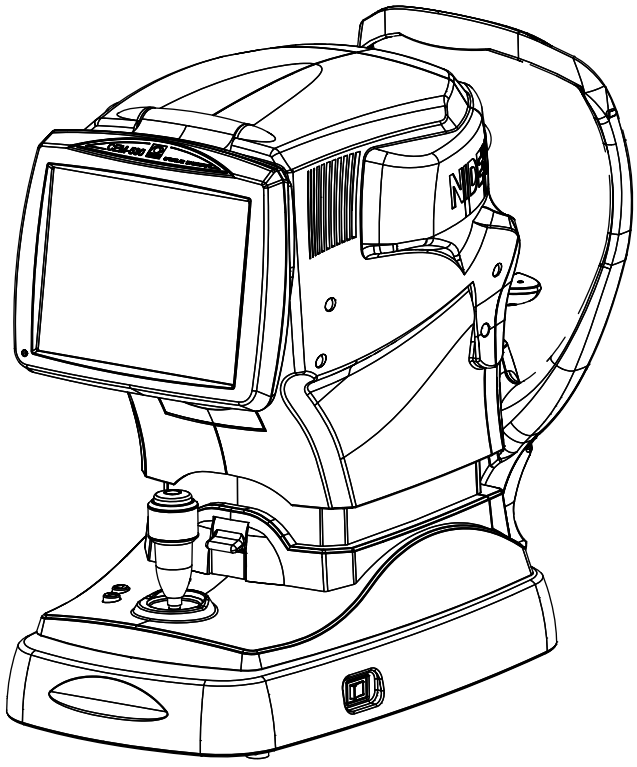
NIDEK

SPECULAR MICROSCOPE

# CEM-530

*OPERATOR'S MANUAL*



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

Original instructions

# NIDEK CO., LTD.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# Before Use

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 this product, please contact NIDEK or your authorized distributor.

15201-P902-G3

**IMPORTANT - READ CAREFULLY**

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

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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.

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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.

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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.

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

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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.

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

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

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

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

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

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

## 7. TERMINATION

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

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

## 8. NO WARRANTIES

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

## 9. LIMITATION OF LIABILITY

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

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

## 10. GOVERNING LAW AND ARBITRATION

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

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

## 11. SEVERABILITY

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

## 12. SURVIVAL

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

## 13. ASSIGNMENT

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

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

## 14. ENTIRE AGREEMENT

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

## 15. NO WAIVER

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

## 16. NO THIRD PARTY RIGHTS

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

## 17. HEADINGS

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

## 18. LANGUAGE

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

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

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

## 19. APPLICATION OF SOFTWARE LICENSE AGREEMENT

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

# Table of Contents

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# 1. SAFETY PRECAUTIONS



## 1.1 For Safe Use

⚠ **BEFORE USE, READ THIS MANUAL.**

**Be sure to read the operator's manual before operating the device to understand the safety precautions and operating procedures thoroughly.**

**Keep this manual handy for reference.**

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

## Safety precautions

In this manual, a signal word is used to designate the degree or level of safety alerting. The definition is as follows.

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

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

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

# 1.2 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.**
- **Connect the power plug to a grounded power outlet or the grounding wire to a ground terminal.**
  Electric shock or fire may occur in the event of device malfunction or power leakage.

**⚠ CAUTION**

- **Do not use the device for other than the intended purpose.**
  NIDEK will not assume responsibility for accidents or malfunction caused by misuse.
- **Information derived from analysis of endothelial images and corneal thickness values must be approved by doctors for use or to save.**
- **Images or analysis results may be affected by the capture conditions. Make a comprehensive diagnosis in combination with other examinations.**
  **Depending on the patient's condition, there may be cases where detection of endothelial cells by automatic analysis is difficult. Visually check the corneal endothelium image in conjunction with analysis results before making a final diagnosis.**
- **The safety precautions and operating procedures must be thoroughly understood prior to operation of the device.**
  Use of the device outside the scope of this manual may cause adverse events.
- **Never modify or touch the internal structure of the device.**
  Electric shock or malfunction may result.
- **Install the device in an environment that meets the conditions listed below. The following conditions must be maintained during use.**
  Ambient temperature: 10 to 35˚C (50 to 95˚F)
  Humidity: 30 to 90% (Non-condensing)
  Atmospheric pressure: 800 to 1060 hPa
  A well ventilated place free from hazardous particles, smoke or fumes
  Level, stable surface free from vibration and bumping
  If the device is not installed and used under the above conditions, the reliability of image capture results is lowered, and malfunction may result. In addition, injury may result if the device is bumped or topples over.

⚠ **CAUTION**

- **Do not use the device immediately after it has been exposed to radical temperature differences because condensation may occur inside the device. Wait until the device is at room temperature (1 to 2 hours).**

  If the device is used with condensation present, satisfactory capture images may not be obtained. In addition, fire or device malfunction may occur.

- **Install the device in an environment where no contaminant such as corrosive gas, acid, or salt is contained in the air.**

  Corrosion or malfunction of the device may occur.

- **Avoid installing the device where it is exposed to direct air flow from an air conditioner.**

  Changes in temperature may result in condensation inside the device or adversely affect captured results.

- **Keep the capturing window away intense light such as direct sunlight.**

  Capture image failure caused by interference light or capture accuracy failure may occur.

- **Install the device on a level, stable surface free from vibration and bumping.**

  If the device is installed on an unstable surface, injury or device malfunction may occur.

- **Be sure to use a power outlet which meets the specified power requirements.**

  If the supplied voltage is too high or low, the device may not perform up to specifications, and malfunction or fire may result.

- **Insert the power plug fully into the power outlet.**

  Imperfect connection may result in fire.

- **Never use power strips or extension cables for the power supply of the device.**

  Overloading the electric outlet may cause overheating and fire.

- **Do not use any power cord other than the one provided. Do not use the provided power cord for any other device.**

  Malfunction or fire may result.

- **Install the device in an area where the outlet that the mains plug is inserted into is easily accessible during use. In addition, ensure that the power cord can be disconnected without the use of a tool.**

  Otherwise, it may interfere with disconnecting of the power from the input power source in case of abnormality.

- **Never crush or pinch the power cord with heavy objects.**

  Damage may result in electric shock or fire.

- **Before connecting any cables to the device, be sure to turn off power to the device and unplug the power cord.**

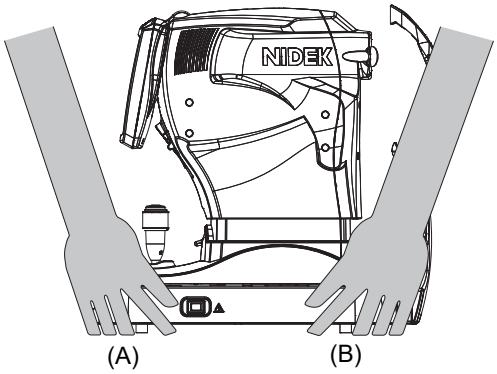
  Malfunction may result.

- **Insert the plug into the connector according to the proper indication and orientation and do not apply undue force to make the connections.**

⚠ **CAUTION**

- **When carrying the device to another location, its base should be held by two hands from both sides by two persons as indicated by (A) and (B) in the figure shown to the right. Never hold any parts other than the base such as the forehead rest, main unit or capturing unit.**

  If the device is carried by only one person or held by any parts other than the base, the device may fall and injury or failure may result.




- **Keep the screen touch panel away from direct sunlight or excessive ultraviolet rays.**

  They will damage the screen touch panel.

## During use

⚠ **CAUTION**

- **Do not perform servicing or maintenance on the device during use.**
- **Perform visual and operational checks before using the device. Do not use the device if any error is found.**
  Use of a malfunctioning device may cause harm or produce improper results that lead to inappropriate diagnoses resulting in health hazards.
- **Be sure not to touch the patient's face during alignment or when switching the right and left of the patient's eye.**
- **Before and after use, and before every patient, clean the forehead rest and chinrest with a clean gauze or cloth dampened with rubbing alcohol. For severe stains, wipe with a clean cloth dampened with rubbing alcohol instead of wiping them repeatedly with a dry cloth.**
  When the chinrest paper is used, remove a sheet for each patient.
- **Take care not to catch hands or fingers in moving parts such as the base unit, capturing unit, or chinrest. Be sure to also give this caution to patients.**
  Hands or fingers may be pinched and injury may result.
- **Keep the capturing window free of fingerprints and dust.**
  The capture accuracy may decrease substantially.
- **In the event of smoke or strange odors, immediately turn off the device and disconnect the power plug from the outlet. Once it is determined that the smoke will not become more serious, contact NIDEK or your authorized distributor.**
  Continued use may result in electric shock or fire. In case of fire, use a dry chemical (ABC) extinguisher.
- **Before image capture, explain the capture purpose or method sufficiently to patients.**
- **Instruct the patient not to touch the device carelessly.**
- **When the patient comes off from the device, instruct the patient not to stand up while holding the chinrest support.**
  The device may topple over resulting in injury.
- **Special care must be taken with infants and persons suffering from aphakia or other eye diseases to apply this device.**
  They are at greater risk of light hazard.
- **Instruct the patient to fix on the fixation lamp with their eyes wide open. Start image capture after confirming that the instruction is properly followed by the patient.**
  Proper capture may not be performed.
- **Immediately replace the power cord if the internal wires are exposed, the power turns on or off when the power cord is moved, or the cord or plug is too hot.**
  Malfunction or fire may result.
  Immediately remove the plug from the power outlet and contact NIDEK or your authorized distributor for replacement. Failure to do so may result in electric shock or fire.

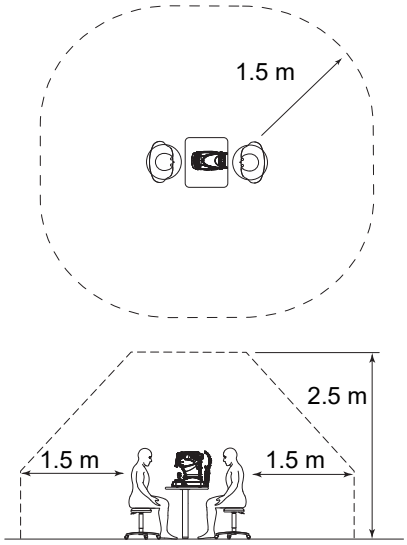
⚠ **CAUTION**

- **Never touch the screen touch panel with wet hands.**
  If the inside of the device is exposed to water, malfunction may occur.
- **There may be a few defective pixels in the screen which are a characteristic of any LCD monitor. This does not represent a failure, and the LCD monitor can be used normally and image data is unaffected.**
- **Never touch the screen touch panel with any object other than fingers or the touch-screen pen tip.**
  Touching with any hard or sharp object such as a ball-point pen may damage the screen touch panel. Also, even though the touch-screen pen is protected with a resin tip to prevent damage to the touch panel, pushing too firmly may still damage the touch panel.
- **Never press two or more points on the screen touch panel at the same time.**
  Malfunction may result.
- **Be sure to use only the printer paper (80620-00001) specified by NIDEK.**
- **This device is classified as Group 1 set by ISO 15004-2: 2007 Light Hazard and conforms to the standard.**
- **If the device fails, disconnect the power cord from the power outlet, then contact NIDEK or your authorized distributor without touching the interior of the device.**
- **If the 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.**
  Contact NIDEK or your authorized distributor for installing isolation transformers.
- **When connecting to peripheral equipment such as a PC with LAN port via a medical facility network, insert or connect an isolation transformer between the medical electrical equipment and network devices (such as HUB), or the network devices and other electrical equipment.**
  Depending on the types or numbers of other electrical equipment connected to the network, electric shock or malfunction/failure of the electrical equipment may occur.
  For installation of the network isolation transformer, consult NIDEK or your authorized distributor.

⚠ **CAUTION**

- **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, install the device outside the patient environment. For a generalized information system, use the device that complies with IEC 60950-1 or IEC 62368-1. For other devices, use any separation device that complies with IEC 60601-1 and keep sufficient distance between the device and patient environment.**

  The patient environment where any contact can occur between the patient and any part of the device (including connecting devices) or between the patient and any other person(s) touching the device (including connecting devices) is as shown to the right.



## After use

⚠ **CAUTION**

- **This device uses a heat-sensitive printer paper. The paper degrades over time and the printed characters may become illegible.**
  **If glue containing organic solvents or adhesives such as on adhesive tape comes in contact with the printer paper, the printed characters may become illegible.**
  To keep the printed data for a long period of time, make copies of the printouts or write the captured results down.
- **When the device is not in use, turn off the power switch and put the dust cover over the device.**
  Dust may affect the accuracy of image capture.
- **Always hold the power plug, not the cord, when removing it from the power outlet.**
  The metal core of the cord may be damaged and electric shock, malfunction, or fire may result.
- **Check that the power switch is turned off before connecting or disconnecting the power cord to or from the power outlet.**
  If the power cord is connected or disconnected with the power switch on, device malfunction may occur.
- **Occasionally clean the prongs of the power plug with a dry cloth.**
  If dust settles between the prongs, the dust could collect moisture, and short circuit or fire may occur.
- **If the device will not be used for an extended period of time, disconnect the power cord from the power outlet.**
  Failure to do so may leave the device vulnerable to electric disturbances which may result in fire.
- **Before using the device after a prolonged period of non-use, ensure that the device operates normally and safely.**
- **During transport or storage, maintain an environment that meets the following conditions:**
  Ambient temperature: -10 to 55°C (14 to 131°F)
  Humidity: 10 to 95% (non-condensing)
  Atmospheric pressure: 700 to 1,060 hPa
  No large amount of dust content in the air
  A place not exposed to direct sunlight
- **Before transporting, set the mode to packing mode and pack the device in the provided packing material with the locking lever for the main unit unlocked.**
  It may result in failure when excessive vibration and shock are applied.
  For packing mode setting, see “3.2.4 Shutoff before transporting the device” (page 56).

## Maintenance and check

⚠ **CAUTION**

- **Only service personnel trained by NIDEK are allowed to repair the device or update the software.**
  NIDEK assumes no responsibility for any adverse events resulting from improper servicing.
- **When performing maintenance work, secure a sufficient maintenance space.**
  Maintenance work in an insufficient space may result in injury.
- **Before performing maintenance, clean the surface of the device properly with a clean cloth dampened with rubbing alcohol.**
- **When replacing the printer paper, use those specified.**
  Failure to do so may damage the printer head.
- **Never use organic solvents such as a thinner, or detergents with abrasives to clean the covers or screen touch panel.**
  The covers or screen touch panel may be corroded or scratched.
- **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.**
- **Do not use the device beyond its service life.**
  Even with proper maintenance and checks, after time, the device reliability or safety may begin to fail to achieve the target values.
- **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.

## Disposal

⚠ **CAUTION**

- **Follow local governing ordinances and recycling plans regarding disposal or recycling of device components. The device contains a circuit board with a lithium battery mounted. Because the disposal method of lithium batteries varies according to the local government, follow the local governing ordinances and recycling plans when disposing of the circuit board with the lithium battery.**
  It is recommended to entrust the disposal to a designated industrial waste disposal contractor. Inappropriate disposal may contaminate the environment.
- **When disposing of packing materials, sort them by material and follow local ordinances and recycling regulations.**
  Inappropriate disposal may contaminate the environment.

## Connection to network

⚠ **CAUTION**

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

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

- **Incorrect network setting may result in the network malfunction. Under the supervision by network administrator, confirm that the network settings are correct.**
- **Check the network connection if the network is disconnected or fails. Consult with network administrator as necessary.**
- **When using the networking equipment such as a switching hub and router, ensure the security of them.**
- **When connecting with a peripheral equipment such as a computer via network within medical care facilities with LAN port, be sure to connect the medical electrical equipment with network system (hub system or such), and the network system with other electrical equipment by using an isolation transformer.**

  Electric shock may result. Contact NIDEK or your authorized distributor for installing network isolation transformers.

- **If the medical system is configured with a network, do not connect the network to a wide area network such as the internet.**
  **It is recommend to use the device in a medical system that comprises a secure and closed network.**

  NIDEK will not assume responsibility or compensate for damages caused by any virus infection and development due to the connection of the device to the Internet.

- **When connecting with other device via medical system network, make sure that none of patient, operator, and third party is exposed to hazards. When connecting/ disconnecting or upgrading the equipment in the network, also confirm that none of patient, operator, and third party is exposed to hazards.**

# 2. INTRODUCTION

## 2.1 Device Outline

The NIDEK Specular Microscope CEM-530 provides non-contact, high magnification image capture of endothelium enabling observation of the size and shape of cells. Information such as the number of endothelial cells, cell density, and cell area is analyzed through the captured images.
The captured images and analysis results of endothelium are used to assist in intraocular or corneal surgery, postoperative follow-up, and corneal observation such as for endothelial disorders or the corneal state of patients who wear extended-wear contact lenses.
Observation is possible in the central area (visual angle: 5°) and peripheral area (visual angle: 27°) using a periphery capture function as well as in the center of the cornea.
The captured images and analysis results can be printed on the built-in printer or optional video printer, or output to an external device over LAN connection.



## 2.2 Intended Use

This device is intended for observing, capturing, or recording images of the endothelium to provide electronic imaging information for diagnosis.

## 2.3 Intended Patient Population

- Age

  All ages except babies and infants

- Health condition

  Able to undergo an examination in a sitting position

- Conditions - Visual function

  One or both eyes are normal or have disease.

  Eyes that have lost the visual function are not targeted.

## 2.4 Intended User Profile

Doctors or persons qualified by the law of each country

## 2.5 Intended use environment

Medical facility

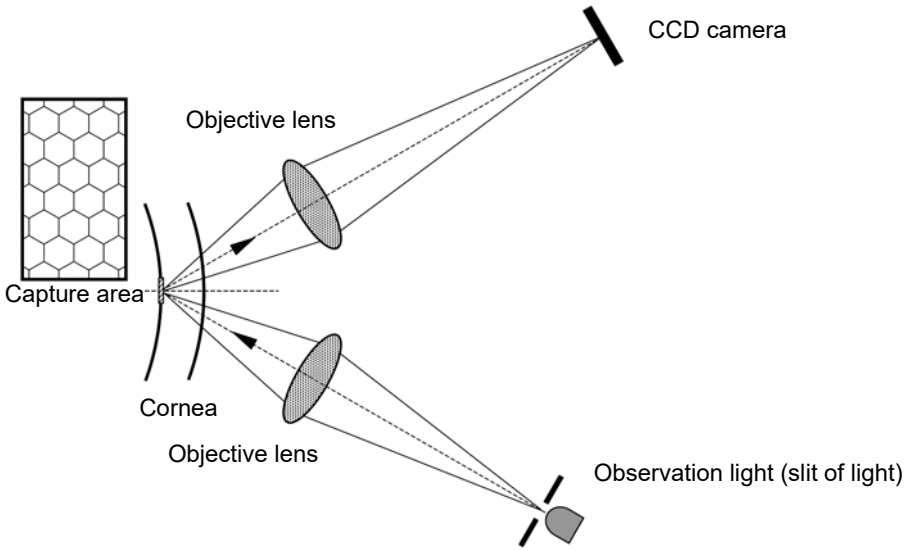
⚠ **CAUTION** • **If the device is used outside the specified use location, intended performance and security level cannot be maintained.**

# 2.6 Principles



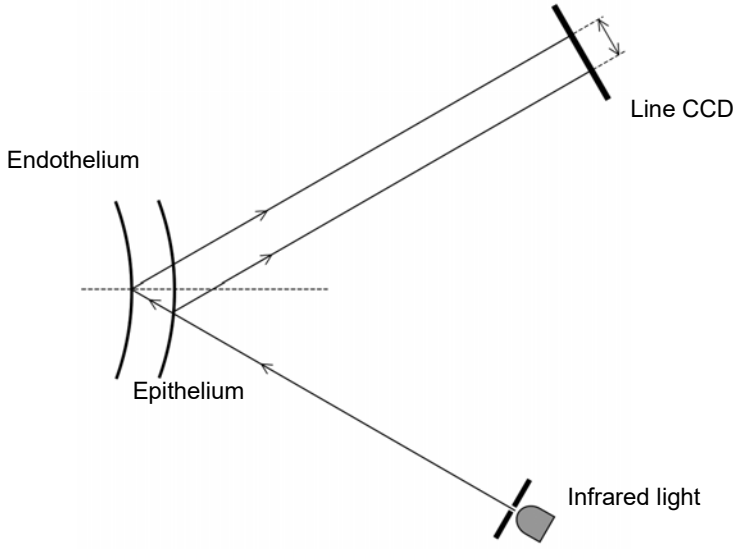
**Endothelial image capture**

This device captures endothelial images in a non-contact method using the principle of specular reflection. A slit of light is projected diagonally onto the endothelium of the patient, and the specular reflected light from the surface of the endothelium at the border of the anterior chamber is captured by a CCD camera positioned at the same angle of incidence as the light source. The portion illuminated by the slit is the capture area.



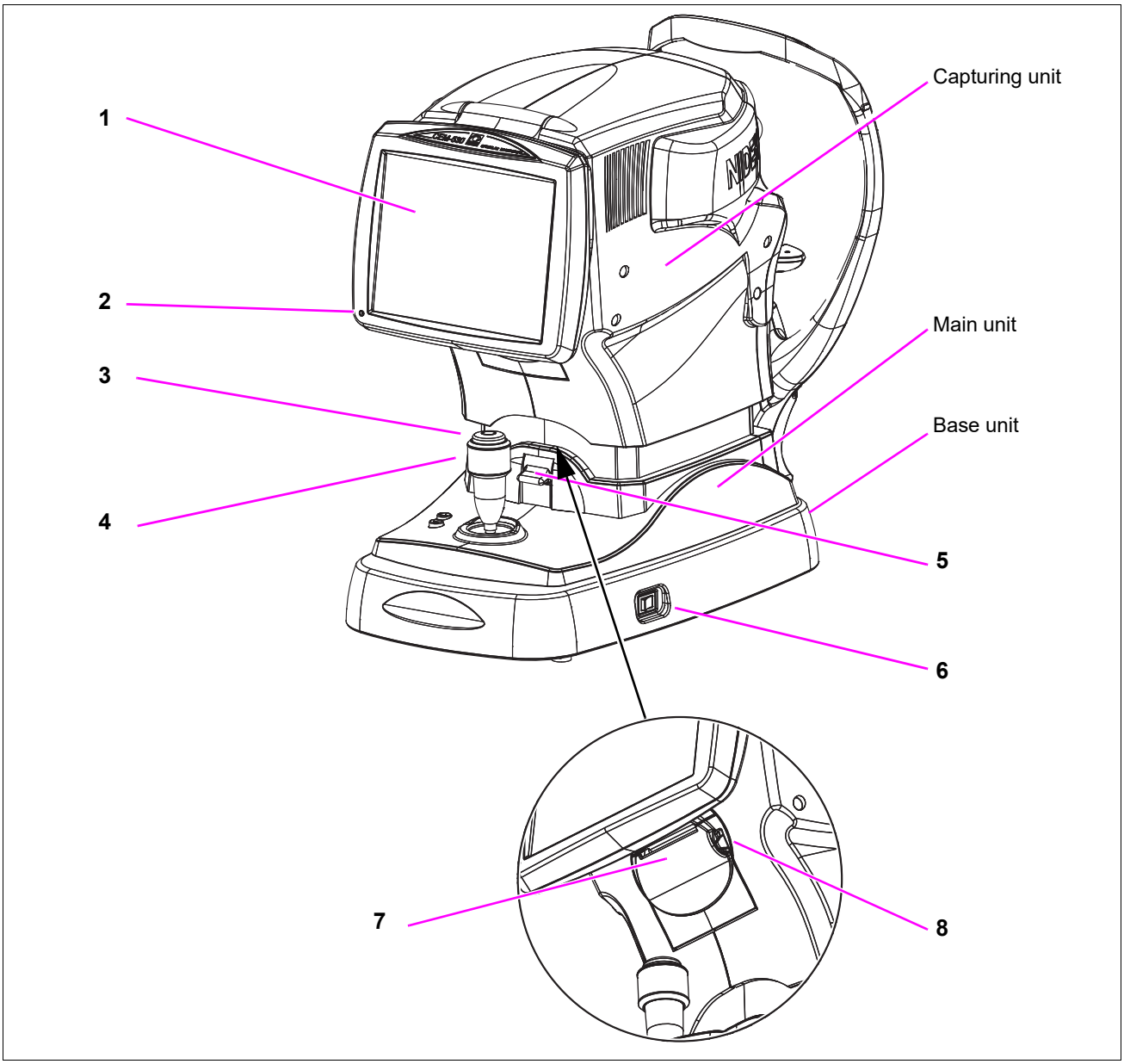

**Pachymetry**

The corneal thickness is optically measured in a non-contact method. The corneal thickness measuring beam (infrared light) projected diagonally on the cornea is reflected from both the epithelial surface and endothelial surface. The different paths of reflected light are detected by the line CCD. The corneal thickness is calculated from the distance between the paths of the epithelial reflection and endothelial reflection on the line CCD.



## 2.7 Device Configuration

○ Front view




**1. Screen touch panel**

Displays various operation screens and captured results.

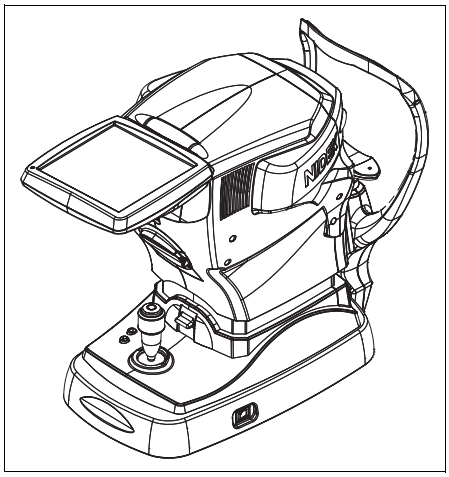
The device can be operated by touching the buttons on the screen.

The screen touch panel is a 8.4-inch color LCD. It can be tilted by pulling its bottom and fixed at various angles.

If the operator uses the device in a standing posture, tilt the screen at a suitable angle.

To return the screen to the original position, raise it to the horizontal position, then slowly lower it.

The screen is fastened to the original position by magnet.





**2. Memory indicator**

Indicates that capture data is being stored in memory.

| | |
|---|---|
| **ON** | Capture data is stored in the internal memory. |
| **OFF** | Capture data is not stored in the internal memory. |
| **Blinking** | Sleep mode |

**3. Start button**

When the start button is pressed, image capture takes place regardless of the alignment and focusing status of the device.

**4. Joystick**

Used for alignment and focusing.

For horizontal alignment, move the joystick to the right and left. For vertical alignment, rotate the joystick. For focus adjustment, move the joystick forward and back.

**5. Locking lever**

Used to lock the main unit to the base unit.

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

**6. Power switch**

Turns on and off power to the device.

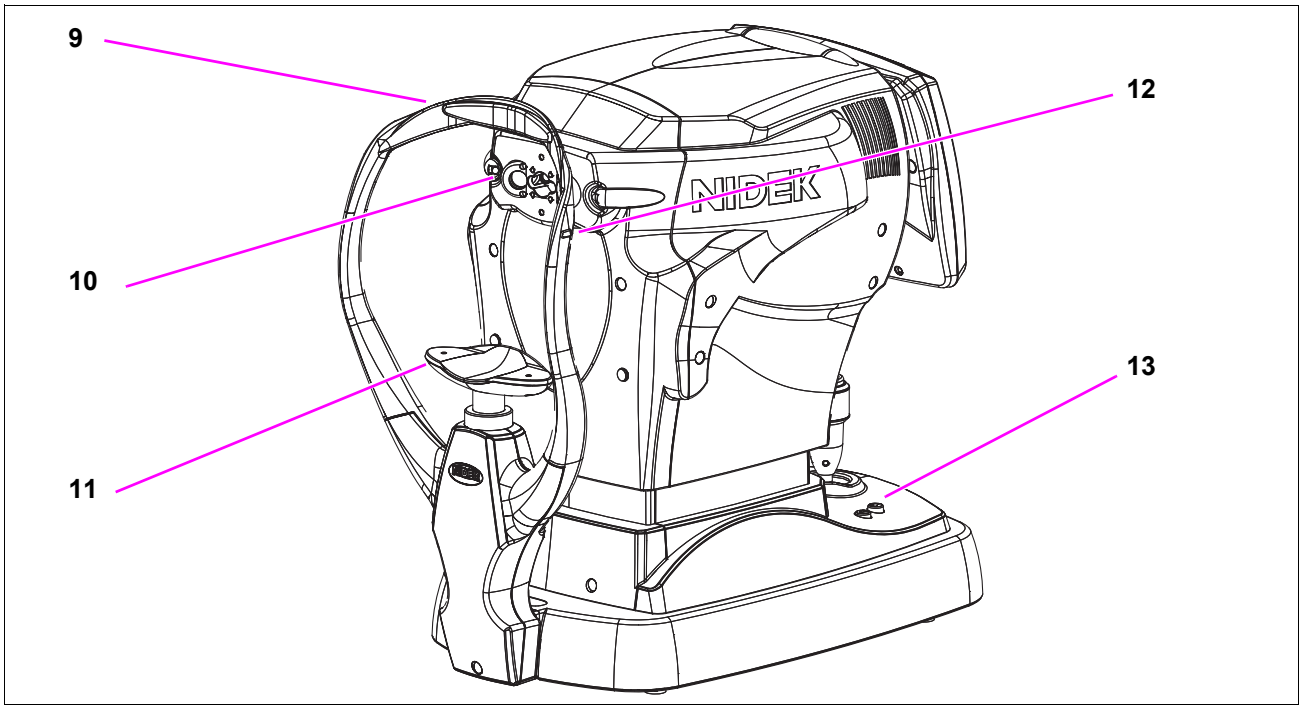
**7. Printer cover**

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

**8. Cover open button**

To open the printer cover, press this button.

## ○ Rear view




**9. Forehead rest**

Used to rest the patient's forehead to restrict head movement during image capture.

Clean it for each patient.

**10. Capturing windows**

Check the window cleanliness before image capture.

There are three windows for image capture: anterior segment observation / alignment, endothelium illumination, and endothelium focus/capture.

At the periphery of the capturing windows, peripheral fixation lamps and anterior segment illumination are provided.

**11. Chinrest**

Clean the chinrest for each patient.

**12. Eye level marker**

Used as a guide to adjust the patient's eye level.

Adjust the height of the chinrest so that the patient's eyes are roughly aligned with this line.

**13. Chinrest up and down buttons ( ▲ , ▼ )**

Used to move the chinrest up and down.

Note

- Parts that come into contact with the patient or the operator during image capture are composed of the following materials:

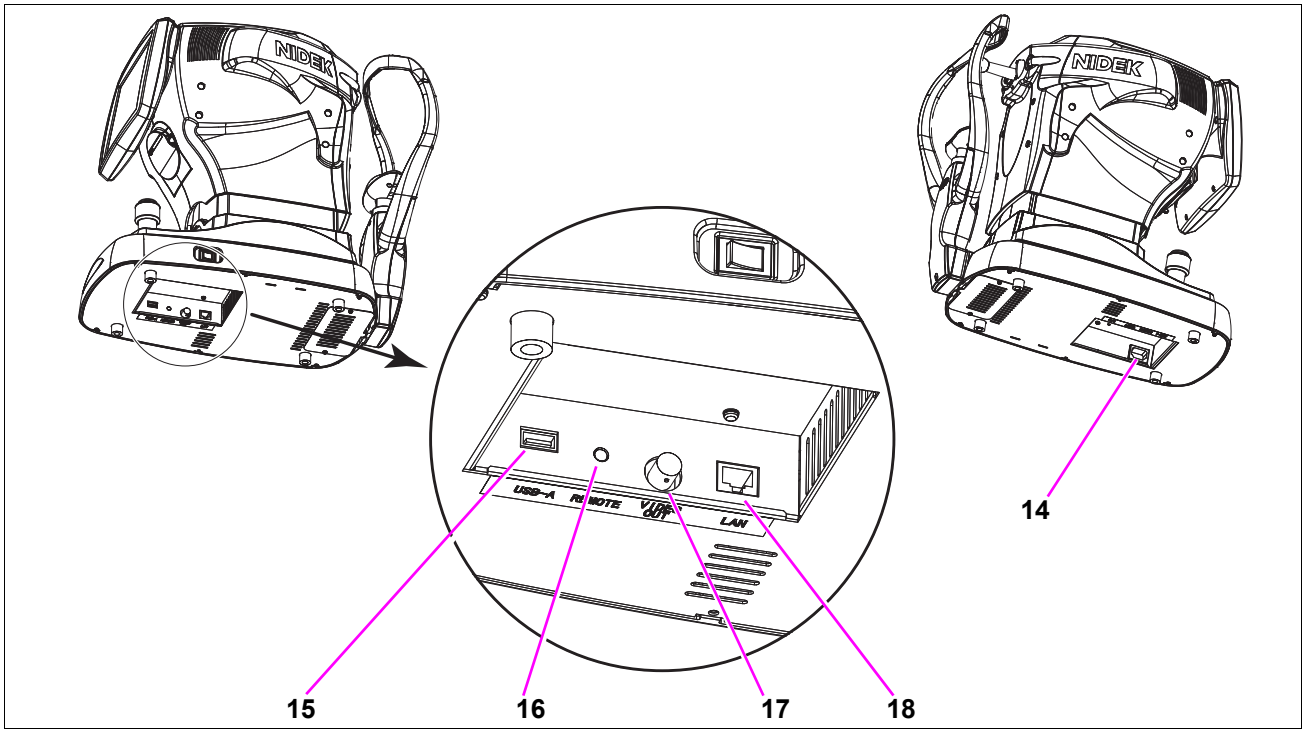
  Forehead rest - Polyester elastomer
  Locking lever - Aluminum
  Chinrest, start button, chinrest up/down button - ABS resin
  Joystick - ABS resin, synthetic rubber
  Power switch - Polyamide resin (common electrical parts)
  Touch-screen pen grip - ABS resin, elastomer

## ○ Bottom view

Provides the connectors for the video printer, barcode reader, and magnetic card reader.

**⚠ CAUTION • Equipment connected to the analog or digital interfaces must be certified according to the representative appropriate national standards (such as EN 60601-1 and IEC 60601-1). Furthermore, all configurations must comply with the system standard IEC 60601-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system is therefore responsible that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department of your local representative.**






**14. Power inlet**

A detachable power cord is connected here.

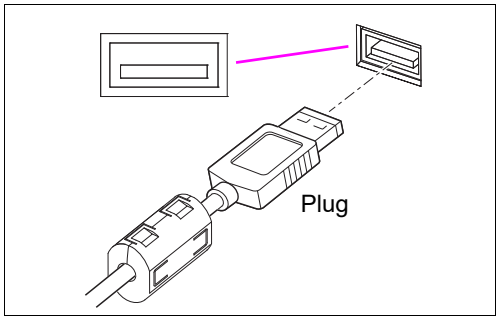
**15. USB-A connector**

The USB cable of the USB device is connected here. (USB 1.1 compliance, Terminal A (female))

They can be used to connect a barcode reader and magnetic card reader.

Cable connection

Ensure that the plug is inserted into the connector in the proper orientation.



### 16. REMOTE connector

The remote control cable of the optional video printer is connected here.

Connect the remote control cable to the REMOTE terminal of the video printer.
There is no orientation for the REMOTE connector.

### 17. VIDEO OUT connector

This is a BNC type connector to connect the video signal cable of the optional video printer.

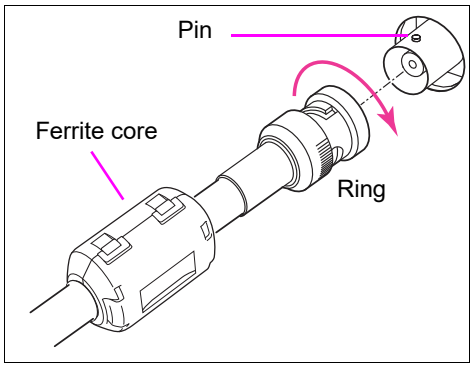
Connect the video signal cable to the VIDEO IN connector (video signal input) of the video printer.

Cable connection

Connect the end of the plug with the ferrite core attached to the CEM-530 connector.

With the groove in the plug aligned with the connector pin, insert the plug straight and then turn the ring clockwise until it stops and is locked.

To remove the plug, turn the ring counterclockwise until it stops and pull out the plug.




### 18. LAN connector

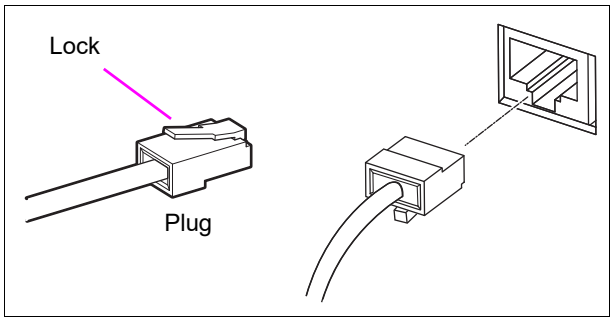
This is the connector to connect the device to an Ethernet network.

Setting up of a LAN is required for connection to an Ethernet network. Set up a LAN in the LAN Settings screen that is displayed by pressing the LAN Settings button in the Maintenance screen.

Cable connection

With the lock of the plug facing down, insert the plug into the LAN connector until it snaps.

To remove the plug, hold the plug with the lock released and pull out the plug.




**⚠ CAUTION**

- **Before connecting any cables to the device, be sure to turn off power and unplug the power cord. Check the indication and orientation of the connector and be sure not to connect it at an angle.**

  Malfunction may occur.

- **Insert the plug into the connector according to the proper indication and orientation and do not apply undue force to make the connections.**

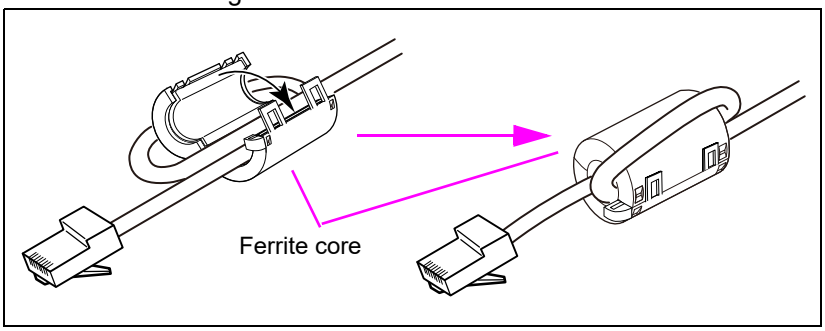
- **Be sure to use a hub for network connections. Do not connect directly to a PC using a LAN cross cable.**

  Data communication may not be correctly performed.

## ○ Ferrite core attachment

Attach the supplied ferrite core near the plug of the LAN cable.

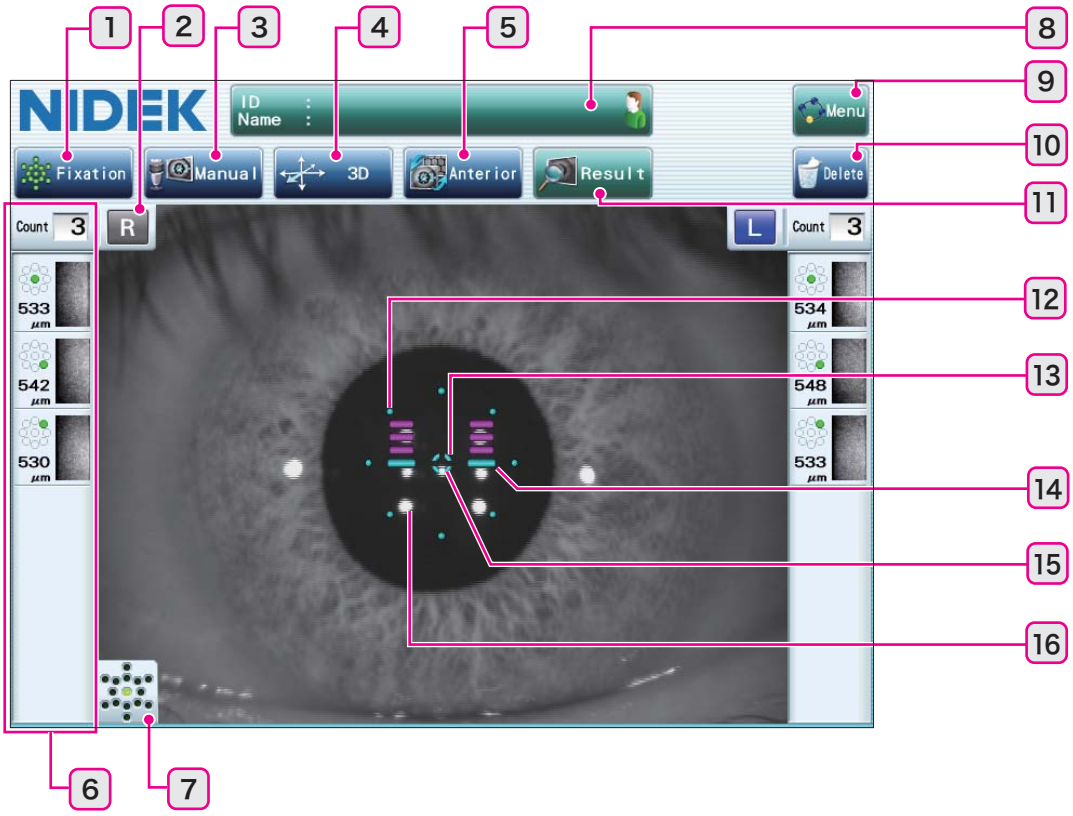
Loop the cord around the ferrite core as shown in the figure below.



# 2.8 Screen Configuration

## 2.8.1 Capture screen

This is the screen for capturing endothelial images and observing the anterior segment.
Image capture method settings such as fixation lamp, auto tracking, and auto shot are also performed here.




**1. [Fixation] button** 


Used to display the Fixation window that allows setting of the illumination position of the fixation lamp.

The fixation lamp at the selected position lights up or blinks. Steady lighting or blinking is set by a parameter.

| | |
|---|---|
| C | Center of the cornea (default setting) |
| Paracentral | Paracentral eight points (5° visual angle, 45° spacing) |
| Peripheral | Peripheral six points (27° visual angle, 60° spacing) |

Set one position in single mode and multiple mode.
Set maximum of 15 positions together with the measurement order in paracentral mode.


Fixation window (paracentral mode)

**2. R/L indication**

Displays the patient eye (right eye / left eye) shown on the screen in blue.

**3. Auto shot button**

Used to toggle use of the auto shot function (automatically starting image capture when proper vertical and horizontal alignment and focus is achieved).

| | |
|---|---|
|  Manual | The auto shot function is disabled. |
|  Auto | The auto shot function is enabled. |

**4. Tracking button**

Used to toggle use of the auto tracking function (automatic alignment).

| | |
|---|---|
|  3D | The auto tracking function in the forward/backward, right/left, and up/down directions is enabled. |
|  2D | The auto tracking function in the right/left, and up/down directions is enabled. Focus is manually adjusted. |
|  OFF | The auto tracking function is disabled. Alignment and focus are manually adjusted. |

**5. Image toggle button**

Used to toggle the display image between the anterior segment and endothelium.

| | |
|---|---|
|  [Anterior] | Used to display the anterior segment.<br>Endothelial image capture is performed by the following procedure.<br>When alignment and focus are obtained with the auto shot function set to Auto, endothelial image capture starts. To perform anterior segment observation only, disable the auto shot function beforehand.<br>When the auto shot function is disabled, pressing the start button initiates endothelial image capture. |
|  [Cell] | Used to display the endothelial image.<br>The auto shot and auto tracking functions are disabled. Pressing the start button initiates endothelial image capture. |

**6. Captured results**

Captured image results are displayed.

Image thumbnails, fixation lamp illumination position, and corneal thickness are displayed in the capture order. The capture count is displayed at the upper part of the display field.

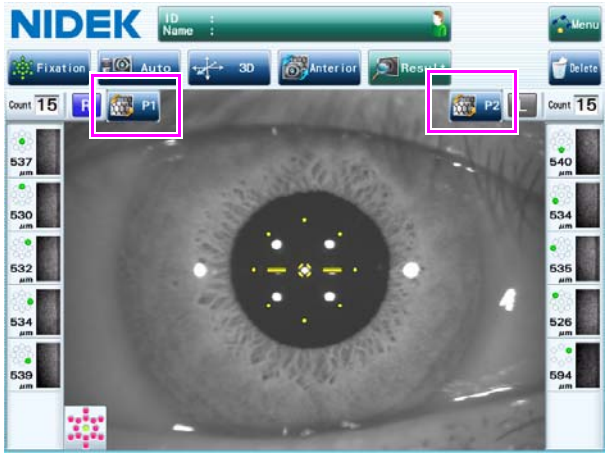
In single mode, image capture is performed once for each eye. When image capture is performed more than once, the previous image data is deleted.

In multiple mode / paracentral mode, image capture can be performed a maximum of 15 times for each eye. If image data sets exceed 15, the image data is deleted in order from the oldest.

**•Page change button for captured image display**

A maximum of 10 captured images may be displayed on the same page for one eye. When more than 10 images are captured, the page change button appears and the images are divided into three pages. Pressing the button changes the display page.

| | | |
|---|---|---|
| P1 | P1 | Displays images 1 to 5 |
| P2 | P2 | Displays images 6 to 10 |
| P3 | P3 | Displays images 11 to 15 |




**7. Fixation lamp indication**

Displays the position of the currently illuminated fixation lamp in green.

In paracentral mode, the selected and not yet captured positions are displayed in red.

**8. Patient information field**

Displays the patient information (ID, name) that is currently being captured. Pressing this button displays the Patient Information screen.

Patient information can be entered after image capture. Once capture data has been printed or output, patient information cannot be changed.


**9. [Menu] button** 


Used to display the Menu window.

The Menu window allows display of the Maintenance screen or Settings screen.


Menu window

**10. [Delete] button** 


Used to delete all capture data (patient information, image data, and analysis data).

Pressing this button displays the message “Are you sure you want to delete the capture data? Yes/No”. Pressing “Yes” deletes the capture data.

**11. [Result] button** 


Used to finish capturing and display the capture results screen.

Used to manually display the capture results screen such as when image capture is finished for one eye, or in multiple mode / paracentral mode.

When image data is not stored in the memory, this button is disabled (grayed out).

**12. Capture area marks**

Indicate the area where image capture is possible.

If the pupil is smaller than this circle or eyelashes cover this circle, image capture may not be possible.

**13. Alignment target**

Used as a guide to center the patient's eye on the screen.

**14. Focus indicator**

Indicates the distance between the capturing unit and the patient's eye.

Operate the joystick until the ( -○- ) mark indicates that focus is proper.

**15. Alignment light**

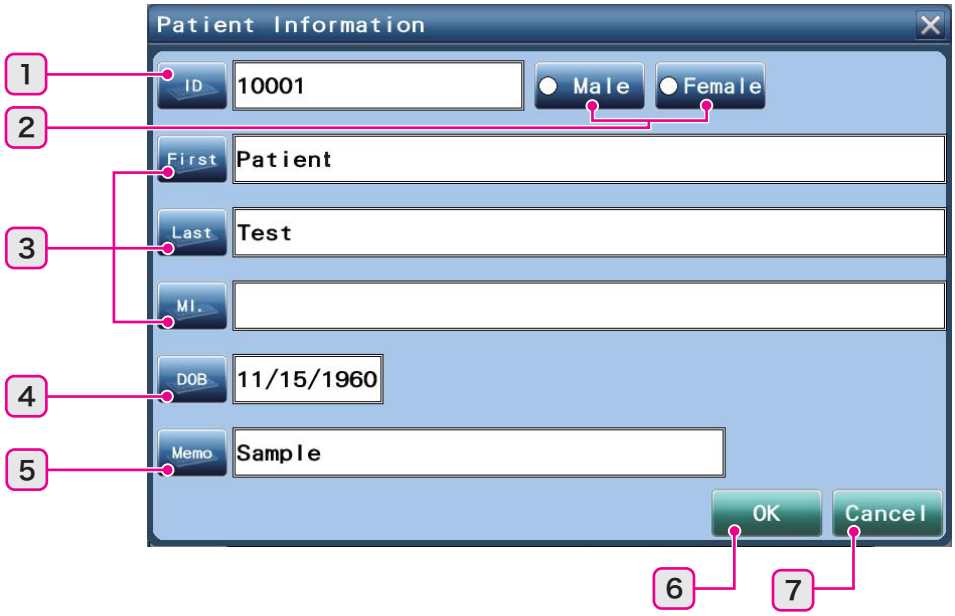
This bright light reflected from the cornea indicates the center (apex) of the cornea.

**16. Anterior segment illumination spots**

If these four light spots around the alignment light reflected from the anterior segment are obscured by eyelashes or such, a capture error may occur.

## 2.8.2 Patient Information screen

Patient information can be newly created as desired. Pressing the patient data field in the capture screen displays this screen.




**1. [ID] button/box**

Press this button to display the on-screen keyboard and enter the ID.

For patient information, patient ID entry is required.


On-screen keyboard

**2. Sex select buttons**

Press either button to select the sex of the patient.

Initially, neither button is selected.

**3. [First], [Last], [Middle] buttons/boxes**

Press these buttons to display the on-screen keyboard and enter the name of the patient.

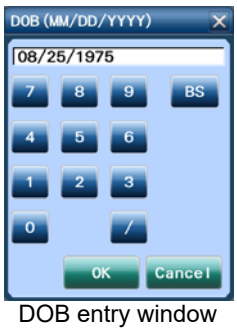
A maximum of 50 characters can be entered.

Selecting “L, F MI.” or “L F MI.” for “Name” in the Settings screen (Others) displays the patient name in the order of last name, first name, and middle name. If “F L MI.” is selected, the patient name is displayed in the order of the first name, last name, and middle name.

**4. [DOB] button/box**

Press this button to enter the date of birth.

Press the [DOB] button to display the DOB entry window and enter the date of birth. Enter data with slashes in the order, “Y/M/D”, “M/D/Y”, or “D/M/Y” set on the Settings screen. The date format set by the parameter is displayed in the title bar of the DOB entry window. When data is entered in an improper format or numeric value, the entered contents are not reflected on the Patient Information screen.




DOB entry window

**5. [Memo] button/box**

Press this button to display the on-screen keyboard and take notes.

**6. [OK] button**

Press this button to confirm the entered patient data and return to the capture screen.

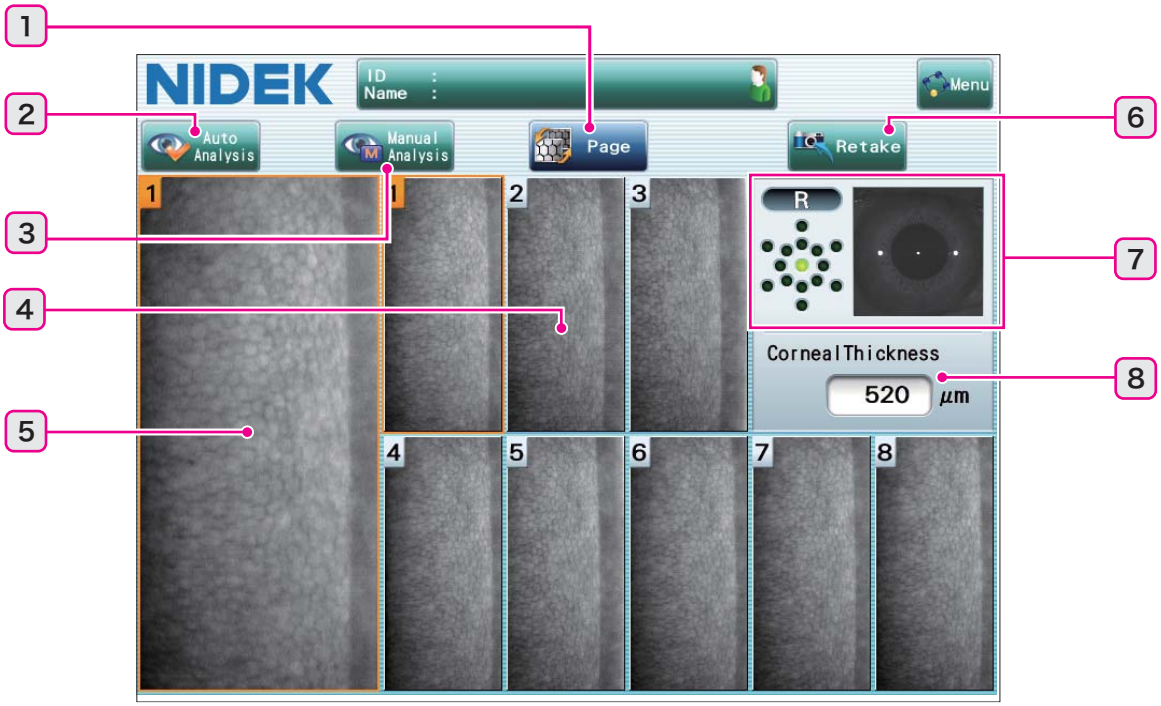
**7. [Cancel] button**

Press this button to cancel the entered patient data and return to the capture screen.



## 2.8.3 Image select screen

This is the screen for selecting the most suitable image for analysis from the 16 images captured in one shooting. This screen is displayed automatically upon completion of one shooting.




**1. [Page] button**

Used to switch the captured image pages.

The 16 total images are displayed on two pages of eight each.

**2. [Auto Analysis] button**

Used to confirm the currently selected images for saving and automatic analysis.

Manual analysis is possible on auto analyzed images on the detail analysis screen.

**3. [Manual Analysis] button**

Used to confirm the currently selected images for saving and manual analysis.

When this button is selected, automatic analysis is not performed and analysis values are not displayed on the capture result screen.

Perform manual analysis on the detail analysis screen.

**4. Thumbnail images**

The 16 captured images are displayed in thumbnail view. Pressing a thumbnail selects its image.

Thumbnails are displayed in order of image quality.

The displayed thumbnail images are switched by the [Page] button.

**5. Enlarged image**

The currently selected thumbnail image is displayed in enlarged view.

**6. [Retake] button**

Used to display the capture screen for recapture.

The currently displayed image data is discarded.

**7. Captured eye display**

Captured eye information (right/left eye, fixation lamp illumination position, and anterior segment image) of the endothelial image shown on the screen is displayed.

**8. [Corneal Thickness] indication**

The corneal thickness (μm) obtained at the same time as capture is displayed.

The corneal thickness is the measured results captured in the center where the alignment light is located.

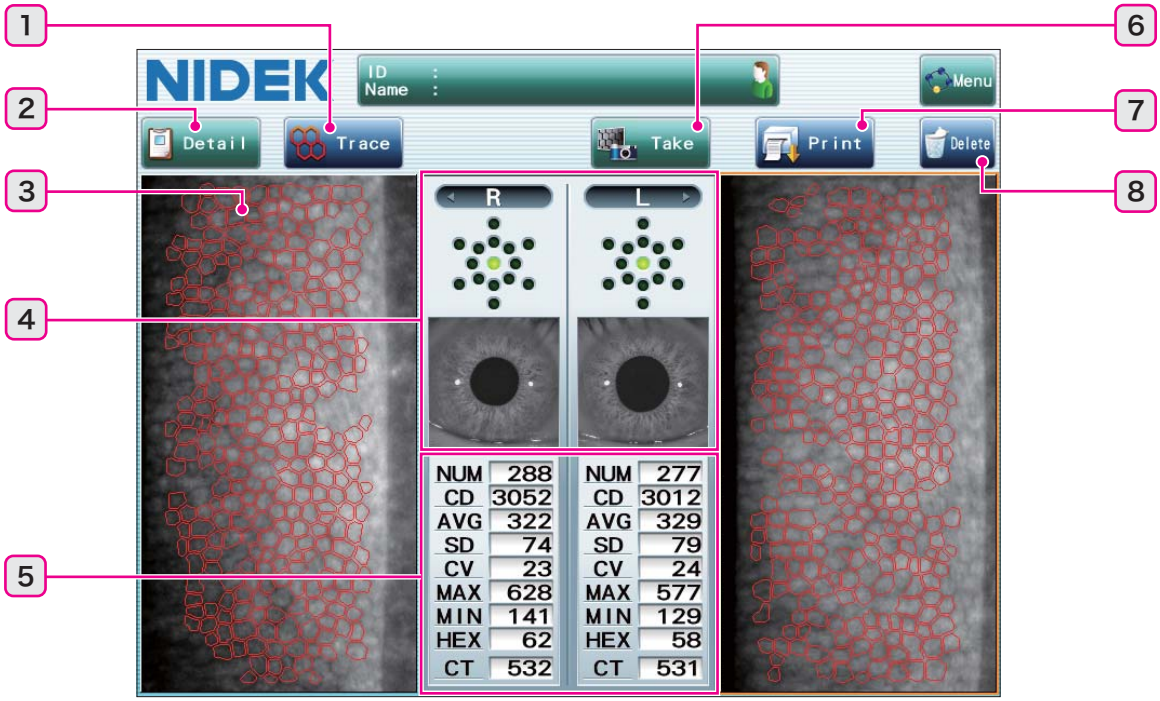
## 2.8.4 Capture results screen

This is the screen for displaying each analysis value based on the captured endothelial images.
This screen is displayed when image capture is complete. In this screen, printing of the analysis results and display of the detail analysis screen are performed.
In single mode, the capture results screen is always shown as a single display. In multiple mode / paracentral mode, the capture results screen is shown automatically as a single or multiple display depending on the capture count.



### ○ Single mode (Single display)

In single mode, when the right and left eye images are captured once each, the capture results screen is automatically shown as a single display.
In multiple mode / paracentral mode, pressing the [Result] button after the right and left eye images have been captured only once each displays the capture results screen as a single display.




**1. Analysis image select button**

Used to select the image display used for analysis from among Photo, Trace, Area, and Apex.

Pressing this button displays the Analysis Display window. Select the desired image and press the [OK] button.

| | |
|---|---|
| Photo | Original endothelial image |
| Trace | The identified endothelial outline is displayed in red. |
| Area | The identified endothelium is distinguished by area and displayed in different colors. |
| Apex | The identified endothelium is distinguished by apex and displayed in different colors. |

When the analysis range is set, display according to Trace, Area, or Apex is performed only within the analysis range.

**2. [Detail] button**

Used to display the selected data in the detail analysis screen.

**3. Endothelial image**

An image selected in the image select screen for analysis is displayed.

An orange border indicates the image selected to be initially displayed in the detail analysis screen by pressing the [Detail] button.

**4. Captured eye display**

Shows captured eye information (right/left eye, fixation lamp illumination position, and anterior segment image) of the displayed endothelial image.

**5. Analysis values**

Analysis results of the displayed endothelial image are shown.

| Abbreviation | Analysis item | Unit | Details |
|---|---|---|---|
| NUM | Number of Cells | cells | Number of endothelial cells analyzed |
| CD | Cell Density | cells/mm$^2$ | Number of endothelial cells per unit area (1 mm$^2$) |
| AVG | Average Area | μm$^2$ | Average area of endothelium analyzed |
| SD | Standard Deviation | μm$^2$ | Standard deviation of the endothelium area analyzed |
| CV | Coefficient of Variation | % | Standard deviation (SD) divided by the calculated average (AVG) |
| MAX | Max Area | μm$^2$ | Largest area of endothelium analyzed |
| MIN | Min Area | μm$^2$ | Smallest area of endothelium analyzed |
| HEX | Hexagonal Cells | % | Proportion of hexagonal cells found in the analyzed endothelium |
| CT | Corneal Thickness | μm | Corneal thickness obtained through capture procedure |

**6. [Take] button**

Used to display the capture screen and start a new image capture.

The function differs depending on before or after capture data is printed or output.

| | |
|---|---|
| Before printing or outputting | Displays the capture screen and performs additional image capture.<br>The captured image data is added to the current image data.<br>To start image capture of a new patient without printing or outputting the capture data, press the [Delete] button to delete the capture data and display the capture screen. |
| After printing or outputting | Displays the capture screen and performs image capture of a new patient.<br>A confirmation message appears before the capture screen is displayed. Starting image capture after the capture screen is displayed deletes the capture data (patient information, image data, and analysis data) of the previous patient.<br>Whether to display a confirmation message can be set by the “Check Data Clear” parameter. |

**7. [Print] button**

Used to print the displayed endothelial images and analysis values on the built-in printer.

When the video printer is set, they are printed on the video printer.

When LAN setting is enabled, pressing the [Print] button performs data output at the same time.

**8. [Delete] button**

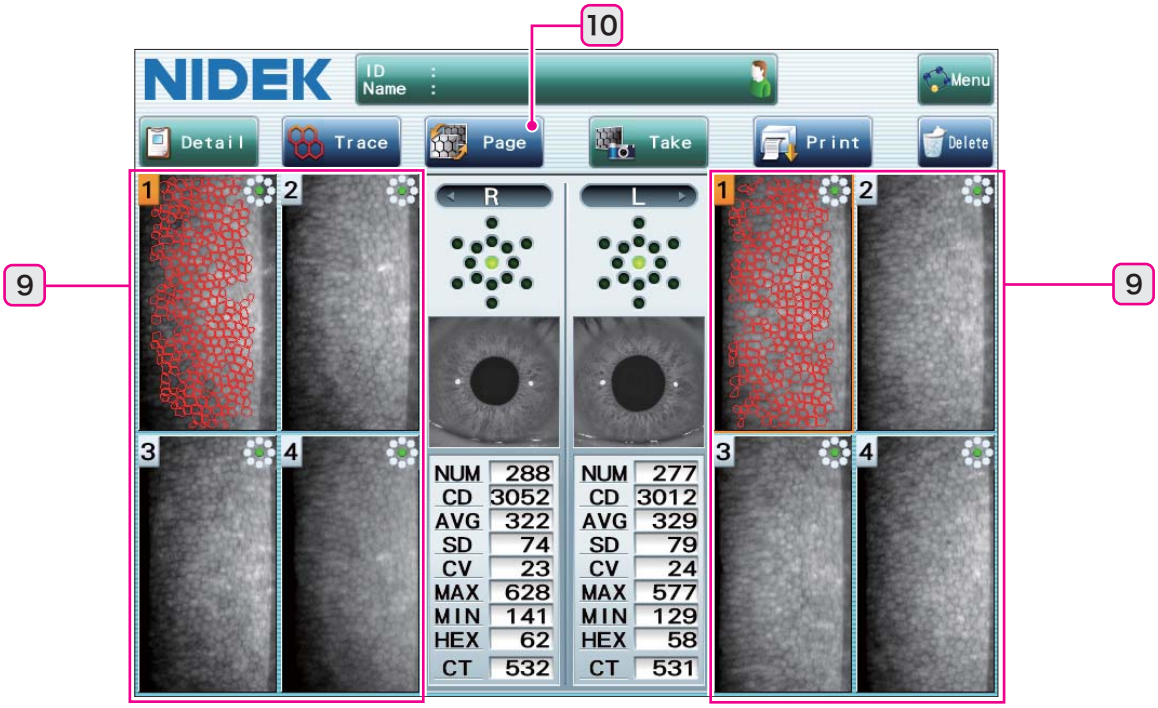
Used to delete the capture data (patient information, image data, and analysis data). After data is deleted, the capture screen appears automatically.

The confirmation message “Delete all data? [OK]/[Cancel]” appears. Pressing the [OK] button deletes the capture data and displays the capture screen.

## ○ Multiple mode (Multiple display)

In multiple mode, pressing the [Result] button after either the right or left eye image has been captured more than once displays the capture results screen as a multiple display.

Select the data used to display analysis values from the multiple capture results.




**9. Image select fields**

Select one image for both the right and left eyes to display analysis values.

The thumbnails with their numbers highlighted in orange are those whose analysis values are displayed.

The image bordered in orange is being selected and initially displayed in the detail analysis screen by pressing the [Detail] button.

The illumination position of the fixation lamp is shown in the upper right of each image.

| | |
|---|---|
|  | When “C (center)” or “Center (central eight points)” is selected:<br>The green illumination shows the position being lit. |
|  | When “Peripheral (peripheral six points)” is selected:<br>The green illumination shows the position being lit. |

**10. [Page] button**

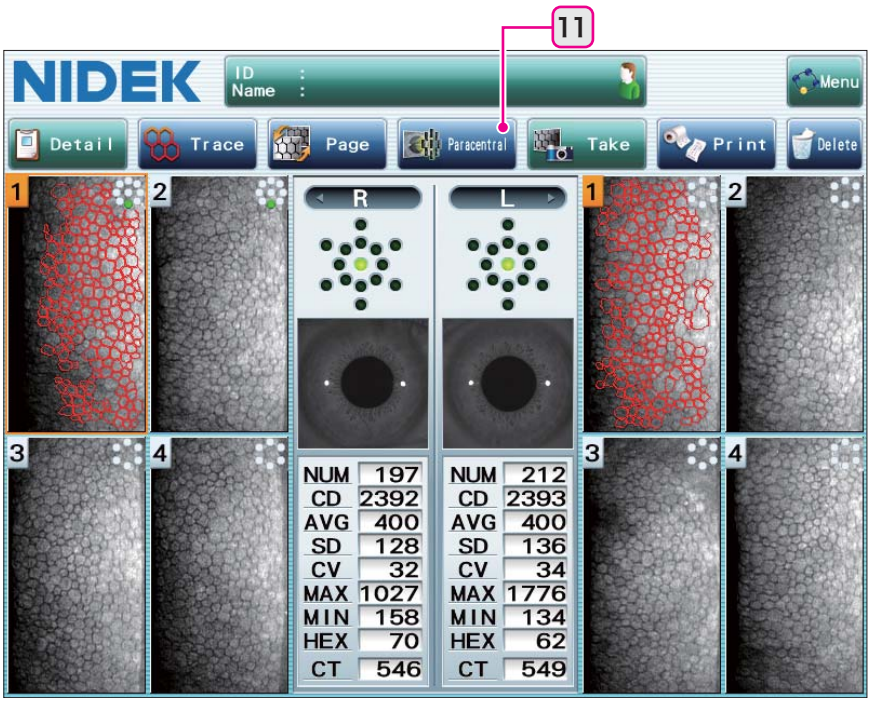
Used to switch the page when the maximum of four images per page are exceeded for one eye.

Up to 10 images are displayable for one eye.

## ○ Paracentral mode

In paracentral mode, pressing the [Result] button after images have been captured displays the capture results screen as a multiple display.

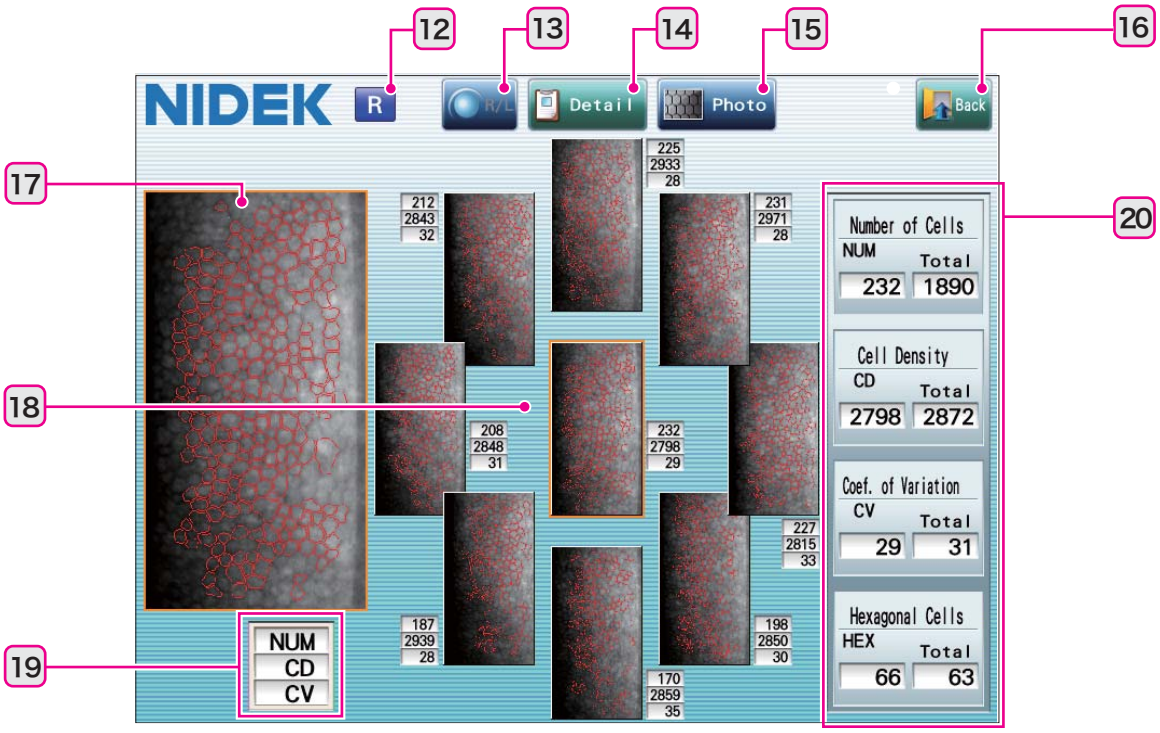
In multiple display of paracentral mode, the [Paracentral] button is added to the multiple mode screen. Pressing the [Result] button after the right and left eye images have been captured only once each displays the capture results screen as a single display with the [Paracentral] button displayed.




**11. [Paracentral] button**

Used to display the paracentral screen.

**Paracentral screen**




**12. R/L indication**

Displays the patient eye (right eye / left eye) shown on the screen.

**13. R/L button**

Used to display the captured image results of the other eye.

When only one eye has been captured, this button is disabled (grayed out).

**14. [Detail] button**

Displays the selected data in the detail analysis screen.

**15. Analysis image select button**

Functions the same as on the capture results screen.

**16. [Back] button**

Used to return to the previous capture results screen.

**17. Enlarged image**

The currently selected thumbnail image is displayed in enlarged view.

**18. Thumbnail images**

The central and paracentral captured images are displayed in thumbnail view. Pressing a thumbnail selects it as the image.

**19. Analysis value index**

Indicates the contents of the analysis values shown next to each thumbnail image (NUM: Number of Cells, CD: Cell Density, CV: Coefficient of Variation).

**20. Analysis values**

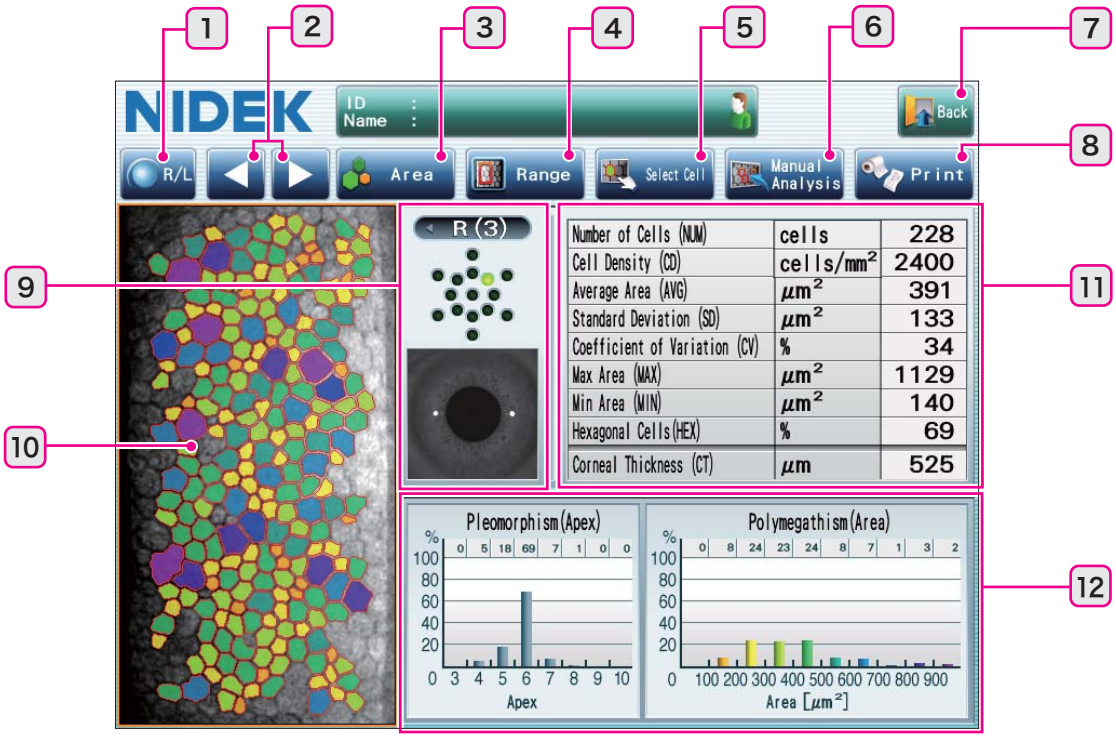
The analysis values of the selected image and the total values for all captured images are displayed.

Note

- Total value is the recalculation result of Number of Cells (NUM), Cell Density (CD), Coefficient of Variation (CV), and Hexagonal Cells (HEX) taken from all the cells of the images displayed in the paracentral screen.

## 2.8.5 Detail analysis screen

This is the screen for displaying and confirming the details of capture data. In addition, analysis conditions may be changed and then analysis can be performed again.
Compared to the capture results screen, the histograms of Pleomorphism (Apex) and Polymegathism (Area) allow easy visual recognition of the variations. (The contents of the analysis values are the same as in the capture results screen.)




**1. [R/L] button**

Used to display the captured image results of the other eye.

When only one eye has been captured, this button is disabled (grayed out).

**2. Data select buttons**

Used to switch images for display when more than one image has been captured for one eye.

When only one image has been captured for the displayed patient's eye, these buttons are disabled (grayed out).

**3. Analysis image select button**

Used to select the image display used for analysis from among Photo, Trace, Area, and Apex.

Pressing this button displays the Analysis Display window. Select the desired image and press the [OK] button.

| | |
|---|---|
| Photo | Original endothelial image |
| Trace | The identified endothelial outline is displayed in red. |

| | |
|---|---|
| Area | The identified endothelium is distinguished by area and displayed in different colors. |
| Apex | The identified endothelium is distinguished by apex and displayed in different colors. |

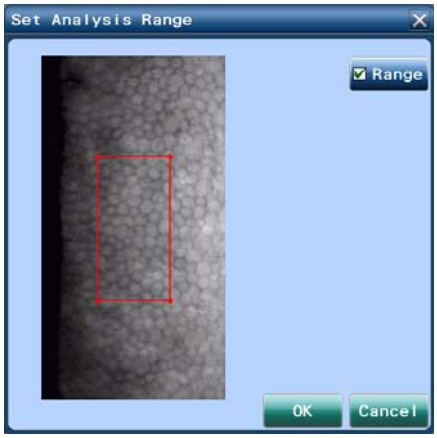
When the analysis range is set, display according to Trace, Area, or Apex is performed only within the analysis range.

**4. [Range] button**

Used to display the Set Analysis Range window to reset the analysis range.

Checking the [Range] button in the Set Analysis Range window changes the analysis range from the whole screen to the selection range.

The selection range can be changed by dragging the anchor points (displayed in red) on the screen. Pressing the [OK] button confirms the selected range and closes the Set Analysis Range window. Then, reanalysis is performed for the set range.

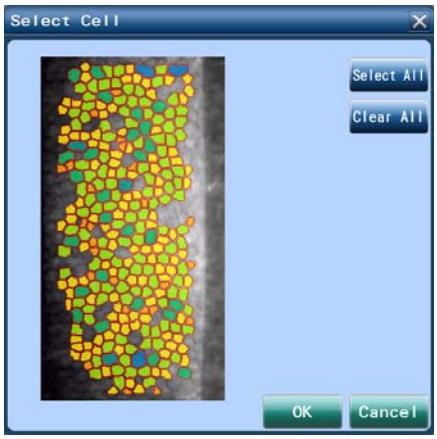



**5. [Select Cell] button**

Used to display the Select Cell window and reset cells to be analyzed.

Press the cells in the Select Cell window to be excluded from analysis. The identification display for cells considered to be improper is cleared.

When “Photo” is selected for the Analysis Display window, the Select Cell window is displayed by the trace image.




**6. [Manual Analysis] button**

Used to display the Manual Analysis window and select cells for analysis.

In manual analysis, the cells are selected by the operator for analysis.

The analysis may be made by the center point, corner point, or pattern select method.

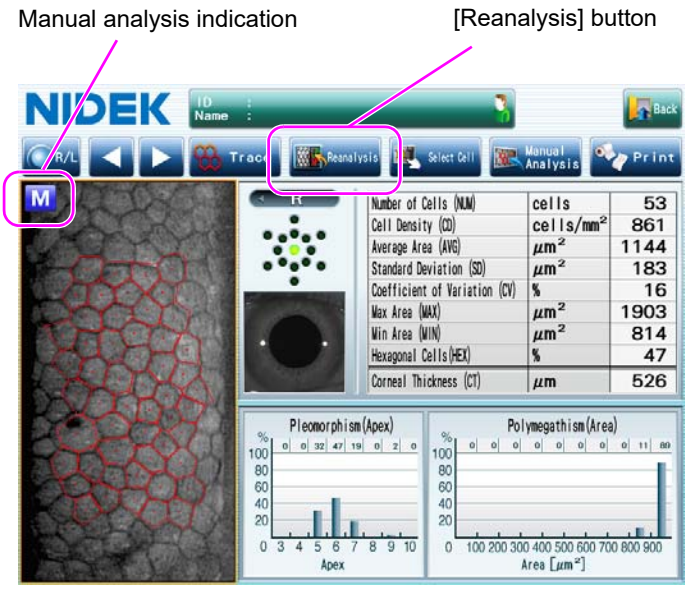
## ○ Detail screen after manual analysis

When manual analysis is performed, the analysis values are displayed in the detail analysis screen. The screen display changes as follows.

- The [Range] button changes to [Reanalysis].
- When manual analysis is performed, an indication mark appears on the upper left corner of the endothelial image.

| | |
|---|---|
| M | Manual analysis has been performed. |
| +M | Manual analysis has been performed on an auto analyzed image. |

Pressing the [Reanalysis] button performs automatic analysis and cancels the manual analysis results.




**7. [Back] button**

Used to return to the previous page.

**8. [Print] button**

Used to print the displayed endothelial image and analysis values on the built-in printer.

When the video printer is set, they are printed on the video printer.

When LAN setting is enabled, pressing the [Print] button outputs data at the same time.

**9. Captured eye display**

Shows captured eye information (right/left eye, fixation lamp illumination position, and anterior segment image) of the displayed endothelial image.

The number enclosed in parentheses next to the patient eye (R/L) indication is the image number.

**10. Endothelial image**

An image selected in the image select screen for analysis is displayed.

**11. Analysis values**

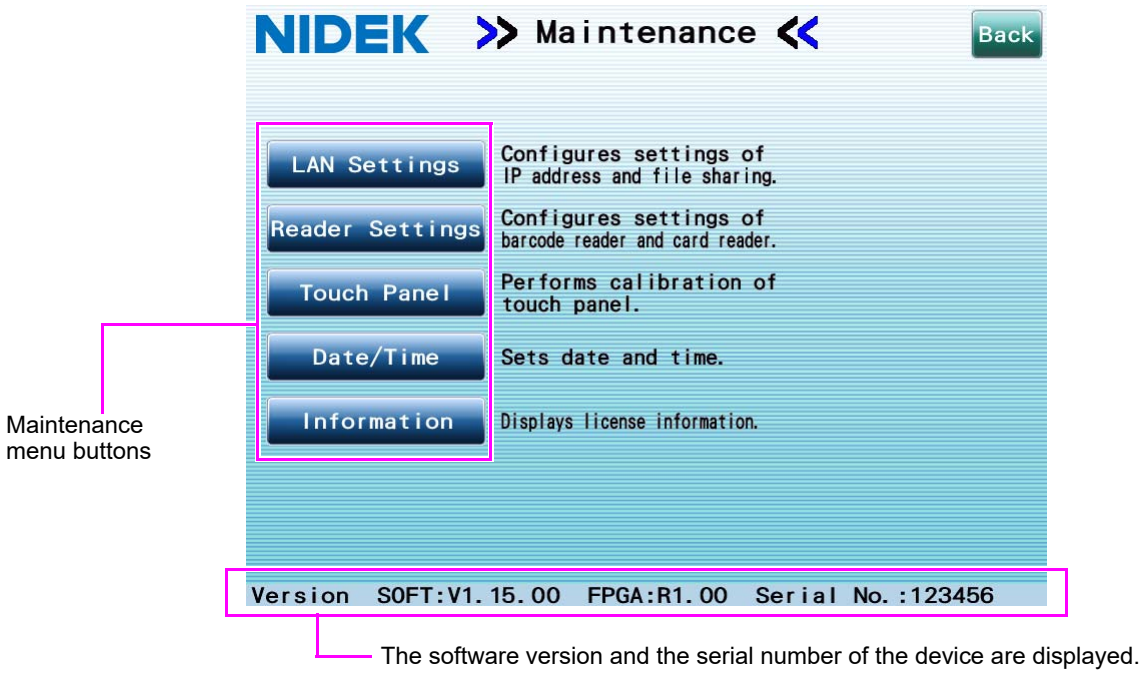
Analysis results of the displayed endothelial images are displayed.

**12. Distribution histograms**

The distributions of apex and area variations are displayed as a histogram.

## 2.8.6 Maintenance screen

The Maintenance screen allows selection and execution of the desired maintenance operations.




**Maintenance menu buttons**

Used to display the corresponding maintenance screen.

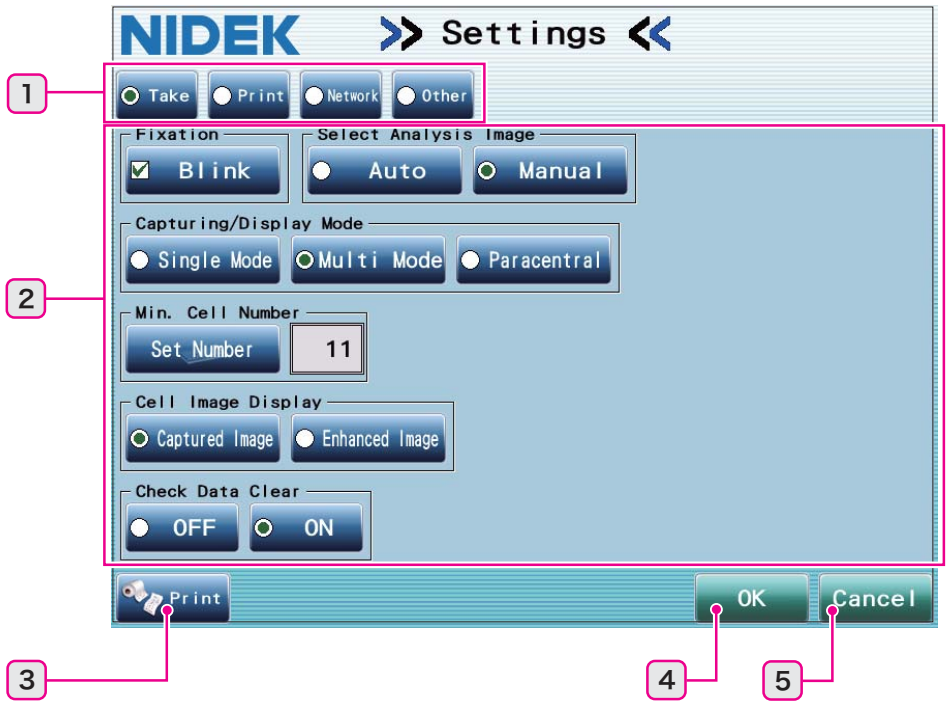
| | |
|---|---|
| LAN Settings | Sets the IP address and other settings for LAN and file sharing |
| Reader Settings | Sets parameters for the barcode reader or magnetic card reader. |
| Touch Panel | Calibrates the screen touch panel.<br>Corrects any displacement between the actual position touched and the screen touch panel. |
| Date, Time | Sets the current date and time. |
| Information | Displays license information<br>This is the license information regarding the JPEG format used for image compression and MD4 used for verification of data. |

**[Back] button**

Used to close the Maintenance screen and return to the capture screen.

## 2.8.7 Settings screen

The Settings screen allows setting of various parameters: “Take”, “Print”, “Network”, and “Other”.




**1. Item buttons**

Used to select one from four parameters: “Take”, “Print”, “Network” and “Other”.

| Item button | Options |
|---|---|
| Take | Fixation, Capturing/Display Mode, Min. Cell Number, Cell Image Display, Check Data Clear |
| Print | Printer, Printer Mode, Patient No. (Set No.), Data Clear, Built-in Printer Option (Date Print, Patient No., Econo. Print, Name Print, Image Print, Comment Print), Video Printer Options |
| Network | Output Item (output folder, Data, Report, ACK, Timeout) |
| Other | Language, Beep, LCD Backlight, Name, Sleep Time, Date Format |

**2. Options field**

Used to select itemized setting options.

Setting options are selected using radio buttons (◯/◉) or check boxes (☐/☑). The keyboard is used to enter a value in the entry field.

**3. [Print] button**

Used to print the current parameter settings on the built-in printer.

Pressing this button displays the confirmation message “Continue? [OK]/[Cancel]”. Pressing the [OK] button prints the data out.

**4. [OK] button**

Used to save the current parameter settings and close the Settings screen.

**5. [Cancel] button**

Used to cancel the changed parameter settings and close the Settings screen.

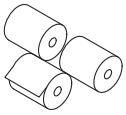
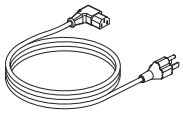
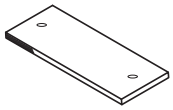
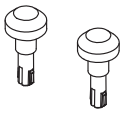
## 2.9 Symbols

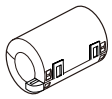
To call attention to users, labels and indications are provided on the device. If labels are peeling off, characters are fading, or otherwise becoming illegible, contact NIDEK or your authorized distributor.

| | |
|---|---|
|  | Indicates that the operator is advised to refer to the related instructions in the operator's manual. |
|  | Indicates that the degree of protection against electric shock is of a Type B Applied Part.<br>*The applied parts are the forehead rest and chinrest (see "9 Forehead rest" (page 24) and "11 Chinrest" (page 24) in "2.7 Device Configuration" (Page 22)). |
|  | Indicates the state of the power switch. If this symbol side of the switch is pressed down, power is not supplied to the device. |
|  | Indicates the state of the power switch. If this symbol side of the switch is pressed down, power is supplied to the device. |
|  | Indicates that the device must be supplied only with alternating current. |
|  | Indicates the date of manufacture. |
|  | Indicates the manufacturer. |
|  | Indicates that this product must be disposed of in a separate collection of electrical and electronic equipment in EU. |
|  | Medical device |
|  | EU Authorized Representative |
|  | Serial number |
|  | Unique Device Identifier |
|  | Catalogue number |

# 2.10 Checking Contents

Standard accessories are as follows. Unpack and confirm contents from the shipping.

| | Part name | Qty. | Appearance |
|---|---|---|---|
| ☐ | Main body | 1 |  |
| ☐ | Printer paper | 3 |  |
| ☐ | Power cord | 1 |  |
| ☐ | Dust cover | 1 |  |
| ☐ | Pack of chinrest paper | 1 |  |
| ☐ | Fixing pin for chinrest paper | 2 |  |

| | Part name | Qty. | Appearance |
|---|---|---|---|
| ☐ | Magnetic forehead rest pad (The magnetic forehead rest pad does not come attached to the device and is included in the packed contents.) | 1 |  |
| ☐ | Ferrite core | 1 |  |
| ☐ | Touch-screen pen | 1 |  |
| ☐ | Touch-screen pen stand | 1 |  |
| ☐ | Operator’s manual | 1 |  |

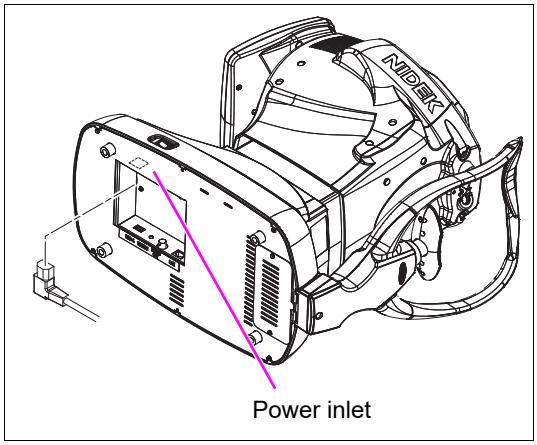
## 2.11 Before First Use

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

***1*** Place the device on a stable table.

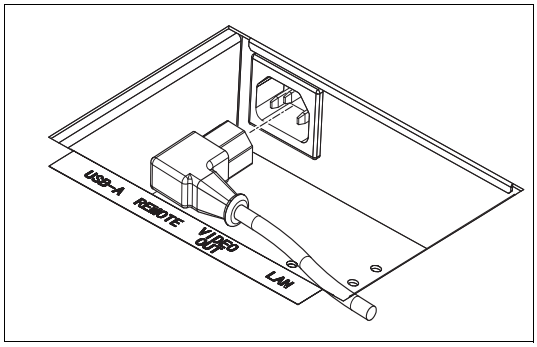
***2*** Pull the main unit fully to a side, then gently lay down the device on the same side.

***3*** Connect the power cord to the power inlet.




Power inlet

With the power plug aligned with the power inlet, insert the plug straight as far as it goes.




***4*** Connect peripheral devices as necessary.

Connect the video printer, barcode reader, magnetic card reader, LAN communication cable before turning on the device.

See “○ Bottom view (Page 25)” of “2.7 Device Configuration” for the method of connecting peripheral devices.

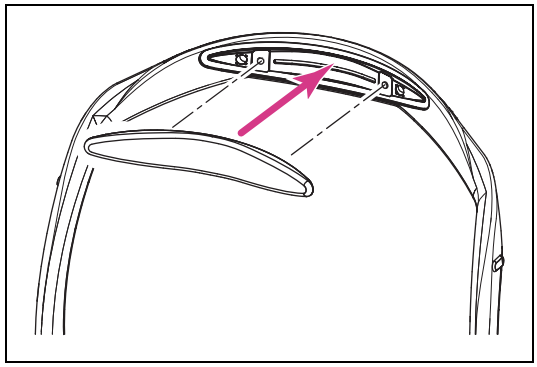
**⚠ CAUTION**

- **Before connecting any cables to the device, be sure to turn off power and unplug the power cord. Check the indication and orientation of the connector and be sure not to connect it at an angle.**
  Malfunction may occur.
- **Insert the plug into the connector according to the proper indication and orientation and do not apply undue force to make the connections.**

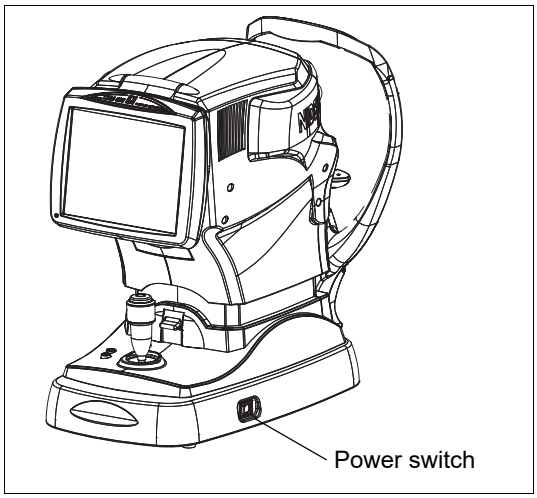
***5*** Stand the device upright.

**6** Attach the magnetic forehead rest pad to the device.

The magnetic forehead rest pad does not come attached to the device and is included in the packed contents. The magnetic forehead rest pad is attachable in the orientation as shown to the right.



**7** Confirm that the power switch is turned off ( ○ ) then plug the power cord into the power outlet.




⚠ **WARNING** • **Connect the power plug to a grounded power outlet or the grounding wire to a ground terminal.**

Electric shock or fire may occur in the event of device malfunction or power leakage.

**8** Turn on ( | ) the power switch.

The title screen is displayed on the screen touch panel and the device begins initialization.


Title screen

**9** Confirm that the capture screen is displayed.


Capture screen

**10** Set the printer paper.

See “4.3 Replacing Printer Paper” (page 106) for details on the printer paper setting procedure.

The setup procedure is complete.

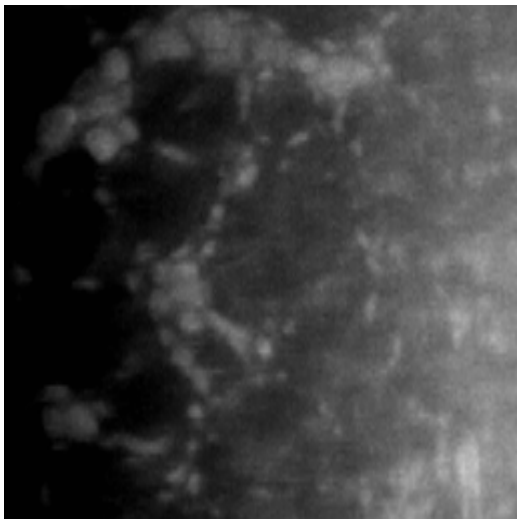
Note

- Set the parameters in the Settings screen as desired.

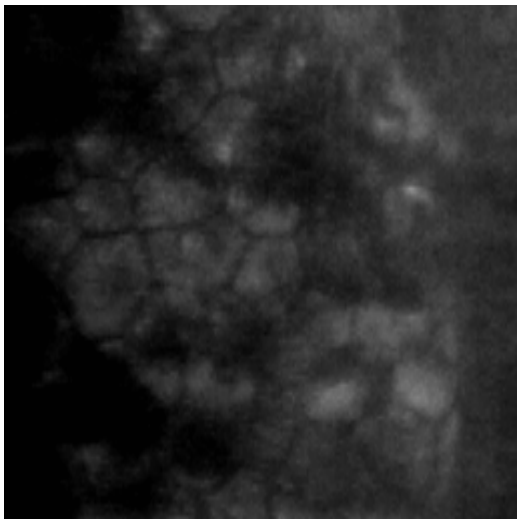
  See “4.7 Parameter Settings” (page 118) for the parameters and their setting methods.

## 2.12 Automatic Analysis Results Considerations

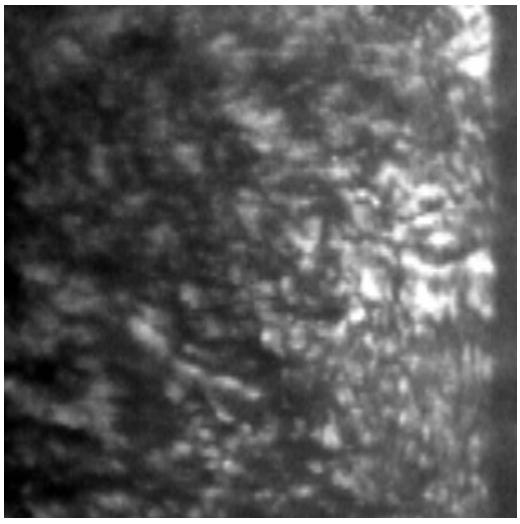
Depending on the patient's condition, there may be cases where detection of endothelial cells by automatic analysis is difficult.



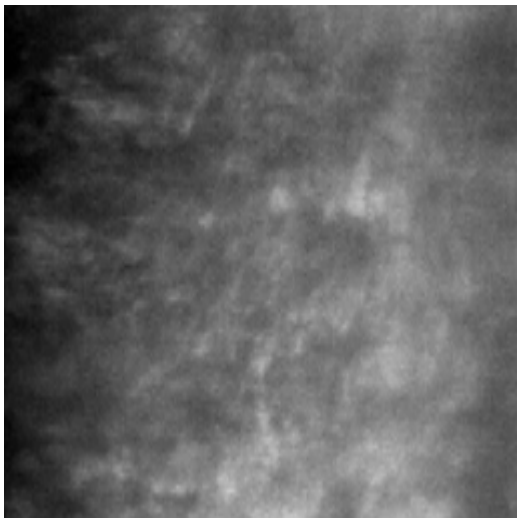
Case where there is extensive deficiency of endothelial cell



Case where cell recognition requires careful visual observation



Case where visual cell recognition is difficult and complex patterns that are not cells appear



Case where the whole image looks blurred for reasons such as corneal inflammation

In these cases, detection of endothelial cells by automatic analysis is difficult. Perform the items below if necessary.

- Perform additional manual analysis in addition to the automatic analysis results.
- Perform manual analysis without automatic analysis (clear all cells detected by automatic analysis).

⚠ **CAUTION** • **When automatic analysis has been performed, visually check the corneal endothelium image in conjunction with analysis results before making a final diagnosis.**

# 3. OPERATING PROCEDURE

## 3.1 Operation Flow

Turning on the device

3.2.1 Start up (see page 53)

Turn on power to the device, and change the parameter settings of the device if necessary.

Entering patient names

3.3 Entering Patient Information (see page 57)

Enter patient information if necessary.

Image capture

3.4 Setting Capture Conditions (see page 61)

3.5 Image Capture Procedure (see page 66)

Confirming analysis results

3.6 Capture Results Screen Operation (see page 80)

Endothelial images and analysis results of both eyes are displayed.

3.7 Detail Analysis Screen Operation (see page 89)

An endothelial image, analysis results, distribution graph of one eye are displayed.

After analysis conditions are changed, reanalysis can be performed.

Printout

3.9 Printing (see page 98)

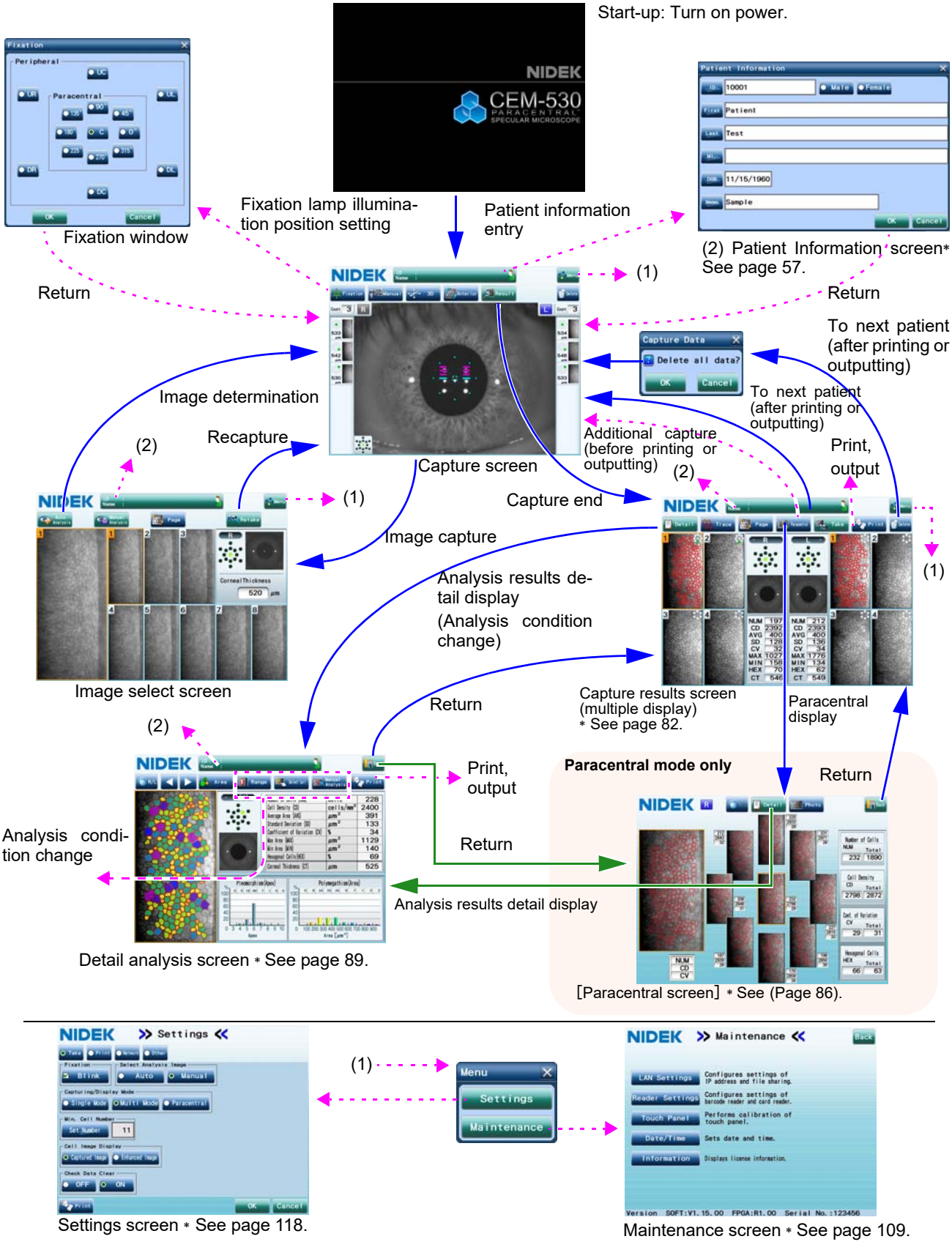
Data is output over a LAN along with printing.

Turning off the device

3.2.3 Normal shut down (see page 55)

Turn off the power switch in the capture screen.

## ○ Screen and operation flow



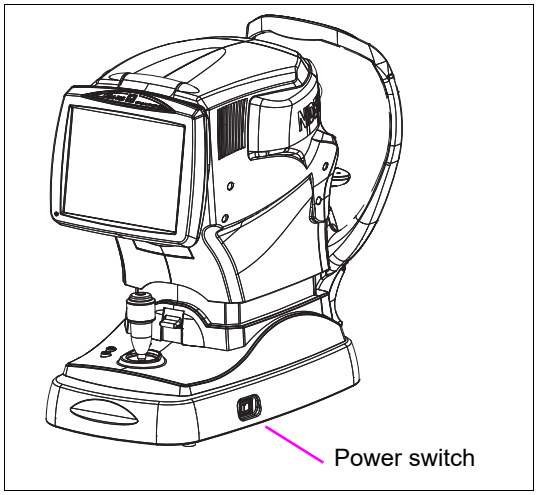
# 3.2 Start Up and Shut Down

## 3.2.1 Start up

***1*** To use a video printer, turn on power to the printer.

***2*** Turn on ( | ) the power switch of the device.

The device starts up.




The title screen appears and the device is initialized.

Wait for until the screen to switch to the capture screen.

When power to the CEM-530 is turned on, the capturing unit makes up/down, right/left, and forward/backward movements to determine the initial position for auto tracking. It is not a failure of the device.


Title screen

***3*** The capture screen is displayed.


Capture screen

***4*** Perform checks before use.

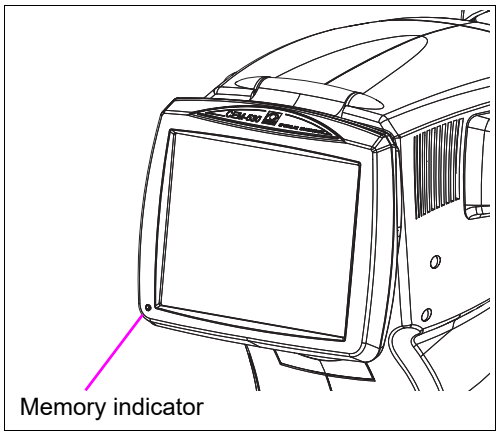
Perform the following checks before use.

- ☐ No error message appears.
- ☐ The main unit moves smoothly using the joystick.
- ☐ The capturing window is clean.
- ☐ The chinrest moves up and down by pressing the chinrest up/down button.
- ☐ Printer paper is sufficient.
- ☐ Cables are securely connected.

If any abnormality is found, stop using the device, then refer to “4.1 Troubleshooting” (page 103).

## 3.2.2 Recovery from power saving mode

The device automatically enters power saving mode when it is left idle for a preset period of time. In power saving mode, the screen touch panel goes off and the memory indicator blinks.




Note

- This idle time can be selected from among 5 minutes, 10 minutes, 15 minutes, and “OFF” (No power saving mode) with the Sleep Time setting in the Settings screen (Others). (Factory setting “5 minutes”)

  See “4.7 Parameter Settings” (page 118) for the setting procedure.

To recover from power saving mode, perform any of the following operations:

- Touch the screen touch panel.
- Press the start button.
- Manipulate the joystick to move the capturing unit so that the eye detected by the device is switched (from right to left, or left to right).
- Manipulate the joystick to move the capturing unit up or down.
- Move the chinrest up or down with the chinrest up/down button.
- Read an ID with the barcode reader or magnetic card reader.

### 3.2.3 Normal shut down

Note

- Before packing the device, turn off power to the device in packing mode.
  For details of packing mode, see “3.2.4 Shutoff before transporting the device” (page 56).

***1*** Return to the capture screen.


***2*** Turn off ( ○ ) the power switch.

***3*** If the video printer is connected, turn off power to the printer.

***4*** Check the capturing window for dirt. Clean it if necessary.
See “4.8.1 Cleaning the capturing window” (page 129).

***5*** Clean the forehead rest and chinrest. Then place the dust cover on the device.
Use clean gauze or absorbent cotton dampened with rubbing alcohol for cleaning.
Always keep them clean for the next use.

Note

- Be sure to always place the dust cover on the device when it is not in use.

## 3.2.4 Shutoff before transporting the device

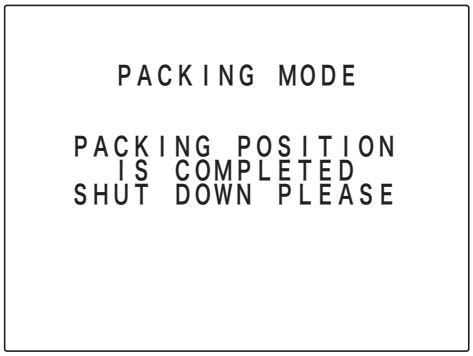
Before the device is transported, put the device in packing mode. In packing mode, the capturing unit and chinrest are automatically set in preparation for transportation.

⚠ **CAUTION** • **Before transporting, set the mode to packing mode and pack the device in the provided packing material with the locking lever for the main unit unlocked.**
It may result in failure when excessive vibration and shock are applied.

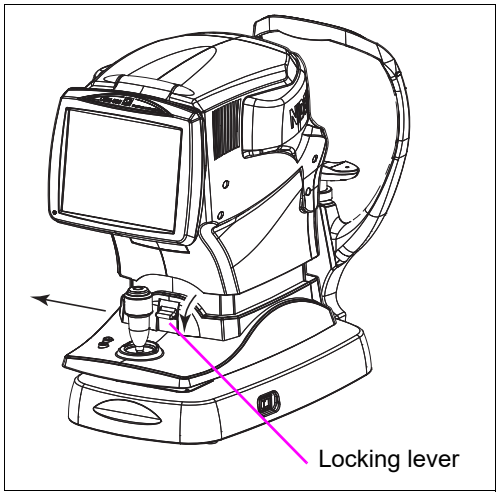
***1*** Turn the power switch off ( ○ ) to shut off the device once.

***2*** Turn on the power switch ( | ) while pressing the chinrest down button (▼).
The device starts putting itself into packing mode. Wait until a message is displayed on the screen.

***3*** When the message “PACKING POSITION IS COMPLETED / SHUT DOWN PLEASE” is displayed, turn the power switch off ( ○ ).
Ensure that the chinrest and capturing unit are at their lowest limits.




***4*** Pull the main unit fully to the side to which the main unit will be laid down, and fix the main unit with the locking lever. Then gently lay down the device on its side.




***5*** Disconnect the power cord, interface cables, etc.

***6*** Raise up the device and pull up the locking lever to release the main unit.
Pack the device in the provided packing material.

Note
- To restore from packing mode, turn on the power switch in the same manner as the usual start-up.

# 3.3 Entering Patient Information

Enter patient information if necessary. (Patient information entry is not necessarily needed.)

Note

- Data can be identified with patient number (automatically provided 4-digit number) in addition to capture data.

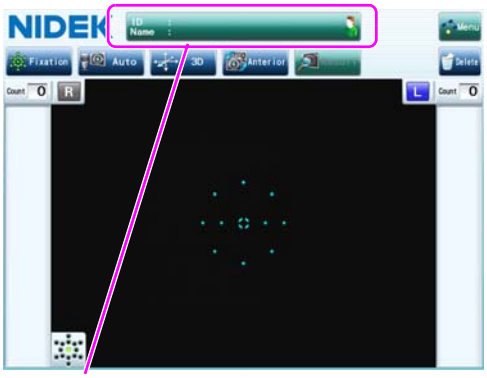
  Patient information number is enabled or disabled by the Print parameter in the Settings screen. See “4.7.3 Print parameter” (page 124).
- When only a patient ID is entered using the barcode reader or magnetic card reader, it can be entered without displaying the Patient Information screen.

  Read a barcode or magnetic card while the patient information field is displayed on the screen.

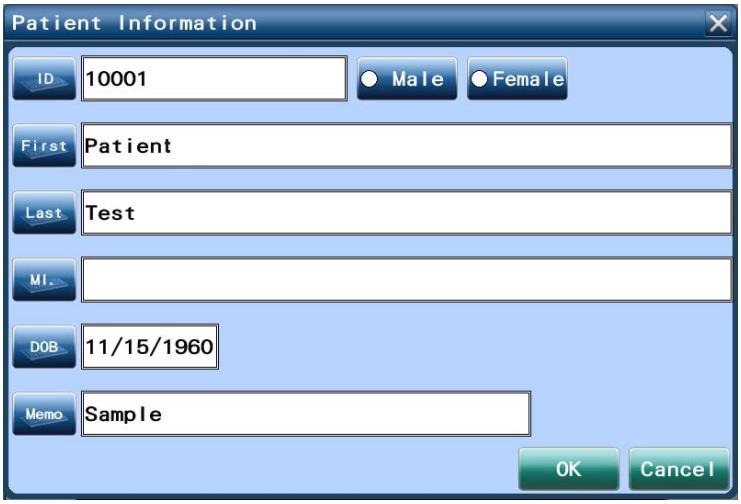


**1** Press the patient information field on the screen to display the Patient Information screen.

As long as the patient information field is displayed, the Patient Information screen can be accessed.




Patient information field




**2** Enter the patient information.

Enter the ID, sex, first name, last name, middle name, date of birth, and memo.

Use the on-screen keyboard (or DOB entry window) that is displayed by pressing the item buttons.

Note

- For buttons (example: ID ) with a keyboard illustration, pressing the buttons displays the on-screen keyboard (or entry window).

The various patient information is presented as in the following accordingly.

The "—" indication means the patient information is not presented. For example, even if data is entered for DOB or Memo as patient information, it is not displayed in the screen (patient information field). It is not included in the print contents from the built-in printer, either.

| Patient information | Screen display | Built-in printer | Video printer | LAN output | |
|---|---|---|---|---|---|
| | | | | Data | Report |
| ID, First / Last / MI. | ○ | ○ | ○ | ○ | ○ |
| Sex | — | ○ | ○ | ○ | — |
| DOB, Memo | — | — | — | ○ | — |

Note

- The "First/Last/MI." field is limited to the valid print number of characters (including slashes) allowed by the screen display and built-in printer.

  A maximum of 26 characters are supported for the screen display and 15 characters for the built-in printer.

1) Enter the patient ID. ID is a required entry item. (max. 20 characters)

   Press the [ID] button to display the on-screen keyboard and enter the ID.

   When the barcode reader or magnetic card reader is connected, read the barcode or magnetic card reader in the Patient Information screen.


Note

- If no ID has been entered, patient information cannot be preserved.
- When patient information is entered, the ID cannot be read by the barcode reader or magnetic card reader while the on-screen keyboard for ID entry is displayed.

  Read an ID while the Patient Information screen is displayed.

Enter the other items by the following procedure as necessary.

2) Select the sex by pressing the [Male] or [Female] button.

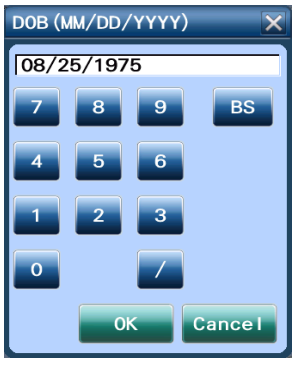
   Initially, neither button is selected.


3) Enter the date of birth.

   Pressing the [DOB] button displays the DOB entry window. Enter data with slashes in the order, Year/Month/Date, Month/Date/Year, or Date/Month/Year set on the Settings screen.

   It is not necessary to precede single digit months or days with a zero.

   Press the [OK] button to close the DOB entry window.



Note

- If an improper date is entered in the DOB entry window, the date is not reflected in the Patient Information screen.

  In such a case, reenter the data in the DOB entry window.

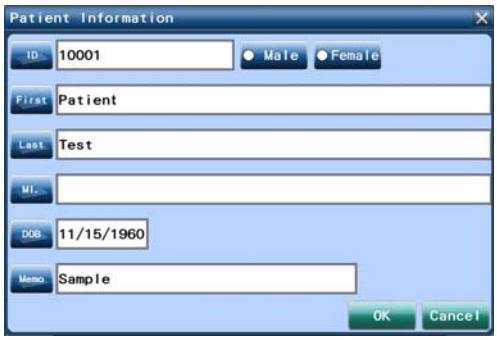
4) Press [First], [Last], [MI.] or [Memo] to display the on-screen keyboard and enter each content.

   A maximum of 50 characters can be entered in [First], [Last], or [MI.] and 34 characters in [Memo].


**3** Press the [OK] button in the Patient Information screen to return to the capture screen.

The entered ID and name are displayed in the patient information field on the capture screen.

Pressing the [Cancel] button cancels the entry and closes the Patient Information screen.




## ○ Entry using on-screen keyboard

To enter alphanumerical characters or symbols in the item field, an on-screen keyboard displayed by pressing the item button can be used.

### On-screen keyboard


| | |
|---|---|
| BS | Deletes a character on the left of the cursor. If characters are selected, the selected characters are deleted. |
| Shift | Toggles the alphabetic characters between upper and lower case letters. |
| Space | Enters a space.<br>Even if a space is entered as a first entry in the ID field, the space is deleted when the [OK] button is pressed. |

| | |
|---|---|
| ← / → | Moves the cursor to right or left by one position. |

Other keys can be used as a usual keyboard.

Symbols that are not displayed on the on-screen keyboard cannot be entered.

Note

- When the on-screen keyboard is displayed to edit the entered contents, all the contents are selected (highlighted). Pressing the [Delete] button or entering a character deletes all the highlighted contents. To partly change the entered contents, place a text cursor by pressing the entry field or pressing either arrow button.

## ○ Clearing patient information

To clear the entered patient information, press the [Delete] button in the capture screen or capture results screen. However, care should be taken because once the image data is deleted, it cannot be recovered.

1) Press the [Delete] button in the capture screen or capture results screen to display the confirmation message “Delete all data? [OK]/[Cancel]”.


2) Press the [OK] button to close the message dialog box and the capture data (patient information, image data, and analysis data) is deleted.

   Pressing the [Delete] button in the capture results screen displays the capture screen automatically.

   Pressing the [Cancel] button closes the message dialog box without deleting the capture data.

# 3.4 Setting Capture Conditions

Set the capture conditions (Capturing/ Display Mode, illumination position of fixation lamp, auto shot, auto tracking) in advance.

## ○ Capturing/ Display Mode

Set the capture count (one time only / 1 to 15 times) and whether to perform paracentral image capture.

Select Single Mode, Multi Mode, or Paracentral in the “Capturing/ Display Mode” parameter.

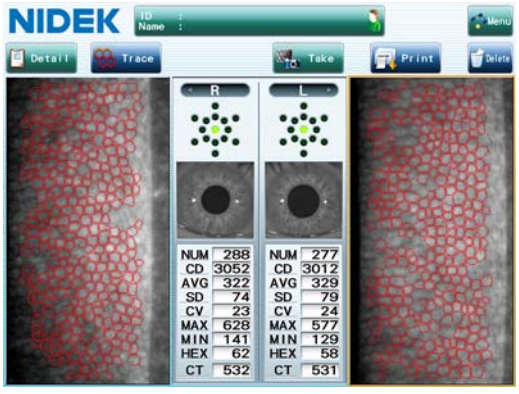
For the setting procedure, see “4.7.2 Take parameter” (page 121).

| Capturing/ Display Mode | Measurement count for one eye | Capture results screen | Paracentral auto image capture |
|---|---|---|---|
| Single Mode | one time | Single display | Unavailable |
| Multi Mode | 1 to 15 times | Single display / Multiple display Selected automatically | |
| Paracentral | | | Available |

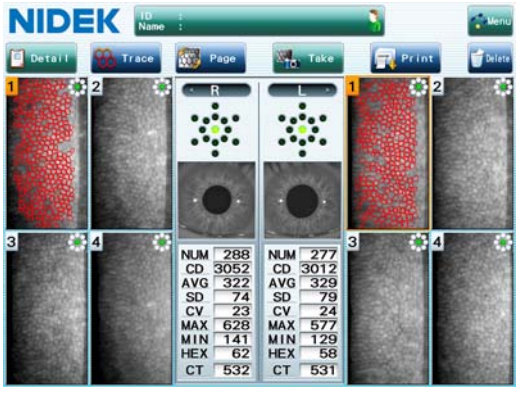
Note

- In paracentral auto image capture, the images are captured at the selected center and paracentral capture points continuously and displayed in graphical layout on the paracentral screen. The total values of the analysis values are also calculated from the entire captured data.
- In multiple mode / paracentral mode, a maximum of 15 capture data sets can be saved for each eye.

  If capture data sets exceed 15, the data is erased in order from the oldest and displayed in the erased image data field. (For example, the 16th image data is displayed as No. 1.)

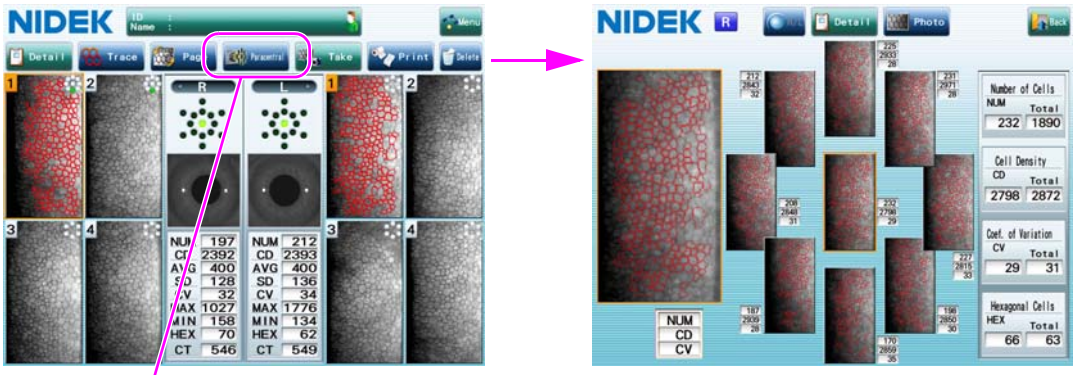



Capture results screen (single display)




Capture results screen (multiple display)

| | |
|---|---|
| Single mode | Regardless of the capture count, the capture results screen is always shown as a single display.<br>After completion of each image capture for both eyes, the capture results screen appears.<br>When image capture is performed more than once for one eye, after each capture, the previous data is overwritten. |
| Multiple mode | Depending on the capture count, the capture results screen is automatically shown as a single display or multiple display.<br>When image capture is performed only once for either eye, the capture results screen is shown as a single display for that eye. In other cases, it is shown as a multiple display. The capture results screen is displayed by pressing the [Result] button.<br>In multiple mode, a maximum of 15 capture data sets can be saved for each eye. |
| Paracentral mode | The capture results screen is shown as a multiple display with the [Paracentral] button.<br>The capture results screen is displayed by pressing the [Result] button.<br>Pressing the [Paracentral] button displays the paracentral screen.<br>When image capture is performed only once for either eye, the capture results screen is shown as a single display for that eye. |




[Paracentral] button

Paracentral screen

## ○ Fixation lamp

By setting the fixation lamp, the visual axis of the patient may be guided to enable selection of the capture area. This window is used if image capture cannot be performed correctly with the central fixation lamp or an area other than the center of the cornea needs to be captured.

Pressing the [Fixation] button displays the Fixation window that allows setting of the illumination point of the fixation lamp.

| | |
|---|---|
| C (corneal center) | The center of the cornea is captured. (Default setting)<br>When no setting is specified for the fixation lamp, image capture is performed in the center (C). |
| Paracentral (visual angle: 5°) | Paracentral eight points (45° spacing)<br>The fixation lamp lights up inside the capturing window. (internal fixation lamp) |
| Peripheral (visual angle: 27°) | Peripheral six points (60° spacing)<br>The fixation lamp lights up outside the capturing window. |

The setting for the fixation lamp differs depending on the setting of the “Capturing/ Display Mode” parameter (Single Mode / Multi Mode / Paracentral).

### Single mode / Multiple mode

Select one point from among C (corneal center), Paracentral (paracentral eight points, 5° visual angle), and Peripheral (peripheral six points, 27° visual angle).

The fixation lamp of the selected point lights up.

When capturing images of various points in multiple mode, set the illumination point of the fixation lamp before capturing images.


### Paracentral mode

Select the image capture points and order.

Press the corresponding button to set the capture points and order. The number that appears in orange indicates the capture order.

Pressing a selected button (fixation lamp point) again cancels its selection.


| | |
|---|---|
| Load | Displays the capture order saved in the device.<br>After the capture order has been changed temporarily, pressing this button loads the standard capture order. |
| Save | Saves the currently-set capture order as the standard order.<br>This capture order becomes the standard order that is displayed when the [Load] button is pressed. The order is also the one that is displayed when the Fixation window is opened. |

Note

- Peripheral six points (27° visual angle) can also be selected. However, they cannot be displayed in the paracentral screen.

After completing the fixation lamp setting, press the [OK] or [Cancel] button to close the Fixation window.

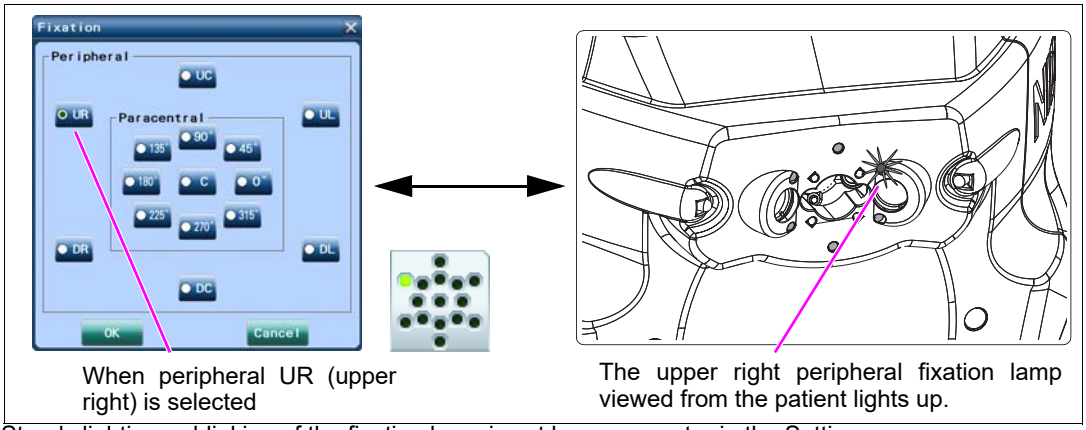
| | |
|---|---|
| OK | Applies the currently-set capture order and returns to the previous screen.<br>When the capture order has been changed temporarily from that of the initial display, pressing the [OK] button instead of [Save] button applies the setting to the current patient only. |
| Cancel | Cancels the currently-set capture points and capture order and returns to the previous screen. |

Note

- After setting the capture order in the Fixation window, when the capture screen is displayed either by pressing the [Delete] button to delete the captured data or the [Print] button to print the captured data, the fixation lamp saved as No.1 will light up.

The arrangement of the fixation lamps shown in the Fixation window is as viewed from the patient's side. (the same indications as the cylinder axis)

| | | |
|---|---|---|
| | UC: Upper center | |
| UR: Upper right | | UL: Upper left |
| DR: Down right | | DL: Down left |
| | DC: Down center | |




When peripheral UR (upper right) is selected

The upper right peripheral fixation lamp viewed from the patient lights up.

Steady lighting or blinking of the fixation lamp is set by a parameter in the Settings screen.

Note

- Blinking the fixation lamp draws the patient's attention and allows the patient to fixate more easily.

For the setting procedure, see "4.7.2 Take parameter" (page 121).

## ○ Auto shot function

Press the button to select the auto shot function.

| | |
|---|---|
| Manual Manual | The auto shot function is disabled.<br>Press the start button to start image capture. |
| Auto Auto | The auto shot function is enabled.<br>Image capture starts automatically when the eye is best aligned and focused.<br>When endothelium observation is selected, the auto shot function is disabled. |

Note

- When the auto shot function is enabled, no operation is enabled during the time from the auto alignment to the start of image capture.
- Even when the auto shot function is enabled, the operator can start image capture by pressing the start button.

  Press the start button to start image capture when image capture has difficulty starting for patients who blink often.

## ○ Auto tracking function

Press the button to select the auto tracking function.

| | |
|---|---|
|  3D | The auto tracking function in the forward and back, right and left, and up and down directions is enabled.<br>When endothelium observation is selected, the auto tracking function in the forward and back direction is disabled. |
|  2D | The auto tracking function in the right and left, and up and down directions is enabled. |
|  OFF | The auto tracking function is disabled. Manually align the device and bring the eye into focus. |

Note

- The settings of the auto shot and auto tracking functions are maintained in the subsequent captures.

## 3.5 Image Capture Procedure

Start endothelial image capture after alignment with the image toggle button at “Anterior” in the screen display.

***1*** Turn on power to the device.

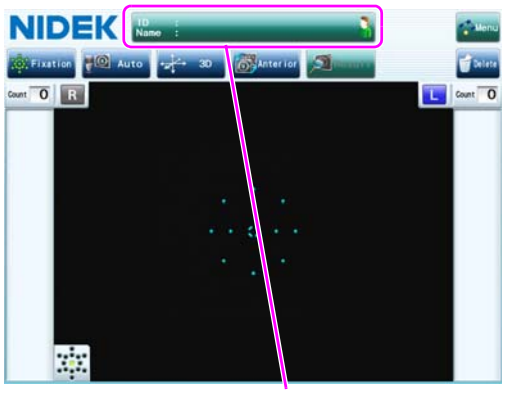
The device starts up, and the capture screen appears.


Capture screen

***2*** Enter the patient information as necessary.

Enter the ID, sex, first name, last name, middle name, date of birth, and memo.

For the entering method, see “3.3 Entering Patient Information” (page 57). Patient information may be entered after image capture.




Patient information field

***3*** Set the capture conditions.

Set the fixation lamp, auto shot, and auto tracking.

The default setting sets the fixation lamp to light at one point in the center. Auto shot and auto tracking are initially set to the settings used in the previous capture.

See “3.4 Setting Capture Conditions” (page 61) for details.


Setting buttons

Fixation lamp illumination indication

## *4* Prepare the patient.

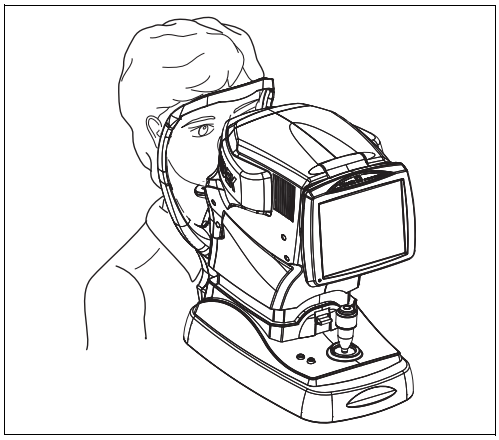
⚠ **CAUTION** • **Be careful not to get fingers of the patient or operator caught in the moving parts during image capture.**

1) Clean the forehead rest and chinrest that come into contact with the patient with clean gauze or absorbent cotton dampened with rubbing alcohol.

   If a stack of chinrest paper is on the chinrest, remove one sheet.

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

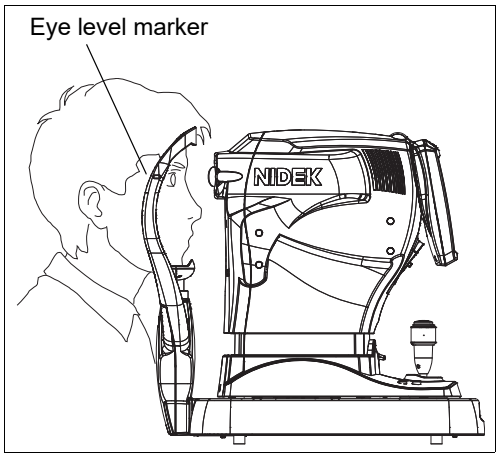
3) Have the patient place their chin on the chinrest as deeply as possible, with their forehead gently resting on the forehead rest.



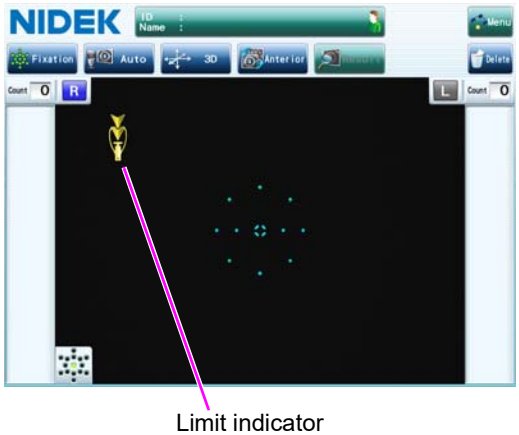
4) Adjust the height of the chinrest with the chinrest up/down button ( ▲ , ▼ ) so that the patient's eyes are roughly aligned with the eye level marker.

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

   Be sure to watch the patient carefully when moving the chinrest up or down.




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



**5** Instruct the patient to look into the capturing window and stare at the green spot with eyes wide open.

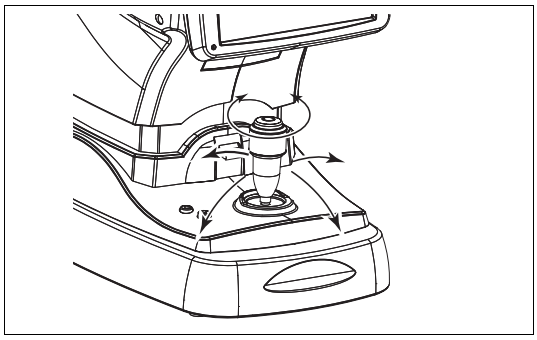
Note

- Instruct the patient not to blink during image capture. For successful capture, it is recommended to have the patient blink once then open their eyes wide just before image capture.
- Instruct the patient to open both eyes wide during image capture.
  Closing one eye may cause unstable fixation and insufficient opening of the other eye.

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

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

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



⚠ **CAUTION** • **Take care that the device does not contact the patient's face during alignment or when switching the patient's eye between right and left.**

Note

- The operator can move the capturing unit from side to side so that the eye to be captured is displayed on the screen to allow automatic switching of right and left eye capture.

**7** Perform alignment and focus adjustment.

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

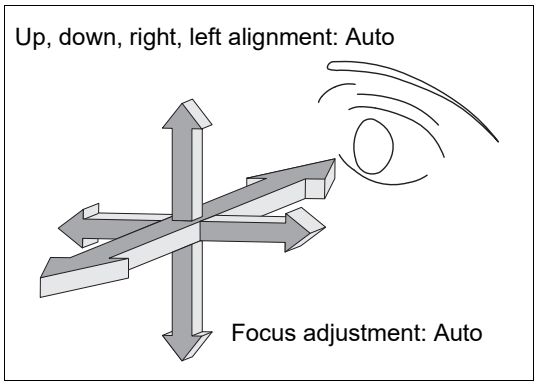
* See "3.5 Image Capture Procedure" (page 66) for details.

Perform alignment by bringing the alignment light (center of the eye) in the alignment target.

Adjust the focus while referring to the focus indicator displayed in the center of the screen.

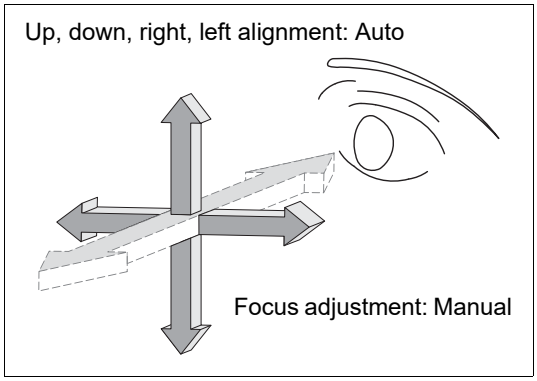
**3D auto tracking** 

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



### 2D auto tracking 

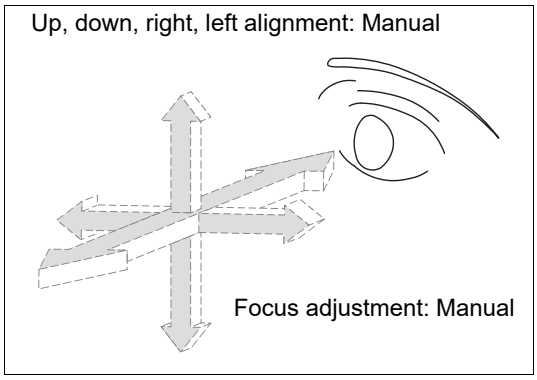
1) Perform rough alignment and focus adjustment to the working range of the auto tracking function.
2) When the capturing unit is brought into the working range of the auto tracking function, fine alignment automatically starts.
3) As the focus indicator is displayed, manipulate the joystick until the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




### Auto tracking OFF 

1) Perform alignment and focus adjustment.
2) Manipulate the joystick to bring the alignment light reflected on the patient's eye into the alignment target.
3) When the focus indicator is displayed, adjust the focus so that the focus indicator indicates the best focus condition.

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




Note

- If eyelashes cover the capture area marks, proper capture may not be achieved.

  In such a case, instruct the patient to open their eyes wider.

  If the patient cannot open their eyes wider, lift the patient's eyelid while paying attention not to press against the eyeball.

### If alignment is outside the working range of the auto tracking function

The limit indicator is displayed. Manipulate the joystick or the chinrest up/down button while referring to the limit indicator.

<Example of limit indicator>


The capturing unit is too high from the patient's eye.
Move the capturing unit down.


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

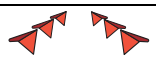
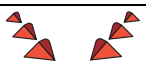
| | |
|---|---|
|  | Move the capturing unit up. |
|  | Move the capturing unit down. |
|  | Tilt the joystick slightly to the right. |
|  | Tilt the joystick slightly to the left. |

## ○ Focus indicator display

If the focus is outside the working range of the auto tracking function, the limit indicator appears.


Focus limit indicator

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

| | |
|---|---|
|  | Push the joystick forward to move the capturing unit closer to the patient. |
|  | Pull the joystick back to move the capturing unit away from the patient. |

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

Too close to the patient's eye

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

Best focus condition

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

Too far from the patient's eye

## *8* Image capture starts.

The capture start procedure differs according to the auto shot setting.

| | |
|---|---|
|  Manual | Press the start button to start image capture. |
|  Auto | Image capture starts automatically when the eye is best aligned and focused. |

When image capture starts, an endothelium observation image is displayed. After the endothelium position is detected, 16 images are successively captured as the focus is moved around the endothelium.

Do not manipulate the joystick during image capture (about 2 seconds from the start).

Note

- Even when the auto shot function is enabled, the operator can initiate image capture by pressing the start button.

  If image capture does not start automatically due to frequent blinks or other causes, press the start button to start image capture.
- Instruct the patient not to blink or move their head or eyes during image capture.
- If the capture resulted in an error, possible causes are as shown below. If the error occurs successively, identify the cause.
  a. Patient blinks during image capture
  b. Eyelid or eyelashes cover the capture area marks
  c. Light is reflected on the cornea during image capture
  d. Cornea is extremely distorted
- Image capture stops if alignment or focus is off. However, when capture is performed again, the capture data is added to the memory along with the previous capture data.



**9** When image capture is complete, the image select screen appears.

Instruct the patient to blink to rest their eyes and wait for a while.


Note

- If "Select Analysis Image" of the Take parameter is set to "Auto", the image select screen is displayed and the image is automatically selected. The next screen is then displayed.

  For details, see "4.7.2 Take parameter" (page 121).

**10** In the image select screen, select an image for analysis.

Select the most suitable image for analysis from the endothelial thumbnail images. The thumbnail bordered in orange indicates that the image is being selected and its enlarged view is displayed at the left of the screen.

The number of the thumbnail indicates the order by quality that the device identified.

Note

- The captured images are displayed by quality as determined by automatic calculation (that is, the number of cells that can be widely seen). However, this may not be the optimum image. The image to select should be determined by the operator according to their expertise.
- When focusing is not aligned to the endothelium during image capture, no image is acquired. In such a case, a black image is displayed in thumbnail.

Confirm the selected image for analysis.

| | |
|---|---|
| [Auto Analysis] button | Confirms the selected image for automatic analysis and returns to the capture screen.<br>The message "Analyzing" appears before the capture screen is displayed. Wait until the message disappears.<br>In single mode, after completion of one capture for each eye, the capture results screen is displayed as a single display. |
| [Manual Analysis] button | Confirms the selected image for manual analysis and returns to the capture screen.<br>When auto analysis is not possible due to image quality, the operator selects all cells for analysis. Confirm the image for analysis by canceling auto analysis.<br>Display the Manual Analysis window from the detail analysis screen to perform manual analysis. |

Display thumbnail images that are not displayed.

| | |
|---|---|
| [Page] button | Switches the captured image pages. The 16 total images are displayed on two pages of eight each. |

Delete image for recapture.

| | |
|---|---|
| [Retake] button | Displays the capture screen for recapture.<br>Image data displayed in the image select screen is discarded.<br>Image capture is performed under the same capture conditions in the Image screen.<br>When recapture is complete, the image select screen appears again. |

⚠ **CAUTION** • **If only unclear images are obtained, do not select them for analysis. Recapture images until satisfactory images are obtained.**

Correct analysis values may not be obtained.

## *11* Perform image capture until all necessary image capture procedures are complete. (Repeat from Step 8.)

Before performing image capture, change the illumination position of the fixation lamp as necessary. Set it in the Fixation window that is displayed by pressing the [Fixation] button.

For setting of the fixation lamp, see "3.4 Setting Capture Conditions" (page 61).

In paracentral mode, the fixation lamp positions are changed according to the set order.

Switching between the right eye and left eye is automatically performed when the patient's eye is aligned.

## ○ Capture screen operation

Note

- Setting for entering patient information, auto shot, and auto tracking can be performed after image capturing is started.

**Single mode**

| | |
|---|---|
| Multiple image capture for one eye | Start image capture. (The previous image data is deleted.) |
| Finish image capture for one eye and perform image capture for the other eye | Perform alignment for the other eye by operating the joy stick. |
| Finish image capture after only one eye and check the analysis result | Press the [Result] button to display the capture results screen. |
| Delete the image data and restart image capture | Press the [Delete] button.<br>For details, see Step 16 (page 76). |

Note

- In single mode, one capture data set is displayed for each eye.
  When image capture is performed more than once for one eye, only the latest capture data is displayed.

**Multiple mode**

| | |
|---|---|
| Multiple image capture for one eye | Press the [Fixation] button to display the fixation lamp screen, and change the fixation lamp point. Start image capture. |
| Finish image capture for one eye and perform image capture for the other eye | Confirm the fixation lamp position and perform alignment for the other eye by operating the joy stick. |
| Finish image capture and check the analysis results | Press the [Result] button to display the capture results screen. |
| Delete the image data and restart image capture | Press the [Delete] button.<br>For details, see Step 16 (page 76). |

Note

- In multiple mode / paracentral mode, a maximum of 15 capture data sets can be saved for each eye.
  If capture data sets exceed 15, the data is erased in order from the oldest.

**Paracentral mode**

| | |
|---|---|
| Multiple image capture for one eye | The fixation lamp points are changed automatically. Start image capture. |
| Finish image capture for one eye and perform image capture for the other eye | Perform alignment for the other eye by operating the joy stick.<br>Confirm the fixation lamp point is set to its No.1 point. |
| Finish image capture and check the analysis results | Press the [Result] button to display the capture results screen. |
| Delete the image data and restart image capture | Press the [Delete] button.<br>For details, see Step 16 (page 76). |

Note

- In paracentral mode, the “Image capture at the selected fixation point has been completed.” message appears after the set image capture is complete.

  Press the [OK] button to proceed to next operation.


- After starting image capture, press the [Fixation] button to display the fixation lamp screen, and then press the [OK] button to reset the fixation lamp to its No.1 point and begin illumination.

  If the fixation lamp point is not set to its No.1 point when starting image capture, reset the fixation lamp point.

- If image capture is stopped before image capture has been completed at all selected fixation lamp points, press the [Fixation] button to display the fixation lamp screen, and press the [OK] button. The fixation lamp point is reset to its No.1 point and illuminated.

## 12 Instruct the patient to release their head from the chinrest.

Instruct the patient to release their head from the chinrest slowly. In addition, instruct the patient not to push against the chinrest or forehead rest when standing up.

## 13 To finish image capture manually, press the [Result] button in the capture screen to switch to the capture results screen.

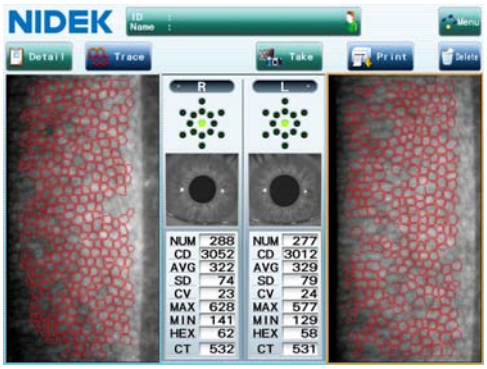
Only after completion of each image capture for both eyes in single mode, the image select screen changes to the capture results screen.

Note

- Even after moving to the capture results screen, image capture can be performed again by pressing the [Take] button.

## 14 The capture results screen is displayed.

When both the right and left eye images are captured once each, the capture results screen is shown as a single display regardless of the setting for single or multiple mode (This applies to single mode as well as multiple mode / paracentral mode with one capture of each eye).

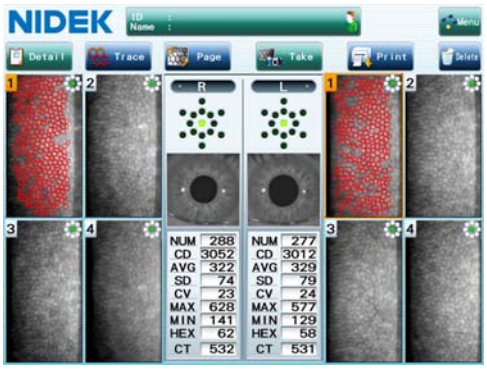



Capture results screen (single mode)

When either eye image is captured more than once, the capture results screen is shown as a multiple display. (This applies to multiple mode and paracentral mode.)

Select one image to display analysis values from the thumbnails.

For the setting procedure for the “Capturing/ Display Mode” parameter (Single Mode / Multi Mode / Paracentral), see “3.4 Setting Capture Conditions” (page 61).



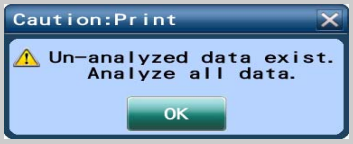

Capture results screen (multiple mode)

## *15* Perform operations for analysis as necessary.

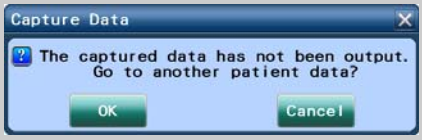
| | |
|---|---|
| [Detail] button | Displays the selected data in the detail analysis screen. |
| Analysis image select button | Used to select the image display used for analysis from among Photo, Trace, Area, and Apex. |
| [Page] button<br>* Only for multiple mode and paracentral mode | Switches the page when the maximum of four images per page is exceeded for one eye.<br>Both the right and left images are switched at the same time. If the number of captures is different between the right and left, images for one eye may not be displayed. |
| [Paracentral] button<br>* Only for paracentral mode | Displays the selected data in the paracentral screen. |
| [Take] button | Displays the capture screen and performs additional image capture when this button is pressed before printing or outputting the capture data.<br>The captured image data is added to the current image data.<br>Displays the capture screen and starts image capture of a new patient when this button is pressed after printing or outputting the capture data.<br>A confirmation message appears before the capture screen is displayed. Starting image capture after the capture screen is displayed deletes the capture data (patient information, image data, and analysis data) of the previous patient. |
| [Print] button | Prints the displayed endothelial image and analysis values on the built-in printer.<br>When the video printer is set, they are printed on the video printer.<br>When LAN setting is enabled, pressing the [Print] button outputs data at the same time.<br>See “3.9 Printing” (page 98) for the print contents. |
| [Delete] button | Deletes the capture data (patient information, image data, and analysis data). |
| Patient information field | Pressing the patient information field displays the Patient Information screen that allows entry or edit of patient information. |
| [Menu] button | Displays the Maintenance screen or Settings screen.<br>In the Settings screen, settings such as display or printing can be changed. |

Note

- If there are images that are not analyzed yet, printing or outputting is not possible. Pressing the [Print] button displays the message “Un-analyzed data exist. Analyze all data”. Perform manual analysis on the detail analysis screen.



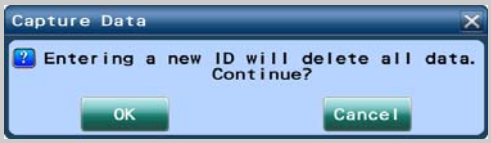

- Pressing the patient information field or reading a patient ID using the barcode reader or magnetic card reader before printing/outputting capture data with the [Print] button displays the confirmation message “The captured data has not been output. Go to another patient data? [OK]/[Cancel]”.




- Confirm that patient information is correctly entered before printing or outputting the capture data by pressing the [Print] button.

  Once capture data has been printed or output, patient information cannot be changed.

  Pressing the patient information field or reading a patient ID using the barcode reader or magnetic card reader after printing or outputting the capture data displays the confirmation message “Entering a new ID will delete all data. Continue? [OK]/[Cancel]”.




  - When the patient information field was pressed, pressing the [OK] button displays the Patient Information screen. Entering a new patient ID deletes the previous capture data.
  - When the patient ID was read by the barcode reader or magnetic card reader, pressing the [OK] button deletes the previous capture data and displays the capture screen in which the entered patient ID is shown.

- Printing or outputting the capture data by pressing the [Print] button with the “Print&Clear” check box of the “Data Clear” parameter selected deletes the capture data automatically and displays the capture screen.

## *16* For image capture of the next patient, display the capture screen.

Before image capture of a new patient, follow the procedure below to delete the capture data (patient information, image data, and analysis data) of the previous patient.

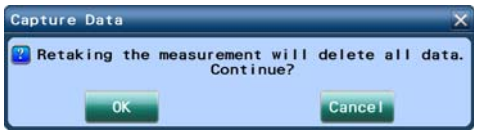
### Image capture of a new patient after printing or outputting capture data

The following three operating procedures are available.

#### (1) Pressing the [Take] button

1) Press the [Take] button.

The confirmation message “Retaking the measurement will delete all data. Continue? [OK]/[Cancel]” appears.



Note

- When the “Check Data Clear” parameter is set to “OFF”, pressing the [Take] button displays the capture screen without displaying a confirmation message.

2) Press the [OK] button.

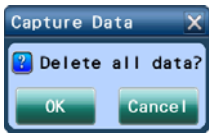
The capture screen is displayed. The previous capture data is preserved at this time.

Starting the next image capture deletes the previous capture data.

### (2) Pressing the [Delete] button

1) Press the [Delete] button.

The confirmation message “Delete all data? [OK]/[Cancel]” appears.




2) Press the [OK] button.

The capture data is deleted and then the capture screen is displayed.

### (3) Entering new patient information

1) Press the patient information field.

The confirmation message “Entering a new ID will delete all data. Continue? [OK]/[Cancel]” appears.


Note

- When the “Check Data Clear” parameter is set to “OFF”, pressing the patient information field displays the capture screen without displaying a confirmation message.

2) Press the [OK] button.

The Patient Information screen is displayed.

3) Enter a new patient ID.

The capture data is deleted and patient information other than the ID in the Patient Information screen is cleared.

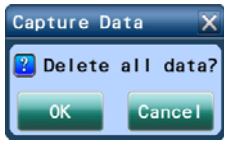
4) Enter patient information and close the Patient Information screen.

The capture screen is displayed.

## Image capture of a new patient without printing or outputting capture data

1) Press the [Delete] button.

The confirmation message “Delete all data? [OK]/[Cancel]” appears.




2) Press the [OK] button.

The capture data is deleted and then the capture screen is displayed.

Note

- Patient information or image data cannot be stored in the device. Print out or output all necessary data before deleting in preparation for the next patient.
- Patient information and image data can be cleared by pressing the [Delete] button in the capture screen.
- Pressing the [Delete] button clears both patient information and image data. Only patient information or image data cannot be cleared.

***17*** Continue image capture from Step 3.

For finishing of image capture, see “3.2.3 Normal shut down” (page 55).

## ○ Observing endothelial cells

In addition to the endothelial image capture, endothelium observation can be performed on the device screen. The image displayed on the screen for observation can be captured if necessary.
Pressing the image toggle button to set “Cell” switches the screen from the anterior segment to the endothelial image.

Note

- When the image toggle button is switched to “Cell”, the endothelium observation light is emitted repeatedly. After endothelium observation, press the image select button to set it to “Anterior”.

  As a safety precaution, when endothelium observation mode exceeds 60 seconds, the mode automatically ends.

1) When the image select button is set to “Anterior”, disable the auto shot function.
2) Roughly align with the patient’s eye.

   Adjust alignment and focus with the image select button at “Anterior”.
3) Press the image toggle button to set “Cell”.

   The device is ready for endothelium observation.


| | |
|---|---|
| Screen touch panel | The anterior segment image changes to the endothelium observation image.<br>The alignment target, focus indicator, and such are not displayed. |
| Auto shot button | Grayed out and disabled.<br>When the auto shot function is enabled, it is deactivated. |
| Tracking button | Grayed out and disabled.<br>When 2D tracking or 3D tracking is enabled, it is deactivated. |

4) Manipulate the joystick to bring the endothelial cell in focus for observation.

The tracking function is deactivated. Change the observation range by moving the position up, down, right and left.

| | |
|---|---|
| Start button | Pressing the start button performs image capture at the position.<br>Image capture is performed without eye tracking.<br>Sixteen images are captured in the same manner as “Anterior”. Do not manipulate the joystick and wait until the image select screen is displayed.<br>For the procedure after the image select screen is displayed, analysis value display, printing, and data output can be performed in the same manner as “Anterior” (Step 9 and later). |

5) After the intended observation, immediately press the image toggle button to set it to “Anterior”.

Emission of endothelium observation light is stopped.

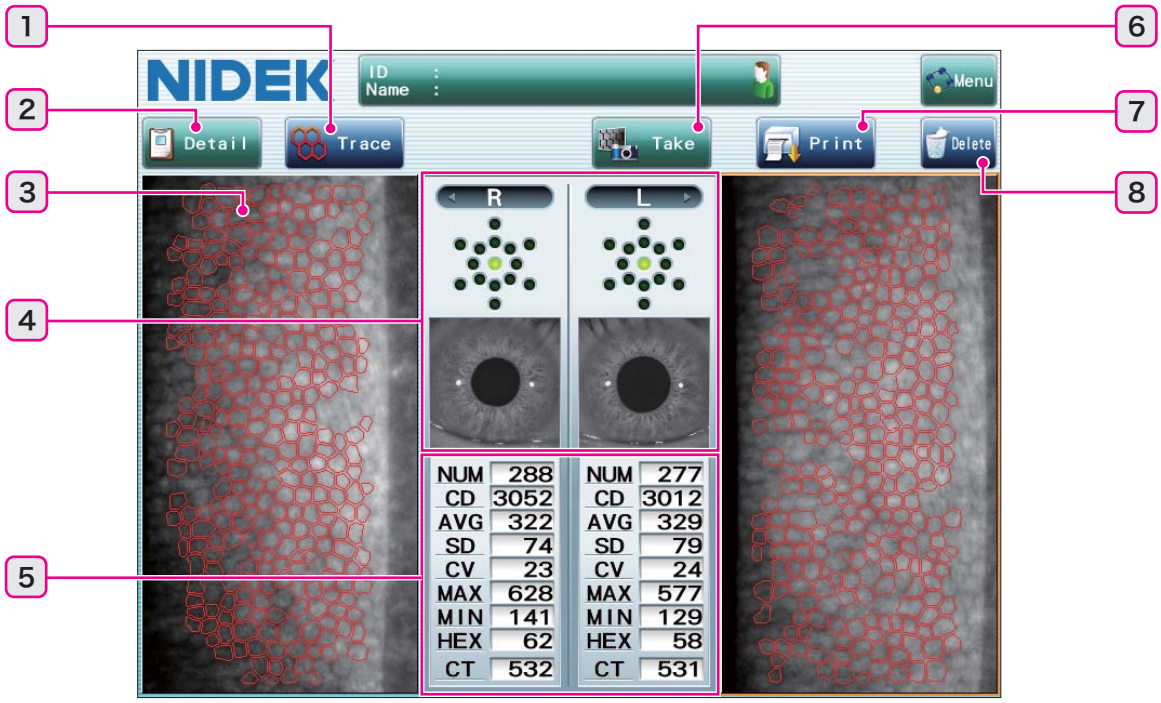
## 3.6 Capture Results Screen Operation

The capture results screen displays each analysis value based on the captured endothelial images. The capture results screen is displayed as a single display or multiple display that is set by the “Capturing/ Display mode” parameter in the Settings screen.

| Capturing/ Display Mode parameter | Display method |
|---|---|
| Single mode | Regardless of the capture count, the capture results screen is always shown as a single display.<br>After completion of each image capture for both eyes, the capture results screen is automatically shown.<br>When image capture is performed more than once for one eye, only the latest capture data is displayed. |
| Multiple mode | Depending on the capture count, the capture results screen is automatically shown as a single display or multiple display.<br>When image capture is performed only once for either eye, the capture results screen is shown as a single display for that eye. In other cases, it is shown as a multiple display.<br>The capture results screen is displayed by pressing the [Result] button.<br>In multiple mode, a maximum of 15 capture data sets can be saved for each eye. |
| Paracentral mode | The capture results screen is shown as a multiple display with the [Paracentral] button.<br>The capture results screen is displayed by pressing the [Result] button.<br>Pressing the [Paracentral] button displays the paracentral screen.<br>When image capture is performed only once for either eye, the capture results screen is shown as a single display for that eye. |

## ○ Capture results screen (single mode)

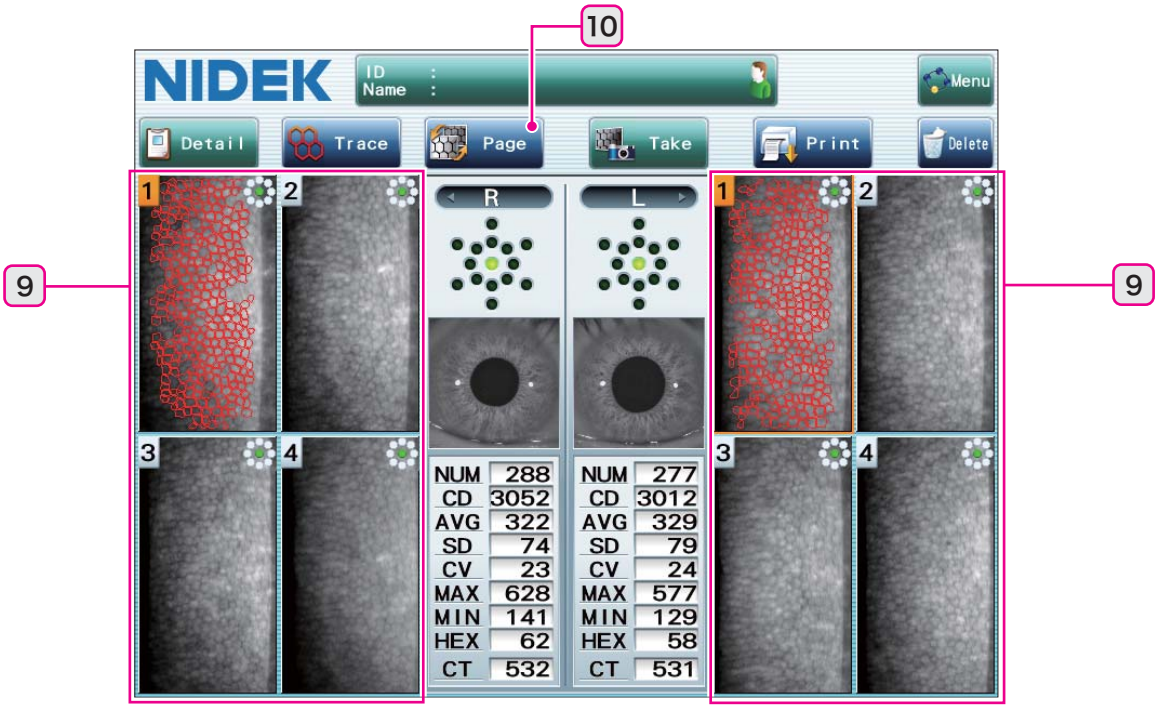
In single mode, one capture data set is displayed for each eye.




| | | | | | |
|---|---|---|---|---|---|
| 1 | Analysis image select button | 2 | [Detail] button | 3 | Endothelial image |
| 4 | Captured eye display | 5 | Analysis values | 6 | [Take] button |
| 7 | [Print] button | 8 | [Delete] button | | |

## ○ Capture results screen (multiple mode)

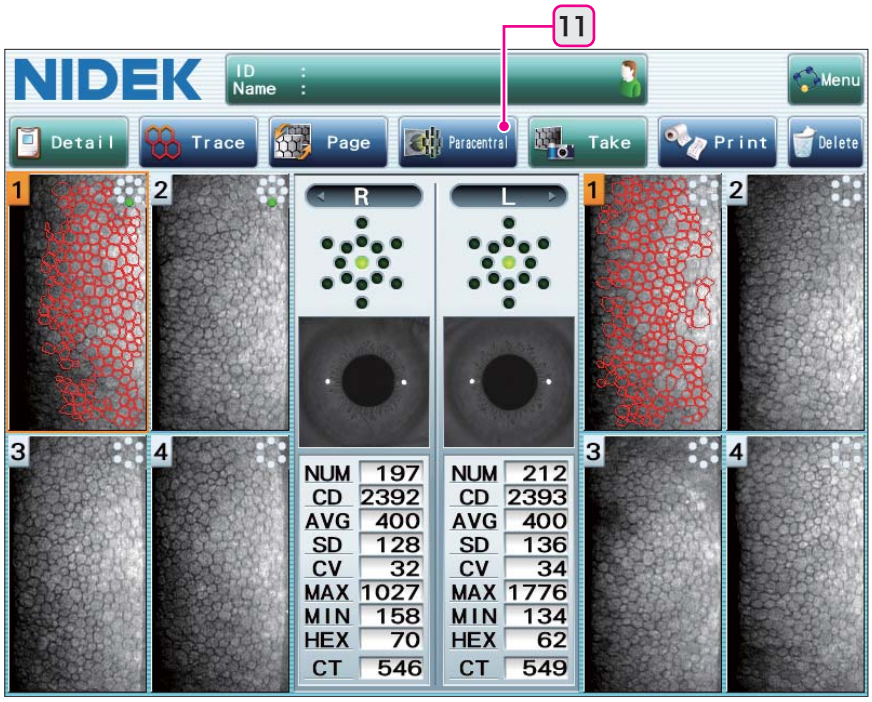
In multiple mode, select the data for analysis from the multiple display of two or more captured images.




| | | | |
|---|---|---|---|
| 9 | Image select fields | 10 | [Page] button |

## ○ Capture results screen (paracentral mode)

In multiple display (or single display) of paracentral mode, the [Paracentral] button is added to the multiple mode screen.




| | |
|---|---|
| 11 | [Paracentral] button |

## ○ Confirming analysis values

Analysis results and corneal thickness of the displayed endothelial image are shown.
In multiple display, select the image whose analysis values are displayed from the image select field. The image whose number is displayed in orange is being selected. Up to four images may be displayed at one time in the image select field for each eye. If there are more than four images, press the [Page] button to switch the image display.

Note

- If no cell is recognized for analysis, an analysis error occurs and the analysis value field displays "– – –".

  The minimum number of cells required to display analysis values can be set from the range of 1 to 15 by the "Min. Cell Number" parameter.

### Contents of analysis values

| Abbreviation | Analysis item | Unit | Details |
|---|---|---|---|
| NUM | Number of Cells | cells | Number of endothelial cells analyzed |
| CD | Cell Density | cells/mm$^2$ | Number of endothelial cells per unit area (1 mm$^2$) |
| AVG | Average Area | μm$^2$ | Average area of endothelium analyzed |
| SD | Standard Deviation | μm$^2$ | Standard deviation of the endothelium area analyzed |
| CV | Coefficient of Variation | % | Standard deviation (SD) divided by the calculated average (AVG) |

| Abbreviation | Analysis item | Unit | Details |
|---|---|---|---|
| MAX | Max Area | $\mu m^2$ | Largest area of endothelium analyzed |
| MIN | Min Area | $\mu m^2$ | Smallest area of endothelium analyzed |
| HEX | Hexagonal Cells | % | Proportion of hexagonal cells found in the analyzed endothelium |
| CT | Corneal Thickness | μm | Corneal thickness obtained through capture procedure |

⚠ **CAUTION** • Corneal thickness measurements are provided as additional information. Due to differences in the measurement principle, the captured results may differ from those taken by the ultrasonic pachymeter or Scheimpflug pachymeter. Care must be taken when handling the measured results.

## ○ Displaying the capture data in the detail analysis screen

Select an image and press the [Detail] button.

The selected image (orange frame) is displayed in the detail analysis screen. The image to be displayed can be changed in the detail analysis screen.

For the operation in the detail analysis screen, see “3.7 Detail Analysis Screen Operation” (page 89).

## ○ Changing the endothelial image display

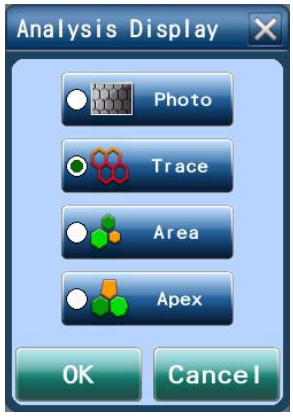
In addition to the Photo display of the original endothelial image, Trace, Area, or Apex overlaid with cell identification results are available for the image display.

Settings previously displayed in the capture results screen are initially shown.

In multiple display, Trace, Area, or Apex is applied only to the selected image. Other images are shown as Photo.

| | |
|---|---|
| Photo | Original endothelial image |
| Trace | The identified endothelial outline is displayed in red. |
| Area | The identified endothelium is distinguished by area and displayed in different colors. |
| Apex | The identified endothelium is distinguished by apex and displayed in different colors. |

1) Press the analysis image select button to display the Analysis Display window.
2) Press the desired image button.
3) Press the [OK] button to close the Analysis Display window.
4) The selected image is displayed in the capture results screen.




Note • Changing the endothelial image display (Photo, Trace, Area, or Apex) does not affect the analysis results.

## ○ Performing additional image capture

Press the [Take] button.

The previous capture data is preserved and the capture screen is displayed.

The newly captured data is then added to the currently captured data.

Note

- Additional image capture is only possible before printing or outputting.
  If the [Take] button is pressed after printing or outputting, a confirmation message for deleting data appears. The current image data must be deleted in order to perform additional image capture.
- In single mode, one capture data set is displayed for each eye.
  If image capture is performed more than once for either eye, only the most recent capture is displayed. Even though previous captures seem to be erased, they are stored in the device. Switching to multiple mode allows them to be displayed or selected.



## ○ Printing (outputting) contents in the detail analysis screen

Press the [Print] button to print the contents. The images and analysis values that are displayed (or selected in multiple display) by the parameter settings are printed (and output).

In multiple display, confirm that the intended image is being selected and its analysis values are displayed before pressing the [Print] button.

To change the settings for printing, press the [Menu] button and then press the [Settings] button to display the Settings screen.

For the contents of printing, see “3.9 Printing” (page 98).

| | |
|---|---|
| Built-in printer print | The analysis results for the selected right and left eye and their images are printed. |
| Video printer print | The images and analysis values of the displayed screen along with the patient information are printed.<br>When five or more images have been captured for one eye in multiple display, a maximum of latest 10 images are printed on two pages. |
| Data output | Image data, analysis data, and report data that are specified by the Network parameter are output over a LAN. |

Note

- Confirm that patient information is correctly entered before printing or outputting the capture data by pressing the [Print] button.
  Patient information cannot be changed after printing or outputting.
- To print the analysis data of a different image, select another image and then press the [Print] button again.
- Printing or outputting the capture data by pressing the [Print] button with the “Print&Clear” check box of the “Data Clear” parameter selected deletes the capture data automatically and displays the capture screen.

## ○ Image display in paracentral screen (in paracentral mode only)

Press the [Paracentral] button to display the paracentral screen. In the paracentral screen, the images are displayed in graphical layout. The total values of the analysis values are calculated from the entire captured data.

Note

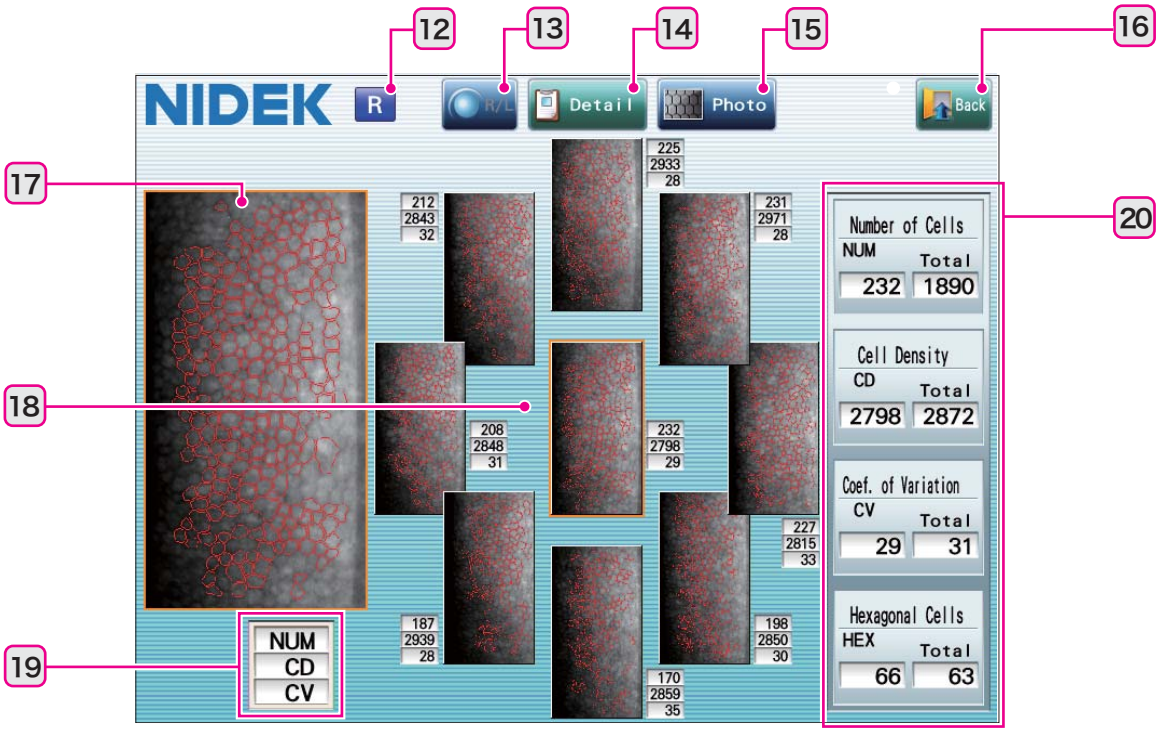
- Total value is the recalculation result of the Number of Cells (NUM), Cell Density (CD), Coefficient of Variation (CV), and Hexagonal Cells (HEX) taken from all the cells of the images displayed in the paracentral screen.

In the paracentral screen, the images captured at the center and paracentral fixation lamp points are displayed with their analysis values. Images captured at the peripheral fixation lamp points are not displayed and their analysis values are not included in the calculation for total values.

Depending on the situation, the messages below are displayed before the paracentral screen is displayed.

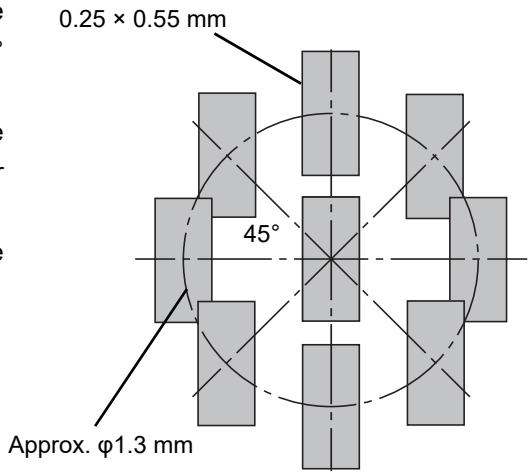
| | |
|---|---|
| Image captured at peripheral fixation point is selected. | The message “The selected image is not paracentral data. A paracentral image will be selected automatically.” appears, and then the paracentral screen is displayed. Displayed images are selected automatically. |
| No image is captured at the center or paracentral fixation point. | The message “There is no paracentral data for the right (left) eye.” appears, and the paracentral screen with no image/analysis values is displayed. |

**Paracentral screen**




| | | | | | |
|---|---|---|---|---|---|
| 12 | R/L indication | 13 | R/L button | 14 | [Detail] button |
| 15 | Analysis image select button | 16 | [Back] button | 17 | Enlarged image |
| 18 | Thumbnail images | 19 | Analysis value index | 20 | Analysis values |

In paracentral image capture, the endothelial cells are captured at a 5° visual angle in the center and at 45° surrounding paracentral points.
These images are displayed in graphical layout, and the cells in the paracentral area can be observed in a wider range than the central image capture range.
The analysis values of each captured image and the total values for all images can be checked.






Note

- In the paracentral screen, the layout of images is based on the captured fixation lamp points.

Paracentral screen operation

| | |
|---|---|
| R/L button | Used to display the captured image results of the other eye. |
| [Back] button | Used to return to the previous page. |
| Thumbnail images | The central and paracentral captured images are displayed in thumbnail view. Pressing a thumbnail selects it as the image.<br>The selected thumbnail image is displayed as an enlarged image. The analysis values of the selected image are displayed in the analysis values field. |
| Analysis value index | Indicates the contents of the analysis values shown next to each thumbnail image. (NUM: Number of Cells, CD: Cell Density, CV: Coefficient of Variation) |
| Analysis values | The analysis values of the selected image and the total values for all captured images are displayed. |

Note

- When image capture is performed more than once for one eye, the latest image and its analysis results will be displayed.
- Non-captured area will be displayed in gray.

## ○ Capturing images of new patient

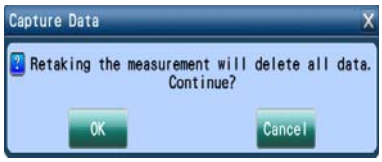
Before image capture of a new patient, follow the procedure below to delete the capture data (patient information, image data, and analysis data) of the previous patient.

The deleted capture data cannot be restored. Print out or output all necessary data before following the procedure below.

### Image capture of a new patient after printing or outputting capture data

1) Press the [Take] button.

The confirmation message “Retaking the measurement will delete all data. Continue? [OK]/[Cancel]” appears.




Note

- When the “Check Data Clear” parameter is set to “OFF”, pressing the [Take] button displays the capture screen without displaying any confirmation message.

2) Press the [OK] button.

The capture screen is displayed. The previous capture data is preserved at this time.

Starting the next image capture deletes the previous capture data.

Note

- With operation other than pressing the [Take] button, image capture of a new patient can be started.

  See the description of Step 16 in “3.5 Image Capture Procedure”.

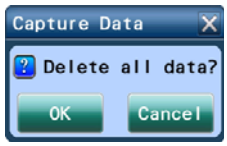
### Image capture of a new patient without printing or outputting capture data

1) Press the [Delete] button.

The confirmation message “Delete all data? [OK]/[Cancel]” appears.

2) Press the [OK] button.

The capture data is deleted and then the capture screen is displayed.

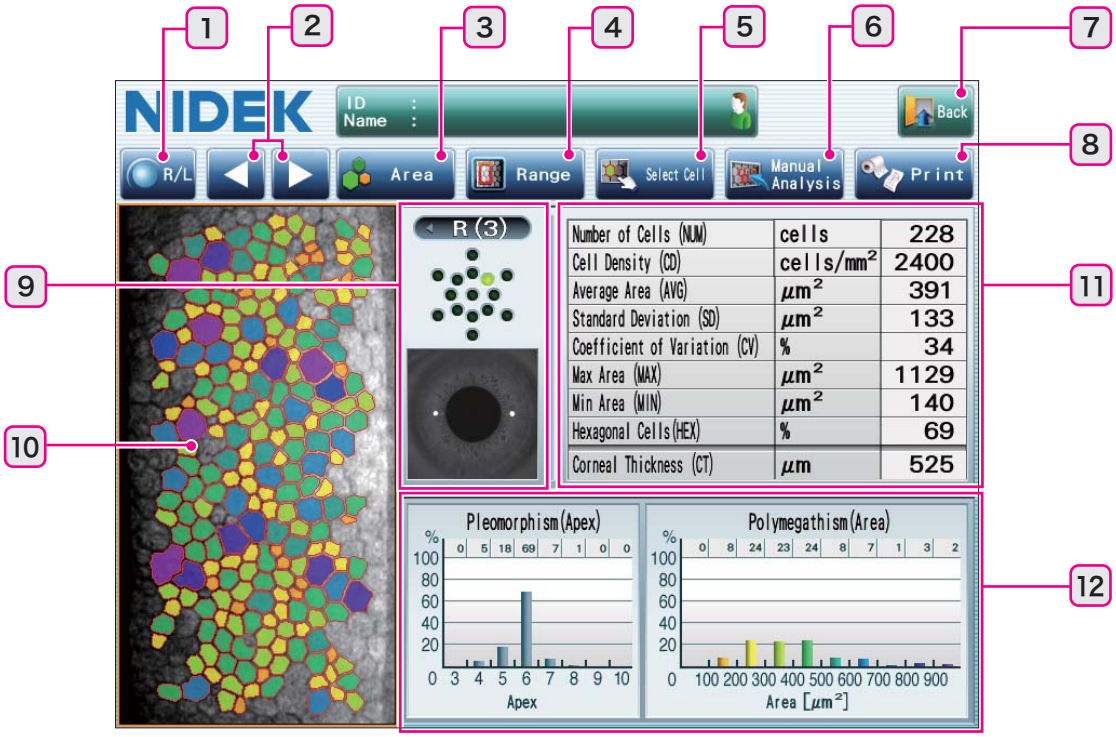



Note

- Capture data can be cleared by pressing the [Delete] button in the capture screen.
- Pressing the [Delete] button clears both patient information and image data. Only patient information or image data cannot be cleared.

# 3.7 Detail Analysis Screen Operation

The detail analysis screen displays the distribution of endothelial apex and area as histograms in addition to analysis values. Reanalysis can be also performed with the changed analysis conditions.
The detail analysis screen is displayed by pressing the [Detail] button in the capture results screen.




| | | | | | |
|---|---|---|---|---|---|
| 1 | R/L button | 2 | Data select button | 3 | Analysis image select button |
| 4 | [Range] button | 5 | [Select Cell] button | 6 | [Manual Analysis] button |
| 7 | [Back] button | 8 | [Print] button | 9 | Captured eye indication |
| 10 | Endothelial image | 11 | Analysis values | 12 | Distribution histograms |

Pressing the [Back] button in the detail analysis screen returns to the capture results screen (single/multiple display).
The analysis values in the capture results screen are updated to the latest values in the detail analysis screen.

### ○ Selecting an image to display on the screen

Select an image using the R/L button or data select button.

| | |
|---|---|
| R/L button | Displays the captured image results of the patient's other eye (R/L).<br>When only one eye has been captured, this button is disabled (grayed out). |
| Data select buttons | Switches the image to be displayed when more than one image has been captured for one eye.<br>When only one image has been captured for the displayed patient eye, these buttons are disabled (grayed out).<br>The selected image is the one being displayed or the one displayed last. If the selected image is changed in the detail analysis screen, it is also changed in the capture results screen. |

## ○ Changing the endothelial image display

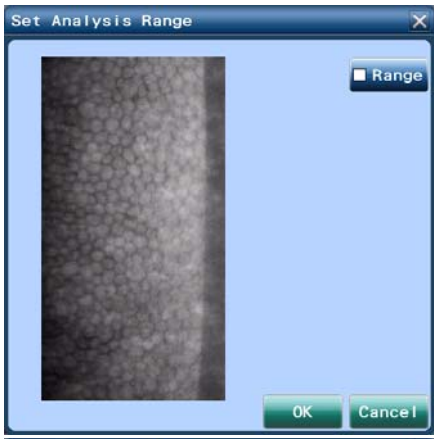
The endothelial image may be changed to be displayed as Photo, Trace, Area, or Apex.
When Area or Apex is selected, the corresponding histogram is displayed by the corresponding color as Pleomorphism or Polymegathism.

The operation is the same as that in the capture results screen. For details, see “3.6 Capture Results Screen Operation” (page 80).

## ○ Changing the analysis range

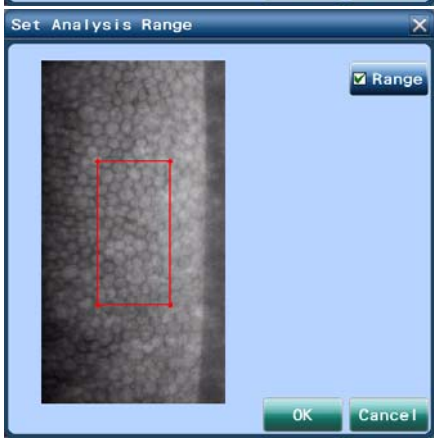
Initially, the entire endothelial image on the screen is intended for analysis. If it contains a part unsuitable for analysis, the analysis range can be specified.

1) Press the [Range] button to display the Set Analysis Range window.




2) Press to select the [Range] button check box.

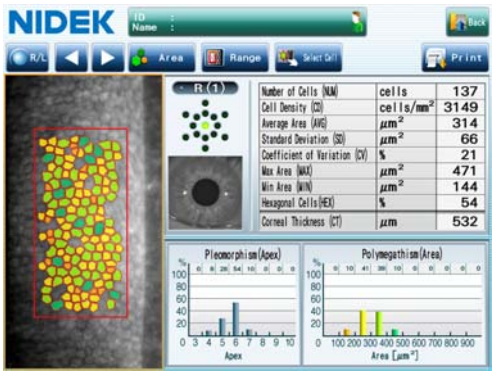
   A red frame indicating the analysis range is displayed on the endothelial image.




3) Drag the anchor points to change the size or position of the frame.
4) Press the [OK] button to close the Set Analysis Range window.

5) After “Reanalysis - Analyzing” is displayed, the image specified in the Set Analysis Range window is displayed in the detail analysis screen.

   The red frame indicating the analysis range is displayed. Cells are displayed according to Trace, Area, or Apex within the frame only. They are displayed as Photo outside the red frame.




Note

- When resetting the set analysis range, press the [Range] button to display the Set Analysis Range window and then press to clear the [Range] button check box.
- The analysis range is preserved even if the screen is switched to the capture results screen.
- The analysis range setting is not reflected in the image to be printed (built-in printer only).

3

## ○ Changing the cell selection

If the cell identification results are not proper, disable the identification results cell by cell. However, the cells selected in manual analysis cannot be disabled.
All identified cells are intended for analysis after image capture.

1) Press the [Select Cell] button to display the Select Cell window.

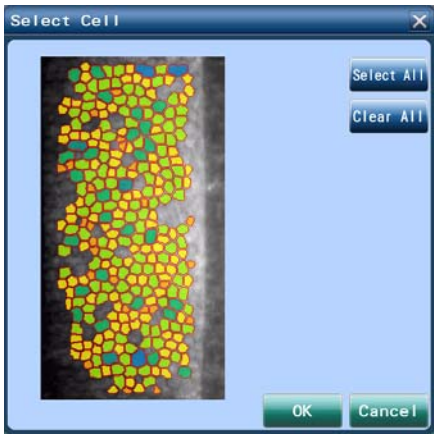
   When Photo is selected for the endothelial image, it is displayed as Trace in the Select Cell window.

2) Press the cell to be excluded from analysis with a touch-screen pen.

   Selection of the pressed cell is cleared and the identification display (outline or coloration) disappears.

3) Repeatedly press all cells to be excluded from analysis.

   When the canceled cells are pressed again, they become selective.




Other button operations

| | |
|---|---|
| [Select All] button | All identified cells are selected for analysis. |
| [Clear All] button | All identified cells are excluded from analysis. |

Note

- If the number of cells to be analyzed is less than the selected number in the “Min. Cell Number” parameter, an analysis error occurs and the analysis value field displays “– – –”.

4) Press the [OK] button to close the Set Analysis Range window.
5) The changed endothelial image is displayed on the detail analysis screen, then the analysis values and graph display are changed.

## ○ Manual analysis

If cells cannot be identified automatically due to image quality, the operator selects the cells for analysis. Manual analysis of auto analyzed images is possible.
Display the Manual Analysis window by pressing the [Manual Analysis] button to perform manual analysis. For details, see “3.8 Manual Analysis” (page 93).

## ○ Printing (outputting) contents in the detail analysis screen

Press the [Print] button to print the contents. The displayed (or selected) right and left eye image and analysis values are printed (output).

Before pressing the [Print] button to print from the built-in printer or output data in multiple mode / paracentral mode, ensure that the desired image is selected for each eye.

Press the R/L button 

to ensure that both images are displayed.

To change the settings for printing or output, press the [Back] button to return to the capture results screen and then press the [Menu] button. Press the [Settings] button in the Menu window to display the Settings screen.

For the contents of printing, see “3.9 Printing” (page 98).

| | |
|---|---|
| Built-in printer print | The analysis results for the selected right and left eye and their images are printed.<br>The contents displayed in the capture results screen are printed. |
| Video printer print | The images and analysis values of the displayed screen along with the patient information are printed.<br>When more than four images have been captured for one eye in multiple display, the latest 10 images are printed on two pages. |
| Data output | Image data, analysis data, and report data that are specified by the Network parameters are output over a LAN. |

Note

- Confirm that patient information is correctly entered before printing or outputting the capture data by pressing the [Print] button.
  After printing or outputting, the patient information cannot be changed.
- To print the analysis data of a different image, select another image and then press the [Print] button again.
- Printing or outputting the capture data by pressing the [Print] button with the “Print&Clear” check box of the “Data Clear” parameter selected deletes the capture data automatically and displays the capture screen.

# 3.8 Manual Analysis

The following methods are available.

| | |
|---|---|
| Center point method | Select the center of a cell. The outlines of the cells to be analyzed are applied according to the point distribution. |
| Corner point method | Trace the outlines of the cells to be analyzed by selecting the corners of each cell (polygon). |
| Pattern select method | Select a hexagonal reference pattern that is similar to the cell size and drag it onto the cell to be analyzed. |

All three analysis methods can be performed on the same image. When an additional manual analysis is performed, the manual analysis results are added to the manual analysis results.
When manual analysis is performed to an auto analyzed image, the manual analysis results are added to the auto analysis results.
Selecting manual analysis disables the analysis range setting.

Note

- When manual analysis is performed, the [Range] button on the detail analysis screen changes to the [Reanalysis] button.
  Pressing the [Reanalysis] button performs automatic analysis and clears the manual analysis results.

## 3.8.1 Center point method

1) Press the [Manual Analysis] button to display the Manual Analysis window.

   The endothelial image is displayed in Photo.

2) Press the [Center] button to select the center point method.


3) Touch the approximate center of a cell on the endothelial image with the touch-screen pen.

   A red dot is displayed on the endothelial image.

   Touching a pressed point again clears the dot.

Other operation

| | |
|---|---|
| Delete | Clears the selected points in reverse order. |

4) Touch the screen again to enter additional points.

A maximum of 300 points can be entered.

Take the general distance between cell centers into consideration when selecting points.

Note

- A maximum of 300 center points can be entered. When the 300th point is entered, the message “You have already entered 300 center points. Center points cannot be added anymore.” appears.
- In the center point method, the cells are calculated based on the surrounding points. Cells not identified are excluded from the analysis results. Select as many cells as possible.
- Failure to select sufficient points or inadvertently selecting points twice may lead to a large deviation in the analysis results.

5) After selecting points, press the [OK] button to close the Manual Analysis window.

The changed endothelial image is displayed on the detail analysis screen, then the analysis values and graph display are updated.

Pressing the [Cancel] button cancels manual analysis and clears the entered points. The screen returns to the detail analysis screen.

## 3.8.2 Corner point method

1) Press the [Manual Analysis] button to display the Manual Analysis window.

The endothelial image is displayed in Photo.

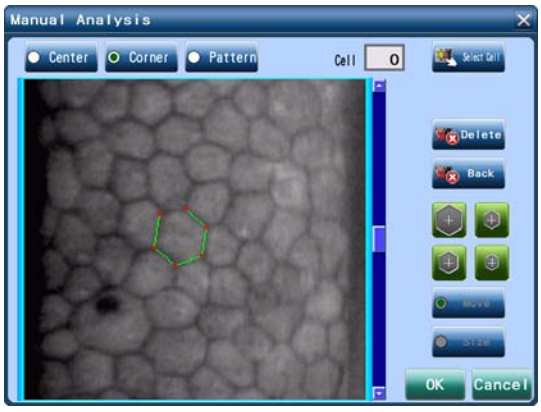
2) Press the [Corner] button to select the corner point method.


3) Touch the corners of a cell for tracing.

The touched points are displayed as red dots. The lines connecting the corner points are displayed in green.

A cell pattern is complete when the first selected corner is touched again.

A single cell pattern may be created by touching from 3 to 15 corners.



Other operation

| | |
|---|---|
| Back | Clears the selected corners in reverse order.<br>(Undo) |
| Delete | Clears entire cell patterns in reverse order. |

Note

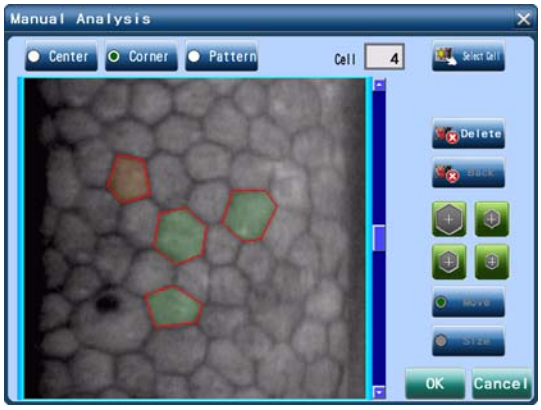
- A maximum of 15 corners can be selected for a single cell pattern. When the 16th corner is selected, the message “You have already entered 15 apex points. Apex points cannot be added anymore.” appears. Press the [Back] button and create a new cell pattern.

4) Repeat the steps to create additional cell patterns.

   The number of the created cell patterns is displayed in the Cell field.

   A maximum of 50 cell patterns can be created.

   In the corner point method, patterns can be created on top of automatically analyzed cells or cells previously created using the corner point method.




Note

- In the corner point method, create patterns so that each cell will not overlap.
  If the overlapped section of cell pattern is excessive, correct analysis values cannot be obtained.
- A maximum of 50 cell patterns can be created. When the 50th pattern is created, the message “You have already entered 50 cells. Cells cannot be added anymore.” appears.

5) After selecting points, press the [OK] button to close the Manual Analysis window.

   The changed endothelial image is displayed on the detail analysis screen, then the analysis values and graph display are updated.

   Pressing the [Cancel] button cancels manual analysis and deletes the entered patterns. The screen returns to the detail analysis screen.

## 3.8.3 Pattern select method

1) Press the [Manual Analysis] button to display the Manual Analysis window.

   The endothelial image is displayed in Photo.

2) Press the [Pattern] button to select the pattern select method.

3) Select a hexagonal reference pattern button appropriate to the size of a cell.

   The hexagonal mark of the selected button turns orange.

4) Press the cell to be analyzed on the endothelial image with the touch-screen pen.

The selected cell is indicated by an orange hexagon on the endothelial image.

The number of the created cell patterns is displayed in the Pattern field.


5) Repeat Step 4 to select other cells to be analyzed.

The hexagon size can be changed by pressing a hexagonal reference pattern button.

In the selected cell pattern, the most recently selected cell is indicated in blue.

6) Perform fine adjustment for the pattern position and size.

| | |
|---|---|
| To change the currently selected pattern | Deselect the hexagonal reference pattern button ( - ), and then touch the desired cell pattern on the endothelial image. |
| To move the selected pattern position   | Select the [Move] button, and then press and drag the selected pattern or touch the desired position to move. |
| To change the selected pattern size   | Select the [Size] button, and then drag the selected pattern to the desired direction. |
| To delete the selected pattern   | Select the pattern to be deleted, and then press the [Delete] button. |

Note

- A maximum of 50 reference patterns can be created. When the 50th pattern is created, the message “You have already entered 50 cell patterns. Cell patterns cannot be added anymore.” appears.

7) Press the [OK] button to close the Manual Analysis window.

The changed endothelial image is displayed on the detail analysis screen, then the analysis values and graph display are updated.

Pressing the [Cancel] button cancels manual analysis and deletes the entered reference patterns. The screen returns to the detail analysis screen.

Note

- After manual analysis, the entered contents can be changed in the Manual Analysis window or Select Cell window.

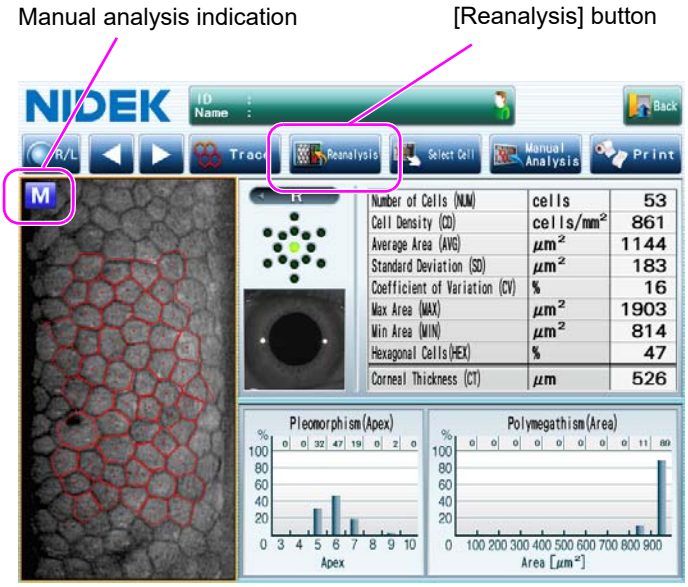
## 3.8.4 Detail screen after manual analysis

When manual analysis is performed, the analysis values are displayed in the detail analysis screen. The screen display changes as follows.

- The [Range] button changes to the [Reanalysis] button.
- When manual analysis is performed, an indication mark appears on the upper left corner of the endothelial image.

| | |
|---|---|
| M | Manual analysis has been performed. |
| +M | Manual analysis has been performed on an auto analyzed image. |

Pressing the [Reanalysis] button performs automatic analysis and cancels the manual analysis results.



# 3.9 Printing

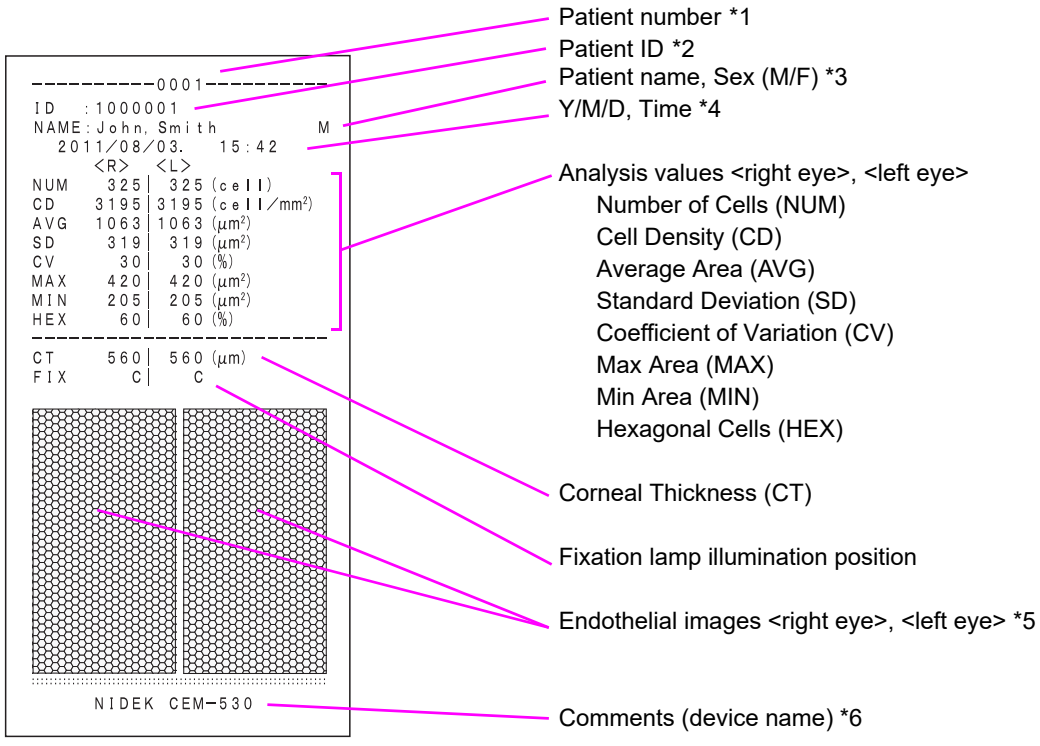
## 3.9.1 Printing captured results (built-in printer)

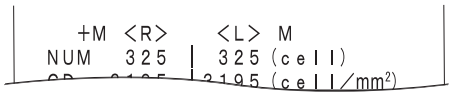
After image capture, pressing the [Print] button prints the endothelial image and analysis values on the built-in printer.

Note

- Do not touch the printer paper while the printer is in operation.
  Printed characters may become blurred or obscured.
- The print contents are the same whether printed from the capture results screen or the detail analysis screen.
- For details of the built-in printer settings, see “4.7.3 Print parameter” (page 124).
- Use the specified printer paper only.
  Otherwise, correct printing may not be performed or printer failure may result.
- Printing or outputting the capture data by pressing the [Print] button with the “Print&Clear” check box of the “Data Clear” parameter selected deletes the capture data automatically and displays the capture screen.

**[Sample printout 1]**

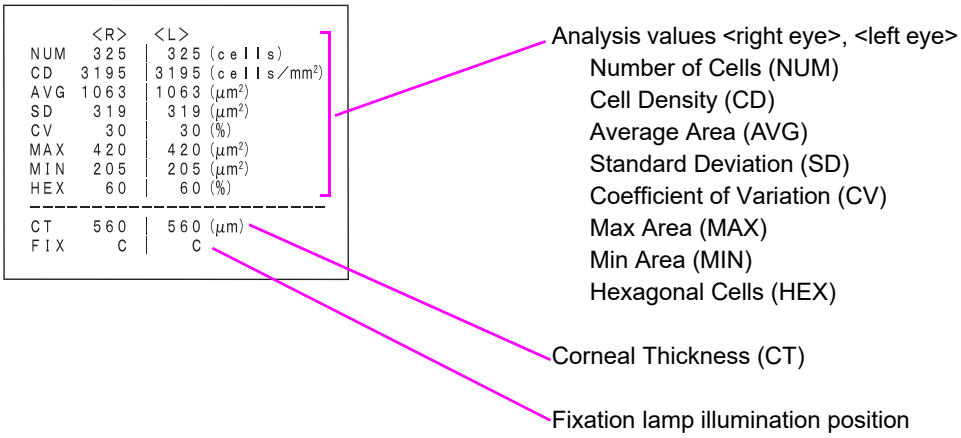


| | |
|---|---|
| *1 | Printed when the “Built-in Printer Option” - “Patient No.” parameter check box is selected<br>“Patient No.” increases in 1 increments automatically from 0001 to 9999.<br>The number can be reset or the desired number can be specified by the “Patient No.” - “Set No.” parameter. |
| *2 | Printed when patient information (patient ID) is entered |
| *3 | Printed when the “Built-in Printer Option” - “Name Print” parameter check box is selected<br>When no patient name is entered as patient information, only “NAME:” is printed.<br>When no sex is entered as patient information, “M/F” is printed. |
| *4 | Printed when the “Built-in Printer Option” - “Date Print” parameter check box is selected<br>Indicates the time when printing is conducted |
| *5 | When manual analysis has been performed, a mark is printed next to <R> and <L>.<br>“M”: Manual analysis has been performed.<br>“+M”: Manual analysis has been performed on an auto analyzed image.<br>  |
| *6 | Printed when the “Built-in Printer Option” - “Image Print” parameter check box is selected |
| *7 | Printed when the “Built-in Printer Option” - “Comment Print” parameter check box is selected |

**[Sample printout 2]**

When no print option is selected, only analysis values and fixation lamp illumination position are printed.

* When the patient ID is entered, it is printed.



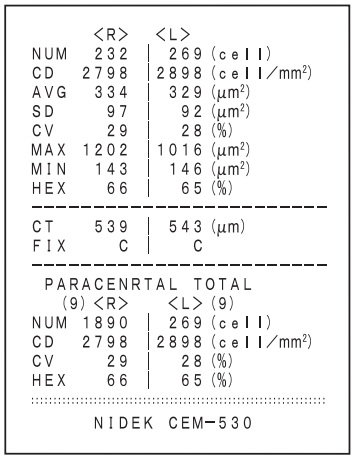
## ○ Printing in multiple mode / paracentral mode

When the “Capturing/ Display Mode” parameter is set to “Multi Mode”/ “Paracentral”, one image for each eye is selected from the multiple image data sets as indicated below and printed.

| | |
|---|---|
| Printing in capture results screen (multiple display) | One image for each eye selected in the capture results screen (multiple display) is printed. |
| Printing in detail analysis screen | Image data displayed in the detail analysis screen and the image data for the other eye displayed in the capture results screen (multiple display) are printed.<br>If the displayed image is changed in the detail analysis screen, the selected image in the capture results screen is also changed. |

In paracentral mode, total values of paracentral image capture are printed.
However, capture results of the peripheral fixation lamps are not included in the total values.
The numbers printed next to <R> and <L> show the number of measurement values used for calculating the total values.

**[Sample printout: Paracentral mode]**




Paracentral total values
(number of measurement values) <R>, <L> (number of measurement values)
- Number of Cells (NUM)
- Cell Density (CD)
- Coefficient of Variation (CV)
- Hexagonal Cells (HEX)

## 3.9.2 Printing captured results (video printer)

When the optional video printer is set, pressing the [Print] button prints the endothelial image and analysis values on the video printer.

Ensure that necessary information is displayed on the screen (whether selected in multiple mode / paracentral mode) before printing.

⚠ **CAUTION** • The video printer is activated only by the screen print button. If the print button is pressed on the printer, information that differs from those in the displayed screen may be printed.

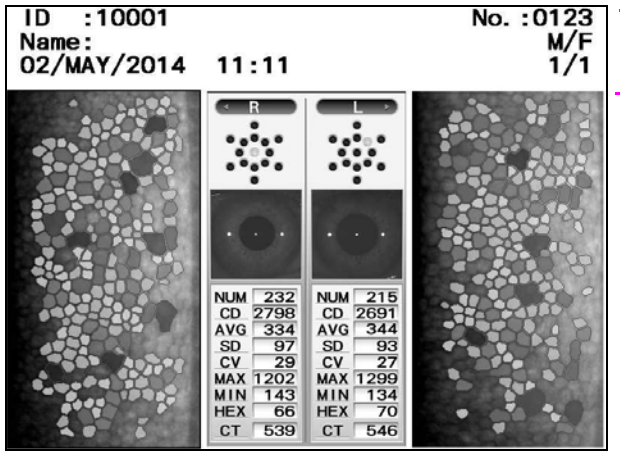
Note

- Do not touch the printer paper while the printer is in operation.
  Printed characters may become blurred or obscured.
- Printing or outputting the capture data by pressing the [Print] button with the “Print&Clear” check box of the “Data Clear” parameter selected deletes the capture data automatically and displays the capture screen.
- For details of the video printer operation, refer to the operator’s manual included with the video printer.
- Use the specified printer paper only.
  Otherwise, correct printing may not be performed or printer failure may result.



○ Sample printout

**Capture results screen (single display)**

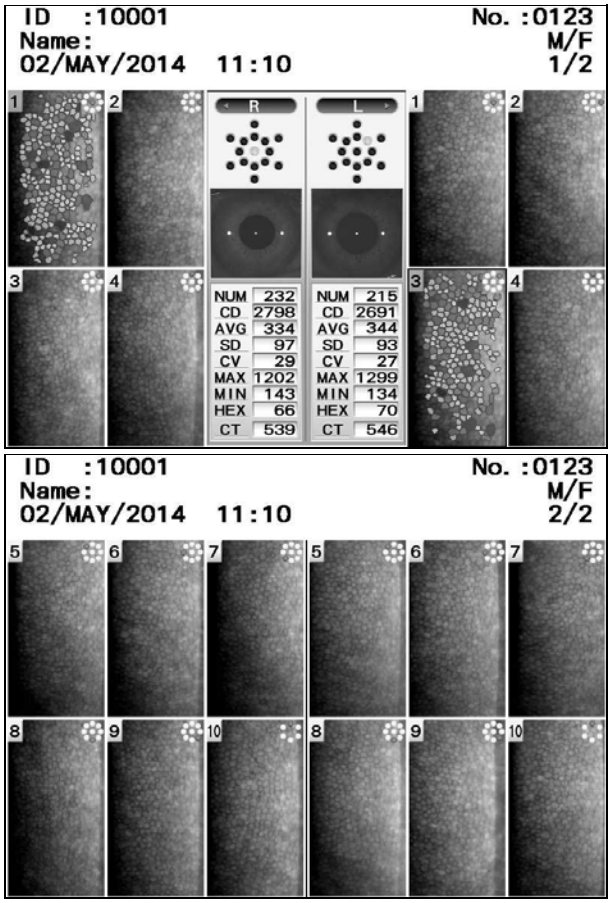



Patient information
ID, patient number,
patient name, sex,
print date and time, print page

Note

- In multiple mode / paracentral mode, when image capture is performed only once for both eyes, the data is printed in the same format.
- When “Video Printer Options” of the Print parameter is set to “Single Image”, the selected images for each eye are printed out in the same format.

### Capture results screen (multiple mode / paracentral mode)

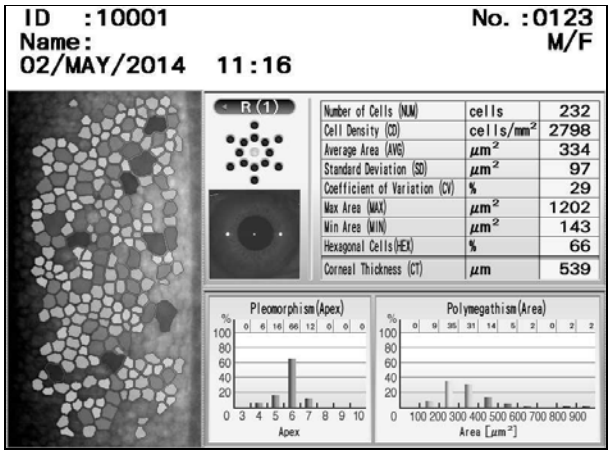



Patient information
ID, patient number,
patient name, sex,
print date and time, print page

Print page “1/2” indicates the first page when two pages are printed in total.
Two pages are printed when more than four images are captured for one eye.

Patient information
ID, patient number,
patient name, sex,
print date and time, print page

### Detail analysis screen




Patient information
ID, patient number,
patient name, sex,
print date and time

When the detail analysis screen is printed, only the capture data currently displayed on the screen can be printed. To print capture data for both eyes, switch the screen display and press the [Print] button again.

# 4. MAINTENANCE

## 4.1 Troubleshooting

In the event that the device does not work correctly, correct the problem according to the following table before contacting NIDEK or your authorized distributor.

| Symptom | Remedy |
|---|---|
| The LCD monitor does not turn on. | • The power cord may not be correctly connected.<br>Reconnect it securely.<br>• The power switch may not have been turned on. Check the power switch. |
| The screen suddenly disappears. | • The sleep function may have been executed. Try to recover the monitor ON condition by pressing any button. |
| The main unit cannot be moved laterally. | • The locking lever may be locked.<br>Raise up the locking lever. |
| Data is not printed out. | • Check the printer paper. If the paper has been used up, load new printer paper.<br>• The “Printer” setting in the Setting screen (Print) may be set to “OFF”.<br>Check the setting. |
| The printer does operate, however, printed results cannot be obtained. | • The printer paper may be loaded with the incorrect side up.<br>Set it with the correct side up. |
| Printer paper does not feed. | • Printer paper may be loaded in a tilted position or the core of the roll may not be placed properly.<br>Open the printer cover and make sure that printer paper is properly loaded. |
| The auto tracking function or auto shot function does not work. | • The auto tracking function or auto shot function may not have been enabled.<br>Set the setting to ON with the tracking button or auto shot button.<br>• Room illumination may be reflecting on the cornea.<br>Change the location and try image capture again.<br>• The auto tracking function or auto shot function may not work on some eyes such as keratoconus or recently-operated cornea.<br>In such cases, turn off the auto tracking function and start image capture.<br>• For patients who have severe eye nystagmus or who cannot fixate their eyes, the auto tracking function may not work.<br>In such cases, turn off the auto tracking function and start image capture.<br>• If the device is located near a window where the device is exposed to sunshine, light interference may adversely affect these functions.<br>Change the location of the device and start image capture again. |
| Image capture does not complete.<br>(The alignment screen remains.) | • The patient may not have fixated their eyes during image capture.<br>Instruct the patient to fixate their eyes steadily and try image capture again.<br>• The eyelid or eyelashes may obstruct image capture.<br>Instruct the patient to open his/her eye wider.<br>If the patient cannot open wider, lift the patient’s lid, paying attention not to press against the eyeball. |

If the symptom cannot be corrected with the above actions, contact NIDEK or your authorized distributor.

## 4.2 Error Messages and Remedies

If one of the following error codes is displayed on the screen, follow the suggestions in the cause and remedy column.
The error code, detailed indications and serial number of your device are helpful for proper servicing.

| Error code and message | Cause and remedy |
|---|---|
| No.001 EEPROM error. | • Data error of backup memory (EEPROM)<br>Data loss due to external noise such as static electricity or malfunction of the electric circuit board or EEPROM on the electric circuit board is probable.<br>• If the same error code is displayed again even after the device is turned off and on again, shut off the device and contact NIDEK or your authorized distributor. |
| No.002 Clock error. | • Date and time setting error<br>The built-in battery has become discharged after about one month or longer of nonuse, and the date and time settings became incorrect, or malfunction of the electric circuit board or timer IC on the electric circuit board is probable.<br>• If the same error code is displayed again even after the date and time are reset in parameter setting mode, shut off the device and contact NIDEK or your authorized distributor. |
| No.031 Up/Down motor error.<br>No.032 Right/Left motor error.<br>No.033 Back/Forth motor error. | • A device internal error was detected.<br>• If the same error code is displayed again even after the device is turned off and on again, shut off the device and contact NIDEK or your authorized distributor. |
| Out of paper. | • Check the printer paper supply and make sure that the printer cover is closed. |
| No.043 Printer error. | • Error related to the printer<br>• If the same error code is displayed again even after the device is turned off and on again, shut off the device and contact NIDEK or your authorized distributor. |
| No.700 CIFS error. | • Error related to Windows file sharing |
| No.703 Hardware error. | • Error related to the IC board<br>The IC was damaged by some cause such as an electrostatic discharge.<br>• If the same error code is displayed even after the device is turned on again, turn off power to the device and contact NIDEK or your authorized distributor. |
| No.704 DHCP error. | • Error related to DHCP<br>The IP address cannot be obtained. |
| No.750 Unable to access to the network. | • Error related to network access<br>Access to the network initiation may require some time after the device start-up.<br>• Check the LAN cable connection and the set IP address and subnet mask. |

| Error code and message | Cause and remedy |
|---|---|
| No.751 Unable to write files to the PC. | • Error related to network writing<br>Write-protection is enabled or no free space is available.<br>• Check whether write permission is granted to the destination folder in the PC and sufficient free space is available. |
| No.754 No PC under the computer name found in the network. | • Error related to the PC name<br>No PC with the specified name exists.<br>• Check the connection of the LAN cable. Or check that the specified PC name is correct. |
| No.756 Unable to logon to the PC. | • Error related to logon<br>The PC cannot be logged on (The domain name, user name, or password is not correct.)<br>• Check the domain name, user name, or password, and enter it correctly. |
| No.757 No shared folders found. | • Error related to the shared folder<br>The shared folder does not exist. (The name of the shared folder is not correct.)<br>• Check the folder name and whether the folder is set to share. |
| No.758 Network timeout. | • Error related to time-out<br>The PC did not finish the process in a specified time.<br>• Send the data again. |
| No.760 Initializing the network. Wait and try again later. | • Error indicating that the network initiation did not complete (The initialization requires some time after the device startup.)<br>• Retry access to the network later. |
| No.761 Access denied. | • Error indicating that access is not allowed<br>The folder sharing setting is improper.<br>• Check the file sharing setting of the PC. |
| No.762 This account is invalid. | • Error related to the account<br>The account is disabled. (The user setting is improper.)<br>• Check the network setting of the device. |
| No.763 Unable to read files on the PC. | • Error related to data read<br>Improper file sharing setting of the PC prevents access of the file.<br>• Check the setting for the file sharing of the PC. |
| No.766 The entered file name already exists. Unable to write the file to the PC. | • A file with the same name exists in the PC. Retry access to the network later. |
| No.771 Network cable is not connected. | • Error related to the cable connection<br>The LAN cable is not connected.<br>• Connect the cable or check that connection is proper.<br>• When data is not output, select the “File Sharing” parameter and set “Output Mode” to “OFF” in LAN Settings. |
| No.772 There is no response. | • Reply error<br>The file is deleted or not renamed within a time frame set in “Timeout” of LAN Settings.<br>• Check that the capture software on the PC is properly activated.<br>• Prolong the set time for “Timeout” of LAN settings in the Maintenance screen. |

# 4.3 Replacing Printer Paper

When a red line appears on the side of the printer paper, it means that paper is running short.
In such a case, stop using the printer and replace the roll with a new one.

Note

- Do not run the printer when printer paper is not loaded.
  It may ruin the printer head.
- Do not pull the paper in the printer forcefully.
  This may cause malfunction of the printer.

***1*** Press the cover open button to open the printer cover.

***2*** Remove the used printer paper.

⚠ **CAUTION** • **When replacing printer paper, be sure not to touch the printer head on the upper part inside printer cover.**
The printer head is extremely hot immediately after printing. Injury may occur.

**3** Set new printer paper.

Set paper as shown in the picture to the right.

Leave the end of paper out from the cover.

Note

- If the roll is set upside down, printing will not occur.
- Make sure that the printer paper roll is not tilted or the shaft misaligned.
  The paper will not be properly fed.

**4** Close the printer cover.

Press the right and left sides of the printer cover to close the printer.

Note

- Make sure that the cover is securely closed.
  The auto cutter may not operate normally. In addition, when the error message is displayed, printing may not be performed.

## 4.4 Attaching a Stack of Chinrest Paper

***1*** Pull out the two fixing pins from the chinrest.

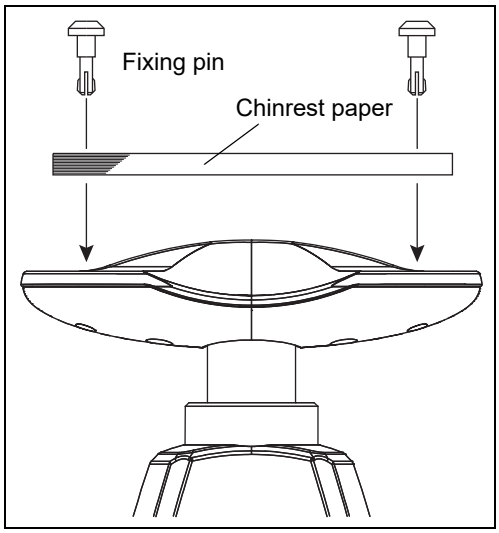
To attach the stack of chinrest paper at first, remove the fixing pins from the accessory package.

***2*** Take out the proper amount of chinrest papers from a whole stack.

A whole stack of chinrest paper cannot be fixed at a time. Be sure to fix the stack with a thickness of 6 mm or less. Pay attention not to scatter the sheets of chinrest paper.

***3*** Insert the fixing pins into the holes in the paper.

Insert the removed pins into both holes of the stack.



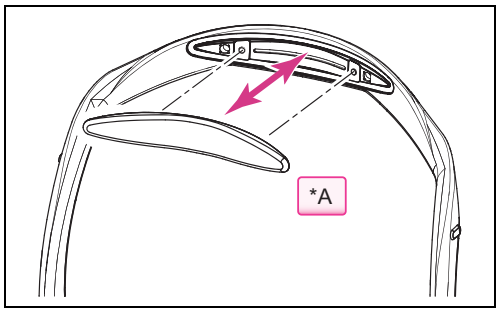

***4*** Fix the stack of chinrest paper onto the chinrest.

1) Insert a pin into a hole in the chinrest while holding both fixing pins and stack of paper.
2) Push the remaining pin into the other hole of the chinrest with the other hand.

# 4.5 Replacing the Forehead Rest Pad

**Magnetic forehead rest pad (30611-1520)**

The forehead rest pad (*A) (made of ABS resin) included in the standard configuration is magnetically attachable. Attach or remove it in the orientation as shown to the right.



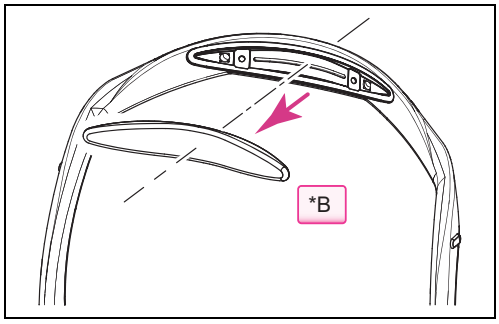

**Forehead rest pad (15411-M752)**

To replace with the softer, designated replacement, polyester elastomer forehead rest pad, use the procedure below.



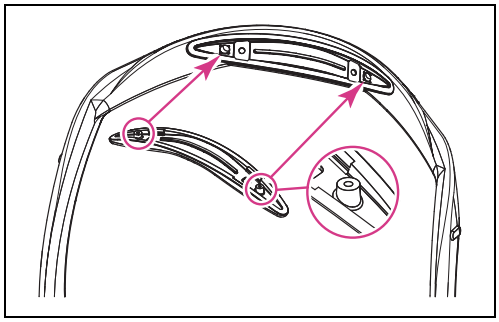
***1*** Remove the forehead rest pad (*B) from the frame.

Hold the edge of the forehead rest pad with two fingers and pull it out.




***2*** Attach a new forehead rest pad.

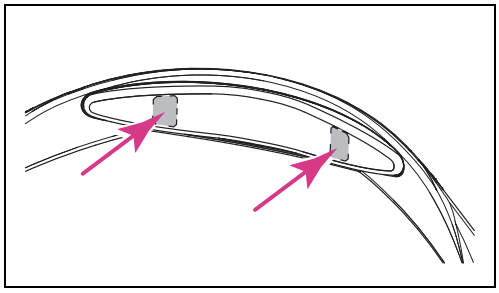
1) Align the clasps of the forehead rest pad to the holes in the frame.



2) Attach the forehead rest pad by pressing over the fastener positions on both sides.

The forehead rest pad is locked by the fasteners.

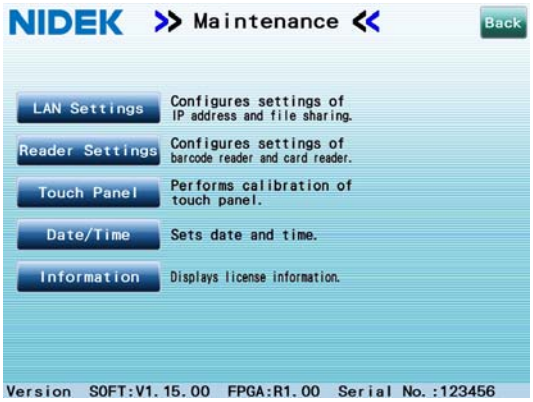
3) Confirm that the forehead rest pad is securely attached.



# 4.6 Maintenance Screen Operation

LAN settings, barcode reader / magnetic card reader, screen touch panel calibration, and license information display are performed by selecting a menu in the Maintenance screen.

The Maintenance screen is displayed by pressing the [Maintenance] button from the menu displayed by pressing the [Menu] button in the capture screen, image select screen, or capture results screen.




| Maintenance menu buttons | Maintenance description |
|---|---|
| **LAN Settings** | Sets the IP address or file sharing. |
| **Reader Settings** | Sets the barcode reader or card reader. |
| **Touch Panel** | Performs calibration of the screen touch panel. |
| **Date, Time** | Sets the current date and time. |
| **Information** | Displays license information. |

Note

- LAN settings, reader setting contents, and the current date and time can be printed out by pressing the [Print] button in the Settings screen.

## 4.6.1 LAN setting

When connecting the device to the external PC via LAN connection, set the IP address, subnet mask, and account.

If the CEM-530 and external PC belong to the different domain in the network, set the account so that access between each other become possible.

Set the shared folder so that it is accessed from both the CEM-530 and external PC.

When the output destination for the data is outside the network the device belongs to, set the default gateway.

* Connection to the hospital LAN and external network is not covered under warranty by NIDEK.

⚠ **CAUTION**

- **Be sure to use a hub for network connections. Do not connect directly to a PC using a LAN cross cable.**

  Data communication may not be properly performed.

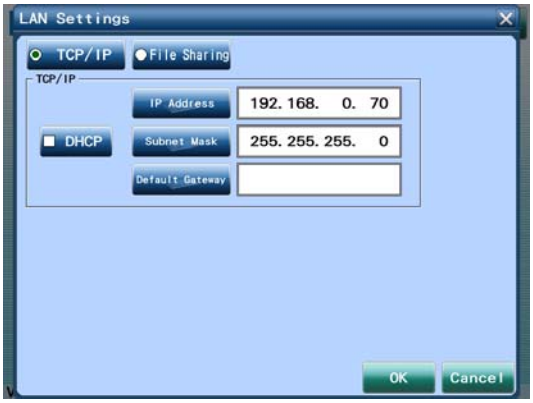
Note

- For the detailed LAN setting, contact the network administrator of the facility.
- Prepare the domain name, PC name, login user name, and login password of the destination PC before setting the shared folder to save data.

**1** While the device is turned off, connect the LAN cable to the LAN connector.

**2** Turn on the power switch to activate the device.

**3** Press the [LAN Settings] button in the Maintenance screen to display the LAN Settings screen.




**4** Select the [TCP/IP] button.

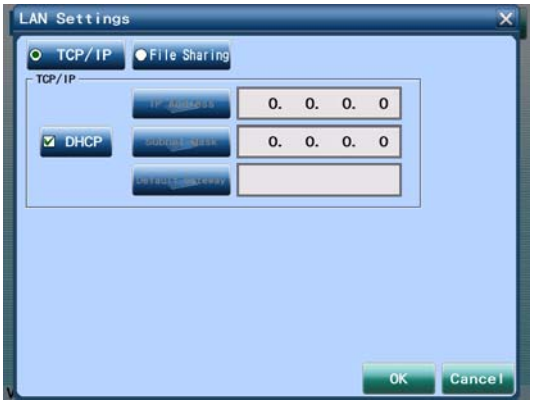
**5** Specify the IP address and subnet mask of the device.

When the DHCP server is on the LAN, select the DHCP box. In such a case, it is not necessary to specify the IP address and subnet mask.

Set the default gateway only when the shared folder in the output destination is outside

the LAN.

The setting change is reflected after the device is restarted.




| | |
|---|---|
| DHCP | Select when the DHCP server is on the LAN.<br>If this check box is selected, 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 | IP address field<br>Change the default “192. 168. 0. 70” as necessary. |
| Subnet Mask | Subnet mask field<br>Change the default “255. 255. 255. 0” as necessary. |
| Default Gateway | Default gateway field<br>It is not necessary when the output destination for the data is within the network the device belongs to. The default setting is blank. |

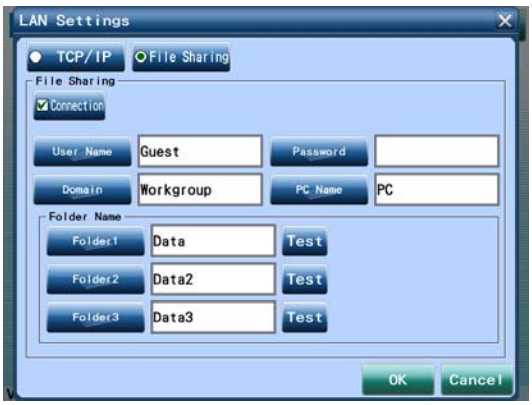
**6** Restart the device, then press the [LAN Settings] button in the Maintenance screen to display the LAN Settings screen.

**7** Select the [File Sharing] button.

## 8 Perform file sharing settings.

Enter the user name (User Name), domain name (Domain), and PC name (PC Name) of the output destination PC using the on-screen keyboard displayed by pressing the corresponding button.

Enter the password if it is required to connect to the PC in the same manner.

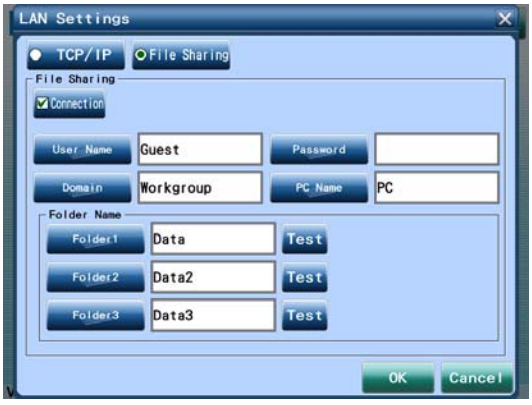



| | |
|---|---|
| User Name | Enter the user name of the destination PC. |
| Password | Enter the login password for the destination PC user name. |
| Domain | Enter the domain name of the destination network. |
| PC Name | Enter the PC name of the PC in which the shared folder exists.<br>The IP address of the PC may be entered instead of the PC name.<br>When the output destination for the data is outside the network the device belongs to, enter the IP address of the destination computer in the PC Name field, along with the default gateway. |

## 9 Specify necessary parameters for the shared folders.

Up to three shared folders can be set as output destination of data. When data output from the CEM-530 is used by two or more devices, set the shared folders for each device.

If both electronic medical record software or filing software and IOL-Station acquire data from one shared folder, after data is acquired by electronic medical record software or filing software, the data is automatically deleted from the shared folder and cannot be acquired by IOL-Station.




Note

- When connecting electronic medical record software or filing software and IOL-Station using a LAN, create a folder for each output destination.

  Example:

  Specify Folder1 as the data output destination in electronic medical record software or filing software.

  Specify Folder2 as the report output destination in IOL-Station.

  Specify Folder3 as the data output destination in IOL-Station.

| | |
|---|---|
| Folder Name | Enter the folder name of up to three shared folders as output destination of data. |
| Test | Performs connection testing.<br>Before connection testing, check the LAN cable connection.<br>If an error occurs, check the setting contents. |

1) Press the [Folder1] button, then enter the shared folder name in the Folder1 box.

   On the output destination PC, create the shared folder with a name the same as the entered folder name.

2) Press the [Test] button to the right of the folder name to confirm that the communication is properly performed.

   If communication was successfully achieved, the “CIFS connected successfully” message appears.

   Should the communication not be successful, an error message appears.

   Before performing the test, shut down the data acquisition software (such as the electronic medical record software, filing software, or IOL-Station) in the output destination PC. If such software is activated, an error may occur during communication test.

3) Specify the [Folder2] and [Folder3] settings as necessary.

   If data output is not necessary, leave the folder name box blank.

***10*** Press the [OK] button to close the LAN Settings screen.

Note

- For setting of data output in LAN communication, use the “Network” tab in the Settings screen.

  For details of settings, see “4.7.4 Network parameter” (page 126).

## 4.6.2 Setting the barcode reader or magnetic card reader

The barcode reader or magnetic card reader to be used for entering the patient ID is set.

⚠ **CAUTION** • **Do not connect any device other than the optional barcode reader or magnetic card reader.**

IDs may not be read correctly or device failure may result.

***1*** While the device is turned off, connect the barcode reader or magnetic card reader into the USB port.

***2*** Turn on the power switch of the device.

***3*** Press the [Maintenance] button from the menu displayed by pressing the [Menu] button to display the Maintenance screen.

***4*** Press the [Reader Settings] button to display the Reader Settings window.


***5*** Press the [Barcode] button or [Card] button to select the reader to be connected.

Selecting “Card” enables the [Start] button and [Length] button.

***6*** When “Card” is selected, enter the start position and length.

Pressing either the [Start] or [Length] button displays the entry window. Enter the numeric values and then press the [OK] button.

The number of characters set in “Length” is read as an ID from the position set in “Start”.

| | |
|---|---|
| Start | Specifies the reading start position of the ID.<br>Enter in the range of “1” to “250”. |
| Length | Specifies the data length to be read as the ID.<br>The data is read up to the set data length or return code.<br>Enter in the range of “1” to “20”. |

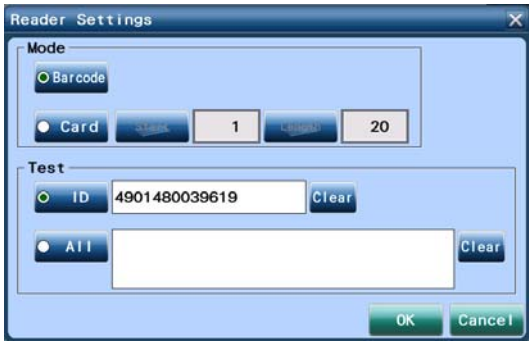
**7** To conduct read testing, select the [ID] button to display the ID only or select the [All] button to display all data. (only for the magnetic card reader)

| | |
|---|---|
| ID field | Displays codes set in the “Start” and “Length” fields. |
| All field | Displays all codes.<br>A return code is also displayed. |

When “Barcode” is selected, the same indication is displayed in the “ID” and “All” fields. (A return mark is also displayed in the “All” field.)

**8** Read the barcode with the barcode reader or read the card with the magnetic card reader.

The read data is displayed in the “ID” or “All” field.




**9** Reset the data range to be captured as necessary (for magnetic card reader only).

Pressing the [Clear] button beside the “ID” field or “All” field clears the field. After changing the setting, read the ID data again and confirm that the ID is correctly displayed in the ID or All field.

**10** Press the [OK] button to close the Reader Settings window and return to the Maintenance screen.

Pressing the [Cancel] button cancels the entered contents and returns to the Maintenance screen.

**11** Press the [Back] button to display the capture screen.

**12** Confirm that the patient ID is correctly displayed in the “ID” field when a patient ID is read with the barcode reader or magnetic card reader.

Note

- Use a magnetic card utilizing a magnetic stripe format compliant with ISO 7811, AAMVA, CA DMV.
- For the patient ID, only alphanumeric characters, “_” and “-” symbols can be used.
  Other symbols are not recognized by the CEM-530. All the unrecognized symbols are converted to “~”.

## 4.6.3 Screen touch panel calibration

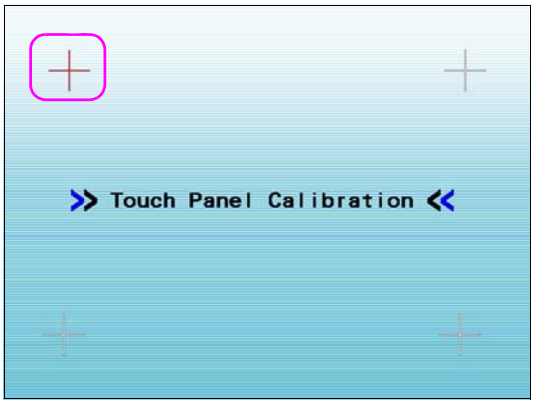
If the response does not correspond to the position touched on the screen touch panel, perform calibration of the screen.

***1*** Prepare the provided touch-screen pen.

***2*** Press the [Touch Panel] button to start the calibration.

***3*** The screen is switched, the message “Touch Panel Calibration” appears in the center of the screen, and cross marks are displayed in the four corners of the screen. Touch the cross mark in the upper left corner using the touch-screen pen.

Touch and hold the mark for about 1 second.

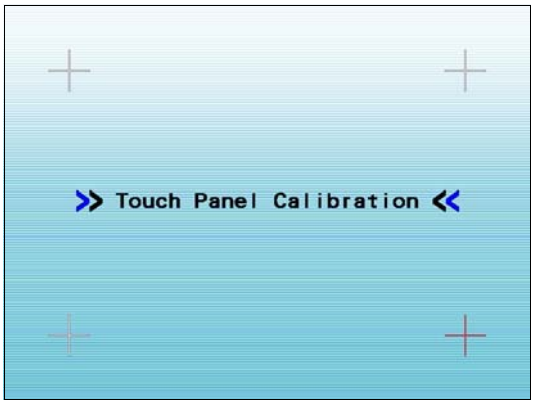



***4*** The display position of the cross mark is changed to the upper right corner of the screen. Touch the center of the cross mark using the touch-screen pen.

***5*** Touch the centers of the cross marks displayed in the lower left and lower right corners of the screen using the touch-screen pen in the same manner.

After the center of the cross mark in the lower right corner of the screen is touched, the calibration is complete.

The screen returns to the Maintenance screen.



## 4.6.4 Setting date and time

The date and time displayed on the output image or print can be set.

Note

- If the device has been left off for about a month, the date and time may have become inaccurate.

***1*** Press the [Date, Time] button in the Maintenance screen to display the Date, Time window.


***2*** Press the ▲ ▼ buttons to adjust the date and time.

While the Date, Time window is displayed, the clock continues running. Pressing any button changes the indication and resets the seconds field to 00.

***3*** Press the [Close] button to close the Date, Time window.

4

○ Battery recharging:

The battery is rechargeable. When the device is used for the first time after unpacking or the device has not been operated for a long time (approximately one month or longer), the battery is discharged, and the internal clock may go wrong.

In such a case, turn on the device and leave it on to recharge the battery. The battery needs 24 hours for a full charge.

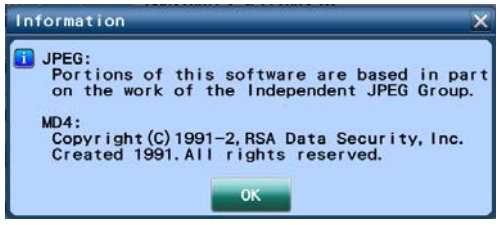
If the device is used for 8 hours a day, the device will have to be kept on for three days before the battery is fully recharged. Once the battery is fully recharged, the device operates normally for daily use.

(The lithium battery is not user replaceable.)

## 4.6.5 Displaying license information

This is the license information regarding the JPEG format used for image compression and MD4 used for verification of data.

***1*** Press the [Information] button on the Maintenance screen to display the Information window.




***2*** Press the [OK] button to close the Information window and return to the Maintenance screen.

# 4.7 Parameter Settings

## 4.7.1 Changing parameter settings

The CEM-530 is provided with parameters that set various functions according to the needs of the operator. The procedures for checking and changing the parameter settings are as follows.

***1*** Press the [Settings] button from the menu displayed by pressing the [Menu] button in the capture screen to display the Settings screen.

The selected setting options are displayed as check boxes or radio buttons.


***2*** Press the item button to select options to be changed.

For details of options, see “4.7.2 Take parameter” (page 121) - “4.7.5 Other parameter” (page 128).


Press to select the item button.

| Item button | Options |
|---|---|
| Take | Fixation, Capturing/ Display Mode, Cell Image Display, Check Data Clear |
| Print | Printer, Printer Mode, Patient No. (Set No.), Data Clear, Built-in Printer Option (Date Print, Patient No., Econo. Print, Name Print, Image Print, Comment Print), Video Printer Options |
| Network | Output Item (output folder, Data, Report, ACK, Timeout) |
| Other | Language, Beep, LCD Backlight, Name, Sleep Time, Date Format |

| | |
|---|---|
| [Print] button | The set contents in the current Maintenance screen and Settings screen are printed from the built-in printer.<br>The set contents of all items are printed at the same time. |

**3** Set options to be changed.

Setting options are set using check boxes, radio buttons, or text boxes.

For the setting contents, see “4.7.2 Take parameter” (page 121) - “4.7.5 Other parameter” (page 128).

Note
- Underlined options indicate factory settings.

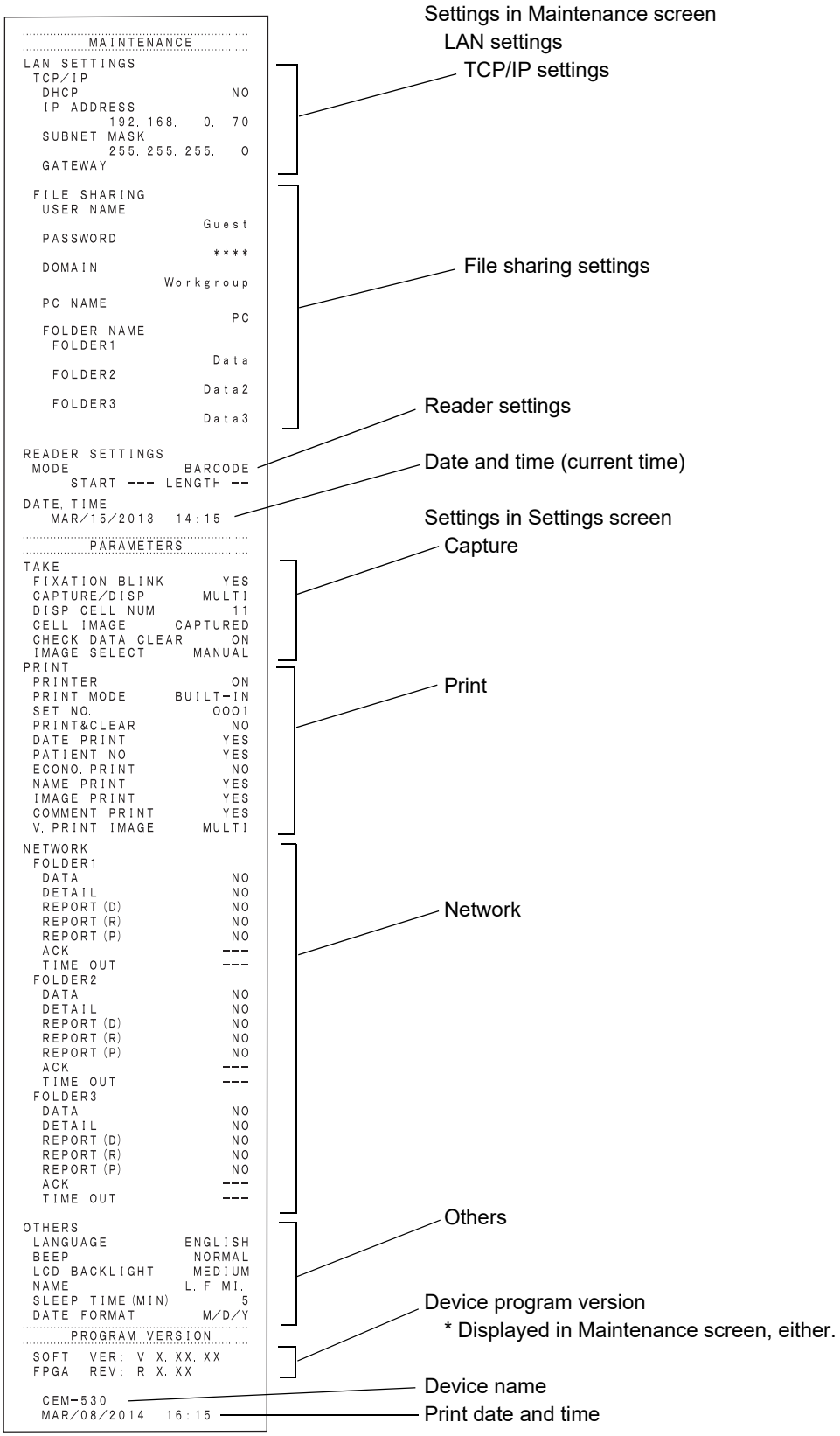
**4** After changing settings, press the [OK] button to save the settings and return to the capture screen.

Pressing the [Cancel] button cancels the entered contents and returns to the capture screen.

Note
- The changed settings are maintained even if the device is turned off.

## ○ Printing parameters

The set contents in the Maintenance screen and Settings screen are printed from the built-in printer by pressing the [Print] button.



## 4.7.2 Take parameter


Fixation: Blink (This parameter check box is selected in the factory setting.)

Sets to blink the internal fixation lamp or peripheral fixation lamp.

Select Analysis Image: Auto, Manual

Sets whether to select the image for analysis automatically or manually.

| | |
|---|---|
| Auto | The most suitable image is automatically selected for analysis.<br>After images are captured, the image select screen appears. The [Auto Analysis] button is automatically selected and the screen changes to the next one (capture screen or capture results screen).<br>Thumbnail image No. 1 is selected for analysis. |
| Manual | The operator selects the image for analysis on the image select screen. |

Note

- If the parameter is set to “Auto”, thumbnail image No.1 is selected for analysis regardless of the image quality.

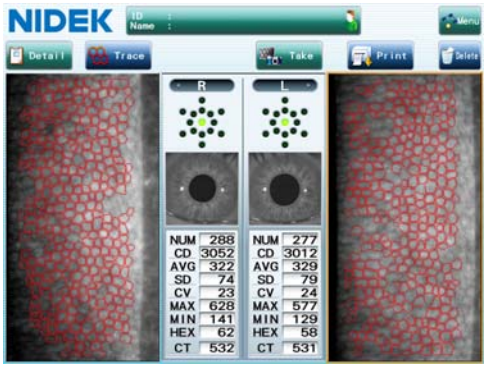
Capturing/ Display Mode: Single Mode, Multi Mode, Paracentral

Sets the capture count for one eye (one time only / 1 to 15 times) and whether to perform paracentral image capture.

Sets whether to display the capture results screen as a single or multiple display (single display and multiple display are switched depending on the capture count) after image capture.

| | |
|---|---|
| Single Mode | Regardless of the capture count, the capture results screen is always shown as a single display.<br>One capture data set is displayed for each eye. When image capture is performed more than once for one eye, only the latest capture data is displayed.<br>Paracentral autoshot and paracentral display are not available. |

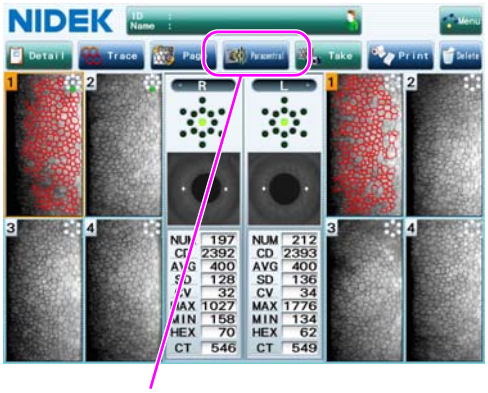
| | |
|---|---|
| Multi Mode | Depending on the capture count, the capture results screen is automatically shown as a single display or multiple display.<br>When image capture is performed only once for either eye, the capture results screen is shown as a single display for that eye. In other cases, it is shown as a multiple display.The capture results screen is displayed by pressing the [Result] button.<br>In multiple mode, a maximum of 15 capture data sets can be saved for each eye.<br>Paracentral autoshot and paracentral display are not available. |
| Paracentral | Paracentral autoshot and paracentral display are available.<br>The capture results screen is shown as a multiple display with the [Paracentral] button.<br>The capture results screen is displayed by pressing the [Result] button.<br>Pressing the [Paracentral] button displays the paracentral screen.<br>When image capture is performed only once for either eye, the capture results screen is shown as a single display for that eye. |



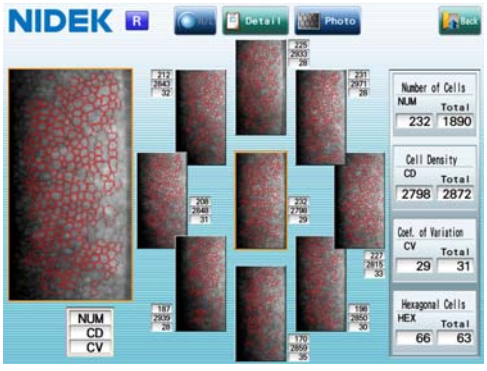

Capture results screen (single display)


Capture results screen (multiple display)

Paracentral mode screen




[Paracentral] button




Paracentral screen

Min. Cell Number: 1 to 15 (default value: 11)

Sets the minimum number of cells to display the analysis values. If the number of cells to be analyzed is less than the selected number in the “Min. Cell Number” parameter, an analysis error occurs and the analysis value field displays “– – –”.

After manual analysis, the analysis values are displayed when more than one cell is selected regardless of the parameter setting.

Cell Image Display: Captured Image, Enhanced Image

Select the endothelial image to be displayed in the capture results screen or detail analysis screen from either “Captured Image (live image)” or “Enhanced Image (sharp image processed image)”.

This setting is also reflected in the endothelial image of the LAN output or video printer output.

| | |
|---|---|
| Captured Image | The captured image (live image) is displayed without image processing |
| Enhanced Image | The captured image is converted into a sharp image by image processing. |

Note

- After the “Cell Image Display” setting is changed after image capture, both “Captured Image” and “Enhanced Image” can be displayed.
- “Captured Image (live image)” is always displayed in the image select screen regardless of the “Cell Image Display” setting.

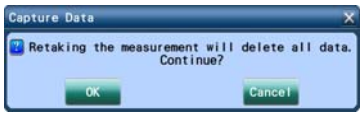
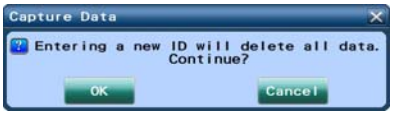
Check Data Clear: OFF, ON

After printing or outputting the capture data, starting image capture of a new patient (a, b, or c below) deletes the capture data (patient information, image data, and analysis data) of the previous patient so that it will not mix up with that of the previous patient. Whether to display a confirmation message before deleting the capture data can be set.

a. Press the [Take] button in the capture results screen.

b. Press the patient information field on each screen.

c. Read the patient ID using the barcode reader or magnetic card reader.

| | |
|---|---|
| OFF | No confirmation message for data deletion does not appear. |
| ON | A confirmation message for data deletion appears.<br>Conducting Procedure a, b, or c below displays a confirmation message for data deletion. Pressing the [OK] button moves to the next procedure. Pressing the [Cancel] button clears the operation and closes the confirmation message.<br>a. Press the [Take] button in the capture results screen.<br>The message "Retaking the measurement will delete all data. Continue? [OK]/[Cancel]" appears.<br>Pressing the [OK] button displays the capture screen and then starting the next image capture clears the previous capture data.<br>  <br>b. Press the patient information field on each screen.<br>The message "Entering a new ID will delete all data. Continue? [OK]/[Cancel]" appears.<br>Pressing the [OK] button displays the Patient Information screen and then entering a new patient ID clears the previous capture data.<br>  <br>c. Read the patient ID using the barcode or magnetic card reader.<br>The same message as the above (b) appears.<br>Pressing the [OK] button clears the previous capture data and displays the capture screen in which the entered patient ID is shown. |

Note

- When the “Print&Clear” check box of the “Data Clear” parameter is selected, the “Check Data Clear” parameter setting is disabled.
  When the “Print&Clear” parameter check box is selected, a confirmation message for data deletion does not appear.

## 4.7.3 Print parameter


Printer: OFF, ON

Sets whether to print the analysis results.

| | |
|---|---|
| OFF | Data is not printed.<br>When data output is enabled in LAN setting, pressing the [Print] button produces data output only. |
| ON | Pressing the [Print] button prints data out.<br>When data output is enabled in LAN setting, pressing the [Print] button produces data output at the same time. |

Print Mode: Built-in, Video

Sets the printing contents.

When the “Printer” parameter is set to “ON”, this parameter is enabled.

| | |
|---|---|
| Built-in | Data is printed from the built-in printer. |
| Video | Data is printed from the optional video printer. |

Patient No.: Set No. (0001 to 9999)

Sets the patient number of the printing contents.

Press the [Set No.] button to display the Set No. window.

To reset the number to “0001”, use this Set No. window.


*The patient number differs from the patient ID. It is automatically assigned and printed.

*For the built-in printer, the patient number is only printed when the “Built-in Printer Option” - “Patient No.” parameter check box is selected. For the video printer, the patient number is always printed.

Data Clear: Print&Clear (This parameter check box is not selected in the factory setting.)

Select this check box to clear the capture data (patient information, image data, and analysis data) and display the capture screen at the time of printing.

When this parameter is selected in paracentral mode, performing both “outputting data in the paracentral screen” and “printing (or outputting data) the capture results screen or detail analysis screen” clears the capture data and displays the capture screen.

4

Built-in Printer Option

Sets the printing contents. Checked items are printed.

All parameter check boxes other than “Econo. Print” are selected in the factory setting.

| | |
|---|---|
| Date Print | The current date and time are printed. |
| Patient No. | Patient No. is printed. |
| Econo. Print | Lessens the space between lines of printout.<br>This saves printer paper. |
| Name Print | Patient name is printed.<br>When no name is entered as patient information, “NAME (space) M/F” is printed to allow the operator to write the name and sex by hand. |
| Image Print | The selected endothelial image is printed.<br>The image to be printed is the central part (approx. 0.2 × 0.4 mm) of the original endothelial image. |
| Comment Print | “NIDEK CEM-530” is printed at the end of each print. |

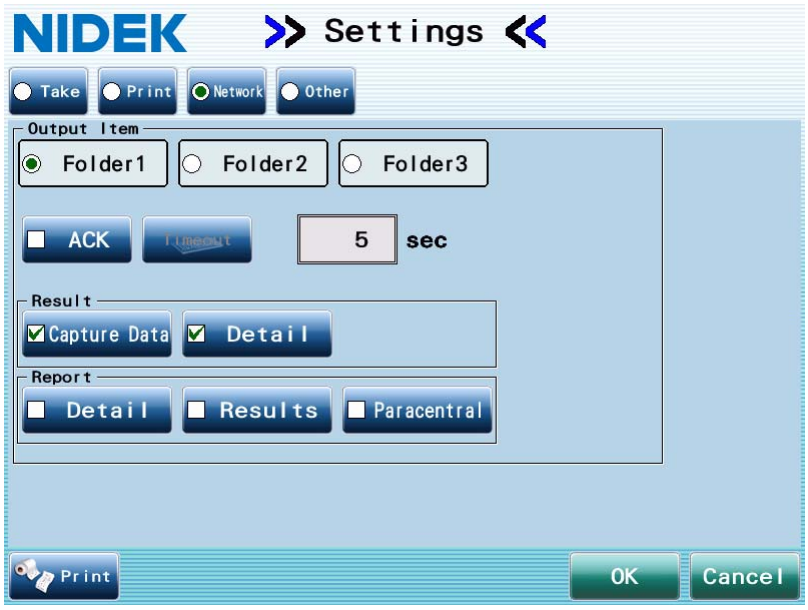
Video Printer Options

Sets the printing contents of the optional video printer.

When printing on the capture results screen in multiple mode or paracentral mode, select whether to print only the selected image or all images.

| | |
|---|---|
| Multi Image | All images are printed.<br>See the sample printout of “Capture results screen (single display)” in “3.9.2 Printing captured results (video printer)” (page 101). |
| Single Image | Only the selected image is printed as a single display.<br>See the sample printout of “Capture results screen (multiple mode / paracentral mode)” in “3.9.2 Printing captured results (video printer)” (page 101). |

## 4.7.4 Network parameter




Output Item: Sets output items to be output to folders on the destination PC.

The following settings are available for each output destination (Folder1 to Folder3).

No parameter check box selected for any folder is the factory setting.

Set “ACK” and “Timeout” as necessary.

| | |
|---|---|
| ACK | Select this check box to output data to electronic medical record software or filing software.<br>After the time specified in the Timeout field has passed from the end of data output, reception of the output data by the electronic medical record software or filing software is confirmed. If the data has not been received by the electronic medical record software or filing software, an error message appears. |
| Timeout | Sets the time between data output and confirmation of data reception.<br>If data is not received within a set time, an error message appears.<br>(enabled only when “ACK” is selected.) |

Select the data to be output from “Result” and “Report”.

Result

| | |
|---|---|
| Capture Data | All captured image data (endothelial image in BMP) and all analysis data (XML) are output. |
| Detail | The detail analysis images (JPEG) of the selected right and left eye are output. |

Report

| | |
|---|---|
| Detail | The contents of the detail analysis screen of the selected right and left eye and patient information (ID, name, patient No., and output date and time) are output in a report for printing (JPEG) over a LAN. |

| | |
|---|---|
| Results | The contents of the capture results screen and patient information (ID, name, patient No., and output date and time) are output in a report for printing (JPEG) over a LAN.<br>A maximum of 10 images can be printed for each eye. When more than 10 images are captured, the latest 10 images are printed out.<br>When more than 10 images are captured, the latest 10 images are printed out regardless of image selection. The latest 10 images are automatically selected. (The analysis values are the results of the latest images) |
| Paracentral | A report of the center and paracentral endothelial image data are output in graphical layout over a LAN. |

Note

- When connecting the electronic medical record software or filing software and IOL-Station using a LAN, create a folder for each output destination.

  Example:

  Specify Folder1 as the data output destination in electronic medical record software or filing software.

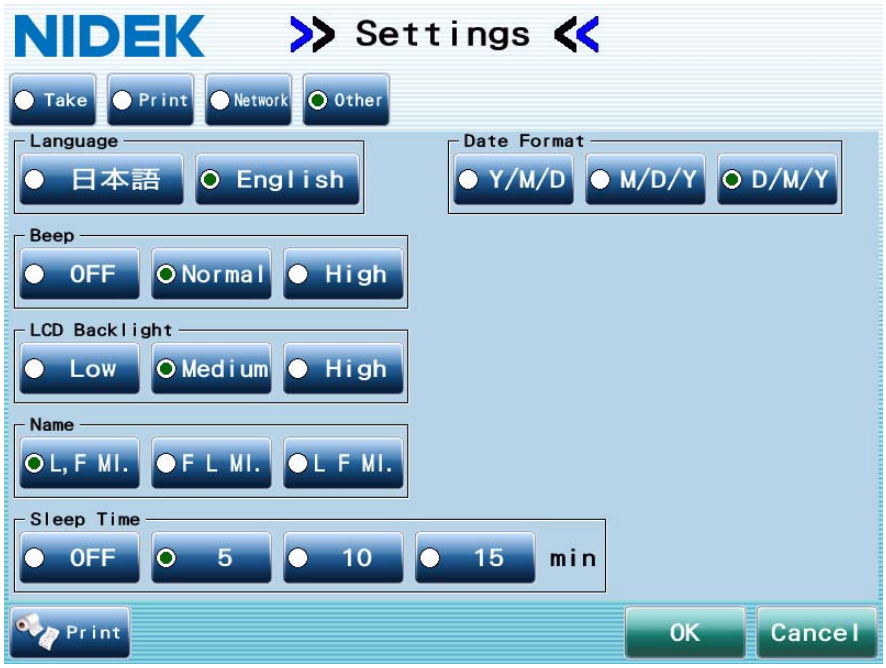
  Specify Folder2 as the report output destination in IOL-Station.

  Specify Folder3 as the data output destination in IOL-Station.
- To print the report of the detail analysis screen using the IOL-Station Print Manager, select only the “Report” parameter check box for the folder specified by the Print Manager.

  When both the “Data” and “Report” parameters are selected, the image data of the detail analysis for both eyes and the report of the detail analysis screen are printed.
- If data is not output using a LAN, clear the “Data” and “Report” parameter check box for Folder1 to Folder3.

* For network, LAN setting is necessary. For details, see “4.6.1 LAN setting” (page 110).

## 4.7.5 Other parameter




Language: Japanese, English

Selects the language displayed on the screen.

Beep: OFF, Normal, High

Sets whether to sound a beep when operations are performed and sets its tone.

LCD Backlight: Low, Middle, High

Sets the LCD brightness.

Name: L, F MI., F L MI., L F MI.

| | |
|---|---|
| L, F MI. | Displayed in the order of the last name, first name, and middle name. |
| F L MI. | Displayed in the order of the first name, last name, and middle name. |
| L F MI. | Displayed in the order of the last name, first name, and middle name. |

The middle name is displayed as the first two upper case letters followed by a period (“.”).

Sleep Time: OFF, 5, 10, 15 min

Sets the time to enter sleep mode when the device has not been used.

When “OFF” is selected, the device is not placed into sleep mode.

Date Format: Y/M/D, M/D/Y, D/M/Y

Print date format.

| | |
|---|---|
| Y/M/D | Year / Month / Day |
| M/D/Y | Month / Day / Year |
| D/M/Y | Day / Month / Year |

# 4.8 Cleaning

When the cover or screen touch panel of the device becomes dirty, clean it with a soft cloth before use. For persistent stains, soak the cloth in a neutral detergent, wring well, and wipe. Finally dry with a soft, dry cloth.

⚠ **CAUTION**

- **Never use an organic solvent such as paint thinner.**
  This could damage the surface of the device.
- **Lightly wipe the exterior of the screen touch panel. Do not press the screen touch panel using an object with a hard tip. In addition, keep magnetic objects away from the screen touch panel.**
  Scratches or failure of the screen touch panel may result.
- **Never use a sponge or cloth soaked in water.**
  Water may leak into the inside of the device and cause device failure.

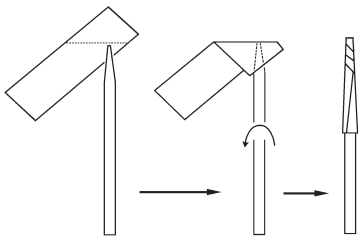


## 4.8.1 Cleaning the capturing window

When the capturing window gets fingerprints or dust on it, reliability of the measurement value is impaired substantially. Check for smudges on the capturing window before use, and then clean it if it is soiled.
The capturing window lens does not usually become soiled through normal use because it is recessed.

***1*** Blow off any dust on the capturing window with a blower.

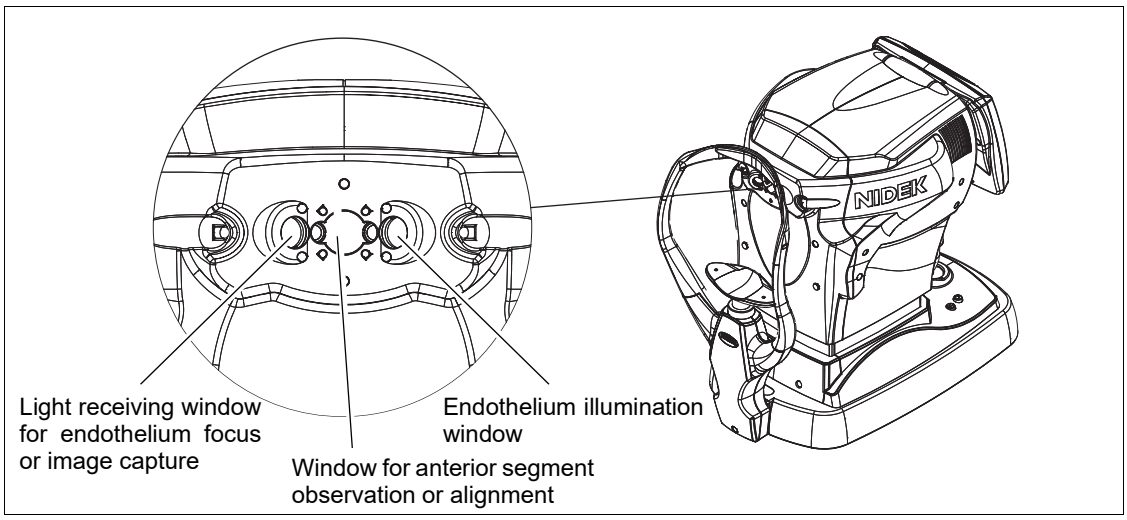
***2*** Wrap lens cleaning paper around some kind of thin stick (or cotton swab) and wipe the lens of the capturing window with the cleaning paper moistened with alcohol.


Wrap cleaning paper around the tip.

Note
- Do not use a stick made of metal or other hard material which may damage glass.
- Wipe gently from the center of the capturing window to the outside in a circular motion.

***3*** Check if the windows are cleaned using a penlight. If not, clean them again with a fresh cleaning paper.

Apply light with a penlight and change the view angle to check the clearness.

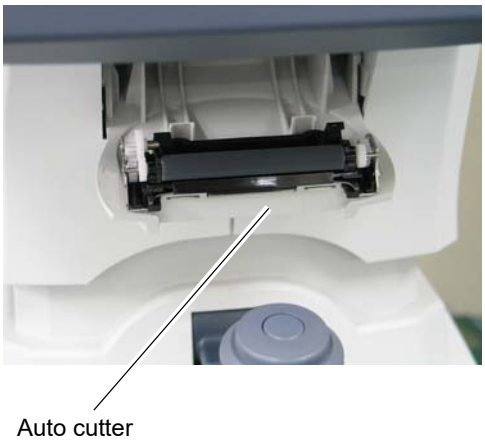



## 4.8.2 Cleaning the printer

After repeated use, paper residue may accumulate in the paper slot of the auto cutter of the printer. If this happens, malfunction of the auto cutter may result. Check the auto cutter before use and clean the cutter if residue has accumulated.

***1*** Open the printer cover and remove the printer paper roll.

See “4.3 Replacing Printer Paper” (page 106).

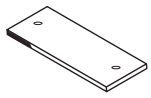
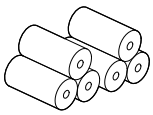



***2*** Apply the nozzle of a vacuum cleaner to the auto cutter to remove any paper residue.

Never blow off paper residue with a blower. If residue is blown into the internal working structure, malfunction may result.

***3*** Supply the printer paper as before.

# 4.9 List of Replacement Parts

| Part name | Part number | Note | |
|---|---|---|---|
| Printer paper | 80620-00001 | For built-in printer, Width 58 mm, Length 25 m |  |
| Chinrest paper | 32903-M047 | Pack of chinrest paper |  |
| Magnetic forehead rest pad | 30611-1520 | Made of ABS resin |  |
| Forehead rest pad | 15411-M752 | Made of polyester elastomer |  |
| Video printer paper | 14610-E304 | For optional video printer, 110 mm × 18 m, 6 rolls |  |

* After replacing consumables, restock them.

# 5. SPECIFICATIONS AND ACCESSORIES

## 5.1 Classifications

Protection against electrical shock: Class I ME equipment

Protection against electrical shock (applied parts): Type B applied part

Protection against harmful ingress of water or particulate matter: IPX0

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

Method(s) of sterilization: ME equipment that does not contain any part that needs sterilization

Mode of operation: Continuous operation

# 5.2 Specifications

## ○ Endothelial image capture

- Capture field 0.25 × 0.55 mm (W × H)
- Fixation lamp (center)
  Nine-point fixation lamp: Central one point + Central eight points (5° visual angle, 45° spacing)
- Fixation lamp (peripheral)
  Six-point fixation lamp: Peripheral six points (27° visual angle, 60° spacing)

## ○ Pachymetry

- Measurement range
  300 to 1,000 µm
  1 µm increments
- Accuracy ±10 µm

## ○ Working range of auto tracking

- Up and down 32 mm
- Right and left During alignment: ±5 mm,
  During capturing: ±8 mm
- Forward and backward During alignment: ±5 mm,
  During capturing: forward — 8 mm, backward — 5 mm

## ○ Movable range

- Capturing unit Forward and backward: 36 mm
  Right and left: 85 mm
- Motorized chin rest Up and down: 62 mm or more

## ○ Other functions

- Display 8.4-inch color LCD (SVGA)
- Printer Thermal line printer with auto cutter
- Interface
  USB (USB1.1)
  LAN (10 BASE-T/100 BASE-TX)
  Video output (BNC connector for video printer)

## ○ Electrical rating

- Power source AC 100 to 240 V 50/60 Hz
- Power consumption 100 VA

## ○ Dimensions and mass

- Dimensions 291 (W) × 495 (D) × 457 mm (H)
- Mass 20 kg

## ○ Environmental conditions (during use)

- Temperature 10 to 35°C (50 to 95°F)
- Humidity 30 to 90%
- Atmospheric pressure
  800 to 1,060 hPa
- Other Indoor, no harmful dust or smoke

## ○ Environmental conditions (during transport and storage, packed condition)

- Temperature –10 to 55°C (14 to 131°F)
- Humidity 10 to 95%
- Atmospheric pressure
  700 to 1,060 hPa

## ○ Others

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

# 5.3 Accessories

## 5.3.1 Standard accessories

| | |
|---|---|
| • Printer paper | 3 rolls |
| • Power cord | 1 unit |
| • Dust cover | 1 unit |
| • Pack of chinrest paper | 1 unit |
| • Fixing pins for chinrest paper | 2 units |
| • Operator’s manual | 1 volume |
| • Touch-screen pen | 1 unit |
| • Touch-screen pen stand | 1 unit |
| • Ferrite core | 1 unit |

## 5.3.2 Optional accessories

- Barcode reader (USB)
- Magnetic card reader (USB)
- Video printer (B/W)
- Video printer paper (6 rolls)
- IOL-Station Print Manager (CD-R)

# 6. APPENDIX

## 6.1 Glossary

- Auto shot

  A function to automatically start image capture as soon as the eye is best aligned and focused.

- Auto tracking

  A function to automatically control the up, down, right, and left movements and focus direction of the capturing unit.

- Domain

  A name that identifies PCs or network on the Internet.

- Expected service life

  A period of time beyond which the reliability and safety of the system cannot be guaranteed even with normal use and regular maintenance that involves proper exchange of maintenance and consumable parts, repair, and overhaul.

- Fixation lamp

  Two kinds of fixation lamps are available. One is an internal fixation lamp viewed through the capturing window while the other is a peripheral fixation lamp located at six positions around the capturing window. The visual line of the patient is guided to enable selection of the capture area of the endothelium.

  Steady lighting or blinking is set by a parameter.

- Focus indicator

  Indicator of focus adjustment indicating the distance between the capturing unit and patient eye. For focus adjustment, manipulate the joystick until the optimum focus indicator ( -O- ) is displayed.

- Limit indicator

  When the capturing unit moves out of the working range of auto tracking, the limit indicator (arrows) is displayed on the screen.

- Paracentral

  Refers to paracentral area (visual angle: 5°).

- Sleep mode

  A mode in which the screen automatically shuts off and power consumption is reduced after no operation has been performed within a specified time.

  Manipulating the screen touch panel or joystick reactivates the device.

- Specular reflection

  Reflection of light entering from one direction exiting to another one-way without diffusion. If a boundary surface exists which causes a difference of the optical reflectivity in the optical path, part of light is reflected. The specular microscope captures images of light reflected at the border between the cornea and anterior chamber.

- Style sheet

  A file that defines information regarding the appearance of a document such as fonts, font size, color, line spacing, and qualification.

# 6.2 List of Abbreviations

This device and operator's manual use the abbreviations below.

○General

| | |
|---|---|
| AAMVA | American Association of Motor Vehicle Administrators |
| ABS | Acrylonitrile Butadiene Styrene |
| ACGIH | American Conference of Industrial Hygienists |
| BNC | Bayonet Neill Concelman |
| CA DMV | California Department of Motor Vehicles |
| DHCP | Dynamic Host Configuration Protocol |
| EMC | Electromagnetic Compatibility |
| ESD | Electrostatic Discharge |
| IP | Internet Protocol |
| ID | Identification |
| JPEG | Joint Photographic Experts Group |
| LAN | Local Area Network |
| LCD | Liquid Crystal Display |
| MD4 | Message Digest Algorithm 4 |
| M/F | Male/Female |
| NTSC | National Television System Committee |
| OS | Operating System |
| PC | Personal Computer |
| RF | Radio Frequency |
| SVGA | Super Video Graphic Array |
| TCP/IP | Transmission Control Protocol/Internet Protocol |
| USB | Universal Serial Bus |
| UV | Ultraviolet |

## ○Analysis parameters

| Abbreviation | Analysis item | Details |
|---|---|---|
| NUM | Number of Cells | Number of endothelial cells analyzed |
| CD | Cell Density | Number of endothelial cells per unit area (1 $mm^2$) |
| AVG | Average Area | Average area of endothelium analyzed |
| SD | Standard Deviation | Standard deviation of the endothelium area analyzed |
| CV | Coefficient of Variation | Standard deviation (SD) divided by the calculated average (AVG) |
| MAX | Max Area | Largest area of endothelium analyzed |
| MIN | Min Area | Smallest area of endothelium analyzed |
| HEX | Hexagonal Cells | Proportion of hexagonal cells found in the analyzed endothelium |
| CT | Corneal Thickness | Corneal thickness obtained through capture procedure |

# 6.3 EMC (ELECTROMAGNETIC COMPATIBILITY)

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

.

⚠ **WARNING**

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

  **The following are examples of electromagnetic disturbance sources:**
  - **Induction cooking appliance and ovens**
  - **RFID readers**
  - **Electronic article surveillance (EAS) systems**
  - **Sponge detection systems**
  - **Equipment used for position detection (e.g. in catheter labs)**
  - **Wireless power transfer charging systems for electrical vehicles**



## O Specified cable

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

## O Essential performance

- Corneal endothelium cells capture function
- Pachymetry measurement function

## ◆ Compliance for Emission Standard

| Phenomenon | Product family standard | Compliance |
|---|---|---|
| Conducted and radiated RF emissions | CISPR 11 | Group 1<br>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<br>18 Hz | 27 |
| 450 | 430 to 470 | GMRS 460, FRS 460 | FM<br>±5 kHz deviation<br>1 kHz sine | 28 |
| 710 | 704 to 787 | LTE Band 13, 17 | Pulse modulation<br>217 Hz | 9 |
| 745 | | | | |
| 780 | | | | |
| 810 | 800 to 960 | GSM 800/900,<br>TETRA 800, iDEN 820,<br>CDMA 850, LTE Band 5 | Pulse modulation<br>18 Hz | 28 |
| 870 | | | | |
| 930 | | | | |
| 1720 | 1700 to 1990 | GSM 1800;<br>CDMA 1900;<br>GSM 1900; DECT;<br>LTE Band 1, 3, 4, 25;<br>UMTS | Pulse modulation<br>217 Hz | 28 |
| 1845 | | | | |
| 1970 | | | | |
| 2450 | 2400 to 2570 | Bluetooth<br>WLAN 802.11 b/g/n<br>RFID 2450<br>LTE Band 7 | Pulse modulation<br>217 Hz | 28 |
| 5240 | 5100 to 5800 | WLAN 802.11 a/n | Pulse modulation<br>217 Hz | 9 |
| 5500 | | | | |
| 5785 | | | | |

## ◆ Compliance for Immunity Standard

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

# 7. INDEX