write-protection is enabled on the destination PC folder. Disable the write-protection.
No.356 Can't Logon PC.	Logging on to the PC is not allowed. (The user name or password is incorrect.) The User Name or Password input in the Utility screen are incorrect.
No.357 There is no Shared Folder.	The shared folder does not exist. (The name of the shared folder is incorrect.) The folder specified in "Folder Name" in "Ext. Save" in the Utility screen does not exist or is not shared.
No.358 Network Timeout.	Time out (The PC did not finish the process in a specified time.)

Message number	Cause and suggested action
No.359 Can't Delete PC Data.	The data cannot be deleted. (Deletion was tried on the data with the read-only attribute.) Write-protection is enabled on the destination PC folder. Disable the write-protection.
No.360 Network Initializing. Please Retry.	The network is being initialized. (The initialization takes a while after the device startup.) Retry access to the Network later.
No.361 Access Denied.	Access is not allowed. (Folder sharing setting is improper.) Check the setting of "PC CIFS" in "Ext. Save" in the Utility screen.
No.362 Account Disabled.	The account is disabled. (The user setting is improper.) Check the setting of "ECHOSCAN" in "Ext. Save" in the Utility screen.

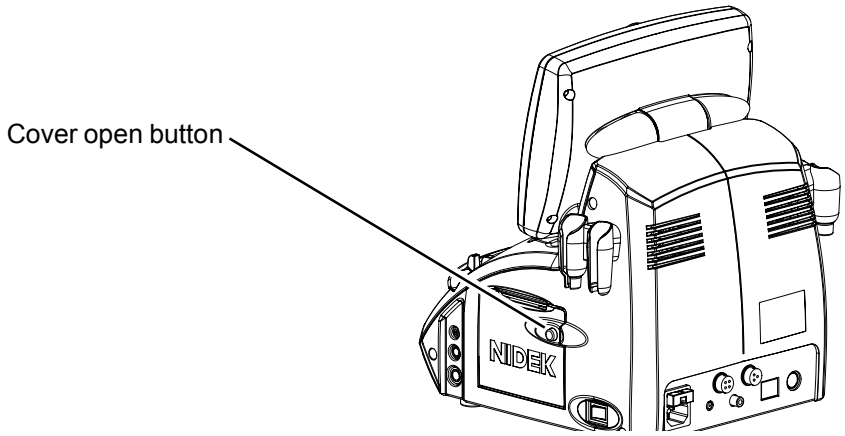
5.3 Replacing Printer Paper

Red lines on the edges of the printer paper indicates that the paper is running short.
When the red lines are printed, stop using the printer and set a new roll of printer paper.

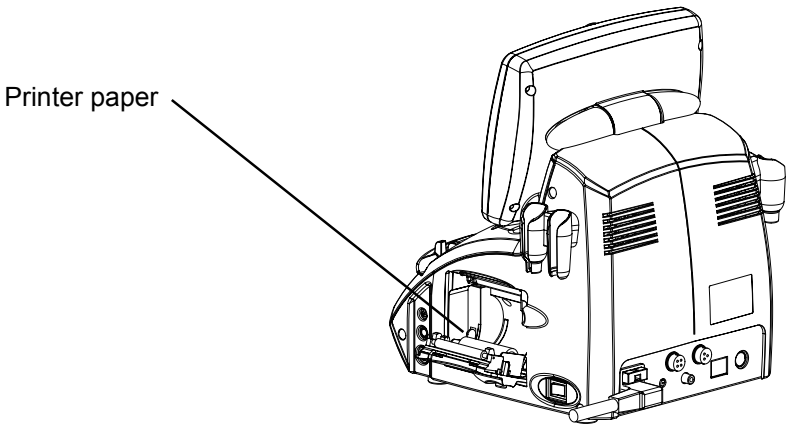
Note

- Do not run the printer while the printer paper is not set.
  The printer head may become damaged.
- Do not pull the paper forcefully from the printer.
  Printer malfunction may result.

1 Press the Cover open button until a click is heard, and open the printer cover.



2 Take out the roll of printer paper.

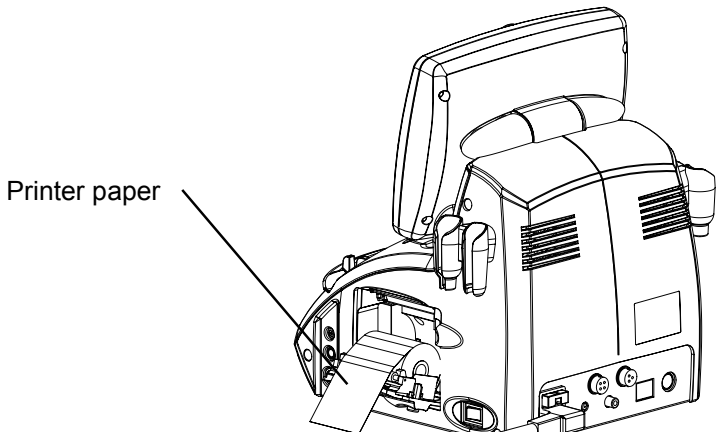


⚠ **CAUTION** • **When replacing the printer paper, take care not to touch the printer head at the upper part of the printer inside the cover.**
The printer head remains heated for a while after printing. Touching it may cause burn.

3 Set a new roll of printer paper.

Set a new roll of printer paper as shown in the figure below.

Pull out the edge of the paper so that it comes out of the printer cover.

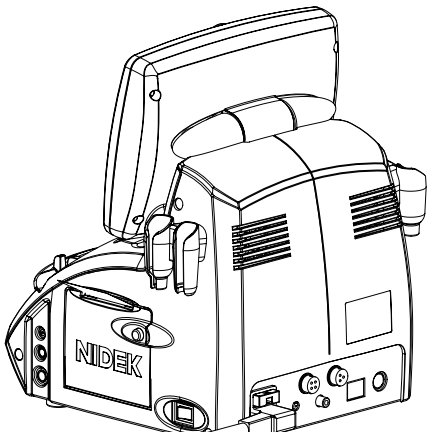


Note

- If the printer paper roll is set in such a way that the paper becomes upside down, data is not printed on the paper.
- Confirm that the roll of printer paper is not set at an angle or shifted to one side.
  The printer paper may not come out properly.

4 Close the printer cover.

Press both edges of the printer cover to close it securely.



Note

- Confirm that the cover is closed securely.
  If the cover is not clsoed securely, the automatic paper cutter may not function properly. Pressing the Print switch may display "No.144 No Paper." or "No.145 Head Up." and printing may not be performed.

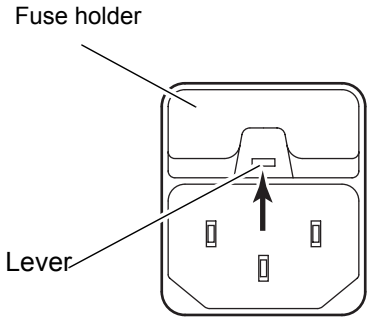
5.4 Replacing Fuses

When the pilot lamp does not illuminate by turning ON (|) the power even if the power cord is connected properly, fuses may be blown. In this case, replace the fuses with new ones according to the procedure below:

1 Turn OFF the power switch and disconnect the power cord from the inlet of the device.

2 Pull out the fuse holder next to the power inlet.

Pull out the fuse holder while pushing the lever in the arrow direction.

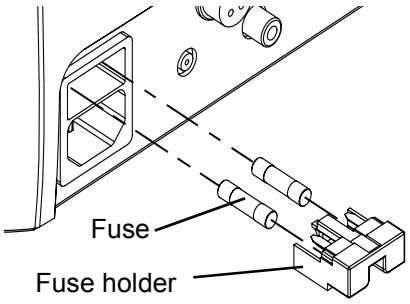


3 Replace blown fuses with new ones.

Always use two specified fuses together.

[250V T1.6A (∅ 5 x 20 mm): 100V region]

[250V T0.8A (∅ 5 x 20 mm): 230V region]



4 Attach the fuse holder.

5 Connect the power cord to both inlets.

6 Turn ON (|) the power, and confirm that the pilot lamp illuminates.

If fuses blow again soon, contact NIDEK or your authorized distributor.

5.5 Cleaning

5.5.1 Cleaning cover

When the cover or panel of the device becomes contaminated, wipe them with a soft cloth. For severe stains, wipe with a soft cloth soaked in a neutral detergent and wrung out. After that, wipe with a dry and soft cloth.

⚠ **CAUTION**

- **Never use an organic solvent such as paint thinner.**
  The surfaces of the device may be ruined.
- **Never use a sponge or cloth soaked in water.**
  The water may leak into the device and malufnciton may result.

5.5.2 Cleaning printer

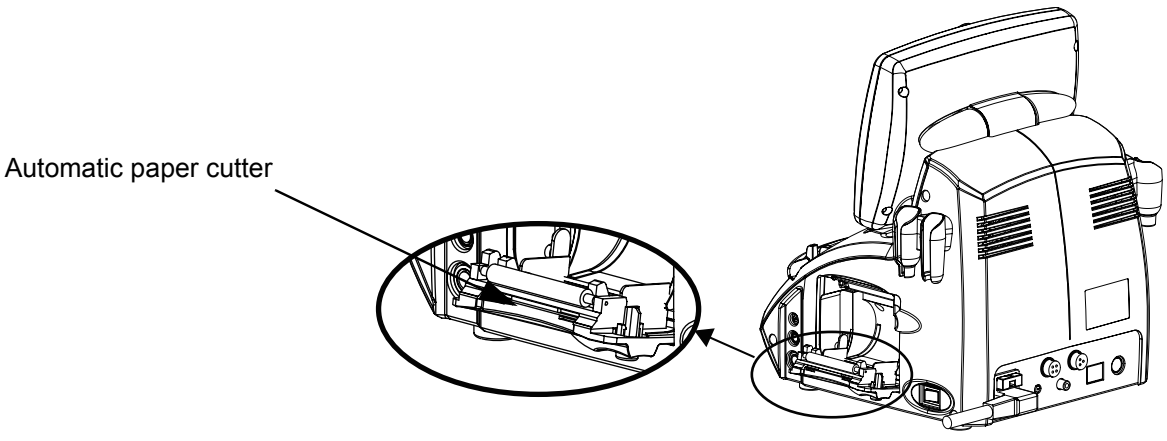
After repeated usage, the paper slot of the auto cutter of the printer is soiled with powdery paper. If powdery paper is settled, a malfunction of the auto cutter may result; clean it.

1 Open the printer cover and take out the printer paper.

See “5.3 Replacing Printer Paper” (Page 128).

2 Apply the nozzle of a vacuum cleaner to the paper slot for the printer paper to suck powdery paper.

Never blow off powdery paper the with a blower. If powdery paper settles on the internal working structure, malufnciton may result.



3 Set the printer paper roll as it was.

5.5.3 Cleaning touch screen

Soak a soft cloth in water or ethanol, and lightly wipe the dirty parts.

⚠ **CAUTION**

- Do not wipe the touch screen with a cloth soaked in ethanol.

  If ethanol seeps into the internal structure of the touch screen through the gap between the screen and the body, the touch panel may malfunction.

- Do not use any solution other than ethanol to clean the touch screen.

5.6 Maintenance of Ultrasound Probe

5.6.1 Cleaning ultrasound probe

Parts to be cleaned

Tip of the A-scan probe

Tip of the B-scan probe

Tip of the Pachymetry probe (only the tip for detachable tip type)

Time to perform cleaning

Before disinfection and sterilization

1 If foreign object is attached to the tip of the probe, wipe of the tip with a soft cloth soaked in water or disinfectant alcohol.

⚠ **CAUTION**

- Do not clean the ultrasound probe with water of 45°C or hotter.
  The ultrasound probe may become damaged.
- Perform cleaning before the body fluid or chemical solution on the probe become dry.
  The body fluid and chemical solution may become difficult to remove.

5.6.2 Disinfecting ultrasound probe

Parts to be cleaned

Tip of the A-scan probe

Tip of the B-scan probe

Tip of the Pachymetry probe (only the tip for detachable tip type)

Time to perform disinfection

Before and after use of the device

1 Clean the tip of the probe.

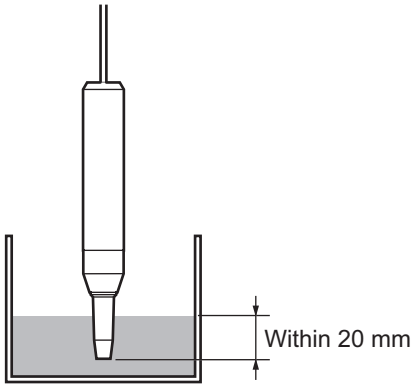
See “5.6.1 Cleaning ultrasound probe” (Page 133).

2 Soak the tip (less than 20 mm) of the probe in disinfectant solution.

See the instruction of the disinfectant for the duration to soak the tip.

ex.) chlorhexidine gluconate solution

Disinfectant alcohol



ex.) A-scan probe

⚠ **CAUTION** • See the instruction of the disinfectant for its use.

3 Wipe the disinfectant solution on the tip of the probe with a sterilized absorbent cotton soaked in ethanol for disinfection.

4 Leave the probe sit until the tip of it becomes dry.

5.6.3 Sterilizing ultrasound probe

Parts to be cleaned

Tip of the A-scan probe

Tip of the B-scan probe

Tip of the Pachymetry probe (only the tip for detachable tip type)

Time to perform sterilization

After using the probe for an infected patient

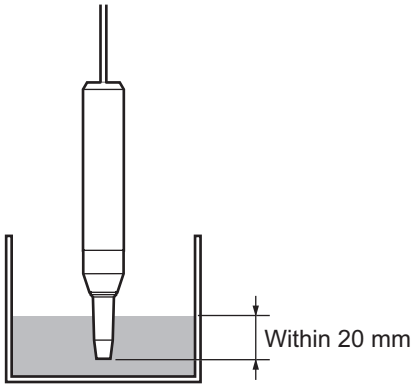
1 Clean the tip of the probe.

See “5.6.1 Cleaning ultrasound probe” (Page 133).

2 Soak the tip (less than 20 mm) of the probe in the glutaraldehyde solution.

See the instruction of the glutaraldehyde solution for the duration to soak the tip.

ex.) Cidex plus 28



ex.: A-scan probe

⚠ **CAUTION** • See the instruction of the glutaraldehyde solution for its use.

3 Wash the tip of the probe soaked in the sterilization solution with a large amount of sterile water or water.

4 Wipe the water on the tip of the probe with a sterilized absorbent cotton.

5 Leave the probe sit until the tip of it becomes dry.

6 Put the protective cap on the probe and store it in the special case.

5.7 List of Replacement Parts

Part name	Part number	Note
Printer paper	80620-00001	Width 58 mm, 25 m
Fuse	80402-02040 (100V) 80402-02038 (230V)	250V T1.6A (∅ 5 x 20 mm): 100V regions 250V T0.8A (∅ 5 x 20 mm): 230Vregions

* After replacement of consumables, restock them.

6. SPECIFICATIONS AND CONFIGURATION

6.1 Classifications

Protection method against electric shock Class I

The US-4000 is classified as a Class I device.

A Class I system provides protection against electric shock and does not rely on basic insulation only, but which includes additional safety grounding of accessible conductive parts in the fixed wiring in such a way that accessible conductive parts cannot become live in the event of a failure of the basic insulation.

Degree of protection against electric shock: Type B applied part

The US-4000 is classified as a device with a Type B applied part.

A device with a Type-B applied part contains an internal electrical power source providing an adequate degree of protection against electric shock in regards to:

- allowable leakage currents

- reliability of the protective ground connection (if present).

Degree of protection against ingress of water: IPX1

The US-4000 is classified as an ordinary device.

An IPX1 is an ordinary unit without protection against an ingress of water. Do not expose water to the device.

Degree of safety application in the presence of flammable anesthetics and/or flammable cleaning agents

The US-4000 should be used in an environment where no flammable anesthetics and/or flammable cleaning agents are present.

Methods of disinfection recommended by manufacturer

The US-4000 is a device that includes parts that need sterilization or disinfection.

Mode of operation

The US-4000 is classified as a continuous operating device.

Classification by transference

The US-4000 is classified as a transportable device.

6.2 Specifications

6.2.1 A-scan biometry/IOL power calculation

- Probe
  Solid probe
  Frequency: 10MHz (± 20%)
  Internal fixation lamp: LED (Red), Illumination
- Display
  Measurement method: Ultrasonic pulse reflective method A-scan biometry
  Measurement value: Axial length, anterior chamber depth, lens thickness, vitreous body thickness, and A-scan waveform (measurement values of 10 times, the average value, and the starndard deviation)
  Measurement range: 12.00 to 40.00mm
  Minimum display unit: 0.01mm
  Accuracy: ± 0.1 mm
- Measurement function: Manual, Auto, Speed
  Gate: Cornea, Lens-F (anterior), Lens-B (posterior), retina
  Sonic velocity to calculate distance:
  Average axial length: 1550m/s (Phakic eye), 1548m/s (Eye with mature cataract: DENSE CAT ON)
  1532m/s (Aphakic eye)
  Setting range: 1000 to 2000m/s
  Anterior chamber, vitreous body: 1532m/s
  Setting range: 1000 to 2000m/s (Anterior chamber)
  Setting range: 500 to 2000m/s (Vitreous body)
  Lens: 1641m/s, 1629m/s (Eye with mature cataract: DENSE CAT ON)
  Setting range: 1000 to 2000m/s
  IOL: 2060m/s (Acrylic)
  2760m/s (PMMA)
  1049m/s (Silicone)
  Setting range: 500 to 3000m/s
- IOL power calculation
  IOL formula: Binkhorst, Holladay, SRK, SRK II, SRK/T, Hoffer Q
  Calculated IOL power: IOL refractive power for ametropia (IOL)
  Postoperative refractive error (ERROR)
  IOL data registration: Manufacturer, model, A-Constant, SF value, ACD value (A maximum of 16 types of IOL data can be registered.)
  IOL power calculation range: A-Constant 100 to 130
  ACD value: 1.60 to 9.99
  SF value: 0.00 to 9.99
  Axial length: 12.00 to 40.00 mm
  Keratometry: 5.00 to 19.99 mm (curvature radius)
  20.00 to 60.00D (refraction)
  Postoperative target refraction: -10.00 to +10.00D
  Calculated IOL power: -99.99 to +99.99D
  Comparison display: Three types of IOL power calculation results are displayed for a single IOL power calculation formula. The calculation results of estimated postoperative refractive power for the IOL power is displayed.
  IOL power calculation comparison: Three types of IOL power calculation results are displayed for multiple calculation method selected by the physician.

6.2.2 B-scan imaging

- Probe
  Permanent oil filled & compact probe
  Frequency: 10 MHz (± 15%)
  Scanning type: Mechanical sector scanning
  Scanning angle: 60°
  Scanning speed: 10 Hz
- Display
  Scanning range: 35 mm or 50 mm from the edge of the probe (± 10%) (equivalent sonic velocity 1550 m\s)
  Gray scale (color scale): 256 levels (Color scale can be displayed.)
  Display mode: B-scan, CV (B+BIO)
  The BIO mode waveform of the line specified with the cross-vector is displayed along with the B-scan cross-sectional image.
  Saving B-scan image: CV mode image can be saved - a maximum of 12 still images (internal volatile memory)
  Saving still images to USB flash drive
  Saving about 20 seconds of moving image (cleared when the measurement is resumed)
  Multiple B-scan images display: A maximum of four saved images can be displayed in a screen.
  Magnifying B-scan image: CV mode image (measurement depth 35 or 50 mm) can be magnified (x 2.5, x 5)
- Measurement function
  Two sets of calipers (precision of measuring the distance between two points: ± 10%)
  Area measurement (precision of area measurement: ± 10%)
- Gain
  For near-field sensitivity (TGC): 0 to -20dB
  For total sensitivity (GAIN): 0 to 90dB
- Scale
  1 mm scales under the B-scan image (5 mm intervals are marked with a medium line, and 10 mm intervals are marked with a long line)
- Resolution
  Distance resolution: 1 mm
  Lateral resolution: 1 mm

6.2.3 Pachymetry

- Probe
  Solid probe
  Frequency: 10 MHz (± 10%)
- Display
  Measurement type: Ultrasonic pulse reflective method
  Measurement value: A maximum of 25 points of corneal thickness values can be saved.
  Measurement range: 200 to 1300 µm
  Minimum display unit: 1 µm
  Accuracy: ± 5 µm
  Sonic velocity to calculate distance: 1640m/s

6.2.4 Other functions

- Observation/Display type: 8.4-inch color LCD
- Printer
  Thermal line printer with automatic paper cutter
  Paper width 57.5 mm
- Interface connector
  RS-232C: 1 port (used to connect the KM manufactured by NIDEK)
  USB: 1 port (1.1)
  VIDEO output: (NTSC)
  LAN: 1 port

6.2.5 Dimensions and weight

- Dimensions 300 (W) x 285 (D) x 330 (H) mm
- Weight 8.5kg
- Power supply AC 100 to 120, 230V ± 10% 50/60Hz
- Power consumption 70VA

6.2.6 Environemntal conditions (during use)

- Temperature +10 to +35°C
- Humidity 30 to 75%
- Atmospharic pressure 800 to 1060 hPa

6.2.7 Environmental conditions (during storage and shipping)

- Temperature - 10 to +55°C
- Humidity 10 to 95% (Non-condensing)

6.2.8 Composition of parts that come into contact with human body

- Biomentry probe - Polystyrene
- B-scan probe - Polymethylpentene
- Pachymetry probe - Polystyrene

6.2.9 Others

• Installation category: II (OVERVOLTAGE CATEGORIES)
• Pollution degree: 2 (IEC60664)
• Unit per package 1 unit

6.3 Configuration

6.3.1 Standard accessories

• Stylus	•1 unit
• B-scan probe	•1 unit
• A-scan probe	•1 unit
• Foot switch	•1 unit
• Test piece (for Biometry measurement)	•1 unit
• Printer paper	•3 rolls
• Power cord	•1 unit
• Ultrasonic gel	•1 unit
• Dust cover	•1 unit
• Spare fuse	•2 units
• Probe rest	•3 units
• Operator's manual	•1 volume

6.3.2 Optional accessories

• Video printer	•1 unit
• Video printer paper	•6 rolls
• Pachymetry 45° probe *	•1 unit
• Pachymetry probe (straight type)	•1 unit
• Pachymetry probe (45° detachable type)	•1 unit
• Test piece (for Pachymetry measurement) *	•1 unit
• Probe stand	•1 unit

* Provided as standard accessories depending on the configuration.

7. IOL FORMULA

7.1 Outline of IOL Formula

The following six types of IOL formulas are preprogrammed into the US-4000, and there may be a difference in the last digit to an extent because of the number of effective digits for the inside calculation.

(1) SRK (SANDERS-RETZLAFF-KRAFF), SRK II, and SRK/T formula

These programs are based on the formula of Dr. Sanders, Dr. Retzlaff and Dr. Kraff. SRK formula is the most famous one among the regression formulas. SRK II is the corrected SRK formula, and SRK/T is a theoretical formula.

(2) Binkhorst formula

This program is based on the formula of Dr. Binkhorst in order to calculate the refractive power of IOLs. This is the most famous formula among the theoretical formulas.

(3) Hoffer-Q formula

This program is based on the formula of Dr. Hoffer. This theoretical formula adopts the predictable anterior chamber depth.

(4) Holladay formula

This program is based on the formula of Dr. Holladay. It calculates reversely the SF value from the stable postoperative refractive power to make an adjustment based on a physician's surgical tendencies for each IOL.

7.1.1 SRK Formula

(1) IOL refractive power for ametropia (IOL)

$$IOL = A - 2.5 \times AL - 0.9 \times K - DR \times (0.0875 \times A - 8.55)$$

(2) Postoperative refractive error (ERROR)

$$ERROR = (A - 2.5 \times AL - 0.9 \times K - LP)/(0.0875 \times A - 8.55)$$

K: Corneal refractive power [D]

AL: Axial length [mm]

A: A-constant

DR: Desired postoperative refractive power of a corrective lens [D]

(+value: hyperopia, -value: myopia)

LP: Refractive power of the IOL to be implanted [D]

7.1.2 SRK II Formula

(1) IOL refractive power for ametropia (IOL)

$$IOL = A' - 2.5 \times AL - 0.9 \times K - DR \times CR$$

(2) Postoperative refractive error (ERROR)

$$ERROR = (A' - 2.5 \times AL - 0.9 \times K \times LP)/CR$$

(3) Personal A-constant

$$A_{INDIV} = SEQ \times R_F + LP + 2.5 \times AL + 0.9 \times K - C$$

AL: Axial length [mm]

K : Corneal refractive power [D]

A : A-constant

DR: Desired postoperative refractive power of a corrective lens [D]

(+value: hyperopia, -value: myopia)

LP: IOL refractive power to be implanted [D]

A': Correction value of A-constant A' = A + C

C : AL < 20.0 mm, C = 3

20.0 mm ≤ AL < 21.0 mm, C = 2

21.0 mm ≤ AL < 22.0 mm, C = 1

22.0 mm ≤ AL < 24.5 mm, C = 0

24.5 mm ≤ AL , C = -0.5

CR: Constant for calculation

P ≤ 14.0, CR = 1.00

P > 14.0, CR = 1.25

* P = A' - 2.5 × AL - 0.9 × K

SEQ: SEQ = SPH + (CYL/2) [D]

SPH: Actual postoperative spherical refractive power [D]

CYL: Actual postoperative cylindrical refractive power [D]

R_F: LP > 16 R_F = 1.25

LP ≤ 16 R_F = 1.00

<Cautions in use>

In the SRK-II formula, the A-constant is corrected when the axial length is outside the range of 22 to 24.5mm, which is said to be the most reliable range in the SRK formulas. Also the calculated constants for IOL refractive power for ametropia and postoperative refractive power are changed at the IOL refractive power (P) for emmetropia of 14D. Thus the conditions are added and the SRK-II formula becomes a non-linear calculation formula. Therefore, when calculation is made with values close to those conditions, the result will vary about 0.5 to 1D.

ex.)K = 45D, DR = -2D, A = 116.5

	SRK,	SRK II,	SRK/T
When the AL = 21.99mm	IOL = 24.31D,	24.53D,	23.87D
When the AL = 22.00mm -	IOL = 24.29D,	23.50D,	23.84D
Difference	0.02D,	1.03D,	0.03D

As explained above, the calculated results of the SRK II formula varies considerably depending on the axial length and IOL refractive power for ametropia. Care should be taken when performing IOL calculation with values close to the conditions described above.

7.1.3 SRK/T Formula

(1) IOL refractive power for ametropia (IOL)

$$IOL = \frac{1000 \times n_a \times (n_a \times R - n_c m1 \times LO - 0.001 \times DR}{(LO - AD') \times (n_a \times R - n_c m1 \times AD' - 0.001 \times DR}$$

$$\frac{\times (V \times (n_a \times R - n_c m1 \times LO) + LO \times R)}{\times (V \times (n_a \times R - n_c m1 \times AD') + AD' \times R)}$$

(2) Postoperative refractive error (ERROR)

$$ERROR = \frac{1000 \times n_a \times (n_a \times R - n_c m1 \times LO) + LP \times (LO - AD')}{n_a \times (V \times (n_a \times R - n_c m1 \times LO) + LO \times R) - 0.001 \times LP}$$

$$\frac{\times (n_a \times R - n_c m1 \times AD')}{\times (LO - AD') \times (V \times (n_a \times R - n_c m1 \times AD') + AD' \times R)}$$

R : Corneal radius [mm] R = 337.5/K

LO : AL + RT [mm]

RT : Retinal thickness [mm] RT = 0.65696 - 0.02029 × AL

AL : Axial length [mm]

AD' : Estimated postoperative anterior chamber depth for the patient [mm]

AD' = H + OF, OF = AD -3.336

AD : Predictable postoperative anterior chamber depth [mm]

AD = 0.62467 × A - 68.747

A : A-constant

H : Height of corneal dome [mm] $H = R - \sqrt{R \times R - ((Cw \times Cw)/4)}$

However, in the case of $(R \times R - ((C_w \times C_w)/4)) < 0$, H = R

Cw : Computed corneal width [mm] $C_w = -5.41 + 0.58412 \times LC + 0.098 \times K$

LC : Corrected axial length [mm]

When the AL ≤ 24.2, LC = AL

When the AL > 24.2, LC = $-3.446 + 1.716 \times AL - 0.0237 \times AL^2$

DR : Desired postoperative refractive power of a corrective lens [D]

LP : Refractive power of the IOL to be implanted [D]

V : Vertex distance

n_a : Refractive index of aqueous and vitreous (= 1.336)

n_c : Refractive index of the cornea (= 1.333)

$n_c$ml : n_c - 1 (= 0.333)

7.1.4 Binkhorst Formula

(1) IOL refractive power for ametropia (IOL)

$$IOL = \frac{1000 \times N2 \times (N2 \times R - (N1 - 1) \times AL' - 0.001 \times DR}{(AL' - AD) \times (N2 \times R - (N1 - 1) \times AD - 0.001 \times DR} \times \frac{(VD \times (N2 \times R - (N1 - 1) \times AL') + AL' \times R))}{(VD \times (N2 \times R - (N1 - 1) \times AD) + AD \times R))}$$

(2) Postoperative refractive error (ERROR)

$$ERROR = \frac{1000 \times N2 \times (N2 \times R - (N1 - 1) \times AL') - LP \times (AL' - AD)}{N2 \times (VD \times (N2 \times R - (N1 - 1) \times AL') + AL' \times R) - 0.001} \times \frac{(N2 \times R - (N1 - 1) \times AD)}{LP \times (AL' - AD) \times (VD \times (N2 \times R - (N1- 1) \times AD) + AD \times R)} + \frac{1}{RD}$$

AL' = AL + B - T × (1 - N2/N3)

N1 : Corneal refractive index (= 4/3 (= 1.333...))

N2 : Refractive index of aqueous and vitreous (= 1.336)

N3 : IOL refractive index (= 1.49)

B : Distance from the vitreoretinal interface to the visual cell layer (= 0.25mm)

T : Thickness of the IOL to be implanted (= 0.5mm)

RD : Refractive distance (= 6m)

R : Corneal radius [mm] R = 337.5/K

AD : Predictable postoperative anterior chamber depth [mm]

AL : Axial length [mm]

LP : IOL refractive power to be implanted [D]

DR : Desired postoperative refractive power of a corrective lens [D]
(+value: hyperopia, -value: myopia)

VD : Vertex distance

7.1.5 Hoffer Q Formula

1) IOL refractive power for ametropia (IOL)

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

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

(2) Postoperative refractive error (ERROR)

$$ERROR = \frac{R}{1 + 0.012R}$$

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

However,

$C = AD + 0.3 \bullet (L - 23.5) + (\tan K)^2 + 0.1M \bullet (23.5 - L)^2 \bullet \tan\{0.1 \bullet (G - L)^2\} - 0.99166$

When the $L \leq 23$, M = +1, G = 28

When the L > 23, M = -1, G = 23.5

When the C > 6.5, C = 6.5

When the C < 2.5, C = 2.5

(3) Personal ACD (PACD)

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

However,

$$N = \frac{1336}{K + R} \qquad R = \frac{Rx}{1 - 0.012Rx}$$

IOL : IOL refractive power [D]

L : Axial length [mm]

C : Predictable anterior chamber depth [mm]

K : Average corneal refractive power ((K1 + K2)/2 [D])

Rx : Desired postoperative refractive power [D] (VD = 12 mm)

P : IOL refractive power to be implanted [D]

ERROR : Refractive power after implanting IOL [D]

AD : Anterior chamber depth [mm:]

Anterior chamber depth after implanting an IOL or PACD

PACD : Personal ACD [mm]

7.1.6 Holladay Formula

(1) IOL refractive power for ametropia (IOL)

$$IOL = \frac{1000 \times N2 \times (N2 \times R - (N1 - 1) \times Alm - 0.001 \times DR}{(Alm - AD - SF) \times (N2 \times R - (N1 - 1) \times (AD + SF) - 0.001 \times DR} \times \frac{(VD \times (N2 \times R - (N1 - 1) \times Alm) + Alm \times R))}{\times (VD \times (N2 \times R - (N1 - 1) \times (AD + SF)) + (AD + SF) \times R))}$$

(2) Postoperative refractive error (ERROR)

$$ERROR = \frac{1000 \times N2 \times (N2 \times R - (N1 - 1) \times Alm) - LP \times (Alm - AD - SF)}{N2 \times (VD \times (N2 \times R - (N1 - 1) \times Alm) + Alm \times R) - 0.001} \times \frac{(N2 \times R - (N1 - 1) \times (AD + SF))}{\times LP \times (Alm - AD - SF) \times (VD \times (N2 \times R - (N1 - 1) \times (AD + SF)) + \{(AD + SF) \times R)}$$

(3) Surgeon factor

$$SF = \frac{(-BQ - \sqrt{BQ \times BQ - 4 \times AQ \times CQ})}{2 \times AQ} - AD$$

$Alm = AL + RT$

$AQ = (N1 - 1) - (0.001 \times ER \times ((VD \times (N1 - 1)) - R))$

$BQ = ER \times 0.001 \times ((Alm \times VD \times (N1 - 1)) - (R \times (Alm - (VD \times N2))))$
$- (((N1 - 1) \times Alm) + (N2 \times R))$

$CQ = (Alm \times N2 \times R) - (0.001 \times ER \times Alm \times VD \times R \times N2) - (1000 \times N2 \times$
$((N2 \times R) - ((N1 - 1) \times Alm) - (0.001 \times ER \times ((VD \times ((N2 \times R) -$
$((N1 - 1) \times Alm))) + \{(Alm \times R)\})))/LP$

$AD = 0.56 + Rag - \sqrt{Rag \times Rag - Ag \times (Ag)/4}$

$AG = 12.5 \times AL/23.45$ If AG > 13.5, then AG = 13.5

N1 : Corneal refractive index (= 4/3 (= 1.333...))

N2 : Refractive index of aqueous and lens (= 1.336)

RT : Retinal thickness (= 0.200 mm)

R : Corneal radius [mm]R = 337.5/K

AD : Predictable postoperative anterior chamber depth [mm]

AL : Axial length [mm]

LP : Refractive power of the IOL to be implanted [D]

DR : Desired postoperative refractive power of a corrective lens [D]
(+value: hyperopia, -value: myopia)

VD : Vertex distance

SF : Surgeon factor

ER : Actual postoperative refractive power [D]

Rag : $R \geq 7$ mm, Rag = R

$R < 7$ mm, Rag = 7 mm

<Feature of Holladay formula>

The correction value of each surgeon (SF value: surgeon factor) for each IOL is reversely calculated from the patient's actual refractive power in the stable postoperative period, and the result can be used for the calculation of IOL refractive power.

The SF value can be used to correct deviations from the IOL data that result from physicians' surgical habits. Eventually, an IOL formula that is suited for each physician can be obtained.

When using a new IOL, the SF value can be obtained with the following equations and registered as a new set of IOL data (see "○ Inputting IOL data (page 64)) to be used for IOL power calculation:

$SF = (A \times 0.5663) - 65.60$

SF: SF value (Surgeon factor)

A : A-constant

ex.) When the A-constant = 116.7

$SF = (116.7 \times 0.5663) - 65.60 = 0.48721$

Use SF value, 0.49

When a reversely calculated postoperative SF value becomes stable after many surgical experiences, register the reversely calculated SF value as the IOL data again and use it for IOL power calculation. (For details, see "○ Inputting IOL data (page 64).)

8. EMC & Acoustic output

8.1 EMC (ELECTROMAGNETIC COMPATIBILITY)

The US-4000 complies with these standard as tabled below. Follow the guidance on the tables for use of the device in the electromagnetic environment.

EMC (IEC 60601-1-2:2001)

Guidance and manufacturer's declaration - electromagnetic emissions		
The US-4000 is intended for use in the electromagnetic environment specified below. The customer or the user of the US-4000 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The US-4000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The US-4000 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The US-4000 is intended for use in the electromagnetic environment specified below. The customer or the user of the US-4000 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage, dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	<5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the US-4000 requires continued operation during power mains interruptions, it is recommended that the US-4000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration - electromagnetic immunity</th></tr>
<tr><td colspan="4">The US-4000 is intended for use in the electromagnetic environment specified below. The customer or the user of the US-4000 should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Comliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conduted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>3 Vrms
(V_1=3)

3 V/m
(E_1=3)</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the US-4000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
d=1.2x $\sqrt{P}$
d=1.2x $\sqrt{P}$ 80 MHz to 800 MHz
d=2.3x $\sqrt{P}$ 800 MHz to 2.5 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the US-4000 is used exceeds the applicable RF compliance level above, the US-4000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the US-4000.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the US-4000			
The US-4000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the US-4000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the US-4000 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

8.2 Acoustic output reporting table(IEC 60601-2-37:2005)

8.2.1 A-scan probe

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$ cm2	$A_{aprt} > 1$ cm2		
Maximum index value			0.142	#	7.17E-3	-	(b)	(a)
Associated acoustic parameters	$p$ra (MPa)		0.448					
	P (mW)			#	0.150		#	#
	Min. of [$P(z$s), Ita,(zs)] (mW)					-		
	zs (cm)					-		
	$z$bp (cm)					-		
	zb (cm)						-	
	z at max. Ipi, (cm)		2.1					
	$d$eq (zb) (cm)						-	
	$f$awf (MHz)		10.0	#	10.0	-	#	#
	Dim of Aaprt	X(cm)		#	0.45	-	#	#
		Y(cm)		#	0.45	-	#	#
Other information	td (μsec)		0.0833					
	prr (Hz)		2000					
	pr at max. Ipi (MPa)		0.927					
	$d$eq at max. Ipi (cm)						#	
	Ipa, at max. MI (W/cm^3)		9.01					
Operating control conditions								

NOTE 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

NOTE 2: nformation need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 3: Information on MI and TI need not be provided if the equipment meets both exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed.

(b) Intended use is Ophthalmic and does not involve bone so TIB is not computed.

No data reported

8.2.2 B-scan probe

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$ cm2	$A_{aprt} > 1$ cm2		
Maximum index value			0.175	0.0114	-	-	-	(a)
Associated acoustic parameters	$p$ra (MPa)		0.522					
	P (mW)			0.268	-		-	#
	Min. of [$P(z$s), Ita,(zs)] (mW)					-		
	zs (cm)					-		
	$z$bp (cm)					-		
	zb (cm)						-	
	z at max. Ipi, (cm)		1.70					
	$d$eq (zb) (cm)						-	
	$f$awf (MHz)		8.91	8.91	-	-	-	#
	Dim of Aaprt	X(cm)		0.450	-	-	-	#
		Y(cm)		0.450	-	-	-	#
Other information	td (μsec)		0.156					
	prr (Hz)		8000					
	pr at max. Ipi (MPa)		0.882					
	$d$eq at max. Ipi (cm)						-	
	Ipa, at max. MI (W/cm^3)		9.74					
Operating control conditions	Scan angle:60 degreees Scan rate:20Hz Scan Lines:400							

NOTE 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

NOTE 2: nformation need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 3: Information on MI and TI need not be provided if the equipment meets both exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

\# No data reported

8

8.2.3 45° angled probe with detachable tip

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$ cm2	$A_{aprt} > 1$ cm2		
Maximum index value			0.150	#	8.62E-4	-	(b)	(a)
Associated acoustic parameters	$p$ra (MPa)		0.486					
	P (mW)			#	0.0173		#	#
	Min. of [P(zs), Ita,(zs)] (mW)					-		
	zs (cm)					-		
	$z$bp (cm)					-		
	zb (cm)						#	
	z at max. Ipi, (cm)		0.2					
	$d$eq (zb) (cm)						#	
	$f$awf (MHz)		10.5	#	10.5	-	#	#
	Dim of Aaprt	X(cm)		#	0.15	-	#	#
		Y(cm)		#	0.15	-	#	#
Other information	td (μsec)		0.103					
	prr (Hz)		3950					
	pr at max. Ipi (MPa)		0.522					
	$d$eq at max. Ipi (cm)						#	
	Ipa, at max. MI (W/cm^3)		6.11					
Operating control conditions								

NOTE 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

NOTE 2: nformation need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 3: Information on MI and TI need not be provided if the equipment meets both exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed.

(b) Intended use is Ophthalmic and does not involve bone so TIB is not computed.

No data reported

8.2.4 45° angled Probe

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$ cm2	$A_{aprt} > 1$ cm2		
Maximum index value			0.177	#	1.30E-3	-	(b)	(a)
Associated acoustic parameters	$p$ra (MPa)		0.567					
	P (mW)			#	0.0264		#	#
	Min. of [P(zs), Ita,(zs)] (mW)					-		
	zs (cm)					-		
	$z$bp (cm)					-		
	zb (cm)						#	
	z at max. Ipi, (cm)		0.32					
	$d$eq (zb) (cm)						#	
	$f$awf (MHz)		10.4	#	10.4	-	#	#
	Dim of Aaprt	X(cm)		#	0.150	-	#	#
		Y(cm)		#	0.150	-	#	#
Other information	td (μsec)		0.110					
	prr (Hz)		3950					
	pr at max. Ipi (MPa)		0.638					
	$d$eq at max. Ipi (cm)						#	
	Ipa, at max. MI (W/cm^3)		8.90					
Operating control conditions								

NOTE 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

NOTE 2: nformation need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 3: Information on MI and TI need not be provided if the equipment meets both exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed.

(b) Intended use is Ophthalmic and does not involve bone so TIB is not computed.

No data reported

8

8.2.5 Pachymetry probe

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$ cm2	$A_{aprt} > 1$ cm2		
Maximum index value			0.174	#	9.53E-4	-	(b)	(a)
Associated acoustic parameters	$p$ra (MPa)		0.551					
	P (mW)			#	0.0198		#	#
	Min. of [P(zs), Ita,(zs)] (mW)					-		
	zs (cm)					-		
	$z$bp (cm)					-		
	zb (cm)						#	
	z at max. Ipi, (cm)		0.2					
	$d$eq (zb) (cm)						#	
	$f$awf (MHz)		10.1	#	10.5	-	#	#
	Dim of Aaprt	X(cm)		#	0.15	-	#	#
		Y(cm)		#	0.15	-	#	#
Other information	td (μsec)		0.108					
	prr (Hz)		3950					
	pr at max. Ipi (MPa)		0.591					
	$d$eq at max. Ipi (cm)						#	
	Ipa, at max. MI (W/cm^3)		8.03					
Operating control conditions								

NOTE 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

NOTE 2: nformation need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 3: Information on MI and TI need not be provided if the equipment meets both exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed.

(b) Intended use is Ophthalmic and does not involve bone so TIB is not computed.

No data reported

8.2.6 GLOBAL ACOUSTIC OUTPUT LIMITS

Probe	MI [Unitless]	$I_{SPTA.3}$ [mW/cm2]	$I_{SPPA.3}$ (mW/cm2)
A-Scan	**0.161**	**2.35**	**15.14**
B-scan	**0.208**	**0.55**	**15.6**
45° angled with detachable tip	**0.174**	**3.36**	**7.79**
45° angled	**0.203**	**5.19**	**12.43**
Pachymetry	**0.194**	**3.79**	**9.46**

Glossary

A-scan

The A-(amplitude) and B-(brightness) scans are basic methods of representing the echoes reflected from portions of the eye interior. The ultrasonic waves are highly directive and reflected by boundaries between materials with different acoustical impedance. The distances of the materials can be calculated from the time taken until the reflected ultrasonic waves are received. The A-scan image is a graph of the distances of materials in the horizontal axis and the amplitude of reflected echoes in the vertical axis.

B-scan

Whereas the A-scan shows the distances of materials with the amplitude of echoes, the B-scan shows the amplitude of echoes in the form of brightness of spots. Only one-dimensional image can be obtained with an ultrasonic beam. However, a two-dimensional image can be created with multiple ultrasonic beams. In most cases, the word "ultrasonography" indicates the B-scan.

Gain

The gain is obtained by comparing the signal values input to and output from the amplifier of the electrical circuit. The unit is dB.

O.D. (Oculus Dexter)

Right eye

O.S. (Oculus Sinister)

Left eye

TGC (Time Gain Control)

Pulses from deep portions of the eye interior, that takes time between the emission and reception, travel long distances and decrease their amplitudes. They needs to be amplified to make the brightness of the spots they represent uniform with that of spots that represents the pulses reflected from shallow portions of the eye.

TGC adjusts the amplitude of pulses according to their distances (time before they are received). This device attenuates the echoes at the anterior segment of the eye so that the brightness of the spots in the B-scan.

USB flash drive

An auxiliary storage to which data is transmitted through the USB port.