NIDEK		
Green Laser Photocoagulator GYC-500		
OPERATOR'S MANUAL	$ \begin{array}{c}                                     $	

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

Original instructions

# NIDEK CO., LTD.

NIDEK CO., LTD. (Manufacturer)

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2023-02-28 17166-P902-B5 Printed in Japan

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# **Before Use**

This operator's manual describes the device configuration, safety precautions, and specifications of the NIDEK Green Laser Photocoagulator GYC-500. For the operating procedure, refer to the operator's manual of the delivery unit to be connected.

Be sure to read the operator's manual prior to operation 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.

This system shall be installed and used in accordance with the requirements of applicable international or national standards for the safe use of laser devices in health care facilities.

### **IMPORTANT - READ CAREFULLY**

THIS AGREEMENT APPLIES TO THE NIDEK SOFT-WARE AND ACCOMPANYING DOCUMENTS. PLEASE READ THIS AGREEMENT CAREFULLY AND THOR-OUGHLY BEFORE USING SOFTWARE.

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

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

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#### 7. TERMINATION

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

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

#### 11. SEVERABILITY

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

### 12. SURVIVAL

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

#### 13. ASSIGNMENT

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

#### **14. ENTIRE AGREEMENT**

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

#### 15. NO WAIVER

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

#### **16. NO THIRD PARTY RIGHTS**

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

#### 17. HEADINGS

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

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

- 19. APPLICATION OF SOFTWARE LICENSE AGREE-MENT
- 19.1.If the terms and conditions of the "Software License Agreement" included in operations manuals for NIDEK product are inconsistent with the terms and conditions of the "Software License Agreement" displayed on NIDEK product, the terms and conditions of the "Software License Agreement" included in operations manuals for NIDEK product prevail.

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# 1.1 For Safe Use

# BEFORE USE, READ THIS MANUAL.

Be sure to read the operator's manual prior to operation of the device to understand the safety precautions and operating procedures thoroughly. Keep this manual handy for reference.

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

## 

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

## 

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

Even situations indicated by A CAUTION may result in serious injury under certain conditions.

Safety precautions must be strictly followed at all times.

# **1.2** Cautions for Administration and Controlled Area

## Administration

## 

- At least one qualified administrator and one sub-administrator must be appointed by the medical institution in which the device is to be used.
- 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.
- 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**

## A 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.

"2.5 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 informations should be indicated. (Warning indications)



If the above label is hidden due to the installation condition of the device, attach the following alternative label to the medical system including this device in a position that can be read by the user.



- 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

## 

- · 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 using the table in *"4.6.2 Checklist" (page 86)*.
  - Administrators are required to prepare the registered user list, store and manage the keycard.
  - Administrators are required to calibrate the laser power at least once a year as described in this Operator's Manual, and record the results using the table in *"4.4 Laser Beam Output Calibration Record"* (page 82).

# 1.3 Usage Precautions

## Before use

## / WARNING

- If any serious device-related incident occurs, report it to NIDEK and the competent authority in the country where the user or patient, or both reside.
- Use of the device is limited to treatment of ocular diseases by qualified physicians in accordance with the instructions in the Operator's Manuals of the main laser device and delivery unit. Physicians are responsible for any applications other than those specified in this Operator's Manual.

Use of the device outside the scope may cause adverse events and adverse device effects.

• The Operator's Manuals of the main laser device and delivery unit must be read before use and the safety precautions and operating procedures must be thoroughly understood.

Use of the device outside the scope may cause an accidental exposure to laser beam, adverse events, and adverse device effects.

- · Only service personnel trained by NIDEK are allowed to install or adjust the device.
- 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 should unexpected failure of the device occur.
- 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.

· Never use accessories other than those specified by NIDEK.

Use of the device outside the scope may cause adverse events and adverse device effects.

" Available delivery units" (page 93)

- Never modify or touch the internal structure of the device.
   Electric shock or malfunction may result.
- Prior to starting the device, make sure that there is no flammable anesthetic gas in the operating room.

Laser emission may cause fire or explosion.

 All personnel in the operating room other than the operator and patient must wear the recommended safety goggles during operation of the device to protect their eyes. In addition, instruct them not to look directly at the laser beam even while wearing the safety goggles because eyes may still be damaged.

Recommended goggles: Wavelength 532 nm, OD ≥ 5, 532 DI LB5 (En207)

- To prevent unexpected accidents, prior to starting the device, perform both the operation check and function check, and record the results.
- To prevent accidents or information leakage caused by unauthorized personnel, never leave the device unattended while it is in operation. If the operator has to be away from the device, remove the keycard and keep it in a secure place.
- Prior to surgery, provide the patient with sufficient information about the expected results and possible adverse events.
- Be sure to use a grounded power outlet.
   Electric shock or fire may result from device malfunction or electric leakage.

## 

• Install the device in an environment that meets the following conditions:

- A location that is not exposed to direct sunlight or ultraviolet radiation
- · A location that is not exposed to water or rain
- A location that is free from condensation
- A location in which chemicals or organic solvent are not present
- A location that is free from salt, sulfur, corrosive gas, or large amount of dust in the air.
- A location that is level, stable surface free from vibration and bumping.
- A location that meets the specifications.

5.1 Specifications" (page 91)

 After unpacking or changing the location of the device, let the device stand at room temperature prior to installation to prevent condensation.

Use of the device outside the scope may cause device error.

- Avoid installing the device where it is exposed to direct air flow from an air conditioner. Changes in temperature may result in condensation inside the device or adversely affect the functionalities.
- Never tilt the device 10° or more when installing or moving it. The device may topple causing injury or malfunction.
- Maintain separation of 10 cm or more between walls and the air vents located on both front and rear sides of the device to allow the device to cool down sufficiently.
- Securely connect the cords and cables to the specified connectors.
   Malfunction may result.
- When connecting or disconnecting the cords and cables, always hold them by the plug, not the cord, with dry hands. Do not coil the cord too tightly, or crush or pinch it with heavy objects.
   Electric shock or fire may result.
- Do not run the cords or cables near any device that emits heat. The casing may be melted.
- 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 the touch.

Malfunction or fire may result.

- Never drag the main laser device or delivery unit by the cords or cables.
   Cables may break and the device may topple causing injury or malfunction.
- Be sure to use a power outlet that meets the specified power requirements.

The device may not work properly, or malfunction or fire may result.

- Never use power strips or extension cables for the power supply of the device.
   The electrical safety may be lowered.
- When connecting to peripheral equipment such as a computer through LAN port via a medical facility network, insert and connect an isolation transformer between the medical electrical equipment and network devices (such as a hub), and between the network devices and other electrical equipment.

Depending on the types or numbers of other electrical equipment connected to the network, electric shock or malfunction and failure of the electrical equipment may result.

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

• 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

- Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- To prevent accidental laser exposure, never look directly at the aiming beam emitted from the laser aperture or point the beam toward others. Always pay attention to the direction of the aiming beam.



• When the treatment beam (wavelength: 532 nm) is applied to tissue, the following symptoms may occur. Always pay attention to the direction of the laser beam.

Eye symptoms: Damage to the cornea and such, or blindness Skin symptoms: Pain, burn injury

# 

- · Do not perform servicing or maintenance on the device during use.
- To ensure laser beam emission from the delivery unit is as selected, be sure to connect the fiber optic cable and delivery unit cable to the corresponding fiber optic cable connector and delivery unit connector.
- Slit lamp delivery units must be connected to CH1.
- For scan delivery units, connect the fiber optic cable to CH1 and connect the delivery cable to the SCAN port of the expansion box (optional).
- Do not coil the fiber optic cable with a radius of 10 cm or less.
   Breakage or deterioration may result.
- Do not impact the fiber optic cable such as by dropping or bumping it.
   Breakage or deterioration may result.
- Do not damage the end surface of the fiber optic cable plug. Laser beam transmittance may be reduced.
- If any abnormal indication (other than laser beam emission conditions) is displayed on the control box during use of the device, follow the applicable instructions.

4.7 Error Messages and Remedies" (page 87)

- When network connection or network communication failure occurs, check the network condition.
- When other computers are connected to the network, virus infection or data tampering may occur. Ensure proper operation condition under supervision of your network administrator.
- Set a screen saver password to the computer so that only authorized personnel can have access to data.
- Confirm that there is no reflective object in the laser optical path.
   Exposure to the reflected laser beam may result.
- Start the treatment beam from the lowest power output, then gradually increase the power until the desired effect is obtained. Be sure to return the output power to the lowest after every operation. Excessively intense treatment beam may be emitted.
- It has been reported that the risk of vitreous hemorrhage is higher in SCAN mode than in normal photocoagulation. In SCAN mode, start the treatment using the Single spot scan pattern at the lowest power output, then gradually increase the power until the desired effect is obtained. Be sure to return the power output to the lowest after the operation.
- To use a slit lamp and a wide-range indirect lens for the laser emission, use the settings recommended by the contact lens manufacturer.

Damage to the cornea or crystalline lens may result.

• When laser beam emission is not intended (such as when observing the eye), set the main laser device to STANDBY mode so that laser emission is not possible.

Accidental exposure to the laser beam may result.

• Perform the following procedure to confirm that the device is in a proper condition for laser beam emission:

• Confirm that the intensity is not lowered and the spot is not obscured.

• Project the aiming beam on a flat surface that is not specular, then confirm that the intensity is even over the entire spot as shown in the figure to the right.



• Confirm that the outline of the aiming beam is clear when the spot is in focus.

If any abnormality is found, contact NIDEK or your authorized distributor for maintenance and calibration.

# 

### Patient environment

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).

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.



## After use

## 

- After using the device, turn it off and place the dust cover over the device. Dust may affect the performance of laser beam emission.
- After using the device, remove the power cord plug from the power outlet to disconnect the device from the power source.
- When removing the power cord plug from the power outlet, maintain separation of 50 cm or more. Working in an insufficient space may result in injury.
- · Follow the instructions below for transportation of the device:
  - Disconnect the delivery unit from the main laser device and store them separately in their shipping cartons.
  - Injury or malfunction may result.
  - Do not bump the delivery unit or main laser device even when they are stored in their shipping cartons. Optical axis may be shifted.
  - 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

# 

- To protect the exterior and maintain the operability of the device, do not use organic or abrasive solvents for cleaning.
- Never damage the laser reflective mirror of the delivery unit to prevent reduction in laser performance.

# 

- Only service personnel trained by NIDEK can repair the device.
  - NIDEK assumes no responsibility for any adverse events resulting from improper servicing.
- Use the specified fuses only.

Malfunction or fire may result.

4.1 Replacing Fuses" (page 75)

- When sending the device back to NIDEK for repair or maintenance, clean the surfaces of the device (especially, the areas that come into contact with the patient) with a clean cloth dampened with rubbing alcohol.
- To ensure the continued safe use of the device, the user must make sure that maintenance and preventive inspection are performed at least once a year.

For details of maintenance and preventive inspection, contact NIDEK or your authorized distributor. If the user cannot perform the maintenance and preventive inspection, contact NIDEK or your authorized distributor.

# Disposal

## 

- When disposing of the device, contact NIDEK or your authorized distributor.
- Follow local governing ordinances and recycling regulations regarding disposal or recycling of device components when disposing of the foot switch or delivery unit.

Inappropriate disposal may contaminate the environment.

For details, contact NIDEK or your authorized distributor.

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

Inappropriate disposal may contaminate the environment.

# 1.4 Safety Devices

Name	Function
Keycard	Only the provided keycard allows operation of the GYC-500 so that only autho- rized personnel can use the device. For safety, when the device is not in use, remove and store the keycard in a secure place. When the keycard is removed while the device is in use, an error occurs. Keep the keycard inserted during use. * Commercial SD cards cannot be used.
Status button	Toggles between READY (treatment beam can be emitted) and STANDBY (treatment beam cannot be emitted) modes. Unless the device is set to READY mode, the treatment beam cannot be emitted even if the foot switch is accidentally pressed. Always set the device to STANDBY mode except when using the treatment beam.
Status indicator	Indicates whether the treatment beam emission is possible. The indicator turns green when the device is in READY mode (treatment beam can be emitted), and turns orange in STANDBY mode (treatment beam cannot be emitted). If a device abnormality occurs, the status indicator blinks in green and orange alternately.
Emergency stop button	If any abnormality occurs with the patient or device, the operator presses this button to stop the surgery. When this button is pressed, the safety shutter blocks the laser beam optical path and the device turns off. To restart the device, press the start button. * Normally, use the start button to turn off the device.
Emission time manual off function	Discontinues the treatment beam emission the instant that the foot switch is released even though the set emission time has not elapsed. This function prevents excessive emission of the treatment beam based on the physician's judgment. In such a case, the actual emission time is displayed for one second in the TIME filed.
Aiming off function	This function automatically sets the device to STANDBY mode (treatment beam cannot be emitted) and closes the shutter when the aiming beam is turned off so that the treatment beam cannot be emitted. While the aiming beam is turned off, the device cannot enter READY mode even when the status button is pressed. This function prevents the treatment beam from being emitted without the aiming beam.
Fiber optic cable detec- tion function	Connection of the fiber optic cable to the device is detected to prevent laser beam emission when the fiber optic cable is disconnected from the device.
Protective filter	Protects the operator's eye from the reflected treatment beam. All delivery units are equipped with a protective filter.
Self-diagnostic function	If a device abnormality occurs, the laser beam optical path is automatically blocked by the shutter to prevent laser beam emission and the device turns off. When the device comes to a stop, a beep sounds and an error is displayed to notify the user of the details.
Remote connector plug	When the remote connector is connected to a signal line of an external switch, turning off the external switch also turns off the device. 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 physician other than the one conducting the surgery to stop the device based on their judgment in case of a danger during laser beam emission.

Name	Function
Improper operation indi- cation function	If improper operation is performed, a series of beeps sounds and the remedy is displayed on the control box. This function informs the operator of the correct operation procedures and allows the operator to continue the laser emission.
Manual reset function	When the device operation has been interrupted by an unexpected event such as malfunction of the external switch or a blackout, this function prevents auto- matic resumption of operation after the interruption cause has been cleared. Press the start button to resume the operation.

# 1.5 Labels and Symbols

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

Ĩ	Indicates that the operator is advised to refer to the related instructions in the operator's manual.
*	Indicates that the degree of protection against electric shock is of a Type BF Applied Part. Applicable only when the endophotocoagulation probe specified by NIDEK is con- nected.
$\sim$	Indicates that the device must be supplied only with alternating current.
0	Indicates the state of the master switch. When the switch is turned to the side of this symbol, power is not supplied to the device.
	Indicates the state of the master switch. When the switch is turned to the side of this symbol, power is supplied to the device.
$\langle \rangle$	Indicates the start button of the control box.
ѱ	Indicates the fuse rating.
**************************************	Indicates the button that should be pressed under emergency occurred during opera- tion of the device.
	Indicates the laser aperture and alerts the operator to hazardous laser exposure.
	Indicates that eye exposure to direct or scattered radiation must be avoided.
	Indicates that skin exposure to direct or scattered radiation must be avoided.
Z	Indicates the date of manufacture.
	Indicates the manufacturer.
	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



# 2.1 Outline

The NIDEK Green Laser Photocoagulator GYC-500 is a laser photocoagulator for ophthalmology using a 532 nm optically-pumped semiconductor laser (green laser beam) as the treatment beam source.

## 2.1.1 Intended use

The device is intended to be used in ophthalmic surgical procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

# 2.1.2 Intended patient population

- Age
  - Infants to elderly
- · Health condition

Patients with eye disease requiring photocoagulation

• Conditions - Visual function One or both eyes are diseased.

## 2.1.3 Intended user profile

Ophthalmologists

# 2.1.4 Intended use environment

Medical facility

# 

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

# 2.1.5 Principles

Laser photocoagulation is thermal coagulation of tissue (protein) with the heat generated by the laser beam that reaches through ocular media to the pigment of the retina or choroid. Normally, protein coagulates and becomes white when its temperature rises to approximately 70°C or higher. The amount of coagulation can be judged by observing the white spots with an ophthalmoscope such as a slit lamp or binocular indirect ophthalmoscope. The generation of white spots varies slightly within the same treatment beam emission area. The higher the laser power and the longer the laser emission time is, the greater the heat generation becomes. With greater heat generation, the coagulation effect spreads to surrounding tissues.

The emitted green laser beam (532±3 nm, treatment beam) and the aiming beam (635±5 nm, Red) are fed coaxially into the fiber optic cable. The output terminal of the fiber optic is connected to a delivery unit. The laser beam is formed into the desired spot size by the optical system, then the laser beam is emitted to the target area (the emission area of the green laser beam and aiming beam is the same). The delivery units are equipped with a protective filter which protects the physician's eyes from exposure to the treatment beam reflected from the patient's eye or contact lens.

# 2.2 Contraindications

- Patients with foveal choroidal neovascularization (CNV)
- · Patients with myopic choroidal neovascularization

# 2.3 Precautions in Patient Selection

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

- · Patients with progressive eye disease
- Patients who have difficulty in eye fixation due to nystagmus or have a condition that may induce nystagmus
- · Infant, aphakia
- · Patients with low intraocular transparency due to a disease that causes intraocular hemorrhage
- · Diabetic patients
- Patients with acute attack of primary angle closure (with corneal edema)
- · Patients with late stage glaucoma with progressed visual field loss

# 2.4 Adverse Events and Adverse Device Effects

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

## **O** Adverse device effects

• If any abnormality is found with the main laser device or delivery unit during the pre-operation check, do not use them. For details, see "4.6 Checks Before Use" (page 84).

If the main laser device or delivery unit becomes inoperable due to malfunction, laser beam emission may be interrupted or need to be reattempted.

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

## O Adverse events

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

Increased intraocular pressure	• Vitreous hemorrhage
Narrowed visual field	Color vision deficiency
<ul> <li>Dark adaptation disturbance</li> </ul>	• Corectopia
• Hyphema	Corneal opacity
Corneal damage	Retinal tear
Epimacular membrane	Reduction in visual acuity
Corneal burn	Scleral perforation
Reduction in intraocular pressure	Dilated pupil
Bullous keratitis	Postoperative iritis
Choroidal detachment	Optic neuritis
Localized cataract	Paracentral scotoma
Posterior synechia	• Муоріа
Closure of perforating wound	Retinal hemorrhage
Choroidal hemorrhage	Phthisis bulbi
Posterior vitreous membrane detachment	Reduction in contrast sensitivity
Chorioretinal atrophy (or its spread)	Development of neovascularization
Abscess dissemination in vitreous body	Peripheral anterior synechia (PAS)
Effects of false photocoagulation on retina	<ul> <li>Retinal detachment (Tractional retinal detachment)</li> </ul>
Macular edema (Cystoid macular edema)	Effects of excessive photocoagulation
Formation of subretinal connective tissue	Atrophic creep (Expansion of laser scar)
Effects of false photocoagulation on fovea	Formation of retinochoroidal collateral veins
Effects of false photocoagulation on iris	• Eye pain
• Ache	Subretinal fibroplasia
Branch retinal artery occlusion	Photophobia

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# 2.5 Packed Contents

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

Part name	Quantity	Appearance
Control box	1 unit	O.
Foot switch	1 unit	
Power cord	1 unit	
Remote connector plug	1 unit	
Keycard	1 unit	
Fuse (spare)	2 units	a de la
Burn paper	1 unit	
DANGER label	1 unit	
Alternative label	1 unit	CC-Leventa, See Day See Constraints (Constraints) CC-Leventa, See Day See Constraints) CC-Leventa, See Day See Constraints CC-Leventa, See Day See Constraints CC-Leventa, See Constraints
Dust cover	1 unit	

\_

Part name	Quantity	Appearance
Operator's Manual	1 volume	

# 2.6 Device Configuration

## 2.6.1 Main body (rear view)



### **1** Fiber optic cable connector

The fiber optic cable of the delivery unit is connected to CH1. CH2 is available for dual delivery model or dual unit (optional).

### 2 Delivery unit connector

The delivery unit cable is connected here.

### **3** FOOT SW connector

The foot switch (JUNIOR 124-SWNO) cable is connected here.

#### 4 Master switch

## **5** 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.

#### 🥢 Note

• To connect an external switch, contact NIDEK or your authorized distributor.

### 6 CONTROL BOX connector

The control box cable is connected here.

### 7 Power inlet

The power cable is connected here.

### 8 Fuse holder

# 2.6.2 Control box



### 1 LCD

Displays and sets the laser emission conditions.

### 2 Start button

Turns on or off the control box.

### 3 Pilot lamp

Lights up in green when the master switch is turned on (

### 4 USB-A port

The specified 3D mouse (optional) is connected here.

### 5 Status indicator

Indicates whether the treatment beam emission is possible.

Possible: Green / Not possible: Orange

### 6 Emergency stop button

Used to stop the device in case of an emergency. Pressing this button turns off power to the device and stops operations of the device.

## 7 Access indicator

Lights up in orange when the keycard is inserted. The indicator blinks while writing data to the keycard.

### 8 Stand

### 9 Keycard slot

The keycard is inserted here. Insert the keycard then press the start button to turn on the device. When the device is not in use, remove and store the keycard in a secure place.





- · The keycard has the write-protection switch.
  - Writing to the keycard is not possible when the write-protection switch is in the LOCK position. Be sure to unlock the write-protection at all times.
- · If the keycard is lost, as a temporary measure, the device can be started by entering the password.

For details, contact NIDEK or your authorized distributor.



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# 2.6.3 Rear view of expansion box (optional)



## 1 LAN port

The LAN cable is connected here. Summary of treatment data can be exported to an external computer over a LAN connection.

## 2 USB-A port

The specified barcode scanner or magnetic card reader is connected here.

"> "O Supported barcode scanner and magnetic card reader" (page 72)

## 3 SCAN port

The scan delivery unit cable is connected here.

# 2.7 Screens and Functions

# 2.7.1 Main screen

The screen indications differ depending on the connected delivery unit.

♥ "O Scan delivery unit" (page 27)

↔ "O Other delivery units" (page 34)

## O Scan delivery unit



### **1** Status button

Toggles between READY (treatment beam can be emitted) and STANDBY (treatment beam cannot be emitted) modes. For safety, when the treatment beam is not to be emitted, set the device to STANDBY mode.

Mode	Function
READY READY	To emit the treatment beam, set the device to READY READY mode. Both the status button and status indicator turn green. While the treatment beam is emitted, the emission indicator indicator indicator indicator with the treatment beam is emitted.
	When the treatment beam is not to be emitted, set the device to STANDBY TANDBY mode. The status button turns yellow and the status indicator turns orange.

#### 🥢 Note

• When the "Summary Display Settings" parameter is set to "STANDBY", the Summary of treatment screen appears when the status button is changed to STANDBY.

For the setting procedure, see "3.2.1 Summary display setting" (page 48).

# 2 COUNT 123

Indicates the total shot number of treatment beam shots in the range from 0 to 9999. The counter is cleared when the device is turned on. Pressing the numeric field displays the pop-up window allowing the counter to be cleared.



### 🥢 Note

• When the "Summary Display Settings" parameter is set to "COUNTER Reset", the Summary of treatment screen appears when the counter is cleared.

For the setting procedure, see "3.2.1 Summary display setting" (page 48).

### 3 S.SIZE $\rightarrow \bigcirc \leftarrow$

Indicates the spot size of the laser beam in the range from 50 to 500  $\mu$ m.

# 4 SCAN/AUTO.M button

Toggles between SCAN mode and AUTO.M mode.

Mode	Function
	A short-time laser emission is possible with the selected scan pattern. In this mode, the functions are limited as follows:
SCAN (SCAN mode)	• The selectable value for the emission time (TIME) is limited to the range between 0.01 to 0.05 second.
	<ul> <li>The interval time setting (INT) is enabled only for the Single scan pattern. For other scan patterns, the interval time setting (INT) is enabled when the Auto For- ward function is active.</li> </ul>
AUTO.M (Auto Manipulation mode)	Laser emission is possible with the selected scan pattern for the desired emission time (TIME) and interval (INT).
# 5 SGL/TEST button • SGL

When this button is set to "SGL" (Single mode), pressing the foot switch emits the treatment beam in the Single scan pattern.

When a scan pattern other than Single is selected, the button changes to "TEST" oTEST.

Pressing the TEST button displays the TEST screen. Pressing the foot switch with the TEST screen displayed emits the treatment beam in the Single scan pattern.

Pressing the BACK button **BACK** displays the selected scan pattern.



🥢 Note

• When the SGL/TEST button •TEST is pressed with the TEST screen displayed, the button changes

to "SGL" (Single mode)  $\bullet \frac{SGL}{TEST}$  and the scan pattern selection is cleared.

#### 6 Pattern memory button

The three most frequently used scan patterns can be registered.

For the registration procedure, see "3.4 Registering Pattern Memory Button" (page 67).

#### 7 Scan pattern display field

Press the scan pattern display field to select a scan pattern.



Pattern	Name	Pattern	Name
·	Single Squar		Square
Ē	Line		Triangle
*,*,*,*,	Equal Space	•••	Curve
$\bigcirc$	Circle		Arc
	Rectangle		Triple Arc
	Triple Curve		Arcade Grid

The scan patterns are named as follows:

Selecting a scan pattern displays the buttons around the pattern as shown to the right. These buttons allow fine adjustment of the scan pattern.



Button	Function
	Changes the space between spots. The value is shown next to "SP:" that is displayed under the scan pattern display field. When the setting is 1.00, the spots are separated by a distance equal to their diameter.
$\bigcirc \bigcirc$	Changes the radius of the circle. The value is shown next to "R:" that is displayed under the scan pattern display field. The value indicates the radius of the circle (unit: $\mu$ m).
	Rotates the scan pattern. For the Arcade Grid scan patterns, the patterns are rotated 90° in each direction. The value is shown next to "ANG:" that is displayed under the scan pattern display field. The value indicates the clockwise rotation angle.
U	Activates the Auto Forward function. This button only appears when a scan pattern to which the Auto Forward function can be applied is selected. Black: Selectable Gray: Not selectable For details, see <i>"3.1 Activating the Auto Forward Function" (page 45)</i> .

#### 🥢 Note

- Selectable values may be limited depending on the scan pattern.
- When the spot size is changed, depending on the selected value, the radius and space between spots of the scan pattern may be changed automatically in accordance with the spot size.

## 8 POWER button

Indicates the power output (unit: mW) of the treatment beam on the cornea.

Button	Function
	Increases the power output.
	Decreases the power output.

## 9 TIME button → ←

Indicates the emission time (unit: second) of the treatment beam.

Button	Function
	Increases the emission time.
	Decreases the emission time.

· In SCAN mode:

The emission time can be changed in 0.01 second increments within the range from 0.01 to 0.05 second. However, when the Single scan pattern is selected, the emission time can be set to a time between 0.01 to 3.00 seconds in the same manner as AUTO.M mode.

• In AUTO.M mode:

The emission time can be changed in 0.01 second increments within the range from 0.01 to 0.10 second, in 0.05 second increments within the range from 0.10 to 0.50 second, in 0.10 second increments within the range from 0.50 to 1.00 second, and in 1.00 second increments within the range from 1.00 to 3.00 seconds.

## **10** INT (INTERVAL) button

Sets the device to Single mode or Repeat mode and indicates the interval time in Repeat mode (unit: second). This button is disabled in Single mode.

Button	Function
	Increases the interval time.
	Decreases the interval time. Holding down this button disables the INT button and sets the device to Single mode.

· In SCAN mode:

When the Single scan pattern is selected, the interval time can be set to a time between 0.05 to 1.0 second. For other scan patterns, "INT" is not displayed except when the Auto Forward function is active. The INT setting in Auto Forward function indicates the interval time between scan pattern emissions.

In AUTO.M mode:

When the Single scan pattern is selected, the interval time can be set to a time between 0.05 to 1.0 second. For other scan patterns, the interval time can be set to a time between 0.1 to 1.0 second.

#### 🥢 Note

• Depending on the parameter setting, for POWER, TIME, and INT, pressing the numeric field displays the pop-up window allowing the values to be selected from the preset ones.

J≇POW	ER mW			
100	200	300	400	500
600	700	800	900	1000
				Exit

♥ PopUP Function Settings" (page 40)

## **11** AIMING button $-\dot{\varphi}$ -

Indicates the intensity of the aiming beam from a total of 15 levels.

Button	Function	
	Increases the intensity.	
	Decreases the intensity.	

#### 12 Information display field

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

↔ "Information Display Settings" (page 40).

Pressing the information display field displays the screen to load an actual spot size setting and a memory.

Button	Function
1.00	Loads the actual spot size setting.
Edit	Displays the Actual Spot Size Settings screen.
1	Loads the treatment beam setting data.
Next	Displays Memories 6 to 10.

Select Act SPOT SIZE	Scan:Memory 1/2
1.00 CL1	1 test1
1.00 CL2	2 test2
1.00 CL3	3
1.00 CL4	4
1.00 CL5	5
Edit	Next
	Exit

# 13 Delivery unit button

Indicates the currently connected delivery unit(s). When two types of delivery units are connected using the dual delivery model or dual unit (optional), pressing the button toggles between the delivery units. The delivery unit connected to CH1 is shown in the first row. The delivery unit connected to CH2 is shown in the second row.

Indication	Delivery unit
SL	Slit lamp delivery unit
SCAN	Scan delivery unit
BIO	Binocular indirect ophthalmoscope delivery unit
ENDO	Endophotocoagulation delivery unit
СОМВО	Combination delivery unit

#### 🥢 Note

• Only the binocular indirect ophthalmoscope delivery units and endophotocoagulation delivery units can be connected to CH2.

If a delivery unit other than those specified above is connected to CH2, intended treatment results may not be obtained.

CH1 allows all types of delivery units to be connected.

## 14 MENU button MENU

Various settings can be changed.

♥ "2.7.2 MENU screen" (page 38)

# O Other delivery units



#### 1 Status button

Toggles between READY	(treatment beam can be emitted) and STANDBY	<b>Ö</b> STANDBY	(treat-
ment beam cannot be emitted)	nodes. For safety, when the treatment beam is not to	be emitt	ed, set
the device to STANDBY mode			

Mode	Function
	To emit the treatment beam, set the device to READY READY mode. Both the status button and status indicator turn green. While the treatment beam is emitted, the emission indicator indicator indicator indicator with a status up in yellow.
	When the treatment beam is not to be emitted, set the device to STANDBY C C STANDBY mode. The status button turns yellow and the status indicator turns orange.

#### 🥢 Note

• When the "Summary Display Settings" parameter is set to "STANDBY", the Summary of treatment screen appears when the status button is changed to STANDBY.

For the setting procedure, see "3.2.1 Summary display setting" (page 48).

# 2 COUNT 1123

Indicates the total shot number of treatment beam shots in the range from 0 to 9999. The counter is cleared when the device is turned on. Pressing the numeric field displays the pop-up window allowing the counter to be cleared.



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## 🥢 Note

When the "Summary Display Settings" parameter is set to "COUNTER Reset", the Summary of treatment screen appears when the counter is cleared.
 For the setting procedure, see "3.2.1 Summary display setting" (page 48).

## 3 S.SIZE→◯←

Indicates the spot size of the laser beam in the range from 50 to 1000  $\mu\text{m}.$ 

With some specific slit lamp delivery units, binocular indirect ophthalmoscope delivery units, and endophotocoagulation delivery units, S.SIZE  $\rightarrow \bigcirc \leftarrow$  is not displayed.

# **4** AIMING button --

Indicates the intensity of the aiming beam from a total of 15 levels and with a bar graph.

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

## **5** POWER button

Indicates the power output (unit: mW) of the treatment beam applied to the cornea.

Button	Function
	Increases the power output.
	Decreases the power output.

# 6 TIME button ⇒ ] ←

Indicates the emission time (unit: second) of the treatment beam.

Button	Function
	Increases the emission time.
	Decreases the emission time.

# 7 INT (INTERVAL) button

Sets the device to Single mode or Repeat mode and indicates the interval time in Repeat mode (unit: second).

Button	Function
	Increases the interval time.
	Decreases the interval time. Holding down this button disables the INT button and sets the device to Single mode.
	Enables or disables Repeat mode.

#### 🥢 Note

Depending on the parameter setting, for POWER, TIME, and INT, pressing the numeric field displays the pop-up window allowing the values to be selected from the preset ones.

JL⊉POW	'ER mW			
100	200	300	400	500
600	700	800	900	1000
				Exit

↔ " PopUP Function Settings" (page 40)

#### 8 Information display field

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

#### " Information Display Settings" (page 40).]

Pressing the information display field displays the screen to load an actual spot size setting and a memory.

Button	Function
1.00	Loads the actual spot size setting.
Edit	Displays the Actual Spot Size Settings screen.
1	Loads the treatment beam setting data.
Next	Displays Memories 6 to 10.

Select Act SPOT SIZE	Single:Memory 1/2
1.00 CL1	1 test1
1.00 CL2	2 test2
1.00 CL3	3
1.00 CL4	4
1.00 CL5	5
Edit	Next
	Exit

# 9 Delivery unit button

Indicates the currently connected delivery unit(s). When two types of delivery units are connected using the dual delivery model or dual unit (optional), pressing the button toggles between the delivery units. The delivery unit connected to CH1 is shown in the first row. The delivery unit connected to CH2 is shown in the second row.

Indication	Delivery unit
SL	Slit lamp delivery unit
BIO	Binocular indirect ophthalmoscope delivery unit
ENDO	Endophotocoagulation delivery unit
СОМВО	Combination delivery unit

#### 🥢 Note

• Only the binocular indirect ophthalmoscope delivery units and endophotocoagulation delivery units can be connected to CH2.

If a delivery unit other than those specified above is connected to CH2, intended treatment results may not be obtained.

CH1 allows all types of delivery units to be connected.

## **10** MENU button

Various settings can be changed.

"2.7.2 MENU screen" (page 38)

# 2.7.2 MENU screen

Pressing the MENU button MENU on the main screen displays the MENU screen. Press the desired option to display the setting screen.



#### Buttons common to all setting screens

Button	Function
C	Returns to the previous screen.
Exit	Returns to the main screen.

## 1 LCD Brightness button LCD Brightness

Displays the screen to set the LCD brightness. The brightness is indicated in seven levels.

Button	Function
	Increases the brightness.
	Decreases the brightness.

# LCD Brightness at STANDBY LCD Brightness at READY

#### 2 Sound Volume button Sound Volume

Displays the screen to set the sound volume of the device. The sound volume is indicated in three levels.

Button	Function
	Increases the volume.
	Decreases the volume.



## 3 Scan Function button ScanFunction

Displays the screen to set the scan pattern settings

and 3D mouse (optional) settings. Press \_\_\_\_\_ next to the desired option to change the setting.

This button appears only when a scan delivery unit is connected.

	Scan Function Settings
1	Default value for Scan Space
1	Default value for AUTO. M Space
1	Space: Step
1	Rotation: Step
ſ	3D Mouse Settings
	Û Exit

Option	Function and setting
Default value for Scan Space	Displays the screen to set the default value of the space between spots of a scan pattern. The default value of the space between spots in SCAN mode can be set. Space: 0.50 / 0.75 / 1.00 / 1.25
Default value for AUTO.M Space	Displays the screen to set the default value of the space between spots of a scan pattern. The default value of the space between spots in AUTO.M mode can be set. Space: 0.50 / 0.75 / <u>1.00</u> / 1.25
Space: Step	Displays the screen to set the increments for changing the space between spots of a scan pattern. The increments for changing the space can be changed. Step: $0.25 / 0.1/0.25$ When "Step: $0.1/0.25$ " is selected, the increments change as follows: $0.25 \rightarrow 0.3 \rightarrow 0.4 \rightarrow 0.5 \rightarrow 0.6 \rightarrow 0.7 \rightarrow 0.75 \rightarrow 0.8 \rightarrow$
Rotation: Step	Displays the screen to set the rotation increments of a scan pattern. The increments for rotating a scan pattern can be set. Step: 5 deg. / 10 deg. / 15 deg. / <u>30 deg.</u> / 45 deg. / 90 deg.
3D Mouse Settings	Displays the screen to set the 3D mouse (optional) settings. For the setting procedure, see <i>"3.2.6 3D mouse setting" (page 61)</i> .

#### 🥢 Note

• Underlined options indicate factory settings.

• When Circle, Arc, Triple Arc, or Arcade Grid scan patterns is selected, the "Default value for Scan Space" and "Default value for AUTO.M Space" parameters are automatically set to 1.00 regardless of the settings on this screen.



Option	Function and setting		
Summary Display Settings	Sets when to display the Summary of treatment screen. Not display / STANDBY / COUNTER RESET		
PopUP Function Settings	Sets whether to display the pop-up window for adjusting the values for POWER, TIME, and INT. <b>No / Yes</b>		
Information Display Settings	Sets the items to be displayed in the information display field. When "Actual Spot Size" is selected with a delivery unit that cannot display the spot size, nothing is displayed in the information display field. Line 1: Not display / Patient ID / <u>Date</u> / Actual Spot Size Line 2: Not display / Patient ID / Date / <u>Actual Spot Size</u>		
Act Spot Size Set- tings	Sets the "Actual Spot Size" indication settings in the information display field.		
Patient ID Settings	Patient ID can be entered. Enter the desired patient ID using the screen keyboard and press the Enter but- ton Enter. * For the patient ID, alphanumeric charac- ters and "-" can be used. Other characters are converted to "~".		
Data Input settings	Sets the data input settings for the barcode scanner or magnetic card reader.		
Data Output settings	Sets the data output settings such as the IP address or file sharing. This setting is enabled only when the expansion box (optional) is connected.		
Power Foot Switch Settings	Sets the functions of the pedals of the power foot switch (optional).		
Auto Forward Set- tings	Sets whether to enable the Auto Forward function. This setting is enabled only when a scan delivery unit is connected. <b>No</b> / <u>Yes</u>		

Option	Function and	d setting		
Clock Settings	Sets the date and time. Pressing the button displays the numeric keypad for entering values. Pressing the clock field on the MENU screen also displays this screen.	Clock Settings Press the button to change. 2015 / 1 / 16 13 : 19 Jan. 16, 2015, 13:20:00		
Display Language Settings	Sets the display language. <u>English</u> / Japanese			
CALIBRATION	Calibrates the laser power output. 4.3 Laser Power Output Measurement and Calibration" (page 77)			

#### 🕼 Note 🔍 🦳

• Underlined options indicate factory settings.

# 5 Memory List button Memory List

The treatment beam setting data saved in the device can be checked or loaded.

			Scan: Me	mory	1/2		
•	No.	Nane	Power mW	Time sec	INT sec	Ptn	SP
	1	test1	50	0.01	0.00	1	
	2	test2	50	0.01		3v3	1.00
	3						
	4						
	5						
				Next		Û	Exit

Button	Function
1	The desired treatment beam setting data is loaded.
Next	Displays Memories 6 to 10.
Back	Displays Memories 1 to 5.

#### • Ptn (Pattern)

The saved scan pattern is indicated with the following abbreviations:

Pattern	Abbreviation	Pattern	Abbreviation	Pattern	Abbreviation
·	1		2×2		3×3
	4×4		5×5	••••	Lin
<b>…</b>	Tri	::	2v2 <sup>*1</sup>		3v3 <sup>*1</sup>
	4v4 <sup>*1</sup>		5v5 <sup>*1</sup>	•••••	Cuv
$\bigcirc$	Cir	$\bigcirc$	3/4A	$\bigcap$	2/4A
	1/4A		Rect	*	T Arc
	T Cuv		ArcG1		ArcG
***	ArcG2				

\*1. For Equal Space patterns, No. v No. indicates that the horizontal and vertical spots are equal in number though offset horizontally.

#### 🥢 Note

• The treatment beam setting data can be individually saved for SCAN mode (Scan), Auto Manipulation mode (AUTO.M), and Single mode (Single).

When the mode is changed, the screen indications change accordingly.

## 6 Modify Memory button Modify Memory

The treatment beam setting data that is being displayed on the main screen can be saved. The saved data can also be changed or deleted from this screen.

Scan:Memory Settings
Memory: 1~5
Memory: 6~10
Pattern memory buttons
U E

Option	Function and setting
Memory	A maximum of 10 treatment beam setting data can be saved. (************************************
Pattern memory button	The three most frequently used scan patterns can be registered. *3.4 Registering Pattern Memory Button" (page 67)

# 7 Exit button Exit

Returns to the main screen.

**SETTINGS AND CONNECTIONS** 

# 3.1 Activating the Auto Forward Function

When a scan pattern applicable to the Auto Forward function is selected with a scan delivery unit connected, continual pressing of the foot switch automatically advances the scan pattern in the selected direction.

**1** Set S.SIZE  $\rightarrow \bigcirc \leftarrow$  between 100 to 300 and press the scan pattern display field.

The scan patterns appear.



**2** Select any of the scan patterns indicated by the frame.

The auto forward button 😈 appears.



**3** Set the space between spots to 1.00 or less.

Press " i or " i i o change the space between spots.



# **4** Press the auto forward button $\mathbf{U}$ .

The Auto Forward function is activated.

The auto forward button **U** is displayed in black when the Auto Forward function is selectable. When it is not selectable, the button is grayed out.





The available paths differ depending on the selected scan pattern.

To cancel, press Exit .



**6** Check the emission position.

1) Press the status button to set the device to READY mode.



2) Press the Pos button.

The aiming beam shows points on the patient's eye to indicate the emission range covered by the auto-forward function.

3) Check that the emission range is as intended.

The points disappear automatically in the preset time.

While the points are being displayed, the treatment beam cannot be emitted.



7	Press the foot switch to emit the treatment beam.	CANCEL	Pos AUTO.F
	The scan pattern automatically advances in the order of $1 \rightarrow 2 \rightarrow 3$ .		
	Press "I ← " or "I ← " to change the space between spots.		
	To change the path, press " 🛯 🖵 ".		00 - 2 00 3
	To cancel, press the CANCEL button CANCEL.	3 🗜	
	Note		

- The Auto Forward function can be used in Repeat mode. Holding down the foot switch automatically advances the aiming beam to Positions 1, 2, and 3 where the treatment beam is emitted.
  - When the aiming beam is at Position 1, the aiming beam does not appear at Positions 2 or 3. Before emitting the treatment beam, visualize the position of the aiming beam at Positions 2 and 3 based on the aiming beam at Position 1, and make sure that the emission positions are proper. Also, confirm that the iris or contact lens does not block the optical path.
- When the Auto Forward function is used, the treatment beam setting data cannot be saved in the memory.

# 3.2 Other Settings

# 3.2.1 Summary display setting

Set when to display the Summary of treatment screen.

**1** Press the MENU button **MENU** DED COUNT +>+ S.SIZEµm \_ .I.1 POWER mW Ċ 0 200 50 The MENU screen appears. STANDBY TIME SCAN 0.01 SGL INT ं AIMING 10 SCAN **2** Press the Other Other button. MENU The Other Settings screen appears. LCD Brightness Sound Volume Other Exit G Jan. 16, 2015, 13:12:35 **3** Press next to "Summary Display Other Settings 1/3 Settings". Summary Display Settings The Summary Display Settings screen appears. PopUp Function Settings Information Display Settings Act Spot Size Settings Patient ID Settings

Back

Next

**4** Set when to display the Summary of treatment screen by pressing next to the desired option.

Summary Display Settings Not Display
STANDBY
COUNTER Reset
t) Exit

Option	Function
Not Display	The Summary of treatment screen is not displayed.
STANDBY	The Summary of treatment screen is displayed when the device is set from READY mode to STANDBY mode by pressing the status button.
COUNTER Reset	The Summary of treatment screen is displayed when the numeric field for COUNT is pressed.

The Summary of treatment screen is displayed according to the "Summary Display Settings" parameter setting. The current treatment beam emission setting is displayed on the Summary of treatment (\*A) screen, and the previous treatment beam emission setting is displayed on the Previous Settings screen (\*B).

## \*A

Summary of treatment LEFT RIGHT
Jan. 16, 2015, 15:41:45 ID:
POWER Setting (mW) 200~ 200 mW Ave 200 mW
TIME Setting (sec) 0.20~0.20 sec
Actual TIME Ave. (sec) 0.200sec
Ave. 200 um
COUNTER 5 Actual Total Energy (J) 0.2 J
Next Clear Exit

\*B



Button	Function	
Next	Displays the Previous Settings screen.	
Back	Displays the Summary of treatment screen.	
Clear	Clears the counter and the values displayed on the Summary of treatment screen.	
LEFT	Press this button when the treatment beam setting data is for the left eye. The button is disabled on the Previous Settings screen. When the data is for both eyes, select the RIGHT button RIGHT as well.	

Button	Function	
RIGHT	Press this button when the treatment beam setting data is for the right eye. The button is disabled on the Previous Settings screen. When the data is for both eyes, select the LEFT button LEFT as well.	
Output	Outputs the treatment beam setting data to an external device. This button appears when either the LEFT button LEFT or RIGHT button RIGHT is pressed on the Summary of treatment screen.	
Exit	Returns to the main screen.	

#### 🥢 Note

- The previous treatment beam setting data is saved at the following times:
  - When the counter is cleared.
  - When the device is turned off.
- Pressing the Output button Output outputs the data to the following destinations:
  - The folder specified by the "Data Output Settings" parameter
  - "3.2.4 Data output setting" (page 56)
  - The DATA folder in the keycard

In the DATA folder, a folder will be created each month named after the year and month in which a summary of treatment data is saved. A total of 1799 data sets can be saved in each created folder.

```
ex.)
```

January 2015: /DATA/201501/ February 2015: /DATA/201502/

• Pressing the Exit button Exit on the Summary of treatment screen does not delete the values dis-

played on the Summary of treatment screen. To delete the values, press the Clear button Clear

 Due to limitation in digits that can be displayed, the value for "Actual Total ENERGY (J)" displayed on the Summary of treatment screen may not correspond to the values obtained by "POWER" × "TIME".

# 3.2.2 Actual spot size setting

"Act Spot Size" (actual spot size) refers to the size of the spot emitted via the contact lens. The value of an actual spot size can be obtained by multiplying S.SIZE  $\rightarrow \bigcirc$  by contact lens magnification. Set the contact lens magnification on the "Act Spot Size Settings" screen.





**5** Enter the contact lens magnification.

**4** Press the Magnification button 1.00

The numeric keypad appears.

Press the Enter button Enter to close the numeric keypad.

6 Press under "Name".

The screen keyboard appears.

Actual Spot Size Settings





7 Enter the desired name using the screen keyboard and press the Enter button Enter.



**8** Press the Exit button Exit to the main screen.

Actual Spot Size Settings			
	Magnif	ication(0.30~5.00)	Name
	2.00	x2.00	
	1.00	CL2	
	1.00	CL3	
	1.00	CL4	
	1.00	CL5	
			1 Exit
			th

**9** Display "Act SPOT SIZE" in the information display field.

"Information Display Settings" (page 40)

**10** Press the information display field.

The screen to load an actual spot size setting and a memory appears.

50 0 200 STANDB TIME SCAN 0.01 SGL INT ं ♦ AIMING Act SPOT SIZE:x1.00 200um SCAN L\_\_\_\_ - - - -Select Act SPOT SIZE Scan:Memory 1/2 2.00 x2.00 1 test1 1 10 CL2 2 test2 CL3 1

3

4

5

DED COUNT +>+ S.SIZEµm \_\_.I.±. POWER mW

Ċ

1.00 CL4

1.00 CL5

Edit

3

**11** Press a Magnification button 2.00 to load the registered setting.

Confirm that the loaded value is displayed on the information display field.

Next

Exit

# 3.2.3 Data input setting

Set the data input settings for the barcode scanner or magnetic card reader.



**4** Press next to "Data Input settings".

The Data Input Settings (Reader settings) screen appears.

Other Settings 2/3
Data Input settings
Data Output settings
Power Foot Switch Settings
Auto Forward Settings
Clock Settings
Back Next D Exit

**5** Press the button next to "Start position" or "Data Length".

The numeric keypad appears.



**6** Enter the desired values.

Press the Enter button Enter to close the numeric keypad.

**7** Import data using the barcode scanner or magnetic card reader.

Confirm that the patient ID is correctly displayed.





Note
 • If the patient ID cannot be imported, enter the patient ID from the Other Settings screen.
 <sup>4</sup> Other button" (page 40)

3

# 3.2.4 Data output setting

Set the data output settings such as the IP address or file sharing.



**4** Press next to "Data Output settings".

The Data Output Settings (Reader settings) screen appears.

Other Settings 2/3		
Data Input settings		
Data Output settings		
Power Foot Switch Settings		
Auto Forward Settings		
Clock Settings		
Back Next		

# **5** Set the parameters.

Data Output settings (LAN) 1/2
 Set the IP address and subnet mask of the device.

Data (	)utput settings(LAN) 1/2		
Data Output	ON		
DHCP	OFF		
IP Address	192 . 168 . 1 . 101		
Subnet Mask	255 . 255 . 255 . 0		
MAC Address 00:F8:F7:12:34:56			
Next	tj Exit		

Option	Function	
Data Output	Sets whether to output data.	
DHCP	When the DHCP server is available on the LAN, select "ON". When "ON" is selected, IP address and subnet mask do not need to be entered. The IP address and subnet mask are automatically assigned by the DHCP sever.	
IP address	Enter the IP address. Pressing each button displays the numeric keypad for entering values.	
Subnet mask	Enter the subnet mask. Pressing each button displays the numeric keypad for entering values.	

• Data Output settings (LAN) 2/2 Set the file sharing setting.



Option	Function	
User Name	Enter the user name for the computer that has the shared folder.	
Password	Enter the login password associated with the user name for the computer that has the shared folder.	
Domain	Enter the domain name for the connected network.	
PC name	Enter the name of the computer that has the shared folder. The IP address of the computer may be entered instead of the computer name.	
Folder Name	Enter the folder name of the output destination.	
Test	Checks the LAN connection. When communication is successful, "OK!" appears. When communication fails, an error message appears.	

# 3.2.5 Power foot switch setting

Set the functions for each pedal of the power foot switch (optional [Part No.: 17330-0021]).



4 Press next to "Power Foot Switch Settings".

The Power Foot Switch Settings screen appears.

Other Settings 2/3		
Data Input settings		
Data Output settings		
Power Foot Switch Settings		
Auto Forward Settings		
Clock Settings		
Back Next D Exit		

**5** Assign a function to the right and left pedals.



Button	Function	
Left	Press or to select the function to be assigned.	
Right	OFF / Standby / Ready / Interval Down / Interval Up / TIME Down / TIME Up / Power Down / Power Up / AIMING Down / AIMING Up	
Off	Clears the setting.	
	Select the function to be assigned.	
Note		

• Underlined options indicate factory settings.

# 3.2.6 3D mouse setting

Various functions can be assigned to the operations of the 3D mouse (optional). The 3D mouse can only be set when a scan delivery unit is connected.

1	Left Tilt
2	Left Rotation
3	Pull
4	Push
5	Up Tilt
6	Left Button
7	Right Rotation
8	Right Tilt
9	Down Tilt
10	Right Button

**1** Press the MENU button **MENU**.

The MENU screen appears.



Ö STANDB	0 200	JI± POWER mW
SCAN		11 ± 11 ME sec .01
	٠	INT sec
H		<pre>     AIMING     10</pre>
		SCAN MENU
		(h)

2 Press the Scan Function button ScanFunction

The Scan Function Settings screen appears.





4 Press next to the mouse operations to which a function is to be assigned.



**5** Press the desired button next to the functions to be assigned to the mouse operation selected in Step 4.

The function names are abbreviated. See below for the meaning of the abbreviations.



Button	Function	
	No function	
Ready	Changes the status button to "READY".	
Standby	Changes the status button to "STANDBY".	
Pos	Position check	
Power 🔺 , 💌	Increases/decreases the power output.	

Button	Function	
Time 🔺 , 🔽	Increases/decreases the emission time.	
INT 🔺 , 💌	Increases/decreases the interval time.	
Aim 🔺 , 🔽	Increases/decreases the aiming beam intensity.	
Rad. 🔺 , 💌	Increases/decreases radius.	
Space 🔺 , 🔽	Increases/decreases space.	
Rot. R, L	Rotates the scan pattern.	
Patt. 🔺 , 🔽	Changes the pattern memory button being selected on the main screen.	

# 

• Do not touch the 3D mouse during start-up of the device. Also, do not press and hold the Right and Left buttons.

The 3D mouse may be initialized at an improper position resulting in malfunction. In such a case, restart the device.

- If "Power", "Time", "Ready", or "Standby" function is assigned to the 3D mouse, be sure to confirm the settings displayed on the control box screen before laser beam emission.
- If the device is used by multiple physicians, do not assign "Power", "Time", "Ready", or "Standby" function to the 3D mouse.

**6** Press the return button **1** to return to the 3D Mouse Settings screen.

# 3.3 Registering Memory

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

1	Press the MENU button . The MENU screen appears.	COUNT ***S.SIZE# STANDBY 0 200 SO
2	Press the Modify Memory button Modify Memory. The Memory Settings screen appears.	MENU LCD Brightness Sound Volume Scan Function Other Memory List Modify Memory
3	Press next to "Memory".	♥ Jan. 16, 2015, 13:12:35          Scan : Memory Settings         Memory : 1~5         Memory : 6~10         Pattern memory buttons
**4** Press the memory No. 1 button. Scan: Memory Settings 1/2 No. Nane Power Time INT mW sec sec 4 5 Next **5** Press the Write button Write in the pop-up Scan: Memory Settings 1/2 window. Power Time No. Name INT m₩ Sec SBC When the message shown to the right 1 Memory 1 appears, press the Yes button Yes Write 2 Clear 3 Save to Memory 1? 4 Yes 5 Next 🥢 Note Scan: Memory Settings 1/2 • To delete existing memory, press the Clear button Clear . Power Time INT Ptn SP nV sec sec No. Name Sec When the message shown to the right appears, press the 1 Meanry 1 Yes button Yes Write 2 Clear 3 Clear Memory 1? 4 Yes No 5 Next 1 Exit **6** Press the Name field Scan: Memory Settings 1/2 No. Name INT Power Time The screen keyboard appears.

Exit

SP

Exit

SP

Ptn

Ptn

No

Ptn

SBC

m₩

1

2

3

4

5

Sec

Next

50 0.01 0.00 1

SP

Exit

7 Enter the desired memory name using the screen keyboard and press the Enter button Enter.



**8** Confirm that the treatment beam setting data that is being registered matches that on the main screen.

	Scan : N	lemory	Sett	ings	1/2	
No.	Nane	Power mW	Time sec	INT sec	Ptn	SP
1	test1	50	0.01	0.00	1	
2						
3						
4						
5						
			Next		Û	Exit

# 3.4 Registering Pattern Memory Button

The scan pattern that is being displayed on the main screen can be registered as a memory. This setting is enabled only when a scan delivery unit is connected.



4	Press the memory No. 1 button.	Scan:Pattern memory buttons Settings No. Ptn
5	Press the Write button Write in the pop-up window. When the message shown to the right appears, press the Yes button Yes .	Scan:Pattern memory buttons Settings No. Ptn 1 2 3 3 Writ Clear Save to Memory 1? Yes No Exit
	• To delete existing memory, press the Clear button Clear When the message shown to the right appears, press the Yes button Yes .	No. Ptn He 3 Clean Memory 1 Vois No Vois No
6	Confirm that the scan pattern that is being registered matches that on the main screen.	Scan:Pattern memory buttons Settings No. Ptn 1 Equal Space 3x3 2 3
	<ul> <li>Note</li> <li>In this screen, only the scan pattern is registered.</li> <li>Other treatment beam settings are not registered.</li> </ul>	

# 3.5 Connecting Optional Accessories

To connect the LAN cable, barcode scanner, or magnetic card reader to the GYC-500, the expansion box (optional) is necessary.

### 

• Before connecting cables, turn off (  $\bigcirc$  ) the master switch.

Failure to do so may cause errors or malfunction.

### 3.5.1 Connecting the 3D mouse

Turn off ( $\bigcirc$ ) the master switch. Insert the USB cable of the 3D mouse into the USB-A port (<sup>\*A)</sup> located on the top of the control box.





Only the specified 3D mouse can be connected.
 Supported 3D mouse: 17166-6300

### 3.5.2 Network connection (LAN)

#### 🥢 Note

 For LAN connection, use the following LAN cable and ferrite core: LAN cable: Commercial LAN cable Cat7 (category 7) with shield connector (2 m) Ferrite core: Part number 80203-00050 (1 unit)

EMC may be reduced.

- Be sure to connect the device to the computer (running Windows 10) via a network hub. Never directly connect the device to the computer. A connection failure may result.
- **1** Connect a LAN cable to the LAN port <sup>(\*A)</sup> of the expansion box.



**2** Connect the LAN cable to the network (hub) to which the computer is connected. Set the necessary settings.

Consult the network administrator regarding network setting of the device and computer.

- Set the LAN setting of the device.
   "3.2.4 Data output setting" (page 56)
- 2) Set the "Summary Display Settings" parameter.

↔ "3.2.1 Summary display setting" (page 48)

### 3.5.3 Connecting barcode scanner or magnetic card reader

Turn off the master switch ( $\bigcirc$ ). Insert the USB connector <sup>(\*C)</sup> of the barcode scanner <sup>(\*A)</sup> or magnetic card reader <sup>(\*B)</sup> into the USB-A port <sup>(\*D)</sup> of the expansion box (optional).



🥢 Note

• Only the specified barcode scanner and magnetic card reader can be connected.

"O Supported barcode scanner and magnetic card reader" (page 72)

• When the start button is pressed with the barcode scanner or magnetic card reader connected, a beep sounds.

This beep is to confirm the connection. It is not an error.

### O Importing patient ID

Patient IDs can be imported using the barcode scanner or magnetic card reader.



• The most recently imported patient ID will be assigned to the Summary of treatment to be transferred.

A patient ID can be imported before and after the surgery. However, note that the previous patient ID will be overwritten by the newly imported one. If an incorrect patient ID has been imported, import the correct ID again before transferring the data.

### O Supported barcode scanner and magnetic card reader

Name	Part number
Barcode scanner	19701-E006
Magnetic card reader	17166-6310

#### 🥢 Note

- Use a CODE39 barcode.
- Use magnetic cards utilizing a magnetic stripe format compliant with ISO 7811, AAMVA, and CA DMV.
- For the patient ID, alphanumeric characters and "-" can be used. Other symbols are not recognized. All unrecognized symbols are converted to "~".
- Barcode scanner

Place the scanner window over the barcode and press the trigger button (\*A).

When the barcode has been read successfully, a beep sounds, and the confirmation LED  $^{(^{\ast}B)}$  lights up.



• Magnetic card reader

Swipe the card through magnetic card reader.

When the card has been read successfully, a beep sounds, and the LED lights up in green.

If the reading fails, the LED lights up in red (for about 0.5 seconds).



### O Patient ID indication and data transfer

A patient ID can be displayed in the information display field on the main screen. Make sure that "Patient ID" is selected for the "Information Display Settings" parameter.

↔ "Information Display Settings" (page 40)

- **1** Import a patient ID with the barcode scanner or magnetic card reader.
- **2** When the patient ID has been imported successfully, a beep sounds and the patient ID is displayed in the information display field on the main screen.



#### 🥢 Note

If the patient ID cannot be imported, enter the patient ID from the Other Settings screen.
 "4 Other button" (page 40)

**3** Display the Summary of treatment screen. For the procedure to display the Summary of treatment screen, see "3.2.1 Summary display setting" (page 48).

4 Select either the LEFT button LEFT or RIGHT button RIGHT and press the Output button Output

The patient ID and the summary of treatment are transferred.

Summary of treatment LEFT RIGHT
Jan. 16, 2015, 15:41:45 ID: Output
POWER Setting (wW) 200~ 200 mW
TIME Setting (sec) 0.20~0.20 sec
Ave. 0.200sec Actual TIME Ave.(sec) 0.200sec
SPOT SIZE (um) 200~ 200 um Ave 200 um
COUNTER 5
Actual Total Energy (J) 0.2 J
Next Clear Exi

Note
 The Output button Output appears when either the LEFT button LEFT or RIGHT button
 RIGHT is pressed to select the eye.

**5** When data transfer is complete, a confirmation message appears.



# 4.1 Replacing Fuses

If the pilot lamp does not light up when the master switch is turned on (), the fuses may be blown. In such a case, replace the fuses according to the procedure below.

Part name	Part number	Remarks
Fuse	80402-01027	250 V 2.5 A (ø5 × 20 mm)

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

Confirm that the pilot lamp goes out.

- **2** Remove the power cord from the power outlet.
- **3** Remove the power cord from the power inlet.
- **4** Hold down the clasp to remove the fuse holder.



**5** Replace the fuses.



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

### 

If the fuses are blown frequently, contact NIDEK or your authorized distributor.
 The device or power supply may be malfunctioning. NIDEK assumes no responsibility for any adverse events resulting from negligence of proper maintenance.

# 4.2 Cleaning the Device Exterior

When the cover or panel of the device becomes dirty, clean it with a soft, dry cloth. For severe stains, soak the cloth in a neutral detergent, wring well, and wipe. Finally wipe it with a soft, dry cloth.

### 

- Never use organic solvents such as paint thinner or alcohol.
- Lightly wipe the LCD surface. Do not press the LCD using an object with a hard tip. Keep magnetic objects away from the LCD.

The surface of the LCD may be damaged. 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.

## 4.3 Laser Power Output Measurement and Calibration

If the difference between the indicated laser power output and the actual laser power output is out of the tolerance, the laser power needs to be calibrated. Record the results using the table in *"4.4 Laser Beam Output Calibration Record" (page 82)*.

#### 

- Only service personnel trained by NIDEK or NIDEK distributor are allowed to calibrate the laser power output.
- Before emitting the laser, confirm that there is no reflective object in the laser optical path.
   Laser beam may be reflected in unexpected directions resulting in accidental exposure to the laser beam.

🥢 Note

• For measurement and calibration of the laser power output, a power meter is necessary.

- **1** Aim the laser aperture of the delivery unit in a safe direction.
- **2** To calibrate the treatment beam, attach a laser power meter to the delivery unit.
  - 1) Fix the detector of the power meter securely to the laser aperture of the delivery unit.
  - Connect the detector cable to the main body of the power meter.
     If necessary, connect the power cord of the power meter to the power outlet.

### **3** Prepare for measurement.

- 1) Turn off the illumination of the delivery unit.
- 2) Project the aiming beam on the receiving surface of the detector.
- Adjust the aiming beam to an appropriate intensity using the control box.
- 4) Secure the delivery unit at a position where the aiming beam spot fills the entire surface of the receiving surface with no obstruction.

If the treatment beam is focused on the receiving surface, it may be damaged.

### **4** Measure the laser power output.

#### • Treatment beam calibration

1) Set the laser emission conditions as follows:

Condition	Setting
Emission time	3.00 seconds
Spot size (Slit lamp delivery unit, scan delivery unit)	200 µm
Working distance (Binocular indirect ophthal- moscope delivery unit)	400 mm
Power output	50 mW, 200 mW, 1,700 mW (For scan delivery unit: 1,500 mW)

- 2) Press the status button to set the device to READY mode
- 3) Press the foot switch to emit and measure the treatment beam.
- 4) Determine whether the measured power outputs of the treatment beam are within acceptable tolerance of the indicated power outputs at 50 mW, 200 mW, and 1,700 mW (for scan delivery unit: 1,500 mW).

Criteria

- The difference between the measured value and indicated value is within ±20% When the measured power output is out of this tolerance, the laser power needs to be calibrated.
- Aiming beam calibration
  - 1) Measure the minimum and maximum power output of the aiming beam.

Adjust the aiming beam to the minimum or maximum using the control box to measure the values.

- 2) Determine whether the measured power outputs of the aiming beam are within acceptable tolerance of the indicated minimum and maximum power outputs.
  - Criteria
  - Maximum aiming beam: 0.2 to 0.4 mW
  - Minimum aiming beam: 0.01 mW or less

When the measured power output is out of this tolerance, the laser power needs to be calibrated.

- **5** Display the CALIBRATION mode screen.
  - 1) Press the MENU button MENU .

The MENU screen appears.



Other 2) Press the Other button.

The Other Settings screen appears.

MENU LCD Brightness Sound Volume Other Mod orv Exit G Jan. 16, 2015, 13:12:35 Other Settings 1/3 3) Press the Next button Next to display the Other Settings 3/3 screen. Summary Display Settings PopUp Function Settings Information Display Settings Act Spot Size Settings Patient ID Settings Back Next Exit

4) Press next to "CALIBRATION"	Other Settings 3/3
	Display Language Settings
	CAL IBRATION
	Back Next D Exit
5) When the message shown to the right	Other Settings 3/3
appears, press the Yes button <u>Yes</u> .	Display Language Settings
The numeric keypad appears.	CALIBRATION
6) Enter the password and press the Enter button	Serious damage may occur if this procedure
Enter	is not performed by qualified personnel. Please refer to the operator's manual.
Only administrators qualified by NIDEK are	Yes No.
informed of the password.	
	Back Nex 1 Exit

**6** Change the parameters of the minimum and maximum power outputs.

#### 🥢 Note

• Before changing the parameters, be sure to confirm that a delivery unit is connected to the channel to be calibrated.

When attempting to change the parameters with no delivery unit connected, a warning beep sounds and the screen does not proceed.

• Treatment beam calibration

1) Press next to "Power".

CALIBRATION mode	
Power	
Aiming Power	
Û Ex	ît

- 2) Pressing the numeric field of each parameter Power turns the frame green allowing the parameter Gain Offset to be changed. 120 130 Maximum power output: Gain CH1:SL Gain Enter Enter Minimum power output: Offset Pressing down the numeric field displays the numeric keypad to enter the desired value. 10Step 1Step 10Step 1Step 3) Change the value with the up button or down button CH=1 SL (SCAN) 4) Press the Enter button Enter to confirm the entry. 5) Perform Step 4 again to confirm that the output power is correct. 🥢 Note • The offset value is common to all delivery units when they are connected to the same channel. Aiming beam calibration CALIBRATION mode 1) Press next to "Aiming Power". Power Aiming Power Exit Aiming Power next to each parameter to make 2) Press 95 Scan Aim Offset changes. Minimum power output: Scan Aim Offset 100 Scan Aim Gain Maximum power output: Scan Aim Gain Pressing down the numeric field displays the numeric keypad to enter the desired value. 3) Change the value with the up button Enter or 10Step 1Step down button CH=1 SL (SCAN) 4) Press the Enter button Enter to confirm the entry.
  - 5) Perform Step 4 again to confirm that the output power is correct.

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# 4.4 Laser Beam Output Calibration Record

Dete	Laser beam	Maximum output (mW)		Minimum output (mW)	
Dale		Before	After	Before	After
1 1	Treatment beam	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	Aiming beam				
1 1	Treatment beam	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	Aiming beam				
/ /	Treatment beam	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	Aiming beam				
/ /	Treatment beam	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	Aiming beam				
	Treatment beam	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	Aiming beam				
/ /	Treatment beam	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:	Displayed: Measured:
	Aiming beam				

# 4.5 Administration List

## **O** Administrator

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Post	Name	Approval

## O Registered user list

Post	Name	Approval

# 4.6 Checks Before Use

## 4.6.1 Check item

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Before using the device, check the following items. Record the results using the table in *"4.6.2 Check-list" (page 86)*.

	Check item	Details
1	Appearance	<ul> <li>Check the main body and accessories for any deformation or stains (including cleanliness of the mirror) that may interfere with operation of the device.</li> <li>Chemical stains may cause malfunction.</li> </ul>
2	Power cord	<ul> <li>Confirm that the power cord is properly connected to a power outlet that meets the power requirements specified on the ID label attached to the main body.</li> </ul>
3	Control box	Confirm that the pilot lamp lights up when the master switch is turned on     (         ). Then confirm that the control box activates when its start is pressed.         If the display and pilot lamp do not light up, contact NIDEK or your authorized distributor,
4	Keycard	<ul> <li>Insert the keycard into the control box. Then confirm that a beep sounds when the start button of the control box is pressed.</li> </ul>
5	POWER	<ul> <li>Confirm that the power output can be correctly adjusted in the range from 50 mW to 1,700 mW (scan delivery unit: 1,500 mW) by the Up button and Down button . Also, confirm that a beep sounds when the setting is changed.</li> <li>When using a slit lamp delivery unit, set the spot size to the maximum for the check.</li> </ul>
6	TIME	<ul> <li>Confirm that the emission time can be correctly adjusted by the Up button and Down button . Also, confirm that a beep sounds when the setting is changed.</li> </ul>
7	INTERVAL	• Confirm that device can be set to Single mode, and the interval time in Repeat mode can be adjusted. Also, confirm that a beep sounds when the setting is changed.
8	AIMING	<ul> <li>Confirm that the aiming beam intensity can be adjusted by the Up button         and Down button         . Also, confirm that a beep sounds when         the setting is changed.         When the fiber optic cable is not connected, the AIMING button becomes dis-         abled and a warning appears on the control box.         Check the connection of the fiber optic cable.     </li> </ul>
9	Laser beam optical axis	<ul> <li>Project the aiming beam spot on a flat surface that is not reflective. Then confirm that the intensity is even over the entire spot without intensity irregularities or partial blocking as shown in the figure to the right.</li> <li>Confirm that the outline of the aiming beam is clear when the spot is in focus.</li> </ul>

	Check item	Details			
10	Status button	<ul> <li>Confirm that pressing the button toggles between STANDBY and READY modes. Also, confirm that a beep sounds when the setting is changed.</li> <li>Be sure to turn on the aiming beam. While the aiming beam is turned off, the device cannot enter READY mode even when the status button is pressed. An error appears on the control box.</li> </ul>			
11	Foot switch	<ul> <li>Confirm button to beam is</li> </ul>	• Confirm that the foot switch can be pressed smoothly. Press the status button to set the device to READY mode, then confirm that the treatment beam is emitted when the foot switch is pressed.		
12	COUNT	<ul> <li>Confirm that pressing the numeric field displays the message window allowing the counter to be changed to "0" (zero).</li> <li>Confirm that pressing the Clear button Clear on the Summary of treatment screen changes the counter to "0" (zero).</li> </ul>			
	Delivery unit button	correct in accordance with the following table:			
			Indication	Delivery unit	
			SL	Slit lamp delivery unit	
10			SCAN	Scan delivery unit	
13			BIO	Binocular indirect ophthalmoscope delivery unit	
			ENDO	Endophotocoagulation delivery unit	
			СОМВО	Combination delivery unit	
14	Emergency stop but- ton	Confirm that the device turns off when this button is pressed.			

# 4.6.2 Checklist

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	Check item	Date					
1	Appearance						
2	Power cord						
3	Control box						
4	Keycard						
5	POWER						
6	TIME						
7	INTERVAL						
8	AIMING						
9	Laser beam optical axis						
10	Status button						
11	Foot switch						
12	COUNT						
13	Delivery unit button						
14	Emergency stop button						

# 4.7 Error Messages and Remedies

The GYC-500 is equipped with a self-diagnostic function, which automatically monitors the device during operation. If a device abnormality occurs, the safety shutter blocks the laser beam. After the device is turned off, the status indicator blinks in green and orange alternately, and beeps sound intermittently.

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

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

#### **O** Interlock

Message	Cause and remedy
In. 4.7 High temperature in the sys- tem	<ul> <li>Adjust the location of the device and air conditioning to achieve an appropriate surrounding environment.</li> <li>If a radical change in temperature or humidity occurs due to location change or such, let the device sit in the environment for at least 30 minutes before using the device.</li> </ul>
In. 6.3 Remote interlock	<ul><li>Check whether the remote connector plug is connected securely.</li><li>Check the condition of the switch connected to the plug.</li></ul>
In. 12.7 Excessive power output	Contact NIDEK or your authorized distributor.

#### **O Warning message**

Message No.	Cause and remedy		
Related to control box			
601	CB EE-PROM:Check Sum error CB EE-PROM was initialized.		
631	Voltage reduction for clock data backup Please keep power to the main body on for more than 5 minutes for charging the battery.		
633	RTC:Clock data initialize Please set the clock.		
641	KEY card:Error KEY card has fault and it suspends the recording function. Please don't use this KEY card.		
644	KEY card:Not enough free disk space. Please free up disk space of this KEY card.		
Related to expansion box			
410	Exp BOX EEPROM:Check Sum error Exp BOX EEPROM was initialized. Contact Nidek or your authorized distributor.		
700	CIFS error. Error related to Windows file sharing.		
703	Hardware error. If the same error code is displayed even after the device is turned on again, turn off power to the device and contact NIDEK or your authorized distributor.		
704	DHCP Error. The IP address cannot be obtained. Consult the system administrator.		

Message No.	Cause and remedy		
750	Unable to access to the network. Check the LAN cable connection and the set IP address and subnet mask.		
751	Unable to write files to the PC. Check whether write permission is granted to the destination folder in the PC and sufficient free space is available.		
754	No PC under the computer name found in the network. Check the connection of the LAN cable. Or check that the specified PC name is correct.		
756	Unable to logon to the PC. Check the user name or password and enter it correctly.		
757	No shared folders found. Check the folder name and whether the folder is set to share.		
758	Network timeout. Send the data again.		
760	Initializing the network. Wait and try again later.		
761	Access denied. Check the file sharing setting of the PC.		
762	This account is invalid. Check the network setting of the device.		
771	Network cable is not connected. Connect the cable or check that connection is proper.		

## ○ Error Messages

The following are errors related to the mechanism inside the device. Press the start button to turn off the device, then restart the device.

If the problem persists, contact NIDEK or your authorized distributor.

Errors related to main body			
Err 2	Malfunction of protective filter	Err 3	Malfunction of safety shutter
Err 7	Channel change failure	Err 13	Laser power supply failure
Err 53	Foot switch failure	Err 54	Fiber signal error
Err 55	Protective filter signal failure	Err 90	Program data failure
Err 91	EEPROM data failure	Err 93	Data failure
Err 94	KEYLOCK error	Err 95	CPU communication error
Err 96	Coag time error	Err 110	Laser malfunction
Err 113	Malfunction of circuit for driving the laser	Err 115	Low laser power output
Err 120	Laser diode temperature control failure	Err 121	SHG temperature control failure
Err 122	BRF temperature control failure		

• Errors r	elated to expansion box			
Err 420	Exp BOX:BOOT update error!	Err 421	Exp BOX:APPLI update error!	
Err 423	Exp BOX:USB memory error	Err 490	Exp BOX:LAN controller error	
Err 491	Exp BOX:EEPROM access error	Err 492	Exp BOX:USB host controller error	
Err 493	Exp BOX:FAN stop error	Err 494	Exp BOX:Temperature error	
Err 495	Exp BOX:ROM error			
Errors r	elated to scan			
Err 505	Scan position failure (FPGA)	Err 510	Scan position failure (X axis)	
Err 511	Scan position failure (Y axis)	Err 512	Scan current failure (X axis)	
Err 513	Scan current failure (Y axis)			
Errors related to control box				
Err 602	EEPROM:Access error	Err 612	Flash memory-Appli:Check Sum error	
Err 613	Process:Program Check Sum error	Err 614	Process:Data mismatch error	
Err 615	Process:Calculation error	Err 616	Process:Sequence error	
Err 622	KEY card :Use of unauthorized KEY card.	Err 632	RTC:Access error	
Err 642	KEY card :KEY card is not inserted.	Err 643	KEY card :Write-protected.*1	
Err 651	No response error.	Err 652	Communication error.	
Err 661	Cannot turn off power.	Err 671	LCD BL driver:Error	
Err 681	VerUP:File Error	Err 683	VerUP CB:Erase Error	
Err 684	VerUP CB:Write Error	Err 685	VerUP CB:Verify Error	
Err 692	VerUP MAIN:Bootmode Error	Err 693	VerUP MAIN:Erase Error	
Err 694	VerUP MAIN:Write Error	Err 695	VerUP MAIN:Verify Error	

\*1 The keycard has the write-protection switch. Writing to the keycard is not possible when the write-protection switch is in the LOCK position. Be sure to unlock the write-protection at all times.



## **O** Indications of Improper Operation

If improper operation occurs, a series of beeps sounds and the remedy is displayed on the control box.

Indication and remedy	Cause
Press the AIMING button to emit the aiming beam.	The status button was pressed to set the device to READY mode even though the aiming beam was turned off.
Connect the fiber optic cable to the main body.	The AIMING button was pressed to emit the aiming beam even though the fiber optic cable was not connected.
Place the delivery or/and its laser mirror at the position where laser emission is possible.	The AIMING button was pressed to emit the aiming beam with the delivery unit or its laser mirror being set to a position where the laser emission is not possible.
Set the manual protective filter to the IN posi- tion.	The foot switch was pressed without the manual protective filter being inserted.
Press the status button to set the device to READY mode.	The foot switch was pressed in STANDBY mode.



# 5.1 Specifications

Device specifications				
Treatment beam				
Light source	Ontically-numbed semiconductor laser			
g	····			
	Wavelength	532 nm (green)		
Power output	Photocoagula-	50 to 1,700 mW		
	tion power output	Scan delivery unit: 50 to 1,500 mW		
	(on the cornea)	50 to 500 mW: 10 mW increments		
		500 mW and greater: 50 mW increments		
Time	Emission time	Range: 0.01 to 1.00, 2.00, 3.00 seconds		
		0.01 to 0.10 second: 0.01 increments		
		0.10 to 0.50 second: 0.05 increments		
		0.50 to 1.00 second: 0.1 increments		
	Interval	0.05 to 1.0 second (0.05 increments)		
		* For scan delivery unit, AUTO.M, and Auto Forward: 0.1 to		
		1.0 second		
<ul> <li>Aiming beam</li> </ul>	• Aiming beam			
Light source	Light source Laser diode			
	Wavelength	635 nm (Red)		
Power output	Aiming beam	Maximum: 0.2 to 0.4 mW		
	power output	Minimum: 0.01 mW and less		
	(on the cornea)	Indication: OFF (no indication), 1 to 15 levels		
<ul> <li>Power supply specifi</li> </ul>	cations			
Voltage	AC 100 to 240 V			
Frequency	50/60 Hz ± 1Hz			
Power consumption	250 VA			
Dimensions and mass				
Dimensions	237 (W) × 318 (D) × 90 (H) mm			
Mass	6.2 kg (excluding the control box)			

Device specifications				
Environmental condi-	Temperature	10 to 35°C (50 to 95°F)		
tions (during use)	Humidity	30 to 90%		
	Atmospheric pres- sure	800 to 1,060 hPa		
	Installation loca- tion	Indoors		
	Other	No harmful dust or smoke		
• Environmental condi- tions	Temperature	During transport: -10 to 60°C (14 to 140°F) During storage: -10 to 55°C (14 to 131°F)		
(during transport	Humidity	10 to 95%		
storage)	Atmospheric pres- sure	500 to 1060 hPa (during transport), 700 to 1060 hPa (during storage)		
• Other	Expected service life	7 years from the date of initial operation. * Proper maintenance is necessary.		
	Scan pattern	Single, Square (2×2, 3×3, 4×4, 5×5), Line, Triangle, Equal		
		Space (2v2, 3v3, 4v4, 5v5) <sup>*1</sup> , Curve, Circle, Arc (3/4 circle, 2/ 4 circle, 1/4 circle), Rectangle, Triple Arc, Triple Curve, Arcade Grid		
<ul> <li>Classifications</li> </ul>	Protection against electrical shock: Class I ME equipment			
	Laser classification (IEC 60825-1): Class 4			
	Protection against harmful ingress of water or particulate matter: IPX0 (main body), IPX8 (foot switch)			
	Method(s) of sterilization: ME equipment that does not contain any part that needs sterilization.			
	Suitability for use in an oxygen rich environment: ME system that is not intended for use in an oxygen rich environment			
	Mode of operation: Continuous operation			
Accessories				
Standard accessories	Main body, control box, foot switch, power cord, keycard, fuses (spare), burn paper DANGER label, alternative label, dust cover, Operator's Manual			
Optional accessories	Optional accessories Power foot switch, dual unit, expansion box, CB top plate attachment unit, sa gles, 3D mouse, barcode scanner, magnetic card reader			

\*1. For Equal Space patterns, No. v No. indicates that the horizontal and vertical spots are equal in number though offset horizontally.

Available delivery units				
Single delivery unit				
Attachable Delivery Unit	Spot size	ø50 to ø990 μm		
<ul> <li>(for ZEISS 30SL/M)</li> <li>(GYC4SZ-1A)</li> <li>Attachable Delivery Unit</li> <li>(for Nidek SL-1600 / SL-1800) (GYC4SZ-2A)</li> <li>Attachable Delivery Unit</li> <li>(for ZEISS SL 130)</li> <li>(GYC4SZ-4A)</li> <li>Slit Lamp Delivery Unit</li> <li>(for Nidek SL-1800)</li> <li>(C(GYC-4))</li> <li>Attachable Delivery Unit</li> <li>(for HAAG STREIT</li> <li>900BQ) (GYC4SG-2)</li> </ul>	Accuracy	Within ±50% (less than 100 μm) Within ±20% (100 μm and greater)		
Attachable Delivery Unit	Spot size	ø50 to ø1000 μm		
<ul> <li>(for ZEISS 30SL/M)</li> <li>(GYC5SZ-1)</li> <li>Attachable Delivery Unit</li> <li>(for Nidek SL-1600 / SL-1800 / SL-2000)</li> <li>(GYC5SZ-2)</li> <li>Attachable Delivery Unit</li> <li>(for ZEISS SL 130)</li> <li>(GYC5SZ-4)</li> <li>Slit Lamp Delivery Unit</li> <li>(for Nidek SL-1800)</li> <li>(C(GYC-5))</li> <li>Attachable Delivery Unit</li> <li>(for HAAG STREIT</li> <li>900BQ) (GYC5SG-1)</li> </ul>	Accuracy	Within ±50% (less than 100 μm) Within ±20% (100 μm and greater)		
Scan delivery unit				
Scan Attachable Deliv- ery Unit (for ZEISS 30SL/M) (GYC5PS-1)	Spot size	ø50 to ø500 μm For scan function, 100 μm and greater		
<ul> <li>Scan Attachable Delivery Unit (for Nidek SL-1600 / SL-1800 / SL-2000) (GYC5PS-2)</li> <li>Scan Attachable Delivery Unit (for ZEISS SL 130) (GYC5PS-4)</li> <li>Scan Attachable Delivery Unit (for HAAG STREIT 900BQ) (GYC5PS-7)</li> <li>Scan Slit Lamp Delivery Unit (for Nidek SL-1800) (CS(GYC-5))</li> </ul>	Accuracy	Within ±50% (less than 100 μm) Within ±20% (100 μm and greater)		

Combination delivery unit				
Combination delivery	Spot size	ø50 to ø500 μm		
unit (Attachable to Nidek YC-1800 / YC- 200) (GYC2SZ-3A)	Accuracy	Within ±50% (less than 100 μm) Within ±20% (100 μm and greater)		
Endophotocoagulation delivery unit				
Endophotocoagulation Del	Endophotocoagulation Delivery Unit (for sterilized endophoto probe) (for Nidek GYC-500) (EP-3)			
Binocular indirect ophtha	Imoscope delivery unit			
Binocular Indirect Oph- thalmoscope Delivery Unit (for HEINE OMEGA 500) (GYC4BO-3)	Working distance	300 to 700 mm		

# 5.2 Glossary

The following terms and abbreviations are used in reference to the device and in the Operator's Manual.

## ○ Glossary

Term	Details	
Photocoagulation	To coagulate human tissues using the heat generated by the laser beam.	
Delivery unit	The light-guiding system to deliver the laser beam emitted from the laser head to the tissue.	
Single delivery unit	Slit lamp delivery units and attachable delivery units	
<ul> <li>Scan delivery unit</li> </ul>	Scan slit lamp delivery units and scan attachable delivery units	
Power output	Laser energy emitted from the terminal of the light-guiding path, or laser energy that passes the ø8 mm aperture at the position equivalent to the patient's pupil. (Unit: mW)	
Laser beam	Aiming beam and treatment beam	
Treatment beam	Laser beam that is used for photocoagulation. The GYC-500 uses a green laser beam (532 nm).	
<ul> <li>Aiming beam</li> </ul>	Laser beam that indicates the position to which the treatment beam is to be emitted.	
Emission time	Length of time that the treatment beam is emitted. (Unit: second)	
Spot size	Diameter of the laser beam spot (Unit: μm)	
Protective filter	The device to protect the operator's eyes from beams reflected from a location where the laser beam is applied.	
Repeat mode	In Repeat mode, the treatment beam is interrupted by specified intervals during which treatment emission is paused. As long as the foot switch is pressed, the treatment beam is repeatedly emitted and paused for the specified intervals.	
Single mode	In Single mode, one shot of treatment beam is emitted for the specified time for each press of the foot switch.	
• Pos button	The Pos button is displayed in READY mode when the auto forward function is used in SCAN mode. Pressing this button shows a pattern showing the four corners of the range of the auto forward function on the patient's eye.	
Auto Forward function	The function that automatically advances the scan pattern in the selected direction by continually pressing the foot switch with a scan pattern applicable to the Auto Forward function selected.	
Act Spot Size	"Act Spot Size" (actual spot size) refers to the size of the spot emitted via the contact lens. The value of an actual spot size can be obtained by multiplying the spot size by contact lens magnification.	
TEST screen	The screen that allows treatment beam emission in the Single scan pattern when a scan pattern other than Single is selected.	
Main laser device	The GYC-500 to be connected with a delivery unit	
• CB	Control box	
• Expansion box	The optional accessory that is used to connect a scan delivery unit and the external devices (LAN cable, barcode scanner, or magnetic card reader) to the GYC-500.	

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Term	Details
Expected service life	A period of time beyond which the reliability and safety of the device cannot be guar- anteed even under normal use and regular maintenance that involves repeated replacement of maintenance parts and consumable parts, repair, and overhaul.

## 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.

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- 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)
Communication cable for control box	Yes	No	1.1
USB cable for 3D mouse	Yes	Yes	1.0
USB cable for barcode scanner	Yes	Yes	2.0
LAN cable	Yes	No	2.0
Scan delivery unit cable	Yes	Yes	2.0
Foot switch cable	Yes	Yes	2.9
Fiber optic cable (SCAN)	No	No	20.0
Fiber optic cable (BIO)	No	No	5.0
Lamp cable	No	No	2.0
AC adapter cable	No	No	1.8
Dimmer cable	No	No	0.8
Lamp cable	No	No	0.7
Power cord for main body	No	No	2.5
Power cord for slit lamp	No	No	2.5
Power cord for motorized optical table	No	No	2.5

# O Specified multimedia equipment

• Network switch: Complied with CISPR 32 Class B

## **O** Essential performance

• Laser irradiation function

### Compliance for Emission Standard

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

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

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

Test frequency (MHz)	Band (MHz)	Service	Modulation	Immunity test level (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	28
710				
745	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
780				
810		GSM 800/900,		
870	800 to 960	TETRA 800, iDEN 820,	Pulse modulation 18 Hz	28
930		CDMA 850, LTE Band 5		
1720	1700 to 1000	GSM 1800;		
1845		CDMA 1900;	Pulse modulation	ion 28
1970	1700 10 1990	LTE Band 1, 3, 4, 25; UMTS	217 Hz	
2450	2400 to 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	28
5240				
5500	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5785				

# Compliance for Immunity Standard

Phenomenon	Basic EMC standard	Immunity test levels
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF electromagnetic field	IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See "Test specifications for enclosure port immunity to RF wireless communications equipment".
Electrical fast transients / bursts	IEC 61000-4-4	Input power port ±2 kV 100 kHz repetition frequency
		Signal input/output parts port ±1 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	Input power port ±0.5 kV, ±1 kV
Surges Line-to-ground	120 01000-4-3	Input power port ±0.5 kV, ±1 kV, ±2 kV Signal input/output parts port ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Voltage dips	IEC 61000-4-11	0% U⊤; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°
		0% U⊤; 1 cycle and 70% U⊤; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U⊤; 250/300 cycles