

Canon

Digital Retinal Camera

CX-1

Instructions for Use

For European Union

CE

Important Information

- This product must only be used by a doctor or a legally qualified person.
- 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.

1 Introduction

Features

The Canon Digital Retinal Camera is used to observe the retinas of patients' eyes and take photographs of them.

Indications for Use

The device is intended to be used for taking digital images of retina of human eye with non-mydratic and mydratic.

Composition

- Digital Retinal Camera
- Digital camera
- Control Software

Optional products

Internal eye fixation target
Chin rest paper—500 sheets

Regulatory Information

CE marking

This device 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 device 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 this product near a flammable solvent. Fire may result if the solvent spills or evaporates and makes contact with the internal electric parts. Some disinfectants are flammable. Be sure to take precautions when using them.

Do not clean this product with flammable solvent.

For safety reasons, before cleaning this product, be sure to turn off the power of all the devices and unplug the power cord from the AC outlet. Do not use alcohol, benzene, thinner or any other flammable solvent.

Otherwise, fire or electric shock may result.

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

Otherwise, electric shock may result.

Use an isolation transformer when this system is connected to a network.

Connect an isolation transformer conforming to IEC 60601-1 for networks between the computer and HUB.

Otherwise, there is a risk of electric shock if the network is faulty.

Do not use or store the instrument in a location with the conditions listed below.

- Close to facilities where water is used.
- Where it will be exposed to direct sunlight.
- Close to air-conditioner or ventilation equipment.
- Close to heat source such as a heater.
- Surfaces or areas prone to vibration.
- Insecure place.
- Dusty environment.
- Saline or sulfurous environment.
- High temperature or humidity.
- Freezing or condensation.

Place the instrument on a firm table.

Do not place it extremely near the edge of a table or it may fall and cause damage or injury.

Do not connect the instrument except in the manner specified.

Otherwise, fire or electric shock may result.

Also, when other equipment is going to be connected to the instrument using the connector for interface, be sure that leakage current is within the tolerable value. For details, please contact your sales representative or local Canon dealer.

Do not place your hands or fingers on the base.

Your hand or fingers may be pinched and injured when the stage moves to either side. Similarly, instruct the patient not to place his/her hands or fingers on the base.

Do not hit or drop the instrument.

The instrument may be damaged if it receives a strong jolt, which may result in fire or electric shock if the instrument is used without first being repaired.

Do not hold the head rest or digital camera when moving this product.

When carrying this product, be sure to tighten the stage lock, the panning lock knob and the tilting lock lever, hold the carrying indentations at the left and right of the base panel, and keep this product level. Do not hold it by the digital camera or the head rest or any other parts, as they may come off and result in injury.

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

Use the computer, monitor, and other equipment that conform to the system standard IEC 60601-1 or IEC 60950-1 for this product. Be sure that the entire system conforms to IEC 60601-1-1. Be sure to also use an isolation transformer conforming to IEC 60601-1 when a computer or monitor conforming to IEC 60950-1 is used. 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 incorrect, patients may be mixed up and misdiagnosed, which may result in physical injury to the patient.

Keep the forehead rest and chin rest clean.

To prevent the risk of infection, wipe the forehead rest with disinfectant ethanol for each patient. To ensure cleanliness, replace the chin rest paper for each patient. If the chin rest paper is not being used, be sure to disinfect the chin rest for each patient. If the chin rest paper is not being used, be sure to disinfect the chin rest for each patient. For details on how to disinfect, consult a specialist. The forehead rest may be corroded if a disinfectant other than those above is used.

Slowly move the main unit toward the patient's eye when taking an image.

When adjusting the position of the main unit in the front-back direction, slowly bring the main unit closer to the patient while looking at the patient's eye 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 present that can affect image readings or diagnosis.

Be sure to turn off the power when not in use.

For safety reasons, be sure to turn off the power of all the devices when this product is not being used. Also, unplug the power plug from the AC outlet and put on the cover when this product is not going to be used for a long time. Otherwise, dust or any foreign matter may accumulate and result in fire.

Do not turn off this product, the digital camera, or the computer during image capture, data transfer, or backup.

Doing so might damage the computer or corrupt the data.

Do not disconnect the cable between this product and the computer during image capture or data transfer.

Doing so might damage the computer or corrupt the data.

When you are using this product together with any equipment that may generate power supply noise, power supply voltage fluctuation, electromagnetic waves, or other disturbances, check if this product works properly.

Such equipment may cause malfunctions or other trouble.

Do not change the OS settings (e.g. screen resolution, date format, date, or language) while the control software is running.

If changes are made while the control software is running, it may not function properly.

Do not operate the retinal camera while operating the control software

Otherwise, the control software may not function properly.

After taking the image of the retina, do not operate the control software until transferring of the image is completed.

Otherwise, the control software may not function properly.

Do not turn off the computer while the control software is running.

Be sure to exit the control software before shutting down the computer. Doing so the measured data is not saved correctly or might corrupt the data.

On the Patient Info Edit screen, use care when editing the patient information.

Regardless of all the essential data, input-disabled data and input format settings which were set on the **Study Input/Manual Input** screen, all the data can be changed and input.

Be sure to log off the control software when not in use.

To prevent unauthorized operation, be sure to log off the control software when it is not being used.

Maintain and manage the operating environment of the control software properly.

If you add, change or update the OS, driver, or other software after installing the control software, the control software may not function properly. Contact your sales representative or local Canon dealer beforehand.

Do not change the Windows Update settings.

Otherwise, the updates and upgrades for Windows automatically start. While updating or upgrading Windows, the control software may operate slowly or may not be able to operate. The control software also may not function properly after updating or upgrading Windows.

Notes on Using This Product

Digital camera

- The attached digital camera is designed for this product. The specifications differ from commercially available Canon digital cameras. Use only for observing and taking photographs of peoples' eyes. Do not detach the digital camera from the main unit to use separately. Otherwise, failure of this product may result.
- If any problems occur or repairs are needed with this product's digital camera, contact your sales representative or local Canon dealer.

Before use

- Inspect this product daily. Make sure that no foreign matter is present that can affect image readings or diagnoses.
- Check and clean the objective lens before taking an image. Any stains or scratches on the objective lens will appear as white spots.
- 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. In this case, wait until condensation disappears before taking images.
- Do not touch the lens of the retinal camera or the mirror of the digital camera when attaching and detaching the digital camera from the retinal camera. If any dirt, fingerprints, dust, or other foreign objects are on the lens or mirror, you will not be able to take a good image.
- Be sure to adjust the diopter of the viewfinder to match the diopter of the photographer's eye. Otherwise, focusing will not be able to be performed correctly.

After use

- After using this product, turn off the power, cover the objective lens with the objective lens cap to protect it from dust, and place the dust cover over this product. You cannot take good images if the objective lens is dusty.
- If the digital camera is detached and left unattached, dirt and dust may enter the retinal camera and the digital camera. Be sure to always attach the caps to their respective mounts.

Cleaning and disinfection

- Do not allow the blower to touch the lens.
- Do not wipe or rub the lens if there is dirt or dust on it. Doing so could scratch the lens.
- Do not wipe the lens with disinfectant ethanol, eyeglass cleaner, or silicone-coated paper. Doing so could corrode the surface of the lens or leave streaks.
- Do not clean the outside of this product with a lens cleaner. Doing so could damage the outside of this product.
- Never use alcohol, benzine, thinner, or other solvents to clean the outside of this product. Doing so damages the outside of this product.
- Never use disinfectant ethanol to clean the outside of this product, with the exception of the forehead rest and the chin rest. Doing so damages the outside 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.
- For information about lens cleaning paper, lens cleaner, and blowers, contact your sales representative or local Canon dealer.

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)	700 to 1060 hPa
Storage and transportation environment	−30 to 50°C	10 to 95% RH (no condensation)	700 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 a malfunction or misoperation.
- When this product is not being used, attach the objective lens cap and place the dust cover over this product.

Installation

- Request your sales representative or local Canon dealer to install this product.
- A strong shock to this product may put it out of alignment. Please handle the unit carefully.

Transportation

- When lifting the main unit, do not hold the head rest or digital camera. Hold the main unit by the indentations for lifting at its front and rear, and keep it level.
- When transporting this product, align the stage with the base, and then lock the stage with the stage lock lever.
- This product needs to be protected from vibration and shocks when it is transported in a vehicle or over long distances. For details, contact your sales representative or local Canon dealer.

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 (WEEE). 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 WEEE. 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 your household waste disposal service. For more information regarding return and recycling of WEEE products, please visit www.canon-europe.com/weee.

Symbols on the labels and their meanings.

	Alternating current	
	Type B	
	Product that WEEE directive, Directive on Waste Electrical and Electronic Equipment, requires separate collection. The directive is effective in the European Union only.	
	Symbol for "Consult instructions for use".	
	This symbol indicates medical device which complies with the Regulation (EU) 2017/745	
	This mark shows a certification mark in European Economic Area.	
	Symbol for "Authorised Representative in the European Community".	
	Manufacturer's name and address	
	Month and year of manufacture	Example: November 2014
	Serial number in six digits	Example: 123456

3 Basic Operations

Connecting Cables

- 1 Make sure that the power switch for this product is turned off.
- 2 Connect the power cord and the USB cable to the retinal camera.
- 3 Insert the power plug all the way into an AC outlet.

Preparing for an Examination

- 1 Turn on the computer and start the control software.
- 2 Remove the objective lens cap and turn the retinal camera's power switch to the ON position.
- 3 Select the observation mode.
- 4 Select the photography mode.

Patient Setup

- 1 Start an examination on the control software.
- 2 Seat and position the patient.
- 3 Move the chin rest with the CHIN REST button so that the patient's eye is aligned with the height adjustment mark.
- 4 Move the stage toward the eye to be photographed.

Alignment and Photography

- 1 Align the retinal camera with the eye to be photographed.
- 2 Adjust brightness in the field of view for observation.
- 3 Determine the area to be photographed.
- 4 Focus on patient's eye.
- 5 Take the image.
- 6 Check the photographed image.

Finishing an Examination

- 1 End the examination on control software.
- 2 Align the stage with the base and slide the stage lock to LOCK side to lock the stage.
Turn off the power to this product.
- 3 Exit the control software and turn off the computer.

4 Maintenance

Daily Inspections

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 the main unit and the AC outlet.

Main unit

- 1) The digital camera cover and parts are not damaged or loose.
- 2) The stage moves when the operation lever is tilted back and forth and right to left.
- 3) The digital camera is securely installed.
- 4) The stage lock operates properly.
- 5) There are no scratches or dirt on the objective lens. Clean the objective lens if it is dirty.
- 6) Turn the operation lever, and check that the retinal camera main unit moves smoothly up and down as far as the upper and lower limits.
- 7) Check that the panning and tilting operations can be performed smoothly, and that there are no unusual sounds. Also check that the locking of the panning and tilting operates properly.
- 8) Check that there is no dust or other substances on the viewfinder.

Checks after turning on the power

Turn on this product and start the control software. Check the following items after starting an examination.

Main unit

- 1) The POWER lamp lights.
- 2) Place a sheet of paper in front of the objective lens, turn the brightness adjuster, and check that the brightness for observation changes.
- 3) Place a sheet of paper in front of the objective lens and press the shutter release button to confirm that the flash has emitted.
- 4) Set to fluorescein angiography mode and press the TIMER/C switch to check that the timer starts and stops properly.
- 5) The chin rest moves up and down as the CHIN REST button is pressed.

Photographed image

- 1) Foreign objects that affect the reading of the images or diagnosis do not appear in the photographed image. Place a piece of white paper in front of the objective lens and photograph an image under the following conditions:
 - Flash intensity: Standard
 - Diopter compensation: lever: 0
 - Focus knob: Turn the knob on the right (viewed from you) all the way clockwise.

5 Troubleshooting

If any of the symptoms listed here occurs or if a warning appears in the control software while using this product, try the relevant remedy described below.

If these remedies do not eliminate the symptoms or the warning, turn off the power and contact your sales representative or local Canon dealer. Be ready to provide a detailed description of the symptoms and message.

Symptom	Cause and remedy
5 short beeps sound and the operation panel lamps blink when the power is turned on.	A system error has occurred. Contact your sales representative or local Canon dealer.
An error (Err xx) appears on the observation monitor.	The digital camera detects a malfunction. Turn off and on the power of the retinal camera.

Appendix

Specifications

Resolution	63 lp/mm (center), 40 lp/mm (periphery)
Field angle	Mydriatic mode 50°, Non-mydriatic mode 45°
Photographic magnification	1.1 x (image size on the sensor)
Required pupil diameter	
Mydriatic mode	ø 5.1 mm or more; ø 4.3 mm or more when SP function works
Non-mydriatic mode	ø 4.3 mm or more; ø 3.8 mm or more when SP function works
Working distance	35 mm
Focus adjustment range	-10 to +15 D (without compensation lens) -31 to -7 D (when using negative compensation lens) +11 to +33 D (when using positive compensation lens) (Split-line alignment type focusing)
Viewfinder diopter range	±5 D
Range of motion	
Stage	110 mm side to side, 65mm front to back
Main unit vertical movement	30 mm
Chin rest range of motion	60 mm
Panning	30° to the right and left
Tilting	15° up and 10° down

EMC (Electromagnetic Compatibility)

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.

Warranty and Repair Service

Service life

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

Expendable parts replaced by service personnel

The following parts are consumable or may deteriorate because of characteristics of their material or construction.

These parts cannot be replaced by the user. If these parts are found to be worn out or to have deteriorated during daily or regular inspection, contact your sales representative or local Canon dealer for repairs.

- Baseboard (USB connector)
- Xenon flash tube for photography
- Halogen lamp for observation

Technical Description

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



BT8-1757-EN01

Canon

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