Canon

Optical Coherence Tomography

OCT-S1

Instructions for Use

CE 2797
UK CA 0086

For European Union

Important

- The user is responsible for managing the usage and maintenance of medical equipment. We suggest that a dedicated individual is assigned responsibility for maintenance to ensure that this product is kept in good condition and can be used safely.
- Connection of a system that uses this product to a network could result risks to patients, operators, or third parties. A dedicated individual who is assigned responsibility for maintenance should assess these risks in advance.
  The responsible person should also assess the risks when changes to the network (including changes in the network configuration, addition or disconnection of items to the network, or update or upgrade of equipment connected to the network) occur after connection.

Operator Profile

- This product can only be used by a doctor or legally qualified person who has general knowledge of ophthalmology and can understand this manual.

Patient Target Group

- Pediatric and adult patients who can hold their head against the forehead rest and chin rest while capturing (including pregnant and breast-feeding women), who do not meet contraindications, and regardless of gender.

Indications

- This product is indicated for in-vivo imaging of the retina, retinal nerve fiber layer, and optic nerve head to provide image information for diagnosis in diseases such as glaucoma, diabetic retinopathy, or agerelated macular degeneration.

1 Introduction

Overview

This product takes digital photographic images and tomogram images of patient's eyes non-invasively using a swept light source. Wider and deeper three dimensional retinal images can be acquired in a single capture.
The RX Capture for OCT-S1 (referred to as "OCT control software" in this manual) controls this product, manages the patient's data and study information, observes and displays the images of the patient's eye.

Indications for Use

This product is an optical coherence tomography system indicated for the in-vivo imaging and measurement of the retina, retinal nerve fiber layer and optic nerve head.
It is intended for use as an aid in the diagnosis and management of eye diseases.

The Canon OCT-S1 is not intended to be used as the sole diagnostic instrument for disease. A qualified doctor is responsible for the definitive diagnosis referring to other measurement results with other instruments.

Contraindication

Do not use this product for those patients who:

- Have an anamnestic history of photodermatosis.
- Have undergone photodynamic therapy (PDT) within a short period (refer to the product document of administered photosensitizer about the prohibition period).
- Are on medication with side effects that possibly cause photodermatosis.

Composition

Composition

- OCT-S1
- Power cord
- RX Capture for OCT-S1 Software

Optional Products

- External eye fixation lamp unit EL-1
- RX Server Software (license)

  Server Software
- RX Viewer Software (license)

  Viewer Software
- OCT Angiography (license)

  Function for OCT Angiography photography.
- OCTA2 (license)

  Function for the wide angle of view, high resolution, averaging and panorama for OCTA images.
- Intelligent denoise (license)

  Function for the noise reduction for OCTA images.

Software Operating Environment

The Control PC, Monitor, Printer and Isolation transformer are general purpose equipment.
Each devices need to meet the following specifications.

Hardware or software	Specifications
CPU	Core i7 3.3 GHz or higher (6 or more cores)
RAM	64 GB or more 128 GB or more (When using the mosaic capturing of OCTA examinations)
GPU	NVIDIA video card supporting Compute Capability 5.0 or later (graphics cards with a higher performance than Quadro K2200 and a video memory of 4 GB or more)
Display	Screen resolution: 1920 x 1080 pixels Screen colors: 24 bits or more
Hard disk	4 TB or more: RAID-1 (mirroring)
Interface	USB 2.0
Network	1000BASE-T or more
OS	Microsoft Windows 10 Pro Version 22H2 (64-bit)* Microsoft Windows 11 Pro Version 23H2 (64-bit)*
Application software	Microsoft .NET Framework Version 4.8 SQL Server 2019 Express US version (64-bit) NVIDIA CUDA Toolkit 11.7
AD converter board	AVALDATA APX-5200B-CA
Mouse	Wheel mouse

* Touch screen operations are not supported.

2 Safety

Regulatory Information

Device Classification

Type of protection against electric shock	Class 1 equipment
Degree of protection against electric shock	Type B applied parts (chin rest and forehead rest)

CE marking

This product complies with the following:
• Regulation (EU) 2017/745
• Directive 2011/65/EU

For European Union

Notification of Serious Incident

Any serious incident (defined in Article 2(65) of the Regulation (EU) 2017/745) that has occurred in relation to the product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Electronic Instructions for Use

Instructions for use are available on the website for viewing and download by customers.
• https://global.canon/en/ifu/medcom/index.html
For details, please contact your sales representative or local Canon dealer.

Safety Precautions

To prevent injuries and data loss, operate this product correctly by following the safety precautions.

Do not leave alcohol, thinner, or any flammable chemicals near the instrument.

Do not place a flammable solvent near the instrument. Fire could result if the solvent spills or evaporates and makes contact with internal electric parts. Some disinfectants are flammable. Be sure to take precautions when using them.

Do not touch conductive parts of non-medical equipment and the patient simultaneously.

Otherwise, electric shock could result.

Do not install in locations exposed to water, steam, moisture or dust.

Doing so may cause problems or malfunctions.

Do not install in locations exposed to salt, sulfur or corrosive gas.

Doing so may result in corrosion of the instrument, problems or malfunctions.

Do not install in locations that are unstable or exposed to vibration.

The vibration may knock over the instrument or the instrument may become unbalanced and fall, resulting in a malfunction or injury.

Do not place your hands or fingers under the chin rest or around the measurement unit.

Your hands or fingers may be pinched and injured. Similarly, instruct the patient not to place he/she hands under the chin rest around the measurement unit.

Do not place your hands or fingers between the measurement unit and the base.

Your hands or fingers may be pinched and injured when the measurement unit moves in any direction. Similarly, instruct the patient not to place his/her hands or fingers between the measurement unit and the base.

Do not hold the face rest or the measurement unit when moving this product.

When moving this product, hold the indentations for lifting of the base, and keep this product level. Do not hold it by the face rest or the measurement unit, as they may come off and result in injury.

Ensure that the entire system conforms to IEC 60601-1.

In the patient environment, use a computer and monitor that conform to the system standard IEC 60601-1 for this product. A computer and a monitor conforming to IEC 62368-1 can be also used. However, be sure to use an isolation transformer. Otherwise, electric shock may occur. For details, please contact your sales representative or local Canon dealer.

Keep the forehead rest and chin rest clean.

To prevent the risk of infection, wipe the forehead rest with disinfectant ethanol for each patient. Similarly, to prevent the risk of infection, replace the chin rest paper for each patient.
For details on how to disinfect, consult a specialist. The forehead rest may corrode if a disinfectant other than those above is used.

Slowly move the measurement unit towards the patient's eye when taking an image.

When adjusting the position of the measurement unit in the front-back direction, slowly bring the measurement unit closer to the patient while looking at the patient's face from the side.
The patient's eye may be injured if the objective lens makes contact with it.

Check the image before using this product.

Before using this product, be sure to take a test image to ensure that there is no foreign matter that can affect image readings or diagnosis.

Make sure that the patient's name, ID, birth date, and sex match those that are entered for the patient.

If the entered information is in error, patient identities may be incorrect. This may result in misdiagnosis and physical injury to the patient.

Do not touch the measurement unit while it is moving.

The measurement unit moves to the center position when this product is turned on. Do not touch the measurement unit while it is moving. Keep the patient's chin away from the chin rest.

Before packing this product, move the measurement unit to the position for packing.

Use the product’s packaging to transport it.

When transporting this product, use the original packaging to protect it from vibration and shock.
Vibration and shock may cause failure of or damage to this product.
For details, please contact your sales representative or local Canon dealer.

This Product is not intended to be used as the sole diagnostic instrument for disease.

A qualified doctor is responsible for the definitive diagnosis referring to other analysis results with other instruments.

Precautions for IT security

Have a network administrator configure and manage the network to connect the system to the network.
When connecting to the network, the network administrator should configure the settings and check if the network is working properly.

Be sure to log off this software when not in use.
To prevent unauthorized operation, be sure to log off this software when it is not being used.

Scan for computer viruses when importing the external data.
When connecting a USB memory device or hard disk drive or importing data from another computer, scan for computer viruses. If the computer has been infected with a virus, patient information and examination data may be damaged or taken by unauthorized individuals.

Perform backup of the data to an external memory device on a regular basis.
Otherwise, stored patient data may be inaccessible in the event of this software or computer malfunction.

Do not disconnect the cable between this product and the computer during image capture or data transfer.
Doing so may damage the computer or corrupt the data.

Do not turn off this product or the computer during image capture, data transfer or backup.
Doing so may damage the computer or corrupt the data.

Do not install any other software after installing this software.
Do not install any other software than that of specified by your sales representative or local Canon dealer. Otherwise, this software and this product may not function properly.

Do not change the OS settings (e.g. screen resolution, date format, date, or language) while this software is running.
Otherwise, this software may not function properly.

Do not operate this software until importing or transferring of the image is completed.
Otherwise, this software may not function properly.

Laser Safety

This product complies with 21 CFR Chapter 1 Subchapter J as a Class 1 laser product under the U.S. Department of Health and Human Services (DHHS) Radiation Performance Standard according to the Radiation Control for Health and Safety Act of 1968. Also, this product is certified as a Class 1 laser product under IEC 60825-1:2007, IEC 60825-1:2014, EN 60825-1:2007 , EN 60825-1:2014 and EN 60825-1:2014+A11:2021. Since radiation emitted inside the device is completely confined within protective housings and external covers, the laser beam cannot escape during any phase of normal user operation.

Information for IT security

- User requirement

  This product can only be used by a doctor or legally qualified person who has general knowledge of ophthalmology and can understand this manual.

- Environment of use

  This product should connect to the Hospital Network. When connecting to the network, the network administrator should configure the settings and check if network is working properly.

- Risk profile

  It is possibility that a malicious assailant uses a system, so please be sure to log off this software when not in use.

- Provisions to ensure integrity/validation of software updates and security patches

  Please contact details to your sales representative or local Canon dealer since service persons apply to appropriate security patches to users. Manufacturer informs service persons of application method of security patches after operation check.

- Security configuration options

  Firewall setting is automatically configured so that someone cannot access to the system via network. This firewall setting is done by software installer as default.

- Initial configuration guidances

  After new user is added, the default user account that was configured at new installation must be changed the password or delete this account itself. If this step is skipped, any security issues.

- Instructions for deploying security updates

  Windows updates are applied for security updates.

- Failsafe mode

  This system has a failsafe mode to continue to use the system even in network trouble. When the network trouble is detected, the system automatically start failsafe mode. In the failsafe mode, examination date is stored locally instead of network location. Then the local data will be automatically moved to network location and exits from failsafe mode after network trouble will disappear.

- IT Security controls

  The following security settings are recommended and set by default.
  Windows firewall is automatically configured so that someone cannot access to the system via external network. Windows defender is enabled.

- Actions for alert messages related to IT security

Message	Remedy
There should be at least one administrator.	This user cannot be deleted when only one person is registered as the administrator. Add a user as the administrator, and then delete the user.
Current logged user can not be deleted.	- The user who is logged in at the moment cannot be deleted. The other administrator has to log in to the user. - This user cannot be deleted when only one person is registered as the administrator. Add a user as the administrator, and then delete the user.
Unable to lock Database	After other users log out, try the operation again.
Unable to lock patient Unable to delete patient	After another user deselects the patient, try the operation again.

- Backup and restore features

  (see page 19)

Notes on Use

Before Use

- Inspect this product daily. Make sure that no foreign matter is present that can affect image readings or diagnoses.
- Any dirt or scratches on the objective lens appear as black spots which may affect the OCT image quality. Check and clean the objective lens before taking an image.
- Sudden heating of a room during winter or in cold regions may cause condensation to form on the objective lens or on optical parts inside this product, resulting in an inability to obtain optimal images. In this case, wait until condensation disappears before taking images.

After Use

- After using this product, turn off the power, attach the objective lens cap to protect the objective lens from dust, and place the dust cover over this product. You cannot take good images if the objective lens is dusty.

Cleaning and Disinfecting

- Do not allow the blower to touch the lens.
- Do not wipe or rub the lens if there is dirt or dust on it.
- Do not wipe the lens with ethanol solution, eyeglass cleaner, or silicone-coated paper. Doing so could damage the surface of the lens or leave streaks.
- Do not clean the exterior of this product with lens cleaner. Doing so could damage the exterior of this product.
- Do not use alcohol, benzine, thinner, or other solvents to clean the exterior of this product. Doing so damages the exterior of this product.
- Do not use ethanol solution to clean the exterior of this product, except the forehead rest and the chin rest. Otherwise, damage may occur to the exterior of this product.
- If the chin rest paper is not being used, disinfect the chin rest for each patient in the same manner as you do for the forehead rest.

Environment of Use

- Use, store, and transport this product in an environment that is within the range of the following conditions. Use the original packaging to store or ship it.

	Temperature	Humidity	Atmospheric pressure
Environment of use	10 to 35 °C	30 to 90% RH (no condensation)	600 to 1060 hPa
Storage and transportation environment	- 30 to 50 °C	10 to 95% RH (no condensation)	600 to 1060 hPa

- Do not install, store, or leave this product in a very hot or humid environment. Also, do not use this product outside. Doing so may cause problems or malfunctions.
- Always try to keep the room as clean as possible. After many years of usage, airborne dust in the room may get on the objective lens and the optical parts inside the measurement unit. You cannot take good images if the equipments are dusty.
- When this product is not being used, attach the objective lens cap and place the dust cover over this product.

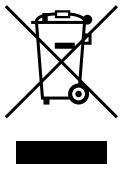
Installation

- Ask your sales representative or local Canon dealer to install it.
- Use a synchronous cable and a data cable that are attached to the supplied ferrite core. Ask your sales representative or local Canon dealer to attach the ferrite core. Also, use a USB cable that is 2 meters long or less.
- A strong shock to this product may put it out of alignment. Please handle the unit carefully.

Disposal

Disposal of this product in an unlawful manner may have a negative impact on human health and on the environment. Therefore, when disposing of this product, be absolutely certain to follow the procedure which conforms with the laws and regulations applicable to your area.

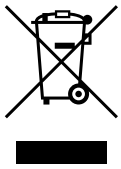
Only for European Union and EEA (Norway, Iceland and Liechtenstein)



This symbol indicates that this product is not to be disposed of with your household waste, according to the WEEE Directive (2012/19/EU) and national legislation. This product should be handed over to a designated collection point, e.g., on an authorized one-for-one basis when you buy a new similar product or to an authorized collection site for recycling waste electrical and electronic equipment (EEE). Improper handling of this type of waste could have a possible negative impact on the environment and human health due to potentially hazardous substances that are generally associated with EEE. At the same time, your cooperation in the correct disposal of this product will contribute to the effective usage of natural resources. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, waste authority, approved WEEE scheme or supplier where you purchased the product.

The information above, including information on batteries, is on our website in the official languages of each EU country.
Please access https://global.canon/en/ifu/medcom/envfile/weee-battery-eu.pdf.

Only for the United Kingdom



This symbol indicates that this product is not to be disposed of with your household waste, according to the UK Waste Electrical and Electronic Equipment Regulations. This product should be handed over to a designated collection point, e.g., on an authorized one-for-one basis when you buy a new similar product or to an authorized collection site for recycling waste electrical and electronic equipment (EEE). Improper handling of this type of waste could have a possible negative impact on the environment and human health due to potentially hazardous substances that are generally associated with EEE. At the same time, your cooperation in the correct disposal of this product will contribute to the effective usage of natural resources. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, waste authority, approved WEEE scheme or supplier where you purchased the product.

The information above, including information on batteries, is on our website.
Please access https://global.canon/en/ifu/medcom/envfile/weee-battery-uk.pdf.

Software

(1) Ask your sales representative or local Canon dealer to install and update this software and drivers.

(2) For instructions on operating the computer and Windows software, refer to the respective operation manuals.

(3) This software can be used only by the users with [Users] or [Administrators] privileges.

(4) Make sure that the appropriate access rights are set for the drive or folder when performing the following operations.
- Add an HDD on the [Storage Management] screen.
- Output DICOM, JPEG, and BMP data.
- Import CSV files of the patient information.
- Import retinal images.
- Perform backup of the data to the backup drive.
- Import and export examination data.

(5) Do not use [Switch User] (which switches users without logging off) in Windows. When two or more users are using this software, be sure to select [Log Off], and then log on again as a different user.

(6) Be sure to set the screen saver, power options and font settings on the computer as shown below.

Items	Settings
Screen saver	None
Turn off the display	Never
Put the computer to sleep	Never
Turn off hard disks	Never
When I press the power button	Shut down
Start menu power button	Shut down
Font size	Smaller - 100% (default)

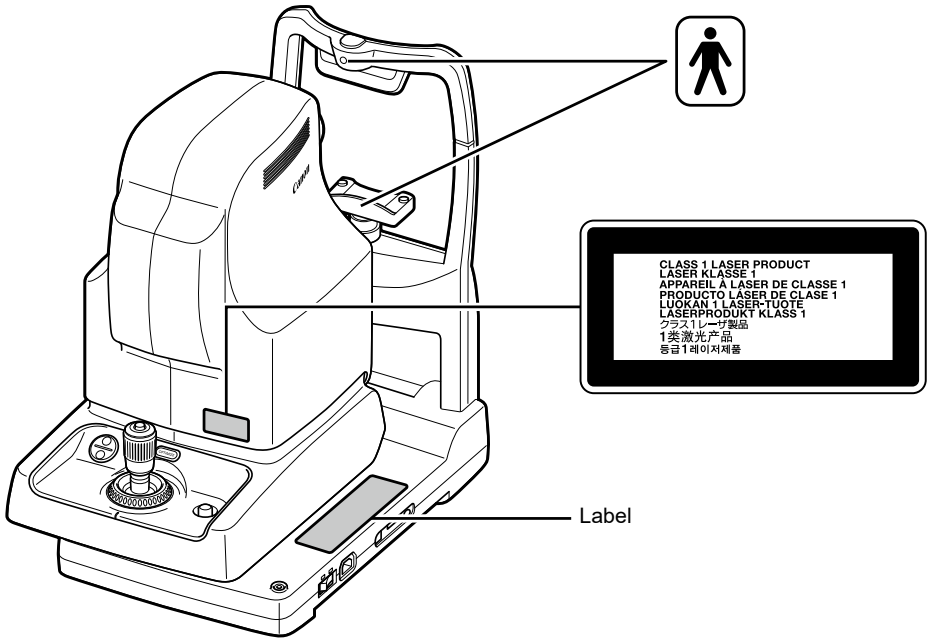
(7) Do not put the Windows computer into sleep or hibernate mode.

(8) If an application error appears or this software freezes on use, follow the instruction below.
1) Turn off the power to the computer.
2) Turn off the power to this product.
3) Turn on the power to this product.
4) Turn on the power to the computer.

(9) Do not update and upgrade Windows while this software is running. While updating or upgrading Windows, this software may operate slowly or may not be able to operate.

Product Labels

The labels and the marks attached to the OCT-S1 are shown below.
Follow the information on the label to use the OCT-S1 appropriately.



The following table describes the marks and indications on this product.

~	Alternating current
	Type B applied part
	Product that WEEE directive, Directive on Waste Electrical and Electronic Equipment, requires separate collection. The directive is effective in the European Union only.
	Consult instructions for use
MD	This symbol indicates medical device which complies with the Regulation (EU) 2017/745.
EC REP	Authorised Representative in the European Community
	Manufacturer
SN	Serial number
	Date of manufacture

3 Basic Operation

Preparing to Capture Images

Preparing this product

1 **Remove the dust cover and the objective lens cap.**

2 **Insert the power plug all the way into an AC outlet.**

3 **Turn on the power to this product.**

4 **Press the stage lock button.**

Preparing the OCT Control Software

1 **Turn on the power to the computer and the monitor.**

2 **Enter the user ID and password, and then click [Log In].**

Entering Patient Information

1 **Enter the patient ID of a new patient.**

2 **Enter other patient information.**

3 **Click the [OCT Capture] tab.**

Preparing for Patients

1 **Disinfect the forehead rest and replace the chin rest paper.**

2 **Instruct the patient how to sit in front of this product.**

3 **Adjust the height of the chin rest.**

4 **Move the stage toward the eye to be photographed.**

Capturing Tomogram Images

Selecting an Examination Set

1 **Select the [Wide Field] examination set from the list box.**

Alignment and Capturing Images

1 **Align the measurement unit with the position of eye.**

2 **Tilt the operation lever forward or backward to match the position of the horizontally separated image of the eye.**

3 **Press the capture button.**

4 **Press the OPTIMIZE button.**

5 **Adjust the image so that the image quality indicator shows a higher level.**

6 **Make sure that the OCT live images at the top and bottom edges appear.**

7 **Adjust the tilt of the tomogram image.**

8 **Adjust the vertical position of the tomogram image.**

9 **Press the capture button.**

10 **Adjust the position of the tomogram image to be captured.**

Checking the Captured Image

1 **Click [OK] or [NG].**

Viewing Reports

Viewing Reports

1 **After the capturing is completed, click the [Report] tab.**

Outputting and Printing Reports

1 **Click [Output].**

2 **Select the output destination, and then click [OK].**

Shutting Down the Software

1 **Click [Log out].**

2 **Click [[Shutdown].**

3 **Press the stage lock button**

4 **Turn off the power to this product.**

5 **Disconnect the power plug from the AC outlet.**

6 **Attach the objective lens cap, and place the dust cover over this product.**

Backup and Restoration

On the [Backup and restore] screen, perform backup of the patient information and the examination data that were acquired with the OCT-S1 and restore them. The backup can be performed either automatically or manually. In the automatic backup, the backup schedule can be set. If a problem occurs to the database, restore the patient information and examination data. When you select [Local] on [Database], [Backup and restore] can be set.

Setting a Drive for the Backup

Enter a path for the backup destination to [Backup destination] or click [Browse] to select a backup destination.

Automatic Backup Settings

Select the day of the week when the automatic backup is performed, and select the type of backup from the list box.

- [Full Backup]: Performs backup of all data.
- [Incremental Backup]: Backs up only the data that is modified from previous backup.

Select a time when the automatic backup is performed from the list box.
If [At Exit] is selected, the backup will be performed when you exit the RX Capture for OCT-S1/RX Server.

The old backup log is deleted after full backup succeeds. To save the old backup log, clear the [Delete all old logs after succeeding to full backup] check box.

Manual Backup

Click [Full Backup] or [Incremental Backup].
Backup starts.
Click [Cancel] to cancel the backup.

Displaying the Backup Log

When the [Backup Logs] tab is clicked, the list of the backup log appears.

Restoring Data

By restoring data, the state of data can be returned up to the stage of the selected backup log.

1 **Select a backup log, and then click [Restore].**

For example, if restoring the backup log of 5/16/2012, the status returns to 5/16/2012. Therefore, the patient information and examination data acquired on and after 5/17/2012 are deleted.
Restoring starts.
When the screen where the progress bar is indicated disappears, restoring is finished.

4 Maintenance

Daily Inspections

Perform the following inspections before using this product to ensure that it is used safely and correctly. If a problem is found during the inspection and you are unable to correct the problem, please contact your sales representative or local Canon dealer.

Checks Before Turning On the Power

Check the following items before turning on the power.

Cables

1) The power cord and connection cable are not damaged and their insulation is not torn.
2) The power cord is fully and securely inserted into the AC connector on this product and the AC outlet.
3) The cables are fully and securely inserted into the connectors and are not loose.

OCT-S1

1) The exterior of this product is not damaged or loose.
2) The stage moves as you hold the operation lever and tilt it forward, backward, right and left.
3) The measurement unit moves up and down as you turn the operation lever.
4) Confirm that the stage lock works properly.
5) There are no scratches or dirt on the objective lens. Clean the objective lens if it is dirty.

Checks After Turning On the Power

Turn on this product, and then turn on the computer. Check the following items after you log in.

OCT-S1

1) The POWER lamp lights.
2) The chin rest moves up and down smoothly as the Chin Rest adjustment button is pressed.
3) The SLO live image can be observed as the capture button is pressed.

Cleaning and Disinfecting

Objective Lens

If the objective lens is dirty, clean it according to the procedure below.

1 **Check for any dirt.**

Illuminate the objective lens with a penlight to check for dirt.

2 **Blow away any dust or dirt.**

Use a blower to blow away any dust or dirt on the lens. Do not use a brush to dust off.

3 **Wipe the objective lens.**

1) Wipe the objective lens lightly with a lens cleaning paper moistened with lens cleaner.
2) Starting from the center of the lens, wipe the lens in spirals toward the circumference.
3) Change the lens cleaning paper and wipe the objective lens until the dirt is gone and there are no streaks.

Forehead Rest / Chin Rest

Clean the intended parts with a sanitized gauze or a similar material that is moistened with disinfectant.

Exterior Surface

If the exterior of this product is dirty, clean it according to the procedure below.

1 **Turn off the power to this product.**

Turn off the power switch and unplug the power cord from the AC outlet.

2 **Wipe with a cloth soaked in cleanser.**

Wipe it with a soft cloth that has been soaked in diluted neutral cleanser and well wrung out.

3 **Wipe with a cloth soaked in water.**

Wipe it with a cloth that has been soaked in water and well wrung out.

Appendix

Specifications

OCT Image

Resolution	Depth (Z direction): 8 μm or less Width (X-Y direction): 30 μm or less
Scanning area	3 (H) x 3 (V) to 23 (H) x 20 (V) mm (±5%)
Light source	Swept Light Source 1010~1110nm

SLO Image

Angle of view	78 degrees (H) × 68 degrees (V) (23 × 20 mm)
Resolution	40 μm
Light source	LD 780 nm

Power supply rating	AC 100 to 240 V, 50/60 Hz, 1.6 to 0.8 A

Types of Analysis

Macula Thickness Analysis

This shows the tomogram image of the macula and analysis results of retinal thickness.

NFL+GCL+IPL Analysis / GCL+IPL Analysis

This shows the tomogram image from the macula up to the optic disc, and analysis results of retinal thickness.

Optic Disc Analysis

This shows the thickness of RNFL (Retinal Nerve Fiber Layer) and analysis results of the shape of the optic disc.

Wide 3D Scan Analysis

This scans the macula and the optic disc one time and then shows the analysis results.

2D Tomogram Analysis

This shows the tomogram image and the retinal thickness of the specified part.

General Tomogram Analysis

This shows the tomogram image and the retinal thickness of the specified part.

OCTA Images

This shows the OCTA tomogram images.

3D Analysis

This shows the 3D tomogram image.

EMD (Electromagnetic Disturbances)

This product is designed and tested to comply with IEC 60601-1-2 (EN 60601-1-2) which is applicable regulations regarding EMD for medical devices and need to be installed and put into service according to the following information.

1. Medical electrical equipment needs special precautions regarding EMD and needs to be installed and put into service according to the information provided in the manual.
2. This product is suitable for use in hospital (professional healthcare facility) environments, with the exception of environments near active HF SURGICAL EQUIPMENT or the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of ELECTROMAGNETIC DISTURBANCES is high.
3. To maintain the optimum EMD performance, use only the designated cables.

Name	Type	Length	Remarks
AC Power Cord	Non-Shielded	3.0 m fixed-length	Supplied
Synchronous Cable	Shielded	2.0 m	Supplied
USB Cable	Type AB connector plug supporting USB 2.0 Hi-Speed	Max. 2.0 m	Not supplied
Data Cable	Shielded	2.0 m	Supplied

4. WARNING:
   Use of accessories, transducers and cables other than those specified or provided by Canon sales representative or local Canon dealer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
5. WARNING:
   Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
6. WARNING:
   Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this product, including cables specified by Canon sales representative or local Canon dealer. Otherwise, degradation of the performance of this equipment could result.
7. Essential Performance (against Electromagnetic Disturbances)
   Controlling Laser power or irradiation level of laser beam
   If the laser controlling function is experiencing a failure or a loss of functionality, this product notifies you of either situation via a sound and message.
8. Due to electromagnetic disturbances, it may be necessary for the customer or the user of this product to take the measurement again or to restart the equipment, the software or the computer.

Electromagnetic Emission

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment – Guidance
RF emissions EN 55011 CISPR11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electromagnetic equipment.
RF emissions EN 55011 CISPR11	Class B	This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions EN IEC 61000-3-3*	Complies	

* Not applicable to regions where the rated voltage is less than 220 V.

Warranty and Repair Service

Service Life

The service life of this product is eight years if specified inspections and maintenance are performed.

Technical Description

For the technical description, see the operation manual of the product.

BT8-2547-EN02

Canon

Manufacturer:
CANON INC.
30-2, Shimomaruko 3-chome, Ohta-ku, Tokyo 146-8501, Japan
Telephone: (81)-3-3758-2111

Revision Date: 2025-06
BT8-2547-EN02 0625P0.001