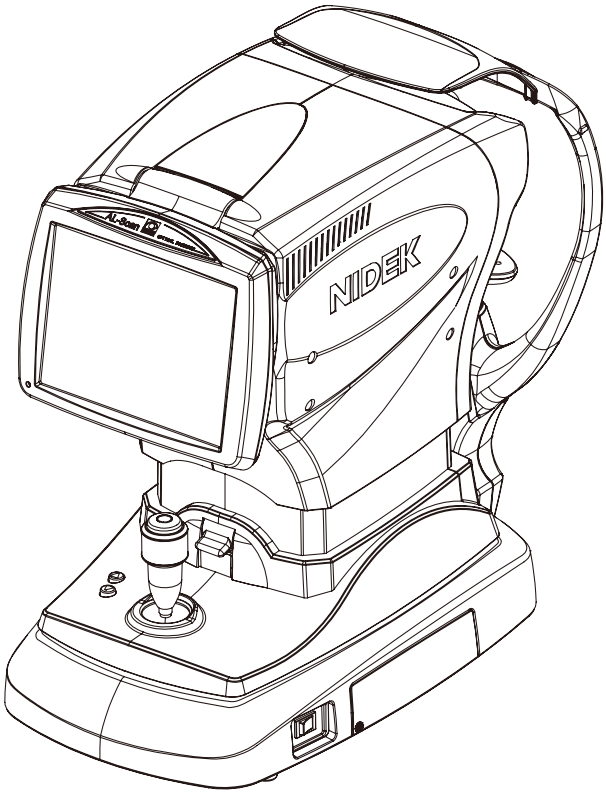
NIDEK

OPTICAL BIOMETER
AL-Scan

OPERATOR'S MANUAL



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

Original instructions

NIDEK CO., LTD.

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CE
0344

2023-03-31
14101-P902-G1
Printed in Japan

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 includes operating procedures, safety precautions, and specifications for the OPTICAL BIOMETER AL-Scan.

Cautions for safety and operating procedures must be thoroughly understood before using this device.

Keep this manual handy for reference.

Use of the device is limited to the medical practice by qualified physicians or personnel engaged in medical practice who received instruction from the qualified physician in accordance with the instructions in the operator's manual. The physicians are responsible for the application of the device.

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

There are no parts within the device that require servicing by the user other than printer paper.

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

***The device complies with ISO 10343:2014 (Ophthalmic instruments - Ophthalmometers).**

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

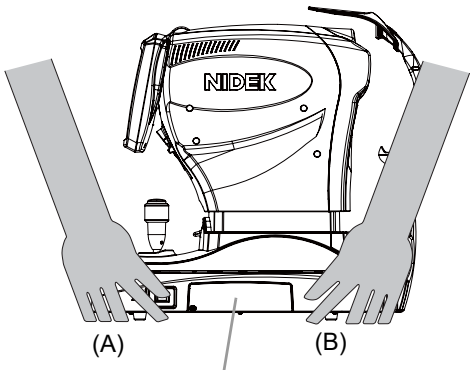
- **If any serious device-related incident occurs, report it to Nidek and the competent authority in the country where the user or patient, or both reside.**
- **Be sure to use a grounded power outlet.**
  Electric shock or fire may result in the event of malfunction or power leakage.
- **Never modify or touch the internal structure of the device.**
  Electric shock or malfunction may result.

⚠ CAUTION

- **Never use the device for other than its intended purpose.**
  Nidek will not assume responsibility for accidents or malfunction caused by misuse.
- **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 adverse events.
- **Be sure to use accessories specified by Nidek.**
  Use of the device outside the scope of this manual may cause adverse events.
- **Perform visual and operational checks before using the device. Do not use the device if any error is found.**
  If any abnormalities in output, communication, or operation are found, it may not possible to use the device.
  Use of a malfunctioning device will not produce the expected results and may cause troubles or lead to inappropriate diagnoses that may induce health hazards.
- **Install the device in an environment that meets the conditions listed below. The following conditions must be maintained during use.**
  Ambient temperature: 10 to 35ºC (50 to 95ºF)
  Humidity: 30 to 90% (Non-condensing)
  Atmospheric pressure: 800 to 1,060 hPa
  Indoor enclosed air-conditioned spaces in the medical facility
  Protected from exposure to water
  Dust free environment with air containing no sulfur or salt
  Protection from extraneous light sources
  Level and stable surface free from vibration and bumping
  If the device is not installed and used under the above conditions, the reliability of measurements is lowered, and malfunction may result. In addition, injury may result if the device is bumped or topples over.
- **Install the device in an environment where no contaminant such as corrosive gas, acid, or salt is 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 measurements.

⚠ CAUTION

- **This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen, or nitrous oxide.**
- **Install the device so that the air vent on the cover of the main body is not blocked.**
- **Do not use this device in an operating room.**
- **Be sure to use a power outlet which meets the specified power requirements.**
  If the supplied voltage is too high or low, the device may not perform up to specifications, and malfunction or fire may result.
- **Insert the power plug fully into the power outlet.**
  Imperfect connection may result in fire.
- **Never use power strips or extension cables for the power supply of the device.**
  Electrical safety may be reduced.
- **Do not use any power cord other than the one provided. Do not use the provided power cord for any other instrument.**
  Malfunction or fire may result.
- **Never crush or pinch the power cord with heavy objects.**
  Damage may result in electric shock or fire.
- **Install the device where the outlet that the power plug is inserted into is easily accessible during use. In addition, ensure that the power plug can be disconnected without the use of a tool.**
  Otherwise, it may interfere with disconnection of the device from the input power source in case of abnormality.
- **Before connecting any cables to the device, be sure to turn off power to the device and unplug the power cord.**
  Malfunction may result.
- **When carrying the device to another location, its base should be held by two hands from both sides by two persons as indicated by (A) and (B) in the figure shown to the right. Never hold any parts other than the base such as the forehead rest and main unit.**
  If the device is carried by a person, or any parts other than the base are held, the device may fall and injury or failure may result.



⚠ **CAUTION**

- **Keep the touch screen away from direct sunlight or excessive ultraviolet rays.**
  They will damage the touch screen.
- **Do not install the device where it is exposed to strong electromagnetic waves during operation.**
  Measurement values may not be obtained properly.
  When the AL-Scan is installed in the same room as other equipment that generates strong electromagnetic waves, always turn off power to the other equipment before performing measurement using the AL-Scan.

During use

⚠ **CAUTION**

- **Do not perform servicing or maintenance on the device during use.**
- **Be sure to have the data measured or calculated using the AL-Scan checked by the doctors before use.**
- **Be sure to confirm that the cables are properly connected before use.**
- **Be sure not to touch the patient's face during alignment or when switching the right and left of the patient's eye.**
- **Before and after use, and before every patient, clean the forehead rest and chinrest with clean gauze or cloth dampened with rubbing alcohol.**
  If the chinrest paper is used, remove a sheet after each patient.
  For severe stains, wipe with a clean cloth dampened with rubbing alcohol instead of wiping them repeatedly with a dry cloth.
- **Take care not to catch hands or fingers in moving parts such as the measurement unit, main unit, and chinrest. The measurement unit makes vertical and horizontal movement during auto alignment. Be sure to also give this caution to patients.**
  Hands or fingers may be pinched and result in injury.
- **Take care not to catch hands or fingers when opening or closing the touch screen panel, printer cover, or side panel cover.**
  Injury may result.
- **Keep the measuring window and mire ring free from fingerprints and dust.**
  The measurement accuracy may decrease substantially.
- **In the event of smoke or strange odors, immediately turn off the device and disconnect the power plug from the outlet. Once it is determined that the smoke will not become more serious, 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.
- **Immediately replace the power cord if the internal wires are exposed, the power turns on or off when the power cord is moved, or the cord or plug is too hot.**
  Immediately remove the plug from the power outlet and contact Nidek or your authorized distributor for replacement. Failure to do so may result in electric shock or fire.
- **Prior to measurement, explain the purpose and method sufficiently to the patient.**
- **Be sure to perform measurement with sufficient eye fixation and eyelid opening.**
  Accurate measurement value may not be obtained.
- **Never press two or more points on the touch-screen panel at the same time.**
  A malfunction may result.
- **Never touch the LCD monitor with any object other than the finger or touch pen tip.**
  Touching with the monitor with any hard pointed object such as a ball-point pen may damage the monitor.
  Although the touch pen tip is provided with a resin tip intended to protect the display, excessive pressure of the touch pen may result in damage.

⚠ **CAUTION**

- **Keep magnetic objects away from the LCD monitor.**
  Malfunction may result.
- **Never touch the LCD monitor with wet hands.**
  Water intrusion may result in malfunction of the device.
- **There may be a few “constantly-lit”, “missing” or “dead” pixels in the LCD monitor which is a characteristic of the LCD monitor manufacturing process. This does not represent a failure of the LCD monitor, and the monitor can be used with no problem.**
- **Be sure to securely connect cables to specific connectors (with their port shapes matching the plug shape). Be sure not to apply too much pressure on the connectors when connecting or disconnecting them.**
  Failure may result.
- **If the device is connected to a computer 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 computer through an isolation transformer.**
  Electric shock may result. 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.
- **Equipment connected to the analog or digital interfaces must be certified according to the representative appropriate national standards (such as EN 60601-1 and IEC 60601-1). Furthermore, all configurations must 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 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 of your local representative.**
- **Perform the measurements using appropriate sonic velocity values (when using the optional A-scan or pachymetry probe).**
  Accurate axial length and corneal thickness measurement cannot be obtained with inappropriate sonic velocity values.
- **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 IOL power calculation formula to be used and with reference to the cataract surgery technique and other examination results.**

⚠ **CAUTION**

- **When calculating IOL power, use the A-constant optimized for the measured value of axial length to be used for the calculation.**

  See “1.8 Axial Length Measurement as Measured by Optical and Ultrasonic Methods” (page 4).

- **Do not turn off (◯) power to the device during data backup or settings backup.**

  Backup procedure may not be performed properly, and the data may be broken.

- **This device uses a heat-sensitive printer paper. To keep the printed data for a long period of time, make copies of the printouts.**

  The paper degrades over time and the printed data may become illegible.

- **If the device fails, disconnect the power cord from the power outlet, then contact Nidek or your authorized distributor without touching the interior of the device.**

- **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.**

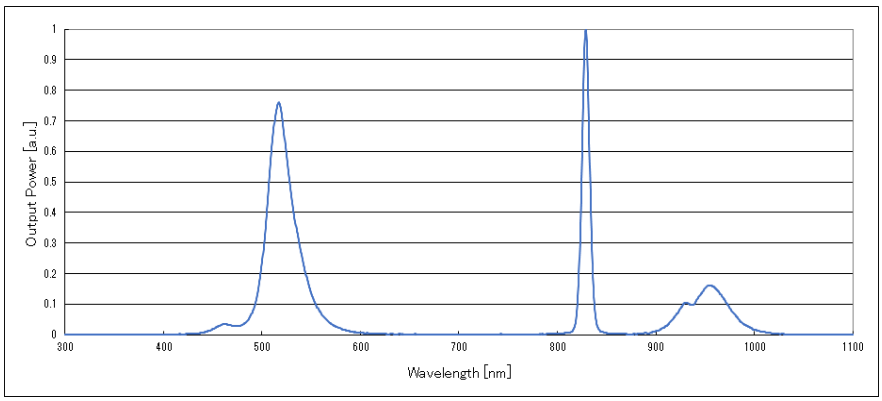
  Be sure to configure the local network with the connected PCs. Nidek will not assume responsibility or compensate for damages caused by any virus infection and development.

- **Provision of information on the avoidance of light hazard from the optical device is required in ISO 15004-2:2007 “Ophthalmic instruments - Fundamental requirements and test methods -”.**

  The light emitted from this device is potentially hazardous. The longer the duration of exposure and the greater the number of pulses, the greater the risk of ocular damage. Exposure to light from this device when operated at maximum output will exceed the safety guideline after 1,357 seconds (the number of pulses is converted to scan time).

Spectrum output of all light source during optical measurement

(maximum light intensity)

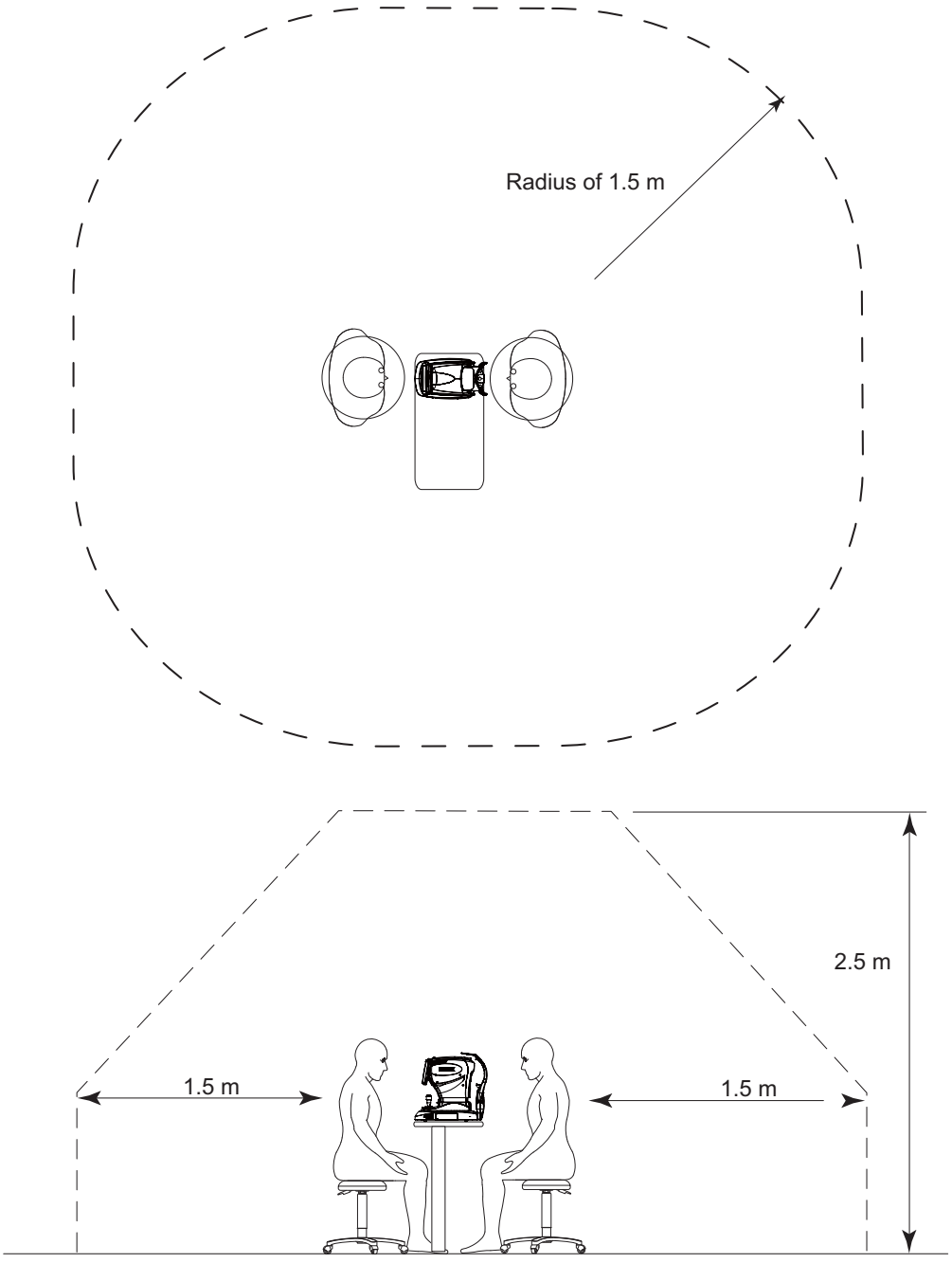


* The values in the graph were obtained using separate measurement devices.

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.



Optional A-scan and pachymetry probes

⚠ **CAUTION**

- **Always hold the housing of the cable plug, not the cable, when connecting or disconnecting the probe. Do not pull on the cable.**
  If the cable breaks, it is necessary to replace the whole probe.
  For the method of connecting and disconnecting the probe, see “5.7.1 Disconnecting ultrasound probe (cleaning preparation)” (page 219).
- **Never connect or disconnect the cable connectors of the probes during measurement.**
  The probes may become damaged.
- **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 which contacts the cornea.**
  Proper measurement may 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 optional 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.
- **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.
- **Never perform autoclaving, EOG sterilization, or ultrasonic cleaning of the A-scan or pachymetry probe.**
  The probes may become damaged.
- **Use the A-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.**
  The paper degrades over time and the printed data may become illegible. If adhesive tape or an adhesive containing an organic solvent is applied to the printer paper, the printed data may disappear and become illegible.
- **When the device is not in use, turn off power to the device and protect the main body from dust by placing the dust cover over the unit.**
  Dust may affect the accuracy of measurement.
- **Always hold the power plug, not the cord, when removing it from the power outlet.**
  The metal core of the cord may be damaged and electric shock, short circuit, or fire may result.
- **Occasionally clean the prongs of the power plug with a dry cloth.**
  If dust settles between the prongs, the dust could collect moisture, and short circuit or fire may occur.
- **If the device will not be used for an extended period of time, disconnect the power cord from the power outlet.**
  Failure to do so may leave the device vulnerable to electric disturbances which may result in fire.
- **If the device is used after a long period of disuse, check for any abnormality before use.**
- **During transport or storage, use dedicated packaging materials and maintain an environment that meets the following conditions:**
  Ambient temperature: –10 to 55ºC (14 to 131ºF)
  Humidity: 10 to 95% (non-condensing)
  Atmospheric pressure: 700 to 1,060 hPa (during storage)
  500 to 1,060 hPa (during transport)
  No large amount of dust content in the air
  A place not exposed to direct sunlight
- **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.
- **Before transporting the device, set the mode to Packing mode and pack the main body in the original packing material with the locking lever unlocked.**
  Excessive vibration or bumping may result in device failure.
  For details of the Packing mode, see “2.14.2 Completion of operation in order to transport the device” (page 127).

Maintenance

⚠ **CAUTION**

- **When performing maintenance work, secure a sufficient maintenance space.**
  Maintenance work in an insufficient space may result in injury.
- **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 (and calibration if necessary) 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.
- **Before performing maintenance, clean the surface of the device properly with a clean cloth dampened with rubbing alcohol.**
- **When sending the device back to Nidek for repair or maintenance, clean the surfaces of the device (especially, the areas that come into contact with the patient) with a clean cloth dampened with rubbing alcohol.**
- **When replacing the printer paper, use the specified type.**
  Failure to do so may cause a malfunction of the printer.
- **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.
- **Only service personnel trained by Nidek are allowed to repair and service the device.**
  Nidek assumes no responsibility for any adverse events resulting from improper servicing.
- **Do not use the device beyond the expected service life.**
  The reliability and safety of the device cannot be guaranteed even with regular maintenance that involves proper exchange of maintenance and consumable parts, repair, and overhaul.

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 the device, accessories, or replaced maintenance parts. In particular, follow the instruction of the local government when disposing of the lithium battery, printed-circuit board, plastic parts containing brominated flame retardants, LCD, or power cord.**

  It is recommended to entrust 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.

Connection to network

⚠ **CAUTION**

- **If the medical system is to be configured using an IT network, implement IT security measures with the network administrator, and check that the system operates properly.**

  Virus infection, unauthorized access, or data tampering may result.

Table of Contents

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1. BEFORE USE

1.1 Device Outline

The OPTICAL BIOMETER AL-Scan is a measuring device that can measure as a single unit the values necessary to calculate the power of an IOL for cataract surgery such as axial length, corneal curvature radius, and anterior chamber depth.
It measures these necessary values successively through a non-contact optical measurement method.
An optional A-scan probe is also available to scan axial length with an ultrasonic measurement function by touching it to the cornea should optical measurement not be successful.
In addition, an anterior eye segment image overlaid with the corneal meridians can be created as a reference for toric IOL implantation.
The AL-Scan also has the function to calculate the power of an IOL using measured values such as axial length.

⚠ **CAUTION** • **Be sure to have the data measured or calculated using the AL-Scan checked by the doctors before use.**

There are two modes for the AL-Scan: the standard mode and EX mode.
This Operator's Manual describes the AL-Scan in standard mode. The AL-Scan in EX mode can be used in the same manner as in standard mode. However, the EX mode has differences from the standard mode in the input patient information and partially unavailable functions.
The differences between the two modes are described in “7 EX MODE” (page 233). Check the differences before use.
(The two modes cannot be switched by the user.)

1.2 Intended Use

The OPTICAL BIOMETER AL-Scan is a medical device that optically measures eye components such as corneal curvature radius, corneal thickness, anterior chamber depth, and axial length. Axial length and corneal thickness can also be measured using ultrasound.

1.3 Intended Patient Population

• Age
  All ages except babies and infants
• Health condition
  Able to undergo an examination in a sitting position
• Conditions - Visual function
  One or both eyes are normal or have disease.
  Eyes that have lost the visual function are not targeted.

1.4 Intended User Profile

Ophthalmologist, clinical laboratory technician, nurse, visual trainer

1.5 Intended Use Environment

Medical facility or optical store

⚠ **CAUTION** • **If the device is used outside the specified use location, intended performance and security level cannot be maintained.**

1.6 Principles

1. **Axial length measurement**

   The axial length of the patient's eye is measured by the optical interference principle.

2. **Corneal curvature radius measurement**

   The AL-Scan measures corneal curvature radius (refractive power) and the steepest and flattest meridian directions by detecting ring image projected on the patient's cornea with a photo detector and calculating the image.

3. **Anterior chamber depth measurement and central corneal thickness measurement**

   The anterior chamber depth and central corneal thickness of the patient's eye are measured using the Scheimpflug principle.

4. **White-to-white measurement and pupil size measurement**

   The white-to-white and pupil size of the patient's eye are measured based on a captured anterior eye segment image.

In addition, an AL-Scan equipped with the optional ultrasonic measurement function can detect the echo of the ultrasound transmitted by the A-scan probe from each eye segment and calculate the axial length and anterior chamber depth based on the time difference of each echo in BIO mode measurement. In Pachy mode measurement, it calculates the corneal thickness by measuring the time difference between the echos of the ultrasound transmitted by the pachymetry probe from the anterior and posterior surfaces of the patient's cornea. If the directions of the ultrasonic waves are not perpendicular to each boundary surface when conducting BIO or Pachy mode measurement, 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.

1.7 Contraindications

Do not press the probe against the patient’s cornea with excessive force.

Note

- The measurement result becomes unstable and the patient’s eye may be damaged.

1.8 Axial Length Measurement as Measured by Optical and Ultrasonic Methods

In A-scan biometry (BIO mode measurement for the AL-Scan), axial length is measured by touching the A-scan probe to the cornea. In non-contact optical measurement, axial length is measured by the optical interference principle. Because there is no corneal applanation by the probe, optical measurement has the following features:

(1) The measurement accuracy is higher than A-scan biometry.
(2) The axial length measured by optical measurement is slightly longer than the axial length measured by A-scan biometry in general.
(3) Because there is no variation in corneal applanation due to difference in the force used to touch the probe to the cornea among operators, the measured value rarely differs among operators.
(4) When measuring eyes with mature cataract, the AL-Scan may not detect the light reflected from the fundus. Measurement of the axial length may not be possible through the optical measurement method. In such a case, measure the axial length through the optional BIO mode measurement method.

The AL-Scan normally calculates IOL power using the axial length value obtained from the optical measurement. Note the following points:

(1) The A-constant provided by the IOL manufacturer is generally for axial length (AL) measurement using A-scan biometry. Therefore, it is necessary to calculate IOL power using A-constant optimized for optical measurement. See “3.3 IOL Constant Optimization” (page 161).
(2) When the number of measurement data sets used for IOL constant optimization is insufficient, and A-constant optimized for optical measurement has not been obtained,
   a. Input the US offset in the axial length in advance so that the axial length value measured in optical measurement is almost the same as the value obtained from ultrasonic measurement. See “3.1.2 Opt tab” (page 135).
   b. Use the A-constant for ultrasonic measurement.
(3) (When the optical measurement value cannot be obtained due to mature cataract) Use the axial length value measured in BIO mode measurement after inputting the A-constant optimized for optical measurement and input the optical offset so that the BIO measured axial length value is almost the same as the optically measured axial length. See “3.1.4 BIO tab” (page 137).
(4) When the axial length obtained by the immersion measurement is used for IOL calculation, the A-constant or offset used for the calculation is the same as that of optical measurement.

1.8.1 AL offset (US offset, optical offset)

The AL-Scan is equipped with the function to calculate IOL power, and for this calculation, constants such as the A-constant unique to each IOL are necessary. However, this constant differs depending on the measurement method (optical measurement or ultrasonic measurement) used to obtain the axial length value necessary for IOL power calculation. An optical A-constant is necessary for optically measured axial length values, and an ultrasonic A-constant is necessary for BIO measured axial length values.

However, selecting the measurement method appropriate to the constant type or resetting the constant appropriate to the measurement method makes the operator's job more difficult and may lead to improper examination. To prevent such a situation, both optical measurement and ultrasonic A-constants are input to the AL-Scan and the constant appropriate to the measurement method is automatically selected.

Moreover, when only the optical A-constant or the ultrasonic A-constant is given for an IOL, the axial length value can be corrected by inputting one of two types of AL offsets.

- US offset: Used to correct the optically measured value to the BIO measured value when only a constant such as the A-constant for ultrasonic measurement is registered (see page 135).
- Optical offset: Used to correct the BIO measured value to the optically measured value when only the constant for optical measurement is registered (see page 137).

As a constant is registered separately for optical measurement and ultrasonic measurement, the AL-Scan can automatically determine the appropriate constant, or whether to use the AL offset when no applicable constant exists.
Setting the AL offset enables optical measurement of the axial length even when only the ultrasonic constant is registered.
In addition, should optical measurement not be possible due to advanced cataract, the axial length is measured using the ultrasound, and there is only an optical A-constant, the IOL power is calculated with the optical offset added automatically.

● Combination of axial length measurement method and constant type

<table>
<tr><th>Measurement method of axial length value used for calculation</th><th>A-constant type</th><th>AL offset</th><th>ACD value</th><th>KM value measurable area</th></tr>
<tr><td rowspan="3">Optical measurement</td><td>For optical measurement (optimized value)</td><td rowspan="2">—</td><td rowspan="10">ACD value measured by the AL-Scan (Scheimpflug value)</td><td rowspan="2">ø2.4</td></tr>
<tr><td>For optical measurement (value defined by the manufacturer)</td></tr>
<tr><td rowspan="2">For ultrasonic measurement</td><td>US offset</td><td rowspan="2">ø3.3</td></tr>
<tr><td rowspan="3">Ultrasonic measurement</td><td>—</td></tr>
<tr><td>For optical measurement (optimized value)</td><td rowspan="2">Optical offset</td><td rowspan="4">ø2.4</td></tr>
<tr><td>For optical measurement (value defined by the manufacturer)</td></tr>
<tr><td rowspan="3">Immersion</td><td>For optical measurement (optimized value)</td><td rowspan="2">—</td></tr>
<tr><td>For optical measurement (value defined by the manufacturer)</td></tr>
<tr><td>For ultrasonic measurement</td><td>US offset</td><td>ø3.3</td></tr>
</table>

* Calculation is performed after the AL offset and KM value appropriate to the axial length measurement method and A-constant type have been automatically selected.

Note

- When the A-constant is for ultrasonic measurement, it is necessary to set the US offset before the measurement so that calculation is performed based on the optically measured value. See “3.1.2 Opt tab” (page 135).
- When the A-constant is for optical measurement, it is necessary to set the optical offset before the measurement so that calculation is performed based on the BIO measured value. See “3.1.4 BIO tab” (page 137).

The difference between the axial length values in optical measurement and ultrasonic measurement is a cause of the difference between the constants for optical measurement and ultrasonic measurement. Because in ultrasonic measurement, measurement is performed by actual contact of the ultrasonic probe, it is considered that the eye is deformed by the applanation. As a result, the measurement value is usually shorter than the one measured by a non-contact optical measurement method. Because contact of the probe to the cornea has an influence on the measured value, the measured value slightly differs among operators. The optical offset can be specified for each operator using the AL-Scan.

[Example of deciding optical offset]

Measure axial length in optical measurement and BIO mode measurement multiple times for each operator to calculate the difference between the measured values.

Input the average of the difference (subtracting the BIO measured value from the optically measured value) as the optical offset for each operator.

[Example of deciding US offset]

Input the average value of the optical offsets for all the operators. However, set the sign to be the inverse of the optical offset.

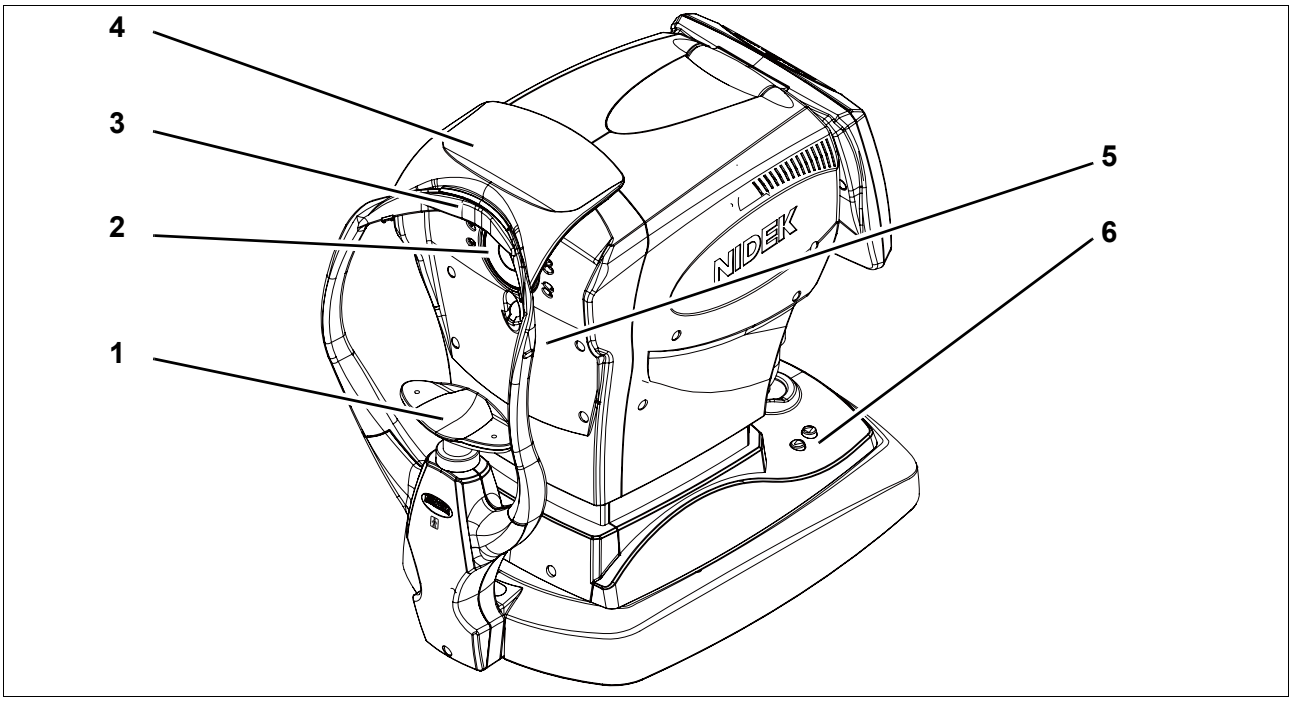
Example: If the optical offset is positive (+), the US offset is negative (-).

⚠ **CAUTION** • **When the IOL power has been calculated using an axial length value corrected using the AL offset, use of the calculation result needs to be decided by doctors after proper evaluation of the measurement result.**

The IOL formulas are designed on the precondition that the measurement value obtained using the same type of measurement method (optical/ultrasonic) as the constant unique to each IOL (A-constant and such). When the IOL power has been calculated using an axial length value corrected using the AL offset, decide whether or not to use the calculated IOL power taking that into consideration.

1.9 Device Configuration

○ Patient's side



1. Chinrest

During measurement, the patient's chin should rest on the chinrest.

Clean the chinrest for each patient.

2. Measuring window

Performs optical measurement.

Check the window cleanliness before optical measurement.

3. Forehead rest

During measurement, the patient's forehead should gently rest against the forehead rest.

Clean the forehead rest for each patient.

4. Shading plate

Blocks interference light.

Do not place any objects on the shading plate.

5. Eye level marker

Used as a guide for the patient's eye level during measurement.

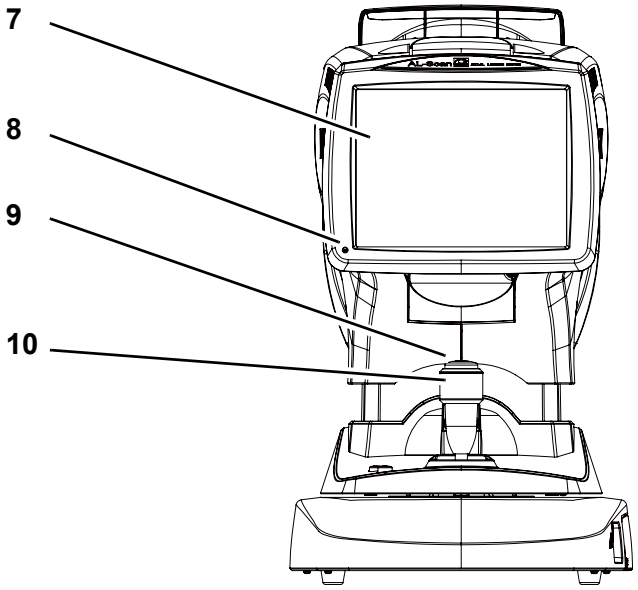
The height of the chinrest should be adjusted so that the center level of the patient's eye roughly aligns with this line.

6. Chinrest up/down button (▲ , ▼)

Moves the chinrest up or down (▲ : Up, ▼ : Down).

In the optional BIO or Pachy mode measurement, the buttons are used to adjust the gain (see page 73 and 84).

○ Operator's side



7. LCD touch screen

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

Pulling the bottom of the display panel provides an adjustable viewing angle. When performing measurement while standing, tilt the screen for the operator's convenience. To lower the raised display panel, lift the panel further to the upper limit, then release it.
The panel is held in its original position by magnet.

8. Pilot lamp

Illuminates when the power is supplied to the device and blinks in sleep mode.

9. Start button

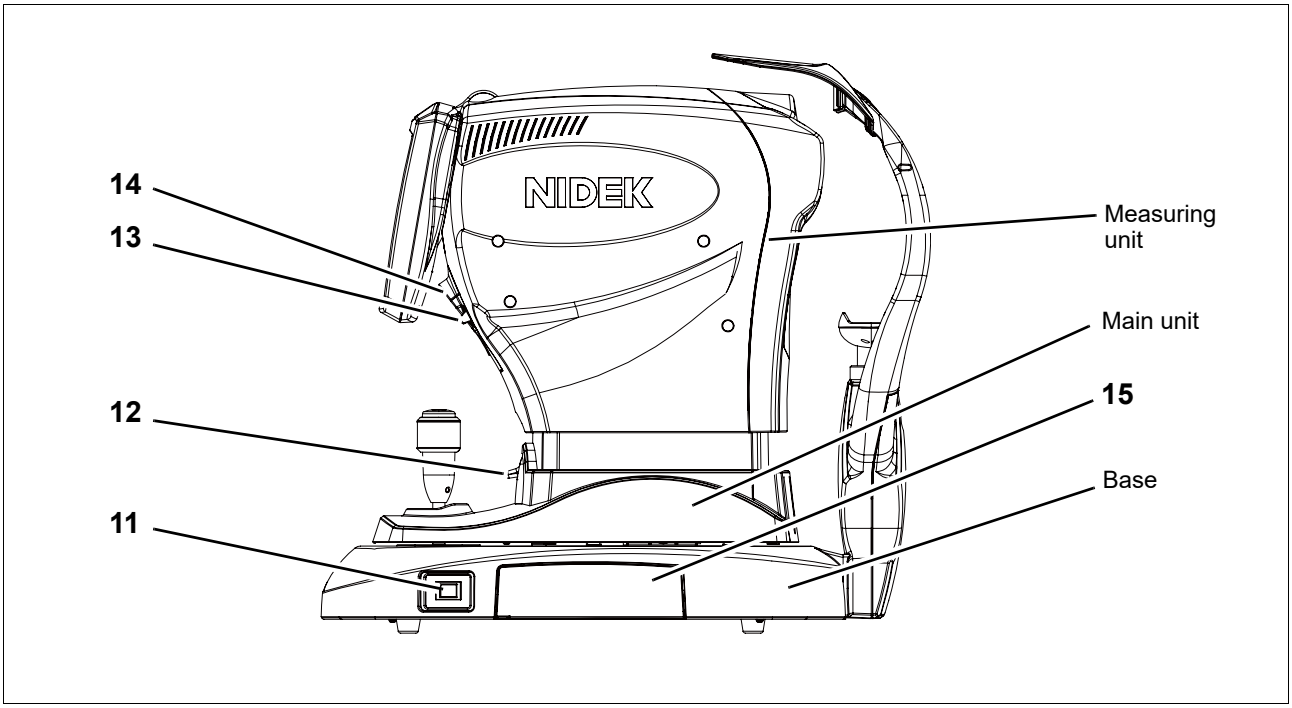
Starts measurement irrespective of alignment and focusing condition.

10. Joystick

Used for adjustment and focusing.

Alignment in the side-to-side direction can be performed by moving the joystick to the right and left. Rotating the joystick is for alignment in the up-and-down direction. For focusing, move the joystick forward and backward. Rotating the joystick moves the gate in the optional BIO mode measurement (see page 79) and the measurement point in the optional Pachy mode measurement.

○ Right side as viewed from operator's side



11. Power switch

Turns on or off power to the device.

12. Locking lever

Secures the main unit to the base.

To lock the main unit, press the locking lever down.

13. Cover open button

Opens the printer cover.

14. Printer cover

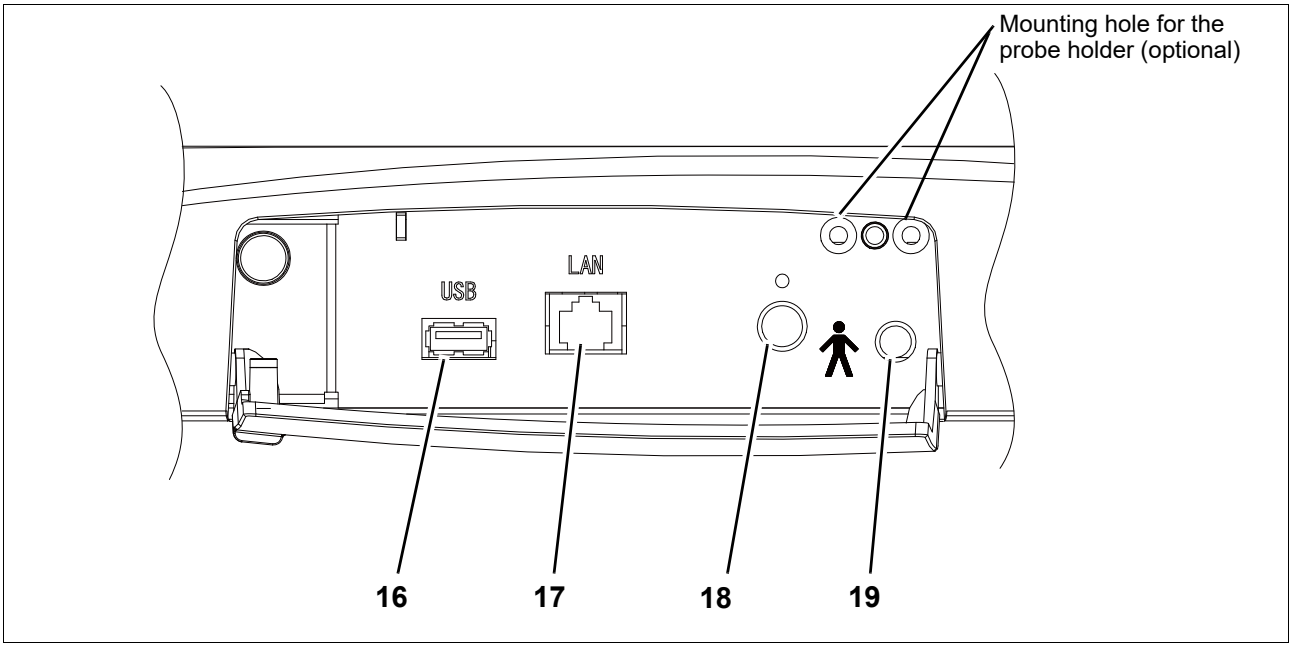
Protects a printer equipped with an auto cutter. Open the printer cover to replace printer paper by pressing the cover open button.

15. Side panel cover

Protects a side panel.

Pushing down the tab in the lower left corner opens the cover.

○ Side panel



16. USB port

Used to backup database and device parameters by connecting a USB flash drive to this port.

ID information can be entered by connecting barcode reader to this port.

For precaution during connection, see “ During use” (page VIII).

Note

- Operation check for all the devices supporting USB connection is not necessarily performed. Therefore, operation of all the devices supporting USB connection is not necessarily ensured.

17. LAN port

By connecting a LAN cable, the data can be exported to an external computer with a LAN connection.

Nidek service personnel sets the LAN connection with permission from the network administrator of the facility. Be sure to turn off the power of each device before connection (see “ Before use” (page V) and “ During use” (page VIII)).

18. Connector (BIO)

Mounted on the AL-Scan equipped with the optional ultrasonic measurement function.

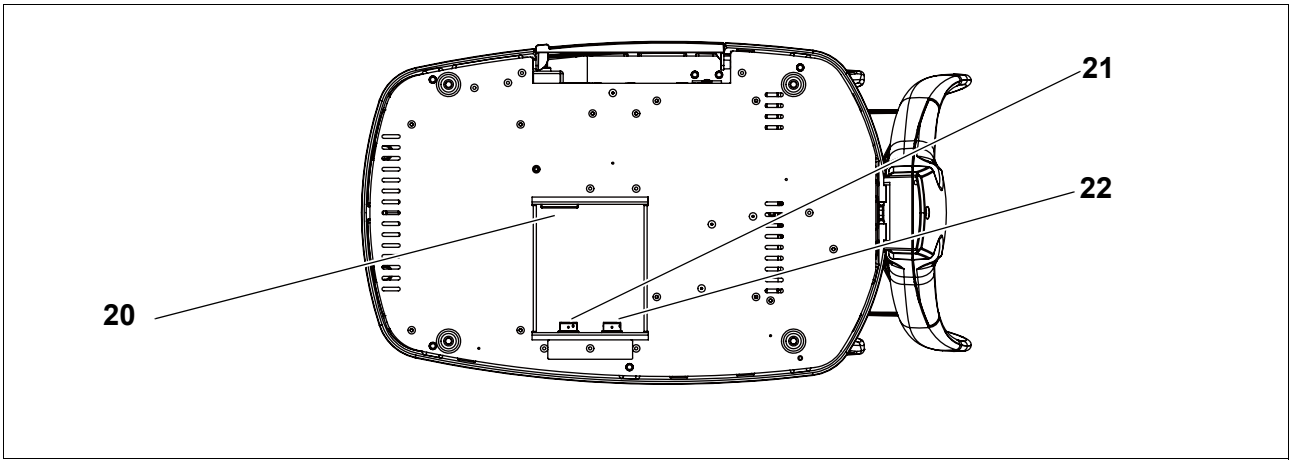
It is used to connect the A-scan probe.

19. Connector (P)

Mounted on the AL-Scan equipped with the optional ultrasonic measurement function.

It is used to connect the pachymetry probe.

○ Underside view



20. Power inlet

A power cord is connected here.

21. Foot switch connector ( )

Mounted on the AL-Scan equipped with the optional ultrasonic measurement function.

The cable plug of the optional foot switch is connected here.

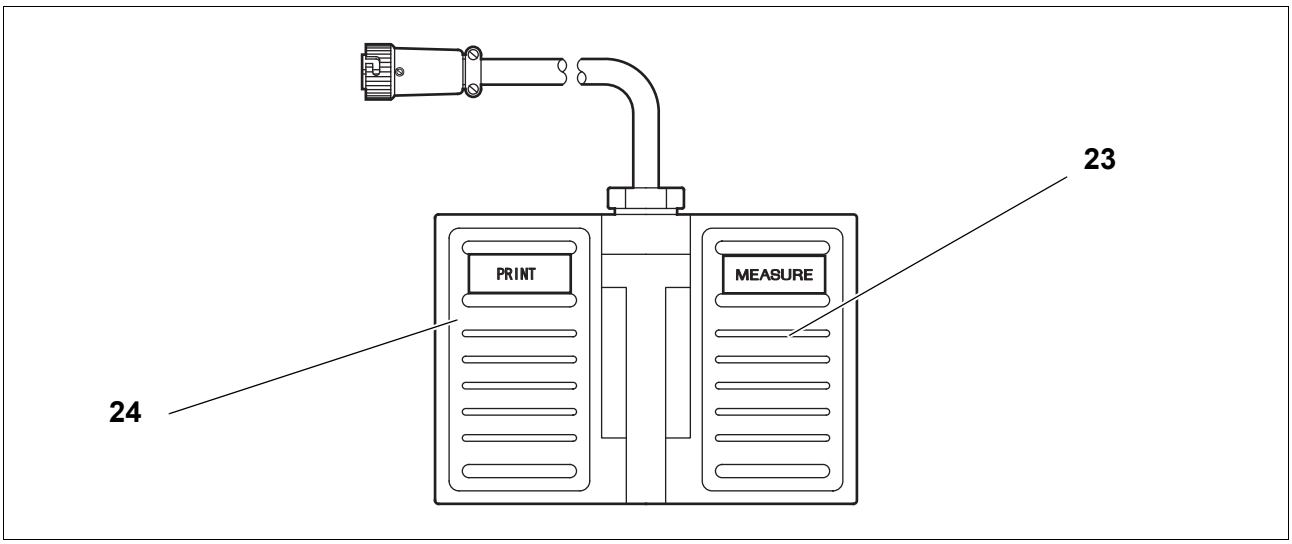
22. External fixation lamp connector ( )

Mounted on the AL-Scan equipped with the optional ultrasonic measurement function.

When using the optional probe stand, the fixation lamp cable is connected here.

○ Foot switch (optional)

Used for optional ultrasonic measurement only. The foot switch does not function in the screens that pertain to optical measurement.



23. MEASURE switch

Used to start or stop the BIO or Pachy mode measurement.

24. PRINT switch

Switches the data capture methods (Auto, SemiAuto, Speedy, or Manual) in the BIO mode screen.

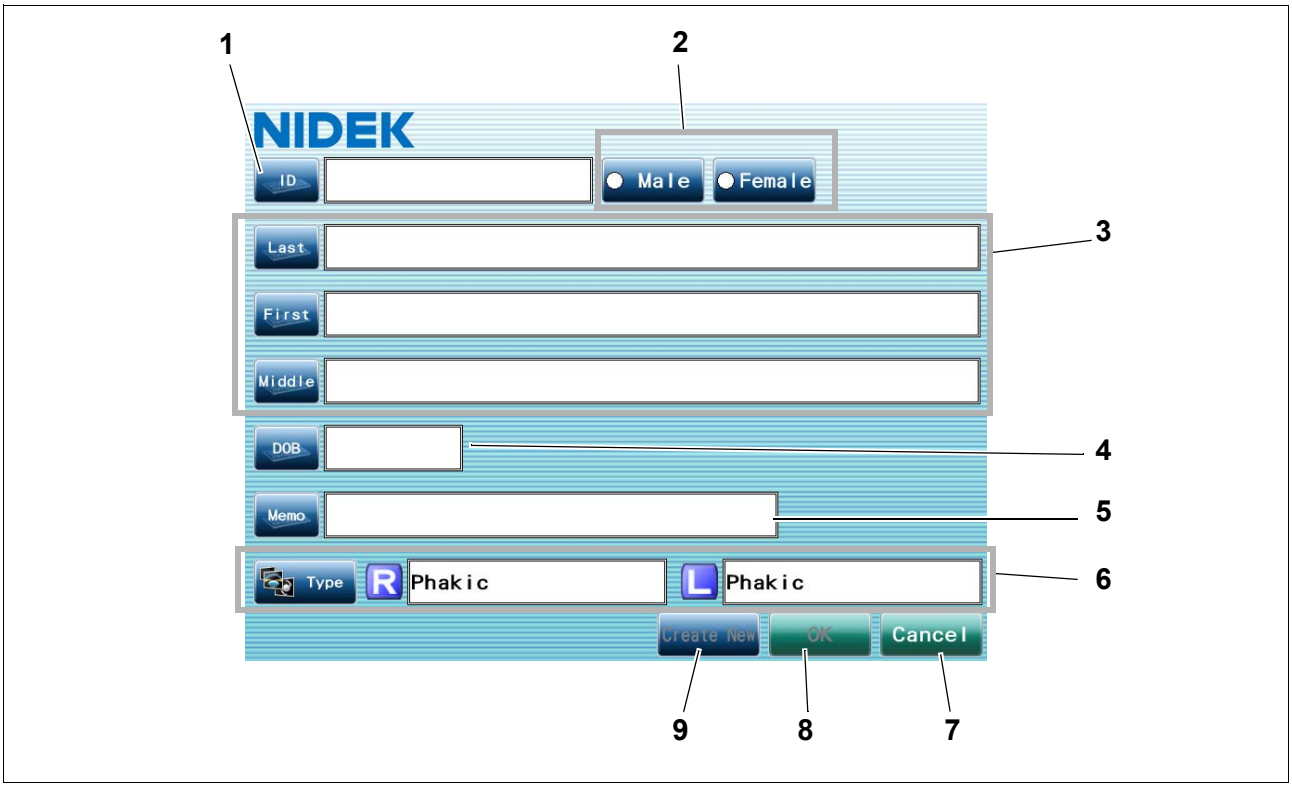
The switch moves the measurement point in the Pachy mode screen.

However, when the Print button is displayed in the screen that pertains to the BIO or Pachy mode measurement, the PRINT switch functions as the Print button.

1.10 Screen Configuration

○ Patient information screen

The patient information is input in this screen. The patient information can be deleted or edited as well. Be sure to input the ID and the type of the eye to be measured before measurement.



1. ID button / entry field

Pressing this button displays the keyboard window to input the patient's ID.

Checking the Auto ID box in the Other tab automatically assigns ID numbers in numerical order. See "3.1.9 Other tab" (page 157).

2. Male/Female button

Pressing either button selects the patient's sex.

3. Name buttons / entry field

Pressing any button displays the keyboard window to input the patient's name.

Input the patient's first and last names, and the middle name if necessary.

4. DOB button / entry field

Pressing this button displays the numeric keypad window to input the patient's birth date.

Input it in the format set by the Date Format parameter. See"3.1.9 Other tab" (page 157).

5. Memo button / entry field

Pressing this button displays the keyboard window to fill in the Memo box if necessary.

6. Type button / entry fields

Pressing this button displays the Eye Type window to select the conditions of the right and left eyes to be measured.

7. Cancel button

Pressing this button displays the Patient List screen without registering the input patient information on the patient information screen.

8. OK button

Pressing this button registers the input patient information on the Patient List and displays the optical measurement screen.

This button becomes enabled after the ID has been input.

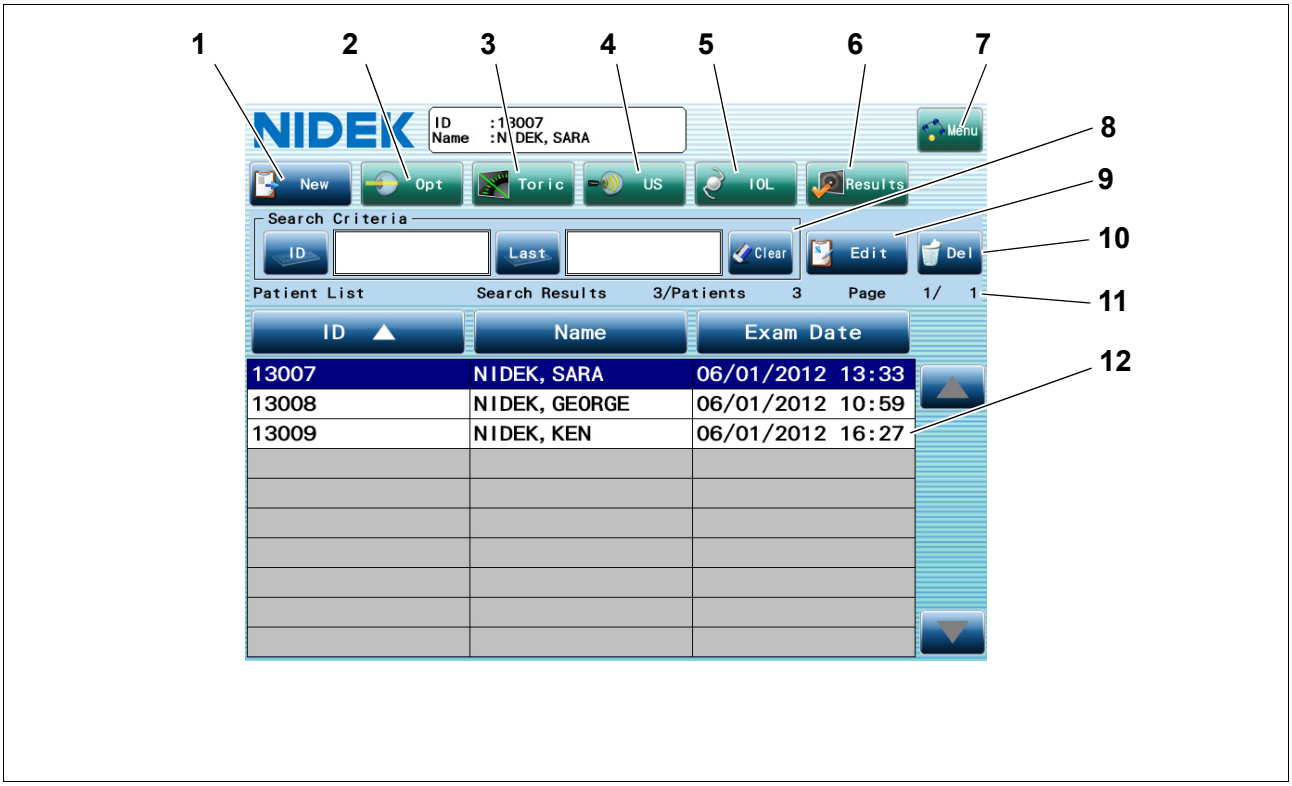
9. Create New button

Pressing this button registers the input patient information on the Patient List and displays the patient information screen for the next patient.

This button becomes enabled after the ID has been input.

○ Patient List screen

The desired patient for measurement or IOL calculation can be selected from the screen.



1. New button

Used to create new patient information.

The patient information screen is displayed. Input new patient information.

2. Opt button

Used to move to the optical measurement screen.

The measurement is performed for the patient being selected in the Patient List.

3. Toric button

Used to move to the toric lens assist mode screen.

The measurement is performed for the patient being selected in the Patient List.

4. US button

Used to move to the screen for ultrasonic measurement.

The measurement is performed for the patient being selected in the Patient List.

This button is not displayed at the time of shipment. It is displayed after calibration of the ultrasonic probes is complete for the AL-Scan equipped with the optional ultrasonic measurement function.

5. IOL button

Used to move to the IOL power calculation screen.

The power of an IOL to be implanted to the patient being selected in the Patient List is calculated.

6. Results button

Used to move to the result screen.

The measured result or calculated result is displayed for the patient being selected in the Patient List.

7. Menu button

Used to display the Menu window.

8. Search Criteria field

Used to display data sets that meet the criteria entered in the ID and Last boxes. If multiple search criteria are entered, the AND search is executed.

ID button: Displays the keyboard window for inputting the ID.

Data sets with the patient ID beginning with the entered ID number are displayed in the Patient List.

Last button: Displays the keyboard window for inputting the last name.

Data sets with the last name beginning with the entered character(s) are displayed in the Patient List.

When the setting for the Name parameter is “F L MI.”, this button becomes the First button.

Clear button: Clears the entered search criteria.

9. Edit button

Used to edit patient information.

The patient information screen is displayed. Edit information of the patient being selected in the Patient List.

10. Del button

Used to delete all the patient data being selected in the Patient List.

11. Patient List status

Indicates the status of the data sets displayed in the Patient List.

Search Results: The number of the patients extracted under the search criteria

Patients: The number of all the registered patients

Page: The page of the displayed patient list / the total number of pages

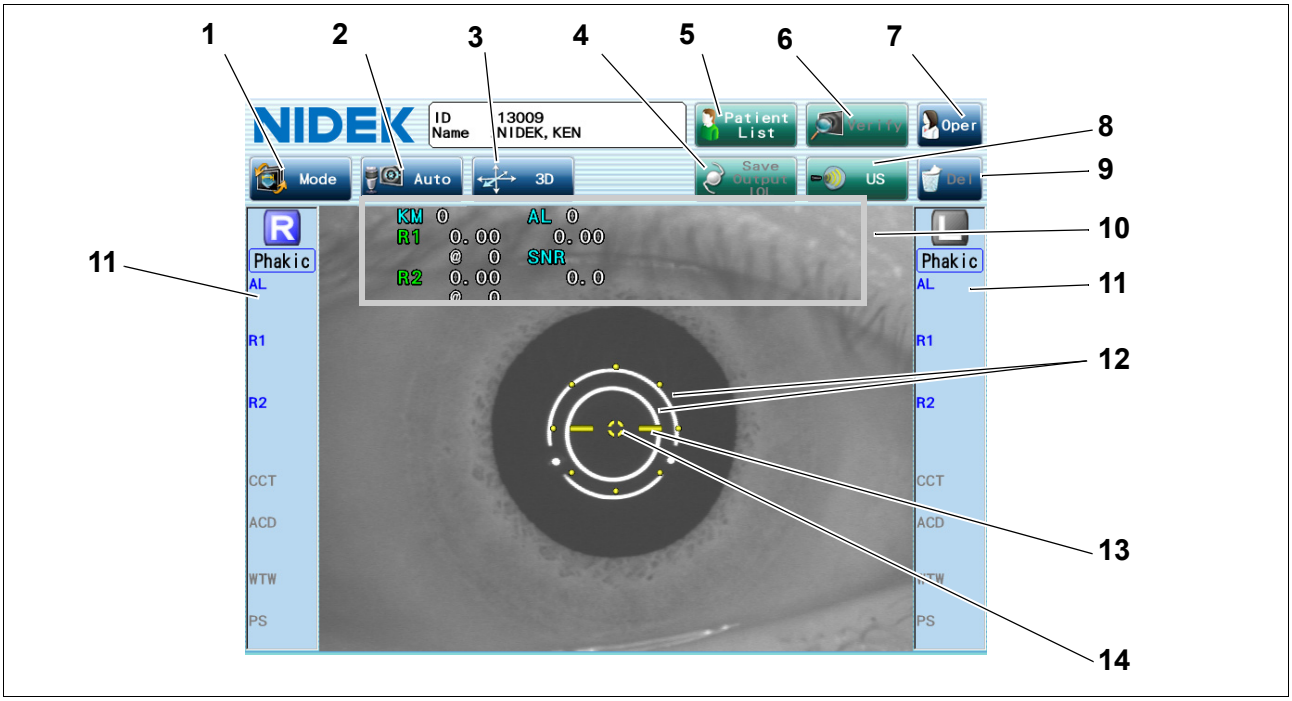
12. Patient List

Shows the registered patients. Select the line of the patient to perform the measurement or calculation.

Pressing the item at the top of the Patient List (ID, Name, and Exam Date) sorts the data sets in ascending order of the item, and pressing the item again sorts the data sets in descending order of the item.  or  adjacent to the item name indicates that the data sets are sorted in ascending () or descending () order of the item. If there are many patient data sets, press the  or  button to scroll the page up or down. Pressing and holding the  or  button scrolls the page up or down continuously.

○ Optical measurement screen

Optical measurement is performed in the screen.



1. Mode button

Displays the Measurement Mode window to select the measurement item.

2. Auto shot button

Used to toggle the auto shot function (that automatically starts measurement when proper vertical and horizontal alignment and focus to the patient eye is achieved) between on and off.

Auto: The auto shot function is enabled.
Manual: The auto shot function is disabled.

3. Tracking button

Used to toggle the auto tracking function (that automatically performs alignment to the patient eye) between on and off.

See “○ Auto tracking function (Page 60)”.

3D: The auto tracking function in the forward and back, right and left, and up and down directions is enabled.
2D: The auto tracking function in the right and left, and up and down directions is enabled. The focus is manually adjusted.
OFF: The auto tracking function is disabled. The alignment and focusing are manually performed.

4. Save Output IOL button

Used to finalize and save the measured data being displayed, then move to the IOL power calculation screen to calculate the IOL power.

It is possible to set the parameter so that the displayed measured value is printed and output to another device. This button becomes enabled after measurement.
When the “Measurement Print Mode”, “Network Mode”, and “USB Mode” parameters are set to Manual, the button indication becomes Save IOL button.

5. Patient List button

Pressing this button displays the Patient List screen.

6. Verify button

Used to move to the measured value confirmation screen.

This button becomes enabled after measurement.

7. Oper button

Displays the Operator List window to select the operator.

8. US button

Used to move to the screen for ultrasonic measurement.

The measurement is performed for the patient being displayed in the upper part of the screen.

9. Del button

Used to delete the measurement data being displayed. The measurement data of ultrasonic measurement is not deleted.

10. Latest data display

Displays the latest measurement data.

When each measurement is complete, the measured values disappear, then “Fin” appears to the right of KM, AL, CCT, ACD, WTW, and PS (“!” in yellow appears if the measurement was failed).

Note

- The value following the @ mark on the screen and printed data indicates the axis angle (unit: °).

11. Measured results of right and left eyes

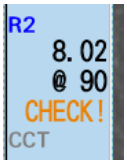
When the right eye is aligned, the background of “R” is blue, and that of “L” is gray. When the left eye is aligned, the background of “L” is blue, and that of “R” is gray. Moving the main unit to the right and left using the joystick switches the background color of “R” and “L” between blue and gray along with the measured eye.

The measured results of the right and left eyes are displayed.

The KM measured values (R1, R2) indicate the median values, the AL measured value indicates the peak value detected by combining all the waveforms (combined wave value), and the other values indicate the average values.

The numbers displayed next to “AL”, “R1”, “CCT”, and “ACD” indicate the number of times of measurement.

If the measured results of AL, KM, or ACD greatly vary, a message “CHECK!” prompting the operator to check the measured results appears.



12. Mire rings

Used as alignment reference rings.

When the auto tracking function is on (3D or 2D), bringing the mire rings close to the alignment target automatically starts alignment.

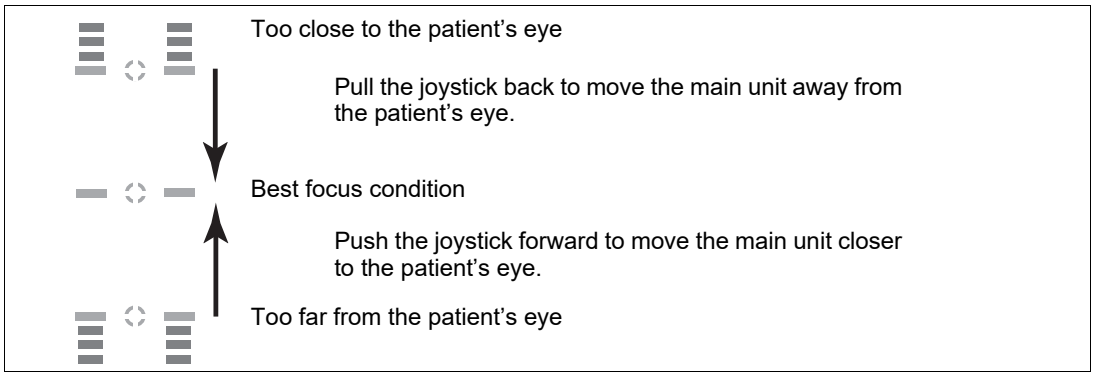
When the auto tracking function is off, align the mire rings to the alignment target.

If eyelid or eyelashes cover the mire rings, KM measurement cannot be performed.

13. Focusing indicator

Indicates the distance between the measurement unit and the eye to be measured.

Manipulate the joystick until the (▬ ⛶ ▬) mark indicates that focus is proper.

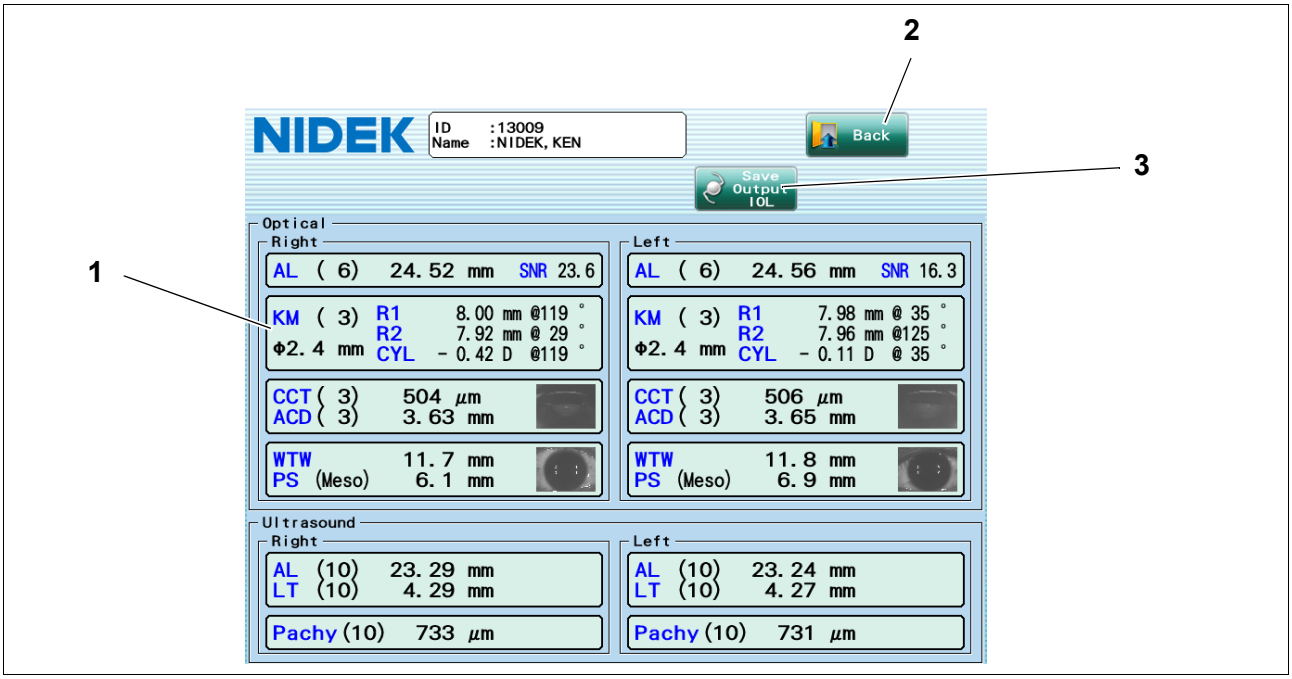


14. Alignment target

Used as a guide to center the eye to be measured on the screen. When performing alignment manually, align the mire rings center to the alignment target.

○ Measured result confirmation screen

Measured values are confirmed in the screen.



1. Measured value

Displays the measured values of the right and left eyes.

The KM measured values indicate the median values, the AL value indicates combined wave value, the BIO values indicate the average or selected value, and the other values indicate the average values.
The numbers in the parentheses indicate the numbers of times of measurement.
Pressing the field of each measured item displays the detail of the measured value.

AL: Axial length measured value
KM: KM measured value
SNR: Proportion of noise to signal
R1 (K1): Corneal curvature radius (corneal refractive power) and axis angle along the flattest meridian
R2 (K2): Corneal curvature radius (corneal refractive power) and axis angle along the steepest meridian
(Or AVG: Average of R1 and R2)
CYL: Corneal cylindrical power (D) and corneal cylinder axis angle
ø2.4 mm is the measurement area.
CCT: Central corneal thickness
ACD: Anterior chamber depth
WTW: White-to-white
PS (Meso): Pupil size while the illumination is turned off, PS (Photo): Pupil size while the illumination is turned on
LT: Lens thickness
Pachy: Corneal thickness measured value

2. Back button

Used to return to the measurement screen.

3. Save Output IOL button

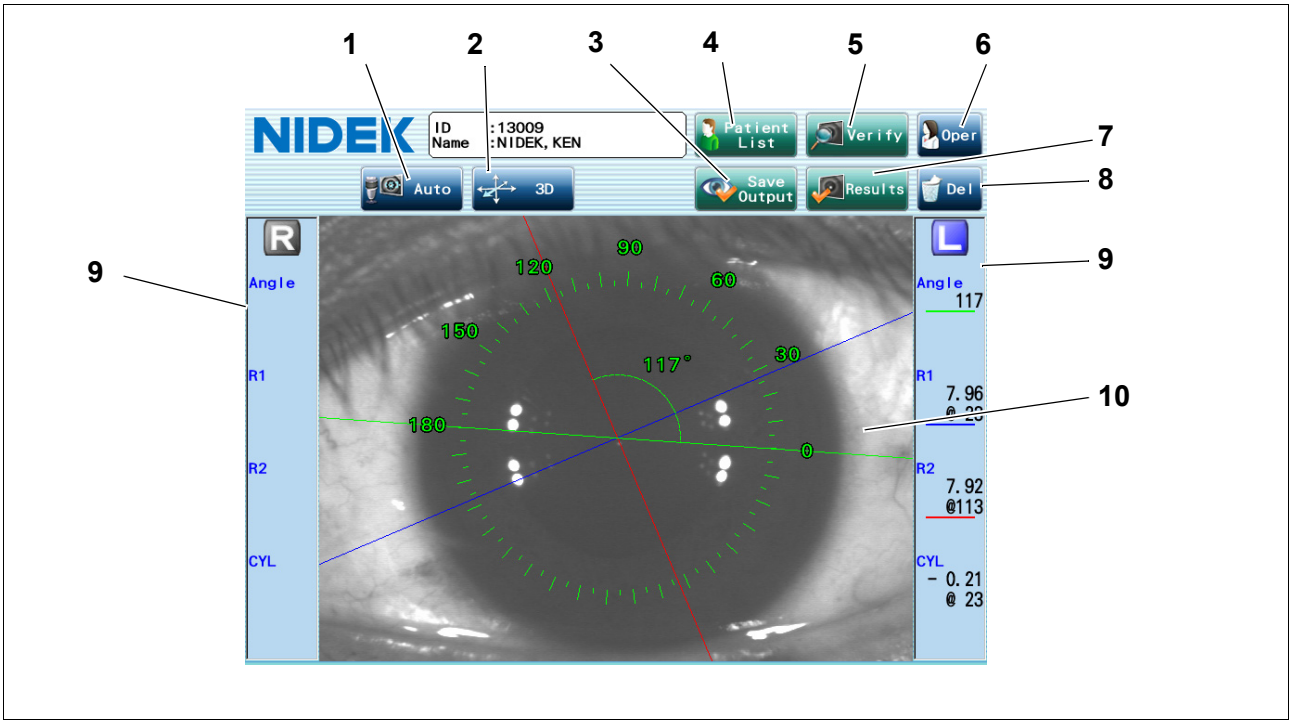
Used to finalize and save the measured data being displayed, then move to the IOL power calculation screen to calculate the IOL power.

It is possible to set the parameter so that the displayed measured values are printed and output to another device.

When the “Measurement Print Mode”, “Network Mode”, and “USB Mode” parameters are set to Manual, the button indication becomes Save IOL button.

○ Toric lens assist mode screen

Toric lens angle measurement useful for toric IOL implantation is performed in the screen.



1. Auto shot button

Used to toggle the auto shot function (that automatically starts measurement when proper vertical and horizontal alignment and focus to the patient eye is achieved) between on and off.

Auto: The auto shot function is enabled.
Manual: The auto shot function is disabled.

2. Tracking button

Used to toggle the auto tracking function (that automatically performs alignment to the patient eye) between on and off.

3D: The auto tracking function in the forward and back, right and left, and up and down directions is enabled.
2D: The auto tracking function in the right and left, and up and down directions is enabled. The focus is manually adjusted.
Manual: The auto tracking function is disabled. The alignment and focusing are manually performed.

3. Save Output button

Used to save the measured results. When the printing is enabled, the measured results are printed as well. After the measured results are saved, the screen returns to the Patient List screen.

This button is enabled after the measurement.
When the “Measurement Print Mode”, “Network Mode”, and “USB Mode” parameters are set to Manual, the button indication becomes “Save”.

4. Patient List button

Pressing this button displays the Patient List screen.

5. Verify button

Used to move to the screen to verify the KM values in detail.

This button becomes enabled after measurement.

6. Oper button

Displays the Operator List window to select the operator.

7. Results button

Used to move to the toric lens assist mode result screen.

Pressing this button displays the saved measurement result data. Pressing this button during measurement deletes the data of unfinished measurement.

8. Del button

Used to delete the measurement data being displayed.

9. Measured result

Displays the measured results of the right and left eyes.

"Angle" is the angle between the steepest meridian and the angle reference line.
The KM measured values (R1, R2, and CYL) indicate the median values.

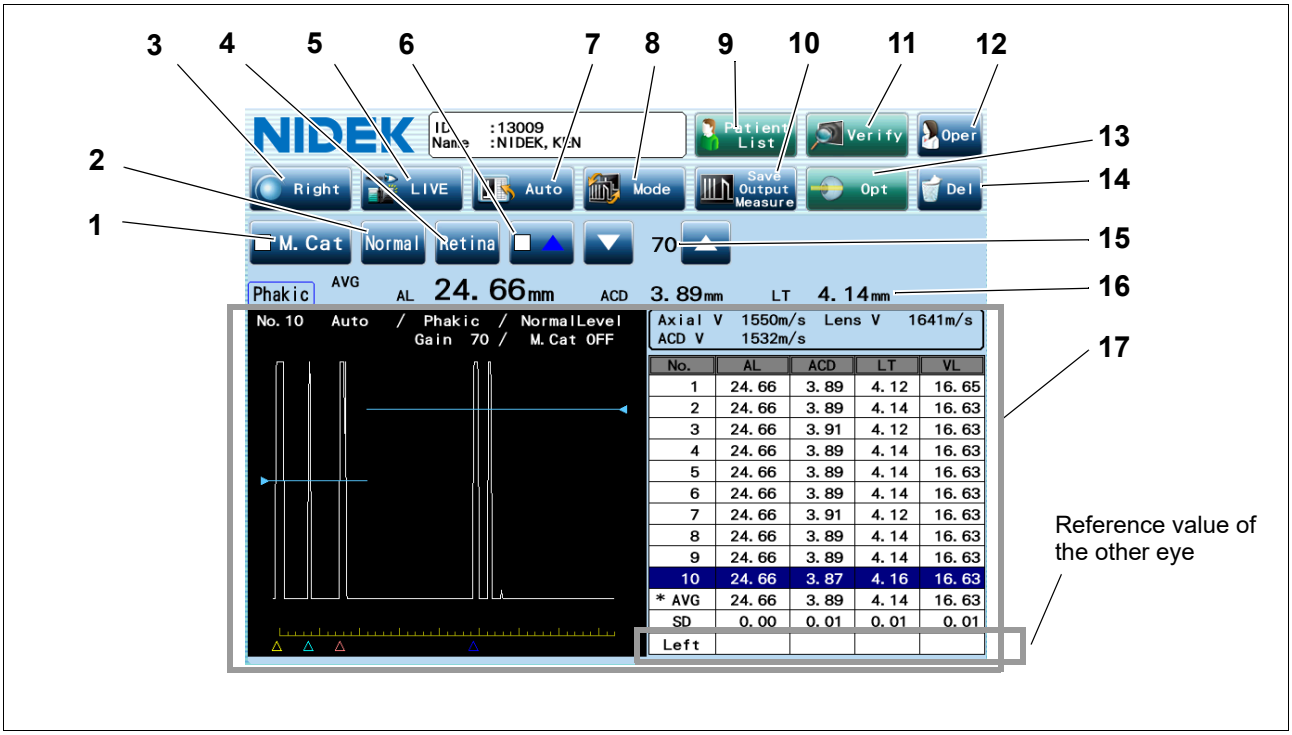
10. Anterior eye segment image

An anterior eye segment image is overlaid with the steepest/flattest meridian and the angle reference line.

Red line: The steepest meridian
Blue line: The flattest meridian
Green line: The angle reference line
Aligning the angle reference line (green line) with the markers displays the angle between the angle reference line and the steepest meridian.

○ BIO mode screen

Axial length measurement with ultrasonic measurement function is performed in the screen.



1. M. Cat button

When eyes with mature cataract are measured, pressing this button checks the box and enables the button.

The parameters are changed as follows: Threshold to “Flat Low”, gain to 100%, axial velocity to 1,548 m/s, and lens velocity to 1,629 m/s. The velocities are changed as specified in the Parameter Settings screen.

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

2. Threshold button

Used to change the programmed threshold which automatically determines the acceptability of the measured value of each intraocular part.

Each time the button is pressed, the threshold indication on the button 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”.

3. Right/Left button

Used to specify the right or left eye to be measured.

4. Gate button

Used to select the desired gate. Four gate types are available: Cornea, Ant-lens (anterior), Post-lens (posterior), and Retina.

5. LIVE/FREEZE button

Used to start or stop the BIO mode measurement.

The BIO mode measurement can be started or stopped also with the foot switch or start button.

The indication of the button becomes “FREEZE” during measurement.

6. Gate display button

Used to toggle display of each gate between ON and OFF. Pressing this button checks the box and enables the button.

7. Capture mode button

Used to select the data capture method.

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

SemiAuto: The operator 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 operator determines the time to start and complete the measurement.

8. Mode button

Used to display the Measurement Mode window.

Select “Pachy” on the Measurement Mode window to measure corneal thickness with ultrasonic measurement function.

9. Patient List button

Pressing this button displays the Patient List screen.

10. Save Output Measure button

Used to save the BIO measured data and clears the data on the screen. This allows measurement to be continued on the same patient.

It is possible to set the parameter so that the displayed measured values are printed and output to another device.

When the “Measurement Print Mode”, “Network Mode”, and “USB Mode” parameters are set to Manual, the button indication becomes Save Measure button.

11. Verify button

Used to move to the measured value confirmation screen.

This button becomes enabled after measurement.

12. Oper button

Displays the Operator List window to select the operator.

This button is disabled during measurement.

13. Opt button

Used to move to the optical measurement screen.

The measurement is performed for the patient being displayed in the upper part of the screen.

14. Del button

Used to delete the measurement data of both eyes.

15. Gain display

Displays the gain during the BIO mode measurement.

Pressing the  /  button on the both side or the chinrest up/down button ( , ) adjusts the gain.

16. Median values

Displays the median values of the axial length, anterior chamber depth, and lens thickness.

17. Measured result

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.

The waveform used to calculate the measured value being displayed inverted in the list is displayed to the left.

Whenever the measurement data is obtained, the average (AVG) and standard deviation (SD) in the list are calculated and indicated.

The measured values of the eye opposite to the eye being measured are displayed as reference values at the bottom of the list (the line is blank if the other eye has not been measured).

*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	Displayed	Displayed	Depend on the situation[a]	Depend on the situation[a]
Aphakic	Displayed	Not displayed	Not displayed	Not displayed
Acrylic IOL Silicone IOL PMMA IOL	Displayed	Displayed	Not displayed	Displayed

a. Those measurement values may not be displayed when the M. Cat button is on.

Note

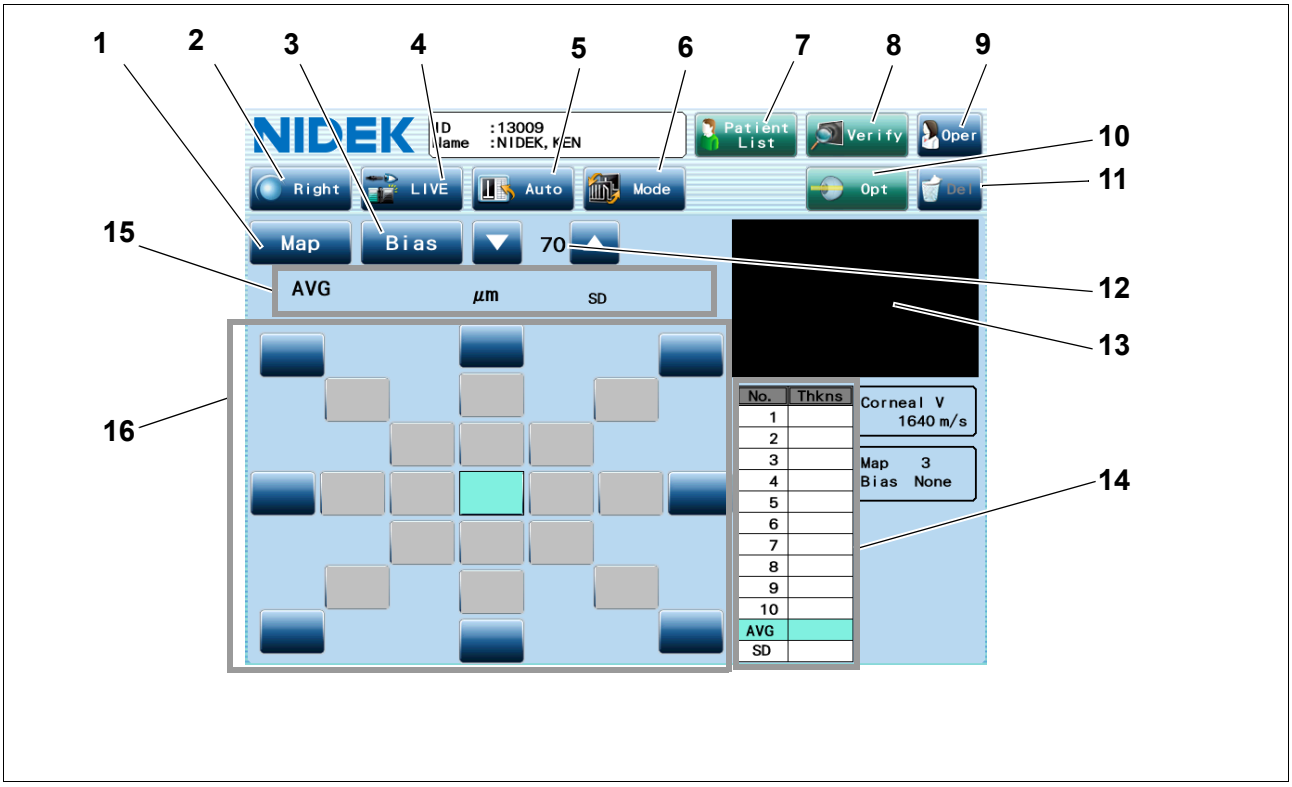
- The waveform displayed in “17. Measured result” is not necessarily the same waveform as “16. Median values”.

  The waveform displayed in “17. Measured result” is that for the measured value displayed in reverse font.

  “16. Median values” are the measured values displayed with an asterisk in the No. field of the list. (The default setting is the average value, and the value to be displayed can be selected in the measured result details screen (see page 76).)

○ Pachy mode screen

Corneal thickness measurement with ultrasonic measurement function is performed in the screen.



1. Map button

Displays the Map window to select the measurement map.

Six types of measurement map are available from No. 1 to 6.

2. Right/Left button

Used to specify the right or left eye to be measured.

3. Bias button

Displays the Bias window to select the bias for the measured value.

4. LIVE/FREEZE button

Used to start or stop the Pachy mode measurement.

The Pachy mode measurement can be started or stopped also with the foot switch or start button.

The indication of the button becomes “FREEZE” during measurement.

5. Capture mode button

Used to select the data capture method.

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

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

6. Mode button

Used to display the Measurement Mode window.

Select “BIO” on the Measurement Mode window to measure axial length with ultrasonic measurement function.

7. Patient List button

Pressing this button displays the Patient List screen.

8. Verify button

Used to move to the measured value confirmation screen.

This button becomes enabled after measurement.

9. Oper button

Displays the Operator List window to select the operator.

10. Opt button

Used to move to the optical measurement screen.

The measurement is performed for the patient being displayed in the upper part of the screen.

11. Del button

Used to delete the measurement data of both eyes.

12. Gain display

Displays the gain during the Pachy mode measurement.

Pressing the / button on the both side or the chinrest up/down button (,) adjusts the gain.

13. Waveform display area

Displays the waveform during the Pachy mode measurement.

14. Measured value list

Displays the corneal thickness at the specified measurement point.

The measured values and their average (AVG) and standard deviation (SD) are displayed.

15. Corneal thickness display

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

16. Measurement point display

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

The measurable areas are highlighted in dark blue, and the measurement point is highlighted in light blue.
The measurement point also can be moved by rotating the joystick.

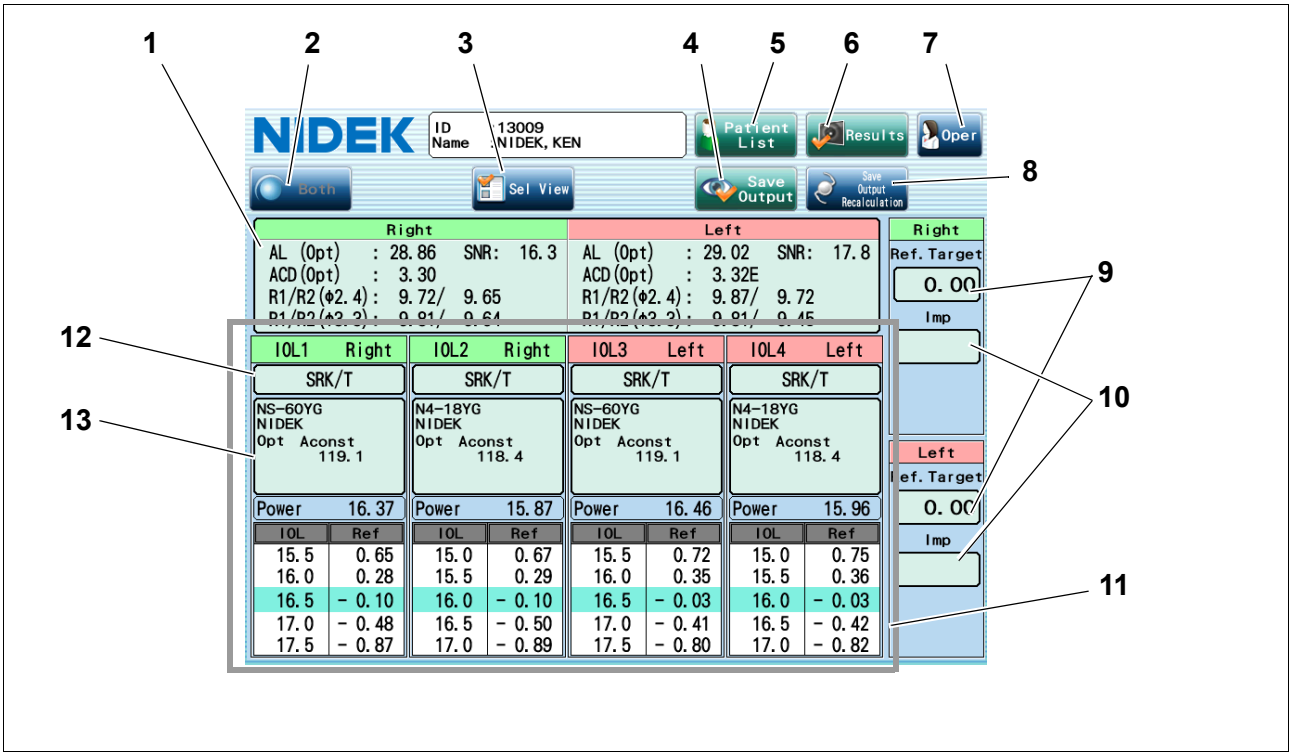
Note

- The average of the measured values for the measurement point displayed in light blue in the “16. Measurement point display” is displayed in “15. Corneal thickness display” and is used as the median value.

  Unless the measured value for the desired measurement point is specified as the median value, the average value for the point measured last is used as the median value.

○ IOL power calculation screen

IOL power is calculated in the screen.



1. Measured result

Displays measured values to be used for IOL power calculation.

When using the values measured by other devices for calculation, press this field to display the Measured Values window.

2. Selected eye button

Indicates the eye for which single eye calculation results are displayed. Pressing this button switches the display to the calculation results of the other eye.

This button is disabled when both eye data is displayed.

3. Sel View button

Displays the Select View window to select the desired display setting of the calculated results.

4. Save Output button

Used to save the calculation results and to change the screen to the patient information screen.

It is possible to set the parameter so that the displayed calculated value is printed and output to another device. When the “Calculation Print Mode”, “Network Mode”, and “USB Mode” parameters are set to Manual, the button indication becomes “Save”.

5. Patient List button

Pressing this button displays the Patient List screen.

6. Results button

Used to return to the screen to the result screen.

7. Oper button

Displays the Operator List window to select the operator.

8. Save Output Recalculation button

Saves the calculation results.

After results are saved, only IOL model is cleared while other conditions are retained.
When the “Calculation Print Mode”, “Network Mode”, and “USB Mode” parameters are set to Manual, the button indication becomes Save Recalculation button.

9. Ref. Target field

Used to input the desired postoperative refraction.

10. Imp field

Pressing the button displays the Select Implant IOL window.

Selecting the IOL to be implanted displays the model name, manufacturer’s name, and power of the IOL.

11. Calculated result display area

Displays the calculated results of the IOL power when inputting the values necessary for calculation is complete. The IOL power close to the calculation result and expected postoperative refraction when the IOL is implanted are displayed for each IOL.

The expected postoperative refraction closest to the desired postoperative refraction is highlighted in light blue. If the IOL to be implanted is selected, the selected refraction is displayed in dark blue.

12. IOL Formula button

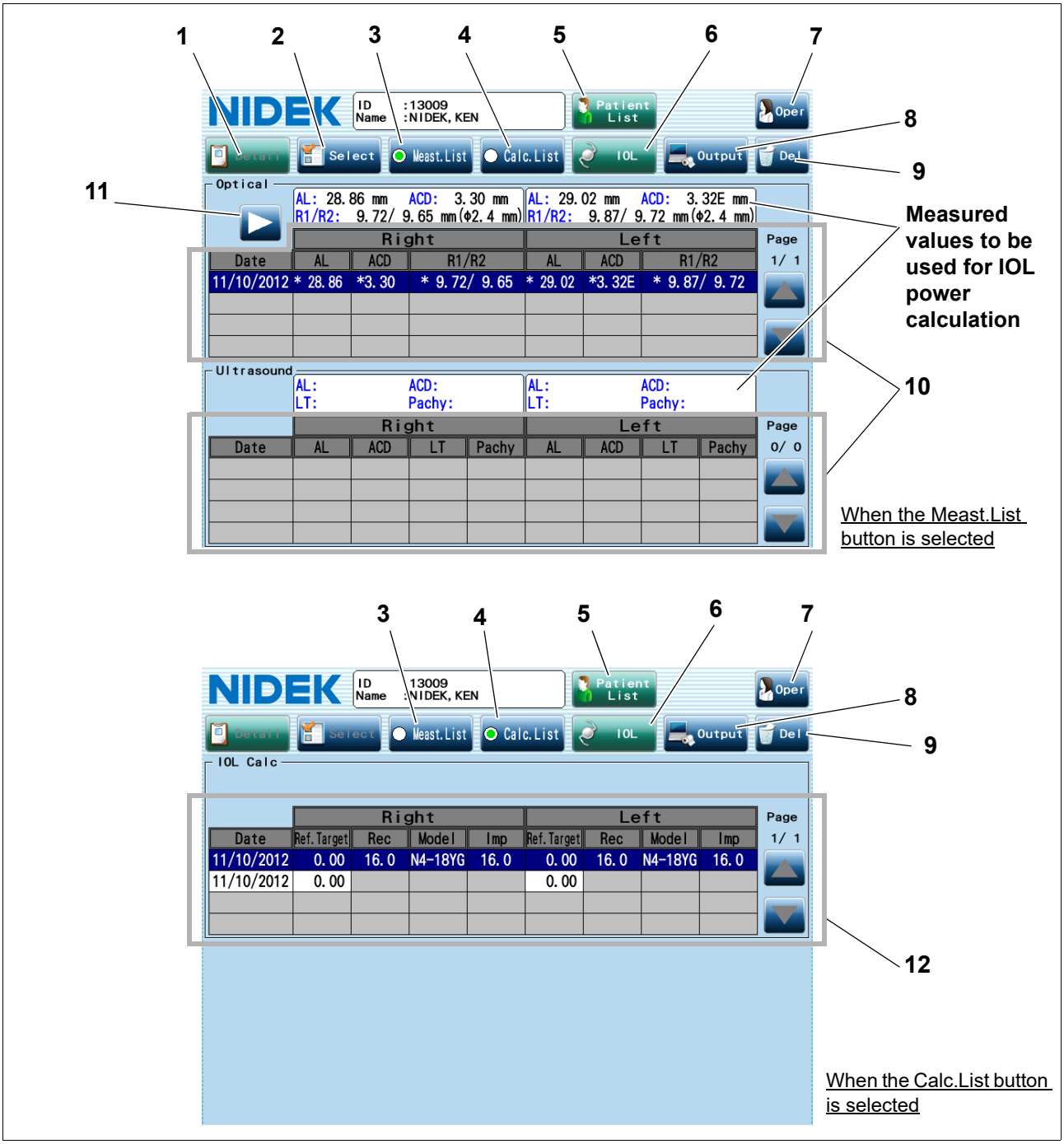
Displays the formula used for calculation. A formula can be selected by pressing this button.

13. IOL name button

Displays the IOL model, the constant used for calculation, and the value of AL offset if used. An IOL model can be selected by pressing this button.

○ Result screen

Measured results or IOL power calculation results are displayed in the screen.



1. Detail button

Displays the details of the item selected in the measured result list.

2. Select button

Used to make the measured value selected in the measured result list become a measured value to be used for IOL power calculation when there are multiple measured results.

The measured values to be used for IOL power calculation are displayed with an asterisk in the measured result list. Selecting one measured value with an asterisk changes the Select button to Clear button. Press the Clear button to remove the asterisk from the measured value.

3. Meast.List button

Displays measured result list.

4. Calc.List button

Displays IOL power calculation result list.

5. Patient List button

Pressing this button displays the Patient List screen.

6. IOL button

Used to move to the IOL power calculation screen.

Pressing the button in the screen when the Calc.List button is selected recalculates the IOL power.

7. Oper button

Used to check the operator.

8. Output button

Displays the Output window to print the measured results or calculated results or output the results through a LAN or USB flash drive.

The measured results or calculated results being selected in the list are printed or output.

9. Del button

Used to delete all data of the selected measured results. If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.

The saved optical and ultrasonic measurement results are deleted together.

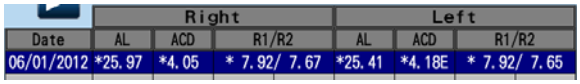
10. Measured result list

The measured results are listed. The measured value to be used for IOL power calculation is indicated with an asterisk.

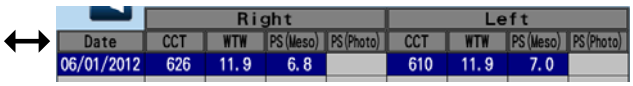
If there are many measured results, press the  or  button to scroll the page up or down.

11. Display button

Toggles the displayed items of optical measurement results.



	Right			Left		
Date	AL	ACD	R1/R2	AL	ACD	R1/R2
06/01/2012	*25.97	*4.05	* 7.92/ 7.67	*25.41	*4.18E	* 7.92/ 7.65



	Right				Left			
Date	CCT	WTW	PS(Meso)	PS(Photo)	CCT	WTW	PS(Meso)	PS(Photo)
06/01/2012	626	11.9	6.8		610	11.9	7.0	

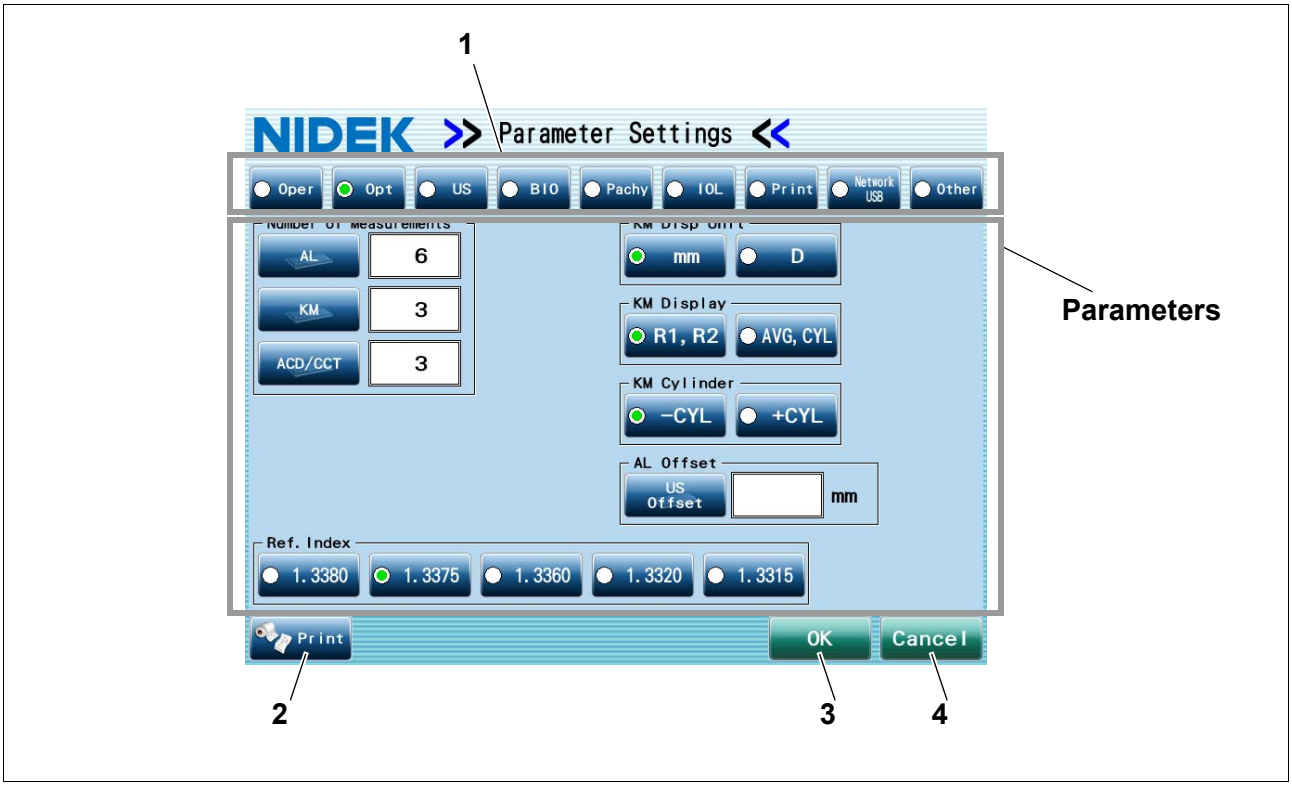
12. Calculated result list

The IOL power calculation results are listed.

If there are many calculated results, press the  or  button to scroll the page up or down.

○ Parameter Settings screen

The Parameter Settings screen allows setting of various parameters of the device.



1. Setting parameter tabs

Used to select the desired tab that contains the parameters to be changed.

See “3.1 Changing Device Parameters” (page 130).

2. Print button

Used to print the settings of all the parameters.

3. OK button

Saves the changed parameter settings, and the screen returns to the Patient List screen.

4. Cancel button

Cancels saving the changed parameter settings, and the screen returns to the Patient List screen. However, the settings specified in the IOL List window, IOL Settings screen, or View Pattern window are not canceled. These windows are accessed by pressing corresponding button in the IOL tab of the Parameter Settings screen.

1.11 Labels and Symbols

To call attention to users, labels and indications are provided on the device. If labels are peeling off, characters are fading, or otherwise becoming illegible, contact Nidek or your authorized distributor.

	Indicates that the operator is advised to refer to the related instructions and precautions in the operator's manual.
	Indicates that the degree of protection against electric shock is of a Type B Applied Part. The applied parts are chinrest, forehead rest, optional A-scan probe, and optional pachymetry probe (see **1**, **3**, **18**, and **19** in "1.9 Device Configuration" (page 8)).
	Indicates the state of the power switch. If this symbol side of the switch is pressed down, power is not supplied to the device.
	Indicates the state of the power switch. If this symbol side of the switch is pressed down, power is supplied to the device.
	Indicates that the device must be supplied only with alternating current.
	Indicates foot switch connector.
	Indicates the connector for the fixation lamp cable of the probe stand.
	Indicates that this product must be disposed of in a separate collection of electrical and electronic equipment in EU.
	Indicates the manufacturer.
	Indicates the date of manufacture.
MD	Medical device
EC REP	EU Authorized Representative
SN	Serial number
UDI	Unique Device Identifier
REF	Catalogue number

1.12 Packed Contents

Unpack the contents and check the items.

The following items are contained in the standard configuration:

- AL-Scan main body
- Printer paper (3 rolls)
- Power cord
- Dust cover
- Pack of chinrest paper
- Fixing pins for chinrest paper (2 units)
- Magnetic forehead rest pad (that does not come attached to the main body and is included in the packed contents)
- Shading plate
- Model eye (1set)
- Operator's manual
- Touch pen
- Pen stand

1.13 Before First Use

Place the device on a stable table and connect the power cord to it.

Note

- Avoid installing the device in the place where it is exposed to direct sunlight or directly under lighting equipment.
  Intense light entering the measuring window may interfere with proper measurement.
- Interference light may disrupt optical measurement depending on the illumination position. Confirm that measurement can be performed at the position to install the device.

1 Place the main body on a stable table.

2 Pull the main unit fully to the side on which the device is laid down, lock the main unit to the base unit with the locking lever and lay the device down gently.

3 Connect the power cord to the power inlet.

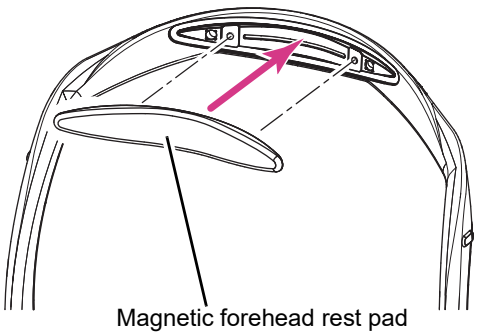
4 Connect peripheral devices if necessary.

5 Stand the device upright.

6 Attach the magnetic forehead rest pad to the device.

The magnetic forehead rest pad does not come attached to the main body and is included in the packed contents.

The magnetic forehead rest pad is attachable in the orientation as shown to the right.

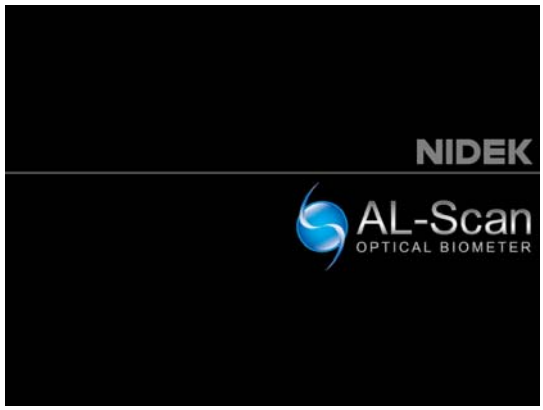


7 Confirm that the power switch is turned off (○) and plug the power cord into a wall outlet.

WARNING • **Be sure to use an outlet equipped with a ground terminal.**
Electric shock or fire may occur in the event of device malfunction or power leakage.

8 Turn on (|) the power switch.

The initial screen is displayed on the LCD screen and the device starts initializing.



9 The Model Eye window appears. Press the Close button or X button.

The Model Eye window is closed, then the patient information screen on the background appears.

The measurement date for the model eye at the factory is displayed in the Model Eye window.

10 Input the following items referring to “3.1 Changing Device Parameters” (page 130).

- □ Operator’s name (see page 134)
- □ Optical offset (for the device equipped with the optional ultrasonic measurement function only) (see page 137)
- □ US offset (see page 135)
- □IOL information (see page 143)

The general values are specified for the following items. Change the values if necessary.

- □ Refractive index (see page 135)
- □ Sonic velocity (for the device equipped with the optional ultrasonic measurement function only) (see Pages 137 to 139.)
- □ VD (see page 140)

Note

- The settings for all the items except IOL information, Optical offset, and US offset at the time are saved as well as the measured values. The settings cannot be changed after measurement. Be sure to input proper settings before measurement.

11 Set the printer paper.

See “5.3 Replacing Printer Paper” (page 210) for details on the setting procedure.

12 Attach the shading plate.

To attach the shading plate, see “1.14 Attaching Shading Plate” (page 40).

This completes setup procedure.

1.14 Attaching Shading Plate

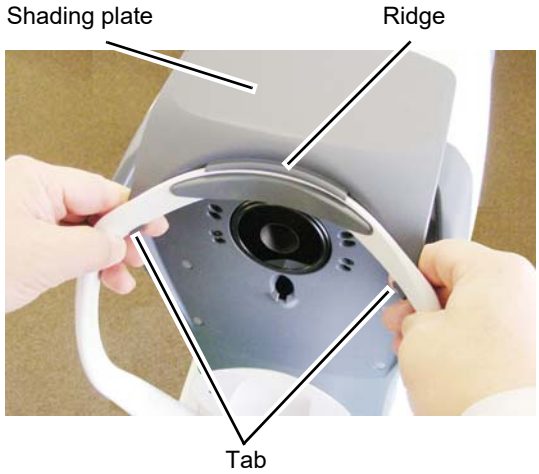
Interference light disrupts optical measurement of anterior chamber depth and central corneal thickness. To block interference light, attach the provided shading plate to the forehead rest.

Note

- The shading plate is detachable. Should the shading plate become detached, simply reattach it to the forehead rest.
- Interference light may disrupt optical measurement depending on the illumination position even if the shading plate is attached. In such a case, install the device in other place or dim the illumination.

1 Align the ridge in the middle of the shading plate with the top of the forehead rest.

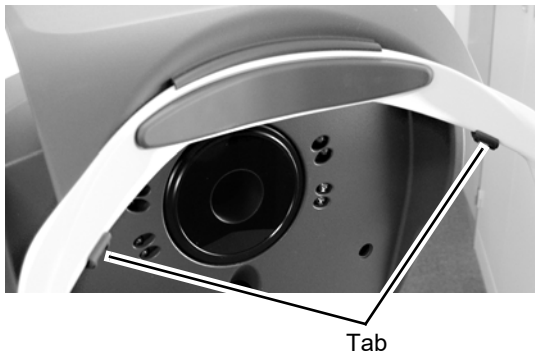
2 Push the both ends of the shading plate from the rear side to hook the tabs on the forehead rest.



○ Removing shading plate

Remove the shading plate if necessary (for example, when it is difficult to assist the patient in opening his/her eyelid).

Pushing down the tabs on either side of the shading plate removes the shading plate.



1.15 Recovery from Sleep Mode

The device enters sleep mode for power saving when it is left idle for a preset period of time. See “3.1.9 Other tab” (page 157).
In sleep mode, the display turns off, and the pilot lamp blinks.

Note

- The device does not enter sleep mode during measurement.

To recover from sleep mode, press the touch screen, press the start button, or manipulate the joystick.

2. OPERATING PROCEDURE

2.1 Operation Flow and Major Function

2.1.1 Operation flow

Turning on the device

2.2 Preparation (Page 45)
Turn on power to the device and set it up as necessary.
Prepare the patient for measurement.

Model eye measurement

4.2 Model Eye Use (Page 189)

For the AL-Scan equipped with the optional ultrasonic measurement function
4.3 Use of Test Piece for Ultrasonic Measurement (Page 195)

Inputting patient's name

2.3 Registering and Selecting Patient (Page 48)

Measurement

2.4 Optical Measurement (Page 54)
2.7 Toric Lens Assist Mode (Page 87)

For the AL-Scan equipped with the optional ultrasonic measurement function
2.5 BIO Mode Measurement (Optional) (Page 71)
2.6 Pachy Mode Measurement (Optional) (Page 81)

IOL power calculation

2.8 Calculation of IOL Power (Page 90)

Printing/output of results

2.10 Printing Measured Results and Calculated Results (Page 114)
2.11 Checking and Printing Toric Lens Assist Mode Measured Results (Page 119)
2.12 Output of Measured Results and Calculated Results (Page 124)
2.13 Output of Toric Lens Assist Mode Measured Results (Page 125)

Turning off the device

2.14 Completion of Operation (Page 126)

2.1.2 Major functions

 (Optical measurement)	Auto1 mode	Axial length and corneal curvature radius are measured.
	Auto2 mode	Axial length, corneal curvature radius, anterior chamber depth, central corneal thickness, white-to-white, and pupil size are measured.
	AL mode	Axial length is measured.
	KM mode	Corneal curvature radius is measured.
	ACD/CCT mode	Anterior chamber depth and central corneal thickness are measured.
	WTW/PS mode	White-to-white and pupil size are measured.
 (Optional)	BIO mode	Axial length, anterior chamber depth, lens thickness, and vitreous body length are measured.
	Pachy mode	Corneal thickness is measured.
	The power of an IOL to be implanted is calculated.	
	An anterior eye segment image overlaid with the steepest and flattest meridians can be created to measure the angle between the marker and steepest meridian.	

2.2 Preparation

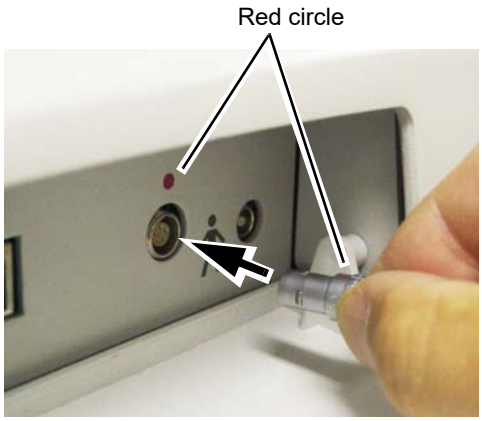
If the AL-Scan is not equipped with the optional ultrasonic measurement function, go to Step 4.

1 When performing ultrasonic measurement, connect the disinfected ultrasound probe (for the AL-Scan equipped with the optional ultrasonic measurement function only).

For the optional A-scan probe

Connect the cable plug of the A-scan probe to the connector (BIO) on the side panel.

Be sure to check the orientation of the connector to insert. Align the red circle on the cable plug to the one on the connector (BIO), then insert the plug straight into the connector completely.



For the optional pachymetry probe

Connect the cable plug of the pachymetry probe to the connector (P) on the side panel.

Insert the plug straight into the connector completely.

⚠ **CAUTION**

- **Never connect or disconnect the cable connectors of the A-scan and pachymetry probes during measurement.**
  The probes may become damaged.
- **Be sure to use only the A-scan and pachymetry probes specified by Nidek. Using other probes may cause failure or other troubles.**
  The A-scan probe specified by Nidek is indicated with “ID 14610-0006” on its case.
  The pachymetry probe specified by Nidek is indicated with “ID 14900-0005” on its case.

2 If necessary, connect the optional probe holder and foot switch.

See “3.10 Connection with Optional Accessories” (page 185).

3 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 initial screen appears.

After a few seconds, the Model Eye window appears.

- If it is hard to see the indication on the screen, adjust the inclination of the LCD touch screen.

⚠ **CAUTION** • **Remove the USB flash drive when turning on (|) power to the AL-Scan.**
Data may become corrupted.

Note
- Avoid turning on the power switch while the patient is seated in front of the device.
- When power to the AL-Scan is turned on, the main body makes slight movement in horizontal directions to determine the initial position for auto tracking. It is not a failure of the device.

The window to the right is that of the AL-Scan equipped with the optional ultrasonic measurement function. If the AL-Scan is not equipped with the optional ultrasonic measurement function, the measurement dates of BIO and Pachy mode measurements are not displayed.

4 Press the Model Eye button, then perform model eye measurement and pre-use inspection.

Check the device referring to “4.1 Checks Before Use” (page 187).

Before using the optional A-scan probe and pachymetry probe, check the probes and perform measurement using the test pieces.

After checks, record each result in the check list.

Note
- When the number of saved measurement data exceeds 900, the message “The save number of data has exceeded the permitted number. Please back up and delete data.” appears at startup. See “Message” in “3.1.9 Other tab” (page 157) and “3.4 Database Management” (page 164).

5 Prepare the patient for measurement.

For optical measurement

1) Clean the forehead rest and chinrest that come into contact with the patient.

   Use clean gauze or cloth dampened with rubbing alcohol for the cleaning.

2) Instruct the patient to remove glasses or contact lenses and sit on a chair.

For BIO/Pachy mode measurement with an ultrasonic measurement function

1) Instruct the patient to remove glasses or contact lenses.
2) Apply the surface anesthesia to the patient's eye to be measured.
3) Ask the patient to take a posture suitable for the measurement.
4) 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.

2.3 Registering and Selecting Patient

2.3.1 Registering new patient

Register new patient information on the patient list.

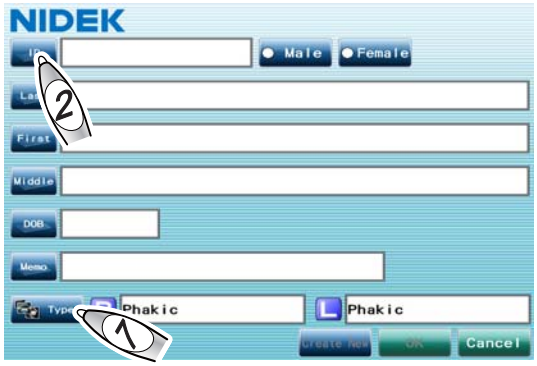
Note

- Patient can be registered should the items other than ID not be input. In such a situation, measured values are printed or output to another device without the patient information. Be sure to input the patient information before measurement. If the measured eye type is improper, it is not possible to obtain proper measured values.
- When the number of the registered patients reaches 10000, the message “Database has reached its maximum number of entries. To save, delete the oldest entry from the database.” appears before the Patient information screen is displayed. See “Message” in “3.1.9 Other tab” (page 157).

1 Display the patient information screen.

After device start-up, closing the Model Eye screen displays the patient information screen.

Pressing the New button in the Patient List screen also displays the patient information screen.



2 Input the patient’s ID in the patient information screen.

Pressing the ID button displays the keyboard window. Input the patient’s ID using the keyboard window, then press the OK button.

See “O Keyboard window use” (Page 132).

Input the patient information specified in Steps 4 to 6 below in the same manner.

It is also possible to input the ID by reading the ID using the optional barcode reader. See “3.7 Reading ID with Barcode Reader” (page 176).

Checking the Auto ID box in the Other tab automatically assigns ID numbers in numerical order.

3 Select Male or Female.

4 Input the patient's first and last names, and the middle name if necessary.

5 Input the patient's birth date.

Input it in the format set by the Date Format parameter.

See "○ Numeric keypad window use" (Page 131).

6 Fill in the Memo box if necessary.

7 Select the conditions of the right and left eyes to be measured.

1) Press the Type button to display the Eye Type window.
2) Select the condition of the right eye.
3) Select the condition of the left eye.
4) Press the OK button.

The Eye Type window is closed, and the patient information screen appears.

8 Confirm that the items input in the patient information screen are correct, then press the OK button.

The input patient information is registered on the Patient List, then the optical measurement screen appears. Go to "2.4 Optical Measurement" (page 54).

Cancel button ⇒ Closes the patient information screen, and the Patient List screen appears. The input patient information is not added to the Patient List.

Create New button ⇒ Used to input information of multiple patients subsequently. The input patient information is registered on the Patient List, and the patient information screen for the next patient appears.

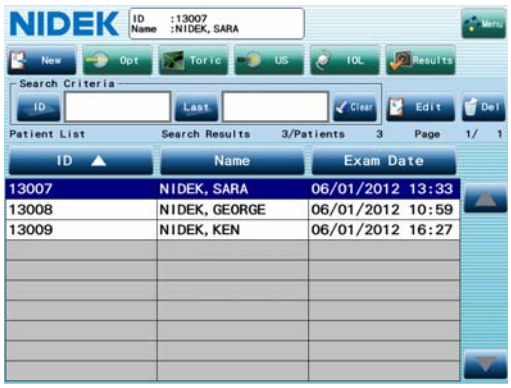
2.3.2 Selecting patient

Select the desired patient in the Patient List screen.

1 Display the Patient List screen.

Press the Patient List button on each measurement screen.

Pressing the Cancel button on the patient information screen also displays the Patient List screen.



2 Select the patient for measurement or IOL calculation from the Patient List.

If the Patient List has multiple pages, press the or button to switch the page.

button ⇒ The previous page appears.

button ⇒ The next page appears.

When performing measurement for a new patient, register the patient data. See “2.3.1 Registering new patient” (page 48).

3 Select the function by pressing the following buttons.

Opt button ⇒ Performs optical measurement.

Toric button ⇒ Creates an anterior eye segment image with corneal meridians or displays the saved results of toric lens angle measurement.

US button ⇒ Performs ultrasonic measurement.

IOL button ⇒ Calculates the power of an IOL.

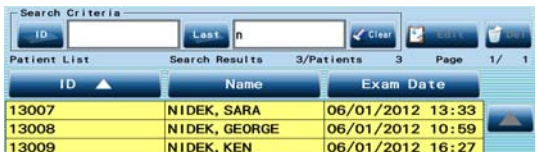
Results button ⇒ Displays the measured or calculated results.

For details, see “2.1 Operation Flow and Major Function” (page 43).

○ Patient List search

The search function can display only the patient data that meets the entered search criteria for easy patient selection.

Input the desired search criterion to the corresponding search box.



1) Press the ID or Last (or First) button in the Search Criteria field.

2) Input the desired search criterion using the keyboard window, then press the OK button.

[ID]: Data sets with the patient ID beginning with the entered ID number are displayed in the Patient List.

[Last]: Data sets with the last name beginning with the entered character(s) are displayed in the Patient List.

[First]: Data sets with the first name beginning with the entered character(s) are displayed in the Patient List. When the setting for the Name parameter is “F L MI.”, the Last button becomes the First button.

When search result is displayed, the background of the Patient List is changed from white to yellow.

If multiple search criteria are entered, the AND search is executed.

The search result is maintained until the device is turned off.

To restore the Patient List to the original condition, press the Clear button to clear the search criteria. Registering new patient information, editing the patient information, or optimization also clears the search criteria.

2.3.3 Deleting patient data

Delete the patient data specified in the Patient List.

Note

- All the measured values and calculated IOL power as well as the patient information are deleted from the database of the device.

1 Select the patient data to be deleted by pressing the line of the desired patient in the Patient List screen.

2 Press the Del button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.

A message to confirm whether to delete the patient data appears.

3 Press the OK button.

The patient data selected in Step 1 is deleted, and the Patient List screen appears again.

2.3.4 Editing patient information

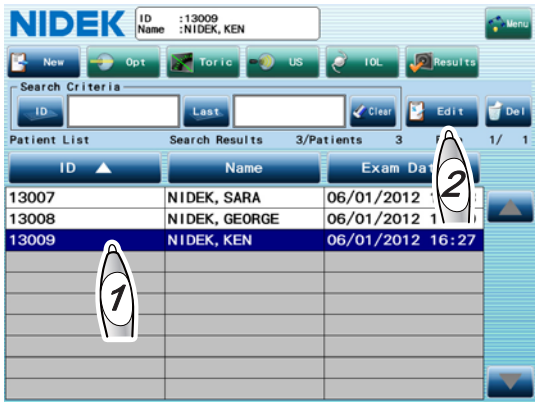
Edit the patient information specified in the Patient List.

Note

- The ID cannot be edited.
- Change of the eye type is not reflected to the measured data. This change is effective from the next measurement.

1 Select the patient information to be edited by pressing the line of the desired patient in the Patient List screen.

The selected line is highlighted in blue.



2 Press the Edit button.

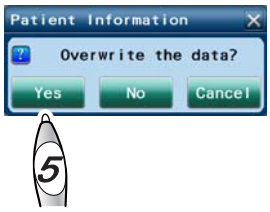
The patient information screen that can be edited appears.

3 Edit the desired items.

See “2.3.1 Registering new patient” (page 48).

4 Press the OK button.

A message to confirm whether to overwrite the patient information appears.



5 Press the Yes button.

The changes are registered, and the Patient List screen is displayed again.

Pressing the No button displays the Patient List screen again without registering the changes.

Pressing the Cancel button displays the patient information screen being edited again.

2.4 Optical Measurement

The AL-Scan measures the AL (axial length), KM (corneal curvature radius), ACD (anterior chamber depth), CCT (central corneal thickness), WTW (white-to-white), and PS (pupil size) of the patient's eye through a non-contact optical measurement method.

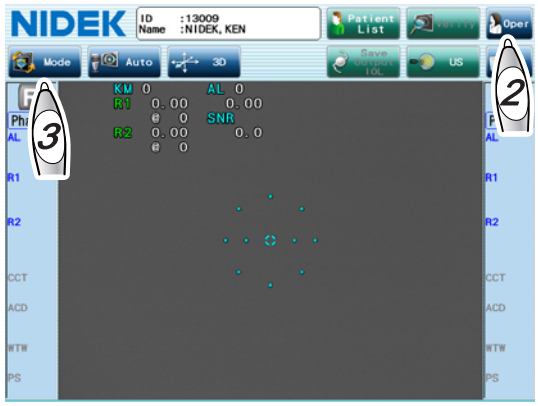
1 Input the patient information in the patient information screen, then press the OK button.

Note

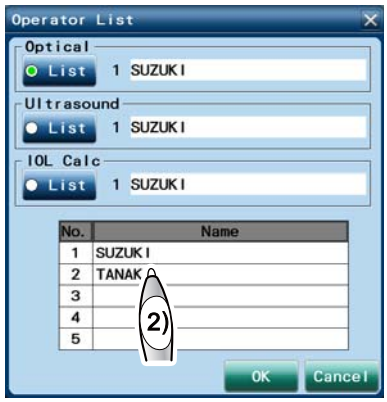
- When the number of saved measurement data reaches 1000, regardless of whether optical or ultrasonic measurement, or when the number of saved measurement data for one patient reaches 99, the message "Database has reached its maximum number of entries. To save, delete the oldest entry from the database." appears. See "Message" in "3.1.9 Other tab" (page 157).

The optical measurement screen appears.

Selecting the information the patient to perform the measurement in the Patient List screen, then pressing the Opt button displays the optical measurement screen.



2 Specify the operator.



1) Press the Oper button to display the Operator List window.
2) Select the desired operator who performs optical measurement.
3) If necessary, press the List button on the Ultrasound field to select the desired operator who performs ultrasonic measurement.
4) If necessary, press the List button on the IOL Calc field to select the desired surgeon who performs IOL implantation.
5) Press the OK button.

It is necessary to register operator's names in the Oper tab of the Parameter Settings screen in advance. See “O Registering operator’s name” (Page 134).

Note

- The specified operator name is printed or output to another device.

3 Select the measurement item (default setting: Auto1).

1) Press the Mode button to display the Measurement Mode window.
2) Select the measurement item by pressing the desired button from the Auto1 to WTW/PS buttons.
3) Press the OK button.
4) When the measurement mode “WTW/PS” is selected in Step 2), the PS (Meso), PS (Photo), or WTW button is displayed on the optical measurement screen. Each pressing of the button changes the indication. Select pupil size measurement or white-to-white measurement.

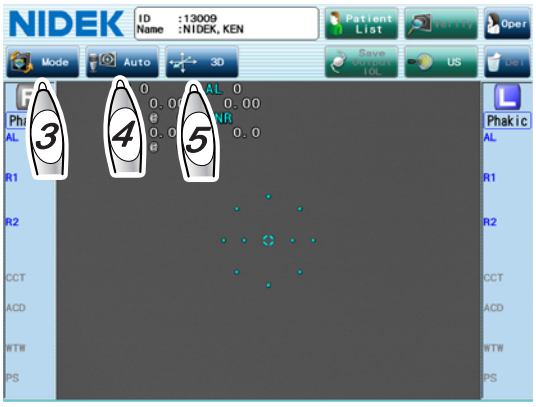
PS (Meso): Pupil size is measured while the illumination is turned off.

PS (Photo): Pupil size is measured while the illumination is turned on.

WTW: White-to-white is measured.

If the pupil size is measured for both PS (Meso) and PS (Photo), the measured value for PS (Meso) is displayed in the PS fields on both sides of the optical measurement screen.

4 Specify whether or not to use the auto shot function using the auto shot button (default setting: Auto).



Auto: The auto shot function is enabled.

Manual: The auto shot function is disabled.

Each pressing of the auto shot button toggles the setting.

5 Specify the alignment method with the tracking button (default setting: 3D).

3D: The auto tracking function in the forward and back, right and left, and up and down directions is enabled.

2D: The auto tracking function in the right and left, and up and down directions is enabled.

OFF: The auto tracking function is disabled. The alignment and focusing are manually performed.

Each pressing of the tracking button changes the setting. See "○ Auto tracking function (Page 60).

6 Prepare the patient for measurement.

1) Clean the forehead rest and chinrest that contact the patient.

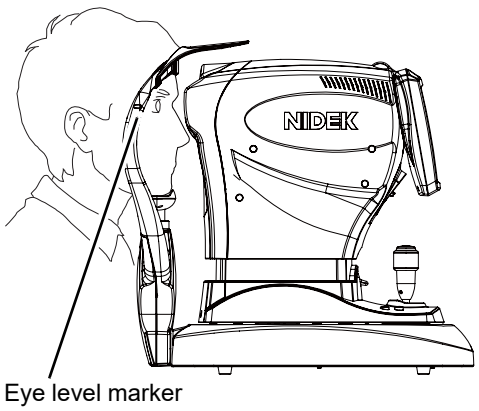
Wipe them with clean gauze or absorbent cotton dampened with ethanol for disinfection.

When a stack of chinrest paper is secured to the chinrest, remove one sheet of paper.

2) Instruct the patient to remove glasses or contact lenses and sit on a chair.

7 Have the patient place his/her chin on the chinrest as deeply as possible, and his/her forehead on the forehead rest lightly.

If it is difficult for the patient to do so, it is necessary for the operator or patient's helper to facilitate the patient into assuming the measurement position with care.

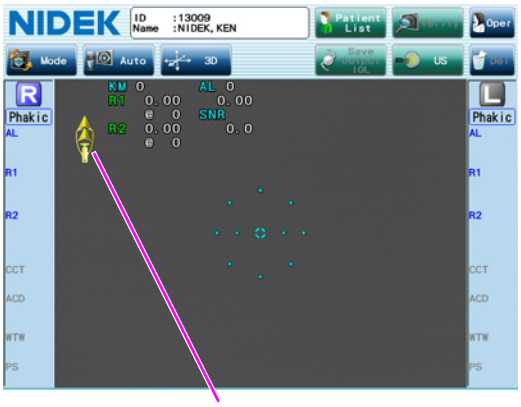


Eye level marker

8 Adjust the height of the chinrest with the chinrest up/down button (▲ , ▼) until the center level of the patient's eye aligns with the eye level marker.

Before adjusting the height of the chinrest, let the patient know that the chinrest moves up and down.

When the chinrest is at the upper (or lower) mechanical limit, the upper limit indicator (or lower limit indicator) is displayed on the screen.



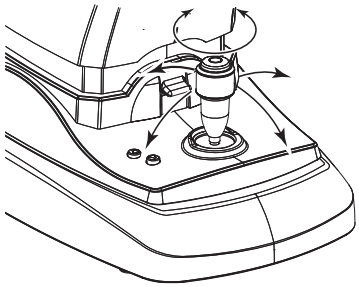
Lower limit indicator of the chinrest

9 Instruct the patient to blink once or twice, then fix on the red fixation lamp in the measuring window with his/her eyes wide open.

10 Manipulate the joystick so that the patient's eye is displayed in the screen.

Moving the joystick right, left, forward, and back moves the main unit of the device in the same direction. Rotating the knob of the joystick moves the measuring unit up and down.

Move the main unit up, down, right and left to align it with the patient's eye. Then adjust the focus to the patient's eye by moving the main unit forward and back.

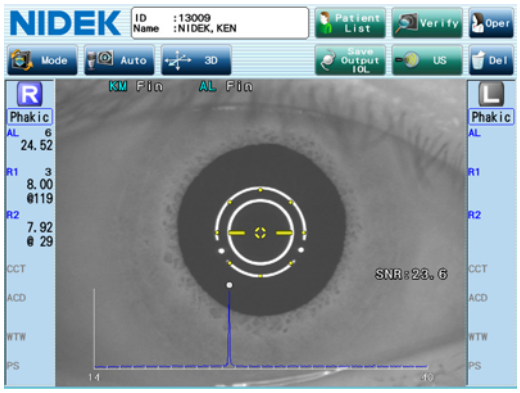


11 Perform alignment and focusing, then start measurement.

Alignment and focusing procedures differ depending on the tracking setting in Step 5.

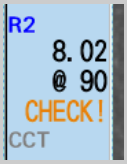
See "○ Auto tracking function" (Page 60).

When the auto shot button is set to "Auto", measurement will be started automatically if the eye is aligned and focused. When the auto shot button is set to "Manual", press the start button on the joystick to start measurement.



Note

- When the patient's eye type is aphakic or pseudophakic, the ACD measurement result is in error.
- If the measured results of AL, KM, or ACD greatly vary, a message "CHECK!" appears. Check the measured values or perform measurement again.



12 Measure the other eye in the same manner.

13 After the measurement, release the patient from the chinrest.

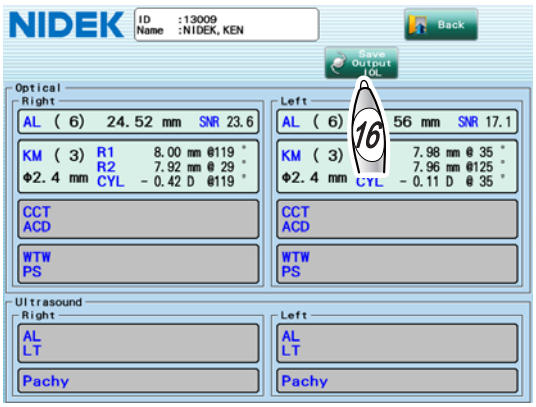
Instruct him/her to remain seated when removing his/her head from the chinrest. If the patient suddenly rises up, he/she may hit his/her face on the upper part of the forehead rest.

14 Press the Verify button.

The measured value confirmation screen appears.

15 Check the details of the measured results.

Only a single value such as the median value for each item is displayed on the measured value confirmation screen. Press the field for each measurement item to check the detail of the measured result (all the measured values). See "○ Checking measured result details from measured value confirmation screen" (Page 64).



Note

- Be sure to check the measured result details to enhance the reliability of the measured values used for IOL power calculation.

  The measured data has not yet been finalized at this moment. If necessary, improper data can be deleted, or the detection point can be modified. However, after the measured data is saved, the finalized data cannot be deleted.

16 Check the measured results and press the Save Output IOL button to save the measured data, then proceed to IOL calculation.

The measured data is saved, and also output or printed depending on the setting. The IOL power calculation screen appears. Go to "2.8 Calculation of IOL Power" (page 90).

If IOL power calculation is not going to be performed, conduct any of the following procedure.

To perform measurement again

1) Press the Back button to return to the optical measurement screen.
2) Press the Del button on the optical measurement screen. The message whether to delete the measured data appears.
3) Press the OK button to delete the data, then go back to Step 11 to perform measurement again.

To perform ultrasonic measurement subsequently

1) Press the Back button to return to the optical measurement screen.
2) Press the US button on the optical measurement screen to display the BIO mode screen (or Pachy mode screen).
3) Confirm that the A-scan probe or pachymetry probe is connected. See "2.2 Preparation" (page 45).

4) Go to “2.5 BIO Mode Measurement (Optional)” (page 71) or “2.6 Pachy Mode Measurement (Optional)” (page 81).

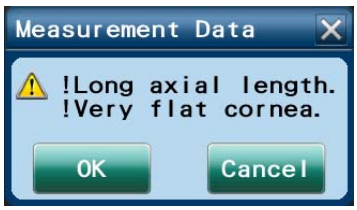
To save the measured data and complete the measurement

1) Press the Back button to return to the optical measurement screen.
2) Press the Patient List button on the optical measurement screen. The message whether to save/output the measured data appears.
3) Press the Yes button.

   The measured data is saved, and also output or printed depending on the setting.

   Pressing the No button deletes the measured data, and the Patient List screen appears again.

●Messages related to measurement data



If the AL measured value or KM measured value is outside the standard range, a message calling the operator's attention appears before the measured results are saved and output.

Check the contents of the message, then determine whether to use the measured value.

[OK]: The measured results are saved and output. The save confirmation message is not displayed.

[Cancel]: The measured data is not saved or output.

In addition, when the data is printed with the built-in printer or output in jpg format (Page 155), the message is added.

Message on the screen	Message on the printout from the built-in printer	Contents
! Short axial length	!Short axis length	AL < 22 mm
! Long axial length	!Long axis length	AL > 26 mm
! Axial lengths of right and left eyes differ by more than 0.3 mm.	!ΔAL |R-L| > 0.3 mm	The difference between the right and left exceeds 0.3 mm.
! Very flat cornea	!Flat corneal	R > 8.4 mm (K < 40 D)
! Very steep cornea	!Steep corneal	R < 7.2 mm (K > 47 D)
! Corneal refractive powers of right and left eyes differ by more than 1 D.	!ΔK |R-L| > 1D	The difference between the right and left exceeds 1 D.
! Very high corneal astigmatism	!High astigmatism	R1-R2 > 0.5 mm (|K1-K2| > 2.5 D)
! Corneal refractive powers of ø2.4 mm and ø3.3 mm mire rings differ by more than 0.5 D.	!ΔK |Phi2.4-3.3| > 0.5D	|ø2.4 mm - ø3.3 mm| > 0.5 D

Note

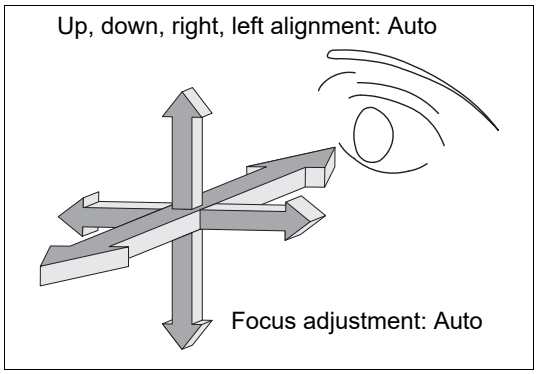
- The messages prompting the operator to check the measured values are displayed regardless of the right or left eye, and the optical measurement or BIO mode measurement.

○ Auto tracking function

The method of alignment and focus adjustment varies depending on the setting of the auto tracking function.

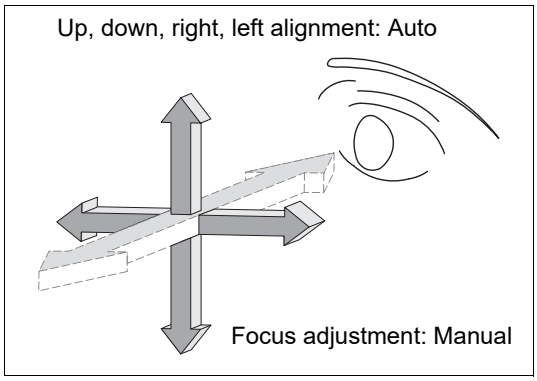
3-D auto tracking

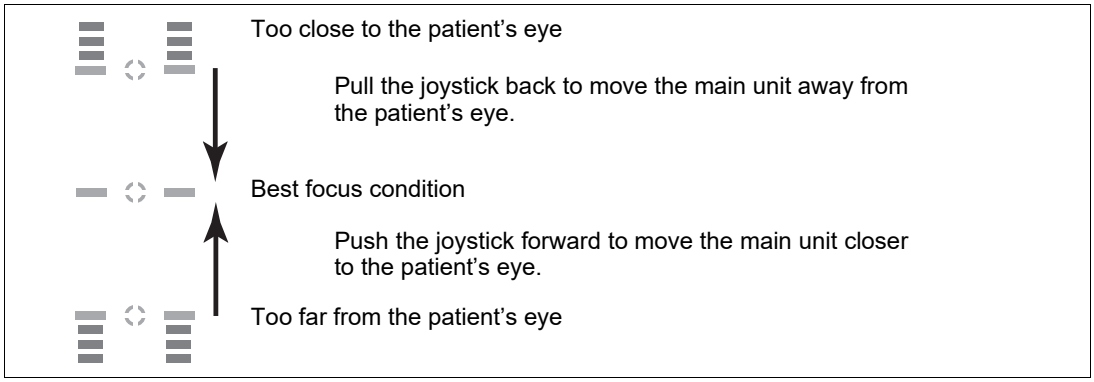
1) Perform rough alignment and focus adjustment to the working range of the auto tracking function.
2) When the main unit is brought into the working range of the auto tracking function, fine alignment and focus adjustment automatically start.



2-D auto tracking

1) Perform rough alignment and focus adjustment to the working range of the auto tracking function.
2) When the main unit is brought into the working range of the auto tracking function, fine alignment automatically starts.
3) As the focusing indicator is displayed, manipulate the joystick until the optimum focusing indicator is displayed.

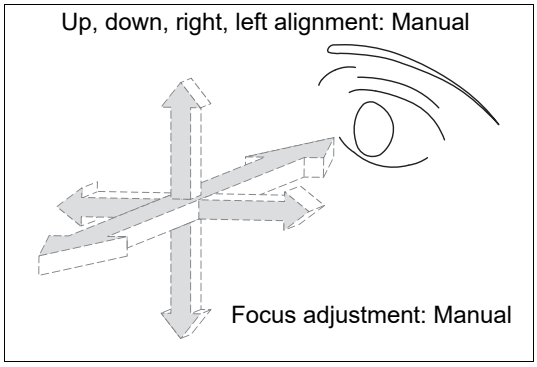




Auto tracking OFF

1) Manipulate the joystick to perform rough alignment and focus adjustment.
2) Manipulate the joystick to bring the mire ring center reflected on the patient's eye to the alignment target.
3) As the focusing indicator is displayed, manipulate the joystick until the optimum focusing indicator is displayed.

   During the focusing, maintain the alignment between the device and the patient's eye.

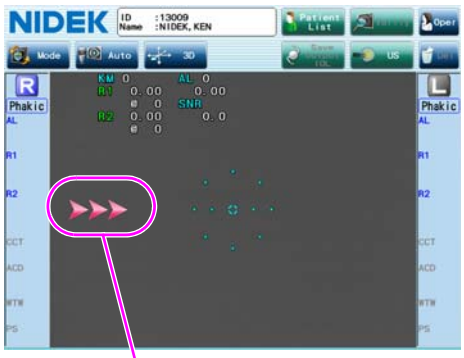


If triple red arrows appear

If the alignment is outside the working range of the auto tracking function, the limit indicator (triple red arrows) appears (unless the auto tracking is off). Manipulate the joystick or the chinrest up/down button while referring to the limit indicator.

<Example of limit indicator>

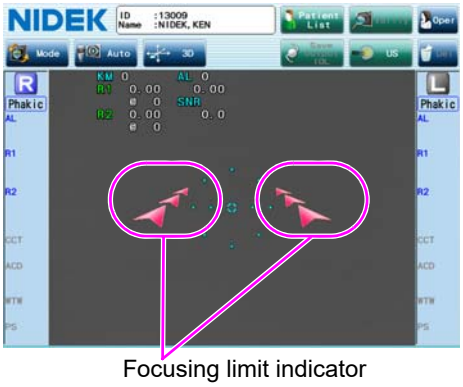
The patient's eye is too low from the measuring unit.
Move the chinrest up.



The measuring unit is too far to the left from the patient's eye.
Tilt the joystick to the right to move the measuring unit to the right.

▲▲▲	Move the chinrest up.
▼▼▼	Move the chinrest down.
▶▶▶	Tilt the joystick slightly to the right.
◀◀◀	Tilt the joystick slightly to the left.

If the focus is outside the working range of the auto tracking function, the limit indicator appears (when the 3-D auto tracking is enabled only).

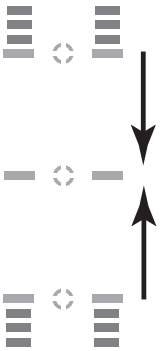


Focusing limit indicator

When the focus indicator appears, manipulate the joystick while referring to it.

	Push the joystick forward to move the measuring unit closer to the patient.
	Pull the joystick back to move the measuring unit away from the patient.

Refer to the number of the bars of the focus indicator for the amount to move the joystick forward and back.



Too close to the patient's eye

Pull the joystick back to move the main unit away from the patient's eye.

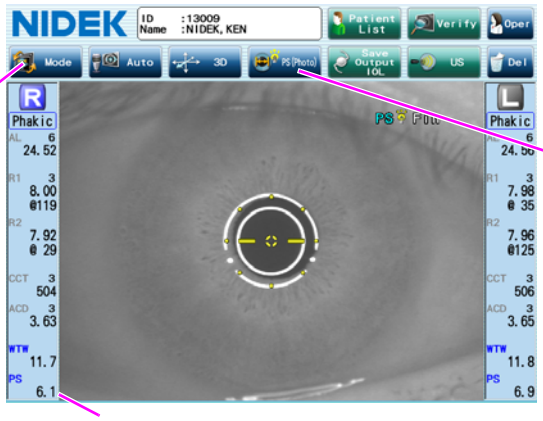
Best focus condition

Push the joystick forward to move the main unit closer to the patient's eye.

Too far from the patient's eye

○ Pupil size (PS) measurement while the anterior eye segment is illuminated

Pupil size measurement included in the Auto2 measurement mode is performed while the illumination is turned off. Setting the measurement mode to “WTW/PS” and selecting the PS (Photo) button enables pupil size measurement while the anterior eye segment is illuminated.



Select the WTW/PS mode.

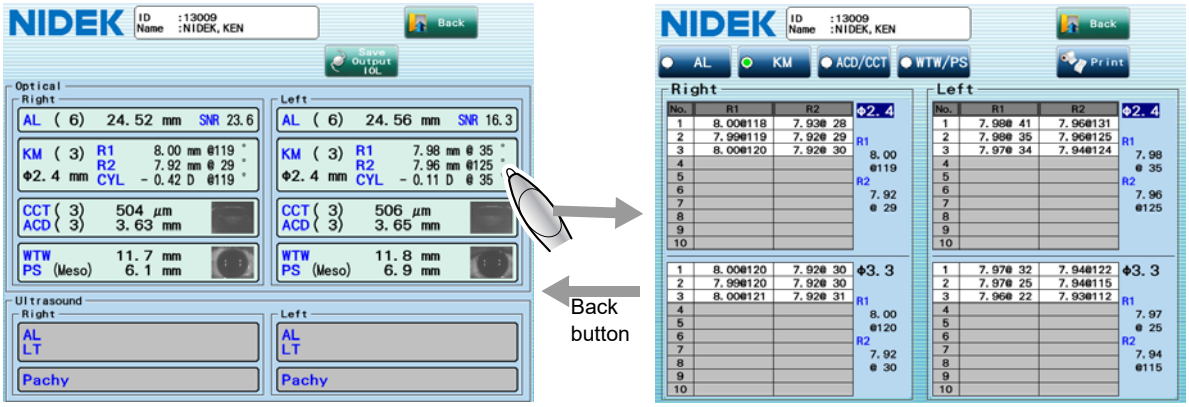
Select the PS (Photo) button.

If the pupil size is measured for both PS (Meso) and PS (Photo), the measured value for PS (Meso) is displayed in the PS fields.

○ Checking measured result details from measured value confirmation screen

Pressing the desired field of the measured result in the measured value confirmation screen displays the measured result details.

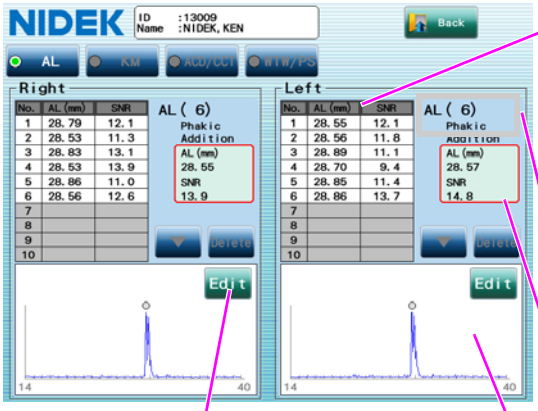
Pressing the AL, KM, ACD/CCT, or WTW/PS button on the measured result details screen switches the screen to the screen corresponding to the button pressed.



Pressing the Back button in the measured result details screen returns to its original screen.

The following are examples of the measured result details screens.

(1) AL (axial length) detail



The retinal pigment epithelium detection position can be modified. See “○ Modifying retinal pigment epithelium detection position of AL combined wave” (Page 68).

Measured value list

Up to 20 sets of AL measured values and SNRs are displayed.

SNR is the ratio of signal power to noise power. The greater the SNR is, the more reliable the measured value is.

Should measurement be performed 21 times or more consecutively, the oldest data is deleted, and only the most recent 20 measured data sets are retained. If there is error data, the error data is deleted first.

Up to ten sets of measured data are displayed in the list. When there are eleven or more sets of measured data, press the ▲ or ▼ button to switch the page of the list.

The number of measurements and the patient's eye type

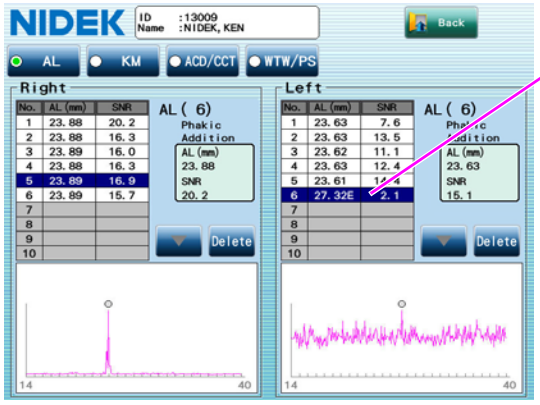
Combined wave value

The AL combined wave value is not the average of the measured numerical values. It is calculated from the waveform generated by combining all the measured waveforms.

Waveform

The position of the peak with a solid gray circle indicates where the retinal pigment epithelium is detected.

The waveform generated by combining all the measured waveforms is displayed in blue, and a waveform for an individual measured value is displayed in purple.



Selecting a measured value on the list displays in purple the waveform from which the value was calculated.
A proper waveform is one that detects the retinal pigment epithelium at a high peak with low noise around it.

If the noise is so high that the peak is not discernible, or the retinal pigment epithelium is not detected at an appropriate position, delete the measured value to improve the combined wave value accuracy.

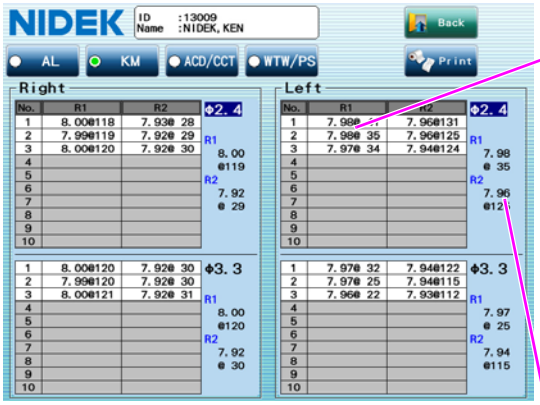
<SNR>

2.0 to 2.4: The measured value is displayed with an "E" attached to the end.

1.9 or less: The measured value is displayed as an error.

Pressing the Delete button deletes the measured value being selected. Pressing the Retrieve button restores the deleted measured value.

(2) KM (corneal curvature radius) detail



Measured value list

Up to ten sets of KM measured values

The values measured with the 2.4-diameter mire ring are listed in the upper table, and those measured with the 3.3-diameter mire ring are listed in the lower table.

R1: Corneal curvature radius along the flattest meridian (mm) and axis angle (°)

R2: Corneal curvature radius along the steepest meridian (mm) and axis angle (°)

K1: Corneal refractive power along the flattest meridian (D) and axis angle (°)

K2: Corneal refractive power along the steepest meridian (D) and axis angle (°)

AVG: Average of R1 and R2 (mm or D)

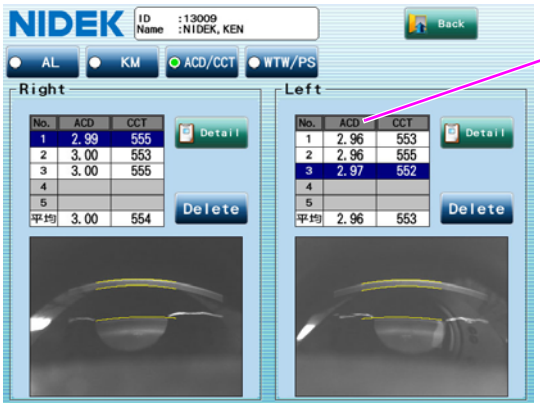
CYL: Corneal cylindrical power (D)

Axis: Corneal cylinder axis angle (°)

* The display format of KM measured values can be changed depending on the setting of the KM Disp Unit parameter. The figure to the left is the screen for when the parameter is set to "mm".

Median value

(3) ACD (anterior chamber depth) and CCT (central corneal thickness) details



Measured value list

Up to five sets of ACD and CCT measured values

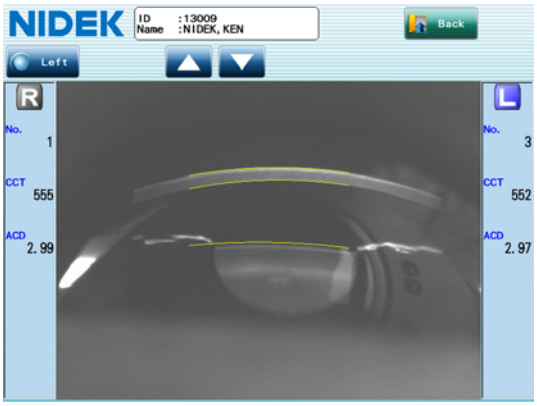
The Scheimpflug image used to calculate the highlighted measured value is displayed below.

The ACD value with low detection reliability for anterior surface of lens is marked with “E” and displayed as a reference value. In such a case, an error of around 0.1 mm is included.

Selecting a measured value on the list displays a Scheimpflug image used to calculate the measured value. If the cornea or lens is not properly detected with the measured value, press the Delete button while the value is being selected (the background is highlighted in blue) to delete the measured value. Pressing the Retrieve button restores the deleted measured value.

The Scheimpflug image of the measured value being selected on the list is output.

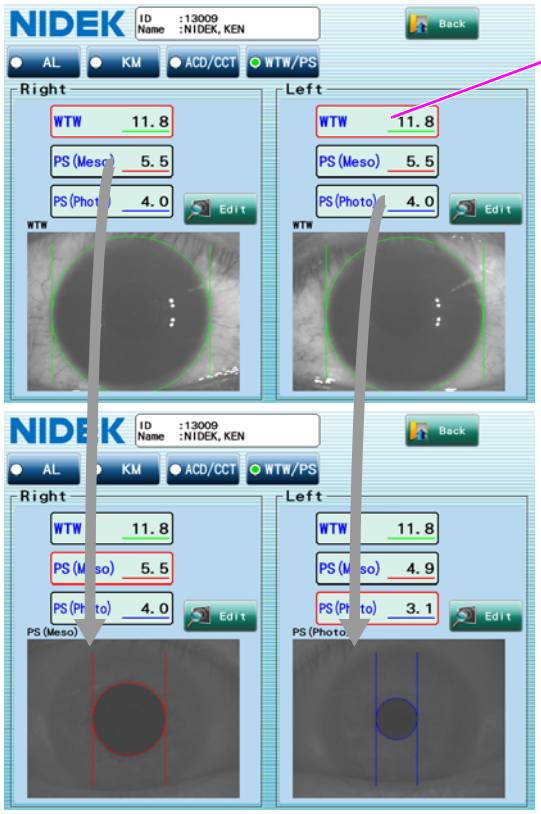
Pressing the Detail button enlarges the Scheimpflug image.



In the enlarged display, pressing the ▲ / ▼ button switches the image to the previous/next image in the list.

Pressing the Left/Right button switches the image to that of the other eye.

(4) WTW (white-to-white) and PS (pupil size) details



Measured value
WTW and PS measured values
WTW: White-to-white (mm)
PS (Meso): Pupil size when the illumination is off (mm)
PS (Photo): Pupil size when the illumination is on (mm)

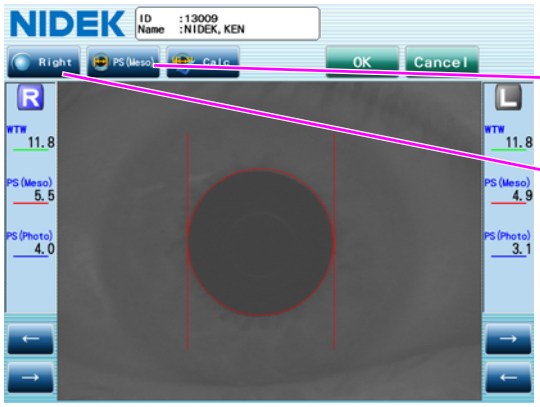
Pressing the WTW, PS (Meso), or PS (Photo) measured value displays the anterior eye segment image and two vertical lines that indicate the measured area. Confirm that a proper distance is measured.

2

Note

- When the measurement results are saved or output, the WTW and PS images are combined into one image. Therefore, when viewing the saved or output data, pressing the WTW, PS (Meso), or PS (Photo) button on the detail screen does not change the image. Additionally, should a measurement image with blink error be saved or output, that image will be included in the composition image.

If the positions of the two vertical lines are improper, correct them by following the instructions below.



WTW / PS (Meso) / PS (Photo) button
Used to toggle the measured diameter to be corrected.

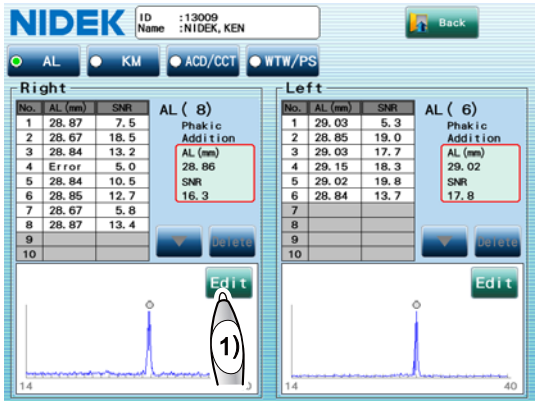
Right/Left button
Used to toggle display of the right and left eyes. The indication of the button indicates the eye being displayed.

1) Press the Edit button to display the screen for correction.
2) Press the ← and → buttons to move the vertical lines to the proper positions.
   Dragging the vertical line also moves the line.
3) Press the Calc button to recalculate the measured value.
4) Press the OK button to return to the measured result details screen.

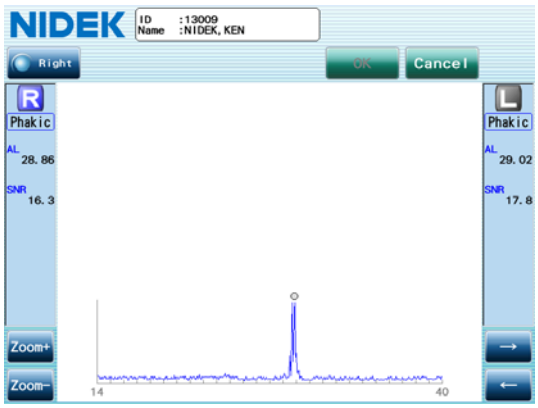
○ Modifying retinal pigment epithelium detection position of AL combined wave

In the measured result details screen of AL (axial length), the peak with a solid gray circle on the waveform generated by combining all the measured waveforms indicates the location of the retinal pigment epithelium. A peak of the waveform marked with a solid gray circle is improper if there are multiple peaks on the waveform, so the axial length cannot be measured properly. In such a case, modify the detection position.

1) Press the Edit button for the combined wave to modify the detection position in the measured result details screen of AL (axial length).



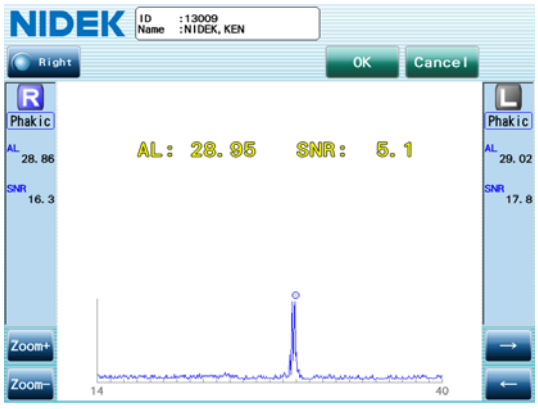
The AL manipulation screen appears.



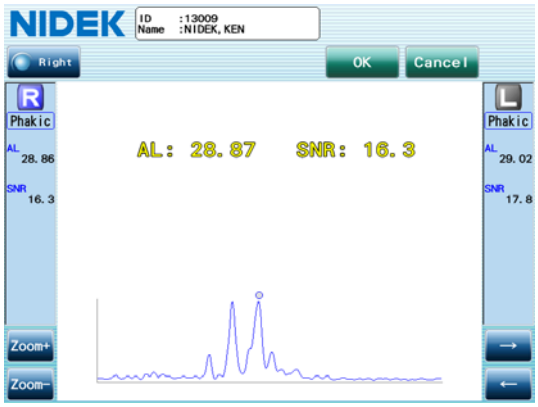
2) Press the peak on the retinal pigment epithelium position to specify the proper detection position.

A solid gray circle (outlined in blue) is newly displayed at the specified position. The AL value and SNR on the position are displayed.

Press the ← or → button to precisely adjust the position.



If there are multiple peaks close to each other, enlarge the waveform horizontally using the “Zoom+” button to more easily specify the proper position. Pressing the “Zoom-” button reduces the waveform horizontally.



3) Press the OK button to return to the measured result details screen of AL (axial length).

The specified position becomes the retinal pigment epithelium position. The AL value and SNR on the measured result details screen are marked with “#” that indicates that the values are for a waveform where the retinal pigment epithelium position was modified.

Pressing the Cancel button returns to the measured result details screen without modifying the retinal pigment epithelium position.

○ Error message during optical measurement

<Error message during AL measurement>

Message	Contents
Error	SNR is less than 2.0. The signal may not be obtained due to advanced cataract. Should the combined wave value not be obtained after additional measurement, perform ultrasonic measurement. See “2.5 BIO Mode Measurement (Optional)” (page 71).
ALM (Alignment error)	Alignment is not proper. Perform the alignment and the measurement again.

<Error message during KM measurement>

Message	Contents
BLK (Blinking of the eye)	The measurement is not possible because of blinking of the eye. Instruct the patient not to blink their eye until the measurement is complete. After the eye stops blinking, perform measurement again.
ALM (Alignment error)	Alignment is not proper. Perform the alignment and the measurement again.
FAR (Focus error: Farther from the measured eye)	Alignment is not proper. Perform the alignment and the measurement again.
NEAR (Focus error: Nearer from the measured eye)	Alignment is not proper. Perform the alignment and the measurement again.

+OVR (Over the corneal curvature radius measurement range)	The corneal curvature radius exceeds the measurement range.
-OVR (Less than the corneal curvature radius measurement range)	The corneal curvature radius is less than the measurement range.
COVR (Over the cylinder measurement range)	The CYL value exceeds the measurement range.

<Error message during ACD measurement>

Message	Contents
BLK (Blinking of the eye)	The measurement is not possible because of blinking of the eye. Instruct the patient not to blink their eye until the measurement is complete. After the eye stops blinking, perform measurement again.
ALM (Alignment error)	Alignment is not proper. Perform the alignment and the measurement again.
FAR (Focus error: Farther from the measured eye)	Alignment is not proper. Perform the alignment and the measurement again.
NEAR (Focus error: Nearer from the measured eye)	Alignment is not proper. Perform the alignment and the measurement again.
+OVR (Over the measurement range)	The corneal thickness or anterior chamber depth exceeds the measurement range.
-OVR (Less than the measurement range)	The corneal thickness or anterior chamber depth is less than the measurement range.
IMG (Corneal image error)	The measurement is not possible because of slight movement of the eye. Instruct the patient not to move their eye until the measurement is complete. After the eye stops moving, perform measurement again.

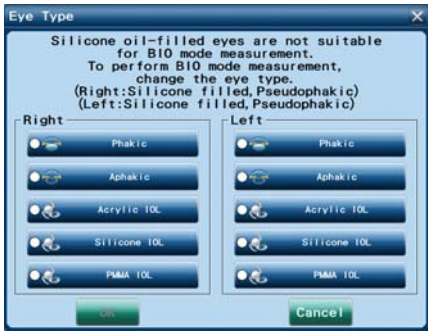
2.5 BIO Mode Measurement (Optional)

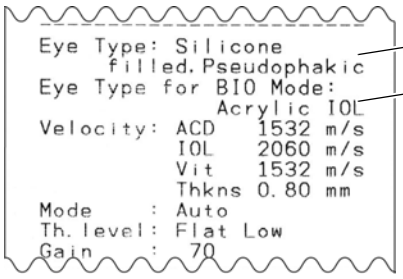
An optional A-scan probe is also available to scan AL (axial length) with an ultrasonic measurement function by touching it to the cornea should optical measurement not be successful. The optional ultrasonic measurement function and A-scan probe are necessary.

- Eyes filled with silicone oil are not suitable for BIO mode measurement.

  When the eye type is set to “Silicone filled, Phakic”, “Silicone filled, Aphakic”, or “Silicone filled, Pseudophakic” and the BIO mode screen is displayed, the Eye Type window appears. If the eye type is changed, the patient's eye is measured as the eye type specified here.

  In this case, both the original eye type and the eye type specified for the BIO mode measurement are printed for the BIO mode measurement result.

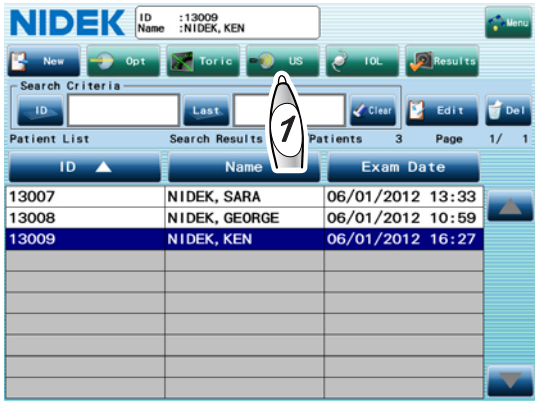




Original eye type

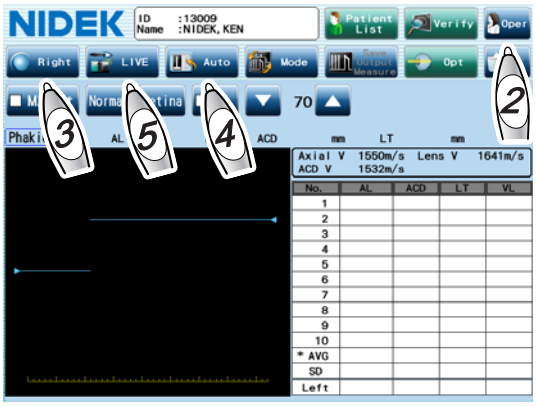
Eye type specified for BIO mode

1 Select or enter the patient information in the Patient List screen, then press the US button.

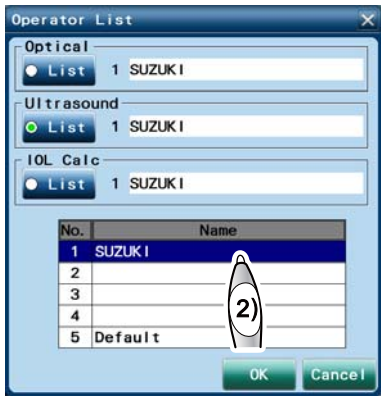


The BIO mode screen appears.

If the Pachy mode screen appears, press the Mode button, select the BIO button in the Measurement Mode window, then press the OK button.



2 Specify the operator.



1) Press the Oper button to display the Operator List window.
2) Select the desired operator who performs ultrasonic measurement.
3) If necessary, press the List button on the Optical field to select the desired operator who performs optical measurement.
4) If necessary, press the List button on the IOL Calc field to select the desired surgeon who performs IOL implantation.
5) Press the OK button.

It is necessary to register operator's names in the Oper tab of the Parameter Settings screen in advance. See “O Registering operator’s name” (Page 134).

Note

- Because the sonic velocity used to calculate the measured value and optical offset are set for each operator, be sure to specify the operator.
- The specified operator name is printed or output to another device.
- Changing the operator after the measurement clears the measurement data.

3 Press the Right/Left button to select the right or left eye to be measured.

Each time the button is pressed, the eye to be measured is indicated such as “Right” or “Left”.

4 Press the capture mode button to specify the data capture method.

Each time the button is pressed, the data capture method is indicated such as “Auto”, “Semi-Auto”, “Speedy”, or “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 operator when the measurement is started.

The operator observes the waveform when the measurement is started, and presses the foot switch or the CAPTURE button when he/she 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 are obtained.

The measurement data of the past three times (nine data sets in total because a single measurement generates three data sets) are listed. If the measurement is performed more than three times, the oldest three sets of data are deleted.

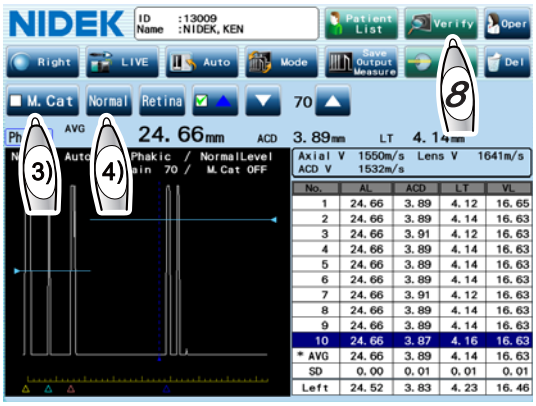
Manual: The operator performs data sampling when the measurement is started.

* Changing the data capture method during measurement stops the measurement.

5 Press the LIVE button or the MEASURE switch of the foot switch to start BIO mode measurement.

The indication of the button becomes “FREEZE”, and BIO mode measurement starts.

6 Touch the A-scan probe to the center of the cornea.

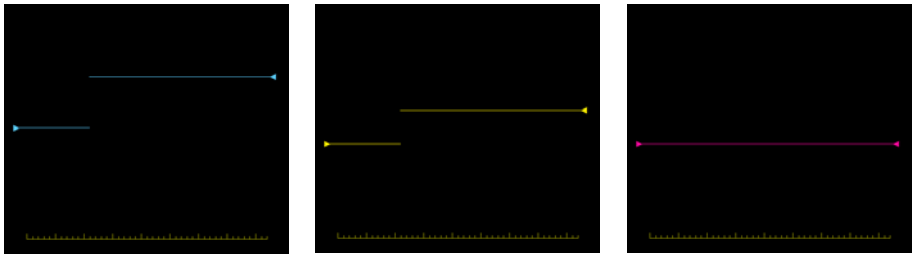


1) A-scan waveform appears, and BIO mode measurement is performed according to the selected data capture method.
2) Adjust the gain with the ▲ / ▼ button on the both sides of the gain display or the chinrest up/down button (▲, ▼) so that a proper A-scan waveform can be obtained. The gain can be changed in the range between 0 and 100 in 10 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, enable the M. Cat button.
4) If necessary, press the threshold button to change the programmed threshold among “Normal”, “Low”, and “Flat Low” with which the program determines the acceptability of the measured value of each intraocular part.

“Normal” “Low” “Flat Low”



* If there is an additional echo near the threshold preceding any of the valid echoes, redo the measurement referring to “2.5.2 Manual gate” (page 79).

Note

- When the patient’s eye type is Aphakic, the anterior chamber depth (ACD), lens thickness (LT), and vitreous body length (VL) are not measured. For IOL implanted eyes, the lens thickness (LT) 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 BIO mode measurement operation. It is not intended for clinical judgment. When using the values obtained in Auto mode for IOL power calculation, operators have to examine the obtained values.
- Changing the threshold during the measurement clears the measurement data of before changing the threshold.

7 Repeat Step 6.

Repeat measurement several times to ensure validity of the obtained data.

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

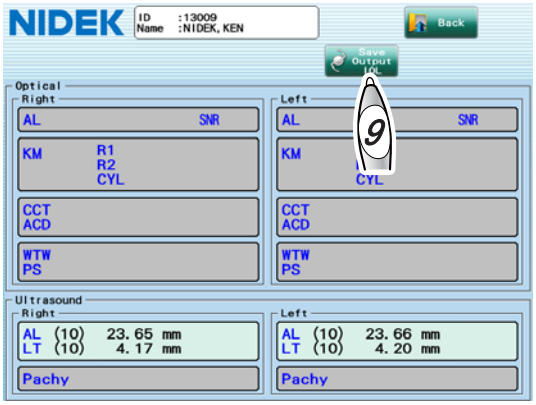
8 After the measurement, press the Verify button.

The measured value confirmation screen appears.

AL: Axial length

LT: Lens thickness

See “O Checking measured result details from measured value confirmation screen” (Page 76).



9 Check the measured results and press the Save Output IOL button to save the measured data, then proceed to IOL calculation.

The measured data is saved, and also output or printed depending on the setting. The IOL power calculation screen appears. Go to “2.8 Calculation of IOL Power” (page 90).

If IOL power calculation is not going to be performed, conduct any of the following procedure.

To save the BIO measured data and continue to perform the BIO measurement on the same patient

1) Press the Back button to return to the BIO mode screen.
2) Press the Save Measure button on the BIO mode screen.

   The BIO measured data is saved and output.
3) The measured data on the screen is cleared and this allows the measurement to be continued on the same patient.

To perform measurement again

1) Press the Back button to return to the BIO mode screen.

2) Press the Del button on the BIO mode screen. The message whether to delete the measured data appears.

3) Press the OK button to delete the data, then go back to Step 5 to perform measurement again.

To perform optical measurement subsequently

1) Press the Back button to return to the BIO mode screen.

2) Press the Opt button on the BIO mode screen to display the optical measurement screen.

3) Go to “2.4 Optical Measurement” (page 54).

To save the measured data and complete the measurement

1) Press the Back button to return to the BIO mode screen.

2) Press the Patient List button on the BIO mode screen. The message whether to save/output the measured data appears.

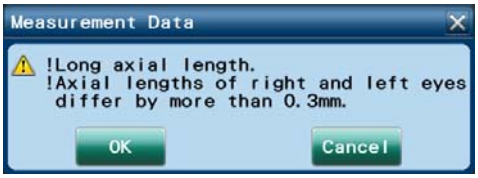
3) Press the Yes button.

The measured data is saved, and also output or printed depending on the setting.

Pressing the No button deletes the measured data, and the Patient List screen appears again.

●Messages related to measurement data

If the AL measured value is outside the standard range, a message calling the operator's attention appears before the measured results are saved and output.



Check the contents of the message, then determine whether to use the measured value.

[OK]: The measured results are saved and output. The save confirmation message is not displayed.

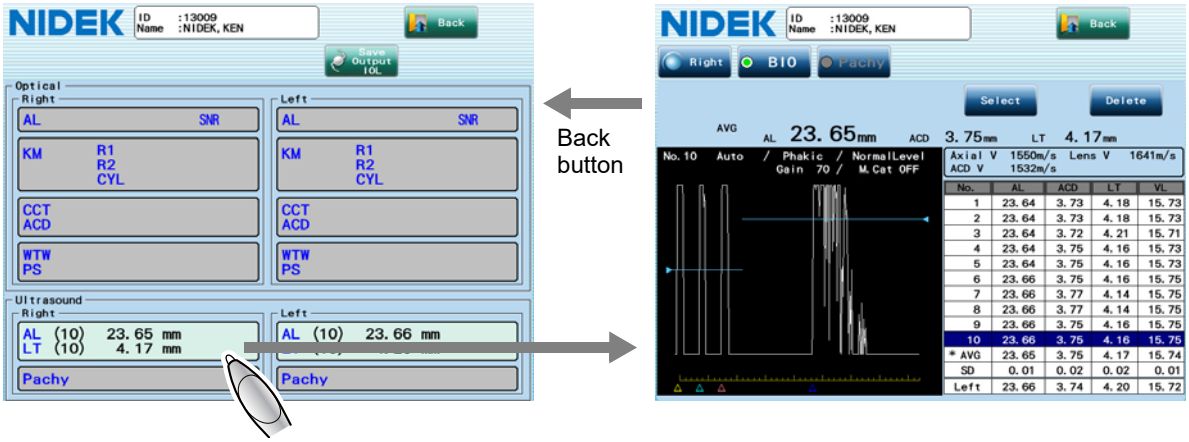
[Cancel]: The measured data is not saved or output.

In addition, when the data is printed with the built-in printer or output in jpg format (Page 155), the message is added.

Message on the screen	Message on the printout from the built-in printer	Contents
! Short axial length	!Short axis length	AL < 22 mm
! Long axial length	!Long axis length	AL > 26 mm
! Axial lengths of right and left eyes differ by more than 0.3 mm.	!ΔAL |R-L| > 0.3 mm	The difference between the right and left exceeds 0.3 mm.

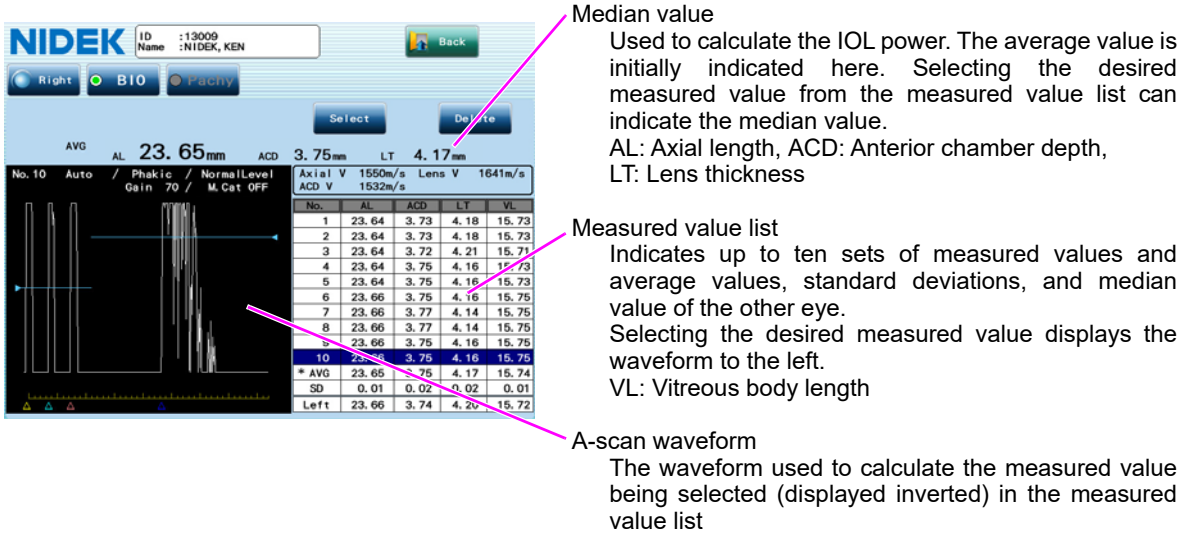
○ Checking measured result details from measured value confirmation screen

Pressing the desired field of the measured result in the measured value confirmation screen displays the measured result details.



Pressing the Back button in the measured result details screen returns to its original screen.

The following is an example of the measured result details screen.



(1) The A-scan waveform of each measurement can be viewed by pressing the measured value list.

(2) Checking the waveform of each measured value then deleting improper measured value can improve the accuracy of the average value.

Pressing the Delete button deletes the measured value being selected. Pressing the Retrieve button restores the deleted measured value.

(3) Pressing the Select button can set the value being selected in the measured value list to be the median value.

The number of the median value is indicated with an asterisk.

Note

- The displayed A-scan waveform is not necessarily the waveform to obtain the median value.

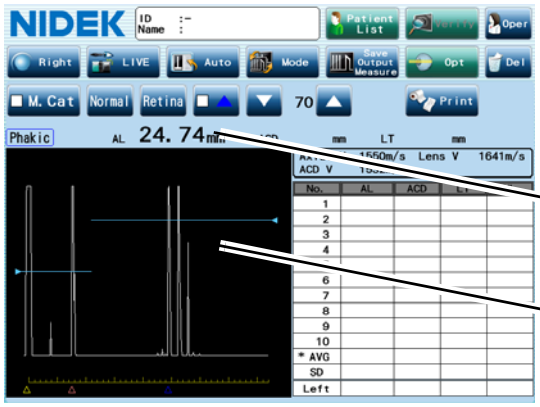
  The A-scan waveform is that of the measured values displayed inverted in the list. This waveform is printed or output to another device.

  The median value is the measured values with the asterisk displayed in the No. field of the list (the default setting is the average value).

○ When measured value cannot be obtained with the eye type set to “Phakic”

Because the waveform is not stable, or a certain measured value cannot be obtained, the measured values may not appear in the list even if the gain adjustment or manual gate setting is performed. In such a case, the values above the waveform cannot be saved as measured values. However, the values can be printed as reference values by the following procedure.

1) Set the data capture mode to “Auto”.
2) Perform measurement, then stop the measurement by pressing the FREEZE button on the screen or the MEASURE switch of the foot switch when a proper waveform is obtained.



3) Check the waveform and values, then press the Print button to print them as reference values.

   The values displayed above the waveform are printed.

   If the waveform or values are improper, perform the measurement again.

   The Print button is displayed only when the data cannot be obtained while the type of the eye to be measured is “Phakic” and the data capture method is “Auto”.

Note

- The procedure above is enabled only when the eye type is “Phakic”.
- The printed values are reference values. If these values are to be used for IOL power calculation, manually enter the values in the IOL power calculation screen. See Step 5 of “2.8 Calculation of IOL Power” (Page 94).

2.5.1 Cautions in BIO mode measurement

To carry out BIO mode measurement smoothly and accurately, pay attention to the following:

(1) Instruct the patient not to move his/her eyes.

If the patient is nervous, instruct him/her to relax.

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

Contact between the probe and cornea is an important factor in obtaining accurate BIO mode measured 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. A proper A-scan waveform has also a large retinal echo which rises sharply accompanying a small scleral echo.

When the echoes of the retina and sclera are not separated, press the button or chin-rest down button ( ) to decrease the gain.

(3) Check the following points before freezing the obtained BIO mode measurement value:

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

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

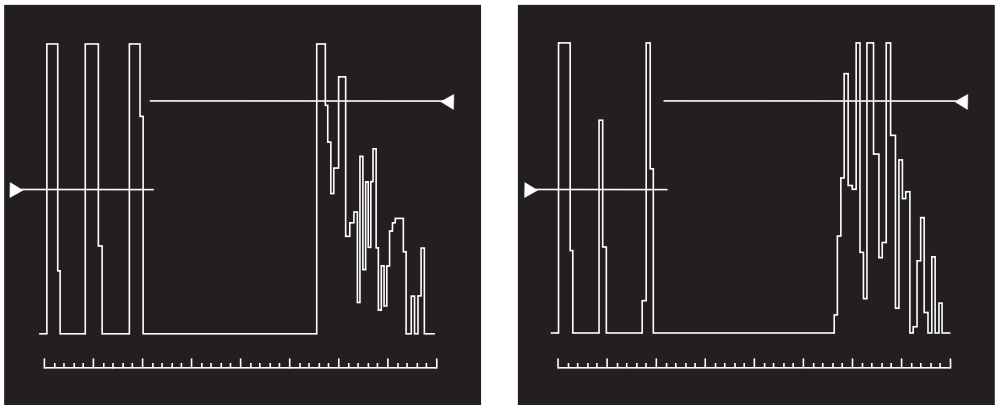
c) Is the patient's eye fixed?

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

* If the BIO mode measurement is performed hurriedly, accurate values cannot be obtained. Take enough time for the BIO mode measurement.

(4) In Auto mode, if the display does not stop 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.

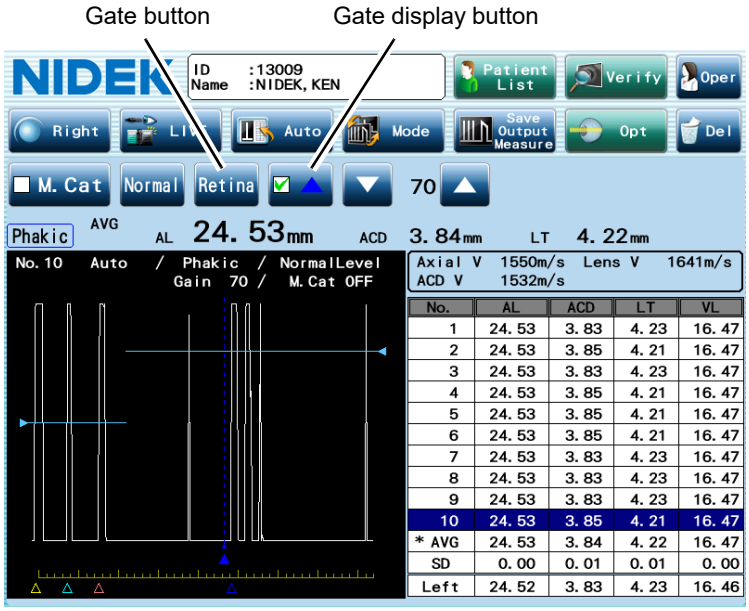


Proper Improper

* The gate can also be moved using the touch pen.

2.5.2 Manual gate

If there is an additional echo near the threshold value preceding any of the valid echoes, this additional echo is mistakenly considered as 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, Ant-lens (anterior), Post-lens (posterior), or Retina) with the gate button and pressing the gate display button so that it becomes enabled. Then the displayed gate position can be adjusted.



1 In the BIO mode 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 FREEZE button to stop BIO mode measurement.
2) In the BIO mode screen, observe the A-scan waveform and intraocular biometry values.

   If the BIO mode measurement 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 button and check the box on the gate display button to display the manual gate.

   * There are gates for cornea, anterior lens, posterior lens, and retina. Move each gate to the respective echo.

   Manual gate for cornea (Cornea) ⇒ yellow dotted line
   Manual gate for anterior lens (Ant-lens) ⇒ light blue dotted line
   Manual gate for posterior lens (Post-lens) ⇒ pink dotted line
   Manual gate for retina (Retina) ⇒ blue dotted line

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

* The gate can also be moved using the touch pen.

Note

- Changing the manual gate during the measurement clears the measurement data of before changing the manual gate.

3 Repeat the BIO mode measurement and confirm the change of the values of each intraocular part by the manual gate.

1) Press the MEASURE switch of the foot switch or the LIVE button 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 as valid echoes, and all intraocular values are changed by the manual gate function.

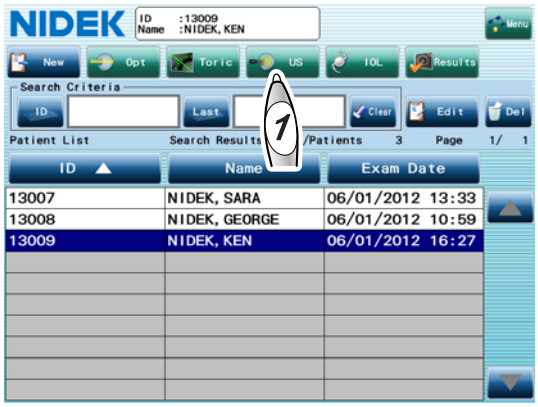
Note

- Because an extraneous echo in the BIO mode measurement may indicate an intraocular lesion, it is recommended to check for such a possible lesion using other methods (such as ultrasound imaging).

2.6 Pachy Mode Measurement (Optional)

Corneal thickness can be measured with ultrasonic measurement function by touching the optional pachymetry probe to the cornea. The optional ultrasonic measurement function and pachymetry probe are necessary.

1 Select or enter the patient information in the Patient List screen, then press the US button.



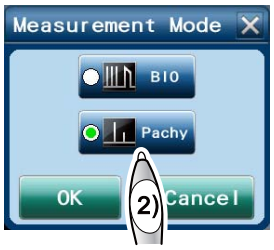
The BIO mode screen appears.

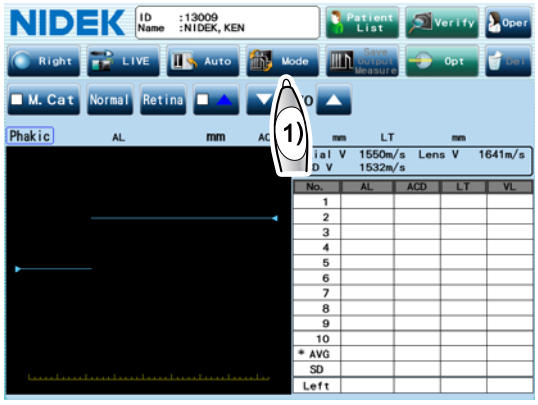
If the Pachy mode screen appears, it is not necessary to follow Step 2.

2 Display the Pachy mode screen.

1) Press the Mode button.

The Measurement Mode window appears.

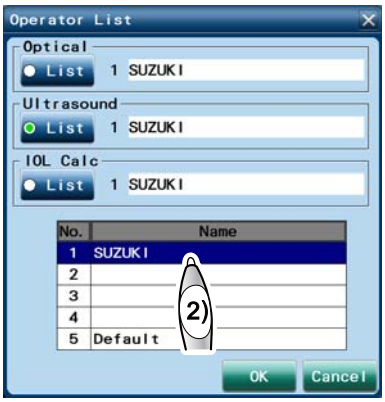




2) Select the Pachy button, then press the OK button.

The Pachy mode screen appears.

3 Specify the operator.



1) Press the Oper button to display the Operator List window.
2) Select the desired operator who performs ultrasonic measurement.
3) If necessary, press the List button on the Optical field to select the desired operator who performs optical measurement.
4) If necessary, press the List button on the IOL Calc field to select the desired surgeon who performs IOL implantation.
5) Press the OK button.

It is necessary to register operator's names in the Oper tab of the Parameter Settings screen in advance. See "O Registering operator's name" (Page 134).

Note

- Because the sonic velocity used to calculate the measured value and the measurement map are set for each operator, be sure to specify the operator.
- The specified operator name is printed or output to another device.
- Changing the operator after the measurement clears the measurement data.

4 Press the Right/Left button to select the right or left eye to be measured.

Each time the button is pressed, the eye to be measured is indicated such as "Right" or "Left".

5 Press the capture mode button to specify the data capture method.

Each time the button is pressed, the data capture method is indicated such as "Auto" or "Speedy".

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.

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

The measurement data of the past three times (nine data sets in total because a single measurement generates three data sets) are listed. If the measurement is performed more than three times, the oldest three sets of data are deleted.

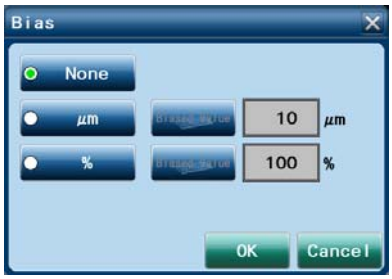
6 Select the desired measurement map.

1) Press the Map button to display the Map window.
2) Select the number of the measurement map to be used, then press the OK button.

Note

- When using the Camellin-Calossi formula for the measured value, select 3.

7 Press the Bias button to set the bias indication and bias amount.



(A) To indicate an unbiased value

Select “None”.

* The measured value is displayed as it is.

(B) To indicate a biased value

1) Select “µm” or “%”.

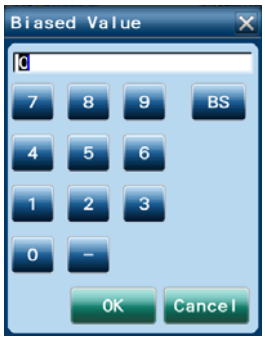
* µm: The biased value (adding the bias value to the measured value) is indicated as the measured value.

%: The biased value (multiplying the measured value by the bias value) is indicated as the measured value.

2) Press the Biased Value button next to the button selected in Step 1).
3) Input the desired value using the numeric keypad window, then press the OK button.

The following are 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 that the average value may differ from the one obtained by adding the bias value to the averaged measurement value.
- The biased value is not added to the IOL calculation or result screen. Values without biased value are used.
- The bias setting is common to right and left eyes.

8 Press the MEASURE switch of the foot switch or the LIVE button to restart the measurement.

The indication of LIVE changes to FREEZE, and Pachy mode measurement is started.

9 Touch the pachymetry probe tip to the point of the cornea corresponding to the measurement point highlighted in light blue 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 measured values, average value, and standard deviation of each measurement are indicated. In the waveform display above the list, the current waveform is indicated.

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

When the auto measurements for the set times are finished, a beeping sound, and the indication of FREEZE changes to LIVE.

If the waveform is improper or its height is low, the measured value may not be displayed. In such a case, adjust the gain by pressing the / button on the both sides of the gain display or the chinrest up/down button (,).

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

10 Release the probe tip from the cornea.

11 Press the PRINT (next) switch of the foot switch or press the next desired measurement point with the touch pen to change the measurement point highlighted in cyan.

The measurement point also can be moved by rotating the joystick.

12 Press the MEASURE switch of the foot switch or the LIVE button to start the measurement at the new measurement point.

13 Repeat Steps 8 to 11 until the measurements of all the measurement points on the map are completed.

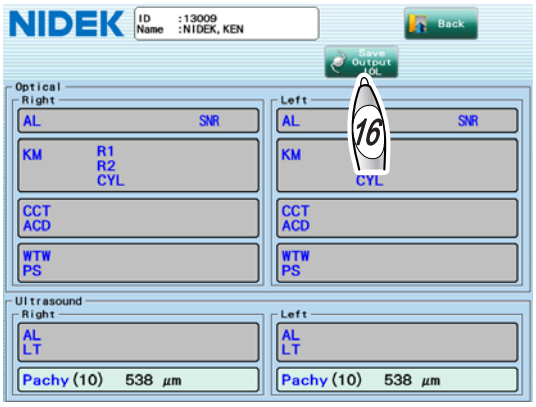
14 Specify the measured value on the desired measurement point as the median value.

The average value on the measurement point highlighted in light blue on the map becomes the median value. Press the measurement value on the map for the proper median value.

15 After the measurement, press the Verify button.

The measured value confirmation screen appears.

See “○ Checking measured result details from measured value confirmation screen” (Page 86).



16 Check the measured results and press the Save Output IOL button to save the measured data, then proceed to IOL calculation.

The measured data is saved, and also output or printed depending on the setting. The IOL power calculation screen appears. Go to “2.8 Calculation of IOL Power” (page 90).

If IOL power calculation is not going to be performed, conduct any of the following procedure.

To perform measurement again

1) Press the Back button to return to the Pachy mode screen.
2) Press the Del button on the Pachy mode screen. The message whether to delete the measured data appears.
3) Press the OK button to delete the data, then go back to Step 8 to perform measurement again.

To perform optical measurement subsequently

1) Press the Back button to return to the Pachy mode screen.
2) Press the Opt button on the Pachy mode screen to display the optical measurement screen.
3) Go to “2.4 Optical Measurement” (page 54).

To save the measured data and complete the measurement

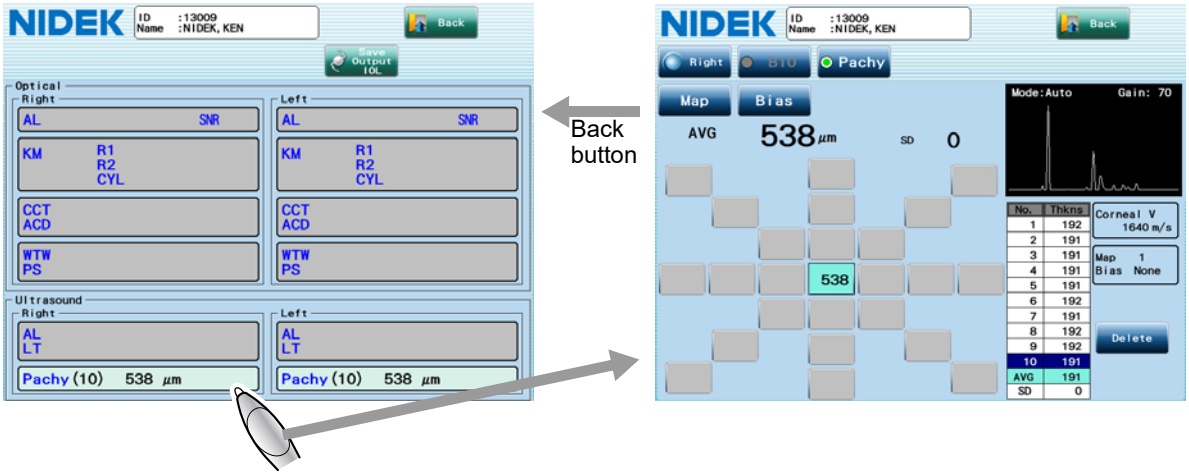
1) Press the Back button to return to the Pachy mode screen.
2) Press the Patient List button on the Pachy mode screen. The message whether to save/output the measured data appears.
3) Press the Yes button.

   The measured data is saved, and also output or printed depending on the setting.

   Pressing the No button deletes the measured data, and the Patient List screen appears again.

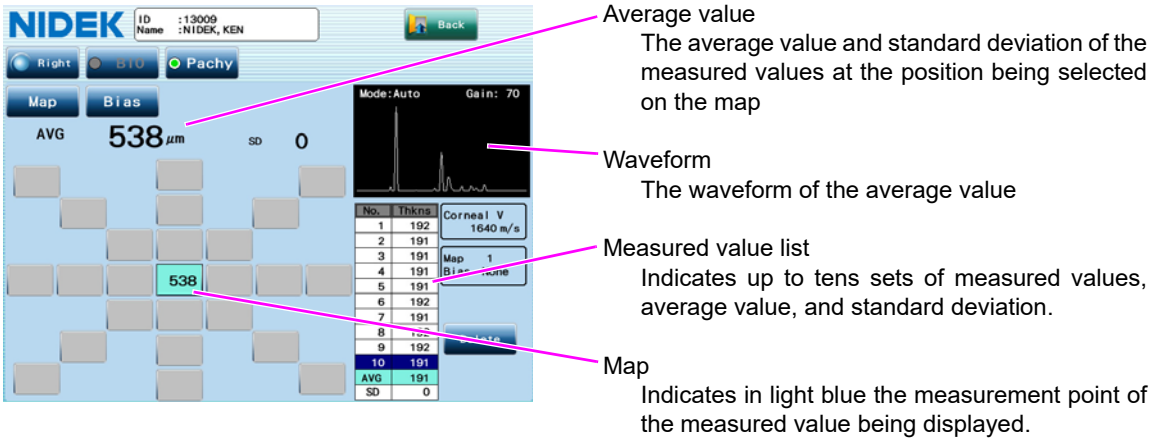
○ Checking measured result details from measured value confirmation screen

Pressing the desired field of the measured result in the measured value confirmation screen displays the measured result details.



Pressing the Back button in the measured result details screen returns to its original screen.

The following is an example of the measured result details screen.



(1) If the measurement is performed at multiple positions, specify the measured value at the desired position to be displayed on the map.

(2) Deleting improper measured value in the measured value list can improve the accuracy of the average value.

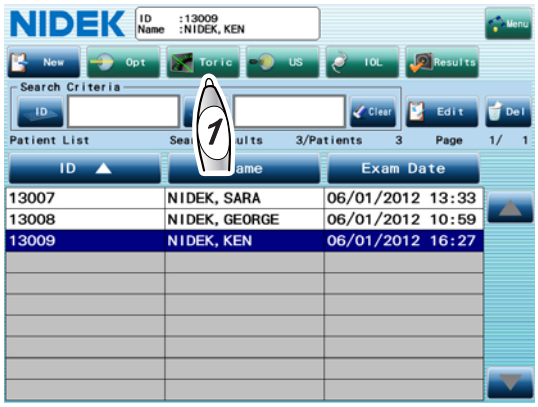
Pressing the Delete button deletes the measured value being selected. Pressing the Retrieve button restores the deleted measured value.

(3) Pressing the Bias button changes the bias setting.

2.7 Toric Lens Assist Mode

An anterior eye segment image is overlaid with the steepest and flattest meridians to measure the angle between the meridians and markers so as to use the value as a reference for toric IOL implantation.

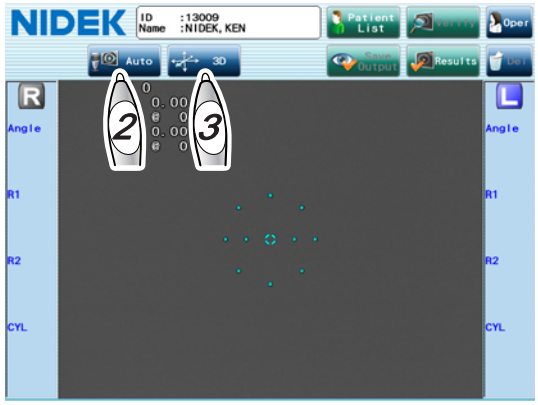
1 Select or enter the patient information in the Patient List screen, then press the Toric button.



Note

- When the number of saved measurement data reaches 1000 in Toric lens assist mode, or when the number of saved measurement data for one patient reaches 99, the message “Database has reached its maximum number of entries. To save, delete the oldest entry from the database.” appears. See “Message” in “3.1.9 Other tab” (page 157).

The toric lens assist mode screen appears.



2 Specify whether or not to use the auto shot function using the auto shot button.

Auto: The auto shot function is enabled.

Manual: The auto shot function is disabled.

3 Specify the alignment method with the tracking button.

3D: The auto tracking function in the forward and back, right and left, and up and down directions is enabled.

2D: The auto tracking function in the right and left, and up and down directions is enabled.

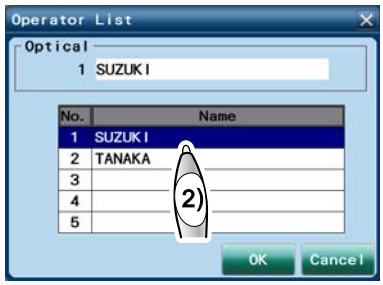
OFF: The auto tracking function is disabled. The alignment and focusing are manually performed.

4 Specify the operator.

1) Press the Oper button to display the Operator List window.

2) Select the operator, then press the OK button.

It is necessary to register operator's names in the Oper tab of the Parameter Settings screen in advance. See “O Registering operator’s name” (Page 134).



Note

- The specified operator name is printed or output to another device.

5 Prepare the patient for measurement.

1) Clean the forehead rest and chinrest that contact the patient.

Wipe them with clean gauze or absorbent cotton dampened with ethanol for disinfection.

When a stack of chinrest paper is secured to the chinrest, remove one sheet of paper.

2) Instruct the patient to remove glasses or contact lenses and sit on a chair.

6 Have the patient place his/her chin on the chinrest as deeply as possible, and his/her forehead on the forehead rest lightly.

7 Adjust the height of the chinrest with the chinrest up/down button (▲ , ▼) until the center level of the patient’s eye aligns with the eye level marker.

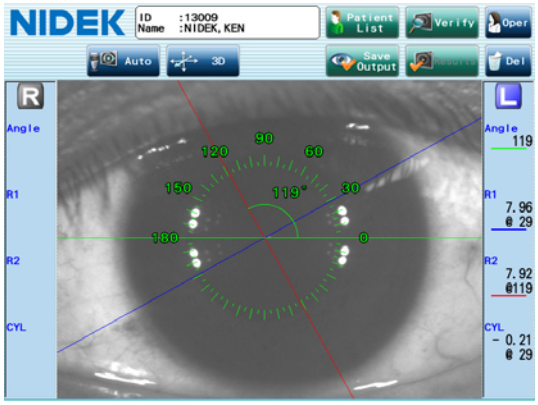
Before adjusting the height of the chinrest, let the patient know that the chinrest moves up and down.

8 Perform alignment and focusing, then start measurement.

An anterior eye segment image is captured, and the steepest and flattest meridians are displayed on the image.

Red line: The steepest meridian

Blue line: The flattest meridian

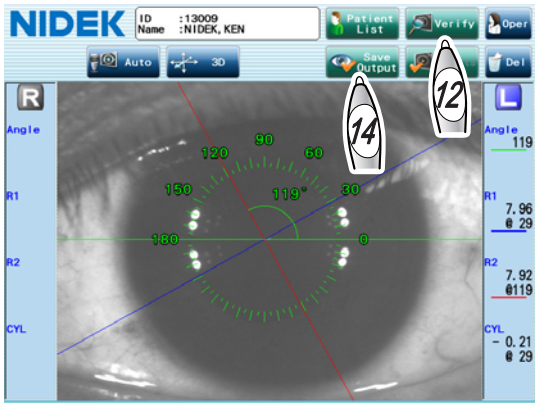


9 If necessary, measure the other eye in the same manner as Step 8.

10 After the measurement, release the patient from the chinrest.

Instruct him/her to remain seated when removing his/her head from the chinrest. If the patient suddenly rises up, he/she may hit his/her face on the upper part of the forehead rest.

11 Align the angle reference line (green line) with the markers. Specify the positions where the markers are overlaid on the displayed anterior eye segment image using the touch pen.



The angle reference line can be moved to the marker position by specifying the marker positions on the anterior eye segment image with the touch pen or by dragging the angle reference line.

Dragging the angle scale can change its size.

When both eyes have been measured, moving the main unit to the right or left switches the highlighted measured results for the corresponding eye.

Note

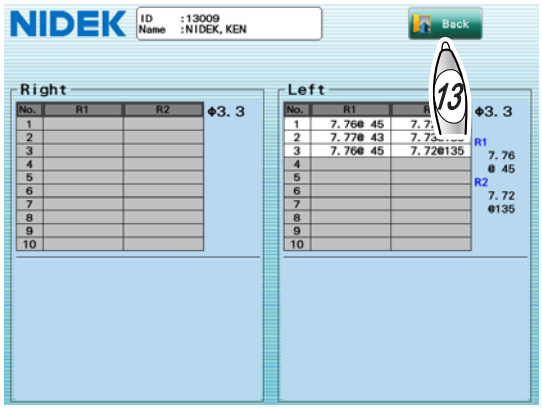
- In this case "marker" means mark directly placed on the cornea of the patient's eye. During surgery, implant the IOL so that the angle of this markers and the toric lens axis mark is the same as the angle obtained in the toric lens assist mode screen.

12 Press the Verify button to verify the detailed KM measured value.

Check the KM measured values in the measured value confirmation screen.

13 Press the Back button.

The toric lens assist mode screen appears again.



14 Save the result obtained in the toric lens assist mode screen.

1) Press the Save Output button on the toric lens assist mode screen.

   A message to confirm whether to save or print the measured data appears.

2) Press the OK button.

   The measured data is saved, and output or printed depending on the setting, then the screen returns to the Patient List screen.

   Pressing the Yes button on the message displayed by pressing the Patient List button instead of the Save Output button saves/prints/outputs the measured data as well. Pressing the No button deletes the measured data, and the Patient List screen appears again.

To perform measurement again without saving the result

1) Press the Del button on the toric lens assist mode screen. The message whether to delete the measured data appears.
2) Press the OK button to delete the data, then go back to Step 8 to perform measurement again.

2.8 Calculation of IOL Power

Pressing the Save Output IOL button after the axial length measurement saves the measured data and displays the IOL power calculation screen in which the IOL power is calculated. The calculation is performed if the necessary data has been input, and the calculated results of the selected IOL type are listed.

The following are explanations for the IOL power calculation screen for both eye data and single eye data.

When both eye data is displayed (View1 to View4)

When single eye data is displayed (View5 to View8)

Specify whether to display both eye data or single eye data referring to “○ Display setting for IOL power calculated results” (Page 148).

Note

- When the number of saved calculated results reaches 1000, or when the number of saved calculated results for one patient reaches 99, the message “Database has reached its maximum number of entries. To save, delete the oldest entry from the database.” appears. See “Message” in “3.1.9 Other tab” (page 157).

2.8.1 When both eye data is displayed in the IOL power calculation screen

The figure to the right is an example of the IOL power calculation screen for when the display setting is selected from View1 to View4. Two sets of the calculation results of the right eye are displayed in IOL1 and IOL2 fields, and those of the left eye are displayed in IOL3 and IOL4 fields. The IOL formula and model are specified for each eye.

Note

- When the values measured by the axial length measurement of the device are used for IOL power calculation, the validity of the measured results should be carefully evaluated by doctors.
- To calculate the IOL power, register the IOL information and set the IOL constants to be used in advance. See "○ IOL settings (registering IOL information) (Page 143)".

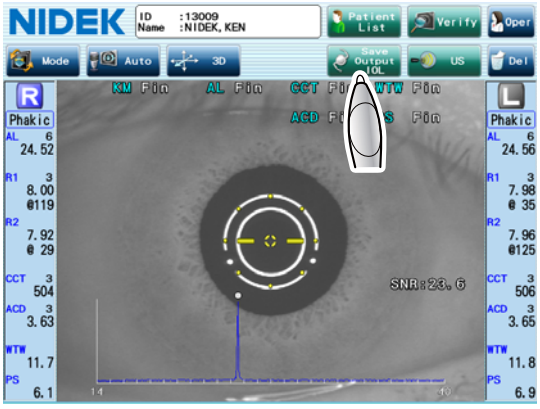
1 Display the IOL power calculation screen.

There are four methods to move to the IOL power calculation screen as shown below, from (A) to (D).

Follow Step (A) to calculate the IOL power immediately after the measurement, and follow Step (B) or (C) to calculate the IOL power using the saved data in the database. Follow Step (D) to recalculate the IOL power that has already been calculated. To select the measured value to be used for IOL power calculation, select the desired measured value in the result screen shown in Step (C), then enter the IOL power calculation screen.

(A) Press the Save Output IOL button on the optical measurement screen or the measured result confirmation screen.

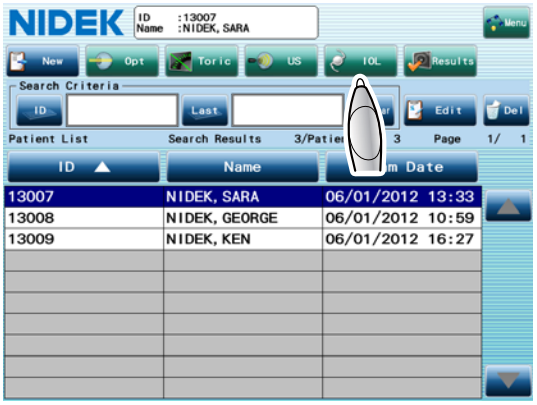
The measured data is saved or printed, then the IOL power calculation screen appears.



(B) Select the desired patient in the Patient List screen, then press the IOL button.

The IOL power calculation screen appears.

The latest measured value is used for IOL power calculation.

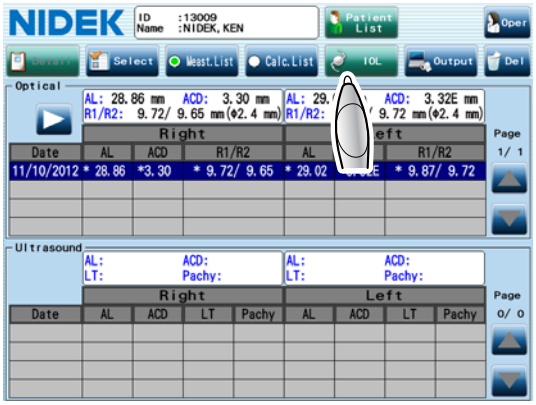


(C)Select the desired patient in the Patient List screen, and press the Results button to display the result screen. Then press the IOL button.

The measured values marked with an asterisk are used for IOL power calculation.

To select the measured value to be used for IOL power calculation, select the desired measured value and press the Select button. The asterisk moves to the selected measured value.

When the desired date is selected and the Select button is pressed, the asterisk moves to all the measured values of the day.



(D)When recalculating the IOL power that has already been calculated, press the Calc.List button in the result screen to display the result screen for IOL calculation. Then press the IOL button

If the patient's postoperative data has been registered, the postoperative data is deleted when the IOL power recalculation is performed.

Whether both eye data or single eye data (right or left eye) is displayed in the IOL power calculation screen depends on the display setting for when the calculation result was saved.

The following are the relation between the methods (A) to (D) to move to the IOL power calculation screen and the measured values used for IOL calculation.

Method	Measured value used for calculation
(A)	The latest median value
(B)	The latest median value
(C)	The value marked with an asterisk (Default setting: The latest median value)
(D)	The value used for the previous calculation

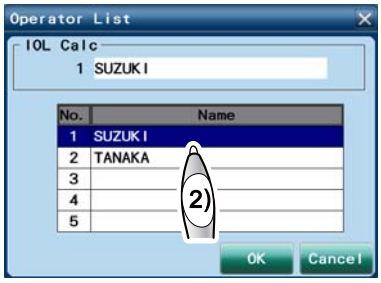
Note

- In Method (D), for an already calculated IOL power displayed in the IOL power calculation screen, the A-constant for the calculated results is that of the prior calculation. When the IOL power is recalculated, the current A-constant is used.

2 Specify the surgeon.

1) Press the Oper button on the IOL calculation screen to display the Operator List window.

2) Select the surgeon, then press the OK button.

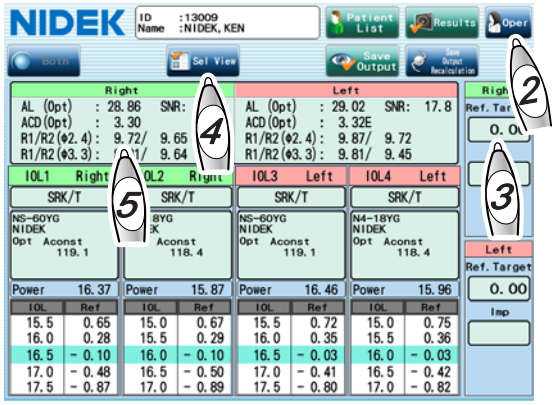


It is necessary to register surgeon's names in the Oper tab of the Parameter Settings screen in advance. See "O Registering operator's name" (Page 134).

3 Press the numeric field in the Ref. Target field to display the numeric keypad window, and input the desired postoperative refraction.

The desired postoperative refraction of each operator specified in parameter setting is input as the default value.

The range of the desired postoperative refraction is between –10.00 D and +10.00 D, and the value cannot be input outside the range.

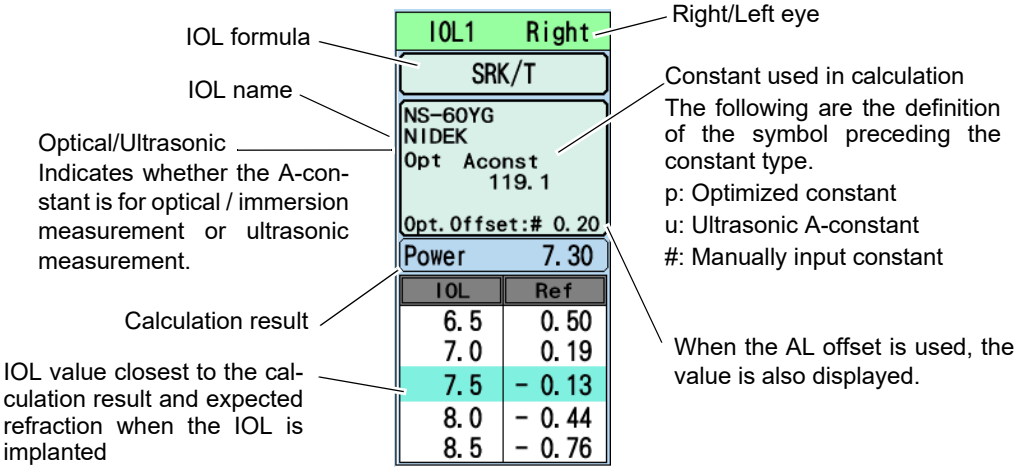


The IOL powers are calculated, then the result is displayed.

Note

- If the IOL constants such as A-constant are not registered, the IOL power is not calculated.
- If the measured values necessary for calculation are not input, the IOL power is not calculated.
- With the Formula/H formula, the IOL power can be calculated even without ACD measurement value. However, that is for exceptional cases such as when ACD cannot be measured due to aphakia. Such a calculation result needs to be used with an understanding that it contains data for exceptional cases.

The IOL power that is the closest to the desired postoperative refraction is displayed in the middle line on the calculation list.



4 If necessary, select the desired display setting in the Select View window.

The display setting of the IOL power calculation screen can be set by selecting items frequently used by each operator. When using other display setting, select the desired setting in the Select View window.

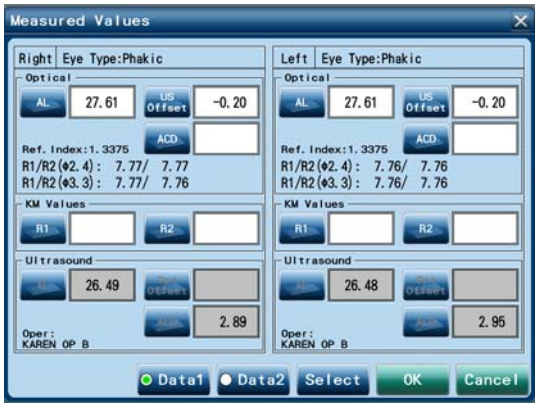
If there is no desired setting among View 1 to 8, follow Steps 7 and 8 to change the setting for each item.

1) Press the Sel View button to display the Select View window.
2) Select the desired display setting from View1 to View8 buttons.

   In Views from 1 to 4, the IOL powers of the both eyes are displayed. In Views from 5 to 8, the IOL powers for a single eye are displayed. For Steps 5 and on, see “2.8.2 When single eye data is displayed in the IOL power calculation screen” (page 101) when the display setting is selected from View5 to View8.
3) Press the OK button.

   Press the Cancel button not to change the setting.

5 To use the measured values obtained using another device for calculation and change the values, input them in the Measured Values window.



1) Press the numeric field of the measured value to display the Measured Values window.
2) Press the button for the measured value to be changed or newly input.

   The buttons in the Optical/Ultrasound field not to be used for calculation are disabled. The figure to the right is the screen for when the optical measured values are used for calculation. In such a case, the AL, Opt offset (optical offset), and ACD buttons in the Ultrasound field are disabled. To input these values, change the setting so that the measured values obtained from ultrasonic measurement are used for calculation (see Step 6).
3) The numeric keypad window appears. Input the desired measured value then press the OK button.

   “#” is indicated with the changed measured value.
4) Repeat Steps 2) and 3) to change the measured value.
5) Press the OK button.

   Press the Cancel button not to change the measured value.

When the Camellin-Calossi formula is used, input the refractive surgical history. See “○ When the Camellin-Calossi formula is used (Page 100)”.

Note

- When using a K value measured by another device, set the corneal refractive index of the other device to the same value as that of the Ref. Index of the AL-Scan.

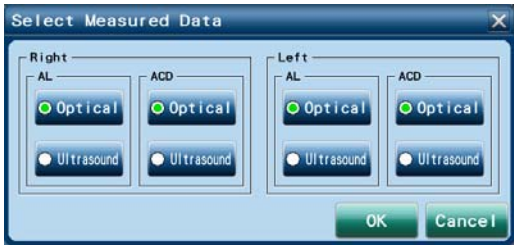
  See “3.1.2 Opt tab” (page 135).

6 If necessary, select either the measured result of optical measurement or ultrasonic measurement to be used for AL and ACD.

The measured value of optical measurement is used for ACD by default. If there are measured values of both optical measurement and ultrasonic measurement, the measured value of optical measurement is selected for AL. To use the measured value of ultrasonic measurement, change the setting by following the procedure as described below.

1) Press the numeric field of the measured value to display the Measured Values window.
2) Press the Select button.

   The Select Measured Data window appears.
3) Select which measured value to be used, then press the OK button.



Note

- An A-constant for optical measurement is required when the optically measured axial length value is used, and an A-constant for ultrasonic measurement is required when the BIO measured axial length value is used. When the applicable A-constant does not exist, one of the following happens.
  (1) When only the A-constant for ultrasonic measurement is input, using the axial length value obtained from the optical measurement automatically adds the US offset to the axial length value.
  (2) When only the A-constant for optical measurement is input, using the axial length value obtained from the BIO mode measurement automatically adds the Optical offset to the axial length value.
  (3) When the US offset or Optical offset to be used for calculation is not input, the calculation cannot be performed. In such a case, input the offset in the Measured Values window.

  See “3.1.2 Opt tab” (page 135), “3.1.4 BIO tab” (page 137), and “1.8.1 AL offset (US offset, optical offset)” (page 4).

⚠CAUTION

- **When the IOL power has been calculated using an axial length value corrected using the AL offset, use of the calculation result needs to be decided by doctors after proper evaluation of the measurement result.**

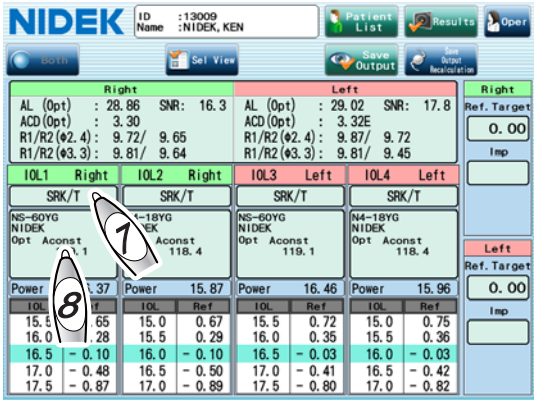
  The IOL formulas are designed on the precondition that the measurement value obtained using the same type of measurement method (optical/ultrasonic) as the constant unique to each IOL (A-constant and such) is used. When the IOL power has been calculated using an axial length value corrected using the AL offset, decide whether or not to use the calculated IOL power taking that into consideration.

7 If necessary, change the IOL formula.

1) Press the button for the IOL formula to be changed.

   The Formula window appears.

   For details of the IOL formula, see “8 IOL FORMULA” (page 241).



2) Select the desired IOL formula, then press the OK button.

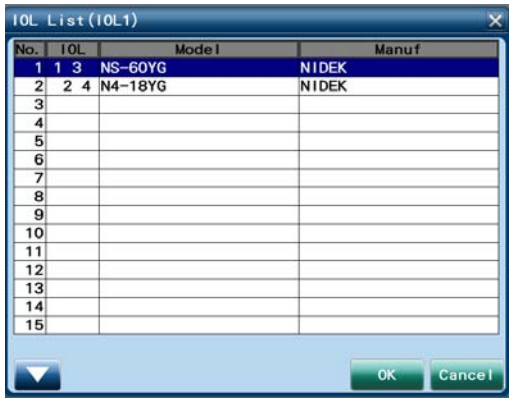
   For the Auto formula, see Page 140.

8 If necessary, change the IOL model.

1) Press the button for the IOL name to be changed.

   The IOL List window appears.

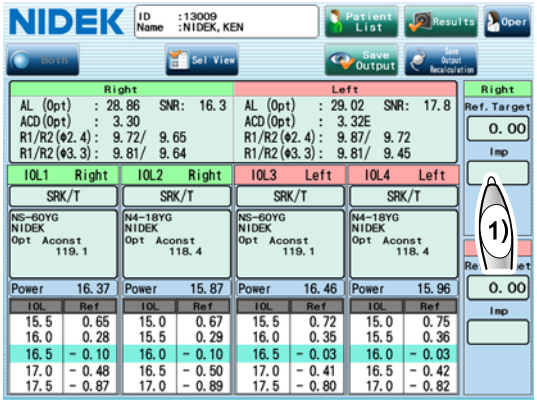
2) Select the desired line of the IOL, then press the OK button.



9 Select the IOL to be implanted.

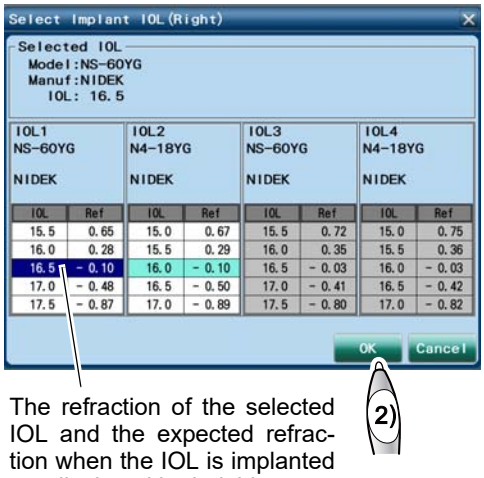
1) Press the button in the Imp field.

   The Select Implant IOL window appears.



2) Select the IOL to be implanted, then press the OK button.

3) Select the IOL to be implanted to the other eye in the same manner as Steps 1) and 2).



The refraction of the selected IOL and the expected refraction when the IOL is implanted are displayed in dark blue.

Note

- Specify the IOL to be implanted and save the calculated results because they are necessary for IOL constant optimization.

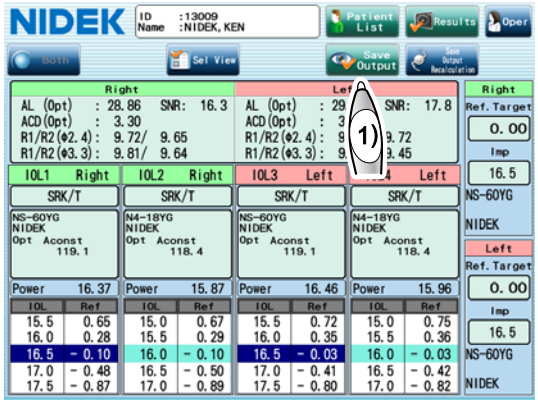
10 Save the calculated result.

1) Press the Save Output button.

   A message to confirm whether to save or print the calculated result appears.

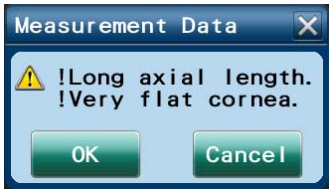
2) Press the OK button.

   The calculated result is saved, and output or printed if necessary, then the screen returns to the patient information screen appears.



To calculate again after saving, printing, or outputting the calculated result without proceeding to the patient information screen, press the Save Output Recalculation button instead of the Save Output button.

●Messages related to measurement data



If the AL measured value or KM measured value used for calculation is outside the standard range, a message calling the operator's attention appears before the IOL calculation result is saved and output.

Check the contents of the message, then determine whether to use the calculation result.

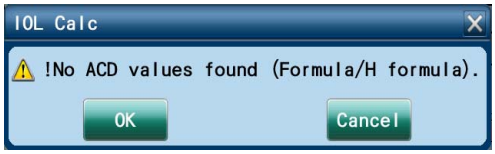
[OK]: The calculation result is saved and output. The save confirmation message is not displayed.

[Cancel]: The calculation result is not saved or output.

In addition, when the data is printed with the built-in printer or output in jpg format (Page 155), the message is added.

Message on the screen	Message on the printout from the built-in printer	Contents
! Short axial length	!Short axis length	AL < 22 mm
! Long axial length	!Long axis length	AL > 26 mm
! Axial lengths of right and left eyes differ by more than 0.3 mm.	!ΔAL |R-L| > 0.3 mm	The difference between the right and left exceeds 0.3 mm.
! Very flat cornea	!Flat corneal	R > 8.4 mm (K < 40 D)
! Very steep cornea	!Steep corneal	R < 7.2 mm (K > 47 D)
! Corneal refractive powers of right and left eyes differ by more than 1 D.	!ΔK |R-L| > 1D	The difference between the right and left exceeds 1 D.
! Very high corneal astigmatism	!High astigmatism	R1-R2 > 0.5 mm (|K1-K2| > 2.5 D)
! Corneal refractive powers of ø2.4 mm and ø3.3 mm mire rings differ by more than 0.5 D.	!ΔK |Phi2.4-3.3| > 0.5D	|ø2.4 mm - ø3.3 mm| > 0.5 D

●Messages related to IOL calculation



A message calling the operator's attention appears before the IOL calculation result is saved and output in the following cases.

- For Formula/H formula, there is no ACD value (optical or ultrasonic).
- For Formula/H formula, the KM measured value measured with the 3.3-diameter mire ring, the BIO measured AL value, or the BIO measured ACD is used.
- Calculation is performed with the Formula/H formula using the data for the eye type other than phakic eye (“Phakic” and “Silicone filled, Phakic”).
- The optical offset or US offset is used.

Check the contents of the message, then determine whether to use the calculation result.

[OK]: The calculation result is saved and output. The save confirmation message is not displayed.

[Cancel]: The calculation result is not saved or output. Implement the solution shown in the following table.

In addition, when the data is printed with the built-in printer or output in jpg format (Page 155), the message is added.

Message on the screen	Message on the printout from the built-in printer	Solution
! No ACD values found (Formula/H formula)	!No ACD	Check the eye type. If the eye type is Phakic, perform ACD measurement. In another way, perform calculations using another IOL power calculation formula.

Message on the screen	Message on the printout from the built-in printer	Solution
! Ultrasound data is used (Formula/H formula).	!US	Perform optical measurement. In another way, perform calculations using another IOL power calculation formula.
! Eye Type is other than Phakic (Formula/H formula).	!Eye Type	Check the eye type. If the eye type is proper, perform calculations using another IOL power calculation formula.
! AL offset is used.	!AL offset	The type of the constant unique to each IOL and the type of the measurement value (optical/ultrasonic) are different. Use the same type of the measurement value as the constant unique to each IOL.

⚠CAUTION • **When the IOL power has been calculated using an axial length value corrected using the AL offset, use of the calculation result needs to be decided by doctors after proper evaluation of the measurement result.**

The IOL formulas are designed on the precondition that the measurement value obtained using the same type of measurement method (optical/ultrasonic) as the constant unique to each IOL (A-constant and such) is used. When the IOL power has been calculated using an axial length value corrected using the AL offset, decide whether or not to use the calculated IOL power taking that into consideration.

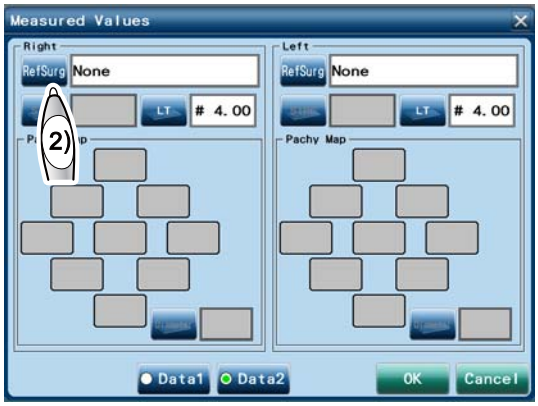
Note

- With the Formula/H formula, the IOL power can be calculated even without ACD measurement value. However, that is for exceptional cases such as when ACD cannot be measured due to aphakia. Such a calculation result needs to be used with an understanding that it contains data for exceptional cases.

○ When the Camellin-Calossi formula is used

When the Camellin-Calossi formula is used, input the refractive surgical history in Step 5 (Page 94).

1) Press the Data2 button.



2) Press the RefSurg button.

   The History of Refractive Surgery window appears.

3) Select the refractive surgical history of the patient, then press the OK button.

   None: No refractive surgical history

   Incisional-RK, AK, CK: Surgery with incision

   Laser-PRK, LASIK: Laser ablation

   Transplant, PTK, or Unknown: Keratoplasty, PTK, or the surgical history is not clear.

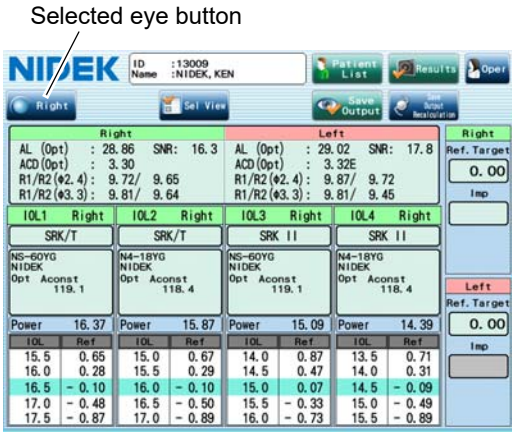
4) When the “Incisional-RK, AK, CK” button or “Laser-PRK, LASIK” button is selected, input the refractive power variation amount in the refractive surgery in the SIRC box.

5) When the “Transplant, PTK, or Unknown” button is selected, input the diameter (the measurement range of the peripheral corneal thickness) using the numeric keypad window displayed by pressing the Diameter button.

   Measure in advance the central corneal thickness and corneal thickness at eight points 45 degrees apart in a circle of “x” mm in diameter (“x” can be input from 1.0 to 7.0 mm). See “2.6 Pachy Mode Measurement (Optional)” (page 81).

2.8.2 When single eye data is displayed in the IOL power calculation screen

The figure to the right is an example of the IOL power calculation screen for when the display setting is selected from View5 to View8. Four sets of the calculation results of the right eye or left eye are displayed in IOL1 to IOL4 fields. The display setting (IOL formula and model) is common to the both eyes.
Press the selected eye button to switch the right and left eye data.



Note

- When the values measured by the axial length measurement of the device are used for IOL power calculation, the validity of the measured results should be carefully evaluated by doctors.
- To calculate the IOL power, register the IOL information and set the IOL constants to be used in advance. See "○ IOL settings (registering IOL information) (Page 143)".

1 Display the IOL power calculation screen in the same manner as Step 1 of "2.8.1 When both eye data is displayed in the IOL power calculation screen" (page 90).

2 Specify the surgeon.

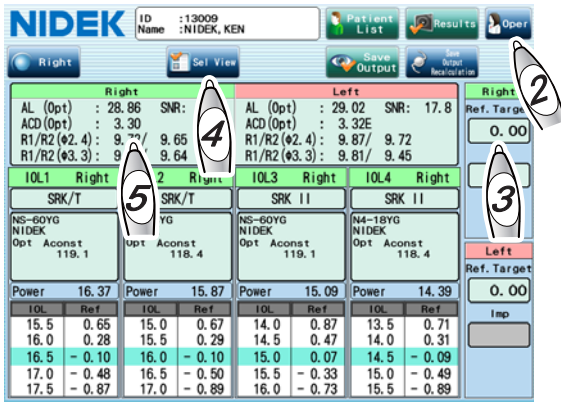
1) Press the Oper button on the IOL calculation screen to display the Operator List window.
2) Select the surgeon, then press the OK button.

   It is necessary to register surgeon's names in the Oper tab of the Parameter Settings screen in advance. See "○ Registering operator's name" (Page 134).

3 Press the numeric field in the Ref. Target field to display the numeric keypad window, and input the desired postoperative refraction.

The desired postoperative refraction of each operator specified in parameter setting is input as the default value.

The range of the desired postoperative refraction is between –10.00 D and +10.00 D, and the value cannot be input outside the range.

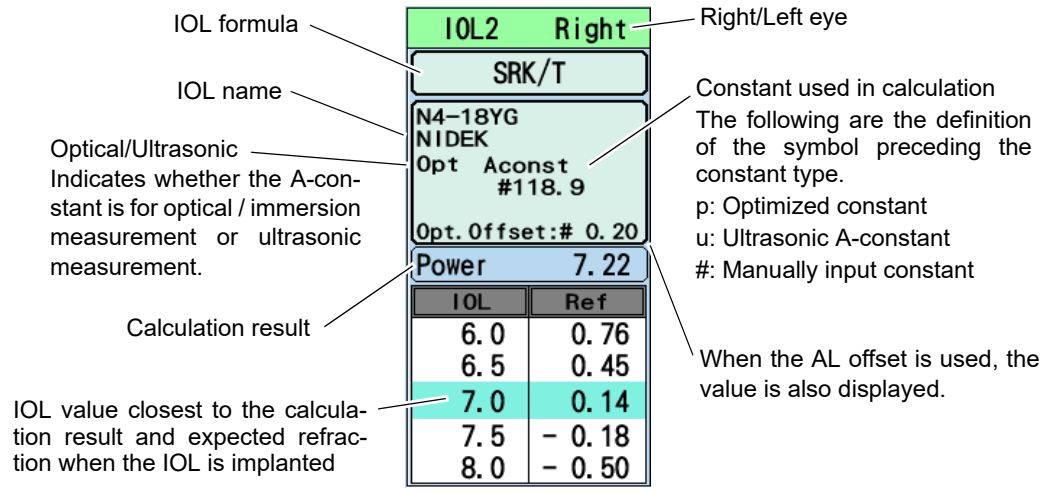


The IOL powers are calculated, then the result is displayed.

Note

- If the IOL constants such as A-constant are not registered, the IOL power is not calculated.
- If the measured values necessary for calculation are not input, the IOL power is not calculated.
- With the Formula/H formula, the IOL power can be calculated even without ACD measurement value. However, that is for exceptional cases such as when ACD cannot be measured due to aphakia. Such a calculation result needs to be used with an understanding that it contains data for exceptional cases.

The IOL power that is the closest to the desired postoperative refraction is displayed in the middle line on the calculation list.



4 If necessary, select the desired display setting in the Select View window.

The display setting of the IOL power calculation screen can be set by selecting items frequently used by each operator. When using other display setting, select the desired setting in the Select View window.

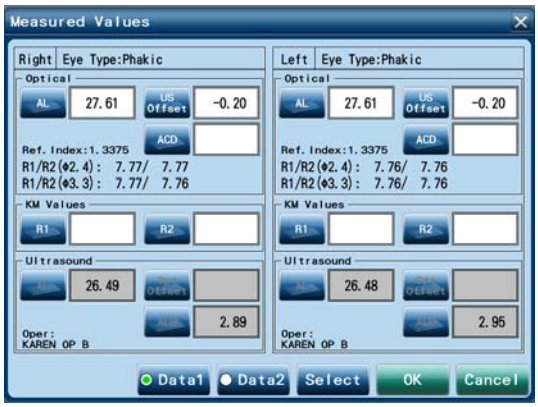
If there is no desired setting among View 1 to 8, follow Steps 7 and 8 to change the setting for each item.

1) Press the Sel View button to display the Select View window.
2) Select the desired display setting from View1 to View8 buttons.

   In Views from 1 to 4, the IOL powers of the both eyes are displayed. In Views from 5 to 8, the IOL powers for a single eye are displayed. For Steps 5 and on, see “2.8.1 When both eye data is displayed in the IOL power calculation screen” (page 90) when the display setting is selected from View1 to View4.
3) Press the OK button.

   Press the Cancel button not to change the setting.

5 To use the measured values obtained using another device for calculation and change the values, input them in the Measured Values window.



1) Press the numeric field of the measured value to display the Measured Values window.

2) Press the button for the measured value to be changed or newly input.

   The buttons in the Optical/Ultrasound field not to be used for calculation are disabled. The figure to the right is the screen for when the optical measured values are used for calculation. In such a case, the AL, Opt offset (optical offset), and ACD buttons in the Ultrasound field are disabled. To input these values, change the setting so that the measured values obtained from ultrasonic measurement are used for calculation (see Step 6).

3) The numeric keypad window appears. Input the desired measured value then press the OK button.

   "#" is indicated with the changed measured value.

4) Repeat Steps 2) and 3) to change the measured value.

5) Press the OK button.

   Press the Cancel button not to change the measured value.

When the Camellin-Calossi formula is used, input the refractive surgical history. See "○ When the Camellin-Calossi formula is used (Page 100)".

Note

- When using a K value measured by another device, set the corneal refractive index of the other device to the same value as that of the Ref. Index of the AL-Scan.

  See "3.1.2 Opt tab" (page 135).

6 If necessary, select either the measured result of optical measurement or ultrasonic measurement to be used for AL and ACD.

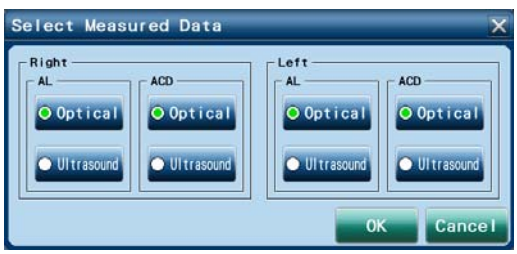
The measured value of optical measurement is used for ACD by default. If there are measured values of both optical measurement and ultrasonic measurement, the measured value of optical measurement is selected for AL. To use the measured value of ultrasonic measurement, change the setting by following the procedure as described below.

1) Press the numeric field of the measured value to display the Measured Values window.

2) Press the Select button.

   The Select Measured Data window appears.

3) Select which measured value to be used, then press the OK button.



Note

- An A-constant for optical measurement is required when the optically measured axial length value is used, and an A-constant for ultrasonic measurement is required when the BIO measured axial length value is used. When the applicable A-constant does not exist, one of the following happens.
  (1) When only the A-constant for ultrasonic measurement is input, using the axial length value obtained from the optical measurement automatically adds the US offset to the axial length value.
  (2) When only the A-constant for optical measurement is input, using the axial length value obtained from the BIO mode measurement automatically adds the Optical offset to the axial length value.
  (3) When the US offset or Optical offset to be used for calculation is not input, the calculation cannot be performed. In such a case, input the offset in the Measured Values window.

  See "3.1.2 Opt tab" (page 135), "3.1.4 BIO tab" (page 137), and "1.8.1 AL offset (US offset, optical offset)" (page 4).

⚠CAUTION • **When the IOL power has been calculated using an axial length value corrected using the AL offset, use of the calculation result needs to be decided by doctors after proper evaluation of the measurement result.**

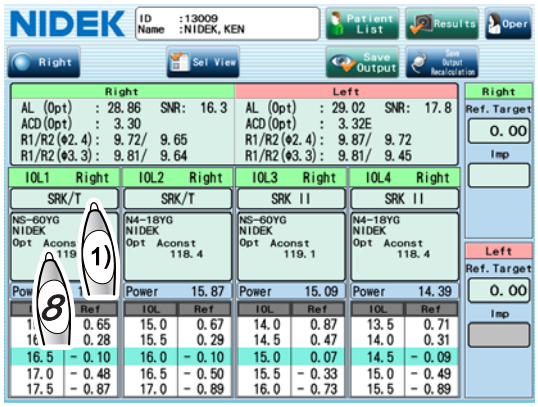
The IOL formulas are designed on the precondition that the measurement value obtained using the same type of measurement method (optical/ultrasonic) as the constant unique to each IOL (A-constant and such). When the IOL power has been calculated using an axial length value corrected using the AL offset, decide whether or not to use the calculated IOL power taking that into consideration.

7 If necessary, change the IOL formula.

1) Press the button for the IOL formula to be changed.

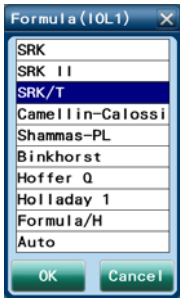
   The Formula window appears.

   For details of the IOL formula, see "8 IOL FORMULA" (page 241).



2) Select the desired IOL formula, then press the OK button.

   For the Auto formula, see Page 140.



Note

- The IOL formula settings for IOL1 to IOL4 are common to the both eyes. When the IOL formula setting for an eye is changed, that for the other eye is also changed.

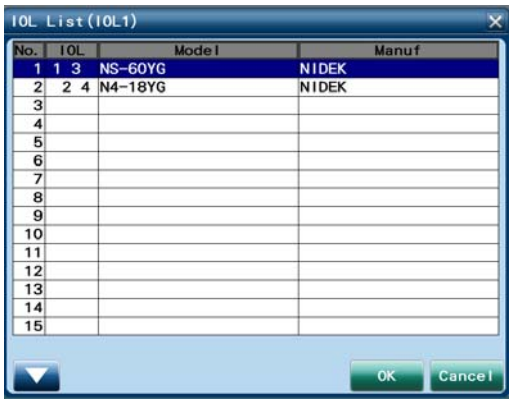
  While the IOL to be implanted for a single eye is selected, when the IOL formula for the other eye with the same IOL number (IOL1 to IOL4) is changed, the selected IOL to be implanted is canceled.

8 If necessary, change the IOL model.

1) Press the button for the IOL name to be changed.

   The IOL List window appears.

2) Select the desired line of the IOL, then press the OK button.



Note

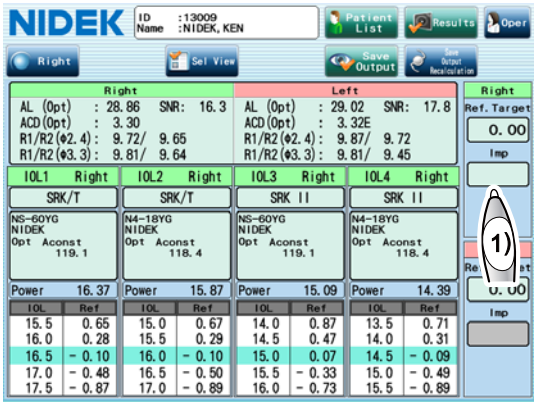
- The IOL models for IOL1 to IOL4 are common to both eyes. When the IOL model for an eye is changed, that for the other eye is also changed.

  While the IOL to be implanted for a single eye is selected, when the IOL model for the other eye with the same IOL number (IOL1 to IOL4) is changed, the selected IOL to be implanted is canceled.

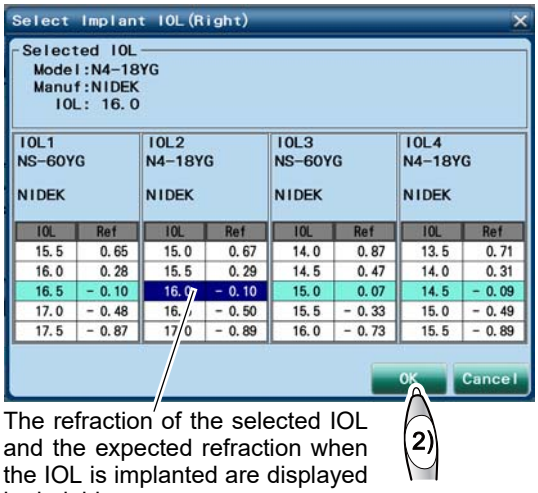
9 Select the IOL to be implanted.

1) Press the button in the Imp field.

   The Select Implant IOL window appears.



2) Select the IOL to be implanted, then press the OK button.



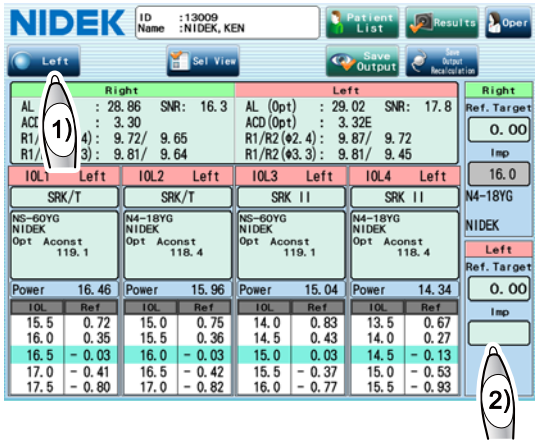
The refraction of the selected IOL and the expected refraction when the IOL is implanted are displayed in dark blue.

10 Select the IOL to be implanted to the other eye.

Select the IOL to be implanted from the calculation results displayed in the IOL power calculation screen. When the display setting is selected from View5 to View8, single eye data is displayed. Therefore, switch the data for right and left eye in the IOL power calculation screen to select the IOL to be implanted to the other eye.

1) Switch the right and left eye data in the IOL power calculation screen using the selected eye button.

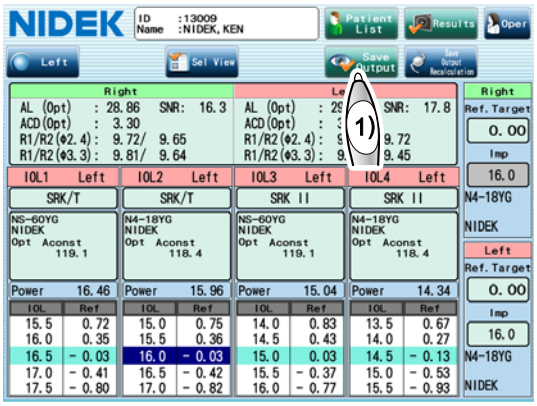
2) Check the calculation results. Then select the IOL to be implanted to the other eye in the same manner as Step 9.



Note

- Specify the IOL to be implanted and save the calculated results because they are necessary for IOL constant optimization.

11 Save the calculated result.



1) Press the Save Output button.

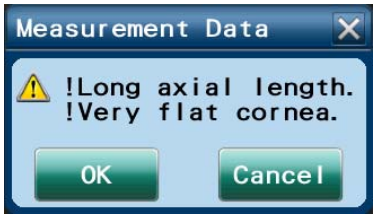
   A message to confirm whether to save or print the calculated result appears.

2) Press the OK button.

   The calculated result is saved, and output or printed if necessary, then the screen returns to the patient information screen appears.

   Pressing the Yes button on the message displayed by pressing the Patient List button instead of the Save Output button saves/outputs/prints the calculated result as well. In such a situation, the Patient List screen appears again. Pressing the No button deletes the calculated result, and the Patient List screen appears again.

●Messages related to measurement data



If the AL measured value or KM measured value used for calculation is outside the standard range, a message calling the operator's attention appears before the IOL calculation result is saved and output.

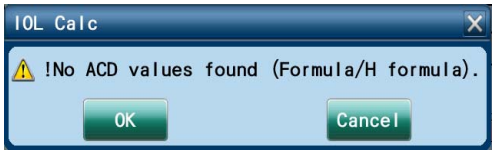
Check the contents of the message, then determine whether to use the calculation result.

[OK]: The calculation result is saved and output. The save confirmation message is not displayed.

[Cancel]: The calculation result is not saved or output.

For the explanation of the messages, see "● Messages related to measurement data" (page 97).

●Messages related to IOL calculation



A message calling the operator's attention appears before the IOL calculation result is saved and output in the following cases.

- For Formula/H formula, there is no ACD value (optical or ultrasonic).
- For Formula/H formula, the KM measured value measured with the 3.3-diameter mire ring, the BIO measured AL value, or the BIO measured ACD is used.
- Calculation is performed with the Formula/H formula using the data for the eye type other than phakic eye ("Phakic" and "Silicone filled, Phakic").
- The optical offset or US offset is used.

Check the contents of the message, then determine whether to use the calculation result.

[OK]: The calculation result is saved and output. The save confirmation message is not displayed.

[Cancel]: The calculation result is not saved or output. Implement the solution shown in the following table.

In addition, when the data is printed with the built-in printer or output in jpg format (Page 155), the message is added.

Message on the screen	Message on the printout from the built-in printer	Solution
! No ACD values found (Formula/H formula)	!No ACD	Check the eye type. If the eye type is Phakic, perform ACD measurement. In another way, perform calculations using another IOL power calculation formula.
! Ultrasound data is used (Formula/H formula).	!US	Perform optical measurement. In another way, perform calculations using another IOL power calculation formula.
! Eye Type is other than Phakic (Formula/H formula).	!Eye Type	Check the eye type. If the eye type is proper, perform calculations using another IOL power calculation formula.
! AL offset is used.	!AL offset	The type of the constant unique to each IOL and the type of the measurement value (optical/ultrasonic) are different. Use the same type of the measurement value as the constant unique to each IOL.

⚠CAUTION • **When the IOL power has been calculated using an axial length value corrected using the AL offset, use of the calculation result needs to be decided by doctors after proper evaluation of the measurement result.**

The IOL formulas are designed on the precondition that the measurement value obtained using the same type of measurement method (optical/ultrasonic) as the constant unique to each IOL (A-constant and such) is used. When the IOL power has been calculated using an axial length value corrected using the AL offset, decide whether or not to use the calculated IOL power taking that into consideration.

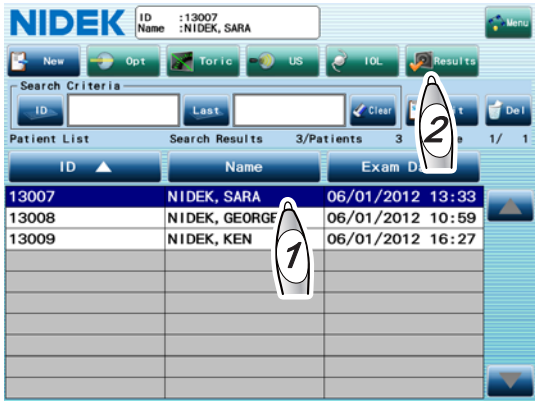
Note

• With the Formula/H formula, the IOL power can be calculated even without ACD measurement value. However, that is for exceptional cases such as when ACD cannot be measured due to aphakia. Such a calculation result needs to be used with an understanding that it contains data for exceptional cases.

2.9 Checking Measured Results and Calculated Results

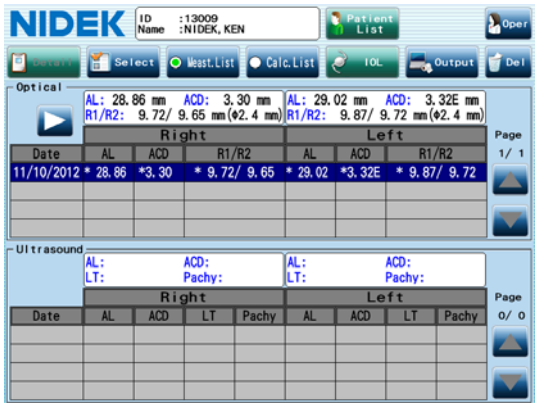
The measured results and calculated results saved in the database can be viewed.

1 Select the desired patient whose measured results and calculated results are going to be viewed in the Patient List screen.

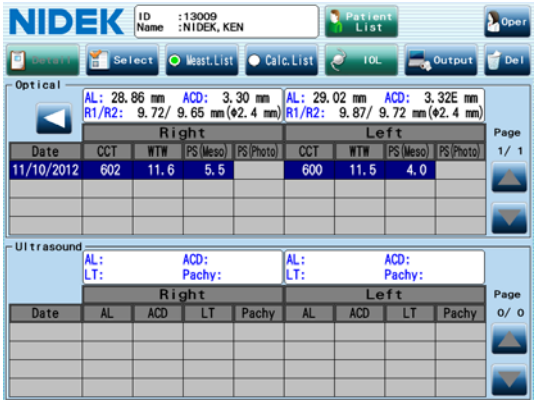


2 Press the Results button.

The result screen appears.



To check the measured result of CCT, WTW, and PS, press the ▷ button to toggle the display of the optical measurement result list.

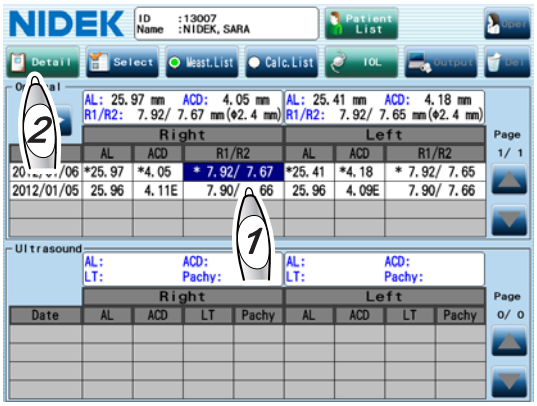


3 To check the calculated result, press the Calc.List button.

The measured results and calculated results can be printed. See “2.10 Printing Measured Results and Calculated Results” (page 114).

○ Displaying measured results details

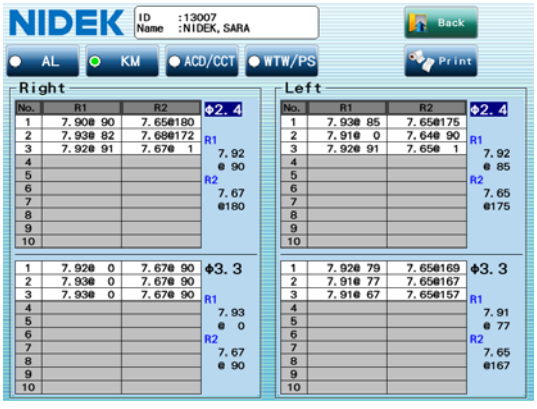
1 Select the desired item to display the details.



2 Press the Detail button.

The details of the measured result selected in Step 1 are displayed.

For the contents of the measured result details screen, see “○ Checking measured result details from measured value confirmation screen” (Page 64), “○ Checking measured result details from measured value confirmation screen” (Page 76), and “○ Checking measured result details from measured value confirmation screen” (Page 86). However, the data has been already finalized. The measured values cannot be removed or modified.



Note

- In the measured result details screen of AL, the retinal pigment epithelium detection position on the combined wave can be modified using the Edit button. See “○ Modifying retinal pigment epithelium detection position of AL combined wave” (Page 68).

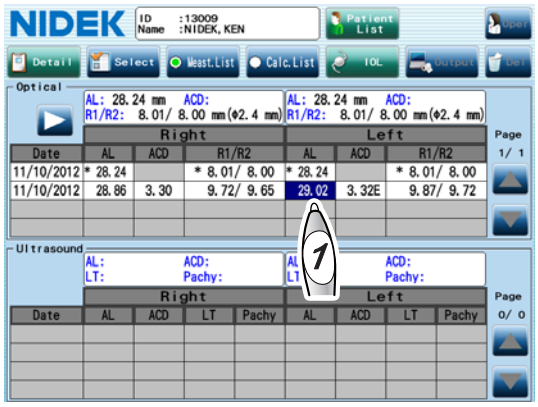
3 Pressing the Back button returns to its original result screen.

○ Selecting measured value used to calculate IOL power

The measured value to be used for IOL power calculation is indicated with an asterisk in the result screen.

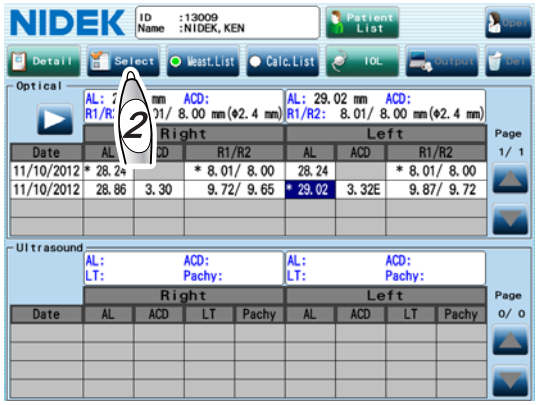
1 Select the desired measured value to be used for IOL power calculation.

Pressing the date field selects the entire line.



2 Press the Select button.

The value being selected becomes the measured value to be used for IOL power calculation and is indicated with an asterisk.



Note

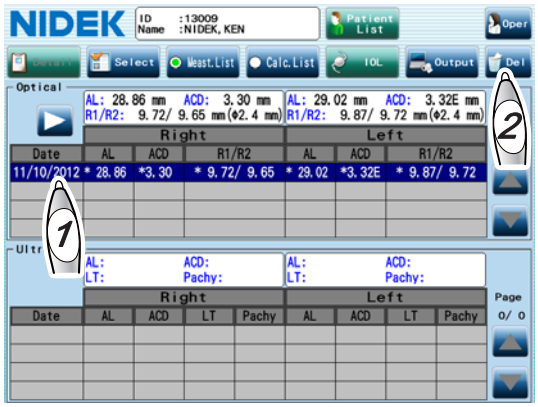
- There are two methods to prevent a measured value with an asterisk from being used for IOL power calculation.
  a. Select another measured value from the same column and press the Select button.
  b. Select the measured value with an asterisk and press the Clear button. (Selecting a measured value with an asterisk changes the Select button to Clear button.)

○ Deleting measured results

The unnecessary measurement results can be deleted from the result screen.

1 Select a date of the measured result to be deleted.

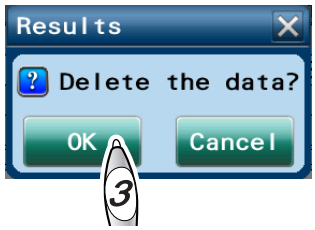
The Del button becomes enabled.



2 Press the Del button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.

The confirmation message asking whether or not to delete the measured result is displayed.



3 Press the OK button.

The line of the measured result selected in Step 1 is deleted.

Note

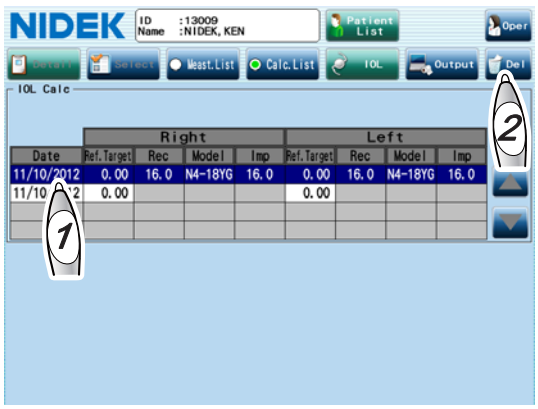
- If there is a calculated result obtained using the deleted measured result, the calculated result is not deleted.

○ Deleting calculated results

The unnecessary IOL power calculated results can be deleted from the result screen.

1 Select a date of the calculated result to be deleted.

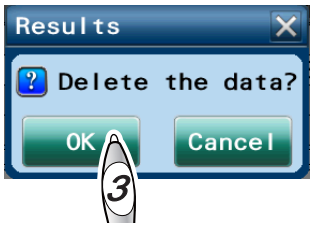
The Del button becomes enabled.



2 Press the Del button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.

The confirmation message asking whether or not to delete the calculated result is displayed.



3 Click the OK button.

The line of the calculated result selected in Step 1 is deleted.

2.10 Printing Measured Results and Calculated Results

To print the measured results and calculated results using the internal printer, there are two methods below.

(1) Automatically printing the measured results and calculated results when they are saved in the database after being finalized

(2) Manually printing the results from the result screen

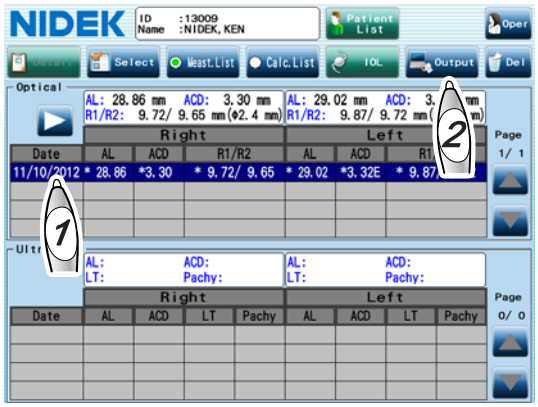
In the both cases, the printing contents are based on the settings in the Print tab of the Parameter Settings screen. See “3.1.7 Print tab” (page 150).

○ Setting for automatic printing

To print the results automatically as described in Method (1) above, set the Mode parameter to “Auto” in the Print tab of the Parameter Settings screen.

○ Procedure for manual printing

1 Select the measured data or calculated results to be printed in the result screen.



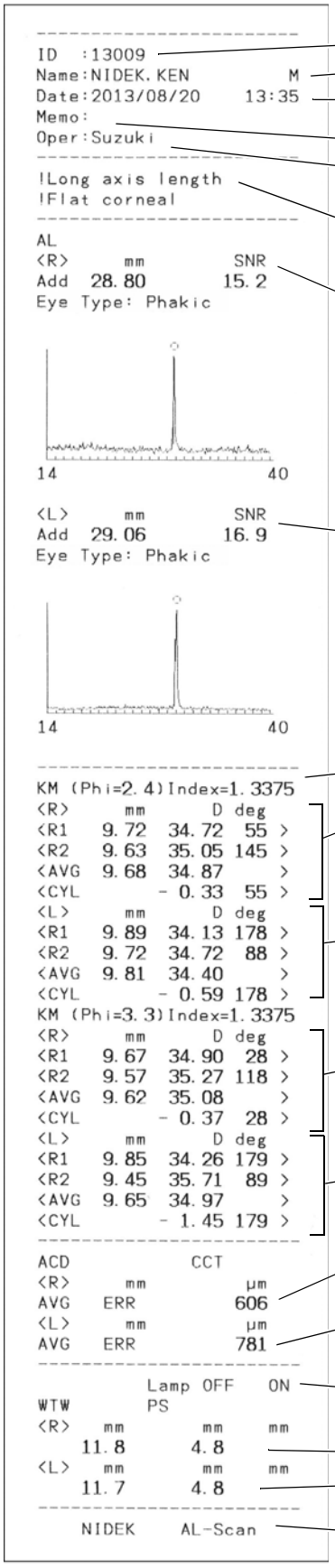
2 Press the Output button.

The Output window appears.

3 Check the Print box, then press the OK button.

The measured data or calculated results selected in Step 1 are printed.

● Optical measurement sample printout



ID

Patient's name and sex

Measurement date and time

Memo

Operator's name

Messages related to measurement data (see page 59)

Axial length combined wave value, SNR of the right eye, and eye type

Axial length combined wave value, SNR of the left eye, and eye type

* The value displayed with an "E" attached is a reference value.

Corneal refractive index to obtain KM values

KM measured values of the right eye (ø2.4)

R1: The flattest meridian
R2: The steepest meridian
AVG: Average of R1 and R2
CYL: Corneal cylindrical power and axis

KM measured values of the left eye (ø2.4)

KM measured values of the right eye (ø3.3)

KM measured values of the left eye (ø3.3)

The average ACD and CCT measured values of the right eye

The average ACD and CCT measured values of the left eye

* The value displayed with an "E" attached is a reference value.

Lamp is on/off in PS measurement

WTW and PS for the right eye

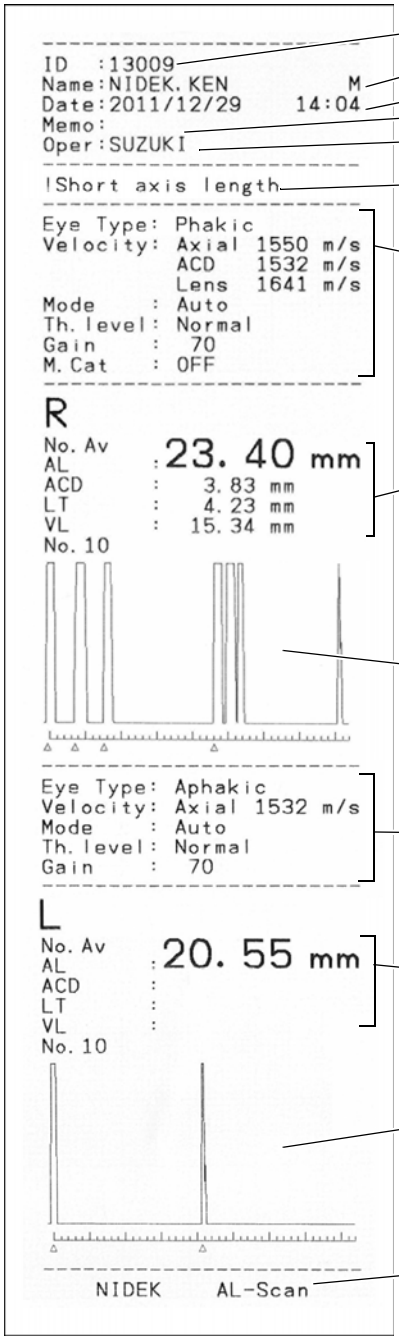
WTW and PS for the left eye

Comments

The figure shown to the left is a sample printout for when the Format parameter is set to "Items". When the parameter is set to "R->L", all the measured values for the right eye are printed, then those for the left eye are printed.

2

● BIO mode measurement sample printout



ID

Patient's name and sex

Measurement date and time

Memo

Operator's name

Messages related to measurement data (see page 75)

Measurement conditions for the right eye
- Eyetype: Type of the eye to be measured
- Velocity: Sonic velocity to calculate distance
- Mode: Data capture mode
- Th. level: Threshold
- Gain: Gain
- M. Cat: Mature cataract button setting

Median values of the right eye
- AL: Axial length
- ACD: Anterior chamber depth
- LT: Lens thickness
- VL: Vitreous body length

Waveform of the measured value most recently obtained or selected in the measured value list

Measurement conditions for the left eye
- Omitted if they are the same as those for the right eye.

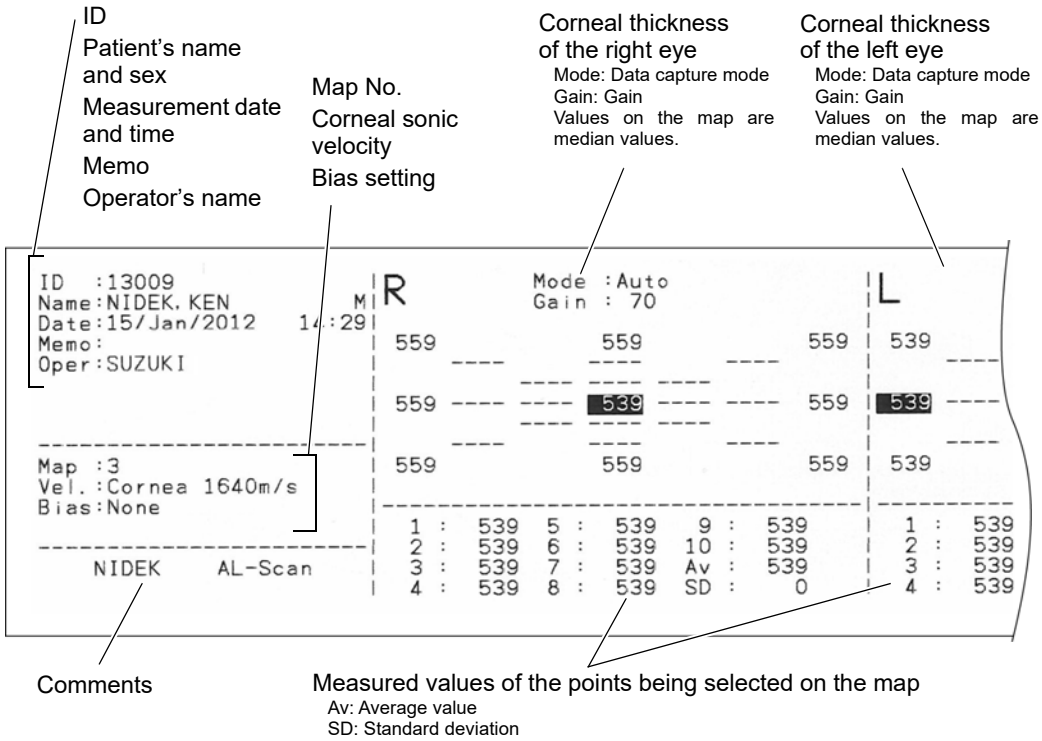
Median values of the left eye

Waveform of the measured value most recently obtained or selected in the measured value list

Comments

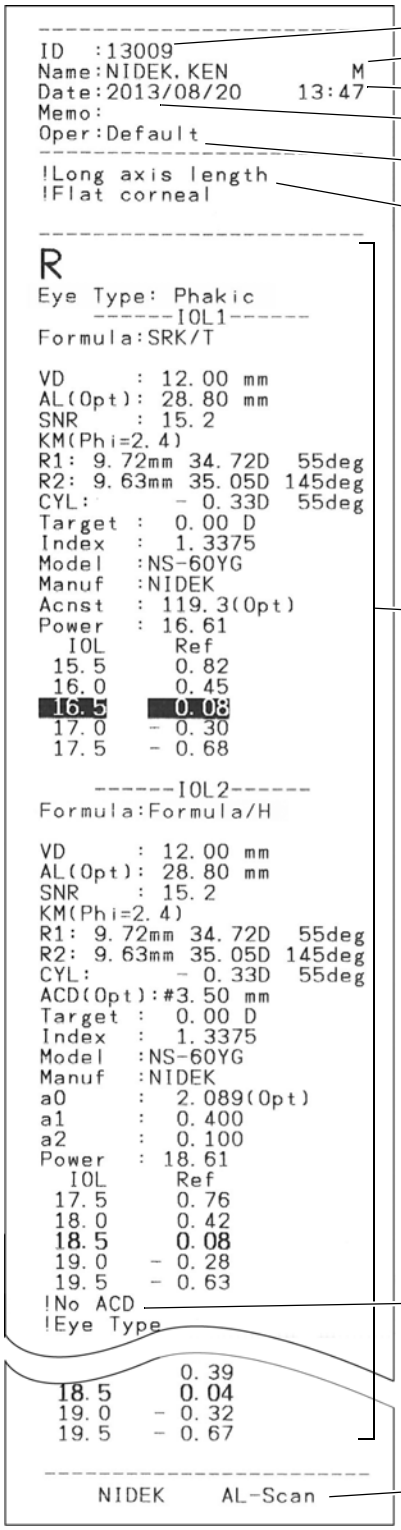
For eyes filled with silicone oil, both the original eye type and the eye type specified for the BIO mode measurement are printed.

● Pachy mode measurement sample printout



* When Map 1 is selected, the map is not printed, and the measured values are printed in the vertical format.

● IOL calculated result sample printout



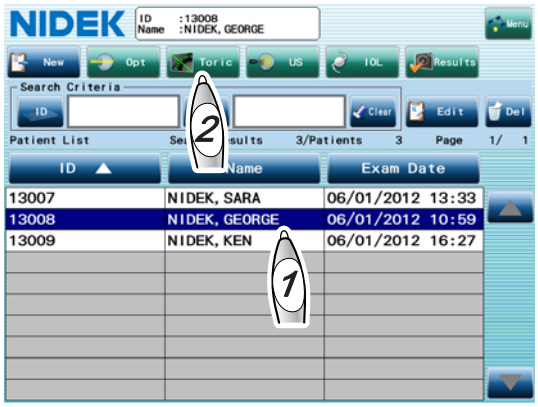
Note

- A maximum of 15 characters of a patient's name, and 19 characters of an operator's name can be printed. No additional characters beyond this limit are printed.
- A maximum of 15 characters of an IOL model name, and 15 characters of an IOL manufacturer's name can be printed with the IOL calculation result. No additional characters beyond this limit are printed.

2.11 Checking and Printing Toric Lens Assist Mode Measured Results

The measured results of the toric lens angle saved in the database can be viewed.

1 Select the patient in the Patient List screen to check the toric lens angle measurement result.



2 Press the Toric button.

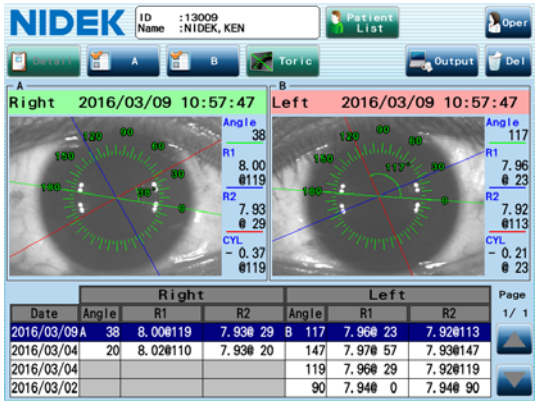
The toric lens assist mode screen appears.

3 Press the Results button.

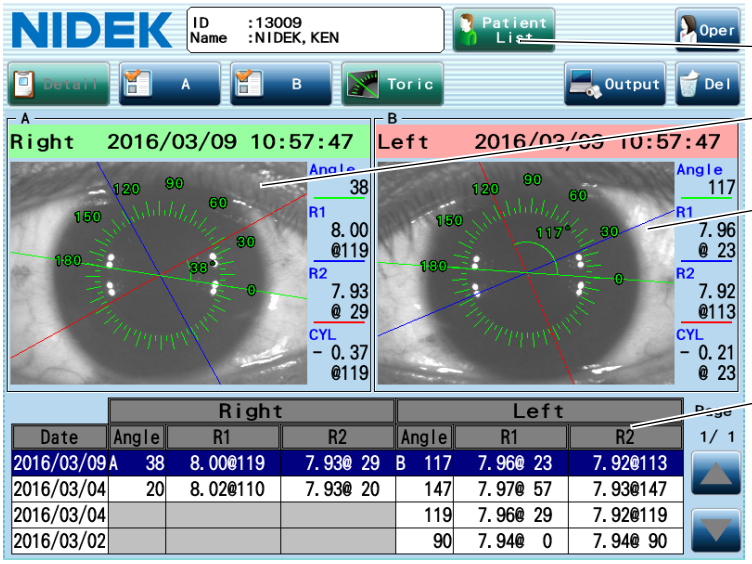
The toric lens assist mode result screen appears.

"A" in the Angle field indicates that the data is for the anterior eye segment image A, and "B" in the Angle field indicates that the data is for the anterior eye segment image B.

4 Select the desired measured result to check in the measured result list.



● Toric lens assist mode result screen



Patient List button: Used to display the Patient List screen.

Oper button: Used to display the operator.

A button: Used to display the anterior eye segment image of the data being selected in the measured result list in the anterior eye segment image A field.

B button: Used to display the anterior eye segment image of the data being selected in the measured result list in the anterior eye segment image B field.

The A and B buttons are used to select the images for side-by-side display in the toric lens assist mode result screen. This selection does not influence output/print calculation results or detail displayed by pressing the Detail button.

Toric button: Used to display the toric lens assist mode screen.

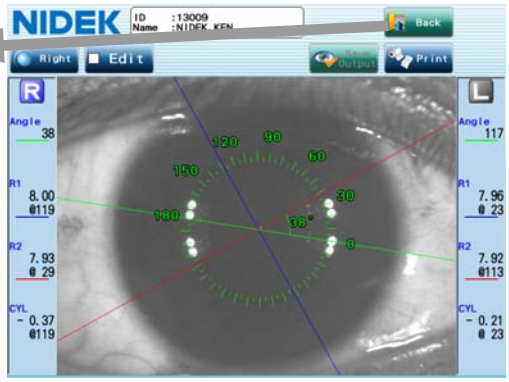
Output button: Used to display the Output window to print or output the data. The button is enabled when the data is selected in the measured result list along with the date.

Del button: Used to delete the selected measured result. If the administrator password is set, the keyboard window appears, and password entry is required. The button is enabled when the data is selected in the measured result list together with the date field.

Anterior eye segment image A/B field: Displays the anterior eye segment image, the steepest and flattest meridians, and angle reference line. Dragging the angle scale can change its size.

Measured result list: “A” in the Angle field indicates that the data is for the anterior eye segment image A, and “B” in the Angle field indicates that the data is for the anterior eye segment image B.

Detail button: Used to enlarge the anterior eye segment image of the data being selected in the measured result list. The button is disabled while the data of the both of the eyes is selected.



Back button: Used to return to the toric lens assist mode result screen.

Right/Left button: Used to toggle display of the right and left eyes.

Print button: Used to print the measured results.

Edit button: When checked, the direction of the angle reference line can be changed.

Save Output button: Saves or outputs the change of the angle reference line.

Note

- The image enlarged in the detail screen is not necessarily the same anterior eye segment image displayed in the toric lens assist mode result screen. The enlarged image is the anterior eye segment image of the data selected (reverse font) in the measured result list when the Detail button is pressed.
- Pressing the Right/Left button in the detail screen switches the image to that for the other eye measured on the same date.

5 If necessary, print the measured results.

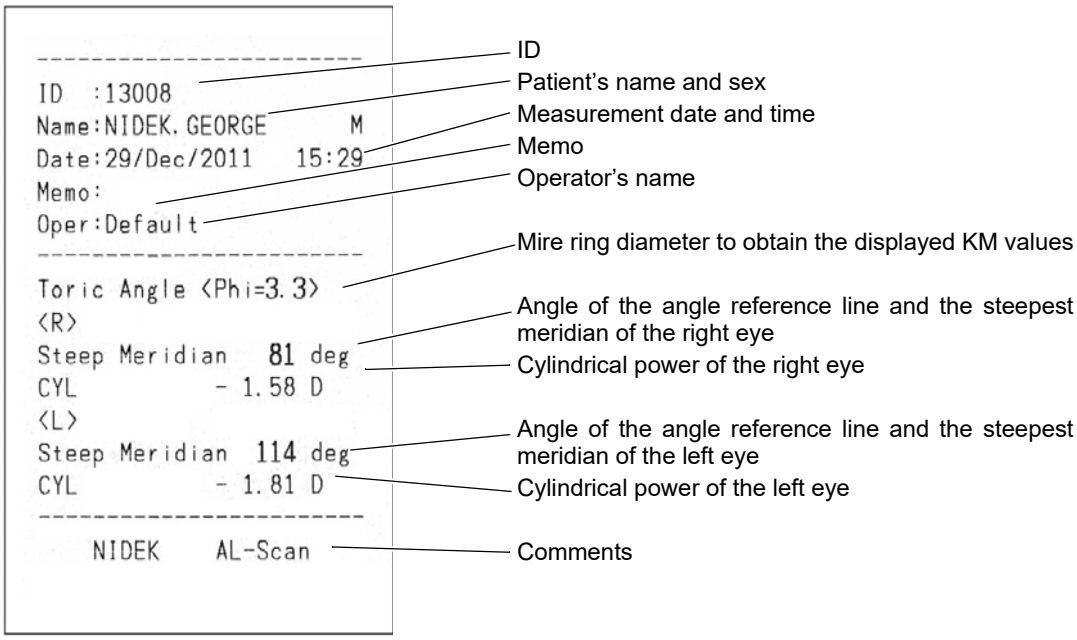
1) Press the Output button.

   The Output window appears.

2) Check the Print box, then press the OK button.

   The measured results being selected in the measured result list are printed.

● Sample printout



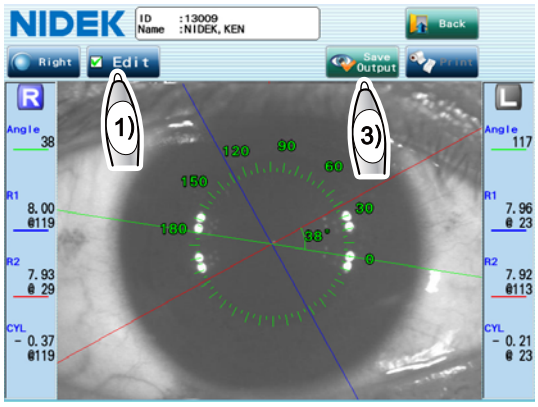
Pressing the Print button while the image is enlarged by pressing the Detail button also prints the measured results.

○ Modifying angle reference line direction of the saved data

The angle reference line direction of the saved toric lens angle measurement result can be modified in the detail screen (Page 120).

1) Check the Edit button in the detail screen.
2) Align the angle reference line (green line) with the markers.

   The angle reference line can be moved to the marker position by specifying the marker positions on the anterior eye segment image with the touch pen or by dragging the angle reference line.



Note

- In this case “marker” means mark directly placed on the cornea of the patient’s eye. During surgery, implant the IOL so that the angle of this markers and the toric lens axis mark is the same as the angle obtained in the toric lens assist mode screen.

3) Press the Save Output button.

   A message to confirm whether to save or output the modification result appears.

4) Press the OK button.

   The modification result is saved, and output or printed depending on the setting, then the screen returns to the toric lens assist mode result screen.

   Pressing the Yes button on the message displayed by pressing the Back button instead of the Save Output button saves/prints/outputs the measured data as well. Pressing the No button deletes the modification result, and the toric lens assist mode result screen appears again.

2.12 Output of Measured Results and Calculated Results

To output the measured results and calculated results to another device through a network or USB flash drive, there are two methods below.

(1) Automatic output of the measured results and calculated results when they are saved in the database after being finalized

(2) Manual output of the results from the result screen

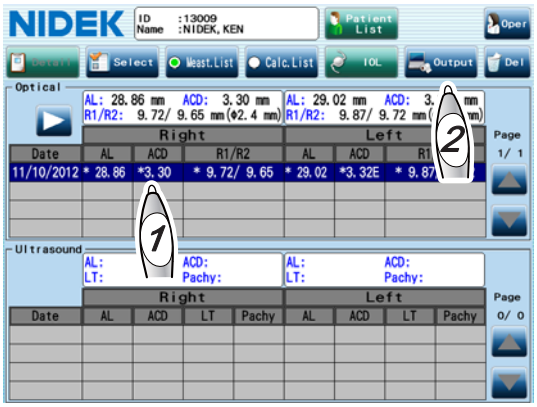
In the both cases, the output contents are based on the settings in the Network USB tab of the Parameter Settings screen. See “3.1.8 Network USB tab” (page 153).
Specify the output destination referring to “3.9.1 LAN connection settings” (page 180).

○ Setting for automatic output

To output the results automatically as described in Method (1) above, set the Network Mode or USB Mode parameter to “Auto” in the Network USB tab of the Parameter Settings screen.

○ Procedure for manual output

1 Select the measured data or calculated results to be output in the result screen.



2 Press the Output button.

The Output window appears.

3 Check the box of the desired output method, then press the OK button.

The measured data or calculated results selected in Step 1 are output.

Note

- The Network and USB button are available only when the details of the output items are specified in the Network USB tab of the Parameter Settings screen.

2.13 Output of Toric Lens Assist Mode Measured Results

To output the measured results of the toric lens angle to another device through a network or USB flash drive, there are two methods below.

(1) Automatic output of the anterior eye segment image and marker positions when they are saved in the database after being finalized

(2) Manual output of the results from the result screen

In the both cases, the output contents are based on the settings in the Network USB tab of the Parameter Settings screen. See “3.1.8 Network USB tab” (page 153).
Specify the output destination referring to “3.9.1 LAN connection settings” (page 180).

○ Setting for automatic output

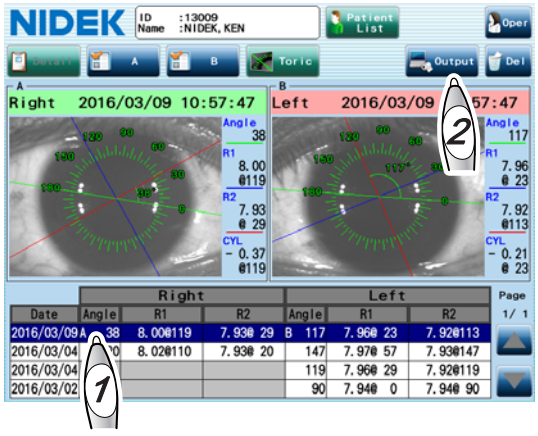
To output the results automatically as described in Method (1) above, set the Network Mode or USB Mode parameter to “Auto” in the Network USB tab of the Parameter Settings screen.

○ Procedure for manual output

1 Display the toric lens assist mode result screen referring to Steps 1 to 4 of “2.11 Checking and Printing Toric Lens Assist Mode Measured Results” (page 119) and select the measured result to be output.

Note

- The measured result of the anterior eye image being displayed is not necessarily output. Select the desired measured result to be output from the measured result list along with the date.



2 Press the Output button.

The Output window appears.

3 Check the box of the desired output method, then press the OK button.

The toric lens assist mode measured results selected in Step 1 are output.

Note

- The Network and USB button are available only when the details of the output items are specified in the Network USB tab of the Parameter Settings screen.

2.14 Completion of Operation

2.14.1 Usual completion of operation

When the measurement or IOL power calculation is finished, complete the operation by following the procedure below.

1 Measure any additional patients.

To measure an additional patient, go back to “2.2 Preparation” (page 45).

2 Turn off (○) the device.

Do not turn off the device during measurement and data processing such as saving and backup.

3 Check and clean the measuring window.

4 Clean the forehead rest and chinrest.

5 If necessary, clean the device exterior and touch screen.

6 After cleaning and disinfecting the used probes, store them in a clean place (when ultrasonic measurement is performed).

See “5.7 Cleaning/Disinfecting Ultrasound Probe” (page 217).

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

The operation of the device is complete.

2.14.2 Completion of operation in order to transport the device

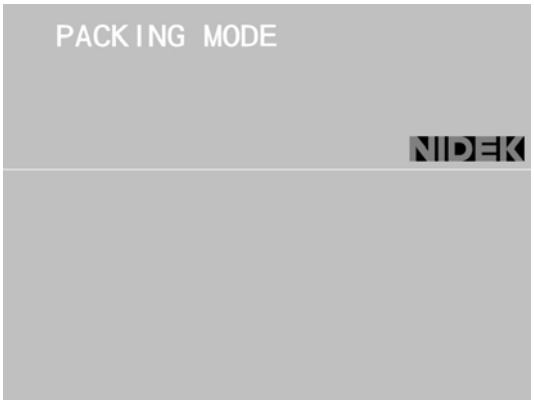
When the device is to be transported, set the device to Packing mode.
In Packing mode, the main unit and the chinrest are automatically set to the position for transport.

⚠ **CAUTION** • **Before transporting the device, set the mode to Packing mode and pack the main body in the original packing material with the locking lever unlocked.**
Excessive vibration may result in device failure.

1 After Step 5 of “2.1.2 Major functions” (page 44), turn on (|) the power switch while pressing the chinrest down button ▼.

2 Keep the chinrest down button ▼ pressed until the PACKING MODE screen (monochrome) is displayed.

After the PACKING MODE screen (monochrome) is displayed, the main unit and chinrest starts moving down.



3 After the screen to the right is displayed, and the main unit and chinrest stop moving down, turn off (○) the device.

Note
- To restore the device from Packing mode, turn on (|) the power switch as in the usual device startup.

3. ADVANCED OPERATION

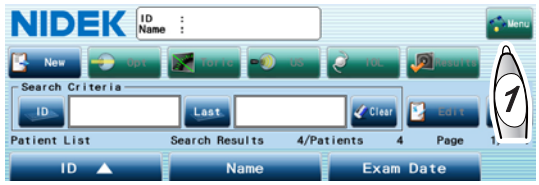
This section provides the following explanations for advanced use of the AL-Scan.

- Registering the IOL information
  ⇒ ○ IOL settings (registering IOL information) (Page 143)
- Specifying the IOL constants used for IOL power calculation
  ⇒ ○ IOL settings (registering IOL information) (Page 143)
- Specifying the IOL model and formula to calculate the IOL power
  ⇒ ○ Display setting for IOL power calculated results (Page 148)
- Registering the operator's name
  ⇒ ○ Registering operator's name (Page 134)
- Database backup
  ⇒ 3.4.1 Database backup (Page 164)
- Parameter setting backup
  ⇒ 3.5.1 Parameter backup (Page 170)
- Setting the internal clock
  ⇒ 3.6 Setting Date and Time (Page 174)
- Inputting patient ID using barcode
  ⇒ 3.7 Reading ID with Barcode Reader (Page 176)
- Calculating IOL constant optimized for each IOL
  ⇒ 3.3 IOL Constant Optimization (Page 161)
- Inputting correction value for measurement error due to the force to touch the probe to the cornea that varies depending the operator in case of BIO mode measurement
  ⇒ 3.1.4 BIO tab (Page 137)
- Changing password
  ⇒ "3.8 Protecting IOL Settings with Password" (page 178)
- Setting of internal fixation lamp of the A-scan probe
  ⇒ 3.1.4 BIO tab (Page 137)

3.1 Changing Device Parameters

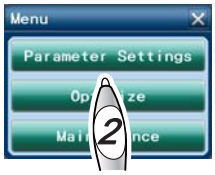
The AL-Scan is equipped with the function to change the device parameters in accordance with the needs of the operator. Follow the procedure below to check and change the parameters. There are settings necessary for measurement or IOL power calculation. Check the parameter settings in advance, and change them if necessary.

1 Press the Menu button in the Patient List screen.



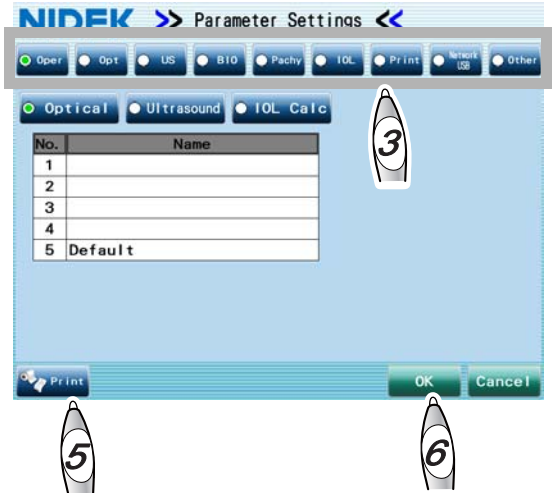
2 The Menu window appears. Then press the Parameter Settings button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.



3 The Parameter Settings screen appears. Then select the desired tab, from the Oper to Other, that contains the parameter to be changed.

For the detail of the parameters, see “3.1.1 Oper tab” (page 133) to “3.1.9 Other tab” (page 157).



Tab	Settings
Oper	Operator’s name (optical and ultrasonic measurements, IOL power calculation)
Opt	Optical measurement condition such as the number of measurements and refractive index
US	Ultrasonic measurement condition such as measurement mode
BIO	Settings for BIO mode measurement
Pachy	Settings for Pachy mode measurement
IOL	Settings for IOL power calculation
Print	Settings for contents of printing by the internal printer
Network USB	Settings for contents of the data to be output through a network/USB
Other	Settings for name and date

4 Change the desired parameter to the desired setting.

Items to be selected: Select them with the radio buttons.

Items to be input: Pressing the dark blue button of the desired item displays the numeric keypad or keyboard window. Input the desired setting with the window.

For the Oper tab: Select the Optical, Ultrasound, or IOL Calc button, and press the Name field of the desired number to display the keyboard window. Then input the operator's name.

See "○ Numeric keypad window use" (Page 131) and "○ Keyboard window use" (Page 132).

5 After changing the settings, press the Print button if necessary.

The settings of all the parameters except for the IOL Settings and View Pattern are printed.

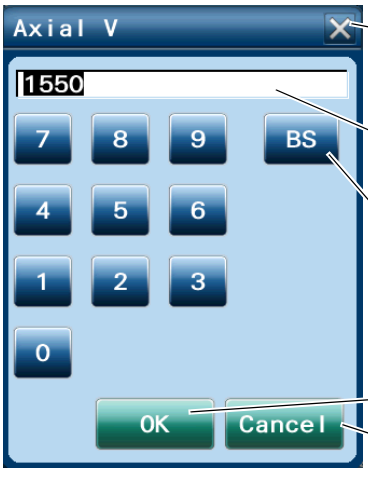
6 Press the OK button.

The changed settings are saved, and the Patient List screen appears again.

Pressing the Cancel button cancels saving, and the screen returns to the Patient List screen. However, the settings specified in the IOL List window, IOL Settings screen, or View Pattern window are not canceled. These windows are accessed by pressing corresponding button in the IOL tab of the Parameter Settings screen.

○ Numeric keypad window use

Input the desired value using the number buttons, then press the OK button.



Functions as the cancel button.
The input value is not saved, the value returns to the one before change, and the numeric keypad window is closed.

Current setting value or newly input value

When the numeric field is displayed inverted (1550) ⇒ The button deletes the value displayed inverted.
When the cursor blinks (1550) ⇒ The button deletes the number to the left side of the cursor.

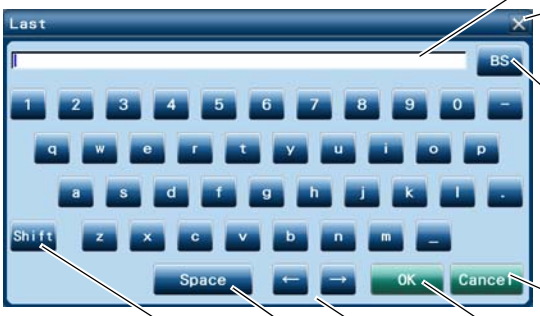
The input value is determined, and the numeric keypad window is closed.

The input value is not saved, the value returns to the one before change, and the numeric keypad window is closed.

*Some keys in the numeric keypad window are different depending on the input item.

○ Keyboard window use

Input the desired characters or values, then press the OK button.



Current setting value or newly input value

Functions as the cancel button.
The input character is not saved, the character returns to the one before change, and the keyboard window is closed.

When the characters are displayed inverted (NIDEK) ⇒ The button deletes the characters displayed inverted.
When the cursor blinks (NIDEK) ⇒ The button deletes the character to the left side of the cursor.

The input characters are not saved, they return to the one before change, and the keyboard window is closed.

The input contents are determined, and the keyboard window is closed.

Moves the cursor to the right or left.

Inputs a space at the cursor position.

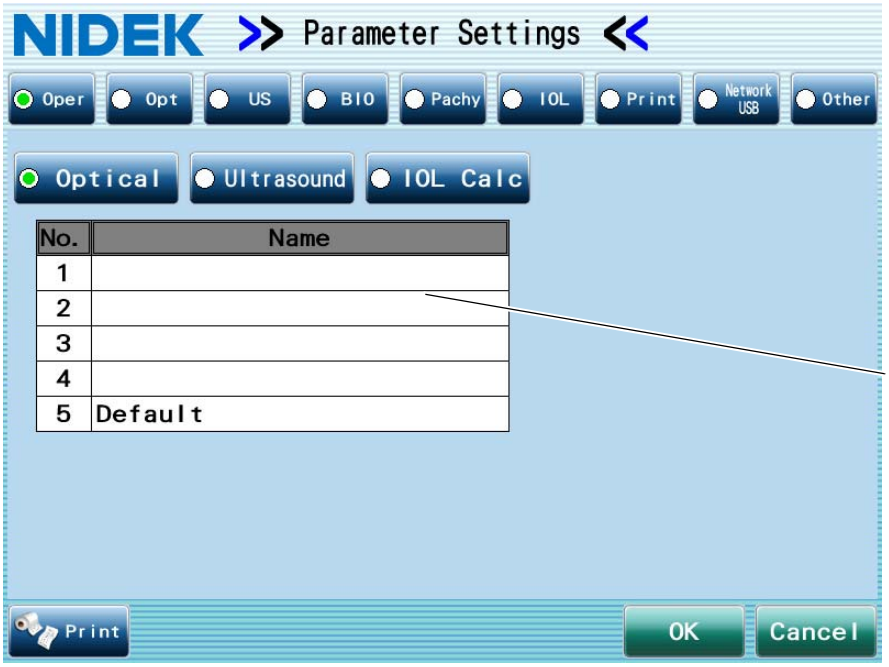
Toggles the case of the alphabetic keys.
When the characters are displayed inverted, pressing the button toggles the characters between the upper and lower cases.
nidek ⇒ NIDEK ⇒ nidek ⇒ and so on.

Keyboard window with the upper case by pressing the Shift button

The keyboard windows for the operator's name and ID do not contain this period key.

*Some keys in the keyboard window are different depending on the input item.

3.1.1 Oper tab



Up to five operators each for optical measurement, ultrasonic measurement, and IOL power calculation can be registered.

Optical/Ultrasound/IOL Calc

Selects the operator for the desired measurement.

Optical: Operators who perform optical measurement and toric lens angle measurement

Ultrasound: Operators who perform ultrasonic measurement (BIO and Pachy mode measurements)

IOL Calc: Surgeons who perform IOL implantation

List

Input the operator's name using the keyboard window displayed by pressing the Name field.

○ Registering operator’s name

Register the operator’s names for optical measurement, ultrasonic measurement, and IOL implantation.

1 Press the Optical button in the Oper tab of the Parameter Settings screen.

2 Press the Name field of the No. 1 in the list.

The keyboard window appears.

3 Enter the name of the operator who performs optical measurement.

4 Press the Name field of the No. 2 to display the keyboard window, then enter the desired operator’s name.

5 Enter other operators’ names in the same manner if necessary.

Up to five operators (from No. 1 to 5) can be registered.

6 Press the Ultrasound button in the Oper tab of the Parameter Settings screen.

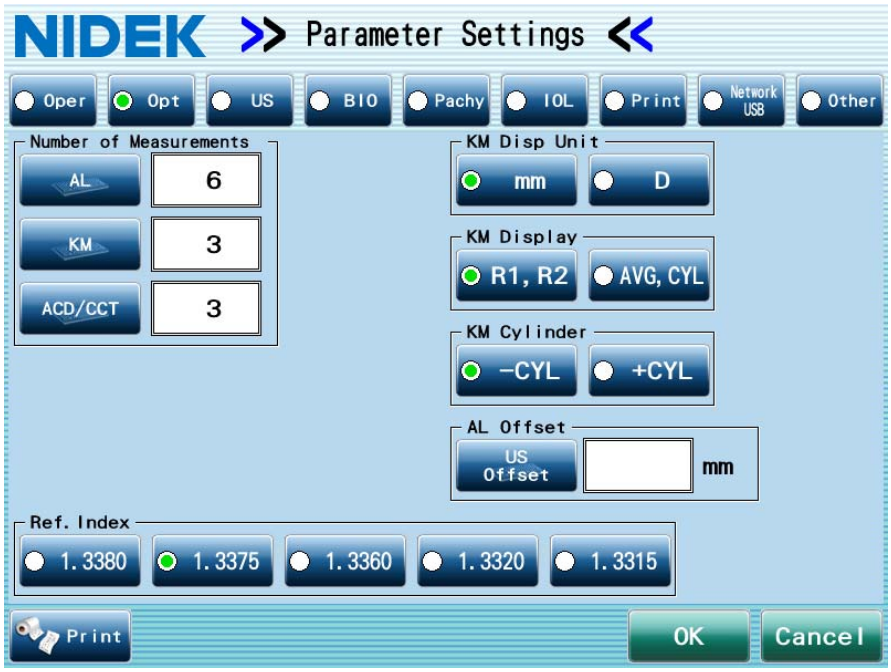
7 Enter the name of the operator who performs ultrasonic measurement (BIO and Pachy mode measurements) in the same manner as in Steps 2 to 5.

8 Press the IOL Calc button in the Oper tab of the Parameter Settings screen.

9 Enter the name of the surgeon who performs IOL implantation in the same manner as in Steps 2 to 5.

10 After the entry is complete, press the OK button.

3.1.2 Opt tab



Number of Measurements: Settings for the number of measurements for axial length (AL), corneal curvature radius (KM), and anterior chamber depth / central corneal thickness (ACD/CCT)

Input the number of measurements using the numeric keypad window displayed by pressing the AL, KM, or ACD/CCT button. The following values can be input.

AL: 1 to 20 (The default is “6”.)

KM: 3 to 10 (The default is “3”.)

ACD/CCT: 1 to 5 (The default is “3”.)

KM Disp Unit: mm, D (The default is “mm”.)

Setting for the display unit of the corneal curvature radius measured value

The corneal curvature radius data during KM measurement can be displayed in mm (corneal curvature radius) or D (corneal refractive power).

KM Display: “R1, R2”, “AVG, CYL” (The default is “R1, R2”.)

Toggles the display setting between R1 (the flattest meridian measured value) / R2 (the steepest meridian measured value) and AVG (the average of R1 and R2 values) / CYL (corneal astigmatism amount).

KM Cylinder: -CYL, +CYL (The default is “-CYL”.)

Setting for the display of cylinder values (cylindrical refractive power)

-CYL: Indicates the cylindrical power by negative reading.

+CYL: Indicates the cylindrical power by positive reading.

Ref. Index: 1.3380, 1.3375, 1.3360, 1.3320, 1.3315 (The default is “1.3375”.)

Setting for refractive index used to convert the unit of the corneal curvature radius from mm to D (diopter) during measurement

Note

- When using a K value measured by another device, set the corneal refractive index of the other device to the same value as that of the Ref. Index of the AL-Scan.

* When the saved data is displayed, the current settings for the KM Disp Unit, KM Display, and KM Cylinder parameters are reflected.

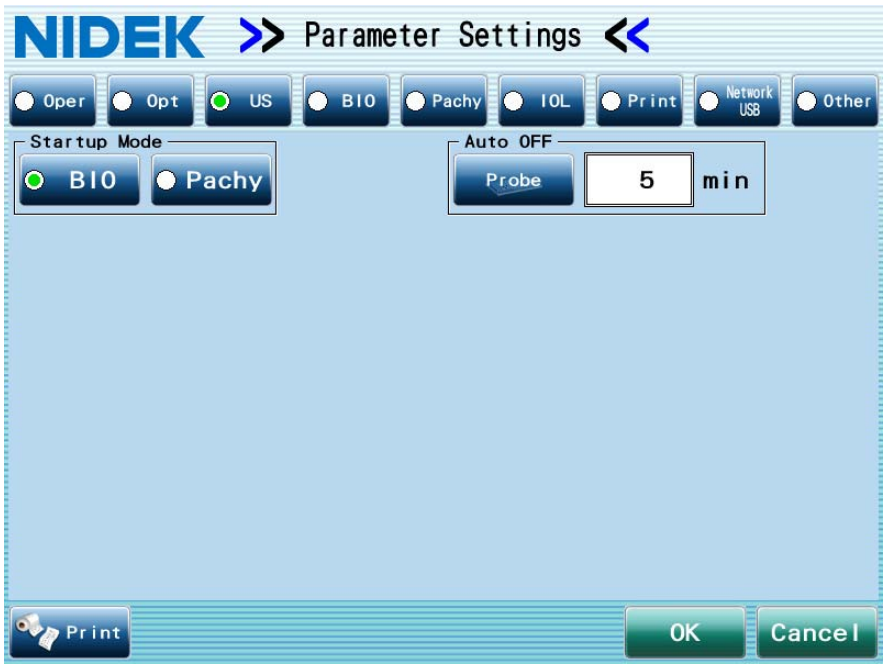
AL Offset: US Offset -1.00 to 1.00 mm

Corrects the difference between optically measured and BIO measured AL values. When the A-constant is for ultrasonic measurement, this value is added to the optically measured AL value to correct it to the ultrasonic measurement value.

Note

- When only the A-constant for ultrasonic measurement is input, the US offset is required to calculate the IOL power using the optical measured value.

3.1.3 US tab



This tab is for the AL-Scan equipped with the optional ultrasonic measurement function only.

Startup Mode: BIO, Pachy (The default is “BIO”.)

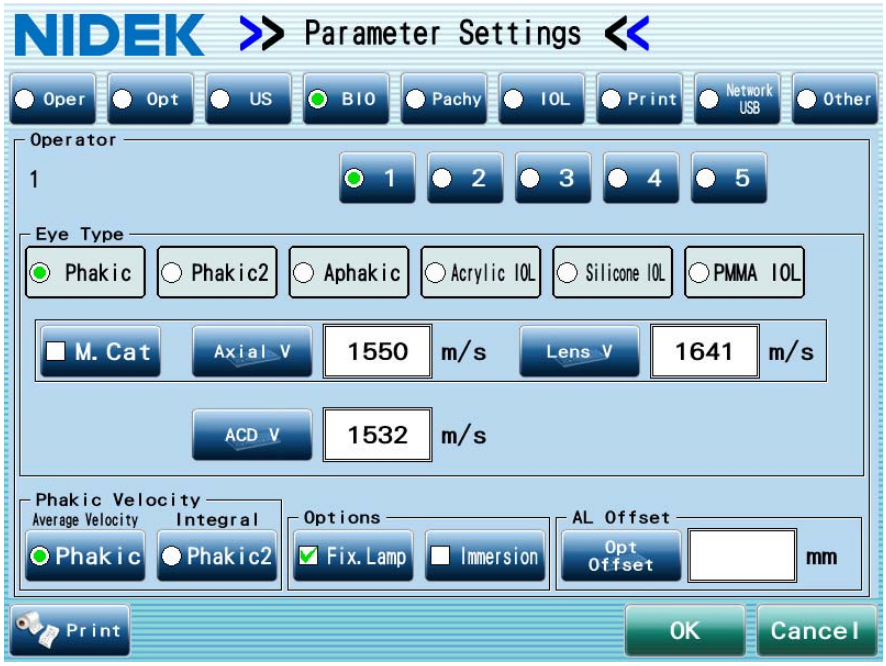
Toggles the display between the BIO and Pachy mode measurement screens when the US button is pressed.

Auto OFF: 1 to 30 minutes (The default is “5”.)

If the A-scan probe or pachymetry probe does not receive any signals for the time specified in the box, the measurement is automatically finished.

Input the desired value using the numeric keypad window displayed by pressing the Probe button.

3.1.4 BIO tab



This tab is for the AL-Scan equipped with the optional ultrasonic measurement function only.

The optional setting, optical offset, and sonic velocity for each eye type can be set for each operator.

Operator: 1 to 5

Selects the desired operator, who had been registered in the Oper tab, by pressing the corresponding number button. The following settings are registered for the selected operator.

Eye Type: Sets the sonic velocity and IOL thickness used for calculation for each type of the eye to be measured, from Phakic to PMMA IOL, if necessary.

For Phakic and Phakic2, check the “M. Cat” box to set the sonic velocities when this button is enabled.

- Sonic velocity default settings

	Phakic	Phakic2	Aphakic	Acrylic IOL	Silicone IOL	PMMA IOL
Axial V (Average velocity)	1550 m/s	—	1532 m/s	—	—	—
Lens V	1641 m/s	1641 m/s	—	—	—	—
ACD V	1532 m/s	1532 m/s	—	1532 m/s	1532 m/s	1532 m/s
Vit V	—	1532 m/s	—	1532 m/s	1532 m/s	1532 m/s
Axial V for mature cataract	1548 m/s	—	—	—	—	—

	Phakic	Phakic2	Aphakic	Acrylic IOL	Silicone IOL	PMMA IOL
Lens V for mature cataract	1629 m/s	1629 m/s	—	—	—	—
IOL V	—	—	—	2060 m/s	1049 m/s	2760 m/s
IOL thkns	—	—	—	0.80 mm	0.80 mm	0.80 mm

Phakic Velocity: Phakic (Average Velocity), Phakic2 (Integral) (The default is “Phakic”.)

Selects the sonic velocity of Phakic or Phakic2 to calculate the axial length when the eye type is set to “Phakic” in the patient information screen.

Phakic: Average sonic velocity is used for axial length calculation.

Phakic2: Sonic velocity of each eye segment is used for axial length calculation.

Options: Check the box for the optional setting to be used.

Fix. Lamp: Checked when the internal fixation lamp is used. The setting is reflected the next time the BIO mode screen appears. (The default is “checked”.)

Immersion: Checked when the immersion cap is used. The setting is reflected the next time the BIO mode screen appears. (The default is “not checked”.)

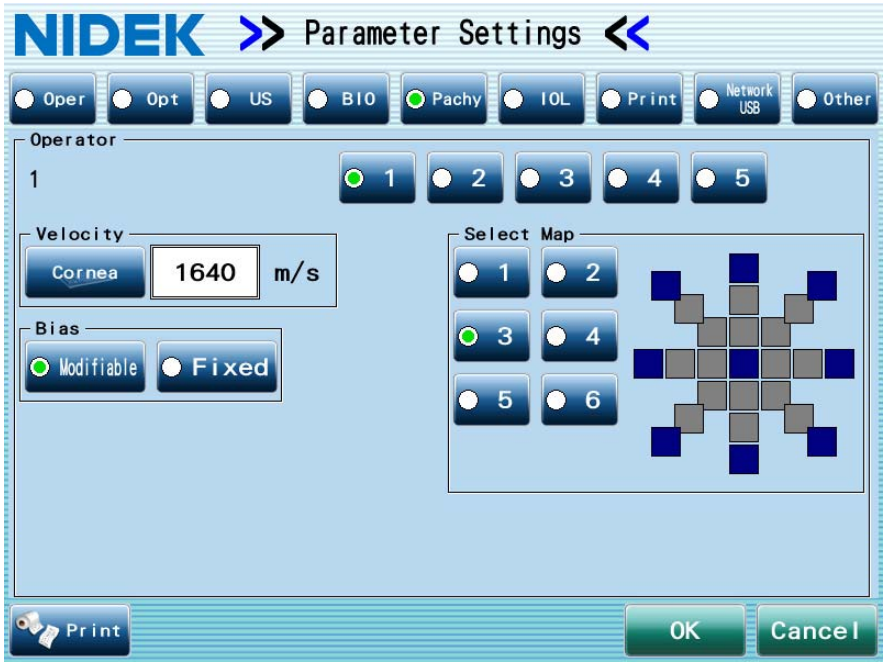
AL Offset: Opt Offset (optical offset) -1.00 to 1.00 mm

The force used to touch the probe to the cornea varies depending on the operator. Therefore, the measured value during BIO mode measurement may vary among operators. The AL offset is a correction value for each operator to match the BIO measured value to the optically measured axial length value so that the measured value variation among operators is reduced. The axial length value is calculated by adding the AL offset value to the BIO measured value when the A-constant is for optical measurement.

Note

- When the A-constant is for optical measurement, it is necessary to set the optical offset before the measurement so that calculation is performed based on the BIO measured value.

3.1.5 Pachy tab



This tab is for the AL-Scan equipped with the optional ultrasonic measurement function only.

The sonic velocity, whether or not to lock the biased value, and measurement map can be set for each operator.

Operator: 1 to 5

Selects the desired operator, who had been registered in the Oper tab, by pressing the corresponding number button. The following settings are registered for the selected operator.

Velocity: Setting range 1000 to 2000 m/s (The default is “1640”.)

Setting for the sonic velocity in the cornea used for corneal thickness calculation

Input the desired value using the numeric keypad window displayed by pressing the Cornea button.

Bias: Setting for the bias condition (The default is “Modifiable”.)

Selecting the Fixed button disables the Bias button in the Pachy mode measurement screen.

Select Map: 1 to 6 (The default is “3”.)

Selects the default setting of the map in the Pachy mode measurement screen, from Map No. 1 to 6.

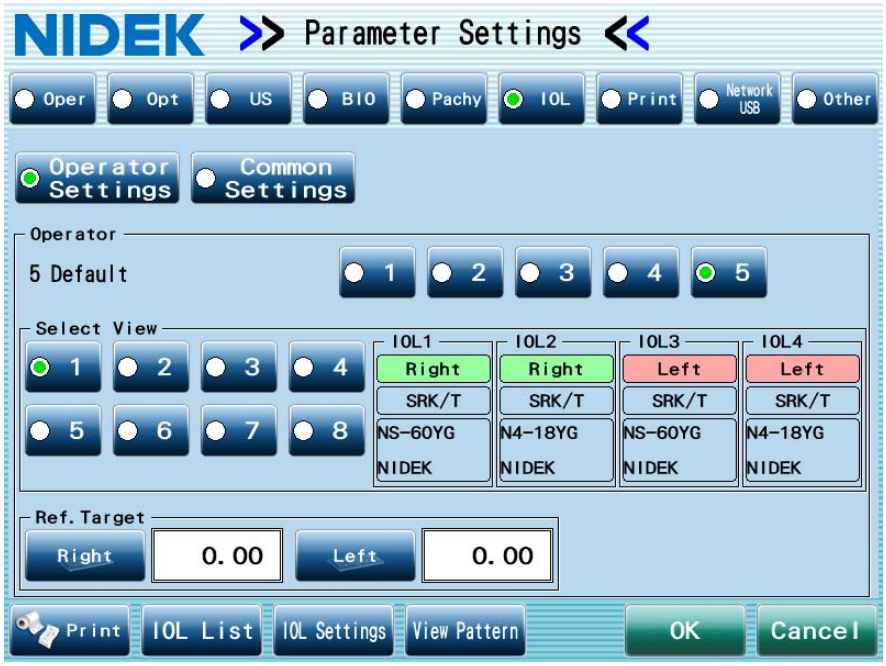
Note

- When using the Camellin-Calossi formula for the measured value, select 3.

3.1.6 IOL tab

In the IOL tab, there are buttons for Operator Settings and Common Settings to display the corresponding screen. Up to five operators may be registered on the Operator Settings screen. The Common Settings screen is the same for all operators.

○ Operator Settings



Operator: 1 to 5

Selects the desired surgeon, who had been registered in the Oper tab, by pressing the corresponding number button. Select the desired display settings for the selected surgeon.

Select View: 1 to 8 (The default is “1”.)

Selects the default display setting of the IOL power calculation screen from No. 1 to 8 (it can be set for each operator).

To change the contents of display setting, press the View Pattern button and change the setting in the View Pattern window.

Ref. Target

Specify the default value of the desired postoperative refraction. (The default is 0.00)

○ Common Settings

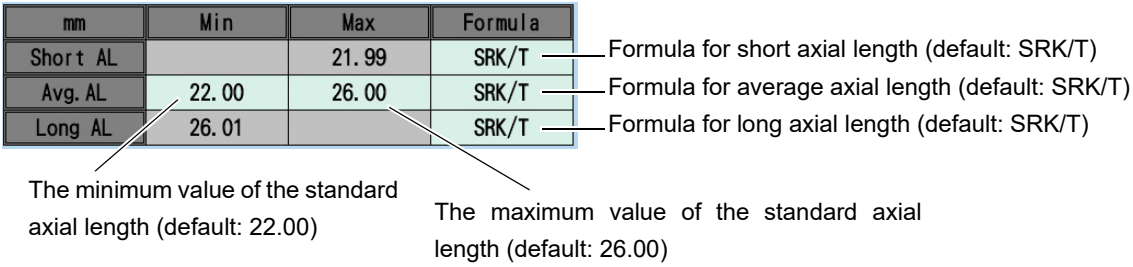
The VD (vertex distance) and VA display (decimal or fraction) can be set. IOL formula to be used for an individual axial length type can be set when the formula is set to “Auto”.

Auto Formula: Settings for the IOL formula used when the IOL formula is set to “Auto”.

When the IOL formula is set to “Auto”, the IOL formula appropriate to the axial length is automatically selected.

Press the light green box in the table to input the minimum and maximum values and formula.

* The Shammas-PL formula is not available for the Auto Formula.



The minimum and maximum values of the average axial length specified here do not affect the criteria of whether to display the messages related to measurement data such as “!Short axial length” and “!Long axial length”.

VD: Setting for the vertex distance to be used for IOL power calculation

Input the desired value using the numeric keypad window displayed by pressing the VD button.

Setting range: 0.0 to 17.0 mm (The default is “12.00”.)

Show BCVA in: Decimal, Fraction (feet) (The default is “Decimal”.)

Toggles the display setting of the best-corrected visual acuity between decimal and fraction.

○ IOL list

The IOL information registered in the IOL Settings screen is listed.

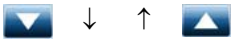
1 Press the IOL List button in the IOL tab of the Parameter Settings screen.

The IOL List window appears.

Page switching button

Each pressing of the button toggles the page.

IOL information list for No. 1 to 15



IOL information list for No. 16 to 30

Constant switching button

Each pressing of the button changes the IOL constant display.

[SRK], [SRK II], [SRK/T]

↕

[Camellin-Calossi], [Shammas-PL]

↕

[Binkhorst], [Hoffer Q], [Holladay 1]

↕

[Formula/H a0], [Formula/H a1], [Formula/H a2]

The indication preceding the constant specifies the constant type.

u: Ultrasonic A-constant

(No indication): Optical A-constant

Opt, US button

Used to specify whether to display the constant for optical measurement or the constant for ultrasonic measurement.

○ IOL settings (registering IOL information)

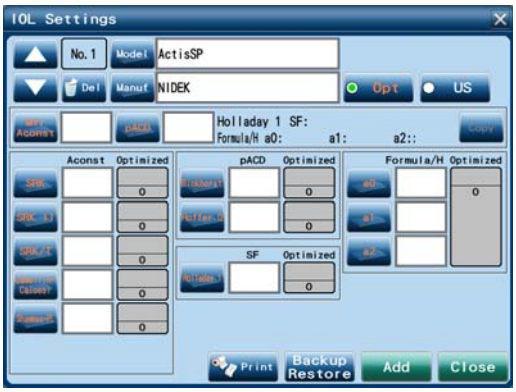
Register the model name, manufacturer's name, A-constant, predicted ACD value, and SF value of the IOLs.

For the Optimized box in the IOL Settings screen, see "3.3 IOL Constant Optimization" (page 161).

1 Press the IOL Settings button in the IOL tab of the Parameter Settings screen.

The IOL Settings screen appears.

Pressing the IOL Settings button in the Patient List screen for optimization also displays the IOL Settings screen.



2 Select the desired No. by pressing ▲ or ▼ button.

3 Press the Model button to display the keyboard window, then enter the IOL model name.

Entering the model name makes the other boxes available.

Note

- Changing the model name or manufacturer's name of the IOL information that has been entered displays the message, "Change to another IOL brand? The entered data will be cleared." appears. Pressing the Yes button clears the IOL information, and pressing the No button does not register the changed model name or manufacturer's name.
- The same model cannot be registered with the same manufacturer's name.

4 Press the Manuf button to display the keyboard window, then enter the IOL manufacturer's name.

5 Input the A-constant specified by the IOL manufacturer and press the Opt or US button.

When the A-constant specified by the IOL manufacturer is for optical measurement, press the Opt button. When the A-constant specified by the IOL manufacturer is for ultrasonic measurement, press the US button.

6 Press the Mfr Aconst button to display the numeric keypad window, then enter the A-constant specified by the IOL manufacturer.

The A-constant for each formula to be entered in Steps 8 to 10 below is used for IOL power calculation.

7 Press the pACD button to display the numeric keypad window, then enter the predicted ACD value specified by the IOL manufacturer.

The SF value to be used for the Holladay 1 formula, and a0, a1, and a2 values to be used for the Formula/H formula, calculated automatically based on the values entered in Steps 6 and 7, are displayed under the IOL manufacturer's name.

8 Press the Copy button.

The message to confirm whether to copy the data appears.

9 Press the OK button.

The entered A-constant specified by the IOL manufacturer, predicted ACD, and SF, a0, a1, and a2 values calculated using the A-constant, are copied to the boxes for each formula.

They are not copied to the boxes where values are displayed with “#” or “p” attached to the beginning. “#” indicates the individually entered constant, and “p” indicates the optimized value.

The A-constant as specified by the IOL manufacturer can be input up to two places after the decimal point. However, when the A-constant is copied to Aconst box of each formula, it is rounded up to the first decimal place.

10 If necessary, enter the constant used for each formula. Press the button for each formula, then enter the constant using the numeric keypad window.

The individually entered constant is displayed with a “#” attached to the beginning.

The A-constants for optical and ultrasonic measurements can be input individually for each formula. Toggle the screen by pressing the Opt or US button. Input the A-constant for optical measurement in the Opt screen and A-constant for ultrasonic measurement in the US screen.

Note

- When the values input for a0, a1, and a2 of the Formula/H formula are rejected for some reason, delete those three values using the numeric keypad window, then input the values again.

  Values that do not satisfy the inequalities of a0, a1, and a2 cannot be input. See“8.9 Formula/H Formula” (page 252).
- The A-constant for Shammas-PL formula must be same as that of SRK/T formula.

11 Press the Print button as necessary.

All the input IOL information is printed out.

12 Press the Add button.

The entered information is registered. The IOL Settings screen is closed.

Pressing the Cancel button closed the IOL Settings screen without registering the entered information.

● Input range of constants

Constant	Input range
A-constant specified by the IOL manufacturer	100.00 to 132.00
Predicted ACD	-7.00 to +20.00
A-constant for SRK formula	100.0 to 132.0
A-constant for SRK II formula	
A-constant for SRK/T formula	
A-constant for Camellin-Calossi formula	
A-constant for Shammas-PL formula	
Predicted ACD for Binkhorst formula	-7.00 to +20.00
Predicted ACD for Hoffer Q formula	
SF value for Holladay 1 formula	-10.00 to +20.00
a0 for Formula/H formula	-9.999 to +9.999
a1 for Formula/H formula	-0.999 to +0.999
a2 for Formula/H formula	

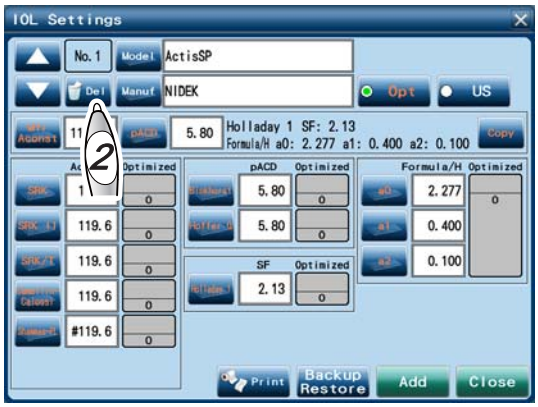
○ Deleting IOL information

Delete the registered IOL information such as the model name, manufacturer's name, A-constant, predicted ACD value, and SF value of the IOLs.

1 Select the No. of the IOL information to be deleted by pressing ▲ or ▼ button in the IOL Settings screen.

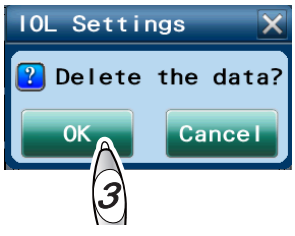
2 Press the Del button.

A message to confirm whether to delete the IOL information appears.



3 Press the OK button.

The specified IOL information is deleted. The IOL Settings screen appears again.



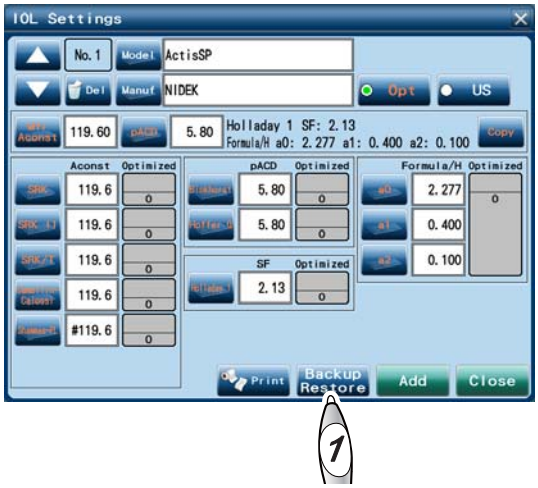
4 Press the Add button.

The IOL Settings screen is closed. The change is saved.

○ IOL information backup

All the registered IOL information can be backed up.

1 Press the Backup Restore button in the IOL Settings screen.



2 When the Backup/Restore IOL Settings window is displayed, select the backup destination.

[USB]: A USB flash drive

[LAN]: A shared folder on a computer connected by a LAN

[Internal CF]: Internal CompactFlash card

3 Confirm that the Backup button is selected in the Mode field and press the OK button.

The backup of the settings begins.

If the backup data already exists in the backup destination, the confirmation message asking whether or not to overwrite the data appears. Pressing the OK button overwrites the backup data, and pressing the Cancel button cancels the backup.

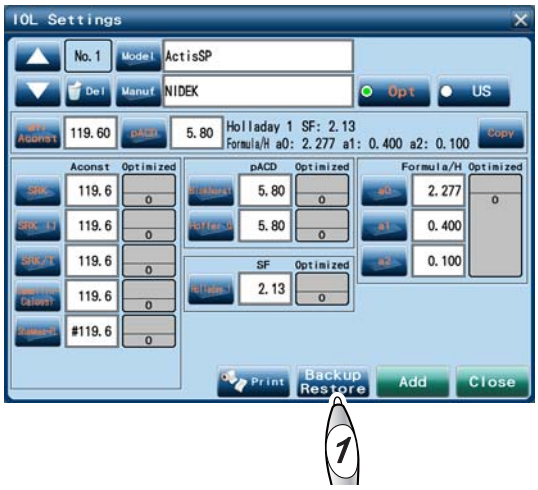
○ Restoring the backup IOL information

The backup IOL information can be restored and added to the existing IOL information.

Note

- If the restored data registered to same IOL No. has different IOL information, the confirmation message asking whether or not to overwrite the data is displayed.
- The IOL information of the IOL No. that did not exist at the time of backup is not changed.

1 Press the Backup Restore button in the IOL Settings screen.

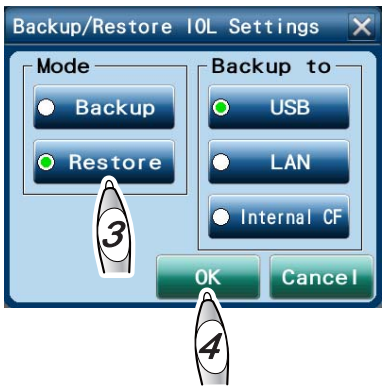


2 When the Backup/Restore IOL Settings window is displayed, select the backup destination.

[USB]: A USB flash drive

[LAN]: A shared folder on a computer connected by a LAN

[Internal CF]: Internal CompactFlash card



3 Click the Restore button in the Mode field.

4 Press the OK button.

The confirmation message asking whether or not to restore backup data is displayed.

5 Press the OK button.

The IOL information is restored and the screen returns to the IOL Settings screen.

If the restored data registered to same IOL No. has different IOL information, the confirmation message asking whether or not to overwrite the data is displayed. Pressing the OK button overwrites the information of the IOL No. with that of restored data and pressing the Cancel button does not overwrite the data.

6 Check the IOL information and press the Add button.

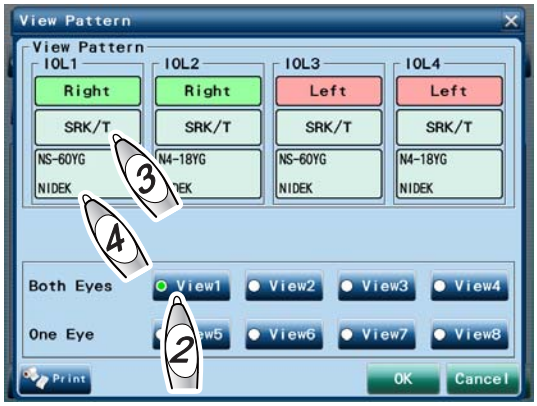
The restored IOL information is added to the existing IOL information and the IOL Settings screen is closed.

○ Display setting for IOL power calculated results

Eight display formats of the IOL measured results can be set (View1 to View8).
Up to four types of IOL power calculated results (IOL1 to IOL4) can be set for each display format.

1 Press the View Pattern button in the IOL tab of the Parameter Settings screen.

The View Pattern window appears.



2 Select the desired display format to change the setting by pressing any of the buttons from View1 to View8.

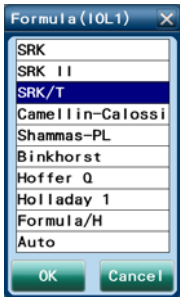
The items with the light green background can be edited.

3 Change the IOL formula for IOL1.

1) Press the IOL formula button for IOL1.

   The Formula (IOL1) window appears.

2) Select the desired IOL formula, then press the OK button.

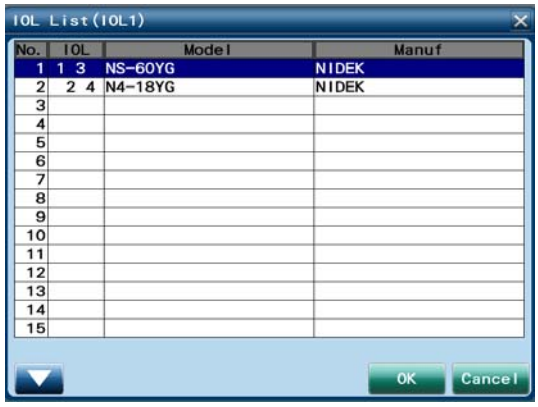


4 Change the IOL model for IOL1.

1) Press the IOL name button for IOL1.

   The IOL List window appears.

2) Select the line of the desired IOL, then press the OK button.



5 If necessary, change the settings for IOL2 to IOL4 in the same manner as Steps 3 to 4.

6 Press the Print button as necessary.

The display format is printed out.

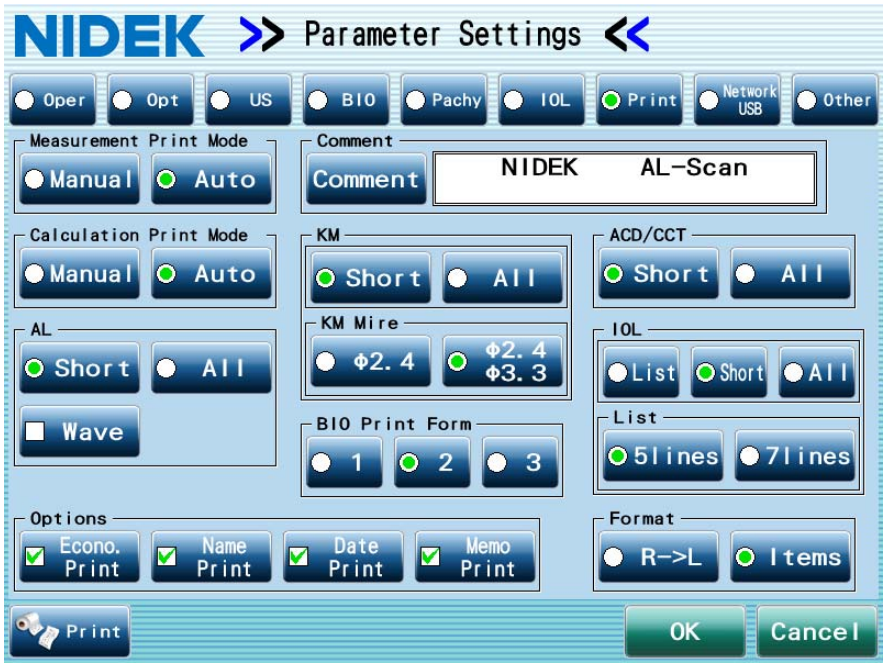
7 Press the OK button.

The View Pattern window is closed. The change is saved.

Note

- When the display setting is selected from View1 to View4, both eye data is displayed. Two sets of the calculation results of the right eye can be set in IOL1 and IOL2 fields, and those of the left eye can be set in IOL3 and IOL4 fields.
- When the display setting is selected from View5 to View8, single eye data is displayed. Four sets of the calculation results can be set in IOL1 to IOL4 fields. This setting is common to the both eyes.

3.1.7 Print tab



Printing contents and methods can be set.

Measurement Print Mode: Manual, Auto (The default is “Auto”.)

Setting for printing method of measurement result

Manual: Prints the printing contents using the Output window displayed on the result screen.

Auto: Prints automatically the measured results being finalized.

Calculation Print Mode: Manual, Auto (The default is “Auto”.)

Setting for printing method of IOL power calculation result

Manual: Prints the printing contents using the Output window displayed on the result screen.

Auto: Prints automatically the calculated results being finalized.

Comment: Input the desired printing contents in the Comment box.

KM, ACD/CCT: (The default is “Short”.)

Settings for printing contents of measured values

Short: Prints the median value or average value only.

All: Prints all the measured values.

AL: (The default is “Short”.)

Settings for printing contents of measured values

Short: Prints the median value only.

All: Prints all the measured values.

Wave: Prints the waveform formed by adding all the measured waveforms.

KM Mire: ø2.4, ø2.4 ø3.3 (The default is “ø2.4 ø3.3”.)

KM measurement is performed with the 2.4-diameter and 3.3-diameter mire rings. Set whether to print measured values using both of the mire rings or measured value using either mire ring.

ø2.4: Prints measured values using the 2.4-diameter mire ring.

ø2.4 ø3.3: Prints measured values using both the 2.4-diameter and 3.3-diameter mire rings.

IOL: List, Short, All (The default is “Short”.)

Setting for printing contents of IOL power calculation results

List: Prints the calculated results.

Short: Prints all the input parameters such as measured values used for the calculation separately from the calculated results.

All: Prints the input parameters for each IOL power calculation result.

List: 5lines, 7lines (The default is “5lines”.)

Setting for number of lines for the calculated results printed out by the internal printer.

BIO Print Form: Setting for the printing contents of BIO measured result. Select the print format from 1 to 3. (The default is 2.)

Printing contents	1	2	3
Patient data	O	O	O
Print date and time	O	O	O
Operator’s name	O	O	O
Measurement conditions	O	O	O
Measured data list, the average value, and standard deviation	O	X	X
Axial length measured value used for IOL power calculation	O	O	O
Selected A-scan waveform	O	O	X

O: Printed, X: Not printed

Format: R->L, Items (The default is “Items”.)

Setting for printing order of optically measured results for when there are measured data of both eyes

R->L: Prints all the data of the right eye, then prints all the data of the left eye.

Items: Prints data of both eyes for each measurement item.

Options: Check the desired function.

Econo.Print: Lessens the space between lines of printout when optically measured results re printed. (Default: Checked)

Name Print: Prints the patient information (name and sex). (Default: Checked)

Date Print: Prints the measurement date and time. (Default: Checked)

Memo Print: Prints the contents of the Memo box. (Default: Checked)

3.1.8 Network USB tab

For communication using a LAN or USB flash drive, methods and contents of data output can be set.

Network Mode: Manual, Auto (The default is “Manual”.)

Setting for method to output the data to a PC

Manual: Outputs the output contents using the Output window displayed on the result screen.

Auto: Outputs automatically the measured results and calculated results being finalized.

USB Mode: Manual, Auto (The default is “Manual”.)

Setting for method to output the data to a USB flash drive

Manual: Outputs the output contents using the Output window displayed on the result screen.

Auto: Outputs automatically the measured results and calculated results being finalized.

Output to: Setting for items to be output to folders on the destination PC and a USB flash drive

The following settings are available for each output destination (Folder1 to Folder3, USB)

Data: Outputs all the measured and calculated values (file format is xml).

Report: Outputs a report for printing in jpeg format.

Uncheck the Data and Report boxes for the folders that do not need to be output.

Note

- Even if the Data or Report box is checked, the items not checked in the Output Items field are not output.
- When connecting electronic medical record software or filing software and IOL-Station using a LAN, create a folder for each output destination.

  Example:

  Specify the Folder1 as the data output destination in electronic medical record software or filing software.

  Specify the Folder2 as the report output destination in IOL-Station.

  Specify the Folder3 as the data output destination in IOL-Station.

For the Folder1 to Folder3, the following can be set.

ACK ⇒ Used to output the data for electronic medical record software or filing software. After the time specified in the Timeout box has passed from the end of data output, confirm that the output data has been acquired by electronic medical record software / filing software. If the data has not been acquired by electronic medical record software / filing software, an error message is displayed.

Timeout: Sets the time between data output and confirmation of data acquisition (enabled when the "ACK" button is checked only).

For the AL-Scan in EX mode, "NAVIS-EX" is added as an output destination. See "7.6 Using Communication Function of NAVIS-EX" (page 240).

Output Items: Setting for output contents of optical, ultrasonic, and toric lens angle measurements, and IOL calculation

Data: Outputs all the measured and calculated values (file format is xml).

Report: Outputs a report for printing in jpeg format.

Note

- If the Data box is checked, the style sheet and jpeg images are output as well as xml files. This style sheet specifies the display format for xml files. Because the style sheet is not overwritten, changing the style sheet displays the xml file in a unique style.

  Should the style become improper, delete the style sheet and output the data again.

File Name: Setting for the file name of the output file.

With Patient Name: Checking this box adds a patient name to the beginning of the file name. Do not check this box when communicating with NAVIS or IOL-Station.

* For network, LAN setting is necessary. See "3.9 LAN Connection" (page 180).

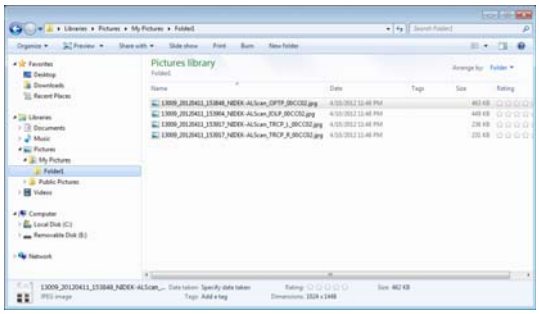
○ Printing the data of the items specified by checking the Report box

When the Report box is checked, the corresponding item data is output in jpeg format for printing. Open the jpeg file to be printed using image editing software or image viewer, then print the file.

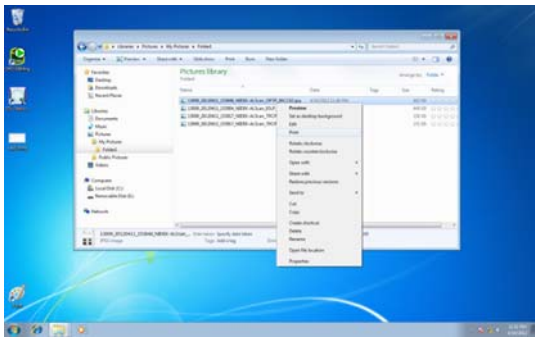
[Printing procedure example]

(The printing procedure differs depending on the software or operating system of the computer to be used.)

1) Open the folder in the output destination.



2) Right-click the jpeg file to be printed, then select “Print” from the menu.



The file name is specified according to the following example. Select the jpeg file to be printed referring to the patient ID or output data type.

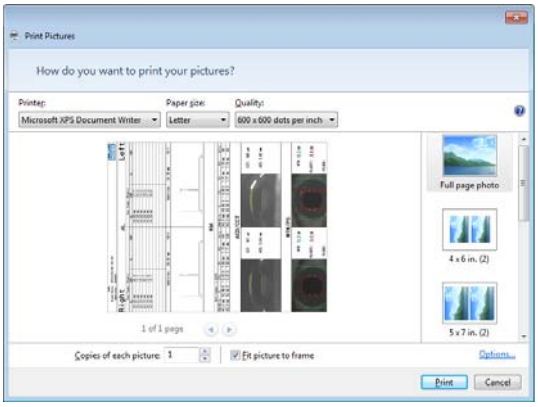
Example

13009_20120409_162414_NIDEK-ALScan_OPTP_00CC02.jpg

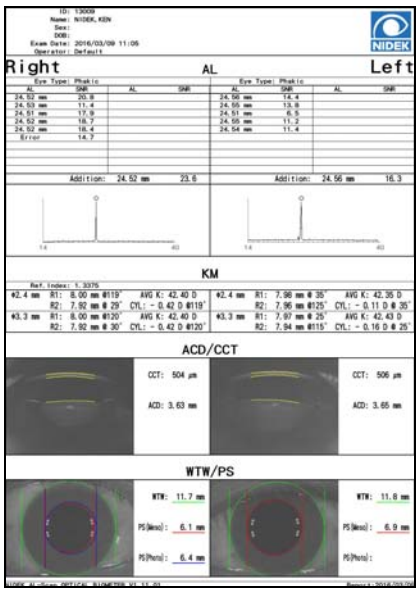
- 13009: Patient ID
- 20120409: Output date
- 162414: Output time
- OPTP: Output data type
- 00CC02: Mac address of the AL-Scan

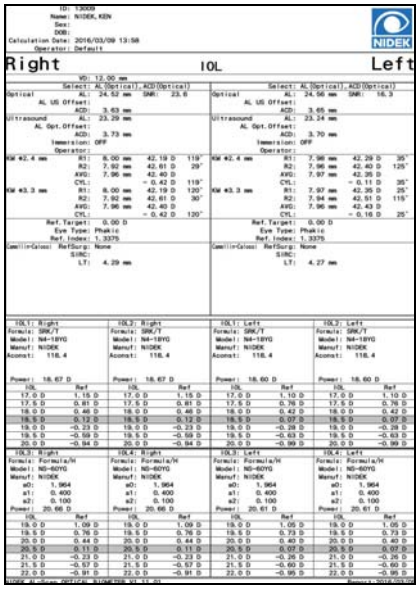
Output data type
OPTP: Printing optical measurement data
BIOP: Printing BIO measurement data
PACHYP: Printing Pachy measurement data
IOLP: Printing IOL data
TRCP_R: Printing toric lens angle measurement result for right eye
TRCP_L: Printing toric lens angle measurement result for left eye

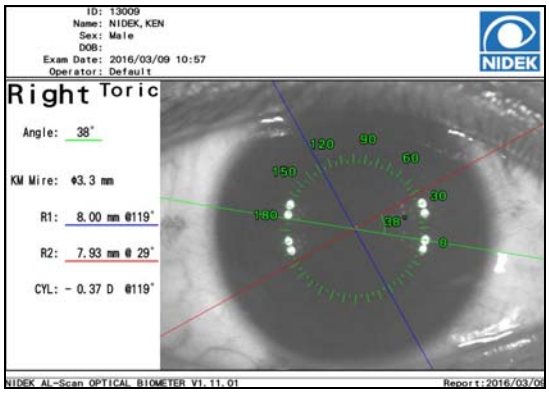
3) The Print Pictures window appears. Select the desired printer and paper size, then click the Print button.

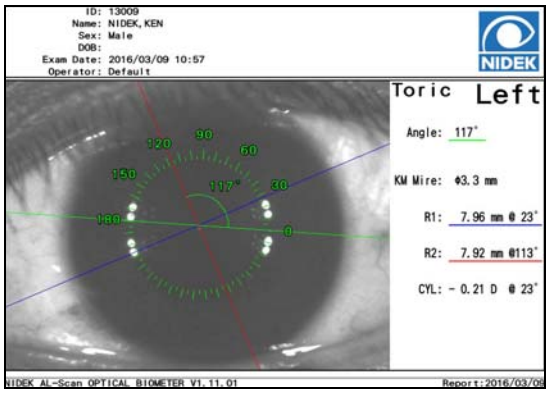


[Sample printout]









3.1.9 Other tab

Language: Setting for the language in the screen. (The default is “English”.)

Pressing the Language button displays the Language window to select a display language.

Date Format: Y/M/D, M/D/Y, D/M/Y (The default is “D/M/Y”.)

Setting for the display format of the DOB and measurement date. Input the date in the format specified here.

Beep: OFF, Normal, High (The default is “Normal”.)

Setting for the beep. Pressing each button produces the sound.

Should the parameter be set to “OFF”, the beep sounds at the volume specified by the “Normal” setting during ultrasonic measurement.

Message

Notice: Setting to display the message “The save number of data has exceeded the permitted number. Please back up and delete data.” at startup when the number of saved measurement data exceeds 900.

Patient: Setting to display the message “Database has reached its maximum number of entries. To save, delete the oldest entry from the database.” before the patient information screen is displayed when the number of the registered patients reaches 10000.

* When this box is not checked, the oldest data item is overwritten by the new data without displaying the message.

Measurement: Setting for whether or not to display the message “Database has reached its maximum number of entries. To save, delete the oldest entry from the database.” before the measurement screen is displayed when the number of saved measurement data reaches 1000 or when the number of saved measurement data for one patient reaches 99.

* When this box is not checked, the oldest data item is overwritten by the new data without displaying the message.

LCD Backlight: Low, Medium, High (The default is “Medium”.)

Setting for the brightness of the touch screen. Pressing each button allows the brightness to be checked.

Options

Auto ID: Setting of whether or not to automatically assign patient ID numbers in numerical order. (The default is “not checked”.)

A number from 000001 to 010001 is assigned as a patient ID in numerical order. Since only a maximum of 10000 patients can be registered, when patient data for patient ID 010001 is saved, the patient data for patient ID 000001 is deleted and patient ID 000001 is assigned to the new patient.

The AL-Scan in EX mode does not provide this parameter.

Birth Date Display: Checking this parameter displays the patient's birth date in the ID field in the patient list or the ID field at the top of the screen. In addition, it is printed along with the measurement result. (The default is “not checked”.)

Name: “L, F MI.”, “F L MI.”, “L F MI.” (The default is “L, F MI.”)

Setting for the display and printing formats of the name

Sleep Time: OFF, 5, 10, 15 minutes (The default is “5”.)

If the device is idle for the time specified here, the touch screen turns off, then the device enters sleep mode. The time while measurement is in process is not included to the idle time.

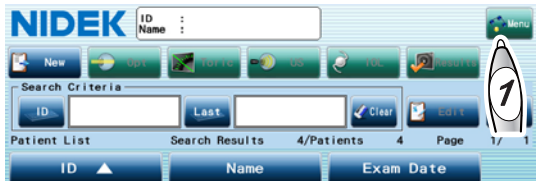
3.2 Postoperative Data Entry

Enter the postoperative data (such as refraction and visual acuity of the eye measured after surgery) necessary for calculation of IOL constant optimized for optically measured values.

Note

- To enter the postoperative data, specify the IOL to be implanted in the IOL power calculation screen and save the calculated results in advance. See “2.8 Calculation of IOL Power” (page 90).
- The postoperative data is entered to calculate the IOL constant optimized for optically measured value. Therefore, the patient is not displayed in the Patient List screen for optimization in the following situation.
  - The eye type is not “Phakic”.
  - The IOL power calculation result is saved without specifying the IOL to be implanted.
  - The value obtained from ultrasonic measurement is used for IOL power calculation.
  - Calculation is performed by the Formula/H formula without ACD measurement value.

1 Press the Menu button in the Patient List screen.



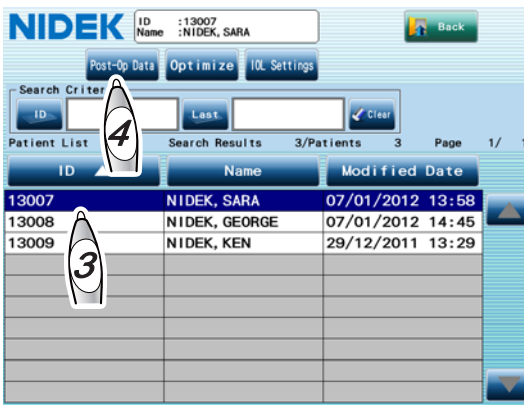
2 The Menu window appears. Then press the Optimize button.

The Patient List screen for optimization appears.

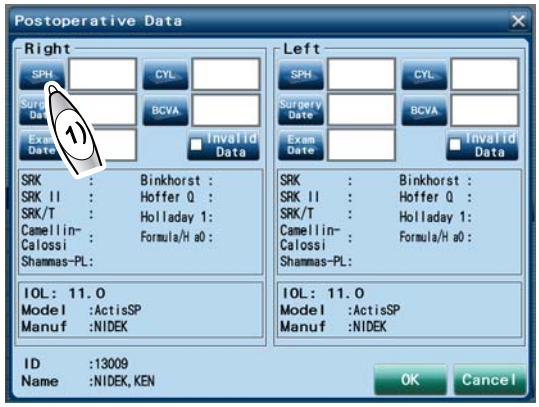
If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.

3 The Patient List screen for optimization appears. Then select the desired patient to enter the postoperative data.

4 Press the Post-Op Data button.



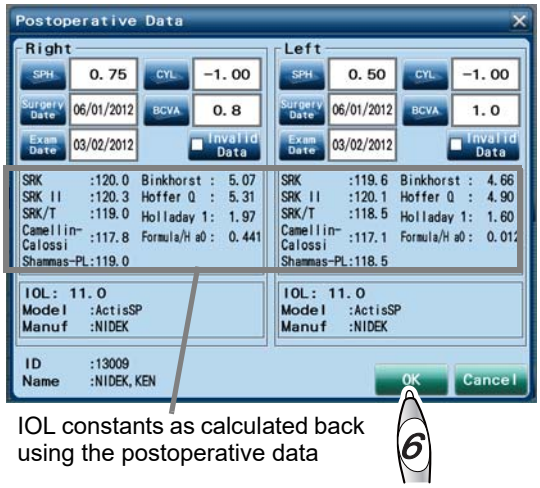
5 The Postoperative Data window appears. Enter the surgery date, SPH (sphere), CYL (cylinder), BCVA (best corrected visual acuity), and exam date.



1) Press the SPH button, then enter the postoperative sphere measured value using the numeric keypad window.
2) Enter the postoperative cylinder measured value, BCVA, surgery date, and exam date in the same manner.

   Enter the surgery date and exam date in the format specified in the Date Format field in the IOL tab of the Parameter Settings screen.
3) If the entered postoperative data is not used for IOL constant optimization, check the Invalid Data box.
4) Enter the postoperative data of the other eye in the same manner.

   After the postoperative data entry is complete, the IOL constants as calculated back using the postoperative data are displayed.



6 Press the OK button.

The entered postoperative data is saved. The Patient List screen for optimization appears again.

Note

- Only one set of postoperative data of right and left eyes can be saved for each patient. When entering the new postoperative data, edit the saved prior postoperative data in the same manner as Steps 1 to 5.

7 Press the Back button.

The screen returns to the Patient List screen.

Note

- The postoperative data is not reflected to the optimized IOL constant by merely entering the data. It is reflected in the next IOL constant optimization. See “3.3 IOL Constant Optimization” (page 161).

3.3 IOL Constant Optimization

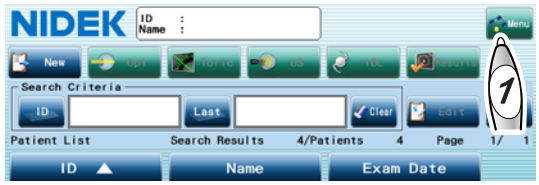
The optimized IOL constant of the optical measurement used for the surgery can be calculated by statistically processing the IOL constants as calculated back using postoperative refraction.

Note

- To optimize the IOL data, specify the IOL to be implanted in the IOL power calculation screen and save the calculated results in advance. See “2.8 Calculation of IOL Power” (page 90).
- To optimize the IOL data, enter the postoperative data in advance. See “3.2 Postoperative Data Entry” (page 159).

  The IOL constants for an IOL model can be optimized using eight or more valid samples (postoperative data sets). It is acceptable to use samples for both eyes of four patients, for example. With more samples, the optimization accuracy is improved.
- The optimization of IOL constants cannot be performed in the following cases.
  - ·The eye type is not “Phakic”.
  - · When the BIO measured axial length is used for IOL power calculation
  - · When the Camellin-Calossi formula is used with the History of Refractive Surgery set to anything other than None.
  - · When the Shammas-PL formula is used
  - · Calculation is performed by the Formula/H formula without ACD measurement value.
- Deleting the patient data or deleting the postoperative data by recalculation of the IOL power changes the data used for optimization. This change is not automatically reflected to the optimized IOL constant. It is reflected in the next IOL constant optimization.
- With the Formula/H formula, the IOL power can be calculated even without ACD measurement value. However, that is for exceptional cases such as when ACD cannot be measured due to aphakia.

1 Press the Menu button in the Patient List screen.

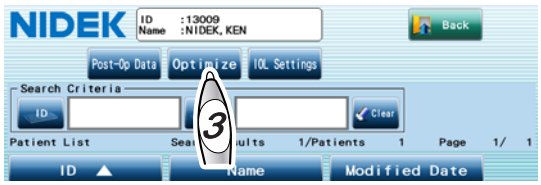


2 The Menu window appears. Press the Optimize button.

The Patient List screen for optimization appears.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.

3 The Patient List screen for optimization appears. Then press the Optimize button.

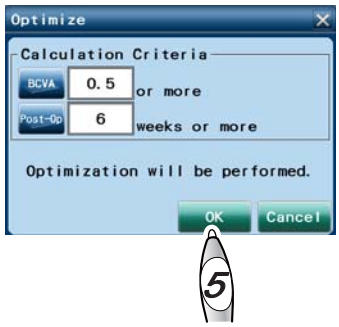


4 The Optimize window appears. Check the calculation condition.

BCVA: The samples with postoperative corrected visual acuity less than the value in this box are not used for optimization.

Post-Op: If the period from the surgery date to the postoperative visual acuity exam date is within the period specified in this box, the samples are not used for optimization.

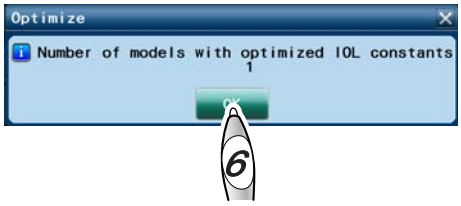
When changing the calculation condition, enter the desired value using the numeric keypad window that appears by pressing the BCVA or Post-Op button.



5 Press the OK button.

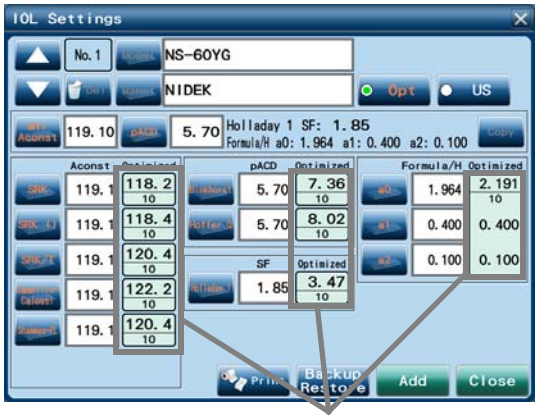
The number of models with optimized IOL constants is displayed.

6 Press the OK button.



The IOL constants are optimized. The IOL Settings screen appears.

The value input in the Optimized field for the Shammas-PL formula is same as that of the SRK/T formula.



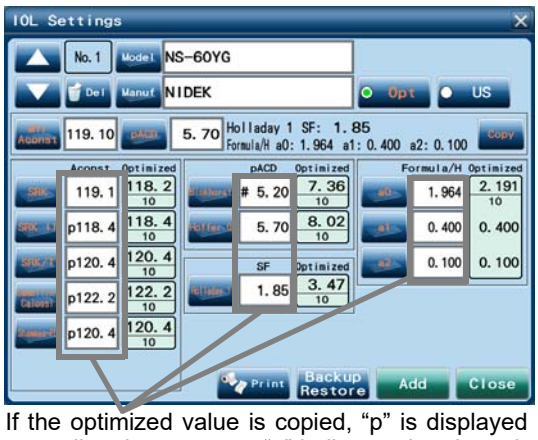
Optimized IOL constant

Number of samples used for optimization

7 The optimized IOL constants are displayed in the Optimized field. Change the IOL constants referring to the optimized IOL constants.

See “○ IOL settings (registering IOL information)” (Page 143).

Pressing the optimized value displays the message to confirm whether to copy the value to the Aconst box to the left. When copying the optimized value, press the OK button.



If the optimized value is copied, “p” is displayed preceding the constant. “p” indicates that the value is optimized.

8 Back up the IOL setting as necessary.

See “○ IOL information backup“(Page 146).

9 Press the Print button as necessary.

The IOL setting is printed out.

10 Press the Add button.

The changed constants are saved.

3.4 Database Management

3.4.1 Database backup

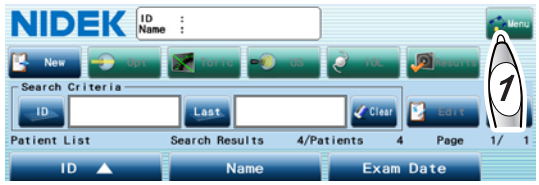
The database can be backed up to a USB flash drive or a PC through a LAN. All the patient information, measured results, and IOL power calculation results are backed up at once. It is not possible to back up individual patient information, measured results, or calculated results.

CAUTION • **Do not turn off (○) power to the device during data backup.**
The data may be broken.

Note

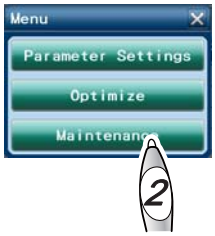
- If the number of the registered patients is large, the time required to transfer the data may increase. Backup on a PC through a LAN is recommended more than the USB flash drive, which requires more time for data transfer.

1 Press the Menu button in the Patient List screen.

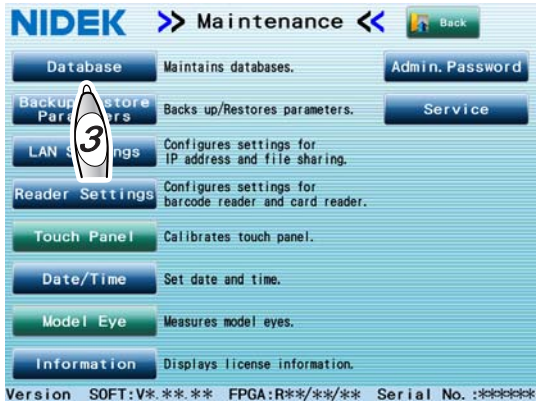


2 The Menu window appears. Press the Maintenance button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.



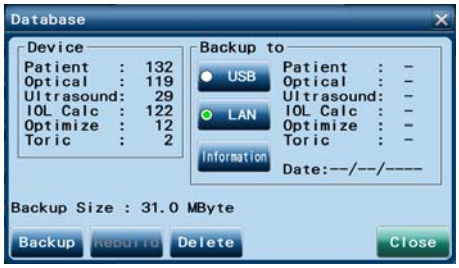
3 The Maintenance screen appears. Press the Database button.



4 The Database window appears. Select the backup destination.

[USB]: A USB flash drive

[LAN]: A shared folder on a computer connected by a LAN



In the backup destination, it is necessary to free up space considerably more than the file size shown in the “Backup size” field.

5 Press the Backup button.

A message to confirm whether to backup the database appears.

6 Press the OK button.

The database is backed up.

Pressing the Cancel button during the data backup stops the backup. In such a case, the backup data is not changed.

7 Press the Close button to close the Database window.

8 Press the Back button to return to the Patient List screen.

Note

- The backup data is saved in the following location.

When the backup destination is set to “USB”

AL3X
- DATABASE_BACKUP (The most recent backup data)
- 20121015_143052_DATABASE_BACKUP (Prior backup data)

The backup date_time

When the backup destination is set to “LAN”

AL3X110001 (This folder is created in the shared folder of backup destination (see page 180). 6-digit number indicates the serial number of the backed up AL-Scan.)
- DATABASE_BACKUP (The most recent backup data)
- 20121015_143052_DATABASE_BACKUP (Prior backup data)

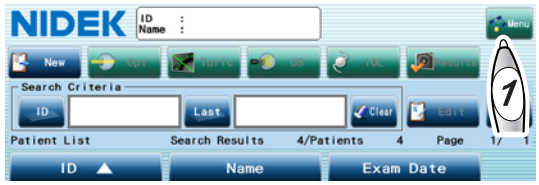
The backup date_time

- There is a csv file in the backup data. Opening the file in Excel shows the patient information list of the backup data.

3.4.2 Restoring database to prior database backup (rebuilding)

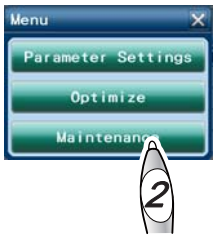
The database can be restored to the prior database backup.
After the backup, the current measured data is deleted.

1 Press the Menu button in the Patient List screen.

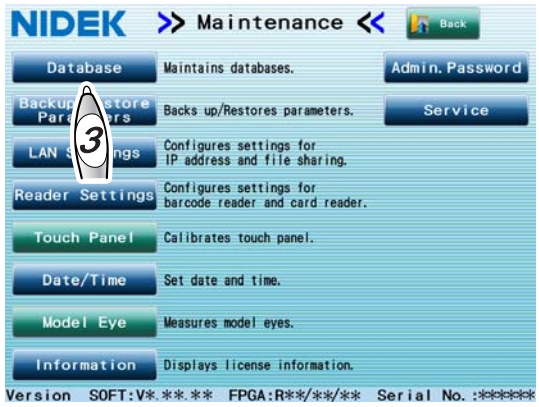


2 The Menu window appears. Press the Maintenance button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.



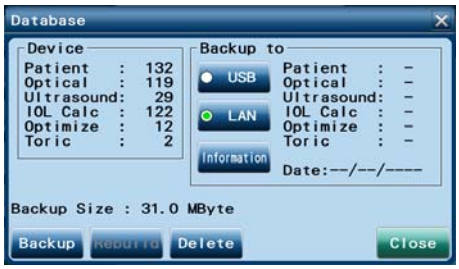
3 The Maintenance screen appears. Press the Database button.



4 The Database window appears. Select the backup destination.

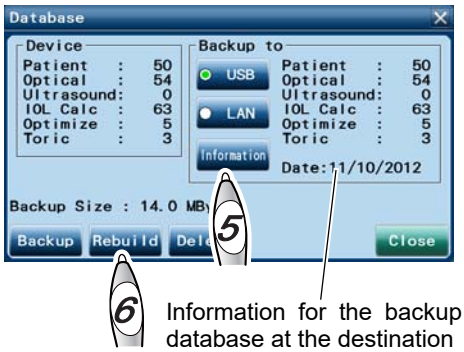
[USB]: A USB flash drive

[LAN]: A shared folder on a computer connected by a LAN



5 Press the Information button.

The information for the backup database at the destination is displayed.



6 Check the information for the backup database at the destination. Press the Rebuild button to restore the database to the database indicated there.

A message to confirm whether to rebuild the database appears.

If restoration to the prior database backup is no longer desired, go to Step 8.

7 Press the OK button.

The database is rebuilt.

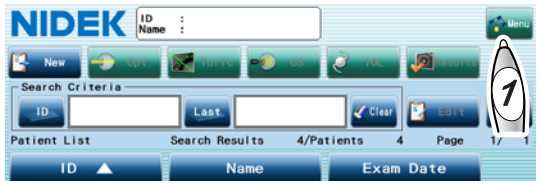
8 Press the Close button to close the Database window.

9 Press the Back button to return to the Patient List screen.

3.4.3 Deleting old data from database

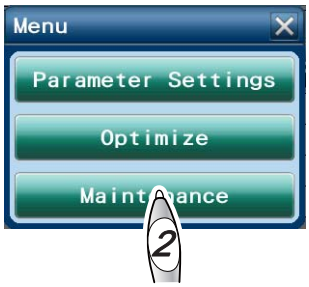
The number of data to be deleted starting from the oldest data on the database can be specified.

1 Press the Menu button in the Patient List screen.



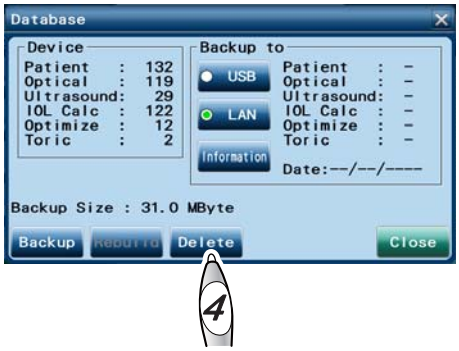
2 The Menu window appears. Press the Maintenance button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.



3 The Maintenance screen appears. Press the Database button.

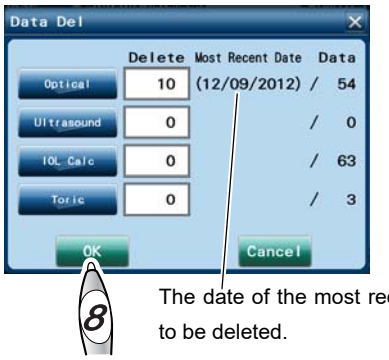
4 The Database window appears. Press the Delete button.



5 The Data Del window appears. Press the Optical button and input the number of data to be deleted starting from the oldest data using the numeric keypad window.

6 Inputting the number of data to be deleted displays the date of the most recent data to be deleted in the Most Recent Date field. Confirm that the date of the most recent data to be deleted is acceptable.

7 Same as Steps 5 and 6, specify the number of data to be deleted for ultrasonic measurement data, IOL calculated results, and toric data.



The date of the most recent data to be deleted.

8 Press the OK button.

The specified number of data is deleted from the oldest data. The Data Del window is closed.

9 Press the Close button to close the Database window.

10 Press the Back button to return to the Patient List screen.

3.5 Parameter Backup

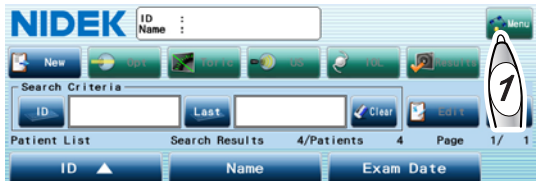
Parameter backup allows saving parameter settings of the device or using the same settings for another device.

3.5.1 Parameter backup

The parameter settings can be backed up to the internal CompactFlash card, USB flash drive, or PC through a LAN.
The settings of the Maintenance screen, settings of the Parameter Settings screen (including IOL settings), and measurement conditions are backed up.

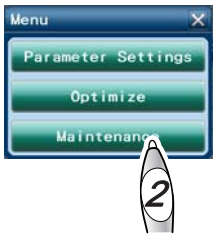
⚠ **CAUTION** • **Do not turn off (○) power to the device during parameter backup.**
The data may be broken.

1 Press the Menu button in the Patient List screen.

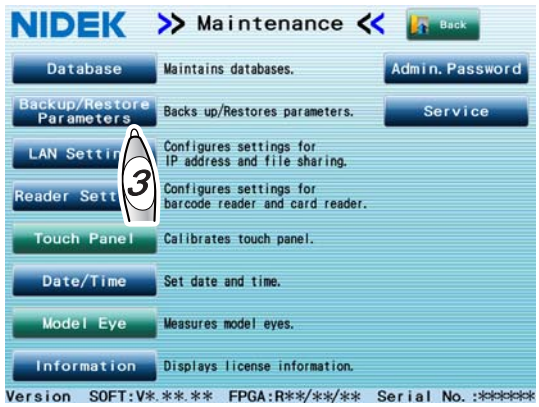


2 The Menu window appears. Press the Maintenance button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.



3 The Maintenance screen appears. Press the Backup/Restore Parameters button.



4 The Backup/Restore Parameters window appears. Select the backup destination.

[USB]: A USB flash drive

[LAN]: A shared folder on a computer connected by a LAN

[Internal CF]: Internal CompactFlash card

5 Confirm that the Backup button in the Mode field is selected, then press the OK button.

The settings are backed up.

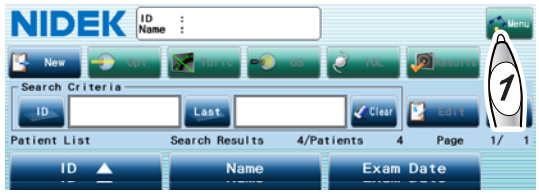
When backup data already exists in the backup destination, a message to confirm whether to overwrite the backup data appears. Pressing the OK button overwrites the backup data. Pressing the Cancel button cancels backup.

6 Press the Back button to return to the Patient List screen.

3.5.2 Restoring settings to prior setting backup

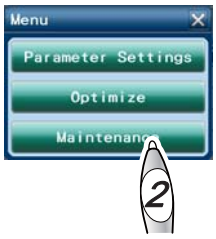
The parameter settings can be restored to the prior setting backup.

1 Press the Menu button in the Patient List screen.



2 The Menu window appears. Press the Maintenance button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.



3 The Maintenance screen appears. Press the Backup/Restore Parameters button.

4 The Backup/Restore Parameters window appears. Select the backup destination.

[USB]: A USB flash drive

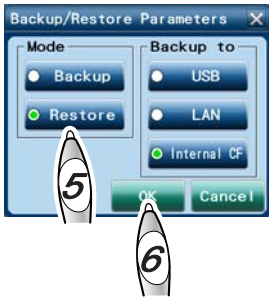
[LAN]: A shared folder on a computer connected by a LAN

[Internal CF]: Internal CompactFlash card

5 Press the Restore button in the Mode field.

6 Press the OK button.

A message to confirm whether to restore the settings appears.



7 Press the OK button.

The settings are restored.

8 Press the Back button to return to the Patient List screen.

3.6 Setting Date and Time

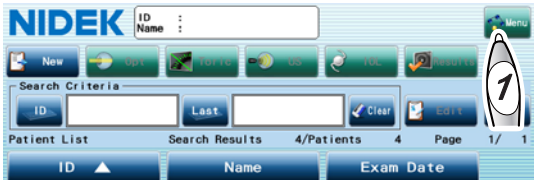
The measurement date and time are automatically registered based on the clock in the device. Should the measurement date and time not be correct, set the internal clock to the correct date and time.

Note

- This device is equipped with an internal battery for date and time display function. 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.

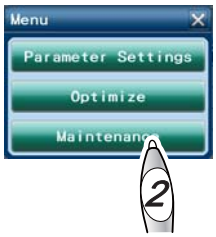
  In such a case, turn on the device and leave it on to recharge the battery. The battery needs 24 hours for a full charge. If the device is used for 8 hours a day, the device will have to be kept on for three days before the battery is fully recharged. Once the battery is fully recharged, the device operates normally for daily use. (The battery cannot be replaced by users.)
- Should measurement be performed when the date and time are not correct, the measured data is saved according to that incorrect date and time. Therefore, the selected measured data may not be the desired data.
- Should the date and time indicated by the internal clock be prior to those of the previous measurement, an error message on the clock error at device start-up. Then the Date/Time window appears. Set the internal clock to correct date and time by following Steps 4 and on.

1 Press the Menu button in the Patient List screen.



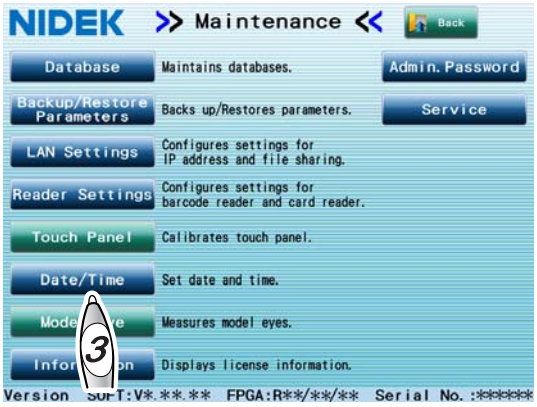
2 The Menu window appears. Press the Maintenance button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.



3 The Maintenance screen appears. Press the Date/Time button.

The Date/Time window appears.



4 Confirm that “Y” (year) is correctly set. To change the setting, press the ▲ or ▼ button to set the indication to the correct year.

5 Set “M” (month), “D” (day), “H” (hour), and “M” (minute) in the same manner. Then press the Close button.

Set “H” in the 24-hour time notation.

The date and time are set when the ▲ or ▼ button is released.

When “M” (minute) is changed, “S” (second) becomes cleared to zero.

6 Press the Back button to return to the Patient List screen.

3.7 Reading ID with Barcode Reader

Note

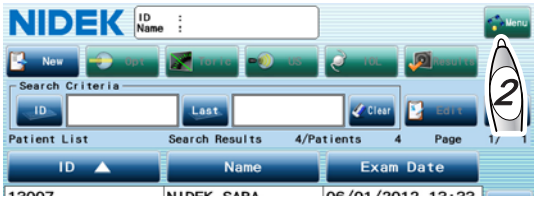
- Be sure to use the optional barcode reader specified by Nidek.
  Nidek does not guarantee that a barcode reader other than the one specified by Nidek will operate properly.

3.7.1 Setting barcode reader to read ID

1 Connect the optional barcode reader cable to the USB port on the side panel.

The device cannot recognize the barcode reader through a USB hub. Connect the reader directly to the USB port.

2 Press the Menu button in the Patient List screen.

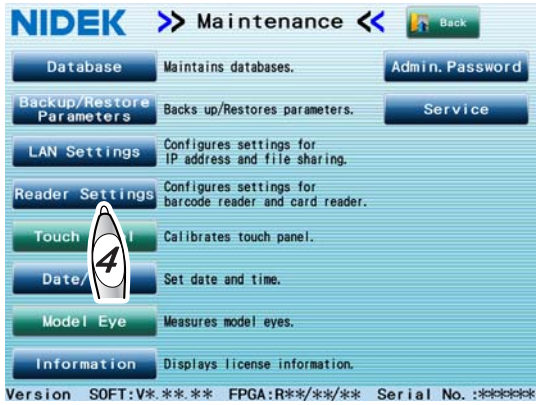


3 The Menu window appears. Press the Maintenance button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.

4 The Maintenance screen appears. Press the Reader Settings button.

The Reader Settings window appears.



5 Select the Barcode button in the Mode field.

6 Read the patient barcode with the barcode reader, then confirm that the ID is displayed in the Test field.

Pressing the Print button prints the settings.

7 Press the OK button to return to the Maintenance screen.

8 Press the Back button to return to the Patient List screen.

3.7.2 Reading ID with barcode reader

The patient ID can be read with the optional barcode reader.

Read the patient barcode with the optional barcode reader while the Patient List screen is displayed.

When a registered patient ID is read, the patient is selected on the Patient List.

When a new patient ID is read, the patient information screen appears with the read ID entered.

The ID can contain numeric characters, upper case letters, lower case letters, spaces, hyphens, and underscores.

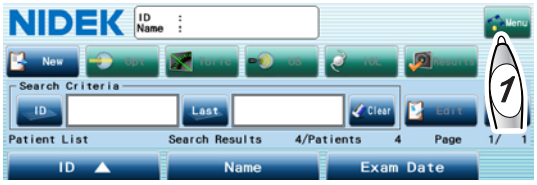
Note

- While the keyboard window for ID input is displayed, the barcode reader cannot read the ID.

3.8 Protecting IOL Settings with Password

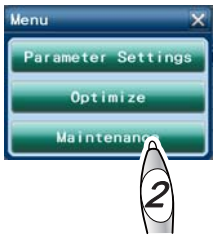
To prevent change of various settings or deletion of data from the database by unauthorized personnel, an administrator password can be set to limit operators who can change the settings.

1 Press the Menu button in the Patient List screen.



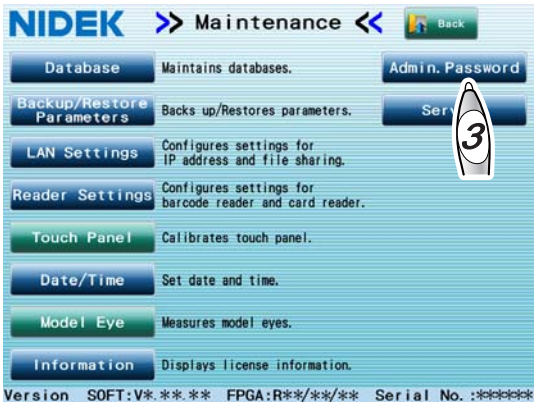
2 The Menu window appears. Press the Maintenance button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.



3 The Maintenance screen appears. Press the “Admin. Password” button.

The “Admin. Password” window appears.



4 Press the Current Password button, then enter the current password using the keyboard window.

Because the administrator password is not specified when the device is shipped, enter nothing in the Current Password box when specifying the administrator password for the first time.

5 Press the New Password button, then enter the new password using the keyboard window.

A maximum of ten characters of a password can be entered.

6 Press the Confirm New Password button, then enter the password specified in Step 5 using the keyboard window.

7 Press the OK button to return to the Maintenance screen.

Pressing the Cancel button cancels registration of the entered password.

8 Press the Back button to return to the Patient List screen.

The administrator password setting is complete. Administrator password entry is required in the following situations.

- When the patient data, measured results, or calculated results is deleted
- When the Parameter Settings, Optimize, or Maintenance button in the Menu window is pressed

3.9 LAN Connection

3.9.1 LAN connection settings

To output measured or calculated results to the shared folder on the PC through a LAN, specify the following parameters in the LAN Settings window.

- IP address and subnet mask of the device
- PC and shared folder as output destinations
- When the output destination for the data is outside the network the device belongs to, set the default gateway.

Note

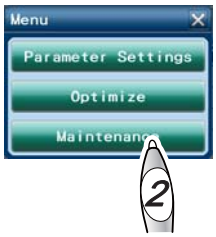
- After the setting, turn off power to the device. Then connect the LAN cable.

  Should the LAN cable be connected before setting, the device is connected to a LAN using the default IP address. In such a case, turn the device off and on again after the setting.

1 Press the Menu button in the Patient List screen.

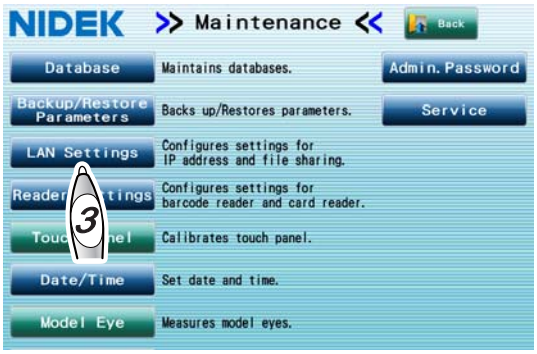
2 The Menu window appears. Press the Maintenance button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.



3 The Maintenance screen appears. Press the LAN Settings button.

The LAN Settings window appears.

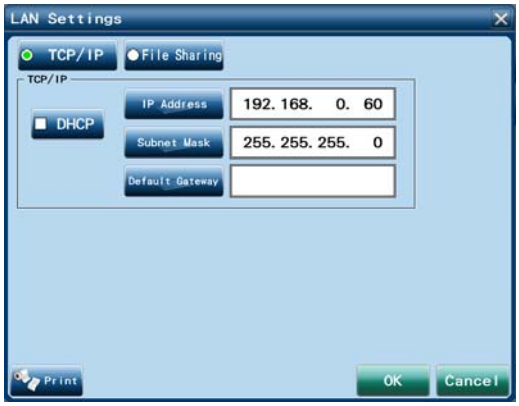


4 Select the TCP/IP tab.

5 Specify the IP address and subnet mask of the device.

When the DHCP server is on the LAN, check the DHCP box. In such a case, it is not necessary to specify the IP address and subnet mask.

The setting change is reflected after the device is restarted.



6 Set the default gateway only when the shared folder in the output destination is outside the LAN.

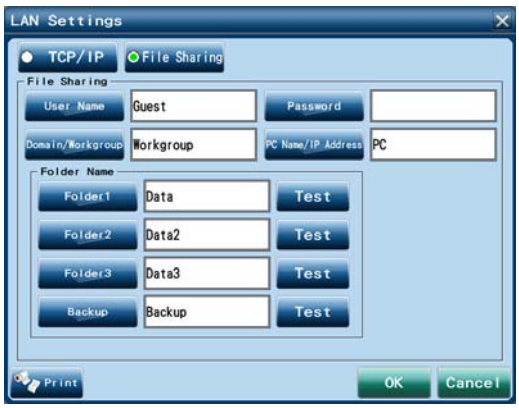
7 Turn off the power switch, then connect the LAN cable.

See “3.9.2 LAN connection” (page 184).

8 Restart the device, then display the LAN Settings window in the same manner as in Steps 2 to 3.

9 Select the File Sharing tab.

10 Enter the user name (User Name), domain name (Domain) / Workgroup name, and computer name (PC Name) / IP address of the output destination PC using the keyboard window displayed by pressing the corresponding button. Enter the password in the same manner if it is required to connect to the computer.



11 Specify necessary parameters for the shared folders.

Up to three shared folders can be set as output destinations of measured or calculated results. Set the shared folders for each application to use the data. A shared folder can be set as an output destination of backup data.

Note

- When connecting electronic medical record software or filing software and IOL-Station using a LAN, create a folder for each output destination.

  Example:

  Specify the Folder1 as the data output destination in electronic medical record software or filing software.

  Specify the Folder2 as the report output destination in IOL-Station.

  Specify the Folder3 as the data output destination in IOL-Station.

1) Press the Folder1 button, then enter the shared folder name in the Folder1 box.

   On the output destination PC, create the shared folder with a name the same as the entered folder name.

2) Press the Test button to the right of the folder name to confirm that the communication is properly performed.

   Should the communication not be successful, an error message appears.

   Before performing the test, shut down the data acquisition software (such as the electronic medical record software / filing software and IOL-Station) in the output destination PC. If such software is activated, an error may occur during communication test.

3) Specify the Folder2 and Folder3 settings as necessary.

If the data output is not necessary, uncheck the Data and Report boxes for the folders in the “Output to” field in the Network USB tab of the Parameter Settings screen (see page 153).

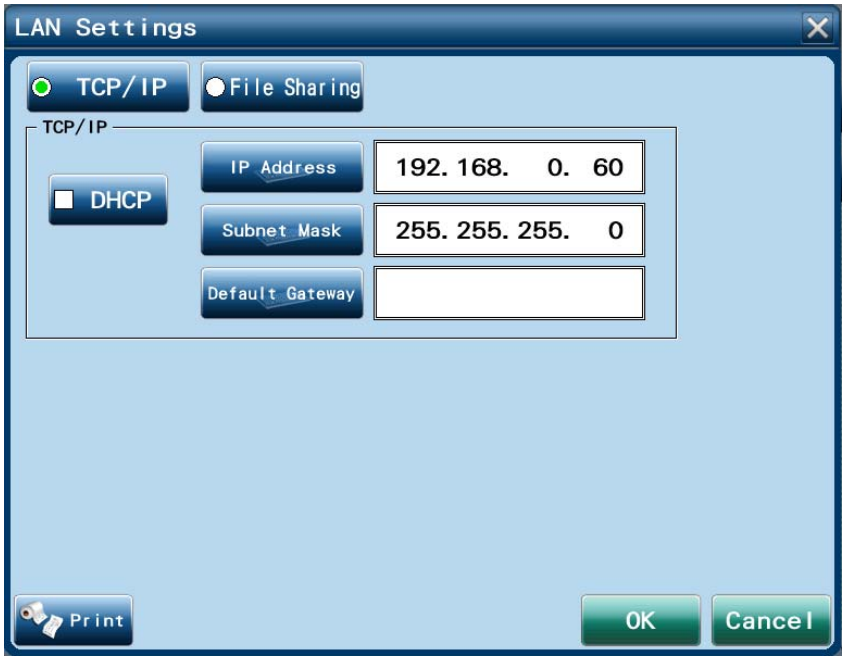
4) To create the backup data of the database or parameter settings on the computer, select the Backup button, then enter the shared folder name in the backup destination.

   On the output destination PC, create the shared folder with a name the same as the entered folder name.

5) Press the OK button to return to the Maintenance screen.

12 Press the Back button to return to the Patient List screen.

○ LAN Settings window



Settings for the IP address and subnet mask of the AL-Scan

DHCP: Checked when the DHCP server is on the LAN.

If the box is checked, it is not necessary to enter the IP address and subnet mask. In such a case, the IP address and subnet mask are automatically assigned by the DHCP server.

IP Address: Used to enter the IP address.

Change the default “192. 168. 0. 60” as necessary.

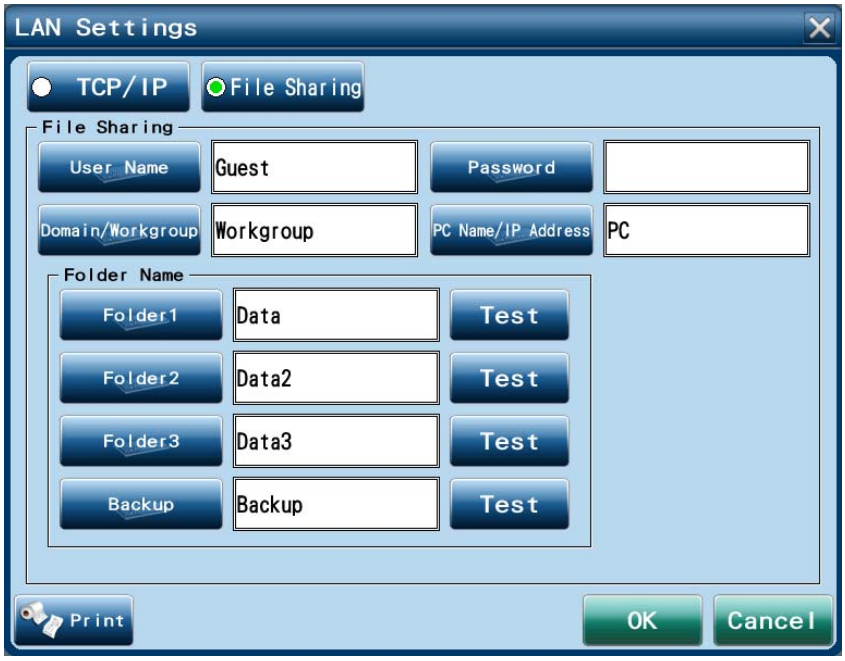
Subnet Mask: Used to enter the subnet mask.

Change the default “255. 255. 255. 0” as necessary.

Default Gateway: Input the default gateway.

It is not necessary when the output destination for the data is within the network the device belongs to.

The default setting is blank.



Settings for file sharing

Up to three shared folders can be set as output destinations. To use the data output by the AL-Scan for multiple applications, separate the shared folders for each application to be used. If both the electronic medical record software / filing software and IOL-Station read the data from a single shared folder, the data in the shared folder may be automatically deleted after the electronic medical record software / filing software reads the data, so that it may not possible to read the data by IOL-Station.

User Name: Used to enter the user name for the computer where the shared folders are created.

Password: Used to enter the login password associated with the user name for the computer where the shared folders are created.

Domain/Workgroup: Used to enter the domain name of the connected network or workgroup name.

When 21 or more characters are entered, those after the 18th character are indicated with "...".

PC Name/IP Address: Used to enter the name of the computer where the shared folders are created. (It is acceptable to enter the IP address for the computer instead of the computer name.)

When the output destination for the data is outside the network the device belongs to, enter the IP address of the destination computer in the PC Name / IP Address field, along with the default gateway.

Folder Name: Used to enter the name of the shared folders in the data output destination (a maximum of three shared folders) and backup destination.

Test button: Used for communication test.

Note

- Specify which data is output to which shared folder referring to "3.1.8 Network USB tab" (page 153).

3.9.2 LAN connection

Obtain approval from the network administrator of the facility for network connection (LAN connection).

1 Turn off (○) the power switch.

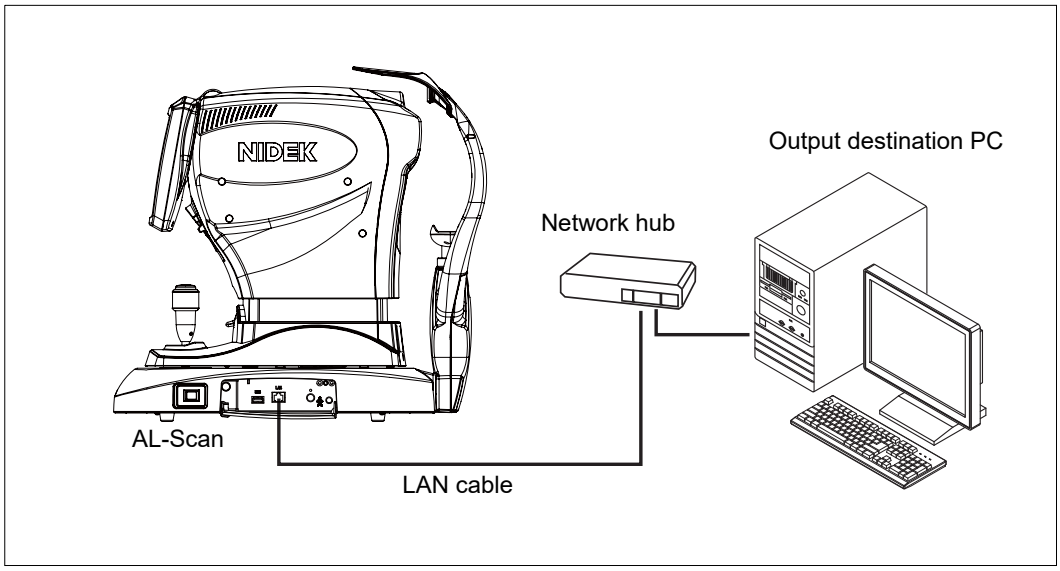
2 Connect the LAN cable to the device.

Connect the LAN cable (straight 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.

• **The LAN cable with a shield is recommended.**



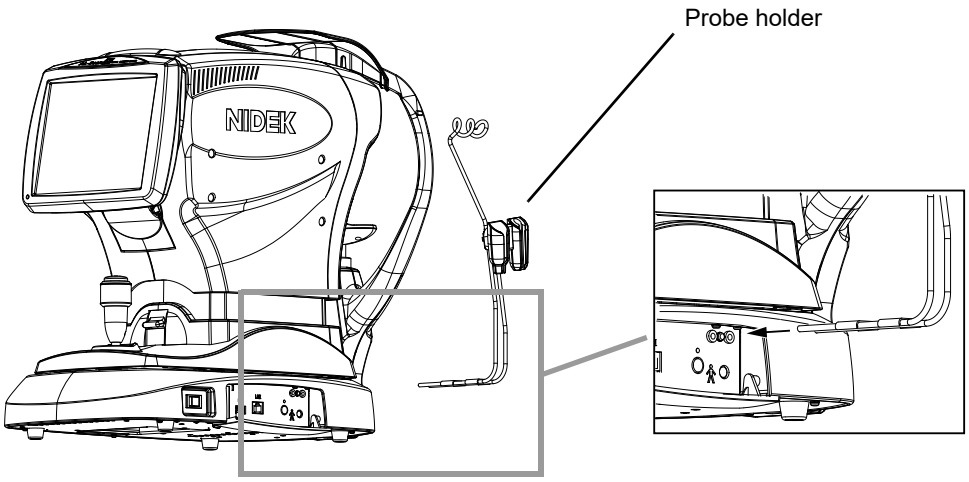
3 Turn on (|) the power switch.

3.10 Connection with Optional Accessories

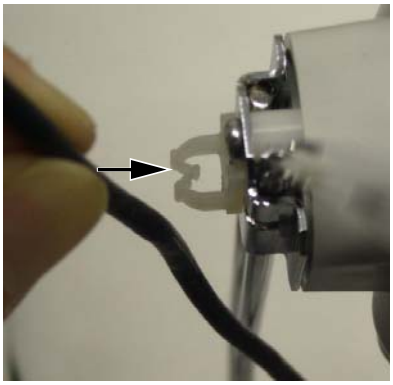
3.10.1 Connecting probe holder

The probe holder comes with the device equipped with the ultrasonic measurement function only.

1 Insert the probe holder into the probe holder mounting hole at the upper right corner of the side panel on the device.



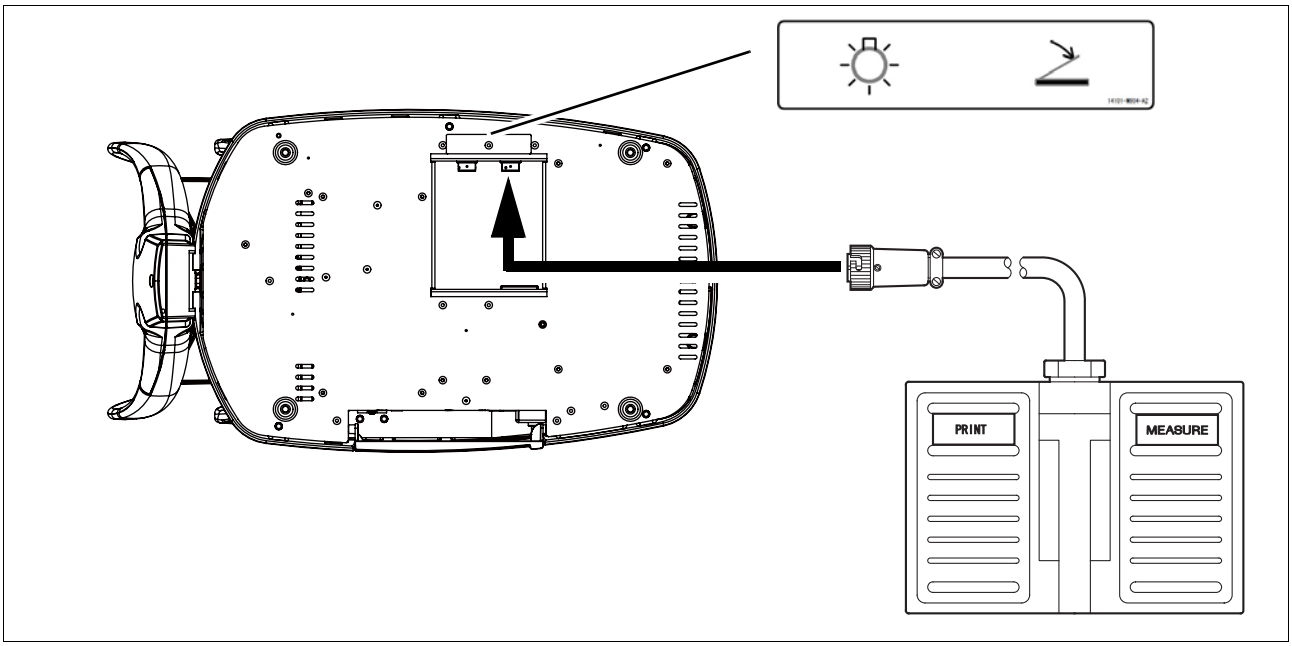
2 Secure the probe cable to the hook on the probe holder, then place the probe on the probe holder with the probe tip up.



Secure the cable to the hook.

Place the probe with its tip up.

3.10.2 Connecting optional foot switch



1 Place the foot switch at the position where it is easy to use, and position the cable so that it will not interfere with the operation.

2 Align the notch of the foot switch cable plug to the foot switch connector (⋋) on the underside of the device, then insert the plug into the connector.

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

⚠ **CAUTION** • **Be sure to use only the foot switch specified by Nidek. Using other foot switches may cause failure or other troubles.**
The foot switch specified by Nidek is indicated with “14610-9000” on its case.

4. CHECKS

4.1 Checks Before Use

Before using the device, be sure to check the following items. Prepare a check list and record each result in the list. The Items (7) to (9) are necessary for the AL-Scan equipped with the optional ultrasonic measurement function only.

(1) Appearance

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

(2) Power cord

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

(3) Start-up

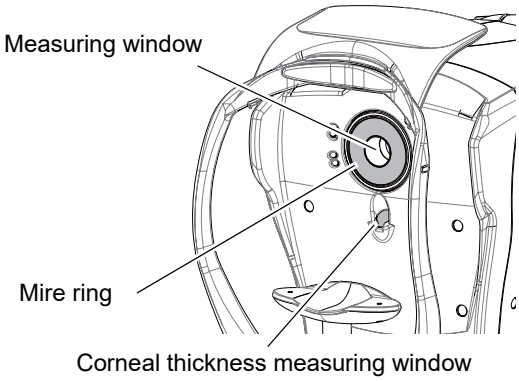
When the power switch is turned on (|), the pilot lamp lights up and a beep sounds, as the initial screen appears. Confirm that the Model Eye window appears a few seconds later.

(4) Main unit

Check the cleanliness of the measuring window, mire ring, and corneal thickness measuring window.

(For details of cleanliness check and cleaning, see “5.6.4 Cleaning the mire ring and corneal thickness measuring window” (page 215) and “5.6.5 Cleaning the measuring window” (page 216).)

Check that the main unit moves smoothly using the joystick.



(5) Chinrest

Check that the chinrest moves up or down with the chinrest up/down button.

(6) Optically measured axial length (AL), corneal curvature radius (R1, R2), and anterior chamber depth (ACD)

Perform measurement of the model eye, and confirm that the measured values are within the range indicated on the model eye.

For the measurement procedure, see “4.2.1 AL model eye use” (page 189) and “4.2.2 ACD model eye use” (page 191).

(7) Probe

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

(8) BIO mode measurement operation/value

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

For measurement procedure, see “4.3.1 Use of test piece for BIO mode measurement” (page 195).

(9) Pachy mode measurement operation/value

Measure the corneal thickness using the test piece to check whether the operation is normal and the measured value is within the range indicated on the test piece.

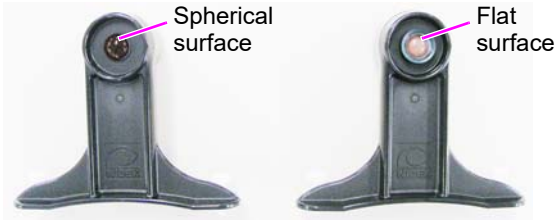
For measurement procedure, see “4.3.2 Use of test piece for Pachy mode measurement” (page 197).

(10) Printer operation

Print the result of items (6), (8), or (9). Confirm that there are no misaligned and blurred areas on the printout.

4.2 Model Eye Use

Before using the device be sure to check the operation using the model eyes, and record the results on the check list.
There are two types of model eyes provided with the device. Use the AL model eye to check AL or KM measurement. Use the ACD model eye to check ACD measurement.



AL model eye ACD model eye

Note

- During checks before use immediately after device start-up, perform AL model eye measurement, then ACD model eye measurement.

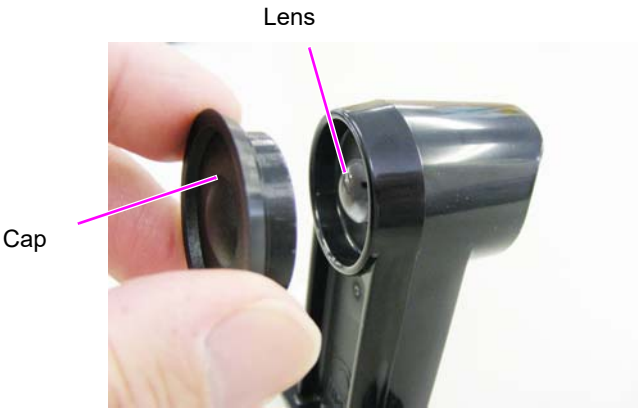
4.2.1 AL model eye use

To check the accuracy of AL and KM measured data, use the provided AL model eye.

1 Pull out the two fixing pins and remove the stack of chinrest paper from the chinrest.

2 Remove the cap from the AL model eye.

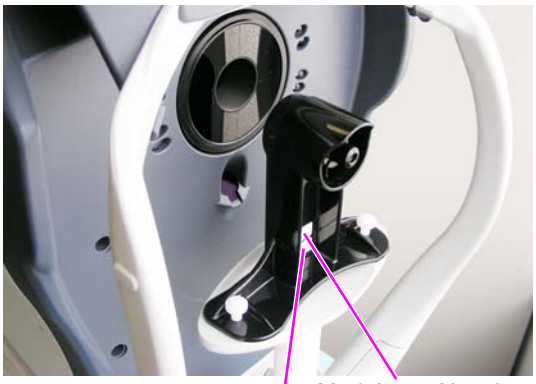
Confirm that the lens surface of the model eye is clean.



3 Place the model eye on the chinrest with its lens toward the measuring window, then insert the fixing pins.

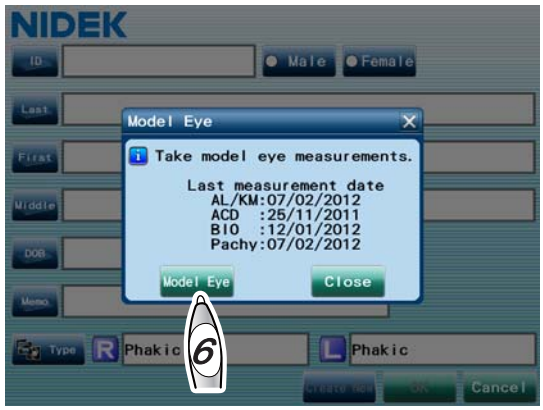
4 Turn on (|) the power switch of the device.

5 Adjust the height of the chinrest with the chinrest up/down button (▲ , ▼) until the lens of the model eye aligns with the eye level marker.



6 Press the Model Eye button on the Model Eye window displayed immediately after device start-up.

The Model Eye screen appears.

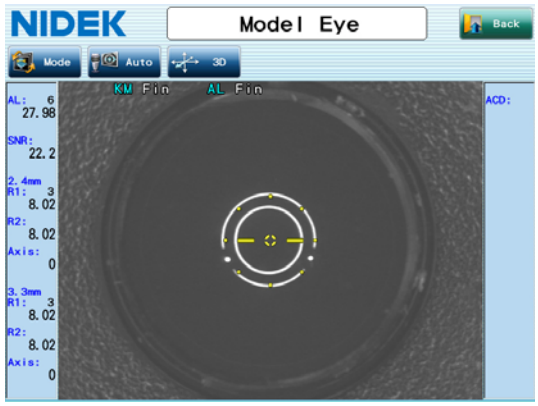


Pressing the Model Eye button on the Maintenance screen also displays the Model Eye screen.

The window to the right is that of the AL-Scan equipped with the optional ultrasonic measurement function. If the AL-Scan is not equipped with the optional ultrasonic measurement function, the measurement dates of BIO and Pachy mode measurements are not displayed.

7 Perform measurement using the model eye in the same manner as the optical measurement.

8 Confirm that the measured values are within the range indicated on the model eye.



Note

- If the AL and KM measurement values are not within the range indicated on the model eye, contact Nidek or your authorized distributor.
- Always store the model eye with the cap on.

  If the lens surface is soiled or flawed, measurement accuracy cannot be properly checked.

9 Remove the AL model eye from the chinrest, then put the cap on the model eye.

10 Proceed to ACD model eye measurement.

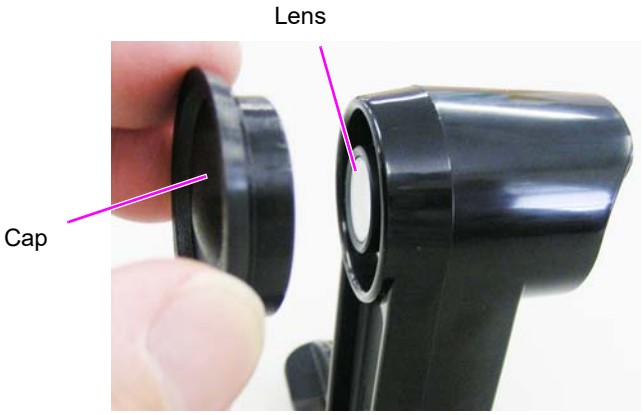
Go to “4.2.2 ACD model eye use” (page 191).

4.2.2 ACD model eye use

After checking the accuracy of AL and KM measured data (see page 189), check the accuracy of ACD measured data. To check the accuracy of ACD measured data, use the provided ACD model eye.

1 Remove the cap from the ACD model eye.

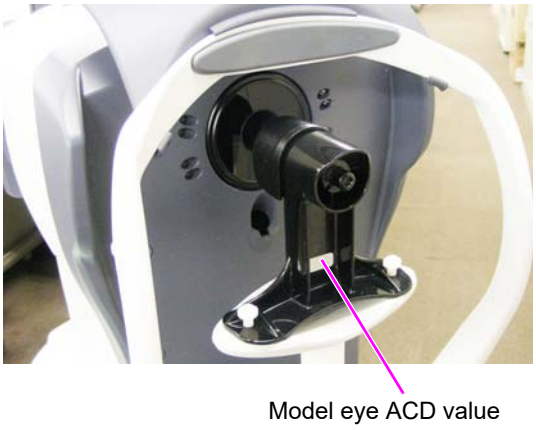
Confirm that the lens surface of the model eye is clean.



2 Attach the shield to the ACD model eye.

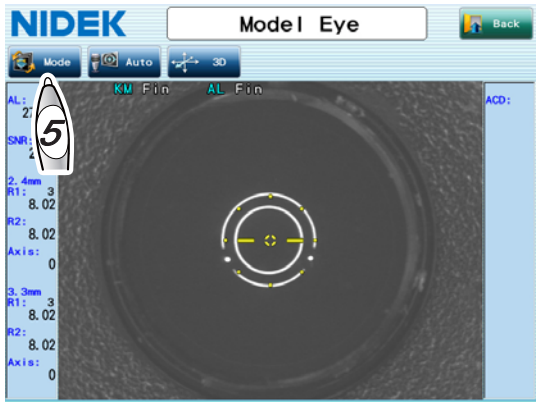
3 Place the model eye on the chinrest with its lens toward the measuring window, then insert the fixing pins.

4 Adjust the height of the chinrest with the chinrest up/down button (▲ , ▼) until the lens of the model eye aligns with the eye level marker.

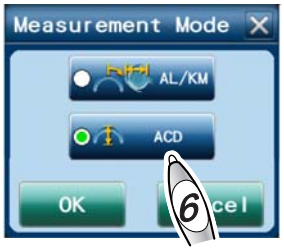


5 Following Step 9 of “4.2.1 AL model eye use” (Page 190), press the Mode button in the Model Eye screen.

The Measurement Mode window appears.



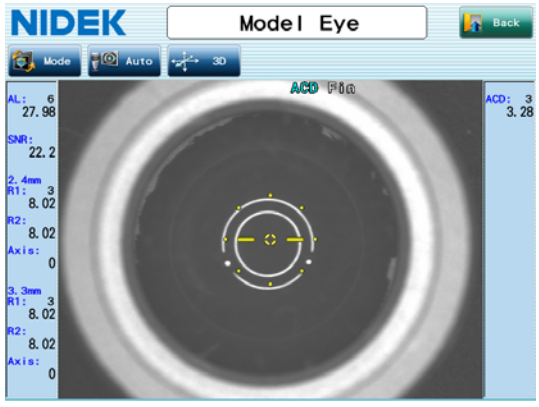
6 Select the ACD button in the Measurement Mode window, then press the OK button.



Standard window

Window for the AL-Scan equipped with the optional ultrasonic measurement function

7 Perform measurement using the model eye in the same manner as the optical measurement.



8 Confirm that the measured values are within the range indicated on the model eye.

Note

- If the ACD measurement value is not within the range indicated on the model eye, contact Nidek or your authorized distributor.
- Always store the model eye with the cap on.

  If the lens surface is soiled or flawed, measurement accuracy cannot be properly checked.

9 Remove the ACD model eye from the chinrest, remove the shield, then put the cap on the model eye.

10 Press the Back button to move to the patient information screen. When using the optional A-scan probe or pachymetry probe, follow the procedure below.

To use the optional A-scan probe

Do not press the Back button, then go to “4.3.1 Use of test piece for BIO mode measurement” (page 195).

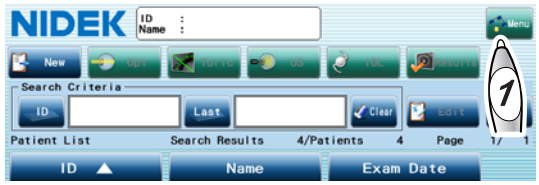
To use the optional pachymetry probe

Do not press the Back button, then go to “4.3.2 Use of test piece for Pachy mode measurement” (page 197).

4.2.3 Model eye measurement during device operation

Model eye measurement can be performed from the Maintenance screen during device operation as well as immediately after device start-up.

1 Press the Menu button in the Patient List screen.

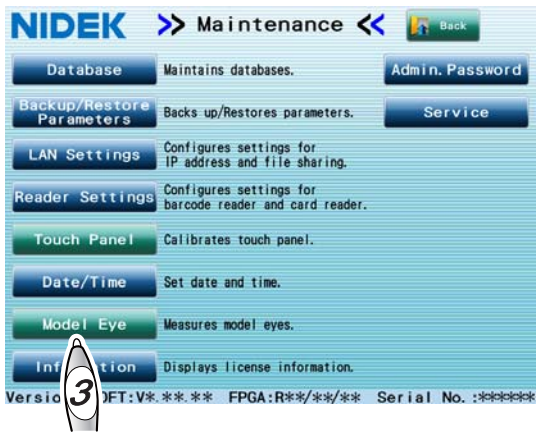


2 The Menu window appears. Press the Maintenance button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.

3 The Maintenance screen appears. Press the Model Eye button.

The Model Eye screen appears.



4 Perform measurement using the model eye in the same manner as the procedures in “4.2.1 AL model eye use” (page 189) or “4.2.2 ACD model eye use” (page 191).

4.3 Use of Test Piece for Ultrasonic Measurement

* For the AL-Scan equipped with the optional ultrasonic measurement function only
Before using the device be sure to check the operation using the test piece, and record the results on the check list.

4.3.1 Use of test piece for BIO mode measurement

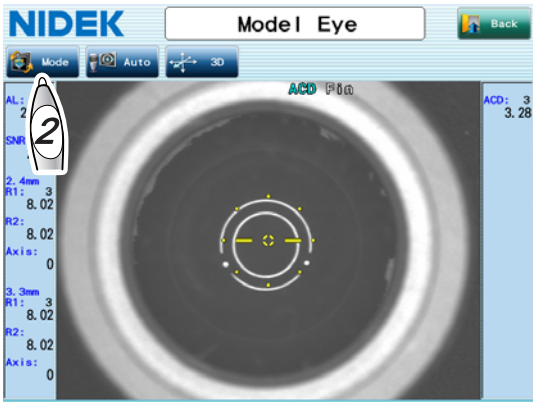
⚠ CAUTION • **Never connect or disconnect the cable connector of the A-scan probe during measurement.**
The probes may become damaged.

Note

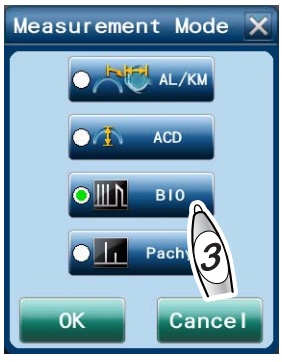
- The measurement value for when the temperature of the test piece for BIO mode measurement is at 20ºC (68ºF) is indicated on the test piece. The sonic velocity of the test piece changes depending on the test piece temperature.
  When the test piece is at a high temperature, the sonic velocity is increased, and when it is at a low temperature, the sonic velocity is decreased.
- The test piece comes with the optional A-scan probe.

1 Confirm that the A-scan probe is connected.
See “2.2 Preparation” (page 45).

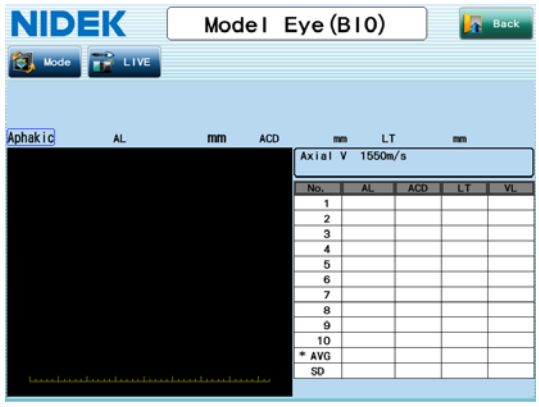
2 Following Step 10 of “4.2.2 ACD model eye use” (Page 193), press the Mode button in the Model Eye screen.
The Measurement Mode window appears.



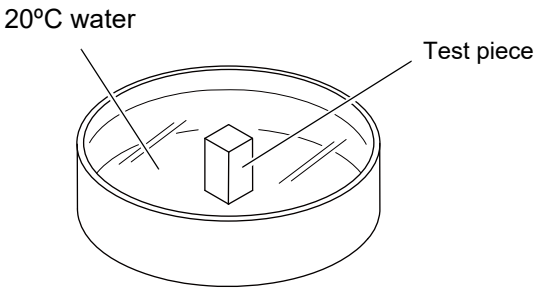
3 Select the BIO button in the Measurement Mode window, then press the OK button.



The Model Eye (BIO) screen appears.



4 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.



5 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.

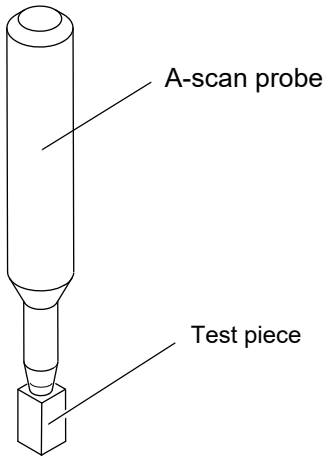
6 Remove the test piece from the water and wipe it dry.

After that, place the test piece on the table.

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

8 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.



9 Press the LIVE button on the screen or the MEASURE switch of the foot switch to start the measurement.

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

11 Press the Back button to move to the patient information screen.

4.3.2 Use of test piece for Pachy mode measurement

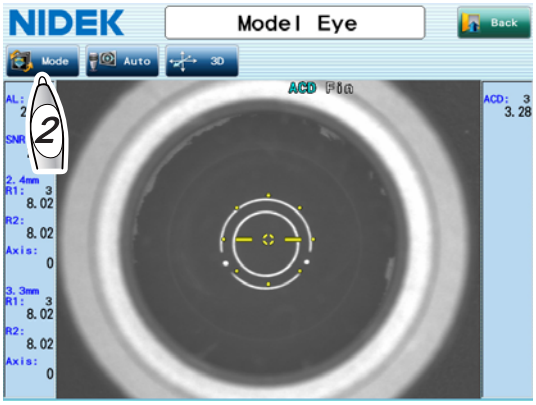
⚠ CAUTION • **Never connect or disconnect the cable connector of the pachymetry probe during measurement.**
The probes may become damaged.

Note

- The measurement value for when the temperature of the test piece for Pachy mode measurement 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.
- The test piece comes with the optional pachymetry probe.

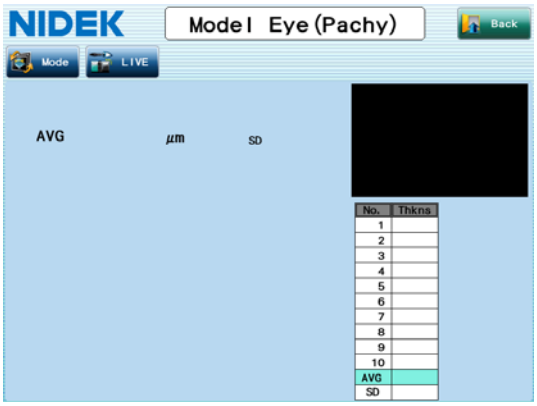
1 Confirm that the pachymetry probe is connected.
See “2.2 Preparation” (page 45).

2 Following Step 10 of “4.2.2 ACD model eye use” (Page 193), press the Mode button in the Model Eye screen.
The Measurement Mode window appears.



3 Select the Pachy button in the Measurement Mode window, then press the OK button.

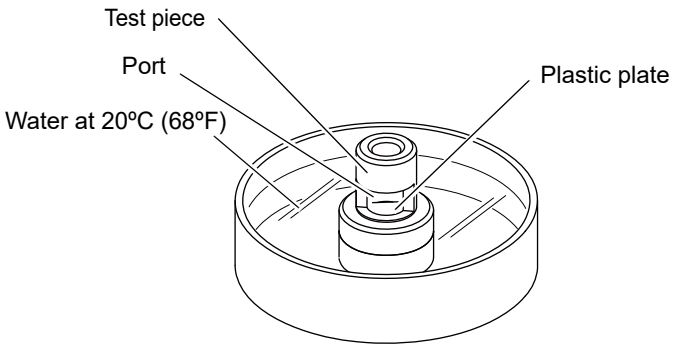
The Model Eye (Pachy) screen appears.



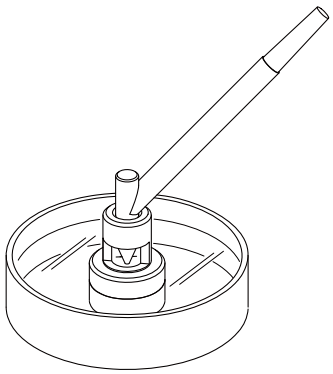
4 Prepare the test piece.

1) Place the test piece on a dish (such as petri dish) and fill the dish with water at 20ºC (68ºF) 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 space of the lower part of the test piece is filled with water.

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



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



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

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

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

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

8 Press the Back button to move to the patient information screen.

4.3.3 Test piece measurement during device operation

Test piece measurement can be performed from the Maintenance screen during device operation as well as immediately after device start-up.

1 Display the Model Eye screen in the same manner as the procedures in Steps 1 to 3 of “4.2.3 Model eye measurement during device operation” (page 194).

2 Perform measurement using the test piece in the same manner as the procedures in “4.3.1 Use of test piece for BIO mode measurement” (page 195) or “4.3.2 Use of test piece for Pachy mode measurement” (page 197).

4.4 Check List

Record the results of items in “4.1 Checks Before Use” (page 187) on the list below.

Date	Check items								
	Appearance	Power cord	start-up	AL model eye measurement	ACD model eye measurement	Probe appearance	BIO mode measurement using test piece	Pachy mode measurement using test piece	Printer
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5. MAINTENANCE

5.1 Troubleshooting

If the device does not function properly, troubleshoot with the table below before contacting Nidek or your authorized distributor for repairs.

Symptom	Remedy
The pilot lamp does not illuminate.	• The power cord may not be plugged. Securely plug the power cord again. • The power switch may not be turned on. Check that the power switch is turned on.
The pilot lamp blinks, and the LCD screen does not display anything.	• The device may be in sleep mode. Press the screen or the start button.
The main unit cannot be moved horizontally.	• The main unit may be locked with the locking lever. Raise the locking lever.
Printing cannot be executed.	• Check the printer paper. If the printer paper runs out, install a new roll. See “5.3 Replacing Printer Paper” (page 210). • In the Print tab screen, check the mode setting.
Printer paper is fed, but nothing is printed.	• The printer paper orientation may not be correct. Set the printer paper correctly. See “5.3 Replacing Printer Paper” (page 210).
Printer paper is stuck and cannot be fed through.	• The printer paper roll may be installed at an angle, or shifted sideways. Open the printer cover and check that the printer paper roll is properly installed.
Neither auto tracking nor auto shot can be executed.	• Auto tracking and auto shot may not be enabled. Check the setting of the auto shot and auto tracking buttons. • Extraneous light may be exposed to the cornea. In such a case, change the installation position, then perform measurement again. • Auto tracking and auto shot may not function for eyes with keratoconus or immediately after surgery. In such a case, disable auto tracking, then perform the measurement. • Auto tracking and auto shot may not function when movement of the eye or face cannot be stopped. In such a case, disable auto tracking, then perform measurement. • If the device is installed near a sunny window or directly below a lamp, effect of interference light is suspected. Change the installation position then perform measurement again.

Symptom	Remedy
Measurement error occurs.	• The patient may have blinked during measurement. Instruct the patient to refrain from blinking, then perform measurement again. • Eyelid or eyelashes of the patient may be interfering with measurement. Instruct the patient to open their eyes wider. If the patient is unable to open their eye wide enough, hold up the patient's eyelid paying attention not to press against the eye. • The patient may not be looking at the fixation lamp. Instruct the patient to keep looking at the fixation lamp. The intended part may be outside the range of measurement. • Interference light may disrupt optical measurement of anterior chamber depth and central corneal thickness. Attach the provided shading plate to the forehead rest.
In the Pachy mode measurement, measured values are displayed even though the probe tip is not in contact with cornea or test piece.	• There may be water drops on the probe tip used for Pachy mode measurement. Wipe the probe tip with sterilized cotton.

If the symptom cannot be remedied by the above actions, contact Nidek or your authorized distributor.

5.2 Error Messages and Remedies

If any message shown in the list below appears in the screen, remedy the problem following the instruction in “Cause and remedy”.
When contacting Nidek or your authorized distributor, inform of the serial number of the device, message number, and symptom for proper service.

Message	Cause and remedy
No.001 EEPROM error	• Data error of backup memory (EEPROM) Data loss due to exogenous noise such as static electricity or malfunction of the 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 off and on again, shut off the device and contact Nidek or your authorized distributor.
No.002 Clock error	• Date and time setting error The built-in battery is empty after about one month or longer of nonuse, and the date and time settings went wrong, or malfunction of the electric circuit board or timer IC on the electric circuit board is probable. • If the same error code is displayed even after the date and time are reset, shut off the device and contact Nidek or your authorized distributor.
No.006 BA01 FPGA error **No.007 BA02 FPGA error** **No.008 BA03 FPGA error**	• Shut off the device and contact Nidek or your authorized distributor.
No.009 SPI network error	• Shut off the device and contact Nidek or your authorized distributor.
No.031 Up/Down motor error	• Up/Down tracking error Malfunction of the up/down motor, up/down sensor, or the electric circuit board, or a broken cable is probable. • Shut off the device and contact Nidek or your authorized distributor.
No.032 Right/Left motor error	• Right/Left tracking error Malfunction of the right/left motor, right/left sensor, or the electric circuit board, or a broken cable is probable. • Shut off the device and contact Nidek or your authorized distributor.
No.033 Back/Forth motor error	• Forward/Backward tracking error Malfunction of the forward/backward motor, forward/backward sensor, or the electric circuit board, or a broken cable is probable. • Shut off the device and contact Nidek or your authorized distributor.
No.043 Printer Error	• The built-in printer failed. • If the same error code is displayed again even after the device is turned off and on again, shut off the device and contact Nidek or your authorized distributor.
No.046 Printer head temperature is too high.	• The head temperature increased due to continuous printing. Wait for a while before performing printing again.

Message	Cause and remedy
No.150 Axial length scanning error	• Shut off the device and contact Nidek or your authorized distributor.
No.151 Anterior filter switching error	• Shut off the device and contact Nidek or your authorized distributor.
No.160 SLD light error	• Shut off the device and contact Nidek or your authorized distributor.
No.161 SLD light level is low.	• Shut off the device and contact Nidek or your authorized distributor.
No.170 No A-scan probe signal detected	• Check the connection of the A-scan probe. • If the same error code is displayed even after the device is turned off and on again, shut off the device and contact Nidek or your authorized distributor.
No.180 No pachymetry probe signal detected	• If the same error code is displayed even after the device is turned off and on again, shut off the device and contact Nidek or your authorized distributor.
No.181 Pachymetry probe is not connected.	• Check the connection of the pachymetry probe. • If the same error code is displayed even after the device is turned off and on again, shut off the device and contact Nidek or your authorized distributor.
No.400 CF error	• Shut off the device and contact Nidek or your authorized distributor.
No.410 Unable to access the CF	
No.411 Unable to write files to the CF	
No.414 Unable to delete files on the CF	
No.415 Unable to read files on the CF	
No.416 No files found on the CF	
No.417 Unable to rename files on the CF	
No.418 The entered file name already exists. Unable to write the file to the CF	
No.601 USB device error	• The USB device is not recognized. • If the same error code is displayed even after connecting the USB device again, shut off the device and contact Nidek or your authorized distributor.
No.602 USB flash drive error	• USB flash drive error (Such as a file deletion error that occurs when the USB flash drive is removed while a file is being deleted) • If the same error code is displayed even after replacing the USB flash drive, shut off the device and contact Nidek or your authorized distributor.
No.610 Unable to access the USB flash drive	• No USB flash drive is connected. Connect a USB flash drive. • The USB flash drive may not be supported. Replace the USB flash drive.
No.611 Unable to write files to the USB flash drive	• USB flash drive writing error The USB flash drive is write-protected or full. Remove write-protection of the USB flash drive or check the free space of the USB flash drive.

Message	Cause and remedy
No.614 Unable to delete files on the USB flash drive	• The USB flash drive is write-protected. Remove write-protection of the USB flash drive.
No.615 Unable to read files on the USB flash drive	• Files on the USB flash drive cannot be read. Failure of the USB flash drive or corruption of data is possible. Replace the USB flash drive with a new one.
No.616 No files found on the USB flash drive	• The desired data cannot be found when it is searched. Failure of the USB flash drive or corruption of data is possible. Replace the USB flash drive with a new one.
No.617 Unable to rename files on the USB flash drive	• The USB flash drive is write-protected. Remove write-protection of the USB flash drive.
No.618 The entered file name already exists. Unable to write the file to the USB flash drive	• Try writing again. • Output the data from the result screen.
No.700 CIFS error	• Windows file sharing error Set the network properly. See “3.9.1 LAN connection settings” (page 180).
No.703 Hardware error	• If the same error code is displayed again even after the device is turned off and on again, shut off the device and contact Nidek or your authorized distributor.
No.704 DHCP error	• IP address cannot be obtained from the DHCP server.
No.750 Unable to access the network	• Check the connection of the LAN cable. Check also that the IP address and subnet mask in the LAN Settings window are correct.
No.751 Unable to write files to the PC	• Network writing error (write-protected or full) Check the authority to write data to the destination folder in the specified computer, and that there is enough free space.
No.754 No PC under the computer name found in the network	• The PC under the specific computer name is not found. • The computer name specified in the LAN Settings window is not correct, or the LAN connection is not established. • In case the name problem is not solved normally, enter the IP address of the output destination in the PC Name box of the LAN Settings window.
No.756 Unable to log on to the PC	• Unable to log on to the PC (due to wrong Domain/Workgroup, user name, or password) • The Domain/Workgroup, user name, or password input in the LAN Settings window is not correct.
No.757 No shared folders found	• The folder specified in the LAN Settings window does not exist. Create a shared folder. • The specified folder is not shared. Set the folder to share.
No.758 Network timeout	• Time out (The PC does not finish its processing in time) Perform the desired operation again after a while. • In case the name problem is not solved normally, enter the IP address of the output destination in the PC Name box of the LAN Settings window.
No.759 Unable to delete files on the PC	• Data cannot be deleted. (Deletion of a read only file was attempted.) • The destination folder in the specific PC is write-protected. Remove write-protection of the destination folder.

Message	Cause and remedy
No.760 Initializing the network. Wait and try again later.	• Network is initialized (for a while after the device startup) Perform the desired operation again after a while.
No.761 Access denied	• Access was denied. (File sharing is not set correctly.) Check the user name and password setting in the LAN Settings window. Set the access authority for file sharing and security of the output destination PC to full access.
No.762 This account is invalid.	
No.763 Unable to read files on the PC	• The file is corrupted. Check the PC condition.
No.764 No files found on the PC	• The desired data cannot be found when it is searched.
No.765 Unable to rename files on the PC	• The shared folder is write-protected. Remove write-protection of the shared folder.
No.766 The entered file name already exists. Unable to write the file to the PC.	• Try writing again.
No.771 Network cable is not connected.	• The LAN cable is not connected or not properly connected. Check the connection of the LAN cable.
No.772 There is no response.	• Acknowledgment error The data acquisition software on the computer (electronic medical record software or filing software) could not delete data within the specific period of time (about in 5 seconds after receiving command). Check the setting of the data acquisition software on the computer.
No.773 Response is invalid.	• If the language setting of the parameter is neither Japanese nor English, patient information including Japanese cannot be received from NAVIS-EX.
No.800 Database version is incompatible.	• Reading of new database was attempted with old software. To install new software, contact Nidek or your authorized distributor.
No.802 Patient database is corrupted. New patient database will be created.	• Shut off the device and contact Nidek or your authorized distributor.
No.803 Optical database index is corrupted. New optical database will be created.	
No.804 Ultrasound database index is corrupted. New ultrasound database will be created.	
No.805 IOL calculation database index is corrupted. New IOL calculation database will be created.	
No.806 Optimized database index is corrupted. New optimized database will be created.	
No.807 Toric measurement database index is corrupted. New toric measurement database will be created.	
No.810 Optical measurement database is corrupted.	
No.811 Ultrasound database is corrupted.	
No.812 IOL calculation database is corrupted.	
No.813 Optimized database is corrupted.	
No.814 Toric measurement database is corrupted.	
No.820 Image file is corrupted.	

Message	Cause and remedy
Backup data is invalid.	• Backup data of the database, setting information, and adjustment data is corrupted.
Out of paper	• The printer is out of paper. Set a new roll of printer paper. See “5.3 Replacing Printer Paper” (page 210).

5.3 Replacing Printer Paper

When a red line appears on the side of the printer paper, it means that paper is running short. In such a case, stop using the printer and replace the roll with a new one.

Note

- Do not run the printer when printer paper is not loaded.
  It may ruin the printer head.
- Do not pull the paper in the printer forcefully.
  Printer malfunction may result.

1 Press the cover open button until a click is heard to open the printer cover.

2 Remove the used printer paper roll.

⚠ **CAUTION**

- **When replacing printer paper, be sure not to touch the printer head on the upper part inside printer cover.**
  The printer head is extremely hot immediately after printing. Injury may occur.

3 Set a new roll of printer paper.

Set paper so that the end of the printer paper sticks a little out of the cover.

Note

- If the roll is set upside down, data cannot be printed on the printer paper.
- Make sure that the printer paper roll is not tilted or the shaft misaligned.

  The paper will not be properly fed.

4 Close the printer cover.

Press the right and left sides of the printer cover to close the printer.

Note

- Make sure that the cover is securely closed.

  The auto cutter may not operate normally. In addition, when the error message is displayed, printing may not be performed.

5.4 Attaching a Stack of Chinrest Paper

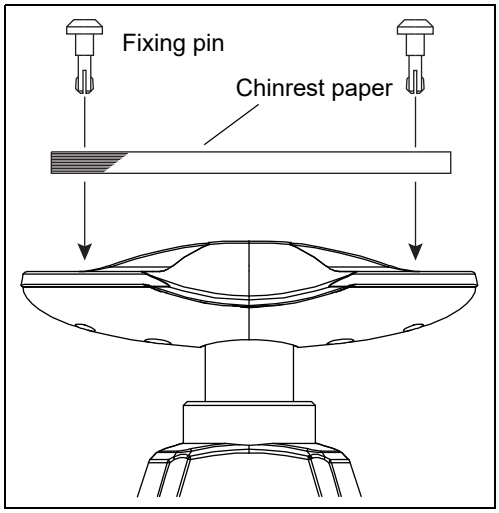
1 Pull out the two fixing pins from the chinrest.

2 Take out a proper amount of chinrest paper from a whole stack.

It is not possible to fix a whole stack of chinrest paper at a time. Be sure to fix the stack with a thickness of 6 mm or less. Pay attention not to scatter the sheets of chinrest paper.

3 Insert the fixing pins into the holes in the paper.

Insert the removed pins into both holes of the stack.



4 Fix the stack of chinrest paper onto the chinrest.

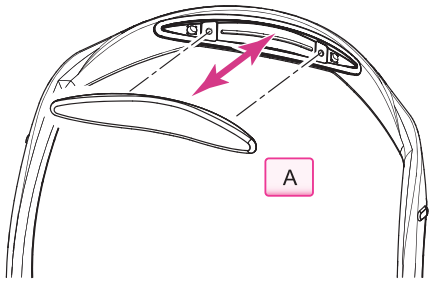
1) Insert a pin into a hole in the chinrest while holding both fixing pins and stack of paper.
2) Push the remaining pin into the other hole of the chinrest with the other hand.

5.5 Replacing Forehead Rest Pad

When the forehead rest pad is deteriorated over time or soiled, replace the magnetic forehead rest pad.

○ Magnetic forehead rest pad (part number: 30611-1520)

The forehead rest pad (made of ABS resin) (A) included in the standard configuration is magnetically attachable. Attach or remove it in the orientation as shown to the right.

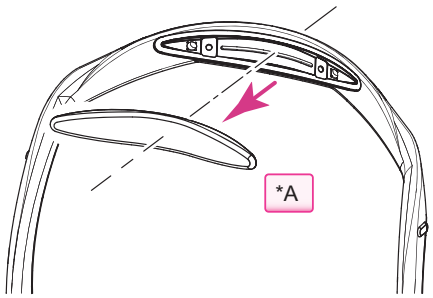


○ Forehead rest pad (part number: 15411-M752)

To replace with the softer, designated replacement, polyester elastomer forehead rest pad, use the procedure below.

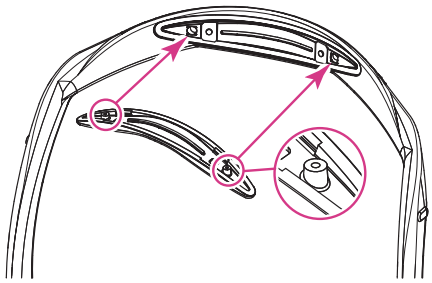
1 Remove the forehead rest pad or magnetic forehead rest pad (*A) from the frame.

Hold the edge of the forehead rest pad or magnetic forehead rest pad with two fingers and pull it out.



2 Attach a new forehead rest pad.

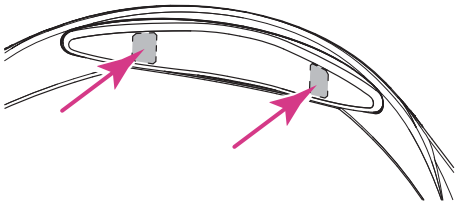
1) Align the clasps of the forehead rest pad to the holes in the frame.



2) Attach the forehead rest pad by pressing over the fastener positions on both sides.

   The forehead rest pad is locked by the fasteners.

3) Confirm that the forehead rest pad is securely attached.



5.6 Cleaning

5.6.1 Cleaning the cover

When the cover of the device becomes dirty, clean it with a soft cloth. For persistent stains, soak the cloth in a neutral detergent, wring well, and wipe. Finally dry with a soft, dry cloth.

⚠ **CAUTION**

- **Never use an organic solvent such as paint thinner.**
  The surface of the device may be damaged.
- **Never use a sponge or cloth soaked in water.**
  The water may leak into the inside of the device and cause device failure.

5.6.2 Cleaning the printer

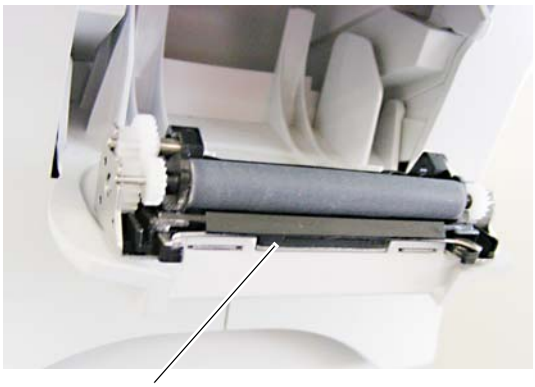
After repeated use, paper residue accumulates in the paper slot of the printer auto cutter and may cause malfunction of the auto cutter. Periodically clean the cutter.

1 Open the printer cover and remove the printer paper roll.

See “5.3 Replacing Printer Paper” (page 210).

2 Apply the nozzle of a vacuum cleaner to the auto cutter to remove paper residue.

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



3 Supply the printer paper as it was.

5.6.3 Cleaning the LCD touch screen

If the LCD touch screen is soiled, wipe it with a soft, dry cloth or a cloth dampened with a small amount of rubbing alcohol. If rubbing alcohol is used, dry the LCD touch screen with a soft, dry cloth so that streaks or specks do not remain.

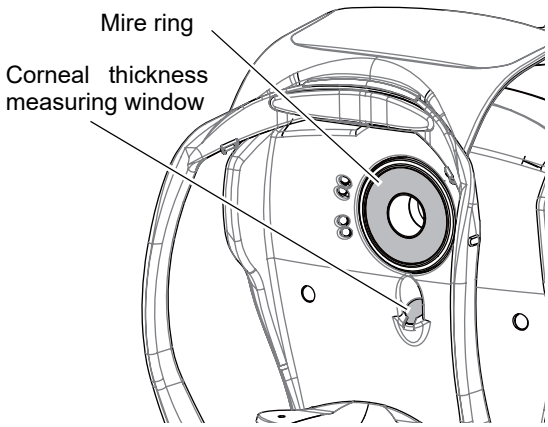
⚠ **CAUTION**

- **Never wipe the LCD touch screen using a cloth dampened with a lot of rubbing alcohol.**
  Rubbing alcohol may enter between the body and the screen, or into the screen and cause the LCD touch screen to fail.
- **Never use liquid other than rubbing alcohol to wipe the LCD touch screen.**

5.6.4 Cleaning the mire ring and corneal thickness measuring window

If the mire ring and corneal thickness measuring window are smeared with fingerprints and dust, reliability of the measurement is substantially reduced. Before using the device, check the mire ring and corneal thickness measuring window. If they are dirty, clean them.

1 Look at the mire ring and corneal thickness measuring window (glass part) at an angle to check whether they are dirty.



2 Blow off dust and extraneous matter with a blower.

3 Gently wipe the glass part of the mire ring with a gauze dampened with a small amount of alcohol.

⚠ **CAUTION** • **Be sure to wipe gently. Never rub the mire ring forcefully or wipe with dust or extraneous matter on it.**
The glass part may be scratched.

4 Gently wipe the corneal thickness measuring window with a cotton swab dampened with a small amount of alcohol.

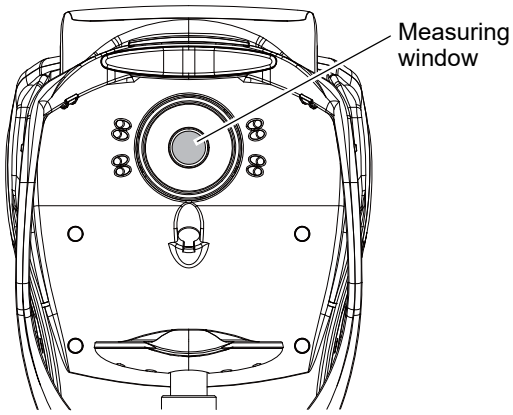
⚠ **CAUTION** • **Be sure to wipe gently. Never rub the corneal thickness measuring window forcefully or wipe with dust or extraneous matter on it.**
The glass part may be scratched.

5 Check the mire ring and corneal thickness measuring window again to check whether they are dirty.

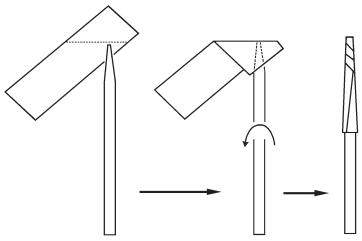
5.6.5 Cleaning the measuring window

When the measuring window gets fingerprints or dust on it, the reliability of the measurement is substantially reduced. Before using the device, check the measuring window. If it is soiled, clean it.
The measuring window lens does not usually get soiled through normal use because it is recessed.

1 Blow off dust on the measuring window with a blower.



2 Wrap lens cleaning paper around a thin stick such as a chopstick (or cotton swab) and wipe the lens of the measuring window with a material moistened with alcohol.



Wrap cleaning paper around the tip.

Note

- Use a thin stick which does not damage glass lenses.
- Wipe lightly from the center of the measuring window to the outside in a circular motion.

3 Check if the window is cleaned using a penlight. If not, clean it again with new cleaning paper.

Apply light with a penlight and change the view angle to check the clearness.

5.7 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 has 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 items enter normally sterile parts of the human body.	Sterilization
Semi-critical (Medium risk level)	Semi-critical items come into contact with mucous membranes or non-intact skin.	High level disinfection Intermediate level disinfection
Non-critical (Low risk level)	Non-critical items come into contact with intact skin only or are devices not intended for direct patient contact.	Low level disinfection Only device wiping and cleaning

Note

- The ultrasound probe is classified as “Semi-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 ultrasound probe is classified as Semi-critical according to its infection risk. Perform the high or intermediate level disinfection on it.
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 187).

Target part for cleaning and disinfection
A-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	“5.7.1 Disconnecting ultrasound probe (cleaning preparation)” (page 219)
2	Cleaning	“5.7.2 Cleaning ultrasound probe” (page 219)
3	Disinfection	“5.7.3 Disinfecting ultrasound probe (by immersion)” (page 220) “5.7.4 Disinfecting ultrasound probe (by wiping)” (page 222)
4	Storage for next use	“5.7.5 Storing ultrasound probe” (page 223)

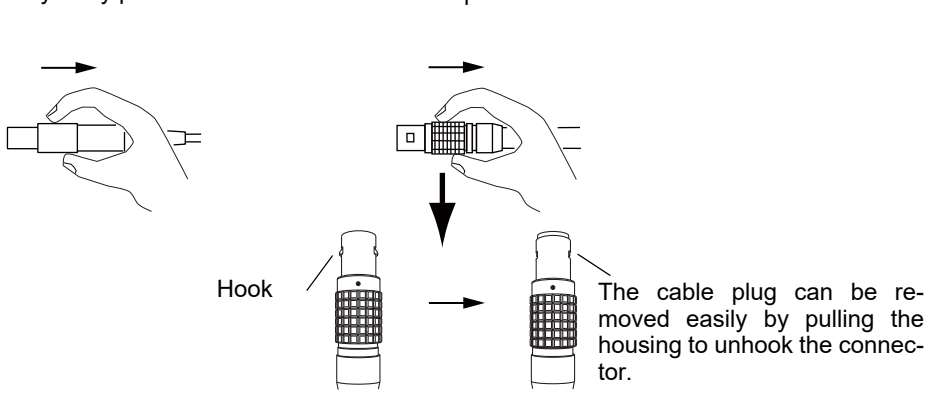
5.7.1 Disconnecting ultrasound probe (cleaning preparation)

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.



5.7.2 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.

5.7.3 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)	Sodium hypochlorite
Optimal concentration	0.1%
Immersion time	10 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.)

⚠ **CAUTION**

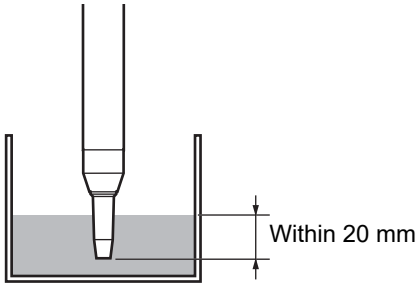
- **Be careful that the immersed ultrasound probes are not scratched by bumping against each other.**
- **After the disinfection, rinse the probe tip sufficiently.**
- **For the use of the disinfectant, refer to each manufacturer's manual.**

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.

5.7.4 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.)

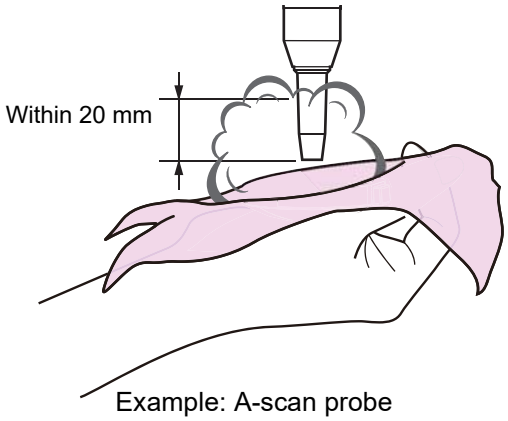
⚠ CAUTION

- **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.

5.7.5 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.

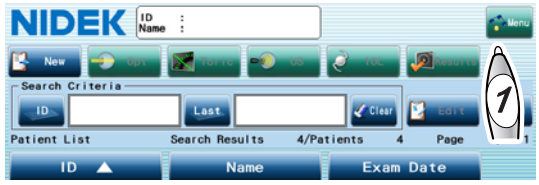
2 Clearly describe on the case or bag that the contents have been disinfected properly.

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.

5.8 LCD Touch Screen Calibration

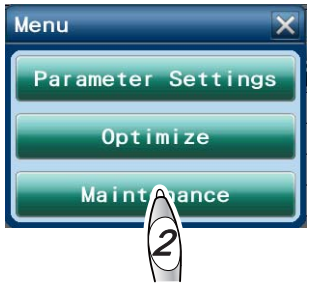
If the LCD touch screen is out of alignment and its reactions do not correspond with the operation on the screen, perform calibration of the LCD touch screen.

1 Press the Menu button in the Patient List screen.



2 When the Menu window appears, press the Maintenance button.

If the administrator password is set, the keyboard window appears, and password entry is required. Enter the password.

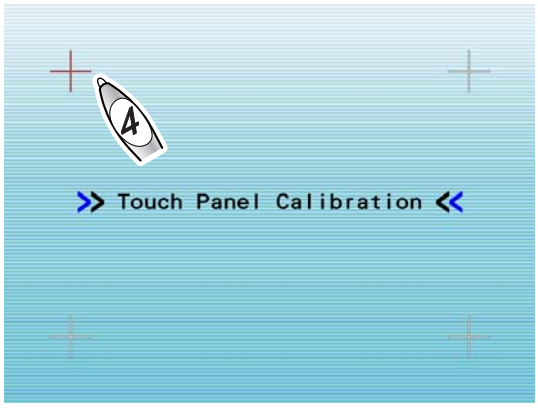


3 When the Maintenance screen is displayed, press the Touch Panel button.

The Touch Panel Calibration screen is displayed.

4 Press the center of each red cross (four crosses in total) beginning with the one at the top left of the screen.

When the center of the red cross at the top left of the screen, the crosses become red in the order of the one at the top right, at the bottom left, and at the bottom right of the screen. When the center of the cross at the bottom right of the screen is pressed, the calibration is complete, and the Maintenance screen is displayed again.



Note

- If the LCD touch screen has been misaligned so considerably that the screen does not react at all, turn on power to the device while pressing the LCD touch screen.

  Alignment of the LCD touch screen is enabled again.

5.9 List of Replacement Parts

Part name	Part number	Note
Chinrest paper	32903-M047	
Printer paper	80620-00001	Width 58 mm, Length 25 m
Magnetic forehead rest pad	30611-1520	Forehead rest pad: Made of ABS resin
Forehead rest pad	15411-M752	Forehead rest pad: Made of polyester elastomer

* After replacing the parts above, restock them.

6. SPECIFICATIONS AND ACCESSORIES

6.1 Classifications

[Protection against electric shock]

Class I ME equipment
Type B applied part

[Protection against harmful ingress of water or particulate matter]

Main body: IPX0
Foot switch: IPX1
Probe: IPX7

[Method(s) of sterilization]

ME equipment that does not contain any part that needs 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 operation

6.2 Specifications

6.2.1 Optical measurement

- Optical interference measurement
  - Axial length (AL)
    - Measurement range: 14 to 40 mm
    - Display increments: 0.01 mm
    - Measurement accuracy: ±0.05 mm (with the Nidek model eye)
  - Measuring light source: 830 nm SLD (460 μW or less)
- Double mire ring keratometry
  - Corneal curvature radius (R1, R2, average)
    - Measurement range: 5.00 to 13.00 mm
    - Display increments: 0.01 mm
    - Measurement accuracy: ±0.05 mm (with the Nidek model eye)
    - The measuring accuracy is in accordance with Type B, ISO 10343:2014.
  - Corneal refractive power (K1, K2, average)
    - Measurement range: 25.96 to 67.50 D (n = 1.3375)
    - Display increments: 0.01 D
    - Corneal refractive index: n = 1.3380/1.3375/1.3360/1.3320/1.3315
  - Corneal cylindrical power (CYL)
    - Measurement range: 0 to ±12.00 D
    - Display increments: 0.01 D
  - Corneal cylinder axis (AXIS)
    - Measurement range: 0 to 180°
    - Display increments: 1°
    - Measurement accuracy: ±2° (with the Nidek model eye)
  - Measurement area: ø2.4 mm (for mire ring / corneal curvature radius of 7.8 mm); ø3.3 mm (for mire ring / corneal curvature radius of 7.7 mm)
  - Light source: 970 nm LED
- Scheimpflug measurement
  - Anterior chamber depth (ACD)
    - Measurement range: 1.5 to 6.5 mm
    - Display increments: 0.01 mm
    - Measurement accuracy: ±0.1 mm (with the Nidek model eye)
  - Central corneal thickness (CCT)
    - Measurement range: 250 to 1,300 μm
    - Display increments: 1 μm
    - Measurement accuracy: ±10 μm (with the Nidek model eye)
  - Measuring light source: 470 nm LED
- White-to-white (WTW) measurement
  - Measurement range: 7 to 14 mm
  - Display increments: 0.1 mm
  - Measurement accuracy: ±0.2 mm (with the Nidek model eye)
  - Measuring light source: 525 nm LED
- Pupil size (PS) measurement
  - Measurement range: 1 to 10 mm
  - Display increments: 0.1 mm
  - Measurement accuracy: ±0.2 mm (with the Nidek model eye)
  - Measuring light source: 970 nm LED
  - Miotic light source: 470 nm LED

- Working distance

Working distance	45 mm

- Fixation

Fixation target	Fixation lamp
Light source	700 nm LED

6.2.2 Ultrasonic measurement (optional)

- BIO mode

Probe type	10 MHz solid probe Internal fixation lamp: LED (Red)
Measurement item	Axial length, anterior chamber depth, lens thickness, and vitreous body thickness
Axial length (AL)	Measurement range: 12 to 40 mm (average sonic velocity: 1,550 m/s) Display increments: 0.01 mm Measurement accuracy: ±0.1 mm (with the Nidek model eye)

- Pachy mode

Probe type	10 MHz solid probe
Corneal thickness (CT)	Measurement range: 200 to 1,300 μm A maximum of 25 points of corneal thickness values can be saved. Display increments: 1 μm Measurement accuracy: ±10 μm (with the Nidek test piece)

6.2.3 Other functions

- IOL power calculation

IOL formula	SRK, SRK II, SRK/T, Binkhorst, Hoffer Q, Holladay 1, Formula/H Camellin-Calossi, Shammas-PL * The AL-Scan in EX mode does not provide the IOL power calculation function.

- Auto tracking

Working range	Up and down: 32 mm Side to side / Forward and backward: 10 mm

- Movable range

Measurement unit	Forward and backward: 36 mm Side to side: 85 mm
Motorized chinrest	Up and down: 62 mm

- Recording method

Easy-loading thermal line printer with automatic paper cutter

- Observation/Display type

Display	8.4 inch (SVGA: 800 x 600 pixel) Color LCD with a touch screen Equipped with 5-step tilting mechanism
Displayed item	Measurement values, settings, button icons, alignment mark, anterior eye segment image, measurement ring image

- Interface function

USB
LAN

6.2.4 Dimensions and mass

- Dimensions 283 (W) x 504 (D) x 457 mm (H)
- Mass 21 kg

6.2.5 Power supply

- Power supply AC 100 to 240 V ±10% 50/60 Hz
- Power consumption 100 VA

6.2.6 Environmental conditions (during use)

- Temperature 10 to 35°C (50 to 95°F)
- Humidity 30 to 90%
- Atmospheric pressure 800 to 1,060 hPa
- Installation location Indoor enclosed air-conditioned spaces in the medical facility
- Others Dust-free, smoke-free, and non-condensing

6.2.7 Environmental conditions (during transport and storage: packed)

- Temperature -10 to 55°C (14 to 131°F)
- Humidity 10 to 95% (Non-condensing)
- Atmospheric pressure 700 to 1,060 hPa (during storage) / 500 to 1,060 hPa (during transport)

6.2.8 Composition of parts that come into contact with human body

Main body

- Start button ABS resin
- Joystick ABS resin, synthetic rubber
- Chinrest up/down button ABS resin
- Locking lever Aluminum
- Forehead rest Polyester elastomer or ABS resin
- Chinrest ABS resin
- Power switch General electrical component
- Touch pen ABS resin, polyester elastomer

Optional ultrasound probes

- A-scan probe Tip - Polystyrene resin
  Handle - Polyacetal resin
- Pachymetry probe (45° fixed type) Tip - Polystyrene resin
  Handle - Polyacetal resin

6.2.9 Others

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

6.3 Accessories

6.3.1 Standard accessories

• Printer paper	3 rolls
• Power cord	1 unit
• Dust cover	1 unit
• Pack of chinrest paper	1 unit
• Fixing pins for chinrest paper	2 units
• Shading plate	1 unit
• Touch pen	1 unit
• Pen stand	1 unit
• Model eye	1 set
• Operator's Manual	1 volume

6.3.2 Optional accessories

• Ultrasonic measurement function	(Requires installation of a special board by service personnel.)
• A-scan probe	(Including the test piece)
• Pachymetry probe (45° fixed type)	(Including the test piece)
• Foot switch	
• Barcode reader	
• Probe holder	(For the device equipped with the ultrasonic measurement function only)
• USB flash drive	
• IOL-ST Print Manager (CD-R)	
• Myopia Viewer MV-1	

7. EX MODE

- Operations of EX mode (supporting NAVIS-EX) different from those of standard mode are explained.

7.1 Main Operation Flow

In EX mode, the AL-Scan is used for the measurement, and the measured data is stored and managed with NAVIS-EX.

Inputting patient information

Information of new patients is input with NAVIS-EX.

Loading patient information from NAVIS-EX.

See “7.4 Inputting Patient Information” (Page 236).
1) Input the patient ID in the patient information screen.
2) Patient information is loaded from NAVIS-EX.
3) Select the eye type.
4) Press the OK button in the patient information screen.

Measurement

2.4 Optical Measurement (see page 54)
2.7 Toric Lens Assist Mode (see page 87)

With ultrasonic measurement (optional)
2.5 BIO Mode Measurement (Optional) (see page 71)
2.6 Pachy Mode Measurement (Optional) (see page 81)

Checking the measurement data

Press the Verify button to display the measured result confirmation screens, and check the measurement result.

Outputting the measurement result

Press the Save Output button to output the measurement result to NAVIS-EX.
After the output, display the patient information screen.

7.2 Functions Not Available in EX Mode

EX mode differs from the standard mode as shown below.

(1) The IOL power calculation function is not available.
Perform IOL power calculation using AL-Scan Viewer, which is optional software that operates on NAVIS-EX.

(2) Postoperative data entry is not available.

(3) IOL information registration and IOL constant optimization are not available.

(4) Backup and rebuilding of the internal database are not available.
To distinguish from the NAVIS-EX database, the database in the AL-Scan is called the internal database here.

(5) Only up to 100 datasets can be saved in the internal database for each of the optical measurement data, ultrasonic measurement data, and toric measurement data.
When the number of data sets is over 100, the oldest output data is deleted.

(6) The auto ID function that sequentially assigns patient IDs is not available.

7.3 Japanese Characters in Patient Information

Although Japanese characters cannot be input with the AL-Scan. Those input in the patient information with NAVIS-EX can be displayed. However, the internal printer of the AL-Scan cannot print Japanese characters.
Any items containing even a single Japanese character cannot be printed. It becomes blank.

7.4 Inputting Patient Information

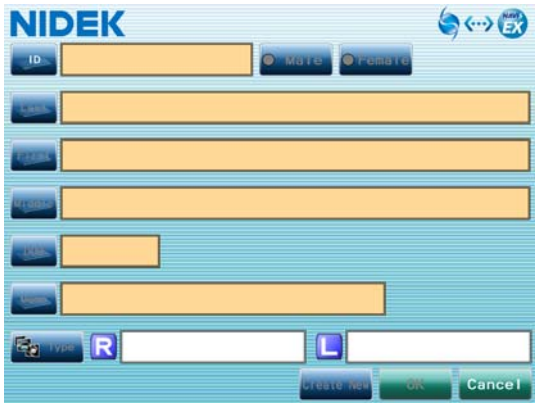
Input patient information with NAVIS-EX.
If an ID is input in the patient information screen of the AL-Scan, information of that patient is loaded from NAVIS-EX. The only patient information that can be changed with the AL-Scan is the eye type.

1 Display the patient information screen.

After device start-up, closing the Model Eye screen displays the patient information screen.

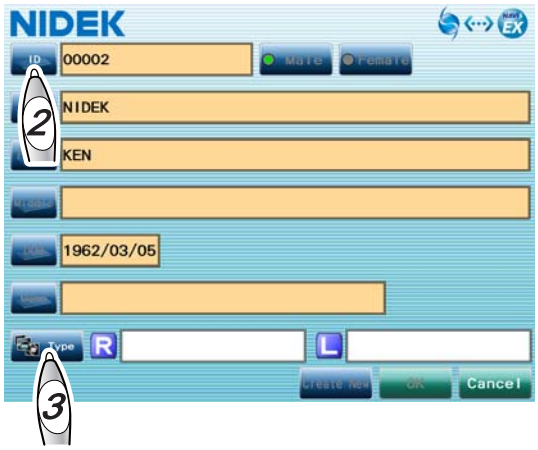
Pressing the New button in the Patient List screen also displays the patient information screen.

Fields other than “Type” is displayed in orange.



2 Input the ID. Patient information is loaded from NAVIS-EX.

Pressing the ID button displays the key-board window. Input the patient’s ID using the keyboard window, then press the OK button.



3 Select the eye type for both the right and left eyes.

1) Press the Type button to display the Eye Type window.
2) Select the condition of the right eye.
3) Select the condition of the left eye.
4) Press the OK button.

The Eye Type window is closed, and the patient information screen appears.

4 Confirm that the items input in the patient information screen are correct, then press the OK button.

The input patient information is registered on the Patient List, then the optical measurement screen appears.

If the eye type has not been set, the OK button cannot be pressed.

Note

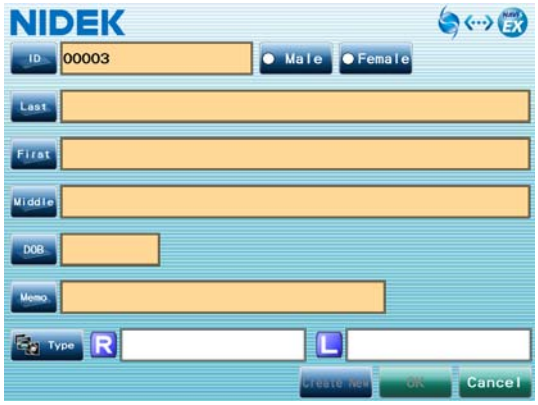
- Patient information is managed with NAVIS-EX. If patient information is moved to the dust bin on NAVIS-EX, the patient data cannot be viewed and measurement for the patient cannot be performed with the AL-Scan.

○ For patients who have not been registered to NAVIS-EX

If the patient with the specified ID cannot be loaded from NAVIS-EX, the message “Patient ID is not registered to NAVIS-EX” appears.

If this message appears after inputting the ID on the patient information screen, pressing the OK button allows the patient information to be input on the patient information screen.

The input patient information is output to NAVIS-EX together with the measurement result, and registered.

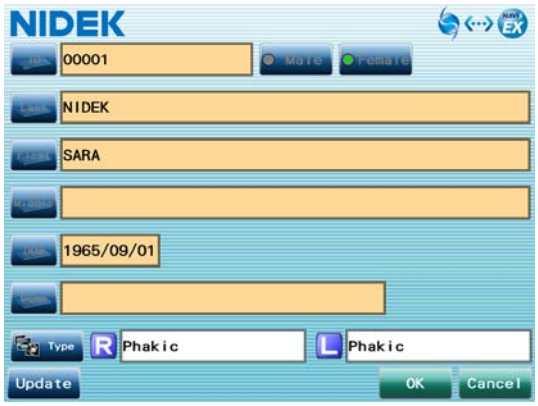


7

○ Editing patient information

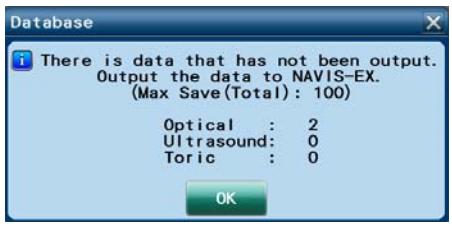
Patient information is edited with NAVIS-EX.
Pressing the Update button loads the patient data of the displayed ID from NAVIS-EX to the AL-Scan, then updates the data.

The only patient information that can be edited with the AL-Scan is the eye type.



7.5 Data That Has Not Been Output to NAVIS-EX

If the message “There is data that has not been output.” appears at the device start-up, data that has not been output to NAVIS-EX exists in the internal database. Output the data manually. (When the parameter “Notice” is not checked, the message does not appear.)



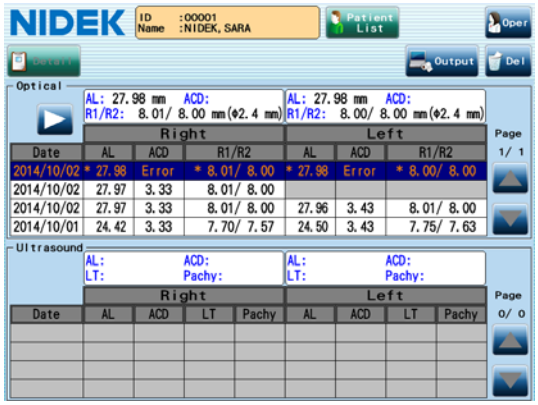
1 Select the patient displayed in orange characters from the Patient List screen.

There is data that has not been output for the patients displayed in orange characters.

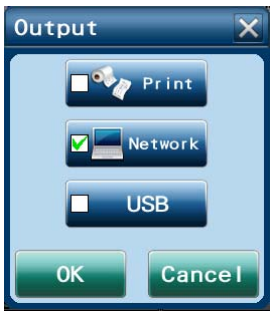
2 Display the measurement result screen to identify the data that has not been output.

The data displayed in orange characters has not been output.

3 Select the data that has not been output, then press the Output button.



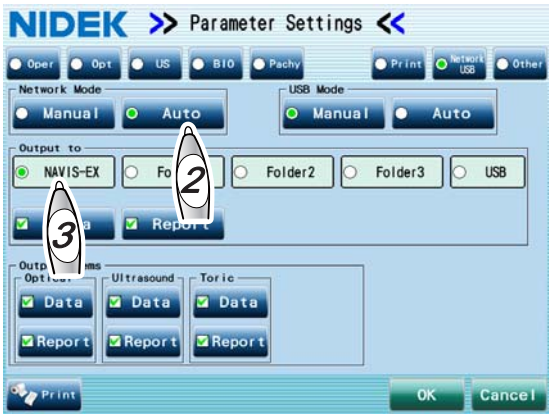
4 Check “Network” in the Output window, then press the OK button.



7

7.6 Using Communication Function of NAVIS-EX

To output data to NAVIS-CL/NAVIS-HP via NAVIS-EX using the communication function, set the items to be output.



1 Display the Parameter Settings screen for the Network USB tab.

2 Press the Auto button in “Network Mode”.

3 Press the NAVIS-EX button.

4 Check the items to be output in the “Output to” and “Output Items” fields.

5 Press the OK button.

8. IOL FORMULA

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

8.1 SRK Formula

(1) IOL 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: Power of the IOL to be implanted [D]

***1. "n_k" is the corneal refractive index specified in the Opt tab of the Parameter Settings screen.**

8.2 SRK II Formula

(1) IOL 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: Power of the IOL 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

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

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

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

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

8.3 SRK/T Formula

(1) IOL power for ametropia (IOL)

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

(2) Postoperative refractive error (ERROR)

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

R : Corneal radius [mm] $R = (n_k - 1.000) \times 1000/K$[*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 : Predicted 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 : 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 specified in the Opt tab of the Parameter Settings screen.**

8.4 Camellin-Calossi Formula

This formula can also be used for implantation of an IOL to the eye that has undergone refractive surgery.
The values necessary for the calculation vary depending on the refractive surgical history of the eye.

Eye for IOL implantation	AL measured value	KM measured value	ACD value	LT value	Refractive correction amount	Pachy measured value (center and eight points around the center)	Pachy peripheral measurement point diameter
1. No surgical history	O	O	O	O	X	X	X
2. Underwent refractive surgery with incision	O	O	O	O	O	X	X
3. Underwent refractive surgery using laser emission	O	O	O	O	O	X	X
4. Surgical history is not clear.	O	O	O	O	X	O	O

O: Necessary X: Not necessary

If the refractive surgical history is not clear, measure the corneal thickness of the corneal center and at eight points around the corneal center using the optional Pachy mode measurement function.

(1)IOL power for ametropia (IOL)

$$IOL = \frac{1336 \times (4 \times RC - AL - 0.2)}{(AL + 0.2 - CA) \times (4 \times RC - CA)}$$

(2)Postoperative refractive error (ERROR)

$$ERROR = \frac{((25 \times CA^2 - (25 \times AL + 5) \times CA) \times LP + 33400 \times AL + 6680) \times KC}{(25 \times CA^2 - (25 \times AL + 5) \times CA) \times LP}$$

$$\frac{+ (33190 \times AL - 33190 \times CA + 6638) \times LP - 44341840}{+ 33400 \times AL + 6680}$$

AL: Axial Length [mm]

RC: Corrected corneal curvature radius [mm] $RC = \frac{331.9}{KC + DR}$

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

CA: Predicted postoperative anterior chamber depth

When AL >25.8 mm $CA = \frac{C \times 26}{23.45}$

When AL ≤ 25.8 mm $CA = \frac{C \times (AL + 0.2)}{23.45}$

C: Predicted postoperative anterior chamber depth (median value)

For the first IOL transplant surgery

When ACD < 3 [mm] and LT < 5 [mm]: C = Atemp – 0.3

When ACD < 3 [mm] and LT ≥ 5 [mm] C = Atemp

When 3 [mm] ≤ ACD< 3.5 [mm] and LT < 5 [mm] C = Atemp

When 3 [mm] ≤ ACD < 3.5 [mm] and LT ≥ 5 [mm] C = Atemp + 0.2

When ACD ≥ 3.5 [mm] and LT < 5 [mm] C = Atemp + 0.3

When ACD ≥ 3.5[mm] and LT ≥ 5 [mm] C = Atemp + 0.4

For the second or subsequent IOL transplant surgery

C = Atemp

Atemp: Anterior chamber constant $Atemp = \frac{0.5663x(A - 65.6 + 3.595)}{0.9704}$

A: A constant

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

KC: Corrected corneal refractive power [D] $KC = \frac{1000x(n_{post} - 1)}{337.5}xK$

K: Average corneal refractive power [D] $K = \frac{K1 + K2}{2}$

n_{post}: Corrected corneal refractive index

No history of refractive surgery $n_{post} = n_{pre}$

History of refractive surgery with incision $n_{post} = n_{pre} - \frac{SIRC \times (1.3223 - n_{pre})}{10}$

History of refractive surgery with laser $n_{post} = n_{pre} - \frac{SIRC \times (1.3206 - n_{pre})}{10}$

Transplant, PTK or corrective power unknown $n_{post} = \frac{Ptot \times Rcon}{1000} + 1$

n_{pre}: Preoperative corneal refractive index 1.3319

SIRC: Refractive correction amount [D]

Rcon: Corneal curvature radius [mm]

Ptot: Corneal refractive power including anterior and posterior refractive power of the cornea [D]

$$Ptot = Pant + Ppost - \left(\frac{CCT}{1000 \times 1.376}\right) \times Pant \times Ppost$$

Pant: Refractive power of anterior surface of cornea [D] $Pant = \frac{0.376 \times 1000}{Rcon}$

Ppost: Refractive power of posterior surface of cornea [D] $Ppost = \frac{(1.336 - 1.376) \times 1000}{Rkpost}$

Rkpost：Posterior corneal surface curvature radius [mm]

CCT：Central corneal thickness [mm]

8.5 Shammas-PL Formula

This formula is can be used to implant an IOL to the eye that has undergone LASIK surgery or PRK surgery for myopia.

IOL power for ametropia (IOL)

$$IOL = \frac{1336}{L - 0.1\,(L - 23) - (C + 0.05)} - \frac{1}{\frac{1.0125}{K_C + R} - \frac{C - 0.05}{1336}}$$

L : Axial Length [mm]

C : Predicted postoperative anterior chamber depth [mm] C = (0.5835 x A) - 64.40

Kc : Corrected mean corneal power [D] Kc = 1.14Kpost - 6.8

Kpost : Post-LASIK corneal refractive power [D] (The corneal refractive power used for calculation is 1.3375)

R : Desired refraction at the corneal plane [D]

8.6 Binkhorst Formula

(1) IOL power for ametropia (IOL)

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

$$\frac{\times (VD \times (N2 \times R - (N1 - 1) \times AL') + AL' \times R))}{\times (VD \times (N2 \times R - (N1 - 1) \times AD) + AD \times R))}$$

(2) Postoperative refractive error (ERROR)

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

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

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

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 (= 0.25 mm)

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

RD : Refractive distance (= 6 m)

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

AD : Predicted postoperative anterior chamber depth [mm]

AL : Axial length [mm]

LP : 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 specified in the Opt tab of the Parameter Settings screen.**

8.7 Hoffer Q Formula

(1) IOL power for ametropia (IOL)

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

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

(2) Postoperative refractive error (ERROR)

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

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

However,
$C = AD + 0.3 \bullet (L - 23.5) + (\tan K)^2 + 0.1M \bullet (23.5 - L)^2 \bullet \tan\{0.1 \bullet (G - L)^2\} - 0.99166$
When the $L \leq 23$, M = +1, G = 28
When the L > 23, M = -1, G = 23.5
When the 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 power [D]
L : Axial length [mm]
C : Predicted anterior chamber depth [mm]
K : Average corneal refractive power ((K1 + K2)/2 [D])
Rx : Desired postoperative refractive power [D] (VD = 12 mm)
P : Power of the IOL 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]

8.8 Holladay 1 Formula

(1) IOL power for ametropia (IOL)

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

(2) Postoperative refractive error (ERROR)

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

(3) Surgeon factor (SF)

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

$Alm = AL + RT$

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

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

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

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

$AG = 12.5 \times AL/23.45$ 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 : Predicted postoperative anterior chamber depth [mm]

AL : Axial length [mm]

LP : Power of the IOL to be implanted [D]

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

VD : Vertex distance

SF : Surgeon factor

***1. "n_k" is the corneal refractive index specified in the Opt tab of the Parameter Settings screen.**

ER : Actual postoperative refractive power [D]

Rag : R ≥ 7 mm, Rag = R

R < 7 mm, Rag = 7 mm

<Feature of Holladay 1 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 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 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.

8.9 Formula/H Formula

(1) IOL power for ametropia (IOL)

$$IOL = \frac{n_a}{AL - d} - \frac{n_a}{n_a/z - d}$$

$$z = D_c + \frac{R_x}{1 - R_x \times VD}$$

(2) Postoperative refractive error (ERROR)

$$ERROR = \frac{q - D_c}{1 + VD \times (q - D_c)}$$

$$q = \frac{n_a \times [n_a - IOL \times (AL - d)]}{n_a(AL - d) + d \times [n_a - IOL \times (AL - d)]}$$

When AC ≠ 0

$d = a0 + a1 \times AC + a2 \times AL$

When AC = 0 (AC data is not input)

$d = (a0 - 0.241 \times a1) + (a2 + 0.139 \times a1) \times AL$

D_c : Corneal refractive power [D] $D_c = (n_c - 1)/R$

R_x : Desired postoperative refractive power of the corrective lens [D]

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

n_c : Imaginary corneal refractive index (= 1.3315)

VD : Vertex distance (= 12 mm)

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

AL : Axial length [mm]

d : Predicted postoperative anterior chamber depth [mm]

AC : Anterior chamber depth [mm]

a0, a1, a2 : IOL constant

Default value: a0 = 0.62467 × A - 72.434

a1 = 0.4

a2 = 0.1

A: A-constant

***1. "n_k" is the corneal refractive index specified in the Opt tab of the Parameter Settings screen.**

9. EMC & ACOUSTIC OUTPUT

9.1 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

- Axial length measurement function (optical measurement)
- Corneal curvature radius measurement function (optical measurement)
- Axial length measurement function (ultrasonic measurement)
- Pachymetry function (ultrasonic measurement)

◆ 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

9.2 Acoustic Output Reporting Table (IEC 60601-2-37:2015)

9.2.1 A-scan probe

MODE: A

Index Label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.09	5.42E-3		(b)		(a)
Index component value			(c)	(c)	(c)	(c)	
Acoustic parameters	$p_{r,a}$ at z_{MI} (MPa)	(c)					
	P (mW)		(c)		(c)		(c)
	$P_{1\times1}$ (mW)		(c)		(c)		
	z_s (cm)			(c)			
	z_b (cm)					(c)	
	z_{MI} (cm)	(c)					
	$z_{pii,\alpha}$ (cm)	(c)					
	f_{awf} (MHz)	(c)	(c)		(c)		(c)
Other information	prr (Hz)	(c)					
	srr (Hz)	(c)					
	n_{pps}	(c)					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	(c)					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	(c)					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	(c)					
	p_r at z_{pii} (MPa)	(c)					
Operating control conditions							

(a): The intended use does not include cephalic applications. Therefore, data concerning TIC is not listed.

(b): The intended use is for ophthalmic applications and does not include bone applications. Therefore, data concerning TIB is not listed.

(c): All the exemption conditions cited in 201.12.4.2 a) and b) are satisfied. Therefore, no data is listed in columns concerning TIS, TIB, TIC, and MI.

* The thermal indexes and mechanical indexes are 1.0 or less with all device settings.

9.2.2 Pachymetry probe (45° fixed type)

MODE: A

Index Label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.15	5.60E-4		(b)		(a)
Index component value			(c)	(c)	(c)	(c)	
Acoustic parameters	$p_{r,a}$ at z_{MI} (MPa)	(c)					
	P (mW)		(c)		(c)		(c)
	$P_{1\times1}$ (mW)		(c)		(c)		
	z_s (cm)			(c)			
	z_b (cm)					(c)	
	z_{MI} (cm)	(c)					
	$z_{pii,\alpha}$ (cm)	(c)					
	f_{awf} (MHz)	(c)	(c)		(c)		(c)
Other information	*prr* (Hz)	(c)					
	srr (Hz)	(c)					
	n_{pps}	(c)					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	(c)					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	(c)					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	(c)					
	p_r at z_{pii} (MPa)	(c)					
Operating control conditions							

(a): The intended use does not include cephalic applications. Therefore, data concerning TIC is not listed.

(b): The intended use is for ophthalmic applications and does not include bone applications. Therefore, data concerning TIB is not listed.

(c): All the exemption conditions cited in 201.12.4.2 a) and b) are satisfied. Therefore, no data is listed in columns concerning TIS, TIB, TIC, and MI.

* The thermal indexes and mechanical indexes are 1.0 or less with all device settings.

9.2.3 Global acoustic output limits

Probe	MI [Unitless]	$I_{SPTA.3}$ [mW/cm^2]	$I_{SPPA.3}$ [W/cm^2]
A-Scan probe	**0.14**	**0.72**	**8.5**
Pachymetry probe	**0.18**	**1.45**	**8.8**

9.2.4 Low output summary table

Transducer Model	$I_{SPTA.3}$ [mW/cm^2]	TI Type	TI Value [Unitless]	MI [Unitless]	$I_{PA.3}$@MI max [W/cm^2]
A-Scan probe	**0.72**	**TIS**	**5.42E-3**	**0.14**	**8.5**
Pachymetry probe	**1.45**	**TIS**	**5.60E-4**	**0.18**	**8.8**

10. GLOSSARY

- ACD

  Anterior chamber depth

- Administrator password

  A password can be set to prevent change of various settings or deletion of data from the database by unauthorized personnel.

- AL

  Axial length

- BCVA

  Best corrected visual acuity

- CCT

  Central corneal thickness

- Desired postoperative refraction

  Targeted refraction after IOL implantation

- Drag

  Moving an object with a finger or touch pen while the object is pressed on the screen.

- 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.

- LT

  Lens thickness

- Optical measurement

  Non-contact measurement using light

  Axial length (AL) measurement using the optical interference principle
  Anterior chamber depth (ACD) measurement and central corneal thickness (CCT) measurement using the Scheimpflug principle
  White-to-white (WTW) measurement and pupil size (PS) measurement

- **Optimization**

  The constant such as A-constant to be used for IOL power calculation is optimized using postoperative measured results so that the constant can be used when the axial length value is optically measured.

- **Optical offset**

  The offset to convert the BIO measured (contact) axial length into the one equivalent to optically measured axial length. This offset is used when the A-constant to be used for IOL power calculation is for optical measurement.

- **PS**

  Pupil size (diameter)

  Pupil size can be measured while the anterior eye segment is illuminated.

- **SLD**

  Superluminescent diode

- **SNR**

  Signal-to-noise ratio. The greater this value is, the higher the reliability of the measured value becomes.

- **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.

- **Toric lens assist mode**

  The steepest/flattest meridian and angle reference line are displayed on an anterior eye segment image.

- **Ultrasonic measurement**

  Measurement using ultrasound (The ultrasonic measurement function is optional.)

  BIO mode: Axial length (AL) / anterior chamber depth (ACD) / lens thickness (LT) measurement
  Pachy mode: Corneal thickness measurement

- **US offset**

  The offset to convert the optically measured axial length into the one equivalent to BIO measured (contact) axial length. This offset is used when the A-constant to be used for IOL power calculation is for ultrasonic measurement.

- **VD**

  Vertex distance

- **VL**

  Vitreous body length

- WTW

  White-to-white

11. INDEX

T

U

V

W