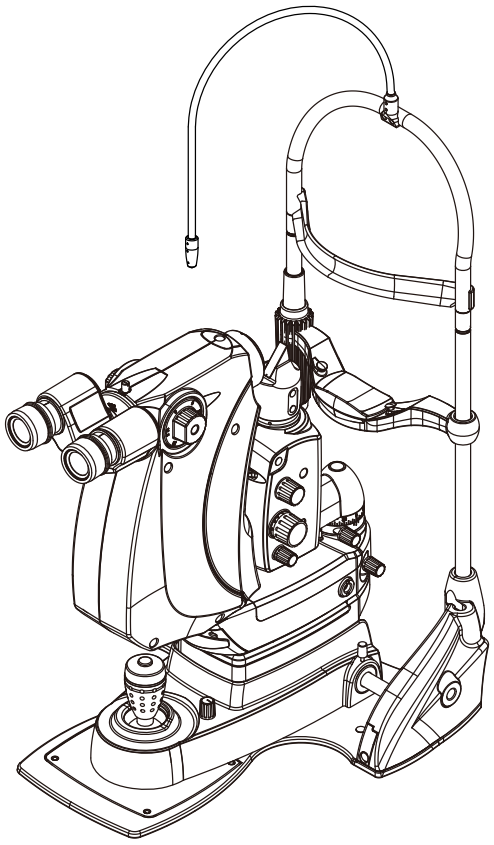
NIDEK

# OPHTHALMIC YAG LASER SYSTEM

# YC-200

*OPERATOR'S MANUAL*



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

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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0344


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# Before Use

This operator's manual describes the operating procedure, safety precautions, maintenance, and specifications of the NIDEK Ophthalmic YAG Laser System YC-200. Be sure to read the operator's manual prior to use of the device to understand the safety precautions and operating procedures thoroughly.

Keep this manual handy for reference.

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

YC020-P902-B2

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## 11. SEVERABILITY

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## 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.

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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.

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# 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 use of the device to understand the safety precautions and operating procedures thoroughly.<br>Keep this manual handy for reference. |

## 1.2 Signal Words for Safety

| |
|---|
| In this manual, signal words are used to designate the degree or level of safety alerting. The definitions are as follows. |
| ⚠ **WARNING**<br>Indicates a potentially hazardous situation which, if not avoided, may result in death or serious injury. |
| ⚠ **CAUTION**<br>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.<br>Safety precautions must be strictly followed at all times. |

# 1.3 Cautions for Administration and Controlled Area

## Administration

### ⚠ CAUTION

- The medical institution in which the device is to be used must appoint at least one qualified administrator and one sub-administrator.
- Administrators are responsible for the storage and administration of the device within the area in which the device is to be used.
- Administrators should appoint personnel who can use the device, conduct necessary training, and provide them with the latest information (seminars, workshops, and conferences may be regarded as a training).
- Authorized personnel must follow the instructions of the administrators.
- Administrators should prepare and keep a registered user list.
  *"5.4 Administration List" (page 97)*
- Authorized personnel must be appointed by the administrators and are required to thoroughly understand the operating procedures and safety control of the device.

## Controlled area

### ⚠ CAUTION

- A controlled area in which the device is to be used must be specified by the medical institution. Indications specifying the controlled area are required (Controlled area indication).
  Attach the DANGER label to the entrance of the controlled area.
  *"2.9 Packed Contents" (page 21)*
- In the controlled area, notices that are necessary for administration of the device such as the laser name, warnings, and other information should be indicated (Warning indications).
- Any persons entering the controlled area (except the authorized personnel specified in the registered user list) are required to obtain permission from the administrators, understand the precautions, and take necessary protections prior to entering the controlled area.
- It is recommended that all personnel entering the controlled area take a visual acuity test before entering and after leaving the controlled area to make sure that their visual acuity is not impaired.

## Preparation of controlled area facilities and equipment

### ⚠ CAUTION

- Administrators should prepare the facilities necessary for introducing the device.
- Administrators should prepare the facilities and all equipment necessary for maintenance and safety control of the device.
- Administrators should regularly conduct maintenance and checks as described in this operator's manual, and record the results.

# 1.4 Usage Precautions

## Installation

### ⚠ WARNING

- Only service personnel trained by NIDEK can install and adjust the device.
- Ensure that there is no flammable anesthetic gas in the operating room.
  Laser emission may cause fire or explosion.
- Be sure to connect the power plug to a grounded power outlet.
  Electric shock or fire may result from device malfunction or electric leakage.

### ⚠ CAUTION

- Install the device in an environment that meets the specifications.
  *"5.1 Specifications" (page 87)*
- Install the device in a location that is not exposed to water or rain.
  Malfunction may result.
- Be sure to use a (hospital grade) power outlet which meets the power specification requirements.
  The device may not work properly, or malfunction or fire may result.
- Do not use a power cord other than the one provided. Also do not connect the provided power cord to any other device.
- Install the device so that the outlet that the power plug is inserted into is easily accessible during use. In addition, ensure that the power plug can be disconnected without the use of any tool.
  Failure to do so may interfere with disconnecting the power from the input power source in case of an abnormality.
- Securely connect the power cord and cables to the specified connectors.
  Malfunction may result.
- Do not coil the power cord or cables too tightly, or crush or pinch them with heavy objects.
  Electric shock or fire may result.
- If the internal wires are exposed, replace the cords and cables with new ones.
  Electric shock or fire may result.
- Immediately replace the cords and cables if the power is intermittent, or the cord or plug is hot to touch.
  Malfunction or fire may result.
- Do not drag the device by the power cord or cables.
  Cables may break and the device may topple causing injury or malfunction.

## 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.
- Do not use this device for any purposes other than the intended purpose.
  *"2.2 Intended Use" (page 17)*
- Use of this device is limited to ophthalmologists.
  Unanticipated adverse events and adverse device effects may result.
- Be sure to read the operator's manual prior to operation of the device to understand the safety precautions and operating procedures thoroughly.
  Use of the device outside the scope may cause unanticipated adverse events and adverse device effects.
- Do not perform operations by procedures different from those described in the operator's manual.
  Control and adjustment of the device in procedures outside the scope may cause exposure to hazardous laser radiation.
- Use the device with at least one assistant in the room.
  This is in precaution to a case such as electric shock. It is desirable that the assistant is trained in resuscitation.
- Backup measures for the scheduled surgery must be prepared.
  This is in precaution to device failure.
- Pay attention when using the device with other equipment that comes into contact with the patient.
  Electromagnetic wave or other interference may cause a danger.
  Using an electrocautery for coagulation may cause electric shock or burns to the contact area.
- Do not use accessories other than those specified by NIDEK.
  Use of the device outside the scope may cause unanticipated adverse events and adverse device effects.
- Do not modify or touch the device interior.
  Electric shock or malfunction may result.
- Have personnel in the operating room wear safety goggles. Instruct them never to gaze directly at the treatment beam even while wearing the safety goggles.
  YAG treatment beam: Wavelength 1,064 nm, OD > 7, 950-1080 D LB6 + IRM LB7 (EN207)
  SLT treatment beam: Wavelength 532 nm, OD > 7, 315-532 DIRM LB6 (EN207)
- When the device is not in use, remove and store the keycard in a secure place.
  Accidents or information leakage caused by unauthorized personnel may result.
- When connecting to other devices via a networked medical system, confirm that no hazard affects patients, operators, or third parties. In addition, when a device is added or removed from the network, or the device is updated or upgraded, confirm that no hazard affects patients, operators, and third parties in the same manner.

## During use

### ⚠ WARNING

- Before using the device, perform operation check and record the results. If abnormal conditions are encountered during the check, do not use the device.
  If the device is used under abnormal conditions, intended results may not be achieved. Also unanticipated malfunctions or health hazards due to improper diagnosis may occur.
- Check the setting values before emitting the treatment beam.
  The treatment beam may be emitted in unintended settings.
- Start the treatment beam from the lowest energy output, then gradually increase the energy until the desired effect is obtained. Be sure to return the output energy to the lowest after every operation.
  Excessively intense treatment beam may be emitted.
- When laser beam emission is not intended (such as during observation of an eye), set the device to STANDBY mode so that laser emission is not possible.
  Accidental exposure to the laser beam may result.
- Before connecting and removing the power cord from the power outlet, confirm that the master switch is turned off.
  Electric shock or malfunction may result.
- If any abnormal indication (other than laser beam emission conditions) is displayed on the control box, follow the applicable instructions.
  *"4.2 Error Messages and Remedies" (page 67)*
- Before lowering the table, check that there are no objects that may get caught in it.
  The feet of the patient or operator may be caught and may be injured.

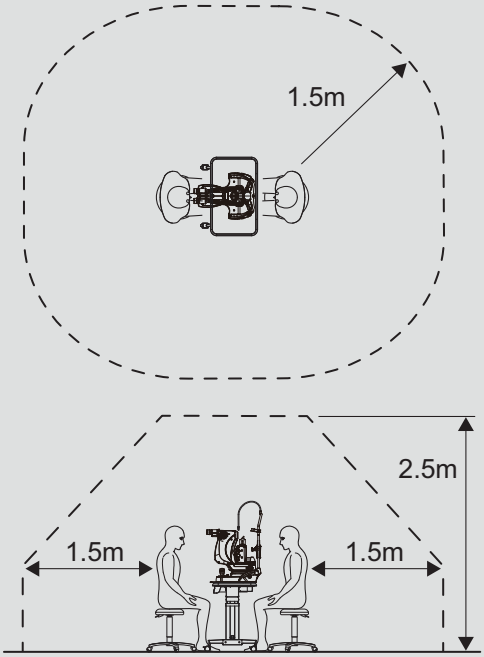
### ⚠ CAUTION

- Do not perform servicing or maintenance on the device during use.
- Prior to surgery, provide the patient with sufficient information about the surgery purposes and methods, expected results, and possible adverse events.
- If the illumination light is not perceived, stop the surgery.
  The affected area may not be observed. Unanticipated adverse effects on laser beam emission may result.
- Always pay attention to the direction of the aiming beam.
  When the treatment beam is applied to tissue, damage to the cornea and such, blindness, pain of skin, or burn injury may result.
- Do not look directly at the aiming beam or point the beam toward others.
  Unnecessary exposure to the laser beam may result.
- Before emitting the treatment beam, confirm that there is no reflective object in the laser optical path.
  Exposure to the reflected laser beam may result.
- Take care not to catch hands or fingers in moving parts. Be sure to also caution patients.
  Hands or fingers may be pinched and may result in injury.
- When the patient comes off from the device, instruct the patient not to stand up while holding the chinrest.
  The device may topple over resulting in injury.
- If the device fails, disconnect the power cord from the power outlet without touching the device interior.
  Contact NIDEK or your authorized distributor.

### ⚠ CAUTION

- If power failure or device failure occurs while the patient is wearing the head belt, loosen the head belt immediately.
  Unanticipated malfunctions or adverse events 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.
  The patient environment is the volume of space in which contact can occur between the patient and any part of the device (including connecting devices) or between the patient and any other person(s) touching the device (including connecting devices).




## After use

### ⚠ CAUTION

- Clean the forehead rest, chinrest, grips, and head belt for each patient. Use alcoholic disinfectants if necessary.
  When using the chinrest paper, remove one sheet of paper.

- After using the device, turn it off and cover it with its dust cover.
  Dust may affect the performance of laser beam emission.

- After using the device, disconnect the power cord from the power outlet.

## During transport

### ⚠ CAUTION

- Before moving the device to another room, tighten the knobs to secure the device.
  Hands or fingers may be pinched and may result in injury.

- Store the device in an environment that meets the specifications during transport and storage.
  *"5.1 Specifications" (page 87)*

- Before transporting the device, pack it in the packaging material.
  Pack it with the moving parts locked and the slit opened.
  Malfunction may result.

- Do not bump the device during transport.
  Optical axis may be shifted.

### ⚠ CAUTION

- Care should be taken so that the temperature varies as little as possible during transport.
  Changes in temperature may result in condensation inside the device or adversely affect the functionalities.

## Maintenance



### ⚠ CAUTION

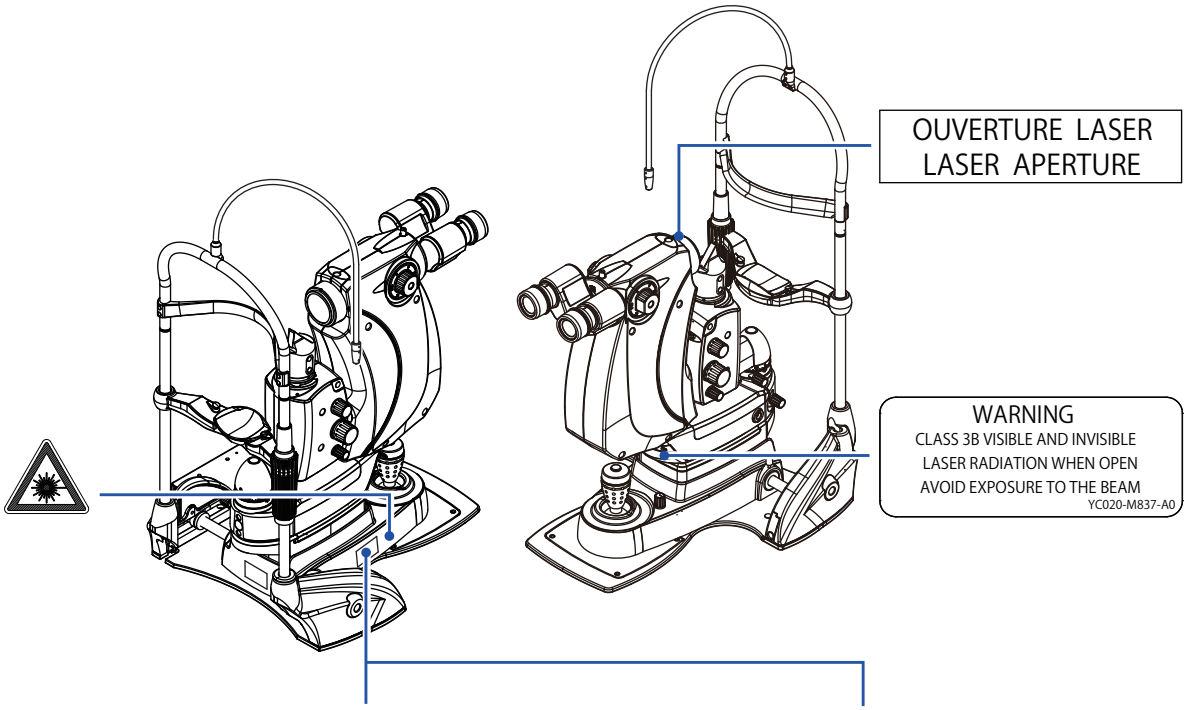
- Only service personnel trained by NIDEK can repair the device.
  NIDEK assumes no responsibility for any adverse events resulting from improper servicing.
- To ensure the continued safe use of the device, the manager of this device must make sure that maintenance and preventive inspection are performed 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.
- 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.
- It is recommended to replace the device before its service life expires.
  Even with proper maintenance and check, after the expected service life, the device reliability or safety may become degraded and fail to achieve the target values.

## Disposal

### ⚠ CAUTION

- When disposing of the device, contact NIDEK or your authorized distributor.
- Observe the local ordinances and recycling plans concerning disposal and recycling. Especially when disposing of lithium battery, printed circuit board, plastic parts containing brominated flame retardant, LCD, and power cord used internally, observe the instructions of local governments.
  For details on local ordinances, contact your local governments.
- When disposing of packaging materials, sort them by material and dispose according to the local ordinances and recycling plans.

# 1.5 Labels and Symbols




YC-200 YC-200 S plus

| | | | |
|---|---|---|---|
| | Refer to the operator's manual. | | Type B applied part<br>The applied parts of the device are the forehead rest and chinrest. |
| | "OFF" (power) | | "ON" (power) |
| | Alternating current | | Start (of action) |
| STOP | Emergency laser stop | | Warning; Laser beam<br>Background color: Yellow |
| | Manufacturer | | Date of manufacture |
| | Indicates that this product is to be disposed of in a separate collection of electrical and electronic equipment in EU. | MD | Medical device |
| EC REP | EU authorized representative | SN | Serial number |

| | | | |
|---|---|---|---|
| UDI | Unique device identifier | REF | Catalog number |
| CH REP | Swiss authorized representative | | |

# 2 INTRODUCTION

## 2.1 Outline

This device is an ophthalmic pulsed laser system using a 1,064 nm Q-switched pulsed Nd: YAG laser as the treatment beam source.

Two types are available, differing in the available types of laser emission.*1

The operation mode available differs depending on the type.

| Type name | Emitted laser (wavelength) | Operation mode available |
|---|---|---|
| YC-200 | Nd: YAG laser (1,064 nm) | YAG mode*(page 30)* |
| YC-200 S plus | Nd: YAG laser (1,064 nm)<br>SLT laser (532 nm) | YAG mode*(page 30)*<br>SLT mode*(page 33)* |

## 2.2 Intended Use

The OPHTHALMIC YAG LASER SYSTEM YC-200 is indicated for the performance of posterior capsulotomy, pupillary membranectomy, iridotomy (hole in the iris) and selective laser trabeculoplasty in phakic, aphakic and pseudophakic subjects.

## 2.3 Intended Patient Population

- Age
  Infants to elderly (for whom the chinrest can be used)
- Health condition
  Patient with eye disease requiring any of the treatments described in the intended use
- Conditions - Visual function
  One or both eyes have disease.

## 2.4 Intended User Profile

Ophthalmologists

*1. This operator's manual describes the device using the YC-200 illustration.

# 2.5 Intended Use Environment

Medical facility

**⚠ CAUTION**

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

## 2.6 Principles

This device uses passive Q-switching for laser oscillation. With passive Q-switching, the device first accumulates sufficient energy within the laser cavity then emits laser pulses of high peak power for extremely short durations by use of the Q-switched optical element which changes between transparent and opaque according to the accumulation of energy.

- YAG mode

  The emitted YAG laser beam becomes coaxial with the aiming beam in the optical system within the laser system and converges at the intraocular target such as the posterior lens capsule after being emitted from the aperture of the device toward the patient's eye. When the YAG laser beam temporarily converges at a spot, and the power density exceeds a certain degree, plasma is formed. Sudden expansion and heating of the plasma generates shock waves. The shock waves destroy fine tissue around the focal point. In addition, the formed plasma absorbs and scatters the incident light. This feature protects the tissue posterior to the focal point.

  A red diode laser (wavelength: 635±5 nm) is used for the aiming beam that indicates the position to which the YAG laser beam is to be emitted. The device was designed so that the aiming beam becomes coaxial with the YAG laser beam in the optical system in the laser system, and that the spot where the two alignment spots coincide becomes the target of the YAG laser beam.

- SLT mode (YC-200 S plus)

  The emitted YAG laser beam is converted to a 532 nm green laser beam (hereafter SLT laser beam) by means of a wavelength transducer within the device. In addition, it becomes coaxial with the aiming beam in the optical system within the laser system and is irradiated so that the spot diameter becomes 400 µm at the intraocular target such as open anterior chamber angle after being emitted from the aperture of the device toward the patient's eye. Selectively emitting the SLT laser beam onto the anterior chamber angle affects pigmented cells in the tissue to lower the intraocular pressure without destroying the affected tissue (less-invasive).

  A red diode laser (wavelength: 635±5 nm) is used for the aiming beam that indicates the position to which the SLT laser beam is to be emitted. The device was designed so that the aiming beam becomes coaxial with the SLT laser beam in the optical system in the laser system, and that the laser beam converges with the 400 µm laser emission size at the target.

## 2.7 Precautions in Patient Selection

Caution should be taken when using the device in regards to patients with the following conditions:

- Posterior capsulotomy when the IOL has become strongly adhered to the posterior capsule
- Patients with progressive eye disease
- Patients who have difficulty in eye fixation due to nystagmus or have a condition that may induce nystagmus
- Patients with opacity of the aqueous humor or cornea
- Patients whose intraocular lens is not sufficiently fixed after the surgery due to posterior capsule rupture or zonular rupture
- Patients with acute attack of primary angle closure (with corneal edema)
- Patients with advanced glaucoma with progressed visual field loss

## 2.8 Adverse Events and Adverse Device Effects

Possible adverse events and adverse device effects may include, but are not limited to the following:

● Adverse device effects

If any abnormality is found with the device during the pre-use check, do not use the device.

If the device fails, intended treatment results may not be obtained, and health hazards or unexpected adverse events described in [Adverse events] below may result.

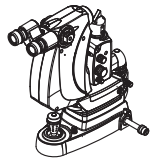
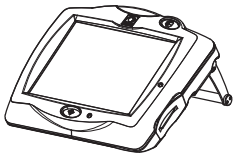
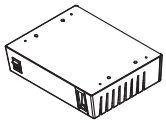
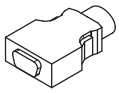
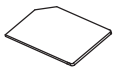
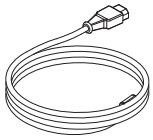
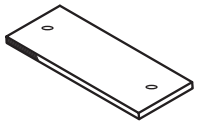
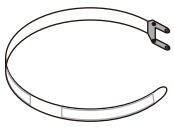
● Adverse events

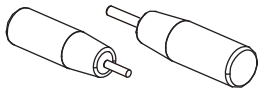
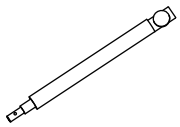
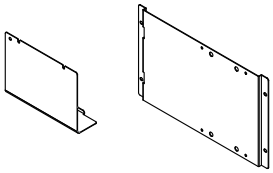
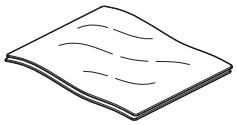
Possible adverse events (complications) may include, but are not limited to the following:

- Increased intraocular pressure
- Hyphema
- Bullous keratopathy
- Localized cataract
- Closure of perforating wound
- Pupillary block
- Iris injury
- Intraocular lens malpositioning and intraocular lens drop into the vitreous chamber
- Corneal burn
- Corneal endothelial damage
- Retinal detachment
- Ache
- Cystoid macular edema
- Anterior chamber inflammation
- Redness
- Corectopia
- Corneal opacity
- Irritation such as iritis, hyalitis, and uveitis
- Posterior synechia
- Peripheral anterior synechia (PAS)
- Corneal edema
- Damage to the intraocular lens
- Effects of erroneous irradiation to the retina
- Scleral perforation
- Macular hole
- Endophthalmitis
- Conjunctival hyperemia
- Anterior chamber angle hemorrhage
- Choroidal effusion
- Eye pain

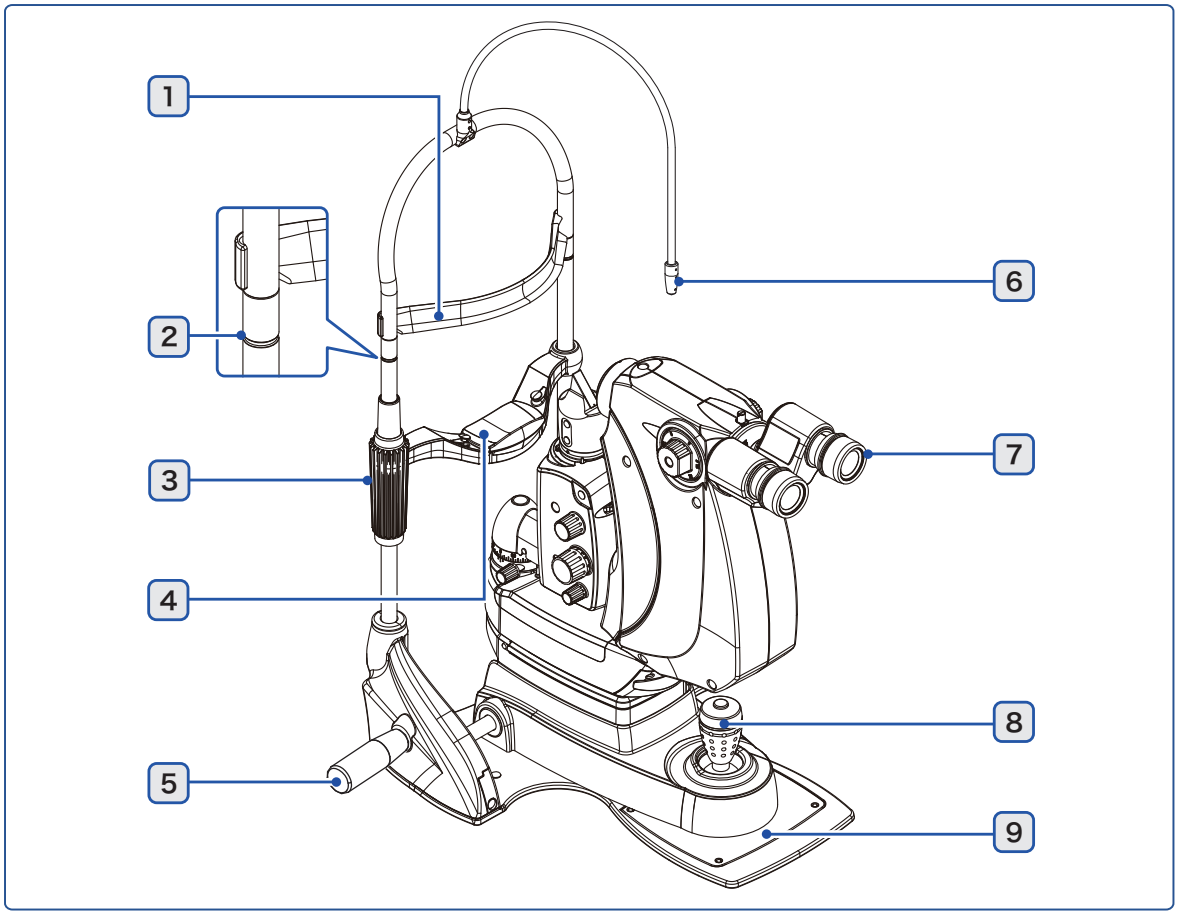
# 2.9 Packed Contents

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

| | Part name | Quantity | Appearance |
|---|---|---|---|
| ☐ | Main body | 1 unit |  |
| ☐ | Head rest | 1 unit |  |
| ☐ | Control box | 1 unit |  |
| ☐ | Connector box | 1 unit |  |
| ☐ | Remote connector plug | 1 unit |  |
| ☐ | Keycard | 1 unit |  |
| ☐ | Power cord | 1 unit |  |
| ☐ | Chinrest paper | 2 units |  |
| ☐ | Head belt | 1 unit |  |

| | Part name | Quantity | Appearance |
|---|---|---|---|
| ☐ | Grips | 1 set |  |
| ☐ | Focusing rod | 1 unit |  |
| ☐ | Attachment plates | 1 set |  |
| ☐ | Arm rest | 1 unit |  |
| ☐ | Cap | 1 unit |  |
| ☐ | Dust cover | 1 unit |  |
| ☐ | DANGER label | 1 unit |  |
| ☐ | Operator’s Manual | 1 volume |  |

# 2.10 Device Configuration




**1 Forehead rest**

**2 Eye level marker**

The patient's eyes are aligned to this height. Align the position by adjusting the height of the chinrest.

**3 Chinrest elevation control**

Adjusts the height of the patient’s chin.

**4 Chinrest**

**5 Grips**

Patients hold them.

**6 Fixation lamp**

Used to steady the patient's visual axis by having the patient focus on the lamp. The position of the fixation lamp can be adjusted by the flexible arm.

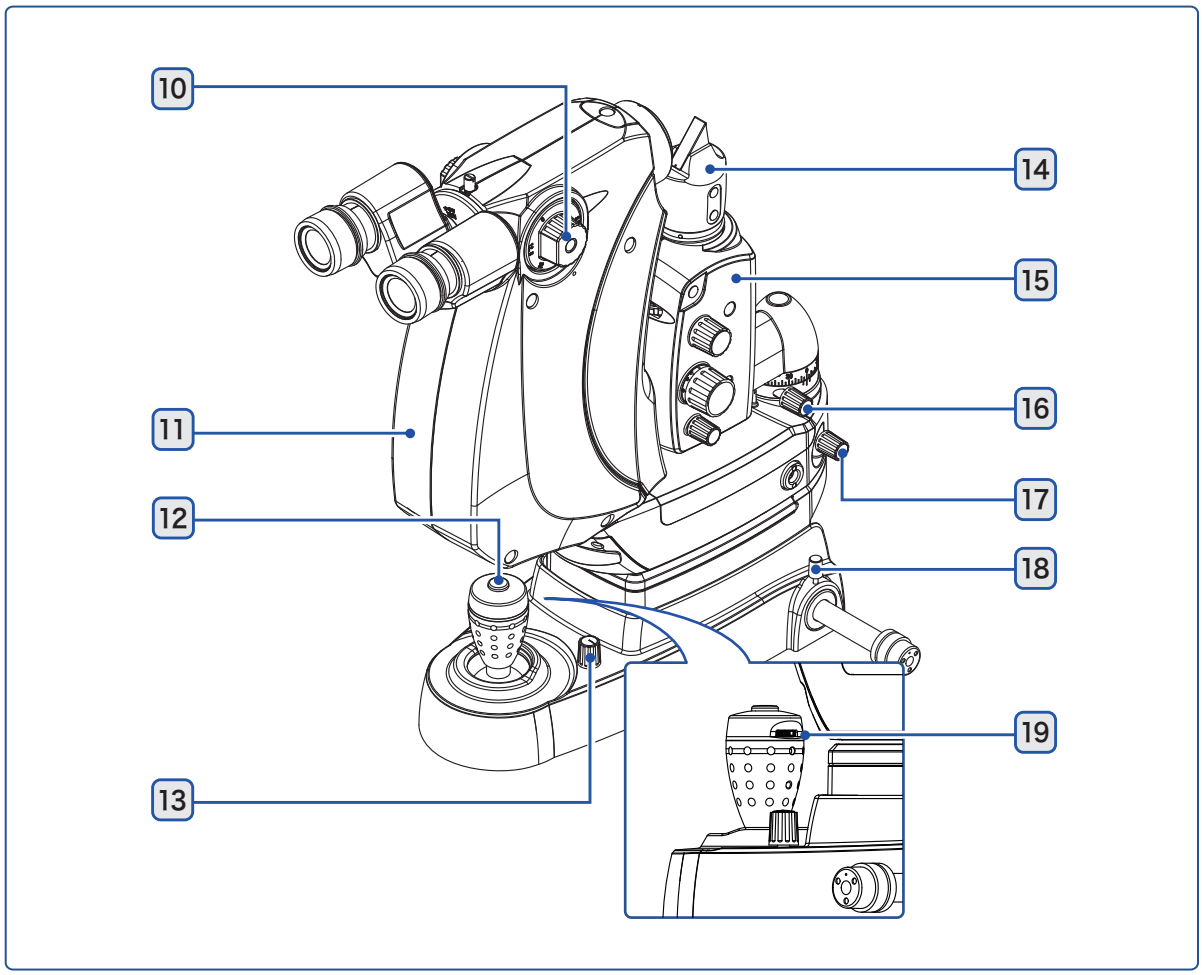
**7 Microscope**

**8 Joystick**

Used for alignment and focusing.

By manipulating the joystick right and left, adjust right and left movement. By rotating the joystick, adjust up and down movement. Adjust the focus with forward and backward movements.

**9 Slide plate**




**10 Magnification changer**

Used to select the total magnification of the microscope.

**11 Microscope arm**

**12 Hand switch**

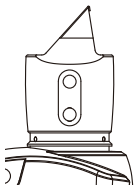
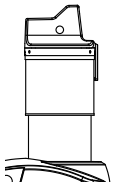
Used to emit the treatment beam. The beam is not emitted in STANDBY mode.

**13 Illumination control**

Used to adjust the intensity of the illumination light.

**14 Illumination tower**

Emits the illumination light rays that became parallel in the illumination optical system onto the affected area.

| | |
|---|---|
|  |  |
| YC-200 | YC-200 S plus<br>Equipped with a function to change the upward angle of the illumination light (tilting function)<br>(Rotating the illumination tower changes the upward angle.) |

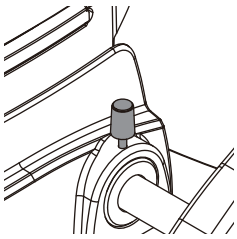
**15 Illumination unit arm**

**16 Illumination unit arm fastening knob**

**17 Microscope arm fastening knob**

**18 Base unit fastening knob**

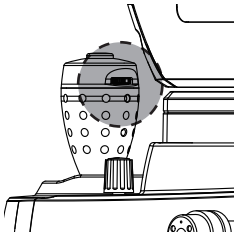
Used to fasten the device so that the device may not move horizontally.

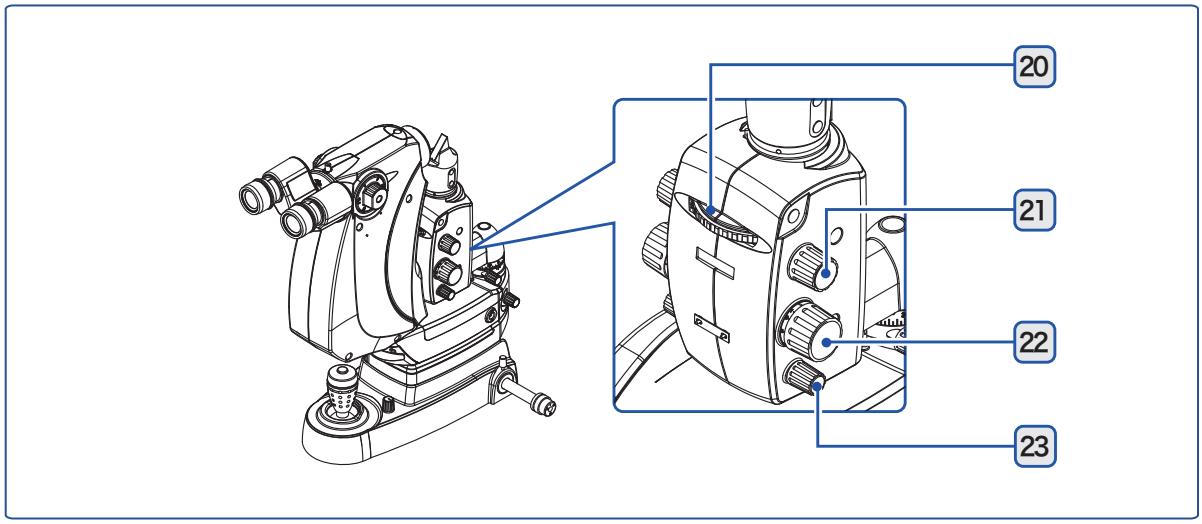




**19 S-Switch**

An auxiliary switch built in the joystick. Three functions can be assigned as desired.






**20 Filter changer**

Used to insert a filter into the illumination optical path.

**21 Slit rotation control**

Used to rotate the slit. A click is felt in the horizontal and vertical axes.

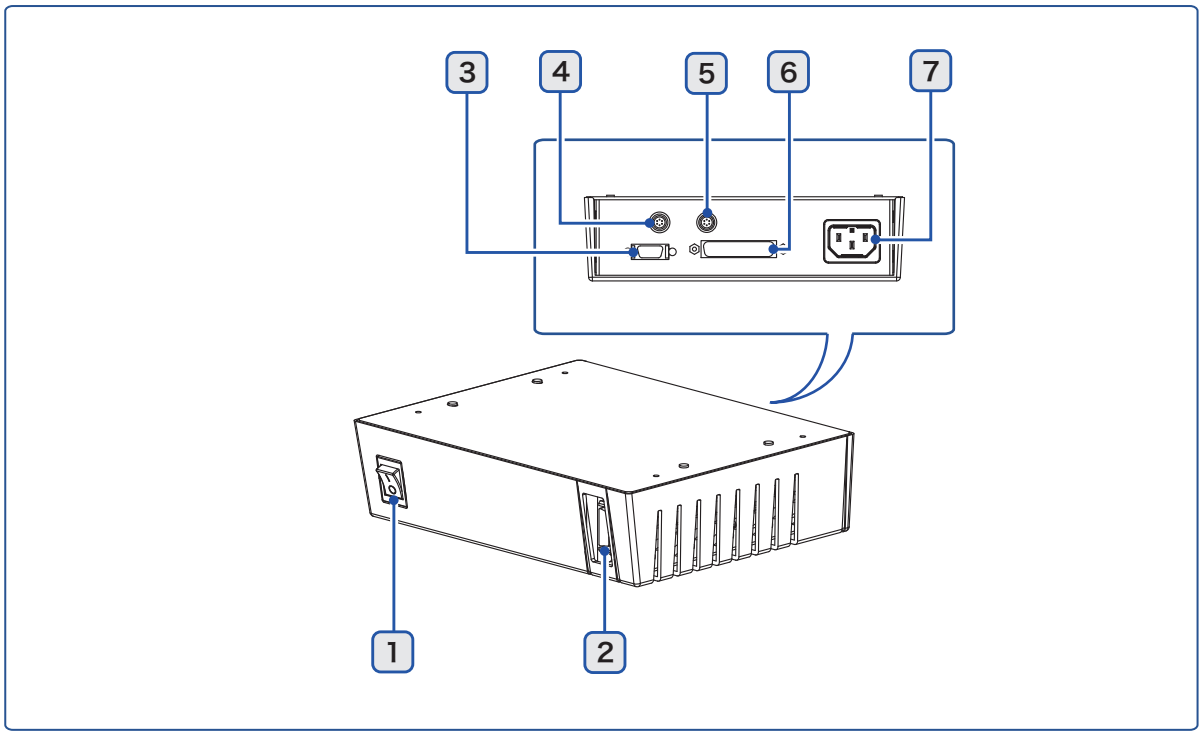
**22 Slit width control**

Used to adjust the slit width of the illumination light.

**23 Slit length control**

Used to adjust the aperture diameter or slit length of the illumination light.

## 2.10.1 Connector box




**1 Master switch**

**2 CB connector**

The control box cable is connected here.

**3 REMOTE connector**

An external switch for the remote interlock is connected here. If no external switch is to be used, insert the remote connector plug.

**4 Foot switch connector**

The optional foot switch cable is connected here.

**5 Fixation lamp connector**

The fixation lamp cable is connected here.

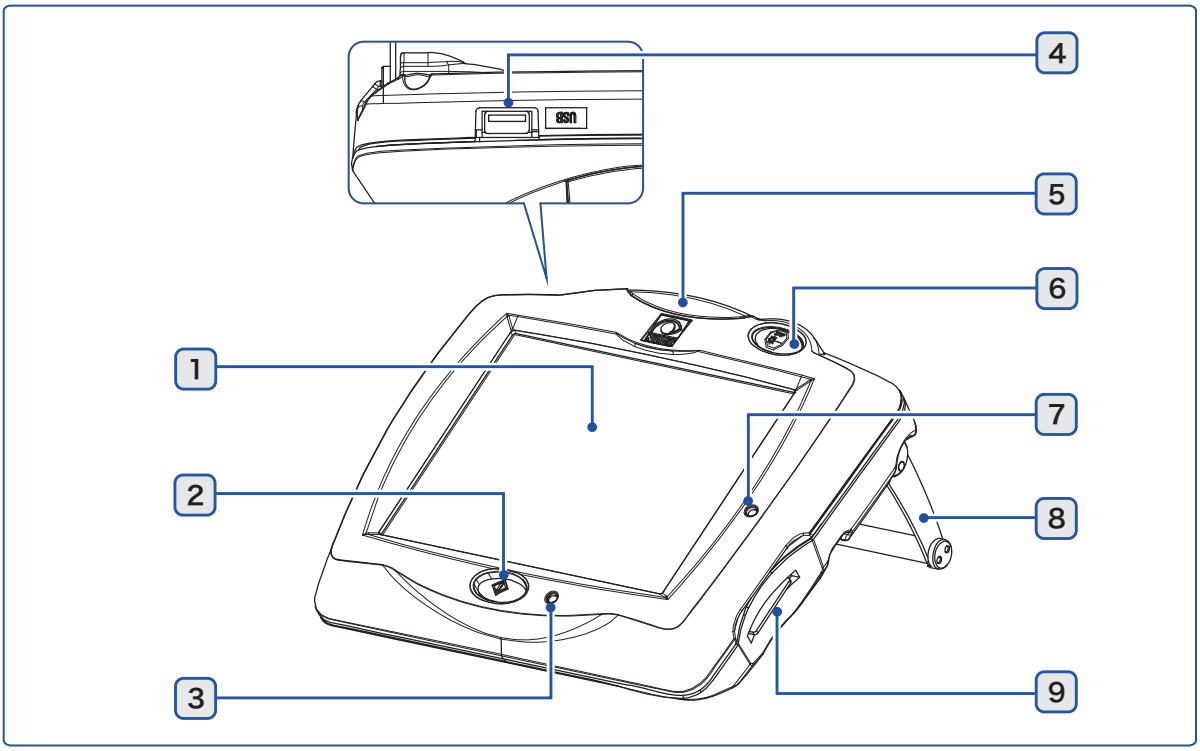
**6 Main body connector**

The main body cable is connected here.

**7 Power inlet**

The power cord is connected here.

## 2.10.2 Control box




**1 Touch screen**

**2 Start button**

Used to activate or stop the device.

**3 Power indicator**

Lights up when the master switch is turned on ( | ).

**4 USB-A port**

Cannot be used.

**5 Status indicator**

Indicates the device status.

| Status indicator | Status |
|---|---|
| Lit in orange | STANDBY (Treatment beam cannot be emitted.) |
| Lit in green | READY (Treatment beam can be emitted.) |
| Slow orange blink | Sleep mode*a |

*a. The device automatically enters sleep mode (the screen turns off) when the device is left idle for 10 minutes without any key operation. To return from sleep mode, touch the touch screen or press the start button of the control box.

**6 Emergency laser stop button**

Used to stop the device in case of an emergency.

To restart the device, press the start button.

**7 Access indicator**

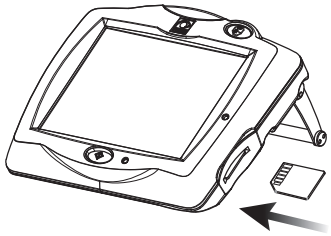
Lights up when the keycard is inserted. The indicator blinks while data is being written to the keycard.

**8 Stand**

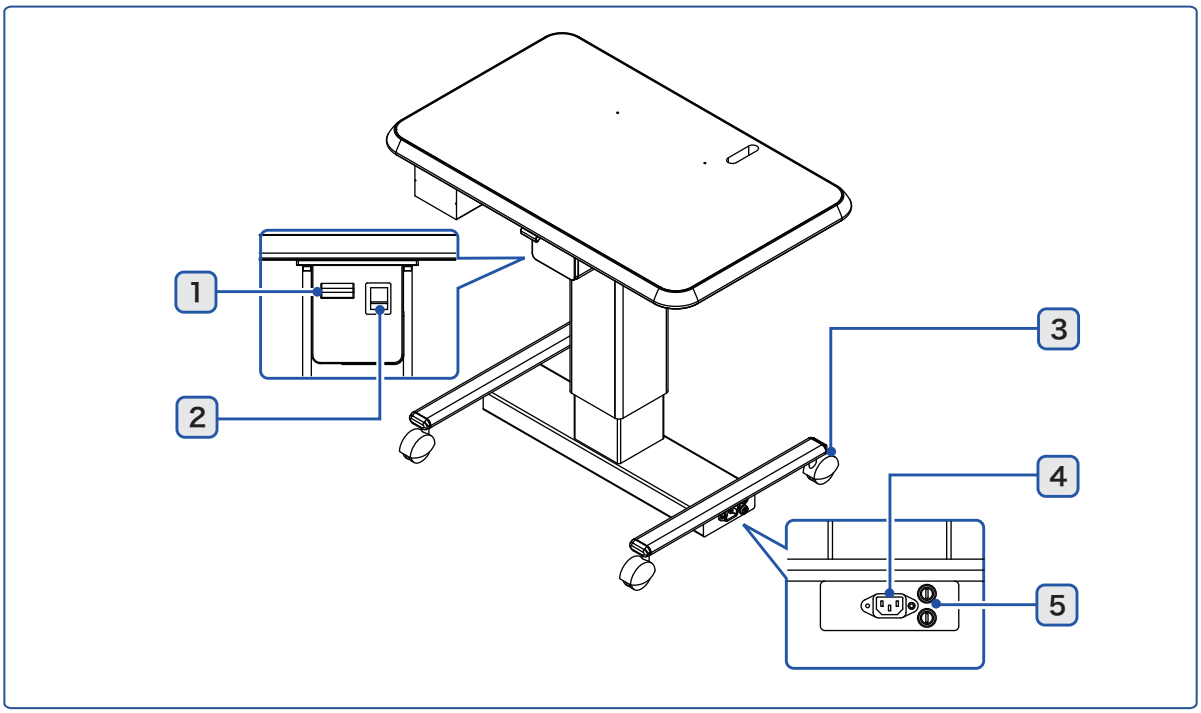
**9 Keycard slot**

The keycard is inserted here.

The device does not start without the keycard inserted.



## 2.10.3 Optional optical table




**1 Table up/down switch**

Used to move the optional optical table up and down.

**2 Master switch**

Turns the power on or off.

**3 Caster lock**

**⚠ CAUTION**

- Unlock the caster before moving the optional optical table.
  The device may topple over resulting in injury.

**4 Power inlet**

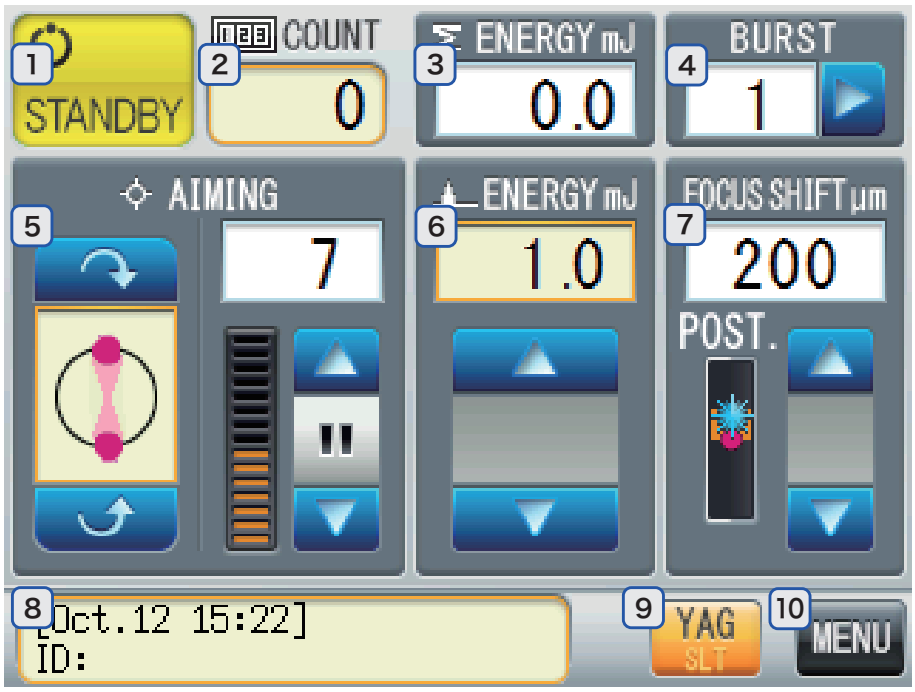
The power cord is connected here.

**5 Fuse holder*1**

*1. The position of the fuse holder may differ depending on the destination.

# 2.11 Screens and Functions

## 2.11.1 Main screen (YAG mode)




### 1 Status button

Toggles between READY (treatment beam can be emitted) and STANDBY (treatment beam cannot be emitted) modes.

| Mode | Function |
|---|---|
| READY (green) | To emit the treatment beam, set the device to READY mode.<br>While the treatment beam is emitted, the EMISSION indicator lights up in yellow. |
| STANDBY (yellow) | When the treatment beam is not to be emitted, set the device to STANDBY mode. |

### 2 COUNT

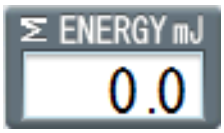
Indicates the total number of treatment beam shots.


**Knowledge**

- Pressing the indication displays a confirmation window. Press “Yes” to reset the counter.

### 3 Σ ENERGY(TOTAL ENERGY)

Displays the integrated energy value of the emitted treatment beam.




**Knowledge**

- When the integrated energy is over 999.9 mJ, “OVER” is displayed.
- The value is cleared when the device power is turned on or the total number of treatment beam shots is cleared.
- The displayed integrated energy value is calculated from the setting values, not from the actual energy values.

### 4 BURST

Sets the number of pulses emitted in each laser emission.


### 5 AIMING

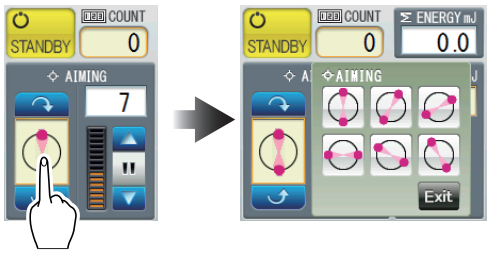
Sets the inclination and intensity of the aiming beam.

In conjunction with the set inclination, the inclination of  changes.


| Button | Function |
|---|---|
|  | Rotates clockwise. |
|  | Rotates counterclockwise. |
|  | Increases the intensity. |
|  | Decreases the intensity. |
|  | Turns on or off the aiming beam. |

**Knowledge**

- Pressing  displays the pop-up window to select the angle from the specified ones.



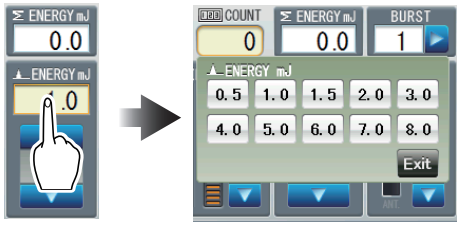
### 6 ENERGY


Sets the energy value of the treatment beam per pulse.

| Button | Function |
|---|---|
|  | Increases the energy output. |
|  | Decreases the energy output. |

**Knowledge**

- Pressing the indication displays the pop-up window to select the energy value from the predetermined options.




### 7 FOCUS SHIFT


Sets the focus position of the treatment beam relative to the aiming beam.

The bar graph changes according to the specified focus position.

| Button | Function |
|---|---|
|  | Moves to the POST. (posterior chamber) side. |
|  | Moves to the ANT. (anterior chamber) side. |

### 8 Information display field

Displays various information. Contents can be selected by the parameter setting.

*"3.4 Changing Device Settings" (page 50)*

### 9 Mode change button  (YC-200 S plus)



Toggles between YAG mode and SLT mode.

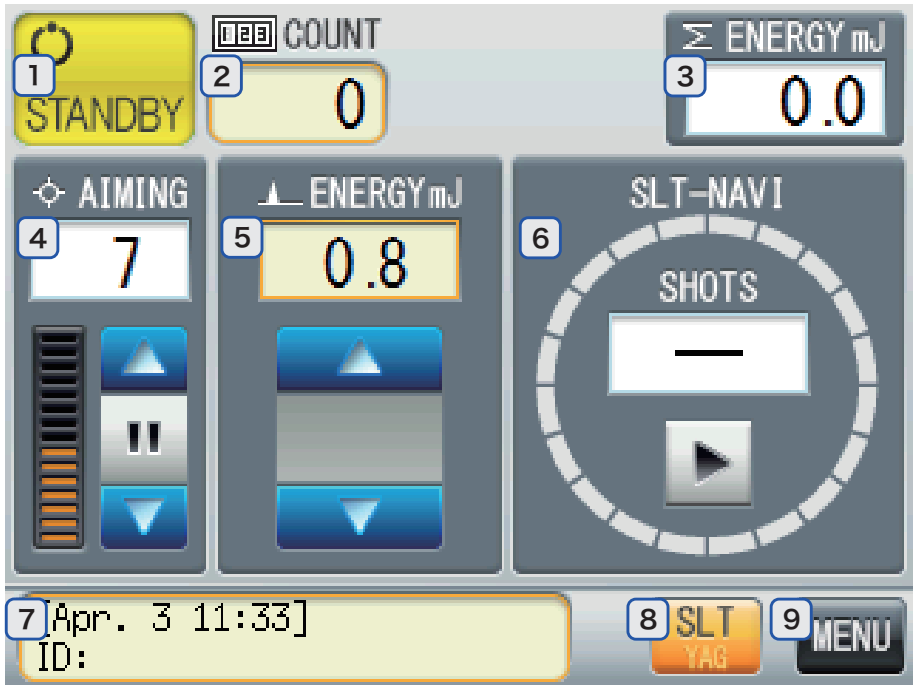
### 10 MENU button 



Various settings can be changed.

*"3.4 Changing Device Settings" (page 50)*

## 2.11.2 Main screen (SLT mode)



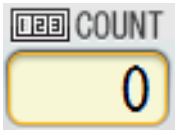

### 1 Status button

Toggles between READY (treatment beam can be emitted) and STANDBY (treatment beam cannot be emitted) modes.

| Mode | Function |
|---|---|
| READY (green) | To emit the treatment beam, set the device to READY mode.<br>While the treatment beam is emitted, the EMISSION indicator lights up in yellow. |
| STANDBY (yellow) | When the treatment beam is not to be emitted, set the device to STANDBY mode. |

### 2 COUNT

Indicates the total number of treatment beam shots.

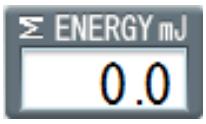



**Knowledge**

- Pressing the indication displays a confirmation window. Press “Yes” to reset the counter.

### 3 Σ ENERGY (TOTAL ENERGY)

Displays the integrated energy value of the emitted treatment beam.




**Knowledge**

- When the integrated energy is over 999.9 mJ, “OVER” is displayed.
- The value is cleared when the device power is turned on or the total number of treatment beam shots is cleared.
- The displayed integrated energy value is calculated from the setting values, not from the actual energy values.

### 4 AIMING

Sets the intensity of the aiming beam.


| Button | Function |
|---|---|
|  | Increases the intensity. |
|  | Decreases the intensity. |
|  | Turns on or off the aiming beam. |

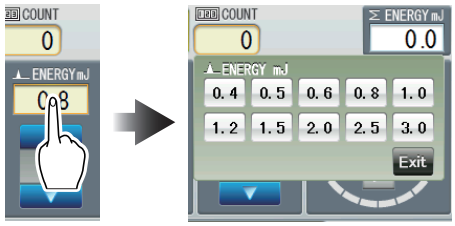
### 5 ENERGY

Sets the energy value of the treatment beam per pulse.


| Button | Function |
|---|---|
|  | Increases the energy output. |
|  | Decreases the energy output. |

**Knowledge**

- Pressing the indication displays the pop-up window to select the energy value from the predetermined options.




### 6 SLT-NAVI

Sets the emission area, emission start position, and emission direction.

*“3.3 Using SLT-NAVI (SLT Mode)” (page 48)*


### 7 Information display field

Displays various information. Contents can be selected by the parameter setting.

*“3.4 Changing Device Settings” (page 50)*

**8 Mode change button** 


Toggles between YAG mode and SLT mode.

**9 MENU button** 

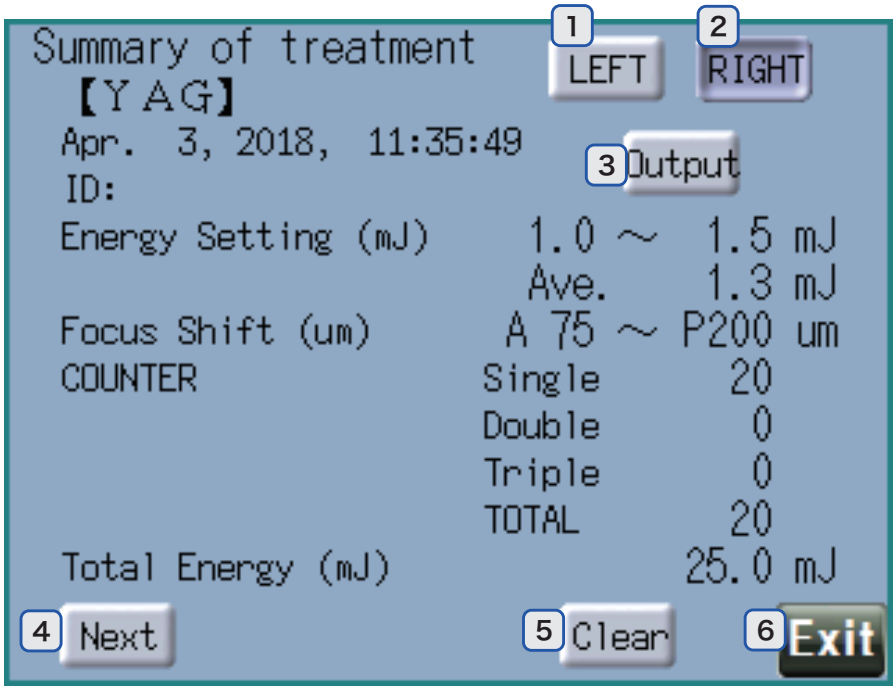

Various settings can be changed.

*"3.4 Changing Device Settings" (page 50)*

## 2.11.3 Summary of treatment (YAG mode)

The Summary of treatment screen is displayed at the time specified in “Summary Display Settings”.

“3.4.2 Setting items” (page 51)




**1 LEFT button** LEFT

Press this button when the treatment beam setting data is for the left eye. When the data is for both eyes, press RIGHT as well. The button is disabled on the Previous Settings screen.

**2 RIGHT button** RIGHT

Press this button when the treatment beam setting data is for the right eye. When the data is for both eyes, press LEFT as well. The button is disabled on the Previous Settings screen.

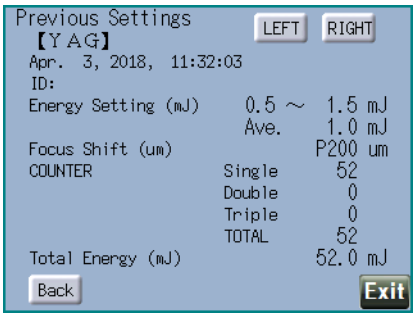
**3 Output button** Output

Outputs the treatment beam setting data to the keycard.

It is displayed when LEFT or RIGHT is pressed.

### ⚠ CAUTION

- When both eyes are treated but the summary data needs to be transmitted for each eye, transmit the summary data after the treatment of an eye.
  After the treatment of both eyes, the summary data cannot be transmitted for each eye.




**4 Next button** Next

Displays the Previous Settings screen (Summary of treatment).

**5 Clear button** Clear

Clears the treatment beam setting and saves it as the Previous Settings.

Knowledge

- The following operations save data as the Summary of treatment of the Previous Settings.
  - Press Clear.
  - Clear the counter on the main screen.
  - Shut down the device.

**6 Exit button** Exit

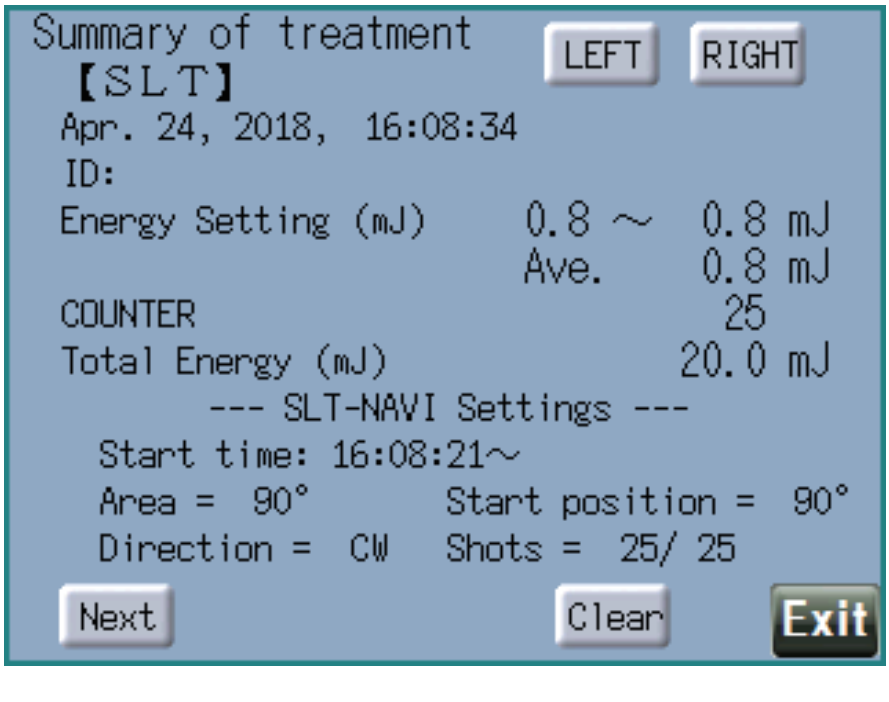
Returns to the main screen.

*“3.4 Changing Device Settings” (page 50)*

## 2.11.4 Summary of treatment (SLT mode)

The Summary of treatment screen is displayed at the time specified in “Summary Display Settings”.

*“3.4.2 Setting items” (page 51)*

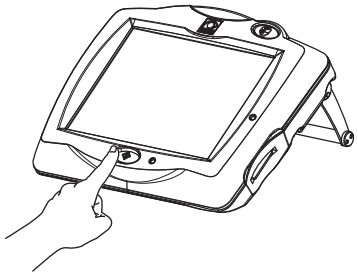
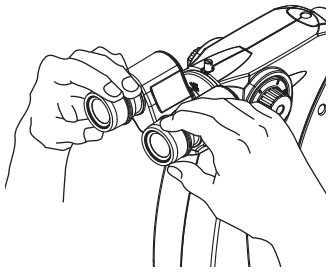
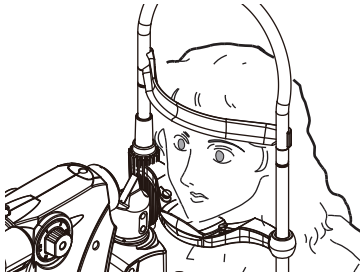


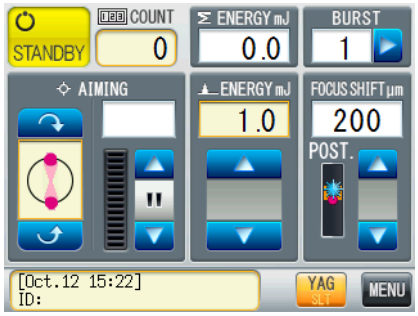
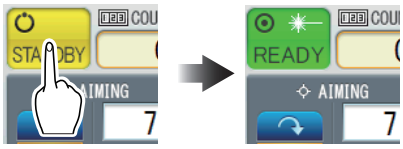
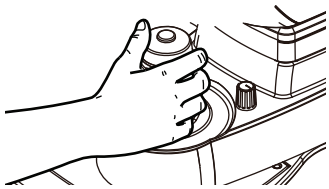
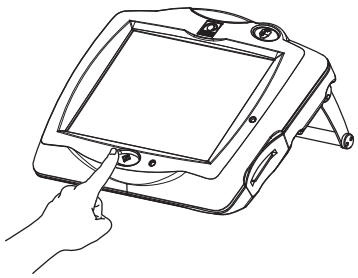

Knowledge

- The displayed items on the Summary of treatment screen differ in SLT mode and YAG mode.
- “SLT-NAVI Settings” is not displayed on the screen when SLT-NAVI is inactive.

# 3 OPERATING PROCEDURE

## 3.1 Operation Flow

| | | |
|---|---|---|
| 1 |  | • Turn on power to the device.<br>*"3.2.1 Activating the device" (page 41)*<br>• Perform pre-use checks.<br>*"5.6 Pre-use Checklist" (page 100)* |
| 2 |  | • Adjust the eyepiece diopter and pupillary distance for the operator. |
| 3 |  | • Observe the patient's eye.<br>*"3.2.2 Preparing for emission" (page 42)* |

| | | |
|---|---|---|
| 4 |  | • Set the laser emission conditions. |
| 5 |  | • Press the status button to set the device to READY mode. |
| 6 |  | • Emit the treatment beam. |
| 7 |  | • Turn off power to the device.<br>*"3.2.4 Stopping the device" (page 47)* |

# 3.2 Operating Procedure

## 3.2.1 Activating the device

***1*** Connect the power cord to the power outlet.

**⚠ WARNING**

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

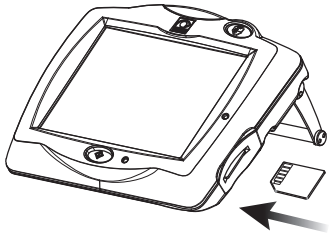
***2*** Have all personnel in the operating room other than the operator and patient wear safety goggles.

**⚠ WARNING**

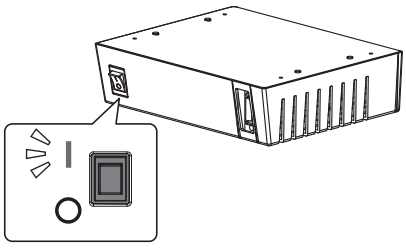
- Have personnel in the operating room wear safety goggles. Instruct them never to gaze directly at the treatment beam even while wearing the safety goggles.
  YAG treatment beam: Wavelength 1,064 nm, OD > 7, 950-1080 D LB6 + IRM LB7 (EN207)
  SLT treatment beam: Wavelength 532 nm, OD > 7, 315-532 DIRM LB6 (EN207)

***3*** Activate the device.

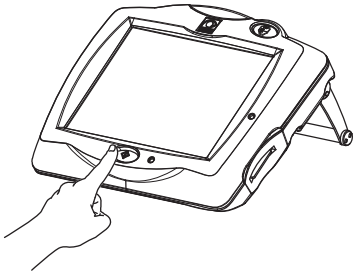
1) Insert the keycard into the control box.



2) Turn on ( | ) the master switch.



3) Press the start button.
   The device enters STANDBY mode.



***4*** Perform pre-use checks of the device.

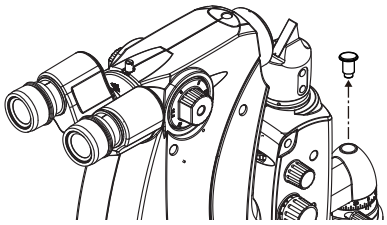
Record the results on the checklist.

*"5.6 Pre-use Checklist" (page 100)*

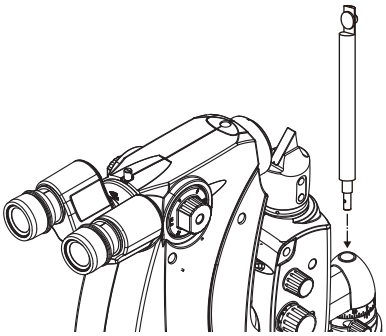
## 3.2.2 Preparing for emission

***1*** Adjust the eyepiece diopter and pupillary distance for the operator.

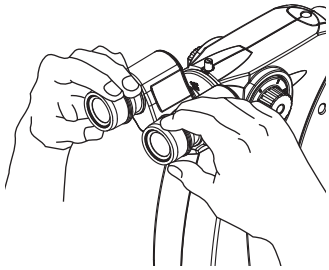
1) Remove the cap.



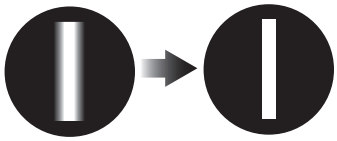
2) Insert and turn the focusing rod so that its flat surface faces the microscope.
3) Project the illumination light on the focusing rod.



4) Fully turn the diopter adjustment rings to the + side and look through the microscope.



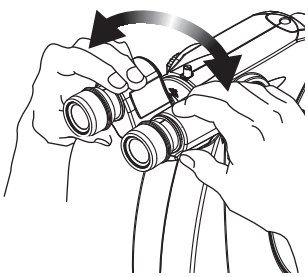
5) While observing the slit image with one eye, slowly turn the diopter adjustment ring until the slit image is focused sharply.



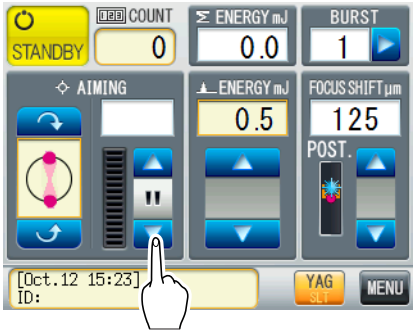
### ⚠ WARNING

- Be sure to adjust the eyepiece diopter for each eye and do not turn the diopter adjustment ring from the - side to the + side.
  Inaccurate diopter adjustment may adversely affect laser beam emission.

6) In the same manner, adjust the diopter of the other eye.
7) Move the binoculars so that the slit image to be observed can be viewed stereoscopically by both eyes.
8) Remove the focusing rod and attach the cap to the slit lamp.

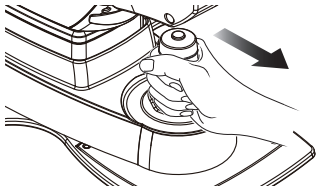


**2** Press the AIMING button to turn off the aiming beam.




**3** Conduct patient preparation.

1) Pull the joystick all the way toward the operator.

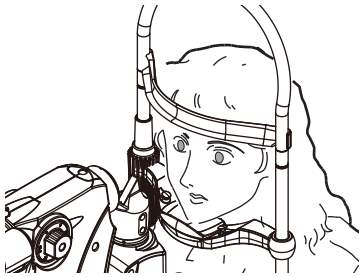


**⚠ CAUTION**

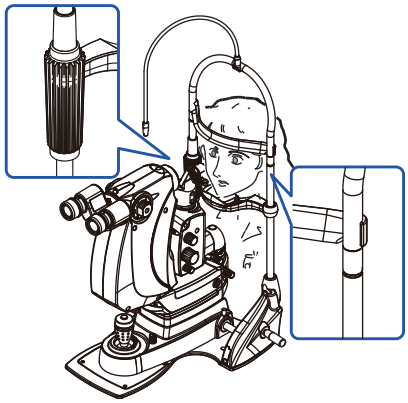
- Be sure to pull the joystick all the way toward the operator before the patient is seated.
  This is to prevent the device from coming into contact with the patient's face.

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

3) Instruct the patient to place their chin on the chinrest.
   Ask them to rest their forehead on the forehead rest and hold the grips to keep them in a stable posture.

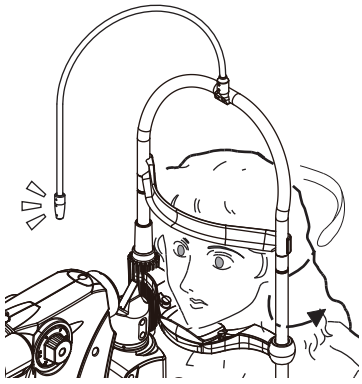


4) Rotate the chinrest elevation control to align the level of the patient's eye with the eye level marker.



5) Fasten the patient's head with the head belt so that the patient's head may not move.

6) Instruct the patient to focus on the fixation lamp to stabilize their visual axis.

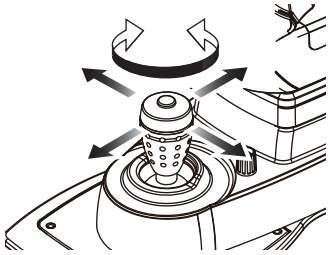


## *4* Observe the patient's eye.

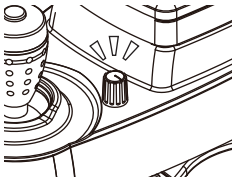
### ⚠ CAUTION

- Be sure to set the light intensity to the minimum level at the beginning, and raise it as necessary. Be sure to return the light intensity to the minimum level after every examination.
- Minimize the illumination area size as much as possible.
- Maximize the angle between the illumination light and visual axis as much as possible.
- Use an illumination filter as necessary.
- Pay particular attention when projecting the illumination light into the eyes of infants, aphakic patients and patients with eye disease.

1) Manipulate the joystick to project the illumination light on the patient's eye.



2) Adjust the intensity of the illumination light by turning the illumination control.



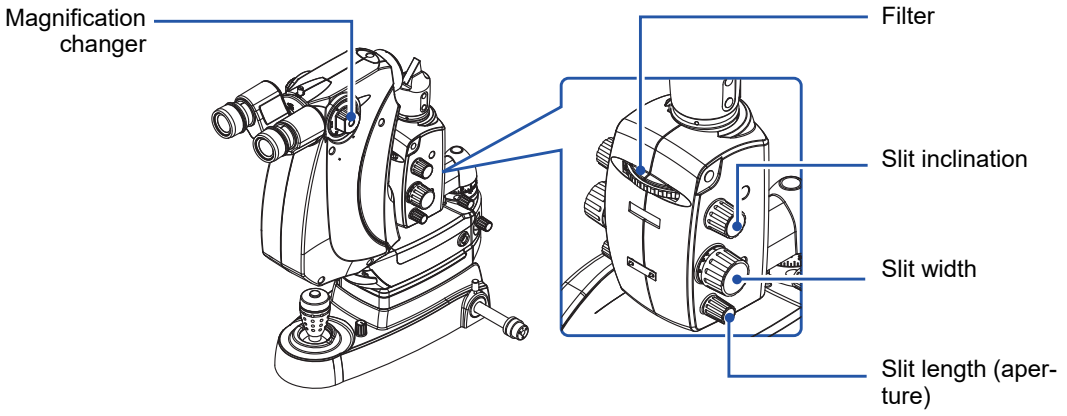
3) Manipulate the joystick to focus the slit image on the cornea.

4) Place either a contact lens or hand-held lens in front of the patient's eye.

   When using a contact lens, apply topical anesthesia beforehand. If necessary, use a corneal protectant.

5) Look through the microscope to observe the affected areas.

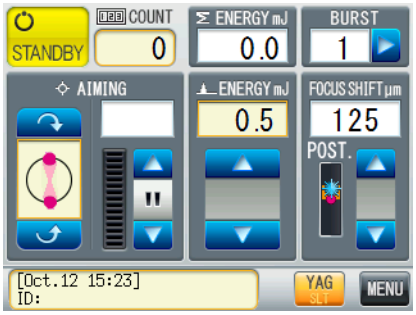
6) As necessary, change the observation conditions.



### 3.2.3 Emitting the treatment beam

**1** Set the laser emission conditions.

Changing “ENERGY” or “BURST” automatically performs the test fire.



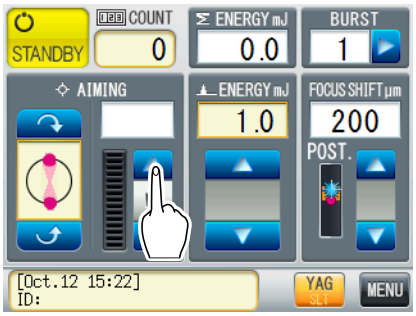

**⚠ WARNING**

- Check the setting values before emitting the treatment beam.
  The treatment beam may be emitted in unintended settings.

**Knowledge**

- During the test fire, a message indicating that no operation is possible appears on the control box.

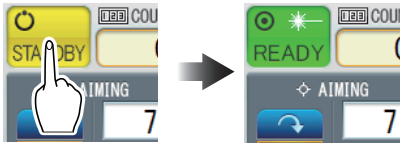
**2** Press the AIMING button to turn on the aiming beam.



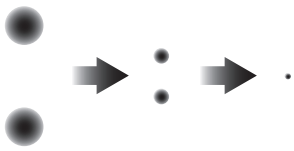

**⚠ CAUTION**

- The aiming beam blinks if the path of the treatment beam is blocked by the illumination tower only when the illumination tower equipped with a tilting function is used. In this case, lower the illumination tower or move the illumination unit arm to the right or left.

**3** Press the status button to set the device to READY mode.



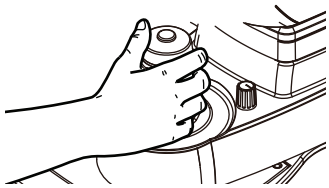

**4** Adjust the joystick and contact lens to align the aiming beam focus with the target position.



**5** Press the hand switch to emit the treatment beam.

**⚠ CAUTION**

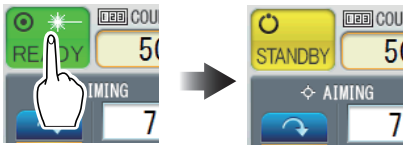
- If the patient's fixation is unstable, emit the treatment beam with great care, paying attention to the position of the aiming beam.



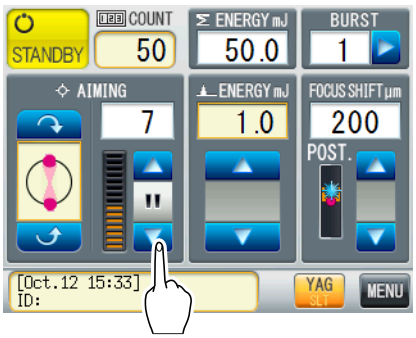
**Knowledge**

- As a guideline for continuous irradiation, the number of times the hand switch is pressed should not exceed 18 times/minute in Single mode or 6 times/minute in Burst mode.
  If continuous irradiation that exceeds the above guideline is performed, an error may occur.
- If the laser emission repetition rate exceeds the specified continuous irradiation / repetition time (Single mode: 3 Hz, Burst mode: 1.5 Hz), a message indicating that no operation is possible appears on the control box.

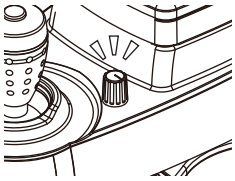
**6** When treatment beam emission is complete, press the status button to set the device to STANDBY mode.



***7*** Press the AIMING button to turn off the aiming beam.




***8*** Turn off the illumination light by turning the illumination control.

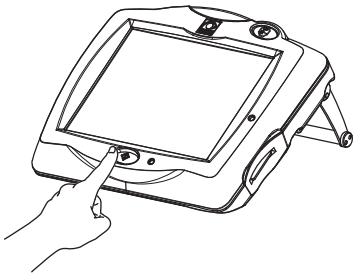


***9*** Remove the head belt from the patient.

### 3.2.4 Stopping the device

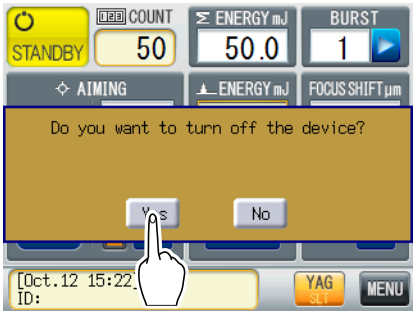
**1** Turn off the device.

1) Press the start button.

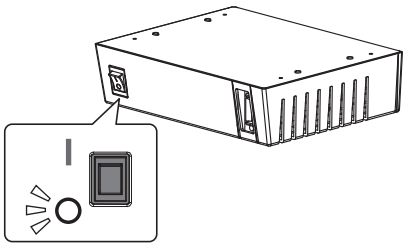


2) Press Yes .

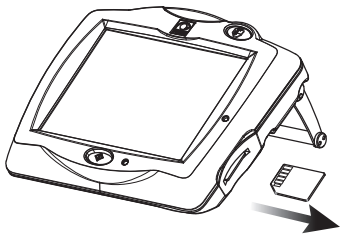
3) Instruct all personnel to remove their safety goggles.




4) Turn off ( ◯ ) the master switch.



5) Remove the keycard and store it in a secure place.



**2** Disconnect the power cord from the power outlet.

**3** Clean the forehead rest, chinrest, grips, and head belt.

*“4.4.2 Cleaning areas that come into contact with patients” (page 71)*

**4** Place the dust cover on the device.

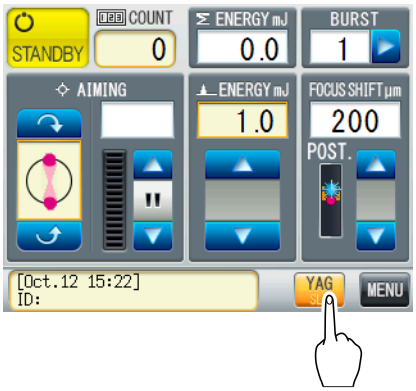
# 3.3 Using SLT-NAVI (SLT Mode)

■ SLT-NAVI assists the operator in surgery by specifying the laser emission positions and orders before the treatment.

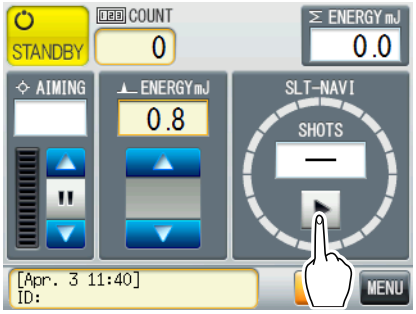
**Knowledge**

- This function is used to guide the laser emission, not to record the laser emission positions or number of emissions for each area.

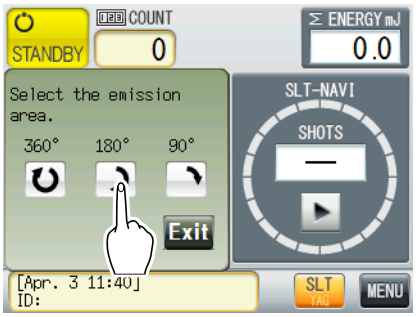
***1*** Set the device to SLT mode.



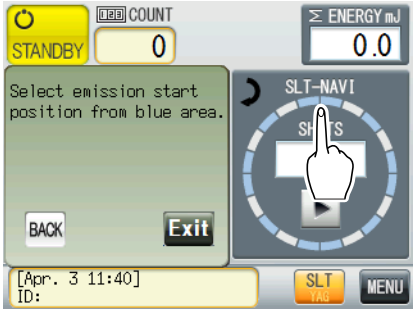

***2*** Press ▶ .



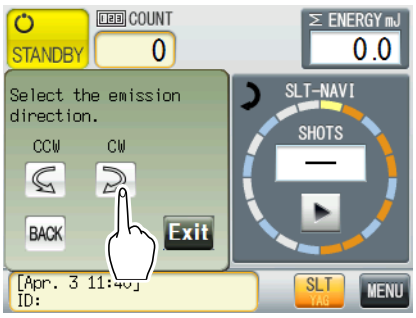

***3*** Select the emission area.




***4*** Press a light blue area to select the emission start position.



**5** Select the emission direction.




**6** Press OK.


**7** Emit the treatment beam while checking SLT-NAVI.

The procedure for treatment beam emission is the same as that of YAG mode.

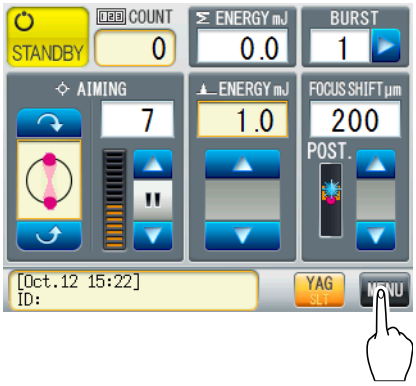
*"3.2.3 Emitting the treatment beam" (page 45)*


| Button | Indication/function |
|---|---|
| Circular shot progress indicator | Orange: Emission target area<br>Blink in yellow and orange: Area that is being irradiated<br>Green: Area that has been irradiated |
| SHOTS | Number of laser emissions / scheduled number of shots<br>Pressing an area before the treatment beam shot enables changing the scheduled number of shots. |
| End | End |
| ❚❚ | Pause<br>The emission during the pause is not counted. |
| ▶ | Restart |

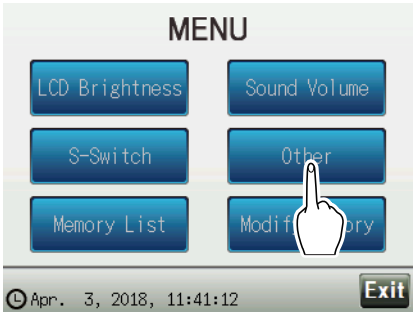
# 3.4 Changing Device Settings

## 3.4.1 Changing the settings

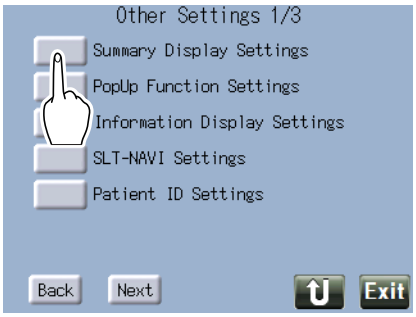
***1*** Press MENU .




***2*** Press a button corresponding to the setting item to be changed.




***3*** Change the setting as desired.




| Button | Function |
|---|---|
| | Selected (cannot be selected if the text is grayed out) |
| | Returns to the previous screen. |
| Next | Goes to the next page. |
| Back | Returns to the previous page. |

***4*** Press Exit .

The main screen is displayed again. The changed settings are saved.

## 3.4.2 Setting items

Setting

• Underlined options indicate factory settings.

| LCD Brightness | Setting contents |
|---|---|
| LCD Brightness at STANDBY | **1, 2, 3, 4, <u>5</u>, 6, 7** |
| | Select the brightness of the touch screen in STANDBY mode. |
| LCD Brightness at READY | **<u>1</u>, 2, 3, 4, 5, 6, 7** |
| | Select the brightness of the touch screen in READY mode. |

| Sound Volume | Setting contents |
|---|---|
| Beep Volume:Laser Emission | **1, <u>2</u>, 3** |
| | Select the beep volume when the laser is emitted. |
| Beep Volume:Button | **1, <u>2</u>, 3** |
| | Select the beep volume when a button is pressed. |

| S-Switch | Setting contents |
|---|---|
| Left switch | OFF, READY/STANDBY, AIMING ROTATION START/STOP,<br>**BURST, ENERGY UP, <u>ENERGY DOWN</u>,**<br>**FOCUS SHIFT UP, FOCUS SHIFT DOWN,**<br>**AIMING POWER UP, AIMING POWER DOWN** |
| | Select a function to be assigned to the switch. |
| Right switch | **OFF, READY/STANDBY, AIMING ROTATION START/STOP,**<br>**BURST, <u>ENERGY UP</u>, ENERGY DOWN,**<br>**FOCUS SHIFT UP, FOCUS SHIFT DOWN,**<br>**AIMING POWER UP, AIMING POWER DOWN** |
| | Select a function to be assigned to the switch. |
| Push switch | **OFF, <u>READY/STANDBY</u>, AIMING ROTATION START/STOP,**<br>**BURST, ENERGY UP, ENERGY DOWN,**<br>**FOCUS SHIFT UP, FOCUS SHIFT DOWN,**<br>**AIMING POWER UP, AIMING POWER DOWN** |
| | Select a function to be assigned to the switch. |
| Default switch | |
| | Restore the functions assigned to the switch to the default settings. |

| Other | Setting contents |
|---|---|
| Summary Display Settings | **<u>Not Display</u>, STANDBY, COUNTER Reset** |
| | Select when to display the Summary of treatment screen. |
| PopUP Function Settings | **No, <u>Yes</u>** |
| | Select whether to display the pop-up window for selection of the aiming beam angle and energy value. |

| Other | Setting contents |
|---|---|
| Information Display Settings | Line 1: **Not Display, Patient ID, <u>Date</u>**<br>Line 2: **Not Display, <u>Patient ID</u>, Date, Memory Name** |

Select the items to be displayed in the information display field.

| | |
|---|---|
| SLT-NAVI Settings (SLT mode) | **90, <u>100</u>, 110, 120, 130, 140, 150, 160** |

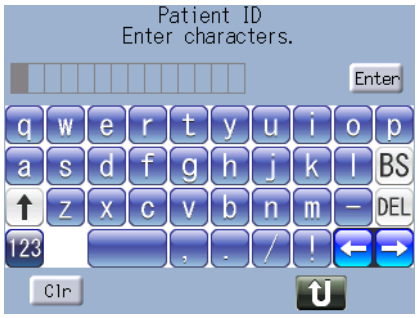
Select the number of shots for entire circumference when SLT-NAVI is active.

**Patient ID Settings**

Enter a patient ID with the on-screen keyboard.

Confirm it by pressing Enter .

Pressing a button other than “a to z”, “A to Z”, “0 to 9”, and “-” displays “~” (tilde).




**Data Input settings**

Cannot be selected.

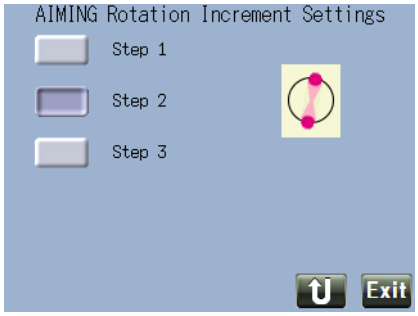
**Data Output settings**

Cannot be selected.

| | |
|---|---|
| AIMING Rotation Increment Settings (YAG mode) | **Step1, <u>Step2</u>, Step3** |

Select the increments for rotating the aiming beam.

displays the increments for rotation.

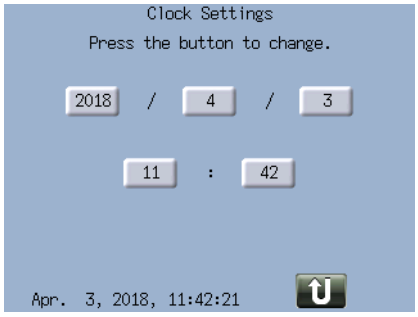



| | |
|---|---|
| Σ ENERGY Display Settings | **No, <u>Yes</u>** |

Select whether to display the integrated energy value.

**Clock Settings**

Sets the date and time.
Enter values in the numeric keypad displayed when a button is pressed.
Values from 2017 to 2099 can be entered as a year.



| Other | Setting contents |
|---|---|
| Display Language Settings | **English**, **Japanese** |

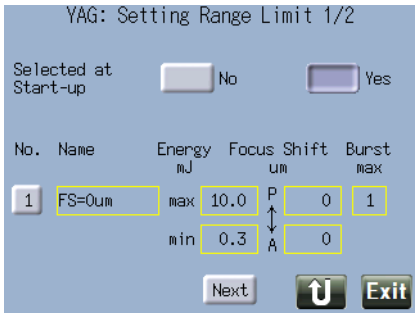
Select the display language.

| | |
|---|---|
| Trigger Switch Selection | **Hand Switch**, **Foot Switch (optional)** |

Select the trigger switch used to emit the laser.

| | |
|---|---|
| Setting Range Limit (Selected at Start-up) (YAG mode) | **No**, **Yes** |

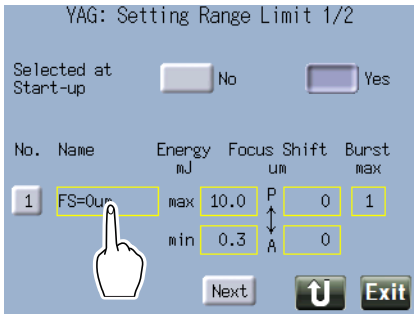
Select whether to enable Limit mode at device start-up.

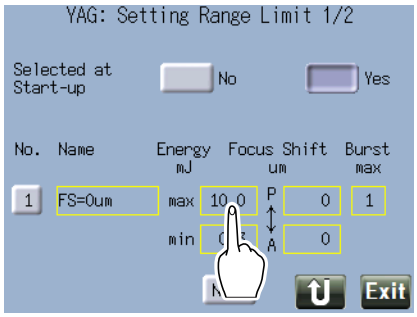
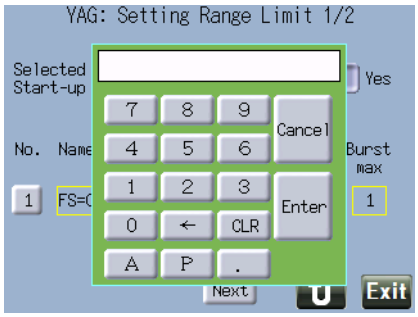



| | |
|---|---|
| Setting Range Limit (Name) (YAG mode) | |

Press a yellow frame to enter a name.

Confirm it by pressing Enter .




| Other | Setting contents |
|---|---|
| Setting Range Limit (Energy, Focus Shift, Burst) (YAG mode) | Press a yellow frame and enter a value with the numeric keypad.<br>Energy: Set in the range from 0.3 (mJ) to 10.0 (mJ).<br>Focus Shift: Set in the range from P500 (Post: 500 um) to A500 (Ant: 500 um). Values can be entered in 25 um increments.<br>Burst: Set in the range from 1 to 3. It can be set in combination with the following Energy.<br>• Burst 1: 0.3 to 10.0 mJ<br>• Burst 2: 0.3 to 9.0 mJ<br>• Burst 3: 0.3 to 8.0 mJ<br>Confirm it by pressing Enter .<br>  <br>  |
| CALIBRATION | Calibrate the laser energy output. |

# 3.5 Using Limit Mode (YAG Mode)

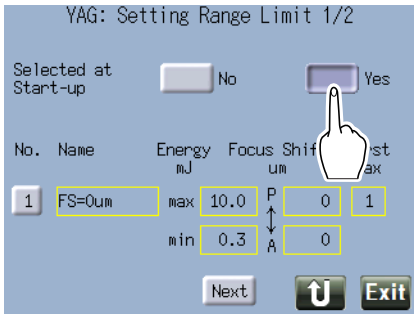
■ In Limit mode, the setting ranges of Energy, Focus Shift, and Burst are limited to use the device more safely. Up to three settings can be registered to Limit mode.

## 3.5.1 Using Limit mode from start-up

**Setting**

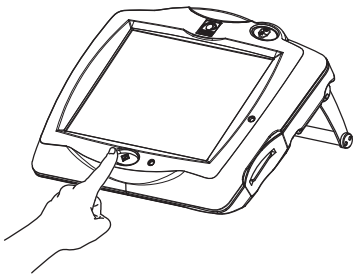
• Set “Selected at Start-up” of “Setting Range Limit” to Yes in advance.

“3.4 Changing Device Settings” (page 50)



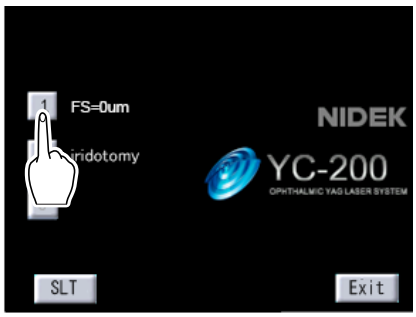

***1*** Activate the device.

“3.2.1 Activating the device” (page 41)



***2*** Press 1, 2, or 3.

| Button | Function |
|---|---|
| 1 to 3 | Activates Limit mode. |
| SLT | Activates normal SLT mode. |
| Exit | Activates normal YAG mode. |

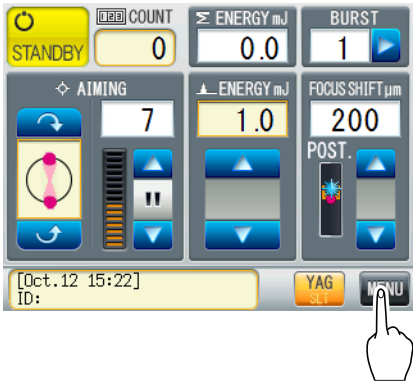



***3*** The Limit mode is activated.

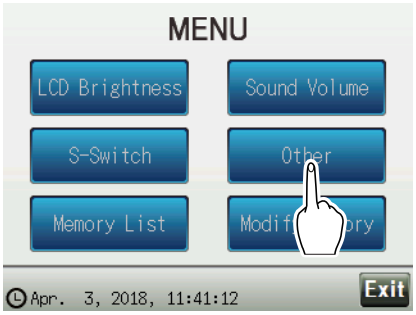
“Limit Mode” is displayed in the information display field.

## 3.5.2 Using Limit mode after activating YAG mode

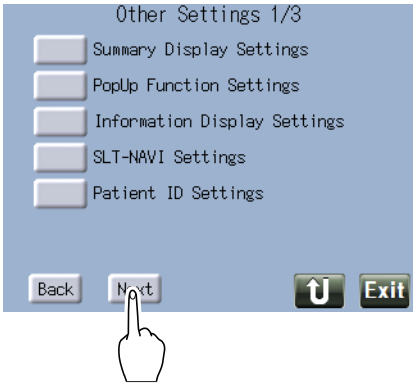
***1*** Press MENU .



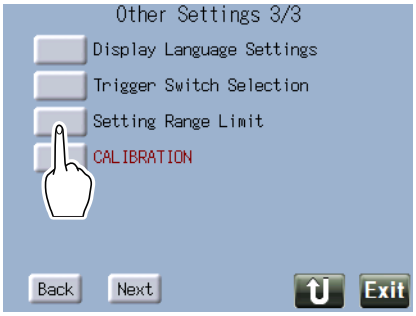

***2*** Press “Other”.



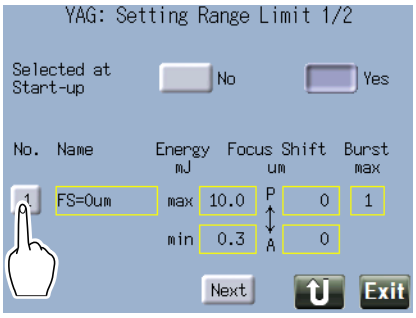

***3*** Press Next to display the Other Settings 3/3 screen.



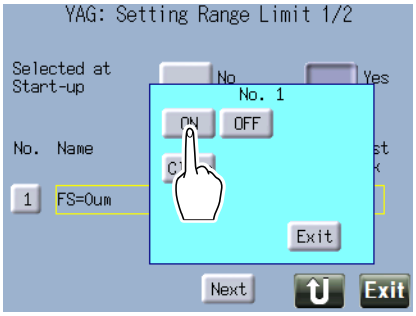

***4*** Press “Setting Range Limit”.



**5** Press the No. button of the desired Limit mode.




**6** Press ON.




| Button | Function |
|---|---|
| ON | Turns on Limit mode. |
| OFF | Turns off Limit mode. |
| Clear | Deletes the data. Energy, Focus Shift, and Burst are changed to the default value. |
| Exit | Closes the pop-up window. |

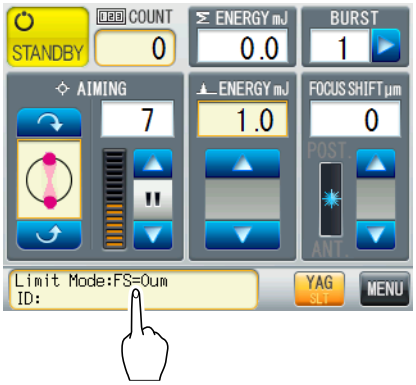
**7** Press Exit.

**8** The Limit mode is activated.

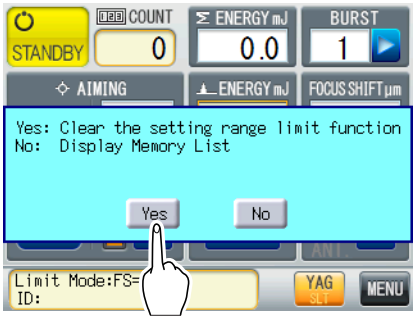
"Limit Mode" is displayed in the information display field.

### 3.5.3 Deactivating Limit mode

***1*** Press the information display field.




***2*** Press Yes .

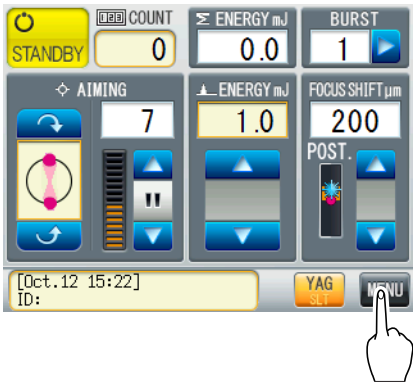


# 3.6 Using Memory

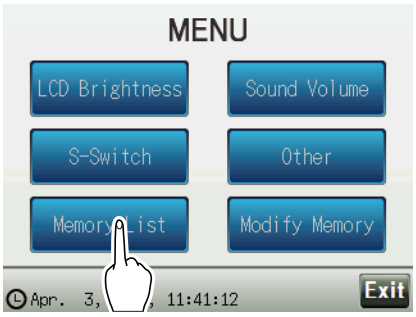
■ Treatment beam settings frequently used can be registered to the memory for easy setting.

## 3.6.1 Loading memory

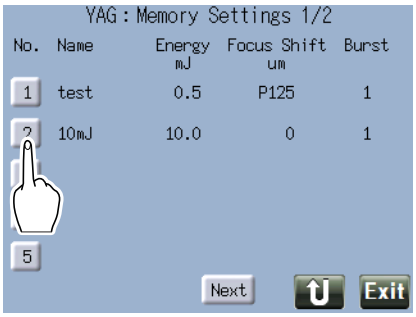
***1*** Press MENU .




***2*** Press “Memory List”.

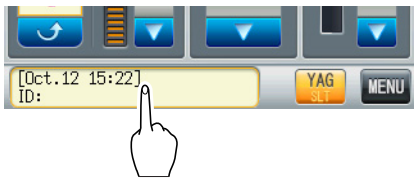



***3*** Press the No. button of the memory to be loaded.




**Tip**

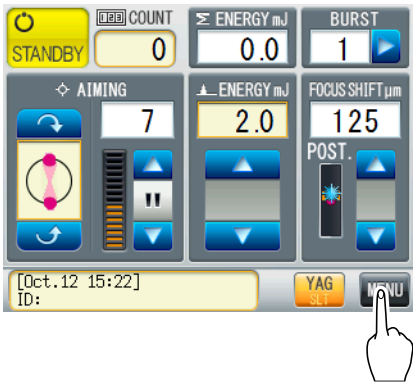
- Pressing the information display field displays the memory list in a single action.
- When Limit mode is activated, select the memory list or deactivate Limit mode.



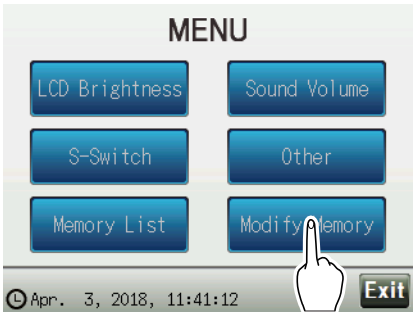
## 3.6.2 Registering memory

The treatment beam setting that is displayed on the main screen can be registered to memory. Registered memory can be loaded from the memory list.

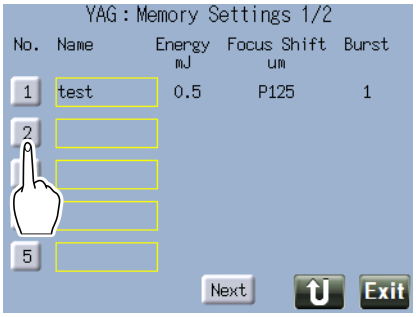
***1*** Press MENU .



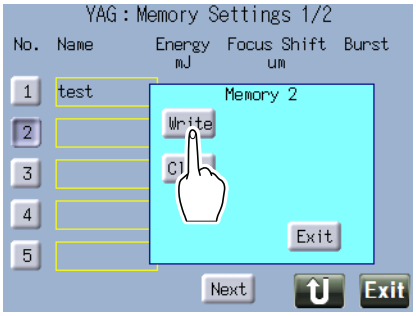

***2*** Press “Modify Memory”.



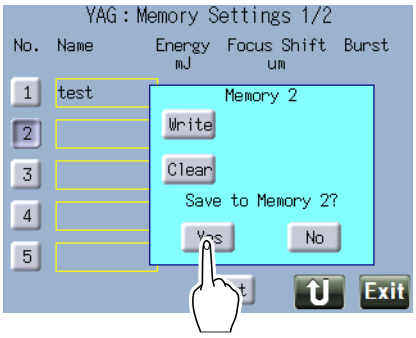

***3*** Press the No. button of the memory to be registered.



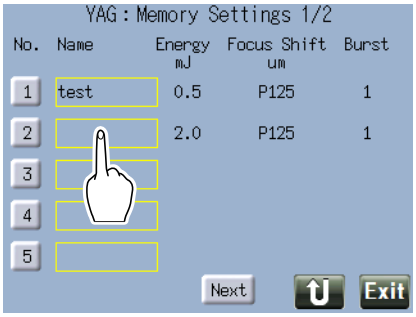

***4*** Press Write .



**5** Press Yes .

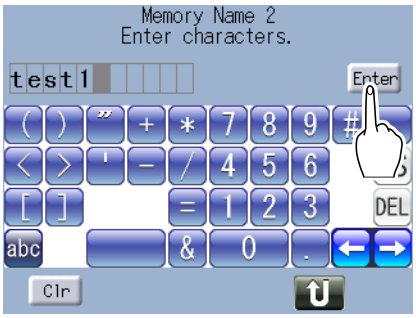



**6** Press the yellow frame of the memory to be registered.

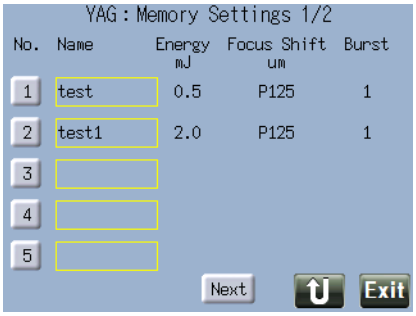



**7** Enter the name.


**8** Press Enter .

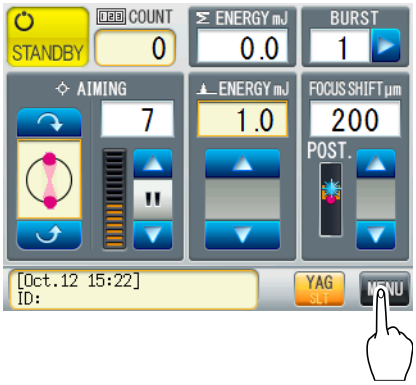



**9** Confirm that the treatment beam setting data is registered.

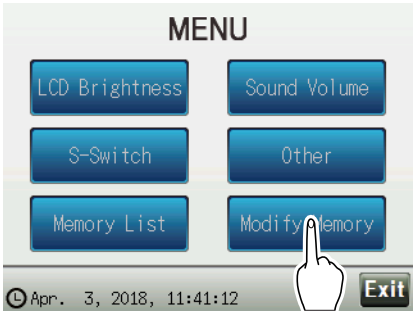


## 3.6.3 Deleting memory

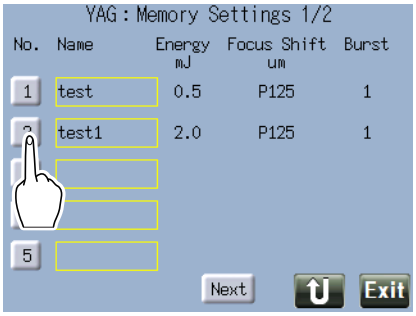
***1*** Press MENU .



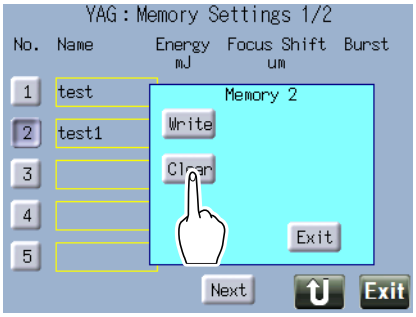

***2*** Press “Modify Memory”.



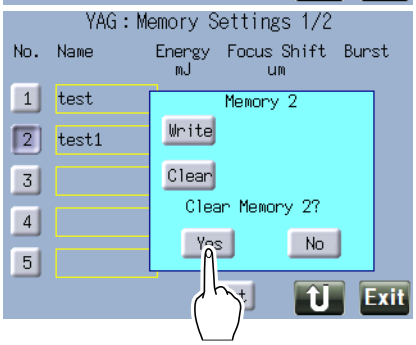

***3*** Press the No. button of the memory to be deleted.



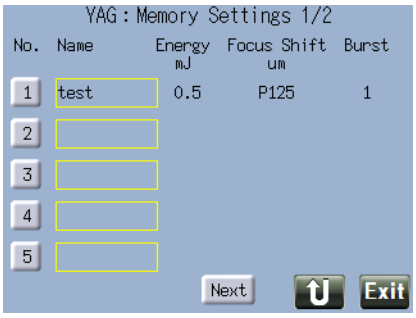

***4*** Press Clear .




***5*** Press Yes .



**6** Confirm that the treatment beam setting data is deleted.



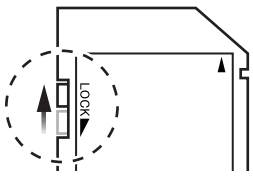
# 4 MAINTENANCE

## 4.1 Troubleshooting

If the device does not function properly, attempt to correct the problem according to the following table before contacting NIDEK or your authorized distributor.

If the symptom cannot be corrected by the actions shown in the following table, contact NIDEK or your authorized distributor.

| When | Remedy |
|---|---|
| The power indicator does not illuminate even though the master switch is on ( ▎ ). | • The power cord may not be correctly connected.<br>Check the power cord.<br>• Check whether proper voltage is applied to the power outlet. |
| The screen of the control box blacked out. | • The device may be in sleep mode. In sleep mode, the status indicator slowly blinks in orange.<br>Touch the touch screen or press the start button of the control box. |
| A message “The KEY card is not inserted. Please enter password.” is displayed. | • The keycard is not inserted.<br>Insert the keycard. |
| The illumination light is not projected. | • The illumination light may be turned off.<br>Adjust the intensity of the illumination light by turning the illumination control.<br>• The slit may be closed.<br>Increase the slit width by turning the slit width control.<br>• It may be blocked by the filter.<br>Adjust the filter position by turning the filter changer.<br>• The cable may not be correctly connected to the connector box.<br>Check the cable. |
| The fixation lamp does not illuminate. | • The fixation lamp cord may not be correctly connected to the connector box.<br>Check the fixation lamp cord. |
| The device does not move up or down. | • The device has reached the upper or lower limit of its movement range.<br>Rotate the joystick in an opposite direction. |
| The aiming beam is not projected. | • The aiming beam may be turned off.<br>Press the AIMING button to turn on the aiming beam.<br>• The aiming beam may be blocked by the illumination tower.<br>Move the illumination unit arm to the right or left to adjust the position so that the aiming beam is not blocked.<br>In another way, lower the illumination tower to the position where the aiming beam is not blocked (when the illumination tower equipped with a tilting function is used). |
| The aiming beam blinks. | • The aiming beam blinks if the treatment beam is blocked due to the position of the illumination tower (when the illumination tower equipped with a tilting function is used).<br>Move the illumination unit arm to the right or left to adjust the position so that the treatment beam is not blocked.<br>In another way, lower the illumination tower to the lowest level. |

| When | Remedy |
|---|---|
| When the illumination tower is replaced with the optional one or that of the combination delivery unit, the laser beam is blocked by the illumination tower. | • Move the illumination unit arm to the right and left to adjust the position so that the laser beam is not blocked. |
| The treatment beam cannot be emitted. | • The treatment beam is not emitted if it is blocked due to the position of the illumination tower.<br>Move the illumination unit arm to the right or left to adjust the position so that the treatment beam is not blocked.<br>In another way, lower the illumination tower to the lowest level (when the illumination tower equipped with a tilting function is used). |
| Writing to the keycard is not possible. | • The write-protection switch may be in the LOCK position.<br>Release write-protection.<br>  |

# 4.2 Error Messages and Remedies

If one of the following error codes is displayed on the screen, follow the instructions of the message.

Notify NIDEK of the error code, message number, and serial number of your device so that NIDEK can offer appropriate service.

## ◆ Warning message

| Message No. | Message |
|---|---|
| • Related to control box | |
| 601 | CB EEPROM: Check Sum error<br>CB EEPROM was initialized. |
| 631 | Voltage reduction for clock data backup<br>Operate the device for more than 5 minutes for battery charge. |
| 633 | Clock data initialized<br>Set the clock. |
| 641 | KEY card: Error<br>KEY card has fault. Recording function is suspended.<br>Do not use this KEY card. |
| 644 | KEY card: Insufficient free space<br>Free up space of this KEY card. |

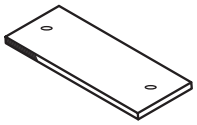
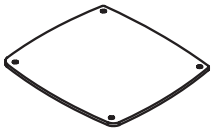
## ◆ Error Messages

| The following are errors related to the mechanism inside the device. Turn off the device, then restart the device. If the problem persists, contact NIDEK or your authorized distributor. | | | |
|---|---|---|---|
| • Errors related to main body | | | |
| ERR1 | High temperature in the system | ERR5 | Malfunction of YAG shutter |
| ERR6 | Malfunction of SLT shutter | ERR7 | Malfunction of safety shutter |
| ERR10 | Insufficient laser emission | ERR12 | Excessive laser emission |
| ERR13 | Incorrect laser emission | ERR14 | Laser emission failed |
| ERR15 | Unstable YAG laser output | ERR16 | Unstable SLT laser output |
| ERR30 | Laser power supply malfunction | ERR31 | Improper PFN voltage of laser power supply |
| ERR32 | Improper PFN voltage for automatic discharge | ERR50 | Energy monitor malfunction |
| ERR51 | Unable to set YAG energy | ERR52 | Unable to set focus shift |
| ERR53 | Trigger switch input signal failure | ERR54 | Pulse number setting signal failure |
| ERR56 | Unable to set aiming beam rotation | ERR61 | Unable to switch between YAG and SLT |
| ERR62 | Unable to set SLT energy | ERR65 | Unable to control KTP temperature |
| ERR71 | Improper reference voltage | ERR80 | Slit lamp malfunction |
| ERR90 | Program data failure | ERR91 | EEPROM data failure |
| ERR93 | RAM data failure | ERR94 | KEYLOCK error |
| ERR95 | CPU communication error | ERR131 | PFN voltage upper limit error of laser power |

| | | | |
|---|---|---|---|
| ERR165 | KTP temp control upper/lower limit error | ERR191 | EEPROM data editing failure |
| ERR192 | System reset error | | |
| • Errors related to control box | | | |
| ERR602 | EEPROM:Access error | ERR612 | Flash memory-Appli:Check Sum error |
| ERR613 | Process:Program Check Sum error | ERR614 | Process:Data mismatch error |
| ERR615 | Process:Calculation error | ERR616 | Process:Sequence error |
| ERR622 | KEY card :Use of unauthorized KEY card. | ERR632 | RTC:Access error |
| ERR642 | KEY card :KEY card is not inserted. | ERR643 | KEY card :Write-protected. |
| ERR651 | No response error. | ERR652 | Communication error. |
| ERR661 | Cannot turn off power. | ERR671 | LCD BL driver:Error |
| ERR681 | VerUP:File Error | ERR683 | VerUP CB:Erase Error |
| ERR684 | VerUP CB:Write Error | ERR685 | VerUP CB:Verify Error |
| ERR692 | VerUP MAIN:Bootmode Error | ERR693 | VerUP MAIN:Erase Error |
| ERR694 | VerUP MAIN:Write Error | ERR695 | VerUP MAIN:Verify Error |

# 4.3 Replacing Consumables

## 4.3.1 Consumable list

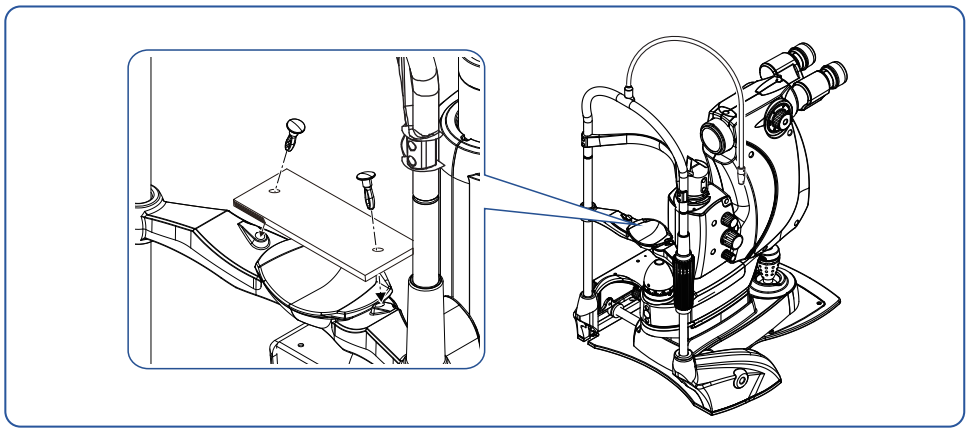
| Part name (part number) | Appearance | Remarks |
|---|---|---|
| Chinrest paper<br>(32903-M047) |  | 1 pack |
| Fuse<br>For 100 V regions: 80402-02148<br>For 200 V regions: 80402-02043 |  | For optional optical table<br>For 100 V regions: 125 V T 10 A<br>For 200 V regions: 250 V T 5 A |
| Slide plate<br>(YC020-M216) |  | For replacement, contact NIDEK or your authorized distributor. |

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

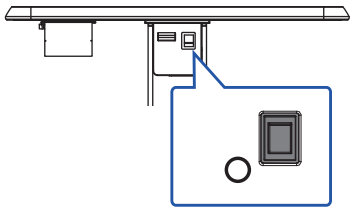
## 4.3.2 Attaching chinrest paper

Attach an appropriate amount of chinrest paper onto the chinrest using the fixing pins.

Take out a stack of chinrest paper from the chinrest paper pack so that the thickness of the stack is 6 mm or less, then attach the stack of the chinrest paper.

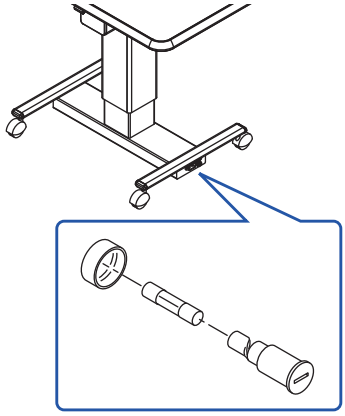


### 4.3.3 Replacing fuses of optional optical table



***1*** Turn off ( ◯ ) the master switch.

***2*** Disconnect the power cord from the power outlet.



***3*** Remove the fuse holders.

Turn the fuse holders counterclockwise with a flatblade screw-driver while applying pressure.

***4*** Replace the fuses.

Replace the two fuses at the same time.

***5*** Reassemble the parts in the reverse order.

# 4.4 Cleaning

## 4.4.1 Cleaning the device exterior

**⚠ CAUTION**

- Disconnect the power cord from the power outlet.
  This is to prevent electric shock.
- Never use an organic solvent (such as paint thinner and benzine) or abrasive cleanser.
  It may damage the surface of the device.
- Gently wipe the touch screen surface with a soft cloth.
  It may scratch the touch screen. Device malfunction may also result.
- Never use an overly wet sponge or cloth.
  Water may leak into the interior of the device resulting in malfunction.

***1*** Turn the power off ( ○ ).

***2*** Disconnect the power cord from the power outlet.

***3*** Wipe off the stains with a soft cloth.

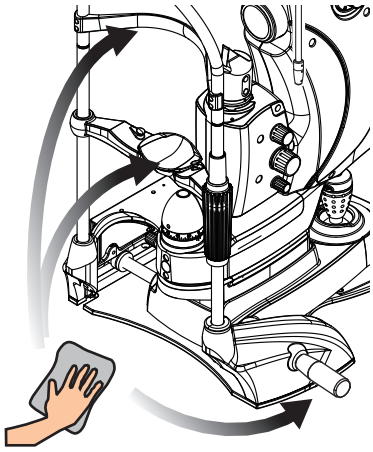
For persistent stains, soak the cloth in a neutral detergent, wring well, and wipe. Then wipe them off with a soft, dry cloth.

***4*** Let it dry in a well-ventilated area.

## 4.4.2 Cleaning areas that come into contact with patients

Clean the forehead rest, chinrest, grips, and head belt for each patient. Use alcoholic disinfectants if necessary.

When using the chinrest paper, remove one sheet of paper.



### 4.4.3 Cleaning optical parts

**⚠ CAUTION**

- Wipe up to clean the optical parts.
  It the optical parts are not clean, the laser energy output may be unstable.
- Take care not to scratch or smear the optical parts, or accumulate dust on them.
  This prevents reduction in laser performance.

***1*** Remove any dust by using the blower.

***2*** Wrap lens cleaning paper around a thin stick (or use cotton swab / gauze), damp it with alcohol, and wipe the optical parts.

Gently wipe the lens circularly from the center to periphery.

**Check**

- Do not use a metal stick or something made of hard materials.

***3*** Confirm that there is no dust or smudge.

If the optical parts are not cleaned satisfactorily, repeat the cleaning procedure with new lens cleaning paper until they become clean.

# 4.5 Checking Optical Axis of Treatment Beam (YAG mode)

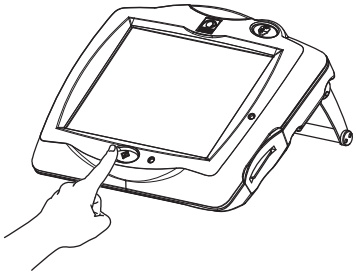
■ Confirm that the aiming beam and treatment beam are coaxial.

**1** Prepare the following things.

- Test paper (business card-sized black paper)
- Cellophane tape

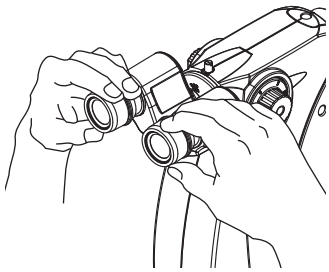
**2** Activate the device.

*"3.2.1 Activating the device" (page 41)*



**3** Adjust the eyepiece diopter and pupillary distance for the operator.

*"3.2.2 Preparing for emission" (page 42)*

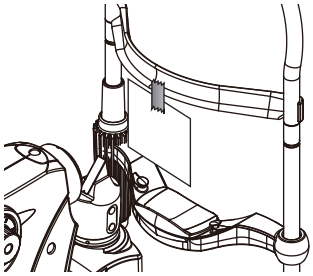


**4** Specify the settings of the device.

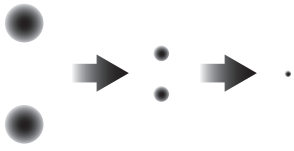
| Item | Setting |
|---|---|
| Microscope magnification | 32x |
| ENERGY | 0.3 to 0.5 mJ |
| FOCUS SHIFT | 0 µm |

**5** Attach the test paper to the forehead rest with cellophane tape.

Position it perpendicularly to the optical axis as much as possible.

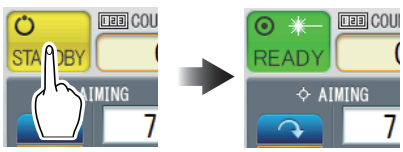


**6** Emit the aiming beam onto the test paper to adjust the focus.



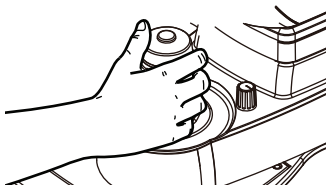
**7** Press the status button to set the device to 

mode.



***8*** Emit the treatment beam.

***9*** Confirm that the aiming beam is aligned with the burn on the test paper.



# 4.6 Checking Optical Axis of Treatment Beam (SLT mode)

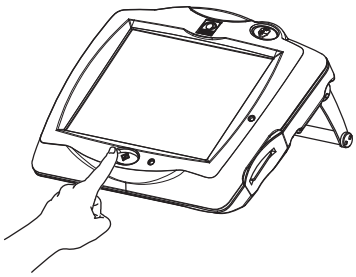
■ Confirm that the aiming beam and treatment beam are coaxial.

**1** Prepare the following things.

- Test paper (business card-sized black paper)
- Cellophane tape

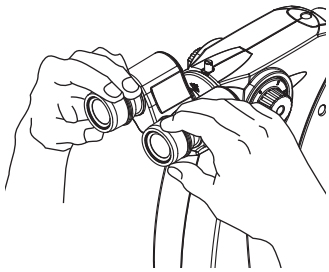
**2** Activate the device.

*"3.2.1 Activating the device" (page 41)*



**3** Adjust the eyepiece diopter and pupillary distance for the operator.

*"3.2.2 Preparing for emission" (page 42)*

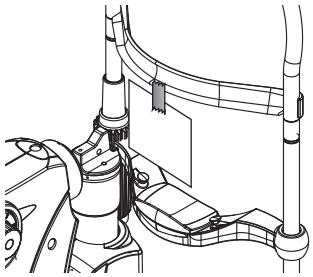


**4** Specify the settings of the device.

| Item | Setting |
|---|---|
| Microscope magnification | 32x |
| ENERGY | 0.3 to 0.5 mJ |

**5** Attach the test paper to the forehead rest with cellophane tape.

Position it perpendicularly to the optical axis as much as possible.



**6** Emit the aiming beam onto the test paper to adjust the focus.

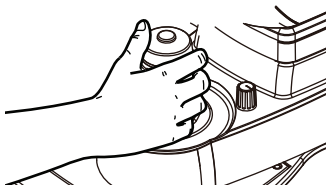
**7** Check the aiming beam.

- The intensity is even.
- The intensity is not lowered. The periphery is not obscured.
- The outline of the aiming beam is clear at the focal position.

**8** Press the status button to set the device to READY mode.

***9*** Emit the treatment beam.

***10*** Confirm that the aiming beam is aligned with the burn on the test paper.



# 4.7 Measuring and Calibrating Treatment Beam Energy Output

■ If the energy output of the treatment beam is out of tolerance, calibration is required.

An energy meter is necessary for energy output measurement and calibration.

**⚠ CAUTION**

- Only service personnel trained by NIDEK or NIDEK distributor are allowed to calibrate the laser energy output.
- Follow the procedure at least once a year.

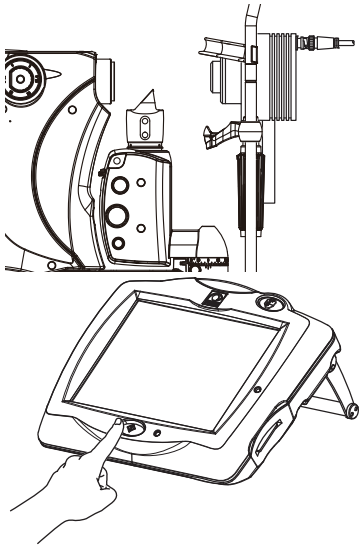
## 4.7.1 Measuring treatment beam energy output

***1*** Mount an energy meter.

1) Secure the detector of the energy meter to the chinrest.

   Align the height of the center of the detector's receiving surface with the eye level marker.

2) Connect the detector cable to the energy meter.

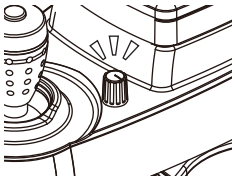


***2*** Activate the device.

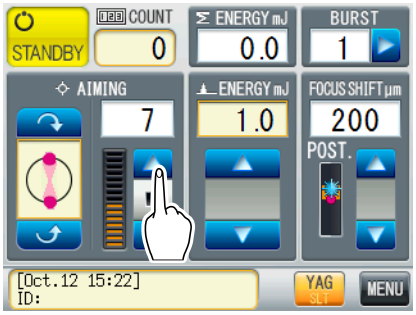
*"3.2.1 Activating the device" (page 41)*

***3*** Align the aiming beam with the receiving surface of the detector.

1) Turn off the illumination light by turning the illumination control.

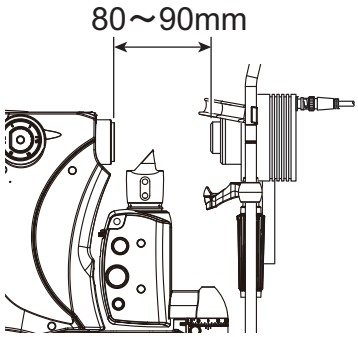


2) Project the aiming beam on the receiving surface of the detector.



3) Manipulate the joystick to move the objective lens of the device from 80 to 90 mm[*1] away from the receiving surface of the detector.

If the laser beam is focused on the receiving surface, the treatment beam may damage the receiving surface.




**4** Measure the treatment beam for all the combinations in the table.

| Mode | ENERGY | BURST | Tolerance |
|---|---|---|---|
| YAG mode | 0.3 mJ | 1, 2, 3 | ±20%.<br>For energy output stability, see *"5.1 Specifications" (page 87)*. |
| | 0.5 mJ | 1, 2, 3 | |
| | 1.0 mJ | 1, 2, 3 | |
| | 3.0 mJ | 1, 2, 3 | |
| | 5.0 mJ | 1, 2, 3 | |
| | 7.0 mJ | 1, 2, 3 | |
| | 8.0 mJ | 3 | |
| | 9.0 mJ | 2 | |
| | 10.0 mJ | 1 | |
| SLT mode | 0.3 mJ | - | ±20%.<br>For energy output stability, see *"5.1 Specifications" (page 87)*. |
| | 0.5 mJ | - | |
| | 1.0 mJ | - | |
| | 2.0 mJ | - | |
| | 3.0 mJ | - | |

**5** Record the measurement values.

*"5.5 Laser Beam Output Calibration Record" (page 98)*

**6** When the measurement values are out of the tolerance, the energy output needs to be calibrated.

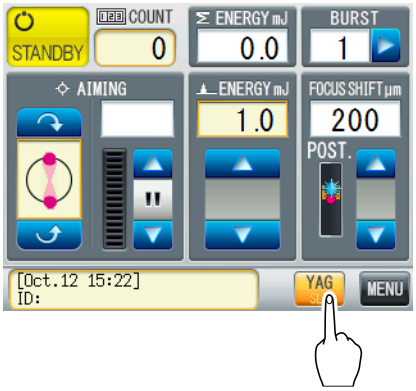
*"4.7.2 Calibrating treatment beam energy output" (page 79)*

*1. Leave this space when using an energy meter PE50-DIF-C manufactured by OPHIR. The required distance depends on energy meters. Decide the distance necessary for the energy meter to be used.

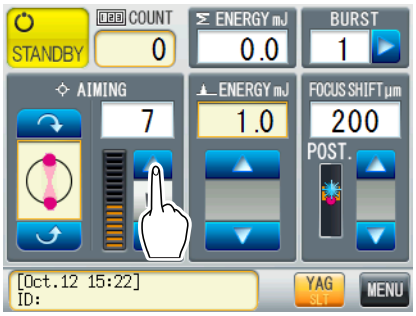
## 4.7.2 Calibrating treatment beam energy output

***1*** Change the mode for the treatment beam to be calibrated. (YC-200 S plus)

The treatment beam to be calibrated corresponds to the mode when CALIBRATION mode is activated.



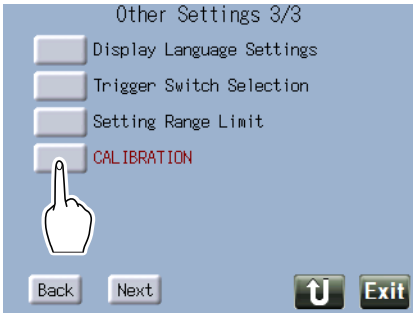

***2*** Press the AIMING button to turn on the aiming beam.



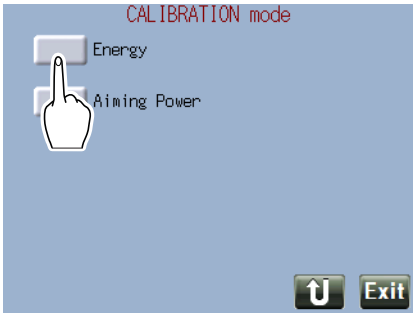

***3*** Activate CALIBRATION mode.

*"3.4 Changing Device Settings" (page 50)*

Only administrators qualified by NIDEK are informed of the password.

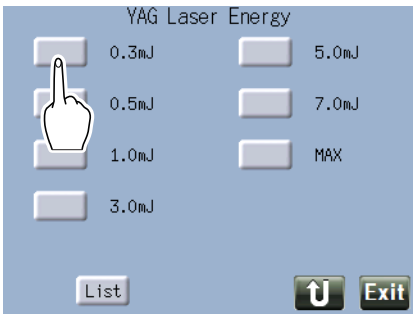



***4*** Press "Energy".

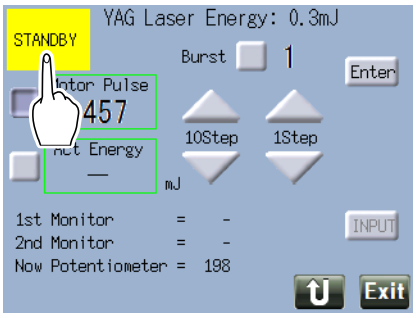



***5*** Change the parameters for 0.3 mJ energy value.

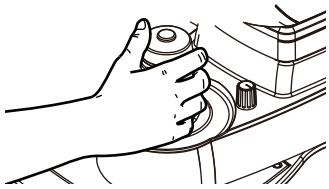
1) Press "0.3 mJ".



2) Press “STANDBY”.

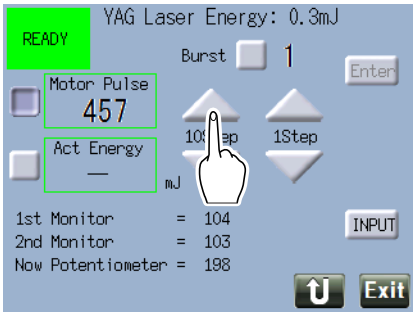



3) Emit the treatment beam and measure the energy.



4) Confirm that the measurement value is within 0.3 mJ ±0.01 mJ.

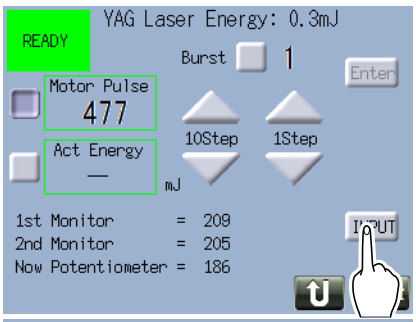
- The measurement value is within 0.3 mJ ±0.01 mJ.
  Proceed to *Step 5)*.
- The measurement value is not within 0.3 mJ ±0.01 mJ.
  Change the parameter for “Motor Pulse” and press Enter .
  Repeat from *Step 3)* to *Step 4)* until the value is within the criteria.




5) Press [Input] to save the parameter for “Motor Pulse”

Knowledge

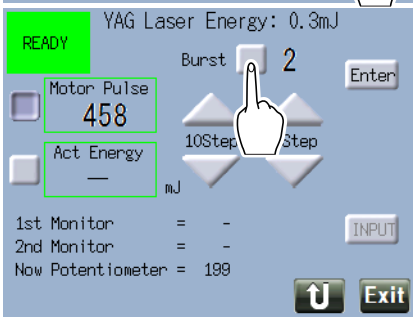
- [Input] can be pressed after the laser is emitted.




6) Change “Burst” to 2.

Repeat the treatment beam emission and change the parameter for “Motor Pulse” until the measurement value is within 0.6 mJ ±0.02 mJ.

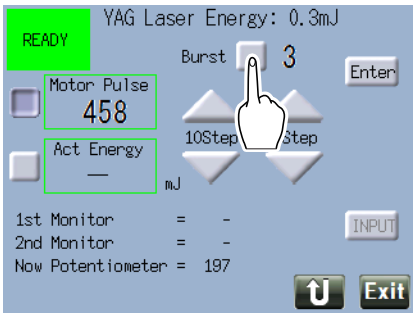
When the measurement value is within the criteria, press [Input] to save the parameter.



7) Change “Burst” to 3.

Repeat the treatment beam emission and change the parameter for “Motor Pulse” until the measurement value is within 0.9 mJ ±0.03 mJ.

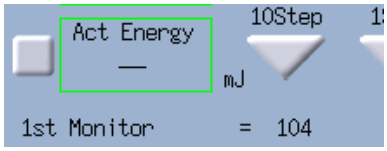
When the measurement value is within the criteria, press [Input] to save the parameter.




8) Press  .

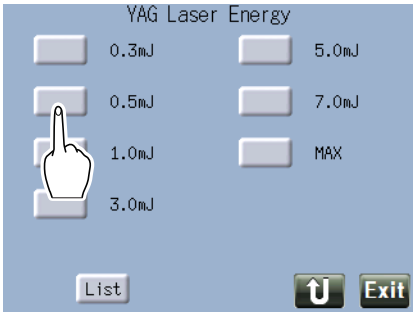
**Knowledge**

- When the parameter for 0.3 mJ is changed, “Act Energy” cannot be selected.

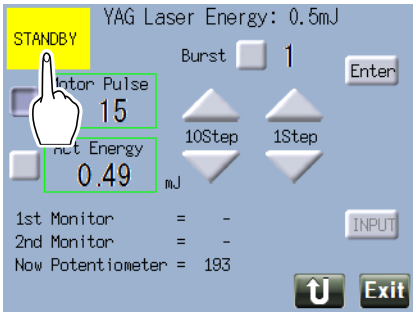



## 6 Change the parameters for 0.5 mJ energy value.

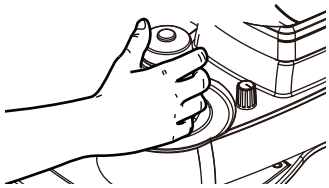
1) Press “0.5 mJ”.




2) Press “STANDBY”.




3) Emit the treatment beam and measure the energy.

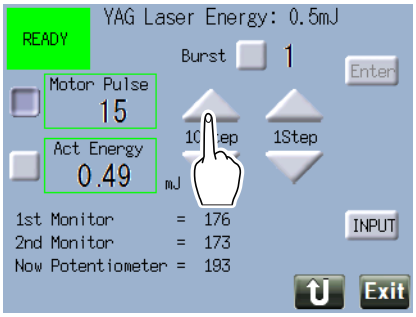


4) Confirm that the measurement value is within ±10% of the setting value.

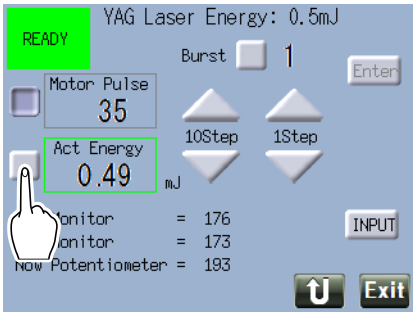
- The measurement value is within ±10% of the setting value.
  Proceed to *Step 5)*.
- The measurement value is not within ±10% of the setting value.

  Change the parameter for “Motor Pulse” and press Enter .

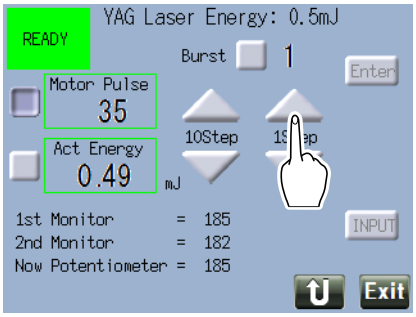
  Repeat from *Step 3)* to *Step 4)* until the value is within the criteria.




5) Press “Act Energy”.



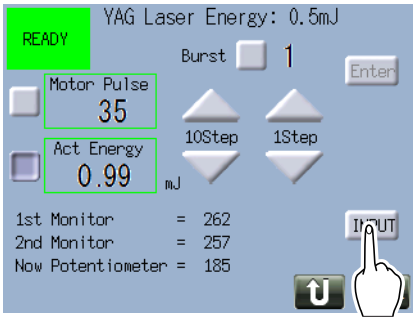

6) Enter the measurement value after the calibration.




7) Press [Input] to save the parameters for “Motor Pulse” and “Act Energy”.

**Knowledge**

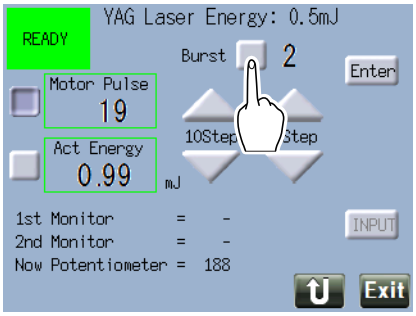
- [Input] can be pressed after the laser is emitted.



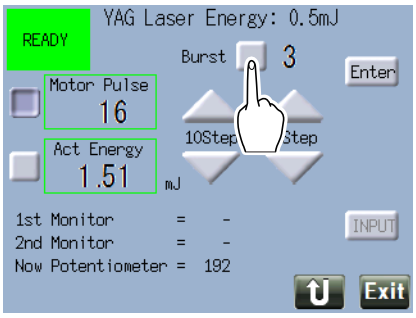

8) Change “Burst” to 2.

Repeat the treatment beam emission and change the parameter for “Motor Pulse” until the measurement value is within ±10% of the setting value. Enter the measurement value after the calibration (the sum of the 2 pulses) to the “Act Energy”.

When the measurement value is within the criteria, press [Input] to save the parameter.

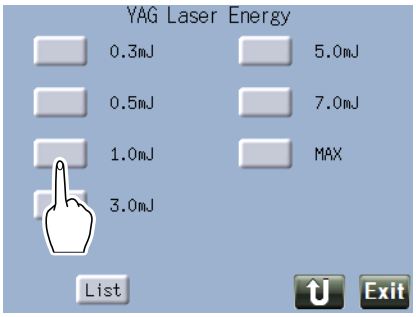


9) Change “Burst” to 3.
Repeat the treatment beam emission and change the parameter for “Motor Pulse” until the measurement value is within ±10% of the setting value. Enter the measurement value after the calibration (the sum of the 3 pulses) to the “Act Energy”.
When the measurement value is within the criteria, press [Input] to save the parameter.




10) Press .

## 7 Change the parameters for 1.0 mJ to MAX energy values.




Change the parameters in the same manner as with 0.5 mJ energy value, starting from the smallest energy value.

Concerning “MAX”, perform calibration for the following combinations.

| Mode | ENERGY | BURST |
|---|---|---|
| YAG mode | 8.0 mJ | 3 |
| | 9.0 mJ | 2 |
| | 10.0 mJ | 1 |

## 8 Record the measurement values.

*“5.5 Laser Beam Output Calibration Record” (page 98)*

## 9 Press Exit.

**Knowledge**

- In SLT mode, calibrate the treatment beam for 0.3 mJ, 0.5 mJ, 1.0 mJ, 2.0 mJ, and 3.0 mJ energy values.
  In the same manner as YAG mode, change the parameters in the order starting from the smallest energy value.
  In SLT mode, the Burst button is not displayed.

# 4.8 Measuring and Calibrating Aiming Beam Power Output

■ If the power output of the aiming beam is out of tolerance, calibration is required.

A power meter is necessary for power output measurement and calibration.

**⚠ CAUTION**

- Only service personnel trained by NIDEK or NIDEK distributor are allowed to calibrate the laser power output.
- Follow the procedure at least once a year.

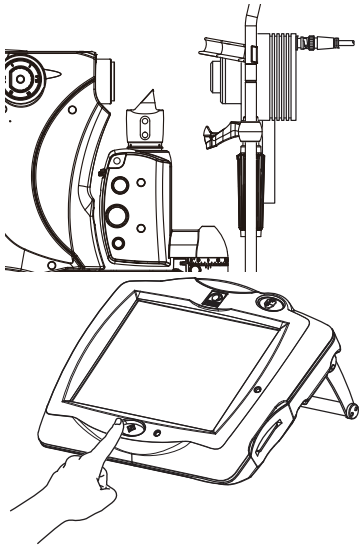
## 4.8.1 Measuring aiming beam power output

***1*** Mount a power meter.

1) Secure the detector of the power meter to the chinrest.

   Align the height of the center of the detector's receiving surface with the eye level marker.

2) Connect the detector cable to the power meter.

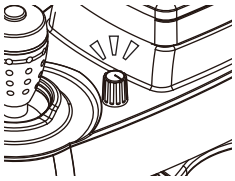


***2*** Activate the device.

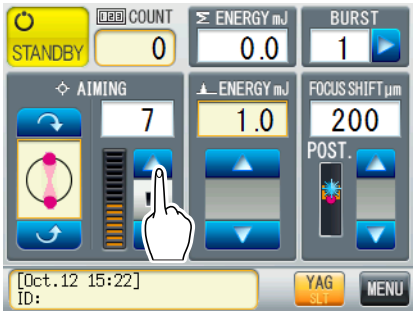
*"3.2.1 Activating the device" (page 41)*

***3*** Align the aiming beam with the receiving surface of the detector.

1) Turn off the illumination light by turning the illumination control.

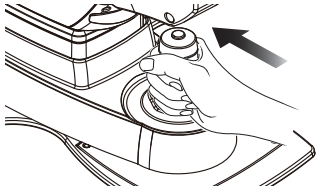


2) Project the aiming beam on the receiving surface of the detector.




3) Manipulate the joystick to align the aiming beam with a position where the aiming beam spot is within the receiving surface.

   It is not necessary to adjust the focus.



**4** Measure the aiming beam for the combinations in the table.

| Mode | Setting | Tolerance |
|---|---|---|
| YAG mode | 1 | 0.5 ±0.3 µW |
| | 15 | 25 ±5 µW |
| SLT mode | 1 | 0.04 mW or less |
| | 15 | 0.3 ±0.1 mW |

**5** Record the measurement values.

*"5.5 Laser Beam Output Calibration Record" (page 98)*

**6** When the measurement values are out of the tolerance, the power output needs to be calibrated.

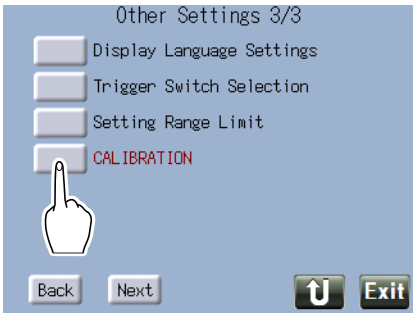
*"4.8.2 Calibrating aiming beam power output" (page 86)*

## 4.8.2 Calibrating aiming beam power output

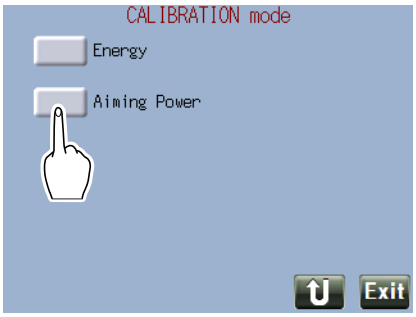
**1** Activate CALIBRATION mode.

"3.4 Changing Device Settings" (page 50)

Only administrators qualified by NIDEK are informed of the password.




**2** Press "Aiming Power".

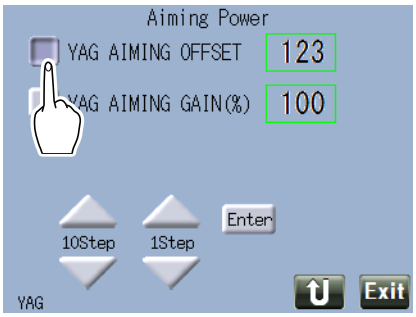



**3** Change the parameters.

1) Press a button to change the corresponding parameter.

Minimum power output: AIMING OFFSET

Maximum power output: AIMING GAIN




**Knowledge**

- The tolerance of the measurement values compared to the setting values is described below.
- YAG mode
  Maximum: 25 ±5 μW
  Minimum: 0.5 ±0.3 μW
- SLT mode
  Maximum: 0.3 ±0.1 mW
  Minimum: 0.04 mW or less

2) Press Enter.

3) Press ↑.

**4** Record the measurement values.

"5.5 Laser Beam Output Calibration Record" (page 98)

**5** Press Exit.

# 5 SPECIFICATIONS AND TECHNICAL INFORMATION

## 5.1 Specifications

| Device specifications | | |
|---|---|---|
| YAG treatment beam | • Wavelength | 1,064 nm |
| | • Energy output | BURST 1: 0.3 to 10.0 mJ ±20%<br>BURST 2: 0.3 to 9.0 mJ ±20%<br>BURST 3: 0.3 to 8.0 mJ ±20% |
| | • Energy output stability | The energy output meets the specification 90% or greater (out of continuous 20 shots). |
| | • Number of emitted pulses | Single mode: one shot / trigger<br>Burst mode: two or three shots / trigger |
| | • Spot size | 8 µm |
| | • Pulse width | 3 ns ±20% |
| | • Pulse interval | 60 to 200 µs |
| | • Continuous irradiation / repetition time | Single mode: 3 Hz<br>Burst mode: 1.5 Hz |
| | • Cone angle | 16° ±2° |
| | • Focus shift | ±500 µm |
| | • Nominal Ocular Hazard Distance (NOHD) | Single mode: 2.65 m<br>Burst mode: 1.71 m |
| YAG aiming beam | • Wavelength | 635 nm |
| | • Power output | OFF, 0.5 to 25 µW<br>Max. 25 ±5 µW, Min. 0.5 ±0.3 µW |
| Protection of operator's eye (YAG) | • Optical density (O.D.) | 5 or more |

| Device specifications | | |
|---|---|---|
| SLT treatment beam (YC-200 S plus) | • Wavelength | 532 nm |
| | • Energy output | 0.3 to 3.0 mJ ±20% |
| | • Energy output stability | The energy output meets the specification 90% or greater (out of continuous 120 shots). |
| | • Spot size | 400 µm |
| | • Pulse width | 3 ns ±20% |
| | • Continuous irradiation / repetition time | Single mode: 3 Hz |
| | • Cone angle | 5.5° ±1° |
| | • Nominal Ocular Hazard Distance (NOHD) | 13.7 m |
| SLT aiming beam (YC-200 S plus) | • Wavelength | 635 nm |
| | • Power output | OFF, 0.04 to 0.3 mW<br>Max. 0.3 ±0.1 mW, Min. 0.04 mW or less |
| | • Cone angle | 7.5° or less |
| | • Spot size | 400 µm |
| Protection of operator's eye (SLT) (YC-200 S plus) | • Optical density (O.D.) | 5 or more |
| Microscope optical system | • Optical axis | Galilean type |
| | • Distance between right and left optical axes | 22 mm |
| | • Objective lens focal length | f = 125 mm |
| | • Total magnification | 5x, 8x, 12.5x, 20x, 32x |
| | • Real field of view | ø 40.7 mm, 25.7 mm, 16.1 mm, 10.1 mm, 6.4 mm |
| Binocular microscope | • Optical system | Convergence angle 6° |
| | • Distance between right and left optical axes | 22 mm |
| | • Minimum interpupillary adjustment range | 50 to 78 mm |
| | • Eye relief | 20 mm or more |
| | • Eyepiece magnification | 12.5x |
| | • Lens aperture | 23 mm |
| | • Diopter adjustment range | ±8 D |

| Device specifications | | |
|---|---|---|
| Slit illumination | • Illumination light source | White LED |
| | • Slit length | 14 mm, 9 mm, 5 mm, 3 mm, 1 mm, 0.2 mm |
| | • Slit width | 0 to 14 mm |
| | • Slit rotation | 360° |
| | • Illuminance | OFF, minimum illuminance to maximum illuminance (continuously variable)<br>Max. 208,000 lx to 160,000 lx<br>* Illuminance at 0° when the illumination tower equipped with a tilting function is used |
| | • Filter | Blue, red-free, 15% ND |
| Illumination tower (SLT)<br>Illumination tower equipped with a tilting function<br>(YC-200 S plus) | • Illumination incidence angle | 0 to 20° (downward) |
| Illumination tower (YAG)<br>Illumination tower with the base fixed | • Illumination incidence angle | 18° (downward) |
| Head rest | • Eye level height | 395 mm |
| | • Distance between supports | 220 mm |
| | • Chinrest up and down movement | 80 mm (manual) |
| Fixation lamp | • Light source | LED (green) |
| Main body horizontal movement | • Forward and backward | 80 mm |
| | • Right and left | 100 mm |
| | • Fine movement distance | ±5 mm |
| Main body up and down movement | • Up and down | 30 mm (motorized) |
| Power supply | • Voltage | AC 100 to 240 V ±10% |
| | • Frequency | 50/60 Hz |
| | • Power consumption | A maximum of 100 VA |
| Dimensions and mass | • Dimensions | 346 mm (W) × 422 mm (D) × 577 mm (H) |
| | • Mass | 17.0 kg (YC-200)<br>18.0 kg (YC-200 S plus) |

| Device specifications | | |
|---|---|---|
| Environmental conditions (during use) | • Temperature | 15 to 30°C (59 to 86°F) |
| | • Humidity | 30 to 90% (non-condensing) |
| | • Atmospheric pressure | 800 to 1,060 hPa |
| | • Installation location | Indoors<br>On a level, stable location in a darkened room or laser treatment room with laser protective enclosure |
| | • Other | No harmful dust or smoke |
| Environmental conditions (during transport [packed condition] and storage) | • Temperature | -10 to 55°C (14 to 131°F) |
| | • Humidity | 10 to 95% (non-condensing) |
| | • Atmospheric pressure | 500 to 1,060 hPa |
| Expected service life | • 7 years (defined by manufacturer)* Proper maintenance is necessary. | |
| Equipment to be used in combination | • NIDEK ophthalmic laser photocoagulator<br>Green Laser Photocoagulator GYC-500 | |
| Classifications | • Laser classification (IEC 60825-1): Class 3B<br>Laser product that are normally hazardous when intrabeam ocular exposure occurs within the NOHD including accidental short time exposure. It is necessary to avoid exposure to laser. Viewing diffuse reflections is normally safe.<br>• Protection against electrical shock: Class I ME equipment<br>• Protection against electrical shock (applied parts): Type B applied part<br>• Protection against harmful ingress of water or particulate matter: IPX0 (main body), IPX8 (optional foot switch)<br>• Method(s) of sterilization: ME equipment that does not contain any part that needs sterilization.<br>• Suitability for use in an oxygen rich environment: ME equipment that is not intended for use in an oxygen rich environment<br>• Mode of operation: Continuous operation<br>• Conformity to the standard for slit-lamp microscope: In compliance with ISO 10939:2007 | |

| Device specifications | | |
|---|---|---|
| **Accessories** | | |
| Standard accessories | Main body, head rest, control box, connector box, remote connector plug, keycard, power cord, chinrest paper, head belt, grips, focusing rod, attachment plates, arm rest, cap, dust cover, DANGER label, operator's manual | |
| Optional accessories | Foot switch, optical table, illumination tower (tilting / with the base fixed / split mirror illumination), stand for CB, safety goggles | |
| **Optional optical table specifications** | | |
| Operation | • Elevation range | 653 to 851 mm (Table top height) |
| | • Elevation time | 12 s (60 Hz) |
| Power supply | • Voltage | For 100 V regions: AC 120 V ±10%<br>For 200 V regions: AC 230 V ±10% |
| | • Frequency | 50/60 Hz |
| | • Power consumption | 1000VA |
| Dimensions and mass | • Dimensions | 742 mm (W) × 463 mm (D) × 653 to 851 mm (H) |
| | • Mass | 25 kg |
| Environmental conditions | • The same as those of the main body specifications | |

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

# 5.2 Light Hazard

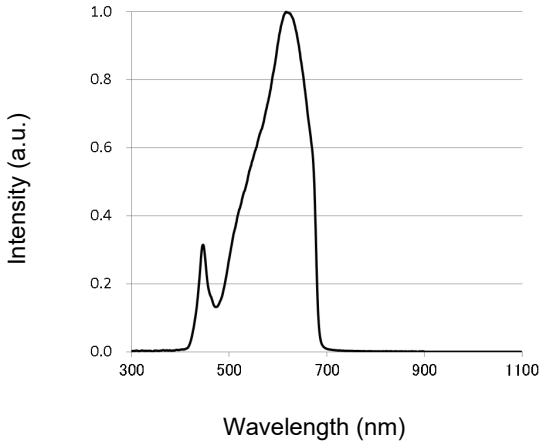
■ Provision of information on the avoidance of light hazard from the optical device is required in ISO 15004-2:2007 “Ophthalmic instruments - Fundamental requirements and test methods -”.

**⚠ CAUTION**

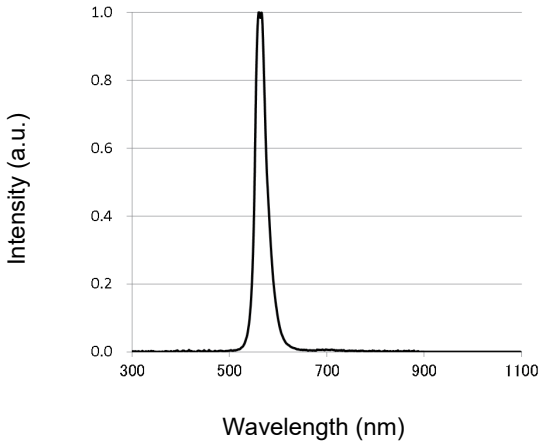
- The light emitted from this device is potentially hazardous. The longer the duration of exposure is, the greater the risk of ocular damage becomes.
  Exposure to light from this device when operated at maximum intensity will exceed the safety guideline at the following duration (except for the treatment beam).
  During treatment of posterior capsule (YC-200): 303 seconds
  During treatment of anterior chamber angle (YC-200 S plus): 347 seconds

● Graphs of relative spectral power output

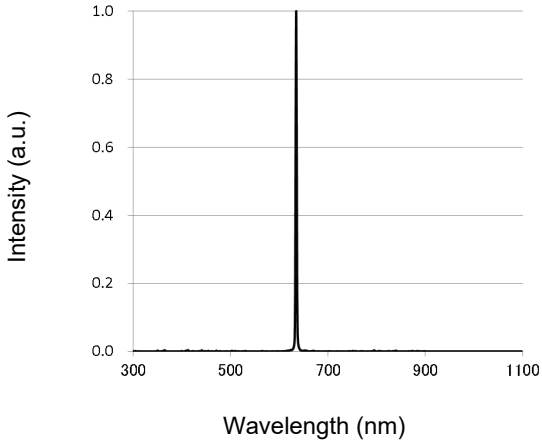
Slit illumination



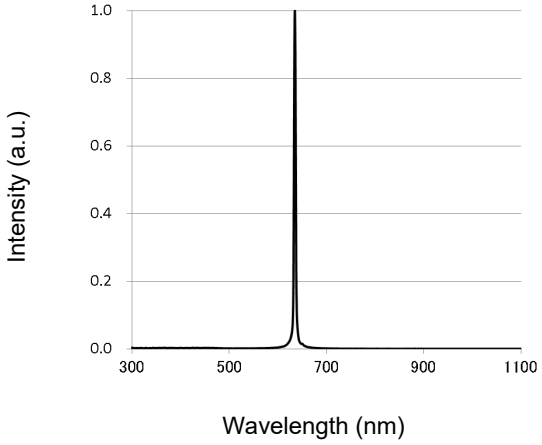

Fixation lamp




YAG aiming beam

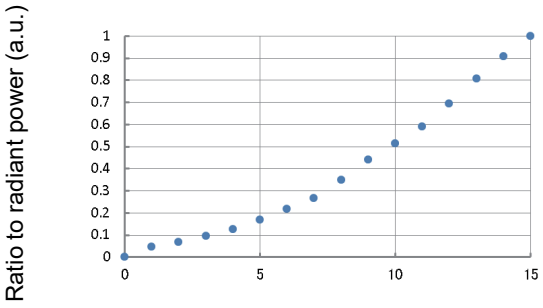



SLT aiming beam (YC-200 S plus)

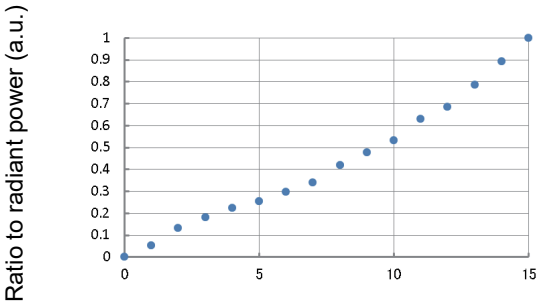


● Maximum intensity and ratio to maximum intensity

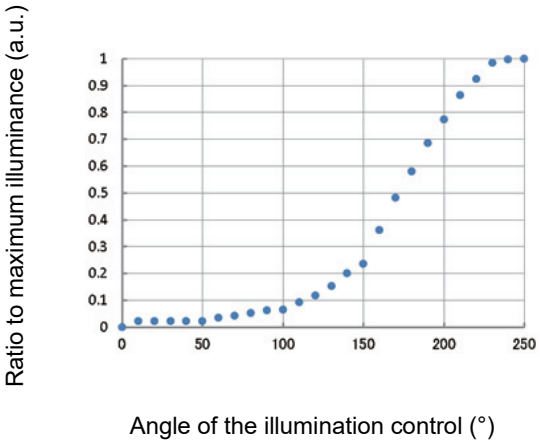
YAG aiming beam




SLT aiming beam (YC-200 S plus)




Slit illumination



# 5.3 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) |
|---|---|---|---|
| Communications cable for CB | Yes | No | 1.1 |
| Main body connection cable | Yes | No | 0.55 |
| Fixation lamp connection cable | Yes | No | 0.7 |
| YC connection cable | Yes | No | 1.3 |
| GYC connection cable | Yes | Yes | 2.9 |
| Fiber optic cable (COMBO) | No | No | 3.0 |
| Foot switch cable | Yes | No | 2.9 |
| Power cord | No | No | 3.0 |

## ◆ Essential performance

- Laser irradiation function

## ◆ Compliance for Emission Standard

| Phenomenon | Product family standard | Compliance |
|---|---|---|
| Conducted and radiated RF emissions | CISPR 11 | Group 1<br>Class B |
| Harmonic distortion | IEC 61000-3-2 | *1 |
| Voltage fluctuations and flicker | IEC 61000-3-3 | *2 |

* 1 For the regions where the rated voltage is 220 V to 240 V, this device complies with this standard.
* 2 For the regions where the rated voltage (line to neutral) is 220 V to 250 V, this device complies with this standard.

## ◆ Test specifications for enclosure port immunity to RF wireless communications equipment

| Test frequency (MHz) | Band (MHz) | Service | Modulation | Immunity test level (V/m) |
|---|---|---|---|---|
| 385 | 380 to 390 | TETRA 400 | Pulse modulation<br>18 Hz | 27 |
| 450 | 430 to 470 | GMRS 460, FRS 460 | FM<br>±5 kHz deviation<br>1 kHz sine | 28 |
| 710 | 704 to 787 | LTE Band 13, 17 | Pulse modulation<br>217 Hz | 9 |
| 745 | | | | |
| 780 | | | | |
| 810 | 800 to 960 | GSM 800/900,<br>TETRA 800, iDEN 820,<br>CDMA 850, LTE Band 5 | Pulse modulation<br>18 Hz | 28 |
| 870 | | | | |
| 930 | | | | |
| 1720 | 1700 to 1990 | GSM 1800;<br>CDMA 1900;<br>GSM 1900; DECT;<br>LTE Band 1, 3, 4, 25;<br>UMTS | Pulse modulation<br>217 Hz | 28 |
| 1845 | | | | |
| 1970 | | | | |
| 2450 | 2400 to 2570 | Bluetooth<br>WLAN 802.11 b/g/n<br>RFID 2450<br>LTE Band 7 | Pulse modulation<br>217 Hz | 28 |
| 5240 | 5100 to 5800 | WLAN 802.11 a/n | Pulse modulation<br>217 Hz | 9 |
| 5500 | | | | |
| 5785 | | | | |

## ◆ Compliance for Immunity Standard

| Phenomenon | Basic EMC standard | Immunity test levels |
|---|---|---|
| Electrostatic discharge | IEC 61000-4-2 | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air |
| Radiated RF electromagnetic field | IEC 61000-4-3 | 3 V/m<br>80 MHz - 2.7 GHz<br>80% AM at 1 kHz |
| Proximity fields from RF wireless communications equipment | IEC 61000-4-3 | See “Test specifications for enclosure port immunity to RF wireless communications equipment”. |
| Electrical fast transients / bursts | IEC 61000-4-4 | Input power port ±2 kV<br>100 kHz repetition frequency |
| | | Signal input/output parts port ±1 kV<br>100 kHz repetition frequency |
| Surges<br>Line-to-line | IEC 61000-4-5 | Input power port ±0.5 kV, ±1 kV |
| Surges<br>Line-to-ground | | Input power port ±0.5 kV, ±1 kV, ±2 kV<br>Signal input/output parts port ±2 kV |
| Conducted disturbances induced by RF fields | IEC 61000-4-6 | 3 V 0.15 MHz – 80 MHz<br>6 V in ISM bands between 0.15 MHz and 80 MHz<br>80% AM at 1 kHz |
| Rated power frequency magnetic fields | IEC 61000-4-8 | 30 A/m<br>50 Hz or 60 Hz |
| Voltage dips | IEC 61000-4-11 | 0% $U_T$; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° |
| | | 0% $U_T$; 1 cycle<br>and<br>70% $U_T$; 25/30 cycles<br>Single phase: at 0° |
| Voltage interruptions | IEC 61000-4-11 | 0% $U_T$; 250/300 cycles |

## 5.4 Administration List

### ◆ Administrator

| Main/ Sub | Post | Name | Approval |
|---|---|---|---|
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### ◆ Registered user list

| Post | Name | Approval |
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# 5.5 Laser Beam Output Calibration Record

■ Print it if necessary.

● YAG treatment beam

| Setting | Measurement value (mJ) | | |
|---|---|---|---|
| | Single (Burst 1) | Burst 2 | Burst 3 |
| 0.3 mJ | | | |
| 0.5 mJ | | | |
| 1.0 mJ | | | |
| 3.0 mJ | | | |
| 5.0 mJ | | | |
| 7.0 mJ | | | |
| MAX | | | |

● SLT treatment beam

| Setting | Measurement value (mJ) |
|---|---|
| 0.3 mJ | |
| 0.5 mJ | |
| 1.0 mJ | |
| 2.0 mJ | |
| 3.0 mJ | |

● YAG aiming beam

| Setting | Tolerance | Measurement value (μW) |
|---|---|---|
| 1 | 0.5 ±0.3 μW | |
| 15 | 25 ±5 μW | |

- SLT aiming beam

| Setting | Tolerance | Measurement value (mW) |
|---|---|---|
| 1 | 0.04 mW or less | |
| 15 | 0.3 ±0.1 mW | |

# 5.6 Pre-use Checklist

■ Print it if necessary.

| Item | Date and person responsible for check |
|---|---|
| The lenses and mirrors are clean. | |
| The forehead rest, chinrest, grips, and head belt are clean. | |
| The power cord is connected to a grounded power outlet that meets the power requirements. | |
| The power indicator on the control box illuminates. | |
| Inserting the keycard and pressing the start button turns on the screen of the control box. | |
| YAG mode | |
| The AIMING value increases and decreases. | |
| AIMING rotates. | |
| The ENERGY value increases and decreases. After the change, the test fire is performed. | |
| The FOCUS SHIFT value increases and decreases. | |
| The BURST value changes. After the change, the test fire is performed. | |
| After AIMING lights up, “READY” and “STANDBY” can be switched. | |
| After the device enters READY mode, pressing the hand switch emits the treatment beam. | |
| The aiming beam and treatment beam are coaxial. *(page 73)* | |
| Pressing COUNT clears the value. | |
| The device is turned off when the emergency laser stop button is pressed. | |
| SLT mode (YC-200 S plus) | |
| Pressing  toggles YAG mode and SLT mode. | |
| The AIMING value increases and decreases. | |
| The ENERGY value increases and decreases. After the change, the test fire is performed. | |
| SLT-NAVI can be set. | |
| After AIMING lights up, “READY” and “STANDBY” can be switched. | |
| After the device enters READY mode, pressing the hand switch emits the treatment beam. | |
| The aiming beam and treatment beam are coaxial. *(page 75)* | |
| Pressing COUNT clears the value. | |
| The device is turned off when the emergency laser stop button is pressed. | |

# 5.7 Glossary

| Term | Details |
|---|---|
| Device | The main laser device of YAG laser system<br>Two types are available: YC-200 and YC-200 S plus |
| YC-200 | The device equipped with YAG mode function only. |
| YC-200 S plus | The device equipped with YAG and SLT mode functions. |
| CB | Control box |
| Connector box | A unit that contains the power supply and connectors of the device. |
| YAG mode | An operation mode in which treatment using the YAG treatment beam (wavelength: 1,064 nm) is available.<br>It is used mainly for posterior capsulotomy and iridotomy. |
| SLT mode | An operation mode in which treatment using the SLT treatment beam (wavelength: 532 nm) is available.<br>It is used for selective laser trabeculoplasty. |
| Laser beam | Treatment beam and aiming beam |
| YAG laser<br>YAG treatment beam | Laser beam for treatment of the affected tissue in YAG mode.<br>A 1,064 nm pulsed laser beam is used. |
| SLT laser<br>SLT treatment beam | Laser beam for treatment of the affected tissue in SLT mode.<br>A 532 nm pulsed laser beam (green) is used. |
| Laser energy output | Laser energy emitted from the laser aperture of the device.<br>(Unit: mJ) |
| YAG aiming beam | Laser beam that indicates the position to which the treatment beam is to be emitted in YAG mode.<br>The two-beam system (separating the YAG aiming beam into two beams) is used. The focus position is determined according to the alignment of the beams. |
| SLT aiming beam | Laser beam that indicates the position to which the treatment beam is to be emitted in SLT mode.<br>The parfocal optical system is used. The focus position is determined according to the projection status of the beams. |
| Test fire | Checking that there are no abnormalities with the laser by emitting the laser within the device before the laser is actually emitted toward the patient's eye |
| Spot size | Diameter of the laser beam spot |
| Single mode | One shot of treatment beam is emitted each time the trigger switch is pressed in this mode. |
| Burst mode<br>(YAG mode) | Two or three shots of treatment beam are emitted each time the trigger switch is pressed in this mode. |
| Focus shift<br>(YAG mode) | To shift the focal points (focus) of the YAG treatment beam and YAG aiming beam.<br>It is mainly used for the treatment of secondary cataract in which the focal point of the YAG treatment beam is shifted to the posterior chamber (POST.) side from the aiming beam to prevent inclusion of pit in the intraocular lens. |
| Aiming beam rotation<br>(YAG mode) | To rotate the spot order of the YAG aiming beam in order to set the spots to the desired positions.<br>The function of continuous rotation for the specified durations is also available. |
| SLT-NAVI<br>(SLT mode) | The function that assists the operator in surgery by specifying the laser emission positions and orders before the treatment<br>Enter the emission area, emission start position, and emission direction. |

| Term | Details |
|---|---|
| READY | The treatment beam can be emitted. Pressing the status button of the control box toggles between “STANDBY” and “READY”. |
| STANDBY | The treatment beam cannot be emitted. Pressing the status button of the control box toggles between “STANDBY” and “READY”. |
| Protective filter | The optical filter to protect the operator’s eye from the reflected light of the treatment beam<br>Inserted and fixed within the device.<br>YC-200: Only YAG treatment beam (1,064 nm) is blocked.<br>YC-200 S plus: YAG treatment beam (1,064 nm) and SLT treatment beam (532 nm) are blocked. |
| Grips | Patients hold them to keep themselves in a stable posture during surgery. |
| Chinrest elevation control | Used to adjust the height of the patient’s chin. |
| Chinrest | Used to rest the patient's chin. |
| Fixation lamp | Used to steady the patient's visual axis by having the patient focus on the lamp.<br>The position of the fixation lamp can be adjusted by the flexible arm. |
| Forehead rest | Used to rest the patient’s forehead to keep them in a stable posture. |
| Eye level marker | Markers to adjust the height of the patient's eyes. |
| Base unit fastening knob | Used to fasten the device so that the device may not move horizontally. |
| Illumination unit arm fastening knob | Used to secure the illumination unit arm. |
| Microscope arm fastening knob | Used to secure the microscope arm. |
| Eyepieces | Lenses attached to the part closest to the operator’s eyes. |
| Magnification changer | Used to select the total magnification of the microscope. |
| Slit rotation control | Used to rotate the illumination light. |
| Slit width control | Used to continuously adjust the width of the illumination light. |
| Slit length control | Used to select the aperture diameter (slit length) of the illumination light. |
| Filter changer | A disk to select a filter to be inserted into the observation optical path |
| Joystick | Used to adjust the position of the observation unit.<br>By manipulating the joystick right, left, forward, and backward, the unit moves right, left, forward, and backward. By tilting the joystick, the unit slightly moves to the direction of tilt. |
| Hand switch | Used to emit the treatment beam.<br>Select either the hand switch or the optional foot switch as a trigger switch. |
| S-Switch | An auxiliary switch built-in the joystick.<br>Three functions can be assigned as desired. |
| Illumination control | Used to adjust the intensity of the illumination light. |
| Power indicator | Lights up when the master switch is turned on while power is supplied. |
| Emergency laser stop button | An emergency button to stop the power and operation of the device<br>After the stop, pressing the start button restarts the device. |
| Start button | A button to activate and stop the device |
| Keycard | A memory card equipped with a function as a key necessary to activate the device<br>The configuration information of the device and error log information are also recorded. |

| Term | Details |
|---|---|
| Access indicator | An indicator that indicates whether the keycard is inserted and whether data is read or written in the keycard.<br>It lights up when the keycard is inserted and blinks when data is read or written in the keycard. |
| Touch screen | A screen to specify and display conditions |
| Limit mode<br>(YAG mode) | A function to limit the setting ranges of Energy, Focus Shift, and Burst to use the device more safely |
| REMOTE connector | A connector designed to turn off the device when an external switch connected by a signal line is turned off. Connect this connector to an external switch such as the door switch of the operating room so that the device is stopped when an outsider enters the operating room. In addition, this function allows a surgeon other than the one conducting the surgery to stop the device by turning off the external switch connected to the connector based on their judgment in case of a danger during surgery. |
| Nominal Ocular Hazard Distance (NOHD) | The Nominal Ocular Hazard Distance (NOHD) is the distance along the axis of the unobstructed beam from the laser aperture where the irradiance falls below the applicable exposure limit. |
| Parfocal optical system<br>(YC-200 S plus) | An optical system in which the image of an object surface is formed on the target surface. The SLT aiming beam is emitted from the fiber tip (the object surface) in the parfocal optical system so that it appears as a sharply-edged spot on the target surface. |
| Expected service life | A period of time beyond which the reliability and safety of the device cannot be guaranteed even under normal use and regular maintenance that involves repeated replacement of maintenance parts and consumable parts, repair, and overhaul. |

# 6 INDEX

## T



## Y