

Original instructions

NIDEK CO., LTD.

NIDEK CO., LTD. (Manufacturer)

NIDEK INC. (United States Agent)

NIDEK S.A. (EU Authorized Representative) : 34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, JAPAN Telephone: +81-533-67-6611 URL: https://www.nidek.com/

- : 2040 Corporate Court, San Jose, CA 95131, U.S.A. Telephone: +1-800-223-9044 (USA Only) URL: https://usa.nidek.com/
- : Ecoparc, rue Benjamin Franklin, 94370 Sucy En Brie, FRANCE



2024-05-10 14102-P902-A4 Printed in Japan

© 2022 NIDEK CO., LTD.



Be sure to read the SOFTWARE LICENSE AGREEMENT (page 2) before using this product.

This operator's manual includes information such as the operating procedure, safety precautions, maintenance, and specifications. Be sure to read this operator's manual before using this product. Keep this manual handy for reference.

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

- The device complies with ISO 10343:2014 (Ophthalmic instruments Ophthalmometers).
- "OPTICAL BIOMETER AL-Scan" is the official name for this device. This model of AL-Scan is commonly referred to as "AL-Scan M".

IMPORTANT - READ CAREFULLY

THIS AGREEMENT APPLIES TO THE NIDEK SOFT-WARE AND ACCOMPANYING DOCUMENTS. PLEASE READ THIS AGREEMENT CAREFULLY AND THOR-OUGHLY 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 result-ing 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 WAR-RANTIES OF ANY KIND, EXPRESS OR IMPLIED, CONCERNING THE SOFTWARE AND THE THIRD- PARTY-SOFTWARE, INCLUDING, WITHOUT LIMITA-TION, WARRANTIES OF MERCHANTABILITY, FIT-NESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THIRD PARTY RIGHTS, INCLUD-ING, WITHOUT LIMITATION, THIRD PARTY INTEL-LECTUAL 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 MAIN-TENANCE OR REPAIR SERVICE OF THE SOFT-WARE IF ANY (collectively, the "DAMAGES"). THE ABOVE LIMITATIONS WILL APPLY REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, STRICT PRODUCT LIABILITY, OR OTHER-WISE, EVEN IF NIDEK IS NOTIFIED OF THE POSSI-BILITY 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 ACCOR-DANCE WITH THE LAWS. EVEN IN SUCH CASE, NIDEK SHALL NOT BE LIABLE FOR ANY CONSE-QUENTIAL, 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 LIMITA-TION 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 AGREE-MENT
- 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.

The following indications are used in this operator's manual.

• Repeatedly used descriptions are expressed with the following indications.

| Indication | Meaning | Example |
|----------------|--|---|
| [XXX] | A term enclosed in brackets indicates a button, setting, and such. | [OK], [Next] |
| \rightarrow | Moves to a different screen. | Patient information registration screen |
| ₹ } | For details, see the following page. | "Indications in This Manual" (page 5) |

• Information related to operations is indicated by the icon display.

| | Check Indicates items to be checked. |
|-----|---|
| ? | Help Indicates workarounds for when intended operation or intended results cannot be obtained. |
| ÷Ģ. | Tip Indicates tips useful for product operation. |
| | Setting Indicates information on settings. |
| Ø | Knowledge Indicates detailed information on the product. |

1 SAFETY PRECAUTIONS - - - 9

- 1.1 Usage Precautions - 9
- 1.2 Labels and Symbols - 15

2 INTRODUCTION - - - 17

- 2.1 Device Outline - 17
- 2.2 Device Configuration - 19
- 2.3 Screen Configuration - 22
- 2.4 Packed Contents - 39

3 OPERATING PROCEDURE - - - 41

- 3.1 Before Initial Use - 41
- 3.2 Turning on and off the Device - 42
 - 3.2.1 Turning on the device - 42
 - 3.2.2 Turning off the device - 42
- 3.3 Adjusting Touch Screen Angle - 43
- 3.4 Setting Printer Paper - 44
- 3.5 Setting Chinrest Paper - 46
- 3.6 Operating Chinrest - 47
- 3.7 Manipulating Joystick - 48
- 3.8 Auto Shot Setting and Tracking Operation - 49

4 MEASUREMENT - - - 53

- 4.1 Exam Mode and Measurement Flow - 53
 - 4.1.1 Exam Mode settings to suit operator's use - 53
 - 4.1.2 Measurement flow - 54
- 4.2 Inspection Before Measurement - 56
 - 4.2.1 Measuring model eye - 57
- 4.3 Patient Information Selection - 60
 - 4.3.1 Specifying patient from the patient list - 60
 - 4.3.2 Registering patient information - 62
 - 4.3.3 Selecting operator - 65
- 4.4 Measurement - 66
 - 4.4.1 Setting measurement conditions - 66
 - 4.4.2 Measuring patient's eye - 67
- 4.5 Measurement Result Check - 71
 - 4.5.1 Checking measurement result - 71
 - 4.5.2 Correcting retinal pigment epithelium detection position of AL measurement - 75
 - 4.5.3 Entering refractive error - 76
- 4.6 Printing and Exporting Measurement Results - 77
 - 4.6.1 Printing measurement results - 77
 - 4.6.2 Exporting measurement results - 80

- 4.7 Editing Patient Information - 82
 - 4.7.1 Deleting all the information and data of the patient - 82
 - 4.7.2 Editing patient list information - 82
- 4.8 Checking and Editing Follow-up - 84
 - 4.8.1 Checking Follow-up (Trend Graph) - 84
 - 4.8.2 Checking Follow-up (Progression Chart) - 86
 - 4.8.3 Checking Follow-up (Data) - 88
- 4.9 Exporting Follow-up Data - 91
 - 4.9.1 Exporting follow-up data - 91
 - 4.9.2 Printing the exported data using computer-connected printer - 93

5 DEVICE SETTINGS AND CONNECTION - - - 95

- 5.1 Parameter Settings - 95
- 5.2 Maintenance Operation - 104
 - 5.2.1 Backing up database - 104
 - 5.2.2 Restoring the database using backup - 107
 - 5.2.3 Deleting old data from database - 108
 - 5.2.4 Backing up parameter settings - 109
 - 5.2.5 Restoring parameter settings using backup - 110
 - 5.2.6 Touch screen calibration - 111
 - 5.2.7 Setting date and time - 112
 - 5.2.8 Setting administrator password - 113
- 5.3 Peripheral Device Connection - 114
 - 5.3.1 LAN connection and settings - 116
 - 5.3.2 Connecting and setting barcode scanner - 121

6 DEVICE MAINTENANCE - - - 123

- 6.1 Troubleshooting - 123
- 6.2 Error Messages and Remedies - 125
 - 6.2.1 Error during measurement - 125
 - 6.2.2 Messages related to measurement data - 126
 - 6.2.3 Error messages - 127
- 6.3 Completion of Operation Before Transporting Device - 131
- 6.4 Cleaning - 132
 - 6.4.1 Cleaning the cover - 132
 - 6.4.2 Cleaning the touch screen - 132
 - 6.4.3 Cleaning the chinrest and forehead rest - 133
 - 6.4.4 Cleaning the measuring unit - 133
 - 6.4.5 Cleaning the printer - 134
- 6.5 Replacement Parts - 135
- 6.6 Checklist - 136

7 SPECIFICATIONS AND TECHNICAL INFORMATION - - - 139

7.1 Specifications - - - 139

- 7.2 EMC (Electromagnetic Compatibility) - 142
- 7.3 Glossary - 145

8 INDEX - - - 147



SAFETY PRECAUTIONS

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

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

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

Even situations indicated by <u>A</u>CAUTION may result in serious injury under certain conditions. Safety precautions must be strictly followed at all times.

1.1 Usage 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 connect the power plug to a protective grounded power outlet. Device malfunction, electric leakage, electric shock, or fire may result.
- Do not disassemble or modify the device. Furthermore, do not touch the inside of the device.
- Use the device in hospitals or their equivalent places.

The device malfunction or abnormality in measurement values may occur.

• Do not use this device for any purposes other than those intended.

Nidek will assume no responsibility for accidents or malfunctions caused by improper use.



- " Environmental conditions" (page 140)
 - Non-condensing
- Do not subject the device to vibration or shock.
 Incorrect measurement or malfunction may result.
- Do not install the device in an unstable location.

The device may fall resulting in injury.

- Do not allow direct sunlight or other strong light to enter the measurement window. Strong light can cause incorrect measurement.
- Use a power outlet that meets the power supply specifications.

" Power supply" (page 140)

- Do not use multiple socket outlets or extension cables for the power supply. The noise immunity or electrical safety may be degraded.
- Do not use any power cord other than the one provided. Also do not use the provided power cord for any other equipment.

Device malfunction or fire may result.

- Be sure to connect cables to specific connectors (with their port shapes matching the plug shapes). Do
 not to apply excessive force on the connectors when connecting or disconnecting them.
 Device malfunction may result.
- Install the device in an area 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 any tool.
 Failure to do so may interfere with disconnecting the power from its power source in case of an abnormality.
- 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. For installation of the isolation transformer, consult Nidek or your authorized distributor.

 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. 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).



• Devices connected to the analog or digital interfaces must comply with relevant international standards concerning safety such as EN 60601-1, IEC 60601-1: Medical electrical equipment, etc. Furthermore, all configurations must comply with the system standard IEC 60601-1. When connecting a digital device to an input or output section on a medical system, the entire system, including the connected device, must conform to the IEC 60601-1 standard. If you have any questions, contact Nidek or your authorized distributor.

Light hazard

• 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, the greater the risk of ocular damage. Exposure to light from this device when operated at maximum output will exceed the safety guideline after 6,812,697 seconds.

· Spectrum output of all light source during optical measurement (maximum light intensity)



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

During use

- Do not connect or disconnect the power plug while the power switch is turned on. Device malfunction may result.
- Ensure that the device does not come in contact with the patient's face when switching the target between the right and left eyes for the alignment or measurement.
- Wipe the forehead rest and chinrest with clean absorbent cotton or gauze dampened with rubbing alcohol before and after using the device, and before examining next patient.

Remove 1 sheet of paper when using the chinrest paper.

- Do not place hands or fingers under the measurement unit, main unit, and chinrest. The measurement unit makes vertical and horizontal movement during auto alignment. Warn the patient as well. Hands or fingers may be caught and may result in injury.
- Be careful not to have hands or fingers caught when opening or closing the touch screen or printer cover.

Otherwise, injury may result.

· Keep the measuring window free from dust and dirt.

The measurement accuracy may decrease.

• Do not turn off the power switch while data communication or access to the USB flash drive is performed.

Device malfunction or patient data loss may result.

• This device uses 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 glue is applied to the heat-sensitive printer paper, the print may disappear.

- Properly manage devices and printed copies that contain patient information or exam data.
 If they are seen or passed on to other unauthorized third parties, personal information may be leaked.
- If the device fails, disconnect the power cord from the power outlet, and then contact Nidek or your authorized distributor. Do not touch the inside of the failed device.

After use

Store the device in an environment that meets the specifications during transport and storage.
 ** Environmental conditions" (page 140)*

Cover the device with the dust cover after use.
 This is to prevent the device malfunction caused by ingress of fluid or dust.

Maintenance

• Only personnel trained by Nidek are allowed to disassemble or repair the device.

Nidek assumes no responsibility for any adverse events resulting from improper servicing.

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

• 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.

- Clean the surfaces of the device (especially the areas that come into contact with the patient) with a clean cloth dampened with rubbing alcohol before maintaining or inspecting the device.
- It is recommended that the device be replaced before its service life expires.

Even with proper maintenance and check, after the expected service life expires, the device reliability or safety may not be maintained.

- 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 using the printer, use only the paper specified by Nidek.

Use of paper other than the specified one may cause printing defects or malfunctions.

Disposal

• 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 cannot be restored before disposing of the storage media (device, external equipment, computer, etc.) on which data was stored.

Take measures such as outsourcing to Nidek or a disposal contractor, or physically destroying the storage media to make them unreadable. Select the disposal method that suits the purpose.

 Follow the local ordinances and recycling plans regarding disposal of the device and its accessories. It is also recommended to entrust the disposal to a designated industrial waste disposal contractor. The following materials are included.

Lithium batteries used in internal circuit, printed-circuit boards, plastic parts containing brominated flame retardants, LCD, and power cord

Inappropriate disposal may contaminate the environment.

For details on local ordinances, contact your local governments.

• When disposing of packaging materials, sort them by material and dispose of them according to the local ordinances and recycling plans.

Inappropriate disposal may contaminate the environment.

Connection to network

• 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.

• Do not connect the network to a wide area network such as the internet if a medical system is configured with a network.

It is recommended to establish a local network that consists only of devices configuring the medical system. Nidek is not responsible for virus infection or adverse consequences of infection caused by connecting the device to the internet.

• It is recommended to install security software for the computer connected to the network.

The computer may become infected with virus resulting in data deletion or data alteration.

• When connecting the device to peripheral equipment such as a computer through a LAN port via a medical facility network, insert an isolation transformer between the medical electrical equipment and network devices such as a network switch, and between the network devices and other electrical equipment.

Electric shock or malfunction or failure of the electric instruments may occur depending on the type and number of the electric instruments connected to the network.

For installation of the network isolation transformer, contact Nidek or your authorized distributor.

• When connecting the network to devices other than this device, virus infection or data alteration may occur due to external factors. Confirm that the network is operated properly under the supervision of the network administrator.

1.2 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.

| Ĩ | Refer to the operator's manual. | Ŕ | Type B applied part The applied parts of the device are the chinrest and forehead rest (see page 20). |
|--------|---------------------------------|--------|--|
| 0 | Power off | I | Power on |
| \sim | Alternating current | | Manufacturer |
| | Date of manufacture | | Indicates that this product must be dis- posed of in a separate collection of elec- trical and electronic equipment in EU. |
| UDI | Unique device identifier | MD | Medical device |
| SN | Serial number | EC REP | EU authorized representative |
| REF | Catalogue number | CH REP | Swiss authorized representative |



2.1 Device Outline

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.

The corneal thickness, anterior chamber depth, and ultrasonic measurements cannot be performed with the AL-Scan M.

Intended patient population

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

Intended user profile

Ophthalmologists, eye specialists, optometrists, orthoptists, nurses and opticians. The instrument must be used by qualified persons.

Intended use environment

Medical facility or optical store

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

Principles

• Axial length measurement

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

Corneal curvature radius measurement

A ring image projected onto the patient's cornea is detected by a photo detector and calculated to measure the corneal curvature radius (refractive power) and direction of the principal meridian.

Pupil diameter measurement

The pupil diameter of the patient's eye is measured from the captured anterior segment image.

Axial length measured by optical measurement

The biometry with this device is a non-contact measurement based on the optical interference principle. The measurement has the following features:

- The measurement accuracy is higher than A-scan biometry because there is no corneal applanation by the probe.
- The measurements are generally slightly longer than those of A-scan biometry due to the lack of corneal applanation.
- The difference of measurement values among operators can be minimized because there is no difference in applanation caused by the way the probe is applied.
- In some eyes such as those with mature catarat, where reflected light from the fundus cannot be obtained, it may not be possible to measure the axial length.

Internal database

- A maximum of 10,000 patient data and measurement data can be saved, linked to the patient's ID.
- For the patients measured before, specify them on the patient list screen before measurement.
- The patient's measurement results can be graphed to see changes with age.

2.2 Device Configuration



1 Touch screen

Displays the screen. The tilt can be adjusted by hand to a comfortable viewing angle.

2 Power indicator

| Power indicator | Status |
|-----------------|----------------------|
| Off | Power switch is off. |
| Illuminating | Power switch is on. |
| Blinking | Sleep mode |

Knowledge

Sleep mode

- While the device is in sleep mode, the touch screen turns off and the power indicator blinks.
- To recover from sleep mode, press the touch screen or manipulate the joystick.

3 Printer cover open button

Opens the printer cover.

4 Joystick

Used for adjustment and focusing. Pressing the start button a starts the measurement.



2

5 Chinrest up/down button

Moves the chinrest up and down (Up (, Down ()).

6 Locking lever

Locks the main unit.

To lock the main unit, lower the locking lever. Raising the locking lever unlocks the main unit.

7 Power switch



8 Eye level marker

Used as a guide for adjusting the height of the patient's eyes.

9 Release tab

Pushing down the release tab opens the cover.

10 Forehead rest

Used to rest the patient's forehead to stabilize the head.

11 Measuring window

The part the patient looks into during measurement

12 Chinrest

Used to rest the patient's chin or attach the model eye.

Underside view

13 Power inlet

A power cord is connected here.



Side panel

14 USB port

Used to connect the USB flash drive or barcode scanner.

15 LAN port

Used to connect a LAN cable.

2.3 Screen Configuration

Patient list screen

When the device is started, this screen is initially displayed.



1 New button 🕒 New

Used to display the new patient information registration screen.

2 Measure button

Displays the measurement screen.

3 Patient ID field

Displays all the patients and their corresponding IDs being selected.

4 Follow-up button

Displays the Follow-up screen.

When a patient with measurement data in database is selected, the button becomes enabled.

5 Menu button

Used to display the menu.



6 Search Criteria field

Used to enter the search criteria such as IDs or names of patients. A patient list is displayed according to the criteria.

| Button | Function |
|--------|--|
| ID | Enters a patient ID or the first character of the ID. |
| Last | Enters a last name or the first letter of the last name. |
| First | Enters a first name or the first letter of the first name. |
| Clear | Clears the entered search criteria. |

7 Sort button

Used to sort and display the patient list. The button for the item being sorted displays \land (ascending order) or \checkmark (descending order).

| Button | Function |
|-----------|-------------------------------|
| ID | Sorts by ID. |
| Name | Sorts by name of the patient. |
| Exam Date | Sorts by exam date. |

8 Patient List

A list of registered patients. The patient in the pressed row is selected.

9 Edit button 🛂 Edit

Used to display the patient information registration screen to make edits.

10 Del button

Used to delete the data of the selected patient.

11 Search Results, Patients, Page

- Indicates the number of patients extracted under the search criteria.
- Indicates the total number of the registered patients except during a patient search.
- Indicates the page number of the displayed patient list.

12 Page button 🔼 /

If the patient list has multiple pages, press these buttons to change the page. Pressing and holding either of the buttons fast-forwards the pages.





1 ID button

Used to enter the patient ID.

2 Last button

Used to enter the last name of the patient.

3 First button

Used to enter the first name of the patient.

4 Middle button Middle

Used to enter the middle name of the patient.

5 DOB button

Used to enter the date of birth of the patient.

6 Memo button

Used to enter a memo.

7 Type button **Start**

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

- 8 Male/Female buttons O Male / Female
- 9 Chart button 😂 Chart

Used to select the applicable progression chart.

10 Create New button Create New

Used to register the entered patient information and display the new patient information registration screen.

↔ "4.3.2 Registering patient information" (page 62)

11 OK button

Used to register the entered patient information and display the measurement screen.

12 Cancel button Cancel

Used to cancel registration of patient information and return to the patient list screen.

Measurement screen



1 Mode button 🔕 Mode

Used to display the window for selecting the measurement mode.

2 Auto / Manual buttons 🚰 Auto / 🖓 Manual

Used to specify whether to start the measurement automatically or manually. Pressing the button alternates between the two.

3 Patient ID field

Displays the patient ID and their name.

4 Tracking button

Used to change the tracking method. Each press of this button changes the setting.

| Button | Function |
|--------------|---|
| Get → 3D | Auto-tracks left/right, up/down, and forward/backward directions. |
| ←→ 2D | Auto-tracks left/right and up/down directions. Forward and backward directions are adjusted manually. |
| ↓ OFF | Adjusts left/right, up/down, and forward/backward directions manually. |

5 Patient List button Patient

Used to return to the patient list screen.

6 Result Display button Result / Save/Output button save

Moves to the next screen. (The screen displayed next differs depending on the setting of the Exam Mode parameter.)

7 Ref.Input button Ref. Input

Used to display the Ref.Input window.

8 Oper button

Used to display the Operator List window to select the operator.

↔ "4.3.3 Selecting operator" (page 65)

9 Del button

Used to delete the measurement data being displayed.

10 Latest data display

Displays the latest measurement data.

| Item | Description | |
|-------------|--|--|
| AL | Axial length: The distance from the corneal epithelium to the retinal pigment epithelium | |
| SNR | Confidence coefficient in AL measurement value Confidence coefficient is the signal-to-noise ratio. A higher number indicates higher confi- dence. | |
| KM (R1, R2) | R1: Corneal curvature radius and axis angle in the direction of the flattest meridian R2: Corneal curvature radius and axis angle in the direction of the steepest meridian | |
| PS | Pupil diameter (mesopic vision) | |



Setting

• The display of R1, R2, or K1, K2 can be specified in the parameter settings.

♥ * Measure settings" (page 98)

11 Measurement results of right and left eyes

Displays the measurement results of the right and left eyes (median values).

| Item | Description |
|----------------|--|
| R, L | The background of the side to be measured is displayed in blue. |
| Phakic or such | Type of the measured eye selected in patient information |
| AL | Axial length (combined wave value): Value obtained from all waveforms measured |
| R1, R2 | R1 (median value): Corneal curvature radius and axis angle in the direction of the flat- test meridian R2 (median value): Corneal curvature radius and axis angle in the direction of the steepest meridian |
| K1, K2 | K1 (median value): Corneal refractive power and axis angle in the direction of the flat- test meridian K2 (median value): Corneal refractive power and axis angle in the direction of the steepest meridian |
| PS | Pupil diameter (mesopic vision) |

12 Alignment target

Used as a guide to center the eye to be measured on the screen. Align the center of the mire ring with the alignment target for alignment.

13 Focusing indicator

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

Manipulate the joystick so that the optimal state — 🛟 — is displayed.

14 Mire ring

Used as a reference ring for alignment.

Measurement result confirmation screen

• Measurement result confirmation screen (Overview)



1 Overview tab Overview

Displays the measurement results of AL, KM, and PS and the input value of refractive error (Ref.).

2 AL tab 🖸 🔼

Displays the measurement result confirmation screen (AL).

3 KM tab 🔾 🚾

Displays the measurement result confirmation screen (KM).

4 Back button 🜆 Back

Used to return to the measurement screen.

5 Save/Output button

Confirms the measurement data being displayed and saves it to the database. The button exports or prints the measurement data according to the parameter settings.

6 Ref.Input button Ref. Input

Used to display the Ref.Inputwindow.

7 Display of AL values

Displays the values and waveform of the axial length.

8 Display of KM values

Displays the KM value (median value).

9 Display of refraction

Displays the entered refraction values.

10 Display of mesopic pupil diameter

Displays the mesopic pupil diameter.

• Measurement result confirmation screen (AL)

The details on the axial length measurement values are displayed. For the same items as in the measurement result confirmation screen (Overview), see "• *Measurement result confirmation screen* (Overview)" (page 29).



1 List of AL measurements

Up to 10 sets of AL measurement values and SNR are displayed.

- **2** Number of measurements
- 3 Type of eye measured

4 AL combined wave value and SNR

| ltem | Description |
|------|--|
| AL | Combined wave value obtained by adding up all measured waveforms |
| SNR | Confidence coefficient of AL values |

5 Delete button Delete

Used to delete the selected value in the list of AL measurements.

6 Edit button Edit

Used to correct the peak position that is detected incorrectly due to noise.

7 AL waveform

The AL waveform obtained by adding up all measured waveforms is displayed in blue.

The peak marked with \bigcirc is the location of the detected retinal pigment epithelium.

Selecting a measurement value on the list displays $\stackrel{0}{\equiv}$ the AL waveform of that measurement in pink.



• Measurement result confirmation screen (KM)

The details on the KM values are displayed.

For the same items as in the measurement result confirmation screen (Overview), see "• Measurement result confirmation screen (Overview)" (page 29).



1 KM values

A list of KM 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.

Up to 10 sets of KM values are displayed. The values are listed by the size of the mire ring and the eye measured.

2 KM median values

Follow-up screen

• Follow-up screen (Trend Graph)

The changes of AL, KM, and refraction measurement values are displayed in a trend graph.



1 Trend Graph tab

Displays the Follow-up screen (Trend Graph).

2 Progression Chart tab

Displays the Follow-up screen (Progression Chart).

3 Data tab O Data

Displays the Follow-up screen (Data).

4 Patient List button Patient

Used to return to the patient list screen.

5 Report Output button Report Output

Used to export the contents of the Follow-up screen in jpeg format.

6 Right/Left buttons Right / Left

Used to toggle the display of right eye data or left eye data.

7 Years on the horizontal axis 3 years / 5 years / 10 years

Displays the number of years on the horizontal axis of the trend graph. Pressing this button changes the number of years.

8 Vertical axis of the graph

Indicates AL (blue), refraction (purple), and KM (orange) values.

9 Horizontal axis of the graph

Indicates the patient's age.

- **10** Measurement values for the selected AL, refraction, refraction and KM plot points
- **11** AL trend graph (blue) Displays the changes in axial length with age.
- **12** Refraction trend graph (purple) Displays the changes in refractive error with age.
- **13 KM trend graph (orange)** Displays the changes in KM values with age.

14 Date of the selected plot points
2

• Follow-up screen (Progression Chart)

The progression charts and the trend graphs of the patient's axial length are overlaid.

For the same items as in the Follow-up screen (Trend Graph), see "• Follow-up screen (Trend Graph)" (page 33).



1 Chart button 🔩 Chart

Displays the menu of the progression charts.

2 Axial length value

- **3** Graph (green) of changes in AL with age for the left eye
- 4 Graph (red) of changes in AL with age for the right eye

5 Progression chart

A graph to compare changes in the axial length with age with the statistical information based on a published article by Tideman

They are 2nd, 5th, 10th, 25th, 50th, 75th, 90th, 95th, and 98th percentile curves from bottom to top.

6 Age

7 Percentage of people found to have myopia (children at age 9)

Indicates statistical percentage of children at age 9 with the applicable axial length who were found to have myopia.

8 Percentage of people found to have myopia (adults)

Indicates statistical percentage of adults with the applicable axial length who were found to have myopia.

9 Percentage of people found to have high myopia (adults)

Indicates statistical percentage of adults with the applicable axial length who were found to have high myopia.

10 Percentile

Indicates the percentage of children at ages 6, 9, and 15 and adults who have axial lengths the same as or shorter than those on each percentile curve of the progression chart.

• Follow-up screen (Data)

Displays the measurement history of the patient in a list.

For the same items as in the Follow-up screen (Trend Graph), see "• Follow-up screen (Trend Graph)" (page 33).



1 Output button

Used to export the data selected in the data list.

2 Ref.Input button Ref. Input

Used to display the Ref.Input window.

3 Del button 🧋 🔤

Used to delete the data selected in the data list from the database.

4 Data list

List of the measurement history of the patient

5 Page button 🔼 / 🔽

If the measurement history extends to multiple pages, press this button to change the page.

Numeric keypad window

1 Entry display

Displays the entered number.

2 Numeric character keys

3 Close button 🗙

Used to cancel the entry and close the numeric keypad window. The button functions as with a Cancel button.

4 BS button BS

Used to delete the number being selected or the number to the left side of the cursor.

- When the entered numbers are highlighted as **1990** The button deletes the numbers highlighted.
- When the blinking cursor is placed next to a number as **1550** The button deletes the number to the left side of the cursor.

5 OK button

Used to confirm the entered value and close the numeric keypad window.

6 Cancel button Cancel

Used to cancel the entry and close the numeric keypad window.



Keyboard window

Some keys on the keyboard window may be different depending on the item to be entered.



1 Entry display

Displays the character entered.

2 Alphanumeric key

3 Shift key Shift

- Toggles between lowercase and uppercase alphabetical keys.
- When the characters are highlighted, the button toggles between lowercase and uppercase characters.

nidek —> NIDEK —> nidek

4 Space key Space

Enters a space at the cursor position.

5 Cursor move buttons \leftarrow / \rightarrow

Moves the cursor to the right or left.

6 OK button

Used to confirm the entry and close the keyboard window.

7 Cancel button Cancel

Used to cancel the entry and close the keyboard window.

8 Close button 🔀

Used to cancel the entry and close the keyboard window. The button functions as with a Cancel button.

9 BS button BS

- When the entered characters are highlighted as **1990**, the button deletes the characters highlighted.
- When the blinking cursor is placed next to a number as $\overline{1550}$, the button deletes the character to the left side of the cursor.

2.4 Packed Contents

The following items are contained in the standard configuration: Confirm that all of the following items below are packed before using the device.

| Part name | Quantity | Appearance |
|--------------------------------|----------|------------|
| AL-Scan M main body | 1 | |
| Model eye | 1 | |
| Touch pen | 1 | |
| Pen stand | 1 | |
| Chinrest paper | 1 | °. |
| Fixing pins for chinrest paper | 2 | |
| Printer paper | 3 | |
| Dust cover | 1 | |
| Power cord | 1 | |
| Operator's manual | 1 | |

=

| Part name | Quantity | Appearance |
|--------------------|----------|------------|
| Myopia Viewer MV-1 | | |
| Installation CD | 1 | |
| License card | 1 | 1950 frage |
| Operator's manual | 1 | |



OPERATING PROCEDURE

3.1 Before Initial Use

🕂 WARNING

• Be sure to connect the power plug to a protective grounded power outlet. Device malfunction, electric leakage, electric shock, or fire may result.

- Place the device on a stable table and connect the power cord to the power inlet of the device.
 - 1) Pull the main unit to the side (right or left) a where the device will be laid down.
 - 2) Lower the locking lever b to lock the main unit.
 - Place the padding to the side where the device will be laid down.
 - 4) Lay the device down gently.
 - 5) Orient the power plug C of the power cord properly when inserting it to the power inlet.
 - 6) Stand the device upright.
- **2** Connect peripheral devices to the side panel if necessary.

5.3 Peripheral Device Connection" (page 114)

3 Attach the magnetic forehead rest pad **d** 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 magnetically attachable and detachable.

- 4 Confirm that the power switch is turned off(O) and plug the power cord into a wall outlet.
- **5** Set the printer paper.

↔ "3.4 Setting Printer Paper" (page 44)





3.2 Turning on and off the Device

3.2.1 Turning on the device

1 Turn on (**|**) the power switch. The opening screen is displayed, and the day

The opening screen is displayed, and the device is initialized.

- 2 To measure the model eye, press Model Eye. ↓ "4.2.1 Measuring model eye" (page 57) When the model eye is not measured, press X or Close.
- Check the parameter settings as necessary.
 ^t→ "5.1 Parameter Settings" (page 95)
 ^t→ "5.2 Maintenance Operation" (page 104)
 ^t→ "5.3 Peripheral Device Connection" (page 114)

3.2.2 Turning off the device

- **1** Turn off (\bigcirc) the power switch.
- 2 Inspect and clean the device as needed. [↓] "6.4 Cleaning" (page 132) [↓] "6.6 Checklist" (page 136)
- **3** Put the dust cover on the device.
- **4** Unplug the power cord when the device will not be used for an extended period of time.





3.3 Adjusting Touch Screen Angle

- Changing the angle of the touch screen
- **1** Lift the bottom of the touch screen.

2 Release the touch screen at the desired position.

The touch screen remains in the position where it was released. The angle can be adjusted in 5 levels.

- Returning the touch screen to the original position
- **1** Lift the touch screen to the top.
- **2** Release the touch screen.

The touch screen comes down slowly and returns to its original position. The touch screen is secured with magnet.









3.4 Setting Printer Paper

When no printer paper is loaded or a red line appears at the edge of the printer paper, set or replace a new roll of printer paper.

- **1** Lift the touch screen to the horizontal position.
- **2** Press the printer cover open button until a click is heard.

The printer cover opens.

3 When replacing the printer paper, remove the used printer paper roll.



If the roll is set with the wrong side up, data cannot be printed on the printer paper.

Confirm that the roll of the printer paper is not tilted or the printer paper tube is not shifted to the side.



5 Close the printer cover.

- 1) Allow the leading edge of the printer paper to protrude slightly from the cover.
- 2) Press the right and left ends of the printer cover to close the printer securely.

If the printer cover is not closed, the auto cutter may not operate properly. In addition, an error may be displayed and printing may not be performed.



3.5 Setting Chinrest Paper

- **1** Pull out the 2 fixing pins **a** from the chin-rest.
- **2** Remove an appropriate amount of chinrest paper from a bundle.

The total thickness of the chinrest paper should be 6.0 mm or less.

- **3** Insert the 2 fixing pins into the holes at both ends of the chinrest paper **b**.
- **4** Set the chinrest paper on the chinrest. While holding the fixing pins and chinrest paper stack, push the pins into the 2 holes on the chinrest.



3.6 Operating Chinrest

1 Ask the patient to place their chin on the chinrest to lightly rest the forehead on the forehead rest.

Check the position of the patient's eyes. Guide the patient to the right position if the eyes are not positioned correctly.



2 Use the chinrest up/down buttons **a** to adjust the position of the patient's eyes to the eye level marker **b**.

Before adjusting the height of the chinrest, explain to the patient that the chinrest moves up and down.

| The chinrest moves up. |
|--------------------------|
| The chinrest moves down. |



When the chinrest has reached the upper or lower limit, the limit indicator ^C is displayed on the measurement screen.

| NO. | Upper limit indicator |
|-----|-----------------------|
| | Lower limit indicator |



3.7 Manipulating Joystick

Adjust the alignment and focus with the joystick by the following procedure.

 Adjust the alignment (right or left and up or down) when measuring the patient's eye.
 Moving the joystick right or left moves the main unit of

the device in the same direction.

Turning the knob of the joystick moves the measuring unit up or down.

| Clockwise | The measuring unit moves up. |
|------------------|--------------------------------|
| Counterclockwise | The measuring unit moves down. |

2 Adjust the focus (forward or backward) on the patient's eye.

Moving the joystick forward or backward moves the main unit of the device in the same direction.

3 Press the start button **a** if necessary.

Pressing the start button starts the measurement regardless of the alignment and focus status.



3.8 Auto Shot Setting and Tracking Operation

This section describes the auto shot, tracking operation, and limit indicator.

 On the measurement screen, press Auto to set the auto shot on or off according to the needs.

| FO Auto | Auto shot on (Auto) Measurement starts automatically. |
|---------|--|
| Manua I | Auto shot off (Manual) Pressing the start button on the joy- stick starts measurement. |



The operations for adjusting the alignment (right or left and up or down) and focus (forward or backward) are different depending on the tracking type.

• Tracking types and differences in operations

Auto-tracking is a function that automatically adjusts the alignment and focus when the measurement window is brought close to the patient's eye.

| 3D auto tracking | 2D auto tracking | Auto tracking off |
|---|--|--|
| fz d 3D | ←→ 2D | ↓ OFF |
| | | |
| Auto-tracking for right/left, up/ down, and forward/backward directions | Auto-tracking for right/left and up/down directions Manual operation for forward/ backward directions | Manual operation for right/left, up/ down, and forward/backward directions |
| Auto tracking | | |
| Manual operation | | |



3 Adjust the alignment and focus.

When set to

While looking at the alignment target and focusing indicator, move the main unit in the directions of the arrows in the illustration below with the joystick. Move the main unit until is displayed.

"3.7 Manipulating Joystick" (page 48)

• When set to 4 or 4 2D

Adjust the alignment and focus according to the setting of the tracking type.



Image of directions and distance displayed in the focusing indicator



When set to Marto

When the eye is in alignment and focus, the measurement starts automatically.

When set to

Adjust the alignment and focus, then press the start button (a) of the joystick.



• When the limit indicator appears

When the patient's eye is out of the auto-tracking range for the alignment, the limit indicator (triple red arrows) appears. Adjust the alignment as directed by the limit indicator.

When when we can be a selected, the limit indicator does not appear.

Ex.— Display of limit indicator





| | Turn the knob of the joystick clockwise to move the measuring unit up. |
|--------|---|
| ₩ ¥ | Turn the knob of the joystick counterclockwise to move the measuring unit down. |
| | Move the joystick to the right to move the measuring unit to the right. |
| | Move the joystick to the left to move the measuring unit to the left. |

The limit indicator also appears when the patient's eye is out of the auto-tracking range for the focus (only

when \checkmark 3D is selected).



Manipulate the joystick according to the direction of the limit indicator.

| Move the joystick forward to move the measuring unit closer to the patient. |
|--|
| Move the joystick backward to move the measuring unit away from the patient. |



4.1 Exam Mode and Measurement Flow

4.1.1 Exam Mode settings to suit operator's use

The setting of the parameter "Exam Mode" determines whether the screen displayed after the measurement is the measurement result confirmation screen or the Follow-up screen. Select the setting that best suits the operator's usage.

✤ "5.1 Parameter Settings" (page 95)





In this chapter, the notations such as "Results/Follow-up" indicate that the operation is performed when Exam Mode is in that setting.



- When "Results" is set in Exam Mode, the Follow-up screen can be displayed from the patient list screen.
- When "Follow-up" is set in Exam Mode, the measurement result confirmation screen is not displayed.

4.1.2 Measurement flow

"4.2 Inspection Before Measurement" (page 56)

Results/Follow-up

"4.3 Patient Information Selection" (page 60)

Results/Follow-up

- "4.3.1 Specifying patient from the patient list" (page 60)
- *"4.3.2 Registering patient information" (page 62)*
- "4.3.3 Selecting operator" (page 65)

"4.4 Measurement" (page 66)

Results/Follow-up

"4.4.1 Setting measurement conditions" (page 66) "4.4.2 Measuring patient's eye" (page 67)

"4.5 Measurement Result Check" (page 71)

Results

"4.5.1 Checking measurement result" (page 71)

"4.5.2 Correcting retinal pigment epithelium detection position of AL measurement" (page 75)

"4.5.3 Entering refractive error" (page 76)

"4.6 Printing and Exporting Measurement Results" (page 77)

Results/Follow-up

"4.6.1 Printing measurement results" (page 77) "4.6.2 Exporting measurement results" (page 80)

"4.8 Checking and Editing Follow-up" (page 84)

Follow-up



4.2 Inspection Before Measurement

| Exam Mode | Results/Follow-up |
|-----------|-------------------|
| | · |

This section describes the daily inspection performed before using the device. It is recommended that the results of the inspection be documented in the inspection record. \checkmark "6.6 Checklist" (page 136)

- **1** Check that the device exterior is not deformed or dirty.
- **2** Check that the power cord is properly connected to the power outlet.
- **3** Check that the main unit is clean.
 - Check the cleanliness of the mire ring a and measuring window b.

☆ "6.4.4 Cleaning the measuring unit" (page 133)

Clean the forehead rest and chinrest.
 "6.4.3 Cleaning the chinrest and forehead rest" (page 133)



- **4** Turn on (**|**) the power switch of the device.
- **5** Check that the main unit moves up, down, right, left, forward or backward smoothly with the joystick.

↔ "3.7 Manipulating Joystick" (page 48)

6 Check that the chinrest moves up or down smoothly with the chinrest up/down button.

Measure the model eye to check the accuracy of AL and KM measurement data.
 *4.2.1 Measuring model eye" (page 57)

8 Check that the paper residue is not remained in the printer.
 ^t→ "6.4.5 Cleaning the printer" (page 134)

- 9 Confirm that the printer paper is sufficient.
 ^t→ "3.4 Setting Printer Paper" (page 44)
- Set a stack of chinrest paper if necessary.
 "3.5 Setting Chinrest Paper" (page 46)
- Check the parameter settings and change them accordingly if necessary.
 **5.1 Parameter Settings" (page 95)*

4.2.1 Measuring model eye

To measure the accuracy of the AL and KM measurement data, use the provided model eye.

- 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 smudged or flawed, measurement

accuracy cannot be properly measured.



Lens

а

Lens

- **1** Remove the chinrest paper and fixing pins from the device when they are attached.
- 2 Remove the cap a from the 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 2 fixing pins **b**.





5 Display the Model Eye screen. • When the device is started Model Ev Press Model Eye in the Model Eye window. 🗓 Take model eye measurements 3007 13:35 Last measurement date AL/KM:11/05/2022 3009 12:34 13008 12:14 Close • When the device is in use ID :13007 Name :NIDEK, SARA 1) Press series on the patient list screen. arch Criteria Last Patient List Search Results 13/Patients 13 Page Name Exam Date 13007 NIDEK, SARA 11/05/2022 13:35 13009 NIDEK, KEN 11/05/2022 12:34 13008 NIDEK, GEORGE 26/04/2022 12:14 Maintenance 2) Press Menu Enter the password if the administrator password is set. Parameter Settings Maintenance

3) Press Model Eye

| | ≫ Maintenance < | Back |
|------------------------------|--|-----------------|
| Database | Maintains databases. | Admin. Password |
| Backup/Restore Parameters | Backs up/Restores parameters. | Service |
| LAN Settings | Configures settings for IP address and file sharing. | |
| Reader Settings | Configures settings for barcode scanner and card reader. | |
| Touch Panel | Calibrates touch panel. | |
| Date/Time | Set date and time. | |
| Model Eye | Measures model eyes. | |
| Info | Displays license information. | |
| Versic OFT: | /*. **. ** FPG <mark>A:R**/** Se</mark> | rial No.:****** |

2

×

6 Measure the model eye.

Adjust the alignment and focus with the joystick.

♥ "3.8 Auto Shot Setting and Tracking Operation" (page 49)

7 Confirm that the measurement accuracy is proper from the measurement results.



8 Remove the model eye from the chinrest and attach the cap.

4.3 Patient Information Selection

| Exam Mode | Results/Follow-up | |
|---|---|--|
| Specify the patient from the patient list before measurement. | | |
| For patients who have been registered to the database | ³⁻ ⁴ .3.1 Specifying patient from the patient list" (page 60) | |
| For patients who have not been registered to the database | 4.3.2 Registering patient information" (page 62) | |

4.3.1 Specifying patient from the patient list

Specify the desired patient from the patient list to load their registered patient information from the database.

on

- **1** Select the patient from the patient list screen.
- 2 Press Measure

Measurement screen

When "Ref.Input" in "Before Meas. is checked, the Ref.Input window appears before the measurement screen is displayed. Enter the refractive error measured by other devices.

Press Follow-up screen.

- Searching patient list
 - When the patient list has multiple pages a

Change and select a page with or the right edge of the screen.

| Pressing this button displays the previous page. |
|---|
| Pressing this button displays the next page. |
| Pressing and holding either button fast-forwards the pages. |

• When refining the displayed patient under the search conditions

The patient refined by ID or Last (or First) can be displayed. In this case, the patient list is high-lighted in yellow.

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

| ID Name | :13007 :NIDEK, SARA | | Menu |
|---------------|------------------------|------------------|------|
| New Measure | | Follow-up | |
| Search Criter | Last | 🖌 🖉 Edit | Del |
| Patient List | Search Results 13/Pa | ntients 13 Page | 2/ 2 |
| ID | Name | Exam Date 🔻 | |
| 13007 | NIDEK, SARA | 11/05/2022 13:35 | |
| 13009 | NIDEK, KEN | 11/05/2022 12:34 | |
| 13008 | NIDEK, GEORGE | 26/04/2022 12:14 | |
| <u> </u> | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| ID Name | :13007 :NIDEK, SARA | | | | Menu |
|-----------------|------------------------|-------------|---------|-----------|-----------|
| 📴 New 🔶 Measure | | | 8 | Follow-up | |
| Search Criteria | Last | | Clear | Edit | De I |
| Patient List | Search Results | 13/Patients | 13 | Page | 2/ 2 |
| ID | Name | Ex | am Date | | a |
| 13007 | NIDEK, SARA | 11/0 | 5/2022 | 13:35 | |
| 13009 | NIDEK, KEN | 11/0 | 05/2022 | 12:34 | |
| 13008 | NIDEK, GEORGE | 26/0 | 04/2022 | 12:14 | V |
| | | | | | / |
| | | | | | |
| | | | | | Γ' |
| | | | | | |
| | | | | | |
| | | | | | |

| ID Name | :13007 :NIDEK, SARA | | Menu |
|-----------------|------------------------|------------------|--------|
| 🕒 New 🔶 Measure | | Follow-up | |
| | Last | 🖌 🖉 Edit | 觉 De I |
| Patie | Search Results 13/Pa | tients 13 Page | 2/ 2 |
| | Name | Exam Date 🔻 | |
| 1300 | NIDEK, SARA | 11/05/2022 13:35 | |
| 13009 | NIDEK, KEN | 11/05/2022 12:34 | |
| 13008 | NIDEK, GEORGE | 26/04/2022 12:14 | |
| | | | |

2) Enter the desired search criteria with the keyboard window.

| | Data sets with the patient ID beginning with the entered alphanumeric characters are displayed. |
|-----------------|---|
| Last (or First) | Data sets with the last name (or first name) beginning with the entered char- acter(s) are displayed. When the setting for the Name parameter is "F L MI.", [Last] becomes [First]. |
| (or | If both the ID and Last or First are entered, the AND search is executed. |
| Clear | The search criteria is cleared. Registering new patient information or editing the patient information also clears the search criteria. |

• Sorting the patient list display

| ID | Sorts by ID. |
|-----------|-------------------------------|
| Name | Sorts by name of the patient. |
| Exam Date | Sorts by exam date. |

 \bigtriangleup (ascending order) or \bigtriangledown (descending order) is displayed on the item be sorted.



Reading ID with the barcode scanner (optional)

The patient ID can be read with the barcode scanner to specify the patient from the patient list.

1 Display the patient list screen and scan the barcode by aligning the barcode scanner and pressing the trigger switch.



2 The patient with the read ID is selected.

If a patient ID that has not been registered is read, the patient information registration screen is displayed. The read ID is displayed in the ID field.

The ID can contain numeric characters, upper case letters, lower case letters, and hyphens. Other characters cannot be recognized by this device. All unrecognized characters are converted to "~" (tilde).

| ID Nar | :13009 ne :NIDEK, KEN | | | Menu |
|-------------------|--------------------------|--------------|-----------|--------|
| New Measure | | | Follow-up | |
| - Search Criteria | | | | |
| | Last | Clear | 🛂 Edit | 👕 De I |
| Patient List | Search Results | 3/Patients 3 | Page | 1/ 1 |
| ID 🔺 | Name | Exam | Date | |
| 13007 | NIDEK, SARA | 11/05/20 | 22 10:02 | |
| 13008 | NIDEK, GEORGE | 26/04/20 | 22 12:14 | |
| 13009 | NIDEK, KEN | 26/04/20 | 22 15:29 | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

4.3.2 Registering patient information

Check

· Be sure to register the patient information before measurement.

- Patient can be registered with the ID only. In such a situation, measurement values are printed or exported to another device without the patient information.
- When the chart is not selected, the progression chart is not displayed.

Registering new patient information

When the patient has not been registered to the database, register the patient information.

1 Press 🔄 New on the patient list screen.

→ Patient information registration screen



2 Enter each item.

| Ð | Used to enter the patient ID. When "Auto ID" is checked, ID numbers are automatically assigned in numerical order. | |
|-------|---|--|
| Last | Used to enter the patient's last name. | |
| First | Used to enter the patient's first name. | |
| DOB | Used to enter the date of birth of the patient. Enter it according to the setting of the Date Format parame- ter. | |
| | | |

| 13007 Male O Female | |
|-------------------------------------|--------|
| NIDEK | |
| Irst SARA | |
| idale | |
| 01/04/2010 🛃 Chart Tideman [Female] | |
| Aemo | |
| 🗴 Type 🥂 Phakic | |
| Create New OK | Cancel |
| | |

| Male Female Used to select male or female. |
|--|
|--|

• Optional items to be specified if necessary

| Middle | Used to enter the patient's middle name. | |
|----------------------------|---|---|
| Chart | Used to select the applicable progression chart on the Chart). | Follow-up screen (Progression |
| 1) Sele ੯ੵ੶" 2) Pres | ct the applicable progression chart. ● <i>Progression chart" (page 87)</i> s . | Chart X Tideman [Male] O Tideman [Female] |
| | | OK Cancel |

| Memo | Used to fill in the Memo box. | |
|---------------------------|--|--|
| Бу Туре | Used to select the eye type. | |
| 1) Sele and 2) Pres | ect the eye type for both the right left eyes. as or | Eve Type Right Phakic Phakic Aphakic Silicone 10L FMA 10L File File </td |

3 Press 0K

The entered patient information is registered to the database, then the measurement screen is displayed.

♥ "4.4 Measurement" (page 66)

| | 13007 • Male O Female |
|--------|-------------------------------------|
| Last | NIDEK |
| First | SARA |
| Middle | |
| DOB | 01/04/2010 🛃 Chart Tideman [Female] |
| Memo | |
| Sa Ty | Pe R Phakic Phakic |
| | Create New OK Cance I |
| | |

| Cancel | Used to cancel he patient information entry. The screen returns to the patient list screen. |
|------------|---|
| Create New | The entered patient information is registered, and the patient information registration screen for the next patient is displayed. |

Automatically assigning patient ID

Setting

• Check "Auto ID" to assign ID numbers automatically. ID numbers are assigned in numerical order.

When this function is used, the patient is not registered in the database until the information is saved or exported, or printed.

•ૻૢૢૢૢૢૢૢૢ૽- Tip

• Registration of patient information is necessary to perform measurement with this device. When measuring a large number of patients such as in a group medical examination, successive measurement of patients is possible with only an ID automatically assigned as the patient information.

Press without specifying the patient on the patient list screen.

| I | D : lame : | | Menu |
|----------------|----------------|-------------------|--------|
| | ire | Porton-up | |
| Search Criteri | Last | 🖉 Clear 💟 Edit | 💣 De I |
| Patient List | Search Results | 3/Patients 3 Page | 1/ 1 |
| ID 🔺 | Name | Exam Date | |
| 13007 | NIDEK, SARA | 11/05/2022 10:02 | |
| 13008 | NIDEK, GEORGE | 26/04/2022 12:14 | |
| 13009 | NIDEK, KEN | 26/04/2022 15:29 | |
| | | | |
| | | | |
| | | | |

The measurement screen with the automatically assigned ID number is displayed.

♥ "4.4 Measurement" (page 66)



4.3.3 Selecting operator

Select the operator if necessary.

Register the operator's name on the Parameter Settings screen in advance.

♥ *• Registering operator's name" (page 96)

1 Press **D**oor on the measurement screen.



2 Select the operator's name.



The operator's name is indicated when the measurement data is printed or exported.



4.4 Measurement

2 Press 🔕 Mode

| Exam Mode | Results/Follow-up |
|-----------|-------------------|
| | |

4.4.1 Setting measurement conditions

1 Select the patient on the patient list screen and press Skeasure.

→ Measurement screen





3 Specify the measurement mode and press

| • Auto | AL (axial length), KM (corneal cur- vature radius), PS (pupil diameter) |
|--------|--|
| AL | AL (axial length) |
| С КМ | KM (corneal curvature radius) |



- **4** If necessary, press **Auto** to specify whether or not to use the auto shot function.
- **5** If necessary, press **b** to specify the tracking method (default setting: 3D).

(page 49) "3.8 Auto Shot Setting and Tracking Operation"



4.4.2 Measuring patient's eye

Measure the patient eye one eye at a time. Depending on the main unit position, the device automatically switches between the right eye and left eye measurement.

• Wipe the forehead rest and chinrest with clean absorbent cotton or gauze dampened with rubbing alcohol before examining each patient. Remove 1 sheet of paper when using the chinrest paper.

1 Wipe the forehead rest **a** and chinrest **b** with clean absorbent cotton or gauze dampened with rubbing alcohol before examining each patient.

Remove 1 sheet of paper when using the chinrest paper.

2 Instruct the patient to remove their glasses or contact lenses and be seated.



- **3** Ask the patient to place their chin on the chinrest, and their forehead on the forehead rest lightly.
- **4** Before adjusting the height of the chinrest, explain to the patient that the chinrest moves up and down. Adjust the height of the chinrest with the chinrest up/down button until the patient's eye level aligns with the eye level marker **c**.

☆ "3.6 Operating Chinrest" (page 47)

5 Instruct the patient to blink once or twice, then look at the red fixation lamp in the measuring window with their eyes wide open.

6 Perform rough alignment and focusing to the right or left eye with the joystick.

Alignment and focusing procedures differ depending on the tracking setting.

↔ "3.7 Manipulating Joystick" (page 48)

(page 49) "3.8 Auto Shot Setting and Tracking Operation"

When the eye is aligned and focused, measurement starts automatically.



7 Check the measured values of the right or left eye on the measurement screen.



• Checking the latest measurement values

| AL | Axial length | |
|---------------------------|--|--|
| SNR | Confidence coefficient in AL measurement value | |
| KM (R1, R2) ^{*a} | R1: Corneal curvature radius and axis angle in the direction of the flattest meridian The @ mark indicates the axis angle (unit: °). R2: Corneal curvature radius and axis angle in the direction of the steepest meridian The @ mark indicates the axis angle (unit: °). | ID :13007 Name :NIDEK, SARA Auto |
| KM (K1, K2) ^{*a} | K1: Corneal refractive power (D) and axis angle in the direction of the flattest meridian The @ mark indicates the axis angle (unit: °). K2: Corneal refractive power (D) and axis angle in the direction of the steepest meridian The @ mark indicates the axis angle (unit: °). | |
| PS | Pupil diameter (mesopic vision) | |

*a. For the display method of the KM values, select the parameters on the measurement setting screen. ↔ Measure settings" (page 98)

Check

- When each measurement is complete, the measurement values disappear, then "Fin" appears to the right of KM, AL, and PS.
- If the measurement of any item fails, "REMEASUREMENT?" appears with "!" displayed for the failed item.



| R, L | Displays the eye to be measured in blue. | |
|---------------------------|---|--|
| Phakic | Measurement eye type selected in the patient list | |
| AL | Axial length The numbers displayed next to "AL" indicate the number of times of measurement. | ID :13007 Name :NIDEK, SARA |
| KM (R1, R2) ^{*a} | R1: Corneal curvature radius and axis angle in the direction of the flattest meridian (median value) The numbers displayed next to "R1" indicate the number of times of measurement. The @ mark indicates the axis angle (unit: °). R2: Corneal curvature radius and axis angle in the direction of the steepest meridian (median value) The @ mark indicates the axis angle (unit: °). | Mode Auto Auto |
| KM (K1, K2) ^{*a} | The numbers displayed next to "KM" indicate the number of times of measurement. K1: Corneal refractive power (D) and axis angle in the direction of the flattest meridian The @ mark indicates the axis angle (unit: °). K2: Corneal refractive power (D) and axis angle in the direction of the steepest meridian The @ mark indicates the axis angle (unit: °). | PS 5. 2 |
| PS | Pupil diameter (mesopic vision) | |

• Checking the measurement values in measurement results

*a. For the display method of the KM values, select the parameters on the measurement setting screen. *" Measure settings" (page 98)*

Check

• If the measurement results of AL or KM vary considerably, a message "CHECK!" appears. Check the measurement values, and adjust the alignment and focus to the eye to take the measurement again.



8 Measure the other eye.

Adjust the alignment and focus to the other eye with the joystick. The settings for right and left eye type automatically toggles.

- **9** Conduct measurement in the same manner as *Step* 6.
- **10** After the measurement, release the patient from the chinrest. If the patient suddenly rises up, they may hit their face on the upper part of the forehead rest.

11 Press Result when the measurements for both eyes are complete.

> Depending on the setting selected in Exam Mode, the button indication and the screen display change.

| Exam Mode | Button | Next screen |
|-----------|-------------------|---|
| Results | Result Display | Measurement result confir- mation screen (page 71) |
| Follow-up | Save Save | A window to confirm saving or exporting the measure- ment data Proceed to Step 12. After Step 12 is performed, the Follow-up screen is dis- played. |



12 When a window to confirm the export destination of the measurement data is displayed, press the desired export destination and press 0K

The measurement data is saved to the database.

When "Follow-up" is selected in Exam Mode, the Follow-up screen is displayed.

4.8 Checking and Editing Follow-up" (page 84)





Setting

• When "Select Each Time" is not checked in "Output After Meas.", the measurement data is printed or exported according to the selected parameter setting.


4.5 Measurement Result Check

| Exam Mode | Results |
|-----------|---------|

4.5.1 Checking measurement result

Check the measurement results on the measurement result confirmation screen. The displayed contents can be switched among the [Overview], [AL], or [KM] tab.

| Tab | Displayed contents |
|------------|---|
| [Overview] | Combined wave value of AL and median values of KM, PS value, and entered refractive error (Ref.value) |
| [AL] | AL measurement value |
| [KM] | KM value |

Measurement result confirmation screen (Overview)

Check the AL, KM, and PS values.

1 When the measurement is complete, the measurement result confirmation screen (Overview) is automatically displayed. Check the measurement results.



*a. For the display method of the KM values, select the parameters on the measurement setting screen. ↔ Measure settings" (page 98)

2 If necessary, enter the refractive error (Ref.) measured by another device.

♥ "4.5.3 Entering refractive error" (page 76)

| ID :13007 Name :NIDEK, SARA | Back |
|---|---|
| O Overvier 💿 AL 💿 KM | Save Ref. Input |
| Right | Left |
| AL (3) 25.71 mm SNR 13.8 | AL (3) (3); 29 m (2) NR 17.9 |
| 14 40 | 14 40 |
| KM (3) \$ +3.3 mm R1 7.88 mm \$ 167 ° R2 7.69 mm \$ 77 ° CYL 1.06 D \$ \$ 167 ° | KM (3) \$ 43.3 mm R1 7.89 mm \$ 25 \$ R2 7.65 mm \$ 115 \$ CYL -1.34 D \$ 25 \$ |
| Ref. SPH - 0.50 D CYL - 0.50 D Axis 5 | Ref. SPH - 1.00 D CYL - 0.50 D Axis 10 |
| PS (Meso) 5.7 mm | PS (Meso) 5.1 mm |
| | |

3 Press Save

The measurement results are confirmed and saved to the database.

Check

• The measurement results are not confirmed on the measurement result confirmation screen.

Pressing save confirms the measurement results and saves them to the database.

Setting

• When "Select Each Time" is not checked in "Output After Meas.", the measurement data is printed or exported according to the selected parameter setting.



Measurement result confirmation screen (AL)

- **1** Press [AL].
- ${\bf 2}$ Check the details on the results on the AL measurement.

| а | Measurement value list SNR (confidence coefficient of the AL measurement values) is the ratio of signal power to noise power. The greater the SNR is, the more reliable the measured value is. SNR 2.0 to 2.4: The measurement value is displayed with "E" attached to the end. 1.9 or less: The measurement value is displayed as an error. Up to 10 sets of ALmeasurement values and SNR are displayed. If measurement is performed 11 times or more, the oldest data is deleted. If there is error data, the error data is deleted first. | a b c ID : 3007 Name : 1 IDEX, SARA |
|---|---|--|
| b | The number of measurements | Chervies C L C KM |
| с | AL combined wave value and SNR The AL combined wave value is a value obtained by adding up all the measured waveforms. The median value of SNR is the confidence coef- ficient in median value of AL. | No. AL (m) SNR AL (3) 1 25.69 7.8 AL (m) 1 25.2 3 25.76 5.5 AL (m) 2 3 25.7 4 4 Addition 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.7 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 25.2 3 3 25.2 3 3 3 25.2 3 <t< td=""></t<> |
| d | AL waveform The AL waveform obtained by adding up all mea- sured waveforms is displayed in blue. The posi- tion of the peak with () indicates where the retinal pigment epithelium is detected. Selecting a measurement value on the list dis- plays the AL waveform of that measurement in pink. When the field for AL combined wave value is pressed, the AL waveform obtained by adding up all measured waveforms is displayed again. | |
| е | Edit Allows correction of the retinal pigment epithelium detection position. 4.5.2 Correcting retinal pigment epithelium detection position of AL measurement" (page 75) | |
| f | Delete Deletes the measurement values being selected in the list. Pressing Retrieve restores the deleted measure- ment values. | |

AL(3)

Measurement result confirmation screen (KM)

1 Press [KM].

2 Check the details on the results of the KM measurement.



*a. For the display method of the KM values, select the parameters on the measurement setting screen. ↔ Measure settings" (page 98)

4.5.2 Correcting retinal pigment epithelium detection position of AL measurement

If an incorrect peak of the waveform is detected as the retinal pigment epithelium position on the measurement result confirmation screen (AL), correct the detection position.

Knowledge

- The detection position can be corrected only for the AL waveform obtained by adding up all measured waveforms.
- **1** Press **Edit** on the measurement result confirmation screen (AL).



4

2 Press the peak on the retinal pigment epithelium position.

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

Press \leftarrow or \rightarrow to precisely adjust the position. If there are multiple peaks close to each other,

enlarge the waveform horizontally using Zoom+ to specify the proper position more easily. Pressing

zoom- reduces the waveform horizontally.

3 Press **t** return to the measurement result confirmation screen (AL).

The specified position becomes the retinal pigment epithelium position. The combined wave value of AL and SNR are marked with "#" that indicates that the values are for a waveform where the retinal pigment epithelium position was corrected.

Pressing Cancel returns to the measurement result confirmation screen (AL) without executing the correction.





4.5.3 Entering refractive error

- Manually enter the refractive error (Ref. value) measured with other device into a measurement result of the AL-Scan M.
- Press Ref. Input on the measurement screen, measurement result confirmation screen (Overview), or Follow-up screen (Data) to enter the refractive error. When the "Ref.Input" parameter in "Before Meas." is selected, the Ref.Input window appears before the measurement screen is displayed.



→ Ref.Input window



- **2** Enter each item with the numeric keypad window.
 - 1) Press of "Right" to enter the spherical refractive error (D) of the right eye.



- 2) Press of "Right" to enter the cylindrical power (D) of the right eye.
- 3) Press of "Right" to enter the cylinder axis angle (°) of the right eye.

If the cylindrical power is 0, the axis angle cannot be entered.

- 4) Enter the above values of the left eye in the same manner as in Steps 1) to 3).
- 5) Press OK

Ev

KM Disp Uni

Output After M

alect Each Time

Ref. Inde

4.6 Printing and Exporting Measurement Results

| Exam Mode | Results/Follow-up |
|-----------|-------------------|

This section describes the procedure with the case when "Results" is selected in Exam Mode. When "Follow-up" is selected, the measurement result confirmation screen is not displayed. The measurement results can be exported or printed after they are saved on the measurement screen.

4.6.1 Printing measurement results

Setting

 To print the measurement results automatically after they are saved in the database

Uncheck "Select Each Time" in "Output After Meas.", and check "Print".

• To print the measurement results manually

Check "Select Each Time" in "Output After Meas.". Both the settings for printing and exporting can be set to "Select Each Time" in "Output After Meas.".

• For the contents to be printed, set the parameters in the Print tab.

♥ Print settings" (page 100)

Automatic printing

Press **Save** on the measurement result confirmation screen.

When "Follow-up" is selected in "Exam Mode", press the button on the measurement screen.

The measurement results are automatically printed after they are saved in the database.



з

>> Parameter Settings •

ut Desti atio

Print []Network

з

Manual printing

1 Press **ESOUTPI** on the measurement result confirmation screen.

When "Follow-up" is selected in "Exam Mode", press the button on the measurement screen. Measurement result is saved to the database.

- **2** Check [Print].
- 3 Press OK

The measurement results are printed.



Sample printout

The figure shown below is a sample printout for when the Format parameter is set to "Items". When the parameter is set to "R->L", the measurement values for the right eye are printed, then those for the left eye are printed.

| abode f | ID :13009 Name:NIDEK.KEN M Date:11/May/2022 13:35 Memo: Oper:Suzuki ILong axis length IFlat corneal | |
|---------|---|---|
| h | L> mm SNR Add 29.06 16.9 Eye Type: Phakic | |
| | 14 40 | |
| i | KM (Phi=2.4)Index=1.3375 <r> m D deg <r1< td=""> 9.72 34.72 55 <r2< td=""> 9.63 35.05 145 <avg< td=""> 9.68 34.87 > <cyl< td=""> -0.33 55 ></cyl<></avg<></r2<></r1<></r> | |
| k | <pre><l> mm D deg <r1 178="" 34.13="" 9.89=""> <r2 34.72="" 88="" 9.72=""> <avg 34.40="" 9.81=""> <cyl -="" 0.59="" 178=""> </cyl></avg></r2></r1></l></pre> | |
| | <r> mm D deg <r1< td=""> 9.67 34.90 28 <r2< td=""> 9.57 35.27 118 <avg< td=""> 9.62 35.08 > <cyl< td=""> -0.37 28 ></cyl<></avg<></r2<></r1<></r> | |
| ľ | <l> mm D deg <r1< td=""> 9.85 34.26 179 > <r2< td=""> 9.45 35.71 89 > <rvg< td=""> 9.65 34.97 > <cyl< td=""> - 1.45 179 ></cyl<></rvg<></r2<></r1<></l> | ; |
| n | PS <r>mm</r> | |
| 0 | 6.6 <l> mm 6.1</l> | - |
| p | Ref. (External input) <r> S C A</r> | |
| q | $\begin{array}{cccccccccccccccccccccccccccccccccccc$ | |
| r | NIDEK AL-Scan M | - |

| а | ID |
|---|--|
| b | Patient name*and gender* |
| С | Measurement date and time* |
| d | Memo* |
| е | Operator's name |
| f | Messages related to measurement data |
| g | Axial length combined wave value and SNR for right eye Eye type for right eye AL waveform of the right eye* |
| h | Axial length combined wave value and SNR for left eye Eye type for left eye AL waveform of the left eye* |
| i | Corneal refractive index to obtain KM values |
| j | KM 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 |
| k | KM values of the left eye (ø2.4)* |
| I | KM values of the right eye (ø3.3) |
| m | KM values of the left eye (ø3.3) |
| n | Pupil diameter for the right eye |
| 0 | Pupil diameter for the left eye |
| р | Entered Ref. value for the right eye |
| q | Entered Ref. value for the left eye |
| r | Comment |

For the items indicated with *, they might not be printed depending on the parameter settings.

4.6.2 Exporting measurement results

This section describes the procedure to export the measurement results to a shared folder of the computer or a USB flash drive.

Setting

- To export the measurement results automatically after they are saved in the database
 - Uncheck "Select Each Time" in "Output After Meas.", and check "Network" or "USB".
- · To export the measurement results manually

Check "Select Each Time" in "Output After Meas.". Both the settings for printing and exporting can be set to "Select Each Time" in "Output After Meas.".

• The measurement results can be exported for each export destination ("Folder1" to "USB").

Check "Data" to export the measurement results.



Exporting the measurement results to a shared folder or USB flash drive automatically

Press **Save** on the measurement result confirmation screen.

When "Follow-up" is selected in "Exam Mode", press the button on the measurement screen.

When the measurement results are saved to the database, they are automatically exported.



Exporting the measurement results to a shared folder or USB flash drive manually

1 Press **server** on the measurement result confirmation screen.

When "Follow-up" is selected in "Exam Mode", press the button on the measurement screen. Measurement result is saved to the database.

2 Check "Network" or "USB".

3 Press OK

The measurement results are saved in the specified export destination.



4.7 Editing Patient Information

Exam Mode

Results/Follow-up

4.7.1 Deleting all the information and data of the patient

1 Select the patients to be deleted on the patient list screen.

2 Press

Enter the password if the administrator password is set.





All the patient data to be selected are deleted.



4.7.2 Editing patient list information

1 Select the patient to be edited on the patient list screen.

The selected line of the patient is highlighted in blue.

2 Press 📴 Edit

| ID | :13009 :NIDEK, KEN | - Menu |
|-----------------|-----------------------|-------------------|
| 📑 New 🔶 Measure | | Follow-up |
| Search Criteria | | |
| | Last | Clear Edit 🕤 Del |
| Patient List | Search Results 3 | 3/Patients 3 1/ 1 |
| ID 🔺 | Name | Exam Dat 2 |
| 13007 | NIDEK, SARA | 11/05/2022 |
| 13008 | NIDEK, GEORGE | 26/04/2022 12:14 |
| 13009 | NIDEK, KEN | 26/04/2022 15:29 |
| \square | | |
| (1) | | |
| <u> </u> | | |
| | | |
| | | |
| | | |
| | | |

3 Edit the desired items.

└ * "4.3.2 Registering patient information" (page 62) The ID cannot be changed.



| | 13009 O Male Female |
|-------------|-----------------------------------|
| Last | NIDEK |
| First | KEN |
| Middle | |
| DOB | 05/05/2010 🛃 Chart Tideman [Male] |
| Memo | |
| S 19 | Po R Phakic Phakic |
| | OK Cancel |
| | 4 |

5 Press Yes

The changes are saved, and the patient list screen is displayed again.

| No | Cancels saving the changes, and the patient list screen is displayed again. |
|--------|---|
| Cancel | Cancels saving the changes, and the patient information registration screen is displayed again. |



4.8 Checking and Editing Follow-up

| Exam Mode | Results/Follow-up |
|-----------|-------------------|
| | |

This section describes the procedures for checking and editing the change in patients with age on the Follow-up screen (Trend Graph, Progression Chart, and Data).

When "Follow-up" is selected in Exam Mode, the Follow-up screen for the patient is automatically displayed after the measurement results are saved.

4.8.1 Checking Follow-up (Trend Graph)

The graph (trend graph) showing a change in measurement value with age of the patient is displayed.

- **1** Select the patient to check their follow-up on the patient list screen.
- 2 Press Follow-up

| ID | :13009 :NIDEK, KEN | | Menu |
|-----------------|-----------------------|------------------|--------|
| New Measure | | Fol low-up | |
| Search Criteria | Last | | 💣 De I |
| Patient List | Search Results | 3/Patients 3 | 1/ 1 |
| ID 🔺 | Name | Exam Date | |
| 13007 | NIDEK, SARA | 11/05/2022 10:02 | |
| 13008 | NIDEK, GEORGE | 26/04/2022 12:14 | |
| 13009 | NIDEK, KEN | 26/04/2022 15:29 | 5 |
| | | | |
| (1) | | | |
| | | | |
| 1 - 1 | | | |
| | | | |
| | | | |
| | | | |

17

3 Check the change in the measurement values with age on the Follow-up screen (Trend Graph).

| а | Used to toggle the graphs of the right and left eyes. | |
|---|--|---|
| b | Used to change the number of years for the hori- zontal axis. | O Trend rig sin Data |
| С | AL trend graph (blue) Displays the change in axial length with age. | Graph 3 years AL:2- 32[mm] • Ref0.94[D] • KM:7 |
| d | Ref. trend graph (purple) Displays the change in refractive error with age. | |
| е | KM trend graph (orange) Displays the change in KM with age. | |
| f | Heart Output Used to export the Follow-up data in the Report format (jpeg file for printing). | r (rest) 15 16 |
| g | Measurement values of touched plot points (verti- cal line in blue) | |
| h | Vertical axis AL (blue), Ref. (purple), and KM (orange) values | |
| i | Horizontal axis Age (If the date of birth is not entered, the year is displayed instead.) | |
| j | Measurement date of touched plot points | |



Knowledge

• If the interval between the measurement dates is short, not all the data are displayed in the trend graph.

The minimum display interval varies depending on the number of years displayed on the horizontal axis.

If there are multiple data in the minimum display interval, only the latest data is displayed. The minimum display interval is as follows:

For 3 years:14 days

For 5 years: 26 days

For 10 years: 56 days

4.8.2 Checking Follow-up (Progression Chart)

Trend graphs of patients can be viewed with a progression chart overlaid.

The progression chart is a graph showing axial length change with physical growth based on the published article by Tideman.

Help

- When date of birth is not entered, "DOB not entered" is displayed and the progression chart is not displayed.
- **1** Select the patient to check their follow-up on the patient list screen.
- 2 Press Follow-up.
- 3 Press Progression Chart

The progression chart and the graph of change in axial length with age are overlaid.

| | ID :13009 Name :NIDEK, KEN |
|-----------------------------|--|
| Trend Graph | Progression Chart Data |
| Right | 3 ars |
| KM Ref. AL [mm] [D] [mm] | WRL.24. Sz [img] Wier O. S4[b] WRL.7. S5 [img] |
| 7.0 -6.0 26 | |
| 7.5 -3.0 24 | • • • • • • • • • |
| | |
| 0 0 0 22 | |

4 Check the graphs on the Follow-up screen (Progression Chart).

| а | Chart Used to toggle the progression chart. | a b c d e |
|---|--|---|
| b | AL trend graph of the left eye (green) Displays the change in axial length with age. | ID INDEX, KEN |
| с | AL trend graph of the right eye (red) Displays the change in axial length with age. | Chart Tidem v[Male] • Right: 32[m] • Left:24.38[mm] Percentile 27 Tidem • Sight: 955 955 |
| d | Progression chart A graph to compare changes in the axial length with age with the statistical information based on the published article by Tideman | 26 Male 105 k 105 k) -905 25 73 k a 05 k 15 k) -905 26 73 k a 05 k 15 k) -905 26 73 k a 05 k 15 k) -905 36 a 75 k 35 k) -905 -905 23 75 k 35 k) -905 -905 30 a 75 k 35 k) -905 -905 |
| е | Measurement values of touched plot points | 22 00 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 |
| f | Vertical axis Axial length value | 20 (n = mycpia, hm = high mycpia) 12/05/2022 Age [years] R 8 10 12 14 16 18 20 22 Adults |
| g | Horizontal axis Age | |
| h | Measurement date of touched plot points | |
| i | Percentile Percentage of children at ages 6, 9, and 15 and adults who have axial lengths the same as or shorter than those on each percentile curve of the progression chart | |



Knowledge

• If the interval between the measurement dates is short, not all the data are displayed in the progression chart.

- If there are multiple data in 141 days, only the latest data is displayed.
- Toggling progression chart
 - 1) Press 🔛 Chart .
 - 2) Select the chart for male or female if necessary.
 - 3) Press OK



Progression chart

AL measurement values are plotted on the Growth chart based on the published article by Tideman and others listed below.

Tideman[Male] is a chart for males and Tideman[Female] is for females.

This chart is based on studies conducted in some parts of Europe.

Reference: Axial length growth and the risk of developing myopia in European children

Tideman JWL, Polling JR, Vingerling JR et al.

Acta Ophthalmol. 2018: 96: 301-309

| j | Percentage of people found to have myopia (chil- dren at age 9) Statistical percentage of children at age 9 with the applicable axial length who were found to have myopia | |
|---|---|--|
| k | Percentage of people found to have myopia (adults) Statistical percentage of adults with the applica- ble axial length who were found to have myopia | Or raph Onit Data 27 rideman [Mate] • Right:24.48[m] • Left:: 1.42[r] J. Pricetilie 27 Tideman 005.15 m 995 995 25 726 005.15 m 995 |
| I | Percentage of people found to have high myopia (adults) Statistical percentage of adults with the applica- ble axial length who were found to have high myopia High myopia: Myopia with spherical equivalent of -6 D or worse | AL (Im) 23 24 33 25 22 33 24 68 23 24 33 25 68 25 75 26 22 3a 68 10 10 26 75 26 76 26 76 26 76 26 7 |

4.8.3 Checking Follow-up (Data)

The measurement history of the patient saved in the database is displayed.

- **1** Select the patient to check their follow-up in the patient list.
- 2 Press **Follow-up**.
- 3 Press Data

| | | | ID Name | :13009 Be :NIDEK, KEN | |
|-------------|-------------|-------------|----------------------|---|--|
| • 2 | ire Gra | nd ph | Progression Chart | O Data | |
| | Ri | ght | 3 years | 24.32[mm] = Bef :=0.94[D] = KW-7.99[mm] | |
| KM [100] | Ref. [D] | А. [111] | | | |
| 7.0 | -6.0 | 26 | | | |
| 7.5 | -3.0 | 24 | | | |
| 7.5 | 0.0 | 2.4 | | | |
| | | 22 | | • • • • • • | |

4 Check or edit the data list.

| а | Used to print the data of a selected measure- ment or export it in a data format (xml file). | a | | | ID : Name : | 13009 NIDEK, KEN | | D Patient List | | C port (ut t | |
|---|---|---------------------------------------|---------------------------|--------------------------|--|---|--|--|---|--------------------------------------|---------------------|
| b | Ref. Input Used to enter the Ref. value in the selected data. | | ind iph utput te | Progre Ch R/L R | AL 24. 32 | Data КМ (R1, 7.99, | , R2) 7.99 | Ref. Input Ref. (SPH, CYL -0.72, -0.4 | , Axis) 4, 49 | De I PS 4.40 | Page 1/7 |
| с | Used to delete the selected data. | 12/05 13/02 16/11 | /2022 /2022 /2021 | L R L R L | 24. 38 24. 30 24. 37 24. 30 24. 38 | 8.00, 8.00, 8.01, 8.01, 8.01, | 7.99 7.99 7.98 8.00 7.99 | -0. 86, -0. 14 -0. 65, -0. 44 -0. 81, -0. 14 -0. 67, -0. 44 -0. 84, -0. 14 | 3, 97 3, 49 3, 97 3, 45 3, 45 | 4.60 4.20 4.30 4.50 4.30 | _ _ _ _ |
| d | Data list Displays the list of measurement history of the patient. | 13/08, 09/05, 08/02, | /2021 /2021 /2021 | R L R L R | 24. 28 24. 37 24. 28 24. 37 24. 25 24. 25 | 8. 02, 8. 01, 8. 03, 7. 99, 8. 05, 8. 01 | 7.99 7.98 8.00 7.99 7.99 7.99 | -0. 62, -0. 42 -0. 81, -0. 14 -0. 63, -0. 42 -0. 84, -0. 14 -0. 56, -0. 4 | 2, 55 3, 97 2, 54 3, 96 1, 47 | 4.50 4.40 4.50 4.60 4.30 | |
| е | If the patient list has multiple pages, press this button to change the page. | | | | | | | | | | e |

- Deleting the selected measurement data
 - 1) On the Follow-up screen (Data), select the data to be deleted.
 - 2) Press 🕤 🔤 .

A message is displayed.

3) Press OK

The selected data is deleted from the database.

| | | ID Name | : 13009 : NTDEK, KEN | Patient Eist | Report Output |
|------------------|---------------|------------|-------------------------|-----------------------|---------------|
| • Trend Graph | Progre Cha | ssion 💽 I | Data | | |
| Output | | | | Ref. Input | Del |
| Date | R/L | AL | KM(R1, R2) | Ref. (SPH, CYL, Axis) | Pf 1/ 7 |
| 12/05/2022 | R | 24. 32 | 7. 99, 7. 99 | -0. 72, -0. 44, 49 | 4. |
| 12/05/2022 | | 2A38 | 8.00, 7.99 | -0. 86, -0. 18, 97 | 4. (2) |
| 12/02/2022 | R | - A | 8.00, 7.99 | -0.65, -0.43, 49 | 4. |
| 13/02/2022 | L | _(1)_ | 8.01, 7.98 | -0.81, -0.18, 97 | 4.30 |
| 16/11/0001 | R | | 8.01, 8.00 | -0. 67, -0. 43, 45 | 4.50 |
| 16/11/2021 | L | 24. 38 | 8.00, 7.99 | -0.84, -0.18, 90 | 4.30 |
| 12/08/2021 | R | 24. 28 | 8. 02, 7. 99 | -0. 62, -0. 42, 55 | 4.50 |
| 13/08/2021 | L | 24. 37 | 8.01, 7.98 | -0.81, -0.18, 97 | 4.40 |
| 00 /05 /0004 | R | 24. 28 | 8.03, 8.00 | -0.63, -0.42, 54 | 4.50 |
| 09/05/2021 | L | 24. 37 | 7.99, 7.99 | -0.84, -0.18, 96 | 4.60 |
| 00/02/2021 | R | 24. 25 | 8.05, 7.99 | -0. 56, -0. 41, 47 | 4.30 |
| 06/02/2021 | L | 24. 36 | 8.01, 7.98 | -0. 79, -0. 18, 91 | 4. 20 |

- Entering refractive error
 - 1) Select a data line in which to enter the refractive error on the Follow-up screen (Data).
 - 2) Press Ref. Input .



3) Enter the refractive error for both right and left eyes.

↔ "4.5.3 Entering refractive error" (page 76)

4) Press OK



- Exporting the selected measurement data
 - 1) On the Follow-up screen (Data), select the data to be exported.
 - 2) Press Soutput.

| | | ID : Name : | 13009 NIDEK, KEN | | Patient List | P | aport Output | |
|---------------------|---------------|----------------|---------------------|------|-------------------|----------|--------------|------|
| • Trend Graph | Progre Cha | ssion 💽 🖸 | Data | | | | | |
| Output | | | | | Ref. Input | 2 | Del | Dama |
| | R/L | AL | KM(R1, | R2) | Ref. (SPH, CYL, A | xis) | PS | 1/ 7 |
| | R | 24. 32 | 7. 99, | 7.99 | -0. 72, -0. 44, | 49 | 4.40 | |
| Z) Z | | 2A38 | 8. 00, | 7.99 | -0. 86, -0. 18, | 97 | 4.60 | |
| 12/02/2022 | R | 7/20 | 8. 00, | 7.99 | -0.65, -0.43, | 49 | 4. 20 | |
| 13/02/2022 | L | -/1»- | 8.01, | 7.98 | -0.81, -0.18, | 97 | 4. 30 | |
| 16/11/2021 | R | -121- | 8.01, | 8.00 | -0.67, -0.43, | 45 | 4. 50 | |
| 16/11/2021 | L | 24. 38 | 8. 00, | 7.99 | -0.84, -0.18, | 90 | 4. 30 | |
| 12/00/2021 | R | 24. 28 | 8. 02, | 7.99 | -0.62, -0.42, | 55 | 4. 50 | |
| 13/08/2021 | L | 24. 37 | 8.01, | 7.98 | -0.81, -0.18, | 97 | 4.40 | |
| 00 /05 /0001 | R | 24. 28 | 8. 03, | 8.00 | -0.63, -0.42, | 54 | 4. 50 | |
| 09/05/2021 | L | 24. 37 | 7. 99, | 7.99 | -0.84, -0.18, | 96 | 4.60 | |
| 00/02/2021 | R | 24. 25 | 8. 05, | 7.99 | -0.56, -0.41, | 47 | 4. 30 | |
| 06/02/2021 | L | 24. 36 | 8.01, | 7.98 | -0. 79, -0. 18, | 91 | 4. 20 | |
| | | | | | | | | |

 When a window to confirm the export destination of the measurement data is displayed, press the desired export destination and press





• To export the Follow-up data to the destination specified in advance

Uncheck "Select Each Time" in "Measurement Data Output" of the Follow-up parameter, and check "Print", "Network", or "USB".

• To export the Follow-up data after specifying a shared folder or USB flash drive

Check "Select Each Time" in "Measurement Data Output" of the Follow-up parameter.

• The measurement data can be exported to each export destination ("Folder1" to "USB").

The measurement data is exported to the export destination for which "Data" is checked.

| | >> Parameter Settings • |
|--|--|
| | ● Oper ● Measure ● Followup ● Print ● Output ● Other |
| | Trend Graph |
| | Report Output |
| | Resourcement Data Output Select Each Time Print Network USB |
| | Cutput Destination |
| | >> Parameter Settings • |
| | Oper Messure fillerup Print Output Other |
| | Output to Folder1 Folder2 Folder Name: Data |

4.9 Exporting Follow-up Data

4.9.1 Exporting follow-up data

This section describes the procedure for exporting the follow-up data as a jpeg file for printing.

When exporting the data of a selected measurement on the Follow-up screen (Data), see "• *Exporting the selected measurement data*" (page 89).

Setting To export the follow-up data to the destination specified in advance

Uncheck "Select Each Time" in "Report Output" of the Follow-up parameter, and check "Network" or "USB".

 To export the follow-up data after specifying a shared folder or USB flash drive

Check "Select Each Time" in "Report Output" of the Follow-up parameter.

• The follow-up data can be exported to each export destination ("Folder1" to "USB").

When "Report" is checked, the follow-up data is exported as a jpeg file for printing.



- **1** Select the patient to export their follow-up data on the patient list screen.
- 2 Press Follow-up.

→ Follow-up screen

ID Name :13009 :NIDEK, KEN Search Criteria ID> Last Search Result atient List 13007 NIDEK, SARA 11/05/2022 10:02 13008 NIDEK, GEORGE 26/04/2022 12:14 26/04/2022 15:29 13009 NIDEK, KEN



3 Press Report Output

4 When the Output window is displayed, press the desired export destination and press **C**K**C**.

| Network | Shared folder |
|---------|-------------------|
| USB | A USB flash drive |

The follow-up data is exported.



4.9.2 Printing the exported data using computer-connected printer

This section describes the procedure for printing a jpeg file exported in the Report format using a computer-connected printer.

The printing procedure differs depending on the software or operating system of the computer to be used.

- **1** Open the folder containing the data to be exported.
- **2** Right-click the jpeg file to be printed, then select "Print" from the menu.



The files are named as shown below. Select the jpeg file to be printed referring to the patient ID or exported date.

| 1: | 3009_20220526_154704_NIDEK-ALScan_MYO-D_00CC07_000.jpg |
|----|--|
| | a b c d e |
| а | ID |
| b | Exported date |
| С | Exported time |
| d | Mac address of the AL-Scan M |
| е | Page number |

- **3** Specify the printer settings if necessary.
- **4** Press [Print].



• Measurement results sample printout





Z

Setting

• When the report on the second page of the jpeg file is not necessary, uncheck "2nd page".



Knowledge

- The following items depend on the settings on the Follow-up screen at the time of export.
 - Types of progression chart
 - The number of years for the horizontal axis in trend graph



DEVICE SETTINGS AND CONNEC-TION

5.1 Parameter Settings

This section describes how to change the parameters and explains each setting.

1 Press **on the patient list screen**.





Enter the password if the administrator password is set.

3 Select the parameters to be changed from [Oper] to [Other].



>> Parameter Settings <

| 2 | |
|-----------|--|
| 3 | |
| 4 | |
| 5 Default | |
| | |
| | |
| Settings | |

O Print O Outr

| Button | Settings |
|-----------|--|
| Oper | Settings of operator Settings of operator's name" (page 96) |
| Measure | Measurement condition such as the number of measurements and refractive index * Measure settings" (page 98) |
| Follow-up | Settings for Follow-up screen ↓ "♦ Follow-up settings" (page 99) |
| Print | Settings for printing using the printer ↓ "♦ Output settings" (page 101) |
| Output | Settings of the data to be exported through a network/USB |
| Other | Settings for various items such as name and date ↓ "♦ Other settings" (page 102) |

- **4** Change the parameter settings.
 - Items to be selected

Select them with the buttons. The selected parameter turns ().

• Items to be entered

Press the button of the desired item to be entered. Enter the desired setting with the numeric keypad or keyboard window.

↔ "♦ Numeric keypad window" (page 37)

☆ "♦ Keyboard window" (page 38)

Items for functions to be turned on and off

The desired function is turned on when the button is checked by pressing it.

Registering operator's name

Up to 5 operators can be registered.

- 1) Press [Oper] on the Parameter Settings screen.
- 2) Press the Name field of No. 1 in the list.

KM Disp Unit







3) Enter the name of the operator and press Operator Na

The operator's name can be registered for No.2 to 5 in the same manner.



- Changing display language
- 1) Press [Other] on the Parameter Settings screen.
- 2) Press Language

0K

| >> Parameter Settings < |
|--|
| Oper Okesure follow Print Output O Other |
| Language English |
| Beep 2 O Normal O High I D Burdeht Octions |
| Low O Medium O High Auto ID Birth Date Display |
| OL, F. MI. OFL. MI. OL F. MI. |
| Sleep Time ● 0FF ○ 5 ● 10 ● 15 min |
| Print OK Cancel |

- 3) Select the display language.
- 4) Press OK



5 Print the parameter settings if necessary.

Pressing **Print** prints all the parameter settings.

6 Press OK

The settings are saved, and the patient list screen is displayed again.

| Print AL Print S AL Wave KM Print S KM Mire Phi=2.4 Format I Econo.Print Name Print Date Print Memo Print Comment NIDEK AL-Scan | hort No hort, 3. 3 tems Yes Yes Yes Yes |
|--|--|
| Network, USB Output to Folder1 Measure Data Follow-up Report ACK Timeout Folder2 Measure Data Follow-up Report ACK | Yes Yes No 5sec No No |

Measure settings



The setting options in the brackets indicate the factory initial settings. The same applies to other settings.

Settings Item [Results], Follow-up Setting for the screen to be displayed after the measurement Exam Mode Results: Measurement result confirmation screen Follow-up: Follow-up screen Initial setting: Unchecked Before Meas. Checking this box displays the Ref.Input window before the measurement screen is dis-Ref.Input played. AL: 1 to 10 (Initial setting: 3) KM: 3 to 10 (Initial setting: 3) Sets the number of times of measurements for the axial length (AL) and corneal curvature Number of Measurements radius (KM). Press each button and enter the number of successive measurements using the numeric keypad window. [mm], D Sets the KM value whether to display in corneal curvature radius or corneal refractive KM Disp Unit power. mm: corneal curvature radius display (R1, R2) D: corneal refractive power (K1, K2) [-CYL], +CYL Sets the display of cylindrical values (cylindrical refractive error). KM Cylinder -CYL: Indicates the cylindrical value by minus reading +CYL: Indicates the cylindrical value by plus reading [R1, R2], AVG, CYL Sets the display method of the KM value. KM Display R1, R2: R1 (flattest meridian measurement value), R2 (steepest meridian measurement value) display AVG, CYL: AVG (average of R1 and R2 values), CYL (corneal cylindrical power) display 1.3380, [1.3375], 1.3360, 1.3320, 1.3315 Ref.Index Sets the corneal refractive index used to convert the unit of the corneal curvature radius from mm to D (diopter). Initial setting: Select Each Time, Print, and Network are checked.

 Output After Meas.
 Initial setting: Select Each Time, Print, and Network are checked.

 Select Each Time: Setting whether to confirm the export destination every time when the measurement data is exported

 Output Destination: Setting for export destination when Select Each Time is not checked



Knowledge

• The current settings for the KM Disp Unit, KM Cylinder, and KM Display parameters are used in the save data display as well.

Follow-up settings

| >> Parameter Settings < | K |
|---|--------------------|
| ● Oper ● Messure ○ Follows ● Print ● Output ● Other | |
| Trend Graph | 5 years 🔵 10 years |
| Report Output | |
| Measurement Data Output Output Destination Select Each Time Print Network USB | |
| Report Output Destination | |
| Print | OK Cancel |

| Item | Settings | |
|------------------------------|---|--|
| Trend Graph | AL, KM, Ref. | |
| | Sets the type of trend graph displayed on the Follow-up screen (Trend Graph). AL: Displays the AL trend graph (Checked, cannot be changed) KM: Display the KM trend graph. (Initial setting: Checked) Ref.: Display the Ref. trend graph. (Initial setting: Checked) | |
| Saala | [3 years], 5 years, 10 years | |
| Scale | Sets the number of years for the horizontal axis of the trend graph. | |
| Report Output | Initial setting: Checked | |
| 2nd page | If the second page in Report format is not necessary, uncheck the button. | |
| | Initial setting: Select Each Time, Print, and Network are checked. | |
| Measurement Data Out- put | Select Each Time: Sets whether to confirm the export destination every time when | |
| | is pressed on the Follow-up screen (Data). | |
| | Output Destination: Sets export destination when Select Each Time is not checked | |
| | Initial setting: Select Each Time and Network are checked. | |
| Report Output | Select Each Time: Sets whether to confirm the export destination every time when | |
| | Report Output is pressed on the Follow-up screen. | |
| | Output Destination: Sets export destination when Select Each Time is not checked | |

Print settings



| Item | Settings | |
|---------|--|--|
| | [Short], All | |
| AL | Sets the printing contents of AL measurement values. Short: Prints the combined wave value only. All: Prints all the measurement values. | |
| | Initial setting: Unchecked | |
| Wave | Checking this parameter prints the AL waveform obtained by adding up all measured waveforms. | |
| | R->L, [Items] | |
| Format | Sets the printing order of measurement results for when there are measurement data of both eyes. R->L: Prints all the data of the right eye, then prints all the data of the left eye. Items (initial setting): Prints data of both eyes for each measurement item. | |
| | [Short], All | |
| КМ | Sets the printing contents of KM values. Short: Prints the median value only. All: Prints all the measurement values. | |
| KM Mire | Φ3.3, [Φ2.4 Φ3.3] | |
| | KM measurement is performed with the 2.4-diameter and 3.3-diameter mire rings. Set whether to print measurement values using both of the mire rings or using the 3.3-diameter mire ring only. Φ3.3: Prints measurement values using the 3.3-diameter mire ring. Φ2.4 Φ3.3: Prints measurement values using both the 2.4-diameter and 3.3-diameter mire rings. | |
| | Econo. Print, Name Print, Date Print, Memo Print | |
| Options | Sets the options for printing. Econo. Print: Lessens the space between lines of printout. (Initial setting: Checked) Name Print: Prints the patient information (name and gender). (Initial setting: Checked) Date Print: Prints the measurement date and time. (Initial setting: Checked) Memo Print: Prints the contents of the Memo box in the patient information. (Initial setting: Checked) | |
| Comment | Enter the desired printing contents in the Comment box. | |

Output settings

| ≫ Parameter Settings < | ≫ Parameter Settings < |
|--|---|
| ● Oper ● Messure ● Follow ● Print ◎ Output ● Other | ● Oper ● Messure ● Follows ● Print ◎ Output ● Other |
| Output to Folder1 Folder2 Folder3 USB Folder Name:Data | Output to Folder1 Folder2 Folder3 USB |
| Measure Data Follow-up | Veasure Data Follow-up |
| ACK 5 sec | Report |
| File Name | File Name |
| Print OK Cancel | V Cancel |

| Item | Settings | | |
|---|---|--|--|
| Folder1 (The settings for Folder2 and Folder3 are the same.) (Settings for exporting to a shared folder) | | | |
| Folder Name: | Displays the folder name specified in the LAN Settings window. 🏷 (page 118) | | |
| Measure | Initial setting: Checked (Folder1 only) | | |
| Data | When the button is unchecked, the measurement data (xml file) is not exported to Folder1. | | |
| Follow-up | Initial setting: Checked (Folder1 only) | | |
| Report | When the button is unchecked, the Follow-up data (jpeg file for printing) is not exported to Folder1. | | |
| | Initial setting: Unchecked | | |
| ACK | When the time specified in the Timeout box has passed after the end of data export, con- firm that the exported data has been acquired by the acquisition software. If the data has not been acquired by the software, an error message is displayed. | | |
| Timeout | 1 to 120 sec (Initial setting: 5 sec) | | |
| | Sets the time between data export and confirmation of data acquisition (enabled only when the "ACK" button is checked). | | |
| File Name | Initial setting: Unchecked | | |
| With Patient Name | Checking this box adds the patient name to the file name of the data to be exported. Do not check this box when communicating with NAVIS-EX. | | |
| USB (Settings to export to a | a USB flash drive) | | |
| Measure | Initial setting: Checked | | |
| Data | When the button is unchecked, the measurement data (xml file) is not exported to the USB flash drive. | | |
| Follow-up | Initial setting: Checked | | |
| Report | When the button is unchecked, the Follow-up data (jpeg file for printing) is not exported to the USB flash drive. | | |
| File Name | Initial setting: Unchecked | | |
| With Patient Name | Checking this box adds the patient name to the file name of the data to be exported. | | |



Setting

For network, LAN setting is necessary.
 ♥→ *◆ Setting the LAN connection" (page 119)

S Knowledge

• When "Data" in "Measure is checked, the style sheet and jpeg images are exported 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 the desired format.

Should the style become improper, delete the style sheet and export the data again.

Other settings



| Item | Settings | |
|---------------|---|--|
| | 日本語, [English], Français, Deutsch, Italiano, Português, Español | |
| Language | Sets the display language. | |
| | Pressing Language displays the Language menu. | |
| | OFF, [Normal], High | |
| Веер | Sets the beep. The sound can be confirmed by pressing each button. | |
| | Low, [Medium], High | |
| LCD Backlight | Sets the brightness of the touch screen. Pressing each button allows you to check the brightness. | |
| Namo | [L,F MI.], F L MI., L F MI. | |
| Name | Sets the display method of the name. | |
| | OFF, [5 min], 10 min, 15 min | |
| Sleep Time | Sets the time when the screen is turned off and the device enters sleep mode when the device is idle. OFF: The device does not enter sleep mode. | |
| | Y/M/D, M/D/Y, [D/M/Y] | |
| Date Format | Sets the display format of the DOB and measurement date. This format setting is also used when the date of birth is entered. | |

| Item | Settings | |
|---------|--|--|
| Message | Notice, Patient, Measurement | |
| | Notice: Displays the message "The number of saved exams has exceeded the limit. Back up and delete data." at startup when the number of saved measurement data exceeds 9,000. (Initial setting: Checked) | |
| | Patient: Displays the message "Database has reached its maximum number of entries. To save, delete the oldest entry from the database." before the patient registration information screen is displayed when the number of the registered patients reaches 10,001. (Initial setting: Checked) | |
| | When this box is not checked, the oldest data item is overwritten by the new data without displaying the message. | |
| | Measurement: Displays 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 10,001 or when the number of saved measurement data for one patient reaches 99. (Initial setting: Checked) When this box is not checked, the oldest data item is overwritten by the new data without | |
| | displaying the message. | |
| | Auto ID, Birth Date Display | |
| Options | Auto ID: Setting of whether or not to automatically assign patient ID numbers in numerical order. (Initial setting: Unchecked) A number from 000001 to 010001 is assigned as a patient ID in numerical order. Since only a maximum of 10,000 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. | |
| | in the patient list and the ID field at the top of the screen. In addition, it is printed along with the measurement results. (Initial setting: Unchecked) | |

5.2 Maintenance Operation

This section describes the maintenance operations on the Maintenance screen.

• To back up data in a USB flash drive, be sure to use only the optional USB flash drive specified by Nidek.

• Do not turn off the power switch of the device during data backup. The data may be broken.

5.2.1 Backing up database

This section describes the procedure to back up a database to a USB flash drive or a computer. All the patient information and measurement results are backed up at once. It is not possible to back up individual patient information or measurement results.

1 Press **e** on the patient list screen.



Menu



Enter the password if the administrator password is set.



| | Maintenance | |
|------------------------|--|-----------------|
| > Maintenance < 🚺 Back | | |
| Database | Maintains databases. | Admin. Password |
| ackur Parters | Backs up/Restores parameters. | Service |
| LAN S jings | Configures settings for IP address and file sharing. | |
| eader Settings | Configures settings for barcode scanner and card reader. | |
| Touch Panel | Calibrates touch panel. | |
| Date/Time | Set date and time. | |
| Model Eye | Measures model eyes. | |
| Information | | |

Version SOFT:V*.***.** FPGA:R**/** Serial No.:******

4 Select the backup destination.

In the backup destination, it is necessary to free up space more than the file size shown in the "Backup Size" a field.

| Database | | X |
|---|---|---|
| Device Patient : 7 Weasurement Data : 1 | Backup to Patient : - USB Wessurement Data : - Date:// Information | |
| Backup Size : 987 Backup Rebuird | . 7 KByte Clos | e |

- When [USB] is selected
 - 1) Open the side panel cover.
 - 2) Insert the USB flash drive to the USB port **b**.



When [LAN] is selected

A shared folder on a computer connected by a LAN is the backup destination. *5.3.1 LAN connection and settings" (page 116)




5.2.2 Restoring the database using backup

This section describes the procedure to restore (rebuilding) the database contents to the backed-up state. Measurement data taken after the backup is deleted.

- **1** Press **form** on the patient list screen.
- 2 Press Maintenance

Enter the password if the administrator password is set.

3 Press Database

4 Select the backup destination.

| [USB] | A USB flash drive When [USB] is selected, insert the USB flash drive. |
|-------|---|
| [LAN] | A shared folder on the computer con- nected by a LAN |



5 Press Information.

6 Check the information a for the backup database at the destination. Press Rebuild to restore the database to the backed-up state.

→ Confirmation message



7 Press OK

Database is restored to the backed-up state.

8 Press **Close** to return to the Maintenance screen.

5.2.3 Deleting old data from database

This section describes the procedure to delete the old data from the database by specifying the number of data to be deleted.

- **1** Press **mean** on the patient list screen.
- 2 Press Maintenance

Enter the password if the administrator password is set.

- 3 Press Database
- 4 Press g Delete



- **5** Press Measurement Data and enter the number of data to be deleted starting from the oldest data.
- 6 Entering the number of data to be deleted displays the date a of the most recent data to be deleted in "Most Recent Date". Confirm the range of data to be deleted.



7 Press ok

The specified number of data is deleted from the oldest data.

Database screen

8 Press **Close** to return to the Maintenance screen.

5.2.4 Backing up parameter settings

This section describes the procedure to back up the parameter settings to the internal CF card, USB flash drive, or computer via LAN.

| | Settings of the Maintenance screen |
|--------------------|---|
| Backed up contents | Settings of the Parameter Settings screen |
| | Measurement conditions |

1 Press **e** on the patient list screen.

2 Press Maintenance

Enter the password if the administrator password is set.

3 Press Backup/Restore Parameters



4 Select the backup destination.

| [USB] | A USB flash drive When [USB] is selected, insert the USB flash drive. |
|---------------|---|
| [LAN] | A shared folder on a computer connected by a LAN |
| [Internal CF] | Internal CompactFlash card |



5 Select [Backup].



ess ok

The setting is backed up.

If the backup data already exists in the backup destination, the confirmation message asking whether or not to overwrite the data appears. Pressing overwrites the backup data.

5.2.5 Restoring parameter settings using backup

This section describes the procedure to restore the parameter settings to the backed-up status.

- **1** Press **____** on the patient list screen.
- 2 Press Maintenance

Enter the password if the administrator password is set.

3 Press Backup/Restore Parameters

4 Select the backup destination.

| [USB] | A USB flash drive When [USB] is selected, insert the USB flash drive. |
|---------------|---|
| [LAN] | A shared folder on a computer connected by a LAN |
| [Internal CF] | Internal CompactFlash card |



5 Select [Restore].

6 Press OK

Confirmation message

7 Press OK

The parameter settings are restored to the backed-up state.



5.2.6 Touch screen calibration

If the touched position and the activated position are misaligned on the touch screen, perform calibration of the touch screen.

- **1** Press **m** on the patient list screen.
- 2 Press Maintenance

Enter the password if the administrator password is set.

3 Press Touch Panel

→ Touch Panel Calibration screen



4 Press the center of each red cross (4 crosses in total) beginning with the one at the top left of the screen.

The red cross at the top left moves to top right, bottom left, then bottom right. Pressing the red cross at the bottom right finishes the calibration, and the Maintenance screen is displayed again.

| >> Touch | Panel | Calibrat | |
|----------|-------|----------|--|
| | | | |

Help

• If the touch screen has been misaligned so considerably that the screen does not react at all, turn on power to the device while pressing the touch screen.

Alignment of the touch screen is enabled again.

5.2.7 Setting date and time

Knowledge

- If the date and time settings in the device are not correct, 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, it takes about three days before the battery is fully recharged.
- Should measurement be performed when the date and time are not correct, the measurement data is saved with incorrect date and time. Therefore, changes in patients' in axial lengths with age cannot be confirmed properly.

Help

• When the device is operated for the first time after unpacking or when the device has not been operated for a long time (approximately 1 month), the internal clock may go wrong.

🏷 " No. 002 Clock error" (page 127)

- 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 appears at device start-up. Then the Date/ Time window appears. Set the internal clock to correct date and time by following *Step 4* and later below.
- **1** Press **content** on the patient list screen.

2 Press Maintenance

Enter the password if the administrator password is set.







Pressing or increases or decreases the value for the selected item.

Set "H" in the 24-hour time notation.

5 Press Close

The internal clock is updated to the set date and time.



5.2.8 Setting administrator password

| | Check To prevent change of various settings or data from the database by unauthorized personnel, an administrator password can be set to limit operators who can change the settings. Entering the administrator password is required in the following cases: When the patient data or measurement results are deleted When Parameter Settings or Maintenance is pressed on the menu screen |
|--------|---|
| 1 | Press common the patient list screen. |
| 2 | Press Maintenance . Enter the password if the administrator password is set. |
| 3 | Press Admin. Password . Database Maintenance C Back up/Restores parameters. Database Maintains databases. Admin. Password Backup/Restore Backs up/Restores parameters. LAN Settings Configures settings for Parameter S Configures settings for Parameter S Configures settings for Backs up/Restores parameters. LAN Settings Configures settings for Backs up/Restores parameters. LAN Settings Configures settings for Backs up/Restores parameters. Date/Time Set date and time. Model Eye Measures model eyes. |
| 4 | Press Current Password to enter the current password with the keyboard. The administrator password is not specified when the device is shipped. Enter nothing in the Current Password for the first time. |
| 5 | Press New Password to enter the new password with the keyboard. A maximum of 10 characters of a password can be entered |
| 6 7 | Press online Researce to enter the same password as in <i>Step 5</i> with the keyboard. Press ok to return to the Maintenance screen. |

5.3 Peripheral Device Connection

This section describes the procedures for LAN and barcode scanner connections.

- After consulting with the network administrator of the facility for network connection (LAN connection), specify the parameters for the computer.
- Turn off power to the device when connecting any cables.
- Use a computer compatible with CISPR32 when connecting a computer.
- Use only the barcode scanner specified by Nidek.
- Connect a LAN cable to the computer via the network switch. Proper communication may not be performed.
- When connecting the device with other devices, confirm that no patients, operators, or third parties are exposed to hazards. When connecting, removing, or upgrading devices, also confirm that there is no risk to the patient, operator, or third parties.
- Devices connected to the analog or digital interfaces must comply with relevant international standards concerning safety such as EN 60601-1, IEC 60601-1: Medical electrical equipment, etc. Furthermore, all configurations must comply with the system standard IEC 60601-1. When connecting a digital device to an input or output section on a medical system, the entire system, including the connected device, must conform to the IEC 60601-1 standard. If you have any questions, contact Nidek or your authorized distributor.



• Example of connecting LAN cables to the AL-Scan M and a computer

| No. | Communication method / communi- cation device | Connection destina- tion | Function |
|-----|--|-----------------------------|-------------------------------|
| 1 | Main body and LAN cable | LAN port | - |
| 2 | Computer and LAN cable | LAN port | Measurement data con- trol |
| 3 | Barcode scanner (optional) | USB port | Patient ID entry |
| 4 | Network switch | LAN port | _ |

5.3.1 LAN connection and settings

Connecting the LAN cable to the device

- **1** Turn off (\bigcirc) the power switch.
- **2** Connect the LAN cable to the device.
 - 1) Connect the LAN cable (straight cable) to the LAN port on the side panel.
 - 2) Connect the other end of the LAN cable to the network switch.
 - 3) Connect the export destination computer and the network switch with a LAN cable.
- **3** Turn on (**|**) the power switch.



LAN Settings window

• IP address and subnet mask



| Item | Settings | |
|-----------------|---|--|
| DHCP | Checks 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 initial setting "192. 168. 0. 60" as necessary. | |
| Subnet Mask | Used to enter the subnet mask. Change the initial setting "255. 255. 255. 0" as necessary. | |
| Default Gateway | Enter the default gateway. It is not necessary when the export destination for the data is within the network the device belongs to. The initial setting is blank. | |

• File Sharing

Up to 3 shared folders can be set as data export destinations. If the data exported from the AL-Scan M is used for multiple devices, create a separate shared folder for each device.

Specify which data is exported to which shared folder seeing "5.3.1 LAN connection and settings" (page 116).



| Item | Settings |
|--------------------|--|
| User Name | Enter the user name for the computer where the shared folders are created. |
| Password | Enter the login password associated with the user name for the computer where the shared folders are created. |
| Domain/Workgroup | 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 | Enter the name or IP address of the computer where the shared folders are created. When the export 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 (page 117). |
| Folder Name | Enter the name of the shared folders in the data export destination (a maximum of 3 shared folders) and backup destination. |
| Test | Press this button to test the communication. |

Setting the LAN connection

To export measurement results to the shared folder on the computer through a LAN, specify the following parameters in the LAN Settings window:

- The IP address and subnet mask of the AL-Scan M
- · Computer and shared folder as export destinations
- Default gateway if the export destination for the data is outside the network the device belongs to
- **1** Press **form** on the patient list screen.
- 2 Press Maintenance

Enter the password if the administrator password is set.

3 Press LAN Settings



- **4** Press [TCP/IP].
- **5** Specify the IP address and subnet mask of the AL-Scan M.

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 becomes effective after the device is restarted.

- LAN Settings
- **6** Set the default gateway only when the shared folder in the destination is outside the LAN network.
- **7** Turn off (\bigcirc) the power switch, then connect the LAN cable.
- **8** Restart the device, then display the LAN Settings window in the same manner as in *Step 1* to *Step 3*.

9 Press [File Sharing].



| LAN Settings | X |
|------------------------|-----------------------|
| • TCP/IP OFile Sharing | |
| File Sharing | <u></u> |
| User Name Guest | Password |
| Domain/Workgroup | PC Name/IP Address PC |
| FEALder Name | |
| Folder1 Data | |
| Folder2 Data2 | Test |
| Folder3 Data3 | Test |
| Backup | Test |
| <u> </u> | / |
| Pr int | 0K Cancel |
| | |

10 Enter the following information for the destination computer with the keyboard window by pressing the corresponding button.

- User Name
- · Password (when a password is required to connect to the computer)
- Domain/Workgroup
- PC Name/IP Address
- **11** Specify necessary parameters for the shared folders.

Up to 3 shared folders can be set as destinations of measurement results. Set the shared folders for each application to use the data. A shared folder can be set as a destination of backup data.

- Folder1 then enter the shared folder name. 1) Press
- 2) On the export destination computer, create the shared folder with a name the same as the entered folder name.
- 3) Press Test 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 in the destination computer. If such software is activated, an error may occur during communication test.

4) Specify Folder2 Folder3 settings as necessary. to

If the data export is not necessary, uncheck the "Data" and "Report" boxes for the folders in "Output to".

(page 101)

5) To create the backup data of the database or parameter set-

tings on the computer, press Backup then enter the shared folder name in the backup destination.

6) On the export destination computer, create the shared folder with a name the same as the entered folder name.



- 7) Press to return to the Maintenance screen. 0K

5.3.2 Connecting and setting barcode scanner

- **1** Connect the barcode scanner (optional).
 - 1) Open the side panel cover.
 - 2) Connect the barcode scanner cable to the USB

port a.

Connect the barcode scanner directly to the USB port. The device cannot recognize the barcode scanner through a USB hub.



- **2** Press on the patient list screen.
- 3 Press Maintenance

Enter the password if the administrator password is set.

4 Press Reader Settings



- **5** Select [Barcode] in "Mode".
- **6** Read the patient barcode with the barcode scanner, then confirm that the ID is displayed in "Test".

Pressing Print prints the settings.

7 Press **o** to return to the Maintenance-screen.





DEVICE MAINTENANCE

6.1 Troubleshooting

If the device does not function properly, attempt to correct the problem before contacting Nidek or your authorized distributor.

| Symptom | Remedy |
|---|--|
| The power indicator does not illuminate. | The power cord may not be plugged. Check the connection to a power outlet. The power switch may not be turned on. Check that the power switch is turned on. |
| The power indicator 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 horizon- tally. | 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. "3.4 Setting Printer Paper" (page 44) |
| Printer paper is fed, but nothing is printed. | The printer paper may be set wrong side up. Set the printer paper correctly. *3.4 Setting Printer Paper" (page 44) |
| Printer paper is stuck and cannot be fed through. | The printer paper roll may be installed at an angle, or shifted side- ways. Open the printer cover and check that the printer paper roll is prop- erly installed. |
| 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 red fixation lamp. |

| Symptom | Remedy |
|---|---|
| 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 the patients with the following conditions. Patients with severe nystagmus Patients with uncontrollable facial movement Eyes with keratoconus Eyes immediately after surgery In such a case, turn off 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. |

If the symptom cannot be remedied by the above actions, contact Nidek or your authorized distributor.

6.2 Error Messages and Remedies

6.2.1 Error during measurement

When the error occurred during the measurement, "Error" is displayed in the measurement results field on the measurement screen.



<Error message during AL measurement>

| Message | Cause and remedy |
|----------------------|--|
| Error | SNR is less than 2.0. |
| Acknowledgment error | The signal may not be obtained due to advanced cataract. |
| ALM | Alignment is not proper. |
| (Alignment error) | Perform the alignment and the measurement again. |

<Error message during KM measurement>

| Message | Cause and remedy |
|---|--|
| 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 mea- sured eye) | Focus is not proper. Perform the alignment and the measurement again. |
| NEAR (Focus error: Nearer from the measured eye) | Focus is not proper. Perform the alignment and the measurement again. |
| +OVR (Over the corneal curvature radius mea- surement 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. |

6.2.2 Messages related to measurement data

If the AL measurement value or KM value is outside the standard range, a message appears before the measurement results are saved and exported.

Check the contents of the message, then determine whether to use the measurement value. The messages prompting the operator to check the measurement values are displayed regardless of the right or left eye.

| ОК | The measurement results are saved and exported. |
|--------|--|
| Cancel | The measurement results are not saved or exported. |

When the results are printed with the printer, the message is also added.



| ID :13009 | |
|---------------------|-------|
| Name:NIDEK,KEN | м |
| Date:11/May/2022 | 13:35 |
| Memo: | |
| Oper:Suzuki | |
| | |
| I !Long axis length | 1 |
| Flat corneal | 1 |
| `- <u></u> | |
| AL | |

| Message on the screen | Message on the printout from the printer | Contents |
|--|---|---|
| !Long axial length. | !Long axis length | AL > 26 mm |
| !Axial lengths of right and left eyes differ by more than 0.3mm. | !ΔAL R-L >0.3mm | 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 1D. | !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 Φ2.4mm and Φ3.3mm mire rings dif- fer by more than 0.5D. | !ΔK Phi2.4-3.3 >0.5D | K in ø2.4 mm - K in ø3.3 mm > 0.5 D |

6.2.3 Error messages

If any of the following messages is displayed, follow the suggestions in the cause and remedy column. If the problem persists, notify Nidek or your authorized distributor of the serial number, error message number, and symptom or such.

| Message | Cause and remedy |
|--|---|
| No. 001 EEPROM error | Data error of backup memory (EEPROM) The possible causes are data loss due to exogenous noise such as static electricity, or malfunction of the electric circuit board or EEPROM on the electric circuit board. If the same error code is displayed even after the device is turned off and on again, turn off the device and contact Nidek or your authorized distributor. |
| No. 002 Clock error | Data and time setting error The possible cause is the empty built-in battery after about one month or longer of nonuse, causing the date and time settings to go wrong. Another possible cause is malfunction of the electric circuit board or timer IC on the electric circuit board. If the same error code is displayed even after the date and time are reset, turn off the device and contact Nidek or your authorized distribu- tor. |
| No. 006 BA01 FPGA error No. 007 BA02 FPGA error | Turn off the device and contact Nidek or your authorized distributor. |
| No. 009 SPI communication error | Turn off the device and contact Nidek or your authorized distributor. |
| No. 031 Up/Down motor error | Up/Down tracking error The possible causes are malfunction of the up/down motor, up/down sensor, or the electric circuit board, or a broken cable. Turn off the device and contact Nidek or your authorized distributor. |
| No. 032 Right/Left motor error | Right/Left tracking error The possible causes are malfunction of the right/left motor, right/left sensor, or the electric circuit board, or a broken cable. Turn off the device and contact Nidek or your authorized distributor. |
| No. 033 Back/Forth motor error | Forward/Backward tracking error The possible causes are malfunction of the forward/backward motor, forward/backward sensor, or the electric circuit board, or a broken cable. Turn 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 even after the device is turned off and on again, turn 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 | | |
| No. 160 SLD light error | | |
| No. 161 SLD light level is low. | | |
| No. 400 CF error | | |
| No. 410 Unable to access the CF | Turn off the device and contact Nidek or your authorized distributor. | |
| 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 | Turn off the device and contact Nidek or your authorized distributor. | |
| 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, turn off the device and contact Nidek or your authorized distributor. | |
| No. 602 USB flash drive error | USB flash drive error (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, turn off the device and contact Nidek or your authorized distribu- tor. | |
| 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 with a new one. | |
| No. 611 Unable to write files to the USB flash drive | USB flash drive writing error Check the free space of the USB flash drive. | |
| 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. The possible causes are failure of the USB flash drive or corruption of data. 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. The possible causes are failure of the USB flash drive or corruption of data. 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. Export the data from the measured result confirmation screen or the Follow-up screen. | |
| No. 700 File sharing error | Windows file sharing error Set the network properly. | |
| No. 703 Hardware error | If the same error code is displayed even after the device is turned off and on, turn off the device and contact Nidek or your authorized distributor. | |
| No. 704 DHCP error | IP address cannot be obtained from the DHCP server. | |

| Message | Cause and remedy |
|--|---|
| No. 750 Unable to access the network | Check the connection of the LAN cable. Also, check whether the IP address and subnet mask in the LAN Settings window are correct. |
| No. 751 Unable to write files to the computer | Network writing error (write-protected or full) Check the authority to write data to the destination folder in the speci- fied computer, and that there is enough free space. |
| No. 754 No computer under the computer name found in the network | The specified computer name is not found. The computer name specified in the LAN Settings window is not correct, or the LAN connection is not established. Enter the IP address of the export destination in the Computer Name box of the LAN Settings window. |
| No. 756 Unable to log on to the computer | Unable to log on to the computer (due to wrong Domain/Workgroup, User Name, or password) The Domain/Workgroup, User Name, or password entered 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 computer does not finish its processing in time) Perform the operation again after a while. Enter the IP address of the export destination in the Computer Name box of the LAN Settings window. |
| No. 759 Unable to delete files on the computer | Data cannot be deleted. (Deletion of a read-only file was attempted.) The destination folder in the specific computer is write-protected. Remove write protection of the destination folder. |
| No. 760 Initializing the network. Wait and try again later. | Network is being initialized. (It takes a while after startup.) Try again after a while. |
| No. 761 Access denied No. 762 This account is invalid. | 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 export destination computer to full access. |
| No. 763 Unable to read files on the computer | The file is corrupted. Check the computer condition. |
| No. 764 No files found on the computer | The desired data cannot be found when it is searched. |
| No. 765 Unable to rename files on the computer | 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 com- puter | 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 (such as NAVIS-EX or Myopia Viewer MV-1) could not delete data within the specified period of time (about in 5 seconds after receiving command). Check the set- ting of the data acquisition software on the computer. Time acquisition software is taking a long time to acquire data. Lengthen the time to "Timeout". |
| 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. |

| Message | Cause and remedy |
|--|--|
| No. 802 Patient database index is corrupted. New patient database will be created. | |
| No. 803 Measurement database index is corrupted. New measurement database will be created. | Turn off the device and contact Nidek or your authorized distributor. |
| No. 810 Measurement database is cor- rupted. | |
| No. 820 Image file is corrupted. | |
| Backup data is invalid. | Backup data of the database, setting information, or adjustment data is corrupted. |
| Out of paper | The printer is out of paper. Set a new roll of printer paper. |

6.3 Completion of Operation Before Transporting Device

When the device is to be transported due to the malfunction or such, set the device to Packing mode. In Packing mode, the main unit and the chinrest are automatically set to the position for transport.

- When transporting the device, contact Nidek or your authorized distributor.
- Observe the following precautions when transporting the device:
 - Set the device to Packing mode.
 - Do not lock the main unit with the locking lever.
 - Pack the device in the specified packing materials.
- **1** Perform device maintenance and cleaning if necessary.

☆ "6.4 Cleaning" (page 132)

2 While pressing v of the chinrest up/down buttons, turn on (1) the power switch.



3 Press v until the PACKING MODE screen is displayed.

After the PACKING MODE screen is displayed, the main unit and chinrest starts moving down.



4 After "Packing position is completed Shut down please" is displayed and the main unit and chinrest stop moving down, turn off the power switch.

The device recovers from packing mode when the device is started.

5 Disconnect the power cord.

| hut Init the | PACKING MODE Packing position is completed Shut down please | |
|--------------------|---|-------|
| the | | NIDEK |
| | | |
| | | |
| | | |

6.4 Cleaning

6.4.1 Cleaning the cover

• Do not use any organic solvent such as paint thinner. The surface of the device may be damaged.

• Do not use a sponge or cloth soaked in water. Water may leak into the interior of the device resulting in malfunction.

Wipe the cover with a soft cloth.

Wipe severe stains with a cloth dampened with a neutral detergent and wrung well. Finally dry with a soft, dry cloth.

6.4.2 Cleaning the touch screen

• Do not wipe the 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 touch screen to malfunction.

• Do not use liquid other than rubbing alcohol to wipe the touch screen.

Gently wipe off the touch screen with a soft, dry cloth, or a cloth dampened with rubbing alcohol. If rubbing alcohol is used, dry the touch screen with a soft, dry cloth so that streaks or specks do not remain.



6.4.3 Cleaning the chinrest and forehead rest

Clean the forehead rest and chinrest with clean absorbent cotton or gauze dampened with rubbing alcohol.



6.4.4 Cleaning the measuring unit

• Do not wipe the measuring unit with dust on it or rub the measuring unit strongly. Doing so may damage the glass part.

Cleaning the mire ring

Fingerprints and dust on the mire ring reduce the measurement accuracy. Check the mire ring for cleanliness before use of the device. Clean it if it is dirty.

- **1** Blow off dust or debris on the mire ring window **a** with a blower.
- **2** Gently wipe the glass part of the mire ring with a gauze dampened with a small amount of alcohol.
- **3** Confirm that the mire ring is clean. If the mire ring is dirty, wipe it again.



6

Cleaning the measuring window

Dust on the measuring window reduces the measurement accuracy. Check the measuring window for cleanliness before use of the device. Clean it if it is dirty.

- **1** Blow off dust on the measuring window **b** with a blower.
- **2** If necessary, gently wipe the measuring window with a cotton swab dampened with a small amount of alcohol.

Gently wipe the measuring window from the center to periphery in a circular motion.



3 Confirm that the measuring window is clean using a penlight. If the measuring window is dirty, wipe it again.

6.4.5 Cleaning the printer

After repeated use, paper residue accumulates in the auto cutter of the printer. Periodically clean the cutter.

1 Open the printer cover to remove the printer paper roll.



2 Apply the nozzle of a vacuum cleaner to the auto cutter to remove paper residue.

Do not blow off paper residue with a blower. If residue settles on the device interior, malfunction may result.

3 Supply the printer paper as it was.



6.5 Replacement Parts

| Part name | Part number | Note |
|----------------------------|-------------|---------------------------------------|
| Chinrest paper | 32903-M047 | 1 set: 100 sheets |
| Printer paper | 80620-00001 | Width 58 mm, length 25 m |
| Magnetic forehead rest pad | 30611-1520 | Forehead rest pad (made of ABS resin) |

* After replacing any consumables, be sure to restock them with spares.

6.6 Checklist

Daily inspection checklist

| Device to be inspected | | OPTICAL BIOMETER AL-Scan M | |
|------------------------|----------------------------------|--|--|
| | | | |
| | Item | Procedure | |
| Before use | | | |
| 1. | Appearance | Check the appearance of the device and its accessories for any deformation or uncleanliness that could interfere with use. | |
| 2. | Power cord | Confirm that the power cord is properly connected to the inlet of the device and power outlet. | |
| 3. | Mire ring, measuring win- dow | Check the cleanliness of the mire ring and measuring window. Clean the mire ring and measuring window if it is dirty. | |
| 4. | Start-up | Confirm that an error message does not appear at start-up. | |
| 5. | Joystick | Confirm that the measuring unit moves up, down, right, left, forward and backward smoothly with the joystick. | |
| 6. | Chinrest | Confirm that the chinrest moves up and down. | |
| 7. | Printer paper | Confirm that the printer paper is sufficient. | |
| After use | | | |
| 8. | Appearance | Check the appearance of the device and its accessories for any deformation or uncleanliness that could interfere with use. | |
| 9. | Power switch | Check that turning off the switch turns off the device. | |
| 10. | Mire ring, measuring win- dow | Check the cleanliness of the mire ring and measuring window. Clean the mire ring and measuring window if it is dirty. | |
| 11. | Dust cover | Confirm that the dust cover is covered on the device. | |

Inspection record

| Device to be inspected | | OPTICAL BIOMETER AL-Scan M | | | | |
|------------------------------|---------|----------------------------|-----------------------|----------|---|--|
| Serial number (S/N) | | | Inspection mo year | onth and | / | |
| | | | | | I | |
| Day | | | | | | |
| Before use | | | | | | |
| Person responsible for insp | pection | | | | | |
| 1. Appearance | | | | | | |
| 2. Power cord | | | | | | |
| 3. Mire ring, measuring dow | win- | | | | | |
| 4. Start-up | | | | | | |
| 5. Joystick | | | | | | |
| 6. Chinrest | | | | | | |
| 7. Printer paper | | | | | | |
| After use | | | | | | |
| Person responsible for insp | pection | | | | | |
| 8. Appearance | | | | | | |
| 9. Power switch | | | | | | |
| 10. Mire ring, measuring dow | win- | | | | | |
| 11. Dust cover | | | | | | |



SPECIFICATIONS AND TECHNICAL INFORMATION

7.1 Specifications

| Measurement | | | |
|---|---|---|--|
| Item | Settings | | |
| Axial length measurement (optical interference) | Measurement range: 14 to 40 mm Display unit: 0.01 mm Measurement accuracy: ±0.05 mm | | |
| Double mire ring keratometry | Corneal curvature radius (R1, R2, aver- age) | Measurement range: 5.00 to 13.00 mm Display unit: 0.01 mm Measurement accuracy: ±0.05 mm The measuring accuracy is in accordance with Type B, ISO 10343:2014. | |
| | Corneal refractive power (K1, K2, aver- age) | Measurement range: 25.96 to 67.50 D (n = 1.3375) Display unit: 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 unit: 0.01 D | |
| | Corneal cylinder axis (AXIS) | Measurement range: 0 to 180° Display unit: 1° Measurement accuracy: ±2° | |
| | Measurement range Ø2.4 mm (for mire ring / corneal curvature radius mm) Ø3.3 mm (for mire ring / corneal curvature radius mm) | | |
| Pupil diameter (PS) measure- ment | Measurement range: 1 to 10 mm Display unit: 0.1 mm Measurement accuracy: ±0.2 mm | | |
| Working distance (From the measuring window to the corneal surface) | 45 mm | | |
| Other functions | | | |
| Item | Settings | | |
| Auto tracking | Working range Up and down: 32 mm Side to side / Forward and backward: 10 mm | | |
| Movable range | Measurement unit | Main 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 × 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, measure- ment ring image | |
| Interface function | • USB • LAN | · | |

| Power supply | | | |
|---------------------|----------------------|--|--|
| ltem | Settings | | |
| Voltage | 100 to 240 V AC ±10% | | |
| Frequency | 50/60 Hz | | |
| Power consumption | 100 VA | | |
| Dimensions and mass | | | |

| Item | Settings | |
|------------|--------------------------------------|--|
| Dimensions | 283 mm (W) x 504 mm (D) x 457 mm (H) | |
| Mass | 21 kg | |

Environmental conditions

| Item | Settings |
|--|--|
| Operating environment | Temperature: 10 to 35°C (50 to 95°F) Humidity: 30 to 90% (non-condensing) 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 |
| Storage environment | Temperature: -10 to 55°C (14 to 131°F) Humidity: 10 to 95% (non-condensing) Atmospheric pressure: 700 to 1,060 hPa |
| Transport environment (packed condition) | Temperature: -10 to 55°C (14 to 131°F) Humidity: 10 to 95% (non-condensing) Atmospheric pressure: 500 to 1,060 hPa |

| Others | |
|-----------------------|--|
| Item | Settings |
| Expected service life | 8 years from the date of initial operation (defined by manufacturer) * Proper maintenance, inspection, and consumable parts replacement are necessary. |
| Classifications | Protection against electrical shock: Class I ME equipment Applied part: Type B applied part Protection against harmful ingress of water or particulate matter: IPX0 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 |

| Standard accessories and optional accessories | | | |
|---|---|--|--|
| Item | Settings | | |
| Standard accessories | Model eye, touch pen, pen stand, printer paper (3 rolls), chinrest paper, fixing pins for chinrest paper (2 units), dust cover, power cord, operator's manual, Myopia Viewer MV-1 | | |
| Optional accessories | Barcode scanner, USB flash drive, IOL-ST Print Manager | | |

* If you need information to ensure cybersecurity, contact Nidek or your authorized distributor.

7.2 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.

- 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

Specified cable

| Part name | Connector shielded | Cable shielded | Ferrite core | Length (m) |
|------------|-----------------------|-------------------|--------------|------------|
| Power cord | No | No | No | 2.5 |
| LAN cable | Yes | Yes | No | 10.0 |

Specified multimedia equipment

| Specified multimedia equipment | Standard compliance | |
|--------------------------------|--------------------------------|--|
| Network switch | Complied with CISPR 32 Class B | |
| Computer | | |

Essential performance

Axial length measurement function Corneal curvature radius measurement function
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 | | | | | | | |
| 745 | 704 to 787 | LTE Band 13, 17 | Pulse modulation 217 Hz | 9 | | | |
| 780 | | | | | | | |
| 810 | | GSM 800/900, | | | | | |
| 870 | 800 to 960 | TETRA 800, iDEN 820, | Pulse modulation 18 Hz | 28 | | | |
| 930 | | CDMA 850, LTE Band 5 | | | | | |
| 1720 | | GSM 1800; | | | | | |
| 1845 | 1700 to 1990 | CDMA 1900; GSM 1900: DECT: | Pulse modulation | 28 | | | |
| 1970 | 1700 10 1000 | LTE Band 1, 3, 4, 25; UMTS | 217 Hz | 20 | | | |
| 2450 | 2400 to 2570 | Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7 | Pulse modulation 217 Hz | 28 | | | |
| 5240 | | | | | | | |
| 5500 | 5500 5100 to 5800 WLAN 802.11 a/n | | Pulse modulation 217 Hz | 9 | | | |
| 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 | IEC 61000-4-4 | Input power port ±2 kV 100 kHz repetition frequency | | | | | | | | | |
| / bursts | | Signal input/output parts port ±1 kV 100 kHz repetition frequency | | | | | | | | | |
| Surges Line-to-line | | Input power port ±0.5 kV, ±1 kV | | | | | | | | | |
| Surges Line-to-ground | 120 01000-4-3 | 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 | | | | | | | | | |
| | | 0% U⊤; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° | | | | | | | | | |
| Voltage dips | IEC 61000-4-11 | 0% U⊤; 1 cycle and 70% U⊤; 25/30 cycles Single phase: at 0° | | | | | | | | | |
| Voltage interruptions | IEC 61000-4-11 | 0% U⊤; 250/300 cycles | | | | | | | | | |

7.3 Glossary

| AL | Axial length |
|------------------------|--|
| KM measurement | Corneal curvature radius measurement |
| PS | Pupil diameter |
| Ref. | Refractive error |
| SLD | Superluminescent diode |
| SNR | Signal-to-noise ratio. A higher number indicates higher confidence. |
| Administrator password | A password can be set to prevent change of various settings or deletion of data from the database by unauthorized personnel. |
| Progression Chart | A graph showing axial length change from the published article by Tideman. |
| Sleep mode | After a specified time of idle use, the touch screen automatically turns off and the device goes into a low power state. Pressing any button or touch screen returns to the normal state. |
| Drag | Moving an object with a finger or touch pen while the object is pressed on the screen. |
| Trend Graph | A graph that indicates the change of measurement value with age |

7



INDEX

| Α |
|--|
| Administrator password |
| Alignment target |
| Auto shot |
| В |
| Backing up104Barcode scanner121 |
| С |
| Chinrest |
| D |
| Daily inspection |
| E |
| Exam Mode 53 Export .80, 91 Eye level marker .20, 67 |
| F |
| Focusing indicator.28, 50Follow-up (progression chart) |
| J |
| Joystick |
| К |
| Keyboard window |
| М |
| Magnetic forehead rest pad |
| Measurement result confirmation screen (KM) |

 Measurement result confirmation screen (Overview)
 .29, 71

 Measurement screen
 .26

 Measuring window
 .20, 134

 Mire ring
 .28, 133

 Model eye
 .57

Ν

Numeric keypad window 37

0

Ρ

| Parameter |
|---|
| Patient information |
| Patient information registration screen |
| Patient list screen |
| Power indicator |
| Power switch |
| Printer |
| Printer paper |
| Printing |
| Progression Chart |
| PS |

R

| Refractive error | |
|------------------|--|
| _ | |

S

| Setting date and time | 112 |
|-----------------------|-----|
| Shared folder101, | 120 |
| Sleep mode | 145 |
| SNR | 145 |

Т

| Touch screen | | | | | | | | . ' | 19 |), | 4 | 3, | 111 | , | 13 | 32 |
|--------------|-----|------|--|--|--|--|--|-----|----|----|---|----|----------|---|-----|----|
| Tracking | ••• | | | | | | | | | | | | | | . 4 | 19 |
| Trend Graph | ••• | | | | | | | | | | | | . 33 | , | 14 | 15 |