



Ophthalmic Software Platform RX

# RX Capture for Retinal Camera RX Server RX Viewer

Instructions for Use

---



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 software is kept in good condition and can be used safely.
- Connection of a system that uses this software 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 software 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**

- Patients who can hold their head against the forehead rest and chin rest while capturing.

## **Indications**

- This device is indicated for non-contact imaging of the retinal fundus through the pupil to assist in the diagnosis of retinal diseases.

# 1 Introduction

## Overview

The Ophthalmic Software Platform RX is an ophthalmic software for acquiring, storing, managing, processing and displaying the patient images which are taken data from Canon Optical Coherence Tomography and Canon Digital Retinal Camera. The Ophthalmic Software Platform RX consists of three software, RX Capture for Retinal Camera, RX Server and RX Viewer.

The RX Capture for Retinal Camera has a special screen for acquiring retinal images taken with the Canon Digital Retinal Camera. It provides with Image Display, and Image Processing as follows.

The RX Server stores patient information and image information acquired the OCT and the retinal cameras. In the RX Server, updating patient information, viewing study information are possible.

The RX Viewer displays images acquired by the OCT and the retinal cameras.

## Indications for Use

The Ophthalmic Software Platform RX is an ophthalmic software system indicated for acquiring, storing, managing, processing, and display of patient, diagnostic, image data from computerized diagnostic instruments.

And it is also indicated for review of patient, diagnostic and image data and analysis by trained healthcare professional.

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 measurement results with other instruments.

# Composition

## Ophthalmic Software Platform RX

- RX Capture for Retinal Camera Software
- RX Server Software
- RX Viewer Software

# Software Operating Environment

Each software runs under the following operating environment.  
For details on the system, contact your sales representative or local Canon dealer.

## RX Capture for Retinal Camera Software

Hardware or software	Specifications
CPU	Intel CPUs
RAM	16 GB or more
Display	Screen resolution: 1920 x 1080 pixels Screen colors: 24 bits or more
Hard disk	500 GB or more: RAID-1 (mirroring); for a local server (when not introducing the RX Server yet) 100 GB or more: For a remote server (when introducing the RX Server)
Interface	USB 2.0
Network	1000BASE-T or more
OS	Microsoft Windows 11 Pro Version 23H2 or later (64-bit)* Microsoft Windows 11 Pro Version 24H2 or later (64-bit)*

\* Touch screen operations are not supported.

## RX Viewer

Hardware or software	Specifications
CPU	Intel CPUs
RAM	16 GB or more
GPU	Full HD and 24/32-bit color compatible
Display	Screen resolution: 1920 x 1080 pixels Screen colors: 24 bits or more
Hard disk	100 GB or more
Interface	USB 2.0
Network	1000BASE-T or more
OS	Microsoft Windows 11 Pro Version 23H2 (64-bit)* Microsoft Windows 11 Pro Version 24H2 (64-bit)*

\* Touch screen operations are not supported.

## RX Server

Hardware or software	Specifications
CPU	Intel CPUs
RAM	4 GB or more
GPU	Full HD and 24/32-bit color compatible
Display	Screen resolution: 1920 x 1080 pixels Screen colors: 24 bits or more
Hard disk	2 TB or more: RAID-1 (mirroring); when not introducing the NAS server is not installed yet 100 GB or more: when introducing the NAS server is installed
Interface	USB 2.0
Network	1000BASE-T or more
OS	Microsoft Windows Server 2019 Standard*

\* Touch screen operations are not supported.

## 2 Safety

### Regulation information

#### CE marking

These software comply with the following

- Regulation (EU) 2017/745

#### 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 software correctly by following the safety precautions.

---

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

Otherwise, electric shock could result.

---

**Ensure that the entire system conforms to IEC 60601-1.  
Use the equipment conforming to IEC 60601-1 in the patient environment.**

In the patient environment, use a computer and monitor that conform to the system standard IEC 60601-1 for this software. 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.

---

**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.

---

**While images are being transferred, never turn off the computer, the retinal camera, or the digital camera.**

Doing so may damage the hardware or corrupt the data.

---

**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 the retinal camera while operating these software.**

Otherwise, these 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.

---

**While images are being transferred, do not disconnect the DC coupler of the digital camera or the USB cable between the computer and retinal camera.**

Doing so may damage the hardware or corrupt the data.

---

---

**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 a computer malfunction.

---

**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.

---

**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.

---

**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.

---

## 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.

---

## 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 16)

## Notes on Use

- (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) When the following operations are performed, on the [Security] tab of the drive/folder property, allow [Modify] for the [Users] group and [Full control] for the [Administrators] group.
  - 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, this software freezes, or the captured image does not appear during an examination, take the following steps:
- 1) Turn off the retinal camera and digital camera.
  - 2) Exit this software. Perform a force-quit in the task manager when it is unable to exit.
  - 3) Turn off the computer.
  - 4) Remove the DC coupler from the digital camera, and then re-insert it.
  - 5) Turn on the computer.
  - 6) After the OS starts up, turn on the retinal camera and digital camera.
  - 7) Start up this software.
- (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.
- (10) To prevent a wizard or menu from automatically opening while the digital camera is connected to the Windows computer, take the following steps:
- 1) Open the [Control Panel], click [Hardware and Sound], and click [Play CDs or other media automatically].
  - 2) Select [Take no action] from the dropdown list for [Canon EOS XXD RETINA]. Then, click [Save].
- (11) This software does not support environment-dependent characters extended in Windows.

## Product Marking

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

	Consult instructions for use
	This symbol indicates medical device which complies with the Regulation (EU) 2017/745.
	Authorized Representative in the European Community
	Manufacturer
	Date of manufacture

## 3 Basic Operation

### RX Capture for Retinal Camera

#### Starting Up the 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 [RC Capture] tab.

#### Capturing Images

- 1 Perform a preliminary check before taking photos. Control the operation lever and take the image.
- 2 Check the captured image.

#### 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].

## RX Server

### Starting Up the Software

- 1 Turn on the power to the computer and the monitor.
- 2 Double-click icon on the desktop.
- 3 Enter the user ID and password, and then click [Log In].

### Shutting Down the Software

- 1 Click [Log out].
- 2 Click [Shutdown].

## RX Viewer

### Starting Up the Software

- 1 Turn on the power to the computer and the monitor.
- 2 Double-click icon on the desktop.
- 3 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 [RC Capture] tab.

### 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].

## Backup and Restoration

On the [Backup and restore] screen, perform backup of the patient information and the examination data that were acquired with the software 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 RC/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.

# Appendix

## Technical Description

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





\*BT8-1836-EN01\*

# Canon



Manufacturer:

CANON INC.

30-2, Shimomaruko 3-chome, Ohta-ku, Tokyo 146-8501, Japan

Telephone: (81)-3-3758-2111

Revision Date: 2025-11

BT8-1836-EN01

1125P0.001

© CANON INC. 2025