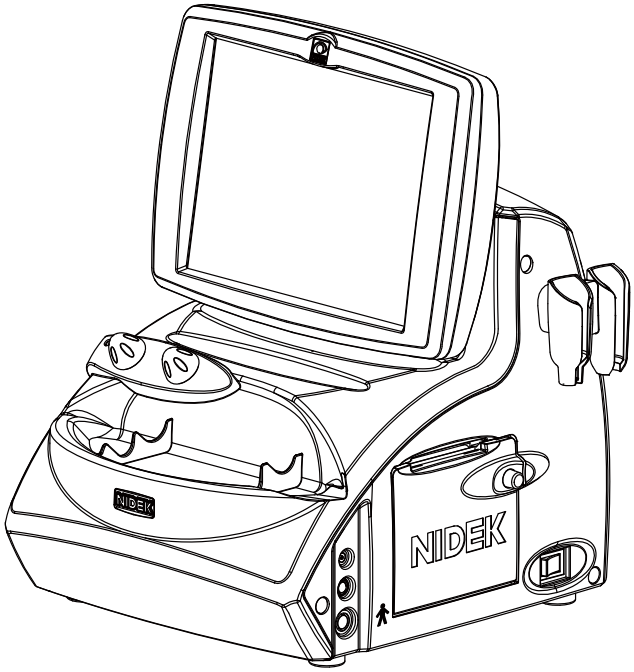
NIDEK

ECHOSCAN

US-4000 (B-scan model)

OPERATOR'S MANUAL



Be sure to read the SOFTWARE LICENSE AGREEMENT (page I) before using this product.

Original instructions

NIDEK CO., LTD.

NIDEK CO., LTD.
(Manufacturer) : 34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, JAPAN
Telephone: +81-533-67-6611
URL: https://www.nidek.com/

NIDEK INC.
(United States Agent) : 2040 Corporate Court, San Jose, CA 95131, U.S.A.
Telephone: +1-800-223-9044 (USA Only)
URL: https://usa.nidek.com/

NIDEK S.A.
(EU Authorized Representative) : Ecoparc, rue Benjamin Franklin, 94370 Sucy En Brie, FRANCE

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IMPORTANT - READ CAREFULLY

THIS AGREEMENT APPLIES TO THE NIDEK SOFTWARE AND ACCOMPANYING DOCUMENTS. PLEASE READ THIS AGREEMENT CAREFULLY AND THOROUGHLY BEFORE USING SOFTWARE.

SOFTWARE LICENSE AGREEMENT

This SOFTWARE LICENSE AGREEMENT (this "Agreement") is an agreement between you, whether person or legal entity, and NIDEK CO., LTD., a Japanese corporation, ("NIDEK") for software (including but not limited to software linked dynamically or statically with other software) supplied by NIDEK or its designee pursuant to this Agreement, whether software alone or embedded software in a NIDEK hardware product, whether on disk or in read only memory, or on other media, or through an authorized website or network, and any accompanying documents or materials (including, but not limited to, operation manuals and electronic documents for such software, and other software for displaying or saving the data acquired from or through other NIDEK hardware product) (collectively, the "Software").

The Software and NIDEK hardware product (collectively, "NIDEK product") may include a third party's software which is linked, whether dynamically or statically, with the Software (the "Third-Party-Software"). The Third-Party-Software shall not be included in the definition of the "Software" in this Agreement. The rights and title of the Third-Party-Software belong to the third party, and the terms of use of the Third-Party-Software are set forth separately from this Agreement. The terms in this Agreement will not apply to the use of the Third-Party-Software except as expressly stipulated herein.

By using or installing the Software, you agree to be bound to the terms and conditions of this Agreement. If you do not agree with this Agreement, please do not use or install the Software and return the Software to the company from which you obtained the Software.

1. GRANT OF LICENSE

1.1. Subject to the terms and conditions set forth in this Agreement, NIDEK grants to you, and you accept, a limited, non-transferable and non-exclusive license to use the Software.

1.2. Unless otherwise agreed in writing by NIDEK or its designee, the license is limited to using the Software on a single computer or a single NIDEK hardware product and if you replace such computer or NIDEK hardware product, you may not use the Software without a new license of the Software.

1.3. Notwithstanding the provision of 1.2, if you connect a single server computer with the Software installed to a plurality of client computers, you may use the Software on such client computers; provided, however, that the upper limit of the number of said client computers will be determined by NIDEK in writing separately and individually from this Agreement.

1.4. Notwithstanding the provision of 1.2, if NIDEK permits you to install the Software on a plurality of computers using one license key of the Software, you may install and use the Software on such computers up to the upper limit of the number determined by NIDEK in writing separately and individually from this Agreement.

1.5. The Software is only to be used for its intended purpose provided in the specifications, operation manual or related documents in accordance with applicable laws and regulations. If the Software is embedded software in a NIDEK hardware product, you will use such Software only as embedded software for the use of such NIDEK hardware product.

1.6. For the license of the Software granted in this Agreement, unless the license is granted by NIDEK or its designee explicitly free of charge, you will pay to NIDEK or its designee the price for the Software, or if the Software is embedded software in a NIDEK hardware product, the price for the NIDEK hardware product in which the Software is embedded.

2. INTELLECTUAL PROPERTY RIGHTS

2.1. NIDEK, or an owner of the Third-Party-Software, retains any and all legal rights, title and interests in and to the Software or the Third-Party-Software. Any and all rights under copyright law, patent law, design law and other intellectual property laws not expressly granted herein are reserved by NIDEK or the owner of the Third-Party-Software. The license granted herein will not be intended as, or construed to be, any assignment of the rights of NIDEK or the owner of the Third-Party-Software. The Software and the Third-Party-Software are protected by copyright and other intellectual property laws and international treaties.

3. LIMITATIONS

3.1. You may not use the Software for any products without a license of the Software.

3.2. Unless otherwise permitted and other than the part specified by NIDEK in operation manuals or any accompanying documents for the Software, you may not analyze, reverse-engineer, decompile, disassemble or otherwise attempt to discover the source code of the Software.

3.3. You may not alter, reproduce, modify, translate, adapt, or divert the Software.

3.4. You may not remove, delete or change the copyright notice or other legends of the Software.

3.5. You may not sell, distribute, rent, license, sublicense, lease, assign or otherwise transfer the Software to third parties, or operate the Software for the benefit of third parties without prior written consent of NIDEK.

3.6. You may not create derivative works or cause or permit others to create derivative works based upon the Software without prior written consent of NIDEK.

3.7. You may not disclose operation manuals for the Software to any third party without prior written consent of NIDEK; provided, however, for the avoidance of doubt, the "third party" in this section will not include doctors, examiners, nurses, employees, patients and other persons who need to know the Software.

3.8. You may not use NIDEK’s trademarks or trade names without prior written consent of NIDEK.

4. CONDITIONS OF USE

4.1. You shall take necessary measures (including but not limited to antivirus software) to prevent failure of NIDEK product due to external factors; provided, however, that in the case where it is otherwise provided in the provisions of operation manuals for NIDEK product or other documents, you shall take such necessary measures to the extent not inconsistent with such provisions.

4.2. If you enter data into NIDEK product or obtain data by the use of NIDEK product, you shall obtain and save backup of such data.

5. EXPORT RESTRICTIONS

5.1. If you export or re-export, directly or indirectly, the Software, you must comply with applicable export laws and regulations of Japan and other countries, and obtain any licenses or approvals required by governmental authorities.

6. UPDATES

6.1. The Software and/or the Third-Party-Software may be, at NIDEK's own discretion, changed, updated or modified from time to time without any prior notice to you. If such changes, updates, and modifications are applied to the Software licensed to you under this Agreement, such changes, updates, and modifications will be deemed a constituent part of the Software, and the terms and conditions of this Agreement will apply to such changes, updates, and modifications.

6.2. NIDEK may, at its own discretion, make amendments to any provisions of this Agreement (the "Amendments"), if NIDEK deems that:

a) such Amendments are appropriate in terms of interests for customers of this Software; or

b) such Amendments are commercially reasonable and not contrary to the objective of this Agreement, even if such Amendments are disadvantageous to you.

Prior to the amendments, NIDEK will notify you of the terms and the effective date of such Amendments on the website or by any other means.

6.3. If you use the Software after the effective date of such Amendments, you shall be deemed to have agreed to such Amendments.

7. TERMINATION

7.1. This Agreement is effective until terminated. If you breach any term or condition of this Agreement, NIDEK may, without giving any prior notice to you, terminate this Agreement with immediate effect. Upon termination of this Agreement due to the breach of this Agreement, NIDEK reserves all the rights to claim damages resulting from such breach.

7.2. If this Agreement is terminated in accordance with the provision of 7.1., you must immediately cease the use of the Software, and delete, destroy and erase all the Software. Any fees paid by you for the license of the Software will not be refund for any reasons.

8. NO WARRANTIES

8.1. NIDEK MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, CONCERNING THE SOFTWARE AND THE THIRD-PARTY-SOFTWARE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THIRD PARTY RIGHTS, INCLUDING, WITHOUT LIMITATION, THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ACCURACY, RELIABILITY OR AVAILABILITY, ABSENCE OF OR RECOVERY FROM ANY INTERRUPTION, ERROR-FREE OPERATION OR CORRECTION OF DEFECTS OR MALFUNCTIONS.

9. LIMITATION OF LIABILITY

9.1. EXCEPT OTHERWISE EXPRESSLY STIPULATED IN THIS AGREEMENT, IN NO EVENT WILL NIDEK BE LIABLE FOR ANY INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES, LOSS, CLAIMS OR COSTS WHATSOEVER, INCLUDING, WITHOUT LIMITATION, ANY LOST DATA, PROFITS, REVENUES, BUSINESS OPPORTUNITIES OR INFORMATION, LOSS OF USE OF ANY PRODUCT, PROPERTY OR EQUIPMENT, DOWNTIME COST , COST OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES, OR ANY CLAIMS BY A THIRD PARTY, ARISING OUT OF OR RELATED TO THE USE OR INABILITY TO USE THE SOFTWWARE AND/ OR THE THIRD-PARTY-SOFTWARE, CHANGES, UPDATES OR MODIFICATIONS OF THE SOFTWARE AND/OR THE THIRD-PARTY-SOFTWARE, OR MAINTENANCE OR REPAIR SERVICE OF THE SOFTWARE IF ANY (collectively, the "DAMAGES"). THE ABOVE LIMITATIONS WILL APPLY REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, STRICT PRODUCT LIABILITY, OR OTHERWISE, EVEN IF NIDEK IS NOTIFIED OF THE POSSIBILITY OF SUCH DAMAGES.

9.2. THE LIMITATIONS PROVIDED IN THE PROVISION OF 9.1. SHALL NOT APPLY IN THE CASE WHERE THE DAMAGES ARE ATTRIBUTABLE TO NIDEK OR NIDEK IS LIABLE FOR SUCH DAMAGES IN ACCORDANCE WITH THE LAWS. EVEN IN SUCH CASE, NIDEK SHALL NOT BE LIABLE FOR ANY CONSEQUENTIAL, INDIRECT, INCIDENTAL, PUNITIVE OR SPECIAL LOSS OR DAMAGE. NIDEK'S TOTAL AGGREGATE LIABILITY FOR THE DAMAGES SHALL NOT EXCEED AN AMOUNT ACTUALLY PAID BY YOU FOR PURCHASE OF NIDEK PRODUCT; PROVIDED, HOWEVER, THAT THE LIMITATION OF THE AMOUNT SHALL NOT APPLY IN THE CASE WHERE THE APPLICABLE LAW PROHOBITS SUCH LIMITATION OR THE DAMAGES ARISING FROM NIDEK'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

10. GOVERNING LAW AND ARBITRATION

10.1. This Agreement will be governed by and construed in accordance with the laws of Japan.

10.2. All disputes arising between you and NIDEK relating to this Agreement or the interpretation or performance thereof will be finally settled by binding arbitration in Tokyo in accordance with the Commercial Arbitration Rules of The Japan Commercial Arbitration Association. Judgment upon the award rendered by arbitration will be final and may be entered in any court having jurisdiction thereof.

11. SEVERABILITY

11.1. If any provision or any portion of any provision of this Agreement will be held to be invalid or unenforceable, that provision will be severed from this Agreement and such invalidity or unenforceability will not affect the remaining provisions of this Agreement. The remaining provisions of this Agreement will continue in full force and effect.

12. SURVIVAL

12.1. The provisions of 2, 3, 5, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 18, 19 and this provision will survive the termination of this Agreement and will be binding after the termination of the Agreement.

13. ASSIGNMENT

13.1. This Agreement or any part of this Agreement may not be assigned or transferred without prior written consent of NIDEK. The permitted assignee or transferee must agree to all the terms and conditions of this Agreement prior to the assignment or transfer.

13.2. This Agreement will be binding upon the permitted assignee or transferee and be enforceable by NIDEK.

14. ENTIRE AGREEMENT

14.1. This Agreement constitutes the entire agreement between you and NIDEK concerning the Software, and supersedes any prior written or oral agreement between you and NIDEK. No modification of this Agreement will be binding unless otherwise agreed in writing.

15. NO WAIVER

15.1. The failure of NIDEK to enforce at any time or for any period the provisions hereof in accordance with its terms will not be construed to be a waiver of such provisions or of the rights thereafter to enforce each and every provision.

16. NO THIRD PARTY RIGHTS

16.1. This Agreement is intended to be solely for the benefit of you and NIDEK and is not intended to confer any benefits upon or create any rights in favor of any person other than you and NIDEK.

17. HEADINGS

17.1. All headings are for convenience only and will not affect the meaning of any provision of this Agreement.

18. LANGUAGE

18.1. The license agreement for the Software may be provided in multiple languages. In such event, unless otherwise agreed in writing, the following shall apply:

a) If you use the Software in any countries outside Japan, the license agreement for the Software shall be executed and delivered in a text using the English language. The text using the English language shall prevail and control; and

b) If you use the Software in Japan, the license agreement for the Software shall be executed and delivered in a text using Japanese language. The text using the Japanese language shall prevail and control.

19. APPLICATION OF SOFTWARE LICENSE AGREEMENT

19.1. If the terms and conditions of the "Software License Agreement" included in operations manuals for NIDEK product are inconsistent with the terms and conditions of the "Software License Agreement" displayed on NIDEK product, the terms and conditions of the "Software License Agreement" included in operations manuals for NIDEK product prevail.

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.

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 manual may cause unexpected troubles and adverse events.

There are no user-serviceable parts inside the device except printer paper and fuses.

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

⚠ **CAUTION** • **Federal Law restricts this device to sale by or on the order of a licensed practitioner.**

Safety precautions

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

⚠ **WARNING** • Indicates a potentially hazardous situation which, if not avoided, may result in death or serious injury.

⚠ **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

⚠ WARNING

- **Be sure to use a grounded power outlet.**
  Electric shock or fire may result in the event of malfunction or power leakage.
- **Never modify the device.**
  Electric shock or malfunction may result.

⚠ 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 manual may cause unexpected troubles and adverse events.
- **Be sure to use accessories specified by NIDEK.**
  Use of the accessories other than specified in the Operator's Manual may cause unexpected troubles and adverse events.
- **Do not use the device 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 failed device and unexpected health hazard may result from unexpected troubles and misdiagnosis.
- **Never touch the internal structure of the device.**
  Other than printer paper and fuses, there is no internal parts that requires servicing by the user.
- **Install the device in an environment that meets the following conditions. The following conditions must be maintained during use.**
  Use conditions
  Ambient temperature: 10 to 35ºC (50 to 95ºF)
  Humidity: 30 to 90% (Non-condensing)
  Atmospheric pressure: 800 hPa to 1060 hPa
  Protected from exposure to water
  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 and falls over 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 that 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.
- **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 specified 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 device so that the air vent on the cover of the main body is not blocked.**
- **Be sure to install the device with power to the device turned off and with no patient around.**
- **Do not use this device in an operating room.**
- **This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.**

During Use

⚠ CAUTION

- **Do not use the device if any abnormality is found in the visual check or operation check before use.**
  Intended effect cannot be obtained with a failed device and unexpected health hazard may result from unexpected troubles and misdiagnosis.
- **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 that are a characteristic of the LCD screens. This does not represent a failure of the LCD screen, and the monitor can be used with no problem.**
- **If the device is connected to a PC that does not comply with IEC 60601-1 (except one that uses an AC adapter that meets the Class II requirements of IEC 60950-1 or IEC 62368-1), supply power to the device and PC through isolation transformers.**
  Contact NIDEK or your authorized distributor for installing isolation transformers.
- **When using the LAN port to connect the device to a peripheral device such as a PC through the network of a medical facility, interpose or connect an isolation transformer between the device and network device (such as a hub) and between the network device and other electrical instruments.**
  Electric shock or malfunction or failure of the electric instruments may occur depending on the types and number of the electric instruments connected to the network.
  For the installation of network isolation transformers, contact NIDEK or your authorized distributors.
- **If the PC of this system is connected by a LAN to other devices such as an external computer via a network of the medical facility, do not connect the system to a network that can connect to the Internet.**
  Be sure to configure the local network with the connected PCs. NIDEK will not assume responsibility or compensate for damages caused by any virus infection and development.

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⚠ **CAUTION**

- **Accessory equipment connected to the analog and digital interfaces must be certified according to the representative appropriate national standards (for example, UL 1950 for Data Processing Equipment, UL 60601-1 for Medical Equipment, and CSA C22.2 No. 601-1, EN 60601-1, and IEC 60601-1.) Furthermore, all configurations shall comply with the system standard IEC 60601-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department or your local representative.**

- **In the A-scan biometry, carefully evaluate the validity of the measurement results from the steadiness of the measurement values and waveforms. If the measurement does not seem to be correct, perform the measurement again, or refer to other measurement results.**
  If an IOL power calculation result obtained with incorrect measurement results is used to select an intraocular lens, reoperation may result.

- **When using the IOL power calculation formulas programmed in the device, use the calculated values for selection of IOLs based on full knowledge of the characteristics of the formula to be used and with reference to the cataract surgery technique and other examination results.**

- **When using the intraocular pressure correction function of this device, be sure to set the proper correction coefficients, Param1 and Param2, beforehand.**
  The obtained result (corrected intraocular pressure value) is a reference value, and it is the responsibility of the user to determine whether or not to use it.

- **Perform the measurements using appropriate sonic velocity values.**
  Accurate axial length and pachymetry cannot be obtained with inappropriate sonic velocity values.

- **When connecting interface devices to the device, confirm the symbols, then connect them securely without applying unnecessarily great force.**
  Terminals or cables may become damaged.

- **Be sure to use only the printer paper (80620-00001) specified by NIDEK.**
  Other printer papers may cause improper printing and make the data unreadable.

- **If the device is used after a long period of disuse, check for any abnormality before use.**

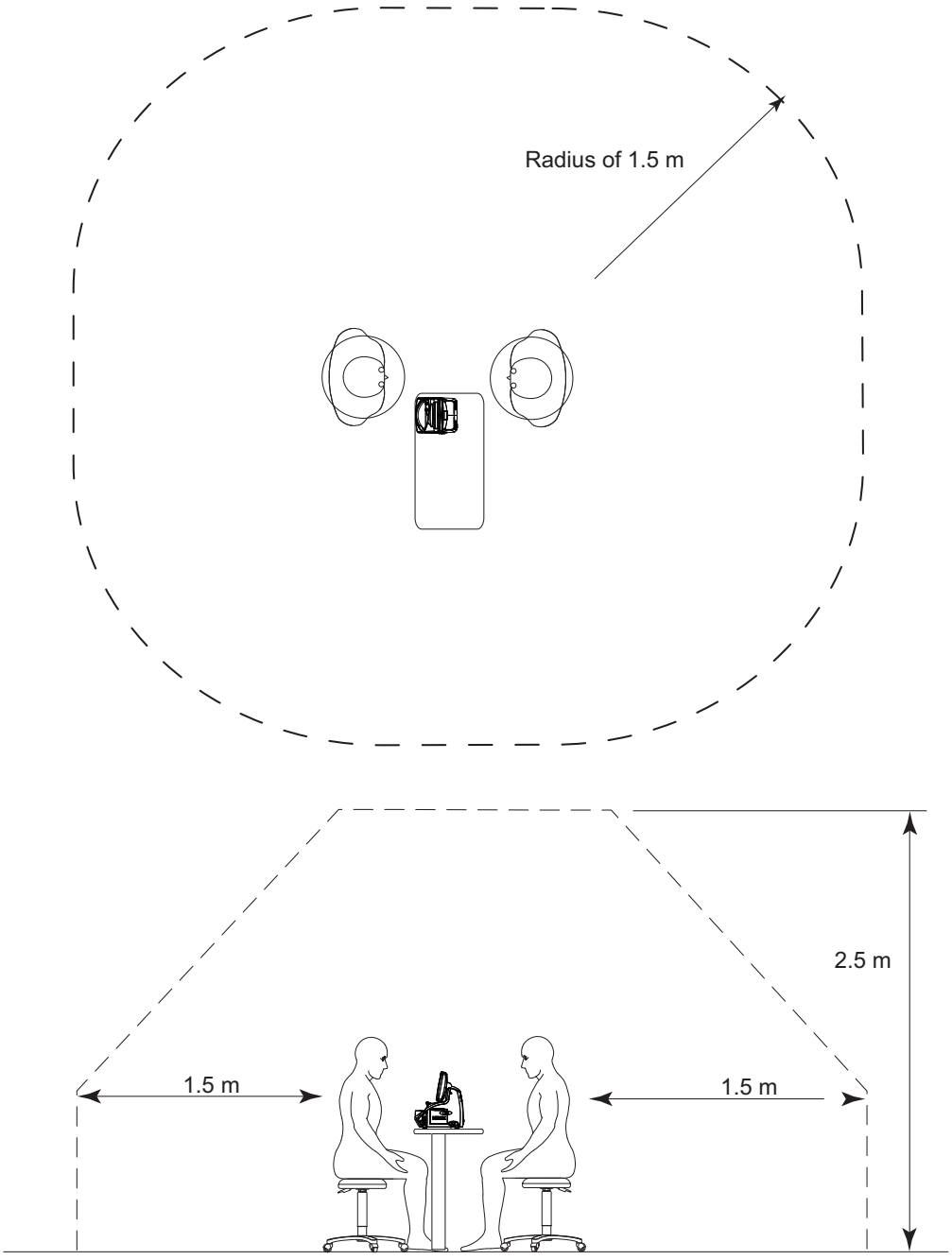
- **In the event of a malfunction, do not touch the inside of the device, but disconnect the power cord from the power outlet and contact your authorized distributor.**

- **Do not perform servicing or maintenance on the device during use.**

Patient environment

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

Use devices that comply with IEC 60601-1 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.



Probe

⚠ **CAUTION**

- **Always hold the housing of the cable 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.
  For the method of connecting and disconnecting the probe, see “2.2.4 Connecting probe (page 34)”, and “5.6.1 Disconnecting ultrasound probe (cleaning preparation) (page 143)”.
- **If the probes are contaminated or any extraneous matter is on them, clean them before performing disinfection.**
- **After using the probes, perform cleaning, disinfection, and, if necessary, high level disinfection.**
- **Disinfect the probe tip for every patient.**
  Failure to do so may cause infection of patient’s cornea.
- **Perform high level disinfection after using the probes for the patient with infectious disease.**
- **Before measurement, confirm that there are no scratches or chips on the surface of the probe tip that contacts the cornea.**
  Proper measurement my not be possible and the cornea might be damaged.
- **Before measurement, confirm that there are no damages on the probe cable and that the cable is connected securely.**
  Proper measurement may not be possible.
- **Be sure to keep the cords out of the way.**
- **When the probe is not being used during use of the device, be sure to place the probe on the probe holder.**
  The probe tip may come into contact with other objects and denting, chipping, or cracking of the probe tip may result.
- **Do not apply unnecessarily strong force to the probes to prevent them from folding or bending.**
- **Pay attention not to bump the probes.**
- **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.
- **If the probes will not be used for a long period of time, put the provided protection caps on their tips and store them in a dedicated case.**
- **Do not move the probe while it is in contact with the patient’s cornea.**
  The corneal epithelium may become damaged.

⚠ **CAUTION**

- **Never perform autoclaving, EOG sterilization, or ultrasonic cleaning of the A-scan, B-scan, or Pachymetry probe.**
  The probes may become damaged.
- **Use the A-scan, B-scan, and Pachymetry probes correctly according to the intended purpose.**
  Proper measurement cannot be performed with incorrect probes.

After use

⚠ **CAUTION**

- **This device uses a heat-sensitive printer paper. To keep the printed data for a long period of time, make copies of the printouts. In addition, do not apply glue containing organic solvent or adhesive tape to the printer paper.**
  The paper degrades over time or by applying adhesive material and the printed data may become illegible.
- **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 (14 to 131ºF)
  Humidity: 10 to 95% (non-condensing)
  Protected from exposure to water
  Minimal dust in the air
  Protected from direct sunlight
  Level and stable surface free from vibration and bumping
  No chemicals or organic solvents are present, or a place where corrosive gas may be generated
- **Do not drag the power cord by carrying the device with the power cord connected to the device.**
  If the cord gets caught on anything or stepped on, the device may fall and cause injury or failure.
- **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 disassemble, repair, or update the device.**
  NIDEK assumes no responsibility for accidents resulting from improper servicing.
- **When performing maintenance work, secure a sufficient maintenance space, and make sure that power to the device is turned off and no patient is around.**
  Maintenance work in an insufficient space may result in injury.
- **Do not use the device beyond the expected service life.**
  Beyond the expected service life, the reliability and safety of the device cannot be guaranteed even with regular maintenance.
- **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 fuses, use the specified ones.**
  Failure to do so may cause a malfunction or a fire.
- **When cleaning the cover of the device and LCD 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 touch 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.
- **To ensure the continued safe use of the device, it is recommended that the manager of this device make sure that maintenance and preventive inspection are performed at least once a year.**
  For details of maintenance and preventive inspection, ask NIDEK or your authorized distributor. If the manager of this device cannot perform the maintenance and preventive inspection, contact NIDEK or your authorized distributor.

Disposal

⚠ **CAUTION**

- **To prevent the leakage of data such as personal information (patient information) to any unauthorized third party, it is the customer's responsibility to make sure that data on the built-in storage cannot be restored before disposing of the device.**
  Take measures such as outsourcing to Nidek or a disposal contractor, or physically destroying the storage to make it unreadable.
- **Follow local governing ordinances and recycling plans regarding disposal or recycling of device components. The device contains the circuit board with a lithium battery mounted. Because the disposal method of lithium batteries varies according to the local government, follow the local governing ordinates and recycling plans when disposing of the circuit board with the lithium battery.**
  It is recommended to commission the disposal to a designated industrial waste disposal contractor. Inappropriate disposal may contaminate the environment.
- **When disposing of the accessories such as the probes, container, or gauze used for disinfection, follow the disposal procedure specified by each medical facility and make sure that no infection or environmental contamination occurs.**
- **When disposing of packing materials, sort them by material and follow local governing ordinances and recycling plans.**
  Inappropriate disposal may contaminate the environment.

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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, B-scan probe, and foot switch. Items such as an A-scan probe, Pachymetry probe, and video printer are also available as optional accessories.

1.2 Intended 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 thickness, 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 that 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.

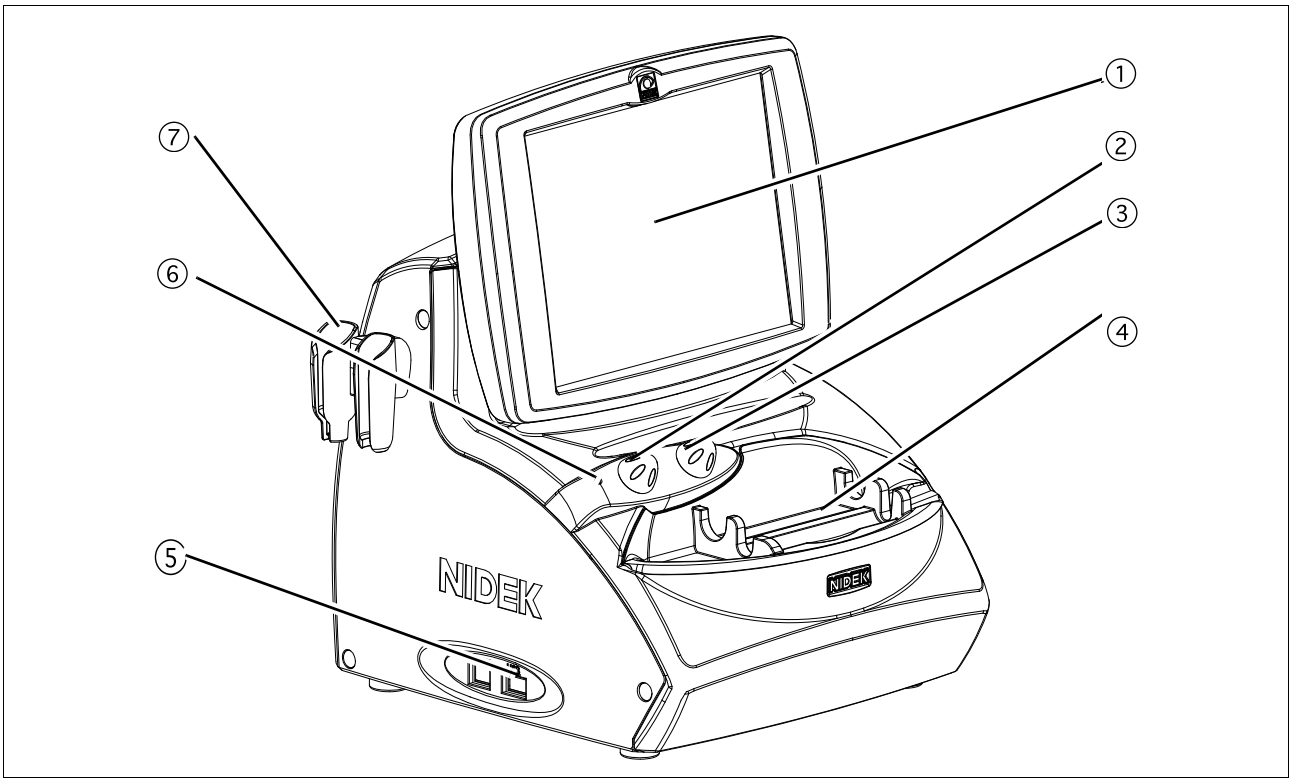
In B-scan imaging, touching the mechanical sector scan probe with a built-in transducer to the eye emits the ultrasonic pulses that travel inside the eye. These pulses are reflected at boundaries of the cornea, anterior chamber, crystalline lens, vitreous body, and retina. The reflected pulses (echoes) 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.
The image on the LCD is used mainly to diagnose diseases of the retina or the vitreous body.

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



①LCD 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 physician's convenience.

②Knob 1

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

③Knob 2

Used to change the gain or area of magnification.

④Probe rest

Used to keep the probes when not in use.

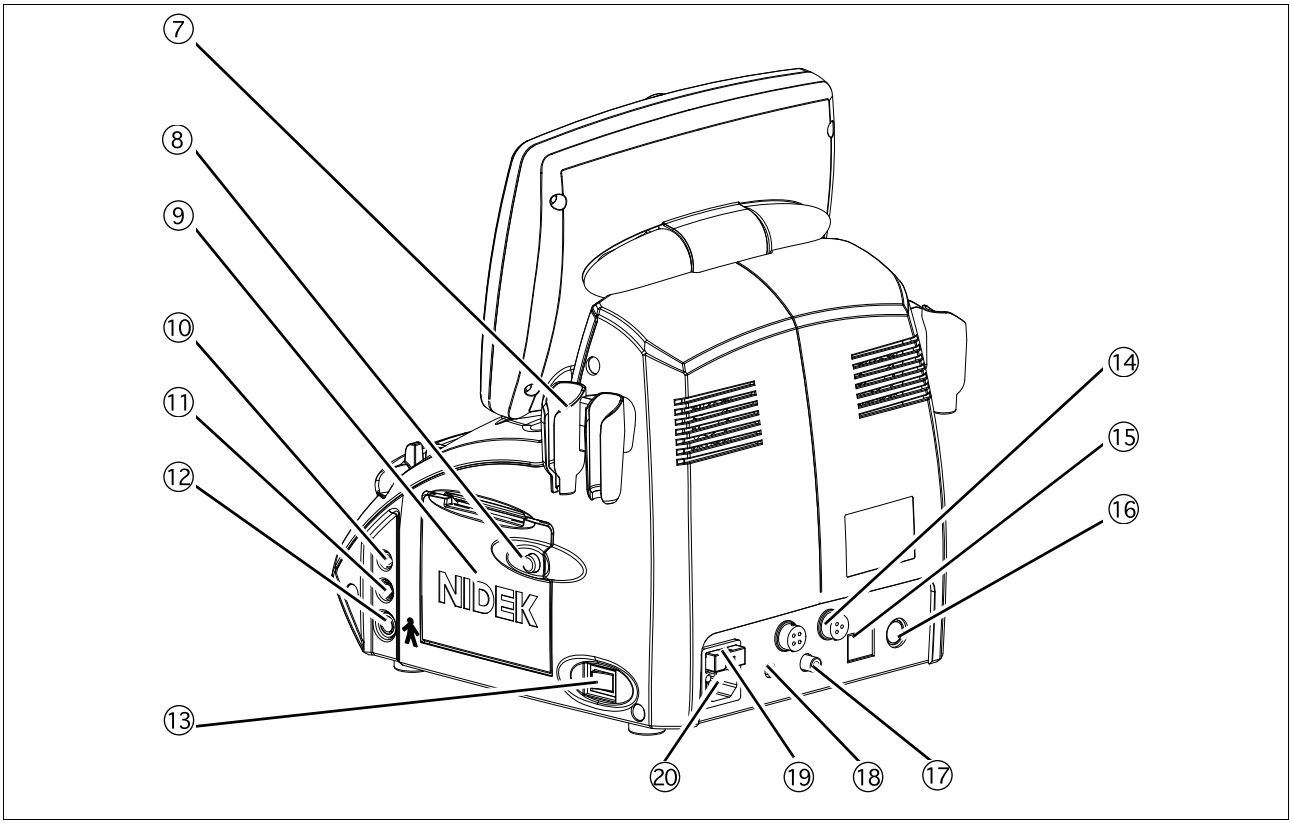
⑤USB port

Used to connect the USB flash drive to save images, measurement data, and device parameters, or the barcode reader to input ID information.

⑥Pilot lamp

Illuminates when power is supplied to the device.

○ Rear view



⑦Probe holder

Place for keeping the probe.

⑧Cover open button

Pressed to open the printer cover.

⑨Printer 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.

⑩Connector (P)

Used to connect a Pachymetry probe (45° fixed type, 45° detachable type, or straight type).

⑪Connector (BIO)

Used to connect the A-scan probe.

⑫Connector (B)

Used to connect the B-scan probe.

⑬ Power switch

Pressed to turn ON (|) and OFF (○) power to the device.

⑭**Foot switch connector**

The cable plug of the foot switch is connected here.

⑮**LAN port**

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

⑯**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.

⑰**Video output terminal**

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

⑱**Remote connector**

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

⑲**Fuse holder**

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

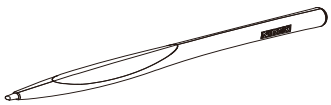
⑳**Inlet**

Used to connect the power cord.

㉑Stylus

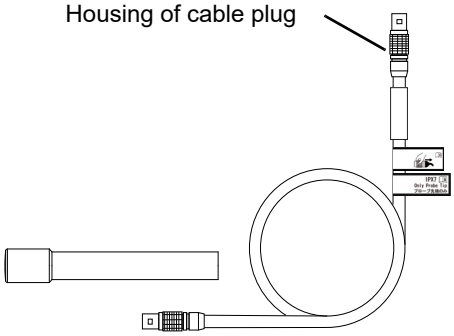
Used to manipulate the screen.

* Use of the stylus is recommended for touch-screen operation.



㉒B-scan probe

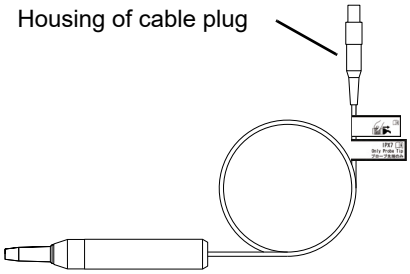
* Always hold the housing of the cable plug, not the cable, when connecting or disconnecting the probe. Refer to “Probe” (page X), “2.2.4. Connecting probe” (page 34), and “5.6.1. Disconnecting ultrasound probe (cleaning preparation)” (page 143).



㉓A-scan probe (optional)

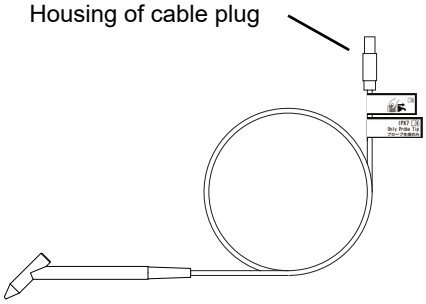
A solid probe with a built-in fixation lamp

* Always hold the housing of the cable plug, not the cable, when connecting or disconnecting the probe. Refer to “Probe” (page X), “2.2.4. Connecting probe” (page 34), and “5.6.1. Disconnecting ultrasound probe (cleaning preparation)” (page 143).



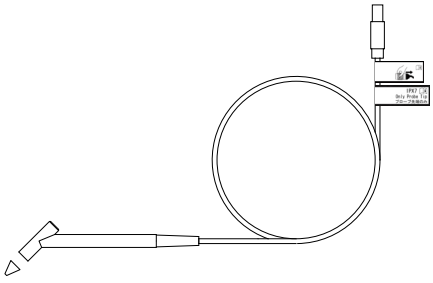
㉔Pachymetry probe (optional)

* Always hold the housing of the cable plug, not the cable, when connecting or disconnecting the probe. Refer to “Probe” (page X), “2.2.4. Connecting probe” (page 34), and “5.6.1. Disconnecting ultrasound probe (cleaning preparation)” (page 143).



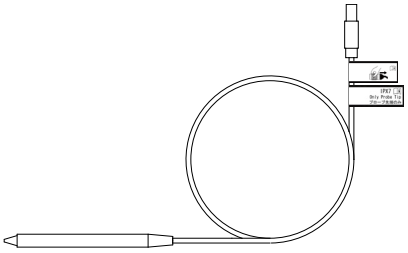
45° fixed type

A solid probe for pachymetry



45° detachable type

A solid probe for pachymetry with a detachable tip

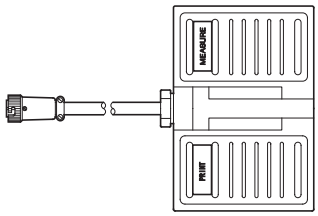


Straight type

A straight-type solid probe for pachymetry

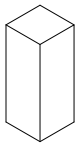
㉕**Foot switch**

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

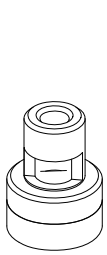


㉖**Test piece (optional)**

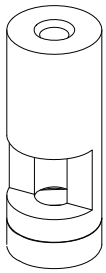
(for A-scan biometry)



(for pachymetry)

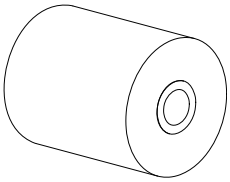


For 45° probe



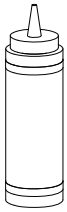
For straight probe

㉗**Printer paper (3 rolls)**



㉘**Ultrasound gel**

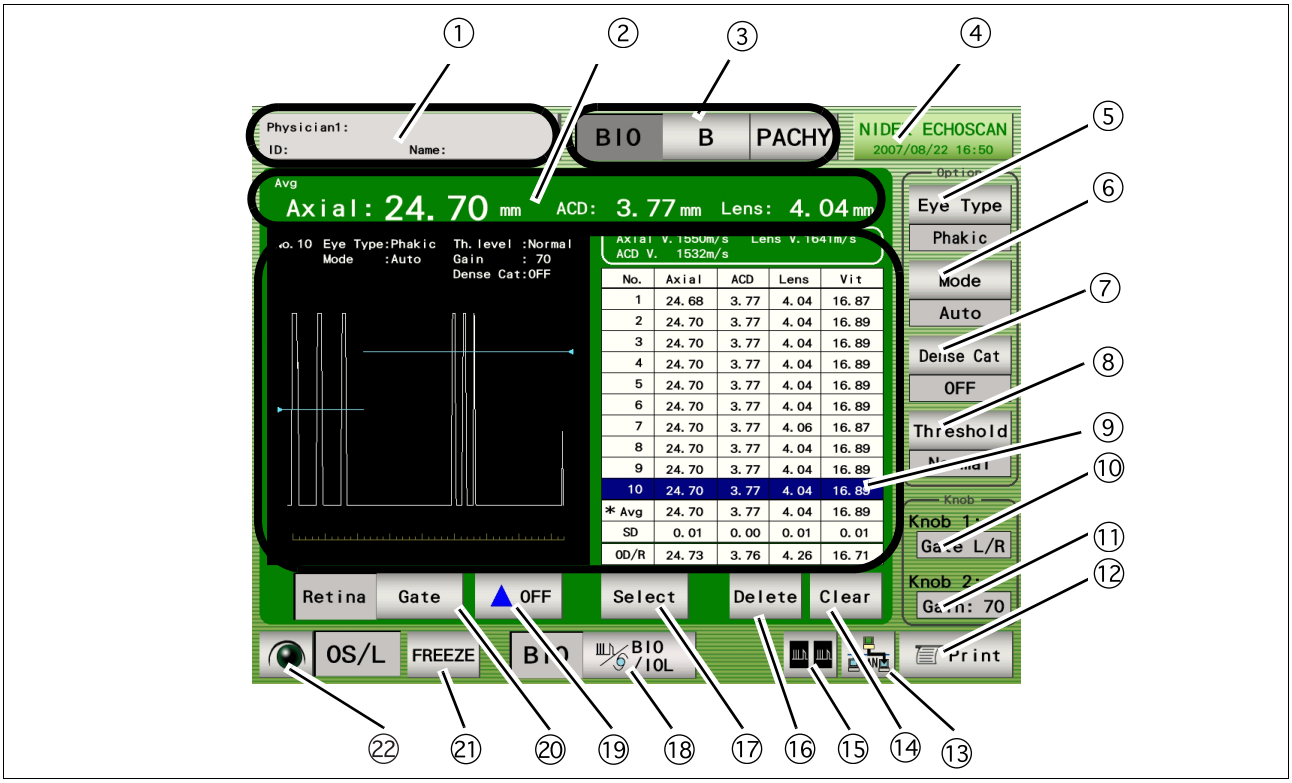
Applied to the eyelid for B-scan imaging.



㉙**Dust cover**

1.5 Screen Description

1.5.1 A-scan biometry screen



①Patient switch

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

②Measurement value

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

③BIO/B/PACHY switch

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

④Date and time switch

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

⑤Eye 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

⑥Mode switch

Pressed to change the measurement method.

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

SemiAuto: The physician determines the time to start the measurement, and 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 pressing the FREEZE/LIVE switch or by depressing the foot switch.

⑦ Dense Cat switch

OFF: A normal eyes are measured.

ON: An eye with a mature cataract is 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.

⑧Threshold switch

Pressed to change the programmed threshold that 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 measurement may become possible by changing the threshold to “Low” or “Flat Low.”

⑨Measurement data list indication area

Up to 10 measurement values (three times of three measurement values (a maximum of 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	○	○	△ a	△ a
Phakic2	○	○	○	○
Aphakic	○	-	-	-
IOL	○	○	-	○

a. Those measurement values may not be displayed when the Dense Cat switch is ON.

⑩Gate display

The specified gate can be moved using Knob 1.

⑪Gain display

Displays the gain during the A-scan biometry.

The gain is adjusted with Knob 2.

⑫Print switch

Pressed to print the data being displayed.

* The icon on the switch changes according to the communication setting.
  Refer to “Setting Communication” (page 106).

⑬Data save switch

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

* The switch icon changes according to the data save destination setting. See “1.5.8. Utility screen (1/2)” (page 23).

⑭Clear switch

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

⑮Dual 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.

⑯Delete switch

Pressed to delete the measurement data in the list.

To delete data, highlight the data to delete by pressing it with the stylus, then press the Delete switch.
When the Delete switch is pressed, it changes to the Recall switch that restores the deleted data.

⑰Select 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 that 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.

⑱BIO/IOL Select switch

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

⑲Gate display switch

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

⑳Gate 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.

㉑FREEZE/LIVE switch

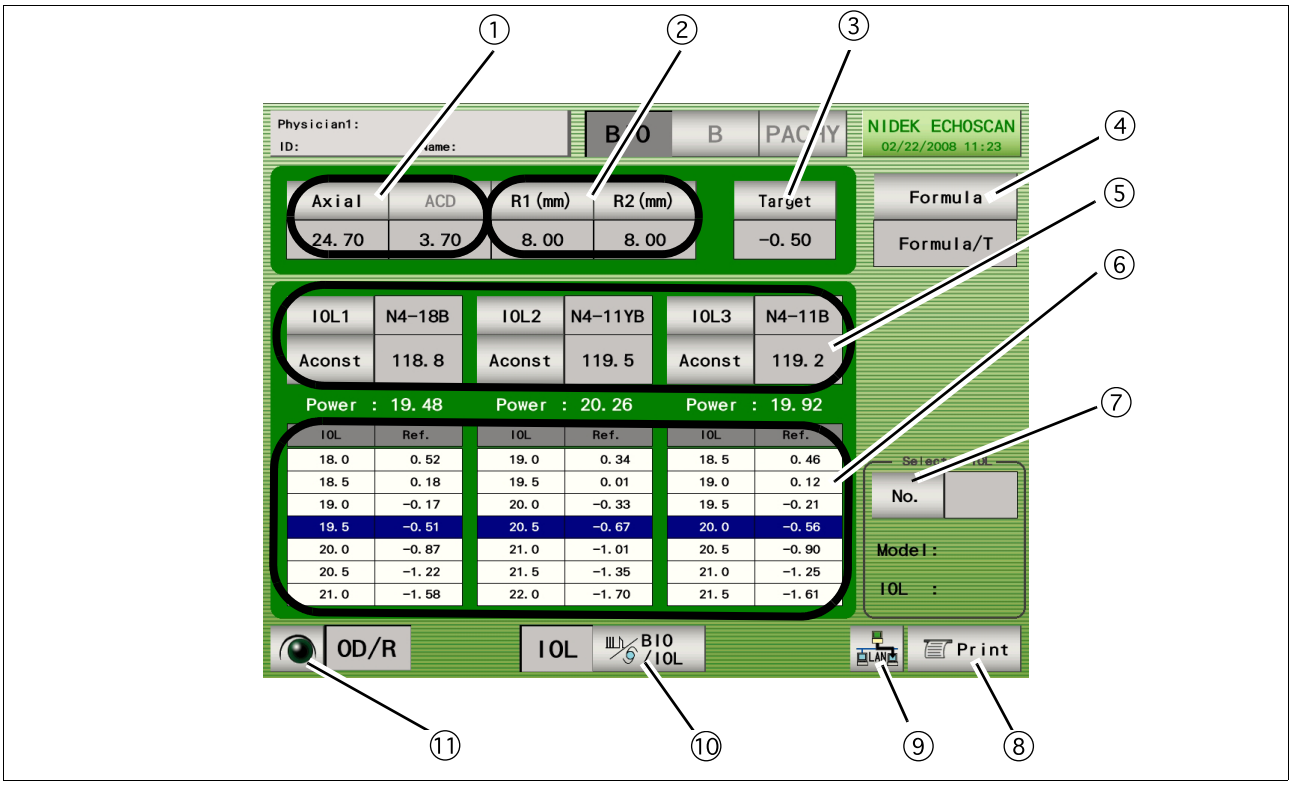
Pressed to start or stop the A-scan biometry.

The A-scan biometry can be started or stopped also with the foot switch.

㉒OD/OS switch

Pressed to change the eye to be measured.

1.5.2 IOL power calculation screen



①A-scan biometry data

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

②Keratometer reading

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

③Target switch

Target postoperative refractive power is input.

④Formula switch

Pressed to select the desired IOL formula.

⑤IOL 1/IOL 2/IOL 3 Select switch

Three types of IOLs can be selected for the IOL calculation using the IOL 1, IOL 2, and IOL 3 switches.

The constant used for the IOL calculation can be changed temporarily using the constant switch (A constant in the screen above).

⑥IOL 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.

⑦IOL 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.

* The icon on the switch changes according to the communication setting.
  Refer to “Setting Communication” (page 106).

⑨Data save switch

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

* The switch icon changes according to the data save destination setting. See “1.5.8. Utility screen (1/2)” (page 23).

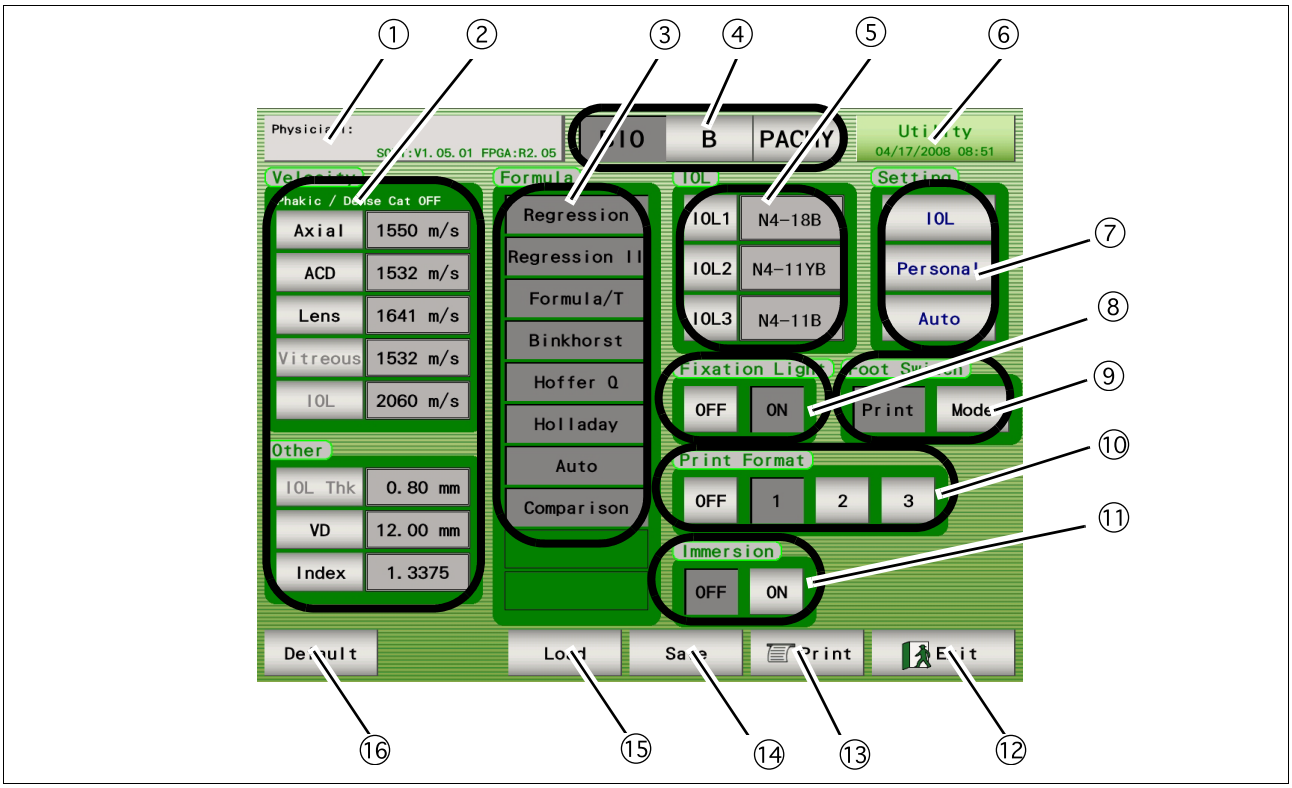
⑩BIO/IOL Select switch

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

⑪OD/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 ⑪ 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 BIO/B/PACHY switch

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 switch

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 switch**

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

⑨**Foot Switch switch**

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

⑩**Print Format switch**

Pressed to select the desired print format.

⑪**Immersion switch**

Pressed to toggle use of the Immersion mode.

⑫**Exit switch**

Pressed to return to the A-scan biometry screen.

⑬**Print switch**

Pressed to print the A-scan biometry utility settings.

⑭**Save switch**

Pressed to save the A-scan biometry utility settings.

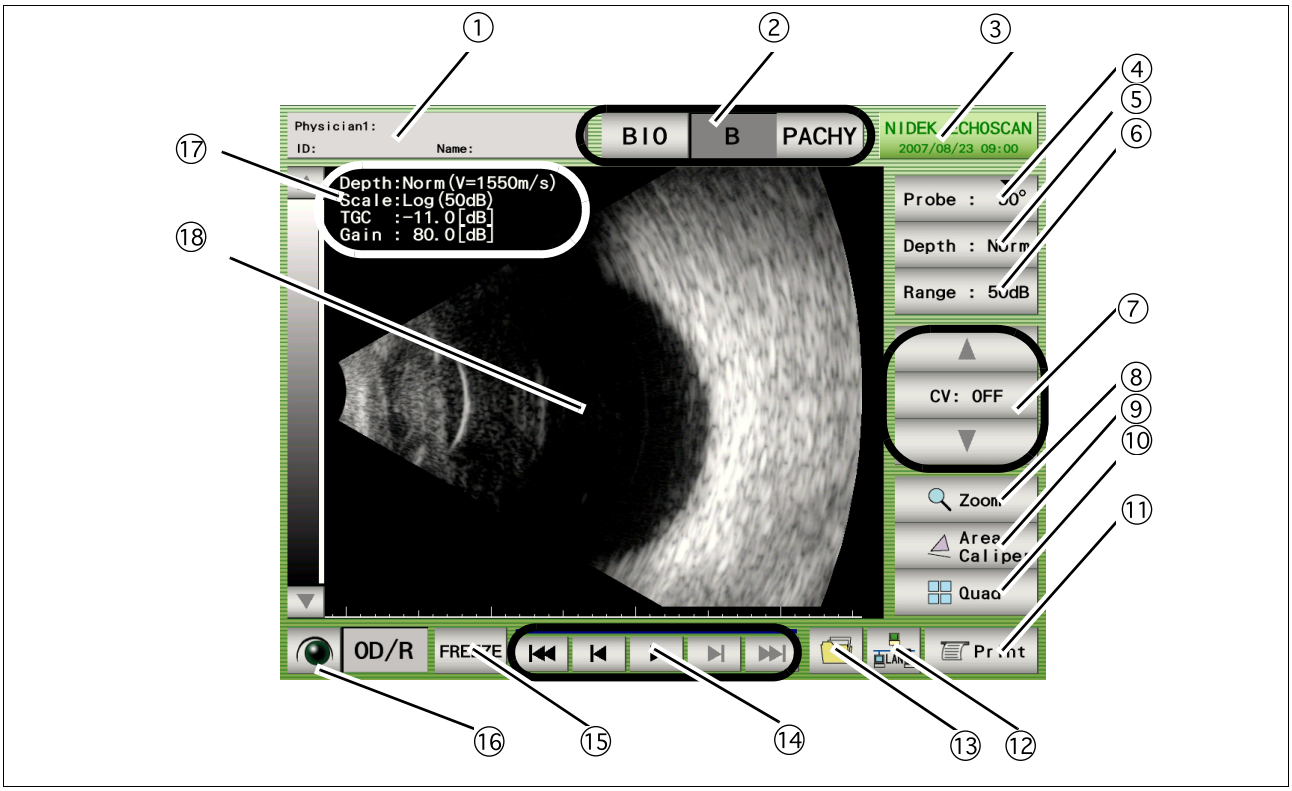
⑮**Load switch**

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

⑯**Default switch**

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

1.5.4 B-scan imaging screen



①Patient switch

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

②BIO/B/PACHY switch

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

③Date and time switch

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

④Probe 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°.

⑤Observation depth switch

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

Norm (35 mm) ⇔ Long (50 mm)　* Average sonic velocity 1550 m/s

⑥Display 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 switch

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

⑧Zoom switch

Pressed to magnify the image on the screen to "×2.5" or "´5.0"

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

⑨Area/Caliper screen switch

Pressed to display the Area/Caliper screen.

⑩Quad 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.

⑪Print switch

Pressed to print the data being displayed.

* The icon on the switch changes according to the communication setting.
Refer to "Setting Communication" (page 106).

⑫Data save switch

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

* The switch icon changes according to the data save destination setting. See "1.5.8. Utility screen (1/2)" (page 23).

⑬Data read switch

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

⑭Moving image operation switch

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

⑮FREEZE/LIVE switch

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

⑯OD/OS switch

Pressed to switch the eye to be measured.

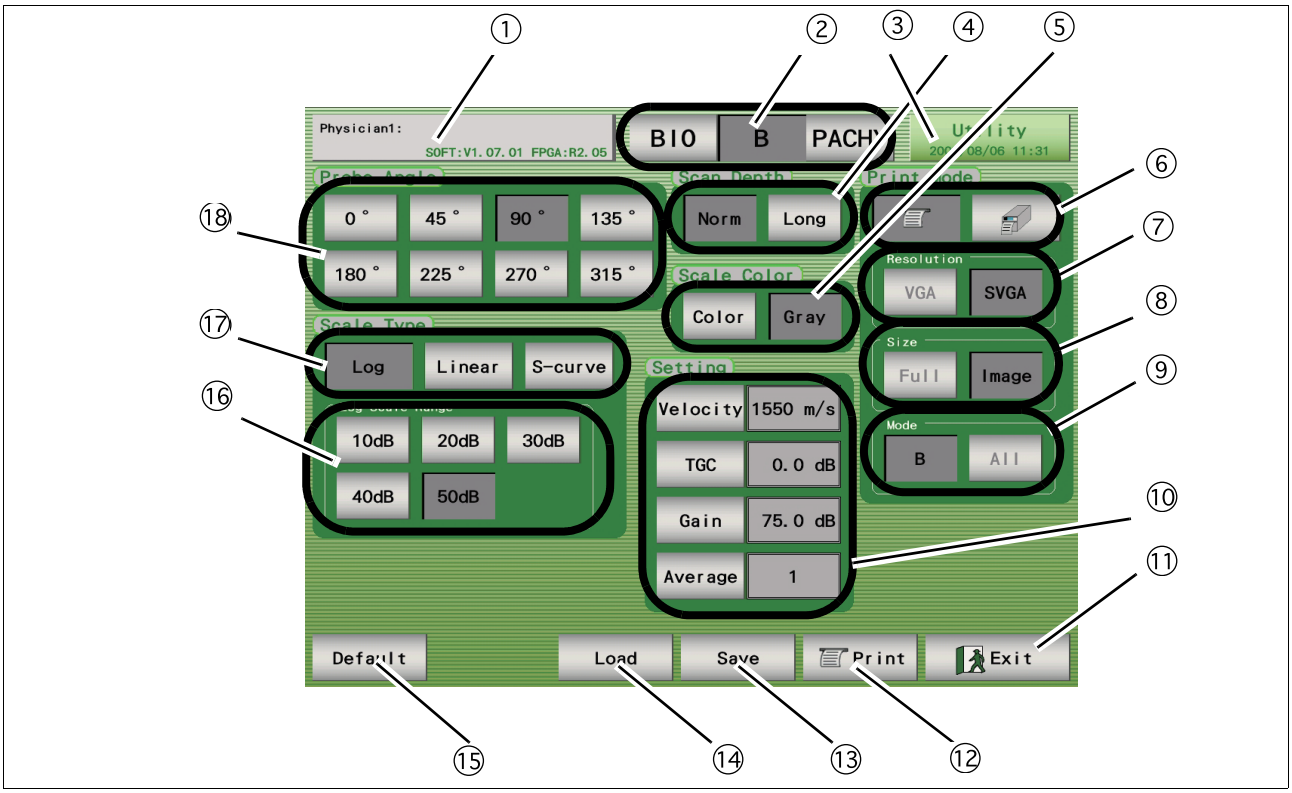
⑰Measurement condition display

Displays the B-scan imaging conditions.

⑱B-scan image display

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

1.5.5 B-scan imaging utility screen



①Physician switch

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

Conditions set in ④ to ⑩, and ⑯ to ⑱ can be set for each physician.

②BIO/B/PACHY switch

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

③Utility switch

Pressed to display the Utility screen.

④Scan Depth switch

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

⑤Scale Color switch

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

⑥Print Mode switch

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

⑦Resolution switch

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

When the built-in printer is selected, this switch is disabled.

⑧Size switch

Pressed to toggle the area to be printed between Full (Entire screen image) and Image (only waveform image). This switch is available only for the B-scan imaging. This switch is disabled when the built-in printer is selected.

⑨Mode switch

Pressed to toggle between printing of only the B-scan imaging result and printing of the results of all the measurements when an external printer is selected with the Print Mode switch.

When the built-in printer is selected, this switch is disabled.

⑩ Setting switch

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.

⑪Exit switch

Pressed to return to the B-scan imaging screen.

⑫Print switch

Pressed to print the B-scan imaging utility settings.

⑬Save switch

Pressed to save the B-scan imaging utility settings.

⑭Load switch

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

⑮Default switch

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

⑯Log Scale Range switch

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.)

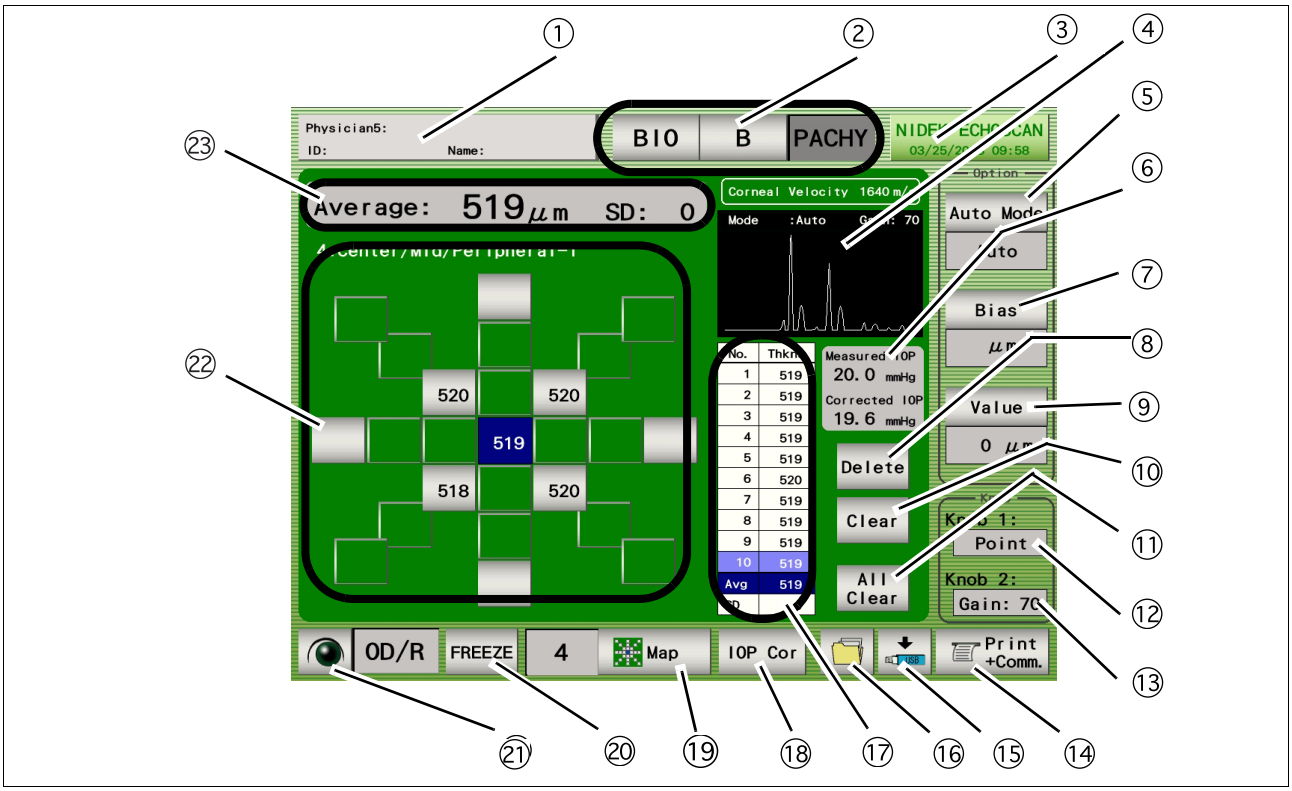
⑰ Scale Type switch

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

⑱ Probe Angle switch

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 (optional)



①Patient switch

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

②BIO/B/PACHY switch

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

③Date and time switch

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

④Waveform display area

Displays the waveform during pachymetry.

⑤Auto Mode switch

Pressed to toggle the measurement mode between “Auto” and “Speedy.”

⑥IOP (Intraocular Pressure) display

Pressed to display the intraocular pressure of before and after the correction with the intraocular pressure correction function.

Before correction: Measured IOP (intraocular pressure)

After correction: Corrected IOP (intraocular pressure)

⑦Bias switch

Pressed to change the displays of the pachymetry value.

None: 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%).

⑧**Delete switch**

Pressed to delete the selected data in the list.

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

When the Delete switch is pressed, it changes to the Recall switch that restores the deleted data.

⑨ **Value switch**

Pressed to input the bias value. The bias values are not displayed when the Bias switch is “None.”

⑩ **Clear switch**

Pressed to delete the measurement data at each measurement point.

⑪ **All Clear switch**

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

⑫ **Point display**

The specified measurement point can be moved using Knob 1.

⑬ **Gain display**

Displays the gain during pachymetry measurement.

The Knob 2 is used to adjust the gain.

⑭ **Print switch**

Pressed to print the data being displayed.

* The icon on the switch changes according to the communication setting.

Refer to “Setting Communication” (page 106).

⑮**Data save switch**

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

* The switch icon changes according to the data save destination setting. See “1.5.8. Utility screen (1/2)” (page 23).

⑯**Data read switch**

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

⑰**Measurement value list**

Displays the corneal thickness at the specified measurement point.

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

⑱**IOP Cor switch**

Pressed to execute the IOP correction function.

⑲**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.

⑳**FREEZE/LIVE switch**

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

㉑**OD/OS switch**

Pressed to switch the eye to be measured.

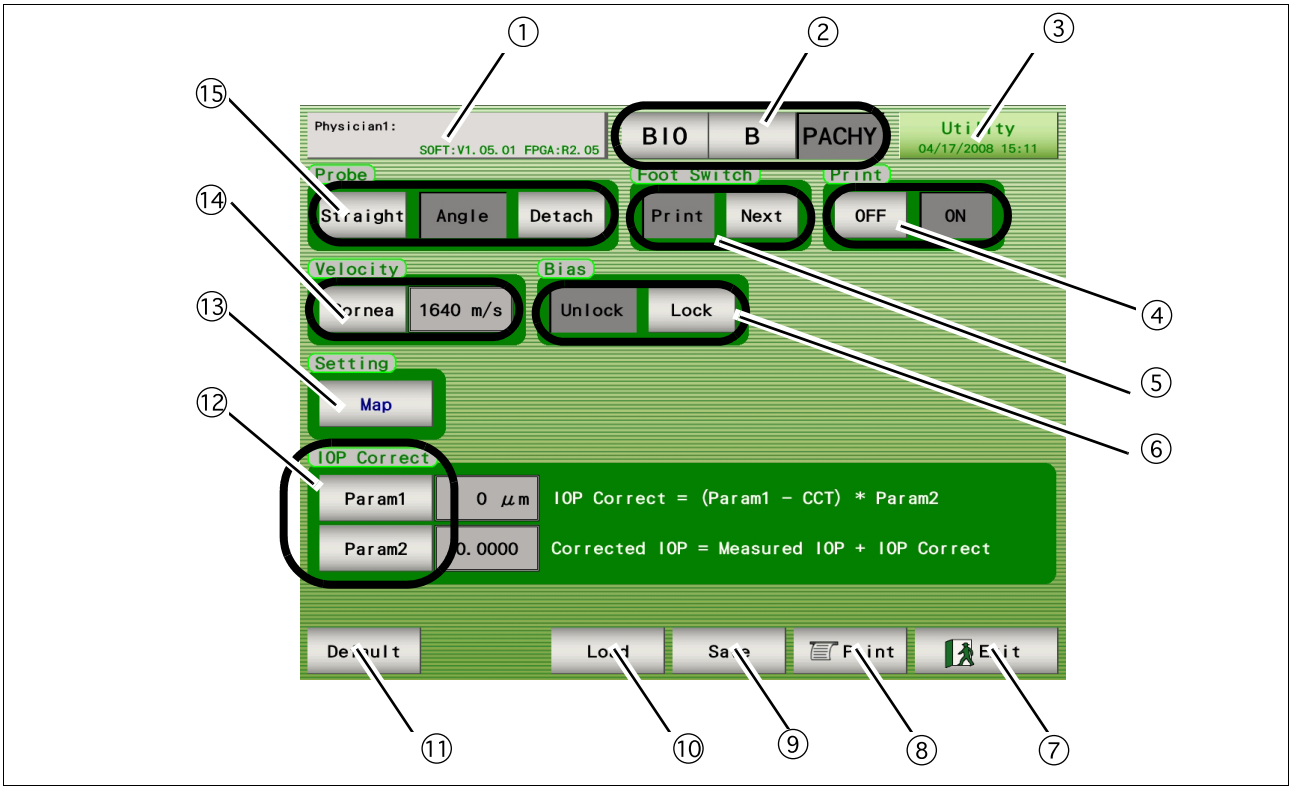
㉒**Measurement point display**

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

㉓**Corneal thickness display**

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

1.5.7 Pachymetry utility screen (optional)



①Physician switch

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

Conditions set in ④, ⑤, ⑥, ⑫, ⑭, and ⑮, and the Map No. selected in ⑬ can be set for each physician.

②BIO/B/PACHY switch

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

③Utility switch

Pressed to display the Utility screen.

④Print ON and OFF switch

Pressed to enable or disable printing of the pachymetry results.

⑤Foot Switch switch

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

⑥Bias switch

Pressed to toggle allowing and disallowing changing of the bias value.

⑦Exit switch

Pressed to return to the Pachymetry screen.

⑧Print switch

Pressed to print the Pachymetry utility settings.

⑨ Save switch

Pressed to save the Pachymetry utility settings.

⑩Load switch

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

⑪Default switch

Pressed to return the Pachymetry utility settings to the default.

⑫Param1 and Param2 switches

Pressed to set the correction coefficient for the IOP correction function using the Param1 or Param2 switch.

⑬Map switch

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

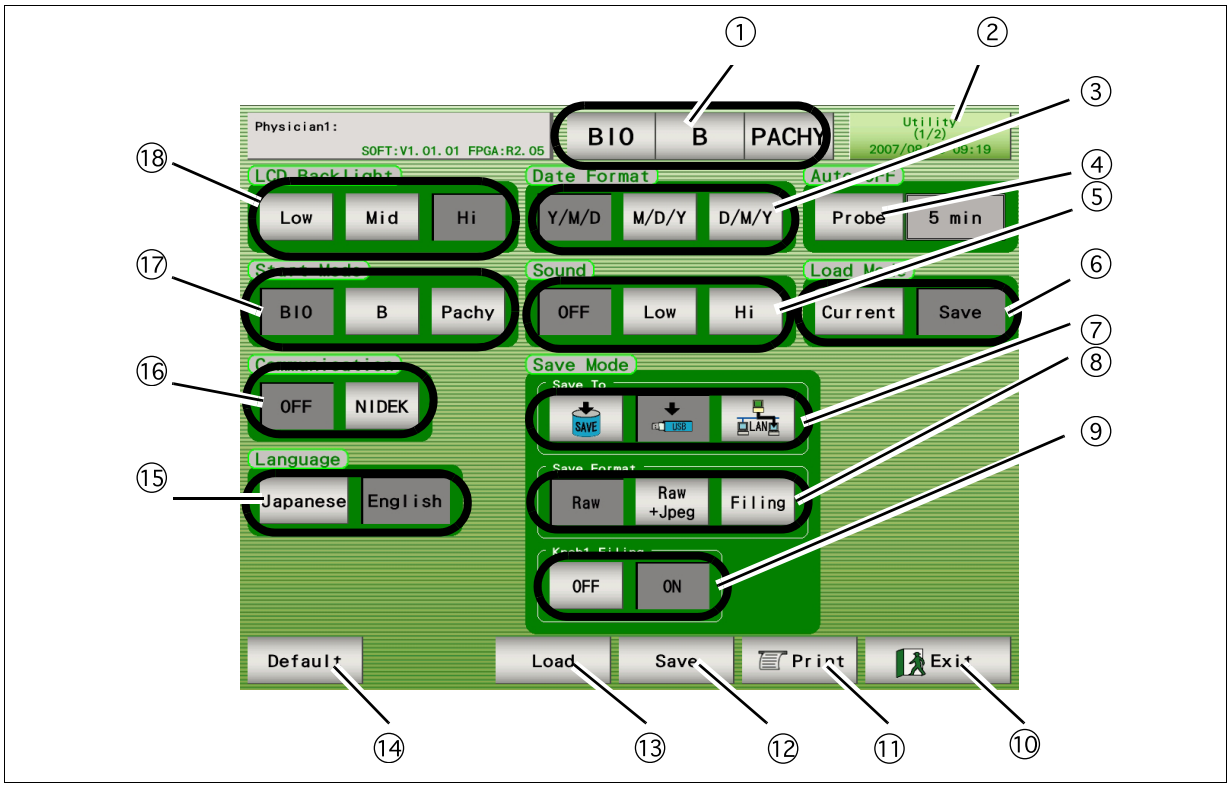
⑭Velocity switch

Pressed to set the sonic velocity to calculate distance.

⑮Probe switch

Pressed to select the type of the Pachymetry probe.

1.5.8 Utility screen (1/2)



①BIO/B/PACHY switch

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

②Utility switch

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

③Date Format switch

Pressed to select the desired date display format.

④Auto OFF switch

Pressed to set the maximum time of the LIVE condition.

⑤Sound switch

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

⑥Load Mode switch

Pressed to toggle the setting of the data to be loaded between the current one and the one of when the data was saved.

⑦Save To switch

Pressed to select the destination to save the data.

Internal memory

USB memory

LAN (PC)

* The Data save switch in each measurement screen changes according to the selected destination.

⑧**Save Format switch**

Pressed to select the save format.

Raw: Raw data + XML data

Raw + Jpeg: Raw data + Jpeg data (Full screen image) + XML data

Filing: Jpeg data (only waveform image) + XML data

* Raw data is not saved in the IOL power calculation screen.

(Only raw data can be displayed in the screen of the device.)

⑨**Knob 1 Filing switch**

Pressed to toggle saving screen images (Jpeg) between enabling and disabling.

⑩ **Exit switch**

Pressed to return to the measurement screen.

⑪**Print switch**

Pressed to print the utility setting.

⑫**Save switch**

Pressed to save the utility setting.

⑬**Load switch**

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

⑭**Default switch**

Pressed to return the utility setting to the default.

⑮**Language switch**

Pressed to toggle the language in the screen between English and Japanese.

⑯**Communication switch**

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

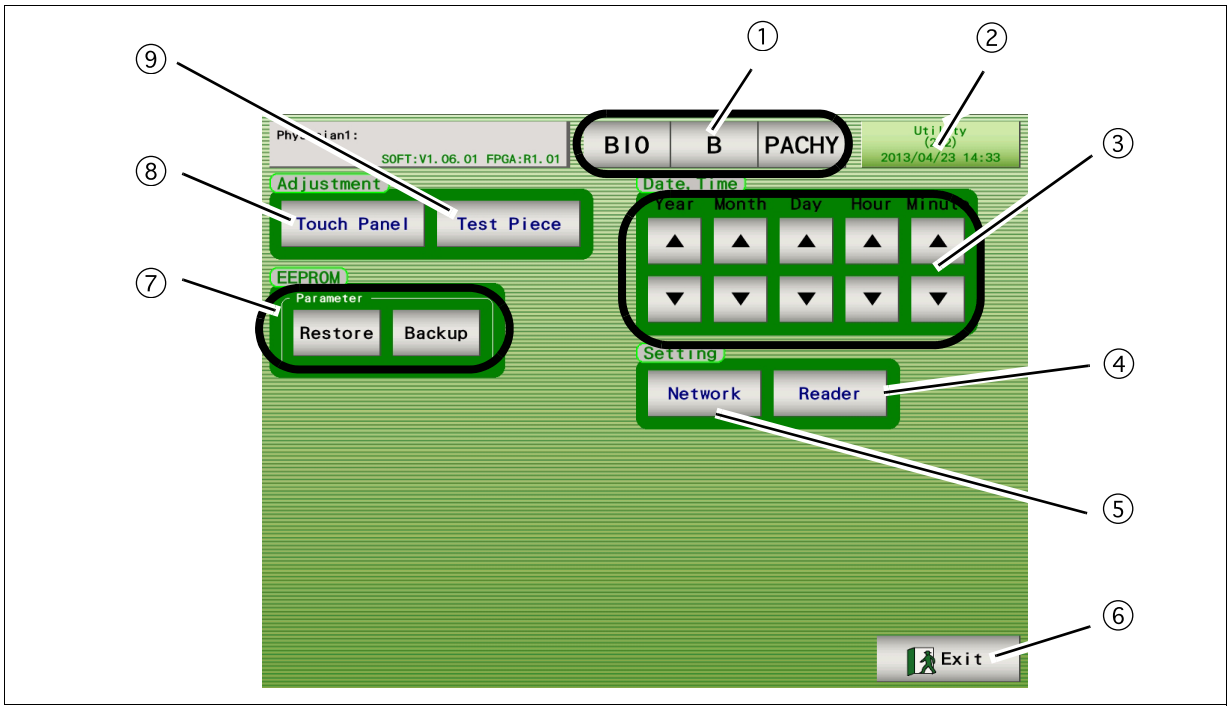
⑰**Start Mode switch**

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

⑱**LCD backlight switch**

Pressed to select the brightness of the backlight.

1.5.9 Utility screen (2/2)



①BIO/B/PACHY switch

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

②Utility switch

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

③Date and time switches

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

④Reader switch

Pressed to set the conditions for reading by the barcode reader.

⑤Network switch

Pressed to set the network.

⑥Exit switch

Pressed to return to the measurement screen.

⑦Parameter switch

Pressed to restore or backup the specified settings.

⑧Touch Panel switch

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

⑨Test Piece switch

Pressed to perform measurement for the test piece (for pre-operation check).

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. * The applied parts are the connector (P), connector (BIO), and connector (B) (see ⑩, ⑪, and ⑫ in “1.4 Device Description” (page 3)).
	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 foot 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.

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
- Foot switch
- Printer paper
- Power cord
- Stylus
- Ultrasonic gel
- Dust cover
- Spare fuses
- Probe rest
- Operator's manual

See “6.3.1. Standard accessories” (page 153) for details.

2. OPERATING PROCEDURE

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)
"2.2.4 Connecting probe" (Page 34)
"○ Connecting A-scan probe (optional) (Page 34)"
"○ Connecting B-scan probe (Page 34)"
"○ Connecting pachymetry probe (optional) (Page 35)"

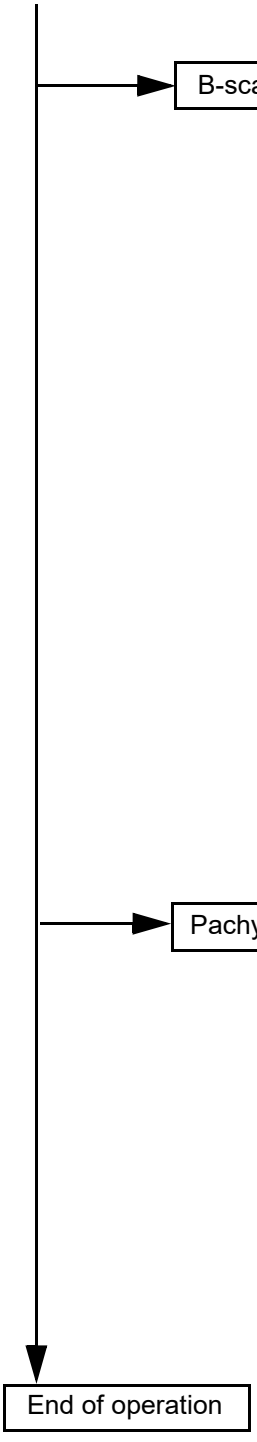
Preparing for measurement

"2.3 Preparation" (Page 36)
"2.3.1 Adding new patient data" (Page 38)
"2.3.2 Setting physician data" (Page 40)

Starting measurement

A-scan biometry

"2.4 A-scan Biometry" (Page 43)
"2.4.1 Basic operation of A-scan biometry" (Page 43)
"2.4.2 Cautions in A-scan biometry" (Page 49)
"2.4.3 Manual gate" (Page 50)
"2.4.4 Calculation of IOL refractive power" (Page 52)
"2.4.5 Comparison in Dual screen" (Page 56)
"2.4.6 Setting A-scan biometry utility" (Page 59)
"○ Changing sonic velocity to calculate distance (Page 59)"
"○ Setting IOL formula (Page 61)"
"○ Setting normally used IOL (Page 62)"
"○ Setting fixation light ON/OFF (Page 63)"
"○ Setting print format (Page 64)"
"○ Setting Immersion mode(Page 65)"
"○ Inputting IOL data (Page 66)"
"○ Calculating personal value (Page 68)"
"○ Setting IOL power calculation formula in specified axial length range (Page 71)"



Initial setting

2.2 Device Setup

2.2.1 Connecting power cord

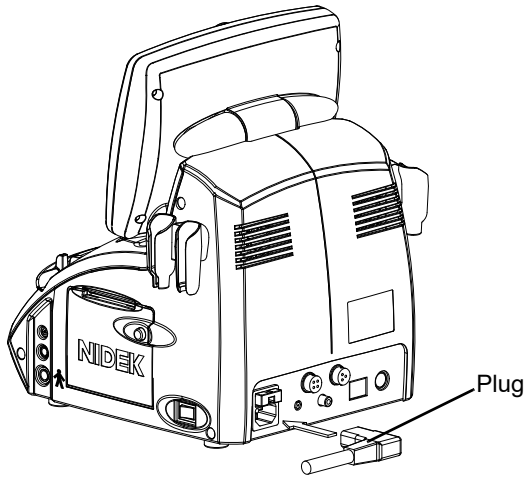
1 Turn OFF (○) the power switch.

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.



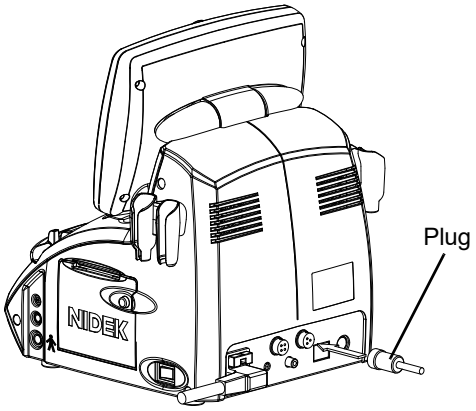
⚠ WARNING • **Be sure to use a grounded power outlet.**
Electric shock or fire may result in the event of malfunction or power leakage.

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.

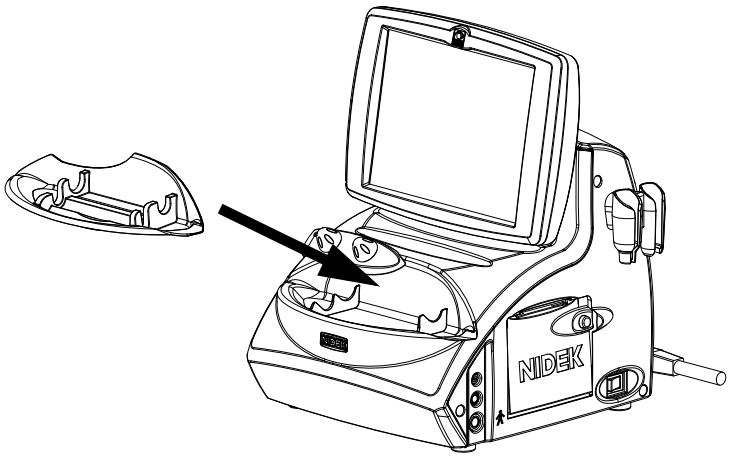
3 Rotate the knurled ring of the plug clockwise to secure.



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.

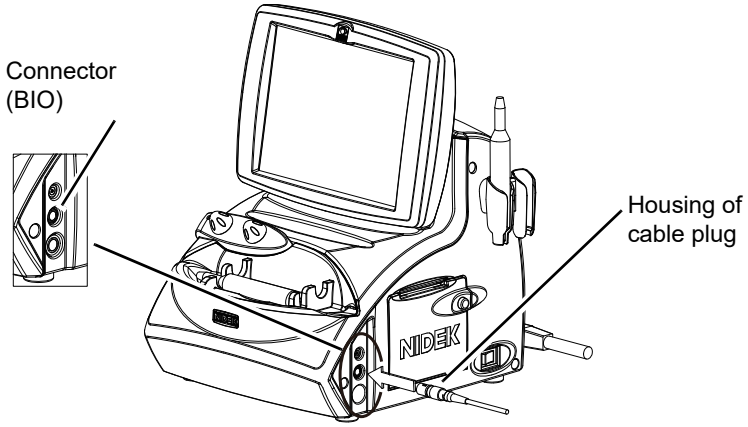


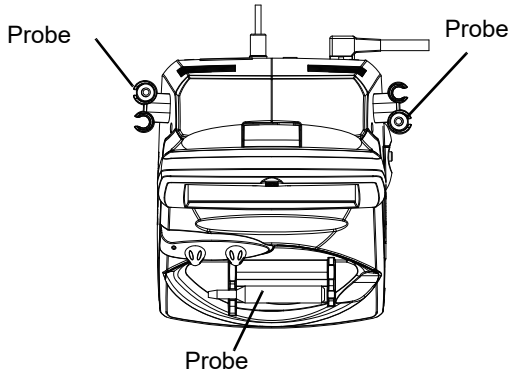
2.2.4 Connecting probe

○ Connecting A-scan probe (optional)

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

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

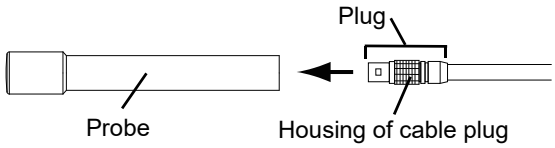




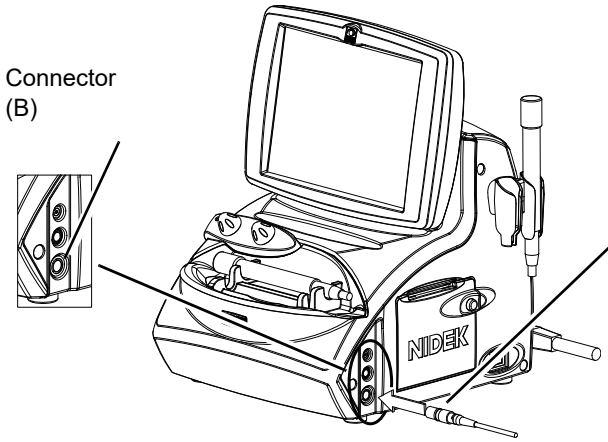
○ Connecting B-scan probe

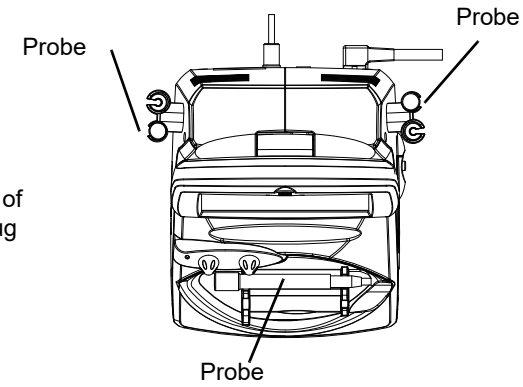
1 Connect the probe and the plug of the probe cable.

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



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

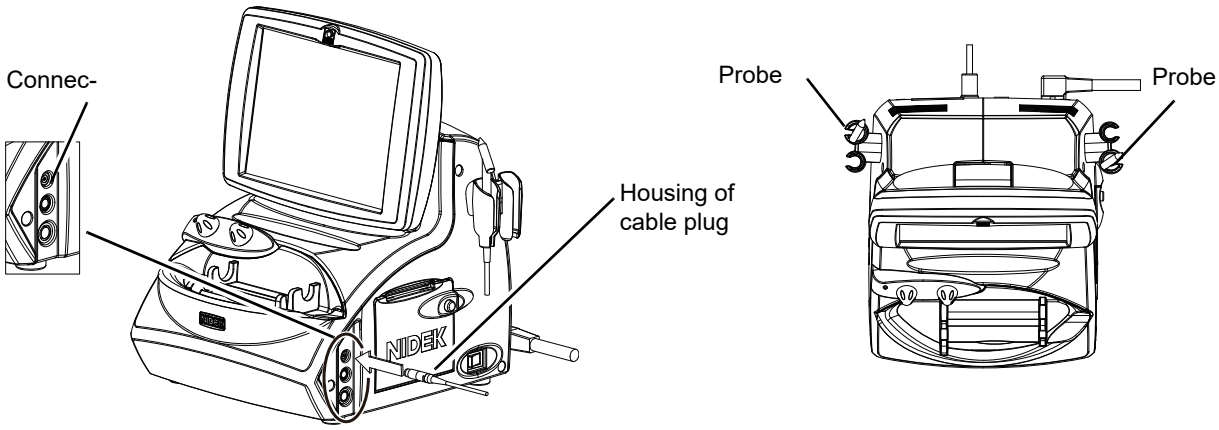




○ Connecting pachymetry probe (optional)

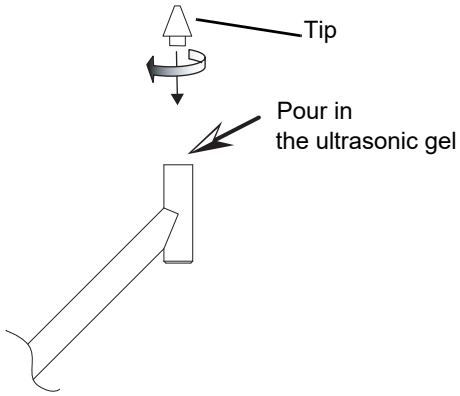
1 While holding the housing of the cable plug, insert the plug into the connector (P) on the right side of the device, and insert the cable plug as far as it goes.

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

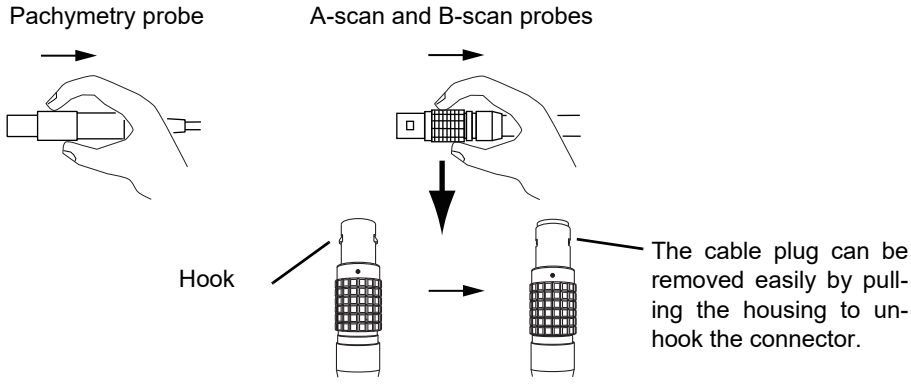


* When using the 45° detachable type pachymetry probe (optional), additionally perform the procedure below.

1) Remove the tip of the probe by rotating it counterclockwise.
2) Orient the opening of the probe from which the tip has been removed upward, and pour an appropriate amount of the ultrasonic gel.
3) Screw the tip back into the probe.
4) Confirm that there is no leakage of the ultrasonic gel.



⚠ CAUTION • **Always hold the housing of the cable plug, not the cable, when connecting or disconnecting the probe.**



2.3 Preparation

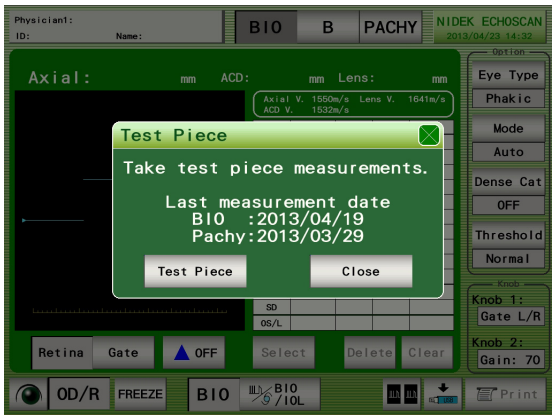
1 Connect the disinfected ultrasound probe.

2 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.

Wait for the initial screen at start-up (set for Start Mode in the Utility screen) to automatically appear after a few seconds.

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



When BIO is set for Start Mode

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

3 Perform the pre-operation check referring to “4.1 Checks Before Use” (Page 125).

After checks, record each result in the list “4.3 Check List” (Page 130).

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.

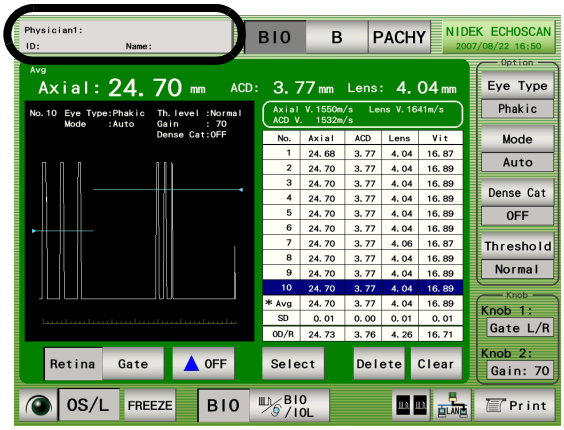
For B-scan imaging

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.

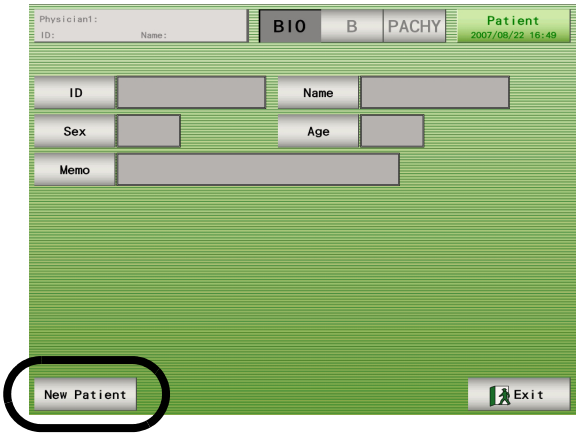
1 Pressing the Patient switch displays the screen shown in Step 2.



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

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

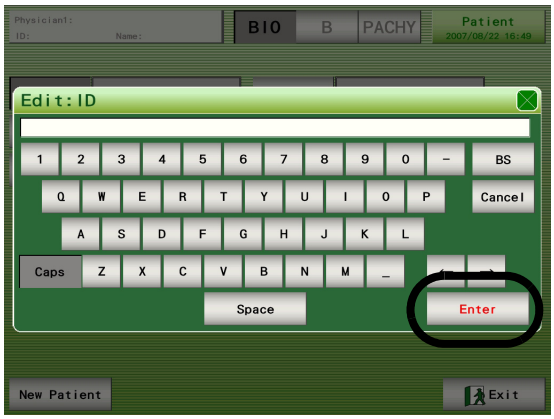
Pressing down the Patient switch for 1.5 seconds or more, like pressing the New Patient switch, deletes the saved patient information and measurement results and blanks the fields beside the switches.



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.

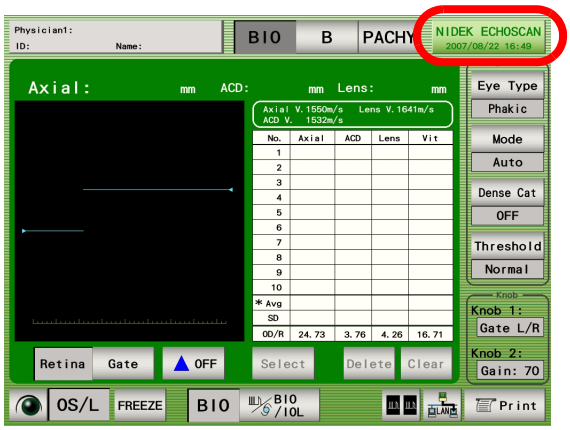
* A maximum of 34 characters can be input.

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

2.3.2 Setting physician data

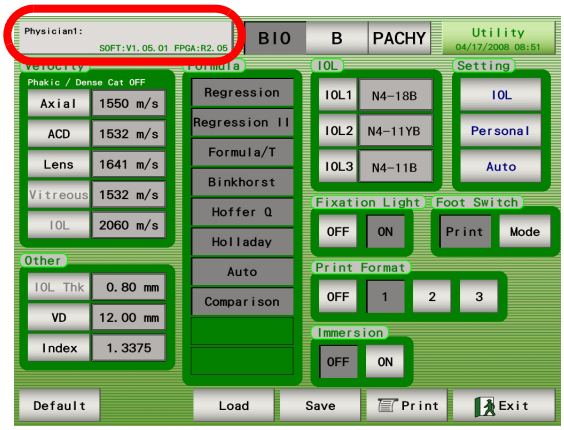
A maximum of five physicians can be saved with individual settings.

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



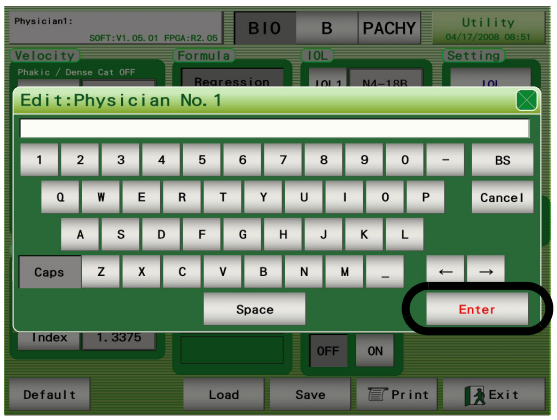
2 Press the Physician switch to display the setting of the physician to check or change.

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 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.

Ex.) In A-scan biometry and IOL power calculation

Switch	Input value	Default value	Input range
Axial	Axial length average sonic velocity to calculate distance	1550 m/s	800 to 2000 m/s
		1532 m/s when Eye Type is Aphakic	
		1548 m/s when Dense Cat is ON	
ACD	Anterior chamber sonic velocity to calculate distance	1532 m/s	1000 to 2000 m/s
Lens	Lens sonic velocity to calculate distance	1641 m/s	1000 to 2000 m/s
		1629 m/s when Dense Cat is ON	
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
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
Index	Corneal refractive index	1.3375	1.3315 to 1.338

* IOL switch: The default value is for when the IOL material is acrylic.

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 66).

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 64).

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.

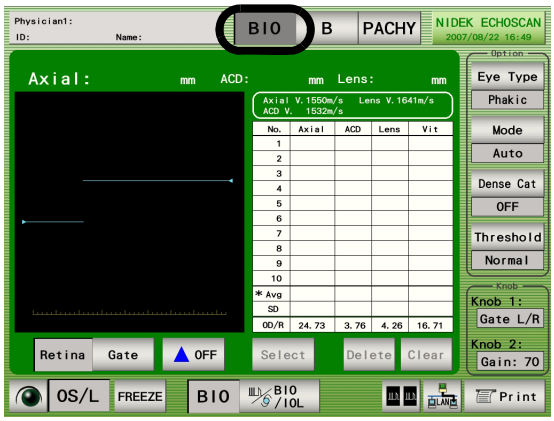
12 Press the Exit switch to return to the measurement screen.

2.4 A-scan Biometry

The A-scan probe is an optional accessory.

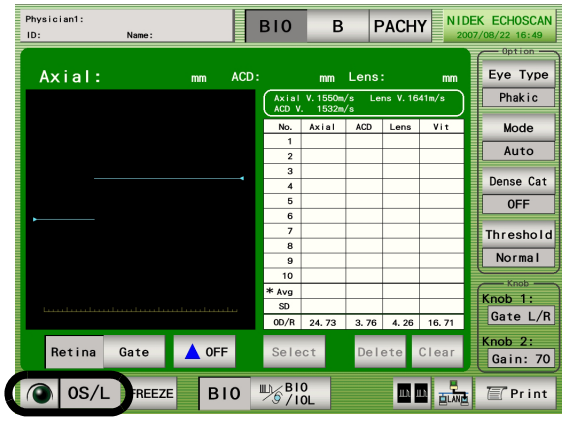
2.4.1 Basic operation of A-scan biometry

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”.

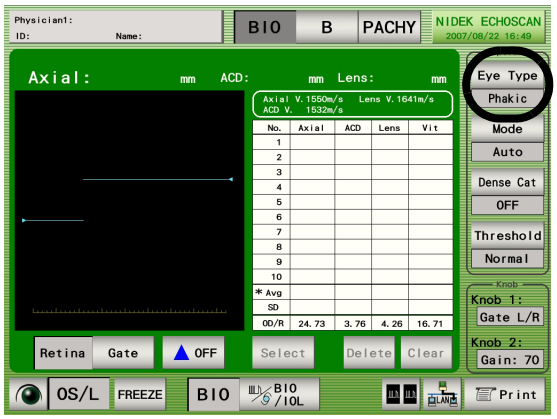
* When the patient’s eye type is changed, contents of the sonic velocity to calculate distance indicated on the left side of the switch are also changed. The patient’s eye type and sonic velocity to calculate distance are as follows:

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,” “SemiAuto,” “Speedy,” and “Manual.”

Auto: The measurement conditions are evaluated by the device 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.

SemiAuto: The measurement conditions are evaluated by the physician when the measurement is started.

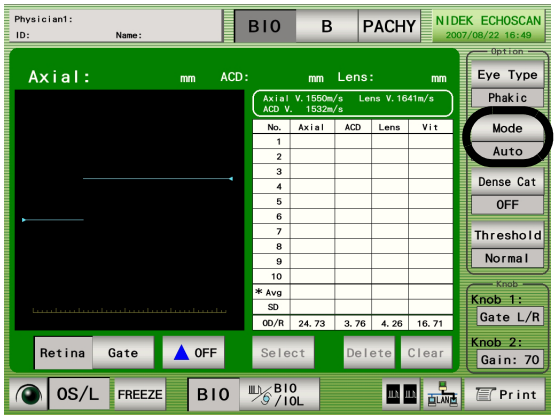
The physician observes the waveform when the measurement is started, and presses the footswitch or the LIVE button when they determines that a proper waveform is obtained to start data sampling. The stability of the measurement data is continuously evaluated during the data sampling. When ten sets of 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.

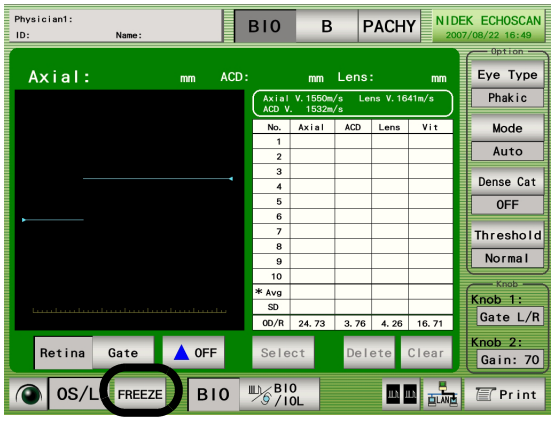
Manual: The physician performs data sampling when the measurement is started.

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



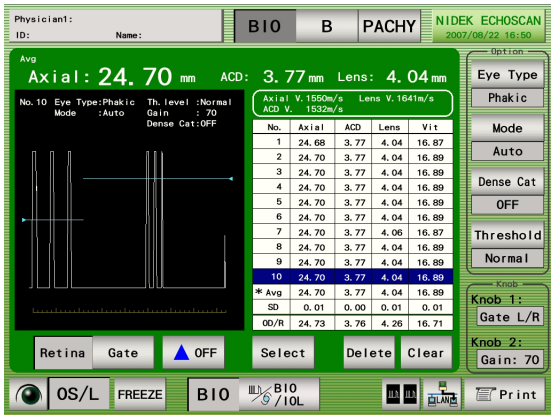
5 Press the FREEZE switch or the Measure switch of the foot switch to start A-scan biometry.

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



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

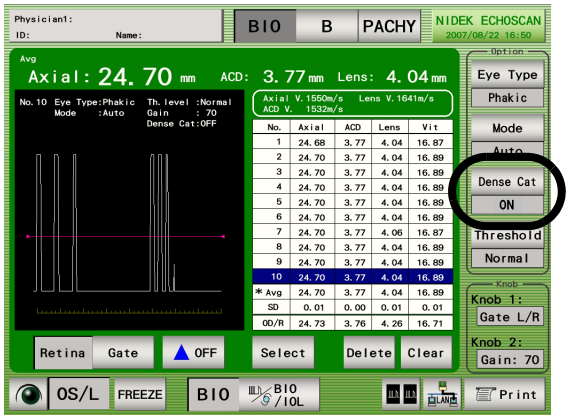
1) A-scan waveform appears, and A-scan biometry is performed according to the selected measurement mode.



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.

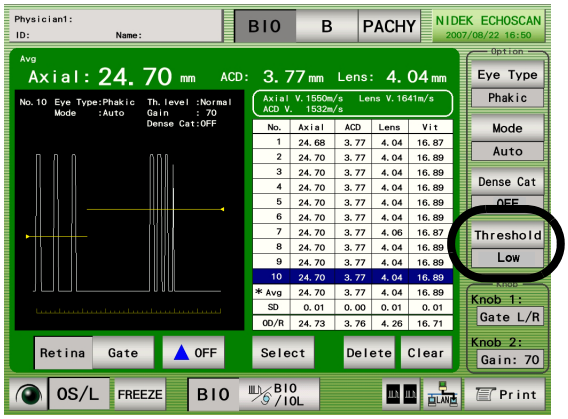
   * The most recently selected gain is indicated in this screen after the device power is turned ON (|) again.

3) To measure eyes with mature 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 50).



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 judgment. When using the values obtained in Auto mode for IOL power calculation, physicians have to examine the obtained values.

7 Repeat Step 5.

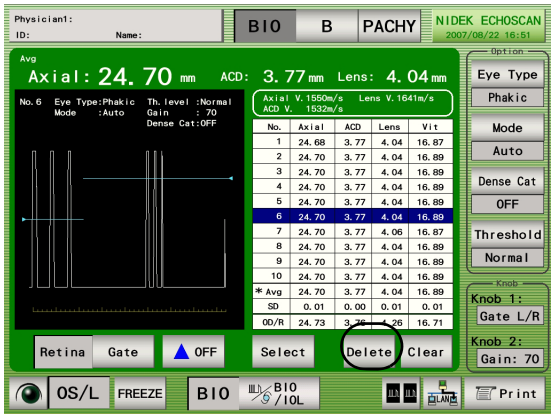
Repeat Step 5 several times to ensure validity of the obtained data.

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

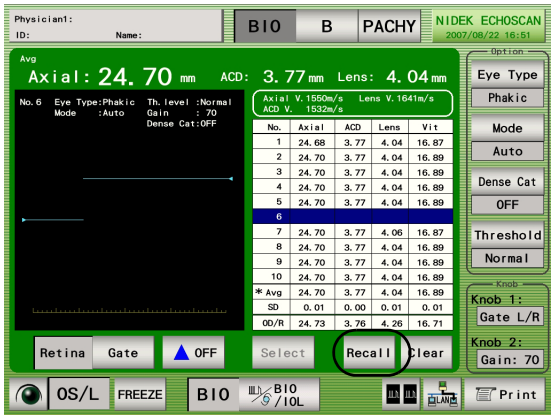
8 Arrange the data if necessary.

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.

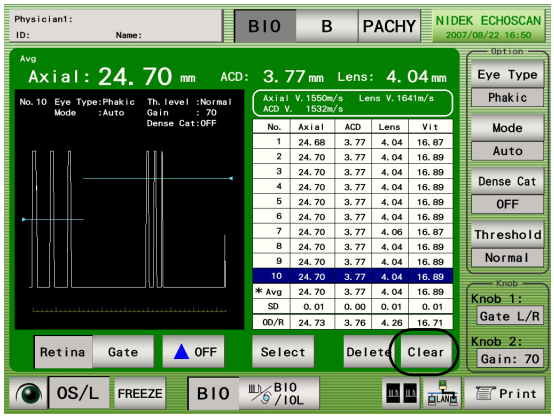


To undo deletion of a set of data, highlight the No. of the deleted data with the stylus or finger and press the Recall switch.



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.)

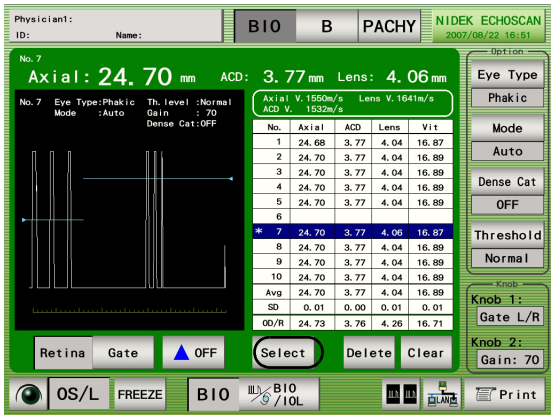
* Each time the data is deleted and the deletion is undone, the average (Avg) and standard deviation (SD) are recalculated.



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, 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 read from an external memory although there is no limit to the number of sets of data that can be saved to 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 that 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?

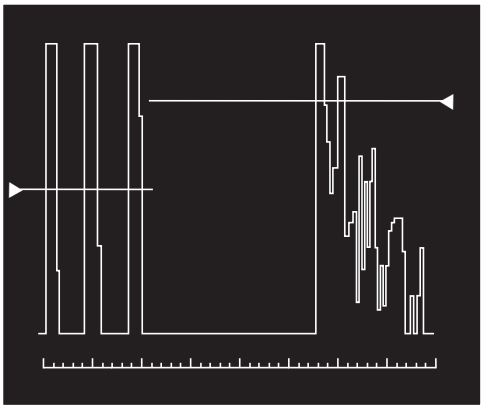
c) Is the patient's eye fixed?

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

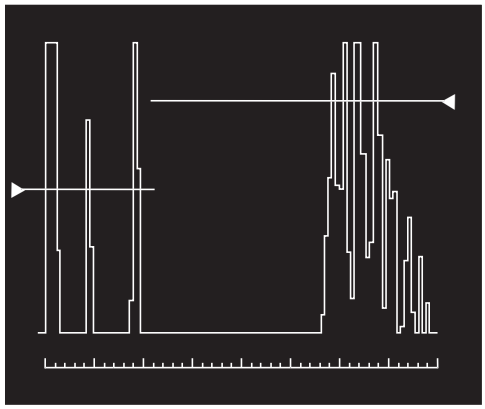
* If the A-scan biometry is performed hurriedly, accurate values cannot be obtained. Take enough time for the A-scan biometry.

(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

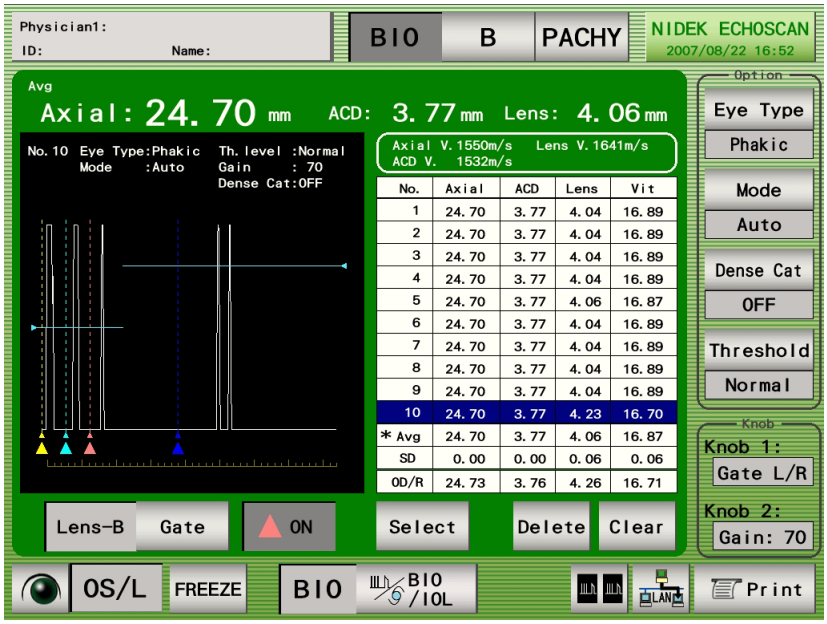


Improper

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.

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.

Note

- 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 ultrasound imaging).

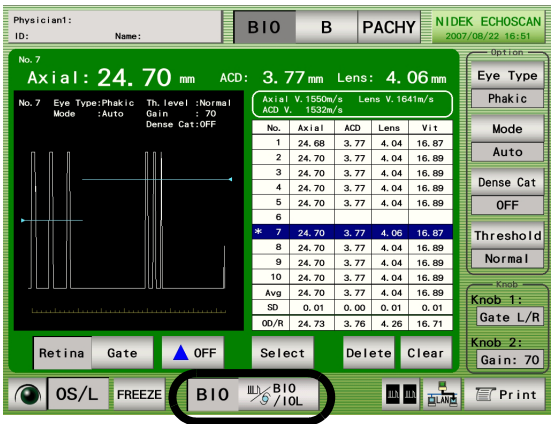
2.4.4 Calculation of IOL refractive power

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 66).

Note

- When using the values measured by the A-scan biometry of the device for IOL power calculation, carefully evaluate the validity of the measurement results.

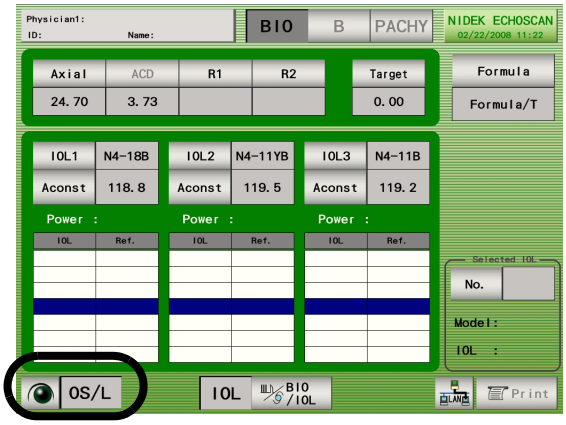
1 After the A-scan biometry, press the BIO/IOL switch to display the IOL power calculation screen.



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) 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.

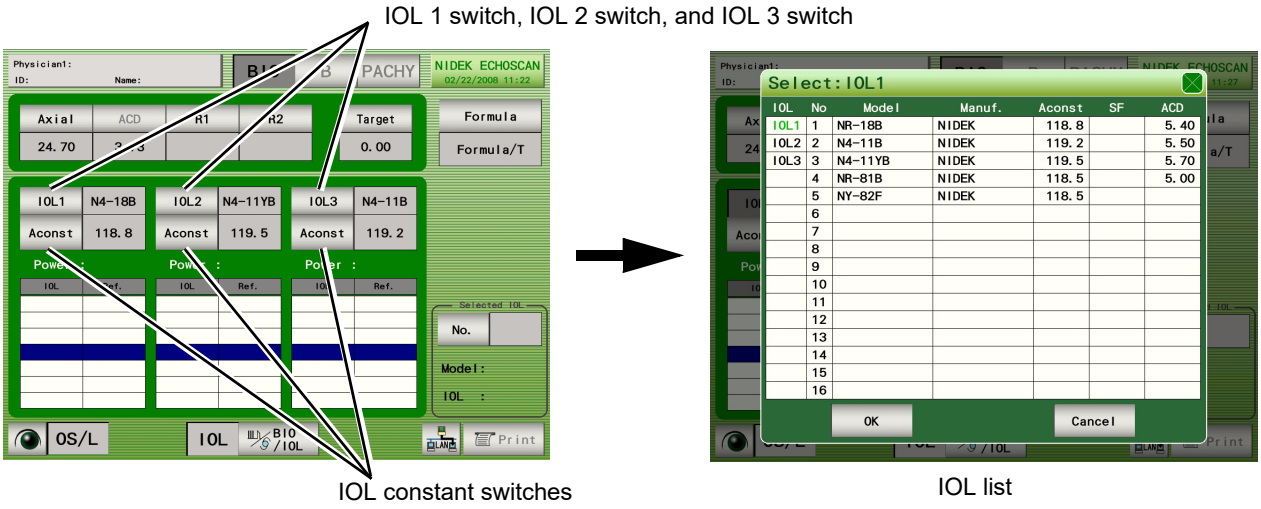
Comparison: The IOL power is calculated with all the IOL formula.

* 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.*1

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

* In the explanation below, the IOL 1 is selected.

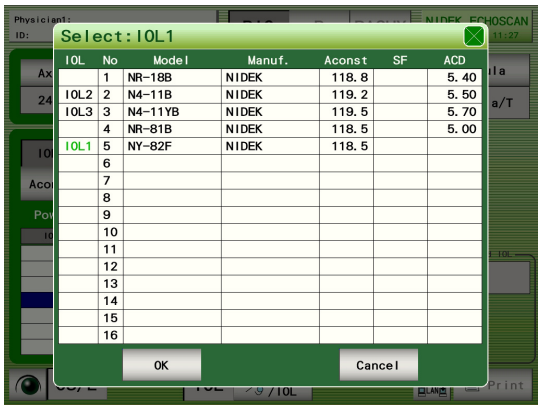


2) Select the IOL in the list with the stylus or finger.

* If a blank is selected, the refractive power is not calculated.

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

For the registration procedure, see "○Inputting IOL data" (Page 66).



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 the IOL 1, IOL 2, and IOL 3 switches.

6 If necessary, temporarily change the IOL constant selected in Step 5.*2

*1. 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 66).) 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 (○).

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

   * The indicated name of the IOL constant switch differs such as “Aconst,” “SF,” and “ACD” according to the IOL formula to be used (being selected).

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 132

     ACD (Predicted postoperative anterior chamber depth) (ACD switch)..... -7.00 to 20.00

     SF (Surgeon factor) (SF switch)... -10.00 to 20.00

   * 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 that is the closest to the desired postoperative refractive power is highlighted in the middle row on the calculation list.

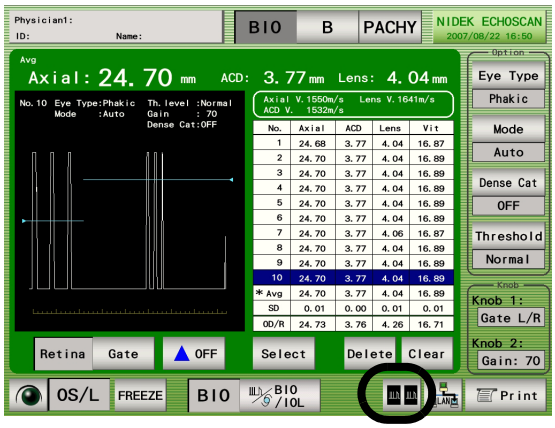
6) Input the data for the other eye in the same manner as Steps 2) to 5) to calculate the IOL power for it.

*2. Changes made in this step are temporary, and the values return to the original once power to the device is turned OFF (◯).

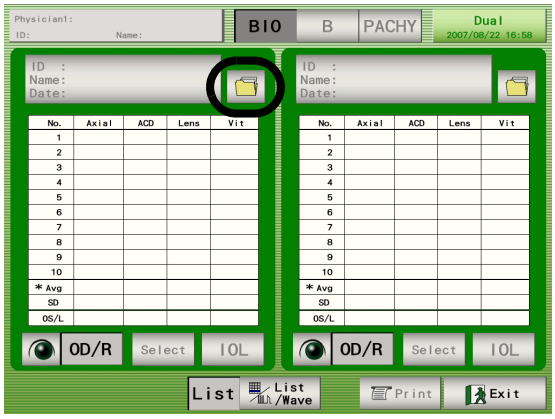
8 Press the Print switch to print the calculation results.

2.4.5 Comparison in Dual screen

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

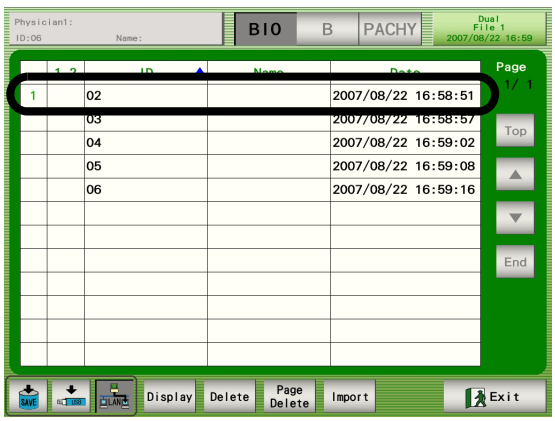


2 Press the Data Read switch above the table on the left side of the screen to display the file list.

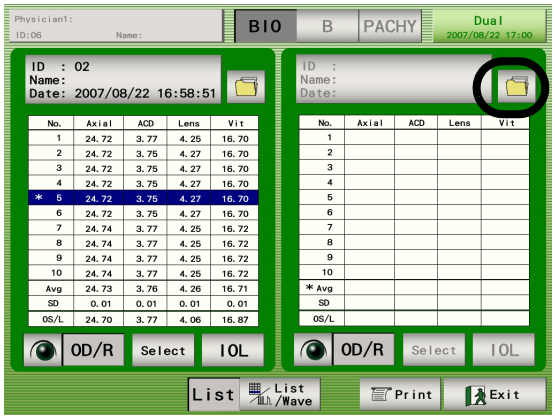


3 Select the desired file from the list to be displayed on the left side (1) of the screen by the stylus, and press the Display switch.

To indicate that this data is for the left side of the screen, “File 1” is displayed at the top right of the file list. When a file is selected, “1” is displayed to the left of the file.

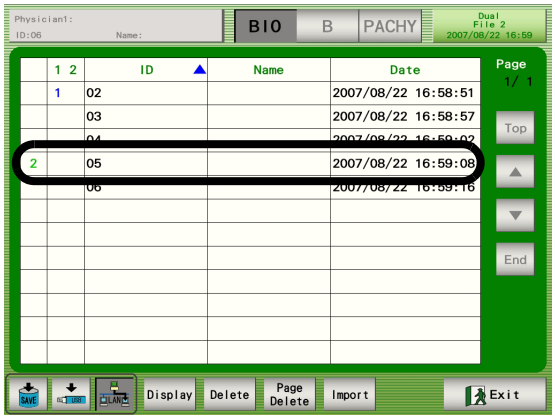


4 Press the Data Read switch above the table on the right side of the screen to display the file list.

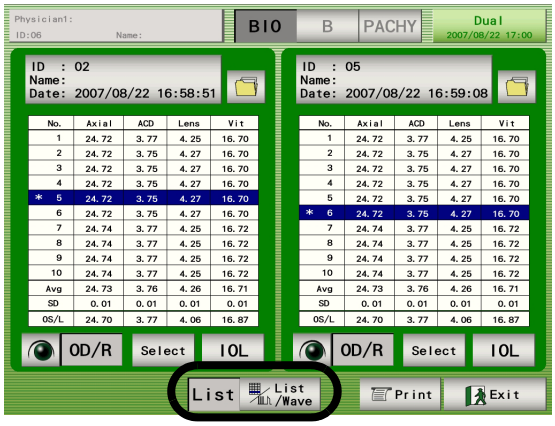


5 Select the desired file from the list to be displayed on the right side (2) of the screen by the stylus, and press the Display switch.

To indicate that this data is for the right side of the screen, “File 2” is displayed at the top right of the file list. When a file is selected, “2” is displayed to the left of the file.



6 Select an appropriate set of data each from the left and right file using the stylus. Then press the List/Wave switch.

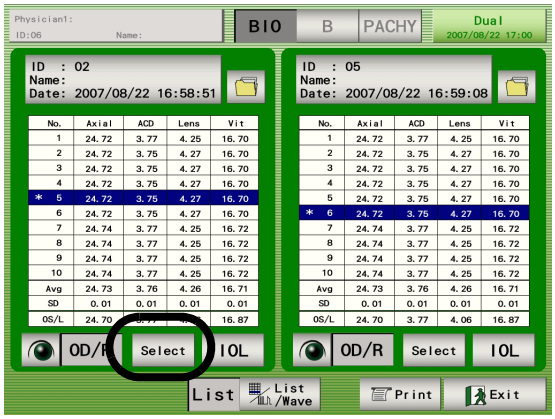


7 The waveform of the selected set of data is displayed on each side of the screen. Check if the waveforms are appropriate.

8 Press the List/Wave switch again and repeat Steps 6 and 7 to find appropriate sets of data.

9 When appropriate sets of data are found, press the Select switch under the data list. An asterisk "✱" appears on the side of the number of the selected set of data.

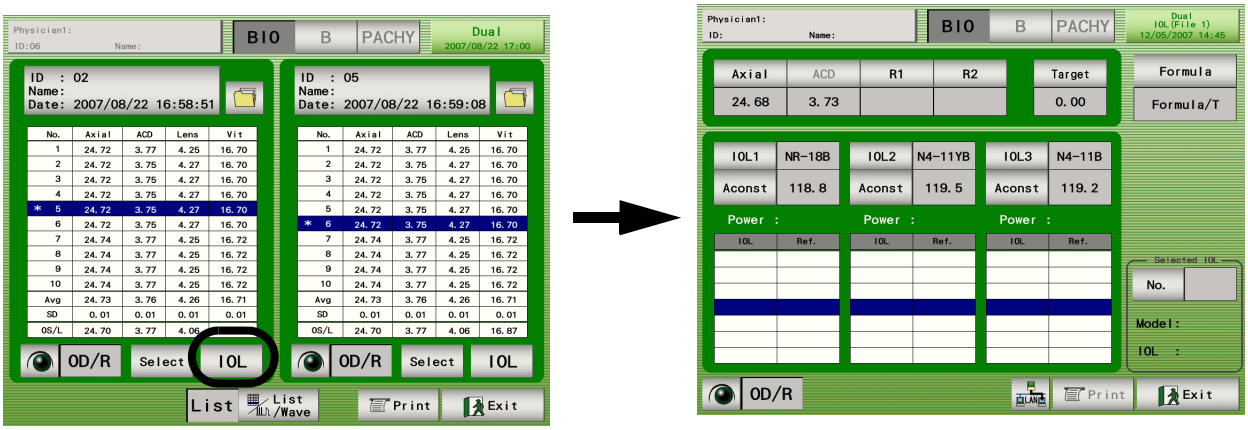
(IOL calculation using the data with "✱" is enabled.)



10 Press the IOL switch to calculate the IOL power.

For the calculation procedure, see "2.4.4 Calculation of IOL refractive power" (Page 52).

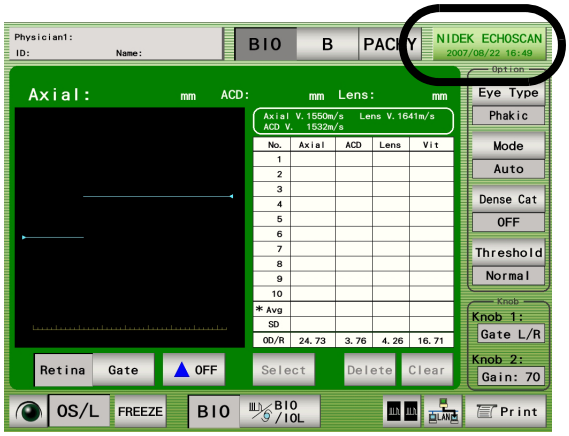
* The screen below shows the calculation on the left side on the screen. The calculation can be performed in the same way also in the right side of the screen.



11 Press the Print switch to print the calculation results.

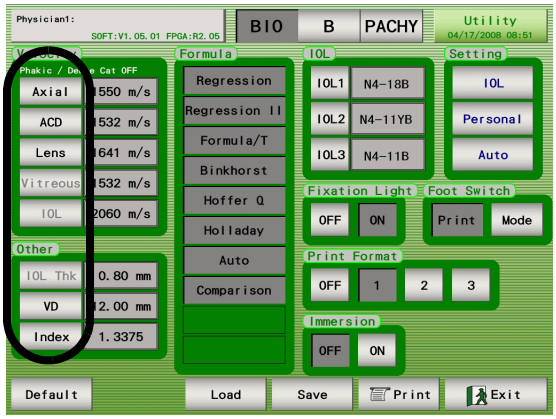
2.4.6 Setting A-scan biometry utility

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

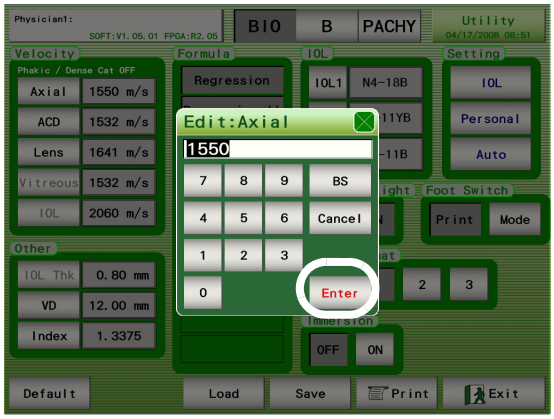


○ Changing sonic velocity to calculate distance

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, VD, or Index 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	Axial length average sonic velocity to calculate distance	1550 m/s	800 to 2000 m/s
		1532 m/s when Eye Type is Aphakic	
		1548 m/s when Dense Cat is ON	
ACD	Anterior chamber sonic velocity to calculate distance	1532 m/s	1000 to 2000 m/s
Lens	Lens sonic velocity to calculate distance	1641 m/s	1000 to 2000 m/s
		1629 m/s when Dense Cat is ON	
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
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
Index	Corneal refractive index	1.3375	1.3315 to 1.338

* IOL switch: The default value is for when the IOL material is acrylic.

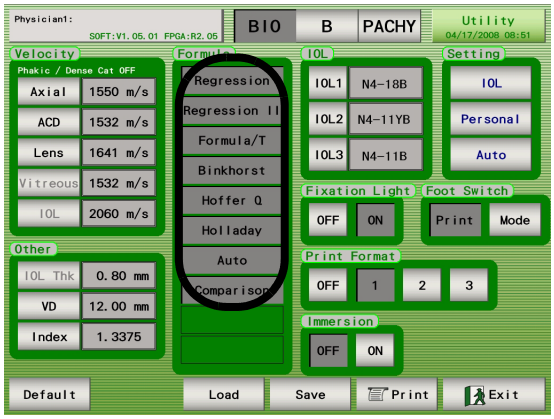
Pressing the Default switch resets all the settings to the default values.

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.

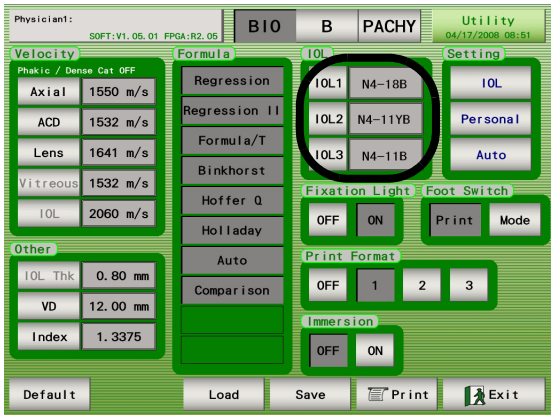
Auto: An IOL formula is automatically selected based on the axial length.



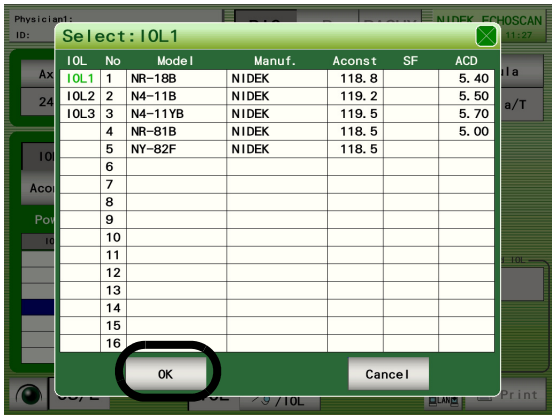
2 Press the Save switch to save the setting.

○ 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.

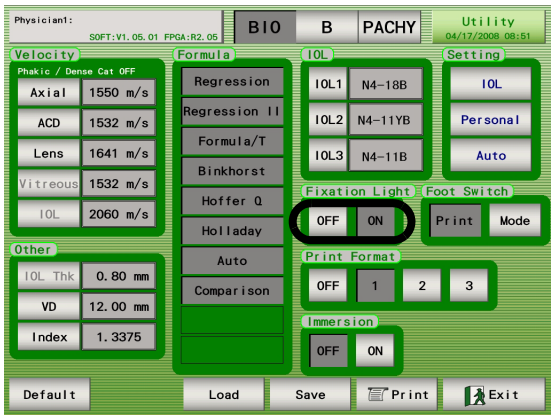


3 Press the Save switch to save the setting.

○ 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

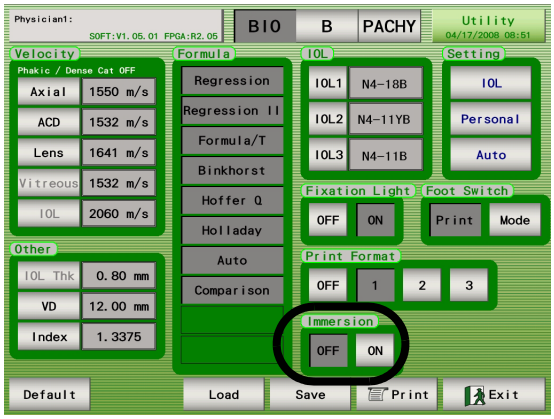
	Printed item	Off	1	2	3
IOL power calculation	Patient data	-	O	O	O
	Physician's name	-	O	O	O
	Operation conditions	-	-	-	O
	IOL formula	-	O	O	O
	Eye (left or right)	-	O	O	O
	A-scan biometry value used for IOL power calculation Value with “*” in the IOL list on the screen	-	-	-	O
	Selected A-scan waveform	-	-	-	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 (◯).

○ Setting Immersion mode

Toggle the use of the Immersion mode.



Note

- To use Immersion mode, an immersion holder is necessary. To purchase one, contact your authorized distributor.

1 Toggle between ON and OFF.

2 Press the Save switch to save the setting.

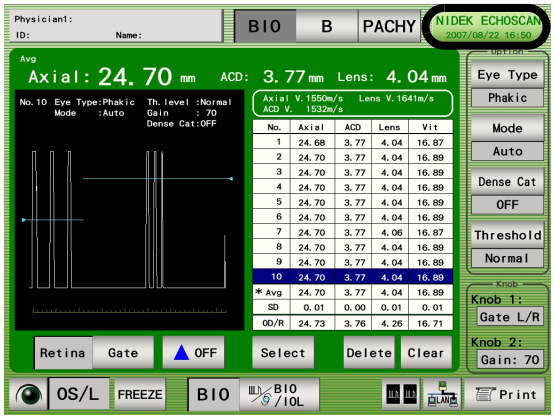
Note

- This switch is disabled when measurement data is in the A-scan biometry screen. Be sure to confirm that no measurement data is in the A-scan biometry screen before toggling the use of the Immersion mode with this switch. When the Immersion mode is ON, the device automatically eliminates the initial waveform at the probe tip and begins the waveform display from the anterior surface of the cornea.

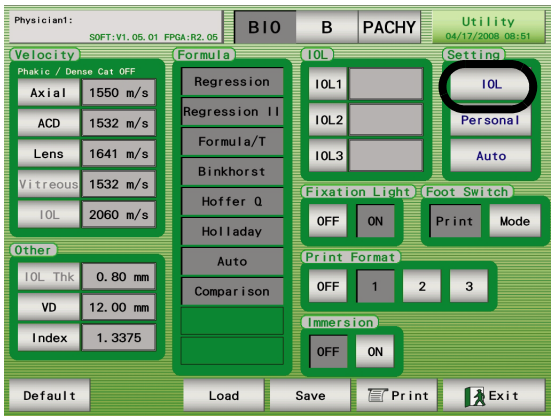
○ Inputting IOL data

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.

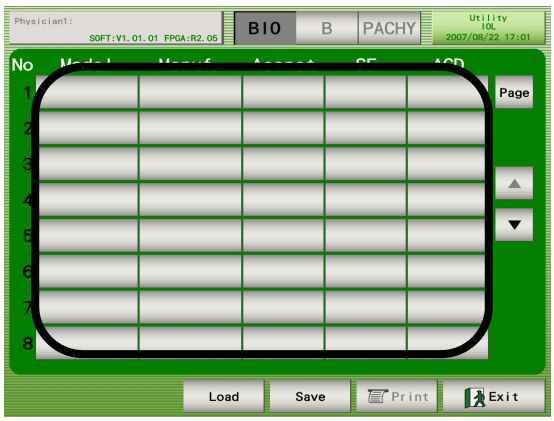


2 Press the IOL switch.



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

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

IOL constant

Aconst: A constant

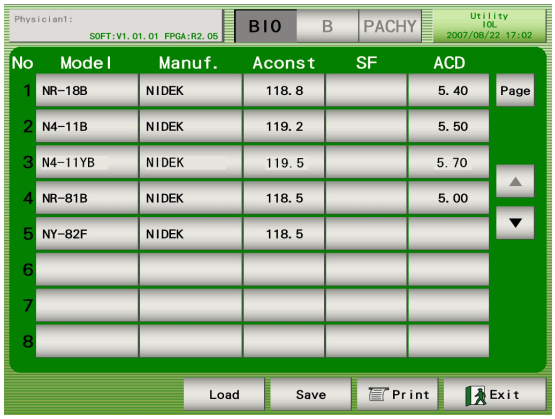
SF: Surgeon factor

ACD: Predicted postoperative anterior chamber depth

* A maximum of 16 sets of IOL data can be input.

* 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.

* A maximum of 12 characters can be input for “Model” and “Manuf.” each. However, all the characters may not be displayed in the screen or printed.

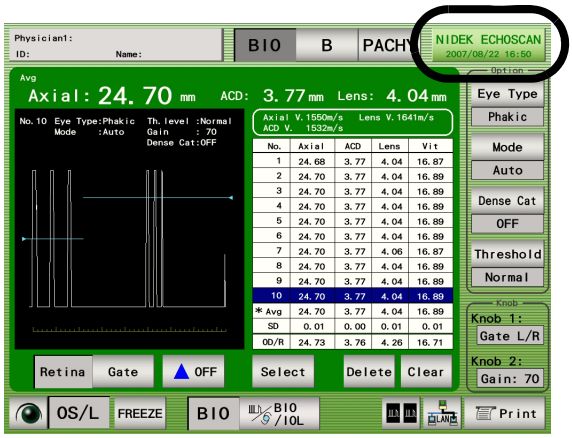


5 Press the Save switch to save the data.

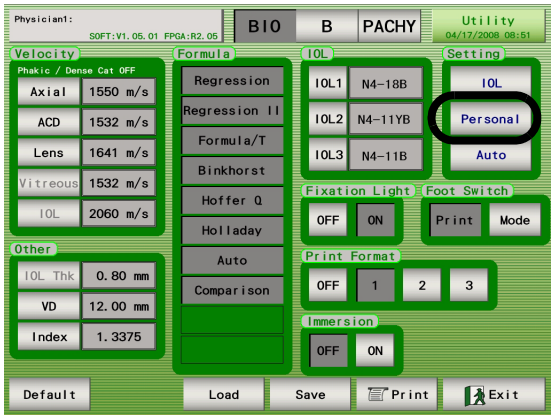
○ Calculating personal value

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.



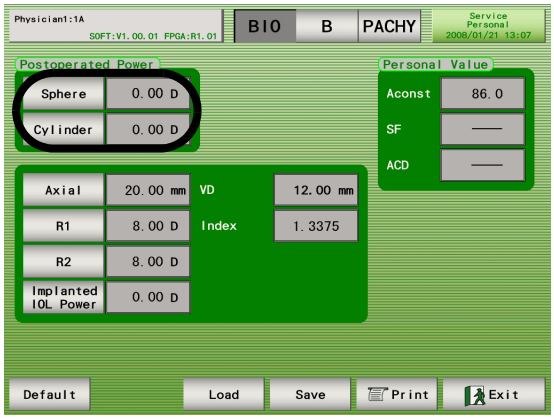
3 Input the postoperative refractive power.

Pressing any of the postoperative power switches displays the ten-key window that 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 that 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 that 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

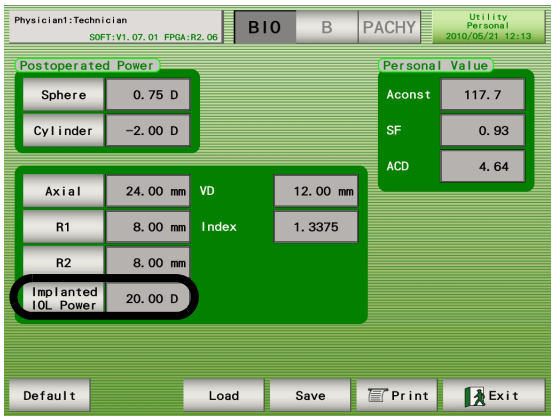
Refractive power 20.00 to 60.00 D

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

Pressing this switch displays the ten-key window that 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”.

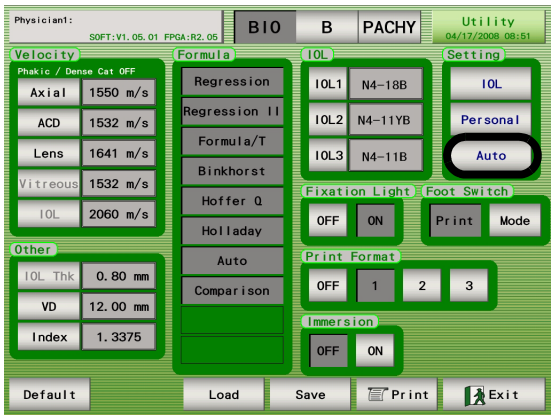


7 If necessary, press the Print switch to print the data on this screen.

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 or 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.

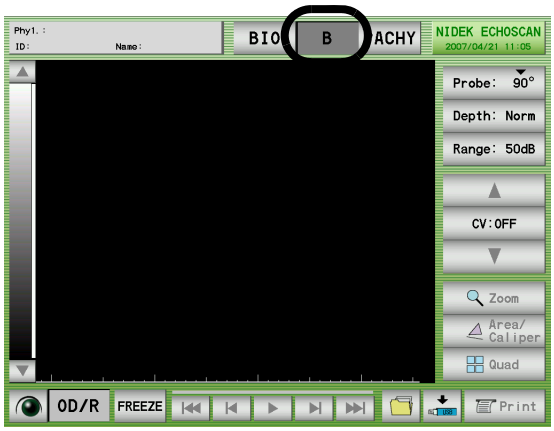
5 If necessary, press the Print switch to print the setting.

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

2.5 B-scan Imaging

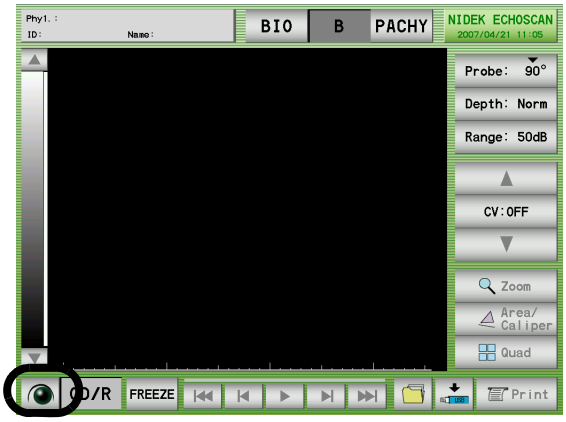
2.5.1 Basic operation of B-scan imaging

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

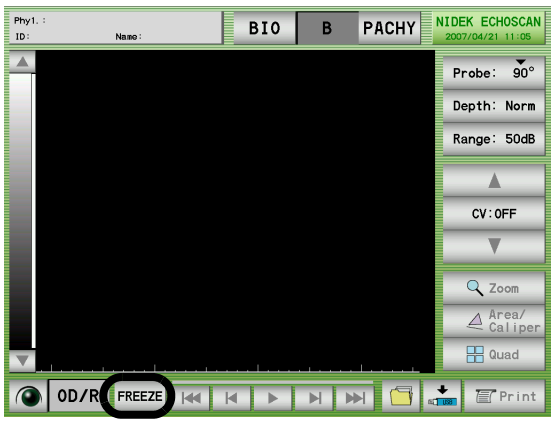


2 Press the OD/OS switch to select the right or left eye for which the B-scan imaging is to be performed.

Each time the switch is pressed, the eye indication on the right side of the switch changes between “OD/R” (right eye) and “OS/L” (left eye).



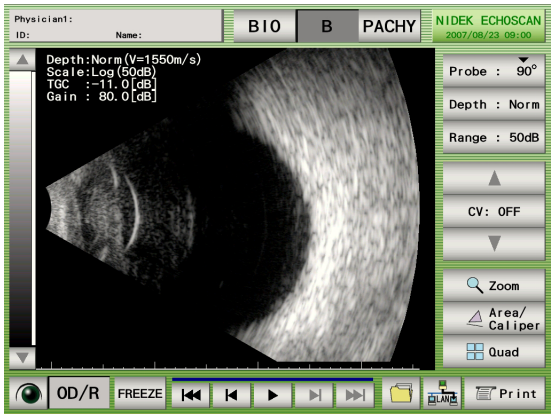
3 Press the FREEZE switch or the Measure switch of the foot switch to start the image observation.



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.

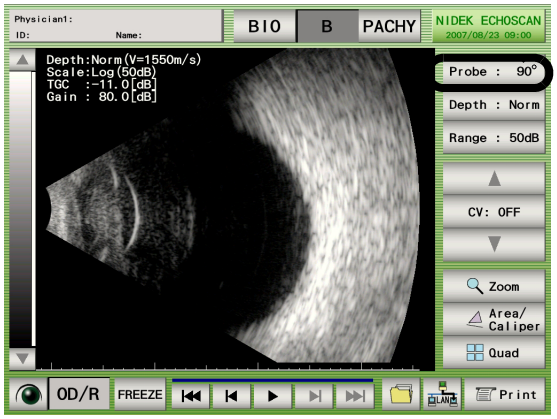
6 When the desired image is captured, press the LIVE switch or press the Measure switch of the foot switch to freeze the image.



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

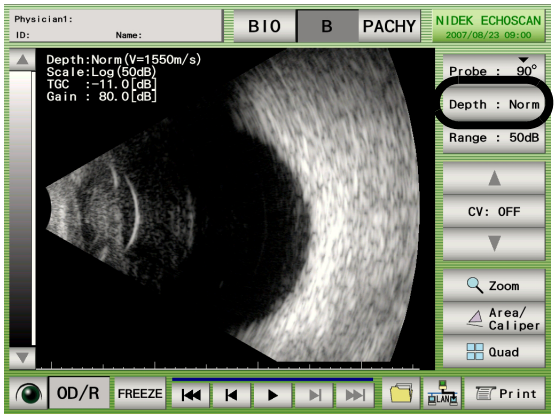
2.5.2 Probe angle

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° → ...)



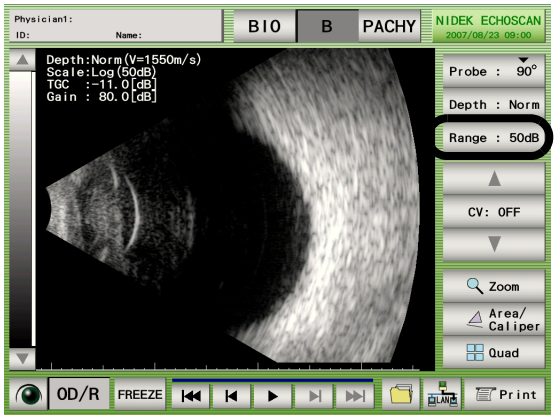
2.5.3 Changing observation depth

Press the Depth switch to change the observation depth.
* The observation depth cannot be changed during the measurement.



2.5.4 Changing display range

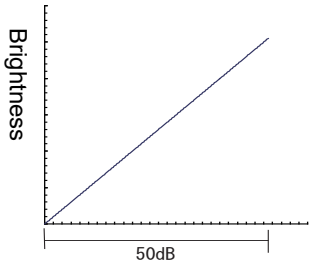
The Range switch is available when the gain curve is set to “Log.” Each pressing of the Range switch changes the value as “50 → 40 → 30 → 20 → 10 → 50dB...”

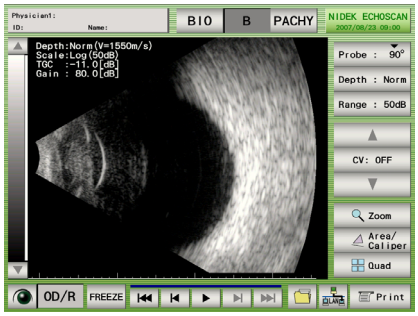


The B-scan image is displayed in 256 gray scales within the range of the echo intensity (50 dB).

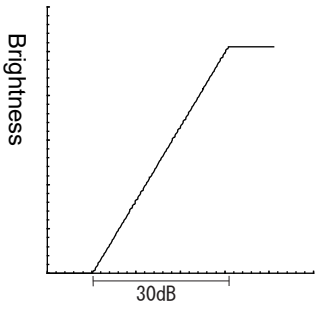
The range of the echo intensity can be changed as necessary. For example, when the range is changed to 30 dB, the echo intensity is displayed in 256 gray scales within the range of 30 dB. By adjusting the range of 30 dB to the desired echo intensity, the image of the selected echo intensity can be displayed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

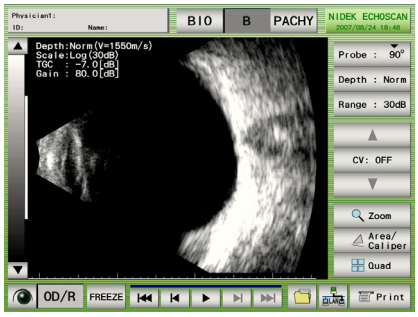
・Range: 50 dB



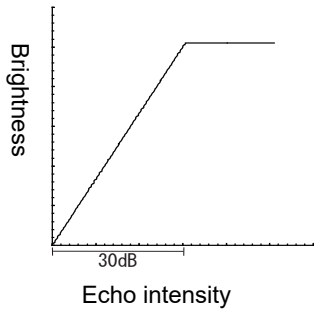


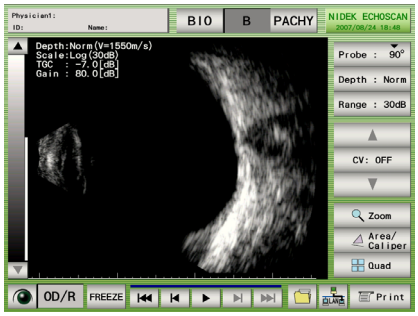
・Range: 30 dB　Middle intensity echoes are displayed clearly



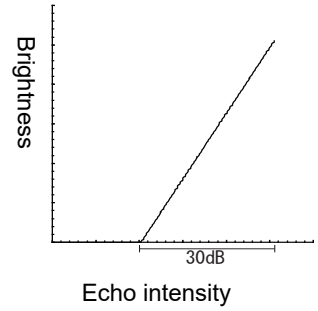


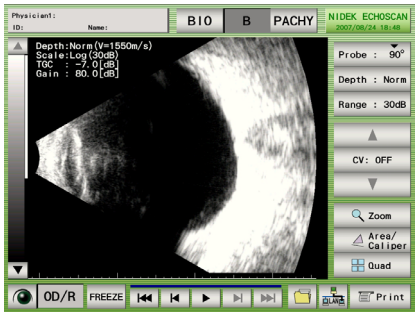
・Range: 30 dB　Low intensity echoes are displayed clearly





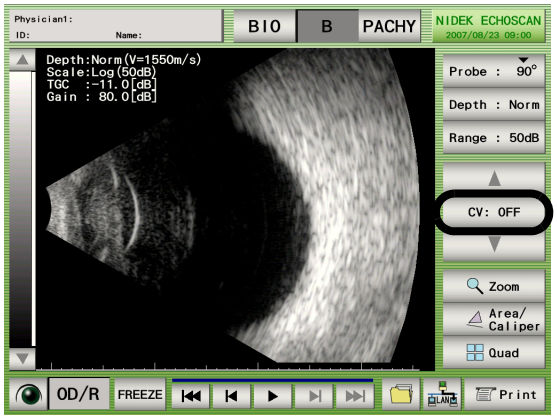
・Range: 30 dB　High intensity echoes are displayed clearly



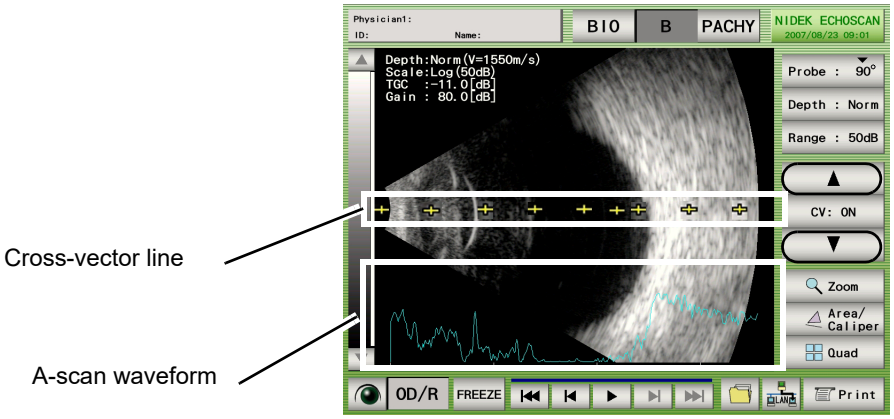


2.5.5 CV mode

1 Press the “CV:OFF” switch.

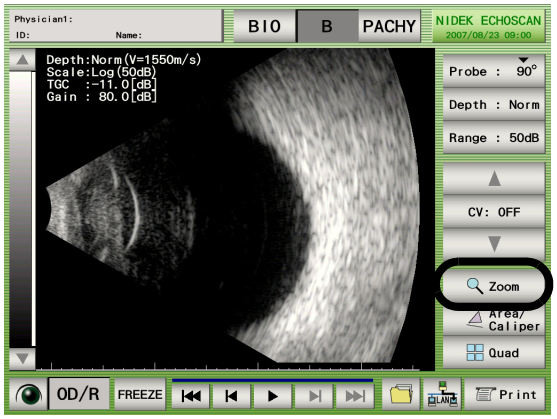


2 Pressing the triangle switches moves the cross-vector line. The A-scan waveform for the cross-vector line and the entire B-scan image are displayed together. The cross-vector line also can be moved with the stylus.

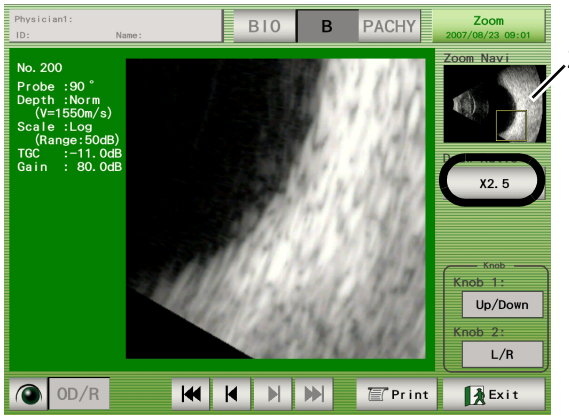


2.5.6 Zoom

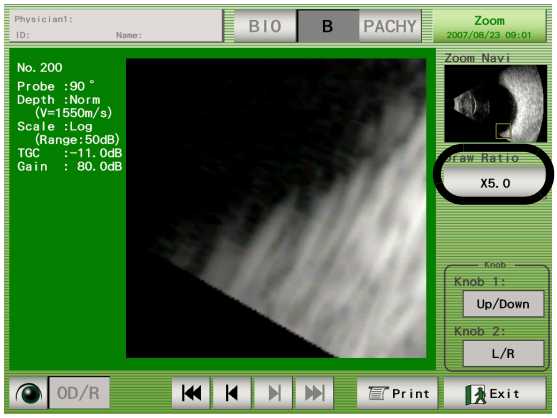
1 Press the Zoom switch in the B-scan imaging screen to display the Zoom screen.



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



Zoom Navi



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.

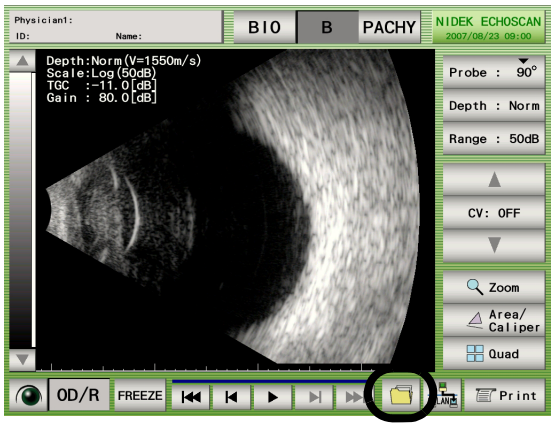
4 Press the Print switch to print the image on the screen.

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

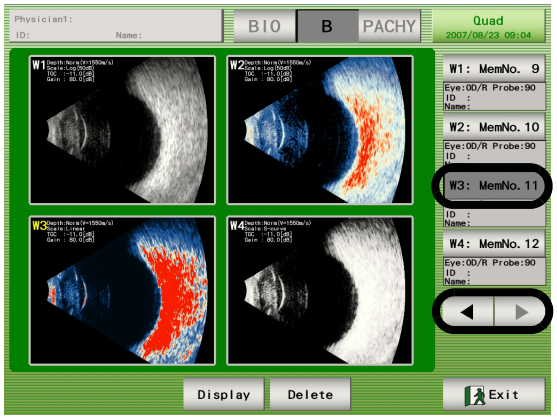
2.5.7 Four image display

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

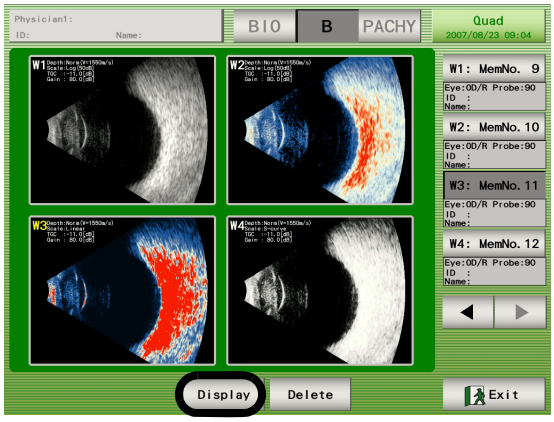
If the desired data is stored in an external storage device, import the data by pressing the Data Read switch.



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.

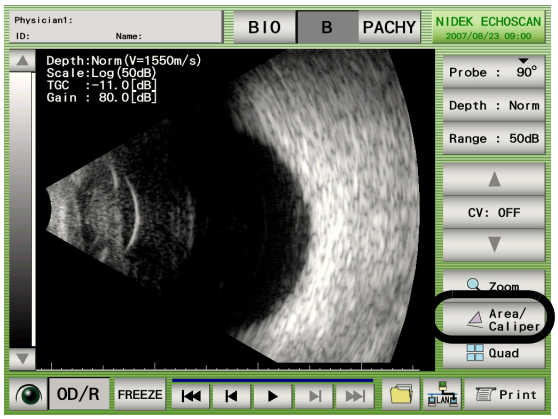


4 Press the Delete switch to delete the selected image.

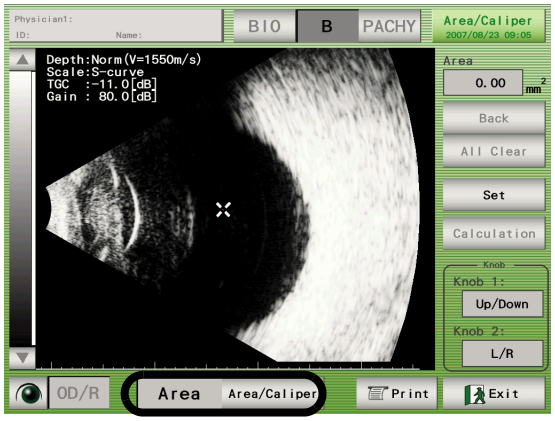
5 Press the Exit switch to return to the B-scan imaging screen.

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

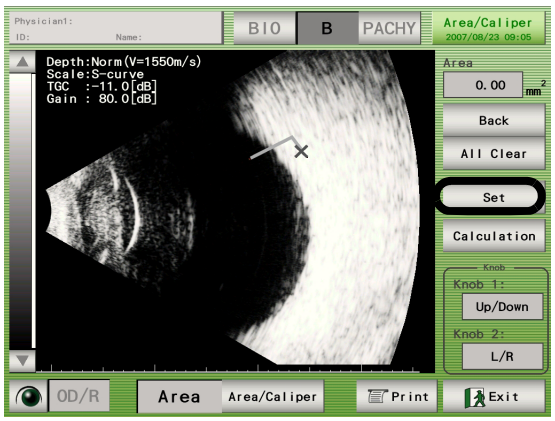
1 Press the Area/Caliper switch in the B-scan imaging screen to display the Area/Caliper screen.



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.

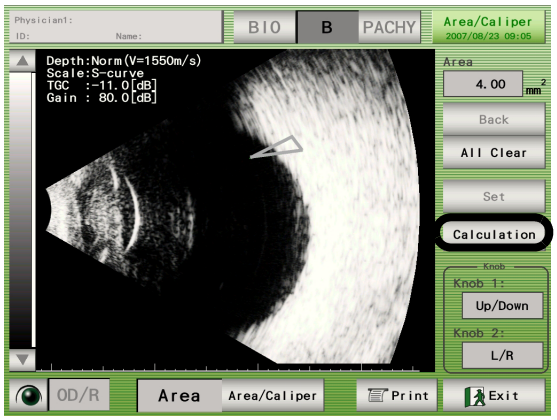


4 Repeat Step 3 to specify the desired range.

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.

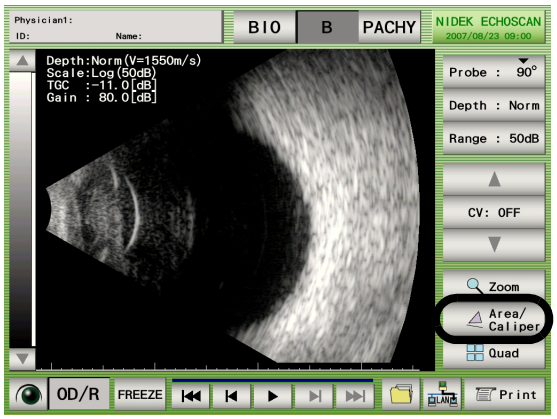


6 Press the Print switch to print the image in the screen.

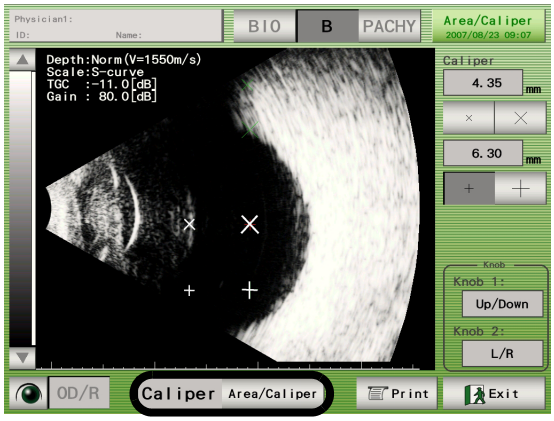
7 Press the Exit switch to return to the B-scan imaging screen.

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

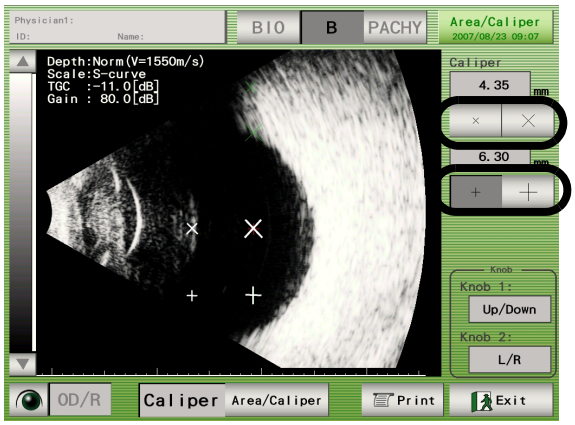
1 Press the Area/Caliper switch in the B-scan imaging screen to display the Area/Caliper screen.



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



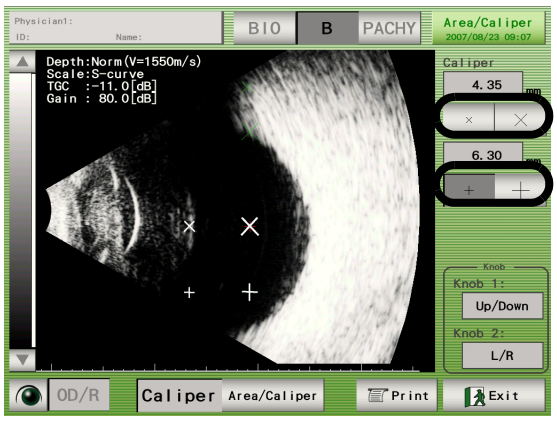
3 Select the desired marker (+, +, X, or x).



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.

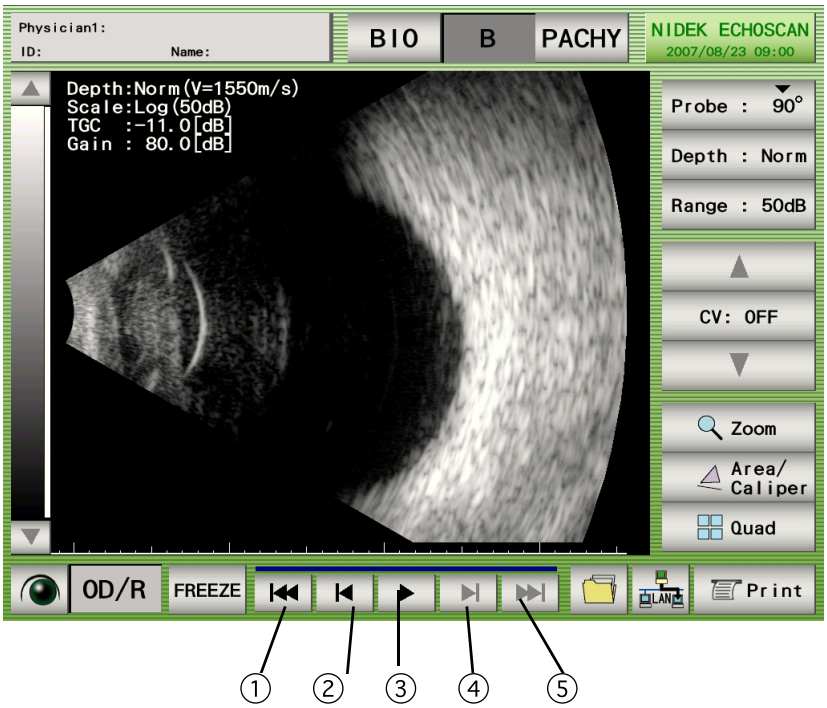


6 Press the Print switch to print the image in the screen.

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 (200 still images) of about 20 seconds' LIVE condition just before the FREEZE switch was pressed.

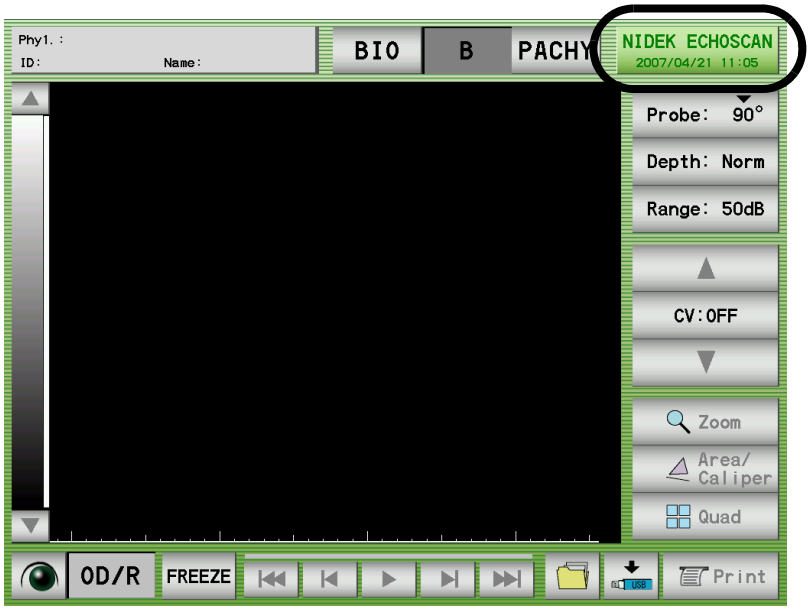
③ Stop switch: The Play switch becomes the Stop switch while the moving image is played.

② ④ Scroll backward and forward switches: 1 image

① ⑤ Skip backward and forward switches: 5-image jumps

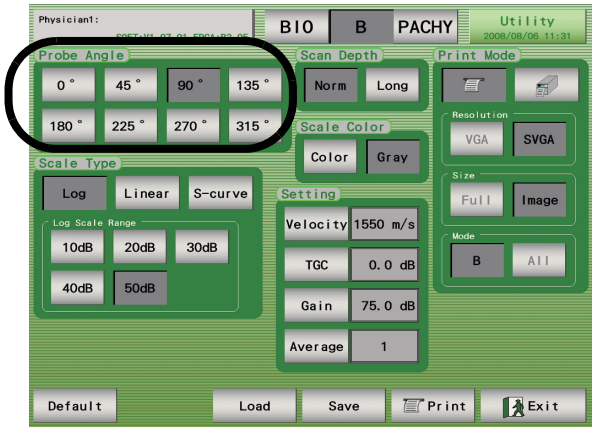
2.5.11 Setting B-scan imaging utility

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 (○).

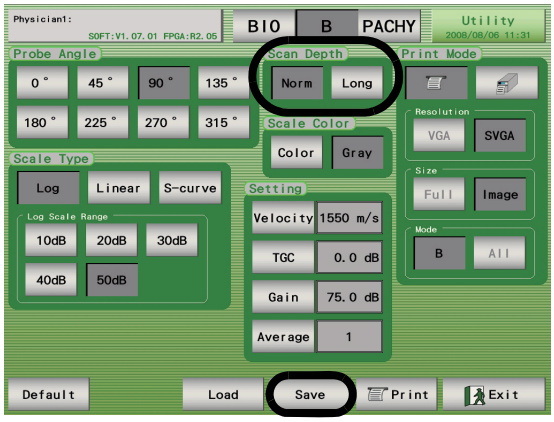
○ Setting scan depth

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

Norm: 35 mm from a distance of 2 mm from the probe tip

Long: 50 mm from a distance of 2 mm from the probe tip

(When Velocity is 1550 m/s)

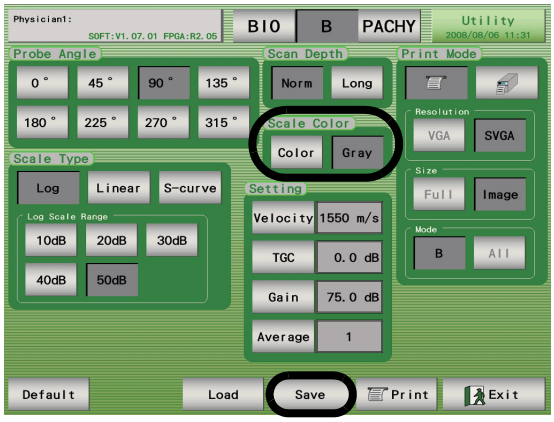


2 Press the Save switch.

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.

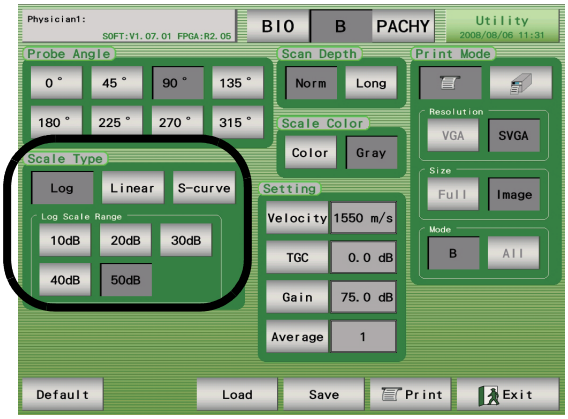
Areas of echo intensity a little higher than the middle intensity are displayed in high contrast.

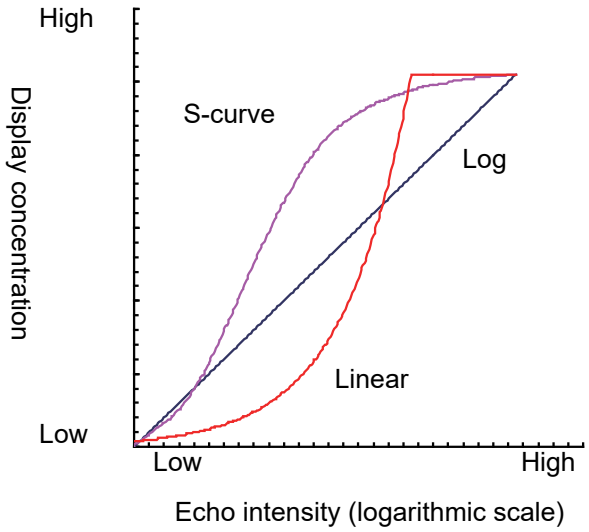
Areas of high echo intensity are displayed in white.

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.



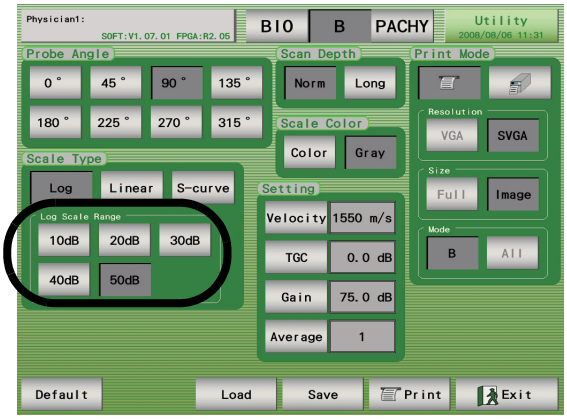


2 Press the Save switch.

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."

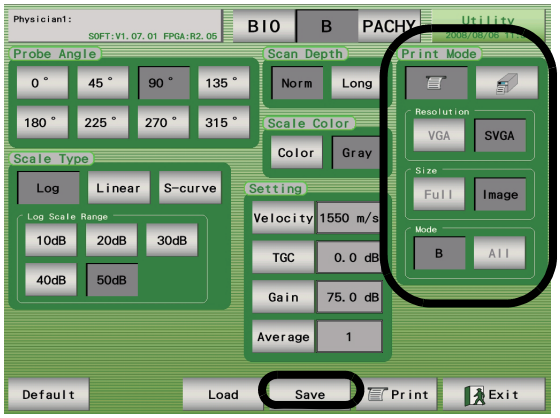


2 Press the Save switch.

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 result between the built-in printer (Int.) and an external printer (Ext.).



2 Select the resolution, size, and mode (printed contents) for the external printer.

This parameters cannot be changed when the built-in printer is selected.

Resolution - VGA: 640 × 480 pixels

SVGA: 800 × 600 pixels

Size - Full screen: Entire screen image in the display

Image: Measurement image in the display

The Size setting applies only to the B-scan imaging result.

Mode - B: Only the B-Scan imaging result is printed.

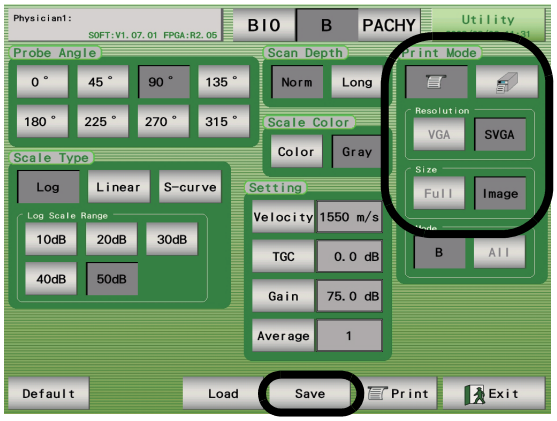
All: Results of all measurement modes (A-scan biometry, B-scan imaging, and pachymetry) are printed.

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.

○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.

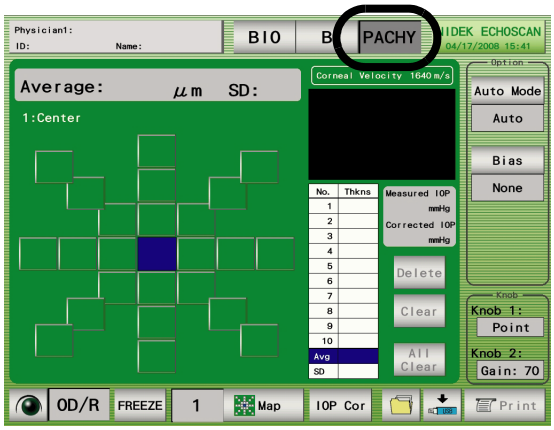
Unless the Save switch is pressed, the settings above at the time of device power-up return to the original once power to the device is turned OFF (○).

2.6 Pachymetry (optional)

The pachymetry probes are optional accessories.

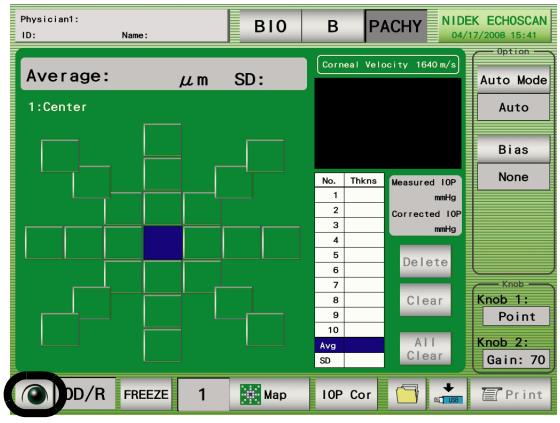
2.6.1 Basic operation of pachymetry

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).

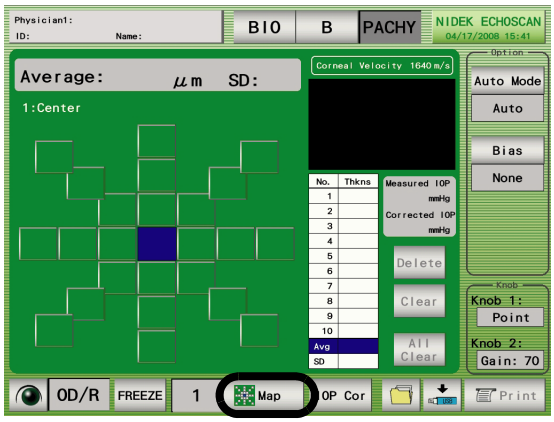


3 Press the Map No. switch to select the desired map.

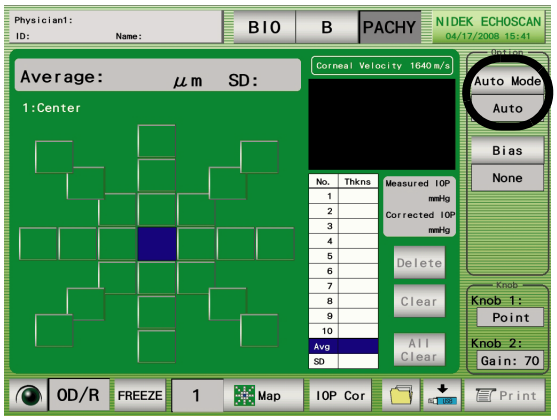
Six types of maps are available. Each map is indicated with a number from “1” to “6” on the left side of the switch.

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.”

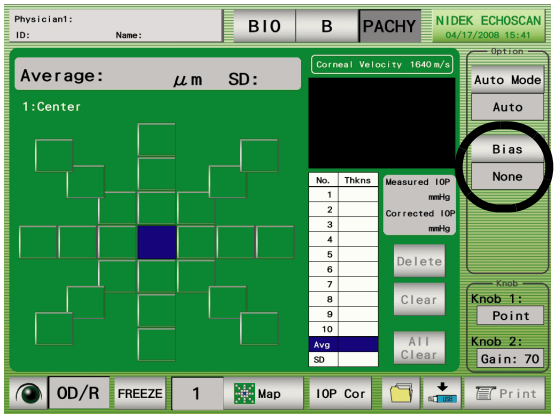


5 Press the Bias switch to set the bias indication and bias amount.

(A) To indicate an unbiased value

Press the Bias switch until “None” is indicated below the switch.

* None: The measurement value is displayed as it is.



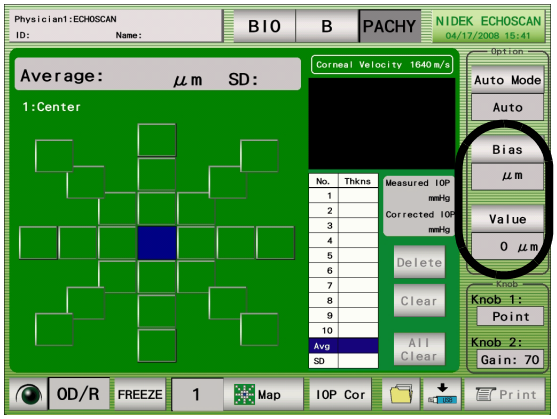
(B) To indicate a biased value

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

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

* 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:

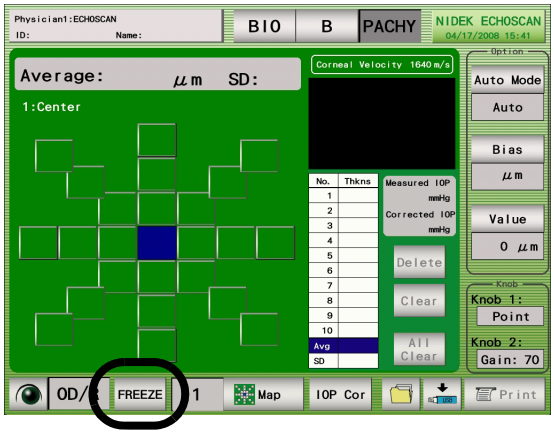
µm : - 999 to 999 µm % : 10 to 200%

Note

- When the bias indication is selected, the average value in each measurement point is calculated after adding the specified amount of bias to each measurement result at the measurement point. Be careful since the average value may differ from the one obtained by adding the bias value to the averaged measurement value.

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.

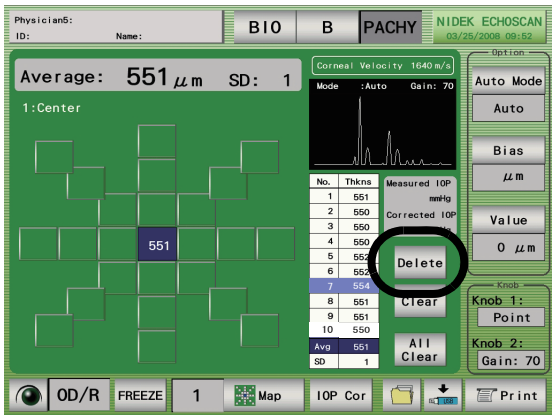
When the Auto-measurements for the set times are finished, a beeping sounds, and the indication on the LIVE switch changes to “FREEZE.”

8 Release the probe tip from the cornea.

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

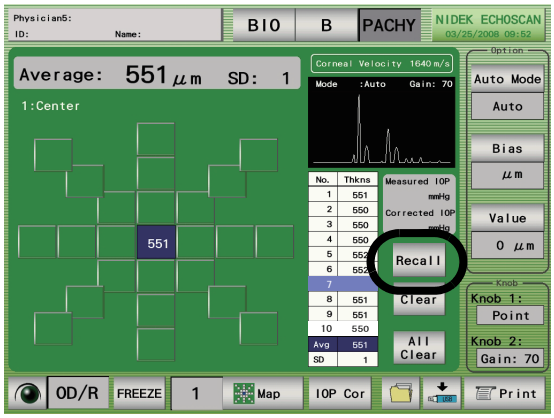
If the dispersions in the measurement data is great compared to other data, manipulate the data with the procedure below.

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.

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



To delete the measurement data of all the selected measurement points in the map, press the Clear switch, then the OK switch on the confirmation window.

(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.)

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

See “○Setting Print switch of foot switch” (Page 99).

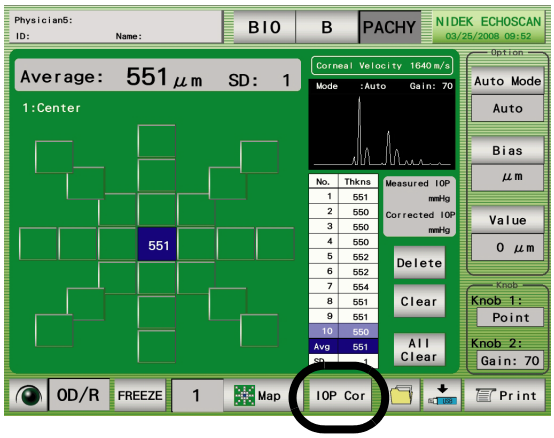
11 Press the Measure switch of the foot switch or the FREEZE switch to start measurement at the new measurement point.

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

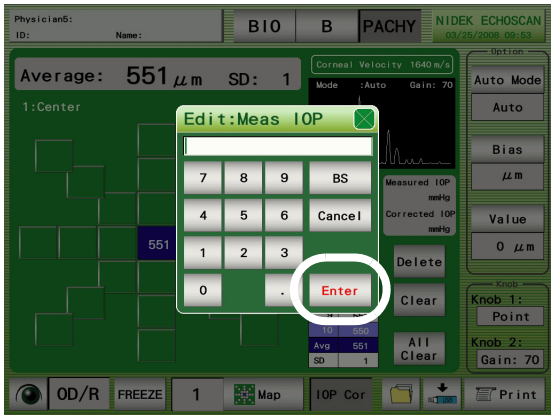
2.6.2 Intraocular pressure correction

The US-4000 can calculate a corrected intraocular pressure by using the measured pachymetry value to correct the intraocular pressure obtained with any other measurement device. When using the intraocular pressure correction function, be sure to set proper correction coefficients for both Param1 and Param2 beforehand. The obtained corrected intraocular pressure is a referential value, and must be used under the responsibility of the user. See “○Setting intraocular pressure correction coefficient” (Page 101).

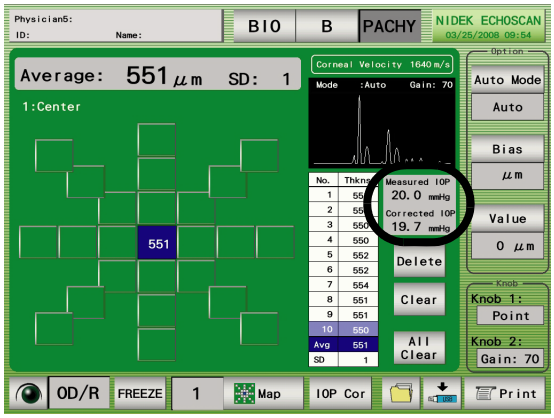
1 Press the IOP Cor switch after pachymetry measurement.



2 The ten-key window is displayed. Input the measured intraocular pressure, and press the Enter switch.



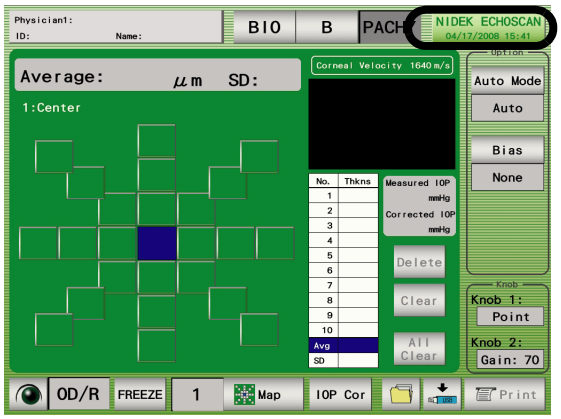
3 The measured intraocular pressure and the corrected intraocular pressure calculated with the Intraocular pressure correction function are displayed.



* Not only the Pachymetry value of the central measurement point, but the intraocular pressure correction function can be used for the pachymetry values at any measurement point.

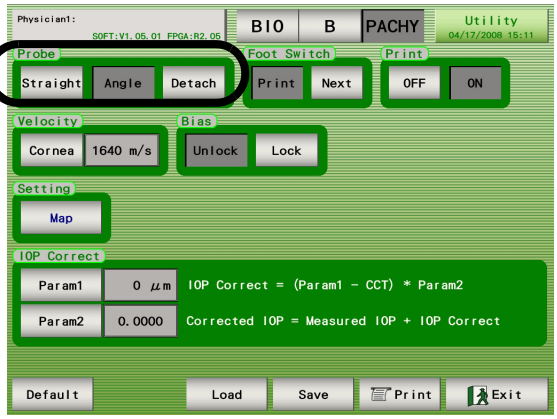
2.6.3 Setting pachymetry utility

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.

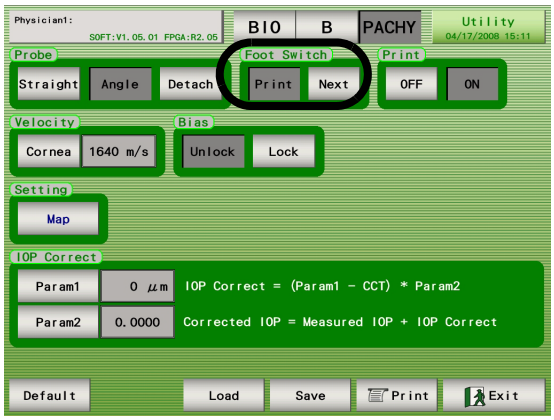


2 Press the Save switch.

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 switch between “Print (printing)” and “Next (moving to the next measurement point).”

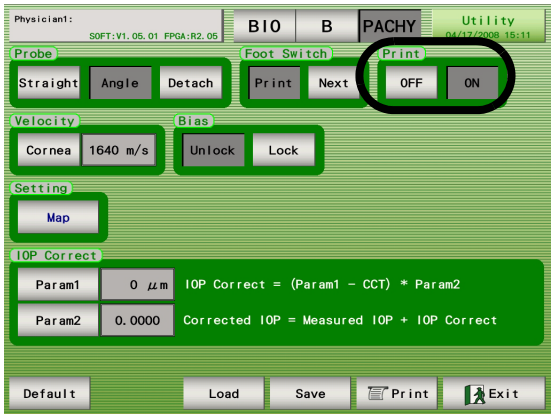


2 Press the Save switch.

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.”

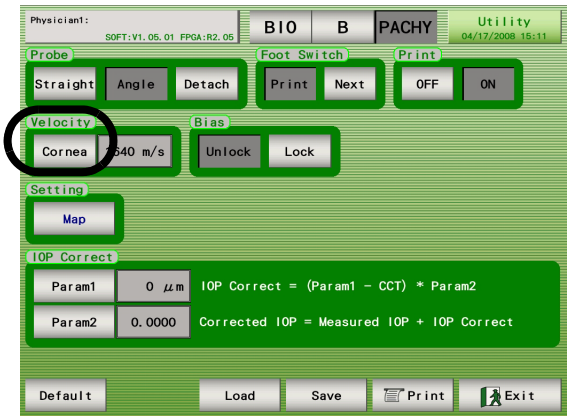


2 Press the Save switch.

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 When the ten-key window appears, input the sonic velocity to calculate distance and press the Enter switch.

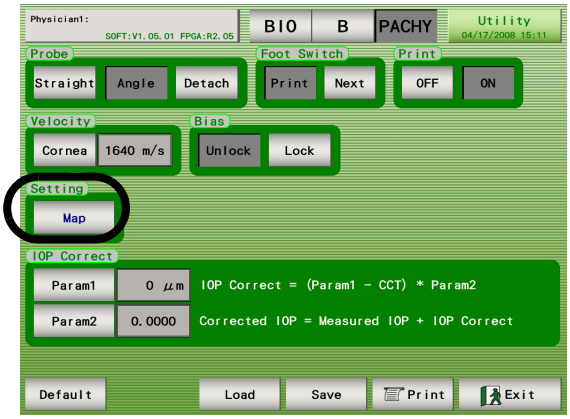
Default value - 1640 m/s Input range - 1000 to 2000 m/s

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 (◯).

○ Setting intraocular pressure correction coefficient

Note

- Be sure to input the correction coefficients for both Param1 and Param2.
  If not, Error No.32 is displayed even when the IOP Cor switch is pressed, and the intraocular pressure correction value becomes ineffective.

1 Press the Param1 switch.*1

Input the desired coefficient value.

Input range for Param1 - 0 to 1500μm

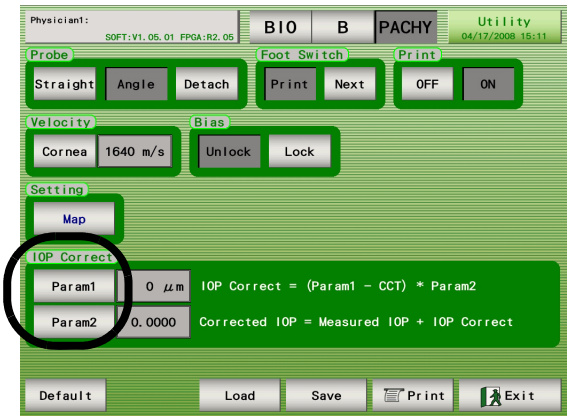
2 Press the Param2 switch.

Input the desired coefficient value.

Input range for Param2 - 0 to 1.0000

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 (◯).



○ Intraocular pressure correction formula

The device provides the formulas below for correcting intraocular pressure (IOP).
For the coefficients used for the formulas, refer to the literature for this subject matter.
The obtained values can be used as reference values.

Corrected IOP value = Measured IOP value + IOP correction value
IOP correction value = (Param1 − Pachymetry value) × Param2

Measured IOP value: IOP value measured using a tonometer

Pachymetry value: Pachymetry value measured using this device (μm)

Param1: Reference pachymetry value (μm)

Param2: Correction amount adjustment coefficient

*1. “CCT” in the formula indicates the corneal pachymetry value at the selected measurement point in the map.

2.7 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 36).

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

3 After cleaning and disinfecting the used probes, store them in a clean place.

See “5.6 Cleaning/Disinfecting Ultrasound Probe” (Page 141).

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

Clean them referring to “5.5 Cleaning” (Page 139).

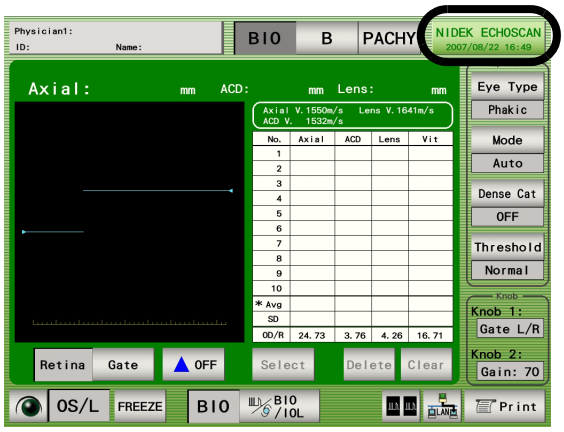
5 Put the dust cover on the device to keep dust out.

The operation of the device is complete.

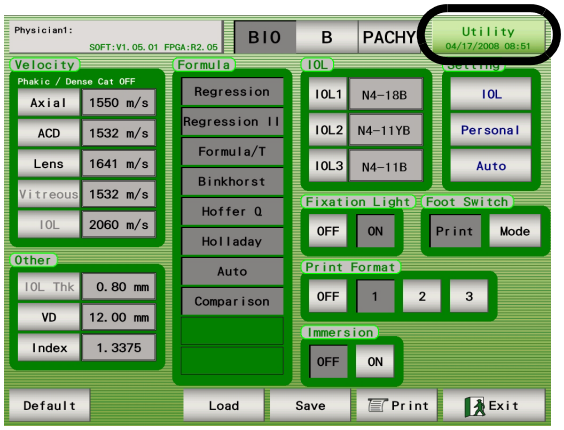
2.8 Utility

2.8.1 Displaying Utility screen

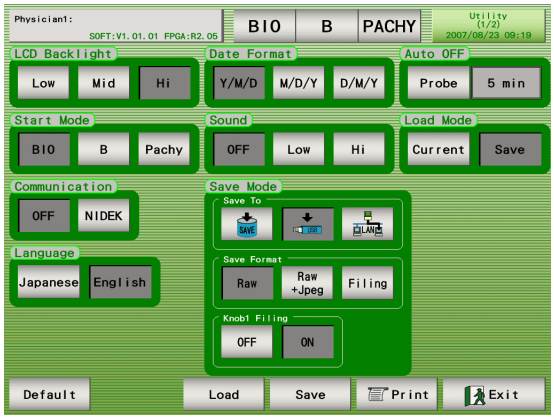
1 Press the switch that indicates the date and time in each measurement screen.



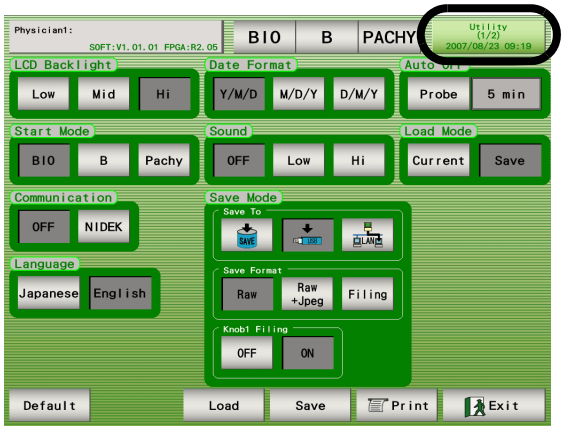
2 Press the Utility switch.



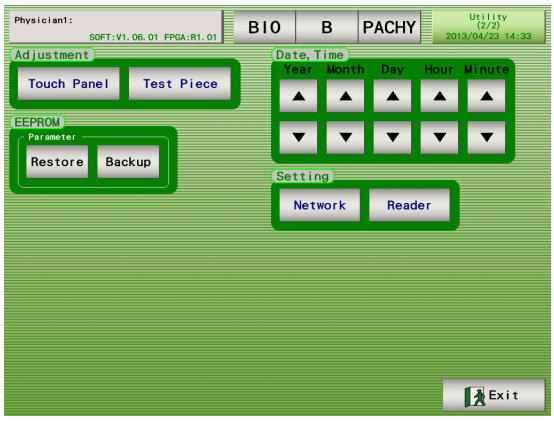
3 Change the settings in the Utility (1/2) screen.



4 Press the Utility switch.



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

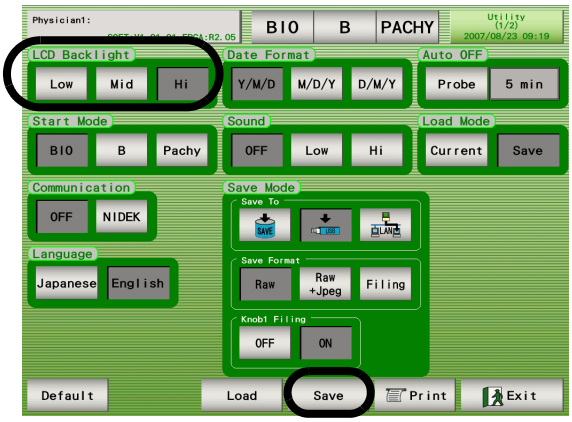


6 Press the Exit switch to return to the measurement screen.

2.8.2 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.”

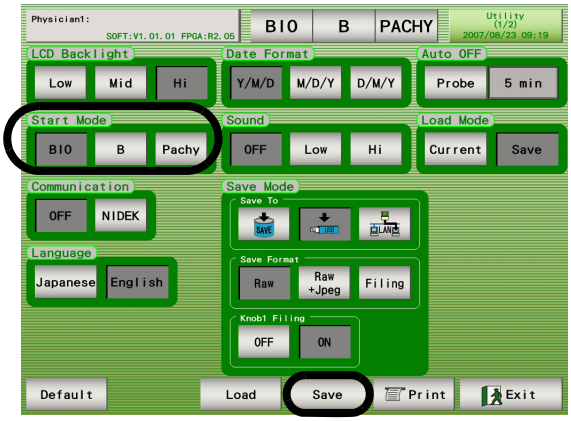


2 Press the Save switch.

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.”



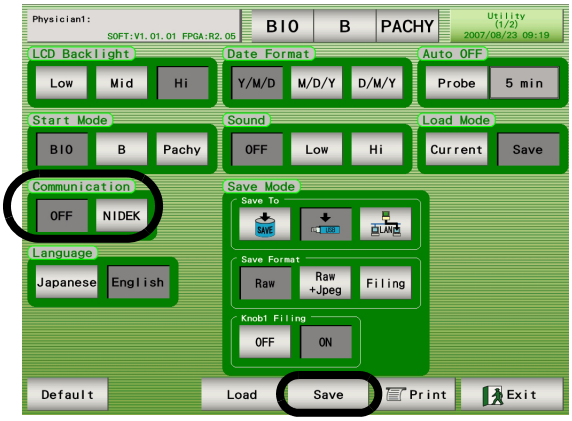
2 Press the Save switch.

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 between “OFF” and “NIDEK.” The default setting is “OFF.”



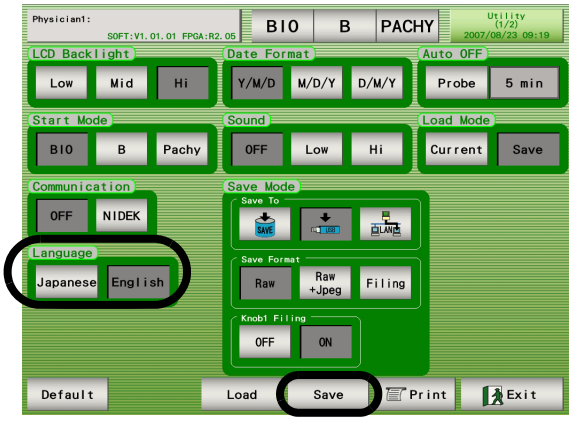
2 Press the Save switch.

In the A-Scan biometry, IOL power calculation, and Pachymetry (optional) screen, the Print button at the bottom right of the screen changes to the button for transmitting measurement data.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned OFF (○).

○ Setting Language

1 Select English or Japanese.

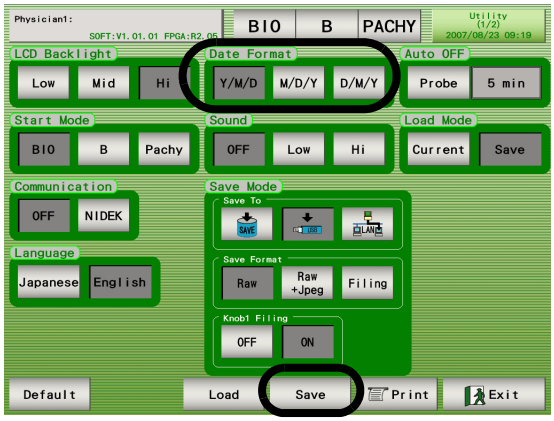


2 Press the Save switch.

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.

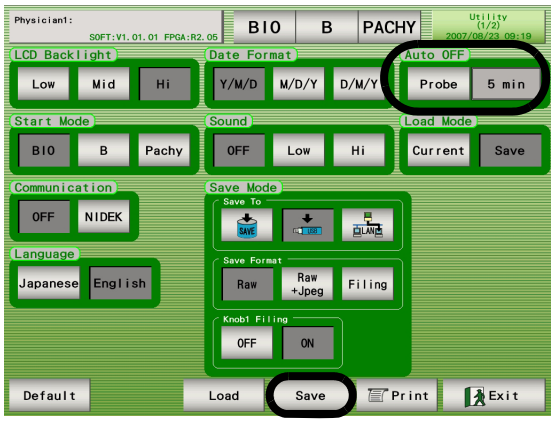
If the Save switch is not pressed, the setting is reset to the original once power to the device is turned OFF (◯).

Battery recharging:

The battery is rechargeable. When the device is operated for the first time after unpacking or when the device has not been operated for a long time (approximately one month or longer), the battery is discharged, and the internal clock may go wrong. In such a case, turn on the device and leave it on to recharge the battery. The battery needs 24hours for a full charge. If the device is used for 8 hours a day, the device will have to be kept on for three days before the battery is fully recharged. Once the battery is fully recharged, the device operates normally for daily use. (The battery cannot be replaced by users.)

○ Setting Auto OFF

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



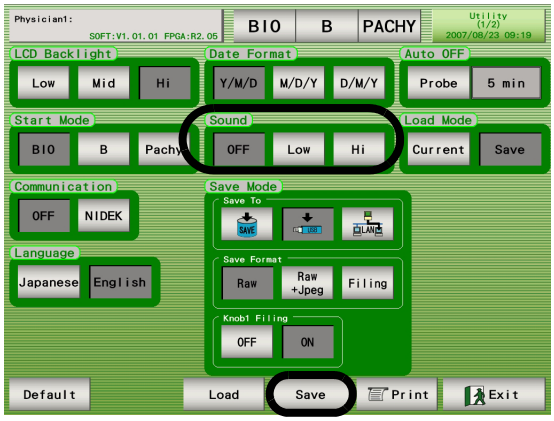
2 Press the Save switch.

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.

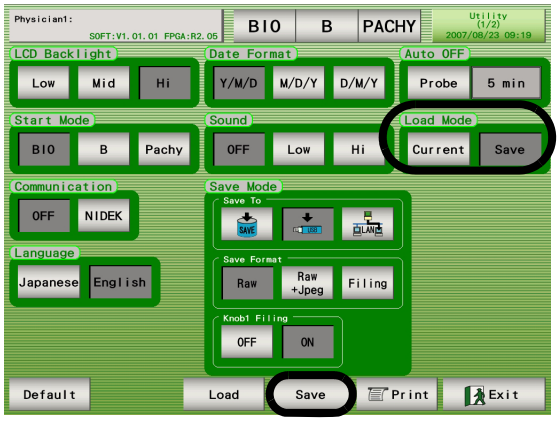
If the Save switch is not pressed, the setting is reset to the original once power to the device is turned OFF (◯).

○ Setting Load Mode

1 Select Current or Save.

Current: Displays the data according to the setting of the current device setting.

Save: Displays the data according to the setting of the device of when the data was saved.

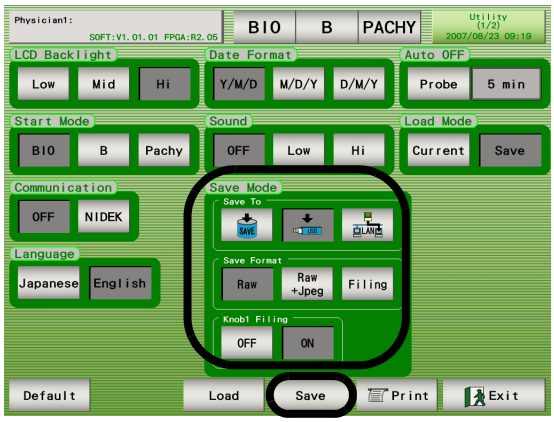


2 Press the Save switch.

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 Select the location to save the data among the internal memory, USB flash drive, or LAN.



Internal memory

USB flash drive

LAN (PC)

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 (◯).

3 If “USB” or “LAN” is selected, select the Save Format.

Raw: Raw data + XML data

Raw + Jpeg: Raw data + Jpeg data (Full screen image) + XML data

Filing: Jpeg data (only waveform image) + XML data

4 Select ON or OFF for Knob 1 Filing.

ON: When the location to save data is set to a USB flash drive or LAN-connected device, pressing the Knob 1 creates a folder named “US4X¥F_JPG” and a Jpeg file of the screen image is saved in the folder.

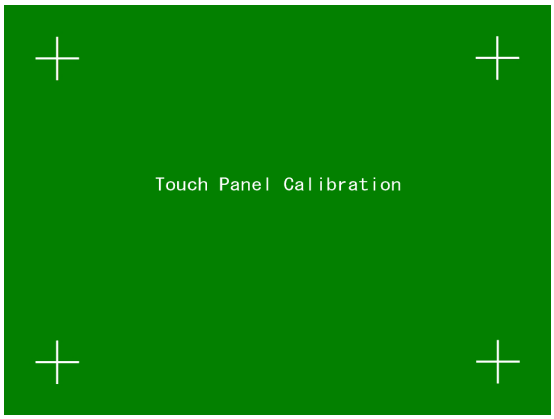
5 Press the Save switch.

If the Save switch is not pressed, the setting is reset to the original once power to the device is turned OFF (◯).

2.8.3 Setting Utility (2/2)

○ Adjusting touch screen

1 Press the Touch Panel switch in the Utility (2/2) screen to display the screen shown below. Press the centers of the four red crosses with the stylus.



Note

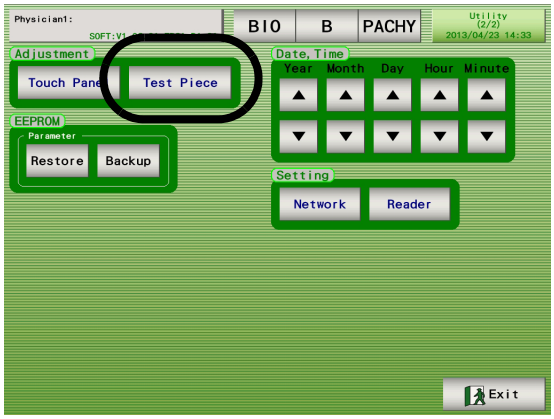
- If any place other than the center of the red cross is touched with the stylus and the position of the screen is adjusted improperly, turn ON (|) power to the device while pressing Knob 2.

  The touch screen can be adjusted again.

○ Measurement of test piece

1 Press the Test Piece switch.

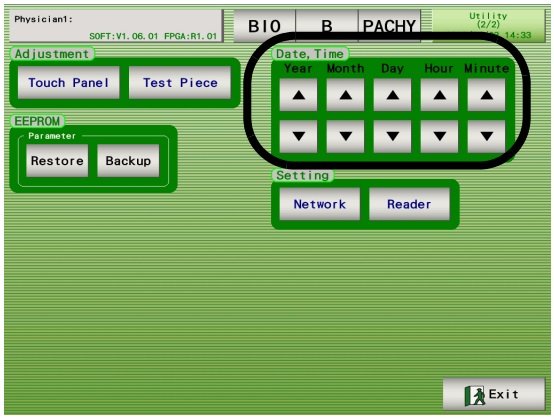
The function of this switch is the same as that of the Test Piece switch displayed at the start-up of the device. Measure the test piece referring to “4.2 Usage of the Test Piece” (Page 126).



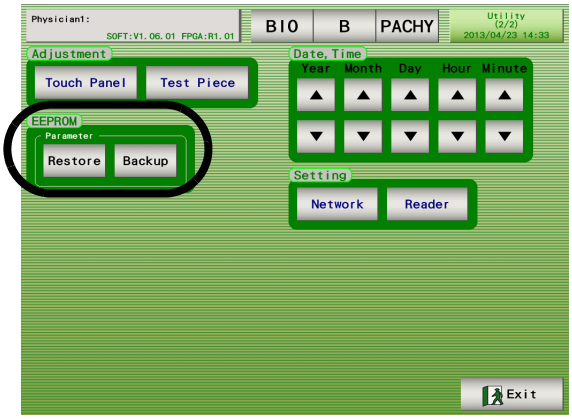
○ Setting date and time

1 Set the date and time with the arrow mark switches. The setting is reflected in the date and time display at the top right of the screen.

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



○ Handling EEPROM parameters



Loading backup of various settings (from USB flash drive)

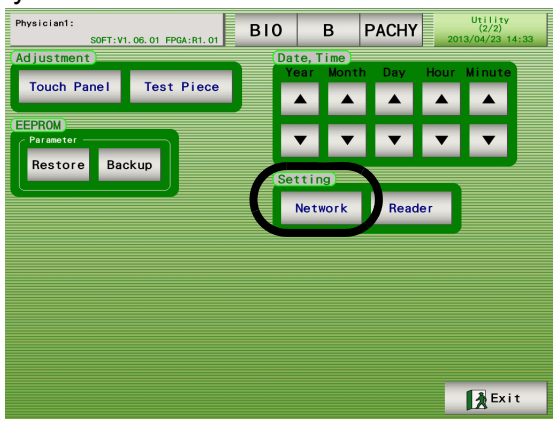
1) Connect the USB flash drive that contains the backup data to the USB port of the device.
2) Press the Restore switch.

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.

○ Setting network

1 Press the Network switch to display the Utility network screen.



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

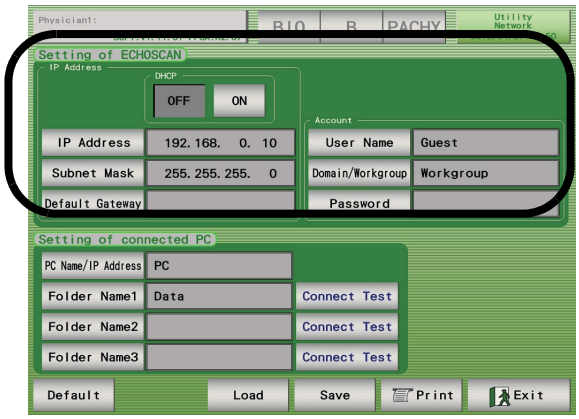
1. Can DHCP be set to ON? (ON when the DHCP server is active.)
2. IP address

   IP Address, Subnet Mask, Default Gateway
3. Account

   User Name, Domain/Workgroup, Pass word, Domain

3 Input the information obtained from the network administrator.

Press the desired switch to input data with the keyboard window.



IP Address:

When DHCP is set to ON, it is not necessary to set this. (Configuration information is automatically obtained from the DHCP server. When automatic setting fails, “0. 0. 0. 0” is displayed.)

Subnet Mask:

When DHCP is set to ON, it is not necessary to set this. (Configuration information is automatically obtained from the DHCP server. When automatic setting fails, “0. 0. 0. 0” is displayed.)

Default Gateway:

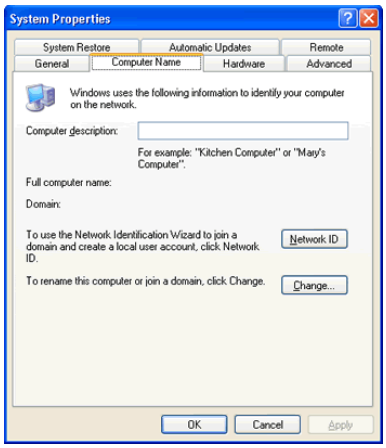
When DHCP is set to ON, it is not necessary to set this. (Configuration information is automatically obtained from the DHCP server. When automatic setting fails, the field is left blank.)

When data is input to a location within the network the device belongs to, the setting is not required.

The field is left blank as the default setting.

4 Confirm the computer name and domain in the System Properties window on the PC.

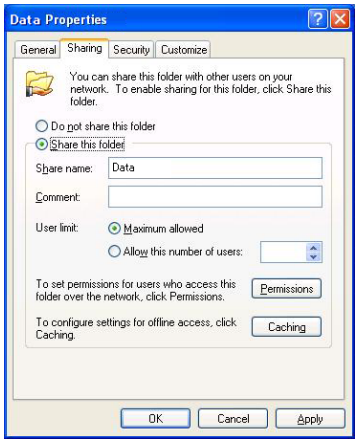
(Ask the network administrator for detailed procedure.)



5 Create a folder for saving data on the PC.

A maximum of three folders can be created.

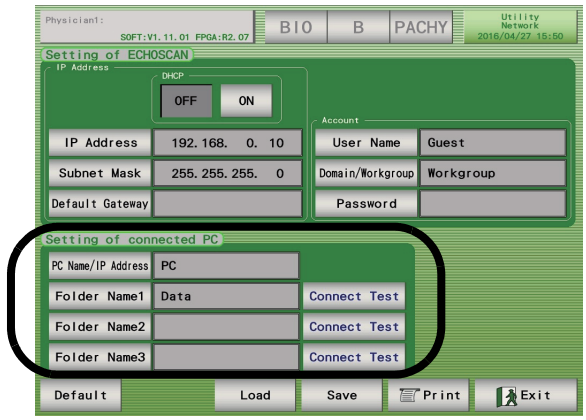
6 Select “Share this folder” under the Sharing tab in the Properties window of the created folder. Press the Permissions switch and set the access permission. Then press the OK switch.



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

Press the switch to input data with the keyboard window.

Blank boxes indicate no input (no setting).



PC Name/ IP Address:

Enter the computer name. (Instead of the computer name, the IP address of the computer can be entered.)

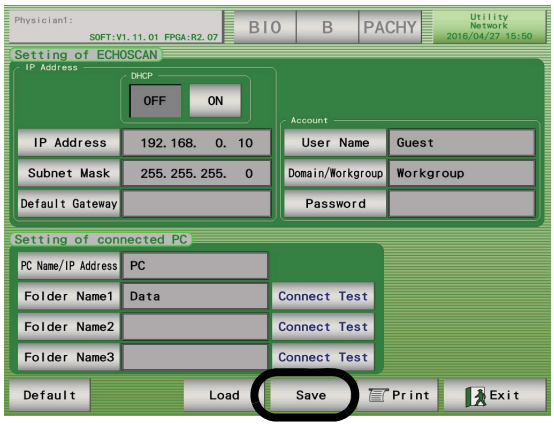
When data is output to a location outside of the network the device belongs to, enter the default gateway as well as the IP address of the computer at the specified location.

Note

- Identical folder names are not allowed.
  Specify different names for the folders.
- Set the folders in the order of 1, 2, and 3.
  To set only one folder, select Folder 1.

8 Press the Connect Test switch to check the operation.

9 Press the Save switch.

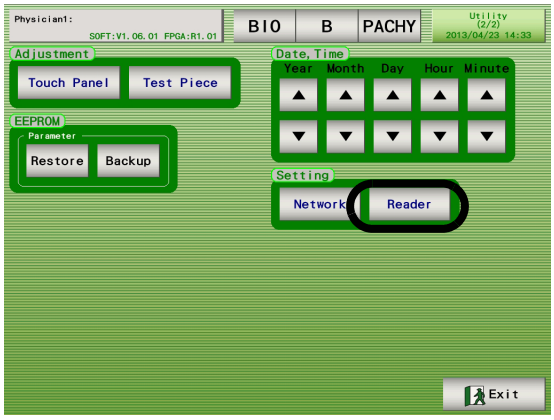


Note

- If a change is made to the DHCP, IP address, subnet mask or default gateway, and saved with the Save switch, the message “After Save, Restart ECHOSCAN.” appears. Close the message window and restart the system accordingly.

○ Setting barcode reader

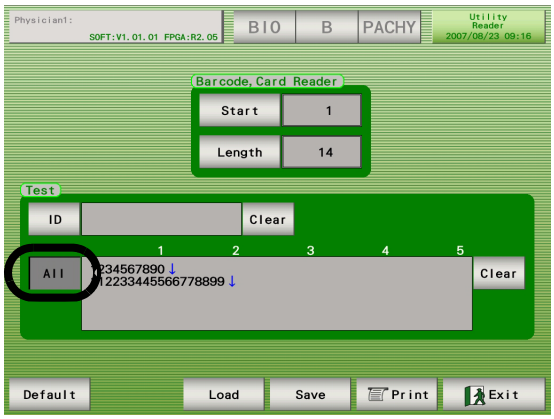
1 Press the Reader switch.



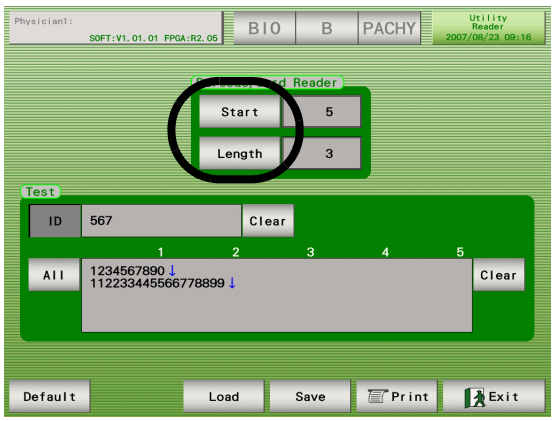
2 Connect the barcode reader to the USB port of the device.

3 Press the All switch to read the data using the reader.

For the usage of the reader, see its user's manual of the reader.

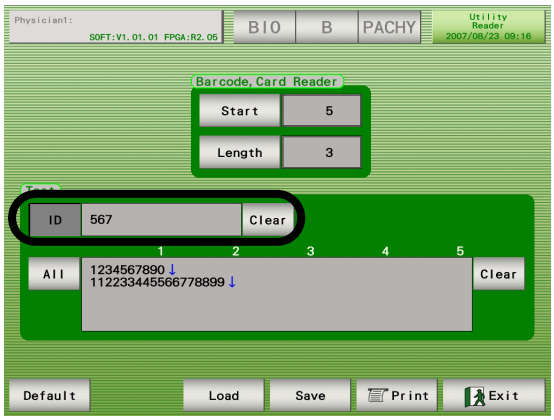


4 Input the start position and length for reading the ID data.



5 Press the ID switch to read the data. Confirm that the correct ID is displayed at this time.

Readable characters are as follows: numerical characters, upper-case and lower-case alphabetical characters, space, and hyphen.



6 Press the Save switch.

3. OPERATION FOR 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.
- **Accessory equipment connected to the analog and digital interfaces must be certified according to the representative appropriate national standards (for example, UL 1950 for Data Processing Equipment, UL 60601-1 for Medical Equipment, and CSA C22.2 No. 601-1, EN 60601-1, and IEC 60601-1.) Furthermore, all configurations shall comply with the system standard IEC 60601-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department or your local representative.**

Note
- The measurement data transferred to an external device such as a PC does not include waveform information.

3.1 Connecting to Keratometer

3.1.1 Outline

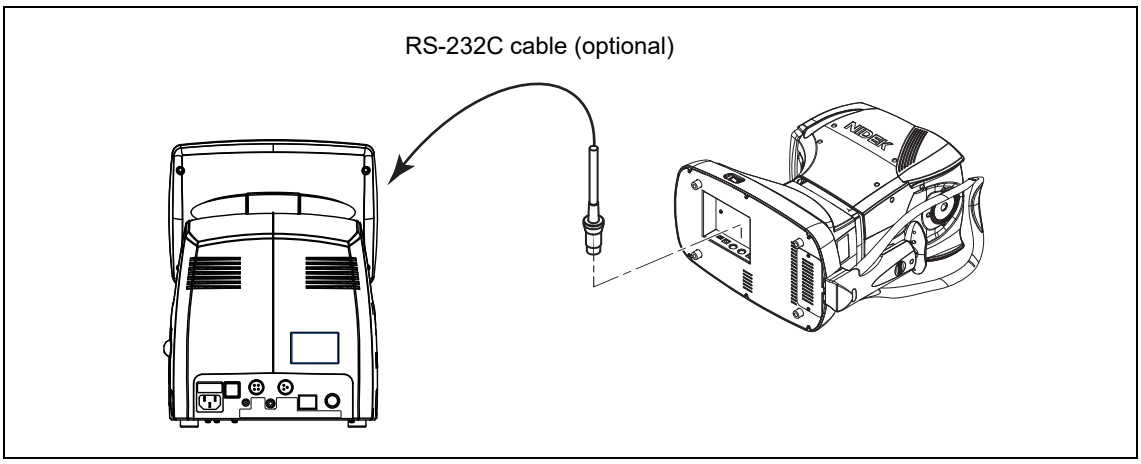
The US-4000 can be connected to devices such as the Auto Ref/Keratometer (ARK-530 series and ARK-700 series), Keratometer (KM-500, etc.), Handy Auto Ref/Keratometer (ARK-30, etc.), OPD-SCAN (ARK-10000, etc.), and Auto Ref/Kerato/Tonometer (RKT-7700, etc.).

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.



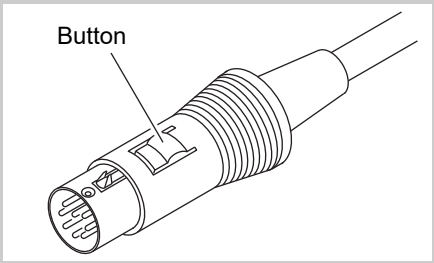
3.1.3 Operating procedure

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.

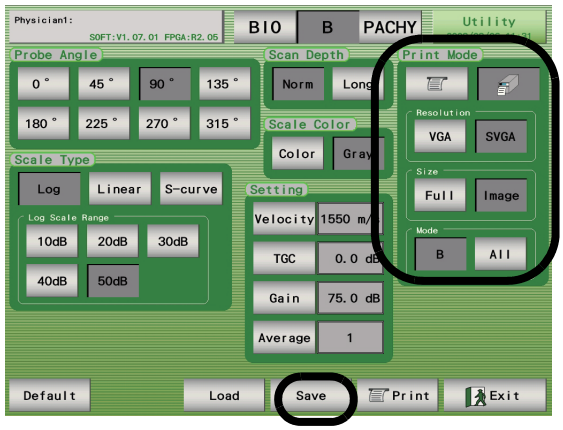
  When the cable is connected, the button is located on the underside of the connector.



3.2 Connecting to Video Printer

The Video printer is used to print B-scan images. When printing screen images other than B-scan images (except during measurement), video signals of a VGA size are always output (to update the image every second).
Use a video printer that complies with IEC60601-1.

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



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

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

This parameter setting is effective only for the B-scan imaging.

4 Select the mode (B (printing of only B-scan imaging result)/All (printing results of all measurement modes)).

5 Press the Save switch to save the setting.

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

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

8 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

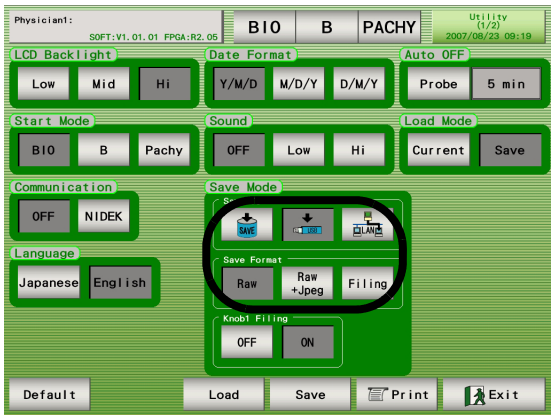
3.3.1 Connecting USB flash drive

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.

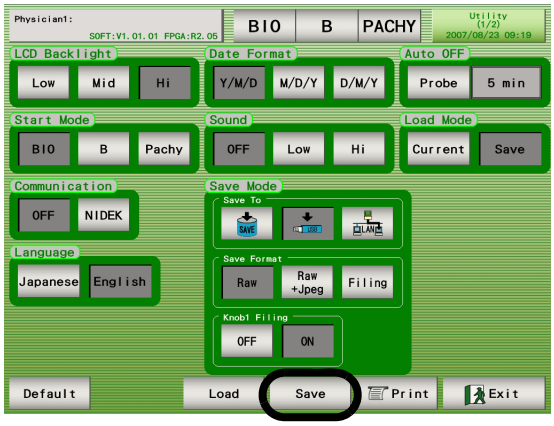
Recommended USB flash drives:

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 Set the USB flash drive for the “Save To” setting in the Utility (1/2) screen, and select the desired Save Format.



2 Press the Save switch in the Utility (1/2) screen.

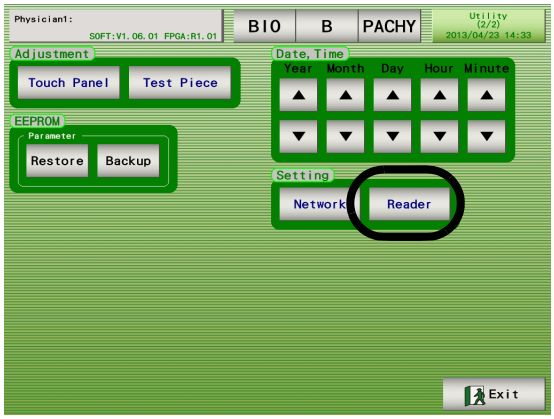


⚠ **CAUTION**

- **Do not remove the USB flash drive from the US-4000 during data transfer.**
- **Remove the USB flash drive prior to turning (|) power to the US-4000.**

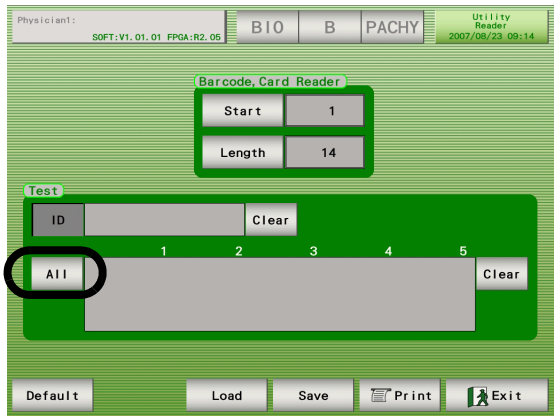
3.3.2 Connecting barcode reader

1 Press the Reader switch in the Utility (2/2) screen.



2 Connect the barcode reader to the USB port of the device.

3 Press the All switch in the Reader screen.



4 Confirm the start position and length for reading the ID data of all the data displayed in the screen.

5 Then input the start position and length for reading the ID data in the Start and Length boxes.

Readable characters are as follows: numerical characters, upper-case and lower-case alphabetical characters, space, and hyphen.

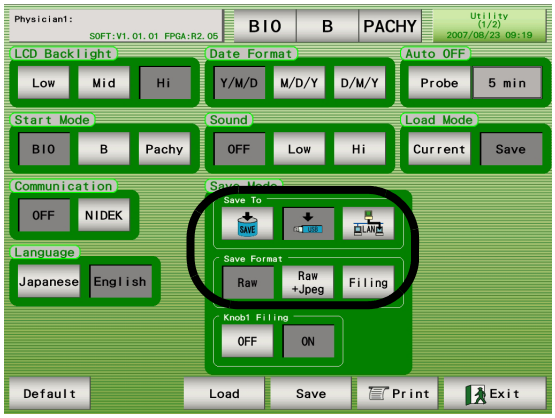
6 Press the ID switch to confirm that the ID can be recognized.

7 Press the Save switch.

3.4 Connecting to LAN Port

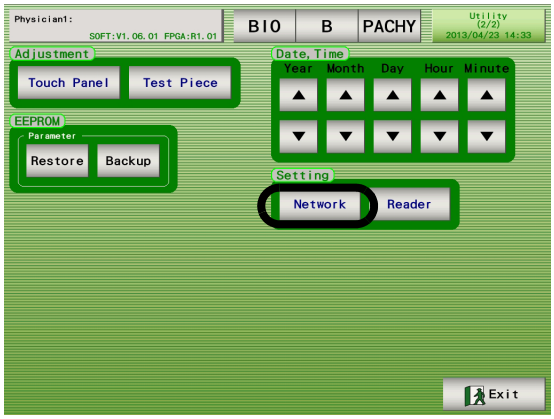
Connect the device to the network with permission from the network administrator of the facility.
For details of the setting, see “Setting network” (Page 112).

1 In the Utility (1/2) screen, set “Save To” to LAN, and select the desired Save Format.



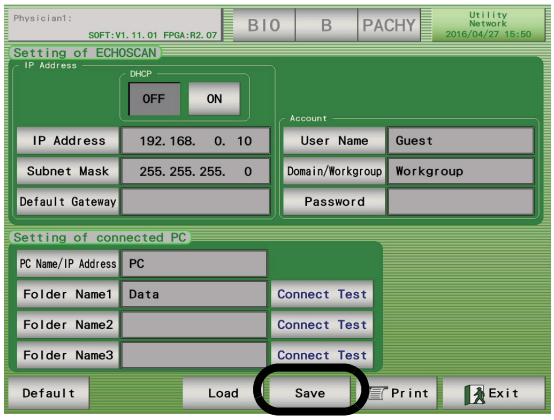
2 Press the Save switch.

3 Press the Network switch in the Utility (2/2) screen to display the Network Utility screen.



4 Input necessary information according to “○Setting network (page 112)”.

5 Press the Save switch to save the settings.



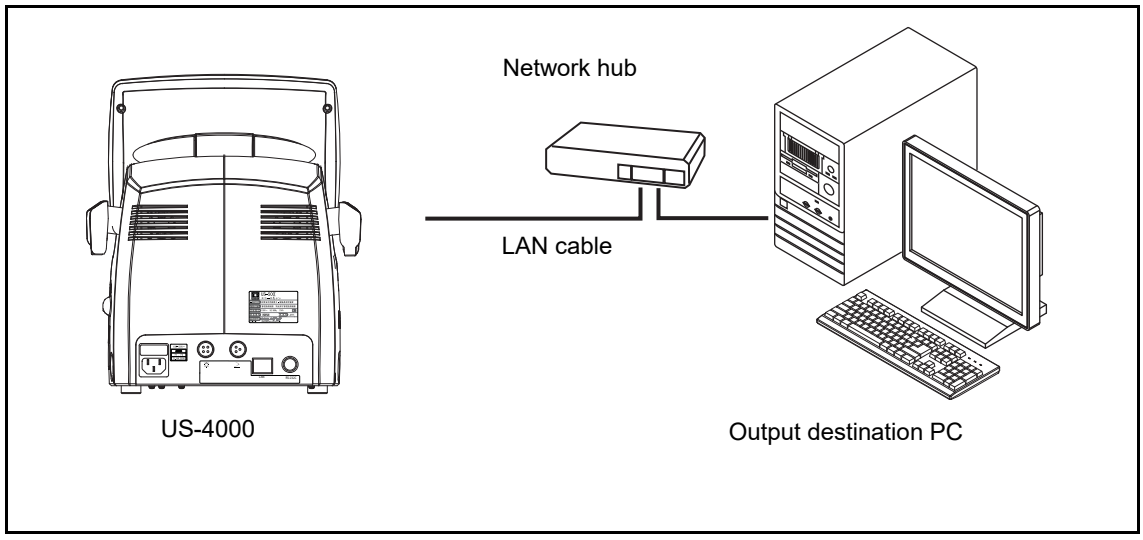
6 Turn OFF (○) power to the device.

7 Connect a LAN cable to the device.

Connect the LAN cable to the LAN port on the side panel.

Connect the other end of the LAN cable to the hub connected to the output destination PC.

⚠ CAUTION • **Be sure to connect the device to the PC through a network hub.**
Do not connect to the PC directly. A connection failure may occur.



8 Turn ON (|) power to the device.

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 “4.3 Check List” (Page 130).

(1)Appearance

Check the appearance of the device for damage and/or stains that 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 with the Start Mode setting 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

Check in the measurement screen exclusively for test piece for A-scan biometry.

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 (optional)” (Page 126).)

(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

Check in the measurement screen exclusively for test piece for pachymetry.

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 (optional)” (Page 128).)

(8)Printer operation

Press the Print switch for printing. Confirm that there are no misaligned 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 130).

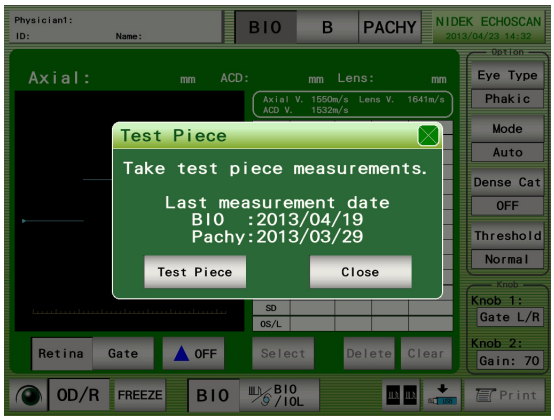
Note

- The measurement value for when the temperature of the test piece (A-scan biometry / pachymetry) is at 20ºC (68ºF) is indicated on the test piece. The sonic velocity of the test piece changes depending on the test piece temperature.

  When the test piece is at a high temperature, the sonic velocity is increased, and when it is at a low temperature, the sonic velocity is decreased.

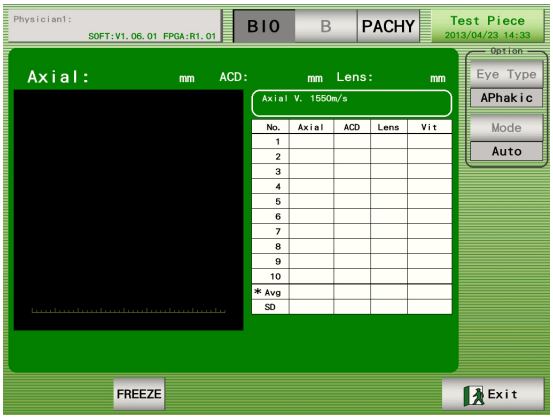
4.2.1 Usage of test piece for A-scan biometry (optional)

1 Press the Test Piece button.



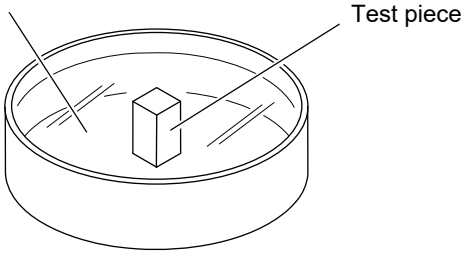
The screen for test piece for A-scan biometry is displayed.

The settings for average sonic velocity or such are converted into the values for test piece measurement.



2 Place the test piece on a dish (such as a petri dish) and pour 20ºC water into the dish until the entire test piece is under the water.

20ºC water



3 Leave the test piece under water for about 5 minutes so that it is completely soaked.

Maintain the temperature of the test piece at 20ºC.

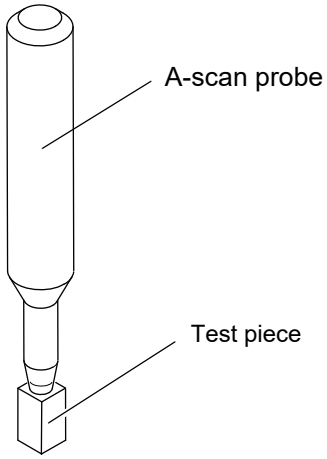
4 Remove the test piece from the water and wipe it dry.

After that, place the test piece on the table.

5 Wet the tip of the A-scan probe by dipping it into the dish (or petri dish) used to soak the test piece.

6 Hold the A-scan probe vertical to the test piece as shown to the right.

For proper measurement, make sure that the contact surface between the A-scan probe and the test piece is damp and that the contact surface between the test piece and the table is dry.



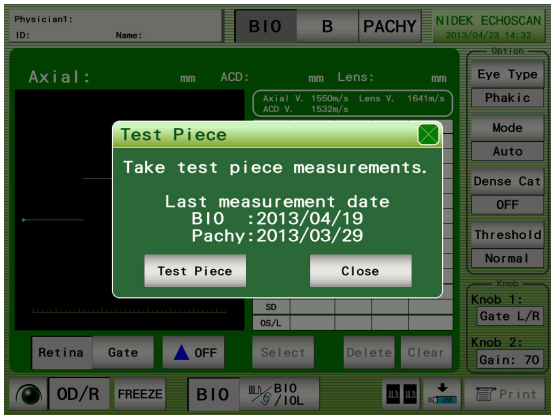
7 Press the FREEZE switch on the screen or the MEASURE switch of the foot switch to start the measurement.

The measurement value and A-scan waveform are indicated.

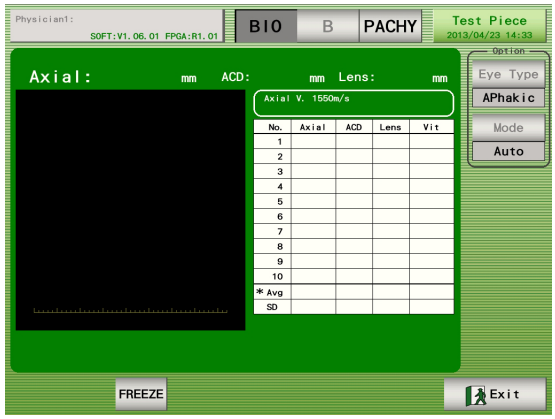
8 Confirm that the measured value is within the range indicated on the test piece.

4.2.2 Usage of test piece for pachymetry (optional)

1 Press the Test Piece switch.



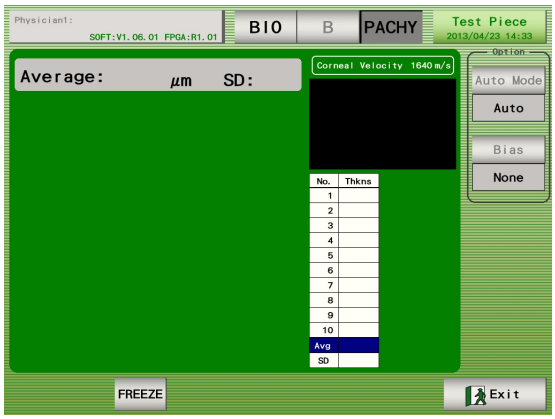
The screen for test piece for A-scan biometry is displayed.



2 Press the Pachy switch.

The screen for test piece for pachymetry is displayed.

The settings for sonic velocity for cornea or such are converted into the values for test piece measurement.

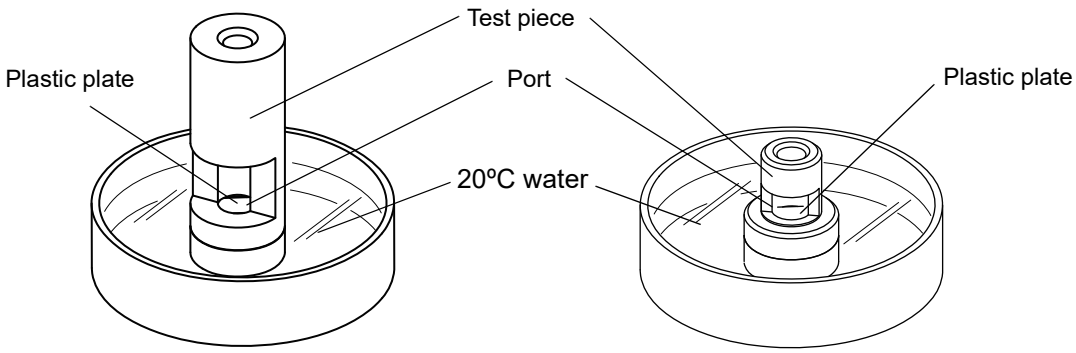


3 Prepare the test piece.

1) Place the test piece on a dish (such as petri dish) and pour 20ºC water into the dish until the plastic plate of the test piece is under the water.

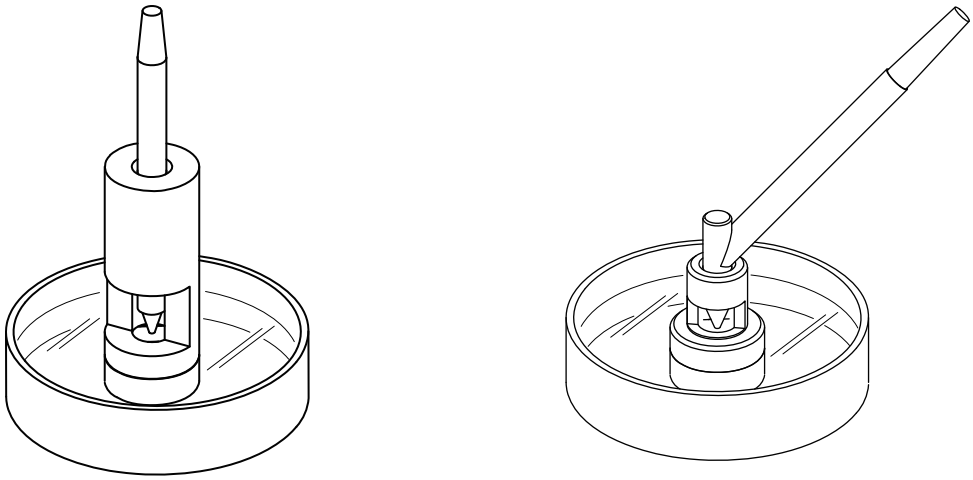
2) Pour water into the port using an injector or the equivalent until the dish of the lower part of the test piece is filled with water.

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



For straight probe　　For 45° probe

4 Insert the pachymetry probe into the test piece so that the tip of the probe vertically comes into contact with the plastic plate inside the test piece.



For straight probe　　For 45° probe

5 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?

6 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 125) on the list below.

Date	Check items							
	Appearance	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.
At the time of pachymetry measurement, the measurement values are displayed without the probe tip in contact with the cornea or the test piece.	• Some liquid may be on the tip of the pachymetry probe tip. Wipe any liquid away from the tip of the pachymetry probe.

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 turned 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, turn OFF (○) power to 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, turn OFF (○) power to 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, turn OFF (○) power to 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, turn OFF (○) power to 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, turn OFF (○) power to 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, turn OFF (○) power to 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, turn OFF (○) power to the device and contact NIDEK or your authorized distributor.
No.032 There are no Parameter.	Input the intraocular pressure correction coefficients. Input proper values for Param1 and Param2.
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, turn OFF (○) power to the device and contact NIDEK or your authorized distributor.
No.065 Com Time Up Error	No response is received during the communication. 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, turn OFF (○) power to the device and contact NIDEK or your authorized distributor.

Message number	Cause and suggested action
No.100 Printer Error.	Printer error (Failure of the printer) If the same error code is displayed, turn OFF (○) power to the device and contact NIDEK or your authorized distributor.
No.101 Initialize Error.	Printer initialization error (Failure of the printer) If the same error code is displayed, turn OFF (○) power to 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, turn OFF (○) power to 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, turn OFF (○) power to 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, turn OFF (○) power to the device and contact NIDEK or your authorized distributor.
No.141 Hardware Error.	Printer connection error (Printer connection error or failure) Confirm that the printer cover is closed securely. If the same error code is displayed, turn OFF (○) power to 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.200 USB Device Error.	The USB flash drive is failed. If replacing the USB flash drive does not solve the error, turn OFF (○) power to the device and contact NIDEK or your authorized distributor.
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, turn OFF (○) power to 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-protected or full. Disable the write protection or check the free space of the USB flash drive.

Message number	Cause and suggested action
No.252 There is no Raw Data File.	USB flash drive There is no raw data file. Raw data files are deleted.
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.
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, turn OFF (○) power to the device and contact NIDEK or your authorized distributor.
No.304 DHCP Error.	The IP address cannot be obtained.
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 PC.	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.	Network There is no Raw data file. Raw data file has been deleted.
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 PC Name in this Network.	The PC of the specified name does not exist. The PC name specified in “PC Name” in the Network 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.

Message number	Cause and suggested action
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 the Network 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.)
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 folder sharing in the Network Utility screen.
No.362 Account Disabled.	The account is disabled. (The user setting is improper.) Check the setting of “Account” in “Setting of ECHOSCAN” in the Network Utility screen.
No.371 Network Cable is not connected.	The LAN cable is not connected or the connection is improper. Check the LAN cable connection.

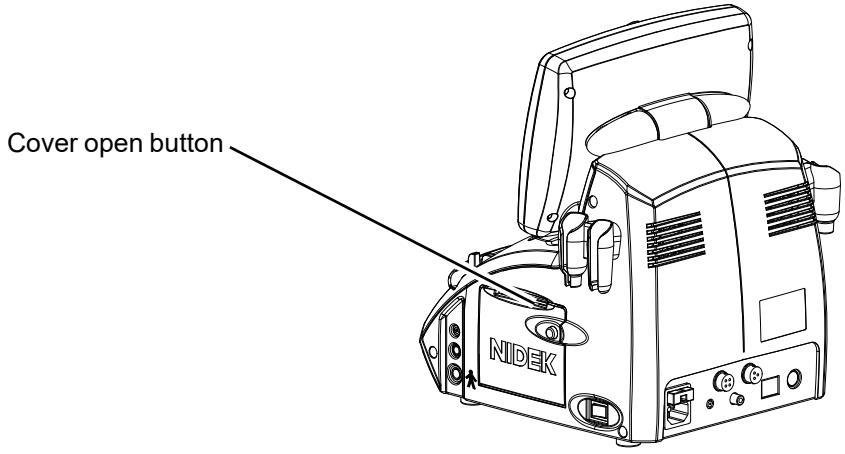
5.3 Replacing Printer Paper

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.

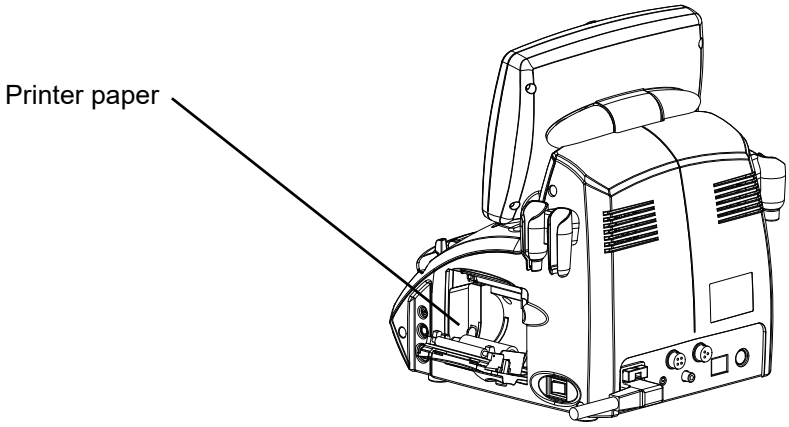
Note

- 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.



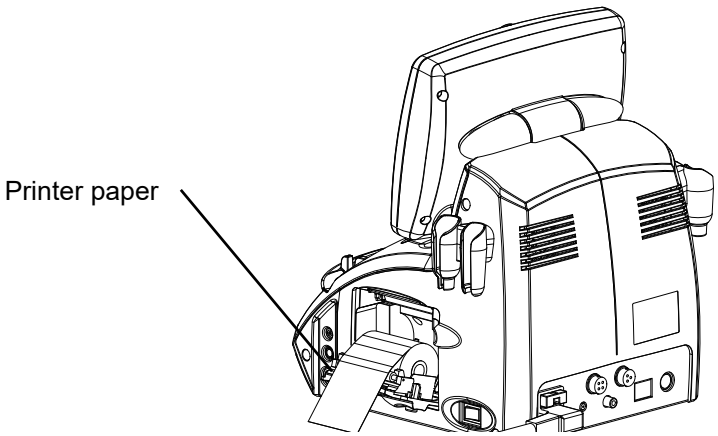
⚠ **CAUTION**

- **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.

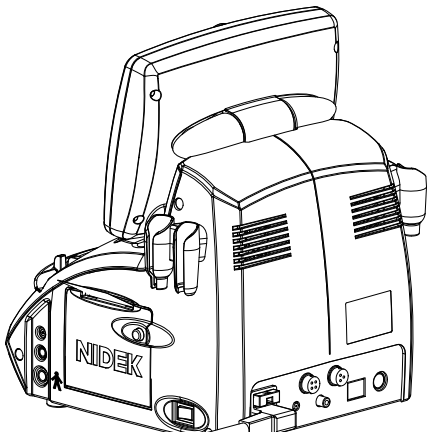


Note

- 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 closed securely, the automatic paper cutter may not function properly. Pressing the Print switch may display “No.141 Hardware Error.”, “No.144 No Paper.” or “No.145 Head Up.” and printing may not be performed.

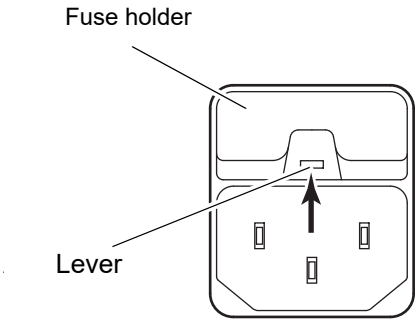
5.4 Replacing Fuses

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.

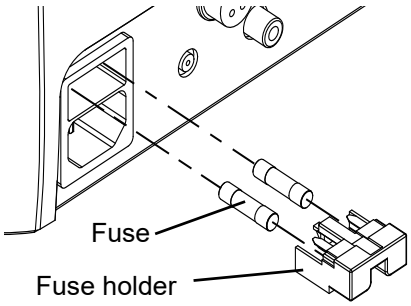
Pull out the fuse holder while pushing the lever in the arrow direction.



3 Replace blown fuses with new ones.

Always use two specified fuses together.

[T1.6 AL 250V (∅ 5 x 20 mm)]



4 Attach the fuse holder.

5 Connect the power cord to the inlet and outlet.

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 malfunction may result.

5.5.2 Cleaning printer

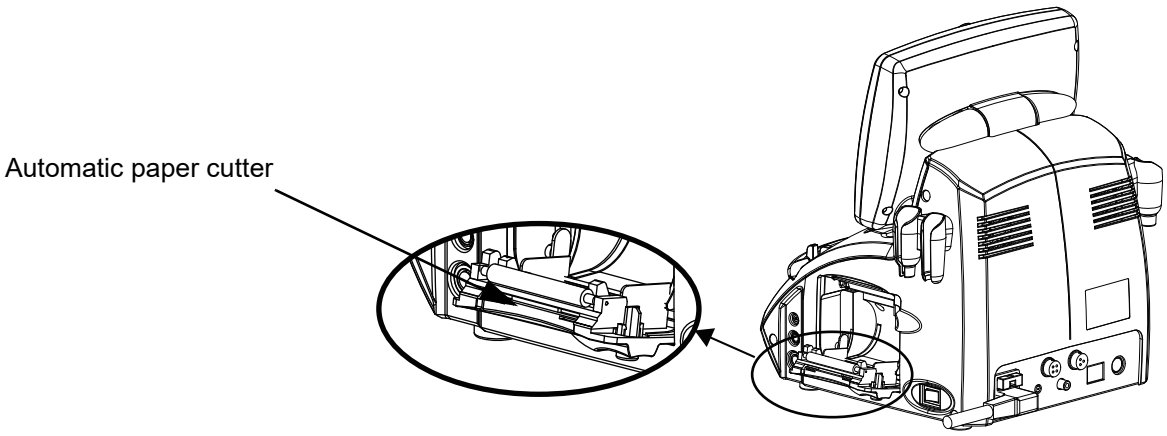
After repeated usage, the paper slot of the auto cutter of the printer is soiled with powdery paper. If powdery paper is settled, a malfunction of the auto cutter may result; clean it.

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

See “5.3 Replacing Printer Paper” (Page 136).

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, malfunction may result.



3 Set the printer paper roll as it was.

5.5.3 Cleaning touch screen

Soak a soft cloth in 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 Cleaning/Disinfecting Ultrasound Probe

The ultrasound probe needs to be cleaned and disinfected after each use. Follow the recommendations described in procedure to clean and disinfect the ultrasound probe properly.

⚠ CAUTION

- **The ultrasound probe is shipped without being cleaned or disinfected. Prior to the first use, be sure to clean and disinfect it.**
- **Use proper protective equipment such as protective eye glasses, goggles, or gloves as recommended by the manufacturer of the cleaning agent or disinfectant.**
- **For the use of cleaning agent or disinfectant, read the handling manual (attached document) thoroughly. Confirm that the concentration, temperature, and immersion time are proper for clinical use.**
- **Confirm that the use-by date for cleaning agents, disinfectants, and absorbent cotton have not expired.**
- **Use the appropriate disinfectant according to its approval in each country.**
- **Perform cleaning before the body fluid and chemical solution on the probe become dry.**
  The body fluid and chemical solution may become difficult to remove.
- **Do not store the used ultrasound probe in the dedicated case.**
  The inside of the case may become contaminated.
- **Take care that the ultrasound probes do not contact with other equipment in the sterilized case or bag.**

● Infection risk classification (Spaulding classification)

The tables below describe three categories of infection and their disinfection methods. The degree of risk for infection are classified into Critical, Semi-critical, and Non-critical based on the clinical use and presumable hazards. These degrees designate the disinfection and sterilization criteria according to the body tissue that contacts medical equipment.

Degree (infection risk)	Definition	Treatment
Critical (High risk level)	Critical devices are devices that are introduced directly into the bloodstream or that contact a normally sterile tissue or body-space during use.	Sterilization
Semi-critical (Medium risk level)	Semi-critical devices are devices that contact intact mucous membranes or non-intact skin. They do not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body.	High level disinfection

Non-critical (Low risk level)	Non-critical devices are instruments and other devices whose surfaces contact only intact skin and do not penetrate it. Non-critical devices also include devices that do not directly contact the patient but may become contaminated with microorganisms and organic soil during patient care (e.g., blood, body fluids); such devices may not be visibly contaminated.	Intermediate level disinfection Low level disinfection

Note

- The A-scan and Pachymetry probes are classified as “Semi-critical”, and the B-scan probe is classified as “Non-critical” according to the Spaulding classification. The FDA[a] and CDC[b] guidelines recommend medical devices used on intact mucous membranes be processed with high level disinfection.

a.FDA (Food and Drug Administration), Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 17, 2015)
b.CDC (Centers for Disease Control and Prevention). Guideline for Disinfection and Sterilization in Healthcare Facilities 2008

The A-scan and Pachymetry probes are classified as Semi-critical according to their infection risks. Perform the high level disinfection on them.
The B-scan probe is classified as Non-critical.
Perform the high or intermediate level disinfection on the B-scan probe.
The ultrasound probe tip will be gradually deteriorated by repeated disinfection. It is recommended to replace the ultrasound probe after disinfection has been performed the number of times specified in the table below.

For checking the ultrasound probe, see “4.1 Checks Before Use” (Page 125).

Target part for cleaning and disinfection
A-scan probe tip
B-scan probe tip
Pachymetry probe tip

Processing	Number of times
High level disinfection (immersion in glutaraldehyde solution)	2,000 times
High level disinfection (wiping by Tristel Duo OPH)	2,000 times
Intermediate level disinfection (immersion in sodium hypochlorite)	2,000 times
Intermediate level disinfection (immersion in ethanol for disinfection)	2,000 times

● Disinfection procedure

1	Removal	“5.6.1 Disconnecting ultrasound probe (cleaning preparation)” (Page 143)
2	Cleaning	“5.6.2 Cleaning ultrasound probe” (Page 144)
3	Disinfection	“5.6.3 Disinfecting ultrasound probe (by immersion)” (Page 145) “5.6.4 Disinfecting ultrasound probe (by wiping)” (Page 146)
4	Storage for next use	“5.6.5 Storing ultrasound probe” (Page 147)

5.6.1 Disconnecting ultrasound probe (cleaning preparation)

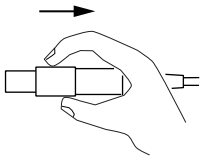
Disconnect the ultrasound probe from the device to clean and disinfect it.

1 After the measurement, wipe the dirt on the probe tip.

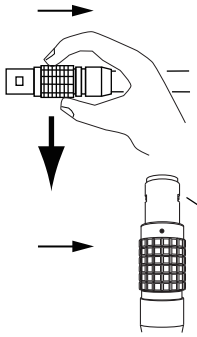
2 Hold the housing of the cable plug and disconnect the ultrasound probe from the main body.

⚠ **CAUTION** • Always hold the housing of the cable plug, not the cable, when connecting or disconnecting the probe.

Pachymetry probe



A-scan and B-scan probes



5

5.6.2 Cleaning ultrasound probe

To disinfect the ultrasound probe thoroughly, be sure to remove any foreign matters (such as microbial) from the ultrasound probe as much as possible.

⚠ CAUTION

- **Clean the ultrasound probe by hand. Do not clean the ultrasound probe with an ultrasound washer or washer disinfector (WD). Doing so may damage the ultrasound probe.**
- **Do not clean the ultrasound probe with water at 45°C (113°F) or above.**
  The ultrasound probe may become damaged.

1 Wipe the ultrasound probe with a clean absorbent cotton dampened with ethanol for disinfection.

2 Wipe the ultrasound probe with a clean absorbent cotton dampened with neutral detergent while cleaning it with running water at room temperature.

Water temperature: 5 to 45**°C** (reference)

3 Rinse the ultrasound probe under running water to remove the residual detergent completely.

4 Immediately wipe off any moisture on the surface with absorbent cotton and let the ultrasound probe air dry in a clean and well-ventilated place.

Wipe without rubbing so as not to scratch the probe.

5 Confirm that no foreign matters remain on the ultrasound probe surface. If foreign matters still remain, repeat the above procedure until they are removed completely.

5.6.3 Disinfecting ultrasound probe (by immersion)

Immerse the ultrasound probe in any of the disinfectants.

Chemical disinfectant (High level disinfection)	Glutaraldehyde solution
Optimal concentration	3.5%
Immersion time	60 minutes (Follow the instruction by the disinfectant manufacturer.)

Chemical disinfectant (Intermediate level disinfection)	Ethanol for disinfection
Optimal concentration	76.9 to 81.4Vol%
Immersion time	10 minutes (Follow the instruction by the disinfectant manufacturer.)

Chemical disinfectant (Intermediate level disinfection)	Sodium hypochlorite
Optimal concentration	0.1%
Immersion time	10 minutes (Follow the instruction by the disinfectant manufacturer.)

⚠ CAUTION

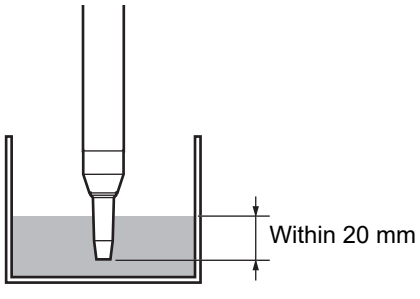
- **Be careful that the immersed ultrasound probes are not scratched by bumping against each other.**
- **After the disinfection, rinse the probe tip sufficiently.**
- **For the use of the disinfectant, refer to each manufacturer's manual.**

1 Prepare a small container and fill it with the disinfectant with the concentration and at the temperature recommended by the manufacturer of the disinfectant.

2 Immerse the probe tip (within 20 mm) in the disinfectant.

3 Remove air bubbles completely from the ultrasound probe.

Make sure that all air bubbles are removed. Proper disinfection is not achieved if air bubbles remain.



Example: A-scan probe

4 Leave the ultrasound probe immersed at the temperature and for the duration recommended by the manufacturer of the disinfectant.

5 Rinse the ultrasound probe with sterile purified water and remove the disinfectant completely.

1) Clean the ultrasound probe tip with running sterile purified water for at least 30 seconds.
2) Wipe the probe tip with a sterilized gauze and dry sufficiently.
3) Dry the probe completely.

5.6.4 Disinfecting ultrasound probe (by wiping)

Wipe the ultrasound probe with the following disinfectant for high level disinfection.

Chemical disinfectant (High level disinfection)	Tristel Duo OPH, Tristel Solutions Ltd.
Optimal concentration	Undiluted solution (foam consisting of mixture of two solutions)
Immersion time	30 seconds or more (Follow the instruction by the disinfectant manufacturer.)

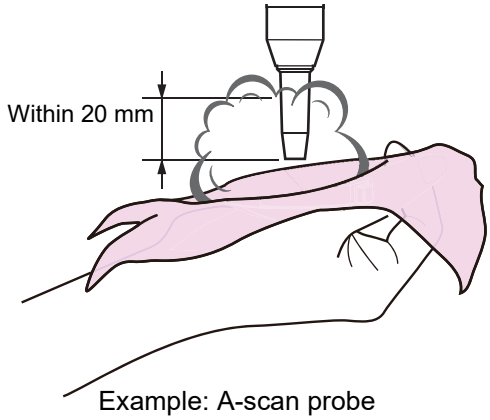
⚠ CAUTION

- **Be sure to cover the surface of the probe tip completely with the foam. Any uncovered parts will not be disinfected sufficiently.**
- **After the disinfection, rinse the probe tip sufficiently.**
- **For the use of the disinfectant, refer to each manufacturer's manual.**

1 Apply an appropriate amount of Tristel Duo OPH on a dry sterile gauze.

2 Spread the foam disinfectant on the probe tip (within 20 mm).

Check that the entire probe tip is covered with the foam disinfectant.



Example: A-scan probe

3 Let the probe tip be covered with the foam disinfectant for 30 seconds or more.

Be careful that the probe tip does not become partially dry because any dried part will not be disinfected properly.

Dispose of the sterile gauze used for the application of the disinfectant. Do not reuse it.

4 Rinse it with sterile purified water and remove the residual disinfectant completely.

1) Clean the ultrasound probe tip under running sterile purified water for at least 30 seconds.
2) Wipe the probe tip with a sterilized gauze and dry sufficiently.
3) Dry the probe completely.

5.6.5 Storing ultrasound probe

Store the disinfected ultrasound probe in a clean condition until the next use.

⚠ CAUTION

- **Do not contact the disinfected ultrasound probe to any other contaminated equipment.**
- **Store the ultrasound probe in the location free from ultraviolet radiation or direct sunlight, under room temperature, in a clean and well-ventilated environment.**
- **Store the ultrasound probe according to each medical facility's guidelines to prevent re-contamination.**

1 Store the ultrasound probe in a sterilized case or bag.

2 Clearly describe on the case or bag that the contents have been disinfected properly.

If the probe will not be used for a long period of time, put the provided protection cap, store it in a dedicated case, and disinfect its tip before use.

5.7 List of Replacement Parts

Part name	Part number	Note
Printer paper	80620-00001	Width 58 mm, 25 m
Fuse	80402-02040	T1.6 AL 250 V (∅ 5 x 20 mm)

* After replacement of consumables, restock them.

6. SPECIFICATIONS AND CONFIGURATION

6.1 Classifications

[Protection against electric shock]

Class I ME equipment

[Protection against electric shock (applied parts)]

Type B applied part

[Protection against harmful ingress of water or particulate matter][*1]

IPX0 (Main body)

IPX1 (Foot switch)

IPX7 (Probe)

[Method(s) of sterilization]

ME equipment that does not include parts that need sterilization.

[Suitability for use in an oxygen rich environment]

ME equipment that is not intended for use in an oxygen rich environment.

[Mode of operation]

Continuous operating device

***1. In accordance with IEC 60529**

6.2 Specifications

6.2.1 A-scan biometry/IOL power calculation

- Probe
  Solid probe
  Frequency: 10MHz (± 20%)
  Internal fixation lamp: LED (Red), Illumination
  Maximum ultrasound output: MI - 0.23 or less
- 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 standard deviation)
  Measurement range: 12.00 to 40.00mm
  Minimum display unit: 0.01mm
  Accuracy: ± 0.1 mm
- Measurement function: Manual, Auto, SemiAuto, Speedy
  Gate: Cornea, Lens-F (anterior), Lens-B (posterior), retina
  Sonic velocity to calculate distance:
  Average axial length: 1550m/s (Phakic eye), 1548 m/s (Eye with mature cataract: Dense Cat ON)
  1532m/s (Aphakic eye)
  Setting range: 800 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, 1629 m/s (Eye with mature cataract: Dense Cat ON)
  Setting range: 1000 to 2000 m/s
  IOL: 2060 m/s (Acrylic)
  2760 m/s (PMMA)
  1049 m/s (Silicone)
  Setting range: 500 to 3000m/s
- IOL power calculation
  IOL formula: Binkhorst, Holladay, Regression, Regression II, Formula/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 132
  Predicted ACD value: -7.00 to 20.00
  SF value: -10.00 to 20.00
  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
  Maximum ultrasound output: MI - 0.23 or less
- Display
  Scanning range: 35 mm or 50 mm from a distance of 2 mm from the tip of the probe (± 10%) (Averaged 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)
  Display accuracy: ±20% (when using Video Printer)
- 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 -20 dB
  For total sensitivity (GAIN): 0 to 90 dB
- 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%)
  Maximum ultrasound output: MI - 0.23 or less
- 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
  Variable range: 1000 to 2000 m/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 mass

- Dimensions 300 mm (W) x 285 mm (D) x 330 mm (H)
- Mass 8.5 kg

6.2.6 Power supply

- Power supply AC 100 to 120V ± 10% 50/60 Hz
- Power consumption 70 VA

6.2.7 Environmental conditions (during use)

- Temperature 10 to 35°C (50 to 95°F)
- Humidity 30 to 90%
- Atmospheric pressure 800 to 1060 hPa

6.2.8 Environmental conditions (during storage and shipping)

- Temperature - 10 to 55°C (14 to 131°F)
- Humidity 10 to 95% (Non-condensing)

6.2.9 Composition of parts that come into contact with human body

Main body

- Stylus ABS resin, Polyester elastomer
- Knob 1 and Knob 2 ABS resin
- Cover open button ABS resin
- A-scan probe Tip - Polystyrene resin
  Holder - Polyacetal resin
- B-scan probe Tip - Polymethylpentene
  Holder - Polyacetal resin
- Pachymetry probe (straight type, 45° fixed type, 45° detachable type)
  Tip - Polystyrene resin
  Holder - Polyacetal resin

6.2.10 Others

- Unit per package 1 unit
- Expected service life (defined by manufacturer)
  8 years from the date of initial operation
  * Proper maintenance is necessary.

6.3 Configuration

6.3.1 Standard accessories

• Stylus	•1 unit
• B-scan probe	•1 unit
• Foot switch	•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
• A-scan probe	•1 unit
• Pachymetry 45° probe *	•1 unit
• Pachymetry probe (straight type)	•1 unit
• Pachymetry probe (45° detachable type)	•1 unit
• Test piece (for Biometry measurement)	•1 unit
• Test piece for 45° Pachymetry probes*	•1 unit
• Test piece for straight Pachymetry probes	•1 unit
• Barcode reader	•1 unit
• Communication cable	•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) Regression and Regression II

Regression is famous among the regression formulas. Regression II is the corrected Regression formula.

(2) Formula/T

This formula is a theoretical formula.

(3) 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.

(4) Hoffer Q formula

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

(5) 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 Regression

(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] $K = (n_k - 1.000) \times 1000/R$*1
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 Regression II

(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)

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

(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] $K = (n_k - 1.000) \times 1000/R$*1
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, $C = 3$
$20.0 \text{ mm} \leq AL < 21.0$ mm, $C = 2$
$21.0 \text{ mm} \leq AL < 22.0$ mm, $C = 1$
$22.0 \text{ mm} \leq AL < 24.5$ mm, $C = 0$
$24.5 \text{ mm} \leq AL$, $C = -0.5$

*1. "n_k" is the corneal refractive index input in the A-scan biometry utility screen.

CR: Constant for calculation

$P \leq 14.0$, CR = 1.00

$P > 14.0$, CR = 1.25

* $P = A' - 2.5 \times AL - 0.9 \times K$

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

SPH: Actual postoperative spherical refractive power [D]

CYL: Actual postoperative cylindrical refractive power [D]

R_F: $LP > 16$ $R_F = 1.25$

$LP \leq 16$ $R_F = 1.00$

<Cautions in use>

In the Regression 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 Regression 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 Regression 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

		Regression,	Regression II,	Formula/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 Regression 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 Formula/T

(1) IOL refractive power for ametropia (IOL)

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

(2) Postoperative refractive error (ERROR)

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

R : Corneal radius [mm] $R = (n_k - 1.000) \times 1000/K$*1

LO : AL + RT [mm]

RT : Retinal thickness [mm] $RT = 0.65696 - 0.02029 \times AL$

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]

$AD = 0.62467 \times A - 68.747$

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 $AL \leq 24.2$, $LC = AL$

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)

*1. "n_k" is the corneal refractive index input in the A-scan biometry utility screen.

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)

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

$AL' = AL + B - T \times (1 - N2/N3)$

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] $R = (n_k - 1.000) \times 1000/K$*1

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

*1. "n_k" is the corneal refractive index input in the A-scan biometry utility screen.

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,

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

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

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

When the L > 31, L = 31, M = - 1, G = 23.5

When the L < 18.5, L = 18.5, M = + 1, G = 28

(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)

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

(2) Postoperative refractive error (ERROR)

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

(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] $R = (n_k - 1.000) \times 1000/K$*1

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

*1. "n_k" is the corneal refractive index input in the A-scan biometry utility screen.

SF : Surgeon factor

ER : Actual postoperative refractive power [D]

Rag : R ≥ 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 66)) to be used for IOL power calculation:

SF = (A × 0.5663) - 65.60

SF: SF value (Surgeon factor)

A : A-constant

ex.) When the A-constant = 116.7

SF = (116.7 × 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 66).)

8. EMC & ACOUSTIC OUTPUT

8.1 EMC (Electromagnetic Compatibility)

The device is suitable for use in stores and hospitals except for near active HF surgical equipment and RF shielded rooms with an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high, electrophysiology laboratories, or areas where short-wave therapy equipment is used.

⚠ WARNING

- Do not use the device near, on, or under other electronic equipment or electromagnetic disturbance sources. Otherwise, it could result in improper operation. If such use is necessary, the device and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) or electromagnetic disturbance sources as shown below should be used no closer than 30 cm (12 inches) to any part of the device, including the specified or provided cables. Otherwise, degradation of the performance of this equipment could result.

  The following are examples of electromagnetic disturbance sources:

  - Induction cooking appliance and ovens
  - RFID readers
  - Electronic article surveillance (EAS) systems
  - Sponge detection systems
  - Equipment used for position detection (e.g. in catheter labs)
  - Wireless power transfer charging systems for electrical vehicles

O Specified cable

Part name	Cable Shielded	Ferrite Core	Length (m)
Power cord	No	No	2.5

O Essential performance

A-scan biometry, B-scan imaging, Pachymetry

◆ Compliance for Emission Standard

Phenomenon	Product family standard	Compliance
Conducted and radiated RF emissions	CISPR 11	Group 1 Class B
Harmonic distortion	IEC 61000-3-2	*1
Voltage fluctuations and flicker	IEC 61000-3-3	*2

* 1 For the regions where the rated voltage is 220 V to 240 V, this device complies with this standard.
* 2 For the regions where the rated voltage (line to neutral) is 220 V to 250 V, this device complies with this standard.

◆ Test specifications for enclosure port immunity to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Immunity test level (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

◆ Compliance for Immunity Standard

Phenomenon	Basic EMC standard	Immunity test levels
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF electromagnetic field	IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See “Test specifications for enclosure port immunity to RF wireless communications equipment”.
Electrical fast transients / bursts	IEC 61000-4-4	Input power port ±2 kV 100 kHz repetition frequency
		Signal input/output parts port ±1 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	Input power port ±0.5 kV, ±1 kV
Surges Line-to-ground		Input power port ±0.5 kV, ±1 kV, ±2 kV Signal input/output parts port ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

8.2 Acoustic Output Reporting Table (requested by FDA)

8.2.1 A-scan probe

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (mW/cm^2)
Global Maximum value			0.142	1.50	9.01
Associated acoustic parameters	$p_{r.3}$ (MPa)		0.448		
	W_0 (mW)			0.150	0.150
	f_c (MHz)		9.99	9.99	9.99
	Z_{sp} (cm)		2.10	2.10	2.10
	Beam dimensions	X_{-6} (cm)		0.171	0.171
		Y_{-6} (cm)		0.173	0.173
	PD (μsec)		0.0833		0.0833
	PRF (Hz)		2000		2000
	EBD	Az. (cm)		0.45	
		Ele. (cm)		0.45	
Operating control conditions					

8.2.2 B-scan probe

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (mW/cm^2)
Global Maximum value			0.175	0.476	9.743
Associated acoustic parameters	$p_{r.3}$ (MPa)		0.522		
	W_0 (mW)			0.268	0.0.2688
	f_c (MHz)		8.91	8.91	8.91
	Z_{sp} (cm)		1.70		1.70
	Beam dimensions	X_{-6} (cm)			0.0955
		Y_{-6} (cm)			0.0999
	PD (μsec)		0.0833		0.156
	PRF (Hz)		8000		8000
	EBD	Az. (cm)		0.450	
		Ele. (cm)		0.450	
Operating control conditions					

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8.2.3 Pachymetry probe (45° detachable type)

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (mW/cm^2)
Global Maximum value			0.15	2.49	6.11
Associated acoustic parameters	$p_{r.3}$ (MPa)		0.486		
	W_0 (mW)			0.0173	0.0173
	f_c (MHz)		10.5	10.5	10.5
	Z_{sp} (cm)		0.200	0.200	0.200
	Beam dimensions	X_{-6} (cm)		0.0867	0.0867
		Y_{-6} (cm)		0.0914	0.0914
	PD (μsec)		0.103		0.103
	PRF (Hz)		3950		3950
	EBD	Az. (cm)		0.15	
		Ele. (cm)		0.15	
Operating control conditions					

8.2.4 Pachymetry probe (45° fixed type)

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (mW/cm^2)
Global Maximum value			0.177	3.88	8.9
Associated acoustic parameters	$p_{r.3}$ (MPa)		0.569		
	W_0 (mW)			0.0264	0.0264
	f_c (MHz)		10.4	10.4	10.4
	Z_{sp} (cm)		0.317	0.317	0.317
	Beam dimensions	X_{-6} (cm)		0.0875	0.0875
		Y_{-6} (cm)		0.0927	0.0927
	PD (μsec)		0.110		0.110
	PRF (Hz)		3950		3950
	EBD	Az. (cm)		0.150	
		Ele. (cm)		0.150	
Operating control conditions					

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8.2.5 Pachymetry probe (straight type)

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (mW/cm^2)
Global Maximum value			0.174	3.40	8.03
Associated acoustic parameters	$p_{r.3}$ (MPa)		0.551		
	W_0 (mW)			0.0198	0.0198
	f_c (MHz)		10.1	10.1	10.1
	Z_{sp} (cm)		0.200	0.200	0.200
	Beam dimensions	X_{-6} (cm)		0.0896	0.0896
		Y_{-6} (cm)		0.0934	0.0934
	PD (μsec)		0.108		0.108
	PRF (Hz)		3950		3950
	EBD	Az. (cm)		0.150	
		Ele. (cm)		0.150	
Operating control conditions					

8.2.6 Global acoustic output limits

Probe		MI [Unitless]	$I_{SPTA.3}$ [mW/cm2]	$I_{SPPA.3}$ (W/cm2)
A-Scan		0.142	1.50	9.01
B-scan		0.175	0.476	9.743
Pachymetry probe				
	45° detachable type	0.15	2.49	6.11
	45° fixed type	0.177	3.88	8.9
	Straight type	0.174	3.40	8.03

9. 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.

High level disinfection

Removes all microbial excluding the case where spore exists abundantly.

Intermediate level disinfection

Removes much of tubercle bacillus, vegetative bacterias, and virus excluding spores.

Low level disinfection

Removes much of vegetative bacterias, specified virus and fungus.

O.D. (Oculus Dexter)

Right eye

O.S. (Oculus Sinister)

Left eye

Spaulding classification

Classifies medical equipment into three categories based on their clinical use and infection risks on target body tissue, designating proper disinfection or sterilization method for each category.

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 becomes uniform.

USB flash drive

An auxiliary storage to which data is transmitted through the USB port.

10. INDEX