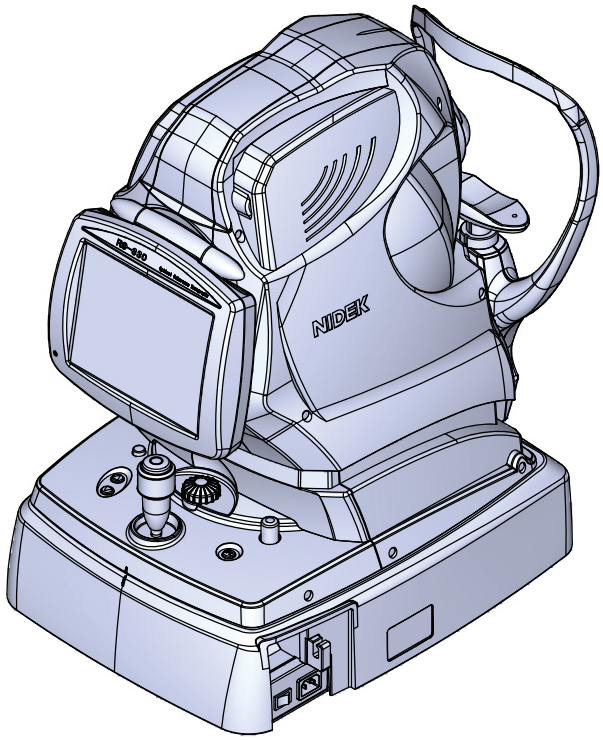
NIDEK

OPTICAL COHERENCE TOMOGRAPHY

RS-330

OPERATOR'S MANUAL



Original instructions

NIDEK CO., LTD.

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

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

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

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Before Use

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

This operator's manual includes information such as the operating procedure, safety precautions, maintenance, and specifications.

Be sure to read this operator's manual before using this product.

Keep this manual handy for reference.

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

IMPORTANT - READ CAREFULLY

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

SOFTWARE LICENSE AGREEMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. CONDITIONS OF USE

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

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

5. EXPORT RESTRICTIONS

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

6. UPDATES

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

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

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

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

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

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

7. TERMINATION

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

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

8. NO WARRANTIES

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

9. LIMITATION OF LIABILITY

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

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

10. GOVERNING LAW AND ARBITRATION

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

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

11. SEVERABILITY

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

12. SURVIVAL

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

13. ASSIGNMENT

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

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

14. ENTIRE AGREEMENT

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

15. NO WAIVER

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

16. NO THIRD PARTY RIGHTS

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

17. HEADINGS

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

18. LANGUAGE

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

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

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

19. APPLICATION OF SOFTWARE LICENSE AGREEMENT

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

Table of Contents

1 SAFETY PRECAUTIONS

1.1 For Safe Use

⚠ **BEFORE USE, READ THIS MANUAL.**
Be sure to read the operator's manual prior to operation of the system to understand the safety precautions and operating procedures thoroughly.

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.

1.2 Usage Precautions

Before use

⚠ WARNING

- If any serious device-related incident occurs, report it to Nidek and the competent authority in the country where the user or patient, or both reside.
- Connect the power plug to a grounded outlet.

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

⚠ CAUTION

- Do not use this system for any purposes other than the intended purpose.

  NIDEK is not responsible for accidents or malfunctions caused by misuse.
- Be sure to read the operator's manual prior to operation of the system to understand the safety precautions and operating procedures thoroughly. Use the accessories specified by NIDEK only.

  Use of the system outside the scope of this manual may cause adverse events or adverse device effects.
- To use the system, a computer and a computer monitor are required. They do not come with the system. Before using the system, prepare ones that satisfy the specifications. Contact NIDEK or your authorized distributor for details.
- Use of the system is limited to doctors or persons qualified by the law of each country.

  Use of the system outside the scope of this manual may cause adverse events or adverse device effects. NIDEK is not responsible for accidents or malfunctions caused by misuse.
- Be sure to install the system where the conditions below can be maintained.

  In addition, use the system under the conditions below.

  Ambient temperature: 10 to 35°C (50 to 95°F)

  Humidity: 30 to 90%

  Atmospheric pressure: 800 to 1,060 hPa

  A well ventilated place free from hazardous particles, smoke, or fumes

  A location not exposed to water

  A level and stable surface free from vibration and shock

  A location not exposed to strong electromagnetic waves

  The room can be darkened to the degree that a newspaper can barely be read.

  If the system is not installed and used under the above conditions, the image quality is compromised, and malfunction may result. In addition, there is a possibility of injury if the system receives shock and falls down.
- Do not modify the system, or touch its interior.

  There is no part within the system that requires servicing by the user.
- Only trained service personnel are allowed to install the system at the time of delivery.

  A failure of the system, electric shock, or fire may result.
- Install the system in an environment where no contaminant such as corrosive gas, acid, or salt is contained in the air.

  Corrosion or malfunction of the system may result.
- Avoid installing the system where it is exposed to direct air-conditioning flow.

  Changes in temperature may result in condensation inside the system or adversely affect the system performance.

⚠ CAUTION

- Be sure to use a (HOSPITAL GRADE) power outlet which meets the power specification requirements.

  The system may not perform properly, or malfunction or fire may occur.

- Never use a power strip or extension cable to supply the system with power.

  The electrical safety may be lowered.

- Do not use a power cord other than the one provided. In addition, do not connect the provided power cord to any other device.

  Failure or fire may result.

- Do not place heavy objects on the power cord.

  A damaged power cord may cause fire or electric shock.

- To connect 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) to the system, supply power to the system and computer through isolation transformers.

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

- Before connecting the cable, turn off the power switch of the isolation transformer and disconnect the power cord from the power outlet.

  Malfunction of the system may result.

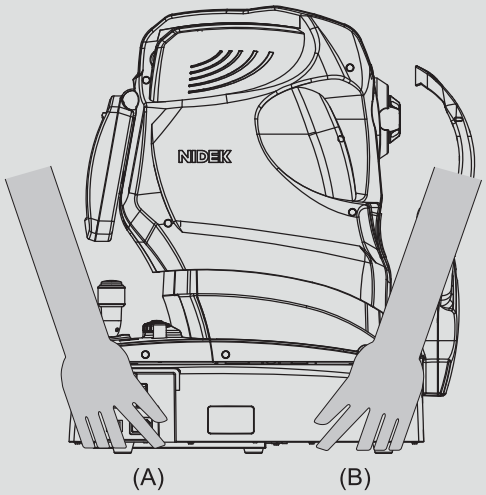
- Install the system so that the outlet that the mains plug is inserted into is easily accessible during use. In addition, ensure that the power cord can be disconnected without the use of any tool.

  Failure to do so may interfere with disconnecting the power from the input power source in case of an abnormality.

- Insert the plug properly into the connector with the correct orientation according to the indication. Do not apply undue force to make the connections.

- The system main body should be carried by two persons holding it at positions (A) and (B) (both right and left sides).
  Hold it by the bottom of the base unit. Avoid lifting it by the forehead rest or the main unit.

  If only one person carries the system, or areas other than the base are used for lifting and the system falls, there is a possibility of injury or malfunction.



During use

⚠ CAUTION

- Before use, perform visual and operation checks. If abnormal conditions are encountered, stop using the system.

  If the system is used under abnormal conditions, intended results may not be achieved. Also unanticipated malfunctions or health hazards may occur due to improper diagnosis.

- Do not perform service or maintenance during use.
- Take care not to place hands or fingers under (or between) the moving parts (image capturing unit, main unit, and chinrest). Be sure to also caution patients.

  Hands or fingers may be pinched and may result in injury.

- Before and after use of the system, and before examining each patient, clean the chinrest and forehead rest with clean gauze or absorbent cotton. If necessary, dampen a cloth with rubbing alcohol and gently wipe them off.

  If the chinrest paper is used, remove a single sheet from the stack of sheets.

- Do not use a cloth that is overly dampened with rubbing alcohol to clean the forehead rest.

  Deterioration of the forehead rest may result.

- Keep the objective lens free of fingerprints and dust. Also confirm that it is not dirty before use.

  The quality of the captured image may be compromised.

- In the event of smoke or strange odors, immediately turn off the system and disconnect the power plug from the power outlet. After confirming that the system no longer generates smoke, contact NIDEK or your authorized distributor.

  Use of the system under such abnormal conditions may cause fire or electric shock. In case of fire, use a dry chemical (ABC) extinguisher to extinguish the fire.

- Before image capture, explain the purpose and method sufficiently to patients.
- Instruct the patient to focus on the fixation lamp with their eyes wide open. Start image capture after confirming that the instruction is properly followed by the patient.

  If the instructions are not properly followed, proper image capture may not be performed.

- Do not make a diagnosis based on a single captured image. Doctors are responsible for making the final diagnosis based on the present and past medical records of the patient such as captured images.

  Without sufficient information, proper diagnosis may not be made.

- When the patient comes off from the system main body after measurement, instruct the patient not to stand up while holding the chinrest support.

  The system main body may topple over resulting in injury.

- Should the system fail, disconnect the power cord from the power outlet and contact NIDEK or your authorized distributor without touching the interior of the system.
- After a long period of disuse, check for any abnormality before use.
- Do not remove or connect the retina map dongle from the USB port while the system is turned on.
- When connecting to peripheral equipment such as a computer via a medical facility network, insert or connect an isolation transformer between the medical electrical equipment and network devices (HUB etc.), or the network devices and other electrical equipment.

  Electric shock may result. For installation of the network isolation transformer, consult NIDEK or your authorized distributor.

⚠ CAUTION

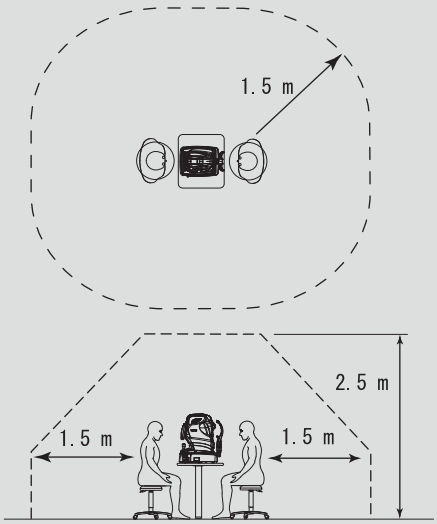
- Equipment connected to the analog or digital interfaces must be certified according to the applicable international standards for safety (such as EN 60601-1 and IEC 60601-1). Furthermore, all configurations shall comply with the system standard IEC 60601-1. Anyone who connects additional equipment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

  Malfunction or failure of the system may result.

- Use devices that comply with IEC 60601-1 in the patient environment. If any device that does not comply with IEC 60601-1 is to be used, use an isolation transformer or common protective grounding.

  If a person handling a conductive part of the system comes into contact with a patient at the same time, hazard may occur due to leakage current exceeding the value specified in the applicable standard. Be careful not to touch patients when connecting or removing the power plug or cable connectors.

  The figure to the right shows the volume of space (patient environment) in which contact can occur between the patient and any part of the system or between the patient and any other person(s) touching the system.



During use of the anterior segment adapter (optional)

⚠ WARNING

- Be sure to set the safety stopper before the anterior segment cross-sectional image capture.

  The anterior segment adapter may come into contact with the patient's eye and damage the cornea.

⚠ CAUTION

- During the anterior segment cross-sectional image capture, pull the joystick toward the operator before adjusting the alignment and focus, or switching the eye to prevent the anterior segment adapter from coming into contact with the patient's face or eyes.

  The anterior segment adapter may come into contact with the face or eyes of the patient.

- Keep the objective lens of the anterior segment adapter free of fingerprints and dust. Also confirm that it is not dirty before use.

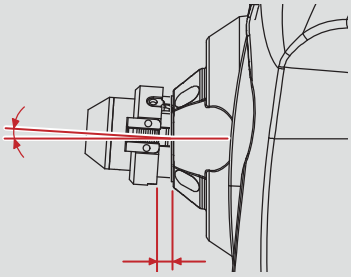
  The quality of the captured image may be compromised.

- The anterior segment adapter or its peripheral parts may come into contact with the patient's eyelashes. If the anterior segment adapter is used for patients with any infectious disease, be sure to clean the anterior segment adapter after image capture with cotton swab moistened with alcohol.

  Secondary infection may result.

- Check that the anterior segment adapter is attached straight to the objective lens.

  If the anterior segment adapter is angled or there is a large gap in the attached part, images of intended parts may not be captured.



After use

⚠ CAUTION

- When the system is not in use, turn off the power switch and place the dust cover over the system main body.

  Dust may affect the image capturing performance.

- Make sure that the power switch is turned off before connecting or disconnecting the power cord to or from the power outlet.

  If the power cord is connected or disconnected with the power switch on, system malfunction may occur.

- If the system is not to be used for a long time, disconnect the power cord from the power outlet.

- Maintain the ambient temperature and humidity in the following ranges during transport and storage of the system in the packed condition.

  Temperature: -30 to 60ºC (-22 to 140ºF) (during transport), -10 to +55ºC (14 to 131ºF) (during storage)

  Humidity: 10 to 95%

  Atmospheric pressure: 700 to 1,060 hPa

- When transporting, set the mode to packing mode and pack the main unit in the specified packing material with the locking knob unlocked. In addition, avoid vibration or shock to the system.

  Excessive vibration or shock may reduce the system reliability.

Maintenance

⚠ CAUTION

- Only service personnel trained by NIDEK can repair the device.

  NIDEK will not be responsible for accidents caused by improper servicing.

- Do not use the system beyond its service life.

  Even with proper maintenance and check, after time, the system reliability or safety may become degraded and fail to achieve the target values.

- 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.
- To ensure the continued safe use of the device, it is recommended that the manager of this device make sure that maintenance and preventive inspection are performed at least once a year.

  For details of maintenance and preventive inspection, ask NIDEK or your authorized distributor. If the manager of this device cannot perform the maintenance and preventive inspection, contact NIDEK or your authorized distributor.

Disposal

⚠ CAUTION

- To prevent the leakage of data such as personal information (patient information) to any unauthorized third party, it is the customer's responsibility to dispose of the device after making sure that data on the hard disk cannot be read or restored.

  When the disposal is conducted by an industrial disposal service, data may be physically destroyed to make it unreadable. Select the disposal method that suits the purpose.

- When disposing of the system and accessories, sort them by material and follow local ordinances and recycling regulations. Follow local governing ordinances and recycling plans regarding disposal or recycling of device components, particularly when disposing of the lithium ion battery, circuit board, plastic parts that contain brominated flame retardant, touch screen, or power cord.

  It is recommended to entrust the disposal to a designated industrial waste disposal contractor.

  Inappropriate disposal may contaminate the environment.

- When disposing of packing materials, sort them by material and follow local ordinances and recycling regulations.

  Inappropriate disposal may contaminate the environment.

Connection to Network

⚠ CAUTION

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

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

1.3 Symbol Information

■ Cautionary labels are provided on the system. If the labels are peeling off or the characters are wearing off, contact NIDEK or your authorized distributor.

	Indicates that the operator is advised to refer to the related instructions in the operator's manual.
	Indicates that the degree of protection against electric shock is of a Type B Applied Part. The applied parts are the forehead rest and chinrest. *"2.2 Configuration and Functions" (page 17)*
	Indicates that when the switch is pressed to this symbol side, power is not supplied to the system.
	Indicates that when the switch is pressed to this symbol side, power is supplied to the system.
	Indicates that the system must be supplied only with alternating current.
	Indicates the date of manufacture.
	Indicates the manufacturer.
	Indicates that this product must be disposed of in a separate collection of electrical and electronic equipment in EU.
USB 2.0	Indicates a connector to connect devices that support USB 2.0.
USB 3.0	Indicates a connector to connect devices that support USB 3.0.
EXT. FIXATION	Indicates a connector to connect the external fixation lamp.
MD	Medical device
EC REP	EU Authorized Representative
SN	Serial number
UDI	Unique Device Identifier
REF	Catalogue number
CH REP	Swiss authorized representative

2 BEFORE USE

2.1 System Outline

■ The NIDEK Optical Coherence Tomography RS-330 is an ophthalmic camera that allows non-invasive and non-contact observation of the shape of the fundus, anterior segment, and retina, and any disease that may be present. The system offers the following features:

- Capturing of cross-sectional images of the retina (OCT image) using the principle of the optical interferometer with an 880 nm infrared light source
- Capturing of color fundus images using a built-in non-mydriatic fundus camera without the use of mydriatic agents
- Capturing of fundus autofluorescence images (FAF image capture) (optional) by inserting an optical filter in the optical path for color fundus image capture

OCT images, color fundus images, and fundus autofluorescence images are saved to the computer connected to the system main body. The saved images can be managed and used for various image analyses using the image filing software, NAVIS-EX (hereafter referred to as “NAVIS-EX”).

2.1.1 Intended use

The NIDEK Optical Coherence Tomography RS-330 with Normative Database is a non-contact ophthalmic imaging system that incorporates a digital camera which is suitable for the viewing and axial cross sectional imaging of ocular structures. It is used for in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as an aid in the diagnosis and management of the retinal disease. In addition, the anterior segment adapter (special lens unit) attached over the objective lens of the system main body enables non-invasive and non-contact observation of the shape of the anterior segment of the eye such as the cornea or anterior chamber angle.

2.1.2 Intended patient population

- Age
  All ages except babies and infants
- Health condition
  Able to sit in a chair
  Able to answer the operator’s questions
- Conditions - Visual function
  One or both eyes are normal or have disease.

2.1.3 Intended user profile

Ophthalmologist or other doctors, nurse, clinical laboratory technician, OD

2.1.4 Intended use environment

Medical facility

⚠ CAUTION

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

2.1.5 Principles

- Formation of anterior chamber cross-sectional image, retinal cross-sectional image, and fundus image

  To form retinal cross-sectional images (OCT images) and fundus images (OCT Phase Fundus images), the system main body scans light over the eye to obtain interference light. The obtained interference light is dispersed into individual wavelengths and detected by the line CCD. The detected light is converted to signals, and then computed to form images. With the anterior segment adapter (optional), an anterior segment cross-sectional images (OCT image) can be formed.

- Color fundus image capture

  The system main body captures the live image of the patient's eye front illuminated with the eye front illumination LED (infrared light), and performs the alignment. Then the system main body captures the live image of the fundus of the patient's eye illuminated by the fundus illumination LED (infrared light), and aligns and focuses the image capturing unit to the fundus.

  Still images are captured by emitting white light from the xenon flash lamp to the anterior segment or the fundus, and then by receiving the reflected light with the color CCD for fundus image capture.

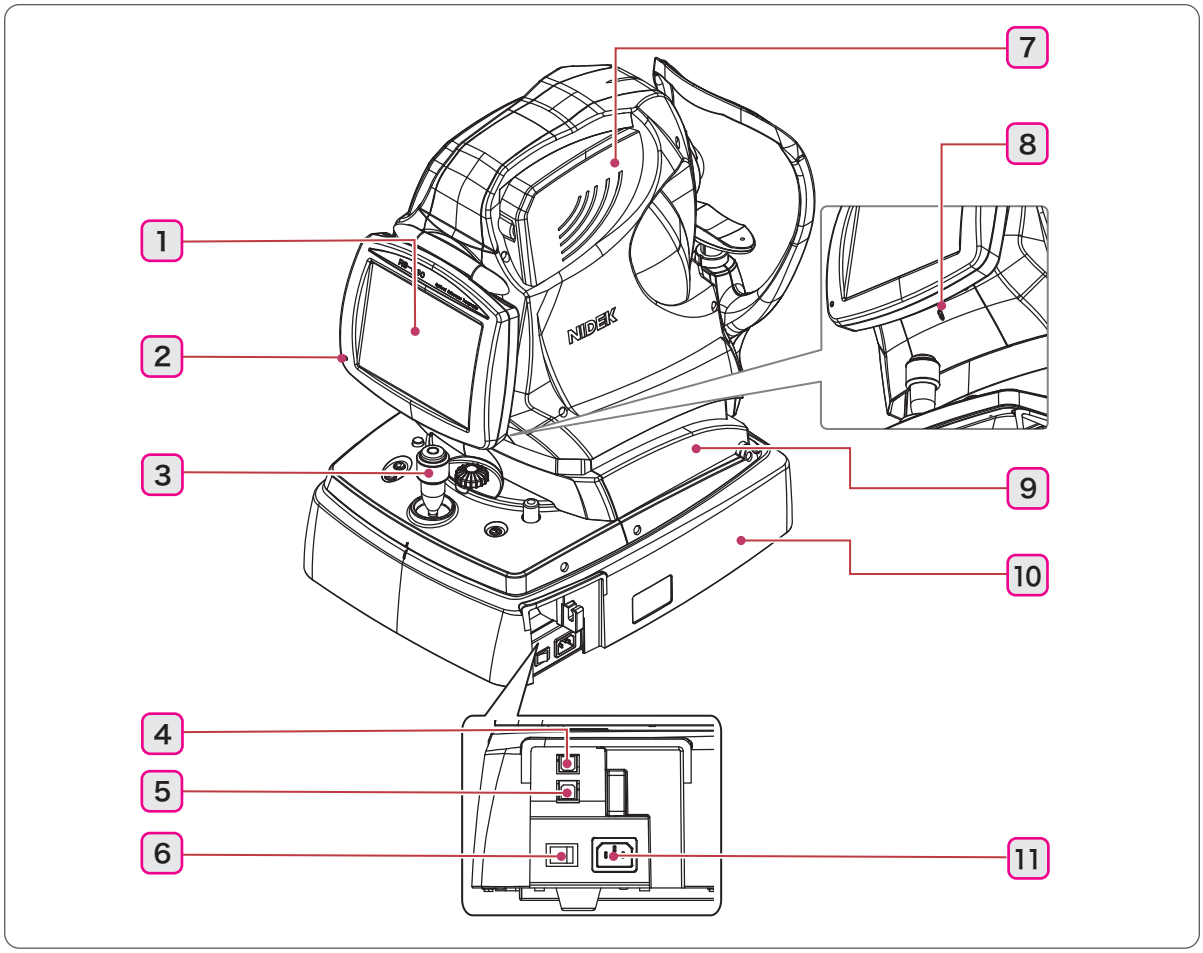
  With the fundus autofluorescence (FAF) imaging model, fundus autofluorescence images can be captured with the FAF setting that inserts an exciter filter into the illumination optical path and a barrier filter into the image capture optical path.

2.1.6 Contraindication and prohibition

Do not use this device for the following patients.

- Patients who have undergone photodynamic therapy (PDT) within 48 hours

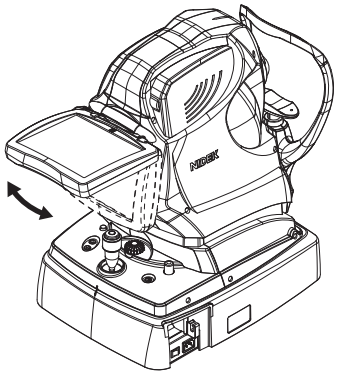
2.2 Configuration and Functions



1 Touch screen

8.4-inch color touch LCD

Pulling the bottom of the touch screen provides an adjustable viewing angle. To lower the touch screen, pull it to the top position before lowering it.



2 Pilot lamp

Illuminates when the power switch of the system is on (|). It blinks in Sleep mode.

3 Joystick

Used for alignment and focusing.

Moving the joystick to the right and left moves the main unit to the right and left. Rotating the joystick moves the image capturing unit up and down. Moving the joystick forward and backward adjusts the focus.

4 USB 2.0 connector

5 USB 3.0 connector

6 Power switch

7 Image capturing unit

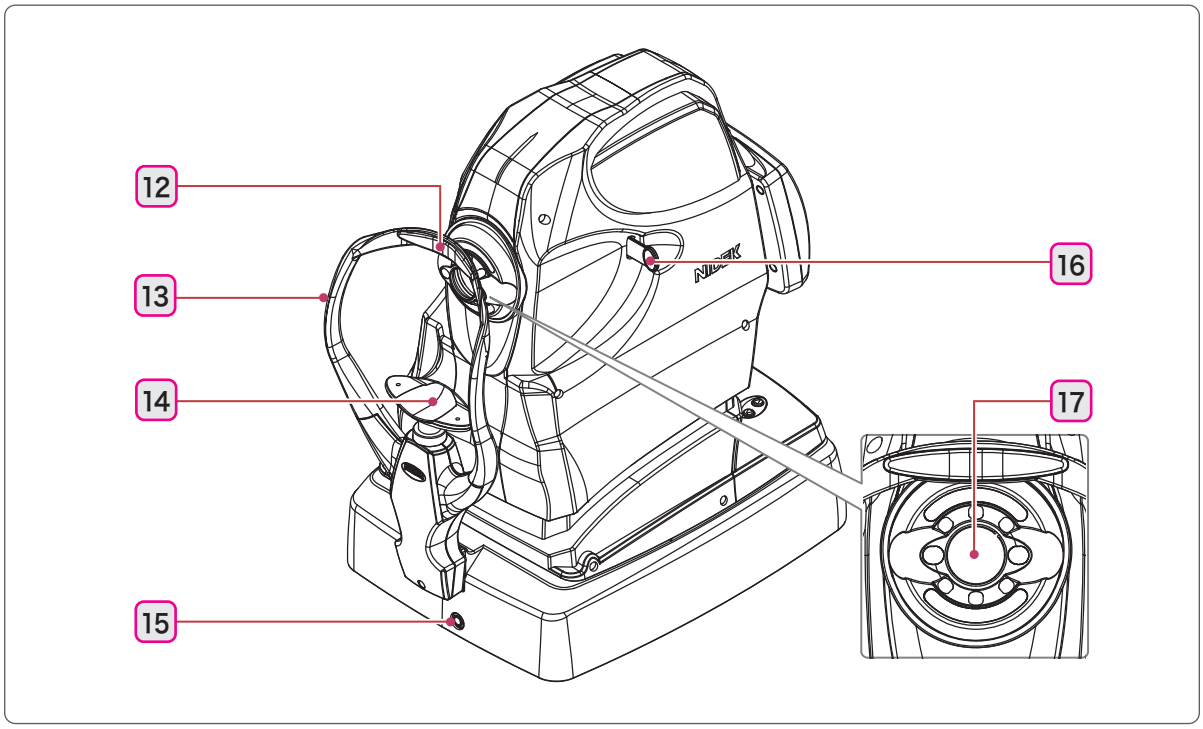
8 Hand light

Illuminates the buttons around the joystick to facilitate the device operation in a dark room.

9 Main unit

10 Base unit

11 Power inlet



12 Forehead rest

13 Eye level marker

The height of the chinrest is adjusted so that the patient's eyes roughly align with this line.

14 Chinrest

15 External fixation lamp connector

The optional external fixation lamp is connected here. *“4.8.1 External fixation lamp” (page 159)*

16 Compensation lens select lever

Used to insert the plus or minus compensation lens. It is used when the refractive error of the patient's eye is out of the range between -12 D and +15 D or when eye front images are to be captured.

-: For eyes with refractive error between -33 D and -7 D

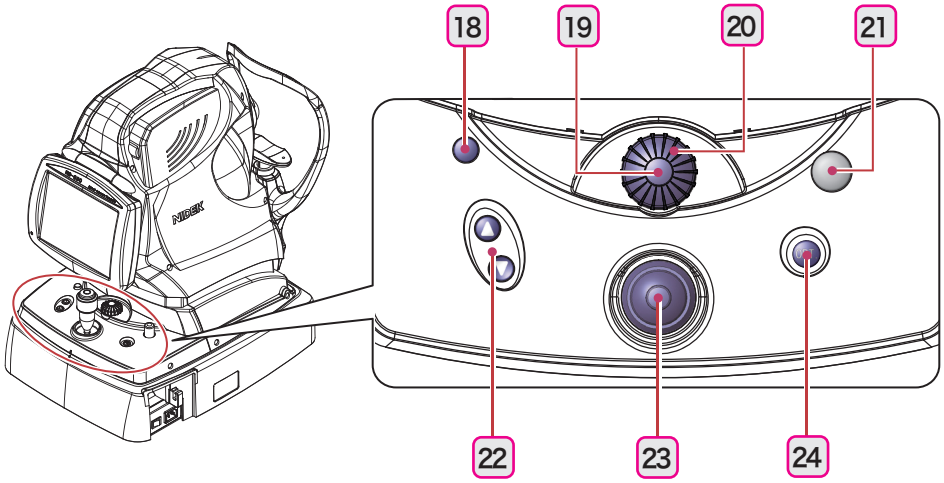
+: For eyes with refractive error between +11 D and +35 D or when eye front images are to be captured

Note

- Be sure to set the compensation lens select lever where a click is felt.

  If the lever is at an intermediate position, the right or left side of the screen becomes dark, and proper images cannot be captured.

17 Objective lens



18 Safety stopper

Used to restrict the movable range of the main unit so that the anterior segment adapter (optional) does not come into contact with the patient's eye when anterior segment cross-sectional images are captured. Adjust the position of the safety stopper for each patient before image capture to secure a safe distance.

19 Eye front / fundus observation toggle switch

Used to toggle the touch screen display between the eye front observation screen and the fundus observation screen.

In Combo Combo (OCT image capture), OCT/FC OCT/FC, or OCT release mode OCT, this button is enabled only during the scanning ("Scan Start" Scan Start is blue).

20 Focus knob

Used to adjust the focus for image capture.

21 Locking knob

Used to lock the main unit to the base unit. The main unit is locked differently depending on the direction in which the locking knob is rotated.

BRAKE side (clockwise)	Used to temporarily lock the main unit during image capture.
LOCK side (counterclockwise)	Used to securely lock the main unit to move the system to another room or such. *"O Finishing image capture before moving the system to a different room" (page 81)*

22 Chinrest up/down button (,)

Used to move the chinrest up and down.

23 Release button

Used to capture images. Pressing it again stops the image capture.

In Combo Combo (OCT image capture), OCT/FC OCT/FC , or OCT release mode OCT , this button is enabled only during the scanning ("Scan Start" Scan Start is blue).

24 OPT. button

Used to automatically optimize the focus, Z position, and polarization.

Pressing it again cancels the optimization.

This button is enabled only during the scanning ("Scan Start" Scan Start is blue).

2.3 Main Body Screen Description

2.3.1 Eye front observation screen

1 Start/Stop button 

Used to start and stop the scanning. The button shows the scan status with blue color.

 Scan Start is blue	The scanning is being performed.
 Scan Stop is blue	The scanning is stopped.

2 R / L indication

Indicates the eye (right or left) being observed in blue.

3 Patient ID 

Shows the ID number of the selected patient.

4 Release mode select buttons

Used to select the release mode. The selected button is shown in orange.

	By setting combinations of various release modes in advance, images can be captured in the desired modes in the preset order without changing the setting.
	In OCT/FC release mode, the OCT image capture, then the color fundus image capture are performed consecutively.

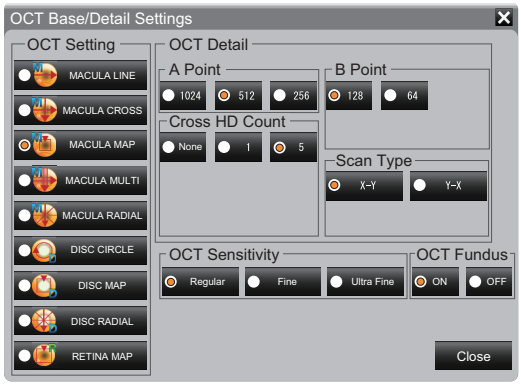
OCT	In OCT release mode, only OCT images are captured. By setting up the system so that the optional anterior segment adapter is ready for use, the button for eye front OCT image capture and the button for the retinal OCT image capture are displayed. The desired image capture type can be selected.
FC	In FC release mode, only color fundus images are captured. The image capture type can be selected from standard , stereo , panorama , and eye front .

5 OCT setting button

A dialog showing the parameters for OCT settings appears.

In the OCT Base/Detail Settings dialog, the OCT setting can be changed, or detailed parameters for the selected OCT setting can be set.

The RETINA MAP button RETINA MAP is displayed while the retina map dongle is connected to the USB port of the computer.



6 Next patient button

Used to automatically acquire a new patient ID for the next patient. At the same time, the captured images allowed to be saved (with the check mark) are saved to the database.

This button can be used only when the scanning is stopped (“Scan Stop” is blue).

Display of this button is enabled by the setting of NAVIS-EX.

NAVIS-EX ➔ Setup ➔ Setting ➔ Configuration dialog ➔ Common tab ➔ Input patient ID mode ➔ Select “PT + Date + ID number” or “Serial number”.

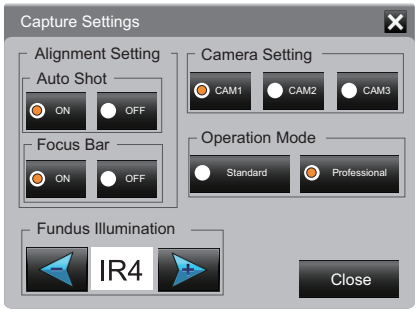
7 Auto/Manual toggle switch

Used to toggle between the automatic and manual image capture. The selected image capture type is shown in orange.

Auto is orange.	Alignment, focusing, and image capture are automatically performed (when the auto shot function is enabled).
Manual is orange.	All operations are performed manually.

8 Menu button

The Capture Settings dialog appears.



9 Small pupil image capture button

Used to capture images of the eye with a pupil smaller than the required pupil diameter mark ◯. Pressing this button changes it to orange and enables image capture with a pupil as small as the minimum pupil diameter mark ◌.

"3.6.1 Small pupil image capture" (page 117)

10 Low-light image capture button

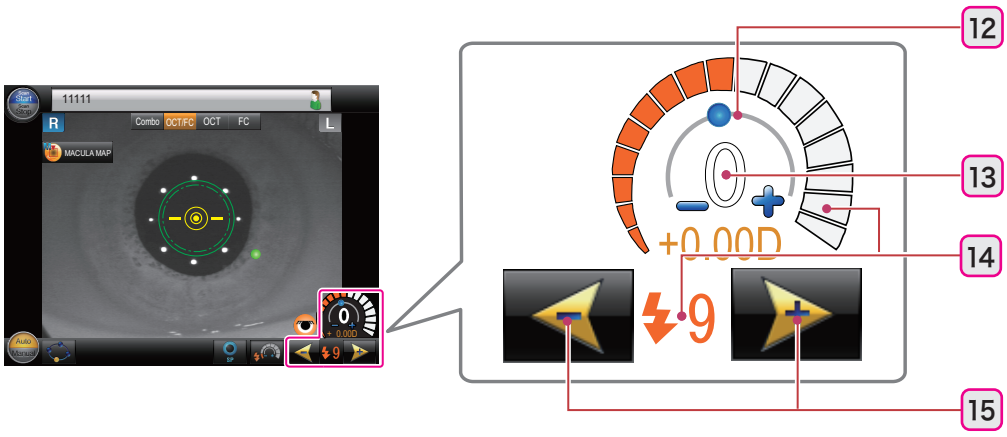
Used to lower the set flash intensity for image capture. When the button is being selected, it is shown in orange.

"3.6.2 Low-light image capture" (page 118)

11 Required pupil diameter detection mark

Indicates whether or not the pupil diameter is large enough for image capture.

	Indicates that the patient's eyelid is not covering the eye, and that the pupil diameter is large enough for image capture. Images can be captured.
(Black and white)	Indicates that the patient's eyelid is covering the patient's eye, or that the eye is not detected. Check the condition of the patient's eye.
(Color)	Indicates that the patient's eyelid is detected, that the pupil diameter is not large enough, or that extraneous light (noise) or such is detected. Check the condition of the patient's eye.



12 Focus gauge 

The gauge moves in accordance with the focus.

Note

- The focus adjustment value of the optical system used for color fundus image capture is shown in diopter.

  For NAVIS-EX, the focus adjustment value of the optical system used for OCT image capture is shown in diopter. Therefore the value differs from the one shown by the system main body.

13 Compensation lens

Indicates the condition of the compensation lens as set using the compensation lens select lever.

0	The compensation lens is not inserted.
+	The plus diopter compensation lens is inserted.
−	The minus diopter compensation lens is inserted.

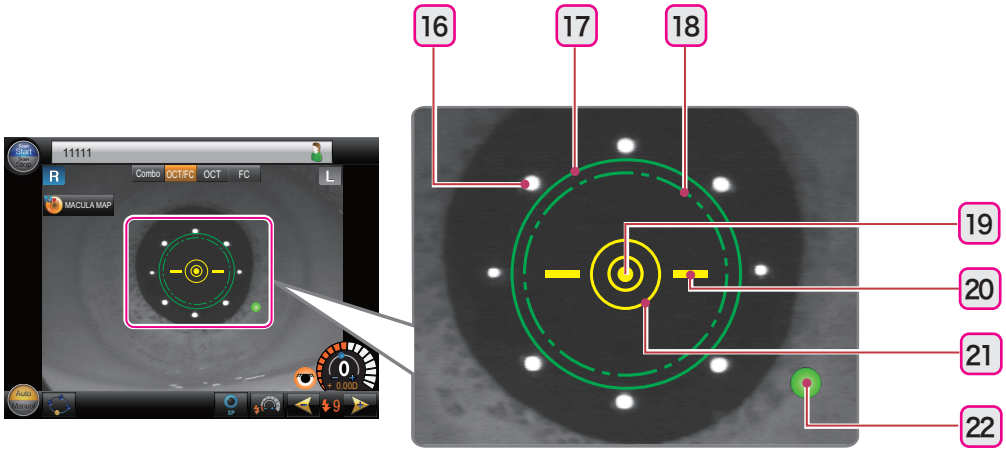
14 Flash intensity 

Displays the flash intensity set for the color fundus image capture.

15 Flash intensity up/down buttons

Used to adjust the flash intensity for image capture.

	Reduces the intensity.
	Increases the intensity.



16 Cornea-reflected spots 

Eight corneal-reflected spots appear when the patient's eye is displayed in the eye front observation screen.

17 Required pupil diameter mark

Indicates the required pupil diameter (pupil diameter required for proper image capture).

If the pupil diameter is smaller than this mark, or eyelashes are on this mark, images may not be captured.

18 Minimum pupil diameter mark

Indicates the required pupil diameter (pupil diameter required for proper image capture) for the small pupil image capture.

19 Electronic working dot

Shown in yellow and used as the reference point for alignment.

Note

- If the patient's eyelid is not opened wide enough or their cornea has any lesions or such, the electronic working dot may not be displayed due to improper detection of the cornea-reflected spots.

20 Working distance indicator

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

21 Target mark

Indicates the center of the screen. The electronic working dot is aligned to the target mark. When the alignment is complete, the target mark changes from light blue to yellow.

In addition, the appearance of the target mark changes when the electronic working dot is detected. 

22 Internal fixation lamp

Indicates the current fixation lamp position in green. Pressing the screen moves the internal fixation lamp to the pressed position.

To stabilize the patient's eye fixation, instruct the patient to focus on the fixation lamp during image capture.

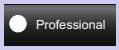
The internal fixation lamp cannot be used when “RETINA MAP” is selected.

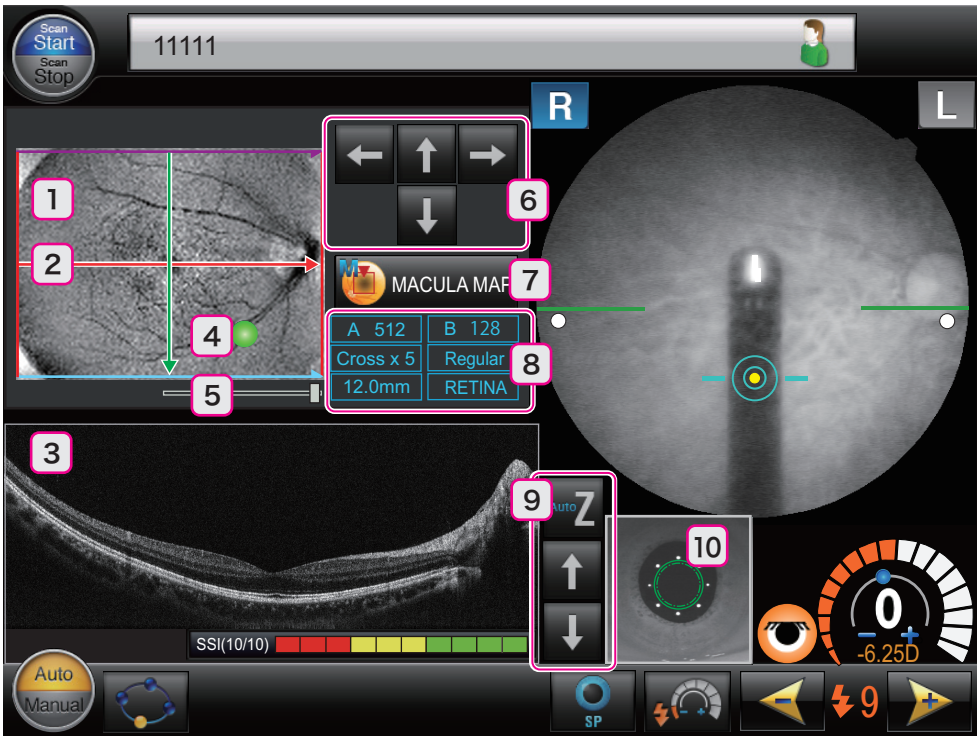
2.3.2 Fundus observation screen (Operation mode: Professional)*1

○ OCT/FC display

For the button and icons that are not explained below, see *"2.3.1 Eye front observation screen" (page 21)*.

This screen is displayed with the following setting:

Menu button  ➔ Capture Settings dialog ➔ Operation Mode ➔ Professional  ➔ Eye front observation screen ➔ Select Combo  (during OCT image capture), OCT/FC  , or OCT  release mode.



1 OCT Phase Fundus image

Displays an OCT-generated fundus image.

When the OCT setting button  ➔ OCT Base/Detail Settings dialog ➔ OCT Fundus ➔ OFF are selected, a fundus image obtained with infrared light is displayed.

*1. The factory-set operation mode is Standard. *"2.3.1 Eye front observation screen" (page 21)*

2 Scan line

Shows the position of the scan line for OCT image capture.

Operate the slider 5 or the scan line operation button 6 to move the scan line or change its shape. The scan line cannot extend out of the OCT Phase Fundus image.

The position and shape of the scan lines can be changed as shown below.

OCT Setting	Scan Position	Scan Width	Scan Pitch	Scan Angle
MACULA LINE	Yes	Yes	No	Yes
MACULA CROSS	Yes	Yes	No	No
MACULA MAP	Yes	Yes	No	No
MACULA MULTI	Yes	Yes	Yes	No
MACULA RADIAL	Yes	Yes	No	No
DISC CIRCLE	Yes	No	No	No
DISC MAP	Yes	Yes	No	No
DISC RADIAL	Yes	Yes	No	No
RETINA MAP*1	No	No	No	No
CORNEA LINE (During anterior segment cross-sectional image capture [optional])	No	Yes	No	Yes
CORNEA CROSS (During anterior segment cross-sectional image capture [optional])	No	Yes	No	No
CORNEA RADIAL (During anterior segment cross-sectional image capture [optional])	No	Yes	No	No
ACA LINE (During anterior segment cross-sectional image capture [optional])	No	Yes	No	Yes

*1. “RETINA MAP” can be selected when the retina map dongle is connected to the USB port of the computer.

3 OCT image

Displays the OCT image of the scan line position.

At the bottom of the image, the SSI indication shows the evaluation of the OCT image quality (on a scale of 10 with a bar graph).

4 Internal fixation lamp

Indicates the current fixation lamp position in green. Pressing the screen moves the internal fixation lamp to the pressed position.

To stabilize the patient's eye fixation, instruct the patient to focus on the fixation lamp during image capture.

The internal fixation lamp cannot be used when “RETINA MAP” is selected.

5 Slider

Used to change the scan line width. It cannot be used for the Disc Circle scan line or Retina Map scan line.

6 Scan line operation button

Used to move the scan line or change its shape. The displayed button changes depending on the selected OCT setting.

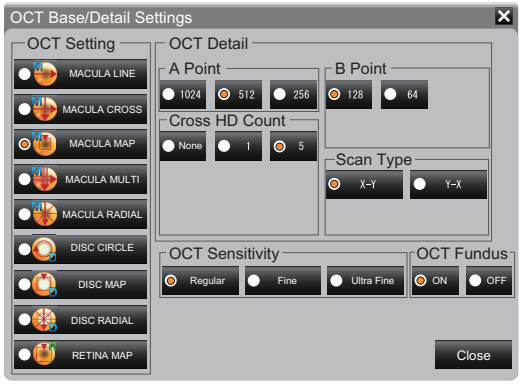
7 OCT setting button

A dialog showing the parameters for OCT settings appears.

In the OCT Base/Detail Settings dialog, the OCT setting can be changed, or detailed parameters for the selected OCT setting can be set.

The RETINA MAP button 

is displayed while the retina map dongle is connected to the USB port of the computer.



8 Image capture information

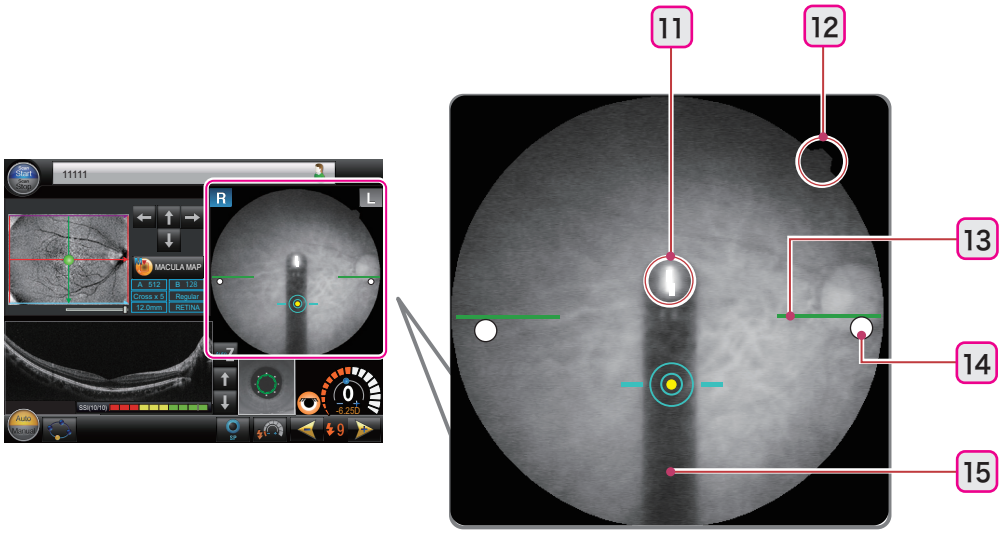
Displays the selected OCT setting.

9 Z position adjustment button

Used to adjust the Z position (vertical position in the screen) of the OCT image.

AutoZ	Used to automatically optimize the Z position (vertical position in the screen) of the OCT image.
↑	Moves the OCT image up.
↓	Moves the OCT image down.

10 Eye front image



11 Focus split

Indicates the focus condition on the fundus by the displacement between the upper and lower lines.

The focus is optimum when the upper and lower lines form a single line.

12 Orientation tab

Used to show the orientation of the captured image.

13 Optical working dot charts

Displayed in the form of green lines on the right and left sides of the screen. They are used as a guide-line of the vertical position for image capture.

14 Optical working dots

Displayed in the form of bright spots on the right and left sides of the screen. They are used for fine alignment or focusing, or when the electronic working dot cannot be displayed.

For the alignment, the optical working dots need to be brightly displayed and aligned symmetrically to the optical working dot charts.

15 Focus Bar

Operates inside the system main body. The focus bar can be either shown or hidden.

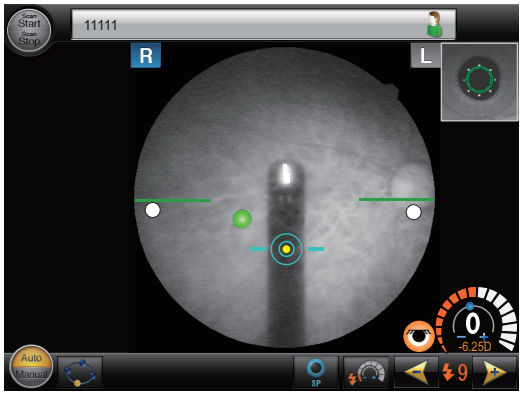
"3.7.1 Image capture setting" (page 120)

○ FC display

For the displayed buttons and icons, see *"○ OCT/FC display" (page 26)*.

Pressing the button shown below in the eye front observation screen displays this screen.

- Combo release mode Combo (during color fundus image capture)
- FC release mode FC



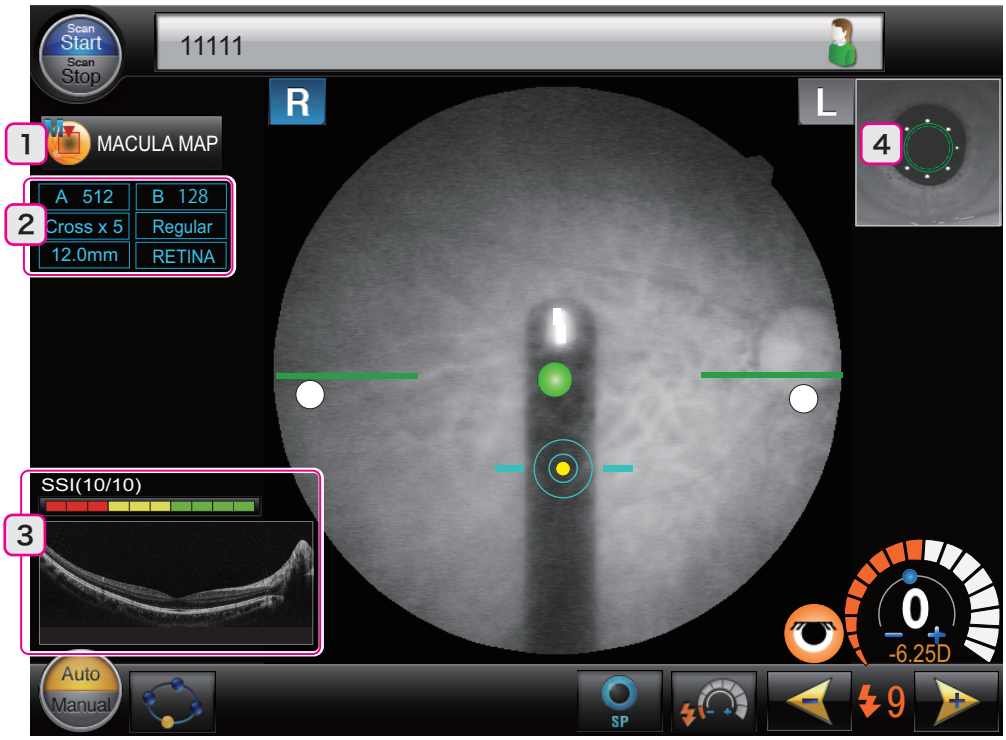
2.3.3 Fundus observation screen (Operation mode: Standard)*1

○ OCT/FC display

For the button and icons that are not explained below, see *"2.3.1 Eye front observation screen" (page 21)*.

This screen is displayed with the following setting:

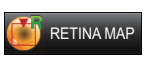
Menu button  ➔ Capture Settings dialog ➔ Operation Mode ➔ Standard  ➔ Eye front observation screen ➔ Select Combo  (during OCT image capture), OCT/FC  , or OCT  release mode.

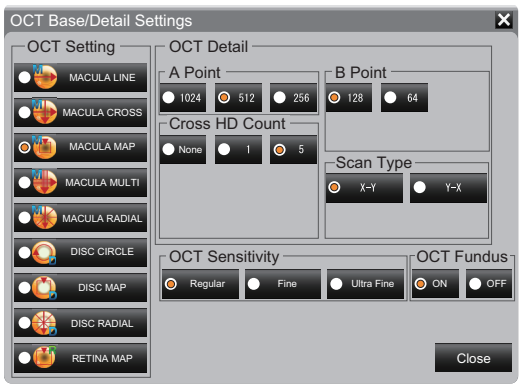


1 OCT setting button

A dialog showing the parameters for OCT settings appears.

In the OCT Base/Detail Settings dialog, the OCT setting can be changed, or detailed parameters for the selected OCT setting can be set.

The RETINA MAP button  is displayed while the retina map dongle is connected to the USB port of the computer.



*1. Factory setting. The standard mode offers a simple screen configuration more specialized in screening than the Professional operation mode, without items such as the OCT Phase Fundus image, scan line, and Z position adjustment button.

2 Image capture information

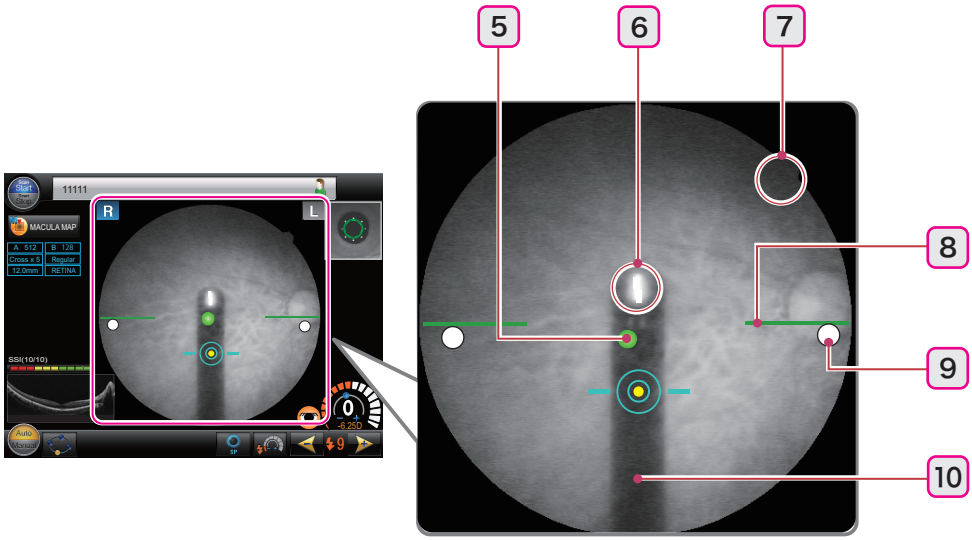
Displays the selected OCT setting.

3 OCT image

Displays the OCT image of the scan line position.

The SSI indication shows the evaluation of the OCT image quality (on a scale of 10 with a bar graph).

4 Eye front image



5 Internal fixation lamp

Indicates the current fixation lamp position in green. Pressing the screen moves the internal fixation lamp to the pressed position.

To stabilize the patient's eye fixation, instruct the patient to focus on the fixation lamp during image capture.

The internal fixation lamp cannot be used when “RETINA MAP” is selected.

6 Focus split

Indicates the focus condition on the fundus by the displacement between the upper and lower lines.

The focus is optimum when the upper and lower lines form a single line.

7 Orientation tab

Used to show the orientation of the captured image.

8 Optical working dot charts

Displayed in the form of green lines on the right and left sides of the screen. They are used as a guide-line of the vertical position for image capture.

9 Optical working dots

Displayed in the form of bright spots on the right and left sides of the screen. They are used for fine alignment or focusing, or when the electronic working dot cannot be displayed.

For the alignment, the optical working dots need to be brightly displayed and aligned symmetrically to the optical working dot charts.

10 Focus Bar

Operates inside the system main body. The focus bar can be either shown or hidden.

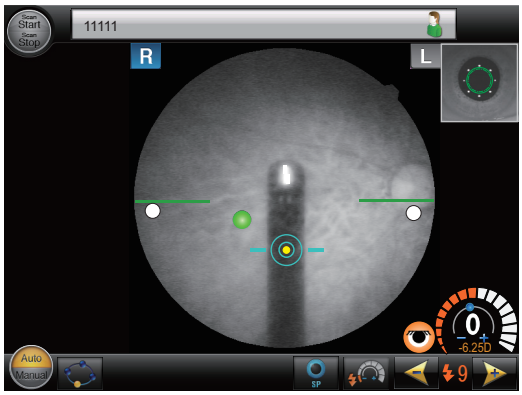
"3.7.1 Image capture setting" (page 120)

○ FC display

For the displayed buttons and icons, see *"○ OCT/FC display" (page 30)*.

Pressing the button shown below in the eye front observation screen displays this screen.

- Combo release mode Combo (during color fundus image capture)
- FC release mode FC



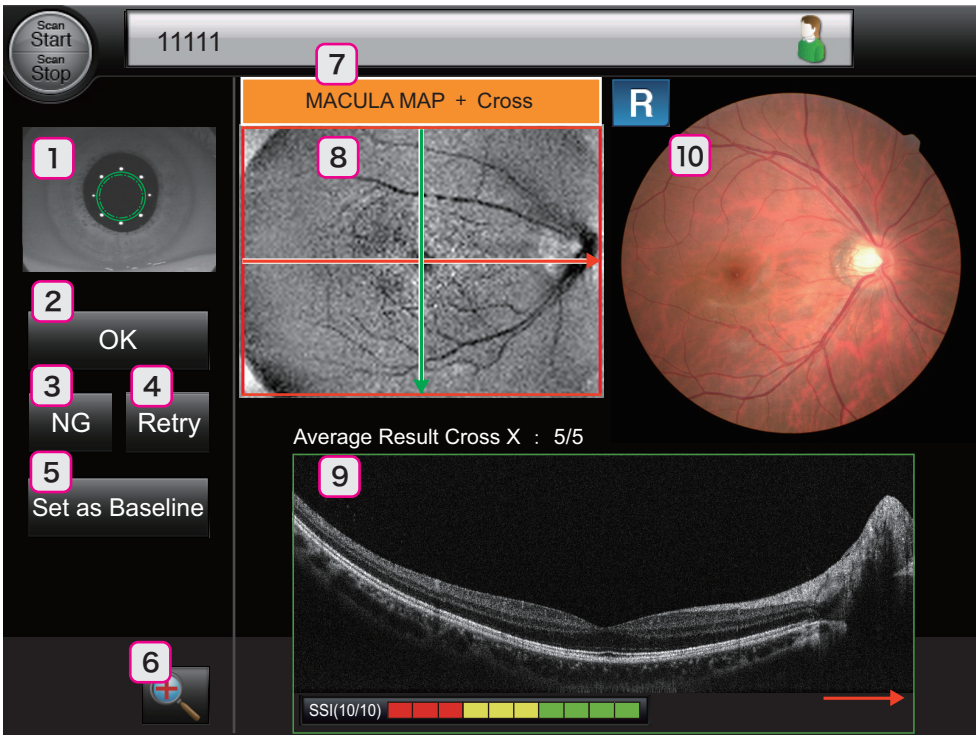
2.3.4 Image confirmation screen

○ OCT/FC display

For the button and icons that are not explained below, see *"2.3.1 Eye front observation screen" (page 21)*.

Pressing any of the buttons shown below in the eye front observation screen displays this screen.

- Combo release mode Combo (during OCT image capture)
- OCT/FC release mode OCT/FC
- OCT release mode OCT



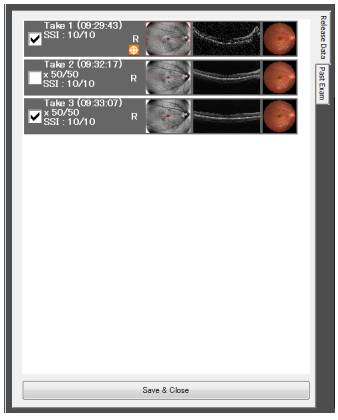
1 Eye front image

Displays the captured eye front image.

2 OK button OK *1

Displays the thumbnail of the captured image in the Release Data tab of RS-330 Capture.

The check box shown to the left side of the thumbnail is selected to allow saving of the data.



*1. Displayed only when the image is captured using the release button of the system main body, or using the auto shot function.

3 NG button NG *1

Displays the thumbnail of the captured image in the Release Data tab of RS-330 Capture.

The check box shown to the left of the thumbnail is not selected (It can be checked later).

4 Retry button Retry *1

Discards the captured image and displays the eye front observation screen.

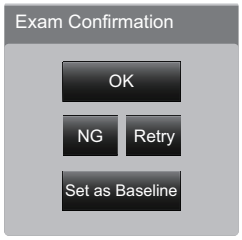
5 "Set as Baseline" button Set as Baseline *1 *2

Registers the captured image as the baseline . The thumbnail of the registered image is displayed in the Release Data tab of RS-330 Capture.

The check box shown to the left side of the thumbnail is selected to allow saving of the data.

Note

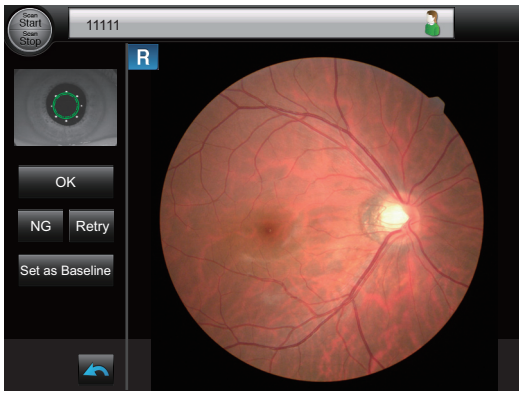
- When images are captured using RS-330 Capture, the Exam Confirmation dialog is displayed in the touch screen of the system main body.



6 Zoom button

Used to enlarge the color fundus image. In Combo release mode Combo (during OCT image capture) or OCT release mode OCT, the button is not displayed because fundus images are not captured.

To close the enlarged view, press the return button .



7 OCT setting

An OCT setting at the time of image capture appears.

8 OCT Phase Fundus image

Displays an OCT-generated fundus image.

When the OCT setting button MACULA MAP ➔ OCT Base/Detail Settings dialog ➔ OCT Fundus ➔ OFF are selected, a fundus image obtained with infrared light is displayed.

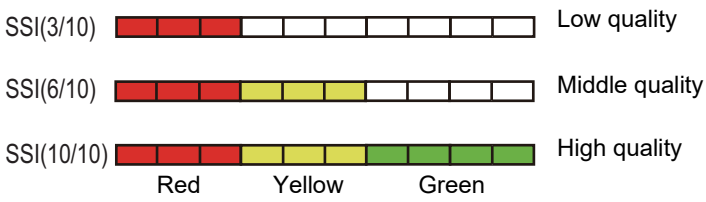
*1. Displayed only when the image is captured using the release button of the system main body, or using the auto shot function.
*2. It is not displayed when the image capture is performed with "RETINA MAP" selected.

9 OCT image

Displays the OCT image of the scan line position. The arrow at the bottom right of the image correspond to the arrow on the OCT Phase Fundus image. In addition, the SSI indication and the image averaging result are displayed.

- SSI

  As the SSI becomes higher, a finer image can be obtained.



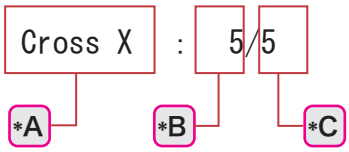
- Image averaging result

  The number of successfully averaged images out of the number of the specified HD scan images is displayed. As the number of successfully averaged images becomes larger, finer images can be obtained. The frame color of the OCT image changes depending on the proportion of successfully averaged images.

  70% or higher: Green

  51 to 69%: Yellow

  50% or lower: Red



*A	Scan line of the displayed averaging result
*B	The number of successfully averaged images
*C	Number of HD scan images

10 Color fundus image

Displays the captured color fundus image.

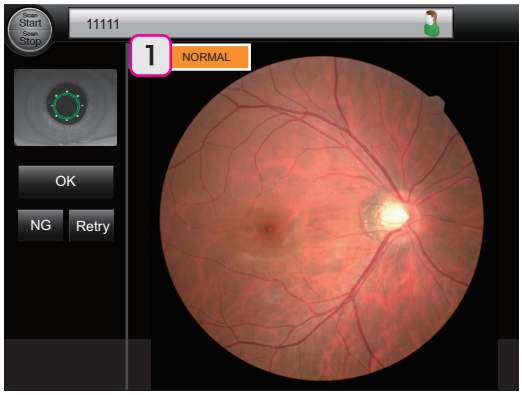
In Combo release mode Combo (during OCT image capture) or OCT release mode OCT, color fundus images are not captured or displayed on the image confirmation screen.

○ FC display

For the displayed buttons and icons, see *"○ OCT/FC display" (page 33)*.

Pressing the button shown below in the eye front observation screen displays this screen.

- Combo release mode Combo (during color fundus image capture)
- FC release mode FC



1 Release mode

Displays the release mode selected for image capture.

2.4 RS-330 Capture Screen

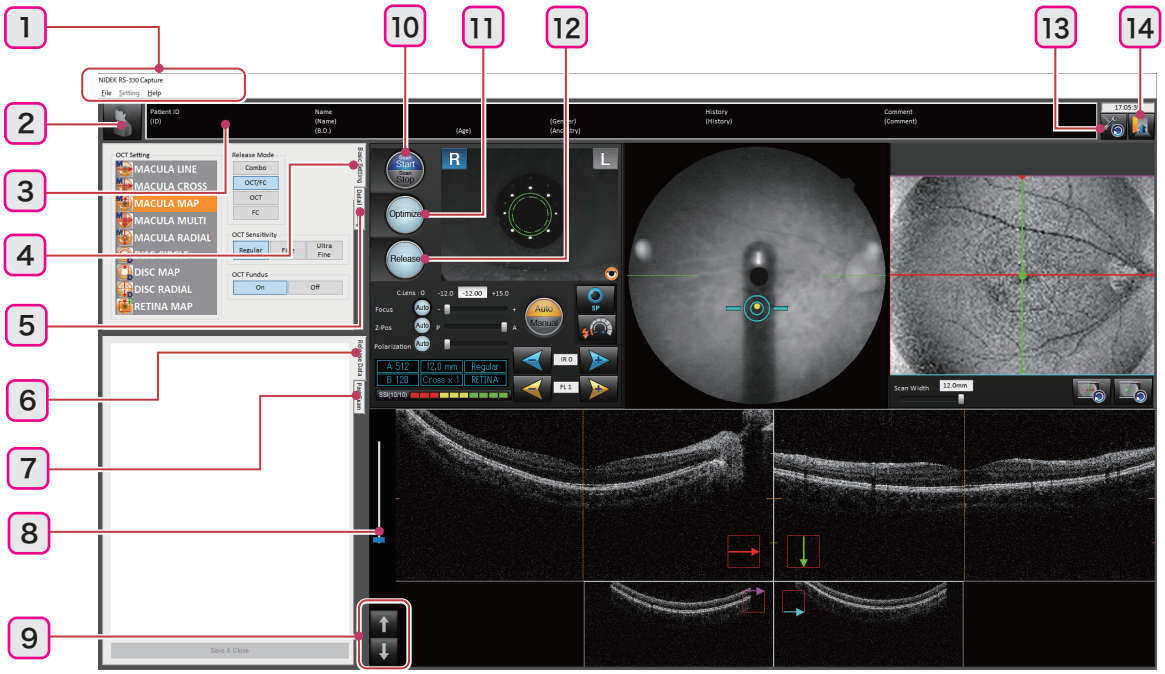
■ RS-330 Capture is software used to operate the RS-330 from the computer and to transfer the captured images to NAVIS-EX. Most of the operations related to image capture are linked between the system main body and RS-330 Capture, and can be operated using either of them. Use the convenient one.

2.4.1 Eye front / fundus observation screen

○ OCT/FC display

Pressing any of the buttons shown below in the Basic Setting tab displays this screen.

- Combo release mode [Combo] (during OCT image capture)
- OCT/FC release mode [OCT/FC]
- OCT release mode [OCT]



1 Menu bar

Provides the File, Setting, and Help menus. Clicking the menu displays a pull-down menu.

File	Save	Saves the thumbnails checked with a check mark in the Release Data tab.
	Save All	Saves all thumbnails in the Release Data tab regardless of the check mark. After the images are saved, the thumbnails are deleted from the Release Data tab.

File	Delete All	Deletes all thumbnails in the Release Data tab regardless of the check mark. Before the deletion, a confirmation dialog appears. Clicking the OK button deletes the thumbnails.
	Close	Closes RS-330 Capture. If there is any thumbnail in the Release Data tab, a dialog appears to confirm closing of the software. Clicking the OK button closes RS-330 Capture.
Setting	Edit Combo	Allows editing of the Combo release mode parameters. This button can be used only when the scanning is stopped ("Scan Stop"  is blue).
	Setting	Allows setting of RS-330 Capture parameters. This button can be used only when the scanning is stopped ("Scan Stop"  is blue).
Help	About	Shows the version information.

2 Next patient button 

Used to automatically acquire a new patient ID for the next patient. At the same time, the captured images allowed to be saved (with the check mark) are saved to the database.

This button can be used only when the scanning is stopped ("Scan Stop"  is blue).

Display of this button is enabled by the setting of NAVIS-EX.

NAVIS-EX ➔ Setup ➔ Setting ➔ Configuration dialog ➔ Common tab ➔ Input patient ID mode ➔ Select "PT + Date + ID number" or "Serial number".

3 Patient information

Shows the ID, name and other information of the patient selected with NAVIS-EX.

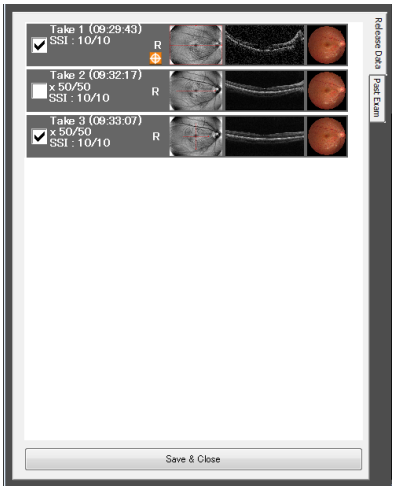
4 Basic Setting tab

Allows setting of the basic image capture parameters such as release mode and OCT setting.

5 Detail Setting tab

Allows setting of the scan type, the number of A scan points, and such for the selected OCT setting. In addition, the camera and alignment settings are possible.

6 Release Data tab



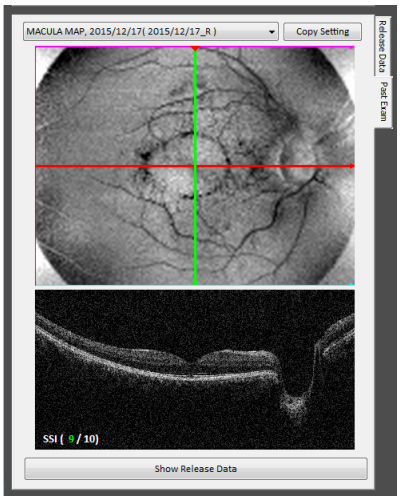
Displays the thumbnails of the captured images.

The thumbnails show the time and quality evaluation (HD scan image averaging result and SSI) of the captured images.

Note

- Double-clicking a thumbnail enlarges the image.
  Images can be confirmed before saving them.
  "3.2.4 Image confirmation" (page 79)
- If the captured image is not registered as the baseline, the Release Data tab is displayed when RS-330 Capture is activated.

7 Past Exam tab



By registering an image captured with the RS-330 as a baseline image, the image capture conditions of the baseline image can be copied to the RS-330.

"3.8 Copying Image Capture Conditions (for OCT images only)" (page 124)

Note

- When the captured image is registered as the baseline, the Past Exam tab is displayed when RS-330 Capture is activated.

8 Auto Z adjustment position slider

Used to adjust the OCT image position where the Z position is optimized.

To move the position, click and drag the slider.

9 Z position adjustment button

Used to adjust the Z position (vertical position in the screen) of the OCT image.

	Moves the OCT image up.
	Moves the OCT image down.

10 Start/Stop button 

Used to start and stop the scanning. The button shows the scan status with blue color.

 Scan Start is blue	The scanning is being performed.
 Scan Stop is blue	The scanning is stopped.

11 Optimize button 

Used to automatically optimize the focus, Z position, and polarization.

 (Orange)	Optimization is being performed. Clicking it again cancels the optimization.
 (Light blue)	Optimization can be performed.
 (Gray)	The button is disabled.

12 Release button 

Used to capture images.

 (Orange)	Images are being captured. Pressing it again stops the image capture.
 (Light blue)	Images can be captured.
 (Gray)	The button is disabled.

13 Clear button 

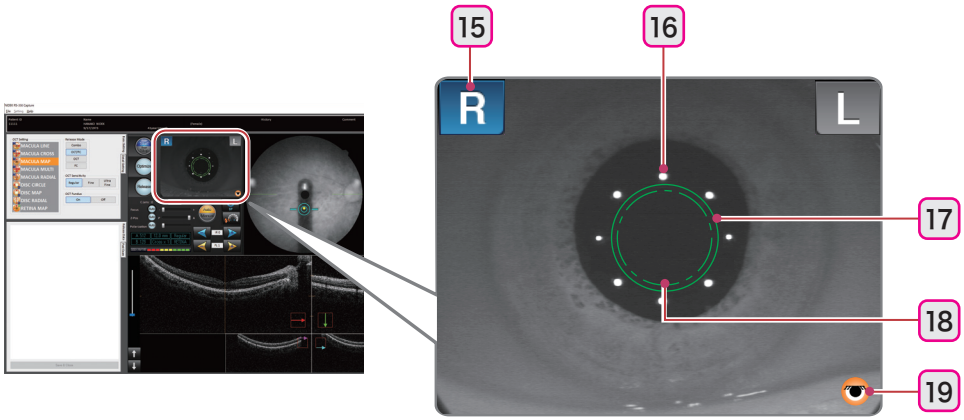
Resets the image capture conditions.

14 Close button 

Closes RS-330 Capture.

⚠ CAUTION

- The thumbnails in the Release Data tab are deleted without being saved. To save the thumbnails, close RS-330 Capture by clicking the “Save & Close” button [Save & Close] in the Release Data tab.



15 R / L indication

Indicates the eye (right or left) being observed in blue.

16 Cornea-reflected spots

Eight corneal-reflected spots appear when the patient's eye is displayed in the eye front observation screen.

17 Required pupil diameter mark

Indicates the required pupil diameter (pupil diameter required for proper image capture).

If the pupil diameter is smaller than this mark, or eyelashes are over this mark, images may not be captured.

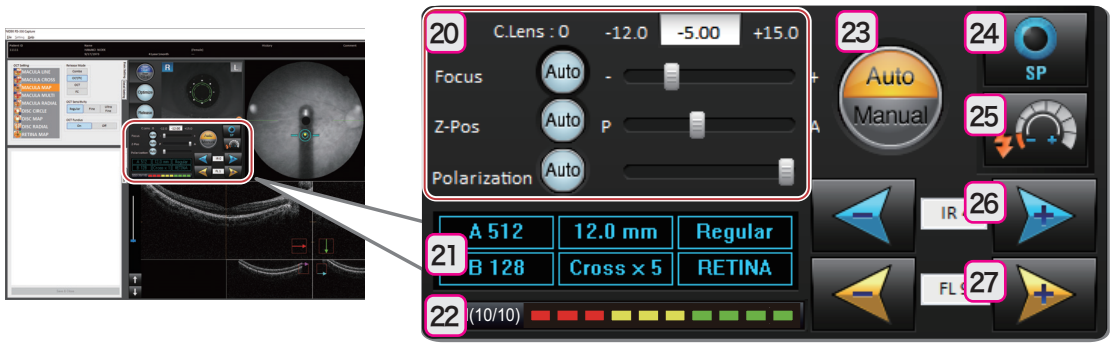
18 Minimum pupil diameter mark

Indicates the required pupil diameter (pupil diameter required for proper image capture) for the small pupil image capture.

19 Required pupil diameter detection mark

Indicates whether or not the pupil diameter is large enough for image capture.

	Indicates that the patient's eyelid is not covering the eye, and that the pupil diameter is large enough for image capture. Images can be captured.
(Black and white)	Indicates that the patient's eyelid is covering the patient's eye, or that the eye is not detected. Check the condition of the patient's eye.
(Color)	Indicates that the patient's eyelid is detected, that the pupil diameter is not large enough, or that extraneous light (noise) or such is detected. Check the condition of the patient's eye.



20 Controller

Allows individual adjustment of the focus, Z position, and polarization of the image.

Clicking the Auto button (Auto) of each item changes it to orange and automatically optimizes the image. The items can also be manually adjusted using the sliders.

Note

- The focus adjustment value of the optical system used for color fundus image capture is shown in diopter.

  For NAVIS-EX, the focus adjustment value of the optical system used for OCT image capture is shown in diopter. Therefore the value differs from the one shown by the system main body.

21 Image capture information

Displays the selected OCT setting.

22 SSI

Shows the evaluation of the OCT image quality (on a scale of 10 with a bar graph).

23 Auto/Manual toggle switch (Auto / Manual)

Used to toggle between the automatic and manual image capture. The selected image capture type is shown in orange.

Auto is orange.	Alignment, focusing, and image capture are automatically performed (when the auto shot function is enabled).
Manual is orange.	All operations are performed manually.

24 Small pupil image capture button (SP)

Used to capture images of the eye with the pupil diameter smaller than the required pupil diameter mark ◯ . Pressing this button changes it to orange and enables image capture with a pupil as small as the minimum pupil diameter mark ◌ .

"3.6.1 Small pupil image capture" (page 117)

25 Low-light image capture button

Used to lower the set flash intensity for image capture. When the button is being selected, it is shown in orange.

"3.6.2 Low-light image capture" (page 118)

26 Fundus observation illumination intensity up/down buttons

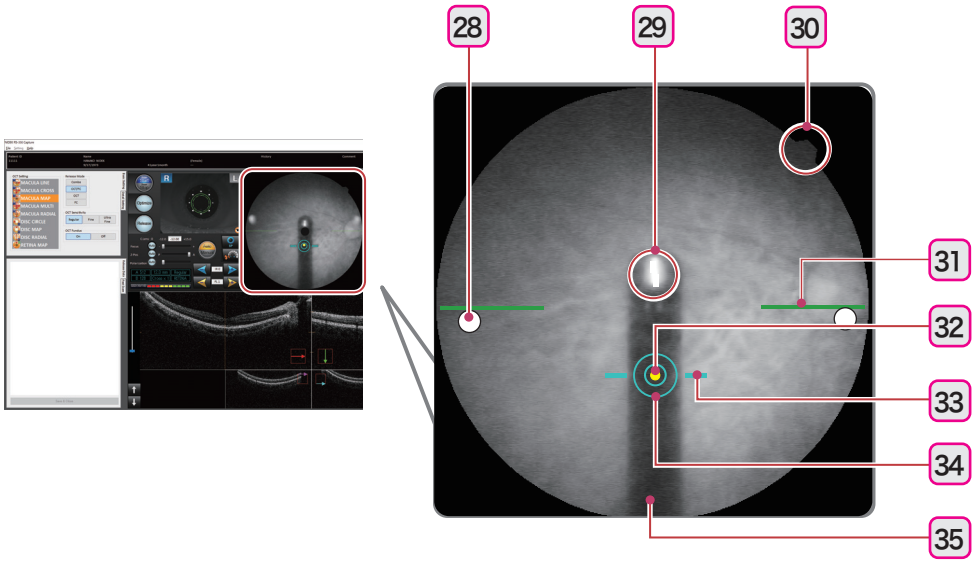
Used to adjust the brightness of the illumination for fundus observation.

	Reduces the intensity.
	Increases the intensity.

27 Flash intensity up/down buttons

Used to adjust the flash intensity for image capture.

	Reduces the intensity.
	Increases the intensity.



28 Optical working dots

Displayed in the form of bright spots on the right and left sides of the screen. They are used for fine alignment or focusing, or when the electronic working dot cannot be displayed.

For the alignment, the optical working dots need to be brightly displayed and aligned symmetrically to the optical working dot charts.

29 Focus split

Indicates the focus condition on the fundus by the displacement between the upper and lower lines.

The focus is optimum when the upper and lower lines form a single line.

30 Orientation tab 

Used to show the orientation of captured images.

31 Optical working dot charts

Displayed in the form of green lines on the right and left sides of the screen. They are used as a guide-line of the vertical position for image capture.

32 Electronic working dot

Shown in yellow and used as the reference point for alignment.

Note

- If the patient's eyelid is not opened wide enough or their cornea has any lesions or such, the electronic working dot may not be displayed due to improper detection of the cornea-reflected spots.

33 Working distance indicator

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

34 Target mark

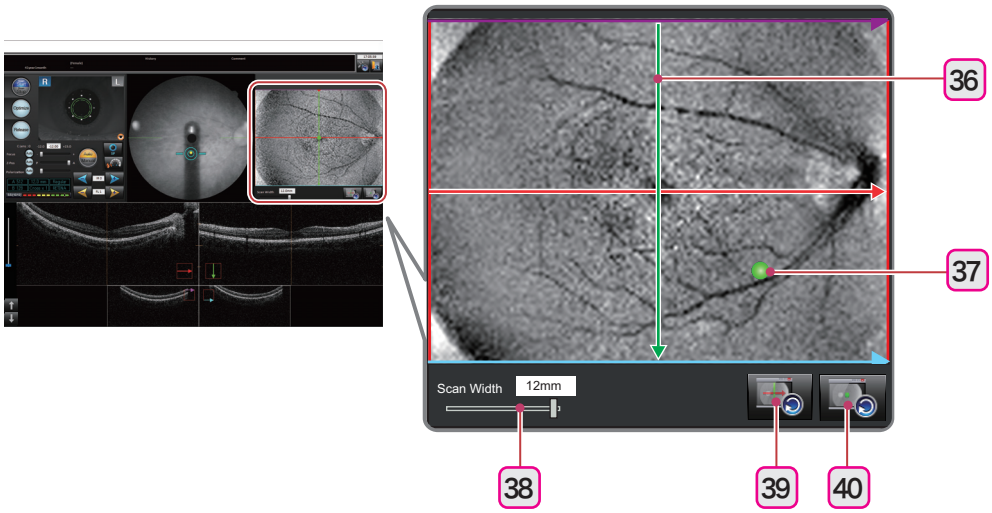
Indicates the center of the screen. The electronic working dot is aligned to the target mark.

In addition, the appearance of the target mark changes when the electronic working dot is detected. 

35 Focus Bar

Operates inside the system main body. The focus bar can be either shown or hidden.

"3.7.1 Image capture setting" (page 120)



36 Scan line

Shows the position of the scan line for OCT image capture.

Dragging the scan line moves it or changes its shape. The scan line cannot extend out of the OCT Phase Fundus image.

The position and shape of the scan lines can be changed as shown below.

OCT Setting	Scan Position	Scan Width	Scan Pitch	Scan Angle
MACULA LINE	Yes	Yes	No	Yes
MACULA CROSS	Yes	Yes	No	No
MACULA MAP	Yes	Yes	No	No
MACULA MULTI	Yes	Yes	Yes	No
MACULA RADIAL	Yes	Yes	No	No
DISC CIRCLE	Yes	No	No	No
DISC MAP	Yes	Yes	No	No
DISC RADIAL	Yes	Yes	No	No
RETINA MAP *1	No	No	No	No
CORNEA LINE (During anterior segment cross-sectional image capture [optional])	No	Yes	No	Yes
CORNEA CROSS (During anterior segment cross-sectional image capture [optional])	No	Yes	No	No
CORNEA RADIAL (During anterior segment cross-sectional image capture [optional])	No	Yes	No	No
ACA LINE (During anterior segment cross-sectional image capture [optional])	No	Yes	No	Yes

*1. “RETINA MAP” can be selected when the retina map dongle is connected to the USB port of the computer.

37 Internal fixation lamp

Indicates the current fixation lamp position in green. Dragging the internal fixation lamp moves it.

To stabilize the patient's eye fixation, instruct the patient to focus on the fixation lamp during image capture.

The internal fixation lamp cannot be used when “RETINA MAP” is selected.

38 Slider

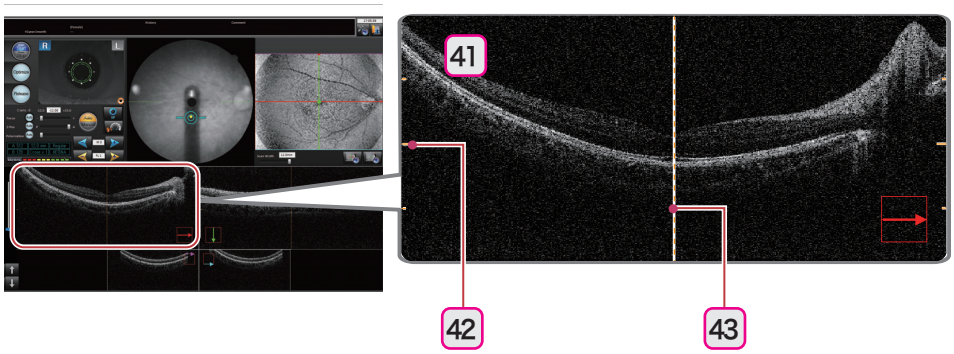
Used to change the scan line width, pitch, and angle. It cannot be used for the Disc Circle scan line or Retina Map scan line.

39 Scan line origin return button 

Returns the moved scan line to the initial position.

40 Internal fixation lamp origin return button 

Returns the moved internal fixation lamp to the initial position.



41 OCT image

Displays the OCT image of the scan line position. The arrow correspond to the arrow on the OCT Phase Fundus image. The display changes depending on the selected scan line.

Dragging the OCT image or rotating the mouse wheel moves the OCT image.

Right-clicking on the OCT image displays the menu that allows the setting shown below.

OCT Color	Color, Negative (B/W), or Positive (B/W) can be selected.
Overlay	Allows selection to show or hide the ruler and the center line.

42 Ruler

Used as a guideline of the vertical position of the OCT image.

43 Center line

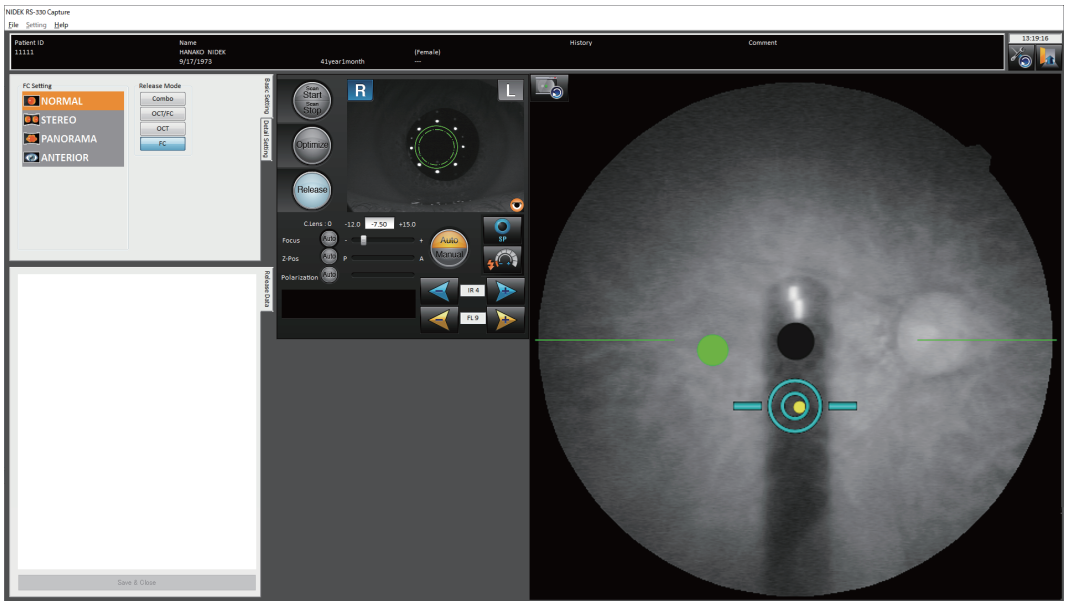
Used as a guideline of the horizontal position of the OCT image.

○ FC display

For the button and icons that are not explained below, see *"O OCT/FC display" (page 36)*.

Pressing the button shown below in the Basic Setting tab displays this screen.

- Combo release mode [Combo] (during color fundus image capture)
- FC release mode [FC]

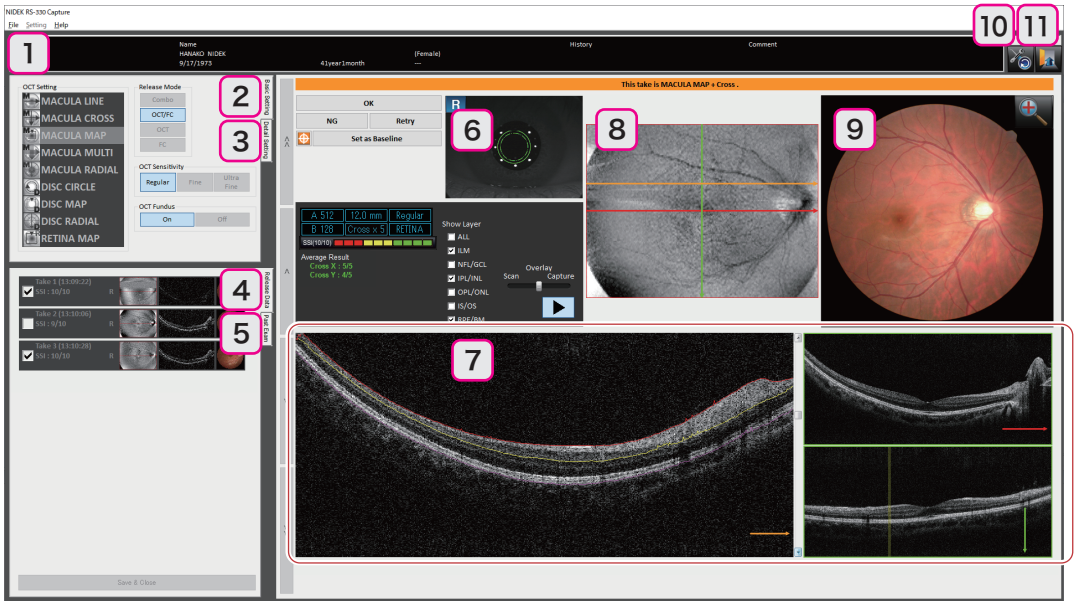


2.4.2 Image confirmation screen

○ OCT/FC display

Pressing any of the buttons shown below in the Basic Setting tab displays this screen.

- Combo release mode [Combo] (during OCT image capture)
- OCT/FC release mode [OCT/FC]
- OCT release mode [OCT]



1 Patient information

Shows the ID, name and other information of the patient selected with NAVIS-EX.

2 Basic Setting tab

It cannot be used on the image confirmation screen.

3 Detail Setting tab

It cannot be used on the image confirmation screen.

4 Release Data tab

Displays the thumbnails of the captured images.

The thumbnails show the time and quality evaluation (HD scan image averaging result and SSI) of the captured images.

5 Past Exam tab

It cannot be used on the image confirmation screen.

6 Eye front image

Displays the captured eye front image.

7 OCT image

Displays the OCT image of the scan line position. The arrow at the bottom right of the image correspond to the arrow on the OCT Phase Fundus image.

8 OCT Phase Fundus image

Displays an OCT-generated fundus image.

When the OCT setting button MACULA MAP ➔ OCT Base/Detail Settings dialog ➔ OCT Fundus ➔ OFF are selected, a fundus image obtained with infrared light is displayed.

9 Color fundus image

Displays the captured color fundus image. Clicking the zoom button enlarges the image. To close the enlarged view, press the return button .

In Combo release mode Combo (during OCT image capture) or OCT release mode OCT, color fundus images are not captured or displayed on the image confirmation screen.

10 Clear button

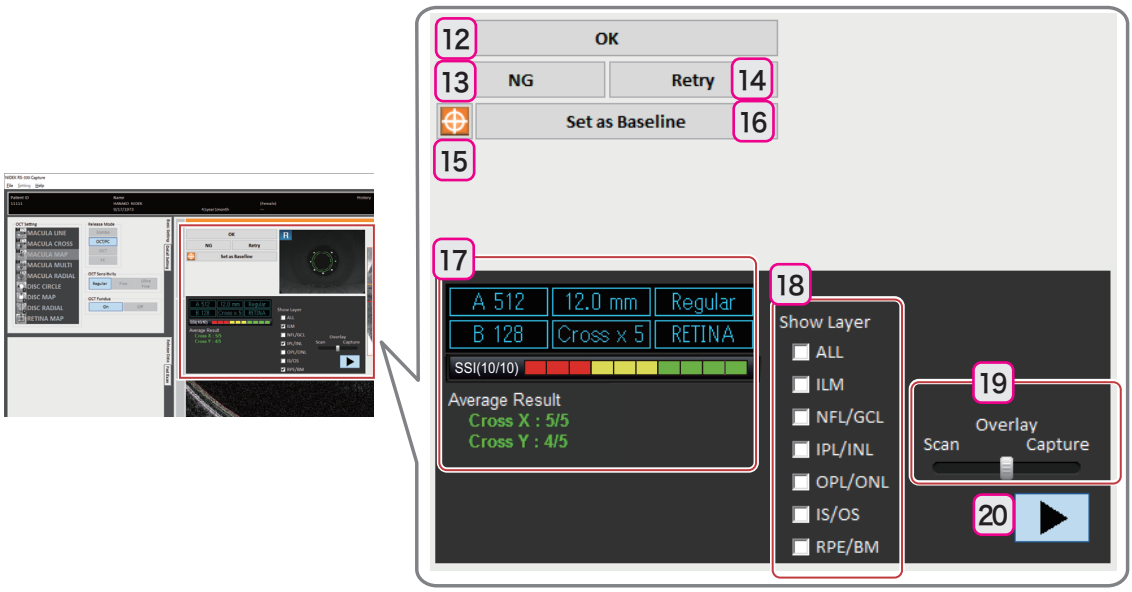
It cannot be used on the image confirmation screen.

11 Close button

Closes RS-330 Capture.

⚠ CAUTION

- The thumbnails in the Release Data tab are deleted without being saved. To save the thumbnails, close RS-330 Capture by clicking the “Save & Close” button Save & Close in the Release Data tab.



12 OK button OK *1

Displays the thumbnail of the captured image in the Release Data tab of RS-330 Capture.

The check box shown to the left side of the thumbnail is selected to allow saving of the data.

13 NG button NG *1

Displays the thumbnail of the captured image in the Release Data tab of RS-330 Capture.

The check box shown to the left of the thumbnail is not selected (It can be checked later).

14 Retry button Retry *1

Discards the captured image and displays the eye front or fundus observation screen.

15 "Set as Baseline" button *1 *2

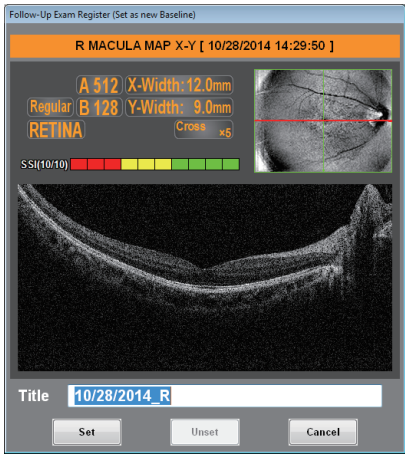
Registers the captured image as the baseline . The thumbnail of the registered image is displayed in the Release Data tab of RS-330 Capture.

The check box shown to the left side of the thumbnail is selected to allow saving of the data.

*1. Displayed only when the image is captured using the release button of RS-330 Capture.

*2. It is not displayed when the image capture is performed with "RETINA MAP" selected.

16 "Set as Baseline" button [Set as Baseline] *1*2



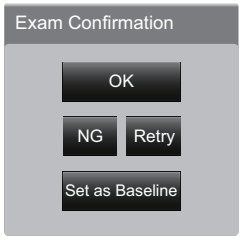
The Follow-Up Exam Register dialog appears.

In the Follow-Up Exam Register dialog, captured images can be named and registered as the baseline.

Changing of the registered baseline name, and deletion of the registration can only be performed with NAVIS-EX. They cannot be performed with RS-330 Capture.

Note

- When images are captured using RS-330 Capture, the Exam Confirmation dialog is displayed in the touch screen of the system main body.

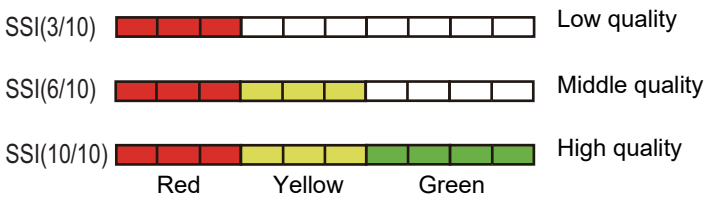


17 Image capture information

Displays the selected OCT setting. In addition, the SSI indication and the image averaging result are displayed.

- SSI

  As the SSI becomes higher, a finer image can be obtained.



*1. Displayed only when the image is captured using the release button of RS-330 Capture.

*2. It is not displayed when the image capture is performed with "RETINA MAP" selected.

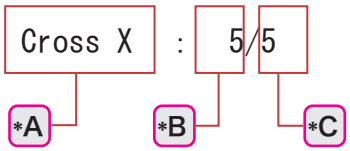
- Image averaging result

  The number of successfully averaged images out of the number of the specified HD scan images is displayed. As the number of successfully averaged images becomes larger, finer images can be obtained. The color of the image averaging result indication and the color of the frame color of the OCT image change depending on the proportion of successfully averaged images.

  70% or higher: Green

  51 to 69%: Yellow

  50% or lower: Red



*A	Scan line of the displayed averaging result
*B	The number of successfully averaged images
*C	Number of HD scan images

18 Layer display check box

The layer borderlines are automatically detected and displayed over the OCT image.

19 Overlay

An OCT image is converted to a map image and overlaid on an OCT Phase Fundus image. The slider is used to change the opacity of the overlaid image. This function allows checking whether the patient blinked or not during OCT image capture.

Scan: Overlay is not performed.

Capture: Overlay is performed.

20 Slide show button 

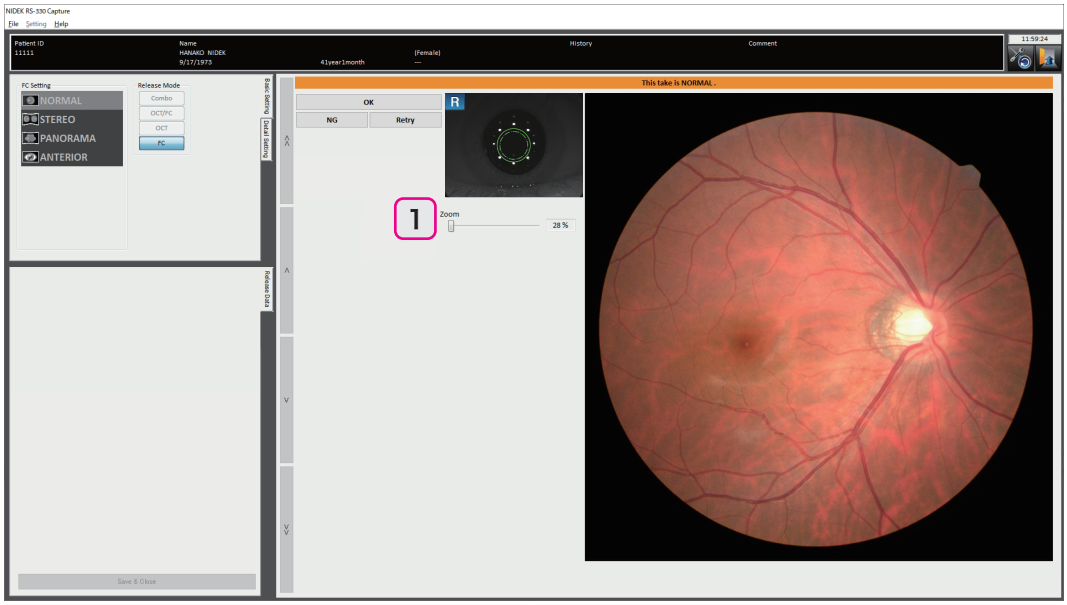
A slide show displays the OCT images of the positions indicated by the moving arrows.

○ FC display

For the button and icons that are not explained below, see *"O OCT/FC display" (page 47)*.

Pressing the button shown below in the Basic Setting tab displays this screen.

- Combo release mode Combo (during color fundus image capture)
- FC release mode FC

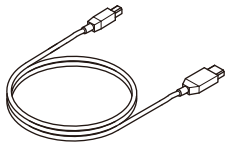
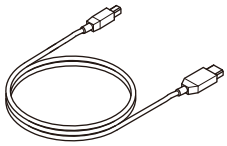
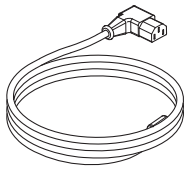
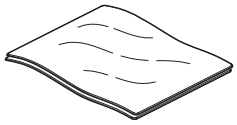
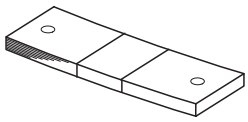
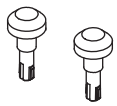
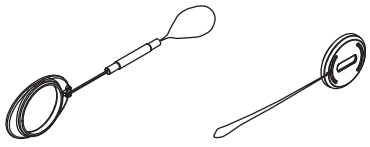
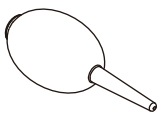


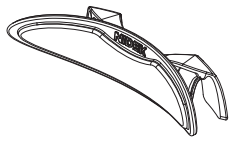
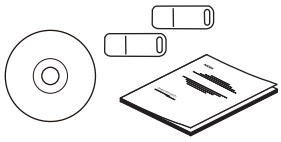
1 Slider

Used to enlarge the color fundus image.

2.5 Packed Contents

■ The following are included in the standard configuration. Check the packed contents before use.

Product name	Quantity	Appearance
USB 2.0 cable	1 unit	
USB 3.0 cable (Blue connector tip)	1 unit	
Power cord (for system main body)	1 unit	
Dust cover	1 unit	
Chinrest paper	1 unit	
Chinrest paper pin	2 unit	
Magnetic forehead rest pad (The magnetic forehead rest pad does not come attached to the system main body and is included in the packed contents.)	1 unit	
Cap holder Objective lens cap (At the time of shipping, the objective lens cap is attached to the objective lens of the system main body.)	1 unit of each	
Blower	1 unit	

Product name	Quantity	Appearance
Spacer for anterior segment image capture	1 unit	
Operator's manual Quick reference guide	1 volume of each	
NAVIS-EX	1 set	
RS-330 Capture installation CD	1 unit	
Retina map dongle and B-scan Denoising Software	1 set	

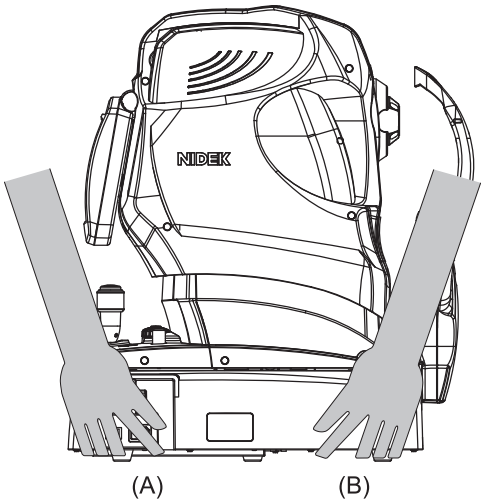
2.6 Initial Use

2.6.1 System installation

Install the system in a location that satisfies the conditions described in “Before Use”.

1 Place the system main body on a stable table.

The system main body should be carried by two persons holding it at positions (A) and (B) (both right and left sides).



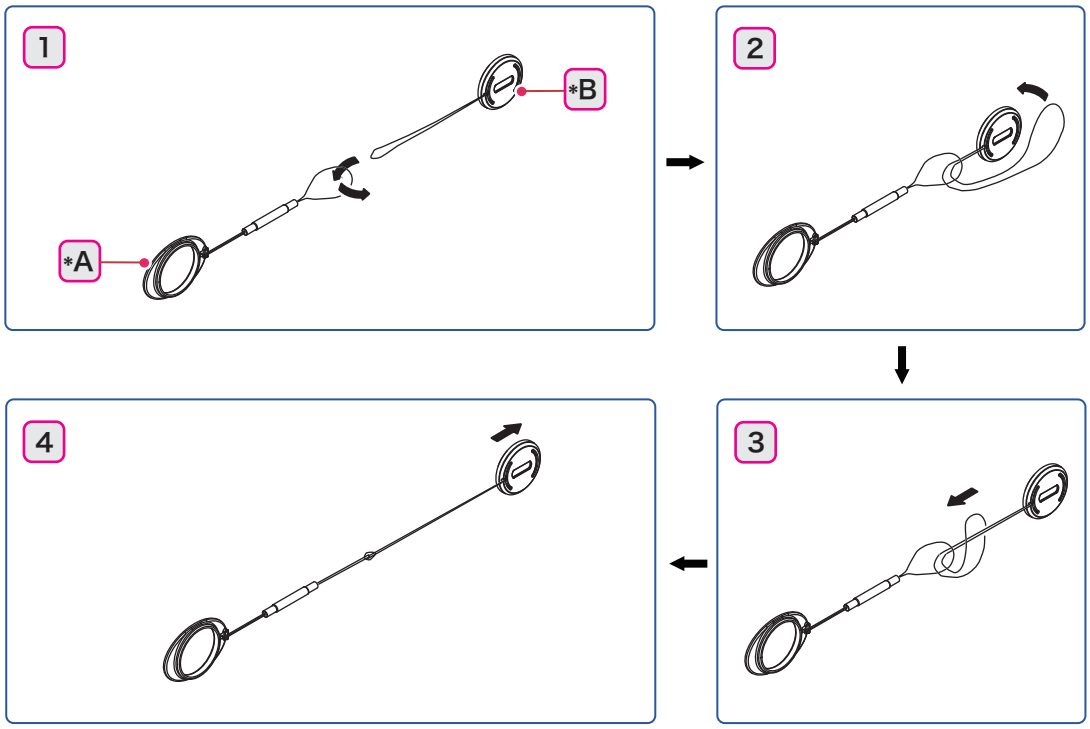
2 Place a computer and computer monitor*1*2 on a stable table. Place an isolation transformer on the floor.

Note

- Using the optional motorized optical table (OT-600BF) and computer cabinet enables a small-footprint installation.

3 Attach the cap holder in accordance with the procedure below.

1) Tie the cap holder (*A) and the objective lens cap (*B) as shown below.

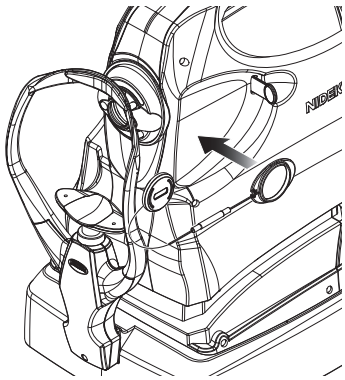


*1. They are not the standard accessories. To use the system, the products that satisfy the required specifications need to be prepared. Contact NIDEK or your authorized distributor for details.

*2. To connect 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) to the system, supply power to the system and computer through isolation transformers. Contact NIDEK or your authorized distributor for installing isolation transformers.

2) Remove the sheet on the back of the cap holder.

3) Adhere the cap holder on the system main body.

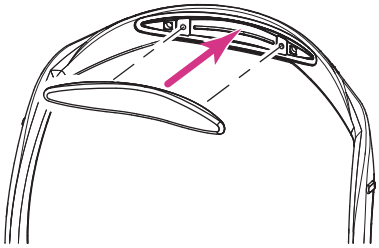


Note

- Place the objective lens cap on the objective lens when the system is not used, and on the cap holder when the device is used.

4 Attach the magnetic forehead rest pad to the system main body.

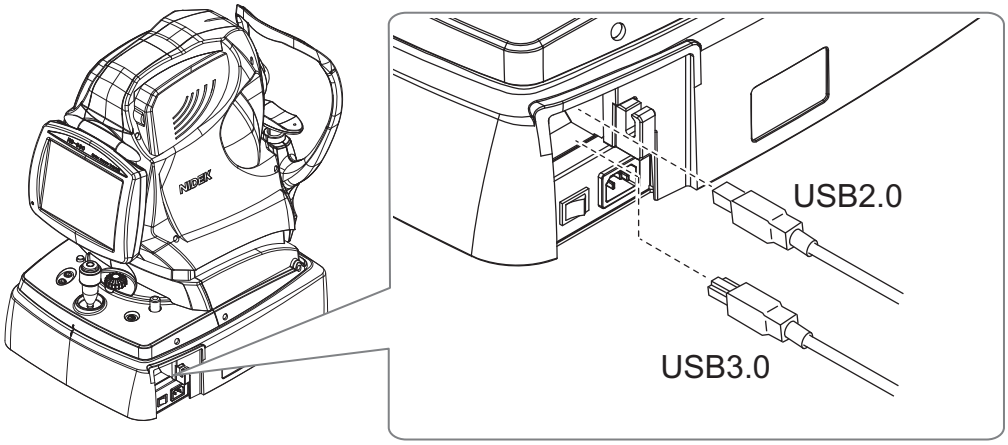
The magnetic forehead rest pad does not come attached to the system main body and is included in the packed contents. The magnetic forehead rest pad is attachable in the orientation as shown to the right.



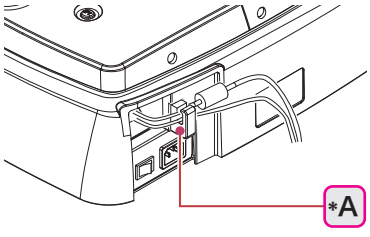
5 Connect the USB 2.0 and USB 3.0 cables to the system main body.

1) Insert the connectors in the correct orientation.

The tip of the USB 3.0 cable connector is blue. Check the color before the connection.

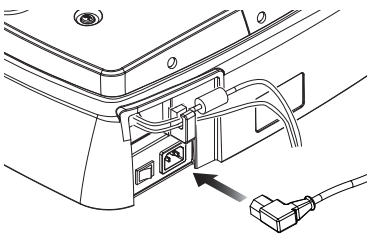


2) Run the USB 2.0 and USB 3.0 cables through the hook(*A).



6 Connect the power cord to the inlet of the system main body.

7 Connect the power cord and the computer monitor cable to the computer monitor.



8 Connect the cables shown below to the computer.

- Power cord
- Mouse cable
- Keyboard cable
- Computer monitor cable
- USB 2.0 cable and USB 3.0 cable connected to the system main body.
  The tip of the USB 3.0 cable connector is blue. Be sure to connect the cables to the correct connectors.

⚠ CAUTION

- Use the provided cables, and connect them properly.
  Malfunction may result.

9 Connect the retina map dongle to the USB port of the computer.

10 Connect the power cord to the isolation transformer.

⚠ CAUTION

- When the optional isolation transformer is used, connect only the power cords of the computer and the computer monitor. Connect the power cord of the system main body to the wall outlet.
  A failure of the system, electric shock, or fire may result.

11 Check that the power switch of the isolation transformer is off (◯). Then connect the power cord of the isolation transformer to the wall power outlet.

⚠ WARNING

- Be sure to connect the power plug to a grounded power outlet.
  Electric shock or fire may result from system malfunction or electric leakage.

12 Turn on (|) power to the isolation transformer.

13 Turn on power to the computer and the computer monitor.

14 Install NAVIS-EX.

For details of installation, refer to the NAVIS-EX Operator's Manual.

15 Install RS-330 Capture.

For details of installation, see *"2.6.3 Installing RS-330 Capture" (page 58)*.

16 Shut down Windows.

17 Turn off (◯) power to the isolation transformer.

2.6.2 System requirements

RS-330 Capture runs on computers using Windows 10 or Windows 11*1.

- System requirements such as hardware and memory

OS	• Windows 10 Pro 64 bit • Windows 11 Pro 64 bit
CPU	Intel Xeon E3-1220v 3: 3.1 GHz / Corei7-4770: 3.4 GHz or more
RAM	4 GB or more
HDD	500 GB for C drive, 2 TB for data recommendation
USB	USB3.0 × 1 port or more + USB2.0 × 1 port or more (Configuration of only USB3.0 ports is not allowed.)
Graphic	On board graphic with Intel HD4000 or more
Chipset	Intel C226/8 Series or more (Intel chipset only)

Note

- Depending on the computer, RS-330 Capture may not work even when the above specifications are satisfied. Before purchasing the computer, contact NIDEK or your authorized distributor.
- In order to use the USB 3.0 PCIE ADD IN CARD, the expansion slot of PCI Express Base Specification Revision 2.0 X 1 Lane or more is required.

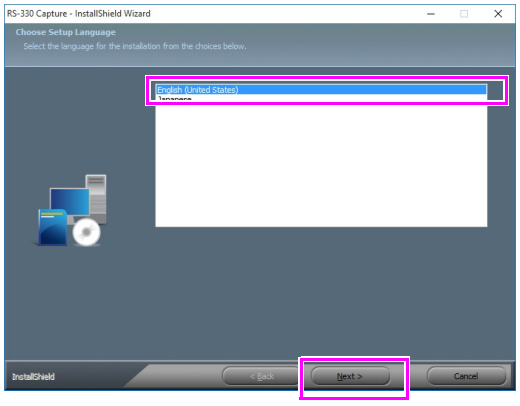
*1 Microsoft and Windows are registered trademarks or trademarks of Microsoft Corp. in the United States and/or other countries. The corporate names and product names described in this Operator's Manual are registered trademarks or trademarks of each manufacturer.

2.6.3 Installing RS-330 Capture

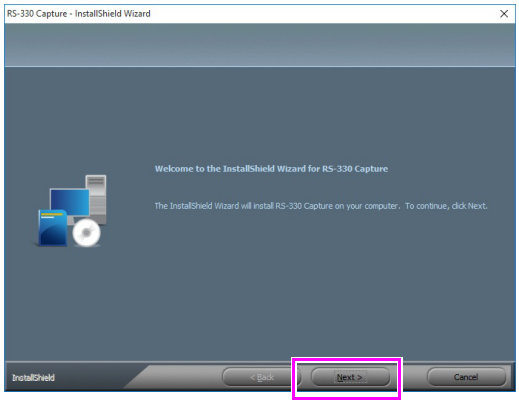
To install RS-330 Capture, NAVIS-EX needs to be installed on the computer. Be sure that NAVIS-EX is installed in advance.

1 Insert the installation CD into the CD-ROM drive, and activate it by opening the install CD using the explorer or such. Then double-click "Setup.exe".

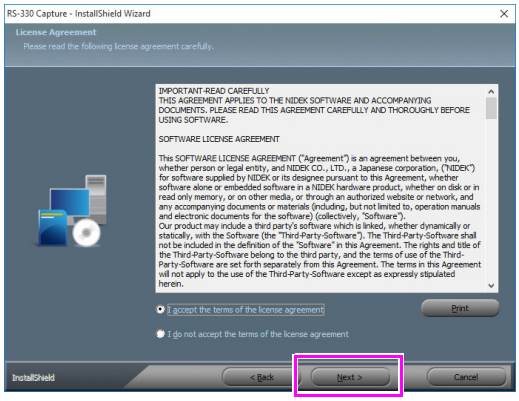
2 Select "English", then click the Next button to start the installation.



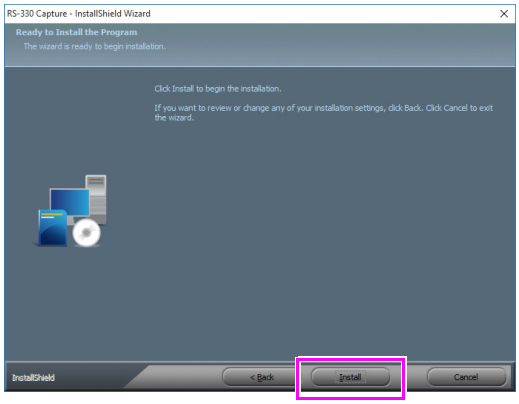
3 Click the Next button.



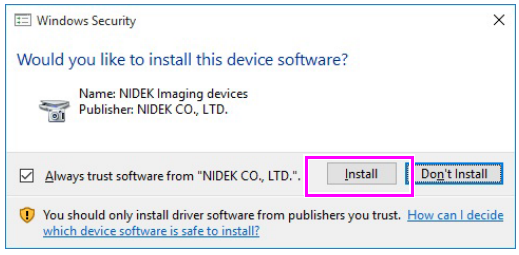
4 The license agreement dialog box appears. Read the contents carefully, check the box for “I accept the terms of the license agreement”, then click the Next button.



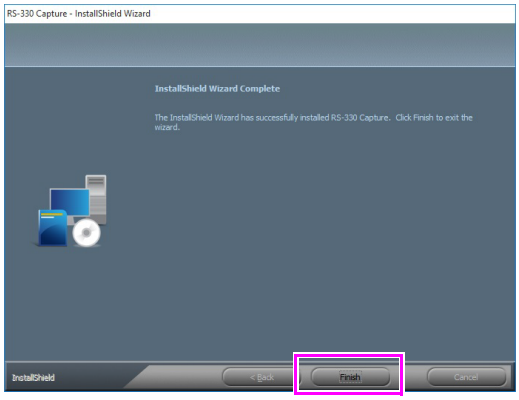
5 Click the Install button to start the installation.



6 After confirming that the box for “Always trust software from “NIDEK CO.,LTD.”.” is checked, click the Install button.



7 Click the Finish button to finish the setup.



8 Remove the installation CD from the CD-ROM drive.

The software installation is complete.

Note

- Store the installation CD in a secure place. It is needed to uninstall the software, or install it again.

2.6.4 Uninstalling RS-330 Capture

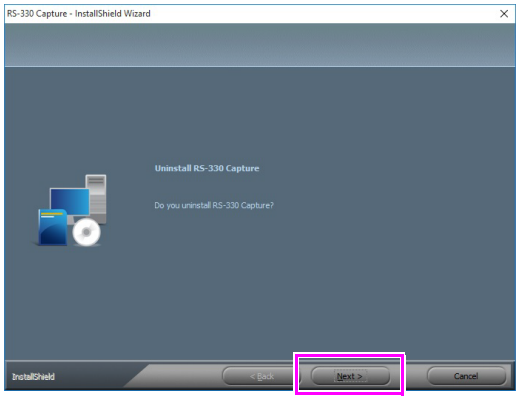
To uninstall RS-330 Capture, use the RS-330 Capture installation CD.

Note

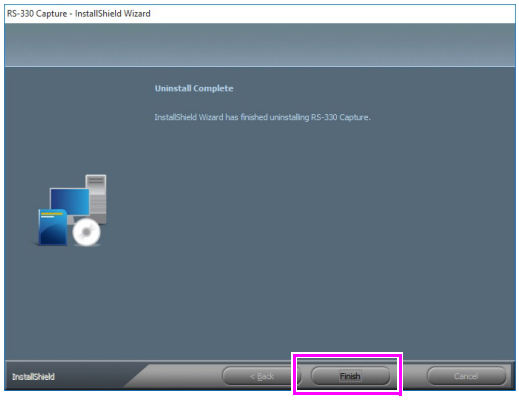
- The software can be uninstalled also with the “Programs (Uninstall a program)” function of Windows.
- Before uninstalling RS-330 Capture, close all the related applications.
- Uninstalling the software may not delete all the files completely. In such a case, restart the computer after the uninstallation, then manually delete the folders in the installation location.

1 Inserting the installation CD into the CD-ROM drive automatically activates the setup program.

2 The InstallShield Wizard dialog appears. Click the Next button.



3 When the uninstallation is finished, a message appears. Click the Finish button.

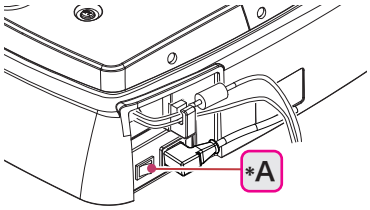


The software uninstallation is complete.

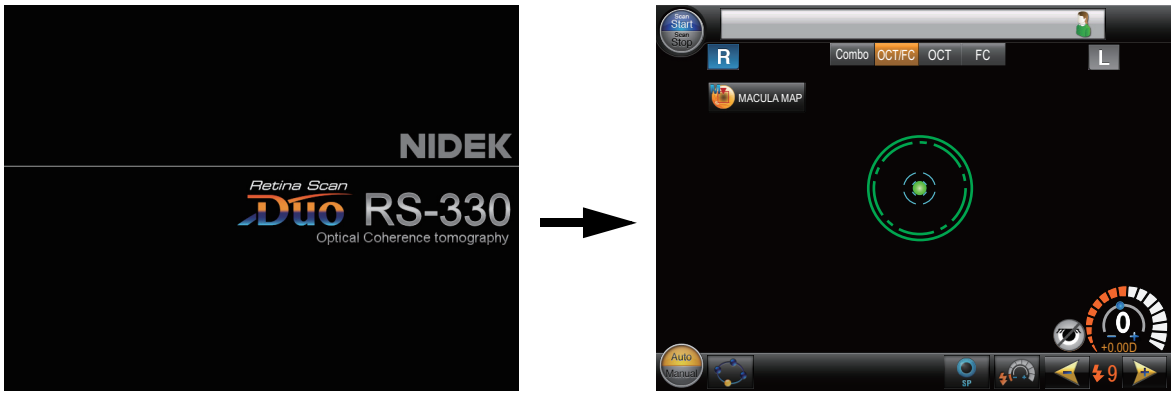
2.6.5 System start-up

1 Turn on (|) power to the isolation transformer.

2 Turn on (|) the power switch (*A) of the system main body.



Wait without operating the system until the front eye observation screen is displayed.



3 Turn on the power switches of the computer monitor and other peripheral devices of the computer.

4 Turn on the power switch of the computer.

5 Double-click the NAVIS-EX icon on the desktop.

The log-in screen appears.

6 Input the log-in name and password.

At the time of the initial start-up, the log-in name “RS-User” is displayed. The password is “user”.

Both the log-in name and password are case-sensitive.

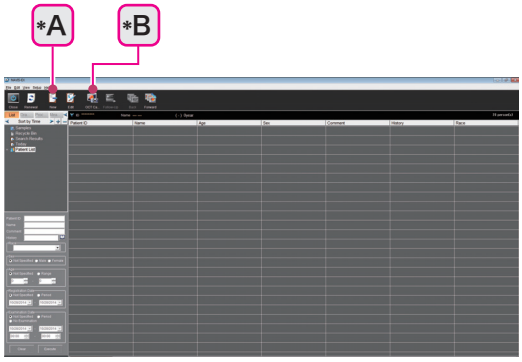
For the log-in name, the previously used log-in name is displayed.

Note

- For security, it is recommended to change the password after the installation.
  For the method of changing the password, refer to the NAVIS-EX Operator's Manual.

7 Click “Log in”.

NAVIS-EX is activated.



8 Register the patient in NAVIS-EX.

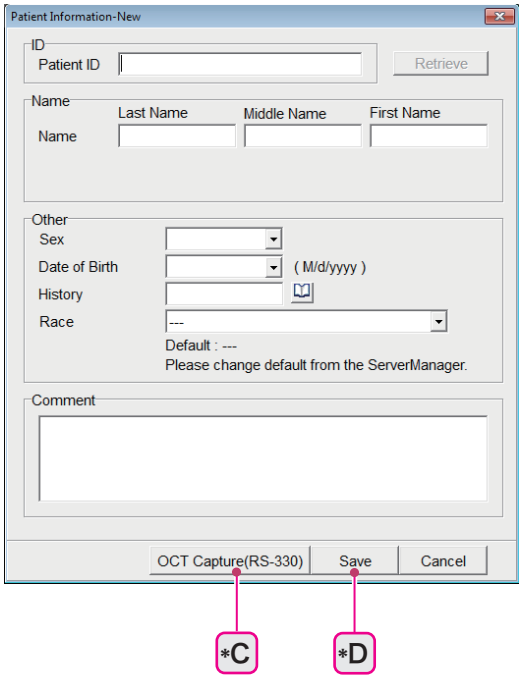
1) Click the New button  (*A).

The Patient Information-New dialog appears.

2) Input the information of the patient to register.

For the detailed patient registration procedure, and for the detailed operating procedures of NAVIS-EX, refer to the NAVIS-EX Operator's Manual.

3) Click the OCT Capture (RS-330) button (*C). Or, click the Save button (*D) to register the patient, then click the OCT Capture button  (*B).

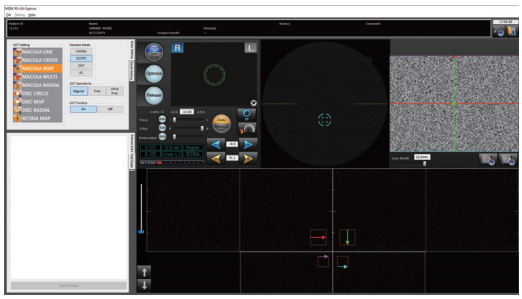


Note

- To capture images for the registered patients, click the patient, then click the OCT Capture button  (*B).

9 RS-330 Capture activates. Then the system main body and the computer are connected.

Depending of the condition of the system, it may require about 20 seconds until connection of the computer is complete.



The system is ready for use.

Note

- Set the parameters to suit the use conditions.

“4.5 Setting of RS-330 Capture” (page 134)

3 OPERATING PROCEDURE

3.1 Operation Flow Chart

Turning on power to the system

"2.6.5 System start-up" (page 62)

"3.2.1 Preparing for image capture" (page 66)

Turn on power to the system, and set the system parameters as necessary.

Conduct patient preparation.

Image capture

"3.2 OCT/FC Release Mode" (page 66)

- *"3.2.2 Automatic image capture" (page 71)*
- *"3.2.6 Manual image capture (Operation mode: Professional)" (page 83)*
- *"3.2.7 Manual image capture (Operation mode: Standard)" (page 88)*

"3.3 OCT Release Mode" (page 93)

- *"3.3.1 Retinal cross-sectional image capture" (page 94)*
- *"3.3.2 Anterior segment cross-sectional image capture (optional)" (page 95)*

"3.4 FC Release Mode" (page 102)

- *"3.4.1 Standard image capture" (page 104)*
- *"3.4.2 Stereo image capture" (page 105)*
- *"3.4.3 Panorama image capture" (page 109)*
- *"3.4.4 Eye front image capture" (page 111)*

"3.5 Combo Image Capture" (page 114)

"3.6 Other Image Capture" (page 117)

- *"3.6.1 Small pupil image capture" (page 117)*
- *"3.6.2 Low-light image capture" (page 118)*
- *"3.6.3 Fundus autofluorescence image capture (optional)" (page 119)*

Turning off power to the system

"3.2.5 Finishing image capture" (page 80)

3.2 OCT/FC Release Mode

■ The basic operating procedure is explained with image capture in OCT/FC release mode OCT/FC.

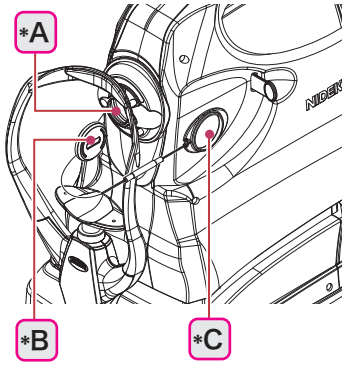
The operating procedure using the system main body is explained below. However, most of the operations can also be performed using RS-330 Capture. Use the convenient one. (For details of the operation using RS-330 Capture, see *"2.4 RS-330 Capture Screen" (page 36)*.)

3.2.1 Preparing for image capture

1 Turn on power to the system, and register the patient for whom images are to be captured.

"2.6.5 System start-up" (page 62)

2 Remove the objective lens cap (*B) from the objective lens (*A).



Attach the removed objective lens cap to the cap holder(*C).

3 Check the system before use.

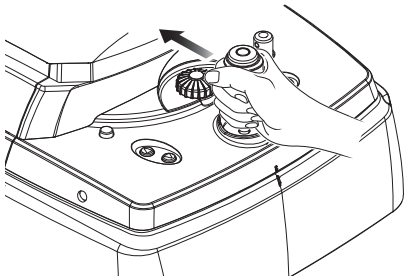
Before using the system, check the following points:

- No error message is displayed.
- The objective lens is clean.
- The main unit can be moved smoothly using the joystick.
- The chinrest can be moved up and down using the chinrest up/down button.
- NAVIS-EX and RS-330 Capture are activated.
- Icons can be operated by pressing them.

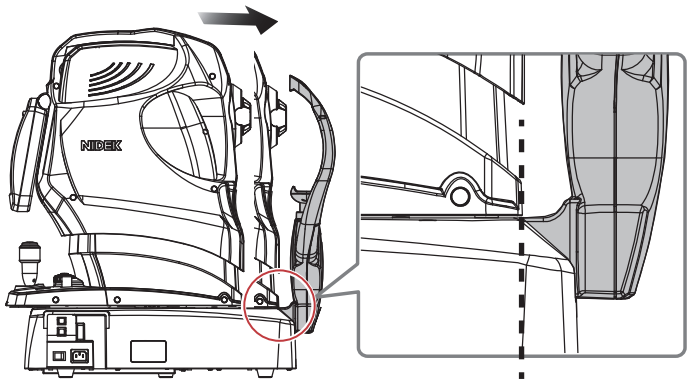
If any abnormality occurs, do not use the system and remedy the problem in accordance with *"4.1 Troubleshooting" (page 127)*.

4 Check the movable range of the main unit.

1) Move the main unit fully to the patient side using the joystick.

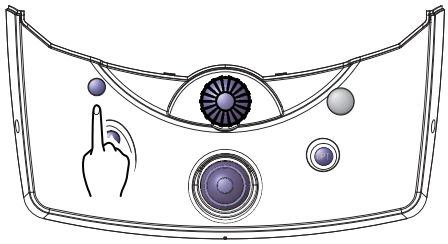


2) Confirm that the main unit can be moved to the edge of the base unit.



3) If the main unit stops halfway, press and hold the safety stopper, then move the main unit to the edge of the base unit.

After moving the main unit, release the safety stopper.



⚠ CAUTION

- The safety stopper limits the movable range of the main unit. It is operated before using the anterior segment adapter (optional) to prevent the adapter from coming into contact with the patient's eye. It is not used for any other purposes. Therefore, usually, set the safety stopper with the main unit fully moved to the patient side.

  If the movable range of the main unit is limited, images may not be captured due to inability to achieve proper focus.

5 Set the image capture conditions.

- Release mode

Press any of the following buttons to select the release mode. The selected button is shown in orange.

Combo	By setting combinations of various release modes in advance, images can be captured in the desired modes in the preset order without changing the setting.
OCT/FC	In OCT/FC release mode, the OCT image capture, then the color fundus image capture are performed consecutively.
OCT	In OCT release mode, only OCT images are captured. By setting up the system so that the optional anterior segment adapter is ready for use, the button for eye front OCT image capture  and the button for the retinal OCT image capture  are displayed. The desired image capture type can be selected.
FC	In FC release mode, only color fundus images are captured. The image capture type can be selected from standard  , stereo  , panorama  , and eye front  .

- Starting and stopping the scanning (only for OCT image capture)

  Press the Start/Stop button 

 to start or stop the scanning. The button shows the scan status with blue color.

 Scan Start is blue	The scanning is being performed.
 Scan Stop is blue	The scanning is stopped.

- Auto and manual image capture

  Press the Auto/Manual toggle switch 

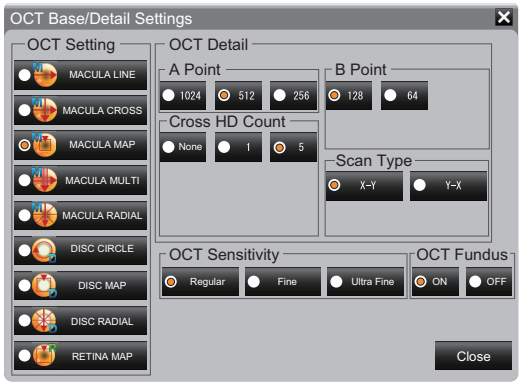
 to select either type of image capture. The selected image capture type is shown in orange.

 Auto is orange.	Alignment, focusing, and image capture are automatically performed (when the auto shot function is enabled).
 Manual is orange.	All operations are performed manually.

- OCT Setting (only for OCT image capture)

  Select the desired OCT setting in the OCT Base/Detail Settings dialog displayed by pressing the OCT setting button 

.

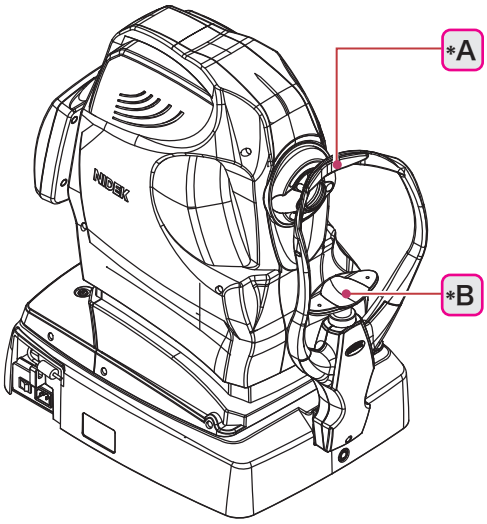


- Image capture flash intensity (only for color fundus image capture)

  Press the flash intensity up/down buttons to set the flash intensity for color fundus image capture.

	Reduces the intensity.
	Increases the intensity.

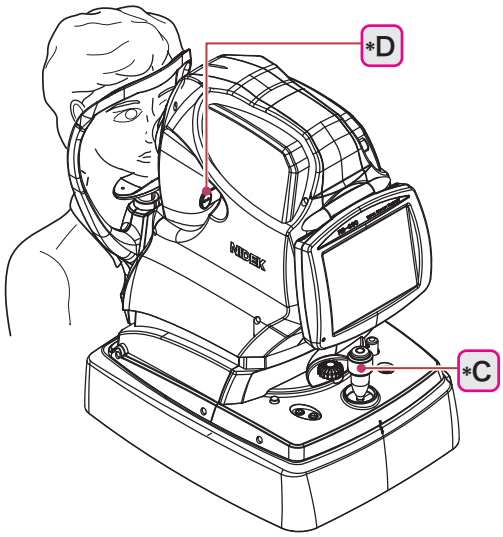
6 Conduct patient preparation.



1) Wipe the forehead rest (*A) and the chinrest (*B) with a clean cotton swab or gauze dampened with rubbing alcohol.

   If the chinrest paper is used, remove a single sheet from the stack of sheets.

2) Hold the joystick (*C) of the system main body, and pull the main unit fully to the operator side.



⚠ CAUTION

- It is recommended to make a habit of pulling the main unit fully to the operator side before having the patient sit in front of the system main body.

  Doing so prevents the image capturing unit coming into contact with the patient's face.

3) Instruct the patient to remove the eye glasses or contact lenses, then have them sit in front of the system main body.

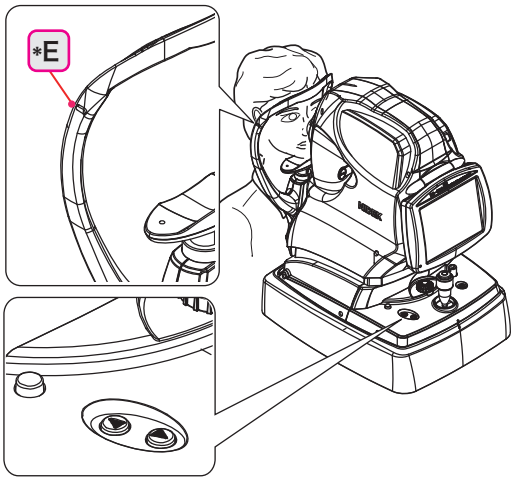
   If the refractive power of the patient is outside the range of focus adjustment, insert a compensation lens using the compensation lens select lever (*D).

4) Have the patient place their chin on the chinrest as far forward as possible with their forehead resting gently on the forehead rest.

5) Align the height of the patient's eyes with the eye level marker (*E) using the chinrest up/down buttons (▲, ▼).

   Perform the operation while checking the condition of the patient's eye.

   For rough height adjustment, have the patient move away from the forehead rest and chinrest.



If the limit indicator (*F) appears in the touch screen of the system main body, move the chin-rest in the indicated direction.

3.2.2 Automatic image capture

Alignment, focusing, and image capture are automatically performed (when the auto shot function is enabled).

1 Conduct image capture preparation.

"3.2.1 Preparing for image capture" (page 66)

2 Give instructions to the patient.

"Look into the device. When you see a green blinking lamp, open both of your eyes wide and focus on it. Refrain from blinking as much as possible."

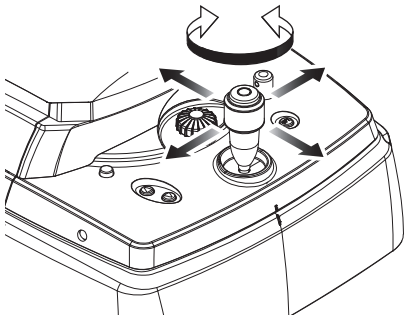
Note

- If eye fixation is difficult for the patient, guide the patient's eye movement with the following instructions:
  "Look straight." "Move your eyes slowly to the right."

3 Display the patient's eye in the touch screen of the system main body.

Moving the joystick horizontally moves the main unit horizontally.

Rotating the upper part of the joystick moves the image capturing vertically.



4 Move the main unit and the image capturing unit so that the patient's eye is displayed in the center of the screen, and that the electronic working dot (*A) is displayed.

If the limit indicator (red arrow) appears, operate the joystick to move the main unit and the image capturing unit in the indicated direction.

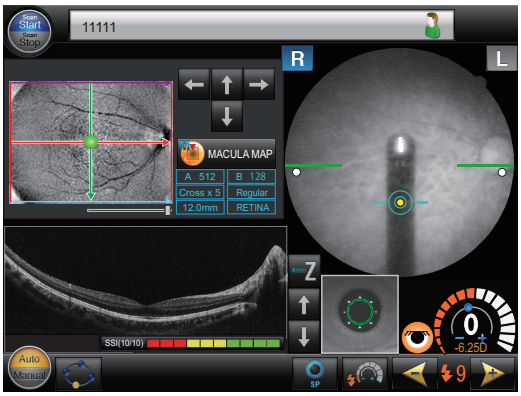
Forward/backward (/)

Right/left (/)

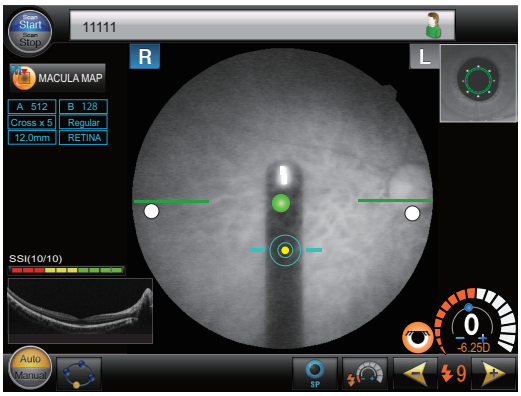
Up/down (/)

Displaying the electronic working dot automatically performs alignment, focusing, and optimization. After that, images are automatically captured (when the auto shot function is enabled).

In OCT/FC release mode OCT/FC, images are captured in the order of OCT image capture and color fundus image capture.



Operation mode: Professional



Operation mode: Standard *1

*1 Factory setting. The standard mode offers a simple screen configuration more specialized in screening than the Professional operation mode, without items such as the OCT Phase Fundus image, scan line, and Z position adjustment button.

Note

- The optimization may be interrupted due to improper alignment or focus, or opacity of the patient's eye.

  In such a case, capture images manually.

  "3.2.6 Manual image capture (Operation mode: Professional)" (page 83)

  "3.2.7 Manual image capture (Operation mode: Standard)" (page 88)

- If the patient's eyelid is detected or the pupil diameter is not large enough, images may not be captured properly.

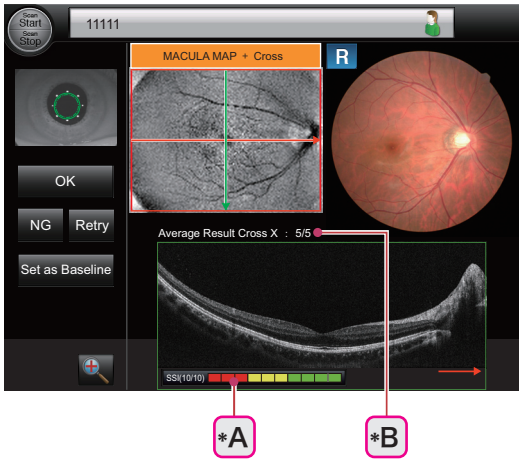
  In such a case, instruct the patient to open their eyes wider.

  If the patient cannot open their eyes wider, lift the patient's lid, paying attention not to press against the eyeballs.

- The auto tracking and auto shot may not function depending on the condition of the patient's eye such as eye diseases like cataract, or severe myopia or hyperopia outside the range between -12D and +15D.

  In such a case, capture images by pressing the release button. Or, capture images with the manual image capture procedure.

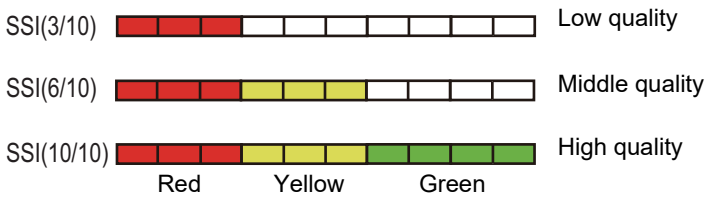
5 Check the captured image.



In addition to the images, check the SSI (*A) and image averaging result (*B) to evaluate the quality of the OCT image.

- SSI

  As the SSI becomes higher, a finer image can be obtained.



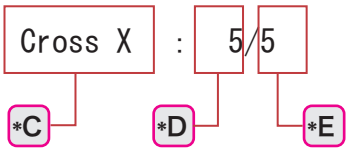
- Image averaging result

  The number of successfully averaged images out of the number of the specified HD scan images is displayed. As the number of successfully averaged images becomes larger, finer images can be obtained. The frame color of the OCT image changes depending on the proportion of successfully averaged images.

  70% or higher: Green

  51 to 69%: Yellow

  50% or lower: Red

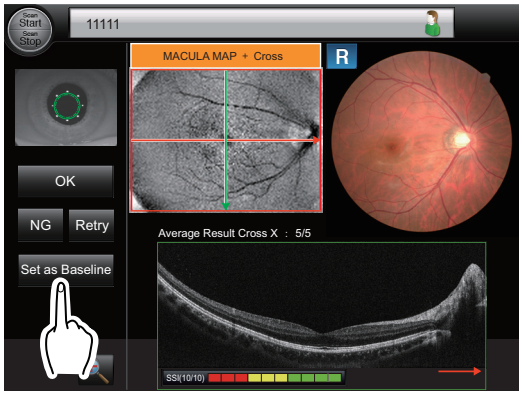


*C	Scan line of the displayed averaging result
*D	The number of successfully averaged images
*E	Number of HD scan images

Note

- If color fundus images cannot be captured properly, see *"3.2.3 If color fundus images cannot be captured properly" (page 76)*.

6 Click the desired button from OK, NG, Retry, and “Set as Baseline”.



- OK button OK

  Displays the thumbnail of the captured image in the Release Data tab of RS-330 Capture.

  The check box shown to the left side of the thumbnail is selected to allow saving of the data.

- NG button NG

  Displays the thumbnail of the captured image in the Release Data tab of RS-330 Capture.

  The check box shown to the left of the thumbnail is not selected (It can be checked later).

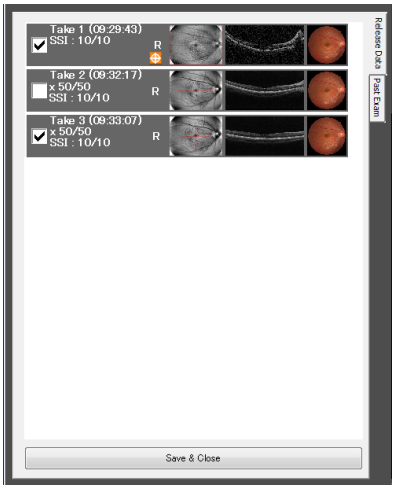
- Retry button Retry

  Discards the captured image and displays the eye front observation screen.

- “Set as Baseline” button Set as Baseline *1

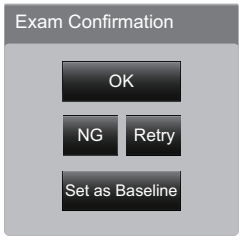
  Registers the captured image as the baseline  . The thumbnail of the registered image is displayed in the Release Data tab of RS-330 Capture.

  The check box shown to the left side of the thumbnail is selected to allow saving of the data.



Note

- Only the checked images can be transferred to the database with the “Save & Close” button Save & Close . At this point, the images are not saved yet.
- The OK button OK , NG button NG , Retry button Retry , and the “Set as Baseline” button Set as Baseline appear when images are captured by pressing the release button or by the auto shot function.
- When images are captured using RS-330 Capture, the Exam Confirmation dialog is displayed in the touch screen of the system main body.



*1. It is not displayed when the image capture is performed with “RETINA MAP” selected.

7 Capture images of the other eye in the same manner.

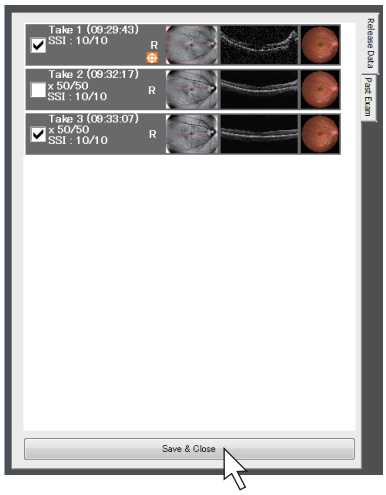
Instruct the patient to close their eye before starting the next image capture.

Let the eye rest to avoid image capture failure by blinking.

8 Save the captured images to the database.

Click the “Save & Close” button [Save & Close] of RS-330 Capture.

The checked images are transferred to the database and RS-330 Capture is closed.



Note

- If there are any images without the check mark, a confirmation dialog appears to confirm saving of the images to the database.
- Double-clicking a thumbnail enlarges the image.

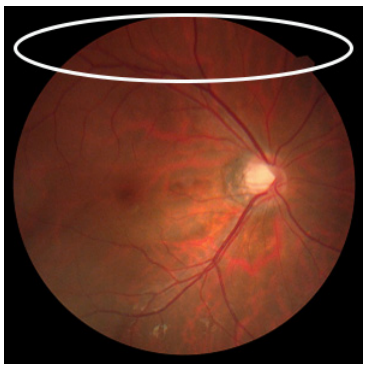
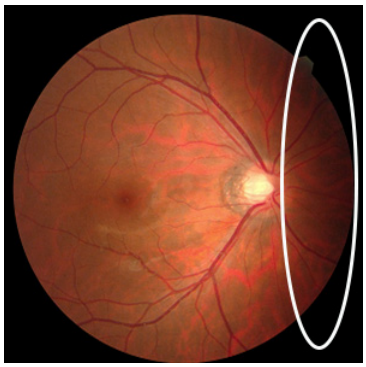
  Images can be confirmed before saving them.

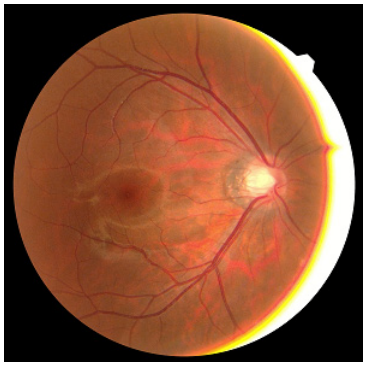
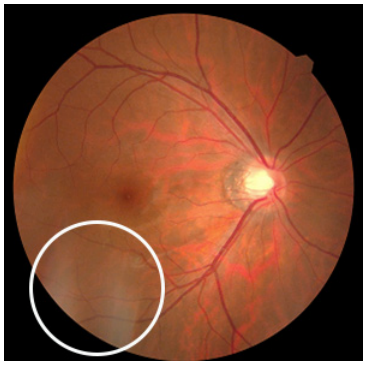
  “3.2.4 Image confirmation” (page 79)

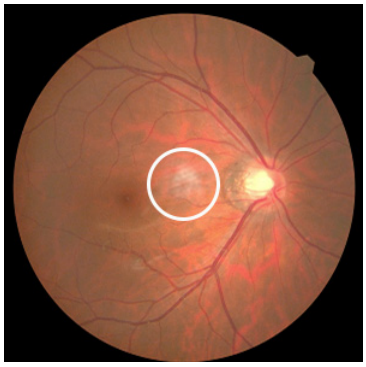
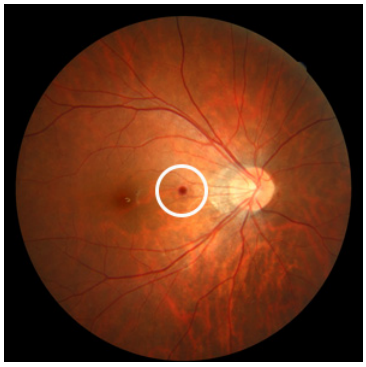
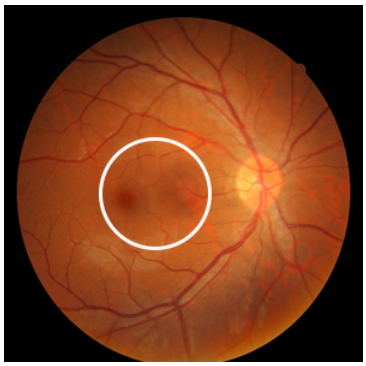
- RS-330 Capture can also be closed by clicking the close button  at the top right of RS-330 Capture screen.

3.2.3 If color fundus images cannot be captured properly

Depending on conditions such as the positional relationship between the system main body and the patient's eye, a black shadow or such may be captured in the color fundus image. In such a case, perform the remedies shown below.

Symptom	Cause and remedy
Fine image	
Top or bottom is dark.	• The image capturing unit may be shifted from the patient's eye. Top is dark: Move the image capturing unit down. Bottom is dark: Move the image capturing unit up. 
Right or left is dark.	• The image capturing unit may be shifted from the patient's eye. Right is dark: Move the image capturing unit to the left. Left is dark: Move the image capturing unit to the right. • The compensation lens select lever may be at an intermediate position. Move the lever to the desired position where a click is felt. 
Around center is dark.	• The patient's pupil dilation may not be sufficient. Improve the pupil dilation of the patient. If the patient's pupil cannot be dilated sufficiently, increase the flash intensity, or perform the small pupil image capture. *"3.6.1 Small pupil image capture" (page 117)* 

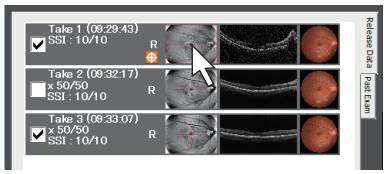
Symptom	Cause and remedy
White reflected light is in the peripheral area.	• The image capturing unit may be shifted from the patient's eye. Reflected light at the top: Move the image capturing unit up. Reflected light at the bottom: Move the image capturing unit down. Reflected light on the right: Move the image capturing unit to the right. Reflected light on the left: Move the image capturing unit to the left. 
White reflected light is at the bottom.	• The patient's eyelid may be nearly closed. Ask the patient to open their eyes wider. If the patient cannot open their eyes wider, lift the patient's lid, paying attention not to press against the eyeballs. • The patient may have blinked at the time of image capture. Capture the image quickly while having the patient refrain from blinking. 
There is a circular or linear white blurry portion in the image.	• The patient's eyelashes may be interfering with the required pupil diameter mark. Ask the patient to open their eyes wider. If the patient cannot open their eyes wider, lift the patient's lid, paying attention not to press against the eyeballs. • The amount of the patient's tear may be excessive. Wipe off the tear before image capture. 
Peripheral area of the image is blurred in white.	• The image capturing unit is too close or too far from the patient's eye. Adjust the alignment and focus so that the working distance indicator becomes the optimum condition (−◎−), or the optical working dots become clear. 

Symptom	Cause and remedy
Center of the image is white. The entire image is white.	• The objective lens may be contaminated. *"4.6.2 Cleaning the objective lens" (page 156)* 
A black shadow is around the center of the image.	• A black shadow may appear with eyes with severe myopia. The appearance of the black shadow is a phenomenon that typically occurs in the optical system of the fundus camera. It appears around the center of the image. Therefore, shift the fixation position so that the black shadow does not interfere with the portion of the eye intended for image capture.  

3.2.4 Image confirmation

With RS-330 Capture, the thumbnails in the Release Data tab can be enlarged. Images can be confirmed before saving them.

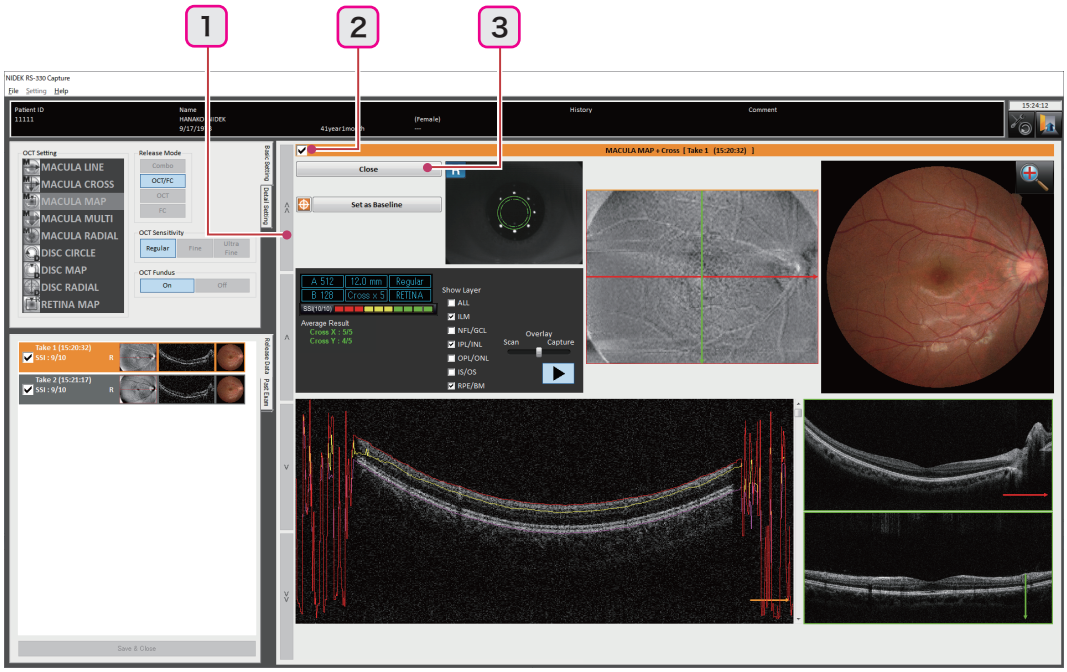
1 Double-click the desired thumbnail in the Release Data tab.



The enlarged view of the selected image is displayed.

2 Check the image.

While the enlarged view is displayed, the system main body cannot be operated.



For the button and icons that are not explained below, see *"2.4.2 Image confirmation screen" (page 47)*.

1 Patient select button

Used to select the image to be enlarged.

<<	First image
<	Previous image
>	Next image
>>	Last image

2 Check box

Used to allow saving of the captured images to the database.

The check box is linked with the one in the Release Data tab.

3 Close button [Close]

Used to close the enlarged view.

3.2.5 Finishing image capture

○ Normal finishing of image capture

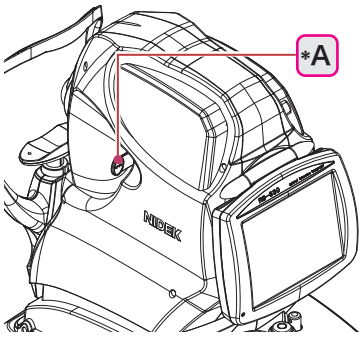
1 Close RS-330 Capture and NAVIS-EX.

2 Shut down Windows.

After a while, power to the computer is turned off.

3 Turn off power to the computer peripheral devices.

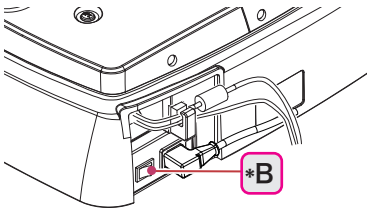
4 Push the compensation lens select lever (*A) to the deepest position (0 position).



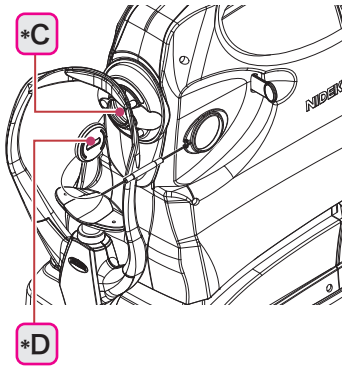
5 Turn off (◯) the power switch (*B) of the system main body.

Power can be turned off regardless of the displayed screen.

6 Turn off (◯) power to the isolation transformer.



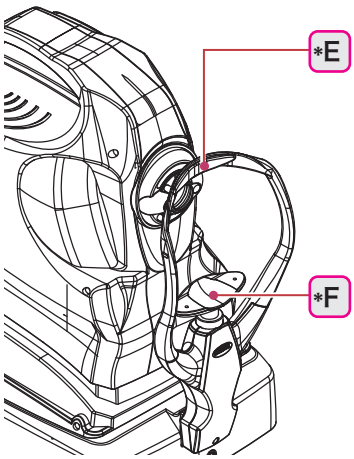
7 Place the objective lens cap (*D) on the objective lens (*C).



8 Clean the forehead rest (*E) and chinrest (*F), then place the dust cover on the system main body.

Use clean gauze or absorbent cotton dampened with rubbing alcohol for cleaning.

Keep the system clean for the next use.



Note

- Be sure to always place the objective lens cap and dust cover on the system when the system is not used.

○ Finishing image capture before moving the system to a different room

To move the system to another room or such, securely lock the main unit by rotating the locking knob to the LOCK side (counterclockwise).

1 Close RS-330 Capture and NAVIS-EX.

2 Shut down Windows.

3 Turn off power to the computer peripheral devices.

4 Push the compensation lens select lever to the deepest position (0 position).

5 Turn off (◯) the power switch of the system main body.

6 Turn off (◯) power to the isolation transformer.

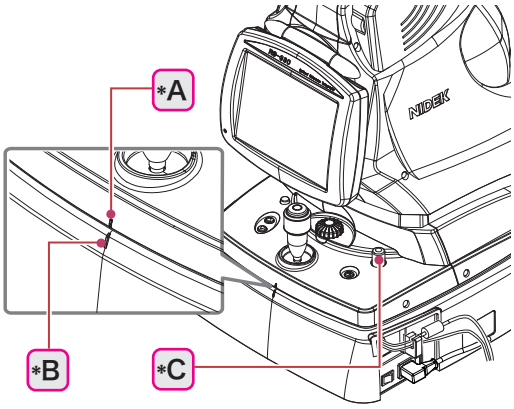
7 Place the objective lens cap on the objective lens.

8 Align the | mark (*A) on the main unit to the | mark (*B) on the base unit.

9 Press and hold the locking knob (*C), then rotate it to the LOCK side (counterclockwise).

The main unit is locked to the base unit.

10 Remove the cables such as the power cord and USB cable.



○ Finishing image capture when the system is transported

To transport the system, set the system to the packing mode. In packing mode, the image capturing unit and chinrest are automatically set to the (lowest) position specified for transport.

⚠ CAUTION

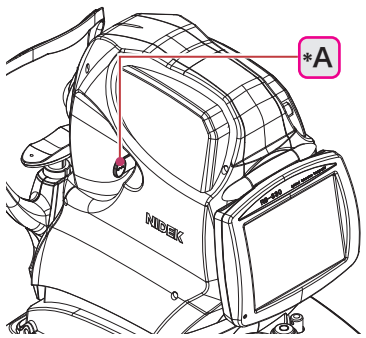
- Never lock the main unit with the locking knob when transporting the system.
  The system main body may get damaged by bumping.

1 Close RS-330 Capture and NAVIS-EX.

2 Shut down Windows.

3 Turn off power to the computer peripheral devices.

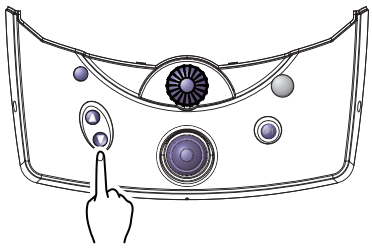
4 Push the compensation lens select lever (*A) to the deepest position (0 position).



5 Turn off (◯) power to the system main body.

6 While pressing and holding the chinrest up/down button (▼), turn on (|) power to the system main body.

Keep holding the chinrest down button (▼) until the message “Please wait...” appears in the touch screen.



Note

- If the compensation lens select lever is not pushed deep enough, a message appears, and the transition to the packing mode is interrupted.

  If the confirmation message appears, pressing the compensation lens select lever to the deepest position resumes the transition to the packing mode.

7 When the message appears, turn off (◯) power to the system main body again.

Make sure that the chinrest and the image capturing unit are at their lowest positions.

8 Turn off (◯) power to the isolation transformer.

9 Place the objective lens cap on the objective lens.

10 Clean the forehead rest and chinrest.

11 Remove the cables such as the power cord and USB cable.

12 Pack the system main body in the packing material that the system was delivered in.

Note

- To cancel the packing mode, turn on power to the system main body again.

  Do not repeatedly turn on and off power to the system main body in short intervals. After turning off the power switch, wait at least 5 seconds before turning it on again.

3.2.6 Manual image capture (Operation mode: Professional)*1

Depending on the status of the patient's eye, automatic image capture may not function. In such a case, images need to be captured manually.

1 Conduct image capture preparation.

"3.2.1 Preparing for image capture" (page 66)

Press the Start/Stop button (Scan Start / Scan Stop) to start the scanning (Scan Start is blue).

Press the Auto/Manual toggle switch (Auto / Manual) to select Manual (Manual).

2 Give instructions to the patient.

"Look into the device. When you see a green blinking lamp, open both of your eyes wide and focus on it. Refrain from blinking as much as possible."

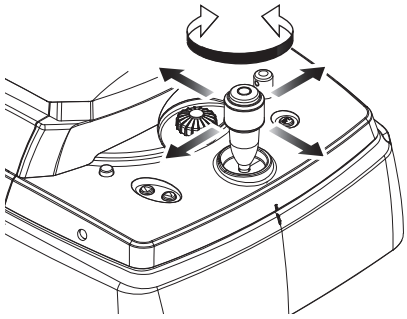
Note

- If eye fixation is difficult for the patient, guide the patient's eye movement with the following instructions:
  "Look straight." "Move your eyes slowly to the right."

3 Display the patient's eye in the touch screen of the system main body.

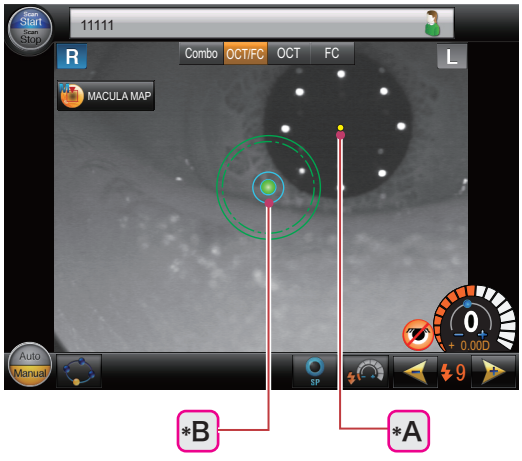
Moving the joystick horizontally moves the main unit horizontally.

Rotating the upper part of the joystick moves the image capturing vertically.



4 Move the main unit and the image capturing unit so that the patient's eye is displayed in the center of the screen, and that the electronic working dot (*A) is displayed.

The appearance of the target mark (*B) changes when the electronic working dot is detected.



*1. The factory-set operation mode is Standard. *"3.2.7 Manual image capture (Operation mode: Standard)" (page 88)*

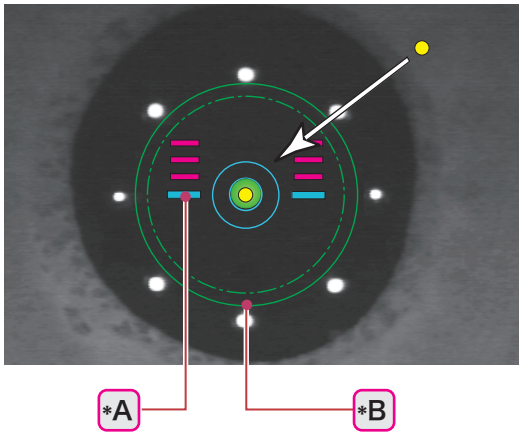
5 Adjust the alignment and focus.

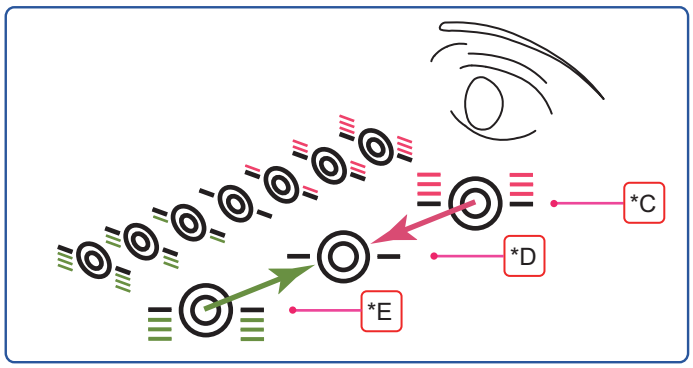
1) Manipulate the joystick to align the electronic working dot to the center of the target mark.

   The working distance indicator (*A) is displayed.

2) While observing the working distance indicator, manipulate the joystick forward and backward to achieve the optimum condition (-◎-).

   When the optimum condition (-◎-) is achieved, the target mark changes from light blue to yellow.





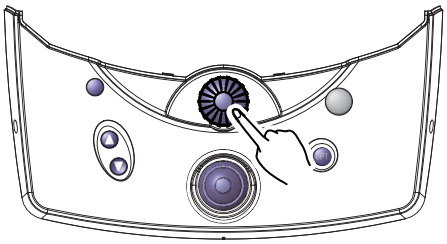
*C	Close to the patient's eye
*D	Optimum condition
*E	Far from the patient's eye

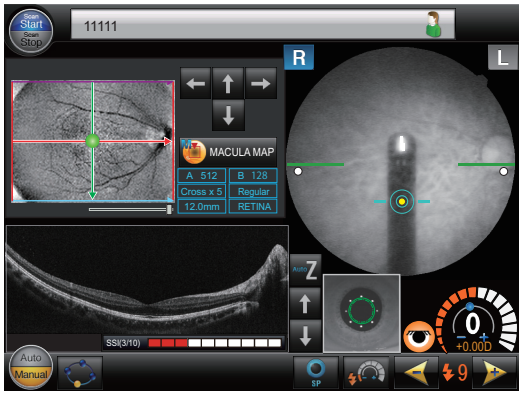
6 Check that the patient's pupil is larger than the required pupil diameter mark ◯ (*B).

If the patient's pupil is smaller than the required pupil diameter mark, proper images cannot be captured.

Perform the procedure in *"3.6.1 Small pupil image capture" (page 117)* or, improve the pupil dilation of the patient.

7 Press the eye front / fundus observation toggle switch to display the fundus observation screen.

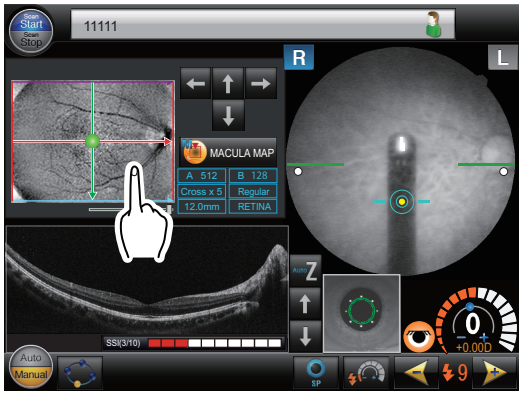




8 To capture images of other parts, press the OCT Phase Fundus image to move the internal fixation lamp.

If the alignment and focus become shifted, adjust them again.

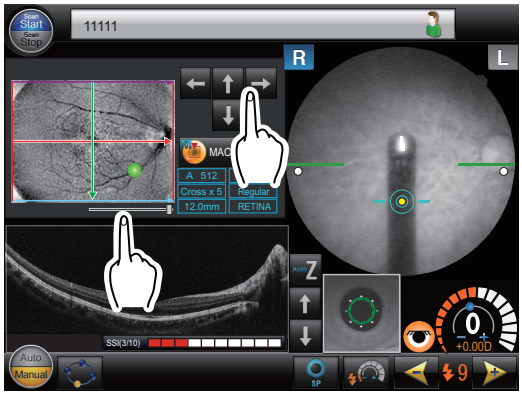
(Step 5)



Note

- The internal fixation lamp cannot be used when “RETINA MAP” is selected.

9 Press the scan line operation button or move the slider to move the scan line or change its shape.

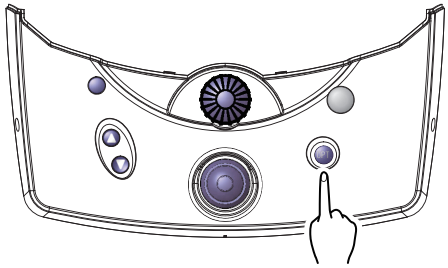


Note

- The scan line cannot extend out of the OCT Phase Fundus image.
- The slider cannot be used when “DISC CIRCLE” or “RETINA MAP” is selected.

10 Optimize the image.

Optimize the focus, Z position, and polarization of the image.

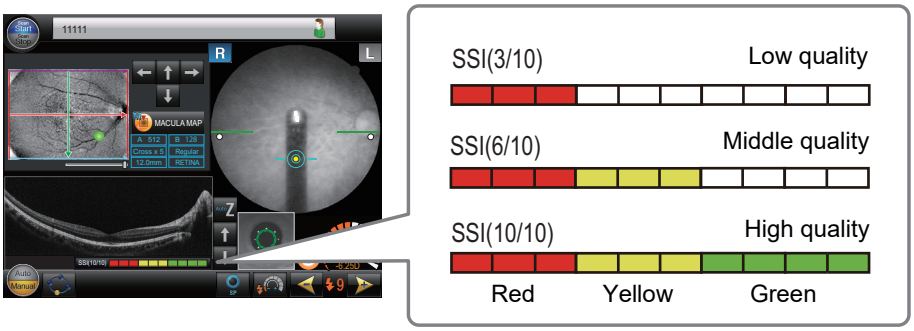


1) Press the OPT. button.

   The image becomes optimized.

2) Check the SSI.

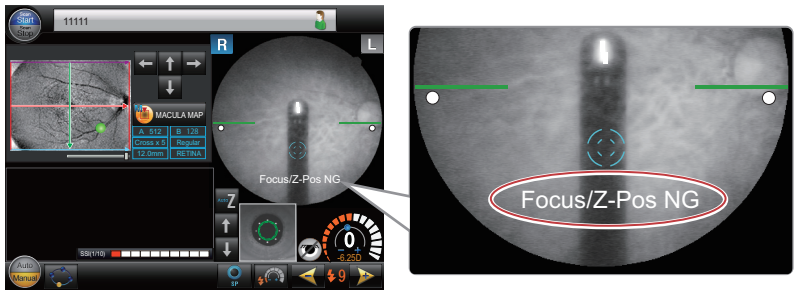
   As the SSI becomes higher, a finer image can be obtained.



The optimization may be interrupted due to improper alignment or focus, or opacity of the patient's eye. If the image capture is interrupted, the interruption is indicated in the screen as shown below.

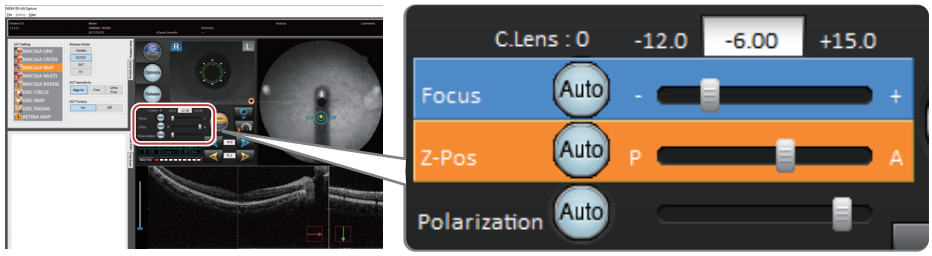
- System main body

  From the focus and Z position, the interrupted item is indicated as “NG” (no good).



- RS-330 Capture

  From the focus, Z position, and polarization, the interrupted item is colored.

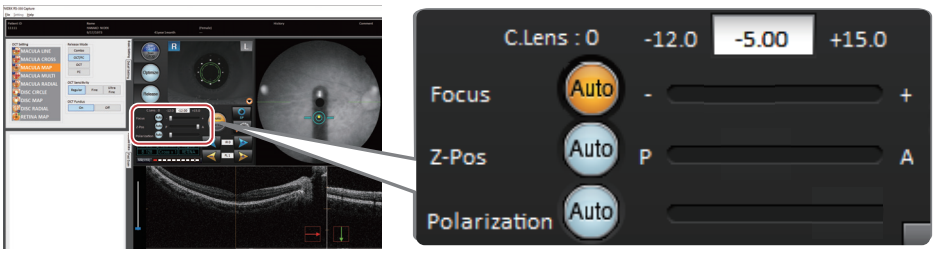


3) If the SSI is low, or the optimization is interrupted, individually adjust the focus, Z position, and polarization.

   There are two methods for the adjustment.

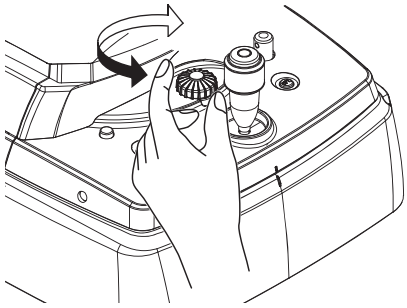
- Operation on RS-330 Capture:

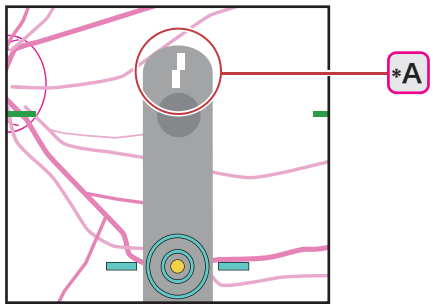
  Clicking the Auto button (Auto) of each item changes it to orange and automatically optimizes the image. The items can also be manually adjusted using the sliders.



- Operation on the system main body:
  - Focus adjustment:

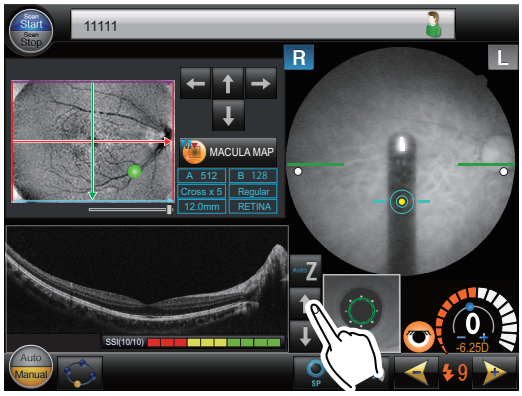
    Rotate the focus knob to align the upper and lower bars of the focus split (*A).





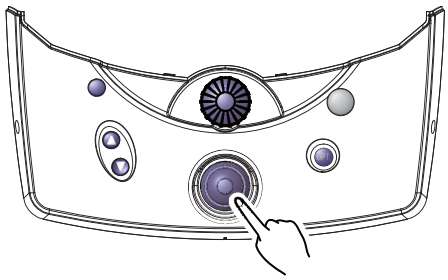
- Z-Pos (Z position) adjustment:

  Press the Auto Z , ↑ , and ↓ buttons to adjust the Z position (vertical position in the screen) of the OCT image.



11 Press the release button to capture the image.

In OCT/FC release mode OCT/FC, images are captured in the order of OCT image capture and color fundus image capture.



Note

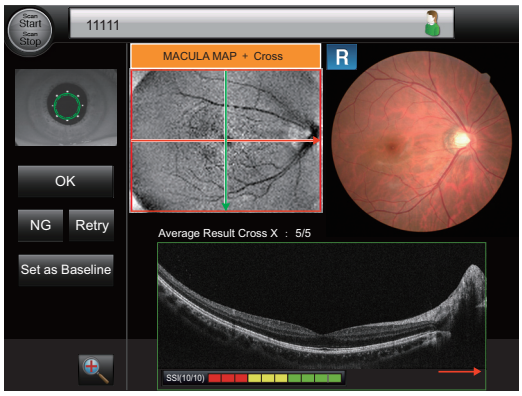
- If the patient's eyelid is detected, the pupil diameter is not large enough, or extraneous light (noise) or such is detected, images may not be captured properly.

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

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

12 Check the captured images and save them.

"3.2.2 Automatic image capture" (page 71) (Step 5) to *(Step 8)*



3.2.7 Manual image capture (Operation mode: Standard)*1

Depending on the status of the patient's eye, automatic image capture may not function. In such a case, images need to be captured manually.

1 Conduct image capture preparation.

"3.2.1 Preparing for image capture" (page 66)

Press the Start/Stop button (Scan Start / Scan Stop) to start the scanning (Scan Start is blue).

Press the Auto/Manual toggle switch (Auto / Manual) to select Manual (Manual).

2 Give instructions to the patient.

"Look into the device. When you see a green blinking lamp, open both of your eyes wide and focus on it. Refrain from blinking as much as possible."

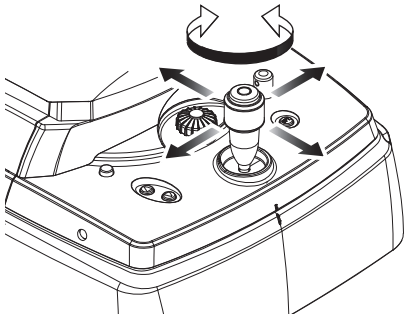
Note

- If eye fixation is difficult for the patient, guide the patient's eye movement with the following instructions:
  "Look straight." "Move your eyes slowly to the right."

3 Display the patient's eye in the touch screen of the system main body.

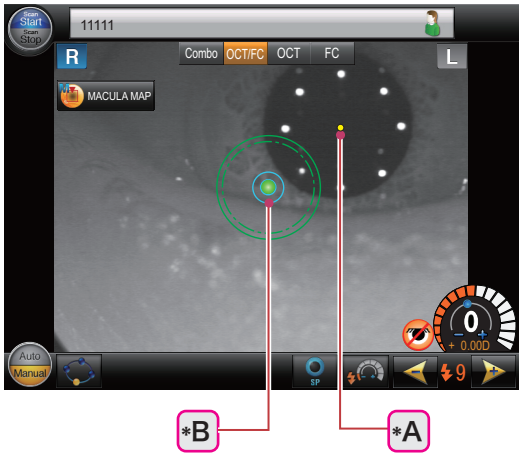
Moving the joystick horizontally moves the main unit horizontally.

Rotating the upper part of the joystick moves the image capturing vertically.



4 Move the main unit and the image capturing unit so that the patient's eye is displayed in the center of the screen, and that the electronic working dot (*A) is displayed.

The appearance of the target mark (*B) changes when the electronic working dot is detected. →



*1. Factory setting. The standard mode offers a simple screen configuration more specialized in screening than the Professional operation mode, without items such as the OCT Phase Fundus image, scan line, and Z position adjustment button.

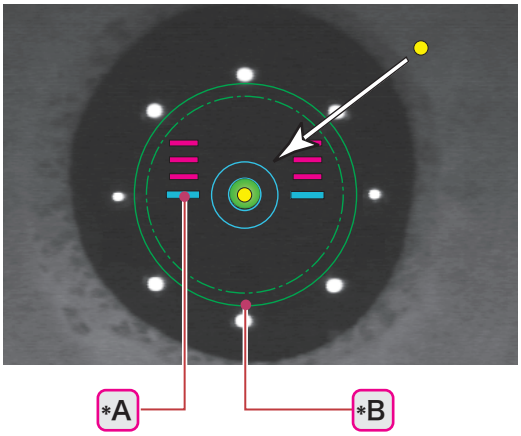
5 Adjust the alignment and focus.

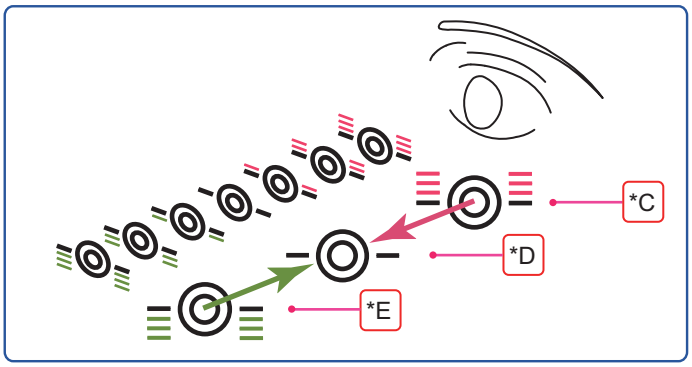
1) Manipulate the joystick to align the electronic working dot to the center of the target mark.

   The working distance indicator (*A) is displayed.

2) While observing the working distance indicator, manipulate the joystick forward and backward to achieve the optimum condition (-◎-).

   When the optimum condition (-◎-) is achieved, the target mark changes from light blue to yellow.





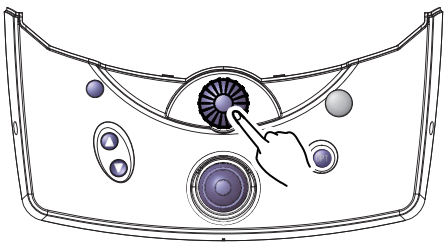
*C	Close to the patient's eye
*D	Optimum condition
*E	Far from the patient's eye

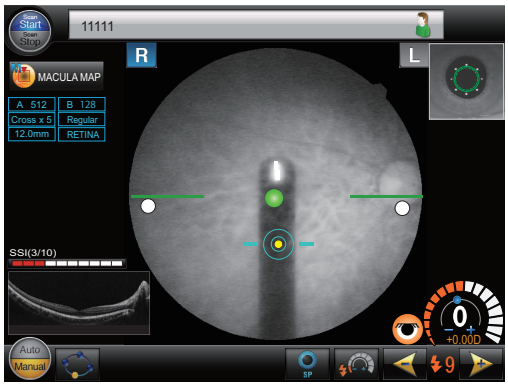
6 Check that the patient's pupil is larger than the required pupil diameter mark ◯ (*B).

If the patient's pupil is smaller than the required pupil diameter mark, proper images cannot be captured.

Perform the procedure in *"3.6.1 Small pupil image capture" (page 117)* or, improve the pupil dilation of the patient.

7 Press the eye front / fundus observation toggle switch to display the fundus observation screen.

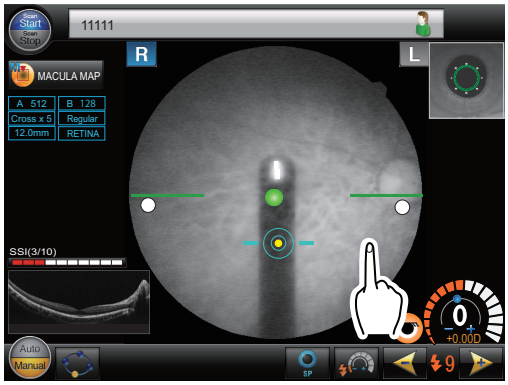




8 To capture images of other parts, press the fundus image to move the internal fixation lamp.

If the alignment and focus become shifted, adjust them again.

(Step 5)

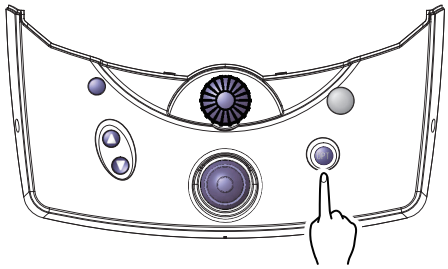


Note

- The internal fixation lamp cannot be used when “RETINA MAP” is selected.

9 Optimize the image.

Optimize the focus, Z position, and polarization of the image.

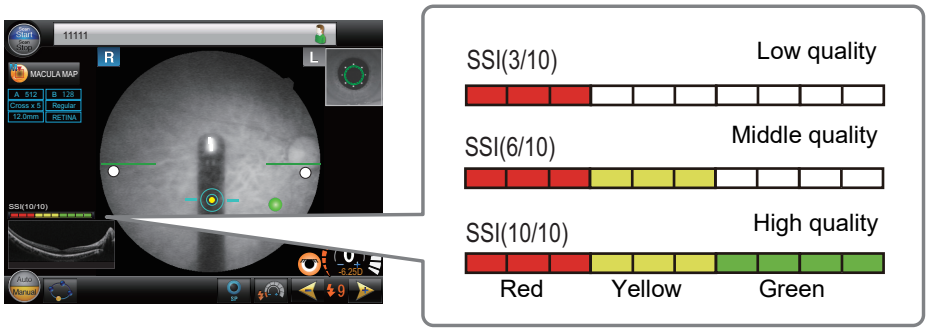


1) Press the OPT. button.

   The image becomes optimized.

2) Check the SSI.

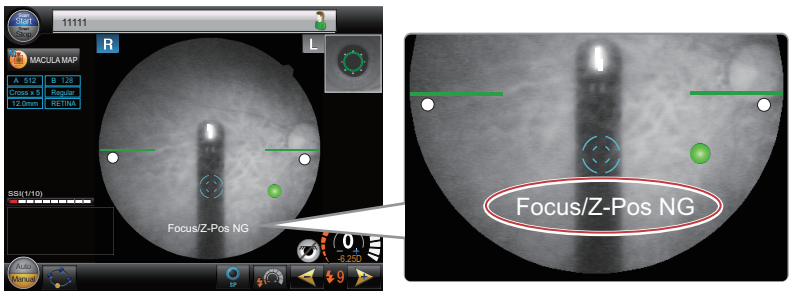
   As the SSI becomes higher, a finer image can be obtained.



The optimization may be interrupted due to improper alignment or focus, or opacity of the patient's eye. If the image capture is interrupted, the interruption is indicated in the screen as shown below.

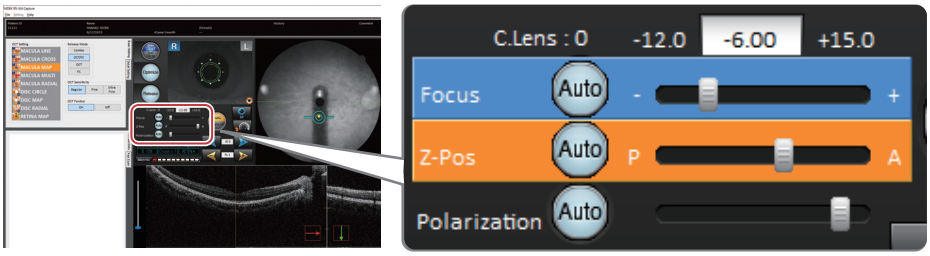
- System main body

  From the focus and Z position, the interrupted item is indicated as “NG” (no good).



- RS-330 Capture

  From the focus and Z position, the interrupted item is colored.

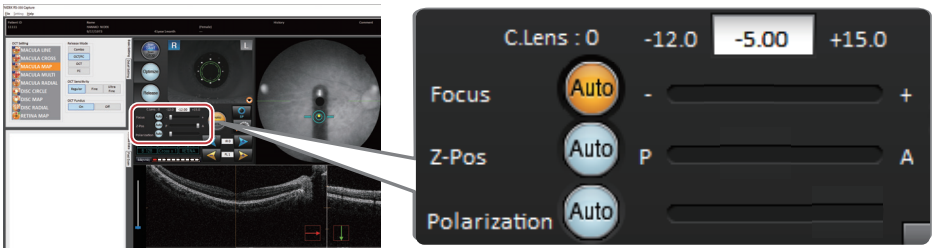


3) If the SSI is low, or the optimization is interrupted, individually adjust the focus, Z position, and polarization.

   There are two methods for the adjustment.

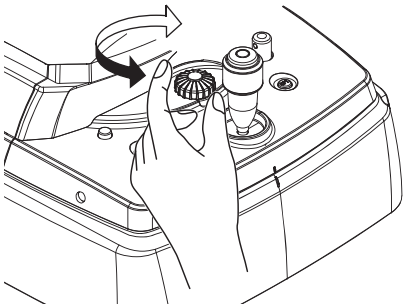
- Operation on RS-330 Capture:

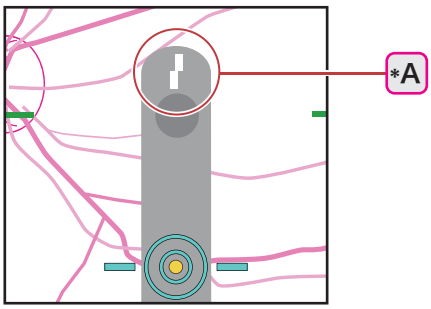
  Clicking the Auto button (Auto) of each item changes it to orange and automatically optimizes the image. The items can also be manually adjusted using the sliders.



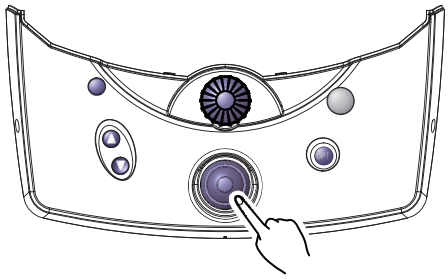
- Operation on the system main body:
  - Focus adjustment:

    Rotate the focus knob to align the upper and lower bars of the focus split (*A).





10 Press the release button to capture the image.



In OCT/FC release mode OCT/FC, images are captured in the order of OCT image capture and color fundus image capture.

Note

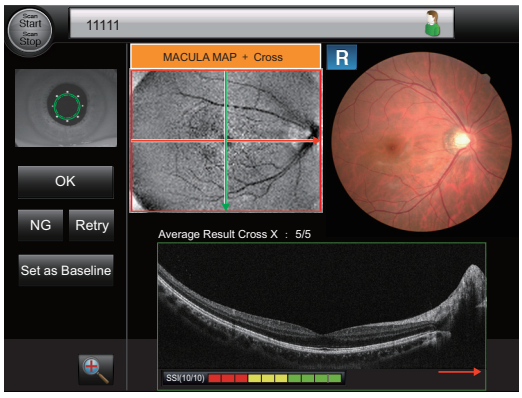
- If the patient's eyelid is detected, the pupil diameter is not large enough, or extraneous light (noise) or such is detected, images may not be captured properly.

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

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

11 Check the captured images and save them.

"3.2.2 Automatic image capture" (page 71) (Step 5) to *(Step 8)*



3.3 OCT Release Mode

■ In OCT release mode, only OCT images are captured. For the button and icons that are not explained below, see *"2.3.1 Eye front observation screen" (page 21)*.

1 Image capture type button (only when the anterior segment adapter (optional) has been set)

Used to select the desired image capture type. The selected button is shown in orange.

Retinal cross-sectional image capture	OCT images of the retina can be captured.
Anterior segment cross-sectional image capture	OCT image capture of the anterior segment with the anterior segment adapter (optional) attached to the system main body

2 Icon

They are used in FC release mode, and cannot be used in OCT release mode OCT .

3.3.1 Retinal cross-sectional image capture

The image capture procedure is the same as that in OCT/FC release mode OCT/FC except the steps described below.

“3.2.2 Automatic image capture” (page 71)

“3.2.6 Manual image capture (Operation mode: Professional)” (page 83)

“3.2.7 Manual image capture (Operation mode: Standard)” (page 88)

1 Conduct image capture preparation.

“3.2.1 Preparing for image capture” (page 66)

Press the release mode select button OCT .

When the anterior segment adapter (optional) has been set, select the image capture type button for retinal cross-sectional image capture .

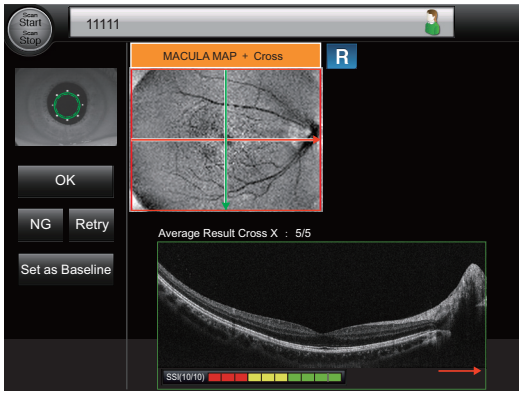
2 Capture images.

“3.2.2 Automatic image capture” (page 71)

“3.2.6 Manual image capture (Operation mode: Professional)” (page 83)

“3.2.7 Manual image capture (Operation mode: Standard)” (page 88)

In OCT release mode OCT , color fundus images are not captured or displayed on the image confirmation screen.

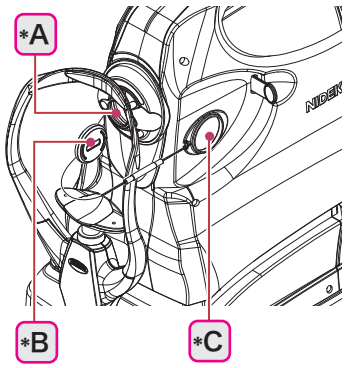


3.3.2 Anterior segment cross-sectional image capture (optional)

By attaching the anterior segment adapter (optional) and the spacer for anterior segment image capture to the system main body, eye front images, and OCT images of the anterior segment such as the cornea and the anterior chamber angle can be captured.

Only manual image capture is available to capture anterior segment cross-sectional images. In addition, the internal fixation lamp and scan line cannot be moved.

○ Preparing for anterior segment cross-sectional image capture



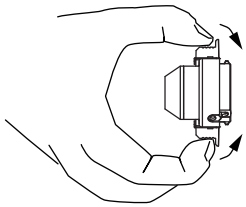
1 Attach the anterior segment adapter (optional) to the system main body

1) Remove the objective lens cap (*B) from the objective lens (*A).

   Attach the removed objective lens cap to the cap holder (*C).

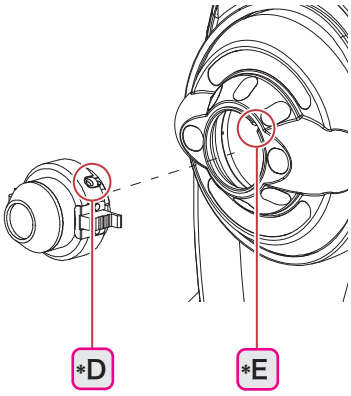
2) Check that the lens surface of the anterior segment adapter is clean.

3) Press and hold the fasteners of the anterior segment adapter with fingers.



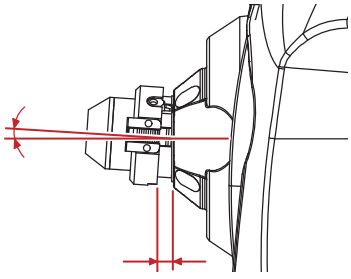
4) Align the pin (*D) of the anterior segment adapter with the notch (*E) of the objective lens, then attach the anterior segment adapter.

   Hold the anterior segment adapter with both hands when attaching or removing it to ensure against dropping it.

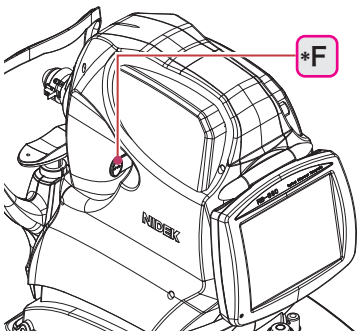


5) Check that the anterior segment adapter is attached straight to the objective lens.

   Check that the anterior segment adapter is not angled or that there is no large gap in the attached part.



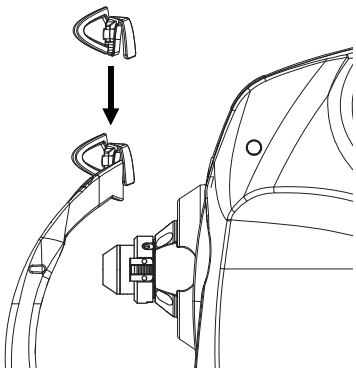
2 Push the compensation lens select lever (*F) to the deepest position (0 position).



3 Attach the spacer for anterior segment image capture.

1) Wipe the spacer with a clean cotton swab or gauze dampened with rubbing alcohol.

2) Attach the spacer to the forehead rest of the system main body.



4 Conduct image capture preparation. *"3.2.1 Preparing for image capture" (page 66)*

⚠ CAUTION

- Be careful so that the patient does not come into contact with the anterior segment adapter when they place their chin on the chinrest.

  The anterior segment adapter may come into contact with the face or eyes of the patient.

○ Anterior segment cross-sectional image capture

⚠ CAUTION

- During the anterior segment cross-sectional image capture, pull the joystick toward the operator before adjusting the alignment and focus, or switching the eye to prevent the anterior segment adapter from coming into contact with the patient's face or eyes.

  The anterior segment adapter may come into contact with the face or eyes of the patient.

- To capture anterior segment cross-sectional images, be sure to attach the spacer for anterior segment image capture in addition to the anterior segment adapter.

  Without the spacer, sufficient working distance cannot be secured, and image capture becomes difficult.

1 Conduct image capture preparation.

"○ Preparing for anterior segment cross-sectional image capture" (page 95)

Press the release mode select button OCT, then the image capture type button for anterior segment cross-sectional image capture .

Note

- The Auto/Manual toggle switch (Auto / Manual) cannot be operated.

  Only manual image capture is available to capture anterior segment cross-sectional images.

- The target mark is not displayed.

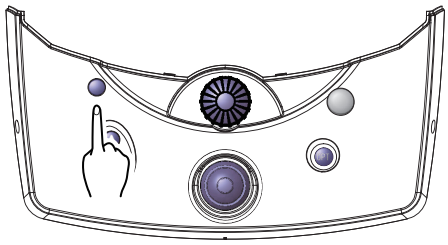
2 Set the distance between the anterior segment adapter and the patient's eye using the safety stopper.

⚠ WARNING

- Be sure to set the safety stopper before the anterior segment cross-sectional image capture.

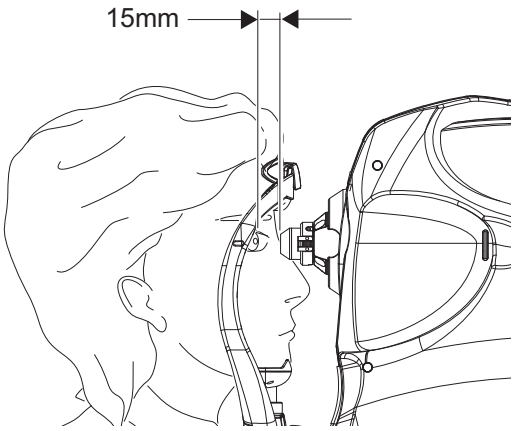
  The anterior segment adapter may come into contact with the patient's eye and damage the cornea.

1) Press and hold the safety stopper. Then manipulate the joystick to slowly move the anterior segment adapter toward the patient's eye.



2) Observe the distance between the anterior segment adapter and the patient's eye from the side of the system main body. When the distance becomes about 15 mm, release the safety stopper.

3) Lightly move the joystick forward and backward to confirm that the anterior segment adapter *(Step 2))* cannot be moved to the patient side beyond the limit set with the safety stopper.



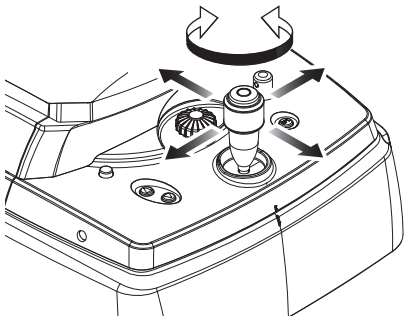
3 Give instructions to the patient.

"Look into the device. When you see a green blinking lamp, open both of your eyes wide and focus on it. Refrain from blinking as much as possible."

4 Display the patient's eye in the touch screen of the system main body.

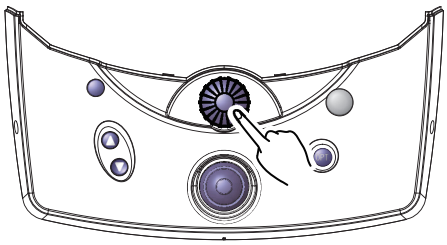
Moving the joystick horizontally moves the main unit horizontally.

Rotating the upper part of the joystick moves the image capturing vertically.



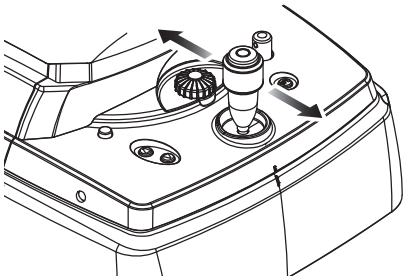
5 Press the eye front / fundus observation toggle switch to display the observation screen.

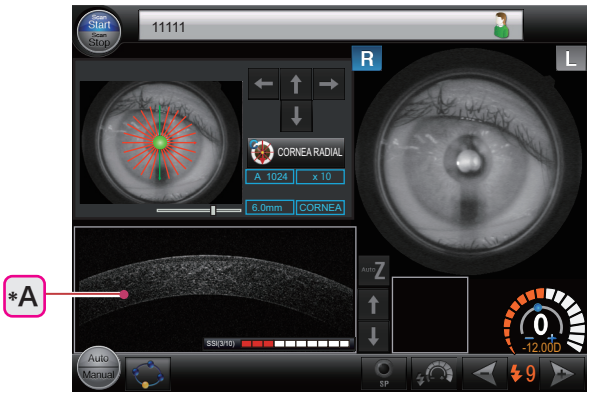
In the anterior segment cross-sectional image capture, the anterior segment observation screen is displayed.



6 Optimize the image.

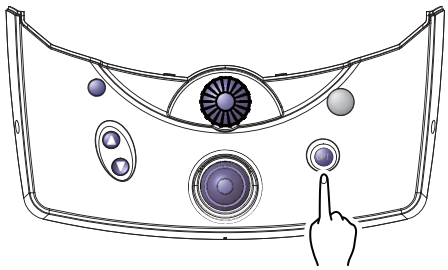
1) Manipulate the joystick forward and backward to display the OCT image (*A).





2) Press the OPT. button to optimize the image.

Only the polarization is optimized in the anterior segment cross-sectional image capture. The focus and Z position are not adjusted.



7 If necessary, move the slider to change the scan line width.

The positions of the internal fixation lamp and the scan line cannot be moved in the anterior segment cross-sectional image capture.

Note

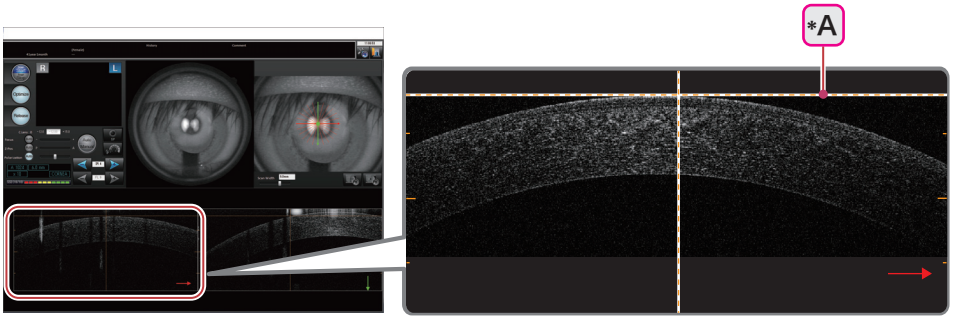
- For the scan line of the Cornea Line and ACA line, the width and angle can be changed.

8 Adjust the intended part to the adjustment target line.

Perform the operation while checking RS-330 Capture. The operation differs depending on the OCT setting.

- Cornea Line, Cornea Cross, Cornea Radial

  Manipulate the joystick forward and backward so that the top of the OCT image (corneal surface) is in contact with the adjustment target line (*A).

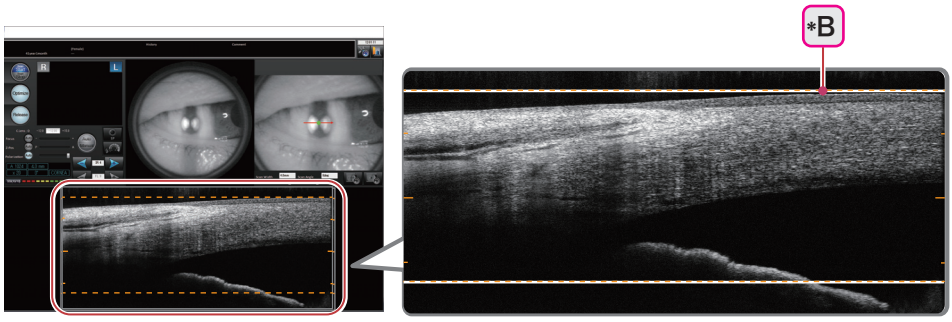


- ACA Line

  For the anterior chamber angle image capture, two adjustment target lines are provided. Adjust the cornea to the upper line, or the iris to the lower line.

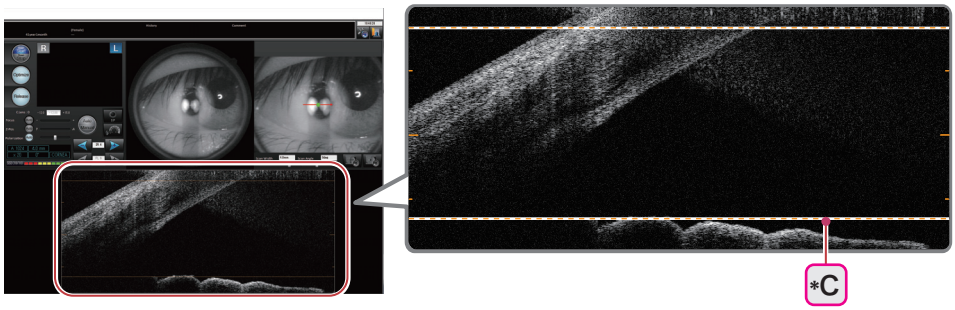
  - Adjusting the cornea to the upper adjustment target line (*B)

    Give the patient instructions to guide their eye so that the corneal surface comes in contact with the upper adjustment target line.



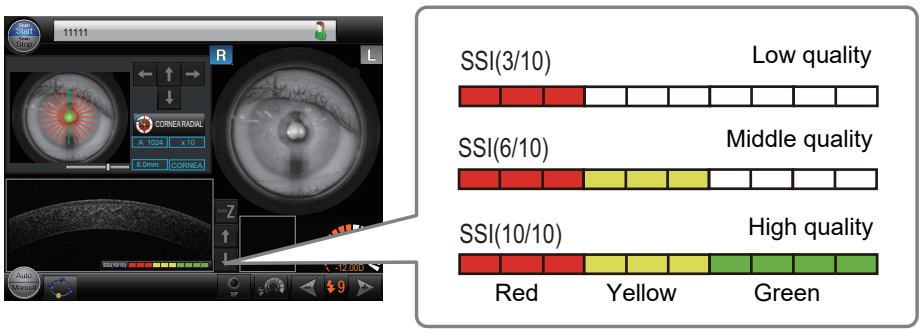
  - Adjusting the iris to the lower adjustment target line (*C)

    Instruct the patient to look forward. Then manipulate the joystick so that the iris comes in contact with the lower adjustment target line.

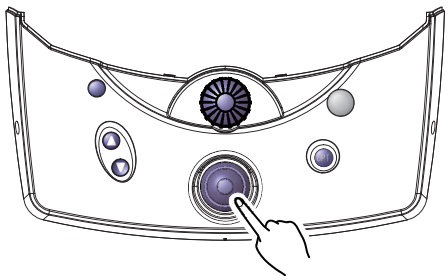


9 Check the SSI.

As the SSI becomes higher, a finer image can be obtained.

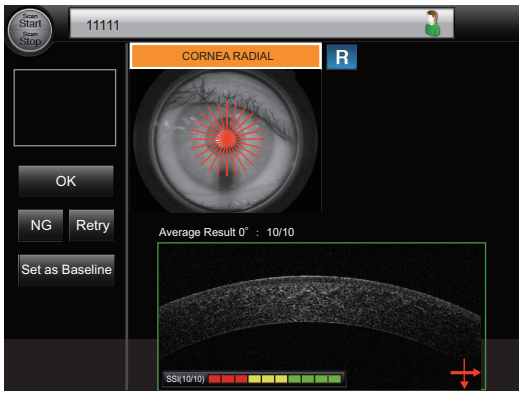


10 Press the release button to capture the image.



11 Check the captured images and save them.

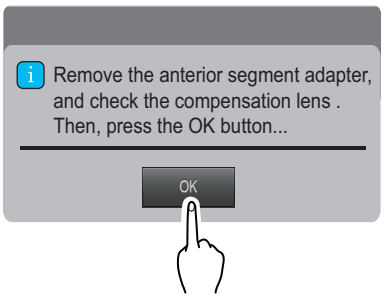
"3.2.2 Automatic image capture" (page 71) (Step 5) to (Step 8)



○ Finishing anterior segment cross-sectional image capture

After the anterior segment cross-sectional image capture, switching to another image capture mode displays the message shown to the right.

Remove the anterior segment adapter from the main body, check the position of the compensation lens, then press the OK button.



⚠ CAUTION

- After the anterior segment cross-sectional image capture, be sure to remove the anterior segment adapter and the spacer for anterior segment image capture.

  The anterior segment adapter may come into contact with the patient's face or eye.

3.4 FC Release Mode

■ In FC release mode, only color fundus images are captured. For the button and icons that are not explained below, see *"2.3.1 Eye front observation screen" (page 21)*.

1 Start/Stop button 

It is used only in OCT release mode, and cannot be used in FC release mode FC .

2 Image capture type select buttons (only for FC release mode FC)

Used to select the desired image capture type. The selected button is shown in orange.

Standard image capture	Color images of the fundus can be captured.
Stereo image capture	Images of the same fundus are captured from two different positions: one from the temporal side and the other from the nasal side. The two captured images are saved in pairs. With the stereo viewer (optional function of NAVIS-EX), the two images offer a stereoscopic view of the image.
Panorama image capture	Images of multiple positions of the fundus are captured as specified with two to nine internal fixation lamps in the preset order. With NAVIS-EX, a pseudo-wide-range fundus image (panorama image) can be composed by arranging multiple fundus images of different positions.
Eye front image capture	Color images of the eye front can be captured.

3 Image capture position select button (for stereo image capture)

Select the positions for stereo image capture. The selected button is shown in orange. The TEMPORAL button is for the temporal side, and the NASAL button is for the nasal side. For the left eye, the positions of the TEMPORAL button and the NASAL button are interchanged.

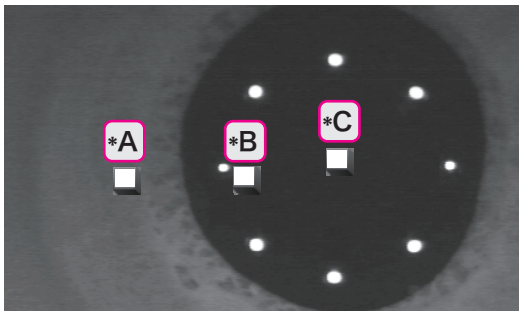
4 Image capture number buttons 1 to 9 (for panorama image capture)

The numbers show the positions of the internal fixation lamps for the panorama image capture. When an image is captured, the internal fixation lamp of the next number illuminates. The internal fixation lamps can also be illuminated at the desired position regardless of the order by pressing the desired image capture number button. For the panorama image capture, the internal fixation lamps can only be illuminated at the positions of the image capture number buttons. With the factory setting, 1 to 7 are displayed.

5 Image capture target icon (only for standard , stereo , and eye front image capture)

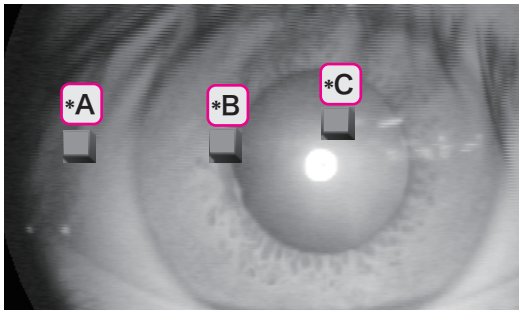
- Standard and stereo image capture

The icons show the optimum internal fixation lamp positions for image capture of the macula, the optic disc, and the intermediate area between the macula and the optic disc. The figure is an example of the right eye. For the left eye, the icon positions are horizontally flipped.



*A	Optic disc
*B	Intermediate area between the macula and optic disc Initial position of the Internal fixation lamp
*C	Macula

- Eye front image capture



*A	Guideline for eye fixation
*B	Guideline for eye fixation
*C	Initial position of the Internal fixation lamp

3.4.1 Standard image capture

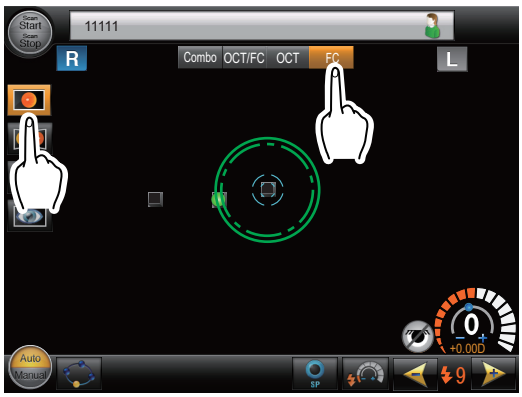
The image capture procedure is the same as that in OCT/FC release mode OCT/FC except the steps described below.

“3.2.2 Automatic image capture” (page 71)
“3.2.6 Manual image capture (Operation mode: Professional)” (page 83)
“3.2.7 Manual image capture (Operation mode: Standard)” (page 88)

1 Conduct image capture preparation.

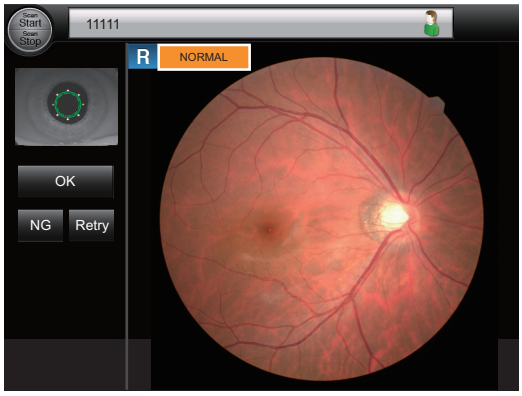
“3.2.1 Preparing for image capture” (page 66)

Press the release mode select button FC, then the standard image capture button .



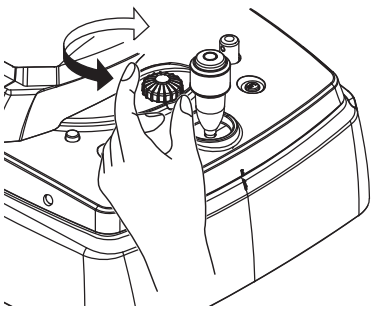
2 Capture images.

“3.2.2 Automatic image capture” (page 71)
“3.2.6 Manual image capture (Operation mode: Professional)” (page 83)
“3.2.7 Manual image capture (Operation mode: Standard)” (page 88)



Note

- FC release mode FC differs from OCT/FC release mode OCT/FC in the points described below.
  - The Start/Stop button and the OPT. button cannot be operated. To optimize images in manual operation, the focus knob is used.
  - The scan line, SSI, image averaging result, and the “Set as Baseline” button Set as Baseline are not displayed.
  - The operation mode (Professional Professional and Standard Standard) cannot be changed.



3.4.2 Stereo image capture

Images of the same fundus are captured from two different positions: one from the temporal side and the other from the nasal side.

The image capture procedure is the same as that in OCT/FC release mode OCT/FC except the steps described below.

"3.2.2 Automatic image capture" (page 71)

"3.2.6 Manual image capture (Operation mode: Professional)" (page 83)

"3.2.7 Manual image capture (Operation mode: Standard)" (page 88)

1 Conduct image capture preparation.

"3.2.1 Preparing for image capture" (page 66)

Press the release mode select button FC, then the stereo image capture button .

2 Give instructions to the patient.

"Look into the device. When you see a green blinking lamp, open both of your eyes wide and focus on it. Refrain from blinking as much as possible."

3 Display the patient's eye in the touch screen of the system main body.

Moving the joystick horizontally moves the main unit horizontally.

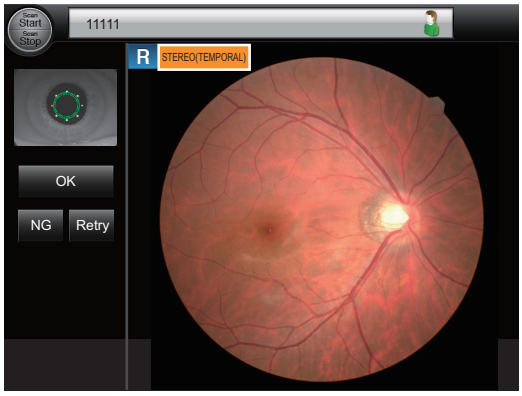
Rotating the upper part of the joystick moves the image capturing vertically.

4 Move the main unit and the image capturing unit so that the patient's eye is displayed around the center of the touch screen to display the light blue electronic working dot (*A).

Displaying the electronic working dot automatically optimizes alignment, and focusing. After that, a temporal-side image is captured.

5 Check the captured image.

6 Click the desired button from OK, NG, and Retry.



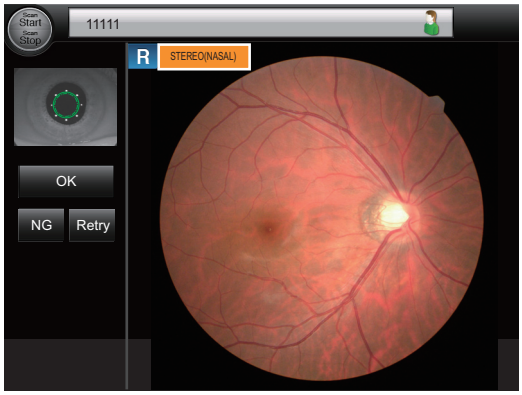
7 Press the OK button to display the purple electronic working dot (*B).

Displaying the electronic working dot automatically optimizes alignment, and focusing. After that, a nasal-side image is captured.

8 Check the captured images and save them.

“3.2.2 Automatic image capture” (page 71) (Step 5) to (Step 8)

The SSI, image averaging result, and the “Set as Baseline” button Set as Baseline are not displayed.



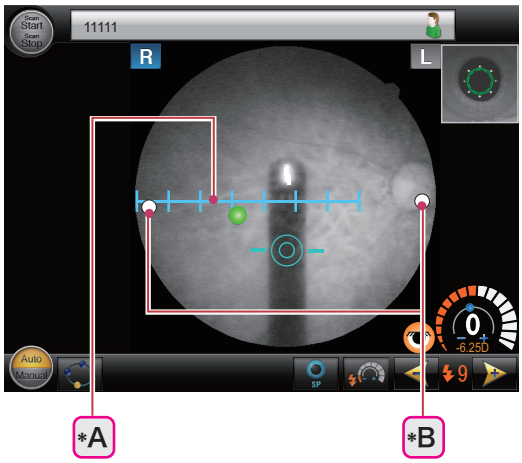
Note

- Pressing the image capture position select button (NASAL) NASAL allows image capture of the nasal side before the temporal side.

○ Using stereo gauge

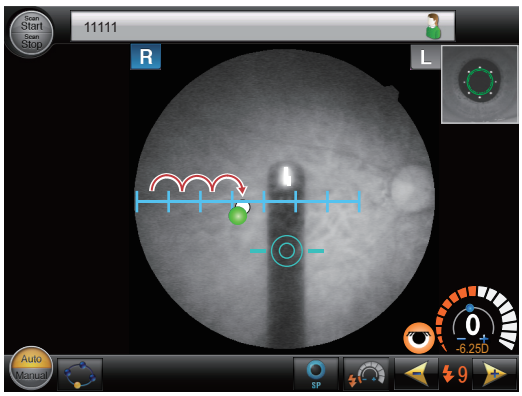
A stereo gauge (*A) is displayed in the fundus observation screen for stereo image capture. It is used as a guideline for alignment when the electronic working dot cannot be displayed.

1 Align the two optical working dots (*B) symmetrically to the stereo gauge.



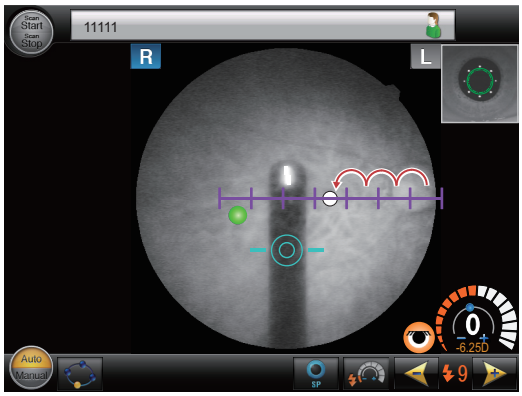
2 To capture a temporal side image of the right eye, shift the left optical working dot by three positions to the right on the scale.

To capture a temporal side image of the left eye, shift the right optical working dot by three positions to the left on the scale.



3 To capture a nasal side image of the right eye, shift the right optical working dot by three positions to the left on the scale.

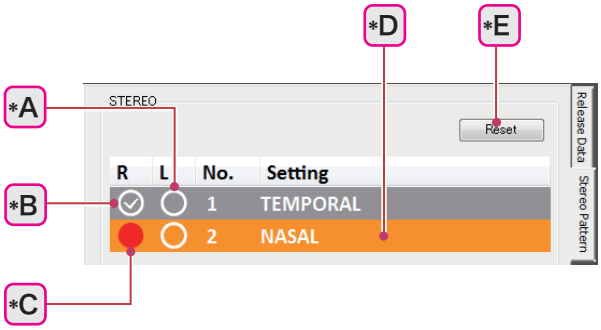
To capture a nasal side image of the left eye, shift the left optical working dot by three positions to the right on the scale.



○ Stereo image capture pattern tab

When the stereo image capture is started, the stereo image capture pattern tab is displayed in RS-330 Capture.

When an image is captured, the image capture advances to the next one. However, the desired image capture can be selected regardless of the preset order by clicking the desired setting in the tab or changing the eye to be captured using the joystick.



*A	Not captured yet
*B	Finished The image can be captured again.
*C	The image is being captured. (Red circle)
*D	Current setting (orange)
*E	Resetting image capture Images already captured are not discarded.

3.4.3 Panorama image capture

Images of multiple positions of the fundus are captured as specified with two to nine internal fixation lamps in the preset order. With the factory setting, 1 to 7 are displayed.

The image capture procedure is the same as that in OCT/FC release mode OCT/FC except the steps described below.

- *"3.2.2 Automatic image capture" (page 71)*
- *"3.2.6 Manual image capture (Operation mode: Professional)" (page 83)*
- *"3.2.7 Manual image capture (Operation mode: Standard)" (page 88)*

1 Conduct image capture preparation.

"3.2.1 Preparing for image capture" (page 66)

Press the release mode select button FC, then the panorama image capture button .

2 Give instructions to the patient.

"Look into the device. When you see a green blinking lamp, open both of your eyes wide and focus on it. Refrain from blinking as much as possible."

3 Display the patient's eye in the touch screen of the system main body.

Moving the joystick horizontally moves the main unit horizontally.

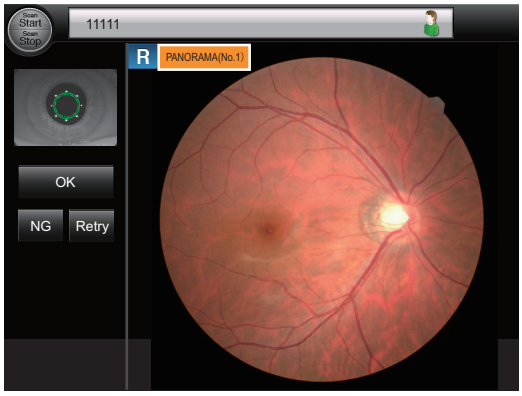
Rotating the upper part of the joystick moves the image capturing vertically.

4 Move the main unit and the image capturing unit so that the patient's eye is displayed in the center of the screen, and that the electronic working dot (*A) is displayed.

Displaying the electronic working dot automatically optimizes alignment, and focusing. After that, images are captured.

5 Check the captured image.

6 Click the desired button from OK, NG, and Retry.



7 Pressing the OK button moves the internal fixation lamp to the next image capture number button (*B).

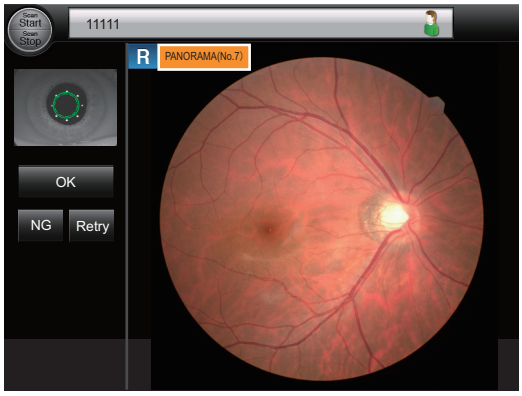
A check mark is placed on the finished image capture number buttons.

8 Repeat *(Step 4)* to *(Step 7)* to capture images at all positions.

9 Check the captured images and save them.

"3.2.2 Automatic image capture" (page 71) (Step 5) to *(Step 8)*

The SSI, image averaging result, and the "Set as Baseline" button Set as Baseline are not displayed.



Note

- Images can be captured at the desired positions by pressing the image capture number buttons 1 to 9 .
- The internal fixation lamps in the panorama image capture can only be illuminated at the positions of the number buttons 1 to 9 .
- When the panorama image capture is started, the panorama image capture pattern tab is displayed in RS-330 Capture. When an image is captured, the image capture advances to the next one. However, the desired image capture can be selected regardless of the preset order by clicking the desired setting in the tab or changing the eye to be captured using the joystick.

  The panorama image capture pattern tab can be operated in the same manner as the stereo image capture pattern tab.

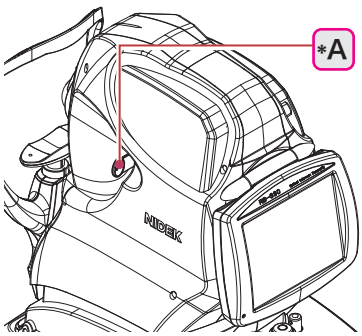
  "O Stereo image capture pattern tab" (page 108)

3.4.4 Eye front image capture

Attaching the spacer for anterior segment image capture to the system main body enables color eye front image capture. Only manual image capture is available to capture eye front images.

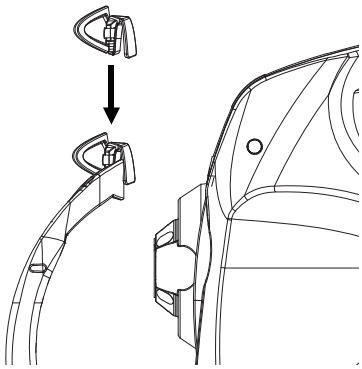
○ Preparing for eye front image capture

1 Pull out the compensation lens select lever (*A) (+ position).



2 Attach the spacer for anterior segment image capture.

1) Wipe the spacer with a clean cotton swab or gauze dampened with rubbing alcohol.
2) Attach the spacer to the forehead rest of the system main body.



3 Conduct image capture preparation.

"3.2.1 Preparing for image capture" (page 66)

○ Eye front image capture

⚠ CAUTION

- To capture eye front images, be sure to attach the spacer for anterior segment image capture.
  Without the spacer, sufficient working distance cannot be secured, and image capture becomes difficult.

1 Conduct image capture preparation.

“O Preparing for eye front image capture” (page 111)

Press the release mode select button FC, then the eye front image capture button .

Note

- The Auto/Manual toggle switch (Auto Manual) cannot be operated.
  Only manual image capture is available to capture eye front images.
- The target mark is not displayed.

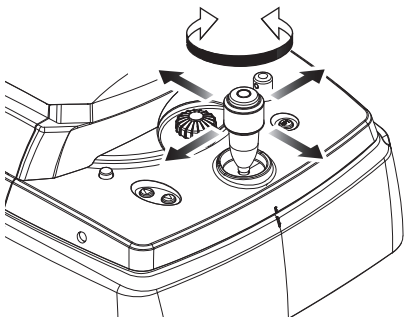
2 Give instructions to the patient.

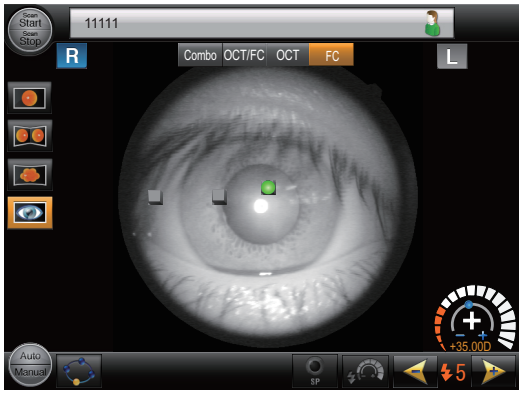
“Look into the device. When you see a green blinking lamp, open both of your eyes wide and focus on it. Refrain from blinking as much as possible.”

3 Display the patient's eye in the touch screen of the system main body.

Moving the joystick horizontally moves the main unit horizontally.

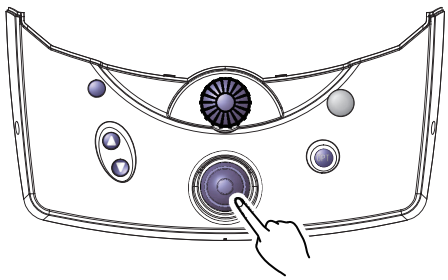
Rotating the upper part of the joystick moves the image capturing vertically.





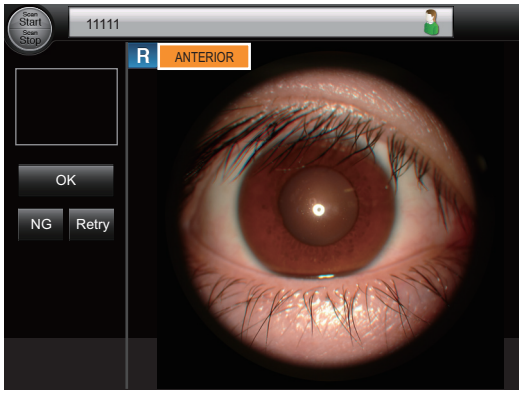
4 Manipulate the joystick forward and backward to display the eye clearly.

5 Press the release button to capture the image.



6 Check the captured images and save them.

“3.2.2 Automatic image capture” (page 71) (Step 5) to (Step 8)



3.5 Combo Image Capture

By setting combinations of various release modes in advance, images can be captured in the desired modes in the preset order without changing the setting.

The image capture procedure is the same as that in OCT/FC release mode OCT/FC except the steps described below.

“3.2.2 Automatic image capture” (page 71)

“3.2.6 Manual image capture (Operation mode: Professional)” (page 83)

“3.2.7 Manual image capture (Operation mode: Standard)” (page 88)

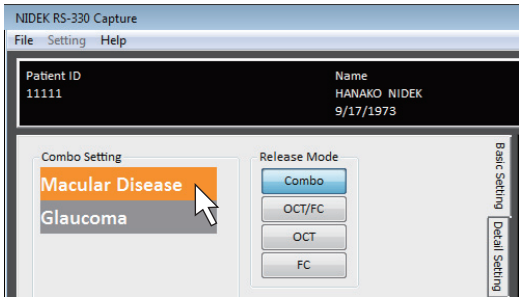
1 Conduct image capture preparation.

“3.2.1 Preparing for image capture” (page 66)

Press the release mode select button Combo .

2 Set the Combo Setting parameter with RS-330 Capture.

In this explanation, “Macular Disease” is selected.



3 Give instructions to the patient.

“Look into the device. When you see a green blinking lamp, open both of your eyes wide and focus on it. Refrain from blinking as much as possible.”

4 Display the patient's eye in the touch screen of the system main body.

Moving the joystick horizontally moves the main unit horizontally.

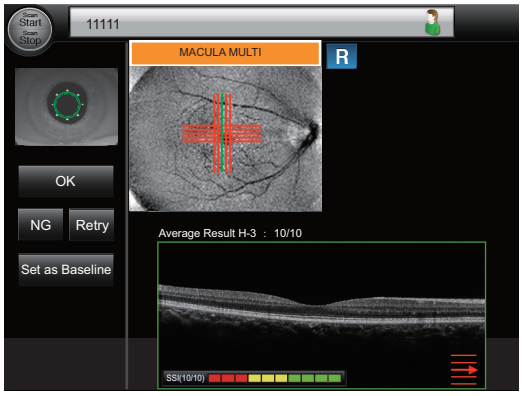
Rotating the upper part of the joystick moves the image capturing vertically.

5 Move the main unit and the image capturing unit so that the patient's eye is displayed in the center of the screen, and that the electronic working dot (*A) is displayed.

When the auto shot function is enabled, displaying the electronic working dot automatically performs alignment, focusing, and optimization. After that, images are automatically captured.

6 Check the captured image.

7 Click the desired button from OK, NG, Retry, and “Set as Baseline”.



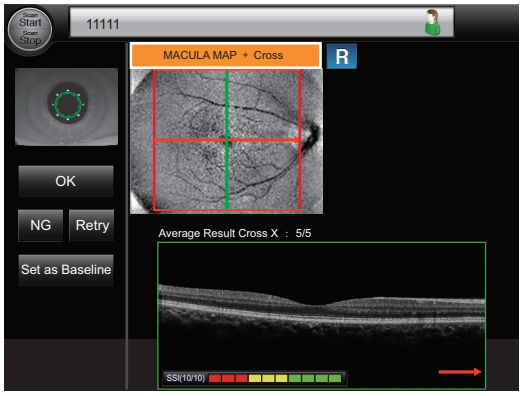
8 Pressing OK or “Set as Baseline” starts the next image capture.

9 Repeat *(Step 5)* to *(Step 8)* to finish all preset image capture.

10 Check the captured images and save them.

“3.2.2 Automatic image capture” (page 71) *(Step 5)* to *(Step 8)*

In Combo release mode Combo (during OCT image capture) or OCT release mode, color fundus images are not captured or displayed on the image confirmation screen.



Note

- When the combo image capture is started, the combo image capture pattern tab is displayed in RS-330 Capture. When an image is captured, the image capture advances to the next one. However, the desired image capture can be selected regardless of the preset order by clicking the desired setting in the tab or changing the eye to be captured using the joystick.

  The combo image capture pattern tab can be operated in the same manner as the stereo image capture pattern tab.

  "O Stereo image capture pattern tab" (page 108)

O Combo image capture of anterior segment

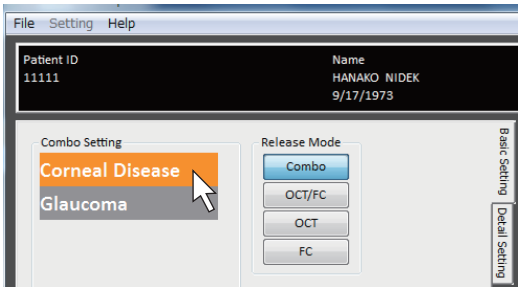
1 Press the release mode select button OCT, then the image capture type button for anterior segment cross-sectional image capture .

2 Press the release mode select button Combo.

3 Set the Combo Setting parameter with RS-330 Capture.

4 Capture images.

"O Anterior segment cross-sectional image capture" (page 97)



5 Finish all preset image capture.

3.6 Other Image Capture

3.6.1 Small pupil image capture

This function allows image capture of eyes with the pupil smaller than the required pupil diameter mark ◯.

The image capture procedure is the same as that in OCT/FC release mode OCT/FC except the steps described below.

"3.2.2 Automatic image capture" (page 71)

"3.2.6 Manual image capture (Operation mode: Professional)" (page 83)

"3.2.7 Manual image capture (Operation mode: Standard)" (page 88)

Note

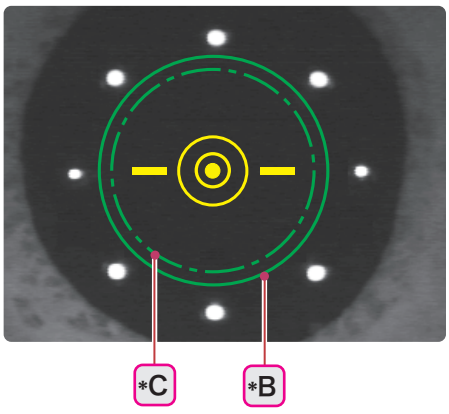
- Flare may appear in fundus images captured through a small pupil.
- The small pupil image capture is available in the following release modes:
  - OCT/FC release mode OCT/FC
  - FC release mode FC → Select the standard , stereo , or panorama image capture.

1 Conduct image capture preparation.

"3.2.1 Preparing for image capture" (page 66)

2 If the patient's pupil is smaller than the required pupil diameter mark (*B), press the small pupil image capture button (*A).

The required pupil diameter mark (*B) disappears.



3 Check that the patient's pupil is larger than the minimum pupil diameter mark (*C).

If the patient's pupil is smaller than the minimum pupil diameter mark, proper images cannot be captured.

Improve the pupil dilation of the patient.

4 Capture images.

"3.2.2 Automatic image capture" (page 71)
"3.2.6 Manual image capture (Operation mode: Professional)" (page 83)
"3.2.7 Manual image capture (Operation mode: Standard)" (page 88)

3.6.2 Low-light image capture

By automatically adjusting the ISO speed, properly bright images can be captured with lower flash intensity. This function is for patients whose pupil easily contract.

The image capture procedure is the same as that in OCT/FC release mode OCT/FC except the steps described below.

"3.2.2 Automatic image capture" (page 71)
"3.2.6 Manual image capture (Operation mode: Professional)" (page 83)
"3.2.7 Manual image capture (Operation mode: Standard)" (page 88)

Note

- Depending on the camera setting, the flash intensity is lowered as shown below.
  - •ISO100: Lowered by 8 levels (About 1/4)
  - •ISO200: Lowered by 4 levels (About 1/2)
  - •ISO400: Flash intensity cannot be lowered.
- The low-light image capture is available in the following release modes:
  - OCT/FC release mode OCT/FC
  - FC release mode FC → Select the standard, stereo, or panorama image capture.

1 Conduct image capture preparation.

"3.2.1 Preparing for image capture" (page 66)

2 Press the low-light image capture button (*A).

The flash intensity (*B) is lowered.

3 Capture images.

"3.2.2 Automatic image capture" (page 71)
"3.2.6 Manual image capture (Operation mode: Professional)" (page 83)
"3.2.7 Manual image capture (Operation mode: Standard)" (page 88)

3.6.3 Fundus autofluorescence image capture (optional)

Fundus images can be captured using the characteristic reaction of lipofuscin in the retinal pigment epithelium to autofluoresce. With the system, green light is used for excitation.

The image capture procedure is the same as that in OCT/FC release mode OCT/FC except the steps described below.

"3.2.2 Automatic image capture" (page 71)
"3.2.6 Manual image capture (Operation mode: Professional)" (page 83)
"3.2.7 Manual image capture (Operation mode: Standard)" (page 88)

Note

- The fundus autofluorescence image capture is available in the following release modes:
  - OCT/FC release mode OCT/FC
  - Color fundus image capture FC → Standard image capture button

1 Conduct image capture preparation.

"3.2.1 Preparing for image capture" (page 66)

2 Press the fundus autofluorescence image capture button FAF (*A).

When the button is being selected, it is shown in orange.

When the fundus autofluorescence image capture is enabled, parameters such as the flash intensity (*B) and ISO speed are automatically changed. The predetermined camera setting is used, and the CAM1 to CAM3 camera settings cannot be used.

3 Capture images.

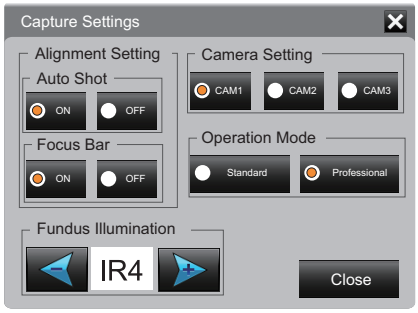
"3.2.2 Automatic image capture" (page 71)
"3.2.6 Manual image capture (Operation mode: Professional)" (page 83)
"3.2.7 Manual image capture (Operation mode: Standard)" (page 88)

3.7 Setting Image Capture Conditions

3.7.1 Image capture setting

1 Press the menu button  .

The Capture Settings dialog appears.



2 Set the parameters as desired.

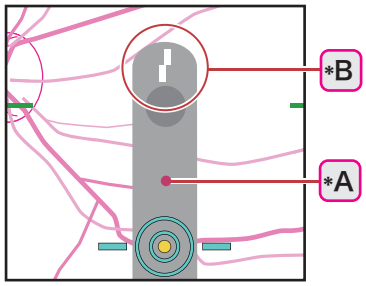
3 Press the Close button Close, or the close button  .

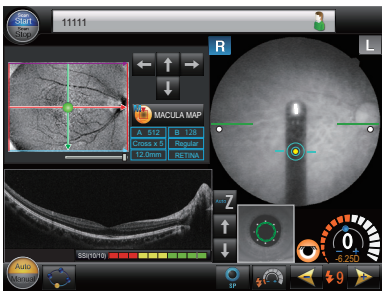
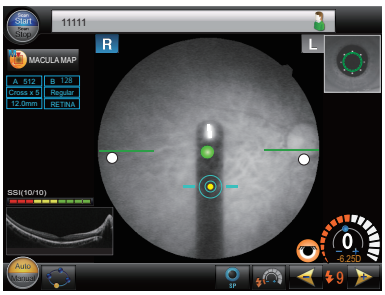
○ Parameters

Note

- Underlined options indicate factory settings.
- Parameters may become unavailable depending on the image capture conditions.

Parameter	Explanation
Alignment setting Auto Shot	**ON / OFF** Automatic image capture
Alignment Setting Focus Bar (*A)	**ON / OFF** **ON:** Used **OFF:** Not used The focus split (*B) is not displayed.

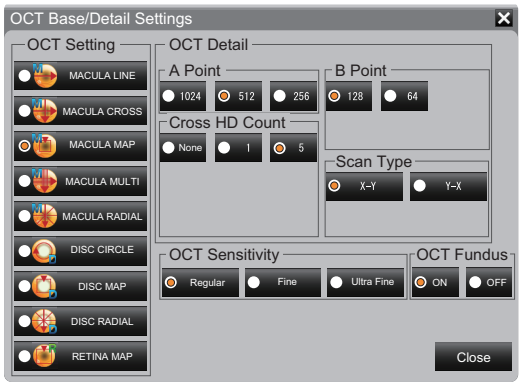


Parameter	Explanation
Camera Setting	**CAM1 / CAM2 / CAM3** The conditions for the color fundus image capture such as the ISO speed and contrast are changed. *"4.5.3 Color fundus image capture setting" (page 147)*
Operation Mode	**Standard / Professional** Screen for fundus observation (in Combo release mode Combo [during OCT image capture], OCT/FC release mode OCT/FC, or OCT release mode OCT)  Professional  Standard
Fundus Illumination	**IR0 to IR7 (Factory setting: IR4)** Brightness of the illumination for fundus observation

3.7.2 OCT image capture setting

1 Press the OCT setting button MACULA MAP.

The OCT Base/Detail Settings dialog appears.



2 Set the parameters as desired.

3 Press the Close button Close, or the close button ✕.

○ Parameters

Note

- Underlined options indicate factory settings.
- Parameters may become unavailable depending on the image capture conditions.

● OCT basic settings

Parameter	Explanation
OCT Setting	**MACULA LINE / MACULA CROSS / <u>MACULA MAP</u> / MACULA MULTI / MACULA RADIAL / DISC CIRCLE / DISC MAP/ DISC RADIAL/ RETINA MAP** Scan line used for retinal cross-sectional image capture
OCT Setting (During anterior segment cross-sectional image capture [optional])	**CORNEA LINE / CORNEA CROSS / <u>CORNEA RADIAL</u> / ACA LINE** Scan line used for anterior segment cross-sectional image capture
OCT Sensitivity	**<u>Regular</u> / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.
OCT Fundus	**<u>ON</u> / OFF** Display of OCT Phase Fundus image **ON:** Display **OFF:** Not display - A fundus image obtained with infrared light is displayed.

● OCT detailed settings

Parameter	A Point	B Point	Cross HD Count	Scan Type
MACULA LINE	512 / 1024	-	1 / 5 / 10 / 15 / 20 / 30 / 50	-
MACULA CROSS	512 / 1024	-	1 / 5 / 10 / 15 / 20 / 30 / 50	-
MACULA MAP	256 / 512 / 1024	64 / 128 / 256	None / 1 / 5 * Cross HD number	X-Y / Y-X
MACULA MULTI	512 / 1024	-	1 / 5 / 10 / 15 / 20 (15 / 20 are only for when the scan type is horizontal or vertical)	Cross / Horizontal / Vertical
MACULA RADIAL	512 / 1024	-	1 / 5 / 10 / 15 / 20 (15 / 20 are only for 6 lines)	6 / 12
DISC CIRCLE	1024	-	1 / 5 / 10 / 15 / 20 / 30 / 50	-
DISC MAP	256 / 512 / 1024	64 / 128 / 256	-	X-Y / Y-X
DISC RADIAL	512 / 1024	-	1 / 5 / 10 / 15 / 20 (15 / 20 are only for 6 lines)	6 / 12
RETINA MAP	1024	128	-	X-Y
CORNEA LINE (During anterior segment cross-sectional image capture [optional])	512 / 1024	-	1 / 5 / 10 / 15 / 20 / 30 / 50	-
CORNEA CROSS (During anterior segment cross-sectional image capture [optional])	512 / 1024	-	1 / 5 / 10 / 15 / 20 / 30 / 50	-
CORNEA RADIAL (During anterior segment cross-sectional image capture [optional])	512 / 1024	-	1 / 5 / 10 / 15 / 20 (15 / 20 are only for 6 lines)	6 / 12
ACA LINE (During anterior segment cross-sectional image capture [optional])	512 / 1024	-	1 / 5 / 10 / 15 / 20 / 30 / 50	-

The numbers of A Point and B Point for the MACULA MAP and DISC MAP can be used in the combinations shown below.

Available combination		Number of A Point		
		A256	A512	A1024
Number of B Point	B64	Yes	Yes	Yes
	B128	Yes	Yes	-
	B256	Yes	-	-

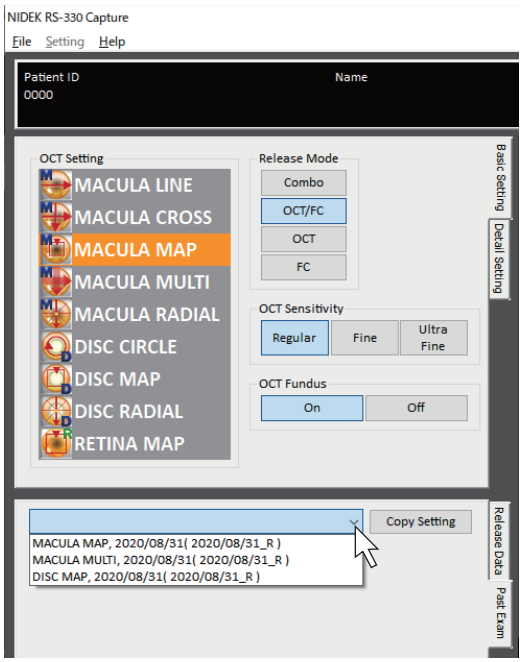
3.8 Copying Image Capture Conditions (for OCT images only)

By registering an image captured with the RS-330 as a baseline image, the image capture conditions of the baseline image can be copied to the RS-330. This function facilitates follow-up examinations.

- This function is available for the OCT/FC image capture OCT/FC and OCT image capture OCT only.

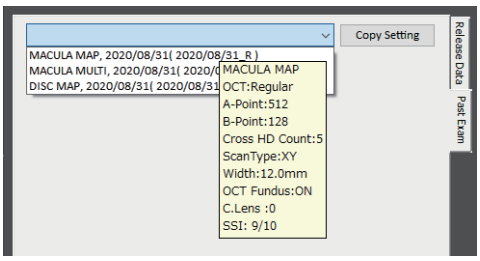
1 From the pull-down menu of the Past Exam tab, select the desired baseline image data to copy its image capture conditions.

The image of the selected data is displayed.



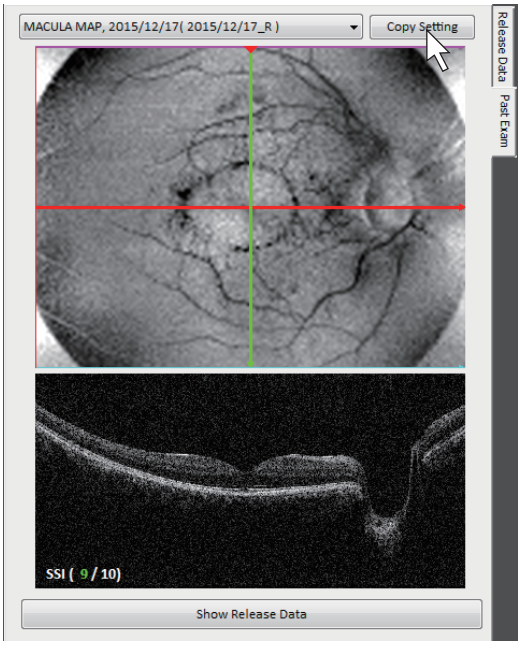
Note

- Baseline image data of the eye to be measured (either right or left) is displayed in the pull-down menu.
- Moving the mouse cursor over image data displays its image capture conditions.



2 Click the Copy Setting button.

The image capture conditions of the selected image data is loaded onto the RS-330.



3 Capture images.

"3.2.2 Automatic image capture" (page 71)

"3.2.6 Manual image capture (Operation mode: Professional)" (page 83)

"3.2.7 Manual image capture (Operation mode: Standard)" (page 88)

Note

- Pressing the Show Release Data button displays the Release Data tab.
- Depending on the patient condition, the best focus value and Z-pos value may vary. After copying the image capture conditions, optimize them.

○ Using baseline images captured with other products

This function is available for baseline images captured with other NIDEK products such as the RS-3000 Lite or RS-3000.

However, some scan line positions, widths, and fixation lamp positions may not be directly compatible with the RS-330 due to differences of the product specifications. In this case, values are automatically converted so that they can be copied to the RS-330.

Be sure to confirm that the copied image capture conditions are as intended before capturing images.

4 SYSTEM SETTINGS AND MAINTENANCE

4.1 Troubleshooting

■ If the system does not function properly, check the table below before asking NIDEK or your authorized distributor for repair.

Symptom	Remedy
The touch screen does not turn on.	• The power cord may not be connected. Check the connection of the power cord. • The power switch may not be turned on. Check whether the power switch is turned on.
The touch screen does not turn on even though the system power is on.	• The system main body may be in Sleep mode. Restore the system main body from Sleep mode by pressing any button on it, or by touching the touch screen.
The touch screen suddenly turns off.	• The system main body may be in Sleep mode. Restore the system main body from Sleep mode by pressing any button on it, or by touching the touch screen.
The computer monitor does not turn on even when the computer is in operation.	• The computer may be in Sleep mode. Restore the computer from Sleep mode by moving the mouse or pressing any key on the keyboard.
The computer monitor suddenly turns off.	• The computer may be in Sleep mode. Restore the computer from Sleep mode by moving the mouse or pressing any key on the keyboard.
The main unit cannot be moved horizontally.	• The main unit may be locked with the locking knob. Rotate the locking knob to unlock the main unit.
The xenon flash lamp for image capture does not illuminate.	• The xenon flash lamp may be degraded or burned out. Contact NIDEK or your authorized distributor. The system main body contains a high voltage part. Touching its interior may cause electric shock.
The image of the intended part cannot be captured.	• The patient may not be looking at the fixation lamp at the time of image capture. Instruct the patient to focus on the fixation lamp. • The intended part may be outside the range for image capture. If the refractive power of the patient is outside the range within which the system can adjust the focus, insert a compensation lens using the compensation lens select lever. • The safety stopper may be the cause. Press and hold the safety stopper, then move the main unit to the position where image capture becomes possible.

Symptom	Remedy
The quality of the captured image is low.	• The objective lens or the lens of the anterior segment adapter (optional) may be contaminated. Perform the cleaning. • The patient's eyelid or eyelashes may be interfering with image capture. Ask the patient to open their eyes wider. If the patient cannot open their eyes wider, lift the patient's lid, paying attention not to press against the eyeballs.
The captured images are dark.	• Alignment to and focus on the anterior eye front may not be proper. Manipulate the joystick to align the electronic working dot to the center of the target mark. • The amount of light for image capture may not be sufficient. Press the flash intensity up button  to increase the flash intensity.
Optic disc images are dark.	• The image capture optical path may be blocked by the iris. Set the Tracking Position Offset parameter. *"4.5.1 Setting of RS-330 Capture" (page 134)*
Electronic working dots and cornea-reflected spots are not in agreement when capturing optic disc OCT images or optic disc color fundus images.	• The tracking position offset may be working to prevent the iris from blocking the image capture optical path. To capture images at the center of the cornea-reflected spots, set the Tracking Position Offset parameter to 0. *"4.5.1 Setting of RS-330 Capture" (page 134)*
The automatic image capture does not function.	• The Manual side may be selected with the Auto/Manual toggle button  . Press the button to select the Auto  side. • The patient's eyelid may be detected or the pupil diameter may not be large enough for image capture. Ask the patient to open their eyes wider. If the patient cannot open their eyes wider, lift the patient's lid, paying attention not to press against the eyeballs. • Room illumination may be reflecting on the cornea. Darken the room or install the system in another location. • The auto tracking and auto shot may not function with the following eyes: • Eyes with keratoconus, or cornea immediately after surgery • Eyes with eye diseases such as cataract • Eyes with severe myopia or hyperopia outside the range between -12D and +15D • Eyes with substantial ocular ataxia or those who cannot keep their head steady In such a case, capture images by pressing the release button. Or, capture images with the manual image capture procedure. *"3.2.6 Manual image capture (Operation mode: Professional)" (page 83)* *"3.2.7 Manual image capture (Operation mode: Standard)" (page 88)*

Symptom	Remedy
The auto shot does not function.	• The auto shot may not be enabled. Enable the auto shot. *"3.7.1 Image capture setting" (page 120)* • The patient's eyelid may be detected or the pupil diameter may not be large enough for image capture. Ask the patient to open their eyes wider. If the patient cannot open their eyes wider, lift the patient's lid, paying attention not to press against the eyeballs. • Room illumination may be reflecting on the cornea. Darken the room or install the system in another location.
The internal fixation lamp is blurred.	• The internal fixation lamp may be blurred because the compensation lens is inserted. Push the compensation lens select lever to the deepest position (0 position) to remove the compensation lens.
NAVIS-EX cannot be activated.	• NAVIS-EX cannot be activated if the data save destination is not valid. Make sure that the connection cable is connected. If NAVIS-EX is connected to a network, make sure that the LAN cable is connected.

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

4.2 Error Messages and Remedies

■ If one of the following error codes is displayed on the screen or printed out, follow the suggestions in the cause and remedy column.

The error code, detailed indications, and serial number of your system are helpful for proper servicing.

Message	Cause and remedy
Flash fails	• The xenon flash lamp for image capture does not illuminate. Capture the image again. • If the message appears repeatedly, the xenon flash lamp may be degraded or burned out. Contact NIDEK or your authorized distributor.
ERROR: 001 EEPROM data error	• Loss of backup memory (EEPROM) data due to exogenous noise such as static electricity or malfunction of the backup memory on the electric circuit board is probable. • If the same error code is displayed again even after the system is turned off and on again, shut off the system and contact NIDEK or your authorized distributor.
ERROR:123 No trigger signal detected	• A communication error has occurred at the time of color fundus image capture. • The USB 3.0 cable may not be connected properly, or may be broken. Connect the cable again both to the system main body and the computer. • If the same error code is displayed again even after the system is turned off and on again, shut off the system and contact NIDEK or your authorized distributor.
ERROR:151 Camera: Device error ERROR:154 Unable to read images	• A communication error has occurred at the time of reading captured images. • The USB 3.0 cable may not be connected properly, or may be broken. Connect the cable again both to the system main body and the computer. • If the same error code is displayed again even after the system is turned off and on again, shut off the system and contact NIDEK or your authorized distributor.
ERROR:602 Line CCD connection error ERROR:604 Line CCD capture failure	• A communication error has occurred at the time of OCT image capture. • The USB 3.0 cable may not be connected properly, or may be broken. Connect the cable again both to the system main body and the computer. • If the same error code is displayed again even after the system is turned off and on again, shut off the system and contact NIDEK or your authorized distributor.

The following are errors related to the mechanism inside the system. Shut off the system and contact NIDEK or your authorized distributor.

ERROR: 007	Base fan1 error	ERROR: 008	Base fan2 error
ERROR: 009	Base fan3 error	ERROR: 010	Galvano fan error
ERROR: 011	Comm error: Init. Failed (Main-Sub)	ERROR: 012	Comm error: Timeout (Main-Sub)
ERROR:013	Comm error: Invalid data (Main-Sub)	ERROR:021	Comm error: Init. Failed (PC-Main)
ERROR:022	Comm error: OCT Calibration	ERROR:031	Motor error: Up and down
ERROR:032	Motor error: Right and left	ERROR:033	Motor error: Back and forth
ERROR:111	Insufficient charge	ERROR:112	Charging error (4s)
ERROR:113	Charging error (1s)	ERROR:115	Charging error (6s)
ERROR:121	QR mirror error	ERROR:145	Motor error: FC focus
ERROR:146	Motor error: Smaller pupil	ERROR:147	Motor error: QR mirror
ERROR:149	Motor error: Barrier	ERROR:150	Motor error: Exciter
ERROR:160	Camera: No hardware detected.	ERROR:201	Optical axis adjustment error
ERROR:211	Spectrometer motor overrun error	ERROR:212	Spectrometer motor stop error
ERROR:213	OPL motor overrun error	ERROR:214	OPL motor stop error
ERROR:215	OCT focus motor overrun error	ERROR:216	OCT focus motor stop error

ERROR:217	OCT compensation motor stop error	ERROR:221	OCT X galvano driver error
ERROR:222	OCT Y galvano driver error	ERROR:223	OCT galvano mirror error
ERROR:225	OCT shutter error	ERROR:226	SLD initialization error
ERROR:227	SLD power1 over error	ERROR:228	SLD power2 over error
ERROR:230	SLD power2 under error	ERROR:242	Polarization motor stop error
ERROR:603	Line CCD initialization error		

4.3 Attaching the Chinrest Paper

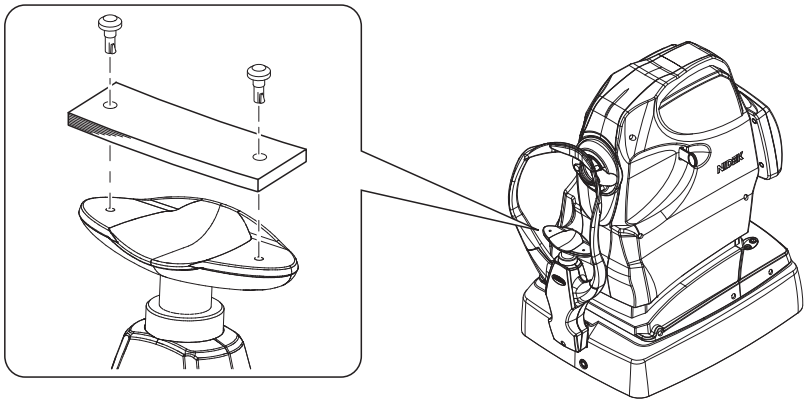
1 Pull out the two fixing pins from the chinrest.

2 Remove a proper amount of chinrest paper from a whole pad.

A whole pad of chinrest paper cannot be attached to the chinrest at a time. Be sure to use a pad of 6 mm or less removed from the whole pad.

3 Insert the fixing pins into the chinrest paper pins.

Insert the fixing pins into the holes on both edges of the chinrest paper.



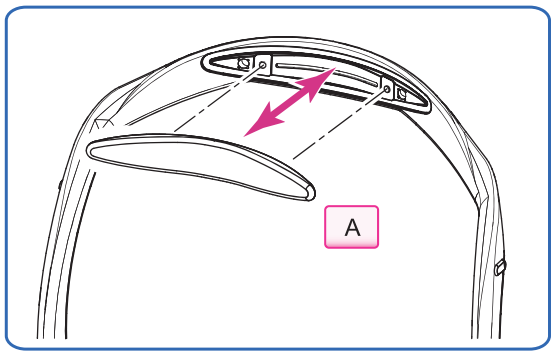
4 Attach the chinrest paper to the chinrest.

1) While holding the fixing pins and chinrest paper, insert a fixing pin into one of the two holes on the chinrest.
2) Insert the other fixing pin into the other hole on the chinrest.

4.4 Forehead Rest Pad Replacement

■ Magnetic forehead rest pad (30611-1520)

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

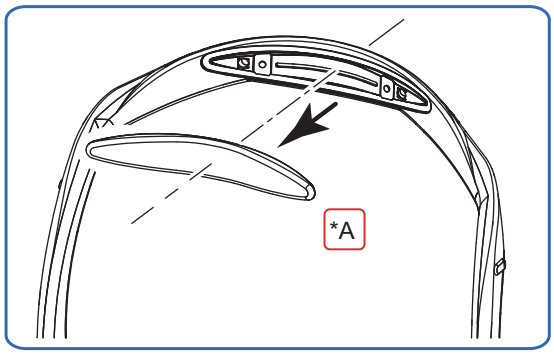


■ Forehead rest pad (15411-M752)

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

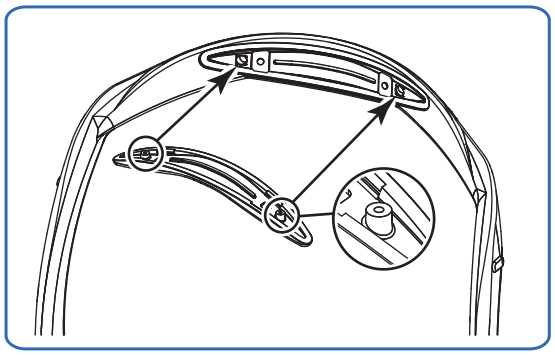
1 Remove the forehead rest pad or magnetic forehead rest pad (*A) from the frame.

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



2 Attach a new forehead rest pad.

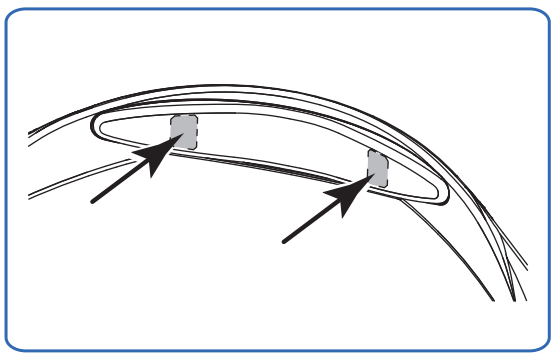
1) Align the clasps of the forehead rest pad to the holes in the frame.



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

   The forehead rest pad is locked by the fasteners.

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

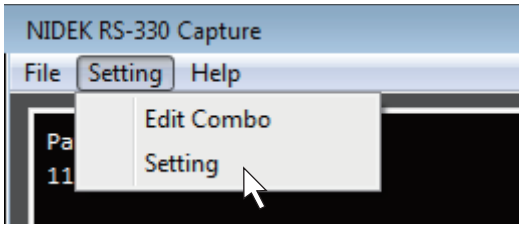


4.5 Setting of RS-330 Capture

4.5.1 Setting of RS-330 Capture

Set the parameters for the system and image capture. The changed parameters are saved and used as the default settings from the next system start-up.

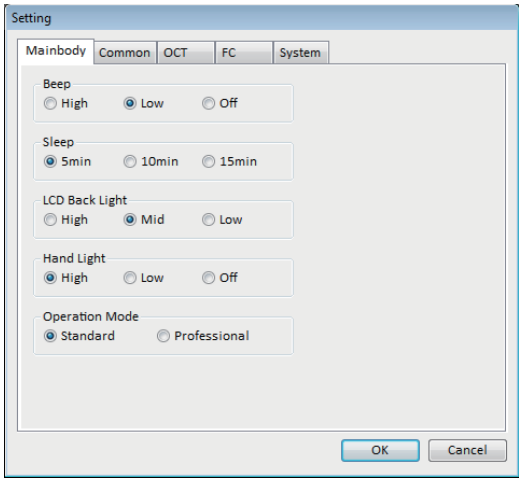
1 Open the pull-down menu from “Setting” in the menu bar. Then press “Setting”.



Note

- During the scanning, “Setting” cannot be selected.

The Setting dialog appears.



2 Set the parameters as desired.

3 Click the OK button [OK] .

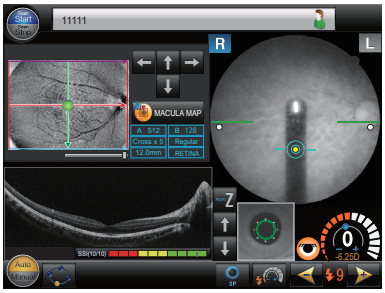
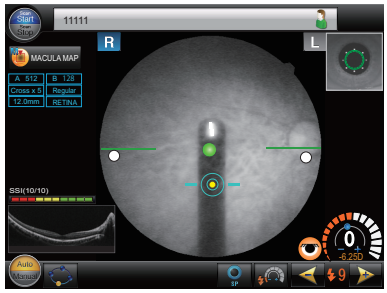
○ Parameters

Note

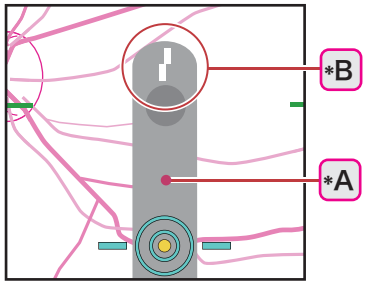
- Underlined options indicate factory settings.
- Parameters may become unavailable depending on the image capture conditions.

● Main body tab

Parameter	Explanation
Beep	**High / <u>Low</u> / Off** Volume of beep (electronic sound) at the time of image capture or such
Sleep	**<u>5 min</u> / 10 min / 15 min** The time to enter sleep mode when the system has not been used (auto sleep function)
LCD Back Light	**High / <u>Mid</u> / Low** Touch screen brightness
Hand Light	**<u>High</u> / Low / Off** Brightness of the illumination for the buttons around the joystick

Parameter	Explanation
Operation Mode	**Standard / Professional** Screen for fundus observation (in Combo release mode Combo [during OCT image capture], OCT/FC release mode OCT/FC , or OCT release mode OCT)  Professional  Standard

● Common tab

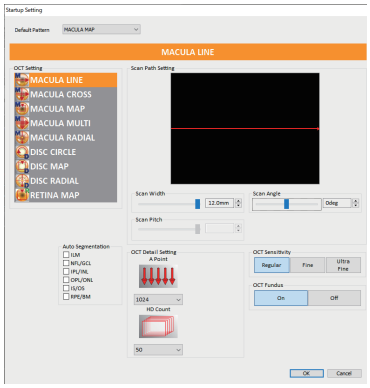
Parameter	Explanation
Release Mode (Startup)	**Combo / OCT/FC / OCT / FC** Release mode at system start-up
Alignment Setting (Startup) Full Auto	**Checked / Not checked** Optimization of alignment, focus, and image quality
Alignment Setting (Startup) Auto Shot	**Checked / Not checked** Automatic image capture
Alignment Setting (Startup) Focus Bar (*A)	**Checked / Not checked** **Checked**: Used **Not checked:** Not used The focus split (*B) is not displayed. 
Tracking Position Offset	**0 / 0.1 / 0.2 / 0.3 / 0.4 / 0.5** The offset value to prevent the image capture optical path from being blocked Active only when capturing optic disc OCT images or optic disc color fundus images

● OCT tab

Parameter	Explanation
OCT Color	**Positive (B/W) / Negative (B/W) / Color** Color setting of OCT image
OCT Polarization Optimize	**Auto / On** Condition to execute polarization for optimization Auto: Executes polarization when the SSI is below the threshold value. On: Executes polarization regardless of the SSI.
OCT Polarization Auto	**Normal / Low** Threshold value for when “Auto” is selected for “Optimize”

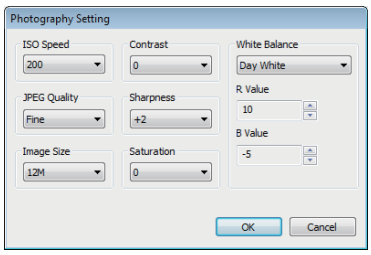
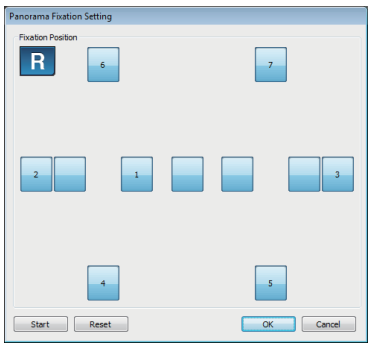
	SSI threshold (SSI bar graph)	
	MACULA LINE, CROSS, MAP, MULTI, RADIAL, RETINA MAP	**DISC CIRCLE, MAP, RADIAL**
Normal	8 (Green)	7 (Green)
Low	7 (Green)	6 (Yellow)

Startup Setting	**Retina / Cornea** OCT setting at start-up Retina : OCT setting for retinal cross-sectional image capture Cornea : OCT setting for anterior segment cross-sectional image capture *“4.5.2 OCT image capture setting at system start-up” (page 138)*



● FC tab

Parameter	Explanation
Flash Level (Startup) ISO100	**FL1 to FL17 (Factory setting: FL13)** Flash intensity at the start-up
Flash Level (Startup) ISO200	**FL1 to FL17 (Factory setting: FL9)** Flash intensity at the start-up
Flash Level (Startup) ISO400	**FL1 to FL17 (Factory setting: FL5)** Flash intensity at the start-up
Flash Level (Startup) Anterior	**FL1 to FL17 (Factory setting: FL5)** Flash intensity at the start-up
Flash Level (Startup) Fundus Illumination	**IR0 to IR7 (Factory setting: IR4)** Brightness of the illumination for fundus observation at system start-up
Camera Startup	**CAM1 / CAM2 / CAM3** Camera selected at system start-up

Parameter	Explanation
Camera Photography Setting	**CAM1 / CAM2 / CAM3** Clicking any button shows a dialog. *"4.5.3 Color fundus image capture setting" (page 147)* 
Option Auto Small Pupil	**On / <u>Off</u>** Automatic detection of the pupil diameter and automatic transition to small pupil image capture
Option FL Offset for Small Pupil	**<u>0</u> / -1 / -2 / -3** Adjustment of flash intensity for small pupil image capture
Panorama Fixation	Clicking any button shows a dialog. *"4.5.4 Panorama fixation lamp setting" (page 149)* 

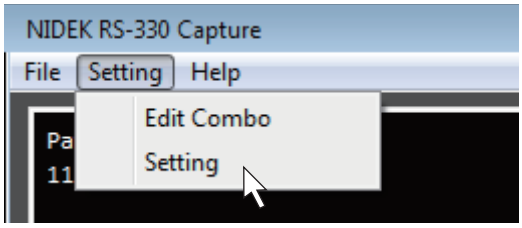
○ System tab

Parameter	Explanation
Setting File Restore	Restores backed-up system settings. Pressing "Restore" shows the explorer. Select the desired setting file. The default setting file name is "RS330_backup.cfg".
Setting File Backup	Backs up the current system settings. Pressing "Backup" shows the explorer. Select the desired save destination. The files can be saved in any location. The default setting file name is "RS330_backup.cfg". The file name can be changed. Take notes of the file name for the file management.

4.5.2 OCT image capture setting at system start-up

OCT image capture parameters at system start-up can be set. The parameters at system start-up can only be set with RS-330 Capture.

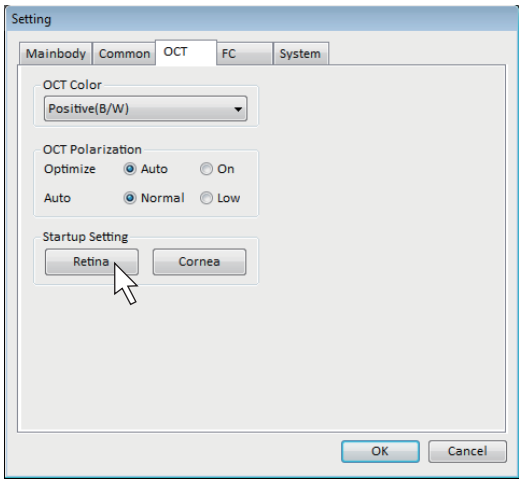
1 Open the pull-down menu from “Setting” in the menu bar. Then press “Setting”.



Note

- During the scanning, “Setting” cannot be selected.

The Setting dialog appears.



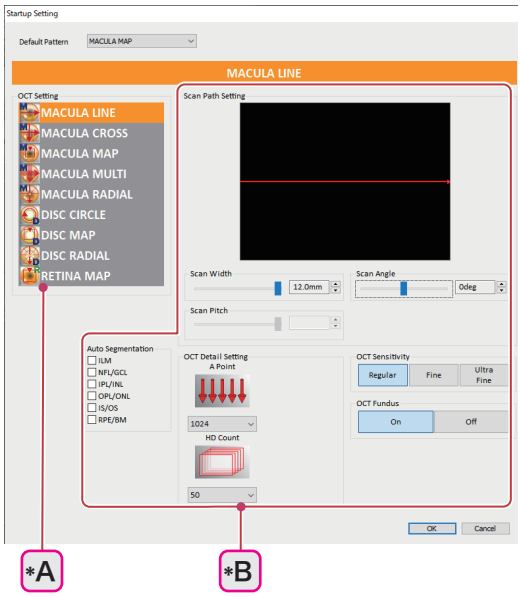
2 Open the OCT tab.

3 Press “Retina” or “Cornea” of “Startup Setting”.

Retina : OCT setting for retinal cross-sectional image capture

Cornea : OCT setting for anterior segment cross-sectional image capture

The Startup Setting dialog appears.



4 Set the parameters as desired.

1) From “OCT Setting” (*A), select the scan line for which the parameters are to be changed.

   The display for the selected scan line appears (*B).

2) Set the parameters as desired.

   The scan line can be changed intuitively by dragging the mouse.

5 Click the OK button OK .

6 Press the OK button OK in the Setting dialog.

○ Parameters

Note

- Underlined options indicate factory settings.
- Parameters may become unavailable depending on the image capture conditions.

● Default Pattern

Parameter	Explanation
Retinal cross-sectional image capture	**MACULA LINE / MACULA CROSS / MACULA MAP / MACULA MULTI / MACULA RADIAL / DISC CIRCLE / DISC MAP / DISC RADIAL / RETINA MAP** OCT setting selected for retinal cross-sectional image capture at system start-up
Anterior segment cross-sectional image capture (optional)	**CORNEA LINE / CORNEA CROSS / CORNEA RADIAL / ACA LINE** OCT setting selected for anterior segment cross-sectional image capture at system start-up

● MACULA LINE

Parameter	Explanation
A Point	**512 / 1024** The number of A-scan points
HD Count	**1 / 5 / 10 / 15 / 20 / 30 / 50** The number of images captured by scanning. The same number of images are used for the image averaging.
Scan Width	**3.0 mm / 6.0 mm / 9.0 mm / 12.0 mm** Scan line width
Scan Angle	**-90° to 89° (Factory setting: 0°, Increments: 1°)** Scan line angle
OCT Sensitivity	**Regular / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.
OCT Fundus	**ON / OFF** Display of OCT Phase Fundus image **ON:** Display **OFF:** Not display - A fundus image obtained with infrared light is displayed.
Auto Segmentation	**Checked / Not checked** Automatic detection of layer borderlines after image capture **Checked**: Automatic detection is performed. **Not checked:** Automatic detection is not performed.

● MACULA CROSS

Parameter	Explanation
A Point	**512 / 1024** The number of A-scan points
HD Count	**1 / 5 / 10 / 15 / 20 / 30 / 50** The number of images captured by scanning. The same number of images are used for the image averaging.

Parameter	Explanation
Scan Width	**3.0 mm / 6.0 mm / 9.0 mm** Scan line width
OCT Sensitivity	**Regular / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.
OCT Fundus	**ON / OFF** Display of OCT Phase Fundus image **ON:** Display **OFF:** Not display - A fundus image obtained with infrared light is displayed.
Auto Segmentation	**Checked / Not checked** Automatic detection of layer borderlines after image capture **Checked**: Automatic detection is performed. **Not checked:** Automatic detection is not performed.

- MACULA MAP

Parameter	Explanation
A Point	**256 / 512 / 1024** The number of A-scan points
B Point	**64 / 128 / 256** The number of images captured by the repeated scanning along the line orthogonal to the scan line. The map data is created from the number of images specified here.
Cross HD Count	**None / 1 / 5** The number of images captured by scanning along the cross lines that are formed in reference to the center of the scan range The same number of images are used for the image averaging.
Scan Type	**X-Y / Y-X** Scan direction **X-Y:** The scan line in the X direction (horizontal) is scanned in the Y direction (vertical). **Y-X:** The scan line is in the Y direction (vertical) and the scanning is performed in the X direction (horizontal).
Scan Width	**6.0 mm / 9.0 mm / 12.0 mm** Scan line width
OCT Sensitivity	**Regular / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.
OCT Fundus	**ON / OFF** Display of OCT Phase Fundus image **ON:** Display **OFF:** Not display - A fundus image obtained with infrared light is displayed.

Parameter	Explanation
Auto Segmentation	**Checked (ILM, IPL/INL, RPE/BM) / Not checked** Automatic detection of layer borderlines after image capture **Checked**: Automatic detection is performed. **Not checked:** Automatic detection is not performed.

The numbers of A Point and B Point can be set in the combinations shown below.

Available combination		Number of A Point		
		A256	A512	A1024
Number of B Point	B64	Yes	Yes	Yes
	B128	Yes	Yes	-
	B256	Yes	-	-

- MACULA MULTI

Parameter	Explanation
A Point	**512 / 1024** The number of A-scan points
HD Count	**1 / 5 / 10 / 15 / 20 (15 / 20 are only for when "Horizontal" or "Vertical" is selected for "Scan Type".)** The number of images captured by scanning. The same number of images are used for the image averaging.
Scan Type	**Cross / Horizontal / Vertical** Shape of scan line **Cross:** 5 cross lines **Horizontal:** 5horizontal lines in X direction **Vertical:** 5 vertical lines in Y direction
Scan Width	**3.0 mm / 6.0 mm / 9.0 mm** Scan line width
Scan Pitch	**0.075 mm to 1.500 mm (Factory setting: 0.225 mm, Increments: 0.075 mm)** Distance between scan lines
OCT Sensitivity	**Regular / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.
OCT Fundus	**ON / OFF** Display of OCT Phase Fundus image **ON:** Display **OFF:** Not display - A fundus image obtained with infrared light is displayed.
Auto Segmentation	**Checked / Not checked** Automatic detection of layer borderlines after image capture **Checked**: Automatic detection is performed. **Not checked:** Automatic detection is not performed.

● MACULA RADIAL

Parameter	Explanation
A Point	**512 / 1024** The number of A-scan points
HD Count	**1 / 5 / 10 / 15 / 20 (15 / 20 are only for when "6" is selected for "Scan Type".)** The number of images captured by scanning. The same number of images are used for the image averaging.
Scan Type	**6 / 12** The number of scan lines
Scan Width	**3.0 mm / 6.0 mm / 9.0 mm** Scan line width
OCT Sensitivity	**Regular / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.
OCT Fundus	**ON / OFF** Display of OCT Phase Fundus image **ON:** Display **OFF:** Not display - A fundus image obtained with infrared light is displayed.
Auto Segmentation	**Checked / Not checked** Automatic detection of layer borderlines after image capture **Checked**: Automatic detection is performed. **Not checked:** Automatic detection is not performed.

● DISC CIRCLE

Parameter	Explanation
A Point	**1024** The number of A-scan points
HD Count	**1 / 5 / 10 / 15 / 20 / 30 / 50** The number of images captured by scanning. The same number of images are used for the image averaging.
Scan Width	**3.45 mm** Scan line width
OCT Sensitivity	**Regular / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.
OCT Fundus	**ON / OFF** Display of OCT Phase Fundus image **ON:** Display **OFF:** Not display - A fundus image obtained with infrared light is displayed.
Auto Segmentation	**Checked (ILM, NFL/GCL) / Not checked** Automatic detection of layer borderlines after image capture **Checked**: Automatic detection is performed. **Not checked:** Automatic detection is not performed.

● DISC MAP

Parameter	Explanation
A Point	**256 / <u>512</u> / 1024** The number of A-scan points
B Point	**64 / <u>128</u> / 256** The number of images captured by the repeated scanning along the line orthogonal to the scan line. The map data is created from the number of images specified here.
Scan Type	**X-Y / <u>Y-X</u>** Scan direction **X-Y:** The scan line in the X direction (horizontal) is scanned in the Y direction (vertical). **Y-X:** The scan line is in the Y direction (vertical) and the scanning is performed in the X direction (horizontal).
Scan Width	**4.5 mm / 5.1 mm / <u>6.0 mm</u>** Scan line width
OCT Sensitivity	**<u>Regular</u> / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.
OCT Fundus	**<u>ON</u> / OFF** Display of OCT Phase Fundus image **ON:** Display **OFF:** Not display - A fundus image obtained with infrared light is displayed.
Auto Segmentation	**<u>Checked (ILM, NFL/GCL)</u> / Not checked** Automatic detection of layer borderlines after image capture **Checked**: Automatic detection is performed. **Not checked:** Automatic detection is not performed.

The numbers of A Point and B Point can be set in the combinations shown below.

Available combination		Number of A Point		
		A256	A512	A1024
Number of B Point	B64	Yes	Yes	Yes
	B128	Yes	Yes	-
	B256	Yes	-	-

● DISC RADIAL

Parameter	Explanation
A Point	**512 / <u>1024</u>** The number of A-scan points
HD Count	**1 / 5 / <u>10</u> / 15 / 20 (15 / 20 are only for when “6” is selected for “Scan Type”.)** The number of images captured by scanning. The same number of images are used for the image averaging.
Scan Type	**6 / <u>12</u>** The number of scan lines

Parameter	Explanation
Scan Width	**3.0 mm / 6.0 mm / 9.0 mm** Scan line width
OCT Sensitivity	**Regular / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.
OCT Fundus	**ON / OFF** Display of OCT Phase Fundus image **ON:** Display **OFF:** Not display - A fundus image obtained with infrared light is displayed.
Auto Segmentation	**Checked / Not checked** Automatic detection of layer borderlines after image capture **Checked**: Automatic detection is performed. **Not checked:** Automatic detection is not performed.

- RETINA MAP

Parameter	Explanation
A Point	**1024** The number of A-scan points
B Point	**128** The number of images captured by the repeated scanning along the line orthogonal to the scan line. The map data is created from the number of images specified here.
Scan Type	**X-Y** Scan direction **X-Y:** The scan line in the X direction (horizontal) is scanned in the Y direction (vertical).
Scan Width	**12.0 mm** Scan line width
OCT Sensitivity	**Regular / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.
OCT Fundus	**ON / OFF** Display of OCT Phase Fundus image **ON:** Display **OFF:** Not display - A fundus image obtained with infrared light is displayed.
Auto Segmentation	**Checked (ILM, IPL/INL, RPE/BM) / Not checked** Automatic detection of layer borderlines after image capture **Checked**: Automatic detection is performed. **Not checked:** Automatic detection is not performed.

● CORNEA LINE (for anterior segment cross-sectional image capture [optional])

Parameter	Explanation
A Point	**512 / 1024** The number of A-scan points
HD Count	**1 / 5 / 10 / 15 / 20 / 30 / 50** The number of images captured by scanning. The same number of images are used for the image averaging.
Scan Width	**2.0 mm / 4.0 mm / 6.0 mm / 8.0 mm** Scan line width
Scan Angle	**-90° to 89° (Factory setting: 0°, Increments: 1°)** Scan line angle
OCT Sensitivity	**Regular / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.

● CORNEA CROSS (for anterior segment cross-sectional image capture [optional])

Parameter	Explanation
A Point	**512 / 1024** The number of A-scan points
HD Count	**1 / 5 / 10 / 15 / 20 / 30 / 50** The number of images captured by scanning. The same number of images are used for the image averaging.
Scan Width	**2.0 mm / 4.0 mm / 6.0 mm / 8.0 mm** Scan line width
OCT Sensitivity	**Regular / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.

● CORNEA RADIAL (for anterior segment cross-sectional image capture [optional])

Parameter	Explanation
A Point	**512 / 1024** The number of A-scan points
HD Count	**1 / 5 / 10 / 15 / 20 (15 / 20 are only for when “6” is selected for “Scan Type”.)** The number of images captured by scanning. The same number of images are used for the image averaging.
Scan Type	**6 / 12** The number of scan lines
Scan Width	**2.0 mm / 4.0 mm / 6.0 mm / 8.0 mm** Scan line width

Parameter	Explanation
OCT Sensitivity	**Regular / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.

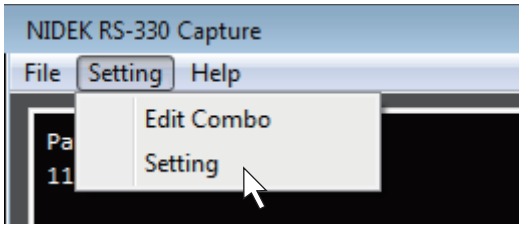
● ACA LINE (for anterior segment cross-sectional image capture (optional))

Parameter	Explanation
A Point	**512 / 1024** The number of A-scan points
HD Count	**1 / 5 / 10 / 15 / 20 / 30 / 50** The number of images captured by scanning. The same number of images are used for the image averaging.
Scan Width	**2.0 mm / 4.0 mm** Scan line width
Scan Angle	**-90° to 89° (Factory setting: 0°, Increments: 1°)** Scan line angle
OCT Sensitivity	**Regular / Fine / Ultra Fine** Adjustment of the exposure time for OCT image capture When Fine or Ultra Fine is selected, image capture takes longer than when Regular is selected. Therefore, depending on the patient's conditions (unstable eye fixation and blinking), proper images may not be captured.

4.5.3 Color fundus image capture setting

Parameters of the color fundus image capture can be set. The changed parameters are saved and used as the default settings from the next system start-up. The parameters of the color fundus image capture can only be set with RS-330 Capture.

1 Open the pull-down menu from “Setting” in the menu bar. Then press “Setting”.



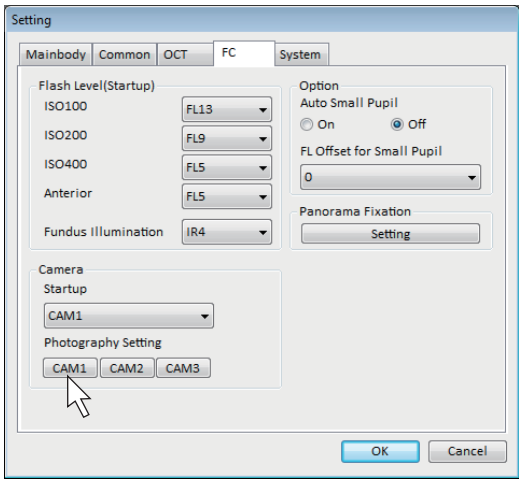
Note

- During the scanning, “Setting” cannot be selected.

The Setting dialog appears.

2 Open the FC tab.

3 Press the button of the desired camera from “CAM1”, “CAM2”, and “CAM3” in “Photography Setting”.

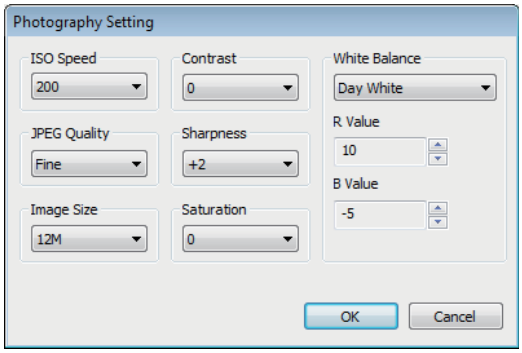


The Capture Settings dialog appears.

4 Set the parameters as desired.

5 Click the OK button [OK] .

6 Press the OK button [OK] in the Setting dialog.



○ Parameters

Note

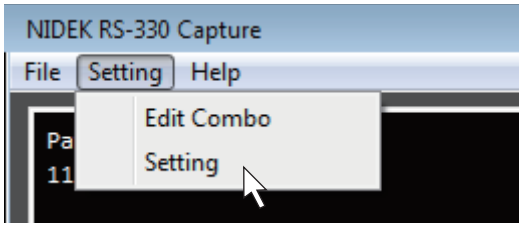
- Underlined options indicate factory settings.
  The initial settings of CAM1, CAM2, and CAM3 are the same.
- Parameters may become unavailable depending on the image capture conditions.

Parameter	Explanation
ISO Speed	**100 / <u>200</u> / 400** Sensitivity of the camera To capture images of the same brightness, the light amount required with ISO200 is 1/2 of ISO100. With ISO400, the required light amount is 1/4 of ISO100. However, as the ISO speed becomes higher, the noise in the image becomes conspicuous.
JPEG Quality	**<u>Fine</u> / Normal / Basic** Level of image compression **Fine**: Low compression rate **Normal**: Medium compression rate **Basic**: High compression rate
Image Size	**<u>12M</u> / 8M / 5M / 3M / 1M** Number of pixels
Contrast	**-2 / -1 / <u>0</u> / +1 / +2** Contrast of bright and dark parts **Minus value**: Softer images with low contrast **Plus value**: Clearer image with high contrast
Sharpness	**0 / +1 / <u>+2</u> / +3 / +4 / +5** Sharpness of image outlines **Minus value**: Softer images with less clear outlines **Plus value**: Clearer image with sharp outlines (with noise also appearing sharply)
Saturation	**-2 / -1 / <u>0</u> / +1 / +2** Color density **Minus value**: Images with light color **Plus value**: Images with deep color
White Balance	**<u>Day White</u> / Color Temperature** Method to adjust the color tone **Day White:** Detailed adjustment of color tone **Color Temperature:** Rough adjustment of color tone
R Value (When “Day White” is selected for “White Balance”)	**-128 to +127 (Factory Setting: +10)** Adjustment of redness **Minus value:** Reduces redness. **Plus value:** Increases redness.
B Value (When “Day White” is selected for “White Balance”)	**-128 to +127 (Factory Setting: -5)** Adjustment of blueness **Minus value:** Reduces blueness. **Plus value:** Increases blueness.
Color (When “Color Temperature” is selected for “White Balance”)	**4000 to 8000 (Factory setting: 5000, Increments: 100)** Color tone **Minus value:** Cold color **Plus value:** Warm color

4.5.4 Panorama fixation lamp setting

Parameters of the fixation lamps at two to nine positions are set for the panorama image capture.
The panorama fixation lamp parameters can only be set with RS-330 Capture.

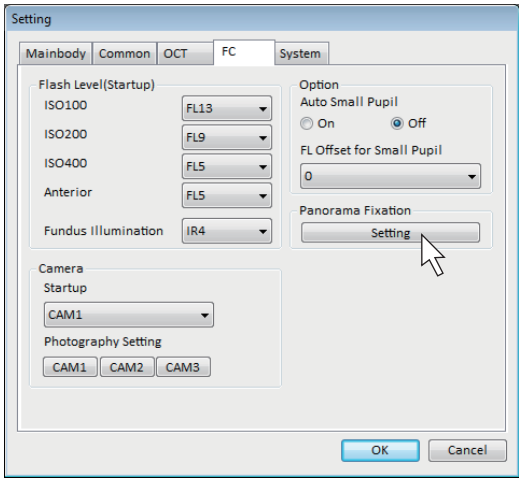
1 Open the pull-down menu from “Setting” in the menu bar. Then press “Setting”.



Note

- During the scanning, “Setting” cannot be selected.

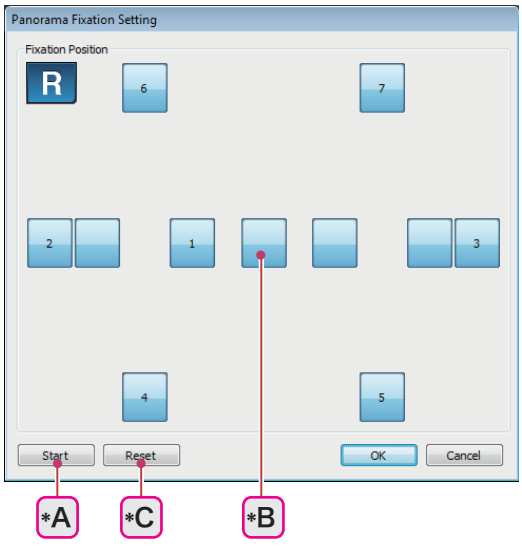
The Setting dialog appears.



2 Open the FC tab.

3 Press “Setting” in “Panorama Fixation”.

The Panorama Fixation Setting dialog appears.



4 Set the parameters as desired.

1) Press the Start button (*A).
   The numbers indicating the order to illuminate the fixation lamp are cleared.
2) Press the marks (*B) in the order to illuminate the fixation lamp.
   Set the order of two to nine positions.
3) Press the Finish button.
4) Click the OK button [OK].
5) To reset the selected positions, press “Reset” (*C).

5 Press the OK button [OK] in the Setting dialog.

4.5.5 Edit Combo

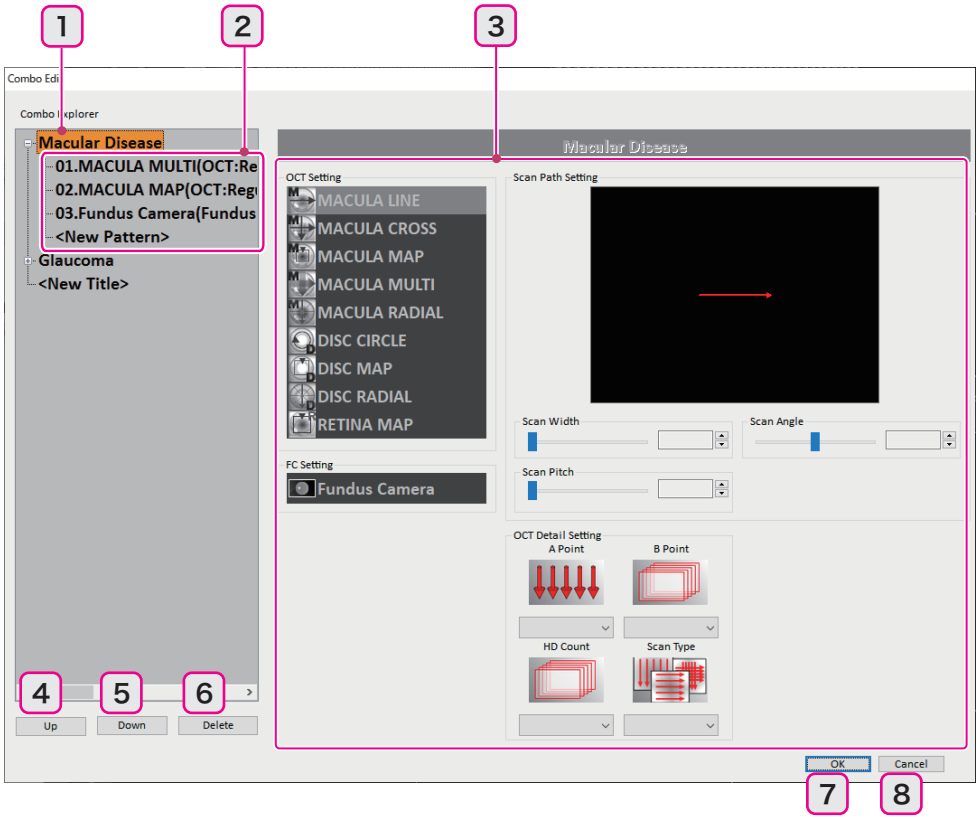
The settings for the combo image capture can be created, edited, and deleted.

Note

- The combo image capture settings can only be edited with RS-330 Capture.
- The following parameters can be set for the combo image capture.
  - Any combination of the following: MACULA LINE / MACULA CROSS / MACULA MAP / MACULA MULTI / MACULA RADIAL / DISC CIRCLE / DISC MAP / DISC RADIAL / RETINA MAP / standard image capture in FC release mode 

    A maximum of 10 combo settings can be registered.
  - Any combination of the following: CORNEA LINE / CORNEA CROSS / CORNEA RADIAL / ACA LINE

    Available only when the anterior segment adapter (optional) is used. A maximum of four combo settings can be registered.



1 Combo setting

Combinations of various settings (combo pattern) can be registered as image capture programs.

2 Combo pattern

Shows the individual settings that comprise the combo setting. Clicking the button  on the left of the combo setting expands the combo setting to show the combo patterns in the tree view. A maximum of 10 combo patterns can be registered for a combo setting.

3 Controller

Changes the settings of the selected combo pattern.

4 Up button Up

Moves the selected combo setting or combo pattern one place up in the list.

5 Down button Down

Moves the selected combo setting or combo pattern one place down in the list.

6 Delete button Delete

Deletes the selected combo setting or combo pattern.

7 OK button OK

Applies the changed combo setting or combo pattern.

8 Cancel button Cancel

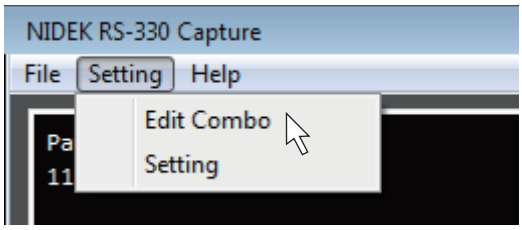
Cancels the changed settings and closes the dialog.

○ Creating combo setting

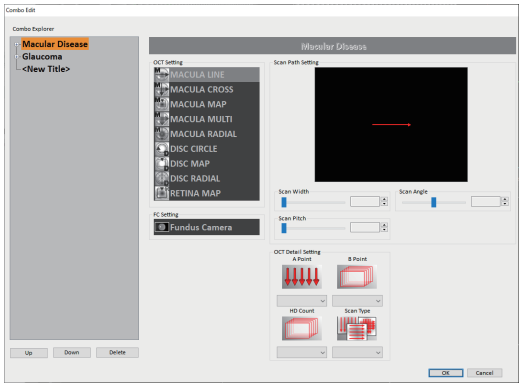
1 Open the pull-down menu from “Setting” in the menu bar. Then click “Edit Combo”.

Note

- During the scanning, “Setting” cannot be selected.



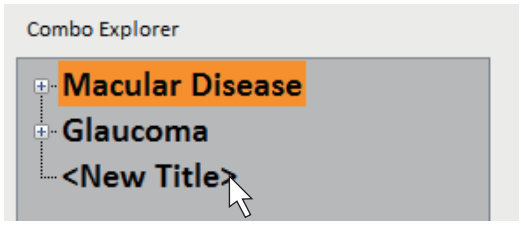
The Combo Edit dialog appears.



2 Register a new combo setting.

1) Press <New Title>.

Selecting <New Title> highlights it in orange.

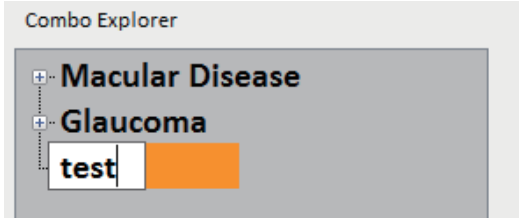


2) Press the highlighted <New Title>.

The title becomes editable.

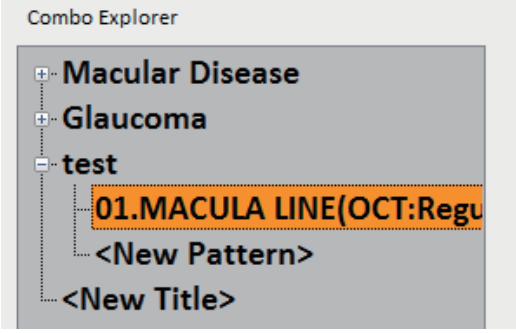
3) Input the title.

A maximum of 30 characters can be input for the title.



4) Press the Enter key of the keyboard, or press any blank position in the Combo Explorer to determine the title.

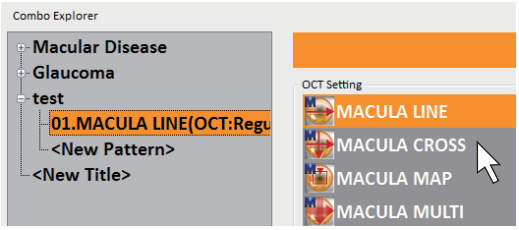
A new combo setting is created. A combo pattern is shown in the expanded tree view.



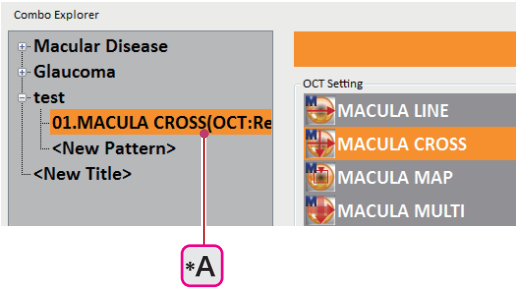
3 Set the combo patterns.

1) Select the desired scan line from the OCT Setting.

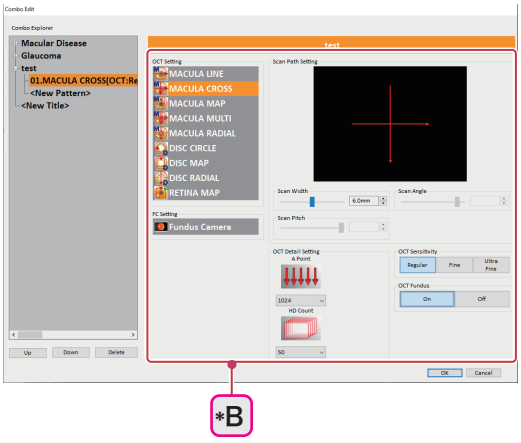
In this explanation, “MACULA CROSS” is selected.



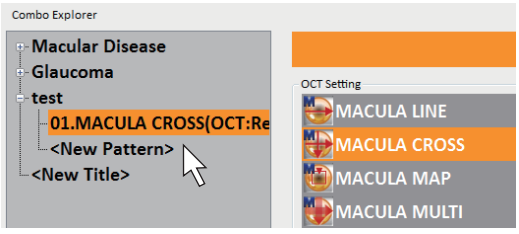
The combo pattern is changed. (*A)



2) Edit the selected combo pattern. (*B)



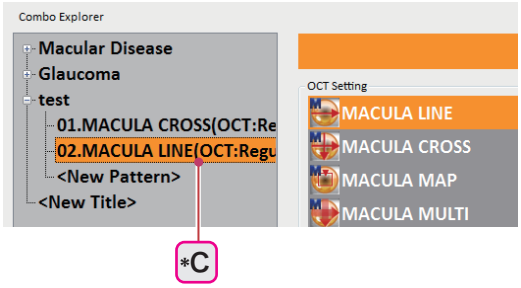
3) To add combo patterns, click <New Pattern>.



A new combo pattern is added. (*C)

4) Other combo patters can be edited and added in the same manner.

4 Click the OK button [OK] .



○ Editing combo setting

1 Open the pull-down menu from “Setting” in the menu bar. Then click “Edit Combo”.

The Combo Edit dialog appears.

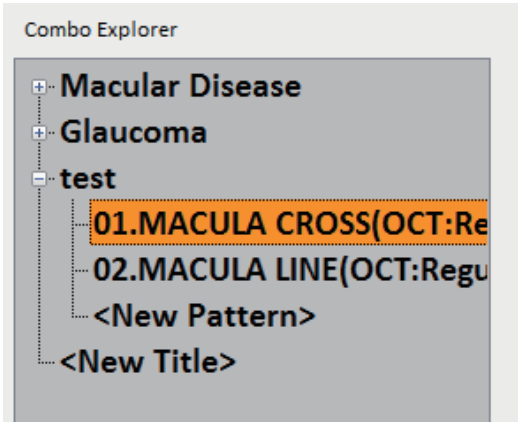
2 Edit the desired combo setting.

1) Click [+] of the combo setting to edit.

The combo setting expands to show the combo patterns in the tree view.

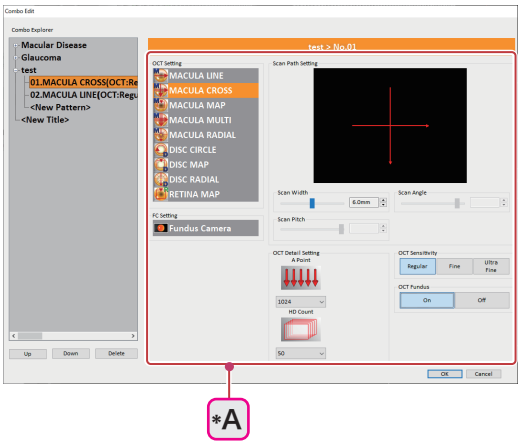
2) Click the combo setting to edit.

The title becomes editable.



3) Edit the selected combo pattern. (*A)

4) To change the order of the combo setting or combo pattern, select the one to move and press the Up button [Up] or Down button [Down] .



3 Click the OK button [OK] .

○ Deleting combo settings and combo patterns

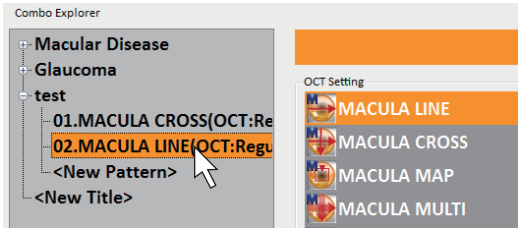
1 Open the pull-down menu from “Setting” in the menu bar. Then click “Edit Combo”.

The Combo Edit dialog appears.

2 Delete the desired combo settings and combo patterns.

1) Click the combo setting or combo pattern to delete.

2) Click the Delete button [Delete] .



3 Click the OK button [OK] .

To cancel the changed settings, click the Cancel button [Cancel] .

○ Factory-set combo setting

Macular Disease												
No.	OCT Setting	A Point	B Point	HD Count	Cross HD Count	Scan Type	Scan Width (mm)	Scan Pitch (mm)	Scan Angle (°)	OCT Sensitivity	OCT Fundus	Fundus Mode
1	MACULA MULTI	1024	-	10	-	Cross	6.0	0.225	-	Regular	On	-
2	MACULA MAP	512	128	-	5	X-Y	9.0	-	-	Regular	On	-
3	Fundus Camera	-	-	-	-	-	-	-	-	-	-	Color

Glaucoma												
No.	OCT Setting	A Point	B Point	HD Count	Cross HD Count	Scan Type	Scan Width (mm)	Scan Pitch (mm)	Scan Angle (°)	OCT Sensitivity	OCT Fundus	Fundus Mode
1	MACULA MAP	512	128	-	5	Y-X	9.0	-	-	Regular	On	-
2	DISC MAP	512	128	-	-	Y-X	6.0	-	-	Regular	On	-
3	Fundus Camera	-	-	-	-	-	-	-	-	-	-	Color

Corneal Disease (optional)												
No.	OCT Setting	A Point	B Point	HD Count	Cross HD Count	Scan Type	Scan Width (mm)	Scan Pitch (mm)	Scan Angle (°)	OCT Sensitivity	OCT Fundus	Fundus Mode
1	CORNEA RADIAL	1024	-	5	-	12	8.0	-	-	Regular	-	-
2	CORNEA CROSS	1024	-	20	-	-	8.0	-	-	Regular	-	-
3	CORNEA LINE	1024	-	50	-	-	8.0	-	0°	Regular	-	-

Glaucoma (optional)												
No.	OCT Setting	A Point	B Point	HD Count	Cross HD Count	Scan Type	Scan Width (mm)	Scan Pitch (mm)	Scan Angle (°)	OCT Sensitivity	OCT Fundus	Fundus Mode
1	CORNEA RADIAL	1024	-	5	-	12	8.0	-	-	Regular	-	-
2	ACA LINE	1024	-	20	-	-	4.0	-	0°	Regular	-	-

4.6 Cleaning

4.6.1 Cleaning the system exterior

If the system cover or the touch screen becomes stained, wipe them with a soft cloth. For severe stains, wipe it off with a soft cloth dampened with neutral detergent diluted with water and wrung well, then dry the wet part with a soft cloth.

⚠ CAUTION

- Do not use any organic solutions such as thinner or alcohol.
- Wipe the touch screen gently with soft cloth. Never press hard objects against or place magnetic objects near the LCD monitor.

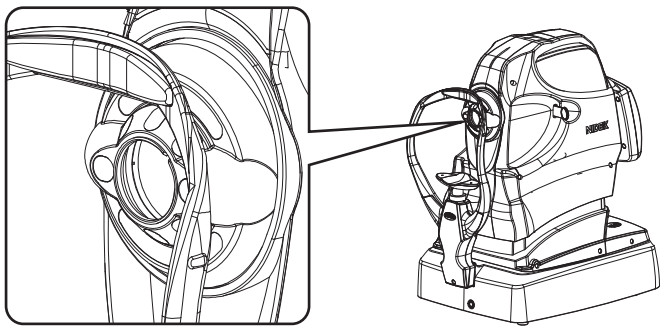
  The touch screen may become damaged. In addition, malfunction of the system may result.
- Do not wipe the LCD monitor with a sponge or cloth soaked with a large amount of liquid.

  If liquid enters the system, the system may fail.

4.6.2 Cleaning the objective lens

Fingerprints or dust on the objective lens compromises the quality of captured images. Check the objective lens for cleanliness before image capture. If necessary, clean it with the procedure below.

1 Remove dust on the objective lens with a blower.



2 Wrap lens cleaning paper around a thin stick such as a chopstick (or cotton swab), and moisten it with a small mount of methanol or alcohol. Then use it to wipe the objective lens.

Note

- Do not use a metal or hard stick. Use one that will not scratch the lens.
- Wipe lightly from the center of the lenses to the outside in a circular motion.
- Do not use rubbing alcohol to clean the lenses.

  If the coating on the lenses is removed, images may not be captured properly.

3 Check if the lens is clean. If soiled areas remain, clean the lens again with new cleaning paper.

4.6.3 Cleaning the anterior segment adapter (optional)

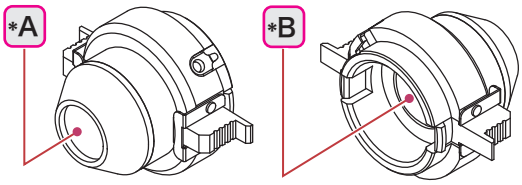
Fingerprints or dust on the anterior segment adapter compromises the quality of captured images. Check the lenses for cleanliness before image capture. If necessary, clean them.

⚠ CAUTION

- The anterior segment adapter or its peripheral parts may come into contact with the patient's eyelashes. If the anterior segment adapter is used for patients with any infectious disease, be sure to clean the anterior segment adapter after image capture with cotton swab moistened with alcohol.
  Secondary infection may result.

1 Remove dust on the lenses with a blower.

The anterior segment adapter is equipped with two lenses: one at the tip (*A), and the other inside (*B).



2 Wrap lens cleaning paper around a thin stick such as a chopstick (or cotton swab), and moisten it with a small mount of methanol, absolute alcohol, or rubbing alcohol. Then use it to wipe the lenses.

Note

- Do not use a metal or hard stick. Use one that will not scratch the lenses.
- Wipe lightly from the center of the lenses to the outside in a circular motion.

3 Check if the lenses are clean. If soiled areas remain, clean the lenses again with new cleaning paper.

4.7 List of Consumables

Product name	Product number	Remarks
Chinrest paper	32903-M047	1 stack
Magnetic forehead rest pad	30611-1520	1 unit Made of ABS resin
Forehead rest pad	15411-M752	1 unit Made of polyester elastomer

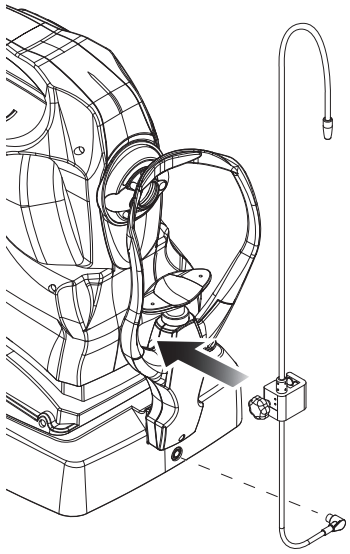
* After using the consumables, prepare spare ones.

4.8 Optional Accessories

4.8.1 External fixation lamp

The external fixation lamp is an optional accessory used for patients who are unable to focus on internal fixation lamp properly. The fixation of the eye that is subject to image capture can be stabilized by having the patient focus on the external fixation lamp with the other eye.

○ Preparation



1 Attach the external fixation lamp to the system main body.

Tighten the knob securely.

2 Connect the cable of the external fixation lamp to the system main body.

Turning on power to the system main body makes the external fixation lamp blink.

○ Operating procedure

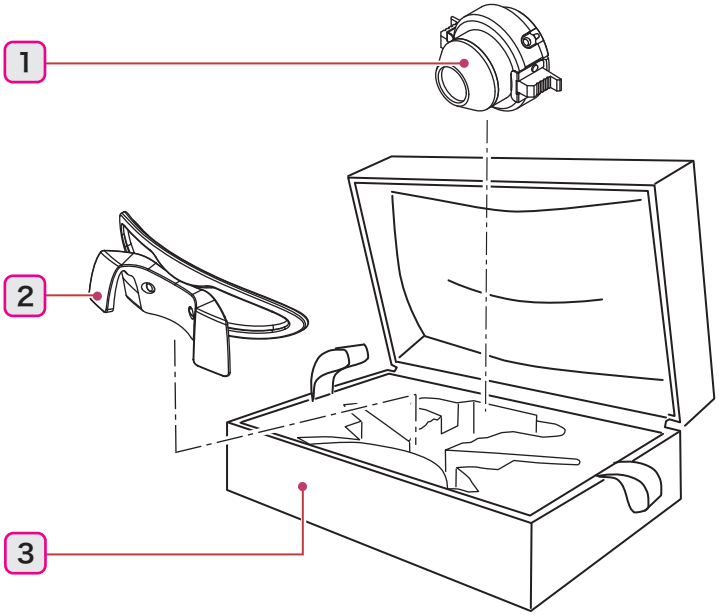
1 Give instructions to the patient.

“Focus on the external fixation lamp with the eye not looking into the device for image capture. Open both of your eyes wide open and focus on the blinking red lamp. Refrain from blinking as much as possible.”

2 Move the external fixation lamp to guide the patient's eye to the desired position.

4.8.2 Anterior segment adapter

The anterior segment adapter is attached over the objective lens of the system main body to capture anterior segment cross-sectional images. It is removed for retinal cross-sectional image capture and color fundus image capture.



1 Anterior segment adapter

Lens unit for anterior segment cross-sectional image capture

2 Spacer for anterior segment image capture

It is an accessory of the system main body. It is not included in the anterior segment adapter.

3 Case

To protect the anterior segment adapter and the spacer for anterior segment cross-sectional image capture from being damaged, store them in the case when they are not to be used.

○ Preparation and operating procedure

"3.3.2 Anterior segment cross-sectional image capture (optional)" (page 95)

5 SPECIFICATIONS AND TECHNICAL INFORMATION

5.1 Specifications

• OCT specifications

Image capture principle	Fundus observation and image capture	OCT Phase Fundus, CCD camera
	Retinal cross-sectional image observation and image capture	Spectral domain OCT
	Eye front observation screen	CCD camera
	Anterior segment cross-sectional image capture (optional)	Spectral domain OCT
OCT light source wavelength	880 nm	
Scan rate (OCT sensitivity: Regular)	For alignment	2.2 fps
	For OCT image capture	70,000 A-Scan/second
Optical resolution	Retinal cross-sectional image capture	Horizontal direction (X-Y directions): 20 µm Depth direction (Z direction): 7 µm
	Anterior segment cross-sectional image capture (optional)	Horizontal direction (X-Y directions): 20 µm Depth direction (Z direction): 7 µm
Image capture angle of view	Fundus surface image capture	40° x 30°
	Retinal cross-sectional image capture	Scan width (X direction): 3 to 12 mm Scan width (Y direction): 3 to 9 mm Scan depth: 2.1 mm
	Anterior segment cross-sectional image capture (optional)	Scan width: 2 to 8 mm Scan depth: 2.1 mm
Digital resolution	Retinal cross-sectional image capture	Horizontal direction (X-Y directions): 3 µm Depth direction (Z directions): 4 µm
	Anterior segment cross-sectional image capture (optional)	Horizontal direction (X-Y directions): 2 µm Depth direction (Z direction): 4 µm
Required pupil diameter	2.5 mm in diameter (3 mm in diameter or larger is recommended.)	

• The device complies with ISO 16971:2015.

• Fundus camera specifications

Type	Non-mydriatic fundus camera
Image capture angle of view	45° (33° for small pupil image capture)
Image capture magnification	x0.42
Resolution	Central area:60 line pairs/mm or more Middle area: 40 line pairs/mm or more Peripheral area: 25 line pairs/mm or more
Dot pitch on fundus	4.4 µm
Required pupil diameter	4 mm in diameter (3.3 mm in diameter for small pupil image capture)
Light source	Xenon flash lamp with a rated power output of 300 W•s at maximum
Flash intensity adjustment range	17 levels from FL1 (F4.0 +0.8 EV) to FL17 (F16 +0.8 EV)
Flash intensity adjustment increments	0.25 EV

• Common specifications

Working distance	45.7 mm (from objective lens to the corneal surface)
Working distance adjustment (for eye front image capture)	Electronic indication of the forward/backward position using the working distance indicator
Image display	8.4-inch color touch screen
Visibility compensation	-33 D to +35 D Without compensation lens: -12 D to +15 D With minus compensation lens: -33 D to -7 D With plus compensation lens: +11 D to +35 D
Internal fixation lamp	Matrix LED internal fixation lamp
Vertical movement	32 mm
Horizontal movement	Forward/backward: 36 mm Right/left: 85 mm
Auto tracking range	Up/down: ±16 mm Right/left: ±5 mm Forward/backward: ±5 mm
Chinrest up/down movement	62 mm
Interface	USB 2.0 (Type B): 1 port USB 3.0 (Type B): 1 port

• Power supply specifications

System main body	AC 100 V to 240 V ±10%, 350 VA, 50/60 Hz

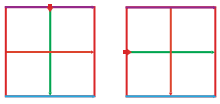
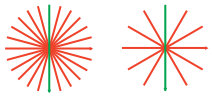
• Dimensions and mass		
System main body	Dimensions	370 mm (W) × 536 mm (D) × 602 mm (H)
	Mass	38 kg (Standard model) 39 kg (Fundus autofluorescence image capture [FAF] model [optional])
Environmental conditions (during use)	Temperature	10 to 35ºC (50 to 95ºF)
	Humidity	30 to 90%
	Atmospheric pressure	800 to 1,060 hPa
	Installation location	Indoors
	Others	A well ventilated place free from hazardous particles, smoke, or fumes A location not exposed to water A level and stable surface free from vibration and shock A location not exposed to strong electromagnetic waves The room can be darkened to the degree that a newspaper can barely be read
• Environmental conditions (during transport and storage)	Temperature	-30 to 60ºC (-22 to 140ºF) (during transport), -10 to 55ºC (14 to 131ºF) (during storage)
	Humidity	10 to 95%
	Atmospheric pressure	700 to 1,060 hPa
• Others	Service life	8 years from the date of initial operation * Proper maintenance, inspection, and consumable parts replacement are necessary.
	Unit per package	1 unit
• Classifications	Protection against electrical shock: Class I ME equipment, Type B applied part	
	Protection against harmful ingress of water or particulate matter: IPX0	
	Method(s) of sterilization: ME equipment that does not contain any part that needs sterilization.	
	Suitability for use in an oxygen rich environment: ME system that is not intended for use in an oxygen rich environment.	
	Mode of operation: Continuous operation	
	Light hazard classification (ISO 15004-2): Group 2	
Accessories to the system		
• Standard accessories	USB 2.0 cable, USB 3.0 cable, power cord (for system main body), dust cover, chinrest paper, fixing pins for chinrest paper, objective lens cap, cap holder, blower, spacer for anterior segment image capture, Operator's Manual, Quick Reference Guide, NAVIS-EX set, RS-330 Capture installation CD, USB 3.0 PCIE ADD IN CARD, retina map dongle and B-scan Denoising Software	
• Optional accessories	Motorized optical table (OT-600BF), external fixation lamp, computer cabinet, anterior segment adapter, isolation transformer, USB 3.0 PCIE ADD IN CARD, OCT-A retina map dongle	

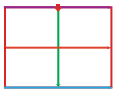
5.2 Glossary and Abbreviations

■ The following terms and abbreviations are used in the system and operator's manual.

○ Glossary

Term	Explanation
ACA LINE	A type of scan line that scans the anterior chamber angle once along a straight line This scan line can only be used when the anterior segment adapter (optional) is used.
Alignment	Moving the image capturing unit to the optimum position for image capture
A-scan	Obtaining image information for one vertical line of an OCT image
Auto shot	Automatic image capture that starts as soon as alignment and focusing become the optimum conditions. Depending on the status of the patient's eye such as blinking, captured images may become unclear, or image capture may not be performed at all.
Auto tracking	A function that automatically controls the up, down, right, and left movements for alignment and the forward and backward movements for focusing
B-scan	Obtaining image information along the horizontal lines (parallel with fundus) orthogonal with the A-scan line of an OCT image. The B-scan resolution can be set with the number of A-scan points.
CORNEA CROSS	A type of scan line that scans the patient's cornea in two directions, vertically and horizontally, to obtain OCT images This scan line can only be used when the anterior segment adapter (optional) is used.
CORNEA LINE	A type of scan line that scans the patient's cornea once along a straight line to obtain an OCT image This scan line can only be used when the anterior segment adapter (optional) is used.
CORNEA RADIAL	A type of scan line that scans the patient's cornea radially at equal angles to obtain OCT images There are two types of scan lines: 12 lines with 15° intervals, and 6 lines with 30° intervals. This scan line can only be used when the anterior segment adapter (optional) is used.
DISC CIRCLE	A type of scan line that scans along a circle centered around the optic disc in the order of “Temporal“, “Superior“, “Nasal“, “Inferior“, and “Temporal“ to obtain OCT images.
DISC MAP	A type of scan line that scans the patient's fundus vertically and horizontally for the specified range centered around the optic disc to obtain OCT images and map data.
DISC RADIAL	A type of scan line that scans the patient's fundus radially at equal angles with the optic disc in the center to obtain OCT images. There are two types of scan lines: 12 lines with 15° intervals, and 6 lines with 30° intervals.
Electronic working dot	Used as an alignment reference.

Term	Explanation
External fixation lamp (optional)	The external fixation lamp is an optional accessory used for patients who are unable to focus on internal fixation lamp properly. The fixation of the eye that is subject to image capture can be achieved by having the patient focus on the external fixation lamp with the other eye.
FC	FC stands for fundus camera, and means the color fundus image capture in this operator's manual.
Fundus autofluorescence image capture (optional)	FAF (Fundus autofluorescence) image capture An image capture mode to capture fundus images using the characteristic reaction of lipofuscin in the retinal pigment epithelium. With the system, green light is used for excitation.
HD scan	HD stands for high definition. The HD scan is a processing used to eliminate noises in the captured image by adding and averaging multiple OCT images. For this processing, B-scan is repeated multiple times. As the number of HD scan images increases, the time required for image capture also increases. The number of times the HD scans is performed is set with the HD number setting.
Low-light image capture	An image capture mode used to capture properly bright images with lower flash intensity by automatically adjusting the ISO speed. This mode is used for patients whose pupil easily contracts.
MACULA CROSS	A type of scan line that scans the patient's fundus in two directions, vertically and horizontally, to obtain OCT images 
MACULA LINE	A type of scan line that scans the patient's fundus once along a straight line to obtain an OCT image
MACULA MAP	A type of scan line that scans the patient's fundus vertically and horizontally for the specified range to obtain OCT images and map data. In accordance with the setting, OCT image capture is performed along the cross lines that are formed in reference to the center of the scan range. 
MACULA MULTI	A type of scan line that scans the patient's fundus along five scan lines either vertically or horizontally, or both, to obtain OCT images 
MACULA RADIAL	A type of scan line that scans the patient's fundus radially at equal angles with the macula in the center to obtain OCT images There are two types of scan lines: 12 lines with 15° intervals, and 6 lines with 30° intervals. 
OCT Phase Fundus image	A fundus image created using three-dimensional data of an OCT fundus image
OCT setting	Setting of scan lines used for OCT image capture
Optical interferometer	Using the principle of the Michelson interferometer, retinal cross-sectional images can be obtained by measuring an interference phenomenon caused when the laser beams reflected from the fundus are combined with the reference laser beams. The near infrared light from a super luminescent diode is used as the observation light, and is divided with a fiber coupler. Interference light is generated when the optical path of the reference light is approximately equal to that of the observation light reflected from the fundus. The interference light is dispersed through a diffraction grating to be received by a photodetector. The received signals are calculated to form a cross-sectional image of the retina.

Term	Explanation
Optical working dots	Bright spots displayed on the right and left sides of the screen They are used for fine alignment or focusing, or when the electronic working dot cannot be displayed. For the alignment, the optical working dots need to be brightly displayed and aligned symmetrically to the optical working dot charts.
Panorama image capture	Images of multiple positions of the fundus are captured as specified with two to nine internal fixation lamps in the preset order. With NAVIS-EX, a pseudo-wide-range fundus image (panorama image) can be composed by arranging multiple fundus images of different positions.
Polarization	The polarization of the light reflected from the retina and that of the reference light are aligned to increase the signal strength for obtaining high quality OCT cross-sectional fundus images.
Required pupil diameter	An indication of the pupil diameter required for proper image capture
RETINA MAP	A type of scan line that scans the patient's fundus in the area that includes both the optic macula and optic disc to obtain OCT images and map data. This scan line can only be used when the retina map dongle is used. 
Small pupil image capture	An image capture mode used to capture images of the eye with the pupil diameter smaller than the required pupil diameter mark
SSI	SSI stands for signal strength index, and evaluates the image signals and back noise in OCT image capture. SSI presents the evaluation on a scale of 10. As the value becomes higher, the obtained OCT image also becomes finer
Stereo image capture	Images of the same fundus are captured from two different positions: one from the temporal side and the other from the nasal side. The two captured images are saved in pairs. With the stereo viewer (optional function of NAVIS-EX), the two images offer a stereoscopic view of the image.
Z-Pos (Z position)	Position of the retinal cross-sectional image in the OCT image. Adjusting the Z position to the P (posterior) side moves the OCT retinal cross-sectional image upward. Adjusting it to the A (anterior) side moves the image downward.

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 system is potentially hazardous. The longer the duration of exposure and the greater the number of pulses, the greater the risk of ocular damage becomes.

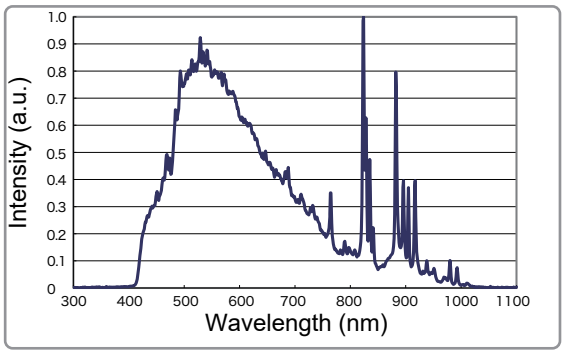
  Exposure to light from this system when operated at maximum output will exceed the safety guideline after 5.0×10^6 seconds for the fundus illumination LED, 4.0×10^6 seconds for the focus split, 2.0×10^9 seconds for the working dot, 8.6×10^7 seconds for the internal fixation lamp, 2.4×10^6 seconds for the external fixation lamp, 9142 pulses for the light source of color fundus image capture, and 9406 pulses for the light source of fundus autofluorescence image capture.

Note

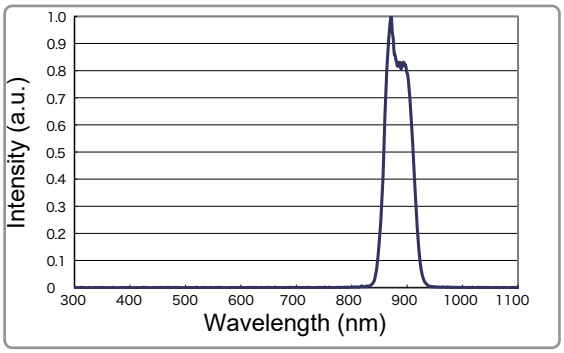
- The exposure time and number of pulses from all light sources is cumulative and additive.
- If the intensity of any of the light sources is reduced to 50% of the maximum intensity, the exposure time or number of pulses for that light source to reach the exposure guideline is doubled. This linear relationship can be used to determine the time to reach the exposure guideline for the combination of light sources at various intensity settings.
- The weighted retinal radiant exposure guideline is 10 J/cm^2.

● Spectrum output during image capture (with all the light sources at the maximum light intensity)

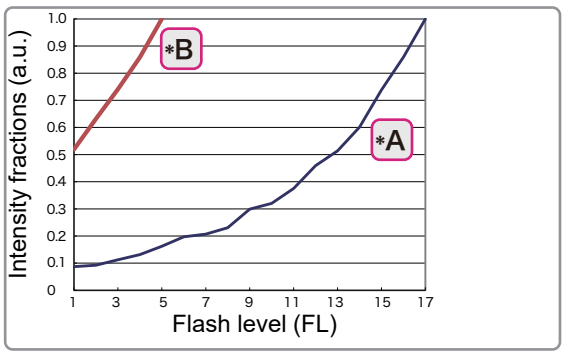
Color fundus image capture



OCT image capture



● Relationship between flash level and maximum light intensity during color fundus image capture (*A) and fundus autofluorescence image capture (optional) (*B) (regarding the maximum intensity as 1)



5.4 EMC (Electromagnetic Compatibility)

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

⚠ WARNING

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

  The following are examples of electromagnetic disturbance sources:
  - Induction cooking appliance and ovens
  - RFID readers
  - Electronic article surveillance (EAS) systems
  - Sponge detection systems
  - Equipment used for position detection (e.g. in catheter labs)
  - Wireless power transfer charging systems for electrical vehicles

○ Specified cable

Part name	Cable Shielded	Ferrite Core	Length (m)
Power cord for RS-330	No	No	2.5
USB 2.0 cable	Yes	Yes	2.0
USB 3.0 cable	Yes	No	2.0
External fixation lamp (optional)	Yes	No	0.4

○ Specified multimedia equipment

Name	Standard compliance
Computer	CISPR 32 Class B

○ Essential performance

Retinal cross-sectional image capture and color fundus image capture

◆ 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	3 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 bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles