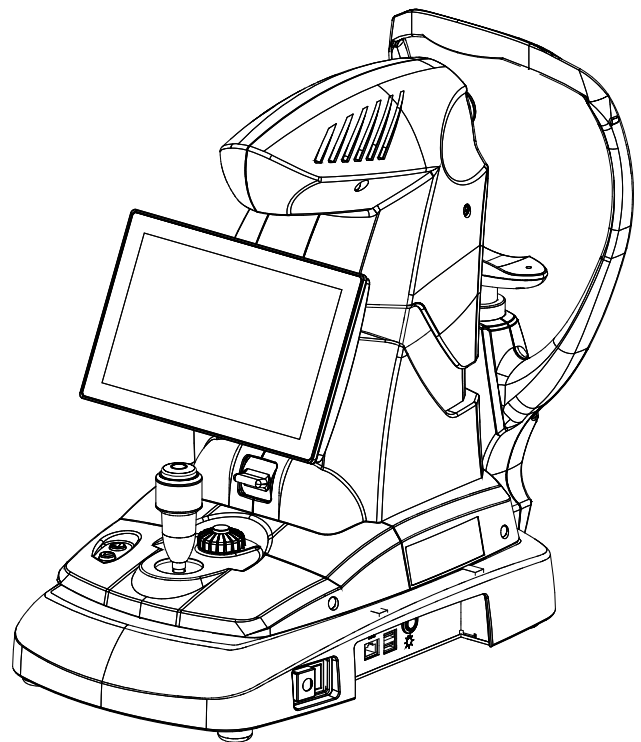


NIDEK

Gonioscope GS-1

OPERATOR'S MANUAL



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

Original instructions

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2023-04-04
GN001-P902-B3
Printed in Japan
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Before Use

This operator's manual includes operating procedures, safety precautions, and specifications for the NIDEK Gonioscope GS-1. Cautions for safety and operating procedures must be thoroughly understood before using this device. Keep this manual handy for reference. If you encounter any problems or have questions about the device, please contact NIDEK or your authorized distributor.

"License Agreement" of embedded software manufactured by Microsoft

Microsoft OS (Windows 10 IoT Enterprise 2016 LTSC) is embedded in the device. Before using this device, be sure to read "SOFTWARE LICENSE AGREEMENT" provided by Microsoft.

For details, visit our website from the URL below.

<http://www.nidek-intl.com/aboutus/entry-3001.html>

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 - 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.

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- 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

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1

SAFETY PRECAUTIONS



BEFORE USE, READ THIS MANUAL.

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

Keep this manual handy for reference.

Use of this device is limited to doctors or health care providers authorized by a doctor.


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



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



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

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


1.1 Usage Precautions

Before use


WARNING

- If any serious device-related incident occurs, report it to Nidek and the competent authority in the country where the user or patient, or both reside.
- Be sure to connect the power cord to a grounded outlet.
Electric shock or fire may result in the event of 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.
- Prior to operation of the device, read this manual so that the safety precautions and operating procedures are thoroughly understood. Never use accessories other than those specified by NIDEK.
Use of the device outside the scope of this manual may cause adverse events or malfunction.
- Only the personnel skilled in image capturing are allowed to use this device.
- Images may be affected by image capturing conditions. For diagnosis, make a comprehensive judgment based on results from several tests.
- Never disassemble or modify the device. Never touch the internal structure of the device.
There are no parts that can be replaced by the user in the internal structure.
- Install the device in an environment that meets the usage conditions.
Usage conditions:  "5.1 Specifications" (page 155)
- Avoid installing the device where it is exposed to direct air flow from an air conditioner.
Drastic changes in temperature may result in condensation inside the device or adversely affect measurement function. When condensation occurs, turn off the device power and leave the device unattended for approximately a few hours or half a day long at room temperature.
- Avoid installing the device where it is exposed to direct sunlight.
Intense light entering the image capturing aperture may result in indistinct images.
- Keep the touch screen away from direct sunlight or excessive ultraviolet rays.
They will damage the touch screen.
- Be sure to use a power outlet which meets the specified power requirements.
- Fully insert the power plug into the power outlet.
- Never use power strips or extension cables for the power supply of the device.
- Do not use any power cord other than the one provided. Do not use the provided power cord for any other instrument.
- 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 any tool.
It may interfere with disconnecting of the power from the input power source in case of an abnormality.
- When connecting or disconnecting cables, check the symbols and orientation. Securely connect them without applying unnecessary force.
- When connecting the LAN cable or external fixation lamp cable, be sure to turn off the device power switch and disconnect the power cord from the power outlet.

CAUTION

- If the device is used after a long period of disuse, check for any abnormality before use.
- When carrying the device to another location, observe the following cautions.
 - Set the device to Packing mode.  “4.3.9 Preparation for device packing (Packing mode)” (page 132)
 - Lock the main unit with the locking lever.
 - Lock the image capturing unit with the locking lever.
 - Disconnect the power cord and cables.
 - When the device is held, its base must be held. Never hold any parts such as the forehead rest or main unit.

During use

CAUTION

- Do not perform servicing or maintenance on the device during use.
- Perform the visual and operation checks before using the device. If any abnormality is found, do not use the device.

Continued use of the device under such abnormal conditions may affect the data accuracy. Unexpected malfunction or faulty diagnosis may induce unexpected health hazards.
- Before and after use, and before every patient’s measurement, clean the forehead rest and chinrest with clean gauze or absorbent cotton. For severe stains, wipe with a clean cloth dampened with rubbing alcohol.

When the chinrest paper is used, remove a sheet after each patient’s measurement.
- Before image capture, explain the purpose and method of image capture sufficiently to the patients.
- Do not place hands or fingers in the space (or gaps) under movable units (such as the main unit, base, or chinrest). Pay particular attention to the main unit because it moves in each direction during automatic alignment. Be sure to also provide the same caution to the patients.

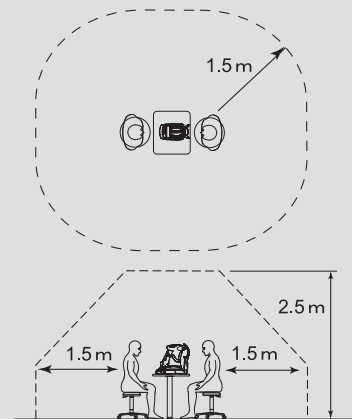
Hands or fingers may be caught and result in injury.
- During the device start-up, do not touch the LCD touch screen or place any electrical components on it.
- Prior to image capture, confirm that patient’s fixation is stable and their eyes are wide-open.

Proper measurement may not be performed.
- When using the multi mirror prism (hereafter, referred to as MM prism), the following must be performed.
 - Clean and disinfect (or sterilize) the device as specified before examining each patient. Otherwise, infection may occur on patient’s cornea.
 - Before image capture, confirm that the MM prism is sufficiently disinfected (or sterilized).
 - Confirm that no damage, dirt, or fog is on the MM prism. Immediately replace the MM prism when its reflection is deteriorated.
 - Be sure to attach the prism cap to the image capturing unit when it is not used.
- For alignment, lift the patient’s eyelid and sufficiently open it.
- Take proper care that the MM prism does not come into direct contact with the patient’s cornea during alignment. When an alarm sound is heard, pull the device away from the patient.

CAUTION

- If the periphery of the MM prism is soiled due to contact with patient's eyelash or tear scattering, disinfect the MM prism with alcohol before next measurement.
- After image capture, check the image quality and retake if any obscure area (caused by air bubbles, eyelashes, or such) is included.
- Do not allow the MM prism to come into contact with a patient when their eye is aligned or switched to the other.
- Do not allow the patient to stand up while holding the chinrest after image capture.
Device may fall and result in injury.
- If the events such as exposed wires, fluctuating power connection/disconnection, and abnormally heated cables or plugs are observed, the power cord is damaged. Immediately disconnect the power cord and replace it
- If the device is defective, disconnect the power cord from the power outlet and contact NIDEK or your authorized distributor. Never touch the device interior or other components.
- Before connecting USB removable disk to the device, be sure to confirm that the USB removable disk is not infected by computer virus.
NIDEK will not compensate for damages caused by any virus infection and development.
- The equipment to be connected with digital or analog interface must conform to the international standards for safe use (IEC 60601-1: Medical electrical equipment, or such). Make sure that all equipment consisting the system must comply with IEC 60601-1. When connecting any digital equipment with data import or export unit of medical system, the entire system including the connected equipment must comply with IEC 60601-1. Contact NIDEK or your authorized distributor for details.
- If the device is connected to a computer that does not comply with IEC 60601-1 (except one that uses an AC adapter that meets the Class II requirements of IEC 60950-1 or IEC 62368-1), supply power to the device and computer through an isolation transformer.
Electric shock may result. Contact NIDEK or your authorized distributor for installing isolation transformers.
- 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.





Gel usage precautions

CAUTION

- Be sure to use a gel that meets the conditions specified in “♦ *Applying gel to MM prism*” (page 51)”.
- Be sure to use or store the gel in the environmental conditions specified by its manufacturer.
- Before use, be sure to confirm that the gel is within its expiration date and the packaging is not damaged. If the use-by date expires or the packaging is damaged, discard the gel without using it.
- Before image capture, confirm that the proper amount of gel is applied on the MM prism.
- Never reuse the gel.
- Do not use the gel when patient is sensitive to any of the gel ingredients.
- Close the packaging after use.
- If the patient wears contact lenses, have the patient take them off before image capture. After image capture, in accordance with the instructions for use of the gel, instruct the patient how long they have to wait before they can safely wear contact lenses again.
- Patient may get blurred vision due to the viscosity of the gel. In this case, it is recommended to wait until the blurring disappears before conducting any activity that requires clear vision, such as operating device or driving a vehicle.
- Once the packaging is opened, use up the gel within the period of time specified by the manufacturer of the gel. Discard the remaining gel after this period. Even if the packaging is opened unintentionally, discard the remaining gel after the specified period.

After use

CAUTION

- Immediately clean and disinfect (or sterilize) the MM prism after image capture.
- When the device is not in use, turn off the power switch, detach the MM prism, attach the prism cap, and put the dust cover on the device.
- Be sure to periodically back up the captured data on removal storage as necessary.
- It is customer’s responsibility to manage the data.
NIDEK assumes no responsibility for accidents or malfunction caused by data loss.
- Always hold the power plug when disconnecting it from the power outlet. Never pull the cord.
- If the device will not be used for an extended period of time, disconnect the power cord from the power outlet.
- During transport or storage in a packed state, maintain an environment that meets the specified conditions:
Storage conditions:  “5.1 Specifications” (page 155)
- When transporting, perform the following.
 - Set the device to Packing mode.  “4.3.9 Preparation for device packing (Packing mode)” (page 132)
 - Do not lock the main unit with locking lever.
 - Lock the image capturing unit with locking lever.
 - Pack the device with specified packaging material.
 - Do not apply excessive vibration or shock to the device during transport.

Maintenance

CAUTION

- To ensure the continued safe use of the device, it is recommended that the manager of this device makes sure that maintenance and preventive inspection are performed at least once a year.
For details of maintenance and preventive inspection, ask NIDEK or your authorized distributor. If the manager of this device cannot perform the maintenance and preventive inspection, contact NIDEK or your authorized distributor.
 - Only service personnel trained by NIDEK are allowed to repair and service the device.
NIDEK assumes no responsibility for any adverse events resulting from improper servicing.
 - When performing maintenance work, secure a sufficient maintenance space.
 - Before performing maintenance, clean the surface of the device properly with a clean cloth dampened with rubbing alcohol.
 - When sending the device back to NIDEK for repair or maintenance, clean the surfaces of the device (especially, the areas that come into contact with the patient) with a clean cloth dampened with rubbing alcohol. Be sure to back up the data beforehand.
 - It is recommended to replace the device before its service life expires.
Even with proper maintenance and check, the device reliability or safety may begin to fail to achieve the desired values by the use of device beyond its service life.
-
-

Disposal

CAUTION

- To prevent the leakage of data such as personal information (patient information) to any unauthorized third party, it is the customer's responsibility to make sure that data on the built-in memory (internal SSD) cannot be restored.
Take measures such as outsourcing to NIDEK or a disposal contractor, or physically destroying the internal SSD (storage) to make it unreadable. Select the disposal method that suits the purpose.
 - Follow local governing ordinances and recycling plans regarding disposal or recycling of device components. Especially when disposing the lithium ion battery, circuit board, plastic parts that contain brominated flame retardant, LCD touch screen, or power cord, the local governing ordinances must be obeyed.
For details, contact your local government.
 - When disposing of the MM prism, gel package, and gauze or cotton stained with gel, follow the disposal procedure by each medical facility and make sure that no infection or environmental contamination occurs.
 - When disposing of packing materials, sort them out by material and follow local ordinances and recycling regulations.
-
-

















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 connecting a network with a device other than the GS-1, be sure to consult with a network administrator and confirm that the network to be connected functions normally. Connection with a network in abnormal state may result in computer virus infection or data falsification caused by external factors.
- 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.
To prevent the electric shock and device malfunction or failure, perform the network connection properly.
Contact NIDEK or your authorized distributor for installing network isolation transformers.
- For the network configuration, never connect the device with wide area network, such as the Internet Explorer.
Configure a local network only with the specified equipment. 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.
The device is a medical device. If the user changes the device settings by installing other software such as anti virus software, NIDEK will not guarantee proper operation of the device.
- 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.

1.2 Symbols

The following symbols are provided on the device

	Type B Applied Part The applied parts are the chinrest, forehead rest, and MM prism. ↗ (page 19)
	Indicates that the operator is advised to refer to the related instructions in the operator's manual.
	Alternating current: Indicates that the device must be supplied only with alternating current.
	Date of manufacture
	Manufacturer
	Medical device
	EU Authorized Representative
	Indicates that this product shall be disposed of in a separate collection of electrical and electronic equipment in EU.
	Indicates that the image capturing unit slider is unlocked.
	Indicates that the image capturing unit slider is locked.
	OFF: Indicates the state of the power switch. When the switch is turned to the side of this symbol, power is not supplied to the device.
	ON: Indicates the state of the power switch. When the switch is turned to the side of this symbol, power is supplied to the device.
	Fixation target lamp connector
	Serial number
	Catalog number
	Unique Device Identifier

2

INTRODUCTION

2.1 Outline

The Gonioscope GS-1 captures anterior chamber angle images using the optical gonioprism and a built-in image sensor without the use of mydriatic agents. With the built-in rotation mechanism a colored circumference image of anterior chamber angle and its peripheral area is captured to examine the state of the patient's eye. The captured image is stored in the device, printed in a report using a printer, or output to an external equipment.

The GS-1 offers three capture modes.

Full capture	Continuously captures images at all the 16 positions created by dividing the entire circumference of the anterior chamber angle. At each position, the device continuously captures 17 images while automatically shifting the focus. After the image capture, the best image is automatically selected. Using the captured images, a stitching image can be generated.
Multi capture	Continuously captures images at preselected capture positions. At each position, the device continuously captures 17 images while automatically shifting the focus. After the image capture, the best image is automatically selected.
Single capture	Captures images at the desired capture positions. The capture positions are selected one by one, and the focus is adjusted manually. At each position, only a single image is captured and saved.

◆ Intended use

The Gonioscope GS-1 is an ophthalmic camera with gonioscopic prism that is intended to capture, display and store images of the anterior chamber angle and its peripheral part.

◆ Intended patient population

- Age
All patients over 6 years old
- Health condition
Able to undergo an examination in a sitting position
Able to answer the operator's questions
Capable of eye fixation
- Conditions - Visual function
One or both eyes are normal or have disease.
Eyes that have lost the visual function are not targeted.

◆ Intended user profile

Ophthalmologists or medical personnel assigned

◆ Intended use environment

Medical facility



CAUTION

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

◆ Principles

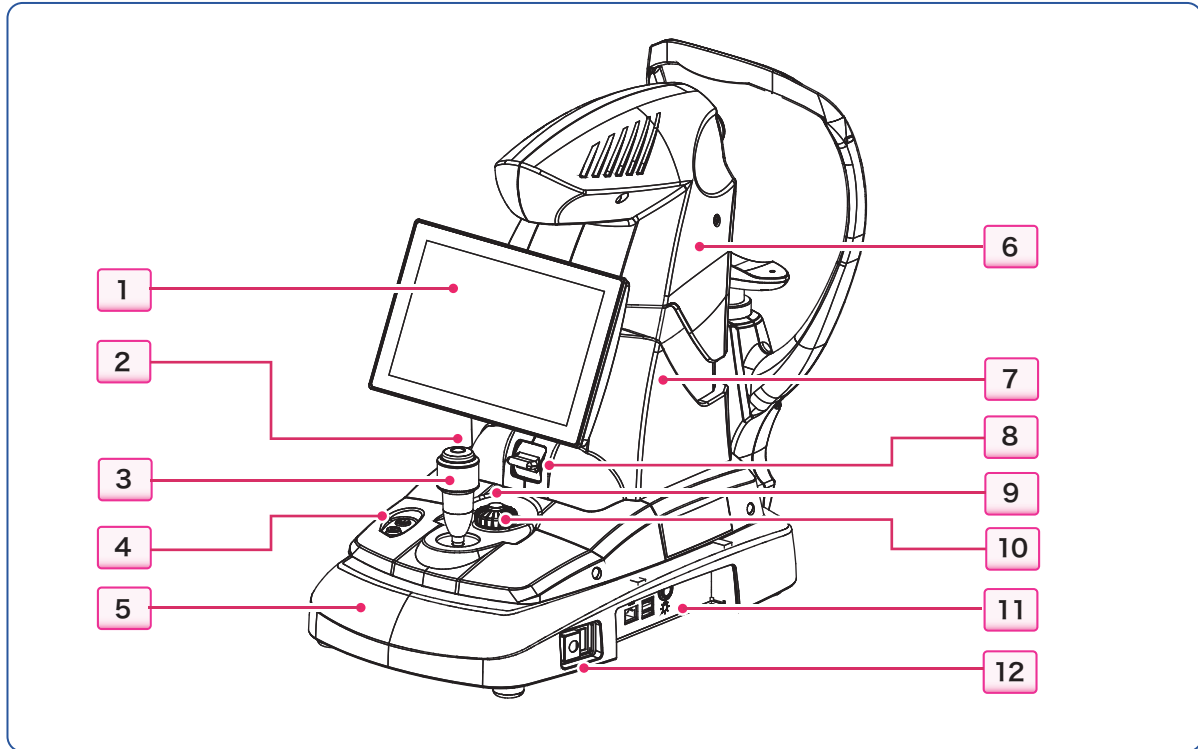
With the multi mirror prism set close to the patient's cornea, illumination light is projected on their anterior chamber angle and its peripheral area. The light is then reflected and received by the image sensor to capture a color image. The rotation mechanism rotates the illumination light optical system and the image capturing optical system with 16 mirrors of the multi mirror prism, capturing an image from each mirror. With this function, the operator can capture a circumference image of anterior chamber angle, which is divided in 16 portions.

● Indications used in this manual

[○○○]	Indicates the button function with brackets.
“○○○○○○”	Indicates the messages with double quotation marks.
 “○○○○” (Page ○)	Indicates the reference destination with “  ” icon.

2.2 Configuration

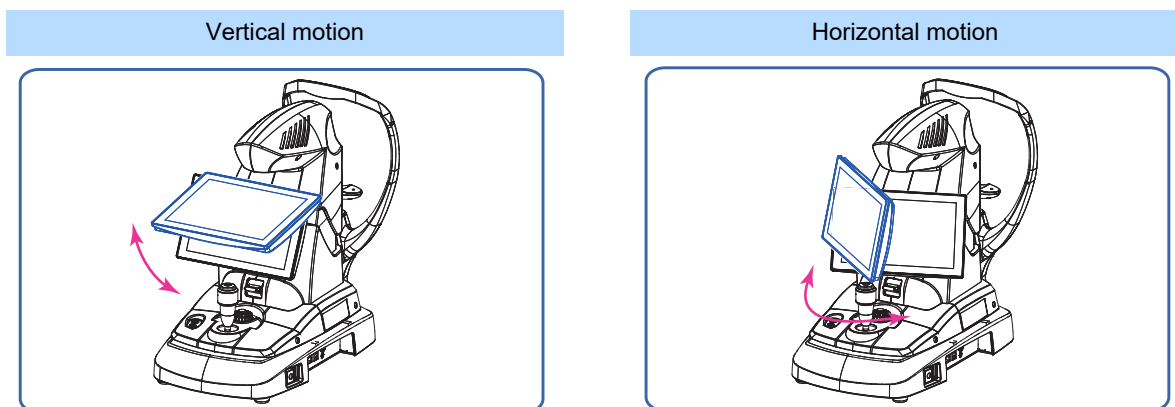
2.2.1 Device configuration



1 LCD touch screen

Color LCD touch screen that displays information such as a captured image, patient information, and device settings when the corresponding icon is pressed.

The screen can be oriented in each direction depending on a image capturing condition.





2 Start button

Pressed to start an image capture. When the auto tracking is activated, pressing this button also starts the auto tracking.

3 Joystick

Used to perform the alignment and achieve the focus on the desired position.

4 Chinrest Up/Down button ( / )

The limit indicator  (or ) appears when the chinrest is moved as far as it goes in upward (or downward) direction.

5 Base

6 Image capturing unit

7 Main unit

8 Locking lever

Used to lock the main unit to the base.

9 Focus knob button

Pressed to switch the screen between auto tracking and image capture in Single capture mode.

10 Focus knob

Turned to tune the focus in Single capture mode.

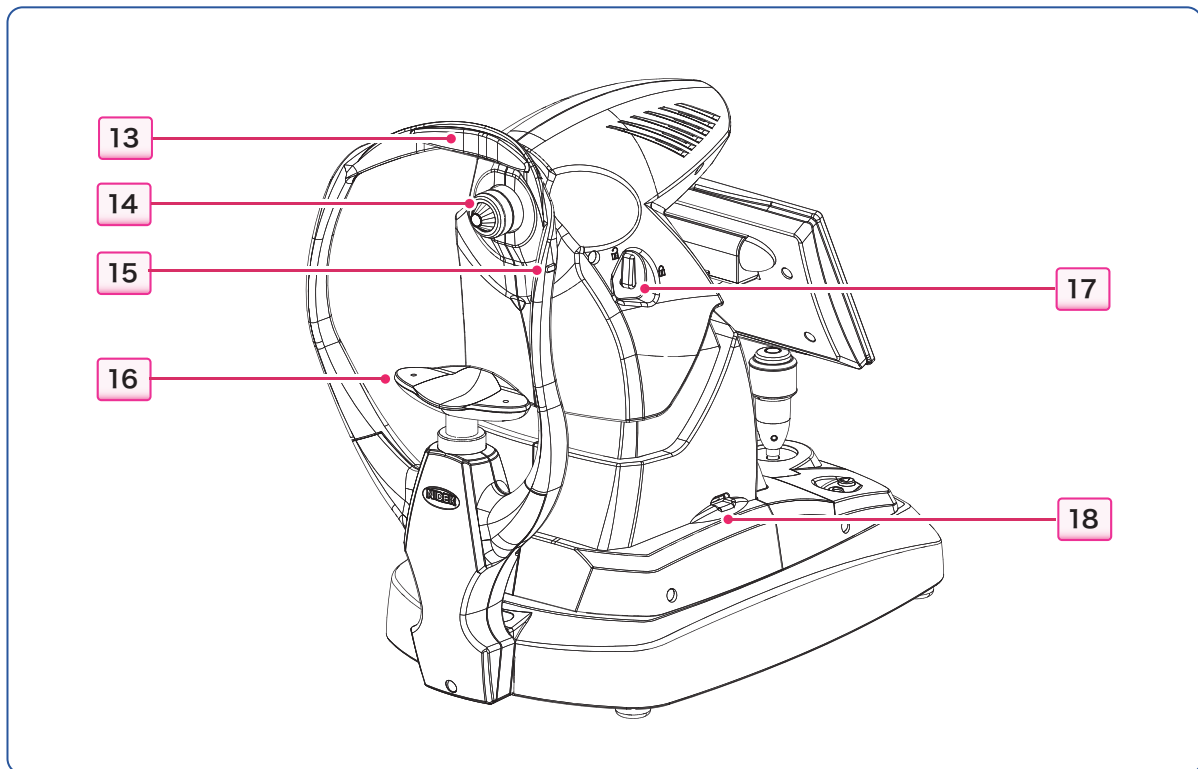
11 Connector panel

Used to connect cables for LAN communication (data output), USB equipment (data export and printing), and external fixation lamp (optional).

12 Power switch

Used to turn on the device.

◆ Patient's side



13 Forehead rest

14 MM prism (multi mirror prism)

Detachable resin prism. This prism is to be used with a gel that meets the conditions specified in “◆ Applying gel to MM prism” (page 51). The prism is aligned to the patient's eye for image capture. Before use, be sure to detach and disinfect (or sterilize) it.

15 Eye level marker

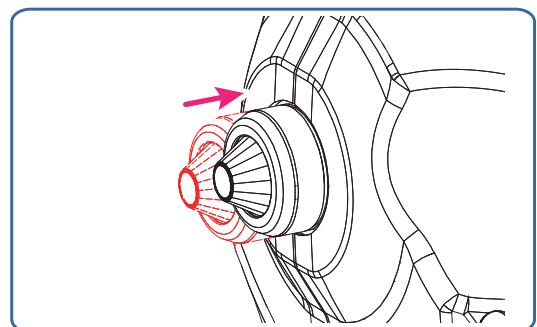
Indicates the reference height of the patient's eyes. Adjust the chinrest height so that the patient's eyes are approximately aligned to this marker.

16 Chinrest

17 Image capturing unit locking lever

Used to lock (🔒) or unlock (🔓) the image capturing unit slider.

Turning this lever to the Lock position (🔒) moves back the MM prism to the stand-by position (as shown in the figure to the right) on the image capturing unit.

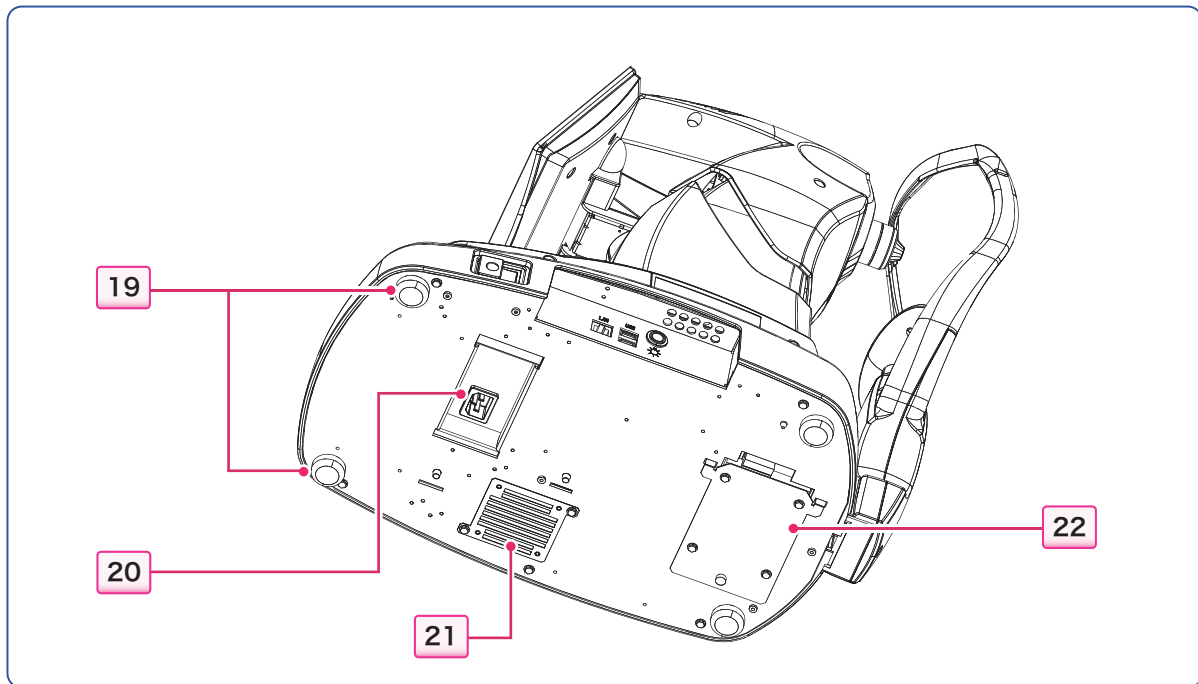


18 Level

Indicates the device tilt in the forward and backward directions.

Turn the adjustable feet so that the device is installed levelly. Using the device at an angle will result in malfunction of the slider unit.

◆ Bottom



19 Adjustable feet

The two feet are located in the front and the other two in the rear. Turn them to adjust the height of the device in order to make it level.

20 Power inlet

21 Cooling fan

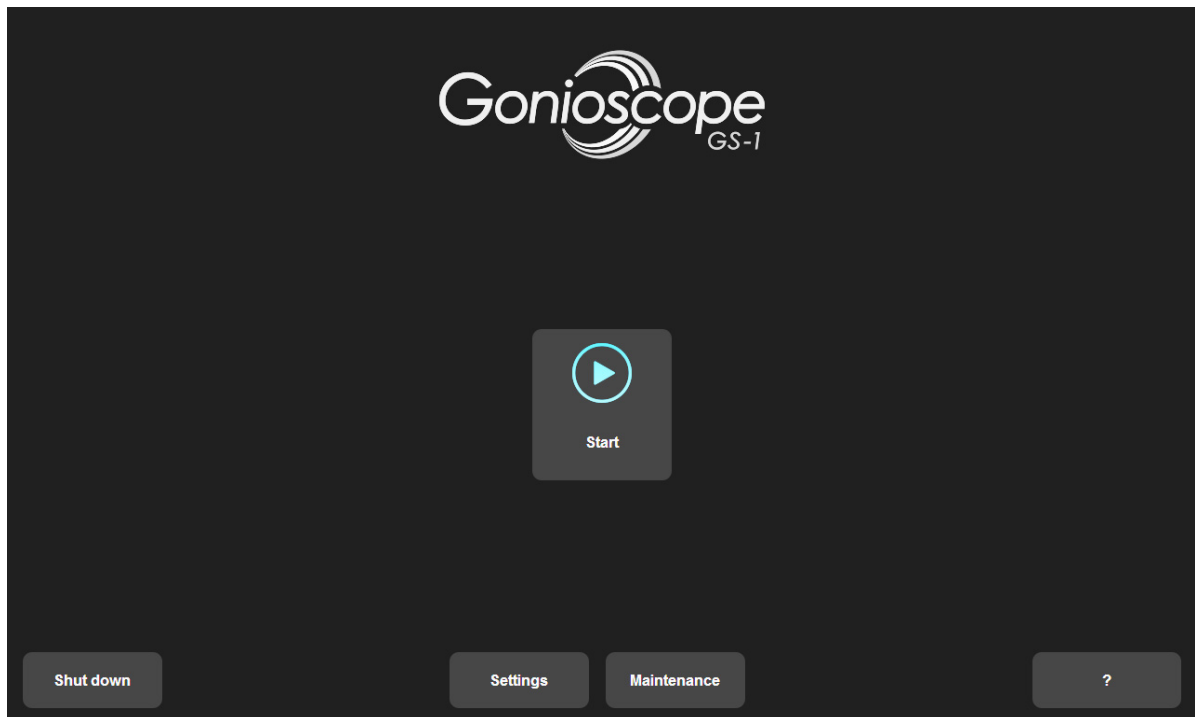
22 Servicing cover

This cover is only for the device servicing and maintenance. Do not open it.

2.3 Screen Configuration

2.3.1 Home screen

The home screen is displayed after the device start-up. On the home screen, the operator can perform image capture, parameter setting, maintenance, information display, and device shutdown.



1 [Start]

Pressed to display the Patient list screen.

2 [Settings]

Pressed to display the User settings screen.

3 [Maintenance]

Pressed to display the Maintenance screen.

4 [Shut down]

Pressed to turn off the device. After the GS-1 is shut down, the device power switch is automatically turned off.

5 [?]

Pressed to display the software version and library license information in use.

This manual is in accordance with software Ver. 1.1. Refer to the manual corresponding to the software version in use.

2.3.2 Other screens

The screens below are displayed at the time of image capture, checking exam results, or other operations in the GS-1.

The displayed screen differs depending on the capture mode (Full/Single/Multi).

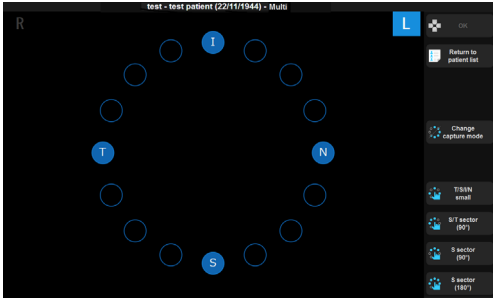
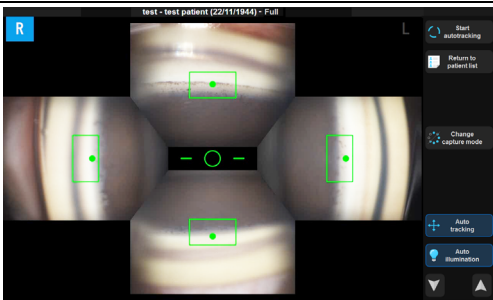
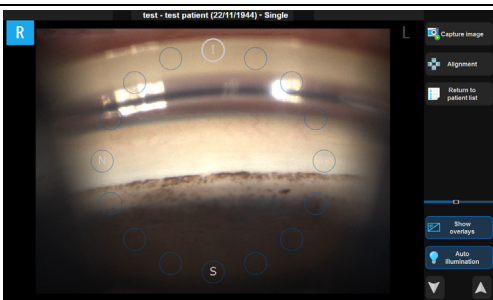
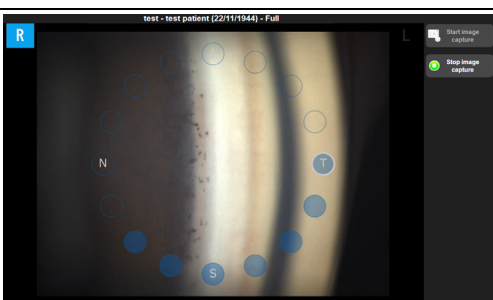
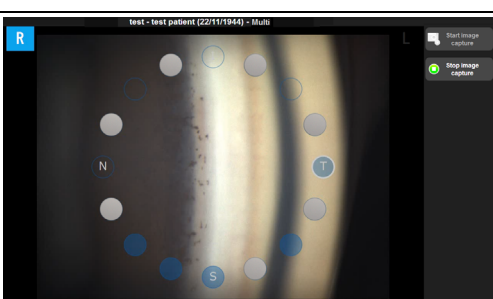
<p>Capture position select screen (Multi capture) Capture positions can be selected. When the selection is complete, the screen is switched to the alignment screen.</p>	
<p>Alignment screen Displayed to align the image capturing unit to the position at a correct working distance. When the image capture starts, the screen is switched to the image capture screen.</p>	
<p>Image capture screen (Single capture) Screen for capturing a single image. Achieve the focus precisely and capture an image.</p>	
<p>Image capture screen (Full capture) Indicates the progress of image capture. When the image capture is complete, the screen is switched to the image confirmation screen.</p>	
<p>Image capture screen (Multi capture) Indicates the progress of automatic image capture at the selected position. When the image capture is complete, the screen is switched to the image confirmation screen.</p>	

Image confirmation screen (Single capture)
 Displayed for checking the captured image before saving it. The image can be retaken if necessary.



Image confirmation screen (Full capture or Multi capture)
 Displayed for checking the captured image before saving it. The image can be retaken if necessary.

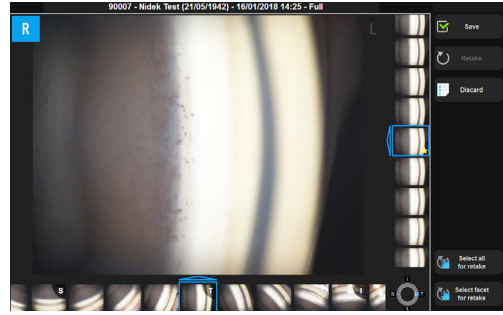
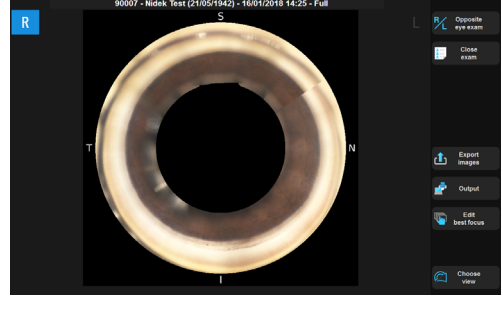


Image display screen (stitching image)
 Shows a stitching image when the entire circumference has been captured in Full or Single capture mode.
 The stitching image can be displayed either as Linear stitching or Circular stitching.



Patient list screen
 Displayed to select a patient, start an image capture, and check the captured images.
 The Register patient screen and Edit patient information screen can be opened from this screen.

Patient list

Search for patient

Patient ID	Name	Sex	Date of birth	Last exam	Comment	History
000000001	nidek nidek	Not specified	28/08/2019	18:28		
000002	k p	Not specified	03/10/2019	11:05		
01490	a s	Not specified	03/10/2019	11:02		
01610	l k	Male	16/04/2018	13:32		
01629	k h	Not specified	21/06/2018	17:59		
10777	o t	Not specified	15/08/2018	13:48		
11348	a o	Male	18/04/2018	13:21		
11354	k n	Male	16/04/2018	13:08		
12150	n i	Not specified	24/07/2018	17:54		
12454	k h	Male	21/12/1989	21/09/2018	12:34	

Buttons on the right: Start exam, Exam list, Home, New patient, Edit patient, Delete patient.

Exam list screen
 Displays the exam list of the selected patient.
 This screen can be displayed from the Patient list screen.

Exam list of patient 000000001 - nidek nidek

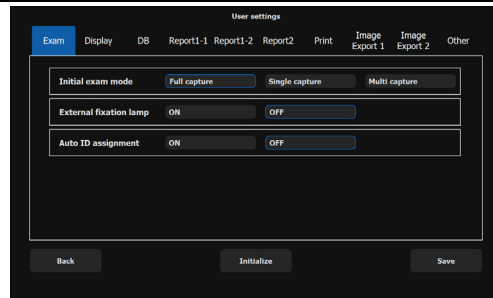
Exam date	Eye	Capture mode	Comment
27/11/2019 19:07	L	Single	
03/10/2019 11:02	L	Full	
03/10/2019 11:01	R	Full	
27/08/2018 17:03	L	Full	
27/08/2018 16:58	R	Full	

Buttons on the right: Display exam result, Return to patient list, Select opposite eyes, Delete exam.

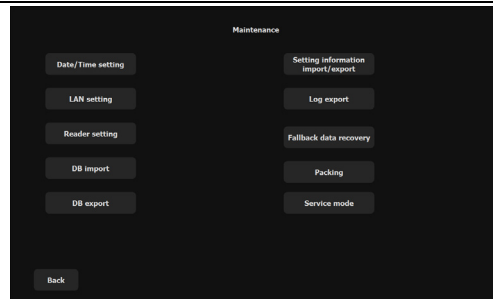
Image display screen
 Displayed to show the captured images of the selected patient.
 The image display format is selectable.



User settings screen
 Displayed to set device parameters




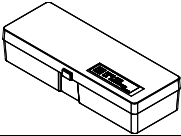

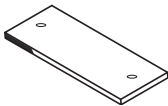
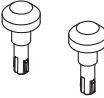

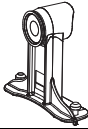
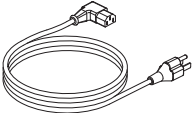
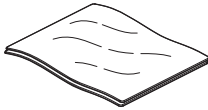

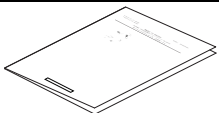


Maintenance screen
 Displayed to select an operation such as data/time setting, LAN setting, data import/export, and entering the packing mode.



2.4 Packed Contents

The standard accessories are as follows. Check all contents prior to use.

	Name (Part number)	Unit	Appearance
<input type="checkbox"/>	Main body	1 unit	
<input type="checkbox"/>	Prism cap (GN001-M371) Attached to the main body	1 unit	
<input type="checkbox"/>	MM prism (GN001-7212) Contained in the prism case	3 units	
<input type="checkbox"/>	Prism case (GN001-7211)	1 unit	
<input type="checkbox"/>	Prism clamp (GN001-M351)	1 unit	
<input type="checkbox"/>	Chinrest paper (32903-M047)	1 unit	
<input type="checkbox"/>	Chinrest paper pin (34131-M112)	2 units	
<input type="checkbox"/>	Forehead arm (15401-M770)	1 unit	
<input type="checkbox"/>	Model eye (GN001-7310)	1 unit	
<input type="checkbox"/>	Power cord (8051100017)	1 unit	
<input type="checkbox"/>	Dust cover (32903-M531)	1 unit	
<input type="checkbox"/>	Operator's Manual (GN001-P902)	1 volume	
<input type="checkbox"/>	Quick Reference Guide (GN001-P972)	1 volume	

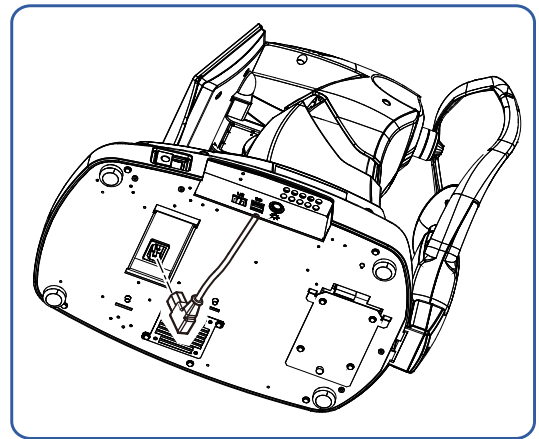
2.5 For First Use (installing the device)

Install the device on a stable table and insert the power cord. Turn on the power switch and confirm that the device starts properly.

WARNING

- Be sure to connect the power cord to a grounded outlet.
Electric shock or fire may result in the event of malfunction or power leakage.

- 1** Install the device on a stable table.
- 2** Lay the device on its side.
- 3** Connect the power cord to the power inlet.

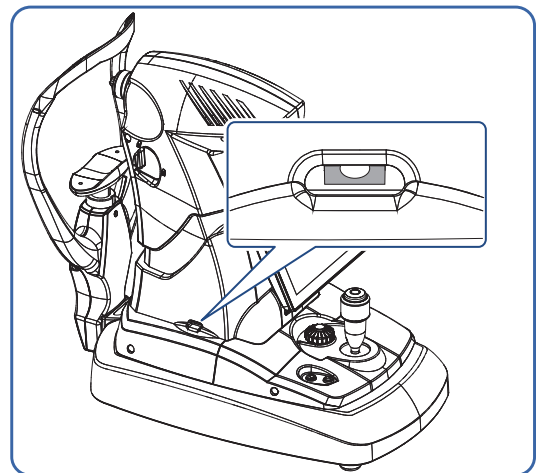


- 4** Stand the device upright.
- 5** Connect any peripheral equipment if necessary.

For the connection of peripheral equipment, see “3.12 Operations when Peripheral Equipment is Connected” (page 104).


- 6** Turn the adjustable feet (four feet) so that the level indicates the horizontality as shown in the figure to the right.

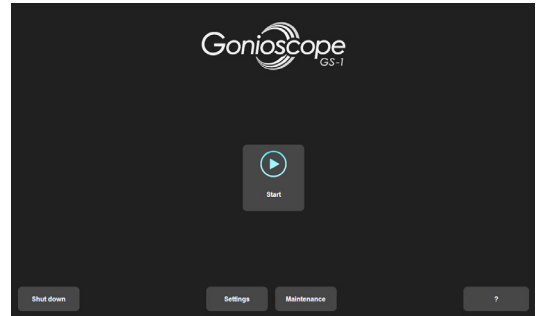
Make sure that the device is installed levelly.



- 7** Confirm that the power switch is turned off (○). Then, connect the power cord to a power outlet.

8 Turn on (I) the power switch.

A white circle () appears and continuously rotates on the screen during the start-up process. When the device starts properly, the device name “GonioscopeGS-1” appears and the home screen is displayed.



CAUTION

- Do not operate the LCD touch screen or the start button on the joystick during the device start-up.

9 Attach the MM prism.

The MM prism is contained in the prism case.


To preserve hygiene, do not attach the disinfected (or sterilized) MM prism until just before the image capture.

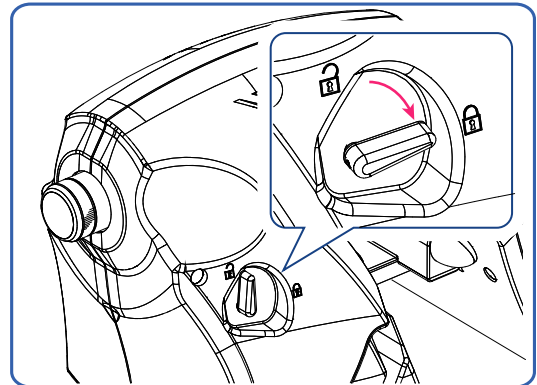
When practicing the operation with the model eye, it is not necessary to use a sterilized or disinfected MM prism. [↪ “3.11 Practicing Image Capture with Model Eye” \(page 103\)](#)

CAUTION

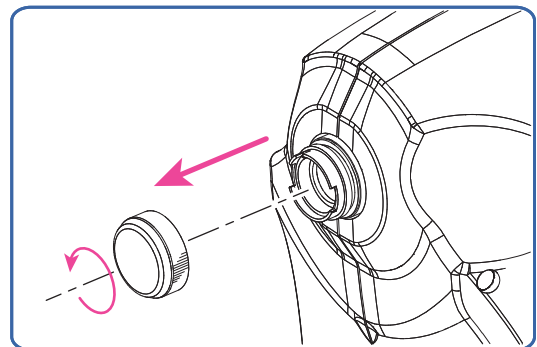
- The GS-1 main body and MM prism are shipped without being cleaned, sterilized, or disinfected. Prior to the first use, be sure to clean and disinfect (or sterilize) them.

- 1) Confirm that the image capturing unit is securely locked.

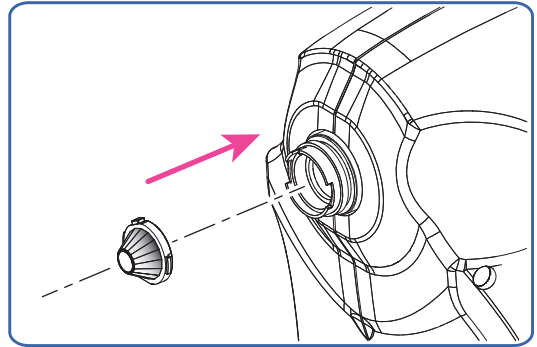
If it is unlocked, move the locking lever to the Lock position  .



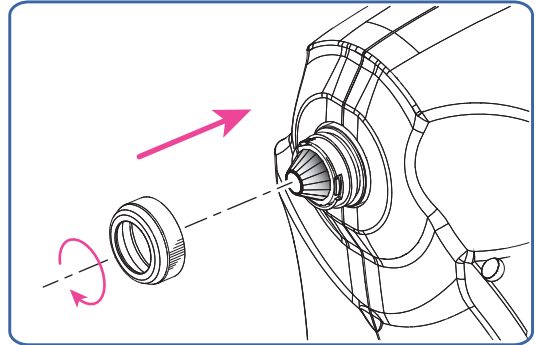
- 2) Turn the prism cap counterclockwise to detach it.



- 3) Attach the MM prism with the flanges aligned with the holder.
Do not touch the MM prism tip or mirrors.



- 4) Turn the prism clamp clockwise to attach it.
The prism clamp is contained in the accessory case.



Note

- Set the device parameters accordingly for the intended use of the device.
For the details of the parameters and setting procedure, see “4.4 Changing Device Parameters” (page 133).
-

3

OPERATING PROCEDURE

3.1 Device Start-up and Shutdown

3.1.1 Starting GS-1

Turn on the GS-1 and perform a pre-use check.

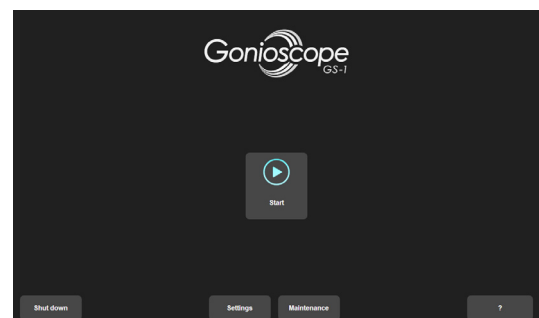
WARNING

- Connect the power cord to a grounded outlet.
Electric shock may result in the event of device malfunction or power leakage.

- 1** Confirm that the power switch is turned off (○). Then, connect the power cord to a power outlet.
- 2** Turn on the connecting equipment.
- 3** Turn on (|) the device.

Wait until the next screen appears.

A white circle appears and continuously rotates on the screen during the start-up process. When the device starts properly, the device name [GonioscopeGS-1] appears and the home screen is displayed.



CAUTION

- Do not operate the LCD touch screen or the start button on the joystick during the device start-up.

4 Perform a pre-use check of the device.

Check the following prior to use.

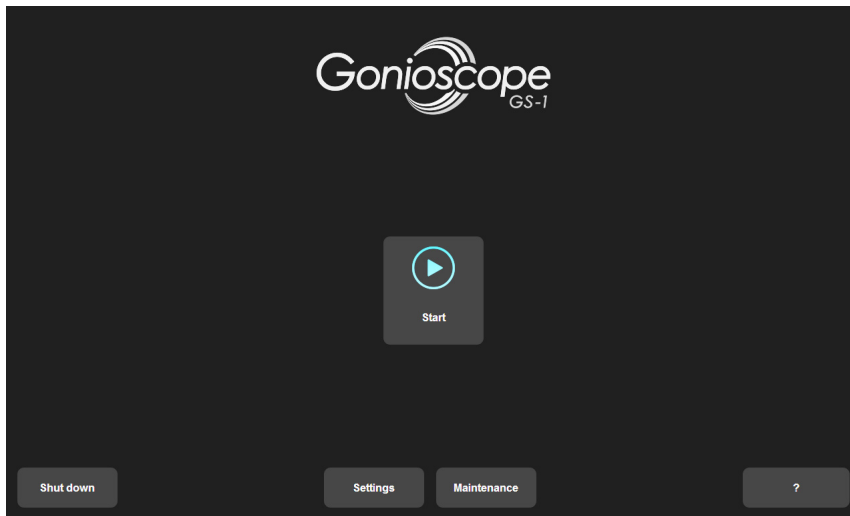
- No error message appears.
- The main unit can be moved smoothly by moving the joystick.
- The chinrest can be raised and lowered by the chinrest Up/Down button.
- The device is installed levelly (check the level).
- The image capturing unit can be operated smoothly.
- The cables are securely connected.
- The power cord is securely inserted into the power outlet.
- A sufficient number of disinfected (or sterilized) MM prisms is prepared.
- A sufficient amount of gel is prepared.

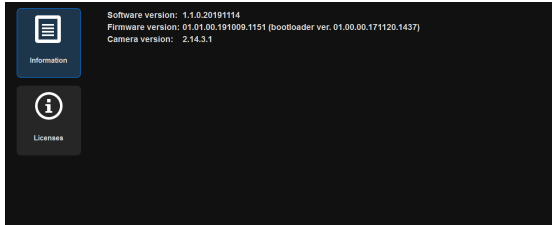
For any abnormalities, immediately stop the use and take measures as described in "4.1 Troubleshooting (Page 59).

5 Select the desired operations on the home screen.

◆ Operations on home screen

On the home screen, the operator can perform image capture, parameter setting, maintenance, information display, and device shutdown.



[Start]	Pressed to display the Patient list screen
[Settings]	Pressed to display the User settings screen The confirmation message appears. Pressing [Yes] displays the User settings screen.
[Maintenance]	Pressed to display the Maintenance screen The confirmation message appears. Pressing [Yes] displays the Maintenance screen.
[Shut down]	Pressed to turn off the device The confirmation message appears. Pressing [Yes] shuts down the GS-1 and the power switch is automatically turned off.
[?]	Pressed to display the software version and license information Pressing [Information] or [Licenses] switches the display. 

3.1.2 GS-1 shutdown (normal shutdown procedure)

The following is the normal shutdown procedure. When shutting down the device in Packing mode, see “4.3.9 Preparation for device packing (Packing mode)” (page 132).

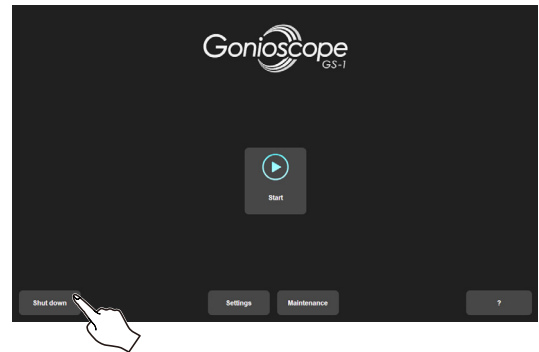
CAUTION

- Never turn off (○) the power switch directly. Be sure to follow the procedure below.
If the operation on the touch screen does not work and the device cannot be shut down, turn off the power switch once. Then, immediately turn it on again and confirm that the device operates properly.

1 Return to the home screen.

2 Press [Shut down].

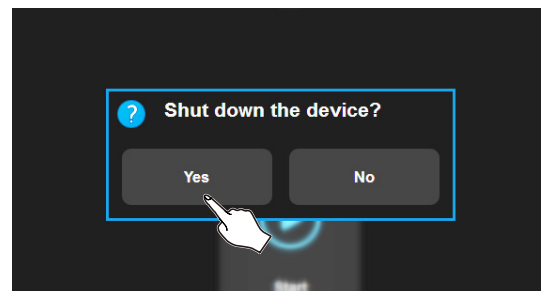
The confirmation message appears.



3 Press [Yes].

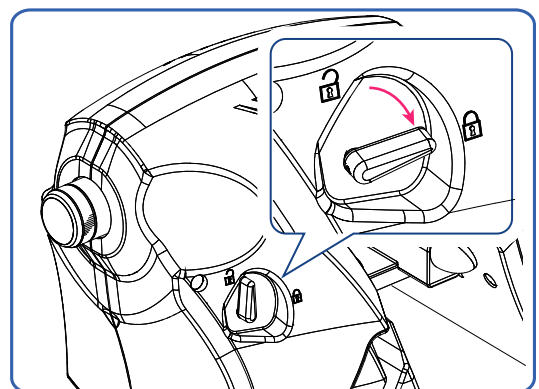
The GS-1 is shut down and the power switch is automatically turned off.

Pressing [No] returns to the home screen.



4 When any external printer is connected, turn it off.

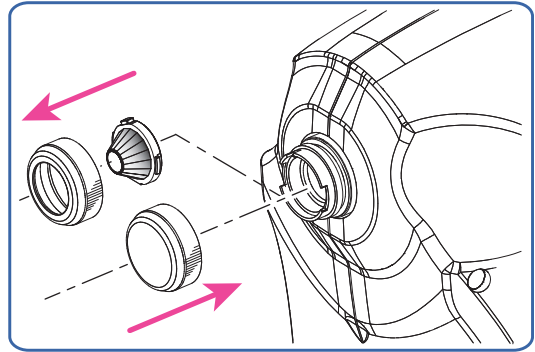
5 Move the locking lever to the Lock position to lock the image capturing unit.



6 Detach the MM prism and disinfect (or sterilize) it.

Detach the prism clamp and MM prism. Then, attach the prism cap to the image capturing unit.

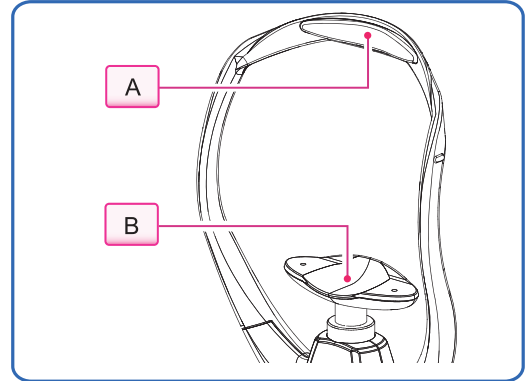
➤ “4.7 Disinfecting/Sterilizing MM prism” (page 144)



7 Clean the forehead rest **A** and chinrest **B**. Then, put the dust cover on the device.

Wipe the forehead rest and chinrest with a clean gauze or absorbent cotton. If necessary, wipe with a clean cloth dampened with rubbing alcohol.

Keep them in a clean state for next use.



Note

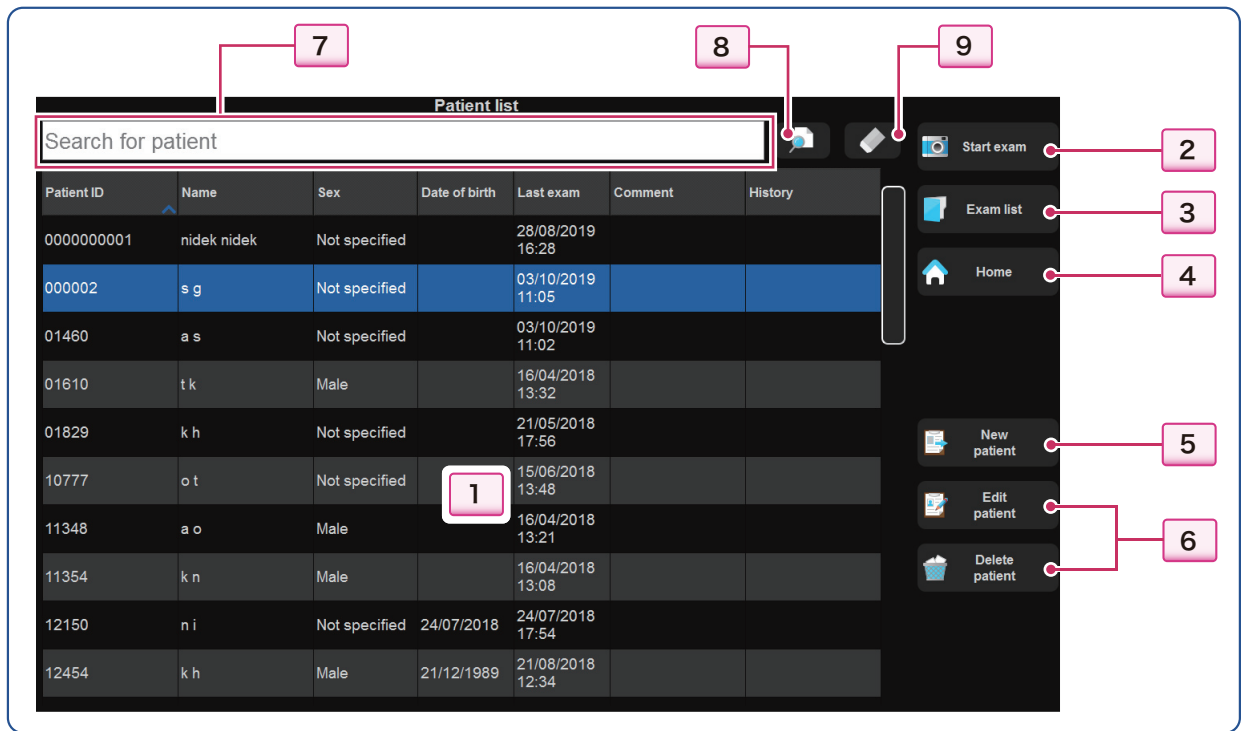
- Be sure to put the dust cover on the device when it is not used.
- If the device will not be used for an extended period of time, be sure to disconnect the power cord from the power outlet.






Accumulation of dust or moisture may result in a short-circuit or fire.





3.2 Entering Patient Information

3.2.1 Operations on Patient list screen

On the Patient list screen, the operator can select a patient, start an image capture, and display the Exam list screen. Registering, editing, and deleting patient information also can be performed on this screen.



1	Patient list	<p>Displays the list of patients.</p> <p>Pressing any of the Patient ID, Name, Sex, Date of birth, Last exam, Comment, or History rearranges the exam list in an ascending / descending order.</p> <p>If a single screen cannot display all the patients, a scroll bar appears on the right side. The list can also be scrolled by swiping.</p>
2	 [Start exam]	Pressed to start the examination of the selected patient.
3	 [Exam list]	Pressed to display the exam data of the selected patient on the Exam list screen.
4	 [Home]	Pressed to return to the home screen.
5	 [New patient]	<p>Pressed to display the Register patient screen for registering a new patient.</p> <p>For details, see “3.2.2 Registering new patient” (page 38).</p>
When the database save destination is an internal SSD or a USB removable disk		
	 [Edit patient]	Pressed to display the details of the selected patient on the Edit patient information screen. Patient information can be edited on the Edit patient information screen.

6	 [Delete patient]	<p>Pressed to delete the information and exam data of the patient selected in the patient list.</p> <p>Deleting the patient on this screen also deletes all their exam data. When deleting the exam data individually, select and delete the data on the Exam list screen.</p>
When the database save destination is NAVIS-EX		
	 [Patient Details]	<p>Pressed to display the details of the selected patient on the patient information screen.</p>
7	Search for patient field	<p>Enter a search condition.</p> <p>Searching is possible with truncated Patient ID, Name, or History.</p>
8	 (Search)	<p>Pressed to detect the patient based on the conditions entered in the Search for patient field.</p>
9	 (Clear)	<p>Pressed to clear the Search for patient field.</p> <p>The patient search is canceled.</p>


Note

- When the database save destination is NAVIS-EX, note the following.
 - When starting image capture, make sure that the data of the selected patient is not used on another device connected to the GS-1. The image capture cannot be performed.
 - Patient information cannot be edited or deleted on this device.
 - Do not edit or delete patient data on NAVIS-EX while the Patient list screen is displayed on this device.
- If patient data is added, deleted, or edited on NAVIS-EX, return to the home screen to redisplay the Patient list screen. Patient information will be updated.

3.2.2 Registering new patient

The operator can register a new patient by performing the following procedure.

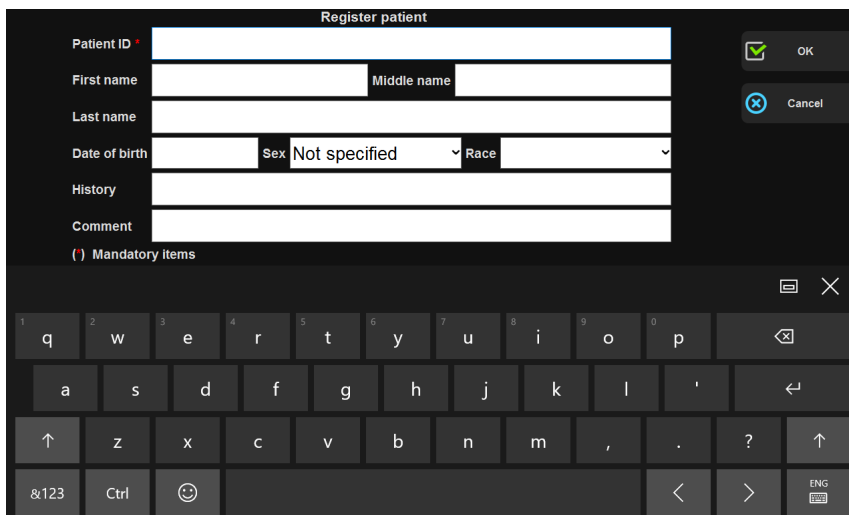
When examining a new patient, the operator must register the patient information beforehand.

1 Press  [New patient] on the Patient list screen to display the Register patient screen.

2 Enter the necessary information.

Enter Patient ID, Last name, Middle name, First name, Date of birth, Sex, Race, History, and Comment. Patient ID is a mandatory item.

Enter the characters with a touch keyboard (for entering the Date of birth, a calendar appears). Select Sex and Race from the pull-down list. Select History from the entry window.



1) Enter Patient ID. (A maximum of 70 characters can be entered)

Enter the patient ID with a numeric keypad (the numeric keypad appears by pressing the Patient ID field).

When the barcode scanner (or magnetic card reader) is connected, read the barcode (or magnetic card) data on the Register patient screen.

If necessary, enter other items (not mandatory).

2) Select Sex and History from the pull-down list.

History:  “◆ Entering History” (page 42)



3) Enter Date of birth.

 “◆ Entering Date of birth” (page 41)

4) Enter Last name, Middle name, First name, and Comment.

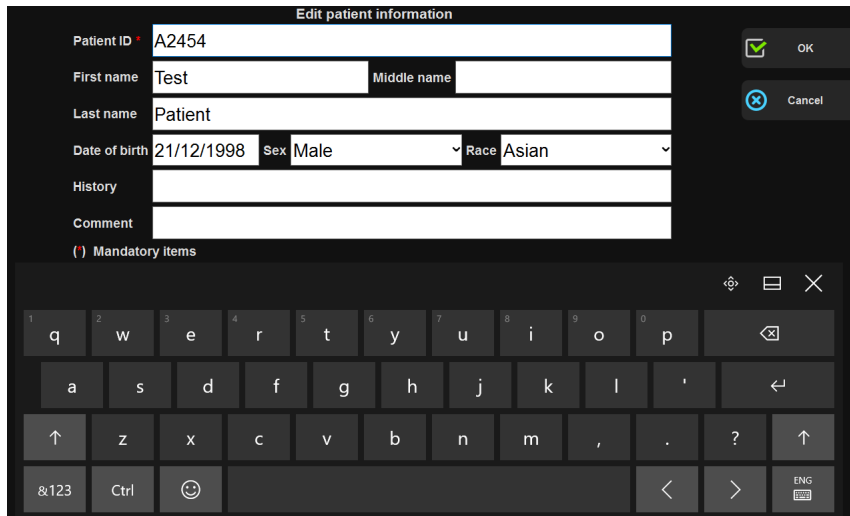
3 Press  [OK] to register the patient information.

The Patient list screen is displayed and the new patient is added to the patient list.

 [OK]	Pressed to save the information and to return to the Patient list screen
 [Cancel]	Pressed to cancel the entry and to return to the Patient list screen

◆ Entering information with touch keyboard

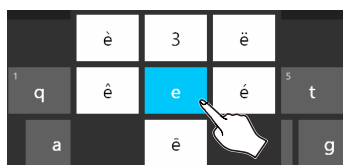
Touching each field displays a touch keyboard. The operation is the same as tablets or tablet mode in which the OS is Windows10.



	Switches between a floating keypad and fixed keypad.
	Turns off a keypad display.
[<], [>]	Pressed to move the cursor.
[<X>]	Pressed to delete a letter on the left of the cursor (Back Space).
[↵]	Confirms the entered information and moves a cursor to the next field.
[↑]	Functions as a shift key and pressed to switch the numeric keypad to upper/lower case letter. Tapping it twice locks the shift key.
[&123]	Pressed to switch the numeric keypad to alphabetic and numeric/symbols.
[Ctrl]	Functions as a short-cut key and displays commands such as Undo or Cut.
[Tab]	Moves a cursor to next field.
[⏪], [⏩]	Switches the symbol page.
[]	Inserts a space.
[😊]	No pictograph can be input in the GS-1.
[ENG], [日本] ,	Switches an entry method and numeric keypad. Entry method switching: English or Japanese IME Keypad switching: Touch keyboard, separated keyboard, direct entry, Japanese numeric keypad

● Flick entry




Holding to press the key registered with several entries displays their contents.





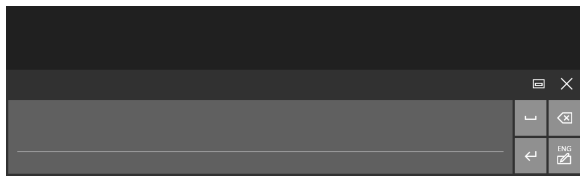
● Switching an entry method and numeric keypad

Press [**ENG**] or [**日本**] to display menus, then select the method.

The current setting is indicated in blue.

	Touch keyboard
	Separated keyboard
	Direct entry



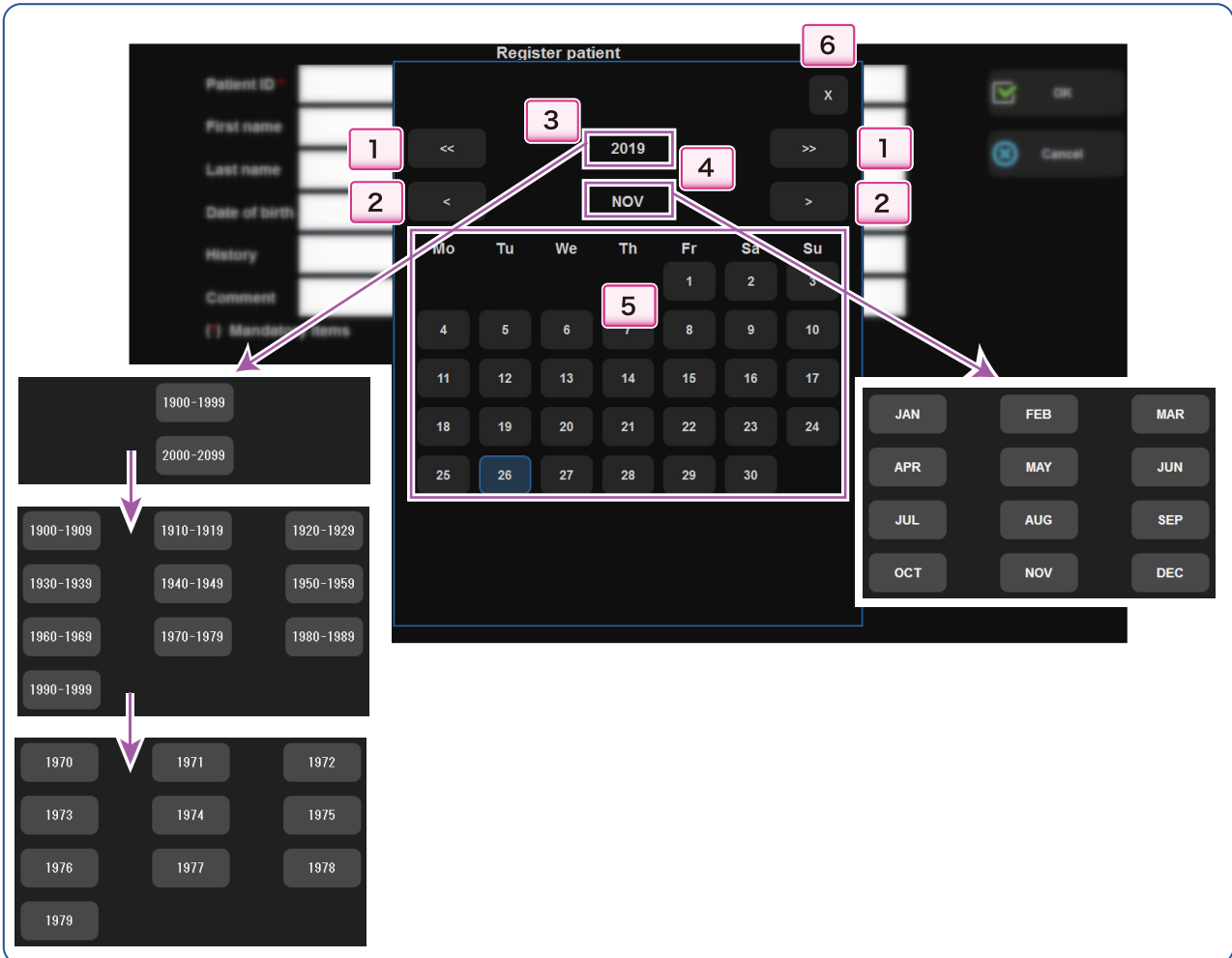
	<p>Touch keyboard Pressing [123] switches [alphabetic] and [numerals/symbols].</p>
	<p>Separated keyboard</p>
	<p>Direct entry Direct entry is automatically detected and the characters are entered. A candidate word appears. Pressing the candidate word enters it in the field. English entry only</p>

 **Note**

- The menu “Language preferences” is unavailable in the GS-1.

◆ Entering Date of birth

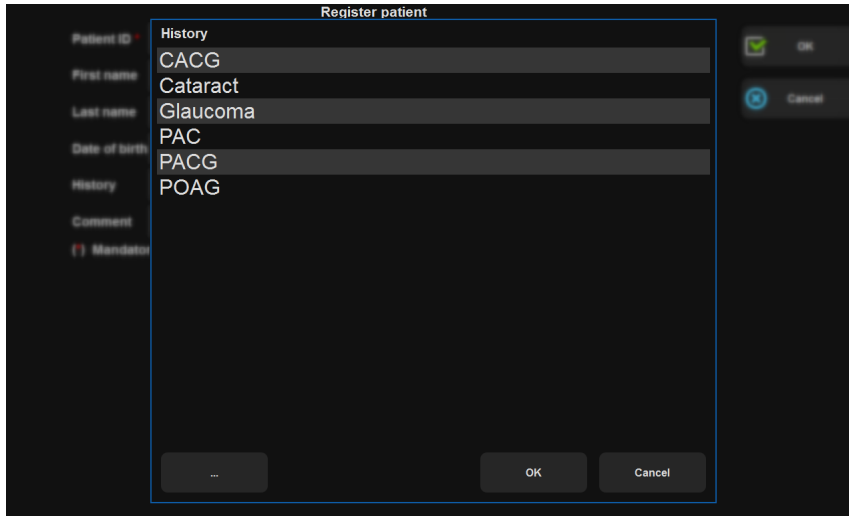
Touching the Date of birth field displays an entry calendar. Set the correct date in the order of year, month, and day by pressing each icon on the calendar. After setting the day, the calendar automatically closes.



1	Pressed to increase/decrease the year.
2	Pressed to increase/decrease the month.
3	Pressed to display the button for entering the year. Every pressing of this button narrows down the selection range of the year. Then, pressing an exact year confirms the year.
4	Pressed to display the button for entering the month.
5	Pressed to set the day. After the day is set, the Date of birth entry is complete. The calendar automatically closes.
6	Pressed to cancel the Date of birth entry and to close the calendar.

◆ Entering History

Select the desired item from the History list.

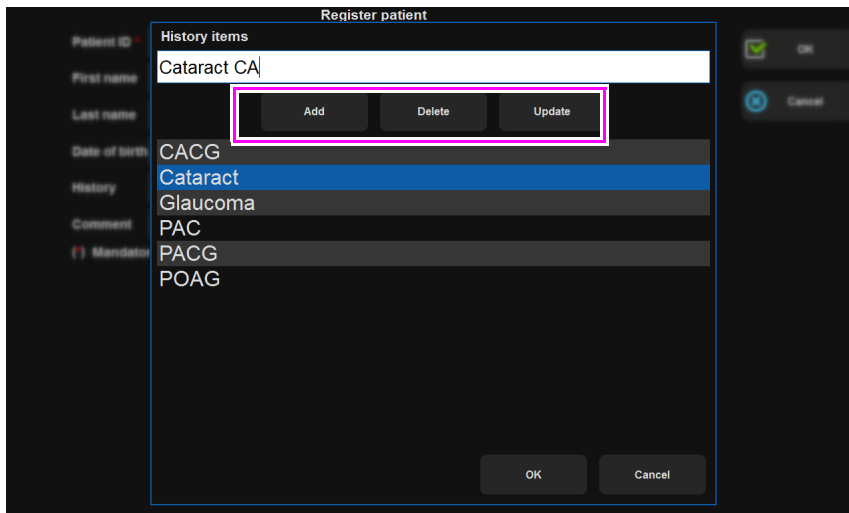


- 1) Press the History field to display the History.
- 2) Select the desired item from the pull-down list and press [OK].
Several items are selectable. Each press of the item selects/deselects it.

● Registering/Editing History

The operator can register, delete, or edit History information in the entry window. The entry window is displayed by pressing [...]. After entering the information, press [OK] to confirm the changes of History.


The touch keyboard hides [OK]. Press  to hide the keyboard, then press [OK].



Adding new History	Enter the information in the field and press [Add].
Deleting the History	Select the desired item and press [Delete].
Updating the History	Select the desired item in the list to display it in the entry field. Then, press [Update].

3.2.3 Editing patient information

The operator can edit the registered patient information on the Edit patient information screen by performing the following procedure.

- 1 On the Patient list screen, select the patient to be edited and press  [Edit patient].

Information of the selected patient is displayed on the Edit patient information screen.

Date of birth	Last exam	Comment	History
28/08/2019	16:28		
03/10/2019	11:05		
03/10/2019	11:02		
16/04/2018	13:32		
21/05/2018	17:56		
15/06/2018	13:48		
16/04/2018	13:21		
16/04/2018	13:08		

- 2 Change the contents.

The procedure is the same as that for registering a new patient on the Register patient screen.


- 3 Press [OK] to save the edited contents.

The Edit patient information screen is closed and the Patient list screen is displayed.

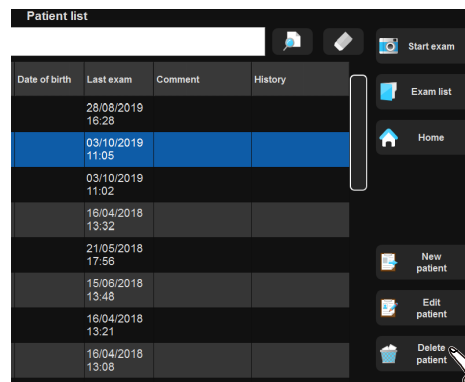
3.2.4 Deleting patient data

The operator can delete patient information by performing the following procedure.

Note that deleting a patient also deletes all their exam data.

- 1 On the Patient list screen, select the patient to be deleted and press  [Delete patient].

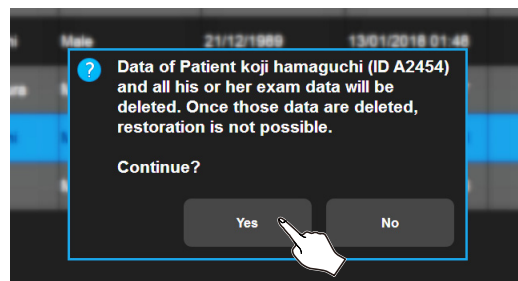
The confirmation message appears.



- 2 Press [Yes] to delete the information of the selected patient.

The confirmation message disappears and the Patient list screen is displayed.

Pressing [No] cancels the process and closes the confirmation message.



Note

- When deleting the exam data individually, select the data on the Exam list screen and press [Delete exam].

For details, see “3.8.2 Operations on Exam list screen” (page 86).

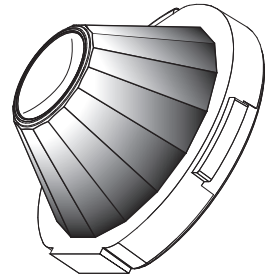
3.3 Attaching/Detaching MM Prism


Be sure to disinfect (or sterilize) the MM prism for every patient.

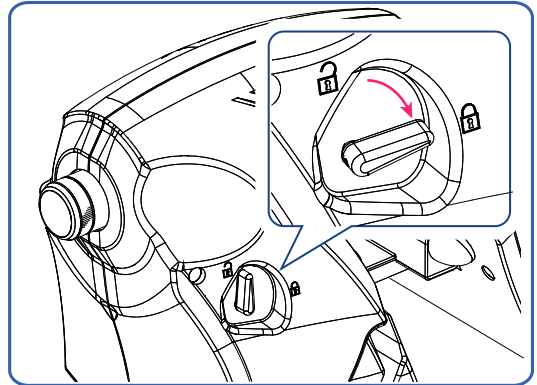
3.3.1 Attaching MM prism before image capture

To preserve hygiene, do not attach the disinfected (or sterilized) MM prism until just before the image capture.

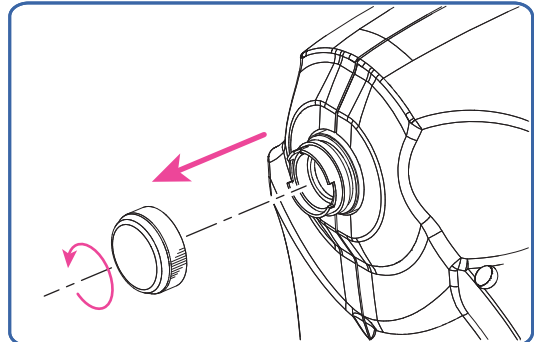
When handling the MM prism, pay attention not to touch the prism tip and prism mirror.



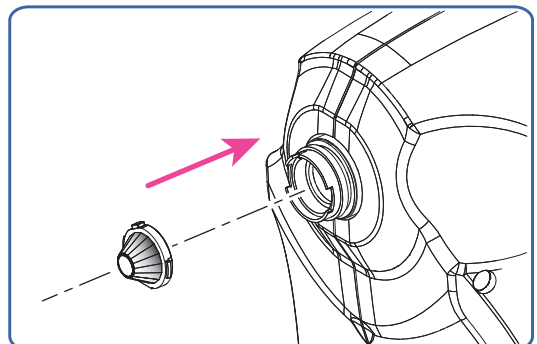
- 1) Confirm that the image capturing unit is securely locked.
If it is unlocked, move the locking lever to the Lock position  .



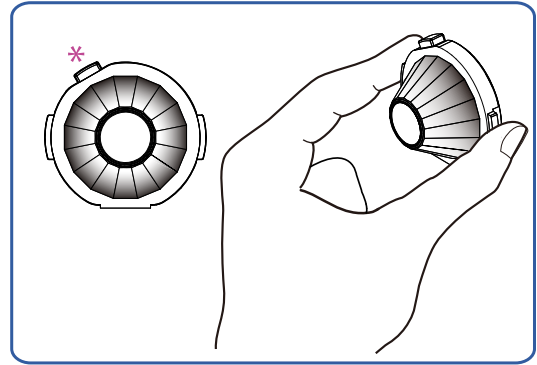
- 2) Turn the prism cap counterclockwise to detach it.



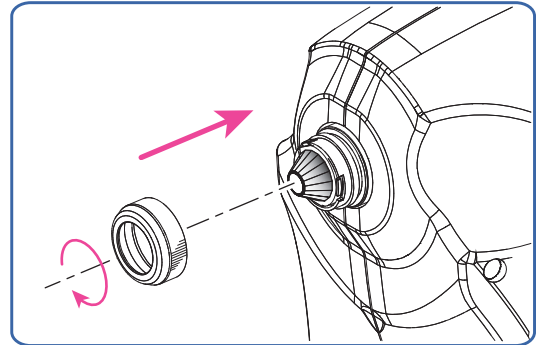
- 3) Attach the MM prism with the flanges aligned with the holder.



Do not touch the MM prism tip and mirror surface. Hold the flanges as shown in the figure to the right.



4) Turn the prism clamp clockwise to attach it.



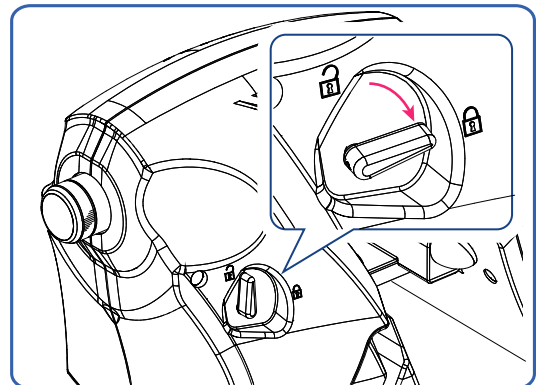
3.3.2 Detaching MM prism after image capture

After the image capture, detach the MM prism for disinfecting (or sterilizing) it.

1 After the image capture, lock the image capturing unit and wipe out the remaining gel.

Wipe out the gel and dirt immediately after the image capture.

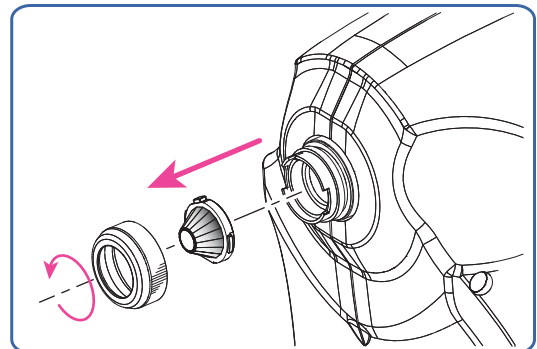
If the gel is dried already, soak a soft cloth in water and wipe out the gel.



2 Turn the prism clamp counterclockwise to loosen it and detach the MM prism from the image capturing unit.

3 Place the MM prism with its tip facing up on a container for cleaning. Store the prism clamp in the specified location.

When continuing the image capture, replace the MM prism with spare one. [↪ "4.7.7 Reattaching MM prism to device" \(page 152\)](#)

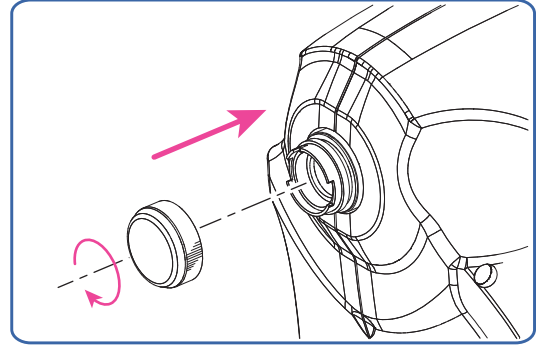


CAUTION

- Never return the used MM prism to the prism case.
Inside of the case may be contaminated.

4 Turn the prism cap clockwise to attach it to the image capturing unit.

When examining another patient, attach the clean MM prism.

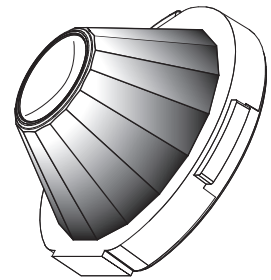


3

3.3.3 Checking MM prism

The MM prism is a consumable part. It should be replaced every six months or 100 times of use.

Note that the coating material on the prism mirror is gradually deteriorated by cleaning, disinfection or sterilization treatment. Continuous use of such MM prism will cause the deterioration in image quality. To prevent this, be sure to replace the prism periodically.



◆ Visual check

Check the mirror surface. If the following are observed, the MM prism should be replaced.

- The mirror is partially peeled off.
- The silver coating has become thinner.
- The opposite side can be seen through.
- Any severe damage is found.

Minor scratches have little effect on image quality.

◆ Checking by attaching it to device

In a dark room, attach the MM prism to the device and turn on the device. Then, confirm that no light is leaked from the prism mirror.

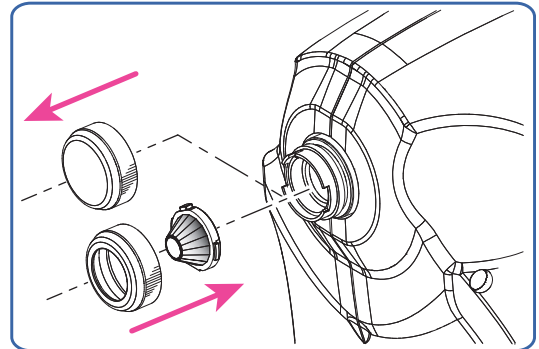
3.4 Image Capture


3.4.1 Before image capture

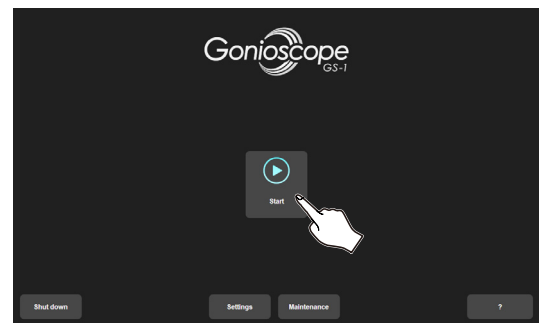
1 Turn on the device power switch.
The device starts and the home screen is displayed.

2 Attach the MM prism to the image capturing unit.

↳ “3.3.1 Attaching MM prism before image capture” (page 45)




3 Press  [Start] on the home screen to display the Patient list screen.



4 Select the desired patient on the Patient list screen.

Search for patient

Patient ID	Name	Sex	Date of birth	Last exam	Comment	History
000000001	nidek nidek	Not specified		28/08/2019 18:28		
000002	s g	Not specified		03/10/2019 11:55		
01460	a e	Not specified		03/10/2019 11:02		
01610	t k	Male		18/04/2018 13:32		
01829	k h	Not specified		21/05/2018 17:56		
10777	o t	Not specified		15/05/2018 13:49		
11348	a o	Male		16/04/2018 13:21		
11354	k n	Male		18/04/2018 19:58		
12150	n l	Not specified	24/07/2018	24/07/2018 17:54		
12454	k h	Male	21/12/1999	21/05/2018 12:34		

When the barcode scanner or magnetic card reader is connected, reading a patient ID with it displays the ID in the Search for patient field. Then, pressing  (Search) specifies the patient.

Patient list

A2454

Patient ID	Name	Sex	Date of birth	Last exam	Comment	History
90006	Exam6 PATIENT	Male	23/11/1960	20/11/2019 07:52		
90007	Sample7 Nidek	Male	23/12/1942	29/10/2019 10:06	OBS	Glaucoma

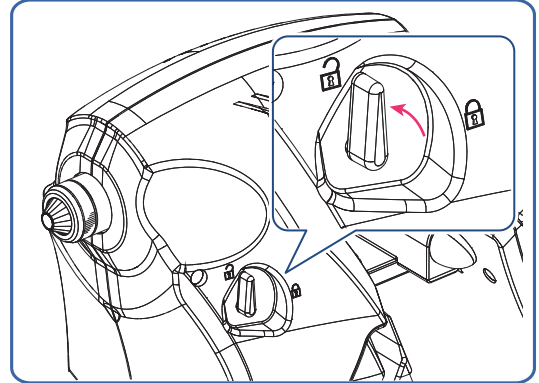
When examining a new patient, register the patient information beforehand. ↳ “3.2.2 Registering new patient” (page 38)

5 Prepare for the image capture.

- 1) Place a chair and the LCD touch screen with the correct orientation.
- 2) Apply the gel to the MM prism tip and spread it out to a thickness of 2 or 3 mm.

↳ “◆ Applying gel to MM prism” (page 51)

- 3) Move the image capturing unit locking lever to the Unlock position to unlock the image capturing unit.

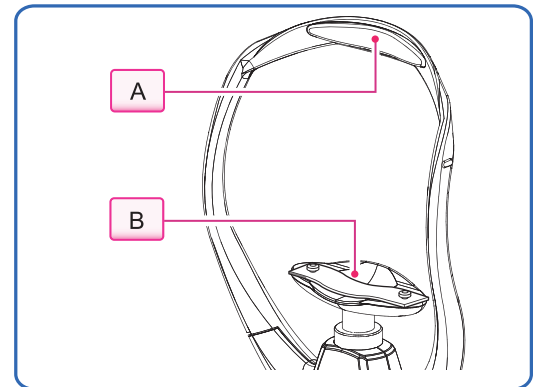


6 Prepare the patient for an image capture.

- 1) Clean the contact parts (forehead rest **A** and chinrest **B**) for patients.

Wipe the forehead rest and chinrest with a clean gauze or absorbent cotton. If necessary, wipe with a clean cloth dampened with rubbing alcohol.

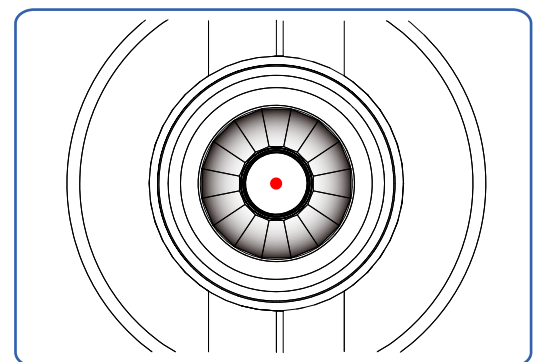
When the chinrest paper is used, remove one sheet.



- 2) Confirm that the patient wears no contact lenses.
- 3) Explain the examination details to the patient to relieve their anxiety. If necessary, apply a surface anesthesia to both eyes.

- The device unit approaches very closely and the gel comes into direct contact with the patient's eye.
- Approximately one minute will take (in Full capture) for each eye capture. The patient should keep on looking at the red point when an image is being captured.
- The operator lifts the patient's eyelid during image capture to prevent the patient from blinking.
- The patient must keep their forehead in contact with the forehead rest and not move their head during the image capture.

If necessary, also apply a surface anesthesia to prevent the patient from blinking before the image capture after certain time of preparations above.



- 4) Instruct the patient to place their chin on the chinrest as far forward as possible with their forehead resting lightly on the forehead rest.

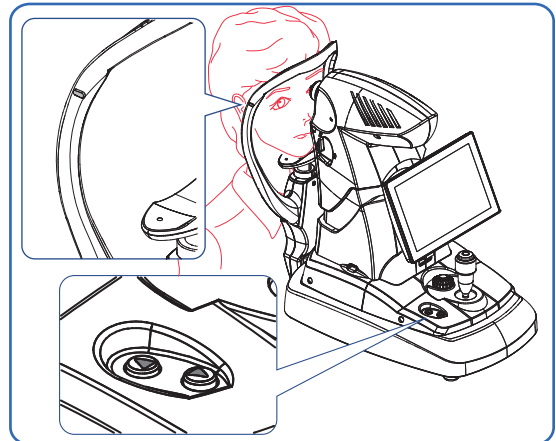
Check the patient's state after each step.

When roughly aligning the height, ask the patient to move back from the chinrest and forehead rest.

- 5) Press the chinrest Up/Down button (▲, ▼) and align the patient's eyes to the eye level marker.

Prior to this step, notify the patient that the chinrest will be raised or lowered. Be sure to raise or lower the chinrest while checking the patient's posture.

If the patient's eye height is largely misaligned from the eye level marker, ask the patient to move back from the device. Then, raise or lower the chinrest.




- 6) After aligning the patient's eyes to the eye level marker, ask the patient to move back from the device.

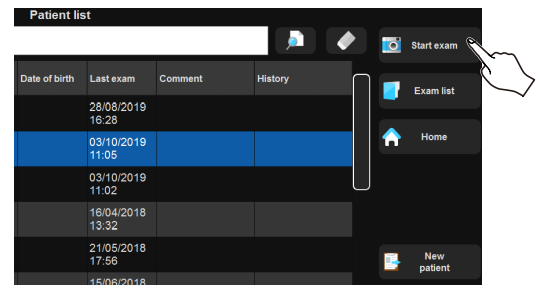
- 7) Apply the gel to the MM prism.

➡ “◆ Applying gel to MM prism” (page 51)

- 8) Ask the patient to place their face to the device again.

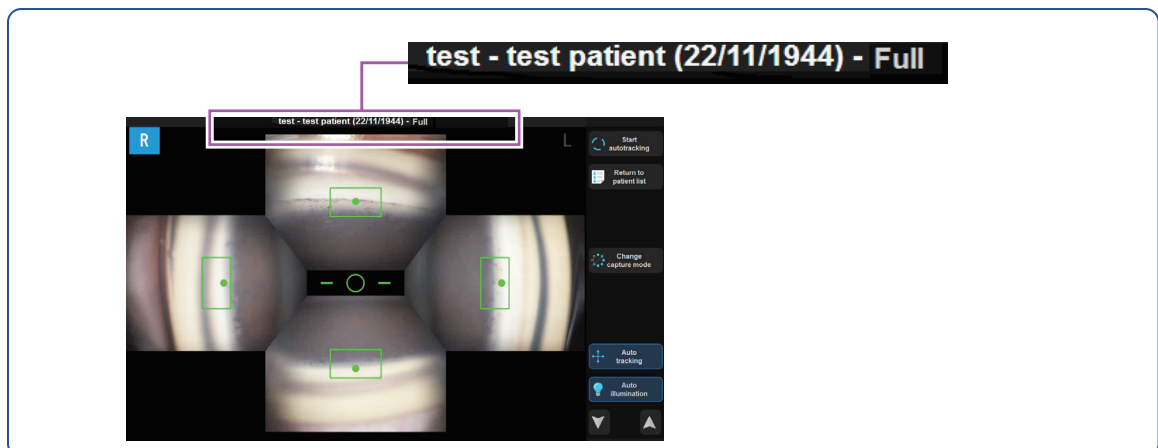
7 Start an image capture.

The procedure varies between Full capture and Single capture. Set the image capture mode in the parameter “Initial exam mode”. The setting image capture mode is activated by pressing  [Start exam] on the Patient list screen.



Full capture	➡ “3.5.2 Image capture procedure (Full capture)” (page 53)
Multi capture	➡ “3.6.2 Image capture procedure (Multi capture)” (page 67)
Single capture	➡ “3.7.2 Image capture procedure (Single capture)” (page 72)

On the alignment screen, confirm that the correct patient ID is displayed at the top of the screen. Patient ID, name, date of birth, and image capture mode are displayed at the top of the screen.



◆ Applying gel to MM prism

Use a colorless ophthalmic gel with a proper viscosity that does not contain bubbles (for example, an ophthalmic gel containing 0.2% or more of carbomer).

CAUTION

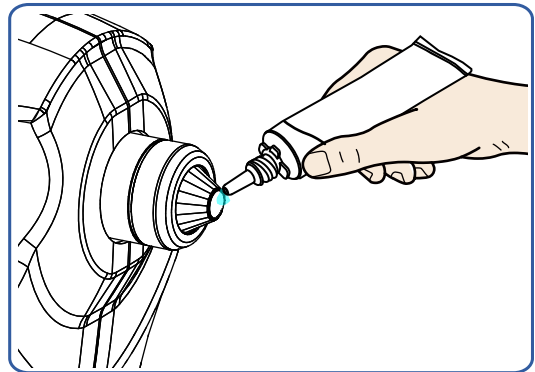
- The gel must be stored in an environment specified by the manufacturer of the gel. In addition, once the packaging is opened, use up the gel within the period of time specified by the manufacturer of the gel. Discard the remaining gel after this period.
- Before use, be sure to confirm that the gel is within its expiration date and the packaging is not damaged. If the use-by date expires or the packaging is damaged, discard the gel without using it.

1) Open the gel packaging.

Make sure that the cap or lid of the packaging is not contaminated.

2) Apply the gel to the MM prism tip.

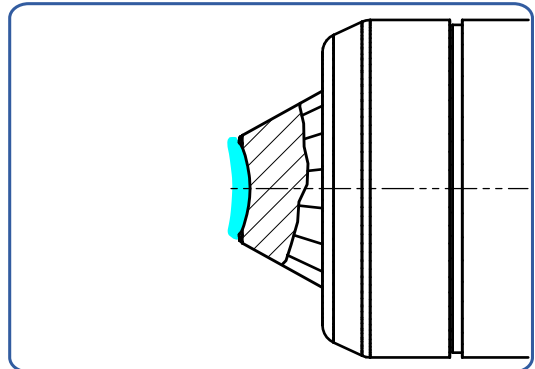
Start applying the gel from the prism tip. Spread it out until the tip surface is covered completely.



Apply the gel to the depressed area of the MM prism tip. Spread it out to a thickness of 2 or 3 mm.

Make sure that no air bubbles are trapped in the applied part.

The operator can perform the alignment smoothly by applying a sufficient amount of gel.



3) When capturing the other eye, apply the gel to the MM prism again.

If air bubbles or impurities are trapped in the applied gel, wipe out the gel then apply it again.

Make sure that the gel is not contaminated.

4) Dispose of the gel package according to the disposal method of infectious waste.

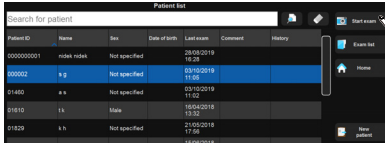
3.5 Image Capture in Full Capture Mode

3.5.1 Outline of Full capture


In Full capture mode, the circumference of the anterior chamber angle is divided into 16 portions, and images are captured continuously at each portion. At each position, 17 images with different focus positions are captured.

After the image capture, an image best focused on the trabecular meshwork is automatically selected. When images are captured in Full capture mode, a stitching image can be displayed.

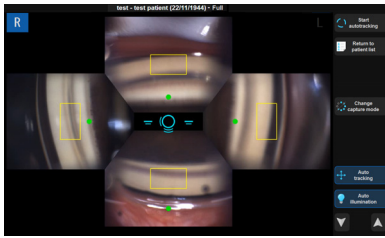
- 1**




Patient list screen

After preparation for the patient and the device, press  [Start exam] to start image capture.

- 2**



Alignment screen

When the alignment and focus are proper, image capture automatically starts. Image capture can also be started by pressing the start button or  [Capture image].

[↩ \(page 59\)](#)

- 3**




Image capture screen

Images are automatically captured. Ensure that the device and patient do not move.

- 4**

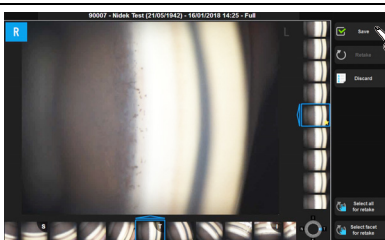



Image confirmation screen

Check the captured image. When it is acceptable, press  [Save] to save it. If necessary, change the best focus image, or retake the image.

To capture the other eye, repeat (2) to (4).

[↩ \(page 64\)](#)

- 5**

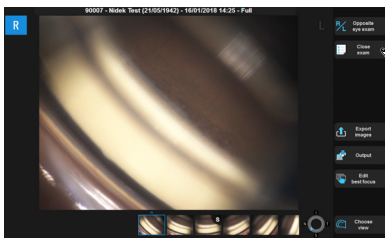



Image display screen

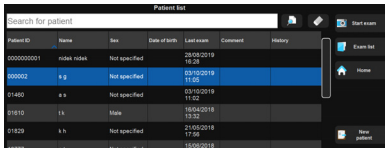
Allows exporting of various images, printing of a report, changing of the best focus image, display of the stitching image, and inputting of image capture comment.

Press  [Close exam] to finish image capture.

The image display screen can also be displayed from the saved exam result.


[↩ \(page 87\)](#)

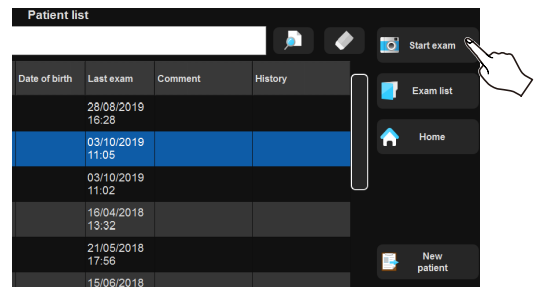
- 6**



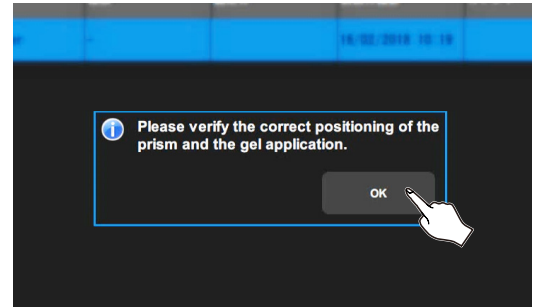
When image capture is finished, the Patient list screen is displayed.



3.5.2 Image capture procedure (Full capture)

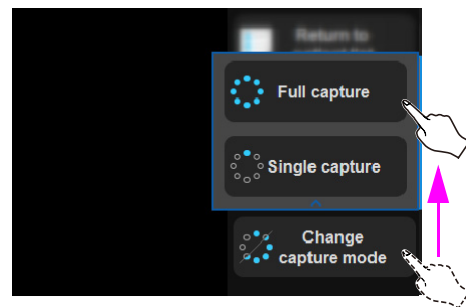
- 1 Press  [Start exam] on the Patient list screen.



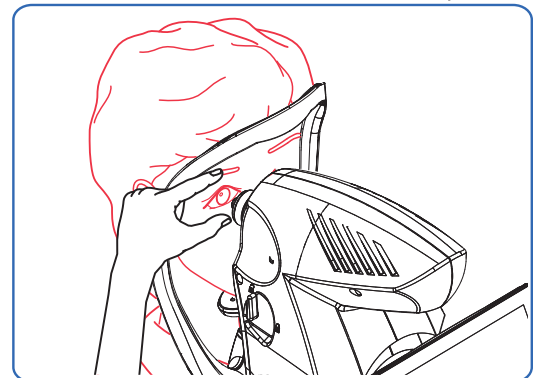
- 2 The confirmation message regarding the MM prism and gel application appears. Check them and press [OK] to display the alignment screen.



When the "Initial exam mode" setting is not "Full capture", the screen for the preset capture mode is displayed. Select  [Change capture mode], then  [Full capture] to enter Full capture mode.

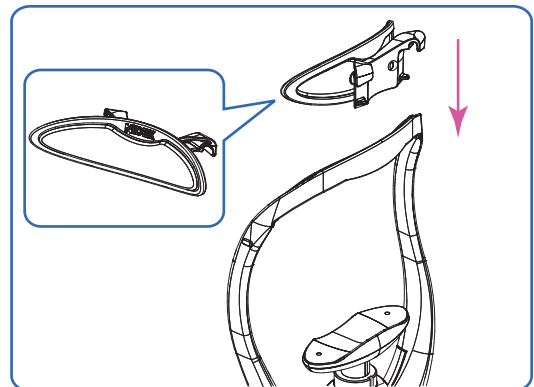


- 3 While lifting the patient's eyelid, slowly move the image capturing unit closer to the patient until the gel slightly contacts the patient's eye.

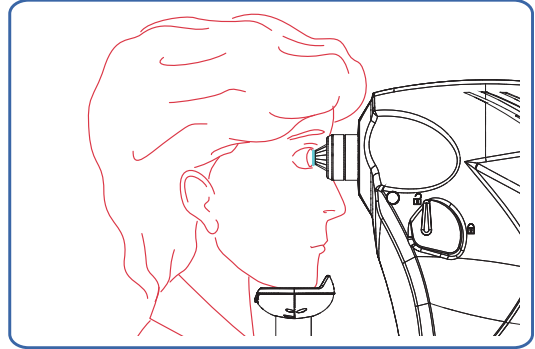


If the distance between the patient's eye and image capturing unit is too close, attach the forehead arm to the device for the image capture.

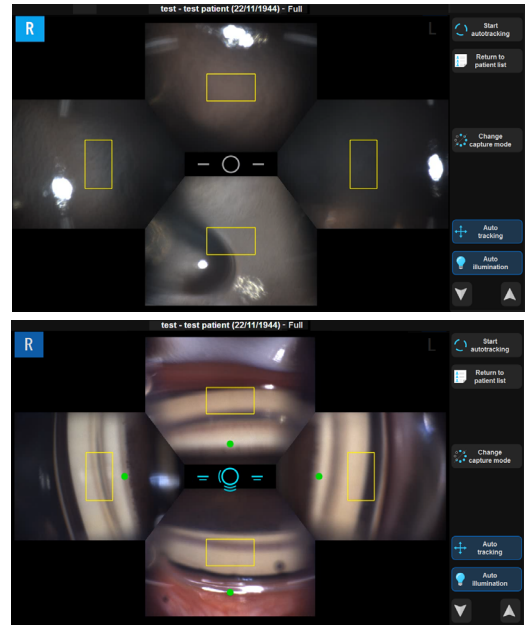
Wipe the area that comes into direct contact with the patient's forehead with a clean gauze or absorbent cotton. If necessary, wipe with a clean cloth dampened with rubbing alcohol.



- 1) Operate the joystick and roughly align the device to the patient's eye. While watching the patient from the side, move the image capturing unit closer to the patient. Take proper care that the image capturing unit does not come into direct contact with the patient's eye.



- 2) A dark image is displayed when the gel directly contacts the patient's eye. The image becomes brighter by moving the device to the WD (approximately 1.5 mm).




Note

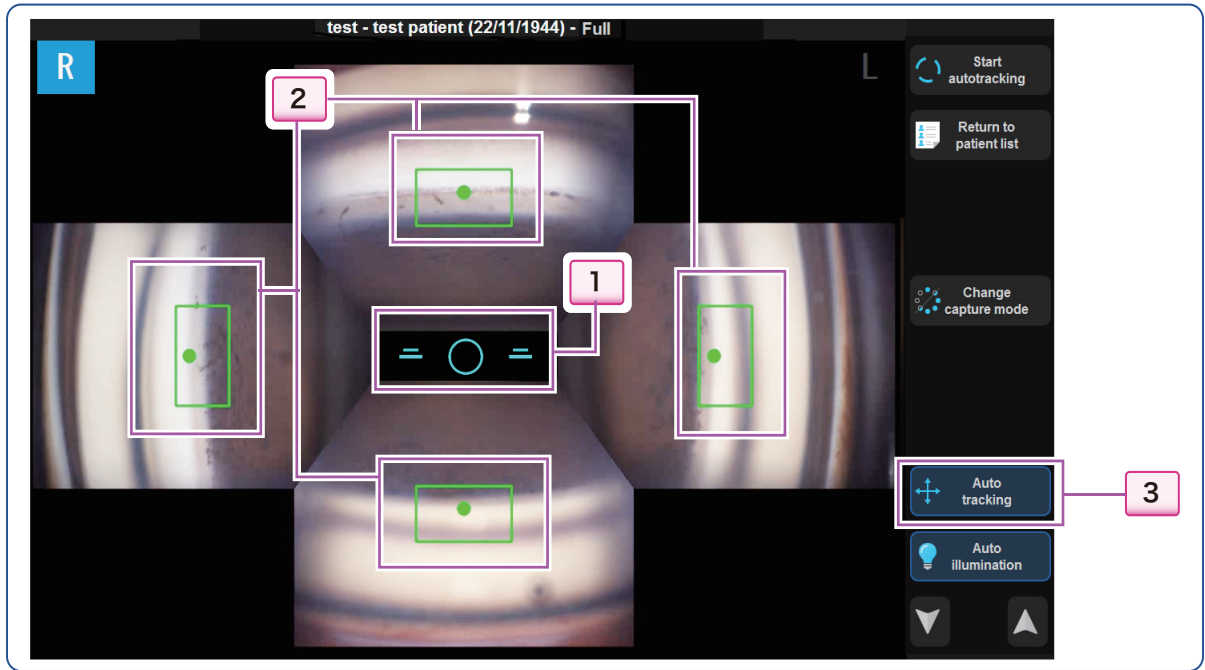
- If an image capture takes longer time than specified (3 minutes and 45 seconds) after the alignment screen is displayed, the message "Illumination LED lighting time beyond specified time for safety. Exam will be canceled." appears. Then, the image capture automatically finishes.
- If the patient has a difficulty in maintaining fixation, use the external fixation lamp (optional). Ask the patient to keep on looking at the external fixation lamp with the unexamined eye. Doing so can fix the patient's visual line.

4 While checking the image on the alignment screen, operate the joystick to adjust the focus and alignment.

On the alignment screen, the operator can align the image capturing unit to the patient's eye properly. For details, see "3.5.3 Adjusting alignment and focus (alignment screen)" (page 59).

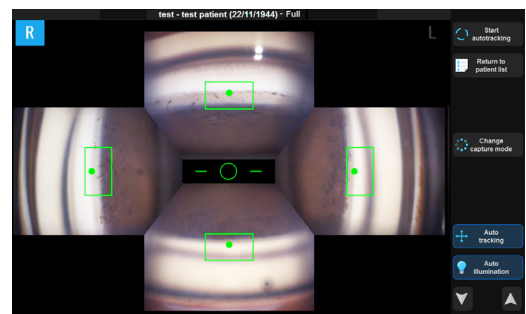
1	The indicator shows the best state (-  -).
2	At least three of the square frames, which indicate the center of capturing area, are shown in green.
3	The alignment in the vertical and horizontal directions can be performed with the auto tracking.


The alignment in the vertical and horizontal directions can be performed automatically. For the alignment in the forward and backward directions, operate the joystick.




3

5 When the alignment and focus are obtained, start an image capture.



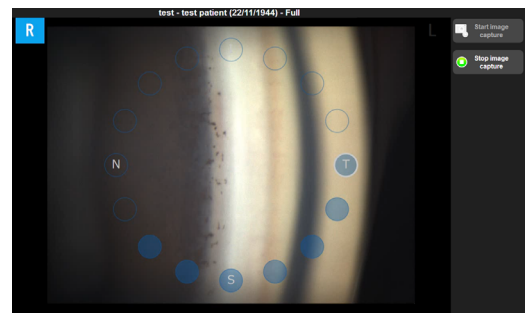
Auto start	The image capture screen is displayed and an image capture starts. When the auto tracking is turned on, the auto start (automatic switching to the image capture screen) functions.
Start button	Pressing the start button (or  [Start image capture] on the touch screen) switches the screen to the image capture screen to start an image capture.

When the auto tracking is enabled, an image capture can be started only while the tracking () is being performed.

6 The image capture screen is displayed. 16 images at 16 different positions are captured and displayed on the screen. Confirm that the captured image is proper.

17 images are captured in all. Each image has a different focal position. The image in focus is captured in a halfway process.

Pay attention not to move the patient and device while an image is being captured. The auto tracking becomes inactive (OFF) momentarily while an image is being captured.



- Points to be checked on the images
 - An image in focus is included.

- The trabecular meshwork is in the center of the screen.
- The brightness of the image is proper.

■ Operations on the image capture screen

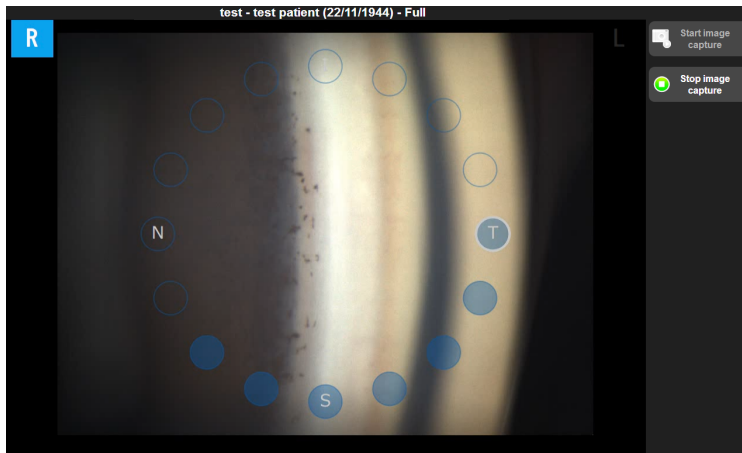



Image display	Displays the captured images in order The captured position (indicated with a blue circle) and the image position that is currently displayed on the screen (indicated with a white ring) are shown in an overlay format.
 [Stop image capture]	The image capture is canceled and the alignment screen is displayed. The captured images are automatically discarded.

7 The message notifying that the captured image is being processed appears and the image confirmation screen is displayed. Pull the device closer to the operator’s side and perform the following.

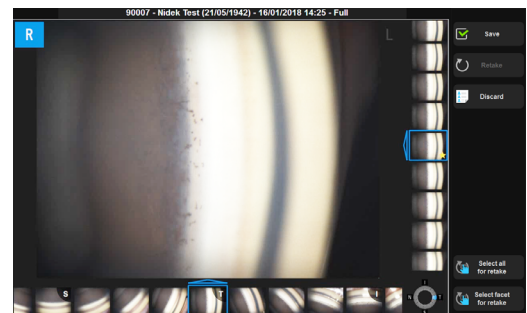
Perform necessary treatment on the examined eye.

- Allow the patient to blink for resting their eyes.
- Wipe out the remaining gel.
- If necessary, instruct the patient to clean their eyes.

8 The image in focus is selected automatically. Check the image on the image confirmation screen and select another if necessary.


On this screen, the operator can perform the operation such as checking/selecting, saving, retaking, or canceling an image capture.

For details, see “3.5.4 Checking captured images (image confirmation screen)” (page 64).

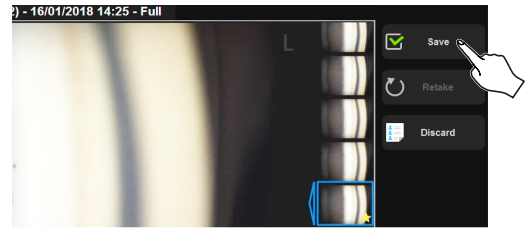


Note

- Even after saving the image, the operator can select an image other than the one automatically selected.

- 9** On the image confirmation screen, press  [Save] to complete the image capture of the current eye.

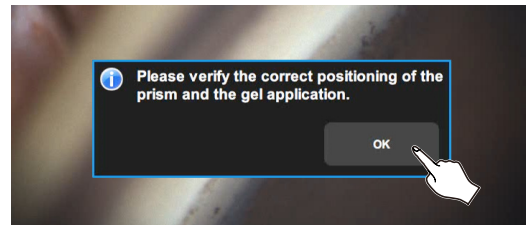
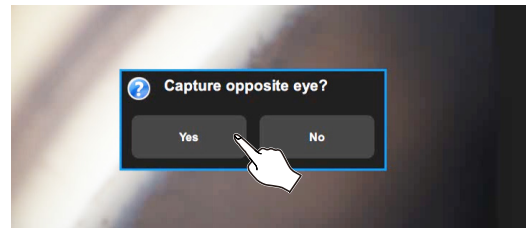
The image is saved and the confirmation message asking whether to capture the opposite eye appears.



[Yes]	Starts an image capture of the other eye.
[No]	Finishes the image capture after right or left eye image is captured, and displays the image display screen.

- 10** When capturing an image of the opposite eye, press [Yes] on the confirmation message and perform the same procedure.

- 1) The confirmation message regarding the MM prism and gel application appears. Check them and press [OK] to display the alignment screen.
- 2) Lock the image capturing unit with the image capturing unit locking lever. Then, apply the gel to the MM prism again.
If air bubbles or impurities are trapped in the applied gel, wipe out the gel then apply it again.
- 3) Keep the device to the operator's side and move the device to the right or left.

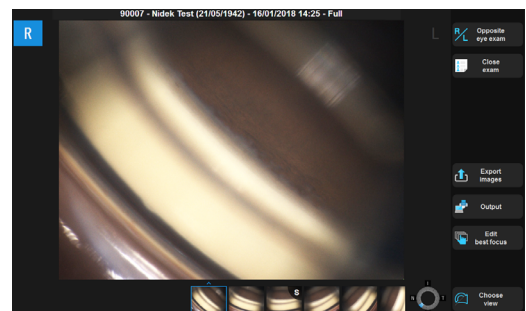


- 4) Unlock the image capturing unit with the image capturing unit locking lever.


- 11** Capture an image of the opposite eye in the same procedure.


- 12** When the image capture is complete, the saved image is displayed on the image display screen. Perform the necessary operations.

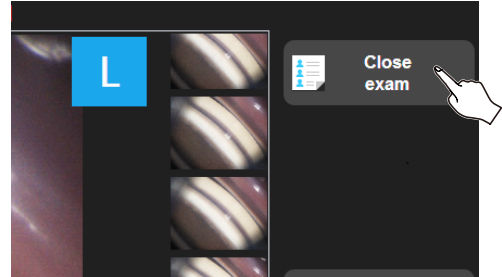
- Checking of saved image
- Exporting of various images
- Printing of the report



- Changing of best focus image
- Display of stitching image
- Inputting of image capture comment

Operations on image display screen:  "3.9 Operations on Image Display Screen" (page 87)

13 Press  [Close exam] on the image display screen to return to the Patient list screen.

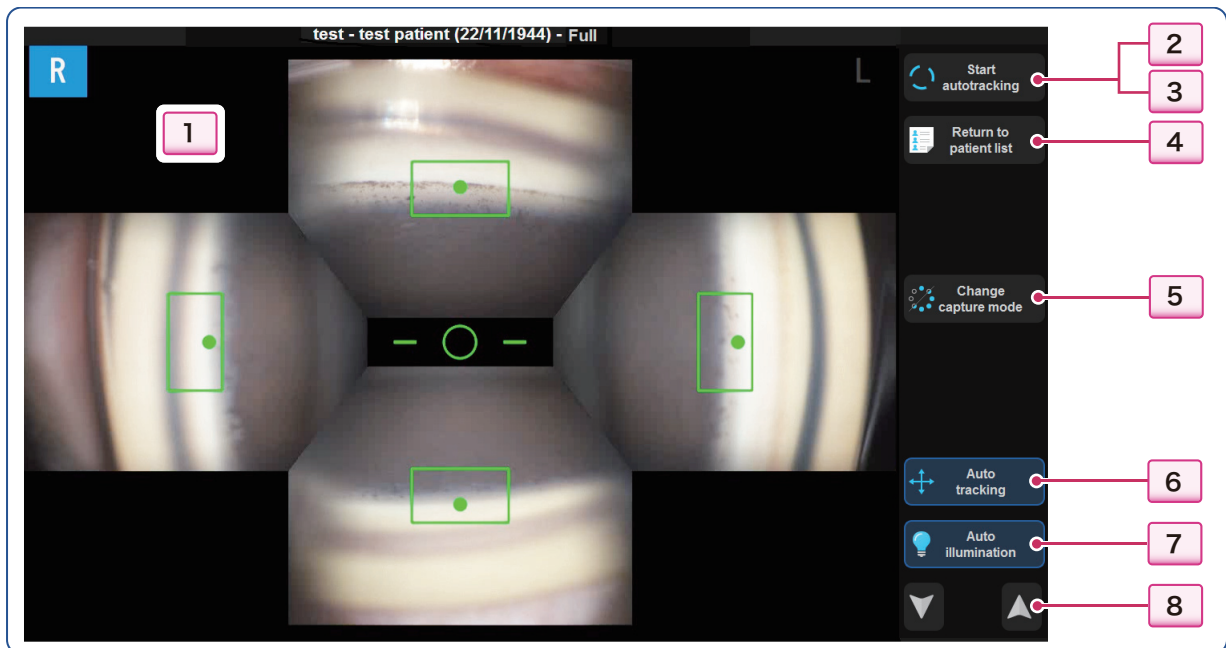













3.5.3 Adjusting alignment and focus (alignment screen)

On the alignment screen, the operator can adjust the alignment in the vertical and horizontal directions, and the focus in the forward and backward directions.

The purpose of the focus adjustment at this point is to bring the image capturing unit to a proper working distance. It is unnecessary to achieve a proper focus on the displayed angle image yet.

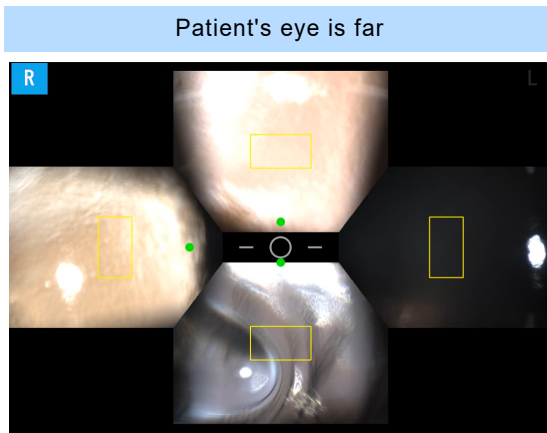
◆ Operations on alignment screen (Full capture)



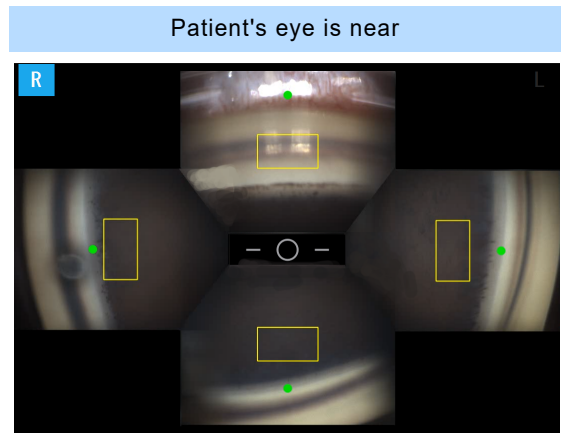
1	Image display	Displays the images for alignment in the vertical and horizontal directions, and an alignment indicator Patient ID, name, date of birth, and image capture mode are displayed in the upper part of the screen. The device detects the current eye and displays it on the screen.
2	 [Start autotracking]	Pressed to start the tracking Pressing the start button also starts the auto tracking. During auto tracking, the icon  [Start autotracking] changes to  [Start image capture].
3	 [Start image capture]	Pressed to display the image capture screen and to start an image capture Pressing the start button also starts an image capture.
4	 [Return to patient list]	The Patient list screen is displayed.
5	 [Change capture mode]	Pressed to toggle between Single and Multi capture modes to switch the alignment screen.
6	 [Auto tracking]	Pressed to turn on or off the auto tracking function. When it is turned off, the icon  [Start autotracking] does not appear. The icon  [Start image capture] remains on the screen.
7	 [Auto illumination]	Pressed to turn on or off the auto illumination function When it is turned off, the operator should adjust the brightness manually.
8	 (Illumination adjustment)	When the auto illumination function is turned off, set the illumination brightness in the range of 0 to 100%

1 Roughly achieve the focus.

Tilt the joystick forward and backward so that anterior chamber angle images are displayed near the rectangle frames in all directions.



ACA image (indicated with green dots) is centered.

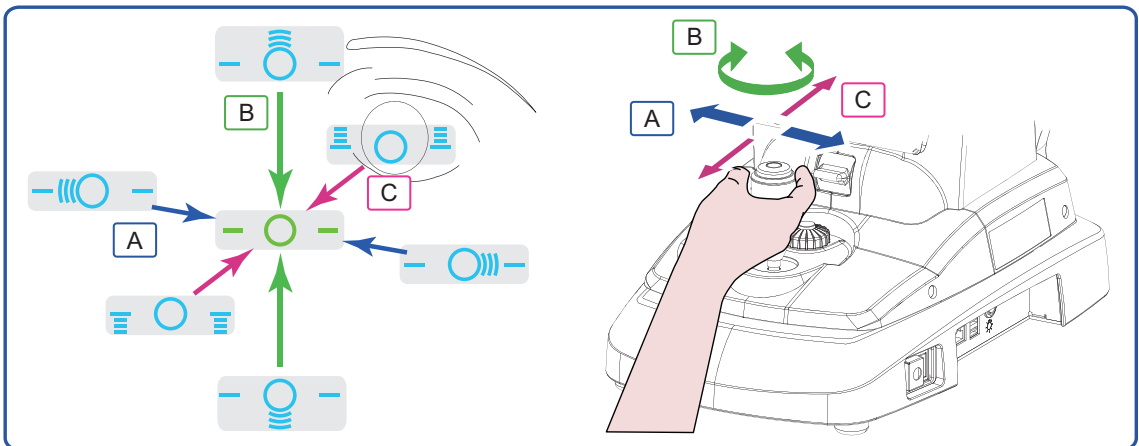


ACA image (indicated with green dots) is spread.

2 Operate the joystick while referring to the focus indicator and alignment display.

Ensure that the indicator shows the best state (- ● -).


A clear image can be captured by achieving a proper working distance from the trabecular meshwork.



A	Alignment in the horizontal direction Tilt the joystick to the right and left.
B	Alignment in the vertical direction Rotate the joystick head.
C	Achieving the focus in the forward and backward directions Tilt the joystick forward/backward.

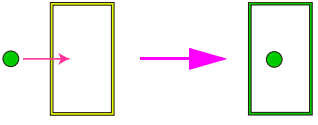
● Alignment in the vertical and horizontal directions

Central indicator of alignment circle



Operate the joystick so that the indicator disappears.
The shift amount in the vertical or horizontal direction is indicated by the number of lines.

Yellow frames displayed on four images




Operate the joystick so that the green dot comes inside the frame. When the dot is in the frame, the frame color changes to green.
The rectangle frame indicates the center of capturing area, and the green dot indicates the automatically detected trabecular meshwork area.

3

● Achieving focus in the forward/backward directions

Match the focus indicator with reference icon.







Tilt the joystick in the forward and backward directions so that the indicator shows the best state.
(- ○ -).

When the indicator lines appear on the upper side, move the device away from the patient. When the indicator lines appear on the lower side, move the device closer to the patient. The number of lines indicates the shift amount.

● When the alignment is not within the auto tracking range

Tilt the joystick in the direction of red arrow for the limit indicator.





The limit indicator appears when the auto tracking function is turned on.

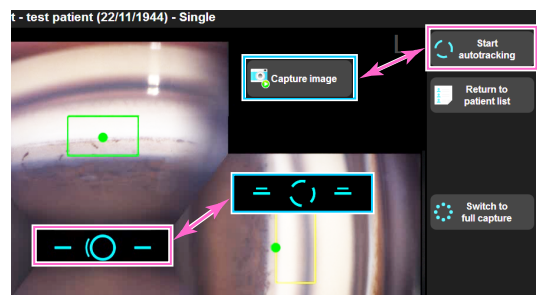
Up/Down ( / )	Move the image capturing unit up or down by turn the joystick.
Left/Right ( / )	Move the image capturing unit (and the main unit) right or left by tilting the joystick.

3 Finely adjust the alignment using the joystick.

The procedure varies depending on whether auto tracking is turned on or off.

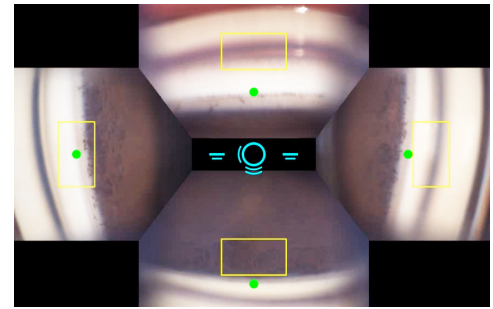
● When auto tracking is turned on

- 1) Adjust the alignment and focus. Then, press the start button (or  [Start autotracking] on the touch screen) to start the auto tracking. As soon as the auto tracking starts, the indication  [Start autotracking] switches to  [Start image capture] ( [Select image]).

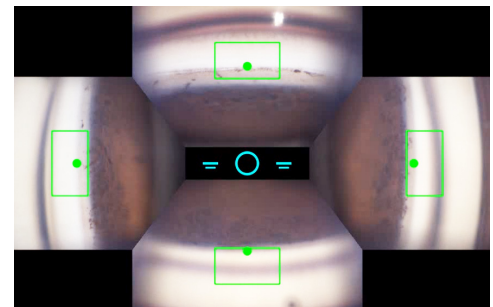


A circle in the center of the screen starts rotating (= 🔄 =), indicating that the auto tracking is being performed.

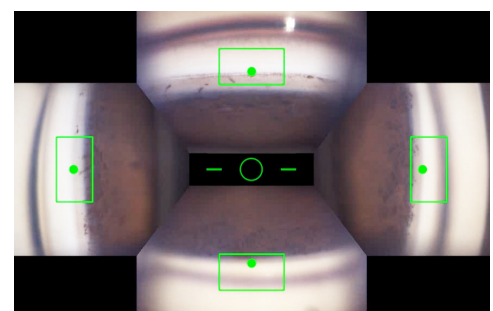
- 2) While referring to the alignment indicator, perform an adjustment so that no indicator line appears in any direction.




- 3) The auto tracking function performs the alignment in the vertical and horizontal directions, and the green frames are displayed.



- 4) While referring to the focus indicator, adjust the focus in the forward and backward directions.



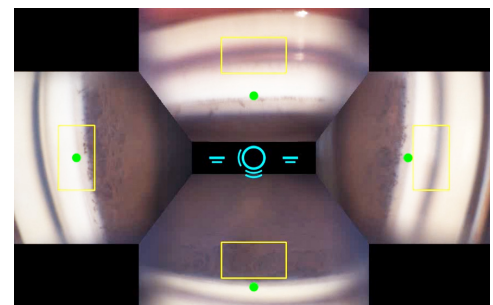
- 5) When the alignment and focus are proper, the image capture screen is displayed by the auto start function. In Full capture mode, automatic image capture starts.

Pressing the start button (or  [Start image capture]) also displays the image capture screen and starts automatic image capture.


After a certain period of time, auto tracking automatically stops. In this case, repeat the procedure from Step 1).

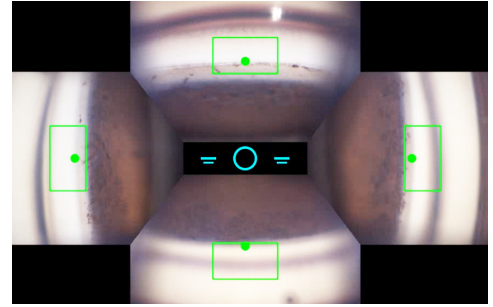
● When auto tracking is turned off

- 1) While referring to the alignment indicator, perform an adjustment so that no indicator line appears in any direction.



- 2) Continue the alignment until green frames are displayed in all of the four images.
- 3) While referring to the focus indicator, adjust the focus in the forward and backward directions.

Pressing the start button (or  [Start image capture]) switches the screen to the image capture screen to start automatic image capture.





3.5.4 Checking captured images (image confirmation screen)




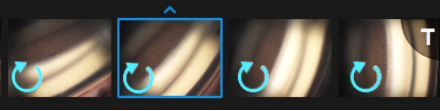


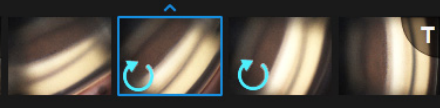
Check the captured images before saving them. According to their quality, the operator performs the operation such as checking, retaking, or canceling an image capture.

In Full capture mode, as necessary, select an image other than the one automatically selected.

◆ Operations in Full or Multi capture mode

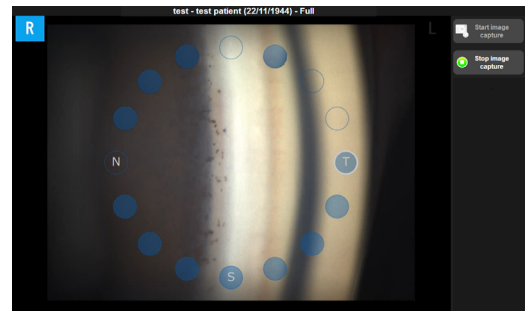


1	Image display	Enlarging or reducing an image: Pinch-out or pinch-in Moving an image: Sliding (Dragging) Displaying image magnifications: Tapping twice
2	Thumbnail images	Dragged to display the thumbnail images at each position. The thumbnail image of current image is indicated with blue frame. Drag the thumbnail image to display another. They indicate the captured position with blue on the TSNIT chart. The Edit icon (✎) appears when the operator selects an image other than that automatically selected.
3	All thumbnail images (Full or Multi capture)	Thumbnail images of all selected images at one position are displayed. The thumbnail image of current image is indicated with blue frame. Drag the thumbnail image to display another image. The image automatically selected is indicated with a star icon (★).
4	 [Save]	Pressed to save the selected image of the setting amount. When selecting any image other than the one automatically selected, the confirmation message regarding this change appears. After the image is saved, a message asking whether to capture an opposite eye image appears. Selecting [Yes] switches right/left eye.
5	 [Retake]	Pressed to discard the selected image and return to the alignment screen. The confirmation message appears. Pressing [Yes] displays the confirmation message regarding the MM prism and gel application. Pressing [OK] displays the alignment screen. On the image capture screen for retake, images are captured only at the position specified for retake.

<p>6</p>	 [Abort]	<p>Pressed to discard the current image and to return to the Patient list screen. The confirmation message appears. Pressing [Yes] returns to the Patient list screen.</p>
<p>7</p>	 [Select all for retake]	<p>Selects all captured images for retake. When [Select all for retake] is set, the button display changes to [Deselect all for retake]. The retake mark () is shown on the thumbnail of the retaken images.</p> 
<p>8</p>	 [Select facet for retake]	<p>Pressed to select or cancel the selected image for retake. According to the setting of the selected image, the button display switches between [Select facet for retake] and [Deselect facet for retake]. The retake mark () is shown on the thumbnail of the retaken images.</p> 

3

When the alignment screen changes to the image capture screen for retake, blank blue circles (○) show the positions selected for retake, and solid blue circles (●) show the positions at which image capture is finished.



3.6 Image Capture in Multi Capture Mode

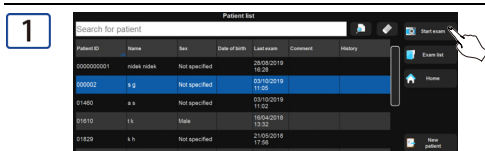
3.6.1 Outline of Multi capture

In Multi capture mode, images are continuously captured only at preselected capture positions. At each position, 17 images with different focus positions are captured.


After the image capture, an image best focused on the iridocorneal angle portion is automatically selected.

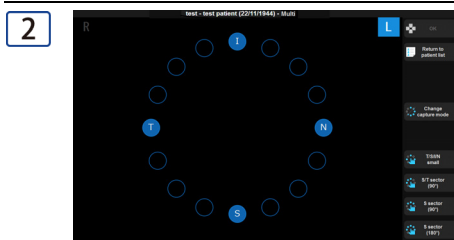
Note

- In Multi capture mode, unlike Full capture mode, images are captured only at the selected positions, and no stitching image can be displayed.
- If all positions are selected in Multi capture mode, the result is treated as that of Full capture mode.




1 Patient list screen

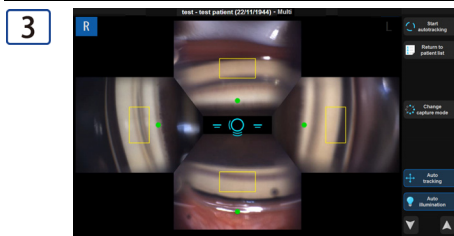
After preparation for the patient and the device, press  [Start exam] to start image capture.



2 Capture position select screen


Select the desired position. Then press [OK] to show the alignment screen.

 (page 69)

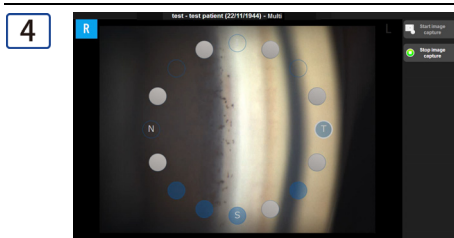


3 Alignment screen

When the alignment and focus are proper, image capture automatically starts.

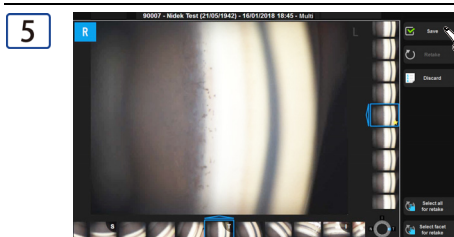
Image capture can also be started by pressing the start button  [Capture image].

* Same as Full capture  (page 59)




4 Image capture screen

Images are automatically captured. Ensure that the device and patient do not move.



5 Image confirmation screen

Check the captured image. When it is acceptable, press  [Save] to save it.

If necessary, change the best focus image, or retake the image.

To capture the other eye, repeat (2) to (4).

* Same as Full capture  (page 64)

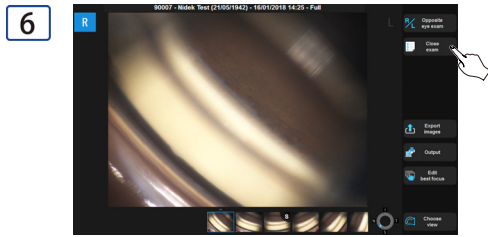


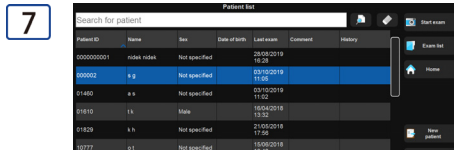
Image display screen

Allows exporting of various images, printing of a report, and changing of the best focus image.

Press [Close exam] to finish image capture.

The image display screen can also be displayed from the saved exam result.

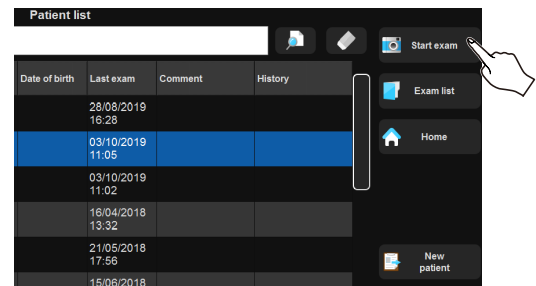
(page 87)



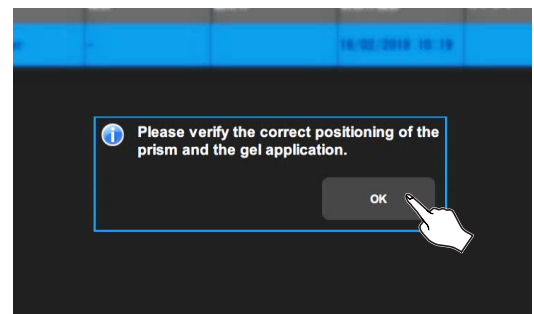
When image capture is finished, the Patient list screen is displayed.

3.6.2 Image capture procedure (Multi capture)

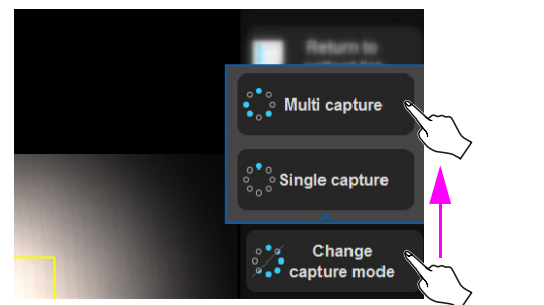
- 1 Press [Start exam] on the Patient list screen.



- 2 The confirmation message regarding the MM prism and gel application appears. Check them and press [OK] to display the capture position select screen.

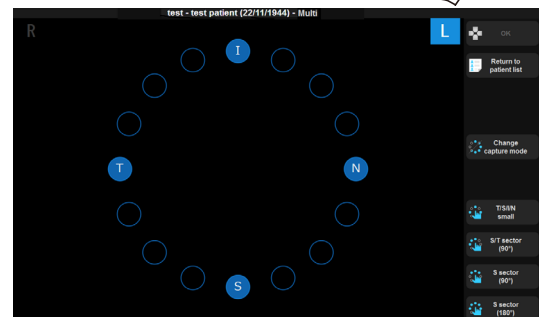


When the “Initial exam mode” setting is not “Multi capture”, the alignment screen is displayed. When Multi capture mode is entered by selecting [Change capture mode] and [Multi capture], the capture position select screen is displayed.



- 3 Select the desired capture position on the capture position select screen. Then press [OK] to show the alignment screen.

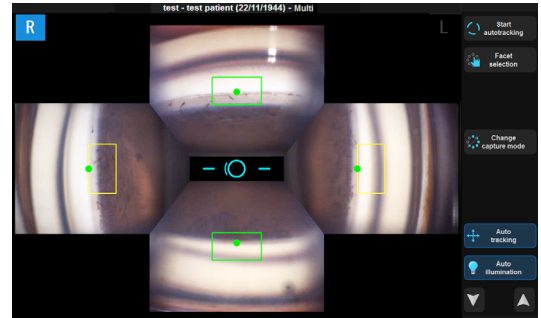
“3.6.3 Operation in capture position select screen (Multi capture)” (page 69)



4 Adjust the alignment and focus.

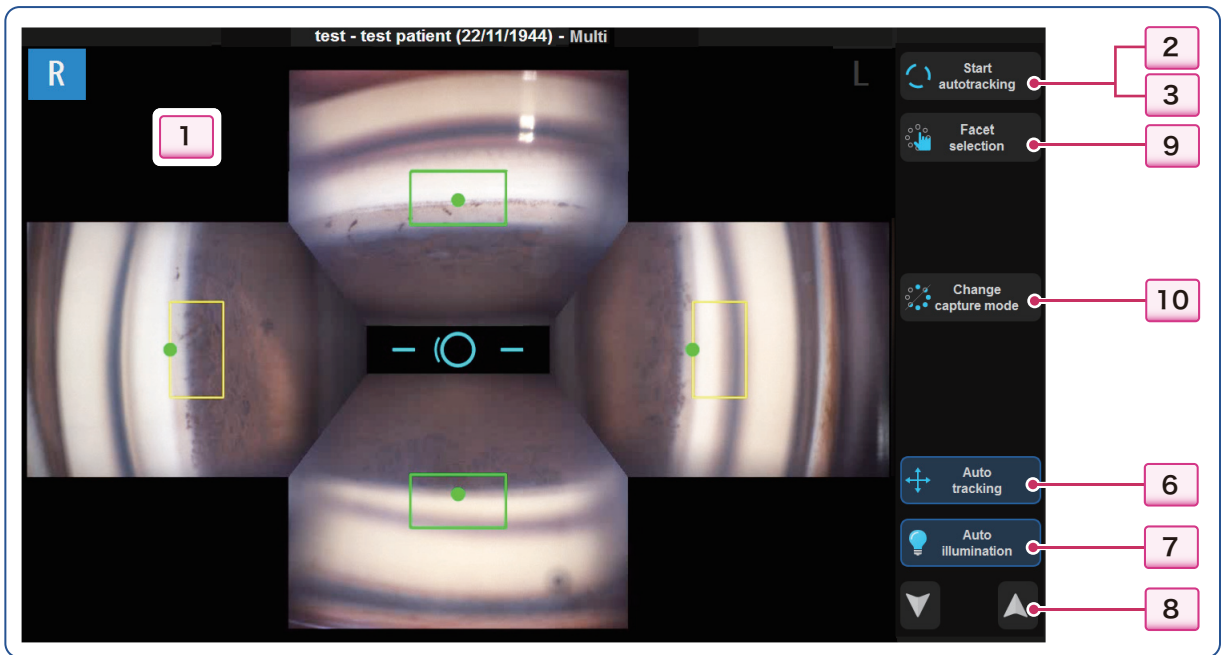
The procedure after displaying the alignment screen is the same as Step 3 and later in Full capture mode.

➡ “3.5 Image Capture in Full Capture Mode” (page 52).



◆ Difference from Full capture mode

Alignment screen (Multi capture)



The functions from **1** to **8** are the same as those in Full capture mode. Only the functions shown below differ.




<p>9</p>  [Facet selection]	<p>Returns to the capture position select screen on which the capture pattern is selected.</p> <p>To cancel image capture, press this button to return to the capture position select screen, then press  [Back].</p>
<p>10</p>  [Change capture mode]	<p>Pressed to toggle between Full and Single capture modes to switch the alignment screen.</p>

Image capture screen (Multi capture)

The positions at which no image is captured are indicated by a solid gray circle (●).

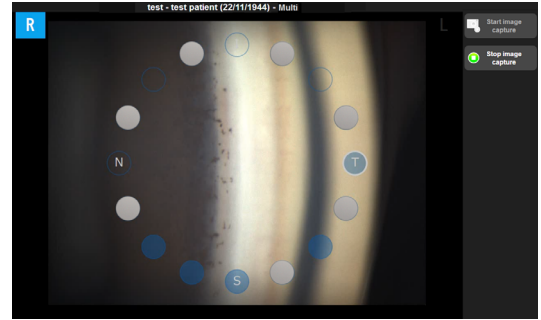




Image display screen (Multi capture)

 [Display comment] is displayed instead of  [Choose view].

In Multi capture mode, the entire circumference is not captured. Therefore, no stitching image can be displayed.

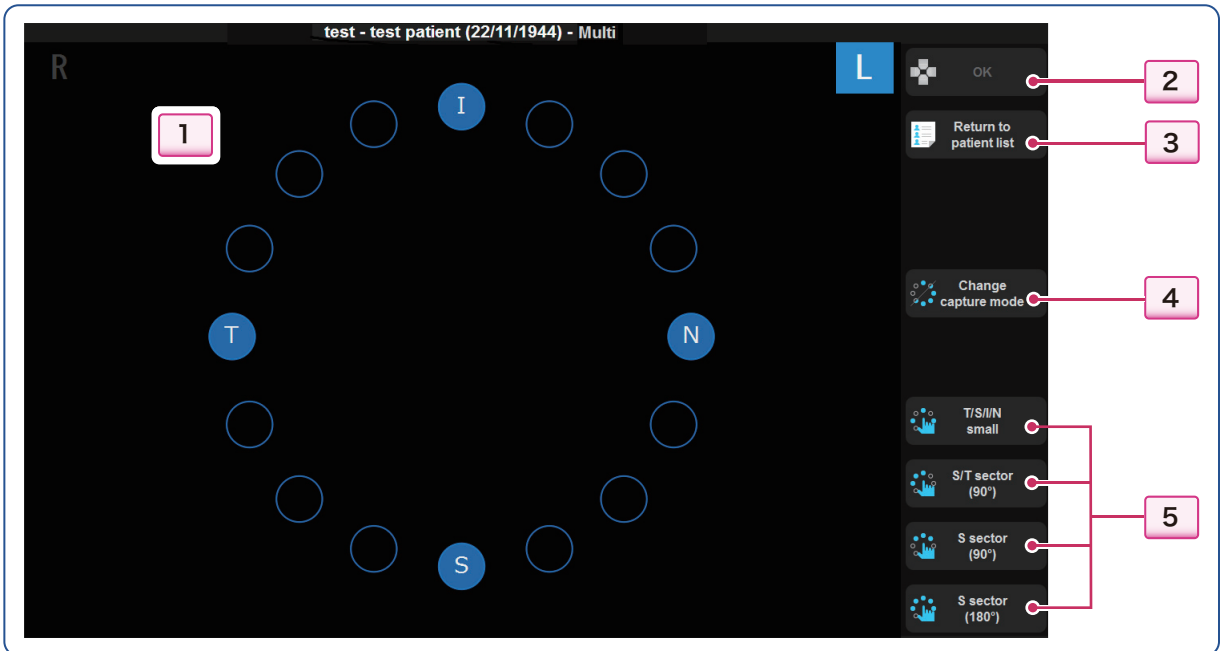






3


3.6.3 Operation in capture position select screen (Multi capture)

When Multi capture mode is selected, the capture position select screen is displayed. When the desired capture position is selected, the alignment screen is displayed.

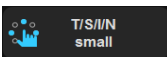


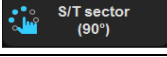




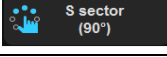




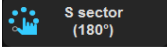




In Multi capture mode, you can select the desired positions, or select from 14 registered patterns to start image capture.



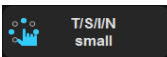







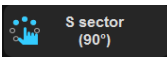




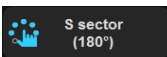




1	Capture position display	<p>The positions selected for image capture are indicated by a solid gray circle (●).</p> <p>To select the positions, press the desired blank blue circle (○) on the screen. Capture positions can also be selected by pressing the desired capture pattern from the registered ones.</p> <p>When all the 16 positions are selected, the image display screen for Full capture mode is displayed after image capture.</p>
2	 [OK]	Pressed to display the alignment screen for the selected position.
3	 [Return to patient list]	The Patient list screen is displayed.
4	 [Change capture mode]	Pressed to toggle between Full and Single capture mode to switch to the alignment screen.
5	 [(Capture pattern)]	<p>Toggles the capture pattern displayed on the screen.</p> <p>The buttons show the names of the capture patterns that can be displayed by pressing the button.</p> <p>After the desired capture pattern is selected, capture positions can be added by the screen operation.</p>

Capture patterns that can be selected with  [(Capture pattern)].

For right eye

T/S//N 	Small 	Large 			
90° sector 	S/T 	I/T 	I/N 	S/N 	
90° sector 	S 	T 	I 	N 	
180° sector 	S 	T 	I 	N 	

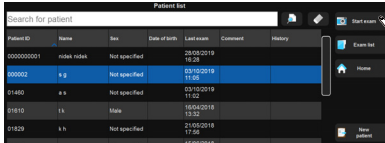
For left eye



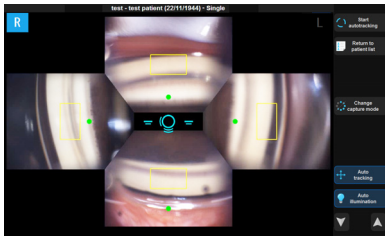
T/S//N 	Small 	Large 			
90° sector 	S/T 	I/T 	I/N 	S/N 	
90° sector 	S 	T 	I 	N 	
180° sector 	S 	T 	I 	N 	



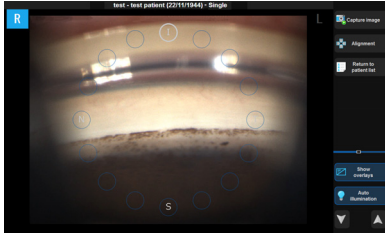
3.7 Image Capture in Single Capture Mode


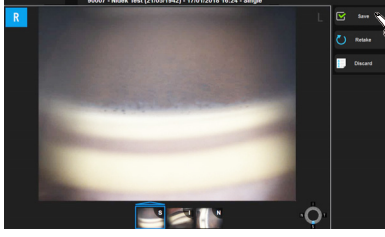
3.7.1 Outline of Single capture


In Single capture mode, images are captured at the positions that the operator selects from the 16 positions created by dividing the circumference of the anterior chamber angle. The operator adjusts the focus while observing the displayed image, and captures an image when the proper conditions are achieved.


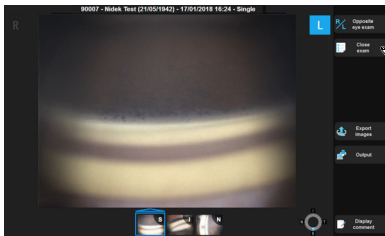
- 1**  **Patient list screen**

After preparation for the patient and the device, press  [Start exam] to start image capture.
 (page 48)
- 2**  **Alignment screen**


Adjust the alignment and focus, start the tracking, then press the focus knob button (or  [Select image]) to display the image capture screen.
 (page 80)
- 3**  **Image capture screen**


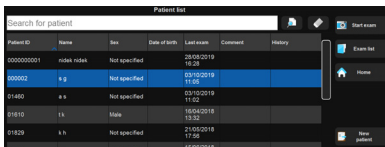
Select the desired capture position, then adjust the focus using the focus knob. Press the start button (or  [Capture image]) to start image capture. Repeat image capture at the selected positions.
- 4**  **Image confirmation screen**

Check the captured image. When it is acceptable, press  [Save] to save it. If necessary, retake images.

To capture the other eye, repeat (2) to (4).
 (page 79)
- 5**  **Image display screen**

Allows exporting of various images, printing of a report, changing of the best focus image, and display of stitching image.


Press  [Close exam] to finish image capture.

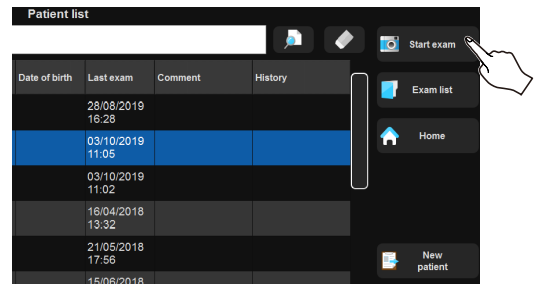
The image display screen can also be displayed from the saved exam result.
 (page 87)
- 6**  **Patient list screen**

When image capture is finished, the Patient list screen is displayed.

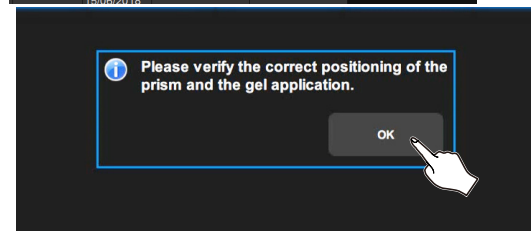
3.7.2 Image capture procedure (Single capture)



In Single capture mode, the operator selects one position from 16 separate positions of anterior chamber angle. While checking the displayed image, tune the focus.

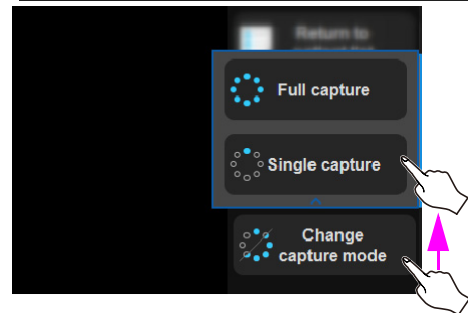
- 1 Press  [Start exam] on the Patient list screen to start an image capture.



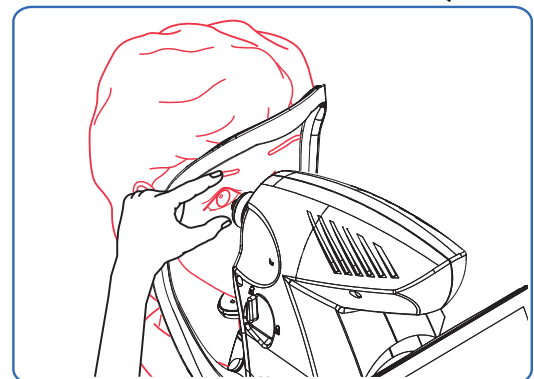
- 2 The confirmation message regarding the MM prism and gel application appears. Check them and press [OK] to display the alignment screen.



When the “Initial exam mode” setting is not “Single capture”, the screen for the preset capture mode is displayed. Select  [Change capture mode], then  [Single capture] to enter Single capture mode.

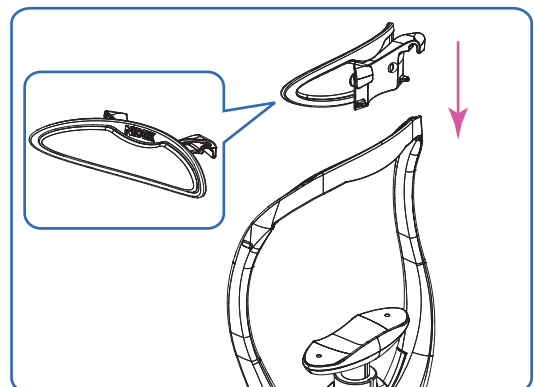


- 3 While lifting the patient's eyelid, slowly move the image capturing unit closer to the patient until the gel slightly contacts the patient's eye.

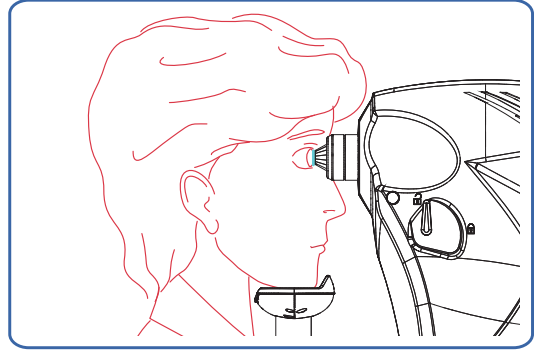


If the distance between the patient's eye and image capturing unit is too close, attach the forehead arm to the device for the image capture.

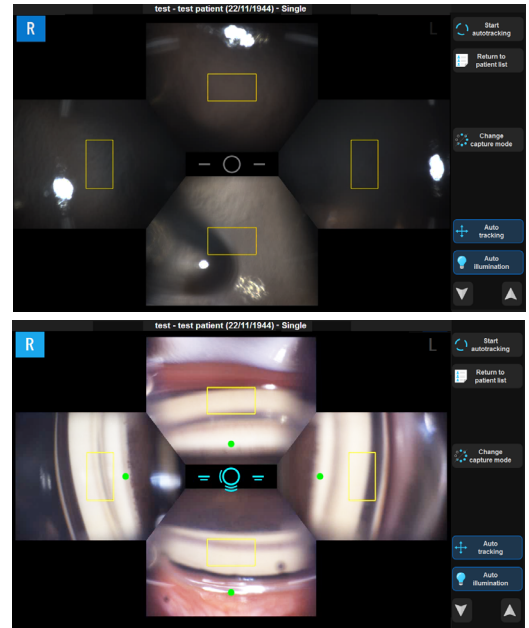
Wipe the area that comes into direct contact with the patient's forehead with a clean gauze or absorbent cotton. If necessary, wipe with a clean cloth dampened with rubbing alcohol.



- 1) Operate the joystick and roughly align the device to the patient's eye. While watching the patient from the side, move the image capturing unit closer to the patient. Take proper care that the image capturing unit does not come into direct contact with the patient's eye.



- 2) A dark image is displayed when the gel directly contacts the patient's eye. The image becomes brighter by moving the device to the WD (approximately 1.5 mm).

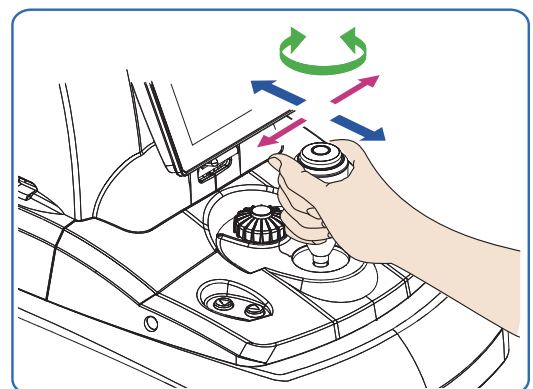


Note

- If an image capture takes longer time than specified (3 minutes and 45 seconds) after the alignment screen is displayed, the message "Illumination LED lighting time beyond specified time for safety. Exam will be canceled." appears. Then, the image capture automatically finishes.
- If a patient has a difficulty in maintaining fixation, use the external fixation lamp (optional). Ask a patient to keep on looking at the external fixation lamp with unexamined eye. Doing so can fix the patient's visual line.

- 4 While checking the image on the alignment screen, operate the joystick to obtain the focus and alignment.

On the alignment screen, the operator can align the image capturing unit to patient's eye properly.

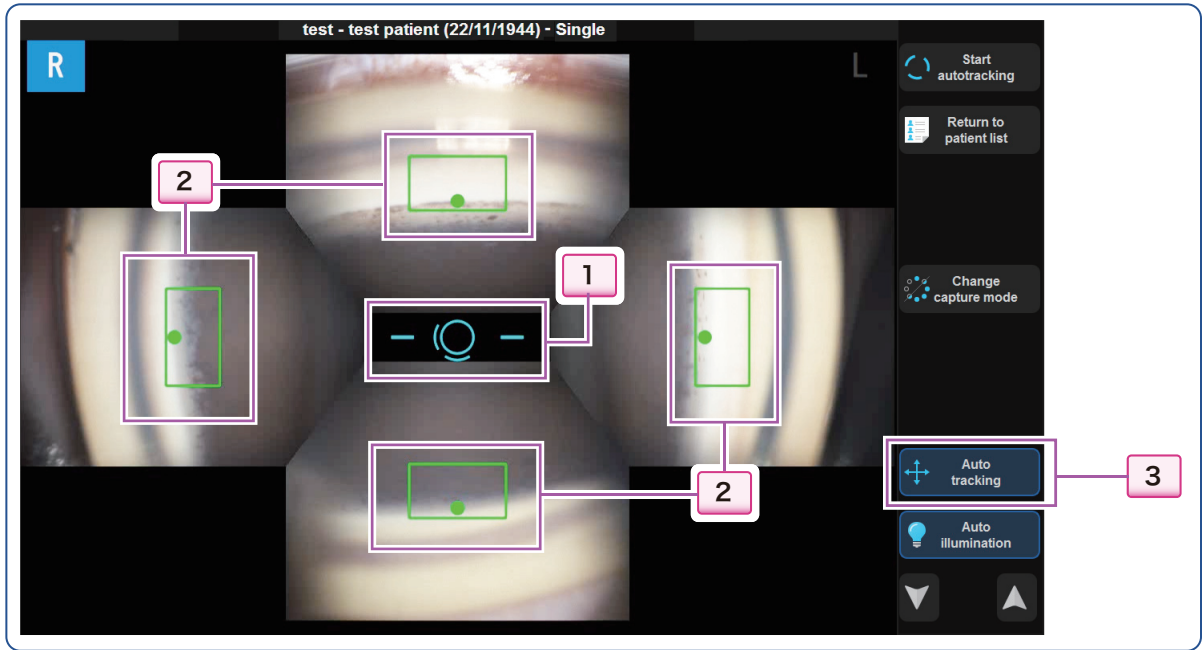


1


Indicator shows the best state (- ● -).


2	At least three of square frames, which indicate the center of capturing area, are shown in green.
3	The alignment in the vertical and horizontal directions can be performed with the auto tracking.

The alignment in the vertical and horizontal directions can be performed automatically. For the alignment in the forward and backward directions, operate the joystick.

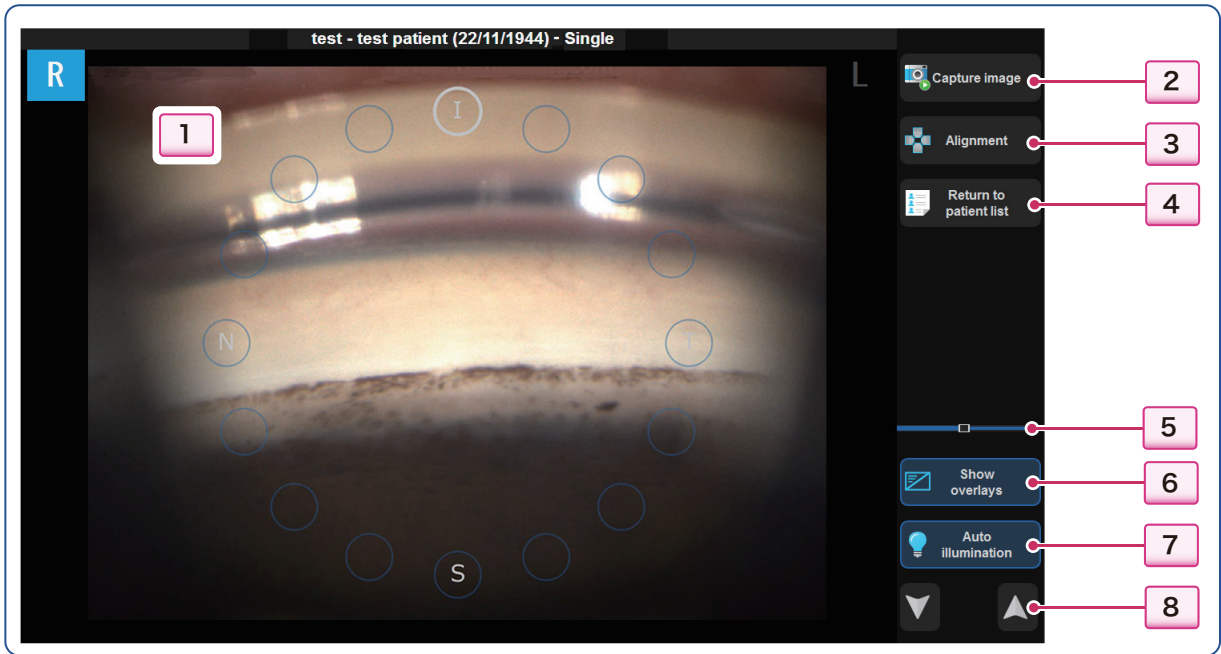


5 When the alignment and focus are obtained, display the image capture screen.









Auto switching	The screen is automatically switched to the image capture screen. When the auto tracking is turned on, the auto start (automatic switching to the image capture screen) functions.
Focus knob button	Pressing the focus knob button (or  [Select image] on the touch screen) switches the screen to the image capture screen and starts an image capture.


When the auto tracking is enabled, the image capture screen can be displayed only during the tracking (=  =).

6 Press an overlay on the image to select the capturing position.



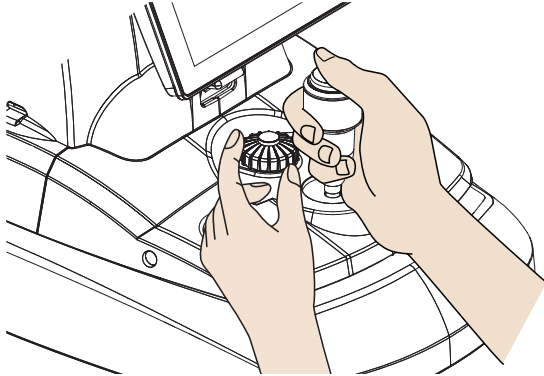
3

1	Image display	The image at the selected position is displayed. The captured position (indicated with a blue circle) and the image position that is currently displayed on the screen (indicated with a white ring) are shown in an overlay format.
2	 [Capture image]	Pressed to start an image capture.
3	 [Alignment]	Pressed to display the alignment screen. The captured image is not discarded.
4	 [Return to patient list]	Pressed to return to the Patient list screen. When an image is captured, the icon changes to  [Done].
	 [Done]	Pressed to finish an image capture and display the image display screen.
5	Focus bar	Indicates the focus position adjusted with the focus knob.
6	 [Show overlays]	Pressed to display/hide the overlay images. To specify a capturing position, it is necessary to display the overlay images.
7	 [Auto illumination]	Pressed to turn on or off the auto illumination function. When it is turned off, the operator should adjust the brightness manually.
8	 (Illumination adjustment)	When the auto illumination function is turned off, set the illumination brightness in the range of 0 to 100%

- 7** Turn the focus knob to tune the focus. Then, press the start button (or  [Capture image] on the touch screen) to start an image capture.

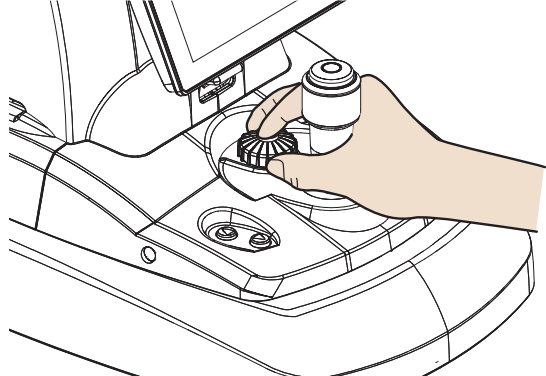
The current focus position is displayed on the focus bar.

Operation with both hands



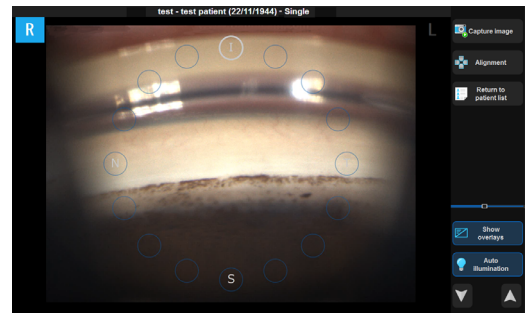
Operate the joystick and focus knob.






Operation with single hand



When lifting patient's eyelid with one hand, turn the focus knob with the other hand.


- 8** After the image capture, the captured image (still image) is displayed on the screen. Check the image and determine whether it is proper. Then, press the button corresponding to the operator's decision.



<p>Accepting the displayed image</p>	<p>Change the capturing position and continue the image capture. When finishing the image capture, press  [Done].</p>
<p>Discarding the captured image and capturing images at the same position</p>	<p>Adjust the focus, then press the start button (or  [Capture image]) to retake images. Only the latest captured image is retained.</p>
<p>Retrying from the alignment</p>	<p>Press the focus knob button (or  [Alignment]) without moving the main body position. The alignment screen is displayed. Return to Step 4 and retake an image.</p>
<p>Discarding the captured image and canceling an image capture</p>	<p>Pull the device to the operator's side and press  [Done]. The image confirmation screen is displayed. Pressing  [Abort] discards the current image and returns to the Patient list screen.</p>


9 Repeat Steps 6 to 8 until an image is captured as intended.

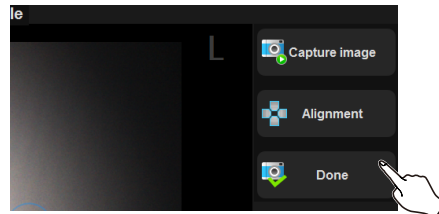
Only one image can be captured at each position. Only the latest image is kept.

If the position is misaligned, press the focus knob button (or  [Alignment] on the touch screen) to return to the alignment screen.

Note

- Capturing a circumference image (consists of 16 separate images) in Single capture mode also can display a stitching image.

10 To finish the image capture, press  [Done].



11 The image confirmation screen is displayed. Pull the device closer to the operator's side and perform the following.

Perform necessary treatment on the examined eye.


- Allow the patient to blink to rest their eyes.
- Wipe out the remaining gel.
- If necessary, instruct the patient to wash their eyes.

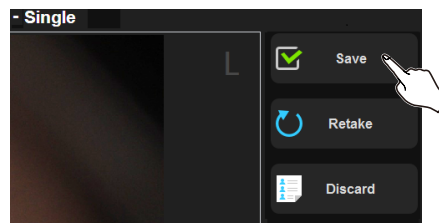


12 Check the image on the image confirmation screen.

On this screen, the operator can perform the operation such as checking/selecting, retaking, or canceling an image capture.

For details, see “3.5.4 Checking captured images (image confirmation screen)” (page 64).

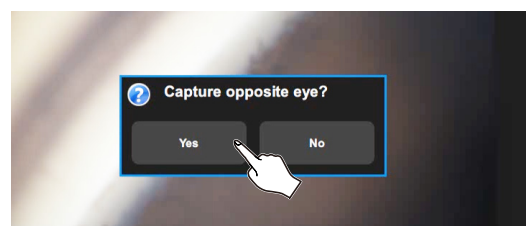
13 On the image confirmation screen, press  [Save] to complete the image capture of current eye.



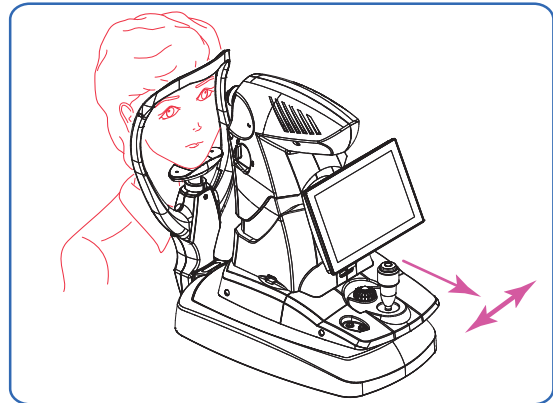
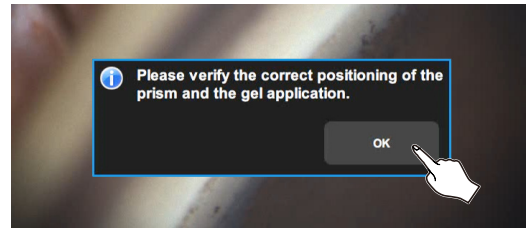
The image is saved and the confirmation message asking whether to switch to the opposite eye appears.

[Yes]	Capture an image of the other eye.
[No]	After the right or left eye image is captured, finish the image capture. Then, display the image display screen.

14 When capturing an image of the opposite eye, press [Yes] on the confirmation message and perform the same procedure.



- 1) The confirmation message regarding the MM prism and gel application appears. Check them and press [OK] to display the alignment screen.
- 2) Lock the image capturing unit with the image capturing unit locking lever. Then, apply the gel to the MM prism again.
If air bubbles or impurities are trapped in the applied gel, wipe out the gel then apply it again.
- 3) Keep the device to the operator's side and move the device in the right and left directions.
- 4) Unlock the image capturing unit with the image capturing unit locking lever.



15 Capture images of the opposite eye with the same procedure.

16 After saving images on the image confirmation screen, pull the device toward the operator and perform necessary treatment for the patient.

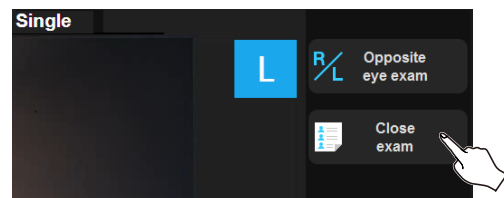
17 When the image capture is complete, the saved image is displayed on the image display screen. Perform the necessary operations.

- Checking of saved image
- Printing of the report
- Outputting of data
- Inputting of image capture comment



Operations on image display screen: "3.9 Operations on Image Display Screen" (page 87)

18 Press [Close exam] on the image display screen to return to the Patient list screen.

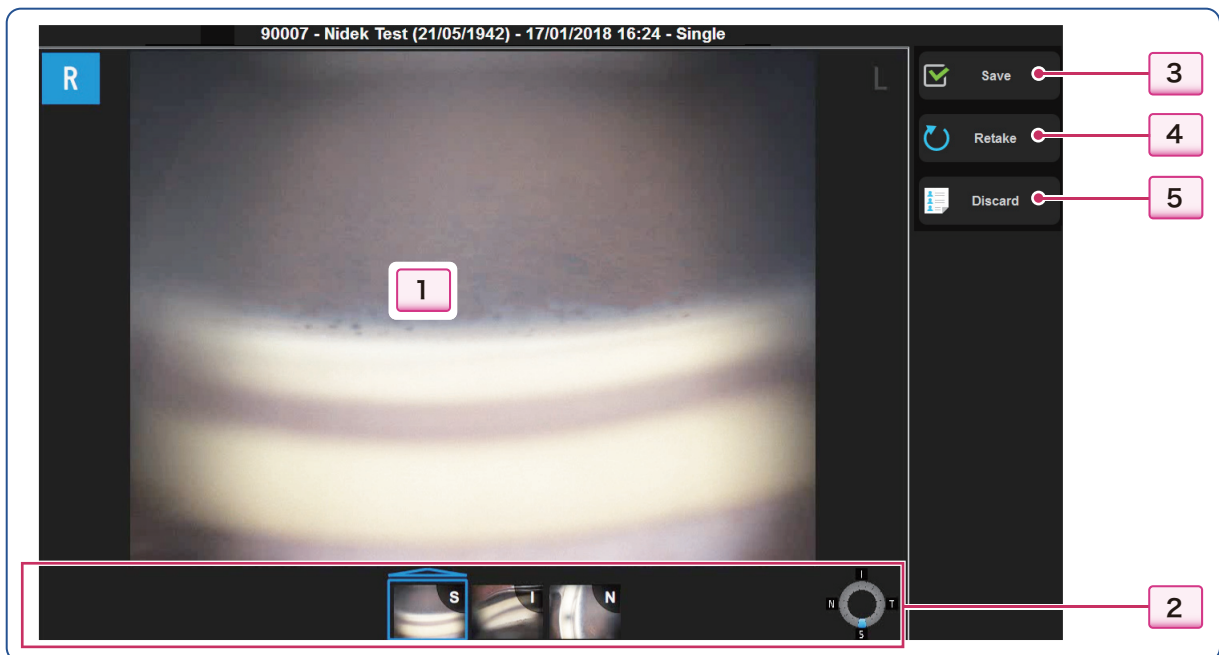





3.7.3 Checking captured images (image confirmation screen)

Check the captured images before saving them. On this screen, the operator can check the data, then save data, retake images, or cancel image capture.

◆ Operations in Single capture mode

In Single capture mode, only one image is captured at each capture position. Therefore, the display of all thumbnail images does not appear.



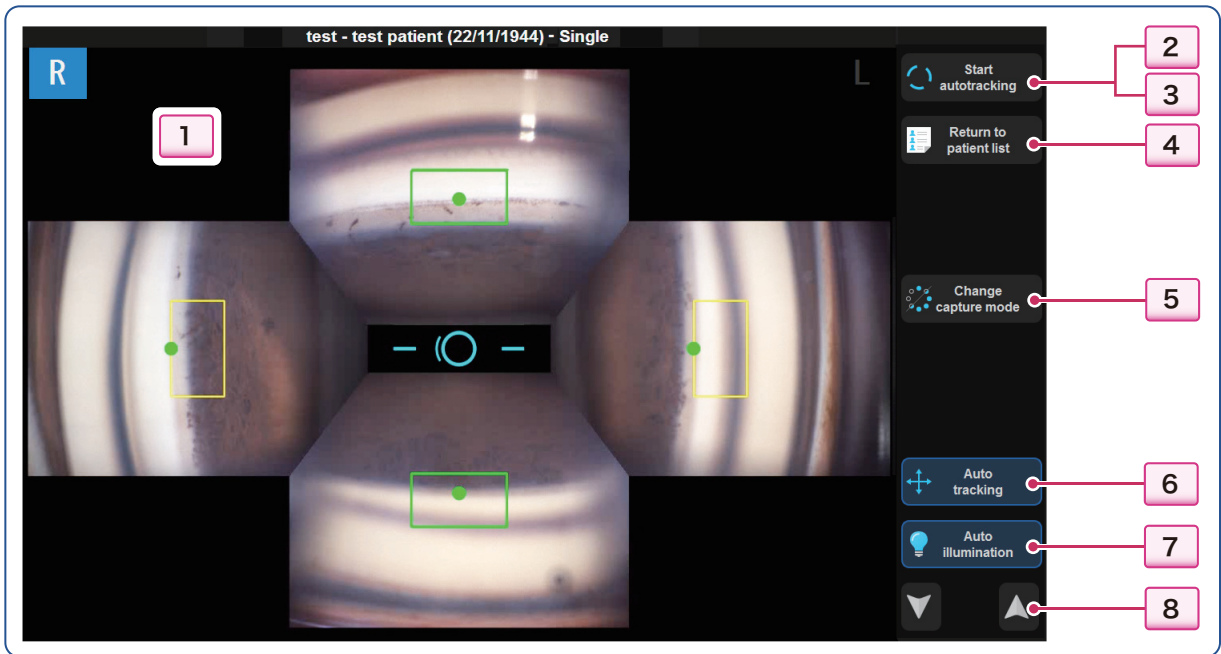
1	Image display	Enlarging or reducing the image: Pinch-out or pinch-in Moving the image: Sliding (Dragging) Displaying image magnifications: Double-tap
2	Thumbnail images	The thumbnails of best focus images at the capture positions are displayed. The thumbnail of the displayed image is indicated with a blue frame. Drag or press the thumbnail image to change the displayed image. The capture position of the selected image is indicated by the blue portion in the T-S-N-I chart.
3	 [Save]	Pressed to save the current image. After the image is saved, a message asking whether to capture the opposite eye image appears. Selecting [Yes] switches the image capture target between right and left eyes. Selecting [No] finishes the image capture, and displays the image display screen.
4	 [Retake]	Pressed to display the alignment screen. The confirmation message for the MM prism and gel application appears. Pressing [OK] displays the alignment screen. When an image is captured with a capture position selected on the capture screen, the previous image is overwritten.
5	 [Abort]	Pressed to discard the captured images and return to the Patient list screen. A message appears to confirm discarding of data. Pressing [Yes] returns to the Patient list screen.











3.7.4 Adjusting alignment and focus (alignment screen)


On the alignment screen, the operator can adjust the alignment in the vertical and horizontal directions, and the focus in the forward and backward directions.

The purpose of the focus adjustment at this point is to bring the image capturing unit to a proper working distance. It is unnecessary to achieve a proper focus on the displayed angle image yet.

◆ Operations on alignment screen (Single capture)



1	Image display	Displays the images for alignment in the vertical and horizontal directions and an alignment and working distance indicator. Patient ID, name, date of birth, and image capture mode are displayed in the upper part of the screen.
2	 [Start autotracking]	Pressed to start the auto tracking. Pressing the start button also starts the auto tracking. During the auto tracking, the icon  [Start autotracking] changes to  [Select image].
3	 [Select image]	Pressed to display the image capture screen. On the image capture screen, the operator can select the image capturing position and start image capture. Pressing the focus knob button also displays the image capture screen.
4	 [Return to patient list]	The Patient list screen is displayed.
5	 [Switch to full capture]	Pressed to switch to the alignment screen in Full capture mode.
6	 [Auto tracking]	Pressed to turn on or off the auto tracking function. When it is turned off, the icon  [Start autotracking] does not appear. The icon  [Select image] remains on the screen.
7	 [Auto illumination]	Pressed to turn on or off the auto illumination function. When it is turned off, the operator should adjust the brightness manually.

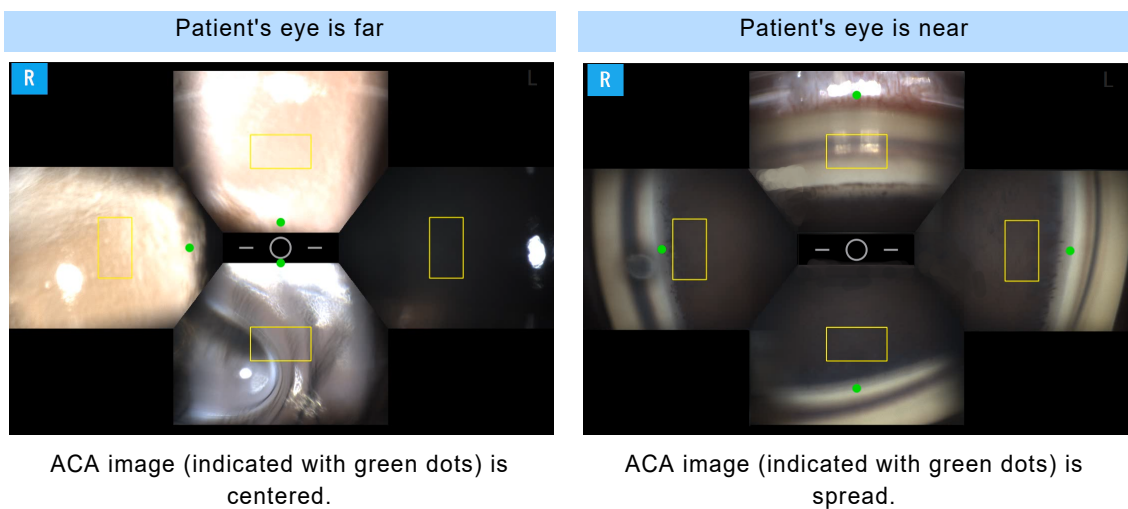
8	 (Illumination adjustment)	When the automatic illumination adjustment function is turned off, set the illumination brightness in the range of 0 to 100%.
----------	--	---

◆ Obtaining alignment and focus (Single capture)

The alignment and focus are adjusted, then the image capture screen is displayed.

1 Roughly adjust the focus.

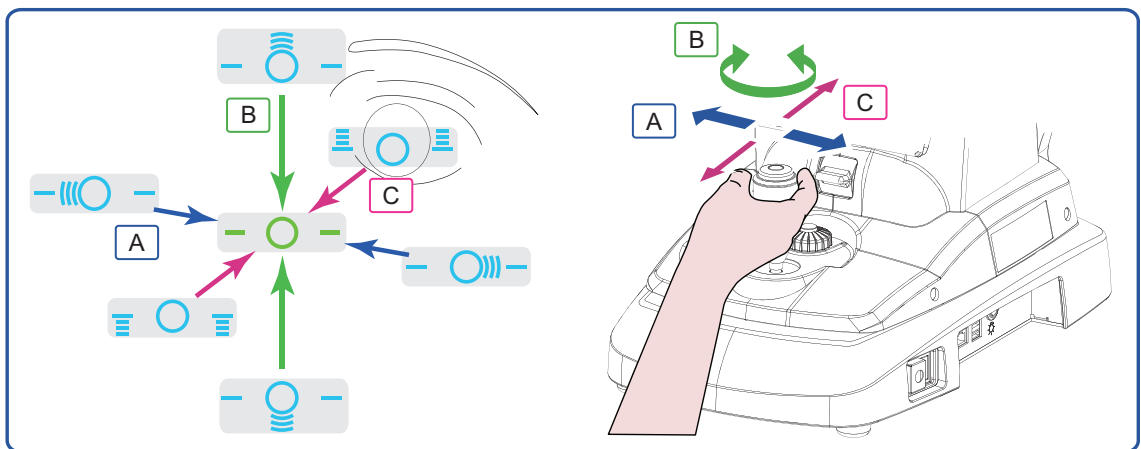
Tilt the joystick forward and backward so that anterior chamber angle images are displayed near the rectangle frames in each direction.



2 Operate the joystick while referring to the focus indicator and alignment display.

Ensure that the indicator shows the best state (- ● -).


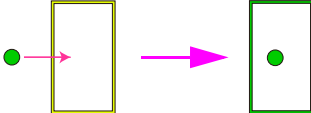
A clear image can be captured by achieving a proper working distance from the trabecular meshwork.




A	Alignment in the horizontal direction Tilt the joystick to the right and left.
B	Alignment in the vertical direction Rotate the joystick head.

C	Achieving the focus in the forward and backward directions Tilt the joystick forward and backward.
----------	---

● Alignment in the vertical and horizontal directions

<p>Central indicator of alignment circle</p>  <p>Operate the joystick so that the indicator disappears. The shift amount in the vertical or horizontal direction is indicated by the number of lines.</p>
<p>Yellow frames displayed on four images</p>  <p>Operate the joystick so that the green dot comes inside the frame. When the dot is in the frame, the frame color changes to green. The rectangle frame indicates the center of capturing area, and the green dot indicates the automatically detected trabecular meshwork area.</p>





● Achieving focus in the forward and backward directions

<p>Match the focus indicator with the reference icon.</p>  <p>Tilt the joystick in the forward and backward directions so that the indicator shows the best state (- ● -). When the indicator lines appear on the upper side, move the device away from the patient. When the indicator lines appear on the lower side, move the device closer to the patient. The number of lines indicates the shift amount.</p>

● When the alignment is not within the auto tracking range

Tilt the joystick in the direction of red arrow for the limit indicator.


The limit indicator appears when the auto tracking function is turned on.




<p>Up/down ( / )</p>	Move the image capturing unit up or down by turning the joystick.
<p>Left/right ( / )</p>	Move the image capturing unit (and the main unit) right or left by tilting the joystick.


3 Finely adjust the alignment using the joystick.

The procedure varies depending on whether auto tracking is turned on or off.

- When auto tracking is turned on

- 1) Adjust the alignment and focus. Then, press the start button (or  [Start autotracking] on the touch screen) to start the auto tracking.

When the auto tracking starts, the indication  [Start autotracking] switches to  [Start image capture] ( [Select image]).


A circle in the center of the screen starts rotating (), indicating that the auto tracking is being performed.

- 2) While referring to the alignment indicator, perform an adjustment so that no indicator line appears in any direction.

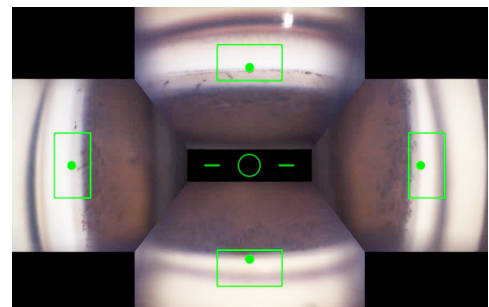
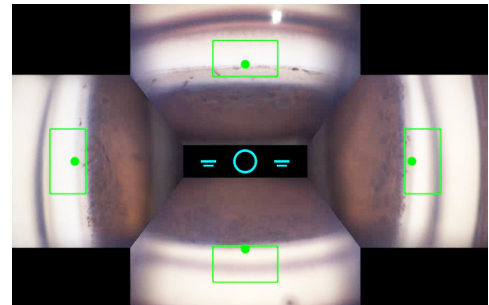
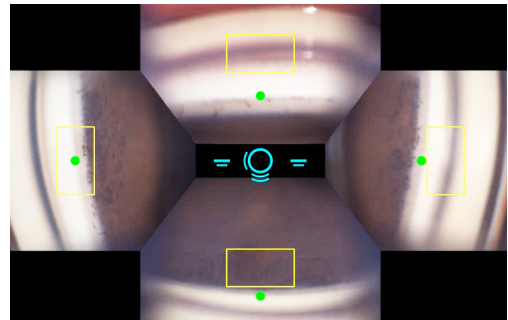
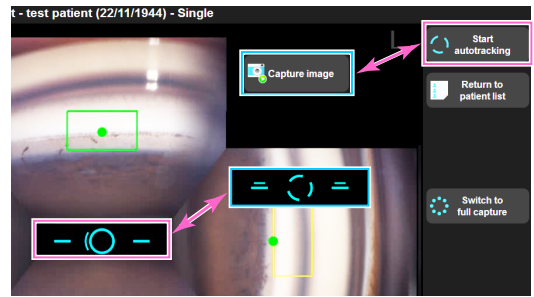
- 3) The auto tracking function performs the alignment in the vertical and horizontal directions, and the green frames are displayed.

- 4) While referring to the focus indicator, adjust the focus in the forward and backward directions.

- 5) When the alignment and focus are proper, the image capture screen is displayed by the auto start function. In Full capture mode, automatic image capture starts.


Pressing the focus knob button (or  [Select image]) also switches the screen to the image capture screen.

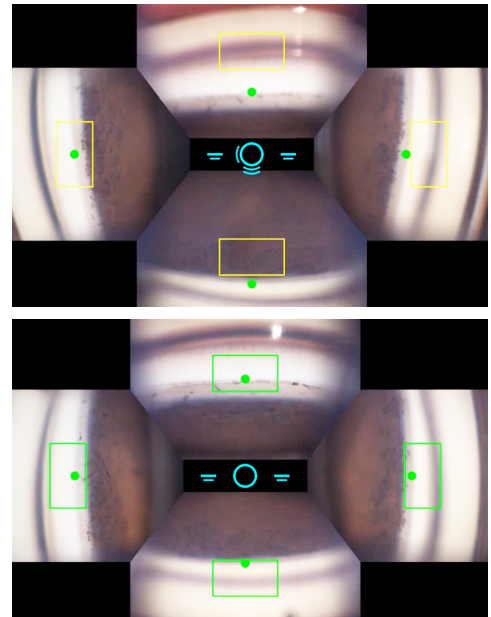
After a certain period of time, auto tracking automatically stops. In this case, repeat the procedure from Step 1).



- When auto tracking is turned off

Because the auto start function is turned off, manually display the image capture screen.


- 1) While referring to the alignment indicator, perform an adjustment so that no indicator line appears in any direction.
- 2) Continue the alignment until green frames are displayed in all of the four images.
- 3) While referring to the focus indicator, adjust the focus in the forward and backward directions.
- 4) Press the focus knob button (or  [Select image]) to display the image capture screen.




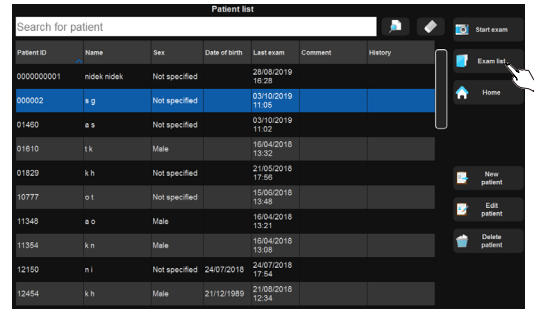
3.8 Displaying Saved Exam Data


3.8.1 Selecting exam data to display on image display screen


The operator can select an exam data from the database, and display it on the image display screen. In addition, observation, exporting, and printing of the data is also available.

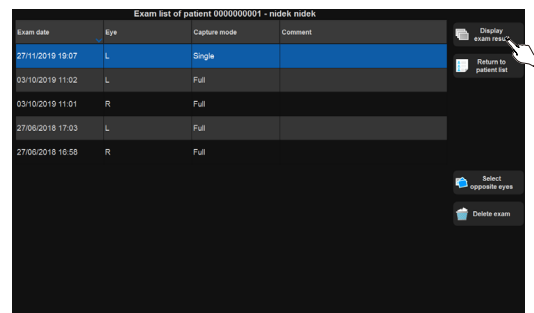
1 Press  [Start] on the home screen to display the Patient list screen.

2 Select the desired patient and press  [Exam list] to display the Exam list screen.

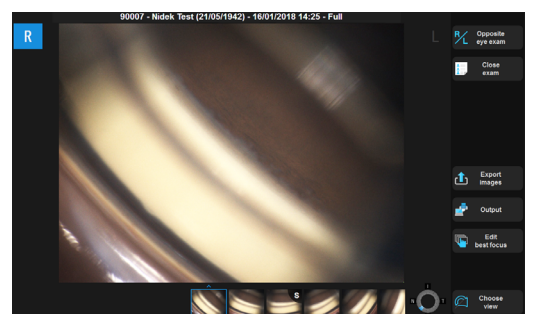


3 Select the exam data and press  [Display exam result]. The exam data is displayed on the image display screen.

Multiple exam data (one eye for each of right and left eyes) can be selected by pressing  [Select opposite eyes].



For the operations on the image display screen, see "3.9 Operations on Image Display Screen" (page 87).



3.8.2 Operations on Exam list screen

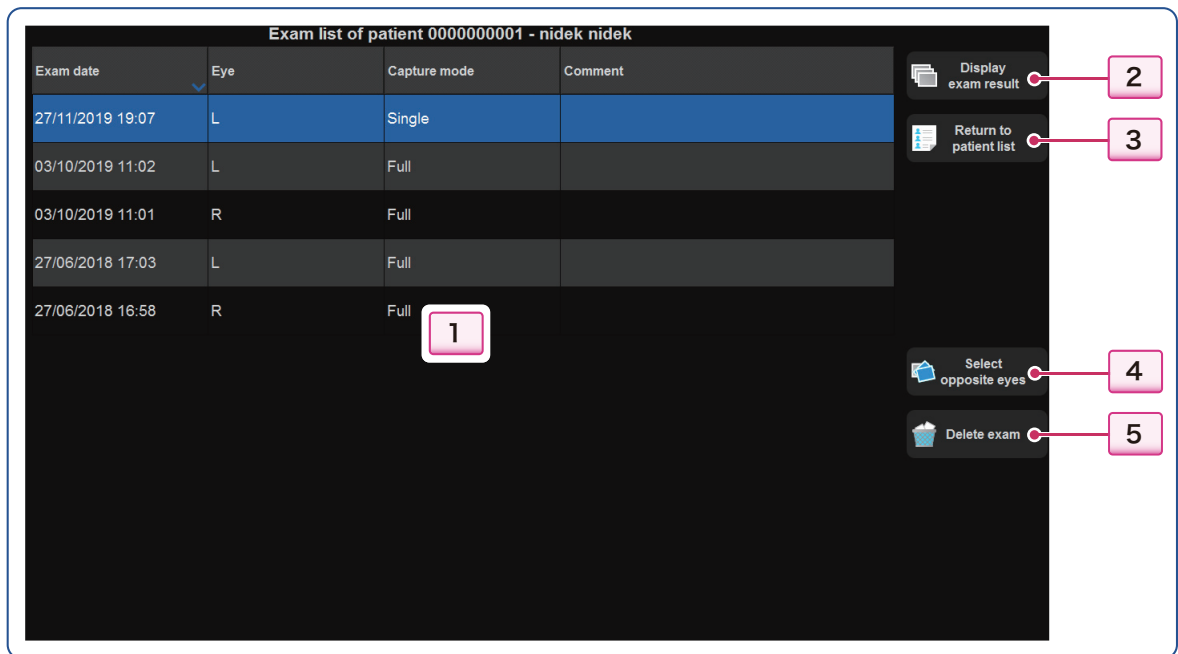
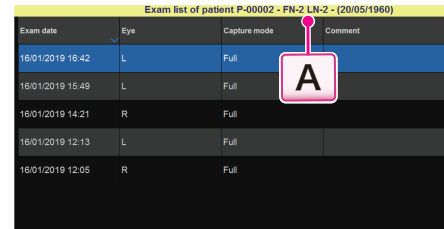
The exam list of the selected patient is displayed on the exam list screen. On this screen, the operator can select exam data, display captured images and report, and delete the exam data.





Note

- On the Exam list screen, exams can be deleted one by one. Deletion of the patient information and all exam data can be performed from the Patient list screen.
- When the database save destination is NAVIS-EX and the selected patient data is used on another device, "Exam list of patient" at the top of the screen **A** is highlighted in yellow.

The exam data cannot be edited or deleted.

Closing the patient data on another device allows the exam data to be edited.




1	Exam list	Displays the list of exam data. The information regarding the image capture (Exam date, eye, and capture mode) of each data is displayed in the list. Select the exam data to be displayed. Pressing the date, eye, or capture mode rearranges the exam list in an ascending/descending order.
2	 [Display exam result]	Pressed to display the selected exam data on the image display screen.
3	 [Return to patient list]	The Patient list screen is displayed.
4	 [Select opposite eyes]	Pressed to enable the operator to select several exam data (both right and left eye data). Pressing each exam data selects/deselects it.
5	 [Delete exam]	Pressed to delete the selected exam data. The confirmation message appears. Pressing [Yes] deletes the selected data. The Delete exam button is not displayed when the device is connected to NAVIS-EX.

3.9 Operations on Image Display Screen

The exam data selected on the Exam list screen is displayed on the image display screen. On this screen, the operator can change, print, and export the image data.

To display the image display screen, press  [Display exam result] on the Exam list screen. At the time of image capture, the image capture screen is displayed after the image confirmation screen.

Note

- When the database save destination is NAVIS-EX and the selected patient data is used on another device, "Exam list of patient" at the top of the screen  is highlighted in yellow.

The exam data cannot be edited or deleted.

Closing the patient data on another device allows the exam data to be edited.

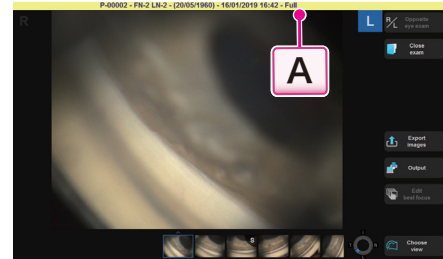


Image confirmation screen (Full capture)

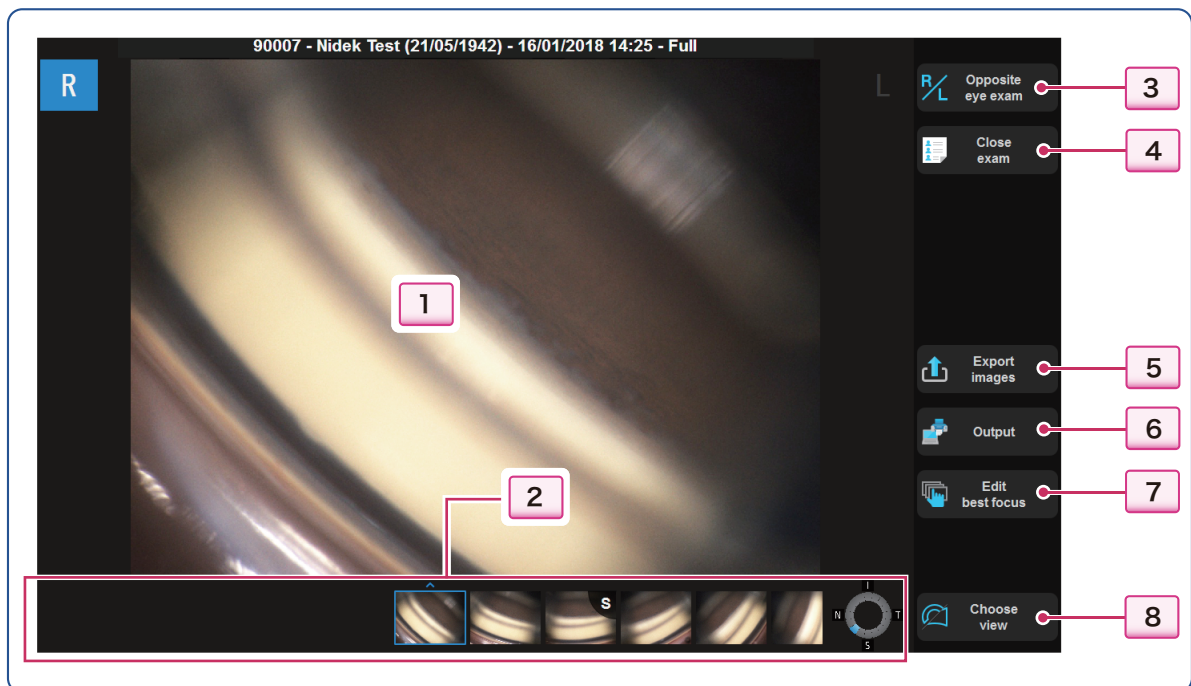
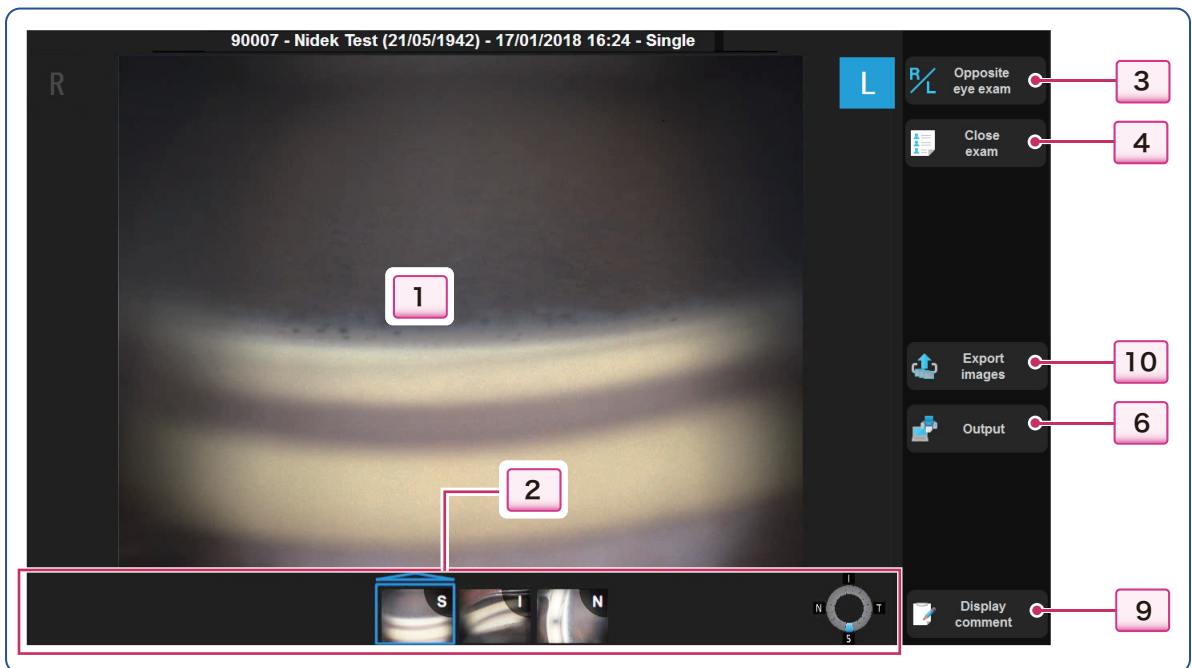








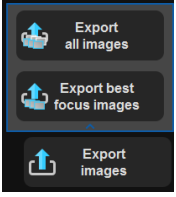




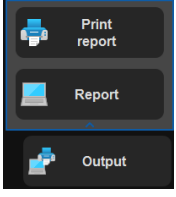









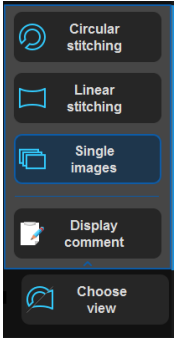

Image display screen (Multi capture)





Image display screen (Single capture)






<p>1</p>	<p>Image display</p>	<p>Enlarging or reducing the image: Pinch-out or pinch-in Moving the image: Sliding (Dragging) Displaying image magnifications: Double-tap</p>
<p>2</p>	<p>Thumbnails</p>	<p>The thumbnails of best focus images at the capture positions are displayed. The thumbnail of the displayed image is indicated with a blue frame. Drag or press the thumbnail image to display another image. The capture position of the selected image is indicated by the blue portion in the T-S-N-I chart.</p>

<p>3</p>	 [Opposite eye exam]	<p>Pressed to switch the display between right and left eye. This button is enabled when both right and left eye exam data are being selected.</p>
<p>4</p>	 [Close exam]	<p>Pressed to close the image display screen and return to the Patient list screen during image capture. When the auto print function, auto export function, or both are turned on, they are executed at the same time.</p>
	 [Close exam]	<p>Pressed to close the image display screen and display the Exam list screen during viewing of the saved image.</p>
<p>5</p>	 [Export images] (Full or Multi capture)	<p>From the pop-up menu,  [Export all images] or  [Export best focus images] is executed. All images or the best focus images of the displayed exam data are exported to the specified destination. In Full capture mode, the stitching image is also exported. Set the destination with the “Image Export 1” tab on the User settings screen. ↩ (page 137)</p> 
	<p>During image capture If Auto export is turned on,  [Export images] is not displayed.</p>	
<p>6</p>	 [Output]	<p>Executes  [Print report] or  [Report] from the pop-up menu during viewing of the saved image. Pressed to output the report of the displayed exam data to the electronic medical record system or USB removable disk.</p> 
	<p>During image capture When Auto print is turned on,  [Print report] is not displayed. When Auto export is turned on,  [Report] is not displayed.</p>	
<p>7</p>	 [Edit best focus] (Full or Multi capture)	<p>Pressed to display the Edit best focus screen to select another image. ↩ (page 94)</p>
<p>8</p>	 [Choose view] (Single capture in Full capture mode or for when the entire circumference has been captured)	<p>From the pop-up menu, select the image view from  [Circular stitching],  [Linear stitching], and  [Single images]. In addition, pressing  [Display comment] shows or hides the capture comment. When the entire circumference has been captured in Single capture mode,  [Choose view] is displayed as well, and the stitching image can be displayed. When the image capture results of both right and left eyes are being displayed, the display settings for both eyes are changed.</p> 
<p>9</p>	 [Display comment] (Single capture, Multi capture)	<p>Shows or hides the capture comment. In the comment, capture comment can be displayed, input, and edited. The input comment is displayed in the comment field on the Exam list screen.</p>

10	 [Export images] (Single capture)	Exports the displayed exam data to the specified save destination. Set the destination with the “Image Export 1” tab on the User settings screen.
During image capture If automatic image output is turned on,  [Export images] is not displayed.		

3.9.1 Exporting image data (Export images)

The image files (JPEG) and patient information file (TXT) of the displayed exam data can be exported to the specified save destination.

Operation button	Capture mode	Best focus image	Images other than best focus image	Stitching image		Patient information*1
				Circular	Linear	
 [Export all images]	Full capture	Yes	Yes	Yes	Yes	Yes
	Multi capture	Yes	Yes	-	-	Yes
 [Export best focus images]	Full capture	Yes	-	Yes	Yes	Yes
	Multi capture	Yes	-	-	-	Yes
 [Export images]	Single capture	Yes	-	_ *2	_ *2	Yes

*1: No data is exported if the "Patient information" parameter is "OFF". No data is exported if neither patient comment nor capture comment has been input.

*2: The file is exported if the entire circumference has been captured in Single capture mode.

CAUTION

- When exporting the data to a USB flash drive by pressing [Export all images], [Export best focus images], or [Report], ensure that the file system of the USB flash drive has been formatted with FAT32.

To check the file system, connect a USB removable disk to the computer and display the Property.

- For the USB removable disk specified as the destination for saving the exported image data, specify one other than those described below specified on the User settings screen. If any of them is specified, an error message appears. [↪ "4.4.3 Parameters list" \(page 135\)](#).

The drive when "Save destination" in the "DB" tab is set to "USB removable disk"

The drive when "Save destination" in the "Report1-1" tab is set to "USB removable disk"

Name of the folder generated in the save destination

It differs depending on the "Patient information" parameter setting. Set "Patient information" under the "Image Export 2" tab on the User settings screen. [↪ \(page 137\)](#)

Folder for each patient

Patient information "ON"	GS-Pat (Patient ID) - Last name - First name Example: GS-Pat00001-Smith -John
Patient information "OFF"	GS-Pat (Patient ID) Example: GS-Pat00001

Sub-folder for each exam

(Image capture date) - (Examined eye)
Example: 201911081050-R

Image capture date	YYYYMMDDhhmm (year, month, day, hour, minute of image capture)
Examined eye	R, L

Note

- If the first name or last name is not entered, “-” is not displayed even if the “Patient information” parameter is “ON”.
- If the same examination data is exported repeatedly, “-Copy (number)” is added to the folder name.
- The folder name is not influenced by the order of the first and last name, or the date in the User settings screen.

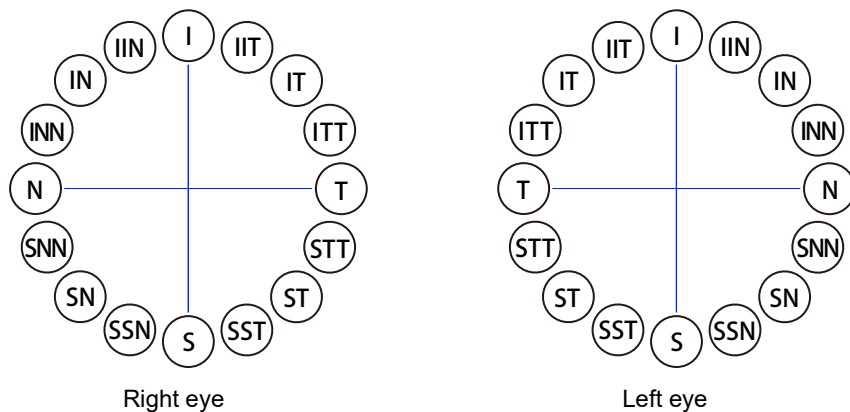
Name of image and patient information files

The files are exported to the sub-folder for each exam.

Best focus image	GS-Img (serial number) - (test eye) - (imaging position) -BF.extension Example: GS-Img008-R-SN-BF.jpg
Images other than best focus image	GS-Img (serial number) - (test eye) - (imaging position) .extension Example: GS-Img001-R-SN.jpg
Circular stitching image	GS-Stitching-Circular. extension
Linear stitching image	GS-Stitching-Linear. extension
Patient information	Comments. extension

Serial number	001-999
Examined eye	R, L
Capture position	1 to 3 digits of alphanumeric characters (See the figure below.)
Extension (image)	jpg
Extension (Patient information)	txt

The capture positions are displayed as shown below (1 to 3 digits of alphanumeric characters).



Note

- The patient information file (Comments.txt) includes the patient comments (Comment:.) and capture comments (Exam comment:).

3.9.2 Outputting reports (report output)

The report image file of the displayed exam data is output to the specified shared folder on the network, or the folder in the USB removable disk (GN001_Report folder).

The report image file to be output is specified under the "Report2" tab on the User settings screen. [↗](#)
(page 136)

Image format (file format)	JPEG, PNG, PDF
Layout (Content of report to be output)	Stitching image, 16 images, or Stitching + 16 images
Report quality (resolution)	LOW, MIDDLE, HIGH

Note

- If the layout setting is "Stitching image", and the entire circumference has not been captured, a report of 16 images is output.
- If there is no "GN001_Report" folder directly under the USB removable disk, it is automatically generated.

Name of report image file

(Patient number) _ (Date and time of image capture) _ (Examined eye) _ (Examination type) _ (Date and time of file creation and serial number).

Patient number	Patient ID (alphanumeric characters, maximum 28 digits)
Image capture date	YYYYMMDDhhmmss (year, month, day, hour, minute, second of image capture)
Examined eye	R, L
Examination type	GS (Gonioscope report)
Date and time of file creation	hhmmsszzz (hours, seconds, milliseconds of file creation)
Serial number	000-999
Extension	jpg, png, pdf


Example of file name

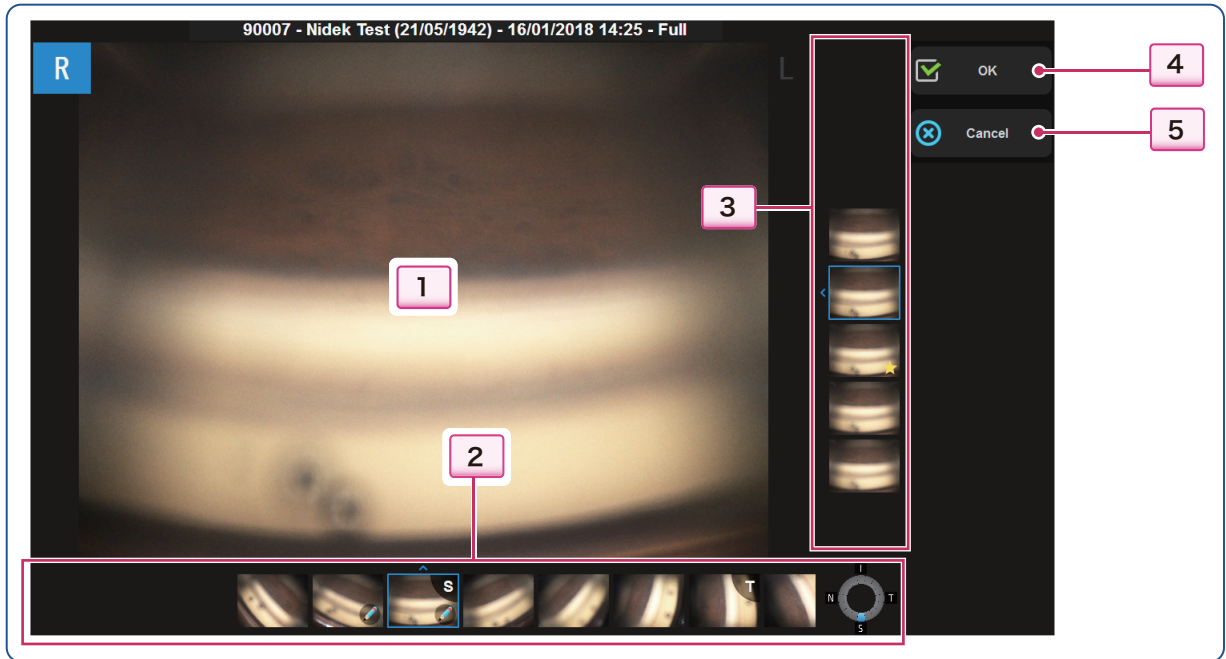
00001_20170620111632_R_GS_104521358000.jpg

00001_20170620111632_R_GS_104521358001.jpg


3.9.3 Changing selected image on the Edit best focus screen (Full capture or Multi capture)

If the automatically selected best focus image is not proper, it can be replaced with another image captured at the same capture position.


Press  [Edit best focus] on the image display screen.





Select the capture position with the image thumbnail **2**, then select the desired image from thumbnails of all images **3**.

When the best focus image is changed, the edit icon () appears on the thumbnail.



1	Image display	Enlarging or reducing the image: Pinch-out or pinch-in Moving the image: Sliding (Dragging) Displaying image magnifications: Double-tap
2	Thumbnails	The thumbnails of best focus images at the capture positions are displayed. The thumbnail of the displayed image is indicated with a blue frame. Drag or press the thumbnail image to display another image. The capture position of the best focus image is indicated by the blue portion in the T-S-N-I chart. If the best focus image is changed, the edit icon () is displayed.
3	All thumbnail images	The thumbnail images of all saved images at the selected position are displayed. The thumbnail image of the displayed image is indicated with a blue frame. Drag or press the thumbnail image to select another image. The best focus image is indicated with a star icon (★). The image in the center is the best focus image if it has not been changed after image capture.

4	 [OK]	Confirms changing of the best focus image, and returns to the image display screen. The best focus image changes to the edited one.
5	 [Cancel]	Discards changing of the best focus image, and returns to the image display screen.




3.9.4 Displaying and editing stitching images (Full capture)

The Circular stitching image or Linear stitching image can be displayed. The stitching image can be adjusted to make the seams less conspicuous.

Note

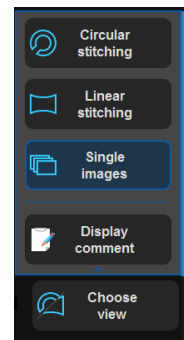
- The stitching image can be displayed and edited also when the circumference has been captured in Single capture mode.

◆ Displaying stitching image

The stitching image can be displayed by pressing  [Circular stitching] or  [Linear stitching] from the pop-up menu displayed by pressing  [Choose view] on the image display screen.

Observe the entire circumference of the anterior chamber angle with the Circular stitching image or Linear stitching image.




Enlarge or move the image for detailed observation.






Circular stitching



Linear stitching

When the stitching image is displayed,  [Edit best focus] changes to  /  [Edit stitching].

 [Edit stitching]	Shows the edit display with the edit tools for the stitching image.
 [Edit stitching]	 ◆ <i>Editing stitching image</i> (page 96)

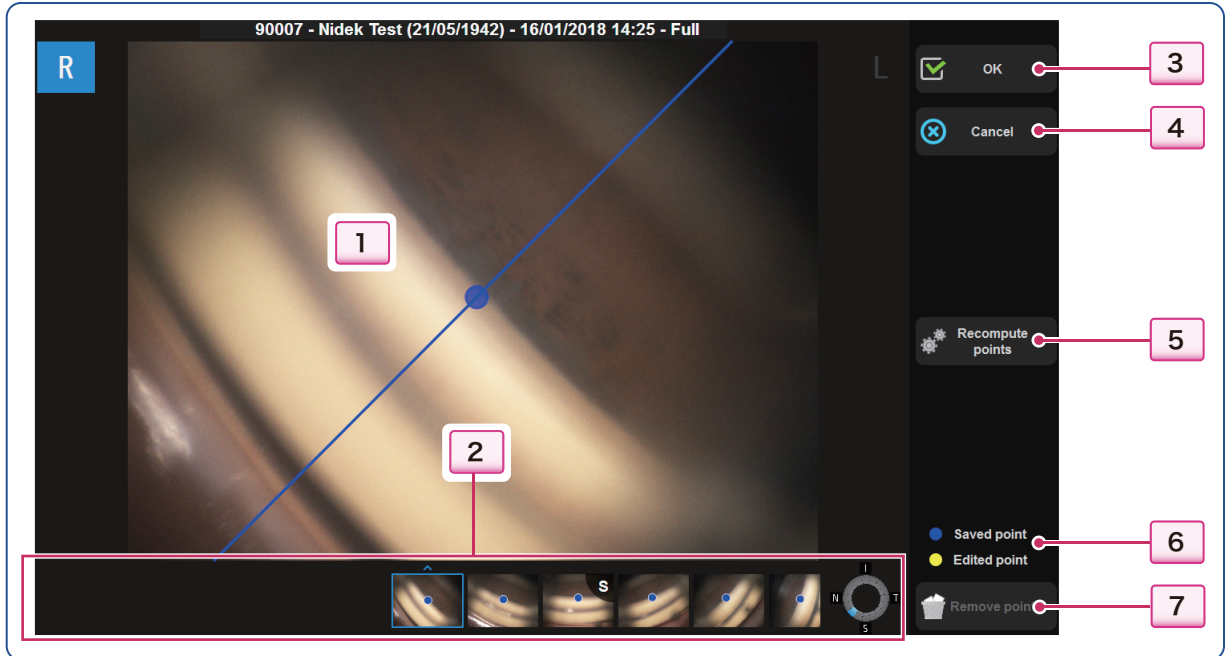
Other buttons are the same as those for single images.

To return to the display of single images, select  [Single images] from  [Choose view].


◆ Editing stitching image

If the seams of the stitching image are conspicuous, they can be adjusted.

The edit display is shown by pressing / [Edit stitching] on the image display screen that displays a Circular or Linear stitching image.



1	Image display	<p>The best focus image, reference point, and line indicating the direction to the center are displayed. The reference point can be moved. Pressing any place on the line moves the reference point to that place. The reference point indicates the anterior chamber angle, and is used for positioning of the images. The stitching image are edited by moving the reference point.</p> <p>Saved point: Blue circle (●) (Blank dotted blue line when edited (⦿)) Edited point: Yellow circle (●)</p>
2	Thumbnails	<p>The thumbnails of images at all capture positions are displayed along with the reference point. The thumbnail of the displayed image is indicated with a blue frame. Drag or press the thumbnail image to display another image. The capture position of the selected image is indicated by the blue portion in the T-S-N-I chart.</p> <p>If the reference point is moved or deleted, the edit icon () is displayed.</p>
3	[OK]	<p>The stitching image is regenerated with the edited reference points, and the stitching image display screen is displayed. The reference point moves to the edited place.</p>
4	[Cancel]	<p>Discards changing of the reference points, and returns to the stitching image display screen.</p>
5	[Recompute points]	<p>Detects reference points again. The confirmation message appears. Pressing [Yes] detects reference points again for all images.</p>
6		Explanation on reference point

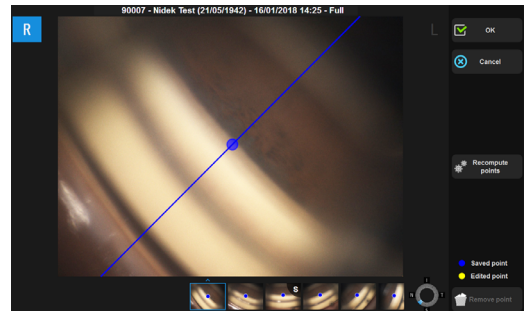
7	 [Remove point]	<p>Deletes the reference point of the selected image.</p> <p>If the reference point has already been edited, the edited reference point (yellow) is deleted. If it has not been edited, the original reference point (blue) is deleted.</p> <p>Delete the reference image if the anterior chamber angle cannot be identified from the image.</p>
----------	--	--

Regardless of whether the edit screen is displayed from the Circular or Linear stitching, the same screen is displayed.

- 1 On the image display screen showing the stitching image, press  /  [Edit stitching].

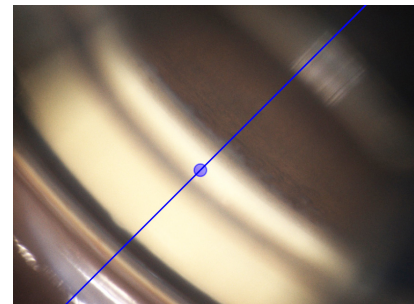


The edit screen is displayed.



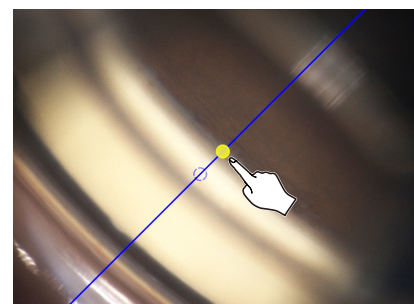
- 2 Select the thumbnail of the image for which the reference point (●) is to be moved.

Select the images on which the reference point is not on the anterior chamber angle.

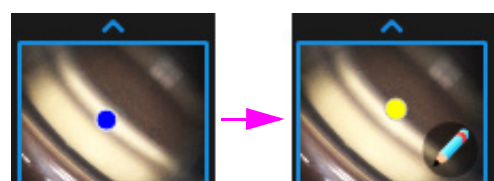


- 3 On the line indicating the direction to the center of the image, press the place to which the reference point is to be moved.

A yellow reference point is displayed at the pressed place. The original reference point is indicated by a blank dotted blue circle.





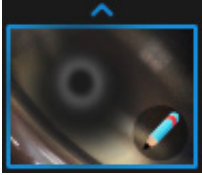
The yellow circle also appears on the thumbnail with the edit mark (✎) indicating that the image has been edited.



3

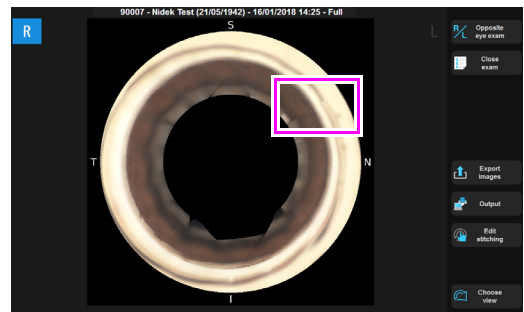
4 Move the reference points for all the necessary images.

During editing, the operations below can be performed as necessary.

 [Recompute points]	Detects reference points again. The confirmation message appears. Pressing [Yes] detects reference points again for all images.
 [Remove point]	If the anterior chamber angle cannot be identified from the selected image, delete the reference point. If the reference point has already been edited, the edited reference point (yellow) is deleted. If it has not been edited, the original reference point (blue) is deleted. 

5 Press [OK] to finish editing.

The stitching image is regenerated with the edited reference points, and the stitching image display screen is displayed.

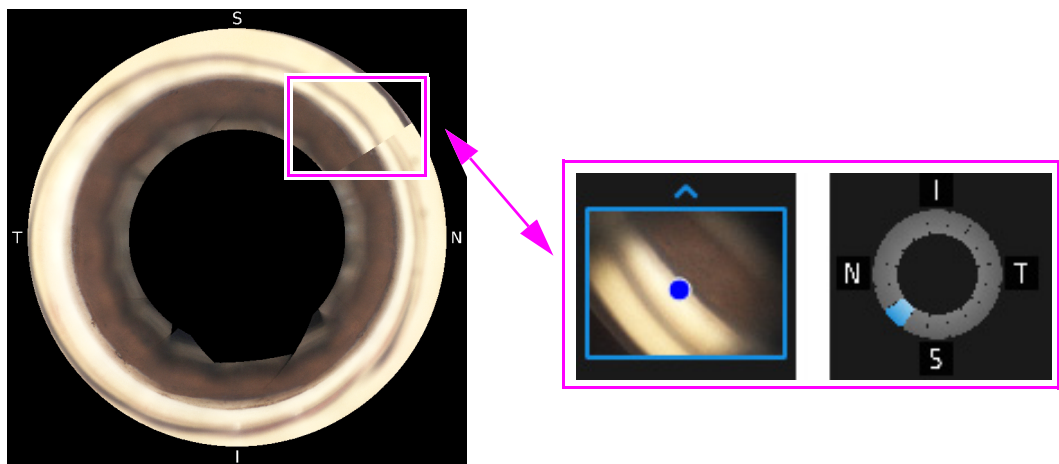


❖ Point to be noted regarding circular stitching images and single images

Single images are inverted (rotated by 180°), on the other hand, circular stitching images are corrected to the upright images.



Therefore, the orientations of the circular stitching images and the single images are different by 180° (the orientation of the T-S-N-I chart is rotated by 180°).

When selecting a thumbnail based on conspicuous seams in the stitching image, keep in mind that the image orientations are different.



3.9.5 Inputting capture comment

A comment can be input for each image. The input comments are displayed in the comment field on the image display screen and Exam list screen.

- 1 Select  [Display comment] from  [Choose view].


The comment field is displayed at the top of the screen.

- 2 Press the comment field to allow input.

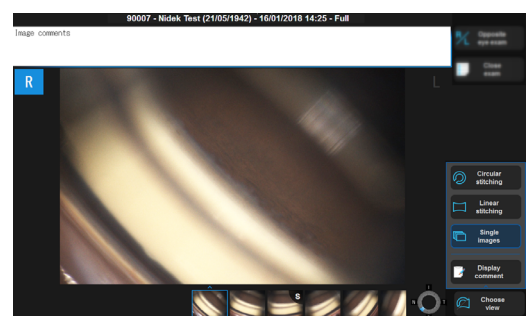
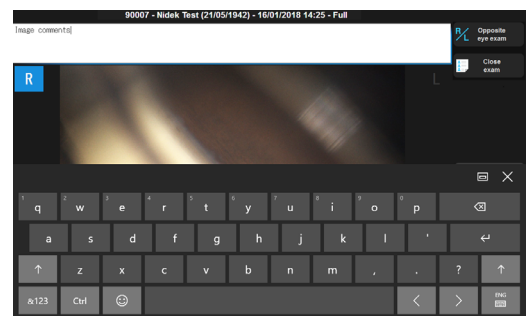
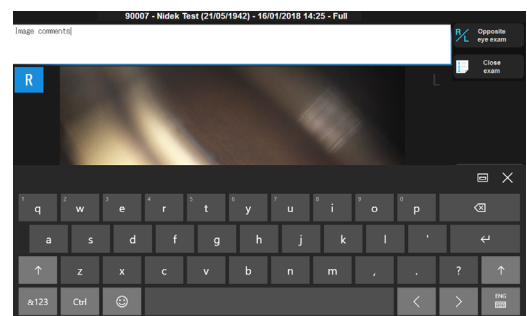
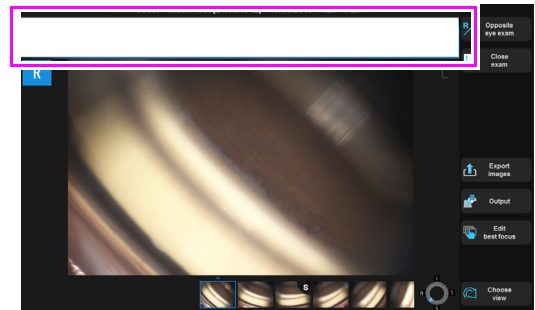
A touch keyboard appears on the screen.

- 3 Input a comment.

- 4 After inputting, press  on the keyboard to close it.

Press  [Close exam] to close the image display screen.

- 5 To close the comment field, select  [Display comment] from  [Choose view] again.



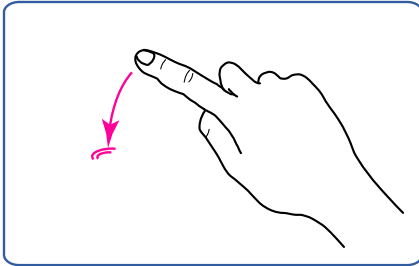
❖ Comments are displayed in the comment field on the Exam list screen.

Exam list of patient 000000001 - nidek nidek				
Exam date	Eye	Capture mode	Comment	
27/11/2019 19:07	L	Single	Image comments	Display exam result
03/10/2019 11:02	L	Full		Return to patient list
03/10/2019 11:01	R	Full		
27/06/2018 17:03	L	Full		
27/06/2018 16:58	R	Full		

3.9.6 Enlarging, reducing, and moving images using touch screen

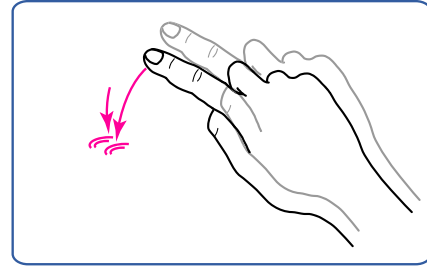
When the image is enlarged, it is not completely displayed on the image display screen. To move, enlarge, or reduce the display area, operate the touch screen as follows.

Pressing or tapping (electing an item)



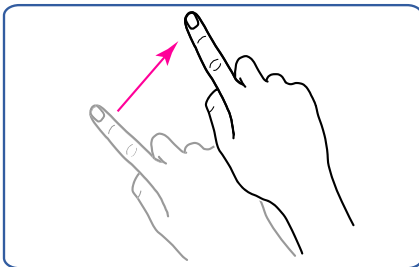
Lightly tapping the screen selects the content.

Tapping twice (executing an operation)



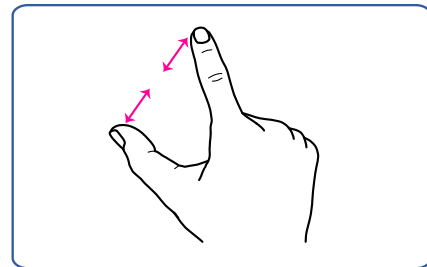
Lightly tapping the touch screen twice executes the operation.

Sliding/Swiping (moving a position)



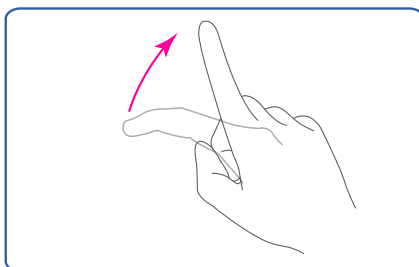
Slide the finger on the touch screen.

Pinch-in / Pinch-out (zooming the display area)



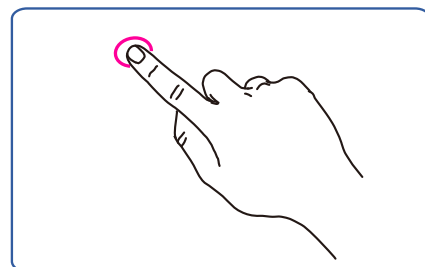
Widen (pinch-out) / Narrow (pinch-in) the distance between two fingers on the touch screen.

Flicking



Press the screen and flick the finger.

Long tap



Hold the finger to the screen momentarily and release it.

3.10 Printing the Report

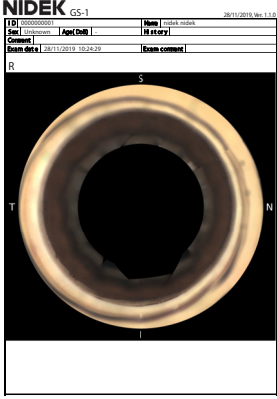
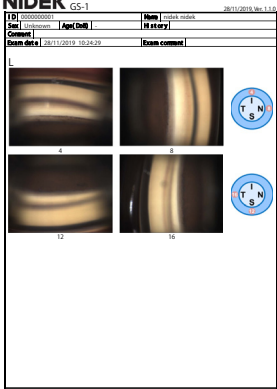
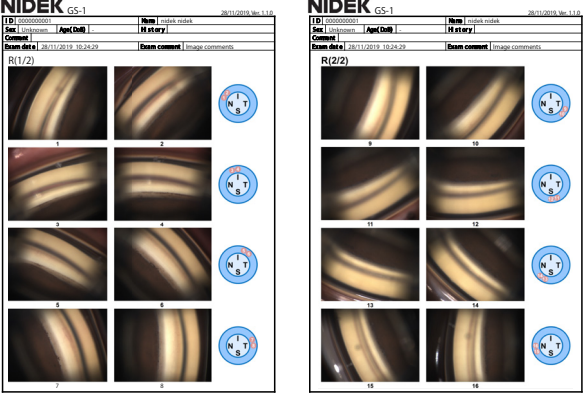
The operator can print a report data by pressing [Print report] on the image display screen.

When the Auto print parameter is set to "ON", the report is automatically printed as soon as an image capture is complete.

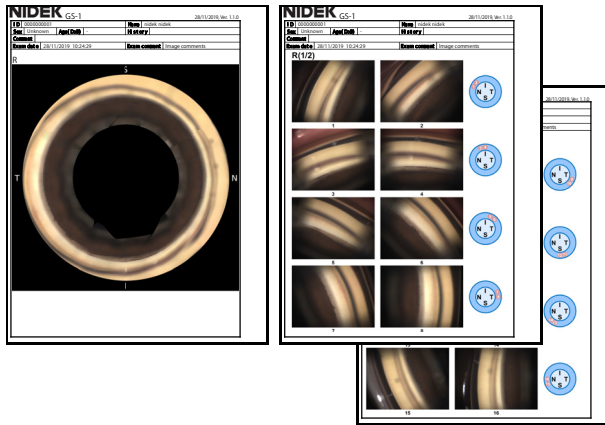
Note

- The report layout can be set for both print and for output to the electronic medical record system.
- When both right and left eye data are being selected, a report is printed for each eye.

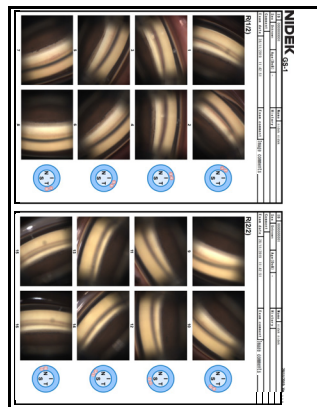
[Printing examples]

	<p>Stitching image (Full capture) When the Layout parameter is set to "Stitching image".</p>
	<p>Single capture image A maximum of eight images can be printed on one side.</p>
	<p>16 images (Full capture) 16 images are printed on two sides. When the Layout parameter is set to "16 images".</p>

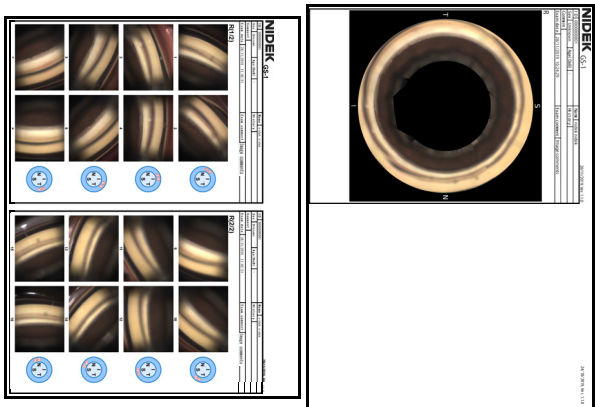
3. OPERATING PROCEDURE : Printing the Report



Stitching + 16 images (Full capture)
 The stitching image is printed on a sheet, and 16 images are printed on two sheets.
 When the "Layout" parameter is set to "Stitching + 16 images".



Allocation print (Full capture)
 Two pages are printed side by side on a sheet.
 When the "Layout" parameter is set to "16 images", and the "Allocation print" parameter is set to "ON".



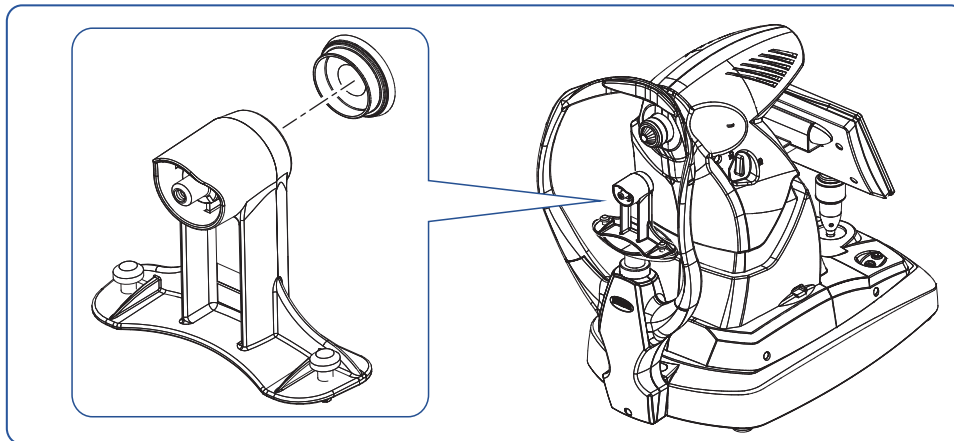
Allocation print (Full capture)
 Two pages are printed side by side on a sheet.
 When the "Layout" parameter is set to "Stitching + 16 images", and the "Allocation print" parameter is set to "ON".

3.11 Practicing Image Capture with Model Eye

Because the GS-1 operates with a short working distance and captures an image using a gel, special training is necessary to operate this device. Prior to actual use, it is recommended to practice operation using the model eye to become familiar with the operation.

1 Detach the cap and attach the model eye to the chinrest.

When the chinrest paper is attached to the chinrest, remove it.



2 Turn on the device and align the model eye height to the eye level marker.

3 Attach the MM prism to the image capturing unit and apply the gel to the MM prism.

“♦ Applying gel to MM prism” (page 51)

4 Perform the same procedure as actual use.

Register dummy patient data.

Capture an image in the same procedure as actual use. Get familiar with the alignment operation particularly.

Confirm that the slider moves back properly if the MM prism comes into direct contact with the patient's eye.

↪ “3.5.2 Image capture procedure (Full capture)” (page 53)

↪ “3.7.2 Image capture procedure (Single capture)” (page 72)

5 After practicing, detach the model eye and wipe out the gel. Clean the model eye with running water if necessary.

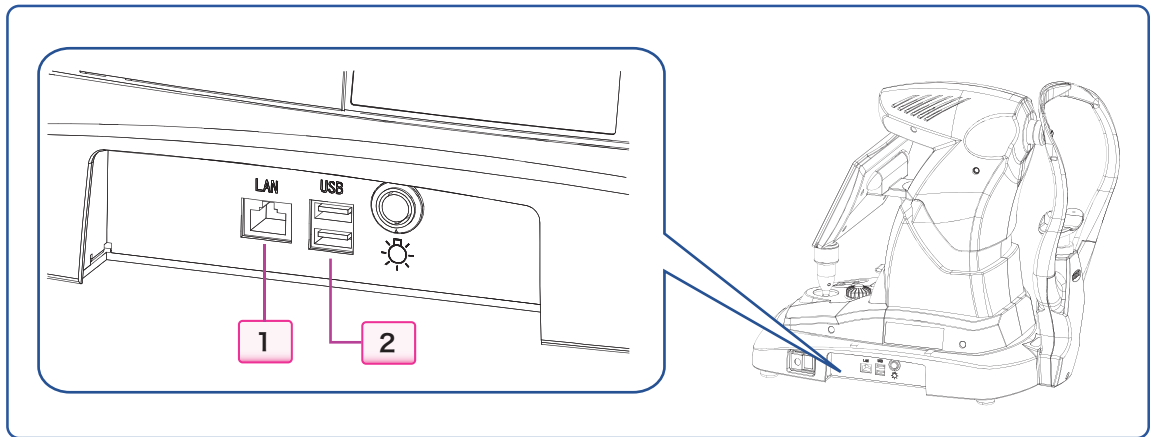
Store the model eye with the cap attached.

6 Clean the MM prism.

3.12 Operations when Peripheral Equipment is Connected

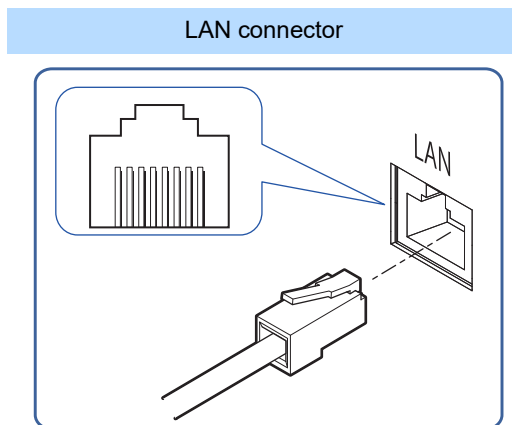
3.12.1 Connecting peripheral equipment

By connecting a peripheral equipment, the operator can import/export the data to the computer or a USB removable disk. Reading a patient ID is also possible with the use of barcode scanner or magnetic card reader.

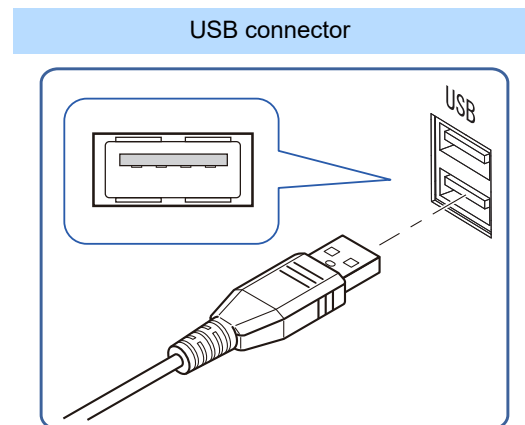


Destination	Connecting equipment	Function
1	LAN connector	Computer
2	Barcode scanner	Reads the patient ID
	Magnetic card reader	
	External HDD	Database saving destination Backs up/Loads the database
	Printer	Prints the report
	USB removable disk	Backs up/Loads the data and setting information file Exports log files from device

Be sure to insert the cable horizontally with correct orientation.



Insert the connector until it clicks.
When disconnecting it, keep on pressing the locking lever and pull out the plug.



This connector is in accordance with USB 2.0.
The connector can be connected/disconnected without turning off the device.

CAUTION

- Never use any USB equipment other than those specified.
Doing so may result in the USB detection failure or malfunction.
- When connecting the device over a LAN, be sure to connect it through a network hub.
The communication may fail.

Note

- When establishing network connection (LAN connection), consult with a network administrator of each facility and set the device and computer parameters.


3.12.2 Operations when peripheral equipment is connected

3

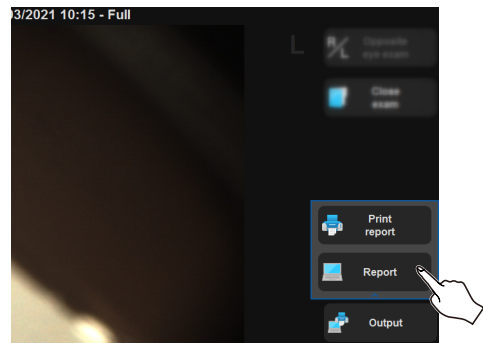
◆ Exporting data to computer (LAN connection)


Select exam data and export it to a shared folder in the computer specified through network.

LAN setting procedure

 [“4.3.2 LAN setting” \(page 117\)](#)


- 1) Select the desired exam data on the Exam list screen to display it on the image display screen.
- 2) Press [Report].

**◆ Reading patient ID with the barcode scanner or magnetic card reader**

When reading the patient ID on the Patient list screen, the patient ID is displayed in the Search for patient field. Then, pressing  (Search) detects the patient.

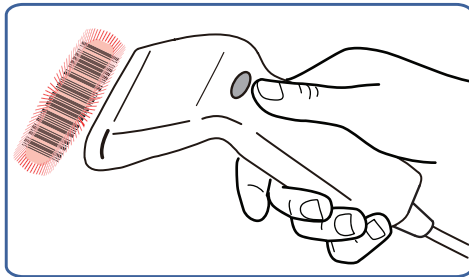
When reading the patient ID on the Register patient or Edit patient information screen, the patient ID is displayed (or overwritten) in the Patient ID field.

Reader setting

 [“4.3.3 Barcode scanner or magnetic card reader setting” \(page 119\)](#)
Note

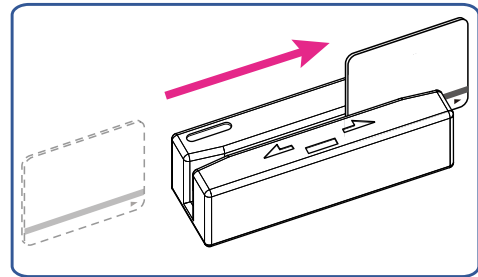
- Be sure to read the patient ID prior to image capture.
- When turning on the device with the barcode scanner (or magnetic card reader) connected, a beep sounds.

Barcode scanner



Hold the scanner close to the barcode and press the trigger button. When the data is read, the confirmation LED illuminates.

Magnetic card reader



Swipe the card through the magnetic card reader. A beep sounds and the green LED turns off. When the data is read, the LED illuminates.

Note

- When using the barcode scanner, use CODE39.
- When using the magnetic card reader, make sure that it conforms to ISO 7811, AAMVA, or CA DMV.
- All alphanumeric characters in single-byte and the codes “!”, “ ’ ”, “(”, “)”, “-”, and “~” are available for the patient ID.
Other codes and symbols are not recognized in the GS-1.

◆ **Specifying external HDD as a database saving destination**

Save the database to an external HDD without using the built-in SSD.

Specifying external HDD	↪ “4.4.3 Parameters list” (page 135) for the “DB” tab
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Perform the same procedure as the case when the database is stored in the internal SSD.

◆ **Saving/Loading the database**

Save the whole database to USB removable disk (external HDD or USB removable disk) as backup data. It is also possible to load and restore the database.

CAUTION

- Use a USB removable disk whose file system format is FAT32.
To check the file system, connect a USB removable disk to the computer and display the property.

Patient information and their exam data can be also saved and imported by specifying it.


Loading the database	↪ “4.3.4 Importing exam data (DB import)” (page 121)
Saving the database	↪ “4.3.5 Exporting exam data (DB export)” (page 124)

◆ Printing the report

Print the exam data that is currently displayed on the screen.

- 1) Select the exam data on the Exam list screen and display the data on the image display screen.
- 2) Press [Print report].

When the Auto print parameter is set to "ON, the report data is automatically printed as soon as a captured image is saved.

Printer settings	 "4.4.3 Parameters list" (page 135) for the "Print" tab
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◆ Saving / Importing data to USB removable disk

Save the setting information file and log files to USB removable disk. It is also possible to load the setting information file from a USB removable disk.

CAUTION

- Use a USB removable disk whose file system format is FAT32.

To check the file system, connect a USB removable disk to the computer and display the property.

Saving/Importing user setting information file	 "4.3.6 Importing/Exporting user setting information" (page 127)
Saving log files	 "4.3.7 Error log export" (page 129)

4

MAINTENANCE

4.1 Troubleshooting

If the device does not function properly, troubleshoot with the table below before contacting NIDEK or your authorized distributor for repairs.

Symptom	Remedy
The LCD touch screen does not turn on.	<ul style="list-style-type: none"> The power cord may not be plugged. Securely plug the power cord again. The power may not be turned on to the device. Check the power switch.
Turning the power on to the device does not turn on the LCD touch screen. (The contents are obscure.)	<ul style="list-style-type: none"> The brightness may be set improperly. Check the light intensity.
The main unit cannot be moved horizontally.	<ul style="list-style-type: none"> The main unit may be locked by the main unit locking lever. Lift the main unit locking lever to release the lock.
Operations on the LCD touch screen do not work.	<ul style="list-style-type: none"> Turn off the power switch and restart the device. Confirm that the device operates properly after re-started.
The chinrest or image capturing unit cannot be raised/lowered.	<ul style="list-style-type: none"> The chinrest or image capturing unit may be locked by the locking lever. Move the locking lever to Unlock position.
The time when the image was captured is incorrect.	<ul style="list-style-type: none"> Set the correct date and time on the Maintenance screen. ↩ (page 116)
The data cannot be printed.	<ul style="list-style-type: none"> Check the printer paper. If it runs out, load the paper. Check the [Print] tab on the user settings screen. ↩ (page 135)
Auto tracking cannot be performed.	<ul style="list-style-type: none"> This error may occur in patients who have severe eye nystagmus or who cannot fix their face position. In such a case, disable the auto tracking and attempt an image capture again. An influences of interference light may occur in the device installed directly under lighting equipment or near a window exposed to sunlight. Move the device to a different position and attempt an image capture again.

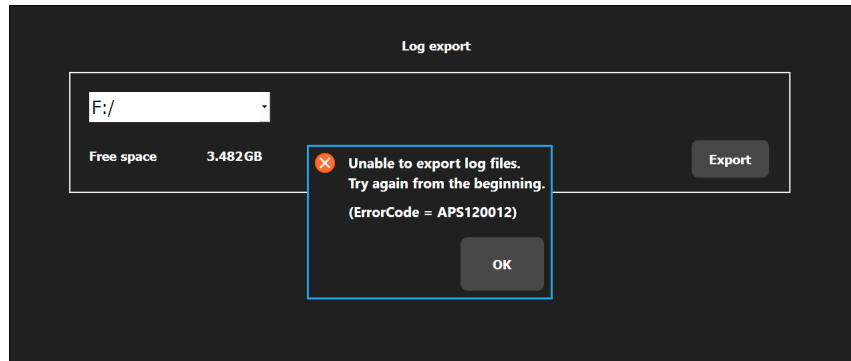
- If the symptom cannot be remedied by the above actions, or any message other than the above is displayed, contact NIDEK or your authorized distributor.

4.2 Error Messages and Remedies

If any message shown in the list below appears on the screens, remedy the problem following the instructions in “Cause and remedy”.

When contacting NIDEK or your authorized distributor, inform of the serial number of the device, message number, and symptom for proper service.

[Message example]



Symptom	Cause and remedy
Unable to load adjustment data. Report error code to NIDEK or your distributor. (ErrorCode = APS110001)	Adjustment setting data or internal SSD may be damaged. Contact NIDEK or your authorized distributor.
Unable to save user settings. Report error code to NIDEK or your distributor. (ErrorCode = APS110002)	User settings data or internal SSD may be damaged. Contact NIDEK or your authorized distributor.
Unable to read initial user setting value. Report error code to NIDEK or your distributor. (ErrorCode = APS110003)	User settings data or internal SSD may be damaged. Contact NIDEK or your authorized distributor.
Unable to load base settings. Report error code to NIDEK or your distributor. (ErrorCode = APS110004)	Base setting data or internal SSD may be damaged. Contact NIDEK or your authorized distributor.
The creation of a new database on the USB removable disk failed. Check the connection of the USB drive and its contents. (ErrorCode = APS110006)	Check the USB removable disk connection.
Unable to load user settings. Import initial setting and continue operation. (ErrorCode = APS130006)	User settings data or internal SSD may be damaged. Contact NIDEK or your authorized distributor.
Unable to open this file. Operation will be canceled. Check the USB removable disk connection. (ErrorCode = APS130007)	User settings import failed. Check the USB removable disk connection.
Unable to import user settings. Try again from the beginning. (ErrorCode = APS120008)	Import the data again. If this error occurs again, contact NIDEK or your authorized distributor.
Unable to export user settings. Try again from the beginning. (ErrorCode = APS120009)	Export the data again. If this error occurs again, contact NIDEK or your authorized distributor.
Unable to import adjustment data. Try again from the beginning. (ErrorCode = APS120010)	Unable to import adjustment data. If this error occurs again, contact NIDEK or your authorized distributor.

Symptom	Cause and remedy
Unable to export adjustment data. Try again from the beginning. (ErrorCode = APS120011)	Unable to export adjustment data. If this error occurs again, contact NIDEK or your authorized distributor.
Unable to export log files. Try again from the beginning. (ErrorCode = APS120012)	Export the data again. If this error occurs again, contact NIDEK or your authorized distributor.
Unable to import the data. Free up space in internal SSD and try again. (ErrorCode = APS120013)	Delete unnecessary exam data and try again.
Unable to export the data. Free up space or change USB removable disk and try again. (ErrorCode = APS120014)	Use a USB removable disk with free space and export the data again.
Unknown error occurred. Report error code to NIDEK or your distributor. (ErrorCode = APS110015)	Report error code to NIDEK or your distributor.
Network configuration failed. Check the settings again. (ErrorCode = APS120016)	Check the settings again. If this error occurs again, contact NIDEK or your authorized distributor.
Unable to import adjustment setting (inconsistent serial No. with main body). Try again from the beginning. (ErrorCode = APS120017)	Unable to import adjustment data. If this error occurs again, contact NIDEK or your authorized distributor.
Unable to save adjustment setting. Report error code to NIDEK or your distributor. (ErrorCode = APS110018)	Unable to save adjustment data. If this error occurs again, contact NIDEK or your authorized distributor.
Unable to enter packing mode. Try again from the beginning. (ErrorCode = APS120019)	Check whether the image capturing unit is unlocked. If this error occurs again, contact NIDEK or your authorized distributor.
Unable to find barcode reader / magnetic card reader. Try again from the beginning. (ErrorCode = APS120020)	Check the barcode scanner / magnetic card reader again. If this error occurs again, contact NIDEK or your authorized distributor.
Unable to set date and time. Try again from the beginning. (ErrorCode = APS120021)	If this error occurs again, contact NIDEK or your authorized distributor.
Unable to load the database. Check the save destination and USB removable disk connection. (ErrorCode = APS120022)	Check the database save destination and USB removable disk connection when the database save destination is a USB removable disk.
Failed to connect to the Navis-Ex database server:review the connection settings. (ErrorCode = APS120023)	Check the server (NAVIS-EX) connection.

The list below shows the error messages regarding failures in the hardware or software. If any message shown in the list below appears on the screens, remedy the problem following the instructions in "Remedy". If the symptom cannot be remedied by the actions below, contact NIDEK or your authorized distributor.

When contacting NIDEK or your authorized distributor, inform of the serial number of the device, message number, and symptom for proper service.

Messages		Remedy
10	Connection error	Contact NIDEK or your authorized distributor.
20	Prism motor error	
30	Tracking motor error	
40	Focusing motor error	
100	Hardware error	
300	Unable to load exam data.	When the database save destination is a USB removable disk, check the USB removable disk connection.
301	Unable to delete exam data.	
302	Unable to start exam. Exam will be canceled.	When the database save destination is NAVIS-EX, check the LAN connection.
303	Unable to save exam data.	Contact NIDEK or your authorized distributor.
304	Unable to load exam data.	When the database save destination is a USB removable disk, check the USB removable disk connection.
305	Unable to find USB removable disk. Check the disk connection.	Check the USB removable disk connection and parameter settings.
306	This USB removable disk is read-only. Connect a writable disk.	Enable data writing to the USB removable disk.
307	Insufficient space in USB removable disk. Free up space for at least ** MB.	Free up some space in the USB removable disk.
308	Export failed.	Check the USB removable disk connection and parameter settings.
309	Unable to find the configured data storage. Check and try again.	When the database save destination is a USB removal disk or NAVIS-EX, check the connection and parameter settings of the database save destination.
310	Error occurred while race list is being retrieved.	Contact NIDEK or your authorized distributor.
311	Unable to delete patient data.	When the database save destination is a USB removable disk, enable data writing to the USB removable disk.
312	Unable to load patient data.	When the database save destination is a USB removal disk or NAVIS-EX, check the connection and parameter settings of the database save destination.
313	Storage error: Unable to perform exams.	When the database save destination is a USB removable disk, check the USB removable disk connection.
314	No exam data found.	
315	Unable to save data to specified destination. Try again or save data to secondary storage?	When the database save destination is a USB removal disk or NAVIS-EX, check the connection and parameter settings of the database save destination. For the restoration of the exam data saved in the secondary storage, see "4.3.8 Fallback data recovery" (page 130).
316	Unable to save exam data. Retry or discard the data?	Contact NIDEK or your authorized distributor.

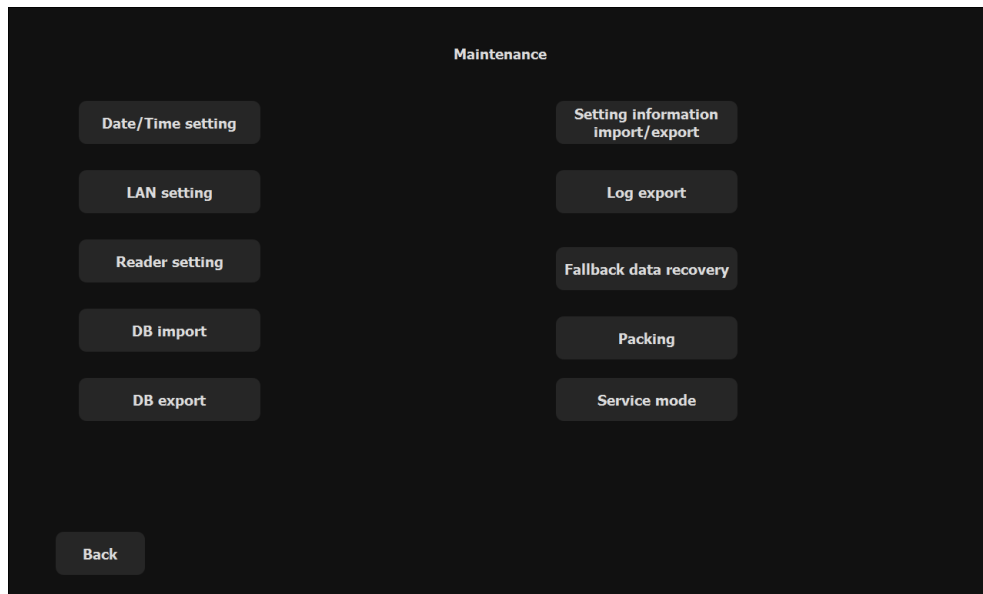
Messages		Remedy
317	Patient locking failed. The patient is locked by another user.	If the data of the selected patient is used on another device connected to the GS-1, close the patient data.
318	Unable to register the patient.	<ul style="list-style-type: none"> • When the database save destination is a USB removable disk, enable data writing to the USB removable disk. • When the database save destination is NAVIS-EX, delete the patient ID in the trashbox on NAVIS-EX if it is the same as the patient ID to be registered, or change the patient ID to be registered.
319	Unable to edit the patient information.	When the database save destination is a USB removable disk, enable data writing to the USB removable disk.
320	Unable to update patient information.	
321	No patient information exists.	When the database save destination is a USB removable disk, check the USB removable disk connection.
322	Low space in the configured data storage.	Save the data to other external storage or delete it to free up some space.
323	Low space in the configured data storage. Free up some space in order to perform new exams.	
324	Unable to find the configured data storage. Check and try again.	When the database save destination is a USB removable disk, check the USB removable disk connection and parameter settings.
339	Application error	Contact NIDEK or your authorized distributor.
400	Unable to print eye report. Try again?	Check the printer connection and print settings.
401	Unable to create report. Try again?	Check the LAN connection and settings.
402	Unable to generate stitching image.	Try again with other data.
403	Unable to output report. Try again?	Check the printer connection and print settings. Check the LAN connection and settings.
404	Exam acquisition failed. Alignment will start.	Contact NIDEK or your authorized distributor.
405	Exam acquisition failed. Exam will be canceled.	

4.3 Settings on Maintenance Screen

The operator can set the device parameters by selecting the setting menu on the Maintenance screen according to the following procedure.

To display the Maintenance screen, press [Maintenance] on the home screen. Then, press [Yes] on the following confirmation message.

◆ Maintenance screen



Menu	Description
[Date/Time setting]	Pressed to set the date and time ↩ (page 116).
[LAN setting]	Pressed to set the IP address or file sharing ↩ (page 117).
[Reader setting]	Pressed to register the barcode scanner or magnetic card reader ↩ (page 119).
[DB import]	Pressed to import an exam data from external storage to device database ↩ (page 121). When the database save destination is [NAVIS-EX], the exam data cannot be imported.
[DB export]	Pressed to export an exam data from device database to specified folder (or external storage) ↩ (page 124). When the database save destination is [NAVIS-EX], the exam data cannot be exported.
[Setting information import/export]	Pressed to back up / load the device settings ↩ (page 127).
[Log export]	Pressed to export error log files ↩ (page 129).
[Fallback data recovery]	Pressed to restore the exam data that failed to be output to the USB removal disk and NAVIS-EX. When the database save destination is [Internal SSD], the exam data cannot be restored.
[Packing]	Pressed to enter the packing mode ↩ (page 132).

Menu	Description
[Service mode]	Service mode is unavailable in this device. If the operator unintentionally presses this tab, a password entry window appears. In such a case, press [Cancel] to close the window.
[Back]	Pressed to return to the home screen

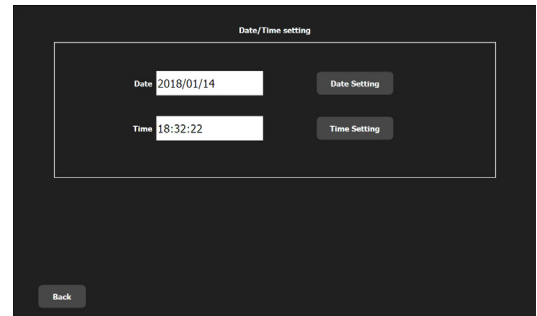
4.3.1 Date and time setting

Set the date and time to be indicated on the screen and on the printed data.

Note

- When the device has not been used for an extended period of time (approximately for a month), the date and time may become inaccurate.

- 1 Press [Date/Time setting] on the Maintenance screen to display the Date/Time setting screen.



- 2 Check the displayed date and time. If the date or time is incorrect, press [Date setting] or [Time setting] to set the correct date or time.

When the date and time are correct, press [Back] to return to the Maintenance screen.

Note

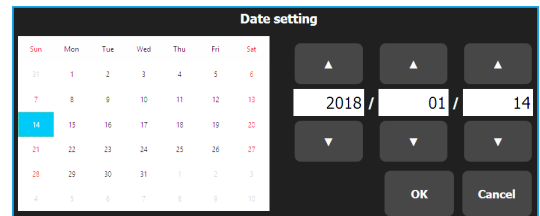
- The clock stops while the Date/Time setting screen is being displayed. When the date and time are correct, immediately close the setting window.

- 3 Press [Date setting] to set the correct date on the Date setting screen.

- 1) Press [▲]/[▼] button on the Date setting screen to set the correct date.

A calendar of the current setting date is displayed on the left side of the screen. Touching the calendar also changes the date.

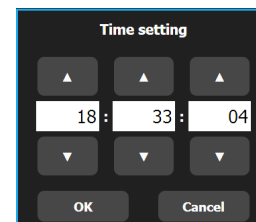
- 2) Press [OK] to close the Date setting screen.



- 4 Press [Time setting] to set the correct time on the Time setting screen.

- 1) Press [▲]/[▼] button on the Time setting screen to set the correct time.

- 2) Press [OK] to close the Time setting screen.



- 5 Press [Back] to close the Date/Time setting screen. The clock will start from the setting date and time.

4.3.2 LAN setting

When connecting the device to an external computer through a LAN, set the domain, IP address, and subnet mask.

If the GS-1 and external computer belong to different network domains, be sure to set the account so that both of them are accessible.

Perform the settings so that the shared folder can be referred to both on the GS-1 and external computer.

When exporting the data outside the network the device belongs to, set the default gateway.

* For the connection with hospital LAN or external network, NIDEK does not guarantee that the connection is performed properly.

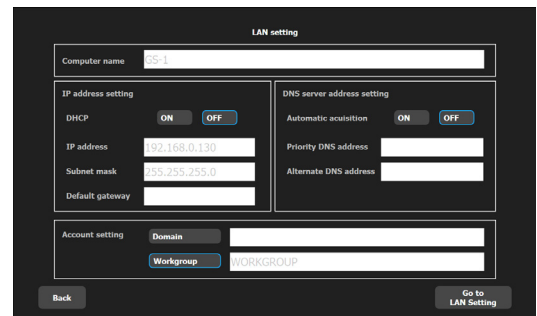
Note

- For LAN settings, consult with your own network administrator.
- Prior to use, be sure to check the connected computer's name, user name, password, and a shared folder that the database will be stored in.

- 1 Press [LAN setting] on the screen to display the LAN setting screen.

The current settings are displayed.

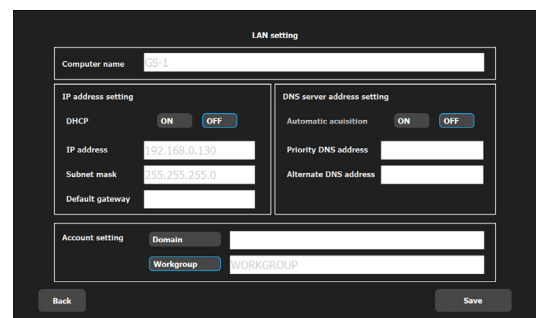
As of this step, only [LAN setting] is enabled.



- 2 Press [LAN setting].

- 3 Before entering LAN setting, the message notifying that the device will be restarted appears. Press [Yes] to restart the device.

After the device restarts, the LAN setting screen is displayed according to the setting mode.



- 4 Perform necessary settings for the device and connected computer.

When the item needs to be selected, press each button to select the item. When the parameter needs to be directly entered, press an entry field and display a touch keypad.


Computer name	Input a unique name to identify the device in the network. Change the default "GS-1" as necessary.
IP address setting	
DHCP	Select ON/OFF of the DHCP activation. When connecting with a DHCP server function computer, select [ON].

IP address	Enter IP address. If necessary, change the IP address from the default setting "192. 168. 0. 130".
Subnet mask	Enter Subnet mask. If necessary, change the subnet mask from the default setting "255. 255. 255. 0".
Default gateway	Enter Default gateway. When exporting the data to the network the device belongs to, this setting is unnecessary.
DNS server address setting	
Automatic acquisition	Select ON or OFF of the automatic acquisition of DNS server address
Priority DNS address	Enter the IP address of prioritized DNS server (domain name system).
Alternate DNS address	If the Priority DNS address is disabled but any alternative DNS server exists, enter the IP address of the alternative DNS server.
Account setting	
Domain	Enter the domain name of the connected network.
Workgroup	Enter the workgroup name of the connected computer.

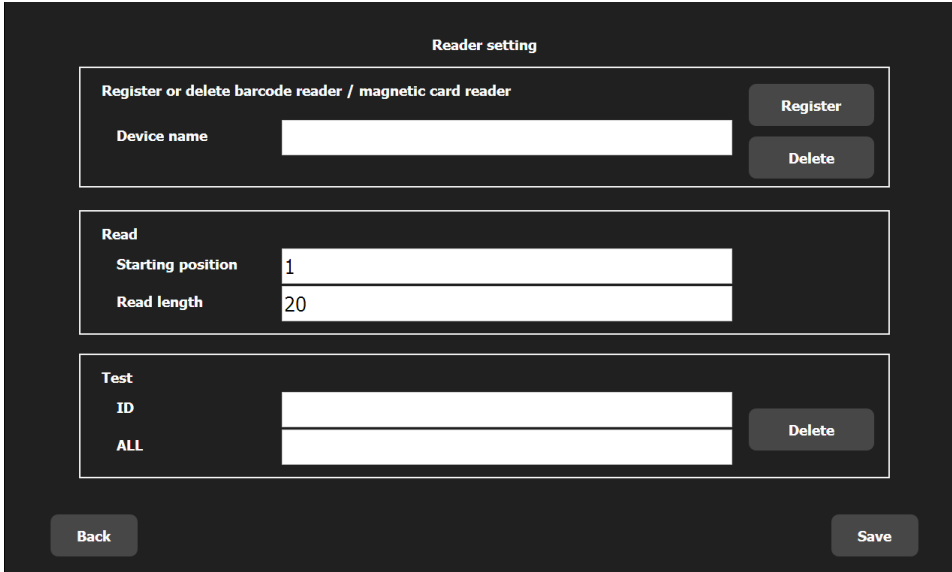
- 5** After performing the settings above, press [Save]. When the confirmation message notifying that the network settings have been changed appears, press [Yes].
- 6** Press [Back]. When the confirmation message notifying that the LAN setting mode will be closed and the device will be restarted appears, press [Yes].
The device starts up and the home screen is displayed.

4.3.3 Barcode scanner or magnetic card reader setting

Specify the data to be read with the barcode scanner or magnetic card reader for patient ID reading. After performing the set-ups of the barcode scanner or magnetic card reader, the following functions are enabled.

New patient	Read the Patient ID on the Register patient screen. The Patient ID is read and displayed in the field.
Registered patient	When reading the patient ID on the Patient list screen, the patient ID is displayed in the Search for patient field. Pressing  (Search) displays the patient in the list.

◆ Reader setting screen

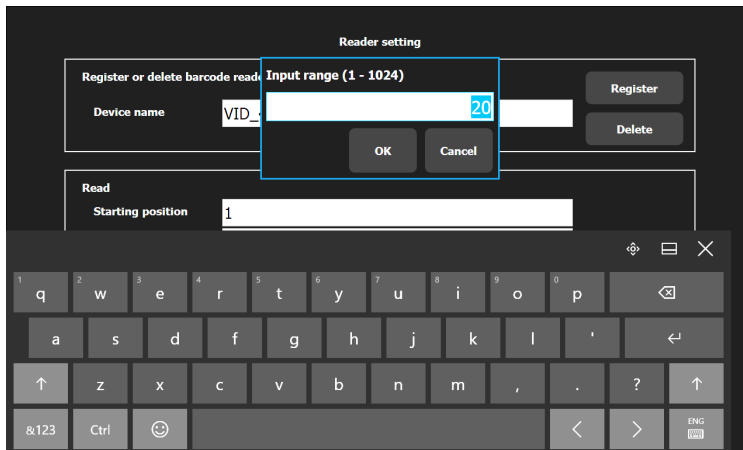


- 1 Connect the barcode scanner or magnetic card reader to the USB connector.
- 2 Press [Reader setting] on the Maintenance screen to display the Reader setting screen.
- 3 Press [Register].
- 4 Register the reader.
 - 1) The confirmation message “Read data with barcode reader / magnetic card reader.” appears. Read the data with barcode scanner or magnetic card reader.
 - 2) The Device name is read and displayed in the field.
 - 3) Check the Device name.
If the device name is incorrect and must be read again, press [Delete] to clear the Device name field.
- 5 Read the data with the barcode scanner or magnetic card reader again.
The data is read and displayed in ID and ALL fields.

6 Specify the data length to be imported.

The number of characters set in [Read length] are read from the position set in [Starting position].

Starting position	Used to set the ID import starting position.
Read length	Used to set the data length to be imported. The data for the setting length is imported. The return code is also included according to the setting.



- 1) Pressing the Starting position or Read length field displays an entry window.
- 2) Enter the information with a touch keyboard and press [OK] after the entry.

7 Press [Delete] to clear the ID and ALL fields.

8 Read the ID again and confirm that the correct ID is displayed in the ID field.

9 Press [Save] to save the settings.

10 Press [Back] to close the Reader setting screen.

11 Display the Patient list screen. Then, confirm that the correct patient ID is read with the barcode scanner or magnetic card reader and it is displayed in the Search for patient field.

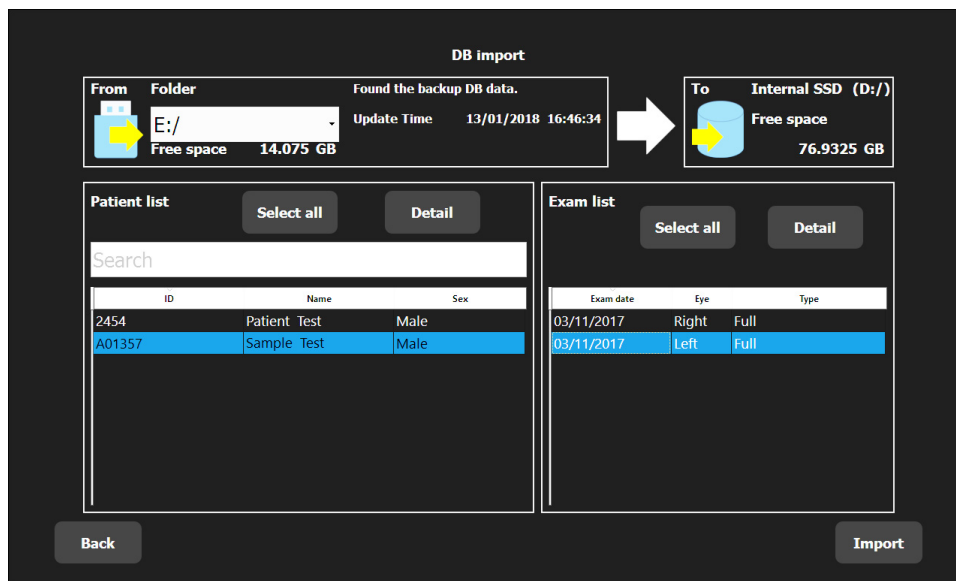
4.3.4 Importing exam data (DB import)

The operator can import an exam data from the configured storage to the database (internal SSD or external HDD) by performing the following procedure.

Note

- If exam data with History that has not been registered in the History list is imported, the History is displayed in the Patient list, but not automatically added to the History list.
For History that has not been registered in the History list, manually add it on the Edit patient information screen.

◆ Operations on DB import screen



From	Folder	Connect the desired data storage to the device. The free space and the last update date of the storage are displayed.
To		Indicates the current DB settings and its free space.
Patient list	[Select all]	Selects all patients displayed in the patient list.
	[Detail]	Displays the details (ID, First name, Last name, Date of birth, Sex, Race, and Notes) of the selected patient.
Exam list	[Select all]	Pressed to select all data on the Exam list field.
	[Detail]	Displays the details of each exam data (ID, exam date, eye, and type).
[Import]		Pressed to import the data. The function becomes enabled by selecting any exam data.
[Back]		Pressed to close the DB import screen and to return to the Maintenance screen.

- 1 Connect the target USB removable disk to the device.
- 2 Press [DB import] on the screen to display the DB import screen.

If the DB import screen is displayed before the USB removable disk is connected, the USB removable disk cannot be detected. Insert the USB removable disk first. Then, close the DB import screen and display it again.

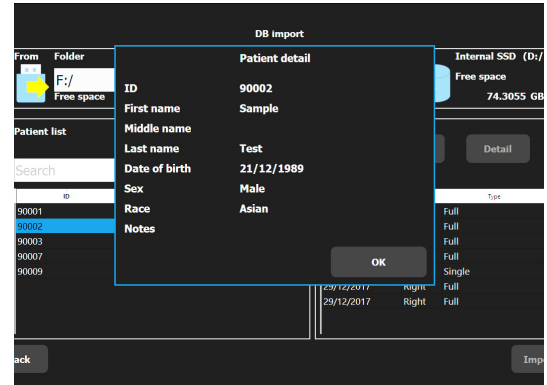
- 3 Check the free space in the data storage and update date displayed in [Folder] field of From column. If it is incorrect, select the correct storage drive from the pull-down list that is displayed by pressing [v] icon.

All data in the storage is displayed in the patient list.

- 4 From the patient list, select the patient to be imported.

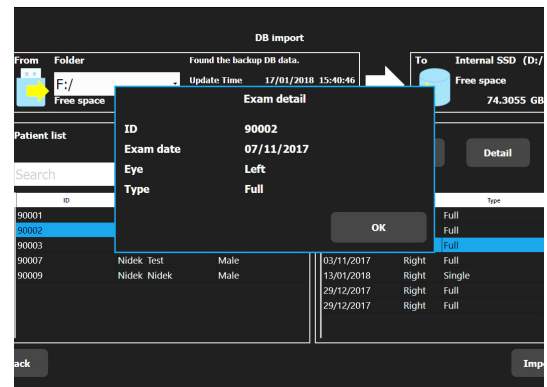
Entering any information performs a truncated searching. Pressing [Select all] selects all patients.

Selecting one patient and pressing [Detail] display the patient's information.



- 5 The patient's exam data is displayed in the Exam list. Select the exam data to be imported.

Selecting one exam data item and pressing [Detail] display the patient's information.



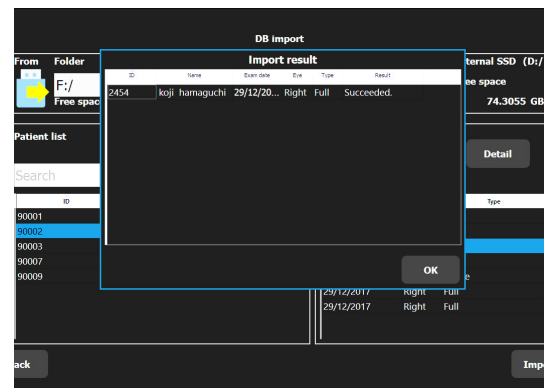
Note

- Selecting several patients imports all their exam data. When importing the exam data individually, select only one patient and import their data.

- 6 Press [Import] to import the data.

When the data is imported properly, the Import result screen is displayed.

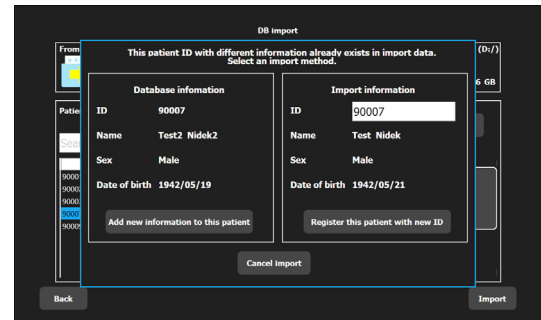
Confirm that the data is imported correctly. If the data already exists in the database, the message "This data already exists." appears.



Note

- If the message "Failed." appears, the data is not imported correctly. Check the save destination and USB removable disk connection. Also free up space as necessary, then try again.

If the patient ID already exists with different exam data, a confirmation window appears.



Check the data and select the import method.

[Add new information to this patient]	Pressed to add new exam data to the existing patient ID (patient information) in the database.
[Register this patient with new ID]	Pressed to create new patient ID and register it to the database in the main body as a different patient data.
[Cancel import]	Pressed to cancel the DB import and to return to the DB import screen.

- 7** Press [OK] to close the Import result screen.
- 8** Press [Back] to close the DB import screen and to return to the Maintenance screen.

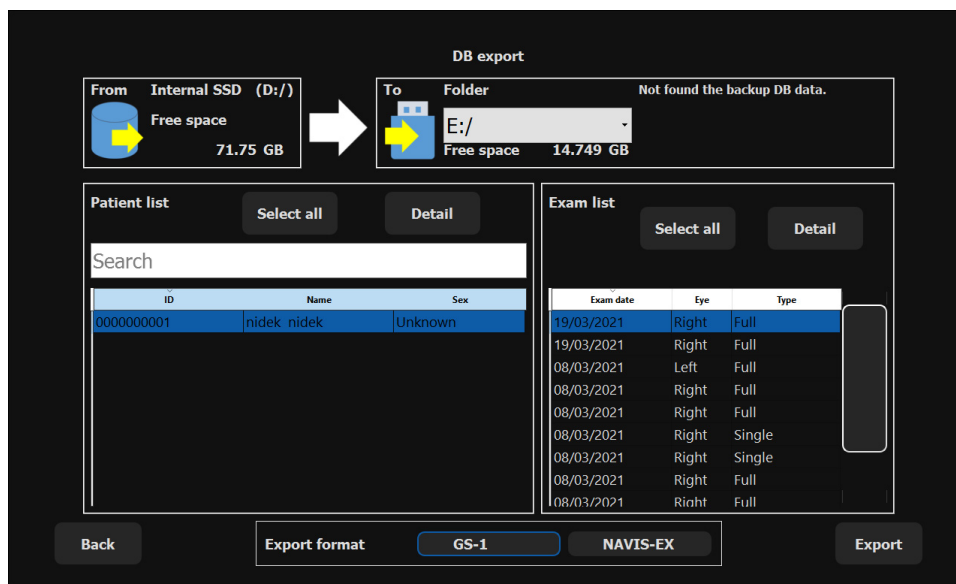
4.3.5 Exporting exam data (DB export)

The operator can export exam data from the database (internal SSD or external HDD) to a configured USB storage by performing the following procedure. Before backing up the database or changing the data saving storage, be sure to save the exam data.

Note

- The folder “GN001_DB” is automatically generated in the configured storage and the exam data is saved there.

◆ Operations on DB export screen



From		Indicates the current DB settings and its free space.
To	Folder	Select the data storage drive that the data will be saved in. The free space and the last update date of the storage are displayed.
Patient list	[Select all]	Selects all patients displayed in the patient list.
	[Detail]	Displays the details (ID, first name, last name, Date of birth, Sex, race, and notes) of the selected patient.
	Search field	Searches a patient with truncated terms based on entered characters.
Exam list	[Select all]	Pressed to select all data on the Exam list field.
	[Detail]	Displays the details of each exam data (ID, exam date, eye, and type).
[Export]		Pressed to export the data. The function becomes enabled by selecting any exam data.
[Back]		Pressed to close the DB export screen and to return to the Maintenance screen.
[Export format]	[GS-1]	Selects the export format according to the database to be imported.
	[NAVIS-EX]	

- 1 Connect a USB removable disk to the device.
- 2 Press [DB export] on the screen to display the DB export screen.

If the DB export screen is displayed before the USB removable disk is connected, the USB removable disk cannot be detected. Insert the USB removable disk first. Then, close the DB export screen and display it again.

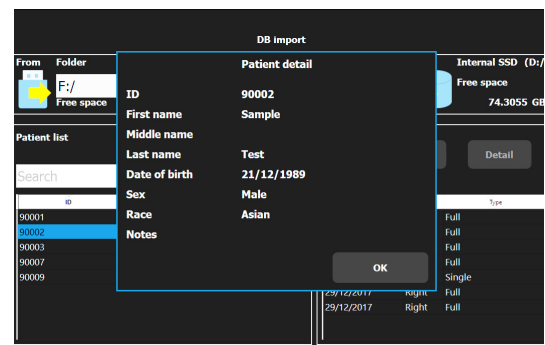
- 3 Check the free space and update date of the storage displayed in the [Folder] field of the [To] column. If it is incorrect, select the correct storage drive from the pull-down list that is displayed by pressing the [v] icon.

- 4 Select [Export format].

- 5 From the patient list, select the patient to be exported.

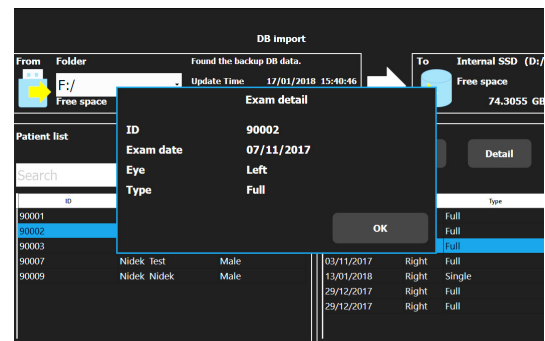
Entering any information performs a truncated searching. Pressing [Select all] selects all patients.

Selecting one patient and pressing [Detail] display their information.



- 6 The patient's exam data is displayed in the Exam list. Select the exam data to be exported.

Selecting one exam data and pressing [Detail] display the patient information.



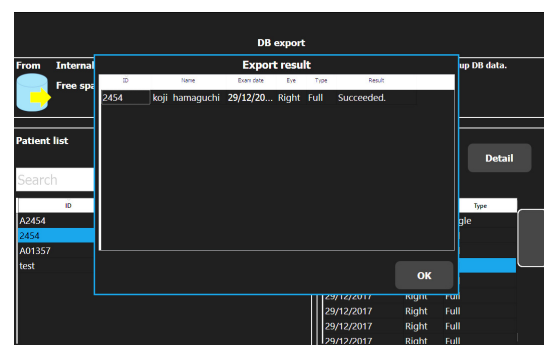
Note

- Selecting several patients exports all exam data of theirs. When exporting the exam data individually, select only one patient and export their data.

- 7 Press [Export] to save the data.

After the data is exported, the Export result window appears.

Confirm that the data is exported correctly.



 **Note**

- If the message “Failed.” appears, the data is not exported correctly. Check the free space and connection of USB removable disk and check whether the disk is writable. Then, try again.
-

- 8** Press [OK] to close the Export result screen.
- 9** Press [Back] to close the DB export screen and to return to the Maintenance screen

4.3.6 Importing/Exporting user setting information

The operator can save and import the user setting information as a setting file by performing the following procedure. With this function, it is also possible to restore the saved settings or perform the same settings in another device.

Be sure to take the backup of the setting file and save it to a USB removable disk.

Note

- The setting file is not generated automatically. Export (or backup) the setting file as necessary.

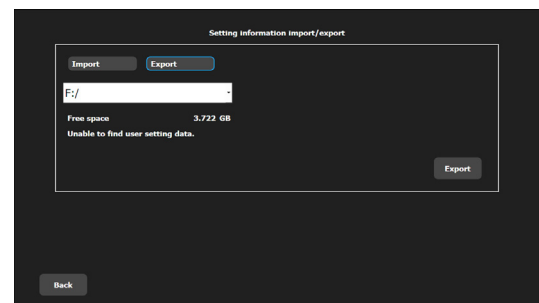
◆ Saving the setting file (Setting file export)

1 Connect a USB removable disk to the USB connector.

2 Press [Setting information import/export] on the Maintenance screen.

The Setting information import/export screen is displayed.

If the Setting information import/export screen is displayed before the USB removable disk is connected, the USB removable disk cannot be detected. Connect the USB removable disk first. Then, close the Setting information import/export screen and display it again.



3 Check the drive of the connected USB removable disk. If it is incorrect, select the correct storage drive from the pull-down list that is displayed by pressing the [v] icon.

4 Press [Export] on the upper part of the screen.

5 Press [Export] on the lower part of the screen to back up the data.

A setting file (.dat) is saved in the USB removable disk.

6 The confirmation message regarding the export result appears. Press [OK] to close the message.

7 Press [Back] to close the Setting information import/export screen and to return to the Maintenance screen

8 Disconnect the USB removal disk.

◆ Importing the setting file

Note

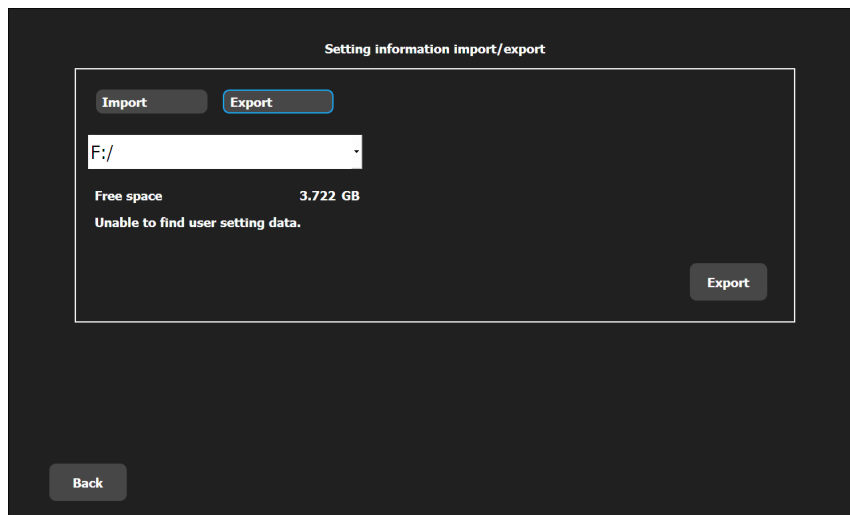
- Importing the setting file automatically updates the device settings.

1 Connect the USB removable disk to the USB connector, taking care that the USB removable disk has the targeted setting file.

2 Press [Setting information import/export] on the Maintenance screen.

The Setting information import/export screen is displayed.

If the Setting information import/export screen is displayed before the USB removable disk is connected, the USB removable disk cannot be detected. Connect the USB removable disk first. Then, close the Setting information import/export screen and display it again.



3 Check the drive of the connected USB removable disk. If it is incorrect, select the correct storage drive from the pull-down list that is displayed by pressing the [v] icon.

4 Press [Import] on the upper part of the screen.

If the setting file is not found, the error message “Unable to find user setting data.” appears. Check the file stored in the USB removable disk.

5 Press [Import] on the lower part of the screen to import the data.

The setting file is imported to the device.

6 The import result message window appears. Press [OK] to close the message.

7 Press [Back] to close the Setting information import/export screen and to return to the Maintenance screen

8 Disconnect the USB removal disk.

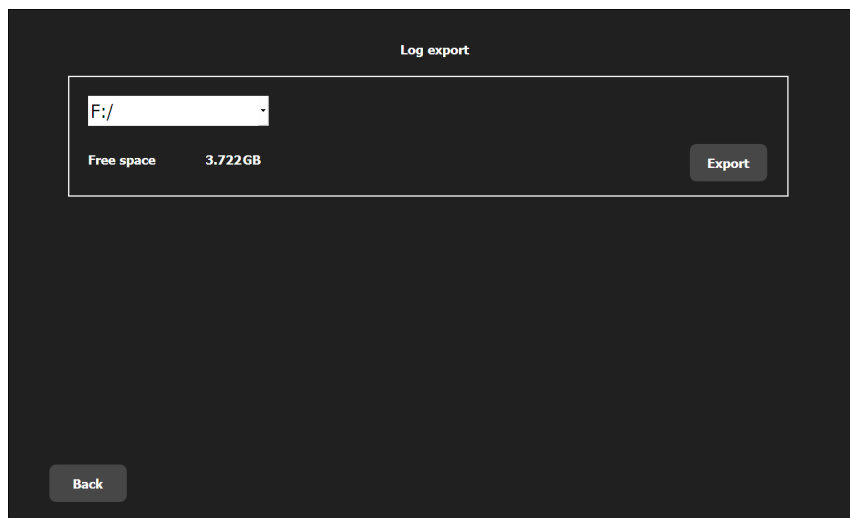
4.3.7 Error log export

The operator can save the device logs (error history) to a USB removable disk by performing the following procedure. In the logs, more than 100 latest information items (variable depending on the device) regarding error occurrence time and their details are contained.

After all log files are exported, check them with a text editor tool.

- 1 Connect a USB removable disk to the USB connector.
- 2 Press [Log export] on the Maintenance screen to display the Log export screen.

If the Log export screen is displayed before the USB removable disk is connected, the USB removable disk cannot be detected. Connect the USB removable disk first. Then, close the Log export screen and display it again.

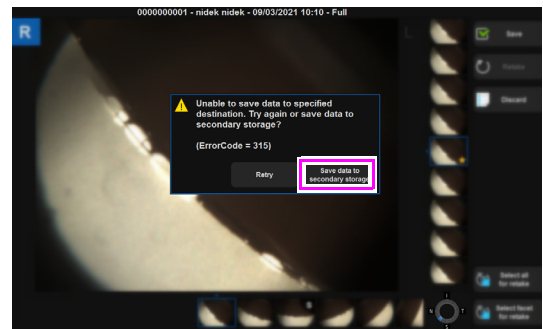


- 3 Confirm that the drive of the connected USB removable disk is correct. If it is incorrect, select the correct storage drive from the pull-down list that is displayed by pressing the [v] icon.
- 4 Press [Export] to export the log files to the USB removable disk.
- 5 The confirmation message regarding the export result appears. Press [OK] to close the message.
- 6 Press [Back] to close the Log export screen and to return to the Maintenance screen
- 7 Disconnect the USB removal disk.

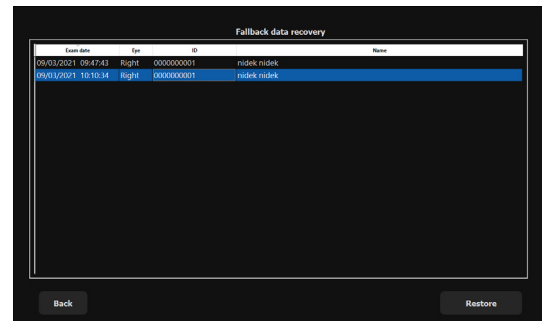
4.3.8 Fallback data recovery

When the exam data cannot be output to the USB removal disk or NAVIS-EX, the data is temporarily saved in the device.

The temporarily saved exam data is output to the USB removal disk or NAVIS-EX connected properly.



- 1 Check whether the USB removal disk or NAVIS-EX is connected properly.
- 2 Press [Fallback data recovery] on the Maintenance screen to display the Fallback data recovery screen.



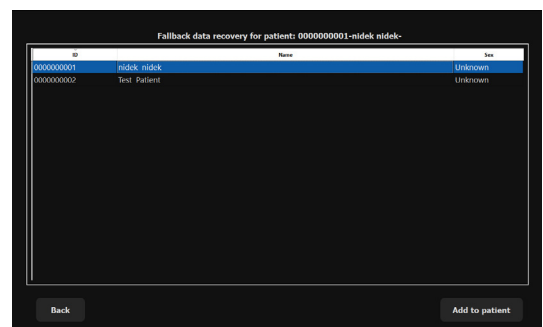
- 3 Select the exam data that needs to be restored and press [Restore].

When there is patient data that matches the data saved in the USB removal disk or NAVIS-EX, "Target patient" is automatically selected.



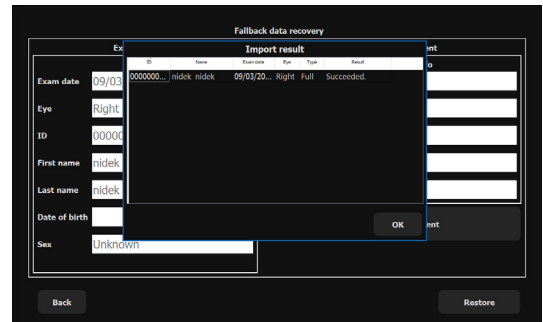
- 4 Check that the exam data to be restored matches the target patient.

If it does not match, press [Change patient] to display the Fallback data recovery for patient screen. Select the target patient and press [Add to patient].



5 Press [Restore].

When the data is restored to NAVIS-EX, if the selected patient data is open on another server, [Restore] cannot be performed.

6 The import result is displayed. Press [OK] to close it.**7** Press [Back] to close the Fallback data recovery screen and return to the Maintenance screen.

4.3.9 Preparation for device packing (Packing mode)

The operator can set the device state properly to be packed and transported by performing the following procedure.

CAUTION

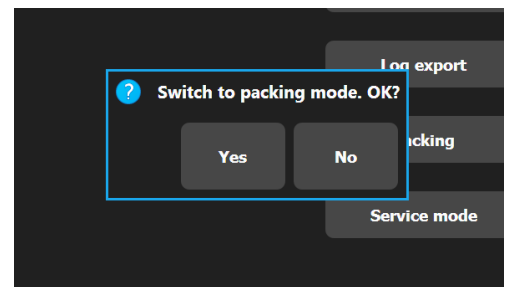
- For transport, set the device to Packing mode and pack the device with specified packaging materials. Excessive vibration or impact may result in device failure.

1 Confirm that the image capturing unit is unlocked ().

If it is locked, move the locking lever to unlock it.

2 Press [Packing] on the Maintenance screen.

The confirmation message appears.



3 Press [Yes] to activate Packing mode.

Packing mode is activated. The image capturing unit and chinrest are lowered automatically as far as they can go.


4 The message notifying the process completion appears. Press [OK] to close the message.

5 Press [Back] to return to the home screen.

6 Press [Shut down] to turn off the device.

7 Move the locking lever to the Lock position ().

8 Also check the following items.

- The locking lever of the image capturing unit is set to the Lock position ().
- The MM prism is detached and the prism cap is on it.
- The chinrest paper pins may come loose during transport. Detach them beforehand or fasten them with velcro tape.

Note

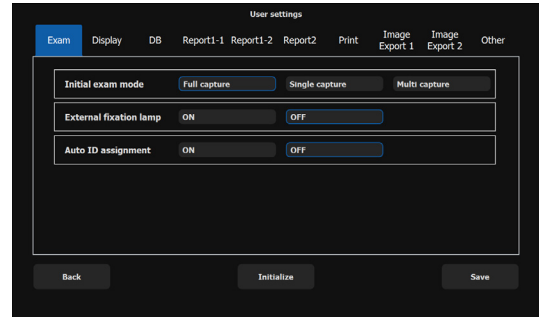
- When starting the device in Packing mode, turn on the power switch (same as normal start-up).

4.4 Changing Device Parameters

4.4.1 Procedure for changing device parameters

Change the device parameters accordingly for the intended use of the device.

- 1 To display the User settings screen, press [Settings] on the home screen. Then, press [Yes] on the following confirmation message.
- 2 On the User settings screen, change the parameter settings.



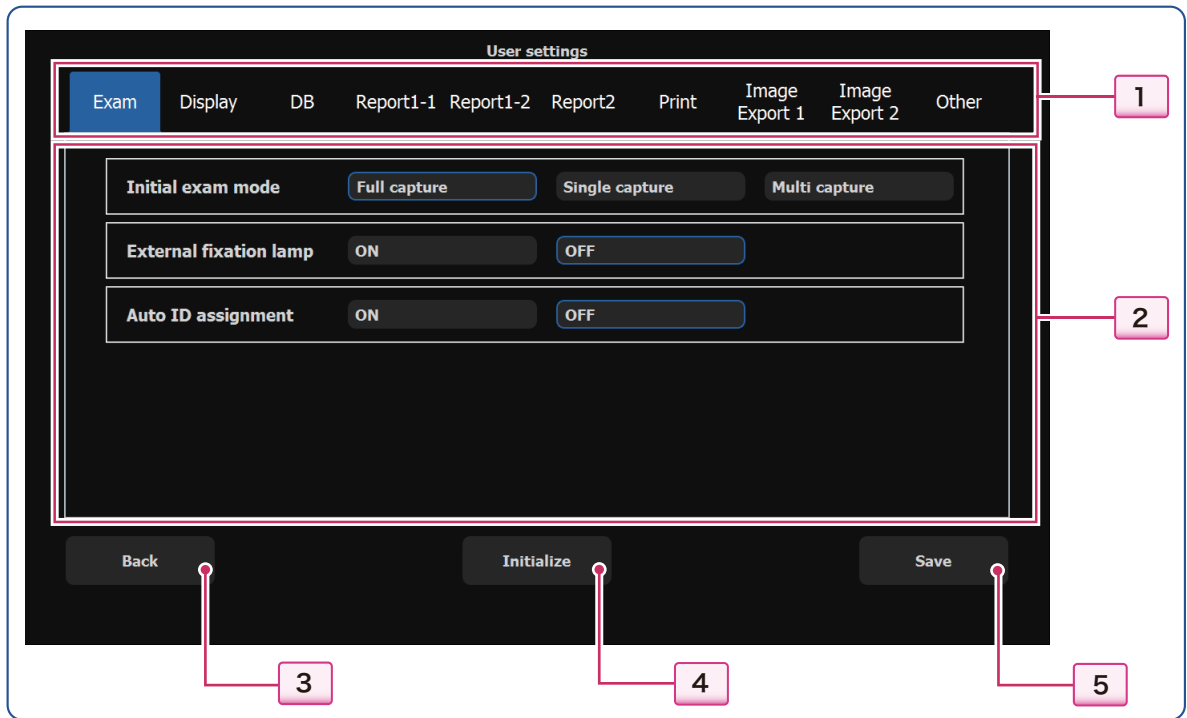
- 3 Change the parameters, then press [Save] to save the current settings.
- 4 The confirmation message notifying the settings are saved appears. Press [OK] to close the message.
- 5 Press [Back] to return to the home screen.

When [Back] is pressed while unsaved data exists, the confirmation message "User settings are changed. Save it?" appears.

[Yes]	Pressed to save the settings and to switch the current screen.
[No]	Pressed to switch the current screen without saving the settings.
[Cancel]	Pressed to close the confirmation message window without saving the settings.

4.4.2 Operations on User settings screen

The user settings screen consists of eight tabs (the first tab is [Exam] and the last tab is [Other]). The current setting parameters are indicated in check boxes, radio buttons, or pull-down list boxes.



1	Tab	Press each tab (starting from [Exam] and ending with [Other]) and select the parameters.
2	Parameter	Set the parameters with the text boxes, radio buttons, or pull-down list boxes. For the parameters in the text boxes, directly enter the information with a numeric keypad that is displayed by touching each text box.
3	[Back]	Pressed to return to the home screen. If the setting changes are unsaved, a confirmation message appears.
4	[Initialize]	Pressed to initialize the parameters on the current tab to defaults.
5	[Save]	Pressed to save and enable the parameters displayed in the current tab.

4.4.3 Parameters list

Note

- The underlined items are the default settings.

[Exam] tab	Setting
Initial exam mode Mode of initial image capture	<u>Full capture</u> , Single capture, Multi capture
External fixation lamp Use of external fixation lamp (optional)	ON, <u>OFF</u>
Auto ID assignment Whether ID will be automatically assigned to a new patient The setting display is grayed out when the device is connected to NAVIS-EX.	ON, <u>OFF</u>

[Display] tab	Setting
Date Date display format	<u>YYYY/MM/DD</u> , MM/DD/YYYY, <u>DD/MM/YYYY</u>
Time Time display format	<u>24H</u> , AM/PM
Eye direction Display format of right/left eye	<u>R/L</u> , OD/OS
Name Name indication	<u>First name. Last name</u> , Last name, First name

[DB] tab	Setting
Number of images saved per mirror surface Number of images saved per mirror surface in Full capture mode and Multi capture mode Number of images saved in the NAVIS-EX database when [NAVIS-EX] is selected as "Save destination"	1, 3, 5, 7, 9, 11, 13, 15 (Default setting: 5)
Save destination Save destination of captured image and patient information	<u>Internal SSD</u> , USB removable disk, NAVIS-EX
USB removable disk setting When the save destination is set to "USB removable disk", also specify the USB port drive. When the data storage is detected, the free space is displayed in "Free space".	E
NAVIS-EX When the save destination is set to NAVIS-EX, specify the Host name and Port number of NAVIS-EX. After the setting, press [Connection test] to check whether the configured storage is accessible. "0" cannot be used for the Port number.	Host name, Port number

[Report1-1] tab

Setting

Save destination	USB removable disk, <u>N</u> etwork folder
Report export destination (for an export to USB removable disk)	

USB removable disk setting	E
When the save destination is set to "USB removable disk", also specify the USB port drive. When the data storage is detected, the free space is displayed in [Free space].	

**Note**

- In [Report1-1] and [Report1-2] tabs, the same save destinations are indicated.
According to the desired destination, perform the setting in the [Report1-1] or [Report1-2] tab.

[Report1-2] tab

Setting

Save destination	USB removable disk, <u>N</u> etwork folder
Report export destination (for an export to network folder)	

Network folder	Set the computer name, user name, password, and folder name.
When the save destination is set to the network folder, also specify the computer name, user name, password, and folder name. After the setting, press [Connection test] to check whether the configured storage is accessible.	

[Report2] tab

Setting

Auto export	ON, <u>O</u> FF
Automatic data export to a report after image capture	

NAVIS export setting	Other, <u>N</u> AVIS-AZU/CL
Selecting a report from NAVIS or other destination When selecting NAVIS-AZU/CL, also set the timeout time (None/5s/10s/15s/30s).	

Image format	<u>J</u> PEG, PNG, PDF
Selecting an image format of report	

Layout	Stitching image, <u>16</u> images, Stitching + 16 images
Setting the printing layout of report	

Report quality	<u>L</u> OW, MIDDLE, HIGH
Selecting the quality (resolution) of the report to be exported The report file size becomes larger as the image quality becomes higher.	

[Print] tab

Setting

Printer	Printer name
Selecting a printer from the pull-down list	

Paper	Paper size
Selecting a paper size from the pull-down list	

Auto print	ON, <u>O</u> FF
Automatic report printing after an image capture	

[Print] tab

Setting

Layout	Stitching image, <u>16 images</u> , Stitching + 16 images
Setting the image layout to be printed on a report	
Allocation print	ON, <u>OFF</u>
Activation of allocation print function (two reports are printed side by side)	

[Image Export 1] tab

Setting

Save destination	<u>USB removable disk</u> , Network folder
Selecting the save destination of exported images	
Network folder	Set the computer name, user name, password, and folder name.
When the save destination is set to the network folder, also specify the computer name, user name, password, and folder name.	
After the setting, press [Connection test] to check that communication has been established properly.	

[Image Export 2] tab

Setting

Auto export	<u>OFF</u> , Best focus, All
Automatic export of images to the save destination	
Type of images to be automatically exported	
Patient information	ON, <u>OFF</u>
When "ON" is selected, the patient name (first name) is included in the name of the folder "GS-Pat (patient ID)" generated in the save destination. In addition, a TxT file of patient information (patient notes and capture notes) is exported along with images.	
However, if neither the patient comment nor capture comment is input, the TxT file is not exported.	

[Other] tab

Setting

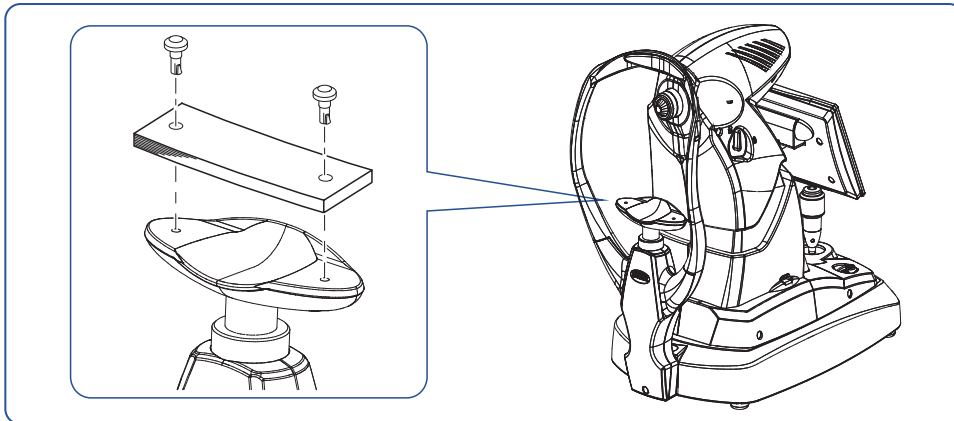
Language	<u>English</u> , Japanese
Language to be displayed and printed in	
Beeps	<u>ON</u> , OFF
Setting ON or OFF of operational beeps	
LCD brightness	High, <u>Medium</u> , Low
Selecting the brightness of LCD touch screen	
Password	ON, <u>OFF</u>
Password certification at the device start-up	
When setting it ON, the [Password change] function becomes enabled and a password change window appears. The default password is "nidek".	

The screenshot shows a dark-themed dialog box for password change. It contains three input fields, each with a password mask of six dots. The first field is labeled 'Current password'. The second and third fields are both labeled 'New password', with the third field having a sub-label '(enter again for confirmation)'. At the bottom right, there are two buttons: 'OK' and 'Cancel'.

4.5 Attaching Standard/Optional Accessories

4.5.1 Attaching chinrest paper

With chinrest pins, attach the proper amount of chinrest paper to the chinrest. Thickness of the attached chinrest paper must be below 6 mm.

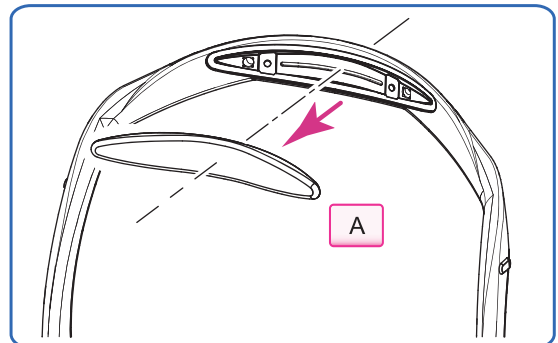


4.5.2 Replacing forehead rest

If the forehead rest material (polyester elastomer) is deteriorated or persistently stained, replace the forehead rest with the replacement one (part number: 15411-M752).

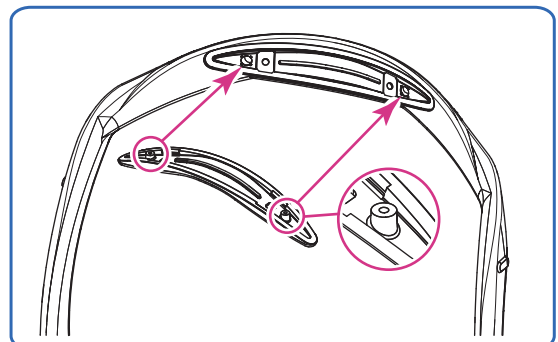
- 1 Remove the forehead rest pad **A** from the frame.

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

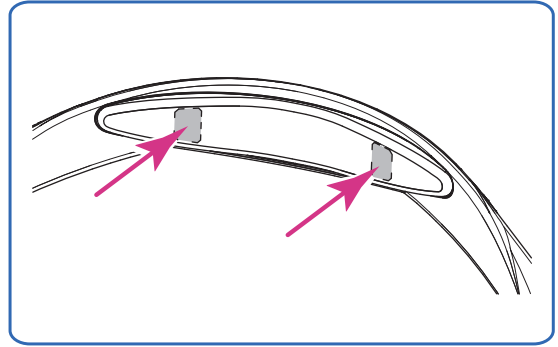


- 2 Attach a new forehead rest.

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

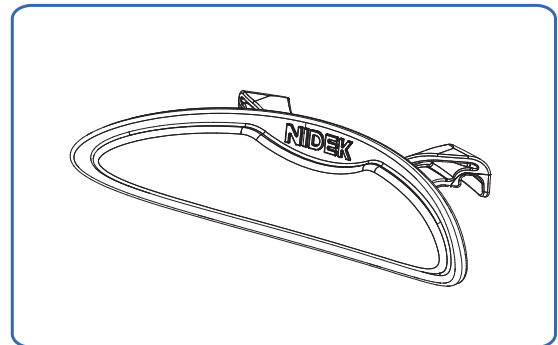


- 2) Attach the forehead rest pad by pressing over the fastener positions on both sides.
The forehead rest pad is locked by the fasteners.
- 3) Confirm that the forehead rest pad is securely attached.

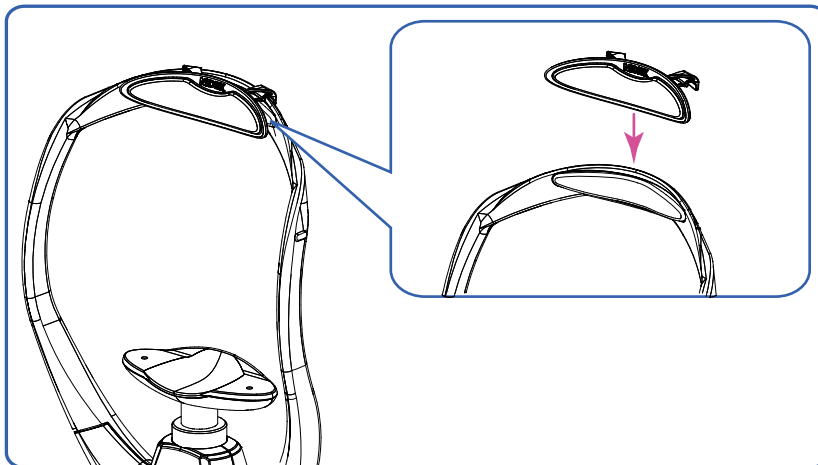


4.5.3 Attaching forehead arm

When the distance between the patient's eye and image capturing unit (MM prism) is too close, attach the forehead arm for the image capture.




Attach the forehead arm to the upper side of forehead rest.




4.5.4 Attaching external fixation lamp

The external fixation lamp (optional) is intended for a patient whose eyes cannot be focused securely by the internal fixation lamp. In such a case, ask the patient to keep on looking at the external fixation lamp with unaligned eye. Doing so can fix the patient's visual line.

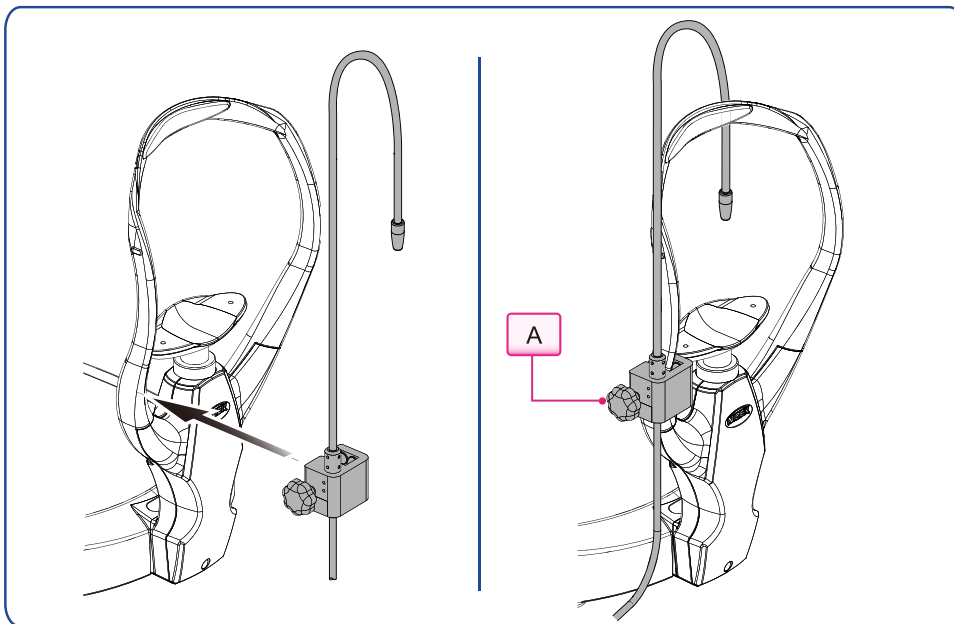
CAUTION

- Never connect any unspecified external fixation lamp to the fixation lamp connector (--).
- Insert the external fixation lamp cable, taking care that the device is turned off.

Note

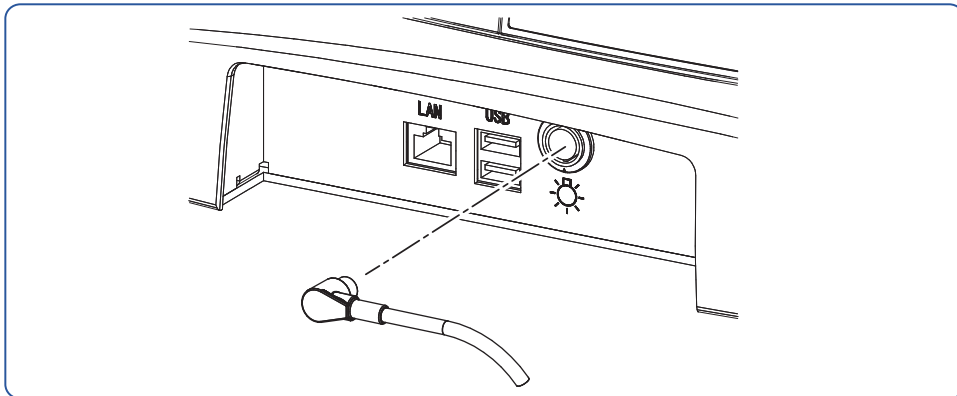
- When using the external fixation lamp, set the parameter "External fixation lamp" to "ON". ( "4.4.3 Parameters list" (page 135))

- 1) Turn off the device.
- 2) Attach the external fixation lamp to the head rest. Then, tighten the knob **A** to securely fasten it.



- 3) Insert the external fixation lamp cable into the fixation lamp connector (☀).

Insert the cable horizontally as shown in the figure below, taking care that it is not inserted at an angle.



4.6 Cleaning the Device

4.6.1 Cleaning device appearance

If dirt occurs on the device cover or panel, wipe it with a soft cloth soaked with water or neutral detergent thinned with water. When using a disinfecting agent, make sure that it contains chlorine or alcohol.

 **CAUTION**

- To prevent an electric shock, be sure to disconnect the power cord prior to cleaning.
 - Never use any organic solvent such as paint thinner or benzine and any other polishing cleanser.
Use of these agents may damage the device.
 - Wipe the LCD touch screen with a soft cloth. Do not apply unnecessary force on it.
 - Never wipe the device with a cloth or sponge heavily dampened in water.
Doing so allows water intrusion and results in device malfunction.
 - When using any cleaning or disinfecting agent, follow the instructions by the agent's manufacturer.
-
-

1 Turn off the GS-1 and disconnect the power cord.

2 Wipe the device with a soft cloth.

When wiping the surface, start wiping from clean area then move to dirty area.

For severe stains, soak a cloth in neutral detergent thinned with water, wring it dry, and wipe the device surface. Then, wipe the device again with a dry, soft cloth.

3 If necessary, use a cleaning or disinfecting agent.

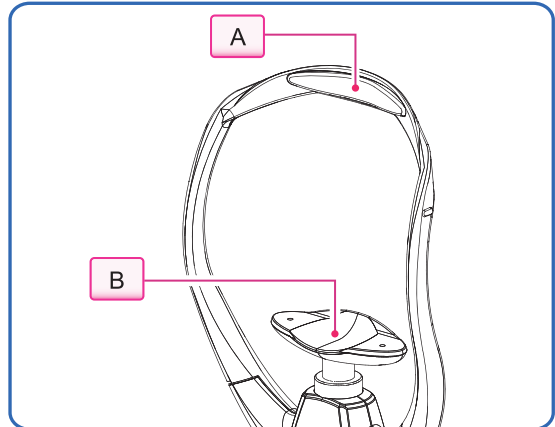
Never spray an agent directly on the device. Apply the agent to a cloth then wipe the device.

4 Dry the device sufficiently in a well-ventilated location.

4.6.2 Cleaning forehead rest and chinrest

Be sure to clean the forehead rest **A** and chinrest **B** after every patient.

Wipe the forehead rest and chinrest with a clean gauze or absorbent cotton. If necessary, wipe with a clean cloth dampened with rubbing alcohol.



CAUTION

- When wiping the forehead rest, never use a cloth heavily dampened with rubbing alcohol. The forehead rest may be deteriorated.

4.7 Disinfecting/Sterilizing MM prism

Be sure to clean and disinfect (or sterilize) the MM prism every time after an image capture. Follow the recommendations described in the procedure to clean and disinfect (or sterilize) the MM prism properly.

CAUTION

- The accessory MM prisms are not cleaned, disinfected, or sterilized before the delivery. Be sure to clean and disinfect (or sterilize) them before use.
- When sterilizing or disinfecting the MM prism according to the criteria of each medical facility, take the measures for Semi-critical degree in the Spaulding classification.
- When the MM prism is detached, be sure to put the prism cap on it to prevent dusts.
- Use proper protective equipment such as protective eye glasses, goggles, or gloves as recommended by the manufacturer of the cleaning or disinfecting agent.
- For the use of cleaning or disinfecting agent, read the handling manual (attached document) thoroughly. Confirm that the concentration, temperature, and immersion time are proper for clinical use.
- Confirm that the use-by date for cleaning agents, disinfecting agents, and sterilization cotton has not expired.

The MM prism is classified into Semi-critical degree according to its infection risk. Perform the high or intermediate level disinfection or low temperature sterilization (EOG sterilization) on it. The MM prism is made from Cycloolefin polymers (COP) resin. The MM prism mirror will be deteriorated gradually by repeated disinfection and sterilization. It is recommended to replace the MM prism after disinfection or sterilization has been performed the number of times specified in the table below.

For checking the MM prism, see “3.3.3 Checking MM prism” (page 47).

Processing	Number of times
Sterilization (EOG sterilization)	30 times
High level disinfection (immersion in glutaral solution)	100 times
High level disinfection (wiping by chlorine dioxide disinfecting agent)	100 times
Intermediate level disinfection (immersion in hydrogen peroxide solution)	100 times

● Disinfection (or sterilization) procedure

1	Removal	“4.7.1 Detaching MM prism (cleaning preparation)” (page 145)
2	Cleaning	“4.7.2 Cleaning MM prism (cleaning procedure)” (page 146)
3	Disinfection or sterilization	“4.7.3 Disinfecting MM prism (by immersion)” (page 147)
		“4.7.4 Disinfecting MM prism (by wiping)” (page 149)
		“4.7.5 EOG sterilization of MM prism” (page 151)
4	Storing for next use	“4.7.6 Storing MM prism” (page 152)
5	Preparation for use	“4.7.7 Reattaching MM prism to device” (page 152)

- Degree of infection risks (Spaulding classification)

The tables below describe three degrees of infection and their disinfection methods. The infection degrees are classified into “critical”, “semi-critical”, and “non-critical” based on the clinical use and presumable hazards. These degrees designate the disinfection and sterilization criteria according to the body tissue that contacts medical equipment.

Degree (infection risk)	Definition	Treatment
Critical (High risk level)	Equipment that is inserted into sterile tissue and blood vessels, or that which passes through skin and membrane	Sterilization
Semi-critical (Medium risk level)	Equipment that contacts damaged skin, intact sterile membranes, blood vessels, or bodily fluid	High level disinfection Intermediate level disinfection
Non-critical (Low risk level)	Equipment that does not contact a patient, or that which contacts intact skin	Low level disinfection Only device wiping and cleaning

Note

- The MM prism is classified into “semi-critical” by the Spaulding classification. The FDA^{*a} and CDC^{*b} guidelines recommend medical devices used on intact membranes be processed with high level disinfection or sterilization.

Therefore, this operator’s manual provides both the disinfection and sterilization procedures.

*a. FDA “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 17, 2015)

*b. CDC “Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)

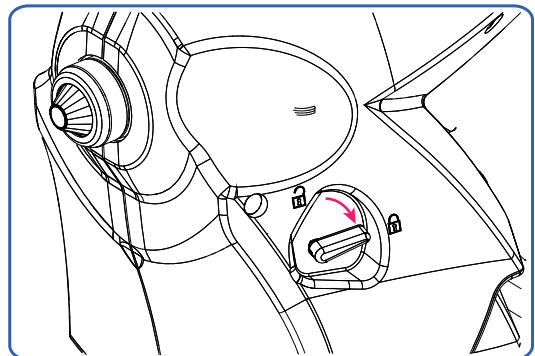
4.7.1 Detaching MM prism (cleaning preparation)

Detach the MM prism. Then, clean and disinfect (or sterilize) it individually.

- 1** After the image capture, lock the image capturing unit and wipe out the remaining gel.

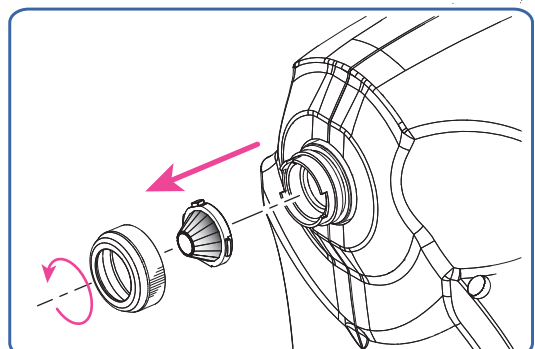
Wipe out the gel and dirt immediately after the image capture.

If the gel is dried already, soak a soft cloth in water and wipe out the gel.



- 2** Turn the prism clamp counterclockwise to loosen it and detach the MM prism from the image capturing unit.

- 3** Place the MM prism with its tip facing upright on a stable place. Store the prism clamp in the specified location.

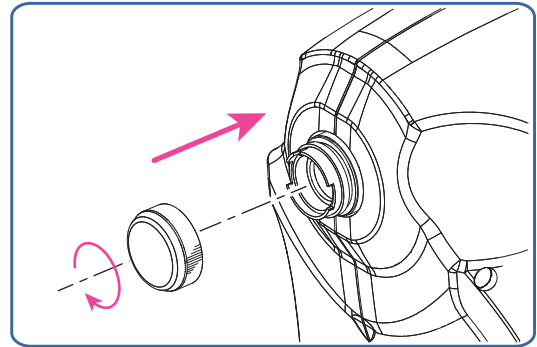


⚠ CAUTION

- Never return the used MM prism to the prism case. Inside of the case may be contaminated.

4 Turn the prism cap clockwise to attach it to the image capturing unit.

When examining another patient, attach the clean MM prism.



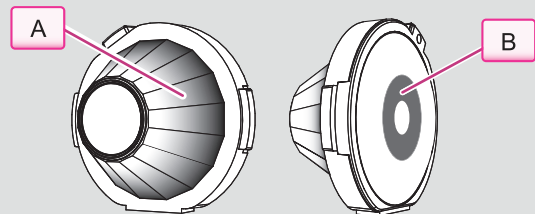
4.7.2 Cleaning MM prism (cleaning procedure)

To disinfect (or sterilize) the MM prism thoroughly, be sure to remove any foreign matters (such as microbial) from the MM prism as completely as possible.

⚠ CAUTION

- Do not bump the MM prisms when soaking them in the cleaning agent. Otherwise the MM prisms may be damaged.
- Clean the MM prism by hand. Never clean the MM prism with an ultrasonic cleaning method. Doing so may damage the prism mirror.
- Avoid unnecessary pressure or continuous rubbing on the prism mirror **A** and ring mask **B**. Also do not use the rubbing alcohol (ethanol) for wiping the ring mask **B**.

They may be damaged or coatings may be peeled off.



1 Clean the MM prism with any of the following methods.

- Clean the MM prism with running sterile water.
- Wipe the MM prism with a clean gauze or cloth dampened with rubbing alcohol.
- Immerse and clean the MM prism in the cleaning agent.
 - 1) The container must have a sufficient depth that the MM prism can be immersed fully.
 - 2) Prepare another small container and fill it with cleaning agent. The concentration and temperature of the cleaning agent should satisfy the requirements specified by the agent's manufacturer.
 - 3) Clean the whole surface by using a soft brush or gauze in the cleaning agent. In this process, pay attention not to rub the prism tip, mirror, and ring mask with unnecessary force on it.
 - 4) Take out the MM prism and immerse it in clean water. Then, gently swing and rinse it.

- 2 Immediately wipe out the water on the prism surface and dry it.
With a clean gauze or such, wipe the MM prism gently not to damage it.
- 3 Confirm that no gel or dirt (foreign matters) remains on the prism surface. If dirt still remains, repeat the above procedure until they are removed completely.

4.7.3 Disinfecting MM prism (by immersion)

Immerse the MM prism in any of the disinfecting agents.

Disinfecting agent (high level disinfection)	Glutaral solution (Glutaraldehyde)
Optimal concentration	2.0 to 3.6%
Immersion time	1 hour (Follow the instruction by the agent manufacturer.)

Disinfecting agent (intermediate level disinfection)	Hydrogen peroxide solution
Optimal concentration	Undiluted solution (containing 2.5 to 3.5 w/v% of hydrogen peroxide solution)
Immersion time	1 hour

Disinfecting agent (low level disinfection)	Chlorhexidine gluconate solution
Optimal concentration	Dilute to 0.5% with ultrapure water
Immersion time	1 hour (Follow the instruction by the agent manufacturer.)

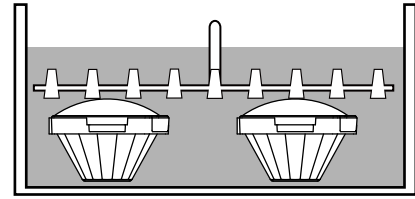
CAUTION

- Do not immerse the MM prism in the solution for over one hour.
Degradation of the mirror surface reduces the lifetime of the MM prism.
- Do not use any peracetic acid. Using it erodes the MM prism. The ultraviolet disinfection is not allowed either because the MM prism is made from resin.
- Do not use alcohol disinfecting agent (ethanol for disinfection, 70% isopropanol, or such)
The ring mask may come off.
- Perform low level disinfection only when primary disinfection is necessary. In this case, be sure to perform intermediate level disinfection as the next process.
- Be sure to immerse the MM prism fully in all the disinfection processes. Proper disinfection will not be achieved if air bubbles remain or the immersion is incomplete.
The MM prism floats to the surface due to its light weight. Place a small lid directly on the prisms to immerse them fully.
- Be careful so that the immersed MM prisms are not scratched by bumping against each other.
- After the disinfection, rinse the MM prism sufficiently.
- For the use of the disinfecting agent, refer to each manual.

- 1 Prepare a small container and fill it with the disinfecting agent at the concentration and temperature recommended by the manufacturer of the disinfecting agent.
The container needs to be deep enough so that the MM prisms can be immersed fully.

2 Immerse the MM prisms in the disinfecting agent.

Immerse the MM prisms with its tip facing downward.
Place a lid on the MM prisms, making sure that they are immersed fully.



3 Remove air bubbles completely from the MM prisms.

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

4 To prevent the disinfecting agent from evaporating, be sure to place a lid on the container. Then, leave the MM prisms immersed at the temperature and for the duration recommended by the manufacturer of the disinfecting agent.

5 Take out the MM prisms from the disinfecting agent.

6 Rinse them with sterile purified water and remove the residual agent completely.

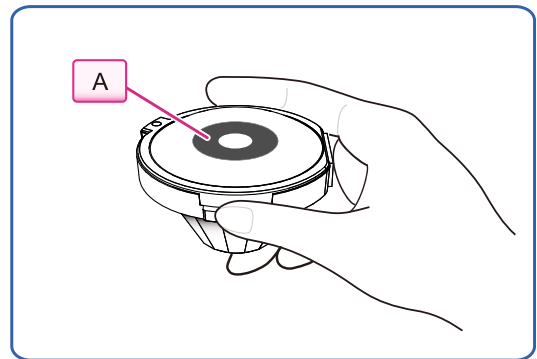
When rinsing them without the use of sterile purified water, wipe them with a sterile absorbent cotton soaked with disinfection ethanol.

Do not wipe the ring mask **A** at this time.

- 1) Clean the MM prism with running sterile purified water for more than 30 seconds.
- 2) Wipe the prism surface with a sterile gauze and dry sufficiently.

Remove water by lightly pressing the gauze against the MM prism without rubbing so as not to scratch the prism.

- 3) Dry the MM prism completely.



7 Store the MM prisms according to the specification.

Handle the MM prisms with care to keep the disinfected MM prisms clean.

4.7.4 Disinfecting MM prism (by wiping)

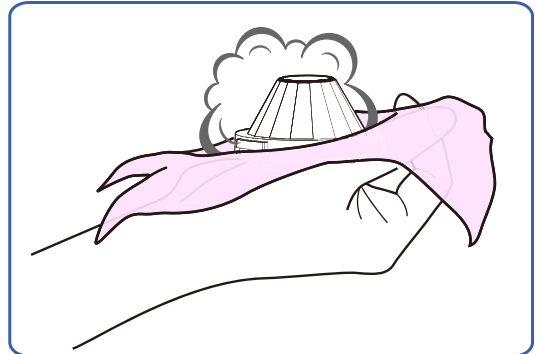
Wipe the MM prism with chlorine dioxide disinfecting agent for high level disinfection.

Disinfecting agent (chlorine dioxide)	Tristel Duo OPH, Tristel Solutions Ltd.
Optimal concentration	Undiluted solution (foam consisting of mixture of two solutions)
Immersion time	30 seconds or more (Follow the instruction by the agent manufacturer.)

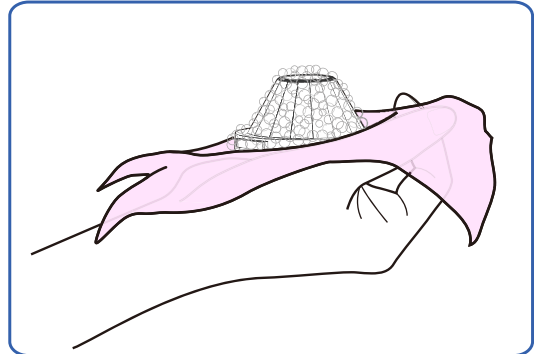
CAUTION

- Be sure to cover the surface of the MM prism completely with the foam. Any uncovered parts will not be disinfected sufficiently.
- After the disinfection, rinse the MM prism sufficiently.
- For the use of the disinfecting agent, refer to each manual.

- 1** Apply an appropriate amount of Tristel Duo OPH on a dry sterile gauze, or directly on the MM prism placed on a dry sterile gauze.
Two liquids are mixed to become a foam agent.



- 2** Spread the foam agent all over the MM prism.
Check that the entire MM prism is covered with the foam agent.



- 3** Hold the MM prism covered with the foam agent for 30 seconds or more.
Be careful so that the agent will not come off by repeated wiping of the MM prism. In addition, make sure that the MM prism does not become partially dry because any dried part will not be disinfected properly.
Dispose of the sterile gauze used for the application of the agent. Do not reuse it.

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

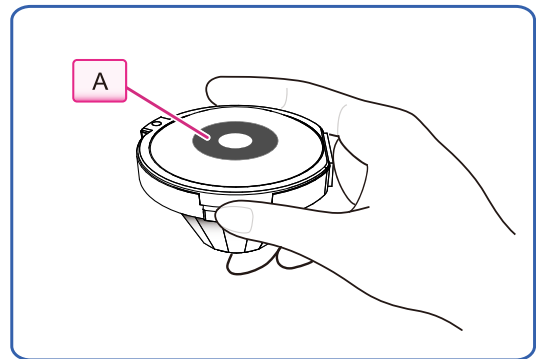
When rinsing it without the use of sterile purified water, wipe the rinsed MM prism with a sterile absorbent cotton soaked with disinfection ethanol.

Do not wipe the ring mask **A** at this time.

- 1) Clean the MM prism with running sterile purified water for more than 30 seconds.
- 2) Wipe the prism surface with a sterile gauze and dry sufficiently.

Remove water by lightly pressing the gauze against the MM prism without rubbing so as not to scratch the prism.

- 3) Dry the MM prism completely.



5 Store the MM prism according to the specification.

Handle the MM prism with care to keep the disinfected MM prism clean.

4.7.5 EOG sterilization of MM prism

Be sure to perform the ethylene oxide gas sterilization (indicated as EOG sterilization in the following) on the MM prism because the EOG sterilization works under low temperature.

CAUTION

- The MM prism is made from non-heat resistant materials. No autoclave sterilization is possible.

Recommended conditions of EOG sterilization

EO gas concentration	621mg/L (20% of mixed gas is used)
Sterilization pressure	100.0 kPa
Sterilization temperature	49°C (37 to 63°C)
Humidity	50%
Sterilization time (exposure time)	5 hours
Aeration time	12 hours
Sterilization bag	Same specification as that generally used in medical facilities

- 1** Prior to the EOG sterilization, dry the MM prism completely.
EOG sterilization is not complete as long as water drops remain.
- 2** Put the MM prism one by one in the EOG sterilization bags according to the procedure specified in each facility. Then, securely seal the bags.
The sterilization bag must conform to EN ISO 11607 or EN 868.
- 3** Sterilize the sterilization bags under the specified conditions.
- 4** Perform the aeration under the specified conditions.
- 5** Store the MM prism according to the specified procedure.
Be sure to store the MM prism under clean and dust-free environment.

4.7.6 Storing MM prism

Before storing the MM prism, make sure that it has been sterilized (or disinfected). Do not handle it until just before the image capture.

CAUTION

- Never contact the disinfected (or sterilized) MM prism to any other contaminated equipment.
- Store the MM prism in the location free from ultraviolet radiation or direct sunlight, under room temperature, with clean and well-ventilated environment.


- 1** Place the MM prisms in the prism case, taking care that they do not contact each other. When the MM prism is packed in the sterilization bag, store the sterilization bag in the prism case without opening it.
- 2** Place the prism case in a storage location.

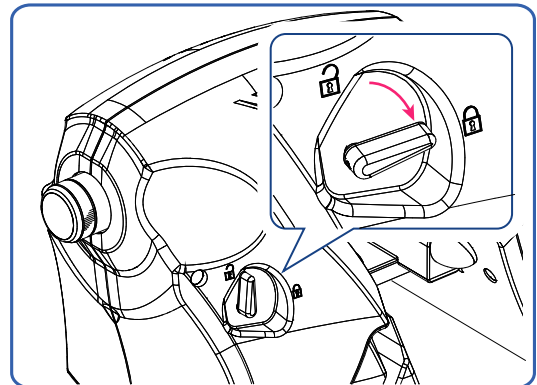
Be sure to clearly describe on the prism case that the contents have been sterilized (or disinfected) properly.

4.7.7 Reattaching MM prism to device

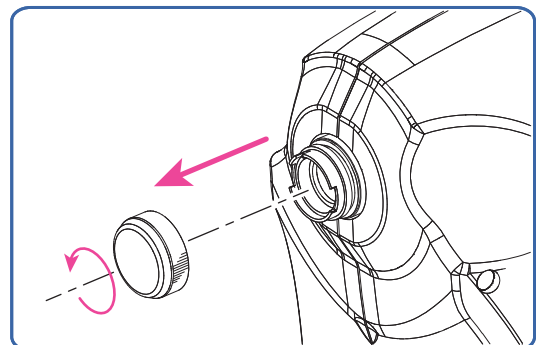
To preserve hygiene, do not attach the disinfected (or sterilized) MM prism until just before the image capture.

When handling the MM prism, pay attention not to touch the prism tip.

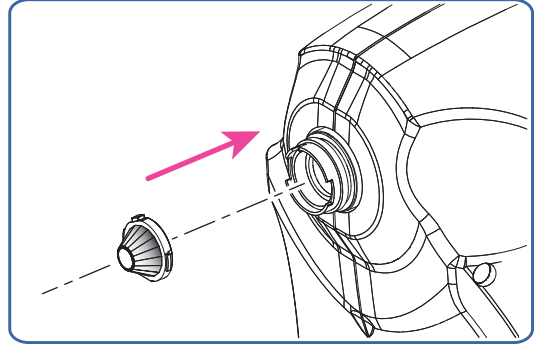
- 1)** Confirm that the image capturing unit is securely locked.
If it is unlocked, move the locking lever to the Lock position  .



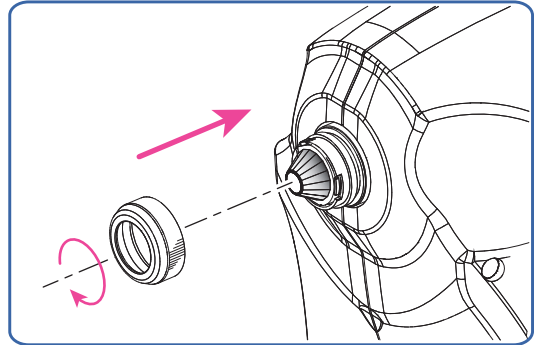
- 2)** Turn the prism cap counterclockwise to detach it.



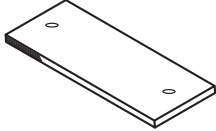
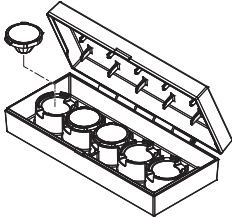

- 3) Attach the MM prism with the flanges aligned with the holder.
Do not touch the MM prism tip and mirrors.



- 4) Turn the prism clamp clockwise to attach it.



4.8 Consumable Parts and Maintenance Parts

Name (Part number)	Appearance	Remarks
Chinrest paper (32903-M047)		1 unit
Prism kit (GN001-7210)		Three units of prism and a box of prism case
Forehead rest (15411-M752)		Forehead rest pad

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



SPECIFICATIONS AND TECHNICAL INFORMATION

5.1 Specifications

ACA image capture	
• Capturing area (per image)	Approximately 2.36 mm (circumference direction) x 2 mm (diameter direction)
• Working distance	1.5 mm
• Light source	White LED
Other functions	
• Auto tracking movable range	Vertical: 32 mm Horizontal: 5 mm
• Main unit movable range	Forward and backward: 36 mm Horizontal: 85 mm
• Chinrest movable range	Vertical: 62 mm
• Display	9.0-inch (WXGA) color LCD touch screen
• Storage	Internal SSD
• Interface	USB-A: 2 ports (for USB 2.0) LAN: 1 port
Power specifications	
• Voltage	AC 100 to 240 V Allowable deviation is nominal voltage $\pm 10\%$ or smaller.
• Frequency	50/60 Hz
• Power consumption	100 VA
Dimensions and mass	
• Dimension	280 mm (W) x 504 mm (D) x 460 mm (H)
• Mass	15 kg

Environmental conditions	
• Environmental conditions (during use)	Temperature: 10 to 35°C (50 to 95°F) Humidity: 30 to 90% (non-condensing) Atmospheric pressure: 800 to 1060 hPa Installation place: Indoor Other: No harmful dust, gas, or smoke, non-condensation, free from interference light, no direct sunlight, no vibration and impact, no exposure to water
• Environmental conditions (during storage)	Temperature: -10 to 55°C (14 to 131°F) Humidity: 10 to 95% (non-condensing) Atmospheric pressure: 700 to 1060 hPa
• Environmental conditions (during transport and packed state)	Temperature: -30 to 60°C (-22 to 140°F) Humidity: 10 to 95% (non-condensing) Atmospheric pressure: 500 to 1060 hPa
Other	
• Expected service life	8 years from the date of purchasing (defined by manufacturer) * Proper maintenance, inspection and consumable parts replacement are necessary.
• Classification	Protection against electrical shock: Class I ME equipment, 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: Ethylene oxide gas sterilization (only for MM prism) Mode of operation: Continuous operation
Product configuration	
• Standard accessories	Power cord, dust cover, chinrest paper, chinrest pin (2 units), forehead arm, model eye, prism kit, prism clamp, prism cap, Operator's Manual, Quick Reference Guide
• Optional configuration	Barcode scanner (19701-E006) Magnetic card reader (14631-E001) Shielded LAN cable (15602-E010) External fixation lamp (15456-0100) Head belt (10126-M001)

5.2 Glossary

To assist in use of this device and this manual, the following glossary is provided.

Glossary	
Auto start	Automatically starts an image capture when the device is aligned to patient's eye at a correct working distance.
Auto tracking	Automatically adjusts the vertical and horizontal positions of the image capturing unit to the patient's eye.
Auto exit from image capture	Automatically exits the image capture mode when LED continues to illuminate for more than 5 minutes in each image capture.
Auto select	Automatically selects one image that focus is achieved most precisely among captured images.
Spaulding classification	Classifies medical equipment into three categories based on their clinical use and infection risks on target body tissue, designating proper disinfection or sterilization method for each category.
High level disinfection	Removes all microbial excluding the case where spore exists abundantly.
Medium level disinfection	Removes much of tubercle bacillus, vegetative bacterias, and virus excluding spores.
Low level disinfection	Removes much of vegetative bacterias, specified virus and fungus.
Multi mirror prism (MM prism)	Prism that also functions as an objective lens. The mirror has 16 portions. With this mirror, the image capturing optical axis is reflected into 16 directions. An image can be captured by the gel applied to the depressed area on the surface.
Mirror	Mirrors on the MM prism side
Single capture	Manually captures an image at the desired positions.
Multi capture	Automatically captures images at the desired positions.
Full capture	Automatically captures the entire circumference of the anterior chamber angle with 16 divided images.
Stitching image	Single composite image of 16 entire circumference images of anterior chamber angle
Slider unit	Moves back the image capturing unit away from patient's eye if the image capturing unit applies excessive force to patient's eye.
Direct print	Prints the report data by connecting the main body and printer with USB cable.

Abbreviations	
CDC	Centers for Disease Control and Prevention
EMC	Electro-Magnetic Compatibility
FDA	Food and Drug Administration
HDD	Hard Disk Drive

Abbreviations	
IC	Integrated Circuit
ID	Identification
IME	Input Method Editor
LAN setting	Local Area Network
LCD	Liquid Crystal Display
LED	Light Emitting Diode
MM	Multi-mirror
OD	Oculus Dexter
OS	Oculus Sinister
RF	Radio Frequency
SSD	Solid State Drive
USB	Universal Serial Bus
WD	Working Distance

5.3 Light Hazard

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

CAUTION

- The light emitted from this device is potentially hazardous. The longer the exposure time is, the greater the risk of ocular damage becomes.

Exposure to light from this device when operated at maximum intensity will exceed the safety guideline after the following duration.

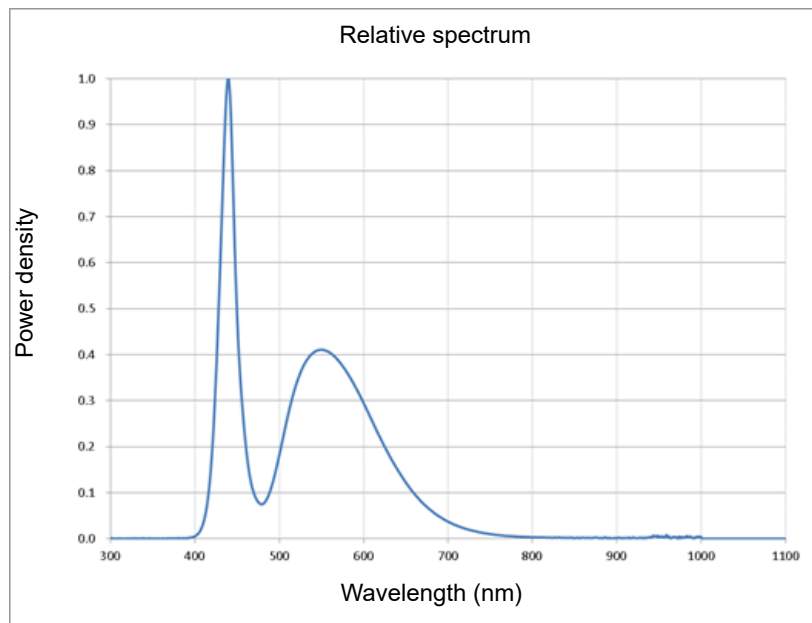
Emission at maximum intensity: 230 seconds

This is the value when the device is used without the MM prism.

The value with the MM prism attached is as follows.

Example) Emission at maximum intensity with the MM prism: 2719 seconds

Relative spectrum during measurement (when all light source is set to maximum)



* The graph above shows the total value of maximum power that has been measured individually.

5.4 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 cause improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) or electromagnetic disturbance sources as shown below should be used no closer than 30 cm (12 inches) to any part of the device, including the specified or provided cables. Otherwise, degradation of the performance of this equipment could result.

The following are examples of electromagnetic disturbance sources:

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

◆ Specified accessories

Part name
External fixation lamp

◆ Specified cables

Part name	Length (m)	Cable Shielded	Ferrite Core
Power cord (GS-1)	2.5	No	No

◆ Essential performance

Anterior chamber angle capture function

◆ Compliance for Emission Standard

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

* 1 For the regions where the rated voltage is 220 V to 240 V, this device complies with this standard.

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

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

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

◆ Compliance for Immunity Standard

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